

AO 120 (Rev. 08/10)

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court _____ for the District of Delaware _____ on the following
 Trademarks or Patents. (the patent action involves 35 U.S.C. § 292.);

DOCKET NO.	DATE FILED 12/10/2014	U.S. DISTRICT COURT for the District of Delaware
PLAINTIFF ENDOHEART AG		DEFENDANT EDWARDS LIFESCIENCES CORPORATION
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 8,182,530	5/22/2012	Endoheart AG
2		
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT		
CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
 Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Table with 5 columns: APPLICATION NO., ISSUE DATE, PATENT NO., ATTORNEY DOCKET NO., CONFIRMATION NO.
Row 1: 11/023,783, 05/22/2012, 8182530, 147-002 (06-692), 1933

72822 7590 05/02/2012
Weiss & Arons, LLP
1540 Route 202, Suite 8
Pomona, NY 10970

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 1552 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Christoph Hans Huber, Boston, MA;

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450**
or **Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fees) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

72822 7590 01/20/2012
Weiss & Arons, LLP
1540 Route 202, Suite 8
Pomona, NY 10970

Certificate of Mailing or Transmission
I hereby certify that this Fees) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

_____ (Depositor's name)
_____ (Signature)
_____ (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/023,783	12/28/2004	Christoph Hans Huber	147-002 (06-692)	1933

TITLE OF INVENTION: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$870	\$300	\$0	\$1170	04/20/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
MASHACK, MARK F	3773	623-002110

<p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.</p>	<p>2. For printing on the patent front page, list</p> <p>(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,</p> <p>(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.</p>	<p>1. Weiss & Arons LLP</p> <p>2. _____</p> <p>3. _____</p>
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3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE _____ (B) RESIDENCE: (CITY and STATE OR COUNTRY) _____

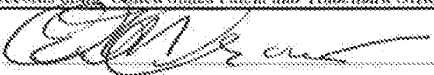
Please check the appropriate assignee category or categories (will not be printed on the patent): Individual Corporation or other private group entity Government

<p>4a. The following fee(s) are submitted:</p> <p><input checked="" type="checkbox"/> Issue Fee</p> <p><input checked="" type="checkbox"/> Publication Fee (No small entity discount permitted)</p> <p><input type="checkbox"/> Advance Order - # of Copies _____</p>	<p>4b. Payment of Fees: (Please first reapply any previously paid issue fee shown above)</p> <p><input type="checkbox"/> A check is enclosed.</p> <p><input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input checked="" type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number <u>504650</u> (enclose an extra copy of this form).</p>
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5. Change in Entity Status (from status indicated above)

a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant, a registered attorney or agent, or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature  Date April 18, 2012

Typed or printed name Edward M. Arons Registration No. 44,511

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11023783			
Filing Date:	28-Dec-2004			
Title of Invention:	METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT			
First Named Inventor/Applicant Name:	Christoph Hans Huber			
Filer:	Edward M. Arons			
Attorney Docket Number:	147-002 (06-692)			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	2501	1	870	870
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1170

Electronic Acknowledgement Receipt

EFS ID:	12568322
Application Number:	11023783
International Application Number:	
Confirmation Number:	1933
Title of Invention:	METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT
First Named Inventor/Applicant Name:	Christoph Hans Huber
Customer Number:	72822
Filer:	Edward M. Arons/Chanie Ziskind
Filer Authorized By:	Edward M. Arons
Attorney Docket Number:	147-002 (06-692)
Receipt Date:	19-APR-2012
Filing Date:	28-DEC-2004
Time Stamp:	17:53:37
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1170
RAM confirmation Number	5083
Deposit Account	504650
Authorized User	WEISS,JOEL

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	147-002_Issue_Fee_Payment_Form_As_Filed.pdf	230610 d871d03d2ab740d7ebc7e72f9055071749a9f00	no	2

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	32094 8e0862ee3ed6ed8fdafdf18460ca8d417cdd9d9e	no	2
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Warnings:

Information:

Total Files Size (in bytes): 262704

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

72822 7590 01/20/2012
Weiss & Arons, LLP
1540 Route 202, Suite 8
Pomona, NY 10970

EXAMINER

MASHACK, MARK F

ART UNIT PAPER NUMBER

3773

DATE MAILED: 01/20/2012

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

11/023,783 12/28/2004 Christoph Hans Huber 147-002 (06-692) 1933

TITLE OF INVENTION: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT

Table with 7 columns: APPLN. TYPE, SMALL ENTITY, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL FEE(S) DUE, DATE DUE

nonprovisional YES \$870 \$300 \$0 \$1170 04/20/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.
B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

72822 7590 01/20/2012
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 1540 Route 202, Suite 8
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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

_____ (Depositor's name)
_____ (Signature)
_____ (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/023,783	12/28/2004	Christoph Hans Huber	147-002 (06-692)	1933

TITLE OF INVENTION: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$870	\$300	\$0	\$1170	04/20/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
MASHACK, MARK F	3773	623-002110

<p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.</p>	<p>2. For printing on the patent front page, list</p> <p>(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, _____ 1</p> <p>(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. _____ 2</p> <p>_____ 3</p>
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3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE _____ (B) RESIDENCE: (CITY and STATE OR COUNTRY) _____

Please check the appropriate assignee category or categories (will not be printed on the patent): Individual Corporation or other private group entity Government

<p>4a. The following fee(s) are submitted:</p> <p><input type="checkbox"/> Issue Fee</p> <p><input type="checkbox"/> Publication Fee (No small entity discount permitted)</p> <p><input type="checkbox"/> Advance Order - # of Copies _____</p>	<p>4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)</p> <p><input type="checkbox"/> A check is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).</p>
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5. Change in Entity Status (from status indicated above)

a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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UNITED STATES PATENT AND TRADEMARK OFFICE

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Pomona, NY 10970

EXAMINER

MASHACK, MARK F

ART UNIT PAPER NUMBER

3773

DATE MAILED: 01/20/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 429 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 429 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	11/023,783	HUBER, CHRISTOPH HANS	
	Examiner	Art Unit	
	MARK MASHACK	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to an amendment dated 10/12/2011.
2. An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
3. The allowed claim(s) is/are 1,2,6-11,45-51 and 53.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date ____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date ____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other ____. |

/Mark Mashack/
Examiner, Art Unit 3773

DETAILED ACTION

This office action is in response to a communication dated 10/12/2011.

Election/Restrictions

1. This application is in condition for allowance except for the presence of **claims 4, 12-44, 54-58** directed to methods and devices non-elected without traverse.

Accordingly, **claims 4, 12-44, 54-58** have been cancelled.

Allowable Subject Matter

2. **Claims 1-2, 6-11, 45-51, 53** are allowed.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,873,366, US 2004/0118415, US 2005/0251251 discloses relevant prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Mashack whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Corrine McDermott, at (571) 272-4754***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/CORRINE M MCDERMOTT/
Supervisory Patent Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 11/023,783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS	
	Examiner MARK MASHACK	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-5,873,366 A	02-1999	Chim et al.	128/898
*	B US-2004/0118415 A1	06-2004	Hall et al.	128/898
*	C US-2005/0251251 A1	11-2005	Cribier, Alain	623/002.11
	D US-			
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			


FOREIGN PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N				
	O				
	P				
	Q				
	R				
	S				
	T				

NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	
V	
W	
X	


*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Issue Classification 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner MARK MASHACK	Art Unit 3773

ORIGINAL						INTERNATIONAL CLASSIFICATION														
CLASS		SUBCLASS				CLAIMED					NON-CLAIMED									
623		2.11				A	6	1	F	2 / 24 (2006.01.01)										
CROSS REFERENCE(S)						A	6	1	B	17 / 3205 (2006.01.01)										
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																			
128	898																			

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant <input type="checkbox"/> CPA <input type="checkbox"/> T.D. <input type="checkbox"/> R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
6	1														
7	2														
8	6														
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14	51														
15	53														

/MARK MASHACK/ Examiner, Art Unit 3773 (Assistant Examiner)	1/4/2012 (Date)	Total Claims Allowed: 16	
/CORRINE M MCDERMOTT/ Supervisory Patent Examiner, Art Unit 3773 (Primary Examiner)	01/15/2012 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 10

Search Notes 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Mark Mashack	Art Unit 3773

SEARCHED			
Class	Subclass	Date	Examiner
623	1.11,2.1,2.11	1/5/2012	MFM
606	139,144-148,166,184-185,191-192,194	1/5/2012	MFM
128	898	1/5/2012	MFM

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor name search	9/17/2008	NS
Class/subclass search	9/17/2008	NS
East text search	9/17/2008	NS
Forward/backward citation search	9/17/2008	NS
Updated Search	7/7/2009	MFM
Updated Search	3/18/2010	MFM
Updated Search	12/4/2010	MFM
Consulted Ex. Julian Woo	1/3/2012	MFM
Updated Search	1/5/2012	MFM

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
623	2.1,2.11	1/5/2012	MFM

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S2	7	"023783".ap.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:27
S3	2	"20050240200".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:30
S4	2	"20060074484".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:36
S5	1	2006-282287.NRAN.	DERWENT	ADJ	ON	2009/06/29 11:36
S6	2	"6425916".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:37
S7	6	"2006012980".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:38
S8	2	"20060012980".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:38
S10	220	623/2.1.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:45
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S12	0	S10 and trocar sam apex	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:47
S13	7	S10 and trocar same apex	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:47
S14	0	"295390.ap"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:49
S15	6	"295390".ap.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2009/06/29 11:49
S16	1	(10/295390).APP.	USPAT; USOCR	ADJ	ON	2010/03/08 10:57
S17	9	("4207903" "4424818" "4936304" "5716392" "5766163" "6079414" "6258069").PN. OR ("6978176").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/08 10:57
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S20	252	623/2.1.ccls.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/08 11:37
S21	126	S20 and (access or punctur\$3 or valve) with ventricle	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/08 11:38
S22	10	S20 and (punctur\$3) with ventricle	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/08 11:51
S24	5196	128/898.ccls.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/08 11:56
S25	40	S24 and (punctur\$3) with ventricle	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/08 11:57
S26	16	S24 and (punctur\$3) with ventricular	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/08 12:18
S27	26	(S20 or S24) and (punctur\$3) with ventricular	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/08 12:18
S28	2	"6425916".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/08 12:25
S29	6	"2006012980".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/08 12:25
S30	32	("20030130571" "3844292" "4207903" "4280510" "4357946" "4424818" "4475560" "4936304" "5336252" "5571215" "5618287" "5665109" "5716392" "5758664" "5766163" "5855592" "5904711" "5964793" "5978714" "6010526" "6079414" "6087394" "6139555" "6162195" "6224617" "6231518" "6258069" "6258105" "6345198"	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/08 12:32

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S33	5	S32 and (trocar or needle) with apex	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 11:53
S34	14	S32 and (trocar or needle or punctur\$3) with apex	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 11:53
S35	23	S32 and (trocar or needle or punctur\$3) same apex	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 11:55
S36	43	S32 and (trocar or needle or punctur\$3) same ventric\$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:07
S37	22	S36 not S35	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:08
S38	4	S32 and (antegrade) same apex	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:12
S39	12	S32 and access with through with ventricle	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:13
S40	4	S32 and transventric\$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:15
S41	4	S32 and transventric\$6	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:15
S42	33	S32 and (trocar or needle or punctur\$3) with wall	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:17
S43	911	623/2.1.ccls. or 623/2.11.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/18 12:18
S44	106	S43 and (trocar or needle or punctur\$3) with wall	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:18
S45	47	S43 and (trocar or needle or punctur\$3) same apex	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:19

S46	8	S43 and transventric\$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:25
S47	49	S43 and transsept\$2	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:25
S48	6	S43 and transatri\$3	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:25
S49	16	S43 and (antegrade) same apex	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:27
S50	12	S49 not S38	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:27
S51	0	"2005020200".pn.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:31
S52	1	"20050240200".pn.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:31
S53	45	S43 and transap\$5	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:32
S54	9	"139741".ap.	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:35
S55	131	S43 and antegrad\$3	US-PGPUB; USPAT; USOCR	ADJ	ON	2010/03/18 12:38
S56	66	(US-20060074484-\$ or US-20050240200-\$ or US-20030130571-\$ or US-20070078297-\$ or US-20040092858-\$ or US-20090192598-\$ or US-20090157174-\$ or US-20090069889-\$ or US-20090030510-\$ or US-20070198082-\$ or US-20060167541-\$ or US-20080029105-\$ or US-20020179098-\$ or US-20090088836-\$ or US-20060025855-\$ or US-20060020327-\$ or US-20080015687-\$ or US-20100004739-\$ or US-20090319037-\$ or US-20090069890-\$ or US-20090069886-\$ or US-20080234813-\$ or US-20070027534-\$ or US-20070112422-\$ or US-20050251251-\$ or US-20030014104-\$).did. or (US-20020123802-\$ or US-20030114913-\$ or US-20050137691-\$).did. or (US-6425916-\$ or US- 6978176-\$ or US-	US-PGPUB; USPAT	ADJ	ON	2010/03/18 13:29

		<p>6079414-\$ or US- 6258069-\$ or US- 5766163-\$ or US- 5716392-\$ or US- 7635386-\$ or US- 7534260-\$ or US- 7213601-\$ or US- 6260552-\$ or US- 6908424-\$ or US- 6755777-\$ or US- 6406420-\$ or US- 7452325-\$ or US- 5275166-\$ or US- 5613947-\$ or US- 5391156-\$ or US- 7217277-\$ or US- 5261459-\$ or US- 5810721-\$ or US- 5720730-\$ or US- 5308336-\$ or US- 5385553-\$ or US- 5209737-\$ or US- 5411491-\$ or US- 6010531-\$).did. or (US- 6464707-\$ or US- 7323004-\$ or US- 7373207-\$ or US- 7513908-\$ or US- 5655548-\$ or US- 6447539-\$ or US- 7445630-\$ or US- 7641686-\$ or US- 7666224-\$ or US- 7320704-\$ or US- 7018406-\$).did.</p>				
S57	9	S56 and iliac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/18 13:29
S58	2	S56 and snare same (guide wire or guidewire)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/18 13:31
S59	16	S56 and filter	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/18 13:33

S60	12	S56 and filter same aortic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/18 13:34
S61	2	"20040093060".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/18 13:42
S62	6	"130355".ap.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/18 13:44
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S65	32	S63 and (femoral or iliac) same aortic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/18 13:51
S66	7	S43 and snare same (guide wire or guidewire) same aortic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2010/03/18 13:58

S67	35	("20030130571" "20060095025" "20080147184" "3844292" "4207903" "4280510" "4357946" "4424818" "4475560" "4936304" "5336252" "5571215" "5618287" "5665109" "5716392" "5758664" "5766163" "5855592" "5904711" "5964793" "5978714" "6010526" "6079414" "6087394" "6139555" "6162195" "6224617" "6231518" "6258069" "6258105" "6269819" "6345198" "6978176" "7146225" "7270669"). PN. OR ("7534260"). URFN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2012/01/04 13:50
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S70	5643	128/898.ccls.	US-PGPUB; USPAT; USOCR	ADJ	ON	2012/01/04 14:08
S71	27	(S68 or S70) and (guide or wire) with (follow\$3 or push\$3) with flow	US-PGPUB; USPAT; USOCR	ADJ	ON	2012/01/04 14:09
S72	93	(S68 or S70) and transapical	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2012/01/04 14:33
S73	41	(S68 or S70) and (punctur\$3 or pierc\$3) with apex	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2012/01/04 14:43
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S75	5643	128/898.ccls.	US-PGPUB; USPAT; USOCR	ADJ	ON	2012/01/04 16:37
S76	45	(S74 or S75) and (punctur\$3 or pierc\$3) with (apex or apical)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2012/01/04 16:37

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S78	19	S77 and (punctur\$3 or pierc\$3) with (apex or apical)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2012/01/04 16:38
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S81	67	S76 or S78 or S80	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2012/01/04 16:39
S82	79	(S74 or S75 or S77) and (punctur\$3 or pierc\$3) with (myocardium)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2012/01/04 16:45
S83	5126	606/139-148.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2012/01/04 16:57
S84	7614	606/166,184-185,191,192,194.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2012/01/04 17:00
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S87	233	("20010000041" "20010003985" "20010008969" "20010018596" "20010020172" "20010029385" "20010034547" "20010037149" "20010039445" "20010044631" "20010049523" "20010053932" "20020004662" "20020007138" "20020058897" "20020077654" "20020092535" "20020092536" "20020095206" "20020100484" "20020138087" "20020143285" "20020143289" "20020161383" "20020165479" "20020165606" "20020179098" "20020183716" "20020193782" "20030018379" "20030044315" "20030045828" "20030055371" "20030073973" "20030078561" "20030100920" "20030105514" "20030120195" "20030149474" "20030158573" "20030163198" "20030181938" "20030191449" "20030195457" "20030195458" "20030204160" "20030212413" "20030216679" "20030229366" "20030236542" "20040006298" "20040015225" "20040019348" "20040044392" "2127903" "3620218"	US-PGPUB; USPAT; USOCR	ADJ	ON	2012/01/04 17:16
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EAST Search History (Interference)

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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 11/023,783 filed 12/28/2004 by Christoph Hans Huber, attorney Weiss & Arons, LLP, examiner MASHACK, MARK F, art unit 3773, and mail date 10/12/2011.

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Applicant-Initiated Interview Summary	Application No. 11/023,783	Applicant(s) HUBER, CHRISTOPH HANS	
	Examiner MARK MASHACK	Art Unit 3773	

All participants (applicant, applicant's representative, PTO personnel):

(1) MARK MASHACK. (3) CHRISTOFF HUBER ET AL.
(2) JULIAN WOO. (4) EDWARD ARONS ET AL.

Date of Interview: 16 September 2011.

Type: Telephonic Video Conference
 Personal [copy given to: applicant applicant's representative]

Exhibit shown or demonstration conducted: Yes No.
If Yes, brief description: Applicant provided a model and animation of the claimed method.

Issues Discussed 101 112 102 103 Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1, 7, 45 and 46.

Identification of prior art discussed: Sequin et al. US 2004/0210304, Sequin US 2004/0093060, Lattouf US 2003/0130571.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicants and Examiners discussed possible claim language including either "the feeding continuing such that the wire follows the blood flow until..." or "the feeding is directed by the blood flow such that the wire follows the blood flow, the feeding continuing..." and deleting "that is pointed toward an aortic valve" of Claim 46. The claim language appears to overcome the prior art of record.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Attachment

/Mark Mashack/
Examiner, Art Unit 3773

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of : Christoph Hans Huber

Application No. : 11/023,783

Confirmation No. : 1933

Examiner : Mark F. Mashack

Filed : December 28, 2004

Group Art Unit : 3773

For : METHODS AND DEVICES FOR REPAIR OR
REPLACEMENT OF HEART VALVES OR ADJACENT
TISSUE WITHOUT THE NEED FOR FULL
CARDIOPULMONARY SUPPORT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

REPLY TO OFFICE ACTION

Dear Sir:

This reply is being filed in response to the Office Action mailed on June 27, 2011 in the above-identified patent application.

Amendments to the claims begin on page 2.

Remarks begin on page 10.

Amendments to the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1 (Currently Amended). A method of operating on a patient comprising:
 accessing the patient's heart by piercing a myocardium at a ventricular apex of the heart with a cannulated needle having a sharp end;
 feeding through the cannulated needle an elongated wire having a length along which the wire is configured to conform to a direction of blood flow, the feeding directed by the blood flow such that the wire follows the blood flow, the feeding continuing until the length extends at least from the ventricular apex to an aorta;
 installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device; and
 performing a surgical procedure of implanting a heart valve.

2 (Original). The method of claim 1 further comprising resecting a native heart valve.

3 (Cancelled).

4 (Withdrawn). The method of claim 1 further comprising repairing an aortic dissection.

5 (Cancelled).

6 (Original). The method of claim 1 wherein installing the access device in the wall of the heart further comprises installing the access device in a ventricular apex of the heart.

7 (Currently Amended). A method for implanting a heart valve comprising:
 accessing a patient's heart by piercing a myocardium with a cannulated needle having a sharp end;
 feeding through the cannulated needle an elongated wire configured to conform to a direction of blood flow, the feeding continuing such that the wire follows the blood

flow until a length of the wire extends at least from a ventricular apex of the heart through an aortic valve of the heart;

installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;

inserting a valve delivery device through the access device; and

installing the heart valve.

8 (Original). The method of claim 7 further comprising resecting a native heart valve.

9 (Original). The method of claim 8 wherein the resecting the native heart valve is performed percutaneously and the installing the heart valve is performed transapically.

10 (Original). The method of claim 7 wherein the installing the heart valve further comprises radially expanding the heart valve.

11 (Original). The method of claim 7 wherein the installing the heart valve further comprises pulling leaflets of a native heart valve downward.

12 (Withdrawn). A device for implanting a heart valve comprising:
means for radially expanding the heart valve; and
means for supplementing blood flow through the device during the implanting the heart valve.

13 (Withdrawn). The device of claim 12 further comprising means for pulling leaflets of a native valve downward.

14 (Withdrawn). The device of claim 12 wherein the radially expanding the heart valve occurs in more than one stage.

15 (Withdrawn). The device of claim 14 wherein the more than one stage is effectuated by a multi-stage balloon.

16 (Withdrawn). A method of visualizing a portion of a patient's circulatory system comprising:

injecting a transparent oxygen-carrying fluid into the portion of the circulatory system; and

inserting an optical device into the portion of the circulatory system containing the transparent oxygen-carrying fluid.

17 (Withdrawn). The method of claim 16 further comprising temporarily exchanging all blood of the patient's circulatory system with the transparent oxygen-carrying fluid.

18 (Withdrawn). Instrumentation for accessing a chamber of a patient's heart, the heart having a myocardium, the instrumentation comprising:

a catheter having a proximal sealing device for sealing the catheter against a proximal surface of the myocardium; and

means for preventing bleeding through the catheter.

19 (Withdrawn). The instrumentation of claim 18 further comprising a distal sealing device for sealing the catheter against the distal surface of the myocardium.

20 (Withdrawn). An implantable heart valve comprising:

a tissue support structure; and

tissue valve leaflets, wherein the tissue valve leaflets are grown inside the tissue support structure by genetic engineering.

21 (Withdrawn). The heart valve of claim 20 wherein the tissue support structure is a stent.

22 (Withdrawn). The heart valve of claim 20 wherein the tissue support structure comprises stainless steel.

23 (Withdrawn). The heart valve of claim 20 wherein the tissue support structure comprises a self-expanding material.

24 (Withdrawn). The heart valve of claim 23 wherein the self-expanding material is nitinol.

25 (Withdrawn). A device for inserting more than one guidewire into a patient comprising:

a wire placement device; and
a guidewire attached to the wire placement device, wherein the wire placement device is configured to track an already placed guidewire.

26 (Withdrawn). The device of claim 25 wherein the guidewire is removably attached to the wire placement device.

27 (Withdrawn). The device of claim 25 wherein the wire placement device comprises a locking mechanism.

28 (Withdrawn). A method of breaking down calcification of a heart valve comprising:

inserting a catheter-based ultrasound device into a calcified heart valve;
and
concentrating ultrasound radiation on the calcification of the calcified heart valve to break down the calcification.

29 (Withdrawn). The method of claim 28 further comprising inserting a reflector into the calcified heart valve to magnify the ultrasound radiation.

30 (Withdrawn). A low-profile heart valve comprising:

at least three leaflets, wherein one side of each leaflet overlaps a neighboring leaflet such that the leaflets open sequentially and close sequentially.

31 (Withdrawn). A heart valve comprising:

an inner circumference and an outer circumference, wherein the inner circumference is a circumference of an annulus formed by leaflets of the heart valve; and the outer circumference is a circumference of a fluid-tight diaphragm, wherein the diaphragm fills a space between the inner circumference and the outer circumference.

32 (Withdrawn). A mitral valve repair device comprising:
a first head defining an operating plane; and
a second head operably attached to the first head and configured to
displace a leaflet with respect to the operating plane.

33 (Withdrawn). The repair device of claim 32 wherein the first head is a U-
shaped head.

34 (Withdrawn). The repair device of claim 32 wherein the first head comprises
an attachment mechanism for attaching at least two portions of the leaflet.

35 (Withdrawn). The repair device of claim 32 further comprising a handle for
operating the second head with respect to the first head.

36. (Withdrawn). A method of repairing an aortic dissection comprising:
accessing a patient's heart;
installing an access device in a wall of the heart, the access device having
means for preventing bleeding through the access device;
inserting a dissection repair device through the access device; and
repairing the aortic dissection.

37 (Withdrawn). A device for repairing an aortic dissection comprising:
annularly enlargeable componentry configured to be inserted into a
patient's aorta; and
means for closing a void created by the aortic dissection.

38 (Withdrawn). The device of claim 37 wherein the means for closing the void
comprise injection needles for injecting a tissue sealant.

39 (Withdrawn). The device of claim 38 wherein the tissue sealant comprises a
biologically compatible glue.

40 (Withdrawn). The device of claim 38 wherein the tissue sealant comprises
mechanical sutures.

41 (Withdrawn). The device of claim 38 wherein the tissue sealant comprises surgical staples.

42 (Withdrawn). The device of claim 38 wherein the annularly enlargeable componentry comprises means for supplementing blood flow through the componentry during the repair.

43 (Withdrawn). A device for resecting a diseased heart valve comprising:
a first set of annularly enlargeable componentry having a first longitudinal axis and a proximal cutting edge;
a second set of annularly enlargeable componentry having a second longitudinal axis and a distal cutting edge;
wherein the device is configured to resect the diseased heart valve when the first set of componentry is enlarged on a distal side of the diseased heart valve and the second set of componentry is enlarged on a proximal side of the diseased heart valve and the sets of componentry are drawn axially together along the longitudinal axes.

44 (Withdrawn). The device of claim 43 wherein the first longitudinal axis and the second longitudinal axis are coaxial.

45 (Currently Amended). A method for implanting an endoprosthesis comprising:
accessing a patient's heart by piercing a myocardium with a cannulated needle having a sharp end;
installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
after the accessing and before the installing, feeding through the cannulated needle an elongated wire having a length along which the wire is configured to conform to a direction of blood flow, the feeding directed by the blood flow such that the wire follows the blood flow, the feeding continuing until the length extends at least from a ventricular apex of the heart to an aorta;
inserting an endoprosthesis delivery device through the access device; and

installing the endoprosthesis.

46 (Currently Amended). A method of operating on a patient comprising:
accessing the patient's heart by piercing a myocardium with a cannulated needle having a sharp end ~~that is pointed toward an aortic valve;~~
installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device; and
after the accessing and before the installing, feeding through the cannulated needle an elongated wire having a length along which the wire is configured to conform to a direction of blood flow, the feeding continuing such that the wire follows the blood flow until the length extends at least from a ventricular apex of the heart to an aorta;
performing a surgical procedure in antegrade direction, wherein the surgical procedure is selected from the group consisting of implanting a heart valve or and removing, resecting or modifying a native heart valve.

47 (Previously Presented). The method according to claim 46, wherein the aortic valve is implanted.

48 (Previously Presented). The method according to claim 47, wherein a guidewire is fed into the left ventricle, and wherein the guidewire is advanced through the aortic valve and into the aorta.

49 (Previously Presented). The method according to claim 48, wherein the guidewire is further advanced into the iliac or femoral arteries.

50 (Previously Presented). The method according to claim 49, wherein wire-guided devices are inserted from the antegrade direction.

51 (Previously Presented). The method according to claim 50, wherein wire-guided devices are inserted from the retrograde direction.

52 (Cancelled).

53 (Currently Amended). The method of claim ~~[[52]]~~ 46 wherein the feeding continues until a distal end of the elongated wire exits the patient via an artery wall.

54 (Withdrawn). A method of operating on a patient, the method comprising:
piercing myocardium with a cannulated needle having a sharp end that is oriented along a trajectory from a ventricular apex to an aortic valve, the piercing opening a transapical channel in myocardial tissue;
placing the outer surface of a catheter in direct contact with the channel tissue; and
delivering a device along a guidewire that extends through the catheter to an aorta.

55 (Withdrawn). The method of claim 54 wherein the placing includes:
positioning a proximal opening of the catheter outside the patient; and
positioning a distal opening of the catheter at a position that is distally spaced apart from a distal end of the channel.

56 (Withdrawn). The method of claim 55 further comprising, after the piercing and before the placing, feeding through the cannulated needle elongated wire having a length along which the wire is configured to conform to a direction of blood flow, the feeding continuing until the length extends at least from the apex to an aorta.

57 (Withdrawn). The method of claim 52 wherein the feeding continues until a distal end of the elongated wire exits the patient via an artery wall.

58 (Withdrawn). The method of claim 54 further comprising providing a purse string suture at the apex to press heart tissue against the catheter outer surface.

REMARKS

Upon entry of the foregoing amendments claims 1-2, 4, 6-51 and 53-58 will be pending in this application. Claims 12-44 and 54-58 have been withdrawn from consideration.

I. Summary of the Office Action

The Examiner rejected claims 1-2, 6-7, 10-11 and 45 under 35 U.S.C. § 103(a) as being unpatentable over Seguin et al. U.S. Patent Publication No. 2004/0093060 (hereinafter, "Seguin '060") in view of Lattouf U.S. Patent Publication No. 2003/0130571 (hereinafter, "Lattouf").

The Examiner rejected claims 1-2, 6-11, 45-51 and 53 under 35 U.S.C. § 103(a) as being unpatentable over Seguin et al. U.S. Patent Publication No. 2004/0210304 (hereinafter, "Seguin '304") in view of Lattouf.

II. Summary of Applicant's Reply

Applicant has amended claims 1, 7, 45 and 46.

Applicant has traversed the Examiner's rejections.

III. Summary of Personal Interview

Applicants wish to thank Examiner Mashack and Primary Examiner Woo for their time, courtesy and consideration during a September 16, 2011, interview at the U.S. Patent and Trademark Office. Dr. Christoph Huber, applicant, Mr. Michael Schwager, President, Endoheart, exclusive licensee of this application, representative Joel Weiss, Esq., and the undersigned representative were present at the interview, along with Primary Examiner Woo and Examiner Mashack.

Independent claims 1, 7, 45 and 46 were discussed relative to the references of record.

Applicant presented two slides, two video sequences, a three-dimensional model illustrating a portion of a human heart and a surgical instrument.

Examiner Mashack proposed amending the claims to express allowable subject matter in method claim phraseology.

Primary Examiner Woo, Examiner Mashack and applicant's representatives discussed and agreed upon the following amendments that, in the Examiners' view would overcome the references of record and be supported by the application:

1. "...the feeding continuing such that the wire follows the blood flow until...[;]" or
2. "...the feeding is directed by the blood flow such that the wire follows the blood flow, the feeding continuing..."

The Examiners and applicant's representatives also agreed upon the cancelation, in claim 46, of "that is pointed toward an aortic valve."

IV. Applicant's Reply to the Rejections Over Seguin '060 in view of Lattouf

The Examiner rejected claims 1-2, 6-7, 10-11 and 45 under 35 U.S.C. § 103(a) as being unpatentable over Seguin '060 in view of Lattouf.

Claims 1, 7 and 45 are independent. Claims 2 and 6 depend from claim 1. Claims 10-11 depend from claim 7.

A. Claims 1, 2 and 6

Claim 1 is independent. Claims 2 and 6 depend from claim 1.

Claim 1 requires (as did the previous version of claim 1) *feeding through a cannulated needle in a myocardium an elongated wire having a length along which the wire is configured to conform to a direction of blood flow.*

Applicant respectfully submits that neither Seguin '060 nor Lattouf, nor a combination of Seguin '060 and Lattouf, shows or suggests *feeding through a cannulated needle in a myocardium an elongated wire having a length along which the wire is configured to conform to a direction of blood flow.* To the contrary, Lattouf teaches guidewires that are configured for advancement against the direction of blood flow through the left ventricle and further advanced through the mitral valve into the left atrium. See, e.g., Lattouf paras. 10 and 57. Applicant respectfully asserts, therefore, that Lattouf does not make up for the deficiency in Seguin '060.

Nevertheless, based on the Examiner's proposal for method claim phraseology, and the discussion mentioned in the foregoing Summary of Personal Interview, applicant has amended claim 1 to require that:

the feeding is directed by the blood flow such that the wire follows the blood flow, the feeding continuing until the length extends at least from a ventricular apex to an aorta.

Applicant respectfully submits that Seguin '060 does not show or suggest ***a feeding directed by the blood flow such that the wire follows the blood flow, the feeding continuing until the length extends at least from a ventricular apex to an aorta.***

Applicant respectfully further submits that, for at least the aforementioned reasons, Lattouf does not make up for the deficiency in Seguin '060.

Applicant respectfully submits that, for at least this reason, claim 1 is patentable over Seguin '060, Lattouf or a combination of Seguin '060 and Lattouf. Applicant respectfully submits that, therefore, claims 2 and 6 are also patentable over Seguin '060, Lattouf or a combination of Seguin '060 and Lattouf.

Applicant respectfully requests that for at least the foregoing reasons, the rejections over Seguin '060 in view of Lattouf of claims 1, 2 and 6 be withdrawn.

B. Claims 7, 10 and 11

Claim 7 is independent. Claims 10 and 11 depend from claim 7.

Claim 7 requires (as did the previous version of claim 7) ***feeding through a cannulated needle in a myocardium an elongated wire configured to conform to a direction of blood flow.***

Applicant respectfully submits that neither Seguin '060 nor Lattouf, nor a combination of Seguin '060 and Lattouf, shows or suggests ***feeding through a cannulated needle in a myocardium an elongated wire configured to conform to a direction of blood flow.*** To the contrary, Lattouf teaches guidewires that are configured for advancement against the direction of blood flow through the left ventricle and further advanced through the mitral valve into the left atrium. See, e.g., Lattouf paras. 10 and 57. Applicant respectfully asserts, therefore, that Lattouf does not make up for the deficiency in Seguin '060.

Nevertheless, based on the Examiner's proposal for method claim phraseology, and the discussion mentioned in the foregoing Summary of Personal Interview, applicant has amended claim 7 to require:

the feeding continuing such that the wire follows the blood flow until a length of the wire extends at least from a ventricular apex of the heart through an aortic valve of the heart.

Applicant respectfully submits that Seguin '060 does not show or suggest ***a feeding that continues such that the wire follows the blood flow until a length of the wire extends at least from a ventricular apex of the heart through an aortic valve of the heart.***

Applicant respectfully further submits that, for at least the aforementioned reasons, Lattouf does not make up for the deficiency in Seguin '060.

Applicant respectfully submits that, for at least this reason, claim 7 is patentable over Seguin '060, Lattouf or a combination of Seguin '060 and Lattouf. Applicant respectfully submits that, therefore, claims 10 and 11 are also patentable over Seguin '060, Lattouf or a combination of Seguin '060 and Lattouf.

Applicant respectfully requests that for at least the foregoing reasons, the rejections over Seguin '060 in view of Lattouf of claims 7, 10 and 11 be withdrawn.

C. Claim 45

Claim 45 is independent. Claim 45 requires (as did the previous version of claim 45) ***feeding through a cannulated needle in a myocardium an elongated wire having a length along which the wire is configured to conform to a direction of blood flow.***

Applicant respectfully submits that neither Seguin '060 nor Lattouf, nor a combination of Seguin '060 and Lattouf, shows or suggests ***feeding through a cannulated needle in a myocardium an elongated wire having a length along which the wire is configured to conform to a direction of blood flow.*** To the contrary, Lattouf teaches guidewires that are configured for advancement against the direction of blood flow through the left ventricle and further advanced through the mitral valve into the left atrium. See, e.g., Lattouf paras. 10 and 57. Applicant respectfully asserts, therefore, that Lattouf does not make up for the deficiency in Seguin '060.

Nevertheless, based on the Examiner's proposal for method claim phraseology, and the discussion mentioned in the foregoing Summary of Personal Interview, applicant has amended claim 45 to require that:

the feeding is directed by the blood flow such that the wire follows the blood flow, the feeding continuing until the length extends at least from a ventricular apex of the heart to an aorta.

Applicant respectfully submits that Seguin '060 does not show or suggest ***a feeding directed by the blood flow such that the wire follows the blood flow, the feeding continuing until the length extends at least from a ventricular apex of the heart to an aorta.***

Applicant respectfully further submits that, for at least the aforementioned reasons, Lattouf does not make up for the deficiency in Seguin '060.

Applicant respectfully submits that, for at least this reason, claim 45 is patentable over Seguin '060, Lattouf or a combination of Seguin '060 and Lattouf.

Applicant respectfully requests that for at least the foregoing reasons, the rejections over Seguin '060 in view of Lattouf of claim 45 be withdrawn.

V. Applicant's Reply to the Rejections Over Seguin '304 in view of Lattouf

The Examiner rejected claims 1-2, 6-11, 45-51 and 53 under 35 U.S.C. § 103(a) as being unpatentable over Seguin '304 in view of Lattouf. Claims 1, 7, 45 and 46 are independent. Claims 2 and 6 depend from claim 1. Claims 8-11 depend from claim 7. Claims 47-51 and 53 depend from claim 46.

A. Claims 1, 2 and 6

Claim 1 is independent. Claims 2 and 6 depend from claim 1.

Claim 1 requires (as did the previous version of claim 1) ***feeding through a cannulated needle in a myocardium an elongated wire having a length along which the wire is configured to conform to a direction of blood flow.***

Applicant respectfully submits that neither Seguin '304 nor Lattouf, nor a combination of Seguin '304 and Lattouf, shows or suggests ***feeding through a cannulated needle in a myocardium an elongated wire having a length along which the wire is configured to conform to a direction of blood flow.*** To the contrary, Lattouf teaches guidewires that are

configured for advancement against the direction of blood flow through the left ventricle and further advanced through the mitral valve into the left atrium. See, e.g., Lattouf paras. 10 and 57. Applicant respectfully asserts, therefore, that Lattouf does not make up for the deficiency in Seguin '304.

Nevertheless, based on the Examiner's proposal for method claim phraseology, and the discussion mentioned in the foregoing Summary of Personal Interview, applicant has amended claim 1 to require that:

the feeding is directed by the blood flow such that the wire follows the blood flow, the feeding continuing until the length extends at least from a ventricular apex to an aorta.

Applicant respectfully submits that Seguin '304 does not show or suggest ***a feeding directed by the blood flow such that the wire follows the blood flow, the feeding continuing until the length extends at least from a ventricular apex to an aorta.***

Applicant respectfully further submits that, for at least the aforementioned reasons, Lattouf does not make up for the deficiency in Seguin '304.

Applicant respectfully submits that, for at least this reason, claim 1 is patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf. Applicant respectfully submits that, therefore, claims 2 and 6 are also patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf.

Applicant respectfully requests that for at least the foregoing reasons, the rejections over Seguin '304 in view of Lattouf of claims 1, 2 and 6 be withdrawn.

B. Claims 7-11

Claim 7 is independent. Claims 8-11 depend from claim 7.

Claim 7 requires (as did the previous version of claim 7) ***feeding through a cannulated needle in a myocardium an elongated wire configured to conform to a direction of blood flow.***

Applicant respectfully submits that neither Seguin '304 nor Lattouf, nor a combination of Seguin '304 and Lattouf, shows or suggests ***feeding through a cannulated needle in a myocardium an elongated wire configured to conform to a direction of blood flow.*** To the contrary, Lattouf teaches guidewires that are configured for advancement against the direction of blood flow through the left ventricle and further advanced through the mitral valve

into the left atrium. See, e.g., Lattouf paras. 10 and 57. Applicant respectfully asserts, therefore, that Lattouf does not make up for the deficiency in Seguin '304.

Nevertheless, based on the Examiner's proposal for method claim phraseology, and the discussion mentioned in the foregoing Summary of Personal Interview, applicant has amended claim 7 to require that:

the feeding continuing such that the wire follows the blood flow until a length of the wire extends at least from a ventricular apex of the heart through an aortic valve of the heart.

Applicant respectfully submits that Seguin '304 does not show or suggest ***a feeding continuing such that the wire follows the blood flow until a length of the wire extends at least from a ventricular apex of the heart through an aortic valve of the heart.***

Applicant respectfully further submits that, for at least the aforementioned reasons, Lattouf does not make up for the deficiency in Seguin '304.

Applicant respectfully submits that, for at least this reason, claim 7 is patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf. Applicant respectfully submits that, therefore, claims 8-11 are also patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf.

Applicant respectfully requests that for at least the foregoing reasons, the rejections over Seguin '304 in view of Lattouf of claims 7-11 be withdrawn.

C. Claim 45

Claim 45 is independent. Claim 45 requires (as did the previous version of claim 45) ***feeding through a cannulated needle in a myocardium an elongated wire having a length along which the wire is configured to conform to a direction of blood flow.***

Applicant respectfully submits that neither Seguin '304 nor Lattouf, nor a combination of Seguin '304 and Lattouf, shows or suggests ***feeding through a cannulated needle in a myocardium an elongated wire having a length along which the wire is configured to conform to a direction of blood flow.*** To the contrary, Lattouf teaches guidewires that are configured for advancement against the direction of blood flow through the left ventricle and further advanced through the mitral valve into the left atrium. See, e.g., Lattouf paras. 10 and 57. Applicant respectfully asserts, therefore, that Lattouf does not make up for the deficiency in Seguin '304.

Nevertheless, based on the Examiner's proposal for method claim phraseology, and the discussion mentioned in the foregoing Summary of Personal Interview, applicant has amended claim 45 to require that:

the feeding is directed by the blood flow such that the wire follows the blood flow, the feeding continuing until the length extends at least from a ventricular apex of the heart to an aorta.

Applicant respectfully submits that Seguin '304 does not show or suggest ***a feeding directed by the blood flow such that the wire follows the blood flow, the feeding continuing until the length extends at least from a ventricular apex of the heart to an aorta.***

Applicant respectfully further submits that, for at least the aforementioned reasons, Lattouf does not make up for the deficiency in Seguin '304.

Applicant respectfully submits that, for at least this reason, claim 45 is patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf.

Applicant respectfully requests that for at least the foregoing reasons, the rejections over Seguin '304 in view of Lattouf of claim 45 be withdrawn.

D. Claims 46-51 and 53

Claim 46 is independent. Claims 47-51 and 53 depend from claim 46.

Claim 46 requires (as did the previous version of claim 46) ***feeding through a cannulated needle in a myocardium an elongated wire having a length along which the wire is configured to conform to a direction of blood flow.***

Applicant respectfully submits that neither Seguin '304 nor Lattouf, nor a combination of Seguin '304 and Lattouf, shows or suggests ***feeding through a cannulated needle in a myocardium an elongated wire having a length along which the wire is configured to conform to a direction of blood flow.*** To the contrary, Lattouf teaches guidewires that are configured for advancement against the direction of blood flow through the left ventricle and further advanced through the mitral valve into the left atrium. See, e.g., Lattouf paras. 10 and 57. Applicant respectfully asserts, therefore, that Lattouf does not make up for the deficiency in Seguin '304.

Nevertheless, based on the Examiner's proposal for method claim phraseology, and the discussion mentioned in the foregoing Summary of Personal Interview, applicant has amended claim 46 to require:

the feeding continuing such that the wire follows the blood flow until a length of the wire extends at least from a ventricular apex of the heart to an aorta.

Applicant respectfully submits that Seguin '304 does not show or suggest *a feeding continuing such that the wire follows the blood flow until a length of the wire extends at least from a ventricular apex of the heart to an aorta.*

Applicant respectfully further submits that Lattouf, which is directed to methods that do not follow blood flow, does not make up for the deficiency in Seguin '304.

Applicant respectfully further submits that, for at least the aforementioned reasons, Lattouf does not make up for the deficiency in Seguin '304.

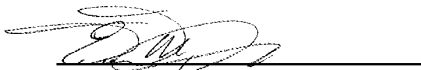
Applicant respectfully submits that, for at least this reason, claim 46 is patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf. Applicant respectfully submits that, therefore, claims 47-51 and 53 are also patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf.

Applicant respectfully requests that for at least the foregoing reasons, the rejections over Seguin '304 in view of Lattouf of claims 46-51 and 53 be withdrawn.

VI. Conclusion

Applicant respectfully submits that this application is in condition for allowance. Applicant respectfully requests reconsideration of the claims as amended and the prompt issue of a Notice of Allowance.

Respectfully Submitted,



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Date: October 12, 2011

Electronic Patent Application Fee Transmittal

Application Number:	11023783			
Filing Date:	28-Dec-2004			
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support			
First Named Inventor/Applicant Name:	Christoph Hans Huber			
Filer:	Joel Weiss			
Attorney Docket Number:	147-002 (06-692)			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with \$0 paid	2251	1	75	75

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				75

Electronic Acknowledgement Receipt

EFS ID:	11172081
Application Number:	11023783
International Application Number:	
Confirmation Number:	1933
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support
First Named Inventor/Applicant Name:	Christoph Hans Huber
Customer Number:	72822
Filer:	Joel Weiss
Filer Authorized By:	
Attorney Docket Number:	147-002 (06-692)
Receipt Date:	12-OCT-2011
Filing Date:	28-DEC-2004
Time Stamp:	15:49:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$75
RAM confirmation Number	2489
Deposit Account	504650
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

- Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)
- Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	147-002_Reply_to_27JUNE11_Non-Final_Office_Action_as_filed.pdf	156066 e25a86d9334c532a84d084b00dd5992c98a6db5	no	18
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30096 126a930142b97fff1d4ecfd8b208335439f06c26	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			186162		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/023,783		Filing Date 12/28/2004		<input checked="" type="checkbox"/> To be Mailed					
APPLICATION AS FILED – PART I														
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY						
FOR		NUMBER FILED	NUMBER EXTRA		RATE (\$)	FEE (\$)	OR		RATE (\$)	FEE (\$)				
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>		N/A	N/A		N/A				N/A					
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (i), or (m))</small>		N/A	N/A		N/A				N/A					
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>		N/A	N/A		N/A				N/A					
TOTAL CLAIMS <small>(37 CFR 1.16(j))</small>		minus 20 =	*		X \$ =		OR		X \$ =					
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>		minus 3 =	*		X \$ =				X \$ =					
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).												
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>														
					TOTAL				TOTAL					
* If the difference in column 1 is less than zero, enter "0" in column 2.														
APPLICATION AS AMENDED – PART II														
(Column 1)			(Column 2)			(Column 3)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY			
AMENDMENT	10/12/2011		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	OR		RATE (\$)	ADDITIONAL FEE (\$)	OR		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(i))</small>		* 55	Minus	** 56	= 0			X \$30 =	0	OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>		* 17	Minus	***17	= 0			X \$125 =	0	OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>													
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>													
					TOTAL ADD'L FEE				TOTAL ADD'L FEE					
(Column 1)			(Column 2)			(Column 3)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY			
AMENDMENT			CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	OR		RATE (\$)	ADDITIONAL FEE (\$)	OR		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(i))</small>		*	Minus	**	=			X \$ =		OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>		*	Minus	***	=			X \$ =		OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>													
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>													
					TOTAL ADD'L FEE				TOTAL ADD'L FEE					
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.														
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".														
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".														
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.														
Legal Instrument Examiner: /LISA THOMAS/														

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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PTOL-113A (08-10)
Approved for use through 07/31/2012. CMB 0851-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 11/023,783 First Named Applicant: Christoph Hans Huber
Examiner: MARK F. MASHACK Art Unit: 3773 Status of Application: Pending

Tentative Participants:
(1) Examiner Mark F. Mashack (2) Dr. Christoph H. Huber (5) Joel Weiss
(3) Mr. Michael Schwager (4) Edward M. Arons

Proposed Date of Interview: September 16, 2011 Proposed Time: 9:00 AM (AM/PM)

Type of Interview Requested:
(1) Telephonic (2) Personal (3) Video Conference

Exhibit To Be Shown or Demonstrated: YES NO
If yes, provide brief description: Undetermined.

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) <u>Rejections</u>	<u>Cl. 1, 7, 45</u>	<u>Seguin '060, Lattouf</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) <u>Rejections</u>	<u>CL 1, 7, 45-6</u>	<u>Seguin '304, Lattouf</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Continuation Sheet Attached Proposed Amendment or Arguments Attached
Brief Description of Arguments to be Presented: Seguin and Lattouf do not render obvious the claimed feeding of a length of flow-conforming wire from a ventricular apex to an aorta or through an aortic valve.

An interview was conducted on the above-identified application on _____

NOTE: This form should be completed and filed by applicant in advance of the interview (see MPEP § 713.01). If this form is signed by a registered practitioner not of record, the Office will accept this as an indication that he or she is authorized to conduct an interview on behalf of the principal (37 CFR 1.32(a)(3)) pursuant to 37 CFR 1.34. This is not a power of attorney to any above named practitioner. See the Instruction Sheet for this form, which is incorporated by reference. By signing this form, applicant or practitioner is certifying that he or she has read the Instruction Sheet. After the interview is conducted, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible. This application will not be delayed from issue because of applicant's failure to submit a written record of this interview.


Applicant/Applicant's Representative Signature

Examiner/SPE Signature

Edward M. Arons
Typed/Printed Name of Applicant or Representative

44,511
Registration Number, if applicable

This collection of information is required by 37 CFR 1.133. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 24 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND PERS OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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WEISS & ARONS

weiss & arons llp | 1540 Route 202, Suite 8, Pomona, New York 10970 | T 845.362.6100 F 845.362.6111

FACSIMILE

To:	Examiner Mark F. Mashack Group Art Unit 3773	From:	Edward M. Arons, Esq.
Fax:	571-273-8300	Pages (incl. cover):	2
Phone:	571-270-3861	Date:	August 30, 2011
Matter:		Subject:	PTOL-413A regarding September 16, 2011, interview
Your ref.:	11/023,783		
Our ref.:	147-002 (06-692)		

PTOL-413A attached, pursuant to the Examiner's request.

The information contained herein is confidential and may be privileged. The information is intended for use only by the person or persons named above. Any other use of the information is strictly prohibited. If you have received the information in error, please notify Weiss & Arons immediately at the telephone number set forth above.



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/023,783	12/28/2004	Christoph Hans Huber	147-002 (06-692)	1933
72822	7590	06/27/2011	EXAMINER	
Weiss & Arons, LLP 1540 Route 202, Suite 8 Pomona, NY 10970			MASHACK, MARK F	
			ART UNIT	PAPER NUMBER
			3773	
			MAIL DATE	DELIVERY MODE
			06/27/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

This office action is in response to a communication dated 6/3/2011. Claims 1-2, 4, 6-51, 53-58 are pending. Claims 4, 12-44, 54-58 have been withdrawn.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/3/2011 has been entered.

Response to Arguments

Applicant's arguments filed 6/3/2011 have been fully considered but they are not persuasive.

"Applicant respectfully submits that neither Seguin '060, nor Lattouf nor a combination of Seguin '060 and Lattouf show or suggest feeding from a ventricular apex of the heart to an aorta, an elongate wire that is configured to conform to a direction of blood flow." Examiner disagrees. **Seguin '060** discloses of extending the guide wire proximal and distal of the valve in order to deploy blades **30** (Paragraph 74) on both sides of the valve or a distal filter (Paragraph 27). **Lattouf** also teaches of advancing a guide wire past the valve to accommodate tools to treat the valve. The aortic valve

separates the left ventricle and the aorta, so that it would have been obvious to pass the guide wire into the aorta in order to accommodate tools to treat the valve. A guide wire is known to be floppy and would be capable of conforming to blood flow.

“Applicant respectfully submits that neither Seguin '304, nor Lattouf nor a combination of Seguin '304 and Lattouf show or suggest feeding from a ventricular apex of the heart to an aorta, an elongate wire that is configured to conform to a direction of blood flow.” Examiner disagrees. **Seguin '304** discloses of extending the guide wire extending proximally and distally of the valve (Paragraph 153). **Lattouf** also teaches of advancing a guide wire past the valve to accommodate tools to treat the valve. The aortic valve separates the left ventricle and the aorta, so that it would have been obvious to pass the guide wire into the aorta in order to accommodate tools to treat the valve. A guide wire is known to be floppy and would be capable of conforming to blood flow.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. **Claim 1-2, 6-7, 10-11, and 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Seguin et al. ("Seguin" US 2004/0093060)** in view of **Lattouf (US 2003/0130571)**.

Regarding Claim 1, 6-7, and 45, Segin '060 discloses a method comprising accessing the patient's heart, resecting a native heart valve percutaneously (Paragraph 21); replacing an aortic valve in the antegrade direction (**Regarding Claim 2 and 8,** Paragraph 28). **Seguin '060** does not disclose of installing an access device in a wall of the heart. However, **Lattouf** teaches of a novel method of accessing the left ventricle involving puncturing the ventricle by piercing a myocardium at a ventricular apex with a cannulate needle (14 gauge needle) having a sharp end; feeding through the cannulated needle an elongate wire (guide wire) which is configured to conform to a direction of blood flow and installing an access valve **30** (Paragraph 10). A guide wire is known to be floppy and would be capable of conforming to blood flow. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of **Seguin '060** with installing the access valve in order to facilitate access to the aortic valve in the antegrade direction especially with the patients that do not have the vasculature that allows for the conventional procedure.

Seguin '060 discloses of extending the guide wire proximal and distal of the valve in order to deploy blades **30** (Paragraph 74) on both sides of the valve or a distal

filter (Paragraph 27). **Lattouf** also teaches of advancing a guide wire past the valve to accommodate tools to treat the valve. The aortic valve separates the left ventricle and the aorta, so that it would have been obvious to pass the guide wire into the aorta in order to accommodate tools to treat the valve.

Regarding Claim 10, the heart valve is radially expanded. **Regarding Claim 11**, the resected heart valve would be removed transapically which is considered to be pulled down.

4. **Claim 1-2, 6-11, 45-51, 53** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Seguin et al.** ("**Seguin '304**" **US 2004/0210304**) in view of **Lattouf (US 2003/0130571)**.

Regarding Claims 1, 6-7, 46-47, Seguin '304 discloses a method comprising accessing the patient's heart; advancing a guidewire through the left ventricle through the aorta into the femoral arteries; and replacing an aortic valve in the antegrade direction by providing the guidewire (Paragraph 153 and Fig 61). **Seguin '304** does not disclose of installing an access device in a wall of the heart. However, **Lattouf** teaches of a novel method of accessing the left ventricle involving puncturing the ventricle by piercing the myocardium with a cannulated needle (Paragraph 10) and installing an access valve **30**. Even though the embodiment represented in the Figures is a method for treating the mitral valve, **Lattouf** also teaches that it can be used to treat an aortic valve (Paragraph 8). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of **Seguin '304** with installing the access

valve in order to facilitate access to the aortic valve in the antegrade direction especially with the patients that do not have the vasculature that allows for the conventional procedure. Examiner asserts that when treating an aortic valve, it would have been obvious for the cannulated needle to create a puncture with a direct path to the aortic valve.

Seguin '304 discloses of extending the guide wire extending proximally and distally of the valve (Paragraph 153). **Lattouf** also teaches of advancing a guide wire past the valve to accommodate tools to treat the valve. The aortic valve separates the left ventricle and the aorta, so that it would have been obvious to pass the guide wire into the aorta in order to accommodate tools to treat the valve.

Regarding Claim 2, 8-9, Seguin discloses of the valve being resected prior to implanting the valve (Paragraph 9). **Seguin** further discloses of the valve being introduced in either direction relative to the native valve (Paragraph 153), and the combination as discussed above has one end of the guide wire extending through apex of the heart and the other end extending through the vasculature and exiting percutaneously. **Seguin '304** further discloses of an embodiment wherein the valve is approached from one direction and a balloon catheter is introduced from the opposite direction (Paragraph 153 and Fig 63-64); therefore it would have been an obvious design choice to introduce the resection device percutaneously and the valve transapically. **Regarding Claim 10**, the heart valve is radially expanded (Paragraph 63-64). **Regarding Claim 11**, the heart valve is depicted to fold the leaflets of the native

heart valve downward (Fig 63-64), additionally, it would have been an obvious design choice to remove a resected heart valve transapically.

Regarding Claim 45-46, Lattouf teaches of piercing the myocardium with a cannulated needle (14 gauge needle), feeding a guide wire through it, then installing the valve (Paragraph 10). A guide wire is known to be floppy and would be capable of conforming to blood flow.

Regarding Claim 50-51, Seguin '304 discloses that the valve can be installed either in the antegrade position or the retrograde position (Paragraph 153).

Regarding Claims 48-49 and 53, the guidewire is intended to extend through the vasculature such that both ends of the guidewire are external of the patient.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


/Mark Mashack/
Examiner, Art Unit 3773

Index of Claims 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Mark Mashack	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE									
Final	Original	09/17/2008	06/29/2009	03/08/2010	12/04/2010	06/22/2011					
	1	✓	✓	✓	✓	✓					
	2	✓	✓	✓	✓	✓					
	3	✓	-	-	-	-					
	4	N	N	N	N	N					
	5	✓	✓	✓	-	-					
	6	✓	✓	✓	✓	✓					
	7	✓	✓	✓	✓	✓					
	8	✓	✓	✓	✓	✓					
	9	✓	✓	✓	✓	✓					
	10	✓	✓	✓	✓	✓					
	11	✓	✓	✓	✓	✓					
	12	N	N	N	N	N					
	13	N	N	N	N	N					
	14	N	N	N	N	N					
	15	N	N	N	N	N					
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	17	N	N	N	N	N					
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	30	N	N	N	N	N					
	31	N	N	N	N	N					
	32	N	N	N	N	N					
	33	N	N	N	N	N					
	34	N	N	N	N	N					
	35	N	N	N	N	N					
	36	N	N	N	N	N					

<i>Index of Claims</i> 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Mark Mashack	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE							
Final	Original	09/17/2008	06/29/2009	03/08/2010	12/04/2010	06/22/2011			
	37	N	N	N	N	N			
	38	N	N	N	N	N			
	39	N	N	N	N	N			
	40	N	N	N	N	N			
	41	N	N	N	N	N			
	42	N	N	N	N	N			
	43	N	N	N	N	N			
	44	N	N	N	N	N			
	45	✓	✓	✓	✓	✓			
	46			✓	✓	✓			
	47			✓	✓	✓			
	48			✓	✓	✓			
	49			✓	✓	✓			
	50			✓	✓	✓			
	51			✓	✓	✓			
	52				✓	-			
	53				✓	✓			
	54				N	N			
	55				N	N			
	56				N	N			
	57				N	N			
	58				N	N			

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Request for Continued Examination (RCE) Transmittal	Application Number	11/023,783
	Filing Date	28-DEC-2004
	First Named Inventor	Christoph Hans Huber
	Art Unit	3773
	Examiner Name	Mark F. Mashack
	Attorney Docket Number	147-002

Address to:
 Mail Stop RCE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
 Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

a. Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

i. Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

ii. Other _____

b. Enclosed

i. Amendment/Reply

ii. Affidavit(s)/ Declaration(s)

iii. Information Disclosure Statement (IDS)

iv. Other _____

2. **Miscellaneous**

a. Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

b. Other _____

3. **Fees** The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

a. The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 50-4650.

i. RCE fee required under 37 CFR 1.17(e)

ii. Extension of time fee (37 CFR 1.136 and 1.17)

iii. Other _____

b. Check in the amount of \$ _____ enclosed

c. Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED			
Signature	/Edward M. Arons/	Date	06/03/2011
Name (Print/Type)	Edward Arons	Registration No.	44,511

CERTIFICATE OF MAILING OR TRANSMISSION			
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.			
Signature		Date	
Name (Print/Type)		Date	

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
 If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Instruction Sheet for RCEs

(not to be submitted to the USPTO)

NOTES:

An RCE is not a new application, and filing an RCE will not result in an application being accorded a new filing date.

Filing Qualifications:

The application must be a utility or plant application filed on or after June 8, 1995. The application cannot be a provisional application, a utility or plant application filed before June 8, 1995, a design application, or a patent under reexamination. See 37 CFR 1.114(e).

Filing Requirements:

Prosecution in the application must be closed. Prosecution is closed if the application is under appeal, or the last Office action is a final action, a notice of allowance, or an action that otherwise closes prosecution in the application (e.g., an Office action under *Ex parte Quayle*). See 37 CFR 1.114(b).

A submission and a fee are required at the time the RCE is filed. If reply to an Office action under 35 U.S.C. 132 is outstanding (e.g., the application is under final rejection), the submission must meet the reply requirements of 37 CFR 1.111. If there is no outstanding Office action, the submission can be an information disclosure statement, an amendment, new arguments, or new evidence. See 37 CFR 1.114(c). The submission may be a previously filed amendment (e.g., an amendment after final rejection).

WARNINGS:

Request for Suspension of Action:

All RCE filing requirements must be met before suspension of action is granted. A request for a suspension of action under 37 CFR 1.103(c) does not satisfy the submission requirement and does not permit the filing of the required submission to be suspended.

Improper RCE will NOT toll Any Time Period:

Before Appeal - If the RCE is improper (e.g., prosecution in the application is not closed or the submission or fee has not been filed) and the application is not under appeal, the time period set forth in the last Office action will continue to run and the application will be abandoned after the statutory time period has expired if a reply to the Office action is not timely filed. No additional time will be given to correct the improper RCE.

Under Appeal - If the RCE is improper (e.g., the submission or the fee has not been filed) and the application is under appeal, the improper RCE is effective to withdraw the appeal. Withdrawal of the appeal results in the allowance or abandonment of the application depending on the status of the claims. If there are no allowed claims, the application is abandoned. If there is at least one allowed claim, the application will be passed to issue on the allowed claim(s). See MPEP 1215.01.

See MPEP 706.07(h) for further information on the RCE practice.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11023783			
Filing Date:	28-Dec-2004			
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support			
First Named Inventor/Applicant Name:	Christoph Hans Huber			
Filer:	Edward M. Arons/Chanie Ziskind			
Attorney Docket Number:	147-002 (06-692)			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with \$0 paid	2253	1	555	555

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Request for continued examination	2801	1	405	405
Total in USD (\$)				960

Electronic Acknowledgement Receipt

EFS ID:	10226063
Application Number:	11023783
International Application Number:	
Confirmation Number:	1933
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support
First Named Inventor/Applicant Name:	Christoph Hans Huber
Customer Number:	72822
Filer:	Edward M. Arons/Chanie Ziskind
Filer Authorized By:	Edward M. Arons
Attorney Docket Number:	147-002 (06-692)
Receipt Date:	03-JUN-2011
Filing Date:	28-DEC-2004
Time Stamp:	12:50:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$960
RAM confirmation Number	10254
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment Submitted/Entered with Filing of CPA/RCE	147-002_Reply_to_Final_OA_12-7-2010_and_RCE.pdf	668750 d5c0a6331d392dfe0af8d858b7cc6e8311fb767fe	no	15

Warnings:

Information:

2	Request for Continued Examination (RCE)	147-002_RCE_As_Filed.pdf	1381290 67268d91e1e46520d6878d9bd27ee3c1048ac460	no	3
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3	Fee Worksheet (SB06)	fee-info.pdf	32256 7f1c025e1bd4eb2800c25189a93c7e4dbdab8f6f	no	2
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of : Christoph Hans Huber

Application No. : 11/023,783

Confirmation No. : 1933

Examiner : Mark F. Mashack

Filed : December 28, 2004

Group Art Unit : 3773

For : METHODS AND DEVICES FOR REPAIR OR
REPLACEMENT OF HEART VALVES OR ADJACENT
TISSUE WITHOUT THE NEED FOR FULL
CARDIOPULMONARY SUPPORT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

**PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. § 1.136(a),
REQUEST FOR CONTINUED EXAMINATION AND
REPLY TO OFFICE ACTION**

Dear Sir:

Petition for Extension of Time

Applicant hereby requests a three-month extension of time under 37 C.F.R. § 1.136(a) to extend to June 7, 2011 the period for filing a reply to the Office Action mailed on December 7, 2010 in the above-identified application. The Director is hereby

Attorney Docket No. 147-002 (06-692)
Application No. 11/023,783

authorized to charge the \$555.00 fee that is set forth in 37 C.F.R. § 1.17(a)(3), as well as any additional fees that may be due under 37 C.F.R. § 1.17, or to refund any overpayments, to Deposit Account No. 50-4650.

Request for Continued Examination

Applicant is concurrently submitting a Request for Continued Examination under 37 C.F.R. § 1.114(a), and is concurrently paying by credit card the \$405.00 fee that is set forth in 37 C.F.R. § 1.17(e). The Director is hereby authorized to charge any additional fees that may be due under 37 C.F.R. § 1.17, or to refund any overpayments, to Deposit Account No. 50-4650.

Reply to Office Action

This reply to the Final Office Action mailed on December 7, 2010 in the above-identified patent application is being filed as a submission accompanying the aforementioned Request for Continued Examination.

Amendments of the claims begin on page 3.

Remarks begin on page 11.

REMARKS

Upon entry of the foregoing amendments claims 1-2, 4, 6-51 and 53-58 will be pending in this application. Claims 12-44 and 54-58 have been withdrawn from consideration.

I. Summary of the Office Action

The Examiner withdrew claims 54-58 as being directed to a non-elected invention.

The Examiner rejected claims 52-53 and 56 under 35 U.S.C. § 112, second paragraph.

The Examiner rejected claims 1-2, 6-11 and 45 under 35 U.S.C. § 103(a) as being unpatentable over Seguin et al. U.S. Patent Publication No. 2004/0093060 (hereinafter, "Seguin '060") in view of Lattouf U.S. Patent Publication No. 2003/0130571 (hereinafter, "Lattouf").

The Examiner rejected claims 7, 11 and 45-54 under 35 U.S.C. § 103(a) as being unpatentable over Seguin et al. U.S. Patent Publication No. 2004/0210304 (hereinafter, "Seguin '304") in view of Lattouf.

II. Summary of Applicant's Reply

Applicant has amended claims 1, 7, 45, 46 and 53.

Applicant has cancelled claim 52.

Applicant has traversed the Examiner's rejections.

III. Applicant's Reply to the Rejections Under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 52-53 under 35 U.S.C. § 112, second paragraph. Office Action, para. 5. The Examiner alleged that the terms "cannulated needle elongated wire" and "elongated wire" lack antecedent basis. *Id.* (The Examiner also rejected withdrawn claim 56 under 35 U.S.C. § 112, second paragraph. Applicant addresses the rejection of withdrawn claim 56 below in Section VI.)

Applicant notes that "cannulated needle elongated wire" was recited in claim 52 and that "elongated wire" was recited in claim 53.

Applicant has cancelled claim 52 and respectfully requests that the rejection of claim 52 under 35 U.S.C. § 112, second paragraph be withdrawn. Applicant expressly reserves the right to pursue claim 52 in one or more continuation or divisional applications.

Claim 53, as amended, depends from claim 46. Claim 46, as amended, recites “an elongated wire” which provides antecedent basis for “the elongated wire” in claim 53.

Applicant respectfully submits that the amendments of claims 46 and 53 overcome the rejection under 35 U.S.C. § 112, second paragraph, and requests that the rejection be withdrawn.

IV. Applicant’s Reply to the Rejections
Over Seguin ‘060 in view of Lattouf

The Examiner rejected claims 1-2, 6-11 and 45 under 35 U.S.C. § 103(a) as being unpatentable over Seguin ‘060 in view of Lattouf. Claims 1, 7 and 45 are independent. Claims 2 and 6 depend from claim 1. Claims 8-11 depend from claim 7.

A. Claims 1 and 45

Claims 1 and 45, as amended, require feeding, from a ventricular apex to an aorta, an elongated wire that is configured to conform to a direction of blood flow.

Applicant respectfully submits that neither Seguin ‘060, nor Lattouf nor a combination of Seguin ‘060 and Lattouf show or suggest feeding, from a ventricular apex of the heart to an aorta, an elongated wire that is configured to conform to a direction of blood flow.

Applicant respectfully submits that, for at least this reason, claims 1 and 45 are patentable over Seguin ‘060, Lattouf or a combination of Seguin ‘060 and Lattouf.

Dependent claims 2-6 include all the requirements of independent claim 1. Therefore, applicant respectfully submits that claims 2-6 which depend from claim 1 are also patentable over Seguin ‘060, Lattouf or a combination of Seguin ‘060 and Lattouf.

Applicant respectfully requests that for at least the foregoing reason, the rejection of claims 1-6 and 45 over Seguin ‘060 in view of Lattouf be withdrawn.

B. Claim 7

Claim 7, as amended, requires feeding, from a ventricular apex of the heart through an aortic valve of the heart, an elongated wire that is configured to conform to a direction of blood flow.

Applicant respectfully submits that neither Seguin '060, nor Lattouf nor a combination of Seguin '060 and Lattouf show or suggest feeding, from a ventricular apex of the heart through an aortic valve of the heart, an elongated wire that is configured to conform to a direction of blood flow.

Applicant respectfully submits that, for at least this reason, claim 7 is patentable over Seguin'060, Lattouf or a combination of Seguin'060 and Lattouf.

Dependent claims 8-11 include all the requirements of independent claim 7. Therefore, applicant respectfully submits that claims 8-11 which depend from claims 7 are also patentable over Seguin '060, Lattouf or a combination of Seguin '060 and Lattouf.

Applicant respectfully requests that for at least the foregoing reason, the rejection of claims 7-11 over Seguin '060 in view of Lattouf be withdrawn.

V. Applicant's Reply to the Rejections
Over Seguin '304 in view of Lattouf

The Examiner rejected claims 7, 11 and 45-53 under 35 U.S.C. § 103(a) as being unpatentable over Seguin '304 in view of Lattouf. Claims 7, 45 and 46 are independent. Claim 11 depends from claim 7. Claims 47-53 depend from claim 46. (The Examiner also rejected withdrawn claim 54 under 35 U.S.C. § 103(a) as being unpatentable over Seguin '304 in view of Lattouf. Applicant addresses the rejection of withdrawn claim 54 below in Section VI.)

A. Claim 7

Claim 7, as amended, requires feeding, from a ventricular apex of the heart through an aortic valve of the heart, an elongated wire that is configured to conform to a direction of blood flow.

Applicant respectfully submits that neither Seguin '304, nor Lattouf nor a combination of Seguin '304 and Lattouf show or suggest feeding, from a ventricular apex of the

heart through an aortic valve of the heart, an elongated wire that is configured to conform to a direction of blood flow.

Applicant respectfully submits that, for at least this reason, claim 7 is patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf.

Dependent claims 8-11 include all the requirements of independent claim 7. Therefore, applicant respectfully submits that claims 8-11 which depend from claims 7 are also patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf.

Applicant respectfully requests that for at least the foregoing reason, the rejection of claims 7-11 over Seguin '304 in view of Lattouf be withdrawn.

B. Claim 45 and 46

Claims 45 and 46, as amended, require feeding, from a ventricular apex to an aorta, an elongated wire that is configured to conform to a direction of blood flow.

Applicant respectfully submits that neither Seguin '304, nor Lattouf nor a combination of Seguin '304 and Lattouf show or suggest feeding, from a ventricular apex to an aorta, an elongated wire that is configured to conform to a direction of blood flow.

Applicant respectfully submits that, for at least this reason, claims 45 and 46 are patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf.

Dependent claims 47-51 and 53 include all the requirements of independent claim 46. Therefore, applicant respectfully submits that claims 47-51 and 53 are also patentable over Seguin '304, Lattouf or a combination of Seguin '304 and Lattouf.

Applicant respectfully requests that for at least the foregoing reason, the rejection of claims 45-51 and 53 over Seguin '304 in view of Lattouf be withdrawn.

VI. Applicant's Reply to the Rejection of
Claim 56 Under 35 U.S.C. § 112, second paragraph and
Claim 54 Under 35 U.S.C. § 103(a).....

In the Office Action, para. 1, claims 54-58 were withdrawn from consideration. However, in the Office Action, para. 5, claim 56 was included in a list of claims rejected under 35 U.S.C. § 112, second paragraph, and in the Office Action, para. 9, claim 54 was included in a list of claims rejected under 35 U.S.C. § 103(a).

Applicant is assuming that the inclusion of claim 56 in the list of claims rejected under 35 U.S.C. § 112, second paragraph and the inclusion of claim 54 in the list of claims rejected under 35 U.S.C. § 103(a) are typographical errors.

VII. Conclusion

Applicant respectfully submits that this application is in condition for allowance. Applicant respectfully requests reconsideration of the claims as amended and the prompt issue of a Notice of Allowance.

Respectfully Submitted,



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Tel.: (845) 362-6100

Dated: June 3, 2011

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/023,783		Filing Date 12/28/2004		<input type="checkbox"/> To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 =	*	X \$ =		OR	X \$ =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =			X \$ =				
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.										
TOTAL			TOTAL			TOTAL		TOTAL		
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	06/03/2011	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(n))	* 55	Minus	** 56	= 0	X \$26 =	0	OR	X \$ =	
	Independent (37 CFR 1.16(h))	* 17	Minus	***16	= 1	X \$110 =	110	OR	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))									
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE	110	OR	TOTAL ADD'L FEE	
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(n))	*	Minus	**	=	X \$ =		OR	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =		OR	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))									
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.										
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".										
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										
Legal Instrument Examiner: /DORRETTA BROOKS/										

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Amendments of the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

- 1 (Currently Amended). A method of operating on a patient comprising:
 accessing the patient's heart by piercing a myocardium at a ventricular apex of the heart with a cannulated needle having a sharp end;
 feeding through the cannulated needle an elongated wire having a length along which the wire is configured to conform to a direction of blood flow, the feeding continuing until the length extends at least from the ventricular apex to an aorta;
 installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device; and
 performing a surgical procedure of implanting a heart valve.
- 2 (Original). The method of claim 1 further comprising resecting a native heart valve.
- 3 (Cancelled).
- 4 (Withdrawn). The method of claim 1 further comprising repairing an aortic dissection.
- 5 (Cancelled).
- 6 (Original). The method of claim 1 wherein installing the access device in the wall of the heart further comprises installing the access device in a ventricular apex of the heart.
- 7 (Currently Amended). A method for implanting a heart valve comprising:
 accessing a patient's heart by piercing a myocardium with a cannulated needle having a sharp end;

feeding through the cannulated needle an elongated wire configured to conform to a direction of blood flow, the feeding continuing until a length of the wire extends at least from a ventricular apex of the heart through an aortic valve of the heart:

installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;

inserting a valve delivery device through the access device; and

installing the heart valve.

8 (Original). The method of claim 7 further comprising resecting a native heart valve.

9 (Original). The method of claim 8 wherein the resecting the native heart valve is performed percutaneously and the installing the heart valve is performed transapically.

10 (Original). The method of claim 7 wherein the installing the heart valve further comprises radially expanding the heart valve.

11 (Original). The method of claim 7 wherein the installing the heart valve further comprises pulling leaflets of a native heart valve downward.

12 (Withdrawn). A device for implanting a heart valve comprising:
means for radially expanding the heart valve; and
means for supplementing blood flow through the device during the implanting the heart valve.

13 (Withdrawn). The device of claim 12 further comprising means for pulling leaflets of a native valve downward.

14 (Withdrawn). The device of claim 12 wherein the radially expanding the heart valve occurs in more than one stage.

15 (Withdrawn). The device of claim 14 wherein the more than one stage is effectuated by a multi-stage balloon.

16 (Withdrawn). A method of visualizing a portion of a patient's circulatory system comprising:

injecting a transparent oxygen-carrying fluid into the portion of the circulatory system; and
inserting an optical device into the portion of the circulatory system containing the transparent oxygen-carrying fluid.

17 (Withdrawn). The method of claim 16 further comprising temporarily exchanging all blood of the patient's circulatory system with the transparent oxygen-carrying fluid.

18 (Withdrawn). Instrumentation for accessing a chamber of a patient's heart, the heart having a myocardium, the instrumentation comprising:

a catheter having a proximal sealing device for sealing the catheter against a proximal surface of the myocardium; and
means for preventing bleeding through the catheter.

19 (Withdrawn). The instrumentation of claim 18 further comprising a distal sealing device for sealing the catheter against the distal surface of the myocardium.

20 (Withdrawn). An implantable heart valve comprising:
a tissue support structure; and
tissue valve leaflets, wherein the tissue valve leaflets are grown inside the tissue support structure by genetic engineering.

21 (Withdrawn). The heart valve of claim 20 wherein the tissue support structure is a stent.

22 (Withdrawn). The heart valve of claim 20 wherein the tissue support structure comprises stainless steel.

23 (Withdrawn). The heart valve of claim 20 wherein the tissue support structure comprises a self-expanding material.

24 (Withdrawn). The heart valve of claim 23 wherein the self-expanding material is nitinol.

25 (Withdrawn). A device for inserting more than one guidewire into a patient comprising:

a wire placement device; and
a guidewire attached to the wire placement device, wherein the wire placement device is configured to track an already placed guidewire.

26 (Withdrawn). The device of claim 25 wherein the guidewire is removably attached to the wire placement device.

27 (Withdrawn). The device of claim 25 wherein the wire placement device comprises a locking mechanism.

28 (Withdrawn). A method of breaking down calcification of a heart valve comprising:
inserting a catheter-based ultrasound device into a calcified heart valve;
and
concentrating ultrasound radiation on the calcification of the calcified heart valve to break down the calcification.

29 (Withdrawn). The method of claim 28 further comprising inserting a reflector into the calcified heart valve to magnify the ultrasound radiation.

30 (Withdrawn). A low-profile heart valve comprising:
at least three leaflets, wherein one side of each leaflet overlaps a neighboring leaflet such that the leaflets open sequentially and close sequentially.

31 (Withdrawn). A heart valve comprising:
an inner circumference and an outer circumference, wherein the inner circumference is a circumference of an annulus formed by leaflets of the heart valve; and the outer circumference is a circumference of a fluid-tight diaphragm, wherein the diaphragm fills a space between the inner circumference and the outer circumference.

32 (Withdrawn). A mitral valve repair device comprising:
a first head defining an operating plane; and
a second head operably attached to the first head and configured to
displace a leaflet with respect to the operating plane.

33 (Withdrawn). The repair device of claim 32 wherein the first head is a U-
shaped head.

34 (Withdrawn). The repair device of claim 32 wherein the first head comprises
an attachment mechanism for attaching at least two portions of the leaflet.

35 (Withdrawn). The repair device of claim 32 further comprising a handle for
operating the second head with respect to the first head.

36. (Withdrawn). A method of repairing an aortic dissection comprising:
accessing a patient's heart;
installing an access device in a wall of the heart, the access device having
means for preventing bleeding through the access device;
inserting a dissection repair device through the access device; and
repairing the aortic dissection.

37 (Withdrawn). A device for repairing an aortic dissection comprising:
annularly enlargeable componentry configured to be inserted into a
patient's aorta; and
means for closing a void created by the aortic dissection.

38 (Withdrawn). The device of claim 37 wherein the means for closing the void
comprise injection needles for injecting a tissue sealant.

39 (Withdrawn). The device of claim 38 wherein the tissue sealant comprises a
biologically compatible glue.

40 (Withdrawn). The device of claim 38 wherein the tissue sealant comprises
mechanical sutures.

41 (Withdrawn). The device of claim 38 wherein the tissue sealant comprises surgical staples.

42 (Withdrawn). The device of claim 38 wherein the annularly enlargeable componentry comprises means for supplementing blood flow through the componentry during the repair.

43 (Withdrawn). A device for resecting a diseased heart valve comprising:
a first set of annularly enlargeable componentry having a first longitudinal axis and a proximal cutting edge;
a second set of annularly enlargeable componentry having a second longitudinal axis and a distal cutting edge;
wherein the device is configured to resect the diseased heart valve when the first set of componentry is enlarged on a distal side of the diseased heart valve and the second set of componentry is enlarged on a proximal side of the diseased heart valve and the sets of componentry are drawn axially together along the longitudinal axes.

44 (Withdrawn). The device of claim 43 wherein the first longitudinal axis and the second longitudinal axis are coaxial.

45 (Currently Amended). A method for implanting an endoprosthesis comprising:
accessing a patient's heart by piercing a myocardium with a cannulated needle having a sharp end;
installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
after the accessing and before the installing, feeding through the cannulated needle an elongated wire having a length along which the wire is configured to conform to a direction of blood flow, the feeding continuing until the length extends at least from a ventricular apex of the heart to an aorta;
inserting an endoprosthesis delivery device through the access device; and
installing the endoprosthesis.

46 (Currently Amended). A method of operating on a patient comprising:
accessing the patient's heart by piercing a myocardium with a cannulated needle having a sharp end that is pointed toward an aortic valve;
installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
after the accessing and before the installing, feeding through the cannulated needle an elongated wire having a length along which the wire is configured to conform to a direction of blood flow, the feeding continuing until the length extends at least from a ventricular apex of the heart to an aorta; and
performing a surgical procedure in antegrade direction, wherein the surgical procedure is selected from the group consisting of implanting a heart valve or and removing, resecting or modifying a native heart valve.

47 (Previously Presented). The method according to claim 46, wherein the aortic valve is implanted.

48 (Previously Presented). The method according to claim 47, wherein a guidewire is fed into the left ventricle, and wherein the guidewire is advanced through the aortic valve and into the aorta.

49 (Previously Presented). The method according to claim 48, wherein the guidewire is further advanced into the iliac or femoral arteries.

50 (Previously Presented). The method according to claim 49, wherein wire-guided devices are inserted from the antegrade direction.

51 (Previously Presented). The method according to claim 50, wherein wire-guided devices are inserted from the retrograde direction.

52 (Cancelled).

53 (Currently Amended). The method of claim ~~[[52]]~~ 46 wherein the feeding continues until a distal end of the elongated wire exits the patient via an artery wall.

54 (Withdrawn). A method of operating on a patient, the method comprising:
 piercing myocardium with a cannulated needle having a sharp end that is oriented along a trajectory from a ventricular apex to an aortic valve, the piercing opening a transapical channel in myocardial tissue;
 placing the outer surface of a catheter in direct contact with the channel tissue; and
 delivering a device along a guidewire that extends through the catheter to an aorta.

55 (Withdrawn). The method of claim 54 wherein the placing includes:
 positioning a proximal opening of the catheter outside the patient; and
 positioning a distal opening of the catheter at a position that is distally spaced apart from a distal end of the channel.

56 (Withdrawn). The method of claim 55 further comprising, after the piercing and before the placing, feeding through the cannulated needle elongated wire having a length along which the wire is configured to conform to a direction of blood flow, the feeding continuing until the length extends at least from the apex to an aorta.

57 (Withdrawn). The method of claim 52 wherein the feeding continues until a distal end of the elongated wire exits the patient via an artery wall.

58 (Withdrawn). The method of claim 54 further comprising providing a purse string suture at the apex to press heart tissue against the catheter outer surface.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/023,783	12/28/2004	Christoph Hans Huber	147-002 (06-692)	1933
72822	7590	12/07/2010	EXAMINER	
Weiss & Arons, LLP 1540 Route 202, Suite 8 Pomona, NY 10970			MASHACK, MARK F	
			ART UNIT	PAPER NUMBER
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Office Action Summary	Application No. 11/023,783	Applicant(s) HUBER, CHRISTOPH HANS	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 September 2010.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4 and 6-58 is/are pending in the application.
 - 4a) Of the above claim(s) 4,12-44 and 54-58 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,6-11 and 45-53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 - Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 9/22/2010. Claims 1-2, 4, 6-58 are pending. Claims 4, 12-44 have been withdrawn.

Election/Restrictions

1. Newly submitted claims 54-58 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally claims were directed toward a method of performing a heart surgery comprising installing a access device and the newly submitted claims are directed to synching the heart muscle around a catheter by placing the outer surface of a catheter in direct contact with the channel tissue.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 54-58 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

2. Applicant's arguments regarding **Claims 1-2, 4-45** filed 9/22/2010 have been fully considered but they are not persuasive. Applicant argues that the method of installing the device of **Lattouf** introduces additional trauma to the patient that is not recognized by **Seguin '060** nor **Seguin '304** so the combination is not obvious. Examiner

disagrees. **Lattouf** acknowledges that the "conventional treatments", as disclosed by **Seguin**, are unsuitable for many of the patient population (Paragraph 7) so the method provides a viable alternative option.

3. Applicant's arguments with respect to **claims 46-51** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 52-53, 56** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "cannulated needle elongate wire" and "elongate wire" lack antecedent basis.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. **Claim 1-2, 6-11, and 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Seguin et al. ("Seguin" US 2004/0093060)** in view of **Lattouf (US 2003/0130571)**.

Seguin '060 discloses a method comprising accessing the patient's heart, resecting a native heart valve percutaneously ("through the skin") (Paragraph 21); replacing an aortic valve in the antegrade direction (Paragraph 28). **Seguin '060** does not disclose of installing an access device in a wall of the heart. However, **Lattouf** teaches of a novel method of accessing the left ventricle involving puncturing the ventricle and installing an access valve **30**. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of **Seguin** with installing the access valve in order to facilitate access to the aortic valve in the antegrade direction especially with the patients that do not have the vasculature that allows for the conventional procedure.

9. **Claim 7,11, 45-54** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Seguin et al. ("Seguin" US 2004/0210304)** in view of **Lattouf (US 2003/0130571)**.

Seguin '304 discloses a method comprising accessing the patient's heart; advancing a guidewire through the left ventricle through the aorta into the femoral arteries; and replacing an aortic valve in the antegrade direction by providing the guidewire. **Seguin '304** does not disclose of installing an access device in a wall of the

heart. However, **Lattouf** teaches of a novel method of accessing the left ventricle involving puncturing the ventricle by piercing the myocardium with a cannulated needle (Paragraph 10) and installing an access valve **30**. Even though the embodiment represented in the Figures is a method for treating the mitral valve, **Lattouf** also teaches that it can be used to treat an aortic valve (Paragraph 8). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of **Seguin** with installing the access valve in order to facilitate access to the aortic valve in the antegrade direction especially with the patients that do not have the vasculature that allows for the conventional procedure. Examiner asserts that when treating an aortic valve, it would have been obvious for the cannulated needle to create a puncture with a direct path to the aortic valve. **Regarding Claims 52-53**, the guidewire is intended to extend through the vasculature such that both ends of the guidewire are external of the patient.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 11/023,783
Art Unit: 3773

Page 7

/Mark Mashack/
Examiner, Art Unit 3773

/Darwin P. Erezol/
Primary Examiner, Art Unit 3773


Search Notes 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Mark Mashack	Art Unit 3773

SEARCHED			
Class	Subclass	Date	Examiner
623	2.11	9/17/2008	NS
623	2.1	7/7/2009	MFM

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor name search	9/17/2008	NS
Class/subclass search	9/17/2008	NS
East text search	9/17/2008	NS
Forward/backward citation search	9/17/2008	NS
Updated Search	7/7/2009	MFM
Updated Search	3/18/2010	MFM
Updated Search	12/4/2010	MFM

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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<i>Index of Claims</i> 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Mark Mashack	Art Unit 3773

✓	Rejected
=	Allowed


-	Cancelled
÷	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE							
Final	Original	09/17/2008	06/29/2009	03/08/2010	12/04/2010				
	1	✓	✓	✓	✓				
	2	✓	✓	✓	✓				
	3	✓	-	-	-				
	4	N	N	N	N				
	5	✓	✓	✓	-				
	6	✓	✓	✓	✓				
	7	✓	✓	✓	✓				
	8	✓	✓	✓	✓				
	9	✓	✓	✓	✓				
	10	✓	✓	✓	✓				
	11	✓	✓	✓	✓				
	12	N	N	N	N				
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	33	N	N	N	N				
	34	N	N	N	N				
	35	N	N	N	N				
	36	N	N	N	N				

<i>Index of Claims</i> 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Mark Mashack	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE							
Final	Original	09/17/2008	06/29/2009	03/08/2010	12/04/2010				
	37	N	N	N	N				
	38	N	N	N	N				
	39	N	N	N	N				
	40	N	N	N	N				
	41	N	N	N	N				
	42	N	N	N	N				
	43	N	N	N	N				
	44	N	N	N	N				
	45	✓	✓	✓	✓				
	46			✓	✓				
	47			✓	✓				
	48			✓	✓				
	49			✓	✓				
	50			✓	✓				
	51			✓	✓				
	52				✓				
	53				✓				
	54				✓				
	55				✓				
	56				✓				
	57				✓				
	58				✓				



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/023,783	12/28/2004	Christoph Hans Huber	06-692

34704
BACHMAN & LAPOINTE, P.C.
900 CHAPEL STREET
SUITE 1201
NEW HAVEN, CT 06510

CONFIRMATION NO. 1933
POWER OF ATTORNEY NOTICE



Date Mailed: 10/28/2010

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/21/2010.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/s/ibrahim/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/023,783	12/28/2004	Christoph Hans Huber	147-002 (06-692)

72822
Weiss & Arons, LLP
1540 Route 202, Suite 8
Pomona, NY 10970

CONFIRMATION NO. 1933
POA ACCEPTANCE LETTER



Date Mailed: 10/28/2010

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/21/2010.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/s/brahim/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS	Application Number	11/023,783
	Filing Date	December 28, 2004
	First Named Inventor	Christoph Hans Huber
	Title	METHOD AND DEVC FOR REPR OR RPLCMNT OF HRT
	Art Unit	3773
	Examiner Name	Mashack, Mark F
	Attorney Docket Number	147-002 (06-692)

I hereby revoke all previous powers of attorney given in the above-identified application.

A Power of Attorney is submitted herewith.

OR

I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

72822

OR

I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

The address associated with the above-mentioned Customer Number.

OR

The address associated with Customer Number:

OR

Firm or Individual Name

Address

City

State

Zip

Country

Telephone

Email

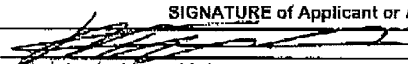
I am the:

Applicant/Inventor.

OR

Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____

SIGNATURE of Applicant or Assignee of Record

Signature		Date	20. October 2010
Name	Christoph Hans Huber	Telephone	+ 41 78 318 33 44
Title and Company	Eubohart AG		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

*Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	8671580
Application Number:	11023783
International Application Number:	
Confirmation Number:	1933
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support
First Named Inventor/Applicant Name:	Christoph Hans Huber
Customer Number:	34704
Filer:	Edward M. Arons/Shoshana Rogovsky
Filer Authorized By:	Edward M. Arons
Attorney Docket Number:	06-692
Receipt Date:	21-OCT-2010
Filing Date:	28-DEC-2004
Time Stamp:	13:03:16
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	Power_of_Attorney_and_Change_of_Corresp_Address_Form_Executed_As_Filed.pdf	70375 8bd252e806727e798f22d61f5860af9abd7c b044	no	1

Warnings:

Information:

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of : Christoph Hans Huber

Application No. : 11/023,783

Confirmation No. : 1933

Examiner : Mark F. Mashack

Filed : December 28, 2004

Group Art Unit : 3773

For : METHODS AND DEVICES FOR REPAIR OR
REPLACEMENT OF HEART VALVES OR ADJACENT
TISSUE WITHOUT THE NEED FOR FULL
CARDIOPULMONARY SUPPORT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

**PETITION FOR EXTENSION OF TIME UNDER
37 C.F.R. §1.136(a) AND REPLY TO OFFICE ACTION**

Sir:

Petition for Extension of Time

Applicant hereby requests a three-month extension of time under 37 C.F.R. §1.136(a) to extend to September 29, 2010 the period for filing a reply to the Office action mailed on March 29, 2010 in the above-identified application. The Director is hereby authorized to charge the \$555.00 fee that is set forth in 37 C.F.R. §1.17(a)(5), as well as any fees

Attorney Docket No. 147-002
Application No. 11/023,783 (06-692)

that may be due under 37 C.F.R. §1.17, or to refund any overpayments, to Deposit Account No. 50-4650.

Reply to Office Action

In reply to the Office action, applicant respectfully amends the application as follows:

Amendments of the claims begin on page 3.

Remarks begin on page 11.

Amendments of the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1 (previously presented). A method of operating on a patient comprising:
 accessing the patient's heart;
 installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device; and
 performing a surgical procedure of implanting a heart valve.

2 (original). The method of claim 1 further comprising resecting a native heart valve.

3 (cancelled).

4 (withdrawn). The method of claim 1 further comprising repairing an aortic dissection.

5 (cancelled).

6 (original). The method of claim 1 wherein installing the access device in the wall of the heart further comprises installing the access device in a ventricular apex of the heart.

7 (original). A method for implanting a heart valve comprising:
 accessing a patient's heart;
 installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
 inserting a valve delivery device through the access device; and
 installing the heart valve.

8 (original). The method of claim 7 further comprising resecting a native heart valve.

9 (original). The method of claim 8 wherein the resecting the native heart valve is performed percutaneously and the installing the heart valve is performed transapically.

10 (original). The method of claim 7 wherein the installing the heart valve further comprises radially expanding the heart valve.

11 (original). The method of claim 7 wherein the installing the heart valve further comprises pulling leaflets of a native heart valve downward.

12 (withdrawn). A device for implanting a heart valve comprising:
means for radially expanding the heart valve; and
means for supplementing blood flow through the device during the implanting the heart valve.

13 (withdrawn). The device of claim 12 further comprising means for pulling leaflets of a native valve downward.

14 (withdrawn). The device of claim 12 wherein the radially expanding the heart valve occurs in more than one stage.

15 (withdrawn). The device of claim 14 wherein the more than one stage is effectuated by a multi-stage balloon.

16 (withdrawn). A method of visualizing a portion of a patient's circulatory system comprising:
injecting a transparent oxygen-carrying fluid into the portion of the circulatory system; and
inserting an optical device into the portion of the circulatory system containing the transparent oxygen-carrying fluid.

17 (withdrawn). The method of claim 16 further comprising temporarily exchanging all blood of the patient's circulatory system with the transparent oxygen-carrying fluid.

18 (withdrawn). Instrumentation for accessing a chamber of a patient's heart, the heart having a myocardium, the instrumentation comprising:

a catheter having a proximal sealing device for sealing the catheter against a proximal surface of the myocardium; and

means for preventing bleeding through the catheter.

19 (withdrawn). The instrumentation of claim 18 further comprising a distal sealing device for sealing the catheter against the distal surface of the myocardium.

20 (withdrawn). An implantable heart valve comprising:

a tissue support structure; and

tissue valve leaflets, wherein the tissue valve leaflets are grown inside the tissue support structure by genetic engineering.

21 (withdrawn). The heart valve of claim 20 wherein the tissue support structure is a stent.

22 (withdrawn). The heart valve of claim 20 wherein the tissue support structure comprises stainless steel.

23 (withdrawn). The heart valve of claim 20 wherein the tissue support structure comprises a self-expanding material.

24 (withdrawn). The heart valve of claim 23 wherein the self-expanding material is nitinol.

25 (withdrawn). A device for inserting more than one guidewire into a patient comprising:

a wire placement device; and

a guidewire attached to the wire placement device, wherein the wire placement device is configured to track an already placed guidewire.

26 (withdrawn). The device of claim 25 wherein the guidewire is removably attached to the wire placement device.

27 (withdrawn). The device of claim 25 wherein the wire placement device comprises a locking mechanism.

28 (withdrawn). A method of breaking down calcification of a heart valve comprising:

inserting a catheter-based ultrasound device into a calcified heart valve;

and

concentrating ultrasound radiation on the calcification of the calcified heart valve to break down the calcification.

29 (withdrawn). The method of claim 28 further comprising inserting a reflector into the calcified heart valve to magnify the ultrasound radiation.

30 (withdrawn). A low-profile heart valve comprising:

at least three leaflets, wherein one side of each leaflet overlaps a neighboring leaflet such that the leaflets open sequentially and close sequentially.

31 (withdrawn). A heart valve comprising:

an inner circumference and an outer circumference, wherein the inner circumference is a circumference of an annulus formed by leaflets of the heart valve; and the outer circumference is a circumference of a fluid-tight diaphragm, wherein the diaphragm fills a space between the inner circumference and the outer circumference.

32 (withdrawn). A mitral valve repair device comprising:

a first head defining an operating plane; and

a second head operably attached to the first head and configured to displace a leaflet with respect to the operating plane.

33 (withdrawn). The repair device of claim 32 wherein the first head is a U-shaped head.

34 (withdrawn). The repair device of claim 32 wherein the first head comprises an attachment mechanism for attaching at least two portions of the leaflet.

35 (withdrawn). The repair device of claim 32 further comprising a handle for operating the second head with respect to the first head.

36. (withdrawn). A method of repairing an aortic dissection comprising:
accessing a patient's heart;
installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
inserting a dissection repair device through the access device; and
repairing the aortic dissection.

37 (withdrawn). A device for repairing an aortic dissection comprising:
annularly enlargeable componentry configured to be inserted into a patient's aorta; and
means for closing a void created by the aortic dissection.

38 (withdrawn). The device of claim 37 wherein the means for closing the void comprise injection needles for injecting a tissue sealant.

39 (withdrawn). The device of claim 38 wherein the tissue sealant comprises a biologically compatible glue.

40 (withdrawn). The device of claim 38 wherein the tissue sealant comprises mechanical sutures.

41 (withdrawn). The device of claim 38 wherein the tissue sealant comprises surgical staples.

42 (withdrawn). The device of claim 38 wherein the annularly enlargeable componentry comprises means for supplementing blood flow through the componentry during the repair.

43 (withdrawn). A device for resecting a diseased heart valve comprising:
a first set of annularly enlargeable componentry having a first longitudinal axis and a proximal cutting edge;

a second set of annularly enlargeable componentry having a second longitudinal axis and a distal cutting edge;

wherein the device is configured to resect the diseased heart valve when the first set of componentry is enlarged on a distal side of the diseased heart valve and the second set of componentry is enlarged on a proximal side of the diseased heart valve and the sets of componentry are drawn axially together along the longitudinal axes.

44 (withdrawn). The device of claim 43 wherein the first longitudinal axis and the second longitudinal axis are coaxial.

45 (original). A method for implanting an endoprosthesis comprising:

accessing a patient's heart;

installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;

inserting an endoprosthesis delivery device through the access device; and
installing the endoprosthesis.

46 (currently amended). A method of operating on a patient comprising:

accessing the patient's heart by piercing a myocardium with a cannulated needle having a sharp end that is pointed toward an aortic valve;

installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device; and

performing a surgical procedure in antegrade direction, wherein the surgical procedure is selected from the group consisting of implanting a heart valve or and removing, resecting or modifying a native heart valve.

47 (previously presented). The method according to claim 46, wherein the aortic valve is implanted.

48 (previously presented). The method according to claim 47, wherein a guidewire is fed into the left ventricle, and wherein the guidewire is advanced through the aortic valve and into the aorta.

49 (previously presented). The method according to claim 48, wherein the guidewire is further advanced into the iliac or femoral arteries.

50 (previously presented). The method according to claim 49, wherein wire-guided devices are inserted from the antegrade direction.

51 (previously presented). The method according to claim 50, wherein wire-guided devices are inserted from the retrograde direction.

52 (new). The method of claim 46 further comprising, after the accessing and before the installing, feeding through the cannulated needle elongated wire having a length along which the wire is configured to conform to a direction of blood flow, the feeding continuing until the length extends at least from the apex to an aorta.

53 (new). The method of claim 52 wherein the feeding continues until a distal end of the elongated wire exits the patient via an artery wall.

54 (new). A method of operating on a patient, the method comprising:
piercing myocardium with a cannulated needle having a sharp end that is oriented along a trajectory from a ventricular apex to an aortic valve, the piercing opening a transapical channel in myocardial tissue;
placing the outer surface of a catheter in direct contact with the channel tissue; and
delivering a device along a guidewire that extends through the catheter to an aorta.

55. (new). The method of claim 54 wherein the placing includes:
positioning a proximal opening of the catheter outside the patient; and
positioning a distal opening of the catheter at a position that is distally spaced apart from a distal end of the channel.

56 (new). The method of claim 55 further comprising, after the piercing and before the placing, feeding through the cannulated needle elongated wire having a length along

which the wire is configured to conform to a direction of blood flow, the feeding continuing until the length extends at least from the apex to an aorta.

57 (new). The method of claim 52 wherein the feeding continues until a distal end of the elongated wire exits the patient via an artery wall.

58 (new). The method of claim 54 further comprising providing a purse string suture at the apex to press heart tissue against the catheter outer surface.

REMARKS

Claims 1-2, 4 and 6-58 are pending in this application. Of the pending claims, claims 12-44 have been withdrawn from consideration.

Summary of the Office Action

The Examiner rejected claims 1, 2, 6-11 and 45 under 35 U.S.C. §103(a) as being unpatentable over Seguin et al. U.S. Patent Publication No. 2004/0093060 (hereinafter, "Seguin '060") in view of Lattouf U.S. Patent Publication No. 2003/0130130571 (hereinafter, "Lattouf").

The Examiner rejected claims 7, 11 and 45-51 under 35 U.S.C. §103(a) as being unpatentable over Seguin et al. U.S. Patent Publication No. 2004/0210304 (hereinafter, "Seguin '304") in view of Lattouf.

Summary of Applicant's Reply

Applicant has amended claim 46.

Applicant has added new claims 52-58.

Applicant provides a Summary of September 14, 2010 Telephonic Interview.

Applicant traverses the Examiner's rejections of claims 1, 2, 6-11 and 45-51.

Summary of September 14, 2010 Telephonic Interview

The undersigned expresses his appreciation to the Examiner for his time and courtesy during a telephonic interview on September 14, 2010. The Examiner and the undersigned were the only participants in the telephonic interview.

The Examiner and the undersigned discussed Seguin '060, Seguin '304 and Lattouf in connection with claims 1 and 46. No agreement was reached regarding patentability of claims 1 and 46.

Applicant's Reply to the
Rejections Over Seguin '060 in view of Lattouf

Claims 1-2, 6-11 and 45 were rejected under 35 U.S.C. §103(a) as being obvious from Seguin '060 in view of Lattouf. Claims 1, 7 and 45 are independent. Claims 2 and 6 depend from claim 1. Claims 8-11 depend directly or indirectly from claim 7.

Claim 1

Claim 1 requires *accessing a heart, installing an access device in a wall of the heart* and *implanting a heart valve*. The Examiner stated that Seguin '060 discloses accessing the patient's heart and replacing an aortic valve in the antegrade direction. The Examiner stated that Seguin '060 does not disclose installing an access device in a wall of the heart. The Examiner stated that Lattouf teaches a "novel method of accessing the left ventricle involving puncturing the ventricle and installing an access valve...." The Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Seguin ['060] with installing the access valve in order to facilitate access to the aortic valve in the antegrade direction especially with patients that do not have the vasculature that allows for the conventional procedure. Office action, paragraph no. 3.

Applicant respectfully traverses.

Seguin '060 teaches peripheral access for heart valve replacement. See, e.g., Seguin '060 FIG. 11 and para. 35. Peripheral access for heart valve replacement is an interventional cardiology approach. In interventional cardiology at the time of applicant's invention, a practitioner would introduce access trauma in the peripheral vasculature instead of in the heart itself. Lattouf is a surgical approach that not only introduces access trauma directly to the heart, but also introduces implant-induced trauma from anchors at the heart access site, both on the interior heart wall and on the exterior heart wall. See, e.g., Lattouf FIGS. 5-6. Anchors placed there puncture the heart wall and, in response to heart contraction, introduce stress concentrations that may further traumatize the heart tissue at the puncture sites. Seguin '060 avoids or reduces access trauma and implant trauma by introducing instrumentation through peripheral vasculature.

Applicant respectfully submits that for at least the foregoing reason, a person of ordinary skill in the art practicing the Seguin '060 method at the time of applicant's invention would not select a method of access to the heart that causes access- and implant-trauma to the

heart, as does Lattouf. Applicant respectfully submits that claim 1, and claims 2 and 6 that depend therefrom, are therefore not obvious from Seguin '060 in view of Lattouf. Applicant respectfully requests that the rejections of claims 1, 2 and 6 be withdrawn.

Claims 7 and 45

Claims 7 and 45 require accessing a heart, installing an access device in a wall of the heart and *installing a heart valve* (claim 7) or *an endoprosthesis* (claim 45). The Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Seguin ['060] with installing the Lattouf access valve in order to facilitate access to the aortic valve in the antegrade direction especially with patients that do not have the vasculature that allows for the conventional procedure.

Applicant submits for at least the reasons stated in connection with claim 1 that a person of ordinary skill in the art practicing the Seguin '060 method at the time of applicant's invention would not select or apply a method of access to the heart that causes access- and implant-trauma to the heart, as does Lattouf. Applicant respectfully submits that claims 7 and 45, along with claims 8-11, which depend from claim 7, are therefore not obvious from Seguin '060 in view of Lattouf. Applicant respectfully requests that the rejections of claims 7-11 and 45 be withdrawn.

Applicant's Reply to the
Rejections Over Seguin '304 in view of Lattouf

Claims 7, 11 and 45-51 were rejected under 35 U.S.C. §103(a) as being obvious from Seguin '304 in view of Lattouf. Claims 7, 45 and 46 are independent. Claims 8-11 depend directly or indirectly from claim 7. Claims 47-51 depend from claim 46.

Claim 7

Claim 7 requires *accessing a heart, installing an access device in a wall of the heart* and *installing a heart valve*. The Examiner stated that Seguin '304 discloses accessing the patient's heart, advancing a guidewire through the left ventricle through the aorta into the femoral arteries, and replacing an aortic valve in the antegrade direction by providing the guidewire. The Examiner stated that Seguin '304 does not disclose installing an access device in a wall of the heart. The Examiner stated that Lattouf teaches a "novel method of accessing the left ventricle involving puncturing the ventricle and installing an access valve...." The Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time

of the invention to modify the method of Seguin ['304] with installing the access valve in order to facilitate access to the aortic valve in the antegrade direction especially with patients that do not have the vasculature that allows for the conventional procedure. Office action, paragraph no. 3.

Applicant respectfully traverses.

Seguin '304 teaches peripheral access for heart valve replacement. See, e.g., Seguin '304 FIG. 11, 61 and 62 and para. 35. As set forth in connection with Seguin '060, peripheral access for heart valve replacement is an interventional cardiology approach. In interventional cardiology at the time of applicant's invention, a practitioner would introduce access trauma in the peripheral vasculature instead of in the heart itself. Lattouf is a surgical approach that not only introduces access trauma directly to the heart, but also introduces implant-induced trauma from anchors at the heart access site, both on the interior heart wall and on the exterior heart wall. See, e.g., Lattouf FIGS. 5-6. Anchors placed there puncture the heart wall and, in response to heart contraction, introduce stress concentrations that may further traumatize the heart tissue at the puncture sites. Seguin '304 avoids or reduces access trauma and implant trauma by introducing instrumentation through peripheral vasculature.

Applicant respectfully submits that for at least the foregoing reason, a person of ordinary skill in the art practicing the method of Seguin '304 at the time of applicant's invention would not select or apply a method of access to the heart that causes access- and implant-trauma to the heart, as does Lattouf. Applicant respectfully submits that claim 7, and claims 8-11 that depend therefrom, are therefore not obvious from Seguin '304 in view of Lattouf. Applicant respectfully requests that the rejections of claims 7-11 be withdrawn.

Claim 45

Claim 45 requires *accessing a heart, installing an access device in a wall of the heart* and *installing an endoprosthesis*. The Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Seguin ['304] with installing the Lattouf access valve in order to facilitate access to the aortic valve in the antegrade direction especially with patients that do not have the vasculature that allows for the conventional procedure.

Applicant submits for at least the reasons stated in connection with claim 7 that a person of ordinary skill in the art practicing the method of Seguin '304 would not select or apply

a method of access to the heart that causes access- and implant-trauma to the heart, as does Lattouf. Applicant respectfully submits that claim 45 is therefore not obvious from Seguin '304 in view of Lattouf. Applicant respectfully requests that the rejection of claim 45 be withdrawn.

Claim 46

Claim 46 requires *accessing a heart, installing an access device in a wall of the heart and performing a surgical procedure in the antegrade direction.*

The Examiner alleged that Seguin '304 discloses accessing the patient's heart, advancing a guidewire through the left ventricle through the aorta into the femoral arteries, and replacing an aortic valve in the antegrade direction by providing the guidewire. The Examiner stated that Seguin '304 does not disclose installing an access device in a wall of the heart. The Examiner stated that Lattouf teaches a "novel method of accessing the left ventricle involving puncturing the ventricle and installing an access valve..." The Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Seguin ['304] with installing the access valve in order to facilitate access to the aortic valve in the antegrade direction especially with patients that do not have the vasculature that allows for the conventional procedure. Office action, paragraph no. 3.

Applicant submits for at least the reasons stated in connection with claim 7 that a person of ordinary skill in the art practicing the method of Seguin '304 at the time of applicant's invention would not select or apply a method of access to the heart that causes access- and implant-trauma to the heart, as does Lattouf.

Also, applicant has amended claim 46 to require *piercing a myocardium with a cannulated needle having a sharp end that is pointed toward an aortic valve.* Applicant respectfully submits that (1) Seguin 304, which is based on peripheral access, does not show *piercing a myocardium with a cannulated needle having a sharp end that is pointed toward an aortic valve*, and (2), Lattouf, which is directed to retrograde mitral valve repair, does not make up for the shortcoming in Seguin 304.

For at least the foregoing reasons, applicant respectfully submits that claim 46, and claims 47-51 that depend therefrom, are not obvious from Seguin '304 in view of Lattouf. Applicant respectfully requests that the rejections of claims 46-51 be withdrawn.

Attorney Docket No. 147-002
Application No. 11/023,783 (06-692)

Conclusion

Applicant respectfully submits that, based on the foregoing Remarks and Amendments that claims 1-2, 4 and 6-58 are in proper form and are allowable. Applicant respectfully requests reconsideration of the claims and the prompt issue of a Notice of Allowance.

