

**Ex. A: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,007,543 By Edwards**

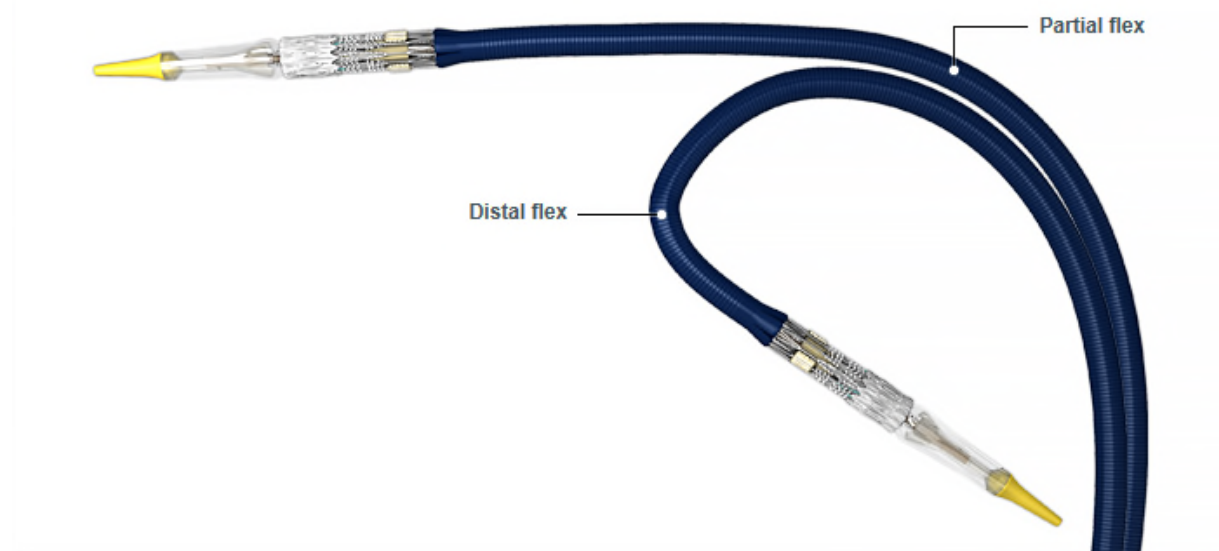
Claim 1	
Element	Accused Products
<p>[1 preamble¹] A stent delivery system comprising:</p>	<p>To the extent the preamble is deemed a limitation, on information and belief, Edwards made, used, offered to sell, and/or sold in the United States, and/or imported into the United States each of the balloon catheters used in its Commander Delivery System (“Commander”), Certitude Delivery System (“Certitude”), NovaFlex Delivery System (“NovaFlex”), and RetroFlex Delivery System (“RetroFlex”) for delivery and deployment of its Sapien 3, Sapien XT, and/or Sapien products.²</p> <p>For example:</p> <p><u>Commander:</u></p> <p style="padding-left: 40px;">The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

¹ The designations in square brackets before the claim language in each row is added to permit convenient reference to specific claim language. These added designations are not part of the claim language and are not intended to limit the claims in any way. No interpretation is intended to be conveyed by the words grouped together with each designation.

² The Sapien 3, Sapien XT, and Sapien, and their corresponding delivery systems, are collectively referred to herein as the “Sapien products.” On information and belief, unless otherwise noted, any differences between various versions or models of the delivery systems identified herein or between the Sapien 3, Sapien XT, and Sapien are immaterial to the assertions set forth herein.

Edwards Commander Delivery System

Dual articulation for coaxiality even in challenging anatomies



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>.

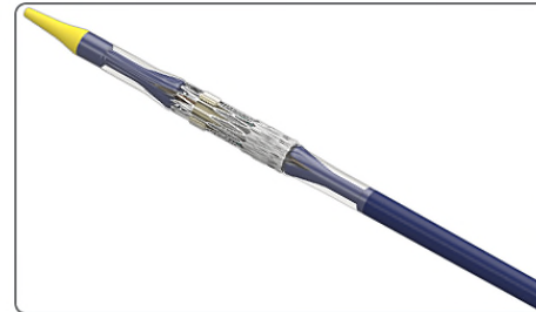
Certitude:

Edwards Certitude Delivery System
designed for seamless deployment

Ultra-low profile system – 18F Certitude sheath compatible*

Integrated pusher

- Streamlines procedure



Articulation feature

- For ease of coaxial positioning



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:

The NovaFlex+ delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN XT THV. The delivery system includes a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system to facilitate advancing to the RVOT, and a balloon catheter for deployment of the THV. The handle also contains a flex indicator depicting articulation of the flex catheter, a valve alignment wheel for fine adjustment of the THV during valve alignment, a button that enables movement between handle positions, and a flush port to flush the flex catheter. The balloon catheter has radiopaque markers defining the valve alignment position and the working length of the balloon. A radiopaque double marker proximal to the balloon indicates flex catheter position during deployment.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.

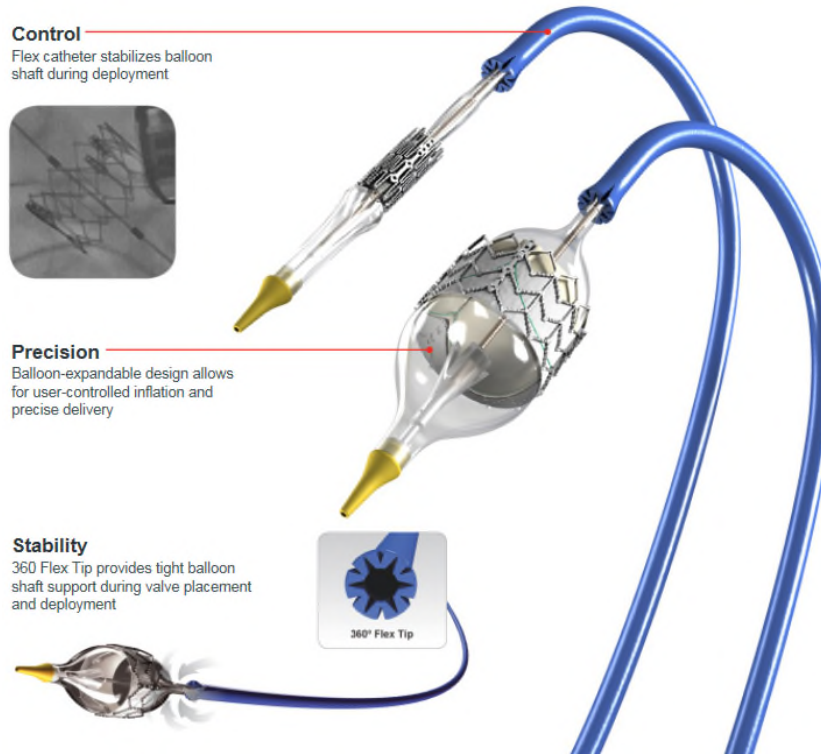
NovaFlex+ Transfemoral System

Expanded Indications
[Learn More](#)

Control
Flex catheter stabilizes balloon shaft during deployment



Precision
Balloon-expandable design allows for user-controlled inflation and precise delivery



Stability
360 Flex Tip provides tight balloon shaft support during valve placement and deployment



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:

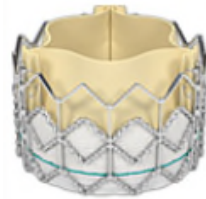
The RetroFlex 3 delivery system includes a rotating wheel within the handle for articulation of flex catheter, a tapered tip at the distal end of the delivery system to facilitate crossing the native valve, a balloon for deployment of the bioprosthesis, and radiopaque markers as indicated in Figure 2.

Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/Adviso...orySystemDevicesPanel/UCM262938.pdf>.

Transcatheter Heart Valves

Edwards SAPIEN Pulmonic Models

Product Description	23 mm	26 mm
RetroFlex 3 Kit	9100RF323	9100RF326
Edwards SAPIEN Valve	9000TFX23	9000TFX26
RetroFlex 3 Delivery System	9120FS23	9120FS26
RetroFlex 3 Introducer Sheath Set	9120S23	9120S26
RetroFlex Balloon Catheter	9120BC20	9120BC23
RetroFlex Dilator Kit	9100DKS7	9100DKS7
Edwards Crimper	9100CR23	9100CR26
Atrion QL2530 Inflation Device	96402	96402



Edwards SAPIEN Valve



RetroFlex 3 Delivery System

Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/pulmonicmodels.aspx>.

<p>[1a] a radially expandable stent of generally cylindrical configuration, having a first end and a second end and a contracted state and an expanded state, and</p>	<p>The Commander, Certitude, NovaFlex, and RetroFlex include delivery systems for the Sapien products.</p> <p>Each of the Sapien products comprises a radially expandable stent. For example:</p> <p style="padding-left: 40px;">The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p style="padding-left: 40px;">The Edwards SAPIEN XT Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.</p> <p style="padding-left: 40px;">The Edwards SAPIEN transcatheter heart valve (bioprosthesis) is comprised of a balloon-expandable, radiopaque, stainless steel (316 L) frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) fabric. The bioprosthesis is treated according to the Carpentier-Edwards ThermaFix process, packaged, and terminally sterilized in glutaraldehyde</p> <p>Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf.</p> <p>Each of the Sapien products has a generally cylindrical configuration with a first end and a second end. For example:</p>
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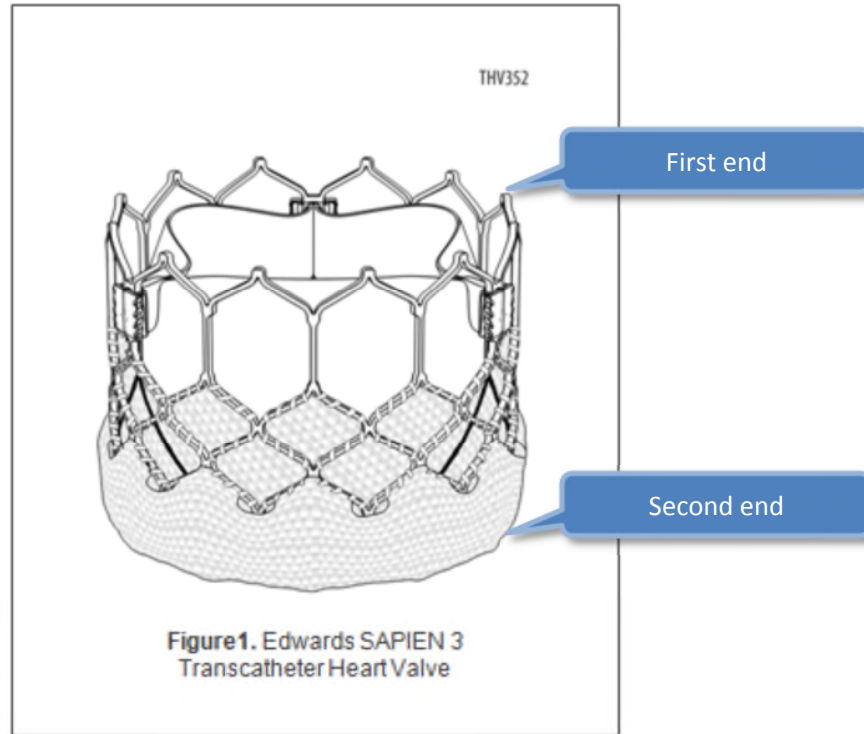


Figure 1. Edwards SAPIEN 3 Transcatheter Heart Valve

Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

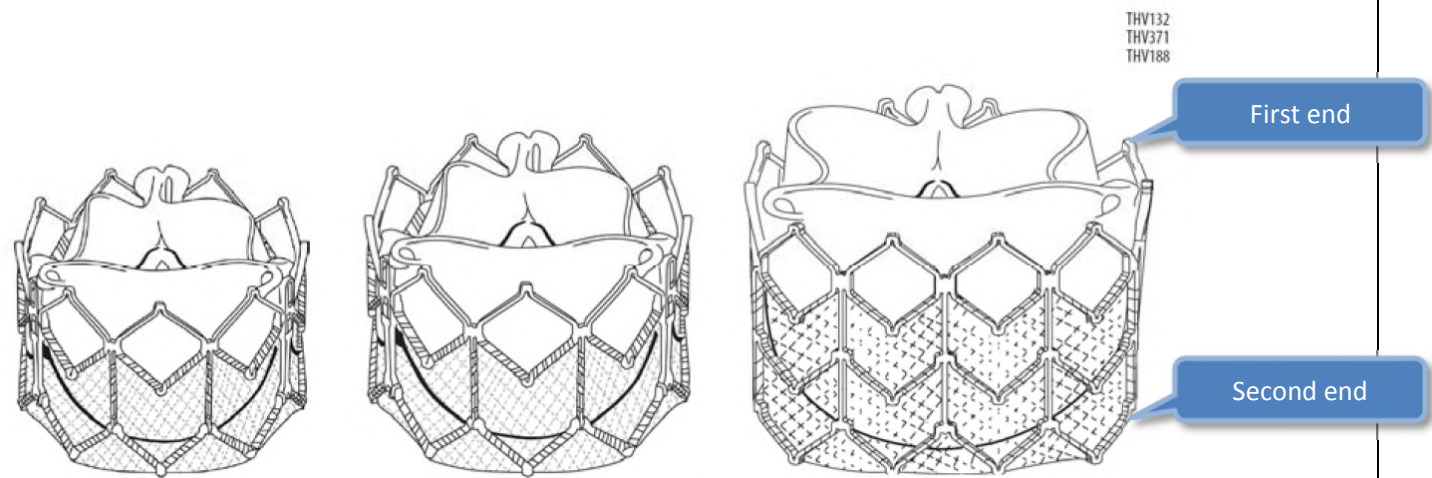
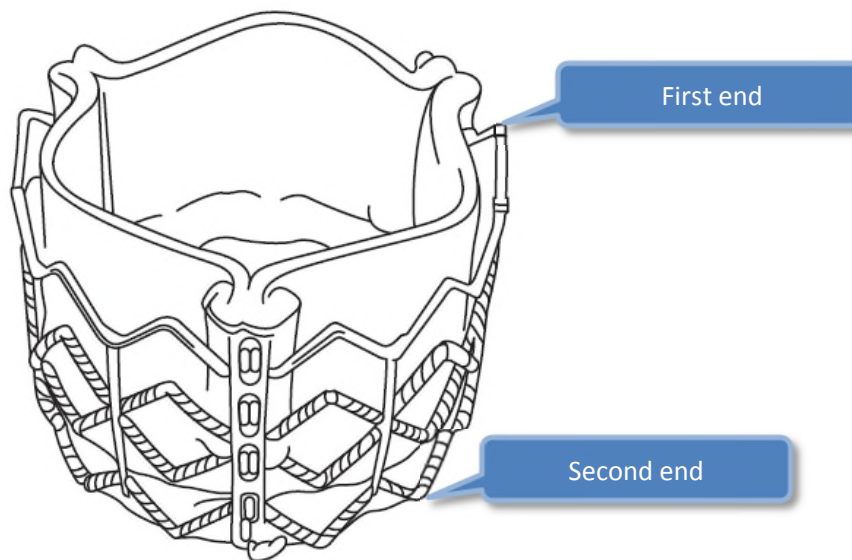


Figure 1. Edwards SAPIEN XT Transcatheter Heart Valve

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.

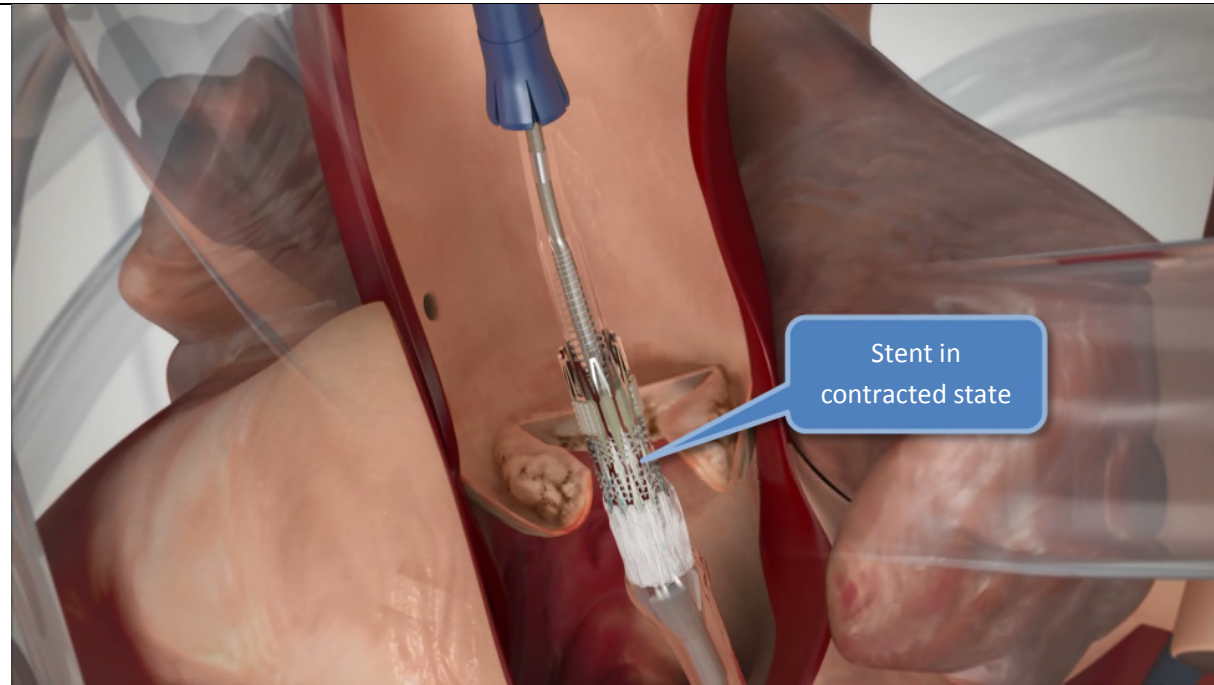
Figure 1. Edwards SAPIEN Transcatheter Heart Valve

THV01

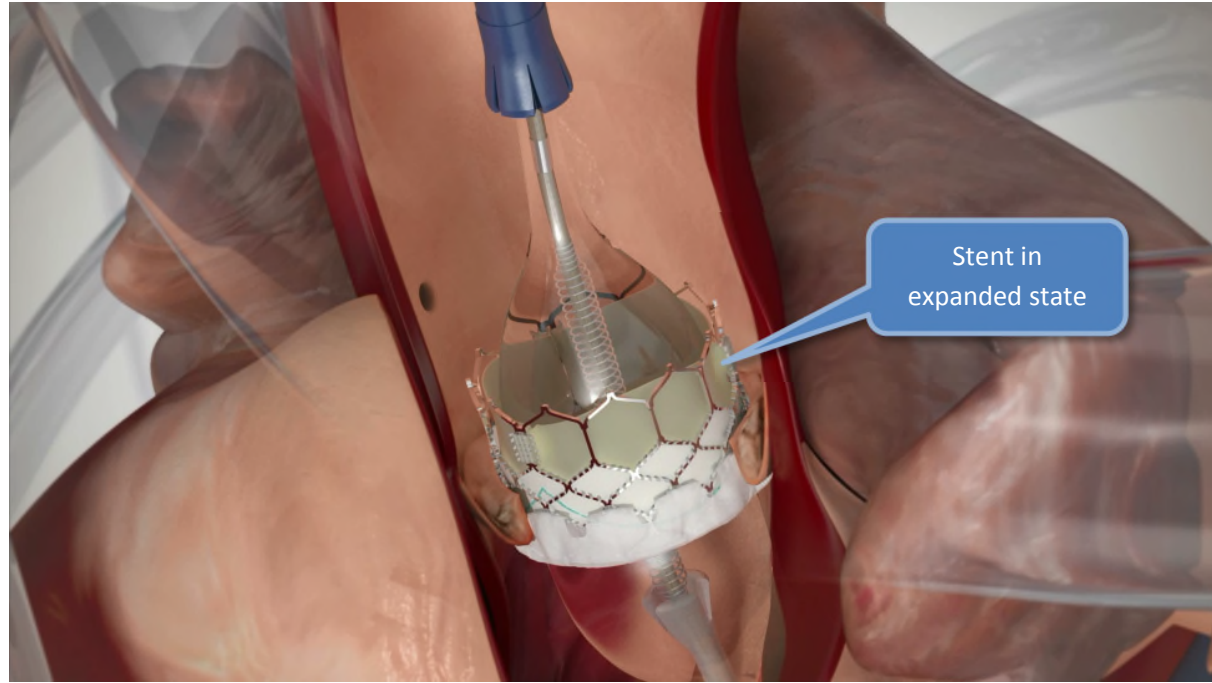


Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf>.

Each of the Sapien products has a contracted state and an expanded state. For example:



Source: "thv_commander.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN 3 Valve" hyperlink; then follow "Transfemoral Procedural Animation" hyperlink)



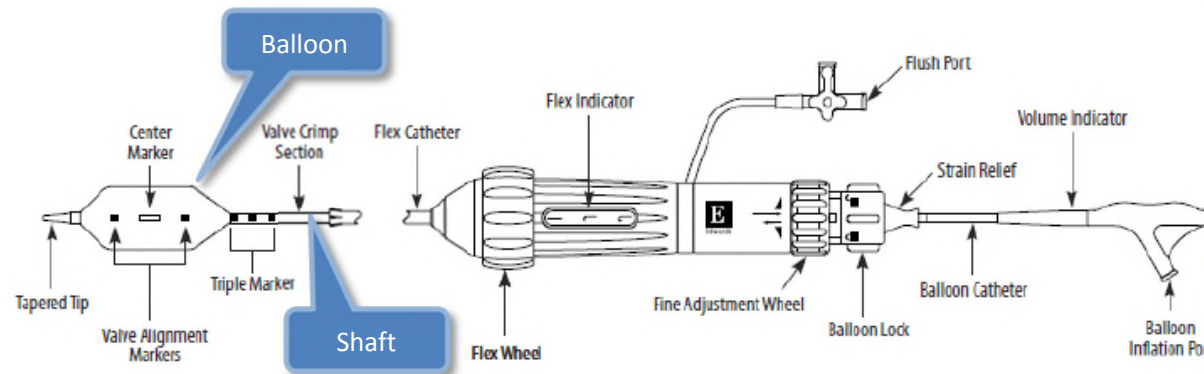
Source: “thv_commander.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN 3 Valve” hyperlink; then follow “Transfemoral Procedural Animation” hyperlink)

[1b]
 a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft, wherein the inflatable means comprises a balloon,

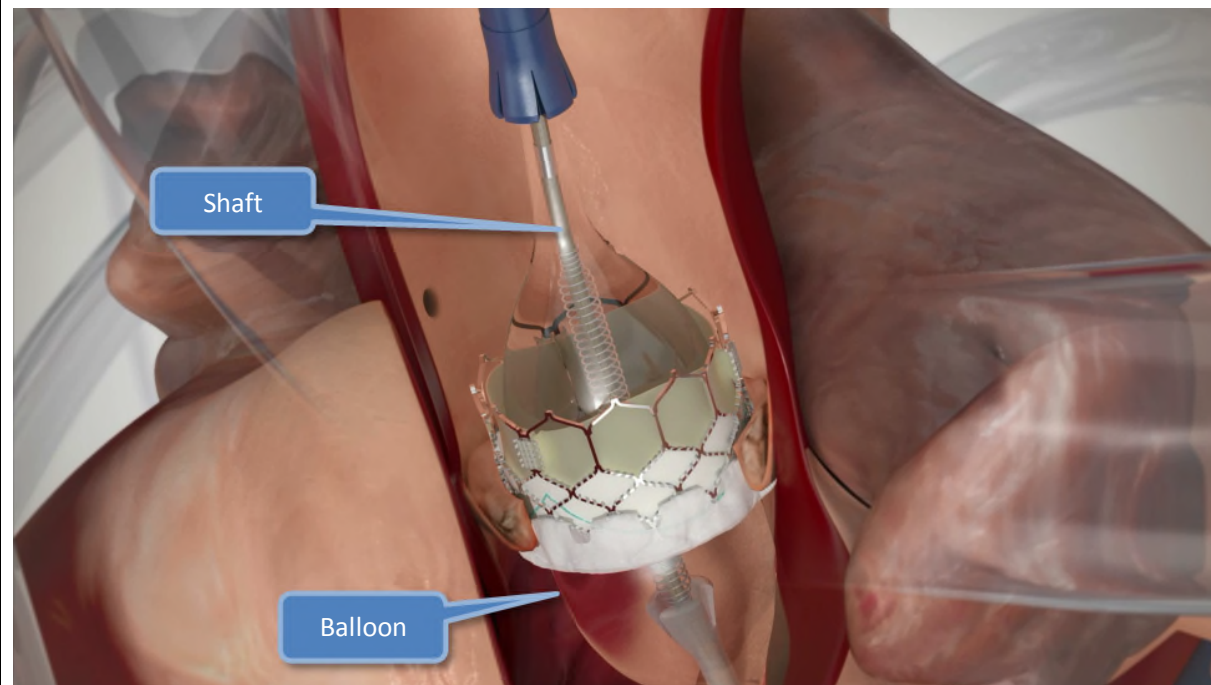
Each of the Sapien products includes a catheter having a shaft. An inflatable means at a distal part of the shaft comprises a balloon. For example:

Commander:

Figure 2 Edwards Commander Delivery System

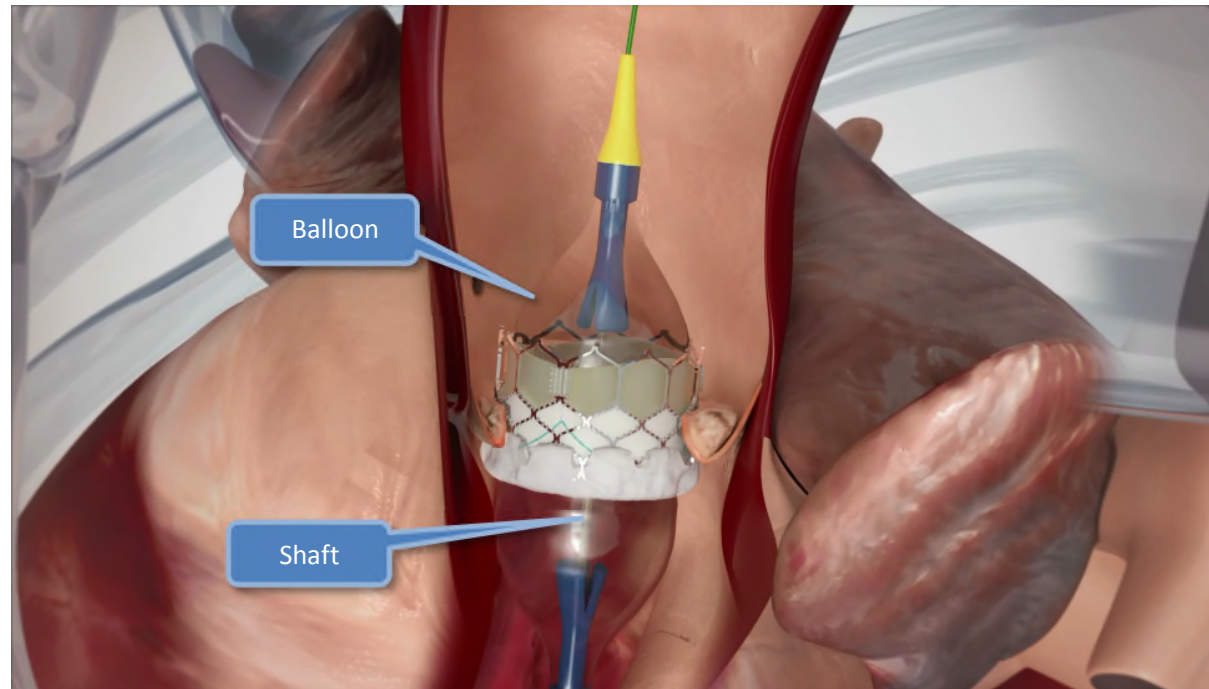


Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 3 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.



Source: "thv_commander.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN 3 Valve" hyperlink; then follow "Transfemoral Procedural Animation" hyperlink)

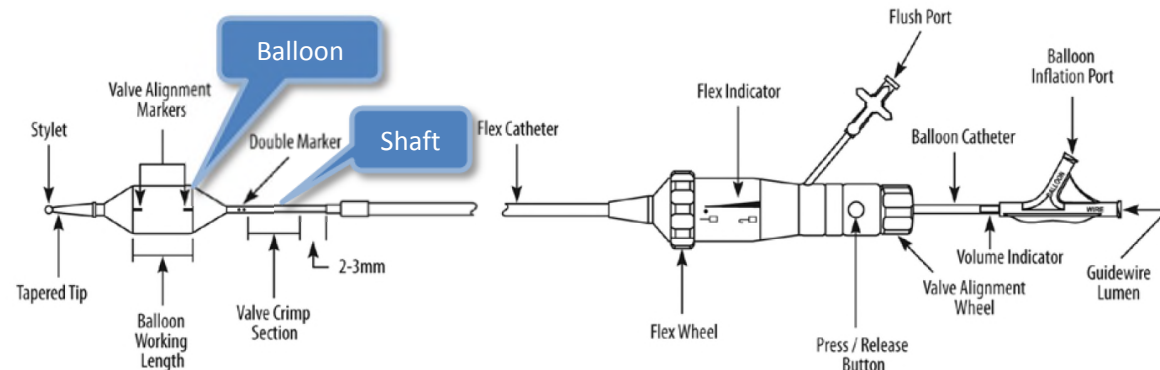
Certitude:



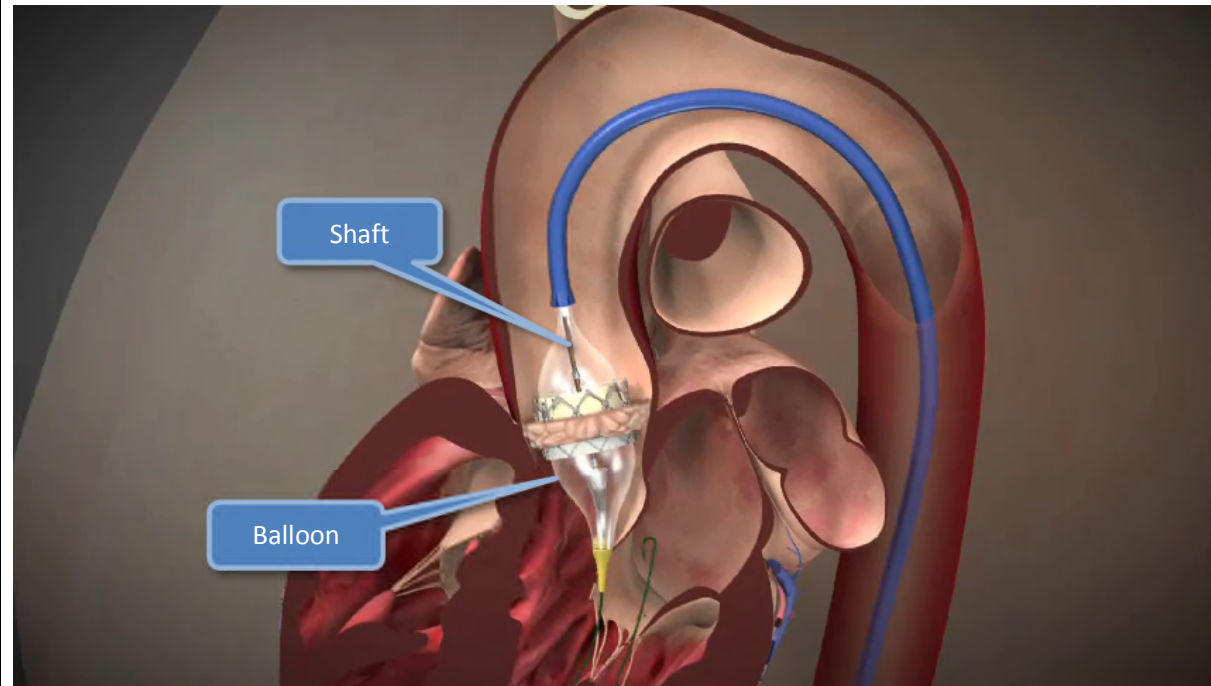
Source: “thv_certitude.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN 3 Valve” hyperlink; then follow “Transapical Procedural Animation” hyperlink)

NovaFlex:

Figure 2a. NovaFlex+ Delivery System



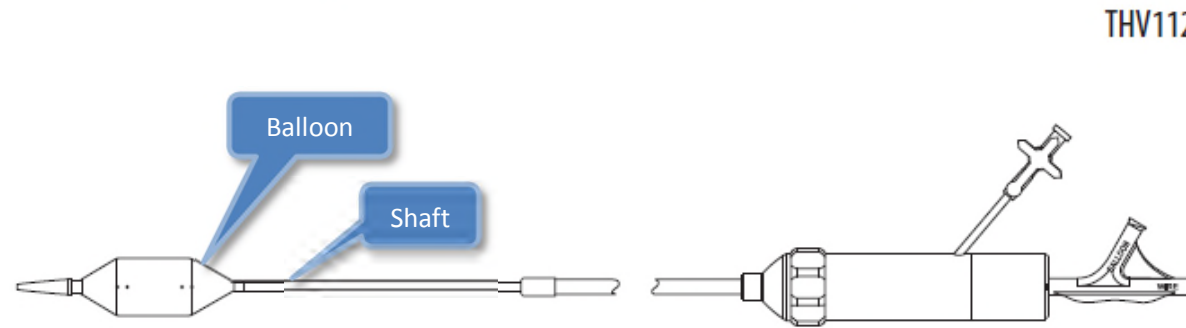
Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.



