46 of the rotor 44. A radial seal 64 is provided in between the wall of the pump body 34 and a distal stepped region 66 on the rotor shaft 46, the function of which will be described below.

~~[0064]~~[0099] The impeller 48 includes a hub 56 and a plurality of blades 58 extending therefrom. The hub 56 is generally conical and, according to the first broad aspect of the present invention, is hollow throughout to form part of the central lumen of the guide mechanism 16. In this regard, the hub 56 is preferably provided with a gasket or seal member 68 at its distal tip. The seal member 68 may be made of any suitable sealing material (including but not limited to silicone) such that the pump 12 and cannula 14 may be easily progressed along the guide wire 22 for delivery to a desired circulatory site. The seal member 68 should also be robust enough to prevent the ingress of blood into the interior of the rotor hub 56 during pump operation, whether the guide wire 22 remains in place or is fully withdrawn. The blades 58 are dimensioned to reside in close tolerance with the interior surface of the shroud 36. In operation, the blades 58 impart both an axial and radial vector on the blood which causes it to flow outward through the flow ports 38 formed in the shroud 36. As used herein, the term "axial flow" is deemed to include flow characteristics like that shown in FIG. 3, which include both an axial and slight radial component. It is to be readily appreciated that, although shown as an axial flow type, blood pump 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps without departing from the scope of the present invention.

~~[0065]~~[00100] The cannula 14 is coupled at its proximal end to the rotor shroud 36. This may be accomplished in any number of fashions, including but not limited to the use of adhesives. This may also be facilitated by dimensioning the shroud 36 to include a narrow inlet region 70 capable of being received flushly within the proximal end of the cannula 14. The inlet region 70 of the shroud 36 should preferably have a tapered interior surface for establishing a smooth flow transition between the cannula 14 and the region containing the impeller blades 58. Although shown as a single integral element, it is to be understood that the pump body 34 and shroud 36 may comprise two separate (and sometimes separable) components, the significance of which will become apparent below. The pump body 34 and shroud 36 may be constructed from any number of suitable materials, including but not limited

to stainless steel or other medical grade compositions or alloys. The cannula 14 may also be constructed from any number of suitable materials, including but not limited to medical grade plastics. As shown, the cannula 14 may also be fortified with spiral-wound reinforcement wire 72 within the walls of the cannula 14.

~~[0066]~~[00101] The drive cable assembly 18 includes the drive cable 62 and the drive cable sheath 32. The drive cable 62 is coupled to the rotor 44 via the cable adapter 60. The drive cable sheath 32 includes a central lumen 74 and a plurality of side lumens 76. The central lumen 74 serves as a protective covering for the drive cable 62. The central lumen 74, along with the side lumens 76, also forms part of the purge fluid delivery system 26 shown above in FIG. 2, which will be described in greater detail below. The side lumens 76 are provided in fluid communication with the fluid inlet conduit 28, while the central lumen 74 is provided in fluid communication with the fluid outlet conduit 30. The side lumens 76 are thus configured to deliver purge, fluid into the pump 12, while the central lumen 74 is configured to transport purge fluid away from the pump 12 along the length of the drive cable 62.

~~[0067]~~[00102] The pressurized purge fluid within the side lumens 76 may take one of two flow paths upon entry into the pump 12. One flow path passes through the interior of the pump 12 and onward past the radial seal 64 to prevent the ingress of blood into the pump body 34 during pump operation. More specifically, the purge fluid flows distally around the cable adapter 60, through the ball bearing assemblies 50, 52, and onward past the radial seal 64. This egress of purge fluid past the radial seal 64 can be controlled to effectively thwart the ingress of blood past the radial seal 64, which might otherwise cause clotting and/or pump damage. The other flow path is directed back out the central lumen 74 for delivery to the fluid outlet conduit 30. In so doing, this flow path bathes the components of the pump 12 and/or drive cable 62 and thereby reduces frictional heating within the pump 12 and/or the central lumen 74 of the sheath 32 during pump operation.

~~[0068]~~[00103] The "over-the-wire" guide mechanism 16 includes a central lumen through which the guide wire 22 may extend for the purpose of slideably advancing the blood pump 12 and cannula 14 into a desired position within the circulatory system of a patient. In the

embodiment shown, this central lumen is established by forming and co-aligning the individual central lumens within each of the drive cable 62, the cable adapter 60, the shaft 46 and hub 56 of the rotor 44, and the cannula 14. In this regard, the drive cable 62 is preferably of wound-wire construction having a central lumen formed therein. The central lumens within the cable adapter 60, rotor 44, and gasket 68 may be formed via machining or molding processes. These central lumens should preferably be sized such that they permit the slideable passage of the pump 12 and cannula 14 therealong, but do not interfere with or constrain the guide wire 22 to cause inadvertent rotation of the guide wire 22 during pump operation. As noted above, it is also contemplated to remove the guide wire 22 after the pump 12 and cannula 14 are properly positioned in the patient. In this case, the gasket or seal 68 on the hub 56 should be robust enough to reseal after the guide wire 22 is withdrawn and prevent the ingress of blood into the interior of the rotor 44.

~~[0069]~~**[00104]** Referring to FIG. 5, the motor coupler 24 includes a housing 78, a drive shaft adapter 80, and a bearing assembly 82. The drive shaft adapter 80 includes a drive shaft coupler 84 dimensioned to receive a drive shaft of a motor (not shown), and a drive cable coupler 86 dimensioned to receive the drive cable 62. Any of a variety of attachment techniques may be employed to securely fasten the drive cable 62 to the drive cable coupler 86, including but not limited to adhesives, crimping, and laser welding. The drive shaft adapter 80 is rotatably disposed within the housing 78 by the bearing assembly 82. The bearing assembly 82 includes a sleeve 88 (which may alternatively be formed as an integral part of the housing 78) for retaining a pair of ball bearing assemblies 90, 92 and a spring 94 of the type described above. That is, each bearing assembly 90, 92 generally comprises an inner race which rotates along with the drive shaft adapter 80, an outer race which remains in a static and fixed position against the inner surface of the retaining sleeve 88, and a plurality of ball bearings disposed between the inner and outer races. The spring 94 is provided to bias each bearing assembly 90, 92 axially away from one another to reduce axial play during operation.

~~[0070]~~**[00105]** The purge fluid delivery system 26 includes a housing 96 having a central lumen 98, an inflow port 100, and an outflow port 102. The housing 96 is also dimensioned to matingly receive a portion of the motor coupler 24. In this regard, a seal element 104 is

provided sandwiched in between the housing 96 and housing 78 and including an aperture which extends about the drive shaft adapter 80 as it exits the housing 78 to prevent the ingress of purge fluid into the motor coupler 24. A fluid guide structure 106 is also provided within the central lumen 98 for the purpose of separating the inflow and outflow ports 100, 102. The fluid guide structure 106 includes a central lumen 108 through which the drive cable 62 extends, and an elevated portion 110 that retains an O-ring 112 against the inner surface of the central lumen 98 of the housing 96. The drive cable sheath 32 is secured to the housing 96 such that the inflow port 100 is communicatively coupled to the side lumens 76, and the outflow port 102 is communicatively coupled to the central lumen 74. In this fashion, pressurized purge fluid may be introduced through the inflow port 100 via inflow conduit 28, and removed through the outflow port 102 via outflow conduit 30. By way of example, the inflow conduit 28 and outflow conduit 30 may be coupled to their respective ports 100, 102 via barbed connectors 114. Similarly, the inflow and outflow conduits 28, 30 may be equipped with any number of suitable connectors (such as those illustrated by way of example in FIG. 2) for establishing fluid communication with a source of pressurized fluid (not shown). The pressurized fluid source (not shown) may include, but is not necessarily limited to, the use of a syringe, an indeflator, a fluid delivery pump, or an accumulator arrangement to provide the requisite delivery of pressurized fluid. The purge fluid delivery system 26 thus provides a two-way transmission of purge fluid within the drive cable sheath 32 for the purposes of cooling the blood pump 12 and preventing the ingress of blood past the radial seal 64 and into blood pump 12.

~~[0071]~~**[00106]** Referring to FIG. 6, shown is a guidable intra-vascular blood pump system 120 according to a second broad aspect of the present invention. As will be described hereinafter, the intravascular blood pump system 120 differs from the intravascular blood pump system 10 described above only as to the type of guide mechanism employed. In the interest of clarity and consistency, then, like reference numerals will be used to denote like elements and distinctions pointed out where necessary. Moreover, due to the commonality of principles employed in both intravascular blood pump systems 10, 120, a discussion to the level of detail set forth above is not deemed necessary with regard to the intravascular blood

pump system 120. Instead, those aspects in common with the intravascular blood pump 10 are hereby incorporated into the discussion of the intravascular blood pump system 120.

~~[0072]~~**[00107]** In its most general form, the intravascular blood pump system 120 of this second broad aspect of the present invention comprises the blood pump 12 and cannula 14 arrangement, wherein the cannula 14 is equipped with a "side-rigger" or "rapid exchange" guide mechanism 122. In an important aspect of the present invention, the "rapid exchange" or "side-rigger" guide mechanism 122 includes a guide carriage 124 formed along at least a portion of the cannula 14, and a suitable guide element (such as guide wire 22) dimensioned to pass slidably through a lumen (not shown) extending through the guide carriage 124. The "rapid exchange" guide mechanism 122 thereby provides the ability to selectively guide the blood pump 12 and cannula 14 to a predetermined position in the circulatory system of a patient in the manner described above. Namely, the guide wire 22 may be first introduced into the vascular system of a patient through any suitable access point and guided to a desired location within the circulatory system of the patient, i.e. the left ventricle as shown. The blood pump 12 and cannula 14 may thereafter be advanced along the guide wire 22 and positioned in the trans-valvular configuration shown for providing left-heart assist.

~~[0073]~~**[00108]** FIGS. 7-9 further illustrate the "side-rigger" or "rapid-exchange" guide mechanism 122 of this second broad aspect of the present invention. In a preferred embodiment, the "side-rigger" guide mechanism 122 includes a lumen 126 formed within the guide carriage 124. The guide carriage 124 is preferably formed as an integral extension of the wall of the cannula 14. FIGS. 7 and 8 comport with the embodiment shown in FIG. 6, namely illustrating the guide carriage 124 formed along the exterior surface of the cannula 14. FIG. 9 illustrates an alternate embodiment wherein the guide carriage 124 may be formed along the interior surface of the cannula 14. In either case, the guide wire 22 is advanced to a desired location in the vasculature of the patient, after which point the blood pump 12 and cannula 14 can be slidably advanced therealong for delivery to the desired location according to the present invention. The guide wire 22 may thereafter be withdrawn from the patient. If the guide carriage 124 is formed along the exterior surface of the cannula 14 (as shown in FIGS. 7-8), then the cannula 14 should preferably be positioned so that the guide carriage 124 does

not extend in a trans-valvular fashion. For example, with reference to FIG. 6, the guide carriage 124 should be positioned wholly within the left ventricle such that the pulsatile blood flow during beating heart procedures will not inadvertently pass through the side lumen 126 and pass through the aortic valve.

~~[0074]~~[00109] The intravascular blood pump system 120 is constructed in virtually the same manner as the intravascular blood pump system 10 shown and described above, with the exception of the location of the respective guide mechanisms 16, 122. More specifically, because the guide mechanism 122 is disposed along the side of the cannula 14, there is no need to form a central lumen extending through the blood pump 12, drive cable assembly 18, purge fluid delivery system 26, and motor coupler 24 as detailed above with regard to the intravascular blood pump system 10. As such, these components need not be specially machined or molded to include such central lumens as was required with the intravascular blood pump system 10 set forth above.

~~[0075]~~[00110] Referring to FIG. 10, shown is a guidable intravascular blood pump system 130 according to a third broad aspect of the present invention. Again, due to the commonality between many of the same components and features of the intravascular blood pump systems described above and the intravascular blood pump system 130, like reference numerals will be used to denote like elements and distinctions pointed out where necessary. As will be explained in greater detail below, the intravascular blood pump system 130 employs yet another unique and useful guide mechanism according to the present invention. However, because many of the same components are employed, a discussion to the level of detail set forth above is not deemed necessary with regard to the intravascular blood pump system 130. Instead, those aspects in common with the intravascular blood pumps described above are hereby incorporated into the discussion of the intravascular blood pump system 130.

~~[0076]~~[00111] In its most general form, the intravascular blood pump system 130 of this third broad aspect of the present invention comprises the blood pump 12 and cannula 14 arrangement, wherein a "guide catheter" 132 is provided as the guide mechanism for positioning the pump 12 and cannula 14 at a desired location within the circulatory system of

the patient. More specifically, with brief reference to FIG. 12, the intravascular blood pump system 130 is formed in two separate assemblies according to the present invention: a conduit assembly 134 and pump assembly 136. In its most basic form, the conduit assembly 134 comprises the guide catheter 132 and cannula 14 coupled to the rotor shroud 36. The pump assembly 136 is constructed such that the pump body 34 and rotor 44 can be disengaged from the rotor shroud 36 and removed entirely from the conduit assembly 134. Referring again to FIG. 10, this dual construction forms a significant feature of the present invention because it provides the ability to form the blood pump 12 at a desired location in a patient using two separate and distinct steps. The first step involves positioning the conduit assembly 134 (with the pump assembly 136 removed) within a patient such that the shroud 36 and cannula 14 are each disposed in a desired location, such as a trans-valvular configuration for cardiac assist procedures. In an important aspect, the task of positioning the conduit assembly 134 within the patient may be advantageously facilitated through the use of any number of well known guidance mechanisms, including but not limited to guide wires, balloon catheters, imaging wires, guide catheters, and/or techniques involving ultra-sound or flouroscopy. The second step in providing the intravascular blood pump system 130 of the present invention involves advancing the pump assembly 136 through the conduit assembly 134 such that the rotor 44 docks within the shroud 36 to form the pump 12 at the desired location.

~~[0077]~~**[00112]** By way of clarification, the term "cannula" is used to denote cannula 14 because it serves a primary purpose of transporting fluid into the blood pump 12, whereas the term "catheter" is used to denote the catheter 132 because it serves a primary purpose of guiding or directing devices or components (i.e. the pump assembly 136) to a desired location within the body. It is to be readily understood, however, that these terms are only used for convenience and in a general fashion such that the cannula 14 may serve certain guiding functions and the catheter 132 may serve certain fluid transportation functions without departing from the scope of the present invention. For example, the cannula 14 may be equipped with dedicated lumens to receive various guide mechanisms (such as guide wires, balloon catheters, selectively deformable elements such as Nitonol, etc). In similar fashion, the guide catheter 132 may be used to transport fluid to and/or from the patient, such as by providing apertures 138 along predetermined regions of the catheter 132.

~~[0078]~~[00113] FIG. 11 demonstrates a significant feature of the present invention involving the use of the guide catheter 132 to transport fluid to and/or from the patient. An optional perfusion assembly 140 is provided as part of the intravascular blood pump system 130 of the present invention. The perfusion assembly 140 includes a conduit 142 in fluid communication with the apertures 138, which in this case are formed near the distal region of the guide catheter 132 a short distance downstream from the blood pump 12. In use, blood will pass along the exterior of the guide catheter 132 for distribution throughout the body, as well as within the interior of the guide catheter 132 after passing into the apertures 138. The perfusion assembly 140 may then be employed to selectively reroute blood from within the guide catheter 132 to a point within the patient's vasculature downstream from the point where the guide catheter 132 enters the body. A hemostasis valve assembly 146 of the perfusion assembly 140 permits the drive cable assembly 18 to pass through to the purge fluid delivery system 26 while preventing blood flow other than into the perfusion assembly 140. A seal assembly 150 of the purge fluid delivery system 26 permits the drive cable 62 to pass through to the motor 20 while preventing the flow of purge fluid other than into and from the purge fluid delivery system 26. The perfusion assembly 140 includes a control mechanism 148 for selectively controlling the distribution of perfusion blood flow from the perfusion assembly 140 into the patient. This control mechanism 148 may be automatic based on certain feedback criteria or manually operated.

~~[0079]~~[00114] FIGS. 12-17 illustrate an exemplary construction of the intravascular blood pump system 130 according to the third broad aspect of the present invention. As shown in FIG. 12, the conduit assembly 134 may be selectively disengaged so as to remove the pump assembly 136 therefrom. According to the present invention, the conduit assembly 134 may be introduced (without the pump assembly 136) into the circulatory system of a patient and selectively guided such that the rotor shroud 36 and cannula 14 are positioned at a desired location. The pump assembly 136 can thereafter be selectively introduced into the conduit assembly 134. A challenge in such a "back-loading" arrangement is ensuring that the pump assembly 136 docks appropriately within the rotor shroud 36 and is maintained in proper engagement during operation of the resulting pump 12.

~~[0080]~~**[00115]** An exemplary docking arrangement will now be described with reference to FIG. 14. In a preferred embodiment, the rotor 44 may be properly and accurately docked within the shroud 36 by forming angled mating surfaces on corresponding portions of the shroud 36 and pump body 34. More specifically, an angled mating surface may be formed on the interior surface of the rotor shroud 36 along that portion extending proximally from the flow aperture 38. A corresponding angled mating surface may be provided along the exterior surface of the pump body 34 along a distal portion thereof. The mating surfaces shown in FIG. 14 may preferably be formed in the range from about 2 degrees to 10 degrees, and more preferably formed in the range from about 3 degrees to 6 degrees. Mating angles within these ranges are adequate to guide the distal end of the pump body 34 to a point generally flush with the proximal edge of the flow aperture 38 as shown in FIG. 14. In this fashion, the pump assembly 136 and the rotor shroud 36 combine to form the blood pump 12. More importantly, this docking is carried out such that the rotor 44 and rotor blades 58 are maintained in proper position for efficient and safe pump operation.

~~[0081]~~**[00116]** An exemplary biasing scheme for maintaining the pump assembly 136 in this docked relationship will now be described with reference to FIGS. 12-13 and 16-17. The conduit assembly 134 is preferably equipped with a male quick-connect coupling 152 capable of engaging with a female quick-connect coupling 154 forming part of the perfusion assembly 140 of the present invention. A bias spring 156 is provided in between the perfusion assembly 140 and the housing 96 of the purge fluid delivery system 26. The bias spring 156 is preferably dimensioned so as to be in tension when the male quick-connect 152 is engaged within the female quick-connect 154 as part of the docking process of the present invention. As such, the bias spring 156 serves to maintain the pump assembly 136 in the docked position within the rotor shroud 36. The bias spring 156 may be coupled to the housing 96 of the purge fluid delivery system 26 in any number of suitable fashions. One such coupling arrangement may comprise a female quick-connect coupling 158 attached to the housing 96 and a male quick-connect coupling 160 attached to the bias spring 156.

~~[0082]~~[00117] An exemplary embodiment of the perfusion assembly 140 is shown with reference to FIGS. 12-13 and 17. The perfusion assembly 140 shown includes the hemostasis valve 146 coupled to the female quick-connect coupling 154. A length of tubing 162 extends between the opposing barb connectors of the hemostasis valve 146 and the female quick-connect coupling 154. A continuous lumen is formed extending through the interior of the male quick-connect coupling 152, the female-quick-connect coupling 154, the tubing 162, and the hemostasis valve 146. The drive cable assembly 18 extends through this continuous lumen and exits through a Touehy-Borst hemostasis seal 164 which prevents the migration of blood out of the proximal end of the perfusion assembly 140. A side-port 166 is disposed in fluid communication with the central lumen of the perfusion assembly 140. In one embodiment, this side-port 166 may be equipped with a conduit 168 having a stop-cock 170 to selectively control the distribution of blood through a perfusion conduit (i.e. conduit 142 of FIG. 11) coupled to the stop-cock 170. It will be appreciated that this type of manual control system for selectively perfusing the patient may be replaced with control circuitry for automatically controlling the rate of perfusion. Such automatic perfusion may be based on control algorithms based on contemporaneous feedback or pre-programmed thresholds.

~~[0083]~~[00118] The foregoing discussion details a host of inventive aspects forming part of the present invention. It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concepts thereof. The following evidences, by way of example only, various additional aspects forming part of the present invention.

~~[0084]~~[00119] FIG. 18 illustrates an alternate configuration of the intravascular blood pump system 130 of the third broad aspect of the present invention having an alternate bearing assembly, purge fluid delivery, and docking scheme. The bearing assembly includes a seal spring 182 and a bearing assembly 180. The bearing assembly 180 includes an inner race 184, an outer race 186, and a plurality of balls 188 which enable the inner race 184 to rotate along with the rotor shaft 46 while the outer race 186 remains in a static and fixed position relative to an inner surface of the pump body 34. An O-ring 190 is disposed within a groove formed in the rotor shaft 46 so as to maintain the bearing assembly 180 against the seal spring 182. The

O-ring 190 is further secured within the groove in the rotor shaft 46 via a contoured lip portion extending from the distal end of the cable adapter 60. The proximal end of the cable adapter 60 flushly engages the drive cable 62.

~~[0085]~~[00120] The purge fluid delivery system of the embodiment shown in FIG. 18 provides for a one way delivery of purge fluid to the blood pump 12. That is, pressurized fluid (namely, fluid pressurized to some level elevated above the blood pressure in the surrounding vessel) is injected in between the drive cable 62 and the interior of the protective sheath 32 during operation. This serves to reduce any frictional heating that exists between the drive cable 62 and sheath 32. The pressurized fluid also flows through the interior of the pump 12 such that, if the seal at 192 is broken, the pressurized fluid will flow past the open seal 192 and onward through the blood flow ports 38 formed in the shroud 36. This serves to keep blood from entering the pump 12 in an effort to avoid clotting and/or damaging the pump 12.

~~[0086]~~[00121] The pump assembly 136 may be docked within the conduit assembly 134 in any number of different fashions without departing from the scope of the present invention. That is to say, the docking scheme shown in FIG. 18 is set forth by way of example only and is not to be deemed limiting or restrictive as to numerous ways to temporarily engage or "dock" the pump assembly 136 within the conduit assembly 134. The only requirement is that the pump assembly 136 and conduit assembly 134 dock such that the rotor 44 is disposed within the shroud 36 to provide the desired axial flow through the cannula 14 and out the shroud 36. The exemplary docking scheme involves forming an annular engagement groove 194 along the interior of the shroud 36, and forming a complementary annular ridge 196 along the exterior surface of the pump body 34. During insertion, the pump assembly 136 will be advanced into the conduit assembly 134 until the annular ridge 196 on the pump body 34 engages within the groove 194 formed in the shroud 36. This docking scheme is generally advantageous in that the engagement action between the annular ridge 196 and groove 194 will provide tactile feedback to the physician during the process of inserting the pump assembly 136 into the conduit assembly 134 such that the physician will be able to determine when the docking has been completed.

~~[0087]~~[00122] As will be appreciated by those skilled in the art, the location of the annular ridge 196 and engagement groove 194 may be varied such that they are disposed closer or farther away from the flow apertures 38. It may be advantageous to form these docking structures close to the flow apertures 38 in an effort to thwart the ingress of blood into the junction extending between the interior of the shroud 36 and the exterior surface of the pump body 34. It is also contemplated to employ selectively inflatable structures, such as balloons, in an effort to temporarily engage or dock the pump assembly 136 within the conduit assembly 134. In this regard, one or more lumens may be formed within the pump body 34 extending from the interior of the pump body 34 in fluid communication with a balloon disposed along the exterior surface of the pump body 34. The pressurized fluid flowing within the interior of the pump body 34 may then be used to inflate the balloon, which will then engage within an annular groove in the shroud 36, such as at 194. Of course, the engagement structures may also be reversed without departing from the scope of the present invention. For example, the shroud 36 may be equipped with a fluid delivery lumen therein for inflating a balloon disposed on the interior surface of the shroud 36, which may in turn be disposed within an annular engagement groove formed along the exterior surface of the pump body 34.

~~[0088]~~[00123] While this invention has been shown in use largely in during left-heart applications it is to be readily appreciated that this does not limit the applications of this invention for use in left heart support only. Rather, the guidable intravascular blood pump of the present invention can be utilized in right-heart support applications and a wide variety of other applications apparent to those skilled in the art. For example, with reference to FIG. 19, shown is an intravascular blood pump 200 (of the type shown and described above with reference to FIGS. 2-5) configured for use in a right-heart support application. In this embodiment, the intravascular blood pump system 200 is equipped, by way of example, with an "over-the-wire" guide mechanism 16 comprising a balloon catheter 202. It is to be readily appreciated that, although shown and described below in terms of an embodiment of the type shown in FIGS. 2-5, the intravascular blood pump systems 120, 130 disclosed herein may also be configured for use in right-heart applications. Such right-heart configurations, and others apparent to those skilled in the art based on the broad principles enumerated in this application, are contemplated as being within the scope of the present invention.

~~[0089]~~[00124] The intravascular blood pump system 200 is shown positioned within the heart, such as may be advantageous to provide right heart support during beating heart surgery. To position the guidable intravascular blood pump system 200 in the right heart according to the present invention, a suitable guide element (such as balloon catheter 202) is first advanced to a desired location within the heart via the "sail" action of an inflated balloon. After the balloon catheter 202 is located in the desired position (such as in the pulmonary artery as shown), the intravascular blood pump system 200 according to the present invention may be advanced over the balloon catheter 202 and guided into a desired arrangement. For right heart support, this would involve advanced into the pump 12 and cannula 14 overt the balloon catheter 202 until the fluid inlet 204 is disposed within the vena cava (or right atrium) and the fluid outlet 206 is positioned within the pulmonary artery. The pump 12 may then be selectively (i.e. automatically or on-demand) controlled to transport blood from the vena cava (or right atrium) in a trans-valvular fashion through the tricuspid valve, the right ventricle, and the pulmonary valve for deposit within the pulmonary artery. Providing right-heart support during beating heart surgery advantageously overcomes conditions where cardiac output may become compromised during beating heart surgery, such as when the heart is lifted to gain access to posterior vessels, thereby avoiding the need for cardiopulmonary bypass.

~~[0090]~~[00125] It is also contemplated as part of the present invention that the guidable intravascular blood pump systems can be introduced into the patient's vasculature to achieve the intravascular access into the right or left heart through any number of access points, including but not limited to the internal jugular vein, the brachiocephalic vein, carotid artery, axillary artery, femoral vein, femoral artery, and subclavian artery. The intravascular blood pump systems of the present invention may also be introduced via direct introduction, such as into the aorta, the atria, and the ventricles. As is well known in the art, such intravascular access may be achieved percutaneously through the use of the Seldinger technique or directly through the use of minimally invasive access techniques.

~~[0091]~~[00126] Those skilled in the art will also appreciate that, although shown and described above in terms of "axial flow," the present invention is not limited to the axial flow

type intravascular blood pumps. Rather, the intravascular blood pumps 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps, without departing from the scope of the present invention.

~~[0092]~~[00127] With regard to the embodiments shown in FIGS. 10-17, it is furthermore contemplated that the guide catheter 132 may be separable from the conduit assembly 134 after the pump assembly 136 is docked within the shroud 36 to form the pump 12 at the desired location within the circulatory system of the patient. This may be accomplished by providing the guide catheter 132 in a detachable fashion via any number of suitable arrangements. By removing the guide catheter 132 after the pump 12 assembled, wound management of the access point into the patient's vasculature may be improved. This is due, in part, to the substantial reduction in size of the device extending into the patient (i.e. the drive cable assembly 18 as opposed to the larger diameter guide catheter 132).

~~[0093]~~[00128] It is also contemplated to incorporate various pressure sensing and/or guidability features into at least one of the cannula, 14 and pump 12. Such features may include, but are not necessarily limited to, those shown and described in commonly-owned and co-pending U.S. Patent Application Ser. No. 09/280,988 (filed March 30, 1999) entitled "Steerable Cannula," and U.S. Patent Application Ser. No. 09/280,970 (filed March 30, 1999) entitled "Pressure Sensing Cannula," the disclosures of which are hereby expressly incorporated by reference as if set forth herein in their entirety and physically incorporated as APPENDIX A and APPENDIX B respectively to the present specification. These pressure sensing features may include, but are not necessarily limited to, the use of fluid-filled lumens, piezo-electric pressure sensing elements, strain gauges, and analysis of the torque/current relationship (based on the dynamic pressure differential between the inlet and outlet of the pump). The guidability features may include, but are not necessarily limited to, the use of side lumens and deformable materials (i.e. Nitonol).

~~[0094]~~[00129] Various pump and cannula arrangements have been described and shown above for providing right and/or left heart support wherein blood is deliberately re-routed

through and past the right and/or left ventricle in an effort to reduce the volume of blood to be pumped by the particular ventricle. While "unloading" the ventricles in this fashion is preferred in certain instances, it is to be readily understood that the pump and cannula arrangements described herein may also be employed to "preload" the ventricles. Ventricular preloading may be accomplished by positioning the outflow cannula from the pump into a given ventricle such that the pump may be employed to fill or preload the ventricle with blood. This may be particularly useful with the right ventricle. On occasion, the right ventricle is not supplied with sufficient levels of blood from the right atrium such that, upon contraction, the right ventricle delivers an insufficient quantity of blood to the pulmonary artery. This may result when the right ventricle and/or right atrium are in a stressed or distorted condition during surgery. Preloading overcomes this problem by actively supplying blood into the right ventricle, thereby facilitating the delivery of blood into the pulmonary artery. The same technique can be used to preload the left ventricle and thus facilitate the delivery of blood from the left ventricle into the aorta.

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~~————————————~~APPENDIX A – (~~23 SHEETS~~

~~————————~~U.S. SERIAL NO. 09/280,988)

~~TITLE OF THE INVENTION~~

~~[0095]~~[00130] STEERABLE CANNULA

~~[0096] CROSS-REFERENCE TO RELATED APPLICATIONS~~

~~[0097] (Not applicable)~~

~~[0098] STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT~~

~~[0099] (Not applicable)~~

BACKGROUND OF THE INVENTION

~~[00100]~~[00131] 1. Field of the Invention

The invention relates to vascular cannulas for use in medical procedures.

~~[00101]~~[00132] 2. Description of Related Art

~~[00102]~~[00133] In medical applications and specifically in surgery, the list of uses for cannulas is exhaustive. Cannulas are to be distinguished from catheters in that catheters generally have a substantially smaller fluid-carrying capacity are used primarily for sampling or measurement purposes or for delivery of small quantities of fluid, whereas cannulas are generally larger and are used for volumetric fluid transfer. One application of cannulas involves the augmenting or supplementing of pulmonary blood flow through the beating heart during cardiac-surgery by use of one or more cannulas involved in the intake and return of blood into the circulatory system. The cannulas interface between the patient's circulatory system and the mechanical pumps that power the augmentation procedure. Such an application is described in co-pending PCT Application no. PCT/US97/18674 entitled "Single Port Cardiac Support Apparatus", filed October 14, 1997 and incorporated herein by reference in its entirety.

~~[00103]~~[00134] As will be appreciated, precise and quick placement of the cannula in surgical applications is critical, given the severe time constraints facing a surgeon whose patient's vital life sustaining functions have been suspended during the procedure. Currently, methods for placing cannulas in a patient's body are crude, in that they rely on guesswork and trial and error. Specifically, a surgeon will insert the cannula and direct it towards the desired destination, but ultimately must feel by hand, through the patient's tissue for example, whether it has reached that destination. The surgeon may be forced to make several retractions and re-

insertions until the process succeeds. Shortcomings of such a procedure are clear and may include damage to the delicate tissue involved and waste of valuable time. Additionally, constraints on the flexibility of the material are imposed since a prescribed amount of rigidity is required to enable the cannula to be felt through the tissue and insure that the cannula does not collapse under insertion force.

~~[00104]~~[00135] Alternatively, the surgeon may rely on the use of guiding devices such as a guide wire threaded through the cannula. The guide wire is often easier to manipulate than the cannula, and its placement precedes placement of the cannula. After the guide wire is in place, the cannula is pushed along the length of the guide wire, following the guide wire to the desired destination.

~~[00105]~~[00136] It is also known that a flow directed balloon catheter can be used as a guide wire. Balloon catheters are well known in the art and have a multitude of uses, including delivery or removal of fluid from the surgical site. However, flow directed balloon catheters are typically at least an order of magnitude smaller than cannulas. Their small size accordingly severely limits their application since both quantity and rate of fluid flow through the catheter are limited. In fact it is precisely because of their small size that flow directed balloon catheters can be used as guiding devices for the larger, more robust and versatile cannulas. During use as a guiding device for a cannula, the flow directed balloon catheter acts as a guide wire in facilitating the advancement of the cannula to the desired destination. The flow directed balloon catheter is first inserted into place in the patient's body, and the cannula, threaded around the flow directed balloon catheter, is then advanced into the desired position.

~~[00106]~~[00137] Insertion of the flow directed balloon catheter is effected using the inflatable balloon disposed at a distal tip of the flow directed balloon catheter. A lumen in communication with the balloon delivers inflating fluid to the balloon, thereby inflating the balloon and causing it to operate as a "sail" which is pulled along in the blood stream through the natural blood flow in the patient's circulatory system.

~~[00107]~~[00138] The above procedures have met with only limited success, and there exists a long felt need for devices and methods that facilitate placement of a cannula in a patient's body. A system that will assist in the manipulation of the cannula through the vascular structure or other bodily regions of the patient would accordingly serve to make the placement

process more efficient and less time-consuming, improving the chance of overall success of a surgical procedure.

BRIEF SUMMARY OF THE INVENTION

~~[00108]~~[00139] The present invention overcomes the deficiencies of the prior art by providing a cannula which can be steered during its advancement in the body of the patient. Steering is implemented using cables connected to a deformable portion of the cannula. The cables extend to the proximal end of the cannula from where the operator can selectively apply tensional forces to thereby cause the cannula to curve at the deformable portion. The deformable portion is disposed preferable at the distal end of the cannula, but may be located at other sites along the length of the cannula.

~~[00109]~~[00140] In accordance with a second embodiment of the invention, the cannula is provided with more than one cable for facilitating deformation along multiple planes. Additionally, preformed curves may be provided along the length of the cannula, which curves can be either augmented or straightened by applied tension to the cables.

~~[00110]~~[00141] The cannula, in accordance with a third embodiment, is provided with a spiraling wire formed in the cannula wall. The spiraling wire operates to provide rigidity to the body of the cannula and maintain good fluid flow therein. The spiraling wire may comprise a portion of the cable used to impart deformation in an arrangement in accordance with a fourth embodiment of the invention.

~~[00111]~~[00142] In accordance with a fifth embodiment of the invention, the steerable cannula is provided with an inflatable balloon at the distal end thereof for assisting in guiding the cannula to its desired destination. The inflatable balloon is selectively inflatable using a lumen which effects fluid communication between an fluid source and the balloon.

~~[00112] In accordance with a fifth embodiment of the invention, the steerable cannula is provided with an inflatable balloon at the distal end thereof for assisting in guiding the cannula to its desired destination. The inflatable balloon is selectively inflatable using a lumen which effects fluid communication between an fluid source and the balloon.~~

~~[00113]~~[00143] In accordance with a sixth embodiment of the invention, a steerable cannula having a pigtail distal tip configuration is provided.

~~[00114]~~**[00144]** In accordance with a seventh embodiment of the invention, a steerable cannula having a movably supported guide wire is provided.

~~[00115]~~**[00145]** In accordance with an eighth embodiment of the invention, a steerable cannula having an integrally formed guide wire is provided.

~~[00116]~~**[00146]** In accordance with a ninth embodiment of the invention, a steerable cannula is used in a co-axial cannula arrangement.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

~~[00117]~~**[00147]** Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

~~[00118]~~**[00148]** FIG. 20~~1~~ is schematic side view of a steerable cannula in the undeformed state in accordance with the first embodiment of the invention;

~~[00119]~~**[00149]** FIG. 21~~2~~ is a schematic cross-sectional view of the steerable cannula of FIG. 20~~1~~ taken along line A-A~~2-2~~;

~~[00120]~~**[00150]** FIG. 22~~3~~ is a schematic side view of the steerable cannula in the deformed state in accordance with the first embodiment;

~~[00121]~~**[00151]** FIG. 23~~4~~ is a schematic cross-sectional view of a steerable cannula having two cables in accordance with a second embodiment of the invention;

~~[00122]~~**[00152]** FIG. 24~~5~~ is a schematic side view of a steerable cannula having a reinforcing wire in accordance with a third embodiment of the invention;

~~[00123]~~**[00153]** FIG. 25~~6~~ is a schematic cut-away view of a steerable cannula in accordance with a fourth embodiment of the invention;

~~[00124]~~**[00154]** FIG. 26~~7~~ is a schematic cross-sectional view taken along line B-B~~7-7~~ of FIG. 25~~6~~;

~~[00125]~~**[00155]** FIG. 27~~8~~ is a schematic side view of a steerable cannula having a preformed curve and an inflatable balloon formed at a distal end thereof in accordance with a fifth embodiment of the invention;

~~[00126]~~**[00156]** FIG. 28~~9~~ is a schematic side view of the inflatable balloon of fifth embodiment of the invention, wherein the balloon is shown in the inflated state;

~~[00127]~~**[00157]** FIG. 29~~10~~ is a schematic cross-sectional view taken along line C-C~~10-10~~ of FIG. 28~~9~~;

~~[00128]~~**[00158]** FIG. 30~~11~~ is a schematic view showing a steerable cannula having a pigtail distal tip configuration in accordance with a sixth embodiment of the invention;

~~[00129]~~**[00159]** FIG. 31~~12~~ is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with a seventh embodiment of the invention;

~~[00130]~~**[00160]** FIG. 32~~13~~ is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with an eighth embodiment of the invention;

~~[00131]~~**[00161]** FIG. 33~~14~~ is a schematic side view showing a steerable cannula used in a co-axial configuration in accordance with a ninth embodiment of the invention, wherein the steerable cannula is advanced to a first relative position;

~~[00132]~~**[00162]** FIG. 34~~15~~ is a schematic side view showing a steerable cannula of FIG. 33~~14~~, wherein the steerable cannula is advanced to a second relative position; and

~~[00133]~~**[00163]** FIG. 35~~16~~ is a schematic side view of a configuration in accordance with a tenth embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

~~[00134]~~**[00164]** The present invention comprises a steerable cannula in which a portion which is adapted for insertion into the body of a patient, preferably into the vascular system of the patient, is configured to be selectively deformable. The deformation aids in changing the direction of the cannula during the insertion process such that the cannula can be steered in a desired direction as it is advanced toward its destination in the patient's body. Deformation is effected using a cable connected with the deformable portion of the cannula. Tension on the cable, induced by for example rotating a portion of a handle disposed at a proximal end of the cannula exterior of the body of the patient, results in tension on one wall of the deformable portion and thereby causes it to bend in the direction of the cable.

~~[00135]~~**[00165]** With reference to FIGS. 20-23~~1-4~~ in which an exemplary arrangement in accordance with a first embodiment of the invention is shown, cannula 1120 can be seen as comprising a substantially cylindrical structure having a wall 1122 which defines a main lumen 1124. Lumen 1124 is adapted for fluid transport to or from the body of the patient and may be provided with one or more holes 1126 located adjacent to distal tip 1128 and

permitting passage of fluid therethrough. Holes 1126 supplement fluid flow through main port 1125, especially in situations of blockage of main port 1125. Cannula 1120 may be one of two complementary cannulas (not shown) used in a surgical procedure, one for intake and the other for removal of blood or other fluid from the patient's body. Alternatively cannula 1120 may comprise a component of a co-axial, single port device in which cannula 1120 is surrounded by a second, larger conduit, with cannula 1120 for example operating to intake blood from the patient towards a pump system and the conduit operating to replace the blood from the pump back into the patient for augmentation of blood flow during beating heart surgery as described in co-pending PCT Application no. PCT/US97/18674 mentioned above.

~~[00136]~~**[00166]** At a proximal end 1130 of cannula 1120 is provided a handle 1132 which serves to transmit turning forces applied by an operator's hand to the cannula to aid in its manipulation in the patient's body. As such, handle 1132 is rigidly attached to wall 1122 of cannula 1120, although portions of handle 1132 may be configured for motion relative to cannula 1120 in order impart the necessary tension on cables used for deforming the cannula 1120 as described below. Rotation of the rigidly attached portion of handle 1132, results in a corresponding rotation of the distal end 1128 of the cannula 1120 within the patient's body, thus aiding in the cannula's manipulation and advancement to the desired destination.

~~[00137]~~**[00167]** Wall 1122, in addition to defining main lumen 1124 of cannula 1120, contains a secondary lumen 1136 formed therein. Movably mounted in lumen 1136 is a cable 1138 which is secured at point 1140 in wall 1122. Point 1140 may be disposed anywhere along the length of the cannula 1120, but in the preferred embodiment lies at distal end 1128.

~~[00138]~~**[00168]** Cannula 1120 is provided with a deformable portion 1142 formed along at least a segment of its length. In the exemplary arrangement shown in FIGS. 20-22~~1-3~~, deformable portion 1142 is disposed in close proximity to distal end 1128 of cannula 1120; however, it is to be understood that this not intended to be limiting and that other regions in the cannula 1120 can alternatively or additionally be made deformable depending on the contemplated application.

~~[00139]~~**[00169]** Deformable portion 1142 serves to cause cannula 1120 to bend in response to tension applied to cable 1138 and thereby assume a configuration as shown in FIG. 22~~3~~. Depending on the location of point 1140 and the location of lumen 1136 radially and axially along wall 1122, applied tension to cable 1138 causes cannula 1120 to turn on itself in the

direction of pull to thereby assume a curve having a predetermined orientation. Additionally, if cannula 1120 is provided with one or more preformed curves, which may be in identical or in different planes along the length of the cannula as is contemplated, tension in cable 1138 can operate to temporarily straighten the cannula along at least one of these planes to facilitate handling during a particular maneuver through the patient's body.

~~[00140]~~[00170] It is also contemplated that more than one cable can be provided, supported in suitable secondary lumens formed in cannula 1120. As can be seen from FIG. 234, a second lumen 1146 can be provided in wall 1122 of cannula 1120, second lumen 1146 movably supporting cable 1144 therein. Cables 1138 and 1144 are thus disposed on opposite sides of cannula 1120 and serve to provide steerability in two directions. The cables are configured such that a pulling of one cable is coordinated with a slacking of the other cable in order permit bending of cannula 1120 at deformable portion 1142. Although shown to be diametrically opposed in position, cables 1138 and 1144 can occupy any position along wall 1122, and it will be appreciated that the number of such cables used can vary depending on the application, as can their distribution in wall 1122, and any desired number of turning directions can accordingly be achieved in accordance with the present invention.

~~[00141]~~[00171] Wall 1122 can be formed of materials ranging from rigid to flexible, and in the preferred embodiment comprises a semi-rigid transparent material such as silicone rubber. Of course it is to be understood that by definition deformable portion 1142 is to be constructed of a flexible material, regardless of the construction of the remainder of the wall 1122, such that cannula 1120 can bend when appropriate pulling forces are imparted through the cable(s).

~~[00142]~~[00172] Selective bending of cannula 1120 can also be facilitated using a core member provided for this purpose. Core member 1182, preferable formed of material having appreciable stiffness relative to wall 1122, is disposed longitudinally within cannula 1120 and serves to provide a deflection point to locate and control the bending point of the cannula. Core 1182 is removable and can be movable distally or proximally within cannula 1120 in order to alter the deflection point. In this manner also flow blockage in the cannula 1120 can be insured during insertion.

~~[00143]~~[00173] As can be seen from FIG. 245, a spiraling wire 1148 can be provided for structural reinforcement of cannula 1120. Wire 1148 is either molded into the wall 1122 or is otherwise supported therein, and extends either partially or fully across the length of the

cannula 1120. Wire 1148 facilitates handling of the cannula 1120 and reduces the possibility of cannula 1120 collapsing or being pinched shut and thus closing off the flow of fluid to or from the patient. Other ways of reinforcing the tubular body of cannula 1120 are known in the art and will adapt equally well to the present invention. In addition, no reinforcement may be needed if the cannula material is sufficiently rigid or if sufficient fluid flow is present within the cannula.

~~[00144]~~[00174] Alternatively, as shown in FIGS. 25-26~~6-7~~, spiraling wire 1148 can itself comprise a portion of cable 1138. In such an arrangement, cannula wall 1122 is formed of two layers 1162 and 1164, between which is formed a lumen 1166. Layers 1162 and 1164 may be discrete layers bonded together at appropriate regions, or they may be a single layer folded back upon itself to form the two layers, with lumen 1166 and wire 1148 occupying predetermined regions therebetween. Cable 1138 is housed in a polymide tube 1170 disposed in lumen 1166 and extends beyond the end 1168 of tube 1170 to then spiral exteriorly of inner layer 1162 and interiorly of outer layer 1164 to thereby lend structural support to the cannula 1120. Metal or other tape 1172 can be used to secure spiraling wire 1148 in place. In a variation of this, cable 1138 and wire 1148 may be two discrete components which are welded or otherwise connected together at any desired point along the body of cannula 1120. Alternatively, as shown in FIG. 35~~16~~, cable 1138 may be secured to a band 1184 disposed radially about or adjacently to tip 1186 of cannula 1120. In all of these variations, cable 1138 may be formed of single or multiple strands of metal, plastic or carbon fiber composite, but preferably cable 1138 is formed of a single strand of stainless steel having a TEFLON™ coating. In the FIGS. 33-35~~14—16~~ arrangements, cannula 1120 is shown with an atraumatic bullet tip 1186 having side holes 1188 and end holes 1190. It will be appreciated that such a tip can be provided for any arrangement of the invention. It will also be appreciated that the tip 1186 can itself serve as the anchor for the cable 1138 in certain arrangements. The tip 1186 is fixedly bonded to distal end 1125 of cannula 1120 and enables a simplified construction of the steering mechanism and provides a blunt surface that will not injure tissue in the body.

~~[00145]~~[00175] Lumens 1136 and 1146, or other similar lumens, in addition to supporting cables 1138 and 1144 therein, may be used to supply inflating fluid to a balloon 1150 provided at the outer surface of the distal end 1128 of cannula 1120. As shown in the exemplary

embodiment of FIGS. 27-298-10, balloon 1150 is in fluid communication with inflating fluid source 1152, via supply tube 1154 and lumen 1156. Fluid source 1152 serves to selectively provide fluid, such as saline, air or other gas, to balloon 1150 to thereby cause the balloon to inflate within the patient's body. Balloon inflation in this manner assists in placement of the cannula 1120, especially when inserting the cannula antegrade, with the inflated balloon serving to float the tip of cannula within the fluid flow to thus transport it to the desired location in the body. Cannula 1120 is provided with one preformed curve 1158 in addition to curve 1160 imparted by the tension in cable 1138. Balloon 1150 is shown in the deflated state in FIG. 278 and in the inflated state in FIGS. 289 and 2910.

[00146][00176] Various distal tip configurations can be selected for cannula 1120, depending on the particular application as appreciated by those of ordinary skill in the art. For example, a pigtail shape can be used for crossing the aortic valve retrograde. The pigtail shape, illustrated in FIG. 3011, can be formed by bonding or thermal welding or otherwise attaching a thermoplastic rod 1174 formed into a loop at the distal end of the cannula 1120. Alternatively, a J-tip wire 1176 can be configured to protrude from the distal tip 1128, as illustrated in FIGS. 3112 and 3213. The J-tip wire can be a conventional guidewire movable or fixedly supported in a dedicated lumen 1178 formed in a rigidly attached tube 1180 (FIG. 3112), or it can be supported, rigidly or movably, between layers of material from which the wall 1122 of cannula 1120 is formed. Guidewires are known in the art and can for example be formed of windings of wire coiled around a core and having one or more preformed curves formed therein.

[00147][00177] An embodiment in which cannula 1120 is used in a coaxial configuration is shown in FIGS. 3314 and 3415. Cannula 1120 serves as an inner cannula, passing through outer conduit 1180 while the two components are disposed in the patient's body. An important advantage of this arrangement is that outer conduit 1180 operates to vary the radius of curvature of inner cannula 1120 by providing a base point as the inner cannula 1120 is advanced. In this manner manipulation of the inner cannula 1120 and outer conduit 1180 is facilitated and advancement to the desired destination in the body of the patient is more efficiently accomplished.

[00148][00178] The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to one of ordinary skill in the art that modifications

thereto can be made without inventive departure from the spirit and scope of the invention ~~as set forth in the following claims~~.

ABSTRACT OF APPENDIX A~~THE DISCLOSURE~~

~~[00149]~~[00179] A steerable cannula is provided with at least one cable through which tension is communicated to a deformable portion of the cannula. The tension causes the cannula to bend at the deformable portion, enabling selective steering of the cannula during insertion into the body of the patient.

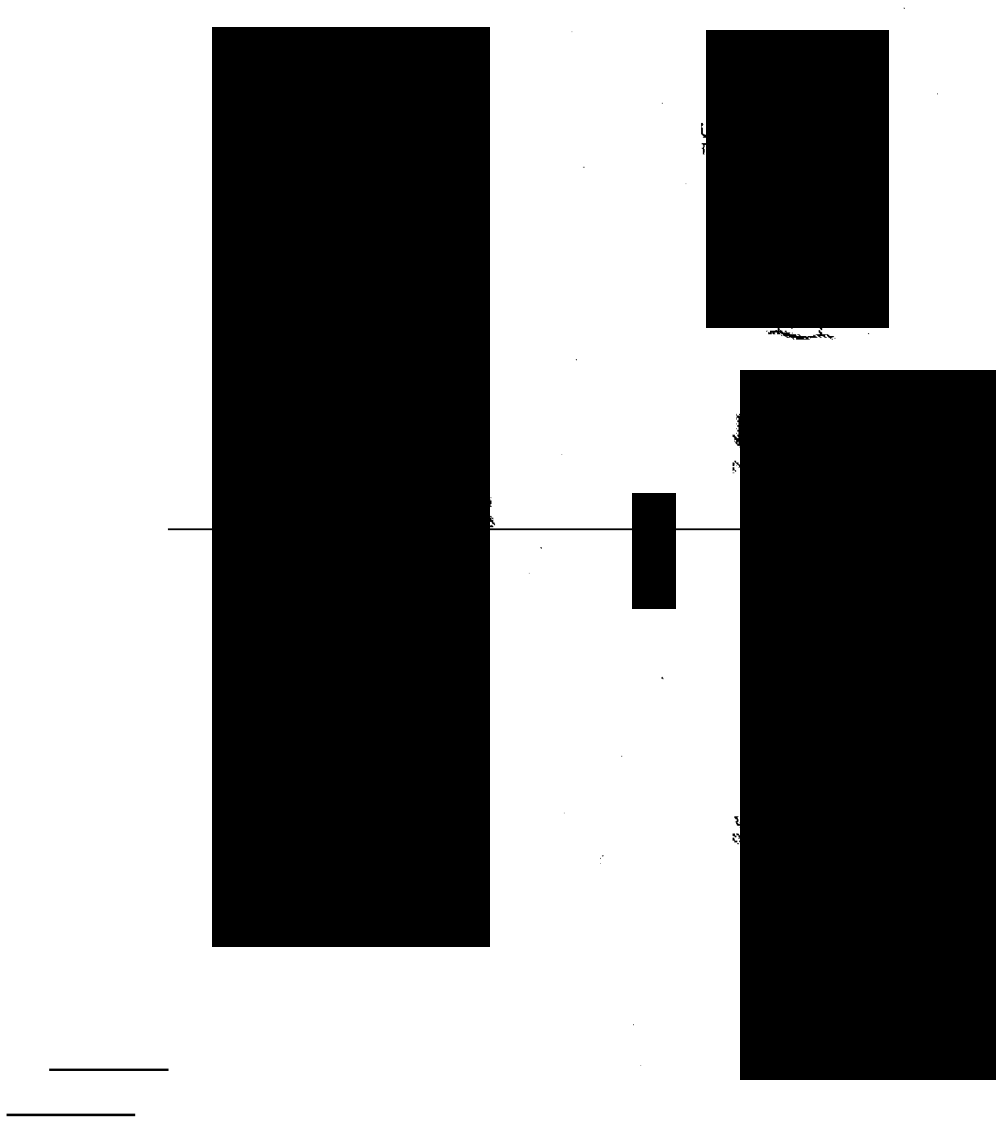


FIG. 2

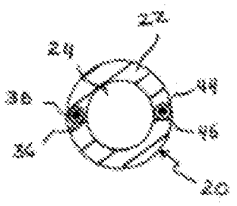


FIG. 4

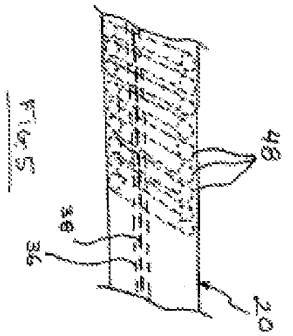
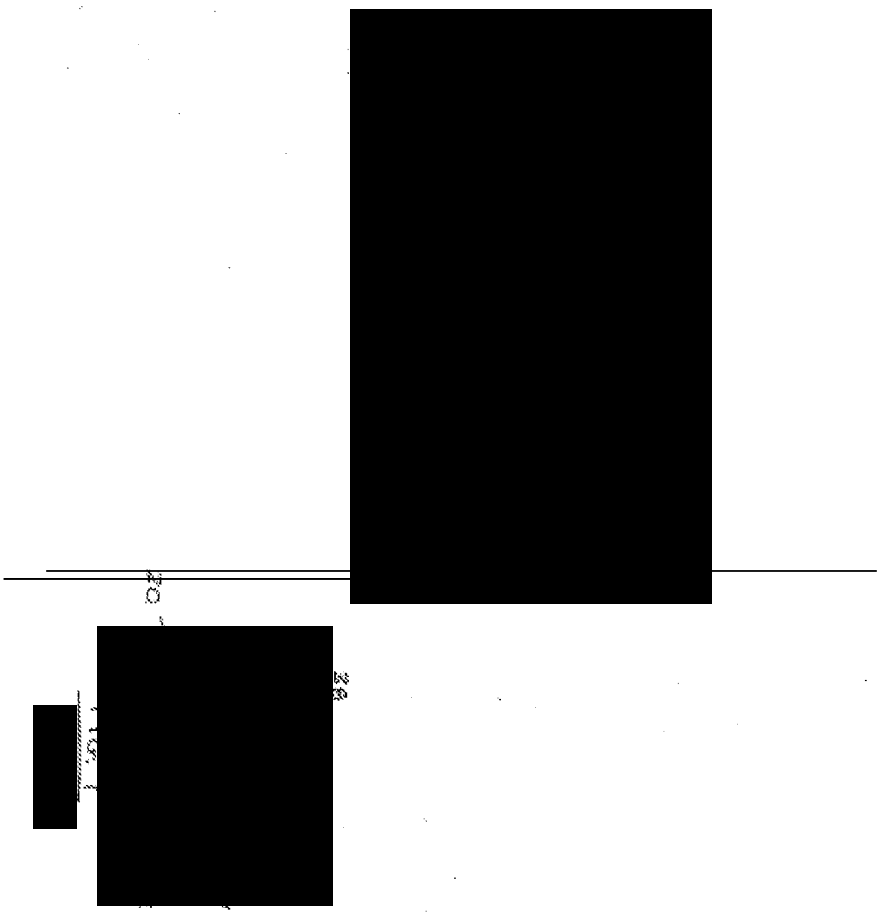
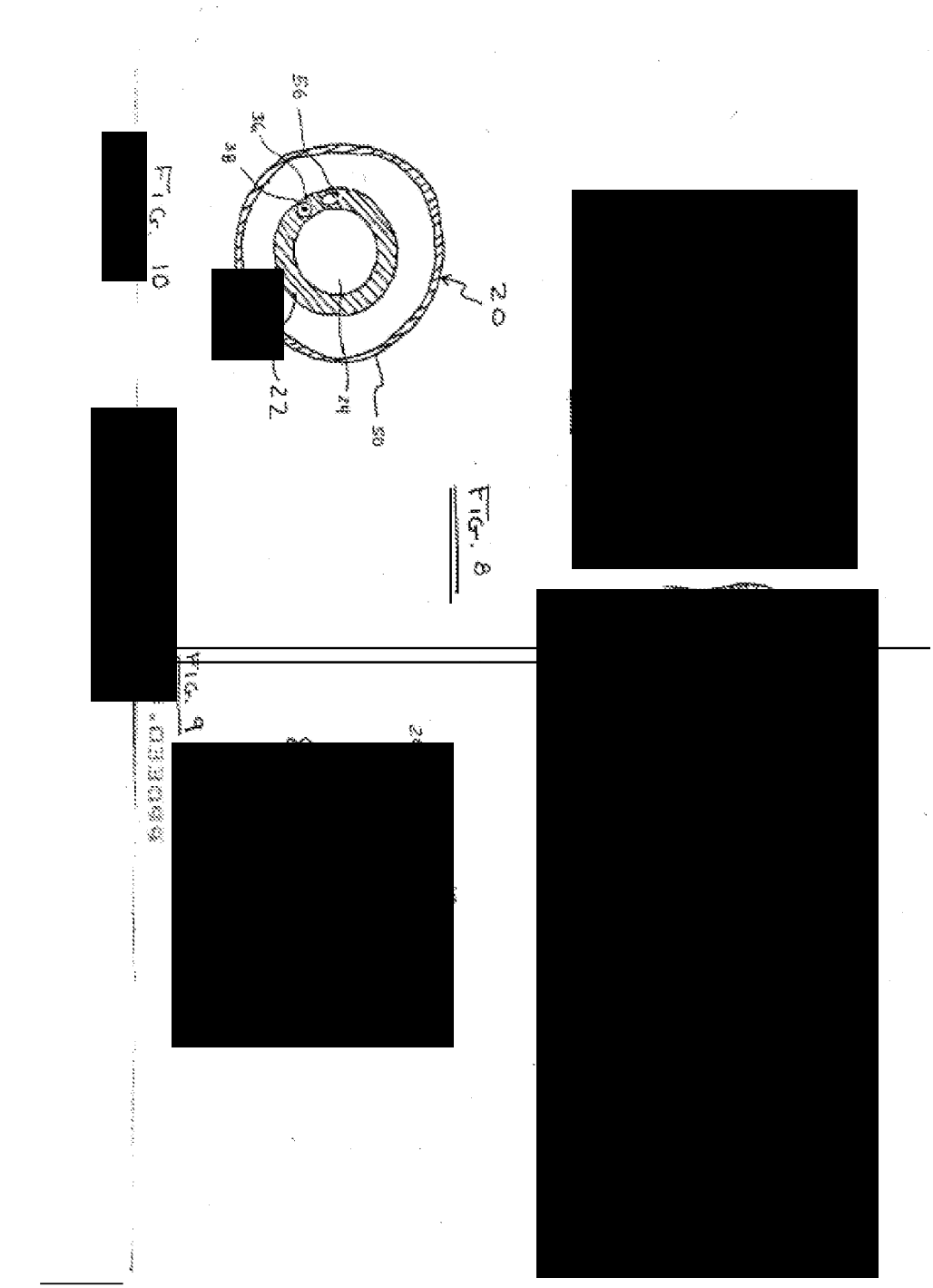
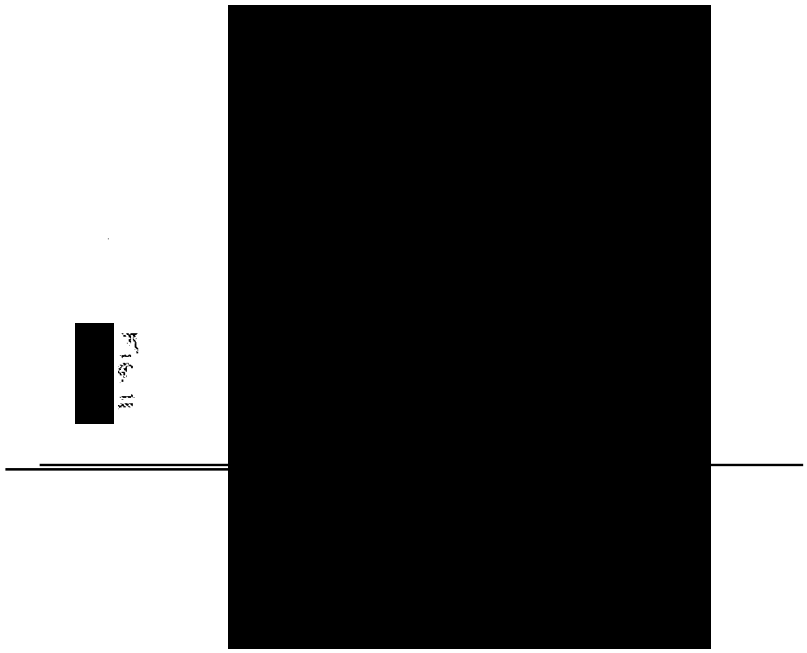


Fig. 5





(51)



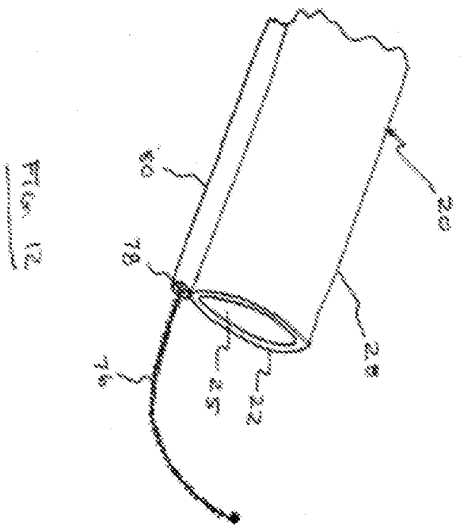
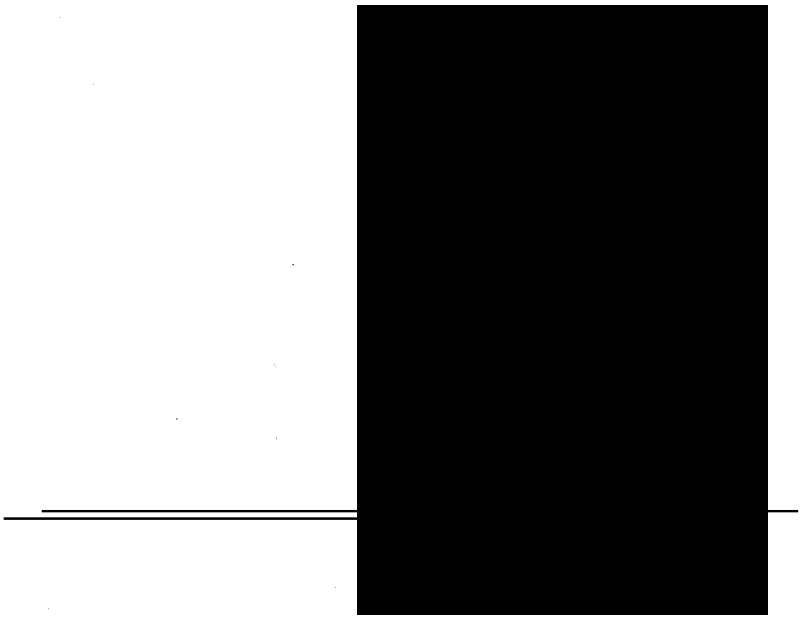
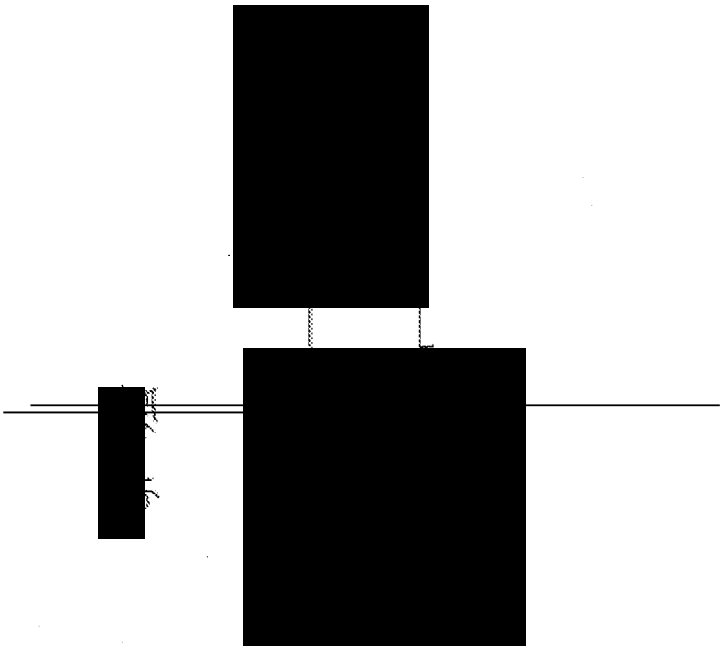


Fig. 12





(56)

~~APPENDIX B – (23 SHEETS~~

~~U.S. SERIAL NO. 09/280,970)~~

(57)

~~PRESSURE SENSING CANNULA~~

[00180] PRESSURE SENSING CANNULA

~~[00150]~~**[00181]** BACKGROUND OF THE INVENTION

~~[00151]~~**[00182]** FIELD OF THE INVENTION

The present invention relates to cannulas used in surgical applications, and more particularly, to a cannula equipped with a pressure/flow rate transducer.

~~[00152]~~**[00183]** DESCRIPTION OF THE RELATED ART

In medical applications and specifically in surgery, the list of uses for cannulas is exhaustive. One application involves the augmenting or supplementing of pulmonary blood flow through the beating heart during cardio-surgery by use of one or more cannulas involved in the intake and return of blood into the circulatory system. The cannulas interface between the patient's circulatory system and the mechanical pumps that power the augmentation procedure. Such an application is described in co-pending PCT Application no. PCT/US97/18674 entitled "Single Port Cardiac Support Apparatus", filed October 14, 1997 and incorporated herein by reference in its entirety.

~~[00153]~~**[00184]** When performing cardiac surgery cannulas are placed within the patient's blood stream and used for inflow and outflow of blood or other fluids. If the operator wishes to determine the rate of fluid flow, either a catheter with appropriate sensors must also be placed in the patient's blood stream, or other sensors such as an external ultrasonic sensor as disclosed in U. S. Patent No. 5,179,862 are used. A shortcoming of ultrasonic systems such as that described in 5,179,862 is that they require significant monitoring. Ultrasonic sensors also require that tubing of a specific diameter be used, thereby adding to the cost and complexity of the surgical procedure. Additionally, ultrasonic sensors are expensive and nondisposable, thereby adding to the cost of the surgical procedure.

~~[00154]~~**[00185]** Another method to measure flow rate is through the use of a thermodilution catheter. Thermodilution catheters require the infusion of a solution, typically saline, of a known temperature, with a distally disposed thermistor measuring the temperature change to determine the flow rate. This method is also expensive, increasing the cost of the surgical procedure. A second problem with using flow-sensing catheters, such as thermodilution catheters, is that they require the operator to place more incisions within the patient. The

catheters must be placed so that they do not interfere with the inflow or out flow of the cannula. Visual markers along the length of the cannula may also be used to determine location, the greater the number of markers the more accurate the placement at the expense of quick readings due to the greater number of markings.

SUMMARY OF THE INVENTION

~~[00155]~~[00186] The present invention overcomes the deficiencies of the prior art by providing a cannula assembly having one or more pressure transducers coupled to a main lumen thereof. In accordance with a first embodiment, the pressure transducers are attached to the substantially tubular wall defining the main lumen.

~~[00156]~~[00187] In accordance with a second embodiment, a partial occlusion is provided in the cannula to increase the pressure drop across the main lumen. In this manner transducer signal is increased, and an improved differential pressure measurement signal achieved.

~~[00157]~~[00188] In accordance with a third embodiment of the invention, one or more pressure transducers are used in conjunction with a pair of coaxial cannulas for measuring pressure.

~~[00158]~~[00189] In accordance with at fourth embodiment of the invention, a differential pressure transducer is used, the differential pressure transducer being mounted in a dedicated secondary lumen in communication with the first lumen.

~~[00159]~~[00190] In accordance with a fifth embodiment of the invention, the secondary lumen housing the differential pressure transducer is disposed across a knee formed in the cannula to augment pressure measurement. Partial occlusions may also be provided for this purpose.

~~[00160]~~[00191] In accordance with a sixth embodiment of the invention, the secondary lumen housing the differential pressure transducer is formed integrally with the tubular wall defining the main lumen.

~~[00161]~~[00192] In accordance with a seventh embodiment of the invention, a soft, flexible tapered tip is provided at the distal end of the cannula. Such a configuration allows for easier negotiation through the patient's body during surgical procedure.

~~[00162]~~[00193] In accordance with an eighth embodiment of the invention, an inflatable balloon is provided at the distal end of the cannula. The inflatable balloon aids in transporting the cannula to the desired destination.

~~[00163]~~[00194] In accordance with a ninth embodiment of the invention, a guide wire lumen is provided for supporting a guide wire in the cannula. The guide wire is used as a predecessor step in the insertion of the cannula.

~~[00164]~~[00195] In accordance with a tenth embodiment of the invention, a light guide is supported in the cannula. The light guide conveys light to a predetermined portion of the cannula to thereby aid in the visualization and location of the cannula during the surgical procedure.

~~[00165]~~[00196] The invention realizes various advantages over the prior art, including a reduction in the number of incisions that a surgeon must make in performing surgical procedures, along with a reduction in the amount of foreign material introduced into the patient's body, while providing safe, rapid, accurate and cost-effective fluid flow rate measurements.

BRIEF DESCRIPTION OF THE DRAWINGS

~~[00166]~~[00197] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

~~[00167]~~[00198] FIG. 36~~1~~ is a schematic side view of a first embodiment of the invention;

~~[00168]~~[00199] FIG. 37~~2~~ is a schematic cross-sectional view taken along line D-D~~2~~ ~~2~~ of FIG. 36~~1~~;

~~[00169]~~[00200] FIG. 38~~3~~ is a schematic cross-sectional view taken along line E-E~~3~~ ~~3~~ of FIG. 36~~1~~;

~~[00170]~~[00201] FIG. 39~~4~~ is a schematic view of a cannula in accordance with the invention in a surgical application;

~~[00171]~~[00202] FIG. 40~~5~~ is a schematic partial cut-away side view of a second embodiment of the invention;

~~[00172]~~[00203] FIG. 41~~6~~ is a schematic cross-sectional view taken along line F-F~~6~~ ~~6~~ of FIG. 40~~5~~;

~~[00173]~~[00204] FIG. 42~~7~~ is a schematic side view of a third embodiment of the invention;

~~[00174]~~[00205] FIG. 43~~8~~ is a schematic side view of a fourth embodiment of the invention;

~~[00175]~~[00206] FIG. 44~~9~~ is a schematic side view of a fifth embodiment of the invention;

~~[00176]~~[00207] FIG. 45~~10~~ is a schematic side view of a sixth embodiment of the invention;

~~[00177]~~[00208] FIG. 46~~11~~ is a schematic cross sectional view taken along line G-G~~11-11~~ of FIG. 45~~10~~;

~~[00178]~~[00209] FIG. 47~~12~~ is a schematic side view of a seventh embodiment of the invention;

~~[00179]~~[00210] FIGS. 48~~13~~ and 49~~14~~ are schematic side views of an eighth embodiment of the invention;

~~[00180]~~[00211] FIG. 50~~15~~ is a schematic cross-sectional view taken along line H-H~~15-15~~ of FIG. 49~~14~~;

~~[00181]~~[00212] FIG. 51~~16~~ is a schematic side view of a ninth embodiment of the invention;

~~[00182]~~[00213] FIG. 52~~17~~ is a schematic side view of a tenth embodiment of the invention; and

~~[00183]~~[00214] FIG. 53~~18~~ is a schematic cross-sectional view taken along line J-J~~18-18~~ of FIG. 52~~17~~; and

~~[00184]~~[00215] FIG. 54~~19~~ is a schematic side view of an eleventh embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

~~[00185]~~[00216] In accordance with the invention, a cannula comprising a substantially tubular, semi-flexible material adapted for fluid transport while inserted in a patient's body is provided with one or more pressure transducers which are fixedly or adjustably supported in the cannula. The pressure transducers are disposed internally or externally of the cannula and are used to provide a measurement of the rate of fluid flow. In the internal configuration, the rate of fluid flow within the cannula is measured. In the external configuration, the rate of fluid flow outside the cannula is measured. The cannula can also be adapted to support a guide wire to aid the operator in its insertion through the patient's body, and/or a light source to provide a visual reference during the insertion procedure. It is to be understood that the use of the term "cannula" is intended to encompass cannulas, catheters, and any related devices having similar application.

~~[00186]~~[00217] An exemplary arrangement in accordance with a first embodiment of the invention is shown FIGS. 36-38~~1-3~~. Cannula 2220 comprises a substantially cylindrical

structure having a wall 2228 defining a main lumen 2221. Wall 2228 can be formed of materials ranging from rigid to flexible, and in the preferred embodiment comprises a semi-rigid transparent material such as polyurethane, silicone rubber or other material. Lumens other than main lumen 2221 may also be provided, as described below. The cannula may also be formed from vinyl plastisol. To form a cannula of vinyl plastisol, a mandrel is dipped into liquid vinyl plastisol and heated. Wire is then wrapped around the mandrel and first formed layer. The mandrel is then dipped again encasing the wire, and then heated. The mandrel is then removed. Lumens and transducers may be formed within the wall of the cannula during the dipping process.

~~[00187]~~[00218] To lend structural support for the thin wall which allows maximum flow with minimal insertion damage, spiraling wire 2230 is provided for reinforcement and is either molded into the wall 2228 or is otherwise supported therein, and extends either partially or fully across the length of the cannula 2220. Wire 2230 facilitates handling of the cannula 2220 and reduces the possibility of cannula 2220 collapsing or being pinched shut and thus closing off the flow of fluid to or from the patient. Other ways of reinforcing the tubular body of cannula 2220 are known in the art and will adapt equally well to the present invention. In addition, no reinforcement may be needed if the cannula material is sufficiently rigid or if sufficient fluid flow is present within the cannula.

~~[00188]~~[00219] A connector 2223 is provided at the proximal 2225 end of cannula 2220. Connector 2223 is suitably sized to interface with various surgical instruments, including but not limited to a reverse flow pump or fluid conduits leading thereto (not shown). Cannula 2220 may also have one or more holes 2226 located adjacent to distal tip 2222 to facilitate fluid flow therethrough. Cannula 2220 may be one of two complementary cannulas used in a surgical procedure, one for intake and the other for removal of blood or other biocompatible fluid from the patient's body. Alternatively, cannula 2220 may comprise a component of a co-axial, single port device in which cannula 2220 is surrounded by a second, larger conduit, with cannula 2220 for example operating to intake blood from the patient towards a pump system and the conduit operating to replace the blood from the pump system back into the patient for augmentation of blood flow during beating heart surgery as described in the co-pending PCT Application No. PCT/US97/18674 mentioned above.

~~[00189]~~[00220] In order to provide real time fluid flow information in accordance with the present invention, a pair of pressure transducers 2224, 2232 are provided at two separate locations as illustrated in FIG. 364. Pressure transducers 2224, 2232 are of the type known in the art and each comprises for instance a piezo-electric crystal housed in an integrated circuit (IC) chip (not shown). The crystal configuration is designed to be pressure sensitive, generating an electrical signal in proportion to the amount of pressure experienced.

~~[00190]~~[00221] The principle governing the relationship between fluid flow and pressure is defined by Bernoulli's equation, herein solved for flow rate V and is determined by:

$$V = \sqrt{\frac{\Delta P \cdot 2d \cdot a^2}{f \cdot L \cdot \rho}}$$

where ΔP is the measured difference in pressure, d is the internal diameter of the lumen, a is the area of the lumen, f is a frictional factor of the lumen material, L is the lumen length over which the pressure measurement is conducted, and ρ is a measurable constant representative of the density of the fluid. The flow rate information can be used for a variety of purposes, including monitoring the patient's condition and controlling the fluid pump used during the procedure.

~~[00191]~~[00222] In the preferred embodiment, transducers 2224, 2232 are imbedded in the wall 2228, which is formed for instance by application of successive layers of laminate and interjecting the transducers therebetween during the layering process. Depending on at what stage in the layering process the transducers 2224, 2232 are put in place in the wall 2228, their proximity to the interior of the cannula 2220 or its exterior can be controlled in order to optimize measurement of cannula interior or exterior pressure. From the interior pressure measurements, a determination of flow rate within main lumen 2221 can be made using the known diameter of the main lumen 2221. Similarly, from the exterior pressure measurements, flow rate of exterior fluid--for example, blood--can be measured if the diameter of the blood

channel, such as the artery, is known, or the cannula can be calibrated with thermodilution catheters which assume the diameter of the vessel or artery they are placed within.

~~[00192]~~[00223] In the FIG. 36~~1~~ exemplary arrangement, pressure transducer 2232 is disposed at a location near the distal tip 2222 of cannula 2220, while pressure transducer 2224 may be disposed anywhere along the length of cannula 2220 between pressure transducer 2232 and proximal end 2225. It is also contemplated that the pressure transducers 2224, 2232 may be detachably disposed in dedicated secondary lumens formed in or along tubular wall 2228, the dedicated secondary lumen extending to the proximal end 2225 and supporting any electrical cables connected to the pressure transducers 2224, 2232. In the detachable arrangement, the location of pressure transducers 2224, 2232 in the cannula 2220 can be adjusted to suit the particular application, such that one transducer can be disposed within one chamber of the heart while the other is at a different of portion of the heart to thereby provide a pressure/flow rate measurement of a predetermined portion of the patient's body, for example flow into the heart from a designated blood vessel. Such an application is shown in~~if~~ FIG. 394.

~~[00193]~~[00224] Pressure transducers 2224, 2232 are in electrical communication with console 2236 via cable 2238, which is supported in secondary lumen 2242 provided in cannula 2220. Calculations for determining fluid flow rate using signals generated by the pressure transducers 2224, 2232 and relayed via cable 2238 are conducted at the console 2236 or at any processor or processing system connected thereto.

~~[00194]~~[00225] As shown in FIGS. 40~~5~~ and 41~~6~~, cannula 2220 may also contain a partial occlusion portion 2247 that forms a venturi 2246 within the main lumen 2221 of cannula 2220. Venturi 2246, which may be disposed anywhere along the length of the cannula 2220, induces a pronounced pressure drop, creating a greater differential in pressure between proximal region 2225 and distal region 2222, thereby requiring less signal amplification of the pressure transducers and less filtering of the signal and consequently yielding a more accurate flow rate measurement. Preferably the location of the pressure transducer 2232 is in the vicinity of venturi 2246 as shown in FIG. 54~~19~~.

~~[00195]~~[00226] FIG. 42~~7~~ shows an embodiment in accordance with the invention in which the pressure transducers 2224, 2232 are used with a co-axial, single port device 2250 in which cannula 2220 is surrounded by a second, larger conduit 2248, with cannula 2220 for example

operating to intake blood from the patient towards a pump system (not shown) and conduit 2248 operating to replace the blood from the pump system, via openings 2252, back into the patient for augmentation of blood flow during beating heart surgery as described in the co-pending PCT Application no. PCT/US97/18674 mentioned above. It is to be understood that pressure transducers 2224, 2232 can be mounted fixedly or detachably either to the interior or exterior of either the cannula 2220 or the conduit 2248 in the above-described manner. More than one pair of these transducers can also be used in a myriad possible combinations in accordance with the invention. In the preferred embodiment, the cannula 2220 is provided with a bullet nosed tip, as illustrated in for example FIGS. 42-447 9. Other tip configurations, such as a bevel, may also be used, as will be appreciated by those skilled in the art.