Respectfully Submitted,



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September 22, 2010

Electronic Patent Application Fee Transmittal

Application Number:	11023783			
Filing Date:	28-Dec-2004			
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support			
First Named Inventor/Applicant Name:	Christoph Hans Huber			
Filer:	Edward M. Arons/Chanie Ziskind			
Attorney Docket Number:	06-692			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	2202	7	26	182
Independent claims in excess of 3	2201	1	110	110
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Extension - 3 months with \$0 paid	2253	1	555	555
Miscellaneous:				
Total in USD (\$)				847

Electronic Acknowledgement Receipt

EFS ID:	8471671
Application Number:	11023783
International Application Number:	
Confirmation Number:	1933
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support
First Named Inventor/Applicant Name:	Christoph Hans Huber
Customer Number:	34704
Filer:	Edward M. Arons/Chanie Ziskind
Filer Authorized By:	Edward M. Arons
Attorney Docket Number:	06-692
Receipt Date:	22-SEP-2010
Filing Date:	28-DEC-2004
Time Stamp:	13:11:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$847
RAM confirmation Number	10828
Deposit Account	504650
Authorized User	WEISS,JOEL

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	147-002_Reply_to_OA_03-29-2010.pdf	130881 7d1bfcd338bb1f099d83c73f357588e0359a a65c	no	16

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	33387 724f3cd0f81c129b2165856c546bf8e21796 6ce	no	2
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Warnings:

Information:

Total Files Size (in bytes): 164268

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/023,783		Filing Date 12/28/2004		<input type="checkbox"/> To be Mailed			
APPLICATION AS FILED – PART I												
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY				
FOR		NUMBER FILED	NUMBER EXTRA		RATE (\$)	FEE (\$)	OR		RATE (\$)	FEE (\$)		
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>		N/A	N/A		N/A				N/A			
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>		N/A	N/A		N/A				N/A			
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>		N/A	N/A		N/A				N/A			
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>		minus 20 =	*		X \$ =		OR		X \$ =			
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>		minus 3 =	*		X \$ =				X \$ =			
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).										
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>												
* If the difference in column 1 is less than zero, enter "0" in column 2.												
APPLICATION AS AMENDED – PART II					SMALL ENTITY		OR		OTHER THAN SMALL ENTITY			
(Column 1)			(Column 2)		(Column 3)			SMALL ENTITY		OTHER THAN SMALL ENTITY		
AMENDMENT	09/22/2010		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(o))</small>		* 56	Minus	** 49	= 7	X \$26 =	182	OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>		* 11	Minus	***16	= 0	X \$110 =	0	OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>											
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>											
							TOTAL ADD'L FEE	182	OR		TOTAL ADD'L FEE	
AMENDMENT			CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(o))</small>		*	Minus	**	=	X \$ =		OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>		*	Minus	***	=	X \$ =		OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>											
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>											
							TOTAL ADD'L FEE		OR		TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.												
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".												
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".												
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.												
Legal Instrument Examiner: /JULIET MCMILLAN/												

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/023,783	12/28/2004	Christoph Hans Huber	06-692	1933
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34704 7590 03/29/2010
 BACHMAN & LAPOINTE, P.C.
 900 CHAPEL STREET
 SUITE 1201
 NEW HAVEN, CT 06510

EXAMINER

MASHACK, MARK F

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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03/29/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/023,783	Applicant(s) HUBER, CHRISTOPH HANS	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 January 2010.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2 and 4-51 is/are pending in the application.
 4a) Of the above claim(s) 4 and 12-44 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,5-11 and 45-51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

This office action is in response to a communication dated 1/5/2010. Claims 1-2, 4, 6-51 are pending. Claims 4, 12-44 have been withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claim 1-2, 6-11, and 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Seguin et al.** ("**Seguin**" **US 2004/0093060**) in view of **Lattouf (US 2003/0130571)**.

Segin '060 discloses a method comprising accessing the patient's heart, resecting a native heart valve percutaneously ("through the skin") (Paragraph 21); replacing an aortic valve in the antegrade direction (Paragraph 28). **Seguin '060** does not disclose of installing an access device in a wall of the heart. However, **Lattouf**

teaches of a novel method of accessing the left ventricle involving puncturing the ventricle and installing an access valve **30**. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of **Seguin** with installing the access valve in order to facilitate access to the aortic valve in the antegrade direction especially with the patients that do not have the vasculature that allows for the conventional procedure.

4. **Claim 7,11, 45-51** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Seguin et al. ("Seguin" US 2004/0210304)** in view of **Lattouf (US 2003/0130571)**.

Seguin '304 discloses a method comprising accessing the patient's heart; advancing a guidewire through the left ventricle through the aorta into the femoral arteries; and replacing an aortic valve in the antegrade direction by providing the guidewire. **Seguin '304** does not disclose of installing an access device in a wall of the heart. However, **Lattouf** teaches of a novel method of accessing the left ventricle involving puncturing the ventricle and installing an access valve **30**. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of **Seguin** with installing the access valve in order to facilitate access to the aortic valve in the antegrade direction especially with the patients that do not have the vasculature that allows for the conventional procedure.

Response to Arguments

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/

Application/Control Number: 11/023,783

Page 5

Art Unit: 3773

Examiner, Art Unit 3773

/Melanie Tyson/

Examiner, Art Unit 3773

March 25, 2010

Notice of References Cited	Application/Control No. 11/023,783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS	
	Examiner MARK MASHACK	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-6,425,916 B1	07-2002	Garrison et al.	623/2.11
*	B US-2003/0130571 A1	07-2003	Lattouf, Omar M.	600/374
*	C US-2004/0093060 A1	05-2004	Seguin et al.	623/001.11
*	D US-2004/0210304 A1	10-2004	Seguin et al.	623/002.11
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			


FOREIGN PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N				
	O				
	P				
	Q				
	R				
	S				
	T				

NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	
V	
W	
X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.


Search Notes 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Mark Mashack	Art Unit 3773

SEARCHED			
Class	Subclass	Date	Examiner
623	2.11	9/17/2008	NS
623	2.1	7/7/2009	MFM

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor name search	9/17/2008	NS
Class/subclass search	9/17/2008	NS
East text search	9/17/2008	NS
Forward/backward citation search	9/17/2008	NS
Updated Search	7/7/2009	MFM
Updated Search	3/18/2010	MFM

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner


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<i>Index of Claims</i> 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Naveen K Singh	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE							
Final	Original	09/17/2008	06/29/2009	03/08/2010					
	1	✓	✓	✓					
	2	✓	✓	✓					
	3	✓	-	-					
	4	N	N	N					
	5	✓	✓	✓					
	6	✓	✓	✓					
	7	✓	✓	✓					
	8	✓	✓	✓					
	9	✓	✓	✓					
	10	✓	✓	✓					
	11	✓	✓	✓					
	12	N	N	N					
	13	N	N	N					
	14	N	N	N					
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	32	N	N	N					
	33	N	N	N					
	34	N	N	N					
	35	N	N	N					
	36	N	N	N					

<i>Index of Claims</i> 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Naveen K Singh	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE							
Final	Original	09/17/2008	06/29/2009	03/08/2010					
	37	N	N	N					
	38	N	N	N					
	39	N	N	N					
	40	N	N	N					
	41	N	N	N					
	42	N	N	N					
	43	N	N	N					
	44	N	N	N					
	45	✓	✓	✓					
	46			✓					
	47			✓					
	48			✓					
	49			✓					
	50			✓					
	51			✓					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

App. No.:	11/023,783	Att'y	06-692
Filing Date:	12/28/2004	Docket:	
Inventor(s):	Christoph Hans Huber	Conf No.:	1933
Title	Methods And Devices..	Group Art	3773
		Unit:	
		Examiner:	Mashack, Mark F.

Correspondence Address:
Customer Number 34704

SUPPLEMENTAL RESPONSE

Dear Sir:

This paper is submitted responsive to the Office Action mailed July 7, 2009 and supplemental to the response which was filed on December 7, 2009.

Amendments to the claims begin on page 2 of this paper.

Remarks/Arguments begin on page 10 of this paper.

Listing of claims

1. (previously presented) A method of operating on a patient comprising:

- accessing the patient's heart;
- installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device; and
- performing a surgical procedure of implanting a heart valve.

2. (Original) The method of claim 1 further comprising resecting a native heart valve.

3. (Cancelled)

4. (Withdrawn) The method of claim 1 further comprising repairing an aortic dissection.

5. (Cancelled)

6. (Original) The method of claim 1 wherein installing the access device in the wall of the heart further comprises installing the access device in a ventricular apex of the heart.

7. (Original) A method for implanting a heart valve comprising:

- accessing a patient's heart;
- installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
- inserting a valve delivery device through the access device;
- and
- installing the heart valve.

8. (Original) The method of claim 7 further comprising

resecting a native heart valve.

9. (Original) The method of claim 8 wherein the resecting the native heart valve is performed percutaneously and the installing the heart valve is performed transapically.

10. (Original) The method of claim 7 wherein the installing the heart valve further comprises radially expanding the heart valve.

11. (Original) The method of claim 7 wherein the installing the heart valve further comprises pulling leaflets of a native heart valve downward.

12. (Withdrawn) A device for implanting a heart valve comprising:
means for radially expanding the heart valve; and
means for supplementing blood flow through the device during the implanting the heart valve.

13. (Withdrawn) The device of claim 12 further comprising means for pulling leaflets of a native valve downward.

14. (Withdrawn) The device of claim 12 wherein the radially expanding the heart valve occurs in more than one stage.

15. (Withdrawn) The device of claim 14 wherein the more than one stage is effectuated by a multi-stage balloon.

16. (Withdrawn) A method of visualizing a portion of a patient's circulatory system comprising:
injecting a transparent oxygen-carrying fluid into the portion of the circulatory system; and
inserting an optical device into the portion of the circulatory system containing the transparent oxygen-carrying

fluid.

17. (Withdrawn) The method of claim 16 further comprising temporarily exchanging all blood of the patient's circulatory system with the transparent oxygen-carrying fluid.

18. (Withdrawn) Instrumentation for accessing a chamber of a patient's heart, the heart having a myocardium, the instrumentation comprising:

a catheter having a proximal sealing device for sealing the catheter against a proximal surface of the myocardium; and
means for preventing bleeding through the catheter.

19. (Withdrawn) The instrumentation of claim 18 further comprising a distal sealing device for sealing the catheter against the distal surface of the myocardium.

20. (Withdrawn) An implantable heart valve comprising:
a tissue support structure; and
tissue valve leaflets, wherein the tissue valve leaflets are grown inside the tissue support structure by genetic engineering.

21. (Withdrawn) The heart valve of claim 20 wherein the tissue support structure is a stent.

22. (Withdrawn) The heart valve of claim 20 wherein the tissue support structure comprises stainless steel.

23. (Withdrawn) The heart valve of claim 20 wherein the tissue support structure comprises a self-expanding material.

24. (Withdrawn) The heart valve of claim 23 wherein the self-expanding material is nitinol.

25. (Withdrawn) A device for inserting more than one

guidewire into a patient comprising:

a wire placement device; and
a guidewire attached to the wire placement device, wherein the wire placement device is configured to track an already placed guidewire.

26. (Withdrawn) The device of claim 25 wherein the guidewire is removably attached to the wire placement device.

27. (Withdrawn) The device of claim 25 wherein the wire placement device comprises a locking mechanism.

28. (Withdrawn) A method of breaking down calcification of a heart valve comprising:

inserting a catheter-based ultrasound device into a calcified heart valve; and
concentrating ultrasound radiation on the calcification of the calcified heart valve to break down the calcification.

29. (Withdrawn) The method of claim 28 further comprising inserting a reflector into the calcified heart valve to magnify the ultrasound radiation.

30. (Withdrawn) A low-profile heart valve comprising:
at least three leaflets, wherein one side of each leaflet overlaps a neighboring leaflet such that the leaflets open sequentially and close sequentially.

31. (Withdrawn) A heart valve comprising:
an inner circumference and an outer circumference, wherein the inner circumference is a circumference of an annulus formed by leaflets of the heart valve; and the outer circumference is a circumference of a fluid-tight diaphragm, wherein the diaphragm fills a space between the inner circumference and the outer circumference.

32. (Withdrawn) A mitral valve repair device comprising:
a first head defining an operating plane; and
a second head operably attached to the first head and
configured to displace a leaflet with respect to the operating
plane.

33. (Withdrawn) The repair device of claim 32 wherein the
first head is a U-shaped head.

34. (Withdrawn) The repair device of claim 32 wherein the
first head comprises an attachment mechanism for attaching at
least two portions of the leaflet.

35. (Withdrawn) The repair device of claim 32 further
comprising a handle for operating the second head with respect to
the first head.

36. (Withdrawn) A method of repairing an aortic dissection
comprising:

accessing a patient's heart;
installing an access device in a wall of the heart, the
access device having means for preventing bleeding through the
access device;

inserting a dissection repair device through the access
device; and

repairing the aortic dissection.

37. (Withdrawn) A device for repairing an aortic dissection
comprising:

annularly enlargeable componentry configured to be inserted
into a patient's aorta; and

means for closing a void created by the aortic dissection.

38. (Withdrawn) The device of claim 37 wherein the means

for closing the void comprise injection needles for injecting a tissue sealant.

39. (Withdrawn) The device of claim 38 wherein the tissue sealant comprises a biologically compatible glue.

40. (Withdrawn) The device of claim 38 wherein the tissue sealant comprises mechanical sutures.

41. (Withdrawn) The device of claim 38 wherein the tissue sealant comprises surgical staples.

42. (Withdrawn) The device of claim 38 wherein the annularly enlargeable componentry comprises means for supplementing blood flow through the componentry during the repair.

43. (Withdrawn) A device for resecting a diseased heart valve comprising:

a first set of annularly enlargeable componentry having a first longitudinal axis and a proximal cutting edge;

a second set of annularly enlargeable componentry having a second longitudinal axis and a distal cutting edge;

wherein the device is configured to resect the diseased heart valve when the first set of componentry is enlarged on a distal side of the diseased heart valve and the second set of componentry is enlarged on a proximal side of the diseased heart valve and the sets of componentry are drawn axially together along the longitudinal axes.

44. (Withdrawn) The device of claim 43 wherein the first longitudinal axis and the second longitudinal axis are coaxial.

45. (Original) A method for implanting an endoprosthesis comprising:

accessing a patient's heart;
installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
inserting an endoprosthesis delivery device through the access device; and
installing the endoprosthesis.

46. (currently amended) A method of operating on a patient comprising:

accessing the patient's heart;
installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device; and
performing a surgical procedure in antegrade direction, wherein the surgical procedure is selected from the group consisting of implanting a heart valve ~~or~~ and removing, resecting or modifying a native heart valve.

47. (previously presented) The method according to claim 46, wherein the aortic valve is implanted.

48. (previously presented) The method according to claim 47, wherein a guidewire is fed into the left ventricle, and wherein the guidewire is advanced through the aortic valve and into the aorta.

49. (previously presented) The method according to claim 48, wherein the guidewire is further advanced into the iliac or femoral arteries.

50. (previously presented) The method according to claim 49, wherein wire-guided devices are inserted from the antegrade direction.

51. (previously presented) The method according to claim 50, wherein wire-guided devices are inserted from the retrograde direction.

REMARKS/ARGUMENTS

This paper is submitted responsive to the office action mailed July 7, 2009 and supplemental to the response filed on December 7, 2009.

In that response, an inadvertent error was made in the typing of claim 46, and that is corrected herein.

The arguments in support of allowability of these claims remain as set forth in the response filed on December 7, 2009.

It is believed that no fee is due in connection with this paper. If any such fee is due, please charge same to deposit account 02-0184.

Respectfully submitted,
Christoph Hans Huber

By /george a. coury/
George A. Coury
BACHMAN & LaPOINTE, P.C.
Reg. No. 34,309
Attorney for Applicant
Telephone: (203)777-6628 ext. 113
Fax: (203)865-0297
Email: docket@bachlap.com

Date: January 5, 2010

Electronic Acknowledgement Receipt

EFS ID:	6749682
Application Number:	11023783
International Application Number:	
Confirmation Number:	1933
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support
First Named Inventor/Applicant Name:	Christoph Hans Huber
Customer Number:	34704
Filer:	George A. Coury/Joann Piscitelli
Filer Authorized By:	George A. Coury
Attorney Docket Number:	06-692
Receipt Date:	05-JAN-2010
Filing Date:	28-DEC-2004
Time Stamp:	13:07:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		06-692_Supplemental_Response_01-05-10.pdf	289430 <small>9062ee2ed58dabf1533c28eb36b416a7a49f42aa</small>	yes	10

Multipart Description/PDF files in .zip description		
Document Description	Start	End
Supplemental Response or Supplemental Amendment	1	1
Claims	2	9
Applicant Arguments/Remarks Made in an Amendment	10	10

Warnings:

Information:

Total Files Size (in bytes):	289430
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/023,783		Filing Date 12/28/2004		<input type="checkbox"/> To be Mailed			
APPLICATION AS FILED – PART I												
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR			OTHER THAN SMALL ENTITY			
FOR		NUMBER FILED	NUMBER EXTRA		RATE (\$)	FEE (\$)	OR		RATE (\$)	FEE (\$)		
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>		N/A	N/A		N/A				N/A			
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>		N/A	N/A		N/A				N/A			
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>		N/A	N/A		N/A				N/A			
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>		minus 20 =	*		X \$ =		OR		X \$ =			
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>		minus 3 =	*		X \$ =		OR		X \$ =			
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).										
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>												
* If the difference in column 1 is less than zero, enter "0" in column 2.												
APPLICATION AS AMENDED – PART II												
(Column 1)			(Column 2)			(Column 3)			SMALL ENTITY OR OTHER THAN SMALL ENTITY			
AMENDMENT	12/07/2009		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(o))</small>		* 49	Minus	** 45	= 4	X \$26 =	104	OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>		* 16	Minus	***15	= 1	X \$110 =	110	OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>											
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>											
							TOTAL ADD'L FEE	214	OR		TOTAL ADD'L FEE	
AMENDMENT	01/05/2010		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(o))</small>		* 49	Minus	** 49	= 0	X \$26 =	0	OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>		* 16	Minus	*** 16	= 0	X \$110 =	0	OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>											
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>											
							TOTAL ADD'L FEE	0	OR		TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.												
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".												
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".												
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.												
Legal Instrument Examiner: /YOLANDA CHADWICK/												

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

App. No.:	11/023,783	Att'y	06-692
		Docket:	
Filing Date:	12/28/2004	Conf No.:	1933
Inventor(s):	Christoph Hans Huber	Group Art	3773
		Unit:	
Title	Methods And Devices...	Examiner:	Mashack, Mark F.
		Correspondence Address:	
		Customer Number	34704

RESPONSE TO OFFICE ACTION

Dear Sir:

This paper is submitted responsive to the Office Action mailed July 7, 2009.

Amendments to the claims begin on page 2 of this paper.

Remarks/Arguments begin on page 9 of this paper.

Listing of claims

1. (previously presented) A method of operating on a patient comprising:

- accessing the patient's heart;
- installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device; and
- performing a surgical procedure of implanting a heart valve.

2. (Original) The method of claim 1 further comprising resecting a native heart valve.

3. (Cancelled)

4. (Withdrawn) The method of claim 1 further comprising repairing an aortic dissection.

5. (Cancelled)

6. (Original) The method of claim 1 wherein installing the access device in the wall of the heart further comprises installing the access device in a ventricular apex of the heart.

7. (Original) A method for implanting a heart valve comprising:

- accessing a patient's heart;
- installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
- inserting a valve delivery device through the access device;
- and
- installing the heart valve.

8. (Original) The method of claim 7 further comprising resecting a native heart valve.

9. (Original) The method of claim 8 wherein the resecting the native heart valve is performed percutaneously and the installing the heart valve is performed transapically.

10. (Original) The method of claim 7 wherein the installing the heart valve further comprises radially expanding the heart valve.

11. (Original) The method of claim 7 wherein the installing the heart valve further comprises pulling leaflets of a native heart valve downward.

12. (Withdrawn) A device for implanting a heart valve comprising:
means for radially expanding the heart valve; and
means for supplementing blood flow through the device during the implanting the heart valve.

13. (Withdrawn) The device of claim 12 further comprising means for pulling leaflets of a native valve downward.

14. (Withdrawn) The device of claim 12 wherein the radially expanding the heart valve occurs in more than one stage.

15. (Withdrawn) The device of claim 14 wherein the more than one stage is effectuated by a multi-stage balloon.

16. (Withdrawn) A method of visualizing a portion of a patient's circulatory system comprising:
injecting a transparent oxygen-carrying fluid into the portion of the circulatory system; and
inserting an optical device into the portion of the circulatory system containing the transparent oxygen-carrying fluid.

17. (Withdrawn) The method of claim 16 further comprising temporarily exchanging all blood of the patient's circulatory system with the transparent oxygen-carrying fluid.

18. (Withdrawn) Instrumentation for accessing a chamber of a patient's heart, the heart having a myocardium, the instrumentation comprising:

a catheter having a proximal sealing device for sealing the catheter against a proximal surface of the myocardium; and means for preventing bleeding through the catheter.

19. (Withdrawn) The instrumentation of claim 18 further comprising a distal sealing device for sealing the catheter against the distal surface of the myocardium.

20. (Withdrawn) An implantable heart valve comprising:
a tissue support structure; and
tissue valve leaflets, wherein the tissue valve leaflets are grown inside the tissue support structure by genetic engineering.

21. (Withdrawn) The heart valve of claim 20 wherein the tissue support structure is a stent.

22. (Withdrawn) The heart valve of claim 20 wherein the tissue support structure comprises stainless steel.

23. (Withdrawn) The heart valve of claim 20 wherein the tissue support structure comprises a self-expanding material.

24. (Withdrawn) The heart valve of claim 23 wherein the self-expanding material is nitinol.

25. (Withdrawn) A device for inserting more than one guidewire into a patient comprising:
a wire placement device; and
a guidewire attached to the wire placement device, wherein

the wire placement device is configured to track an already placed guidewire.

26. (Withdrawn) The device of claim 25 wherein the guidewire is removably attached to the wire placement device.

27. (Withdrawn) The device of claim 25 wherein the wire placement device comprises a locking mechanism.

28. (Withdrawn) A method of breaking down calcification of a heart valve comprising:

inserting a catheter-based ultrasound device into a calcified heart valve; and

concentrating ultrasound radiation on the calcification of the calcified heart valve to break down the calcification.

29. (Withdrawn) The method of claim 28 further comprising inserting a reflector into the calcified heart valve to magnify the ultrasound radiation.

30. (Withdrawn) A low-profile heart valve comprising:
at least three leaflets, wherein one side of each leaflet overlaps a neighboring leaflet such that the leaflets open sequentially and close sequentially.

31. (Withdrawn) A heart valve comprising:
an inner circumference and an outer circumference, wherein the inner circumference is a circumference of an annulus formed by leaflets of the heart valve; and the outer circumference is a circumference of a fluid-tight diaphragm, wherein the diaphragm fills a space between the inner circumference and the outer circumference.

32. (Withdrawn) A mitral valve repair device comprising:
a first head defining an operating plane; and
a second head operably attached to the first head and

configured to displace a leaflet with respect to the operating plane.

33. (Withdrawn) The repair device of claim 32 wherein the first head is a U-shaped head.

34. (Withdrawn) The repair device of claim 32 wherein the first head comprises an attachment mechanism for attaching at least two portions of the leaflet.

35. (Withdrawn) The repair device of claim 32 further comprising a handle for operating the second head with respect to the first head.

36. (Withdrawn) A method of repairing an aortic dissection comprising:

- accessing a patient's heart;
- installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
- inserting a dissection repair device through the access device; and
- repairing the aortic dissection.

37. (Withdrawn) A device for repairing an aortic dissection comprising:

- annularly enlargeable componentry configured to be inserted into a patient's aorta; and
- means for closing a void created by the aortic dissection.

38. (Withdrawn) The device of claim 37 wherein the means for closing the void comprise injection needles for injecting a tissue sealant.

39. (Withdrawn) The device of claim 38 wherein the tissue sealant comprises a biologically compatible glue.

40. (Withdrawn) The device of claim 38 wherein the tissue sealant comprises mechanical sutures.

41. (Withdrawn) The device of claim 38 wherein the tissue sealant comprises surgical staples.

42. (Withdrawn) The device of claim 38 wherein the annularly enlargeable componentry comprises means for supplementing blood flow through the componentry during the repair.

43. (Withdrawn) A device for resecting a diseased heart valve comprising:

a first set of annularly enlargeable componentry having a first longitudinal axis and a proximal cutting edge;

a second set of annularly enlargeable componentry having a second longitudinal axis and a distal cutting edge;

wherein the device is configured to resect the diseased heart valve when the first set of componentry is enlarged on a distal side of the diseased heart valve and the second set of componentry is enlarged on a proximal side of the diseased heart valve and the sets of componentry are drawn axially together along the longitudinal axes.

44. (Withdrawn) The device of claim 43 wherein the first longitudinal axis and the second longitudinal axis are coaxial.

45. (Original) A method for implanting an endoprosthesis comprising:

accessing a patient's heart;

installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;

inserting an endoprosthesis delivery device through the access device; and

installing the endoprosthesis.

46. (new) A method of operating on a patient comprising:
accessing the patient's heart;

installing an access device in a wall of the heart, the
access device having means for preventing bleeding through the
access device; and

performing a surgical procedure in antegrade direction,
wherein the surgical procedure is selected from implanting a
heart valve or modifying a native heart valve.

47. (new) The method according to claim 46, wherein the
aortic valve is implanted.

48. (new) The method according to claim 47, wherein a
guidewire is fed into the left ventricle, and wherein the
guidewire is advanced through the aortic valve and into the
aorta.

49. (new) The method according to claim 48, wherein the
guidewire is further advanced into the iliac or femoral arteries.

50. (new) The method according to claim 49, wherein wire-
guided devices are inserted from the antegrade direction.

51. (new) The method according to claim 50, wherein wire-
guided devices are inserted from the retrograde direction.

REMARKS/ARGUMENTS

This paper is submitted responsive to the office action mailed July 7, 2009. Reconsideration of the application in light of the accompanying remarks and amendments is respectfully requested.

In the present response, claims 1-2 and 4-45 remain pending and new claims 46-51 have been added. No new matter has been introduced, and support for the new claims is explained below. Claim 5 has been cancelled without prejudice.

Claims 4 and 12-44 stand withdrawn, and claims 1, 2, 5, 7-8, 10-11 and 45 have been rejected as anticipated by Garrison while claims 6 and 9 have been rejected as obvious over garrison in view of Lattouf.

Claim 1 calls for installation of an access device in the wall of the heart of a patient, and it is submitted that this is not at all disclosed or suggested by Garrison.

Garrison discloses implanting replacement cardiac valves (col. 1, lines 5-6). The valve is passed through a blood vessel like the femoral artery or femoral vein, so that median sternotomy or major thoracotomy is not required (col. 1, lines 59-61, col. 4, lines 24-26, Figures 1, 1B and 2). Alternatively, the valve is introduced through a small incision between the patient's ribs into the ascending aorta (col. 1, lines 62-64, Figure 31). A valve displacer is used to hold the native valve leaflets open so that the native valve does not need to be removed (col. 1, line 64 through col. 2, line 1). The valve displacer and the valve are introduced into the patient in a collapsed condition and expanded within the patient with an expansion mechanism like a balloon or may be self-expanding (col. 2, lines 1-16). The valve displacer and the valve may be introduced using two different or one single catheter (col. 2, lines 31-39). A temporary valve mechanism prevents regurgitation while the native valve is held open and before deployment of the replacement cardiac valve (col. 2, lines 44-46). Implanting the valve may take place while the heart is beating or stopped (col.

2, lines 49-51). It is noted that along with the above discussion, nothing in Garrison discloses or suggests an access device be installed in the wall of the heart of the patient.

In the action, the Examiner asserts that Garrison discloses this subject matter. However, this is clearly wrong. Figures 31-33 of Garrison, referred to by the Examiner, show introduction of a trocar into the ascending aorta (see col. 11, line 13). The properties of the wall of the heart and the ascending aorta are different. The wall of the heart is basically a muscle and the aorta is a vessel. The ascending aorta is not part of the wall of the heart. Therefore, Garrison does not disclose an important feature of the invention. It is also noted that Garrison makes use of a valve displacer which is not needed according to the invention.

Claim 1 is therefore not anticipated by Garrison, and the rejection of claim 1 should be withdrawn. Dependent claims 2, 5, 7-8, 10-11 and 45 all depend directly or indirectly from claim 1 and are also submitted to be allowable based upon the above arguments.

With respect to claims 6 and 9, in addition to the above arguments, it is submitted that these claims are themselves further allowable. The Examiner concedes that Garrison does not disclose the access device being installed in a ventricular apex of the heart, but instead asserts that this is taught by Lattouf.

Lattouf is directed to repairing a heart valve and does not disclose implanting a heart valve. When repairing a heart valve, instruments adapted for reparation like a grasping device are introduced through the ventricular apex. However, Lattouf does not disclose introducing instruments adapted for replacement of a heart valve through the ventricular apex. Moreover, Lattouf discloses repairing a mitral valve, which is accessed through the ventricular apex in the retrograde direction, i.e., opposite the direction of blood flow. Thus, Lattouf does not disclose replacing the heart valve in an antegrade direction, as disclosed and claimed in the present application. It is therefore submitted that claims 6 and 9 are themselves further patentable

over the art of record.

It is pointed out that the method of the present invention, as disclosed and claimed herein, allows a guiding structure like a guiding catheter or a delivery system to be advanced in an antegrade direction significantly further into the vascular tree.

This generates several crucial advantages and solves several problems not addressed in the art of record as follows:

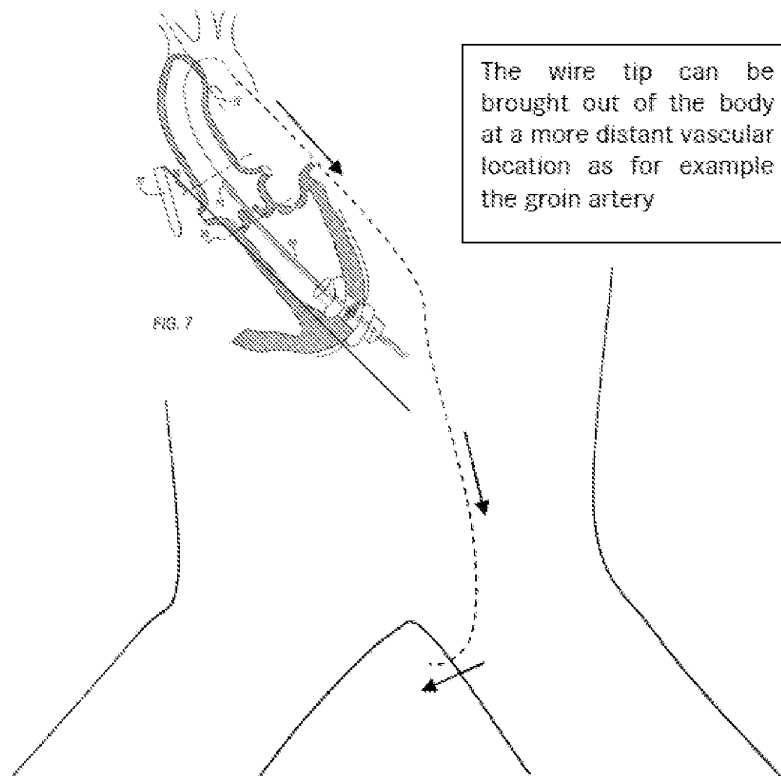
1. A more stable wire anchoring (the wire tip) is placed more distally to the device target or landing zone.

2. There is less risk of perforation of a cardiac or vascular structure with a loose wire end.

3. There is less risk of creating arrhythmias by the loose wire tip curled into the left ventricle.

4. Delivery of the device is more precise.

5. The wire tip can be brought out of the body at a more distant vascular location such as, for example, the groin artery, the neck artery, or arm artery, allowing accessing the targeted structure on a single wire from two directions simultaneously (see illustration below based upon Figure 7 of the specification).



6. Having two free wire ends not only decreases wire mobility to the lowest possible state but also allows insertion of adjuvant devices to increase the patient safety and to improve the delivery process.

7. The delivery system can be advanced further over the target structure and pulled back into the target location allowing multistep delivery strategies.

The above advantages obtained with the novel and non-obvious steps called out in the present claims further reinforce that these claims should be allowed.

Turning to new claims 46-51, these claims are directed further to preferred embodiments of the invention. Note that the antegrade direction called for in claim 46 is recited in paragraph [0016] of the specification. Implanting of an aortic valve as called for in claim 47 is discussed in paragraph [0070].

Advance of the guidewire as called for in claim 48 and 49 is discussed in paragraph [0075]. Direction of insertion as called for in claims 50 and 51 is discussed in paragraph [0076]. Thus, these claims are supported by the specification and do not constitute the introduction of new matter.

With respect to these new claims, nothing in the art of record specifically or otherwise discloses the subject matter set forth therein. Further, the subject matter of these claims allows for additional advantages, namely:

- implanting a heart valve through the wall of a heart (preferably near the apex) is performed without sternotomy, such that hospitalization time for the patient can be reduced.

- at the same time distance between the location where the valve is implanted and the location where instruments have to be manipulated is kept small, which enables a precise positioning of the valve.

- the surgical procedure can be performed in an antegrade direction, such that passing a valve with surgical instruments like a guidewire becomes much easier because the instrument just has to follow the flow of blood.

- a surgical instrument like a guidewire can be fed through the wall of the heart and further into blood vessels, such that the guidewire is held along the blood vessel which enables a firm position of the guidewire and therefore more precision in the surgical procedure.

- the guidewire can even be fed through the blood vessel, such that the guidewire exits the vessel at a retrograde location. On the one hand this enables a more precise positioning of the guidewire from its ends, and on the other hand it enables inserting wire-guided devices from the antegrade and retrograde directions.

With respect to claim 46 specifically, please note the following. Lattouf discloses accessing the heart through the ventricular apex and repairing a heart valve in a retrograde direction, clearly differently from what is called for in claim 46. Claim 46 calls for carrying out a surgical procedure in an

antegrade direction, wherein the procedure can be implanting a heart valve or modifying the native heart valve (removing or repairing for example, as disclosed in paragraphs [0017] and [0018]. As set forth above, this allows the guidewire to be placed by following the flow of blood, and the guidewire is transported through the blood flow to the location where the original heart valve to be replaced is located.

An earnest and thorough effort has been made to address all issues raised in the aforesaid office action and to place the application in condition for allowance. If, upon considering this response, the Examiner is of the opinion that issues remain which could be addressed by telephone interview, the Examiner is invited to telephone the undersigned.

This paper is accompanied by authorization to charge a deposit account for an extension of time fee. It is believed that no other fee is due. If any such fee is due, please charge same to deposit account 02-0184.

Respectfully submitted,
Christoph Hans Huber

By /george a. coury/
George A. Coury
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Email: docket@bachlap.com

Date: December 7, 2009

Electronic Patent Application Fee Transmittal

Application Number:	11023783			
Filing Date:	28-Dec-2004			
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support			
First Named Inventor/Applicant Name:	Christoph Hans Huber			
Filer:	George A. Coury/Joann Piscitelli			
Attorney Docket Number:	06-692			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	2202	4	26	104
Independent claims in excess of 3	2201	1	110	110
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Extension - 2 months with \$0 paid	2252	1	245	245
Miscellaneous:				
Total in USD (\$)				459

Electronic Acknowledgement Receipt

EFS ID:	6581759
Application Number:	11023783
International Application Number:	
Confirmation Number:	1933
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support
First Named Inventor/Applicant Name:	Christoph Hans Huber
Customer Number:	34704
Filer:	George A. Coury/Joann Piscitelli
Filer Authorized By:	George A. Coury
Attorney Docket Number:	06-692
Receipt Date:	07-DEC-2009
Filing Date:	28-DEC-2004
Time Stamp:	11:06:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$459
RAM confirmation Number	7715
Deposit Account	020184
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

- Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)
- Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)
 Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)
 Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		06-692_Response_12-07-09.pdf	119625 9777d4477b4e2f25323a776e8de6b1fedfb6bdc9c	yes	14

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	8
Applicant Arguments/Remarks Made in an Amendment	9	14

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	33577 b48e3f5de9eb05d2ca89624275f81b9dc70691b8	no	2
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Warnings:

Information:

Total Files Size (in bytes): 153202

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/023,783	12/28/2004	Christoph Hans Huber	06-692	1933
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34704 7590 07/07/2009
 BACHMAN & LAPOINTE, P.C.
 900 CHAPEL STREET
 SUITE 1201
 NEW HAVEN, CT 06510

EXAMINER

MASHACK, MARK F

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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07/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/023,783	Applicant(s) HUBER, CHRISTOPH HANS	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 March 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,5 and 45 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,5 and 45 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 - Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

This office action is in response to a communication dated 3/26/2009. **Claims 1-2, 5-11, 45** are pending.

1. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not support a method comprising "implanting a heart valve" and "repairing a heart valve".

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-2, 5, 7-8, 10-11, 45** are rejected under 35 U.S.C. 102(b) as being anticipated by **Garrison et al. ("Garrison" US 6,425,916)**.

Garrison discloses a method of operating on a patient comprising: accessing the patient's heart; installing an access device **116** in a wall of the heart, the access device having means for preventing bleeding through the access device **117**; and performing a surgical procedure of implanting a heart valve **8D** with a valve delivery device **110** (FIGs 31-33). The method further comprises resecting a native heart valve (Column 4, Lines

Art Unit: 3773

49-52). Examiner contends that a drug coating (Column 5, Lines 7-8) at least partially repairs the tissue of the valve. The native valve is pulled down upon radial expansion of the valve (FIG 33).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claim 6 and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Garrison** in view of **Lattouf (US 2003/0130571)**.

Garrison discloses all of the claimed limitations except for the access device being installed in a ventricular apex of the heart. However, **Lattouf** teaches of a method of accessing the mitral valve by installing an access device in the ventricular apex (FIG 9). Given the teachings of **Garrison**, it would have been obvious to modify the method of **Garrison** by installing the access device in a ventricular apex of the heart to facilitate

access to the mitral valve. It would be inherent or obvious that the resecting is performed percutaneously or "through the skin" and the installing is performed transapically.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 11/023,783
Art Unit: 3773

Page 5

/Mark Mashack/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 11/023,783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS	
	Examiner MARK MASHACK	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-6,425,916 B1	07-2002	Garrison et al.	623/2.11
*	B US-2003/0130571 A1	07-2003	Lattouf, Omar M.	600/374
	C US-			
	D US-			
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			


FOREIGN PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N				
	O				
	P				
	Q				
	R				
	S				
	T				

NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	
V	
W	
X	


*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Naveen K Singh	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE							
Final	Original	09/17/2008	06/29/2009						
	1	✓	✓						
	2	✓	✓						
	3	✓	✓						
	4	N	-						
	5	✓	✓						
	6	✓	✓						
	7	✓	✓						
	8	✓	✓						
	9	✓	✓						
	10	✓	✓						
	11	✓	✓						
	12	N	-						
	13	N	-						
	14	N	-						
	15	N	-						
	16	N	-						
	17	N	-						
	18	N	-						
	19	N	-						
	20	N	-						
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	22	N	-						
	23	N	-						
	24	N	-						
	25	N	-						
	26	N	-						
	27	N	-						
	28	N	-						
	29	N	-						
	30	N	-						
	31	N	-						
	32	N	-						
	33	N	-						
	34	N	-						
	35	N	-						
	36	N	-						

<i>Index of Claims</i> 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Naveen K Singh	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE							
Final	Original	09/17/2008	06/29/2009						
	37	N	-						
	38	N	-						
	39	N	-						
	40	N	-						
	41	N	-						
	42	N	-						
	43	N	-						
	44	N	-						
	45	✓	✓						

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

App. No.:	11/023,783	Att'y	06-692
		Docket:	
Filing Date:	12/28/2004	Conf No.:	1933
Inventor(s):	Christoph Hans Huber	Group Art	3773
		Unit:	
Title	Methods And Devices..	Examiner:	Singh, Naveen Kumar

Correspondence Address:
Customer Number 34704

RESPONSE TO OFFICE ACTION

Dear Sir:

This paper is submitted responsive to the Office Action mailed September 26, 2008.

Amendments to the claims begin on page 2 of this paper.

Remarks/Arguments begin on page 9 of this paper.

1. (Currently amended) A method of operating on a patient comprising:
 accessing the patient's heart;
 installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device; and
 performing a surgical procedure of implanting a heart valve.

2. (Original) The method of claim 1 further comprising resecting a native heart valve.

3. (Cancelled)

4. (Withdrawn) The method of claim 1 further comprising repairing an aortic dissection.

5. (Original) The method of claim 1 further comprising repairing a heart valve.

6. (Original) The method of claim 1 wherein installing the access device in the wall of the heart further comprises installing the access device in a ventricular apex of the heart.

7. (Original) A method for implanting a heart valve comprising:
 accessing a patient's heart;
 installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
 inserting a valve delivery device through the access device;
and
 installing the heart valve.

8. (Original) The method of claim 7 further comprising resecting a native heart valve.

9. (Original) The method of claim 8 wherein the resecting the native heart valve is performed percutaneously and the installing the heart valve is performed transapically.

10. (Original) The method of claim 7 wherein the installing the heart valve further comprises radially expanding the heart valve.

11. (Original) The method of claim 7 wherein the installing the heart valve further comprises pulling leaflets of a native heart valve downward.

12. (Withdrawn) A device for implanting a heart valve comprising:
means for radially expanding the heart valve; and
means for supplementing blood flow through the device during the implanting the heart valve.

13. (Withdrawn) The device of claim 12 further comprising means for pulling leaflets of a native valve downward.

14. (Withdrawn) The device of claim 12 wherein the radially expanding the heart valve occurs in more than one stage.

15. (Withdrawn) The device of claim 14 wherein the more than one stage is effectuated by a multi-stage balloon.

16. (Withdrawn) A method of visualizing a portion of a patient's circulatory system comprising:
injecting a transparent oxygen-carrying fluid into the portion of the circulatory system; and
inserting an optical device into the portion of the circulatory system containing the transparent oxygen-carrying fluid.

17. (Withdrawn) The method of claim 16 further comprising temporarily exchanging all blood of the patient's circulatory system with the transparent oxygen-carrying fluid.

18. (Withdrawn) Instrumentation for accessing a chamber of a patient's heart, the heart having a myocardium, the instrumentation comprising:

a catheter having a proximal sealing device for sealing the catheter against a proximal surface of the myocardium; and
means for preventing bleeding through the catheter.

19. (Withdrawn) The instrumentation of claim 18 further comprising a distal sealing device for sealing the catheter against the distal surface of the myocardium.

20. (Withdrawn) An implantable heart valve comprising:
a tissue support structure; and
tissue valve leaflets, wherein the tissue valve leaflets are grown inside the tissue support structure by genetic engineering.

21. (Withdrawn) The heart valve of claim 20 wherein the tissue support structure is a stent.

22. (Withdrawn) The heart valve of claim 20 wherein the tissue support structure comprises stainless steel.

23. (Withdrawn) The heart valve of claim 20 wherein the tissue support structure comprises a self-expanding material.

24. (Withdrawn) The heart valve of claim 23 wherein the self-expanding material is nitinol.

25. (Withdrawn) A device for inserting more than one guidewire into a patient comprising:

a wire placement device; and
a guidewire attached to the wire placement device, wherein the wire placement device is configured to track an already placed guidewire.

26. (Withdrawn) The device of claim 25 wherein the guidewire is removably attached to the wire placement device.

27. (Withdrawn) The device of claim 25 wherein the wire placement device comprises a locking mechanism.

28. (Withdrawn) A method of breaking down calcification of a heart valve comprising:

inserting a catheter-based ultrasound device into a calcified heart valve; and
concentrating ultrasound radiation on the calcification of the calcified heart valve to break down the calcification.

29. (Withdrawn) The method of claim 28 further comprising inserting a reflector into the calcified heart valve to magnify the ultrasound radiation.

30. (Withdrawn) A low-profile heart valve comprising:
at least three leaflets, wherein one side of each leaflet overlaps a neighboring leaflet such that the leaflets open sequentially and close sequentially.

31. (Withdrawn) A heart valve comprising:
an inner circumference and an outer circumference, wherein the inner circumference is a circumference of an annulus formed by leaflets of the heart valve; and the outer circumference is a circumference of a fluid-tight diaphragm, wherein the diaphragm fills a space between the inner circumference and the outer circumference.

32. (Withdrawn) A mitral valve repair device comprising:
a first head defining an operating plane; and
a second head operably attached to the first head and
configured to displace a leaflet with respect to the operating
plane.

33. (Withdrawn) The repair device of claim 32 wherein the
first head is a U-shaped head.

34. (Withdrawn) The repair device of claim 32 wherein the
first head comprises an attachment mechanism for attaching at
least two portions of the leaflet.

35. (Withdrawn) The repair device of claim 32 further
comprising a handle for operating the second head with respect to
the first head.

36. (Withdrawn) A method of repairing an aortic dissection
comprising:
accessing a patient's heart;
installing an access device in a wall of the heart, the
access device having means for preventing bleeding through the
access device;
inserting a dissection repair device through the access
device; and
repairing the aortic dissection.

37. (Withdrawn) A device for repairing an aortic dissection
comprising:
annularly enlargeable componentry configured to be inserted
into a patient's aorta; and
means for closing a void created by the aortic dissection.

38. (Withdrawn) The device of claim 37 wherein the means
for closing the void comprise injection needles for injecting a

tissue sealant.

39. (Withdrawn) The device of claim 38 wherein the tissue sealant comprises a biologically compatible glue.

40. (Withdrawn) The device of claim 38 wherein the tissue sealant comprises mechanical sutures.

41. (Withdrawn) The device of claim 38 wherein the tissue sealant comprises surgical staples.

42. (Withdrawn) The device of claim 38 wherein the annularly enlargeable componentry comprises means for supplementing blood flow through the componentry during the repair.

43. (Withdrawn) A device for resecting a diseased heart valve comprising:

a first set of annularly enlargeable componentry having a first longitudinal axis and a proximal cutting edge;

a second set of annularly enlargeable componentry having a second longitudinal axis and a distal cutting edge;

wherein the device is configured to resect the diseased heart valve when the first set of componentry is enlarged on a distal side of the diseased heart valve and the second set of componentry is enlarged on a proximal side of the diseased heart valve and the sets of componentry are drawn axially together along the longitudinal axes.

44. (Withdrawn) The device of claim 43 wherein the first longitudinal axis and the second longitudinal axis are coaxial.

45. (Original) A method for implanting an endoprosthesis comprising:

accessing a patient's heart;

11/023,783

Response dated March 26, 2009

Page 8 of 10

installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;

inserting an endoprosthesis delivery device through the access device; and

installing the endoprosthesis.

REMARKS/ARGUMENTS

This paper is submitted responsive to the office action mailed September 26, 2008. Reconsideration of the application in light of the accompanying remarks and amendments is respectfully requested.

As requested by the Examiner, applicant hereby affirms the election of Group I and Species A without traverse.

The Examiner rejected claims 1-3, 5-11 and 45 as anticipated by Bergheim. As demonstrated in the accompanying Declaration, Bergheim is not prior art to the present application, because the present invention was invented prior to filing of the Bergheim application.

It is also noted that the cited Dehdashtian publication (filing date of November 16, 2005) is clearly not prior art to the present application.

In addition, the claims have been amended so as to incorporate the subject matter of claim 3 into independent claim 1, and it is submitted that the claims as amended are patentable over the art of record.

An earnest and thorough effort has been made to address all issues raised in the aforesaid office action and to place the application in condition for allowance. If, upon considering this response, the Examiner is of the opinion that issues remain which could be addressed by telephone interview, the Examiner is invited to telephone the undersigned.

11/023,783
Response dated March 26, 2009
Page 10 of 10

This paper is accompanied by authorization to charge a deposit account for an extension of time fee. It is believed that no other fee is due. If any such fee is due, please charge same to deposit account 02-0184.

Respectfully submitted,
Christoph Hans Huber

By /george a. coury/
George A. Coury
BACHMAN & LaPOINTE, P.C.
Reg. No. 34,309
Attorney for Applicants
Telephone: (203)777-6628 ext. 113
Fax: (203)865-0297
Email: docket@bachlap.com

Date: March 26, 2009

Electronic Patent Application Fee Transmittal

Application Number:	11023783
Filing Date:	28-Dec-2004
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support
First Named Inventor/Applicant Name:	Christoph Hans Huber
Filer:	George A. Coury/Alicia Therriault
Attorney Docket Number:	06-692

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with \$0 paid	2253	1	555	555

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				555

Electronic Acknowledgement Receipt

EFS ID:	5037992
Application Number:	11023783
International Application Number:	
Confirmation Number:	1933
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support
First Named Inventor/Applicant Name:	Christoph Hans Huber
Customer Number:	34704
Filer:	George A. Coury/Alicia Therriault
Filer Authorized By:	George A. Coury
Attorney Docket Number:	06-692
Receipt Date:	26-MAR-2009
Filing Date:	28-DEC-2004
Time Stamp:	10:58:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$555
RAM confirmation Number	16258
Deposit Account	020184
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

- Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)
- Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	06-692_Declaration_Huber.pdf	68667 8fa03eebdce359605f550ebc414bc8fd42028e12	no	2

Warnings:

Information:

2		06-692_Amendment_03-26-09.pdf	290719 d330aaf1ba2a9d2ad4decaff509a5eb75f5be48	yes	10
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Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	8
Applicant Arguments/Remarks Made in an Amendment	9	10

Warnings:

Information:

3	Fee Worksheet (PTO-06)	fee-info.pdf	30215 8c1e468a68553984b8741a7b7dae8885fa594a00	no	2
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Warnings:

Information:

Total Files Size (in bytes):			389601		
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

App. No.:	11/023,783	Att'y	06-692
Filing Date:	12/28/2004	Docket:	
Inventor(s):	Christoph Hans Huber	Conf No.:	1933
Title	Methods And Devices...	Group Art	3774
		Unit:	
		Examiner:	Prebilic, Paul B.

Correspondence Address:
Customer Number 34704

Declaration of Christoph Hans Huber

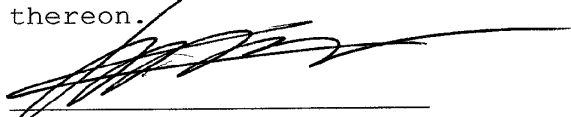
Dear Sir:

1. I, Christoph Hans Huber, am inventor of the invention set forth in the above-identified pending US patent application.
2. I understand that the application is being rejected over US 2005/0240200 to Bergheim ("Bergheim").
3. I understand that the basis for this rejection is that Bergheim was allegedly filed before my invention of the subject matter of my pending claims.
4. Bergheim lists a filing date of April 23, 2004.
5. I conceived the present invention prior to April 23, 2004, and this was followed by constructive reduction to practice through the filing of provisional application 60/615,009 on October 2, 2004.
6. From prior to the April 23, 2004 filing date of Bergheim until the filing of the provisional application on October 2, 2004, I diligently pursued the constructive reduction to practice of this invention by filing the provisional application and later on by contacting a US representative who prepared and filed the present application.
7. Based upon the foregoing, it is my understanding that Bergheim is not prior art to my application.



Declaration of Christoph Hans Huber
Page 2

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Christoph Hans Huber

Date: March 25, 2009

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/023,783		Filing Date 12/28/2004		<input type="checkbox"/> To be Mailed			
APPLICATION AS FILED – PART I												
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY				
FOR		NUMBER FILED	NUMBER EXTRA		RATE (\$)	FEE (\$)	OR		RATE (\$)	FEE (\$)		
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>		N/A	N/A		N/A				N/A			
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>		N/A	N/A		N/A				N/A			
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>		N/A	N/A		N/A				N/A			
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>		minus 20 =	*		X \$ =		OR		X \$ =			
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>		minus 3 =	*		X \$ =		OR		X \$ =			
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).										
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>												
					TOTAL		OR		TOTAL			
* If the difference in column 1 is less than zero, enter "0" in column 2.												
APPLICATION AS AMENDED – PART II												
(Column 1)			(Column 2)			SMALL ENTITY		OR			OTHER THAN SMALL ENTITY	
AMENDMENT	03/26/2009		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(o))</small>		* 44	Minus	** 45	= 0	X \$26 =	0	OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>		* 15	Minus	*** 15	= 0	X \$110 =	0	OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>											
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>											
					TOTAL ADD'L FEE		OR		TOTAL ADD'L FEE			
(Column 1) (Column 2) (Column 3)												
AMENDMENT			CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(o))</small>		*	Minus	**	=	X \$ =		OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>		*	Minus	***	=	X \$ =		OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>											
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>											
					TOTAL ADD'L FEE		OR		TOTAL ADD'L FEE			
(Column 1) (Column 2) (Column 3)												
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.												
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".												
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".												
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.												
							Legal Instrument Examiner: /JACQULYN L. WILLIAMS/					

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

11/023,783 12/28/2004 Christoph Hans Huber 06-692 1933

34704 7590 09/26/2008
BACHMAN & LAPOINTE, P.C.
900 CHAPEL STREET
SUITE 1201
NEW HAVEN, CT 06510

Table with 1 column: EXAMINER

SINGH, NAVEEN KUMAR

Table with 2 columns: ART UNIT, PAPER NUMBER

3773

Table with 2 columns: MAIL DATE, DELIVERY MODE

09/26/2008 PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. This office action is in response to application no. 11/023783 filed on 12/28/2004 and claims priority from provisional application 60/615009 filed on 10/2/2004.

Election/Restrictions

2. Claims 12-17, 20-35, and 37-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected apparatus, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/5/2008.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 36 and 45, drawn to a method of operating on a patient, classified in class 128, subclass 898.
- II. Claims 18-19, drawn to instrumentation for accessing a chamber of a patient's heart, classified in class 623, subclass 2.11.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product. For example, the process as claimed can be performed without a catheter as claimed in the product claim(s).

5. This application contains claims directed to the following patentably distinct species: A) Fig. 6; B) Fig. 31. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly

and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. During a telephone conversation with George Coury on 9/11/2008 a provisional election was made without traverse to prosecute the invention of Group I and Species A), claims 1-3, 5-11, and 45; Group I being drawn to a method for operating on a patient and Species A) being drawn to a method of repairing a heart valve. Affirmation of this election must be made by applicant in replying to this Office action. Since claims 18 and 19 are drawn to instrumentation for accessing a chamber of a patient's heart and claims 4 and 36 are drawn to a method for repairing an aortic dissection, claims 4, 18-

19, and 36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. **Claims 1-3, 5-11, and 45** are rejected under 35 U.S.C. 102(e) as being anticipated by **Bergheim (US 2005/0240200)**.

Regarding claims 1-3, 5-11, and 45, Bergheim discloses a method of operating on a patient comprising: accessing the patient's heart (fig. 1); installing an access device in a wall of the heart (fig. 2, paragraph 0011), the access device having a means for preventing bleeding through the access device (paragraph 0041); performing a surgical procedure (fig.7; paragraph 0047); resecting a native heart valve (paragraph 0059), implanting a heart valve (fig.7; paragraph 0047), repairing a heart valve (paragraph 0001); wherein installing the access device in the wall of the heart further comprises installing the access device in a ventricular apex of the heart (fig. 2, paragraph 0040); inserting a valve delivery device/endoprosthesis through the access device (fig.7; paragraph 0047); wherein resecting the native heart valve is performed percutaneously and the installing the heart valve is performed translapically (fig. 1 and

7); installing the heart valve further comprises radially expanding the heart valve (fig. 10; paragraph 0049); installing the heart valve further comprises pulling leaflets of a native heart valve downward (fig. 5, paragraph 0046).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention: **Dehdashtian (US 20070112422); Gabbay (US 20060142848); Lattouf (US 20030130571); Ortiz et al. (US 6,419,696); and Stevens et al. (US 6,679,268).**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Naveen K. Singh whose telephone number is (571)270-3863. The examiner can normally be reached on Monday-Friday (7:30AM-5:00PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Naveen K. Singh/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 11/023,783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS	
	Examiner Naveen K. Singh	Art Unit 3773	Page 1 of 1

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*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-2005/0240200	10-2005	Bergheim, Bjarne	606/108
*	B US-2007/0112422	05-2007	Dehdashtian, Mark	623/002.11
*	C US-2006/0142848	06-2006	Gabbay, Shlomo	623/001.26
*	D US-2003/0130571	07-2003	Lattouf, Omar M.	600/374
*	E US-6,419,696	07-2002	Ortiz et al.	623/2.37
*	F US-6,679,268	01-2004	Stevens et al.	128/898
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			

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BIB DATA SHEET

CONFIRMATION NO. 1933

SERIAL NUMBER 11/023,783	FILING or 371(c) DATE 12/28/2004 RULE	CLASS 623	GROUP ART UNIT 3773	ATTORNEY DOCKET NO. 06-692			
APPLICANTS Christoph Hans Huber, Boston, MA;							
** CONTINUING DATA ***** This appln claims benefit of 60/615,009 10/02/2004							
** FOREIGN APPLICATIONS *****							
** IF REQUIRED, FOREIGN FILING LICENSE GRANTED *** SMALL ENTITY ** 03/24/2005							
Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Verified and /NAVEEN KUMAR SINGH/ Examiner's Signature	<input type="checkbox"/> Met after Allowance NS Initials	STATE OR COUNTRY MA	SHEETS DRAWINGS 25	TOTAL CLAIMS 45	INDEPENDENT CLAIMS 15
ADDRESS BACHMAN & LAPOINTE, P.C. 900 CHAPEL STREET SUITE 1201 NEW HAVEN, CT 06510 UNITED STATES							
TITLE Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support							
FILING FEE RECEIVED 2325	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit			



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PTO/SB/08A (10-01)

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Substitute for form 1449/PTO		Complete if known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	11/023,783
		Filing Date	December 28, 2004
		First Named Inventor	Christoph Hans Huber
		Art Unit	3735
		Examiner Name	Suzette James J. Chen
Sheet 1 of 3	Attorney Docket Number		293/076

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
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		US-3,671,979	06/27/1972	Moulopoulos	
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Examiner Signature	/Naveen Singh/	Date Considered	09/17/2008
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional).

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(use as many sheets as necessary)		Filing Date	December 28, 2004	First Named Inventor	Christoph Hans Huber
		Art Unit	3773	Examiner Name	Suzette James J. Chubb
Sheet	2	of	3	Attorney Docket Number	293/076

U.S. PATENT DOCUMENTS (continued)						
Examiner initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)				
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		US-6,840,246	B2	01/11/2005	Downing	

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Examiner initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code* - Number ⁵ - Kind Code ⁶					

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³ Applicant is to place a check mark here if English language translation is attached.
⁴ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).
⁵ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if known		
				Application Number	11/023,783	
Sheet		3	of	3	Attorney Docket Number	293/076
				Filing Date	December 28, 2004	
				First Named Inventor	Christoph Hans Huber	
				Art Unit	3733	
				Examiner Name	Suzette-Jane D. Cheri	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
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Examiner Signature	/Naveen Singh/	Date Considered	09/17/2008
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Search Notes 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Naveen K Singh	Art Unit 3773

SEARCHED			
Class	Subclass	Date	Examiner
623	2.11	9/17/2008	NS

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor name search	9/17/2008	NS
Class/subclass search	9/17/2008	NS
East text search	9/17/2008	NS
Forward/backward citation search	9/17/2008	NS

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner


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Index of Claims 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Naveen K Singh	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE									
Final	Original	09/17/2008									
	1	✓									
	2	✓									
	3	✓									
	4	N									
	5	✓									
	6	✓									
	7	✓									
	8	✓									
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	35	N									
	36	N									

<i>Index of Claims</i> 	Application/Control No. 11023783	Applicant(s)/Patent Under Reexamination HUBER, CHRISTOPH HANS
	Examiner Naveen K Singh	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE								
Final	Original	09/17/2008								
	37	N								
	38	N								
	39	N								
	40	N								
	41	N								
	42	N								
	43	N								
	44	N								
	45	✓								

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	88	("3124136" "3874388" "4007743" "4061135" "4345600" "4423730" "4573473" "4598698" "4605002" "4621638" "4628937" "4665906" "4779611" "4786155" "4822345" "4836204" "4901721" "4915107" "4917089" "4943277" "4960424" "5029574" "5053046" "5067957" "5108420" "5147374" "5178133" "5183464" "5188636" "5192301" "5209747" "5242457" "5275166" "5284488" "5293869" "5306234" "5309896" "5309910" "5312341" "5313943" "5314466" "5318525" "5328467" "5329927" "5330492" "5334210"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2008/09/17 08:40

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L8	10	I7 and seal	US-PGPUB; USPAT; USOCR	ADJ	OFF	2008/09/17 09:14
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S18	54	(garrison, michi).in.	US-PGPUB; USPAT	ADJ	OFF	2008/09/15 18:52
S19	27	S18 and (valve same resect\$)	US-PGPUB; USPAT	ADJ	OFF	2008/09/15 18:52
S20	27	S18 and (valve with resect\$)	US-PGPUB; USPAT	ADJ	OFF	2008/09/15 18:52
S21	27	S19 or S20 or S17 and (transapical\$)	US-PGPUB; USPAT	ADJ	OFF	2008/09/15 18:52
S22	0	S18 and (transapic\$)	US-PGPUB; USPAT	ADJ	OFF	2008/09/15 18:53
S25	38	("1331737" "20050240200" "3671979" "4056854" "4327736" "4343048" "4585000" "4777951" "5332402" "5397351" "5792094" "5840081" "5855597" "5895399" "5957949" "5980532" "6168614" "6203561" "6338740" "6425916" "6458153" "6458156" "6482228" "6503272" "6562058" "6569196" "6620182" "6663651" "6679268" "6682558" "6692513" "6726702" "6730118" "6733525" "6764494" "6767362" "6840246" "0832201").PN.	US-PGPUB; USPAT	ADJ	OFF	2008/09/15 18:54

S26	0	S25 and (transapic\$)	US-PGPUB; USPAT	ADJ	OFF	2008/09/15 18:54
S27	0	S17 and (transapic\$)	US-PGPUB; USPAT	ADJ	OFF	2008/09/15 18:54
S28	552	(623/2.11).ccls.	US-PGPUB; USPAT	ADJ	OFF	2008/09/15 18:54
S29	18	S28 and (transapic\$)	US-PGPUB; USPAT	ADJ	OFF	2008/09/15 18:54
S30	105	("3626518" "3691567" "3868956" "3911502" "4030142" "4503569" "4759758" "4994077").PN. OR ("5332402").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2008/09/15 19:06

9/ 17/ 2008 2:58:31 PM

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wsp



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if known		
				Application Number	11/023,783	
Sheet		1	of	1	Attorney Docket Number	293/076

U.S. PATENT DOCUMENTS						
Examiner initials ¹	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)				
/N.S./		US-5,980,532		11/09/1999	Wang	

FOREIGN PATENT DOCUMENTS							
Examiner initials ¹	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ⁴ - Number ⁵ - Kind Code ⁶					
/N.S./		WO 00/47139		08/17/2000	Garrison et al.		
/N.S./		WO 03/028592		04/10/2003	Weadock		
/N.S./		WO 2004/019811		03/11/2004	Wilson		

Examiner Signature	/Naveen Singh/	Date Considered	09/17/2008
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¹ EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

² Applicant's unique citation designation number (optional).

³ See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

⁴ Applicant is to place a check mark here if English language translation is attached.

⁵ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

⁶ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁷ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

Doc code :IDS

Doc description: Information Disclosure Statement (IDS) Filed

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	11023783
	Filing Date	2004-12-28
	First Named Inventor	Christoph Hans Huber
	Art Unit	3774
	Examiner Name	Rebecca Paul D.
	Attorney Docket Number	06-692

U.S. PATENTS							Remove	
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear		
	1							
If you wish to add additional U.S. Patent citation information please click the Add button.							Add	
U.S. PATENT APPLICATION PUBLICATIONS							Remove	
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear		
/N.S./	1	20050240200	A1	2005-10-27	Bjarne Bergheim			
If you wish to add additional U.S. Published Application citation information please click the Add button.							Add	
FOREIGN PATENT DOCUMENTS							Remove	
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² j	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							<input type="checkbox"/>
If you wish to add additional Foreign Patent Document citation information please click the Add button.							Add	
NON-PATENT LITERATURE DOCUMENTS							Remove	
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.					T ⁵	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	11023783	11023783 - GAU: 3773
	Filing Date	2004-12-28	
	First Named Inventor	Christoph Hans Huber	
	Art Unit	3774	
	Examiner Name	Rebilio, Paul D.	
	Attorney Docket Number	06-692	

	1		<input type="checkbox"/>
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If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/Naveen Singh/	Date Considered	09/17/2008
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

App. No.:	11/023,783	Att'y	06-692
Filing Date:	12/28/2004	Docket:	
Inventor(s):	Christoph Hans Huber	Conf No.:	1933
Title	Methods And Devices...	Group Art	3774
		Unit:	
		Examiner:	Prebilic, Paul B.

Correspondence Address:
Customer Number 34704

RESPONSE TO WRITTEN RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This paper is submitted responsive to the Restriction Requirement mailed May 5, 2008. In that action, the Examiner required restriction of the invention between Groups I-VI, as listed on page 1 of the Office Action. Responsive to that requirement, the Applicant elects Group I, claims 1-11, 18, 19, 36 and 45. This election is made without traverse.

The Examiner also entered an election of species beginning on page 6 of the Office Action, and the Applicant elects the species of Figure 8. All claims of the elected invention, that is, all of claims 1-11, 18, 19, 36 and 45 read on either generic figures 1-7, 11-18, 29-30 and 32, or on Figure 8 itself. Thus, with this election of species, all of claims 1-11, 18, 19, 36 and 45 should be examined.

This election of species is likewise made without traverse. Examination on the merits is now respectfully requested.

Respectfully submitted,
Christoph Hans Huber

By /george a. coury/
George A. Coury
BACHMAN & LaPOINTE, P.C.
Reg. No. 34,309
Attorney for Applicants
Telephone: (203)777-6628 ext. 113
Telefax: (203)865-0297
Email: docket@bachlap.com

Date: June 5, 2008

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	11023783
	Filing Date	2004-12-28
	First Named Inventor	Christoph Hans Huber
	Art Unit	3774
	Examiner Name	Prebilic, Paul B.
	Attorney Docket Number	06-692

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	
	1	20050240200	A1	2005-10-27	Bjarne Bergheim		

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FOREIGN PATENT DOCUMENTS								Remove
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² j	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button. Add

NON-PATENT LITERATURE DOCUMENTS							Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.					T ⁵

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	11023783
	Filing Date	2004-12-28
	First Named Inventor	Christoph Hans Huber
	Art Unit	3774
	Examiner Name	Prebilib, Paul B.
	Attorney Docket Number	06-692

	1		<input type="checkbox"/>
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If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	11023783
	Filing Date	2004-12-28
	First Named Inventor	Christoph Hans Huber
	Art Unit	3774
	Examiner Name	Prebilib, Paul B.
	Attorney Docket Number	06-692

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- See attached certification statement.
- Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/george a. coury/	Date (YYYY-MM-DD)	2008-06-05
Name/Print	George A. Coury	Registration Number	34309

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	3408294
Application Number:	11023783
International Application Number:	
Confirmation Number:	1933
Title of Invention:	Methods and devices for repair or replacement of heart valves or adjacent tissue without the need for full cardiopulmonary support
First Named Inventor/Applicant Name:	Christoph Hans Huber
Customer Number:	34704
Filer:	George A. Coury/Alicia Therriault
Filer Authorized By:	George A. Coury
Attorney Docket Number:	06-692
Receipt Date:	05-JUN-2008
Filing Date:	28-DEC-2004
Time Stamp:	13:27:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	06-692_Rsp_Restriction_Re q_06-05-08.pdf	40343 <small>c96358fcc270a9a582b647a99009f1ee d7e48683</small>	no	1

Warnings:

Information:

2	Information Disclosure Statement (IDS) Filed	06-692_US_IDS_Form__SB_08a_06-05-08.pdf	573893 <small>9383ae476604411e15b7107b150c5c719052ae38</small>	no	4
Warnings:					
Information:					
Total Files Size (in bytes):				614236	
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

11/023,783 12/28/2004 Christoph Hans Huber 06-692 1933

34704 7590 05/05/2008
BACHMAN & LAPOINTE, P.C.
900 CHAPEL STREET
SUITE 1201
NEW HAVEN, CT 06510

Table with 1 column: EXAMINER

PREBILIC, PAUL B

Table with 2 columns: ART UNIT, PAPER NUMBER

3774

Table with 2 columns: MAIL DATE, DELIVERY MODE

05/05/2008 PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 18, 19, 36, and 45, drawn to a method of operating on a patient, classified in class 606, subclass 108.
- II. Claims 12-15, 32-35, 37-42, and 43-44, drawn to a device for implanting a heart valve, classified in class 606, subclass 108.
- III. Claims 16 and 17, drawn to means of visualizing the circulatory system, classified in class 600, subclass 100.
- IV. Claims 20-24, 30, and 31, drawn to a heart valve, classified in class 623, subclass 2.14.
- V. Claims 25-27, drawn to a guidewire and placement device, classified in class 606, subclass 164.13.
- VI. Claims 28 and 29, drawn to method of breaking calcification, classified in class 606, subclass 127.

The inventions are distinct, each from the other because of the following reasons:

Inventions II, III, V and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination II has separate utility such as in the gastrointestinal system, subcombination III has a separate

utility such as in the diagnosis of blockages in the veins of the leg, subcombination V has separate utility such as in placing guidewires within the bronchial tubes of the lungs, subcombination VI has separate utility such as in the breaking up of calcification in another part of an artery or in the breaking up of stones in the ureter. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the heart valve could be used as a valve in the gastrointestinal system as to replace the cardiac sphincter.

Inventions II and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not set forth any of the details of the heart valve but the subcombination claims rely on such details for patentability. The subcombination has separate utility such as in the repair of a valve in the veins of the leg.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to George Coury on April 30, 2008 to request an oral election to the above restriction requirement, but did not result in an election being made.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

This application contains claims directed to the following patentably distinct species:

- | | |
|---------------|--------------|
| A. Figure 8 | J. Figure 24 |
| B. Figure 9 | K. Figure 25 |
| C. Figure 10 | L. Figure 26 |
| D. Figure 19 | M. Figure 27 |
| E. Figure 19A | N. Figure 28 |
| F. Figure 20 | O. Figure 31 |
| G. Figure 21 | P. Figure 33 |
| H. Figure 22 | Q. Figure 34 |
| I. Figure 23 | R. Figure 35 |

S. Figure 36

V. Figure 39

T. Figure 37

W. Figures 40 and 41

U. Figure 38

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending

Art Unit: 3774

claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

COPY MAILED

MAR 15 2007

OFFICE OF PETITIONS

**Fish & Neave IP Group
Ropes & Gray LLP
1211 Avenue of the Americas
New York, NY 10036-8704**

In re Application of	:	
Christoph Hans Huber	:	
Application No. 11/023,783	:	
Filed: December 28, 2004	:	DECISION ON PETITION
Attorney Docket No. 293/076	:	TO WITHDRAW
	:	FROM RECORD

This is a decision on the Request to Withdraw as attorney or agent of record under 37 C.F.R. § 1.36(b), filed July 31, 2006.

The request is **NOT APPROVED** as moot.

A review of the file record indicates that the power of attorney to the attorneys associated with Fish & Neave IP Group has been revoked by the applicant of the patent application on January 8, 2007. Accordingly, the request to withdraw under 37 C.F.R. § 1.36(b) is moot.

All future communications from the Office will continue to be directed to the below-listed address until otherwise notified by applicant.

Telephone inquires concerning this decision should be directed to Terri Williams at 571-272-2991.

Terri Williams
Petitions Examiner
Office of Petitions

cc: **Bachman & Lapointe, P.C.**
900 Chapel Street
Suite 1201
New Haven, CT 06510



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/023,783	12/28/2004	Christoph Hans Huber	293/076

34704
 BACHMAN & LAPOINTE, P.C.
 900 CHAPEL STREET
 SUITE 1201
 NEW HAVEN, CT 06510

CONFIRMATION NO. 1933

OC000000022900481

OC000000022900481

Date Mailed: 03/14/2007

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/08/2007.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Terri J. Williams

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199
 ATTORNEY/APPLICANT COPY



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/023,783	12/28/2004	Christoph Hans Huber	293/076

1473
FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1211 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-8704

CONFIRMATION NO. 1933
OC000000022900460
OC000000022900460

Date Mailed: 03/14/2007

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/08/2007.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Terri S. Williams

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199
FORMER ATTORNEY/AGENT COPY



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/023,783	12/28/2004	Christoph Hans Huber	293/076

34704
BACHMAN & LAPOINTE, P.C.
900 CHAPEL STREET
SUITE 1201
NEW HAVEN, CT 06510

CONFIRMATION NO. 1933

OC000000022900481

OC000000022900481

Date Mailed: 03/14/2007

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/08/2007.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

John S. Williams

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199
OFFICE COPY


UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/023,783	12/28/2004	Christoph Hans Huber	293/076

1473
 FISH & NEAVE IP GROUP
 ROPES & GRAY LLP
 1211 AVENUE OF THE AMERICAS
 NEW YORK, NY 10036-8704

CONFIRMATION NO. 1933

OC000000022900460

OC000000022900460

Date Mailed: 03/14/2007

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/08/2007.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Terri S. Williams

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199
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IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 11/023,783 Confirmation No.
Applicant : Christoph Hans Huber
Filed : December 28, 2004
TC/A.U. :
Examiner :

Docket No. : 06-692
Customer No. : 34704

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

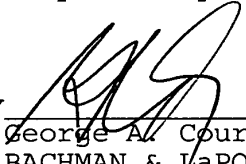
REQUEST TO CHANGE RESIDENCE OF INVENTOR UNDER 37 CFR 1.76

Dear Sir:

Pursuant to 37 CFR 1.76, enclosed is a revised Application Data Sheet indicating a change of residence of the inventor, Christoph Hans Huber.

If any fees are required in connection with this case, it is respectfully requested that they be charged to Deposit Account No. 02-0184.

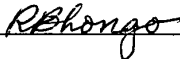
Respectfully submitted,

By 
George A. Coury
BACHMAN & LaPOINTE, P.C.
Reg. No. 34,309
Attorney for Applicants

Telephone: (203)777-6628 ext. 113
Telefax: (203)865-0297
E-mail: docket@bachlap.com

Date: January 4, 2007

I, Rhonda B. Longo, hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313" on January 4, 2007.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REVISED Application Data Sheet 37 CFR 1.76		Attorney Docket Number	06-692
		Application Number	11/023,783
Title of Invention	METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2

Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1				
Applicant Authority <input checked="" type="radio"/> Inventor		<input type="radio"/> Legal Representative under 35 U.S.C. 117		<input type="radio"/> Party of Interest under 35 U.S.C. 118
Prefix	Given Name	Middle Name	Family Name	Suffix
	Christoph	Hans	Huber	
Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
City	Lausanne	State/Province	Country of Residence ⁱ	CH
Citizenship under 37 CFR 1.41(b) ⁱ		CH		
Mailing Address of Applicant:				
Address 1	Av. des Mousquines 38			
Address 2				
City	Lausanne	State/Province	CH	
Postal Code	CH-1005	Country ⁱ	CH	
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button. <input type="button" value="Add"/>				

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
<input checked="" type="checkbox"/> An Address is being provided for the correspondence information of this application.			
Name 1	George A. Coury, Esquire	Name 2	Bachman & LaPointe, P.C.
Address 1	900 Chapel Street, Suite 1201		
Address 2			
City	New Haven	State/Province	CT
Country ⁱ	US	Postal Code	06510-2802
Phone Number	203-777-6628 ext. 113	Fax Number	203-865-0297
Email Address	docket@bachlap.com	<input type="button" value="Add Email"/>	<input type="button" value="Remove Email"/>

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	06-692
		Application Number	11/023,783
Title of Invention	METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT		

Application Information:

Title of the Invention	METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT		
Attorney Docket Number	06-692	Small Entity Status Claimed	<input type="checkbox"/>
Application Type			
Subject Matter			
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	
Publication Information:			
<input type="checkbox"/> Request Early Publication (Fee required at time of Request 37 CFR 1.219)			
<input type="checkbox"/> Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not been and will not be the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing.			

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.			
Please Select One:	<input checked="" type="radio"/> Customer Number	<input type="radio"/> US Patent Practitioner	<input type="radio"/> US Representative (37 CFR 11.9)
Customer Number	34704		

Domestic Priority Information:

This section allows for the applicant to claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c). Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.			
Prior Application Status		<input type="button" value="Remove"/>	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
Additional Domestic Priority Data may be generated within this form by selecting the Add button.			

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

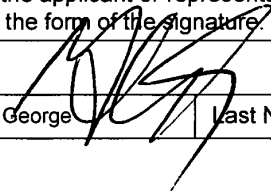
Application Data Sheet 37 CFR 1.76		Attorney Docket Number	06-692
		Application Number	11/023,783
Title of Invention	METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT		

<input type="button" value="Remove"/>			
Application Number	Country ⁱ	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			<input checked="" type="radio"/> Yes <input type="radio"/> No
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.				
Assignee 1				
If the Assignee is an Organization check here. <input type="checkbox"/>				
Prefix	Given Name	Middle Name	Family Name	Suffix
Mailing Address Information:				
Address 1				
Address 2				
City		State/Province		
Country ⁱ		Postal Code		
Phone Number		Fax Number		
Email Address				
Additional Assignee Data may be generated within this form by selecting the Add button.				

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.					
Signature			Date (YYYY-MM-DD)	2007-01-04	
First Name	George	Last Name	Coury	Registration Number	34309

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



IFW

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 11/023,783 Confirmation No.
 Applicant : Christoph Hans Huber
 Filed : December 28, 2004
 TC/A.U. :
 Examiner :
 Docket No. : 06-692
 Customer No. : 34704

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313


SUBMISSION OF
REVOCATION OF POWER OF ATTORNEY
AND CHANGE OF CORRESPONDENCE ADDRESS

Dear Sir:

Applicant submits herewith a Revocation of Power of Attorney and Change of Correspondence Address to be filed in the above-identified case.

If any fees are required in connection with this case, it is respectfully requested that they be charged to Deposit Account No. 02-0184.


Respectfully submitted,

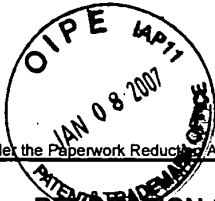
By 
 George A. Coury
 BACHMAN & LAPOINTE, P.C.
 Reg. No. 34,309
 Attorney for Applicants

Telephone: (203)777-6628 ext. 113
 Telefax: (203)865-0297
 E-mail: docket@bachlap.com

Date: January 4, 2007

I, Rhonda B. Longo, hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313" on January 4, 2007.





81984 (HUL-A4/01-WO)

PTO/SB/82 (01-06)
Approved for use through 12/31/2008. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REVOCATION OF POWER OF ATTORNEY WITH NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS	Application Number	11/023,783
	Filing Date	December 28, 2004
	First Named Inventor	Christoph Hans Huber
	Art Unit	
	Examiner Name	
	Attorney Docket Number	06-692

I hereby revoke all previous powers of attorney given in the above-identified application.

A Power of Attorney is submitted herewith.

OR

I hereby appoint the practitioners associated with the Customer Number:

Please change the correspondence address for the above-identified application to:

The address associated with Customer Number:

OR

<input type="checkbox"/> Firm or Individual Name			
Address			
City	State	Zip	
Country			
Telephone	Email		

I am the:

Applicant/Inventor.

Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Signature			
Name	Christoph Hans Huber		
Date	Telephone		
<i>12.12.2006</i>	<i>+41 78 518 33 44</i>		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

*Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.36. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IFW



293/076

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Christoph Hans Huber

Application No. : 11/023,783 Confirmation No. : 1933

Filed : December 28, 2004

For : METHODS AND DEVICES FOR REPAIR OR
REPLACEMENT OF HEART VALVES OR ADJACENT
TISSUE WITHOUT THE NEED FOR FULL
CARDIOPULMONARY SUPPORT

Group Art Unit : 3738

Examiner : Suzette Jaime J. Gherbi

New York, New York 10020
July 24, 2006

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

PETITION UNDER 37 C.F.R. § 1.36
TO WITHDRAW FROM REPRESENTATION

Sir:

Pursuant to 37 C.F.R. § 1.36, the undersigned attorney of record hereby petitions on his own behalf and on behalf of each of the other attorneys of record (viz., Robert R. Jackson, Reg. No. 26,183, and Jeffrey H. Ingerman, Reg. No. 31,069) for permission to withdraw from representation of applicant in the above-identified patent application. No Office action to which a reply is due is currently outstanding. Therefore, should any Office action be issued

3203573_1

in the near future, sufficient time will remain for applicant to file a reply.

Pursuant to MPEP § 402.06, the mailing addresses of the undersigned and of the applicant are set forth at the end of this Petition.

The undersigned undertakes to send copies of the file of this application to the applicant upon granting of this Petition.

Petitioners respectfully request that this petition be granted promptly, and that, in the absence of an assignment, the Patent and Trademark Office direct all future correspondence to the applicant at the following address:

Christoph Huber-Sigwart
Le Chateau
1407 Bioley-Magnoux
Switzerland

An early and favorable action on this Petition
is respectfully requested.

Respectfully submitted,

ROBERT R. JACKSON
JEFFREY H. INGERMAN
STUART W. YOTHERS
Attorneys of Record

By: 

Stuart W. Yothers
Registration No. 53,816
Attorney for Applicant
FISH & NEAVE IP GROUP
ROPES & GRAY LLP
Customer No. 1473
1251 Avenue of the Americas
New York, New York 10020-1104
Tel.: (212) 596-9000
Fax: (212) 596-9090



293/076

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Christoph Hans Huber
Application No. : 11/023,783 Confirmation No. : 1933
Filed : December 28, 2004
For : METHODS AND DEVICES FOR REPAIR OR
REPLACEMENT OF HEART VALVES OR
ADJACENT TISSUE WITHOUT THE NEED FOR
FULL CARDIOPULMONARY SUPPORT
Group Art Unit : 3738
Examiner : Suzette Jaime J. Gherbi

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

TRANSMITTAL LETTER

Sir:

Transmitted herewith: a Preliminary Amendment;
 a Petition Under 37 C.F.R. § 1.36 to Withdraw from
Representation; a Supplemental Amendment; a
substitute Specification; a Supplemental Information
Disclosure Statement; to be filed in the above-identified
patent application.

FEE FOR ADDITIONAL CLAIMS

A fee for additional claims is not required.

- A fee for additional claims is required.

The additional fee has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADD'L FEES
Total Claims		*	0	X \$ 50 =	\$ 0.00
Independent Claims		**	0	X \$200 =	\$ 0.00
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- A check in the amount of \$_____ in payment of the filing fee is transmitted herewith.
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- The Director is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §§ 1.16 and 1.17, in connection with the paper(s) transmitted herewith, or credit any overpayment of same, to deposit Account No. 06-1075, Order No. 000293-6000. A duplicate copy of this transmittal letter is transmitted herewith.
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EXTENSION FEE

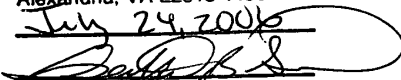
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Respectfully submitted,



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293/076



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Christoph Hans Huber
Application No. : 11/023,783 Confirmation No. : 1933
Filed : December 28, 2004
For : METHODS AND DEVICES FOR REPAIR OR
REPLACEMENT OF HEART VALVES OR ADJACENT
TISSUE WITHOUT THE NEED FOR FULL
CARDIOPULMONARY SUPPORT
Examiner : Suzette Jaime J. Gherbi
Group Art Unit : 3738

New York, New York 10020
September 19, 2005

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.56 and 1.97,
applicant wishes to call the attention of the Examiner to the
following documents:

U.S. Patent Document

Wang

5,980,532

11/09/1999

Foreign Patent Documents

WO 00/47139	Garrison et al.	08/17/2000
WO 03/028592	Weadock	04/10/2003
WO 2004/019811	Wilson	03/11/2004

These documents are listed on the accompanying Form SB/08 (submitted in duplicate). Copies of the "Foreign Patent Documents" are enclosed herewith.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

It is respectfully requested that these documents be (1) fully considered by the Patent and Trademark Office during examination of this application; and (2) printed on any patent which may issue on this application. Applicant requests that a copy of Form SB/08, as considered and initialed by the Examiner, be returned with the next communication.

This Information Disclosure Statement is being transmitted more than three months from the application filing date but before the mailing date of the first Office Action on the merits. In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075, Order

No. 000293-0076. A duplicate copy of this Information Disclosure Statement is transmitted herewith.

Consideration of the foregoing in relation to this patent application is respectfully requested.

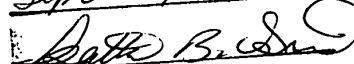
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Substitute for form 1449/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if known	
				Application Number	11/023,783
				First Named Inventor	Christoph Hans Huber
				Art Unit	3738
				Examiner Name	Suzette Jaime J. Gherbi
Sheet	1	of	1	Attorney Docket Number	293/076

U.S. PATENT DOCUMENTS					
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		Number - Kind Code ² (if known)			
		US-5,980,532	11/09/1999	Wang	

FOREIGN PATENT DOCUMENTS						
Examiner initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ⁴ - Number ⁵ - Kind Code ⁶				
		WO 00/47139	08/17/2000	Garrison et al.		
		WO 03/028592	04/10/2003	Weadock		
		WO 2004/019811	03/11/2004	Wilson		

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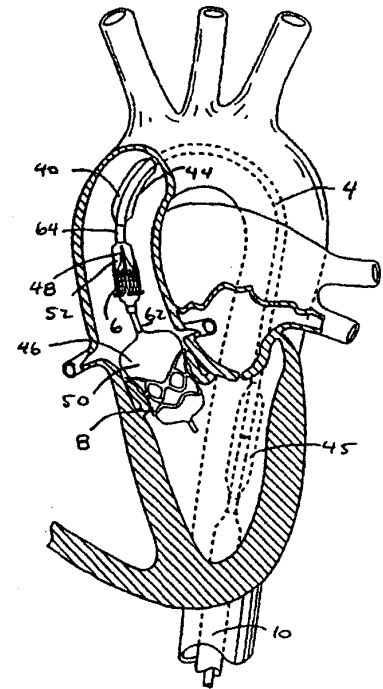
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁷ : A61F 2/24</p>	<p>A1</p>	<p>(11) International Publication Number: WO 00/47139 (43) International Publication Date: 17 August 2000 (17.08.00)</p>
<p>(21) International Application Number: PCT/US00/03336 (22) International Filing Date: 9 February 2000 (09.02.00) (30) Priority Data: 09/248,911 10 February 1999 (10.02.99) US (71) Applicant: HEARTPORT, INC. [US/US]; 700 Bay Road, Redwood City, CA 94063 (US). (72) Inventors: GARRISON, Michi, E.; 212 Roosevelt Boulevard, Half Moon Bay, CA 94019 (US). GIFFORD, Hanson, S., III; 3180 Woodside Road, Woodside, CA 94062 (US). ST. GOAR, Frederick, G.; 2 Frederick Court, Menlo Park, CA 94025 (US). (74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew LLP, 8th Floor, Two Embarcadero Center, San Francisco, CA 94111 (US).</p>		<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i></p>

(54) Title: METHODS AND DEVICES FOR IMPLANTING CARDIAC VALVES

(57) Abstract

The valve implantation system has a valve displacer (8) for displacing, and holding the native valve leaflets open in a first aspect of the invention. A replacement valve (6) may be attached to the valve displacer before or after introduction, and may be positioned independent of the valve displacer. In another aspect of the invention, the valve displacer and the valve are in a collapsed condition during introduction, are expanded to deploy the valve displacer, and valve. The valve is a tissue valve (38) mounted to an expandable support structure (26). The support structure may have protrusions (34) for engaging the valve displacer or barbs for anchoring the valve displacer to the heart or blood vessel. A temporary valve mechanism (40) may be used to provide temporary valve functions during, and after deployment of the valve displacer.



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METHODS AND DEVICES FOR IMPLANTING CARDIAC VALVES**BACKGROUND OF THE INVENTION**

The present invention is directed to methods and devices for implanting
5 replacement cardiac valves. Replacement cardiac valves are implanted when the
patient's native valve exhibits abnormal anatomy and function due to congenial or
acquired valve disease. Congenital abnormalities can be tolerated for years only to
develop into life-threatening problems later. Acquired valve disease may result from
various causes such as rheumatic fever, degenerative disorders of the valve tissue, and
10 bacterial or fungal infections.

Valve dysfunction can be classified as either stenosis, in which the valve does
not open properly, or insufficiency, in which the valve does not close properly.
Stenosis and insufficiency can occur at the same time and both abnormalities increase
the workload on the heart in pumping blood through the body. The ability of the heart
15 to function with the increased workload is a major factor in determining whether the
valve should be replaced.

When the valve must be replaced using conventional methods, the patient
must undergo an invasive, traumatic surgical procedure. The patient's chest is opened
with a median sternotomy or major thoracotomy to provide direct access to the heart
20 through the large opening in the chest. The heart is then stopped and the patient is
placed on cardiopulmonary bypass using catheters and cannulae inserted directly into
the heart and great vessels. The heart, or a great vessel leading to the heart, is then cut
open to access and remove the malfunctioning valve. After removing the valve, the
replacement valve is then sewn into place. After the new valve has been implanted,
25 the chest is then closed and the patient is weaned off cardiopulmonary bypass support.

The conventional open-chest surgery described above is problematic in that it
is highly invasive, traumatic and requires a lengthy recovery time. These drawbacks
to conventional open-chest surgery prevent some patients from undergoing a valve
implantation procedure even though a new cardiac valve is needed.

30 U.S. Patent No. 5,370,685, U.S. Patent No. 5,411,552 and U.S. Patent No.
5,718,725, which are hereby incorporated by reference, describe devices and methods
for implanting a new cardiac valve without requiring a median sternotomy or major

thoracotomy. Such devices and methods reduce the pain, trauma and recovery time as compared to conventional open-chest surgery.

An object of the present invention is to provide additional devices and methods which reduce the trauma associated with conventional open-chest methods
5 and devices for implanting cardiac valves.

SUMMARY OF THE INVENTION

In accordance with the object of the invention, a system and method for
10 implanting a cardiac valve is provided which does not require a median sternotomy or major thoracotomy. The devices and methods of the present invention are preferably carried out by passing the valve through a blood vessel, preferably the femoral artery, so that the median sternotomy or major thoracotomy is not required. Alternatively, the systems of the present invention also permit introduction of the valve through a small incision between the patient's ribs without cutting the ribs or sternum.

15 In a first aspect of the invention, a valve displacer is used to hold the native valve leaflets open so that the native valve does not need to be removed. The valve displacer is preferably introduced into the patient in a collapsed condition and expanded to displace and hold the leaflets open. The valve displacer may either be expanded with an expansion mechanism, such as a balloon, or may be self-expanding.
20 In a preferred embodiment, the valve displacer has a first end, a second end and a central section between the first and second ends. The first and second ends are preferably flared outwardly to form a circumferential recess around the central portion. The native leaflets are trapped within the recess when the valve displacer is deployed.

25 In another aspect of the invention, the valve is also introduced into the patient in a collapsed condition and expanded within the patient. The valve may either be expanded with an expansion mechanism, such as a balloon, or may be self-expanding. The cardiac valve may be coupled to the valve displacer or may be positioned independent from the valve displacer while still substantially performing the functions
30 of the native valve. For instance, a replacement aortic valve may be positioned in the ascending or descending aorta to substantially perform the functions of the native aortic valve.

The cardiac valve is preferably delivered separate from the valve displacer but may also be integrated with the valve displacer during introduction and deployment. In a preferred embodiment, the valve has protrusions which engage openings in the valve displacer. In another embodiment, the valve has sharp elements or barbs which
5 either pierce the native valve tissue or engage the sides of the openings in the valve displacer.

In yet another aspect of the present invention, the valve and valve displacer are preferably introduced into the patient with a catheter system. In a preferred system, the valve displacer is mounted to a first catheter and the valve is mounted to a second
10 catheter which passes through and is slidably coupled to the first catheter. Alternatively, the valve displacer and valve may be mounted to a single catheter. The term catheter as used herein refers to any catheter, trocar or similar device for introducing medical devices into a patient.

In still another aspect of the present invention, the valve delivery catheter has a
15 temporary valve mechanism which provides temporary valve functions after deployment of the valve displacer. The temporary valve mechanism prevents regurgitation while the native valve is held open and before deployment of the replacement cardiac valve. The temporary valve mechanism is preferably a balloon which is inflated and deflated as necessary to permit downstream flow and prevent
20 retrograde flow. Although it is preferred to implant the cardiac valve while the patient's heart is beating, the devices and methods of the present invention may also be used with the patient's heart stopped and the patient supported by a bypass system.

These and other advantages and aspects of the invention will become evident from the following description of the preferred embodiments and claims.

25

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A shows a system for implanting a cardiac valve.

Fig. 1B shows the system of Fig. 1A introduced through a femoral vein.

Fig. 2 shows the system of Fig. 1 with a sheath retracted to expose the cardiac
30 valve, a valve displacer and a temporary valve mechanism.

Fig. 3 shows the valve displacer positioned between the native valve leaflets prior to expansion.

Fig. 4 shows the valve displacer expanded by a first expansion mechanism

Fig. 5 shows the valve expanded by a second expansion mechanism into engagement with the valve displacer.

Fig. 6 shows the valve displacer and valve implanted in the native valve
5 position.

Fig. 7 shows the valve displacer in the collapsed position.

Fig. 8 shows the valve displacer in the expanded position.

Fig. 9 shows the valve and valve displacer in the expanded position.

Fig. 10 shows the valve in a collapsed condition.

10 Fig. 11 is a plan view of the valve showing the leaflets.

Fig. 12 is a cross-sectional view of the catheter along line A-A of Fig. 5.

Fig. 13 shows another system for implanting another cardiac valve.

Fig. 14 is a partial cut-away view of the catheter of Fig. 13 with the valve
contained in a chamber.

15 Fig. 15 is a cross-sectional view of the catheter along line B-B of Fig. 13.

Fig. 16 shows another system for implanting a cardiac valve.

Fig. 17 shows the system of Fig. 16 with a distal portion of the valve displacer
extending from the catheter.

Fig. 18 shows the valve displacer fully deployed to hold the native leaflets
20 open.

Fig. 19 shows the valve partially expanded with the catheter manipulated so
that the valve engages the valve displacer.

Fig. 20 shows the valve fully deployed and the catheter removed.

Fig. 21 is a partial cut-away view of the catheter of Figs. 16-19.

25 Fig. 22 is a cross-sectional view of the catheter along line C-C of Fig. 16.

Fig. 23 shows another system for implanting a cardiac valve with the valve
displacer positioned between the native leaflets.

Fig. 24 shows the valve displacer expanded.

Fig. 25 shows the valve partially deployed within the valve displacer.

30 Fig. 26 shows the valve fully deployed within the valve displacer.

Fig. 27 shows the valve displacer holding the native leaflets open with the
valve deployed in the ascending aorta.

Fig. 28 shows the valve displacer holding the native leaflets open with the valve deployed in the descending aorta.

Fig. 29 shows the cardiac valve of Figs. 23-28 in the collapsed condition.

Fig. 30 shows the cardiac valve of Figs. 23-28 in the expanded condition.

5 Fig. 31 shows another system for delivering a cardiac valve with the delivery catheter passing through a trocar in the ascending aorta.

Fig. 32 shows an expansion mechanism expanding the valve displacer and the valve.

Fig. 33 shows sutures being pulled to invert the valve.

10 Fig. 34 shows the valve being stored in a preservative solution.

Fig. 35 shows the valve inverted and in the expanded condition.

Fig. 36 shows the valve and valve displacer in the collapsed condition before being attached to one another.

15 Fig. 37 shows the valve and valve displacer attached to one another and mounted to the delivery catheter.

Fig. 38 shows the valve and the valve displacer in the expanded condition.

Fig. 39 shows the catheter passing through the femoral vein, into the right atrium, and through the intraatrial septum into the left atrium to access the mitral valve.

20

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figs. 1A, 1B and 2 a system for implanting a replacement cardiac valve is shown. The present invention is described in connection with implantation of a replacement aortic valve but is applicable to any other cardiac valve. The system 2 includes a delivery catheter 4, a cardiac valve 6 and a valve displacer 8. A protective sheath 10 covers the delivery catheter 4, cardiac valve 6 and valve displacer 8 during introduction to prevent contact between the blood vessel and the cardiac valve 6 and valve displacer 8. Figs. 1A and 1B show the sheath 10 extending around the cardiac valve 6 and valve displacer 8 and Fig. 2 shows the sheath 10 retracted to expose the cardiac valve 6 and valve displacer 8.

30

The cardiac valve 6 is preferably introduced through a peripheral vessel such as the femoral artery (Figs. 1A and 2) or femoral vein (Fig. 1B). Fig. 1B shows introduction of the catheter 2 through the femoral vein, into the right atrium, through

the intraatrial septum and into the left atrium to access the mitral valve. The peripheral vessel is preferably a femoral vessel but may also be the internal jugular vein, subclavian artery, axillary artery, abdominal aorta, descending aorta or any other suitable blood vessel. As will be explained below, the delivery catheter 4 may be introduced by surgical cutdown or percutaneously using the Seldinger technique. An advantage of passing the catheter 4 through a peripheral vessel is reduced trauma to the patient as compared to the conventional open-chest procedure described above. Although it is preferred to deliver the cardiac valve 6 through a peripheral vessel, the cardiac valve 6 may also be introduced directly into the ascending aorta through a small incision between ribs. The system 2 of the present invention is small enough to deliver between the patient's ribs so that the advantages of the present invention over conventional open-chest surgery are provided even when introducing the catheter through an incision in the chest.

The valve displacer 8 is expanded within the native valve to hold the native cardiac valve leaflets 6 open. An advantage of the system 2 and method of the present invention is that the native valve does not need to be removed. The replacement cardiac valves described herein may, of course, also be used when removing the native valve rather than using the valve displacer 8. Furthermore, the valve displacer 8 and cardiac valve 6 may be integrated into a single structure and delivered together rather than separately. Thus, all features of any valve displacer described herein may also form part of any of the cardiac valves described herein without departing from the scope of the invention.

The valve displacer 8 is shown in the collapsed condition in Figs. 3 and 7 and in the expanded condition in Figs. 4 and 8. When in the collapsed position, the valve displacer 8 forms a number of longitudinal slots 12 which form openings 14 in the valve displacer 8 when in the expanded condition. The valve displacer 8 is substantially cylindrical in the collapsed condition to facilitate introduction into the patient.

Referring to Fig. 8, first and second ends 16, 18 of the valve displacer 8 flare outwardly to form a circumferential recess 24 at a central section 22. The native leaflets are trapped in the recess 24 when the valve displacer 8 is deployed. The first end 16 has three extensions 20 extending from the central section 22. The valve displacer 8 may be made of any suitable material and preferred materials include

stainless steel, nitinol, kevlar, titanium, nylon and composites thereof. The valve displacer 8 may also be coated with an antithrombogenic coating. The valve displacer 8 is preferably formed from a solid hypotube by etching or micromachining, machining from a solid material, or welding wire elements together. Although it is preferred to provide the flared ends 16, 18, the valve displacer 8 may have any other suitable shape which holds the leaflets open. The valve displacer 8 may also have a fabric cover 17 which can trap calcium fragments which might break free from the valve when the valve displacer is deployed. The cover 17 is preferably made of a polyester knit material, such as dacron, but may be made of any other suitable material.

The cardiac valve 6 has an expandable support structure 26 which moves from the collapsed position of Figs. 4 and 10 to the expanded position of Figs. 5 and 9. The support structure 26 is preferably formed with first and second elongate members 28, 30 which are wound to form windings 31, preferably about 12-18 windings 31, around the circumference of the valve 6. The first and second elongate members 28, 30 are attached to one another at windings 31 which forms three posts 32 extending from the support structure 26.

The support structure 26 has a protrusion 34, preferably three, extending outwardly to form an interrupted lip around an end 35 of the support structure 26. The protrusions 34 engage the openings 14 in the valve displacer 8 as shown in Fig. 9 to secure the cardiac valve 6 to the valve displacer 8. The protrusions 34 are preferably formed by a coil 36 wrapped around the loops 31 in the elongate member 30. As will be described below, the support structure 26 may also have barbs to secure the cardiac valve 6 to the valve displacer 8 or to the blood vessel wall. The cardiac valve 6 may also engage the valve displacer 8 with any other suitable connection.

The posts 32 support a valve portion 38 which performs the functions of the patient's malfunctioning native valve. Referring to Figs. 10 and 11, the valve portion 38 is preferably a stentless tissue valve such as a tri-leaflet 39 stentless porcine valve. The valve portion 38 has a base 41 which is secured to the support structure 26 with sutures (not shown). The valve portion 38 may be stored separately from support structure 26 and attached to the support structure 26 before the procedure. Although it is preferred to provide a tissue valve for the valve portion 38, the valve portion 38 may also be made of a flexible, synthetic material. For example, the valve portion 38

may be made of polyurethane similar to the valves described in "A Tricuspid Polyurethane Heart Valve as Alternative to Mechanical Prostheses or Bioprotheses," by Lo et al., Trans Am Society of Artificial Internal Organs, 1988; 34: pgs valve displacer 839-844, and "Evaluation of Explanted Polyurethane Trileaflet Cardiac Valve Prostheses," Journal Thoracic Cardiovascular Surgery, 1988; 94: pgs 419-429.

Referring to Figs. 2-4, the delivery catheter 4 has a temporary valve mechanism 40 which provides temporary valve functions during and/or after deployment of the valve displacer 8. The temporary valve mechanism 40 ensures proper blood flow regulation when the leaflets are held open by the valve displacer 8 to provide time for accurate positioning and deployment of the valve 6. The temporary valve mechanism 40 is preferably a balloon 44 coupled to an inflation mechanism 47 controlled by a control system 42. The control system 42 senses the patient's heartbeat to time balloon inflation and deflation to permit and prevent flow in the same manner as the native valve. Similar systems for synchronizing inflation and deflation of a balloon with the patient's heartbeat are known in balloon pump technology and are described in U.S. Patents Nos. 5,817,001, 5,413,549 and 5,254,097 which are hereby incorporated by reference. The balloon 44 is preferably inflated with a gas for quick inflation and deflation. The temporary valve mechanism 40 is preferably the balloon 44 but may also be a passive mechanical valve which automatically opens and closes due to blood flow forces.

The catheter 4 may also include an elongate balloon 45 to help pump blood through the patient's body like a blood pump. The balloon 45 is also coupled to an inflation mechanism 49 controlled by the control system 42 which inflates and deflates the balloon 45 to provide pumping assistance to the patient's heart. Balloon pump technology is described in the above-mentioned patents. The elongate balloon 45 may be replaced by any other suitable blood pump, such as a centrifugal pump having an impeller, without departing from the scope of the invention.

The temporary valve mechanism 40 and balloon 45 are, of course, only necessary when implanting the valve with the patient's heart beating. If the patient's heart is stopped and the patient is supported by a bypass system during the valve implantation procedure, the temporary valve mechanism 40 and/or balloon 45 may be used after the procedure for emergency valve functions or pumping assistance. The

balloon 44 is preferably positioned in the ascending or descending aorta and the balloon 45 is preferably positioned in the descending aorta.

Referring to Figs. 3-6, the delivery catheter 4 also has first and second expandable members 46, 48 which deploy the valve displacer 8 and cardiac valve 6, respectively. The expandable members 46, 48 are preferably balloons 50, 52 but may also be mechanically actuated devices. The balloons 50, 52 are coupled to inflation lumens 54, 56 through which inflation fluid is delivered from sources of inflation fluid 58, 60, respectively. The balloon 50 expands greater at the ends to form the flared ends 16, 18 of the valve displacer 8.

The delivery catheter 4 includes a first catheter 62, which carries the valve displacer 8, and a second catheter 64, which carries the cardiac valve 6. Referring to Figs. 2 and 12, the second catheter 64 has a passageway 66 which receives the first catheter 62. A hemostasis valve 68 permits slidable movement between the first and second catheters 62, 64. The first catheter 62 has lumen 54 for inflating balloon 50 and the second catheter 64 has lumen 48 for inflating balloon 52. The second catheter 64 also has a lumen 51 for inflating balloon 44 and a lumen 53 for inflating balloon 45. The first catheter 62 also has a main lumen 70 which receives a guidewire 72.

The slidable connection between the first and second catheters 62, 64 permits introduction of the first catheter 62 over the guidewire 72 with the second catheter 64 being advanced over the first catheter 62 after the valve displacer 8 is in the ascending aorta. In this manner, the first catheter 62 may be advanced more easily over the guidewire 72 and through the patient's vasculature, such as around the aortic arch, as compared to a single, multichannel catheter having all features of the first and second catheters 62, 64. The first and second catheters 62, 64 may be wire-reinforced (not shown) catheters constructed in the manner described in Published PCT Application WO 97/32623 entitled "Cannula and Method of Manufacture and Use" which is hereby incorporated by reference.

A method of implanting a cardiac valve 6 in accordance with the present invention is now described in connection with Figs. 1-6. Although the method is described in connection with the system described above, the method may be practiced with other suitable devices, including the devices and systems described below, without departing from the scope of the invention. Furthermore, the method is described in connection with replacing the aortic valve, however, the method may also

be applied to other other cardiac valves such as the mitral, tricuspid and pulmonary valves.

Before implanting the cardiac valve 6, it may be desirable to perform valvuloplasty to break up pathologic adhesions between the native valve leaflets.

5 Breaking up adhesions ensures that the valve displacer 8 expands fully to provide a large blood flow path. Valvuloplasty is preferably performed with a balloon which is inflated to open the leaflets and break the adhesions. The native cardiac valve and annulus are also sized to determine the proper size valve displacer 8 and cardiac valve 6. Sizing may be carried out using fluoroscopy, intravascular ultrasound or with any
10 other suitable device during or after the valvuloplasty. Size parameters to consider include the cross-sectional profile through the valve, the length and size of the valve leaflets and position of the coronary ostia.

The delivery catheter 4 is preferably introduced into the patient by surgical
15 cutdown in the femoral artery but may also be introduced percutaneously using the Seldinger technique. As mentioned above, the delivery catheter 4 may also be introduced into any other suitable vessel or through a small incision in the chest. The first and second catheters 62, 64 are advanced into the artery through the cutdown a short distance. The guidewire 72 is then advanced ahead of the first and second
20 catheters 62, 64 up the descending aorta, around the aortic arch, into the ascending aorta and across the aortic valve. The first catheter 62 is then advanced over the guidewire 72 to the ascending aorta with the sheath 10 covering the first catheter 62 to prevent contact between the valve displacer 8 and the blood vessel or native valve. The second catheter 64 is then advanced over the first catheter 62 to position the
25 cardiac valve 6 in the ascending aorta. The sheath 10 also prevents contact between the cardiac valve 6 and vessel wall when advancing the second catheter 64. The sheath 10 is then retracted as shown in Fig. 2 to expose the valve displacer 8 and the cardiac valve 6.

The valve displacer 8 is then introduced between the valve leaflets as shown in Fig. 3 and the balloon 50 is inflated to expand the valve displacer as shown in Fig. 4.
30 The valve displacer 8 holds the native valve leaflets open so that the native valve does not have to be removed. When the valve displacer 8 has been deployed, the temporary valve mechanism 40 provides temporary valve functions by inflating and deflating the balloon 44 at appropriate times to permit and block flow in the same manner as the

native valve. The balloon 45 may also be inflated and deflated to provide pumping assistance to the patient's heart during the procedure. Although the above-described method is performed with the patient's heart beating, the procedure may also be performed on a stopped heart with the patient supported by a bypass system.

5 The second catheter 64 is then advanced until the valve 6 is positioned adjacent the valve displacer 8. Although Fig. 5 shows the first catheter 62 extending into the left ventricle, the first catheter 62 may also be designed to be withdrawn into the passageway 66 of the second catheter 64 so that the first catheter 62 does not extend beyond the second catheter 64. The balloon 52 is then partially inflated so that
10 the distal end of the valve 6 having the protrusions 34 expands. The second catheter 64 is then manipulated until the protrusions 34 engage the openings 14 in the valve displacer 8. The balloon 52 is then inflated further to expand the rest of the support structure 26. The catheters 62, 64 are then removed leaving the cardiac valve 6 in place.

15 Referring to Figs. 13 and 14, another system 2A for implanting a cardiac valve 6A is shown wherein the same or similar reference numbers refer to the same or similar structures. The cardiac valve 6A is similar to the cardiac valve 6 described above, however, the cardiac valve 6A is self-expanding and, therefore, does not require an independent expansion mechanism. The support structure 26A is made of a
20 resilient material to naturally bias the support structure 26A to the expanded position. The support structure 26A may be made of any suitable material and preferred materials are stainless steel or shape-memory alloys such as nitinol. Delivery catheter 4A has the expandable member 46, which is preferably the balloon 50, for expanding the valve displacer 8.

25 The cardiac valve 6A is contained within an outer wall 74 of the delivery catheter 4A. The cardiac valve 6A is advanced out of a chamber 76 in the delivery catheter 4A by advancing a rod 78 having a pusher element 80 attached thereto. The pusher element 80 engages the posts 82 on the cardiac valve 6A to move the cardiac valve 6A out of the chamber 76. The rod 78 has threaded connections 80, 82 with a
30 tip 84 and the pusher element 80 to facilitate assembling the delivery catheter 4A and loading the cardiac valve 6A in the chamber 76. The rod 78 has a guidewire lumen 86 for receiving the guidewire 72. Referring to the cross-sectional view of Figs. 15, the catheter 4A has a first lumen 88 coupled to the balloon 50, a second lumen 90 coupled

to the balloon 44 and a third lumen 91 coupled to the balloon 45. The second and third lumens 88, 90 are coupled to the inflation mechanisms 47, 29 which are controlled by the control system 42 described in connection with Figs. 1 and 2. The system 2A preferably includes the sheath 10 which prevents contact between the blood vessel and the valve displacer 8 when the catheter 4A is advanced through the blood vessel.

The cardiac valve 6A is implanted in substantially the same manner as the cardiac valve 6 and the discussion of implantation of the cardiac valve 6 is also applicable here. The delivery catheter 4A may be introduced in any manner described herein and Fig. 13 shows the catheter 4A extending through the femoral artery with the valve displacer 8 positioned between the valve leaflets prior to expansion. The valve displacer 8 is expanded in the manner explained above to hold the leaflets open. After the valve displacer 8 has been expanded, the catheter 4A is retraced a predetermined amount so that the protrusions 34 are exposed outside the distal end of the catheter 4A. The catheter 4A may then be manipulated as necessary so that the protrusions 34 engage the openings 14 in the valve displacer 8. The valve 6A preferably remains coupled to the catheter 4A while the protrusions 34 are exposed for manipulation of the valve 6A until the valve 6A engages the valve displacer 8. After the valve 6A has engaged the valve displacer 8, the rod 78 is then advanced far enough to completely release the cardiac valve 6A.

Referring to Figs. 16-22, another system 4B for implanting the cardiac valve 4A is shown wherein the same or similar reference numbers refer to the same or similar structure. The system has the self-expanding cardiac valve 4A described above. The valve displacer 8B is similar to the valve displacer 8 described above, however, the valve displacer 8B is also self-expanding and, therefore, does not require an independent expansion mechanism. The valve displacer 8B is made of a resilient material to naturally bias the valve displacer 8B to the expanded position. The valve displacer 8B may be made of any suitable material and preferred materials are stainless steel and shape-memory alloys such as nitinol.

The valve displacer 8B and cardiac valve 6A are contained within an outer wall 74 of the delivery catheter 4B as shown in Fig. 21. The valve displacer 8B and cardiac valve 4A are advanced out of a chamber 76B in the delivery catheter 4B by advancing a rod 78B having first and second pusher elements 80B, 81B attached

thereto. The rod 78B has threaded connections 79B, 82B, and 83B with the tip 84 and the first and second pusher elements 80B, 81B to facilitate assembling catheter 4B and loading the valve displacer 8B and cardiac valve 6A in the chamber 76B. The rod 78B has the guidewire lumen 86 for receiving the guidewire 72 (Fig. 14). Referring to
5 Fig. 16 and the cross-sectional view of Fig. 22, the catheter 4B has a lumen 90 coupled to the balloon 44 which serves as the temporary valve mechanism 40 and a lumen 93 which is coupled to the balloon 45. The lumen 90 and lumen 93 are coupled to the inflation mechanisms 47, 29 which are controlled by the control system 42 (Figs. 1A, 1B, and 2).