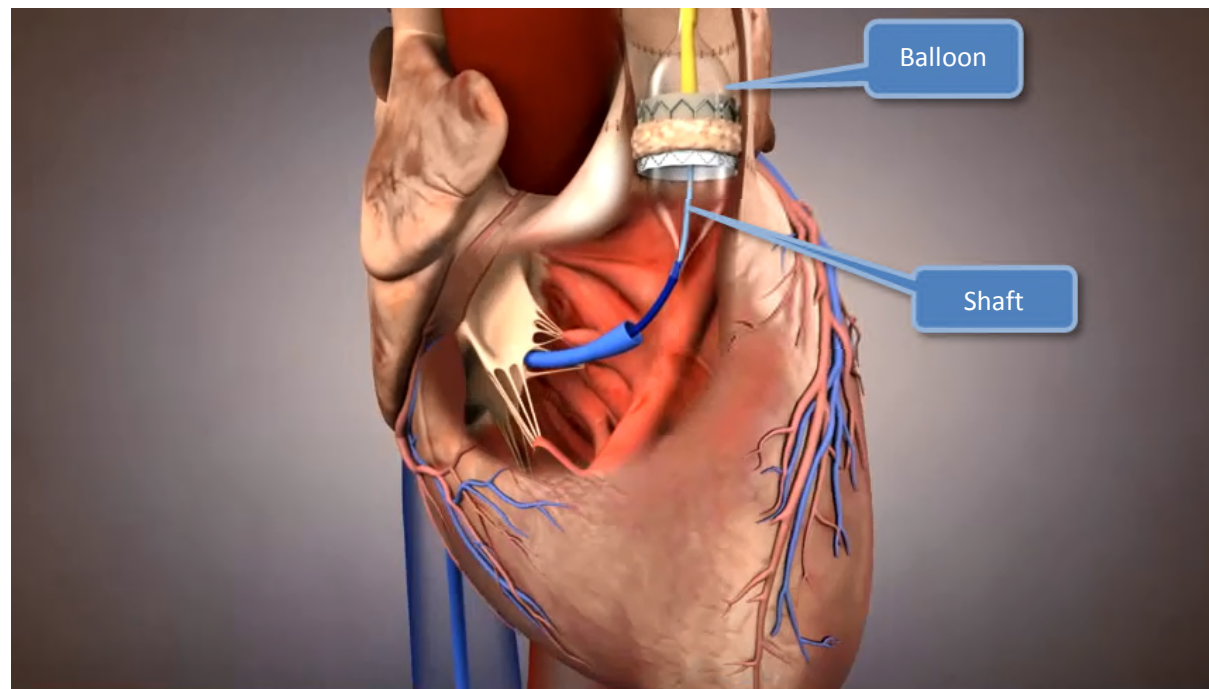
Source: “novaflexplusprocedural.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN XT Valve” hyperlink; then follow “Transfemoral Procedural Animation” hyperlink)

RetroFlex:

Figure 2. RetroFlex 3 Delivery System



Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/Adviso...orySystemDevicesPanel/UCM262938.pdf>.



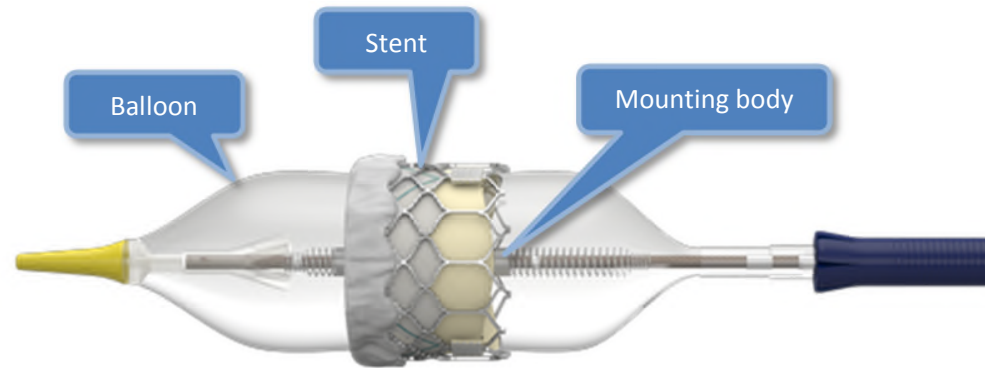
Source: "pulmonicar06026.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN Pulmonic" hyperlink; then follow "Procedural Animation" hyperlink)

[1c]
and including mounting and retaining means for receiving the stent on the expandable inflatable means for radial expansion of the stent upon inflation of the inflatable means, the mounting and retaining means including at

Each of the Commander, Certitude, NovaFlex, and RetroFlex includes a mounting and retaining means (mounting body) carried on and surrounding the shaft inside the inflatable means (balloon). The stent is received on the balloon by the mounting body inside the balloon. Inflation of the balloon causes radial expansion of the stent. For example:

least one mounting body carried on and surrounding the shaft inside the inflatable means,

Commander:

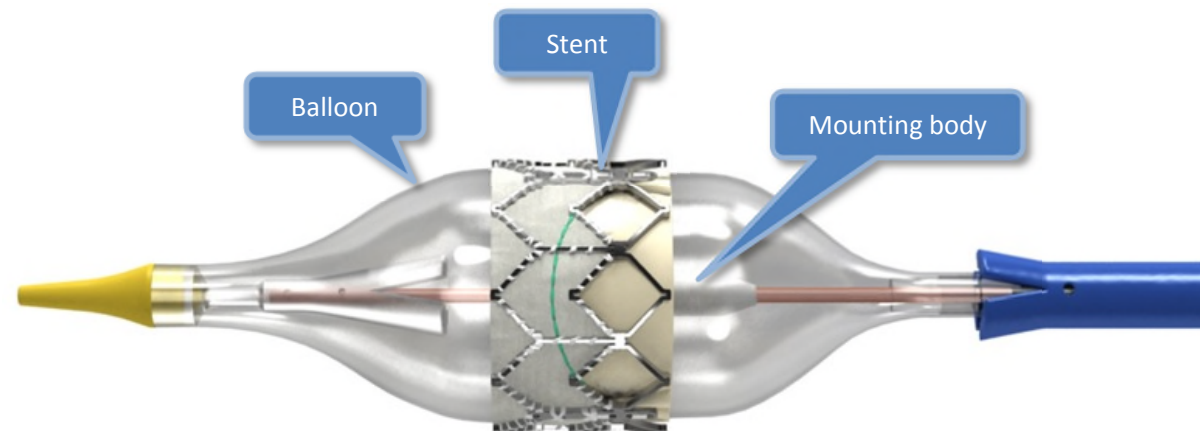


Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

Certitude:

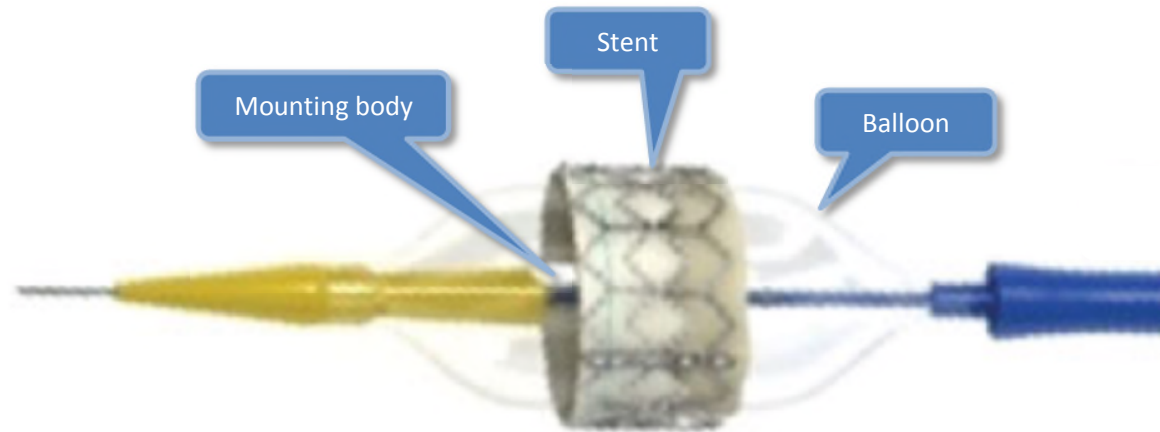
On information and belief, the Certitude has a mounting and retaining means carried on and surrounding the shaft inside the inflatable means, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 *available at* <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:

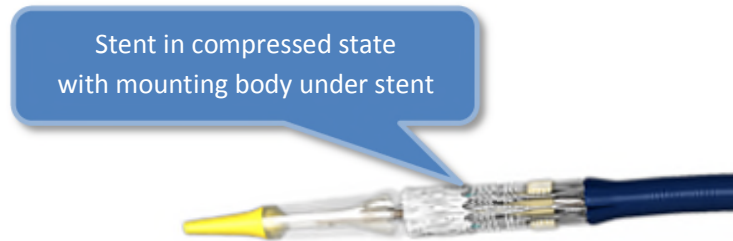


Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, *Catheter Cardiovasc Interv* 2010;75:295–300 at 298.

[1d]
the at least one mounting body being substantially the same length as the stent and being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent,

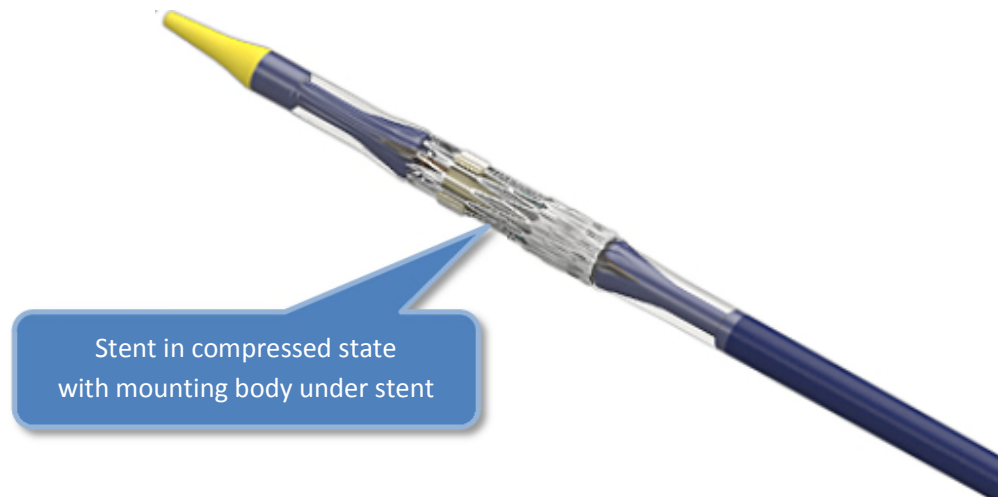
For each of the Commander, Certitude, NovaFlex, and RetroFlex, the mounting body is substantially the same length as the stent. When the stent is loaded onto the balloon and the shaft in the stent's contracted state, at least a portion of the mounting body is under the stent and between first and second ends of the stent. For example:

Commander:



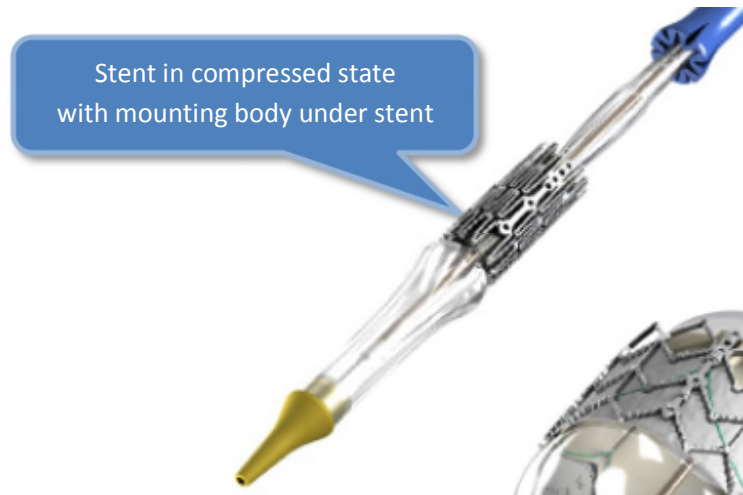
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>.

Certitude:



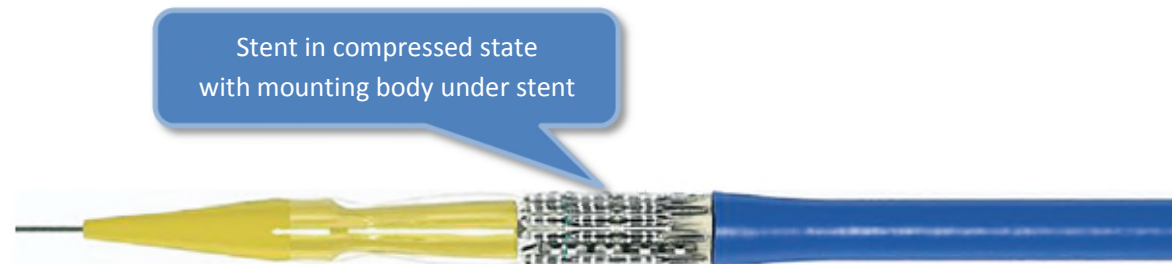
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:



Source: Webb J, Altwegg L, Masson J, Al Bugami S, Al Ali A, Boone R, *A New Transcatheter Aortic Valve and Percutaneous Valve Delivery System*, J Am Coll Cardiol. 2009;53(20):1855-1858 at 1858.

[1e]
whereby the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the mounting and retaining of the stent.

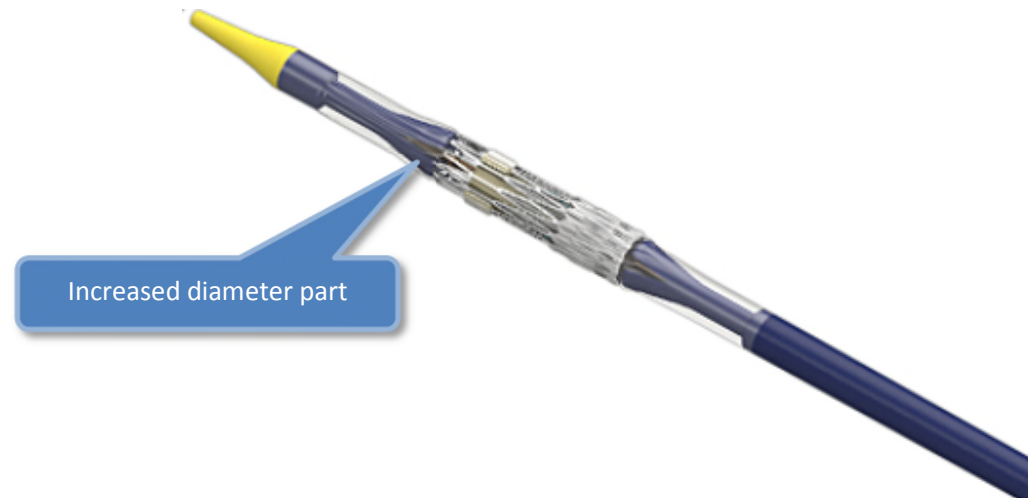
For each of the Commander, Certitude, NovaFlex, and RetroFlex, the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the mounting and retaining of the stent. For example:

Commander:



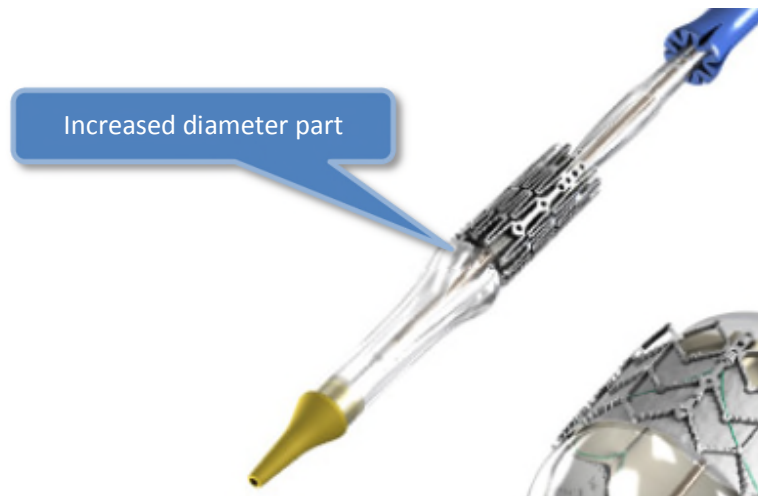
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>.

Certitude:



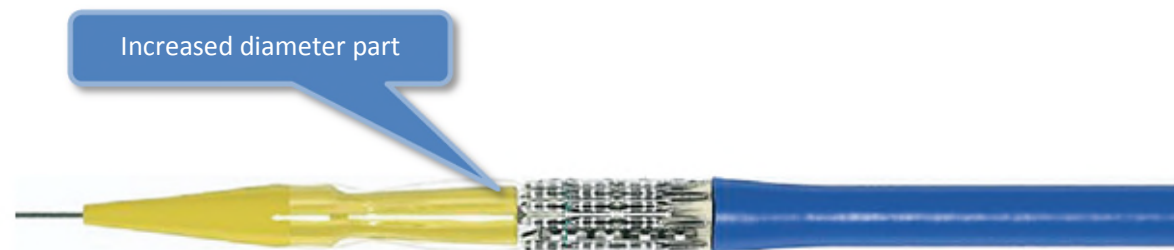
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

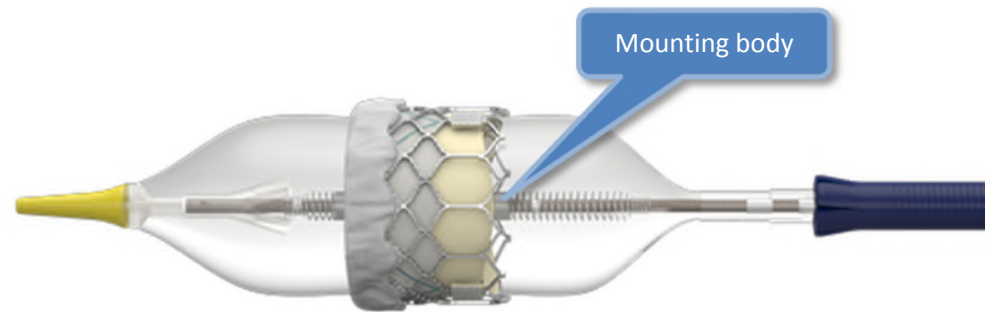
RetroFlex:



Source: Webb J, Altwegg L, Masson J, Al Bugami S, Al Ali A, Boone R, *A New Transcatheter Aortic Valve and Percutaneous Valve Delivery System*, J Am Coll Cardiol. 2009;53(20):1855-1858 at 1858.

Claim 2	
Element	Accused Products
[2 preamble] The stent delivery system of claim 1	<i>See</i> claim chart for claim 1 above.
[2a] wherein the mounting body is of a material which resiliently deforms under radial pressure.	The mounting bodies of each of the Commander, Certitude, NovaFlex, and RetroFlex are of materials which resiliently deform under radial pressure. For example:

Commander:

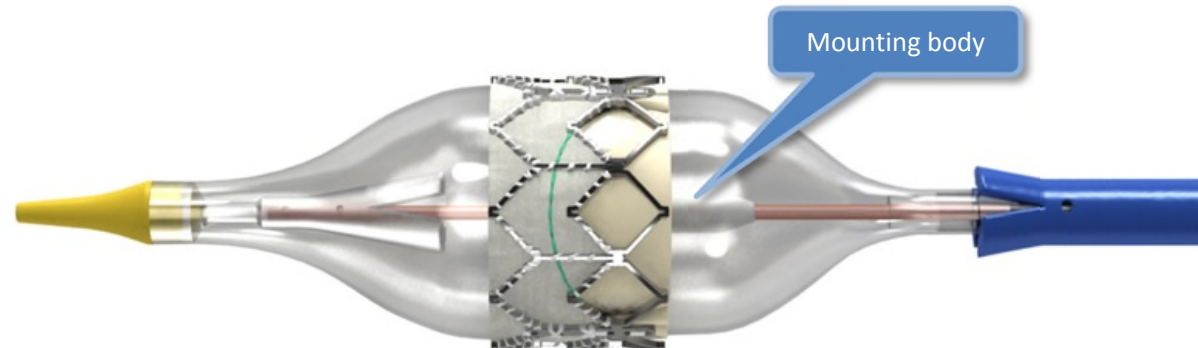


Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

Certitude:

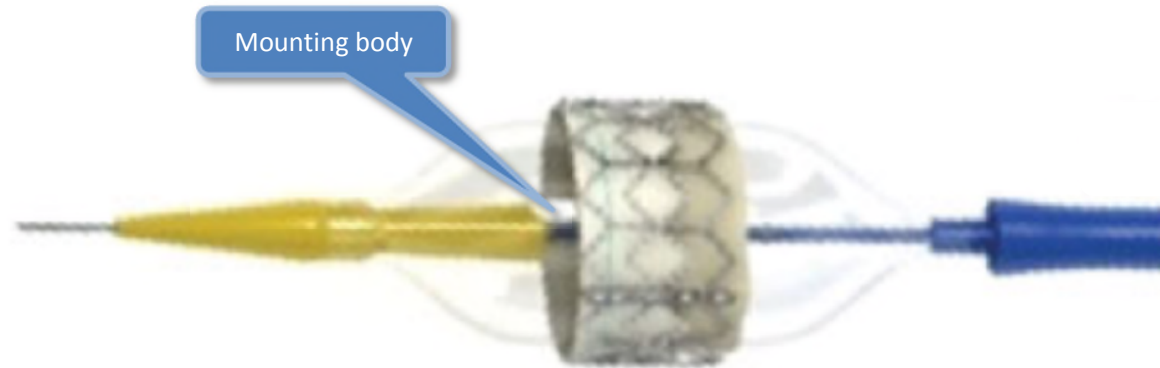
On information and belief, the Certitude has a mounting body of a material which resiliently deforms under radial pressure, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 *available at* <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:



Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, Catheter Cardiovasc Interv 2010;75:295–300 at 298.

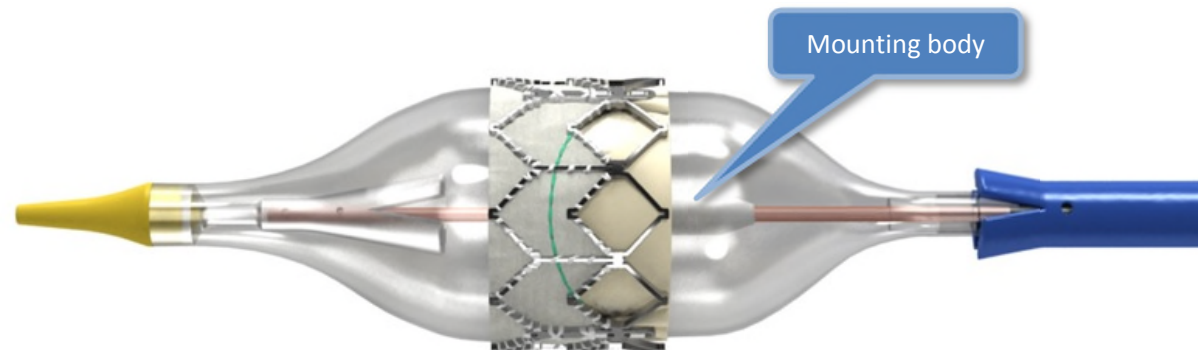
Claim 3

Element	Accused Products
[3 preamble] The stent delivery system of claim 2	See claim chart for claim 2 above.
[3a] wherein the material is elastomeric.	The mounting bodies of the Certitude, NovaFlex, and RetroFlex are of elastomeric material. For example:

Certitude:

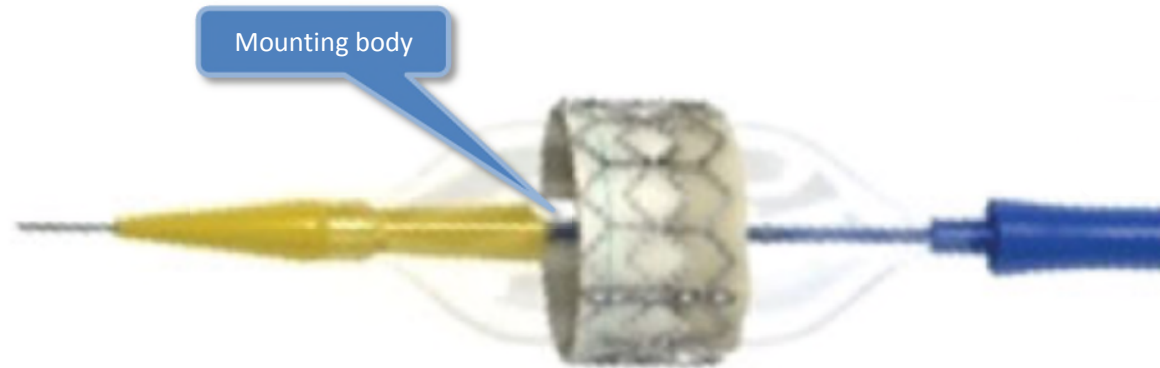
On information and belief, the Certitude has a mounting body of an elastomeric material, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 *available at* <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:



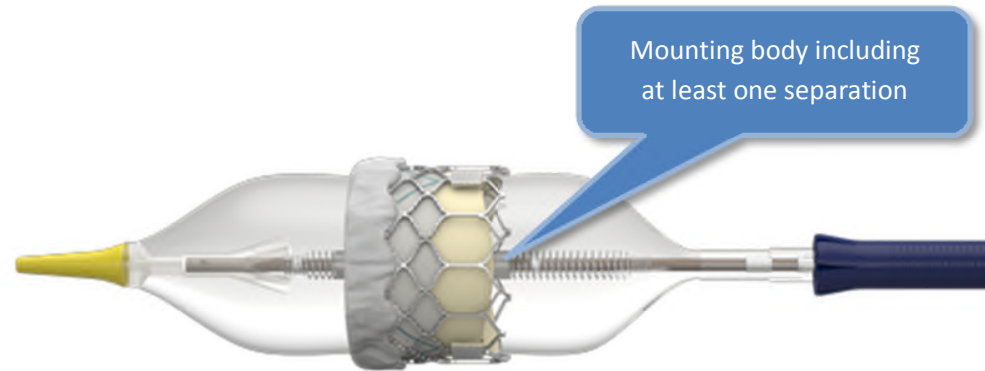
Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, *Catheter Cardiovasc Interv* 2010;75:295–300 at 298.

Claim 6

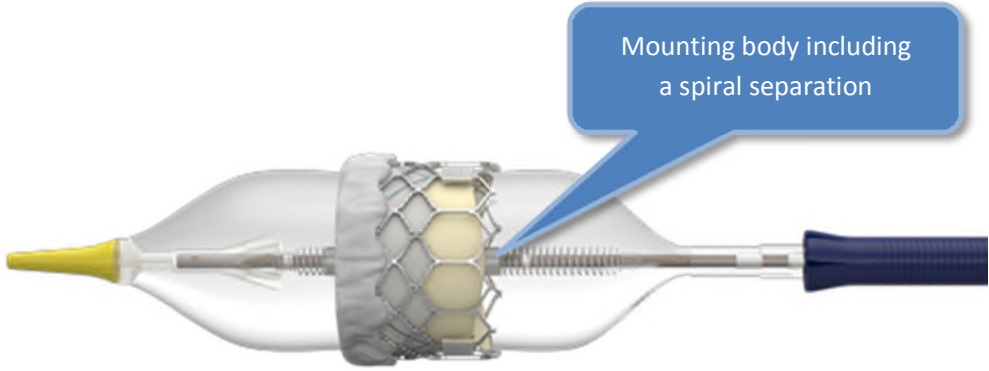
Element	Accused Products
[6 preamble] The stent delivery system of claim 1	See claim chart for claim 1 above.
[6a] wherein the at least one mounting body includes at least one separation whereby the flexibility of the body	The mounting body of the Commander includes a coil having at least one separation. For example:

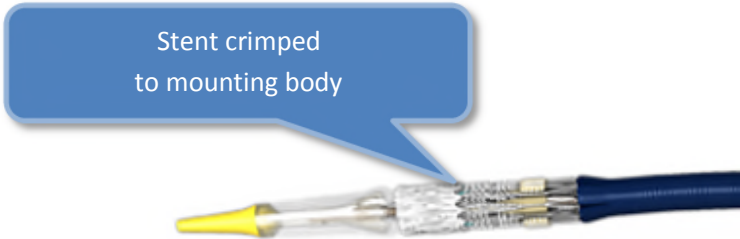
and catheter is increased.