[00196][00227] An alternative to using pairs of pressure transducers such as transducers 2224, 2232 is the use of a single differential pressure transducer 2254, as shown in FIG. 438. Differential pressure transducers are also well known in the art and comprise for example a piezo-electric crystal electro-mechanically configured to be responsive to a pressure difference between two opposing sides thereof. These two sides correspond respectively to proximal end 2257 and distal end 2259 of secondary lumen 2256 in which transducer 2254 is mounted. Proximal and distal ends 2257 and 2259 are attached at any desired points along the length of cannula 2220 to thereby couple secondary lumen 2256 to main lumen 2221 and provide a pressure difference measurement between the desired points. Attachment of lumen 2257 and transducer 2254 across knee 2249 of cannula 2220, as shown in FIG. 449, will provide a stronger signal, with knee 2249 operating in accordance with the same principal as venturi 2246 discussed above. Thus it is to be understood that a venturi could also be used in conjunction with the differential pressure transducer 2254. The ports 2261 and 2263 at which the lumen 2256 interfaces with cannula 2220 may be sealed by an appropriate membrane, with saline or other fluid being permanently housed in the lumen 2256. Alternatively, ports 2261 and 2263 may be open, permitting fluid communication between the cannula 2220 and the lumen 2256 and attached transducer 2254. The latter, open configuration would achieve a more faithful pressure representation. Stopcocks 2274 and 2276 can be provided in the ports 2261 and 2263 to permit priming and/or de-airing of the ports. It should also be noted that although in the arrangements of FIGS. 438 and 449 the lumen 2256 is provided as a separate tubular structure, lumen 2256 may alternatively be formed integrally with wall 2228 of

cannula 2220, again with ports 2261 and 2263 being either open or closed to main lumen 2221 depending on the application. Such an arrangement is illustrated in FIGS. 45~~10~~ and 46~~11~~ in which is shown transducer 225454 in communication with lumen 2272 integrally formed in wall 2228 of cannula 2220.

~~[00197]~~[00228] Various distal tip configurations can be selected for cannula 2220 and used with the pressure sensing transducers, depending on the particular application as appreciated by those of ordinary skill in the art. FIG. 47~~12~~ shows an exemplary embodiment in which the distal tip 2222 is formed of a soft, flexible material having a bullet shape. As shown exemplarily in FIGS. 48-50~~13-15~~, the cannula 2220 may be equipped to support other tools, such as an inflatable balloon 2240 which is deployed for example in order to assist in transporting the distal tip 2222 to the desired destination in the patient's body during the surgical procedure. Balloon 2240 is inflated through an inflating lumen 2244 provided in cannula 2220 using a bio-compatible fluid such as saline or carbon dioxide gas. Preferably inflating lumen 2244 is formed integrally within wall 2228, by leaving an appropriate gap during the fabrication process, and is provided with a fitting (not shown) at its proximal end to interface with an inflating device for supplying the bio-compatible fluid. The lumen 2221 within the cannula 2220 can also be adapted to support a balloon catheter (not shown) which can be used to place the cannula within the patient's body. An obturator (not shown) may also be disposed through the main lumen 2221 to aid in insertion and guiding within the patient's body.

~~[00198]~~[00229] Another tool which cannula 2220 may support is shown in FIG. 51~~16~~ and comprises a J-hook guidewire 2262 disposed slideably within lumen 2264, which is formed integrally in wall 2228 of cannula 2220. In operation, guidewire 2262, easier to manipulate than the cannula 2220, is first inserted into the patient's body and manipulated to the surgical site. Subsequently the cannula 2220 is maneuvering along the guidewire 2262, which passes through lumen 2264, to the desired destination.

~~[00199]~~[00230] As illustrated in FIGS. 52~~17~~ and 53~~18~~, cannula 2220 may also contain a light guide 2266, which may be supported in lumen 2268. Light guide 2266 comprises one or more optical fibers formed of, for example, glass or other materials, such as plastic, known for that purpose. Distal tip of light guide 2266 is configured for light projection, such that light provided at the proximal end of light guide 2266 is projected therefrom. An appropriate shape

for such projection is a spherical shape, although other shapes and projection schemes, such as directional projection, fall within the purview of the invention. The source of light may be any conventional monochromatic (laser/LED) or polychromatic device 2270, and more than one light source with associated light guide can be used for color coding and providing a visual reference to different portions of the cannula 2220, depending on the colors of light used and on the location of the projection terminus of the light guides. In this manner cannula 2220 can be visually guided through the patient's body, relying on the transmissivity of tissue to permit the location of the illuminated cannula in the patient's body. As will be appreciated, the location of the cannula 2220 can also be determined by examining the pressure waveform detected by the pressure transducers 2224, 2232 and 2254. The physiological pressure waveform recorded by the transducers can be used to determine the location of cannula 2220 in relation to the valves of the patient's heart.

~~[00200]~~**[00231]** As will be appreciated by those skilled in the art, cannula 2220 may be provided with one or more preformed curves along its length to aid in its manipulation through the patient's vasculature. Multiple curves may be disposed along the same plane or in different planes, depending on the application.

~~[00201]~~**[00232]** An additional feature in accordance with the invention is the use of radiopaque markings (not shown) anywhere along the cannula body. Such markings render portions of the cannula 2220 visible to x-ray radiation for visualizing the cannula during its use.

~~[00202]~~**[00233]** The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to those skilled in the art that modifications thereto can be made without departure from the spirit and scope of the invention~~as set forth in the following claims~~. It will also be apparent that all devices and methods herein disclosed will adapt equally to animal use as well as human use.

ABSTRACT OF APPENDIX B~~THE DISCLOSURE~~

[0023~~4~~06] A cannula is provided with one or more pressure transducers for measuring fluid pressure interiorly or exteriorly of the cannula. The pressure transducers may be mounted integrally with the tubular wall defining the main lumen of the cannula, or they may comprise differential pressure transducers mounted in dedicated lumens in communication with the main lumen. The pressure measurements from the transducers is used to determine fluid flow rate.

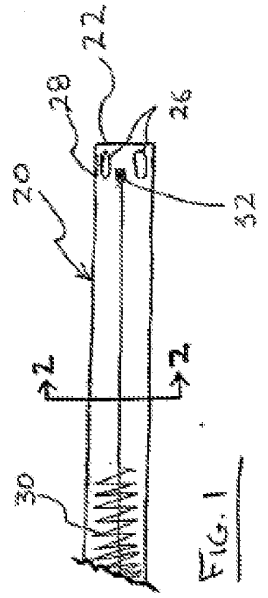


FIG. 1

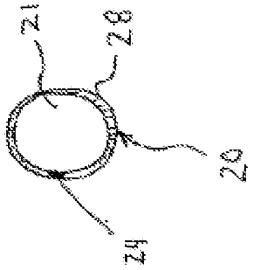
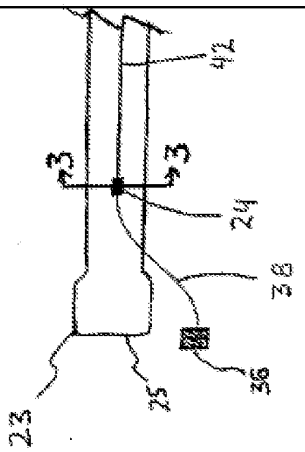


FIG. 3



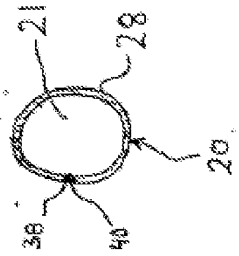


FIG 2

(69)

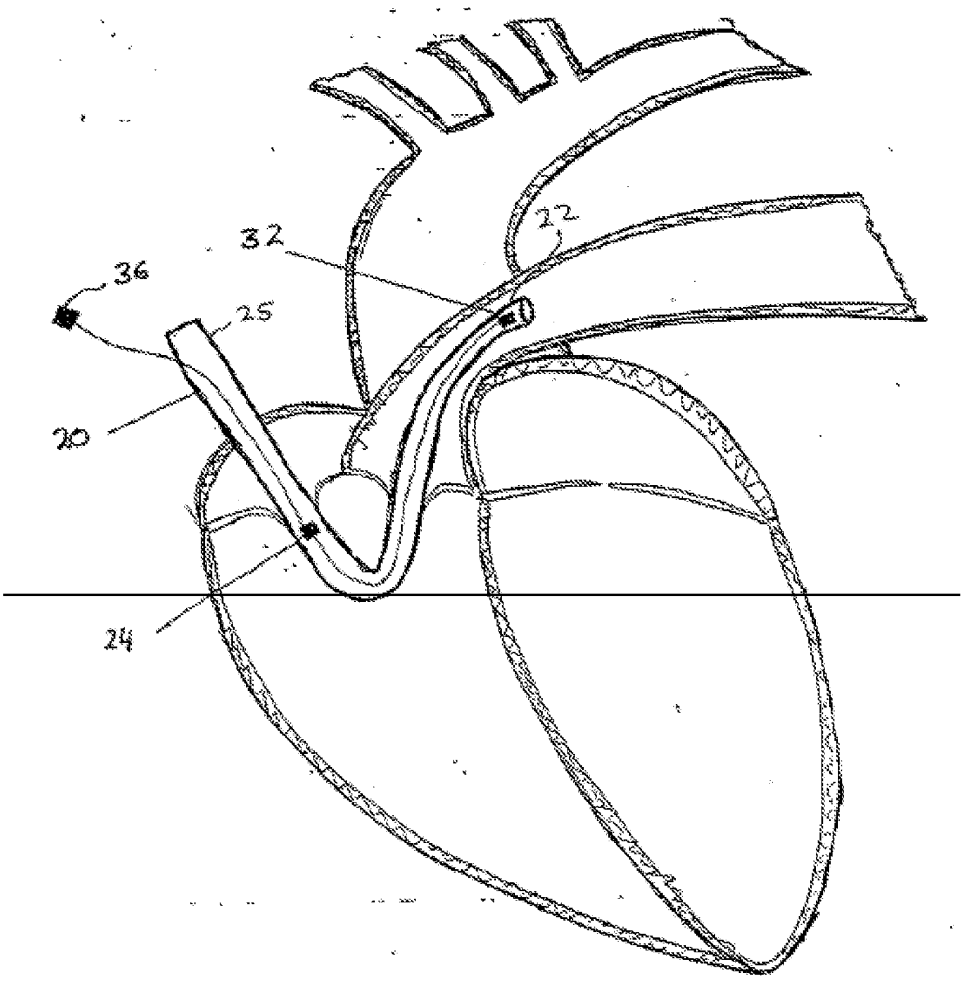
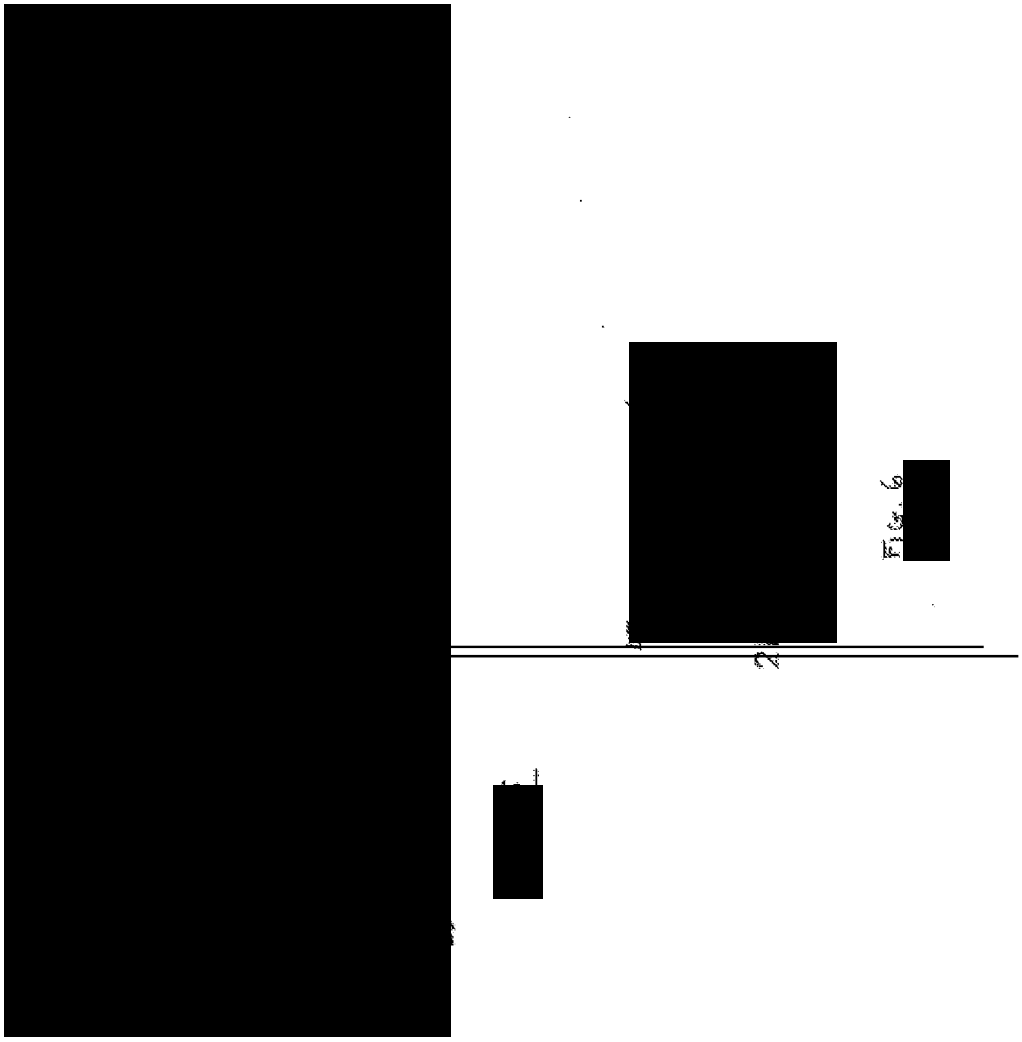


FIG. 4

(70)



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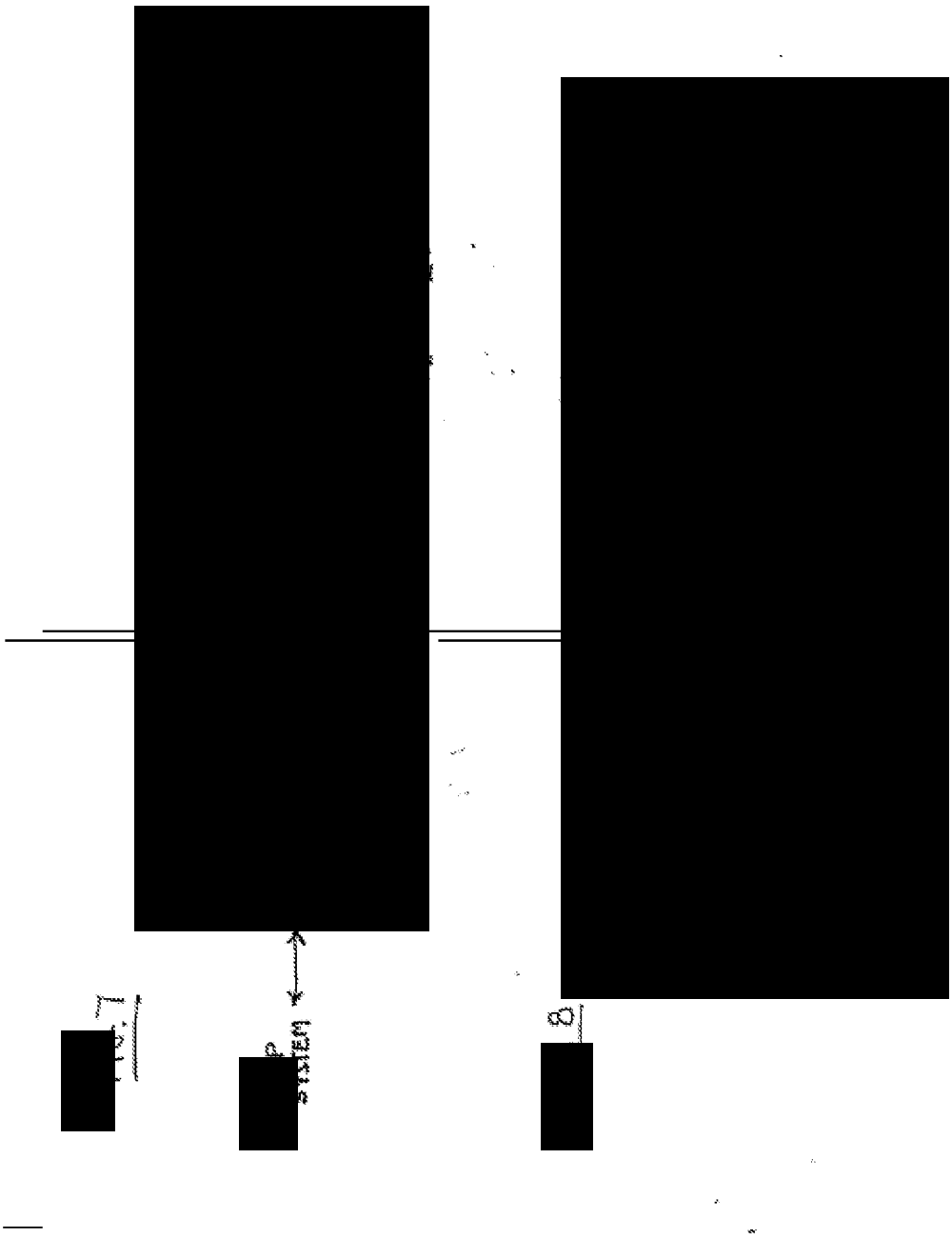

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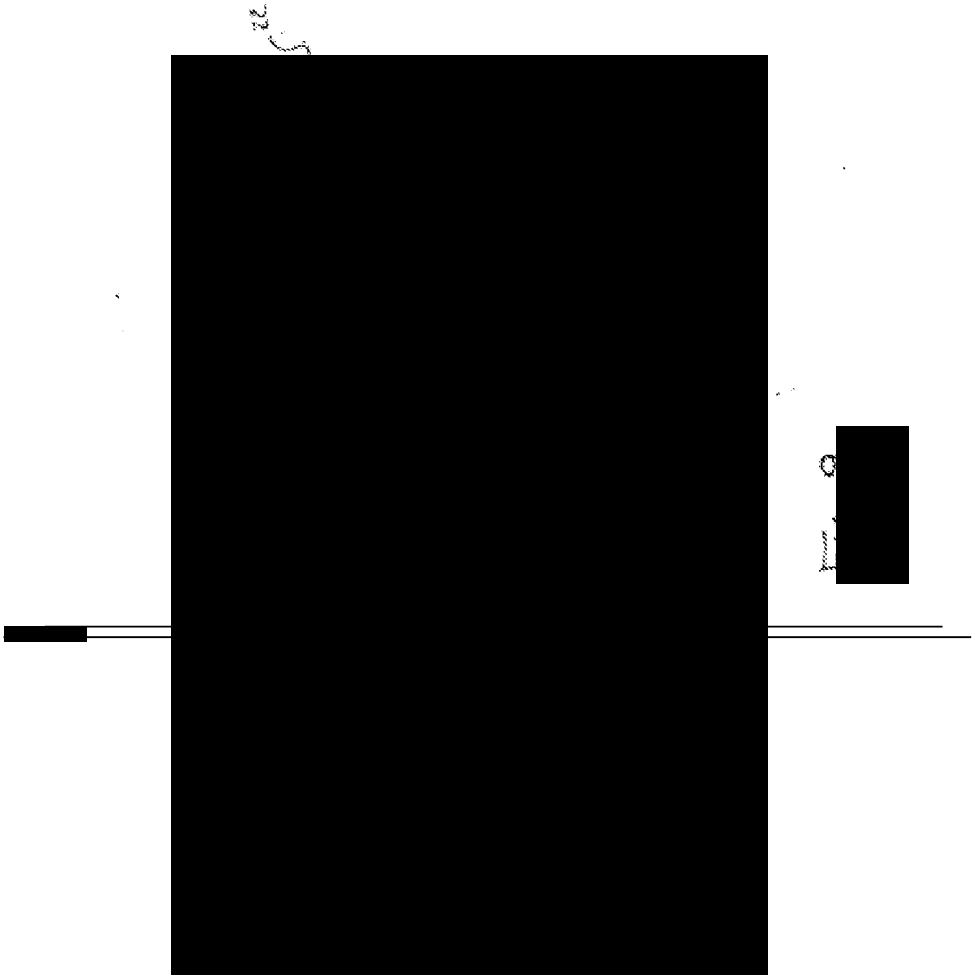


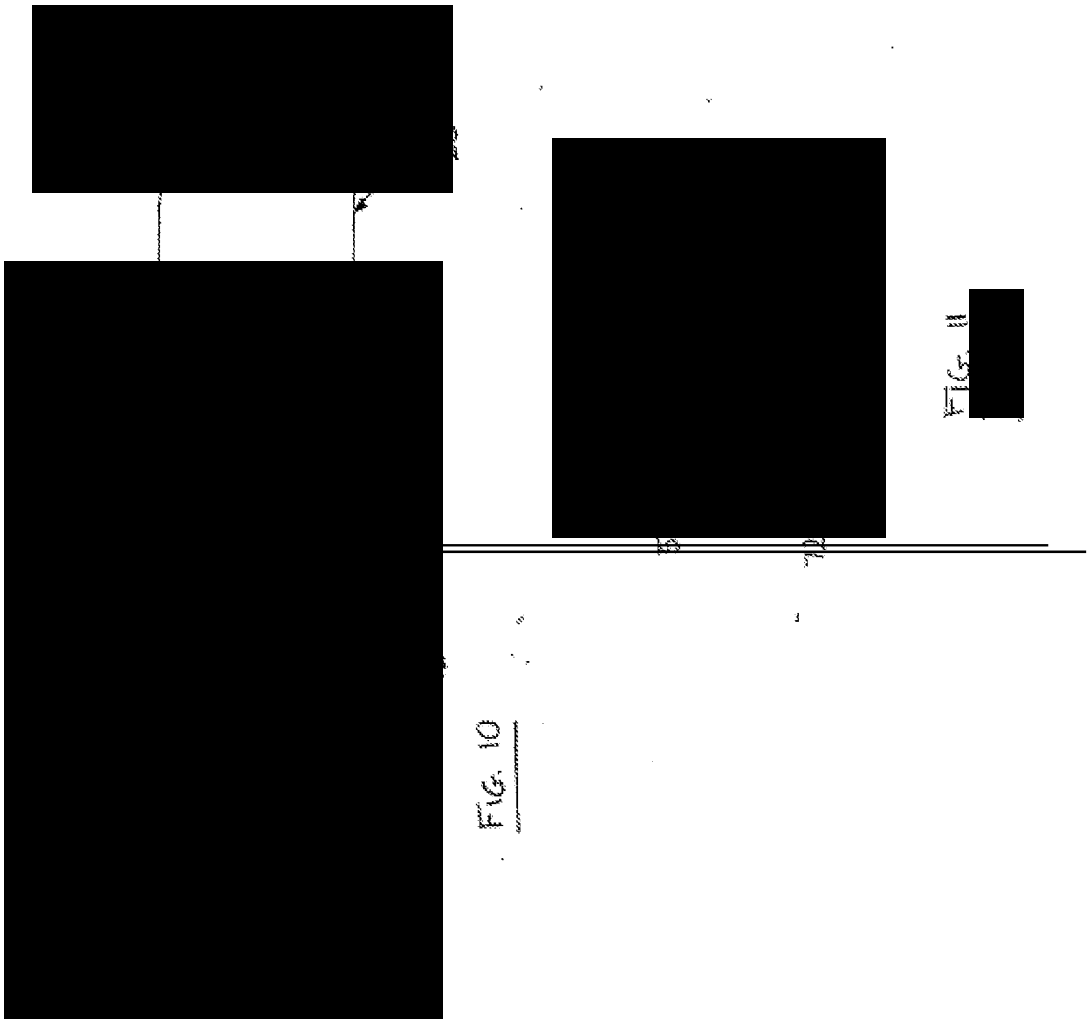
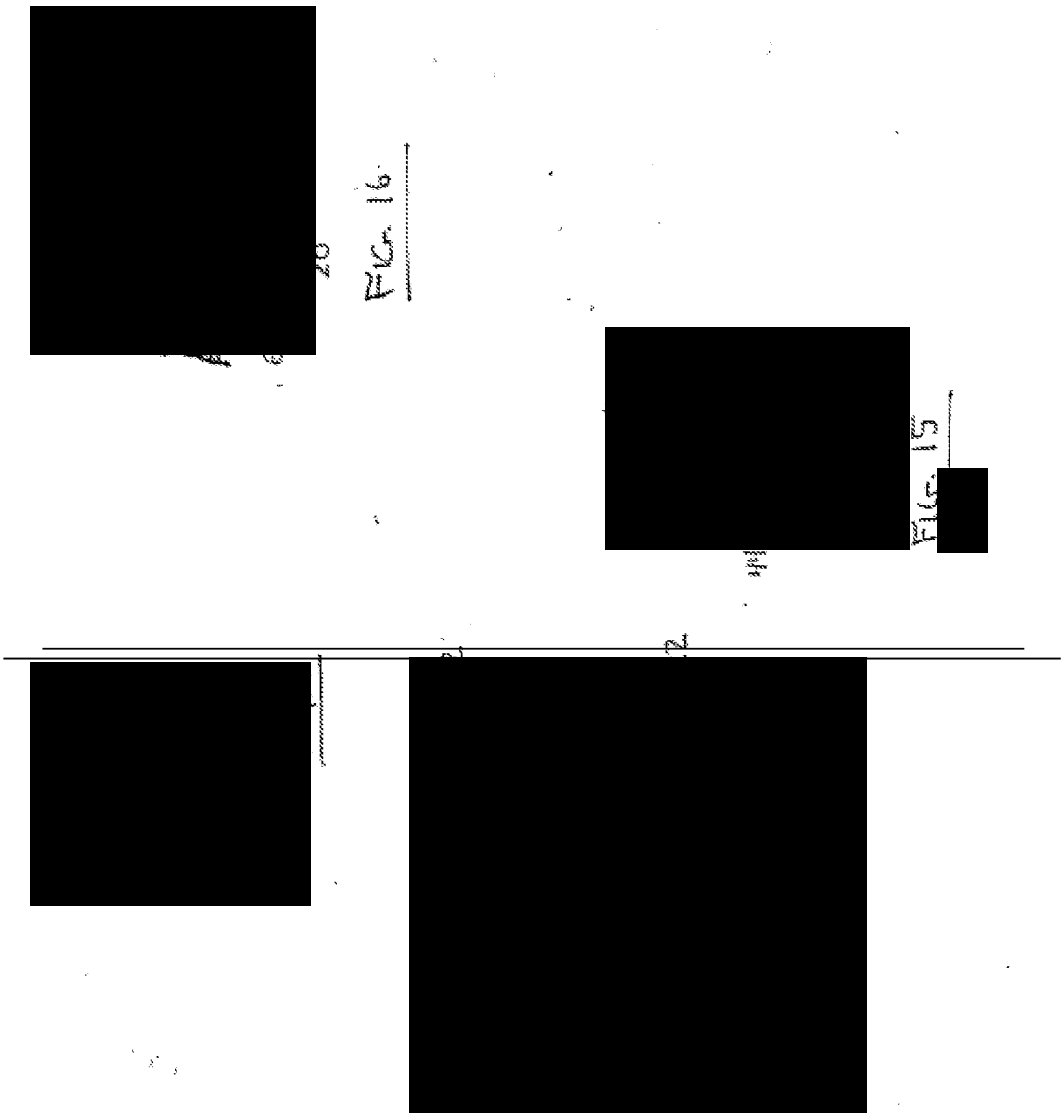


FIG. 10

FIG. 11

(74)



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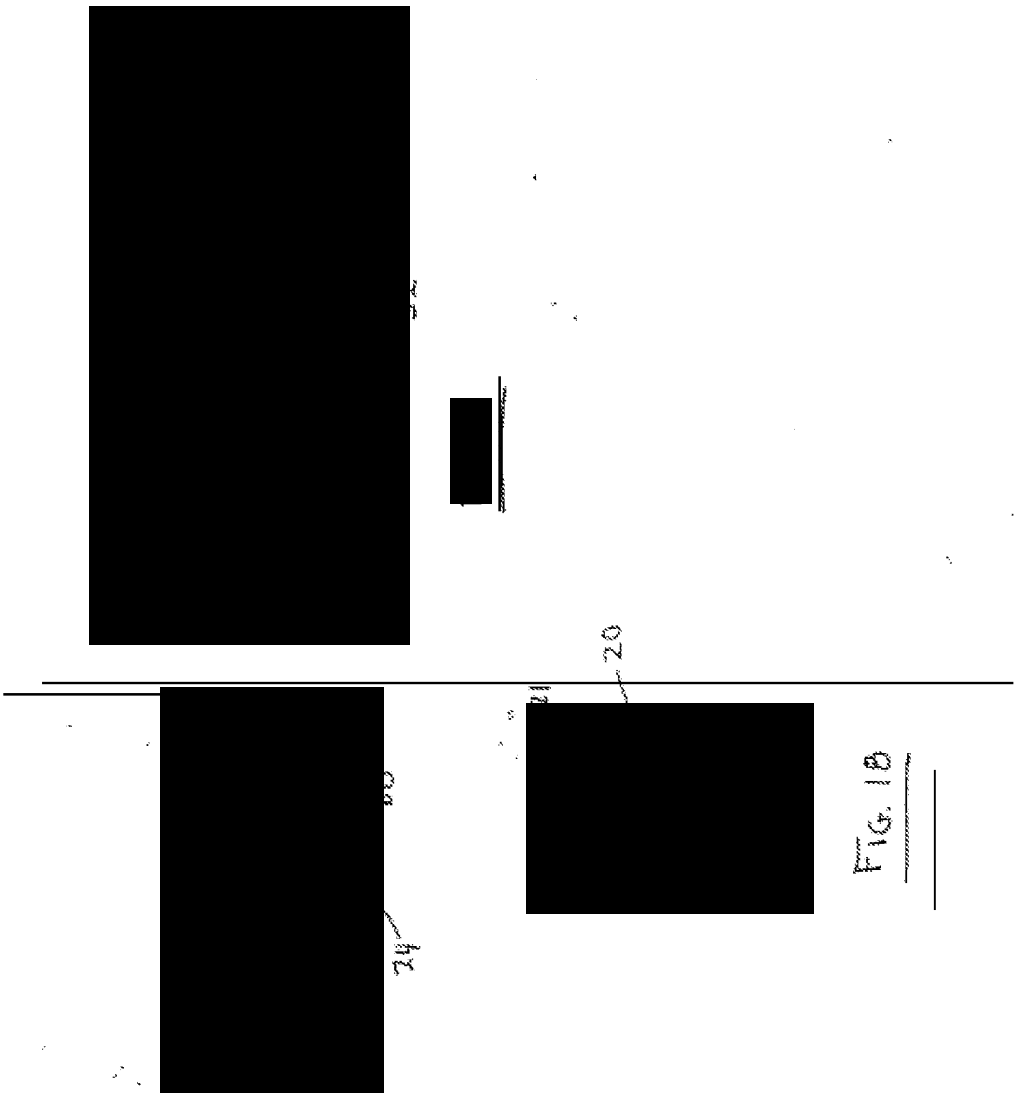


(76)

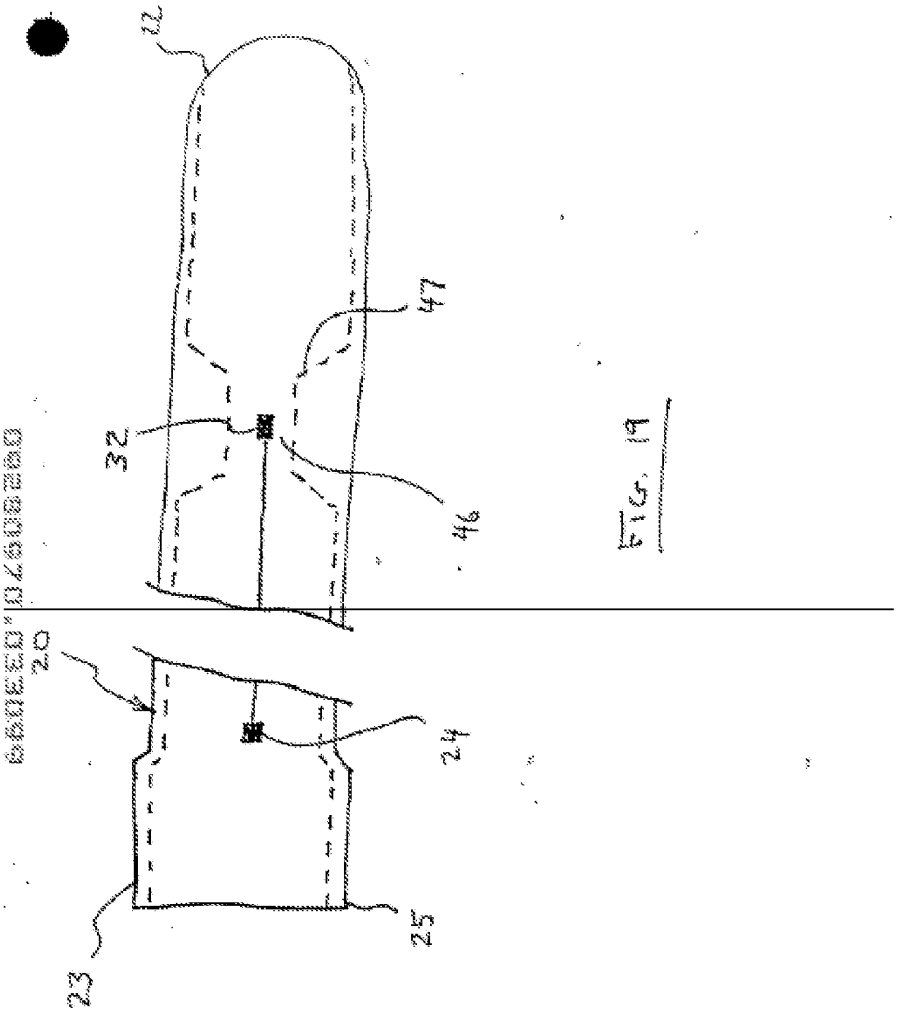


Fig. 19

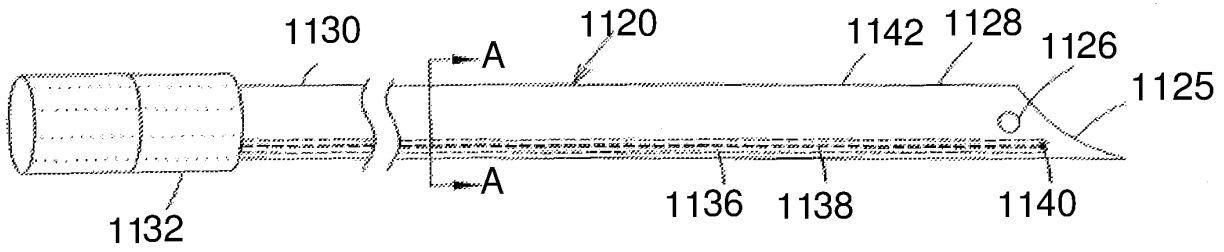


Figure 20

NEW SHEET

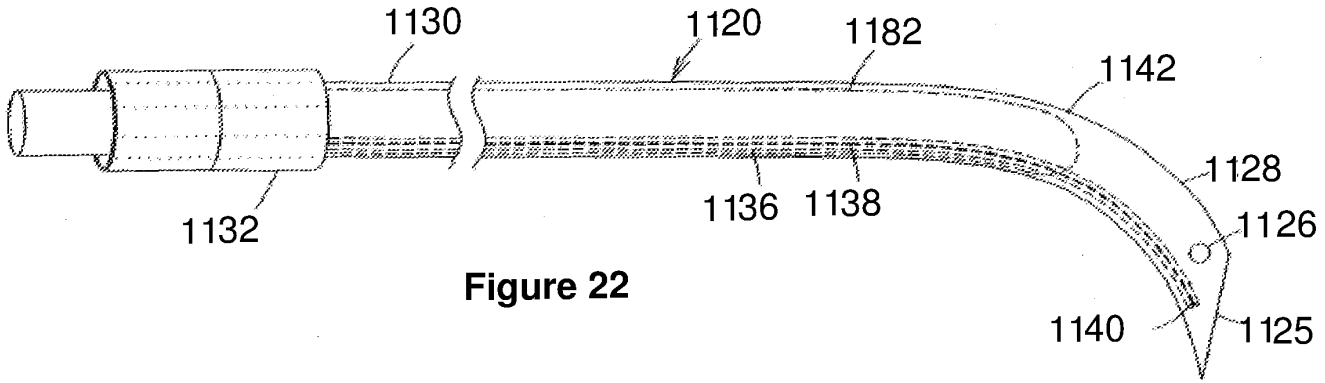


Figure 22

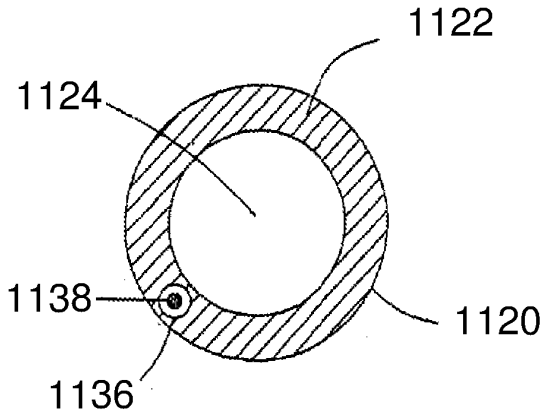


Figure 21

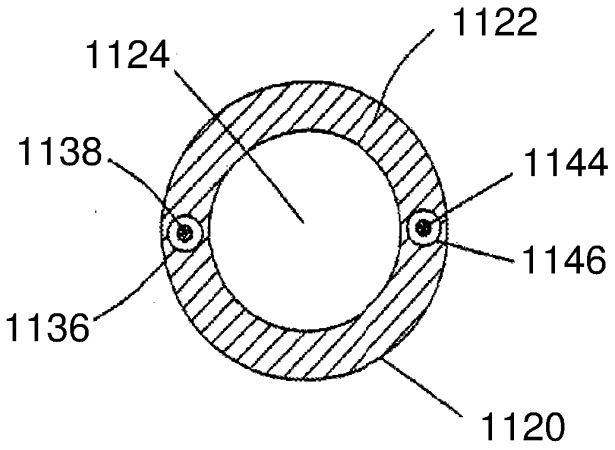


Figure 23

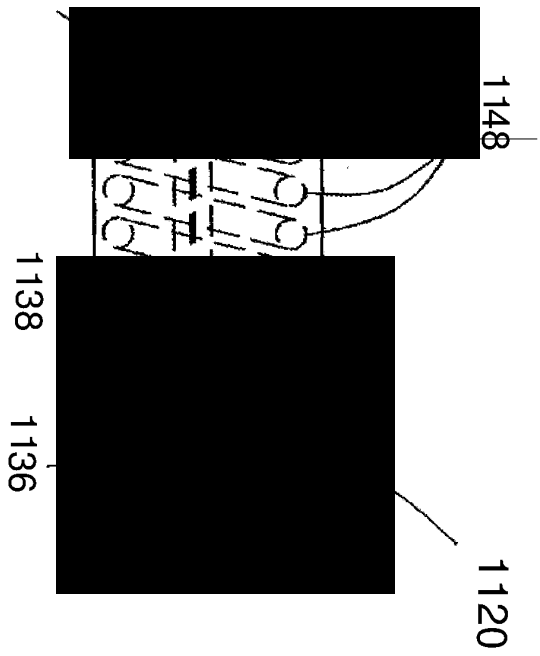


Figure 24

NEW SHEET

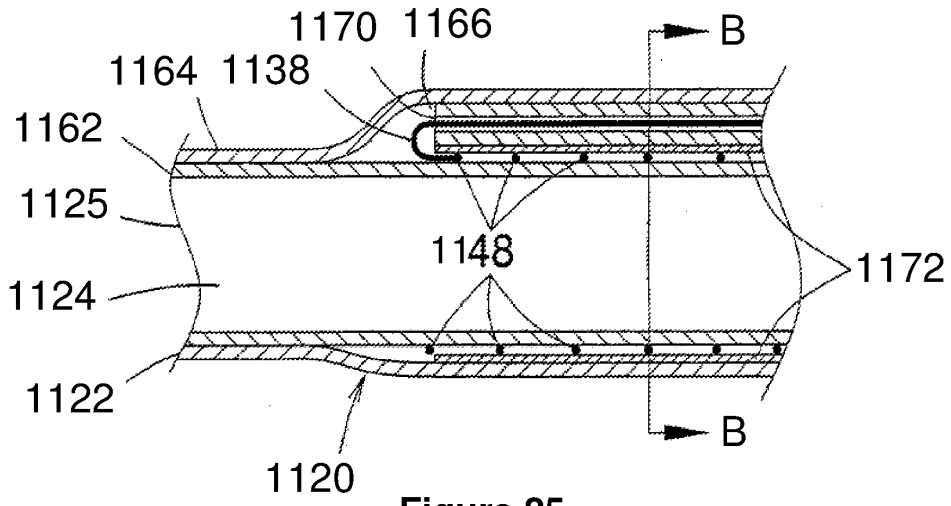


Figure 25

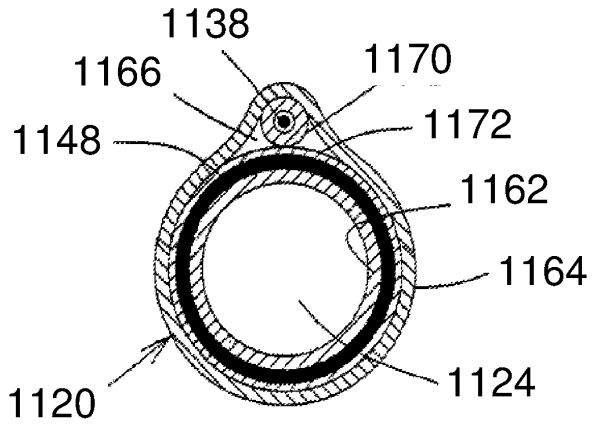


Figure 26

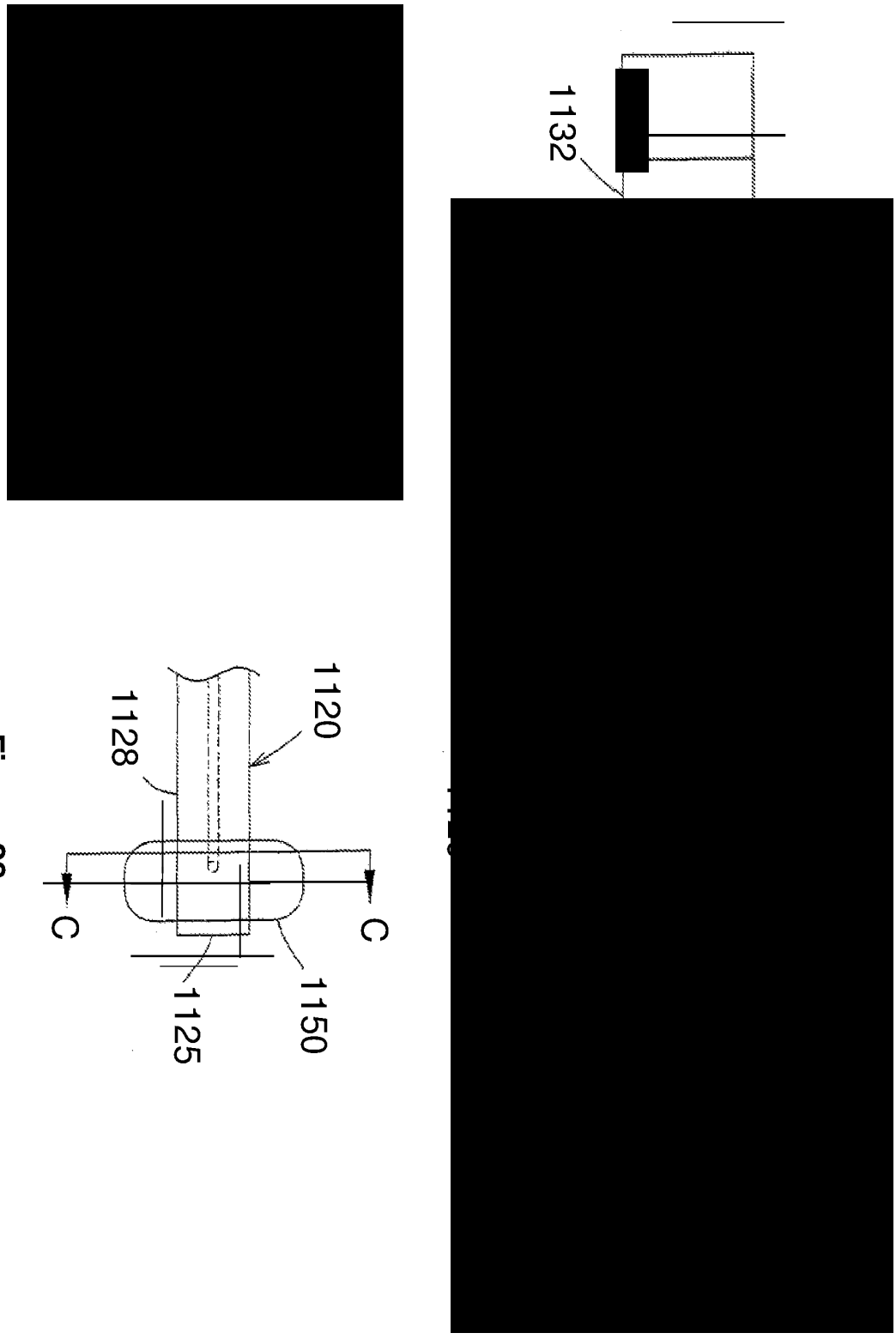


Figure 28

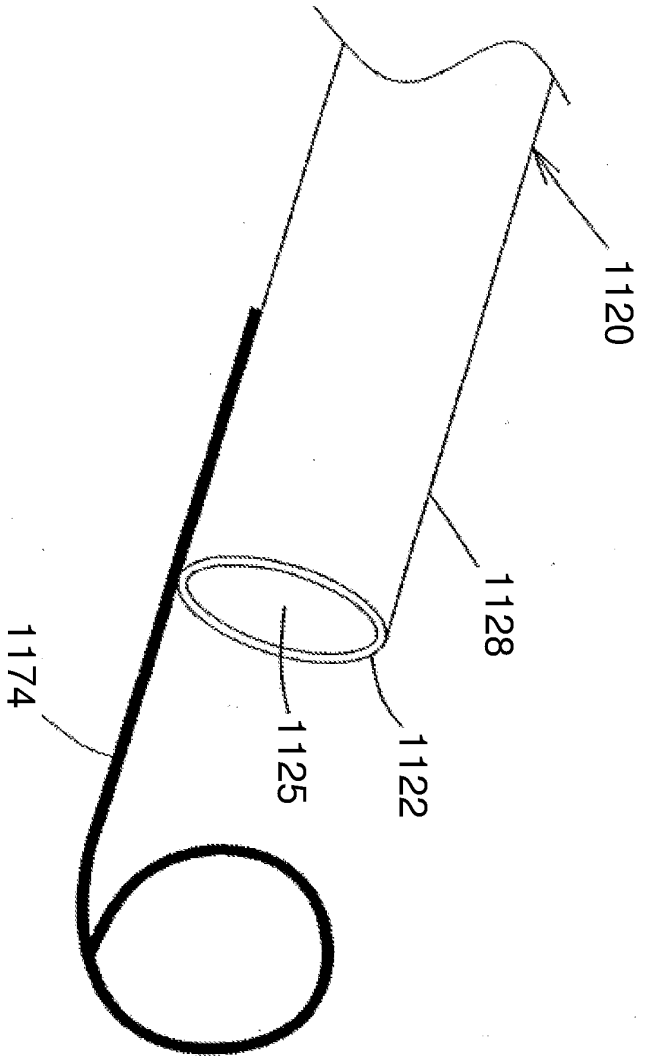


Figure 30

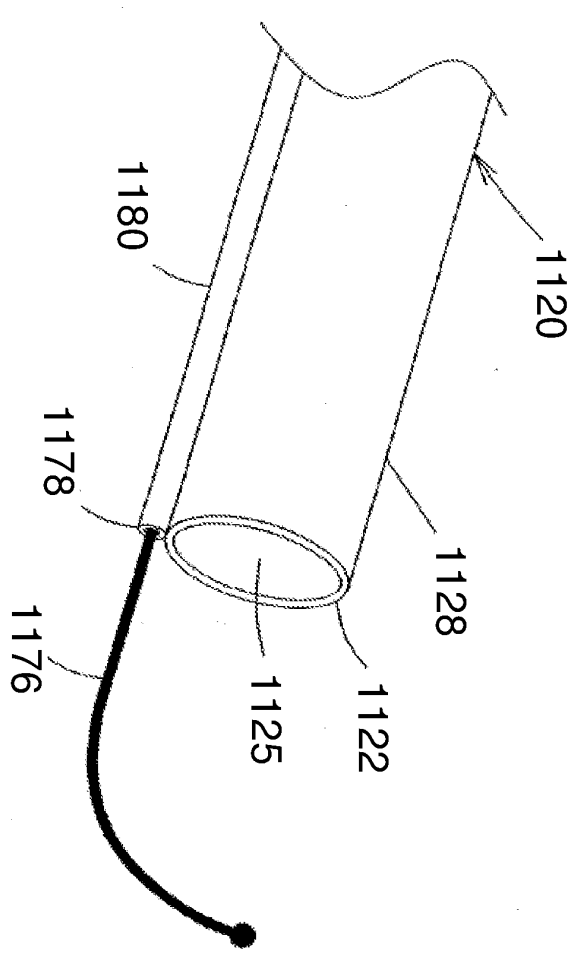


Figure 31

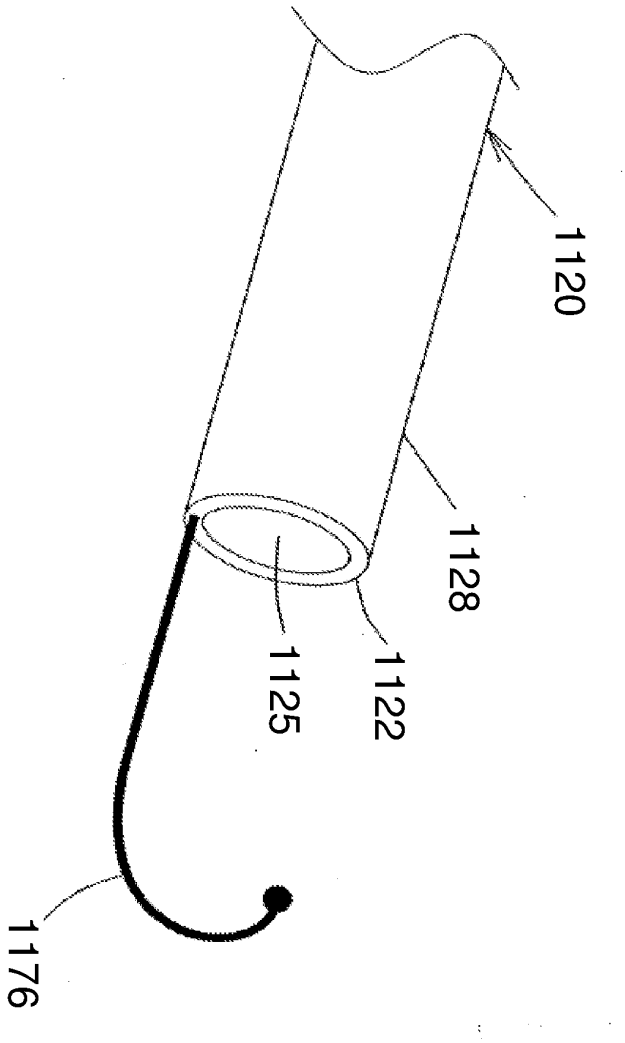
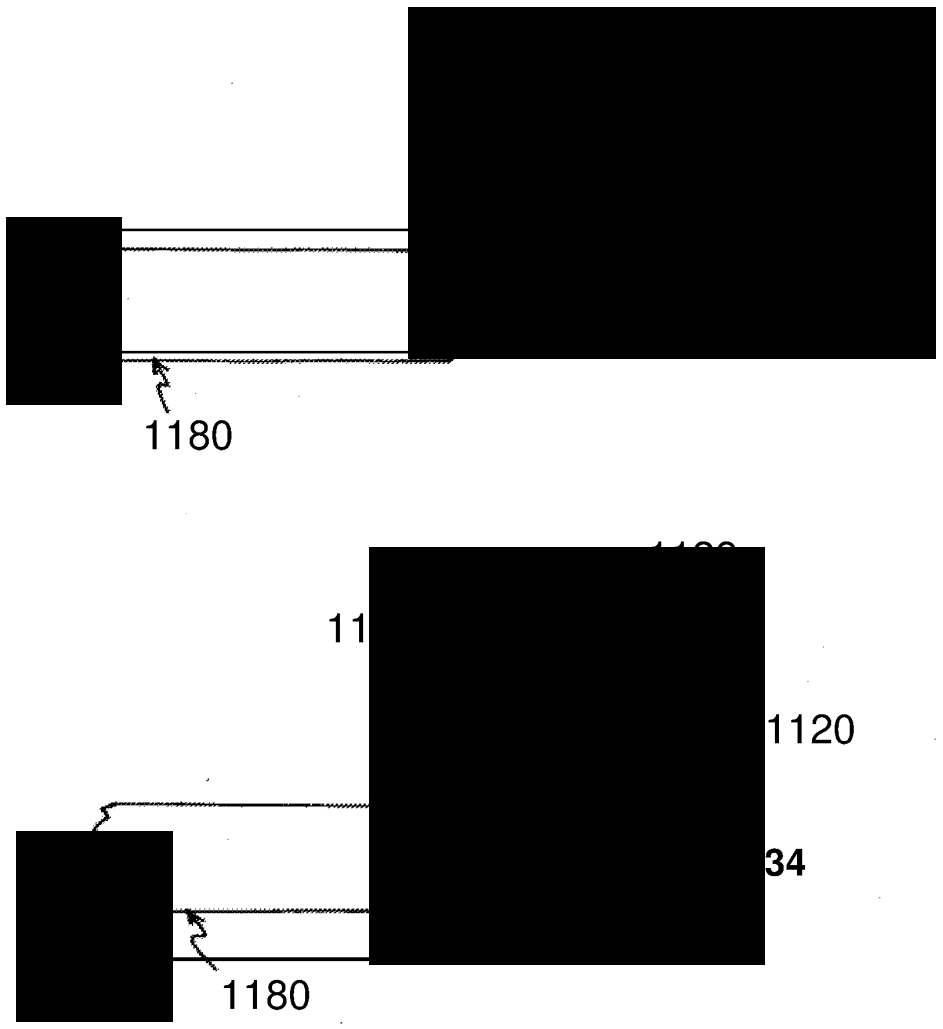


Figure 32

NEW SHEET



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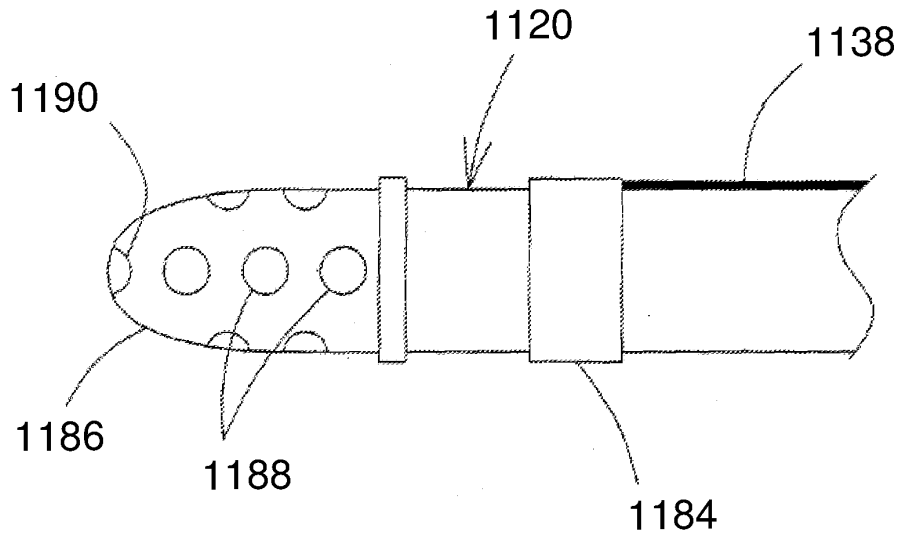

Figure 35

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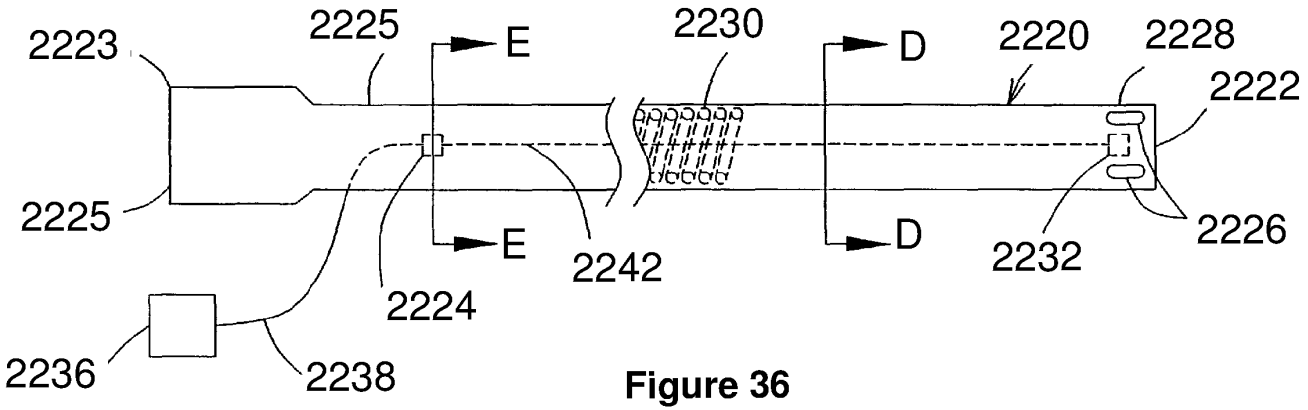


Figure 36

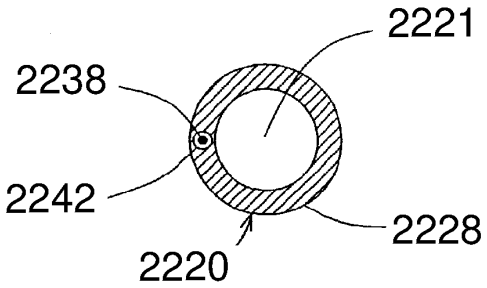


Figure 37

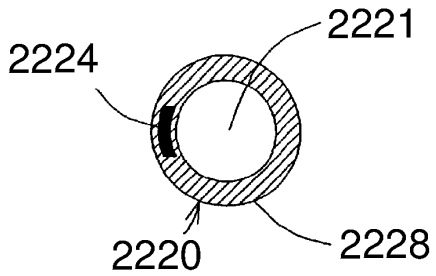


Figure 38

Figure 39

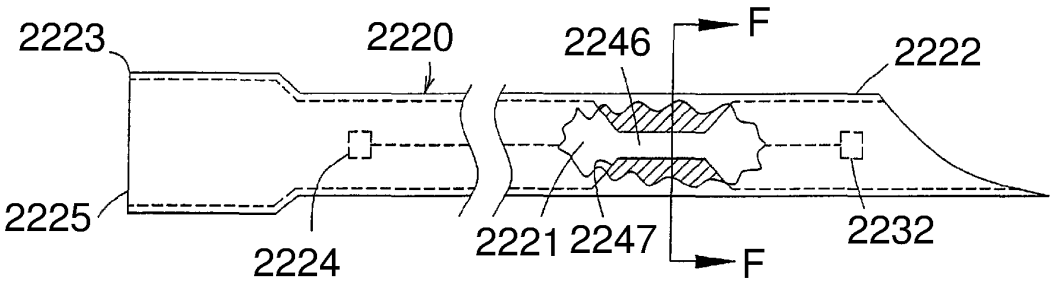


Figure 40

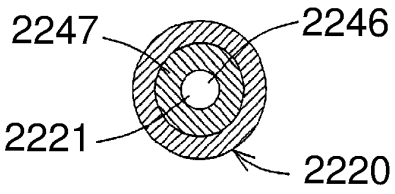


Figure 41

NEW SHEET

Figure 42

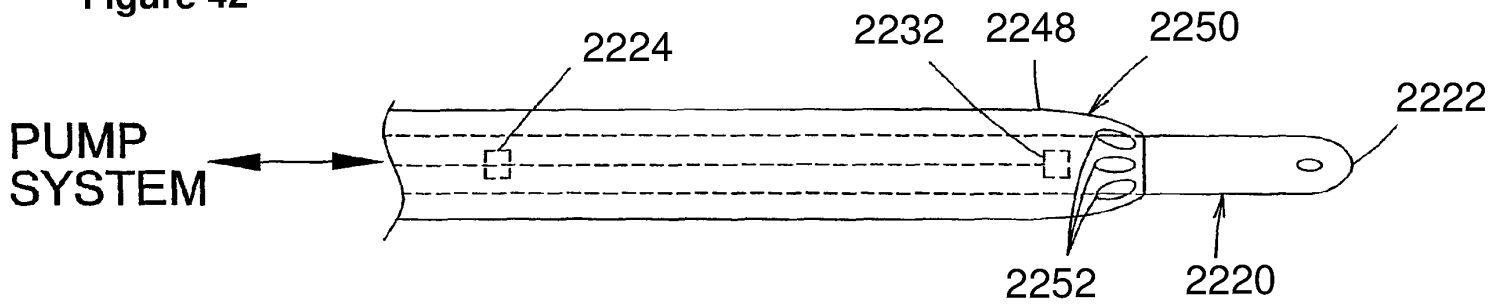
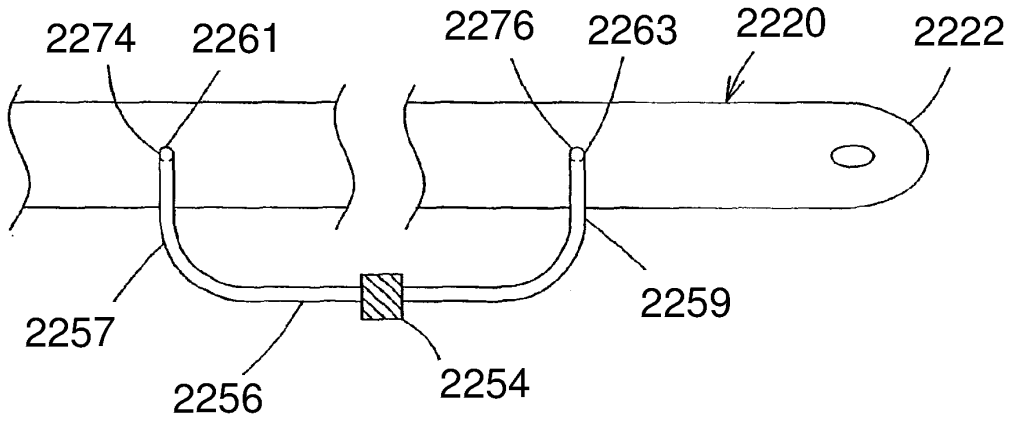


Figure 43



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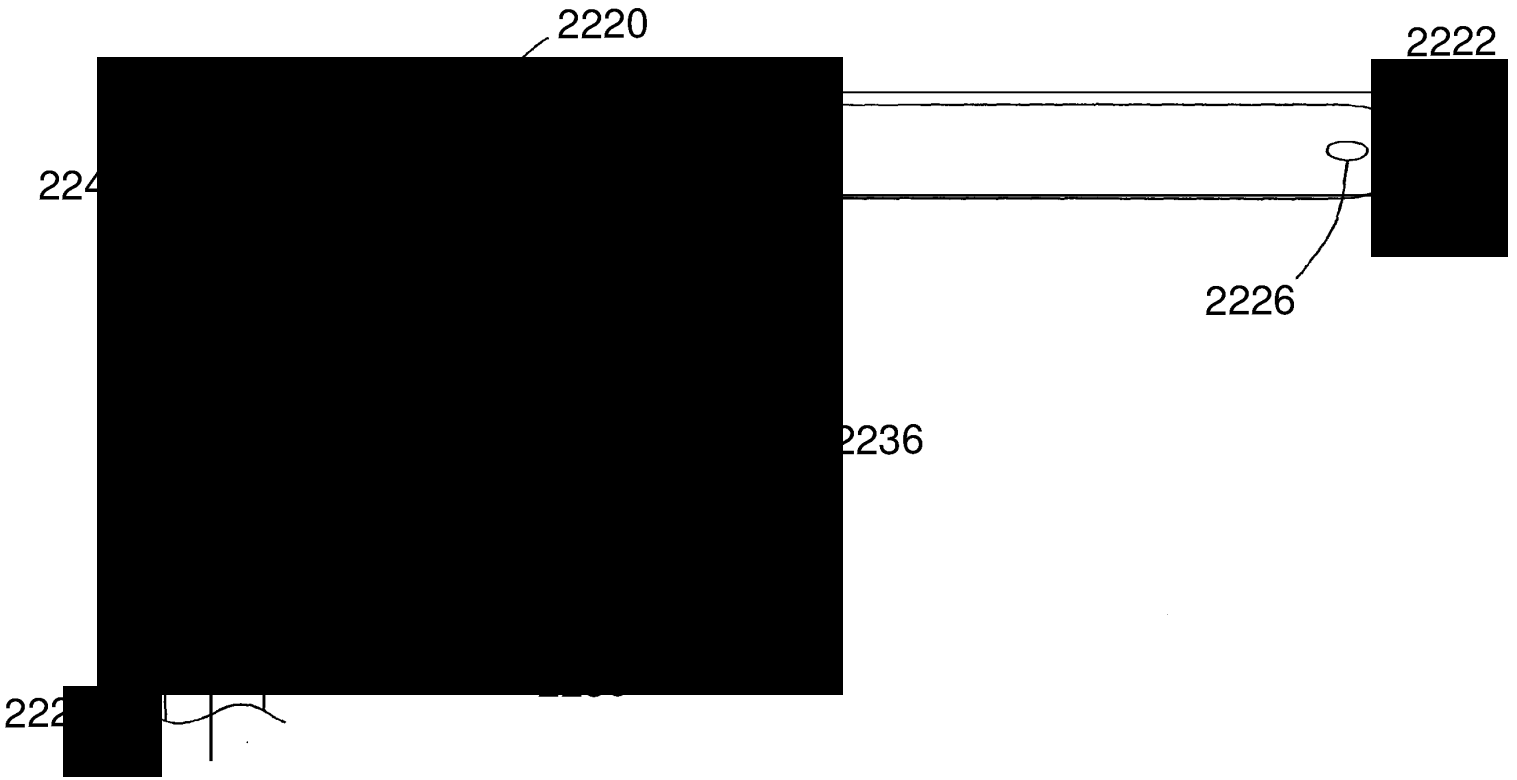


Figure 44

NEW SHEET

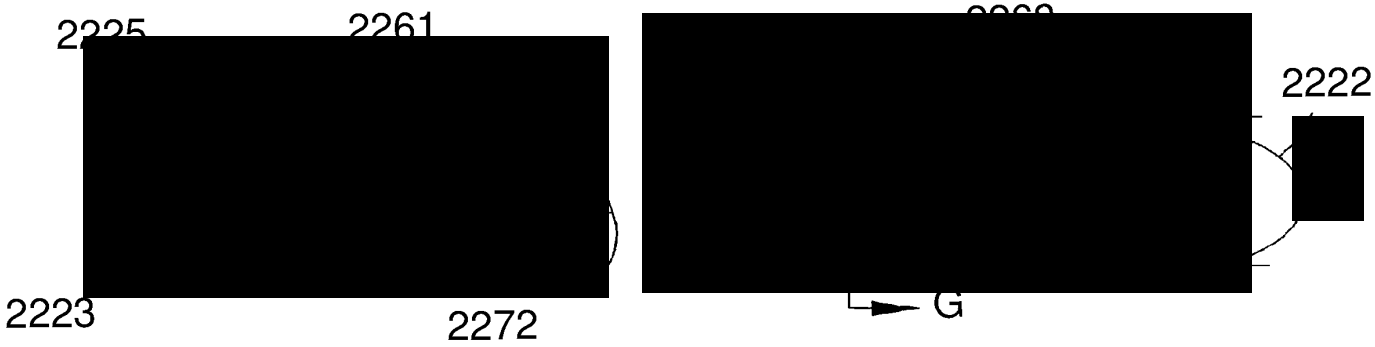
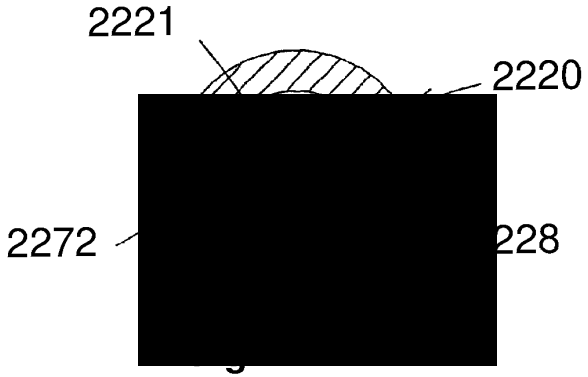


Figure 45



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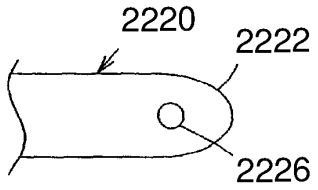

Figure 47

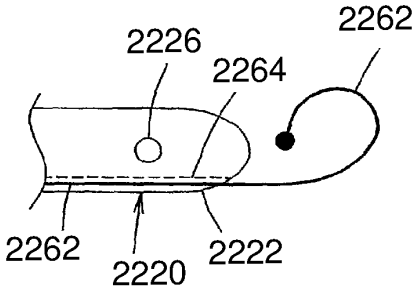

Figure 51

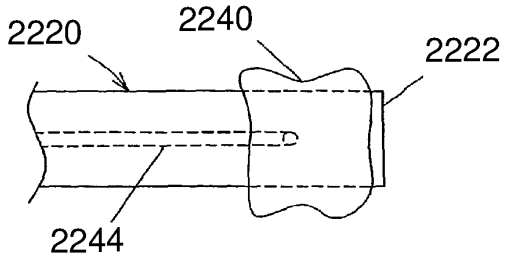

Figure 48

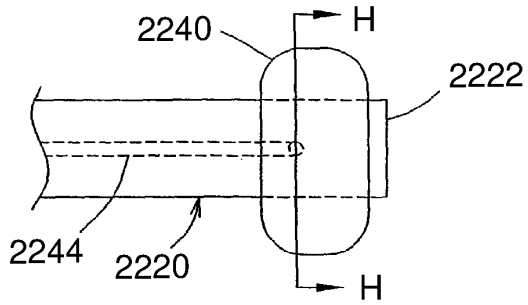

Figure 49

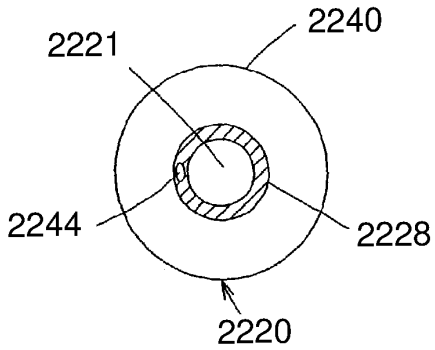

Figure 50

NEW SHEET

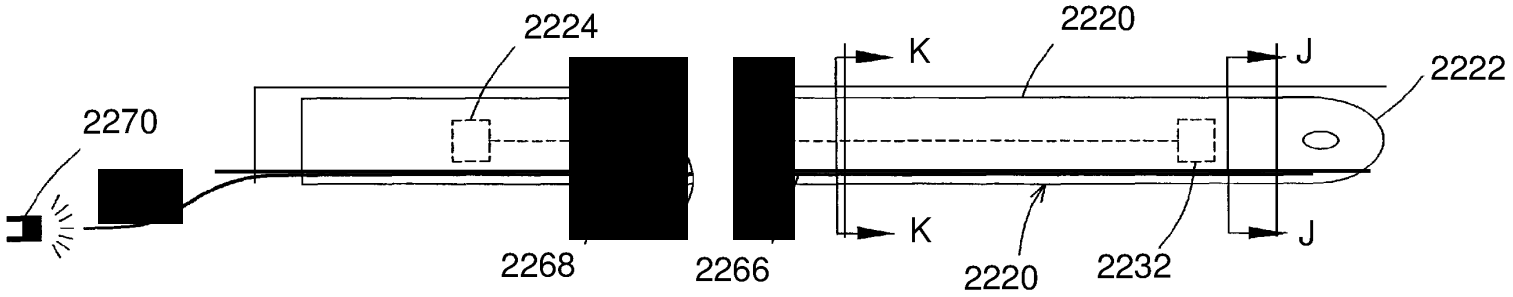

Figure 52

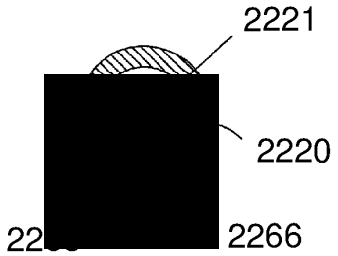

Figure 53

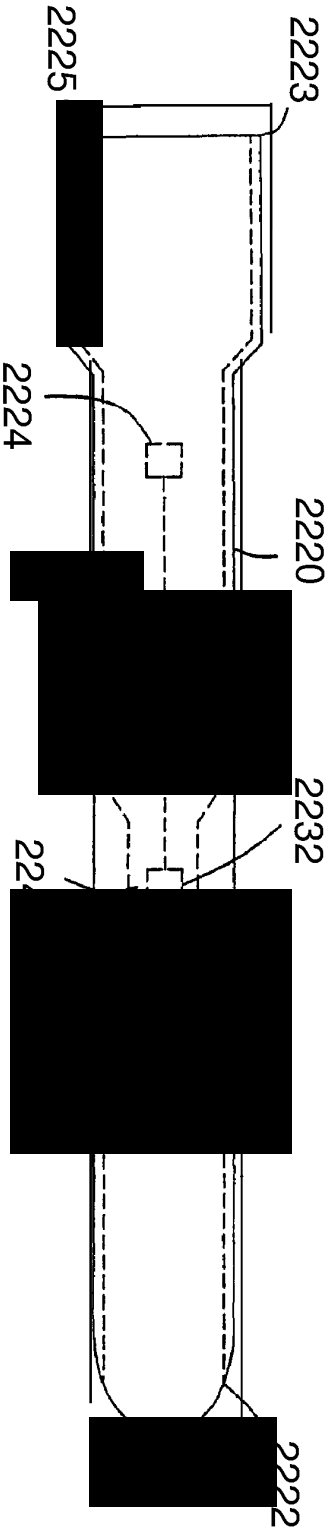

Figure 54

Electronic Acknowledgement Receipt	
EFS ID:	27364587
Application Number:	15239574
International Application Number:	
Confirmation Number:	1024
Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
Customer Number:	99185
Filer:	Wesley Scott Ashton
Filer Authorized By:	
Attorney Docket Number:	06-01506US07
Receipt Date:	31-OCT-2016
Filing Date:	17-AUG-2016
Time Stamp:	11:12:37
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2016-10-31_reviseddraftSecondPreliminary_Amendment_US07.pdf	49921 f1f4e932453b09e4f1f56f96e70a1c646f59431d	yes	4

	Multipart Description/PDF files in .zip description			
	Document Description	**Start**	**End**	
	Preliminary Amendment	1	1	
	Specification	2	2	
	Drawings-only black and white line drawings	3	3	
	Applicant Arguments/Remarks Made in an Amendment	4	4	
Warnings:				
Information:				
2	Specification	06-01506US07_Second_Substitute_Spec_CLEAN.pdf	249763 48bc1fbaf8be2dc227726e82d1e48f6ebe9af7ca	no	51
Warnings:				
Information:				
3	Specification	06-01506US07_Second_Substitute_Spec_marked-up.pdf	823139 7dff0fcff51b20c51d9cc33b44b5b91423365d56	no	77
Warnings:				
Information:				
4	Drawings-only black and white line drawings	US07-New_Sheets_.pdf	10533972 6a045331c92568c7ce716500360ffe2460864ad6	no	19
Warnings:				
Information:				
		Total Files Size (in bytes):	11656795		

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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/239,574	Filing Date 08/17/2016	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 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).			
☐ 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	

APPLICATION AS AMENDED – PART II

AMENDMENT	10/31/2016	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**0**

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						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.

LIE
MARGARET BYARS

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.
15/239,574	08/17/2016	Walid N. ABOUL-HOSN	06-01506US07	1024

99185 7590 11/04/2016

Getinge US Legal Shared Services
1300 MacArthur Boulevard
Mahwah, NJ 07430

EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
11/04/2016	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@getinge.com

Office Action Summary	Application No. 15/239,574	Applicant(s) ABOUL-HOSN ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	AIA (First Inventor to File) Status No

-- 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* MONTHS 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 *17 August 2016*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ 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.

4)☐ 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*

5)☒ Claim(s) *24-53* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *24-39 and 41-53* is/are rejected.

8)☒ Claim(s) *40* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *31 October 2016* 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).

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).

Certified copies:

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)).

** 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) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *6 (six)*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Priority

This application claims a pressure sensing element and pigtail or J-shaped distal tip member. Application 10/070,178 describes these features through incorporations by reference (Aboul-Hosn; Walid N et al., US 7022100, col. 18, lines 21-30, applications 09/280,988 and 09/280,970). The text of the earlier filed applications have been merged and reformatted with the original disclosure. No new matter has been added.

The replacement specification and drawings filed 31 October 2016 have been accepted.

Claim Objections

Claims 25, 26, 28, 29, 32, 47 and 51 contain minor informalities.

Claim 25 should be changed to read "…wherein the rotor **[[comprising]]** **comprises** a second blade…"

Claim 26 should be changed to read "…configured to have the purge fluid pass**[[es]]** through it."

Claim 28 should be changed to read "…wherein the pressure sensing element **[[comprising]]** **comprises** at least one of…"

Claim 29 should be changed to read "…wherein the pressure sensing element further **[[comprising]]** **comprises** a fluid column…"

Claim 32 should be changed to read "…wherein the intravascular blood pump system **[[comprising]]** **comprises** a dual construction arrangement…"

Claims 47 and 51 should be changed to read "…wherein the intravascular blood pump system **[[comprising]]** **comprises** a dual construction arrangement…"

Double Patenting

The following copending and patented applications are relevant to the claimed invention:

- Aboul-Hosn; Walid N. et al. US 9327068 B2
- Aboul-Hosn; Walid N et al. US 7022100 B1
- Aboul-Hosn; Walid N et al. US 7731675 B2
- Aboul-Hosn; Walid N. et al. US 8888728 B2
- Aboul-Hosn; Walid N. et al. US 6926662 B1
- Aboul-Hosn; Walid N. et al. US 7785246 B2
- Aboul-Hosn; Walid Najib et al. US 8540615 B2
- Aboul-Hosn; Walid Najib et al. US 8834344 B2

Each application claims a blood pump system or method for providing heart support. However, none of the cited applications claim a guide wire ***not*** passing through rotor hub and a housing and catheter with a purge lumen. Therefore these references are not cited in a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-39 and 41-53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-32, 34, 38-43, 45, 47 and 48 of copending Application No. 15/239697 to Aboul-Hosn, Walid N et al. (claims amended 18 October 2016). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Regarding instant claim 24, Aboul-Hosn claims an intravascular blood pump system (claim 24, intravascular blood pump system), comprising:

an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a patient by a guide wire and the intravascular blood pump configured to provide left-heart support (claim 24, intravascular blood pump adapted to … provide left-heart support);

the intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub (claim 24, rotor … blade extending radially outward from the rotor hub);

a cannula coupled to a distal end of the intravascular blood pump, one or more first ports and one or more second ports establishing fluid communication between a lumen of the cannula and an exterior region of the cannula (claim 24, cannula coupled to a distal end of the intravascular blood pump, one or more first ports and one or more second ports … exterior region of the cannula);

wherein at least one first port is located in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port (claim 24, one first port … proximity to the rotor and at least one second port … distal to the at least one first port); and

wherein the intravascular blood pump is configured to draw blood from the patient's heart into the at least one second port through the cannula lumen and out the at least one first port to provide left-heart support while the cannula is positioned across an aortic valve of the patient (claim 24, blood pump is configured to draw blood … aortic valve of the patient);

the cannula is configured such that when the intravascular blood pump is positioned in the patient to provide left-heart support the distal end of the cannula and the at least one second port are positioned inside the patient's heart and the proximal end of the cannula and the at least one first port are positioned in the patient's aorta

(claim 24, when the intravascular blood pump is positioned in the patient to provide left-heart support … positioned in the patient's aorta);

a catheter connected to a proximal end of the intravascular blood pump (claim 24, catheter coupled to a proximal end);

a purge lumen extending through the catheter and operatively arranged to deliver purge fluid towards the intravascular blood pump (claim 24, purge lumen extending through … blood pump);

an elongate lumen arranged coaxially with at least a portion of the cannula and in series longitudinally with the cannula (claim 24, elongate lumen associated with the cannula … such that the guide wire passes slidably and coaxially through the elongate lumen); and

an end of the elongate lumen is adjacent an end of the cannula (claim 34, elongate lumen runs longitudinally through and is an integral extension of a wall of the cannula);

the elongate lumen sized to slidably receive the guide wire and having a diameter sized smaller than a diameter of the cannula lumen (claim 24, elongate lumen … sized to slidably receive the guide wire … elongate lumen is sized smaller cross sectionally than the cannula lumen);

a pressure sensing element configured to sense pressure proximate the intravascular blood pump (claim 24, pressure sensing element … blood pump);

a housing connected to a proximal end of the catheter (claim 24, housing connected to a proximal end of the catheter); and

first and second conduits each connected to the housing, at least one of the first conduit and second conduit in fluid communication with the purge lumen (claim 24, first and second conduits … purge lumen).