10 Another method of implanting a cardiac valve is now described with reference to Figs. 16-20 wherein the same or similar reference numbers refer to the same or similar structure. The method describes use of the delivery catheter 4B and cardiac valve 6A, however, the method may be practiced using other suitable structures. The delivery catheter 4B is introduced in any manner described above and is preferably
15 introduced through the femoral artery. The guidewire 72 is advanced ahead of the catheter 4B into the ascending aorta and the delivery catheter 4B is advanced over the guidewire 72. The delivery catheter 4B is then advanced between the valve leaflets. A distal end of the valve displacer 8B is then advanced out of the chamber 76 and the catheter 4B is retracted until the valve displacer 8 contacts the valve opening. The
20 catheter 4B is then retracted while the rod 78B is maintained in the same position so that the valve displacer 8B emerges from the chamber 76B as shown in Fig. 18. The catheter 4B is then advanced a predetermined amount and the rod is advanced to force a distal end of the valve 6A from the chamber 76B. The catheter 4B is then moved as necessary so that the protrusions 34 engage the openings 14 in the valve displacer 8 as
25 shown in Fig. 19. The catheter 4B is then withdrawn further so that the support structure 26A expands to the fully deployed position of Fig. 20. The catheter 4B is then removed leaving the cardiac valve 6A as shown in Fig. 20. During the procedure described above, the temporary valve mechanism 40 provides temporary valve functions while the balloon 45 provides pumping assistance as described above.

30 Referring to Figs. 23-30, another system 2C for implanting a cardiac valve 6C is shown. The system 2C includes the valve displacer 8 and delivery catheter 4 described above. The delivery catheter 4 has the balloon 50 for inflating the valve displacer 8, the balloon 52 for inflating a cardiac valve 6C, the temporary valve

mechanism 40 and the balloon 45. The cardiac valve 6C is similar to the cardiac valves 6, 6A except that the cardiac valve 6C has barbs 100 which extend outwardly from the cardiac valve 6C in the expanded condition of Fig. 30. The barbs 100 secure the cardiac valve 6C to the valve displacer 8 or directly to the vessel wall. The cardiac valve 6C has depressions 102 so that the barbs 100 are recessed from an outer surface 104 of the cardiac valve 6C when in the collapsed position of Fig. 29. The depressions 102 prevent the barbs 100 from interfering with smooth retraction of the sheath 10. When the cardiac valve 6C is expanded, the depressions 102 and barbs 100 rotate and move outwardly to engage the valve displacer 8 or vessel wall.

The system 2C is introduced into the patient in any manner described above and Fig. 23 shows the delivery catheter 4 passing through the femoral artery. The valve displacer 8 is deployed in the manner described above wherein the valve displacer 8 is introduced into the valve leaflets and expanded with the balloon 50 to hold the native leaflets open as shown in Fig. 24. The delivery catheter 4 may then be advanced so that the cardiac valve 6C is expanded in the valve displacer 8 with the barbs 100 passing into the openings 14 to secure the cardiac valve 6C to the valve displacer 8 as shown in Figs. 25 and 26. The barbs 100 may be long enough to pierce and anchor in the native valve leaflets or may be designed to merely pass into and engage the sides of the openings 14.

The term "cardiac valve" as used herein refers to a valve which substantially replaces the function of the patient's malfunctioning cardiac valve. The valve may be positioned in the native valve position or may be positioned in a different location while still substantially performing the functions of the native valve. For example, a replacement aortic valve may be positioned superior to the coronary ostia, in the aortic arch or in the descending aorta. Such a replacement valve will substantially function like the patient's native aortic valve. Referring to Figs. 27 and 28 the cardiac valve 6C is deployed in the ascending and descending aorta with the barbs 100 securing the cardiac valve 6C directly to the vessel wall.

Referring to Figs. 31-38 another system 2D for introducing a valve 6D is shown wherein similar or the same reference numbers refer to similar or the same structure. The valve 6D is coupled to a valve displacer 8D prior to introduction into the patient. The valve 6D has an expandable support structure 26D which is movable from the collapsed position of Figs. 36 and 37 to the expanded position of Figs. 34

and 35. The support structure 26D has flexible joints 106 which bend to radially collapse the support structure 26D. The support structure 26D has protrusions 34D which engage holes 108 in the valve displacer 8D. The valve 6D and valve displacer 8D may engage one another in any other suitable manner.

5 The valve 6D is inverted before being attached to the valve displacer 8D as shown in Fig. 35. A number of sutures 110, preferably three, are then passed through the valve 6D. The sutures 110 are used to invert the valve after introduction into the patient as will be explained below. The valve 6D may be any of the valves described herein or any other suitable valve without departing from the scope of the invention.

10 A circumferential ring 111 extends around the support structure 26D. The ring 111 is preferably made of stainless steel or shape-memory alloy such as nitinol and provides circumferential support of the valve against the aortic wall for hemostasis.

The valve displacer 8D is mounted to a delivery catheter 4D having a balloon 112 for expanding the valve displacer 8D and valve 6D. The balloon 112 is coupled

15 to a source of inflation fluid 114 (Fig. 31) for inflating the balloon 112. The catheter 4D passes through a trocar 116 having a hemostasis valve 117. The sutures 110 and the catheter 4D pass through the hemostasis valve which permits slidable movements of the sutures 110 and catheter 4D.

The valve 6D is preferably stored in a preservative solution until just before

20 the procedure as shown in Fig. 34. The valve is then inverted as shown in Fig. 35 and the sutures 110 are passed through the valve 6D. The valve 6D is then attached to the valve displacer 8D as shown in Fig. 37 and mounted to the delivery catheter 4D.

The valve 6D may be delivered in any manner described above and is preferably introduced through an incision in the patient's chest. Referring to Figs. 31

25 and 32, the trocar 116 is introduced into the ascending aorta through purse-string sutures (not shown). The trocar 116 may have a chamber (not shown) in which the valve 6D is positioned when the trocar 116 is introduced into the ascending aorta. The sheath 10 (see Figs. 1A, 1B and 2) described above may also be used to prevent contact between the valve and trocar and between the valve and the aortic wall. The

30 valve 6D is preferably introduced with the patient's heart beating but may also be implanted with the patient's heart stopped and the patient supported by a bypass system. Although system 2D does not show the balloons 40 and 45, it is understood

that the balloons 40, 45 may also be used with system 2D without departing from the scope of the invention.

After introduction of the trocar 116, the valve 6D is advanced until the valve 6D is between the native valve leaflets. The balloon 112 is then inflated to expand the valve 6D and valve displacer 8D. The catheter 4D is then removed and the sutures 110 are pulled to invert the valve 6D as shown in Fig. 33. An end of each suture 110 is then pulled to remove the sutures 110. The trocar 116 and catheter 4D are then removed leaving the valve 6D (Fig. 38).

Although the foregoing invention has been described by way of illustration and example of preferred embodiments for purposes of clarity and understanding, changes and modifications to the preferred embodiments may be incorporated without departing from the scope of the invention. For example, the native valve may be removed rather than held open with the valve displacer, the replacement cardiac valve may be a completely synthetic or mechanical valve, and the expansion mechanism may be a mechanical mechanism rather than a balloon.

WHAT IS CLAIMED IS:

- 1 1. A method of implanting a cardiac valve, comprising the steps of:
2 introducing a valve and a valve displacer into a patient, the valve and valve
3 displacer being movable from collapsed positions to expanded positions, the valve
4 and valve displacer being introduced into the patient in the collapsed position;
5 positioning the valve displacer between valve leaflets of a native cardiac valve;
6 expanding the valve displacer to the expanded position after the positioning
7 step thereby displacing and holding the valve leaflets in an open position; and
8 securing the valve at a desired location in the patient.

- 1 2. The method of claim 1, wherein:
2 the securing step is carried out with the replacement valve being secured to the
3 valve displacer.

- 1 3 The method of claim 2, wherein:
2 the securing step is carried out with the valve interlocking with the valve
3 displacer.

- 1 4. The method of claim 2, wherein:
2 the securing step is carried out with the valve having sharp elements which
3 penetrate the native valve.

- 1 5. The method of claim 1, wherein:
2 the introducing step is carried out with the valve having a support structure
3 and a valve portion, the support structure being expandable from a collapsed position
4 to an expanded position, the introducing step being carried out with the support
5 structure being in the collapsed position.

- 1 6. The method of claim 1, wherein:
2 the securing step is carried out with the desired valve location being spaced
3 apart from the valve displacer.

- 1 7. The method of claim 6, wherein:
2 the securing step is carried out with the desired location of the valve being
3 between the coronary ostia and the brachiocephalic artery.
- 1 8. The method of claim 1, wherein:
2 the introducing step is carried out with the valve displacer being mounted to a
3 catheter.
- 1 9. The method of claim 8, further comprising the step of:
2 enclosing the valve displacer in a flexible sheath during the introducing step;
3 and
4 uncovering the valve displacer before the expanding step.
- 1 10. The method of claim 8, wherein:
2 the introducing step is carried out with the catheter passing through a
3 penetration in the aortic arch.
- 1 11. The method of claim 8, wherein:
2 the introducing step is carried out through the femoral artery.
- 1 12. The method of claim 1, wherein:
2 the introducing step is carried out with the valve being mounted on a catheter.
- 1 13. The method of claim 8, wherein:
2 the introducing step is carried out with the catheter having an expandable
3 member, the valve displacer being mounted to the expandable member.
- 1 14. The method of claim 12, wherein:
2 the introducing step is carried out with the catheter having a valve mechanism.
- 1 15. The method of claim 12, wherein:

2 the introducing step is carried out with the catheter having a balloon, the
3 balloon being coupled to a control mechanism for inflating and deflating the balloon
4 to provide pumping assistance to the patient's heart.

1 16. The method of claim 1, wherein:

2 the introducing step is carried out with the valve displacer being mounted on a
3 catheter.

1 17. The method of claim 16, wherein:

2 the introducing step is carried out with the catheter having an expandable
3 member, the valve displacer being mounted to the expandable member.

1 18. The method of claim 14, wherein:

2 the introducing step is carried out the valve displacer having an end which
3 flares outwardly when the valve displacer is in the expanded position.

1 19. The method of claim 1, wherein:

2 the introducing step is carried out with the valve displacer having a
3 circumferential recess formed between the first end and a second end.

1 20. The method of claim 1, wherein:

2 the securing step is carried out before the introducing step so that the valve and
3 valve displacement device are introduced together.

1 21. The method of claim 20, further comprising the step of:

2 inverting the valve after the introducing step.

1 22. The method of claim 1, wherein:

2 the valve introducing step is carried out with the valve having an expandable
3 support structure, the expandable support structure having at least three posts
4 extending from the expandable support structure.

1 23. A device for maintaining a patient's native valve leaflets open, comprising:
2 a first end;
3 a second end; and
4 a central section extending between the first and second ends;
5 the first and second ends being flared outwardly from the central section so that the
6 central section forms a recess for receiving the native valve leaflets, the first end,
7 second end and central section forming a structure which is movable from a collapsed
8 condition to an expanded condition.

1 24. The device of claim 23, wherein:
2 the first end, second end and central section are integrally formed.

1 25. The device of claim 23, wherein:
2 the structure is substantially cylindrical in the collapsed condition, the first and
3 second ends flaring outwardly from the central section when the structure is in
4 expanded condition.

1 26. The device of claim 23, wherein:
2 the structure has a circumferential recess for retaining the native valve leaflets,
3 the circumferential recess extending around the central section.

1 27. The device of claim 23, further comprising:
2 a valve portion attached to at least one of the first end, second end and central
3 section, the valve portion permitting blood flow therethrough in one direction and
4 preventing flow in the other direction.

1 28. The device of claim 27, wherein:
2 the valve portion is a tissue valve.

1 29. The device of claim 27, wherein:
2 the valve portion lockingly engages at least one of the first end, second end
3 and central section.

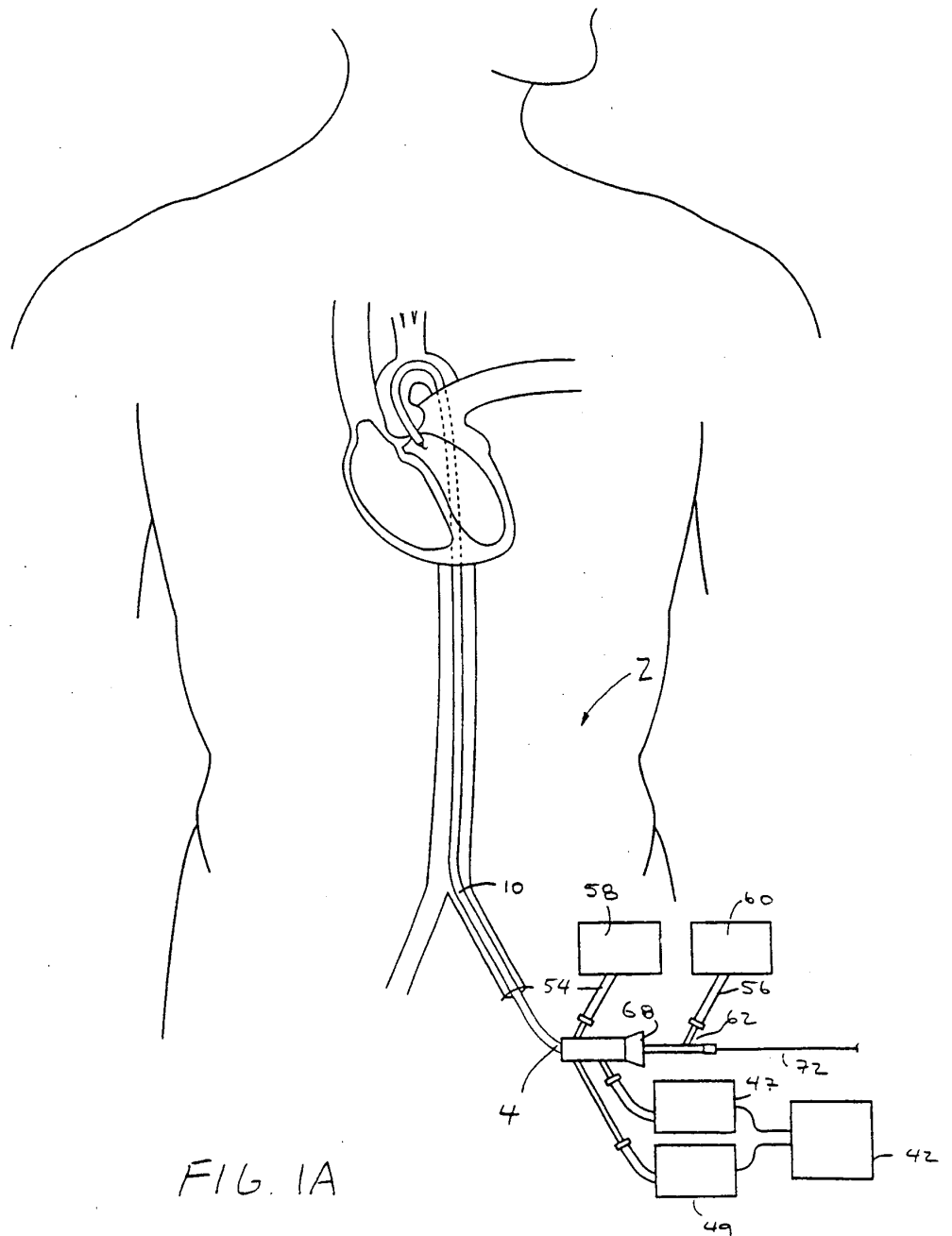


FIG. 1A

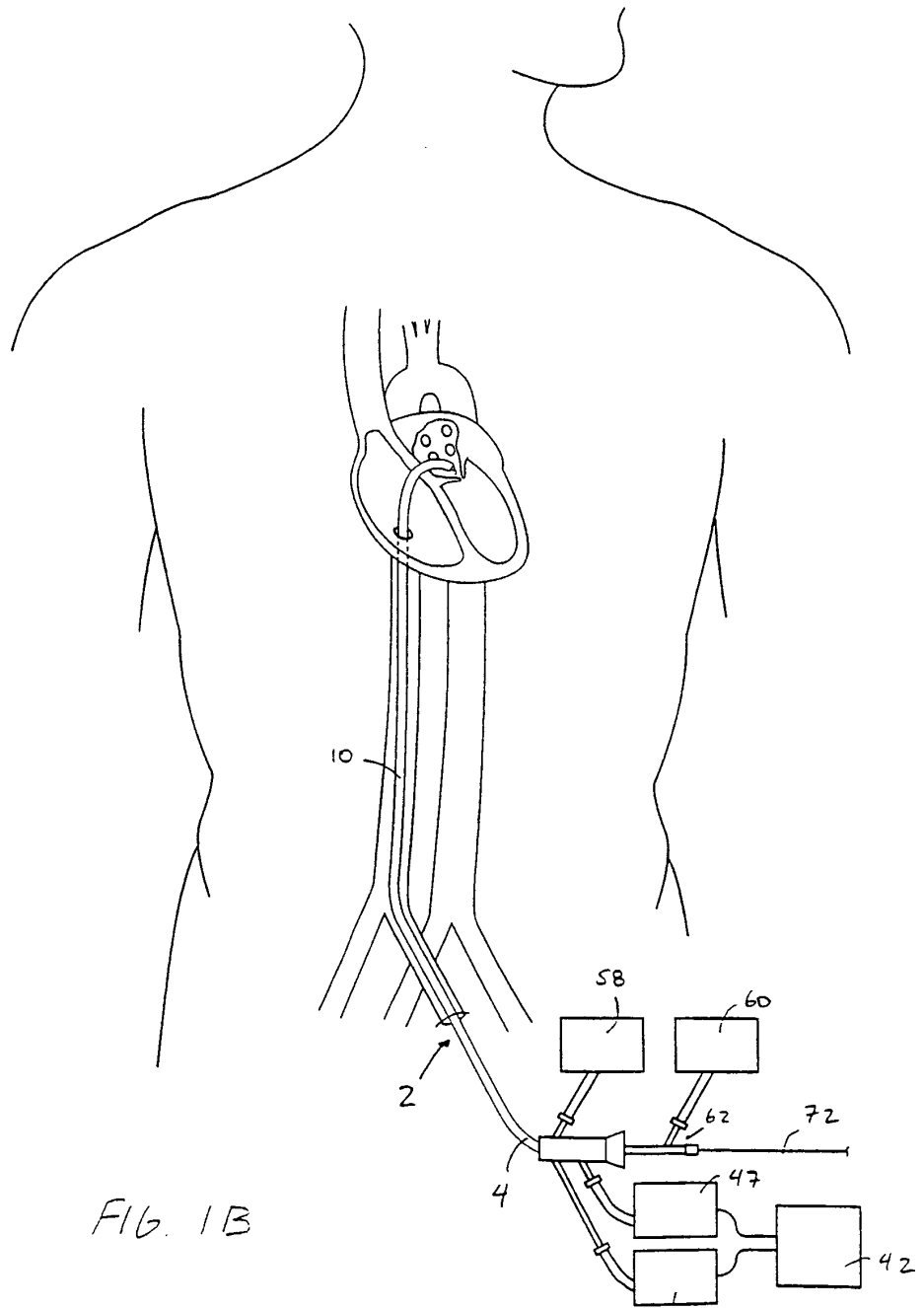


FIG. 1B

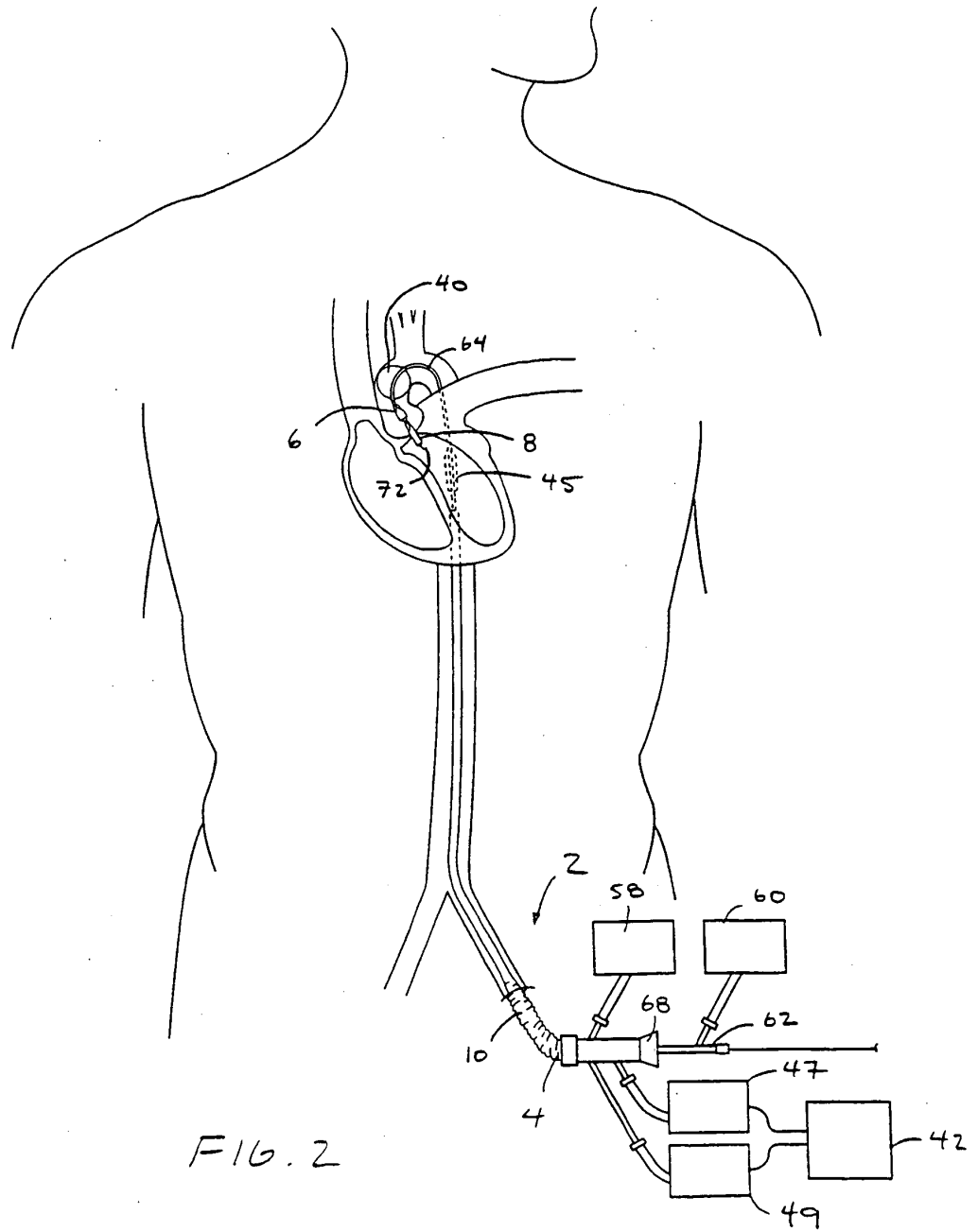


FIG. 2

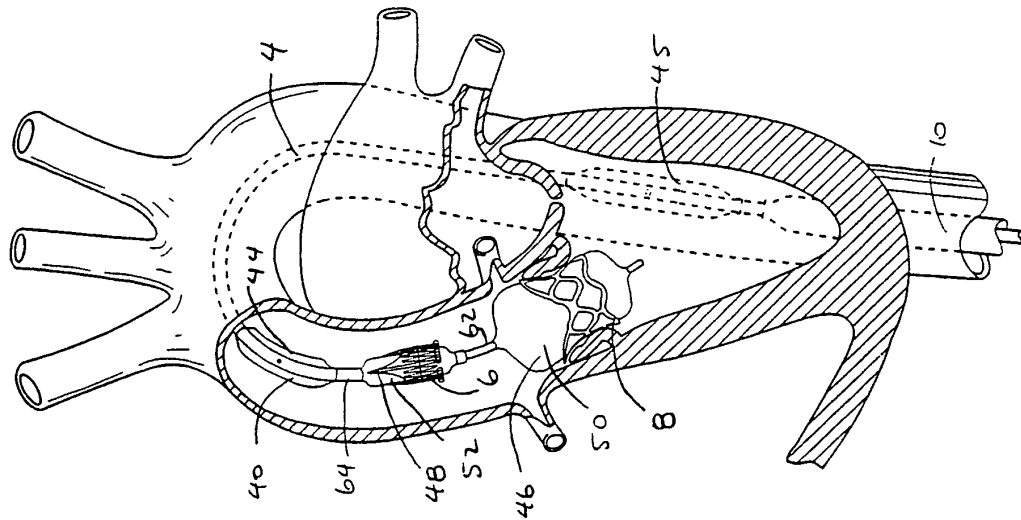


FIG. 4

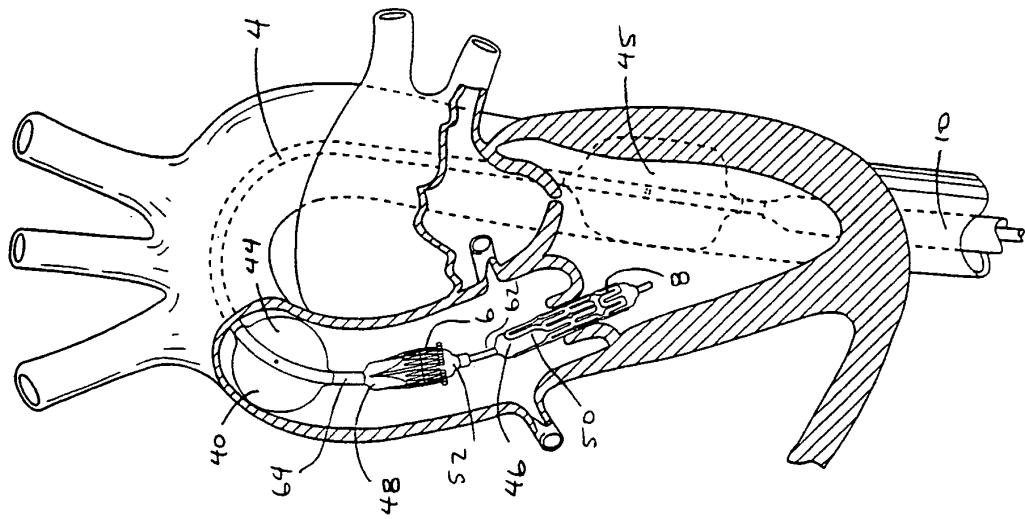


FIG. 3

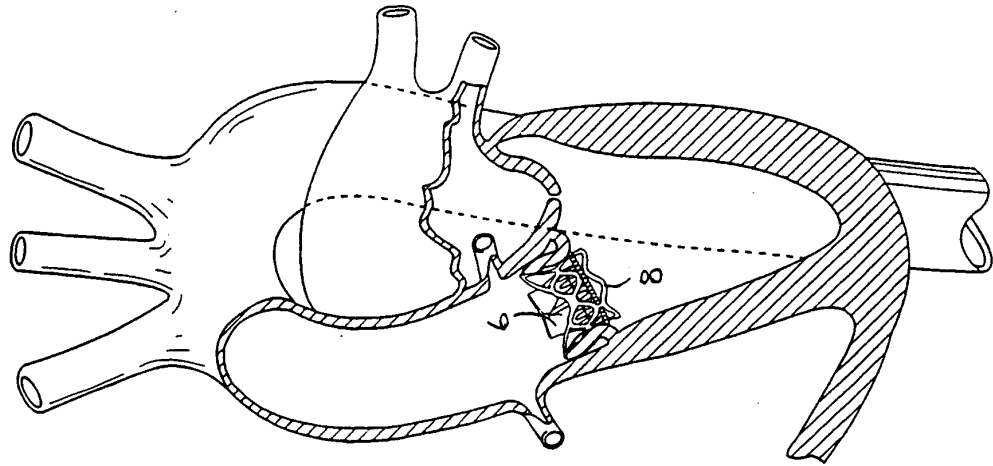


FIG. 6

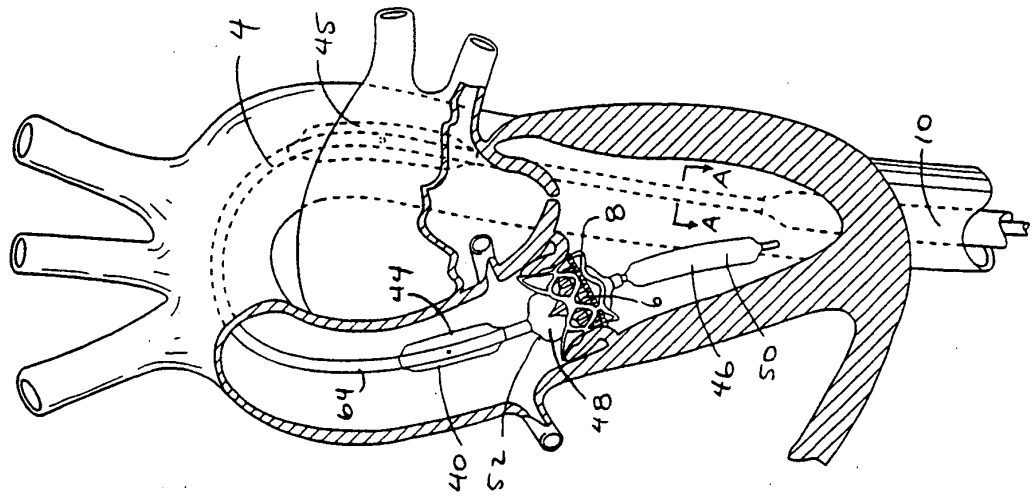


FIG. 5

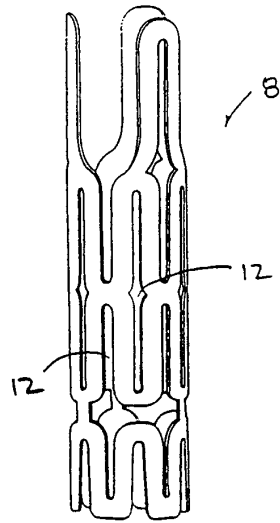


FIG. 7

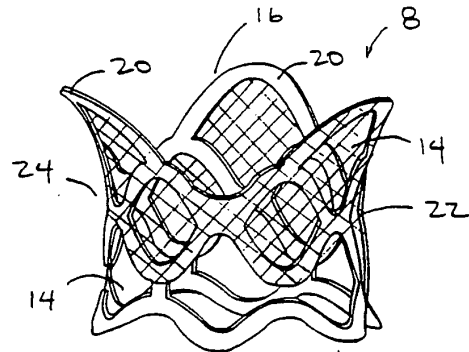


FIG. 8

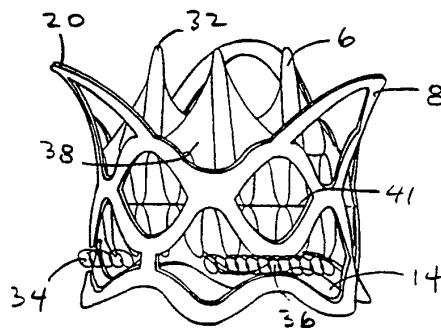


FIG. 9

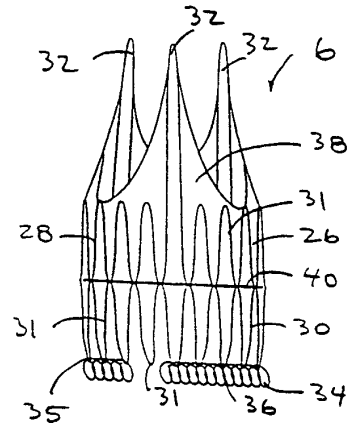
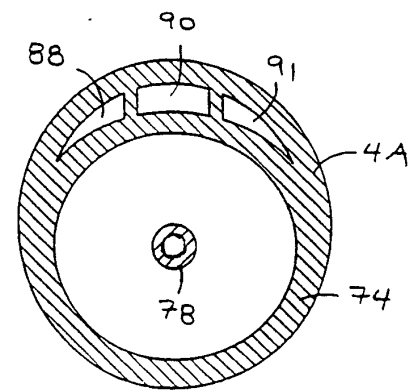
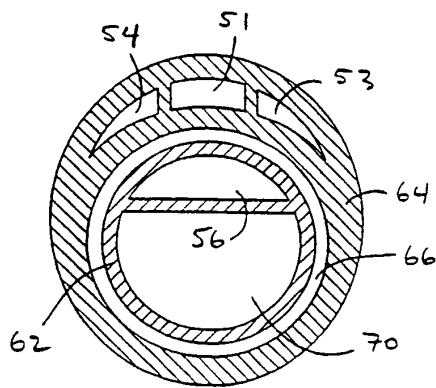


FIG. 10



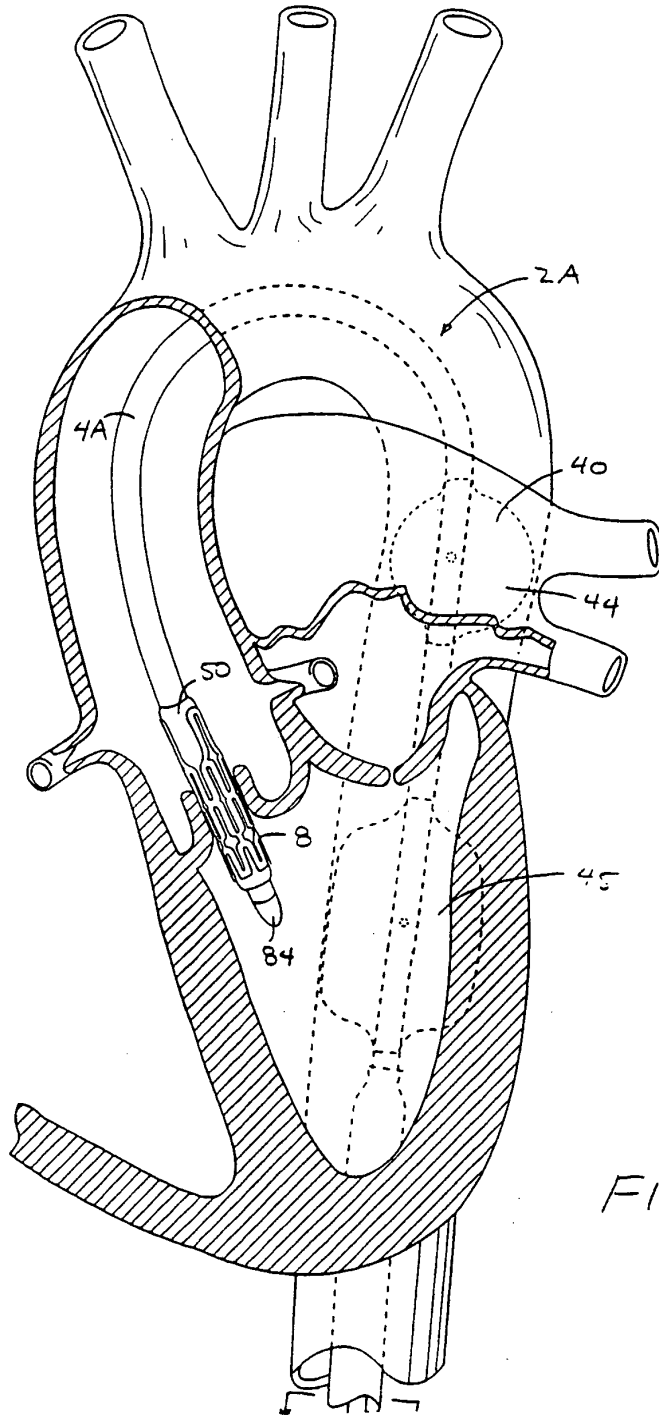


FIG. 13

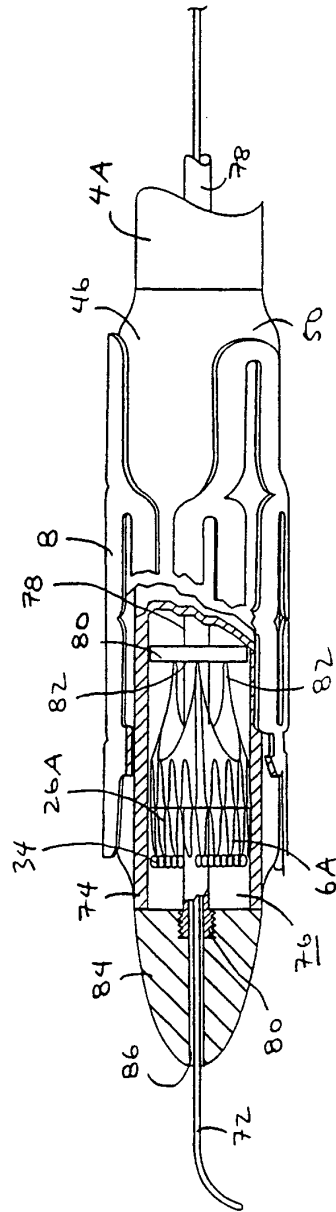


FIG. 14

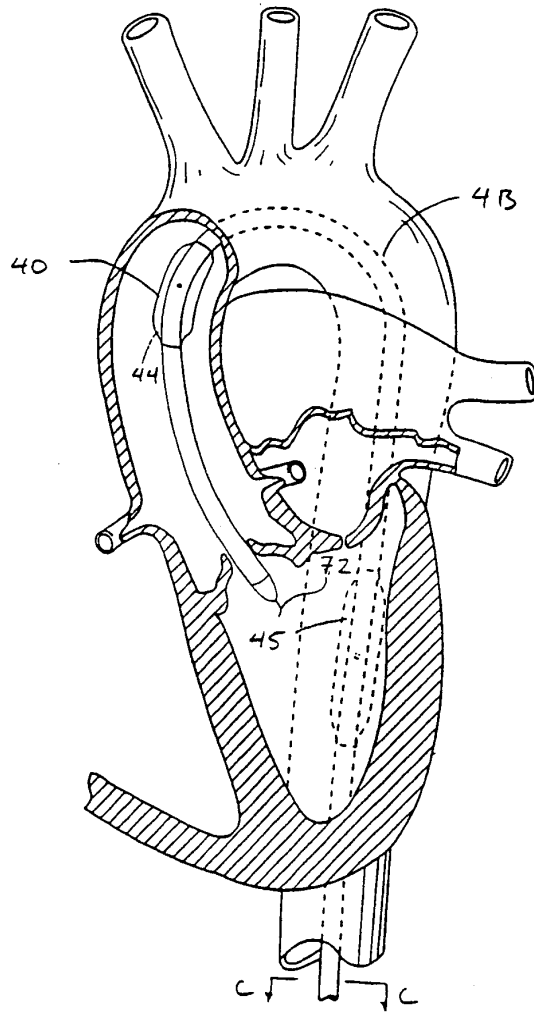
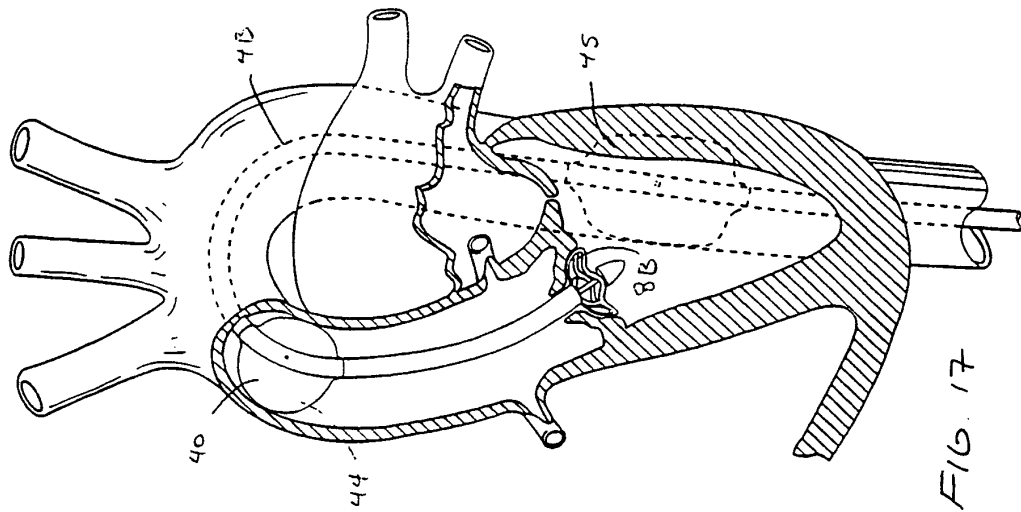
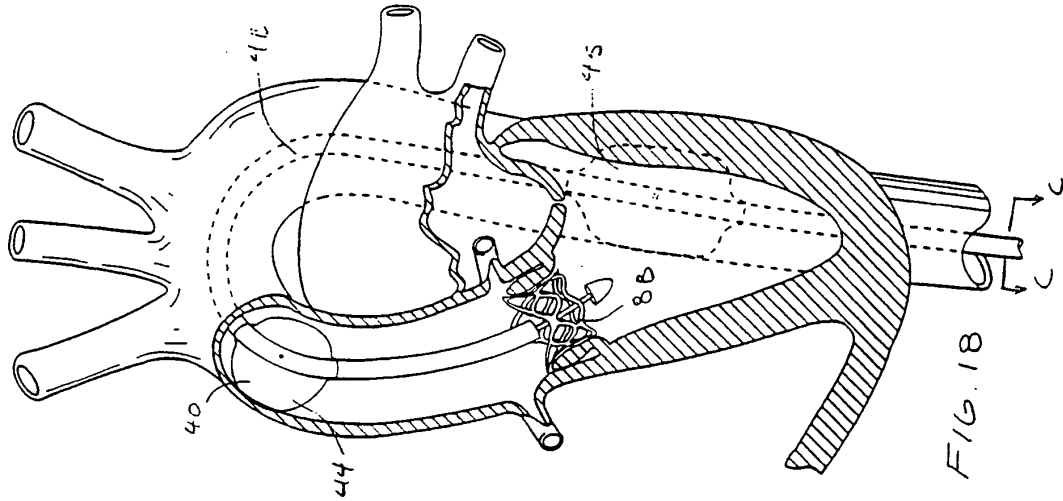
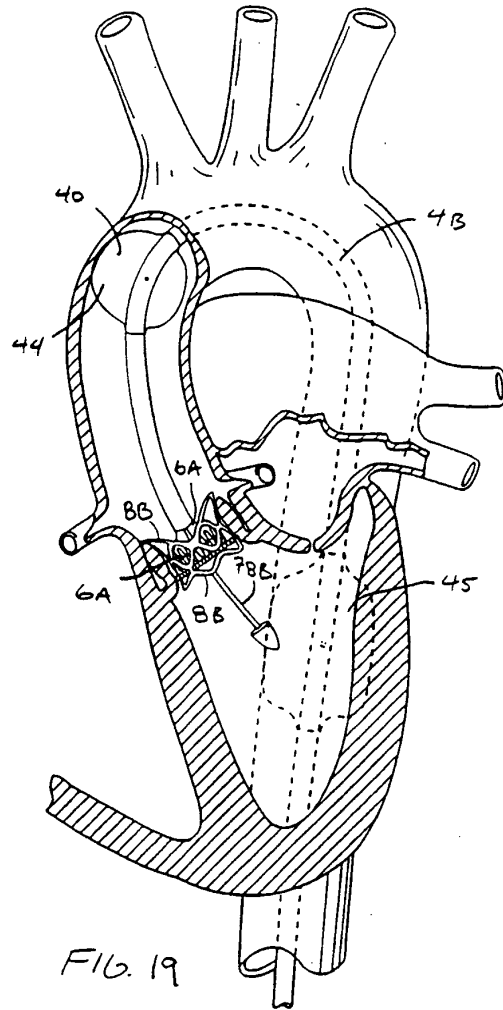


FIG. 16





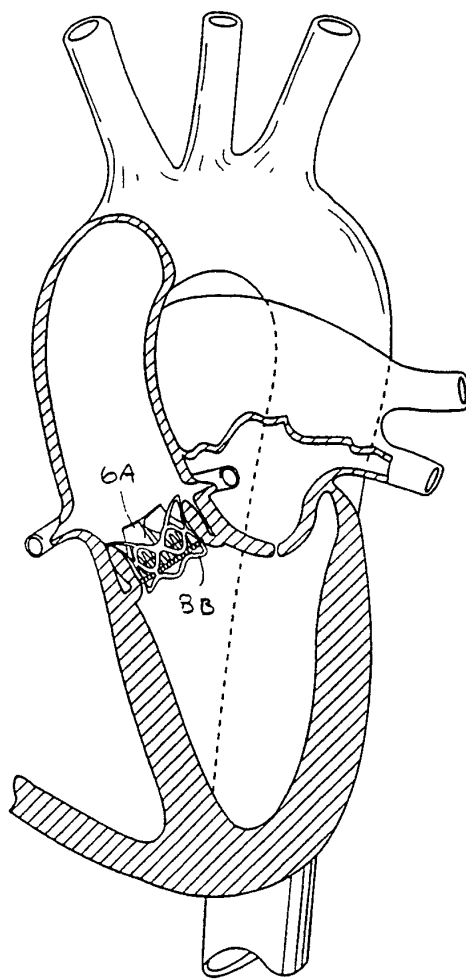


FIG. 20

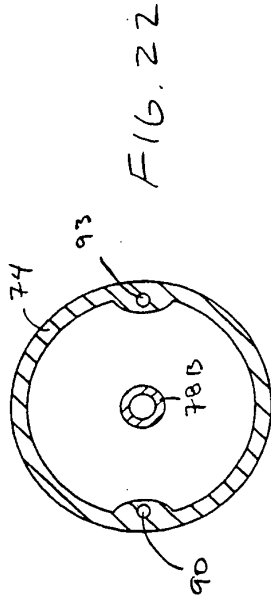


FIG. 22

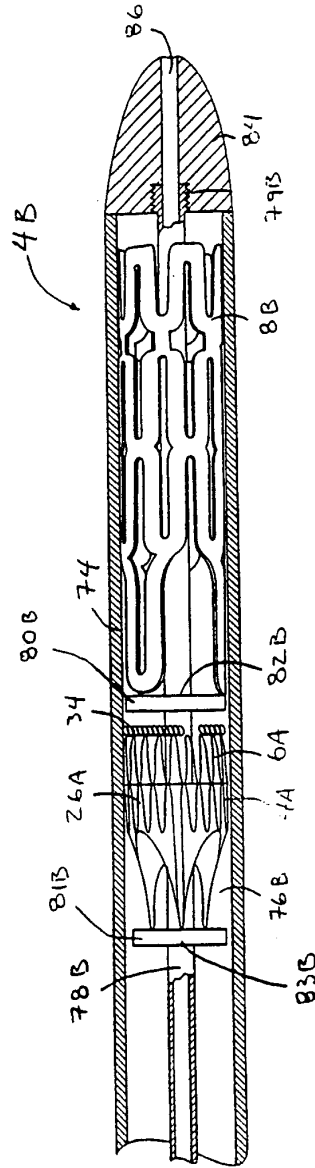


FIG. 21

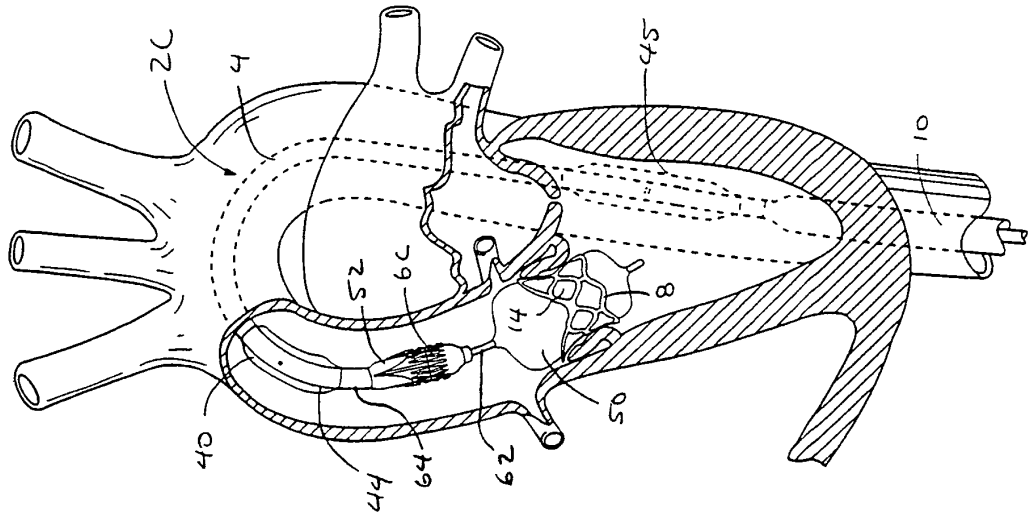


FIG. 24

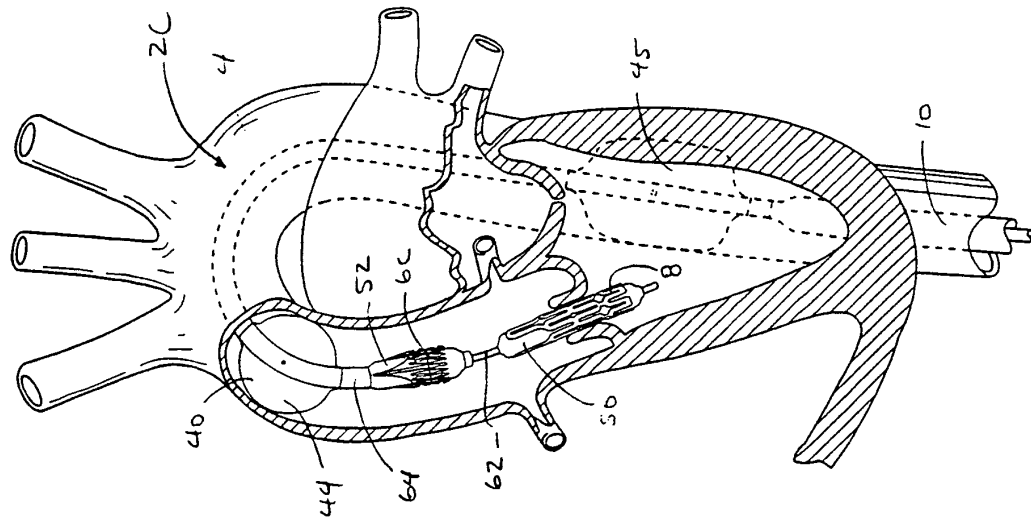


FIG. 23

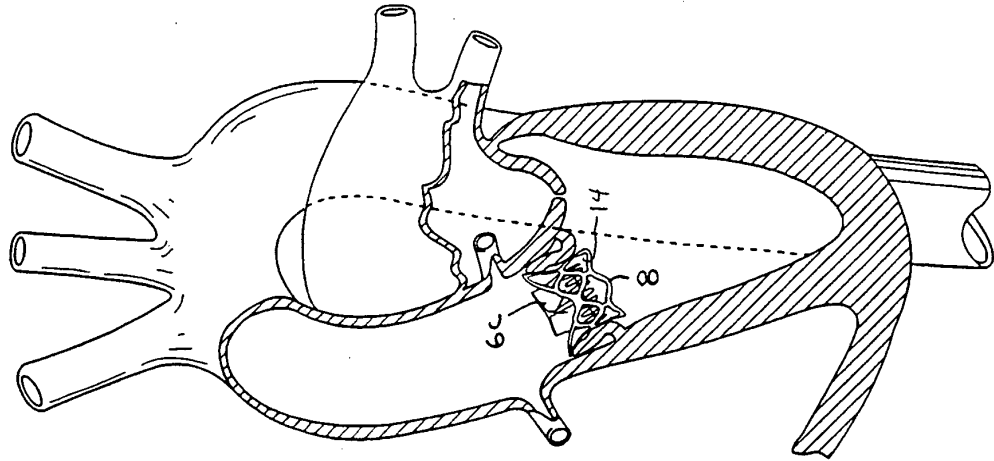


FIG. 26

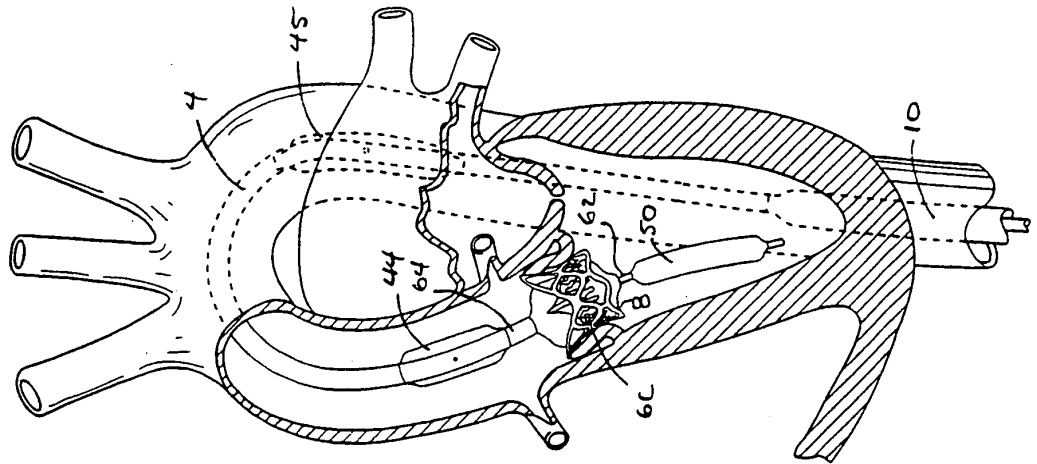


FIG. 25

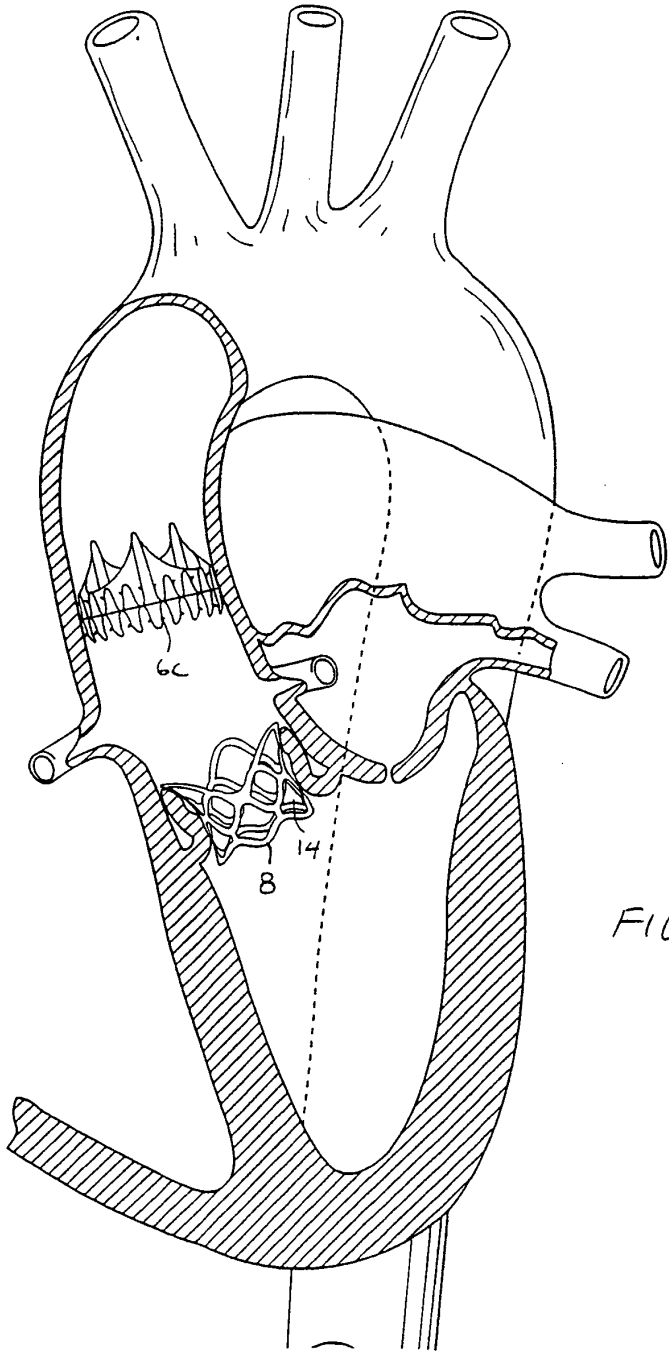


FIG. 27

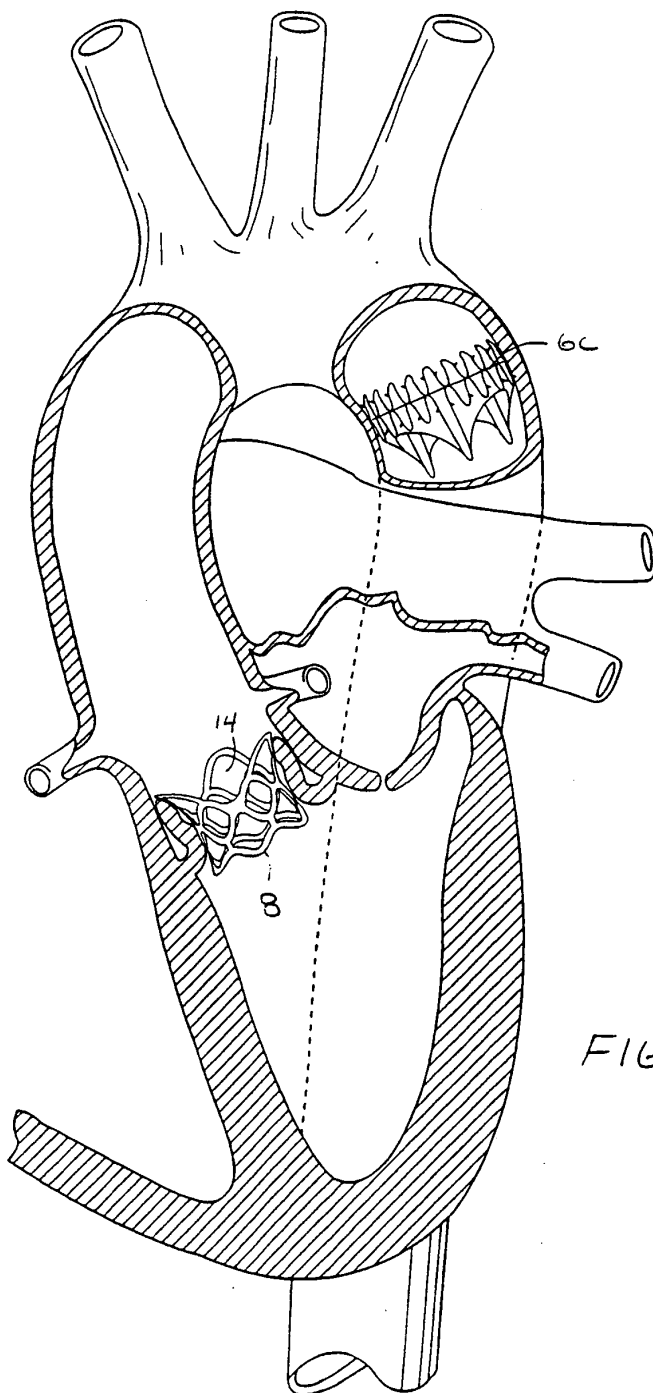


FIG. 28

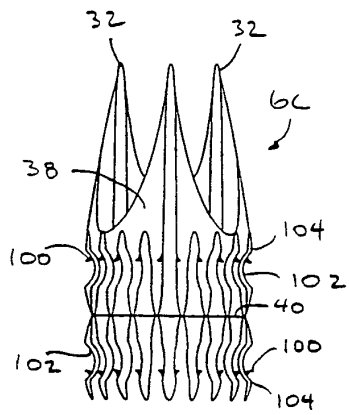


FIG. 29

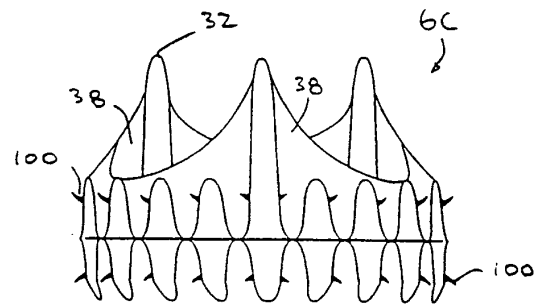


FIG. 30

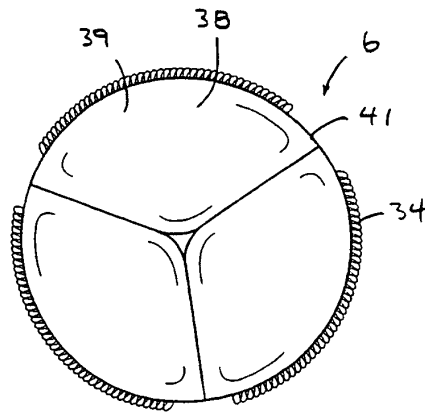


FIG. 11

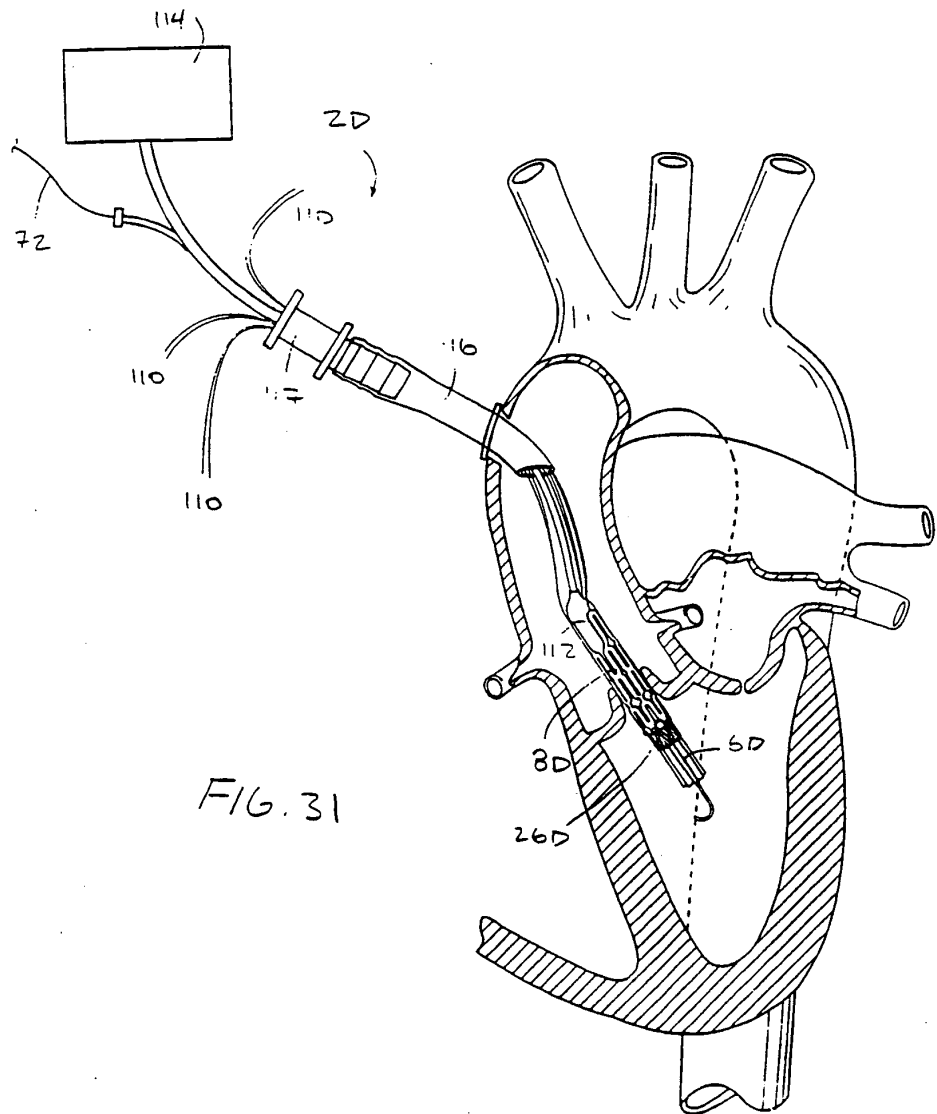


FIG. 31

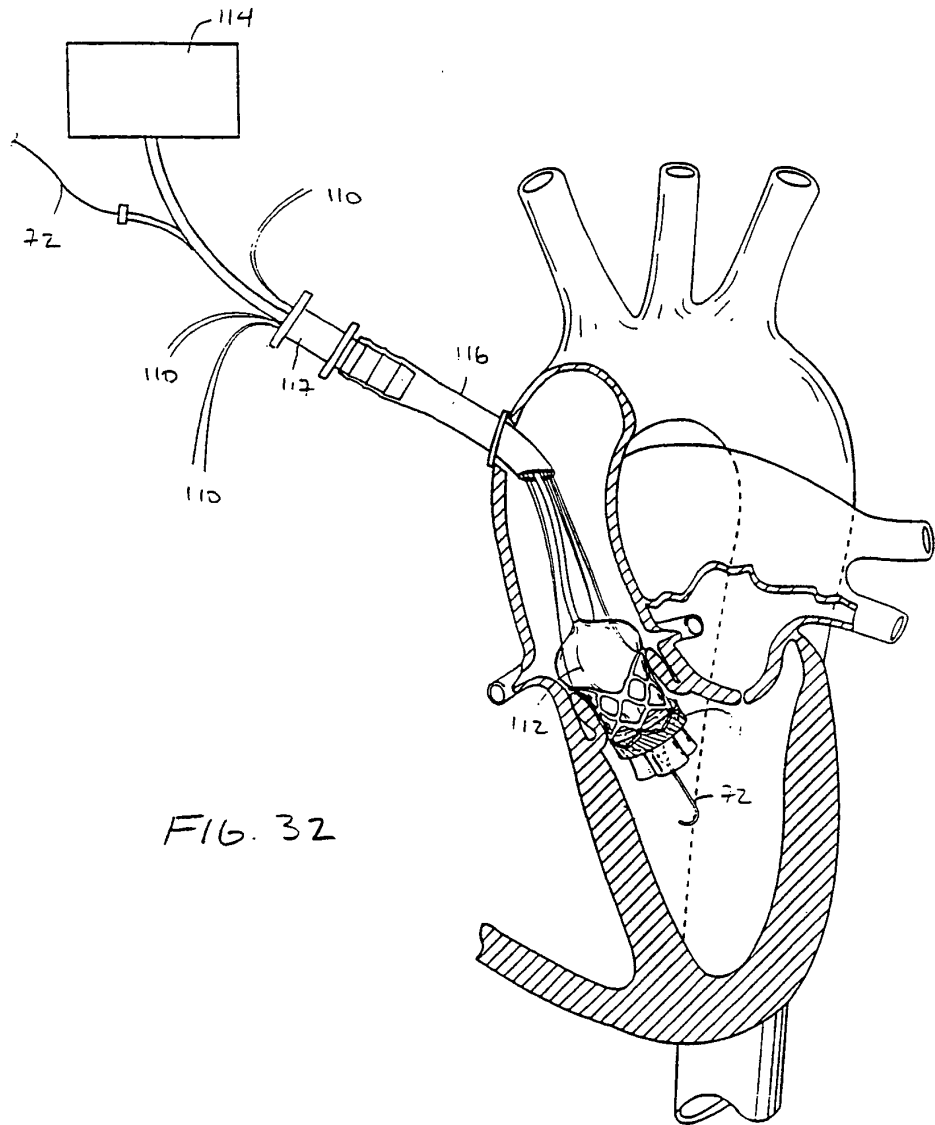


FIG. 32

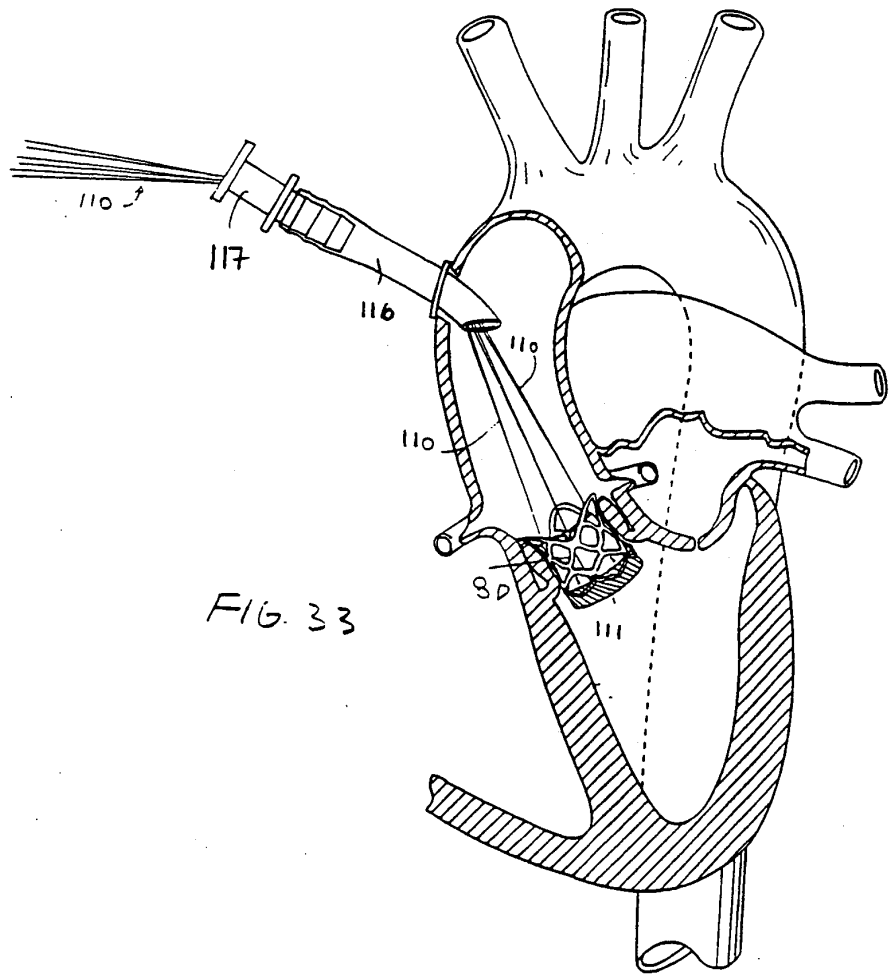


FIG. 33

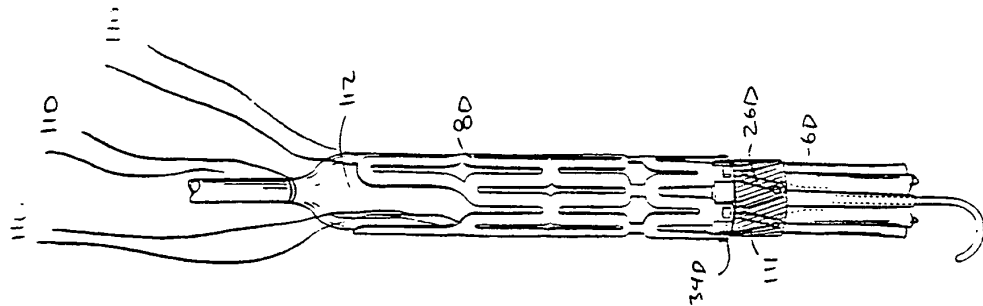


FIG. 37

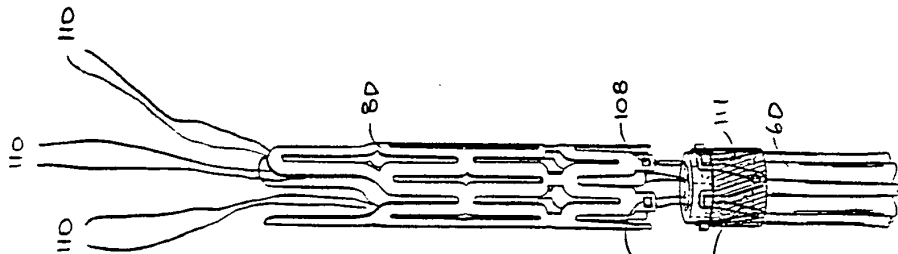


FIG. 36

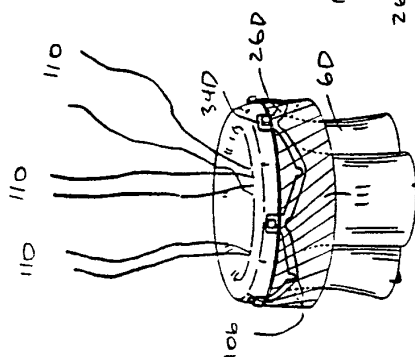


FIG. 35

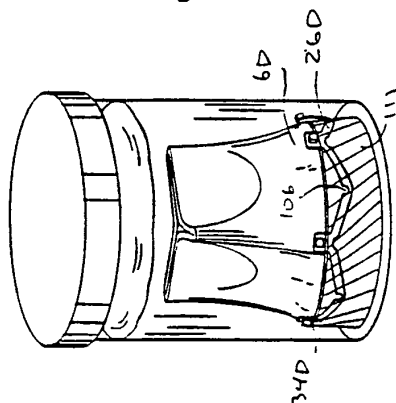


FIG. 34

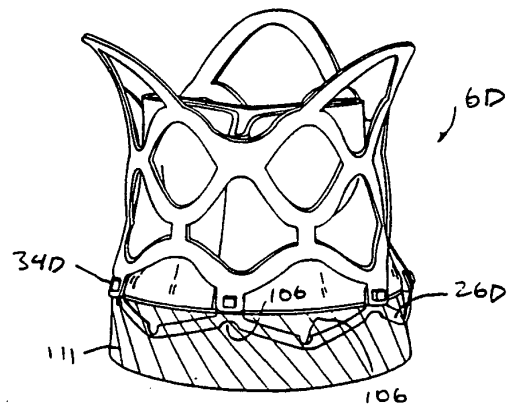


FIG. 38

INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER IPC(7) :A61F 2/24 US CL :632/1.26, 2.11, 2.18 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 632/1.24, 1.26, 2.11, 2.18 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	EP 0 850 607 A (LETAC, et al.) 01 July 1998, entire document.	1-3, 5, 8, 11-20, 22-29 ----- 4, 6, 7, 9, 10, 21
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "Z" document member of the same patent family
Date of the actual completion of the international search 05 APRIL 2000		Date of mailing of the international search report 03 MAY 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer DAVID WILUSE <i>David Wiluse</i> Telephone No. (703) 308-2903

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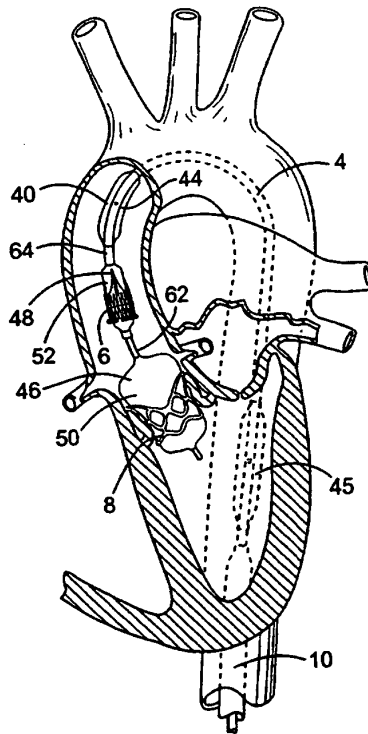
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(54) Title: METHODS AND DEVICES FOR IMPLANTING CARDIAC VALVES



WO 00/47139 A1



(57) Abstract: The valve implantation system has a valve displacer (8) for displacing, and holding the native valve leaflets open in a first aspect of the invention. A replacement valve (6) may be attached to the valve displacer before or after introduction, and may be positioned independent of the valve displacer. In another aspect of the invention, the valve displacer and the valve are in a collapsed condition during introduction, are expanded to deploy the valve displacer, and valve. The valve is a tissue valve (38) mounted to an expandable support structure (26). The support structure may have protrusions (34) for engaging the valve displacer or barbs for anchoring the valve displacer to the heart or blood vessel. A temporary valve mechanism (40) may be used to provide temporary valve functions during, and after deployment of the valve displacer.



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METHODS AND DEVICES FOR IMPLANTING CARDIAC VALVES**BACKGROUND OF THE INVENTION**

The present invention is directed to methods and devices for implanting
5 replacement cardiac valves. Replacement cardiac valves are implanted when the
patient's native valve exhibits abnormal anatomy and function due to congenial or
acquired valve disease. Congenital abnormalities can be tolerated for years only to
develop into life-threatening problems later. Acquired valve disease may result from
various causes such as rheumatic fever, degenerative disorders of the valve tissue, and
10 bacterial or fungal infections.

Valve dysfunction can be classified as either stenosis, in which the valve does
not open properly, or insufficiency, in which the valve does not close properly.
Stenosis and insufficiency can occur at the same time and both abnormalities increase
the workload on the heart in pumping blood through the body. The ability of the heart
15 to function with the increased workload is a major factor in determining whether the
valve should be replaced.

When the valve must be replaced using conventional methods, the patient
must undergo an invasive, traumatic surgical procedure. The patient's chest is opened
with a median sternotomy or major thoracotomy to provide direct access to the heart
20 through the large opening in the chest. The heart is then stopped and the patient is
placed on cardiopulmonary bypass using catheters and cannulae inserted directly into
the heart and great vessels. The heart, or a great vessel leading to the heart, is then cut
open to access and remove the malfunctioning valve. After removing the valve, the
replacement valve is then sewn into place. After the new valve has been implanted,
25 the chest is then closed and the patient is weaned off cardiopulmonary bypass support.

The conventional open-chest surgery described above is problematic in that it
is highly invasive, traumatic and requires a lengthy recovery time. These drawbacks
to conventional open-chest surgery prevent some patients from undergoing a valve
implantation procedure even though a new cardiac valve is needed.

30 U.S. Patent No. 5,370,685, U.S. Patent No. 5,411,552 and U.S. Patent No.
5,718,725, which are hereby incorporated by reference, describe devices and methods
for implanting a new cardiac valve without requiring a median sternotomy or major

thoracotomy. Such devices and methods reduce the pain, trauma and recovery time as compared to conventional open-chest surgery.

An object of the present invention is to provide additional devices and methods which reduce the trauma associated with conventional open-chest methods
5 and devices for implanting cardiac valves.

SUMMARY OF THE INVENTION

In accordance with the object of the invention, a system and method for implanting a cardiac valve is provided which does not require a median sternotomy or
10 major thoracotomy. The devices and methods of the present invention are preferably carried out by passing the valve through a blood vessel, preferably the femoral artery, so that the median sternotomy or major thoracotomy is not required. Alternatively, the systems of the present invention also permit introduction of the valve through a small incision between the patient's ribs without cutting the ribs or sternum.

15 In a first aspect of the invention, a valve displacer is used to hold the native valve leaflets open so that the native valve does not need to be removed. The valve displacer is preferably introduced into the patient in a collapsed condition and expanded to displace and hold the leaflets open. The valve displacer may either be expanded with an expansion mechanism, such as a balloon, or may be self-expanding.
20 In a preferred embodiment, the valve displacer has a first end, a second end and a central section between the first and second ends. The first and second ends are preferably flared outwardly to form a circumferential recess around the central portion. The native leaflets are trapped within the recess when the valve displacer is deployed.

25 In another aspect of the invention, the valve is also introduced into the patient in a collapsed condition and expanded within the patient. The valve may either be expanded with an expansion mechanism, such as a balloon, or may be self-expanding. The cardiac valve may be coupled to the valve displacer or may be positioned independent from the valve displacer while still substantially performing the functions
30 of the native valve. For instance, a replacement aortic valve may be positioned in the ascending or descending aorta to substantially perform the functions of the native aortic valve.

The cardiac valve is preferably delivered separate from the valve displacer but may also be integrated with the valve displacer during introduction and deployment. In a preferred embodiment, the valve has protrusions which engage openings in the valve displacer. In another embodiment, the valve has sharp elements or barbs which
5 either pierce the native valve tissue or engage the sides of the openings in the valve displacer.

In yet another aspect of the present invention, the valve and valve displacer are preferably introduced into the patient with a catheter system. In a preferred system, the valve displacer is mounted to a first catheter and the valve is mounted to a second
10 catheter which passes through and is slidably coupled to the first catheter. Alternatively, the valve displacer and valve may be mounted to a single catheter. The term catheter as used herein refers to any catheter, trocar or similar device for introducing medical devices into a patient.

In still another aspect of the present invention, the valve delivery catheter has a
15 temporary valve mechanism which provides temporary valve functions after deployment of the valve displacer. The temporary valve mechanism prevents regurgitation while the native valve is held open and before deployment of the replacement cardiac valve. The temporary valve mechanism is preferably a balloon which is inflated and deflated as necessary to permit downstream flow and prevent
20 retrograde flow. Although it is preferred to implant the cardiac valve while the patient's heart is beating, the devices and methods of the present invention may also be used with the patient's heart stopped and the patient supported by a bypass system.

These and other advantages and aspects of the invention will become evident from the following description of the preferred embodiments and claims.

25

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A shows a system for implanting a cardiac valve.

Fig. 1B shows the system of Fig. 1A introduced through a femoral vein.

Fig. 2 shows the system of Fig. 1 with a sheath retracted to expose the cardiac
30 valve, a valve displacer and a temporary valve mechanism.

Fig. 3 shows the valve displacer positioned between the native valve leaflets prior to expansion.

Fig. 4 shows the valve displacer expanded by a first expansion mechanism

Fig. 5 shows the valve expanded by a second expansion mechanism into engagement with the valve displacer.

Fig. 6 shows the valve displacer and valve implanted in the native valve
5 position.

Fig. 7 shows the valve displacer in the collapsed position.

Fig. 8 shows the valve displacer in the expanded position.

Fig. 9 shows the valve and valve displacer in the expanded position.

Fig. 10 shows the valve in a collapsed condition.

10 Fig. 11 is a plan view of the valve showing the leaflets.

Fig. 12 is a cross-sectional view of the catheter along line A-A of Fig. 5.

Fig. 13 shows another system for implanting another cardiac valve.

Fig. 14 is a partial cut-away view of the catheter of Fig. 13 with the valve
contained in a chamber.

15 Fig. 15 is a cross-sectional view of the catheter along line B-B of Fig. 13.

Fig. 16 shows another system for implanting a cardiac valve.

Fig. 17 shows the system of Fig. 16 with a distal portion of the valve displacer
extending from the catheter.

Fig. 18 shows the valve displacer fully deployed to hold the native leaflets
20 open.

Fig. 19 shows the valve partially expanded with the catheter manipulated so
that the valve engages the valve displacer.

Fig. 20 shows the valve fully deployed and the catheter removed.

Fig. 21 is a partial cut-away view of the catheter of Figs. 16-19.

25 Fig. 22 is a cross-sectional view of the catheter along line C-C of Fig. 16.

Fig. 23 shows another system for implanting a cardiac valve with the valve
displacer positioned between the native leaflets.

Fig. 24 shows the valve displacer expanded.

Fig. 25 shows the valve partially deployed within the valve displacer.

30 Fig. 26 shows the valve fully deployed within the valve displacer.

Fig. 27 shows the valve displacer holding the native leaflets open with the
valve deployed in the ascending aorta.

Fig. 28 shows the valve displacer holding the native leaflets open with the valve deployed in the descending aorta.

Fig. 29 shows the cardiac valve of Figs. 23-28 in the collapsed condition.

Fig. 30 shows the cardiac valve of Figs. 23-28 in the expanded condition.

5 Fig. 31 shows another system for delivering a cardiac valve with the delivery catheter passing through a trocar in the ascending aorta.

Fig. 32 shows an expansion mechanism expanding the valve displacer and the valve.

Fig. 33 shows sutures being pulled to invert the valve.

10 Fig. 34 shows the valve being stored in a preservative solution.

Fig. 35 shows the valve inverted and in the expanded condition.

Fig. 36 shows the valve and valve displacer in the collapsed condition before being attached to one another.

15 Fig. 37 shows the valve and valve displacer attached to one another and mounted to the delivery catheter.

Fig. 38 shows the valve and the valve displacer in the expanded condition.

Fig. 39 shows the catheter passing through the femoral vein, into the right atrium, and through the intraatrial septum into the left atrium to access the mitral valve.

20

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figs. 1A, 1B and 2 a system for implanting a replacement cardiac valve is shown. The present invention is described in connection with implantation of a replacement aortic valve but is applicable to any other cardiac valve. The system 2
25 includes a delivery catheter 4, a cardiac valve 6 and a valve displacer 8. A protective sheath 10 covers the delivery catheter 4, cardiac valve 6 and valve displacer 8 during introduction to prevent contact between the blood vessel and the cardiac valve 6 and valve displacer 8. Figs. 1A and 1B show the sheath 10 extending around the cardiac valve 6 and valve displacer 8 and Fig. 2 shows the sheath 10 retracted to expose the
30 cardiac valve 6 and valve displacer 8.

The cardiac valve 6 is preferably introduced through a peripheral vessel such as the femoral artery (Figs. 1A and 2) or femoral vein (Fig. 1B). Fig. 1B shows introduction of the catheter 2 through the femoral vein, into the right atrium, through

the intraatrial septum and into the left atrium to access the mitral valve. The peripheral vessel is preferably a femoral vessel but may also be the internal jugular vein, subclavian artery, axillary artery, abdominal aorta, descending aorta or any other suitable blood vessel. As will be explained below, the delivery catheter 4 may be introduced by surgical cutdown or percutaneously using the Seldinger technique. An advantage of passing the catheter 4 through a peripheral vessel is reduced trauma to the patient as compared to the conventional open-chest procedure described above. Although it is preferred to deliver the cardiac valve 6 through a peripheral vessel, the cardiac valve 6 may also be introduced directly into the ascending aorta through a small incision between ribs. The system 2 of the present invention is small enough to deliver between the patient's ribs so that the advantages of the present invention over conventional open-chest surgery are provided even when introducing the catheter through an incision in the chest.

The valve displacer 8 is expanded within the native valve to hold the native cardiac valve leaflets 6 open. An advantage of the system 2 and method of the present invention is that the native valve does not need to be removed. The replacement cardiac valves described herein may, of course, also be used when removing the native valve rather than using the valve displacer 8. Furthermore, the valve displacer 8 and cardiac valve 6 may be integrated into a single structure and delivered together rather than separately. Thus, all features of any valve displacer described herein may also form part of any of the cardiac valves described herein without departing from the scope of the invention.

The valve displacer 8 is shown in the collapsed condition in Figs. 3 and 7 and in the expanded condition in Figs. 4 and 8. When in the collapsed position, the valve displacer 8 forms a number of longitudinal slots 12 which form openings 14 in the valve displacer 8 when in the expanded condition. The valve displacer 8 is substantially cylindrical in the collapsed condition to facilitate introduction into the patient.

Referring to Fig. 8, first and second ends 16, 18 of the valve displacer 8 flare outwardly to form a circumferential recess 24 at a central section 22. The native leaflets are trapped in the recess 24 when the valve displacer 8 is deployed. The first end 16 has three extensions 20 extending from the central section 22. The valve displacer 8 may be made of any suitable material and preferred materials include

stainless steel, nitinol, kevlar, titanium, nylon and composites thereof. The valve displacer 8 may also be coated with an antithrombogenic coating. The valve displacer 8 is preferably formed from a solid hypotube by etching or micromachining, machining from a solid material, or welding wire elements together. Although it is preferred to provide the flared ends 16, 18, the valve displacer 8 may have any other suitable shape which holds the leaflets open. The valve displacer 8 may also have a fabric cover 17 which can trap calcium fragments which might break free from the valve when the valve displacer is deployed. The cover 17 is preferably made of a polyester knit material, such as dacron, but may be made of any other suitable material.

The cardiac valve 6 has an expandable support structure 26 which moves from the collapsed position of Figs. 4 and 10 to the expanded position of Figs. 5 and 9. The support structure 26 is preferably formed with first and second elongate members 28, 30 which are wound to form windings 31, preferably about 12-18 windings 31, around the circumference of the valve 6. The first and second elongate members 28, 30 are attached to one another at windings 31 which forms three posts 32 extending from the support structure 26.

The support structure 26 has a protrusion 34, preferably three, extending outwardly to form an interrupted lip around an end 35 of the support structure 26. The protrusions 34 engage the openings 14 in the valve displacer 8 as shown in Fig. 9 to secure the cardiac valve 6 to the valve displacer 8. The protrusions 34 are preferably formed by a coil 36 wrapped around the loops 31 in the elongate member 30. As will be described below, the support structure 26 may also have barbs to secure the cardiac valve 6 to the valve displacer 8 or to the blood vessel wall. The cardiac valve 6 may also engage the valve displacer 8 with any other suitable connection.

The posts 32 support a valve portion 38 which performs the functions of the patient's malfunctioning native valve. Referring to Figs. 10 and 11, the valve portion 38 is preferably a stentless tissue valve such as a tri-leaflet 39 stentless porcine valve. The valve portion 38 has a base 41 which is secured to the support structure 26 with sutures (not shown). The valve portion 38 may be stored separately from support structure 26 and attached to the support structure 26 before the procedure. Although it is preferred to provide a tissue valve for the valve portion 38, the valve portion 38 may also be made of a flexible, synthetic material. For example, the valve portion 38

may be made of polyurethane similar to the valves described in "A Tricuspid Polyurethane Heart Valve as Alternative to Mechanical Prostheses or Bioprotheses," by Lo et al., Trans Am Society of Artificial Internal Organs, 1988; 34: pgs valve displacer 839-844, and "Evaluation of Explanted Polyurethane Trileaflet Cardiac Valve Prostheses," Journal Thoracic Cardiovascular Surgery, 1988; 94: pgs 419-429.

Referring to Figs. 2-4, the delivery catheter 4 has a temporary valve mechanism 40 which provides temporary valve functions during and/or after deployment of the valve displacer 8. The temporary valve mechanism 40 ensures proper blood flow regulation when the leaflets are held open by the valve displacer 8 to provide time for accurate positioning and deployment of the valve 6. The temporary valve mechanism 40 is preferably a balloon 44 coupled to an inflation mechanism 47 controlled by a control system 42. The control system 42 senses the patient's heartbeat to time balloon inflation and deflation to permit and prevent flow in the same manner as the native valve. Similar systems for synchronizing inflation and deflation of a balloon with the patient's heartbeat are known in balloon pump technology and are described in U.S. Patents Nos. 5,817,001, 5,413,549 and 5,254,097 which are hereby incorporated by reference. The balloon 44 is preferably inflated with a gas for quick inflation and deflation. The temporary valve mechanism 40 is preferably the balloon 44 but may also be a passive mechanical valve which automatically opens and closes due to blood flow forces.

The catheter 4 may also include an elongate balloon 45 to help pump blood through the patient's body like a blood pump. The balloon 45 is also coupled to an inflation mechanism 49 controlled by the control system 42 which inflates and deflates the balloon 45 to provide pumping assistance to the patient's heart. Balloon pump technology is described in the above-mentioned patents. The elongate balloon 45 may be replaced by any other suitable blood pump, such as a centrifugal pump having an impeller, without departing from the scope of the invention.

The temporary valve mechanism 40 and balloon 45 are, of course, only necessary when implanting the valve with the patient's heart beating. If the patient's heart is stopped and the patient is supported by a bypass system during the valve implantation procedure, the temporary valve mechanism 40 and/or balloon 45 may be used after the procedure for emergency valve functions or pumping assistance. The

balloon 44 is preferably positioned in the ascending or descending aorta and the balloon 45 is preferably positioned in the descending aorta.

Referring to Figs. 3-6, the delivery catheter 4 also has first and second expandable members 46, 48 which deploy the valve displacer 8 and cardiac valve 6, respectively. The expandable members 46, 48 are preferably balloons 50, 52 but may also be mechanically actuated devices. The balloons 50, 52 are coupled to inflation lumens 54, 56 through which inflation fluid is delivered from sources of inflation fluid 58, 60, respectively. The balloon 50 expands greater at the ends to form the flared ends 16, 18 of the valve displacer 8.

The delivery catheter 4 includes a first catheter 62, which carries the valve displacer 8, and a second catheter 64, which carries the cardiac valve 6. Referring to Figs. 2 and 12, the second catheter 64 has a passageway 66 which receives the first catheter 62. A hemostasis valve 68 permits slidable movement between the first and second catheters 62, 64. The first catheter 62 has lumen 54 for inflating balloon 50 and the second catheter 64 has lumen 48 for inflating balloon 52. The second catheter 64 also has a lumen 51 for inflating balloon 44 and a lumen 53 for inflating balloon 45. The first catheter 62 also has a main lumen 70 which receives a guidewire 72.

The slidable connection between the first and second catheters 62, 64 permits introduction of the first catheter 62 over the guidewire 72 with the second catheter 64 being advanced over the first catheter 62 after the valve displacer 8 is in the ascending aorta. In this manner, the first catheter 62 may be advanced more easily over the guidewire 72 and through the patient's vasculature, such as around the aortic arch, as compared to a single, multichannel catheter having all features of the first and second catheters 62, 64. The first and second catheters 62, 64 may be wire-reinforced (not shown) catheters constructed in the manner described in Published PCT Application WO 97/32623 entitled "Cannula and Method of Manufacture and Use" which is hereby incorporated by reference.

A method of implanting a cardiac valve 6 in accordance with the present invention is now described in connection with Figs. 1-6. Although the method is described in connection with the system described above, the method may be practiced with other suitable devices, including the devices and systems described below, without departing from the scope of the invention. Furthermore, the method is described in connection with replacing the aortic valve, however, the method may also

be applied to other other cardiac valves such as the mitral, tricuspid and pulmonary valves.

Before implanting the cardiac valve 6, it may be desirable to perform valvuloplasty to break up pathologic adhesions between the native valve leaflets.

5 Breaking up adhesions ensures that the valve displacer 8 expands fully to provide a large blood flow path. Valvuloplasty is preferably performed with a balloon which is inflated to open the leaflets and break the adhesions. The native cardiac valve and annulus are also sized to determine the proper size valve displacer 8 and cardiac valve 6. Sizing may be carried out using fluoroscopy, intravascular ultrasound or with any
10 other suitable device during or after the valvuloplasty. Size parameters to consider include the cross-sectional profile through the valve, the length and size of the valve leaflets and position of the coronary ostia.

The delivery catheter 4 is preferably introduced into the patient by surgical
15 cutdown in the femoral artery but may also be introduced percutaneously using the Seldinger technique. As mentioned above, the delivery catheter 4 may also be introduced into any other suitable vessel or through a small incision in the chest. The first and second catheters 62, 64 are advanced into the artery through the cutdown a short distance. The guidewire 72 is then advanced ahead of the first and second
20 catheters 62, 64 up the descending aorta, around the aortic arch, into the ascending aorta and across the aortic valve. The first catheter 62 is then advanced over the guidewire 72 to the ascending aorta with the sheath 10 covering the first catheter 62 to prevent contact between the valve displacer 8 and the blood vessel or native valve. The second catheter 64 is then advanced over the first catheter 62 to position the
25 cardiac valve 6 in the ascending aorta. The sheath 10 also prevents contact between the cardiac valve 6 and vessel wall when advancing the second catheter 64. The sheath 10 is then retracted as shown in Fig. 2 to expose the valve displacer 8 and the cardiac valve 6.

The valve displacer 8 is then introduced between the valve leaflets as shown in Fig. 3 and the balloon 50 is inflated to expand the valve displacer as shown in Fig. 4.
30 The valve displacer 8 holds the native valve leaflets open so that the native valve does not have to be removed. When the valve displacer 8 has been deployed, the temporary valve mechanism 40 provides temporary valve functions by inflating and deflating the balloon 44 at appropriate times to permit and block flow in the same manner as the

native valve. The balloon 45 may also be inflated and deflated to provide pumping assistance to the patient's heart during the procedure. Although the above-described method is performed with the patient's heart beating, the procedure may also be performed on a stopped heart with the patient supported by a bypass system.

5 The second catheter 64 is then advanced until the valve 6 is positioned adjacent the valve displacer 8. Although Fig. 5 shows the first catheter 62 extending into the left ventricle, the first catheter 62 may also be designed to be withdrawn into the passageway 66 of the second catheter 64 so that the first catheter 62 does not
10 extend beyond the second catheter 64. The balloon 52 is then partially inflated so that the distal end of the valve 6 having the protrusions 34 expands. The second catheter 64 is then manipulated until the protrusions 34 engage the openings 14 in the valve displacer 8. The balloon 52 is then inflated further to expand the rest of the support structure 26. The catheters 62, 64 are then removed leaving the cardiac valve 6 in
15 place.

15 Referring to Figs. 13 and 14, another system 2A for implanting a cardiac valve 6A is shown wherein the same or similar reference numbers refer to the same or similar structures. The cardiac valve 6A is similar to the cardiac valve 6 described above, however, the cardiac valve 6A is self-expanding and, therefore, does not require an independent expansion mechanism. The support structure 26A is made of a
20 resilient material to naturally bias the support structure 26A to the expanded position. The support structure 26A may be made of any suitable material and preferred materials are stainless steel or shape-memory alloys such as nitinol. Delivery catheter 4A has the expandable member 46, which is preferably the balloon 50, for expanding the valve displacer 8.

25 The cardiac valve 6A is contained within an outer wall 74 of the delivery catheter 4A. The cardiac valve 6A is advanced out of a chamber 76 in the delivery catheter 4A by advancing a rod 78 having a pusher element 80 attached thereto. The pusher element 80 engages the posts 82 on the cardiac valve 6A to move the cardiac valve 6A out of the chamber 76. The rod 78 has threaded connections 80, 82 with a
30 tip 84 and the pusher element 80 to facilitate assembling the delivery catheter 4A and loading the cardiac valve 6A in the chamber 76. The rod 78 has a guidewire lumen 86 for receiving the guidewire 72. Referring to the cross-sectional view of Figs. 15, the catheter 4A has a first lumen 88 coupled to the balloon 50, a second lumen 90 coupled

to the balloon 44 and a third lumen 91 coupled to the balloon 45. The second and third lumens 88, 90 are coupled to the inflation mechanisms 47, 29 which are controlled by the control system 42 described in connection with Figs. 1 and 2. The system 2A preferably includes the sheath 10 which prevents contact between the blood vessel and the valve displacer 8 when the catheter 4A is advanced through the blood vessel.

The cardiac valve 6A is implanted in substantially the same manner as the cardiac valve 6 and the discussion of implantation of the cardiac valve 6 is also applicable here. The delivery catheter 4A may be introduced in any manner described herein and Fig. 13 shows the catheter 4A extending through the femoral artery with the valve displacer 8 positioned between the valve leaflets prior to expansion. The valve displacer 8 is expanded in the manner explained above to hold the leaflets open. After the valve displacer 8 has been expanded, the catheter 4A is retraced a predetermined amount so that the protrusions 34 are exposed outside the distal end of the catheter 4A. The catheter 4A may then be manipulated as necessary so that the protrusions 34 engage the openings 14 in the valve displacer 8. The valve 6A preferably remains coupled to the catheter 4A while the protrusions 34 are exposed for manipulation of the valve 6A until the valve 6A engages the valve displacer 8. After the valve 6A has engaged the valve displacer 8, the rod 78 is then advanced far enough to completely release the cardiac valve 6A.

Referring to Figs. 16-22, another system 4B for implanting the cardiac valve 4A is shown wherein the same or similar reference numbers refer to the same or similar structure. The system has the self-expanding cardiac valve 4A described above. The valve displacer 8B is similar to the valve displacer 8 described above, however, the valve displacer 8B is also self-expanding and, therefore, does not require an independent expansion mechanism. The valve displacer 8B is made of a resilient material to naturally bias the valve displacer 8B to the expanded position. The valve displacer 8B may be made of any suitable material and preferred materials are stainless steel and shape-memory alloys such as nitinol.

The valve displacer 8B and cardiac valve 6A are contained within an outer wall 74 of the delivery catheter 4B as shown in Fig. 21. The valve displacer 8B and cardiac valve 4A are advanced out of a chamber 76B in the delivery catheter 4B by advancing a rod 78B having first and second pusher elements 80B, 81B attached

thereto. The rod 78B has threaded connections 79B, 82B, and 83B with the tip 84 and the first and second pusher elements 80B, 81B to facilitate assembling catheter 4B and loading the valve displacer 8B and cardiac valve 6A in the chamber 76B. The rod 78B has the guidewire lumen 86 for receiving the guidewire 72 (Fig. 14). Referring to

5 Fig. 16 and the cross-sectional view of Fig. 22, the catheter 4B has a lumen 90 coupled to the balloon 44 which serves as the temporary valve mechanism 40 and a lumen 93 which is coupled to the balloon 45. The lumen 90 and lumen 93 are coupled to the inflation mechanisms 47, 29 which are controlled by the control system 42 (Figs. 1A, 1B, and 2).

10 Another method of implanting a cardiac valve is now described with reference to Figs. 16-20 wherein the same or similar reference numbers refer to the same or similar structure. The method describes use of the delivery catheter 4B and cardiac valve 6A, however, the method may be practiced using other suitable structures. The delivery catheter 4B is introduced in any manner described above and is preferably

15 introduced through the femoral artery. The guidewire 72 is advanced ahead of the catheter 4B into the ascending aorta and the delivery catheter 4B is advanced over the guidewire 72. The delivery catheter 4B is then advanced between the valve leaflets. A distal end of the valve displacer 8B is then advanced out of the chamber 76 and the catheter 4B is retracted until the valve displacer 8 contacts the valve opening. The

20 catheter 4B is then retracted while the rod 78B is maintained in the same position so that the valve displacer 8B emerges from the chamber 76B as shown in Fig. 18. The catheter 4B is then advanced a predetermined amount and the rod is advanced to force a distal end of the valve 6A from the chamber 76B. The catheter 4B is then moved as necessary so that the protrusions 34 engage the openings 14 in the valve displacer 8 as

25 shown in Fig. 19. The catheter 4B is then withdrawn further so that the support structure 26A expands to the fully deployed position of Fig. 20. The catheter 4B is then removed leaving the cardiac valve 6A as shown in Fig. 20. During the procedure described above, the temporary valve mechanism 40 provides temporary valve functions while the balloon 45 provides pumping assistance as described above.

30 Referring to Figs. 23-30, another system 2C for implanting a cardiac valve 6C is shown. The system 2C includes the valve displacer 8 and delivery catheter 4 described above. The delivery catheter 4 has the balloon 50 for inflating the valve displacer 8, the balloon 52 for inflating a cardiac valve 6C, the temporary valve

mechanism 40 and the balloon 45. The cardiac valve 6C is similar to the cardiac valves 6, 6A except that the cardiac valve 6C has barbs 100 which extend outwardly from the cardiac valve 6C in the expanded condition of Fig. 30. The barbs 100 secure the cardiac valve 6C to the valve displacer 8 or directly to the vessel wall. The cardiac valve 6C has depressions 102 so that the barbs 100 are recessed from an outer surface 104 of the cardiac valve 6C when in the collapsed position of Fig. 29. The depressions 102 prevent the barbs 100 from interfering with smooth retraction of the sheath 10. When the cardiac valve 6C is expanded, the depressions 102 and barbs 100 rotate and move outwardly to engage the valve displacer 8 or vessel wall.

The system 2C is introduced into the patient in any manner described above and Fig. 23 shows the delivery catheter 4 passing through the femoral artery. The valve displacer 8 is deployed in the manner described above wherein the valve displacer 8 is introduced into the valve leaflets and expanded with the balloon 50 to hold the native leaflets open as shown in Fig. 24. The delivery catheter 4 may then be advanced so that the cardiac valve 6C is expanded in the valve displacer 8 with the barbs 100 passing into the openings 14 to secure the cardiac valve 6C to the valve displacer 8 as shown in Figs. 25 and 26. The barbs 100 may be long enough to pierce and anchor in the native valve leaflets or may be designed to merely pass into and engage the sides of the openings 14.

The term "cardiac valve" as used herein refers to a valve which substantially replaces the function of the patient's malfunctioning cardiac valve. The valve may be positioned in the native valve position or may be positioned in a different location while still substantially performing the functions of the native valve. For example, a replacement aortic valve may be positioned superior to the coronary ostia, in the aortic arch or in the descending aorta. Such a replacement valve will substantially function like the patient's native aortic valve. Referring to Figs. 27 and 28 the cardiac valve 6C is deployed in the ascending and descending aorta with the barbs 100 securing the cardiac valve 6C directly to the vessel wall.

Referring to Figs. 31-38 another system 2D for introducing a valve 6D is shown wherein similar or the same reference numbers refer to similar or the same structure. The valve 6D is coupled to a valve displacer 8D prior to introduction into the patient. The valve 6D has an expandable support structure 26D which is movable from the collapsed position of Figs. 36 and 37 to the expanded position of Figs. 34

and 35. The support structure 26D has flexible joints 106 which bend to radially collapse the support structure 26D. The support structure 26D has protrusions 34D which engage holes 108 in the valve displacer 8D. The valve 6D and valve displacer 8D may engage one another in any other suitable manner.

5 The valve 6D is inverted before being attached to the valve displacer 8D as shown in Fig. 35. A number of sutures 110, preferably three, are then passed through the valve 6D. The sutures 110 are used to invert the valve after introduction into the patient as will be explained below. The valve 6D may be any of the valves described herein or any other suitable valve without departing from the scope of the invention.

10 A circumferential ring 111 extends around the support structure 26D. The ring 111 is preferably made of stainless steel or shape-memory alloy such as nitinol and provides circumferential support of the valve against the aortic wall for hemostasis.

 The valve displacer 8D is mounted to a delivery catheter 4D having a balloon 112 for expanding the valve displacer 8D and valve 6D. The balloon 112 is coupled

15 to a source of inflation fluid 114 (Fig. 31) for inflating the balloon 112. The catheter 4D passes through a trocar 116 having a hemostasis valve 117. The sutures 110 and the catheter 4D pass through the hemostasis valve which permits slidable movements of the sutures 110 and catheter 4D.

 The valve 6D is preferably stored in a preservative solution until just before

20 the procedure as shown in Fig. 34. The valve is then inverted as shown in Fig. 35 and the sutures 110 are passed through the valve 6D. The valve 6D is then attached to the valve displacer 8D as shown in Fig. 37 and mounted to the delivery catheter 4D.

 The valve 6D may be delivered in any manner described above and is preferably introduced through an incision in the patient's chest. Referring to Figs. 31

25 and 32, the trocar 116 is introduced into the ascending aorta through purse-string sutures (not shown). The trocar 116 may have a chamber (not shown) in which the valve 6D is positioned when the trocar 116 is introduced into the ascending aorta. The sheath 10 (see Figs. 1A, 1B and 2) described above may also be used to prevent contact between the valve and trocar and between the valve and the aortic wall. The

30 valve 6D is preferably introduced with the patient's heart beating but may also be implanted with the patient's heart stopped and the patient supported by a bypass system. Although system 2D does not show the balloons 40 and 45, it is understood

that the balloons 40, 45 may also be used with system 2D without departing from the scope of the invention.

After introduction of the trocar 116, the valve 6D is advanced until the valve 6D is between the native valve leaflets. The balloon 112 is then inflated to expand the
5 valve 6D and valve displacer 8D. The catheter 4D is then removed and the sutures 110 are pulled to invert the valve 6D as shown in Fig. 33. An end of each suture 110 is then pulled to remove the sutures 110. The trocar 116 and catheter 4D are then removed leaving the valve 6D (Fig. 38).

Although the foregoing invention has been described by way of illustration and
10 example of preferred embodiments for purposes of clarity and understanding, changes and modifications to the preferred embodiments may be incorporated without departing from the scope of the invention. For example, the native valve may be removed rather than held open with the valve displacer, the replacement cardiac valve may be a completely synthetic or mechanical valve, and the expansion mechanism
15 may be a mechanical mechanism rather than a balloon.

WHAT IS CLAIMED IS:

- 1 1. A method of implanting a cardiac valve, comprising the steps of:
2 introducing a valve and a valve displacer into a patient, the valve and valve
3 displacer being movable from collapsed positions to expanded positions, the valve
4 and valve displacer being introduced into the patient in the collapsed position;
5 positioning the valve displacer between valve leaflets of a native cardiac valve;
6 expanding the valve displacer to the expanded position after the positioning
7 step thereby displacing and holding the valve leaflets in an open position; and
8 securing the valve at a desired location in the patient.

- 1 2. The method of claim 1, wherein:
2 the securing step is carried out with the replacement valve being secured to the
3 valve displacer.

- 1 3 The method of claim 2, wherein:
2 the securing step is carried out with the valve interlocking with the valve
3 displacer.

- 1 4. The method of claim 2, wherein:
2 the securing step is carried out with the valve having sharp elements which
3 penetrate the native valve.

- 1 5. The method of claim 1, wherein:
2 the introducing step is carried out with the valve having a support structure
3 and a valve portion, the support structure being expandable from a collapsed position
4 to an expanded position, the introducing step being carried out with the support
5 structure being in the collapsed position.

- 1 6. The method of claim 1, wherein:
2 the securing step is carried out with the desired valve location being spaced
3 apart from the valve displacer.

- 1 7. The method of claim 6, wherein:
2 the securing step is carried out with the desired location of the valve being
3 between the coronary ostia and the brachiocephalic artery.
- 1 8. The method of claim 1, wherein:
2 the introducing step is carried out with the valve displacer being mounted to a
3 catheter.
- 1 9. The method of claim 8, further comprising the step of:
2 enclosing the valve displacer in a flexible sheath during the introducing step;
3 and
4 uncovering the valve displacer before the expanding step.
- 1 10. The method of claim 8, wherein:
2 the introducing step is carried out with the catheter passing through a
3 penetration in the aortic arch.
- 1 11. The method of claim 8, wherein:
2 the introducing step is carried out through the femoral artery.
- 1 12. The method of claim 1, wherein:
2 the introducing step is carried out with the valve being mounted on a catheter.
- 1 13. The method of claim 8, wherein:
2 the introducing step is carried out with the catheter having an expandable
3 member, the valve displacer being mounted to the expandable member.
- 1 14. The method of claim 12, wherein:
2 the introducing step is carried out with the catheter having a valve mechanism.
- 1 15. The method of claim 12, wherein:

2 the introducing step is carried out with the catheter having a balloon, the
3 balloon being coupled to a control mechanism for inflating and deflating the balloon
4 to provide pumping assistance to the patient's heart.

1 16. The method of claim 1, wherein:
2 the introducing step is carried out with the valve displacer being mounted on a
3 catheter.

1 17. The method of claim 16, wherein:
2 the introducing step is carried out with the catheter having an expandable
3 member, the valve displacer being mounted to the expandable member.

1 18. The method of claim 14, wherein:
2 the introducing step is carried out the valve displacer having an end which
3 flares outwardly when the valve displacer is in the expanded position.

1 19. The method of claim 1, wherein:
2 the introducing step is carried out with the valve displacer having a
3 circumferential recess formed between the first end and a second end.

1 20. The method of claim 1, wherein:
2 the securing step is carried out before the introducing step so that the valve and
3 valve displacement device are introduced together.

1 21. The method of claim 20, further comprising the step of:
2 inverting the valve after the introducing step.

1 22. The method of claim 1, wherein:
2 the valve introducing step is carried out with the valve having an expandable
3 support structure, the expandable support structure having at least three posts
4 extending from the expandable support structure.