Commander:

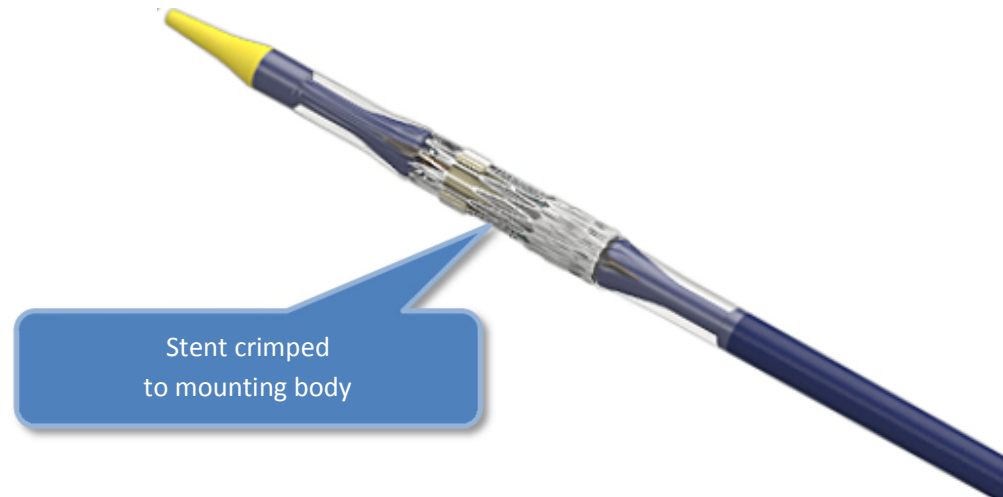


Source: "635907831022739465-EdwardsCommander-Distal.Expand.Valve.png" available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

Claim 7	
Element	Accused Products
[7 preamble] The stent delivery system of claim 6	See claim chart for claim 6 above.
[7a] wherein the separation is in the form of a spiral.	<p>The mounting body of the Commander includes a coil having at least one separation in the form of a spiral. For example:</p> <p><u>Commander:</u></p> <div style="text-align: center;">  </div> <p>Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/.</p>

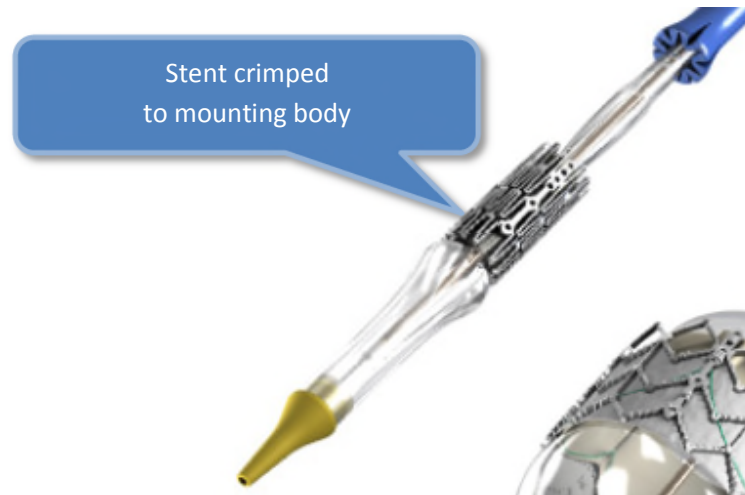
Claim 8	
Element	Accused Products
[8 preamble] The stent delivery system of claim 1	<i>See</i> claim chart for claim 1 above.
[8a] wherein the stent is crimped to the mounting and retaining means for delivery.	<p>For each of the Commander, Certitude, NovaFlex, and RetroFlex, the stent is crimped to the mounting and retaining means for delivery. For example:</p> <p><u>Commander:</u></p> <div style="text-align: center;">  </div> <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx.</p>

Certitude:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:

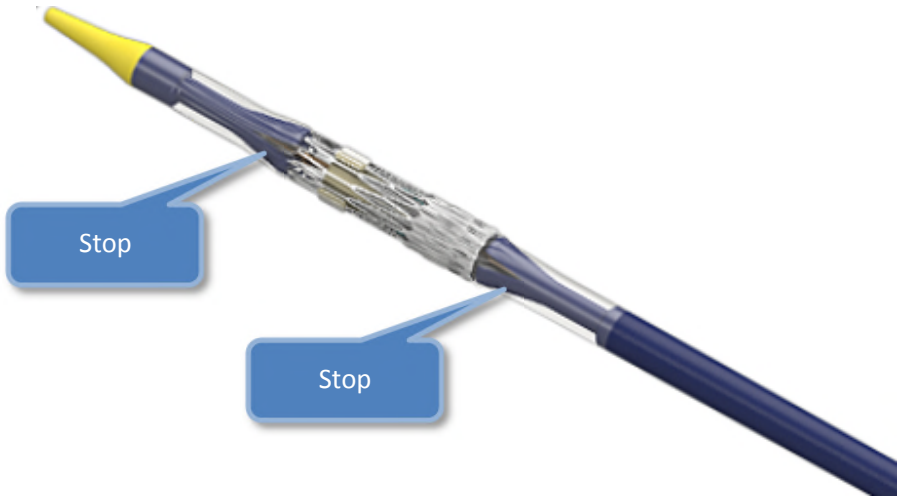


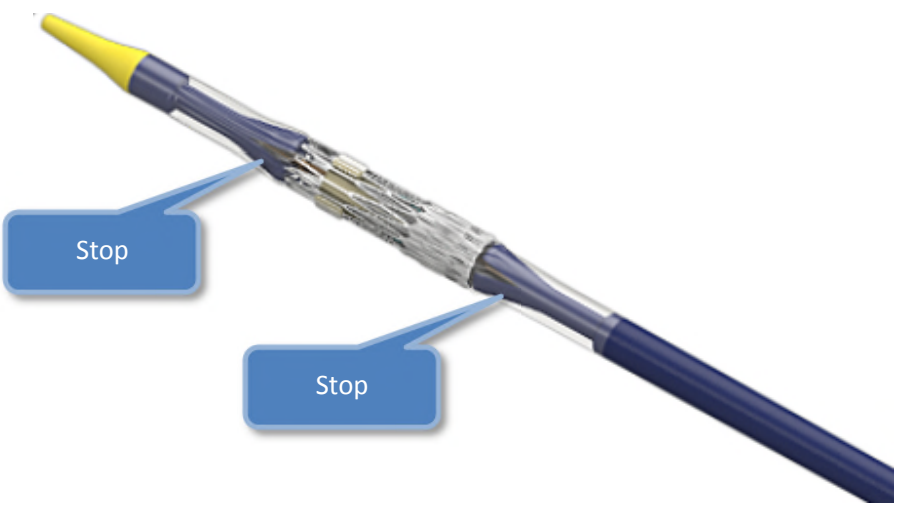
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:

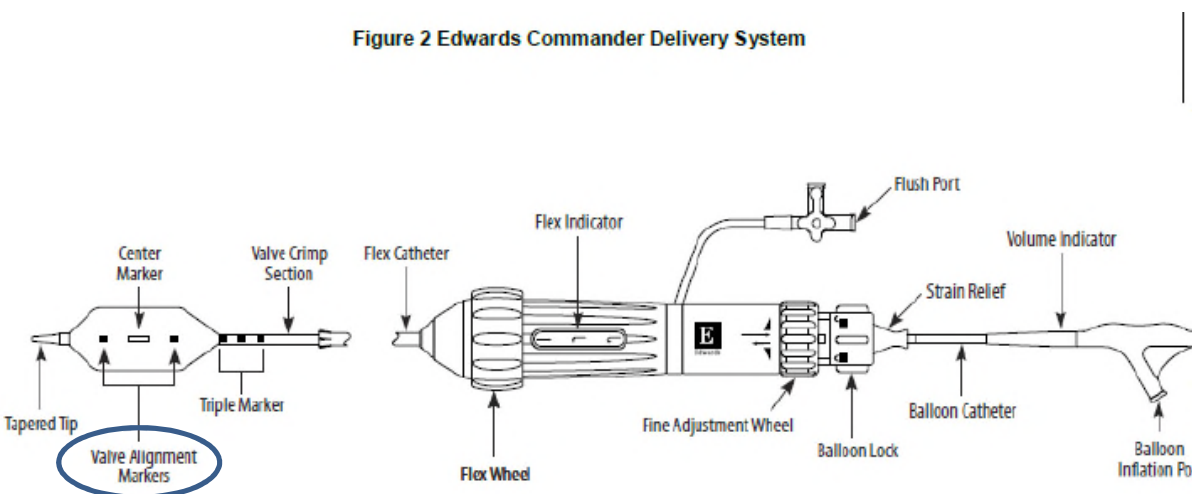


Source: Webb J, Altwegg L, Masson J, Al Bugami S, Al Ali A, Boone R, *A New Transcatheter Aortic Valve and Percutaneous Valve Delivery System*, J Am Coll Cardiol. 2009;53(20):1855-1858 at 1858.

Claim 9	
Element	Accused Products
[9 preamble] The stent delivery system of claim 1,	<i>See claim chart for claim 1 above.</i>
[9a] wherein the stent has two opposite ends, the stent delivery system further including a pair of stops, each of which is respectively positioned at the opposite ends of the stent and carried by the shaft inside the inflatable means.	<p>The Certitude includes a pair of stops positioned at opposite ends of the stent and carried by the shaft inside the inflatable means. For example:</p> <p><u>Certitude:</u></p>  <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx.</p>

Claim 10	
Element	Accused Products
[10 preamble] The stent delivery system of claim 9	See claim chart for claim 1 above.
[10a] wherein the stops are conical in shape.	<p>The stops of the Certitude are conical in shape. For example:</p> <p><u>Certitude:</u></p>  <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx.</p>

Claim 11

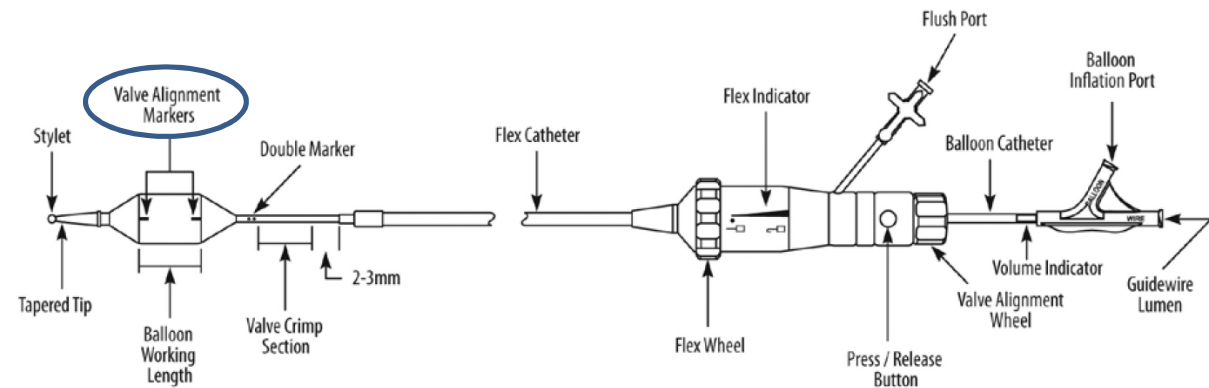
Element	Accused Products
<p>[11 preamble] The stent delivery system of claim 1</p>	<p>See claim chart for claim 1 above.</p>
<p>[11a] further including marker bands positioned proximally and distally of the stent.</p>	<p>Each of the Commander, Certitude, NovaFlex, and RetroFlex includes marker bands positioned proximally and distally of the stent. For example:</p> <p><u>Commander:</u></p> <p align="center">Figure 2 Edwards Commander Delivery System</p>  <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 3 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p>Before deployment, ensure that the THV is correctly positioned between the Valve Alignment Markers and the Flex Catheter tip is over the Triple Marker.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 11 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

Certitude:

On information and belief, the Certitude has marker bands positioned proximally and distally of the stent, as will be demonstrated with further discovery.

NovaFlex:

Figure 2a. NovaFlex+ Delivery System



Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.

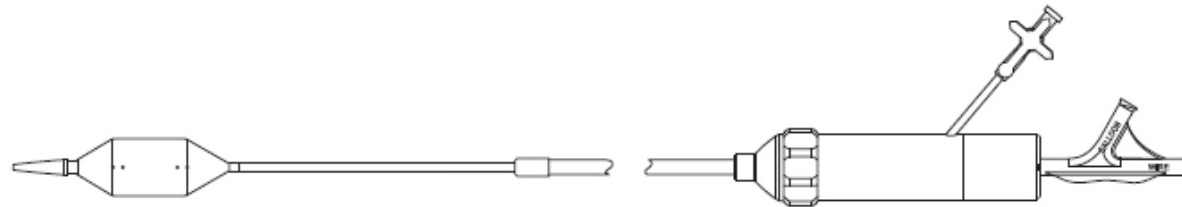
Use the Valve Alignment Wheel to position the THV between the valve alignment markers.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 9 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.

RetroFlex:

Figure 2. RetroFlex 3 Delivery System

THV112



Black dots indicate position of radiopaque markers.

Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf>.

Claim 12

Element	Accused Products
[12 preamble] The stent delivery system of claim 1	See claim chart for claim 1 above.

[12a]
further including a stop
carried by the shaft and
positioned inside the
inflatable means and axially
spaced relative to the stent.

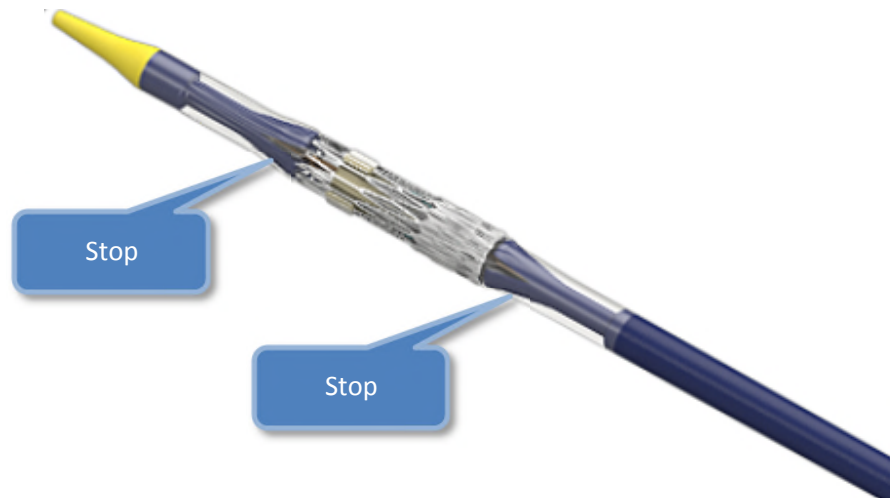
Each of the Commander, Certitude, NovaFlex, and RetroFlex includes a stop carried by the shaft and positioned inside the inflatable means and axially spaced relative to the stent. For example:

Commander:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>.

Certitude:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:



Source: Webb J, Altwegg L, Masson J, Al Bugami S, Al Ali A, Boone R, *A New Transcatheter Aortic Valve and Percutaneous Valve Delivery System*, J Am Coll Cardiol. 2009;53(20):1855-1858 at 1858.

Claim 19	
Element	Accused Products
[19 preamble] A balloon catheter for intraluminal delivery of a stent, the catheter comprising	See chart for claim [1 preamble] above.
[19a] a shaft having a diameter,	See chart for claim [1b] above.
[19b] a balloon associated with a distal portion of the shaft for receiving a stent,	See chart for claim [1b] above.
[19c] the stent having a first end and a second end and a contracted state and an expanded state, and means for inflating the balloon,	See chart for claim [1b] above.
[19d] the shaft including at least one mounting body radially carried on the shaft inside the balloon, the at least one mounting body being substantially the same length as the stent,	See chart for claim [1c] above. See chart for claim [1d] above.
[19e] the at least one mounting body being positioned on the shaft such that when the stent	See chart for claim [1d] above.

is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent.	
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Claim 20	
Element	Accused Products
[20 preamble] The catheter of claim 19	<i>See claim chart for claim 19 above.</i>
[20a] wherein the mounting body is of a material which resiliently deforms under radial pressure.	<i>See claim chart for claim 2 above.</i>

Claim 21	
Element	Accused Products
[21 preamble] The catheter of claim 20	<i>See claim chart for claim 20 above.</i>
[21a] wherein the material is elastomeric.	<i>See claim chart for claim 3 above.</i>

Claim 24	
Element	Accused Products
[24 preamble] The catheter of claim 19	<i>See claim chart for claim 19 above.</i>
[24a] wherein the mounting body is configured with at least one separation whereby trackability of the catheter is improved.	<i>See claim chart for claim 6 above.</i>

Claim 25	
Element	Accused Products
[25 preamble] The catheter of claim 24	<i>See claim chart for claim 24 above.</i>
[25a] wherein the separation is in a spiral configuration.	<i>See claim chart for claim 7 above.</i>

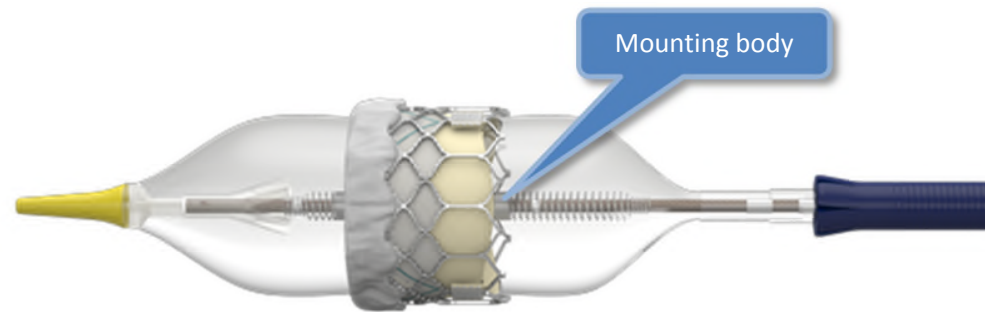
Claim 26	
Element	Accused Products
[26 preamble] The catheter of claim 19	<i>See claim chart for claim 19 above.</i>
[26a] further including a pair of spaced stops.	<i>See claim chart for claim 9 above.</i>

Claim 27	
Element	Accused Products
[27 preamble] The catheter of claim 26	<i>See claim chart for claim 26 above.</i>
[27a] wherein the stops are conical in shape.	<i>See claim chart for claim 10 above.</i>

Claim 28	
Element	Accused Products
[28 preamble] The catheter of claim 19	<i>See claim chart for claim 19 above.</i>
[28a] further including spaced marker bands.	<i>See claim chart for claim 11 above.</i>

Claim 29	
Element	Accused Products
[29 preamble] The catheter of claim 19	<i>See claim chart for claim 19 above.</i>
[29a] wherein the mounting body is cylindrical in shape.	The mounting bodies of each of the Commander, Certitude, NovaFlex, and RetroFlex are cylindrical in shape. For example:

Commander:

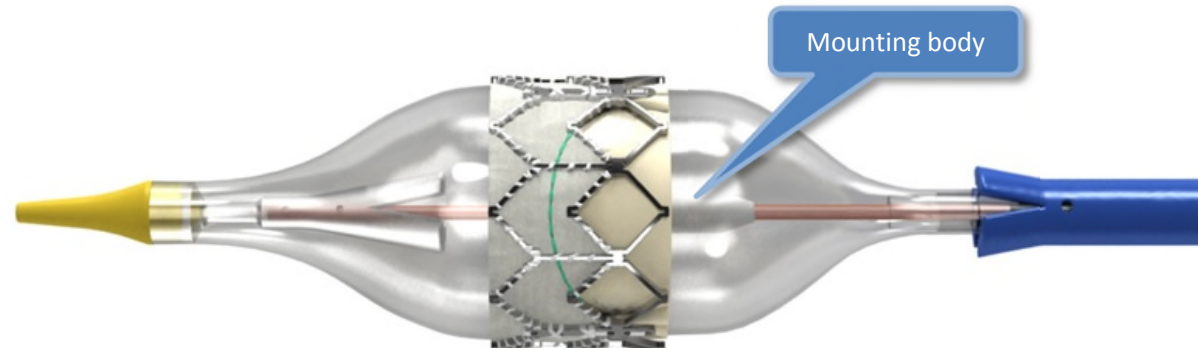


Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

Certitude:

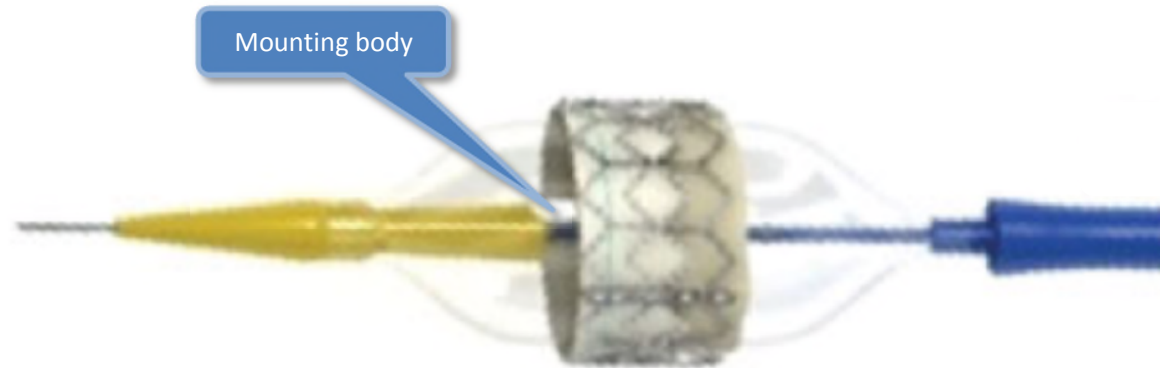
On information and belief, the Certitude has a mounting body that is cylindrical in shape, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 *available at* <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:



Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, *Catheter Cardiovasc Interv* 2010;75:295–300 at 298.

**Ex. B: CLAIM CHART FOR INFRINGEMENT OF
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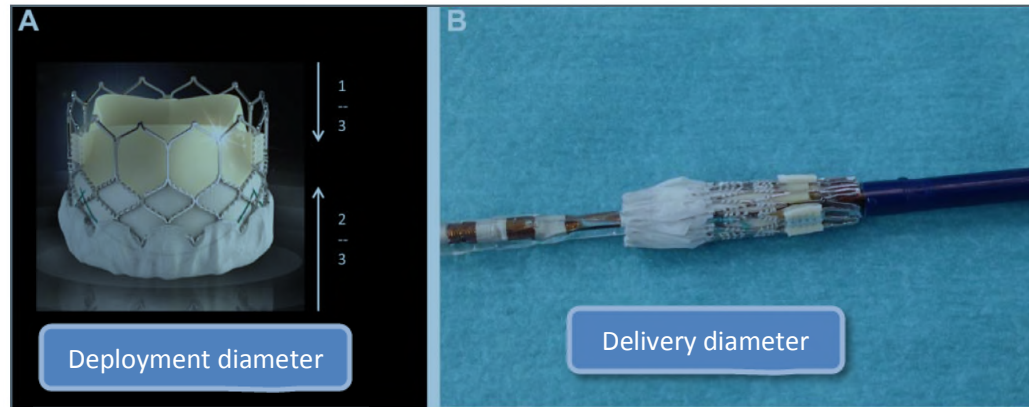
Claim 1	
Element	Accused Products
<p>[1 preamble¹] A system/assembly for delivery and deployment of an inflation expandable stent within a vessel, comprising:</p>	<p>To the extent the preamble is deemed a limitation, on information and belief, Edwards made, used, offered to sell, and/or sold in the United States, and/or imported into the United States the balloon catheter used in its Commander Delivery System (“Commander”) for delivery and deployment of its Sapien 3 product.</p> <p>Sapien 3 comprises an inflation expandable stent that is delivered and/or deployed within a vessel.</p>
<p>[1a] a catheter having proximal and distal ends;</p>	<p>The Commander has proximal and distal ends as further detailed below.</p>
<p>[1b] a stent, inflation expandable from a delivery diameter to a deployment diameter, such that the delivery diameter is reduced from the deployment diameter for conforming the stent to the catheter, such that the stent, in its delivery diameter, is coaxially mounted on the catheter near the catheter distal end;</p>	<p>The Commander comprises balloon-expandable stent which is coaxially mounted on the catheter near the catheter’s distal end. For example:</p> <p>The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p>The Edwards SAPIEN XT transcatheter heart valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and a polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.</p>

¹ The designations in square brackets before the claim language in each row is added to permit convenient reference to specific claim language. These added designations are not part of the claim language and are not intended to limit the claims in any way. No interpretation is intended to be conveyed by the words grouped together with each designation.

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The Edwards SAPIEN transcatheter heart valve (bioprosthesis) is comprised of a balloon-expandable, radiopaque, stainless steel (316 L) frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) fabric. The bioprosthesis is treated according to the Carpentier-Edwards ThermaFix process, packaged, and terminally sterilized in glutaraldehyde

Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/Adviso...orySystemDevicesPanel/UCM262938.pdf>.



Source: Schymik, M.D., et. al., “How to Adapt the Implantation Technique for the New SAPIEN 3 Transcatheter Heart Valve Design,” Journal of Interventional Cardiology, 2014.

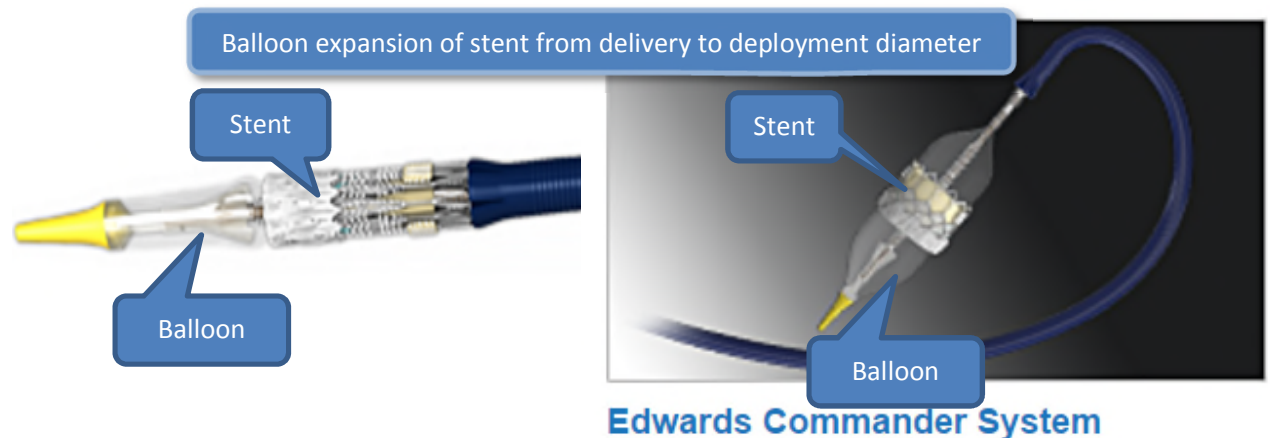
1.0 Device Description

• **Edwards SAPIEN 3 Transcatheter Heart Valve- Model 9600TFX (Figure 1)**

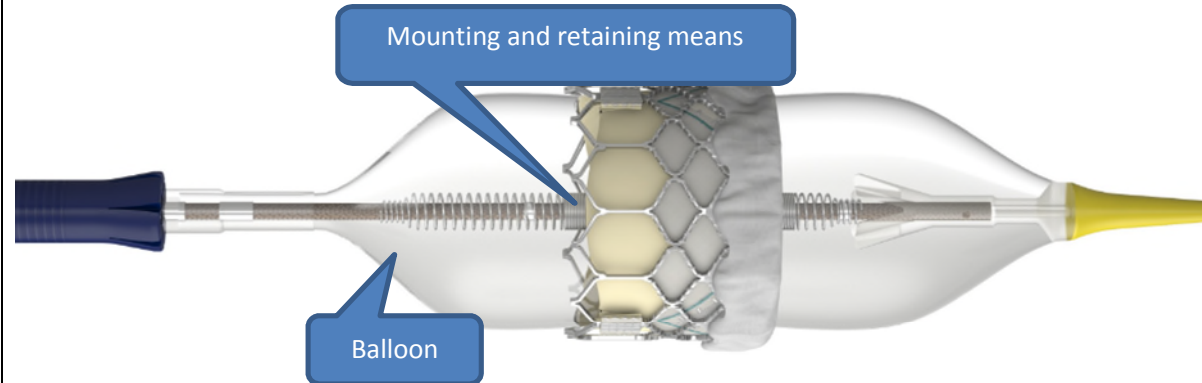
The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

Source: http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf, p. 2.