Regarding instant claim 43, Aboul-Hosn claims an intravascular blood pump system (claim 24, intravascular blood pump system), comprising:

an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a patient by a guide wire and configured to provide left-heart support (claim 24, intravascular blood pump … provide left-heart support);

the intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction (claim 24, rotor having a rotor hub tapering in the distal direction); and

a rotor shroud at least partially disposed about the rotor hub (claim 45, rotor shroud disposed about the rotor);

at least one blade extending radially outward from the rotor hub, a distal end of the hub extending distally beyond a most distal portion of the at least one blade (claim 24, at least one blade extending radially outward from the rotor hub; claim 25, hub has a distal end extending distally beyond a most distal portion of the blades);

a cannula coupled to a distal end of the intravascular blood pump (claim 24, cannula coupled to a distal end of the intravascular blood pump);

a portion of the rotor shroud having an outer diameter matching an inner diameter of a proximal portion of the cannula (claim 31, portion of the rotor shroud … proximal portion of the cannula);

the proximal portion of the cannula disposed about a distal end of the rotor shroud (claim 45, proximal portion of the cannula … rotor shroud);

one or more first ports and one or more second ports establishing fluid communication between a lumen of the cannula and an exterior region of the cannula (claim 24, one or more first ports and one or more second ports establishing fluid communication … exterior region of the cannula);

wherein at least one first port is located in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port (claim 24, one first port is located in proximity to the rotor and at least one second port is spaced apart … one first port); and

wherein the intravascular blood pump is configured to draw blood from the patient's heart into the at least one second port through the cannula lumen and out the at least one first port to provide left-heart support while the cannula is positioned across an aortic valve of the patient (claim 24, blood pump is configured to draw blood … aortic valve of the patient);

the cannula is configured such that when the intravascular blood pump is positioned in the patient to provide left-heart support the distal end of the cannula and the at least one second port are positioned inside the patient's heart and the proximal end of the cannula and the at least one first port are positioned in the patient's aorta

(claim 24, intravascular blood pump is positioned in the patient to provide left-heart support … patient's aorta);

a catheter connected to a proximal end of the intravascular blood pump (claim 24, catheter coupled to a proximal end of the intravascular blood pump);

a purge lumen extending through the catheter and operatively arranged to deliver purge fluid towards the intravascular blood pump (claim 24, purge lumen extending through … blood pump);

an elongate lumen arranged coaxially with at least a portion of the cannula and in series longitudinally with the cannula (claim 24, elongate lumen associated with the cannula … such that the guide wire passes slidably and coaxially through the elongate lumen); and

an end of the elongate lumen is adjacent an end of the cannula (claim 34, elongate lumen runs longitudinally through and is an integral extension of a wall of the cannula);

the elongate lumen sized to slidably receive the guide wire and having a diameter sized smaller than a diameter of the cannula lumen (claim 24, elongate lumen … sized to slidably receive the guide wire … elongate lumen is sized smaller cross sectionally than the cannula lumen);

a pressure sensing element configured to sense pressure proximate the intravascular blood pump (claim 24, pressure sensing element … blood pump); and

comprising a fluid column extending through the catheter (claim 29, pressure sensing element further comprising a fluid column);

a housing connected to a proximal end of the catheter (claim 24, housing connected to a proximal end of the catheter); and

the housing configured to have the purge fluid passing through it (claim 26, housing is configured to have the purge fluid pass through it);

first and second conduits each connected to the housing, at least one of the first conduit and second conduit in fluid communication with the purge lumen (claim 24, first and second conduits … purge lumen); and

a fluid delivery pump configured to deliver purge fluid through at least one of the first and second conduits, and through the housing and the purge lumen towards the intravascular blood pump (claim 42, fluid delivery pump configured to deliver purge fluid through the purge lumen towards the intravascular blood pump).

Regarding instant claim 50, Aboul-Hosn claims an intravascular blood pump system (claim 24, intravascular blood pump system), comprising:

an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a patient by a guide wire and configured to provide left-heart support (claim 24, intravascular blood pump … provide left-heart support);

the intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction (claim 24, rotor having a rotor hub tapering in the distal direction); and

a rotor shroud at least partially disposed about the rotor hub (claim 45, rotor shroud disposed about the rotor);

at least one blade extending radially outward from the rotor hub, a distal end of the hub extending distally beyond a most distal portion of the at least one blade (claim 24, at least one blade extending radially outward from the rotor hub; claim 25, hub has a distal end extending distally beyond a most distal portion of the blades);

a catheter coupled to a proximal end of the intravascular blood pump (claim 24, catheter coupled to a proximal end of the intravascular blood pump);

a purge lumen extending through the catheter and operatively arranged to deliver purge fluid towards the intravascular blood pump (claim 24, purge lumen extending through … blood pump);

a cannula coupled to a distal end of the intravascular blood pump (claim 24, cannula coupled to a distal end of the intravascular blood pump);

a portion of the rotor shroud having an outer diameter matching an inner diameter of a proximal portion of the cannula (claim 31, portion of the rotor shroud … proximal portion of the cannula);

the proximal portion of the cannula disposed about a distal end of the rotor shroud (claim 45, proximal portion of the cannula … rotor shroud);

one or more first ports and one or more second ports establishing fluid communication between a lumen of the cannula and an exterior region of the cannula (claim 24, one or more first ports and one or more second ports establishing fluid communication … exterior region of the cannula);

wherein at least one first port is located in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port (claim

24, one first port is located in proximity to the rotor and at least one second port is spaced apart … one first port);

the cannula is configured such that when the intravascular blood pump is positioned in the patient to provide left-heart support the distal end of the cannula and the at least one second port are positioned inside the patient's heart and the proximal end of the cannula and the at least one first port are positioned in the patient's aorta (claim 24, intravascular blood pump is positioned in the patient to provide left-heart support … patient's aorta);

the intravascular blood pump is configured to draw blood from the patient's heart into the at least one second port through the cannula lumen and out the at least one first port to provide left-heart support while the cannula is positioned across an aortic valve of the patient (claim 24, blood pump is configured to draw blood … aortic valve of the patient);

an elongate lumen associated with the cannula and sized to slidably receive the guide wire (claim 24, elongate lumen associated with the cannula … such that the guide wire passes slidably and coaxially through the elongate lumen); and

dimensioned such that the guide wire passes slidably and coaxially through the elongate lumen, the elongate lumen is sized smaller cross sectionally than the cannula lumen and is shorter in length than the cannula lumen (claim 24, elongate lumen … sized to slidably receive the guide wire … elongate lumen is sized smaller cross sectionally than the cannula lumen);

both the elongate lumen and the cannula lumen not extending through the rotor hub (claim 24, both … not extending through the rotor hub);

the intravascular blood pump system configured for the guide wire to extend proximally away from the intravascular blood pump (claim 24, guide wire to extend proximally away from the intravascular blood pump);

the guide wire not passing through the rotor hub or the catheter (claim 24, the guide wire not passing through the rotor hub or the catheter); and

the guide wire extending out of the intravascular blood pump system in a distal direction through the elongate lumen (claim 24, guide wire extending out … a distal direction through the elongate lumen);

wherein when the intravascular blood pump is positioned in the patient to provide left-heart support the elongate lumen lies wholly within the left ventricle (claim 47, when the intravascular blood pump is positioned … wholly within the left ventricle);

a pressure sensing element configured to sense pressure proximate the intravascular blood pump (claim 24, pressure sensing element … blood pump);

comprising a fluid column extending through the catheter (claim 29, pressure sensing element further comprising a fluid column);

a housing connected to a proximal end of the catheter (claim 24, housing connected to a proximal end of the catheter); and

the housing configured to have the purge fluid pass through it (claim 26, housing is configured to have the purge fluid pass through it);

first and second conduits each connected to the housing, at least one of the first conduit and second conduit in fluid communication with the purge lumen (claim 24, first and second conduits … purge lumen); and

a fluid delivery pump configured to deliver purge fluid through at least one of the first and second conduits, and through the housing and the purge lumen towards the intravascular blood pump (claim 42, fluid delivery pump configured to deliver purge fluid through the purge lumen towards the intravascular blood pump).

Regarding instant claims 25-39, 41, 42, 44-49 and 51-53, Aboul-Hosn claims all limitations in claims 25-32, 38-43, 45 and 48 as shown in Table 1.

Table 1

Instant claim	Aboul-Hosn claim	Instant claim	Aboul-Hosn claim
25	25	38	45
26	26	39	45
27	27	41	48
28	28	42	41
29	29	44	38
30	30	45	39
31	31	46	40
32	32	47	32
33	38	48	28
34	39	49	41
35	40	51	32
36	42	52	40
37	43	53	48

Allowable Subject Matter

Claim 40 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590
Fax 571-273-2590
Email Adam.Marcetich@uspto.gov

The Examiner can be reached 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. 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.

/Adam Marcetich/
Primary Examiner, Art Unit 3761

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15239574
Filing Date	2016-08-17
First Named Inventor	Walid N. Aboul-Hosn
Art Unit	3739
Examiner Name	Not Yet Assigned
Attorney Docket Number	06-01506US07

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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
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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	20030065271	A1	2003-04-03	Baylor College of Medicine	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	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	99/59652	WO	A1	1999-11-25	A-Med Systems, Inc.		
	2	99/58170	WO	A1	1999-11-18	Impella Cardiosystems Gmbh		
	3	0884064	EP	A2	1998-12-16	Schneider (Usa) Inc.		

EFS Web 2.1.17

All references considered except where lined through /AMM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

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First Named Inventor	Walid N. Aboul-Hosn
Art Unit	3739
Examiner Name	Not Yet Assigned
Attorney Docket Number	06-01506US07

	4	0810002	EP	A1	1997-12-03	Cordis Europa N.V.		
	5	00/44417	WO	A1	2000-08-03	Terumo Cardiovascular Systems Corporation		
	6	99/02204	WO	A1	1999-01-21	A-MED SYSTEMS, INC.		

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	1		

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EXAMINER SIGNATURE

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

*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.

All references considered except where lined through /AMM/

Receipt date: 09/06/2016

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15239574
Filing Date	2016-08-17
First Named Inventor	Walid N. Aboul-Hosn
Art Unit	3739
Examiner Name	Not Yet Assigned
Attorney Docket Number	06-01506US07

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.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

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	/Kirk D. Swenson/	Date (YYYY-MM-DD)	2016-09-06
Name/Print	Kirk D. Swenson	Registration Number	52265

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.**

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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.

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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.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L5	0	15/239697.app.	US-PGPUB; USPAT; USOCR	OR	ON	2016/11/01 11:27
L4	3	l3 and (port$1 egress ingress entrance$1).clm.	USPAT; USOCR	OR	ON	2016/11/01 11:22
L3	8	l1 and (pump$3 and (blood heart cardiovascular vascular aort$2 intravascular circulatory) and (impell?R rot?r blade$1 fin fins)).clm.	USPAT; USOCR	OR	ON	2016/11/01 11:21
L2	8	l1 and (pump$3 and (blood heart cardiovascular vascular aort$2) and (impell?R rot?R blade$1 fin fins)).clm.	USPAT; USOCR	OR	ON	2016/11/01 11:20
L1	397	ABOUL-HOSN-WALID$.in. KANZ-WILLIAM$.in. BAKER-BRUCE$.in. maquet$.as.	USPAT	OR	ON	2016/11/01 11:19
S272	1	(10/070,178).app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/10/28 17:03
S271	0	(10/070,178).app.	US-PGPUB; USOCR	OR	ON	2016/10/28 17:03
S270	3	(10/070,178 11/375,926 12/772,810 14/543,815).app.	US-PGPUB; USOCR	OR	ON	2016/10/28 17:02
S269	7	(10/070,178 11/375,926 12/772,810 14/543,815).app.	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/28 17:02
S268	3	"2001017581"	FPRS; EPO	OR	ON	2016/10/28 17:01
S267	0	WO adj "2001017581"	FPRS; EPO	OR	ON	2016/10/28 17:00
S266	1	(09/280988, 09/280970).app.	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/28 16:42
S265	0	15/239574.app.	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/28 15:49
S262	166	S261 and (wire guidewire)	US-PGPUB; USPAT; USOCR; FPRS	OR	ON	2016/10/12 16:57
S261	1062	S260 and (pump$3 blood heart cardiovascular vascular aort$2) and (impell?R rot?R blade$1 fin fins turbine)	US-PGPUB; USPAT; USOCR; FPRS	OR	ON	2016/10/12 16:57

S260	3623	(A61M1/101 A61M1/1034 A61M1/125 A61M2025/0183 A61M1/102 A61M1/122 Y10S415/90).cpc. and @ad<"20000901"	US-PGPUB; USPAT; USOCR; FPRS	OR	ON	2016/10/12 16:57
S259	80	(US-20060161095-$ or US-20060155158-$ or US-20050165269-$ or US-20030023201-$ or US-20150073202-$ or US-20100210895-$ or US-20050049696-$ or US-20030187322-$).did. or (US-7731675-$ or US-7022100-$ or US-6976996-$ or US-6210133-$ or US-6083260-$ or US-6287319-$ or US-4909781-$ or US-6245007-$ or US-4728319-$ or US-4591355-$ or US-4895557-$ or US-4817586-$ or US-4979936-$ or US-5112349-$ or US-6849068-$ or US-6248091-$ or US-5888241-$ or US-6217541-$ or US-6228063-$ or US-6547779-$ or US-6454997-$ or US-6440158-$ or US-6181971-$ or US-7130700-$ or US-6036654-$ or US-5827267-$).did. or (US-5713860-$ or US-7892270-$ or US-6231595-$ or US-6235048-$ or US-6238428-$ or US-6251130-$ or US-6159195-$ or US-5921971-$ or US-5833644-$ or US-5827229-$ or US-5569215-$ or US-5476450-$ or US-5221256-$ or US-6066100-$ or US-5938645-$ or US-6007478-$ or US-6176822-$ or US-3995617-$ or US-5965089-$ or US-5921913-$ or US-5964694-$ or US-6139487-$ or US-6058593-$ or US-4964864-$ or US-7066924-$ or US-6066122-$ or US-5234407-$).did. or (US-6295877-$ or US-6387125-$ or US-6346120-$ or US-6176848-$ or US-6135729-$ or US-5851174-$ or US-4969865-$ or US-4846152-$ or US-5211546-$ or US-5336184-$ or US-5527159-$ or US-8888728-$ or US-6544216-$ or US-5112292-$).did. or (CA-2361972-$).did. or (WO-8905668-$ or US-5741234-$ or WO-9843689-$ or WO-9843688-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2016/10/12 16:54
S258	75	S256 and (pump$3 blood heart cardiovascular vascular aort$2) and (impell?R rot?R blade$1 fin fins turbine)	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/12 16:31
S257	75	S256 and (pump$3 blood heart cardiovascular vascular aort$2) and (impell?R rot?R blade$1 fin fins)	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/12 16:31
S256	134	S252 S253 S254 S255	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/12 16:30
S255	1	("1523957" "5928132" "20030065271").pn. and @ad<"20000901"	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/12 16:29
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		"5160321" "5169378" "5199950" "5250059" "5275580" "5376114" "5405383" "5435308" "5484412" "5507725" "5749855" "5755687" "5762624" "5797948" "5814004" "5863179" "5888241" "5921913" "5938672" "6001078" "6129704" "6183220" "6245007" "6287319" "6533716" "6544216").pn. and @ad<"20000901"				
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S251	1	(14/543815).APP.	US-PGPUB; USOCR	OR	OFF	2016/10/11 16:37
S250	146	ABOUL-HOSN-WALID$.in. or KANZ-WILLIAM$.in. or BAKER-BRUCE$.in.	USPAT	OR	ON	2016/10/11 15:11
S249	498	ABOUL-HOSN-WALID$.in. or KANZ-WILLIAM$.in. or BAKER-BRUCE$.in.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/10/11 15:02
S248	0	15/239697.app.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/10/11 15:00

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S263	1	"Term Removed"	USPAT	OR	OFF	2016/10/12 16:54

11/1/2016 2:34:10 PM
H:\EAST searches\workspaces\15239574CON.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15239574	ABOUL-HOSN ET AL.
	Examiner	Art Unit
	ADAM MARCETICH	3761

CPC- SEARCHED		
Symbol	Date	Examiner
A61M1/101; A61M1/1034; A61M1/125; A61M2025/0183; A61M1/102; A61M1/122; Y10S415/90	11/01/2016	AMM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor search: PALM and EAST (US-PGPUB, USPAT, USOCR)	11/01/2016	AMM
Review cited art for similar case 15239697	11/01/2016	AMM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/ADAM MARCETICH/ Primary Examiner.Art Unit 3761

Customer No.: 99185 Docket No.: 06-01506US07

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re appl. of:	Walid N. ABOUL-HOSN	For:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
Serial No.:	15/239,574		
Conf. No.:	5519		
Filed:	August 17, 2016	Examiner:	Not Yet Assigned
Art Unit:	3739		

INFORMATION DISCLOSURE STATEMENT

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

Sir:

This Information Disclosure Statement (herein IDS) is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested per 37 C.F.R. 1.53 that the information (a) set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, as it is either (i) already of record in a parent application to this application (i.e., an application in which this application is a continuation of, a divisional or, or a continuation-in-part of), and therefore should be considered accordingly, or (ii) otherwise should be considered as a result of this submission. It is further requested that the listing of the information provided herein should be printed on any patent issuing from the above-identified application and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed before the mailing date of a first office action on the merits.

/Adam Marcetich/ 10/28/2016

Docket No. 06-01506US07

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

This application relies on, for an earlier effective filing date under 35 U.S.C. 120, one or more of the following applications:

14/966,669, filed December 11, 2015 (pending)
14/543,815, filed November 17, 2014 (now U.S. Patent No. 9,327,068)
12/722,810, filed May 3, 2010 (now U.S. Patent No. 8,888,728)
11/375,926, filed March 15, 2006 (now U.S. Patent No. 7,731,675)
10/070,178, filed July 19, 2002 (now U.S. Patent No. 7,022,100)

The documents listed on the present PTO/SB/08 (or equivalent form) were cited and/or submitted to the USPTO in at least one of the earlier applications, and are understood to have complied with 37 CFR 1.98(a), 37 CFR 1.98(b) and 37 CFR 1.98(c). Pursuant to 37 CFR 1.98(d), such documents are therefore not required for submission in the present IDS of this application. If the Examiner has any trouble locating such documents, he/she is invited to reach out to the undersigned agent of record for assistance.

The Examiner's attention is directed to co-pending U.S. pending patent applications: (i) U.S. Serial No. 15/239,697 filed August 17, 2016, and (ii) U.S. Serial No. 15/239,574 filed August 17, 2016, both of which are "track 1" prioritized applications and directed to related technical subject matter. U.S. Serial No. 14/966,669 is also pending and directed to related technical subject matter. During the examination of the present application, the Examiner is respectfully requested to consider the cited applications and any art cited therein.

In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of' the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

/Adam Marcetich/ 10/28/2016

Docket No. 06-01506US07

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Respectfully submitted,

DATE: August 19, 2016

/Kirk D. Swenson/

Kirk D. Swenson
Registration No. 52,265
Agent for Applicant(s)
GETINGE GROUP
MAQUET Cardiovascular LLC
1300 MacArthur Boulevard
Mahwah, NJ 07430
Tel: (201) 995-8816

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	15239574
	Filing Date	2016-08-17
	First Named Inventor	Walid N. ABOUL-HOSN
	Art Unit	3739
	Examiner Name	To be assigned
	Attorney Docket Number	06-01506US07

U.S.PATENTS						
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	5928132	A	1999-07-27	LESCHINSKY, Boris	
If you wish to add additional U.S. Patent citation information please click the Add button.						

U.S.PATENT APPLICATION PUBLICATIONS						
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					
If you wish to add additional U.S. Published Application citation information please click the Add button.						

FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	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]
	C12	2250996	CA	A1	1997-10-16	IMPELLA CARDIOTECHNIK GmbH [DE]		☐
If you wish to add additional Foreign Patent Document citation information please click the Add button								

NON-PATENT LITERATURE DOCUMENTS			
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]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Receipt date: 08/25/2016

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15239574
Filing Date	2016-08-17
First Named Inventor	Walid N. ABOUL-HOSN
Art Unit	3739
Examiner Name	To be assigned
Attorney Docket Number	06-01506US07

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

*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.

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Receipt date: 08/25/2016

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(**Not for submission under 37 CFR 1.99)**

Application Number	15239574
Filing Date	2016-08-17
First Named Inventor	Walid N. ABOUL-HOSN
Art Unit	3739
Examiner Name	To be assigned
Attorney Docket Number	06-01506US07

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.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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	/Kirk D. Swenson/	Date (YYYY-MM-DD)	2016-08-25
Name/Print	Kirk D. Swenson	Registration Number	52265

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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

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 record s.

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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS)

Form Used In Lieu of PTO/SB/08a/b (01-10 version)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	*Complete If Known*	
	Attorney Docket	06-01506US07
	Confirmation No.	1024
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	15/239,574
	Filing Date	08-17-2016
	Group Art Unit	3739
	Examiner Name	Not yet assigned.
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 1 of 5		

U.S. PATENTS

Examiner Initial*	Cite No. (A1, A2, ...An)	Patent Number	Kind Code[1]	Issue Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	A1	3966358	A	1976-06-29	Medac Gesellschaft fur Klinische Spezialpraparate mbH	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No. (B1, B2, ...Bn)	Publication Number	Kind Code [1]	Publication Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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] 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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS)

Form Used In Lieu of PTO/SB/08a/b (01-10 version)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	*Complete If Known*	
	Attorney Docket	06-01506US07
	Confirmation No.	5519
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	15/239,574
	Filing Date	08-17-2016
	Group Art Unit	3739
	Examiner Name	Not Yet Assigned
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 2 of 5		

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No. (C1, C2, ...Cn)	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T[5]
	C1	764448	EP	A2	1997-03-26	United States Surgical Corporation		
	C2	1222862	CN	A	1999-07-14	IMPELLA CARDIOTECHNIK GMBH		√
	C3	2349483	CA	A1	2000-06-08	IMPELLA CARDIOTECHNIK AKTIENGESELLSCHAFT		
	C4	2352234	CA	A1	2000-06-08	IMPELLA CARDIOTECHNIK AG		

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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] 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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS)

Form Used In Lieu of PTO/SB/08a/b (01-10 version)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	*Complete If Known*	
	Attorney Docket	06-01506US07
	Confirmation No.	5519
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	15/239,574
	Filing Date	08-17-2016
	Group Art Unit	3739
	Examiner Name	Not Yet Assigned
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 3 of 5		

	C5	2355966	DE	A1	1975-05-22	Heimes et al.		√
	C6	4016013	DE	A1	1991-11-21	Knierbein et al.		√
	C7	4105278	DE	A1	1992-08-27	Rau et al.		√
	C8	10017147	DE	A1	2001-10-18	Voelker Wolfram		√
	C9	10018424	DE	A1	2001-10-25	Impella Cardiotechnik AG		√
	C10	19626224	DE	A1	1998-01-02	Rau et al.		√
	C11	29604787	DE	U1	1996-10-02	Hutzenlaub et al.		√
	C12	200000007	CZ	A3	2000-05-17	SAMMLER ET AL.		√
	C13	2000029056	WO	A3	2001-01-04	CORVASCULAR INC.		
	C14	2000029056	WO	A2	2000-05-25	CORVASCULAR INC.		
	C15	2000033047	WO	A1	2000-06-08	IMPELLA CARDIOTECHNIK AG		√

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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] 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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS)

Form Used In Lieu of PTO/SB/08a/b (01-10 version)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	*Complete If Known*	
	Attorney Docket	06-01506US07
	Confirmation No.	5519
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	15/239,574
	Filing Date	08-17-2016
	Group Art Unit	3739
	Examiner Name	Not Yet Assigned
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 4 of 5		

	C16	2000037139	WO	A1	2000-06-29	A-MED SYSTEMS INC.		
	C17	2000053240	WO	A1	2000-09-14	ABIOMED INC.		
	C18	2000074748	WO	A1	2000-12-14	GOLDOWSKY Michael P.		
	C19	2001039817	WO	A3	2002-1-10	IMPELLA CARDIOTECHNIK AG		√
	C20	2001039817	WO	A2	2001-06-07	IMPELLA CARDIOTECHNIK AG		√
	C21	2042827	CA	A1	1991-11-19	Forschungsgesell-schaft fur Biomedizinische technik e.V.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initial*	Cite No. (D1, D2, ...Dn)	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]
	D1	T. Siess et al., "Concept, Realization, and First In Vitro Testing of an Intraarterial Microaxial Blood Pump", Artificial Organs, Volume 19, Issue 7, pages 644–652, July 1995.	

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	*Complete If Known*	
	Attorney Docket	06-01506US07
	Confirmation No.	5519
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	15/239,574
	Filing Date	08-17-2016
	Group Art Unit	3739
	Examiner Name	Not Yet Assigned
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 5 of 5		

	D2	K.C. Butler et al., "The Hemopump - a New Cardiac Prosthesis Device", IEEE Trans Biomed Eng. 1990;37:193–196.	
	D3	T. Siess, "System Analysis and Development of Intravascular Rotary Pumps to Support the Heart" (original title in German Systemanalyse und Entwicklung intravasaler Rotationspumpen zur Herzunterstützung), Shaker, 189 pages, 1999.	√
	D4	Kirsten-Treptow, P., & Sieß, T. (2000). The intracardiac pump system – High-tech product and Technology Platform (original title in German "Das intrakardiale Pumpsystem - Hightech-Produkt und Technologie-Plattform"). Kardiotechnik, 9(3), pp. 77 - 80.	√
	D5	H. Reul et al., "Artificial Heart and Assist Device: New Developments at the Helmholtz Institute", Chapter from Heart Replacement, publ. Springer (Japan), pages 201-227, 1996.	
	D6	B. Meyns et al., "Coronary Artery Bypass Graft with Biventricular Microaxial Pumps", Journal of Perfusion. 1999 Jul;14(4):pages 287-290.	
	D7	B. Meyns et al., Micro pumps to Support the Heart During CABG, European Journal of Cardiothorac Surg (2000) 17 (2): pages 169-174.	
	D8	Reul et al., "Rotary Blood Pumps in Circulatory Assist", Perfusion, 1995 May; 10(3); pp 153 – 168.	
	D9	U. Lonn et al., "Beating Heart Coronary Surgery Supported by an Axial Blood Flow Pump", The Annals of Thoracic Surgery, January 1999, Vol. 67, Issue 1, pp 99-104.	

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U.S. PATENTS

Examiner Initial*	Cite No. (A1, A2, …An)	Patent Number	Kind Code[1]	Issue Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	A1	4769005	A	1988-09-06	Ginsburg et al.	
	A2	4846152	A	1989-07-11	Nimbus Medical Inc.	
	A3	4944722	A	1990-07-31	Nimbus Medical Inc.	
	A4	5092879	A	1992-03-03	Jarvik, Robert K.	
	A5	5106363	A	1992-04-21	Terumo Kabushiki Kaisha	
	A6	5108411	A	1992-04-28	Cardiovascular Imaging Systems Inc.	
	A7	5137513	A	1992-08-11	Advanced Cardiovoascular Systems Inc.	
	A8	5334142	A	1994-08-02	New York University	

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	Title	Guidable Intravascular Blood Pump and Related Methods
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	A9	5516336	A	1996-05-14	Advanced Cardiovascular Systems Inc.	
	A10	5697948	A	1997-12-16	Endovascular Systems Inc.	
	A11	5746575	A	1998-05-05	Baxter International Inc.	
	A12	5824070	A	1998-10-20	Jarvik, Robert	
	A13	5851174	A	1998-12-22	Jarvik Robert	
	A14	5911702	A	1999-06-15	Heartport Inc.	
	A15	6007478	A	1999-12-28	Impella Cardiotechnik Aktiengesellschaft	
	A16	6071093	A	2000-06-06	Abiomed Inc.	
	A17	6116862	A	2000-09-12	MEDOS Medizintechnik GmbH	
	A18	6136025	A	2000-10-24	Barbut et al.	
	A19	6146354	A	2000-11-14	Horizon Medical Products	
	A20	6176848	B1	2001-01-23	Impella Cardiotechnik GmbH	

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	A21	6197001	B1	2001-03-06	Becton Dickinson and Company	
	A22	6248091	B1	2001-06-19	Voelker, Wolfram	
	A23	6290689	B1	2001-09-18	Corazón Technologies Inc.	
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	A26	6572530	B1	2003-06-03	JMS Co. Ltd.	
	A27	6592567	B1	2003-07-15	CHF Solutions Inc.	
	A28	6673040	B1	2004-01-06	Cardeon Corporation	
	A29	6733459	B1	2004-05-11	Aisin Seiki Kabushiki Kaisha	
	A30	7517352	B2	2009-04-14	Bacchus Vascular Inc.	
	A31	7998054	B2	2011-08-16	Thoratec Corporation	
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Examiner Initial*	Cite No. (B1, B2, ...Bn)	Publication Number	Kind Code [1]	Publication Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
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	B2	20030088151	A1	2003-05-08	Kung et al.	
	B3	20030100816	A1	2003-05-29	Siess, Thorsten	
	B4	20030187322	A1	2003-10-02	Siess, Thorsten	
	B5	20040097995	A1	2004-05-20	Nash et al.	
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	D1		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
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Application Number	15/239,574
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First Named Inventor	Walid N. ABOUL-HOSN
Art Unit	3739
Examiner Name	Not yet assigned.
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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
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Art Unit	3739
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Attorney Docket Number	06-01506US07

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Examiner Name	Not Yet Assigned
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Examiner Name	Not Yet Assigned
Attorney Docket Number	06-01506US07

	5	19622335	DE	A1	1997-12-11	VOELKER, Wolfram		☐
	6	H-0999092	JP	A	1997-04-15	Target Therapeutics Inc.		☐
	7	0916359	EP	B1	1999-05-19	Impella Cardiotech AG		☐
	8	2256427	CA	A	1998-10-08	Impella Cardiotech AG		☐
	9	89/05164	WO	A1	1989-05-15	Nimbus Medical, Inc.		☐
	10	99/02204	WO	A1	1999-01-21	A-Med Systems, Inc.		☐
	11	00/12148	WO	A1	2000-03-09	A-Med Systems, Inc.		☐
	12	00/18448	WO	A1	2000-04-06	A-Med Systems, Inc.		☐
	13	00/19097	WO	A1	2000-04-06	A-Med Systems, Inc.		☐
	14	00/37139	WO	A1	2000-06-26	A-Med Systems, Inc.		☐
	15	00/69489	WO	A1	2000-11-23	A-Med Systems, Inc.		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15/239,574
Filing Date	08-17-2016
First Named Inventor	Walid N. ABOUL-HOSN
Art Unit	3739
Examiner Name	Not Yet Assigned
Attorney Docket Number	06-01506US07

	16	01/78807	WO	A1	2001-10-25	A-Med Systems, Inc.		☐

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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]
	1	Online encyclopedia article "Pyrolytic Carbon" accessed February 19, 2009, http://en.wikipedia.org/wiki/Pyrolytic/carbon, 1 page.	☐
	2	Online encyclopedia article "Ventricular assist device, List of implantable VAD devices" accessed January 12, 2010, http://en.wikipedia.org/wiki/Ventricular_assist_device, 11 pages.	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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[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.

EFS Web 2.1.17

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Receipt date: 08/19/2016

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Art Unit	3739
Examiner Name	Not Yet Assigned
Attorney Docket Number	06-01506US07

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.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

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	/Kirk D. Swenson/	Date (YYYY-MM-DD)	August 19, 2016
Name/Print	Kirk D. Swenson	Registration Number	52265

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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS)

Form Used In Lieu of PTO/SB/08a/b (01-10 version)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	***Complete If Known***	
	Application Number	15/239,574
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	First Named Inventor	Walid N. ABOUL-HOSN
	Art Unit	3739
	Examiner Name:	Not Yet Assigned
	Attorney Docket Number:	06-01506US07
	Confirmation Number	5519
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U.S. PATENTS

Examiner Initial*	Cite No. (A1, A2, …An)	Patent Number	Kind Code[1]	Issue Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	A1	4135253	A	1/23/1979	Reich et al.	
	A2	4153048	A	5/8/1979	Magrini	
	A3	4508535	A	4/2/1985	Joh et al.	
	A4	4679558	A	7/14/1987	Kensey et al.	
	A5	4686982	A	8/18/1987	Nash	
	A6	4728319	A	3/1/1988	Masch	
	A7	4747821	A	5/31/1988	Kensey et al.	
	A8	4747840	A	5/31/1988	Ladika et al.	
	A9	4749376	A	6/7/1988	Kensey et al.	
	A10	4753221	A	6/28/1988	Kensey et al.	
	A11	4919647	A	4/24/1990	Nash	
	A12	5017103	A	5/21/1991	Dahl	
	A13	5030204	A	7/9/1991	Badger et al.	
	A14	5061256	A	10/29/1991	Wampler	
	A15	5135535	A	8/4/1992	Kramer, Barry L.	

Examiner Signature	/Adam Marcetich/	**Date Considered**	10/28/2016

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	Examiner Name:	Not Yet Assigned
	Attorney Docket Number:	06-01506US07
	Confirmation Number	5519
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	A16	5160321	A	11/3/1992	Sahota, Harvinder	
	A17	5169378	A	12/8/1992	Figuera	
	A18	5199950	A	4/6/1993	Schmitt et al.	
	A19	5250059	A	10/5/1993	Andreas et al.	
	A20	5275580	A	6/4/1994	Yamazaki	
	A21	5376114	A	12/27/1994	Jarvik	
	A22	5405383	A	4/11/1995	Barr	
	A23	5435308	A	7/25/1995	Gallup et al.	
	A24	5484412	A	1/16/1996	Pierpont	
	A25	5507725	A	4/16/1996	Savage et al.	
	A26	5749855	A	5/12/1998	Reitan	
	A27	5755687	A	5/26/1998	Donlon, Brian S.	
	A28	5762624	A	6/9/1998	Peters, William S.	
	A29	5797948	A	8/25/1998	Dunham, Susan L.	
	A30	5814004	A	9/29/1998	Tamari, Yehuda	
	A31	5863179	A	1/26/1999	Westphal et al.	
	A32	5888241	A	5/30/1999	Jarvik	
	A33	5921913	A	7/13/1999	Siess	
	A34	5938672	A	8/17/1999	Nash	

Examiner Signature	/Adam Marcetich/	**Date Considered**	10/28/2016

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	Attorney Docket Number:	06-01506US07
	Confirmation Number	5519
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	A35	6001078	A	12/14/1999	Reekers, Jan Albertus	
	A36	6129704	A	10/10/2000	Forman et al.	
	A37	6183220	B1	12/6/2001	Ohara et al.	
	A38	6245007	B1	6/12/2001	Bedingham et al.	
	A39	6287319	B1	9/11/2001	Aboul-Hosn et al.	
	A40	6533716	B1	3/18/2003	Schmitz-Rode et al.	
	A41	6544216	B1	4/8/2003	Sammler et al.	
	A42					
	A43					
	A44					

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No. (B1 B2 ...Bn)	Publication Number	Kind Code [1]	Publication Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages Columns Lines where Relevant Passages or Relevant Figures Appear
	B1	20070118072	A1	2007-05-24	Nash	

FOREIGN PATENT DOCUMENTS

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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	Confirmation Number	5519
Sheet 4 of 7		

Examiner Initial*	Cite No. (C1 C2 ...Cn)	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages Columns Lines where Relevant Passages or Relevant Figures Appear	T[5]
	C1	0364293	EP	A2	1990-04-18	KENSEY NASH CORP [US]		
	C2	0445782	EP	A1	1991-09-11	MISUZU IND CORP [JP] YAMAZAKI KENJI [JP]		
	C3	0916359	EP	A1	1999-05-19	IMPELLA CARDIOTECH GMBH [DE]		
	C4	H04126158	JP	A	1992-04-27	YAMAZAKI KENJI MISUZU KOUGIYOU KK		X
	C5	1994005347	WO	A1	1994-03-17	REITAN OEYVIND [SE]		

Examiner Signature	/Adam Marcetich/	**Date Considered**	10/28/2016

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	Art Unit	3739
	Examiner Name:	Not Yet Assigned
	Attorney Docket Number:	06-01506US07
	Confirmation Number	5519
Sheet 5 of 7		

	C6	1997037696	WO	A1	1997-10-16	RAU GUENTER [DE] REUL HELMUT [DE]		
	C7	1997049440	WO	A2	1997-12-31	UNIV PITTSBURGH [US]		
	C8	1999044651	WO	A1	1999-09-10	GUENTHER ROLF W [DE] SCHMITZ RODE THOMAS [DE]		X
	C9	2000043053	WO	A1	2000-07-27	KRITON MEDICAL INC [US] YU LONG SHENG [US]		
	C10	1999002204	WO	A1	1999-01-21	A-Med Systems, Inc.		
	C11	0280225	EP	A2	1988-08-31	Cardiosistemi S.P.A.		

Examiner Signature	/Adam Marcetich/	**Date Considered**	10/28/2016

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	Confirmation Number	5519
Sheet 6 of 7		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initial*	Cite No. (D1 D2 …Dn)	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]
	D1	Compendium of Technical and Scientific Information for the Hemopump Temporary Cardiac Assist System, 1988 (15 pages)	
	D2	FRAZIER, O.H., et al., "First Human Use of the Hemopump, A Gather-Mounted Ventricular Assist Device," Ann Thorac Surg., 1990 Feb; 49(2): pages 299-304.	
no date	D3	JOMED Reitan Catheter Pump Brochure, www.jomed.com/rcp (undated) (6 pages).	
	D4	REITAN, Oyvind et al., "Hydrodynamic Properties of a New Percutaneous Intraaortic Axial Flow Pump," ASAIO Journal; 2000 Jay-June; Vo1. 16; pages 323- 329.	
	D5	WAMPLER, Richard, K., "In Vivo Evaluation of a Peripheral Vascular Access Axial Flow Blood Pump," ASAIO Trans., 1988 Jul-Sep; 34(3): pages 450-454	
	D6	Letter from Ajey Atre to Michael R. Minogue dated Dec. 15, 2015	
	D7	Letter from Richard T. McCaulley, Jr. to Ajey Atre dated Jan. 19, 2016	
	D8	Letter from Michael S. Connor to Richard T. McCaulley, Jr. dated May 3, 2016	
	D9	Letter from Richard T. McCaulley, Jr. dated May 19, 2016	
	D10	Complaint from *Abiomed Inc. v. Maquet Cardiovascular*, Case No. 1:16-cv-10914, filed in Dist. of Mass. on May 19, 2016	
	D11	File wrapper for U.S. Serial No. 09-280988 entitled "Steerable Cannula" – filed March 30, 1999, USPTO.	
	D12	File wrapper for U.S. Serial No. 09-280987 entitled "Cannula with Balloon Tip" – filed March 30, 1999, USPTO.	

Examiner Signature	/Adam Marcetich/	**Date Considered**	10/28/2016

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	First Named Inventor	Walid N. ABOUL-HOSN
	Art Unit	3739
	Examiner Name:	Not Yet Assigned
	Attorney Docket Number:	06-01506US07
	Confirmation Number	5519
Sheet 7 of 7		

	D13	File wrapper for U.S. Serial No. 10-566423 entitled “Intracardiac Pumping Device”, USPTO, filed on 1-30-2006 and retrieved from PAIR on 8-17-2016.	
	D14	Decision from the Patent Trial and Appeal Board, USPTO, appeal no. 2013-001967 for US Patent Application Serial No. 10-556423 dated 9-30-2015 (4 pages).	
	D15	File wrapper for U.S. Serial No. 09-280970 entitled “Pressure Sensing Cannula” – filed March 30, 1999, USPTO.	

Examiner Signature	/Adam Marcetich/	**Date Considered**	10/28/2016

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Attorney's Docket No. 06-01506US07 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Aboul-Hosn et al.	Confirmation No.:	5519
Appl. No.:	15/239,574	Art Unit:	3739
Filed:	August 17, 2016	Examiner:	Not Yet Assigned
For:	Guidable Intravascular Blood Pump and Related Methods		

INFORMATION DISCLOSURE STATEMENT

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

Sir:

This Information Disclosure Statement (herein IDS) is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested per 37 C.F.R. 1.53 that the information set forth in this statement, and in the listed documents, be considered during the pendency of the above-identified application. It is further requested that the listing of the information provided herein should be printed on any patent issuing from the above-identified application and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed before the mailing date of a first office action on the merits. Attached is a list of documents on form PTO/SB/08 (or a substantial equivalent).

Documents Not In English:

Applicant brings to the Examiner's attention PCT publication WO99/44651A2 (see reference C8) which is published in German. U.S. Pat. Publication 6,533,716 (see reference A40) is believed to be an English equivalent of the WO99/44651A2 application due to their common priority claim.

Docket No. 06-01506US07

/Adam Marcetich/ 10/28/2016

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Applicant brings to Examiner's attention PCT publication WO1997037696A1 (see reference C6) which is published in German. Canadian Patent Publication CA2250996A2 (see reference C12) is believed to be an English equivalent of the WO1997037696A1 application, due to their common priority claim.

Applicant brings to the Examiner's attention Japanese application JPH04126158A, which is published in Japanese (see reference C4). Machine translations of the Japanese patent application are provided by (a) the European Patent Office's Patent Translate website, and (b) the Japan Platform for Patent Information (i.e., "J-Plat-Pat") translation platform, and are appended to the disclosed C4 document. Applicant does not attest to the accuracy of the machine translations.

Related Pending Applications:

The Examiner's attention is directed to co-pending U.S. pending patent applications: (i) (i) U.S. Serial No. 15/239,697 filed August 17, 2016, and (ii) U.S. Serial No. 15/239,574 filed August 17, 2016, both of which are "track 1" prioritized applications and directed to related technical subject matter. U.S. Serial No. 14/966,669 is also pending and directed to related technical subject matter. During the examination of the present application, the Examiner is respectfully requested to consider the cited applications and any art cited therein.

Copies Not Submitted:

US Patent Literature:

Since this application was filed after June 30, 2003, in accordance with 37 CFR § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patent and patent application references.

Foreign Patent Literature and Non-Patent Literature:

This application relies on, for an earlier effective filing date under 35 U.S.C. 120, one or more of the following applications:

14/966,669, filed December 11, 2015 (pending)

14/543,815, filed November 17, 2014 (now U.S. Patent No. 9,327,068)

12/722,810, filed May 3, 2010 (now U.S. Patent No. 8,888,728)

Docket No. 06-01506US07

/Adam Marcetich/ 10/28/2016

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11/375,926, filed March 15, 2006 (now U.S. Patent No. 7,731,675)
10/070,178, filed July 19, 2002 (now U.S. Patent No. 7,022,100)

The documents listed on the present PTO/SB/08 (or equivalent form) were cited and/or submitted to the USPTO in at least one of the earlier applications, and are understood to have complied with 37 CFR 1.98(a), 37 CFR 1.98(b) and 37 CFR 1.98(c). Pursuant to 37 CFR 1.98(d), such documents are therefore not required for submission in the present IDS of this application. If the Examiner has any trouble locating such documents, he/she is invited to reach out to the undersigned agent of record for assistance.

Abiomed Allegations:

Applicant directs Examiner to reference D10, which is a complaint filed by Abiomed, Inc. ("Abiomed") on May 19, 2016 in the District Court of the District of Massachusetts. In this complaint, Abiomed alleges that it does not infringe the claims in U.S. Patent Nos. 7,022,100, 8,888,728, and 9,327,068, which are related patents to the current Application. This litigation is currently pending. This complaint also includes letters exchanged between the parties, and these letters are included as references D6, D7, and D8 in this IDS. Applicant is also listing reference D9, which is an additional letter between the parties, but is not included in the complaint.

In reference D7, Abiomed provides a claim chart alleging that various claims in U.S. Patent Nos. 7,022,100, 8,888,728, and 9,327,068 are invalid in view of alleged prior art. The references cited in Abiomed's claim charts are also listed in this IDS as reference A33, U.S. Patent No. 5,921,913, and reference A41, U.S. Patent No. 6,544,216. Applicant notes that references A33 and A41 contain material that was previously considered by the Examiner in connection with this application's related parent patent applications, including at least this application's parent U.S. Patent Application No. 14/534,815. In prior related applications, Applicant provided Examiner with U.S. Patent No. 5,911,685, which is a divisional of U.S. Patent No. 5,921,913. Applicant also provided Examiner with WO99/58170 in connection with related, parent applications. U.S. Patent No. 6,544,216 claims priority to the PCT application that was published as WO99/58170.

/Adam Marcetich/ 10/28/2016

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Applicant also disagrees with the suggestion in Abiomed's letters, D7 and D9, that Applicant may have violated its duty of candor. Applicant has complied with its duty of candor in all related applications and in this Application. The references that Abiomed's letter D7 asserts were withheld by Applicant were in fact disclosed in an IDS filed by Applicant in U.S. Patent Application No. 14/534,815 on January 5, 2016. In addition, the charts, the combination of references, and the explanation provided by Abiomed, as referenced in Abiomed's letter D9, are submitted herewith.

Applications Incorporated By Reference in the Present Application:

The present application incorporates by reference both (i) U.S. patent application serial no. 09/280,988, filed March 30, 1999, and (ii) U.S. patent application Ser. No. 09/280,970, which is also filed on March 30, 1999. The file wrappers of the two applications are identified in the PTO/SB/08 form as NPL references D11 and D15.

Other:

In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of' the item and Applicant reserves the right to prove that the date of publication is in fact different.

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached IDS form (i.e., PTO/SB/08, PTO-1449 or equivalents thereof) with initials or other appropriate marks. It is requested that the Examiner consider these documents and officially make them of record in accordance with the provisions of 37 C.F.R. § 1.97 and Section 609 of the MPEP. By identifying the listed documents, Applicant in no way makes any admission as to the prior art status of the listed documents, but is instead identifying the listed documents for the sake of full disclosure.

Early and favorable consideration of the above captioned application is earnestly solicited.

Respectfully submitted,

DATE: __August 19, 2016__

/Kirk D. Swenson/
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Docket No. 06-01506US07

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

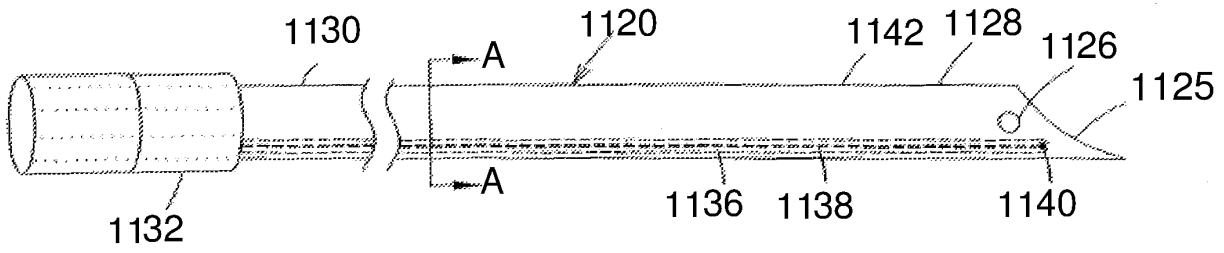

Figure 20

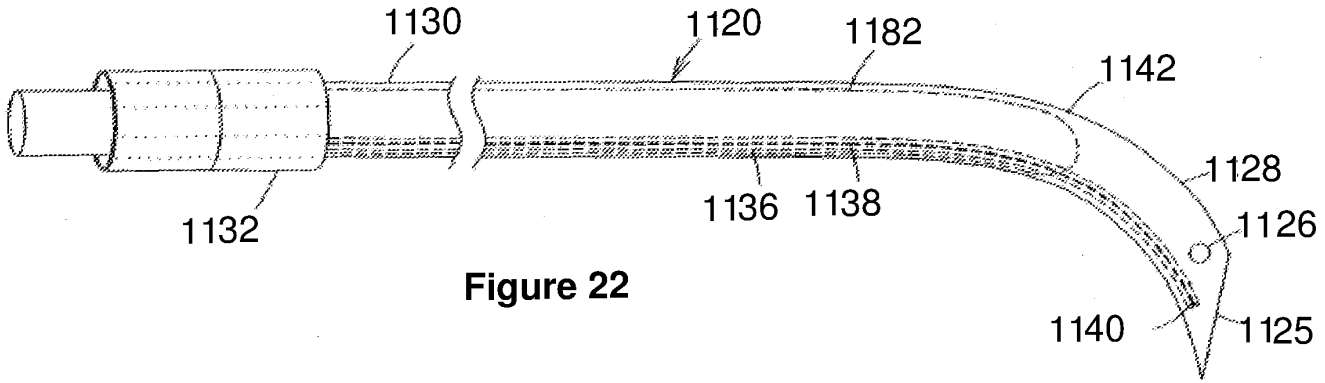

Figure 22

OK TO ENTER: /AMM/

/AMM/ (11/01/2016) OK to enter new specification /AMM/

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

RELATED APPLICATIONS

[0001] This application is a divisional of co-pending U.S. Patent Application Serial No. 14/966,669, filed December 11, 2015, which is a divisional of U.S. Patent Application Serial No. 14/543,815, filed November 17, 2014 (now U.S. Patent 9,327,068, issued May 3, 2016), which is a continuation of U.S. Patent Application Serial No. 12/772,810, filed May 3, 2010 (now U.S. Patent 8,888,728, issued November 18, 2014), which is a continuation of U.S. Patent Application Serial No. 11/375,926, filed March 15, 2006 (now U.S. Patent No. 7,731,675, issued June 8, 2010), which is a divisional of U.S. Patent Application Serial No. 10/070,178, filed July 19, 2002, (now U.S. Pat. No. 7,022,100, issued April 4, 2006) which claims the benefit of PCT/US00/24515 filed September 1, 2000, which claims the benefit of provisional U.S. Patent Application Serial No. 60/152,249 filed September 3, 1999. We hereby claim priority to the aforementioned application(s) and also incorporate herein by reference each of the afore-listed patents and applications in their entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to blood pumps and, more particularly, to an improved intra-vascular blood pump having a guide mechanism which provides the ability to selectively guide the intravascular pump to a desired location within a patient's circulatory system.

DESCRIPTION OF RELATED ART

[0003] Over the years, various types of blood pumps have been developed for the purpose of augmenting or replacing the blood pumping action of damaged or diseased hearts. Blood pumps are commonly used in three situations: (1) for acute support during cardio-pulmonary operations; (2) for short-term support while awaiting recovery of the heart from surgery; or (3) as a bridge to keep a patient alive while awaiting heart transplantation. The pumps may be

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BIB DATA SHEET

CONFIRMATION NO. 1024

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
15/239,574	08/17/2016 RULE	600	3761	06-01506US07

APPLICANTS

MAQUET Cardiovascular LLC, Mahwah, NJ;

INVENTORS

Walid N. ABOUL-HOSN, Btekhnay, LEBANON;
William R. KANZ, Woodinville, WA;
Bruce A. BAKER, Placerville, CA;

**** CONTINUING DATA ***************************

This application is a DIV of 14/966,669 12/11/2015
which is a DIV of 14/543,815 11/17/2014 PAT 9327068
which is a CON of 12/772,810 05/03/2010 PAT 8888728
which is a CON of 11/375,926 03/15/2006 PAT 7731675
which is a DIV of 10/070,178 07/19/2002 PAT 7022100
which is a 371 of PCT/US00/24515 09/01/2000
which claims benefit of 60/152,249 09/03/1999

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

08/29/2016

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ADAM M MARCETICH/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		LEBANON	18	30	3

ADDRESS

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1300 MacArthur Boulevard
Mahwah, NJ 07430
UNITED STATES

TITLE

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

FILING FEE RECEIVED		
3200	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

AMENDMENT Mail Stop: Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket No.	06-01506US07
	Confirmation No.	1024
	First Named Inventor	Walid N. Aboul-Hosn et al.
	Application Number	15/239,574
	Filing Date	August 17, 2016
	Group Art Unit	3761
	Examiner Name	Adam M. MARCETICH
	Title	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

Sir:

In response to the non-final Office Action issued November 4, 2016 regarding the above-identified matter, please amend the above-captioned application as follows.

Amendments to the Claims are reflected by the Listing of Claims that begins on page 2 of this paper.

Remarks/Arguments begin on page 11 of this paper.

I. Amendments to the Claims:

Kindly amend the claims as follows.

The following listing of claims will replace all prior versions and listings of claims in the application identified above.

Listing of the Claims:

1– 23. (CANCELLED)

24. (Previously Presented). An intravascular blood pump system, comprising:
an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a patient by a guide wire and the intravascular blood pump configured to provide left-heart support, the intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub;

a cannula coupled to a distal end of the intravascular blood pump, one or more first ports and one or more second ports establishing fluid communication between a lumen of the cannula and an exterior region of the cannula, wherein at least one first port is located in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port, and wherein the intravascular blood pump is configured to draw blood from the patient's heart into the at least one second port through the cannula lumen and out the at least one first port to provide left-heart support while the cannula is positioned across an aortic valve of the patient, the cannula is configured such that when the intravascular blood pump is positioned in the patient to provide left-heart support the distal end of the cannula and the at least one second port are positioned inside the patient's heart and the proximal end of the cannula and the at least one first port are positioned in the patient's aorta;

a catheter connected to a proximal end of the intravascular blood pump, a purge lumen extending through the catheter and operatively arranged to deliver purge fluid towards the intravascular blood pump;

an elongate lumen arranged coaxially with at least a portion of the cannula and in series longitudinally with the cannula, and an end of the elongate lumen is adjacent an end of the cannula, the elongate lumen sized to slidably receive the guide wire and having a diameter sized smaller than a diameter of the cannula lumen;

a pressure sensing element configured to sense pressure proximate the intravascular blood pump;

a housing connected to a proximal end of the catheter; and

first and second conduits each connected to the housing, at least one of the first conduit and second conduit in fluid communication with the purge lumen.

25. (Currently Amended). The intravascular blood pump system of claim 24 wherein the rotor comprises~~comprising~~ a second blade extending radially from the rotor hub and wherein the hub has a distal end extending distally beyond a most distal portion of the blades.

26. (Currently Amended). The intravascular blood pump system of claim 24 wherein the housing is configured to have the purge fluid pass~~passes~~ through it.

27. (Previously Presented). The intravascular blood pump system of claim 24 wherein the cannula is reinforced with a spiral wire.

28. (Currently Amended). The intravascular blood pump system of claim 24 wherein the pressure sensing element comprises~~comprising~~ at least one of a piezo-electric pressure sensing element and a strain gauge.

29. (Currently Amended). The intravascular blood pump system of claim 28 wherein the pressure sensing element further comprises~~comprising~~ a fluid column extending through the catheter.

30. (Previously Presented). The intravascular blood pump system of claim 24 wherein the pressure sensing element is used to determine a differential pressure.

31. (Previously Presented). The intravascular blood pump system of claim 24 further comprising a rotor shroud, a portion of the rotor shroud having an outer diameter matching an inner diameter of a proximal portion of the cannula.

32. (Currently Amended). The intravascular blood pump system of claim 24 further comprising a rotor shroud, motor assembly and a drive cable, the drive cable at least partially disposed within the catheter,

wherein the motor assembly and drive cable are configured to drive the rotor,

wherein the elongate lumen is proximal to the cannula and the motor assembly is configured to remain external to the patient, and

wherein the intravascular blood pump system comprises~~comprising~~ a dual construction arrangement whereby the rotor is configured to be docked within the rotor shroud.

33. (Previously Presented). The intravascular blood pump system of claim 24 further comprising a distal tip member at one end, the distal tip member comprising a stem portion, extending distally away from a distal end of the cannula lumen, and a curved tail portion located distal to the stem portion.

34. (Previously Presented). The intravascular blood pump system of claim 24 further comprising a pigtail shaped distal tip member at one end.

35. (Previously Presented). The intravascular blood pump system of claim 24 further comprising a J-shaped distal tip member at one end.

36. (Previously Presented). The intravascular blood pump system of claim 24 further comprising a fluid delivery pump configured to deliver purge fluid through the purge lumen towards the intravascular blood pump.

37. (Previously Presented). The intravascular blood pump system of claim 36 wherein the fluid delivery pump is configured to deliver the purge fluid at a pressure than is both sufficient to avoid clotting of the patient's blood and that is higher than a blood pressure of the patient adjacent the intravascular blood pump.

38. (Previously Presented). The intravascular blood pump system of claim 24 further comprising a rotor shroud disposed about the rotor and wherein a proximal end of the cannula is disposed about a distal end of the rotor shroud.

39. (Previously Presented). The intravascular blood pump system of claim 24 further comprising a rotor shroud having a distal portion with a first outer diameter and a more proximal portion with a second outer diameter larger than the first outer diameter.

40. (Previously Presented). The intravascular blood pump system of claim 24 further comprising an elongate tubular element defining the elongate lumen.

41. (Previously Presented). The intravascular blood pump system of claim 33 wherein the elongate lumen is located proximal to the distal tip member.

42. (Previously Presented). The intravascular blood pump system of claim 24 wherein the purge lumen is a side lumen extending longitudinally through the catheter but offset radially from a central axis of the catheter.

43. (Previously Presented). An intravascular blood pump system, comprising:
an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a patient by a guide wire and configured to provide left-heart support, the intravascular blood pump comprising a rotor having a rotor hub tapering in the distal

direction and a rotor shroud at least partially disposed about the rotor hub, at least one blade extending radially outward from the rotor hub, a distal end of the hub extending distally beyond a most distal portion of the at least one blade;

a cannula coupled to a distal end of the intravascular blood pump, a portion of the rotor shroud having an outer diameter matching an inner diameter of a proximal portion of the cannula, the proximal portion of the cannula disposed about a distal end of the rotor shroud, one or more first ports and one or more second ports establishing fluid communication between a lumen of the cannula and an exterior region of the cannula, wherein at least one first port is located in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port, and wherein the intravascular blood pump is configured to draw blood from the patient's heart into the at least one second port through the cannula lumen and out the at least one first port to provide left-heart support while the cannula is positioned across an aortic valve of the patient, the cannula is configured such that when the intravascular blood pump is positioned in the patient to provide left-heart support the distal end of the cannula and the at least one second port are positioned inside the patient's heart and the proximal end of the cannula and the at least one first port are positioned in the patient's aorta;

a catheter connected to a proximal end of the intravascular blood pump, a purge lumen extending through the catheter and operatively arranged to deliver purge fluid towards the intravascular blood pump;

an elongate lumen arranged coaxially with at least a portion of the cannula and in series longitudinally with the cannula, and an end of the elongate lumen is adjacent an end of the cannula, the elongate lumen sized to slidably receive the guide wire and having a diameter sized smaller than a diameter of the cannula lumen;

a pressure sensing element configured to sense pressure proximate the intravascular blood pump and comprising a fluid column extending through the catheter;

a housing connected to a proximal end of the catheter, the housing configured to have the purge fluid passing through it;

first and second conduits each connected to the housing, at least one of the first conduit and second conduit in fluid communication with the purge lumen; and

a fluid delivery pump configured to deliver purge fluid through at least one of the first and second conduits, and through the housing and the purge lumen towards the intravascular blood pump.

44. (Previously Presented). The intravascular blood pump system of claim 43 further comprising a distal tip member at one end of the cannula, the distal tip member comprising a stem portion, extending distally away from a distal end of the cannula lumen, and a curved tail portion located distal to the stem portion.

45. (Previously Presented). The intravascular blood pump system of claim 44 wherein the distal tip member is pigtail shaped.

46. (Previously Presented). The intravascular blood pump system of claim 44 wherein the distal tip member is J-shaped.

47. (Currently Amended). The intravascular blood pump system of claim 43 further comprising a rotor shroud, motor assembly and a drive cable, the drive cable at least partially disposed within the catheter,

wherein the motor assembly and drive cable are configured to drive the rotor,

wherein the elongate lumen is proximal to the cannula and the motor assembly is configured to remain external to the patient, and

wherein the intravascular blood pump system comprises~~comprising~~ a dual construction arrangement whereby the rotor is configured to be docked within the rotor shroud.

48. (Previously Presented). The intravascular blood pump system of claim 43 wherein the pressure sensing element further comprising at least one of a piezo-electric pressure sensing element and a strain gauge.

49. (Previously Presented). The intravascular blood pump system of claim 43 wherein the purge lumen is a side lumen extending longitudinally through the catheter but offset radially from a central axis of the catheter.

50. (Previously Presented). An intravascular blood pump system, comprising:

an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a patient by a guide wire and configured to provide left-heart support, the intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and a rotor shroud at least partially disposed about the rotor hub, at least one blade extending radially outward from the rotor hub, a distal end of the hub extending distally beyond a most distal portion of the at least one blade;

a catheter coupled to a proximal end of the intravascular blood pump, a purge lumen extending through the catheter and operatively arranged to deliver purge fluid towards the intravascular blood pump;

a cannula coupled to a distal end of the intravascular blood pump, a portion of the rotor shroud having an outer diameter matching an inner diameter of a proximal portion of the cannula, the proximal portion of the cannula disposed about a distal end of the rotor shroud, one or more first ports and one or more second ports establishing fluid communication between a lumen of the cannula and an exterior region of the cannula, wherein at least one first port is located in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port, the cannula is configured such that when the

intravascular blood pump is positioned in the patient to provide left-heart support the distal end of the cannula and the at least one second port are positioned inside the patient's heart and the proximal end of the cannula and the at least one first port are positioned in the patient's aorta, the intravascular blood pump is configured to draw blood from the patient's heart into the at least one second port through the cannula lumen and out the at least one first port to provide left-heart support while the cannula is positioned across an aortic valve of the patient;
an elongate lumen associated with the cannula and sized to slidably receive the guide wire and dimensioned such that the guide wire passes slidably and coaxially through the elongate lumen, the elongate lumen is sized smaller cross sectionally than the cannula lumen and is shorter in length than the cannula lumen, both the elongate lumen and the cannula lumen not extending through the rotor hub, the intravascular blood pump system configured for the guide wire to extend proximally away from the intravascular blood pump , the guide wire not passing through the rotor hub or the catheter, and the guide wire extending out of the intravascular blood pump system in a distal direction through the elongate lumen, wherein when the intravascular blood pump is positioned in the patient to provide left-heart support the elongate lumen lies wholly within the left ventricle;

a pressure sensing element configured to sense pressure proximate the intravascular blood pump comprising a fluid column extending through the catheter;

a housing connected to a proximal end of the catheter, the housing configured to have the purge fluid pass through it;

first and second conduits each connected to the housing, at least one of the first conduit and second conduit in fluid communication with the purge lumen; and

a fluid delivery pump configured to deliver purge fluid through at least one of the first and second conduits, and through the housing and the purge lumen towards the intravascular blood pump.

51. (Currently Amended). The intravascular blood pump system of claim 50 further comprising a motor assembly and a drive cable, the drive cable at least partially disposed within the catheter,
wherein the motor assembly and drive cable are configured to drive the rotor,

wherein the elongate lumen is proximal to the cannula and the motor assembly is configured to remain external to the patient, and

wherein the intravascular blood pump system comprises~~comprising~~ a dual construction arrangement whereby the rotor is configured to be docked within the rotor shroud.

52. (Previously Presented). The intravascular blood pump system of claim 50 further comprising a pigtail shaped distal tip member or a J-shaped distal tip member at one end.

53. (Previously Presented). The intravascular blood pump system of claim 52 wherein the elongate lumen is located proximal to the distal tip member.

II. REMARKS

By this paper, claims 25, 26, 28, 29, 32, 47 and 51 have been amended to improve readability and not for a reason related to patentability. Therefore, the present amendment has no further limiting effect on the scope of the claims.

The present amendment overcomes the Examiner's objections to the claims.

The present amendment adds no new matter to the above-captioned application.

i. The Rejection

Claims 24-39 and 41-53 stand provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 24-32, 34, 38-43, 45, 47 and 48 of co-pending Application No. 15/239,697.

Applicants respectfully traverse the Examiner's rejections and request reconsideration of the above-captioned application for the following reasons.

ii. Applicants' Arguments

Claims 24-53 are pending. Applicants file herewith a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) or 37 C.F.R. § 1.321(d) with respect to co-pending U.S. Patent Application No. 15/239,697. This timely filed terminal disclaimer overcomes the Examiner's provisional obviousness-type double patenting rejection.

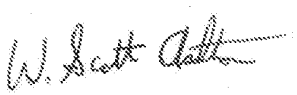
II. CONCLUSION

The claims of the above-captioned application are believed to be in condition for allowance, and a prompt notice of allowance is earnestly solicited.

If the Examiner feels that a telephone interview would expedite prosecution of this patent application, the Examiner is respectfully invited to telephone the undersigned at the number provided.

No fees are believed to be due in association with this filing except for the fee for the terminal disclaimer filed herewith. If any additional fees are required, the Commissioner is hereby authorized to charge any underpayment as well as credit any overpayment of fees associated with this communication to Deposit Account No. 50-5722, reference no. 06-01506US07.

Respectfully submitted,



Date: November 4, 2016

By: _____
Wesley Scott Ashton
Registration No. 47,395

MAQUET Cardiovascular, Getinge Group
1300 MacArthur Blvd
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Phone No: 1-201-995-8980

Electronic Patent Application Fee Transmittal

Application Number:	15239574
Filing Date:	17-Aug-2016
Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
Filer:	Wesley Scott Ashton/Kathleen Andree
Attorney Docket Number:	06-01506US07

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	160	160
		Total in USD ($)		**160**

Electronic Acknowledgement Receipt	
EFS ID:	27421977
Application Number:	15239574
International Application Number:	
Confirmation Number:	1024
Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
Customer Number:	99185
Filer:	Wesley Scott Ashton/Kathleen Andree
Filer Authorized By:	Wesley Scott Ashton
Attorney Docket Number:	06-01506US07
Receipt Date:	04-NOV-2016
Filing Date:	17-AUG-2016
Time Stamp:	14:22:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$160
RAM confirmation Number	110716INTEFSW00010892040170
Deposit Account	040170
Authorized User	Kathleen Andree
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 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	Terminal Disclaimer Filed	2016-11-04_Terminal_Disclaimer_aia0025.pdf	247426 80aa4853a387c21b975ccbf44d539bbf4815ffe4	no	2
Warnings:					
Information:					
2		2016-11-04_Amendment_US07.pdf	83482 303e212a6dfad5d82e4496490dc533fae1c88f5a	yes	12
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	10	
	Applicant Arguments/Remarks Made in an Amendment		11	12	
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30629 9aa700004f0d6abb90490c610a9bcec33cbbac23	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	361537		

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.

PTO/AIA/25 (04-13)
Approved for use through 04/30/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION	Docket Number (Optional) 06-01506US07

In re Application of: Walid N. ABOUL-HOSN, et al.

Application No.: 15/239,574

Filed: 08-17-2016

For:
GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

The applicant, MAQUET Cardiovascular LLC, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number 15/239,697, filed, 08-17-2016, as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said **reference** application, "as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application," in the event that: any such patent granted on the pending **reference** application expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 47,395

/Wesley Scott Ashton/	November 4, 2016
Signature	Date
Wesley Scott Ashton	
Typed or printed name	
Patent Attorney	+1-201-995-8980
Title	Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

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.

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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/239,574	Filing Date 08/17/2016	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	**280**
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 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).			
☐ 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	**280**

APPLICATION AS AMENDED – PART II

AMENDMENT **11/04/2016**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $420 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	**0**

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					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.

LIE
GWENDOLYN MYERS

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.

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	15/239,574	ABOUL-HOSN ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 04 November, 2016	**This patent is subject to a Terminal Disclaimer**	

Approved/Disapproved by:

CHARRISSA BROWN

Technology Center: PLRC

Telephone: (571)272-1558

U.S. Patent and Trademark Office

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

99185 7590 12/06/2016

Getinge US Legal Shared Services
1300 MacArthur Boulevard
Mahwah, NJ 07430

EXAMINER
MARCETICH, ADAM M

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 12/06/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/239,574	08/17/2016	Walid N. ABOUL-HOSN	06-01506US07	1024

TITLE OF INVENTION: GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	03/06/2017

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 ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

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)

99185 7590 12/06/2016
Getinge US Legal Shared Services
1300 MacArthur Boulevard
Mahwah, NJ 07430

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.
15/239,574	08/17/2016	Walid N. ABOUL-HOSN	06-01506US07	1024

TITLE OF INVENTION: GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	03/06/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
MARCETICH, ADAM M	3761	600-016000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "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.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(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.
1 _____
2 _____
3 _____

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

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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 NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/239,574	08/17/2016	Walid N. ABOUL-HOSN	06-01506US07	1024

99185 7590 12/06/2016

Getinge US Legal Shared Services
1300 MacArthur Boulevard
Mahwah, NJ 07430

EXAMINER	
MARCETICH, ADAM M	
ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 12/06/2016

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

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

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.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B 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

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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. 15/239,574	Applicant(s) ABOUL-HOSN ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	AIA (First Inventor to File) Status No

-- 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 *04 November 2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
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 *24-53*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   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. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ 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).
6. ☐ 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. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Adam Marcetich/
Primary Examiner, Art Unit 3761

EXAMINER'S COMMENT / REASONS FOR ALLOWANCE

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Examiner's Comment

Objections to claims 25, 26, 28, 29, 32, 47 and 51 for minor informalities are withdrawn in view of the amendments filed 04 November 2016.

Terminal Disclaimer

The terminal disclaimer filed on 04 November 2016 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of **copending Application No. 15/239697 to Aboul-Hosn, Walid et al.** has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Claims

Claims 24-53 are allowed.

Reasons for Allowance

Applicant's arguments filed 04 November 2016 have been considered and are persuasive.

The previous office action did not reject any claim over prior art. The recently filed terminal disclaimer has overcome all double patenting rejections.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590
Fax 571-273-2590
Email Adam.Marcetich@uspto.gov

The Examiner can be reached 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. 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.

/Adam Marcetich/
Primary Examiner, Art Unit 3761

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S279	8	S278 and (pump$3 and (blood heart cardiovascular vascular aort$2) and (impell?R rot?R blade$1 fin fins)).clm.	USPAT; USOCR	OR	ON	2016/11/30 08:52
S278	398	ABOUL-HOSN-WALID$.in. KANZ-WILLIAM$.in. BAKER-BRUCE$.in. maquet$.as.	USPAT	OR	ON	2016/11/30 08:52

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	115	l2 and (wire guidewire).clm.	US-PGPUB; USPAT	OR	ON	2016/11/30 09:02
L2	4052	pump$3 same (cardiac intracardiac heart intravascular vascular vasculature vessel$1 vein$1 arter$3 venous veinous).clm. and @ad<"20000901"	US-PGPUB; USPAT	OR	ON	2016/11/30 09:02
L1	3925	pump$3 with (cardiac intracardiac heart intravascular vascular vasculature vessel$1 vein$1 arter$3 venous veinous).clm. and @ad<"20000901"	US-PGPUB; USPAT	OR	ON	2016/11/30 09:02

11/30/2016 9:03:35 AM
H:\EAST searches\workspaces\15239574CON.wsp

UNITED STATES PATENT AND TRADEMARK OFFICE

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

BIB DATA SHEET

CONFIRMATION NO. 1024

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
15/239,574	08/17/2016 RULE	600	3761	06-01506US07

APPLICANTS

MAQUET Cardiovascular LLC, Mahwah, NJ;

INVENTORS

Walid N. ABOUL-HOSN, Btekhnay, LEBANON;
William R. KANZ, Woodinville, WA;
Bruce A. BAKER, Placerville, CA;

**** CONTINUING DATA ***************************

This application is a DIV of 14/966,669 12/11/2015
which is a DIV of 14/543,815 11/17/2014 PAT 9327068
which is a CON of 12/772,810 05/03/2010 PAT 8888728
which is a CON of 11/375,926 03/15/2006 PAT 7731675
which is a DIV of 10/070,178 07/19/2002 PAT 7022100
which is a 371 of PCT/US00/24515 09/01/2000
which claims benefit of 60/152,249 09/03/1999

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

08/29/2016

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ADAM M MARCETICH/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		LEBANON	18	30	3

ADDRESS

Getinge US Legal Shared Services
1300 MacArthur Boulevard
Mahwah, NJ 07430
UNITED STATES

total claims: 30
independent: 3
verified Wed 30 Nov 2016
/AMM/

TITLE

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

FILING FEE RECEIVED		
3200	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15239574	ABOUL-HOSN ET AL.
	Examiner	Art Unit
	ADAM MARCETICH	3761

CPC- SEARCHED		
Symbol	Date	Examiner
A61M1/101; A61M1/1034; A61M1/125; A61M2025/0183; A61M1/102; A61M1/122; Y10S415/90	11/01/2016	AMM
search update	11/15/2016	AMM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor search: PALM and EAST (US-PGPUB, USPAT, USOCR)	11/01/2016	AMM
Review cited art for similar case 15239697	11/01/2016	AMM
search update	11/15/2016	AMM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	claim keyword search	11/15/2016	AMM

	/ADAM MARCETICH/ Primary Examiner.Art Unit 3761

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15239574	ABOUL-HOSN ET AL.
	Examiner	**Art Unit**
	ADAM MARCETICH	3761

CPC							
Symbol						**Type**	**Version**
A61M		1	/	125		F	2014-02-04
A61M		1	/	1008		I	2014-02-04
A61M		1	/	1012		I	2014-02-04
A61M		1	/	1029		I	2014-02-04
A61M		1	/	1034		I	2014-02-04
A61M		1	/	1086		I	2013-01-01
A61M		1	/	1096		I	2014-02-04
A61M		1	/	122		I	2014-02-04
A61M		25	/	09		I	2013-01-01
A61M		2025	/	0183		A	2013-01-01
A61M		2025	/	0177		A	2013-01-01
A61M		1	/	101		A	2013-01-01
			/				
			/				
			/				

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/ADAM MARCETICH/ Primary Examiner.Art Unit 3761	11/30/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office

Part of Paper No. 20161115

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15239574	ABOUL-HOSN ET AL.
	Examiner	**Art Unit**
	ADAM MARCETICH	3761

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION											
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED						
604	6.11	A	6	1	M	37 / 00 (2006.01.01)							
CROSS REFERENCE(S)		A	6	1	M	1 / 10 (2006.01.01)							
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)												
604	8	151											
623	3.1	3.15											

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/ADAM MARCETICH/ Primary Examiner.Art Unit 3761	11/30/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office

Part of Paper No. 20161115

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15239574	ABOUL-HOSN ET AL.
	Examiner	**Art Unit**
	ADAM MARCETICH	3761

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	24	18	40												
2	25	11	41												
3	26	19	42												
4	27	20	43												
5	28	21	44												
6	29	22	45												
7	30	23	46												
8	31	24	47												
9	32	25	48												
10	33	26	49												
12	34	27	50												
13	35	28	51												
14	36	29	52												
15	37	30	53												
16	38														
17	39														

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 30	
/ADAM MARCETICH/ Primary Examiner.Art Unit 3761 (Primary Examiner)	11/30/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

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)

99185 7590 12/06/2016
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Mahwah, NJ 07430

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.

Kathleen Andree	(Depositor's name)
/Kathleen Andree/	(Signature)
December 6, 2016	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/239,574	08/17/2016	Walid N. ABOUL-HOSN	06-01506US07	1024

TITLE OF INVENTION: GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	03/06/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
MARCETICH, ADAM M	3761	600-016000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "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.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(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.
1 _____
2 _____
3 _____

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: MAQUET CARDIOVASCULAR LLC
(B) RESIDENCE: (CITY and STATE OR COUNTRY): MAHWAH, NJ

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

4a. The following fee(s) are submitted:
- ■ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ■ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 04-0170 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ☐ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ☐ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Wesley Scott Ashton/ Date December 6, 2016
Typed or printed name Wesley Scott Ashton Registration No. 47,395

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	15239574
Filing Date:	17-Aug-2016
Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
Filer:	Wesley Scott Ashton/Kathleen Andree
Attorney Docket Number:	06-01506US07

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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	1501	1	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**960**

Electronic Acknowledgement Receipt	
EFS ID:	27706375
Application Number:	15239574
International Application Number:	
Confirmation Number:	1024
Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
Customer Number:	99185
Filer:	Wesley Scott Ashton/Kathleen Andree
Filer Authorized By:	Wesley Scott Ashton
Attorney Docket Number:	06-01506US07
Receipt Date:	06-DEC-2016
Filing Date:	17-AUG-2016
Time Stamp:	13:27:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$960
RAM confirmation Number	120616INTEFSW00008475040170
Deposit Account	040170
Authorized User	Kathleen Andree
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.20 (Post Issuance fees) 37 CFR 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)	2016-12-06_TransmittalofFees Due.pdf	519616 4dc8775a57efa917dc2e74f22370f00f02652778	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30618 63c2f220c5b287d8181a24934e4ed8732e9dfedf	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	550234		

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 PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/239,574	08/17/2016	Walid N. ABOUL-HOSN	06-01506US07

CONFIRMATION NO. 1024

99185
Getinge US Legal Shared Services
1300 MacArthur Boulevard
Mahwah, NJ 07430

PUBLICATION NOTICE

OC000000088053388

Title:GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

Publication No.US-2016-0367740-A1
Publication Date:12/22/2016

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

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

AMENDMENT UNDER 37 C.F.R. § 1.312 Mail Stop: ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450		
	Attorney Docket No.	06-01506US07
	Confirmation No.	1024
	First Named Inventor	Walid N. Aboul-Hosn et al.
	Application Number	15/239,574
	Filing Date	August 17, 2016
	Group Art Unit	3761
	Examiner Name	Adam M. MARCETICH
	Title	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

AMENDMENT UNDER 37 C.F.R. § 1.312

Sir:

In view of the Examiner's Interview conducted via telephone on December 30, 2016 between Applicants' representatives and Examiner Marcetich, kindly amend the application identified above as follows.

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

Amendments to the Drawings begin on page 3 of this paper.

Remarks/Arguments begin on page 4 of this paper.

I. Amendments to the Specification:

Amendments to the specification are contained in the attached third substitute specification (without markings). This third substitute specification corresponds to a clean version of the second substitute specification that was filed on October 31, 2016. The attached third substitute specification contains no new matter and is filed to ensure that the correct version of the specification is included in the patent on trajectory to issue from the present application.