1 23. A device for maintaining a patient's native valve leaflets open, comprising:
2 a first end;
3 a second end; and
4 a central section extending between the first and second ends;
5 the first and second ends being flared outwardly from the central section so that the
6 central section forms a recess for receiving the native valve leaflets, the first end,
7 second end and central section forming a structure which is movable from a collapsed
8 condition to an expanded condition.

1 24. The device of claim 23, wherein:
2 the first end, second end and central section are integrally formed.

1 25. The device of claim 23, wherein:
2 the structure is substantially cylindrical in the collapsed condition, the first and
3 second ends flaring outwardly from the central section when the structure is in
4 expanded condition.

1 26. The device of claim 23, wherein:
2 the structure has a circumferential recess for retaining the native valve leaflets,
3 the circumferential recess extending around the central section.

1 27. The device of claim 23, further comprising:
2 a valve portion attached to at least one of the first end, second end and central
3 section, the valve portion permitting blood flow therethrough in one direction and
4 preventing flow in the other direction.

1 28. The device of claim 27, wherein:
2 the valve portion is a tissue valve.

1 29. The device of claim 27, wherein:
2 the valve portion lockingly engages at least one of the first end, second end
3 and central section.

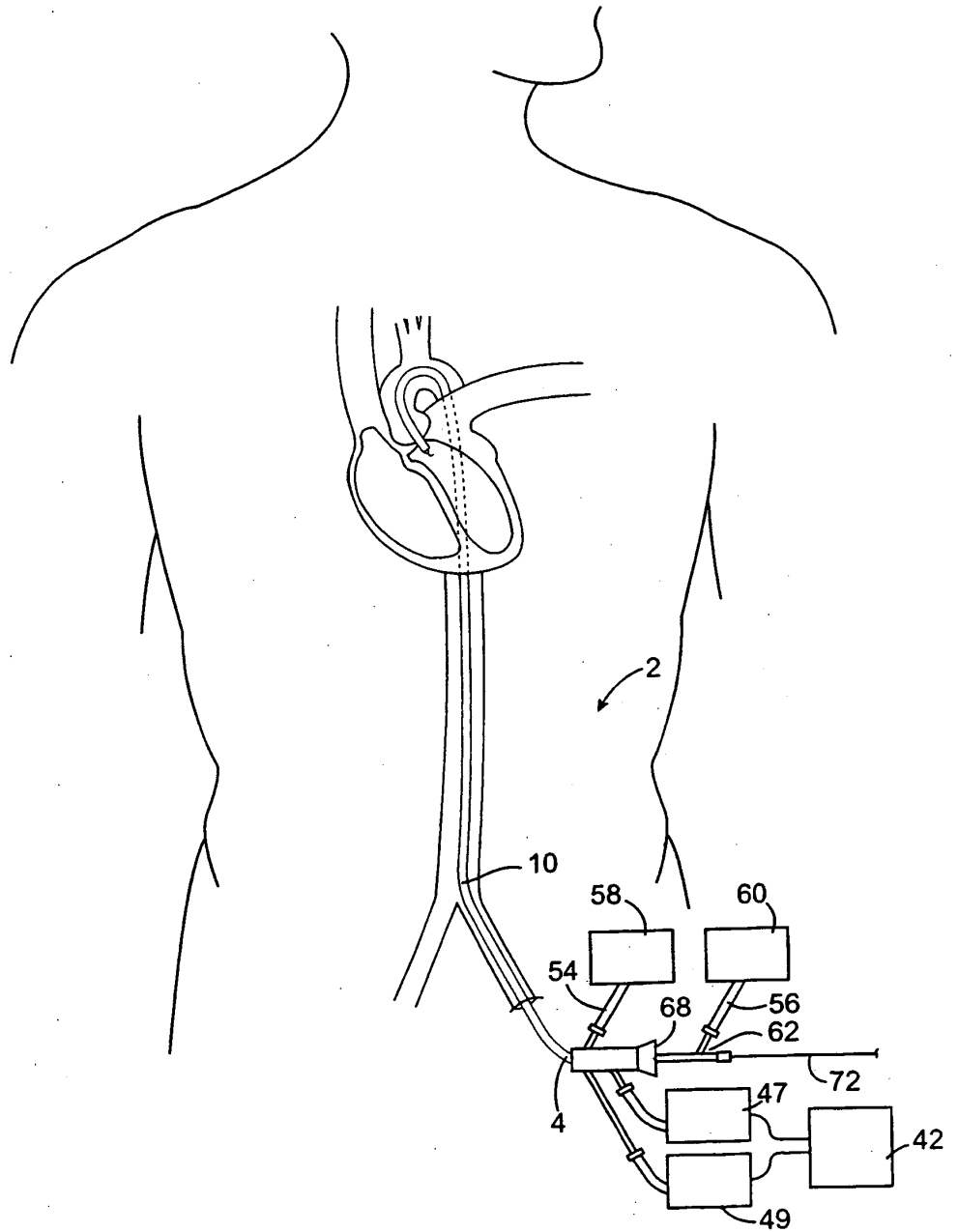


FIG. 1A

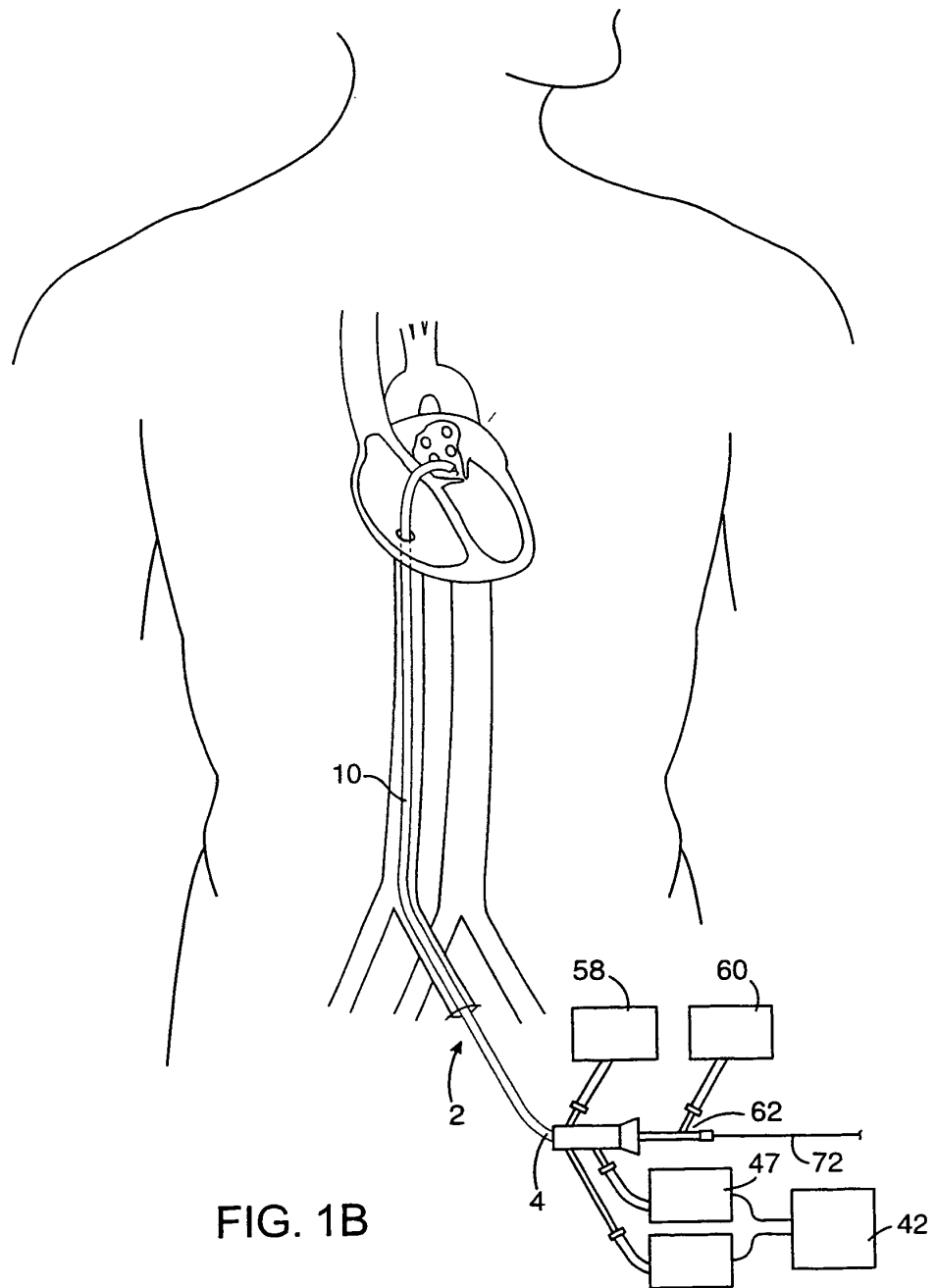
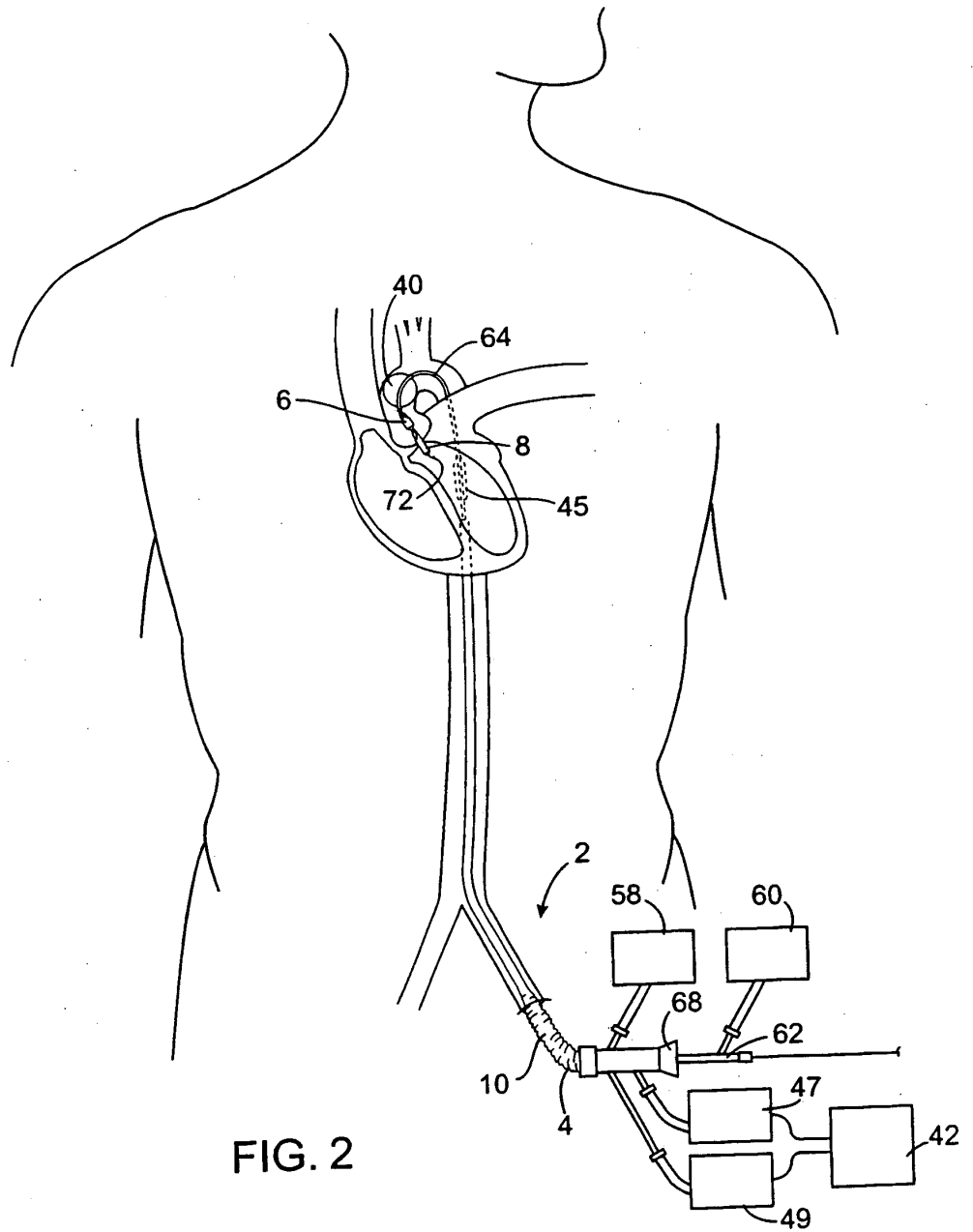


FIG. 1B



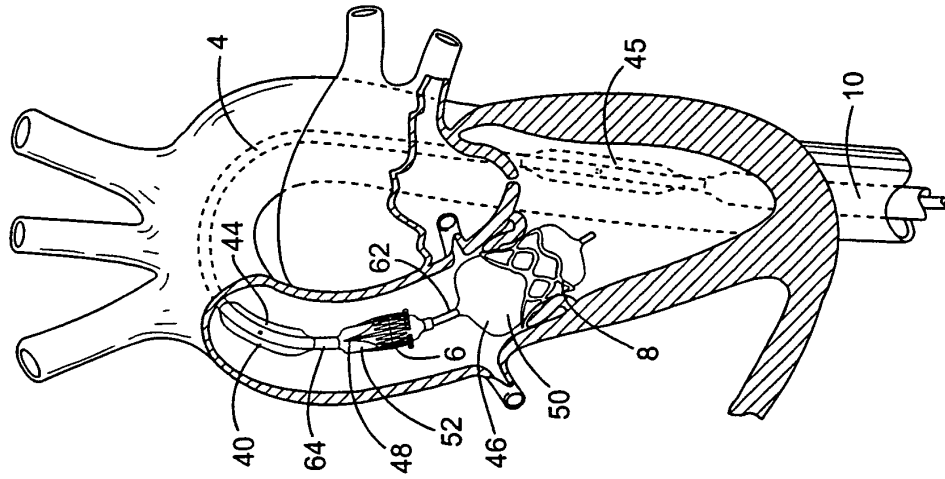


FIG. 4 ✓

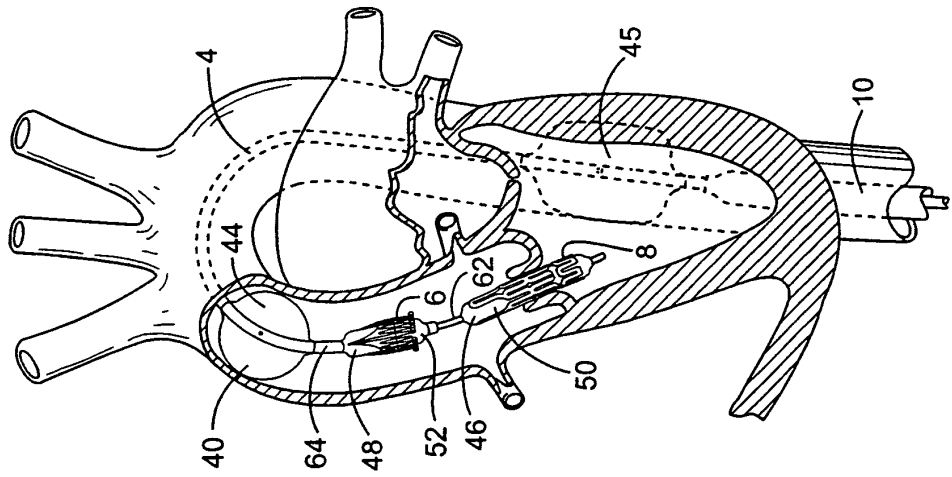


FIG. 3

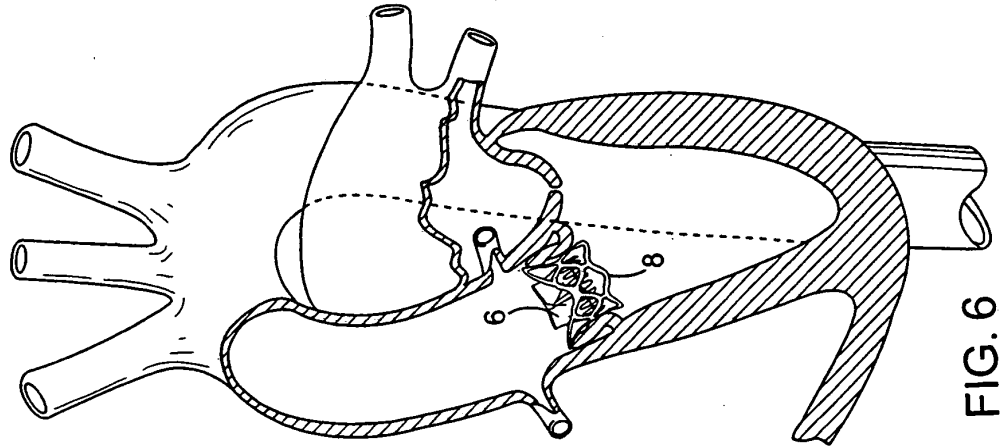


FIG. 6

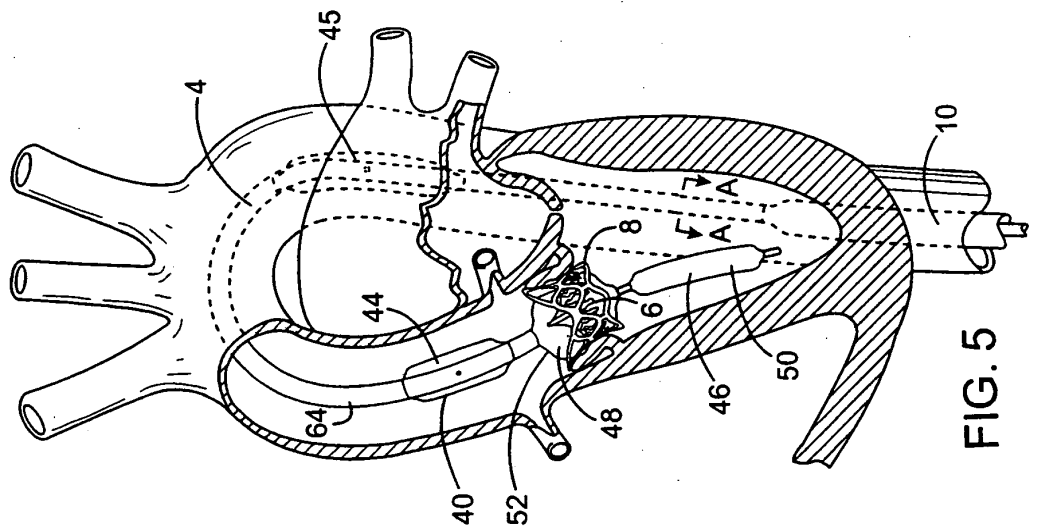


FIG. 5

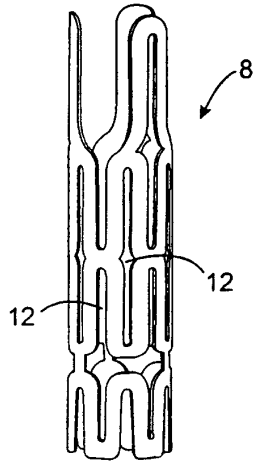


FIG. 7

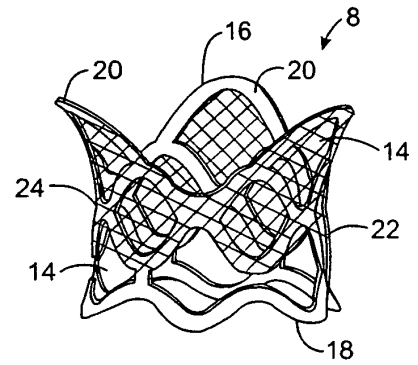


FIG. 8

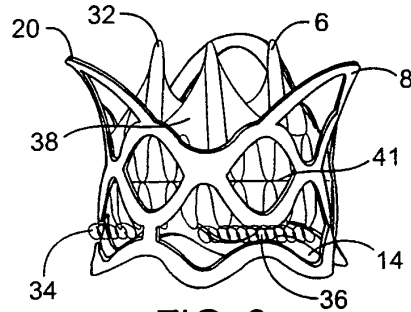


FIG. 9

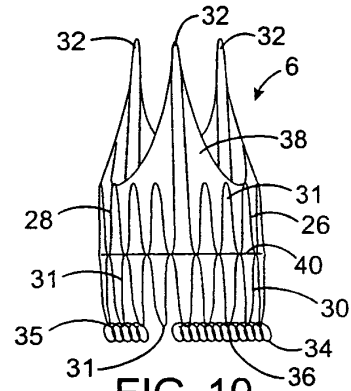


FIG. 10

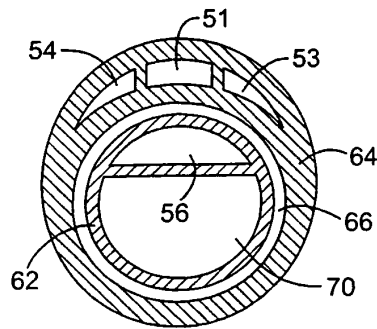


FIG. 12

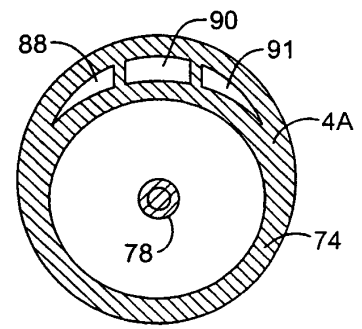


FIG. 15

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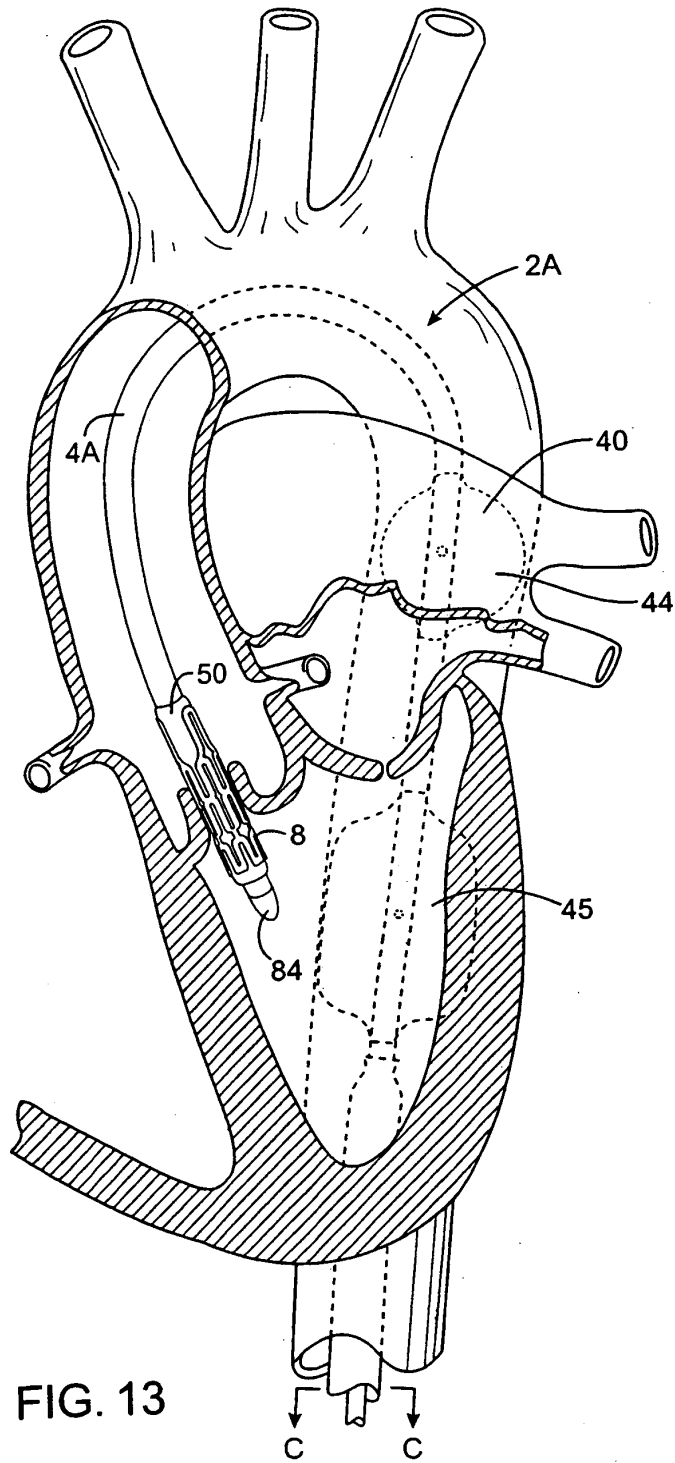


FIG. 13

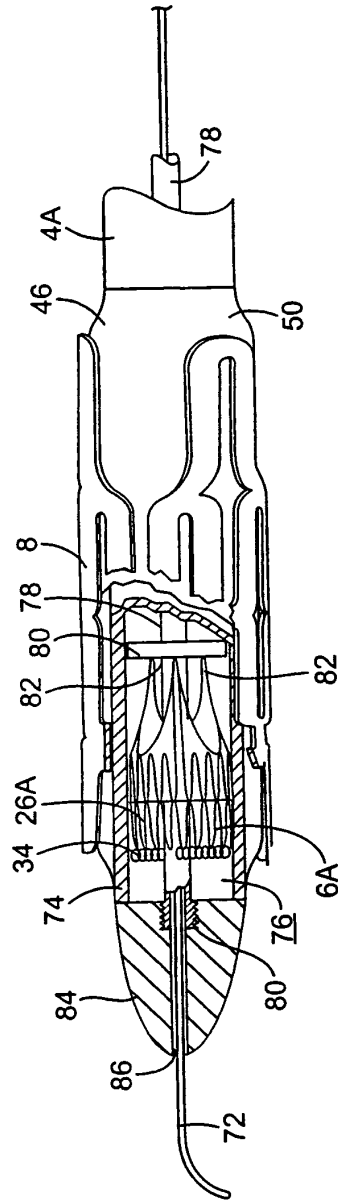


FIG. 14

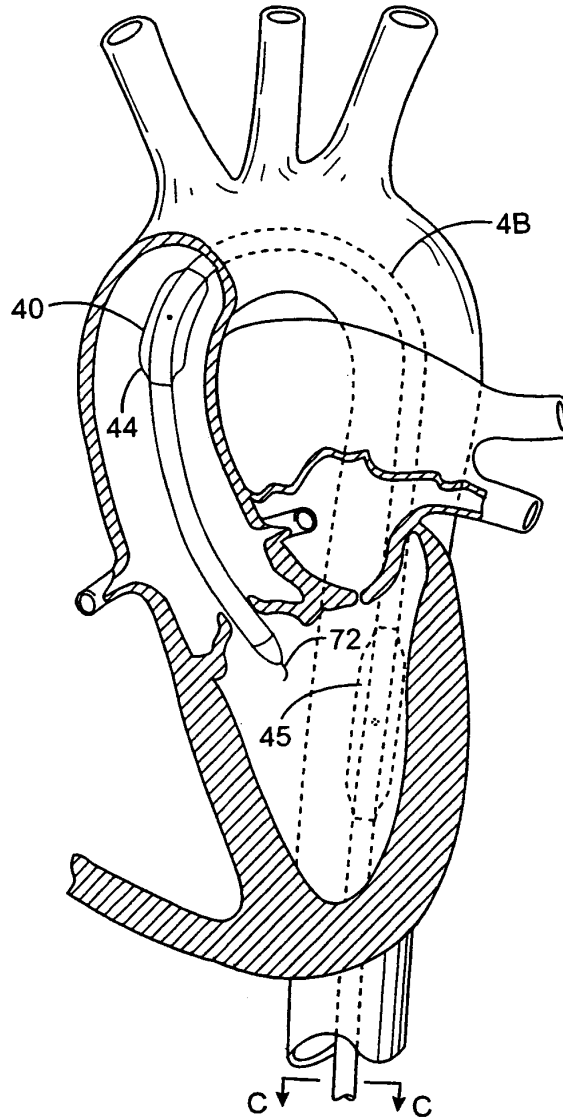
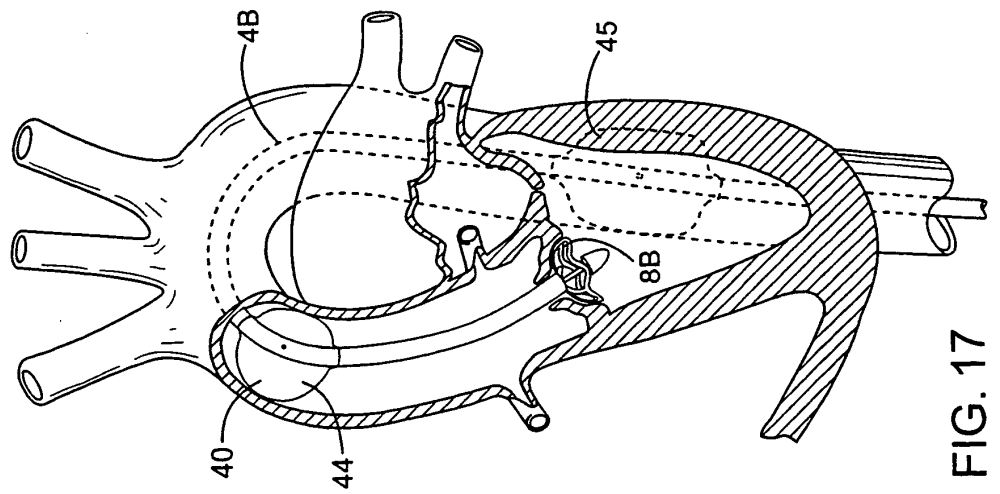
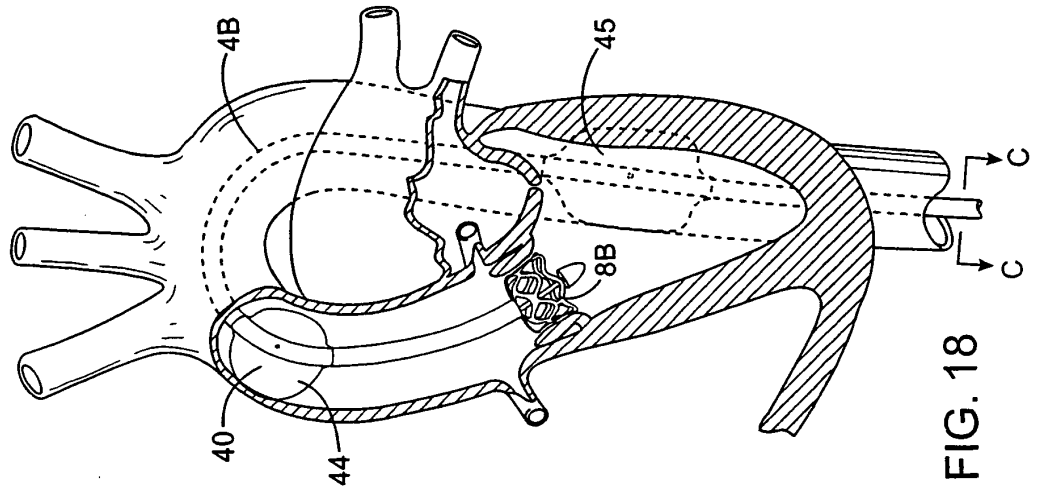


FIG. 16



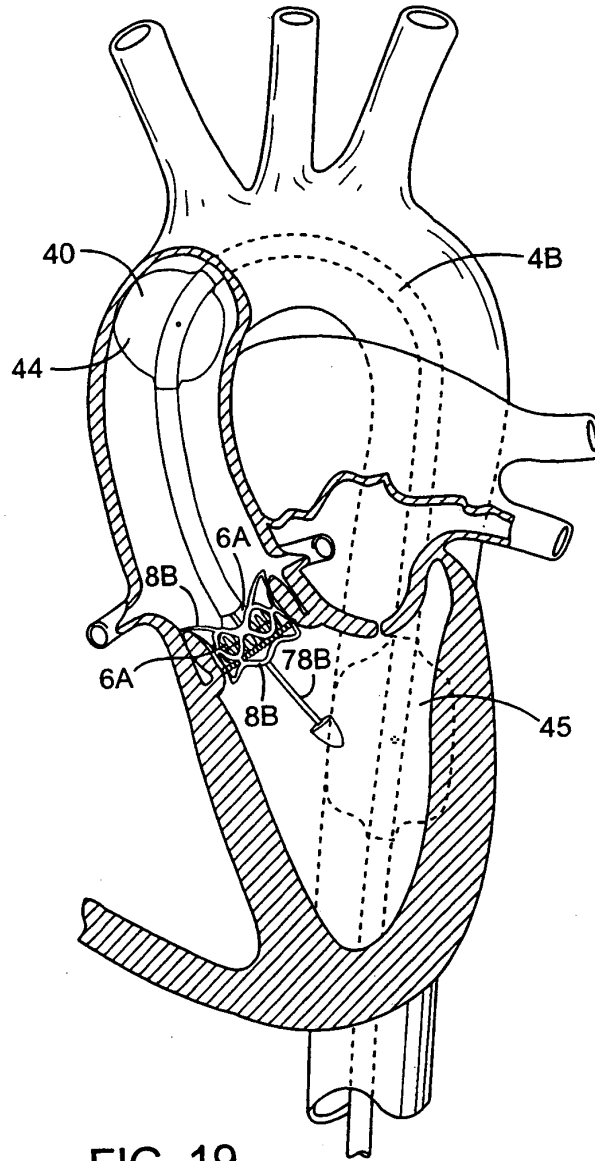


FIG. 19

SUBSTITUTE SHEET (RULE 26)

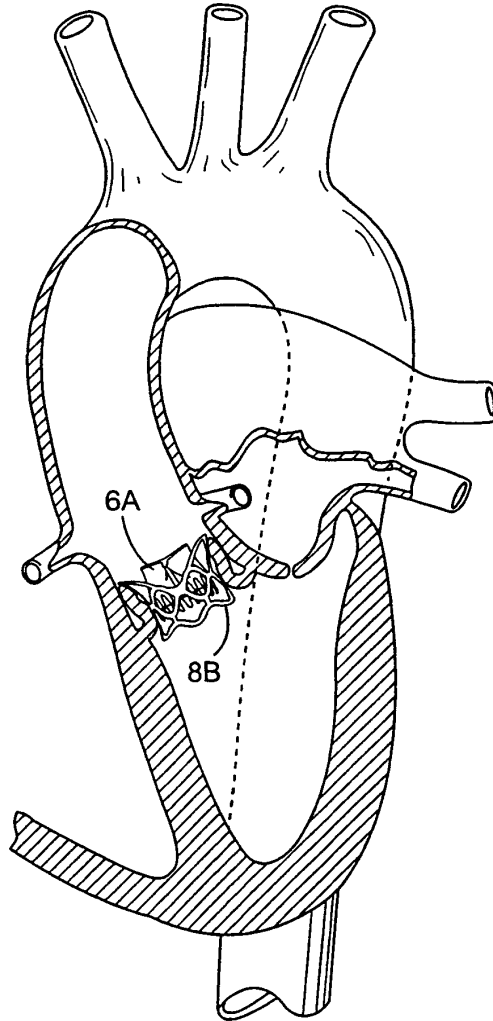


FIG. 20

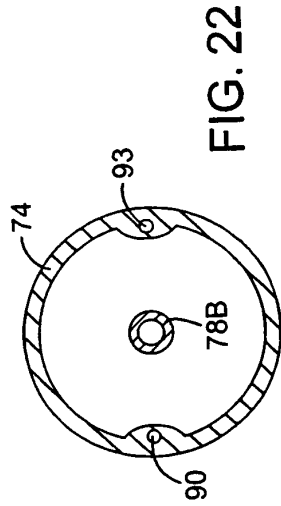


FIG. 22

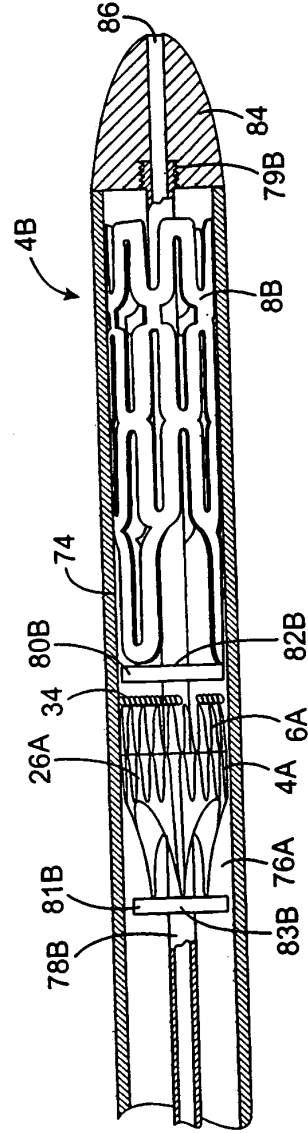


FIG. 21

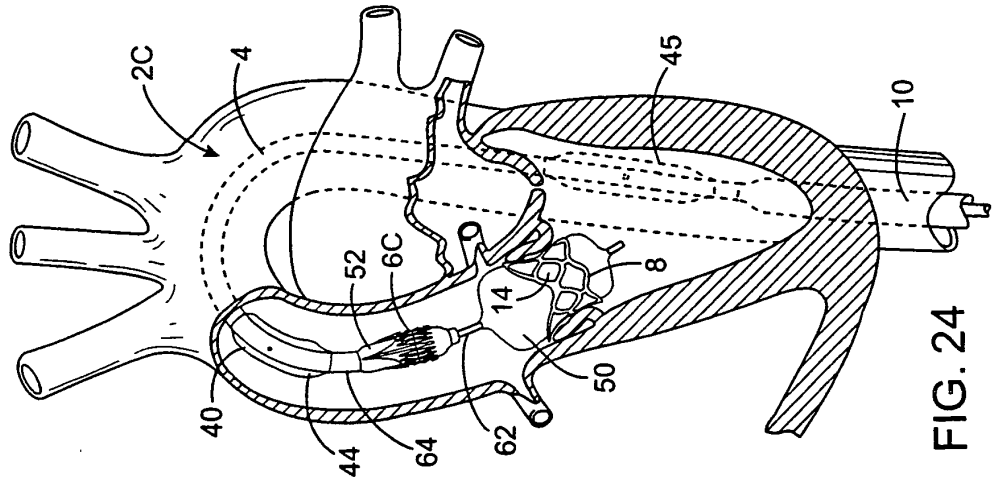


FIG. 24

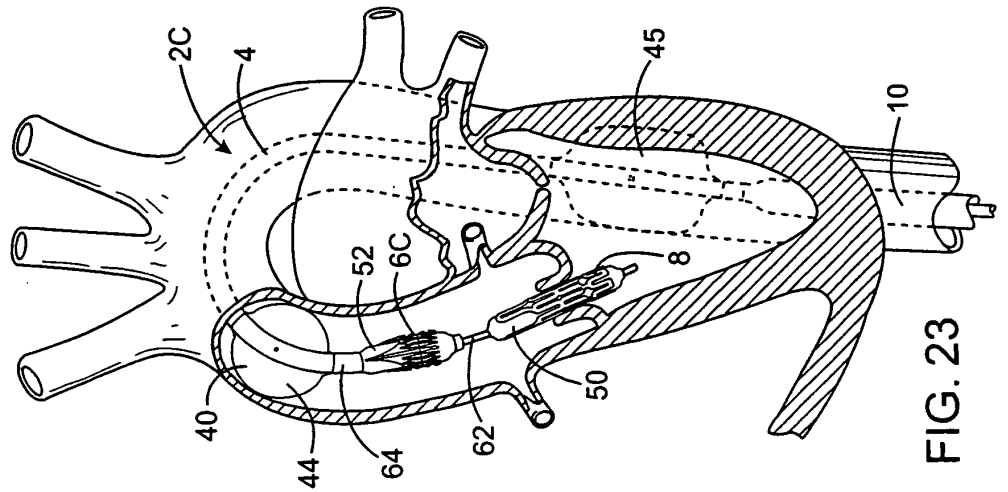


FIG. 23

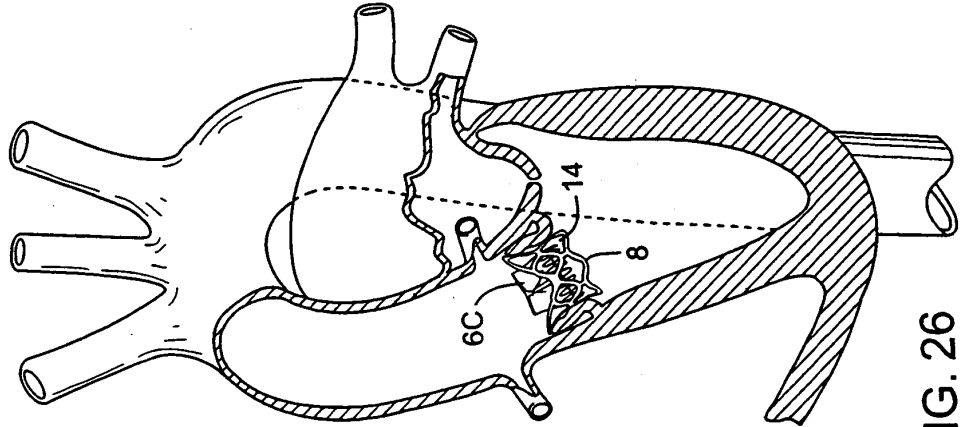


FIG. 26

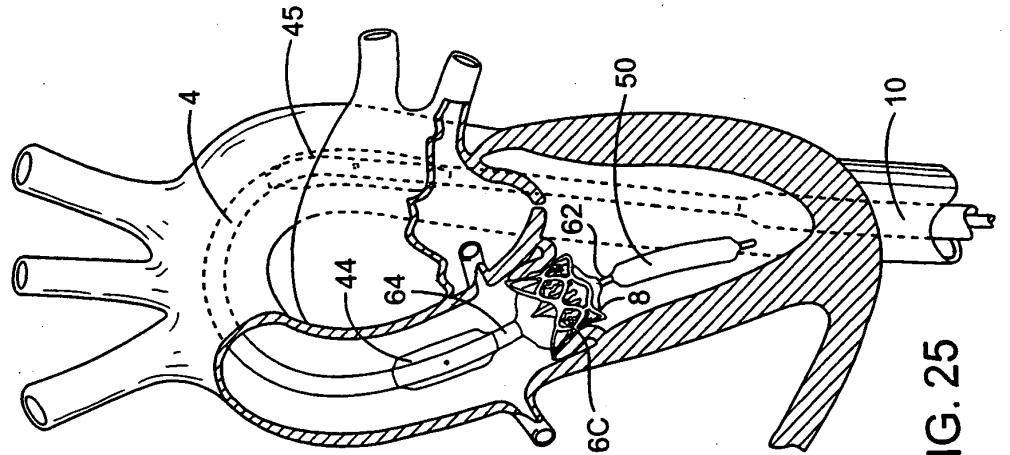


FIG. 25

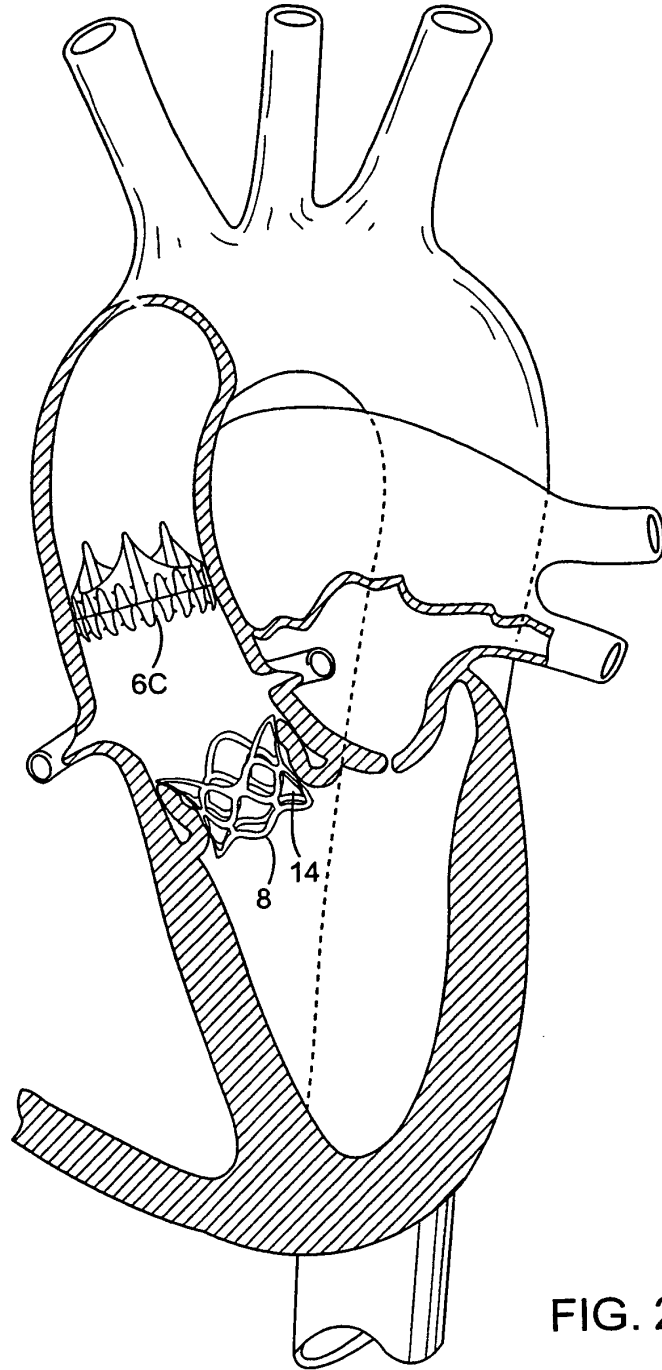


FIG. 27

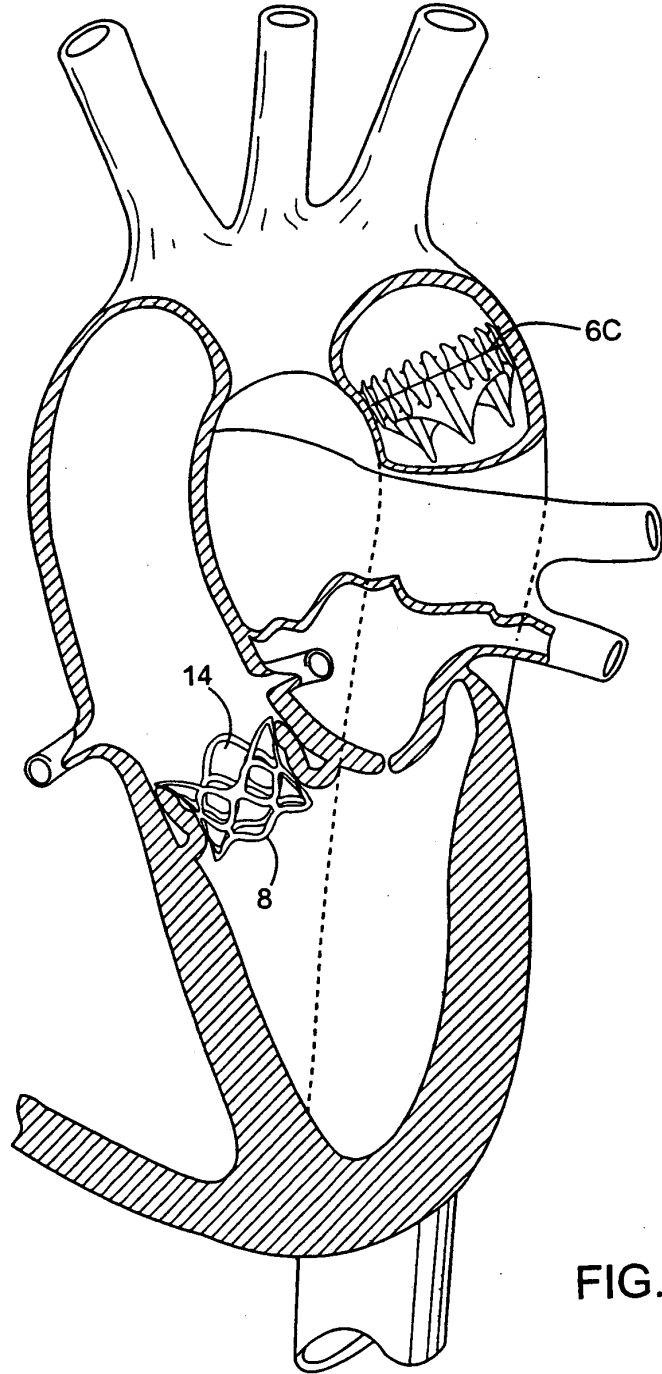


FIG. 28

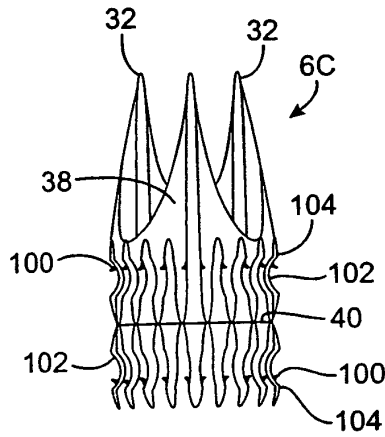


FIG. 29

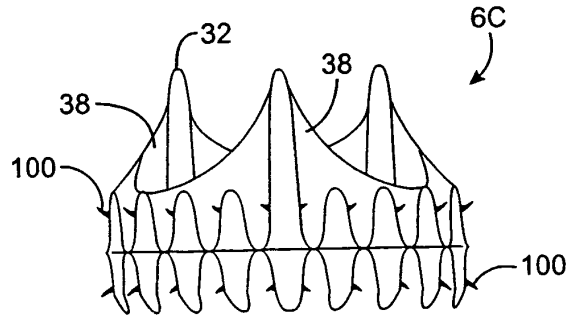


FIG. 30

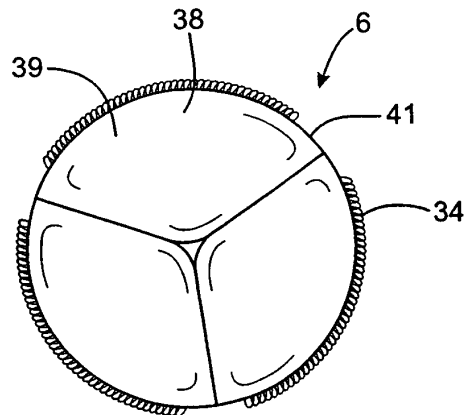


FIG. 11

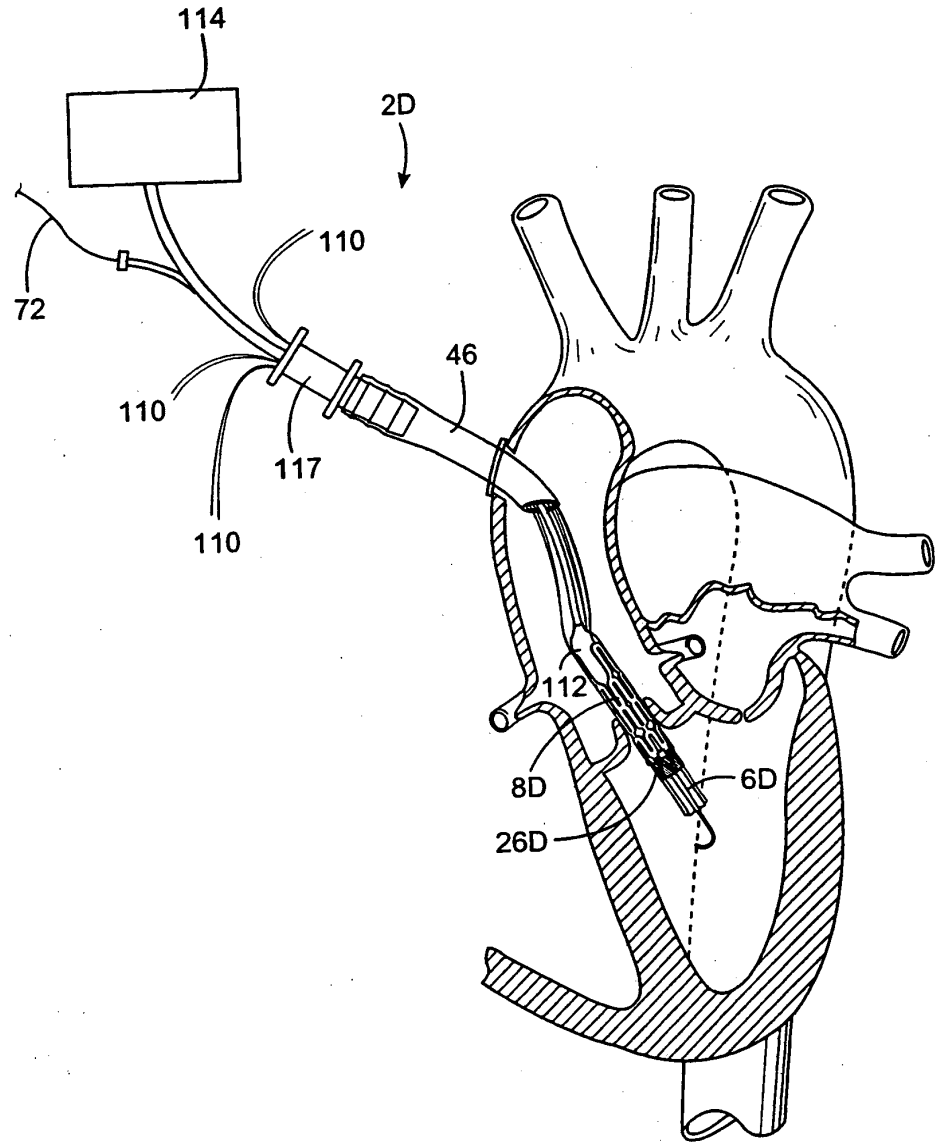


FIG. 31

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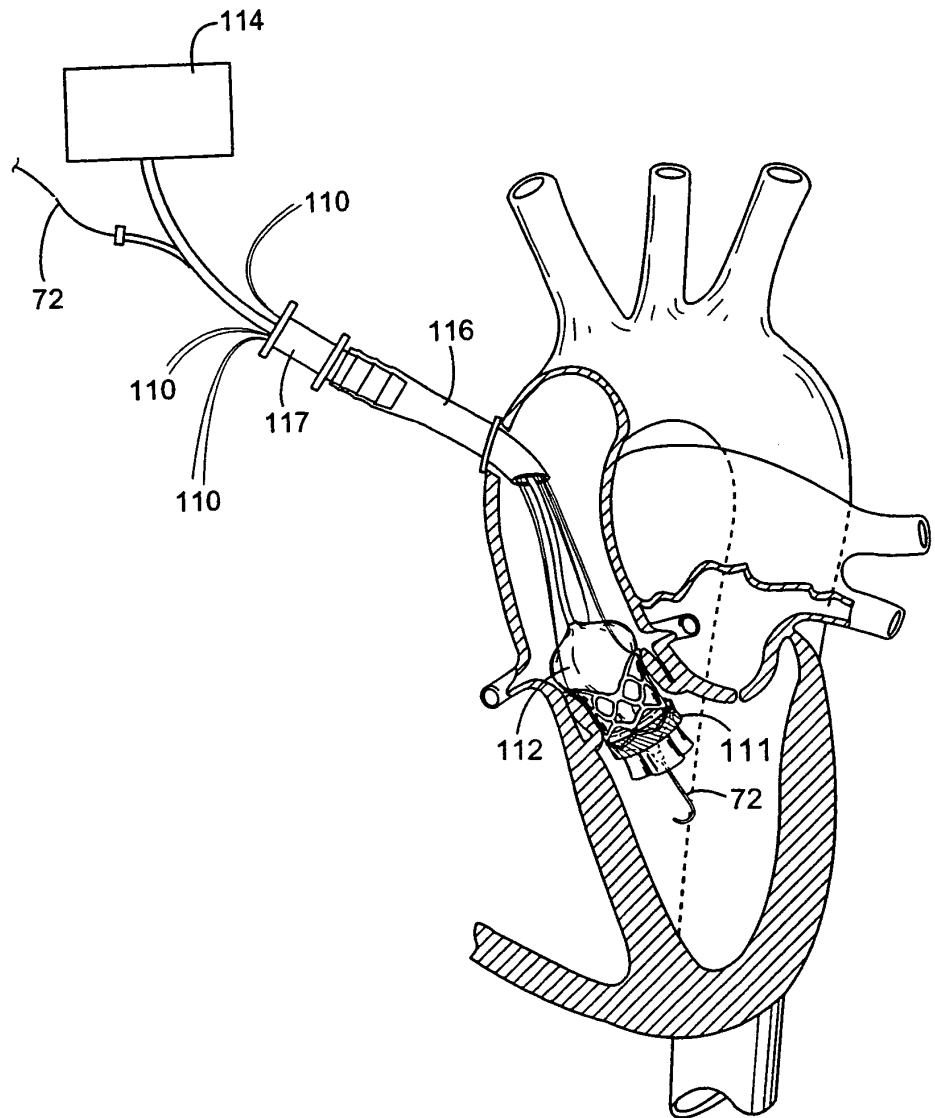


FIG. 32

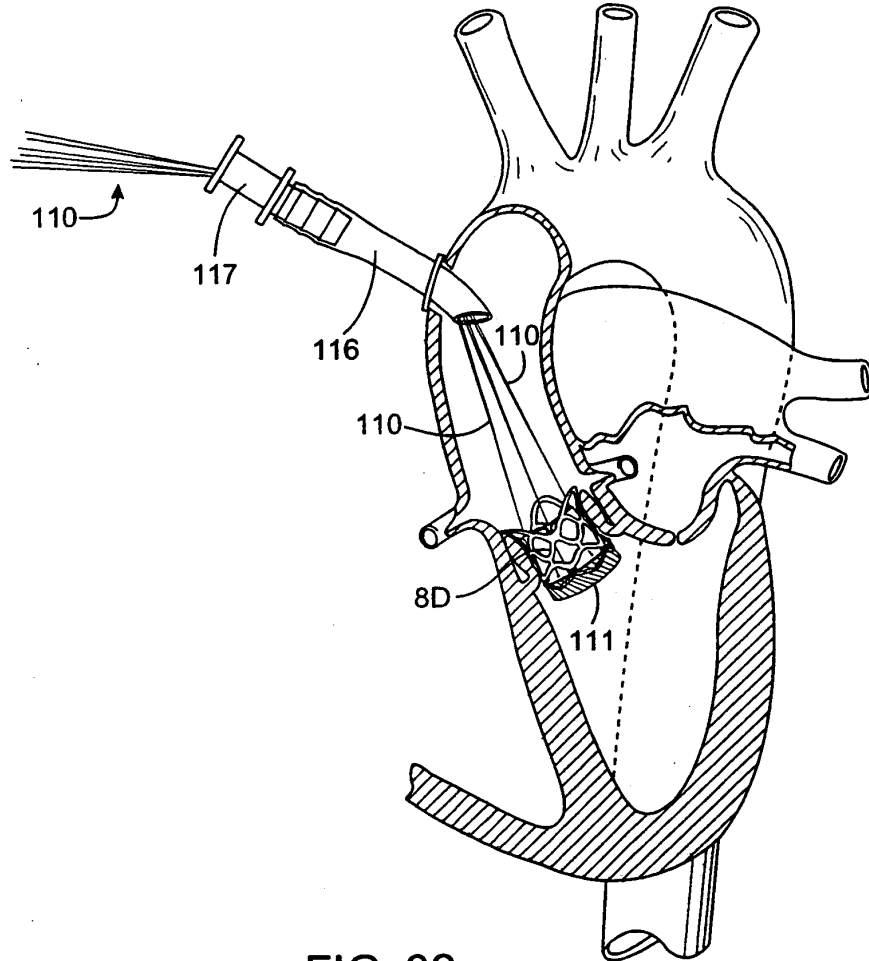


FIG. 33

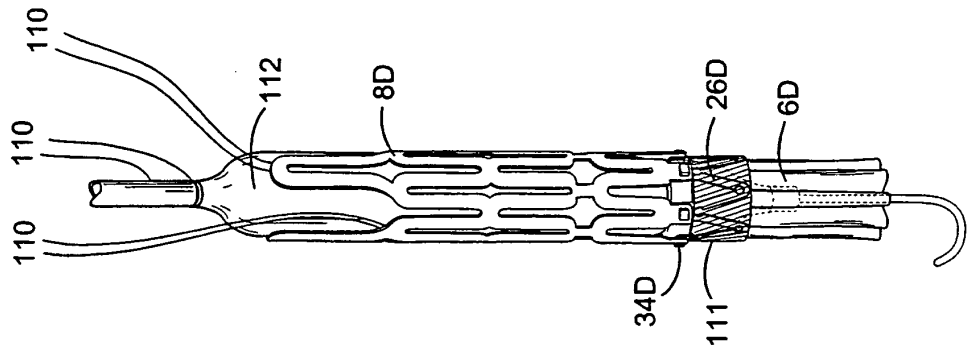


FIG. 37

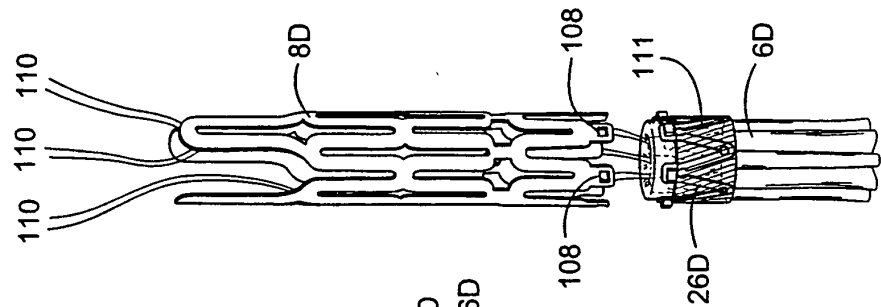


FIG. 36

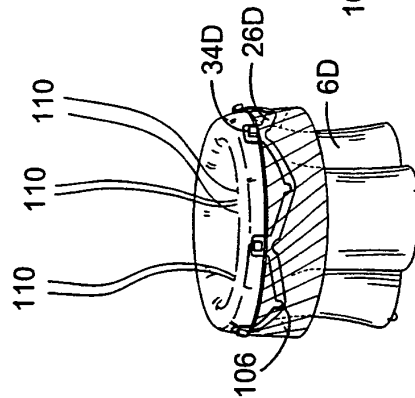


FIG. 35

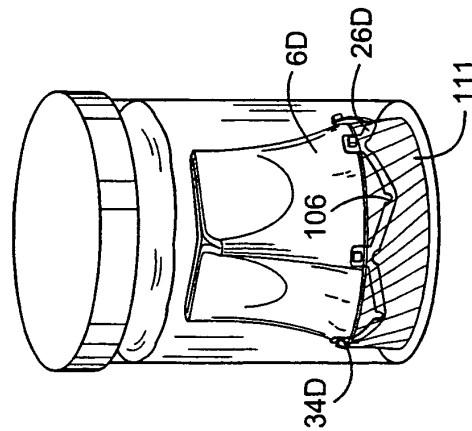


FIG. 34

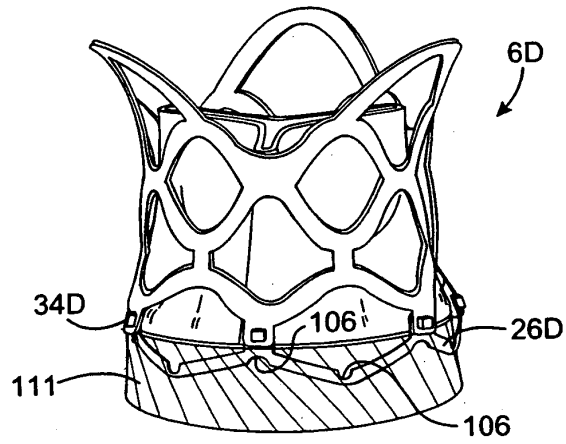


FIG. 38

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/03336

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(7) :A61F 2/24
 US CL :632/1.26, 2.11, 2.18
 According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
 Minimum documentation searched (classification system followed by classification symbols)
 U.S. : 632/1.24, 1.26, 2.11, 2.18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	EP 0 850 607 A (LETAC, et al.) 01 July 1998, entire document.	1-3, 5, 8, 11-20, 22-29 ----- 4, 6, 7, 9, 10, 21

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 05 APRIL 2000	Date of mailing of the international search report 03 MAY 2000
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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer <i>David Willuse</i> DAVID WILUSE Telephone No. (703) 308-2903
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Form PCT/ISA/210 (second sheet) (July 1998)*
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(19) World Intellectual Property Organization
International Bureau



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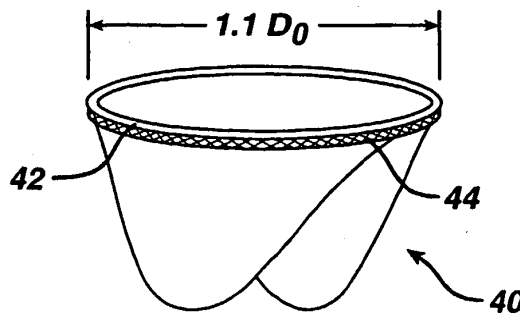
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(54) Title: RADIALLY EXPANDABLE ENDOPROSTHESIS DEVICE WITH TWO-STAGE DEPLOYMENT

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(57) Abstract: A radially expandable endoprosthesis device with a valve prosthesis (40) having a two-stage deployment capability. The valve prosthesis (40) includes a ring construction or annulus (42) made of a superelastic alloy with a bioresorbable material coating (44) thereon. The superelastic alloy and bioresorbable material (44) can be used to adjust the size of the valve prosthesis (40) in response to the growth of a pediatric patient.

5 **RADIALLY EXPANDABLE ENDOPROSTHESIS DEVICE
 WITH TWO-STAGE DEPLOYMENT**

BACKGROUND OF THE INVENTION

1. Field of the Invention

10 The present invention relates to a radially expandable endoprosthesis device with an at
least two stage deployment capability and, more particularly, pertains to an annularly
expandable heart valve prosthesis which is adapted for the long-term treatment of
valvular diseases in infants, children and adolescents.

15 Basically, radially expandable endoprosthesis devices are employed in connection with
the insertion and positioning of stents or stent-grafts into corporeal vessels, such as
arteries or the like, and generally are constituted of stainless steel or nitinol (nickel-
titanium alloy) or similar alloys. In the instance in which an endoprosthesis employed as
20 a stent, it is adapted to counteract acute vessel spasms which are frequently encountered
in the emplacement of nitinol (nickel-titanium alloy) stents in arteries or body vessels.
In coronary arteries, any secondary enlargement of the stent would be adapted to serve
for offsetting contractile forces which may result from intimal hyperplasia; however, the
prior art pursuant to the state of the technology, does not address itself to this aspect.
25 When employed in connection with abdominal aortic aneurysms (AAA), current stent-
graft devices merely concern themselves with anchoring devices the stent-graft in its
location of emplacement.

Heretofore, in the prior art, the problems encountered the use of such endoprosthesis devices have been addressed by various methods and physical and biological means. Thus, in intimal hyperplasia of coronary arteries, additional angioplasty, or in the use of chemicals and pharmaceutical preparates, such as various drugs or radio-isotopes, these
5 may be readily employed in order to attempt to reduce the hyperplasia. Furthermore, the emplacement of external bands around abdominal aortic aneurysms (AAA) which are treated with stent-grafts has also been employed in order to account for any aneurysmal progression which may occur at a site which has been thought to be free of disease. When employed in pediatric heart valve disease cases, secondary surgeries are
10 frequently needed in order to replace the smaller-sized valve prosthesis as the infant or child grows, as a result of an increase in the heart valve sizes requiring larger-sized prosthesis, this being at times the cause of severe discomfort, and even morbidity and increased morbidity rates for such tender patients.

15 **2. Discussion of the Prior Art**

As disclosed in Duerig et al. U.S. Patent No. 6,179,878, a composite self-expanding stent device incorporates a restraining element, in which a restraint sleeve is generally formed of a shape memory alloy, such as binary nickel titanium alloy, referred to generally as nitinol, and wherein restraint can be provided in the form of either sleeve,
20 covering a mesh or perforated sheet. In that instance, the restraining element can be formed of a polymeric material which, in any event is not considered to be possessed of a property to enable the stent device to undergo multiple dimensionally changing

configurations at predetermined intervals in time so as provided a device with an at least two-stage deployment in a patient.

Lenker et al. U.S. Patent No. 6,176,875 discloses an endoluminal prosthesis and
5 methods in the use thereof, which provides for limited radial expansion in controlled mode. However, the stent-graft construction illustrated and described therein is primarily equipped with a belt which may frangible or expansible in order to allow for further or subsequent expansion of the implanted or emplaced stent-graft device. This device also fails to provide for a combination of super-elastic shape memory alloys such
10 as nitinol, and bioresorbable medical materials which enable the devices to undergo at least a two-stage or multiple displacement stages at predetermined intervals in time.

Finally, Lock et al. U.S. Patent No. 5,383,926 discloses an expandable endoprosthesis device which is constituted of the combination of a memory alloy, possibly such as
15 nitinol, with an expansion limiting structure which is selectively removable in order to subsequently allow for further radial expansion of the emplaced device, whereby the expansion limiting structure can be constituted of a dissolvable or severable band-like material. Although this endoprosthesis device may generally incorporate bioresorbable materials, the device described in this patent is not adapted for heart valve prostheses,
20 particularly such as are intended for pediatric applications, which will enable the treatment of valvular diseases in children, whereby the annulus of the heart valve prosthesis can be caused over periods of time to expand as the child grows, thereby

obviating the need for further surgical procedures normally required in order to substitute larger-sized heart valve prosthesis structures or devices in the growing patients.

5 **SUMMARY OF THE INVENTION**

Accordingly, in order to provide an endoprosthesis device which is adapted to essentially provide for a multi-stage deployment and which facilitates a radially and annular expansion which may be required during continual use thereof, the inventive device, such as a stent, stent-graft, or pursuant to a preferred embodiment, a heart valve
10 prosthesis particularly for pediatric case is drawn to a novel combination of super-elastic or shape memory alloys and bioresorbable materials, which enables the devices to undergo multiple or at least two-stage configurations at predetermined time intervals depending upon the type of material employed in conformance with the needs of patients in which the devices are deployed. The bioresorbable materials may also serve
15 as reservoirs for therapeutic agents, such as antibiotics, anticoagulants, and cytostatic drugs.

In one aspect, the device may comprise a coronary stent which is capable of having at least one deployment stage, and that is constituted of a superelastic material with a
20 bioresorbable coating or constraint structure operatively combined therewith. This type of stent may be suitable for counteracting or addressing problems relative to initial hyperplasia when utilized in coronary vessels, and can also be employed for the

stenting of other body vessels subjected to abdominal aortic aneurysms (AAA) when there is encountered the need to maintain contact with a dynamic vessel wall of a body vessel or lumen. In those last-mentioned instances, a stent for the counteracting the effects of the aneurysms, when constituted of the combination of superelastic alloys and
5 bioresorbable materials can offset post-deployment aneurismal dilatation.

In a particularly preferred embodiment of the invention, the endoprosthesis device, which is constituted of a combination of a superelastic alloy and bioresorbable material, is in the configuration of a heart valve prosthesis especially adapted for
10 pediatric medical uses, and which can be made to expand in at least two-steps of its deployment as the infant or child grows, over an extended period of time. In that connection, the endoprosthesis device may be constructed so as to incorporate various types of polymer systems in order to afford multiple stage deployments, wherein particular types of polymers may degrade at time intervals of, for example, ranging
15 from about 6 months to about 200 months after the implanting of the device in the pediatric patient. In particular, such a system is useful in long-term heart valve prostheses, whereas contrastingly another system may utilize a polymer which absorbs in 15 minutes and which is useful in implanting anastomotic devices.

20 Accordingly, it is a primary object of the present invention to provide an endoprosthesis device which is constituted of a combination of superelastic alloys and bioresorbable

materials which facilitates the devices to undergo multistage deployments at predetermined intervals while emplaced in the body vessels or lumens of patients.

Another object of the present invention is to provide an endoprosthesis device as
5 described herein, wherein the device may undergo at least two-stage deployment so as to assume different or expanded annular or radial dimensions at predetermined time intervals responsive to degradation of bioresorbable components of the device which have been combined with a superelastic alloy.

10 A more specific object of the present invention is to provide an endoprosthesis device which is constituted of a heart valve prosthesis for pediatric medical applications, wherein the annulus of the valve prosthesis can be constructed so as to expand in at least two stages of deployment over periods of time during the growth of an infant or
15 child, and wherein the device is constituted of a novel combination of superelastic alloy-materials and bioresorbable materials preferably selected from polymer systems.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Reference may now be made to the following detailed description of embodiments of the invention, taken in conjunction with the accompanying drawings; in which:

20 Figures 1a - 1d disclose, generally diagrammatically, cross-sectional transverse views in the stages of deployment of a coronary stent constituted of a superelastic alloy

combined with a bioresorbable restraining polymer which addresses itself to counteracting the effects of stenosis due to intimal hyperplasia;

Figures 2a - 2d illustrate; diagrammatically in longitudinal sectional views, various stages as to the manner in which a stent comprised of a superelastic alloy and
5 bioresorbable material can offset post-deployment residual aneurysmal dilation encountered which may be at the neck of a stent-graft used for abdominal aortic aneurysms (AAA); and

Figures 3a and 3b illustrate, respectively, the two-stage deployment offered by the construction of the endoprosthesis device as a heart valve possessing an expandable
10 annular ring or neck portion, and which is especially adapted for use in long-term pediatric medical applications.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

15 Reverting more specifically to Figures 1a through 1d of the drawings; Figure 1a illustrates a transverse cross-sectional view through a coronary artery 10 in the pre-stenting stage; showing the interior buildup of plaque 12 along the artery wall 14.

20 Figure 1b illustrates the artery 10 shown in a post-stenting stage wherein there is illustrated a stent 16 forming a wall interiorly of the plaque 12 and vessel or coronary artery wall 14; whereby as shown in Figure 1c there may be encountered in-stent restenosis caused by intimal hyperplasia tending to occlude the artery.

- In contrast with the foregoing, Figure 1d illustrates a stent 20 pursuant to the inventive construction incorporates the combination of a suitable bioresorbable restraining polymer 22 with a superelastic alloy 24 on which it may be coated, such as nitinol (nickel-titanium alloy) or the like which may address the effects of intimal hyperplasia.
- 5 In particular, the secondary radially expanded deployment of the stent 20 as a result of the gradual absorption or degradation of the bioresorbable restraining polymer 22 which allows the superelastic alloy the freedom to expand, provides for an effective lumen or blood flow increase; whereby the body vessel diameter itself may increase only slightly.
- 10 The bioresorbable restraining polymers which may be employed in this connection may be PLA-PGA copolymer systems, polytyrosine systems, or other suitable polymer systems which can be modified to afford different absorption rates and degrading stages. It is also possible to use two different bioresorbable polymer systems in combination with each other (and with the superelastic alloy) which afford further
- 15 secondary and tertiary deployment stages to the implanted device.

Referring to Figures 2a through 2d of the drawings, in Figure 2a there is illustrated a bifurcated blood vessel comprising aortic portion 24 extending between the heart and a pair of iliac branches 26a, 26b showing an abdominal aortic aneurysm 28 prior to

20 stenting. As illustrated in Figure 2b, a suitable abdominal aortic aneurysm (AAA) stent or bifurcated aorto-iliac vascular prosthesis 30 which is constituted of the combination of the superelastic alloy material and bioresorbable polymers system or systems, which

may be in the form of a stent-graft construction possesses suitable anastomosis devices (not shown) adapted to exclude the aneurysm, is deployed in the body vessel or lumen.

As illustrated in Figure 2c of the drawings, in the event that the stent-graft structure
5 does not include the bioresorbable materials, the device fails to exclude the aneurysm as a result of encountered post-deployment dilatation of the proximal neck 30a of the device; whereas contrastingly by utilizing the combined materials, such as the superelastic alloy and bioresorbable polymers of the invention, as shown in Figure 2d of the drawings, the resorption and degradation over time of the polymer material allows
10 the stent-graft to enter a second stage of an additional expansion, thereby forming a protection against the aneurysm and any potential failure of the implanted stent-graft structure or device.

Reverting to the preferred embodiment of the invention, as illustrated in Figures 3a and
15 3b of the drawings, this diagrammatically discloses a heart valve prosthetic device 40 which is particularly adapted for pediatric applications with infants, children or adolescents who are still subject to growth in heart and heart valve dimensions over protracted periods of time.

20 As shown in Figure 3a, the valve prosthesis 40 includes a ring construction or annulus 42 constituted in combination of a superelastic alloy, such as nitinol or the like, and a bioresorbable material 44 coated thereon which is adjusted for the growth of a pediatric

patient. As implemented, the system of the material 44 utilizes a bioresorbable restraining polymer in combination with the superelastic alloy material 42, such as a PLA-PGA copolymer system, polytyrosine system, or other suitable polymer system or combinations thereof, which can be suitably modified for different absorption rates, such as by degrading, for example, at time intervals ranging from between about 6 months to 200 months, so as to allow for the second-stage in expansion of the prosthesis. As indicated, combinations of two different polymer systems can be employed to afford secondary and tertiary deployment stages at specified time intervals.

Thus, as shown in Figure 3a of the drawings, the annulus of the device as initially implanted in a child, for example of 2 years in age, may possess a ring or neck diameter D_0 constituted of a prosthesis of a nitinol ring 42 coated with the polymer system 44.

The secondary expansion, as shown in Figure 3b, which is permitted by the present system, shows the heart valve prosthesis with a diameter of at least $1.1 D_0$ expanded as a result of the polymer absorption, thereby enabling the valve device to be deployed in the body vessel or heart valve of the pediatric patient for extended periods of time during the growth of the patient, without necessitating further surgery for removal of the initial smaller device and substitution of a larger-sized heart valve device. This clearly lowers the risk of possible morbidity or complications due to any second surgical

procedure which have been required for the installation of a larger valve pursuant to the current state in the medical technology.

From the foregoing, it becomes clearly apparent that the invention, wherein in particular
5 a pediatric heart valve prosthesis is constituted of the combination of superelastic alloy,
such as nitinol or the like, and bioresorbable materials comprising various polymers or
polymer systems, counteracts deleterious or natural phenomena which may otherwise
compromise the performance and efficacy of a two-stage deployable endoprosthetic
device which is merely constituted of a superelastic alloy material without resorbable
10 biological materials forming restraining elements degradable over specified periods of
time.

While the invention has been particularly shown and described with respect to preferred
embodiments thereof, it will be understood by those skilled in the art that the foregoing
15 and other changes in form and details may be made therein without departing from the
spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A radially expandable endoprosthesis having an at least two-stage deployment capability, said endoprosthesis comprising an annulus which subsequent to deployment in a patient is expandable from a first diameter to at least a second larger diameter within a
5 specified interval of time.
2. A radially expandable endoprosthesis as claimed in Claim 1, wherein said annulus comprises a valve prosthesis.
- 10 3. A radially expandable endoprosthesis as claimed in Claim 2, wherein said valve prosthesis comprises a heart valve prosthesis including a valve.
4. A radially expandable endoprosthesis as claimed in any one of the preceding claims, wherein said endoprosthesis is constituted of a combination of a superelastic alloy
15 and a bioresorbable material.
5. A radially expandable endoprosthesis as claimed in Claim 4, wherein said superelastic alloy comprises nitinol.
- 20 6. A radially expandable endoprosthesis as claimed in Claim 4, wherein said bioresorbable material comprises a coating on said superelastic alloy.
7. A radially expandable endoprosthesis as claimed in Claim 4, wherein said bioresorbable material comprises a restraint means on said superelastic alloy.
25
8. A radially expandable endoprosthesis as claimed in Claim 4, wherein said bioresorbable material is constituted of a polymer system possessing specified rates of resorption so as to enable said annulus to enter said at least second stage of additional radial expansion.
30
9. A radially expandable endoprosthesis as claimed in Claim 4, wherein the specified interval of time for a resorption of the resorbable material is selected to be in the range of about 6 months to about 200 months at which said annulus expands to the at least second larger diameter.

10. A radially expandable endoprosthesis as claimed in Claim 9, wherein said at least second larger diameter is at least 1.1 times the size of said first diameter.
- 5 11. A radially expandable endoprosthesis as claimed in Claim 4, wherein said endoprosthesis comprises a coronary stent for the counteracting of restenosis.
12. A radially expandable endoprosthesis as claimed in Claim 4, wherein said endoprosthesis comprises a stent for the stenting of aortic aneurysms.
- 10 13. A radially expandable endoprosthesis as claimed in Claim 4, wherein said bioresorbable material is selected to enable said annulus to undergo secondary and tertiary stages of expansion.
- 15 14. A radially expandable endoprosthesis as claimed in Claim 8, wherein said polymer system is selected from the group of materials consisting of PLA-PGA copolymer systems, polytyrosine systems, and combinations of differing polymer systems for controllably varying the resorption rates thereof.
- 20 15. A radially expandable endoprosthesis as claimed in Claim 8, wherein, said polymer system contains a therapeutic agent.
16. A radially expandable endoprosthesis as claimed in Claim 15, wherein said therapeutic agent selectively comprises an antibiotic, cytostatic or anticoagulant.
- 25 17. A method of deploying a radially expandable endoprosthesis having an at least two-stage deployment capability, said endoprosthesis comprising an annulus which subsequent to deployment in a patient is expandable from a first diameter to at least a second larger diameter within a specified interval of time.
- 30 18. A method of deploying a radially expandable endoprosthesis as claimed in Claim 17, wherein said annulus comprises a valve prosthesis.

19. A method of deploying a radially expandable endoprosthesis as claimed in Claim 18, wherein said valve prosthesis comprises a heart valve prosthesis including a valve.
20. A method of deploying a radially expandable endoprosthesis as claimed in any one of the preceding Claims 17 through 19, wherein said endoprosthesis is constituted of a combination of a superelastic alloy and a bioresorbable material.
21. A method of deploying radially expandable endoprosthesis as claimed in Claim 20, wherein said superelastic alloy comprises nitinol.
22. A method of deploying a radially expandable endoprosthesis as claimed in Claim 20, wherein said bioresorbable material comprises a coating on said superelastic alloy.
23. A method of deploying a radially expandable endoprosthesis as claimed in Claim 20, wherein said bioresorbable material comprises a restraint means on said superelastic alloy.
24. A method of deploying a radially expandable endoprosthesis as claimed in Claim 20, wherein said bioresorbable material is constituted of a polymer system possessing specified rates of resorption so as to enable said annulus to enter said at least second stage of additional radial expansion.
25. A method of deploying a radially expandable endoprosthesis as claimed in Claim 20, wherein the specified interval of time for a resorption of the resorbable material is selected to be in the range from about 6 months to about 200 months at which said annulus expands to the at least second larger diameter.
26. A method of deploying a radially expandable endoprosthesis as claimed in Claim 25, wherein said at least second larger diameter is at least 1.1 times the size of said first diameter.
27. A method of deploying a radially expandable endoprosthesis as claimed in Claim 20, wherein said endoprosthesis comprises a coronary stent for the counteracting of restenosis.

28. A method of deploying a radially expandable endoprosthesis as claimed in Claim 20, wherein said endoprosthesis comprises a stent for the stenting of aortic aneurysms.
- 5 29. A method of deploying a radially expandable endoprosthesis as claimed in Claim 20, wherein said bioresorbable material is selected to enable said annulus to undergo secondary and tertiary stages of expansion.
- 10 30. A method of deploying a radially expandable endoprosthesis as claimed in Claim 24, wherein said polymer system is selected from the group of materials consisting of PLA-PGA copolymer systems, polytyrosine systems, and combinations of differing polymer systems for controllably varying the resorption rates thereof.
- 15 31. A method of deploying a radially expandable endoprosthesis as claimed in Claim 24, wherein said polymer system contains a therapeutic agent.
32. A method of deploying a radially expandable endoprosthesis as claimed in Claim 31, wherein said therapeutic agent selectively comprises an antibiotic, cytostatic or anticoagulant.

FIG. 1a

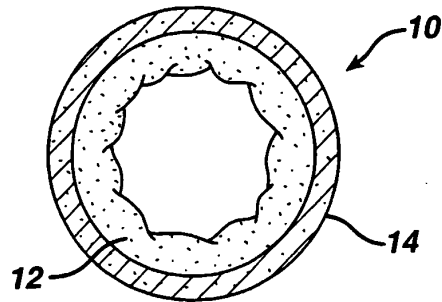


FIG. 1b PRIOR ART

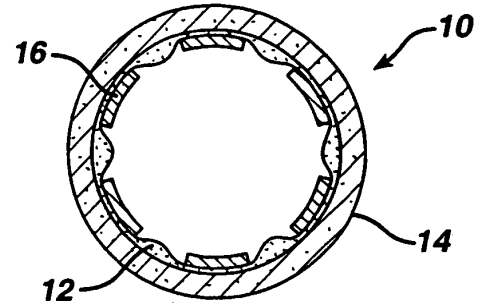


FIG. 1c PRIOR ART

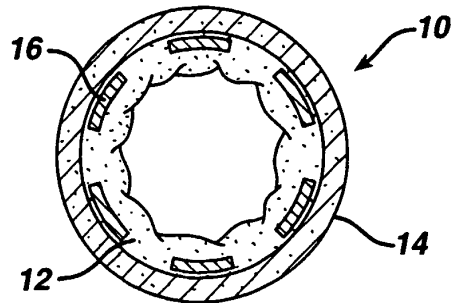


FIG. 1d

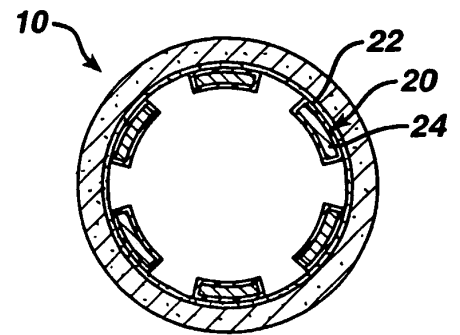


FIG. 2a

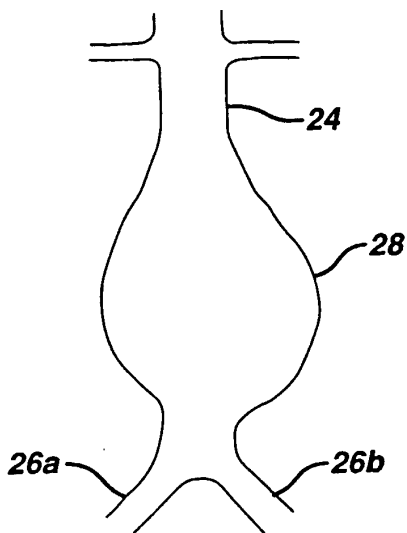


FIG. 2b PRIOR ART

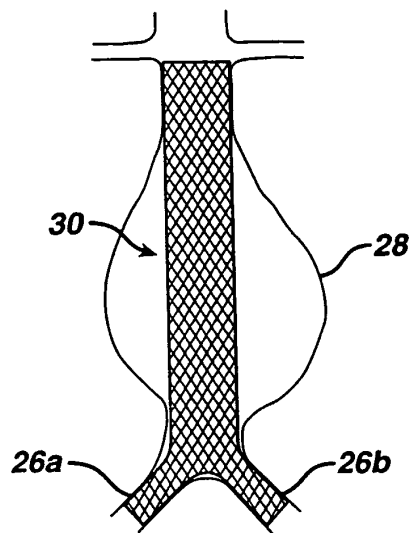


FIG. 2c PRIOR ART

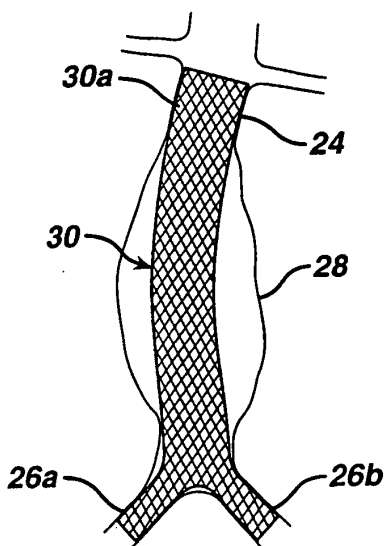


FIG. 2d

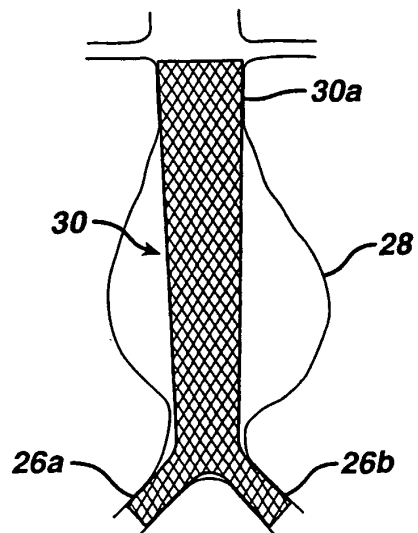


FIG. 3a

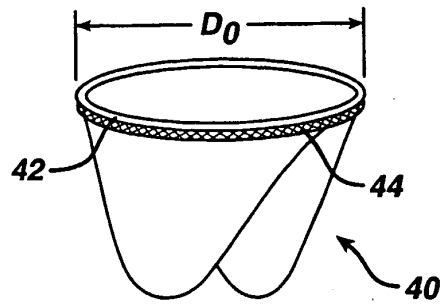
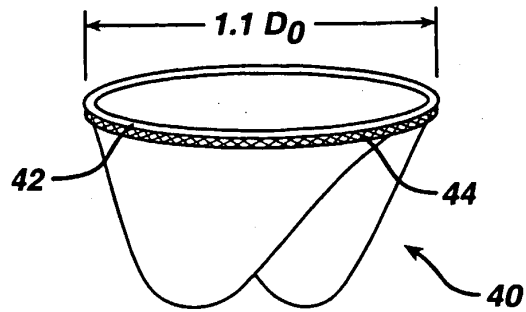


FIG. 3b



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/30828

A. CLASSIFICATION OF SUBJECT MATTER		
IPC(7) : A61F 2/24 US CL : 623/2.38		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) U.S. : 623/2.38, 1.11, 1.23, 2.37, 1.38, 1.26		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,168,614 B1 (ANDERSON et al) 02 January 2001(02.01.2001), see the entire document	1-3 and 17-19
X	US 5,441,515 A (KHOSRAVI et al) 15 August 1995 (15.08.1995), see the entire document.	1 and 17
A,P	US 6,350,277 B1 (KOCUR) 26 February 2002 (26.02.2002).	4 and 20
A, P	US 6,406,493 B1 (TU et al) 18 June 2002 (18.06.2002).	1-32
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:		
*A	document defining the general state of the art which is not considered to be of particular relevance	*T
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*O	document referring to an oral disclosure, use, exhibition or other means	*Z
*P	document published prior to the international filing date but later than the priority date claimed	*&
		later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
		document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
		document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
		document member of the same patent family
Date of the actual completion of the international search		Date of mailing of the international search report
21 November 2002 (21.11.2002)		05 DEC 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230		Authorized officer Paul B. Preblich Telephone No. (703) 308-0858

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INTERNATIONAL SEARCH REPORT

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Continuation of B. FIELDS SEARCHED Item 3:

EAST BRS search terms: nitinol and (bioresorbable or resorbable or biodegradable or degradable or degradeable or biodegradeable or bioabsorbable or absorbable) and stent

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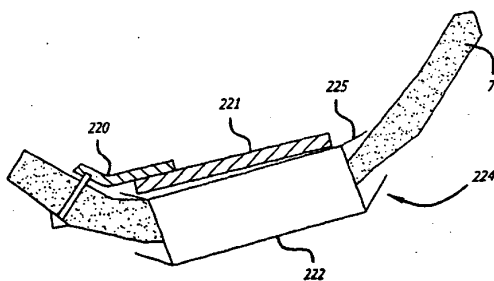
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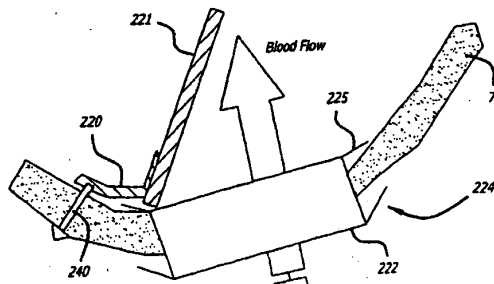
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(54) Title: METHOD AND DEVICE FOR TREATING DISEASED VALVE



(57) Abstract: A device and method for improving flow through a native blood vessel valve, such as the aortic valve, are provided. The present invention allows a miniature valve to be implanted into affected leaflets percutaneously, obviating the need for coronary bypass surgery. The method includes the cutting of small holes, on the order of 4mm, in the leaflets of a targeted valve, thereby allowing blood to flow through the newly formed holes. The holes are used as attachment sites for the miniature valves of the present invention.



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METHOD AND DEVICE FOR TREATING DISEASED VALVE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This invention is related to the invention described in the provisional application serial number 60/407,414 filed on August 28, 2002 entitled, MINI-VALVE HEART VALVE REPLACEMENT, and claims priority therefrom.

BACKGROUND OF THE INVENTION

[0002] Blood vessel valves include flexible tissue leaflets that passively alternate between open and closed positions as the forces of a blood stream act upon them. As blood flows in a first direction, the leaflets are urged apart from each other, and allow the blood to pass. Between pulses, as the blood attempts to flow in a reverse direction, the blood acts upon upstream surfaces of the individual leaflets, causing the leaflets to move inwardly. As the leaflets move inwardly, the edges of the individual leaflets (two, in the case of bicuspid valves, and three in the case of tricuspid valves) abut against each other, effectively blocking the blood flow in the reverse direction.

[0003] Valves are also present within the heart. The heart contains four one-way valves that direct blood flow through the heart and into the arteries. Three of these valves, the aortic valve, the tricuspid valve, and the pulmonary valve, each have three leaflets. The fourth valve, the mitral valve, has two leaflets. By defining a direction in which blood can flow, these valves are responsible for the resulting pump effect a heart has on blood when the heart beats.

[0004] A number of diseases result in a thickening, and subsequent immobility or reduced mobility, of valve leaflets. Valve immobility leads to a narrowing, or stenosis, of the passageway through the valve. The increased resistance to blood flow that a stenosed valve presents eventually leads to heart failure and death.

[0005] Treating severe valve stenosis or regurgitation has heretofore involved complete removal of the existing native valve followed by the implantation of a prosthetic valve. Naturally, this is a heavily invasive procedure and inflicts great trauma on the body leading usually to great discomfort and considerable recovery time. It is also a sophisticated procedure that requires great expertise and talent to perform.

[0006] Historically, such valve replacement surgery has been performed using traditional open-heart surgery where the chest is opened, the heart stopped, the patient placed on cardiopulmonary bypass, the native valve excised and the replacement valve attached. More recently, it has been proposed to perform valve replacement surgery percutaneously, that is, through a catheter, so as to avoid opening the chest.

[0007] One such percutaneous valve replacement method is disclosed in U.S. Patent No. 6,168,614 (the entire contents of which are hereby incorporated by reference) issued to Andersen et al. In this patent, the prosthetic valve is collapsed to a size that fits within a catheter. The catheter is then inserted into the patient's vasculature and moved so as to position the collapsed valve at the location of the native valve. A deployment mechanism is activated that expands the replacement valve against the walls of the body lumen. The expansion force pushes the leaflets of the existing native valve against the lumen wall thus essentially "excising" the native valve for all intents and purposes. The expanded structure, which includes a scaffold configured to have a valve shape with valve leaflet supports, is then released from the catheter and begins to take on the function of the native valve. As a result, a full valve replacement has been achieved but at a significantly reduced physical impact to the patient.

[0008] One particular drawback with the percutaneous approach disclosed in the Andersen '614 Patent is the difficulty in preventing leakage around the perimeter of the new valve after implantation. Since the tissue of the native valve remains within the lumen, there is a strong likelihood that the commissural junctions and fusion points of the valve tissue (as pushed against the lumen wall) will make sealing of the prosthetic valve around the interface between the lumen and the prosthetic valve difficult. Furthermore, in some

patients, the deflection of the leaflets against the lumen walls could potentially obstruct the ostial openings of the lumen.

[0009] Although both the traditional open heart valve replacement surgery and the newer percutaneous valve replacement surgery replace a native valve in entirely different ways and both have their drawbacks, the paradigm of these two approaches is identical: Render the native valve useless, either through excision (open heart) or immobilization (percutaneous), and then implant a completely new replacement prosthetic valve to take over. In other words, both approaches rely entirely on the premise that the native valve must be entirely replaced (physically or functionally) by an entirely new prosthetic valve.

[0010] In contravention of the prior art, the present invention introduces an entirely different paradigm to valve replacement surgery, something neither taught nor contemplated by the open heart approach or the percutaneous approach (e.g., U.S. Patent No. 6,168,614) and something that largely avoids the drawbacks associated with both. More specifically, the present invention is premised on leaving the native valve in place, not on its excision or immobilization, and then utilizing the native valve as a platform for actually treating the diseased valve. This is a wholly new approach to treating diseased valves.

[0011] For example, in one embodiment of the invention, the physician diagnoses that the patient has a stenotic valve and then percutaneously mounts a plurality of small "leaflet valves" or "mini-valves" on one or more of the diseased native valve leaflets. In other words the native valve and its leaflets are used as a planar surface or a type of "bulkhead" on which new mini leaflet valves are mounted. The native valve remains in place but valve disfunction is remedied due to the presence of these new leaflet valves. As a result, the diseased valve is successfully treated without the complication associated with removing the native valve.

[0012] This leads to a much simpler and safer approach as compared to the prior art. It avoids the invasive nature of the open heart approach and avoids the sealing and ostial blockage problems of the percutaneous approach.

BRIEF SUMMARY OF THE INVENTION

[0013] The present invention relates to the treating of narrowed, stiff or calcified heart valves. The aforementioned problems with present treatment methods are addressed by treating the targeted valve leaflets individually, rather than replacing the entire valve using an open-heart or a percutaneous procedure. That is, in the present method, the rigid heart valve leaflet is treated by introducing small prosthetic valves into the leaflet itself.

[0014] The present invention includes a method of treating the individual leaflets of a targeted heart valve that includes installing one or more small, one-way valves into the targeted leaflets. These smaller valves can be placed in the leaflet using catheter systems, obviating the need for opening the heart or great vessels, cardiopulmonary bypass, excision of the diseased valve, and a thoracotomy. Additionally, multiple small valve placements might reduce the long-term risks associated with a complete prosthetic valve, because failure of an individual valve will not necessarily lead to cardiac failure. The remaining small valves and remaining healthy native valves might be sufficient to sustain life.

[0015] One aspect of the present invention provides a method of placing small valves through a target valve that involves puncturing the target valve and pushing the miniature valve through the target valve tissue. The valve is then anchored in place using a variety of mechanisms including tabs, riveting of the valve housing, spines, friction placement or the use of a fixation cuff.

[0016] Another aspect of the present invention provides a variety of valve implant mechanisms constructed and arranged for placement in a target valve leaflet. The valve implant mechanisms include a valve housing that operably houses a valve mechanism such as a duckbill valve, a tilting check valve, a ball and cage valve, or a hinged leaflet valve or a valve using tissue leaflets. The valve implant may also include an anchoring mechanism such as tabs, spines, threads, shoulders, or a deformable housing.

[0017] The present invention also provides a device useable to remove a section of the target valve, without damaging the surrounding valve tissue, and inserting a valve implant into the void left in the target valve. The device is contained within a catheter such that a valve implant insertion procedure can be accomplished percutaneously. Preferably, this delivery system is constructed and arranged to be placed through a 14 French catheter, traverse the aorta, land on a targeted leaflet such as one of the leaflets of the aortic valve, puncture the leaflet at a predetermined spot, cut a hole on the order of 4mm in diameter, capture and remove any cut tissue, place a radially compressed one-way valve including a Nitinol attachment cuff and a stainless steel sizing ring into the leaflet hole, securely attach the valve assembly to the leaflet, dilate the hole and the valve assembly to a precise final diameter, such as 8mm, using a balloon, and be retracted leaving the valve assembly in place in the leaflet.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] Figure 1 is a perspective view of three valve implants of the present invention installed in the leaflets of a tricuspid valve;

[0019] Figure 2 is a side elevation of two valve implants of the present invention installed in a stenotic leaflet;

[0020] Figures 3a-f are side elevations of various embodiments of the valve implant of the present invention;

[0021] Figure 4a is a detailed sectional view of a preferred embodiment of the valve implant of the present invention in a compressed or folded state;

[0022] Figure 4b is a detailed sectional view of the valve implant of Figure 4a in an expanded state;

[0023] Figures 4c-f are sectional views of alternative configurations of the preferred valve implant of the present invention;

[0024] Figure 5a is a sectional view of an embodiment of the delivery system of the present invention;

[0025] Figure 5b is a detailed sectional view of the distal end of the delivery system of Figure 5a;

[0026] Figure 6 is a sectional view of the leaflet capture catheter of the present invention;

[0027] Figure 7a is a sectional view of the delivery catheter of the present invention;

[0028] Figure 7b is a perspective view of an alternative cutter of the present invention;

[0029] Figure 8 is a sectional view of the sheath catheter of the present invention;

[0030] Figure 9a is a detailed sectional view of the handle of the delivery system of the present invention;

[0031] Figure 9b is a side elevation of the handle of Figure 9a;

[0032] Figure 10a is a side elevation of the handle of the present invention in a "Deliver" position;

[0033] Figure 10b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Deliver" position of Figure 10a;

[0034] Figure 11a is a side elevation of the handle of the present invention in an "Insert" position;

[0035] Figure 11b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Insert" position of Figure 11a;

[0036] Figure 12a is a side elevation of the handle of the present invention in a "Cut" position;

[0037] Figure 12b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Cut" position of Figure 12a;

[0038] Figures 13a-e are an operational sequence of the capture device of Figure 6 interacting with the cutting drum of Figure 7a to remove and capture a section of tissue from a target valve leaflet;

[0039] Figure 14a is a side elevation of the handle of the present invention in a "Distal" position;

[0040] Figure 14b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Distal" position of Figure 14a;

[0041] Figure 15a is a side elevation of the handle of the present invention in a "Proximal" position;

[0042] Figure 15b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Proximal" position of Figure 15a;

[0043] Figure 16a is a side elevation of the handle of the present invention in an "Inflate" position;

[0044] Figure 16b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Inflate" position of Figure 16a and a balloon of the delivery system is inflated;

[0045] Figure 17a is a side elevation of the handle of the present invention in an "Inflate" position during a deflating procedure;

[0046] Figure 17b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Inflate" position of Figure 17a and the balloon of the delivery system has been deflated;

[0047] Figure 18 is a sectional view of a valve implant of the present invention in a deployed configuration;

[0048] Figures 19A and 19B are cross-sectional views of a valve implant of the present invention in a deployed configuration;

[0049] Figure 20 is a cross-sectional view of a portion of a catheter delivery system in accordance with a preferred embodiment of the present invention;

[0050] Figure 21 is a flow chart figure showing a tether retraction system for use in a catheter delivery system in accordance with the present invention;

[0051] Figures 22A and 22B are top views of a hinged valve in accordance with another preferred embodiment of the present invention;

[0052] Figures 23A, 23B and 23C are cross-sectional views of a hinged valve in accordance with the present invention; and,

[0053] Figures 24A and 24B are cross-sectional views of a hinged valve in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0054] Referring now to the Figures, and first to Figure 1, there is shown a native tricuspid valve 5 with a valve implant 10 of the present invention installed in each of the three leaflets 7 of the tricuspid valve 5. The valve implants 10 are shown in an open position to demonstrate that blood is allowed to flow through the valve implants 10, in one direction, even though the native tricuspid valve 5 remains closed. These valve implants 10 would similarly work with a native bicuspid valve, unicuspid valve or quadracuspid valve.

[0055] Figure 2 demonstrates the positioning of a valve implant 10 in a native leaflet 7. The leaflet 7 is shown as having calcified tissue 9, characteristic of a stenosed valve. Notably, the valve implants 10 have been inserted through the calcified tissue 7. Also notable is that there may be more than one valve implant 10 inserted into a single leaflet 7 if additional flow capacity is desired. Alternatively, though not shown, the valve implant 10 may be installed between the leaflets 7. This configuration is especially feasible in heavily

stenosed valves that have relatively immovable leaflets. Such leaflets may be fully or partially fused together. The valve implants generally comprise an anchoring mechanism 12 and a valve mechanism 14.

[0056] Figures 3-5 illustrate several embodiments of the valve implants 10 of the present invention. In Figures 3a-f, a family of valve implants 10 is provided that are characterized by a rigid housing 16 with a self-tapping tip 18. The valve implants 10 of Figures 3a-f include a variety of valve mechanisms 14 and anchoring mechanisms 12.

[0057] The valve implant 10 of Figure 3a, as well as those of Figures 3c and 3d, has a valve mechanism 14 that comprises a single flap 20, hinged on one side, that acts against the rigid housing 16 to prevent flow in a reverse direction. A benefit of this valve design is ease of construction. The valve implant 10 of Figure 3a also uses the friction between the rigid housing 16 and the native heart leaflet 7 (Figure 2) as an anchoring mechanism to hold the valve implant 10 in place. The pointed tip 18 allows the valve implant 10 to be urged through, or twisted through, the native heart leaflet without the need for cutting a hole in the leaflet prior to installing the valve implant 10. Thus, in certain cases, there is sufficient gripping power between the housing 16 and the leaflet 7 to hold the housing 16 in place. This holding power may be increased by providing a textured surface (not shown) on the housing 16, or selecting a housing material, such as a mesh or stiff fabric, that allows a controlled amount of ingrowth, sufficient to secure the valve implant 10, but not so much as to cause a flow hindrance within the valve implant 10.

[0058] The valve implant 10 of Figure 3b has a valve mechanism 14 that comprises a pair of members constructed and arranged to form a duckbill valve 22. The duckbill valve 22 operates in a similar way to a tricuspid or bicuspid valve. When fluid flows through the valve in a desired direction, each of the members of the duckbill valve 22 move apart from each other. When the flow reverses, such as during diastole, the fluid forces the members of the duckbill valve 22 together, closing the valve 10.

[0059] Also included in the valve implant 10 of Figure 3b is an anchoring mechanism 12. The anchoring mechanism 12 generally comprises a plurality of radially extending posts 24.

These posts 24 act against an upstream side 26 (Figure 2) of the leaflet 7, thereby counteracting systolic pressure from the blood stream.

[0060] The valve implant 10 of Figure 3c includes a single flap 20 valve mechanism 14 and an anchoring mechanism 12 that includes a plurality of angled barbs 28. The barbs 28 are located near the upstream side of the valve implant 10 and are angled back toward the downstream side. The angled barbs 28 may provide increased gripping power, especially if more than one row, such as shown in Figure 3c, are provided. Because one or more of the rows of barbs 28 will be located within the leaflet 7 when the valve implant is in place, the barbs 28 provide resistance to movement in both directions, and may stimulate ingrowth.

[0061] The valve implant 10 of Figure 3d provides a combination of many of the features already discussed. The valve 10 has an anchoring mechanism 12 that includes both posts 24, on the downstream side to prevent valve movement in the upstream direction, and angled barbs 28 on the upstream side of the valve 10. The valve mechanism 14 demonstrates another valve design. The valve mechanism is an outside-hinged dual flap valve 30. The individual flap members rotate about their outer edges when influenced by fluid flow.

[0062] Figure 3e shows a valve implant 10 with a valve mechanism 14 that uses an inside-hinged dual flap valve 32, with individual flap members that rotate about their inner edges when influenced by fluid flow. The valve implant 10 combines upstream posts 24 with upstream-angled barbs 28 on the downstream side of the valve implant 10.

[0063] The valve implant 10 shown in Figure 3f combines a single flap 20, as a valve mechanism 14, with an anchoring mechanism 12 that uses an external helical thread 34 to anchor the valve implant 10 to a valve leaflet 7. The helical thread 34 provides resistance to movement in both the upstream and downstream directions. The helical thread 34 also provides a self-tapping action when the valve implant 10 is being screwed into place in a leaflet 7.

[0064] One skilled in the art will realize that any of the aforementioned anchoring mechanisms 12 and valve mechanisms 14 may be combined in a single valve implant 10. For example, the valve implants 10 shown in Figure 2 include upstream and downstream posts 24 as well as upstream and downstream angled barbs 28.

[0065] A preferred embodiment of the valve implant 10 of the present invention is shown in Figures 4a and 4b. The valve implant 10 is expandable from the compressed configuration shown in Figure 4a, to the expanded configuration shown in Figure 4b. The valve implant 10 is constructed and arranged to fit within a catheter when in the compressed configuration. Compression may be accomplished radially, helically, longitudinally, or a combination thereof. Preferably, the compression of the valve implant 10 is radial.

[0066] Like the aforementioned embodiments of the valve implants 10, the valve implant 10 of Figure 4 generally includes an anchoring mechanism 12 and a valve mechanism 14. The anchoring mechanism 12 generally comprises a cuff 36 and a sizing ring 38. The cuff 36 is preferably constructed of Nitinol and has a middle portion 40 a set of radially expanding distal legs 42 and a set of radially expanding proximal legs 44.

[0067] In the compressed state, the legs 42 and 44 are somewhat aligned with the middle portion 40 to allow the cuff 36 to be compressed into a catheter, preferably a 14 French catheter. The cuff 36 is either expandable or self-expanding. Upon release from the catheter, the legs 42 and 44 fold outwardly until they radiate from the middle portion 40 at approximately right angles to the longitudinal axis of the cuff 36. The legs 42 and 44 are designed to act against the upstream and downstream sides, respectively, of a valve leaflet, sandwiching the leaflet therebetween and anchoring the cuff 36 to the leaflet.

[0068] The anchoring mechanism 12 of the valve implant 10 shown in Figures 4a and 4b also includes a sizing ring 38. The sizing ring 38 is preferably a stainless steel stent that circumjacently surrounds the middle portion 40 of the cuff 36. The sizing ring 38 is constructed and arranged to expand with the cuff 36 until a predetermined size is reached. Once the predetermined size is reached, the sizing ring 38 prevents further expansion by

the cuff 36. Over expansion of the cuff 36 could render the valve mechanism 14 inoperable, cause calcified tissue to break away from the stenosed valve and become released into the blood stream, tear the leaflet tissue, or weaken the cuff 36.

[0069] The valve mechanism 14 includes a sleeve 46 and one or more valve members 48. The sleeve 46 may be rigid or flexible, but it is preferably flexible. More preferably, the sleeve 46 is constructed of any sufficiently flexible material capable of withstanding the environment to which it will be subjected, including but not limited to, any mammalian tissue, including human or pig tissue, vertebrate tissue, or a polymer or other synthetic material. The valve members 48 are shown as being duckbill valves but may be any of the aforementioned discussed valve designs.