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<p>[1c] an expandable inflation means coaxially mounted on the catheter within the stent, for expansion of the stent from the delivery diameter to the deployment diameter upon application of deployment pressure to the expandable inflation means; and</p>	<p>The Commander has a balloon that functions as an expandable inflation means and is mounted coaxially on the catheter. The stent is then mounted on the catheter and balloon and is expanded by the balloon from the delivery diameter to the deployment diameter. For example:</p>  <p>The diagram illustrates the Edwards Commander System. On the left, a close-up view shows a yellow balloon and a stent mounted on a catheter. Callouts identify the 'Balloon' and 'Stent'. On the right, a larger view shows the system with the balloon expanded, pushing the stent to its deployment diameter. A callout at the top reads 'Balloon expansion of stent from delivery to deployment diameter'. Another callout points to the 'Stent' and a third points to the 'Balloon'. The text 'Edwards Commander System' is centered below the images.</p> <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx Source: http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx</p>
<p>[1d] a mounting and retaining means coaxially mounted on the catheter within the expandable inflation means, the mounting and retaining means designed and adapted to provide a securement for the stent in the delivery diameter to maintain the stent in position on the catheter during delivery to the deployment site,</p>	<p>The Commander has a mounting and retaining means coaxially mounted on the catheter within the expandable inflation means (the balloon) that provides a securement for the stent in the delivery diameter and maintains the stent in position on the catheter during delivery to the deployment site. For example:</p>

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Source: http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg

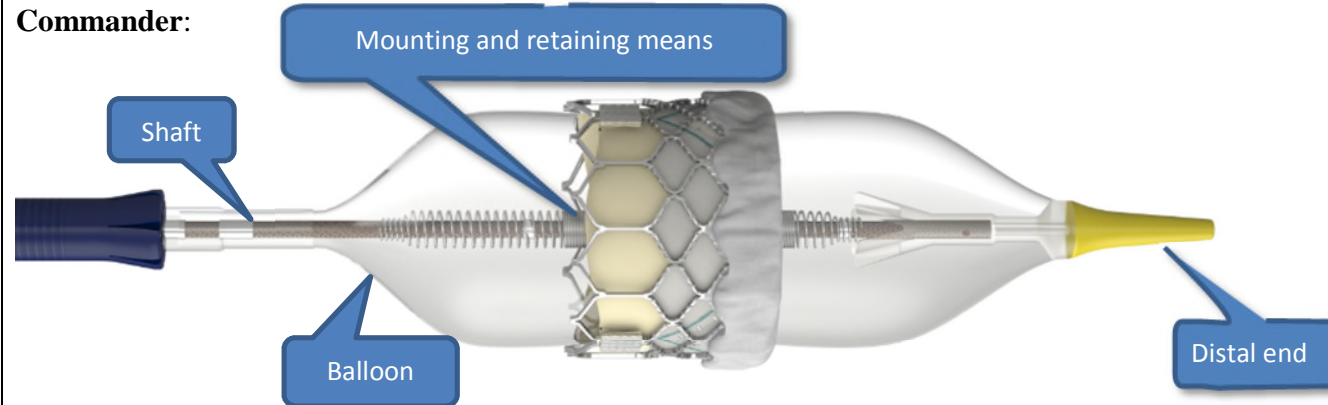


Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>

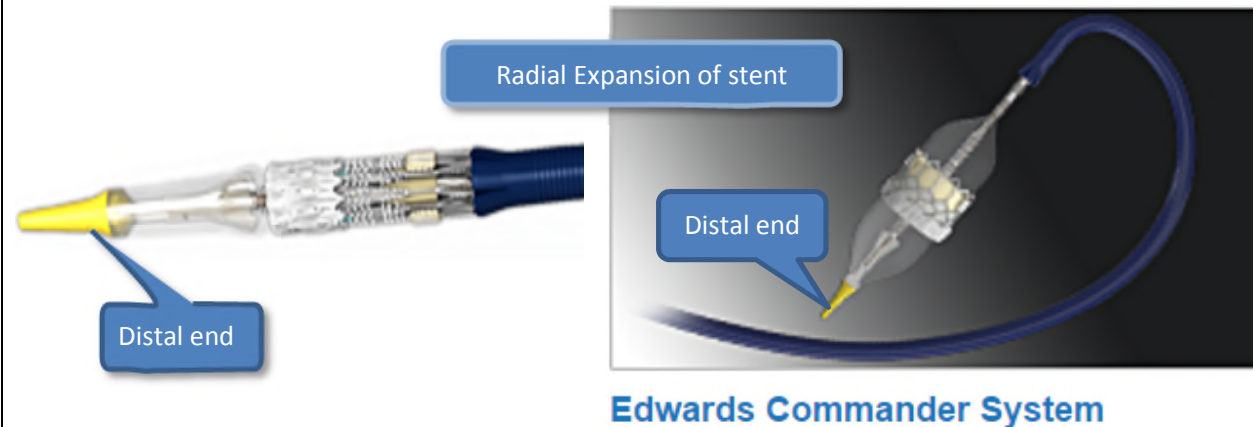
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[1e]
the catheter having a shaft
and the expandable inflation
means being positioned at a
distal part of the shaft, the
mounting and retaining
means being positioned for
receiving the stent on the
expandable inflation means
for radial expansion of the
stent upon expansion of the
expandable inflation means,

The Commander has a shaft, with the expandable inflation means (the balloon) at the distal end. The mounting and retaining means of the Commander is positioned for receiving the stent on the balloon for radial expansion of the stent upon expansion of the balloon. For example:



Source: http://www.healthwellnesscolorado.com/wpcontent/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand_Valve_.jpg



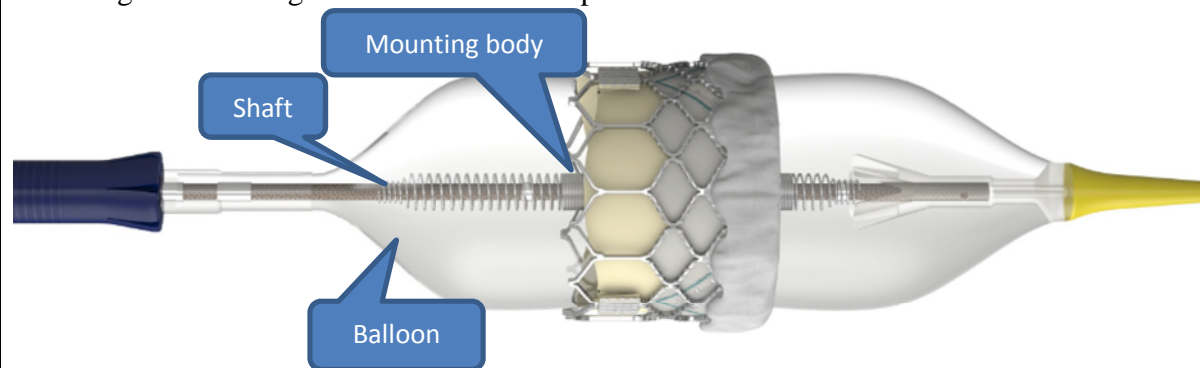
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>

Source: <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx>

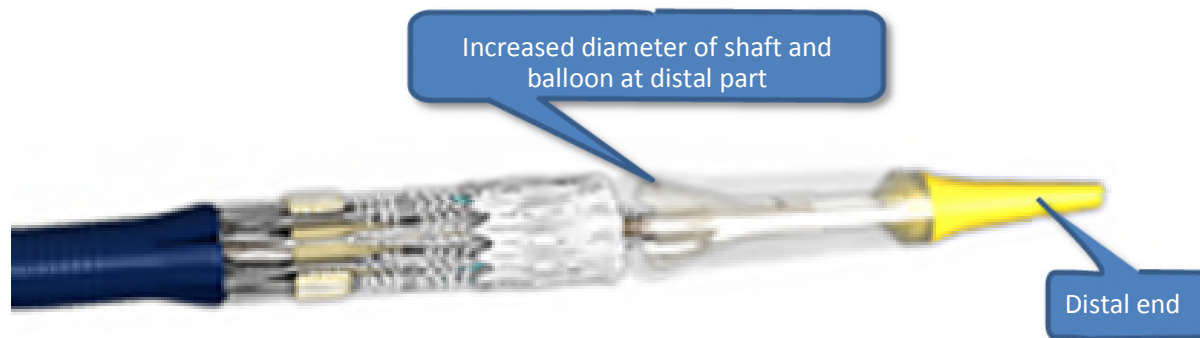
**Ex. B: CLAIM CHART FOR INFRINGEMENT OF
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[1f]
the mounting and retaining means including at least one mounting body carried by the shaft inside the expandable inflation means whereby the diameter of the shaft and expandable inflation means are increased at the distal part for facilitating the mounting and retaining of the sent,

In the Commander, the mounting and retaining means includes a mounting body carried by the shaft inside the balloon whereby the diameter of the shaft and balloon are increased at the distal part for facilitating the mounting and retaining of the sent. For example:



Source: http://www.healthwellnesscolorado.com/wpcontent/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg

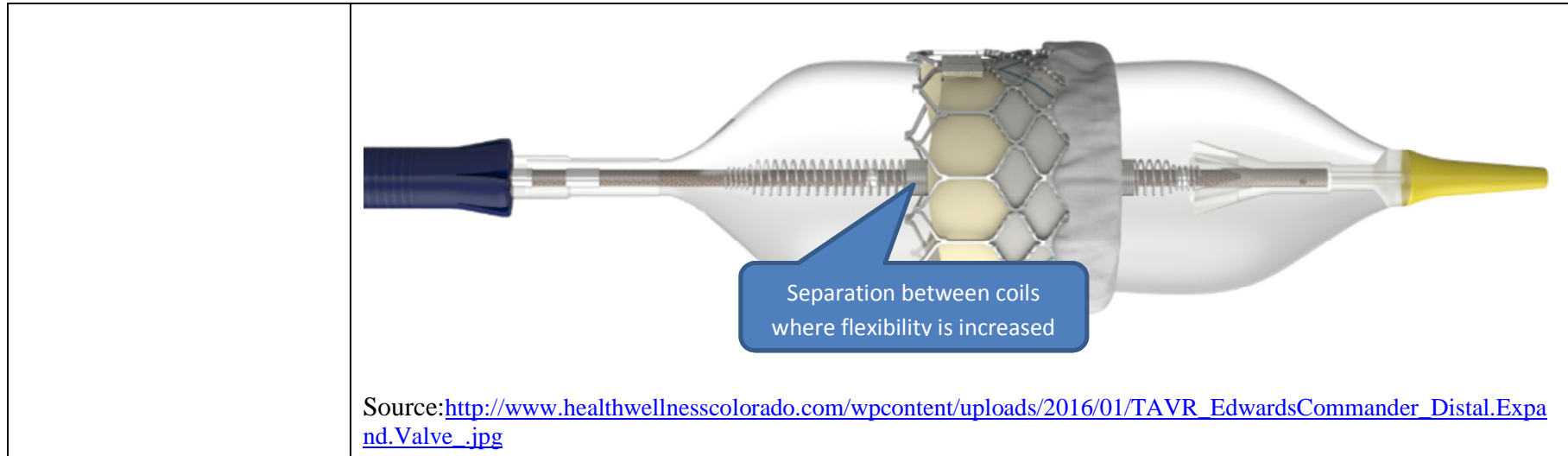


Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>

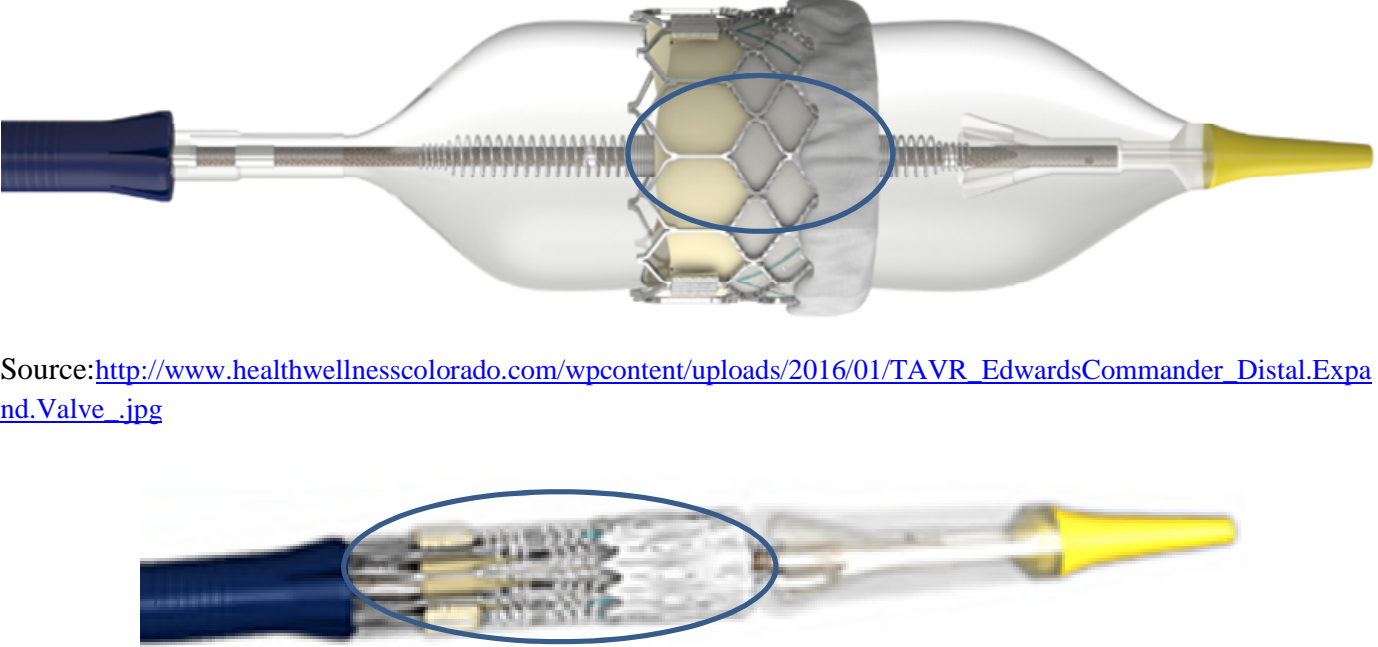
[1g]
the mounting body including at least one separation, whereby the flexibility of the body and catheter is increased.

In the Commander, the mounting body includes at least one separation whereby the flexibility is increased. For example:

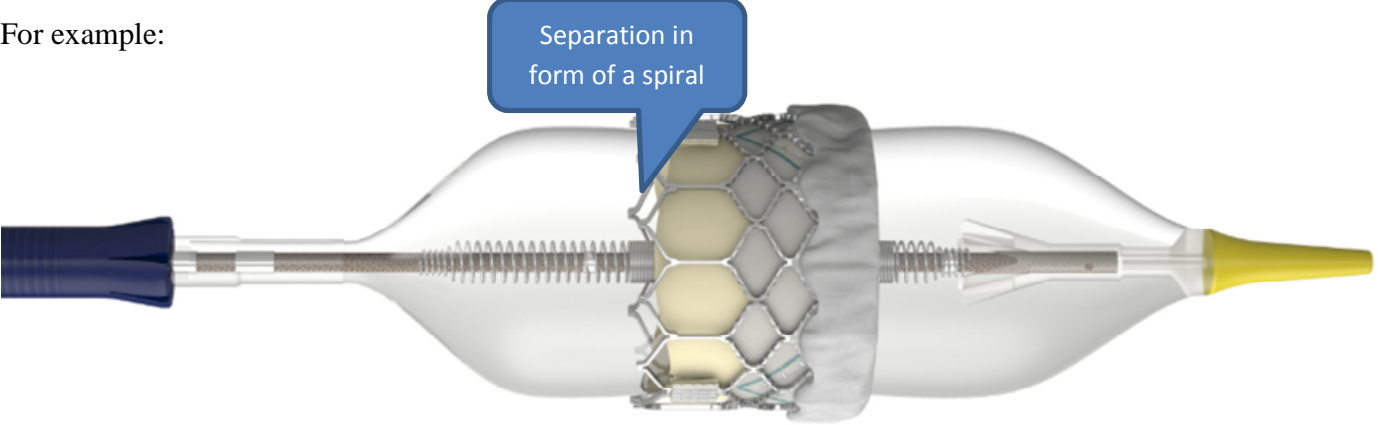
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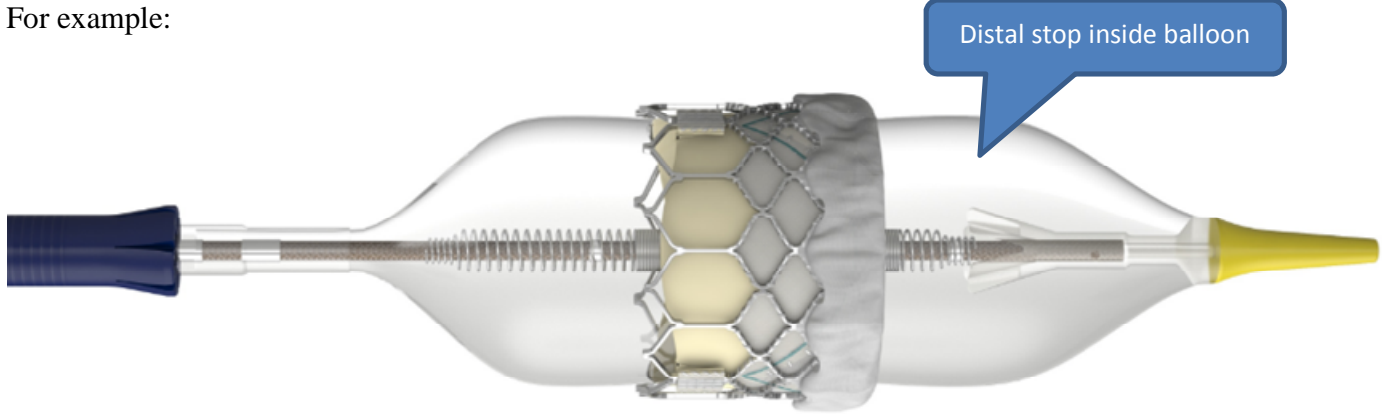
**Ex. B: CLAIM CHART FOR INFRINGEMENT OF
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Claim 2	
Element	Accused Products
[2 preamble] The system of claim 1:	As shown in connection with claim 1, the Commander includes all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[2a] wherein the mounting body is substantially the same length as the stent.	<p>The Commander's mounting body is substantially the same length as the stent. For example:</p>  <p>Source: http://www.healthwellnesscolorado.com/wpcontent/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p> <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx</p>

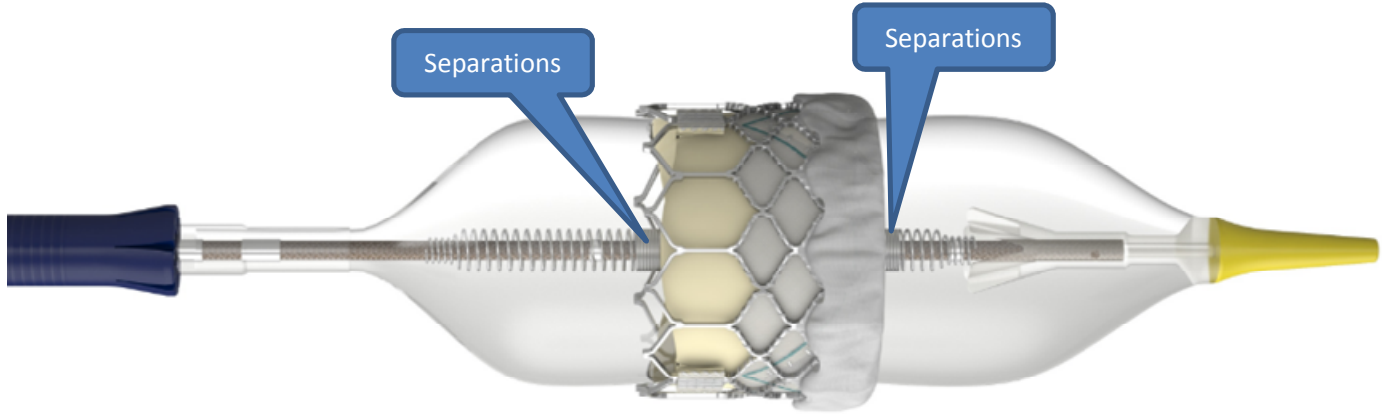
**Ex. B: CLAIM CHART FOR INFRINGEMENT OF
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Claim 9	
Element	Accused Products
[9 preamble] The stent delivery system of claim 1:	As shown in connection with claim 1, the Commander includes all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[9a] wherein the separation is in the form of a spiral.	<p>For example:</p>  <p>Source: http://www.healthwellnesscolorado.com/wpcontent/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

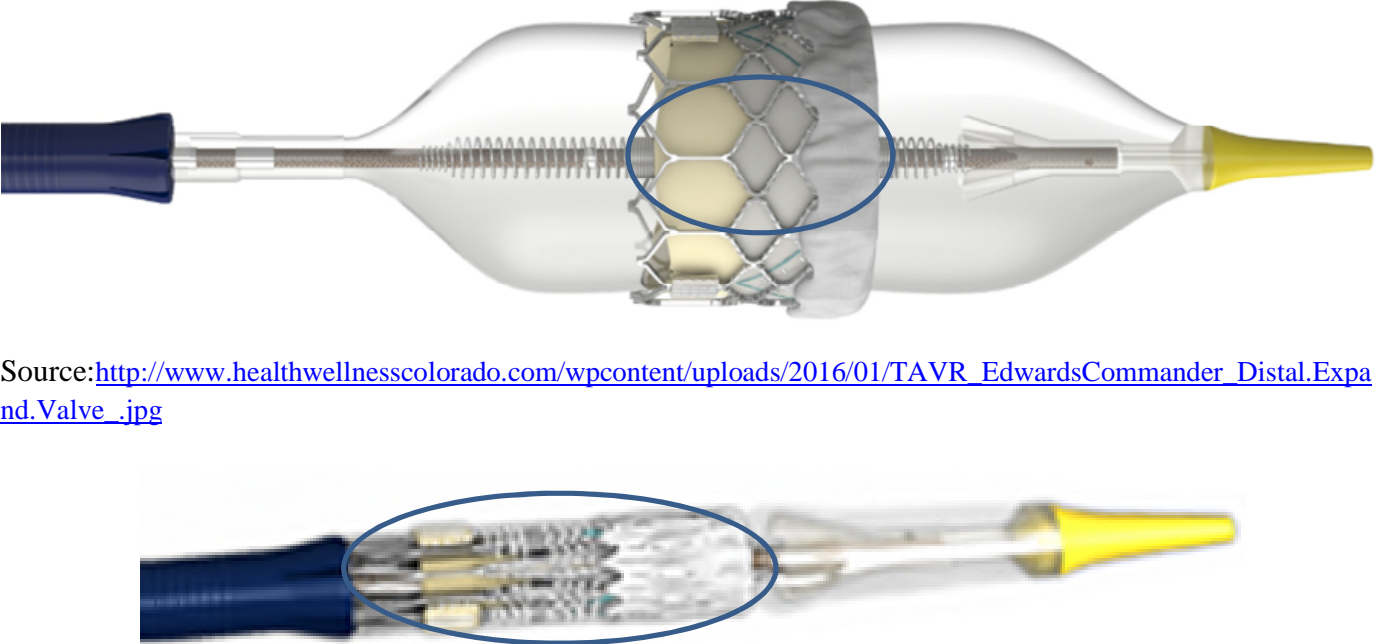
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Claim 14	
Element	Accused Products
[14 preamble] The stent delivery system of claim 9:	As shown in connection with claim 9, the Commander includes all elements of claim 9. <i>See</i> claim chart for claim 9, above.
[14a] including a stop positioned at the distal end of the catheter and carried by the shaft inside the inflatable means.	<p>For example:</p>  <p>Source: http://www.healthwellnesscolorado.com/wpcontent/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

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Claim 20	
Element	Accused Products
[20 preamble] The stent delivery system of claim 9:	As shown in connection with claim 9, the Commander includes all elements of claim 9. <i>See</i> claim chart for claim 9, above.
[20a] wherein the separation is substantially along the entire length of the mounting body.	<p>The separation between the coils of the Commander's mounting body extends substantially along the entire length of the mounting body. For example:</p>  <p>Source: http://www.healthwellnesscolorado.com/wpcontent/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

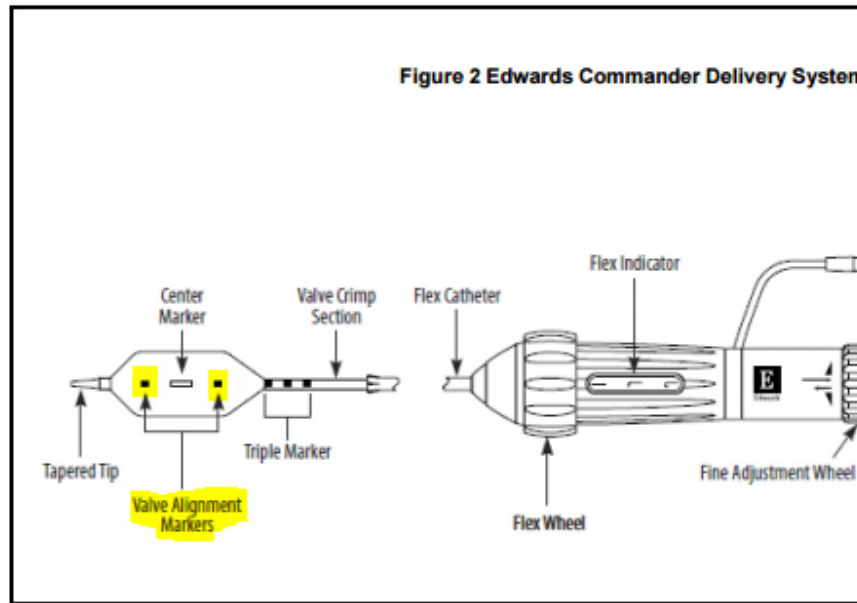
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Claim 21	
Element	Accused Products
[21 preamble] The stent delivery system of claim 9:	As shown in connection with claim 9, the Commander includes all elements of claim 9. <i>See</i> claim chart for claim 9, above.
[21a] wherein the mounting body is substantially the same length as the stent.	<p>The Commander's mounting body is substantially the same length as the stent.</p>  <p>Source: http://www.healthwellnesscolorado.com/wpcontent/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p> <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx</p>

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Claim 22	
Element	Accused Products
[22 preamble] The stent delivery system of claim 14:	As shown in connection with claim 14, the Commander includes all elements of claim 14. <i>See</i> claim chart for claim 9, above.
[22a] including marker bands positioned on the shaft proximally and distally of the stent.	<p>The Commander has marker bands positioned on the shaft at each end of the balloon, and thus proximally and distally of the stent. For example:</p> <ul style="list-style-type: none"> • Edwards Commander Delivery System (Figure 2) <p>The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <p>Source: http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf, p. 2</p>

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Source: http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf, p.3

**Ex. C: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,371,962 By Edwards**

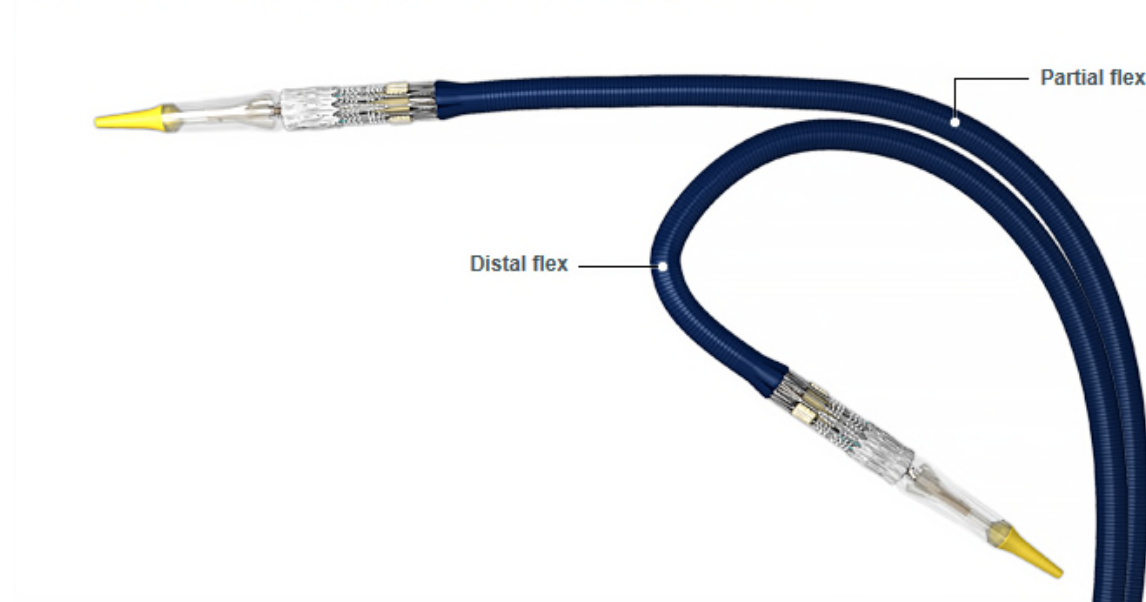
Claim 1	
Element	Accused Products
<p>[1 preamble¹] A stent delivery system for carrying and delivering a stent having a first end and a second end and a contracted state and an expanded state, the system comprising:</p>	<p>To the extent the preamble is deemed a limitation, on information and belief, Edwards made, used, offered to sell, and/or sold in the United States, and/or imported into the United States each of the balloon catheters used in its Commander Delivery System (“Commander”), Ascendra Delivery System (“Ascendra”), Certitude Delivery System (“Certitude”), NovaFlex Delivery System (“NovaFlex”), and RetroFlex Delivery System (“RetroFlex”) for delivery and deployment of its Sapien 3, Sapien XT, and/or Sapien products.² For example:</p> <p><u>Commander:</u></p> <p>The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

¹ The designations in square brackets before the claim language in each row is added to permit convenient reference to specific claim language. These added designations are not part of the claim language and are not intended to limit the claims in any way. No interpretation is intended to be conveyed by the words grouped together with each designation.

² The Sapien 3, Sapien XT, and Sapien, and their corresponding delivery systems, are collectively referred to herein as the “Sapien products.” On information and belief, unless otherwise noted, any differences between various versions or models of the delivery systems identified herein or between the Sapien 3, Sapien XT, and Sapien are immaterial to the assertions set forth herein.

Edwards Commander Delivery System

Dual articulation for coaxiality even in challenging anatomies



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>.

Ascendra:

The Ascendra+ delivery system (useable length 55 cm) is used for delivery of the Edwards SAPIEN XT transcatheter heart valve. The delivery system has radiopaque markers for visualization under fluoroscopy and a balloon for deployment of the THV. A balloon inflation hub, a guidewire hub, and a pusher retraction feature are housed in the handle assembly. The handle is labeled "BALLOON" at the balloon inflation hub and "WIRE 0.035" at the guidewire hub. The system also comes with a loader that is used to cover the THV during delivery. An extension tube is supplied for use with the delivery system during inflation.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.

Ascendra+ System

Expanded Indications
[Learn More](#)

Expanding delivery options

- Designed for transapical and transaortic delivery
- The same easy-to-use system for all 3 valve sizes

Distal tip and balloon shoulder provide a smooth transition from tip to valve



55 cm



Short working length improves handling and control

Introducer sheath with reinforced proximal shaft delivers stability during valve positioning



Trusted balloon-expandable design

- Allows for user-controlled inflation
- Facilitates predictable valve deployment



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>.

The Ascendra Balloon Catheter is used for delivery of the Edwards SAPIEN Transcatheter Heart Valve. The balloon catheter has radiopaque markers for visualization under fluoroscopy and a balloon for deployment of the bioprosthesis. The system also comes with a loader that is used to cover the bioprosthesis during delivery. An extension tubing is supplied for use with the balloon catheter during inflation.

Source: Edwards SAPIEN Transcatheter Heart Valve with the Ascendra Balloon Catheter: Instructions for Use at 1 *available at*

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM307362.pdf>.

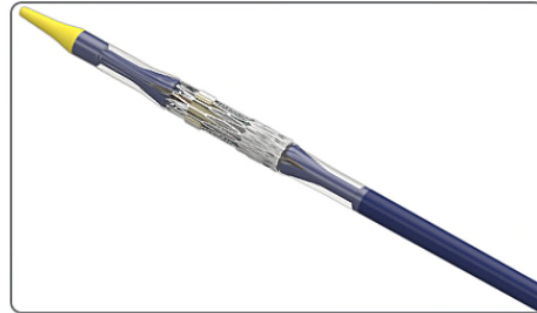
Certitude:

Edwards Certitude Delivery System
designed for seamless deployment

Ultra-low profile system – 18F Certitude sheath compatible*

Integrated pusher

- Streamlines procedure



Articulation feature

- For ease of coaxial positioning



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:

The NovaFlex+ delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN XT THV. The delivery system includes a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system to facilitate advancing to the RVOT, and a balloon catheter for deployment of the THV. The handle also contains a flex indicator depicting articulation of the flex catheter, a valve alignment wheel for fine adjustment of the THV during valve alignment, a button that enables movement between handle positions, and a flush port to flush the flex catheter. The balloon catheter has radiopaque markers defining the valve alignment position and the working length of the balloon. A radiopaque double marker proximal to the balloon indicates flex catheter position during deployment.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.

NovaFlex+ Transfemoral System

Expanded Indications
[Learn More](#)

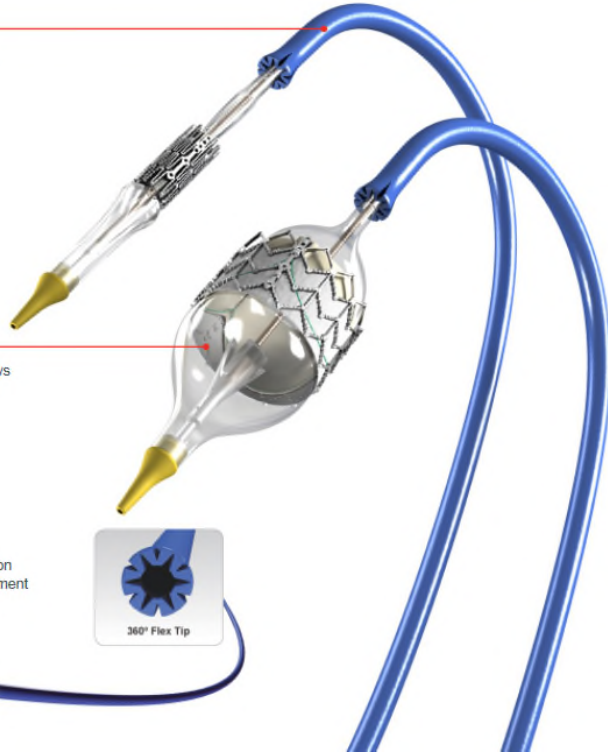
Control

Flex catheter stabilizes balloon shaft during deployment



Precision

Balloon-expandable design allows for user-controlled inflation and precise delivery



Stability

360 Flex Tip provides tight balloon shaft support during valve placement and deployment



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:

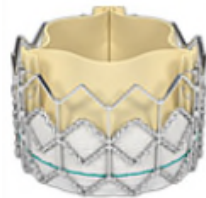
The RetroFlex 3 delivery system includes a rotating wheel within the handle for articulation of flex catheter, a tapered tip at the distal end of the delivery system to facilitate crossing the native valve, a balloon for deployment of the bioprosthesis, and radiopaque markers as indicated in Figure 2.

Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/Adviso...orySystemDevicesPanel/UCM262938.pdf>.

Transcatheter Heart Valves

Edwards SAPIEN Pulmonic Models

Product Description	23 mm	26 mm
RetroFlex 3 Kit	9100RF323	9100RF326
Edwards SAPIEN Valve	9000TFX23	9000TFX26
RetroFlex 3 Delivery System	9120FS23	9120FS26
RetroFlex 3 Introducer Sheath Set	9120S23	9120S26
RetroFlex Balloon Catheter	9120BC20	9120BC23
RetroFlex Dilator Kit	9100DKS7	9100DKS7
Edwards Crimper	9100CR23	9100CR26
Atrion QL2530 Inflation Device	96402	96402



Edwards SAPIEN Valve



RetroFlex 3 Delivery System

Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/pulmonicmodels.aspx>.

Each of the Sapien products comprises a radially expandable stent. For example:

The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

The Edwards SAPIEN XT transcatheter heart valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and a polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.

The Edwards SAPIEN transcatheter heart valve (bioprosthesis) is comprised of a balloon-expandable, radiopaque, stainless steel (316 L) frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) fabric. The bioprosthesis is treated according to the Carpentier-Edwards ThermaFix process, packaged, and terminally sterilized in glutaraldehyde

Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/Adviso...orySystemDevicesPanel/UCM262938.pdf>.

Each of the Sapien products has a generally cylindrical configuration with a first end and a second end.

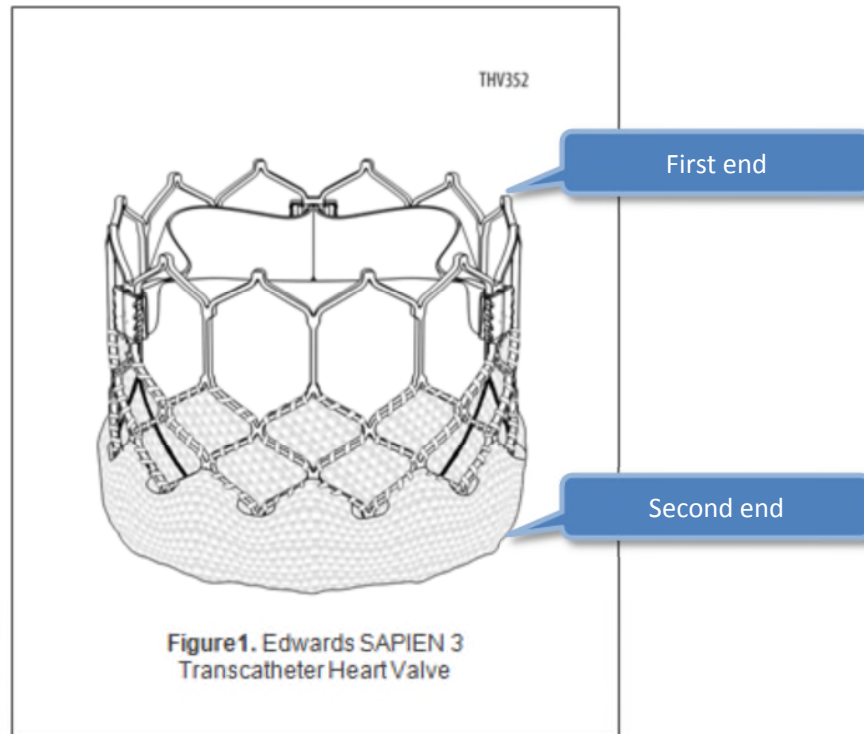


Figure 1. Edwards SAPIEN 3 Transcatheter Heart Valve

Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

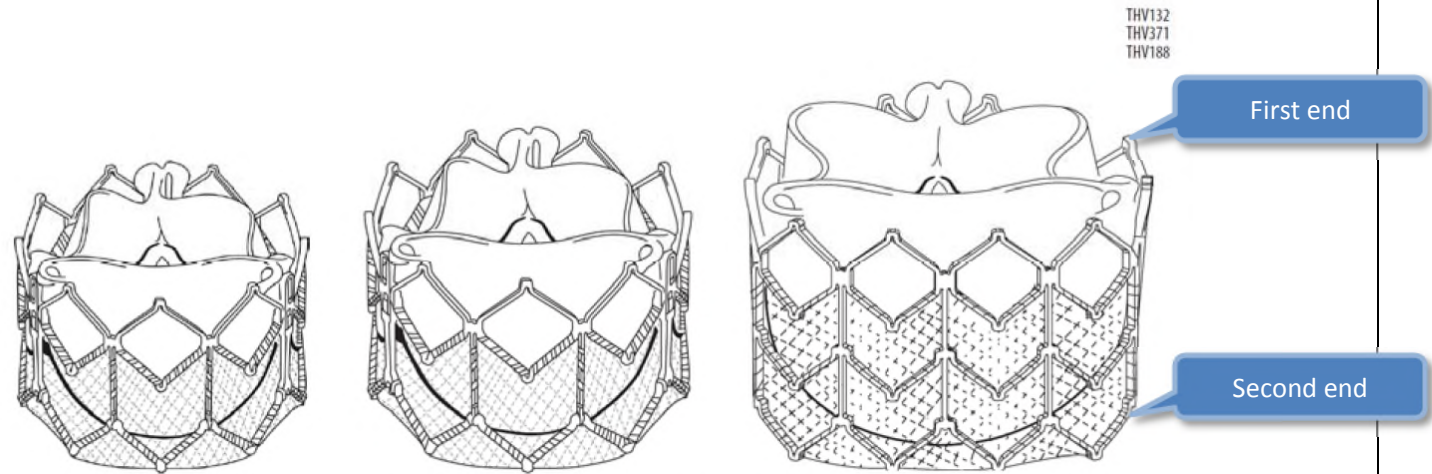
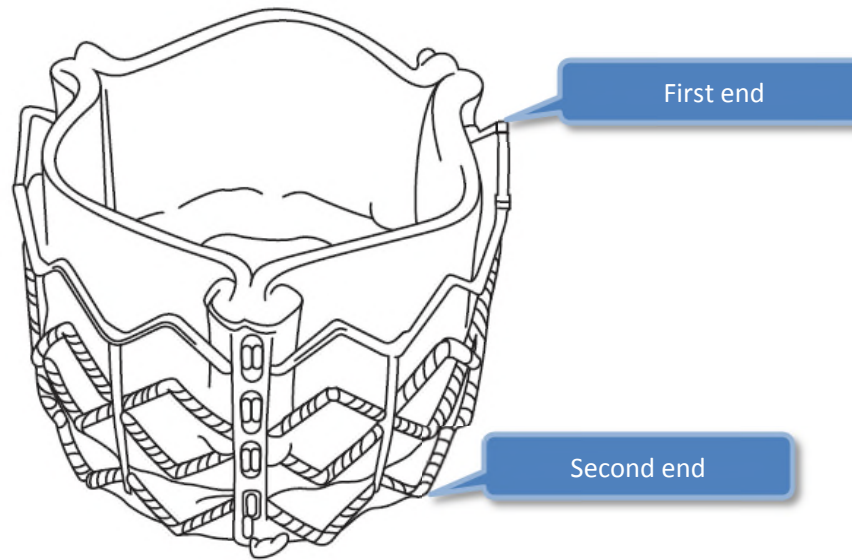


Figure 1. Edwards SAPIEN XT Transcatheter Heart Valve

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.

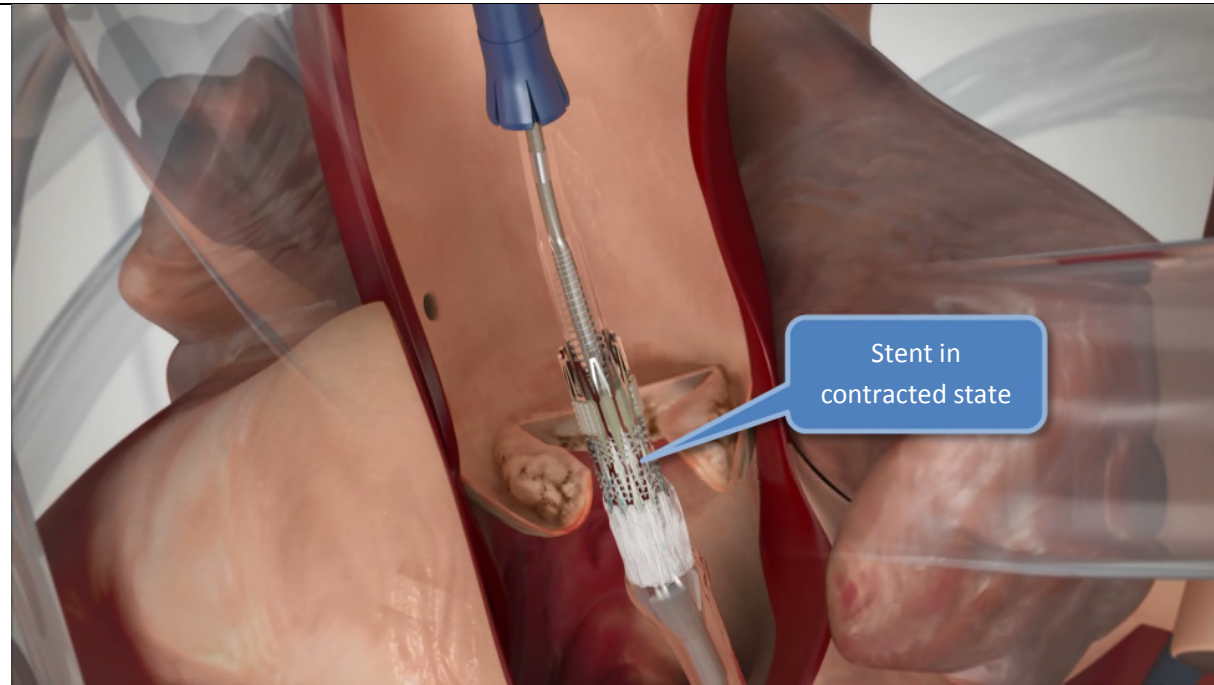
Figure 1. Edwards SAPIEN Transcatheter Heart Valve

THV01

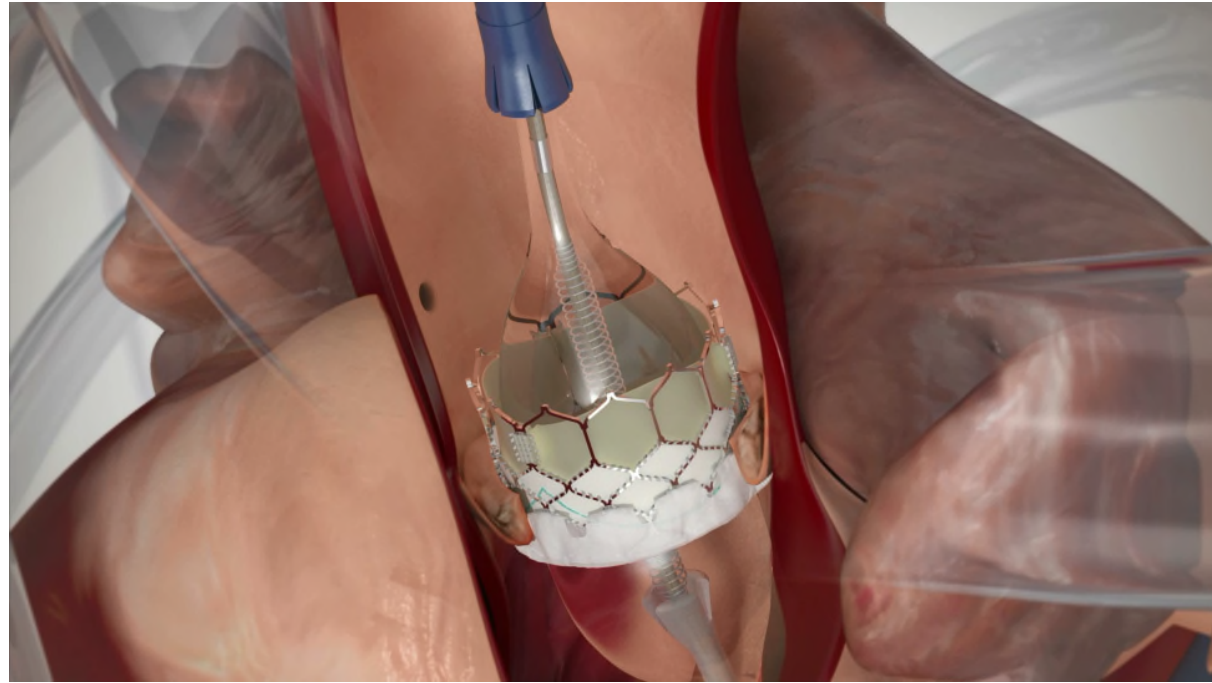


Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf>.

Each of the Sapien products has a contracted state and an expanded state. For example:



Source: "thv_commander.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN 3 Valve" hyperlink; then follow "Transfemoral Procedural Animation" hyperlink)



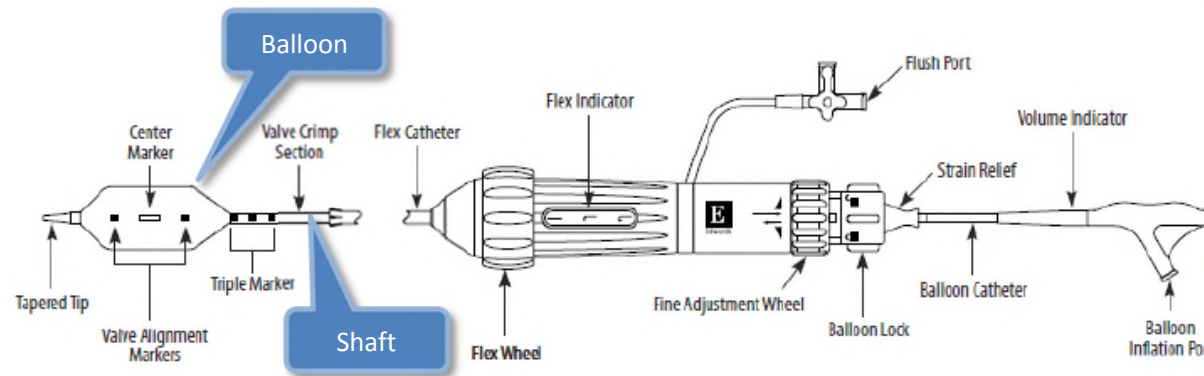
Source: “thv_commander.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN 3 Valve” hyperlink; then follow “Transfemoral Procedural Animation” hyperlink)

[1a]
a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft

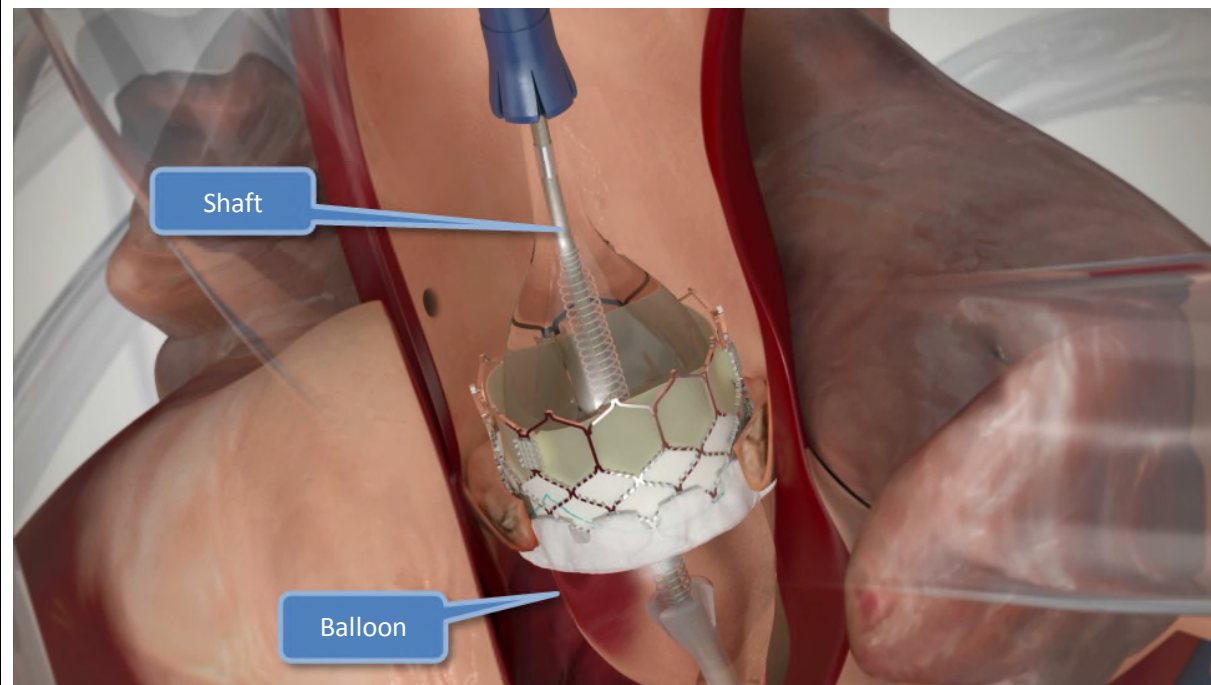
Each of the Sapien products includes a catheter having a shaft having an expandable inflatable means (balloon) associated therewith at a distal part of the shaft.

Commander:

Figure 2 Edwards Commander Delivery System



Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 3 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

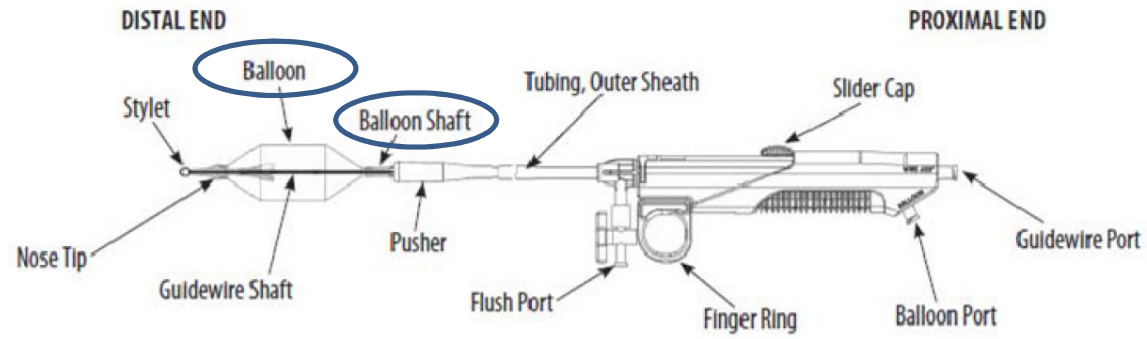


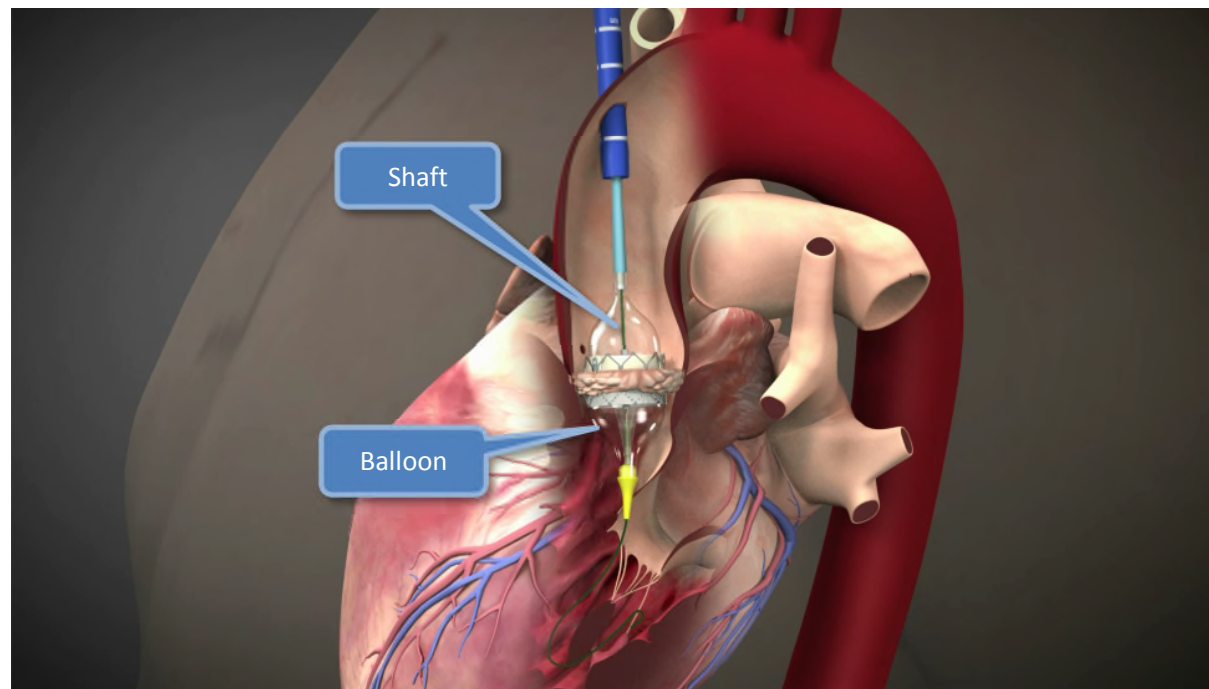
Source: "thv_commander.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN 3 Valve" hyperlink; then follow "Transfemoral Procedural Animation" hyperlink)

Ascendra:

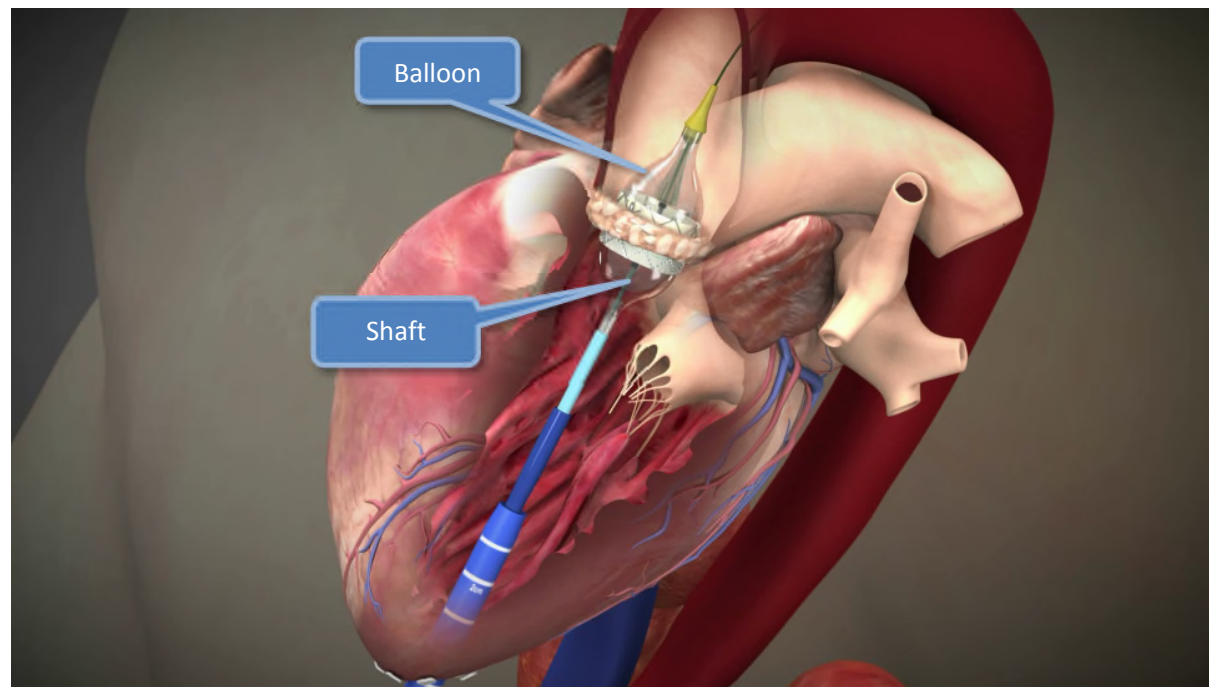
Figure 2A. Ascendra+ Delivery System

THV349



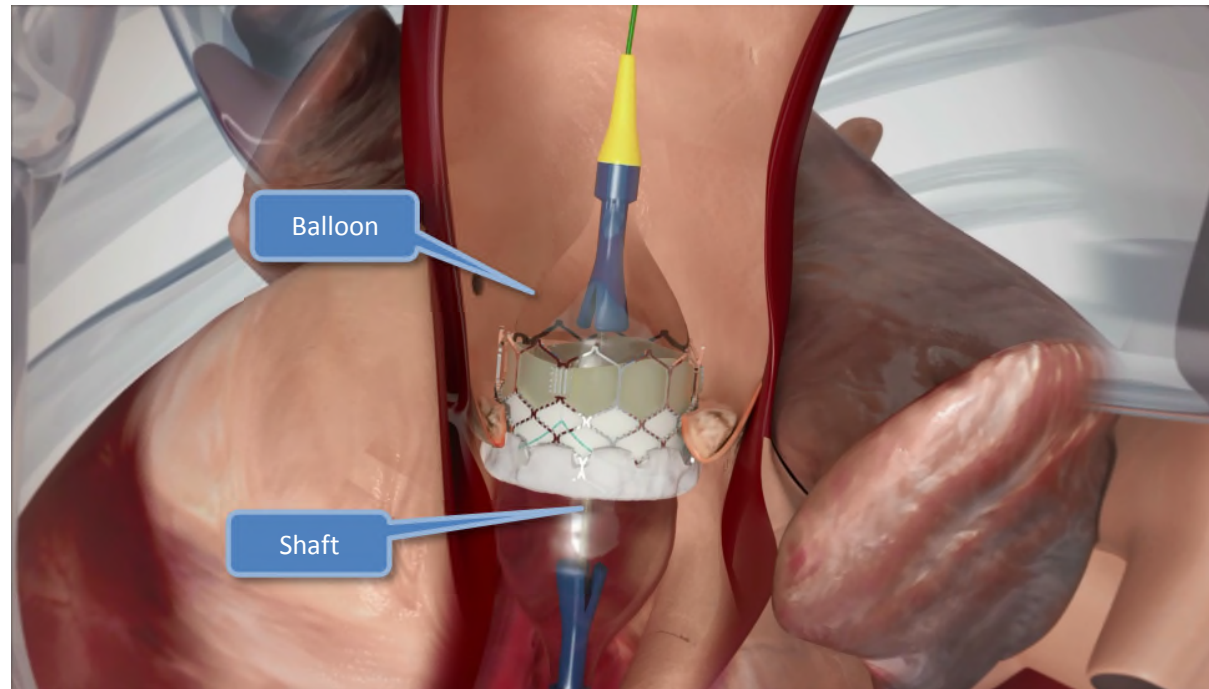


Source: "ascendraplustransaortic.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN XT Valve" hyperlink; then follow "Transaortic Procedural Animation" hyperlink)



Source: "ascendraplustransapical.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN XT Valve" hyperlink; then follow "Transapical Procedural Animation" hyperlink)

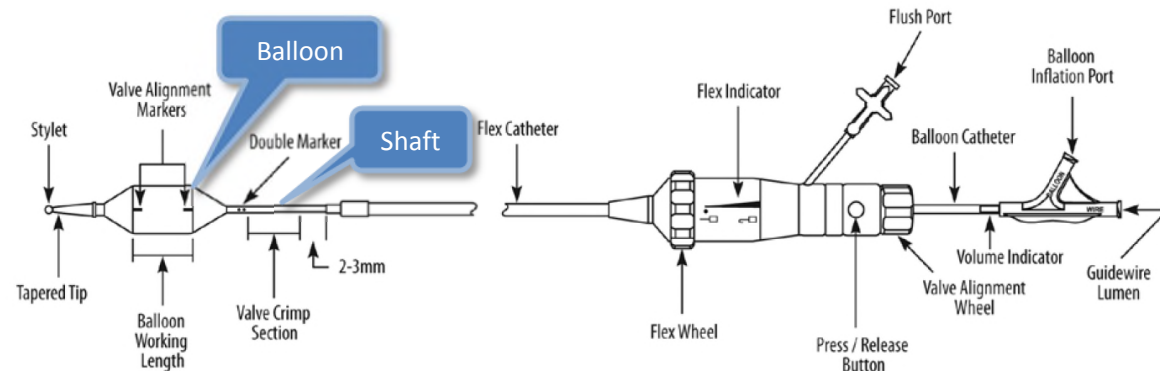
Certitude:



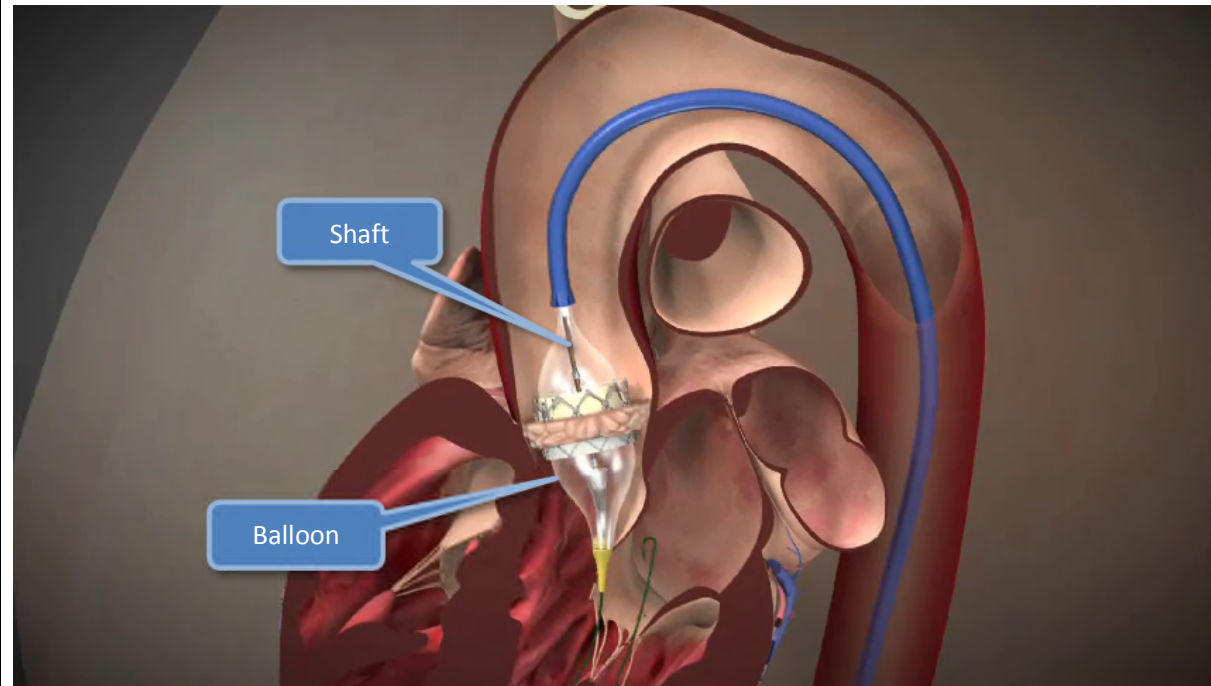
Source: "thv_certitude.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN 3 Valve" hyperlink; then follow "Transapical Procedural Animation" hyperlink)

NovaFlex:

Figure 2a. NovaFlex+ Delivery System



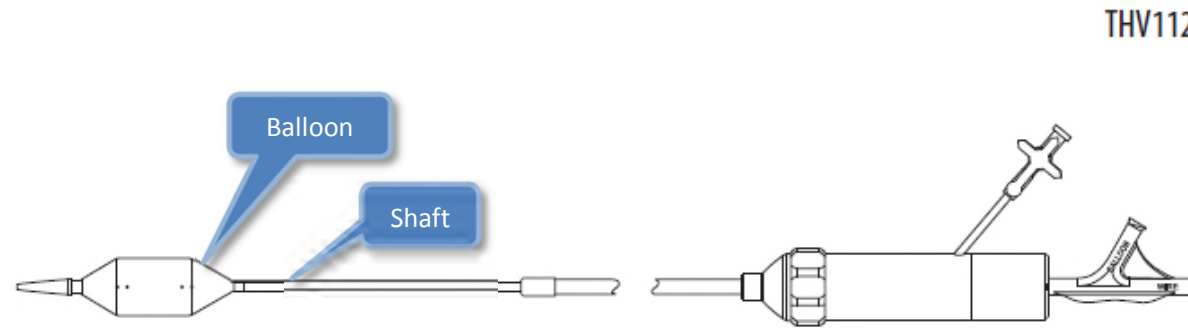
Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.