II. Amendments to the Drawings:

The attached thirty-seven REPLACEMENT SHEETS of drawings include Figures 1 to 54, and replace the previous drawings of this application. The presently filed Replacement Sheets have been filed to ensure the correct drawings are issued in the patent on trajectory to issue from the present application. No new matter has been added to the drawings by the present amendment.

Attachment: Thirty-seven REPLACEMENT SHEETS of Drawings

III. REMARKS

Applicants' representatives, Wesley Ashton and Kirk Swenson, conducted an interview with Examiner Adam Marcetich on December 30, 2016 to discuss errors in the corresponding publication of the above-captioned application, namely, Patent Application Publication No. US 2016/0367740 A1, and how to avoid these errors occurring in the patent on trajectory to issue from this application. Examiner Marcetich recommended filing an amendment under 37 C.F.R. § 1.312 to resolve this issue.

By this paper, Applicants file a clean version of the substitute specification filed on October 31, 2016, and Applicants file replacement drawings for all of the Figures 1-54 in order to ensure that the correct version of the specification and drawings are included in the issued patent.

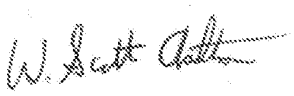
The present amendment adds no new matter to the above-captioned application.

IV. CONCLUSION

The amended application is in condition for issuance for the reasons of record. If the Examiner feels a telephone interview would expedite processing of this patent application, the Examiner is respectfully invited to telephone the undersigned at the number provided.

No fees are believed to be due in association with this filing. If any additional fees are required, the Commissioner is hereby authorized to charge any underpayment as well as credit any overpayment of fees associated with this communication to Deposit Account No. 50-5722, reference no. 06-01506US07.

Respectfully submitted,



Date: December 30, 2016

By: _____
Wesley Scott Ashton
Registration No. 47,395

MAQUET Cardiovascular, Getinge Group
1300 MacArthur Blvd
Mahwah, NJ 07430
Phone No: 1-201-995-8980

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

RELATED APPLICATIONS

[0001] This application is a divisional of co-pending U.S. Patent Application Serial No. 14/966,669, filed December 11, 2015, which is a divisional of U.S. Patent Application Serial No. 14/543,815, filed November 17, 2014 (now U.S. Patent 9,327,068, issued May 3, 2016), which is a continuation of U.S. Patent Application Serial No. 12/772,810, filed May 3, 2010 (now U.S. Patent 8,888,728, issued November 18, 2014), which is a continuation of U.S. Patent Application Serial No. 11/375,926, filed March 15, 2006 (now U.S. Patent No. 7,731,675, issued June 8, 2010), which is a divisional of U.S. Patent Application Serial No. 10/070,178, filed July 19, 2002, (now U.S. Pat. No. 7,022,100, issued April 4, 2006) which claims the benefit of PCT/US00/24515 filed September 1, 2000, which claims the benefit of provisional U.S. Patent Application Serial No. 60/152,249 filed September 3, 1999. We hereby claim priority to the aforementioned application(s) and also incorporate herein by reference each of the afore-listed patents and applications in their entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to blood pumps and, more particularly, to an improved intra-vascular blood pump having a guide mechanism which provides the ability to selectively guide the intravascular pump to a desired location within a patient's circulatory system.

DESCRIPTION OF RELATED ART

[0003] Over the years, various types of blood pumps have been developed for the purpose of augmenting or replacing the blood pumping action of damaged or diseased hearts. Blood pumps are commonly used in three situations: (1) for acute support during cardio-pulmonary operations; (2) for short-term support while awaiting recovery of the heart from surgery; or (3) as a bridge to keep a patient alive while awaiting heart transplantation. The pumps may be

designed to provide right and/or left ventricular assist, although left ventricle assist is the most common application in that it is far more common for the left ventricle to become diseased or damaged than it is for the right ventricle.

[0004] Blood pumps must provide leak-free operation and must avoid contamination of the fluid by the pump components and the external environment. Such pumps must also pump the fluid at a suitable rate without applying excessive Reynolds shear stress to the fluid. It is well known to those skilled in the art that lysis or cell destruction may result from application of shear stress to cell membranes. Red blood cells are particularly susceptible to shear stress damage as their cell membranes do not include a reinforcing cytoskeleton to maintain cell shape. Lysis of white blood cells and platelets also occurs upon application of high shear stress. Lysis of red blood cells can result in release of cell contents which trigger subsequent platelet aggregation. Sublytic shear stress leads to cellular alterations and direct activation and aggregation of platelets and white blood cells.

[0005] Intravascular blood pumps comprise miniaturized blood pumps capable of being percutaneously or surgically introduced into the vascular system of a patient, typically to provide left and/or right heart support. One type of intravascular pump is an axial flow blood pump comprising a cable-mounted rotor surrounded by a protective shroud. The pump, along with the rotor and shroud, are mounted at the end of an elongated flexible catheter. The catheter is inserted into the aorta from a remote entry point, such as an incision below the groin that provides access into a femoral artery. The catheter then passes through the descending aorta until it reaches the ascending aorta, near the heart. The catheter device encloses a rotating drive cable which is coupled to the impeller blade at one end, and which emerges from the exposed end of the catheter, near the patient's groin, at the other end. When the exposed end of the drive cable is mechanically rotated, using a device located outside the patient's body, it conveys the rotational force through the length of the catheter, causing the impeller to spin at high speed near the heart. This type of blood pump finds particular application in providing ventricular assist during surgery or providing temporary bridging support to help a patient survive a crisis.

[0006] While generally effective in providing ventricular assisting functions, prior art intravascular blood pumps nonetheless suffer various drawbacks. A significant drawback is that prior art intravascular blood pumps are difficult to guide into the appropriate position within the circulatory system of a patient. This is due largely to the fact that the elongated catheter is incapable of providing the degree of control necessary to easily negotiate the pump through the tortuous pathways leading up to and into the heart. When attempting to place the blood pump in a trans-valvular configuration (with the inlet in the left ventricle and the pump outlet in the ascending aorta), the natural tendency of the catheter to stay straight may cause the pump to be inadvertently placed in the carotid ostia, which can be dangerous if the pump is operated to withdraw blood from the brain.

[0007] To overcome these difficulties, certain guide mechanisms may be employed to assist the physician placing the pump in the appropriate position within the circulatory system. One type of supplemental guide mechanism is a guide catheter. Guide catheters are designed with certain guidability characteristics such that physicians can selectively position them within the vasculature or heart with relative ease. A central lumen is provided within the guide catheter such that the intravascular pump may be introduced therein and guided while it is advanced towards the predetermined circulatory site. While generally effective at providing a guiding feature for such intravascular blood pumps, employing such supplemental guide mechanisms is nonetheless disadvantageous in that they consume valuable space within the vessels. A guide catheter, for example, would necessarily be larger in diameter than the diameter of the pump and protective shroud in order to provide adequate passage of those components. As will be appreciated, this restricts the amount of space available for blood to flow within the particular vessel, and increases the size of the required puncture wound for accessing the vessel.

[0008] The present invention is directed at eliminating and/or reducing the effects of the foregoing drawbacks of prior art intravascular blood pumps.

SUMMARY OF THE INVENTION

[0009] The present invention overcomes the drawbacks of the prior art by providing an improved intravascular blood pump equipped with integrated features for selectively guiding the intravascular blood pump to a predetermined location in the patient's circulatory system, i.e. heart and/or vasculature. In so doing, the intravascular blood pump of the present invention eliminates the need for supplemental guiding mechanisms, such as a separate, large diameter guide catheter as used in the prior art.

[0010] In a first broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and an "over-the-wire" type guide mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient. To accomplish this, a central lumen is formed through at least a portion of the intravascular blood pump system such that a guide element, such as a guide wire, may be progressed therethrough and advanced to the predetermined location in the circulatory system of the patient. After the guide element is advanced to this desired location, the intravascular blood pump and cannula may thereafter be advanced along the guide element to the desired location.

[0011] In a second broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and a "side-rigger" or "rapid exchange" type guide mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient. To accomplish this, a side lumen is formed along a length of at least one of the intravascular blood pump and the cannula. A guide element, such as a guide wire, may be advanced to the predetermined location in the circulatory system of the patient. After the guide element is advanced to this desired location, the intravascular blood pump and cannula may thereafter be advanced along the guide element to the desired location.

[0012] In a third broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and a "guide catheter" type guide mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient.

The pump system of this broad aspect includes a conduit assembly and a separate pump assembly. The conduit assembly includes a guide catheter, a rotor shroud, and a cannula, with the cannula and guide catheter disposed on either side of the rotor shroud. The pump assembly includes a rotor, a drive member coupled to the rotor, and a pump disposed between the rotor and the drive member. The guide catheter is dimensioned to receive and guide the pump assembly to the point where the rotor docks within the rotor shroud so as to form an operational blood pump. This configuration allows the conduit assembly to be precisely and efficiently guided into a desired position within the body through the use of conventional guiding techniques well known in interventional cardiology. The pump assembly may thereafter be introduced into and guided within the conduit until the pump assembly is docked within the rotor shroud. This dual construction arrangement provides improved placement of the pump assembly by using the conduit as a guiding mechanism.

[0013] The foregoing broad aspects of the present invention may be manifested according to the following recitations:

[0014] According to a first broad recitation of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto, and a guide mechanism adapted to guide the intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient.

[0015] In a further embodiment, the intravascular blood pump includes a rotor, a shroud for receiving the rotor, and a drive cable coupled to the rotor for driving the rotor within the shroud.

[0016] In a further embodiment, the cannula is coupled to the shroud of the intravascular blood pump.

[0017] In a further embodiment, the guide mechanism comprises a guide catheter coupled to the shroud.

[0018] In a further embodiment, the guide catheter may be used to guide the shroud and cannula to the predetermined location within the circulatory system of the patient, after which point the rotor and drive cable of the intravascular blood pump may be docked within the shroud for pump operation.

[0019] In a further embodiment, the drive cable sheath is provided having a central lumen for receiving the drive cable, and wherein a purge fluid delivery system is coupled to the drive cable sheath to deliver purge fluid to the rotor.

[0020] In a further embodiment, the drive cable sheath includes at least one side lumen for delivering the purge fluid towards the rotor.

[0021] In a further embodiment, a portion of the purge fluid is delivered through the at least one side lumen and past the rotor, and a portion of purge fluid is rerouted back from the rotor through the central lumen of the drive cable.

[0022] In a further embodiment, a perfusion assembly is provided communicatively coupled to the guide catheter for selectively rerouting blood from within the guide catheter to a point downstream from the introduction site of the guide catheter into the vasculature of the patient.

[0023] In a further embodiment, the perfusion assembly includes a first conduit communicatively coupled to the guide catheter, a second conduit dimensioned to be introduced into the vasculature of the patient, and a selectively operable valve disposed in between the first conduit and the second conduit.

[0024] In a further embodiment, a blood pressure detection mechanism is provided to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.

[0025] In a further embodiment, the blood pressure detection mechanism comprises at least one of fluid filled column disposed within at least a portion of the cannula, a piezoelectric element coupled to at least one of the intravascular blood pump and cannula, and a strain gauge coupled to at least one of the intravascular blood pump and cannula.

[0026] In a further embodiment, the blood pressure detection mechanism involves calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive the rotor.

[0027] In a further embodiment, the guide mechanism comprises a guide element disposed at least partially within the cannula.

[0028] In a further embodiment, the guide element comprises a guide wire for passage through a side lumen formed in the cannula.

[0029] In a further embodiment, the guide element comprises a selectively deformable element disposed at least partially within the cannula.

[0030] In a further embodiment, the intravascular blood pump and cannula may be selectively advanced to the predetermined location within the vasculature of the patient by first passing the guide wire to the predetermined location and thereafter sliding the intravascular blood pump and cannula along the guide wire to the predetermined location.

[0031] In a further embodiment, the guide element comprises a guide wire for passage through a lumen extending through the drive cable and rotor.

[0032] In a further embodiment, the intravascular blood-pump and cannula may be selectively advanced to the predetermined location within the vasculature of the patient by first passing the guide wire to the predetermined location and thereafter sliding the intravascular blood pump and cannula along the guide wire to the predetermine location.

[0033] In a further embodiment, the guide mechanism further includes guide element for passage through the guide catheter to facilitate placement of the shroud and the cannula at the predetermined location within the vasculature of the patient.

[0034] In a further embodiment, the guide mechanism further includes a guide element for passage through a side lumen formed along at least a portion of the guide catheter.

[0035] In a further embodiment, the guide element comprises at least one of a guide wire and a balloon catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

[0037] FIG. 1 is a partial sectional view of a human heart illustrating an intravascular blood pump system having an "over-the-wire" type guide mechanism according to a first broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

[0038] FIG. 2 is side view of the guidable intravascular blood pump system of the type shown in FIG. 1 including a motor coupler and purge fluid delivery system according to an exemplary embodiment of the present invention;

[0039] FIG. 3 is a cross-sectional view illustrating an exemplary construction of the blood pump, drive cable assembly, and cannula of the intravascular blood pump system according to the first broad aspect of the present invention;

[0040] FIG. 4 is a cross-sectional view taken along lines 4-4 of FIG. 3 illustrating an exemplary construction of the drive cable assembly and guide mechanism according to the first broad aspect of the present invention;

[0041] FIG. 5 is a cross-sectional view illustrating an exemplary construction of the motor coupler and purge fluid delivery system according to the first broad aspect of the present invention;

[0042] FIG. 6 is a partial sectional view of a human heart illustrating an intravascular blood pump system having a "rapid exchange" or "side-rigger" type guide mechanism according to a second broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

[0043] FIG. 7 is side view of the guidable intravascular blood pump system of the type shown in FIG. 6 including a motor coupler and purge fluid delivery system according to an exemplary embodiment of the present invention;

[0044] FIG. 8 is a cross-sectional view taken along lines 8-8 of FIG. 7 illustrating the "side-rigger" or "rapid exchange" type guide mechanism according to the second broad aspect of the present invention;

[0045] FIG. 9 is a cross-sectional view of the type shown in FIG. 8 illustrating an alternate configuration of the guide mechanism according to the second broad aspect of the present invention;

[0046] FIG. 10 is a partial sectional view of a human heart illustrating an intravascular blood pump system having a "guide catheter" type guide mechanism according to a third broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

[0047] FIG. 11 is a schematic view of a human being illustrating the intravascular blood pump system of the type shown in FIG. 10 inserted through the femoral artery and including an optional perfusion assembly for perfusing the vasculature downstream from the incision site where guide catheter enters the femoral artery;

[0048] FIG. 12 is a side view of the intravascular blood pump system shown in FIGS. 10-11 illustrating the separable nature of a pump assembly and a conduit assembly which collectively form the intravascular blood pump system according to the third broad aspect of the present invention;

[0049] FIG. 13 is a side view illustrating the intravascular blood pump system shown in FIG. 12 with the pump assembly docked into the conduit assembly according to the third broad aspect of the present invention;

[0050] FIG. 14 is a cross-sectional view illustrating an exemplary construction of the blood pump, drive cable assembly, cannula, and guide catheter of the intravascular blood pump system shown in FIG. 13;

[0051] FIG. 15 is a cross-sectional view taken along lines 15-15 of FIG. 14 illustrating an exemplary construction of the drive cable assembly and guide catheter according to the third broad aspect of the present invention;

[0052] FIG. 16 is a cross-sectional view illustrating an exemplary construction of the motor coupler, purge fluid delivery system, and a proximal portion of the guide catheter biasing assembly according to the third broad aspect of the present invention;

[0053] FIG. 17 is a cross-sectional view illustrating an exemplary construction of the perfusion assembly and a distal portion of the guide catheter biasing assembly according to the third broad aspect of the present invention;

[0054] FIG. 18 is a cross-sectional view of an intravascular blood pump system of the type shown in FIGS. 12-13 having an alternate configuration for docking the rotor within the shroud according to the principles of the present invention; and

[0055] FIG. 19 is a partial sectional view of a human heart illustrating an alternate intravascular blood pump system having an "over-the-wire" type guide mechanism according to the first broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide right-heart assist.

[0056] FIG. 20 corresponds to Figure 1 of U.S. Serial No. 09/280,988, and is a schematic side view of a steerable cannula in the undeformed state in accordance with the first embodiment of U.S. Serial No. 09/280,988;

[0057] FIG. 21 corresponds to Figure 2 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view of the steerable cannula of FIG. 20 taken along line A-A;

[0058] FIG. 22 corresponds to Figure 3 of U.S. Serial No. 09/280,988, and is a schematic side view of the steerable cannula in the deformed state in accordance with the first embodiment of U.S. Serial No. 09/280,988;

[0059] FIG. 23 corresponds to Figure 4 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view of a steerable cannula having two cables in accordance with a second embodiment of U.S. Serial No. 09/280,988;

[0060] FIG. 24 corresponds to Figure 5 of U.S. Serial No. 09/280,988, and is a schematic side view of a steerable cannula having a reinforcing wire in accordance with a third embodiment of U.S. Serial No. 09/280,988;

[0061] FIG. 25 corresponds to Figure 6 of U.S. Serial No. 09/280,988, and is a schematic cut-away view of a steerable cannula in accordance with a fourth embodiment of U.S. Serial No. 09/280,988;

[0062] FIG. 26 corresponds to Figure 7 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view taken along line B-B of FIG. 25;

[0063] FIG. 27 corresponds to Figure 8 of U.S. Serial No. 09/280,988, and is a schematic side view of a steerable cannula having a preformed curve and an inflatable balloon formed at a distal end thereof in accordance with a fifth embodiment of U.S. Serial No. 09/280,988;

[0064] FIG. 28 corresponds to Figure 9 of U.S. Serial No. 09/280,988, and is a schematic side view of the inflatable balloon of a fifth embodiment of U.S. Serial No. 09/280,988, wherein the balloon is shown in the inflated state;

[0065] FIG. 29 corresponds to Figure 10 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view taken along line C-C of FIG. 28;

[0066] FIG. 30 corresponds to Figure 11 of U.S. Serial No. 09/280,988, and is a schematic view showing a steerable cannula having a pigtail distal tip configuration in accordance with a sixth embodiment of U.S. Serial No. 09/280,988;

[0067] FIG. 31 corresponds to Figure 12 of U.S. Serial No. 09/280,988, and is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with a seventh embodiment of U.S. Serial No. 09/280,988;

[0068] FIG. 32 corresponds to Figure 13 of U.S. Serial No. 09/280,988, and is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with an eighth embodiment of U.S. Serial No. 09/280,988;

[0069] FIG. 33 corresponds to Figure 14 of U.S. Serial No. 09/280,988, and is a schematic side view showing a steerable cannula used in a co-axial configuration in accordance with a ninth embodiment of U.S. Serial No. 09/280,988, wherein the steerable cannula is advanced to a first relative position;

[0070] FIG. 34 corresponds to Figure 15 of U.S. Serial No. 09/280,988, and is a schematic side view showing a steerable cannula of FIG. 33, wherein the steerable cannula is advanced to a second relative position; and

[0071] FIG. 35 corresponds to Figure 16 of U.S. Serial No. 09/280,988, and is a schematic side view of a configuration in accordance with a tenth embodiment of U.S. Serial No. 09/280,988.

[0072] FIG. 36 corresponds to Figure 1 of U.S. Serial No. 09/280,970, and is a schematic side view of a first embodiment of U.S. Serial No. 09/280,970;

[0073] FIG. 37 corresponds to Figure 2 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line D-D of FIG. 36;

[0074] FIG. 38 corresponds to Figure 3 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line E-E of FIG. 36;

[0075] FIG. 39 corresponds to Figure 4 of U.S. Serial No. 09/280,970, and is a schematic view of a cannula in accordance with an embodiment in a surgical application;

[0076] FIG. 40 corresponds to Figure 5 of U.S. Serial No. 09/280,970, and is a schematic partial cut-away side view of a second embodiment of U.S. Serial No. 09/280,970;

[0077] FIG. 41 corresponds to Figure 6 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line F-F of FIG. 40;

[0078] FIG. 42 corresponds to Figure 7 of U.S. Serial No. 09/280,970, and is a schematic side view of a third embodiment of U.S. Serial No. 09/280,970;

[0079] FIG. 43 corresponds to Figure 8 of U.S. Serial No. 09/280,970, and is a schematic side view of a fourth embodiment of U.S. Serial No. 09/280,970;

[0080] FIG. 44 corresponds to Figure 9 of U.S. Serial No. 09/280,970, and is a schematic side view of a fifth embodiment of U.S. Serial No. 09/280,970;

[0081] FIG. 45 corresponds to Figure 10 of U.S. Serial No. 09/280,970, and is a schematic side view of a sixth embodiment of U.S. Serial No. 09/280,970;

[0082] FIG. 46 corresponds to Figure 11 of U.S. Serial No. 09/280,970, and is a schematic cross sectional view taken along line G-G of FIG. 45;

[0083] FIG. 47 corresponds to Figure 12 of U.S. Serial No. 09/280,970, and is a schematic side view of a seventh embodiment of U.S. Serial No. 09/280,970;

[0084] FIGS. 48 and 49 correspond to Figures 13 and 14, respectively, of U.S. Serial No. 09/280,970, and are schematic side views of an eighth embodiment of U.S. Serial No. 09/280,970;

[0085] FIG. 50 corresponds to Figure 15 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line H-H of FIG. 49;

[0086] FIG. 51 corresponds to Figure 16 of U.S. Serial No. 09/280,970, and is a schematic side view of a ninth embodiment of U.S. Serial No. 09/280,970;

[0087] FIG. 52 corresponds to Figure 17 of U.S. Serial No. 09/280,970, and is a schematic side view of a tenth embodiment of U.S. Serial No. 09/280,970;

[0088] FIG. 53 corresponds to Figure 18 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line K-K of FIG. 52; and

[0089] FIG. 54 corresponds to Figure 19 of U.S. Serial No. 09/280,970, and is a schematic side view of an eleventh embodiment of U.S. Serial No. 09/280,970.

DETAILED DESCRIPTION OF THE INVENTION

[0090] Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation may be described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure.

[0091] The present invention involves an intravascular pump system for use in a number of broad ranging applications involving the augmentation of blood flow within the circulatory

system of a patient. As will be described below, the intravascular blood pump system of the present invention overcomes the drawbacks of the prior art by providing a guide mechanism as part of the intravascular blood pump. This advantageously allows the intravascular blood pump to be selectively guided to a predetermined location within the circulatory system of a patient without the need for bulky supplemental guide mechanisms, such as a separate guide catheter.

[0092] The intravascular pump assembly of the present invention is particularly suited for trans-valvular use, such as for left and/or right ventricular assist procedures. By way of example only, such ventricular assist procedures may be employed in cardiac operations including, but not limited to, coronary bypass graft (CABG), cardio-pulmonary bypass (CPB), open chest and closed chest (minimally invasive) surgery, bridge-to-transplant and/or failure-to-wean-from-bypass situations. It is to be readily understood, however, that the intravascular blood pump assembly and methods of the present invention are not to be limited to such applications. Moreover, while illustrated and described largely with reference to left-heart assist applications, it is to be readily understood that the principles of the present invention apply equally with regard to right-heart assist application, which are contemplated as within the scope of the present invention. These and other variations and additional features will be described throughout.

[0093] Referring to FIG. 1, shown is a guidable intra-vascular blood pump system 10 according to a first broad aspect of the present invention shown, by way of example only, in a left-heart assist configuration within a human heart. The system 10 includes an intravascular blood pump 12, a cannula 14, and an "over-the-wire" type guide mechanism 16. A drive cable assembly 18 and a motor assembly 20 are provided to drive the intravascular blood pump 12. The "over-the-wire" guide mechanism 16 comprises a suitable guide element dimensioned to pass slideably through a central lumen extending through the drive cable 18, blood pump 12, and cannula 14. Suitable guide elements may include any number of conventional guiding devices, including but limited to those employed in cardiology. By way of example only, the guide element is shown as a guide wire 22. According to the present invention, the "over-the-wire" guide mechanism 16 provides the ability to selectively guide the blood pump 12 and

cannula 14 to a predetermined position in the circulatory system of a patient, such as the trans-valvular position shown.

[0094] To accomplish this, the guide wire 22 is first introduced into the vascular system of a patient through any suitable access point, such as through the use of the well known Seldinger technique. The guide wire 22 can then be advanced within the patient to a desired location within the circulatory system of the patient. This may be done using the control features of the guide wire 22 itself, or may be facilitated through the use of any number of supplemental guidance mechanisms or techniques to ensure the proper and efficient placement of the guide wire 22. Such supplemental guidance techniques may include, but are not necessarily limited to, guide catheters and/or techniques involving ultra-sound or flouroscopy. Once the guide wire 22 is positioned at the desired location (such as in left ventricle as shown), the blood pump 12 and cannula 14 may thereafter be advanced along the guide wire 22 and positioned in the trans-valvular configuration shown. Under the operation of the motor assembly 20, the blood pump 12 may be used for left-heart assist by selectively withdrawing blood from the left ventricle (through the interior of the cannula 14) for delivery outward through outflow apertures formed in the blood pump 12. This outflow from the blood pump 12 flows along the exterior of the drive cable assembly 18 in a substantially axial fashion for arterial distribution throughout the body.

[0095] Referring to FIGS. 2-5, an exemplary embodiment of the intravascular blood pump system 10 of FIG. 1 will now be described. As shown in FIG. 2, the intravascular blood pump system 10 includes a coupler 24 and, as will be described in greater detail below, a purge fluid delivery system 26 for providing a two-way fluid flow within the drive cable assembly 18 during pump operation. The purge fluid delivery system 26 includes a fluid inlet conduit 28 for introducing pressurized purge fluid from a fluid source (not shown) for delivery into the blood pump 12, and a fluid outlet conduit 30 to withdraw a return flow of purge fluid from the blood pump 12. The motor coupler 24 establishes a mechanical connection between a motor (not shown) and a drive cable (not shown) for providing motive force to the blood pump 12 for pump operation. The drive cable assembly 18 includes a drive cable sheath 32 which, in addition to serving a purge fluid delivery function, also serves as a protective housing for the

drive cable (not shown). Although shown in broken form for clarity, it will be appreciated that the drive cable assembly 18 (and all components thereof) may be provided in any suitable length sufficient for intravascular applications. That is to say, the length of the drive cable assembly 18 must be enough to reach between the motor coupler 24 and purge fluid delivery system 26, located outside the patient, and the desired location within the patient's circulatory system where the blood pump 12 is to be positioned.

[0096] The intravascular blood pump 12 is shown (by way of example only) as an axial flow intravascular blood pump. The blood pump 12 includes pump body 34, a rotor shroud 36 having flow ports 38, and an internally disposed rotor (not shown) having a shaft rotatably disposed within the pump body 34 and an impeller rotatably disposed within the rotor shroud 36. The cannula 14 is fixedly attached to the rotor shroud 36 and may extend any suitable length therefrom depending upon the particular intravascular application. The cannula 14 preferably includes a plurality of ports or fenestrations 40 about its distal region, as well as an end port 42, which allow for the ingress or egress of blood into or from the cannula 14 depending upon the operation of the blood pump 12. That is to say, if the pump 12 is configured for left-heart assist as shown in FIG. 1, then the ports 40, 42 will allow the ingress of blood into the cannula 14 from the left ventricle. If, on the other hand, the blood pump 12 is configured for right-heart assist (i.e. with the pump 12 in the right atrium and the distal end of the cannula 14 located within the pulmonary artery), then the ports 40, 42 will allow the egress of blood from the cannula 14 into the pulmonary artery. (Details on right-heart assist applications will be discussed in greater detail below.) The pump 12 and cannula 14 may be dimensioned to any suitable diameter for intravascular applications. For example, the range of sizes may include, but is not necessarily limited to, 9 French to 30 French, although the range is more preferably from 14 French to 24 French, and most preferably from 18 French to 20 French.

[0097] The "over-the-wire" type guide mechanism 16 includes the guide wire 22 and, as will be explained in greater detail below, a central lumen extending through the cannula 14, blood pump 12, drive cable assembly 18, purge fluid delivery system 26, and motor coupler 24. As noted above, the central lumen is dimensioned to slideably receive the guide wire 22

such that the blood pump 12 and cannula 14 may be slideably advanced along the guide wire 22 to a desired location within the circulatory system of a patient after the guide wire 22 has been so positioned using conventional guidance techniques. It is to be readily understood that, while shown as a conventional guide wire 22, the guide element forming part of the guide mechanism 16 of the present invention may include any number of well known guidance mechanisms depending upon the application, including but not limited to balloon catheters, imaging wires, and guide catheters dimensioned to be slideably received through the central lumen. For example, although not appropriate for retrograde progression (such as the left-heart application shown in FIG. 1), a balloon catheter may be a suitable guidance mechanism for a right-heart assist application. In such a case, the balloon may be inflated and used as a "sail" to direct the catheter to a desired location (such as the pulmonary artery), after which point the blood pump 12 and cannula 14 can be advanced over the catheter to a trans-valvular configuration with the blood pump 12 in the right atrium and the ports 38, 40 of the cannula 14 in the pulmonary artery.

[0098] FIGS. 3 and 4 further detail the construction of the blood pump 12, cannula 14, drive cable assembly 18, and "over-the-wire" guide mechanism 16. The blood pump 12 includes a rotor 44 having a shaft 46 and an impeller 48. The shaft 46 is rotatably disposed within the pump body 34 via a bearing pack comprising, by way of example, ball bearing assemblies 50, 52 and spring 54. Ball bearings assemblies 50, 52 are well known in the art, each comprising an inner race which rotates along with the rotor shaft 46, an outer race which remains in a static and fixed position against the inner surface of the pump body 34, and a plurality of ball bearings disposed between the inner and outer races. The spring 54 biases each bearing assembly 50, 52 axially away from one another to reduce axial play during pump operation. The shaft 46 is generally hollow and dimensioned to receive a cable adapter 60 therein for the purpose of coupling the rotor 44 to a drive cable 62 forming part of the drive cable assembly 18. The drive cable 62 may be secured to the cable adapter 60 in any number of suitable fashions, including but not limited to the use of adhesives, crimping, and laser welding. These same techniques may be used to secure the cable adapter 60 within the shaft 46 of the rotor 44. A radial seal 64 is provided in between the wall of the pump body 34 and a distal stepped region 66 on the rotor shaft 46, the function of which will be described below.

[0099] The impeller 48 includes a hub 56 and a plurality of blades 58 extending therefrom. The hub 56 is generally conical and, according to the first broad aspect of the present invention, is hollow throughout to form part of the central lumen of the guide mechanism 16. In this regard, the hub 56 is preferably provided with a gasket or seal member 68 at its distal tip. The seal member 68 may be made of any suitable sealing material (including but not limited to silicone) such that the pump 12 and cannula 14 may be easily progressed along the guide wire 22 for delivery to a desired circulatory site. The seal member 68 should also be robust enough to prevent the ingress of blood into the interior of the rotor hub 56 during pump operation, whether the guide wire 22 remains in place or is fully withdrawn. The blades 58 are dimensioned to reside in close tolerance with the interior surface of the shroud 36. In operation, the blades 58 impart both an axial and radial vector on the blood which causes it to flow outward through the flow ports 38 formed in the shroud 36. As used herein, the term "axial flow" is deemed to include flow characteristics like that shown in FIG. 3, which include both an axial and slight radial component. It is to be readily appreciated that, although shown as an axial flow type, blood pump 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps without departing from the scope of the present invention.

[00100] The cannula 14 is coupled at its proximal end to the rotor shroud 36. This may be accomplished in any number of fashions, including but not limited to the use of adhesives. This may also be facilitated by dimensioning the shroud 36 to include a narrow inlet region 70 capable of being received flushly within the proximal end of the cannula 14. The inlet region 70 of the shroud 36 should preferably have a tapered interior surface for establishing a smooth flow transition between the cannula 14 and the region containing the impeller blades 58. Although shown as a single integral element, it is to be understood that the pump body 34 and shroud 36 may comprise two separate (and sometimes separable) components, the significance of which will become apparent below. The pump body 34 and shroud 36 may be constructed from any number of suitable materials, including but not limited to stainless steel or other medical grade compositions or alloys. The cannula 14 may also be constructed from any number of suitable materials, including but not limited to medical grade plastics. As shown,

the cannula 14 may also be fortified with spiral-wound reinforcement wire 72 within the walls of the cannula 14.

[00101] The drive cable assembly 18 includes the drive cable 62 and the drive cable sheath 32. The drive cable 62 is coupled to the rotor 44 via the cable adapter 60. The drive cable sheath 32 includes a central lumen 74 and a plurality of side lumens 76. The central lumen 74 serves as a protective covering for the drive cable 62. The central lumen 74, along with the side lumens 76, also forms part of the purge fluid delivery system 26 shown above in FIG. 2, which will be described in greater detail below. The side lumens 76 are provided in fluid communication with the fluid inlet conduit 28, while the central lumen 74 is provided in fluid communication with the fluid outlet conduit 30. The side lumens 76 are thus configured to deliver purge, fluid into the pump 12, while the central lumen 74 is configured to transport purge fluid away from the pump 12 along the length of the drive cable 62.

[00102] The pressurized purge fluid within the side lumens 76 may take one of two flow paths upon entry into the pump 12. One flow path passes through the interior of the pump 12 and onward past the radial seal 64 to prevent the ingress of blood into the pump body 34 during pump operation. More specifically, the purge fluid flows distally around the cable adapter 60, through the ball bearing assemblies 50, 52, and onward past the radial seal 64. This egress of purge fluid past the radial seal 64 can be controlled to effectively thwart the ingress of blood past the radial seal 64, which might otherwise cause clotting and/or pump damage. The other flow path is directed back out the central lumen 74 for delivery to the fluid outlet conduit 30. In so doing, this flow path bathes the components of the pump 12 and/or drive cable 62 and thereby reduces frictional heating within the pump 12 and/or the central lumen 74 of the sheath 32 during pump operation.

[00103] The "over-the-wire" guide mechanism 16 includes a central lumen through which the guide wire 22 may extend for the purpose of slideably advancing the blood pump 12 and cannula 14 into a desired position within the circulatory system of a patient. In the embodiment shown, this central lumen is established by forming and co-aligning the individual central lumens within each of the drive cable 62, the cable adapter 60, the shaft 46

and hub 56 of the rotor 44, and the cannula 14. In this regard, the drive cable 62 is preferably of wound-wire construction having a central lumen formed therein. The central lumens within the cable adapter 60, rotor 44, and gasket 68 may be formed via machining or molding processes. These central lumens should preferably be sized such that they permit the slideable passage of the pump 12 and cannula 14 therealong, but do not interfere with or constrain the guide wire 22 to cause inadvertent rotation of the guide wire 22 during pump operation. As noted above, it is also contemplated to remove the guide wire 22 after the pump 12 and cannula 14 are properly positioned in the patient. In this case, the gasket or seal 68 on the hub 56 should be robust enough to reseal after the guide wire 22 is withdrawn and prevent the ingress of blood into the interior of the rotor 44.

[00104] Referring to FIG. 5, the motor coupler 24 includes a housing 78, a drive shaft adapter 80, and a bearing assembly 82. The drive shaft adapter 80 includes a drive shaft coupler 84 dimensioned to receive a drive shaft of a motor (not shown), and a drive cable coupler 86 dimensioned to receive the drive cable 62. Any of a variety of attachment techniques may be employed to securely fasten the drive cable 62 to the drive cable coupler 86, including but not limited to adhesives, crimping, and laser welding. The drive shaft adapter 80 is rotatably disposed within the housing 78 by the bearing assembly 82. The bearing assembly 82 includes a sleeve 88 (which may alternatively be formed as an integral part of the housing 78) for retaining a pair of ball bearing assemblies 90, 92 and a spring 94 of the type described above. That is, each bearing assembly 90, 92 generally comprises an inner race which rotates along with the drive shaft adapter 80, an outer race which remains in a static and fixed position against the inner surface of the retaining sleeve 88, and a plurality of ball bearings disposed between the inner and outer races. The spring 94 is provided to bias each bearing assembly 90, 92 axially away from one another to reduce axial play during operation.

[00105] The purge fluid delivery system 26 includes a housing 96 having a central lumen 98, an inflow port 100, and an outflow port 102. The housing 96 is also dimensioned to matingly receive a portion of the motor coupler 24. In this regard, a seal element 104 is provided sandwiched in between the housing 96 and housing 78 and including an aperture which extends about the drive shaft adapter 80 as it exits the housing 78 to prevent the ingress

of purge fluid into the motor coupler 24. A fluid guide structure 106 is also provided within the central lumen 98 for the purpose of separating the inflow and outflow ports 100, 102. The fluid guide structure 106 includes a central lumen 108 through which the drive cable 62 extends, and an elevated portion 110 that retains an O-ring 112 against the inner surface of the central lumen 98 of the housing 96. The drive cable sheath 32 is secured to the housing 96 such that the inflow port 100 is communicatively coupled to the side lumens 76, and the outflow port 102 is communicatively coupled to the central lumen 74. In this fashion, pressurized purge fluid may be introduced through the inflow port 100 via inflow conduit 28, and removed through the outflow port 102 via outflow conduit 30. By way of example, the inflow conduit 28 and outflow conduit 30 may be coupled to their respective ports 100, 102 via barbed connectors 114. Similarly, the inflow and outflow conduits 28, 30 may be equipped with any number of suitable connectors (such as those illustrated by way of example in FIG. 2) for establishing fluid communication with a source of pressurized fluid (not shown). The pressurized fluid source (not shown) may include, but is not necessarily limited to, the use of a syringe, an indeflator, a fluid delivery pump, or an accumulator arrangement to provide the requisite delivery of pressurized fluid. The purge fluid delivery system 26 thus provides a two-way transmission of purge fluid within the drive cable sheath 32 for the purposes of cooling the blood pump 12 and preventing the ingress of blood past the radial seal 64 and into blood pump 12.

[00106] Referring to FIG. 6, shown is a guidable intra-vascular blood pump system 120 according to a second broad aspect of the present invention. As will be described hereinafter, the intravascular blood pump system 120 differs from the intravascular blood pump system 10 described above only as to the type of guide mechanism employed. In the interest of clarity and consistency, then, like reference numerals will be used to denote like elements and distinctions pointed out where necessary. Moreover, due to the commonality of principles employed in both intravascular blood pump systems 10, 120, a discussion to the level of detail set forth above is not deemed necessary with regard to the intravascular blood pump system 120. Instead, those aspects in common with the intravascular blood pump 10 are hereby incorporated into the discussion of the intravascular blood pump system 120.

[00107] In its most general form, the intravascular blood pump system 120 of this second broad aspect of the present invention comprises the blood pump 12 and cannula 14 arrangement, wherein the cannula 14 is equipped with a "side-rigger" or "rapid exchange" guide mechanism 122. In an important aspect of the present invention, the "rapid exchange" or "side-rigger" guide mechanism 122 includes a guide carriage 124 formed along at least a portion of the cannula 14, and a suitable guide element (such as guide wire 22) dimensioned to pass slidably through a lumen (not shown) extending through the guide carriage 124. The "rapid exchange" guide mechanism 122 thereby provides the ability to selectively guide the blood pump 12 and cannula 14 to a predetermined position in the circulatory system of a patient in the manner described above. Namely, the guide wire 22 may be first introduced into the vascular system of a patient through any suitable access point and guided to a desired location within the circulatory system of the patient, i.e. the left ventricle as shown. The blood pump 12 and cannula 14 may thereafter be advanced along the guide wire 22 and positioned in the trans-valvular configuration shown for providing left-heart assist.

[00108] FIGS. 7-9 further illustrate the "side-rigger" or "rapid-exchange" guide mechanism 122 of this second broad aspect of the present invention. In a preferred embodiment, the "side-rigger" guide mechanism 122 includes a lumen 126 formed within the guide carriage 124. The guide carriage 124 is preferably formed as an integral extension of the wall of the cannula 14. FIGS. 7 and 8 comport with the embodiment shown in FIG. 6, namely illustrating the guide carriage 124 formed along the exterior surface of the cannula 14. FIG. 9 illustrates an alternate embodiment wherein the guide carriage 124 may be formed along the interior surface of the cannula 14. In either case, the guide wire 22 is advanced to a desired location in the vasculature of the patient, after which point the blood pump 12 and cannula 14 can be slidably advanced therealong for delivery to the desired location according to the present invention. The guide wire 22 may thereafter be withdrawn from the patient. If the guide carriage 124 is formed along the exterior surface of the cannula 14 (as shown in FIGS. 7-8), then the cannula 14 should preferably be positioned so that the guide carriage 124 does not extend in a trans-valvular fashion. For example, with reference to FIG. 6, the guide carriage 124 should be positioned wholly within the left ventricle such that the pulsatile blood

flow during beating heart procedures will not inadvertently pass through the side lumen 126 and pass through the aortic valve.

[00109] The intravascular blood pump system 120 is constructed in virtually the same manner as the intravascular blood pump system 10 shown and described above, with the exception of the location of the respective guide mechanisms 16, 122. More specifically, because the guide mechanism 122 is disposed along the side of the cannula 14, there is no need to form a central lumen extending through the blood pump 12, drive cable assembly 18, purge fluid delivery system 26, and motor coupler 24 as detailed above with regard to the intravascular blood pump system 10. As such, these components need not be specially machined or molded to include such central lumens as was required with the intravascular blood pump system 10 set forth above.

[00110] Referring to FIG. 10, shown is a guidable intravascular blood pump system 130 according to a third broad aspect of the present invention. Again, due to the commonality between many of the same components and features of the intravascular blood pump systems described above and the intravascular blood pump system 130, like reference numerals will be used to denote like elements and distinctions pointed out where necessary. As will be explained in greater detail below, the intravascular blood pump system 130 employs yet another unique and useful guide mechanism according to the present invention. However, because many of the same components are employed, a discussion to the level of detail set forth above is not deemed necessary with regard to the intravascular blood pump system 130. Instead, those aspects in common with the intravascular blood pumps described above are hereby incorporated into the discussion of the intravascular blood pump system 130.

[00111] In its most general form, the intravascular blood pump system 130 of this third broad aspect of the present invention comprises the blood pump 12 and cannula 14 arrangement, wherein a "guide catheter" 132 is provided as the guide mechanism for positioning the pump 12 and cannula 14 at a desired location within the circulatory system of the patient. More specifically, with brief reference to FIG. 12, the intravascular blood pump system 130 is formed in two separate assemblies according to the present invention: a conduit

assembly 134 and pump assembly 136. In its most basic form, the conduit assembly 134 comprises the guide catheter 132 and cannula 14 coupled to the rotor shroud 36. The pump assembly 136 is constructed such that the pump body 34 and rotor 44 can be disengaged from the rotor shroud 36 and removed entirely from the conduit assembly 134. Referring again to FIG. 10, this dual construction forms a significant feature of the present invention because it provides the ability to form the blood pump 12 at a desired location in a patient using two separate and distinct steps. The first step involves positioning the conduit assembly 134 (with the pump assembly 136 removed) within a patient such that the shroud 36 and cannula 14 are each disposed in a desired location, such as a trans-valvular configuration for cardiac assist procedures. In an important aspect, the task of positioning the conduit assembly 134 within the patient may be advantageously facilitated through the use of any number of well known guidance mechanisms, including but not limited to guide wires, balloon catheters, imaging wires, guide catheters, and/or techniques involving ultra-sound or flouroscopy. The second step in providing the intravascular blood pump system 130 of the present invention involves advancing the pump assembly 136 through the conduit assembly 134 such that the rotor 44 docks within the shroud 36 to form the pump 12 at the desired location.

[00112] By way of clarification, the term "cannula" is used to denote cannula 14 because it serves a primary purpose of transporting fluid into the blood pump 12, whereas the term "catheter" is used to denote the catheter 132 because it serves a primary purpose of guiding or directing devices or components (i.e. the pump assembly 136) to a desired location within the body. It is to be readily understood, however, that these terms are only used for convenience and in a general fashion such that the cannula 14 may serve certain guiding functions and the catheter 132 may serve certain fluid transportation functions without departing from the scope of the present invention. For example, the cannula 14 may be equipped with dedicated lumens to receive various guide mechanisms (such as guide wires, balloon catheters, selectively deformable elements such as Nitonol, etc). In similar fashion, the guide catheter 132 may be used to transport fluid to and/or from the patient, such as by providing apertures 138 along predetermined regions of the catheter 132.

[00113] FIG. 11 demonstrates a significant feature of the present invention involving the use of the guide catheter 132 to transport fluid to and/or from the patient. An optional perfusion assembly 140 is provided as part of the intravascular blood pump system 130 of the present invention. The perfusion assembly 140 includes a conduit 142 in fluid communication with the apertures 138, which in this case are formed near the distal region of the guide catheter 132 a short distance downstream from the blood pump 12. In use, blood will pass along the exterior of the guide catheter 132 for distribution throughout the body, as well as within the interior of the guide catheter 132 after passing into the apertures 138. The perfusion assembly 140 may then be employed to selectively reroute blood from within the guide catheter 132 to a point within the patient's vasculature downstream from the point where the guide catheter 132 enters the body. A hemostasis valve assembly 146 of the perfusion assembly 140 permits the drive cable assembly 18 to pass through to the purge fluid delivery system 26 while preventing blood flow other than into the perfusion assembly 140. A seal assembly 150 of the purge fluid delivery system 26 permits the drive cable 62 to pass through to the motor 20 while preventing the flow of purge fluid other than into and from the purge fluid delivery system 26. The perfusion assembly 140 includes a control mechanism 148 for selectively controlling the distribution of perfusion blood flow from the perfusion assembly 140 into the patient. This control mechanism 148 may be automatic based on certain feedback criteria or manually operated.

[00114] FIGS. 12-17 illustrate an exemplary construction of the intravascular blood pump system 130 according to the third broad aspect of the present invention. As shown in FIG. 12, the conduit assembly 134 may be selectively disengaged so as to remove the pump assembly 136 therefrom. According to the present invention, the conduit assembly 134 may be introduced (without the pump assembly 136) into the circulatory system of a patient and selectively guided such that the rotor shroud 36 and cannula 14 are positioned at a desired location. The pump assembly 136 can thereafter be selectively introduced into the conduit assembly 134. A challenge in such a "back-loading" arrangement is ensuring that the pump assembly 136 docks appropriately within the rotor shroud 36 and is maintained in proper engagement during operation of the resulting pump 12.

[00115] An exemplary docking arrangement will now be described with reference to FIG. 14. In a preferred embodiment, the rotor 44 may be properly and accurately docked within the shroud 36 by forming angled mating surfaces on corresponding portions of the shroud 36 and pump body 34. More specifically, an angled mating surface may be formed on the interior surface of the rotor shroud 36 along that portion extending proximally from the flow aperture 38. A corresponding angled mating surface may be provided along the exterior surface of the pump body 34 along a distal portion thereof. The mating surfaces shown in FIG. 14 may preferably be formed in the range from about 2 degrees to 10 degrees, and more preferably formed in the range from about 3 degrees to 6 degrees. Mating angles within these ranges are adequate to guide the distal end of the pump body 34 to a point generally flush with the proximal edge of the flow aperture 38 as shown in FIG. 14. In this fashion, the pump assembly 136 and the rotor shroud 36 combine to form the blood pump 12. More importantly, this docking is carried out such that the rotor 44 and rotor blades 58 are maintained in proper position for efficient and safe pump operation.

[00116] An exemplary biasing scheme for maintaining the pump assembly 136 in this docked relationship will now be described with reference to FIGS. 12-13 and 16-17. The conduit assembly 134 is preferably equipped with a male quick-connect coupling 152 capable of engaging with a female quick-connect coupling 154 forming part of the perfusion assembly 140 of the present invention. A bias spring 156 is provided in between the perfusion assembly 140 and the housing 96 of the purge fluid delivery system 26. The bias spring 156 is preferably dimensioned so as to be in tension when the male quick-connect 152 is engaged within the female quick-connect 154 as part of the docking process of the present invention. As such, the bias spring 156 serves to maintain the pump assembly 136 in the docked position within the rotor shroud 36. The bias spring 156 may be coupled to the housing 96 of the purge fluid delivery system 26 in any number of suitable fashions. One such coupling arrangement may comprise a female quick-connect coupling 158 attached to the housing 96 and a male quick-connect coupling 160 attached to the bias spring 156.

[00117] An exemplary embodiment of the perfusion assembly 140 is shown with reference to FIGS. 12-13 and 17. The perfusion assembly 140 shown includes the hemostasis valve 146

coupled to the female quick-connect coupling 154. A length of tubing 162 extends between the opposing barb connectors of the hemostasis valve 146 and the female quick-connect coupling 154. A continuous lumen is formed extending through the interior of the male quick-connect coupling 152, the female-quick-connect coupling 154, the tubing 162, and the hemostasis valve 146. The drive cable assembly 18 extends through this continuous lumen and exits through a Touehy-Borst hemostasis seal 164 which prevents the migration of blood out of the proximal end of the perfusion assembly 140. A side-port 166 is disposed in fluid communication with the central lumen of the perfusion assembly 140. In one embodiment, this side-port 166 may be equipped with a conduit 168 having a stop-cock 170 to selectively control the distribution of blood through a perfusion conduit (i.e. conduit 142 of FIG. 11) coupled to the stop-cock 170. It will be appreciated that this type of manual control system for selectively perfusing the patient may be replaced with control circuitry for automatically controlling the rate of perfusion. Such automatic perfusion may be based on control algorithms based on contemporaneous feedback or pre-programmed thresholds.

[00118] The foregoing discussion details a host of inventive aspects forming part of the present invention. It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concepts thereof. The following evidences, by way of example only, various additional aspects forming part of the present invention.

[00119] FIG. 18 illustrates an alternate configuration of the intravascular blood pump system 130 of the third broad aspect of the present invention having an alternate bearing assembly, purge fluid delivery, and docking scheme. The bearing assembly includes a seal spring 182 and a bearing assembly 180. The bearing assembly 180 includes an inner race 184, an outer race 186, and a plurality of balls 188 which enable the inner race 184 to rotate along with the rotor shaft 46 while the outer race 186 remains in a static and fixed position relative to an inner surface of the pump body 34. An O-ring 190 is disposed within a groove formed in the rotor shaft 46 so as to maintain the bearing assembly 180 against the seal spring 182. The O-ring 190 is further secured within the groove in the rotor shaft 46 via a contoured lip portion

extending from the distal end of the cable adapter 60. The proximal end of the cable adapter 60 flushly engages the drive cable 62.

[00120] The purge fluid delivery system of the embodiment shown in FIG. 18 provides for a one way delivery of purge fluid to the blood pump 12. That is, pressurized fluid (namely, fluid pressurized to some level elevated above the blood pressure in the surrounding vessel) is injected in between the drive cable 62 and the interior of the protective sheath 32 during operation. This serves to reduce any frictional heating that exists between the drive cable 62 and sheath 32. The pressurized fluid also flows through the interior of the pump 12 such that, if the seal at 192 is broken, the pressurized fluid will flow past the open seal 192 and onward through the blood flow ports 38 formed in the shroud 36. This serves to keep blood from entering the pump 12 in an effort to avoid clotting and/or damaging the pump 12.

[00121] The pump assembly 136 may be docked within the conduit assembly 134 in any number of different fashions without departing from the scope of the present invention. That is to say, the docking scheme shown in FIG. 18 is set forth by way of example only and is not to be deemed limiting or restrictive as to numerous ways to temporarily engage or "dock" the pump assembly 136 within the conduit assembly 134. The only requirement is that the pump assembly 136 and conduit assembly 134 dock such that the rotor 44 is disposed within the shroud 36 to provide the desired axial flow through the cannula 14 and out the shroud 36. The exemplary docking scheme involves forming an annular engagement groove 194 along the interior of the shroud 36, and forming a complementary annular ridge 196 along the exterior surface of the pump body 34. During insertion, the pump assembly 136 will be advanced into the conduit assembly 134 until the annular ridge 196 on the pump body 34 engages within the groove 194 formed in the shroud 36. This docking scheme is generally advantageous in that the engagement action between the annular ridge 196 and groove 194 will provide tactile feedback to the physician during the process of inserting the pump assembly 136 into the conduit assembly 134 such that the physician will be able to determine when the docking has been completed.

[00122] As will be appreciated by those skilled in the art, the location of the annular ridge 196 and engagement groove 194 may be varied such that they are disposed closer or farther away from the flow apertures 38. It may be advantageous to form these docking structures close to the flow apertures 38 in an effort to thwart the ingress of blood into the junction extending between the interior of the shroud 36 and the exterior surface of the pump body 34. It is also contemplated to employ selectively inflatable structures, such as balloons, in an effort to temporarily engage or dock the pump assembly 136 within the conduit assembly 134. In this regard, one or more lumens may be formed within the pump body 34 extending from the interior of the pump body 34 in fluid communication with a balloon disposed along the exterior surface of the pump body 34. The pressurized fluid flowing within the interior of the pump body 34 may then be used to inflate the balloon, which will then engage within an annular groove in the shroud 36, such as at 194. Of course, the engagement structures may also be reversed without departing from the scope of the present invention. For example, the shroud 36 may be equipped with a fluid delivery lumen therein for inflating a balloon disposed on the interior surface of the shroud 36, which may in turn be disposed within an annular engagement groove formed along the exterior surface of the pump body 34.

[00123] While this invention has been shown in use largely in during left-heart applications it is to be readily appreciated that this does not limit the applications of this invention for use in left heart support only. Rather, the guidable intravascular blood pump of the present invention can be utilized in right-heart support applications and a wide variety of other applications apparent to those skilled in the art. For example, with reference to FIG. 19, shown is an intravascular blood pump 200 (of the type shown and described above with reference to FIGS. 2-5) configured for use in a right-heart support application. In this embodiment, the intravascular blood pump system 200 is equipped, by way of example, with an "over-the-wire" guide mechanism 16 comprising a balloon catheter 202. It is to be readily appreciated that, although shown and described below in terms of an embodiment of the type shown in FIGS. 2-5, the intravascular blood pump systems 120, 130 disclosed herein may also be configured for use in right-heart applications. Such right-heart configurations, and others apparent to those skilled in the art based on the broad principles enumerated in this application, are contemplated as being within the scope of the present invention.

[00124] The intravascular blood pump system 200 is shown positioned within the heart, such as may be advantageous to provide right heart support during beating heart surgery. To position the guidable intravascular blood pump system 200 in the right heart according to the present invention, a suitable guide element (such as balloon catheter 202) is first advanced to a desired location within the heart via the "sail" action of an inflated balloon. After the balloon catheter 202 is located in the desired position (such as in the pulmonary artery as shown), the intravascular blood pump system 200 according to the present invention may be advanced over the balloon catheter 202 and guided into a desired arrangement. For right heart support, this would involve advanced into the pump 12 and cannula 14 overt the balloon catheter 202 until the fluid inlet 204 is disposed within the vena cava (or right atrium) and the fluid outlet 206 is positioned within the pulmonary artery. The pump 12 may then be selectively (i.e. automatically or on-demand) controlled to transport blood from the vena cava (or right atrium) in a trans-valvular fashion through the tricuspid valve, the right ventricle, and the pulmonary valve for deposit within the pulmonary artery. Providing right-heart support during beating heart surgery advantageously overcomes conditions where cardiac output may become compromised during beating heart surgery, such as when the heart is lifted to gain access to posterior vessels, thereby avoiding the need for cardiopulmonary bypass.

[00125] It is also contemplated as part of the present invention that the guidable intravascular blood pump systems can be introduced into the patient's vasculature to achieve the intravascular access into the right or left heart through any number of access points, including but not limited to the internal jugular vein, the brachiocephalic vein, carotid artery, axillary artery, femoral vein, femoral artery, and subclavian artery. The intravascular blood pump systems of the present invention may also be introduced via direct introduction, such as into the aorta, the atria, and the ventricles. As is well known in the art, such intravascular access may be achieved percutaneously through the use of the Seldinger technique or directly through the use of minimally invasive access techniques.

[00126] Those skilled in the art will also appreciate that, although shown and described above in terms of "axial flow," the present invention is not limited to the axial flow type

intravascular blood pumps. Rather, the intravascular blood pumps 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps, without departing from the scope of the present invention.

[00127] With regard to the embodiments shown in FIGS. 10-17, it is furthermore contemplated that the guide catheter 132 may be separable from the conduit assembly 134 after the pump assembly 136 is docked within the shroud 36 to form the pump 12 at the desired location within the circulatory system of the patient. This may be accomplished by providing the guide catheter 132 in a detachable fashion via any number of suitable arrangements. By removing the guide catheter 132 after the pump 12 assembled, wound management of the access point into the patient's vasculature may be improved. This is due, in part, to the substantial reduction in size of the device extending into the patient (i.e. the drive cable assembly 18 as opposed to the larger diameter guide catheter 132).

[00128] It is also contemplated to incorporate various pressure sensing and/or guidability features into at least one of the cannula, 14 and pump 12. Such features may include, but are not necessarily limited to, those shown and described in commonly-owned and co-pending U.S. Patent Application Ser. No. 09/280,988 (filed March 30, 1999) entitled "Steerable Cannula," and U.S. Patent Application Ser. No. 09/280,970 (filed March 30, 1999) entitled "Pressure Sensing Cannula," the disclosures of which are hereby expressly incorporated by reference as if set forth herein in their entirety and physically incorporated as APPENDIX A and APPENDIX B respectively to the present specification. These pressure sensing features may include, but are not necessarily limited to, the use of fluid-filled lumens, piezo-electric pressure sensing elements, strain gauges, and analysis of the torque/current relationship (based on the dynamic pressure differential between the inlet and outlet of the pump). The guidability features may include, but are not necessarily limited to, the use of side lumens and deformable materials (i.e. Nitonol).

[00129] Various pump and cannula arrangements have been described and shown above for providing right and/or left heart support wherein blood is deliberately re-routed through

and past the right and/or left ventricle in an effort to reduce the volume of blood to be pumped by the particular ventricle. While "unloading" the ventricles in this fashion is preferred in certain instances, it is to be readily understood that the pump and cannula arrangements described herein may also be employed to "preload" the ventricles. Ventricular preloading may be accomplished by positioning the outflow cannula from the pump into a given ventricle such that the pump may be employed to fill or preload the ventricle with blood. This may be particularly useful with the right ventricle. On occasion, the right ventricle is not supplied with sufficient levels of blood from the right atrium such that, upon contraction, the right ventricle delivers an insufficient quantity of blood to the pulmonary artery. This may result when the right ventricle and/or right atrium are in a stressed or distorted condition during surgery. Preloading overcomes this problem by actively supplying blood into the right ventricle, thereby facilitating the delivery of blood into the pulmonary artery. The same technique can be used to preload the left ventricle and thus facilitate the delivery of blood from the left ventricle into the aorta.

APPENDIX A – (U.S. SERIAL NO. 09/280,988)

[00130] STEERABLE CANNULA

BACKGROUND OF THE INVENTION

[00131] 1. Field of the Invention

The invention relates to vascular cannulas for use in medical procedures.

[00132] 2. Description of Related Art

[00133] In medical applications and specifically in surgery, the list of uses for cannulas is exhaustive. Cannulas are to be distinguished from catheters in that catheters generally have a substantially smaller fluid-carrying capacity are used primarily for sampling or measurement purposes or for delivery of small quantities of fluid, whereas cannulas are generally larger and are used for volumetric fluid transfer. One application of cannulas involves the augmenting or supplementing of pulmonary blood flow through the beating heart during cardiac-surgery by use of one or more cannulas involved in the intake and return of blood into the circulatory system. The cannulas interface between the patient's circulatory system and the mechanical

pumps that power the augmentation procedure. Such an application is described in co-pending PCT Application no. PCT/US97/18674 entitled "Single Port Cardiac Support Apparatus", filed October 14, 1997 and incorporated herein by reference in its entirety.

[00134] As will be appreciated, precise and quick placement of the cannula in surgical applications is critical, given the severe time constraints facing a surgeon whose patient's vital life sustaining functions have been suspended during the procedure. Currently, methods for placing cannulas in a patient's body are crude, in that they rely on guesswork and trial and error. Specifically, a surgeon will insert the cannula and direct it towards the desired destination, but ultimately must feel by hand, through the patient's tissue for example, whether it has reached that destination. The surgeon may be forced to make several retractions and re-insertions until the process succeeds. Shortcomings of such a procedure are clear and may include damage to the delicate tissue involved and waste of valuable time. Additionally, constraints on the flexibility of the material are imposed since a prescribed amount of rigidity is required to enable the cannula to be felt through the tissue and insure that the cannula does not collapse under insertion force.

[00135] Alternatively, the surgeon may rely on the use of guiding devices such as a guide wire threaded through the cannula. The guide wire is often easier to manipulate than the cannula, and its placement precedes placement of the cannula. After the guide wire is in place, the cannula is pushed along the length of the guide wire, following the guide wire to the desired destination.

[00136] It is also known that a flow directed balloon catheter can be used as a guide wire. Balloon catheters are well known in the art and have a multitude of uses, including delivery or removal of fluid from the surgical site. However, flow directed balloon catheters are typically at least an order of magnitude smaller than cannulas. Their small size accordingly severely limits their application since both quantity and rate of fluid flow through the catheter are limited. In fact it is precisely because of their small size that flow directed balloon catheters can be used as guiding devices for the larger, more robust and versatile cannulas. During use as a guiding device for a cannula, the flow directed balloon catheter acts as a guide wire in facilitating the advancement of the cannula to the desired destination. The flow directed balloon catheter is first inserted into place in the patient's body, and the cannula, threaded around the flow directed balloon catheter, is then advanced into the desired position.

[00137] Insertion of the flow directed balloon catheter is effected using the inflatable balloon disposed at a distal tip of the flow directed balloon catheter. A lumen in communication with the balloon delivers inflating fluid to the balloon, thereby inflating the balloon and causing it to operate as a "sail" which is pulled along in the blood stream through the natural blood flow in the patient's circulatory system.

[00138] The above procedures have met with only limited success, and there exists a long felt need for devices and methods that facilitate placement of a cannula in a patient's body. A system that will assist in the manipulation of the cannula through the vascular structure or other bodily regions of the patient would accordingly serve to make the placement process more efficient and less time-consuming, improving the chance of overall success of a surgical procedure.

BRIEF SUMMARY OF THE INVENTION

[00139] The present invention overcomes the deficiencies of the prior art by providing a cannula which can be steered during its advancement in the body of the patient. Steering is implemented using cables connected to a deformable portion of the cannula. The cables extend to the proximal end of the cannula from where the operator can selectively apply tensional forces to thereby cause the cannula to curve at the deformable portion. The deformable portion is disposed preferable at the distal end of the cannula, but may be located at other sites along the length of the cannula.

[00140] In accordance with a second embodiment of the invention, the cannula is provided with more than one cable for facilitating deformation along multiple planes. Additionally, preformed curves may be provided along the length of the cannula, which curves can be either augmented or straightened by applied tension to the cables.

[00141] The cannula, in accordance with a third embodiment, is provided with a spiraling wire formed in the cannula wall. The spiraling wire operates to provide rigidity to the body of the cannula and maintain good fluid flow therein. The spiraling wire may comprise a portion of the cable used to impart deformation in an arrangement in accordance with a fourth embodiment of the invention.

[00142] In accordance with a fifth embodiment of the invention, the steerable cannula is provided with an inflatable balloon at the distal end thereof for assisting in guiding the cannula

to its desired destination. The inflatable balloon is selectively inflatable using a lumen which effects fluid communication between an fluid source and the balloon.

[00143] In accordance with a sixth embodiment of the invention, a steerable cannula having a pigtail distal tip configuration is provided.

[00144] In accordance with a seventh embodiment of the invention, a steerable cannula having a movably supported guide wire is provided.

[00145] In accordance with an eighth embodiment of the invention, a steerable cannula having an integrally formed guide wire is provided.

[00146] In accordance with a ninth embodiment of the invention, a steerable cannula is used in a co-axial cannula arrangement.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[00147] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

[00148] FIG. 20 is schematic side view of a steerable cannula in the undeformed state in accordance with the first embodiment of the invention;

[00149] FIG. 21 is a schematic cross-sectional view of the steerable cannula of FIG. 20 taken along line A-A;

[00150] FIG. 22 is a schematic side view of the steerable cannula in the deformed state in accordance with the first embodiment;

[00151] FIG. 23 is a schematic cross-sectional view of a steerable cannula having two cables in accordance with a second embodiment of the invention;

[00152] FIG. 24 is a schematic side view of a steerable cannula having a reinforcing wire in accordance with a third embodiment of the invention;

[00153] FIG. 25 is a schematic cut-away view of a steerable cannula in accordance with a fourth embodiment of the invention;

[00154] FIG. 26 is a schematic cross-sectional view taken along line B-B of FIG. 25;

[00155] FIG. 27 is a schematic side view of a steerable cannula having a preformed curve and an inflatable balloon formed at a distal end thereof in accordance with a fifth embodiment of the invention;

[00156] FIG. 28 is a schematic side view of the inflatable balloon of fifth embodiment of the invention, wherein the balloon is shown in the inflated state;

[00157] FIG. 29 is a schematic cross-sectional view taken along line C-C of FIG. 28;

[00158] FIG. 30 is a schematic view showing a steerable cannula having a pigtail distal tip configuration in accordance with a sixth embodiment of the invention;

[00159] FIG. 31 is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with a seventh embodiment of the invention;

[00160] FIG. 32 is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with an eighth embodiment of the invention;

[00161] FIG. 33 is a schematic side view showing a steerable cannula used in a co-axial configuration in accordance with a ninth embodiment of the invention, wherein the steerable cannula is advanced to a first relative position;

[00162] FIG. 34 is a schematic side view showing a steerable cannula of FIG. 33, wherein the steerable cannula is advanced to a second relative position; and

[00163] FIG. 35 is a schematic side view of a configuration in accordance with a tenth embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[00164] The present invention comprises a steerable cannula in which a portion which is adapted for insertion into the body of a patient, preferably into the vascular system of the patient, is configured to be selectively deformable. The deformation aids in changing the direction of the cannula during the insertion process such that the cannula can be steered in a desired direction as it is advanced toward its destination in the patient's body. Deformation is effected using a cable connected with the deformable portion of the cannula. Tension on the cable, induced by for example rotating a portion of a handle disposed at a proximal end of the cannula exterior of the body of the patient, results in tension on one wall of the deformable portion and thereby causes it to bend in the direction of the cable.

[00165] With reference to FIGS. 20-23 in which an exemplary arrangement in accordance with a first embodiment of the invention is shown, cannula 1120 can be seen as comprising a substantially cylindrical structure having a wall 1122 which defines a main lumen 1124. Lumen 1124 is adapted for fluid transport to or from the body of the patient and may be

provided with one or more holes 1126 located adjacent to distal tip 1128 and permitting passage of fluid therethrough. Holes 1126 supplement fluid flow through main port 1125, especially in situations of blockage of main port 1125. Cannula 1120 may be one of two complementary cannulas (not shown) used in a surgical procedure, one for intake and the other for removal of blood or other fluid from the patient's body. Alternatively cannula 1120 may comprise a component of a co-axial, single port device in which cannula 1120 is surrounded by a second, larger conduit, with cannula 1120 for example operating to intake blood from the patient towards a pump system and the conduit operating to replace the blood from the pump back into the patient for augmentation of blood flow during beating heart surgery as described in co-pending PCT Application no. PCT/US97/18674 mentioned above.

[00166] At a proximal end 1130 of cannula 1120 is provided a handle 1132 which serves to transmit turning forces applied by an operator's hand to the cannula to aid in its manipulation in the patient's body. As such, handle 1132 is rigidly attached to wall 1122 of cannula 1120, although portions of handle 1132 may be configured for motion relative to cannula 1120 in order impart the necessary tension on cables used for deforming the cannula 1120 as described below. Rotation of the rigidly attached portion of handle 1132, results in a corresponding rotation of the distal end 1128 of the cannula 1120 within the patient's body, thus aiding in the cannula's manipulation and advancement to the desired destination.

[00167] Wall 1122, in addition to defining main lumen 1124 of cannula 1120, contains a secondary lumen 1136 formed therein. Movably mounted in lumen 1136 is a cable 1138 which is secured at point 1140 in wall 1122. Point 1140 may be disposed anywhere along the length of the cannula 1120, but in the preferred embodiment lies at distal end 1128.

[00168] Cannula 1120 is provided with a deformable portion 1142 formed along at least a segment of its length. In the exemplary arrangement shown in FIGS. 20-22, deformable portion 1142 is disposed in close proximity to distal end 1128 of cannula 1120; however, it is to be understood that this not intended to be limiting and that other regions in the cannula 1120 can alternatively or additionally be made deformable depending on the contemplated application.

[00169] Deformable portion 1142 serves to cause cannula 1120 to bend in response to tension applied to cable 1138 and thereby assume a configuration as shown in FIG. 22. Depending on the location of point 1140 and the location of lumen 1136 radially and axially

along wall 1122, applied tension to cable 1138 causes cannula 1120 to turn on itself in the direction of pull to thereby assume a curve having a predetermined orientation. Additionally, if cannula 1120 is provided with one or more preformed curves, which may be in identical or in different planes along the length of the cannula as is contemplated, tension in cable 1138 can operate to temporarily straighten the cannula along at least one of these planes to facilitate handling during a particular maneuver through the patient's body.

[00170] It is also contemplated that more than one cable can be provided, supported in suitable secondary lumens formed in cannula 1120. As can be seen from FIG. 23, a second lumen 1146 can be provided in wall 1122 of cannula 1120, second lumen 1146 movably supporting cable 1144 therein. Cables 1138 and 1144 are thus disposed on opposite sides of cannula 1120 and serve to provide steerability in two directions. The cables are configured such that a pulling of one cable is coordinated with a slacking of the other cable in order permit bending of cannula 1120 at deformable portion 1142. Although shown to be diametrically opposed in position, cables 1138 and 1144 can occupy any position along wall 1122, and it will be appreciated that the number of such cables used can vary depending on the application, as can their distribution in wall 1122, and any desired number of turning directions can accordingly be achieved in accordance with the present invention.

[00171] Wall 1122 can be formed of materials ranging from rigid to flexible, and in the preferred embodiment comprises a semi-rigid transparent material such as silicone rubber. Of course it is to be understood that by definition deformable portion 1142 is to be constructed of a flexible material, regardless of the construction of the remainder of the wall 1122, such that cannula 1120 can bend when appropriate pulling forces are imparted through the cable(s).

[00172] Selective bending of cannula 1120 can also be facilitated using a core member provided for this purpose. Core member 1182, preferable formed of material having appreciable stiffness relative to wall 1122, is disposed longitudinally within cannula 1120 and serves to provide a deflection point to locate and control the bending point of the cannula. Core 1182 is removable and can be movable distally or proximally within cannula 1120 in order to alter the deflection point. In this manner also flow blockage in the cannula 1120 can be insured during insertion.

[00173] As can be seen from FIG. 24, a spiraling wire 1148 can be provided for structural reinforcement of cannula 1120. Wire 1148 is either molded into the wall 1122 or is otherwise

supported therein, and extends either partially or fully across the length of the cannula 1120. Wire 1148 facilitates handling of the cannula 1120 and reduces the possibility of cannula 1120 collapsing or being pinched shut and thus closing off the flow of fluid to or from the patient. Other ways of reinforcing the tubular body of cannula 1120 are known in the art and will adapt equally well to the present invention. In addition, no reinforcement may be needed if the cannula material is sufficiently rigid or if sufficient fluid flow is present within the cannula.

[00174] Alternatively, as shown in FIGS. 25-26, spiraling wire 1148 can itself comprise a portion of cable 1138. In such an arrangement, cannula wall 1122 is formed of two layers 1162 and 1164, between which is formed a lumen 1166. Layers 1162 and 1164 may be discrete layers bonded together at appropriate regions, or they may be a single layer folded back upon itself to form the two layers, with lumen 1166 and wire 1148 occupying predetermined regions therebetween. Cable 1138 is housed in a polymide tube 1170 disposed in lumen 1166 and extends beyond the end 1168 of tube 1170 to then spiral exteriorly of inner layer 1162 and interiorly of outer layer 1164 to thereby lend structural support to the cannula 1120. Metal or other tape 1172 can be used to secure spiraling wire 1148 in place. In a variation of this, cable 1138 and wire 1148 may be two discrete components which are welded or otherwise connected together at any desired point along the body of cannula 1120. Alternatively, as shown in FIG. 35, cable 1138 may be secured to a band 1184 disposed radially about or adjacently to tip 1186 of cannula 1120. In all of these variations, cable 1138 may be formed of single or multiple strands of metal, plastic or carbon fiber composite, but preferably cable 1138 is formed of a single strand of stainless steel having a TEFLON™ coating. In the FIGS. 33-35 arrangements, cannula 1120 is shown with an atraumatic bullet tip 1186 having side holes 1188 and end holes 1190. It will be appreciated that such a tip can be provided for any arrangement of the invention. It will also be appreciated that the tip 1186 can itself serve as the anchor for the cable 1138 in certain arrangements. The tip 1186 is fixedly bonded to distal end 1125 of cannula 1120 and enables a simplified construction of the steering mechanism and provides a blunt surface that will not injure tissue in the body.

[00175] Lumens 1136 and 1146, or other similar lumens, in addition to supporting cables 1138 and 1144 therein, may be used to supply inflating fluid to a balloon 1150 provided at the outer surface of the distal end 1128 of cannula 1120. As shown in the exemplary embodiment

of FIGS. 27-29, balloon 1150 is in fluid communication with inflating fluid source 1152, via supply tube 1154 and lumen 1156. Fluid source 1152 serves to selectively provide fluid, such as saline, air or other gas, to balloon 1150 to thereby cause the balloon to inflate within the patient's body. Balloon inflation in this manner assists in placement of the cannula 1120, especially when inserting the cannula antegrade, with the inflated balloon serving to float the tip of cannula within the fluid flow to thus transport it to the desired location in the body. Cannula 1120 is provided with one preformed curve 1158 in addition to curve 1160 imparted by the tension in cable 1138. Balloon 1150 is shown in the deflated state in FIG. 27 and in the inflated state in FIGS. 28 and 29.

[00176] Various distal tip configurations can be selected for cannula 1120, depending on the particular application as appreciated by those of ordinary skill in the art. For example, a pigtail shape can be used for crossing the aortic valve retrograde. The pigtail shape, illustrated in FIG. 30, can be formed by bonding or thermal welding or otherwise attaching a thermoplastic rod 1174 formed into a loop at the distal end of the cannula 1120. Alternatively, a J-tip wire 1176 can be configured to protrude from the distal tip 1128, as illustrated in FIGS. 31 and 32. The J-tip wire can be a conventional guidewire movable or fixedly supported in a dedicated lumen 1178 formed in a rigidly attached tube 1180 (FIG. 31), or it can be supported, rigidly or movably, between layers of material from which the wall 1122 of cannula 1120 is formed. Guidewires are known in the art and can for example be formed of windings of wire coiled around a core and having one or more preformed curves formed therein.

[00177] An embodiment in which cannula 1120 is used in a coaxial configuration is shown in FIGS. 33 and 34. Cannula 1120 serves as an inner cannula, passing through outer conduit 1180 while the two components are disposed in the patient's body. An important advantage of this arrangement is that outer conduit 1180 operates to vary the radius of curvature of inner cannula 1120 by providing a base point as the inner cannula 1120 is advanced. In this manner manipulation of the inner cannula 1120 and outer conduit 1180 is facilitated and advancement to the desired destination in the body of the patient is more efficiently accomplished.

[00178] The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to one of ordinary skill in the art that modifications thereto can be made without inventive departure from the spirit and scope of the invention.

ABSTRACT OF APPENDIX A

[00179] A steerable cannula is provided with at least one cable through which tension is communicated to a deformable portion of the cannula. The tension causes the cannula to bend at the deformable portion, enabling selective steering of the cannula during insertion into the body of the patient.

APPENDIX B – (U.S. SERIAL NO. 09/280,970)

[00180] PRESSURE SENSING CANNULA

[00181] BACKGROUND OF THE INVENTION

[00182] FIELD OF THE INVENTION

The present invention relates to cannulas used in surgical applications, and more particularly, to a cannula equipped with a pressure/flow rate transducer.

[00183] DESCRIPTION OF THE RELATED ART

In medical applications and specifically in surgery, the list of uses for cannulas is exhaustive. One application involves the augmenting or supplementing of pulmonary blood flow through the beating heart during cardio-surgery by use of one or more cannulas involved in the intake and return of blood into the circulatory system. The cannulas interface between the patient's circulatory system and the mechanical pumps that power the augmentation procedure. Such an application is described in co-pending PCT Application no. PCT/US97/18674 entitled "Single Port Cardiac Support Apparatus", filed October 14, 1997 and incorporated herein by reference in its entirety.

[00184] When performing cardiac surgery cannulas are placed within the patient's blood stream and used for inflow and outflow of blood or other fluids. If the operator wishes to determine the rate of fluid flow, either a catheter with appropriate sensors must also be placed in the patient's blood stream, or other sensors such as an external ultrasonic sensor as disclosed in U. S. Patent No. 5,179,862 are used. A shortcoming of ultrasonic systems such as that described in 5,179,862 is that they require significant monitoring. Ultrasonic sensors also

require that tubing of a specific diameter be used, thereby adding to the cost and complexity of the surgical procedure. Additionally, ultrasonic sensors are expensive and nondisposable, thereby adding to the cost of the surgical procedure.

[00185] Another method to measure flow rate is through the use of a thermodilution catheter. Thermodilution catheters require the infusion of a solution, typically saline, of a known temperature, with a distally disposed thermistor measuring the temperature change to determine the flow rate. This method is also expensive, increasing the cost of the surgical procedure. A second problem with using flow-sensing catheters, such as thermodilution catheters, is that they require the operator to place more incisions within the patient. The catheters must be placed so that they do not interfere with the inflow or out flow of the cannula. Visual markers along the length of the cannula may also be used to determine location, the greater the number of markers the more accurate the placement at the expense of quick readings due to the greater number of markings.

SUMMARY OF THE INVENTION

[00186] The present invention overcomes the deficiencies of the prior art by providing a cannula assembly having one or more pressure transducers coupled to a main lumen thereof. In accordance with a first embodiment, the pressure transducers are attached to the substantially tubular wall defining the main lumen.

[00187] In accordance with a second embodiment, a partial occlusion is provided in the cannula to increase the pressure drop across the main lumen. In this manner transducer signal is increased, and an improved differential pressure measurement signal achieved.

[00188] In accordance with a third embodiment of the invention, one or more pressure transducers are used in conjunction with a pair of coaxial cannulas for measuring pressure.

[00189] In accordance with at fourth embodiment of the invention, a differential pressure transducer is used, the differential pressure transducer being mounted in a dedicated secondary lumen in communication with the first lumen.

[00190] In accordance with a fifth embodiment of the invention, the secondary lumen housing the differential pressure transducer is disposed across a knee formed in the cannula to augment pressure measurement. Partial occlusions may also be provided for this purpose.

[00191] In accordance with a sixth embodiment of the invention, the secondary lumen housing the differential pressure transducer is formed integrally with the tubular wall defining the main lumen.

[00192] In accordance with a seventh embodiment of the invention, a soft, flexible tapered tip is provided at the distal end of the cannula. Such a configuration allows for easier negotiation through the patient's body during surgical procedure.

[00193] In accordance with an eighth embodiment of the invention, an inflatable balloon is provided at the distal end of the cannula. The inflatable balloon aids in transporting the cannula to the desired destination.

[00194] In accordance with a ninth embodiment of the invention, a guide wire lumen is provided for supporting a guide wire in the cannula. The guide wire is used as a predecessor step in the insertion of the cannula.

[00195] In accordance with a tenth embodiment of the invention, a light guide is supported in the cannula. The light guide conveys light to a predetermined portion of the cannula to thereby aid in the visualization and location of the cannula during the surgical procedure.

[00196] The invention realizes various advantages over the prior art, including a reduction in the number of incisions that a surgeon must make in performing surgical procedures, along with a reduction in the amount of foreign material introduced into the patient's body, while providing safe, rapid, accurate and cost-effective fluid flow rate measurements.