[0070] Most preferably, the valve mechanism 14 comprises an intact harvested valve from an animal, such as pig, and is taken from an appropriate location such that the expanded, original size is suitable for use in the leaflets of the stenotic valve being treated. The harvested valve is sutured or otherwise attached to the inside surface of the cuff 36. In operation, the valve implant 10 is compressed such that it can be placed in a small catheter for percutaneous delivery. At the time of delivery, the valve implant 10 is attached to a stenotic leaflet and radially expanded to its functional diameter. Prior to, or during expansion, the distal and proximal legs 42 and 44 expand radially, allowing the cuff 36 to create a strong bulkhead-like fitting on both sides of the leaflet. After attachment is made to the leaflet, the cuff 36, sizing ring 38, and the valve mechanism 14 are radially expanded to the functional diameter of the valve implant 10. During this expansion, the sizing ring 38 exhibits plastic deformation until it achieves the maximum diameter, at which point the sizing ring 38 resists further expansion.

[0071] Figures 4c – 4f depict alternative configurations for the preferred valve implant 10. The valve implant 10 in Figure 4c has a sleeve 46 attached to the anchoring mechanism 12 with two rows of sutures 166 and is configured so an upstream edge 168 of the sleeve 46 is roughly aligned with the distal legs 42 of the anchoring mechanism 12. The valve implant 10 in Figure 4d has a sleeve 46 attached to the anchoring mechanism 12 with one row of

sutures 166 and is configured so the upstream edge 168 of the sleeve 46 is roughly aligned with the proximal legs 44 of the anchoring mechanism 12. The valve implant 10 in Figure 4e has a sleeve 46 attached to the anchoring mechanism 12 with two rows of sutures 166 and is configured so the downstream edge 170 of the sleeve 46 is roughly aligned with the proximal legs 44 of the anchoring mechanism 12. The valve implant 10 in Figure 4f has a sleeve 46 attached to the anchoring mechanism 12 with one row of sutures 166 and is configured so the downstream edge 170 of the sleeve 46 is roughly aligned with the distal legs 42 of the anchoring mechanism 12. The sleeve 46 may comprise a scaffold to which valve members 48 are attached, or the entire valve mechanism 14 may be a harvested tissue valve such as an aortic valve.

[0072] In one preferred embodiment, the valve implant 10 can be configured to include commissural support structure like a wireform stent as sometimes found in known standard sized prosthetic tissue valves. In such a configuration, the valve material will comprise a biologic tissue such as human pericardium or equine pericardium or small intestine submucosal tissue. In the present invention, the material must be thin enough to be compressed and perhaps folded so as to fit the valve implant 10 within the delivery system (described below). In a preferred embodiment, such tissue has a thickness of around 180 microns or less.

[0073] In another alternative embodiment, the cuff mechanism could be a toroidal shaped sack (not shown), similar in shape to a deflated inner tube, attached to the exterior surface of the base of the valve implant 10 and connected to a UV curable liquid polymer reservoir contained within the delivery catheter. The sack material is composed of an elastic material that can be radially expanded by a balloon angioplasty catheter or by the injection of the liquid polymer. The liquid adhesive contained within the sack can be transformed to a solid polymer through UV light activated cross-linking

[0074] This sack, essentially empty, can be manipulated by the delivery catheter to straddle both sides or surfaces around the hole cut in the leaflet for receiving the valve

implant 10. Once located, the sack can be enlarged by an underlying balloon catheter. Then, UV curable liquid polymer can be injected into the sack through the delivery catheter. Once filled with an adequate amount of a polymer and adjusted distally/proximally to form sufficient bulges on both sides of the valve leaflet, a UV light emission source, located within the delivery catheter near the bag is activated to wash the adhesive filled bag with UV curing light. Once hardened by the UV effect, the cuff maintains its enlarged size without balloon support.

[0075] Referring to Figs. 22A-24B, yet another embodiment of a valve implant 10 of the present invention is shown, this embodiment being a hinged valve. In this embodiment, the valve implant 10 comprises a valve "poppet" 221 that is connected to a valve leaflet 7 by an attachment mechanism 220 that operates much like a hinge. The valve poppet 221 pivots between a sealed and an unsealed condition around the pivot point of the attachment mechanism 220 according to the flow of blood (Figures 24A and 24B).

[0076] The poppet 221 or "mini-leaflet" can be comprised of any material sufficiently flexible to allow for the described movement yet sufficiently durable to withstand the environment. For example, the poppet 221 may be made from materials such as biologic tissue, a polymer or a carbon based material. Moreover, the poppet 221 could be coated with tissue from the patient, e.g., tissue from a patient's vein wall. The poppet material may include supporting internal structure and/or an outer ring to ensure the structural integrity of the poppet 221 during operation. The poppet can have a curved in order to better conform the poppet 221 to the contour of the native leaflet 7.

[0077] In this regard, after a hole is created in the leaflet 7 (discussed below), the poppet 221 is pushed or screwed into the leaflet. It may be retained there by barbs or screw threads or by hooks or other types of retaining mechanisms.

[0078] The attachment mechanism 220 (Figs. 22A-22B and 24A-24B), in a preferred embodiment, is a hinge. The hinge may be fabricated from such materials as a polymer strip, a biologic tissue strip, a metal (e.g., stainless steel) strip or a pyrolytic carbon material.

Referring to Figs. 24A and 24B, the hinged mechanism may be attached to the leaflet 7 tissue using a barbed spike 240.

[0079] In an optional embodiment of the invention shown in Figs 22A-24B, the valve implant 10 may also include a support ring 222 that is disposed around the inside perimeter of the hole that is cut in the leaflet 7 to receive the valve implant 10. The support ring 222 may serve to limit embolization and to enhance leaflet integrity (thereby avoiding prolapse). The support ring 222 could be deployed into the hole either with an expanding balloon or it could be mechanically deployed using a mechanical spreader.

[0080] Referring to Figs. 23A-24B, the optional support ring 222 may include struts 224, 225 that serve to capture the edges of the leaflet 7 in the hole so as to support and retain the support ring 220 at the site.

[0081] Catheter Delivery System

[0082] Referring now to Figures 5a and 5b, there is shown a preferred embodiment of a catheter delivery system 50 of the present invention. The catheter delivery system 50 generally comprises a leaflet capture catheter 52, a delivery catheter 54, a catheter sheath 56, and a handle 58. The catheter delivery system 50 is preferably constructed and arranged for use with a guidewire 60.

[0083] As best seen in Figure 6, the leaflet capture catheter 52 includes a cutter die 62 connected to a hemostatic hub 64 with a cannula 66. The cutter die 62 may be of unitary construction and includes a conical distal end 68 that increases in radius proximally until a flat 70 is reached. Proceeding proximally, the flat 70 ends abruptly to form a capture groove 72. At the proximal end of the capture groove 72, the cutter die 62 returns to approximately the same diameter as the flat 70. The purpose of the cutter die 62 is to "grab" tissue that resiliently "pops" into the capture groove 72. Once in the capture groove 72, the tissue is held in place as a cutter 90 (explained below) cuts through the tissue.

[0084] One skilled in the art will realize that alternatives could be used instead of a cutter die 62. For example, the cutter die 62 could be replaced with a balloon, constructed and

arranged to be inflated on the upstream side of the leaflet 7 (or both sides of the leaflet to capture the tissue) and sized to fit within the cutter 90. A second balloon could also be arranged to be inflated on the downstream side of the leaflet, such that the leaflet is captured between the two balloons. The balloon concept, though arguably more complicated and expensive, may prove useful in situations where a cut needs to be made in tissue that has lost the resiliency needed to "pop" into the capture groove 72 of the cutter die 62. Other devices, such as barbs and clamps, are also envisioned to act in this manner.

[0085] The cannula 66 connects with the cutter die 62 and the hemostatic hub 64. At the distal end of the cannula 66 is a needle tip 74. The needle tip 74 is angled to form a sharp point usable to puncture tissue. The cannula 66 includes a lumen 76 extending the length thereof. This lumen 76 is used to accommodate a guidewire 60 (Figure 5).

[0086] The hemostatic hub 64 allows the leaflet capture catheter 52 to be removably attached to the handle 58. The hemostatic hub 64 includes a body 78, a threaded knob 80, and an elastomeric seal 82. The body 78 defines an interior cavity 84 that is shaped to receive and hold a cannula hub 86 that is attached to a proximal end of the cannula 66. The interior cavity 84 is also shaped to receive the elastomeric seal 82, which is compressed between the threaded knob 80 and the body 78. The interior cavity 84 is partially internally threaded to receive the external threads of the threaded knob 80. The threaded knob 80 defines a guidewire port 88 that aligns with the interior cavity 84 and the lumen 76 of the cannula 66 so that a continuous port is available for the guidewire 60 to extend the length of the leaflet capture catheter 52. When a guidewire 60 is inserted through the guidewire port 88, the threaded knob 80 and the elastomeric seal 82 act together as a hemostatic valve. When the threaded knob 80 is rotated to compress the elastomeric seal 82, the elastomeric seal 82 swells inwardly, until it forms a blood-tight seal around the guidewire 60. The cannula 66 and the hub 64 are constructed and arranged to carry the tensile force generated during a hole cutting procedure, discussed in detail below.

[0087] The leaflet capture catheter 52 is slidably and coaxially contained within the delivery catheter 54. The delivery catheter 54 is best shown in Figure 7a, and includes a cutter 90, a balloon catheter 92, and a delivery catheter hub 94. The cutter 90 is constructed and arranged to act with the cutter die 62 (Figure 6) to cut tissue. The cutter 90 includes a cutter drum 96 that is a sharpened cylindrical blade having a cutting tip 98. The cutter tip 98, as shown in Figure 7a, lies in a plane that is substantially perpendicular to a longitudinal axis of the delivery catheter. However, an alternative embodiment of the cutter drum 96, shown in Figure 7b, may provide increased cutting power. The cutter drum 96 in Figure 7b has a curved, non-planar cutting tip 98. Preferably, the cutter drum 96 is sized to cut a hole having a diameter of approximately 4mm through a leaflet. The cutter drum 96 has a cutter bulkhead 100 at its proximal end that is attached to the balloon catheter 92 with an adhesive 102. Other suitable attachment means for attaching the cutter drum 96 to the balloon catheter 92 include threads, welds, unitary construction and the like. To cut tissue, the cutter die 62 is pulled within the cutter drum 90. Thus, the balloon catheter 92, and the adhesive 102 fixing the bulkhead 100 to the balloon catheter 92, must be able to carry the compressive force that results from opposing the equal and opposite tensile force applied to the leaflet capture catheter 52.

[0088] The balloon catheter 92 generally includes an inner tube 104 extending distally and proximally from within an outer tube 106. A balloon 108 is connected at a distal end to the outside of the inner tube 104 and at a proximal end to the outside of the outer tube 106. The outside diameter of the inner tube 104 is smaller than the inside diameter of the outer tube 106, such that a fluid passageway is formed therebetween for inflation of the balloon 108. A flexible valve stop 110 is attached to the outer tube 106 just proximal of the proximal end of the balloon 108. The valve stop 110 has a flexible sleeve 112 that extends distally over the proximal end of the balloon 108. The function of the valve stop 110 is to prevent proximal movement of the valve implant 10 during delivery. The valve implant 10, as will be seen below, will be placed over the balloon 108, distal of the valve stop 110. The flexible sleeve 112 allows the balloon to inflate while maintaining a desired positioning of the valve implant 10. The inner tube 104 has an inner diameter large enough to

accommodate the cannula 66 of the leaflet capture catheter 52. A proximal end of the balloon catheter 92 is attached to the catheter hub 94.

[0089] The catheter hub 94 includes a catheter hub body 114 that defines an inner cavity 116 and a balloon inflation port 118. The proximal end of the inner cavity 116 has internal threads to receive an externally threaded knob 120. An elastomeric seal 122 resides between the threaded knob 120 and the catheter hub body 114. The threaded knob 120 defines a capture catheter port 124 that aligns with the interior cavity 116 of the body 114 and the interior of the balloon catheter 92 so that the leaflet capture catheter 52 may pass therethrough.

[0090] The balloon catheter 92 is attached to the catheter hub 94 in such a manner that fluid introduced into the balloon inflation port 118 will flow between the outer tube 106 and the inner tube 104 to inflate the balloon 108. The outer tube 106 is attached at its proximal end to the distal end of the interior cavity 116 of the catheter hub body 114. Preferably, an adhesive 126 is used to connect the outer tube 106 to the interior cavity 116 of the catheter hub body 114 at a position distal of the balloon inflation port 118. The inner tube 104 extends proximally from the proximal end of the outer tube 108. The proximal end of the inner tube 104 is also attached to the interior cavity 116 of the catheter hub body 114. However, this connection is made at a position proximal of the balloon inflation port 118, preferably with an adhesive 128. Thus, fluid entering the balloon inflation port 118 is blocked from flowing in a proximal direction by the proximal adhesive 128. It is also blocked from traveling in a distal direction on the outside of outer tube 106 by the distal adhesive 126. Instead, the fluid is forced to flow between the inner tube 104 and the outer tube 106 in a distal direction toward the interior of the balloon 108.

[0091] The leaflet capture catheter 52 and the delivery catheter 54 are slideably contained within the sheath catheter 56. Referring now to Figure 8, it can be seen that the sheath catheter 56 includes a large diameter sheath 130 attached to a distal end of sheath tubing 132, which is attached at a proximal end to a sheath hub 134. The sheath hub 134 secures the sheath catheter 56 to the handle 58. The sheath hub 134 includes a tab 154, the

function of which will be explained below. The sheath 130, sheath tubing 132, and the sheath hub 134, all define a delivery catheter port 136 that extends throughout the length of the sheath catheter 56. The large diameter sheath 130, is preferably a 14 French catheter, and sized to accommodate the cutter drum 96.

[0092] Referring now to Figures 9A and 9B, there is shown a preferred embodiment of the handle 58 of the present invention. The handle 58 includes a handle body 138 that defines at a bottom portion a figure grip 140. An actuator 142 is pivotally attached to the handle body 138 with a pivot pin 164. At the top of the actuator 142, is a leaflet capture catheter bracket 144. The leaflet capture catheter bracket 144 is constructed and arranged to hold the leaflet capture hemostatic hub 64. At a top portion of the body 138 there is defined a slotted chamber 146. The slotted chamber 146 is constructed and arranged to hold the delivery catheter hub 94 as well as the sheath hub 134. The slotted chamber 146 includes external threads 148 around which the sheath retraction nut 150 rides. At the top of the slotted chamber 146 there is defined a slot 152 through which the balloon inflation port 118 of the delivery catheter hub 94 and a tab 154 of the sheath hub 134 extend. Below the slotted chamber 146, a sheath retraction indicator 156 extends distally from the handle body 138. Preferably, the handle 58 includes a safety button 158 that prevents a physician from unintentionally depressing the actuator 142.

[0093] The handle 58 is thus constructed and arranged to slide the leaflet capture catheter 52 in a proximal direction relative to the sheath catheter 56 and the delivery catheter 54 when the actuator 142 is squeezed toward the finger grip 140, thereby pulling the hemostatic hub 64 in a proximal direction. The handle 58 is also constructed and arranged to slide the sheath catheter 56 proximally over the leaflet capture catheter 52 and the delivery catheter 54 when the sheath retraction nut 150 is rotated proximally. The operation of the handle 58 and the rest of the delivery system 50 are explained in more detail below.

[0094] Referring to Figs. 19A, 19B and 20, in one embodiment of the present invention, the catheter delivery system 50 includes a tether 190 looped around the proximal legs 44 of

the valve implant 10. The tether extends from the proximal legs 44 all the way through the catheter until both ends of the tether 190 are joined at a connector 192 that resides outside the catheter delivery system 50 near the handle. The tether 190 allows the user to retract the valve implant 10 from the valve placement site after it has been deployed from the catheter if it is determined that the deployment was improper or in the event a complication arises with after deployment.

[0095] For example, if after deployment, it is determined that placement of the valve implant 10 is incorrect, the physician can pull on the tether and retract the valve implant 10 as shown in Figure 19B. If, on the other hand, it is determined that placement of the valve implant 10 has been successful, then the physician simply cuts the tether and pulls the free end out of from the proximal legs 44 and out of the delivery device as shown in Fig. 19A.

[0096] Operation

[0097] Referring now to Figures 10-19, the operation of the present invention is explained. Each of the following figures will include two drawings, a drawing that shows the position of the handle 58, and a drawing of the corresponding catheter configuration.

[0098] Referring now to Figure 10, the first step a physician takes in using the delivery device 50 to place a valve implant 10 in a leaflet of a native valve is to use a guidewire 60 to locate the site of the native valve. The guidewire 60 is thus threaded through the necessary blood vessels to the site of the native valve. For example, if it were desired to place the valve implant 10 in, or between, the leaflets of the aortic valve, the guidewire 60 would be placed percutaneously in the femoral artery, or other suitable arterial access, advanced up the aorta, around the arch, and placed above the target leaflet of the aortic valve. Once the guidewire 60 is in place, the catheter delivery system 50 is advanced along the guidewire 60.

[0099] In Figure 10a, it can be seen that the target leaflet 7 has been located with the guidewire 60 and the catheter delivery system 50 has been advanced along the guidewire 60 the target leaflet 7. Positioning the catheter delivery system 50 on the target leaflet 7

may be aided using imaging methods such as fluoroscopy and/or ultrasound. Figure 10a shows that when this step is performed, the sheath retraction nut 150 is in the "Deliver" position as shown on the sheath retraction indicator 156. In the "Deliver" position, the sheath 130 covers the capture groove 72 of the cutter die 62. The cutter 90 remains retracted proximal of the capture groove 72. Also, the conical distal end 68 of the cutter die 62 extends from the distal end of the sheath 130.

[00100] In this regard, it is helpful to note that the target leaflet may actually include two leaflets if the leaflets are calcified together. For example, with reference to Fig. 1, if two leaflets have become calcified together along their edges or lines of coaptation, the present invention contemplates cutting a hole in a manner that traverses the leaflet edges and thereafter inserting a valve (as explained below) across both leaflet edges.

[00101] Once satisfied that the target site has been reached with the catheter delivery system 50, the next step is to traverse the tissue of the target valve leaflet 7. However, before the cutter die 62 is advanced through the leaflet tissue 7, the sheath catheter 56 must be retracted until the "Insert/Cut" position has been achieved. This is accomplished by rotating the threaded sheath retraction nut 150 until the nut 150 is aligned with the "Insert/Cut" marking on the sheath retraction indicator 156. Rotating the sheath retraction nut 150 causes the nut 150 to act against the tab 154 of the sheath hub 134.

[00102] Referring now to Figures 11a and 11b, it can be seen that the target valve leaflet 7 has been punctured by either the guidewire 60, in the event that a sufficiently sharp guidewire is being used, or more preferably, the needle tip 74 of the leaflet capture catheter 52. When the needle tip 74 of the leaflet capture catheter 52 is used to puncture the leaflet, the guidewire 60 is first retracted so that it does not extend through the needle tip 74.

[00103] In one embodiment, the needle may be configured to have a hollow sharp shaft followed by a conical shank (not shown). This will allow the needle to create an initial penetration of the tissue followed by a more traditional puncturing action from the conical

shank. A needle configured in this manner will also assist in positioning the delivery device over each leaflet.

[00104] The cutter die 62 is advanced through the leaflet 7 until the leaflet 7 snaps into the capture groove 72. The conical distal end 68, as it is being advanced through the leaflet 7, will provide an increasing resistance that is tactily perceptible to the physician. Once the leaflet 7 encounters the flat portion 70, the physician will detect a decreased resistance and can expect a snap when the resilient tissue snaps into the capture groove 72. The guidewire 60 is then re-advanced into the ventricle (assuming the aortic valve is the target valve).

[00105] In this regard, it is notable that in one embodiment of the invention, the guidewire could be fabricated to include a transducer at its distal end (not shown). The guidewire could then be used to measure ventricular pressure (e.g., left ventricular pressure when treating the aortic valve) and thus provide the physician greater ability to monitor the patient during the procedure.

[00106] Once the physician is convinced that the leaflet 7 has entered the capture groove 72, the cutting step may commence. Referring now to Figures 12a and 12b, the cutting step is demonstrated. Cutting is performed by depressing safety button 158 and squeezing the actuator 142. After the safety button 158 and the actuator 142 are squeezed, the spring loaded safety button on 158 will travel from a first hole 160 in the actuator 142 to a second hole 162. When the safety button 158 reaches the second hole 162, it will snap into the second hole 162, thereby locking the actuator 142 in place. This ensures that the cutter die is retracted into the cutter 90, but that excess pressure is not placed on either the cutter die 62 or the cutter 90. When the actuator 142 is squeezed, cutting is effected because the actuator 142 rotates, relative to the handle body 138, around the pivot pin 164. This action causes the leaflet capture catheter bracket 144 to move in a proximal direction thereby pulling the hemostatic hub 64 with it. Pulling the hub 64 causes the cannula 66 and the cutter die 62 attached thereto, to be pulled in a proximal direction relative to the delivery catheter 64. The cutter die 62 enters the cutter 90, thereby

cutting the tissue. The clearance between the cutter die 62 and the cutter drum 96 is sufficiently minimal to prevent the occurrence of hanging "chads" in the cut. Additionally, the sharpened cutting tip 98 of the cutter 90 may be cut at an angle, or even include a point, such that the entire cut does not have to be initiated around the entire circumference of the cutter drum 96 simultaneously.

[00107] A more detailed view of the cutting action of the cutter die 62 and the cutter 90 is shown in Figures 13a-13e. In Figure 13a, the needle tip 74 of the cannula 66 has just reached the leaflet 7. The sheath 130 has been retracted to the "Insert/Cut" position as indicated by the exposed capture groove 72 of the cutter die 62. In Figure 13b, the cutter die 62 is being advanced through the target leaflet 7 such that the target leaflet 7 has reached the conical distal end 68 of the cutter die 62. In Figure 13c, the conical distal end 68 and the flat portion 70 of the cutter die 62 have passed completely through the target leaflet 7, and the target leaflet 7 has snapped into the capture groove 72. Additionally, the guidewire 60 has been re-advanced through the leaflet capture catheter 52 so that it extends beyond the needle tip 74. The guidewire 60 will be used to retain the position of the hole cut through the leaflet 7 after the cutter die 62 is retracted. In Figure 13d, the physician has begun to cut by squeezing the actuator 142 (Figure 12a), as evidenced by the advancement of the cutter 90. The cutting tip 98 of the cutter 90 has been advanced mid-way through the target leaflet 7. This movement is relative to the position of the cutter die 62. More accurately, the cutter die 62 is being retracted into the cutter 90, bringing with it the tissue of the leaflet 7. The movement of the cutter die 62 is evidenced by arrow 172.

[00108] In Figure 13e, the cut is complete as the actuator 142 has been squeezed enough so that the safety button 158 has found the second hole 162 (Figure 12a), as evidenced by the position of the cutter die 62. The cutter die 62 is retracted enough such that the capture groove 72 is completely housed within the cutter drum 96. Notably, the cut tissue of the leaflet 7 remains trapped between the capture groove 72 and the cutter drum 96. The trapping of this tissue prevents the tissue from traveling downstream through the blood vessel and causing damage.

[00109] Referring now to Figures 14a and 14b, once the hole in the tissue 7 is cut, the step of placing the valve implant 10 begins. First, the entire delivery system 50 is moved distally deeper into the patient such that the distal legs 42 pass through the newly formed hole in the tissue 7. It is important that at least the distal legs 42 are located on the upstream (ventricle) side of the tissue 7 prior to deploying the valve implant 10. Once the physician is confident that the distal legs 42 extend beyond the valve leaflet tissue 7, the sheath 130 may be retracted to release the distal legs 42. This is accomplished by rotating the sheath retraction nut 150 until the sheath retraction nut 150 aligns with the "Distal" marking on the sheath retraction indicator 156. Doing so causes the sheath retraction nut 150 to act against the tab 154 thereby withdrawing the sheath 130 until just the distal legs 42 are exposed. The distal legs 42 are preloaded such that they spring outwardly, as shown in Figure 14b, when uncovered by the catheter sheath 130. The distal legs 42 are long enough to extend beyond the radius of the sheath 130, such that they may act against the valve leaflet tissue 7. Once the sheath retraction nut 150 has been rotated to the "Distal" position on the indicator 156, the physician may pull the catheter delivery system 50 in a proximal direction until he or she feels the distal legs 42 catch or act against the valve leaflet tissue 7. Notably, the actuator 142 remains locked in the position it was placed in during the cutting procedure. Leaving the actuator 142 in this position ensures that the valve leaflet tissue trapped between the cutter die 62 and the cutter drum 96 is not released.

[00110] The next step is illustrated in Figs 15a and 15b. The physician maintains the contact between the distal legs 42 and the valve leaflet tissue 7. While maintaining this contact, the sheath retraction nut 150 is rotated to the "Proximal" position as indicated on the marker of the sheath retraction indicator 156. Rotating the sheath retraction nut 150 again acts against the tab 154 causing the sheath 130 to retract further. When the proximal position has been achieved, the sheath will be retracted enough to release the proximal legs 44. Like the distal legs 42, the proximal legs 44 will spring outwardly when released by the sheath 130. The proximal legs 44 act against the opposite side (aorta side) of the valve leaflet tissue 7 sandwiching the valve leaflet tissue 7 between the distal legs 42 and the proximal legs 44. The valve implant 10 is now attached to the patient.

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[00111] The next step is to inflate the balloon 108 thereby expanding the valve implant 10. This step is best shown in Figures 16a and 16b. The physician further rotates the sheath retraction nut 150 to the "Inflate" position on the indicator 156. The sheath retraction nut 150 again acts against the tab 154 thereby retracting the sheath 130 to a point where the valve stop 110 is at least partially exposed and the flexible sleeve 112 of the valve stop 110 is completely exposed.

[00112] Once the sheath 130 has been retracted to the "Inflate" position on the indicator 156, the balloon 108 may be inflated. This is accomplished by injecting fluid into the balloon inflation port 118. Fluid is injected until the sizing ring 38 has achieved its maximum diameter. The physician will feel resistance against further inflation by the sizing ring 38. Additionally, the sizing ring 38 or other parts of the anchoring mechanism 12 may be constructed of a radiopaque material such that monitoring can be accomplished using X-ray equipment. The use of the sizing ring 38 is not required for the practice of the invention. It is, however, preferred in the preferred embodiments of the invention.

[00113] Once the inflation of the balloon 108 is complete, the next step involves deflating the balloon 108. This is illustrated in Figures 17a and 17b. Deflating the balloon involves simply withdrawing fluid through the balloon inflation port 118. As is shown in Figure 17b, when the balloon 108 is deflated, the valve implant 10 retains its inflated proportions. These inflated proportions allow easy retraction of the catheter delivery system through the valve implant 10. As is best seen in Figure 18, once the delivery system 50 has been retracted, the valve implant 10 remains attached to the valve leaflet tissue 7.

[00114] As discussed above with reference to Figures 19A, 19B and 20, one embodiment of the catheter delivery device 50 and the valve implant 10 includes the use of a tether 190 to allow the physician to retract the valve implant 10 in the event of improper deployment. With reference to Figure 21, the operation of the tether 190 under both proper deployment and improper deployment is disclosed.

[00115] On the left side of Figure 21, it is seen that the valve implant 10 has been properly deployed in the valve leaflet. As a result, the physician cuts the tether 190 and pulls the tether away from the catheter handle from the proximal legs 44 of the cuff.

[00116] On the right side of Figure 22, it is seen that the valve implant 10 has been improperly deployed insofar as the legs of the cuff have not adequately grasped the edge of the hole in the leaflet. As a result, the physician may retract the valve implant 10 by pulling on the tether 190 and thus removing the valve implant 10 from its improperly deployed location

What is claimed is:

1. A heart valve comprising:
a valve position securement structure;
a flow control mechanism coupled to said valve position securement structure; and,
said valve position securement structure sized and shaped for placement in a leaflet of a native heart valve.
2. A heart valve according to claim 1, wherein said position securement structure comprises an expandable cuff having a thickness at least as thick as said leaflet of a native heart valve.
3. A heart valve according to claim 2, wherein said cuff includes a plurality of radial extensions extending from said cuff and engagable with said leaflet of a native heart valve so as to secure said cuff in said leaflet of a native heart valve.
4. A heart valve according to claim 2, wherein said heart valve further comprises a sizing ring coupled to said cuff and configured to constrain expansion of said cuff to a substantially predetermined state.
5. A heart valve according to claim 4, wherein said sizing ring is disposed around a mid-portion of said cuff.
6. A heart valve according to claim 1, wherein said flow control mechanism comprises a sleeve containing a plurality of valve members.
7. A heart valve according to claim 6, wherein said plurality of valve members includes duck bill members.

8. A heart valve according to claim 6, wherein said plurality of valve members includes leaflets disposed on a stent form.
9. A heart valve according to claim 8, wherein said leaflets are comprised of material selected from the group consisting of biologic tissue, polymer material, and composite synthetic/biologic material.
10. A device to increase fluid flow through a mammalian valve comprising: a valve mechanism containing a lumen therein;

said valve mechanism actuatable so as to place said lumen in one of an open and closed state;

an anchoring structure connected to said valve mechanism; and,

said anchoring structure sized and shaped for attachment to a leaflet of said mammalian valve.
11. A device according to claim 10, wherein said valve mechanism includes a housing structure and a valve member disposed on said housing structure.
12. A device according to claim 11, wherein said valve mechanism comprises a harvested tissue valve.
13. A device according to claim 11, wherein said valve mechanism comprises leaflets mounted on a scaffold.
14. A device according to claim 10, wherein said anchoring structure includes a plurality of barbs extending radially outwardly from said valve mechanism.
15. A device according to claim 10, wherein said anchoring structure comprises a cuff having a plurality of legs extending therefrom, said legs sized and shaped to engage leaflet tissue.

16. A device according to claim 15, wherein said anchoring structure further comprises a sizing ring disposed around said cuff; said sizing ring sized and shaped so as to constrain expansion of said cuff.
17. A valve device for treating a diseased valve comprising:
- means for controlling fluid flow;
- means for anchoring said fluid flow controlling means at a target site;
- said means for controlling and said means for anchoring being connected to each other; and,
- said means for anchoring being sized to fit on a leaflet of said diseased valve.
18. A valve device according to claim 17, wherein said means for controlling fluid flow is selected from the group consisting of: a duckbill valve, a hinged valve; a leaflet valve; a harvested valve, a tissue valve, a synthetic valve and a composite valve.
19. A valve device according to claim 17, wherein said means for anchoring includes a structure having external retention means.
20. A valve device according to claim 17, wherein said means for anchoring is expandable and includes a means for constraining the expansion of said means for anchoring.
21. A delivery device usable to cut a hole in a valve leaflet and attach a valve implant to the leaflet, comprising:
- a leaflet capture mechanism constructed and arranged to attain an operational grasp of the valve leaflet;
- a cutting mechanism constructed and arranged to cut valve leaflet tissue while the

valve leaflet is being grasped by the leaflet capture mechanism;
a delivery mechanism constructed and arranged to release a valve implant in operational proximity to a cut leaflet and attach the valve implant thereto; and, a handle, operationally attached to the leaflet capture mechanism, the cutting mechanism, and the delivery mechanism, such that an operator has control over any actions taken by said mechanisms.

22. The delivery device of claim 1 further comprising an expansion mechanism, operably attached to the handle, and constructed and arranged to expand the attached valve implant to operational proportions.
23. The delivery device of claim 1 wherein the leaflet capture mechanism comprises a die having a conical distal end that increases in radius in a proximal direction and a groove defined by the die, the groove located proximal of the conical distal end, the die thus constructed to stretch an opening in tissue, when passed therethrough, until the tissue reaches the groove and resiliently snaps into the groove.
24. The delivery device of claim 1 wherein the leaflet capture mechanism comprises a distal balloon constructed and arranged to be inflated after the balloon has been passed through the valve leaflet and, once inflated, may be used to pull the leaflet into a desired position or into the cutting mechanism.
25. The delivery device of claim 1 wherein the cutting mechanism comprises a substantially cylindrical cutting drum sized to allow the capture mechanism to be drawn inside an interior of the cutting drum without allowing tissue to reside between areas of maximum diameter of the leaflet capture mechanism and an interior surface of the cutting drum, the cutting drum including a sharpened distal edge capable of cutting tissue.
26. The delivery device of claim 5 wherein the sharpened distal edge of the cutting drum lies in a plane substantially perpendicular to a longitudinal axis of the cutting drum.

27. The delivery device of claim 5 wherein the sharpened distal edge of the cutting drum is non-planar.

28. The delivery device of claim 1 wherein the delivery mechanism comprises a retractable sheath catheter constructed and arranged to house the valve implant in a compressed state within a lumen of the sheath catheter such that when the sheath catheter is retracted, an attachment mechanism of the valve implant is released and attaches the valve implant to the valve leaflet.

29. The delivery device of claim 2 wherein the expansion mechanism comprises a balloon catheter constructed and arranged such that when a balloon of the balloon catheter is deflated, and the valve implant is in a compressed state within a lumen of the delivery device, the balloon is located within the valve implant such that inflating the balloon causes the valve implant to expand.

30. The delivery device of claim 2 wherein the handle comprises:
a first means for moving the leaflet capture mechanism relative to the cutting mechanism; and
a second means for moving the delivery mechanism relative to the expansion mechanism.

31. The delivery device of claim 10 wherein the first means and the second means are constructed and arranged to be able to be manipulated to achieve the following distinct configurations:

a deliver configuration whereby the delivery mechanism shields the cutting mechanism and at least a portion of the leaflet capture mechanism;

an insert configuration whereby the delivery mechanism is retracted to expose the leaflet capture mechanism;

a cut configuration whereby the leaflet capture mechanism is retracted within the cutting mechanism;

a distal configuration whereby the delivery mechanism is retracted enough to expose a distal portion of the valve implant such that the valve implant can attach itself to a distal side of the valve leaflet;

a proximal configuration whereby the delivery mechanism is retracted enough to expose a proximal portion of the valve implant such that the valve implant can attach itself to a proximal side of the valve leaflet; and,

an inflate configuration whereby the delivery mechanism is retracted to expose the expansion mechanism such that expansion can occur without interference by the delivery mechanism.

32. A device for delivering a valve to a target site comprising:
- a housing;
 - a tissue capture structure disposed in said housing;
 - a tissue cutting structure aligned with said tissue capture structure;
 - a deployment mechanism disposed in said housing and movable to deploy a valve to said target site following operation of said tissue cutting structure; and,
 - said target site being a leaflet of a valve.

33. A device according to claim 12, wherein said housing is sized and shaped to fit within a lumen of a patient.
34. A device according to claim 12, wherein a distal end of said tissue capture structure includes a tissue puncturing element.
35. A device according to claim 14, wherein said tissue capture structure further includes a circumferential slot for receiving tissue of said leaflet.
36. A device according to claim 12, wherein said deployment mechanism includes an expansion device sized to enlarge said valve following deployment.
37. A device according to claim 12, wherein said tissue capture structure is sized for withdrawal through said valve following deployment of said valve.
38. A device according to claim 12, further comprising a tether mechanism attached to said valve.
39. A device according to claim 12, further comprising safety stops operative to control operation of said device.

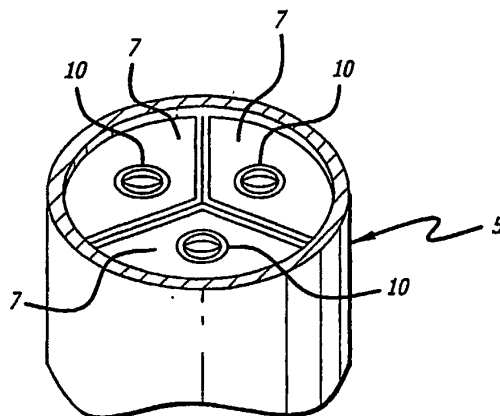


FIG. 1

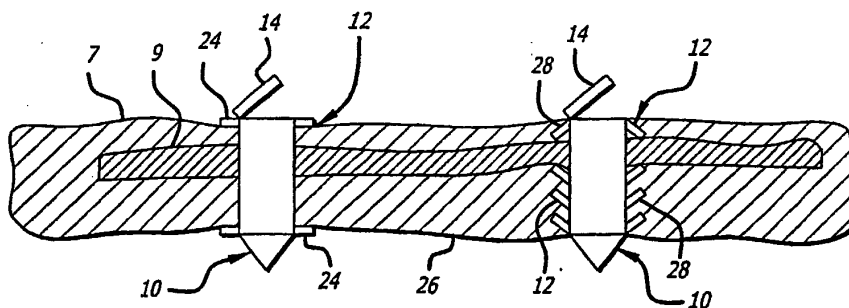


FIG. 2

SUBSTITUTE SHEET (RULE 26)

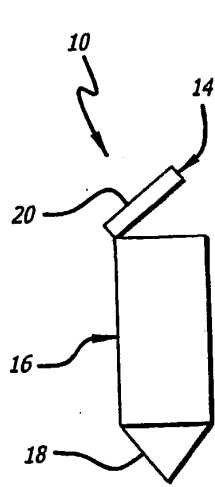


FIG. 3a

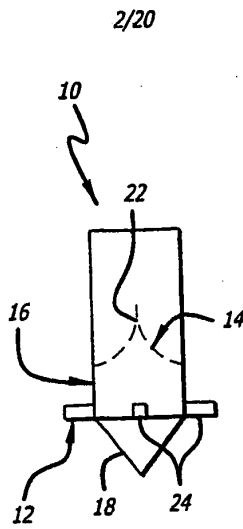


FIG. 3b

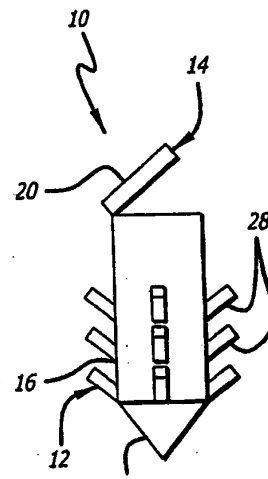


FIG. 3c

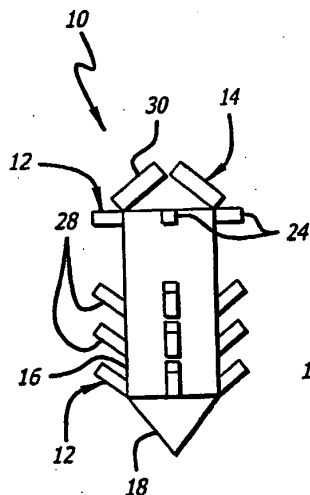


FIG. 3d

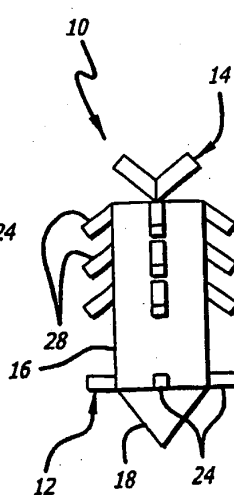


FIG. 3e

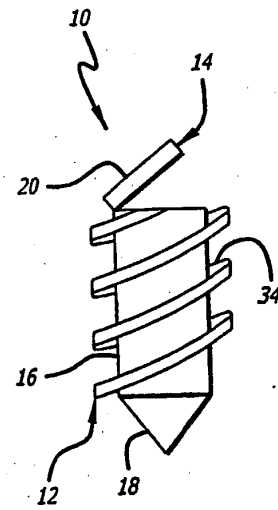


FIG. 3f

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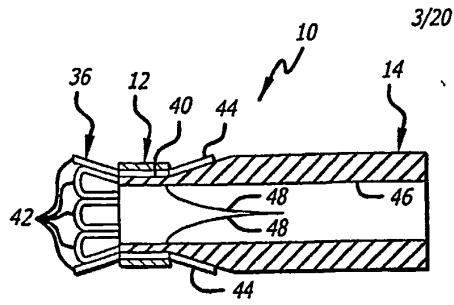


FIG. 4a

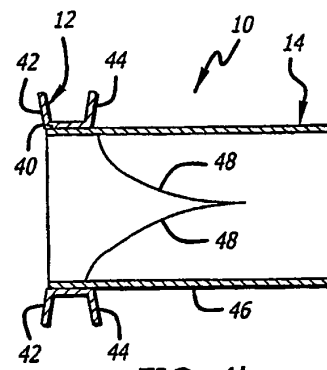


FIG. 4b

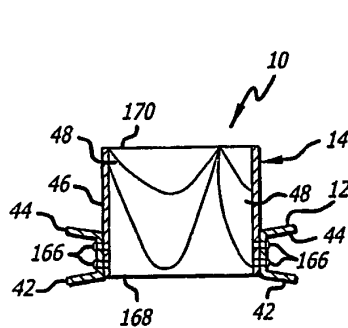


FIG. 4c

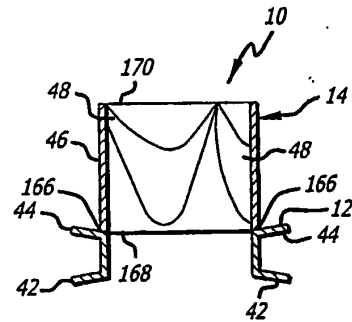


FIG. 4d

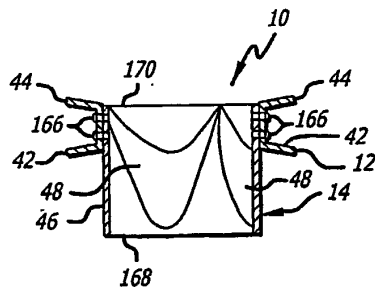


FIG. 4e

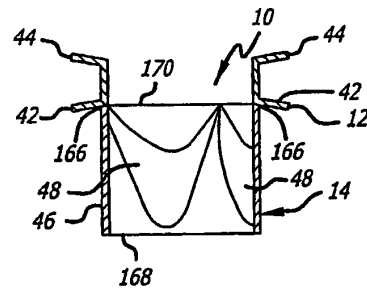


FIG. 4f

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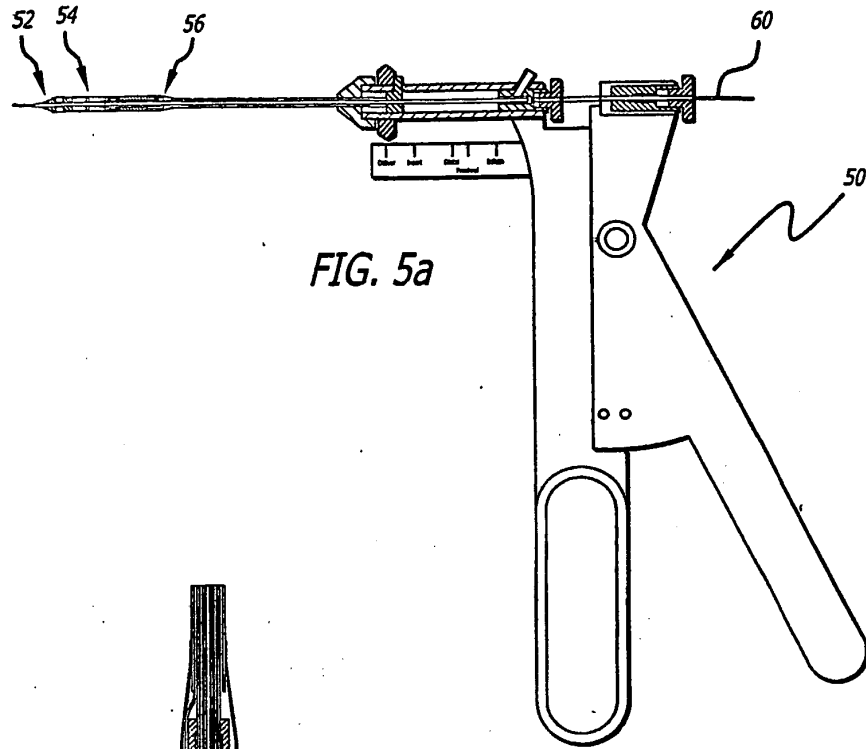


FIG. 5a

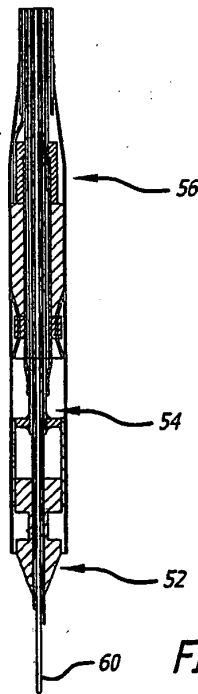


FIG. 5b

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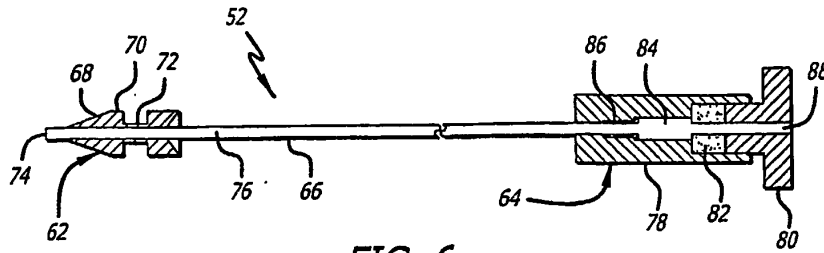


FIG. 6

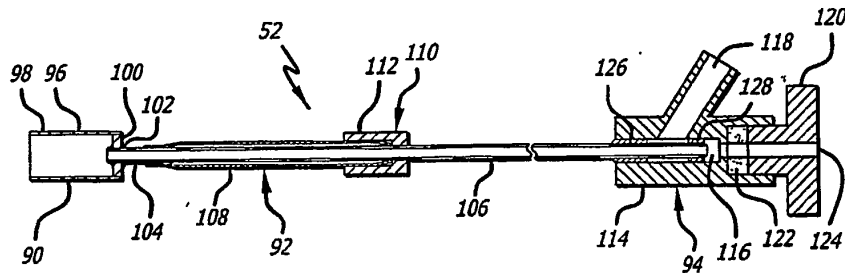


FIG. 7a

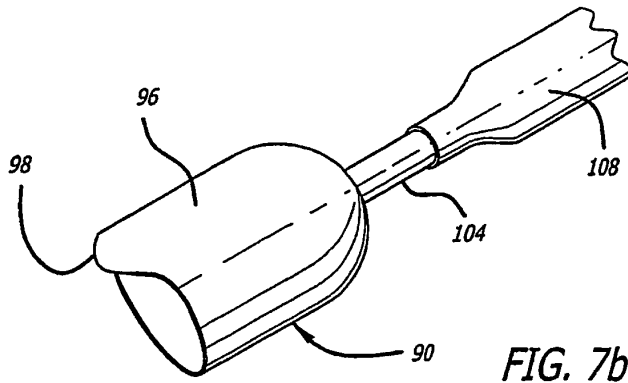


FIG. 7b

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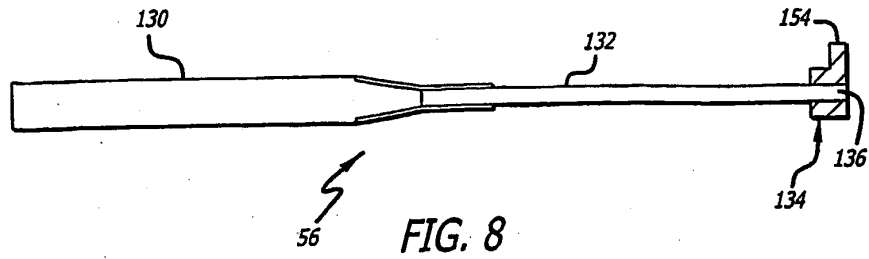


FIG. 8

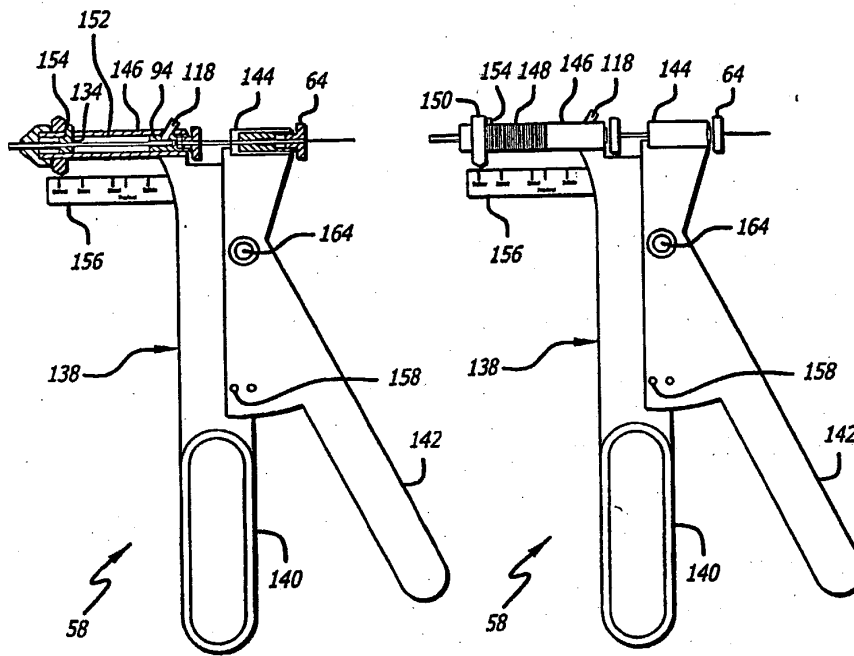


FIG. 9a

FIG. 9b

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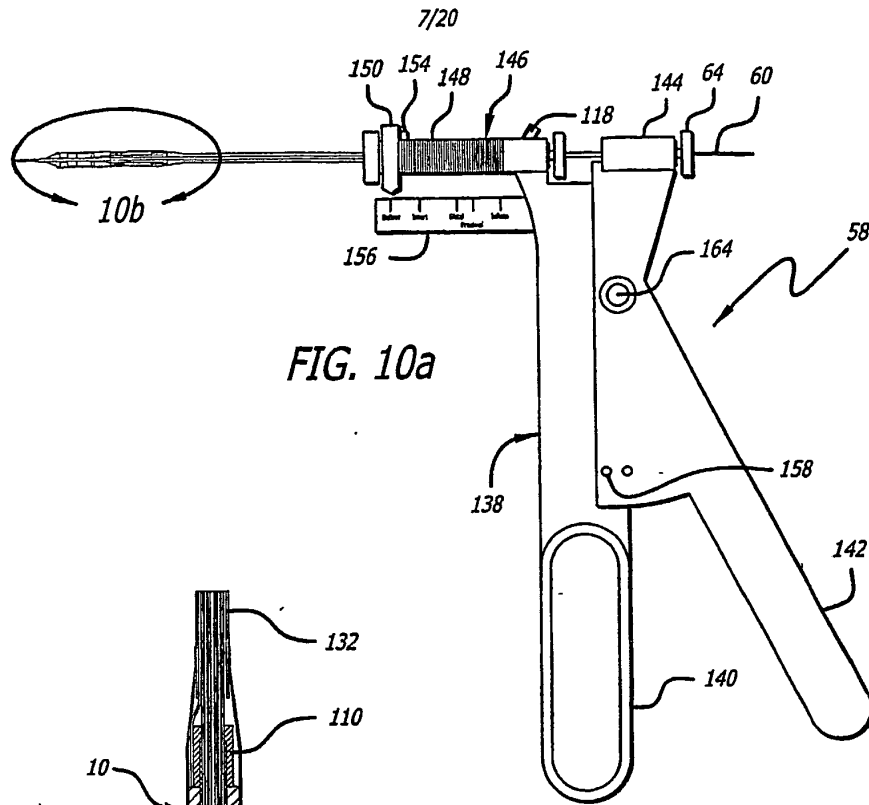


FIG. 10a

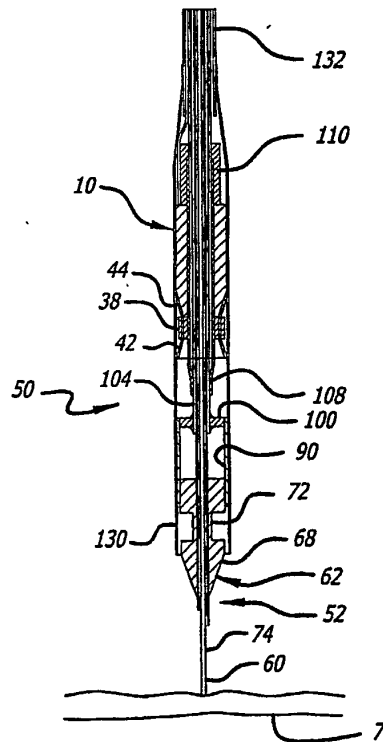


FIG. 10b

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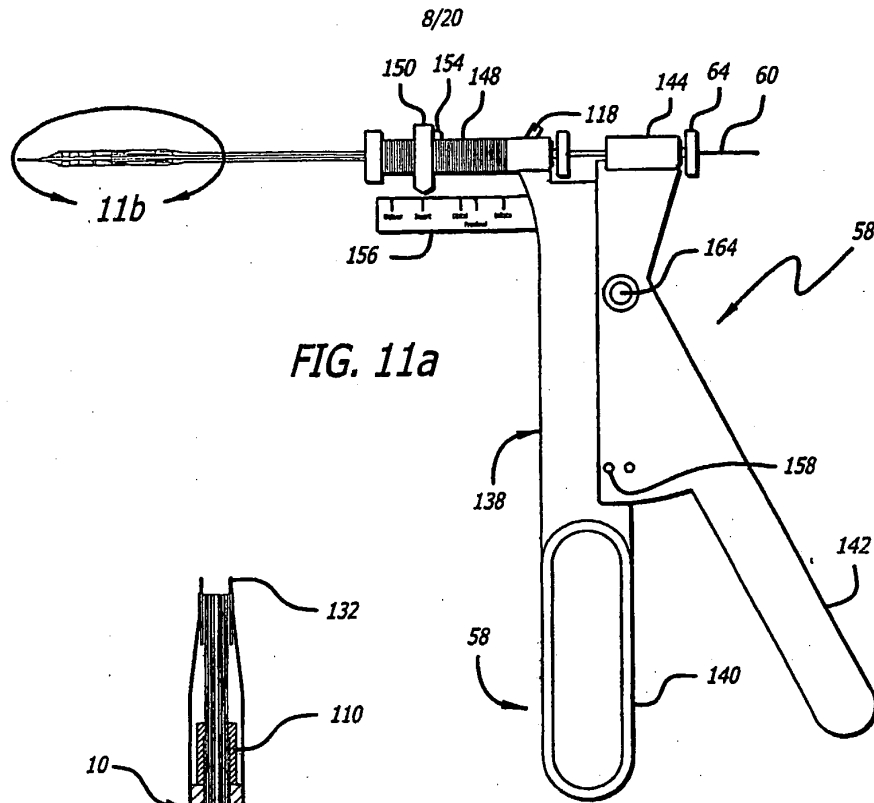


FIG. 11a

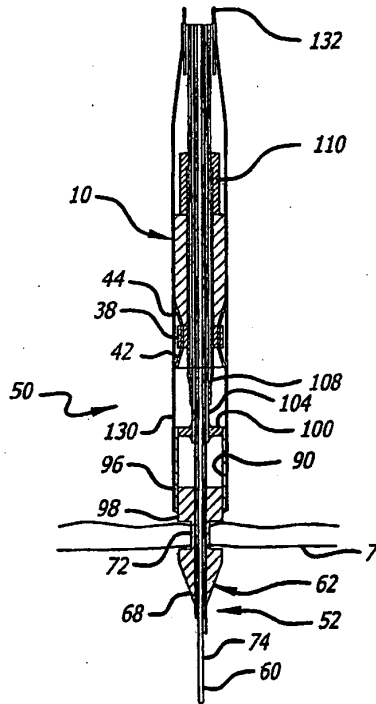


FIG. 11b

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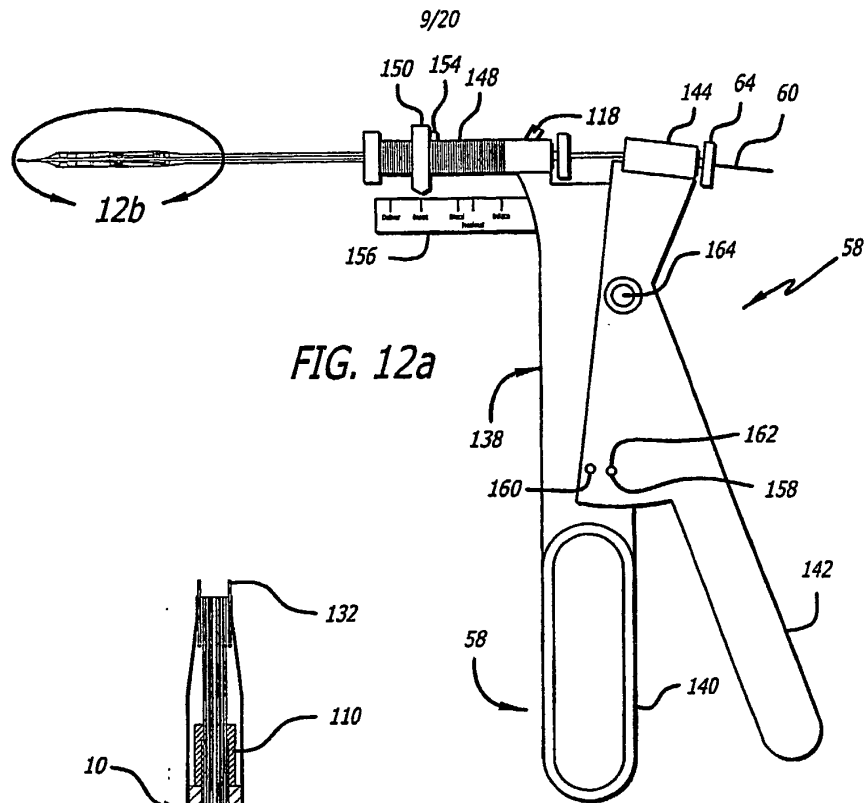


FIG. 12a

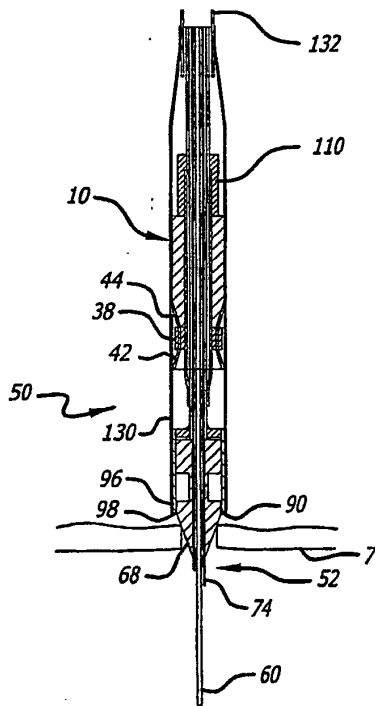


FIG. 12b

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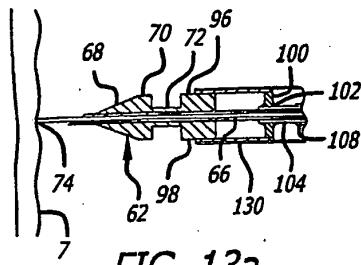


FIG. 13a

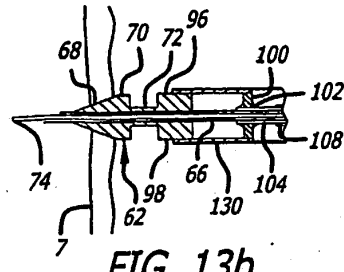


FIG. 13b

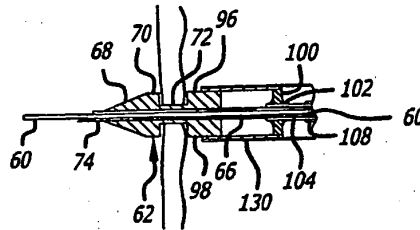


FIG. 13c

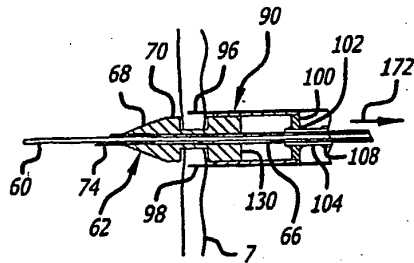


FIG. 13d

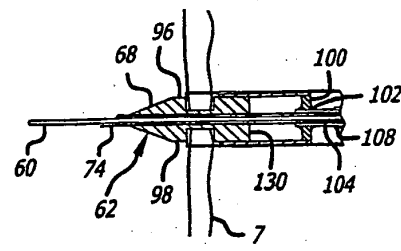


FIG. 13e

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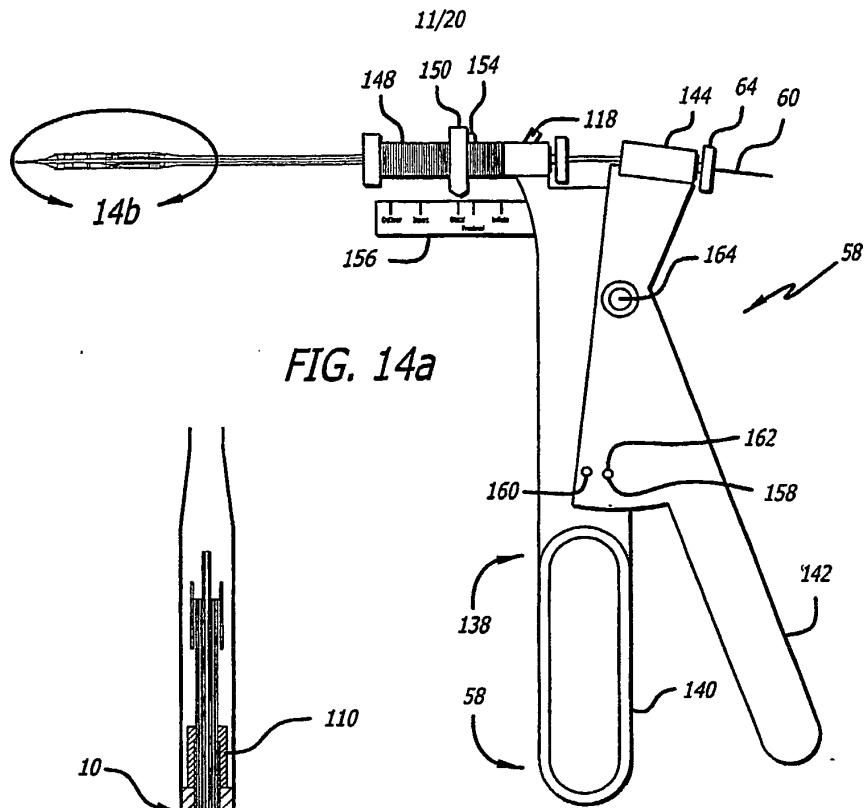


FIG. 14a

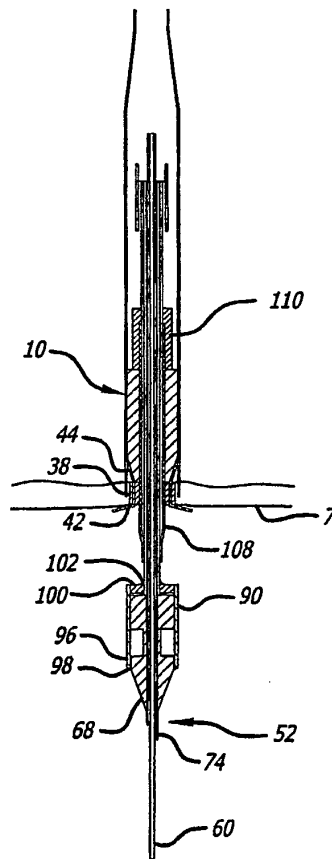


FIG. 14b

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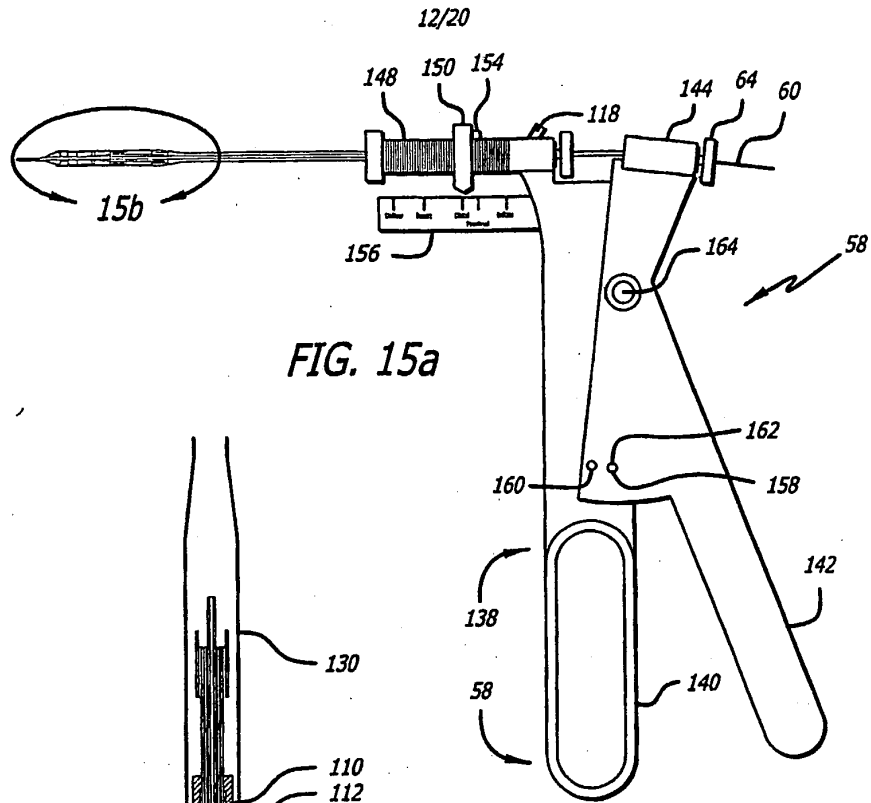


FIG. 15a

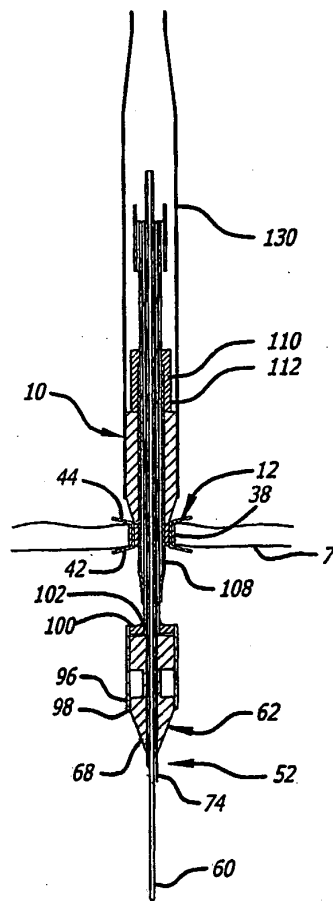


FIG. 15b

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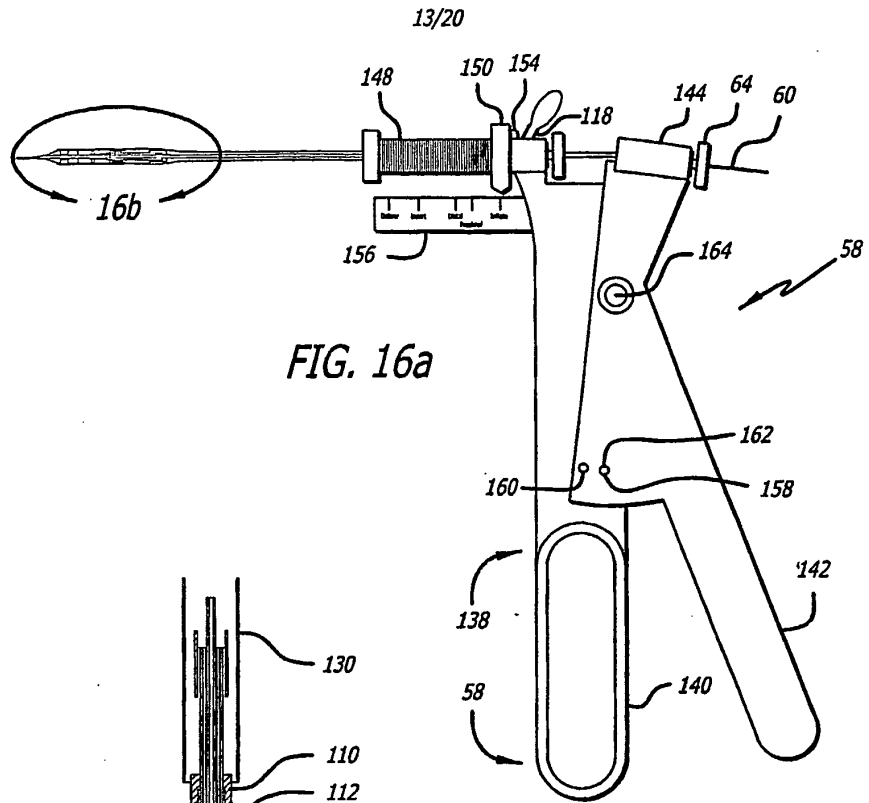


FIG. 16a

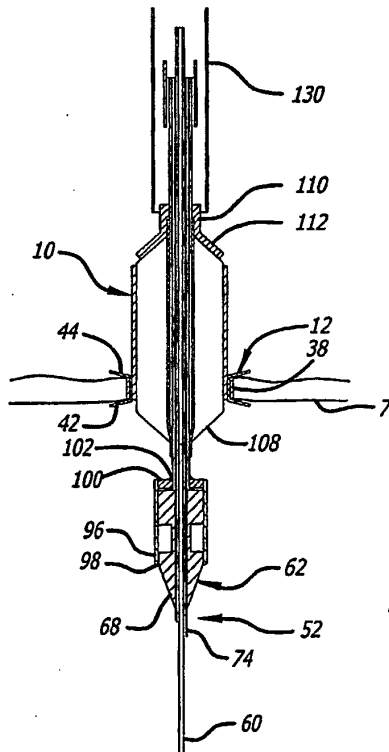


FIG. 16b

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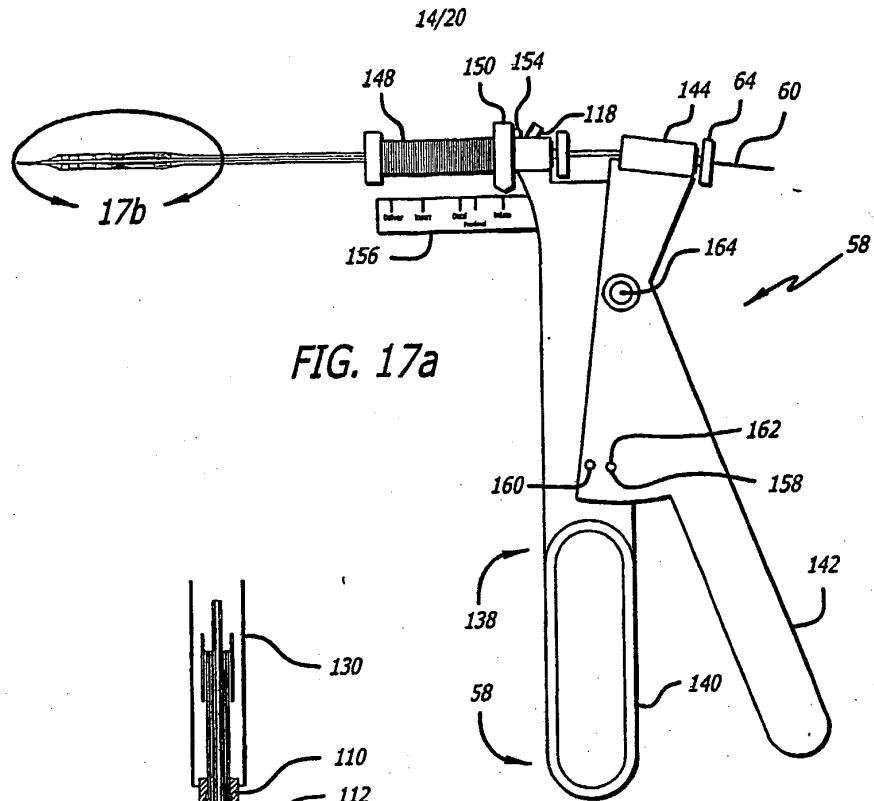


FIG. 17a

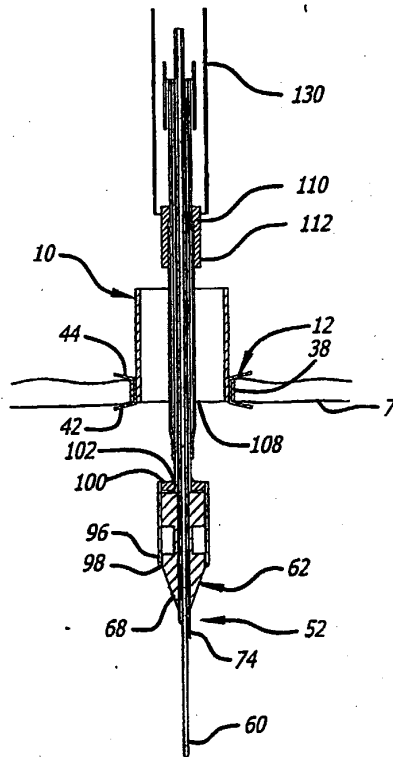


FIG. 17b

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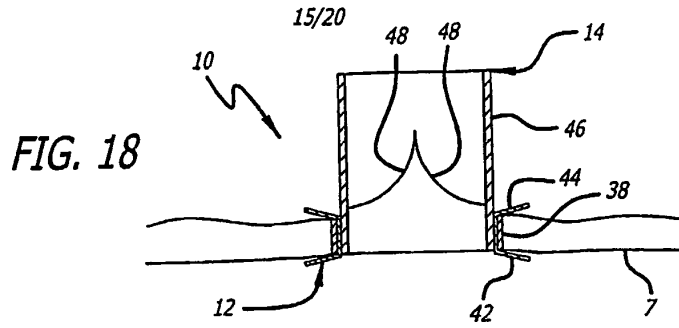


FIG. 18

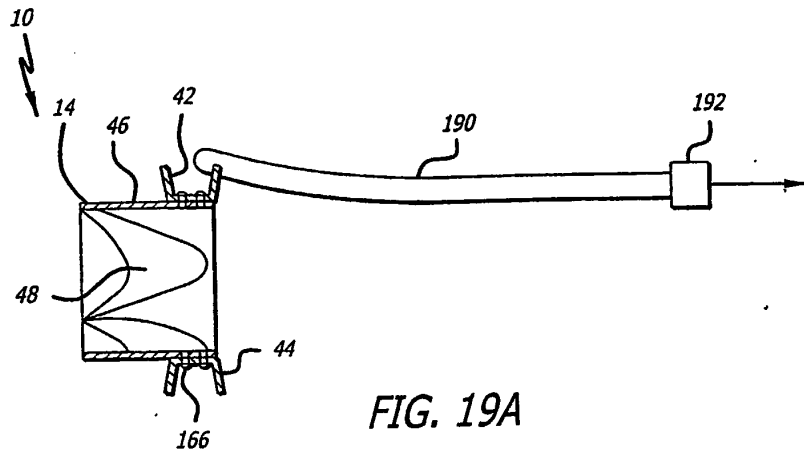


FIG. 19A

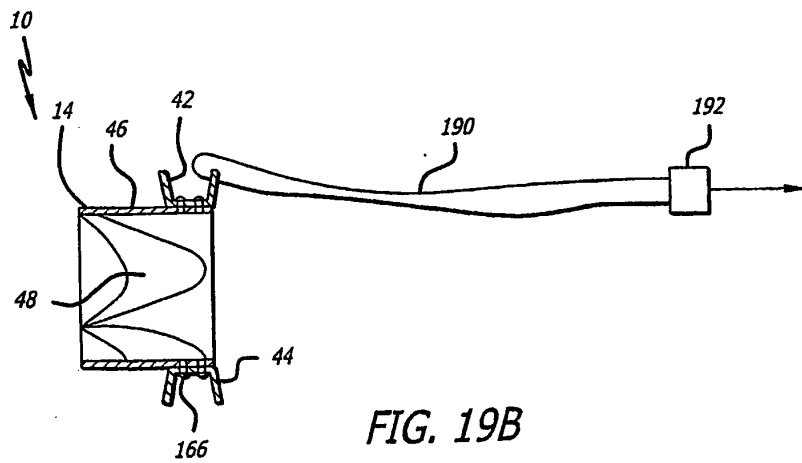
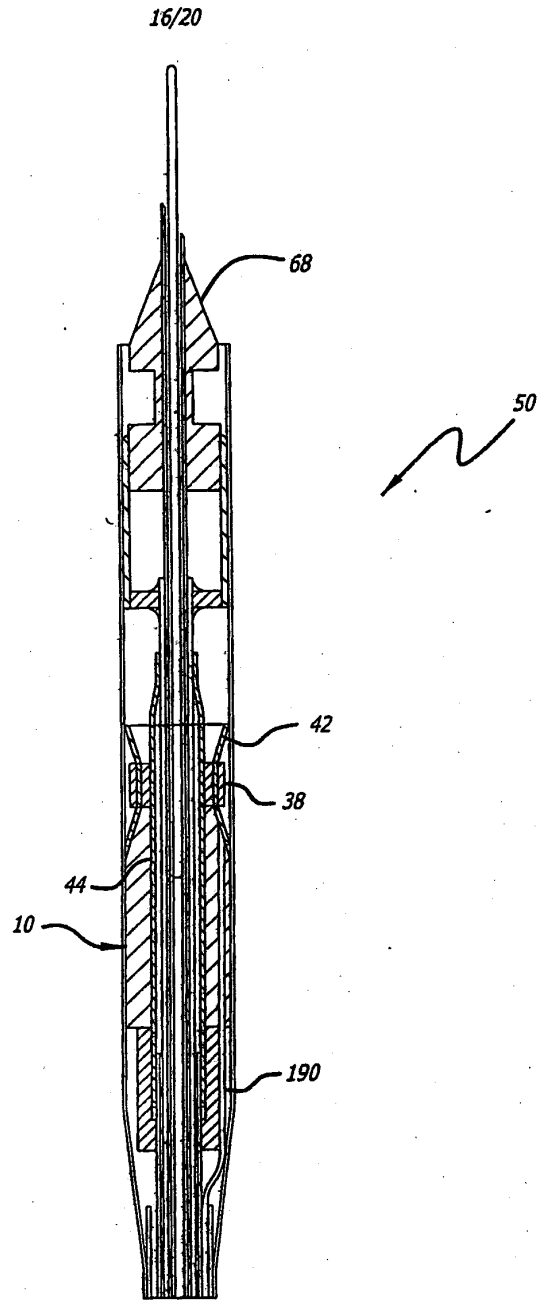


FIG. 19B

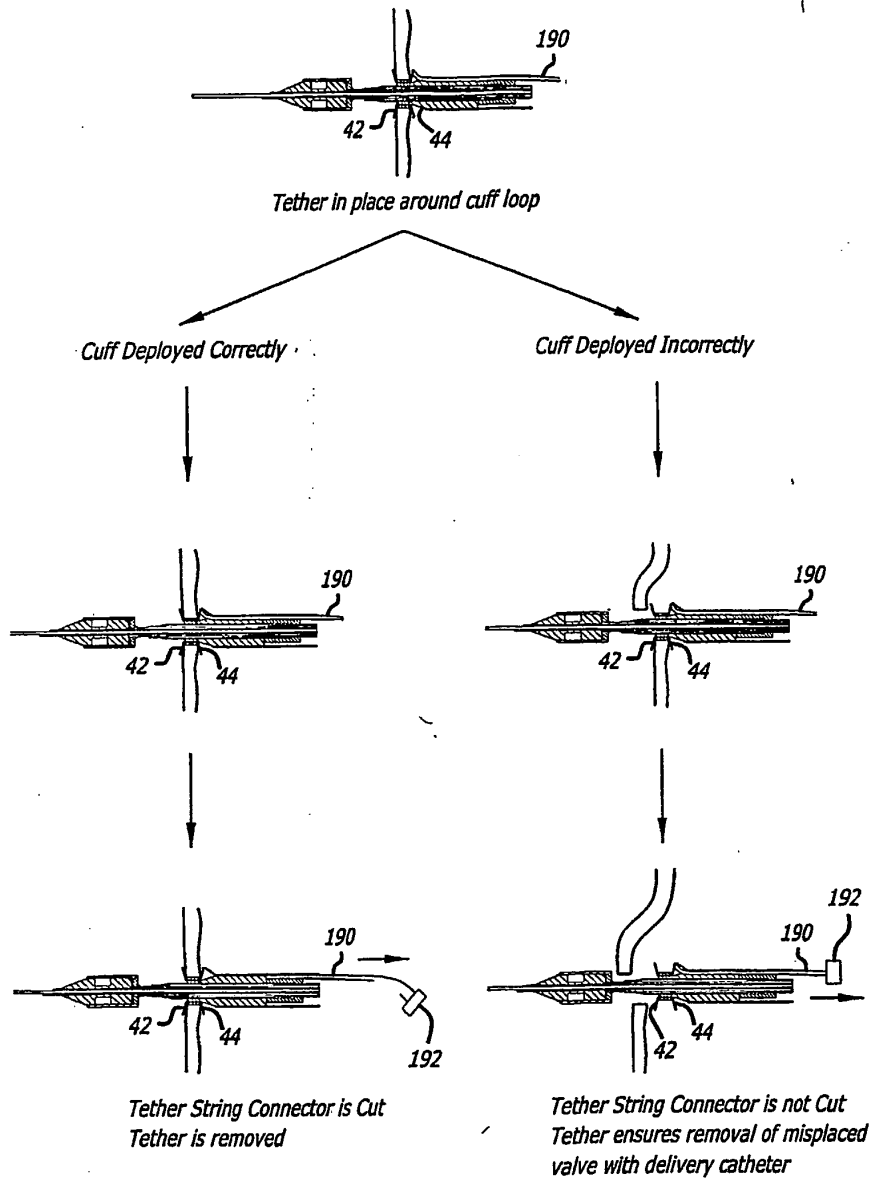
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FIG. 20



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FIG. 21



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FIG. 22A

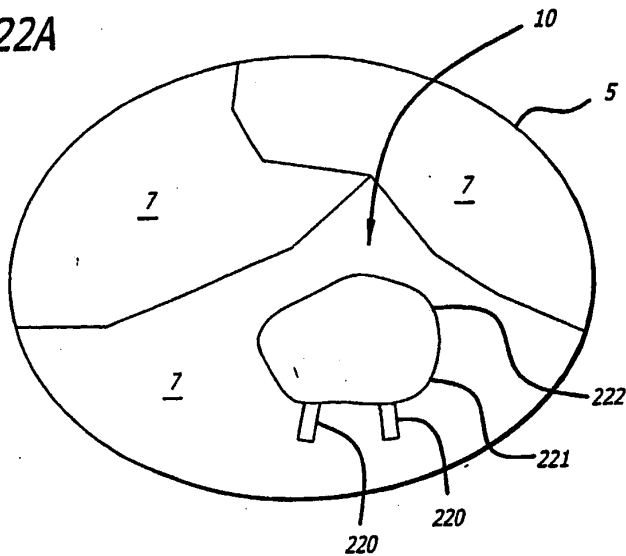
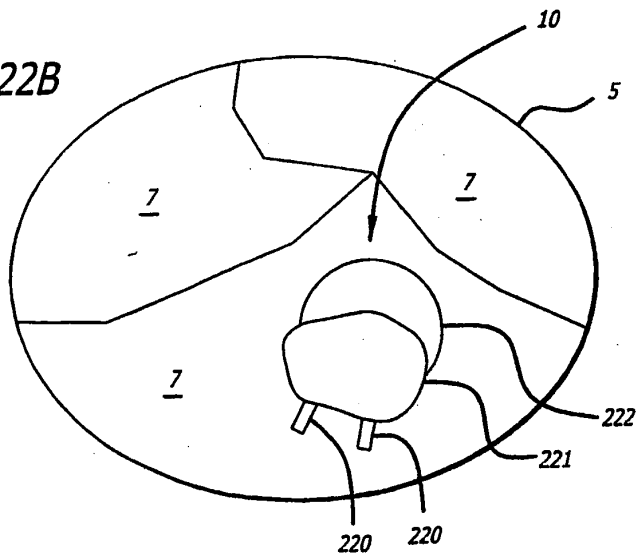


FIG. 22B



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FIG. 23A

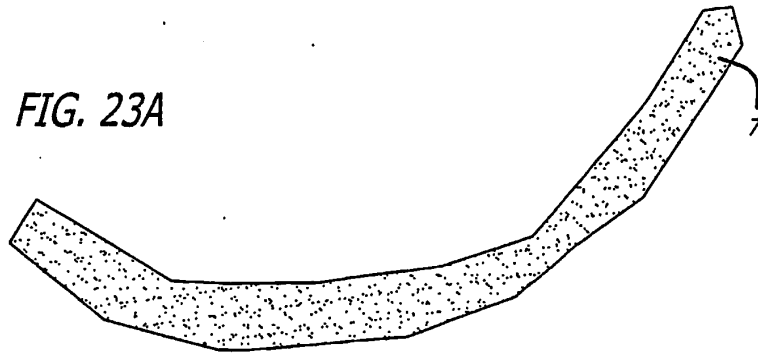


FIG. 23B

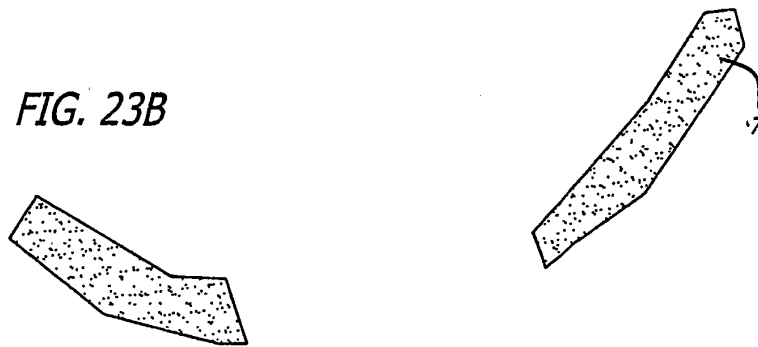
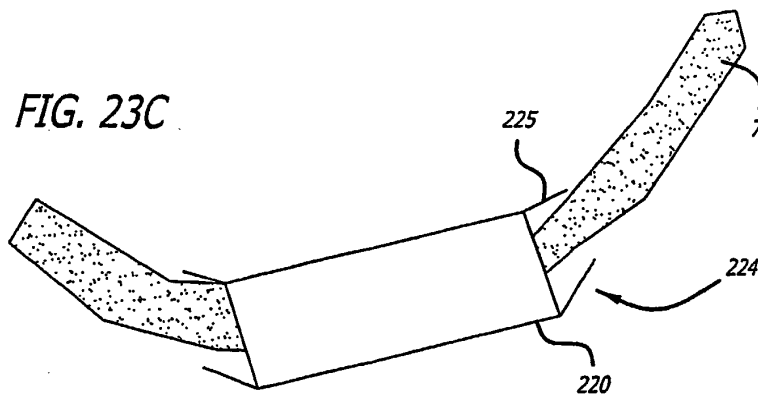


FIG. 23C



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FIG. 24A

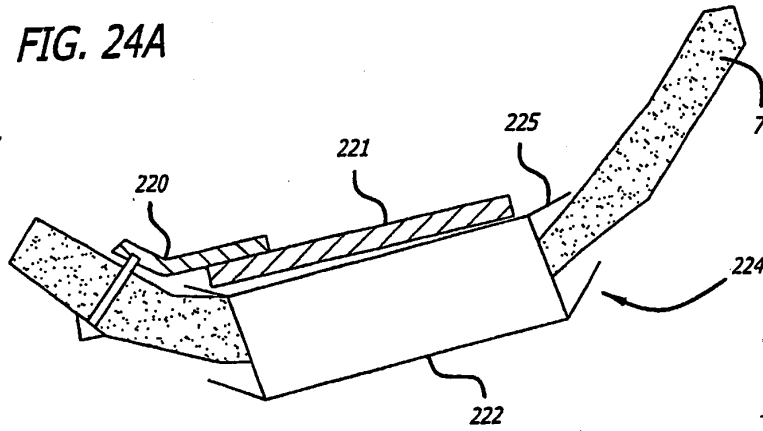
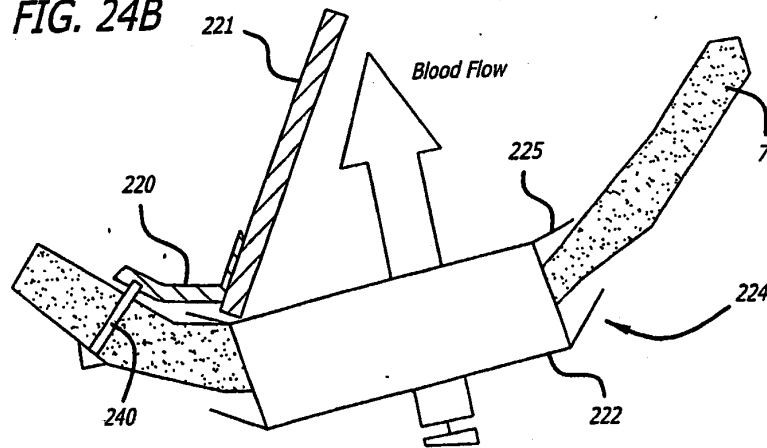


FIG. 24B



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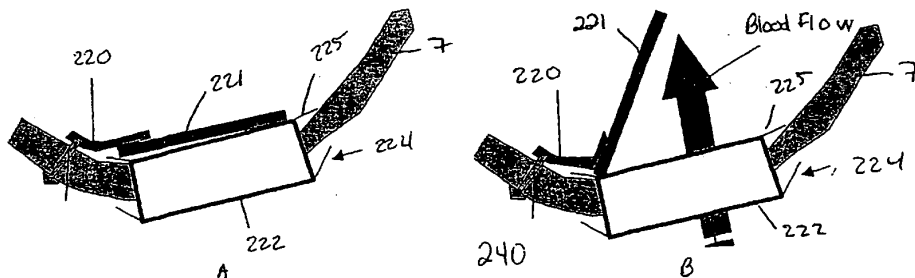
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WO 2004/019811 A2

(54) Title: METHOD AND DEVICE FOR TREATING DISEASED VALVE



(57) Abstract: A device and method for improving flow through a native blood vessel valve, such as the aortic valve, are provided. The present invention allows a miniature valve to be implanted into affected leaflets percutaneously, obviating the need for coronary bypass surgery. The method includes the cutting of small holes, on the order of 4mm, in the leaflets of a targeted valve, thereby allowing blood to flow through the newly formed holes. The holes are used as attachment sites for the miniature valves of the present invention.

METHOD AND DEVICE FOR TREATING DISEASED VALVE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This invention is related to the invention described in the provisional application serial number 60/407,414 filed on August 28, 2002 entitled, MINI-VALVE HEART VALVE REPLACEMENT, and claims priority therefrom.

BACKGROUND OF THE INVENTION

[0002] Blood vessel valves include flexible tissue leaflets that passively alternate between open and closed positions as the forces of a blood stream act upon them. As blood flows in a first direction, the leaflets are urged apart from each other, and allow the blood to pass. Between pulses, as the blood attempts to flow in a reverse direction, the blood acts upon upstream surfaces of the individual leaflets, causing the leaflets to move inwardly. As the leaflets move inwardly, the edges of the individual leaflets (two, in the case of bicuspid valves, and three in the case of tricuspid valves) abut against each other, effectively blocking the blood flow in the reverse direction.

[0003] Valves are also present within the heart. The heart contains four one-way valves that direct blood flow through the heart and into the arteries. Three of these valves, the aortic valve, the tricuspid valve, and the pulmonary valve, each have three leaflets. The fourth valve, the mitral valve, has two leaflets. By defining a direction in which blood can flow, these valves are responsible for the resulting pump effect a heart has on blood when the heart beats.

[0004] A number of diseases result in a thickening, and subsequent immobility or reduced mobility, of valve leaflets. Valve immobility leads to a narrowing, or stenosis, of the passageway through the valve. The increased resistance to blood flow that a stenosed valve presents eventually leads to heart failure and death.

[0005] Treating severe valve stenosis or regurgitation has heretofore involved complete removal of the existing native valve followed by the implantation of a prosthetic valve. Naturally, this is a heavily invasive procedure and inflicts great trauma on the body leading usually to great discomfort and considerable recovery time. It is also a sophisticated procedure that requires great expertise and talent to perform.

[0006] Historically, such valve replacement surgery has been performed using traditional open-heart surgery where the chest is opened, the heart stopped, the patient placed on cardiopulmonary bypass, the native valve excised and the replacement valve attached. More recently, it has been proposed to perform valve replacement surgery percutaneously, that is, through a catheter, so as to avoid opening the chest.

[0007] One such percutaneous valve replacement method is disclosed in U.S. Patent No. 6,168,614 (the entire contents of which are hereby incorporated by reference) issued to Andersen et al. In this patent, the prosthetic valve is collapsed to a size that fits within a catheter. The catheter is then inserted into the patient's vasculature and moved so as to position the collapsed valve at the location of the native valve. A deployment mechanism is activated that expands the replacement valve against the walls of the body lumen. The expansion force pushes the leaflets of the existing native valve against the lumen wall thus essentially "excising" the native valve for all intents and purposes. The expanded structure, which includes a scaffold configured to have a valve shape with valve leaflet supports, is then released from the catheter and begins to take on the function of the native valve. As a result, a full valve replacement has been achieved but at a significantly reduced physical impact to the patient.

[0008] One particular drawback with the percutaneous approach disclosed in the Andersen '614 Patent is the difficulty in preventing leakage around the perimeter of the new valve after implantation. Since the tissue of the native valve remains within the lumen, there is a strong likelihood that the commissural junctions and fusion points of the valve tissue (as pushed against the lumen wall) will make sealing of the prosthetic valve around the interface between the lumen and the prosthetic valve difficult. Furthermore, in some

patients, the deflection of the leaflets against the lumen walls could potentially obstruct the ostial openings of the lumen.

[0009] Although both the traditional open heart valve replacement surgery and the newer percutaneous valve replacement surgery replace a native valve in entirely different ways and both have their drawbacks, the paradigm of these two approaches is identical: Render the native valve useless, either through excision (open heart) or immobilization (percutaneous), and then implant a completely new replacement prosthetic valve to take over. In other words, both approaches rely entirely on the premise that the native valve must be entirely replaced (physically or functionally) by an entirely new prosthetic valve.

[0010] In contravention of the prior art, the present invention introduces an entirely different paradigm to valve replacement surgery, something neither taught nor contemplated by the open heart approach or the percutaneous approach (e.g., U.S. Patent No. 6,168,614) and something that largely avoids the drawbacks associated with both. More specifically, the present invention is premised on leaving the native valve in place, not on its excision or immobilization, and then utilizing the native valve as a platform for actually treating the diseased valve. This is a wholly new approach to treating diseased valves.

[0011] For example, in one embodiment of the invention, the physician diagnoses that the patient has a stenotic valve and then percutaneously mounts a plurality of small "leaflet valves" or "mini-valves" on one or more of the diseased native valve leaflets. In other words the native valve and its leaflets are used as a planar surface or a type of "bulkhead" on which new mini leaflet valves are mounted. The native valve remains in place but valve dysfunction is remedied due to the presence of these new leaflet valves. As a result, the diseased valve is successfully treated without the complication associated with removing the native valve.

[0012] This leads to a much simpler and safer approach as compared to the prior art. It avoids the invasive nature of the open heart approach and avoids the sealing and ostial blockage problems of the percutaneous approach.

BRIEF SUMMARY OF THE INVENTION

[0013] The present invention relates to the treating of narrowed, stiff or calcified heart valves. The aforementioned problems with present treatment methods are addressed by treating the targeted valve leaflets individually, rather than replacing the entire valve using an open-heart or a percutaneous procedure. That is, in the present method, the rigid heart valve leaflet is treated by introducing small prosthetic valves into the leaflet itself.

[0014] The present invention includes a method of treating the individual leaflets of a targeted heart valve that includes installing one or more small, one-way valves into the targeted leaflets. These smaller valves can be placed in the leaflet using catheter systems, obviating the need for opening the heart or great vessels, cardiopulmonary bypass, excision of the diseased valve, and a thoracotomy. Additionally, multiple small valve placements might reduce the long-term risks associated with a complete prosthetic valve, because failure of an individual valve will not necessarily lead to cardiac failure. The remaining small valves and remaining healthy native valves might be sufficient to sustain life.

[0015] One aspect of the present invention provides a method of placing small valves through a target valve that involves puncturing the target valve and pushing the miniature valve through the target valve tissue. The valve is then anchored in place using a variety of mechanisms including tabs, riveting of the valve housing, spines, friction placement or the use of a fixation cuff.

[0016] Another aspect of the present invention provides a variety of valve implant mechanisms constructed and arranged for placement in a target valve leaflet. The valve implant mechanisms include a valve housing that operably houses a valve mechanism such as a duckbill valve, a tilting check valve, a ball and cage valve, or a hinged leaflet valve or a valve using tissue leaflets. The valve implant may also include an anchoring mechanism such as tabs, spines, threads, shoulders, or a deformable housing.

[0017] The present invention also provides a device useable to remove a section of the target valve, without damaging the surrounding valve tissue, and inserting a valve implant into the void left in the target valve. The device is contained within a catheter such that a valve implant insertion procedure can be accomplished percutaneously. Preferably, this delivery system is constructed and arranged to be placed through a 14 French catheter, traverse the aorta, land on a targeted leaflet such as one of the leaflets of the aortic valve, puncture the leaflet at a predetermined spot, cut a hole on the order of 4mm in diameter, capture and remove any cut tissue, place a radially compressed one-way valve including a Nitinol attachment cuff and a stainless steel sizing ring into the leaflet hole, securely attach the valve assembly to the leaflet, dilate the hole and the valve assembly to a precise final diameter, such as 8mm, using a balloon, and be retracted leaving the valve assembly in place in the leaflet.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] Figure 1 is a perspective view of three valve implants of the present invention installed in the leaflets of a tricuspid valve;

[0019] Figure 2 is a side elevation of two valve implants of the present invention installed in a stenotic leaflet;

[0020] Figures 3a-f are side elevations of various embodiments of the valve implant of the present invention;

[0021] Figure 4a is a detailed sectional view of a preferred embodiment of the valve implant of the present invention in a compressed or folded state;

[0022] Figure 4b is a detailed sectional view of the valve implant of Figure 4a in an expanded state;

[0023] Figures 4c-f are sectional views of alternative configurations of the preferred valve implant of the present invention;

[0024] Figure 5a is a sectional view of an embodiment of the delivery system of the present invention;

[0025] Figure 5b is a detailed sectional view of the distal end of the delivery system of Figure 5a;

[0026] Figure 6 is a sectional view of the leaflet capture catheter of the present invention;

[0027] Figure 7a is a sectional view of the delivery catheter of the present invention;

[0028] Figure 7b is a perspective view of an alternative cutter of the present invention;

[0029] Figure 8 is a sectional view of the sheath catheter of the present invention;

[0030] Figure 9a is a detailed sectional view of the handle of the delivery system of the present invention;

[0031] Figure 9b is a side elevation of the handle of Figure 9a;

[0032] Figure 10a is a side elevation of the handle of the present invention in a "Deliver" position;

[0033] Figure 10b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Deliver" position of Figure 10a;

[0034] Figure 11a is a side elevation of the handle of the present invention in an "Insert" position;

[0035] Figure 11b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Insert" position of Figure 11a;

[0036] Figure 12a is a side elevation of the handle of the present invention in a "Cut" position;

[0037] Figure 12b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Cut" position of Figure 12a;

[0038] Figures 13a-e are an operational sequence of the capture device of Figure 6 interacting with the cutting drum of Figure 7a to remove and capture a section of tissue from a target valve leaflet;

[0039] Figure 14a is a side elevation of the handle of the present invention in a "Distal" position;

[0040] Figure 14b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Distal" position of Figure 14a;

[0041] Figure 15a is a side elevation of the handle of the present invention in a "Proximal" position;

[0042] Figure 15b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Proximal" position of Figure 15a;

[0043] Figure 16a is a side elevation of the handle of the present invention in an "Inflate" position;

[0044] Figure 16b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Inflate" position of Figure 16a and a balloon of the delivery system is inflated;

[0045] Figure 17a is a side elevation of the handle of the present invention in an "Inflate" position during a deflating procedure;

[0046] Figure 17b is a sectional view of the distal end of the delivery system of the present invention when the handle is in the "Inflate" position of Figure 17a and the balloon of the delivery system has been deflated;

[0047] Figure 18 is a sectional view of a valve implant of the present invention in a deployed configuration;

[0048] Figures 19A and 19B are cross-sectional views of a valve implant of the present invention in a deployed configuration;

[0049] Figure 20 is a cross-sectional view of a portion of a catheter delivery system in accordance with a preferred embodiment of the present invention;

[0050] Figure 21 is a flow chart figure showing a tether retraction system for use in a catheter delivery system in accordance with the present invention;

[0051] Figures 22A and 22B are top views of a hinged valve in accordance with another preferred embodiment of the present invention;

[0052] Figures 23A, 23B and 23C are cross-sectional views of a hinged valve in accordance with the present invention; and,

[0053] Figures 24A and 24B are cross-sectional views of a hinged valve in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0054] Referring now to the Figures, and first to Figure 1, there is shown a native tricuspid valve 5 with a valve implant 10 of the present invention installed in each of the three leaflets 7 of the tricuspid valve 5. The valve implants 10 are shown in an open position to demonstrate that blood is allowed to flow through the valve implants 10, in one direction, even though the native tricuspid valve 5 remains closed. These valve implants 10 would similarly work with a native bicuspid valve, unicuspid valve or quadracuspid valve.

[0055] Figure 2 demonstrates the positioning of a valve implant 10 in a native leaflet 7. The leaflet 7 is shown as having calcified tissue 9, characteristic of a stenosed valve. Notably, the valve implants 10 have been inserted through the calcified tissue 7. Also notable is that there may be more than one valve implant 10 inserted into a single leaflet 7 if additional flow capacity is desired. Alternatively, though not shown, the valve implant 10 may be installed between the leaflets 7. This configuration is especially feasible in heavily

stenosed valves that have relatively immovable leaflets. Such leaflets may be fully or partially fused together. The valve implants generally comprise an anchoring mechanism 12 and a valve mechanism 14.

[0056] Figures 3-5 illustrate several embodiments of the valve implants 10 of the present invention. In Figures 3a-f, a family of valve implants 10 is provided that are characterized by a rigid housing 16 with a self-tapping tip 18. The valve implants 10 of Figures 3a-f include a variety of valve mechanisms 14 and anchoring mechanisms 12.

[0057] The valve implant 10 of Figure 3a, as well as those of Figures 3c and 3d, has a valve mechanism 14 that comprises a single flap 20, hinged on one side, that acts against the rigid housing 16 to prevent flow in a reverse direction. A benefit of this valve design is ease of construction. The valve implant 10 of Figure 3a also uses the friction between the rigid housing 16 and the native heart leaflet 7 (Figure 2) as an anchoring mechanism to hold the valve implant 10 in place. The pointed tip 18 allows the valve implant 10 to be urged through, or twisted through, the native heart leaflet without the need for cutting a hole in the leaflet prior to installing the valve implant 10. Thus, in certain cases, there is sufficient gripping power between the housing 16 and the leaflet 7 to hold the housing 16 in place. This holding power may be increased by providing a textured surface (not shown) on the housing 16, or selecting a housing material, such as a mesh or stiff fabric, that allows a controlled amount of ingrowth, sufficient to secure the valve implant 10, but not so much as to cause a flow hindrance within the valve implant 10.

[0058] The valve implant 10 of Figure 3b has a valve mechanism 14 that comprises a pair of members constructed and arranged to form a duckbill valve 22. The duckbill valve 22 operates in a similar way to a tricuspid or bicuspid valve. When fluid flows through the valve in a desired direction, each of the members of the duckbill valve 22 move apart from each other. When the flow reverses, such as during diastole, the fluid forces the members of the duckbill valve 22 together, closing the valve 10.

[0059] Also included in the valve implant 10 of Figure 3b is an anchoring mechanism 12. The anchoring mechanism 12 generally comprises a plurality of radially extending posts 24.

These posts 24 act against an upstream side 26 (Figure 2) of the leaflet 7, thereby counteracting systolic pressure from the blood stream.

[0060] The valve implant 10 of Figure 3c includes a single flap 20 valve mechanism 14 and an anchoring mechanism 12 that includes a plurality of angled barbs 28. The barbs 28 are located near the upstream side of the valve implant 10 and are angled back toward the downstream side. The angled barbs 28 may provide increased gripping power, especially if more than one row, such as shown in Figure 3c, are provided. Because one or more of the rows of barbs 28 will be located within the leaflet 7 when the valve implant is in place, the barbs 28 provide resistance to movement in both directions, and may stimulate ingrowth.

[0061] The valve implant 10 of Figure 3d provides a combination of many of the features already discussed. The valve 10 has an anchoring mechanism 12 that includes both posts 24, on the downstream side to prevent valve movement in the upstream direction, and angled barbs 28 on the upstream side of the valve 10. The valve mechanism 14 demonstrates another valve design. The valve mechanism is an outside-hinged dual flap valve 30. The individual flap members rotate about their outer edges when influenced by fluid flow.

[0062] Figure 3e shows a valve implant 10 with a valve mechanism 14 that uses an inside-hinged dual flap valve 32, with individual flap members that rotate about their inner edges when influenced by fluid flow. The valve implant 10 combines upstream posts 24 with upstream-angled barbs 28 on the downstream side of the valve implant 10.

[0063] The valve implant 10 shown in Figure 3f combines a single flap 20, as a valve mechanism 14, with an anchoring mechanism 12 that uses an external helical thread 34 to anchor the valve implant 10 to a valve leaflet 7. The helical thread 34 provides resistance to movement in both the upstream and downstream directions. The helical thread 34 also provides a self-tapping action when the valve implant 10 is being screwed into place in a leaflet 7.

[0064] One skilled in the art will realize that any of the aforementioned anchoring mechanisms 12 and valve mechanisms 14 may be combined in a single valve implant 10. For example, the valve implants 10 shown in Figure 2 include upstream and downstream posts 24 as well as upstream and downstream angled barbs 28.

[0065] A preferred embodiment of the valve implant 10 of the present invention is shown in Figures 4a and 4b. The valve implant 10 is expandable from the compressed configuration shown in Figure 4a, to the expanded configuration shown in Figure 4b. The valve implant 10 is constructed and arranged to fit within a catheter when in the compressed configuration. Compression may be accomplished radially, helically, longitudinally, or a combination thereof. Preferably, the compression of the valve implant 10 is radial.

[0066] Like the aforementioned embodiments of the valve implants 10, the valve implant 10 of Figure 4 generally includes an anchoring mechanism 12 and a valve mechanism 14. The anchoring mechanism 12 generally comprises a cuff 36 and a sizing ring 38. The cuff 36 is preferably constructed of Nitinol and has a middle portion 40 a set of radially expanding distal legs 42 and a set of radially expanding proximal legs 44.

[0067] In the compressed state, the legs 42 and 44 are somewhat aligned with the middle portion 40 to allow the cuff 36 to be compressed into a catheter, preferably a 14 French catheter. The cuff 36 is either expandable or self-expanding. Upon release from the catheter, the legs 42 and 44 fold outwardly until they radiate from the middle portion 40 at approximately right angles to the longitudinal axis of the cuff 36. The legs 42 and 44 are designed to act against the upstream and downstream sides, respectively, of a valve leaflet, sandwiching the leaflet therebetween and anchoring the cuff 36 to the leaflet.

[0068] The anchoring mechanism 12 of the valve implant 10 shown in Figures 4a and 4b also includes a sizing ring 38. The sizing ring 38 is preferably a stainless steel stent that circumjacently surrounds the middle portion 40 of the cuff 36. The sizing ring 38 is constructed and arranged to expand with the cuff 36 until a predetermined size is reached. Once the predetermined size is reached, the sizing ring 38 prevents further expansion by

the cuff 36. Over expansion of the cuff 36 could render the valve mechanism 14 inoperable, cause calcified tissue to break away from the stenosed valve and become released into the blood stream, tear the leaflet tissue, or weaken the cuff 36.

[0069] The valve mechanism 14 includes a sleeve 46 and one or more valve members 48. The sleeve 46 may be rigid or flexible, but it is preferably flexible. More preferably, the sleeve 46 is constructed of any sufficiently flexible material capable of withstanding the environment to which it will be subjected, including but not limited to, any mammalian tissue, including human or pig tissue, vertebrate tissue, or a polymer or other synthetic material. The valve members 48 are shown as being duckbill valves but may be any of the aforementioned discussed valve designs.

[0070] Most preferably, the valve mechanism 14 comprises an intact harvested valve from an animal, such as pig, and is taken from an appropriate location such that the expanded, original size is suitable for use in the leaflets of the stenotic valve being treated. The harvested valve is sutured or otherwise attached to the inside surface of the cuff 36. In operation, the valve implant 10 is compressed such that it can be placed in a small catheter for percutaneous delivery. At the time of delivery, the valve implant 10 is attached to a stenotic leaflet and radially expanded to its functional diameter. Prior to, or during expansion, the distal and proximal legs 42 and 44 expand radially, allowing the cuff 36 to create a strong bulkhead-like fitting on both sides of the leaflet. After attachment is made to the leaflet, the cuff 36, sizing ring 38, and the valve mechanism 14 are radially expanded to the functional diameter of the valve implant 10. During this expansion, the sizing ring 38 exhibits plastic deformation until it achieves the maximum diameter, at which point the sizing ring 38 resists further expansion.

[0071] Figures 4c – 4f depict alternative configurations for the preferred valve implant 10. The valve implant 10 in Figure 4c has a sleeve 46 attached to the anchoring mechanism 12 with two rows of sutures 166 and is configured so an upstream edge 168 of the sleeve 46 is roughly aligned with the distal legs 42 of the anchoring mechanism 12. The valve implant 10 in Figure 4d has a sleeve 46 attached to the anchoring mechanism 12 with one row of

sutures 166 and is configured so the upstream edge 168 of the sleeve 46 is roughly aligned with the proximal legs 44 of the anchoring mechanism 12. The valve implant 10 in Figure 4e has a sleeve 46 attached to the anchoring mechanism 12 with two rows of sutures 166 and is configured so the downstream edge 170 of the sleeve 46 is roughly aligned with the proximal legs 44 of the anchoring mechanism 12. The valve implant 10 in Figure 4f has a sleeve 46 attached to the anchoring mechanism 12 with one row of sutures 166 and is configured so the downstream edge 170 of the sleeve 46 is roughly aligned with the distal legs 42 of the anchoring mechanism 12. The sleeve 46 may comprise a scaffold to which valve members 48 are attached, or the entire valve mechanism 14 may be a harvested tissue valve such as an aortic valve.

[0072] In one preferred embodiment, the valve implant 10 can be configured to include commissural support structure like a wireform stent as sometimes found in known standard sized prosthetic tissue valves. In such a configuration, the valve material will comprise a biologic tissue such as human pericardium or equine pericardium or small intestine submucousal tissue. In the present invention, the material must be thin enough to be compressed and perhaps folded so as to fit the valve implant 10 within the delivery system (described below). In a preferred embodiment, such tissue has a thickness of around 180 microns or less.