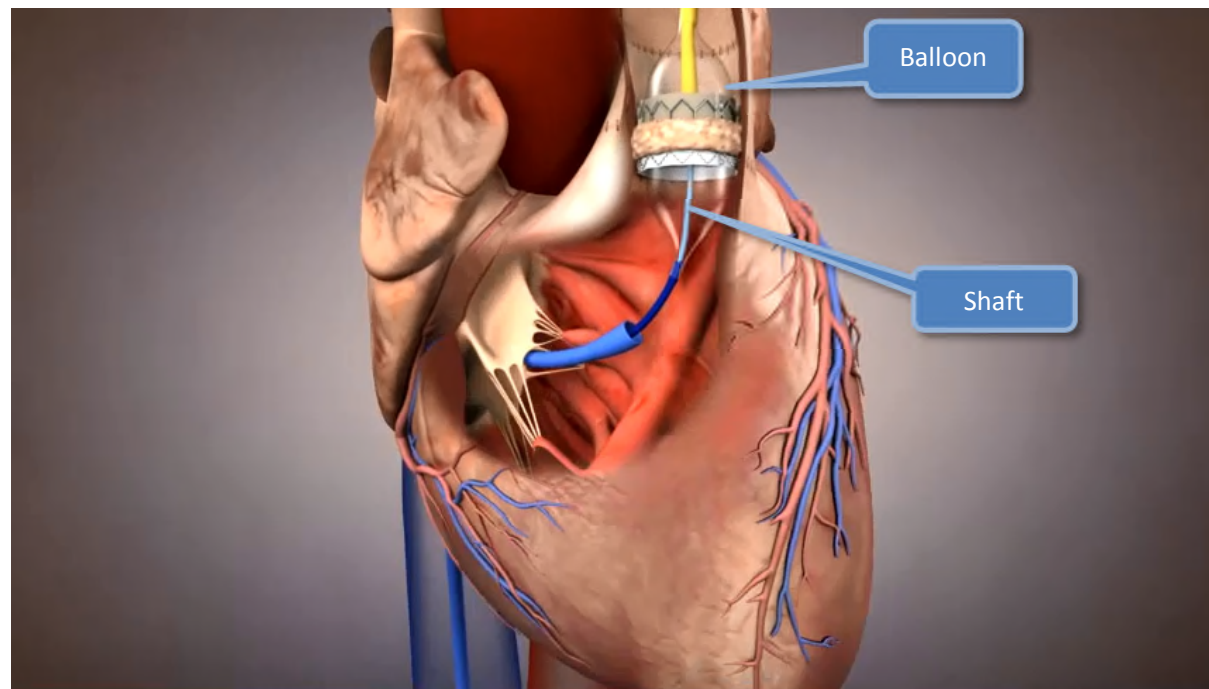
Source: “novaflexplusprocedural.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN XT Valve” hyperlink; then follow “Transfemoral Procedural Animation” hyperlink)

RetroFlex:

Figure 2. RetroFlex 3 Delivery System



Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/Adviso...orySystemDevicesPanel/UCM262938.pdf>.



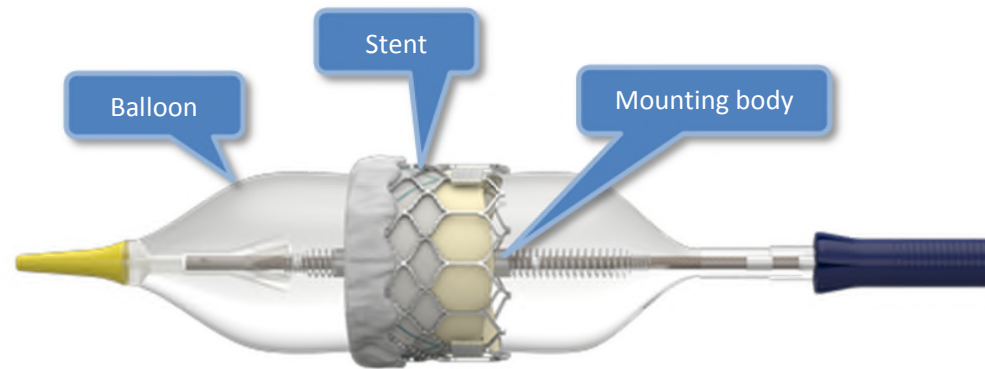
Source: “pulmonicar06026.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN Pulmonic” hyperlink; then follow “Procedural Animation” hyperlink)

[1b]
and including mounting and retaining means for receiving the stent on the expandable inflatable means whereby the stent is radially expanded upon inflation of the inflatable means, the mounting and retaining

Each of the Sapien products includes a mounting and retaining means (mounting body) carried on and for receiving the stent on the expandable inflatable means (balloon). Inflation of the balloon causes radial expansion of the stent.

means including at least one mounting body, the at least one mounting body having a length and an outer surface diameter and being carried on and surrounding the shaft inside the inflatable means

Commander:



Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

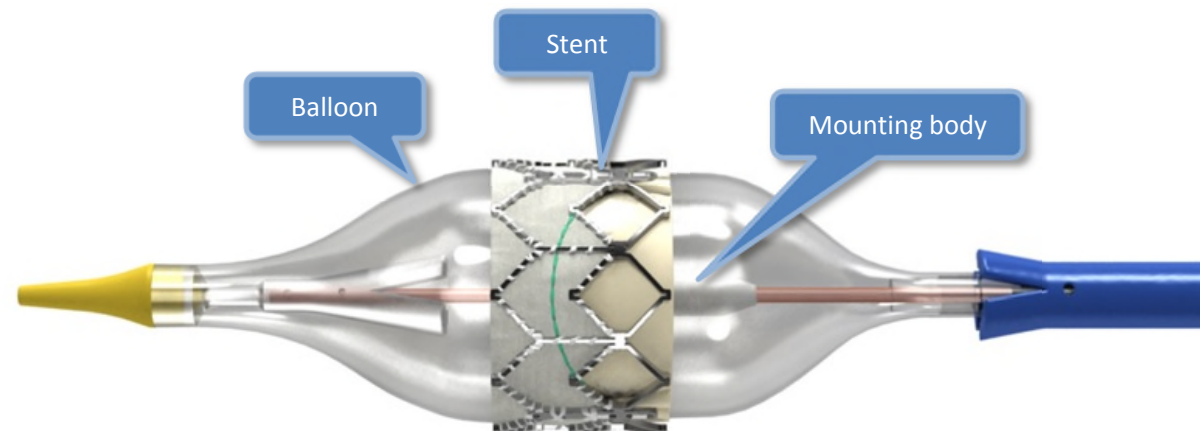
Ascendra:

On information and belief, the Ascendra has a mounting and retaining means carried on and surrounding the shaft inside the inflatable means, as will be demonstrated with further discovery.

Certitude:

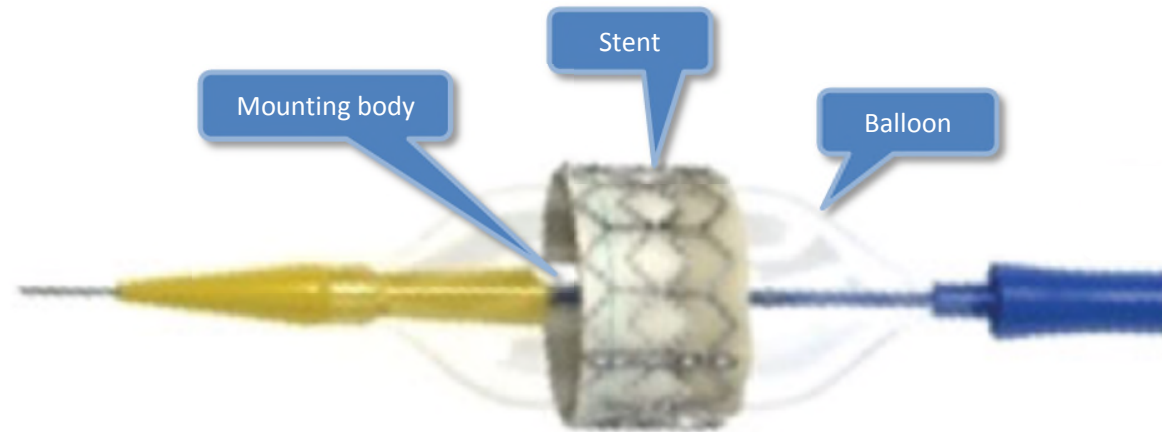
On information and belief, the Certitude has a mounting and retaining means carried on and surrounding the shaft inside the inflatable means, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 available at <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:



Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, Catheter Cardiovasc Interv 2010;75:295–300 at 298.

[1c]
whereby the diameter of the shaft is increased at the distal part for facilitating the mounting and retaining of the stent and

For each of the Sapien products, the diameter of the shaft is increased at the distal part for facilitating the mounting and retaining of the stent.

Commander:



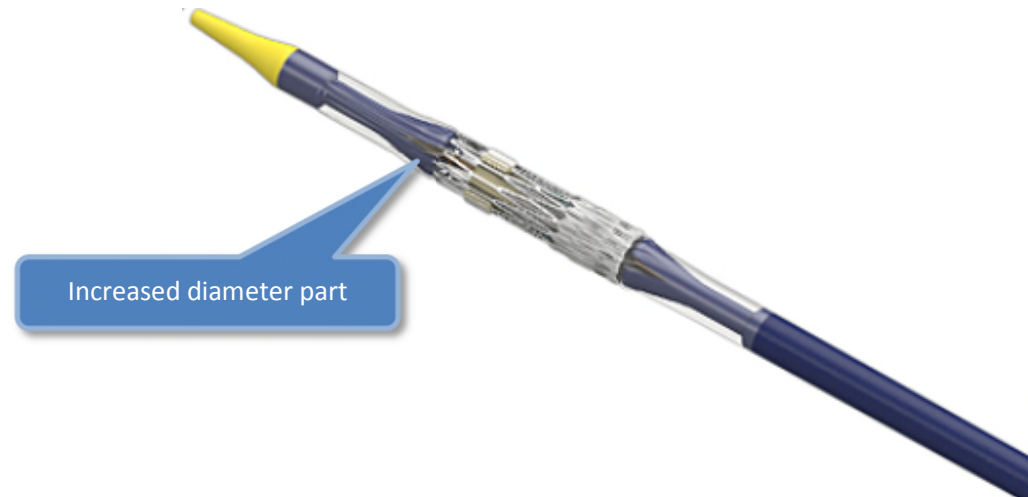
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>.

Ascendra:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>.

Certitude:



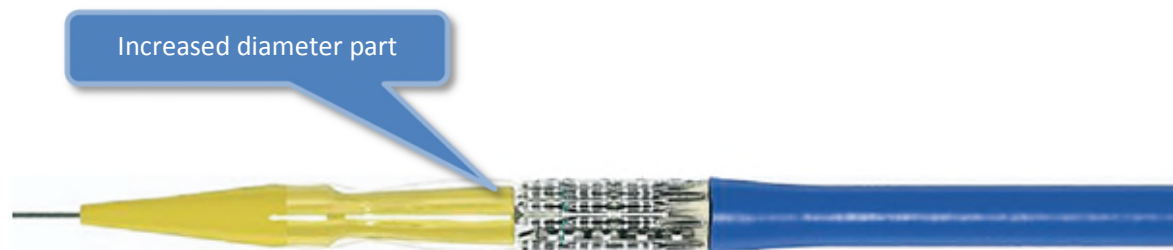
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:

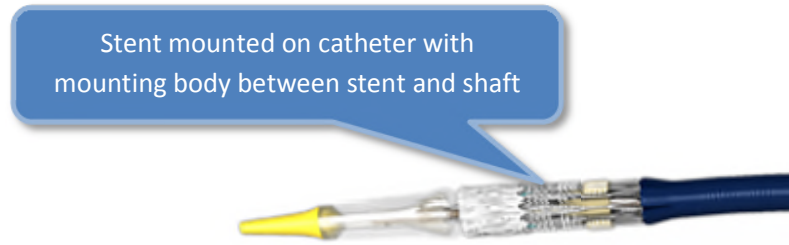


Source: Webb J, Altwegg L, Masson J, Al Bugami S, Al Ali A, Boone R, *A New Transcatheter Aortic Valve and Percutaneous Valve Delivery System*, J Am Coll Cardiol. 2009;53(20):1855-1858 at 1858.

[1d]
wherein, when the stent is mounted on the catheter, the at least one mounting body is between the stent and the shaft, the outer surface diameter of the at least one mounting body being substantially constant along its length.

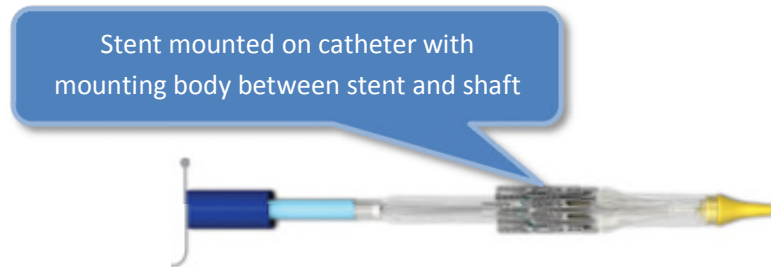
For each of the Sapien products, when the stent is mounted on the catheter, the at least one mounting body is between the stent and the shaft, the outer surface diameter of the at least one mounting body being substantially constant along its length. For example:

Commander:



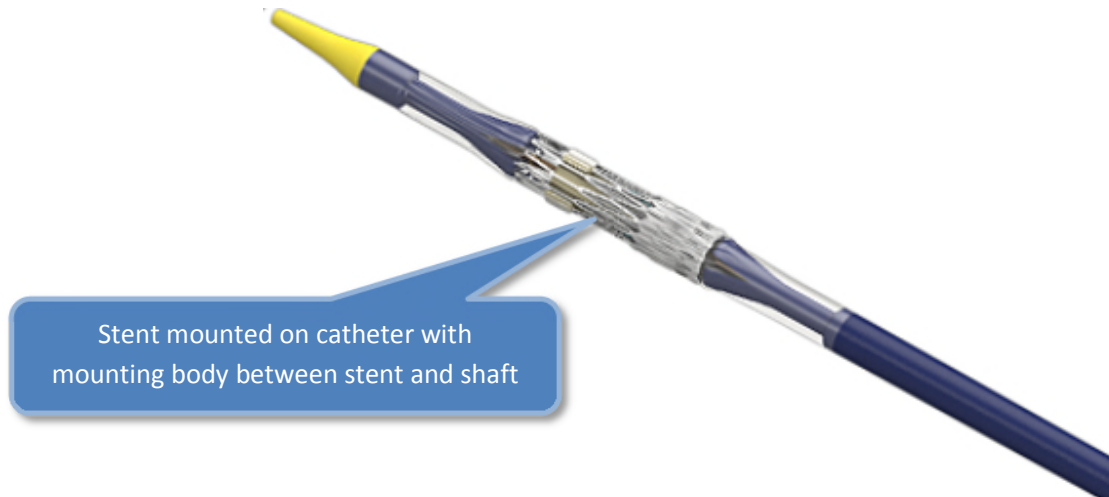
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>.

Ascendra:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>.

Certitude:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:

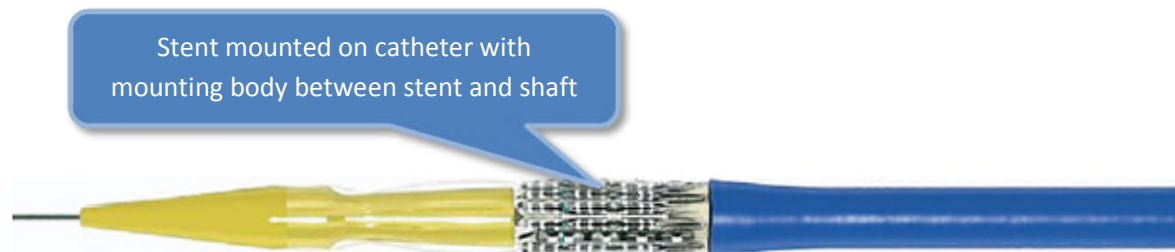
Stent mounted on catheter with mounting body between stent and shaft



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:

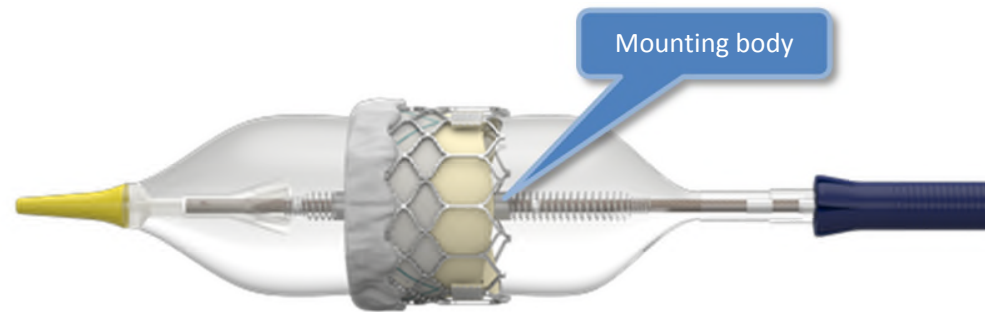
Stent mounted on catheter with mounting body between stent and shaft



Source: Webb J, Altwegg L, Masson J, Al Bugami S, Al Ali A, Boone R, *A New Transcatheter Aortic Valve and Percutaneous Valve Delivery System*, J Am Coll Cardiol. 2009;53(20):1855-1858 at 1858.

Claim 2	
Element	Accused Products
[2 preamble] The stent delivery system of claim 1	<i>See</i> claim chart for claim 1 above.
[2a] wherein the mounting body is of a material which resiliently deforms under radial pressure.	The mounting bodies of each of the Sapien products are of materials which resiliently deform under radial pressure. For example:

Commander:



Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

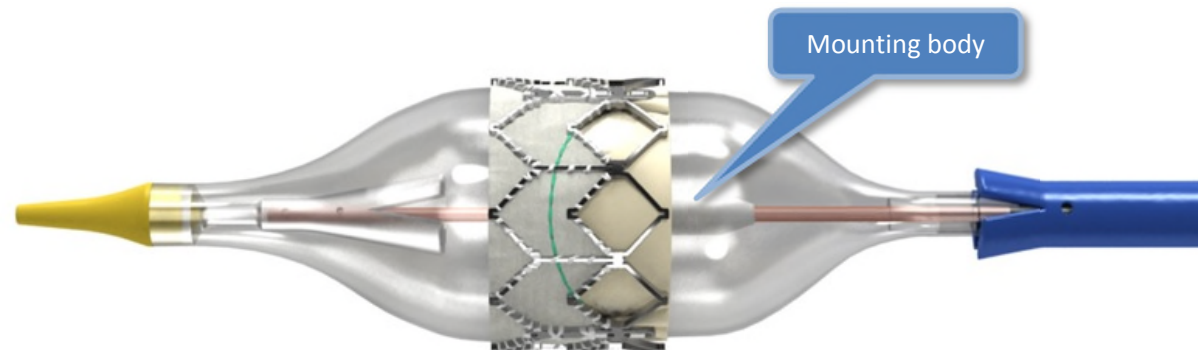
Ascendra:

On information and belief, the Ascendra has a mounting body of a material which resiliently deforms under radial pressure, as will be demonstrated with further discovery.

Certitude:

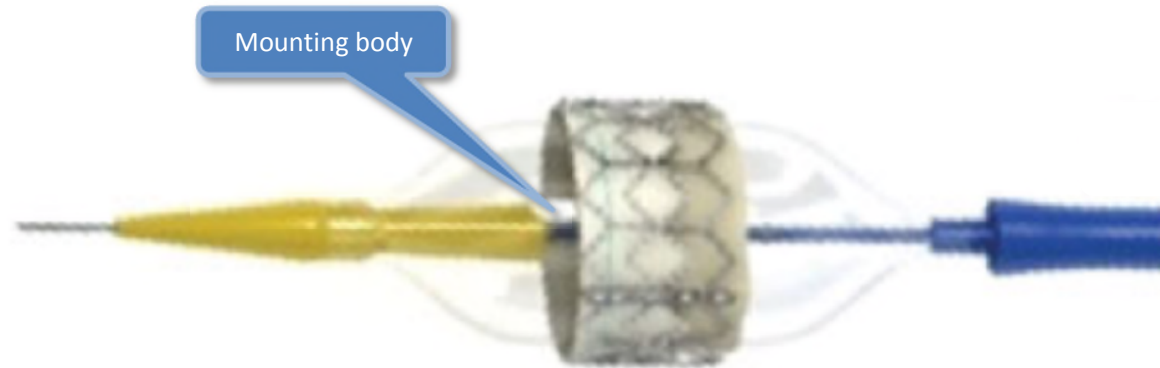
On information and belief, the Certitude has a mounting body of a material which resiliently deforms under radial pressure, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 *available at* <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:



Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, Catheter Cardiovasc Interv 2010;75:295–300 at 298.

Claim 3

Element	Accused Products
[3 preamble] The stent delivery system of claim 2	See claim chart for claim 2 above.
[3a] wherein the material is elastomeric.	The mounting bodies of the Ascendra, Certitude, NovaFlex, and RetroFlex are of elastomeric material.

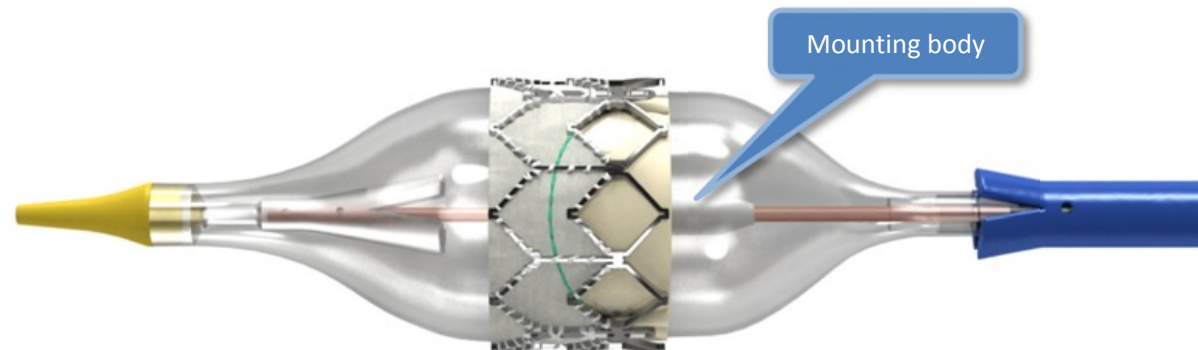
Ascendra:

On information and belief, the Ascendra has a mounting body of an elastomeric material, as will be demonstrated with further discovery.

Certitude:

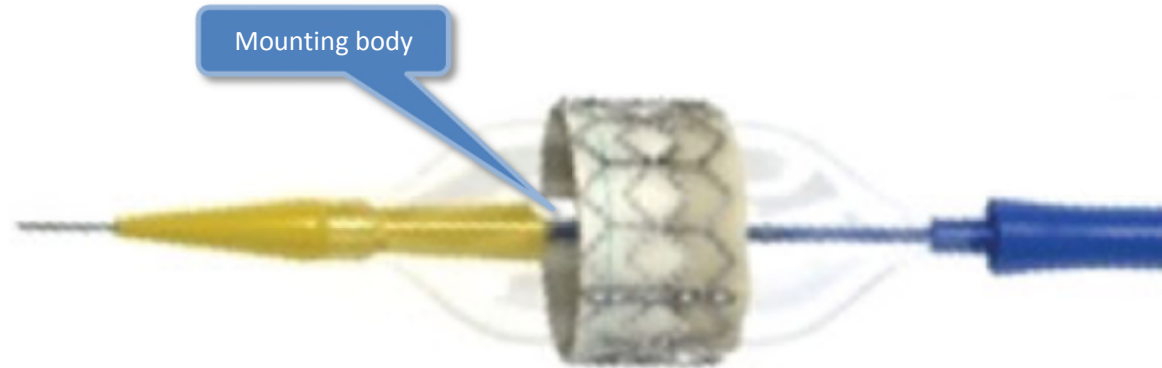
On information and belief, the Certitude has a mounting body of an elastomeric material, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 available at <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:



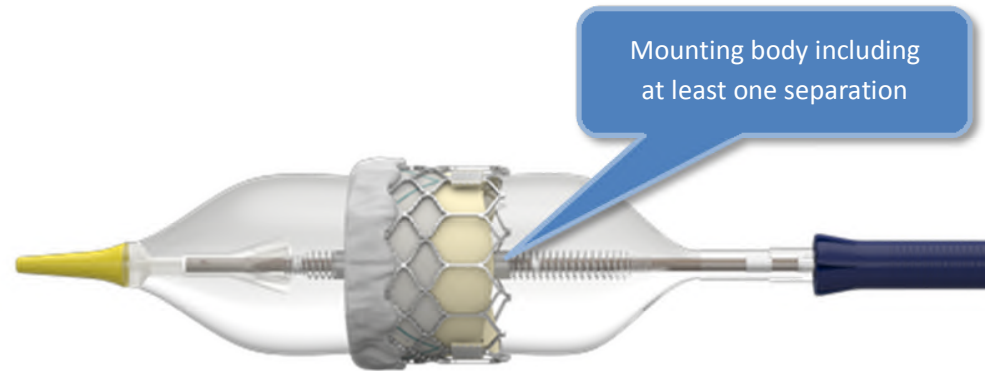
Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, *Catheter Cardiovasc Interv* 2010;75:295–300 at 298.

Claim 6

Element	Accused Products
[6 preamble] The stent delivery system of claim 1	See claim chart for claim 1 above.
[6a] wherein the at least one mounting body includes at	The mounting body of the Commander includes a coil having at least one separation. For example:

least one separation whereby the flexibility of the body and catheter is increased.

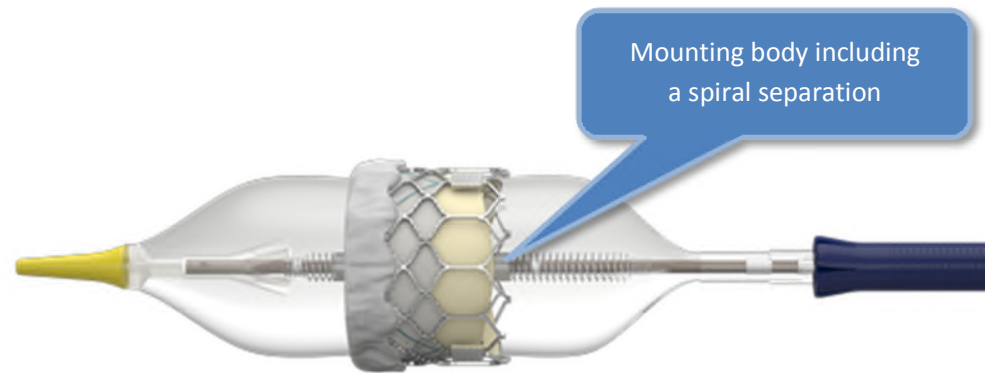
Commander:



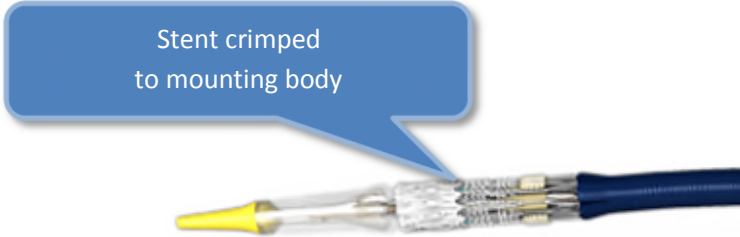
Source: "635907831022739465-EdwardsCommander-Distal.Expand.Valve.png" available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

Claim 7	
Element	Accused Products
[7 preamble] The stent delivery system of claim 6	<i>See claim chart for claim 6 above.</i>
[7a] wherein the separation is in the form of a spiral.	The mounting body of the Commander includes a coil having at least one separation in the form of a spiral. For example:

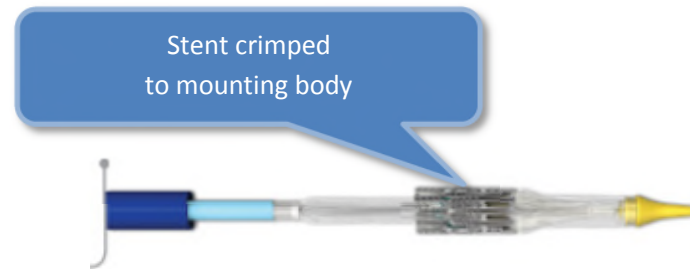
Commander:



Source: "635907831022739465-EdwardsCommander-Distal.Expand.Valve.png" available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

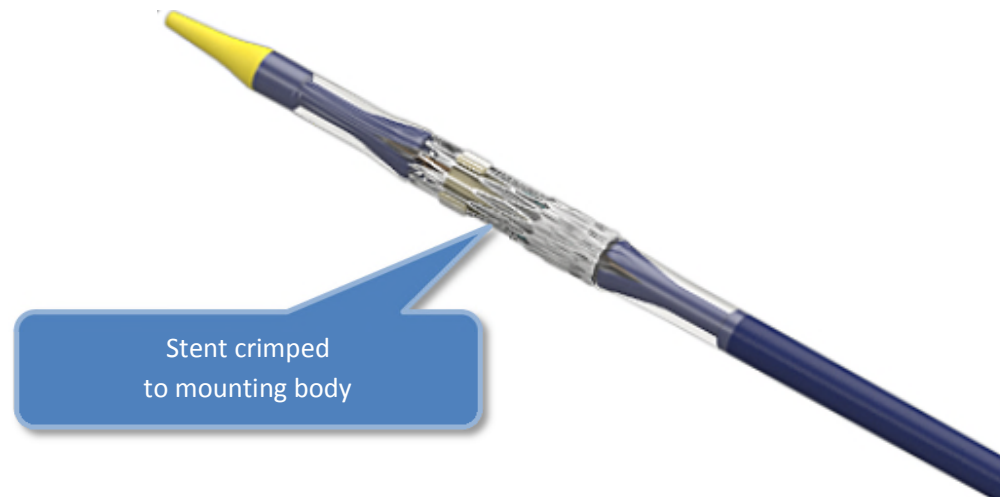
Claim 8	
Element	Accused Products
[8 preamble] The stent delivery system of claim 1	See claim chart for claim 1 above.
[8a] wherein the stent is crimped to the mounting and retaining means for delivery.	<p>For each of the Sapien products, the stent is crimped to the mounting and retaining means for delivery.</p> <p><u>Commander:</u></p> <div style="text-align: center;">  </div> <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx.</p>

Ascendra:



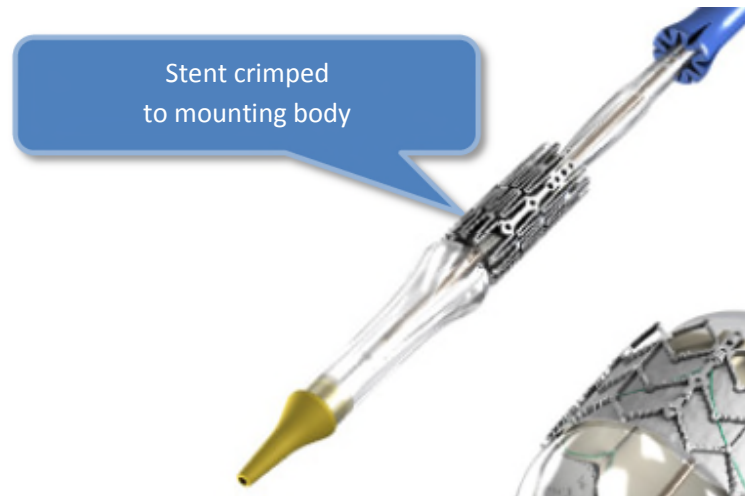
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>.