BRIEF DESCRIPTION OF THE DRAWINGS

[00197] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

[00198] FIG. 36 is a schematic side view of a first embodiment of the invention;

[00199] FIG. 37 is a schematic cross-sectional view taken along line D-D of FIG. 36;

[00200] FIG. 38 is a schematic cross-sectional view taken along line E-E of FIG. 36;

[00201] FIG. 39 is a schematic view of a cannula in accordance with the invention in a surgical application;

[00202] FIG. 40 is a schematic partial cut-away side view of a second embodiment of the invention;

[00203] FIG. 41 is a schematic cross-sectional view taken along line F-F of FIG. 40;

[00204] FIG. 42 is a schematic side view of a third embodiment of the invention;

[00205] FIG. 43 is a schematic side view of a fourth embodiment of the invention;

[00206] FIG. 44 is a schematic side view of a fifth embodiment of the invention;

[00207] FIG. 45 is a schematic side view of a sixth embodiment of the invention;

[00208] FIG. 46 is a schematic cross sectional view taken along line G-G of FIG. 45;

[00209] FIG. 47 is a schematic side view of a seventh embodiment of the invention;

[00210] FIGS. 48 and 49 are schematic side views of an eighth embodiment of the invention;

[00211] FIG. 50 is a schematic cross-sectional view taken along line H-H of FIG. 49;

[00212] FIG. 51 is a schematic side view of a ninth embodiment of the invention;

[00213] FIG. 52 is a schematic side view of a tenth embodiment of the invention; and

[00214] FIG. 53 is a schematic cross-sectional view taken along line J-J of FIG. 52; and

[00215] FIG. 54 is a schematic side view of an eleventh embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00216] In accordance with the invention, a cannula comprising a substantially tubular, semi-flexible material adapted for fluid transport while inserted in a patient's body is provided with one or more pressure transducers which are fixedly or adjustably supported in the cannula. The pressure transducers are disposed internally or externally of the cannula and are used to provide a measurement of the rate of fluid flow. In the internal configuration, the rate of fluid flow within the cannula is measured. In the external configuration, the rate of fluid flow outside the cannula is measured. The cannula can also be adapted to support a guide wire to aid the operator in its insertion through the patient's body, and/or a light source to provide a visual reference during the insertion procedure. It is to be understood that the use of the term "cannula" is intended to encompass cannulas, catheters, and any related devices having similar application.

[00217] An exemplary arrangement in accordance with a first embodiment of the invention is shown FIGS. 36-38. Cannula 2220 comprises a substantially cylindrical structure having a wall 2228 defining a main lumen 2221. Wall 2228 can be formed of materials ranging from rigid to flexible, and in the preferred embodiment comprises a semi-rigid transparent material

such as polyurethane, silicone rubber or other material. Lumens other than main lumen 2221 may also be provided, as described below. The cannula may also be formed from vinyl plastisol. To form a cannula of vinyl plastisol, a mandrel is dipped into liquid vinyl plastisol and heated. Wire is then wrapped around the mandrel and first formed layer. The mandrel is then dipped again encasing the wire, and then heated. The mandrel is then removed. Lumens and transducers may be formed within the wall of the cannula during the dipping process.

[00218] To lend structural support for the thin wall which allows maximum flow with minimal insertion damage, spiraling wire 2230 is provided for reinforcement and is either molded into the wall 2228 or is otherwise supported therein, and extends either partially or fully across the length of the cannula 2220. Wire 2230 facilitates handling of the cannula 2220 and reduces the possibility of cannula 2220 collapsing or being pinched shut and thus closing off the flow of fluid to or from the patient. Other ways of reinforcing the tubular body of cannula 2220 are known in the art and will adapt equally well to the present invention. In addition, no reinforcement may be needed if the cannula material is sufficiently rigid or if sufficient fluid flow is present within the cannula.

[00219] A connector 2223 is provided at the proximal 2225 end of cannula 2220. Connector 2223 is suitably sized to interface with various surgical instruments, including but not limited to a reverse flow pump or fluid conduits leading thereto (not shown). Cannula 2220 may also have one or more holes 2226 located adjacent to distal tip 2222 to facilitate fluid flow therethrough. Cannula 2220 may be one of two complementary cannulas used in a surgical procedure, one for intake and the other for removal of blood or other biocompatible fluid from the patient's body. Alternatively, cannula 2220 may comprise a component of a co-axial, single port device in which cannula 2220 is surrounded by a second, larger conduit, with cannula 2220 for example operating to intake blood from the patient towards a pump system and the conduit operating to replace the blood from the pump system back into the patient for augmentation of blood flow during beating heart surgery as described in the co-pending PCT Application No. PCT/US97/18674 mentioned above.

[00220] In order to provide real time fluid flow information in accordance with the present invention, a pair of pressure transducers 2224, 2232 are provided at two separate locations as illustrated in FIG. 36. Pressure transducers 2224, 2232 are of the type known in the art and each comprises for instance a piezo-electric crystal housed in an integrated circuit (IC) chip

(not shown). The crystal configuration is designed to be pressure sensitive, generating an electrical signal in proportion to the amount of pressure experienced.

[00221] The principle governing the relationship between fluid flow and pressure is defined by Bernoulli's equation, herein solved for flow rate V and is determined by:

$$V = \sqrt{\frac{\Delta P \cdot 2d \cdot a^2}{f \cdot L \cdot \rho}}$$

where ΔP is the measured difference in pressure, d is the internal diameter of the lumen, a is the area of the lumen, f is a frictional factor of the lumen material, L is the lumen length over which the pressure measurement is conducted, and ρ is a measurable constant representative of the density of the fluid. The flow rate information can be used for a variety of purposes, including monitoring the patient's condition and controlling the fluid pump used during the procedure.

[00222] In the preferred embodiment, transducers 2224, 2232 are imbedded in the wall 2228, which is formed for instance by application of successive layers of laminate and interjecting the transducers therebetween during the layering process. Depending on at what stage in the layering process the transducers 2224, 2232 are put in place in the wall 2228, their proximity to the interior of the cannula 2220 or its exterior can be controlled in order to optimize measurement of cannula interior or exterior pressure. From the interior pressure measurements, a determination of flow rate within main lumen 2221 can be made using the known diameter of the main lumen 2221. Similarly, from the exterior pressure measurements, flow rate of exterior fluid--for example, blood--can be measured if the diameter of the blood channel, such as the artery, is known, or the cannula can be calibrated with thermodilution catheters which assume the diameter of the vessel or artery they are placed within.

[00223] In the FIG. 36 exemplary arrangement, pressure transducer 2232 is disposed at a location near the distal tip 2222 of cannula 2220, while pressure transducer 2224 may be

disposed anywhere along the length of cannula 2220 between pressure transducer 2232 and proximal end 2225. It is also contemplated that the pressure transducers 2224, 2232 may be detachably disposed in dedicated secondary lumens formed in or along tubular wall 2228, the dedicated secondary lumen extending to the proximal end 2225 and supporting any electrical cables connected to the pressure transducers 2224, 2232. In the detachable arrangement, the location of pressure transducers 2224, 2232 in the cannula 2220 can be adjusted to suit the particular application, such that one transducer can be disposed within one chamber of the heart while the other is at a different of portion of the heart to thereby provide a pressure/flow rate measurement of a predetermined portion of the patient's body, for example flow into the heart from a designated blood vessel. Such an application is shown in FIG. 39.

[00224] Pressure transducers 2224, 2232 are in electrical communication with console 2236 via cable 2238, which is supported in secondary lumen 2242 provided in cannula 2220. Calculations for determining fluid flow rate using signals generated by the pressure transducers 2224, 2232 and relayed via cable 2238 are conducted at the console 2236 or at any processor or processing system connected thereto.

[00225] As shown in FIGS. 40 and 41, cannula 2220 may also contain a partial occlusion portion 2247 that forms a venturi 2246 within the main lumen 2221 of cannula 2220. Venturi 2246, which may be disposed anywhere along the length of the cannula 2220, induces a pronounced pressure drop, creating a greater differential in pressure between proximal region 2225 and distal region 2222, thereby requiring less signal amplification of the pressure transducers and less filtering of the signal and consequently yielding a more accurate flow rate measurement. Preferably the location of the pressure transducer 2232 is in the vicinity of venturi 2246 as shown in FIG. 54.

[00226] FIG. 42 shows an embodiment in accordance with the invention in which the pressure transducers 2224, 2232 are used with a co-axial, single port device 2250 in which cannula 2220 is surrounded by a second, larger conduit 2248, with cannula 2220 for example operating to intake blood from the patient towards a pump system (not shown) and conduit 2248 operating to replace the blood from the pump system, via openings 2252, back into the patient for augmentation of blood flow during beating heart surgery as described in the co-pending PCT Application no. PCT/US97/18674 mentioned above. It is to be understood that pressure transducers 2224, 2232 can be mounted fixedly or detachably either to the interior or

exterior of either the cannula 2220 or the conduit 2248 in the above-described manner. More than one pair of these transducers can also be used in a myriad possible combinations in accordance with the invention. In the preferred embodiment, the cannula 2220 is provided with a bullet nosed tip, as illustrated in for example FIGS. 42-44. Other tip configurations, such as a bevel, may also be used, as will be appreciated by those skilled in the art.

[00227] An alternative to using pairs of pressure transducers such as transducers 2224, 2232 is the use of a single differential pressure transducer 2254, as shown in FIG. 43. Differential pressure transducers are also well known in the art and comprise for example a piezo-electric crystal electro-mechanically configured to be responsive to a pressure difference between two opposing sides thereof. These two sides correspond respectively to proximal end 2257 and distal end 2259 of secondary lumen 2256 in which transducer 2254 is mounted. Proximal and distal ends 2257 and 2259 are attached at any desired points along the length of cannula 2220 to thereby couple secondary lumen 2256 to main lumen 2221 and provide a pressure difference measurement between the desired points. Attachment of lumen 2257 and transducer 2254 across knee 2249 of cannula 2220, as shown in FIG. 44, will provide a stronger signal, with knee 2249 operating in accordance with the same principal as venturi 2246 discussed above. Thus it is to be understood that a venturi could also be used in conjunction with the differential pressure transducer 2254. The ports 2261 and 2263 at which the lumen 2256 interfaces with cannula 2220 may be sealed by an appropriate membrane, with saline or other fluid being permanently housed in the lumen 2256. Alternatively, ports 2261 and 2263 may be open, permitting fluid communication between the cannula 2220 and the lumen 2256 and attached transducer 2254. The latter, open configuration would achieve a more faithful pressure representation. Stopcocks 2274 and 2276 can be provided in the ports 2261 and 2263 to permit priming and/or de-airing of the ports. It should also be noted that although in the arrangements of FIGS. 43 and 44 the lumen 2256 is provided as a separate tubular structure, lumen 2256 may alternatively be formed integrally with wall 2228 of cannula 2220, again with ports 2261 and 2263 being either open or closed to main lumen 2221 depending on the application. Such an arrangement is illustrated in FIGS. 45 and 46 in which is shown transducer 2254 in communication with lumen 2272 integrally formed in wall 2228 of cannula 2220.

[00228] Various distal tip configurations can be selected for cannula 2220 and used with the pressure sensing transducers, depending on the particular application as appreciated by those of ordinary skill in the art. FIG. 47 shows an exemplary embodiment in which the distal tip 2222 is formed of a soft, flexible material having a bullet shape. As shown exemplarily in FIGS. 48-50, the cannula 2220 may be equipped to support other tools, such as an inflatable balloon 2240 which is deployed for example in order to assist in transporting the distal tip 2222 to the desired destination in the patient's body during the surgical procedure. Balloon 2240 is inflated through an inflating lumen 2244 provided in cannula 2220 using a bio-compatible fluid such as saline or carbon dioxide gas. Preferably inflating lumen 2244 is formed integrally within wall 2228, by leaving an appropriate gap during the fabrication process, and is provided with a fitting (not shown) at its proximal end to interface with an inflating device for supplying the bio-compatible fluid. The lumen 2221 within the cannula 2220 can also be adapted to support a balloon catheter (not shown) which can be used to place the cannula within the patient's body. An obturator (not shown) may also be disposed through the main lumen 2221 to aid in insertion and guiding within the patient's body.

[00229] Another tool which cannula 2220 may support is shown in FIG. 51 and comprises a J-hook guidewire 2262 disposed slideably within lumen 2264, which is formed integrally in wall 2228 of cannula 2220. In operation, guidewire 2262, easier to manipulate than the cannula 2220, is first inserted into the patient's body and manipulated to the surgical site. Subsequently the cannula 2220 is maneuvering along the guidewire 2262, which passes through lumen 2264, to the desired destination.

[00230] As illustrated in FIGS. 52 and 53, cannula 2220 may also contain a light guide 2266, which may be supported in lumen 2268. Light guide 2266 comprises one or more optical fibers formed of, for example, glass or other materials, such as plastic, known for that purpose. Distal tip of light guide 2266 is configured for light projection, such that light provided at the proximal end of light guide 2266 is projected therefrom. An appropriate shape for such projection is a spherical shape, although other shapes and projection schemes, such as directional projection, fall within the purview of the invention. The source of light may be any conventional monochromatic (laser/LED) or polychromatic device 2270, and more than one light source with associated light guide can be used for color coding and providing a visual reference to different portions of the cannula 2220, depending on the colors of light used and

on the location of the projection terminus of the light guides. In this manner cannula 2220 can be visually guided through the patient's body, relying on the transmissivity of tissue to permit the location of the illuminated cannula in the patient's body. As will be appreciated, the location of the cannula 2220 can also be determined by examining the pressure waveform detected by the pressure transducers 2224, 2232 and 2254. The physiological pressure waveform recorded by the transducers can be used to determine the location of cannula 2220 in relation to the valves of the patient's heart.

[00231] As will be appreciated by those skilled in the art, cannula 2220 may be provided with one or more preformed curves along its length to aid in its manipulation through the patient's vasculature. Multiple curves may be disposed along the same plane or in different planes, depending on the application.

[00232] An additional feature in accordance with the invention is the use of radiopaque markings (not shown) anywhere along the cannula body. Such markings render portions of the cannula 2220 visible to x-ray radiation for visualizing the cannula during its use.

[00233] The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to those skilled in the art that modifications thereto can be made without departure from the spirit and scope of the invention. It will also be apparent that all devices and methods herein disclosed will adapt equally to animal use as well as human use.

ABSTRACT OF APPENDIX B

[00234] A cannula is provided with one or more pressure transducers for measuring fluid pressure interiorly or exteriorly of the cannula. The pressure transducers may be mounted integrally with the tubular wall defining the main lumen of the cannula, or they may comprise differential pressure transducers mounted in dedicated lumens in communication with the main lumen. The pressure measurements from the transducers is used to determine fluid flow rate.

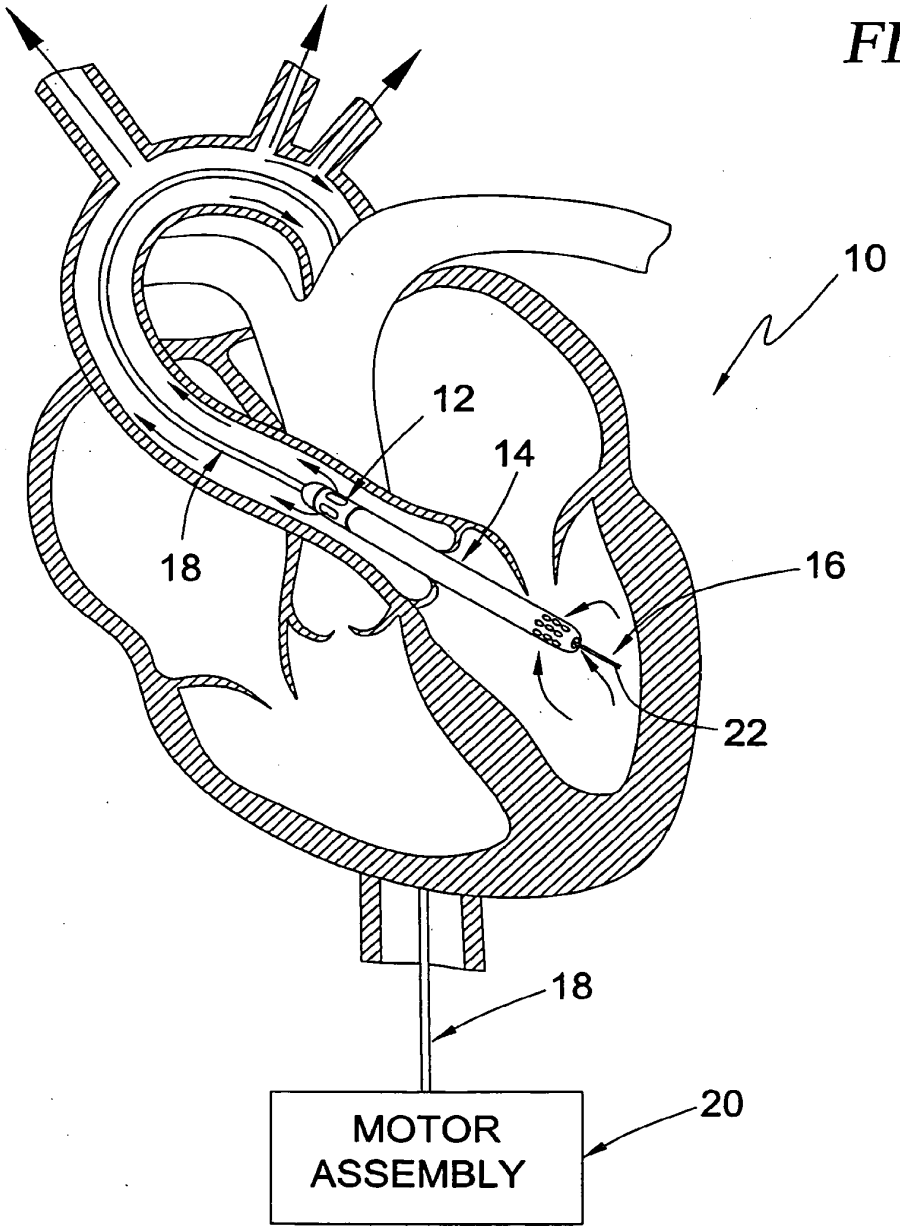
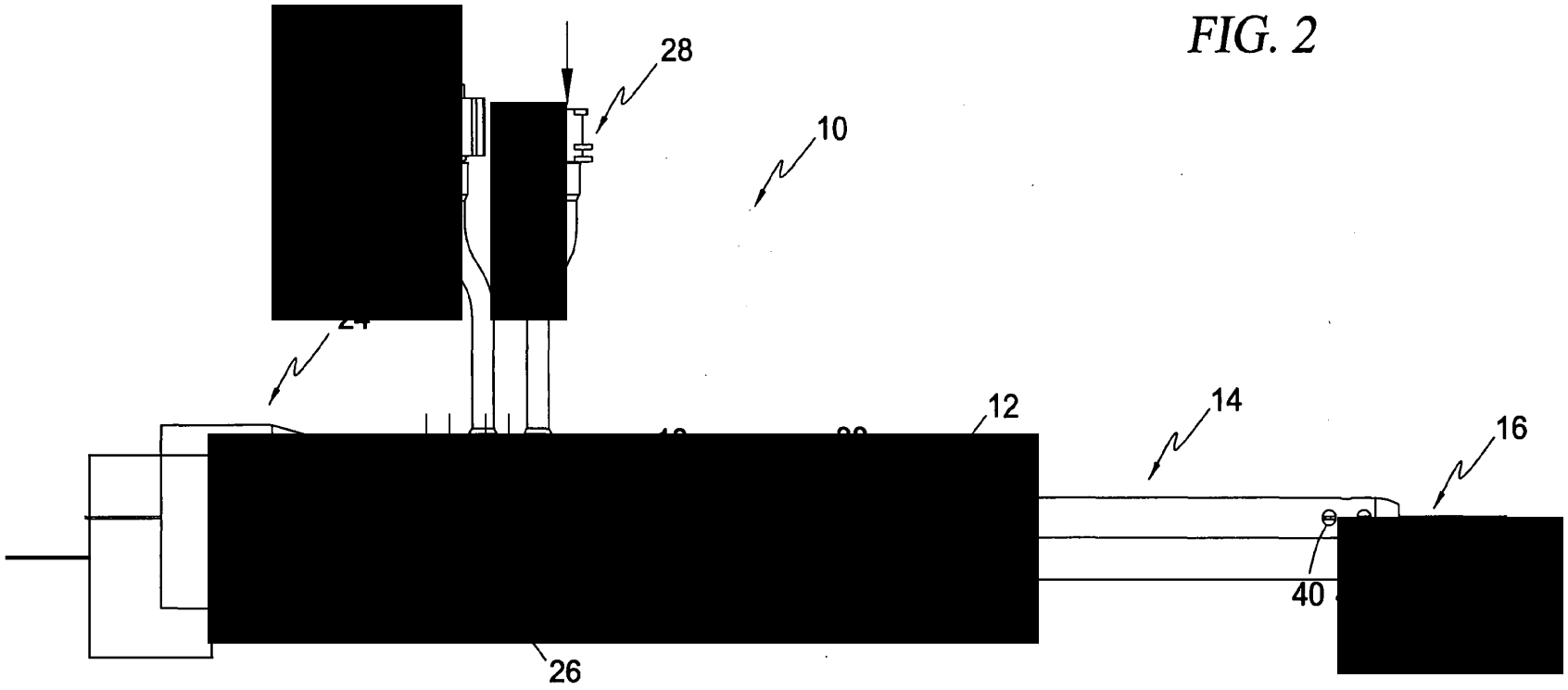


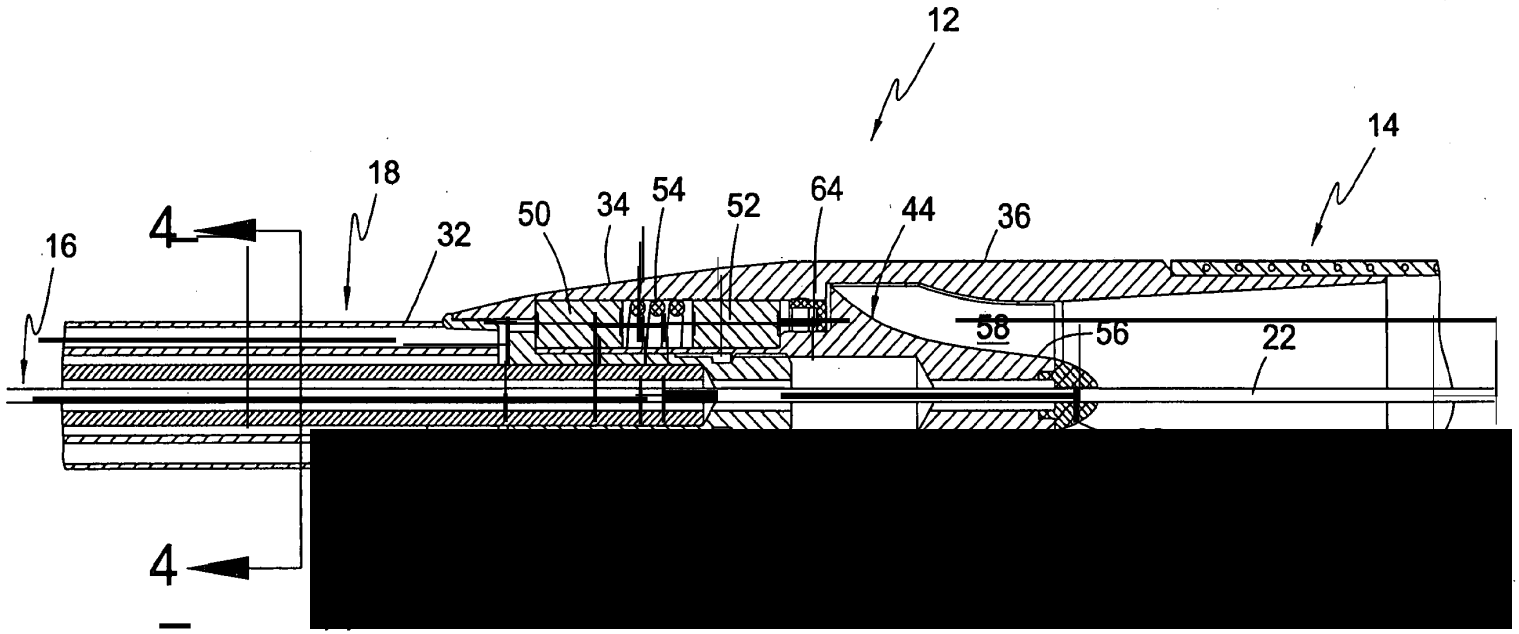
FIG. 1

FIG. 2



REPLACEMENT SHEET

FIG. 3



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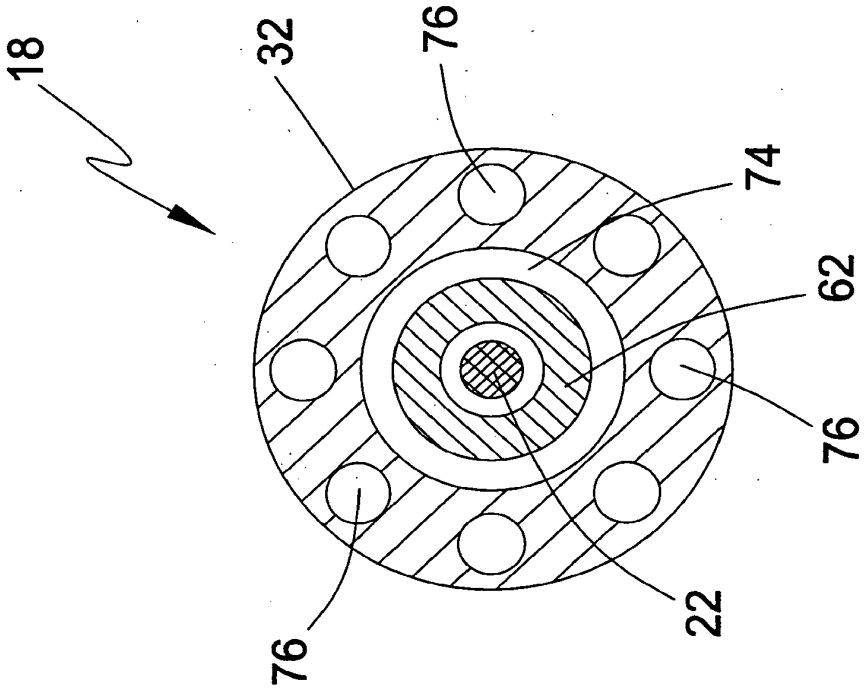

FIG. 4

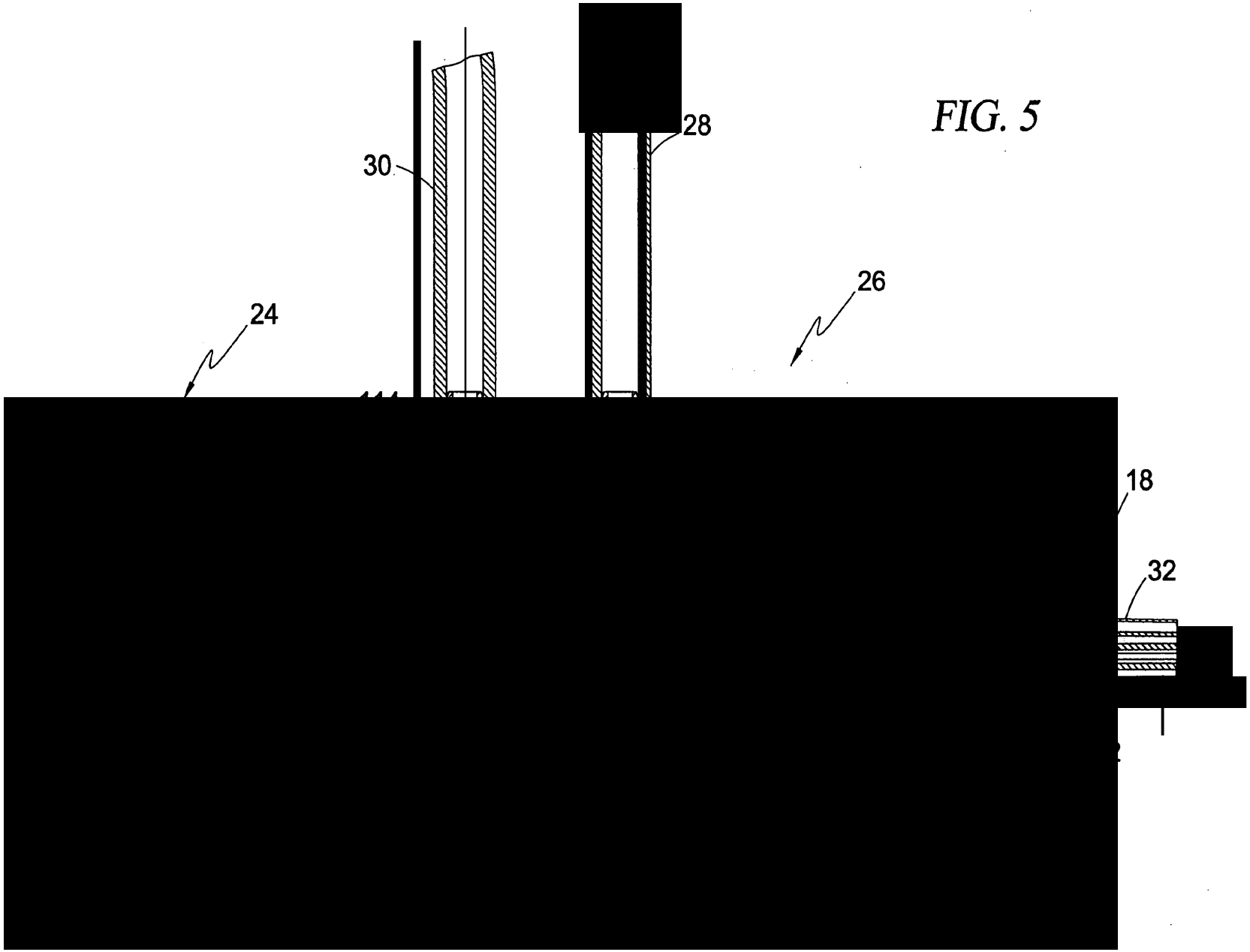

FIG. 5

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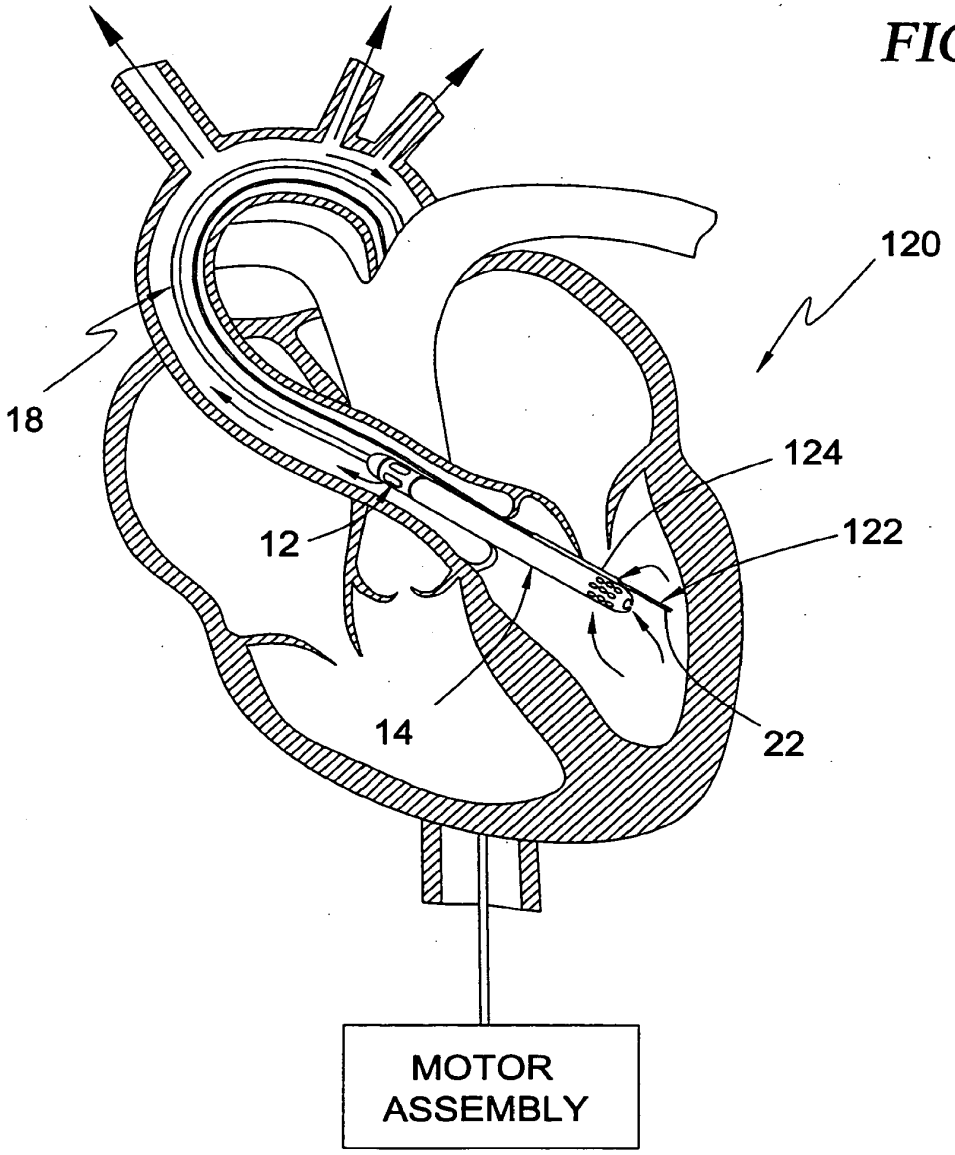
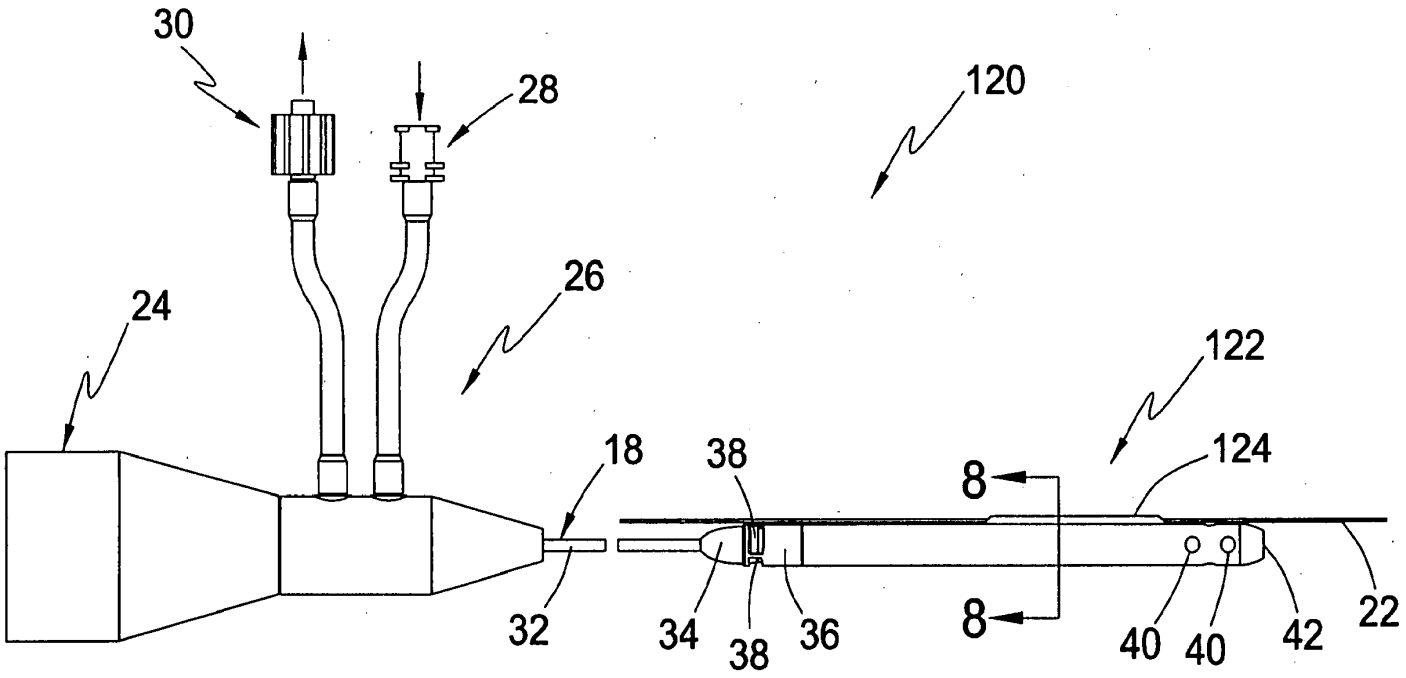


FIG. 6

FIG. 7



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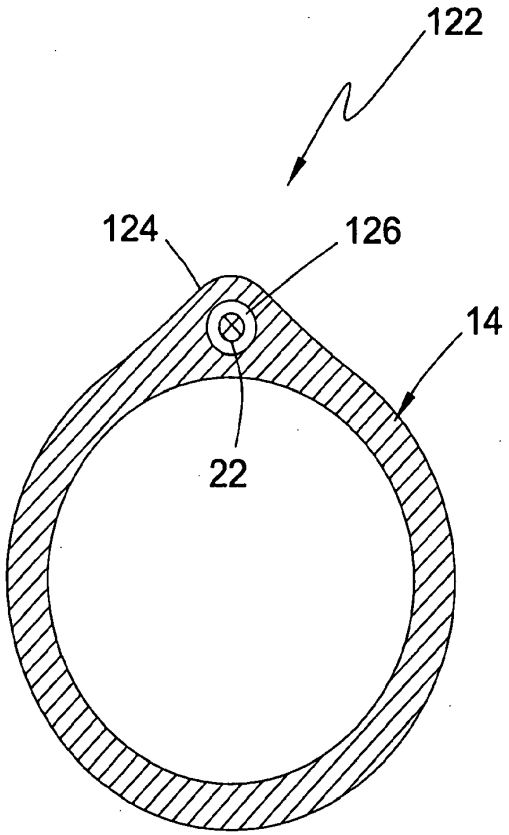

FIG 8

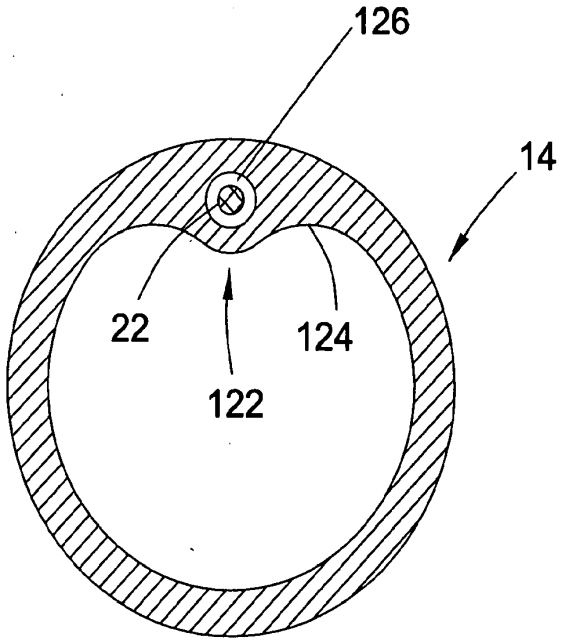

FIG 9

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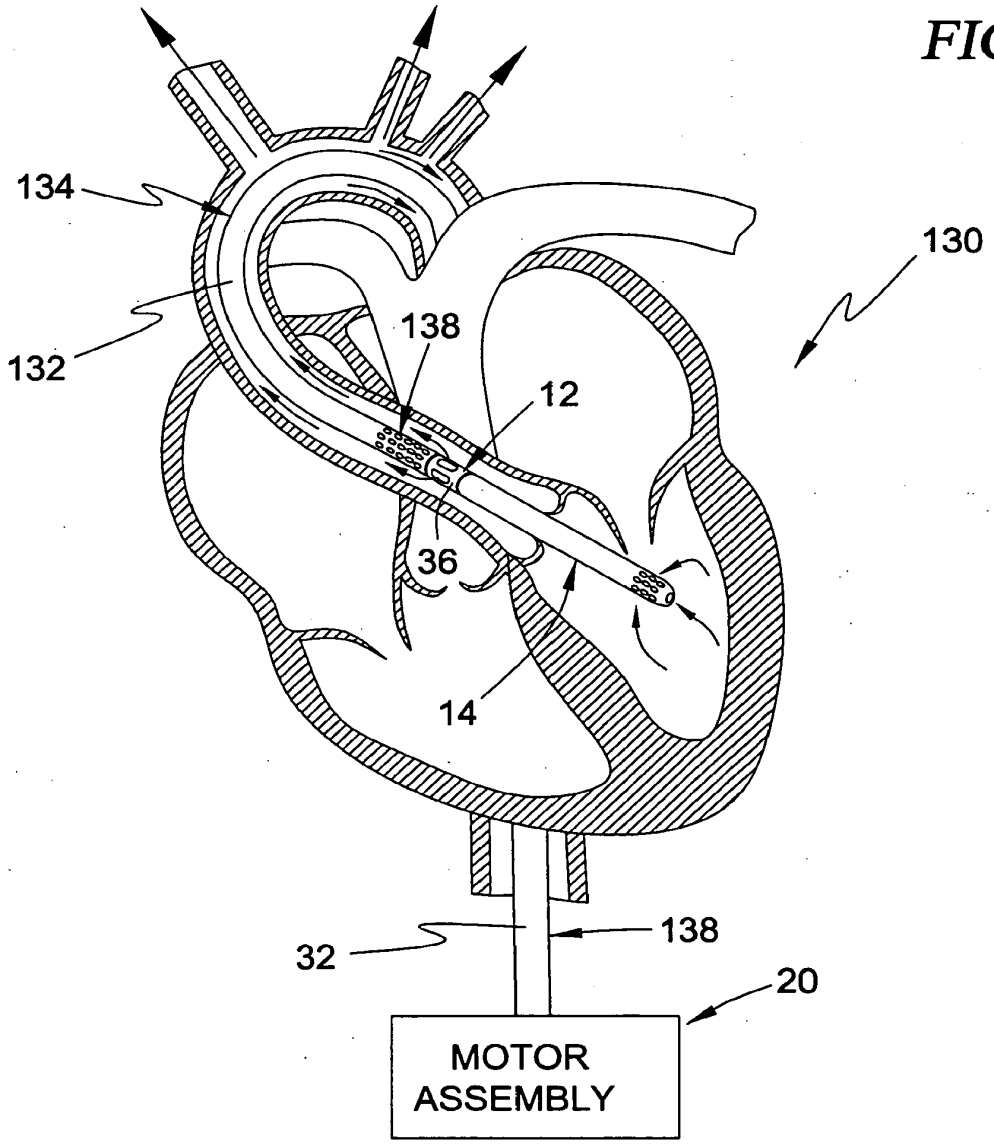

FIG. 10

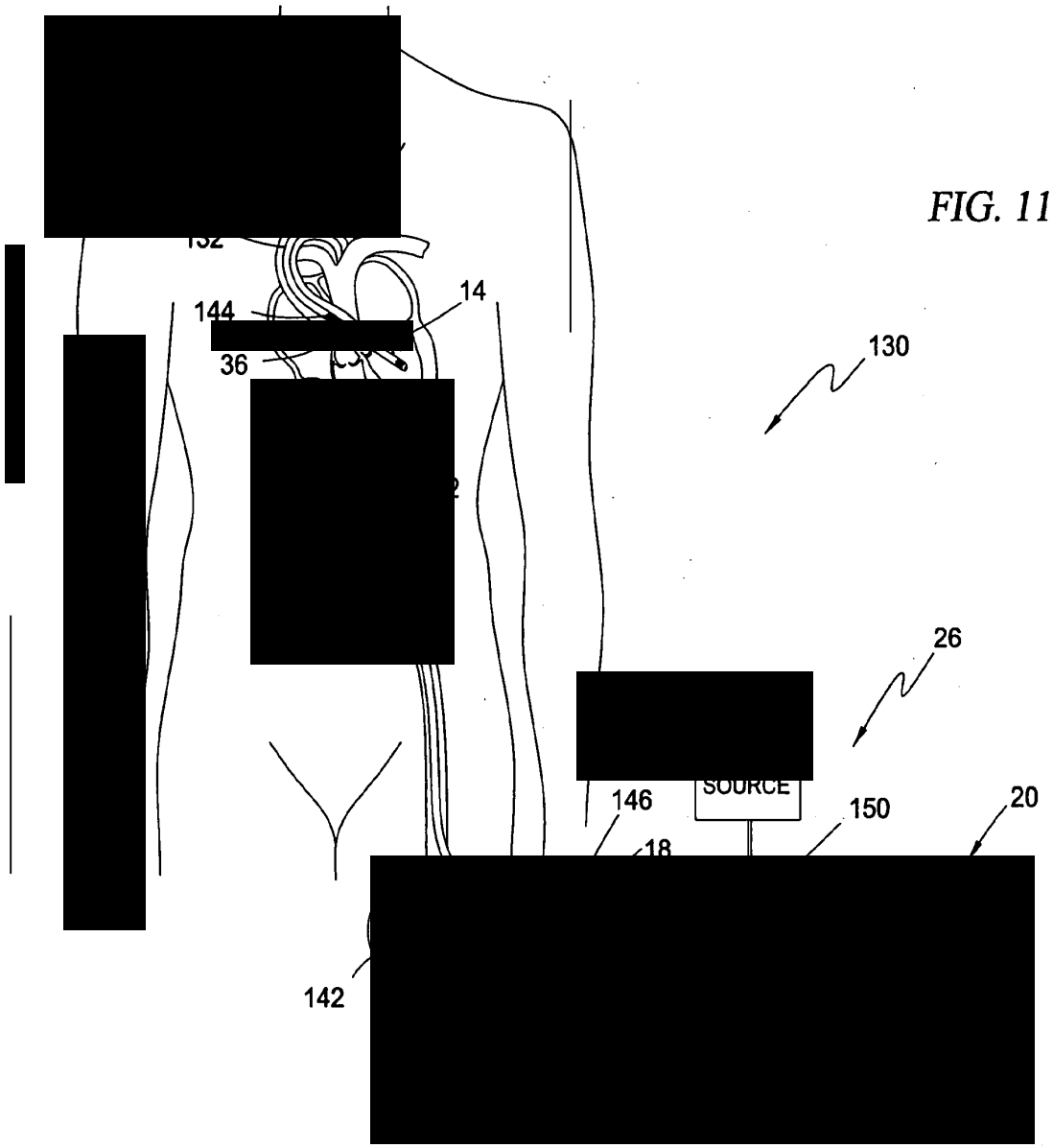

FIG. 11

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FIG. 12

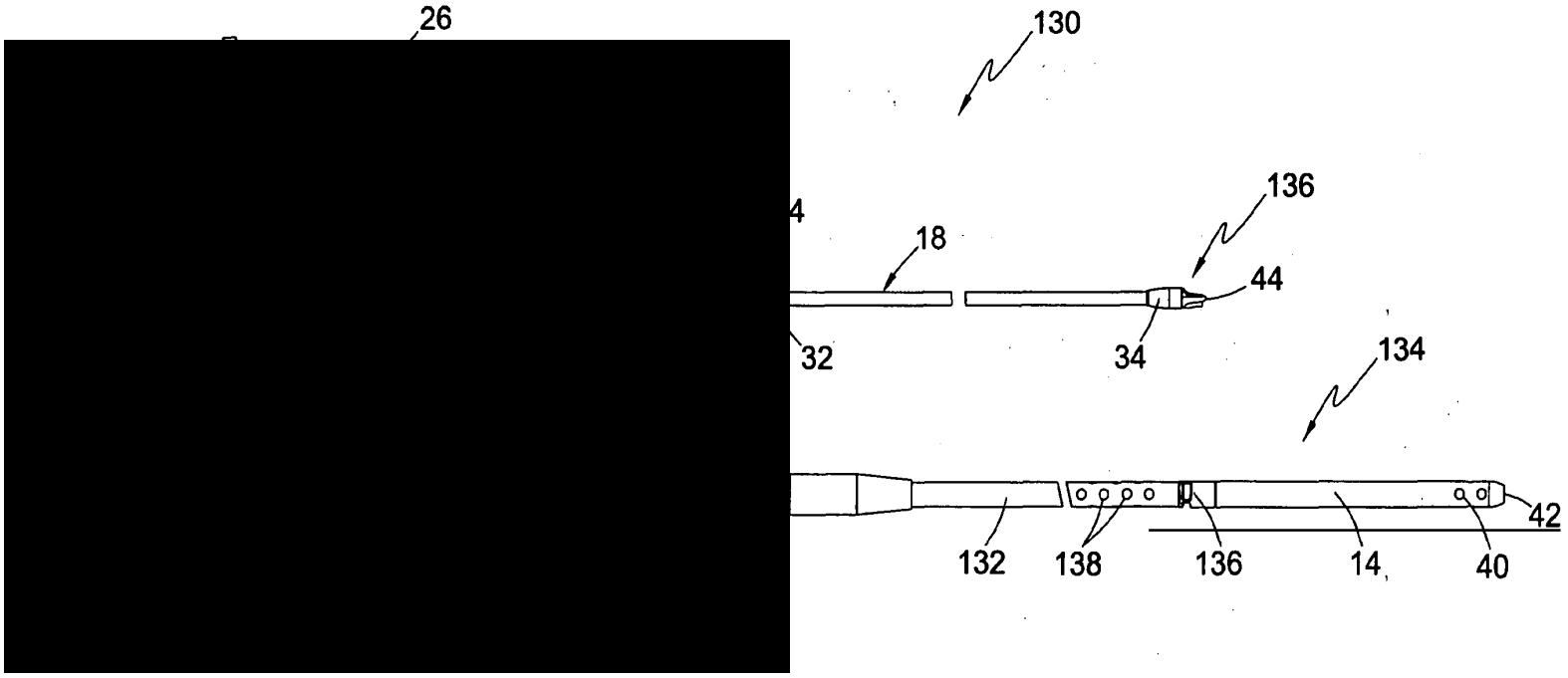

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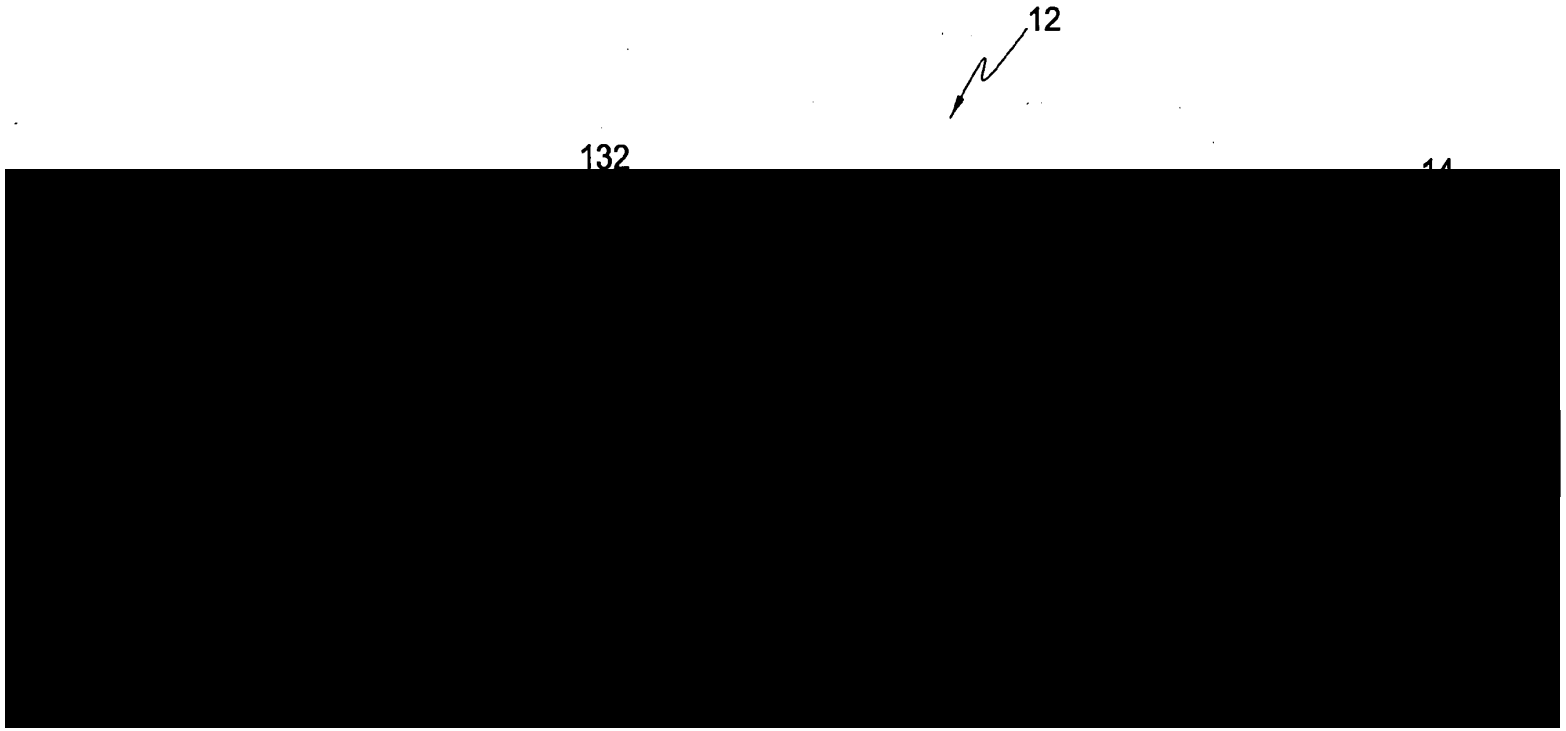
FIG 13

REPLACEMENT SHEET

FIG. 14



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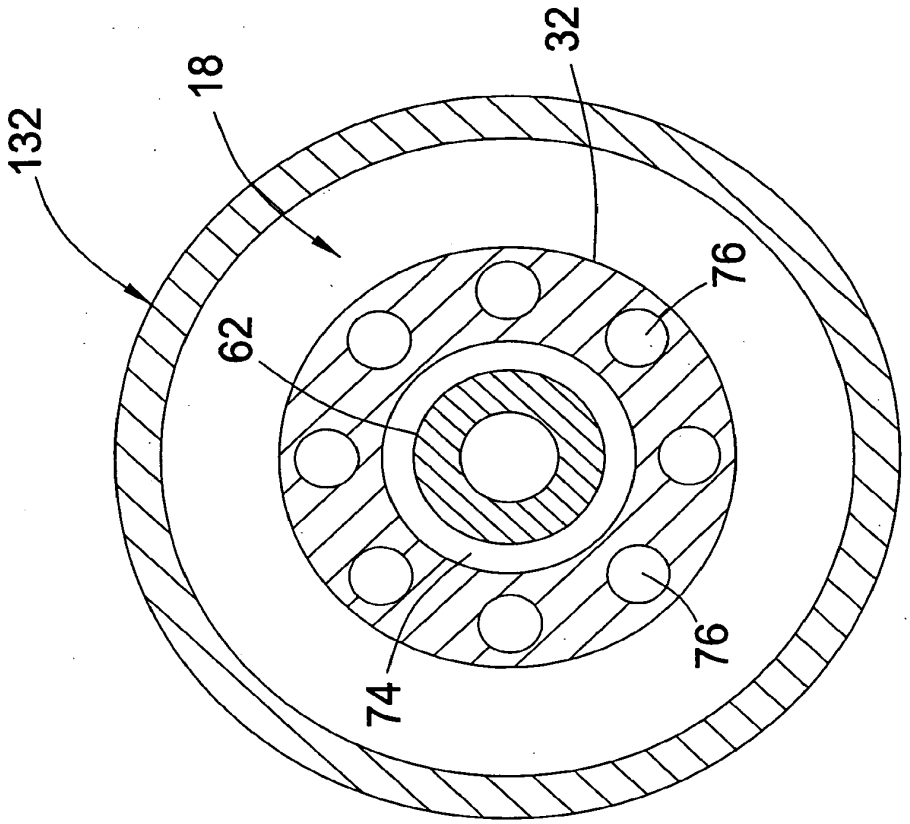

FIG. 15

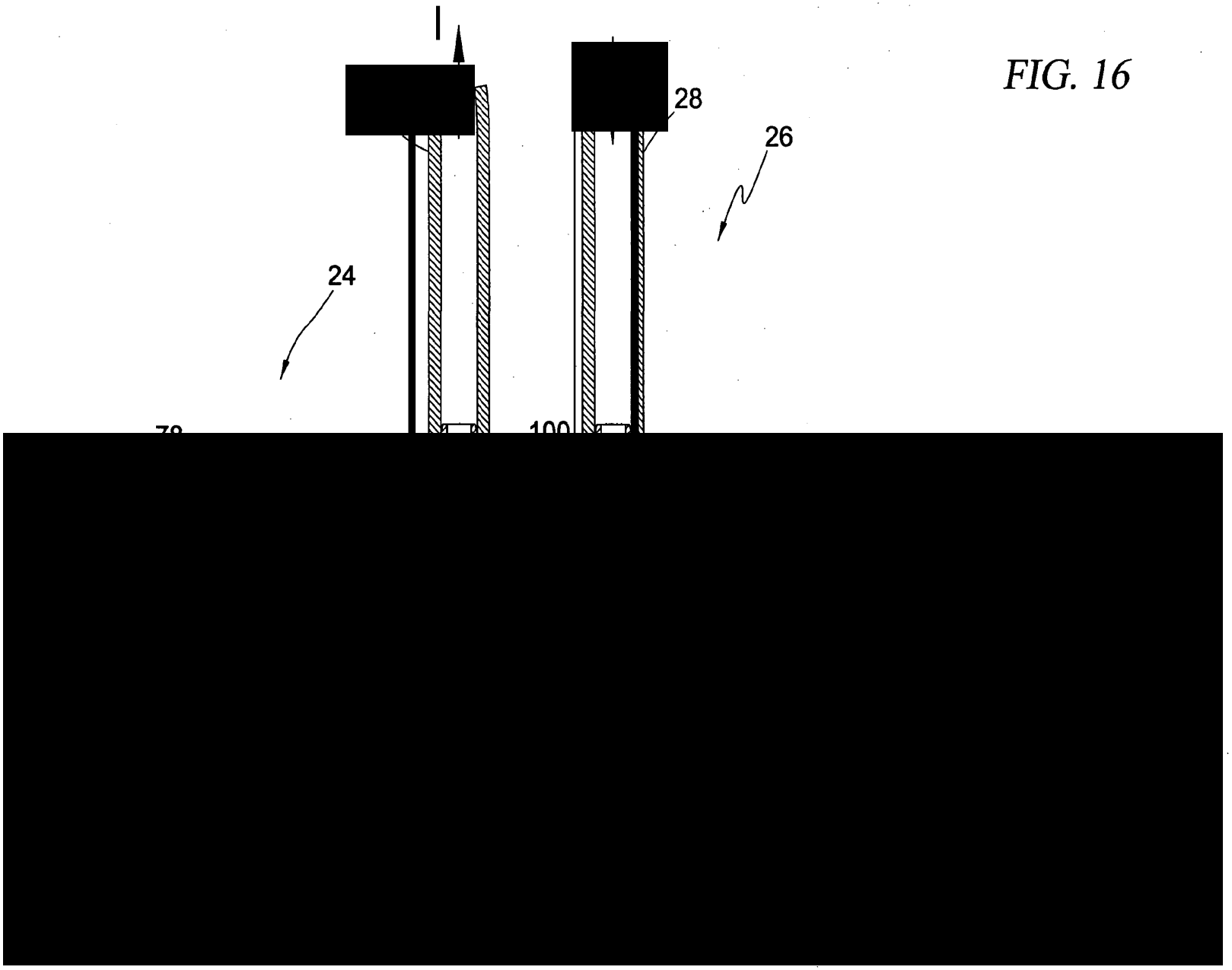

FIG. 16

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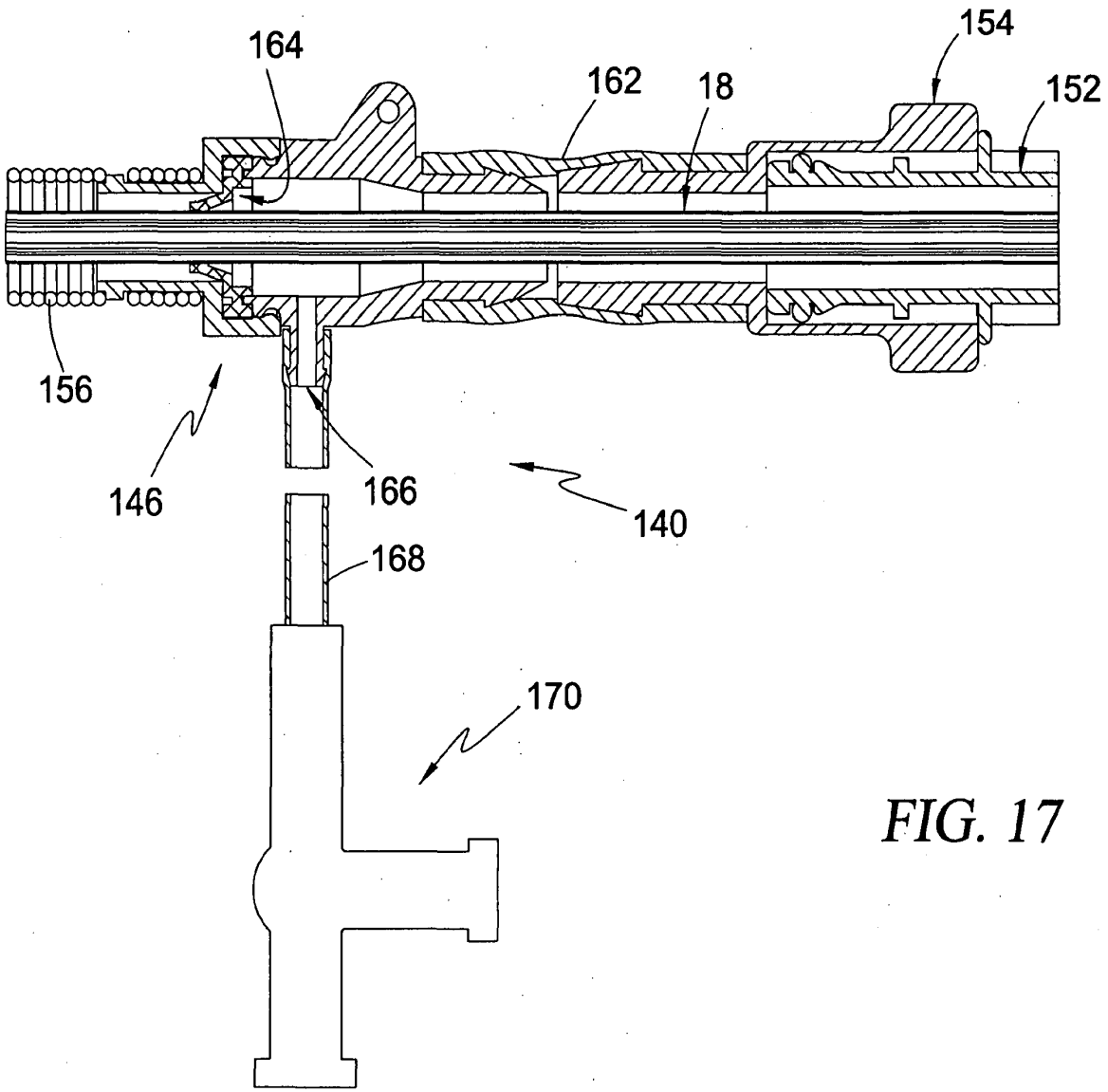

FIG. 17

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FIG. 18

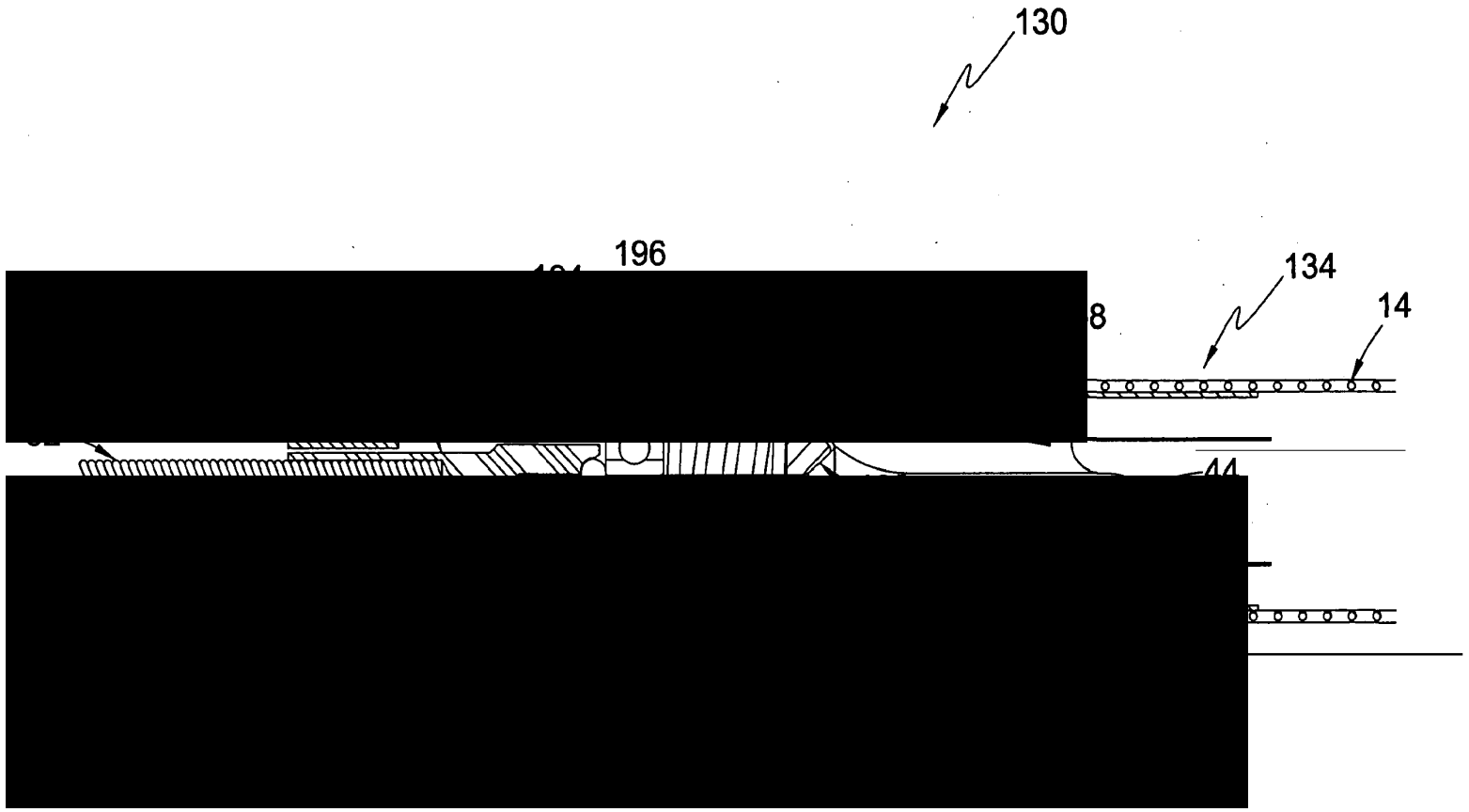

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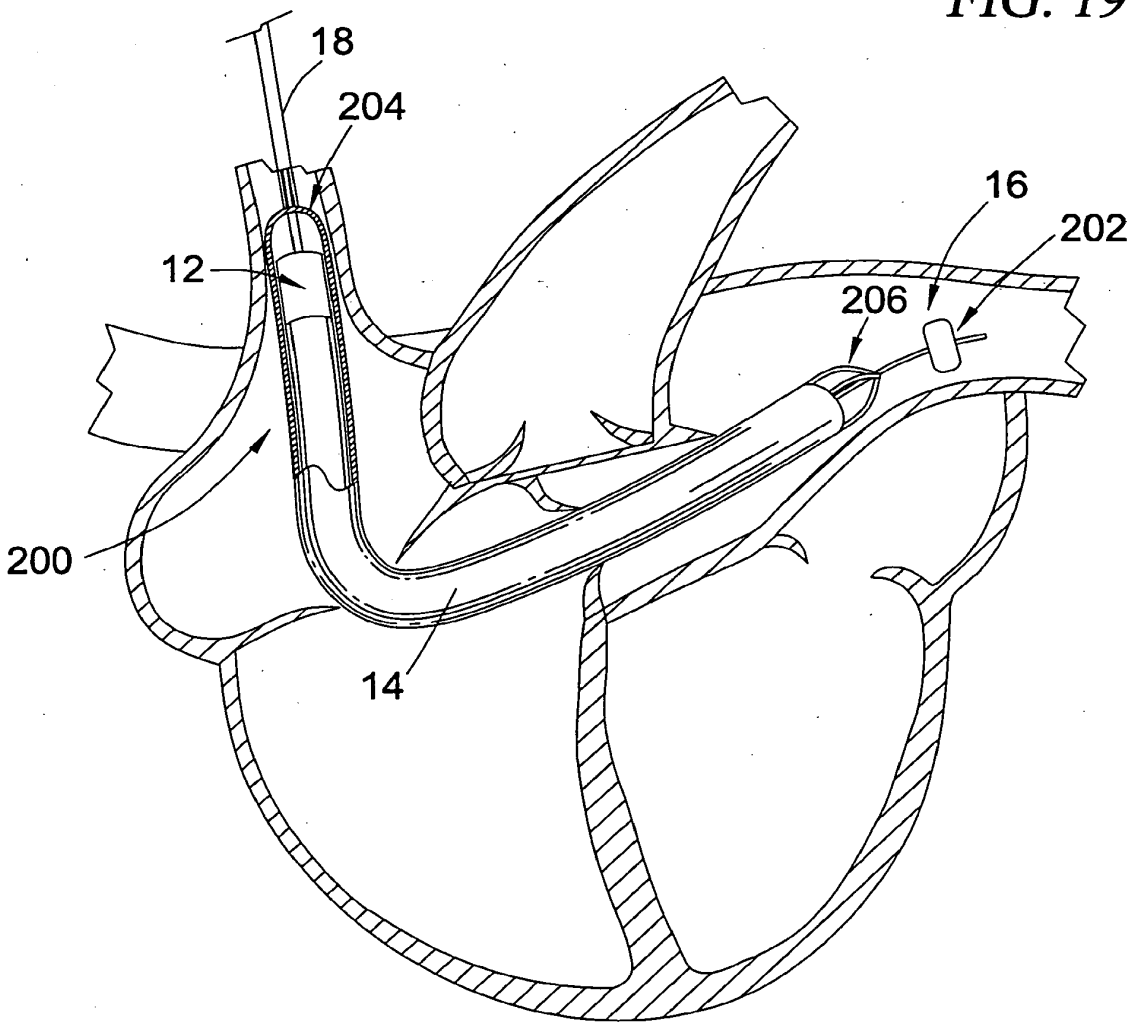
FIG. 19



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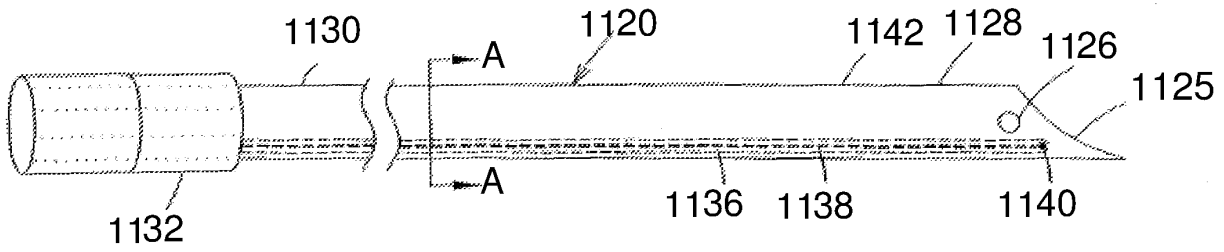