[0073] In another alternative embodiment, the cuff mechanism could be a torroidal shaped sack (not shown), similar in shape to a deflated inner tube, attached to the exterior surface of the base of the valve implant 10 and connected to a UV curable liquid polymer reservoir contained within the delivery catheter. The sack material is composed of an elastic material that can be radially expanded by a balloon angioplasty catheter or by the injection of the liquid polymer. The liquid adhesive contained within the sack can be transformed to a solid polymer through UV light activated cross-linking

[0074] This sack, essentially empty, can be manipulated by the delivery catheter to straddle both sides or surfaces around the hole cut in the leaflet for receiving the valve

implant 10. Once located, the sack can be enlarged by an underlying balloon catheter. Then, UV curable liquid polymer can be injected into the sack through the delivery catheter. Once filled with an adequate amount of a polymer and adjusted distally/proximally to form sufficient bulges on both sides of the valve leaflet, a UV light emission source, located within the delivery catheter near the bag is activated to wash the adhesive filled bag with UV curing light. Once hardened by the UV effect, the cuff maintains its enlarged size without balloon support.

[0075] Referring to Figs. 22A-24B, yet another embodiment of a valve implant 10 of the present invention is shown, this embodiment being a hinged valve. In this embodiment, the valve implant 10 comprises a valve "poppet" 221 that is connected to a valve leaflet 7 by an attachment mechanism 220 that operates much like a hinge. The valve poppet 221 pivots between a sealed and an unsealed condition around the pivot point of the attachment mechanism 220 according to the flow of blood (Figures 24A and 24B).

[0076] The poppet 221 or "mini-leaflet" can be comprised of any material sufficiently flexible to allow for the described movement yet sufficiently durable to withstand the environment. For example, the poppet 221 may be made from materials such as biologic tissue, a polymer or a carbon based material. Moreover, the poppet 221 could be coated with tissue from the patient, e.g., tissue from a patient's vein wall. The poppet material may include supporting internal structure and/or an outer ring to ensure the structural integrity of the poppet 221 during operation. The poppet can have a curved in order to better conform the poppet 221 to the contour of the native leaflet 7.

[0077] In this regard, after a hole is created in the leaflet 7 (discussed below), the poppet 221 is pushed or screwed into the leaflet. It may be retained there by barbs or screw threads or by hooks or other types of retaining mechanisms.

[0078] The attachment mechanism 220 (Figs. 22A-22B and 24A-24B), in a preferred embodiment, is a hinge. The hinge may be fabricated from such materials as a polymer strip, a biologic tissue strip, a metal (e.g., stainless steel) strip or a pyrolytic carbon material.

Referring to Figs. 24A and 24B, the hinged mechanism may be attached to the leaflet / tissue using a barbed spike 240.

[0079] In an optional embodiment of the invention shown in Figs 22A-24B, the valve implant 10 may also include a support ring 222 that is disposed around the inside perimeter of the hole that is cut in the leaflet 7 to receive the valve implant 10. The support ring 222 may serve to limit embolization and to enhance leaflet integrity (thereby avoiding prolapse). The support ring 222 could be deployed into the hole either with an expanding balloon or it could be mechanically deployed using a mechanical spreader.

[0080] Referring to Figs. 23A-24B, the optional support ring 222 may include struts 224, 225 that serve to capture the edges of the leaflet 7 in the hole so as to support and retain the support ring 220 at the site.

[0081] Catheter Delivery System

[0082] Referring now to Figures 5a and 5b, there is shown a preferred embodiment of a catheter delivery system 50 of the present invention. The catheter delivery system 50 generally comprises a leaflet capture catheter 52, a delivery catheter 54, a catheter sheath 56, and a handle 58. The catheter delivery system 50 is preferably constructed and arranged for use with a guidewire 60.

[0083] As best seen in Figure 6, the leaflet capture catheter 52 includes a cutter die 62 connected to a hemostatic hub 64 with a cannula 66. The cutter die 62 may be of unitary construction and includes a conical distal end 68 that increases in radius proximally until a flat 70 is reached. Proceeding proximally, the flat 70 ends abruptly to form a capture groove 72. At the proximal end of the capture groove 72, the cutter die 62 returns to approximately the same diameter as the flat 70. The purpose of the cutter die 62 is to "grab" tissue that resiliently "pops" into the capture groove 72. Once in the capture groove 72, the tissue is held in place as a cutter 90 (explained below) cuts through the tissue.

[0084] One skilled in the art will realize that alternatives could be used instead of a cutter die 62. For example, the cutter die 62 could be replaced with a balloon, constructed and

arranged to be inflated on the upstream side of the leaflet 7 (or both sides of the leaflet to capture the tissue) and sized to fit within the cutter 90. A second balloon could also be arranged to be inflated on the downstream side of the leaflet, such that the leaflet is captured between the two balloons. The balloon concept, though arguably more complicated and expensive, may prove useful in situations where a cut needs to be made in tissue that has lost the resiliency needed to "pop" into the capture groove 72 of the cutter die 62. Other devices, such as barbs and clamps, are also envisioned to act in this manner.

[0085] The cannula 66 connects with the cutter die 62 and the hemostatic hub 64. At the distal end of the cannula 66 is a needle tip 74. The needle tip 74 is angled to form a sharp point usable to puncture tissue. The cannula 66 includes a lumen 76 extending the length thereof. This lumen 76 is used to accommodate a guidewire 60 (Figure 5).

[0086] The hemostatic hub 64 allows the leaflet capture catheter 52 to be removably attached to the handle 58. The hemostatic hub 64 includes a body 78, a threaded knob 80, and an elastomeric seal 82. The body 78 defines an interior cavity 84 that is shaped to receive and hold a cannula hub 86 that is attached to a proximal end of the cannula 66. The interior cavity 84 is also shaped to receive the elastomeric seal 82, which is compressed between the threaded knob 80 and the body 78. The interior cavity 84 is partially internally threaded to receive the external threads of the threaded knob 80. The threaded knob 80 defines a guidewire port 88 that aligns with the interior cavity 84 and the lumen 76 of the cannula 66 so that a continuous port is available for the guidewire 60 to extend the length of the leaflet capture catheter 52. When a guidewire 60 is inserted through the guidewire port 88, the threaded knob 80 and the elastomeric seal 82 act together as a hemostatic valve. When the threaded knob 80 is rotated to compress the elastomeric seal 82, the elastomeric seal 82 swells inwardly, until it forms a blood-tight seal around the guidewire 60. The cannula 66 and the hub 64 are constructed and arranged to carry the tensile force generated during a hole cutting procedure, discussed in detail below.

[0087] The leaflet capture catheter 52 is slidably and coaxially contained within the delivery catheter 54. The delivery catheter 54 is best shown in Figure 7a, and includes a cutter 90, a balloon catheter 92, and a delivery catheter hub 94. The cutter 90 is constructed and arranged to act with the cutter die 62 (Figure 6) to cut tissue. The cutter 90 includes a cutter drum 96 that is a sharpened cylindrical blade having a cutting tip 98. The cutter tip 98, as shown in Figure 7a, lies in a plane that is substantially perpendicular to a longitudinal axis of the delivery catheter. However, an alternative embodiment of the cutter drum 96, shown in Figure 7b, may provide increased cutting power. The cutter drum 96 in Figure 7b has a curved, non-planar cutting tip 98. Preferably, the cutter drum 96 is sized to cut a hole having a diameter of approximately 4mm through a leaflet. The cutter drum 96 has a cutter bulkhead 100 at its proximal end that is attached to the balloon catheter 92 with an adhesive 102. Other suitable attachment means for attaching the cutter drum 96 to the balloon catheter 92 include threads, welds, unitary construction and the like. To cut tissue, the cutter die 62 is pulled within the cutter drum 90. Thus, the balloon catheter 92, and the adhesive 102 fixing the bulkhead 100 to the balloon catheter 92, must be able to carry the compressive force that results from opposing the equal and opposite tensile force applied to the leaflet capture catheter 52.

[0088] The balloon catheter 92 generally includes an inner tube 104 extending distally and proximally from within an outer tube 106. A balloon 108 is connected at a distal end to the outside of the inner tube 104 and at a proximal end to the outside of the outer tube 106. The outside diameter of the inner tube 104 is smaller than the inside diameter of the outer tube 106, such that a fluid passageway is formed therebetween for inflation of the balloon 108. A flexible valve stop 110 is attached to the outer tube 106 just proximal of the proximal end of the balloon 108. The valve stop 110 has a flexible sleeve 112 that extends distally over the proximal end of the balloon 108. The function of the valve stop 110 is to prevent proximal movement of the valve implant 10 during delivery. The valve implant 10, as will be seen below, will be placed over the balloon 108, distal of the valve stop 110. The flexible sleeve 112 allows the balloon to inflate while maintaining a desired positioning of the valve implant 10. The inner tube 104 has an inner diameter large enough to

accommodate the cannula 66 of the leaflet capture catheter 52. A proximal end of the balloon catheter 92 is attached to the catheter hub 94.

[0089] The catheter hub 94 includes a catheter hub body 114 that defines an inner cavity 116 and a balloon inflation port 118. The proximal end of the inner cavity 116 has internal threads to receive an externally threaded knob 120. An elastomeric seal 122 resides between the threaded knob 120 and the catheter hub body 114. The threaded knob 120 defines a capture catheter port 124 that aligns with the interior cavity 116 of the body 114 and the interior of the balloon catheter 92 so that the leaflet capture catheter 52 may pass therethrough.

[0090] The balloon catheter 92 is attached to the catheter hub 94 in such a manner that fluid introduced into the balloon inflation port 118 will flow between the outer tube 106 and the inner tube 104 to inflate the balloon 108. The outer tube 106 is attached at its proximal end to the distal end of the interior cavity 116 of the catheter hub body 114. Preferably, an adhesive 126 is used to connect the outer tube 106 to the interior cavity 116 of the catheter hub body 114 at a position distal of the balloon inflation port 118. The inner tube 104 extends proximally from the proximal end of the outer tube 108. The proximal end of the inner tube 104 is also attached to the interior cavity 116 of the catheter hub body 114. However, this connection is made at a position proximal of the balloon inflation port 118, preferably with an adhesive 128. Thus, fluid entering the balloon inflation port 118 is blocked from flowing in a proximal direction by the proximal adhesive 128. It is also blocked from traveling in a distal direction on the outside of outer tube 106 by the distal adhesive 126. Instead, the fluid is forced to flow between the inner tube 104 and the outer tube 106 in a distal direction toward the interior of the balloon 108.

[0091] The leaflet capture catheter 52 and the delivery catheter 54 are slideably contained within the sheath catheter 56. Referring now to Figure 8, it can be seen that the sheath catheter 56 includes a large diameter sheath 130 attached to a distal end of sheath tubing 132, which is attached at a proximal end to a sheath hub 134. The sheath hub 134 secures the sheath catheter 56 to the handle 58. The sheath hub 134 includes a tab 154, the

function of which will be explained below. The sheath 130, sheath tubing 132, and the sheath hub 134, all define a delivery catheter port 136 that extends throughout the length of the sheath catheter 56. The large diameter sheath 130, is preferably a 14 French catheter, and sized to accommodate the cutter drum 96.

[0092] Referring now to Figures 9A and 9B, there is shown a preferred embodiment of the handle 58 of the present invention. The handle 58 includes a handle body 138 that defines at a bottom portion a figure grip 140. An actuator 142 is pivotally attached to the handle body 138 with a pivot pin 164. At the top of the actuator 142, is a leaflet capture catheter bracket 144. The leaflet capture catheter bracket 144 is constructed and arranged to hold the leaflet capture hemostatic hub 64. At a top portion of the body 138 there is defined a slotted chamber 146. The slotted chamber 146 is constructed and arranged to hold the delivery catheter hub 94 as well as the sheath hub 134. The slotted chamber 146 includes external threads 148 around which the sheath retraction nut 150 rides. At the top of the slotted chamber 146 there is defined a slot 152 through which the balloon inflation port 118 of the delivery catheter hub 94 and a tab 154 of the sheath hub 134 extend. Below the slotted chamber 146, a sheath retraction indicator 156 extends distally from the handle body 138. Preferably, the handle 58 includes a safety button 158 that prevents a physician from unintentionally depressing the actuator 142.

[0093] The handle 58 is thus constructed and arranged to slide the leaflet capture catheter 52 in a proximal direction relative to the sheath catheter 56 and the delivery catheter 54 when the actuator 142 is squeezed toward the finger grip 140, thereby pulling the hemostatic hub 64 in a proximal direction. The handle 58 is also constructed and arranged to slide the sheath catheter 56 proximally over the leaflet capture catheter 52 and the delivery catheter 54 when the sheath retraction nut 150 is rotated proximally. The operation of the handle 58 and the rest of the delivery system 50 are explained in more detail below.

[0094] Referring to Figs. 19A, 19B and 20, in one embodiment of the present invention, the catheter delivery system 50 includes a tether 190 looped around the proximal legs 44 of

the valve implant 10. The tether extends from the proximal legs 44 all the way through the catheter until both ends of the tether 190 are joined at a connector 192 that resides outside the catheter delivery system 50 near the handle. The tether 190 allows the user to retract the valve implant 10 from the valve placement site after it has been deployed from the catheter if it is determined that the deployment was improper or in the event a complication arises with after deployment.

[0095] For example, if after deployment, it is determined that placement of the valve implant 10 is incorrect, the physician can pull on the tether and retract the valve implant 10 as shown in Figure 19B. If, on the other hand, it is determined that placement of the valve implant 10 has been successful, then the physician simply cuts the tether and pulls the free end out of from the proximal legs 44 and out of the delivery device as shown in Fig. 19A.

[0096] Operation

[0097] Referring now to Figures 10-19, the operation of the present invention is explained. Each of the following figures will include two drawings, a drawing that shows the position of the handle 58, and a drawing of the corresponding catheter configuration.

[0098] Referring now to Figure 10, the first step a physician takes in using the delivery device 50 to place a valve implant 10 in a leaflet of a native valve is to use a guidewire 60 to locate the site of the native valve. The guidewire 60 is thus threaded through the necessary blood vessels to the site of the native valve. For example, if it were desired to place the valve implant 10 in, or between, the leaflets of the aortic valve, the guidewire 60 would be placed percutaneously in the femoral artery, or other suitable arterial access, advanced up the aorta, around the arch, and placed above the target leaflet of the aortic valve. Once the guidewire 60 is in place, the catheter delivery system 50 is advanced along the guidewire 60.

[0099] In Figure 10a, it can be seen that the target leaflet 7 has been located with the guidewire 60 and the catheter delivery system 50 has been advanced along the guidewire 60 the target leaflet 7. Positioning the catheter delivery system 50 on the target leaflet 7

may be aided using imaging methods such as fluoroscopy and/or ultrasound. Figure 10a shows that when this step is performed, the sheath retraction nut 150 is in the "Deliver" position as shown on the sheath retraction indicator 156. In the "Deliver" position, the sheath 130 covers the capture groove 72 of the cutter die 62. The cutter 90 remains retracted proximal of the capture groove 72. Also, the conical distal end 68 of the cutter die 62 extends from the distal end of the sheath 130.

[00100] In this regard, it is helpful to note that the target leaflet may actually include two leaflets if the leaflets are calcified together. For example, with reference to Fig. 1, if two leaflets have become calcified together along their edges or lines of coaptation, the present invention contemplates cutting a hole in a manner that traverses the leaflet edges and thereafter inserting a valve (as explained below) across both leaflet edges.

[00101] Once satisfied that the target site has been reached with the catheter delivery system 50, the next step is to traverse the tissue of the target valve leaflet 7. However, before the cutter die 62 is advanced through the leaflet tissue 7, the sheath catheter 56 must be retracted until the "Insert/Cut" position has been achieved. This is accomplished by rotating the threaded sheath retraction nut 150 until the nut 150 is aligned with the "Insert/Cut" marking on the sheath retraction indicator 156. Rotating the sheath retraction nut 150 causes the nut 150 to act against the tab 154 of the sheath hub 134.

[00102] Referring now to Figures 11a and 11b, it can be seen that the target valve leaflet 7 has been punctured by either the guidewire 60, in the event that a sufficiently sharp guidewire is being used, or more preferably, the needle tip 74 of the leaflet capture catheter 52. When the needle tip 74 of the leaflet capture catheter 52 is used to puncture the leaflet, the guidewire 60 is first retracted so that it does not extend through the needle tip 74.

[00103] In one embodiment, the needle may be configured to have a hollow sharp shaft followed by a conical shank (not shown). This will allow the needle to create an initial penetration of the tissue followed by a more traditional puncturing action from the conical

shank. A needle configured in this manner will also assist in positioning the delivery device over each leaflet.

[00104] The cutter die 62 is advanced through the leaflet 7 until the leaflet 7 snaps into the capture groove 72. The conical distal end 68, as it is being advanced through the leaflet 7, will provide an increasing resistance that is tactily perceptible to the physician. Once the leaflet 7 encounters the flat portion 70, the physician will detect a decreased resistance and can expect a snap when the resilient tissue snaps into the capture groove 72. The guidewire 60 is then re-advanced into the ventricle (assuming the aortic valve is the target valve).

[00105] In this regard, it is notable that in one embodiment of the invention, the guidewire could be fabricated to include a transducer at its distal end (not shown). The guidewire could then be used to measure ventricular pressure (e.g., left ventricular pressure when treating the aortic valve) and thus provide the physician greater ability to monitor the patient during the procedure.

[00106] Once the physician is convinced that the leaflet 7 has entered the capture groove 72, the cutting step may commence. Referring now to Figures 12a and 12b, the cutting step is demonstrated. Cutting is performed by depressing safety button 158 and squeezing the actuator 142. After the safety button 158 and the actuator 142 are squeezed, the spring loaded safety button on 158 will travel from a first hole 160 in the actuator 142 to a second hole 162. When the safety button 158 reaches the second hole 162, it will snap into the second hole 162, thereby locking the actuator 142 in place. This ensures that the cutter die is retracted into the cutter 90, but that excess pressure is not placed on either the cutter die 62 or the cutter 90. When the actuator 142 is squeezed, cutting is effected because the actuator 142 rotates, relative to the handle body 138, around the pivot pin 164. This action causes the leaflet capture catheter bracket 144 to move in a proximal direction thereby pulling the hemostatic hub 64 with it. Pulling the hub 64 causes the cannula 66 and the cutter die 62 attached thereto, to be pulled in a proximal direction relative to the delivery catheter 64. The cutter die 62 enters the cutter 90, thereby

cutting the tissue. The clearance between the cutter die 62 and the cutter drum 96 is sufficiently minimal to prevent the occurrence of hanging "chads" in the cut. Additionally, the sharpened cutting tip 98 of the cutter 90 may be cut at an angle, or even include a point, such that the entire cut does not have to be initiated around the entire circumference of the cutter drum 96 simultaneously.

[00107] A more detailed view of the cutting action of the cutter die 62 and the cutter 90 is shown in Figures 13a-13e. In Figure 13a, the needle tip 74 of the cannula 66 has just reached the leaflet 7. The sheath 130 has been retracted to the "Insert/Cut" position as indicated by the exposed capture groove 72 of the cutter die 62. In Figure 13b, the cutter die 62 is being advanced through the target leaflet 7 such that the target leaflet 7 has reached the conical distal end 68 of the cutter die 62. In Figure 13c, the conical distal end 68 and the flat portion 70 of the cutter die 62 have passed completely through the target leaflet 7, and the target leaflet 7 has snapped into the capture groove 72. Additionally, the guidewire 60 has been re-advanced through the leaflet capture catheter 52 so that it extends beyond the needle tip 74. The guidewire 60 will be used to retain the position of the hole cut through the leaflet 7 after the cutter die 62 is retracted. In Figure 13d, the physician has begun to cut by squeezing the actuator 142 (Figure 12a), as evidenced by the advancement of the cutter 90. The cutting tip 98 of the cutter 90 has been advanced mid-way through the target leaflet 7. This movement is relative to the position of the cutter die 62. More accurately, the cutter die 62 is being retracted into the cutter 90, bringing with it the tissue of the leaflet 7. The movement of the cutter die 62 is evidenced by arrow 172.

[00108] In Figure 13e, the cut is complete as the actuator 142 has been squeezed enough so that the safety button 158 has found the second hole 162 (Figure 12a), as evidenced by the position of the cutter die 62. The cutter die 62 is retracted enough such that the capture groove 72 is completely housed within the cutter drum 96. Notably, the cut tissue of the leaflet 7 remains trapped between the capture groove 72 and the cutter drum 96. The trapping of this tissue prevents the tissue from traveling downstream through the blood vessel and causing damage.

[00109] Referring now to Figures 14a and 14b, once the hole in the tissue 7 is cut, the step of placing the valve implant 10 begins. First, the entire delivery system 50 is moved distally deeper into the patient such that the distal legs 42 pass through the newly formed hole in the tissue 7. It is important that at least the distal legs 42 are located on the upstream (ventricle) side of the tissue 7 prior to deploying the valve implant 10. Once the physician is confident that the distal legs 42 extend beyond the valve leaflet tissue 7, the sheath 130 may be retracted to release the distal legs 42. This is accomplished by rotating the sheath retraction nut 150 until the sheath retraction nut 150 aligns with the "Distal" marking on the sheath retraction indicator 156. Doing so causes the sheath retraction nut 150 to act against the tab 154 thereby withdrawing the sheath 130 until just the distal legs 42 are exposed. The distal legs 42 are preloaded such that they spring outwardly, as shown in Figure 14b, when uncovered by the catheter sheath 130. The distal legs 42 are long enough to extend beyond the radius of the sheath 130, such that they may act against the valve leaflet tissue 7. Once the sheath retraction nut 150 has been rotated to the "Distal" position on the indicator 156, the physician may pull the catheter delivery system 50 in a proximal direction until he or she feels the distal legs 42 catch or act against the valve leaflet tissue 7. Notably, the actuator 142 remains locked in the position it was placed in during the cutting procedure. Leaving the actuator 142 in this position ensures that the valve leaflet tissue trapped between the cutter die 62 and the cutter drum 96 is not released.

[00110] The next step is illustrated in Figs 15a and 15b. The physician maintains the contact between the distal legs 42 and the valve leaflet tissue 7. While maintaining this contact, the sheath retraction nut 150 is rotated to the "Proximal" position as indicated on the marker of the sheath retraction indicator 156. Rotating the sheath retraction nut 150 again acts against the tab 154 causing the sheath 130 to retract further. When the proximal position has been achieved, the sheath will be retracted enough to release the proximal legs 44. Like the distal legs 42, the proximal legs 44 will spring outwardly when released by the sheath 130. The proximal legs 44 act against the opposite side (aorta side) of the valve leaflet tissue 7 sandwiching the valve leaflet tissue 7 between the distal legs 42 and the proximal legs 44. The valve implant 10 is now attached to the patient.

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[00111] The next step is to inflate the balloon 108 thereby expanding the valve implant 10. This step is best shown in Figures 16a and 16b. The physician further rotates the sheath retraction nut 150 to the "Inflate" position on the indicator 156. The sheath retraction nut 150 again acts against the tab 154 thereby retracting the sheath 130 to a point where the valve stop 110 is at least partially exposed and the flexible sleeve 112 of the valve stop 110 is completely exposed.

[00112] Once the sheath 130 has been retracted to the "Inflate" position on the indicator 156, the balloon 108 may be inflated. This is accomplished by injecting fluid into the balloon inflation port 118. Fluid is injected until the sizing ring 38 has achieved its maximum diameter. The physician will feel resistance against further inflation by the sizing ring 38. Additionally, the sizing ring 38 or other parts of the anchoring mechanism 12 may be constructed of a radiopaque material such that monitoring can be accomplished using X-ray equipment. The use of the sizing ring 38 is not required for the practice of the invention. It is, however, preferred in the preferred embodiments of the invention.

[00113] Once the inflation of the balloon 108 is complete, the next step involves deflating the balloon 108. This is illustrated in Figures 17a and 17b. Deflating the balloon involves simply withdrawing fluid through the balloon inflation port 118. As is shown in Figure 17b, when the balloon 108 is deflated, the valve implant 10 retains its inflated proportions. These inflated proportions allow easy retraction of the catheter delivery system through the valve implant 10. As is best seen in Figure 18, once the delivery system 50 has been retracted, the valve implant 10 remains attached to the valve leaflet tissue 7.

[00114] As discussed above with reference to Figures 19A, 19B and 20, one embodiment of the catheter delivery device 50 and the valve implant 10 includes the use of a tether 190 to allow the physician to retract the valve implant 10 in the event of improper deployment. With reference to Figure 21, the operation of the tether 190 under both proper deployment and improper deployment is disclosed.

[00115] On the left side of Figure 21, it is seen that the valve implant 10 has been properly deployed in the valve leaflet. As a result, the physician cuts the tether 190 and pulls the tether away from the catheter handle from the proximal legs 44 of the cuff.

[00116] On the right side of Figure 22, it is seen that the valve implant 10 has been improperly deployed insofar as the legs of the cuff have not adequately grasped the edge of the hole in the leaflet. As a result, the physician may retract the valve implant 10 by pulling on the tether 190 and thus removing the valve implant 10 from its improperly deployed location

What is claimed is:

1. A heart valve comprising:
a valve position securement structure;
a flow control mechanism coupled to said valve position securement structure; and,
said valve position securement structure sized and shaped for placement in a leaflet of a native heart valve.
2. A heart valve according to claim 1, wherein said position securement structure comprises an expandable cuff having a thickness at least as thick as said leaflet of a native heart valve.
3. A heart valve according to claim 2, wherein said cuff includes a plurality of radial extensions extending from said cuff and engagable with said leaflet of a native heart valve so as to secure said cuff in said leaflet of a native heart valve.
4. A heart valve according to claim 2, wherein said heart valve further comprises a sizing ring coupled to said cuff and configured to constrain expansion of said cuff to a substantially predetermined state.
5. A heart valve according to claim 4, wherein said sizing ring is disposed around a mid-portion of said cuff.
6. A heart valve according to claim 1, wherein said flow control mechanism comprises a sleeve containing a plurality of valve members.
7. A heart valve according to claim 6, wherein said plurality of valve members includes duck bill members.

8. A heart valve according to claim 6, wherein said plurality of valve members includes leaflets disposed on a stent form.
9. A heart valve according to claim 8, wherein said leaflets are comprised of material selected from the group consisting of biologic tissue, polymer material, and composite synthetic/biologic material.
10. A device to increase fluid flow through a mammalian valve comprising: a valve mechanism containing a lumen therein;
- said valve mechanism actuatable so as to place said lumen in one of an open and closed state;
- an anchoring structure connected to said valve mechanism; and,
- said anchoring structure sized and shaped for attachment to a leaflet of said mammalian valve.
11. A device according to claim 10, wherein said valve mechanism includes a housing structure and a valve member disposed on said housing structure.
12. A device according to claim 11, wherein said valve mechanism comprises a harvested tissue valve.
13. A device according to claim 11, wherein said valve mechanism comprises leaflets mounted on a scaffold.
14. A device according to claim 10, wherein said anchoring structure includes a plurality of barbs extending radially outwardly from said valve mechanism.
15. A device according to claim 10, wherein said anchoring structure comprises a cuff having a plurality of legs extending therefrom, said legs sized and shaped to engage leaflet tissue.

16. A device according to claim 15, wherein said anchoring structure further comprises a sizing ring disposed around said cuff; said sizing ring sized and shaped so as to constrain expansion of said cuff.
17. A valve device for treating a diseased valve comprising:
means for controlling fluid flow;
means for anchoring said fluid flow controlling means at a target site;
said means for controlling and said means for anchoring being connected to each other; and,
said means for anchoring being sized to fit on a leaflet of said diseased valve.
18. A valve device according to claim 17, wherein said means for controlling fluid flow is selected from the group consisting of: a duckbill valve, a hinged valve; a leaflet valve; a harvested valve, a tissue valve, a synthetic valve and a composite valve.
19. A valve device according to claim 17, wherein said means for anchoring includes a structure having external retention means.
20. A valve device according to claim 17, wherein said means for anchoring is expandable and includes a means for constraining the expansion of said means for anchoring.
21. A delivery device usable to cut a hole in a valve leaflet and attach a valve implant to the leaflet, comprising:
a leaflet capture mechanism constructed and arranged to attain an operational grasp of the valve leaflet;
a cutting mechanism constructed and arranged to cut valve leaflet tissue while the

valve leaflet is being grasped by the leaflet capture mechanism;
a delivery mechanism constructed and arranged to release a valve implant in operational proximity to a cut leaflet and attach the valve implant thereto; and, a handle, operationally attached to the leaflet capture mechanism, the cutting mechanism, and the delivery mechanism, such that an operator has control over any actions taken by said mechanisms.

22. The delivery device of claim 1 further comprising an expansion mechanism, operably attached to the handle, and constructed and arranged to expand the attached valve implant to operational proportions.
23. The delivery device of claim 1 wherein the leaflet capture mechanism comprises a die having a conical distal end that increases in radius in a proximal direction and a groove defined by the die, the groove located proximal of the conical distal end, the die thus constructed to stretch an opening in tissue, when passed therethrough, until the tissue reaches the groove and resiliently snaps into the groove.
24. The delivery device of claim 1 wherein the leaflet capture mechanism comprises a distal balloon constructed and arranged to be inflated after the balloon has been passed through the valve leaflet and, once inflated, may be used to pull the leaflet into a desired position or into the cutting mechanism.
25. The delivery device of claim 1 wherein the cutting mechanism comprises a substantially cylindrical cutting drum sized to allow the capture mechanism to be drawn inside an interior of the cutting drum without allowing tissue to reside between areas of maximum diameter of the leaflet capture mechanism and an interior surface of the cutting drum, the cutting drum including a sharpened distal edge capable of cutting tissue.
26. The delivery device of claim 5 wherein the sharpened distal edge of the cutting drum lies in a plane substantially perpendicular to a longitudinal axis of the cutting drum.

27. The delivery device of claim 5 wherein the sharpened distal edge of the cutting drum is non-planar.
28. The delivery device of claim 1 wherein the delivery mechanism comprises a retractable sheath catheter constructed and arranged to house the valve implant in a compressed state within a lumen of the sheath catheter such that when the sheath catheter is retracted, an attachment mechanism of the valve implant is released and attaches the valve implant to the valve leaflet.
29. The delivery device of claim 2 wherein the expansion mechanism comprises a balloon catheter constructed and arranged such that when a balloon of the balloon catheter is deflated, and the valve implant is in a compressed state within a lumen of the delivery device, the balloon is located within the valve implant such that inflating the balloon causes the valve implant to expand.
30. The delivery device of claim 2 wherein the handle comprises:
a first means for moving the leaflet capture mechanism relative to the cutting mechanism; and
a second means for moving the delivery mechanism relative to the expansion mechanism.
31. The delivery device of claim 10 wherein the first means and the second means are constructed and arranged to be able to be manipulated to achieve the following distinct configurations:
a deliver configuration whereby the delivery mechanism shields the cutting mechanism and at least a portion of the leaflet capture mechanism;
an insert configuration whereby the delivery mechanism is retracted to expose the leaflet capture mechanism;
a cut configuration whereby the leaflet capture mechanism is retracted within the cutting mechanism;

a distal configuration whereby the delivery mechanism is retracted enough to expose a distal portion of the valve implant such that the valve implant can attach itself to a distal side of the valve leaflet;

a proximal configuration whereby the delivery mechanism is retracted enough to expose a proximal portion of the valve implant such that the valve implant can attach itself to a proximal side of the valve leaflet; and,

an inflate configuration whereby the delivery mechanism is retracted to expose the expansion mechanism such that expansion can occur without interference by the delivery mechanism.

32. A device for delivering a valve to a target site comprising:
- a housing;
 - a tissue capture structure disposed in said housing;
 - a tissue cutting structure aligned with said tissue capture structure;
 - a deployment mechanism disposed in said housing and movable to deploy a valve to said target site following operation of said tissue cutting structure; and,
 - said target site being a leaflet of a valve.

33. A device according to claim 12, wherein said housing is sized and shaped to fit within a lumen of a patient.
34. A device according to claim 12, wherein a distal end of said tissue capture structure includes a tissue puncturing element.
35. A device according to claim 14, wherein said tissue capture structure further includes a circumferential slot for receiving tissue of said leaflet.
36. A device according to claim 12, wherein said deployment mechanism includes an expansion device sized to enlarge said valve following deployment.
37. A device according to claim 12, wherein said tissue capture structure is sized for withdrawal through said valve following deployment of said valve.
38. A device according to claim 12, further comprising a tether mechanism attached to said valve.
39. A device according to claim 12, further comprising safety stops operative to control operation of said device.

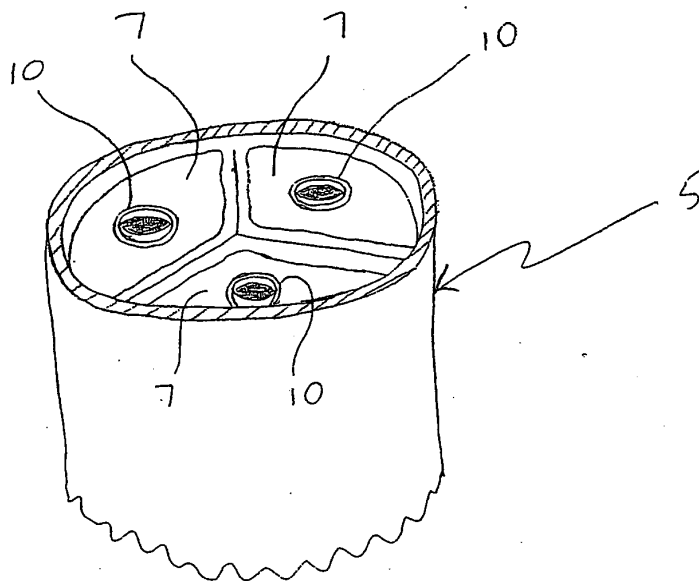


FIGURE 1

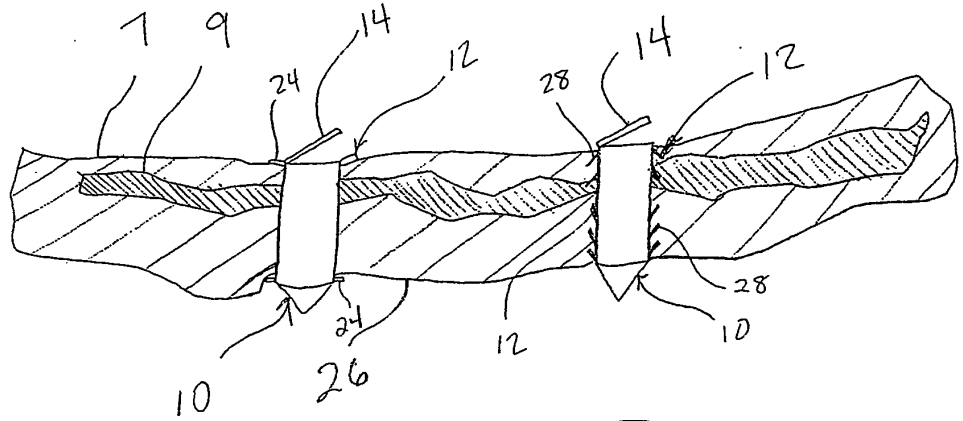


FIGURE 2.

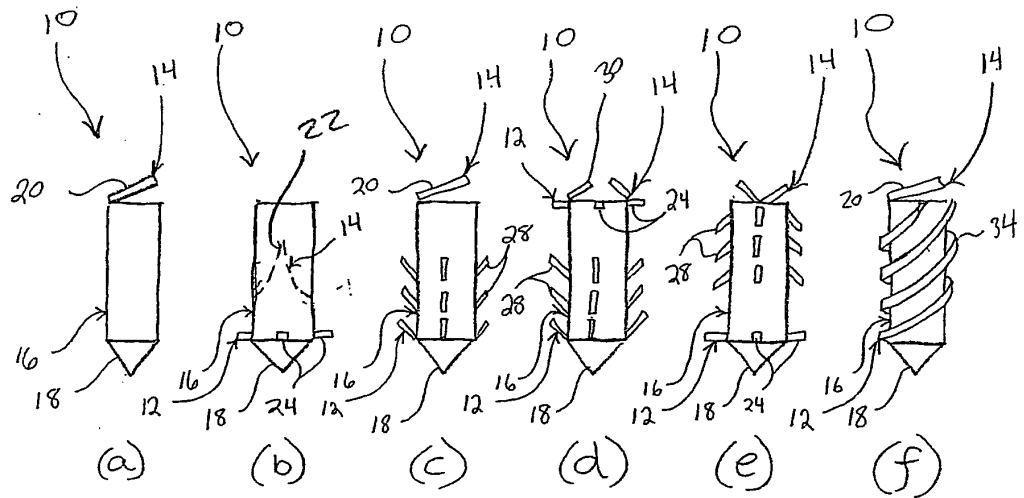


FIGURE 3

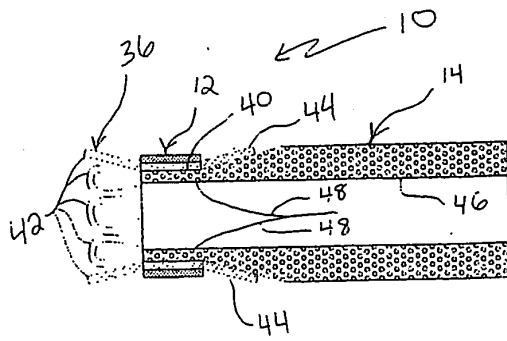


FIG. 4a

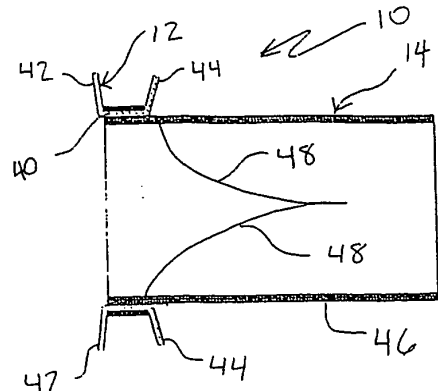


FIG. 4b

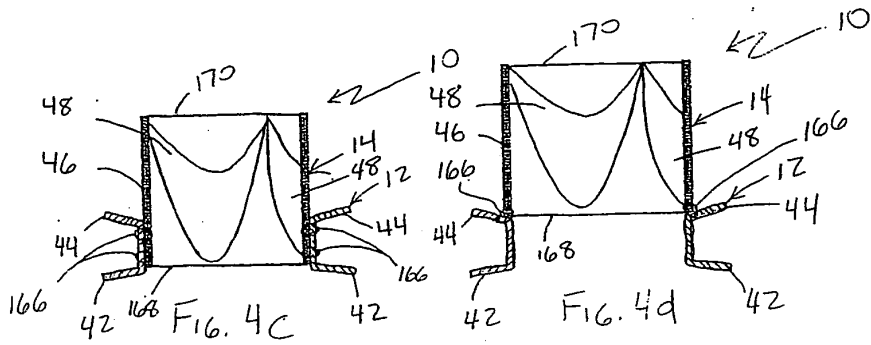


FIG. 4c

FIG. 4d

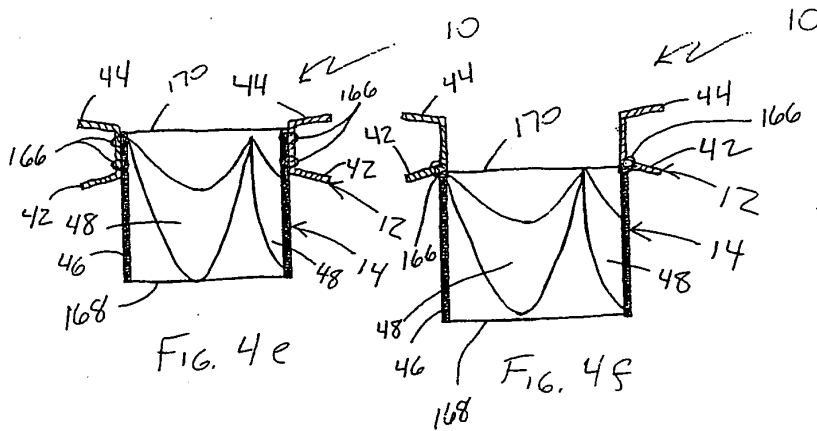


FIG. 4e

FIG. 4f

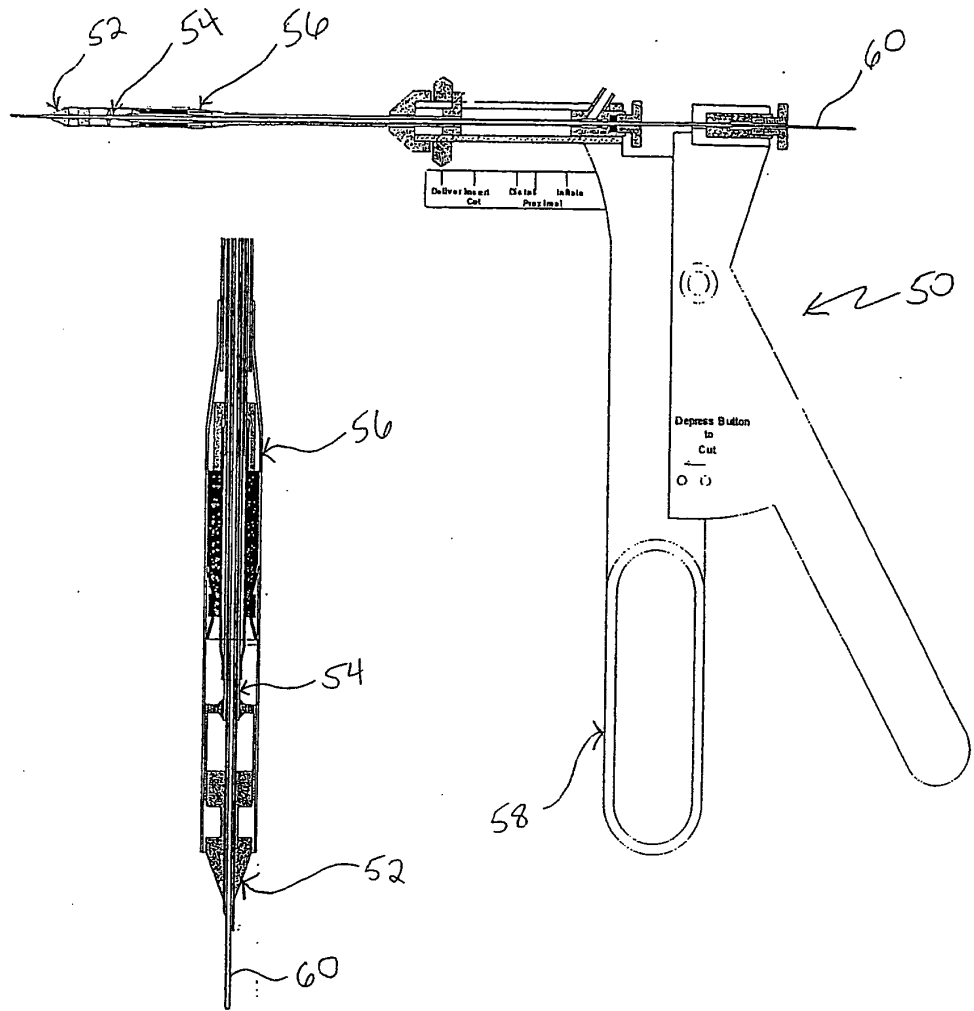


Figure 5b

Figure 5a

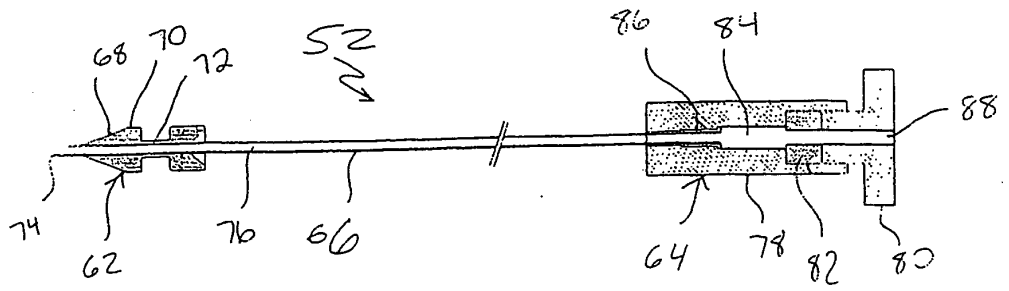


Figure 6

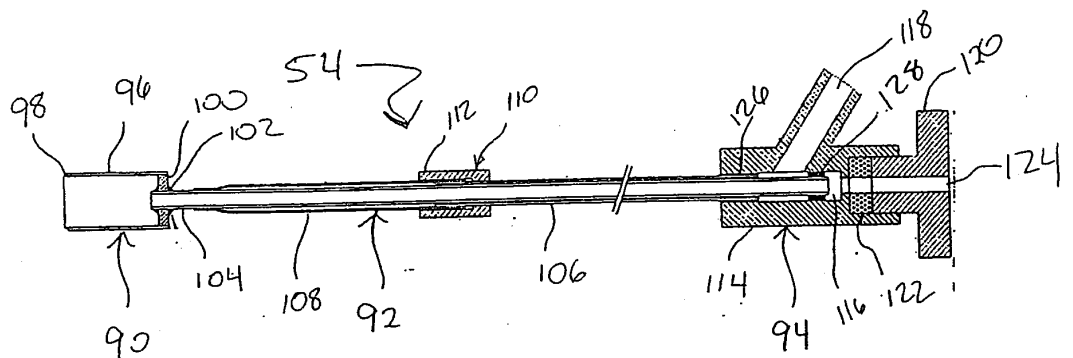


Figure 8
FIGURE 7a

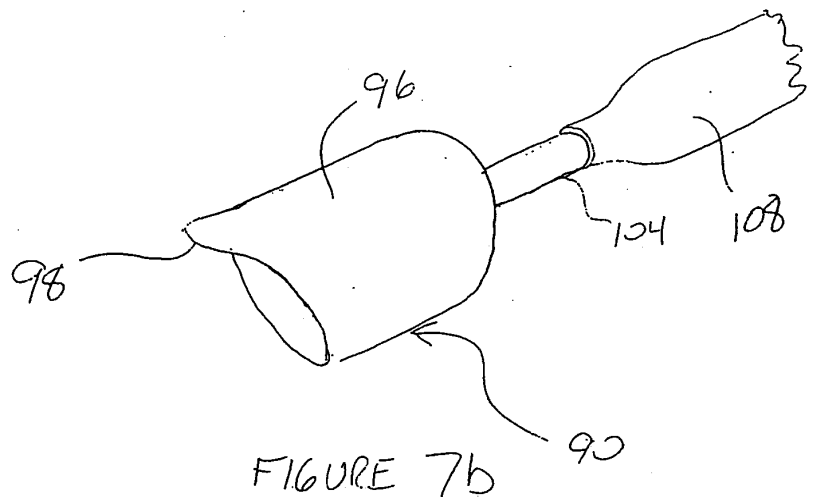


FIGURE 7b

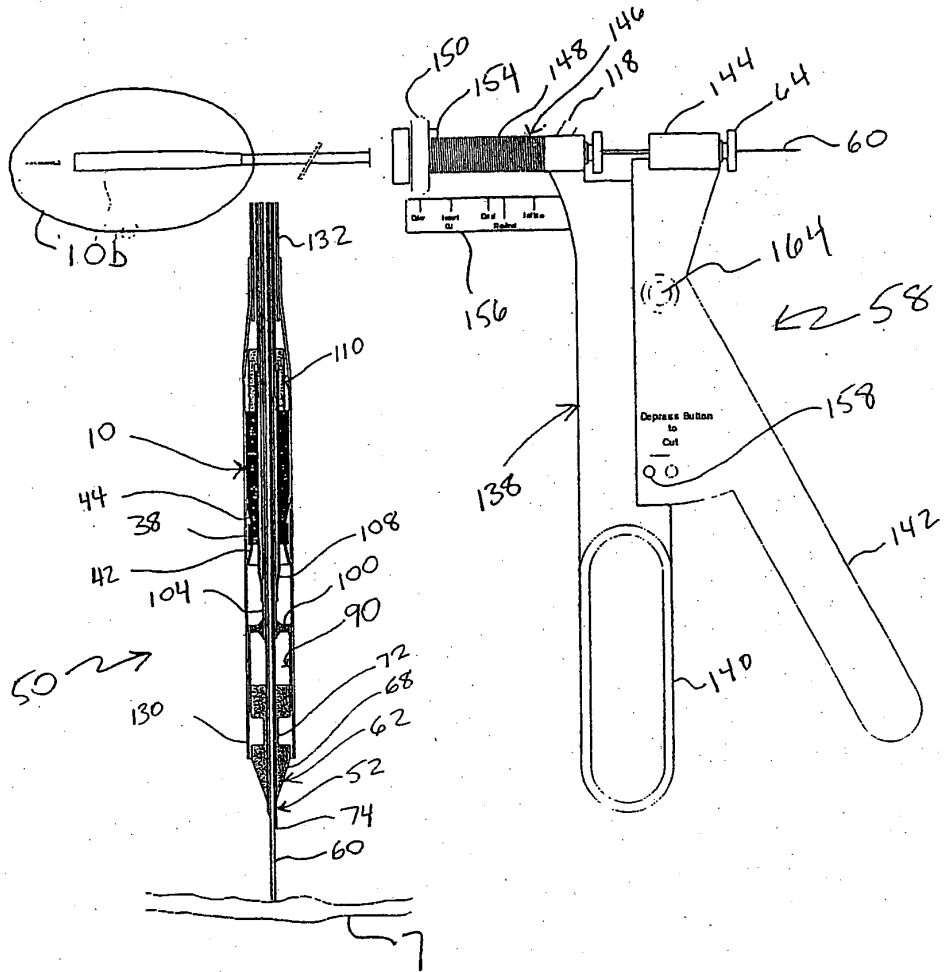


FIG. 10b

FIG. 10a

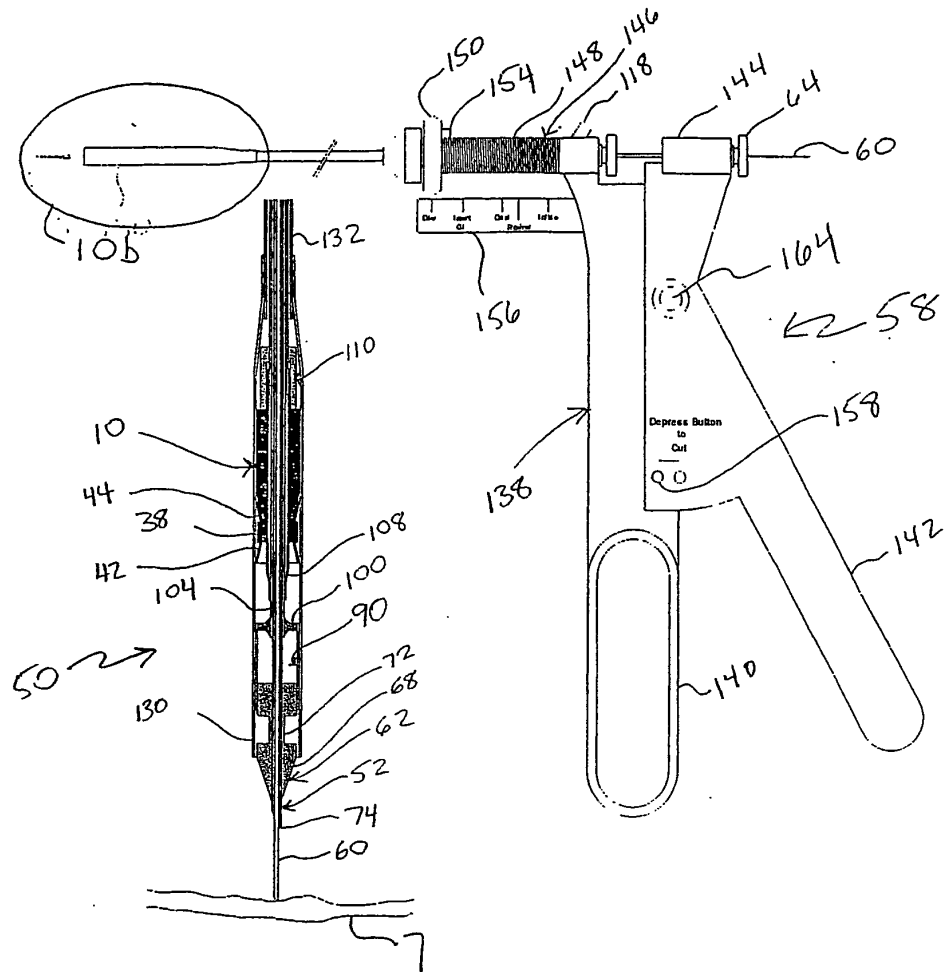


FIG. 10b

FIG. 10a

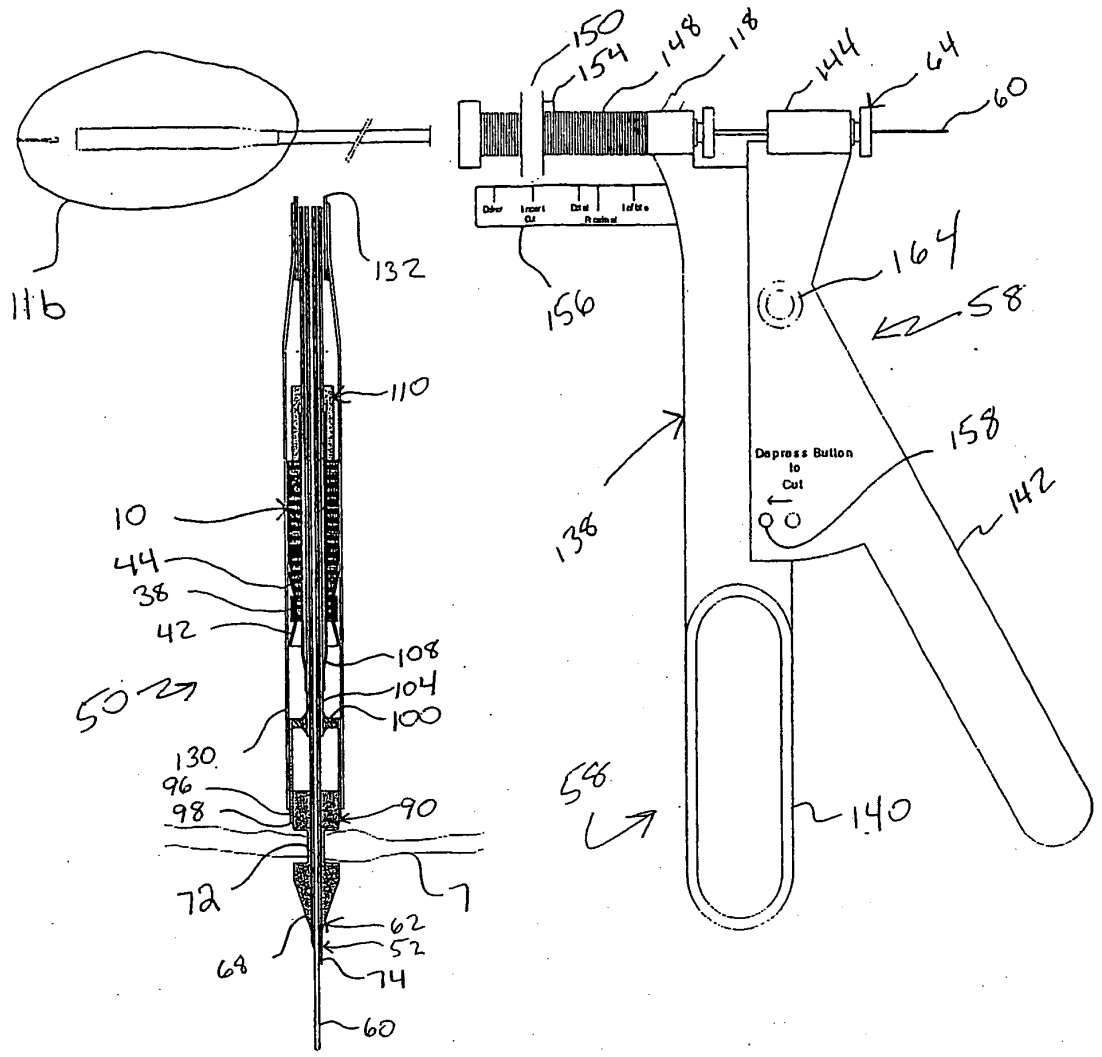


FIG. 11b

FIG. 11a

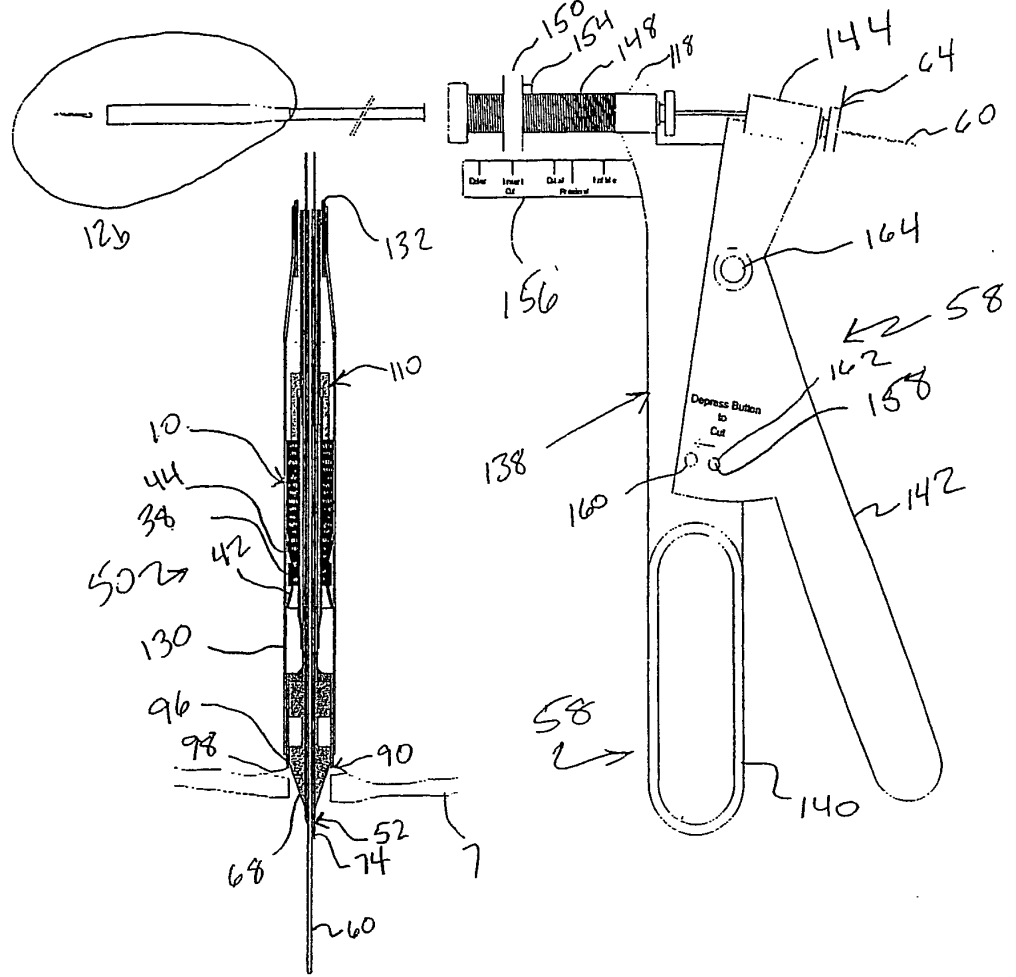
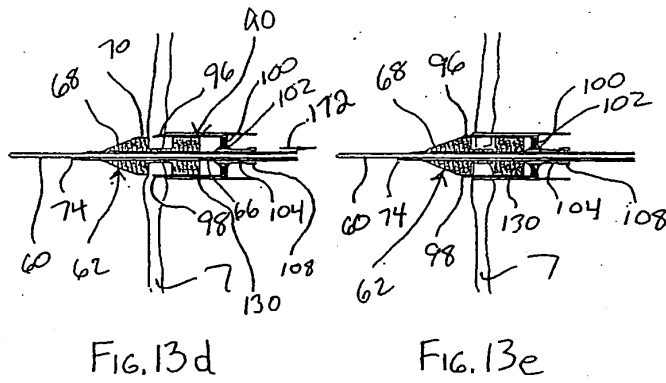
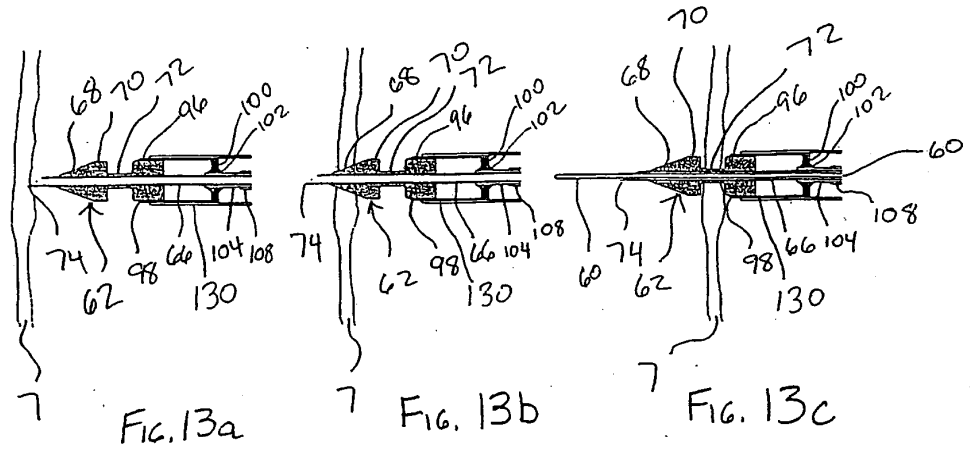


FIG. 12b

FIG. 12a



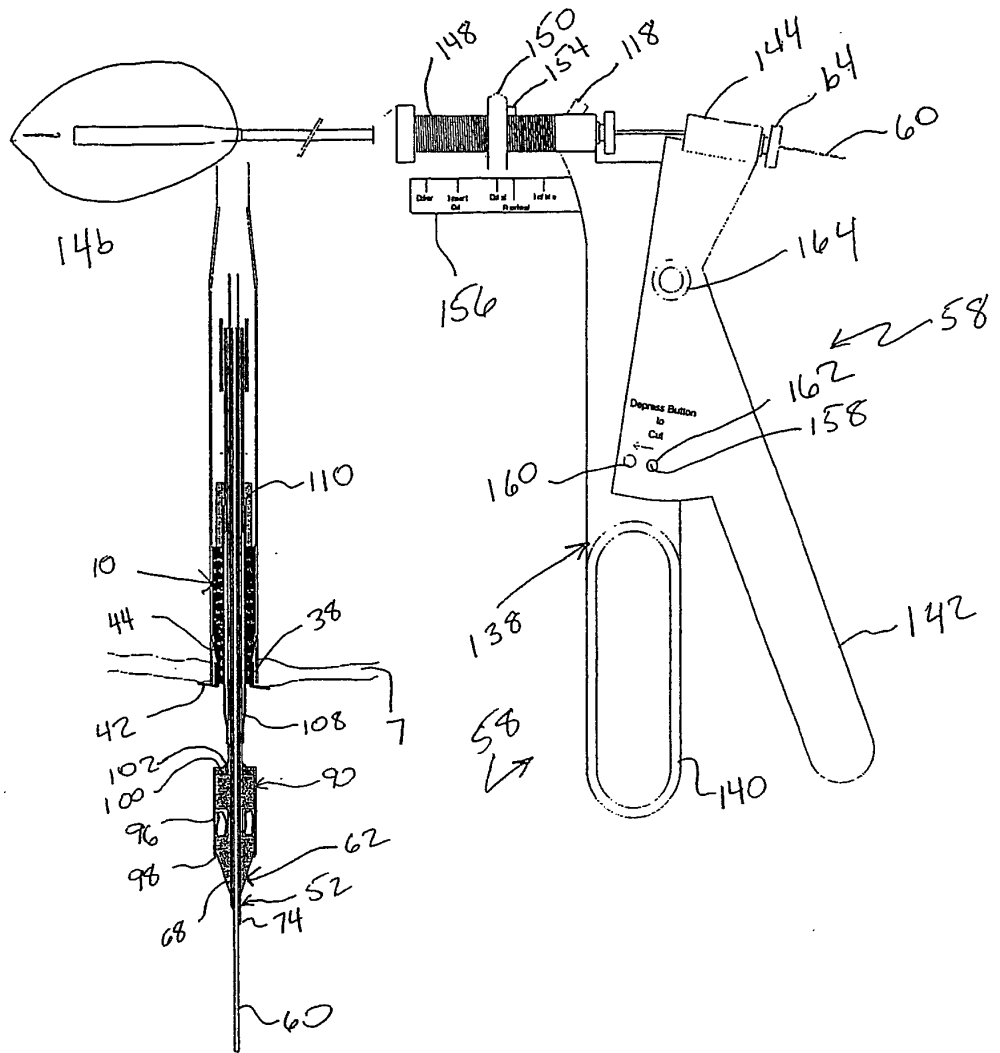


FIG. 14b

FIG. 14a

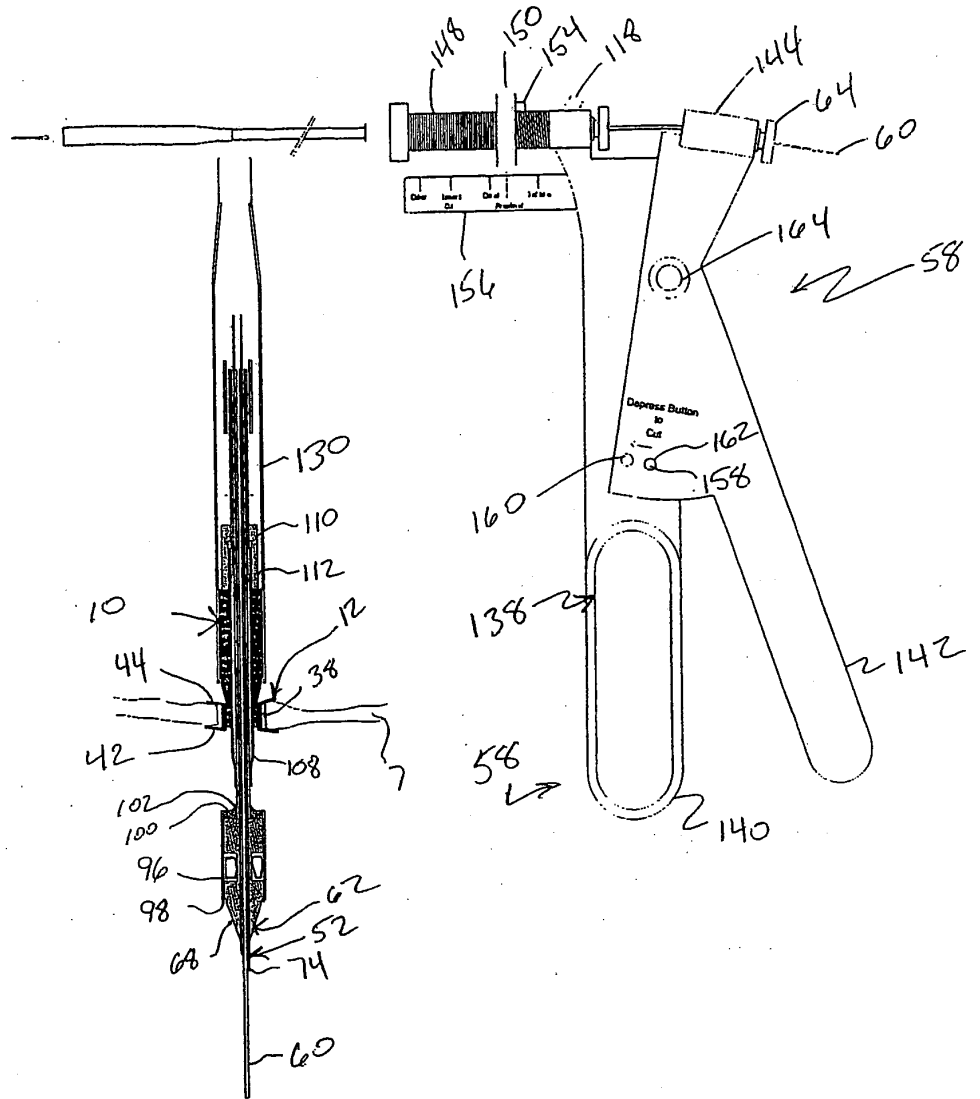


FIG. 15b

FIG. 15a

12/21

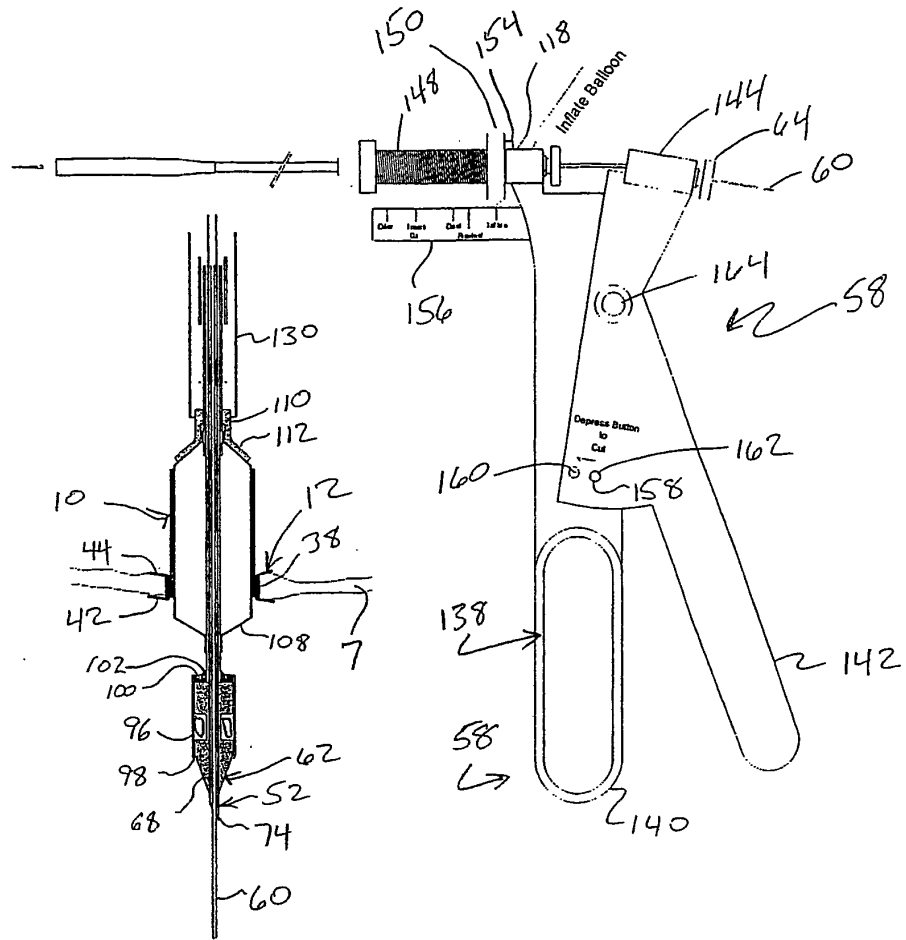


FIG. 16b

FIG. 16a

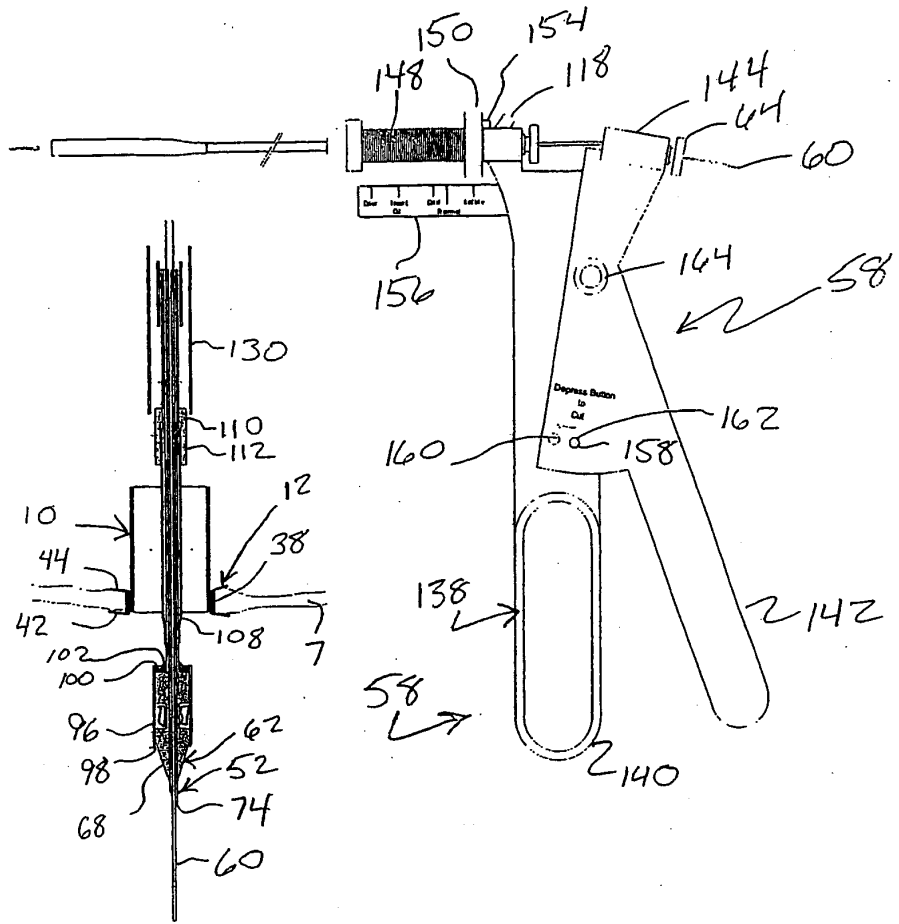


FIG. 17b.

FIG. 17a

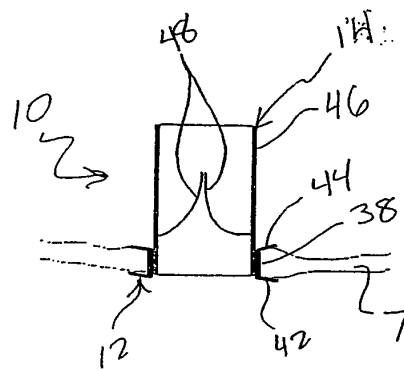
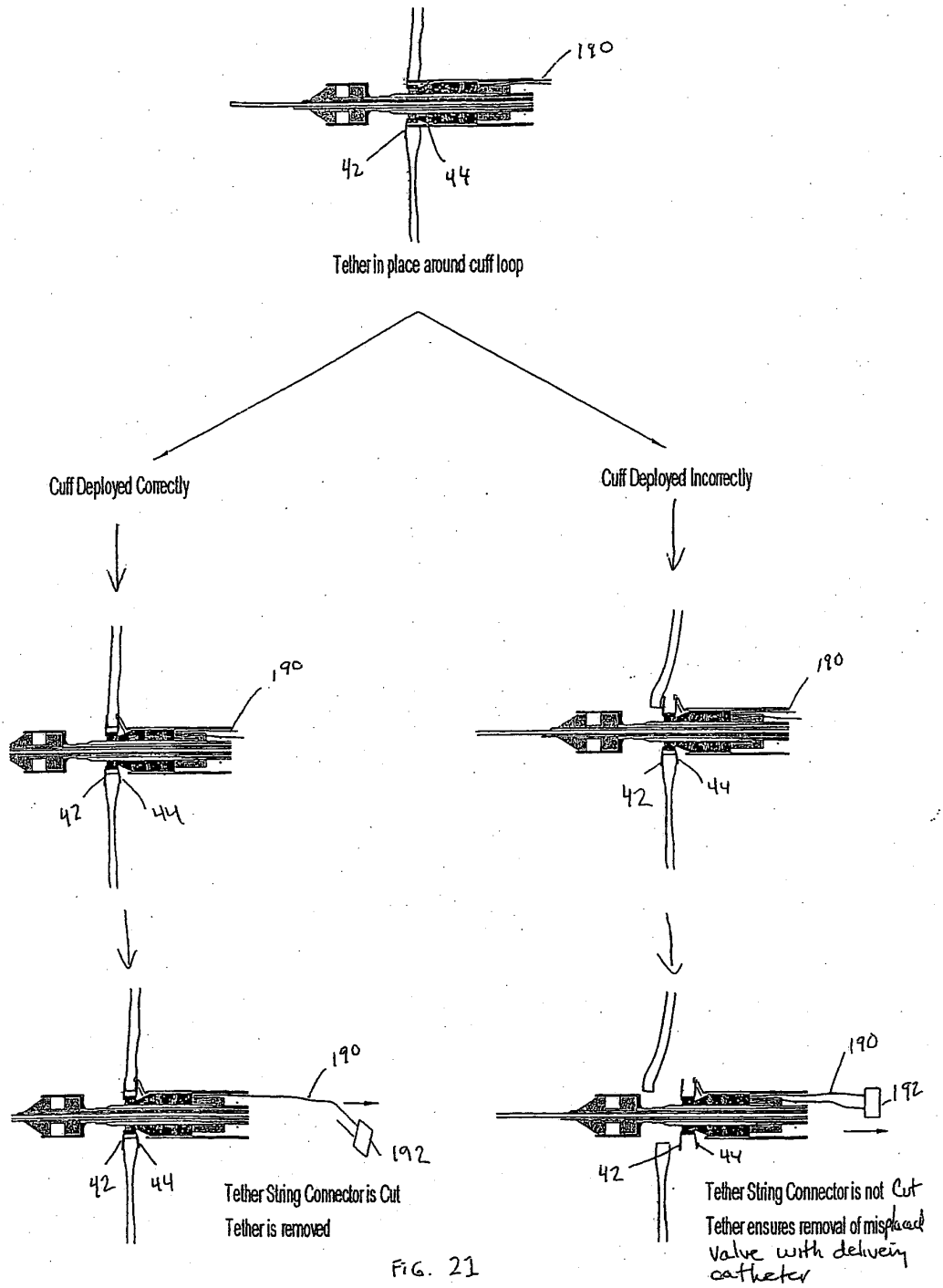


FIG. 18



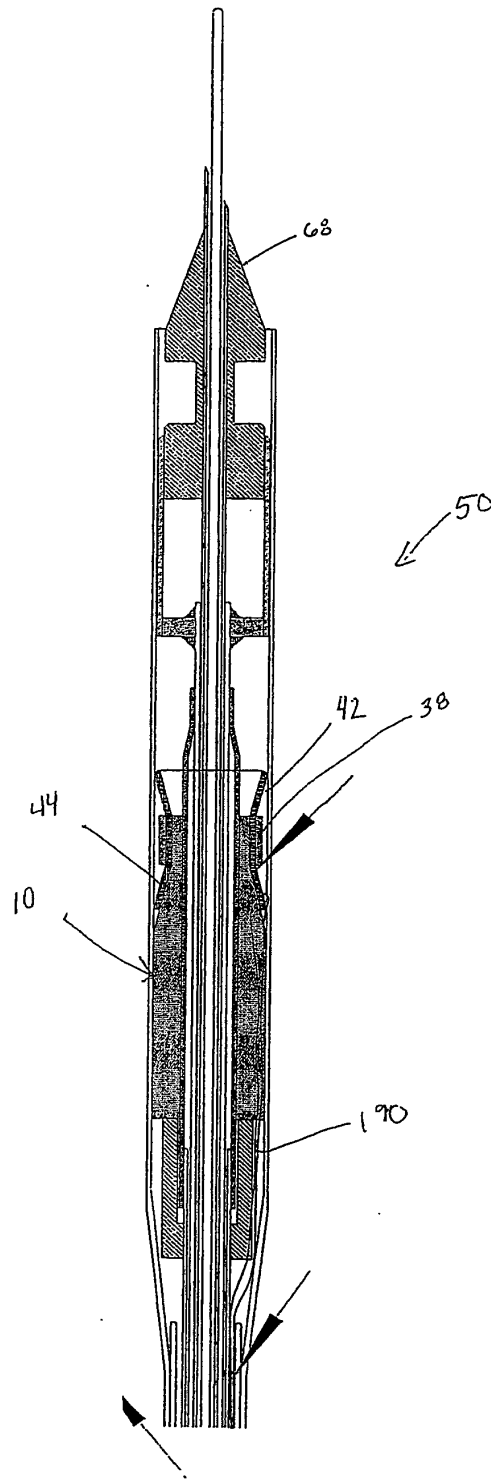
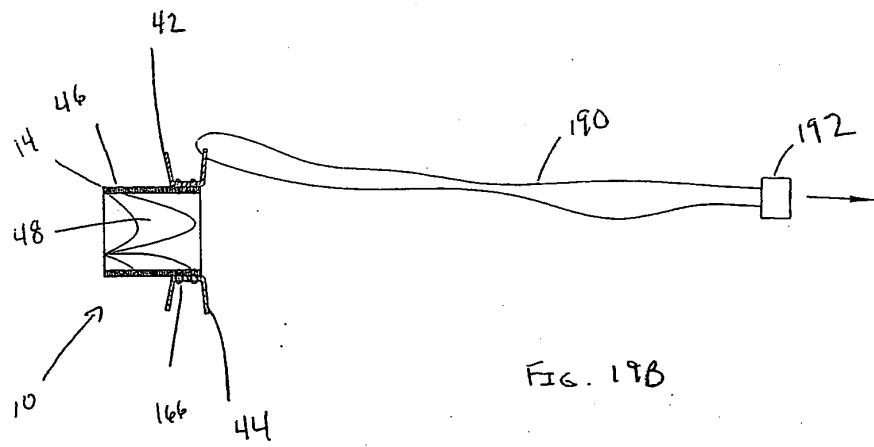
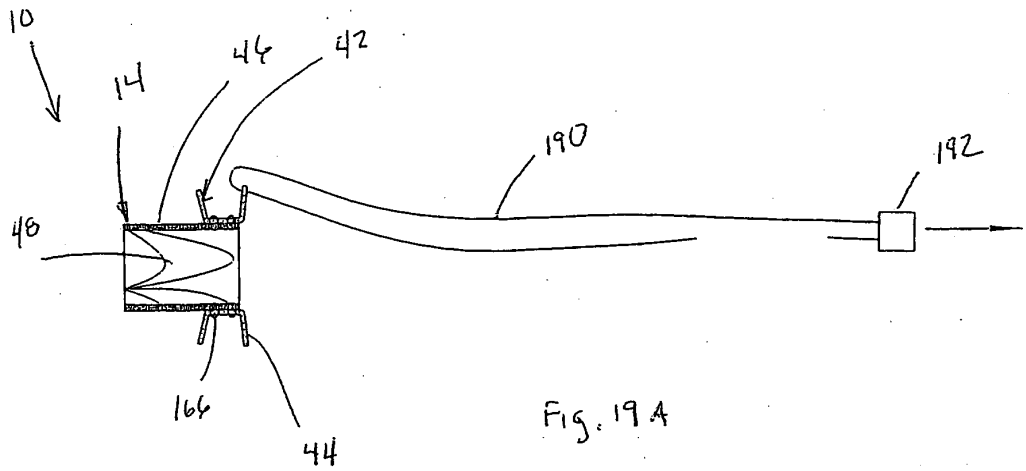
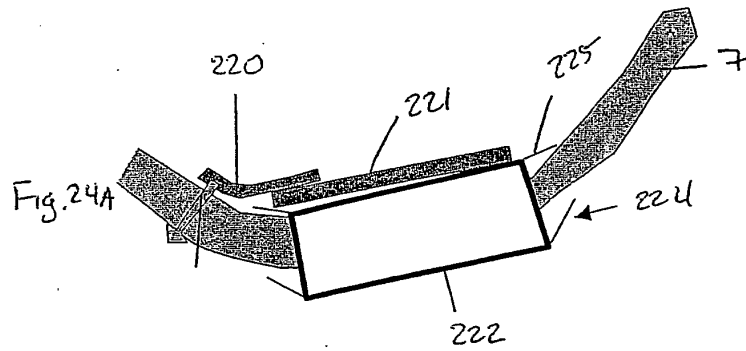
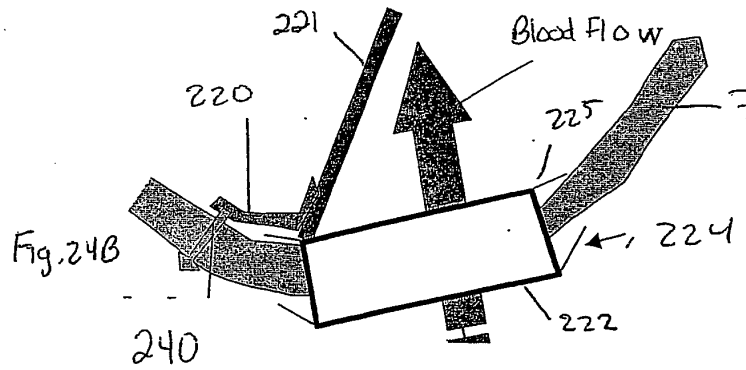


FIG. 20





A+B



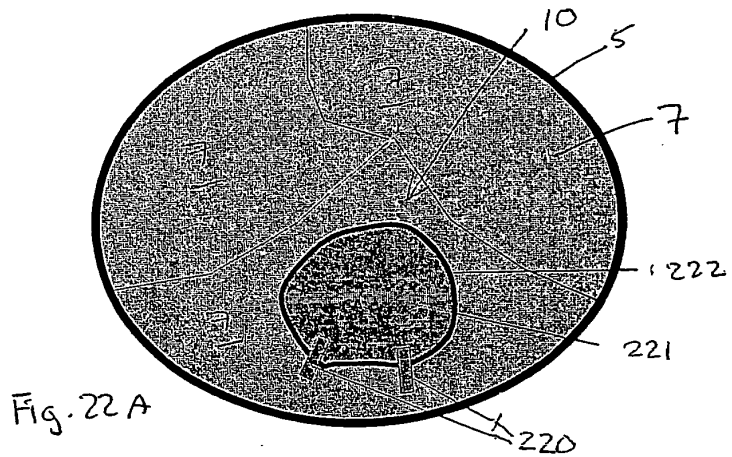


Fig. 22A

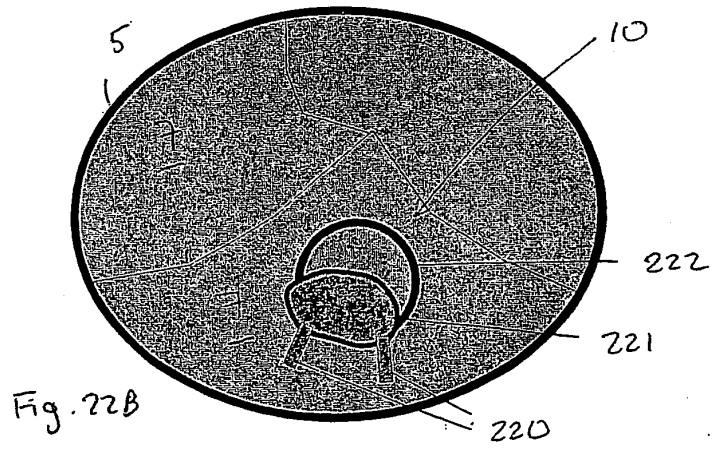
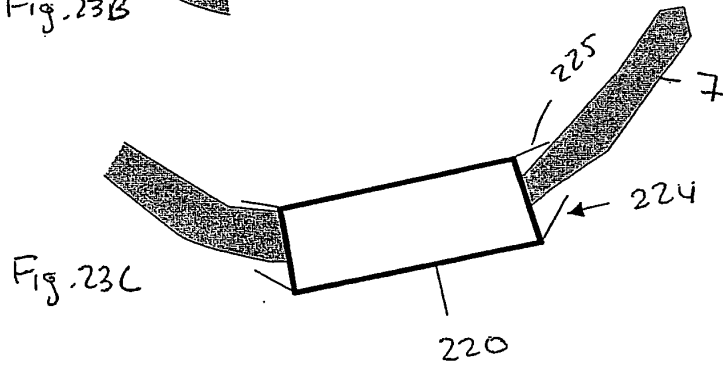
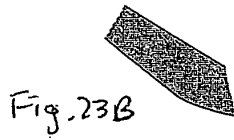
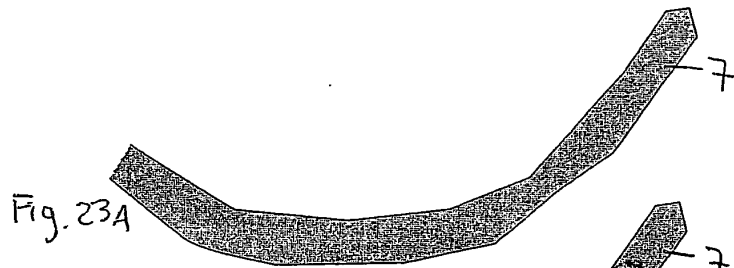


Fig. 22B



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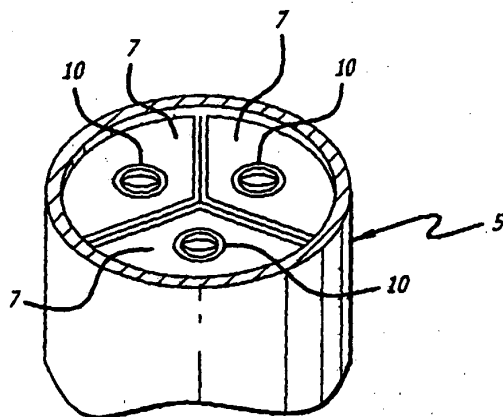
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- (72) Inventor: WILSON, Robert, Foster [US/US]; 3107 West
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- (74) Agent: INSKEEP, James, W.; Inskip Intellectual Prop-
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90248 (US).
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- (84) Designated States (regional): ARIPO patent (GH, GM,
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ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND DEVICE FOR TREATING DISEASED VALVE



(57) Abstract: A native tricuspid valve (5) with a valve implant (10) of the present invention being installed in each leaflet (7). The valve implants (10) allow blood to flow therethrough, in one direction, even though the native tricuspid valve (5) remains closed. The valve implants (10) would similarly work in a native bicuspid valve, unicuspid valve or quadricuspid valve alleviating problems associated with calcified tissue (9) of a stenosed native valve (5).

WO 2004/019811 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/26924

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61F 2/24 US CL : 623/2.11 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 623/2.11, 2.13, 2.36 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,168,614 B1 (ANDERSEN et al) 02 January 2001 (02.01.2002), see the entire document.	1, 2, 6, 8-13, 17-19, 33, 38, and 39
X --- Y	US 6,425,916 B1 (Garrison et al) 30 June 2002 (30.06.2002), see the entire document.	4, 5, 7, 16, and 20 1-3, 6, 8-15, 17-19, and 33
Y	US 6,336,937 B1 (VONESH et al) 08 January 2002 (08.01.2002), see the abstract and Figures 1-3	4, 5, 7, 16, and 20 4, 5, 16, and 20
Y	US 2002/0055772 A1 (MCGUCKIN JR. et al) 09 May 2002 (09.05.2002), see paragraph [0016].	7
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293/076

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Christoph Hans Huber

Application No. : 11/023,783 Confirmation No. : 1933

Filed : December 28, 2004

For : METHODS AND DEVICES FOR REPAIR OR
REPLACEMENT OF HEART VALVES OR ADJACENT
TISSUE WITHOUT THE NEED FOR FULL
CARDIOPULMONARY SUPPORT

Examiner : Suzette Jaime J. Gherbi

Group Art Unit : 3738

New York, New York 10020
May 31, 2005

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.56 and 1.97,
applicant wishes to call the attention of the Examiner to the
following documents:

U.S. Patent Documents

Kistler	832,201	10/02/1906
Ylisto	1,331,737	02/24/1920
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Norred	6,482,228 B1	11/19/2002
Duerig et al.	6,503,272 B2	01/07/2003
Seguin et al.	6,562,058 B2	05/13/2003
Vesely	6,569,196 B1	05/27/2003
Khosravi et al.	6,620,182 B1	09/16/2003
Krolik et al.	6,663,651 B2	12/16/2003
Stevens et al.	6,679,268 B2	01/20/2004
Tu et al.	6,682,558 B2	01/27/2004
Streeter et al.	6,692,513 B2	02/17/2004
Khosravi	6,726,702 B2	04/27/2004
Spenser et al.	6,730,118 B2	05/04/2004

Menz et al.	6,764,494 B2	07/20/2004
Yang et al.	6,733,525 B2	05/11/2004
Schreck	6,767,362 B2	07/27/2004
Downing	6,840,246 B2	01/11/2005

Other Documents

GIBSON, MARK A. and CARELL, EDGAR S., "Direct Right Ventricular Puncture for Hemodynamic Evaluation of a Mechanical Tricuspid Valve Prosthesis: A New Indication for an Old Procedure," Catheterization and Cardiovascular Diagnosis 42:278-282 (1997).

HUBER, CHRISTOPH, et al., "Do valved stents compromise coronary flow?" European Journal of Cardio-thoracic Surgery, 25 (2004) 754-59.

HUBER, CHRISTOPH, et al., "No drive line," Interactive Cardiovascular and Thoracic Surgery, 3 (2004) 336-40.

HUBER, CHRISTOPH, et al., "Rupture of a Polypropylene Suture After Aortic Operation," Ann Thorac Surg, 2003, 75:1318-21.

HUBER, CHRISTOPH, et al., "Ultrasound Navigation Through the Heart for Off-Pump Aortic Valved Stent Implantation," J Endovasc Ther, 2004, 11:503-10.

KHALAF, SALAH A. and MAGEED, NABIL A., "Intraoperative Hemodynamic Improvement After Closed Mitral Valvotomy," J. of Egypt. Society of Cardiothorac. Surg. 2002, Vol. X April No. 2.

MORGAN, J.M., et al., "Left Heart Catheterization by Direct Ventricular Puncture: Withstanding the Test of Time," Catheterization and Cardiovascular Diagnosis 16:87-90 (1989).

OMMEN, S.R., et al., "Summary of the Mayo Clinic Experience with Direct Left Ventricular Puncture," Catheterization and Cardiovascular Diagnosis 44:175-178 (1998).

PATEL, JAI J., et al., "Balloon Valvuloplasty Versus Closed Commissurotomy for Pliable Mitral Stenosis: A Prospective Hemodynamic Study," JACC, Vol. 18, No. 5, November 1, 1991:1318-22.

SIVASUBRAMANIAN, MANI, "Mitral Stenosis," May 4, 1997.
<<http://www.heartdiseaseonline.com/aa/aa050497.htm>>

VON SEGESSER, L.K., et al., "Reparations endovasculaires des anevrismes aortiques," Med Hyg, 2003, 61:1134-38.

WASIR, H.S., et al., "Percutaneous Left Ventricular Puncture in Aortic Valve Disease," Indian Heart Journal, Vol. 32, No. 2, 81-84, 1980.

ZHOU, JUN QING; CORNO, ANTONIO; HUBER, CHRISTOPHE, et al., "Self-expandable valved stent of large size," European Journal of Cardio-thoracic Surgery, 24 (2003) 212-16.

These documents are listed on the accompanying Form SB/08 (submitted in duplicate). Copies of the "Other Documents" are enclosed herewith.

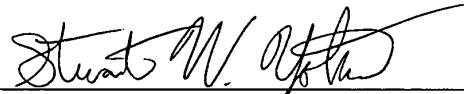
Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

It is respectfully requested that these documents be (1) fully considered by the Patent and Trademark Office during examination of this application; and (2) printed on any patent which may issue on this application. Applicant requests that a copy of Form SB/08, as considered and initialed by the Examiner, be returned with the next communication.

This Information Disclosure Statement is being transmitted more than three months from the application filing date but before the mailing date of the first Office Action on the merits. In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075, Order No. 000293.0076. A duplicate copy of this Information Disclosure Statement is transmitted herewith.

Consideration of the foregoing in relation to this patent application is respectfully requested.

Respectfully submitted,



Stuart W. Yothez
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Tel.: (212) 596-9000

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PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031
 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO				Complete if known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	11/023,783
				Filing Date	December 28, 2004
(use as many sheets as necessary)				First Named Inventor	Christoph Hans Huber
				Art Unit	3738
Sheet 1 of 3				Examiner Name	Suzette Jaime J. Gherbi
				Attorney Docket Number	293/076

U.S. PATENT DOCUMENTS					
Examiner initials	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US-832,201	10/02/1906	Kistler	
		US-1,331,737	02/24/1920	Ylisto	
		US-3,671,979	06/27/1972	Moulopoulos	
		US-4,056,854	11/08/1977	Boretos et al.	
		US-4,327,736	05/04/1982	Inoue	
		US-4,343,048	08/10/1982	Ross et al.	
		US-4,585,000	04/29/1986	Hershenson	
		US-4,777,951	10/18/1988	Cribier et al.	
		US-5,332,402	07/26/1994	Teitelbaum	
		US-5,397,351	03/14/1995	Pavcnik et al.	
		US-5,792,094	08/11/1998	Stevens et al.	
		US-5,840,081	11/24/1998	Andersen et al.	
		US-5,855,597	01/05/1999	Jayaraman	
		US-5,895,399	04/20/1999	Barbut et al.	
		US-5,957,949	09/28/1999	Leonhardt et al.	
		US-6,168,614 B1	01/02/2001	Andesen et al.	
		US-6,203,561 B1	03/20/2001	Ramee et al.	
		US-6,338,740 B1	01/15/2002	Carpentier	
		US-6,425,916 B1	07/30/2002	Garrison et al.	
		US-6,458,153 B1	10/01/2002	Bailey et al.	
		US-6,458,156 B1	10/01/2002	Wan et al.	
		US-6,482,228 B1	11/19/2002	Norred	
		US-6,503,272 B2	01/07/2003	Duerig et al.	
		US-6,562,058 B2	05/13/2003	Seguin et al.	
		US-6,569,196 B1	05/27/2003	Vesely	
		US-6,620,182 B1	09/16/2003	Khosravi et al.	

Examiner Signature	Date Considered
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional).

² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

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Substitute for form 1449/PTO				Complete if known	
				Application Number	11/023,783
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	December 28, 2004
				First Named Inventor	Christoph Hans Huber
(use as many sheets as necessary)				Art Unit	3738
				Examiner Name	Suzette Jaime J. Gherbi
Sheet	2	of	3	Attorney Docket Number	293/076

U.S. PATENT DOCUMENTS (continued)					
Examiner initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US-6,663,651 B2	12/16/2003	Krolik et al.	
		US-6,679,268 B2	01/20/2004	Stevens et al.	
		US-6,682,558 B2	01/27/2004	Tu et al.	
		US-6,692,513 B2	02/17/2004	Streeter et al.	
		US-6,726,702 B2	04/27/2004	Khosravi	
		US-6,730,118 B2	05/04/2004	Spenser et al.	
		US-6,764,494 B2	07/20/2004	Menz et al.	
		US-6,733,525 B2	05/11/2004	Yang et al.	
		US-6,767,362 B2	07/27/2004	Schreck	
		US-6,840,246 B2	01/11/2005	Downing	

FOREIGN PATENT DOCUMENTS						
Examiner initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code* - Number ⁵ - Kind Code ⁶				

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³ Applicant is to place a check mark here if English language translation is attached.

⁴ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

⁵ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Filing Date	December 28, 2004
		First Named Inventor	Christoph Hans Huber
(use as many sheets as necessary)		Art Unit	3738
		Examiner Name	Suzette Jaime J. Gherbi
Sheet	3	of	3
		Attorney Docket Number	293/076

NON PATENT LITERATURE DOCUMENTS			
Examiner initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ³
		GIBSON, MARK A. and CARELL, EDGAR S., "Direct Right Ventricular Puncture for Hemodynamic Evaluation of a Mechanical Tricuspid Valve Prosthesis: A New Indication for an Old Procedure," Catheterization and Cardiovascular Diagnosis 42:278-282 (1997).	
		HUBER, CHRISTOPH, et al., "Do valved stents compromise coronary flow?" European Journal of Cardio-thoracic Surgery, 25 (2004) 754-59.	
		HUBER, CHRISTOPH, et al., "No drive line," Interactive Cardiovascular and Thoracic Surgery, 3 (2004) 336-40.	
		HUBER, CHRISTOPH, et al., "Rupture of a Polypropylene Suture After Aortic Operation," Ann Thorac Surg, 2003, 75:1318-21.	
		HUBER, CHRISTOPH, et al., "Ultrasound Navigation Through the Heart for Off-Pump Aortic Valved Stent Implantation," J Endovasc Ther, 2004, 11:503-10.	
		KHALAF, SALAH A. and MAGEED, NABIL A., "Intraoperative Hemodynamic Improvement After Closed Mitral Valvotomy," J. of Egypt. Society of Cardiothorac. Surg. 2002, Vol. X April No. 2.	
		MORGAN, J.M., et al., "Left Heart Catheterization by Direct Ventricular Puncture: Withstanding the Test of Time," Catheterization and Cardiovascular Diagnosis 16:87-90 (1989).	
		OMMEN, S.R., et al., "Summary of the Mayo Clinic Experience with Direct Left Ventricular Puncture," Catheterization and Cardiovascular Diagnosis 44:175-178 (1998).	
		PATEL, JAI J., et al., "Balloon Valvuloplasty Versus Closed Commissurotomy for Pliable Mitral Stenosis: A Prospective Hemodynamic Study," JACC, Vol. 18, No. 5, November 1, 1991:1318-22.	
		SIVASUBRAMANIAN, MANI, "Mitral Stenosis," May 4, 1997. < http://www.heartdiseaseonline.com/aa/aa050497.htm >	
		VON SEGESSER, L.K., et al., "Reparations endovasculaires des anevrismes aortiques," Med Hyg, 2003, 81:1134-38.	
		WASIR, H.S., et al., "Percutaneous Left Ventricular Puncture in Aortic Valve Disease," Indian Heart Journal, Vol. 32, No. 2, 81-84, 1980.	
		ZHOU, JUN QING; CORNO, ANTONIO; HUBER, CHRISTOPHE, et al., "Self-expandable valved stent of large size," European Journal of Cardio-thoracic Surgery, 24 (2003) 212-16.	

Examiner Signature		Date Considered	
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PATENT APPLICATION SERIAL NO. _____

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FEE RECORD SHEET

Repln. Ref: 03/14/2005 SDIRETA1 0012482000
DAH:061075 Name/Number:11023783
FC: 9204 \$2325.00 CR

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01 FC:2011	150.00	OP
02 FC:2111	250.00	OP
03 FC:2311	100.00	OP
04 FC:2201	1200.00	OP
05 FC:2202	625.00	OP

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01 FC:1011	300.00	OP
02 FC:1111	500.00	OP
03 FC:1311	200.00	OP
04 FC:1201	2400.00	OP
05 FC:1202	1250.00	OP

Adjustment date: 03/14/2005 SDIRETA1
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03 FC:1311	-200.00	OP
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PTO-1556
(5/87)

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293/076

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Christoph Hans Huber
Application No.: 11/023,783
Confirmation No.: Not yet known
Filed: December 28, 2004
For: METHODS AND DEVICES FOR REPAIR OR
REPLACEMENT OF HEART VALVES OR
ADJACENT TISSUE WITHOUT THE NEED FOR
FULL CARDIOPULMONARY SUPPORT

New York, New York 10020
January 25, 2005

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P.O. Box 1450
Alexandria, Virginia 22313-1450

WRITTEN ASSERTION OF ENTITLEMENT TO SMALL ENTITY STATUS
UNDER 37 C.F.R. § 1.27 - PERSON
AND
REQUEST UNDER 37 C.F.R. § 1.28(a) FOR REFUND

Pursuant to 37 C.F.R. § 1.27, applicant hereby respectfully requests small entity status for the purpose of paying reduced fees in the above-identified patent application. Applicant qualifies for small entity status as defined in 37 C.F.R. § 1.27(a)(1) for purposes of paying reduced fees, in that the person is the sole inventor of the above-identified application and is under no obligation to assign, grant, convey, or license, any rights in the invention.

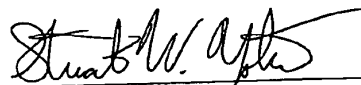
This Request is being filed within three months of the filing date of the above-identified patent

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application. Accordingly, pursuant to 37 C.F.R. § 1.28(a), applicants respectfully request a refund of one-half of the filing fees paid at the time of filing as other than a small entity. Applicants believe that the amount of the refund will be \$2,325.00.

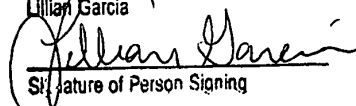
The Director is hereby authorized to credit the refund to Deposit Account No. 06-1075. A duplicate copy of this Request is enclosed herewith.

Respectfully submitted,



Stuart W. Yothers
Registration No. 53,816
Agent for Applicant
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ROPES & GRAY LLP
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293/076

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Applicant : Christoph Hans Huber
Application No. : 11/023,783
Confirmation No. : Not yet known
Filed : December 28, 2004
For : METHODS AND DEVICES FOR REPAIR OR
REPLACEMENT OF HEART VALVES OR
ADJACENT TISSUE WITHOUT THE NEED FOR
FULL CARDIOPULMONARY SUPPORT

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January 25, 2005

Mail Stop 16
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TRANSMITTAL LETTER

Sir:

Applicant transmits herewith a Written Assertion
Of Entitlement To Small Entity Status Under 37 C.F.R. § 1.27
- Person And Request Under 37 C.F.R. § 1.28(a) For Refund.
The Director is hereby authorized to credit any refund
granted on this Request to Deposit Account No. 06-1075. A
duplicate copy of this transmittal is enclosed herewith.

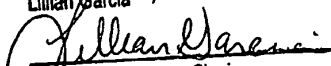
Respectfully submitted,



Stuart W. Yotkers
Registration No. 53,816
Agent for Applicant
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ROPES & GRAY LLP
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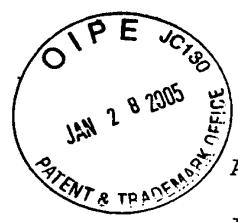
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293/076



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Christoph Hans Huber

Application No. : 11/023,783 Conf. No.: Not yet known

Filed : December 28, 2004

For : METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT

Group Art Unit : Not yet assigned

Examiner : Not yet assigned

EXPRESS MAIL CERTIFICATION

Express Mail mailing label number: EV371745765US

Date of Deposit: January 28, 2005

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Lillian Garcia
 Lillian Garcia

Mail Stop PGPUB Drawings
 Commissioner for Patents
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 Alexandria, VA 22313-1450

SUBMISSION OF FORMAL DRAWINGS AND
 PETITION UNDER 37 C.F.R. § 1.182
FOR ENTRY OF DRAWINGS FOR PUBLICATION

Sir:

Pursuant to 37 C.F.R. § 1.182, applicants hereby petition for entry of the enclosed twenty-five (25) sheets of formal drawings in connection with the publication of this patent application. Please substitute the attached formal drawings (25 sheets; FIGS. 1-41) for the informal

drawings originally filed with the above-identified patent application.

A check in the amount of \$130.00, in payment of the fee set forth in 37 C.F.R. § 1.17(h), is enclosed. The Director is hereby authorized to charge any additional fees due in connection with this Petition, or credit any overpayment of the same, to Deposit Account No. 06-1075. A duplicate copy of this Petition is enclosed.