Certitude:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:

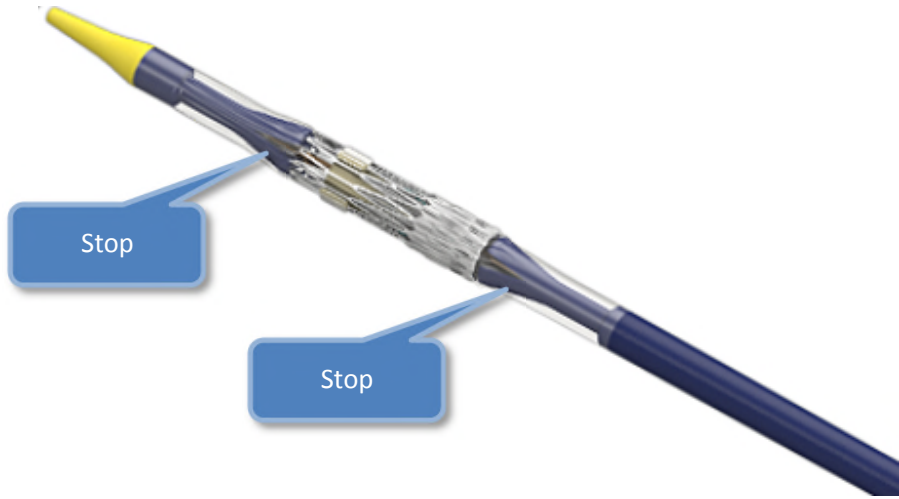


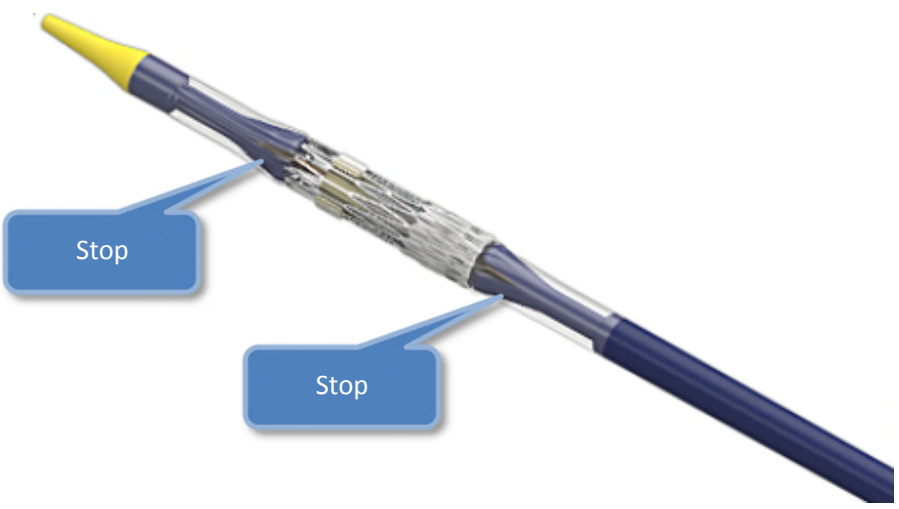
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:

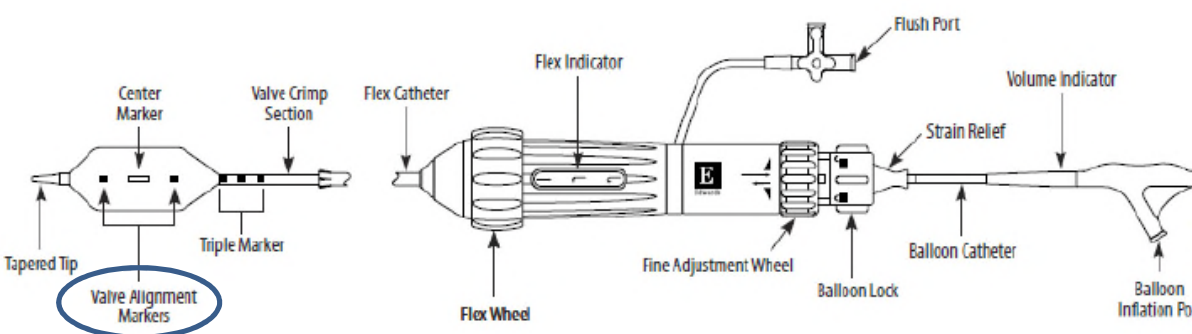


Source: Webb J, Altwegg L, Masson J, Al Bugami S, Al Ali A, Boone R, *A New Transcatheter Aortic Valve and Percutaneous Valve Delivery System*, J Am Coll Cardiol. 2009;53(20):1855-1858 at 1858.

Claim 9	
Element	Accused Products
[9 preamble] The stent delivery system of claim 1,	<i>See</i> claim chart for claim 1 above.
[9a] wherein the stent has two opposite ends, the stent delivery system further including a pair of stops, each of which is respectively positioned at the opposite ends of the stent and carried by the shaft inside the inflatable means.	<p>The Certitude includes a pair of stops positioned at opposite ends of the stent and carried by the shaft inside the inflatable means. For example:</p> <p><u>Certitude:</u></p>  <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx.</p>

Claim 10	
Element	Accused Products
[10 preamble] The stent delivery system of claim 9	See claim chart for claim 1 above.
[10a] wherein the stops are conical in shape.	<p>The stops of the Certitude are conical in shape. For example:</p> <p><u>Certitude:</u></p>  <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx.</p>

Claim 11

Element	Accused Products
<p>[11 preamble] The stent delivery system of claim 1</p>	<p>See claim chart for claim 1 above.</p>
<p>[11a] further including marker bands positioned proximally and distally of the stent.</p>	<p>Each of the Sapien products includes marker bands positioned proximally and distally of the stent. For example:</p> <p><u>Commander:</u></p> <p align="center">Figure 2 Edwards Commander Delivery System</p>  <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 3 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p>Before deployment, ensure that the THV is correctly positioned between the Valve Alignment Markers and the Flex Catheter tip is over the Triple Marker.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 11 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

Ascendra:

Remove the THV from the crimper and place it on the delivery system with the inflow (fabric cuff end) of the THV proximally towards the pusher if accessing antegrade. If accessing retrograde, place the THV on the delivery system with the inflow (fabric cuff end) of the THV towards the distal end away from the pusher. Ensure that the THV is aligned between the radiopaque markers.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 8 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.

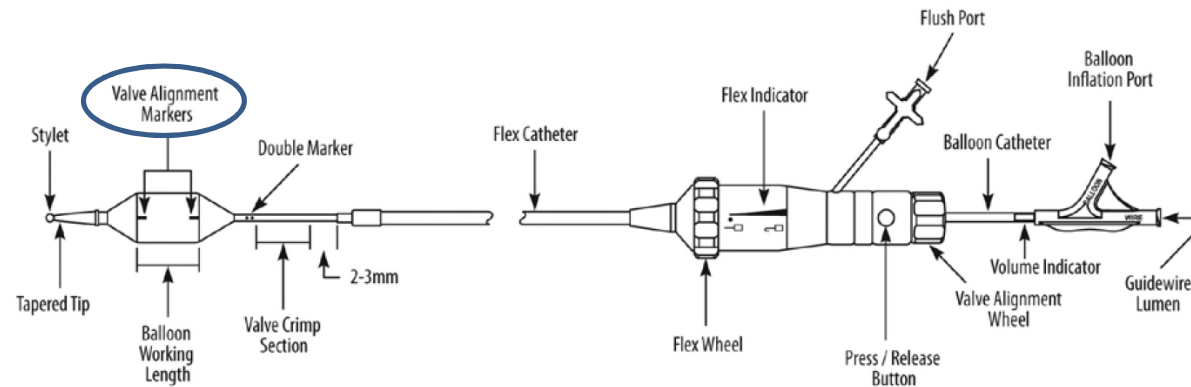
Certitude:

On information and belief, the Certitude has marker bands positioned proximally and distally of the stent, as will be demonstrated with further discovery.

NovaFlex:

Figure 2a. NovaFlex+ Delivery System

NF2THV04



Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.

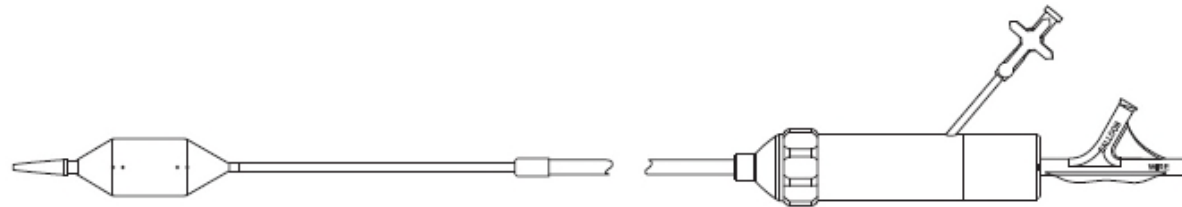
Use the Valve Alignment Wheel to position the THV between the valve alignment markers.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 9 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.

RetroFlex:

Figure 2. RetroFlex 3 Delivery System

THV112



Black dots indicate position of radiopaque markers.

Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf>.

Claim 12

Element	Accused Products
[12 preamble] The stent delivery system of claim 1	See claim chart for claim 1 above.

<p>[12a] Wherein the inflatable means comprises a balloon.</p>	<p>See claim chart for claim [1a] above.</p>
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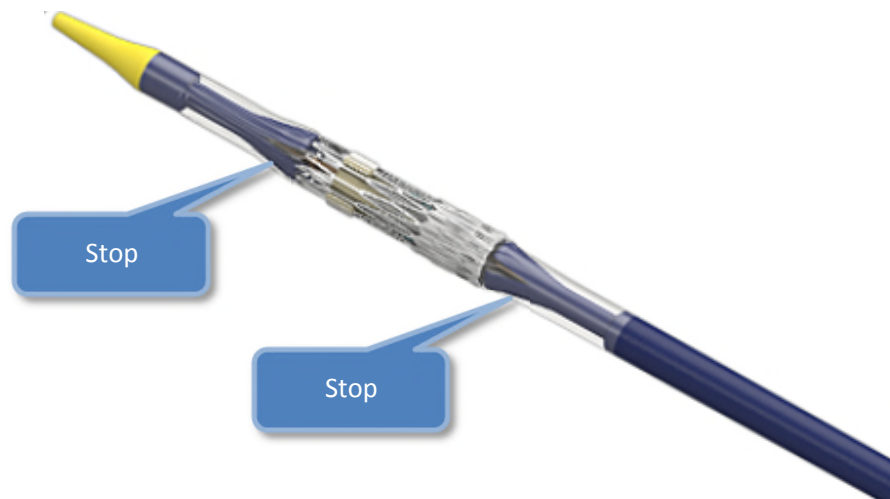
<p align="center">Claim 13</p>	
<p align="center">Element</p>	<p align="center">Accused Products</p>
<p>[13 preamble] The stent delivery system of claim 1</p>	<p>See claim chart for claim 1 above.</p>
<p>[13a] further including a stop carried by the shaft and positioned inside the inflatable means and axially spaced relative to the stent.</p>	<p>Each of the Sapien products includes a stop carried by the shaft and positioned inside the inflatable means and axially spaced relative to the stent. For example:</p> <p><u>Commander:</u></p> <div data-bbox="974 821 1608 1029" data-label="Image"> </div> <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx.</p>

Ascendra:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>.

Certitude:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:



Source: Webb J, Altwegg L, Masson J, Al Bugami S, Al Ali A, Boone R, *A New Transcatheter Aortic Valve and Percutaneous Valve Delivery System*, J Am Coll Cardiol. 2009;53(20):1855-1858 at 1858.

Claim 20	
Element	Accused Products
[20 preamble] A balloon catheter for intraluminal delivery of a stent, the catheter comprising	See claim chart for claim [1 preamble] above.
[20a] a shaft having a diameter, a balloon associated with a distal portion of the shaft for receiving a stent,	See claim chart for claim [1a] above.
[20b] the stent having a first end and a second end and a contracted state and an expanded state, and means for inflating the balloon,	See claim chart for claim [1 preamble] above.
[20c] the shaft including at least one mounting body radially carried on the shaft inside the balloon,	See claim chart for claim [1b] above.
[20d] whereby the diameter of the shaft is increased inside the balloon to facilitate mounting and retaining of a stent to the catheter over the balloon,	See claim chart for claim [1c] above.

<p>[20e] the at least one mounting body being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent, the at least one mounting body having a length and an outer surface diameter, wherein the outer surface diameter is substantially constant along the length.</p>	<p>See claim chart for claim [1d] above.</p>
--	--

Claim 21	
Element	Accused Products
<p>[21 preamble] The catheter of claim 20</p>	<p><i>See claim chart for claim 20 above.</i></p>
<p>[21a] wherein the mounting body is of a material which resiliently deforms under radial pressure.</p>	<p><i>See claim chart for claim 2 above.</i></p>

Claim 22	
Element	Accused Products
[22 preamble] The catheter of claim 20	<i>See claim chart for claim 21 above.</i>
[22a] wherein the material is elastomeric.	<i>See claim chart for claim 3 above.</i>

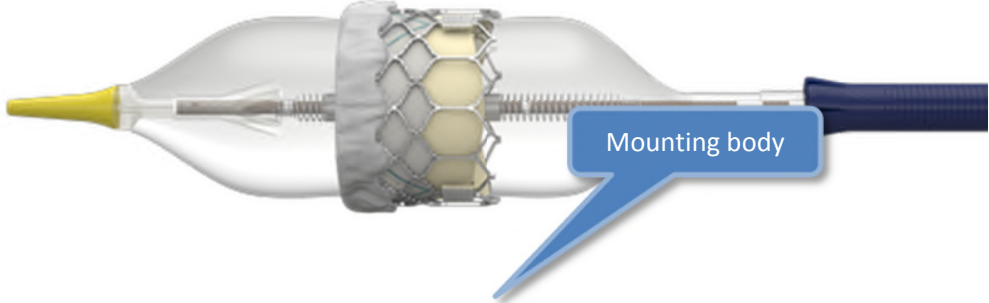
Claim 25	
Element	Accused Products
[25 preamble] The catheter of claim 20	<i>See claim chart for claim 20 above.</i>
[25a] wherein the mounting body comprises at least one separation whereby trackability of the catheter is improved.	<i>See claim chart for claim 6 above.</i>

Claim 26	
Element	Accused Products
[26 preamble] The catheter of claim 25	<i>See claim chart for claim 25 above.</i>
[26a] wherein the separation is in a spiral configuration.	<i>See claim chart for claim 7 above.</i>

Claim 27	
Element	Accused Products
[27 preamble] The catheter of claim 20	<i>See claim chart for claim 20 above.</i>
[27a] further including a pair of spaced stops.	<i>See claim chart for claim 9 above.</i>

Claim 28	
Element	Accused Products
[28 preamble] The catheter of claim 27	<i>See claim chart for claim 27 above.</i>
[28a] wherein the stops are conical in shape.	<i>See claim chart for claim 10 above.</i>

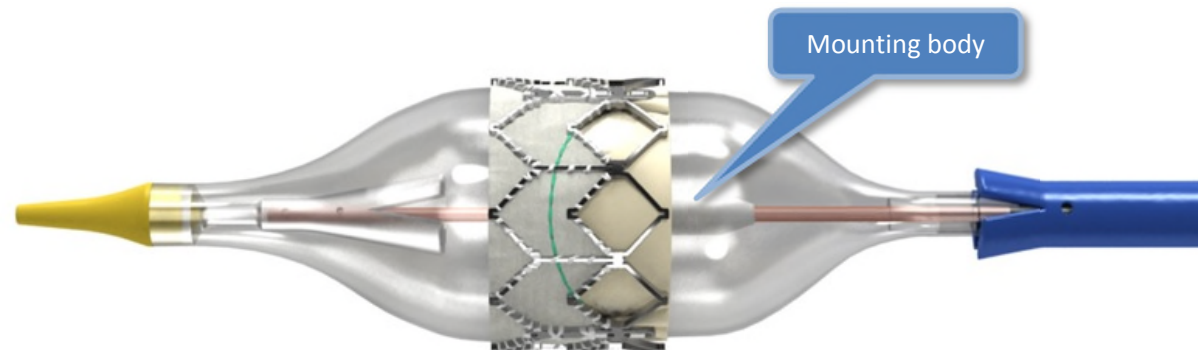
Claim 29	
Element	Accused Products
[29 preamble] The catheter of claim 20	<i>See claim chart for claim 20 above.</i>
[29a] further including spaced marker bands.	<i>See claim chart for claim 11 above.</i>

Claim 30	
Element	Accused Products
[30 preamble] The catheter of claim 20	See claim chart for claim 20 above.
[30a] wherein the mounting body is cylindrical in shape.	<p>The mounting bodies of each of the Sapien products are cylindrical in shape.</p> <p><u>Commander:</u></p>  <p>Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/.</p> <p><u>Ascendra:</u></p> <p>On information and belief, the Ascendra has a mounting body that is cylindrical in shape, as will be demonstrated with further discovery.</p>

Certitude:

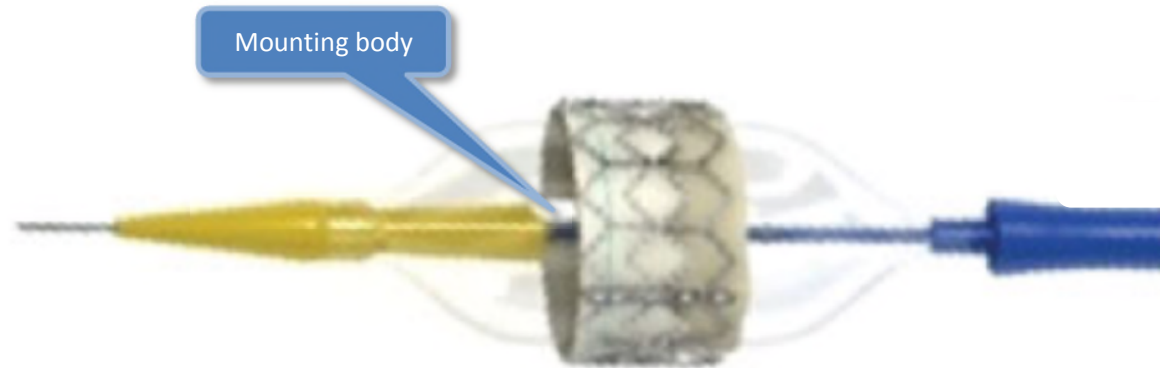
On information and belief, the Certitude has a mounting body that is cylindrical in shape, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 *available at* <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:



Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, *Catheter Cardiovasc Interv* 2010;75:295–300 at 298.

Claim 35

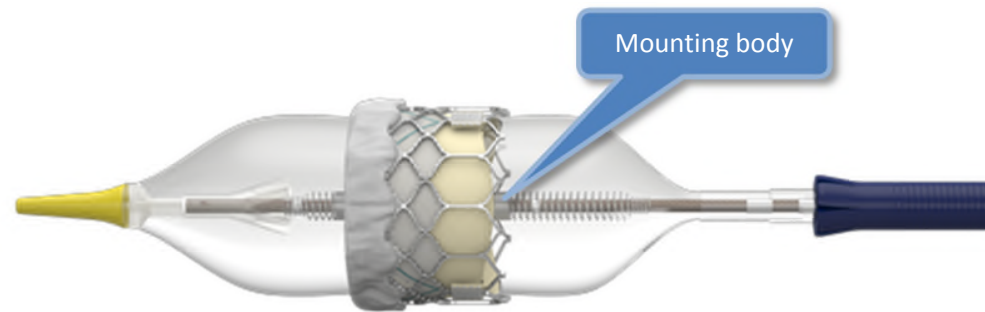
Element	Accused Products
[35 preamble] A stent delivery system comprising:	See claim chart for claim [1 preamble] above.
[35a] a radially expandable stent of generally cylindrical configuration, having a	See claim chart for claim [1 preamble] above.

<p>length, a first end and a second end and a contracted state and an expanded state, and</p>	
<p>[35b] a catheter having a shaft having a diameter and expandable inflatable means associated therewith at a distal part of the shaft, wherein the inflatable means comprises a balloon,</p>	<p>See claim chart for claim [1a] above.</p>
<p>[35c] and including mounting and retaining means for receiving the stent on the expandable inflatable means for radial expansion of the stent upon inflation of the inflatable means, the mounting retaining means including at least one mounting body carried on and surrounding the shaft inside the inflatable means,</p>	<p>See claim chart for claim [1b] above.</p>
<p>[35d] the at least one mounting body being at least $\frac{2}{3}$ the length of the stent and being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's</p>	<p>See claim chart for claim [1c] above.</p>

contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent,	
[35e] whereby the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the mounting and retaining of the stent.	See claim chart for claim [1d] above.

Claim 36	
Element	Accused Products
[36 preamble] The stent delivery system of claim 35,	See claim chart for claim 35 above.
[36a] the at least one mounting body comprising no more than one layer of material.	The mounting bodies of each of the Sapien products comprise no more than one layer of material.

Commander:



Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

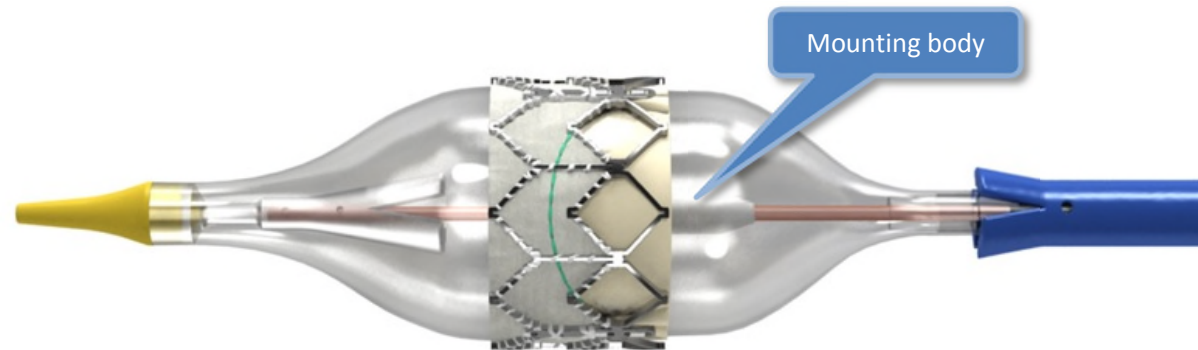
Ascendra:

On information and belief, the Ascendra has a mounting body that that comprises no more than one layer of material, as will be demonstrated with further discovery.

Certitude:

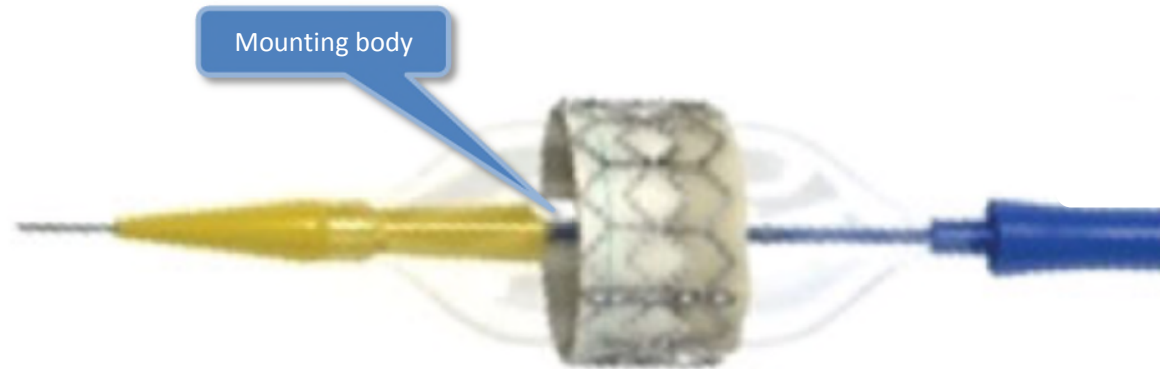
On information and belief, the Certitude has a mounting body that comprises no more than one layer of material, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 available at <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:



Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, *Catheter Cardiovasc Interv* 2010;75:295–300 at 298.

**Ex. D: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,712,827 By Edwards**

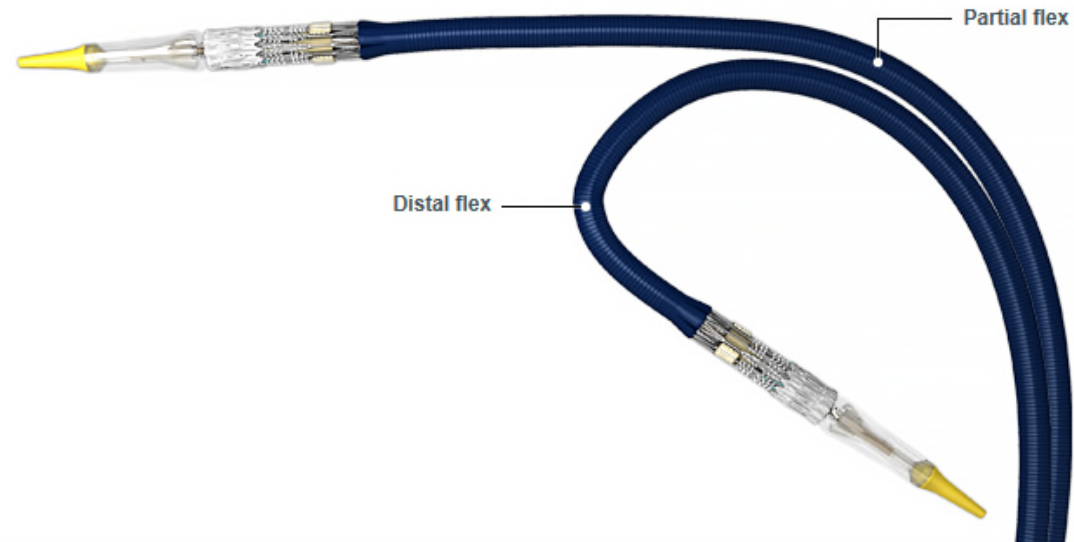
Claim 1	
Element	Accused Products
<p>[1 preamble¹] A balloon catheter for dilating vascular constrictions and for simultaneously introducing a deformable stent into a vessel to be dilated in order to stabilize the vessel in the dilated condition, wherein a distal region of the catheter, which is intended to receive the deformable stent, comprises:</p>	<p>To the extent the preamble is deemed a limitation, on information and belief, Edwards made, used, offered to sell, and/or sold in the United States, and/or imported into the United States each of the balloon catheters used in its Commander Delivery System (“Commander”), Ascendra Delivery System (“Ascendra”), Certitude Delivery System (“Certitude”), NovaFlex Delivery System (“NovaFlex”), and RetroFlex Delivery System (“RetroFlex”) (collectively, the Accused Products) for delivery and deployment of its Sapien 3, Sapien XT, and/or Sapien products.² For example:</p> <p><u>Commander:</u> The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

¹ The designations in square brackets before the claim language in each row is added to permit convenient reference to specific claim language. These added designations are not part of the claim language and are not intended to limit the claims in any way. No interpretation is intended to be conveyed by the words grouped together with each designation.

² The Sapien 3, Sapien XT, and Sapien, and their corresponding delivery systems, are collectively referred to herein as the “Sapien products.” On information and belief, unless otherwise noted, any differences between various versions or models of the delivery systems identified herein or between the Sapien 3, Sapien XT, and Sapien are immaterial to the assertions set forth herein.

Edwards Commander Delivery System

Dual articulation for coaxiality even in challenging anatomies



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>.

Ascendra:

The Ascendra+ delivery system (useable length 55 cm) is used for delivery of the Edwards SAPIEN XT transcatheter heart valve. The delivery system has radiopaque markers for visualization under fluoroscopy and a balloon for deployment of the THV. A balloon inflation hub, a guidewire hub, and a pusher retraction feature are housed in the handle assembly. The handle is labeled "BALLOON" at the balloon inflation hub and "WIRE 0.035"" at the guidewire hub. The system also comes with a loader that is used to cover the THV during delivery. An extension tube is supplied for use with the delivery system during inflation.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.

Ascendra+ System

Expanded Indications
[Learn More](#)

Expanding delivery options

- Designed for transapical and transaortic delivery
- The same easy-to-use system for all 3 valve sizes

Distal tip and balloon shoulder provide a smooth transition from tip to valve



55 cm



Short working length improves handling and control

Introducer sheath with reinforced proximal shaft delivers stability during valve positioning



Trusted balloon-expandable design

- Allows for user-controlled inflation
- Facilitates predictable valve deployment



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>.

The Ascendra Balloon Catheter is used for delivery of the Edwards SAPIEN Transcatheter Heart Valve. The balloon catheter has radiopaque markers for visualization under fluoroscopy and a balloon for deployment of the bioprosthesis. The system also comes with a loader that is used to cover the bioprosthesis during delivery. An extension tubing is supplied for use with the balloon catheter during inflation.

Source: Edwards SAPIEN Transcatheter Heart Valve with the Ascendra Balloon Catheter: Instructions for Use at 1 *available at*

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM307362.pdf>.

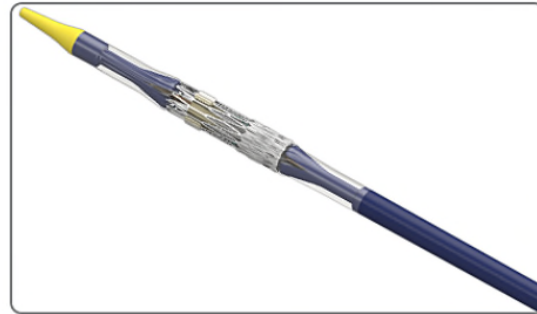
Certitude:

Edwards Certitude Delivery System
designed for seamless deployment

Ultra-low profile system – 18F Certitude sheath compatible*

Integrated pusher

- Streamlines procedure



Articulation feature

- For ease of coaxial positioning



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:

The NovaFlex+ delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN XT THV. The delivery system includes a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system to facilitate advancing to the RVOT, and a balloon catheter for deployment of the THV. The handle also contains a flex indicator depicting articulation of the flex catheter, a valve alignment wheel for fine adjustment of the THV during valve alignment, a button that enables movement between handle positions, and a flush port to flush the flex catheter. The balloon catheter has radiopaque markers defining the valve alignment position and the working length of the balloon. A radiopaque double marker proximal to the balloon indicates flex catheter position during deployment.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.