Figure 20

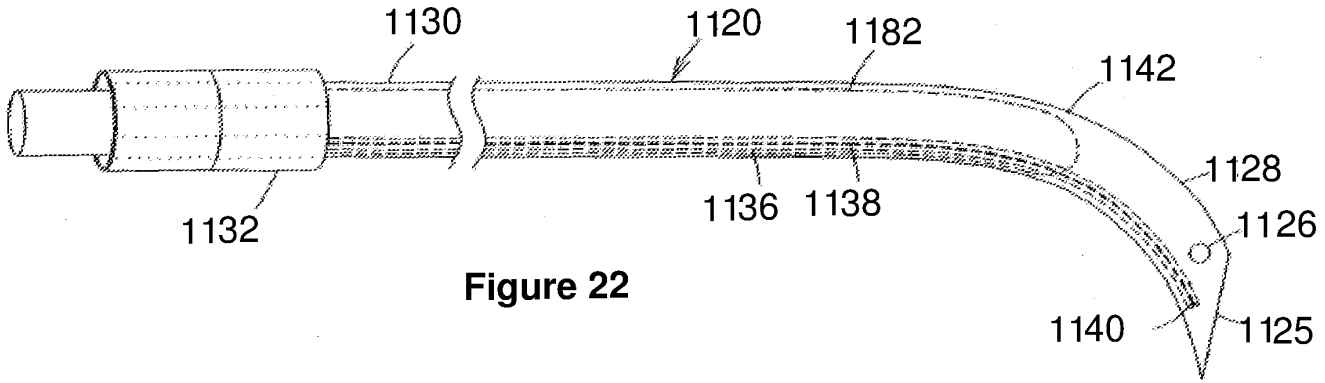


Figure 22

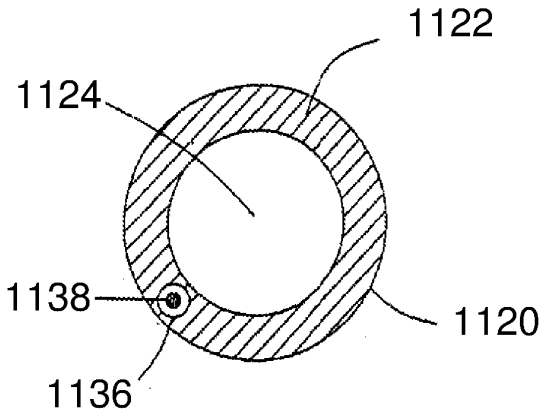


Figure 21

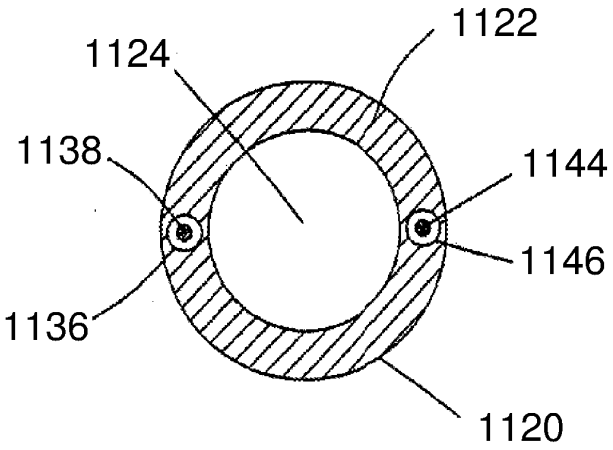


Figure 23

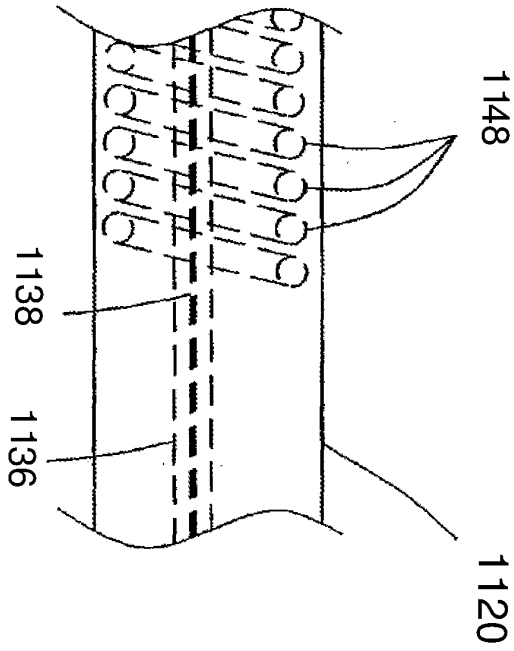


Figure 24

REPLACEMENT SHEET

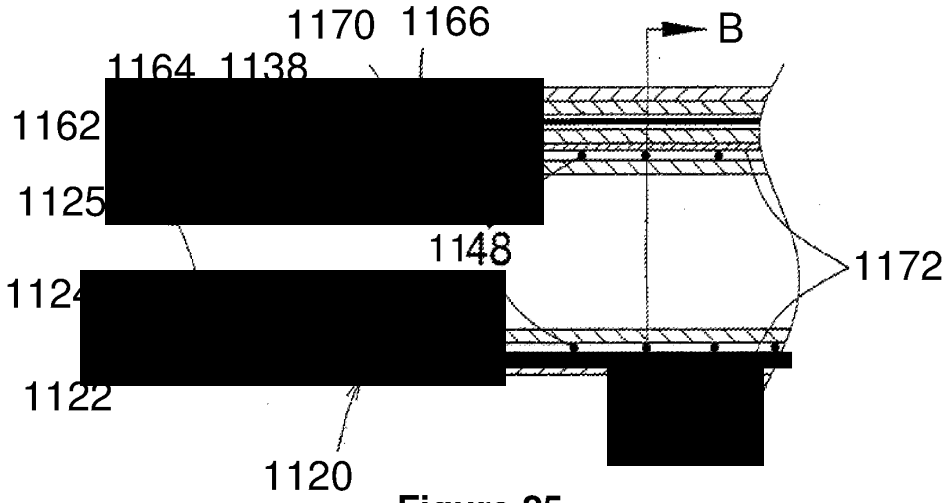


Figure 25

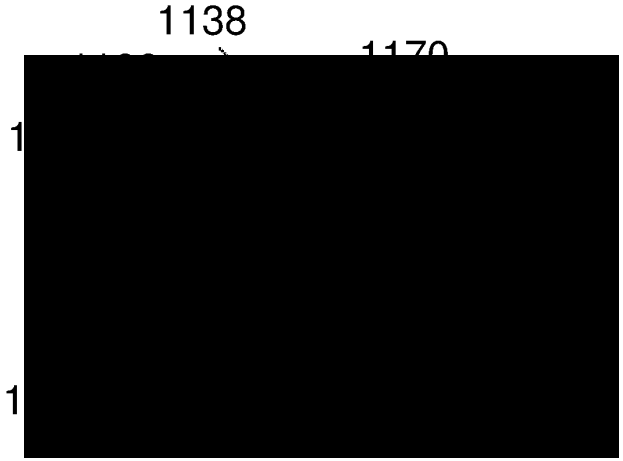


Figure 26

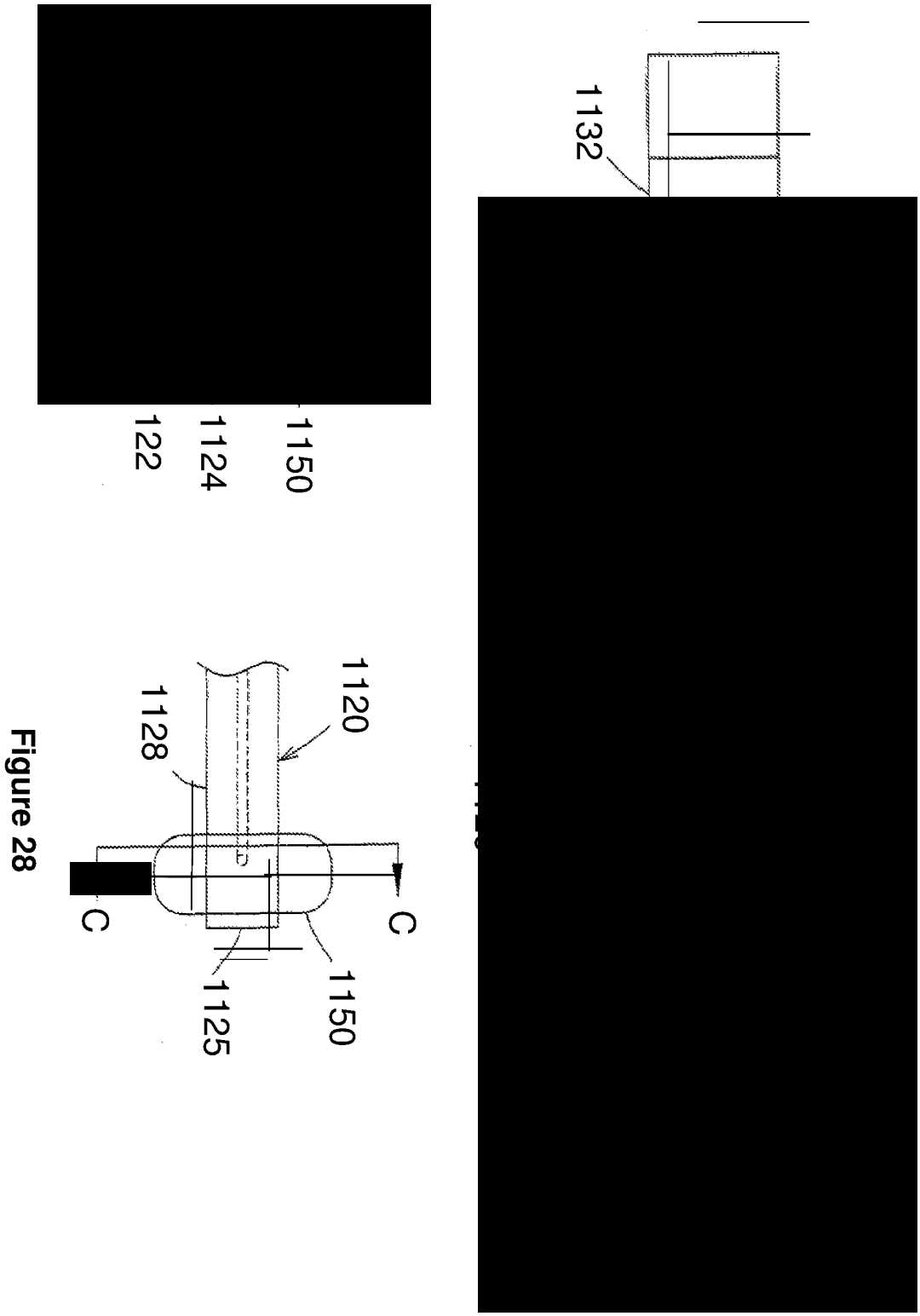


Figure 28

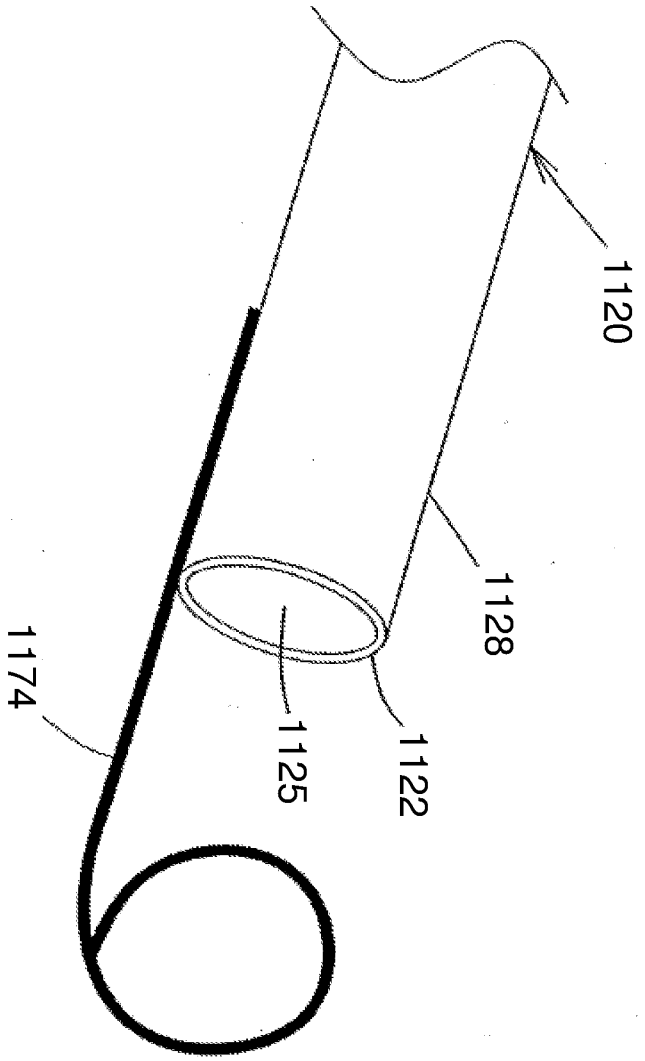


Figure 30

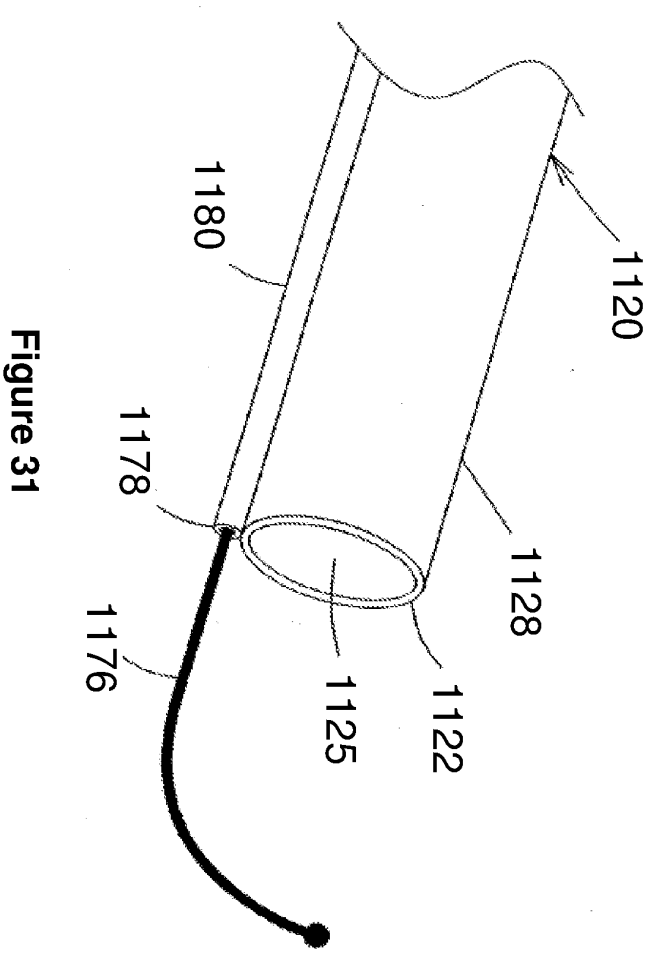


Figure 31

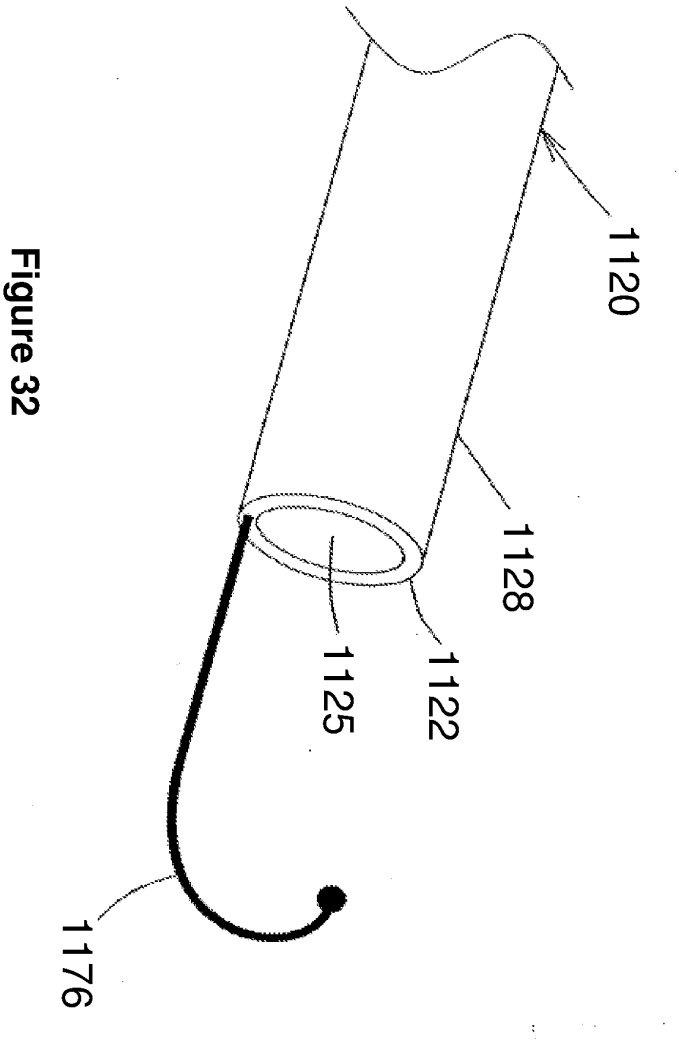


Figure 32

REPLACEMENT SHEET

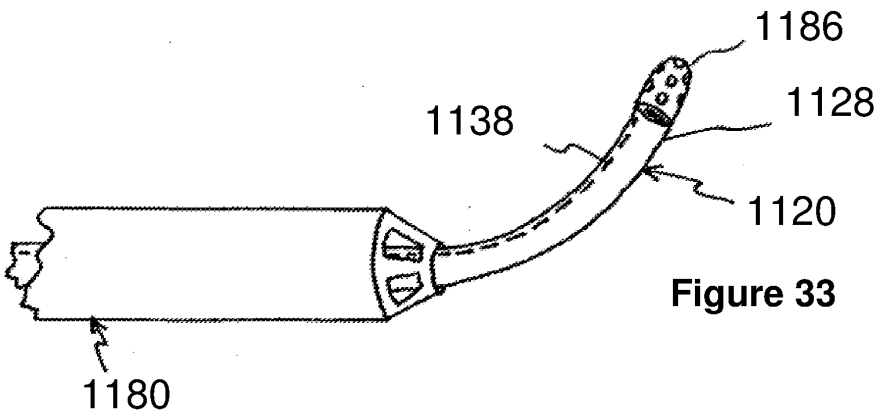


Figure 33

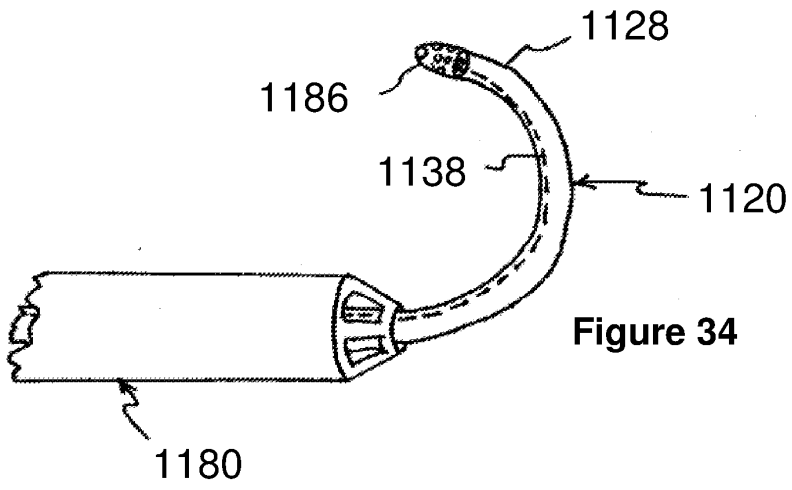


Figure 34

REPLACEMENT SHEET

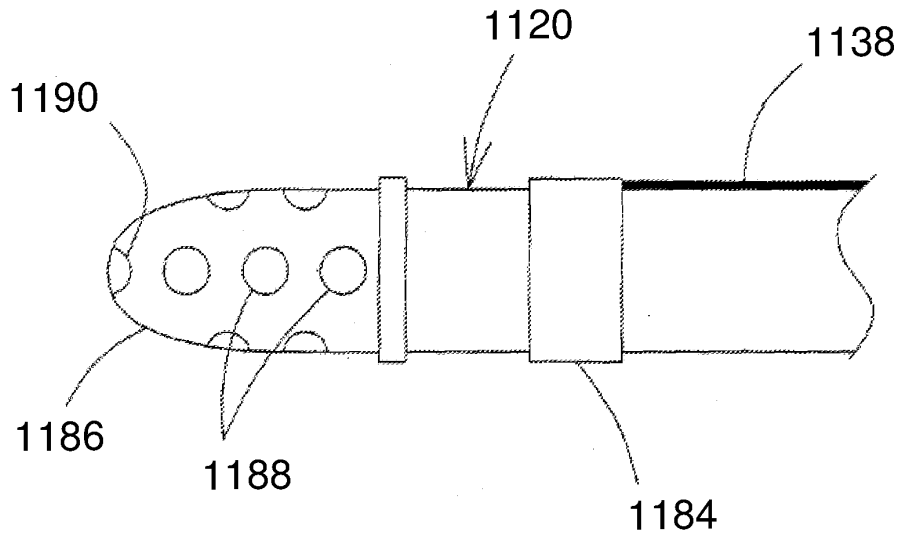


Figure 35

REPLACEMENT SHEET

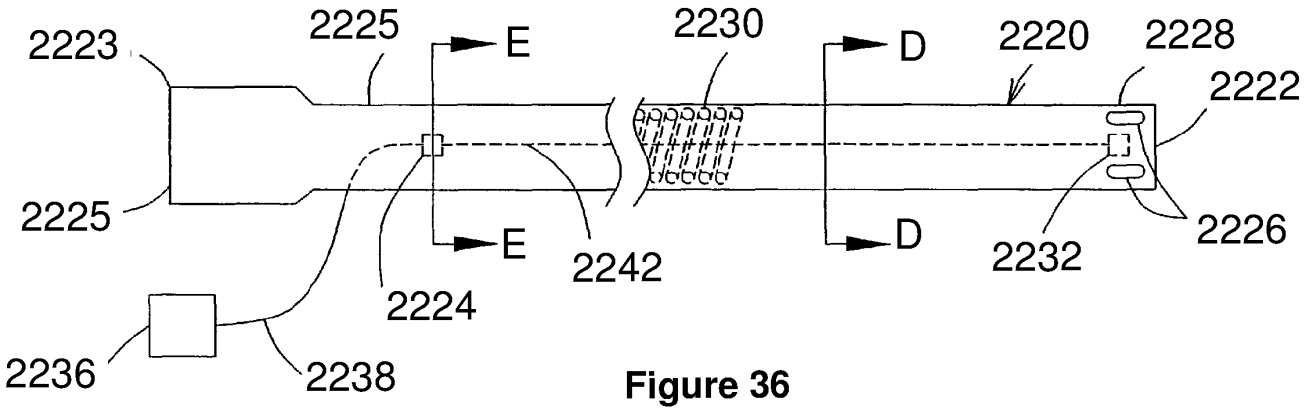


Figure 36

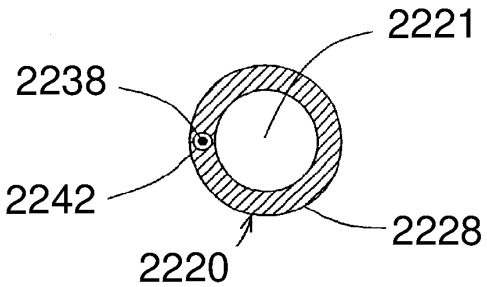


Figure 37

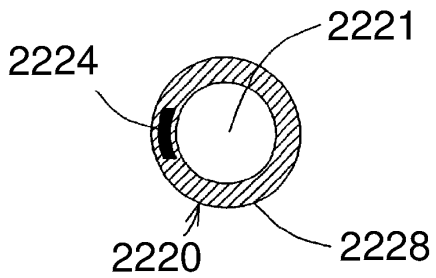


Figure 38

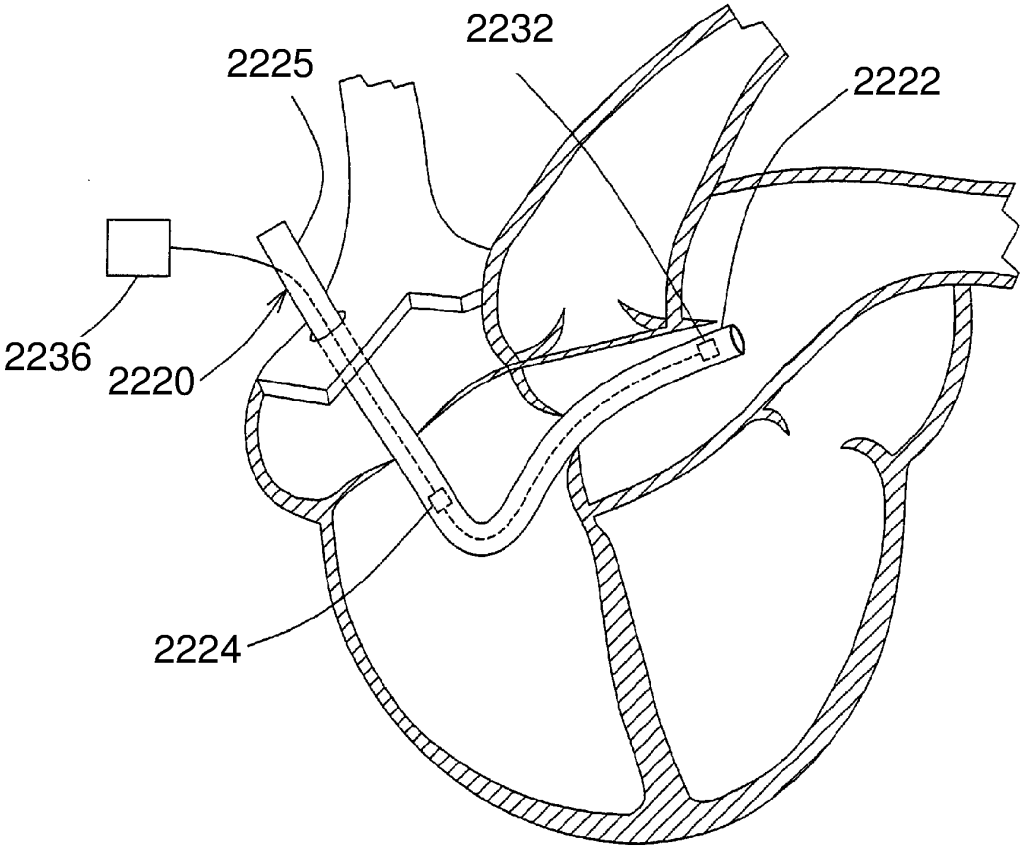


Figure 39

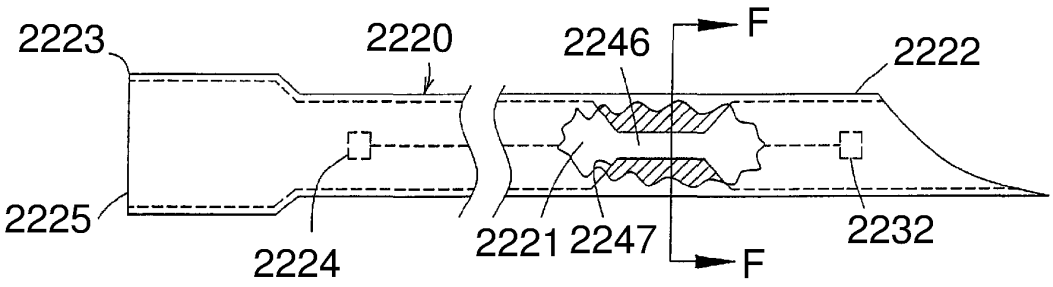


Figure 40

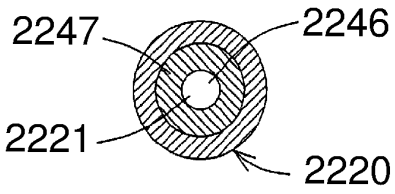


Figure 41

REPLACEMENT SHEET

Figure 42

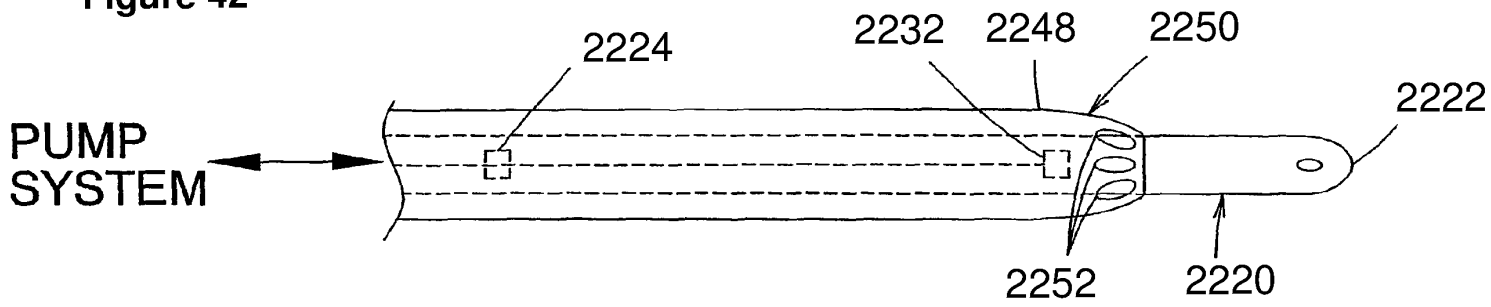
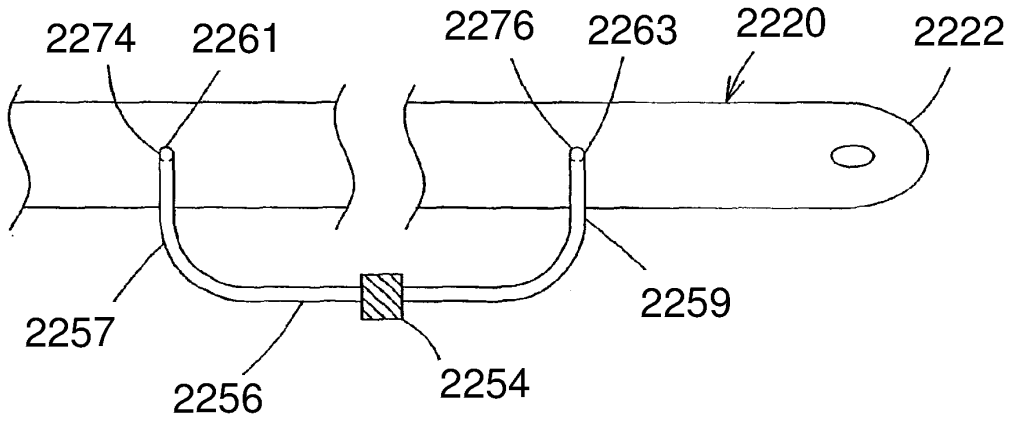


Figure 43



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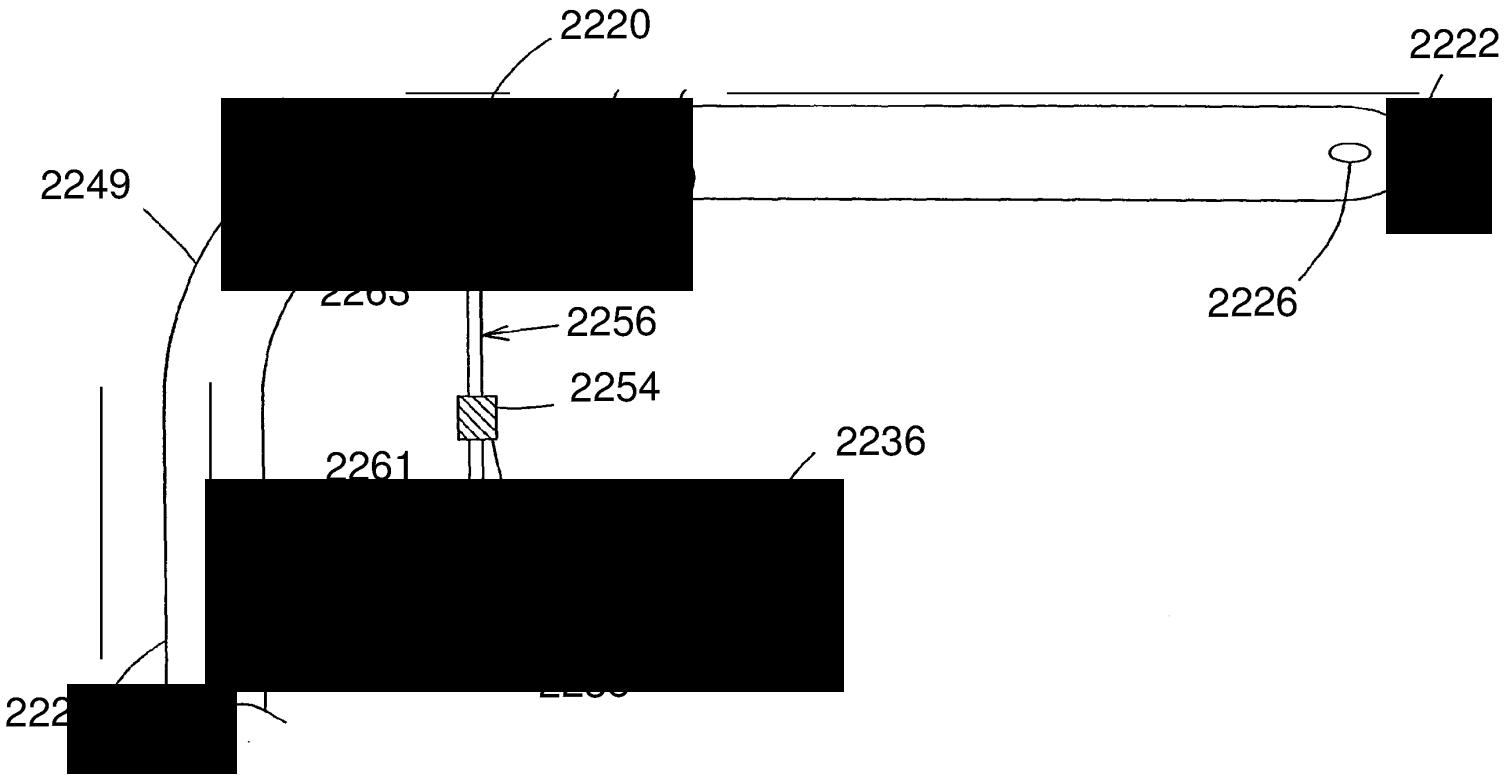


Figure 44

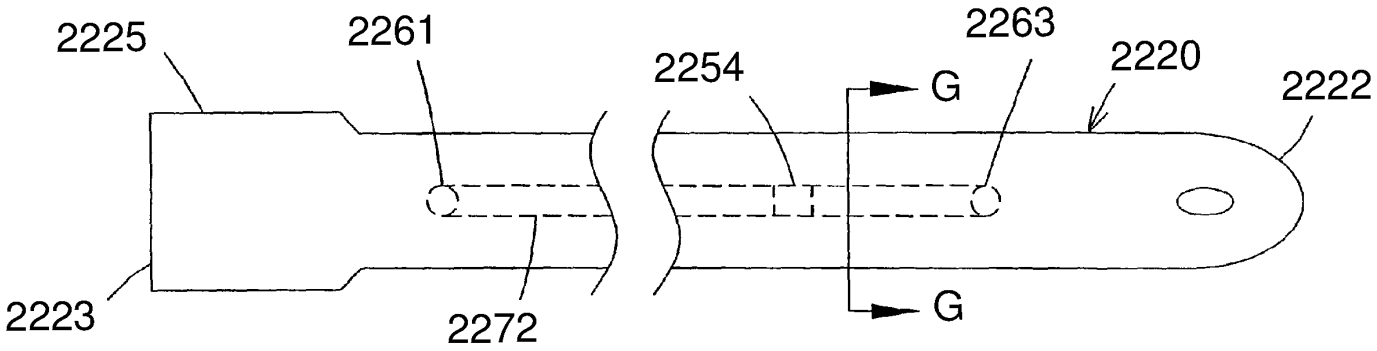


Figure 45

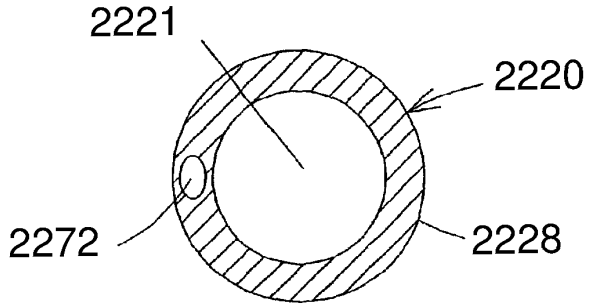


Figure 46

REPLACEMENT SHEET

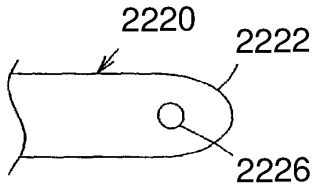
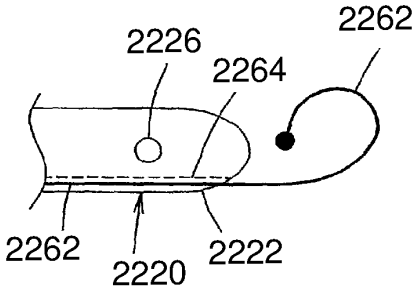


Figure 47



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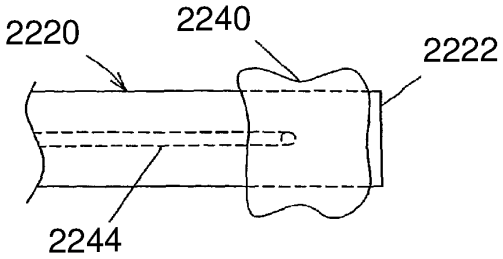

Figure 48

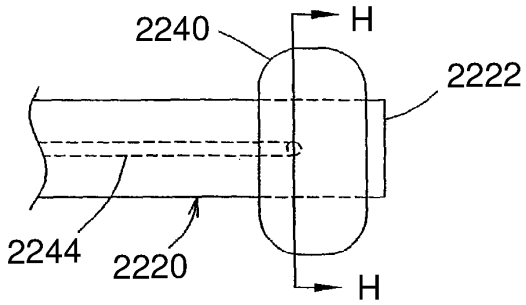

Figure 49

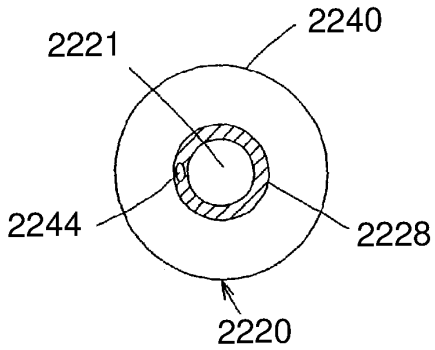

Figure 50

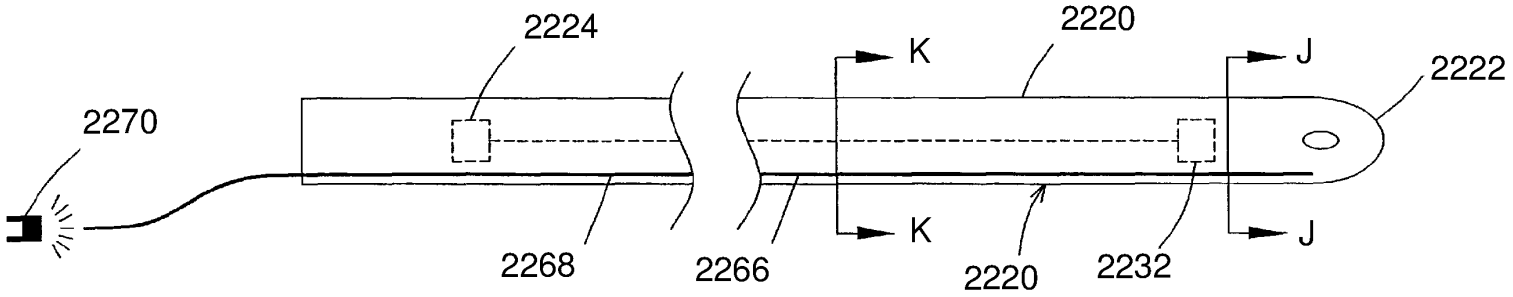

Figure 52

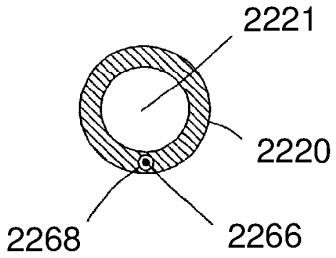

Figure 53

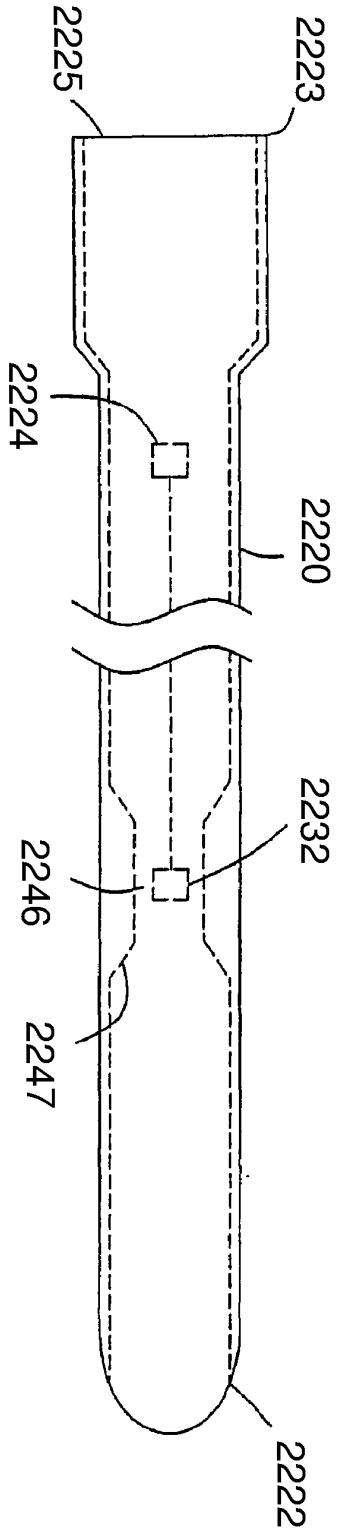

Figure 54

Electronic Acknowledgement Receipt

EFS ID:	27940332
Application Number:	15239574
International Application Number:	
Confirmation Number:	1024
Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
Customer Number:	99185
Filer:	Wesley Scott Ashton
Filer Authorized By:	
Attorney Docket Number:	06-01506US07
Receipt Date:	30-DEC-2016
Filing Date:	17-AUG-2016
Time Stamp:	14:26:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment after Notice of Allowance (Rule 312)	2016-12-30_Rule312Amendment_US07.pdf	51033 a2dcb981c40e7746301af6a9bdf97f38765e2dc4	no	5

Warnings:

Information:					
2	Specification	SubstituteSpec.pdf	2815015 98cbee62e8f4a1ce50a7bce2ff8d84fefe0f84c1	no	51
Warnings:					
Information:					
3	Drawings-only black and white line drawings	ReplacementDrawings.pdf	743850 2f1d7d3b455c723dd6a0e404cd6db221d85fbc13	no	37
Warnings:					
Information:					
		Total Files Size (in bytes):	3609898		

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<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.

<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.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	*Complete If Known*	
	Attorney Docket	06-01506US07
	Confirmation No.	5519
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	15/239,574
	Filing Date	08-17-2016
	Group Art Unit	3739
	Examiner Name	Not Yet Assigned
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 4 of 5		

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No. (B1, B2, ...Bn)	Publication Number	Kind Code [1]	Publication Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
Change(s) applied to document, /S.J.W./ 12/9/2016	B1	20010027287	A1	2001-10-04	~~Trans Vascular Inc.~~	Shmulewitz et al.
	B2	20030088151	A1	2003-05-08	Kung et al.	
	B3	20030100816	A1	2003-05-29	Siess, Thorsten	
	B4	20030187322	A1	2003-10-02	Siess, Thorsten	
	B5	20040097995	A1	2004-05-20	Nash et al.	
	B6	20050049696	A1	2005-03-03	Siess et al.	
	B7	20090024212	A1	2009-01-22	Siess et al.	
	B8	20130304158	A1	2013-11-14	Zarinetchi et al.	

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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Doc description: Information Disclosure Statement (IDS)

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	Attorney Docket	06-01506US07
	Confirmation No.	5519
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	15/239,574
	Filing Date	08-17-2016
	Group Art Unit	3739
	Examiner Name	Not Yet Assigned
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 3 of 5		

	A21	6197001	B1	2001-03-06	~~Becton Dickinson and~~ Company	Wilson , et al.
	A22	6248091	B1	2001-06-19	Voelker, Wolfram	
	A23	6290689	B1	2001-09-18	~~Corazón Technologies~~ Inc.	Delaney , et al.
	A24	6354814	B1	2002-03-12	Kaufmann et al.	
	A25	6544216	B1	2003-04-08	~~Impella Cardiotechnik~~ Aktiengesellschaft	Sammler , et al.
	A26	6572530	B1	2003-06-03	~~JMS Co. Ltd.~~	Araki , et al.
	A27	6592567	B1	2003-07-15	~~CHF Solutions Inc.~~	Levin , et al.
	A28	6673040	B1	2004-01-06	~~Cardeon Corporation~~	Samson , et al.
	A29	6733459	B1	2004-05-11	~~Aisin Seiki Kabushiki~~ Kaisha	Atsumi
	A30	7517352	B2	2009-04-14	~~Bacchus Vascular Inc.~~	Evans , et al.
	A31	7998054	B2	2011-08-16	~~Thoratec Corporation~~	Bolling
	A32	8545447	B2	2013-10-01	Demarais et al.	
	A33	5921913	A	1999-07-13	Siess	

Change(s) applied to document, /S.J.W./ 12/9/2016

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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Doc description: Information Disclosure Statement (IDS)

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	Attorney Docket	06-01506US07
	Confirmation No.	5519
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	15/239,574
	Filing Date	08-17-2016
	Group Art Unit	3739
	Examiner Name	Not Yet Assigned
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 2 of 5		

	A9	5516336	A	1996-05-14	~~Advanced Cardiovascular Systems Inc.~~	McInnes, et al.
	A10	5697948	A	1997-12-16	~~Endovascular Systems Inc.~~	Marin, et al.
	A11	5746575	A	1998-05-05	~~Baxter International Inc.~~	Westphal, et al.
	A12	5824070	A	1998-10-20	Jarvik, Robert	
	A13	5851174	A	1998-12-22	Jarvik Robert	
	A14	5911702	A	1999-06-15	~~Heartport Inc.~~	Romley, et al.
	A15	6007478	A	1999-12-28	~~Impella Cardiotechnik Aktiengesellschaft~~	Siess, et al.
	A16	6071093	A	2000-06-06	~~Abiomed Inc.~~	Hart
	A17	6116862	A	2000-09-12	~~MEDOS Medizintechnik GmbH~~	Rau, et al.
	A18	6136025	A	2000-10-24	Barbut et al.	
	A19	6146354	A	2000-11-14	~~Horizon Medical Products~~	Beil
	A20	6176848	B1	2001-01-23	~~Impella Cardiotechnik GmbH~~	Rau, et al.

Change(s) applied to document, /S.J.W./ 12/9/2016

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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	Attorney Docket	06-01506US07
	Confirmation No.	5519
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	15/239,574
	Filing Date	08-17-2016
	Group Art Unit	3739
	Examiner Name	Not Yet Assigned
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 1 of 5		

U.S. PATENTS

Examiner Initial*	Cite No. (A1, A2, ...An)	Patent Number	Kind Code[1]	Issue Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	A1	4769005	A	1988-09-06	Ginsburg et al.	
	A2	4846152	A	1989-07-11	~~Nimbus Medical Inc.~~	Wampler, et al.
	A3	4944722	A	1990-07-31	~~Nimbus Medical Inc.~~	Carriker, et al.
Change(s) applied to document, /S.J.W./ 12/9/2016	A4	5092879	A	1992-03-03	Jarvik, Robert K.	
	A5	5106363	A	1992-04-21	~~Terumo Kabushiki Kaisha~~	Nobuyoshi
	A6	5108411	A	1992-04-28	~~Cardiovascular Imaging Systems Inc.~~	McKenzie
	A7	5137513	A	1992-08-11	~~Advanced Cardiovoascular Systems Inc.~~	McInnes, et al.
	A8	5334142	A	1994-08-02	~~New York University~~	Paradis

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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	Attorney Docket	06-01506US07
	Confirmation No.	1024
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	15/239,574
	Filing Date	08-17-2016
	Group Art Unit	3739
	Examiner Name	Not yet assigned.
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 1 of 5		

U.S. PATENTS

Examiner Initial*	Cite No. (A1, A2, ...An)	Patent Number	Kind Code[1]	Issue Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
Change(s) applied to document, /S.J.W./ 12/9/2016	A1	3966358	A	1976-06-29	~~Medac Gesellschaft fur Klinische Spezialpraparate mbH~~	Heimes, et al.

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No. (B1, B2, ...Bn)	Publication Number	Kind Code [1]	Publication Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear

Examiner Signature	/Adam Marcetich/	Date Considered	10/28/2016

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Receipt date: 09/06/2016
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	15239574
Filing Date	2016-08-17
First Named Inventor	Walid N. Aboul-Hosn
Art Unit	3739
Examiner Name	Not Yet Assigned
Attorney Docket Number	06-01506US07

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Change(s) applied to document, /S.J.W./ 12/9/2016	1	20030065271	A1	2003-04-03	Khoury ~~Baylor College of Medicine~~	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	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	99/59652	WO	A1	1999-11-25	A-Med Systems, Inc.		
	2	99/58170	WO	A1	1999-11-18	Impella Cardiosystems Gmbh		
	3	0884064	EP	A2	1998-12-16	Schneider (Usa) Inc.		

EFS Web 2.1.17

All references considered except where lined through /AMM/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS)

Form Used In Lieu of PTO/SB/08a/b (01-10 version)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	*Complete If Known*	
	Application Number	15/239,574
	Filing Date	August 17, 2016
	First Named Inventor	Walid N. ABOUL-HOSN
	Art Unit	3739
	Examiner Name:	Not Yet Assigned
	Attorney Docket Number:	06-01506US07
	Confirmation Number	5519
Sheet 3 of 7		

	A35	6001078	A	12/14/1999	Reekers, Jan Albertus	
	A36	6129704	A	10/10/2000	Forman et al.	
	A37	6183220	B1	02 ~~12~~/6/2001	Ohara et al.	
	A38	6245007	B1	6/12/2001	Bedingham et al.	
	A39	6287319	B1	9/11/2001	Aboul-Hosn et al.	
	A40	6533716	B1	3/18/2003	Schmitz-Rode et al.	
	A41	6544216	B1	4/8/2003	Sammler et al.	
	A42					
	A43					
	A44					

Change(s) applied to document, /D.D./ 12/21/2016

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	B1	20070118072	A1	2007-05-24	Nash	

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Receipt date: 08/19/2016

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15/239,574
Filing Date	08-17-2016
First Named Inventor	Walid N. ABOUL-HOSN
Art Unit	3739
Examiner Name	Not Yet Assigned
Attorney Docket Number	06-01506US07

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS)

Form Used In Lieu of PTO/SB/08a/b (01-10 version)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	***Complete If Known***	
	Application Number	15/239,574
	Filing Date	August 17, 2016
	First Named Inventor	Walid N. ABOUL-HOSN
	Art Unit	3739
	Examiner Name:	Not Yet Assigned
	Attorney Docket Number:	06-01506US07
	Confirmation Number	5519
Sheet 2 of 7		

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Change(s) applied to document,
/D.D./
12/21/2016

Examiner Signature	/Adam Marcetich/	**Date Considered**	10/28/2016

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] 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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15/239,574
Filing Date	08-17-2016
First Named Inventor	Walid N. ABOUL-HOSN
Art Unit	3739
Examiner Name	Not Yet Assigned
Attorney Docket Number	06-01506US07

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Change(s) applied to document,
/D.D./
12/21/2016

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/239,574	08/17/2016	Walid N. ABOUL-HOSN	06-01506US07	1024

99185 7590 01/09/2017

Getinge US Legal Shared Services
1300 MacArthur Boulevard
Mahwah, NJ 07430

EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
01/09/2017	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@getinge.com

Response to Rule 312 Communication	Application No.	Applicant(s)
	15/239,574	ABOUL-HOSN ET AL.
	Examiner	Art Unit
	Adam Marcetich	3761

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

1. ☒ The amendment filed on *30 December 2016* under 37 CFR 1.312 has been considered, and has been:

   a) ☒ entered.

   b) ☐ entered as directed to matters of form not affecting the scope of the invention.

   c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
   Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

   d) ☐ disapproved. See explanation below.

   e) ☐ entered in part. See explanation below.

/Adam Marcetich/
Primary Examiner, Art Unit 3761

REPLACEMENT SHEET

All replacement drawings 1-54 are accepted

/AMM/ (01/03/2017)

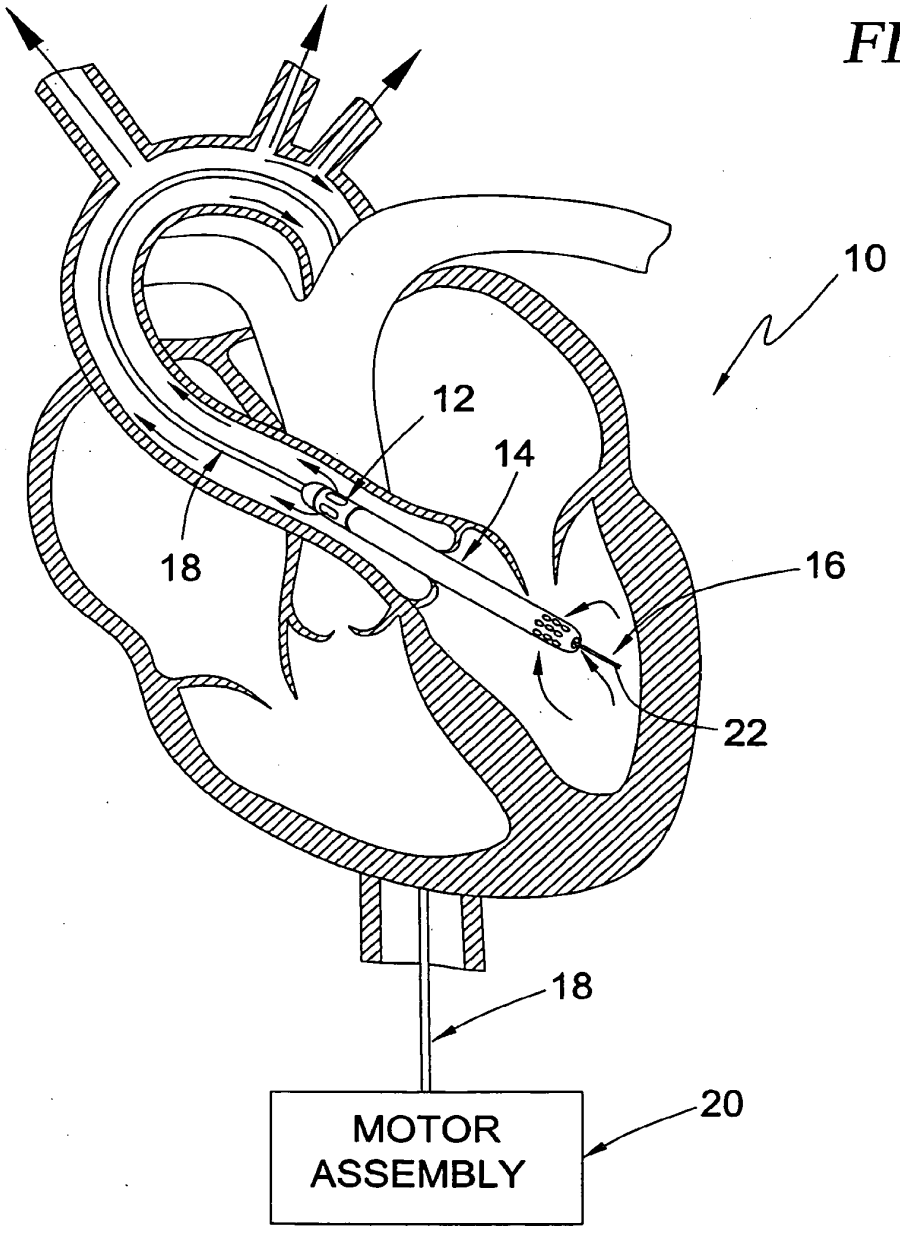


FIG. 1

replacement specification is accepted

/AMM/ (01/03/2017)

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

RELATED APPLICATIONS

[0001] This application is a divisional of co-pending U.S. Patent Application Serial No. 14/966,669, filed December 11, 2015, which is a divisional of U.S. Patent Application Serial No. 14/543,815, filed November 17, 2014 (now U.S. Patent 9,327,068, issued May 3, 2016), which is a continuation of U.S. Patent Application Serial No. 12/772,810, filed May 3, 2010 (now U.S. Patent 8,888,728, issued November 18, 2014), which is a continuation of U.S. Patent Application Serial No. 11/375,926, filed March 15, 2006 (now U.S. Patent No. 7,731,675, issued June 8, 2010), which is a divisional of U.S. Patent Application Serial No. 10/070,178, filed July 19, 2002, (now U.S. Pat. No. 7,022,100, issued April 4, 2006) which claims the benefit of PCT/US00/24515 filed September 1, 2000, which claims the benefit of provisional U.S. Patent Application Serial No. 60/152,249 filed September 3, 1999. We hereby claim priority to the aforementioned application(s) and also incorporate herein by reference each of the afore-listed patents and applications in their entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to blood pumps and, more particularly, to an improved intra-vascular blood pump having a guide mechanism which provides the ability to selectively guide the intravascular pump to a desired location within a patient's circulatory system.

DESCRIPTION OF RELATED ART

[0003] Over the years, various types of blood pumps have been developed for the purpose of augmenting or replacing the blood pumping action of damaged or diseased hearts. Blood pumps are commonly used in three situations: (1) for acute support during cardio-pulmonary operations; (2) for short-term support while awaiting recovery of the heart from surgery; or (3) as a bridge to keep a patient alive while awaiting heart transplantation. The pumps may be

AMENDMENT UNDER 37 C.F.R. § 1.312		
	Attorney Docket No.	06-01506US07
	Confirmation No.	1024
	First Named Inventor	Walid N. Aboul-Hosn et al.
Mail Stop: ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number	15/239,574
	Filing Date	August 17, 2016
	Group Art Unit	3761
	Examiner Name	Adam M. MARCETICH
	Title	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

SECOND AMENDMENT UNDER 37 C.F.R. § 1.312

Sir:

In view of the interview conducted via telephone on January 9, 2017 between Applicants' attorney, Wesley Ashton, and Mr. Son Lam, USPTO Quality Control Specialist (703-756-4627), kindly amend the application identified above as follows.

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

Remarks/Arguments begin on page 3 of this paper.

I. Amendments to the Specification:

Amendments to the specification are contained in the attached fourth substitute specification (without markings) as set forth in 37 C.F.R. § 1.125. In accordance with 37 C.F.R. § 1.125, a copy of the fourth substitute specification showing changes relative to the third substitute specification filed on December 30, 2016 is also attached herewith. The attached fourth substitute specification contains no new matter.

II. REMARKS

Applicants' attorney, Wesley Ashton, conducted an interview with Mr. Son Lam, USPTO Quality Control Specialist (703-756-4627), on January 9, 2017 to discuss processing of the above-captioned patent application for issuance as a patent. Mr. Lam requested Applicants file an amendment under 37 C.F.R. § 1.312 to amend the specification so that the term "Appendix" is replaced with "Incorporated Embodiments."

The present amendment adds no new matter to the above-captioned application.

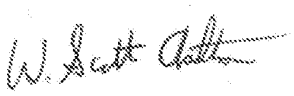
The patent that will issue from the above-captioned application should issue with the entire Substitute Specification filed today, which includes 51 pages, and with the Figures 1-54 filed on December 30, 2016 (which were entered on January 3, 2017 as evident from the Office Communication of January 9, 2017).

III. CONCLUSION

The amended application is in condition for issuance for the reasons of record. If the Patent Office feels a telephone interview would expedite processing of this patent application, the Patent Office is respectfully invited to telephone the undersigned at the number provided.

No fees are believed to be due in association with this filing. If any additional fees are required, the Commissioner is hereby authorized to charge any underpayment as well as credit any overpayment of fees associated with this communication to Deposit Account No. 50-5722, reference no. 06-01506US07.

Respectfully submitted,



Date: January 9, 2017

By: _____
Wesley Scott Ashton
Registration No. 47,395

MAQUET Cardiovascular, Getinge Group
1300 MacArthur Blvd
Mahwah, NJ 07430
Phone No: 1-201-995-8980

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

RELATED APPLICATIONS

[0001] This application is a divisional of co-pending U.S. Patent Application Serial No. 14/966,669, filed December 11, 2015, which is a divisional of U.S. Patent Application Serial No. 14/543,815, filed November 17, 2014 (now U.S. Patent 9,327,068, issued May 3, 2016), which is a continuation of U.S. Patent Application Serial No. 12/772,810, filed May 3, 2010 (now U.S. Patent 8,888,728, issued November 18, 2014), which is a continuation of U.S. Patent Application Serial No. 11/375,926, filed March 15, 2006 (now U.S. Patent No. 7,731,675, issued June 8, 2010), which is a divisional of U.S. Patent Application Serial No. 10/070,178, filed July 19, 2002, (now U.S. Pat. No. 7,022,100, issued April 4, 2006) which claims the benefit of PCT/US00/24515 filed September 1, 2000, which claims the benefit of provisional U.S. Patent Application Serial No. 60/152,249 filed September 3, 1999. We hereby claim priority to the aforementioned application(s) and also incorporate herein by reference each of the afore-listed patents and applications in their entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to blood pumps and, more particularly, to an improved intra-vascular blood pump having a guide mechanism which provides the ability to selectively guide the intravascular pump to a desired location within a patient's circulatory system.

DESCRIPTION OF RELATED ART

[0003] Over the years, various types of blood pumps have been developed for the purpose of augmenting or replacing the blood pumping action of damaged or diseased hearts. Blood pumps are commonly used in three situations: (1) for acute support during cardio-pulmonary operations; (2) for short-term support while awaiting recovery of the heart from surgery; or (3) as a bridge to keep a patient alive while awaiting heart transplantation. The pumps may be

designed to provide right and/or left ventricular assist, although left ventricle assist is the most common application in that it is far more common for the left ventricle to become diseased or damaged than it is for the right ventricle.

[0004] Blood pumps must provide leak-free operation and must avoid contamination of the fluid by the pump components and the external environment. Such pumps must also pump the fluid at a suitable rate without applying excessive Reynolds shear stress to the fluid. It is well known to those skilled in the art that lysis or cell destruction may result from application of shear stress to cell membranes. Red blood cells are particularly susceptible to shear stress damage as their cell membranes do not include a reinforcing cytoskeleton to maintain cell shape. Lysis of white blood cells and platelets also occurs upon application of high shear stress. Lysis of red blood cells can result in release of cell contents which trigger subsequent platelet aggregation. Sublytic shear stress leads to cellular alterations and direct activation and aggregation of platelets and white blood cells.

[0005] Intravascular blood pumps comprise miniaturized blood pumps capable of being percutaneously or surgically introduced into the vascular system of a patient, typically to provide left and/or right heart support. One type of intravascular pump is an axial flow blood pump comprising a cable-mounted rotor surrounded by a protective shroud. The pump, along with the rotor and shroud, are mounted at the end of an elongated flexible catheter. The catheter is inserted into the aorta from a remote entry point, such as an incision below the groin that provides access into a femoral artery. The catheter then passes through the descending aorta until it reaches the ascending aorta, near the heart. The catheter device encloses a rotating drive cable which is coupled to the impeller blade at one end, and which emerges from the exposed end of the catheter, near the patient's groin, at the other end. When the exposed end of the drive cable is mechanically rotated, using a device located outside the patient's body, it conveys the rotational force through the length of the catheter, causing the impeller to spin at high speed near the heart. This type of blood pump finds particular application in providing ventricular assist during surgery or providing temporary bridging support to help a patient survive a crisis.

[0006] While generally effective in providing ventricular assisting functions, prior art intravascular blood pumps nonetheless suffer various drawbacks. A significant drawback is that prior art intravascular blood pumps are difficult to guide into the appropriate position within the circulatory system of a patient. This is due largely to the fact that the elongated catheter is incapable of providing the degree of control necessary to easily negotiate the pump through the tortuous pathways leading up to and into the heart. When attempting to place the blood pump in a trans-valvular configuration (with the inlet in the left ventricle and the pump outlet in the ascending aorta), the natural tendency of the catheter to stay straight may cause the pump to be inadvertently placed in the carotid ostia, which can be dangerous if the pump is operated to withdraw blood from the brain.

[0007] To overcome these difficulties, certain guide mechanisms may be employed to assist the physician placing the pump in the appropriate position within the circulatory system. One type of supplemental guide mechanism is a guide catheter. Guide catheters are designed with certain guidability characteristics such that physicians can selectively position them within the vasculature or heart with relative ease. A central lumen is provided within the guide catheter such that the intravascular pump may be introduced therein and guided while it is advanced towards the predetermined circulatory site. While generally effective at providing a guiding feature for such intravascular blood pumps, employing such supplemental guide mechanisms is nonetheless disadvantageous in that they consume valuable space within the vessels. A guide catheter, for example, would necessarily be larger in diameter than the diameter of the pump and protective shroud in order to provide adequate passage of those components. As will be appreciated, this restricts the amount of space available for blood to flow within the particular vessel, and increases the size of the required puncture wound for accessing the vessel.

[0008] The present invention is directed at eliminating and/or reducing the effects of the foregoing drawbacks of prior art intravascular blood pumps.

SUMMARY OF THE INVENTION

[0009] The present invention overcomes the drawbacks of the prior art by providing an improved intravascular blood pump equipped with integrated features for selectively guiding the intravascular blood pump to a predetermined location in the patient's circulatory system, i.e. heart and/or vasculature. In so doing, the intravascular blood pump of the present invention eliminates the need for supplemental guiding mechanisms, such as a separate, large diameter guide catheter as used in the prior art.

[0010] In a first broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and an "over-the-wire" type guide mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient. To accomplish this, a central lumen is formed through at least a portion of the intravascular blood pump system such that a guide element, such as a guide wire, may be progressed therethrough and advanced to the predetermined location in the circulatory system of the patient. After the guide element is advanced to this desired location, the intravascular blood pump and cannula may thereafter be advanced along the guide element to the desired location.

[0011] In a second broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and a "side-rigger" or "rapid exchange" type guide mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient. To accomplish this, a side lumen is formed along a length of at least one of the intravascular blood pump and the cannula. A guide element, such as a guide wire, may be advanced to the predetermined location in the circulatory system of the patient. After the guide element is advanced to this desired location, the intravascular blood pump and cannula may thereafter be advanced along the guide element to the desired location.

[0012] In a third broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and a "guide catheter" type guide mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient.

The pump system of this broad aspect includes a conduit assembly and a separate pump assembly. The conduit assembly includes a guide catheter, a rotor shroud, and a cannula, with the cannula and guide catheter disposed on either side of the rotor shroud. The pump assembly includes a rotor, a drive member coupled to the rotor, and a pump disposed between the rotor and the drive member. The guide catheter is dimensioned to receive and guide the pump assembly to the point where the rotor docks within the rotor shroud so as to form an operational blood pump. This configuration allows the conduit assembly to be precisely and efficiently guided into a desired position within the body through the use of conventional guiding techniques well known in interventional cardiology. The pump assembly may thereafter be introduced into and guided within the conduit until the pump assembly is docked within the rotor shroud. This dual construction arrangement provides improved placement of the pump assembly by using the conduit as a guiding mechanism.

[0013] The foregoing broad aspects of the present invention may be manifested according to the following recitations:

[0014] According to a first broad recitation of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto, and a guide mechanism adapted to guide the intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient.

[0015] In a further embodiment, the intravascular blood pump includes a rotor, a shroud for receiving the rotor, and a drive cable coupled to the rotor for driving the rotor within the shroud.

[0016] In a further embodiment, the cannula is coupled to the shroud of the intravascular blood pump.

[0017] In a further embodiment, the guide mechanism comprises a guide catheter coupled to the shroud.

[0018] In a further embodiment, the guide catheter may be used to guide the shroud and cannula to the predetermined location within the circulatory system of the patient, after which point the rotor and drive cable of the intravascular blood pump may be docked within the shroud for pump operation.

[0019] In a further embodiment, the drive cable sheath is provided having a central lumen for receiving the drive cable, and wherein a purge fluid delivery system is coupled to the drive cable sheath to deliver purge fluid to the rotor.

[0020] In a further embodiment, the drive cable sheath includes at least one side lumen for delivering the purge fluid towards the rotor.

[0021] In a further embodiment, a portion of the purge fluid is delivered through the at least one side lumen and past the rotor, and a portion of purge fluid is rerouted back from the rotor through the central lumen of the drive cable.

[0022] In a further embodiment, a perfusion assembly is provided communicatively coupled to the guide catheter for selectively rerouting blood from within the guide catheter to a point downstream from the introduction site of the guide catheter into the vasculature of the patient.

[0023] In a further embodiment, the perfusion assembly includes a first conduit communicatively coupled to the guide catheter, a second conduit dimensioned to be introduced into the vasculature of the patient, and a selectively operable valve disposed in between the first conduit and the second conduit.

[0024] In a further embodiment, a blood pressure detection mechanism is provided to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.

[0025] In a further embodiment, the blood pressure detection mechanism comprises at least one of fluid filled column disposed within at least a portion of the cannula, a piezoelectric element coupled to at least one of the intravascular blood pump and cannula, and a strain gauge coupled to at least one of the intravascular blood pump and cannula.

[0026] In a further embodiment, the blood pressure detection mechanism involves calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive the rotor.

[0027] In a further embodiment, the guide mechanism comprises a guide element disposed at least partially within the cannula.

[0028] In a further embodiment, the guide element comprises a guide wire for passage through a side lumen formed in the cannula.

[0029] In a further embodiment, the guide element comprises a selectively deformable element disposed at least partially within the cannula.

[0030] In a further embodiment, the intravascular blood pump and cannula may be selectively advanced to the predetermined location within the vasculature of the patient by first passing the guide wire to the predetermined location and thereafter sliding the intravascular blood pump and cannula along the guide wire to the predetermined location.

[0031] In a further embodiment, the guide element comprises a guide wire for passage through a lumen extending through the drive cable and rotor.

[0032] In a further embodiment, the intravascular blood-pump and cannula may be selectively advanced to the predetermined location within the vasculature of the patient by first passing the guide wire to the predetermined location and thereafter sliding the intravascular blood pump and cannula along the guide wire to the predetermine location.

[0033] In a further embodiment, the guide mechanism further includes guide element for passage through the guide catheter to facilitate placement of the shroud and the cannula at the predetermined location within the vasculature of the patient.

[0034] In a further embodiment, the guide mechanism further includes a guide element for passage through a side lumen formed along at least a portion of the guide catheter.

[0035] In a further embodiment, the guide element comprises at least one of a guide wire and a balloon catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

[0037] FIG. 1 is a partial sectional view of a human heart illustrating an intravascular blood pump system having an "over-the-wire" type guide mechanism according to a first broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

[0038] FIG. 2 is side view of the guidable intravascular blood pump system of the type shown in FIG. 1 including a motor coupler and purge fluid delivery system according to an exemplary embodiment of the present invention;

[0039] FIG. 3 is a cross-sectional view illustrating an exemplary construction of the blood pump, drive cable assembly, and cannula of the intravascular blood pump system according to the first broad aspect of the present invention;

[0040] FIG. 4 is a cross-sectional view taken along lines 4-4 of FIG. 3 illustrating an exemplary construction of the drive cable assembly and guide mechanism according to the first broad aspect of the present invention;

[0041] FIG. 5 is a cross-sectional view illustrating an exemplary construction of the motor coupler and purge fluid delivery system according to the first broad aspect of the present invention;

[0042] FIG. 6 is a partial sectional view of a human heart illustrating an intravascular blood pump system having a "rapid exchange" or "side-rigger" type guide mechanism according to a second broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

[0043] FIG. 7 is side view of the guidable intravascular blood pump system of the type shown in FIG. 6 including a motor coupler and purge fluid delivery system according to an exemplary embodiment of the present invention;

[0044] FIG. 8 is a cross-sectional view taken along lines 8-8 of FIG. 7 illustrating the "side-rigger" or "rapid exchange" type guide mechanism according to the second broad aspect of the present invention;

[0045] FIG. 9 is a cross-sectional view of the type shown in FIG. 8 illustrating an alternate configuration of the guide mechanism according to the second broad aspect of the present invention;

[0046] FIG. 10 is a partial sectional view of a human heart illustrating an intravascular blood pump system having a "guide catheter" type guide mechanism according to a third broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

[0047] FIG. 11 is a schematic view of a human being illustrating the intravascular blood pump system of the type shown in FIG. 10 inserted through the femoral artery and including an optional perfusion assembly for perfusing the vasculature downstream from the incision site where guide catheter enters the femoral artery;

[0048] FIG. 12 is a side view of the intravascular blood pump system shown in FIGS. 10-11 illustrating the separable nature of a pump assembly and a conduit assembly which collectively form the intravascular blood pump system according to the third broad aspect of the present invention;

[0049] FIG. 13 is a side view illustrating the intravascular blood pump system shown in FIG. 12 with the pump assembly docked into the conduit assembly according to the third broad aspect of the present invention;

[0050] FIG. 14 is a cross-sectional view illustrating an exemplary construction of the blood pump, drive cable assembly, cannula, and guide catheter of the intravascular blood pump system shown in FIG. 13;

[0051] FIG. 15 is a cross-sectional view taken along lines 15-15 of FIG. 14 illustrating an exemplary construction of the drive cable assembly and guide catheter according to the third broad aspect of the present invention;

[0052] FIG. 16 is a cross-sectional view illustrating an exemplary construction of the motor coupler, purge fluid delivery system, and a proximal portion of the guide catheter biasing assembly according to the third broad aspect of the present invention;

[0053] FIG. 17 is a cross-sectional view illustrating an exemplary construction of the perfusion assembly and a distal portion of the guide catheter biasing assembly according to the third broad aspect of the present invention;

[0054] FIG. 18 is a cross-sectional view of an intravascular blood pump system of the type shown in FIGS. 12-13 having an alternate configuration for docking the rotor within the shroud according to the principles of the present invention; and

[0055] FIG. 19 is a partial sectional view of a human heart illustrating an alternate intravascular blood pump system having an "over-the-wire" type guide mechanism according to the first broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide right-heart assist.

[0056] FIG. 20 corresponds to Figure 1 of U.S. Serial No. 09/280,988, and is a schematic side view of a steerable cannula in the undeformed state in accordance with the first embodiment of U.S. Serial No. 09/280,988;

[0057] FIG. 21 corresponds to Figure 2 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view of the steerable cannula of FIG. 20 taken along line A-A;

[0058] FIG. 22 corresponds to Figure 3 of U.S. Serial No. 09/280,988, and is a schematic side view of the steerable cannula in the deformed state in accordance with the first embodiment of U.S. Serial No. 09/280,988;

[0059] FIG. 23 corresponds to Figure 4 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view of a steerable cannula having two cables in accordance with a second embodiment of U.S. Serial No. 09/280,988;

[0060] FIG. 24 corresponds to Figure 5 of U.S. Serial No. 09/280,988, and is a schematic side view of a steerable cannula having a reinforcing wire in accordance with a third embodiment of U.S. Serial No. 09/280,988;

[0061] FIG. 25 corresponds to Figure 6 of U.S. Serial No. 09/280,988, and is a schematic cut-away view of a steerable cannula in accordance with a fourth embodiment of U.S. Serial No. 09/280,988;

[0062] FIG. 26 corresponds to Figure 7 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view taken along line B-B of FIG. 25;

[0063] FIG. 27 corresponds to Figure 8 of U.S. Serial No. 09/280,988, and is a schematic side view of a steerable cannula having a preformed curve and an inflatable balloon formed at a distal end thereof in accordance with a fifth embodiment of U.S. Serial No. 09/280,988;

[0064] FIG. 28 corresponds to Figure 9 of U.S. Serial No. 09/280,988, and is a schematic side view of the inflatable balloon of a fifth embodiment of U.S. Serial No. 09/280,988, wherein the balloon is shown in the inflated state;

[0065] FIG. 29 corresponds to Figure 10 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view taken along line C-C of FIG. 28;

[0066] FIG. 30 corresponds to Figure 11 of U.S. Serial No. 09/280,988, and is a schematic view showing a steerable cannula having a pigtail distal tip configuration in accordance with a sixth embodiment of U.S. Serial No. 09/280,988;

[0067] FIG. 31 corresponds to Figure 12 of U.S. Serial No. 09/280,988, and is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with a seventh embodiment of U.S. Serial No. 09/280,988;

[0068] FIG. 32 corresponds to Figure 13 of U.S. Serial No. 09/280,988, and is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with an eighth embodiment of U.S. Serial No. 09/280,988;

[0069] FIG. 33 corresponds to Figure 14 of U.S. Serial No. 09/280,988, and is a schematic side view showing a steerable cannula used in a co-axial configuration in accordance with a ninth embodiment of U.S. Serial No. 09/280,988, wherein the steerable cannula is advanced to a first relative position;

[0070] FIG. 34 corresponds to Figure 15 of U.S. Serial No. 09/280,988, and is a schematic side view showing a steerable cannula of FIG. 33, wherein the steerable cannula is advanced to a second relative position; and

[0071] FIG. 35 corresponds to Figure 16 of U.S. Serial No. 09/280,988, and is a schematic side view of a configuration in accordance with a tenth embodiment of U.S. Serial No. 09/280,988.

[0072] FIG. 36 corresponds to Figure 1 of U.S. Serial No. 09/280,970, and is a schematic side view of a first embodiment of U.S. Serial No. 09/280,970;

[0073] FIG. 37 corresponds to Figure 2 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line D-D of FIG. 36;

[0074] FIG. 38 corresponds to Figure 3 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line E-E of FIG. 36;

[0075] FIG. 39 corresponds to Figure 4 of U.S. Serial No. 09/280,970, and is a schematic view of a cannula in accordance with an embodiment in a surgical application;

[0076] FIG. 40 corresponds to Figure 5 of U.S. Serial No. 09/280,970, and is a schematic partial cut-away side view of a second embodiment of U.S. Serial No. 09/280,970;

[0077] FIG. 41 corresponds to Figure 6 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line F-F of FIG. 40;

[0078] FIG. 42 corresponds to Figure 7 of U.S. Serial No. 09/280,970, and is a schematic side view of a third embodiment of U.S. Serial No. 09/280,970;

[0079] FIG. 43 corresponds to Figure 8 of U.S. Serial No. 09/280,970, and is a schematic side view of a fourth embodiment of U.S. Serial No. 09/280,970;

[0080] FIG. 44 corresponds to Figure 9 of U.S. Serial No. 09/280,970, and is a schematic side view of a fifth embodiment of U.S. Serial No. 09/280,970;

[0081] FIG. 45 corresponds to Figure 10 of U.S. Serial No. 09/280,970, and is a schematic side view of a sixth embodiment of U.S. Serial No. 09/280,970;

[0082] FIG. 46 corresponds to Figure 11 of U.S. Serial No. 09/280,970, and is a schematic cross sectional view taken along line G-G of FIG. 45;

[0083] FIG. 47 corresponds to Figure 12 of U.S. Serial No. 09/280,970, and is a schematic side view of a seventh embodiment of U.S. Serial No. 09/280,970;

[0084] FIGS. 48 and 49 correspond to Figures 13 and 14, respectively, of U.S. Serial No. 09/280,970, and are schematic side views of an eighth embodiment of U.S. Serial No. 09/280,970;

[0085] FIG. 50 corresponds to Figure 15 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line H-H of FIG. 49;

[0086] FIG. 51 corresponds to Figure 16 of U.S. Serial No. 09/280,970, and is a schematic side view of a ninth embodiment of U.S. Serial No. 09/280,970;

[0087] FIG. 52 corresponds to Figure 17 of U.S. Serial No. 09/280,970, and is a schematic side view of a tenth embodiment of U.S. Serial No. 09/280,970;

[0088] FIG. 53 corresponds to Figure 18 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line K-K of FIG. 52; and

[0089] FIG. 54 corresponds to Figure 19 of U.S. Serial No. 09/280,970, and is a schematic side view of an eleventh embodiment of U.S. Serial No. 09/280,970.

DETAILED DESCRIPTION OF THE INVENTION

[0090] Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation may be described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure.

[0091] The present invention involves an intravascular pump system for use in a number of broad ranging applications involving the augmentation of blood flow within the circulatory

system of a patient. As will be described below, the intravascular blood pump system of the present invention overcomes the drawbacks of the prior art by providing a guide mechanism as part of the intravascular blood pump. This advantageously allows the intravascular blood pump to be selectively guided to a predetermined location within the circulatory system of a patient without the need for bulky supplemental guide mechanisms, such as a separate guide catheter.

[0092] The intravascular pump assembly of the present invention is particularly suited for trans-valvular use, such as for left and/or right ventricular assist procedures. By way of example only, such ventricular assist procedures may be employed in cardiac operations including, but not limited to, coronary bypass graft (CABG), cardio-pulmonary bypass (CPB), open chest and closed chest (minimally invasive) surgery, bridge-to-transplant and/or failure-to-wean-from-bypass situations. It is to be readily understood, however, that the intravascular blood pump assembly and methods of the present invention are not to be limited to such applications. Moreover, while illustrated and described largely with reference to left-heart assist applications, it is to be readily understood that the principles of the present invention apply equally with regard to right-heart assist application, which are contemplated as within the scope of the present invention. These and other variations and additional features will be described throughout.

[0093] Referring to FIG. 1, shown is a guidable intra-vascular blood pump system 10 according to a first broad aspect of the present invention shown, by way of example only, in a left-heart assist configuration within a human heart. The system 10 includes an intravascular blood pump 12, a cannula 14, and an "over-the-wire" type guide mechanism 16. A drive cable assembly 18 and a motor assembly 20 are provided to drive the intravascular blood pump 12. The "over-the-wire" guide mechanism 16 comprises a suitable guide element dimensioned to pass slideably through a central lumen extending through the drive cable 18, blood pump 12, and cannula 14. Suitable guide elements may include any number of conventional guiding devices, including but limited to those employed in cardiology. By way of example only, the guide element is shown as a guide wire 22. According to the present invention, the "over-the-wire" guide mechanism 16 provides the ability to selectively guide the blood pump 12 and

cannula 14 to a predetermined position in the circulatory system of a patient, such as the trans-valvular position shown.

[0094] To accomplish this, the guide wire 22 is first introduced into the vascular system of a patient through any suitable access point, such as through the use of the well known Seldinger technique. The guide wire 22 can then be advanced within the patient to a desired location within the circulatory system of the patient. This may be done using the control features of the guide wire 22 itself, or may be facilitated through the use of any number of supplemental guidance mechanisms or techniques to ensure the proper and efficient placement of the guide wire 22. Such supplemental guidance techniques may include, but are not necessarily limited to, guide catheters and/or techniques involving ultra-sound or flouroscopy. Once the guide wire 22 is positioned at the desired location (such as in left ventricle as shown), the blood pump 12 and cannula 14 may thereafter be advanced along the guide wire 22 and positioned in the trans-valvular configuration shown. Under the operation of the motor assembly 20, the blood pump 12 may be used for left-heart assist by selectively withdrawing blood from the left ventricle (through the interior of the cannula 14) for delivery outward through outflow apertures formed in the blood pump 12. This outflow from the blood pump 12 flows along the exterior of the drive cable assembly 18 in a substantially axial fashion for arterial distribution throughout the body.

[0095] Referring to FIGS. 2-5, an exemplary embodiment of the intravascular blood pump system 10 of FIG. 1 will now be described. As shown in FIG. 2, the intravascular blood pump system 10 includes a coupler 24 and, as will be described in greater detail below, a purge fluid delivery system 26 for providing a two-way fluid flow within the drive cable assembly 18 during pump operation. The purge fluid delivery system 26 includes a fluid inlet conduit 28 for introducing pressurized purge fluid from a fluid source (not shown) for delivery into the blood pump 12, and a fluid outlet conduit 30 to withdraw a return flow of purge fluid from the blood pump 12. The motor coupler 24 establishes a mechanical connection between a motor (not shown) and a drive cable (not shown) for providing motive force to the blood pump 12 for pump operation. The drive cable assembly 18 includes a drive cable sheath 32 which, in addition to serving a purge fluid delivery function, also serves as a protective housing for the

drive cable (not shown). Although shown in broken form for clarity, it will be appreciated that the drive cable assembly 18 (and all components thereof) may be provided in any suitable length sufficient for intravascular applications. That is to say, the length of the drive cable assembly 18 must be enough to reach between the motor coupler 24 and purge fluid delivery system 26, located outside the patient, and the desired location within the patient's circulatory system where the blood pump 12 is to be positioned.

[0096] The intravascular blood pump 12 is shown (by way of example only) as an axial flow intravascular blood pump. The blood pump 12 includes pump body 34, a rotor shroud 36 having flow ports 38, and an internally disposed rotor (not shown) having a shaft rotatably disposed within the pump body 34 and an impeller rotatably disposed within the rotor shroud 36. The cannula 14 is fixedly attached to the rotor shroud 36 and may extend any suitable length therefrom depending upon the particular intravascular application. The cannula 14 preferably includes a plurality of ports or fenestrations 40 about its distal region, as well as an end port 42, which allow for the ingress or egress of blood into or from the cannula 14 depending upon the operation of the blood pump 12. That is to say, if the pump 12 is configured for left-heart assist as shown in FIG. 1, then the ports 40, 42 will allow the ingress of blood into the cannula 14 from the left ventricle. If, on the other hand, the blood pump 12 is configured for right-heart assist (i.e. with the pump 12 in the right atrium and the distal end of the cannula 14 located within the pulmonary artery), then the ports 40, 42 will allow the egress of blood from the cannula 14 into the pulmonary artery. (Details on right-heart assist applications will be discussed in greater detail below.) The pump 12 and cannula 14 may be dimensioned to any suitable diameter for intravascular applications. For example, the range of sizes may include, but is not necessarily limited to, 9 French to 30 French, although the range is more preferably from 14 French to 24 French, and most preferably from 18 French to 20 French.

[0097] The "over-the-wire" type guide mechanism 16 includes the guide wire 22 and, as will be explained in greater detail below, a central lumen extending through the cannula 14, blood pump 12, drive cable assembly 18, purge fluid delivery system 26, and motor coupler 24. As noted above, the central lumen is dimensioned to slideably receive the guide wire 22

such that the blood pump 12 and cannula 14 may be slideably advanced along the guide wire 22 to a desired location within the circulatory system of a patient after the guide wire 22 has been so positioned using conventional guidance techniques. It is to be readily understood that, while shown as a conventional guide wire 22, the guide element forming part of the guide mechanism 16 of the present invention may include any number of well known guidance mechanisms depending upon the application, including but not limited to balloon catheters, imaging wires, and guide catheters dimensioned to be slideably received through the central lumen. For example, although not appropriate for retrograde progression (such as the left-heart application shown in FIG. 1), a balloon catheter may be a suitable guidance mechanism for a right-heart assist application. In such a case, the balloon may be inflated and used as a "sail" to direct the catheter to a desired location (such as the pulmonary artery), after which point the blood pump 12 and cannula 14 can be advanced over the catheter to a trans-valvular configuration with the blood pump 12 in the right atrium and the ports 38, 40 of the cannula 14 in the pulmonary artery.