Respectfully submitted,



Stuart W. Yother
Registration No. 53,816
Agent for Applicant
FISH & NEAVE IP GROUP
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Customer No. 1473
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Tel.: (212) 596-9000
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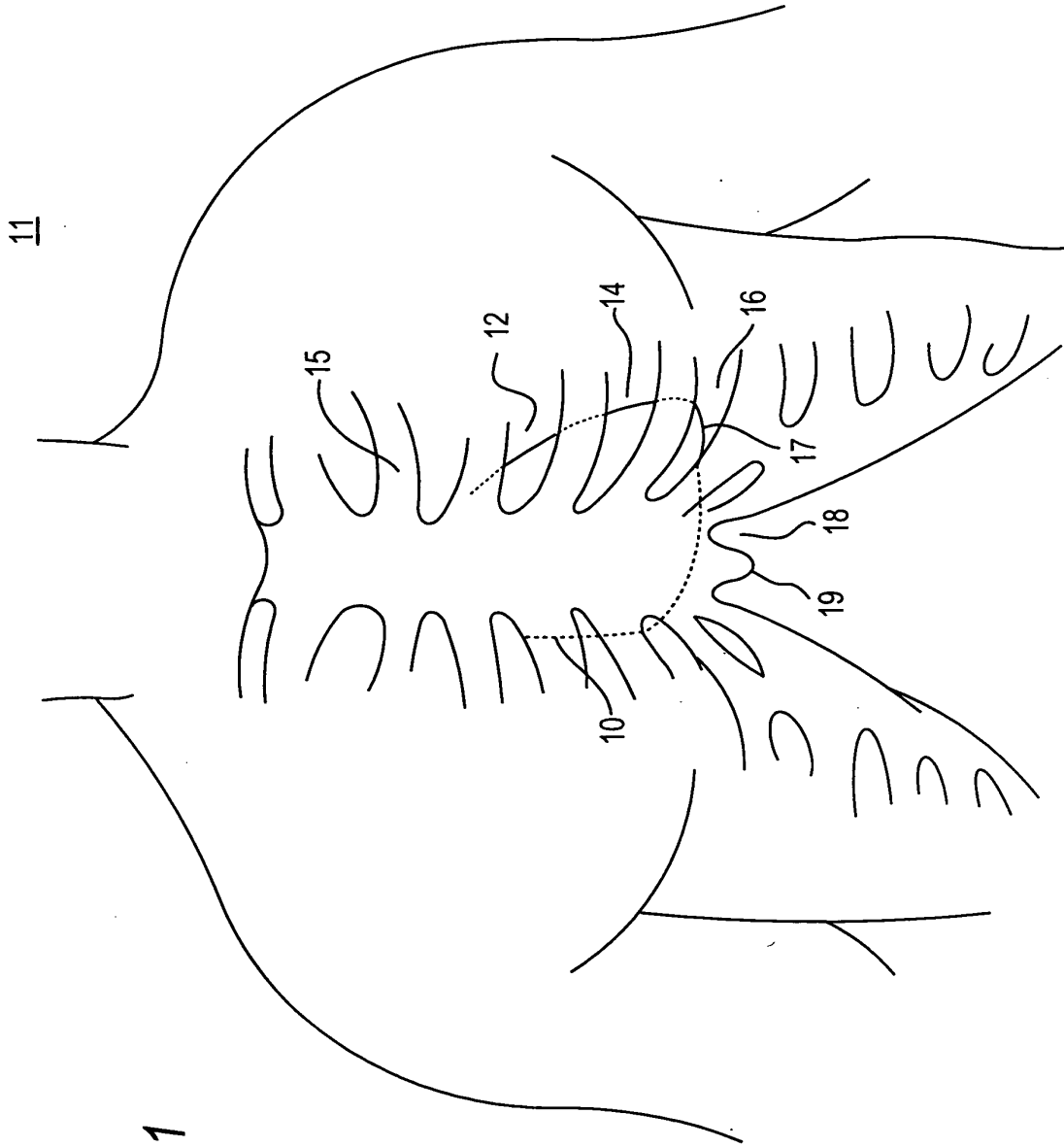
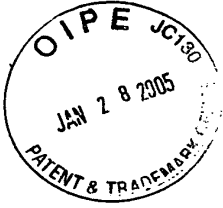


FIG. 1

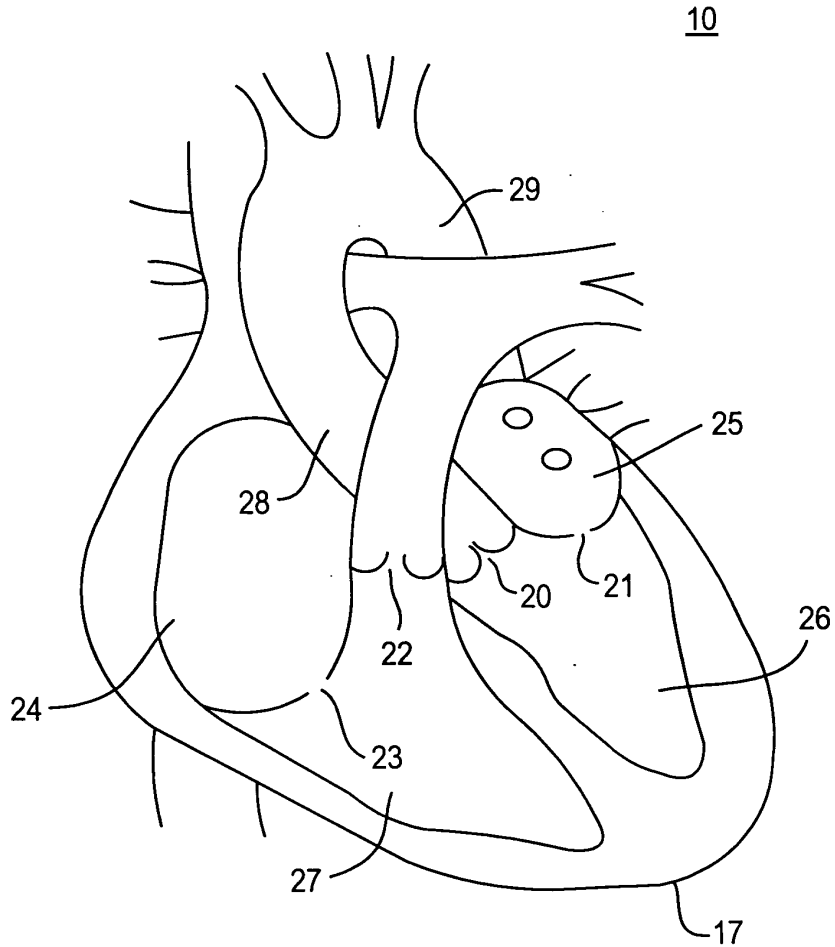


FIG. 2

3 / 25

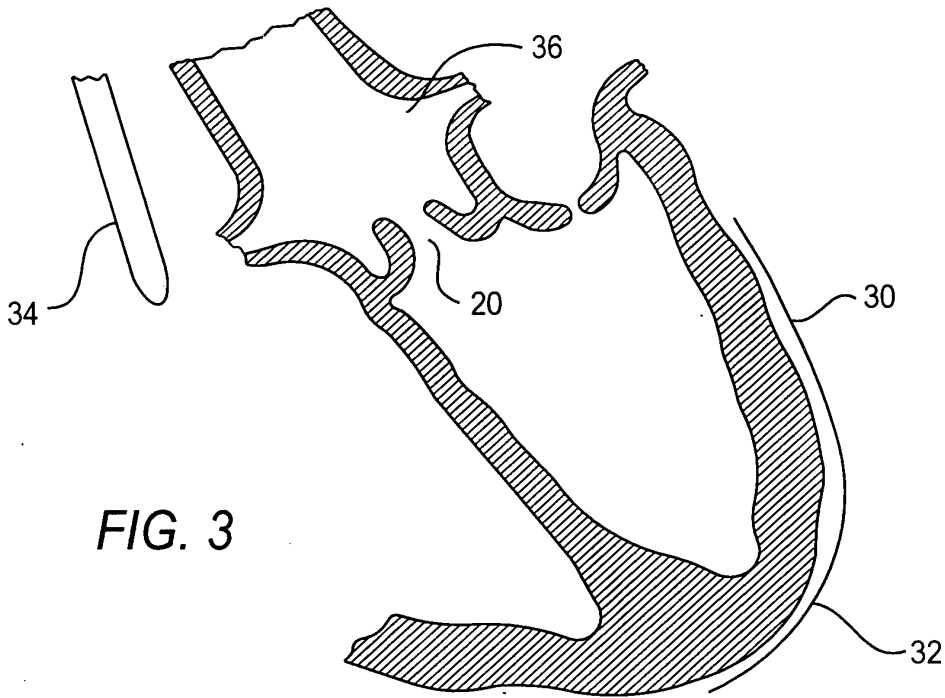


FIG. 3

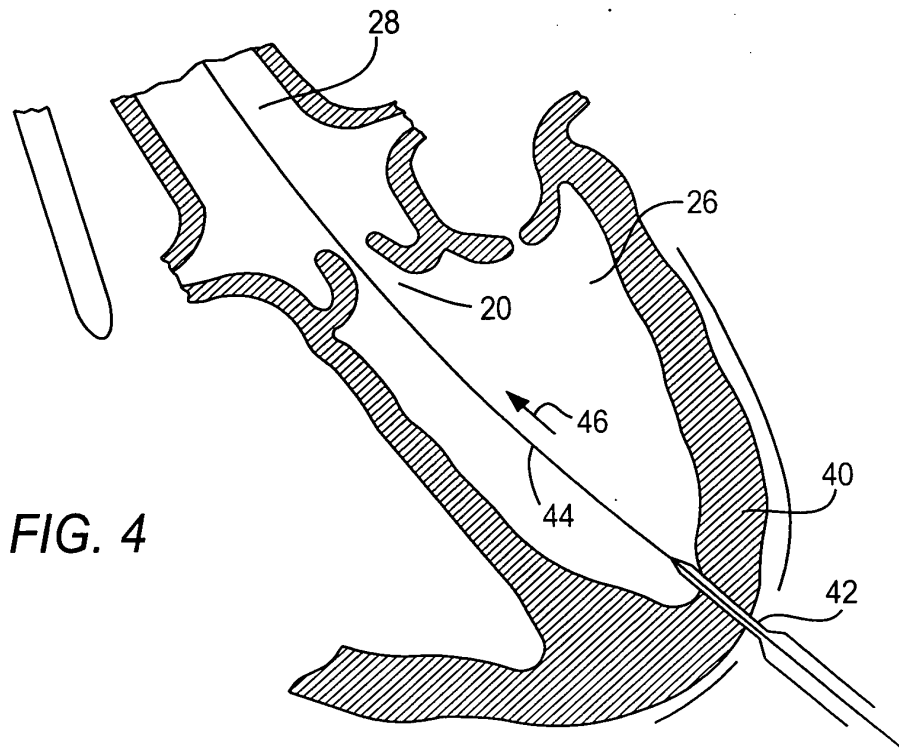


FIG. 4

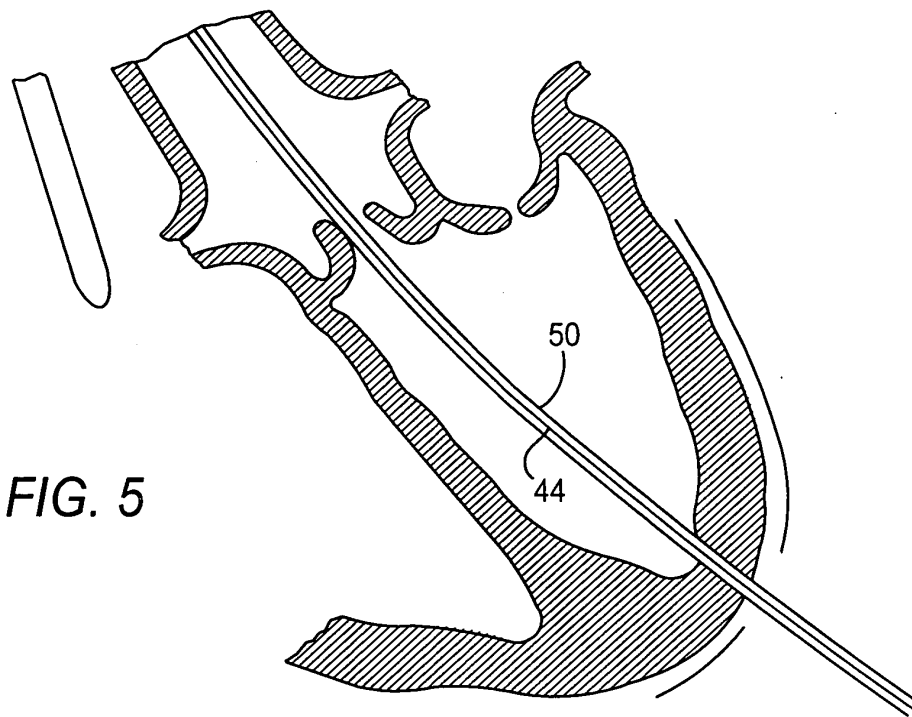


FIG. 5

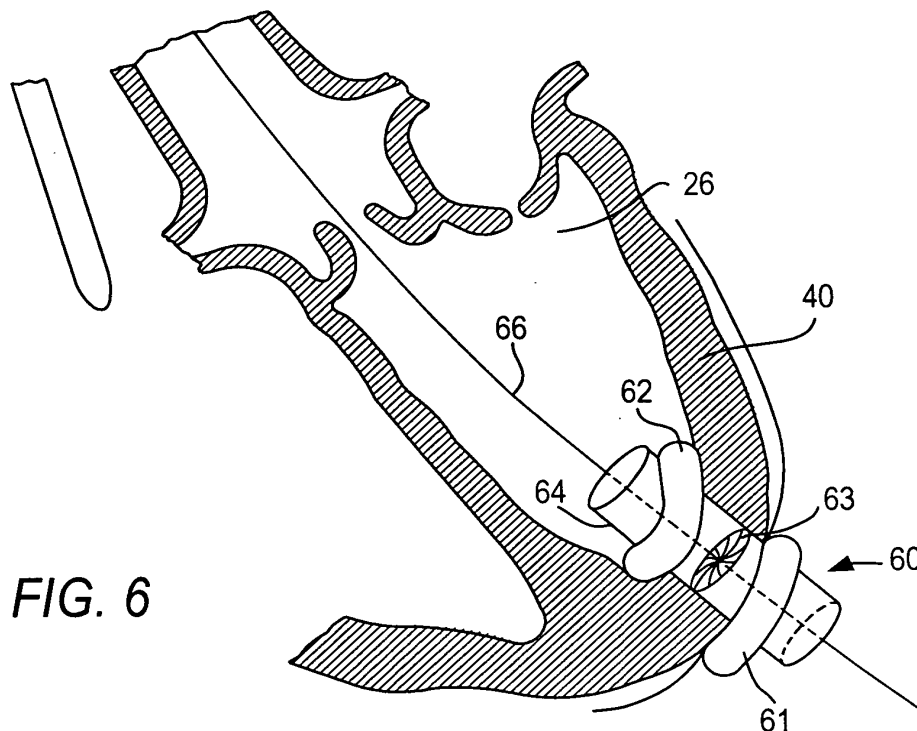
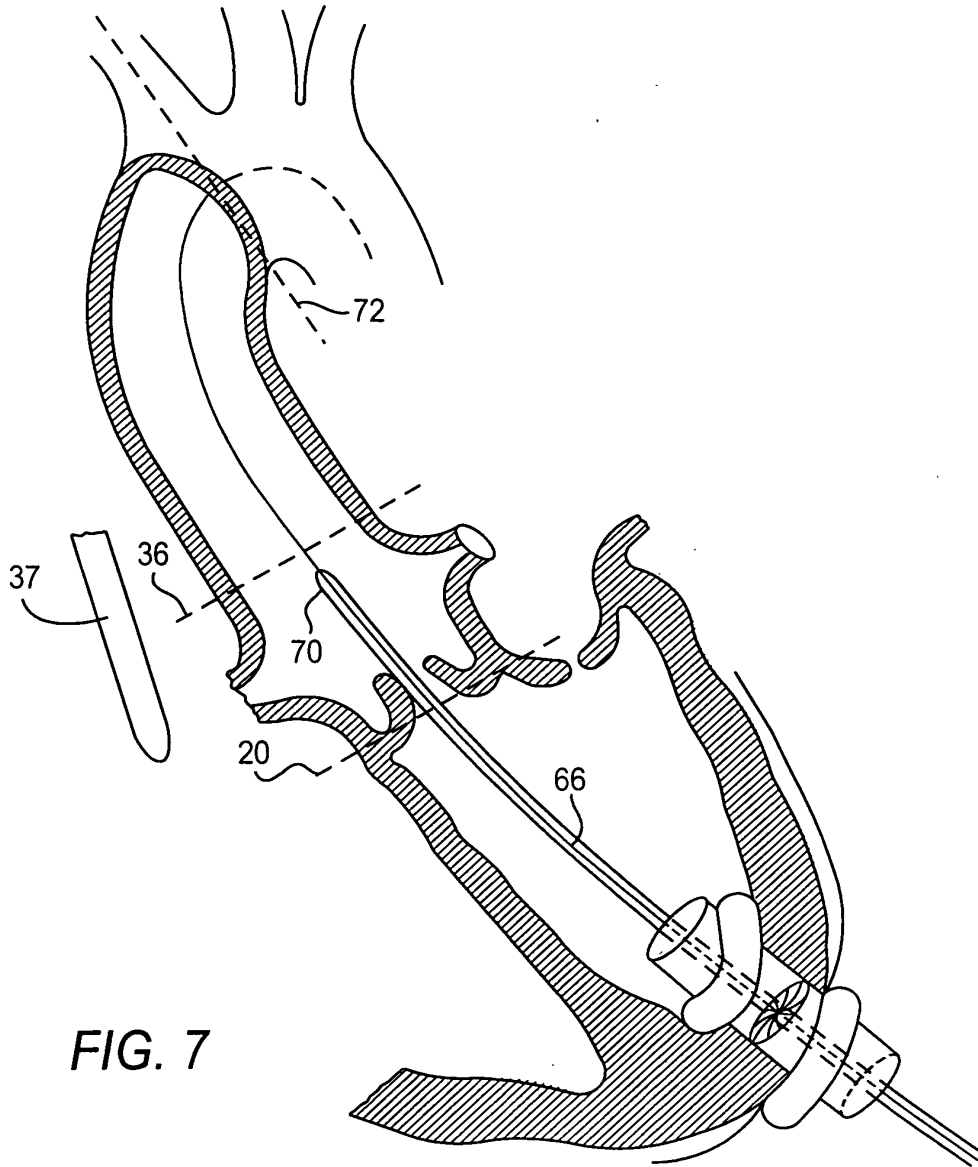


FIG. 6



6 / 25

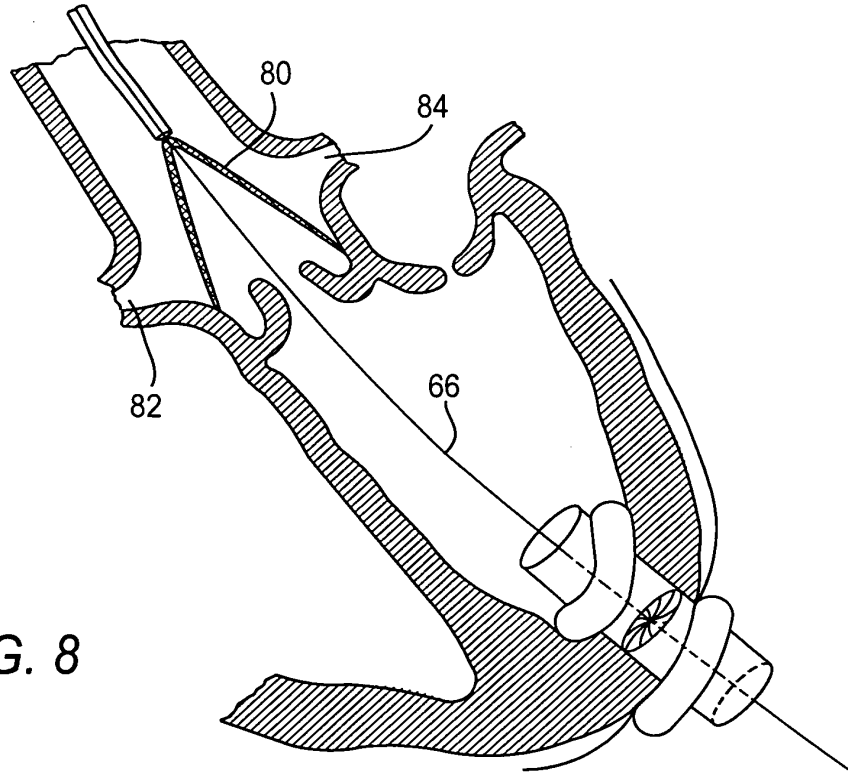


FIG. 8

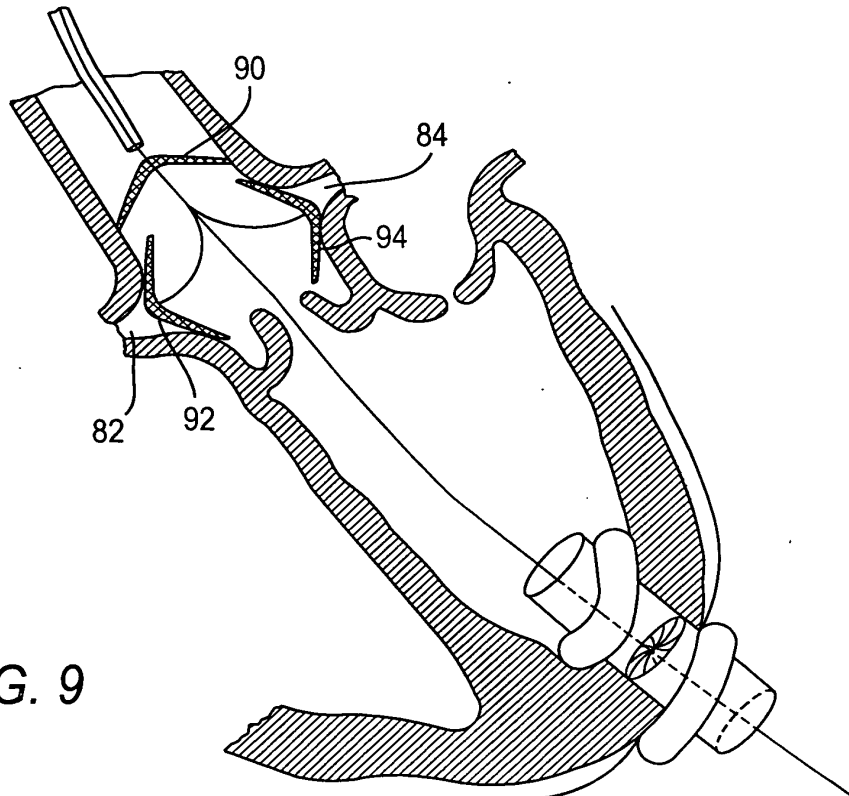


FIG. 9

7 / 25

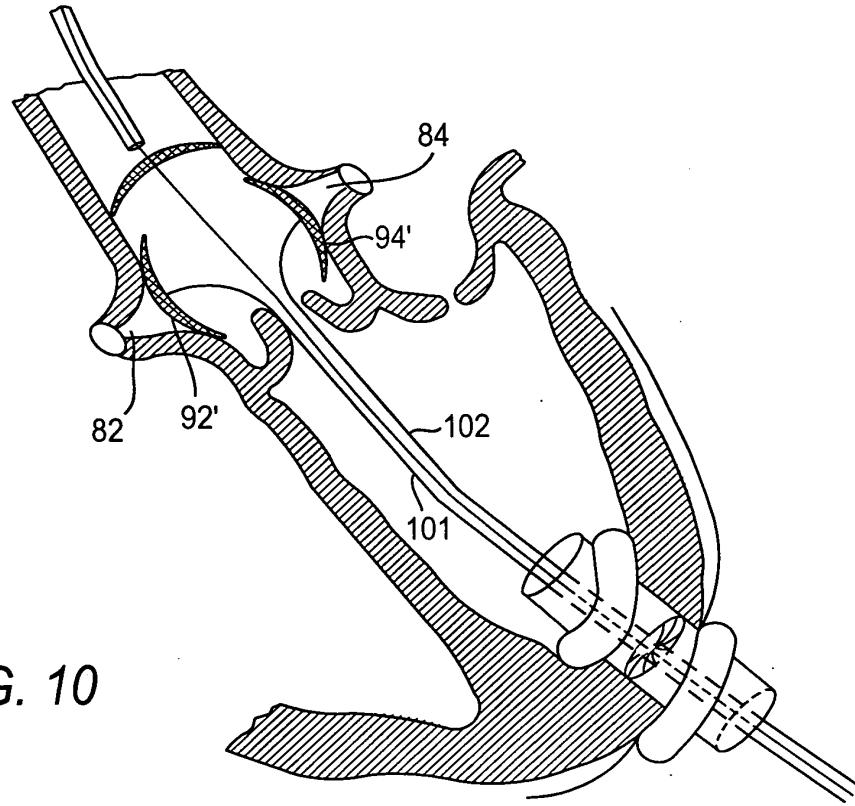


FIG. 10

8 / 25

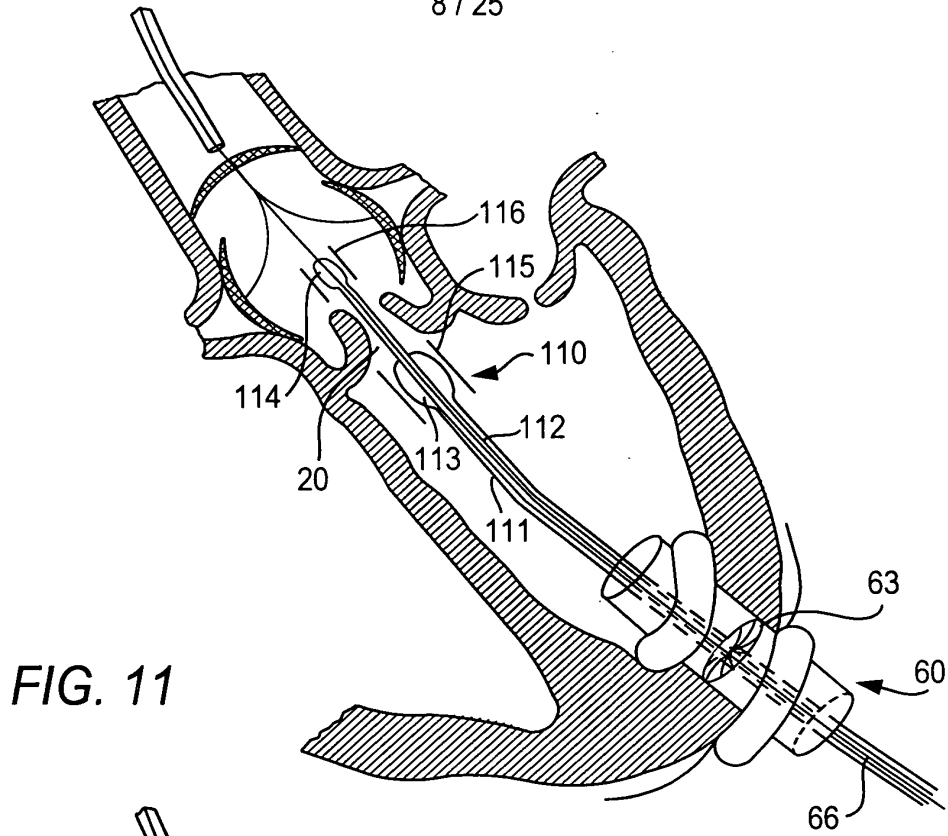


FIG. 11

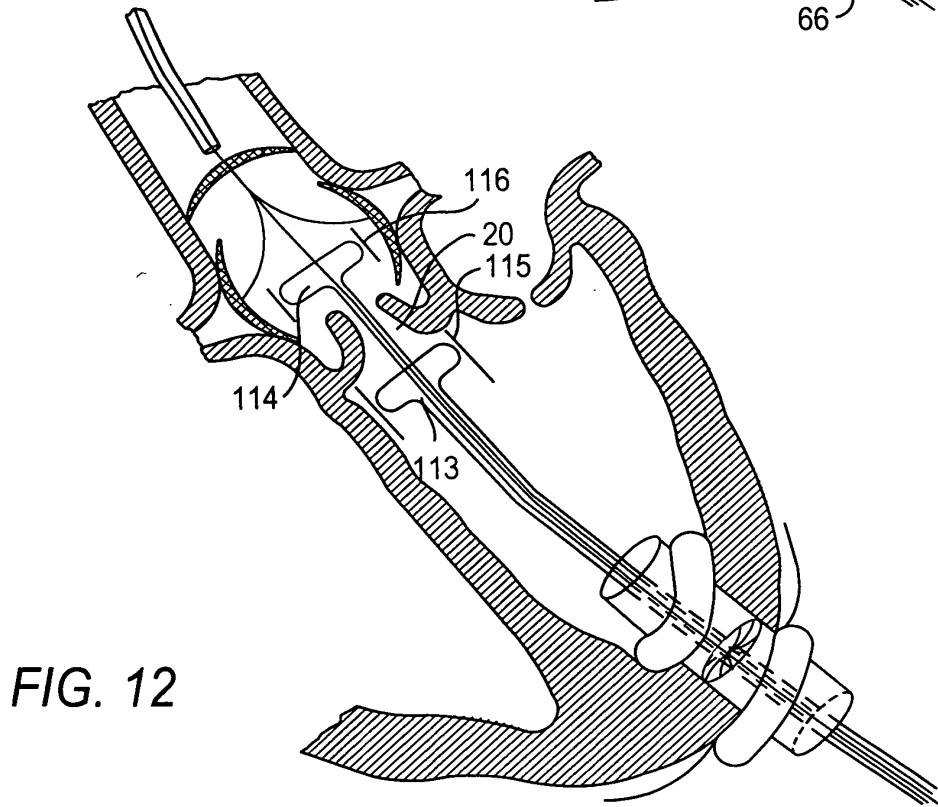


FIG. 12

9 / 25

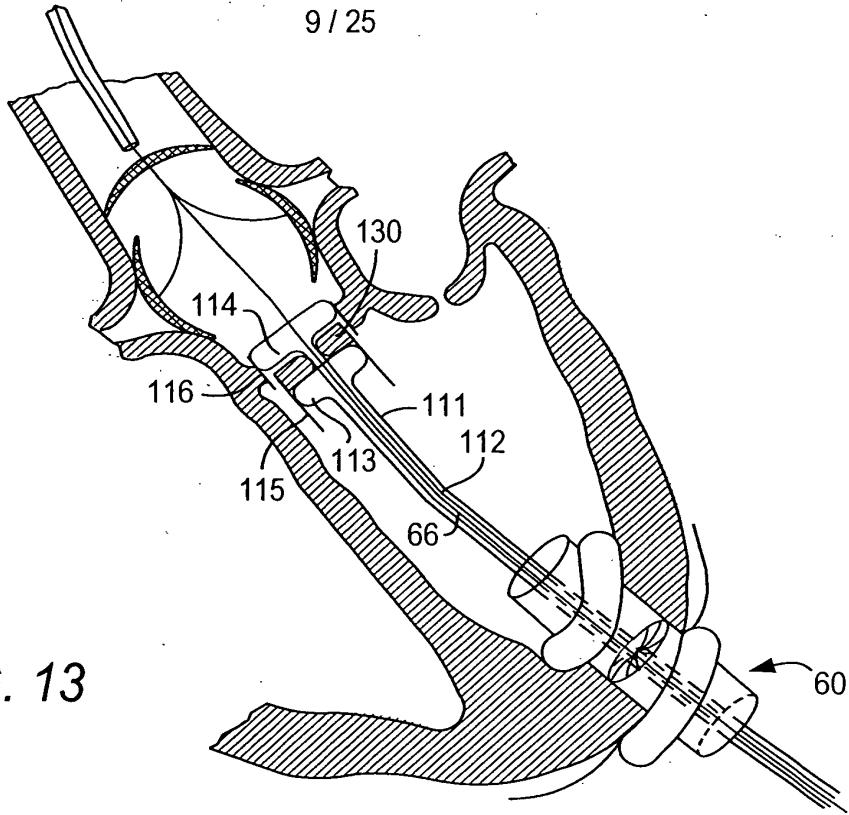


FIG. 13

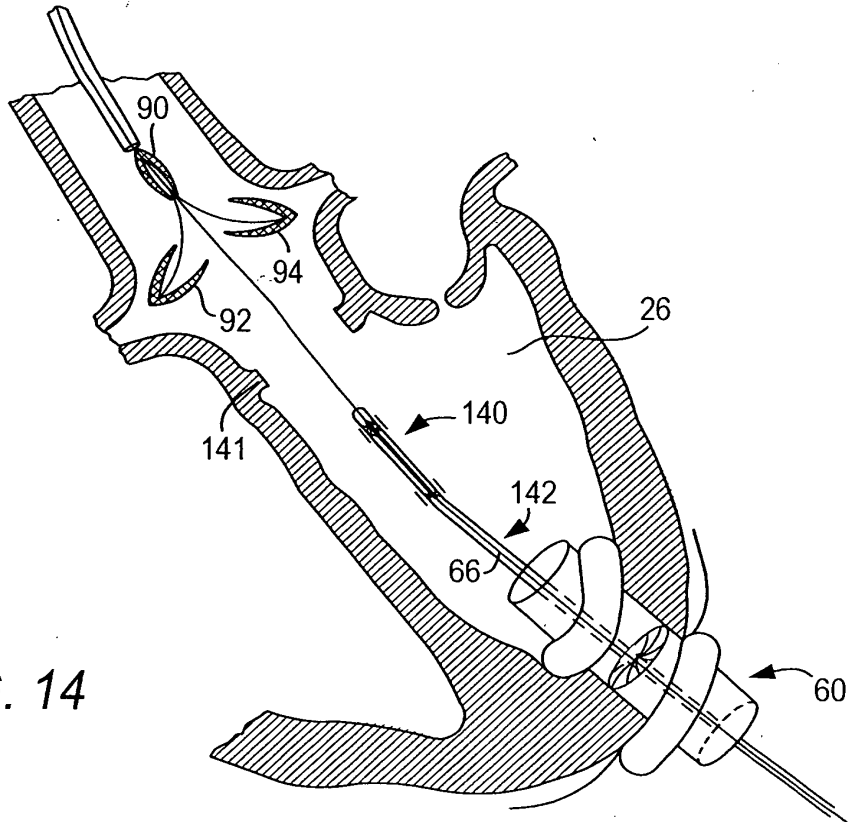


FIG. 14

10 / 25

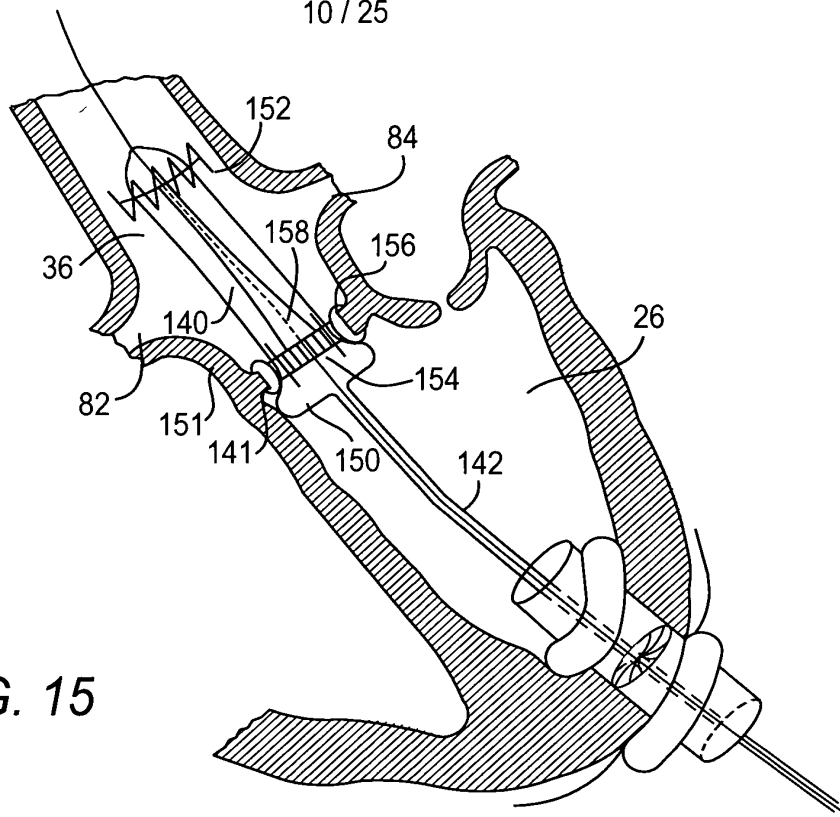


FIG. 15

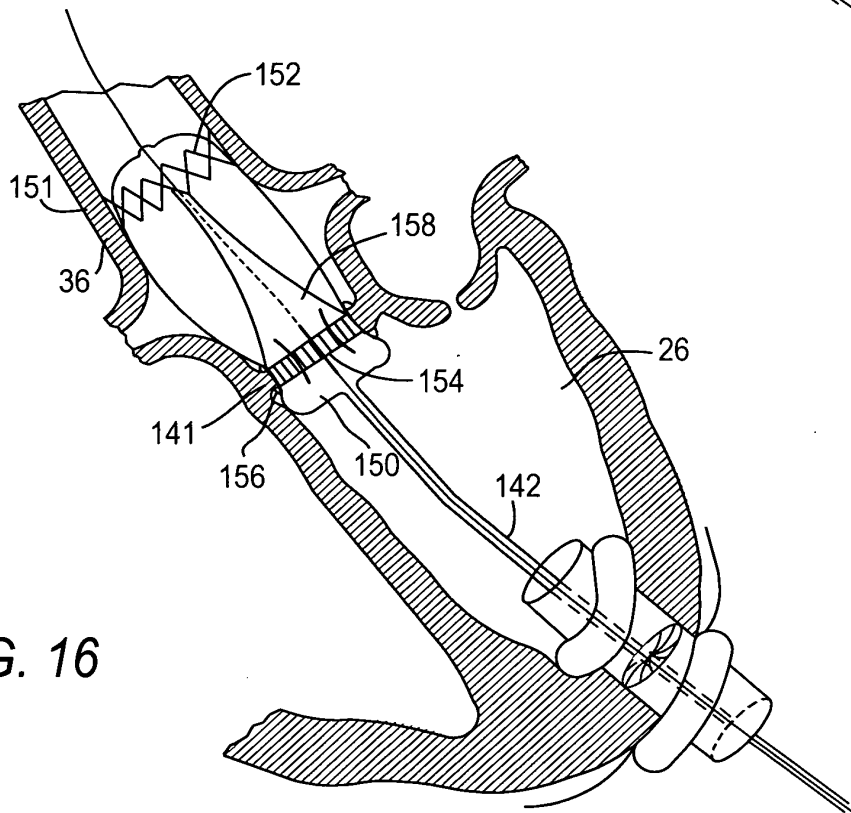
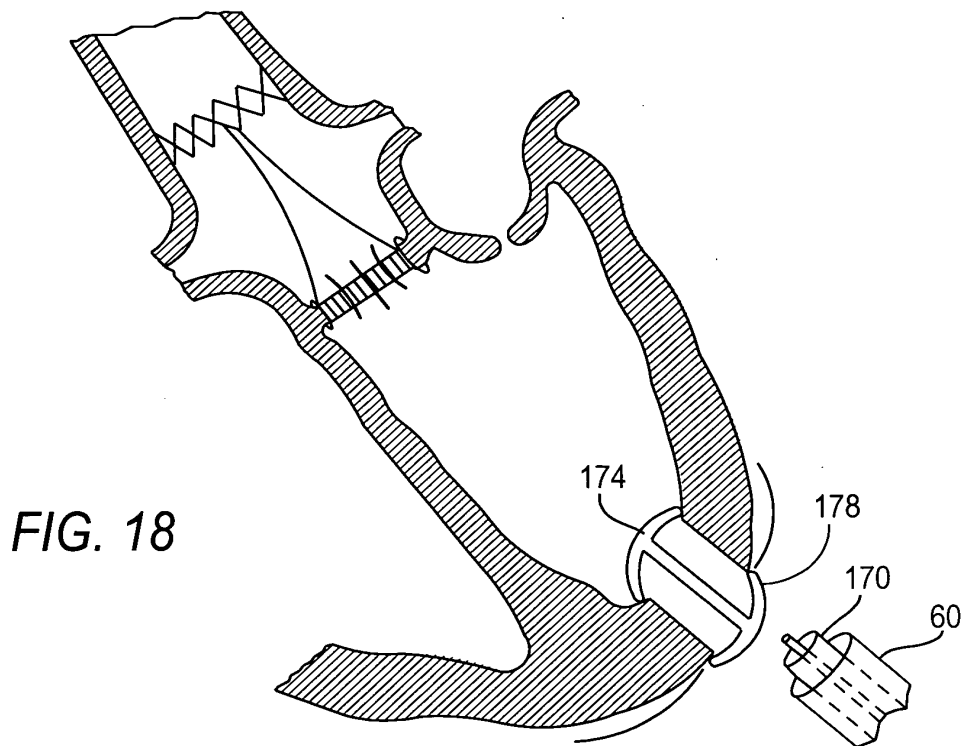
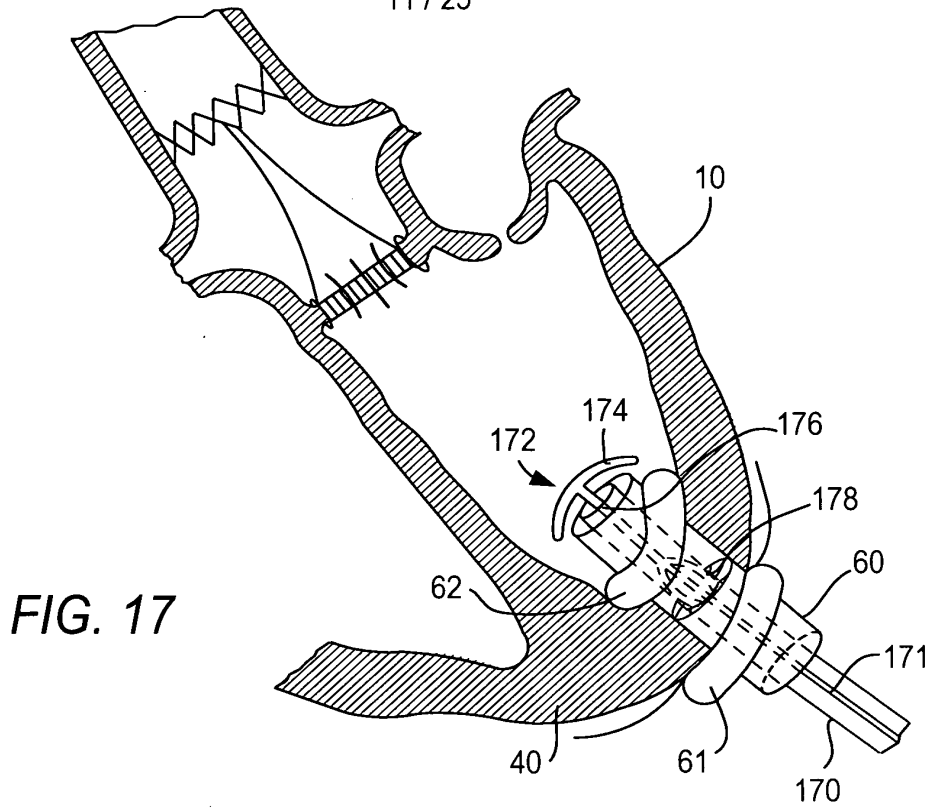


FIG. 16

11 / 25



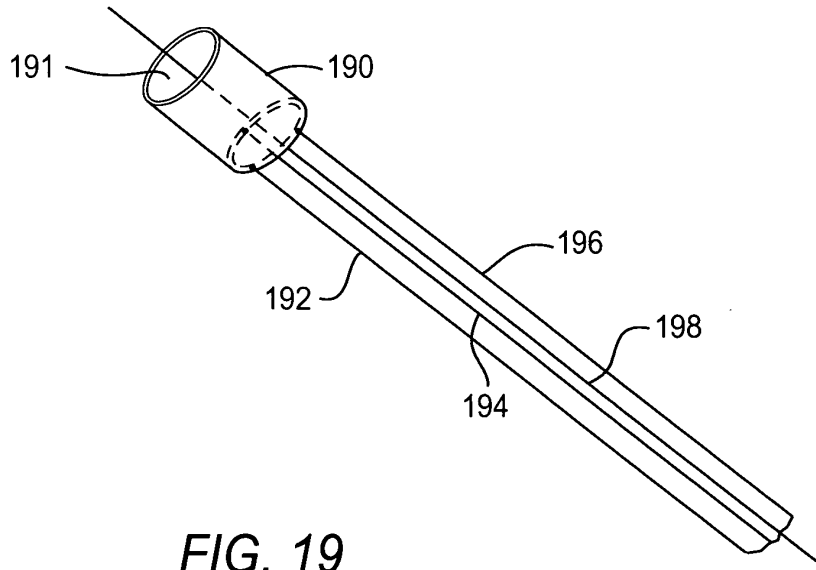


FIG. 19

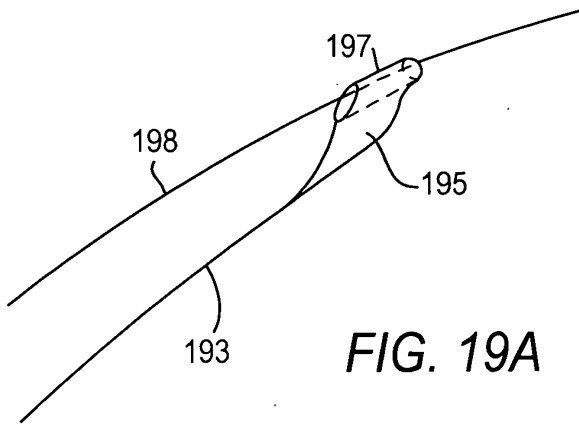


FIG. 19A

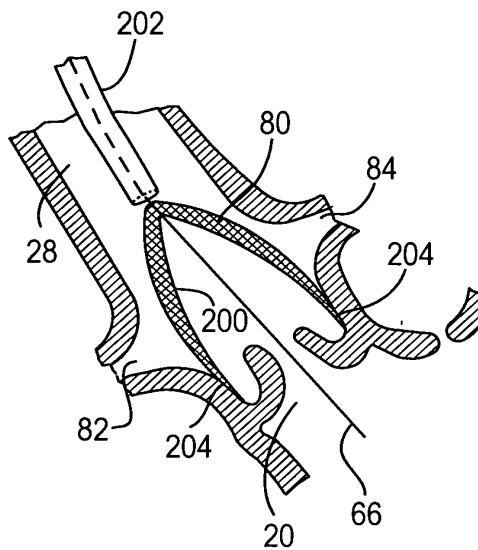


FIG. 20

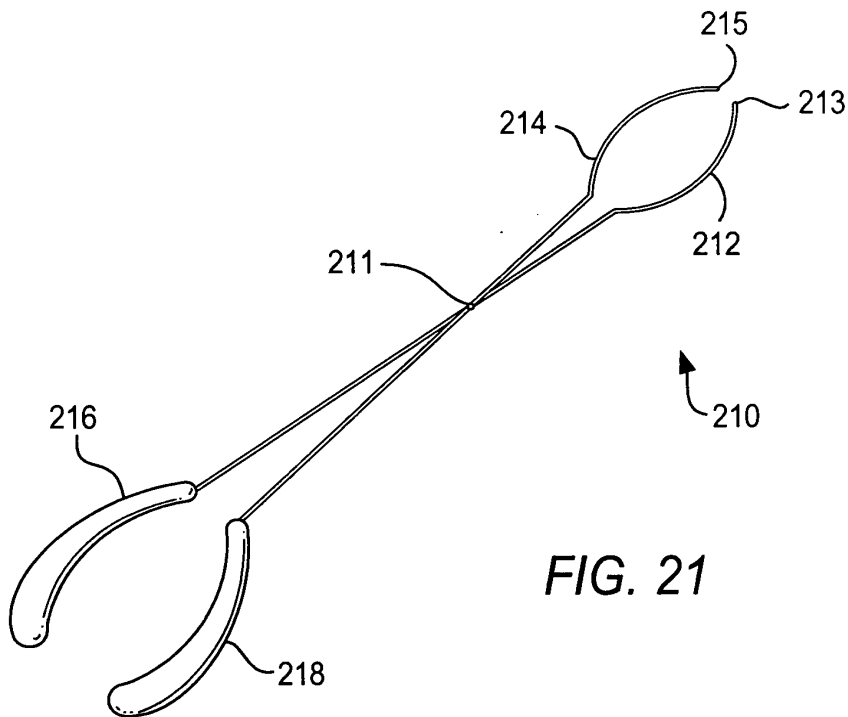


FIG. 21

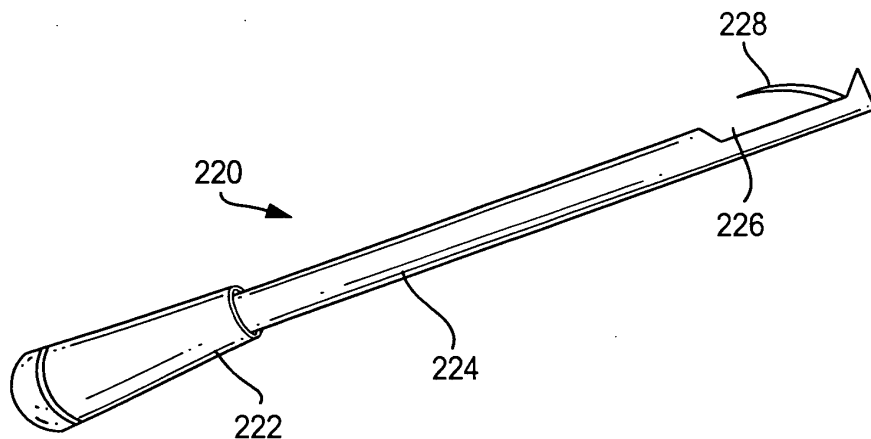


FIG. 22

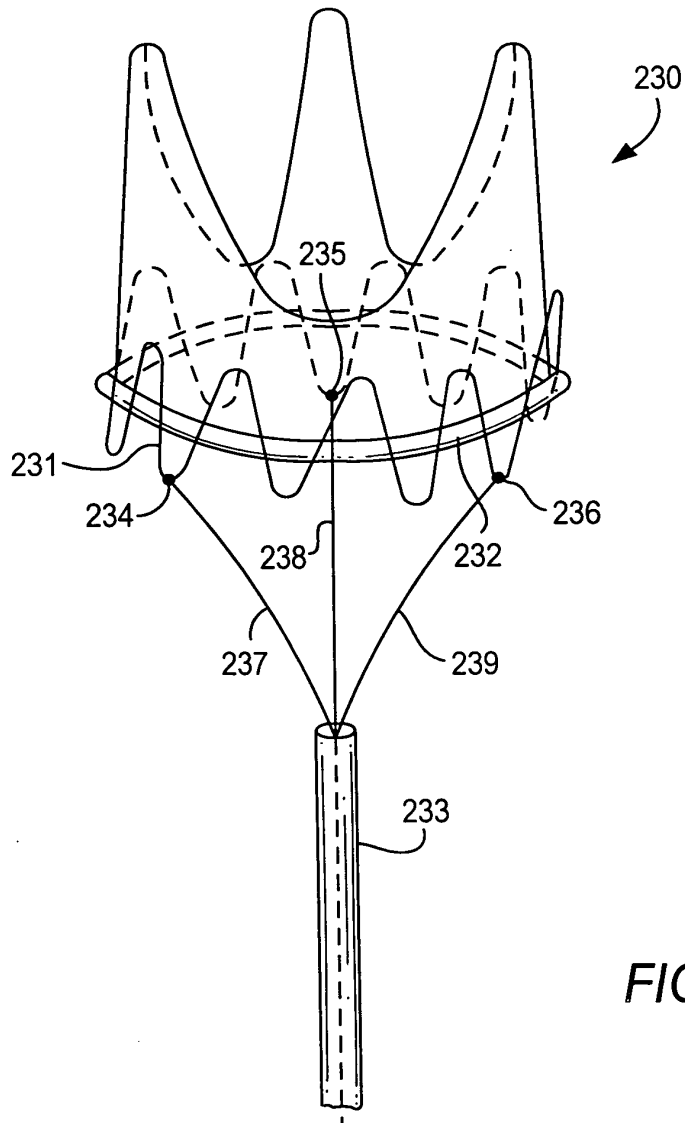


FIG. 23

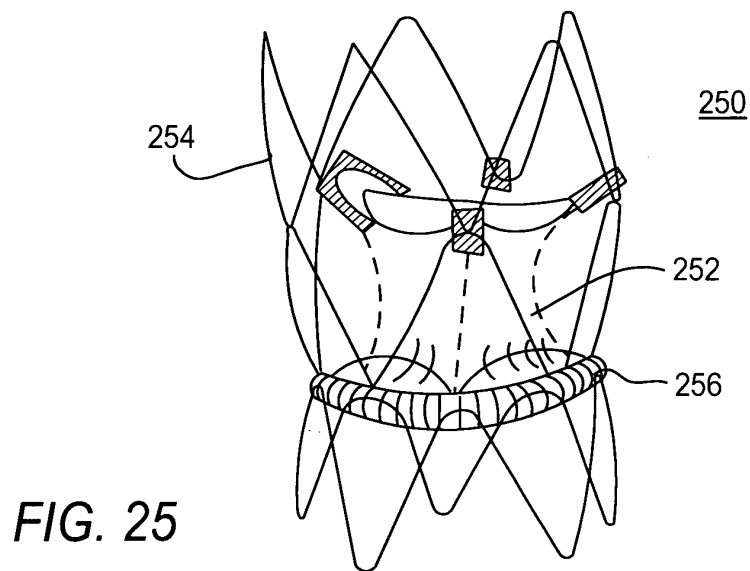
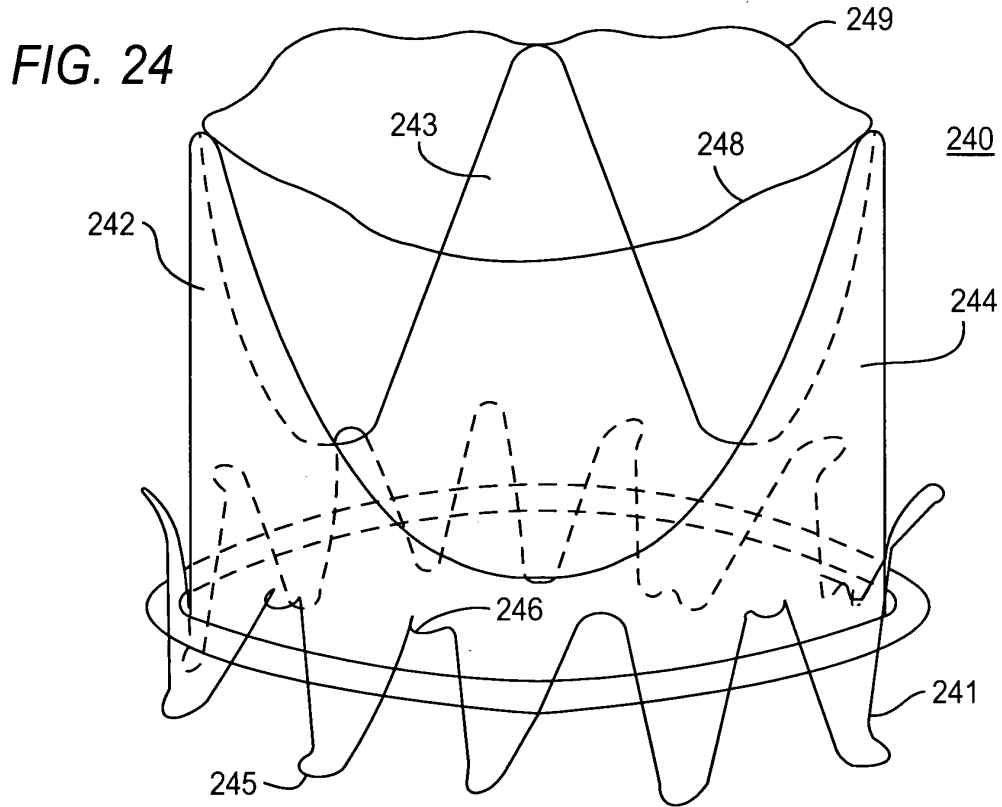


FIG. 26

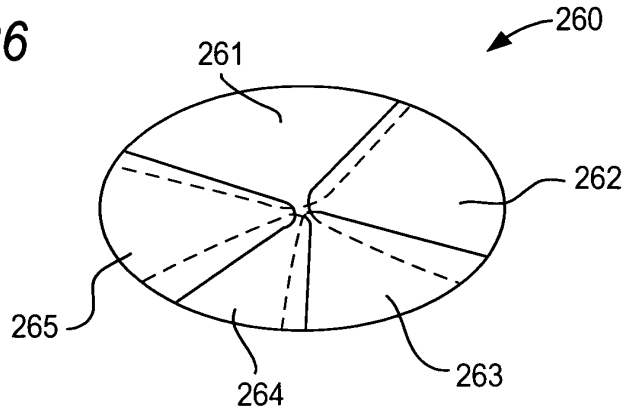
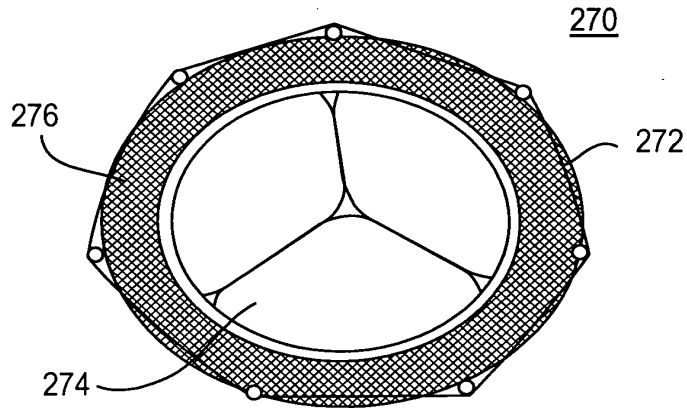
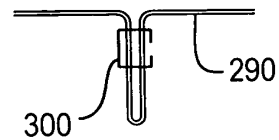
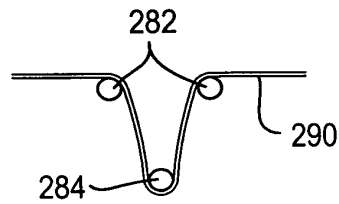
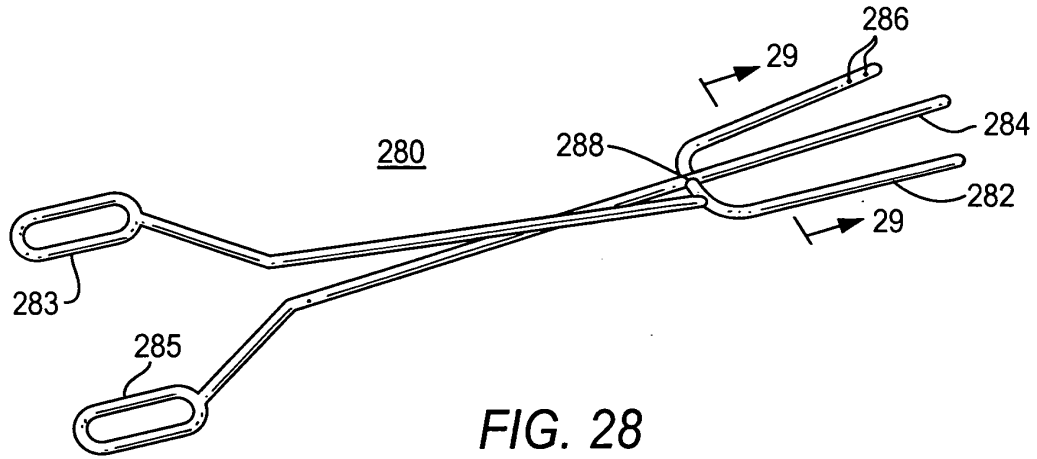
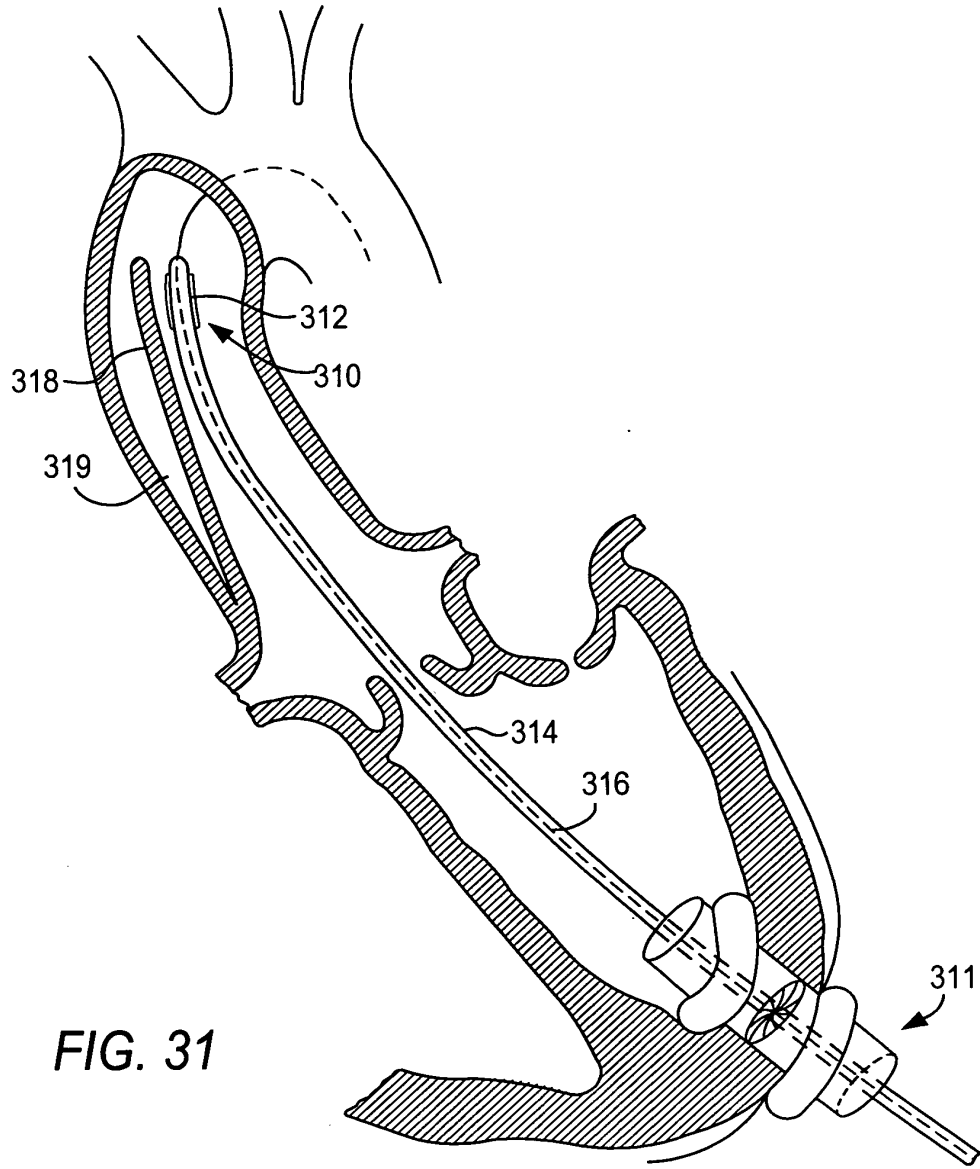


FIG. 27







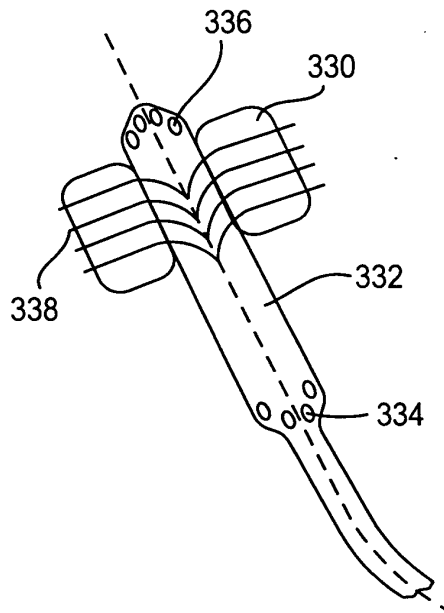


FIG. 33

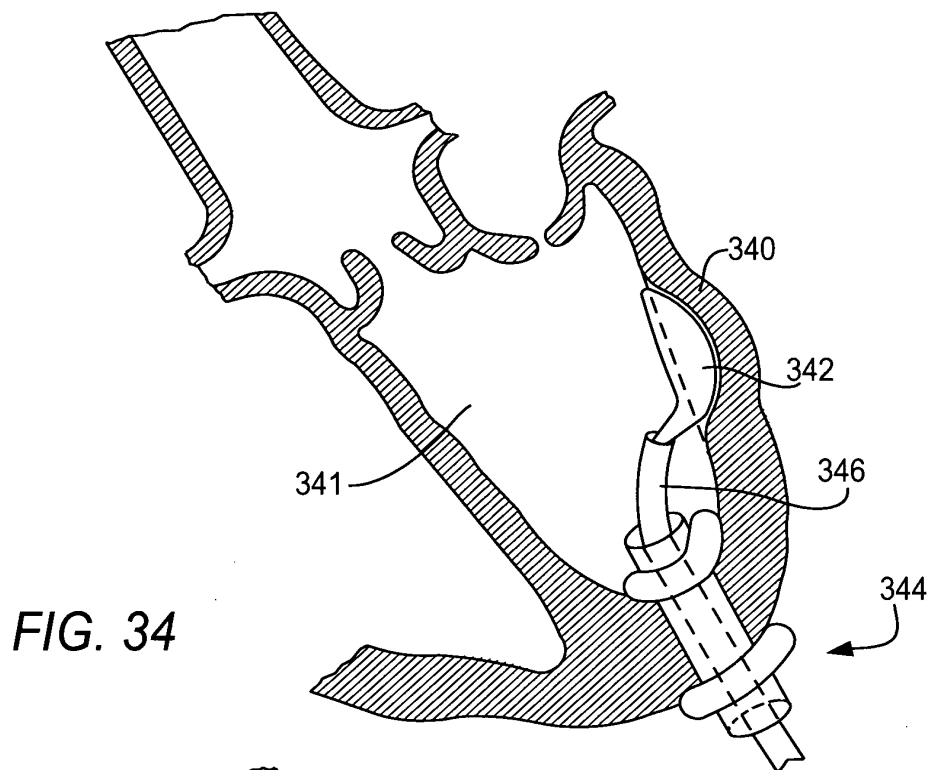


FIG. 34

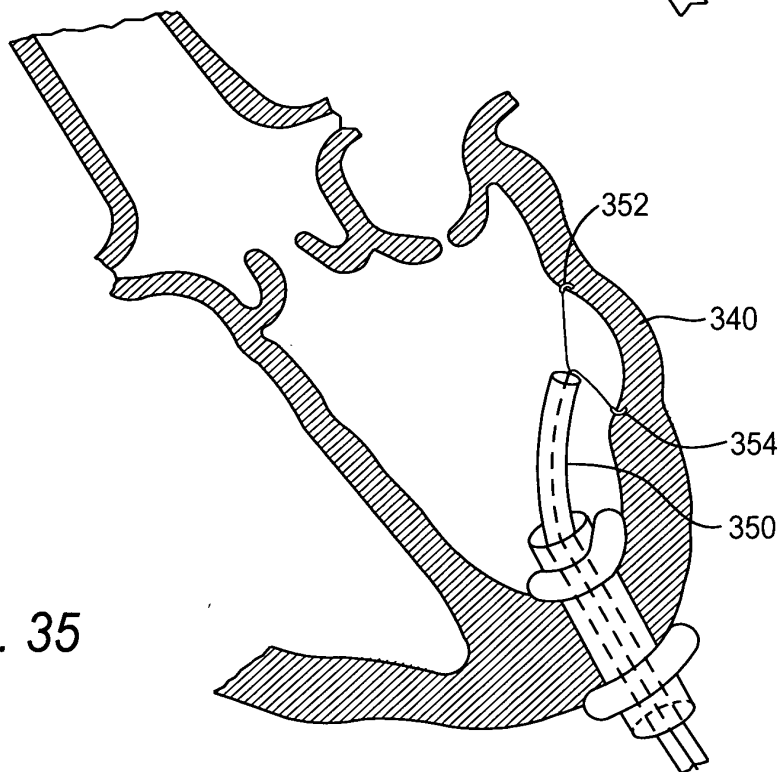


FIG. 35

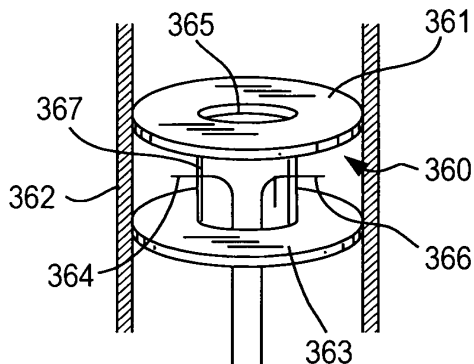


FIG. 36

FIG. 37

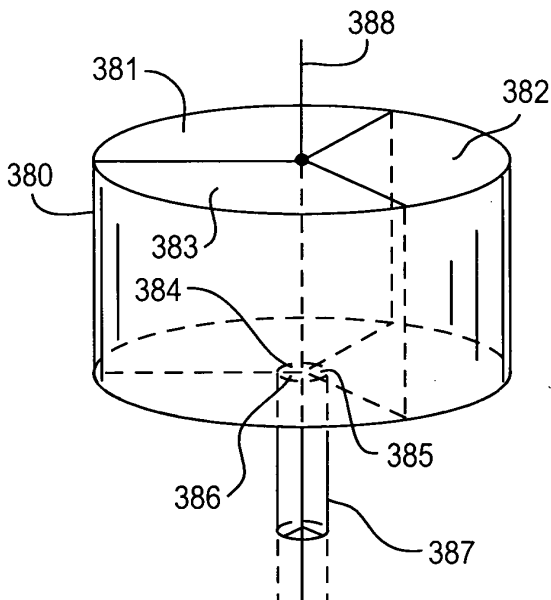
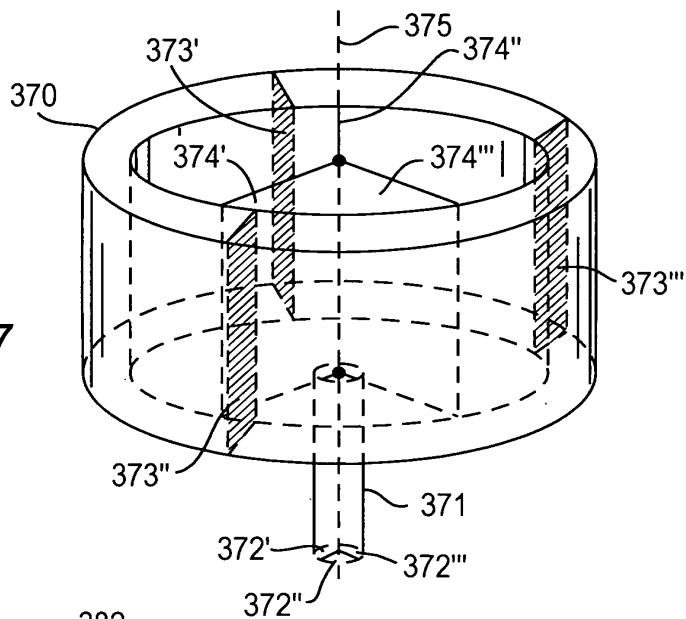


FIG. 38

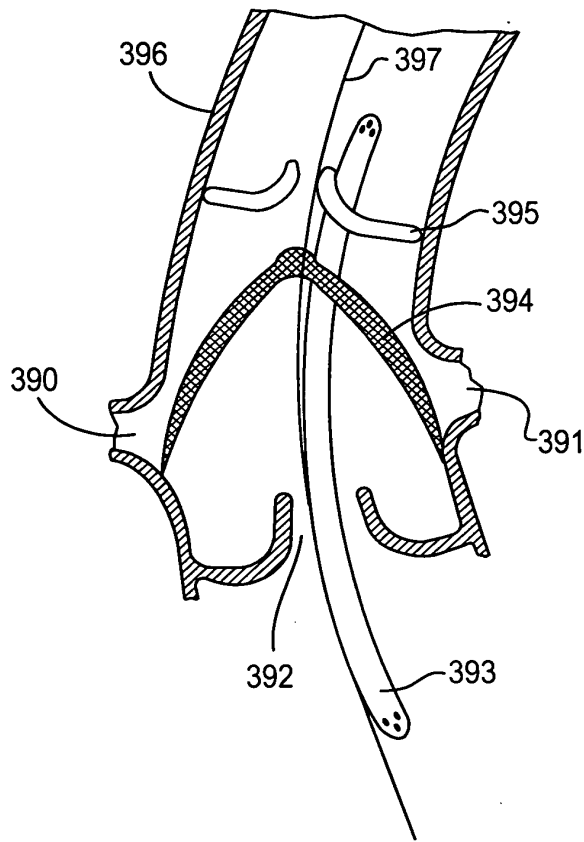


FIG. 39

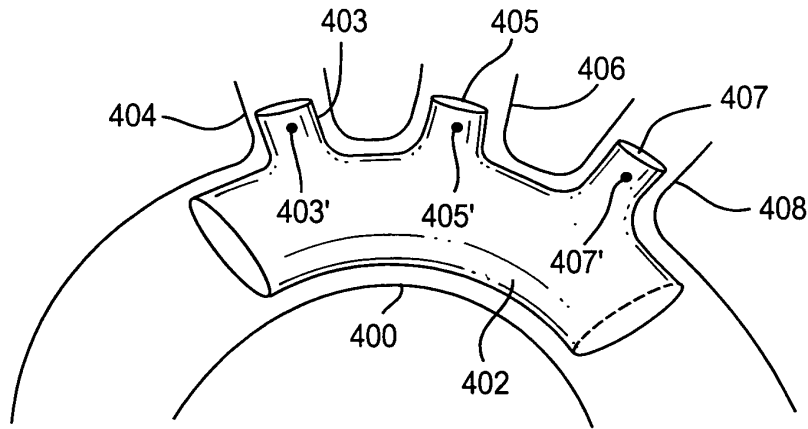


FIG. 40

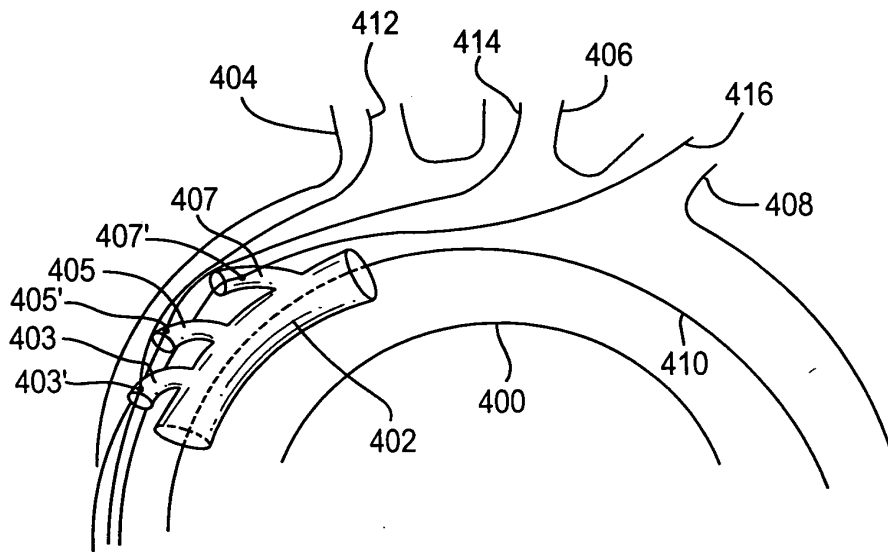


FIG. 41

16805 U.S. PTO
122804

For Other Than A Small Entity

293/076

Applicants : Christoph H. Huber

For : METHODS AND DEVICES FOR REPAIR OR
REPLACEMENT OF HEART VALVES OR ADJACENT
TISSUE WITHOUT THE NEED FOR FULL
CARDIOPULMONARY SUPPORT

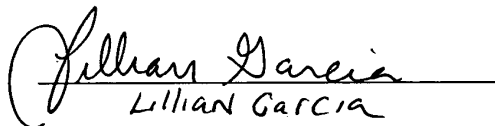
112948 U.S. PTO
11/023783
122804

EXPRESS MAIL CERTIFICATION

Express Mail Label Number EV371745460US

Date of Deposit December 28, 2004

I hereby certify that this transmittal letter and the other papers and fees identified in this transmittal letter as being transmitted herewith are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and are addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.


Lillian Garcia

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

TRANSMITTAL LETTER FOR
ORIGINAL PATENT APPLICATION

Sir:

Transmitted herewith for filing are the:
[X] specification; [X] claims; [X] abstract; [X] executed
declaration and power of attorney; for the above-identified
patent application.

Also transmitted herewith are:

- Twenty-five (25) sheets of:
 - Formal drawings.
 - Informal drawings. Formal drawings will be filed during the pendency of this application.
- Certified copy of application

_____ (country) (appln. no.) (filed)
 from which priority is claimed.


- An assignment of the invention to _____
- A check in the amount of \$ _____ to cover the recording fee.
- Please charge \$40.00 to Deposit Account No. _____ in payment of the recording fee. A duplicate copy of this transmittal letter is transmitted herewith.

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FOR	NUMBER FILED	NUMBER EXTRA	RATE	FEE
BASIC FILING FEE				\$ 300.00
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EXAMINATION FEE				\$ 200.00
TOTAL CLAIMS	45 - 20 =	25	x \$ 50 =	\$ 1250.00
INDEPENDENT CLAIMS	15 - 3 =	12	x \$ 200 =	\$ 2400.00
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIMS			+ \$ 360 =	\$ 0.00
			TOTAL	<u>\$ 4650.00</u>

- [X] A check in the amount of \$4650.00 in payment of the filing fee is transmitted herewith.
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Respectfully submitted,



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Fax: (212) 596-9090

16805 U.S. PTO
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For Other Than A Small Entity

293/076

Applicants : Christoph H. Huber

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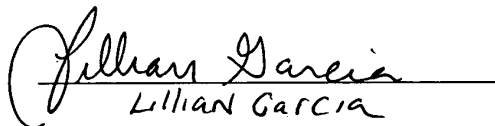
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Lillian Garcia

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

TRANSMITTAL LETTER FOR
ORIGINAL PATENT APPLICATION

Sir:

Transmitted herewith for filing are the:
[X] specification; [X] claims; [X] abstract; [X] executed
declaration and power of attorney; for the above-identified
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Also transmitted herewith are:

- Twenty-five (25) sheets of:
- Formal drawings.
- Informal drawings. Formal drawings will be filed during the pendency of this application.
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(country) (appln. no.) (filed)

from which priority is claimed.

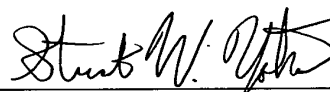
- An assignment of the invention to _____
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			TOTAL	<u>\$ 4650.00</u>

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Respectfully submitted,



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Methods and Devices for Repair or Replacement of Heart
Valves or Adjacent Tissue Without the Need for Full
Cardiopulmonary Support

[0001] This application claims the benefit of U.S.
5 provisional patent application No. 60/615,009, filed
October 2, 2004, which is hereby incorporated by
reference herein in its entirety.

Field of the Invention

[0002] This invention relates generally to devices
10 and methods for performing cardiovascular procedures
wherein a heart valve or segment of the aorta is being
repaired or replaced without the use of extracorporeal
cardiopulmonary support (commonly referred to as
"off-pump" procedures). For example, the invention
15 relates to devices and methods for accessing,
resecting, repairing, and/or replacing one of the heart
valves, in particular the aortic valve. This invention
also relates to methods and systems for performing
minimally-invasive cardiac procedures such as the
20 endovascular, endocardiac or endoluminal placement,
implantation or removal and consecutive replacement of
heart valves. These techniques may be generally

referred to as direct access percutaneous valve replacement ("DAPVR").

Background of the Invention

[0003] Of particular interest to the present
5 invention is the treatment of heart valve disease.
There are two major categories of heart valve disease:
(i) stenosis, which is an obstruction to forward blood
flow caused by a heart valve, and (ii) regurgitation,
which is the retrograde leakage of blood through a
10 heart valve. Stenosis often results from calcification
of a heart valve that makes the valve stiffer and less
able to open fully. Therefore, blood must be pumped
through a smaller opening. Regurgitation can be caused
by the insufficiency of any of the valve leaflets such
15 that the valve does not fully close.

[0004] In the past, repairing or replacing a
malfunctioning heart valve within a patient has been
achieved with a major open-heart surgical procedure,
requiring general anesthesia and full cardiopulmonary
20 by-pass. This requires complete cessation of
cardiopulmonary activity. While the use of
extracorporeal cardiopulmonary by-pass for cardiac
support is a well accepted procedure, such use has
often involved invasive surgical procedures (e.g.,
25 median sternotomies, or less commonly, thoracotomies).
These operations usually require one to two weeks of
hospitalization and several months of rehabilitation
time for the patient. The average mortality rate with
this type of procedure is about five to six percent,
30 and the complication rate is substantially higher.

[0005] Endovascular surgical techniques for heart
surgery have been under recent development. In

contrast to open-heart surgical procedures, endovascular procedures may have a reduced mortality rate, may require only local anesthesia, and may necessitate only a few days of hospitalization.

5 However, the range of procedures that has been developed for an endovascular approach to date has been limited to repair of the coronary arteries, such as angioplasty and atherectomy.

[0006] Some progress has been made in the
10 development of endovascular heart valve procedures. For example, for patients with severe stenotic valve disease who are too compromised to tolerate open-heart surgery to replace the heart valve as described above, surgeons have attempted endovascular balloon aortic or
15 mitral valvuloplasty. These procedures involve endovascularly advancing a balloon dilatation catheter into the patient's vasculature until the balloon of the catheter is positioned between the valve leaflets. Then the balloon is inflated to either: (i) split the
20 commissures in a diseased valve with commissural fusion, or (ii) crack calcific plaques in a calcified stenotic valve. However, this method may only provide partial and temporary relief for a patient with a stenotic valve. Instances of restenosis and mortality
25 following balloon aortic valvuloplasty have led to virtual abandonment of this procedure as a treatment for a diseased aortic valve.

[0007] Endovascular procedures for valve
implantation inside a native and diseased valve have
30 been explored. A catheter-mounted valve is incorporated into a collapsible cylindrical structure, such as a stent (commonly referred to as a "valved stent"). In these procedures, an elongated catheter is

used to insert a mechanical valve into the lumen of the aorta via entry through a distal artery (e.g., the femoral or brachial artery). Such procedures have been attempted on selective, terminally ill patients as a means of temporarily relieving the symptoms of a diseased valve.

[0008] The percutaneous placement of an artificial valve may have certain limitations and ancillary effects. For example, at present, such procedures are only of benefit to a small number of patients and are not meant to become an alternative to surgical heart valve procedures requiring the use of extracorporeal bypass. Another issue is that performing the entire procedure via small diameter vessels (e.g., the femoral, iliac or brachial arteries) restricts the use of larger tools and devices for the resection or repair of the diseased heart valve. Furthermore, this endovascular procedure may increase the risk of various vascular complications such as bleeding, dissection, rupture of the blood vessel, and ischemia to the extremity supplied by the vessel used to perform the operation:

[0009] Moreover, in some cases, one or more of a patient's femoral arteries, femoral veins, or other vessels for arterial and venous access may not be available for introduction of delivery devices or valve removal tools due to inadequate vessel diameter, vessel stenosis, vascular injury, or other conditions. In such cases, there may not be sufficient arterial and venous access to permit the contemporaneous use of the necessary interventional devices (e.g., an angioplasty catheter, atherectomy catheter, or other device) for a single surgical procedure. Therefore, unless alternate

arterial or venous access for one or more of these catheters can be found, the procedure cannot be performed using endovascular techniques.

5 [0010] Another possible disadvantage of the small vessel procedure is that the new valve must be collapsed to a very small diameter that could result in structural damage to the new valve. Additionally, such remote access sites like the femoral artery may make precise manipulation of the surgical tools more
10 difficult (e.g., exchange of guide wires and catheters and deployment of the new valve). Furthermore, placing wires, catheters, procedural tools, or delivery devices through one or more heart structures (e.g., the mitral valve) to reach the target site can result in damage to
15 those structures (e.g., acute malfunctioning or insufficiency of the valve being mechanically hindered by the surgical equipment or valve deterioration resulting from mechanical friction inflicting micro-lesions on the valve).

20 [0011] Also to be considered in connection with such procedures is the potential of obstructing the coronary ostia. The known percutaneous procedures for implanting heart valves do not have a safety mechanism to ensure proper orientation of the new valve.
25 Therefore, there is a possibility that the deployed valve will obstruct the coronary ostia, which can result in myocardial ischemia, myocardial infarction, and eventually the patient's death.

30 [0012] These procedures leave the old valve in place, and the new valve is implanted within the diseased valve after the diseased valve has been compressed by a balloon or other mechanical device. Therefore, there may be a possibility of embolic stroke

or embolic ischemia from valve or vascular wall debris that is liberated into the blood flow as the diseased valve is dilated and compressed. Furthermore, a rim of diseased tissue (e.g., the compressed native valve) decreases the diameter and cross-sectional surface of the implanted valve, potentially under-treating the patient and leading to only partial relief of his symptoms.

[0013] It would therefore be desirable to develop systems and methods for satisfactorily performing various cardiovascular procedures, particularly procedures for heart valve placement or removal and replacement, which do not require the use of an extracorporeal bypass or invasive surgical procedure, such as a sternotomy. It would be further desirable to perform such procedures through very small incisions in the patient (e.g., via several small thoracotomies). The devices and methods will preferably facilitate the access, resection, repair, implantation, and/or replacement of the diseased cardiac structure (e.g., one or more diseased heart valves). The devices and methods should preferably minimize the number of arterial and venous penetrations required during the closed-chest procedures, and desirably, should require no more than one cardiac and one femoral arterial penetration. The present invention satisfies these and other needs.

[0014] The descriptive terms antegrade and retrograde mean in the direction of blood flow and opposite the direction of blood flow, respectively, when used herein in relation to the patient's vasculature. In the arterial system, antegrade refers to the downstream direction (i.e., the same direction

as the physiological blood flow), while retrograde refers to the upstream direction (i.e., opposite the direction of the physiological blood flow). The terms proximal and distal, when used herein in relation to instruments used in the procedure, refer to directions closer to and farther away from the heart, respectively. The term replacement normally signifies removal of the diseased valve and implantation of a new valve. However, a new valve may also be implanted directly over top of a diseased valve. An implantation procedure would be the same as a replacement procedure without the removal of the diseased valve.

Summary of the Invention

[0015] The present invention is directed to a method and system for an endovascular, endocardiac, or endoluminal approach to a patient's heart to perform an operation that does not require an extracorporeal cardiopulmonary bypass circuit and that can be performed through a limited number of small incisions, thus eliminating the need for a sternotomy. The invention contemplates, at least in its preferred embodiments, the possibility of effective aortic valve implantation, aortic valve repair, resection of the aortic valve and replacement of the aortic valve, all without necessitating extracorporeal cardiopulmonary by-pass, a median sternotomy or other grossly thoracic incisions.

[0016] The present invention contemplates replacing any of the four valves of the heart via an antegrade approach through the wall of the appropriate chamber. Preferably, valves are implanted transapically (i.e., through the heart muscle at its left or right

ventricular apex). However, in this case, replacement of the mitral and tricuspid valves may be performed via a retrograde approach, because accessing these valves via the left or right ventricles requires approaching these valves against the flow of blood through the valve.

5
[0017] In accordance with the present invention, a surgeon may perform a minimally invasive operation on a patient that includes accessing the patient's heart and installing an access device in a wall of the heart that has means for preventing bleeding through the access device. A new heart valve may be implanted via the access device. In addition to implanting a heart valve during such a procedure, the surgeon can also resect a diseased native heart valve. The surgeon may also repair an aortic dissection using such a procedure. The surgeon may also choose to repair a damaged heart valve using similar techniques. The access device described may be preferably installed in the ventricular apex of the heart.

10
15
20
[0018] Surgical methods in accordance with the present invention may also include resecting a diseased heart valve percutaneously, while installing the new heart valve transapically. Alternatively, a surgeon may resect a diseased valve transapically and implant a new valve percutaneously. Additionally, both removal and implantation could be performed transapically. The new heart valve is preferably implanted by radially expanding the heart valve. In some embodiments, the radial expansion occurs in multiple stages that may be effectuated by a multi-stage balloon. The implantation device may include a mechanism to pull the leaflets of

a native valve downward while the new valve is installed within the native valve.

[0019] A device for resecting a diseased heart valve in accordance with the present invention may include a first set of annularly enlargeable componentry having a first longitudinal axis and a proximal cutting edge and a second set of annularly enlargeable componentry having a second longitudinal axis and a distal cutting edge. The device resects the diseased heart valve when the first set of componentry is enlarged on a distal side of the diseased heart valve and the second set of componentry is enlarged on a proximal side of the diseased heart valve and the sets of componentry are drawn axially together along the longitudinal axes. The first and second sets of annularly enlargeable componentry may be coaxial.

[0020] In accordance with the present invention, blood flow through the surgical devices placed in the patient (e.g., inside the patient's aorta) may be supplemented with artificial devices such as ventricular assist devices. The surgical site may be visualized with direct optical technology. For example, transparent oxygen-carrying fluid may be injected into a portion of the circulatory system of a patient, and an optical device may be inserted into the transparent fluid to transmit images of the surgical site. Using such techniques, all blood of a patient's circulatory system may be temporarily exchanged with the transparent oxygen-carrying fluid.

[0021] Instrumentation for accessing a chamber of a patient's heart may include a catheter having a proximal sealing device for sealing the catheter against a proximal surface of the myocardium. The

instrumentation may also include means for preventing bleeding through the catheter. In some embodiments, the instrumentation includes a distal sealing device for sealing the catheter against the distal surface of the myocardium.

5 [0022] In accordance with the present invention, an implantable heart valve may include a tissue support structure and tissue valve leaflets that are grown inside the tissue support structure by genetic engineering. The genetically engineered leaflets may grow inside a stainless steel stent, a nitinol stent, or any other suitable tissue support structure. Low-profile heart valves may also be used that include at least three leaflets. One side of each leaflet overlaps a neighboring leaflet such that the leaflets open sequentially and close sequentially. Replacement heart valves may also be used that correct overly-dilated heart valve annuluses. Such a heart valve may include an inner circumference defined by the leaflets of the heart valve and an outer circumference defined by the outer limits of a fluid-tight diaphragm. The diaphragm fills the space between the inner circumference and the outer circumference.

10 15 20 25 30 [0023] Surgeons may be aided by a device for inserting more than one guidewire into a patient. Such a device includes an annular wire placement device and one or more guidewires removably attached to the annular wire placement device. The annular wire placement device is configured to track an already placed guidewire.

[0024] In accordance with the present invention, calcification of a heart valve may be broken down by inserting a catheter-based ultrasound device into a

calcified heart valve and concentrating ultrasound radiation on the calcification of the calcified heart valve to break down the calcification. Such a procedure may be enhanced by inserting a reflector into the calcified heart valve to magnify the ultrasound radiation.

5 [0025] A mitral valve repair device in accordance with the present invention may include a first head defining an operating plane and a second head operably attached to the first head. The second head is configured to displace a leaflet with respect to the operating plane. The first head may be U-shaped and include an attachment mechanism for attaching at least two portions of a mitral valve leaflet. The repair device includes a handle for operating the second head with respect to the first head.

10 [0026] In accordance with the present invention, aortic dissections may be repaired by accessing a patient's heart and placing an access device in a wall of the heart that prevents bleeding through the access device. A dissection repair device is inserted through the access device to repair the aortic dissection. The device may include annularly enlargeable componentry configured to be inserted into the patient's aorta and means for closing a void created by the aortic dissection. The void can be closed by injecting a biologically compatible glue (e.g., fibrin, thrombin, or any other suitable chemical or biological substance) through needles into the void. It may also be closed using mechanical sutures or surgical staples, for example.

Brief Description of the Drawings

[0027] Further features of the invention, its nature, and various advantages will be more apparent from the following detailed description and the accompanying drawings, wherein like reference characters represent like elements throughout, and in which:

[0028] FIG. 1 is a view of a surgical site in accordance with the principles of the present invention.

[0029] FIG. 2 is a detailed cut-away view of a portion of the surgical site illustrated in FIG. 1.

[0030] FIG. 3 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0031] FIG. 4 is a view similar to FIG. 3 showing a later stage in the illustrative procedure depicted in part by FIG. 3, together with related apparatus, all in accordance with this invention.

[0032] FIG. 5 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3 and 4, together with related apparatus, all in accordance with this invention.

[0033] FIG. 6 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3-5, together with related apparatus, all in accordance with this invention.

[0034] FIG. 7 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3-6, together with related apparatus, all in accordance with this invention.

[0035] FIG. 8 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3-7,

together with related apparatus, all in accordance with this invention.

[0036] FIG. 9 shows alternative related apparatus to that shown in FIG. 8 and shows an even later stage in the illustrative procedure depicted in part by
5 FIGS. 3-7, together with related apparatus, all in accordance with this invention.

[0037] FIG. 10 shows alternative related apparatus to that shown in FIGS. 8 and 9 and shows an even later
10 stage in the illustrative procedure depicted in part by FIGS. 3-7, together with related apparatus, all in accordance with this invention.

[0038] FIG. 11 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3-10,
15 together with related apparatus, all in accordance with this invention.

[0039] FIG. 12 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3-11,
together with related apparatus, all in accordance with
20 this invention.

[0040] FIG. 13 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3-12,
together with related apparatus, all in accordance with this invention.

[0041] FIG. 14 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3-13,
together with related apparatus, all in accordance with
25 this invention.

[0042] FIG. 15 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3-14,
30 together with related apparatus, all in accordance with this invention.

[0043] FIG. 16 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3-15, together with related apparatus, all in accordance with this invention.

5 [0044] FIG. 17 shows an even later stage in the illustrative procedure depicted in part by FIGS. 3-16, together with related apparatus, all in accordance with this invention.

[0045] FIG. 18 shows an even later stage in the
10 illustrative procedure depicted in part by FIGS. 3-17, together with related apparatus, all in accordance with this invention.

[0046] FIG. 19 is a perspective view of an illustrative embodiment of apparatus in accordance with
15 the principles of the present invention.

[0047] FIG. 19A is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0048] FIG. 20 is a perspective view of an
20 illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0049] FIG. 21 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

25 [0050] FIG. 22 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0051] FIG. 23 is a perspective view of an
30 illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0052] FIG. 24 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0053] FIG. 25 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

5 [0054] FIG. 26 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0055] FIG. 27 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

10 [0056] FIG. 28 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0057] FIG. 29 is a view showing an illustrative procedure incorporating the apparatus of FIG. 28 in
15 accordance with this invention.

[0058] FIG. 30 is a view similar to FIG. 29 showing a later stage in the illustrative procedure depicted in part by FIG. 29, together with related apparatus, all in accordance with this invention.

20 [0059] FIG. 31 shows an early stage in an illustrative procedure, together with related apparatus, all in accordance with this invention.

[0060] FIG. 32 is a view similar to FIG. 31 showing a later stage in the illustrative procedure depicted in
25 part by FIG. 31, together with related apparatus, all in accordance with this invention.

[0061] FIG. 33 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

30 [0062] FIG. 34 shows an early stage in an illustrative procedure, together with related apparatus, all in accordance with this invention.

[0063] FIG. 35 shows an early stage in an illustrative procedure, together with related apparatus, all in accordance with this invention.

5 [0064] FIG. 36 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0065] FIG. 37 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

10 [0066] FIG. 38 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0067] FIG. 39 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

[0068] FIG. 40 is a perspective view of an illustrative embodiment of apparatus in accordance with the principles of the present invention.

20 [0069] FIG. 41 is a view similar to FIG. 40 showing an earlier stage in an illustrative procedure depicted in part by FIG. 40, together with related apparatus, all in accordance with this invention.

Detailed Description of the Preferred Embodiments

[0070] Because the present invention has a number of
25 different applications, each of which may warrant some modifications of such parameters as instrument size and shape, it is believed best to describe certain aspects of the invention with reference to relatively generic schematic drawings. To keep the discussion from
30 becoming too abstract, however, and as an aid to better comprehension and appreciation of the invention, references will frequently be made to specific uses of

the invention. Most often these references will be to use of the invention to resect and replace or implant an aortic valve with an antegrade surgical approach. It is emphasized again, however, that this is only one
5 of many possible applications of the invention.

[0071] Assuming that the invention is to be used to resect and replace or implant an aortic valve, the procedure may begin by setting up fluoroscopy equipment to enable the surgeon to set and use various reference
10 points during the procedure. The surgeon may begin by performing a thoracotomy to create an access site for the surgical procedure. The endovascular, endocardiac or endoluminal surgical system of the present invention incorporates accessing the interior of the heart by
15 directly penetrating the heart muscle, preferably through the heart muscle at its left or right ventricular apex (hereinafter referred to as "transapically"). Thoracotomy sites may be prepared at any of third intercostal space 12, fourth intercostal
20 space 14, fifth intercostal space 16, or subxyphoidal site 18 (i.e., just below xyphoid process 19) of patient 11, as shown in FIG. 1. Any intercostal space may serve as a suitable surgical site, and in some embodiments of the present invention, the fourth,
25 fifth, or sixth intercostal spaces are the preferred sites. All of these sites provide surgical access to apex 17 of heart 10. A 5-10 cm incision at any one of these sites may allow the surgeon to perform the entire procedure through one access site. However,
30 alternatively, the surgeon may prefer to use an endoscopic technique wherein he or she may utilize 1-3 cm incisions at multiple sites to insert various instruments.

[0072] Once the heart is exposed, the surgeon may place one or multiple purse-string sutures around the ventricular apex surgical site. This will allow the surgeon to synch the heart muscle around any equipment
5 that is passed through the heart wall during surgery to prevent bleeding. Other techniques for preventing bleeding from the heart chamber that is accessed for surgery will be described in more detail below.

[0073] FIG. 2 illustrates the four chambers of
10 heart 10: right atrium 24, left atrium 25, left ventricle 26, and right ventricle 27. FIG. 2 also shows the four valves of heart 10: aortic valve 20, mitral valve 21, pulmonary valve 22, and tricuspid valve 23. Ascending aorta 28 and descending aorta 29
15 are also illustrated. A procedure to replace aortic valve 20 may require a left thoracotomy and a left transapical incision to the heart muscle. Alternatively, a procedure to replace pulmonary valve 22 may require a right thoracotomy and a right
20 transapical incision to the heart muscle. Direct access may be made via incisions to right and left atria 24 and 25 as well to enable antegrade approaches to tricuspid valve 23 and mitral valve 21. While the procedure may be used for antegrade and retrograde
25 repair to any of a patient's heart valves, the following illustrative procedure relates to the resection and antegrade replacement of aortic valve 20. It should be understood that the resection steps may be skipped in the following procedure, and a replacement
30 valve may alternatively be placed concentrically within the diseased valve.

[0074] In addition to the thoracotomy access site, the surgeon may also desire endoluminal (e.g.,

percutaneous) access sites, preferably via the patient's femoral vein or artery. A femoral vein access site may be used to place ultrasound equipment 34 inside the patient's right atrium adjacent aortic valve 20 and sino-tubular junction 36, as shown in FIG. 3. Ultrasound equipment 34 may, for example, be an AcuNav™ Diagnostic Ultrasound Catheter. Ultrasound equipment 34 could also be placed via the internal jugular vein (IJV). Placement of ultrasound equipment 34 via a femoral or iliac access site versus an IJV site may reverse the orientation of ultrasound equipment 34 (i.e., from which direction ultrasound equipment 34 enters the patient's right atrium). As an alternative to percutaneous ultrasound equipment, a surgeon may choose to use esophageal visualization technology such as, for example, TransEsophageal Echo ("TEE") to provide an image of the target valve replacement site.

[0075] After accessing the heart muscle via one or more thoracotomies described above, an incision is made to pericardium 30 at access site 32. Next, myocardium 40 is punctured with needle 42 or other suitable device to gain access to the inner heart structures (in this case, left ventricle 26), as illustrated in FIG. 4. Guidewire 44 is fed into left ventricle 26 in antegrade direction 46. Following the direction of blood flow, guidewire 44 is advanced through aortic valve 20 and into aorta 28. Guidewire 44 may be further advanced into the iliac or femoral arteries. In such embodiments, a wire with a snare loop may be advanced from the femoral endoluminal access site to retrieve guidewire 44 and pull it out the femoral endoluminal access site. This enables

guidewire 44 to pass through the patient's vasculature from transapical access site 17 to the femoral endoluminal access site.

[0076] Guidewire 44 may be a relatively thin and
5 flexible guidewire. In order to provide sturdier support for the exchange of surgical tools, it may be desirable to replace guidewire 44 with a stiffer guidewire. This is accomplished by passing catheter 50 over guidewire 44, removing guidewire 44 from the
10 patient while catheter 50 holds its place, and inserting a stiffer guidewire, as shown by FIG. 5. Once the stiffer guidewire has been passed through catheter 50, catheter 50 can be removed, leaving the stiffer guidewire in place. A guidewire that is
15 externalized from the patient at both ends (i.e., at the transapical site and the femoral endoluminal access site) would allow bi-directional use. Wire-guided devices could be inserted from both ends, allowing the insertion of wire-guided devices from the antegrade and
20 retrograde directions.

[0077] In some embodiments of the present invention, multiple guidewires may be placed to provide access for more surgical devices. Using multiple guidewires may provide advantages such as allowing two devices to be
25 placed next to each other (e.g., intravascular ultrasound could be operated next to valve deployment devices). Multiple guidewires may be placed simultaneously as shown in FIGS. 19 and 19A. Guidewire 198 is the already placed initial guidewire
30 (e.g., guidewire 66 of FIG. 6). Wire placement device 190 or 195 glides over guidewire 198 via hollow opening 191 or 197. Additional guidewires 192, 194, and 196 are attached to wire placement device 190 such

that all three additional wires are placed at one time. Additional guidewire 193 is attached to wire placement device 195. Any number of guidewires can be attached to wire placement device 190 or 195 so that the desired
5 number of additional guidewires can be simultaneously placed. Wire placement device 190 or 195 may be broken-off or cut away from the additional guidewires once they have been placed through the body. Also, wire placement devices 190 and 195 may incorporate
10 locking mechanisms. Thus, if the additional guidewires are not to be passed all the way through the body such that they emerge at a second end, the wires can be clamped in place (e.g., wire placement devices 190 and 195 may clamp to the initially placed guidewire to
15 hold the additional guidewires in place).

[0078] Next, a dilator (not shown) may be advanced over stiffer guidewire 66 (FIG. 6) to dilate the opening created by needle 42 (FIG. 4) in myocardium 40. Once the opening in myocardium 40 has been dilated to
20 the necessary size, access device 60 can be placed. Access device 60 will provide an access port to the surgical site inside left ventricle 26, while preventing the heart chamber from bleeding out. Access device 60 (shown in FIG. 6) allows for easy and rapid
25 insertion of tools, devices, instruments, wires, catheters and delivery systems that will enable the repair or resection of a diseased heart valve or the implantation or replacement of a new heart valve.

[0079] A second access device or introducer may be
30 placed inside the distal artery (e.g., the femoral artery at the endoluminal access site). Furthermore, additional guidewires may be placed from the endoluminal access site. One or more additional

guidewires may be placed using the piggy-back approach described in more detail above.

5 [0080] Access device 60 may include catheter 64 with distal balloon 61 and proximal balloon 62. Balloons 61 and 62 may sandwich myocardium 40 to prevent bleeding from left ventricle 26. Access device 60 may be anchored in other suitable ways, as long as left ventricle 26 is appropriately sealed to prevent bleeding, and such that blood flow through the coronary
10 arteries is not occluded. Access device 60 also includes valve 63. Valve 63 allows the passage of guidewire 66 and the insertion of surgical tools while preventing bleeding through catheter 64. Valve 63 may be mechanically operable as an iris diaphragm (e.g.,
15 like the aperture of a lens). Alternatively, valve 63 may be constructed of an elastic material with a small central opening that is dilated by whatever equipment is inserted therethrough, but always maintains a fluid-tight seal with the inserted equipment. Valve 63 may
20 compose any fluid-tight valve structure.

[0081] Access device 60 can include one or multiple valve-like structures, like valve 63. Multiple valves in series may act as added protection against leakage from the heart chamber. Furthermore, because of the
25 potential for leakage around multiple tools, access device 60 may include multiple valves in parallel. Thus, each tool could be inserted through its own valve. This could ensure that a proper seal is created around each tool being used during the operation.

30 [0082] In some embodiments of the present invention, various endovascular, endocardiac, and/or endoluminal visualization aids may be used. Such devices are illustrated in FIG. 7. Additionally, extracorporeal X-

ray based radiographic devices may be employed. Preferably, intracardiac ultrasound 34 is placed in the right atrium via a femoral vein, and intravascular ultrasound (IVUS) 70 is placed over guidewire 66 and
5 into a heart chamber or into the diseased valve. External fluoroscopy is also utilized to map and visualize the surgical site.

[0083] IVUS 70 may be used to locate aortic valve 20, sino-tubular junction 36, and brachio-
10 cephalic trunk 72. In order to determine the precise location of each, IVUS probe 70's location is simultaneously tracked with AcuNav™ 34 and fluoroscopy. Once each landmark is located, a radioopaque marker may be placed on the patient's skin or the heart's surface
15 so that extracorporeal fluoroscopy can later be used to relocate these points without IVUS 70 taking up space inside the surgical site. The end of the native leaflet in systole may also be marked with a radioopaque marker in order to temporarily define the
20 target zone. This technique requires that the patient and the fluoroscopy equipment not be moved during the procedure, because landmarks inside the heart and aorta are being marked by radioopaque markers placed on the patient's skin outside the body or on the beating
25 heart's surface. It may be desirable to place the radioopaque markers directly on the heart and aorta.

[0084] IVUS 70, AcuNav™ 34, and the fluoroscopy equipment can also be used to take measurements of the diseased valve. This allows the surgeon to chose a
30 properly sized replacement heart valve. As an alternative to fluoroscopy, a surgeon may choose to use standard dye visualization techniques such as angiography. Although it would create material

limitations for manufacturing the replacement heart valve, MRI technology could be used as an alternative means of visualizing the target surgical site.

5 Additionally, with the development of cameras that can see through blood, direct optical technology could be used to create an image of the target site. Real-time three-dimensional construction of ultrasound data is another visualization procedure that is currently under development that could provide a suitable alternative.

10 **[0085]** With respect to direct optical technology, a clear liquid could be introduced to the aorta or other components of the circulatory system near the target surgical site. Placing a clear liquid that is capable of carrying oxygen (i.e., capable of carrying on the
15 blood's biological function, temporarily) in the patient's circulatory system would improve the ability to use direct optical imaging. Furthermore, because the heart is beating, the patient could be transfused with the clear oxygen-carrying fluid for the duration
20 of the procedure so that direct optical visualization is enabled throughout the procedure. The patient's regular blood would be retransfused at the conclusion of the procedure.

[0086] Another option for a direct visualization
25 technique includes placing a transparent balloon (filled with a transparent fluid such as water) in front of the camera. The camera and liquid-filled balloon are pushed against the surface that the surgeon wishes to view. The transparent balloon displaces
30 blood from the camera's line of sight such that an image of what the camera sees through the balloon is transmitted to the surgeon.

[0087] Furthermore, the invention may include the placement of embolic protection device 80 in the ascending aorta by means of a catheter, as shown in FIG. 8. Embolic protection device 80 is preferably placed from the endoluminal femoral access site in a retrograde approach to the aortic valve site. Embolic protection device 80 may comprise a filtering mesh or net made from any suitable material. The chosen material should be able to be collapsed, expanded, and re-collapsed multiple times. Embolic protection device 80 may alternatively be placed from the antegrade direction. Either approach may be made using guidewire 66 or additional guidewires inserted in accordance with the present invention.

[0088] Single embolic protection device 80 may have unique properties to protect the outflow region of the aortic valve which feeds aorta 28 and coronary sinuses 82 and 84. Device 80 may comprise tight mesh 200 (see FIG. 20) formed in a conical shape. Conical mesh 200 may terminate in perimeter 204 that exerts a radially outward force on the wall of aorta 28. Device 80 is operated via catheter 202 and is dimensioned so that it is capable of filtering the blood supply to the aorta and the coronary arteries.

[0089] In some embodiments, embolic protection device 80 may be replaced with multiple embolic protection devices 90, 92, and 94, as illustrated in FIG. 9. In FIG. 9, each of coronary sinuses 82 and 84 is protected by its own embolic protection device (embolic protection devices 92 and 94, respectively), and aorta 28 is protected by embolic protection device 90. Embolic protection devices 92 and 94 may be placed further into the coronary arteries to keep the

surgical site inside the aorta as clear as possible. Embolic protection device 80 of FIG. 8 is designed so that proper placement of the single protection device will prevent the flow of embolic material into any of
5 aorta 28 and coronary sinuses 82 and 84.

[0090] In certain embodiments of the present invention, the embolic protection device may be placed in an antegrade approach. For example, FIG. 10 shows embolic protection devices 92' and 94' having been
10 inserted in the antegrade direction. Placing devices 92' and 94' in the coronary sinuses from the antegrade direction leaves guidewires 101 and 102 to exit the patient at the thoracotomy access site. Coronary sinuses 82 and 84 provide useful landmarks in
15 placing a new aortic valve. Thus, by placing devices 92' and 94' in this manner, the surgeon is provided with a guide to proper placement of the new valve (i.e., guidewires 101 and 102 which terminate at coronary sinuses 82 and 84). The new valve may be
20 inserted in the antegrade direction along guidewires 101 and 102 to ensure proper placement.

[0091] Additionally, embolic filters may be placed in the brachiocephalic, left common carotid, and left subclavian arteries of the aortic arch.

[0092] Some embodiments of the present invention may employ a valve-tipped catheter or other temporary valve device that is capable of temporarily replacing the native valve function during and after resection or removal until the new valve is deployed and functional.
25 Such temporary valve devices may be placed in any number of acceptable locations. For example, when replacing the aortic valve's function, it may be preferable to place the temporary valve in the
30

ascending aorta just distal to the native aortic valve. However, it is possible to temporarily replace the aortic valve function with a device placed in the descending aorta. Such a placement may have the
5 disadvantage of causing the heart to work harder, but such placements have been proven acceptable in previous surgical procedures.

[0093] Additionally, some embodiments of the present invention may include the use of a percutaneously
10 placed small caliber blood pump containing an impellor (e.g., a VAD (Ventricular Assist Device)). The VAD may be inserted in a retrograde or in an antegrade direction over guidewire 66. Alternatively, the VAD may be inserted over a secondary guidewire. Because of
15 the resection and implantation equipment that will be inserted in the antegrade direction, it may be desirable to place the VAD in a retrograde approach from the percutaneous femoral access site. The VAD or other temporary pump device will be used to support the
20 heart's natural function while the native valve is being resected or repaired. The temporary assistance device will remain in place until the new valve is deployed and functional.

[0094] FIG. 39 shows one possible combination of an
25 embolic filter, temporary valve, and VAD. The FIG. 39 embodiment shows VAD 393 passing through embolic filter 394 and temporary valve 395. These components are positioned distal to aortic valve 392 in ascending aorta 396. Embolic filter 394 is designed to also
30 protect coronary arteries 390 and 391. Embolic filter 394, VAD 393, and temporary valve 395 may all be guided by guidewire 397. This is just one possible

arrangement for the components that may be used in a valve repair or replacement procedure.

[0095] In some embodiments of the present invention, the placement of a new valve may first involve the full or partial resection of the diseased valve or cardiac structure. To perform a resection of the diseased valve, a surgeon may use valve removal tool 110, shown in FIG. 11. Valve removal tool 110 incorporates outer inflation lumen 111 and inner inflation lumen 112, which is placed coaxially within outer inflation lumen 111. Outer inflation lumen 111 terminates at proximal balloon 113. Inner inflation lumen 112 terminates at distal balloon 114. Coaxial catheters 111 and 112 can be advanced over guidewire 66 and passed through valve 63 of access device 60. Radially expandable proximal cutting device 115 is mounted to the surface of distal balloon 113. Radially expandable distal cutting device 116 is mounted to the surface of distal balloon 114. Valve removal tool 110 is advanced with balloons 113 and 114 in the deflated state and cutting devices 115 and 116 in the collapsed state until distal cutting device 116 is located just distal to diseased aortic valve 20 and proximal cutting device 115 is positioned just proximal to diseased aortic valve 20.

[0096] As shown in FIG. 12, balloons 113 and 114 are inflated such that cutting devices 115 and 116 are radially expanded to the approximate diameter of the diseased valve. Next, inner inflation lumen 112, distal balloon 114, and distal cutting device 116 are pulled in the retrograde direction. This causes cutting devices 115 and 116 to cooperate with one another to cut away diseased aortic valve leaflets 130,

as shown in FIG. 13. Balloons 113 and 114 can be deflated and cutting devices 115 and 116 collapsed while retaining cut away valve leaflets 130. Thus, valve removal tool 110 and resected leaflets 130 can be removed via access device 60.

5 [0097] Further, valve removal device 110 may possess self-centering properties. Valve removal device 110's cutting mechanism may allow the device to cut or resect any calcified or diseased tissue within the heart cavities or the vasculature. The size or cut of each bite made by the removal device, as well as the shape of the cut may be determined by the surgeon by adjusting the valve removal device.

10 [0098] When performing surgical techniques inside a patient's vasculature, it may be beneficial to use ring-shaped balloons so that blood can continue to circulate through the balloon. Also, whether using ring-shaped balloons or more standardized balloons, it may be beneficial to use a balloon that has more than one chamber, so that the balloon can be selectively inflated. Examples of a ring-shaped balloon and a cylindrical balloon, both having more than one inflation chamber are illustrated in FIGS. 37 and 38, respectively.