[0098] FIGS. 3 and 4 further detail the construction of the blood pump 12, cannula 14, drive cable assembly 18, and "over-the-wire" guide mechanism 16. The blood pump 12 includes a rotor 44 having a shaft 46 and an impeller 48. The shaft 46 is rotatably disposed within the pump body 34 via a bearing pack comprising, by way of example, ball bearing assemblies 50, 52 and spring 54. Ball bearings assemblies 50, 52 are well known in the art, each comprising an inner race which rotates along with the rotor shaft 46, an outer race which remains in a static and fixed position against the inner surface of the pump body 34, and a plurality of ball bearings disposed between the inner and outer races. The spring 54 biases each bearing assembly 50, 52 axially away from one another to reduce axial play during pump operation. The shaft 46 is generally hollow and dimensioned to receive a cable adapter 60 therein for the purpose of coupling the rotor 44 to a drive cable 62 forming part of the drive cable assembly 18. The drive cable 62 may be secured to the cable adapter 60 in any number of suitable fashions, including but not limited to the use of adhesives, crimping, and laser welding. These same techniques may be used to secure the cable adapter 60 within the shaft 46 of the rotor 44. A radial seal 64 is provided in between the wall of the pump body 34 and a distal stepped region 66 on the rotor shaft 46, the function of which will be described below.

[0099] The impeller 48 includes a hub 56 and a plurality of blades 58 extending therefrom. The hub 56 is generally conical and, according to the first broad aspect of the present invention, is hollow throughout to form part of the central lumen of the guide mechanism 16. In this regard, the hub 56 is preferably provided with a gasket or seal member 68 at its distal tip. The seal member 68 may be made of any suitable sealing material (including but not limited to silicone) such that the pump 12 and cannula 14 may be easily progressed along the guide wire 22 for delivery to a desired circulatory site. The seal member 68 should also be robust enough to prevent the ingress of blood into the interior of the rotor hub 56 during pump operation, whether the guide wire 22 remains in place or is fully withdrawn. The blades 58 are dimensioned to reside in close tolerance with the interior surface of the shroud 36. In operation, the blades 58 impart both an axial and radial vector on the blood which causes it to flow outward through the flow ports 38 formed in the shroud 36. As used herein, the term "axial flow" is deemed to include flow characteristics like that shown in FIG. 3, which include both an axial and slight radial component. It is to be readily appreciated that, although shown as an axial flow type, blood pump 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps without departing from the scope of the present invention.

[00100] The cannula 14 is coupled at its proximal end to the rotor shroud 36. This may be accomplished in any number of fashions, including but not limited to the use of adhesives. This may also be facilitated by dimensioning the shroud 36 to include a narrow inlet region 70 capable of being received flushly within the proximal end of the cannula 14. The inlet region 70 of the shroud 36 should preferably have a tapered interior surface for establishing a smooth flow transition between the cannula 14 and the region containing the impeller blades 58. Although shown as a single integral element, it is to be understood that the pump body 34 and shroud 36 may comprise two separate (and sometimes separable) components, the significance of which will become apparent below. The pump body 34 and shroud 36 may be constructed from any number of suitable materials, including but not limited to stainless steel or other medical grade compositions or alloys. The cannula 14 may also be constructed from any number of suitable materials, including but not limited to medical grade plastics. As shown,

the cannula 14 may also be fortified with spiral-wound reinforcement wire 72 within the walls of the cannula 14.

[00101] The drive cable assembly 18 includes the drive cable 62 and the drive cable sheath 32. The drive cable 62 is coupled to the rotor 44 via the cable adapter 60. The drive cable sheath 32 includes a central lumen 74 and a plurality of side lumens 76. The central lumen 74 serves as a protective covering for the drive cable 62. The central lumen 74, along with the side lumens 76, also forms part of the purge fluid delivery system 26 shown above in FIG. 2, which will be described in greater detail below. The side lumens 76 are provided in fluid communication with the fluid inlet conduit 28, while the central lumen 74 is provided in fluid communication with the fluid outlet conduit 30. The side lumens 76 are thus configured to deliver purge, fluid into the pump 12, while the central lumen 74 is configured to transport purge fluid away from the pump 12 along the length of the drive cable 62.

[00102] The pressurized purge fluid within the side lumens 76 may take one of two flow paths upon entry into the pump 12. One flow path passes through the interior of the pump 12 and onward past the radial seal 64 to prevent the ingress of blood into the pump body 34 during pump operation. More specifically, the purge fluid flows distally around the cable adapter 60, through the ball bearing assemblies 50, 52, and onward past the radial seal 64. This egress of purge fluid past the radial seal 64 can be controlled to effectively thwart the ingress of blood past the radial seal 64, which might otherwise cause clotting and/or pump damage. The other flow path is directed back out the central lumen 74 for delivery to the fluid outlet conduit 30. In so doing, this flow path bathes the components of the pump 12 and/or drive cable 62 and thereby reduces frictional heating within the pump 12 and/or the central lumen 74 of the sheath 32 during pump operation.

[00103] The "over-the-wire" guide mechanism 16 includes a central lumen through which the guide wire 22 may extend for the purpose of slideably advancing the blood pump 12 and cannula 14 into a desired position within the circulatory system of a patient. In the embodiment shown, this central lumen is established by forming and co-aligning the individual central lumens within each of the drive cable 62, the cable adapter 60, the shaft 46

and hub 56 of the rotor 44, and the cannula 14. In this regard, the drive cable 62 is preferably of wound-wire construction having a central lumen formed therein. The central lumens within the cable adapter 60, rotor 44, and gasket 68 may be formed via machining or molding processes. These central lumens should preferably be sized such that they permit the slideable passage of the pump 12 and cannula 14 therealong, but do not interfere with or constrain the guide wire 22 to cause inadvertent rotation of the guide wire 22 during pump operation. As noted above, it is also contemplated to remove the guide wire 22 after the pump 12 and cannula 14 are properly positioned in the patient. In this case, the gasket or seal 68 on the hub 56 should be robust enough to reseal after the guide wire 22 is withdrawn and prevent the ingress of blood into the interior of the rotor 44.

[00104] Referring to FIG. 5, the motor coupler 24 includes a housing 78, a drive shaft adapter 80, and a bearing assembly 82. The drive shaft adapter 80 includes a drive shaft coupler 84 dimensioned to receive a drive shaft of a motor (not shown), and a drive cable coupler 86 dimensioned to receive the drive cable 62. Any of a variety of attachment techniques may be employed to securely fasten the drive cable 62 to the drive cable coupler 86, including but not limited to adhesives, crimping, and laser welding. The drive shaft adapter 80 is rotatably disposed within the housing 78 by the bearing assembly 82. The bearing assembly 82 includes a sleeve 88 (which may alternatively be formed as an integral part of the housing 78) for retaining a pair of ball bearing assemblies 90, 92 and a spring 94 of the type described above. That is, each bearing assembly 90, 92 generally comprises an inner race which rotates along with the drive shaft adapter 80, an outer race which remains in a static and fixed position against the inner surface of the retaining sleeve 88, and a plurality of ball bearings disposed between the inner and outer races. The spring 94 is provided to bias each bearing assembly 90, 92 axially away from one another to reduce axial play during operation.

[00105] The purge fluid delivery system 26 includes a housing 96 having a central lumen 98, an inflow port 100, and an outflow port 102. The housing 96 is also dimensioned to matingly receive a portion of the motor coupler 24. In this regard, a seal element 104 is provided sandwiched in between the housing 96 and housing 78 and including an aperture which extends about the drive shaft adapter 80 as it exits the housing 78 to prevent the ingress

of purge fluid into the motor coupler 24. A fluid guide structure 106 is also provided within the central lumen 98 for the purpose of separating the inflow and outflow ports 100, 102. The fluid guide structure 106 includes a central lumen 108 through which the drive cable 62 extends, and an elevated portion 110 that retains an O-ring 112 against the inner surface of the central lumen 98 of the housing 96. The drive cable sheath 32 is secured to the housing 96 such that the inflow port 100 is communicatively coupled to the side lumens 76, and the outflow port 102 is communicatively coupled to the central lumen 74. In this fashion, pressurized purge fluid may be introduced through the inflow port 100 via inflow conduit 28, and removed through the outflow port 102 via outflow conduit 30. By way of example, the inflow conduit 28 and outflow conduit 30 may be coupled to their respective ports 100, 102 via barbed connectors 114. Similarly, the inflow and outflow conduits 28, 30 may be equipped with any number of suitable connectors (such as those illustrated by way of example in FIG. 2) for establishing fluid communication with a source of pressurized fluid (not shown). The pressurized fluid source (not shown) may include, but is not necessarily limited to, the use of a syringe, an indeflator, a fluid delivery pump, or an accumulator arrangement to provide the requisite delivery of pressurized fluid. The purge fluid delivery system 26 thus provides a two-way transmission of purge fluid within the drive cable sheath 32 for the purposes of cooling the blood pump 12 and preventing the ingress of blood past the radial seal 64 and into blood pump 12.

[00106] Referring to FIG. 6, shown is a guidable intra-vascular blood pump system 120 according to a second broad aspect of the present invention. As will be described hereinafter, the intravascular blood pump system 120 differs from the intravascular blood pump system 10 described above only as to the type of guide mechanism employed. In the interest of clarity and consistency, then, like reference numerals will be used to denote like elements and distinctions pointed out where necessary. Moreover, due to the commonality of principles employed in both intravascular blood pump systems 10, 120, a discussion to the level of detail set forth above is not deemed necessary with regard to the intravascular blood pump system 120. Instead, those aspects in common with the intravascular blood pump 10 are hereby incorporated into the discussion of the intravascular blood pump system 120.

[00107] In its most general form, the intravascular blood pump system 120 of this second broad aspect of the present invention comprises the blood pump 12 and cannula 14 arrangement, wherein the cannula 14 is equipped with a "side-rigger" or "rapid exchange" guide mechanism 122. In an important aspect of the present invention, the "rapid exchange" or "side-rigger" guide mechanism 122 includes a guide carriage 124 formed along at least a portion of the cannula 14, and a suitable guide element (such as guide wire 22) dimensioned to pass slidably through a lumen (not shown) extending through the guide carriage 124. The "rapid exchange" guide mechanism 122 thereby provides the ability to selectively guide the blood pump 12 and cannula 14 to a predetermined position in the circulatory system of a patient in the manner described above. Namely, the guide wire 22 may be first introduced into the vascular system of a patient through any suitable access point and guided to a desired location within the circulatory system of the patient, i.e. the left ventricle as shown. The blood pump 12 and cannula 14 may thereafter be advanced along the guide wire 22 and positioned in the trans-valvular configuration shown for providing left-heart assist.

[00108] FIGS. 7-9 further illustrate the "side-rigger" or "rapid-exchange" guide mechanism 122 of this second broad aspect of the present invention. In a preferred embodiment, the "side-rigger" guide mechanism 122 includes a lumen 126 formed within the guide carriage 124. The guide carriage 124 is preferably formed as an integral extension of the wall of the cannula 14. FIGS. 7 and 8 comport with the embodiment shown in FIG. 6, namely illustrating the guide carriage 124 formed along the exterior surface of the cannula 14. FIG. 9 illustrates an alternate embodiment wherein the guide carriage 124 may be formed along the interior surface of the cannula 14. In either case, the guide wire 22 is advanced to a desired location in the vasculature of the patient, after which point the blood pump 12 and cannula 14 can be slidably advanced therealong for delivery to the desired location according to the present invention. The guide wire 22 may thereafter be withdrawn from the patient. If the guide carriage 124 is formed along the exterior surface of the cannula 14 (as shown in FIGS. 7-8), then the cannula 14 should preferably be positioned so that the guide carriage 124 does not extend in a trans-valvular fashion. For example, with reference to FIG. 6, the guide carriage 124 should be positioned wholly within the left ventricle such that the pulsatile blood

flow during beating heart procedures will not inadvertently pass through the side lumen 126 and pass through the aortic valve.

[00109] The intravascular blood pump system 120 is constructed in virtually the same manner as the intravascular blood pump system 10 shown and described above, with the exception of the location of the respective guide mechanisms 16, 122. More specifically, because the guide mechanism 122 is disposed along the side of the cannula 14, there is no need to form a central lumen extending through the blood pump 12, drive cable assembly 18, purge fluid delivery system 26, and motor coupler 24 as detailed above with regard to the intravascular blood pump system 10. As such, these components need not be specially machined or molded to include such central lumens as was required with the intravascular blood pump system 10 set forth above.

[00110] Referring to FIG. 10, shown is a guidable intravascular blood pump system 130 according to a third broad aspect of the present invention. Again, due to the commonality between many of the same components and features of the intravascular blood pump systems described above and the intravascular blood pump system 130, like reference numerals will be used to denote like elements and distinctions pointed out where necessary. As will be explained in greater detail below, the intravascular blood pump system 130 employs yet another unique and useful guide mechanism according to the present invention. However, because many of the same components are employed, a discussion to the level of detail set forth above is not deemed necessary with regard to the intravascular blood pump system 130. Instead, those aspects in common with the intravascular blood pumps described above are hereby incorporated into the discussion of the intravascular blood pump system 130.

[00111] In its most general form, the intravascular blood pump system 130 of this third broad aspect of the present invention comprises the blood pump 12 and cannula 14 arrangement, wherein a "guide catheter" 132 is provided as the guide mechanism for positioning the pump 12 and cannula 14 at a desired location within the circulatory system of the patient. More specifically, with brief reference to FIG. 12, the intravascular blood pump system 130 is formed in two separate assemblies according to the present invention: a conduit

assembly 134 and pump assembly 136. In its most basic form, the conduit assembly 134 comprises the guide catheter 132 and cannula 14 coupled to the rotor shroud 36. The pump assembly 136 is constructed such that the pump body 34 and rotor 44 can be disengaged from the rotor shroud 36 and removed entirely from the conduit assembly 134. Referring again to FIG. 10, this dual construction forms a significant feature of the present invention because it provides the ability to form the blood pump 12 at a desired location in a patient using two separate and distinct steps. The first step involves positioning the conduit assembly 134 (with the pump assembly 136 removed) within a patient such that the shroud 36 and cannula 14 are each disposed in a desired location, such as a trans-valvular configuration for cardiac assist procedures. In an important aspect, the task of positioning the conduit assembly 134 within the patient may be advantageously facilitated through the use of any number of well known guidance mechanisms, including but not limited to guide wires, balloon catheters, imaging wires, guide catheters, and/or techniques involving ultra-sound or flouroscopy. The second step in providing the intravascular blood pump system 130 of the present invention involves advancing the pump assembly 136 through the conduit assembly 134 such that the rotor 44 docks within the shroud 36 to form the pump 12 at the desired location.

[00112] By way of clarification, the term "cannula" is used to denote cannula 14 because it serves a primary purpose of transporting fluid into the blood pump 12, whereas the term "catheter" is used to denote the catheter 132 because it serves a primary purpose of guiding or directing devices or components (i.e. the pump assembly 136) to a desired location within the body. It is to be readily understood, however, that these terms are only used for convenience and in a general fashion such that the cannula 14 may serve certain guiding functions and the catheter 132 may serve certain fluid transportation functions without departing from the scope of the present invention. For example, the cannula 14 may be equipped with dedicated lumens to receive various guide mechanisms (such as guide wires, balloon catheters, selectively deformable elements such as Nitonol, etc). In similar fashion, the guide catheter 132 may be used to transport fluid to and/or from the patient, such as by providing apertures 138 along predetermined regions of the catheter 132.

[00113] FIG. 11 demonstrates a significant feature of the present invention involving the use of the guide catheter 132 to transport fluid to and/or from the patient. An optional perfusion assembly 140 is provided as part of the intravascular blood pump system 130 of the present invention. The perfusion assembly 140 includes a conduit 142 in fluid communication with the apertures 138, which in this case are formed near the distal region of the guide catheter 132 a short distance downstream from the blood pump 12. In use, blood will pass along the exterior of the guide catheter 132 for distribution throughout the body, as well as within the interior of the guide catheter 132 after passing into the apertures 138. The perfusion assembly 140 may then be employed to selectively reroute blood from within the guide catheter 132 to a point within the patient's vasculature downstream from the point where the guide catheter 132 enters the body. A hemostasis valve assembly 146 of the perfusion assembly 140 permits the drive cable assembly 18 to pass through to the purge fluid delivery system 26 while preventing blood flow other than into the perfusion assembly 140. A seal assembly 150 of the purge fluid delivery system 26 permits the drive cable 62 to pass through to the motor 20 while preventing the flow of purge fluid other than into and from the purge fluid delivery system 26. The perfusion assembly 140 includes a control mechanism 148 for selectively controlling the distribution of perfusion blood flow from the perfusion assembly 140 into the patient. This control mechanism 148 may be automatic based on certain feedback criteria or manually operated.

[00114] FIGS. 12-17 illustrate an exemplary construction of the intravascular blood pump system 130 according to the third broad aspect of the present invention. As shown in FIG. 12, the conduit assembly 134 may be selectively disengaged so as to remove the pump assembly 136 therefrom. According to the present invention, the conduit assembly 134 may be introduced (without the pump assembly 136) into the circulatory system of a patient and selectively guided such that the rotor shroud 36 and cannula 14 are positioned at a desired location. The pump assembly 136 can thereafter be selectively introduced into the conduit assembly 134. A challenge in such a "back-loading" arrangement is ensuring that the pump assembly 136 docks appropriately within the rotor shroud 36 and is maintained in proper engagement during operation of the resulting pump 12.

[00115] An exemplary docking arrangement will now be described with reference to FIG. 14. In a preferred embodiment, the rotor 44 may be properly and accurately docked within the shroud 36 by forming angled mating surfaces on corresponding portions of the shroud 36 and pump body 34. More specifically, an angled mating surface may be formed on the interior surface of the rotor shroud 36 along that portion extending proximally from the flow aperture 38. A corresponding angled mating surface may be provided along the exterior surface of the pump body 34 along a distal portion thereof. The mating surfaces shown in FIG. 14 may preferably be formed in the range from about 2 degrees to 10 degrees, and more preferably formed in the range from about 3 degrees to 6 degrees. Mating angles within these ranges are adequate to guide the distal end of the pump body 34 to a point generally flush with the proximal edge of the flow aperture 38 as shown in FIG. 14. In this fashion, the pump assembly 136 and the rotor shroud 36 combine to form the blood pump 12. More importantly, this docking is carried out such that the rotor 44 and rotor blades 58 are maintained in proper position for efficient and safe pump operation.

[00116] An exemplary biasing scheme for maintaining the pump assembly 136 in this docked relationship will now be described with reference to FIGS. 12-13 and 16-17. The conduit assembly 134 is preferably equipped with a male quick-connect coupling 152 capable of engaging with a female quick-connect coupling 154 forming part of the perfusion assembly 140 of the present invention. A bias spring 156 is provided in between the perfusion assembly 140 and the housing 96 of the purge fluid delivery system 26. The bias spring 156 is preferably dimensioned so as to be in tension when the male quick-connect 152 is engaged within the female quick-connect 154 as part of the docking process of the present invention. As such, the bias spring 156 serves to maintain the pump assembly 136 in the docked position within the rotor shroud 36. The bias spring 156 may be coupled to the housing 96 of the purge fluid delivery system 26 in any number of suitable fashions. One such coupling arrangement may comprise a female quick-connect coupling 158 attached to the housing 96 and a male quick-connect coupling 160 attached to the bias spring 156.

[00117] An exemplary embodiment of the perfusion assembly 140 is shown with reference to FIGS. 12-13 and 17. The perfusion assembly 140 shown includes the hemostasis valve 146

coupled to the female quick-connect coupling 154. A length of tubing 162 extends between the opposing barb connectors of the hemostasis valve 146 and the female quick-connect coupling 154. A continuous lumen is formed extending through the interior of the male quick-connect coupling 152, the female-quick-connect coupling 154, the tubing 162, and the hemostasis valve 146. The drive cable assembly 18 extends through this continuous lumen and exits through a Touehy-Borst hemostasis seal 164 which prevents the migration of blood out of the proximal end of the perfusion assembly 140. A side-port 166 is disposed in fluid communication with the central lumen of the perfusion assembly 140. In one embodiment, this side-port 166 may be equipped with a conduit 168 having a stop-cock 170 to selectively control the distribution of blood through a perfusion conduit (i.e. conduit 142 of FIG. 11) coupled to the stop-cock 170. It will be appreciated that this type of manual control system for selectively perfusing the patient may be replaced with control circuitry for automatically controlling the rate of perfusion. Such automatic perfusion may be based on control algorithms based on contemporaneous feedback or pre-programmed thresholds.

[00118] The foregoing discussion details a host of inventive aspects forming part of the present invention. It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concepts thereof. The following evidences, by way of example only, various additional aspects forming part of the present invention.

[00119] FIG. 18 illustrates an alternate configuration of the intravascular blood pump system 130 of the third broad aspect of the present invention having an alternate bearing assembly, purge fluid delivery, and docking scheme. The bearing assembly includes a seal spring 182 and a bearing assembly 180. The bearing assembly 180 includes an inner race 184, an outer race 186, and a plurality of balls 188 which enable the inner race 184 to rotate along with the rotor shaft 46 while the outer race 186 remains in a static and fixed position relative to an inner surface of the pump body 34. An O-ring 190 is disposed within a groove formed in the rotor shaft 46 so as to maintain the bearing assembly 180 against the seal spring 182. The O-ring 190 is further secured within the groove in the rotor shaft 46 via a contoured lip portion

extending from the distal end of the cable adapter 60. The proximal end of the cable adapter 60 flushly engages the drive cable 62.

[00120] The purge fluid delivery system of the embodiment shown in FIG. 18 provides for a one way delivery of purge fluid to the blood pump 12. That is, pressurized fluid (namely, fluid pressurized to some level elevated above the blood pressure in the surrounding vessel) is injected in between the drive cable 62 and the interior of the protective sheath 32 during operation. This serves to reduce any frictional heating that exists between the drive cable 62 and sheath 32. The pressurized fluid also flows through the interior of the pump 12 such that, if the seal at 192 is broken, the pressurized fluid will flow past the open seal 192 and onward through the blood flow ports 38 formed in the shroud 36. This serves to keep blood from entering the pump 12 in an effort to avoid clotting and/or damaging the pump 12.

[00121] The pump assembly 136 may be docked within the conduit assembly 134 in any number of different fashions without departing from the scope of the present invention. That is to say, the docking scheme shown in FIG. 18 is set forth by way of example only and is not to be deemed limiting or restrictive as to numerous ways to temporarily engage or "dock" the pump assembly 136 within the conduit assembly 134. The only requirement is that the pump assembly 136 and conduit assembly 134 dock such that the rotor 44 is disposed within the shroud 36 to provide the desired axial flow through the cannula 14 and out the shroud 36. The exemplary docking scheme involves forming an annular engagement groove 194 along the interior of the shroud 36, and forming a complementary annular ridge 196 along the exterior surface of the pump body 34. During insertion, the pump assembly 136 will be advanced into the conduit assembly 134 until the annular ridge 196 on the pump body 34 engages within the groove 194 formed in the shroud 36. This docking scheme is generally advantageous in that the engagement action between the annular ridge 196 and groove 194 will provide tactile feedback to the physician during the process of inserting the pump assembly 136 into the conduit assembly 134 such that the physician will be able to determine when the docking has been completed.

[00122] As will be appreciated by those skilled in the art, the location of the annular ridge 196 and engagement groove 194 may be varied such that they are disposed closer or farther away from the flow apertures 38. It may be advantageous to form these docking structures close to the flow apertures 38 in an effort to thwart the ingress of blood into the junction extending between the interior of the shroud 36 and the exterior surface of the pump body 34. It is also contemplated to employ selectively inflatable structures, such as balloons, in an effort to temporarily engage or dock the pump assembly 136 within the conduit assembly 134. In this regard, one or more lumens may be formed within the pump body 34 extending from the interior of the pump body 34 in fluid communication with a balloon disposed along the exterior surface of the pump body 34. The pressurized fluid flowing within the interior of the pump body 34 may then be used to inflate the balloon, which will then engage within an annular groove in the shroud 36, such as at 194. Of course, the engagement structures may also be reversed without departing from the scope of the present invention. For example, the shroud 36 may be equipped with a fluid delivery lumen therein for inflating a balloon disposed on the interior surface of the shroud 36, which may in turn be disposed within an annular engagement groove formed along the exterior surface of the pump body 34.

[00123] While this invention has been shown in use largely in during left-heart applications it is to be readily appreciated that this does not limit the applications of this invention for use in left heart support only. Rather, the guidable intravascular blood pump of the present invention can be utilized in right-heart support applications and a wide variety of other applications apparent to those skilled in the art. For example, with reference to FIG. 19, shown is an intravascular blood pump 200 (of the type shown and described above with reference to FIGS. 2-5) configured for use in a right-heart support application. In this embodiment, the intravascular blood pump system 200 is equipped, by way of example, with an "over-the-wire" guide mechanism 16 comprising a balloon catheter 202. It is to be readily appreciated that, although shown and described below in terms of an embodiment of the type shown in FIGS. 2-5, the intravascular blood pump systems 120, 130 disclosed herein may also be configured for use in right-heart applications. Such right-heart configurations, and others apparent to those skilled in the art based on the broad principles enumerated in this application, are contemplated as being within the scope of the present invention.

[00124] The intravascular blood pump system 200 is shown positioned within the heart, such as may be advantageous to provide right heart support during beating heart surgery. To position the guidable intravascular blood pump system 200 in the right heart according to the present invention, a suitable guide element (such as balloon catheter 202) is first advanced to a desired location within the heart via the "sail" action of an inflated balloon. After the balloon catheter 202 is located in the desired position (such as in the pulmonary artery as shown), the intravascular blood pump system 200 according to the present invention may be advanced over the balloon catheter 202 and guided into a desired arrangement. For right heart support, this would involve advanced into the pump 12 and cannula 14 overt the balloon catheter 202 until the fluid inlet 204 is disposed within the vena cava (or right atrium) and the fluid outlet 206 is positioned within the pulmonary artery. The pump 12 may then be selectively (i.e. automatically or on-demand) controlled to transport blood from the vena cava (or right atrium) in a trans-valvular fashion through the tricuspid valve, the right ventricle, and the pulmonary valve for deposit within the pulmonary artery. Providing right-heart support during beating heart surgery advantageously overcomes conditions where cardiac output may become compromised during beating heart surgery, such as when the heart is lifted to gain access to posterior vessels, thereby avoiding the need for cardiopulmonary bypass.

[00125] It is also contemplated as part of the present invention that the guidable intravascular blood pump systems can be introduced into the patient's vasculature to achieve the intravascular access into the right or left heart through any number of access points, including but not limited to the internal jugular vein, the brachiocephalic vein, carotid artery, axillary artery, femoral vein, femoral artery, and subclavian artery. The intravascular blood pump systems of the present invention may also be introduced via direct introduction, such as into the aorta, the atria, and the ventricles. As is well known in the art, such intravascular access may be achieved percutaneously through the use of the Seldinger technique or directly through the use of minimally invasive access techniques.

[00126] Those skilled in the art will also appreciate that, although shown and described above in terms of "axial flow," the present invention is not limited to the axial flow type

intravascular blood pumps. Rather, the intravascular blood pumps 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps, without departing from the scope of the present invention.

[00127] With regard to the embodiments shown in FIGS. 10-17, it is furthermore contemplated that the guide catheter 132 may be separable from the conduit assembly 134 after the pump assembly 136 is docked within the shroud 36 to form the pump 12 at the desired location within the circulatory system of the patient. This may be accomplished by providing the guide catheter 132 in a detachable fashion via any number of suitable arrangements. By removing the guide catheter 132 after the pump 12 assembled, wound management of the access point into the patient's vasculature may be improved. This is due, in part, to the substantial reduction in size of the device extending into the patient (i.e. the drive cable assembly 18 as opposed to the larger diameter guide catheter 132).

[00128] It is also contemplated to incorporate various pressure sensing and/or guidability features into at least one of the cannula, 14 and pump 12. Such features may include, but are not necessarily limited to, those shown and described in commonly-owned and co-pending U.S. Patent Application Ser. No. 09/280,988 (filed March 30, 1999) entitled "Steerable Cannula," and U.S. Patent Application Ser. No. 09/280,970 (filed March 30, 1999) entitled "Pressure Sensing Cannula," the disclosures of which are hereby expressly incorporated by reference as if set forth herein in their entirety and physically incorporated as sections of the present specification. These pressure sensing features may include, but are not necessarily limited to, the use of fluid-filled lumens, piezo-electric pressure sensing elements, strain gauges, and analysis of the torque/current relationship (based on the dynamic pressure differential between the inlet and outlet of the pump). The guidability features may include, but are not necessarily limited to, the use of side lumens and deformable materials (i.e. Nitonol).

[00129] Various pump and cannula arrangements have been described and shown above for providing right and/or left heart support wherein blood is deliberately re-routed through

and past the right and/or left ventricle in an effort to reduce the volume of blood to be pumped by the particular ventricle. While "unloading" the ventricles in this fashion is preferred in certain instances, it is to be readily understood that the pump and cannula arrangements described herein may also be employed to "preload" the ventricles. Ventricular preloading may be accomplished by positioning the outflow cannula from the pump into a given ventricle such that the pump may be employed to fill or preload the ventricle with blood. This may be particularly useful with the right ventricle. On occasion, the right ventricle is not supplied with sufficient levels of blood from the right atrium such that, upon contraction, the right ventricle delivers an insufficient quantity of blood to the pulmonary artery. This may result when the right ventricle and/or right atrium are in a stressed or distorted condition during surgery. Preloading overcomes this problem by actively supplying blood into the right ventricle, thereby facilitating the delivery of blood into the pulmonary artery. The same technique can be used to preload the left ventricle and thus facilitate the delivery of blood from the left ventricle into the aorta.

INCORPORATED EMBODIMENTS OF U.S. SERIAL NO. 09/280,988

[00130] STEERABLE CANNULA

BACKGROUND OF THE INVENTION

[00131] 1. Field of the Invention

The invention relates to vascular cannulas for use in medical procedures.

[00132] 2. Description of Related Art

[00133] In medical applications and specifically in surgery, the list of uses for cannulas is exhaustive. Cannulas are to be distinguished from catheters in that catheters generally have a substantially smaller fluid-carrying capacity are used primarily for sampling or measurement purposes or for delivery of small quantities of fluid, whereas cannulas are generally larger and are used for volumetric fluid transfer. One application of cannulas involves the augmenting or supplementing of pulmonary blood flow through the beating heart during cardiac-surgery by use of one or more cannulas involved in the intake and return of blood into the circulatory system. The cannulas interface between the patient's circulatory system and the mechanical

pumps that power the augmentation procedure. Such an application is described in co-pending PCT Application no. PCT/US97/18674 entitled "Single Port Cardiac Support Apparatus", filed October 14, 1997 and incorporated herein by reference in its entirety.

[00134] As will be appreciated, precise and quick placement of the cannula in surgical applications is critical, given the severe time constraints facing a surgeon whose patient's vital life sustaining functions have been suspended during the procedure. Currently, methods for placing cannulas in a patient's body are crude, in that they rely on guesswork and trial and error. Specifically, a surgeon will insert the cannula and direct it towards the desired destination, but ultimately must feel by hand, through the patient's tissue for example, whether it has reached that destination. The surgeon may be forced to make several retractions and re-insertions until the process succeeds. Shortcomings of such a procedure are clear and may include damage to the delicate tissue involved and waste of valuable time. Additionally, constraints on the flexibility of the material are imposed since a prescribed amount of rigidity is required to enable the cannula to be felt through the tissue and insure that the cannula does not collapse under insertion force.

[00135] Alternatively, the surgeon may rely on the use of guiding devices such as a guide wire threaded through the cannula. The guide wire is often easier to manipulate than the cannula, and its placement precedes placement of the cannula. After the guide wire is in place, the cannula is pushed along the length of the guide wire, following the guide wire to the desired destination.

[00136] It is also known that a flow directed balloon catheter can be used as a guide wire. Balloon catheters are well known in the art and have a multitude of uses, including delivery or removal of fluid from the surgical site. However, flow directed balloon catheters are typically at least an order of magnitude smaller than cannulas. Their small size accordingly severely limits their application since both quantity and rate of fluid flow through the catheter are limited. In fact it is precisely because of their small size that flow directed balloon catheters can be used as guiding devices for the larger, more robust and versatile cannulas. During use as a guiding device for a cannula, the flow directed balloon catheter acts as a guide wire in facilitating the advancement of the cannula to the desired destination. The flow directed balloon catheter is first inserted into place in the patient's body, and the cannula, threaded around the flow directed balloon catheter, is then advanced into the desired position.

[00137] Insertion of the flow directed balloon catheter is effected using the inflatable balloon disposed at a distal tip of the flow directed balloon catheter. A lumen in communication with the balloon delivers inflating fluid to the balloon, thereby inflating the balloon and causing it to operate as a "sail" which is pulled along in the blood stream through the natural blood flow in the patient's circulatory system.

[00138] The above procedures have met with only limited success, and there exists a long felt need for devices and methods that facilitate placement of a cannula in a patient's body. A system that will assist in the manipulation of the cannula through the vascular structure or other bodily regions of the patient would accordingly serve to make the placement process more efficient and less time-consuming, improving the chance of overall success of a surgical procedure.

BRIEF SUMMARY OF THE INVENTION

[00139] The present invention overcomes the deficiencies of the prior art by providing a cannula which can be steered during its advancement in the body of the patient. Steering is implemented using cables connected to a deformable portion of the cannula. The cables extend to the proximal end of the cannula from where the operator can selectively apply tensional forces to thereby cause the cannula to curve at the deformable portion. The deformable portion is disposed preferable at the distal end of the cannula, but may be located at other sites along the length of the cannula.

[00140] In accordance with a second embodiment of the invention, the cannula is provided with more than one cable for facilitating deformation along multiple planes. Additionally, preformed curves may be provided along the length of the cannula, which curves can be either augmented or straightened by applied tension to the cables.

[00141] The cannula, in accordance with a third embodiment, is provided with a spiraling wire formed in the cannula wall. The spiraling wire operates to provide rigidity to the body of the cannula and maintain good fluid flow therein. The spiraling wire may comprise a portion of the cable used to impart deformation in an arrangement in accordance with a fourth embodiment of the invention.

[00142] In accordance with a fifth embodiment of the invention, the steerable cannula is provided with an inflatable balloon at the distal end thereof for assisting in guiding the cannula

to its desired destination. The inflatable balloon is selectively inflatable using a lumen which effects fluid communication between an fluid source and the balloon.

[00143] In accordance with a sixth embodiment of the invention, a steerable cannula having a pigtail distal tip configuration is provided.

[00144] In accordance with a seventh embodiment of the invention, a steerable cannula having a movably supported guide wire is provided.

[00145] In accordance with an eighth embodiment of the invention, a steerable cannula having an integrally formed guide wire is provided.

[00146] In accordance with a ninth embodiment of the invention, a steerable cannula is used in a co-axial cannula arrangement.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[00147] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

[00148] FIG. 20 is schematic side view of a steerable cannula in the undeformed state in accordance with the first embodiment of the invention;

[00149] FIG. 21 is a schematic cross-sectional view of the steerable cannula of FIG. 20 taken along line A-A;

[00150] FIG. 22 is a schematic side view of the steerable cannula in the deformed state in accordance with the first embodiment;

[00151] FIG. 23 is a schematic cross-sectional view of a steerable cannula having two cables in accordance with a second embodiment of the invention;

[00152] FIG. 24 is a schematic side view of a steerable cannula having a reinforcing wire in accordance with a third embodiment of the invention;

[00153] FIG. 25 is a schematic cut-away view of a steerable cannula in accordance with a fourth embodiment of the invention;

[00154] FIG. 26 is a schematic cross-sectional view taken along line B-B of FIG. 25;

[00155] FIG. 27 is a schematic side view of a steerable cannula having a preformed curve and an inflatable balloon formed at a distal end thereof in accordance with a fifth embodiment of the invention;

[00156] FIG. 28 is a schematic side view of the inflatable balloon of fifth embodiment of the invention, wherein the balloon is shown in the inflated state;

[00157] FIG. 29 is a schematic cross-sectional view taken along line C-C of FIG. 28;

[00158] FIG. 30 is a schematic view showing a steerable cannula having a pigtail distal tip configuration in accordance with a sixth embodiment of the invention;

[00159] FIG. 31 is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with a seventh embodiment of the invention;

[00160] FIG. 32 is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with an eighth embodiment of the invention;

[00161] FIG. 33 is a schematic side view showing a steerable cannula used in a co-axial configuration in accordance with a ninth embodiment of the invention, wherein the steerable cannula is advanced to a first relative position;

[00162] FIG. 34 is a schematic side view showing a steerable cannula of FIG. 33, wherein the steerable cannula is advanced to a second relative position; and

[00163] FIG. 35 is a schematic side view of a configuration in accordance with a tenth embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[00164] The present invention comprises a steerable cannula in which a portion which is adapted for insertion into the body of a patient, preferably into the vascular system of the patient, is configured to be selectively deformable. The deformation aids in changing the direction of the cannula during the insertion process such that the cannula can be steered in a desired direction as it is advanced toward its destination in the patient's body. Deformation is effected using a cable connected with the deformable portion of the cannula. Tension on the cable, induced by for example rotating a portion of a handle disposed at a proximal end of the cannula exterior of the body of the patient, results in tension on one wall of the deformable portion and thereby causes it to bend in the direction of the cable.

[00165] With reference to FIGS. 20-23 in which an exemplary arrangement in accordance with a first embodiment of the invention is shown, cannula 1120 can be seen as comprising a substantially cylindrical structure having a wall 1122 which defines a main lumen 1124. Lumen 1124 is adapted for fluid transport to or from the body of the patient and may be

provided with one or more holes 1126 located adjacent to distal tip 1128 and permitting passage of fluid therethrough. Holes 1126 supplement fluid flow through main port 1125, especially in situations of blockage of main port 1125. Cannula 1120 may be one of two complementary cannulas (not shown) used in a surgical procedure, one for intake and the other for removal of blood or other fluid from the patient's body. Alternatively cannula 1120 may comprise a component of a co-axial, single port device in which cannula 1120 is surrounded by a second, larger conduit, with cannula 1120 for example operating to intake blood from the patient towards a pump system and the conduit operating to replace the blood from the pump back into the patient for augmentation of blood flow during beating heart surgery as described in co-pending PCT Application no. PCT/US97/18674 mentioned above.

[00166] At a proximal end 1130 of cannula 1120 is provided a handle 1132 which serves to transmit turning forces applied by an operator's hand to the cannula to aid in its manipulation in the patient's body. As such, handle 1132 is rigidly attached to wall 1122 of cannula 1120, although portions of handle 1132 may be configured for motion relative to cannula 1120 in order impart the necessary tension on cables used for deforming the cannula 1120 as described below. Rotation of the rigidly attached portion of handle 1132, results in a corresponding rotation of the distal end 1128 of the cannula 1120 within the patient's body, thus aiding in the cannula's manipulation and advancement to the desired destination.

[00167] Wall 1122, in addition to defining main lumen 1124 of cannula 1120, contains a secondary lumen 1136 formed therein. Movably mounted in lumen 1136 is a cable 1138 which is secured at point 1140 in wall 1122. Point 1140 may be disposed anywhere along the length of the cannula 1120, but in the preferred embodiment lies at distal end 1128.

[00168] Cannula 1120 is provided with a deformable portion 1142 formed along at least a segment of its length. In the exemplary arrangement shown in FIGS. 20-22, deformable portion 1142 is disposed in close proximity to distal end 1128 of cannula 1120; however, it is to be understood that this not intended to be limiting and that other regions in the cannula 1120 can alternatively or additionally be made deformable depending on the contemplated application.

[00169] Deformable portion 1142 serves to cause cannula 1120 to bend in response to tension applied to cable 1138 and thereby assume a configuration as shown in FIG. 22. Depending on the location of point 1140 and the location of lumen 1136 radially and axially

along wall 1122, applied tension to cable 1138 causes cannula 1120 to turn on itself in the direction of pull to thereby assume a curve having a predetermined orientation. Additionally, if cannula 1120 is provided with one or more preformed curves, which may be in identical or in different planes along the length of the cannula as is contemplated, tension in cable 1138 can operate to temporarily straighten the cannula along at least one of these planes to facilitate handling during a particular maneuver through the patient's body.

[00170] It is also contemplated that more than one cable can be provided, supported in suitable secondary lumens formed in cannula 1120. As can be seen from FIG. 23, a second lumen 1146 can be provided in wall 1122 of cannula 1120, second lumen 1146 movably supporting cable 1144 therein. Cables 1138 and 1144 are thus disposed on opposite sides of cannula 1120 and serve to provide steerability in two directions. The cables are configured such that a pulling of one cable is coordinated with a slacking of the other cable in order permit bending of cannula 1120 at deformable portion 1142. Although shown to be diametrically opposed in position, cables 1138 and 1144 can occupy any position along wall 1122, and it will be appreciated that the number of such cables used can vary depending on the application, as can their distribution in wall 1122, and any desired number of turning directions can accordingly be achieved in accordance with the present invention.

[00171] Wall 1122 can be formed of materials ranging from rigid to flexible, and in the preferred embodiment comprises a semi-rigid transparent material such as silicone rubber. Of course it is to be understood that by definition deformable portion 1142 is to be constructed of a flexible material, regardless of the construction of the remainder of the wall 1122, such that cannula 1120 can bend when appropriate pulling forces are imparted through the cable(s).

[00172] Selective bending of cannula 1120 can also be facilitated using a core member provided for this purpose. Core member 1182, preferable formed of material having appreciable stiffness relative to wall 1122, is disposed longitudinally within cannula 1120 and serves to provide a deflection point to locate and control the bending point of the cannula. Core 1182 is removable and can be movable distally or proximally within cannula 1120 in order to alter the deflection point. In this manner also flow blockage in the cannula 1120 can be insured during insertion.

[00173] As can be seen from FIG. 24, a spiraling wire 1148 can be provided for structural reinforcement of cannula 1120. Wire 1148 is either molded into the wall 1122 or is otherwise

supported therein, and extends either partially or fully across the length of the cannula 1120. Wire 1148 facilitates handling of the cannula 1120 and reduces the possibility of cannula 1120 collapsing or being pinched shut and thus closing off the flow of fluid to or from the patient. Other ways of reinforcing the tubular body of cannula 1120 are known in the art and will adapt equally well to the present invention. In addition, no reinforcement may be needed if the cannula material is sufficiently rigid or if sufficient fluid flow is present within the cannula.

[00174] Alternatively, as shown in FIGS. 25-26, spiraling wire 1148 can itself comprise a portion of cable 1138. In such an arrangement, cannula wall 1122 is formed of two layers 1162 and 1164, between which is formed a lumen 1166. Layers 1162 and 1164 may be discrete layers bonded together at appropriate regions, or they may be a single layer folded back upon itself to form the two layers, with lumen 1166 and wire 1148 occupying predetermined regions therebetween. Cable 1138 is housed in a polymide tube 1170 disposed in lumen 1166 and extends beyond the end 1168 of tube 1170 to then spiral exteriorly of inner layer 1162 and interiorly of outer layer 1164 to thereby lend structural support to the cannula 1120. Metal or other tape 1172 can be used to secure spiraling wire 1148 in place. In a variation of this, cable 1138 and wire 1148 may be two discrete components which are welded or otherwise connected together at any desired point along the body of cannula 1120. Alternatively, as shown in FIG. 35, cable 1138 may be secured to a band 1184 disposed radially about or adjacently to tip 1186 of cannula 1120. In all of these variations, cable 1138 may be formed of single or multiple strands of metal, plastic or carbon fiber composite, but preferably cable 1138 is formed of a single strand of stainless steel having a TEFLON™ coating. In the FIGS. 33-35 arrangements, cannula 1120 is shown with an atraumatic bullet tip 1186 having side holes 1188 and end holes 1190. It will be appreciated that such a tip can be provided for any arrangement of the invention. It will also be appreciated that the tip 1186 can itself serve as the anchor for the cable 1138 in certain arrangements. The tip 1186 is fixedly bonded to distal end 1125 of cannula 1120 and enables a simplified construction of the steering mechanism and provides a blunt surface that will not injure tissue in the body.

[00175] Lumens 1136 and 1146, or other similar lumens, in addition to supporting cables 1138 and 1144 therein, may be used to supply inflating fluid to a balloon 1150 provided at the outer surface of the distal end 1128 of cannula 1120. As shown in the exemplary embodiment

of FIGS. 27-29, balloon 1150 is in fluid communication with inflating fluid source 1152, via supply tube 1154 and lumen 1156. Fluid source 1152 serves to selectively provide fluid, such as saline, air or other gas, to balloon 1150 to thereby cause the balloon to inflate within the patient's body. Balloon inflation in this manner assists in placement of the cannula 1120, especially when inserting the cannula antegrade, with the inflated balloon serving to float the tip of cannula within the fluid flow to thus transport it to the desired location in the body. Cannula 1120 is provided with one preformed curve 1158 in addition to curve 1160 imparted by the tension in cable 1138. Balloon 1150 is shown in the deflated state in FIG. 27 and in the inflated state in FIGS. 28 and 29.

[00176] Various distal tip configurations can be selected for cannula 1120, depending on the particular application as appreciated by those of ordinary skill in the art. For example, a pigtail shape can be used for crossing the aortic valve retrograde. The pigtail shape, illustrated in FIG. 30, can be formed by bonding or thermal welding or otherwise attaching a thermoplastic rod 1174 formed into a loop at the distal end of the cannula 1120. Alternatively, a J-tip wire 1176 can be configured to protrude from the distal tip 1128, as illustrated in FIGS. 31 and 32. The J-tip wire can be a conventional guidewire movable or fixedly supported in a dedicated lumen 1178 formed in a rigidly attached tube 1180 (FIG. 31), or it can be supported, rigidly or movably, between layers of material from which the wall 1122 of cannula 1120 is formed. Guidewires are known in the art and can for example be formed of windings of wire coiled around a core and having one or more preformed curves formed therein.

[00177] An embodiment in which cannula 1120 is used in a coaxial configuration is shown in FIGS. 33 and 34. Cannula 1120 serves as an inner cannula, passing through outer conduit 1180 while the two components are disposed in the patient's body. An important advantage of this arrangement is that outer conduit 1180 operates to vary the radius of curvature of inner cannula 1120 by providing a base point as the inner cannula 1120 is advanced. In this manner manipulation of the inner cannula 1120 and outer conduit 1180 is facilitated and advancement to the desired destination in the body of the patient is more efficiently accomplished.

[00178] The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to one of ordinary skill in the art that modifications thereto can be made without inventive departure from the spirit and scope of the invention.

ABSTRACT OF U.S. SERIAL NO. 09/280,988

[00179] A steerable cannula is provided with at least one cable through which tension is communicated to a deformable portion of the cannula. The tension causes the cannula to bend at the deformable portion, enabling selective steering of the cannula during insertion into the body of the patient.

INCORPORATED EMBODIMENTS OF U.S. SERIAL NO. 09/280,970

[00180] PRESSURE SENSING CANNULA

[00181] BACKGROUND OF THE INVENTION

[00182] FIELD OF THE INVENTION

The present invention relates to cannulas used in surgical applications, and more particularly, to a cannula equipped with a pressure/flow rate transducer.

[00183] DESCRIPTION OF THE RELATED ART

In medical applications and specifically in surgery, the list of uses for cannulas is exhaustive. One application involves the augmenting or supplementing of pulmonary blood flow through the beating heart during cardio-surgery by use of one or more cannulas involved in the intake and return of blood into the circulatory system. The cannulas interface between the patient's circulatory system and the mechanical pumps that power the augmentation procedure. Such an application is described in co-pending PCT Application no. PCT/US97/18674 entitled "Single Port Cardiac Support Apparatus", filed October 14, 1997 and incorporated herein by reference in its entirety.

[00184] When performing cardiac surgery cannulas are placed within the patient's blood stream and used for inflow and outflow of blood or other fluids. If the operator wishes to determine the rate of fluid flow, either a catheter with appropriate sensors must also be placed in the patient's blood stream, or other sensors such as an external ultrasonic sensor as disclosed in U. S. Patent No. 5,179,862 are used. A shortcoming of ultrasonic systems such as that described in 5,179,862 is that they require significant monitoring. Ultrasonic sensors also

require that tubing of a specific diameter be used, thereby adding to the cost and complexity of the surgical procedure. Additionally, ultrasonic sensors are expensive and nondisposable, thereby adding to the cost of the surgical procedure.

[00185] Another method to measure flow rate is through the use of a thermodilution catheter. Thermodilution catheters require the infusion of a solution, typically saline, of a known temperature, with a distally disposed thermistor measuring the temperature change to determine the flow rate. This method is also expensive, increasing the cost of the surgical procedure. A second problem with using flow-sensing catheters, such as thermodilution catheters, is that they require the operator to place more incisions within the patient. The catheters must be placed so that they do not interfere with the inflow or out flow of the cannula. Visual markers along the length of the cannula may also be used to determine location, the greater the number of markers the more accurate the placement at the expense of quick readings due to the greater number of markings.

SUMMARY OF THE INVENTION

[00186] The present invention overcomes the deficiencies of the prior art by providing a cannula assembly having one or more pressure transducers coupled to a main lumen thereof. In accordance with a first embodiment, the pressure transducers are attached to the substantially tubular wall defining the main lumen.

[00187] In accordance with a second embodiment, a partial occlusion is provided in the cannula to increase the pressure drop across the main lumen. In this manner transducer signal is increased, and an improved differential pressure measurement signal achieved.

[00188] In accordance with a third embodiment of the invention, one or more pressure transducers are used in conjunction with a pair of coaxial cannulas for measuring pressure.

[00189] In accordance with at fourth embodiment of the invention, a differential pressure transducer is used, the differential pressure transducer being mounted in a dedicated secondary lumen in communication with the first lumen.

[00190] In accordance with a fifth embodiment of the invention, the secondary lumen housing the differential pressure transducer is disposed across a knee formed in the cannula to augment pressure measurement. Partial occlusions may also be provided for this purpose.

[00191] In accordance with a sixth embodiment of the invention, the secondary lumen housing the differential pressure transducer is formed integrally with the tubular wall defining the main lumen.

[00192] In accordance with a seventh embodiment of the invention, a soft, flexible tapered tip is provided at the distal end of the cannula. Such a configuration allows for easier negotiation through the patient's body during surgical procedure.

[00193] In accordance with an eighth embodiment of the invention, an inflatable balloon is provided at the distal end of the cannula. The inflatable balloon aids in transporting the cannula to the desired destination.

[00194] In accordance with a ninth embodiment of the invention, a guide wire lumen is provided for supporting a guide wire in the cannula. The guide wire is used as a predecessor step in the insertion of the cannula.

[00195] In accordance with a tenth embodiment of the invention, a light guide is supported in the cannula. The light guide conveys light to a predetermined portion of the cannula to thereby aid in the visualization and location of the cannula during the surgical procedure.

[00196] The invention realizes various advantages over the prior art, including a reduction in the number of incisions that a surgeon must make in performing surgical procedures, along with a reduction in the amount of foreign material introduced into the patient's body, while providing safe, rapid, accurate and cost-effective fluid flow rate measurements.

BRIEF DESCRIPTION OF THE DRAWINGS

[00197] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

[00198] FIG. 36 is a schematic side view of a first embodiment of the invention;

[00199] FIG. 37 is a schematic cross-sectional view taken along line D-D of FIG. 36;

[00200] FIG. 38 is a schematic cross-sectional view taken along line E-E of FIG. 36;

[00201] FIG. 39 is a schematic view of a cannula in accordance with the invention in a surgical application;

[00202] FIG. 40 is a schematic partial cut-away side view of a second embodiment of the invention;

[00203] FIG. 41 is a schematic cross-sectional view taken along line F-F of FIG. 40;

[00204] FIG. 42 is a schematic side view of a third embodiment of the invention;

[00205] FIG. 43 is a schematic side view of a fourth embodiment of the invention;

[00206] FIG. 44 is a schematic side view of a fifth embodiment of the invention;

[00207] FIG. 45 is a schematic side view of a sixth embodiment of the invention;

[00208] FIG. 46 is a schematic cross sectional view taken along line G-G of FIG. 45;

[00209] FIG. 47 is a schematic side view of a seventh embodiment of the invention;

[00210] FIGS. 48 and 49 are schematic side views of an eighth embodiment of the invention;

[00211] FIG. 50 is a schematic cross-sectional view taken along line H-H of FIG. 49;

[00212] FIG. 51 is a schematic side view of a ninth embodiment of the invention;

[00213] FIG. 52 is a schematic side view of a tenth embodiment of the invention; and

[00214] FIG. 53 is a schematic cross-sectional view taken along line J-J of FIG. 52; and

[00215] FIG. 54 is a schematic side view of an eleventh embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00216] In accordance with the invention, a cannula comprising a substantially tubular, semi-flexible material adapted for fluid transport while inserted in a patient's body is provided with one or more pressure transducers which are fixedly or adjustably supported in the cannula. The pressure transducers are disposed internally or externally of the cannula and are used to provide a measurement of the rate of fluid flow. In the internal configuration, the rate of fluid flow within the cannula is measured. In the external configuration, the rate of fluid flow outside the cannula is measured. The cannula can also be adapted to support a guide wire to aid the operator in its insertion through the patient's body, and/or a light source to provide a visual reference during the insertion procedure. It is to be understood that the use of the term "cannula" is intended to encompass cannulas, catheters, and any related devices having similar application.

[00217] An exemplary arrangement in accordance with a first embodiment of the invention is shown FIGS. 36-38. Cannula 2220 comprises a substantially cylindrical structure having a wall 2228 defining a main lumen 2221. Wall 2228 can be formed of materials ranging from rigid to flexible, and in the preferred embodiment comprises a semi-rigid transparent material

such as polyurethane, silicone rubber or other material. Lumens other than main lumen 2221 may also be provided, as described below. The cannula may also be formed from vinyl plastisol. To form a cannula of vinyl plastisol, a mandrel is dipped into liquid vinyl plastisol and heated. Wire is then wrapped around the mandrel and first formed layer. The mandrel is then dipped again encasing the wire, and then heated. The mandrel is then removed. Lumens and transducers may be formed within the wall of the cannula during the dipping process.

[00218] To lend structural support for the thin wall which allows maximum flow with minimal insertion damage, spiraling wire 2230 is provided for reinforcement and is either molded into the wall 2228 or is otherwise supported therein, and extends either partially or fully across the length of the cannula 2220. Wire 2230 facilitates handling of the cannula 2220 and reduces the possibility of cannula 2220 collapsing or being pinched shut and thus closing off the flow of fluid to or from the patient. Other ways of reinforcing the tubular body of cannula 2220 are known in the art and will adapt equally well to the present invention. In addition, no reinforcement may be needed if the cannula material is sufficiently rigid or if sufficient fluid flow is present within the cannula.

[00219] A connector 2223 is provided at the proximal 2225 end of cannula 2220. Connector 2223 is suitably sized to interface with various surgical instruments, including but not limited to a reverse flow pump or fluid conduits leading thereto (not shown). Cannula 2220 may also have one or more holes 2226 located adjacent to distal tip 2222 to facilitate fluid flow therethrough. Cannula 2220 may be one of two complementary cannulas used in a surgical procedure, one for intake and the other for removal of blood or other biocompatible fluid from the patient's body. Alternatively, cannula 2220 may comprise a component of a co-axial, single port device in which cannula 2220 is surrounded by a second, larger conduit, with cannula 2220 for example operating to intake blood from the patient towards a pump system and the conduit operating to replace the blood from the pump system back into the patient for augmentation of blood flow during beating heart surgery as described in the co-pending PCT Application No. PCT/US97/18674 mentioned above.

[00220] In order to provide real time fluid flow information in accordance with the present invention, a pair of pressure transducers 2224, 2232 are provided at two separate locations as illustrated in FIG. 36. Pressure transducers 2224, 2232 are of the type known in the art and each comprises for instance a piezo-electric crystal housed in an integrated circuit (IC) chip

(not shown). The crystal configuration is designed to be pressure sensitive, generating an electrical signal in proportion to the amount of pressure experienced.

[00221] The principle governing the relationship between fluid flow and pressure is defined by Bernoulli's equation, herein solved for flow rate V and is determined by:

$$v = \sqrt{\frac{\Delta P \cdot 2d \cdot a^2}{f \cdot L \cdot \rho}}$$

where ΔP is the measured difference in pressure, d is the internal diameter of the lumen, a is the area of the lumen, f is a frictional factor of the lumen material, L is the lumen length over which the pressure measurement is conducted, and ρ is a measurable constant representative of the density of the fluid. The flow rate information can be used for a variety of purposes, including monitoring the patient's condition and controlling the fluid pump used during the procedure.

[00222] In the preferred embodiment, transducers 2224, 2232 are imbedded in the wall 2228, which is formed for instance by application of successive layers of laminate and interjecting the transducers therebetween during the layering process. Depending on at what stage in the layering process the transducers 2224, 2232 are put in place in the wall 2228, their proximity to the interior of the cannula 2220 or its exterior can be controlled in order to optimize measurement of cannula interior or exterior pressure. From the interior pressure measurements, a determination of flow rate within main lumen 2221 can be made using the known diameter of the main lumen 2221. Similarly, from the exterior pressure measurements, flow rate of exterior fluid--for example, blood--can be measured if the diameter of the blood channel, such as the artery, is known, or the cannula can be calibrated with thermodilution catheters which assume the diameter of the vessel or artery they are placed within.

[00223] In the FIG. 36 exemplary arrangement, pressure transducer 2232 is disposed at a location near the distal tip 2222 of cannula 2220, while pressure transducer 2224 may be

disposed anywhere along the length of cannula 2220 between pressure transducer 2232 and proximal end 2225. It is also contemplated that the pressure transducers 2224, 2232 may be detachably disposed in dedicated secondary lumens formed in or along tubular wall 2228, the dedicated secondary lumen extending to the proximal end 2225 and supporting any electrical cables connected to the pressure transducers 2224, 2232. In the detachable arrangement, the location of pressure transducers 2224, 2232 in the cannula 2220 can be adjusted to suit the particular application, such that one transducer can be disposed within one chamber of the heart while the other is at a different of portion of the heart to thereby provide a pressure/flow rate measurement of a predetermined portion of the patient's body, for example flow into the heart from a designated blood vessel. Such an application is shown in FIG. 39.

[00224] Pressure transducers 2224, 2232 are in electrical communication with console 2236 via cable 2238, which is supported in secondary lumen 2242 provided in cannula 2220. Calculations for determining fluid flow rate using signals generated by the pressure transducers 2224, 2232 and relayed via cable 2238 are conducted at the console 2236 or at any processor or processing system connected thereto.

[00225] As shown in FIGS. 40 and 41, cannula 2220 may also contain a partial occlusion portion 2247 that forms a venturi 2246 within the main lumen 2221 of cannula 2220. Venturi 2246, which may be disposed anywhere along the length of the cannula 2220, induces a pronounced pressure drop, creating a greater differential in pressure between proximal region 2225 and distal region 2222, thereby requiring less signal amplification of the pressure transducers and less filtering of the signal and consequently yielding a more accurate flow rate measurement. Preferably the location of the pressure transducer 2232 is in the vicinity of venturi 2246 as shown in FIG. 54.

[00226] FIG. 42 shows an embodiment in accordance with the invention in which the pressure transducers 2224, 2232 are used with a co-axial, single port device 2250 in which cannula 2220 is surrounded by a second, larger conduit 2248, with cannula 2220 for example operating to intake blood from the patient towards a pump system (not shown) and conduit 2248 operating to replace the blood from the pump system, via openings 2252, back into the patient for augmentation of blood flow during beating heart surgery as described in the co-pending PCT Application no. PCT/US97/18674 mentioned above. It is to be understood that pressure transducers 2224, 2232 can be mounted fixedly or detachably either to the interior or

exterior of either the cannula 2220 or the conduit 2248 in the above-described manner. More than one pair of these transducers can also be used in a myriad possible combinations in accordance with the invention. In the preferred embodiment, the cannula 2220 is provided with a bullet nosed tip, as illustrated in for example FIGS. 42-44. Other tip configurations, such as a bevel, may also be used, as will be appreciated by those skilled in the art.

[00227] An alternative to using pairs of pressure transducers such as transducers 2224, 2232 is the use of a single differential pressure transducer 2254, as shown in FIG. 43. Differential pressure transducers are also well known in the art and comprise for example a piezo-electric crystal electro-mechanically configured to be responsive to a pressure difference between two opposing sides thereof. These two sides correspond respectively to proximal end 2257 and distal end 2259 of secondary lumen 2256 in which transducer 2254 is mounted. Proximal and distal ends 2257 and 2259 are attached at any desired points along the length of cannula 2220 to thereby couple secondary lumen 2256 to main lumen 2221 and provide a pressure difference measurement between the desired points. Attachment of lumen 2257 and transducer 2254 across knee 2249 of cannula 2220, as shown in FIG. 44, will provide a stronger signal, with knee 2249 operating in accordance with the same principal as venturi 2246 discussed above. Thus it is to be understood that a venturi could also be used in conjunction with the differential pressure transducer 2254. The ports 2261 and 2263 at which the lumen 2256 interfaces with cannula 2220 may be sealed by an appropriate membrane, with saline or other fluid being permanently housed in the lumen 2256. Alternatively, ports 2261 and 2263 may be open, permitting fluid communication between the cannula 2220 and the lumen 2256 and attached transducer 2254. The latter, open configuration would achieve a more faithful pressure representation. Stopcocks 2274 and 2276 can be provided in the ports 2261 and 2263 to permit priming and/or de-airing of the ports. It should also be noted that although in the arrangements of FIGS. 43 and 44 the lumen 2256 is provided as a separate tubular structure, lumen 2256 may alternatively be formed integrally with wall 2228 of cannula 2220, again with ports 2261 and 2263 being either open or closed to main lumen 2221 depending on the application. Such an arrangement is illustrated in FIGS. 45 and 46 in which is shown transducer 2254 in communication with lumen 2272 integrally formed in wall 2228 of cannula 2220.

[00228] Various distal tip configurations can be selected for cannula 2220 and used with the pressure sensing transducers, depending on the particular application as appreciated by those of ordinary skill in the art. FIG. 47 shows an exemplary embodiment in which the distal tip 2222 is formed of a soft, flexible material having a bullet shape. As shown exemplarily in FIGS. 48-50, the cannula 2220 may be equipped to support other tools, such as an inflatable balloon 2240 which is deployed for example in order to assist in transporting the distal tip 2222 to the desired destination in the patient's body during the surgical procedure. Balloon 2240 is inflated through an inflating lumen 2244 provided in cannula 2220 using a bio-compatible fluid such as saline or carbon dioxide gas. Preferably inflating lumen 2244 is formed integrally within wall 2228, by leaving an appropriate gap during the fabrication process, and is provided with a fitting (not shown) at its proximal end to interface with an inflating device for supplying the bio-compatible fluid. The lumen 2221 within the cannula 2220 can also be adapted to support a balloon catheter (not shown) which can be used to place the cannula within the patient's body. An obturator (not shown) may also be disposed through the main lumen 2221 to aid in insertion and guiding within the patient's body.

[00229] Another tool which cannula 2220 may support is shown in FIG. 51 and comprises a J-hook guidewire 2262 disposed slideably within lumen 2264, which is formed integrally in wall 2228 of cannula 2220. In operation, guidewire 2262, easier to manipulate than the cannula 2220, is first inserted into the patient's body and manipulated to the surgical site. Subsequently the cannula 2220 is maneuvering along the guidewire 2262, which passes through lumen 2264, to the desired destination.

[00230] As illustrated in FIGS. 52 and 53, cannula 2220 may also contain a light guide 2266, which may be supported in lumen 2268. Light guide 2266 comprises one or more optical fibers formed of, for example, glass or other materials, such as plastic, known for that purpose. Distal tip of light guide 2266 is configured for light projection, such that light provided at the proximal end of light guide 2266 is projected therefrom. An appropriate shape for such projection is a spherical shape, although other shapes and projection schemes, such as directional projection, fall within the purview of the invention. The source of light may be any conventional monochromatic (laser/LED) or polychromatic device 2270, and more than one light source with associated light guide can be used for color coding and providing a visual reference to different portions of the cannula 2220, depending on the colors of light used and

on the location of the projection terminus of the light guides. In this manner cannula 2220 can be visually guided through the patient's body, relying on the transmissivity of tissue to permit the location of the illuminated cannula in the patient's body. As will be appreciated, the location of the cannula 2220 can also be determined by examining the pressure waveform detected by the pressure transducers 2224, 2232 and 2254. The physiological pressure waveform recorded by the transducers can be used to determine the location of cannula 2220 in relation to the valves of the patient's heart.

[00231] As will be appreciated by those skilled in the art, cannula 2220 may be provided with one or more preformed curves along its length to aid in its manipulation through the patient's vasculature. Multiple curves may be disposed along the same plane or in different planes, depending on the application.

[00232] An additional feature in accordance with the invention is the use of radiopaque markings (not shown) anywhere along the cannula body. Such markings render portions of the cannula 2220 visible to x-ray radiation for visualizing the cannula during its use.

[00233] The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to those skilled in the art that modifications thereto can be made without departure from the spirit and scope of the invention. It will also be apparent that all devices and methods herein disclosed will adapt equally to animal use as well as human use.

ABSTRACT OF U.S. SERIAL NO. 09/280,970

[00234] A cannula is provided with one or more pressure transducers for measuring fluid pressure interiorly or exteriorly of the cannula. The pressure transducers may be mounted integrally with the tubular wall defining the main lumen of the cannula, or they may comprise differential pressure transducers mounted in dedicated lumens in communication with the main lumen. The pressure measurements from the transducers is used to determine fluid flow rate.

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

RELATED APPLICATIONS

[0001] This application is a divisional of co-pending U.S. Patent Application Serial No. 14/966,669, filed December 11, 2015, which is a divisional of U.S. Patent Application Serial No. 14/543,815, filed November 17, 2014 (now U.S. Patent 9,327,068, issued May 3, 2016), which is a continuation of U.S. Patent Application Serial No. 12/772,810, filed May 3, 2010 (now U.S. Patent 8,888,728, issued November 18, 2014), which is a continuation of U.S. Patent Application Serial No. 11/375,926, filed March 15, 2006 (now U.S. Patent No. 7,731,675, issued June 8, 2010), which is a divisional of U.S. Patent Application Serial No. 10/070,178, filed July 19, 2002, (now U.S. Pat. No. 7,022,100, issued April 4, 2006) which claims the benefit of PCT/US00/24515 filed September 1, 2000, which claims the benefit of provisional U.S. Patent Application Serial No. 60/152,249 filed September 3, 1999. We hereby claim priority to the aforementioned application(s) and also incorporate herein by reference each of the afore-listed patents and applications in their entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to blood pumps and, more particularly, to an improved intra-vascular blood pump having a guide mechanism which provides the ability to selectively guide the intravascular pump to a desired location within a patient's circulatory system.

DESCRIPTION OF RELATED ART

[0003] Over the years, various types of blood pumps have been developed for the purpose of augmenting or replacing the blood pumping action of damaged or diseased hearts. Blood pumps are commonly used in three situations: (1) for acute support during cardio-pulmonary operations; (2) for short-term support while awaiting recovery of the heart from surgery; or (3) as a bridge to keep a patient alive while awaiting heart transplantation. The pumps may be

designed to provide right and/or left ventricular assist, although left ventricle assist is the most common application in that it is far more common for the left ventricle to become diseased or damaged than it is for the right ventricle.

[0004] Blood pumps must provide leak-free operation and must avoid contamination of the fluid by the pump components and the external environment. Such pumps must also pump the fluid at a suitable rate without applying excessive Reynolds shear stress to the fluid. It is well known to those skilled in the art that lysis or cell destruction may result from application of shear stress to cell membranes. Red blood cells are particularly susceptible to shear stress damage as their cell membranes do not include a reinforcing cytoskeleton to maintain cell shape. Lysis of white blood cells and platelets also occurs upon application of high shear stress. Lysis of red blood cells can result in release of cell contents which trigger subsequent platelet aggregation. Sublytic shear stress leads to cellular alterations and direct activation and aggregation of platelets and white blood cells.

[0005] Intravascular blood pumps comprise miniaturized blood pumps capable of being percutaneously or surgically introduced into the vascular system of a patient, typically to provide left and/or right heart support. One type of intravascular pump is an axial flow blood pump comprising a cable-mounted rotor surrounded by a protective shroud. The pump, along with the rotor and shroud, are mounted at the end of an elongated flexible catheter. The catheter is inserted into the aorta from a remote entry point, such as an incision below the groin that provides access into a femoral artery. The catheter then passes through the descending aorta until it reaches the ascending aorta, near the heart. The catheter device encloses a rotating drive cable which is coupled to the impeller blade at one end, and which emerges from the exposed end of the catheter, near the patient's groin, at the other end. When the exposed end of the drive cable is mechanically rotated, using a device located outside the patient's body, it conveys the rotational force through the length of the catheter, causing the impeller to spin at high speed near the heart. This type of blood pump finds particular application in providing ventricular assist during surgery or providing temporary bridging support to help a patient survive a crisis.

[0006] While generally effective in providing ventricular assisting functions, prior art intravascular blood pumps nonetheless suffer various drawbacks. A significant drawback is that prior art intravascular blood pumps are difficult to guide into the appropriate position within the circulatory system of a patient. This is due largely to the fact that the elongated catheter is incapable of providing the degree of control necessary to easily negotiate the pump through the tortuous pathways leading up to and into the heart. When attempting to place the blood pump in a trans-valvular configuration (with the inlet in the left ventricle and the pump outlet in the ascending aorta), the natural tendency of the catheter to stay straight may cause the pump to be inadvertently placed in the carotid ostia, which can be dangerous if the pump is operated to withdraw blood from the brain.

[0007] To overcome these difficulties, certain guide mechanisms may be employed to assist the physician placing the pump in the appropriate position within the circulatory system. One type of supplemental guide mechanism is a guide catheter. Guide catheters are designed with certain guidability characteristics such that physicians can selectively position them within the vasculature or heart with relative ease. A central lumen is provided within the guide catheter such that the intravascular pump may be introduced therein and guided while it is advanced towards the predetermined circulatory site. While generally effective at providing a guiding feature for such intravascular blood pumps, employing such supplemental guide mechanisms is nonetheless disadvantageous in that they consume valuable space within the vessels. A guide catheter, for example, would necessarily be larger in diameter than the diameter of the pump and protective shroud in order to provide adequate passage of those components. As will be appreciated, this restricts the amount of space available for blood to flow within the particular vessel, and increases the size of the required puncture wound for accessing the vessel.

[0008] The present invention is directed at eliminating and/or reducing the effects of the foregoing drawbacks of prior art intravascular blood pumps.

SUMMARY OF THE INVENTION

[0009] The present invention overcomes the drawbacks of the prior art by providing an improved intravascular blood pump equipped with integrated features for selectively guiding the intravascular blood pump to a predetermined location in the patient's circulatory system, i.e. heart and/or vasculature. In so doing, the intravascular blood pump of the present invention eliminates the need for supplemental guiding mechanisms, such as a separate, large diameter guide catheter as used in the prior art.

[0010] In a first broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and an "over-the-wire" type guide mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient. To accomplish this, a central lumen is formed through at least a portion of the intravascular blood pump system such that a guide element, such as a guide wire, may be progressed therethrough and advanced to the predetermined location in the circulatory system of the patient. After the guide element is advanced to this desired location, the intravascular blood pump and cannula may thereafter be advanced along the guide element to the desired location.

[0011] In a second broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and a "side-rigger" or "rapid exchange" type guide mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient. To accomplish this, a side lumen is formed along a length of at least one of the intravascular blood pump and the cannula. A guide element, such as a guide wire, may be advanced to the predetermined location in the circulatory system of the patient. After the guide element is advanced to this desired location, the intravascular blood pump and cannula may thereafter be advanced along the guide element to the desired location.

[0012] In a third broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and a "guide catheter" type guide mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient.

The pump system of this broad aspect includes a conduit assembly and a separate pump assembly. The conduit assembly includes a guide catheter, a rotor shroud, and a cannula, with the cannula and guide catheter disposed on either side of the rotor shroud. The pump assembly includes a rotor, a drive member coupled to the rotor, and a pump disposed between the rotor and the drive member. The guide catheter is dimensioned to receive and guide the pump assembly to the point where the rotor docks within the rotor shroud so as to form an operational blood pump. This configuration allows the conduit assembly to be precisely and efficiently guided into a desired position within the body through the use of conventional guiding techniques well known in interventional cardiology. The pump assembly may thereafter be introduced into and guided within the conduit until the pump assembly is docked within the rotor shroud. This dual construction arrangement provides improved placement of the pump assembly by using the conduit as a guiding mechanism.

[0013] The foregoing broad aspects of the present invention may be manifested according to the following recitations:

[0014] According to a first broad recitation of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto, and a guide mechanism adapted to guide the intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient.

[0015] In a further embodiment, the intravascular blood pump includes a rotor, a shroud for receiving the rotor, and a drive cable coupled to the rotor for driving the rotor within the shroud.

[0016] In a further embodiment, the cannula is coupled to the shroud of the intravascular blood pump.

[0017] In a further embodiment, the guide mechanism comprises a guide catheter coupled to the shroud.

[0018] In a further embodiment, the guide catheter may be used to guide the shroud and cannula to the predetermined location within the circulatory system of the patient, after which point the rotor and drive cable of the intravascular blood pump may be docked within the shroud for pump operation.

[0019] In a further embodiment, the drive cable sheath is provided having a central lumen for receiving the drive cable, and wherein a purge fluid delivery system is coupled to the drive cable sheath to deliver purge fluid to the rotor.

[0020] In a further embodiment, the drive cable sheath includes at least one side lumen for delivering the purge fluid towards the rotor.

[0021] In a further embodiment, a portion of the purge fluid is delivered through the at least one side lumen and past the rotor, and a portion of purge fluid is rerouted back from the rotor through the central lumen of the drive cable.

[0022] In a further embodiment, a perfusion assembly is provided communicatively coupled to the guide catheter for selectively rerouting blood from within the guide catheter to a point downstream from the introduction site of the guide catheter into the vasculature of the patient.

[0023] In a further embodiment, the perfusion assembly includes a first conduit communicatively coupled to the guide catheter, a second conduit dimensioned to be introduced into the vasculature of the patient, and a selectively operable valve disposed in between the first conduit and the second conduit.

[0024] In a further embodiment, a blood pressure detection mechanism is provided to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.

[0025] In a further embodiment, the blood pressure detection mechanism comprises at least one of fluid filled column disposed within at least a portion of the cannula, a piezoelectric element coupled to at least one of the intravascular blood pump and cannula, and a strain gauge coupled to at least one of the intravascular blood pump and cannula.

[0026] In a further embodiment, the blood pressure detection mechanism involves calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive the rotor.

[0027] In a further embodiment, the guide mechanism comprises a guide element disposed at least partially within the cannula.

[0028] In a further embodiment, the guide element comprises a guide wire for passage through a side lumen formed in the cannula.

[0029] In a further embodiment, the guide element comprises a selectively deformable element disposed at least partially within the cannula.

[0030] In a further embodiment, the intravascular blood pump and cannula may be selectively advanced to the predetermined location within the vasculature of the patient by first passing the guide wire to the predetermined location and thereafter sliding the intravascular blood pump and cannula along the guide wire to the predetermined location.

[0031] In a further embodiment, the guide element comprises a guide wire for passage through a lumen extending through the drive cable and rotor.

[0032] In a further embodiment, the intravascular blood-pump and cannula may be selectively advanced to the predetermined location within the vasculature of the patient by first passing the guide wire to the predetermined location and thereafter sliding the intravascular blood pump and cannula along the guide wire to the predetermine location.

[0033] In a further embodiment, the guide mechanism further includes guide element for passage through the guide catheter to facilitate placement of the shroud and the cannula at the predetermined location within the vasculature of the patient.

[0034] In a further embodiment, the guide mechanism further includes a guide element for passage through a side lumen formed along at least a portion of the guide catheter.

[0035] In a further embodiment, the guide element comprises at least one of a guide wire and a balloon catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

[0037] FIG. 1 is a partial sectional view of a human heart illustrating an intravascular blood pump system having an "over-the-wire" type guide mechanism according to a first broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

[0038] FIG. 2 is side view of the guidable intravascular blood pump system of the type shown in FIG. 1 including a motor coupler and purge fluid delivery system according to an exemplary embodiment of the present invention;

[0039] FIG. 3 is a cross-sectional view illustrating an exemplary construction of the blood pump, drive cable assembly, and cannula of the intravascular blood pump system according to the first broad aspect of the present invention;

[0040] FIG. 4 is a cross-sectional view taken along lines 4-4 of FIG. 3 illustrating an exemplary construction of the drive cable assembly and guide mechanism according to the first broad aspect of the present invention;

[0041] FIG. 5 is a cross-sectional view illustrating an exemplary construction of the motor coupler and purge fluid delivery system according to the first broad aspect of the present invention;

[0042] FIG. 6 is a partial sectional view of a human heart illustrating an intravascular blood pump system having a "rapid exchange" or "side-rigger" type guide mechanism according to a second broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

[0043] FIG. 7 is side view of the guidable intravascular blood pump system of the type shown in FIG. 6 including a motor coupler and purge fluid delivery system according to an exemplary embodiment of the present invention;

[0044] FIG. 8 is a cross-sectional view taken along lines 8-8 of FIG. 7 illustrating the "side-rigger" or "rapid exchange" type guide mechanism according to the second broad aspect of the present invention;

[0045] FIG. 9 is a cross-sectional view of the type shown in FIG. 8 illustrating an alternate configuration of the guide mechanism according to the second broad aspect of the present invention;

[0046] FIG. 10 is a partial sectional view of a human heart illustrating an intravascular blood pump system having a "guide catheter" type guide mechanism according to a third broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

[0047] FIG. 11 is a schematic view of a human being illustrating the intravascular blood pump system of the type shown in FIG. 10 inserted through the femoral artery and including an optional perfusion assembly for perfusing the vasculature downstream from the incision site where guide catheter enters the femoral artery;

[0048] FIG. 12 is a side view of the intravascular blood pump system shown in FIGS. 10-11 illustrating the separable nature of a pump assembly and a conduit assembly which collectively form the intravascular blood pump system according to the third broad aspect of the present invention;

[0049] FIG. 13 is a side view illustrating the intravascular blood pump system shown in FIG. 12 with the pump assembly docked into the conduit assembly according to the third broad aspect of the present invention;

[0050] FIG. 14 is a cross-sectional view illustrating an exemplary construction of the blood pump, drive cable assembly, cannula, and guide catheter of the intravascular blood pump system shown in FIG. 13;

[0051] FIG. 15 is a cross-sectional view taken along lines 15-15 of FIG. 14 illustrating an exemplary construction of the drive cable assembly and guide catheter according to the third broad aspect of the present invention;

[0052] FIG. 16 is a cross-sectional view illustrating an exemplary construction of the motor coupler, purge fluid delivery system, and a proximal portion of the guide catheter biasing assembly according to the third broad aspect of the present invention;

[0053] FIG. 17 is a cross-sectional view illustrating an exemplary construction of the perfusion assembly and a distal portion of the guide catheter biasing assembly according to the third broad aspect of the present invention;

[0054] FIG. 18 is a cross-sectional view of an intravascular blood pump system of the type shown in FIGS. 12-13 having an alternate configuration for docking the rotor within the shroud according to the principles of the present invention; and

[0055] FIG. 19 is a partial sectional view of a human heart illustrating an alternate intravascular blood pump system having an "over-the-wire" type guide mechanism according to the first broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide right-heart assist.

[0056] FIG. 20 corresponds to Figure 1 of U.S. Serial No. 09/280,988, and is a schematic side view of a steerable cannula in the undeformed state in accordance with the first embodiment of U.S. Serial No. 09/280,988;

[0057] FIG. 21 corresponds to Figure 2 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view of the steerable cannula of FIG. 20 taken along line A-A;

[0058] FIG. 22 corresponds to Figure 3 of U.S. Serial No. 09/280,988, and is a schematic side view of the steerable cannula in the deformed state in accordance with the first embodiment of U.S. Serial No. 09/280,988;

[0059] FIG. 23 corresponds to Figure 4 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view of a steerable cannula having two cables in accordance with a second embodiment of U.S. Serial No. 09/280,988;

[0060] FIG. 24 corresponds to Figure 5 of U.S. Serial No. 09/280,988, and is a schematic side view of a steerable cannula having a reinforcing wire in accordance with a third embodiment of U.S. Serial No. 09/280,988;

[0061] FIG. 25 corresponds to Figure 6 of U.S. Serial No. 09/280,988, and is a schematic cut-away view of a steerable cannula in accordance with a fourth embodiment of U.S. Serial No. 09/280,988;

[0062] FIG. 26 corresponds to Figure 7 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view taken along line B-B of FIG. 25;

[0063] FIG. 27 corresponds to Figure 8 of U.S. Serial No. 09/280,988, and is a schematic side view of a steerable cannula having a preformed curve and an inflatable balloon formed at a distal end thereof in accordance with a fifth embodiment of U.S. Serial No. 09/280,988;

[0064] FIG. 28 corresponds to Figure 9 of U.S. Serial No. 09/280,988, and is a schematic side view of the inflatable balloon of a fifth embodiment of U.S. Serial No. 09/280,988, wherein the balloon is shown in the inflated state;

[0065] FIG. 29 corresponds to Figure 10 of U.S. Serial No. 09/280,988, and is a schematic cross-sectional view taken along line C-C of FIG. 28;

[0066] FIG. 30 corresponds to Figure 11 of U.S. Serial No. 09/280,988, and is a schematic view showing a steerable cannula having a pigtail distal tip configuration in accordance with a sixth embodiment of U.S. Serial No. 09/280,988;

[0067] FIG. 31 corresponds to Figure 12 of U.S. Serial No. 09/280,988, and is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with a seventh embodiment of U.S. Serial No. 09/280,988;

[0068] FIG. 32 corresponds to Figure 13 of U.S. Serial No. 09/280,988, and is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with an eighth embodiment of U.S. Serial No. 09/280,988;

[0069] FIG. 33 corresponds to Figure 14 of U.S. Serial No. 09/280,988, and is a schematic side view showing a steerable cannula used in a co-axial configuration in accordance with a ninth embodiment of U.S. Serial No. 09/280,988, wherein the steerable cannula is advanced to a first relative position;

[0070] FIG. 34 corresponds to Figure 15 of U.S. Serial No. 09/280,988, and is a schematic side view showing a steerable cannula of FIG. 33, wherein the steerable cannula is advanced to a second relative position; and

[0071] FIG. 35 corresponds to Figure 16 of U.S. Serial No. 09/280,988, and is a schematic side view of a configuration in accordance with a tenth embodiment of U.S. Serial No. 09/280,988.

[0072] FIG. 36 corresponds to Figure 1 of U.S. Serial No. 09/280,970, and is a schematic side view of a first embodiment of U.S. Serial No. 09/280,970;

[0073] FIG. 37 corresponds to Figure 2 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line D-D of FIG. 36;

[0074] FIG. 38 corresponds to Figure 3 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line E-E of FIG. 36;

[0075] FIG. 39 corresponds to Figure 4 of U.S. Serial No. 09/280,970, and is a schematic view of a cannula in accordance with an embodiment in a surgical application;

[0076] FIG. 40 corresponds to Figure 5 of U.S. Serial No. 09/280,970, and is a schematic partial cut-away side view of a second embodiment of U.S. Serial No. 09/280,970;

[0077] FIG. 41 corresponds to Figure 6 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line F-F of FIG. 40;

[0078] FIG. 42 corresponds to Figure 7 of U.S. Serial No. 09/280,970, and is a schematic side view of a third embodiment of U.S. Serial No. 09/280,970;

[0079] FIG. 43 corresponds to Figure 8 of U.S. Serial No. 09/280,970, and is a schematic side view of a fourth embodiment of U.S. Serial No. 09/280,970;

[0080] FIG. 44 corresponds to Figure 9 of U.S. Serial No. 09/280,970, and is a schematic side view of a fifth embodiment of U.S. Serial No. 09/280,970;

[0081] FIG. 45 corresponds to Figure 10 of U.S. Serial No. 09/280,970, and is a schematic side view of a sixth embodiment of U.S. Serial No. 09/280,970;

[0082] FIG. 46 corresponds to Figure 11 of U.S. Serial No. 09/280,970, and is a schematic cross sectional view taken along line G-G of FIG. 45;

[0083] FIG. 47 corresponds to Figure 12 of U.S. Serial No. 09/280,970, and is a schematic side view of a seventh embodiment of U.S. Serial No. 09/280,970;

[0084] FIGS. 48 and 49 correspond to Figures 13 and 14, respectively, of U.S. Serial No. 09/280,970, and are schematic side views of an eighth embodiment of U.S. Serial No. 09/280,970;

[0085] FIG. 50 corresponds to Figure 15 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line H-H of FIG. 49;

[0086] FIG. 51 corresponds to Figure 16 of U.S. Serial No. 09/280,970, and is a schematic side view of a ninth embodiment of U.S. Serial No. 09/280,970;

[0087] FIG. 52 corresponds to Figure 17 of U.S. Serial No. 09/280,970, and is a schematic side view of a tenth embodiment of U.S. Serial No. 09/280,970;

[0088] FIG. 53 corresponds to Figure 18 of U.S. Serial No. 09/280,970, and is a schematic cross-sectional view taken along line K-K of FIG. 52; and

[0089] FIG. 54 corresponds to Figure 19 of U.S. Serial No. 09/280,970, and is a schematic side view of an eleventh embodiment of U.S. Serial No. 09/280,970.

DETAILED DESCRIPTION OF THE INVENTION

[0090] Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation may be described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure.

[0091] The present invention involves an intravascular pump system for use in a number of broad ranging applications involving the augmentation of blood flow within the circulatory

system of a patient. As will be described below, the intravascular blood pump system of the present invention overcomes the drawbacks of the prior art by providing a guide mechanism as part of the intravascular blood pump. This advantageously allows the intravascular blood pump to be selectively guided to a predetermined location within the circulatory system of a patient without the need for bulky supplemental guide mechanisms, such as a separate guide catheter.

[0092] The intravascular pump assembly of the present invention is particularly suited for trans-valvular use, such as for left and/or right ventricular assist procedures. By way of example only, such ventricular assist procedures may be employed in cardiac operations including, but not limited to, coronary bypass graft (CABG), cardio-pulmonary bypass (CPB), open chest and closed chest (minimally invasive) surgery, bridge-to-transplant and/or failure-to-wean-from-bypass situations. It is to be readily understood, however, that the intravascular blood pump assembly and methods of the present invention are not to be limited to such applications. Moreover, while illustrated and described largely with reference to left-heart assist applications, it is to be readily understood that the principles of the present invention apply equally with regard to right-heart assist application, which are contemplated as within the scope of the present invention. These and other variations and additional features will be described throughout.

[0093] Referring to FIG. 1, shown is a guidable intra-vascular blood pump system 10 according to a first broad aspect of the present invention shown, by way of example only, in a left-heart assist configuration within a human heart. The system 10 includes an intravascular blood pump 12, a cannula 14, and an "over-the-wire" type guide mechanism 16. A drive cable assembly 18 and a motor assembly 20 are provided to drive the intravascular blood pump 12. The "over-the-wire" guide mechanism 16 comprises a suitable guide element dimensioned to pass slideably through a central lumen extending through the drive cable 18, blood pump 12, and cannula 14. Suitable guide elements may include any number of conventional guiding devices, including but limited to those employed in cardiology. By way of example only, the guide element is shown as a guide wire 22. According to the present invention, the "over-the-wire" guide mechanism 16 provides the ability to selectively guide the blood pump 12 and

cannula 14 to a predetermined position in the circulatory system of a patient, such as the trans-valvular position shown.

[0094] To accomplish this, the guide wire 22 is first introduced into the vascular system of a patient through any suitable access point, such as through the use of the well known Seldinger technique. The guide wire 22 can then be advanced within the patient to a desired location within the circulatory system of the patient. This may be done using the control features of the guide wire 22 itself, or may be facilitated through the use of any number of supplemental guidance mechanisms or techniques to ensure the proper and efficient placement of the guide wire 22. Such supplemental guidance techniques may include, but are not necessarily limited to, guide catheters and/or techniques involving ultra-sound or flouroscopy. Once the guide wire 22 is positioned at the desired location (such as in left ventricle as shown), the blood pump 12 and cannula 14 may thereafter be advanced along the guide wire 22 and positioned in the trans-valvular configuration shown. Under the operation of the motor assembly 20, the blood pump 12 may be used for left-heart assist by selectively withdrawing blood from the left ventricle (through the interior of the cannula 14) for delivery outward through outflow apertures formed in the blood pump 12. This outflow from the blood pump 12 flows along the exterior of the drive cable assembly 18 in a substantially axial fashion for arterial distribution throughout the body.

[0095] Referring to FIGS. 2-5, an exemplary embodiment of the intravascular blood pump system 10 of FIG. 1 will now be described. As shown in FIG. 2, the intravascular blood pump system 10 includes a coupler 24 and, as will be described in greater detail below, a purge fluid delivery system 26 for providing a two-way fluid flow within the drive cable assembly 18 during pump operation. The purge fluid delivery system 26 includes a fluid inlet conduit 28 for introducing pressurized purge fluid from a fluid source (not shown) for delivery into the blood pump 12, and a fluid outlet conduit 30 to withdraw a return flow of purge fluid from the blood pump 12. The motor coupler 24 establishes a mechanical connection between a motor (not shown) and a drive cable (not shown) for providing motive force to the blood pump 12 for pump operation. The drive cable assembly 18 includes a drive cable sheath 32 which, in addition to serving a purge fluid delivery function, also serves as a protective housing for the

drive cable (not shown). Although shown in broken form for clarity, it will be appreciated that the drive cable assembly 18 (and all components thereof) may be provided in any suitable length sufficient for intravascular applications. That is to say, the length of the drive cable assembly 18 must be enough to reach between the motor coupler 24 and purge fluid delivery system 26, located outside the patient, and the desired location within the patient's circulatory system where the blood pump 12 is to be positioned.

[0096] The intravascular blood pump 12 is shown (by way of example only) as an axial flow intravascular blood pump. The blood pump 12 includes pump body 34, a rotor shroud 36 having flow ports 38, and an internally disposed rotor (not shown) having a shaft rotatably disposed within the pump body 34 and an impeller rotatably disposed within the rotor shroud 36. The cannula 14 is fixedly attached to the rotor shroud 36 and may extend any suitable length therefrom depending upon the particular intravascular application. The cannula 14 preferably includes a plurality of ports or fenestrations 40 about its distal region, as well as an end port 42, which allow for the ingress or egress of blood into or from the cannula 14 depending upon the operation of the blood pump 12. That is to say, if the pump 12 is configured for left-heart assist as shown in FIG. 1, then the ports 40, 42 will allow the ingress of blood into the cannula 14 from the left ventricle. If, on the other hand, the blood pump 12 is configured for right-heart assist (i.e. with the pump 12 in the right atrium and the distal end of the cannula 14 located within the pulmonary artery), then the ports 40, 42 will allow the egress of blood from the cannula 14 into the pulmonary artery. (Details on right-heart assist applications will be discussed in greater detail below.) The pump 12 and cannula 14 may be dimensioned to any suitable diameter for intravascular applications. For example, the range of sizes may include, but is not necessarily limited to, 9 French to 30 French, although the range is more preferably from 14 French to 24 French, and most preferably from 18 French to 20 French.

[0097] The "over-the-wire" type guide mechanism 16 includes the guide wire 22 and, as will be explained in greater detail below, a central lumen extending through the cannula 14, blood pump 12, drive cable assembly 18, purge fluid delivery system 26, and motor coupler 24. As noted above, the central lumen is dimensioned to slideably receive the guide wire 22

such that the blood pump 12 and cannula 14 may be slideably advanced along the guide wire 22 to a desired location within the circulatory system of a patient after the guide wire 22 has been so positioned using conventional guidance techniques. It is to be readily understood that, while shown as a conventional guide wire 22, the guide element forming part of the guide mechanism 16 of the present invention may include any number of well known guidance mechanisms depending upon the application, including but not limited to balloon catheters, imaging wires, and guide catheters dimensioned to be slideably received through the central lumen. For example, although not appropriate for retrograde progression (such as the left-heart application shown in FIG. 1), a balloon catheter may be a suitable guidance mechanism for a right-heart assist application. In such a case, the balloon may be inflated and used as a "sail" to direct the catheter to a desired location (such as the pulmonary artery), after which point the blood pump 12 and cannula 14 can be advanced over the catheter to a trans-valvular configuration with the blood pump 12 in the right atrium and the ports 38, 40 of the cannula 14 in the pulmonary artery.

[0098] FIGS. 3 and 4 further detail the construction of the blood pump 12, cannula 14, drive cable assembly 18, and "over-the-wire" guide mechanism 16. The blood pump 12 includes a rotor 44 having a shaft 46 and an impeller 48. The shaft 46 is rotatably disposed within the pump body 34 via a bearing pack comprising, by way of example, ball bearing assemblies 50, 52 and spring 54. Ball bearings assemblies 50, 52 are well known in the art, each comprising an inner race which rotates along with the rotor shaft 46, an outer race which remains in a static and fixed position against the inner surface of the pump body 34, and a plurality of ball bearings disposed between the inner and outer races. The spring 54 biases each bearing assembly 50, 52 axially away from one another to reduce axial play during pump operation. The shaft 46 is generally hollow and dimensioned to receive a cable adapter 60 therein for the purpose of coupling the rotor 44 to a drive cable 62 forming part of the drive cable assembly 18. The drive cable 62 may be secured to the cable adapter 60 in any number of suitable fashions, including but not limited to the use of adhesives, crimping, and laser welding. These same techniques may be used to secure the cable adapter 60 within the shaft 46 of the rotor 44. A radial seal 64 is provided in between the wall of the pump body 34 and a distal stepped region 66 on the rotor shaft 46, the function of which will be described below.

[0099] The impeller 48 includes a hub 56 and a plurality of blades 58 extending therefrom. The hub 56 is generally conical and, according to the first broad aspect of the present invention, is hollow throughout to form part of the central lumen of the guide mechanism 16. In this regard, the hub 56 is preferably provided with a gasket or seal member 68 at its distal tip. The seal member 68 may be made of any suitable sealing material (including but not limited to silicone) such that the pump 12 and cannula 14 may be easily progressed along the guide wire 22 for delivery to a desired circulatory site. The seal member 68 should also be robust enough to prevent the ingress of blood into the interior of the rotor hub 56 during pump operation, whether the guide wire 22 remains in place or is fully withdrawn. The blades 58 are dimensioned to reside in close tolerance with the interior surface of the shroud 36. In operation, the blades 58 impart both an axial and radial vector on the blood which causes it to flow outward through the flow ports 38 formed in the shroud 36. As used herein, the term "axial flow" is deemed to include flow characteristics like that shown in FIG. 3, which include both an axial and slight radial component. It is to be readily appreciated that, although shown as an axial flow type, blood pump 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps without departing from the scope of the present invention.

[00100] The cannula 14 is coupled at its proximal end to the rotor shroud 36. This may be accomplished in any number of fashions, including but not limited to the use of adhesives. This may also be facilitated by dimensioning the shroud 36 to include a narrow inlet region 70 capable of being received flushly within the proximal end of the cannula 14. The inlet region 70 of the shroud 36 should preferably have a tapered interior surface for establishing a smooth flow transition between the cannula 14 and the region containing the impeller blades 58. Although shown as a single integral element, it is to be understood that the pump body 34 and shroud 36 may comprise two separate (and sometimes separable) components, the significance of which will become apparent below. The pump body 34 and shroud 36 may be constructed from any number of suitable materials, including but not limited to stainless steel or other medical grade compositions or alloys. The cannula 14 may also be constructed from any number of suitable materials, including but not limited to medical grade plastics. As shown,

the cannula 14 may also be fortified with spiral-wound reinforcement wire 72 within the walls of the cannula 14.

[00101] The drive cable assembly 18 includes the drive cable 62 and the drive cable sheath 32. The drive cable 62 is coupled to the rotor 44 via the cable adapter 60. The drive cable sheath 32 includes a central lumen 74 and a plurality of side lumens 76. The central lumen 74 serves as a protective covering for the drive cable 62. The central lumen 74, along with the side lumens 76, also forms part of the purge fluid delivery system 26 shown above in FIG. 2, which will be described in greater detail below. The side lumens 76 are provided in fluid communication with the fluid inlet conduit 28, while the central lumen 74 is provided in fluid communication with the fluid outlet conduit 30. The side lumens 76 are thus configured to deliver purge, fluid into the pump 12, while the central lumen 74 is configured to transport purge fluid away from the pump 12 along the length of the drive cable 62.

[00102] The pressurized purge fluid within the side lumens 76 may take one of two flow paths upon entry into the pump 12. One flow path passes through the interior of the pump 12 and onward past the radial seal 64 to prevent the ingress of blood into the pump body 34 during pump operation. More specifically, the purge fluid flows distally around the cable adapter 60, through the ball bearing assemblies 50, 52, and onward past the radial seal 64. This egress of purge fluid past the radial seal 64 can be controlled to effectively thwart the ingress of blood past the radial seal 64, which might otherwise cause clotting and/or pump damage. The other flow path is directed back out the central lumen 74 for delivery to the fluid outlet conduit 30. In so doing, this flow path bathes the components of the pump 12 and/or drive cable 62 and thereby reduces frictional heating within the pump 12 and/or the central lumen 74 of the sheath 32 during pump operation.

[00103] The "over-the-wire" guide mechanism 16 includes a central lumen through which the guide wire 22 may extend for the purpose of slideably advancing the blood pump 12 and cannula 14 into a desired position within the circulatory system of a patient. In the embodiment shown, this central lumen is established by forming and co-aligning the individual central lumens within each of the drive cable 62, the cable adapter 60, the shaft 46

and hub 56 of the rotor 44, and the cannula 14. In this regard, the drive cable 62 is preferably of wound-wire construction having a central lumen formed therein. The central lumens within the cable adapter 60, rotor 44, and gasket 68 may be formed via machining or molding processes. These central lumens should preferably be sized such that they permit the slideable passage of the pump 12 and cannula 14 therealong, but do not interfere with or constrain the guide wire 22 to cause inadvertent rotation of the guide wire 22 during pump operation. As noted above, it is also contemplated to remove the guide wire 22 after the pump 12 and cannula 14 are properly positioned in the patient. In this case, the gasket or seal 68 on the hub 56 should be robust enough to reseal after the guide wire 22 is withdrawn and prevent the ingress of blood into the interior of the rotor 44.

[00104] Referring to FIG. 5, the motor coupler 24 includes a housing 78, a drive shaft adapter 80, and a bearing assembly 82. The drive shaft adapter 80 includes a drive shaft coupler 84 dimensioned to receive a drive shaft of a motor (not shown), and a drive cable coupler 86 dimensioned to receive the drive cable 62. Any of a variety of attachment techniques may be employed to securely fasten the drive cable 62 to the drive cable coupler 86, including but not limited to adhesives, crimping, and laser welding. The drive shaft adapter 80 is rotatably disposed within the housing 78 by the bearing assembly 82. The bearing assembly 82 includes a sleeve 88 (which may alternatively be formed as an integral part of the housing 78) for retaining a pair of ball bearing assemblies 90, 92 and a spring 94 of the type described above. That is, each bearing assembly 90, 92 generally comprises an inner race which rotates along with the drive shaft adapter 80, an outer race which remains in a static and fixed position against the inner surface of the retaining sleeve 88, and a plurality of ball bearings disposed between the inner and outer races. The spring 94 is provided to bias each bearing assembly 90, 92 axially away from one another to reduce axial play during operation.

[00105] The purge fluid delivery system 26 includes a housing 96 having a central lumen 98, an inflow port 100, and an outflow port 102. The housing 96 is also dimensioned to matingly receive a portion of the motor coupler 24. In this regard, a seal element 104 is provided sandwiched in between the housing 96 and housing 78 and including an aperture which extends about the drive shaft adapter 80 as it exits the housing 78 to prevent the ingress

of purge fluid into the motor coupler 24. A fluid guide structure 106 is also provided within the central lumen 98 for the purpose of separating the inflow and outflow ports 100, 102. The fluid guide structure 106 includes a central lumen 108 through which the drive cable 62 extends, and an elevated portion 110 that retains an O-ring 112 against the inner surface of the central lumen 98 of the housing 96. The drive cable sheath 32 is secured to the housing 96 such that the inflow port 100 is communicatively coupled to the side lumens 76, and the outflow port 102 is communicatively coupled to the central lumen 74. In this fashion, pressurized purge fluid may be introduced through the inflow port 100 via inflow conduit 28, and removed through the outflow port 102 via outflow conduit 30. By way of example, the inflow conduit 28 and outflow conduit 30 may be coupled to their respective ports 100, 102 via barbed connectors 114. Similarly, the inflow and outflow conduits 28, 30 may be equipped with any number of suitable connectors (such as those illustrated by way of example in FIG. 2) for establishing fluid communication with a source of pressurized fluid (not shown). The pressurized fluid source (not shown) may include, but is not necessarily limited to, the use of a syringe, an indeflator, a fluid delivery pump, or an accumulator arrangement to provide the requisite delivery of pressurized fluid. The purge fluid delivery system 26 thus provides a two-way transmission of purge fluid within the drive cable sheath 32 for the purposes of cooling the blood pump 12 and preventing the ingress of blood past the radial seal 64 and into blood pump 12.

[00106] Referring to FIG. 6, shown is a guidable intra-vascular blood pump system 120 according to a second broad aspect of the present invention. As will be described hereinafter, the intravascular blood pump system 120 differs from the intravascular blood pump system 10 described above only as to the type of guide mechanism employed. In the interest of clarity and consistency, then, like reference numerals will be used to denote like elements and distinctions pointed out where necessary. Moreover, due to the commonality of principles employed in both intravascular blood pump systems 10, 120, a discussion to the level of detail set forth above is not deemed necessary with regard to the intravascular blood pump system 120. Instead, those aspects in common with the intravascular blood pump 10 are hereby incorporated into the discussion of the intravascular blood pump system 120.

[00107] In its most general form, the intravascular blood pump system 120 of this second broad aspect of the present invention comprises the blood pump 12 and cannula 14 arrangement, wherein the cannula 14 is equipped with a "side-rigger" or "rapid exchange" guide mechanism 122. In an important aspect of the present invention, the "rapid exchange" or "side-rigger" guide mechanism 122 includes a guide carriage 124 formed along at least a portion of the cannula 14, and a suitable guide element (such as guide wire 22) dimensioned to pass slidably through a lumen (not shown) extending through the guide carriage 124. The "rapid exchange" guide mechanism 122 thereby provides the ability to selectively guide the blood pump 12 and cannula 14 to a predetermined position in the circulatory system of a patient in the manner described above. Namely, the guide wire 22 may be first introduced into the vascular system of a patient through any suitable access point and guided to a desired location within the circulatory system of the patient, i.e. the left ventricle as shown. The blood pump 12 and cannula 14 may thereafter be advanced along the guide wire 22 and positioned in the trans-valvular configuration shown for providing left-heart assist.

[00108] FIGS. 7-9 further illustrate the "side-rigger" or "rapid-exchange" guide mechanism 122 of this second broad aspect of the present invention. In a preferred embodiment, the "side-rigger" guide mechanism 122 includes a lumen 126 formed within the guide carriage 124. The guide carriage 124 is preferably formed as an integral extension of the wall of the cannula 14. FIGS. 7 and 8 comport with the embodiment shown in FIG. 6, namely illustrating the guide carriage 124 formed along the exterior surface of the cannula 14. FIG. 9 illustrates an alternate embodiment wherein the guide carriage 124 may be formed along the interior surface of the cannula 14. In either case, the guide wire 22 is advanced to a desired location in the vasculature of the patient, after which point the blood pump 12 and cannula 14 can be slidably advanced therealong for delivery to the desired location according to the present invention. The guide wire 22 may thereafter be withdrawn from the patient. If the guide carriage 124 is formed along the exterior surface of the cannula 14 (as shown in FIGS. 7-8), then the cannula 14 should preferably be positioned so that the guide carriage 124 does not extend in a trans-valvular fashion. For example, with reference to FIG. 6, the guide carriage 124 should be positioned wholly within the left ventricle such that the pulsatile blood

flow during beating heart procedures will not inadvertently pass through the side lumen 126 and pass through the aortic valve.

[00109] The intravascular blood pump system 120 is constructed in virtually the same manner as the intravascular blood pump system 10 shown and described above, with the exception of the location of the respective guide mechanisms 16, 122. More specifically, because the guide mechanism 122 is disposed along the side of the cannula 14, there is no need to form a central lumen extending through the blood pump 12, drive cable assembly 18, purge fluid delivery system 26, and motor coupler 24 as detailed above with regard to the intravascular blood pump system 10. As such, these components need not be specially machined or molded to include such central lumens as was required with the intravascular blood pump system 10 set forth above.

[00110] Referring to FIG. 10, shown is a guidable intravascular blood pump system 130 according to a third broad aspect of the present invention. Again, due to the commonality between many of the same components and features of the intravascular blood pump systems described above and the intravascular blood pump system 130, like reference numerals will be used to denote like elements and distinctions pointed out where necessary. As will be explained in greater detail below, the intravascular blood pump system 130 employs yet another unique and useful guide mechanism according to the present invention. However, because many of the same components are employed, a discussion to the level of detail set forth above is not deemed necessary with regard to the intravascular blood pump system 130. Instead, those aspects in common with the intravascular blood pumps described above are hereby incorporated into the discussion of the intravascular blood pump system 130.

[00111] In its most general form, the intravascular blood pump system 130 of this third broad aspect of the present invention comprises the blood pump 12 and cannula 14 arrangement, wherein a "guide catheter" 132 is provided as the guide mechanism for positioning the pump 12 and cannula 14 at a desired location within the circulatory system of the patient. More specifically, with brief reference to FIG. 12, the intravascular blood pump system 130 is formed in two separate assemblies according to the present invention: a conduit

assembly 134 and pump assembly 136. In its most basic form, the conduit assembly 134 comprises the guide catheter 132 and cannula 14 coupled to the rotor shroud 36. The pump assembly 136 is constructed such that the pump body 34 and rotor 44 can be disengaged from the rotor shroud 36 and removed entirely from the conduit assembly 134. Referring again to FIG. 10, this dual construction forms a significant feature of the present invention because it provides the ability to form the blood pump 12 at a desired location in a patient using two separate and distinct steps. The first step involves positioning the conduit assembly 134 (with the pump assembly 136 removed) within a patient such that the shroud 36 and cannula 14 are each disposed in a desired location, such as a trans-valvular configuration for cardiac assist procedures. In an important aspect, the task of positioning the conduit assembly 134 within the patient may be advantageously facilitated through the use of any number of well known guidance mechanisms, including but not limited to guide wires, balloon catheters, imaging wires, guide catheters, and/or techniques involving ultra-sound or flouroscopy. The second step in providing the intravascular blood pump system 130 of the present invention involves advancing the pump assembly 136 through the conduit assembly 134 such that the rotor 44 docks within the shroud 36 to form the pump 12 at the desired location.

[00112] By way of clarification, the term "cannula" is used to denote cannula 14 because it serves a primary purpose of transporting fluid into the blood pump 12, whereas the term "catheter" is used to denote the catheter 132 because it serves a primary purpose of guiding or directing devices or components (i.e. the pump assembly 136) to a desired location within the body. It is to be readily understood, however, that these terms are only used for convenience and in a general fashion such that the cannula 14 may serve certain guiding functions and the catheter 132 may serve certain fluid transportation functions without departing from the scope of the present invention. For example, the cannula 14 may be equipped with dedicated lumens to receive various guide mechanisms (such as guide wires, balloon catheters, selectively deformable elements such as Nitonol, etc). In similar fashion, the guide catheter 132 may be used to transport fluid to and/or from the patient, such as by providing apertures 138 along predetermined regions of the catheter 132.

[00113] FIG. 11 demonstrates a significant feature of the present invention involving the use of the guide catheter 132 to transport fluid to and/or from the patient. An optional perfusion assembly 140 is provided as part of the intravascular blood pump system 130 of the present invention. The perfusion assembly 140 includes a conduit 142 in fluid communication with the apertures 138, which in this case are formed near the distal region of the guide catheter 132 a short distance downstream from the blood pump 12. In use, blood will pass along the exterior of the guide catheter 132 for distribution throughout the body, as well as within the interior of the guide catheter 132 after passing into the apertures 138. The perfusion assembly 140 may then be employed to selectively reroute blood from within the guide catheter 132 to a point within the patient's vasculature downstream from the point where the guide catheter 132 enters the body. A hemostasis valve assembly 146 of the perfusion assembly 140 permits the drive cable assembly 18 to pass through to the purge fluid delivery system 26 while preventing blood flow other than into the perfusion assembly 140. A seal assembly 150 of the purge fluid delivery system 26 permits the drive cable 62 to pass through to the motor 20 while preventing the flow of purge fluid other than into and from the purge fluid delivery system 26. The perfusion assembly 140 includes a control mechanism 148 for selectively controlling the distribution of perfusion blood flow from the perfusion assembly 140 into the patient. This control mechanism 148 may be automatic based on certain feedback criteria or manually operated.

[00114] FIGS. 12-17 illustrate an exemplary construction of the intravascular blood pump system 130 according to the third broad aspect of the present invention. As shown in FIG. 12, the conduit assembly 134 may be selectively disengaged so as to remove the pump assembly 136 therefrom. According to the present invention, the conduit assembly 134 may be introduced (without the pump assembly 136) into the circulatory system of a patient and selectively guided such that the rotor shroud 36 and cannula 14 are positioned at a desired location. The pump assembly 136 can thereafter be selectively introduced into the conduit assembly 134. A challenge in such a "back-loading" arrangement is ensuring that the pump assembly 136 docks appropriately within the rotor shroud 36 and is maintained in proper engagement during operation of the resulting pump 12.

[00115] An exemplary docking arrangement will now be described with reference to FIG. 14. In a preferred embodiment, the rotor 44 may be properly and accurately docked within the shroud 36 by forming angled mating surfaces on corresponding portions of the shroud 36 and pump body 34. More specifically, an angled mating surface may be formed on the interior surface of the rotor shroud 36 along that portion extending proximally from the flow aperture 38. A corresponding angled mating surface may be provided along the exterior surface of the pump body 34 along a distal portion thereof. The mating surfaces shown in FIG. 14 may preferably be formed in the range from about 2 degrees to 10 degrees, and more preferably formed in the range from about 3 degrees to 6 degrees. Mating angles within these ranges are adequate to guide the distal end of the pump body 34 to a point generally flush with the proximal edge of the flow aperture 38 as shown in FIG. 14. In this fashion, the pump assembly 136 and the rotor shroud 36 combine to form the blood pump 12. More importantly, this docking is carried out such that the rotor 44 and rotor blades 58 are maintained in proper position for efficient and safe pump operation.

[00116] An exemplary biasing scheme for maintaining the pump assembly 136 in this docked relationship will now be described with reference to FIGS. 12-13 and 16-17. The conduit assembly 134 is preferably equipped with a male quick-connect coupling 152 capable of engaging with a female quick-connect coupling 154 forming part of the perfusion assembly 140 of the present invention. A bias spring 156 is provided in between the perfusion assembly 140 and the housing 96 of the purge fluid delivery system 26. The bias spring 156 is preferably dimensioned so as to be in tension when the male quick-connect 152 is engaged within the female quick-connect 154 as part of the docking process of the present invention. As such, the bias spring 156 serves to maintain the pump assembly 136 in the docked position within the rotor shroud 36. The bias spring 156 may be coupled to the housing 96 of the purge fluid delivery system 26 in any number of suitable fashions. One such coupling arrangement may comprise a female quick-connect coupling 158 attached to the housing 96 and a male quick-connect coupling 160 attached to the bias spring 156.

[00117] An exemplary embodiment of the perfusion assembly 140 is shown with reference to FIGS. 12-13 and 17. The perfusion assembly 140 shown includes the hemostasis valve 146

coupled to the female quick-connect coupling 154. A length of tubing 162 extends between the opposing barb connectors of the hemostasis valve 146 and the female quick-connect coupling 154. A continuous lumen is formed extending through the interior of the male quick-connect coupling 152, the female-quick-connect coupling 154, the tubing 162, and the hemostasis valve 146. The drive cable assembly 18 extends through this continuous lumen and exits through a Touehy-Borst hemostasis seal 164 which prevents the migration of blood out of the proximal end of the perfusion assembly 140. A side-port 166 is disposed in fluid communication with the central lumen of the perfusion assembly 140. In one embodiment, this side-port 166 may be equipped with a conduit 168 having a stop-cock 170 to selectively control the distribution of blood through a perfusion conduit (i.e. conduit 142 of FIG. 11) coupled to the stop-cock 170. It will be appreciated that this type of manual control system for selectively perfusing the patient may be replaced with control circuitry for automatically controlling the rate of perfusion. Such automatic perfusion may be based on control algorithms based on contemporaneous feedback or pre-programmed thresholds.

[00118] The foregoing discussion details a host of inventive aspects forming part of the present invention. It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concepts thereof. The following evidences, by way of example only, various additional aspects forming part of the present invention.

[00119] FIG. 18 illustrates an alternate configuration of the intravascular blood pump system 130 of the third broad aspect of the present invention having an alternate bearing assembly, purge fluid delivery, and docking scheme. The bearing assembly includes a seal spring 182 and a bearing assembly 180. The bearing assembly 180 includes an inner race 184, an outer race 186, and a plurality of balls 188 which enable the inner race 184 to rotate along with the rotor shaft 46 while the outer race 186 remains in a static and fixed position relative to an inner surface of the pump body 34. An O-ring 190 is disposed within a groove formed in the rotor shaft 46 so as to maintain the bearing assembly 180 against the seal spring 182. The O-ring 190 is further secured within the groove in the rotor shaft 46 via a contoured lip portion

extending from the distal end of the cable adapter 60. The proximal end of the cable adapter 60 flushly engages the drive cable 62.

[00120] The purge fluid delivery system of the embodiment shown in FIG. 18 provides for a one way delivery of purge fluid to the blood pump 12. That is, pressurized fluid (namely, fluid pressurized to some level elevated above the blood pressure in the surrounding vessel) is injected in between the drive cable 62 and the interior of the protective sheath 32 during operation. This serves to reduce any frictional heating that exists between the drive cable 62 and sheath 32. The pressurized fluid also flows through the interior of the pump 12 such that, if the seal at 192 is broken, the pressurized fluid will flow past the open seal 192 and onward through the blood flow ports 38 formed in the shroud 36. This serves to keep blood from entering the pump 12 in an effort to avoid clotting and/or damaging the pump 12.

[00121] The pump assembly 136 may be docked within the conduit assembly 134 in any number of different fashions without departing from the scope of the present invention. That is to say, the docking scheme shown in FIG. 18 is set forth by way of example only and is not to be deemed limiting or restrictive as to numerous ways to temporarily engage or "dock" the pump assembly 136 within the conduit assembly 134. The only requirement is that the pump assembly 136 and conduit assembly 134 dock such that the rotor 44 is disposed within the shroud 36 to provide the desired axial flow through the cannula 14 and out the shroud 36. The exemplary docking scheme involves forming an annular engagement groove 194 along the interior of the shroud 36, and forming a complementary annular ridge 196 along the exterior surface of the pump body 34. During insertion, the pump assembly 136 will be advanced into the conduit assembly 134 until the annular ridge 196 on the pump body 34 engages within the groove 194 formed in the shroud 36. This docking scheme is generally advantageous in that the engagement action between the annular ridge 196 and groove 194 will provide tactile feedback to the physician during the process of inserting the pump assembly 136 into the conduit assembly 134 such that the physician will be able to determine when the docking has been completed.

[00122] As will be appreciated by those skilled in the art, the location of the annular ridge 196 and engagement groove 194 may be varied such that they are disposed closer or farther away from the flow apertures 38. It may be advantageous to form these docking structures close to the flow apertures 38 in an effort to thwart the ingress of blood into the junction extending between the interior of the shroud 36 and the exterior surface of the pump body 34. It is also contemplated to employ selectively inflatable structures, such as balloons, in an effort to temporarily engage or dock the pump assembly 136 within the conduit assembly 134. In this regard, one or more lumens may be formed within the pump body 34 extending from the interior of the pump body 34 in fluid communication with a balloon disposed along the exterior surface of the pump body 34. The pressurized fluid flowing within the interior of the pump body 34 may then be used to inflate the balloon, which will then engage within an annular groove in the shroud 36, such as at 194. Of course, the engagement structures may also be reversed without departing from the scope of the present invention. For example, the shroud 36 may be equipped with a fluid delivery lumen therein for inflating a balloon disposed on the interior surface of the shroud 36, which may in turn be disposed within an annular engagement groove formed along the exterior surface of the pump body 34.

[00123] While this invention has been shown in use largely in during left-heart applications it is to be readily appreciated that this does not limit the applications of this invention for use in left heart support only. Rather, the guidable intravascular blood pump of the present invention can be utilized in right-heart support applications and a wide variety of other applications apparent to those skilled in the art. For example, with reference to FIG. 19, shown is an intravascular blood pump 200 (of the type shown and described above with reference to FIGS. 2-5) configured for use in a right-heart support application. In this embodiment, the intravascular blood pump system 200 is equipped, by way of example, with an "over-the-wire" guide mechanism 16 comprising a balloon catheter 202. It is to be readily appreciated that, although shown and described below in terms of an embodiment of the type shown in FIGS. 2-5, the intravascular blood pump systems 120, 130 disclosed herein may also be configured for use in right-heart applications. Such right-heart configurations, and others apparent to those skilled in the art based on the broad principles enumerated in this application, are contemplated as being within the scope of the present invention.

[00124] The intravascular blood pump system 200 is shown positioned within the heart, such as may be advantageous to provide right heart support during beating heart surgery. To position the guidable intravascular blood pump system 200 in the right heart according to the present invention, a suitable guide element (such as balloon catheter 202) is first advanced to a desired location within the heart via the "sail" action of an inflated balloon. After the balloon catheter 202 is located in the desired position (such as in the pulmonary artery as shown), the intravascular blood pump system 200 according to the present invention may be advanced over the balloon catheter 202 and guided into a desired arrangement. For right heart support, this would involve advanced into the pump 12 and cannula 14 overt the balloon catheter 202 until the fluid inlet 204 is disposed within the vena cava (or right atrium) and the fluid outlet 206 is positioned within the pulmonary artery. The pump 12 may then be selectively (i.e. automatically or on-demand) controlled to transport blood from the vena cava (or right atrium) in a trans-valvular fashion through the tricuspid valve, the right ventricle, and the pulmonary valve for deposit within the pulmonary artery. Providing right-heart support during beating heart surgery advantageously overcomes conditions where cardiac output may become compromised during beating heart surgery, such as when the heart is lifted to gain access to posterior vessels, thereby avoiding the need for cardiopulmonary bypass.

[00125] It is also contemplated as part of the present invention that the guidable intravascular blood pump systems can be introduced into the patient's vasculature to achieve the intravascular access into the right or left heart through any number of access points, including but not limited to the internal jugular vein, the brachiocephalic vein, carotid artery, axillary artery, femoral vein, femoral artery, and subclavian artery. The intravascular blood pump systems of the present invention may also be introduced via direct introduction, such as into the aorta, the atria, and the ventricles. As is well known in the art, such intravascular access may be achieved percutaneously through the use of the Seldinger technique or directly through the use of minimally invasive access techniques.

[00126] Those skilled in the art will also appreciate that, although shown and described above in terms of "axial flow," the present invention is not limited to the axial flow type

intravascular blood pumps. Rather, the intravascular blood pumps 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps, without departing from the scope of the present invention.

[00127] With regard to the embodiments shown in FIGS. 10-17, it is furthermore contemplated that the guide catheter 132 may be separable from the conduit assembly 134 after the pump assembly 136 is docked within the shroud 36 to form the pump 12 at the desired location within the circulatory system of the patient. This may be accomplished by providing the guide catheter 132 in a detachable fashion via any number of suitable arrangements. By removing the guide catheter 132 after the pump 12 assembled, wound management of the access point into the patient's vasculature may be improved. This is due, in part, to the substantial reduction in size of the device extending into the patient (i.e. the drive cable assembly 18 as opposed to the larger diameter guide catheter 132).

[00128] It is also contemplated to incorporate various pressure sensing and/or guidability features into at least one of the cannula, 14 and pump 12. Such features may include, but are not necessarily limited to, those shown and described in commonly-owned and co-pending U.S. Patent Application Ser. No. 09/280,988 (filed March 30, 1999) entitled "Steerable Cannula," and U.S. Patent Application Ser. No. 09/280,970 (filed March 30, 1999) entitled "Pressure Sensing Cannula," the disclosures of which are hereby expressly incorporated by reference as if set forth herein in their entirety and physically incorporated as sections of~~APPENDIX A and APPENDIX B respectively to~~ the present specification. These pressure sensing features may include, but are not necessarily limited to, the use of fluid-filled lumens, piezo-electric pressure sensing elements, strain gauges, and analysis of the torque/current relationship (based on the dynamic pressure differential between the inlet and outlet of the pump). The guidability features may include, but are not necessarily limited to, the use of side lumens and deformable materials (i.e. Nitonol).

[00129] Various pump and cannula arrangements have been described and shown above for providing right and/or left heart support wherein blood is deliberately re-routed through

and past the right and/or left ventricle in an effort to reduce the volume of blood to be pumped by the particular ventricle. While "unloading" the ventricles in this fashion is preferred in certain instances, it is to be readily understood that the pump and cannula arrangements described herein may also be employed to "preload" the ventricles. Ventricular preloading may be accomplished by positioning the outflow cannula from the pump into a given ventricle such that the pump may be employed to fill or preload the ventricle with blood. This may be particularly useful with the right ventricle. On occasion, the right ventricle is not supplied with sufficient levels of blood from the right atrium such that, upon contraction, the right ventricle delivers an insufficient quantity of blood to the pulmonary artery. This may result when the right ventricle and/or right atrium are in a stressed or distorted condition during surgery. Preloading overcomes this problem by actively supplying blood into the right ventricle, thereby facilitating the delivery of blood into the pulmonary artery. The same technique can be used to preload the left ventricle and thus facilitate the delivery of blood from the left ventricle into the aorta.

INCORPORATED EMBODIMENTS OF ~~APPENDIX A (~~U.S. SERIAL NO. 09/280,988~~)~~

[00130] STEERABLE CANNULA

BACKGROUND OF THE INVENTION

[00131] 1. Field of the Invention

The invention relates to vascular cannulas for use in medical procedures.

[00132] 2. Description of Related Art

[00133] In medical applications and specifically in surgery, the list of uses for cannulas is exhaustive. Cannulas are to be distinguished from catheters in that catheters generally have a substantially smaller fluid-carrying capacity are used primarily for sampling or measurement purposes or for delivery of small quantities of fluid, whereas cannulas are generally larger and are used for volumetric fluid transfer. One application of cannulas involves the augmenting or supplementing of pulmonary blood flow through the beating heart during cardiac-surgery by use of one or more cannulas involved in the intake and return of blood into the circulatory system. The cannulas interface between the patient's circulatory system and the mechanical

pumps that power the augmentation procedure. Such an application is described in co-pending PCT Application no. PCT/US97/18674 entitled "Single Port Cardiac Support Apparatus", filed October 14, 1997 and incorporated herein by reference in its entirety.

[00134] As will be appreciated, precise and quick placement of the cannula in surgical applications is critical, given the severe time constraints facing a surgeon whose patient's vital life sustaining functions have been suspended during the procedure. Currently, methods for placing cannulas in a patient's body are crude, in that they rely on guesswork and trial and error. Specifically, a surgeon will insert the cannula and direct it towards the desired destination, but ultimately must feel by hand, through the patient's tissue for example, whether it has reached that destination. The surgeon may be forced to make several retractions and re-insertions until the process succeeds. Shortcomings of such a procedure are clear and may include damage to the delicate tissue involved and waste of valuable time. Additionally, constraints on the flexibility of the material are imposed since a prescribed amount of rigidity is required to enable the cannula to be felt through the tissue and insure that the cannula does not collapse under insertion force.

[00135] Alternatively, the surgeon may rely on the use of guiding devices such as a guide wire threaded through the cannula. The guide wire is often easier to manipulate than the cannula, and its placement precedes placement of the cannula. After the guide wire is in place, the cannula is pushed along the length of the guide wire, following the guide wire to the desired destination.

[00136] It is also known that a flow directed balloon catheter can be used as a guide wire. Balloon catheters are well known in the art and have a multitude of uses, including delivery or removal of fluid from the surgical site. However, flow directed balloon catheters are typically at least an order of magnitude smaller than cannulas. Their small size accordingly severely limits their application since both quantity and rate of fluid flow through the catheter are limited. In fact it is precisely because of their small size that flow directed balloon catheters can be used as guiding devices for the larger, more robust and versatile cannulas. During use as a guiding device for a cannula, the flow directed balloon catheter acts as a guide wire in facilitating the advancement of the cannula to the desired destination. The flow directed balloon catheter is first inserted into place in the patient's body, and the cannula, threaded around the flow directed balloon catheter, is then advanced into the desired position.

[00137] Insertion of the flow directed balloon catheter is effected using the inflatable balloon disposed at a distal tip of the flow directed balloon catheter. A lumen in communication with the balloon delivers inflating fluid to the balloon, thereby inflating the balloon and causing it to operate as a "sail" which is pulled along in the blood stream through the natural blood flow in the patient's circulatory system.

[00138] The above procedures have met with only limited success, and there exists a long felt need for devices and methods that facilitate placement of a cannula in a patient's body. A system that will assist in the manipulation of the cannula through the vascular structure or other bodily regions of the patient would accordingly serve to make the placement process more efficient and less time-consuming, improving the chance of overall success of a surgical procedure.

BRIEF SUMMARY OF THE INVENTION

[00139] The present invention overcomes the deficiencies of the prior art by providing a cannula which can be steered during its advancement in the body of the patient. Steering is implemented using cables connected to a deformable portion of the cannula. The cables extend to the proximal end of the cannula from where the operator can selectively apply tensional forces to thereby cause the cannula to curve at the deformable portion. The deformable portion is disposed preferable at the distal end of the cannula, but may be located at other sites along the length of the cannula.

[00140] In accordance with a second embodiment of the invention, the cannula is provided with more than one cable for facilitating deformation along multiple planes. Additionally, preformed curves may be provided along the length of the cannula, which curves can be either augmented or straightened by applied tension to the cables.

[00141] The cannula, in accordance with a third embodiment, is provided with a spiraling wire formed in the cannula wall. The spiraling wire operates to provide rigidity to the body of the cannula and maintain good fluid flow therein. The spiraling wire may comprise a portion of the cable used to impart deformation in an arrangement in accordance with a fourth embodiment of the invention.

[00142] In accordance with a fifth embodiment of the invention, the steerable cannula is provided with an inflatable balloon at the distal end thereof for assisting in guiding the cannula

to its desired destination. The inflatable balloon is selectively inflatable using a lumen which effects fluid communication between an fluid source and the balloon.

[00143] In accordance with a sixth embodiment of the invention, a steerable cannula having a pigtail distal tip configuration is provided.

[00144] In accordance with a seventh embodiment of the invention, a steerable cannula having a movably supported guide wire is provided.

[00145] In accordance with an eighth embodiment of the invention, a steerable cannula having an integrally formed guide wire is provided.

[00146] In accordance with a ninth embodiment of the invention, a steerable cannula is used in a co-axial cannula arrangement.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[00147] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

[00148] FIG. 20 is schematic side view of a steerable cannula in the undeformed state in accordance with the first embodiment of the invention;

[00149] FIG. 21 is a schematic cross-sectional view of the steerable cannula of FIG. 20 taken along line A-A;

[00150] FIG. 22 is a schematic side view of the steerable cannula in the deformed state in accordance with the first embodiment;

[00151] FIG. 23 is a schematic cross-sectional view of a steerable cannula having two cables in accordance with a second embodiment of the invention;

[00152] FIG. 24 is a schematic side view of a steerable cannula having a reinforcing wire in accordance with a third embodiment of the invention;

[00153] FIG. 25 is a schematic cut-away view of a steerable cannula in accordance with a fourth embodiment of the invention;

[00154] FIG. 26 is a schematic cross-sectional view taken along line B-B of FIG. 25;

[00155] FIG. 27 is a schematic side view of a steerable cannula having a preformed curve and an inflatable balloon formed at a distal end thereof in accordance with a fifth embodiment of the invention;

[00156] FIG. 28 is a schematic side view of the inflatable balloon of fifth embodiment of the invention, wherein the balloon is shown in the inflated state;

[00157] FIG. 29 is a schematic cross-sectional view taken along line C-C of FIG. 28;

[00158] FIG. 30 is a schematic view showing a steerable cannula having a pigtail distal tip configuration in accordance with a sixth embodiment of the invention;

[00159] FIG. 31 is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with a seventh embodiment of the invention;

[00160] FIG. 32 is a schematic view showing a steerable cannula having a guidewire distal tip configuration in accordance with an eighth embodiment of the invention;

[00161] FIG. 33 is a schematic side view showing a steerable cannula used in a co-axial configuration in accordance with a ninth embodiment of the invention, wherein the steerable cannula is advanced to a first relative position;

[00162] FIG. 34 is a schematic side view showing a steerable cannula of FIG. 33, wherein the steerable cannula is advanced to a second relative position; and

[00163] FIG. 35 is a schematic side view of a configuration in accordance with a tenth embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[00164] The present invention comprises a steerable cannula in which a portion which is adapted for insertion into the body of a patient, preferably into the vascular system of the patient, is configured to be selectively deformable. The deformation aids in changing the direction of the cannula during the insertion process such that the cannula can be steered in a desired direction as it is advanced toward its destination in the patient's body. Deformation is effected using a cable connected with the deformable portion of the cannula. Tension on the cable, induced by for example rotating a portion of a handle disposed at a proximal end of the cannula exterior of the body of the patient, results in tension on one wall of the deformable portion and thereby causes it to bend in the direction of the cable.

[00165] With reference to FIGS. 20-23 in which an exemplary arrangement in accordance with a first embodiment of the invention is shown, cannula 1120 can be seen as comprising a substantially cylindrical structure having a wall 1122 which defines a main lumen 1124. Lumen 1124 is adapted for fluid transport to or from the body of the patient and may be

provided with one or more holes 1126 located adjacent to distal tip 1128 and permitting passage of fluid therethrough. Holes 1126 supplement fluid flow through main port 1125, especially in situations of blockage of main port 1125. Cannula 1120 may be one of two complementary cannulas (not shown) used in a surgical procedure, one for intake and the other for removal of blood or other fluid from the patient's body. Alternatively cannula 1120 may comprise a component of a co-axial, single port device in which cannula 1120 is surrounded by a second, larger conduit, with cannula 1120 for example operating to intake blood from the patient towards a pump system and the conduit operating to replace the blood from the pump back into the patient for augmentation of blood flow during beating heart surgery as described in co-pending PCT Application no. PCT/US97/18674 mentioned above.

[00166] At a proximal end 1130 of cannula 1120 is provided a handle 1132 which serves to transmit turning forces applied by an operator's hand to the cannula to aid in its manipulation in the patient's body. As such, handle 1132 is rigidly attached to wall 1122 of cannula 1120, although portions of handle 1132 may be configured for motion relative to cannula 1120 in order impart the necessary tension on cables used for deforming the cannula 1120 as described below. Rotation of the rigidly attached portion of handle 1132, results in a corresponding rotation of the distal end 1128 of the cannula 1120 within the patient's body, thus aiding in the cannula's manipulation and advancement to the desired destination.

[00167] Wall 1122, in addition to defining main lumen 1124 of cannula 1120, contains a secondary lumen 1136 formed therein. Movably mounted in lumen 1136 is a cable 1138 which is secured at point 1140 in wall 1122. Point 1140 may be disposed anywhere along the length of the cannula 1120, but in the preferred embodiment lies at distal end 1128.

[00168] Cannula 1120 is provided with a deformable portion 1142 formed along at least a segment of its length. In the exemplary arrangement shown in FIGS. 20-22, deformable portion 1142 is disposed in close proximity to distal end 1128 of cannula 1120; however, it is to be understood that this not intended to be limiting and that other regions in the cannula 1120 can alternatively or additionally be made deformable depending on the contemplated application.

[00169] Deformable portion 1142 serves to cause cannula 1120 to bend in response to tension applied to cable 1138 and thereby assume a configuration as shown in FIG. 22. Depending on the location of point 1140 and the location of lumen 1136 radially and axially

along wall 1122, applied tension to cable 1138 causes cannula 1120 to turn on itself in the direction of pull to thereby assume a curve having a predetermined orientation. Additionally, if cannula 1120 is provided with one or more preformed curves, which may be in identical or in different planes along the length of the cannula as is contemplated, tension in cable 1138 can operate to temporarily straighten the cannula along at least one of these planes to facilitate handling during a particular maneuver through the patient's body.

[00170] It is also contemplated that more than one cable can be provided, supported in suitable secondary lumens formed in cannula 1120. As can be seen from FIG. 23, a second lumen 1146 can be provided in wall 1122 of cannula 1120, second lumen 1146 movably supporting cable 1144 therein. Cables 1138 and 1144 are thus disposed on opposite sides of cannula 1120 and serve to provide steerability in two directions. The cables are configured such that a pulling of one cable is coordinated with a slacking of the other cable in order permit bending of cannula 1120 at deformable portion 1142. Although shown to be diametrically opposed in position, cables 1138 and 1144 can occupy any position along wall 1122, and it will be appreciated that the number of such cables used can vary depending on the application, as can their distribution in wall 1122, and any desired number of turning directions can accordingly be achieved in accordance with the present invention.

[00171] Wall 1122 can be formed of materials ranging from rigid to flexible, and in the preferred embodiment comprises a semi-rigid transparent material such as silicone rubber. Of course it is to be understood that by definition deformable portion 1142 is to be constructed of a flexible material, regardless of the construction of the remainder of the wall 1122, such that cannula 1120 can bend when appropriate pulling forces are imparted through the cable(s).

[00172] Selective bending of cannula 1120 can also be facilitated using a core member provided for this purpose. Core member 1182, preferable formed of material having appreciable stiffness relative to wall 1122, is disposed longitudinally within cannula 1120 and serves to provide a deflection point to locate and control the bending point of the cannula. Core 1182 is removable and can be movable distally or proximally within cannula 1120 in order to alter the deflection point. In this manner also flow blockage in the cannula 1120 can be insured during insertion.

[00173] As can be seen from FIG. 24, a spiraling wire 1148 can be provided for structural reinforcement of cannula 1120. Wire 1148 is either molded into the wall 1122 or is otherwise

supported therein, and extends either partially or fully across the length of the cannula 1120. Wire 1148 facilitates handling of the cannula 1120 and reduces the possibility of cannula 1120 collapsing or being pinched shut and thus closing off the flow of fluid to or from the patient. Other ways of reinforcing the tubular body of cannula 1120 are known in the art and will adapt equally well to the present invention. In addition, no reinforcement may be needed if the cannula material is sufficiently rigid or if sufficient fluid flow is present within the cannula.

[00174] Alternatively, as shown in FIGS. 25-26, spiraling wire 1148 can itself comprise a portion of cable 1138. In such an arrangement, cannula wall 1122 is formed of two layers 1162 and 1164, between which is formed a lumen 1166. Layers 1162 and 1164 may be discrete layers bonded together at appropriate regions, or they may be a single layer folded back upon itself to form the two layers, with lumen 1166 and wire 1148 occupying predetermined regions therebetween. Cable 1138 is housed in a polymide tube 1170 disposed in lumen 1166 and extends beyond the end 1168 of tube 1170 to then spiral exteriorly of inner layer 1162 and interiorly of outer layer 1164 to thereby lend structural support to the cannula 1120. Metal or other tape 1172 can be used to secure spiraling wire 1148 in place. In a variation of this, cable 1138 and wire 1148 may be two discrete components which are welded or otherwise connected together at any desired point along the body of cannula 1120. Alternatively, as shown in FIG. 35, cable 1138 may be secured to a band 1184 disposed radially about or adjacently to tip 1186 of cannula 1120. In all of these variations, cable 1138 may be formed of single or multiple strands of metal, plastic or carbon fiber composite, but preferably cable 1138 is formed of a single strand of stainless steel having a TEFLON™ coating. In the FIGS. 33-35 arrangements, cannula 1120 is shown with an atraumatic bullet tip 1186 having side holes 1188 and end holes 1190. It will be appreciated that such a tip can be provided for any arrangement of the invention. It will also be appreciated that the tip 1186 can itself serve as the anchor for the cable 1138 in certain arrangements. The tip 1186 is fixedly bonded to distal end 1125 of cannula 1120 and enables a simplified construction of the steering mechanism and provides a blunt surface that will not injure tissue in the body.

[00175] Lumens 1136 and 1146, or other similar lumens, in addition to supporting cables 1138 and 1144 therein, may be used to supply inflating fluid to a balloon 1150 provided at the outer surface of the distal end 1128 of cannula 1120. As shown in the exemplary embodiment

of FIGS. 27-29, balloon 1150 is in fluid communication with inflating fluid source 1152, via supply tube 1154 and lumen 1156. Fluid source 1152 serves to selectively provide fluid, such as saline, air or other gas, to balloon 1150 to thereby cause the balloon to inflate within the patient's body. Balloon inflation in this manner assists in placement of the cannula 1120, especially when inserting the cannula antegrade, with the inflated balloon serving to float the tip of cannula within the fluid flow to thus transport it to the desired location in the body. Cannula 1120 is provided with one preformed curve 1158 in addition to curve 1160 imparted by the tension in cable 1138. Balloon 1150 is shown in the deflated state in FIG. 27 and in the inflated state in FIGS. 28 and 29.

[00176] Various distal tip configurations can be selected for cannula 1120, depending on the particular application as appreciated by those of ordinary skill in the art. For example, a pigtail shape can be used for crossing the aortic valve retrograde. The pigtail shape, illustrated in FIG. 30, can be formed by bonding or thermal welding or otherwise attaching a thermoplastic rod 1174 formed into a loop at the distal end of the cannula 1120. Alternatively, a J-tip wire 1176 can be configured to protrude from the distal tip 1128, as illustrated in FIGS. 31 and 32. The J-tip wire can be a conventional guidewire movable or fixedly supported in a dedicated lumen 1178 formed in a rigidly attached tube 1180 (FIG. 31), or it can be supported, rigidly or movably, between layers of material from which the wall 1122 of cannula 1120 is formed. Guidewires are known in the art and can for example be formed of windings of wire coiled around a core and having one or more preformed curves formed therein.

[00177] An embodiment in which cannula 1120 is used in a coaxial configuration is shown in FIGS. 33 and 34. Cannula 1120 serves as an inner cannula, passing through outer conduit 1180 while the two components are disposed in the patient's body. An important advantage of this arrangement is that outer conduit 1180 operates to vary the radius of curvature of inner cannula 1120 by providing a base point as the inner cannula 1120 is advanced. In this manner manipulation of the inner cannula 1120 and outer conduit 1180 is facilitated and advancement to the desired destination in the body of the patient is more efficiently accomplished.

[00178] The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to one of ordinary skill in the art that modifications thereto can be made without inventive departure from the spirit and scope of the invention.

ABSTRACT OF U.S. SERIAL NO. 09/280,988~~APPENDIX A~~

[00179] A steerable cannula is provided with at least one cable through which tension is communicated to a deformable portion of the cannula. The tension causes the cannula to bend at the deformable portion, enabling selective steering of the cannula during insertion into the body of the patient.

INCORPORATED EMBODIMENTS OF ~~APPENDIX B~~ (U.S. SERIAL NO. 09/280,970~~)~~

[00180] PRESSURE SENSING CANNULA

[00181] BACKGROUND OF THE INVENTION

[00182] FIELD OF THE INVENTION

The present invention relates to cannulas used in surgical applications, and more particularly, to a cannula equipped with a pressure/flow rate transducer.

[00183] DESCRIPTION OF THE RELATED ART

In medical applications and specifically in surgery, the list of uses for cannulas is exhaustive. One application involves the augmenting or supplementing of pulmonary blood flow through the beating heart during cardio-surgery by use of one or more cannulas involved in the intake and return of blood into the circulatory system. The cannulas interface between the patient's circulatory system and the mechanical pumps that power the augmentation procedure. Such an application is described in co-pending PCT Application no. PCT/US97/18674 entitled "Single Port Cardiac Support Apparatus", filed October 14, 1997 and incorporated herein by reference in its entirety.

[00184] When performing cardiac surgery cannulas are placed within the patient's blood stream and used for inflow and outflow of blood or other fluids. If the operator wishes to determine the rate of fluid flow, either a catheter with appropriate sensors must also be placed in the patient's blood stream, or other sensors such as an external ultrasonic sensor as disclosed in U. S. Patent No. 5,179,862 are used. A shortcoming of ultrasonic systems such as that described in 5,179,862 is that they require significant monitoring. Ultrasonic sensors also

require that tubing of a specific diameter be used, thereby adding to the cost and complexity of the surgical procedure. Additionally, ultrasonic sensors are expensive and nondisposable, thereby adding to the cost of the surgical procedure.

[00185] Another method to measure flow rate is through the use of a thermodilution catheter. Thermodilution catheters require the infusion of a solution, typically saline, of a known temperature, with a distally disposed thermistor measuring the temperature change to determine the flow rate. This method is also expensive, increasing the cost of the surgical procedure. A second problem with using flow-sensing catheters, such as thermodilution catheters, is that they require the operator to place more incisions within the patient. The catheters must be placed so that they do not interfere with the inflow or out flow of the cannula. Visual markers along the length of the cannula may also be used to determine location, the greater the number of markers the more accurate the placement at the expense of quick readings due to the greater number of markings.

SUMMARY OF THE INVENTION

[00186] The present invention overcomes the deficiencies of the prior art by providing a cannula assembly having one or more pressure transducers coupled to a main lumen thereof. In accordance with a first embodiment, the pressure transducers are attached to the substantially tubular wall defining the main lumen.

[00187] In accordance with a second embodiment, a partial occlusion is provided in the cannula to increase the pressure drop across the main lumen. In this manner transducer signal is increased, and an improved differential pressure measurement signal achieved.

[00188] In accordance with a third embodiment of the invention, one or more pressure transducers are used in conjunction with a pair of coaxial cannulas for measuring pressure.

[00189] In accordance with at fourth embodiment of the invention, a differential pressure transducer is used, the differential pressure transducer being mounted in a dedicated secondary lumen in communication with the first lumen.

[00190] In accordance with a fifth embodiment of the invention, the secondary lumen housing the differential pressure transducer is disposed across a knee formed in the cannula to augment pressure measurement. Partial occlusions may also be provided for this purpose.

[00191] In accordance with a sixth embodiment of the invention, the secondary lumen housing the differential pressure transducer is formed integrally with the tubular wall defining the main lumen.

[00192] In accordance with a seventh embodiment of the invention, a soft, flexible tapered tip is provided at the distal end of the cannula. Such a configuration allows for easier negotiation through the patient's body during surgical procedure.

[00193] In accordance with an eighth embodiment of the invention, an inflatable balloon is provided at the distal end of the cannula. The inflatable balloon aids in transporting the cannula to the desired destination.

[00194] In accordance with a ninth embodiment of the invention, a guide wire lumen is provided for supporting a guide wire in the cannula. The guide wire is used as a predecessor step in the insertion of the cannula.

[00195] In accordance with a tenth embodiment of the invention, a light guide is supported in the cannula. The light guide conveys light to a predetermined portion of the cannula to thereby aid in the visualization and location of the cannula during the surgical procedure.

[00196] The invention realizes various advantages over the prior art, including a reduction in the number of incisions that a surgeon must make in performing surgical procedures, along with a reduction in the amount of foreign material introduced into the patient's body, while providing safe, rapid, accurate and cost-effective fluid flow rate measurements.

BRIEF DESCRIPTION OF THE DRAWINGS

[00197] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

[00198] FIG. 36 is a schematic side view of a first embodiment of the invention;

[00199] FIG. 37 is a schematic cross-sectional view taken along line D-D of FIG. 36;

[00200] FIG. 38 is a schematic cross-sectional view taken along line E-E of FIG. 36;

[00201] FIG. 39 is a schematic view of a cannula in accordance with the invention in a surgical application;

[00202] FIG. 40 is a schematic partial cut-away side view of a second embodiment of the invention;

[00203] FIG. 41 is a schematic cross-sectional view taken along line F-F of FIG. 40;

[00204] FIG. 42 is a schematic side view of a third embodiment of the invention;

[00205] FIG. 43 is a schematic side view of a fourth embodiment of the invention;

[00206] FIG. 44 is a schematic side view of a fifth embodiment of the invention;

[00207] FIG. 45 is a schematic side view of a sixth embodiment of the invention;

[00208] FIG. 46 is a schematic cross sectional view taken along line G-G of FIG. 45;

[00209] FIG. 47 is a schematic side view of a seventh embodiment of the invention;

[00210] FIGS. 48 and 49 are schematic side views of an eighth embodiment of the invention;

[00211] FIG. 50 is a schematic cross-sectional view taken along line H-H of FIG. 49;

[00212] FIG. 51 is a schematic side view of a ninth embodiment of the invention;

[00213] FIG. 52 is a schematic side view of a tenth embodiment of the invention; and

[00214] FIG. 53 is a schematic cross-sectional view taken along line J-J of FIG. 52; and

[00215] FIG. 54 is a schematic side view of an eleventh embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00216] In accordance with the invention, a cannula comprising a substantially tubular, semi-flexible material adapted for fluid transport while inserted in a patient's body is provided with one or more pressure transducers which are fixedly or adjustably supported in the cannula. The pressure transducers are disposed internally or externally of the cannula and are used to provide a measurement of the rate of fluid flow. In the internal configuration, the rate of fluid flow within the cannula is measured. In the external configuration, the rate of fluid flow outside the cannula is measured. The cannula can also be adapted to support a guide wire to aid the operator in its insertion through the patient's body, and/or a light source to provide a visual reference during the insertion procedure. It is to be understood that the use of the term "cannula" is intended to encompass cannulas, catheters, and any related devices having similar application.

[00217] An exemplary arrangement in accordance with a first embodiment of the invention is shown FIGS. 36-38. Cannula 2220 comprises a substantially cylindrical structure having a wall 2228 defining a main lumen 2221. Wall 2228 can be formed of materials ranging from rigid to flexible, and in the preferred embodiment comprises a semi-rigid transparent material

such as polyurethane, silicone rubber or other material. Lumens other than main lumen 2221 may also be provided, as described below. The cannula may also be formed from vinyl plastisol. To form a cannula of vinyl plastisol, a mandrel is dipped into liquid vinyl plastisol and heated. Wire is then wrapped around the mandrel and first formed layer. The mandrel is then dipped again encasing the wire, and then heated. The mandrel is then removed. Lumens and transducers may be formed within the wall of the cannula during the dipping process.

[00218] To lend structural support for the thin wall which allows maximum flow with minimal insertion damage, spiraling wire 2230 is provided for reinforcement and is either molded into the wall 2228 or is otherwise supported therein, and extends either partially or fully across the length of the cannula 2220. Wire 2230 facilitates handling of the cannula 2220 and reduces the possibility of cannula 2220 collapsing or being pinched shut and thus closing off the flow of fluid to or from the patient. Other ways of reinforcing the tubular body of cannula 2220 are known in the art and will adapt equally well to the present invention. In addition, no reinforcement may be needed if the cannula material is sufficiently rigid or if sufficient fluid flow is present within the cannula.

[00219] A connector 2223 is provided at the proximal 2225 end of cannula 2220. Connector 2223 is suitably sized to interface with various surgical instruments, including but not limited to a reverse flow pump or fluid conduits leading thereto (not shown). Cannula 2220 may also have one or more holes 2226 located adjacent to distal tip 2222 to facilitate fluid flow therethrough. Cannula 2220 may be one of two complementary cannulas used in a surgical procedure, one for intake and the other for removal of blood or other biocompatible fluid from the patient's body. Alternatively, cannula 2220 may comprise a component of a co-axial, single port device in which cannula 2220 is surrounded by a second, larger conduit, with cannula 2220 for example operating to intake blood from the patient towards a pump system and the conduit operating to replace the blood from the pump system back into the patient for augmentation of blood flow during beating heart surgery as described in the co-pending PCT Application No. PCT/US97/18674 mentioned above.

[00220] In order to provide real time fluid flow information in accordance with the present invention, a pair of pressure transducers 2224, 2232 are provided at two separate locations as illustrated in FIG. 36. Pressure transducers 2224, 2232 are of the type known in the art and each comprises for instance a piezo-electric crystal housed in an integrated circuit (IC) chip

(not shown). The crystal configuration is designed to be pressure sensitive, generating an electrical signal in proportion to the amount of pressure experienced.

[00221] The principle governing the relationship between fluid flow and pressure is defined by Bernoulli's equation, herein solved for flow rate V and is determined by:

$$v = \sqrt{\frac{\Delta P \cdot 2d \cdot a^2}{f \cdot L \cdot \rho}}$$

where ΔP is the measured difference in pressure, d is the internal diameter of the lumen, a is the area of the lumen, f is a frictional factor of the lumen material, L is the lumen length over which the pressure measurement is conducted, and ρ is a measurable constant representative of the density of the fluid. The flow rate information can be used for a variety of purposes, including monitoring the patient's condition and controlling the fluid pump used during the procedure.

[00222] In the preferred embodiment, transducers 2224, 2232 are imbedded in the wall 2228, which is formed for instance by application of successive layers of laminate and interjecting the transducers therebetween during the layering process. Depending on at what stage in the layering process the transducers 2224, 2232 are put in place in the wall 2228, their proximity to the interior of the cannula 2220 or its exterior can be controlled in order to optimize measurement of cannula interior or exterior pressure. From the interior pressure measurements, a determination of flow rate within main lumen 2221 can be made using the known diameter of the main lumen 2221. Similarly, from the exterior pressure measurements, flow rate of exterior fluid--for example, blood--can be measured if the diameter of the blood channel, such as the artery, is known, or the cannula can be calibrated with thermodilution catheters which assume the diameter of the vessel or artery they are placed within.

[00223] In the FIG. 36 exemplary arrangement, pressure transducer 2232 is disposed at a location near the distal tip 2222 of cannula 2220, while pressure transducer 2224 may be

disposed anywhere along the length of cannula 2220 between pressure transducer 2232 and proximal end 2225. It is also contemplated that the pressure transducers 2224, 2232 may be detachably disposed in dedicated secondary lumens formed in or along tubular wall 2228, the dedicated secondary lumen extending to the proximal end 2225 and supporting any electrical cables connected to the pressure transducers 2224, 2232. In the detachable arrangement, the location of pressure transducers 2224, 2232 in the cannula 2220 can be adjusted to suit the particular application, such that one transducer can be disposed within one chamber of the heart while the other is at a different of portion of the heart to thereby provide a pressure/flow rate measurement of a predetermined portion of the patient's body, for example flow into the heart from a designated blood vessel. Such an application is shown in FIG. 39.

[00224] Pressure transducers 2224, 2232 are in electrical communication with console 2236 via cable 2238, which is supported in secondary lumen 2242 provided in cannula 2220. Calculations for determining fluid flow rate using signals generated by the pressure transducers 2224, 2232 and relayed via cable 2238 are conducted at the console 2236 or at any processor or processing system connected thereto.

[00225] As shown in FIGS. 40 and 41, cannula 2220 may also contain a partial occlusion portion 2247 that forms a venturi 2246 within the main lumen 2221 of cannula 2220. Venturi 2246, which may be disposed anywhere along the length of the cannula 2220, induces a pronounced pressure drop, creating a greater differential in pressure between proximal region 2225 and distal region 2222, thereby requiring less signal amplification of the pressure transducers and less filtering of the signal and consequently yielding a more accurate flow rate measurement. Preferably the location of the pressure transducer 2232 is in the vicinity of venturi 2246 as shown in FIG. 54.

[00226] FIG. 42 shows an embodiment in accordance with the invention in which the pressure transducers 2224, 2232 are used with a co-axial, single port device 2250 in which cannula 2220 is surrounded by a second, larger conduit 2248, with cannula 2220 for example operating to intake blood from the patient towards a pump system (not shown) and conduit 2248 operating to replace the blood from the pump system, via openings 2252, back into the patient for augmentation of blood flow during beating heart surgery as described in the co-pending PCT Application no. PCT/US97/18674 mentioned above. It is to be understood that pressure transducers 2224, 2232 can be mounted fixedly or detachably either to the interior or

exterior of either the cannula 2220 or the conduit 2248 in the above-described manner. More than one pair of these transducers can also be used in a myriad possible combinations in accordance with the invention. In the preferred embodiment, the cannula 2220 is provided with a bullet nosed tip, as illustrated in for example FIGS. 42-44. Other tip configurations, such as a bevel, may also be used, as will be appreciated by those skilled in the art.

[00227] An alternative to using pairs of pressure transducers such as transducers 2224, 2232 is the use of a single differential pressure transducer 2254, as shown in FIG. 43. Differential pressure transducers are also well known in the art and comprise for example a piezo-electric crystal electro-mechanically configured to be responsive to a pressure difference between two opposing sides thereof. These two sides correspond respectively to proximal end 2257 and distal end 2259 of secondary lumen 2256 in which transducer 2254 is mounted. Proximal and distal ends 2257 and 2259 are attached at any desired points along the length of cannula 2220 to thereby couple secondary lumen 2256 to main lumen 2221 and provide a pressure difference measurement between the desired points. Attachment of lumen 2257 and transducer 2254 across knee 2249 of cannula 2220, as shown in FIG. 44, will provide a stronger signal, with knee 2249 operating in accordance with the same principal as venturi 2246 discussed above. Thus it is to be understood that a venturi could also be used in conjunction with the differential pressure transducer 2254. The ports 2261 and 2263 at which the lumen 2256 interfaces with cannula 2220 may be sealed by an appropriate membrane, with saline or other fluid being permanently housed in the lumen 2256. Alternatively, ports 2261 and 2263 may be open, permitting fluid communication between the cannula 2220 and the lumen 2256 and attached transducer 2254. The latter, open configuration would achieve a more faithful pressure representation. Stopcocks 2274 and 2276 can be provided in the ports 2261 and 2263 to permit priming and/or de-airing of the ports. It should also be noted that although in the arrangements of FIGS. 43 and 44 the lumen 2256 is provided as a separate tubular structure, lumen 2256 may alternatively be formed integrally with wall 2228 of cannula 2220, again with ports 2261 and 2263 being either open or closed to main lumen 2221 depending on the application. Such an arrangement is illustrated in FIGS. 45 and 46 in which is shown transducer 2254 in communication with lumen 2272 integrally formed in wall 2228 of cannula 2220.

[00228] Various distal tip configurations can be selected for cannula 2220 and used with the pressure sensing transducers, depending on the particular application as appreciated by those of ordinary skill in the art. FIG. 47 shows an exemplary embodiment in which the distal tip 2222 is formed of a soft, flexible material having a bullet shape. As shown exemplarily in FIGS. 48-50, the cannula 2220 may be equipped to support other tools, such as an inflatable balloon 2240 which is deployed for example in order to assist in transporting the distal tip 2222 to the desired destination in the patient's body during the surgical procedure. Balloon 2240 is inflated through an inflating lumen 2244 provided in cannula 2220 using a bio-compatible fluid such as saline or carbon dioxide gas. Preferably inflating lumen 2244 is formed integrally within wall 2228, by leaving an appropriate gap during the fabrication process, and is provided with a fitting (not shown) at its proximal end to interface with an inflating device for supplying the bio-compatible fluid. The lumen 2221 within the cannula 2220 can also be adapted to support a balloon catheter (not shown) which can be used to place the cannula within the patient's body. An obturator (not shown) may also be disposed through the main lumen 2221 to aid in insertion and guiding within the patient's body.

[00229] Another tool which cannula 2220 may support is shown in FIG. 51 and comprises a J-hook guidewire 2262 disposed slideably within lumen 2264, which is formed integrally in wall 2228 of cannula 2220. In operation, guidewire 2262, easier to manipulate than the cannula 2220, is first inserted into the patient's body and manipulated to the surgical site. Subsequently the cannula 2220 is maneuvering along the guidewire 2262, which passes through lumen 2264, to the desired destination.

[00230] As illustrated in FIGS. 52 and 53, cannula 2220 may also contain a light guide 2266, which may be supported in lumen 2268. Light guide 2266 comprises one or more optical fibers formed of, for example, glass or other materials, such as plastic, known for that purpose. Distal tip of light guide 2266 is configured for light projection, such that light provided at the proximal end of light guide 2266 is projected therefrom. An appropriate shape for such projection is a spherical shape, although other shapes and projection schemes, such as directional projection, fall within the purview of the invention. The source of light may be any conventional monochromatic (laser/LED) or polychromatic device 2270, and more than one light source with associated light guide can be used for color coding and providing a visual reference to different portions of the cannula 2220, depending on the colors of light used and

on the location of the projection terminus of the light guides. In this manner cannula 2220 can be visually guided through the patient's body, relying on the transmissivity of tissue to permit the location of the illuminated cannula in the patient's body. As will be appreciated, the location of the cannula 2220 can also be determined by examining the pressure waveform detected by the pressure transducers 2224, 2232 and 2254. The physiological pressure waveform recorded by the transducers can be used to determine the location of cannula 2220 in relation to the valves of the patient's heart.

[00231] As will be appreciated by those skilled in the art, cannula 2220 may be provided with one or more preformed curves along its length to aid in its manipulation through the patient's vasculature. Multiple curves may be disposed along the same plane or in different planes, depending on the application.

[00232] An additional feature in accordance with the invention is the use of radiopaque markings (not shown) anywhere along the cannula body. Such markings render portions of the cannula 2220 visible to x-ray radiation for visualizing the cannula during its use.

[00233] The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to those skilled in the art that modifications thereto can be made without departure from the spirit and scope of the invention. It will also be apparent that all devices and methods herein disclosed will adapt equally to animal use as well as human use.

ABSTRACT OF U.S. SERIAL NO. 09/280,970~~APPENDIX B~~

[00234] A cannula is provided with one or more pressure transducers for measuring fluid pressure interiorly or exteriorly of the cannula. The pressure transducers may be mounted integrally with the tubular wall defining the main lumen of the cannula, or they may comprise differential pressure transducers mounted in dedicated lumens in communication with the main lumen. The pressure measurements from the transducers is used to determine fluid flow rate.

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Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment after Notice of Allowance (Rule 312)	2017-01-09_SecondRule312Amendment_US07.pdf	48713 72ee8d41e648b6059fbddd4b0bf6ce32d31cc034	no	4

Warnings:

Information:					
2	Specification	06-01506US07_Fourth_Substitute_Spec_clean.pdf	248731 f12bab4b62e7f7a19327824 9f90aa3c57acc99e1	no	51
Warnings:					
Information:					
3	Applicant Arguments/Remarks Made in an Amendment	06-01506US07_Fourth_Substitute_Spec_marked-up.pdf	249424 5d68a245ae085a49f3cc0f3cecf847f0dfc8dde3	no	51
Warnings:					
Information:					
		Total Files Size (in bytes):	546868		

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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.

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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.

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/239,574	02/07/2017	9561314	06-01506US07	1024

99185 7590 01/18/2017

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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 0 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.

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