15 [0099] FIG. 37 shows ring-shaped balloon 370. Balloon 370 may be divided into three inflation chambers by dividers 373', 373'', and 373'''. Each inflation chamber may be attached to an inflation flange (e.g., flanges 374', 374'', and 374'''). Each inflation flange is correspondingly attached to an inflation lumen of catheter 371 (e.g., inflation lumens 372', 372'', and 372'''). Thus, blood flow is able to continue through the three openings left

between inflation flanges 374', 374'', and 374'''.
Furthermore, surgical tools (e.g., VADs, etc.) may be
passed through the openings. Balloon 370 may be guided
by guidewire 375.

5 [0100] FIG. 38 shows cylindrical balloon 380 with
inflation chambers 381, 382, and 383. The inflation
chambers may be selectively inflated by inflation
lumens 384, 385, and 386, respectively of catheter 387.
Balloon 380 may be guided by guidewire 388. By
10 providing selectively inflatable chambers in either
type of balloon, a surgeon may have the ability to
manipulate tissue inside a patient's vasculature or
properly position surgical equipment and prostheses,
for example.

15 [0101] In some embodiments of the present invention,
a valve removal tool such as ronjeur device 210 may be
used (see FIG. 21). Ronjeur device 210 may have spoon-
shaped heads 212 and 214 which are operably controlled
by handles 216 and 218 via hinge 211. Spoon-shaped
20 heads 212 and 214 may have sharpened tips 213 and 215,
respectively. Ronjeur device 210 may be used to bite
away the leaflets of a diseased valve and trap the
dissected tissue within spoon-shaped heads 212 and 214.
Ronjeur device 210 may be operable via access
25 device 60.

[0102] In other embodiments of the present
invention, valve resector 220 of FIG. 22 can be used to
resect the diseased valve. Valve resector 220 has
handle 222, shaft 224, recess 226, and resector
30 tip 228. Resector tip 228 may be used to cut away or
tear away the diseased leaflets of a native valve.
Recess 226 may be used to retain the resected tissue
for removal. Resector tip 228 may also be mechanically

operable to snip away the diseased leaflets.

Resector 220 is also operable via access device 60.

Other suitable techniques for resecting a diseased valve may also be used before implanting a new valve.

5 [0103] In preparation for valve resection, it may be beneficial to soften or break-up the calcification of the diseased valve. Concentrated ultrasound waves could be used to break-up the valve's calcification. A similar procedure is used to break down kidney stones
10 in some patients. Calcification of the aortic valve is often trapped in tissue pockets. Thus the broken-down calcification would likely be retained by the valve leaflets. However, the leaflets would now be more pliable and easier to compress behind a new valve or to
15 remove. An intraluminal ultrasound device may be used to deliver the concentrated ultrasound waves. Furthermore, an intraluminal reflector may be used to magnify the waves' intensity and break-up the calcium deposits even quicker.

20 [0104] In addition to or as an alternative to resecting the diseased valve, plaque or calcification of a diseased valve may be chemically dissolved. With embolic protection devices 90, 92, and 94 in place, a chemical can be introduced to the diseased valve that
25 will dissolve or release the plaque deposits. The target valve site may first be isolated to contain the chemical during this process. This isolation may be achieved by inflating two balloons to create a chemical ablation chamber defined by the wall of the aorta and
30 the two balloons.

[0105] Isolation may also be achieved by a device like ablation chamber 360 shown in FIG. 36. Ablation chamber 360 is positioned inside the patient's

vasculature (e.g., aorta 362). The chamber may be placed percutaneously, by direct access, or by any other suitable technique. Ablation chamber 360 comprises ring-shaped balloons 361 and 363.

5 Balloons 361 and 363 are joined by tubular member 367 which creates a channel for blood to by-pass the ablation site. A ventricular assist device may be inserted through opening 365 in tubular member 367 to aid the patient's blood flow through the temporarily
10 narrowed passageway. Ablation chamber 360 may include chemical introducer 364 and chemical evacuator 366 to introduce a chemical to the ablation site and to clear the chemical from the ablation site when the procedure is completed. Thus, the chemical ablation procedure is
15 performed in the chamber of the isolated segment of the aorta while normal circulatory function takes place. Such a technique isolates the chemical being used from entering the patient's circulatory system. This treatment may be performed to repair a diseased valve,
20 to decalcify a diseased valve before resection by a valve removal tool, or to decalcify a diseased valve before placing a new valve within and over top of the diseased valve. Laser ablation may also be used to break up valve calcification or to remove and destroy
25 diseased valve leaflets.

[0106] As another alternative, the diseased and calcified valve can be left as is and a new valve can be implanted within and over top of the diseased valve. In some embodiments of the present invention, it may be
30 desirable to perform a valvuloplasty to percutaneously destroy the leaflets of the diseased valve. It may be easier to dilate the diseased valve with the new valve if it has been partially destroyed first.

[0107] Once any manipulation of the diseased valve is complete (e.g., marking landmark locations, resecting the diseased leaflets, chemically dissolving calcification, etc.), embolic protection devices 90, 92, and 94 can be removed (FIG. 14). The resection of diseased leaflets 130 (FIG. 13) may leave behind valve rim 141 (FIG. 14). Once the embolic protection devices have been removed, valve delivery device 142 may be inserted into left ventricle 26 via access device 60. Valve delivery device 142 carries new valve 140 in a radially compressed state. Valve 140 has been crimped onto delivery device 142. Alternatively, valve 140 may be folded or collapsed in any other suitable manner. Valve delivery device 142 is advanced along guidewire 66.

[0108] In embodiments like that shown in FIG. 10, valve delivery device 142 may also be guided by guidewires 101 and 102 to ensure safe orientation of valve 140 prior to release and deployment. Such a delivery approach would eliminate the danger of coronary obstruction, because guidewires 101 and 102 terminate at coronary sinuses 82 and 84. The spaces between the commissure supports of valve 140 could be properly aligned with coronary sinuses 82 and 84 to allow maximum blood flow to the coronary arteries.

[0109] In other embodiments of the present invention, the placement of valve 140 may be assisted by intracardiac ultrasound (i.e., ultrasound equipment 34 of FIG. 7) and fluoroscopy. Positioning, release, and deployment of valve 140 could be simultaneously monitored by the intracardiac ultrasound and fluoroscopy equipment. The fluoroscopy equipment would monitor the target zone based on the radioopaque

markers that were placed earlier in the procedure. When the fluoroscopic (marker position) and sonographic (intracardiac ultrasound) target sites are congruent, the proper position for valve deployment has been located. At that moment, valve 140 may be deployed as described below.

5 [0110] Additionally, valve delivery device 142 may contain two radiopaque markers. With the coronaries being visualized with fluoroscopy, the surgeon could visualize the alignment of the two marker bands on delivery device 142. Thus, the surgeon would be able to properly orient the valve such that the commissure posts are properly positioned upon valve deployment.

10 [0111] Valve delivery device 142 may terminate in two phase balloon 150, as shown in FIG. 15. Alternatively, the end of device 142 carrying valve 140 may have two separately operable balloons. The first phase of balloon 150 may be inflated to provide a positioning guide for valve 140. The first phase of balloon 150 provides a bumper such that delivery device 142 is prevented from further advancement when the proximal end of balloon 150 (i.e., the first phase of balloon 150) reaches the region of left ventricle just proximal to the aortic valve site.

15 20 25 30 [0112] Continued expansion of balloon 150 causes base ring 154 of valve 140 to expand. As base ring 154 expands, hooks 156 may bite into remaining aortic rim 141. Alternatively, hooks 156 may not penetrate rim 141, but rather grasp the rim tightly. Commissure support tissue 158 also begins to open up. In some embodiments of the present invention, valve 140 includes distal stent-like structure 152 to support a

replacement aortic valve distal to coronary sinuses 82 and 84 in sino-tubular junction 36.

[0113] During expansion, intracardiac ultrasound and fluoroscopy can be used to monitor the orientation and placement of valve 140. Before valve 140 is fully expanded, the surgeon may rotate delivery device 142 such that the spaces between commissure supports 158 align with coronary sinuses 82 and 84. Upon full expansion of ring 154 (see FIG. 16), hooks 156 may fully engage rim 141, and hooks 156 and rim 141 may be partially embedded in aortic wall 151. Stent-like structure 152 may engage aortic wall 151 in sino-tubular junction region 36. Commissure supports 158 will be fully expanded, too. Support structure 152 may expand in unison with base ring 154. Alternatively, valve placement may take place in a stepped process, wherein base ring 154 expands and secures the base of the valve before support structure 152 expands to secure the distal end of the valve. The location and function of new valve 140 are identified and monitored with IVUS, intracardiac ultrasound, and/or fluoroscopy. Once placement and function is satisfactory to the surgeon, balloon 150 is deflated, and valve delivery device 142 is removed from left ventricle 26.

[0114] The implantation process should be done quickly, because there will be a brief total occlusion of the aorta. It may be desirable to block the inflow to the heart. Thus, the heart is not straining to pump blood out, and a dangerous lowering of the patient's heart rate may be prevented.

[0115] Valve delivery device 142 may be designed to draw the native leaflets downward when a new valve is being implanted over top of an existing diseased valve.

The native leaflets could obstruct blood flow to the coronary arteries. However, pulling the native leaflets downward before compressing them against the aorta wall would prevent such occlusion.

5 [0116] In some embodiments of the present invention, new valve 140 may be a self-expanding valve that can be implanted without the use of a balloon. Base ring 154, hooks 156, and stent-like structure 152 may be constructed of nitinol or some other shape-memory or
10 self-expanding material. In some embodiments, valve 140 may be deployed by mechanical means, such as by releasing a lasso that surrounds the exterior of valve 140 or by operating a mechanical expansion device within valve 140.

15 [0117] In certain embodiments of the present invention, valve 140 may not have a stent-like support structure at the distal end (i.e., stent-like structure 152). If commissure supports 158 are constructed from or supported by a stiff enough support
20 post, valve 140 may not be fixed to the aorta at its distal end. The mounting at base ring 154 may sufficiently secure valve 140 in place to function normally and not obstruct blood flow to the coronary arteries.

25 [0118] Valve 140 may be secured in place by any suitable method for anchoring tissue within the body. The radial expansion forces of base ring 154 may be strong enough to secure valve 140 against dislodgment by radial strength alone. If no native valve rim
30 remains, hooks 156 may be designed to grasp aortic wall 151. Mechanically placed sutures or staples could be used to secure valve 140 in place. Furthermore,

biocompatible glue could be used to secure valve 140 in the appropriate position.

[0119] During a valve implantation procedure, it may be desirable to have the ability to retract expansion
5 of new valve 140. If the commissures are not properly aligned with the coronary arteries or if the valve is not properly positioned within the native annulus, retracting the expansion would enable repositioning or realignment of the valve. Such a retraction technique
10 is illustrated in FIG. 23 wherein valve 230 is one illustration of a possible embodiment of valve 140.

[0120] Valve 230 has radially expandable support ring 232 and radially expandable mounting structure 231. Mounting structure 231 may be a
15 sinusoidal ring of nitinol wire. Mounting structure 231 is attached to wires 237, 238, and 239 at points 234, 235, and 236, respectively. By advancing tube 233 or withdrawing wires 237, 238, and 239, mounting structure 231 may be drawn radially inward,
20 effectively retracting the expansion of valve 230. Other means of retracting valve expansion could be employed in accordance with the principles of the present invention.

[0121] In some embodiments of the present invention,
25 the dilated opening in myocardium 40 is sealed with an automatic closure device. The automatic closure device may be part of access device 60. Alternatively, the automatic closure device may be inserted through access device 60 such that removal of access device 60 leaves
30 the automatic closure device behind.

[0122] For example, FIG. 17 shows automatic closure device 172 being delivered with closure delivery device 170. Closure device 172 may include proximal

umbrella 174, distal umbrella 178, and connecting shaft 176 therebetween. Delivery rod 171 may be used to advance proximal umbrella 174 from delivery device 170 such that umbrella 174 opens. Balloons 61 and 62 of access device 60 are deflated. Then, both access device 60 and delivery device 170 are withdrawn from heart 10. Umbrella 174 will contact the inner surface of myocardium 40, as shown in FIG. 18. Upon further withdrawal of access device 60 and delivery device 170, distal umbrella 178 will be permitted to deploy. Upon deployment of umbrella 178, the hole formed in myocardium 40 will be sealed. Myocardium 40 may be sealed using any acceptable automatic closure device. Alternatively, myocardium 40 may be sutured closed. Additionally, myocardium 40 may be closed with any known closure device, such as an Amplatzer™ occlusion device, other double-button device, plug, or laser plug.

[0123] Bleeding into the space between the myocardium and the pericardium should be prevented. The myocardium can be closed without a need to close the pericardium. However, if the pericardium is to be sealed with the automatic closure device, the seal must be tight enough to prevent bleeding into the void between the two.

[0124] The percutaneous femoral access site will also need to be sealed. This may be done with sutures, or with a self-closing device such as an Angioseal™ Hemostatic Puncture Closure Device.

[0125] Implantable valves in accordance with the preferred embodiments of the present invention may take on a number of forms. However, the implantable valves will likely exhibit several beneficial characteristics.

Implantable valves should preferably be constructed of as little material as possible, and should be easily collapsible. The valve may be radially compressed to a size significantly smaller than its deployed diameter
5 for delivery. The implantable valve or support elements of the valve may contain Gothic arch-type structural support elements to efficiently support and maintain the valve once it is implanted.

[0126] The implantable valve may have an outer stent
10 that is installed before deploying the valve structure. Valves manufactured in accordance with the principles of the present invention are preferably constructed of biocompatible materials. Some of the materials may be bioabsorbable, so that shortly after the implantation
15 procedure, only the anchoring device and tissue valve remain permanently implanted. The valve leaflets may be composed of homograft valve tissue, animal tissue, valve rebuild material, pericardium, synthetics, or alloys, such as a thin nitinol mesh.

[0127] Implantable valves in accordance with the
20 principles of the present invention may be drug eluting to prevent restenosis by inhibiting cellular division or by preventing reapposition of calcium. The drug may act as an active barrier that prevents the formation of
25 calcium on the valve. Additionally, the drug may stimulate healing of the new valve with the aorta. Furthermore, the implantable valves are preferably treated to resist calcification. The support elements of the implantable valve may be exterior to the valve
30 (e.g., between the new valve tissue and the aorta wall), interior to the valve (e.g., valve tissue is between the support elements and the aorta wall), or may form an endoskeleton of the valve (e.g., support

elements of the valve may be within the tissue of the implantable valve).

[0128] FIGS. 24-26 illustrate new valves that could be used for replacement or implantation procedures in accordance with the principles of the present invention. Valve 240 of FIG. 24 has sinusoidal attachment member 241 encircling the base of commissure posts 242, 243, and 244. Attachment member 241 may be any radially compressible and expandable member.

5
10 Member 241 of FIG. 24 has proximal peaks 245 and distal peaks 246 which may be turned outward. Peaks 245 and 246 may be better suited to engage the wall of the aorta when the peaks are turned outward. Peaks 245 and 246 may also be pointed or sharpened so that they
15 penetrate the aorta wall. In embodiments in which a small rim of native valve has been left behind after resection, peaks 245 and 246 may be biased to close outwardly, effectively biting the rim of remaining tissue. Commissure posts 242, 243, and 244 and the
20 valve's leaflets (not shown) fold and collapse when member 241 is radially compressed for delivery.

[0129] Valve 240 may have distal mounting ring 248 in some embodiments. Ring 248 may engage the distal portion of the sino-tubular junction. Ring 248 may
25 have segments 249 that are biased radially outward so as to more securely engage the inner wall of the aorta. The replacement valve may be designed to mimic the natural curvature of the sino-tubular junction. This curvature creates a natural bulge, in which the
30 replacement valve may be able to secure itself against dislodgement.

[0130] Valve 250 of FIG. 25 shows tissue 252 inside stent frame 254. Tissue 252, which forms the leaflets

of the implantable valve may be engineered and/or grown directly inside of stent frame 254. Alternatively, tissue 252 may be glued or sutured to stent frame 254. Stent frame 252 may incorporate peaks that are turned outward that may have pointed or sharpened tips like those described with respect to valve 240 of FIG. 24. Also, ring 256 may have hook features such as hooks of FIG. 15. Stent frame 252 may be constructed from a shape memory or other self-expanding material. Alternatively, stent frame 252 may be constructed from stainless steel or other materials that are balloon expanded or mechanically expanded.

[0131] Valve 260 of FIG. 26 illustrates one embodiment of a low profile valve. Such a low profile valve may reduce the likelihood of coronary artery obstruction. Valve 260 may comprise any number of leaflets. Valve 260 is illustratively shown with five leaflets (i.e., leaflets 261, 262, 263, 264 and 265). The leaflets overlap one another in a domino-type arrangement. Leaflet 265 is the top-most leaflet, overlapping the left side of leaflet 264. The right side of leaflet 264 overlaps the left side of leaflet 263, and so on with leaflet 261 being the bottom-most leaflet. The leaflets may be arranged such that they overlap one another in a clockwise or a counterclockwise fashion. Valve 260 may appear to open like the iris of a camera when viewed from the top (as shown in FIG. 26). The leaflets actually rise out of the plane of the valve annulus. However, because of the valve's very low profile, no commissure supports are needed.

[0132] Additionally, spiral, or rolled valves may be used in the implantation or replacement procedure.

Such valves unwind instead of being radially expanded. Rolled valves are reduced in diameter for percutaneous or minimally invasive implantation by rolling the valve material into a spiral.

5 [0133] It may be beneficial to replace an insufficient valve with a new valve that is designed so that it does not dilate to the size of the diseased valve. Insufficient valves do not fully close, permitting regurgitation in the blood flow. This is
10 often the result of a dilated valve annulus, which does not allow the valve leaflets to come together in the center. Therefore, it may be desirable for the new valve to fill a smaller annulus. This can be achieved by designing a valve such as valve 270 of FIG. 27.
15 Valve 270 has fluid-tight membrane 276. Thus, while support structure 272 dilates to the diameter of the diseased valve's annulus, leaflets 274 of the replacement valve operate in an annulus of fixed size determined by membrane 276.

20 [0134] In some embodiments of the present invention, the new valve may be designed to be exchangeable. Many replacement heart valves have a life expectancy of 10-20 years. Therefore, many patients will require follow-up valve replacements. Certain structural
25 components of the heart valve (e.g., the base ring, hooks, etc.) could be permanent, while the tissue leaflets may be exchangeable. It may be preferable to simply dilate the old valve with the new valve.

[0135] In some embodiments of the present invention,
30 a valve implantation procedure may take place "off-pump," but the patient's heart may be temporarily arrested. The patient's heart is stopped using fibrillation. A surgeon will have just under three

minutes to perform the surgical procedure without risking harm to the patient. However, the anesthetized patient could be cooled to provide the surgeon with more time without increasing the risk for brain damage.

5 [0136] Once the patient's heart is stopped, an incision is made to the aorta just distal to the aortic valve. Blood is cleared from this region so that the surgeon can visualize the valve site. Using a delivery device like that described above (except making a
10 retrograde approach in this case), the new valve is implanted directly over the diseased valve. Because the valve is being installed in a retrograde approach, the native leaflets will be pushed downward before being compressed against the aorta wall. Therefore,
15 there is no concern of coronary artery occlusion.

[0137] Once the new valve is installed, the surgical site inside the aorta is cleared of air, and a side bite clamp is placed on the lesion. The heart is restarted with the electrodes that were used to stop it
20 previously. Once the heart is beating again, the clamped lesion is sutured closed. An introducer device (similar to access device 60) can be used at the incision site to prevent the need for clearing the blood from the surgical site and later deairing the
25 site.

[0138] There are numerous procedures that may be performed transapically in accordance with the principles of the present invention. The following describes several of the illustrative procedures that
30 may be performed via a transapical access device.

[0139] Insufficient mitral valves often result from a dilated posterior leaflet. FIGS. 28-30 demonstrate a tool that could be used to repair an insufficient

mitral valve via a transapical access device. Repair tool 280 may have U-shaped head 282 and single-pronged head 284. Heads 282 and 284 may be operably attached by hinge 288. When posterior leaflet 290 (FIG. 29) is inserted between heads 282 and 284, handles 283 and 285 can be squeezed together to cause a portion of posterior leaflet 290 to be drawn downward. At this point, attachment tool 286 can deploy connector 300 (FIG. 30) to retain posterior leaflet 290 in a constrained state, repairing any excess dilation of the mitral annulus. Connector 300 may be a surgical staple, mechanical suture, or other suitable connector.

[0140] Aortic dissection is another defect that may be repaired via transapical access to the heart. Aortic dissection occurs from a tear or damage to the inner wall of the aorta. Aortic dissection may be caused by traumatic injury or connective tissue diseases such as Marfan syndrome or Ehlers-Danlos syndrome, for example. Aortic dissection may result in atherosclerosis or high blood pressure. As shown in FIG. 31, aortic dissection 318 may result in void 319.

[0141] Aortic dissection repair device 310 may be transapically inserted into a patient via access device 311 (substantially similar to access device 60 of FIG. 6). Repair device 310 may include balloon 312 and catheter 314 and may be guided by guidewire 316. Though not shown, catheter 314 may include several lumens (e.g., a balloon inflation lumen, a guidewire lumen, and a glue delivery lumen).

[0142] Once repair device 310 is properly located, balloon 312 may be inflated as shown in FIG. 32. The inflation of balloon 312 may cause needles 320 to penetrate aortic dissection 318 such that the tips of

needles 320 are exposed to void 319. A biologically compatible glue may be injected through needles 320 via the glue delivery lumen (not shown) of catheter 314. Further inflation of balloon 312 may ensure that
5 dissection 318 is securely affixed to the aorta wall by the biologically compatible glue.

[0143] In order to make sure that the biologically compatible glue is only injected into void 319, and not the remainder of the aorta (which may introduce the
10 biologically compatible glue to the circulatory system), dye may first be injected through select channels (i.e., needles 320). This will allow a surgeon to determine if injected glue would only end up in the desired locations. Repair device 310 may then
15 be rotated to align the needles that will inject the biologically compatible glue with void 319. Alternatively, the needles that will be used to inject the glue may be selectable so that the surgeon activates only the needles aligned with void 319.

[0144] Because balloon 312 fully occludes the aorta, balloon 312 may be doughnut-shaped to allow blood to pass, like balloon 330 of FIG. 33. Additionally, balloon 330 may include VAD device 332 to pump blood
20 from the proximal side of balloon 330 (at inlet ports 334) to the distal side of balloon 330 (at outlet ports 336). The repair device may still include needles 338. The aortic dissection repair procedure may be monitored with any of the visualization
25 equipment discussed in more detail above. Once the aortic dissection has been repaired, balloon 312 or 330
30 may be deflated, and repair device 310 is removed from the patient.

[0145] Left ventricular aneurysms are another deformity of the heart that may be treated transapically. The heart muscle in the area of a blood vessel blockage can die over time. The healing process
5 may form a scar that could thin and stretch to form a ventricular aneurysm. Such aneurysms may be repaired as described below.

[0146] Left ventricular aneurysm 340 may form in left ventricle 341 of a patient, as shown in FIG. 34.
10 Because aneurysm 340 can cause the heart to work harder over time and result in eventual heart failure, the aneurysm should be treated. Aneurysm repair device 336 may be inserted through access device 344

(substantially like access device 60 of FIG. 6).
15 Repair device 346 may include liquid filled bolster 342 that is mounted inside left ventricular aneurysm 340. Bolster 342 may be mounted with a biologically compatible glue, by mechanical means, or by any other suitable mounting technique.

[0147] In some embodiments of the present invention, aneurysm 340 may be repaired by pulling the ends of aneurysm 340 together, as depicted by FIG. 35. In such
20 embodiments, aneurysm repair device 350 may be used to deploy hooks 352 and 354. Hooks 352 and 354 may grasp
25 the interior of the heart at the extremes of the aneurysm and then draw the aneurysm closed. Once the aneurysm has been drawn together, any suitable technique can be used to secure the aneurysm in the closed position (e.g., biologically compatible glue,
30 surgical staples, mechanically placed sutures, etc.)
Once the aneurysm has been fully sealed, repair device 350 may be withdrawn from the patient.

[0148] In some embodiments of the present invention, endoprostheses may be placed percutaneously, transapically, or via any combination of surgical approaches. Endoprostheses may be placed in the ascending aorta that have arms capable of extending
5 into the coronary arteries. Endoprostheses for the ascending aorta could also include a replacement valve or a valved stent. Endoprostheses for the descending aorta could also be placed transapically or
10 percutaneously, for example, to repair an abdominal aortic aneurysm.

[0149] Additionally, endoprostheses may be placed in the aortic arch. One embodiment of an endoprosthesis for the aortic arch is shown in FIG. 40.
15 Endoprosthesis 402 may be placed in aortic arch 400. Furthermore, endoprosthesis 402 may include arms 403, 405, and 407 that extend into brachiocephalic artery 404, left common carotid artery 406, and left subclavian artery 408, respectively.

[0150] Endoprosthesis 402 may be placed using
20 guidewires 410, 412, 414, and 416, as shown in FIG. 41. Guidewire 410 may pass through the body of endoprosthesis 402, while guidewires 412, 414, and 416 may pass through holes 403', 405', and 407' of the ends
25 of arms 403, 405, and 407, respectively. Once endoprosthesis 402 is properly positioned in aortic arch 400, arms 403, 405, and 407 may be extended to a position substantially perpendicular to the body of endoprostheses 402. In order to aid the insertion of
30 the arms of endoprosthesis 402 into the respective arterial branches, small catheters, or other pushing devices, may be inserted over guidewires 412, 414, and 416 to manipulate (e.g., push) the arms of the

endoprosthesis. The arms and body of endoprosthesis 402 may be radially expanded once the endoprosthesis is properly positioned.

[0151] Currently, ventricular arrhythmias are
5 percutaneously repaired with radio frequency, cold, heat, or microwave that is applied to the offending tissue to destroy the source of the arrhythmia. Ventricular arrhythmias could be repaired transapically in accordance with the principles of the present
10 invention. Radio frequency, cold, heat, or microwave devices can be introduced through an access device like access device 60 of FIG. 6.

[0152] Hypertrophic obstructions (i.e., obstructions
15 distal to a heart valve) and subvalvular stenosis (i.e., an obstruction proximal to a heart valve) may also be treated transapically. Devices such as those described above to resect a diseased valve could be inserted transapically to cut away the hypertrophic or subvalvular obstruction. The extra tissue could be
20 removed from the heart in the same way that the diseased valve is resected and removed.

[0153] Robotic technology similar to that currently
25 used in operating rooms could be used to perform some of the steps of the heart valve removal and replacement or implantation procedure. For example, it may be desirable to have a robot perform the delicate resection procedure via the access device.

Furthermore, a robot could exercise precision in rotating and positioning the replacement valve with
30 proper alignment of the commissure posts.

[0154] Because the heart valve operation is being performed inside one or more of the heart's chambers, all of the equipment described above should be

atraumatic to limit damage to the endothelial wall of the heart.

[0155] It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the order of some steps in the procedures that have been described are not critical and can be changed if desired. Also, various steps may be performed with various techniques. For example, the diseased valve may be removed transapically, while the replacement valve is implanted percutaneously, or vice versa. The manner in which visualization equipment and techniques are used for observation of the apparatus inside the patient may vary. Many surgical repair procedures can be performed on or near the heart in accordance with the principles of the present invention.

What is Claimed is:

1. A method of operating on a patient comprising:
 - accessing the patient's heart;
 - installing an access device in a wall of
 - 5 the heart, the access device having means for preventing bleeding through the access device; and
 - performing a surgical procedure.
2. The method of claim 1 further comprising resecting a native heart valve.
3. The method of claim 1 further comprising implanting a heart valve.
4. The method of claim 1 further comprising repairing an aortic dissection.
5. The method of claim 1 further comprising repairing a heart valve.
6. The method of claim 1 wherein installing the access device in the wall of the heart further comprises installing the access device in a ventricular apex of the heart.
7. A method for implanting a heart valve comprising:
 - accessing a patient's heart;
 - installing an access device in a wall of
 - 5 the heart, the access device having means for preventing bleeding through the access device;
 - inserting a valve delivery device through the access device; and
 - installing the heart valve.

8. The method of claim 7 further comprising resecting a native heart valve.

9. The method of claim 8 wherein the resecting the native heart valve is performed percutaneously and the installing the heart valve is performed transapically.

10. The method of claim 7 wherein the installing the heart valve further comprises radially expanding the heart valve.

11. The method of claim 7 wherein the installing the heart valve further comprises pulling leaflets of a native heart valve downward.

12. A device for implanting a heart valve comprising:

means for radially expanding the heart valve; and

5 means for supplementing blood flow through the device during the implanting the heart valve.

13. The device of claim 12 further comprising means for pulling leaflets of a native valve downward.

14. The device of claim 12 wherein the radially expanding the heart valve occurs in more than one stage.

15. The device of claim 14 wherein the more than one stage is effectuated by a multi-stage balloon.

16. A method of visualizing a portion of a patient's circulatory system comprising:

injecting a transparent oxygen-carrying fluid into the portion of the circulatory system; and

5 inserting an optical device into the portion of the circulatory system containing the transparent oxygen-carrying fluid.

17. The method of claim 16 further comprising temporarily exchanging all blood of the patient's circulatory system with the transparent oxygen-carrying fluid.

18. Instrumentation for accessing a chamber of a patient's heart, the heart having a myocardium, the instrumentation comprising:

5 a catheter having a proximal sealing device for sealing the catheter against a proximal surface of the myocardium; and

means for preventing bleeding through the catheter.

19. The instrumentation of claim 18 further comprising a distal sealing device for sealing the catheter against the distal surface of the myocardium.

20. An implantable heart valve comprising:

a tissue support structure; and

5 tissue valve leaflets, wherein the tissue valve leaflets are grown inside the tissue support structure by genetic engineering.

21. The heart valve of claim 20 wherein the tissue support structure is a stent.

22. The heart valve of claim 20 wherein the tissue support structure comprises stainless steel.

23. The heart valve of claim 20 wherein the tissue support structure comprises a self-expanding material.

24. The heart valve of claim 23 wherein the self-expanding material is nitinol.

25. A device for inserting more than one guidewire into a patient comprising:

a wire placement device; and

a guidewire attached to the wire

5 placement device, wherein the wire placement device is configured to track an already placed guidewire.

26. The device of claim 25 wherein the guidewire is removably attached to the wire placement device.

27. The device of claim 25 wherein the wire placement device comprises a locking mechanism.

28. A method of breaking down calcification of a heart valve comprising:

inserting a catheter-based ultrasound device into a calcified heart valve; and

5 concentrating ultrasound radiation on the calcification of the calcified heart valve to break down the calcification.

29. The method of claim 28 further comprising inserting a reflector into the calcified heart valve to magnify the ultrasound radiation.

30. A low-profile heart valve comprising:
at least three leaflets, wherein one
side of each leaflet overlaps a neighboring leaflet
such that the leaflets open sequentially and close
5 sequentially.

31. A heart valve comprising:
an inner circumference and an outer
circumference, wherein the inner circumference is a
circumference of an annulus formed by leaflets of the
5 heart valve; and
the outer circumference is a
circumference of a fluid-tight diaphragm, wherein the
diaphragm fills a space between the inner circumference
and the outer circumference.

32. A mitral valve repair device comprising:
a first head defining an operating
plane; and
a second head operably attached to the
5 first head and configured to displace a leaflet with
respect to the operating plane.

33. The repair device of claim 32 wherein
the first head is a U-shaped head.

34. The repair device of claim 32 wherein
the first head comprises an attachment mechanism for
attaching at least two portions of the leaflet.

35. The repair device of claim 32 further
comprising a handle for operating the second head with
respect to the first head.

36. A method of repairing an aortic dissection comprising:

accessing a patient's heart;
installing an access device in a wall of
5 the heart, the access device having means for
preventing bleeding through the access device;
inserting a dissection repair device
through the access device; and
repairing the aortic dissection.

37. A device for repairing an aortic dissection comprising:

annularly enlargeable componentry
configured to be inserted into a patient's aorta; and
5 means for closing a void created by the
aortic dissection.

38. The device of claim 37 wherein the means for closing the void comprise injection needles for injecting a tissue sealant.

39. The device of claim 38 wherein the tissue sealant comprises a biologically compatible glue.

40. The device of claim 38 wherein the tissue sealant comprises mechanical sutures.

41. The device of claim 38 wherein the tissue sealant comprises surgical staples.

42. The device of claim 38 wherein the annularly enlargeable componentry comprises means for supplementing blood flow through the componentry during the repair.

43. A device for resecting a diseased heart valve comprising:

5 a first set of annularly enlargeable componentry having a first longitudinal axis and a proximal cutting edge;

a second set of annularly enlargeable componentry having a second longitudinal axis and a distal cutting edge;

10 wherein the device is configured to resect the diseased heart valve when the first set of componentry is enlarged on a distal side of the diseased heart valve and the second set of componentry is enlarged on a proximal side of the diseased heart valve and the sets of componentry are drawn axially
15 together along the longitudinal axes.

44. The device of claim 43 wherein the first longitudinal axis and the second longitudinal axis are coaxial.

45. A method for implanting an endoprosthesis comprising:

5 accessing a patient's heart;
installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
inserting an endoprosthesis delivery device through the access device; and
installing the endoprosthesis.

Abstract

[0156] Methods and systems for endovascular, endocardiac, or endoluminal approaches to a patient's heart to perform surgical procedures that may be performed or used without requiring extracorporeal cardiopulmonary bypass. Furthermore, these procedures can be performed through a relatively small number of small incisions. These procedures may illustratively include heart valve implantation, heart valve repair, resection of a diseased heart valve, replacement of a heart valve, repair of a ventricular aneurysm, repair of an arrhythmia, repair of an aortic dissection, etc. Such minimally invasive procedures are preferably performed transapically (i.e., through the heart muscle at its left or right ventricular apex).

Applicants: Christoph H. Huber

Filed: Concurrently herewith

Application No.: Not yet known

For: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT

Agent: Stuart W. Yothers - Reg. No. 53,816

EXPRESS MAIL NO. EV371745460US

Docket No.: 293/076

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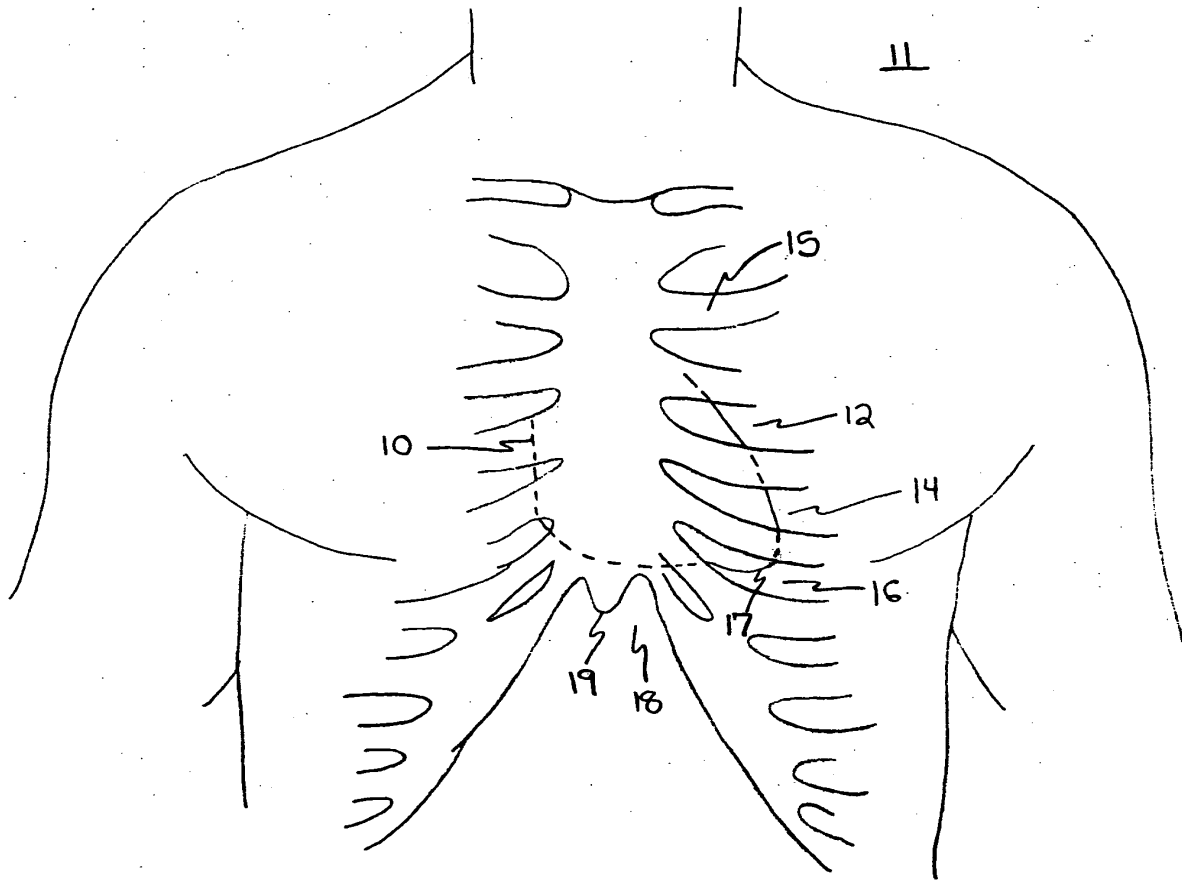


FIG. 1

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Application No.: Not yet known
For: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR
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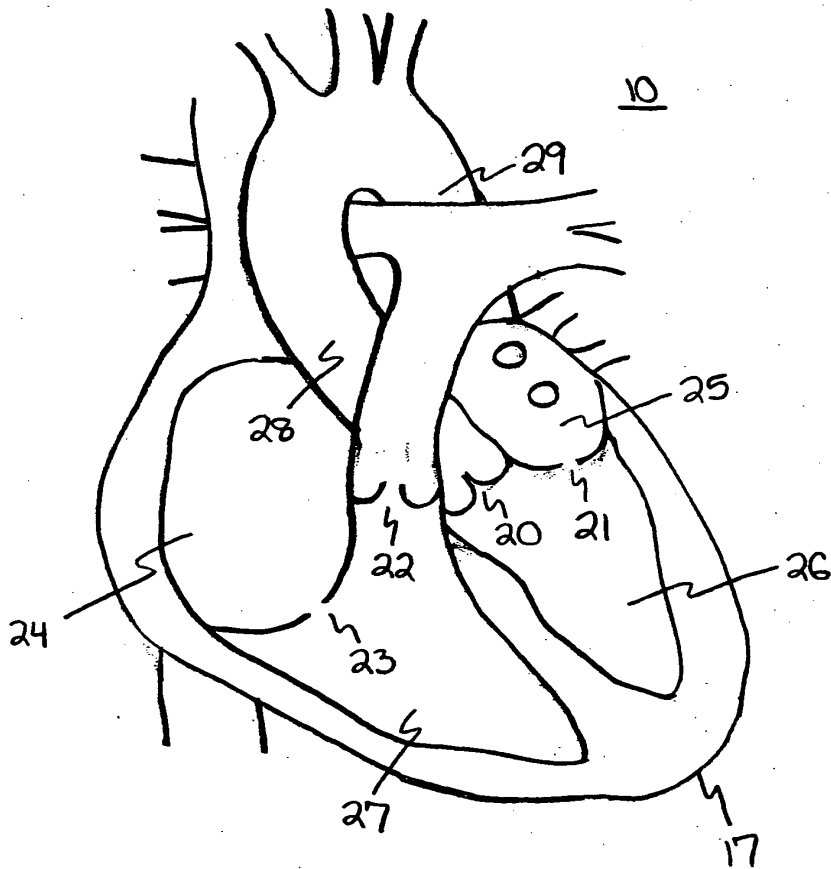


FIG. 2

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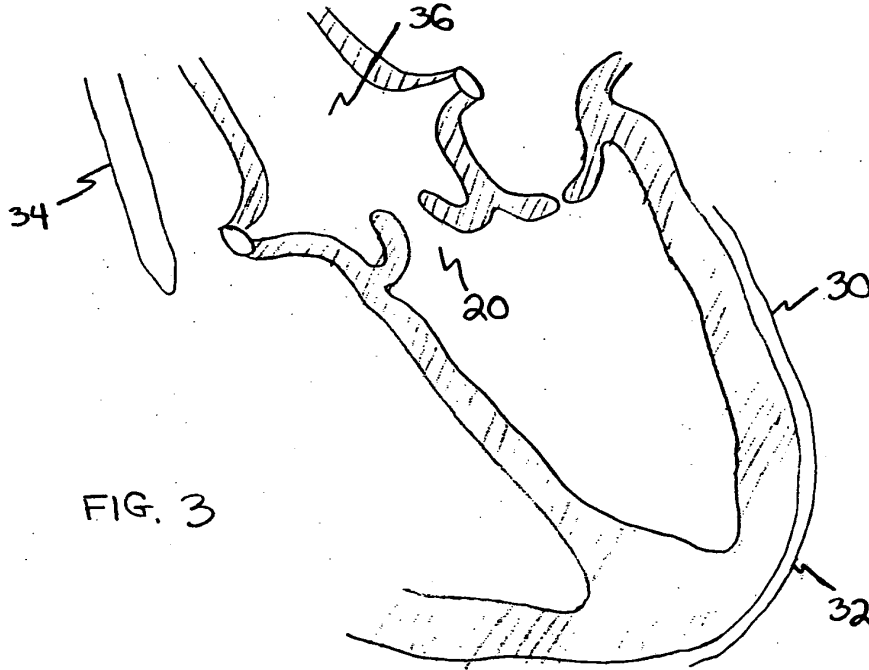


FIG. 3

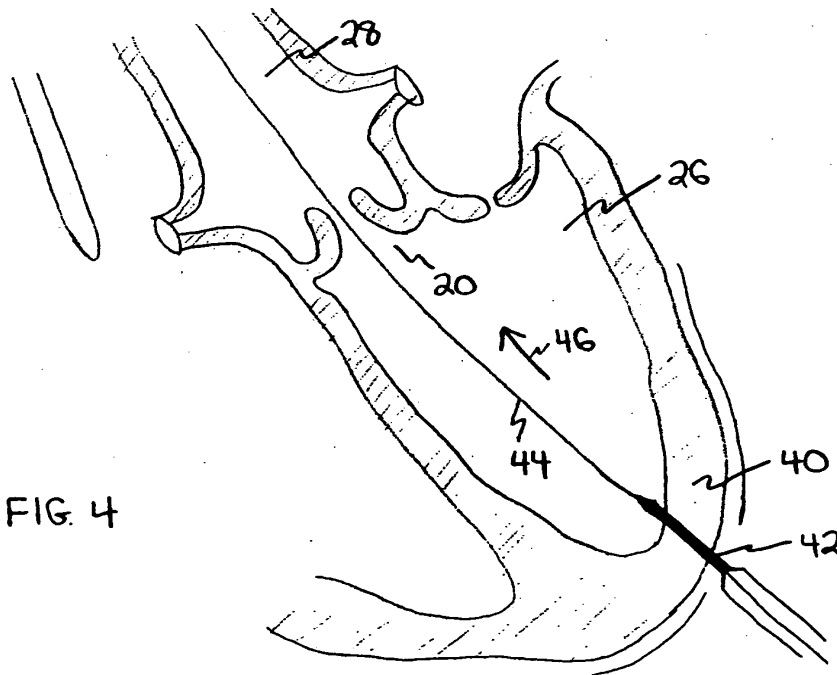


FIG. 4

Applicants: Christoph H. Huber

Filed: Concurrently herewith

Application No.: Not yet known

For: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT

Agent: Stuart W. Yothers - Reg. No. 53,816

EXPRESS MAIL NO. EV371745460US

Docket No.: 293/076

Confirmation No.: Not yet known

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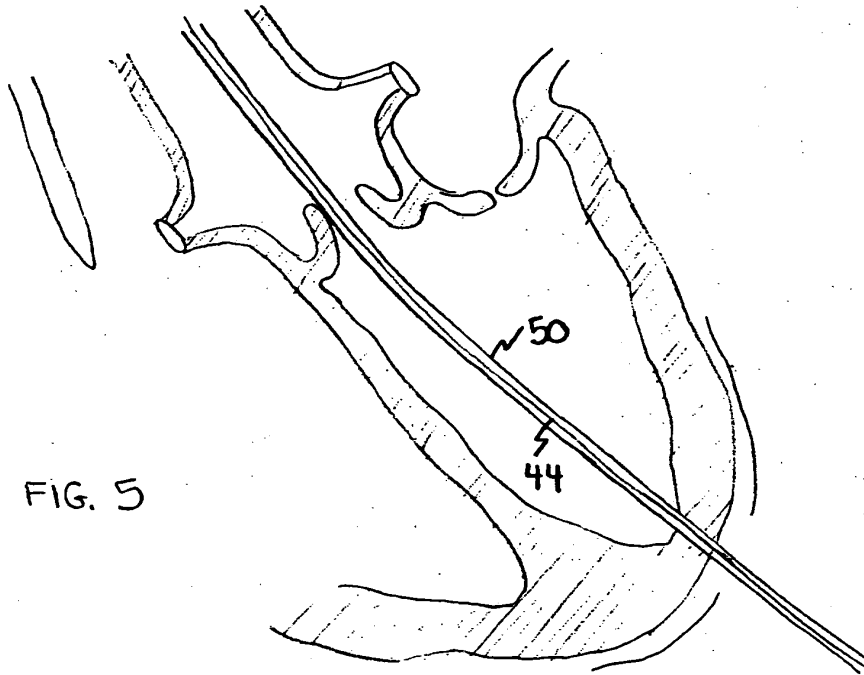


FIG. 5

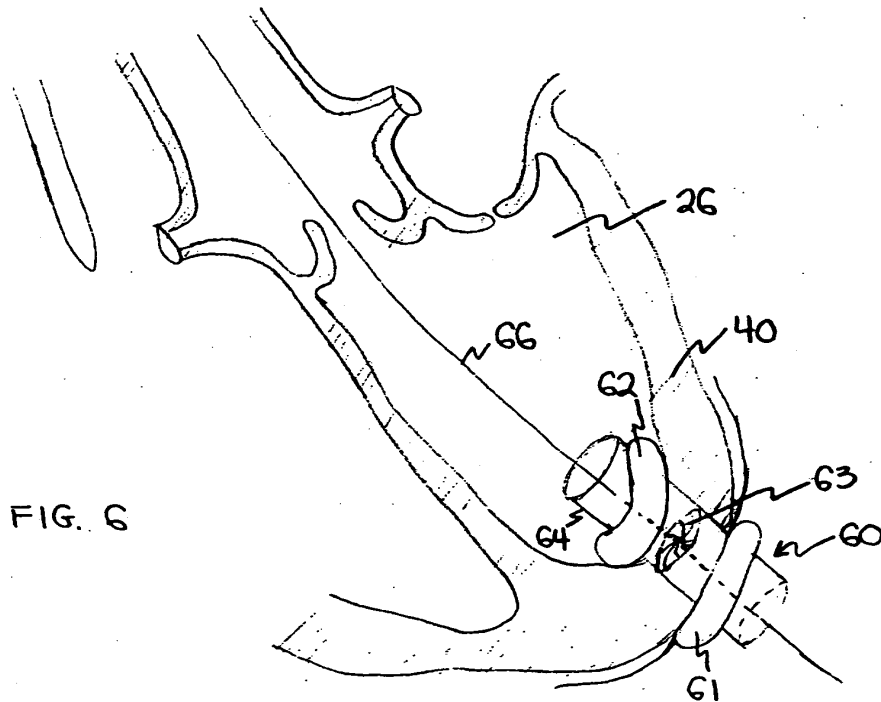


FIG. 6

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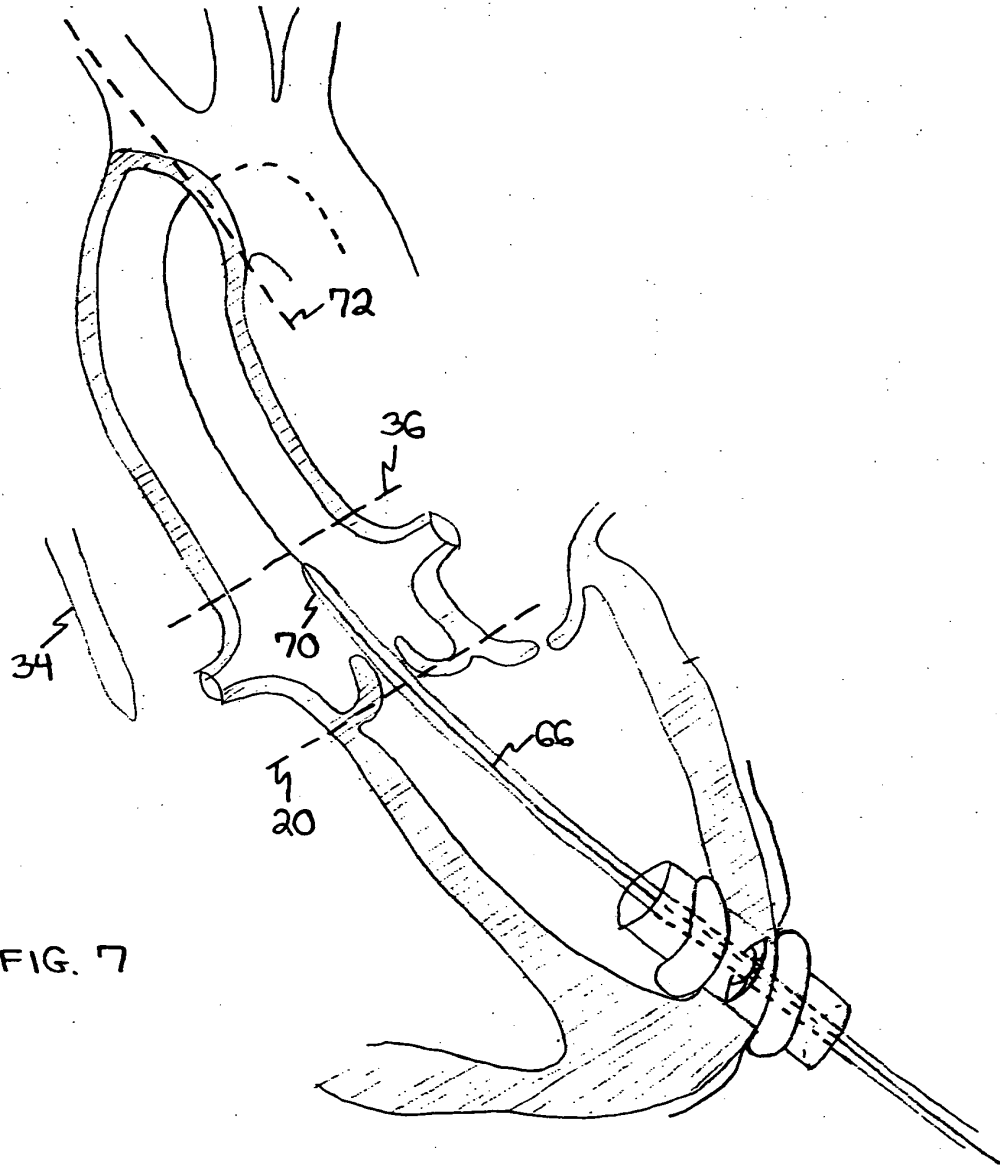


FIG. 7

Applicants: Christoph H. Huber
Filed: Concurrently herewith
Application No.: Not yet known
For: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR
ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT
Agent: Stuart W. Yothers - Reg. No. 53,816

EXPRESS MAIL NO. EV371745460US
Docket No.: 293/076
Confirmation No.: Not yet known

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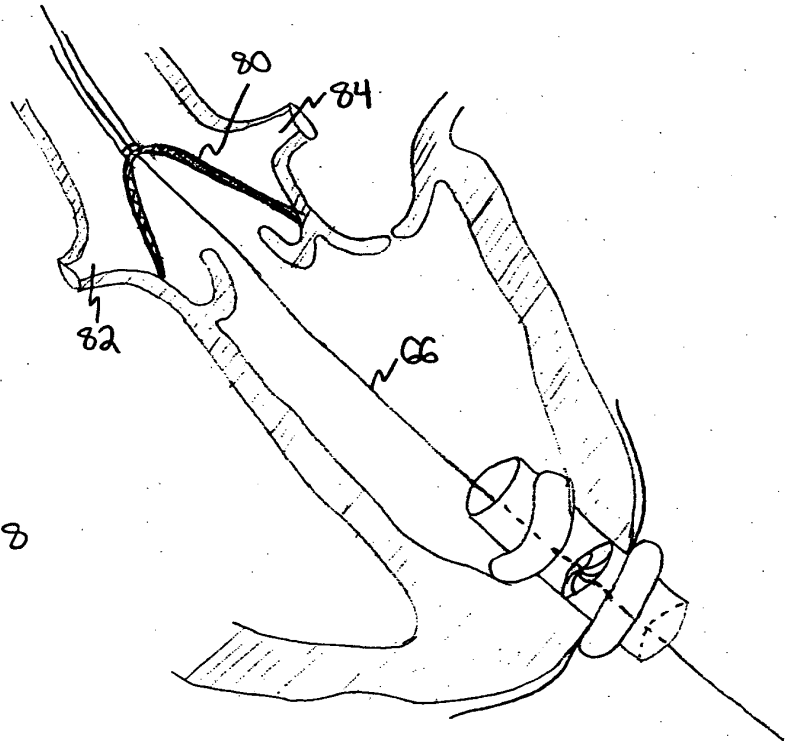


FIG. 8

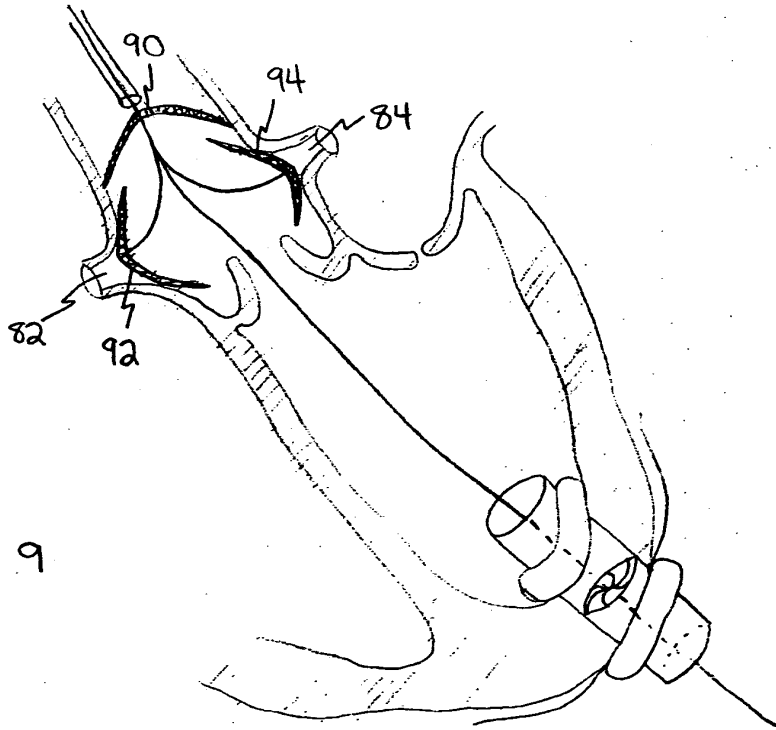


FIG. 9

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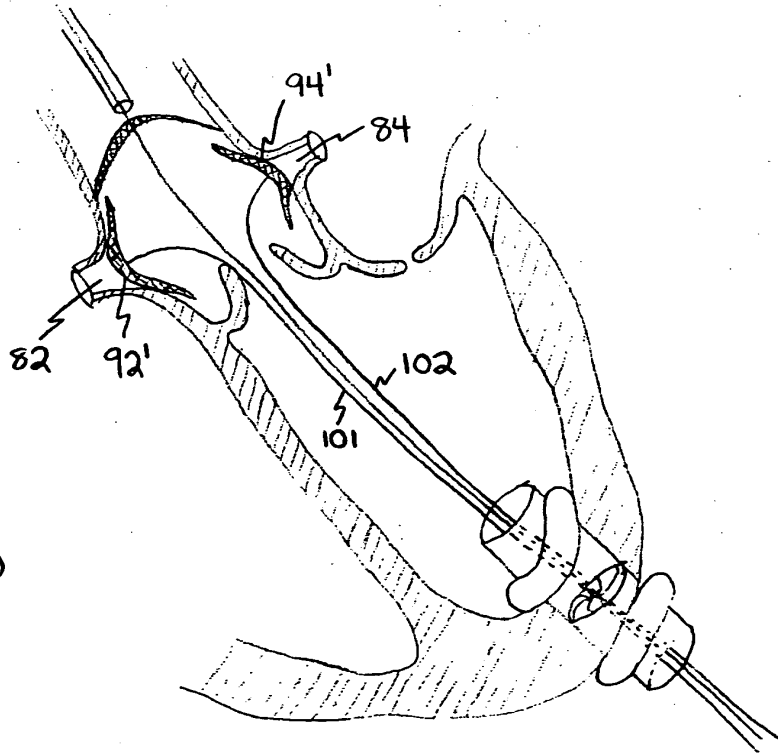


FIG. 10

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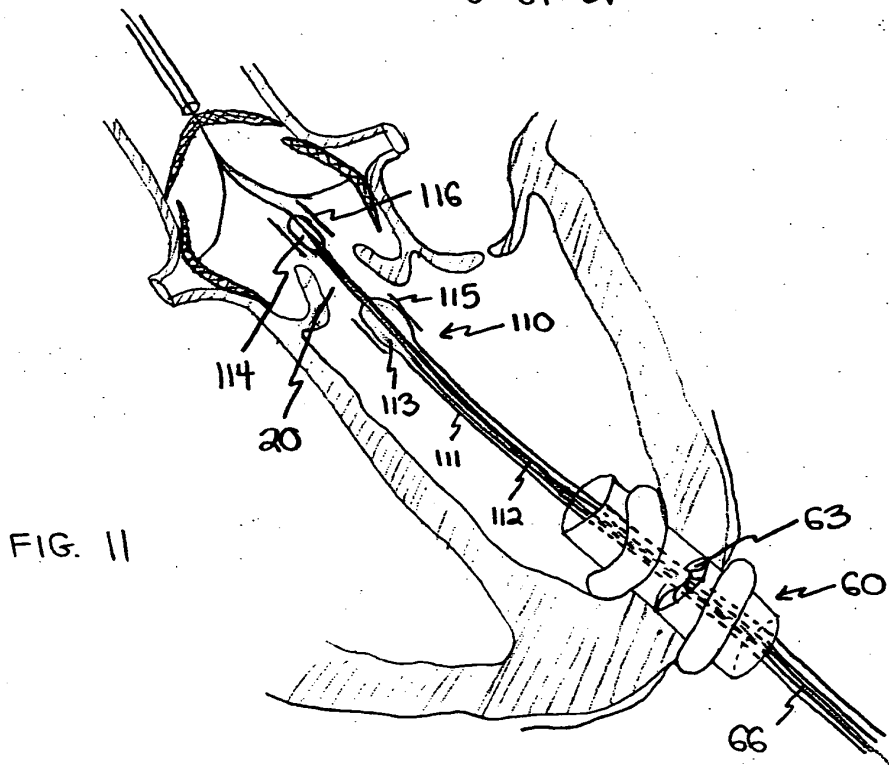


FIG. 11

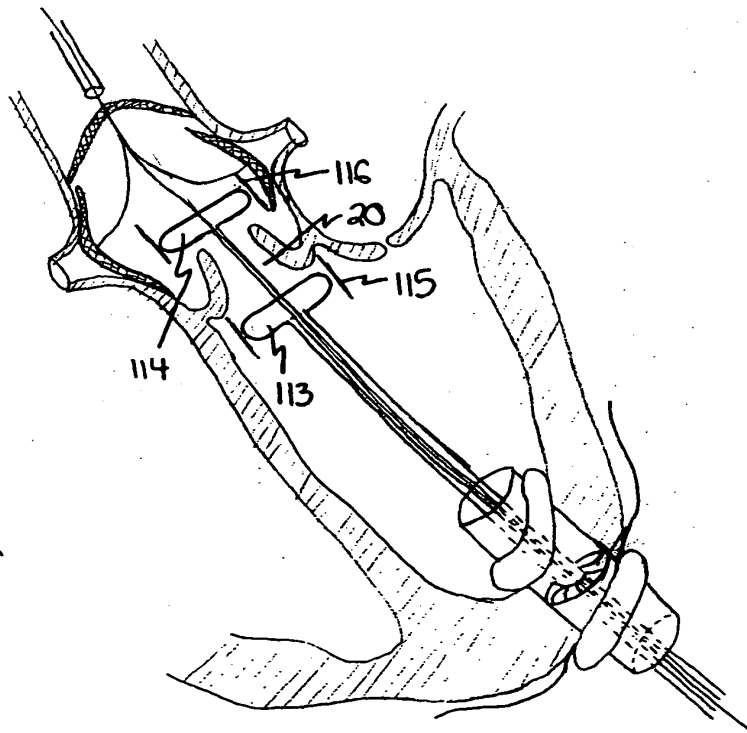


FIG. 12

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FIG. 13

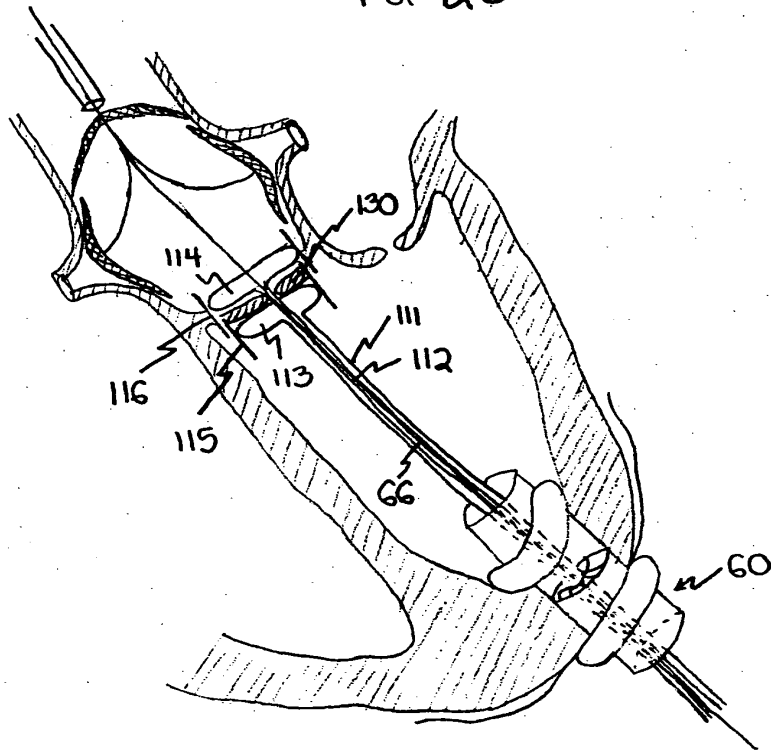
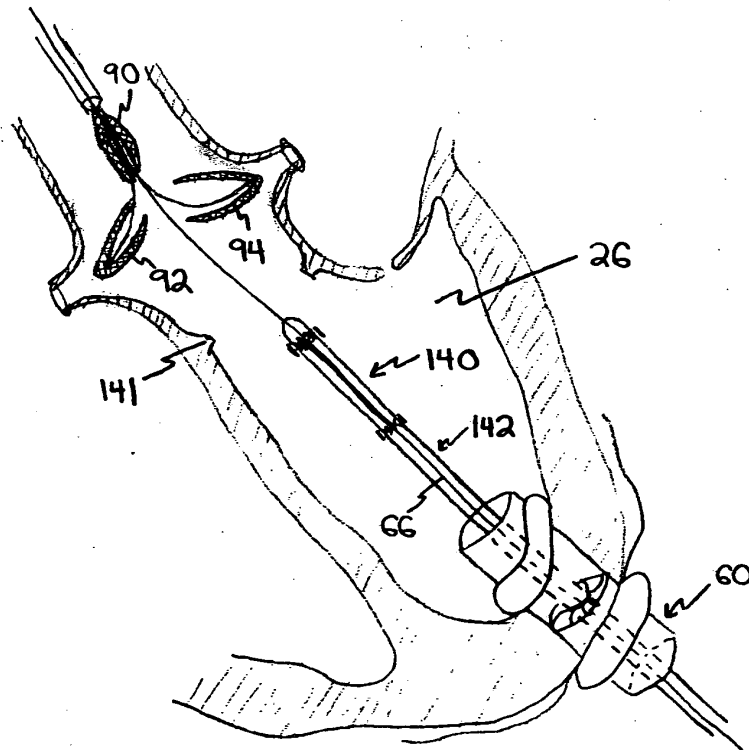


FIG. 14



Applicants: Christoph H. Huber
Filed: Concurrently herewith
Application No.: Not yet known
For: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR
ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT
Agent: Stuart W. Yothers - Reg. No. 53,816

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Docket No.: 293/076
Confirmation No.: Not yet known

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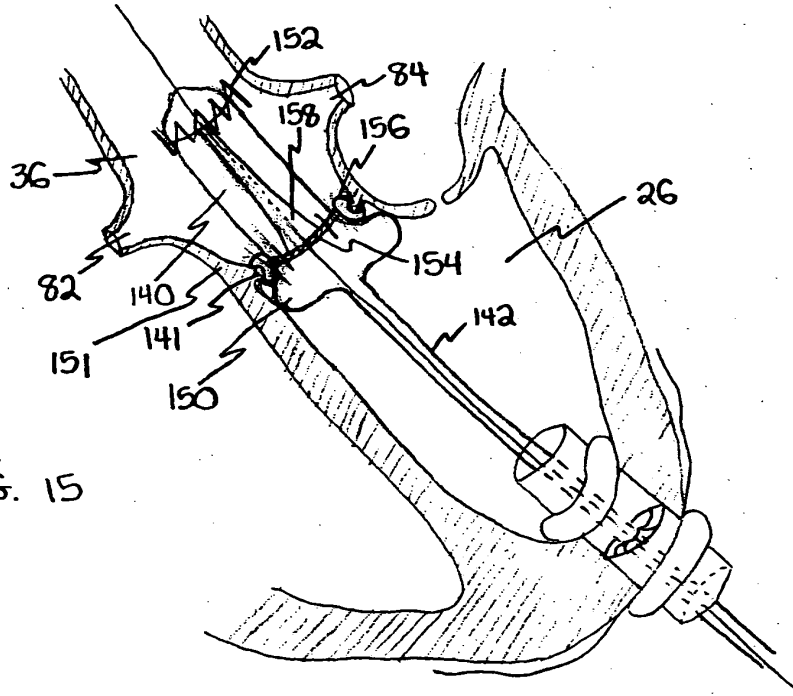


FIG. 15

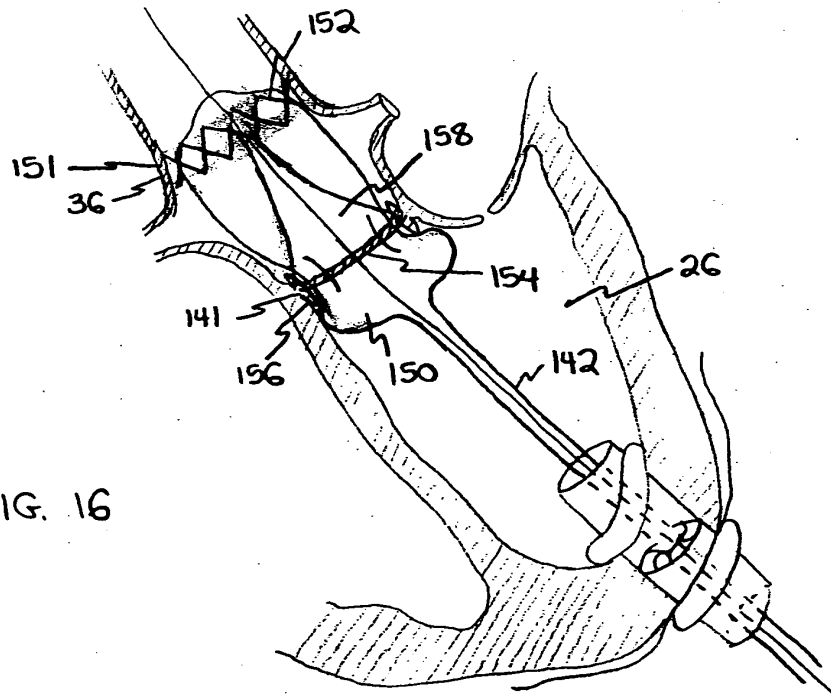


FIG. 16

Applicants: Christoph H. Huber
Filed: Concurrently herewith
Application No.: Not yet known
For: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT
Agent: Stuart W. Yothers - Reg. No. 53,816

EXPRESS MAIL NO. EV371745460US
Docket No.: 293/076
Confirmation No.: Not yet known

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FIG. 17

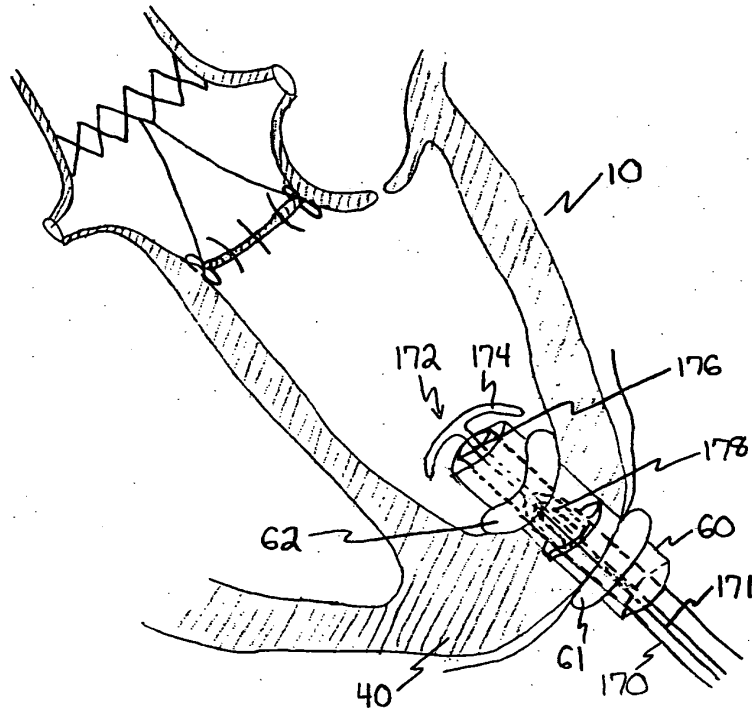
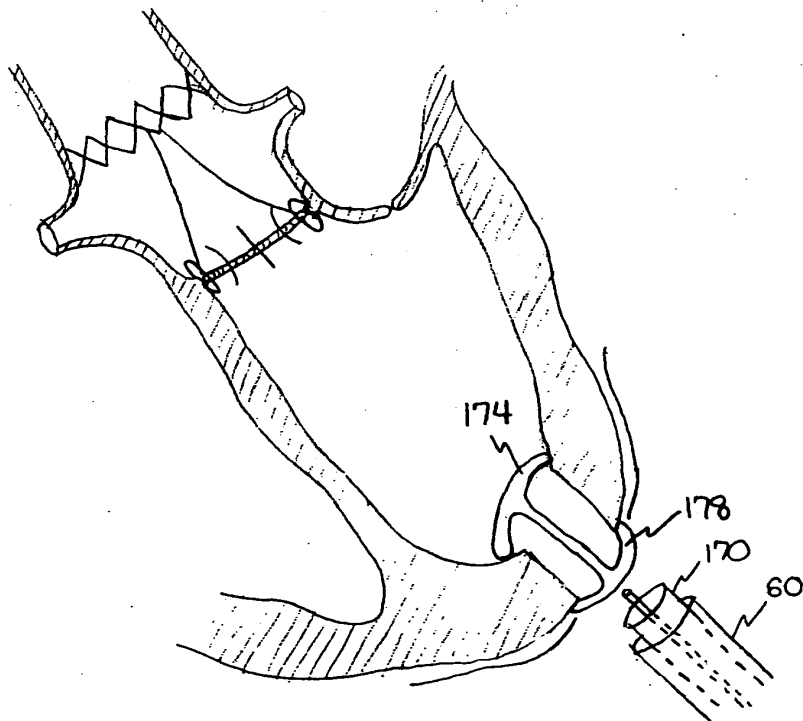


FIG. 18



Applicants: Christoph H. Huber

EXPRESS MAIL NO. EV371745460US

Filed: Concurrently herewith

Docket No.: 293/076

Application No.: Not yet known

Confirmation No.: Not yet known

For: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT

Agent: Stuart W. Yothers - Reg. No. 53,816

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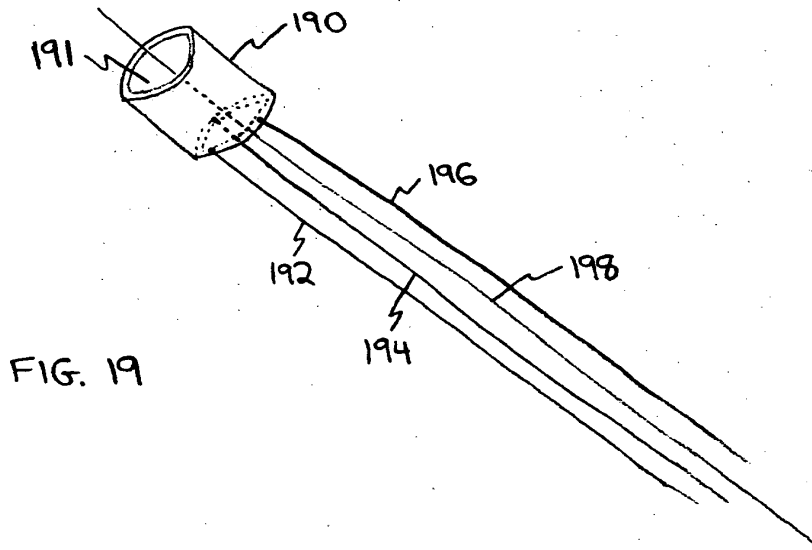


FIG. 19

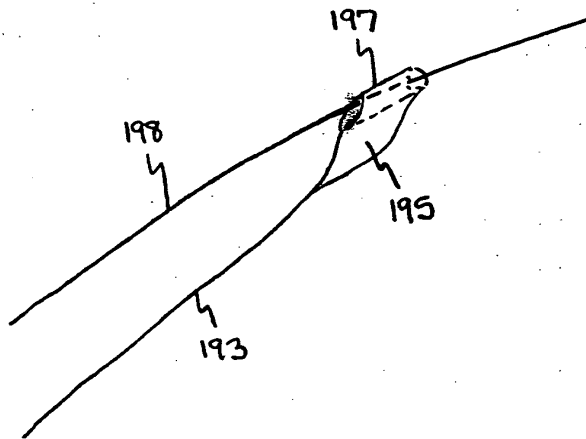


FIG. 19A

Applicants: Christoph H. Huber
Filed: Concurrently herewith
Application No.: Not yet known
For: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT
Agent: Stuart W. Yothers - Reg. No. 53,816

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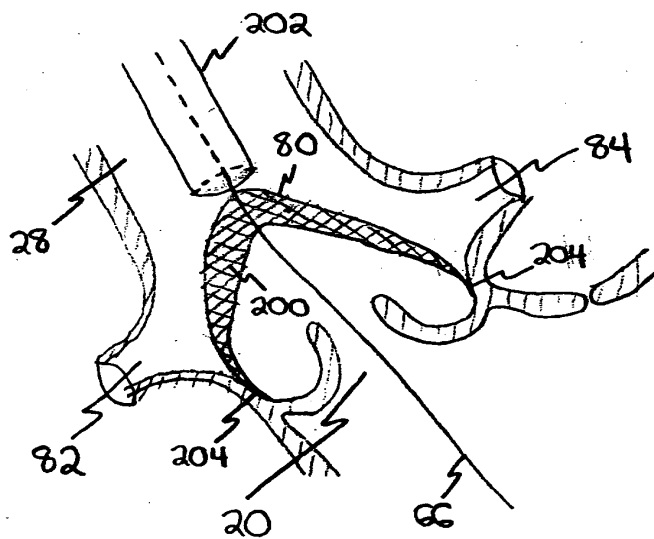
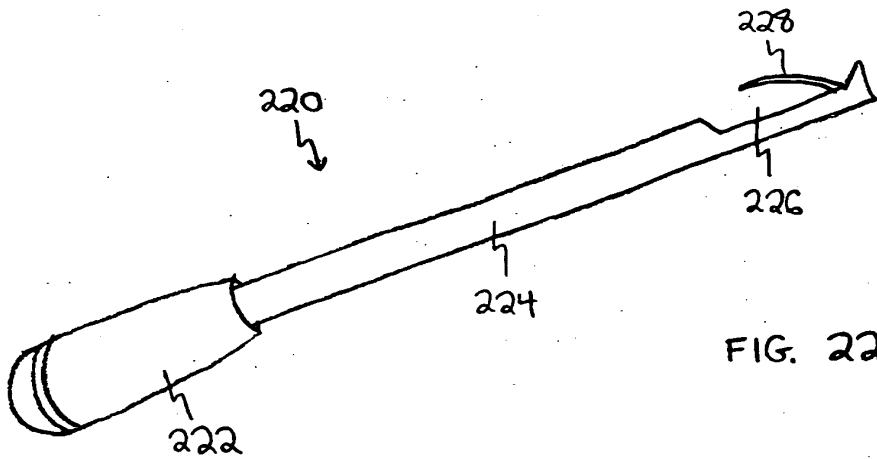
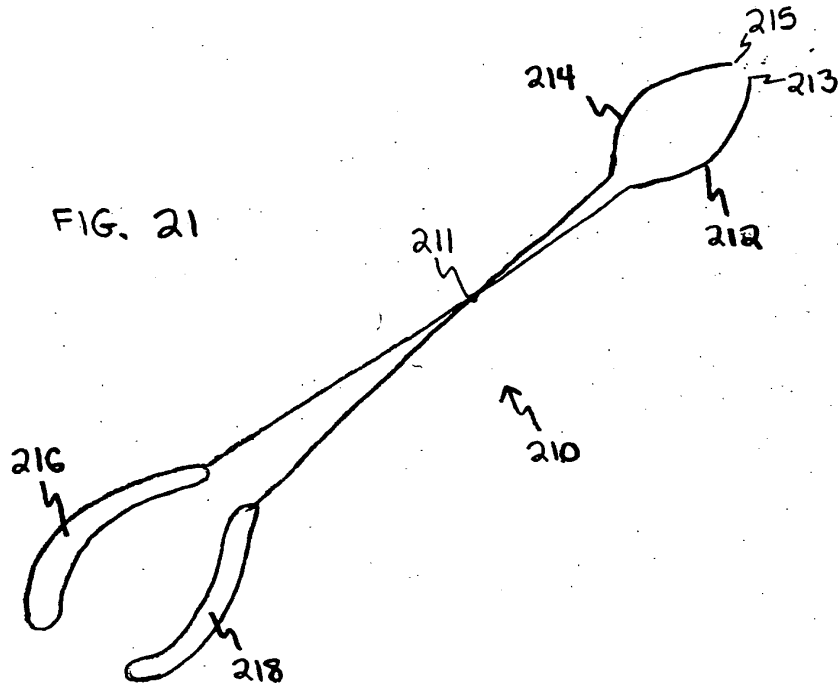


FIG. 20

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Applicants: Christoph H. Huber
Filed: Concurrently herewith
Application No.: Not yet known
For: METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR
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Docket No.: 293/076
Confirmation No.: Not yet known

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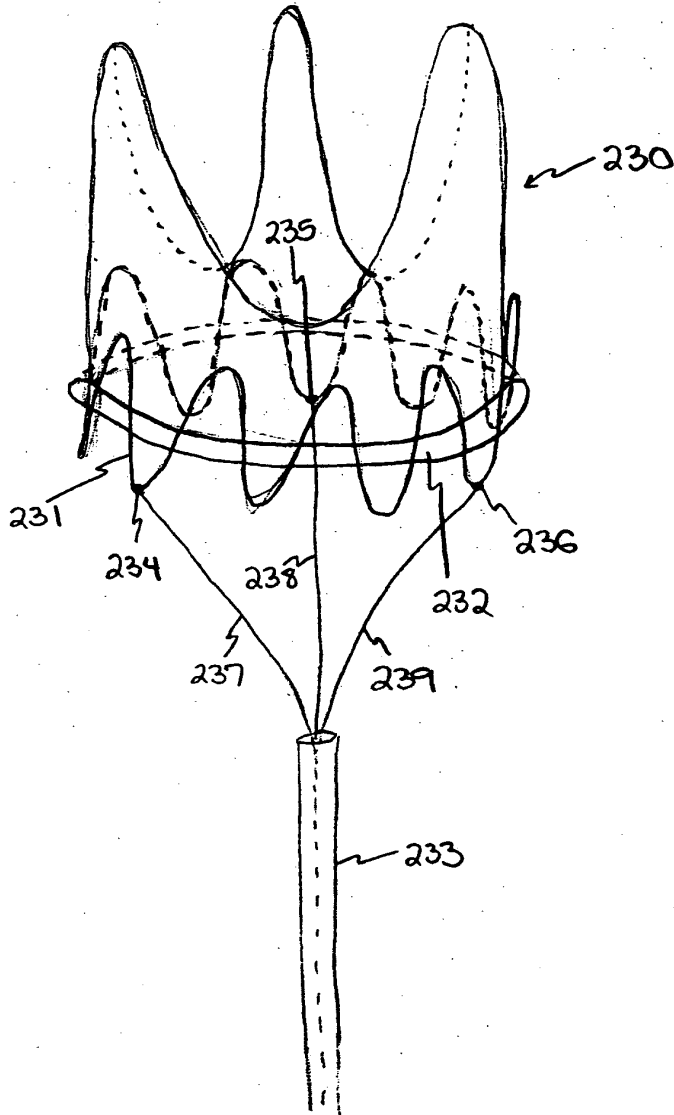


FIG. 23

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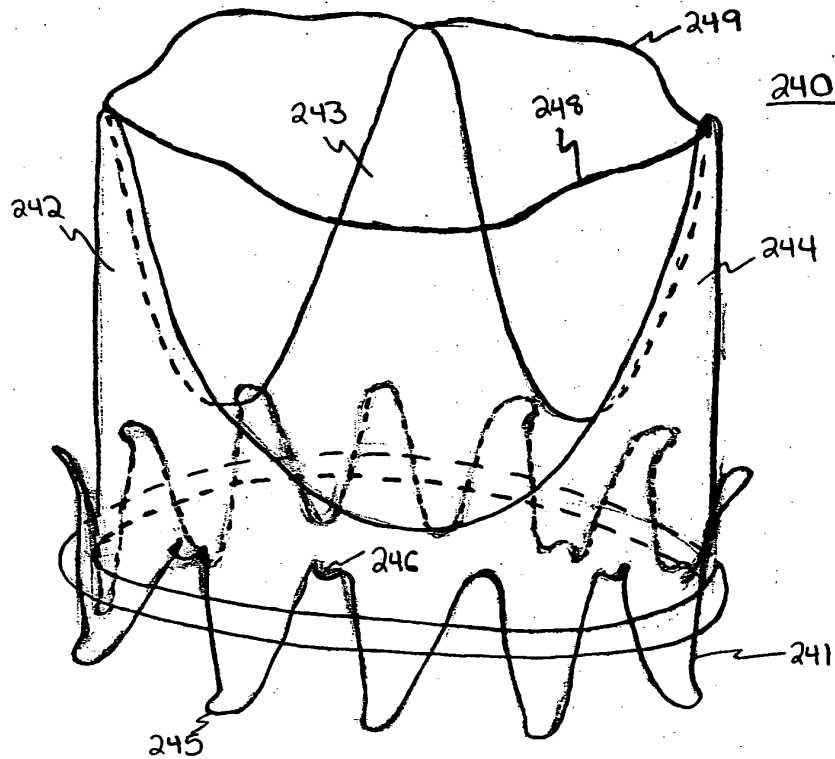


FIG. 24

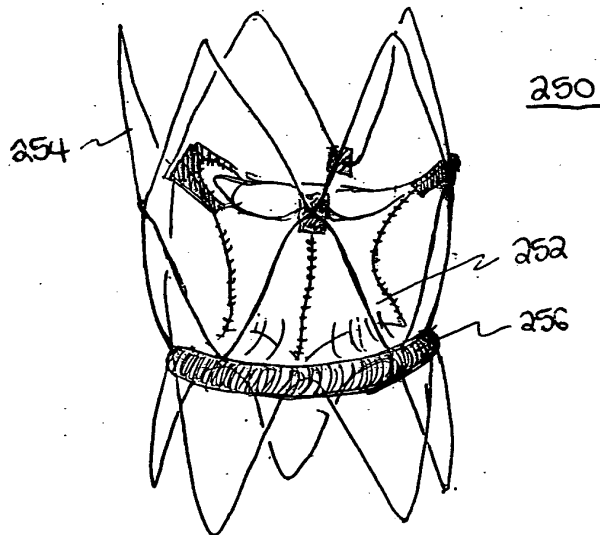


FIG. 25

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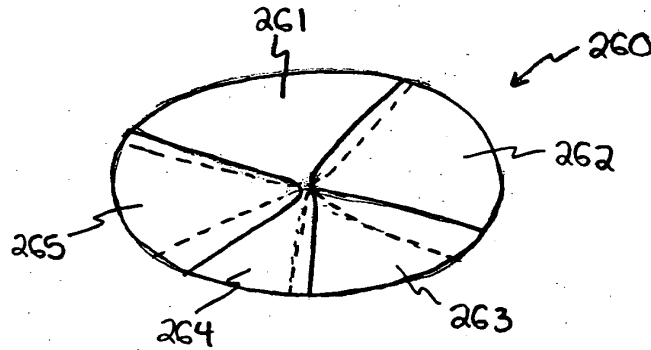


FIG. 26

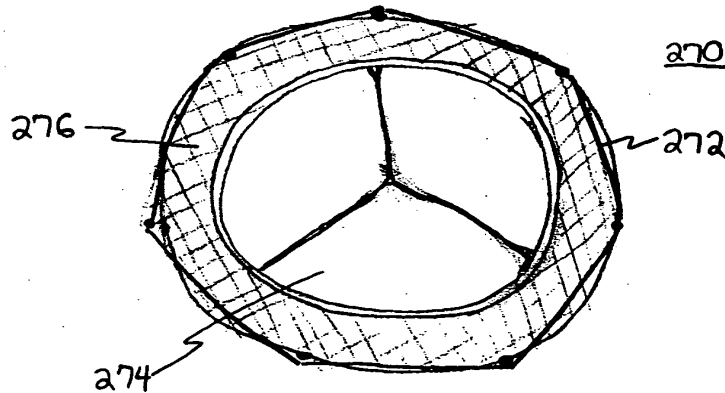


FIG. 27

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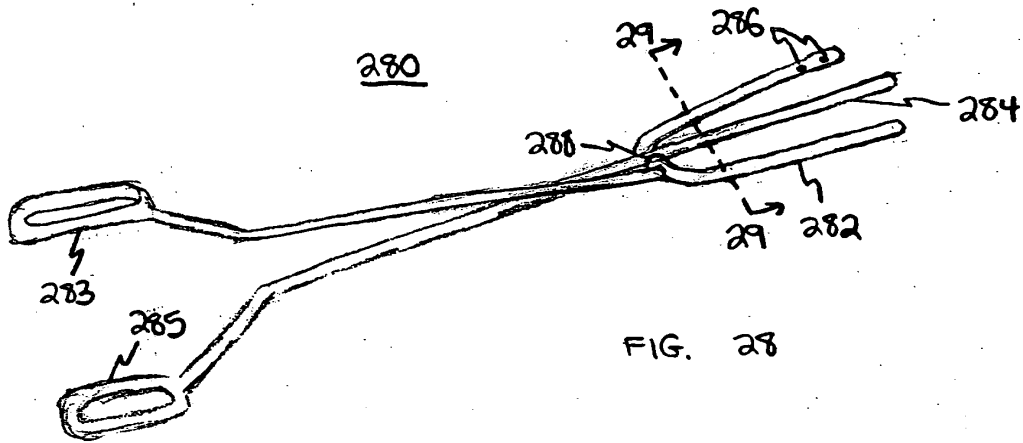


FIG. 28

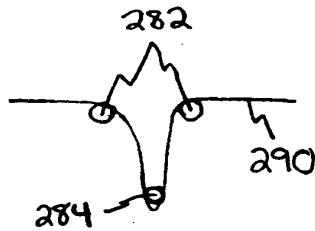


FIG. 29



FIG. 30

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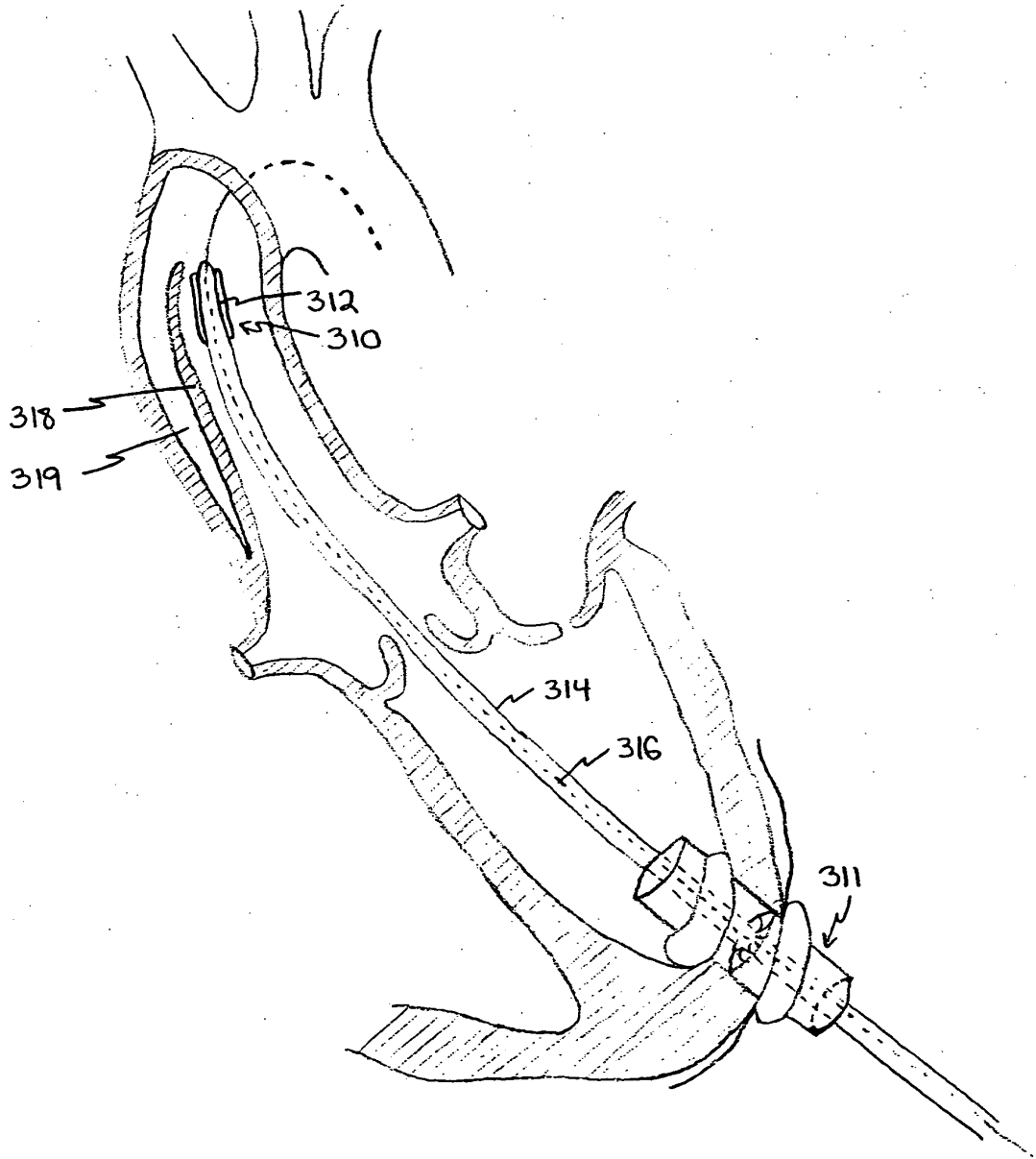


FIG. 31

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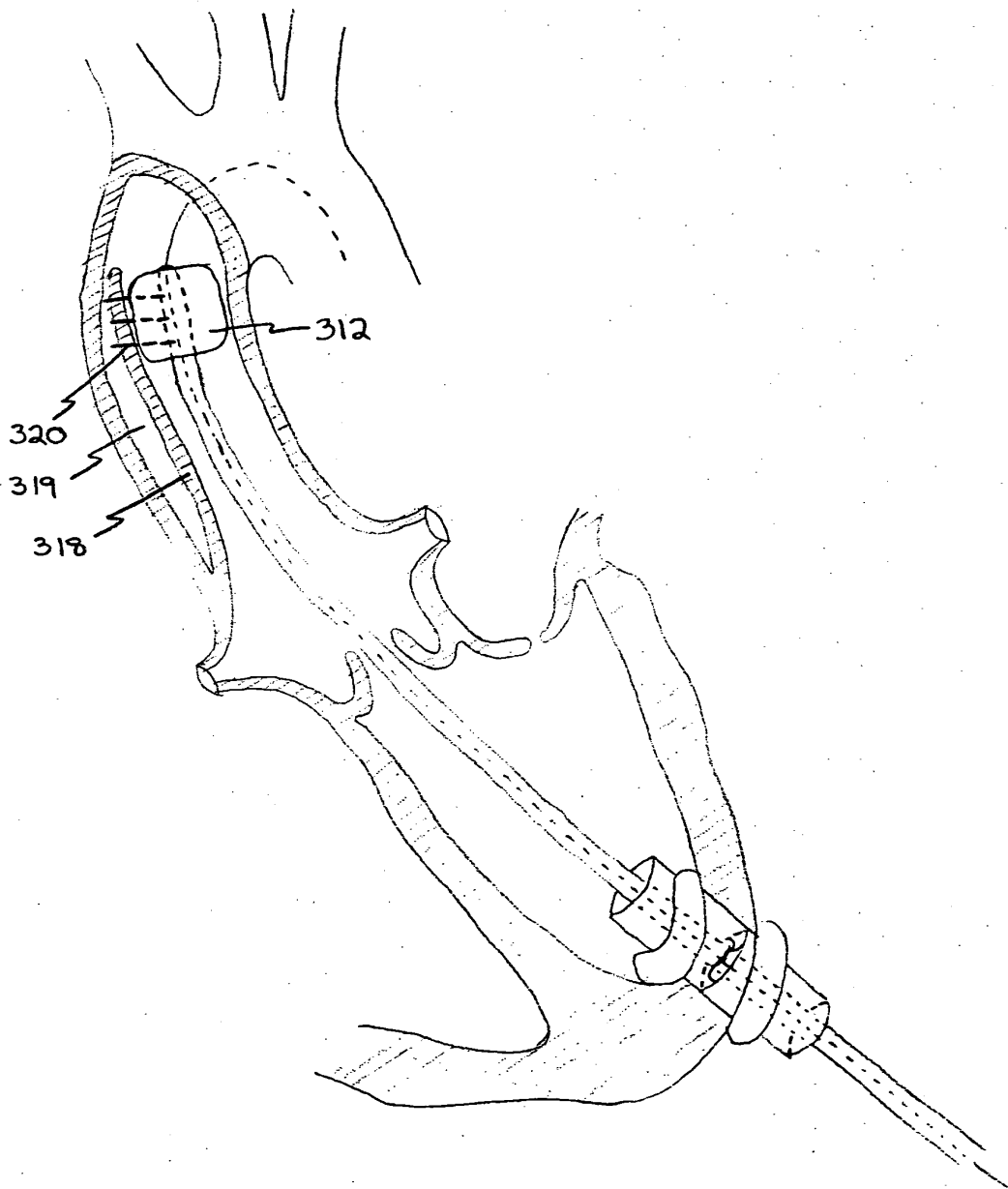


FIG. 32

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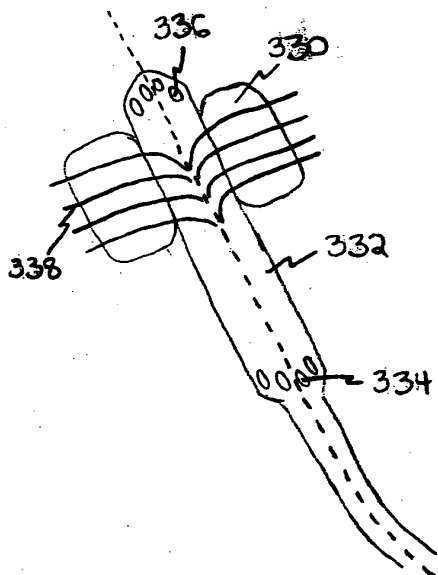
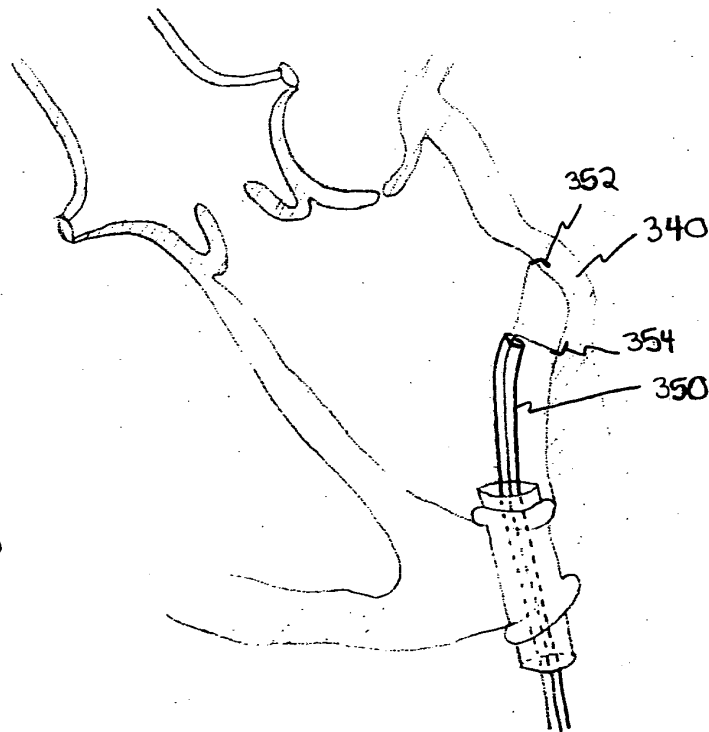
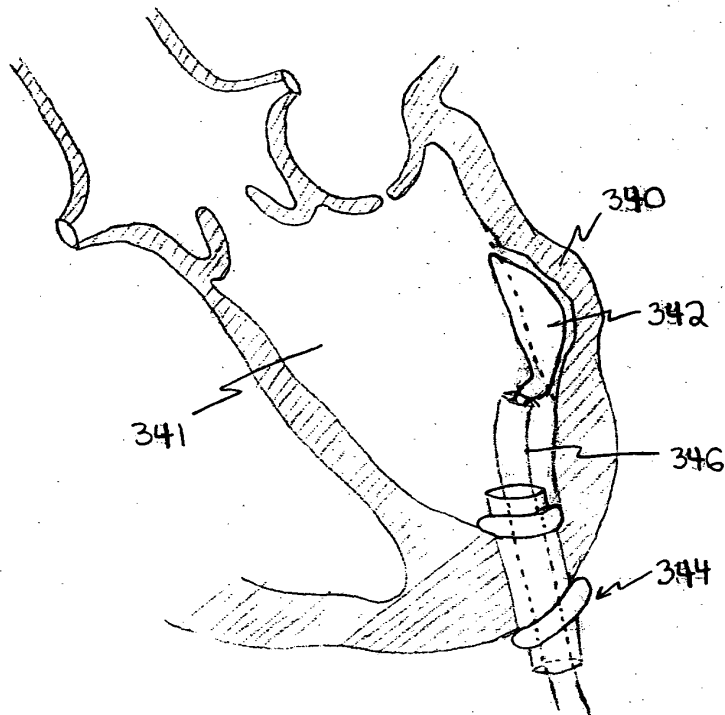


FIG. 33

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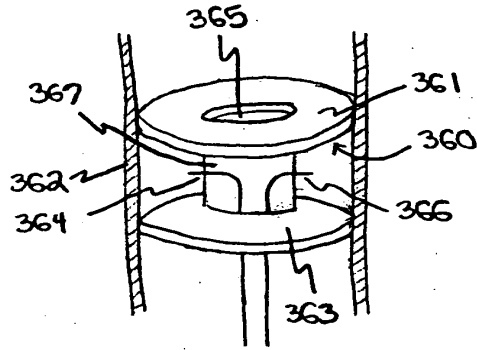


FIG. 36

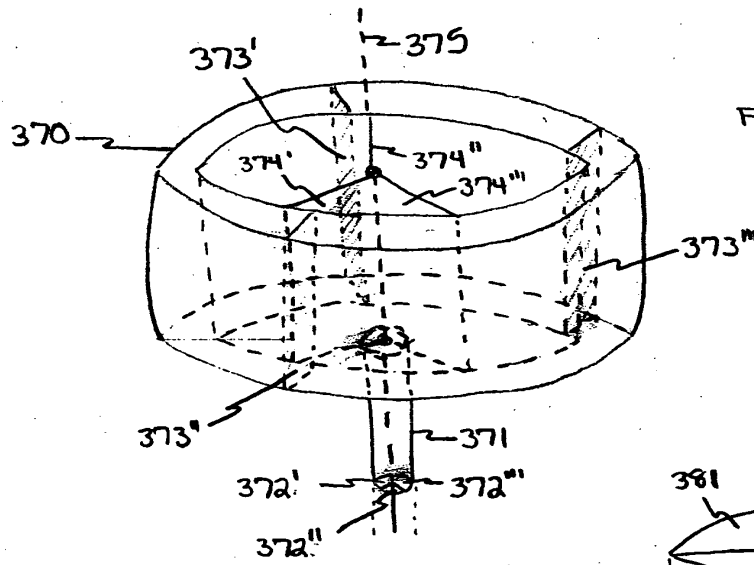


FIG. 37

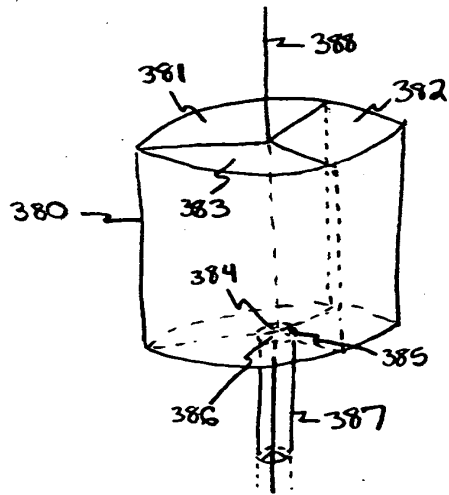


FIG. 38

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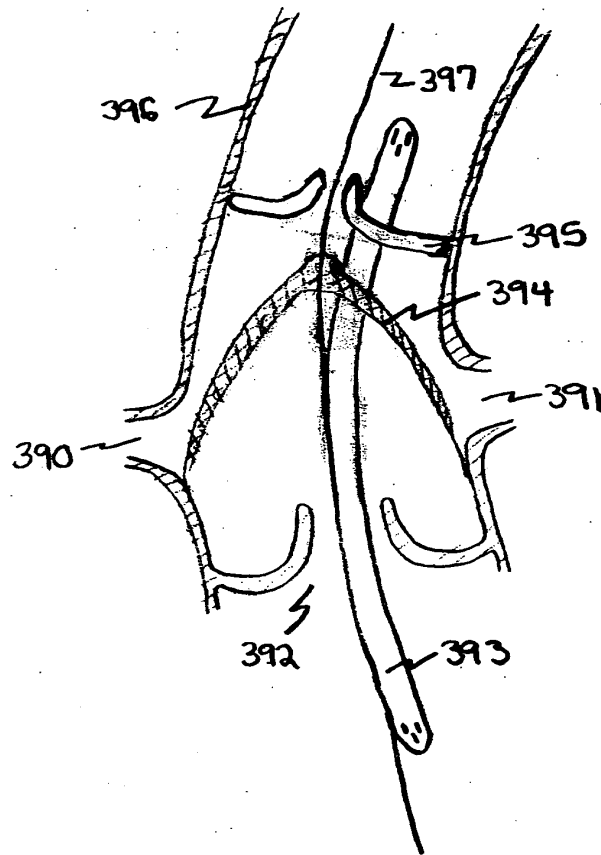


FIG. 39

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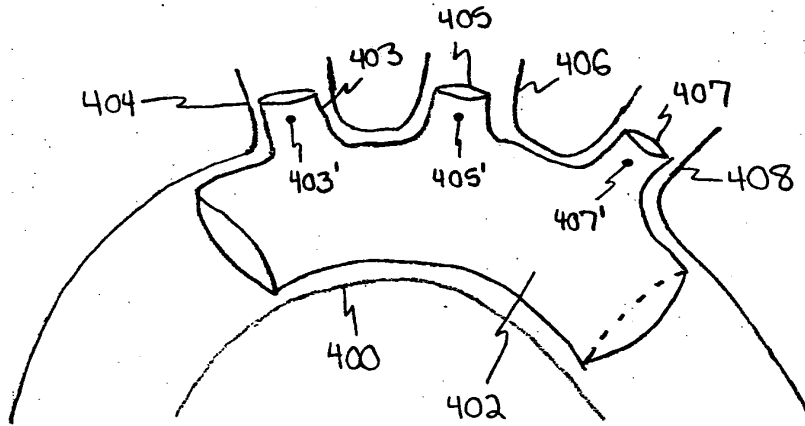


FIG. 40

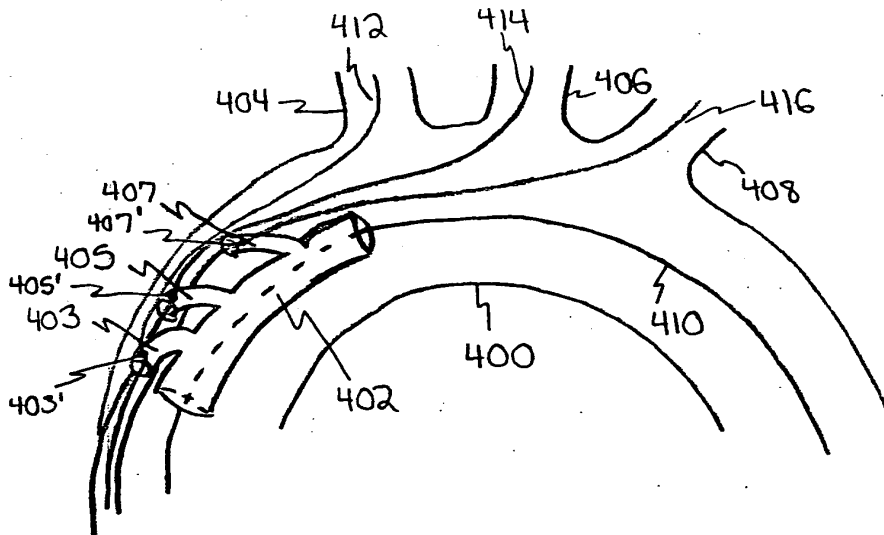


FIG. 41

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293/076

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am an original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT

the specification of which

is attached hereto

was filed on _____ as Application No. _____

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims.

I do not know and do not believe that the invention was ever patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application.

I do not know and do not believe that the invention was in public use or on sale in the United States of America more than one year prior to this application.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known by me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a

filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority
Claimed

(Number) (Country) (Filing Date) [] []
Yes No

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below.

60/615,009 October 2, 2004
(Application No.) (Filing Date)

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known by me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

(Application No.) (Filing Date) (Status) (patented,
pending, abandoned)

As a named inventor, I hereby appoint the following attorneys or agents to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith:

Robert R. Jackson, Reg. No. 26,183
Jeffrey H. Ingerman, Reg. No. 31,069
Stuart W. Yothers, Reg. No. 53,816

Send correspondence to: Stuart W. Yothers
FISH & NEAVE LLP
1251 Avenue of the Americas
New York, New York 10020-1104

Direct telephone calls to: Stuart W. Yothers
(212) 596-9000

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of inventor Christoph Hans Huber

Inventor's signature



12/28/04
Date

Residence 32 Garrison Street
Boston, MA 02116

Citizenship Switzerland and France

Post Office Address 32 Garrison Street
Boston, MA 02116

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

01/04/2005 EFLORES 00000114 11023783

01 FC:1011	300.00	OP
02 FC:1111	500.00	OP
03 FC:1311	200.00	OP
04 FC:1201	2400.00	OP
05 FC:1202	1250.00	OP

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002 — 489-267/69033

PATENT APPLICATION FEE DETERMINATION RECORD
Effective December 8, 2004

11027783

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	45	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	45 minus 20 = *	25
INDEPENDENT CLAIMS	15 minus 3 = *	12
MULTIPLE DEPENDENT CLAIM PRESENT <input type="checkbox"/>		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

1-7 -12 -14 -18 -20
25 -28 -30 -31 32

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

34 -37 -43 -45

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
 The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

SMALL ENTITY TYPE OR

OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	150.00
X\$ 25=	
X100=	
+180=	
TOTAL	

RATE	FEE
BASIC FEE	300.00
X\$50=	1250
X200=	2400
+360=	
TOTAL	

SMALL ENTITY TYPE OR

OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL ADDIT. FEE	

INVENTOR INFORMATION

Inventor One Given Name:: Christoph H
Family Name:: Huber
Postal Address Line One:: 32 Garrison Street
City:: Boston
State or Province:: MA
Country:: USA
Postal or Zip Code:: 02116
City of Residence:: Boston
State or Province of Residence:: MA
Country of Residence:: USA
Citizenship Country:: Switzerland

CORRESPONDENCE INFORMATION

Correspondence Customer Number:: 1473
Electronic Mail One:: syothers@fishneave.com

APPLICATION INFORMATION

Title Line One:: Methods and Devices for Repair or Replac
Title Line Two:: ement of Heart Valves or Adjacent Tissue
Title Line Three:: Without the Need for Full Cardiopulmona
Title Line Four:: ry Support
Total Drawing Sheets:: 25
Formal Drawings?:: No
Application Type:: Utility
Docket Number:: 293/076
Secrecy Order in Parent Appl.?:: No

REPRESENTATIVE INFORMATION

Representative Customer Number:: 1473
Registration Number One:: 53816
Registration Number Two:: 31069
Registration Number Three:: 26183

CONTINUITY INFORMATION

This application is a:: NON PROV. OF PROVISIONAL
> Application One:: 60/615009
Filing Date:: 10-02-2004

Source:: PrintEFS Version 1.0.1