NovaFlex+ Transfemoral System

Expanded Indications
[Learn More](#)

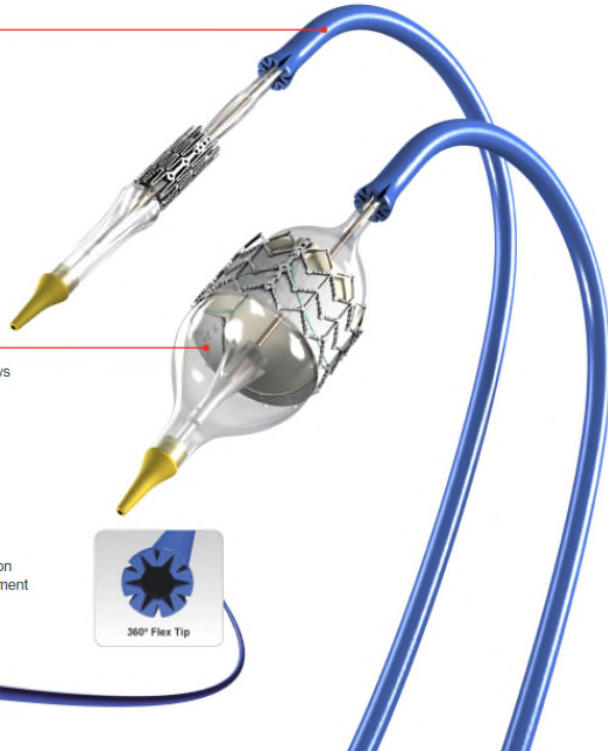
Control

Flex catheter stabilizes balloon shaft during deployment



Precision

Balloon-expandable design allows for user-controlled inflation and precise delivery



Stability

360 Flex Tip provides tight balloon shaft support during valve placement and deployment



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:

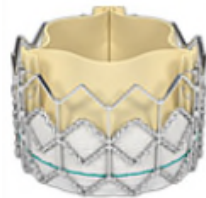
The RetroFlex 3 delivery system includes a rotating wheel within the handle for articulation of flex catheter, a tapered tip at the distal end of the delivery system to facilitate crossing the native valve, a balloon for deployment of the bioprosthesis, and radiopaque markers as indicated in Figure 2.

Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf>.

Transcatheter Heart Valves

Edwards SAPIEN Pulmonic Models

Product Description	23 mm	26 mm
RetroFlex 3 Kit	9100RF323	9100RF326
Edwards SAPIEN Valve	9000TFX23	9000TFX26
RetroFlex 3 Delivery System	9120FS23	9120FS26
RetroFlex 3 Introducer Sheath Set	9120S23	9120S26
RetroFlex Balloon Catheter	9120BC20	9120BC23
RetroFlex Dilator Kit	9100DKS7	9100DKS7
Edwards Crimper	9100CR23	9100CR26
Atrion QL2530 Inflation Device	96402	96402



Edwards SAPIEN Valve



RetroFlex 3 Delivery System

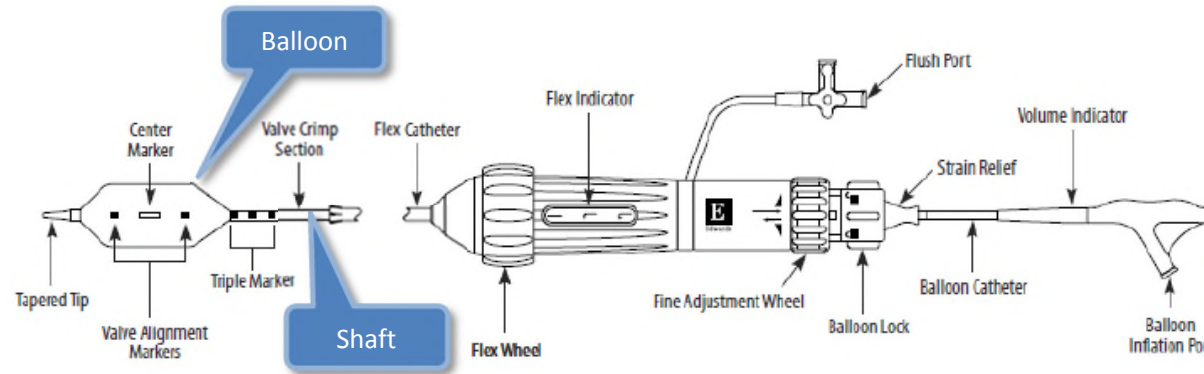
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/pulmonicmodels.aspx>.

[1a]
an inner tube that is surrounded and crimped onto by the deformable stent; a balloon arranged between the deformable stent and the inner tube;

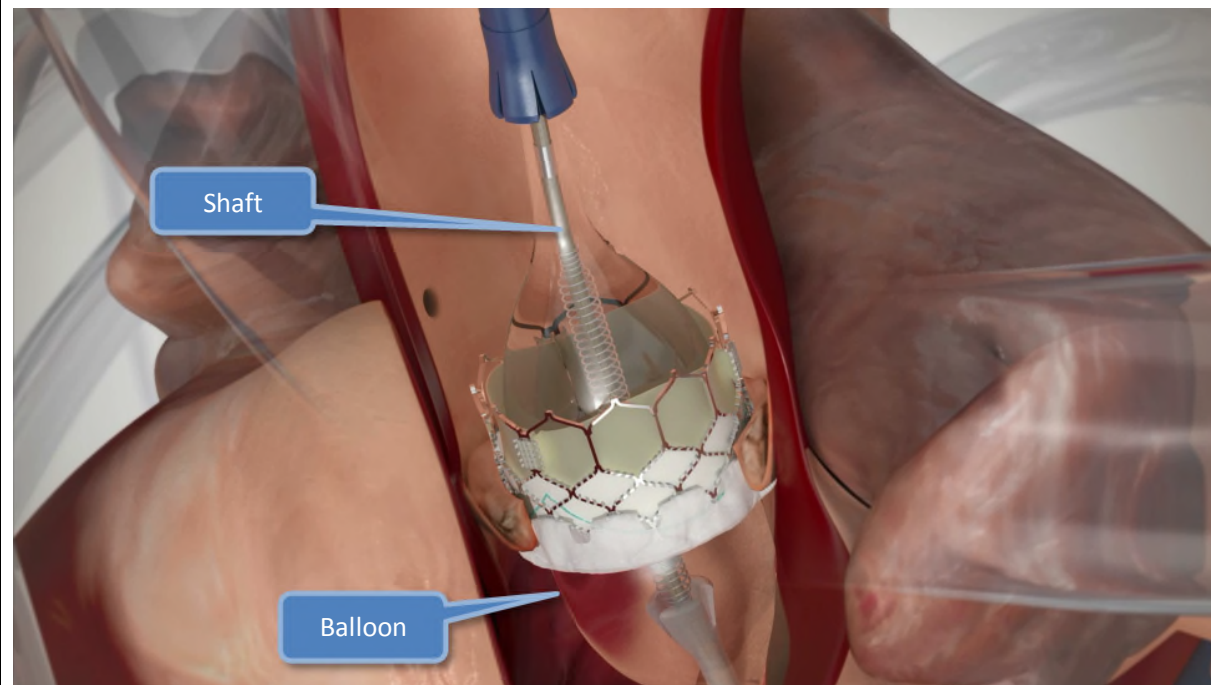
Each of the Sapien products includes an inner tube (shaft) surrounded by a stent, and a balloon arranged between the stent and the inner tube. For example:

Commander:

Figure 2 Edwards Commander Delivery System



Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 3 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.



Source: "thv_commander.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN 3 Valve" hyperlink; then follow "Transfemoral Procedural Animation" hyperlink)

Stent surrounding shaft

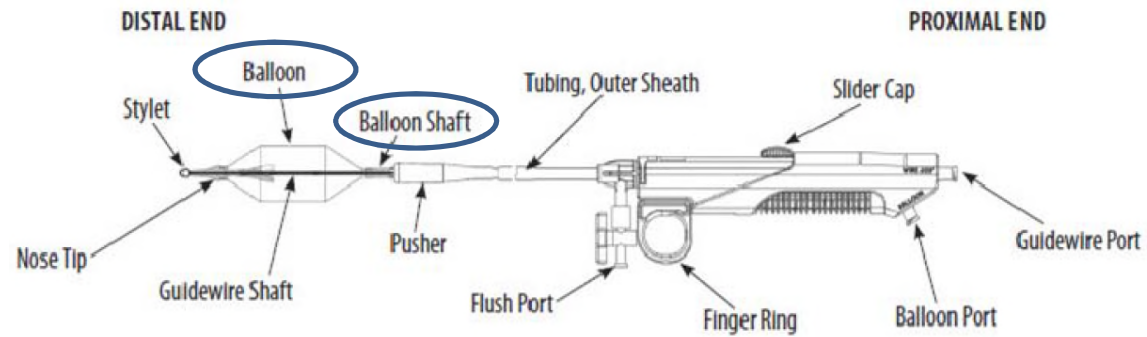


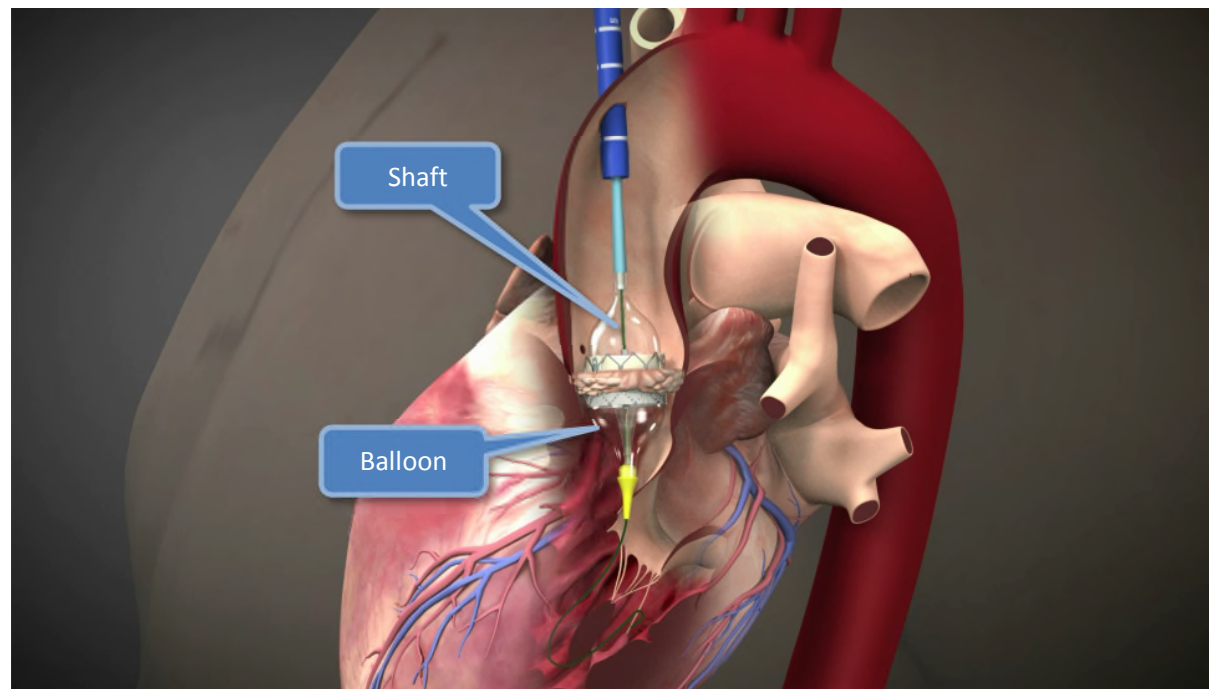
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>.

Ascendra:

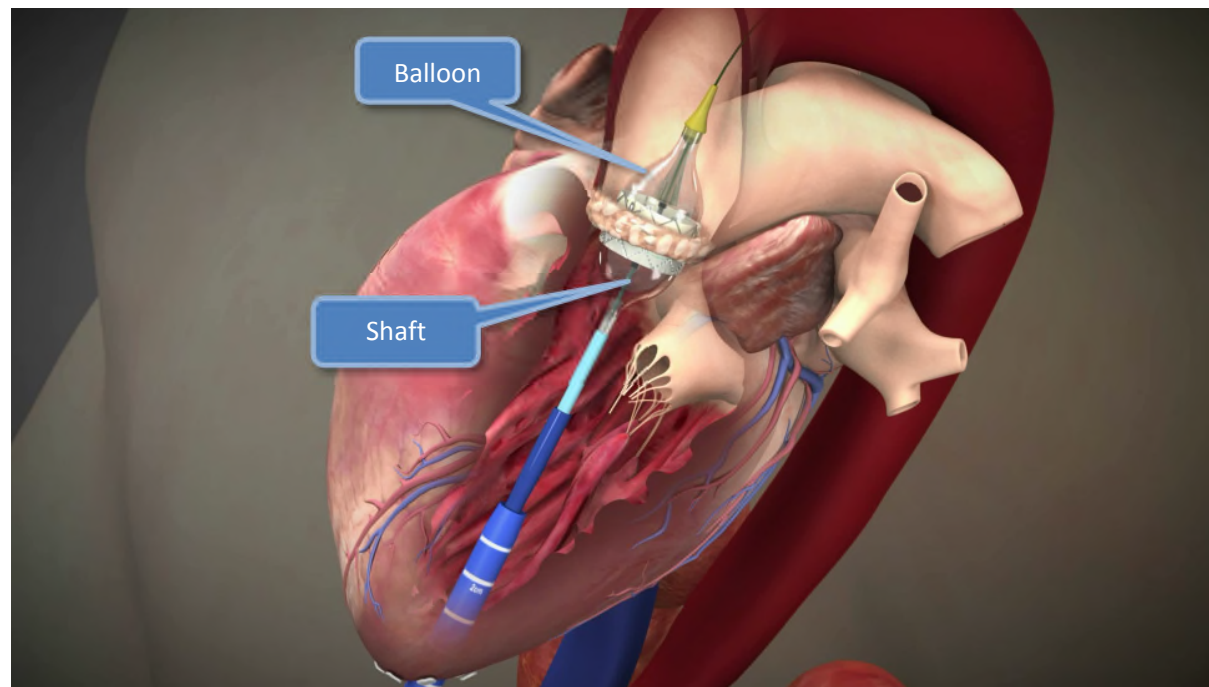
Figure 2A. Ascendra+ Delivery System

THV349





Source: “ascendraplustransaortic.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN XT Valve” hyperlink; then follow “Transaortic Procedural Animation” hyperlink)

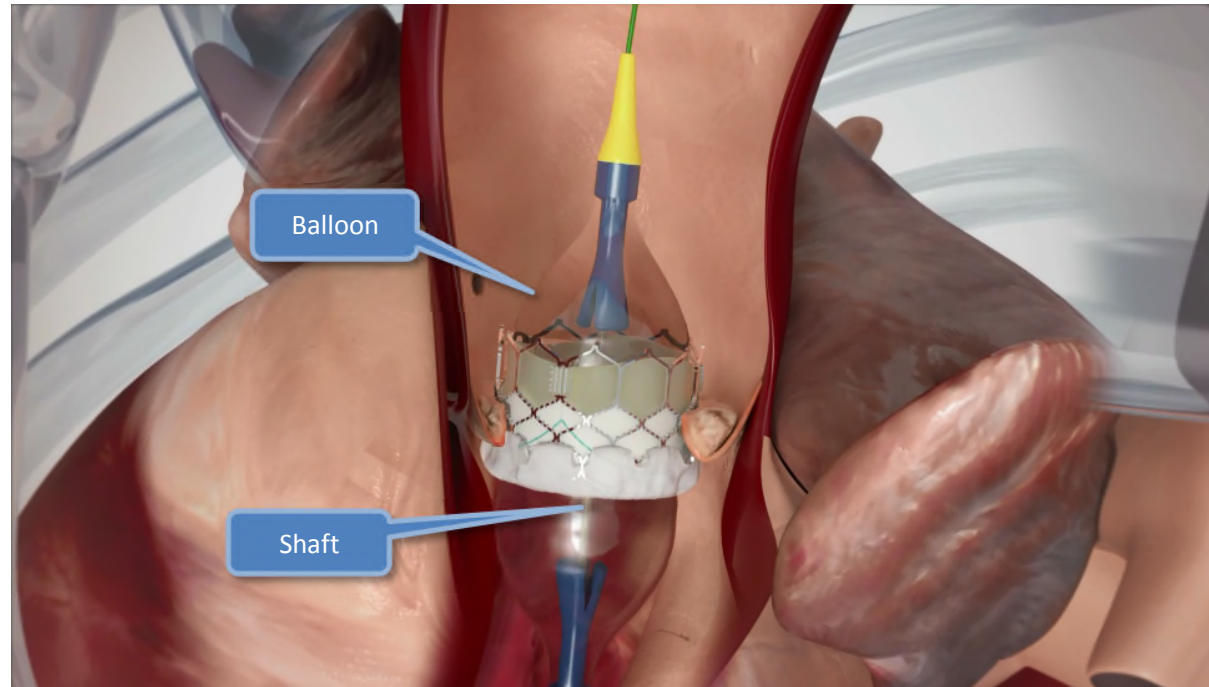


Source: "ascendraplustransapical.mp4" available at <http://www.edwards.com/eu/products/transcatheter valves/Pages/thvhome.aspx> (follow "Edwards SAPIEN XT Valve" hyperlink; then follow "Transapical Procedural Animation" hyperlink)

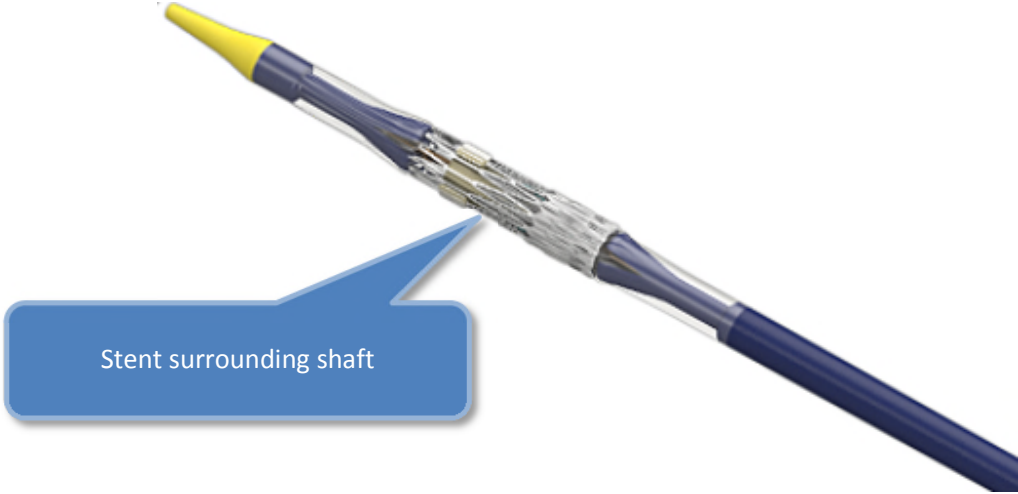


Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>.

Certitude:



Source: “thv_certitude.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN 3 Valve” hyperlink; then follow “Transapical Procedural Animation” hyperlink)

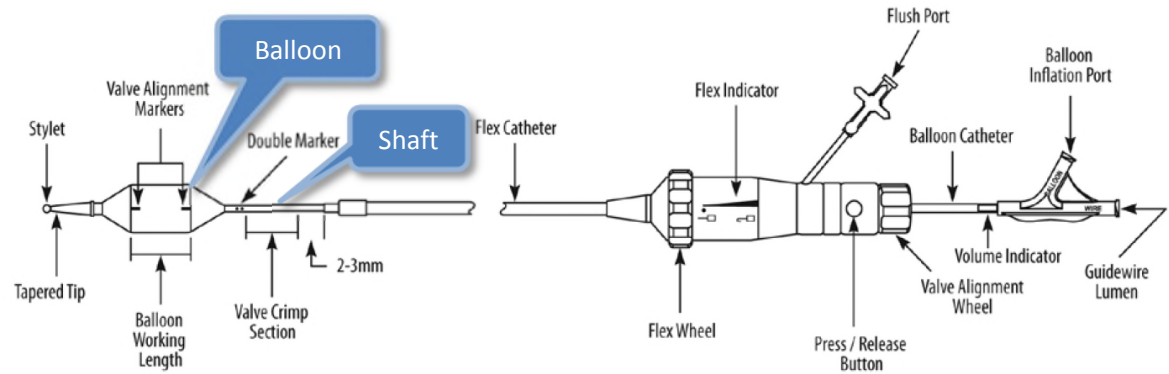


Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

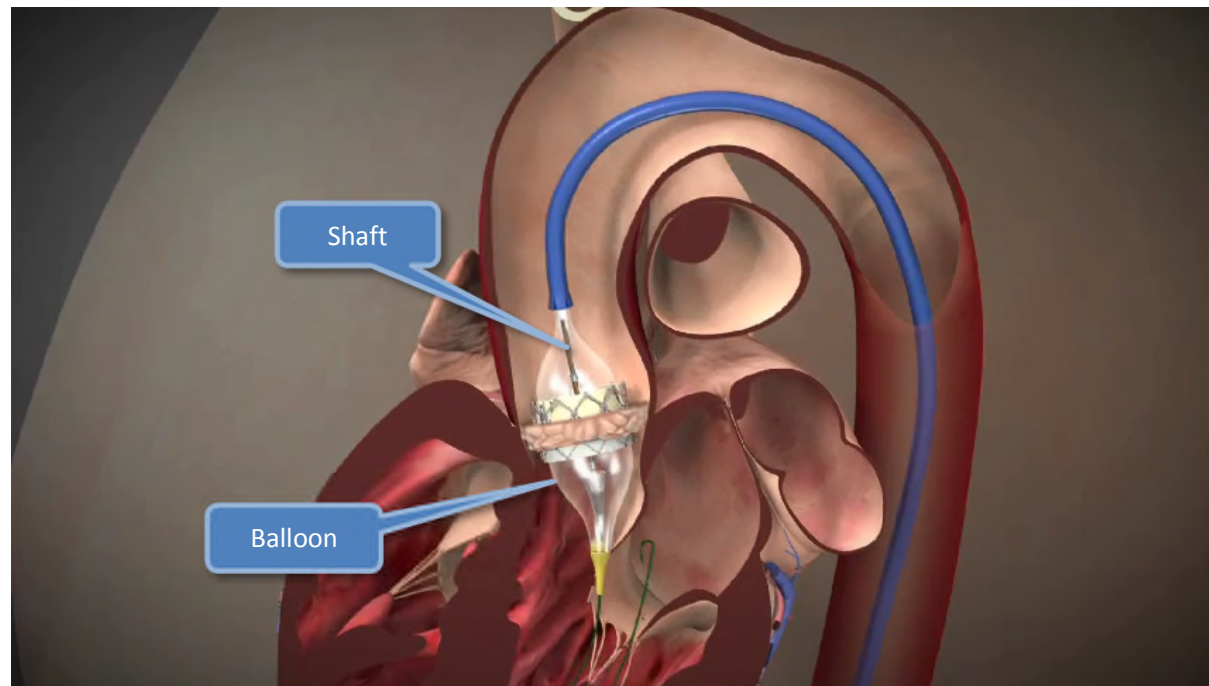
NovaFlex:

Figure 2a. NovaFlex+ Delivery System

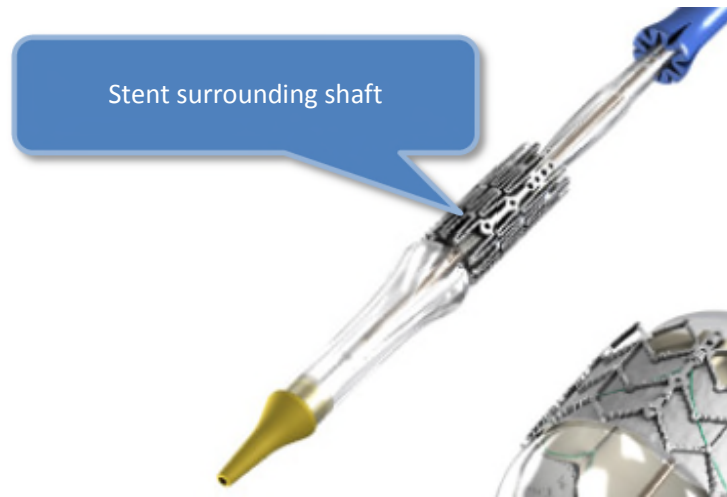
NF21HV04



Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.



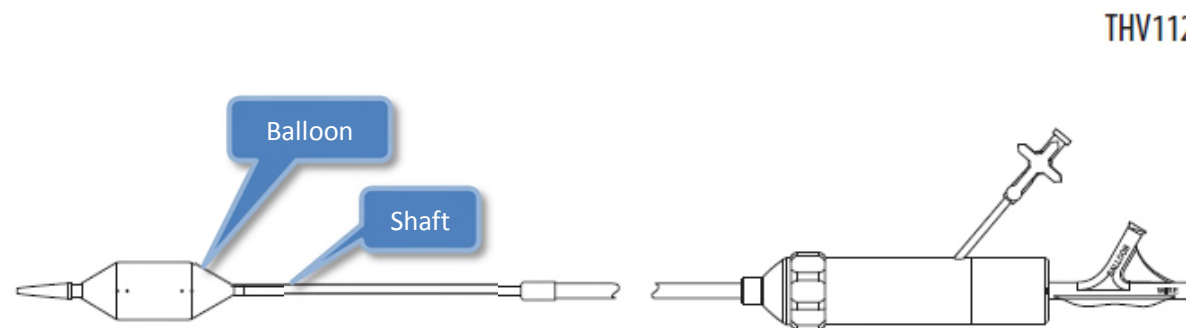
Source: “novaflexplusprocedural.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN XT Valve” hyperlink; then follow “Transfemoral Procedural Animation” hyperlink)



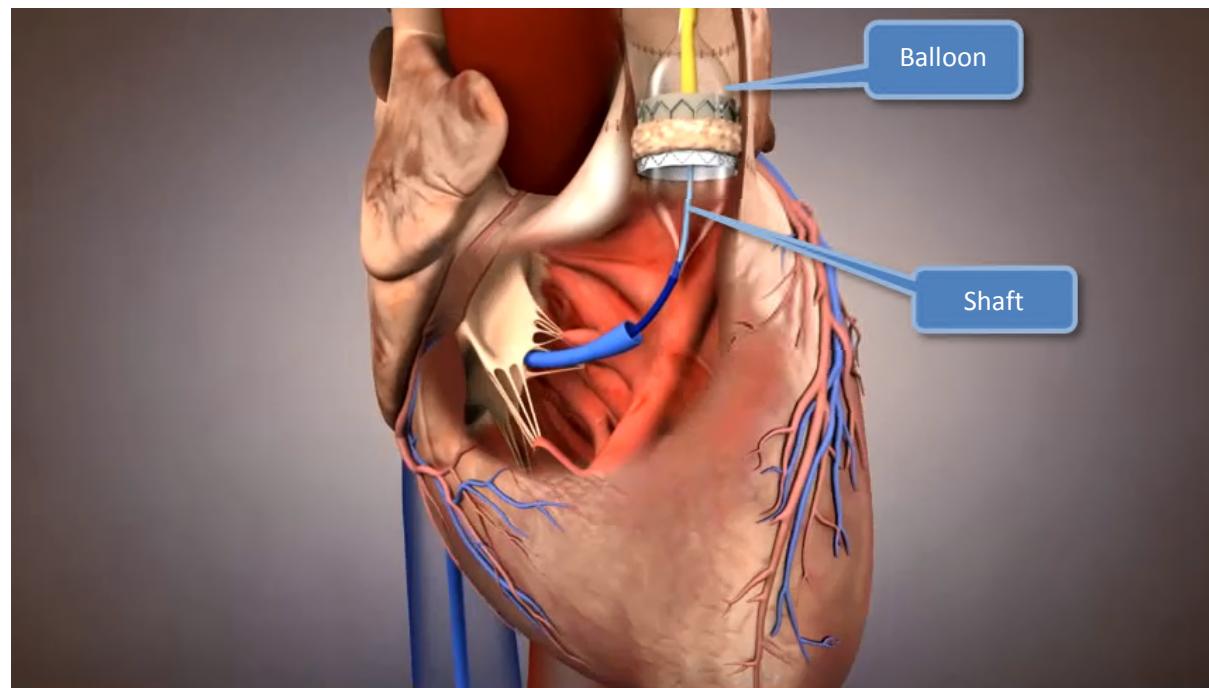
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:


Figure 2. RetroFlex 3 Delivery System



Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/Adviso...orySystemDevicesPanel/UCM262938.pdf>.

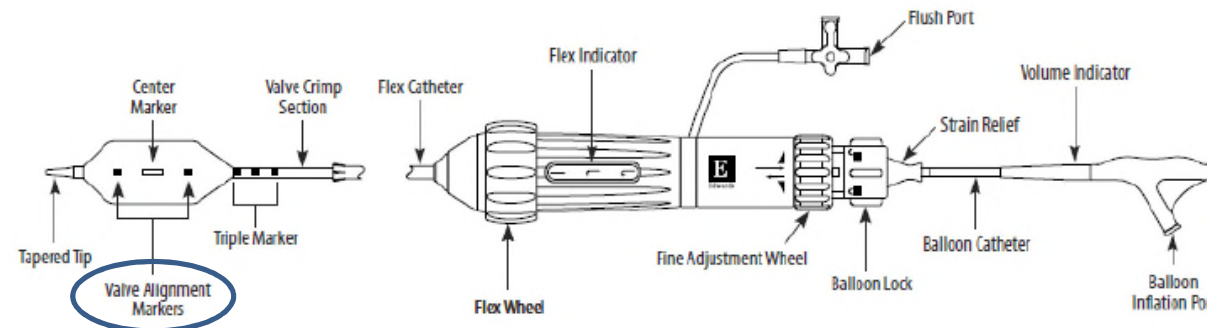


Source: “pulmonicar06026.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN Pulmonic” hyperlink; then follow “Procedural Animation” hyperlink)

	 <p>Source: Webb J, Altwegg L, Masson J, Al Bugami S, Al Ali A, Boone R, <i>A New Transcatheter Aortic Valve and Percutaneous Valve Delivery System</i>, J Am Coll Cardiol. 2009;53(20):1855-1858 at 1858.</p>
<p>[1b] a pair of longitudinally spaced image sensitive marking sleeves carried on the inner tube within the balloon such that there is a longitudinal space on the inner tube extending between the pair of marking sleeves and such that the deformable stent is substantially centered there-between;</p>	<p>Each of the Sapien products includes a pair of longitudinally spaced image sensitive marking sleeves carried on the inner tube within the balloon such that there is a longitudinal space on the inner tube extending between the pair of marking sleeves and such that the deformable stent is substantially centered there-between. For example:</p>

Commander:

Figure 2 Edwards Commander Delivery System



Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 3 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

Before deployment, ensure that the THV is correctly positioned between the Valve Alignment Markers and the Flex Catheter tip is over the Triple Marker.

Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 11 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

Ascendra:

Remove the THV from the crimper and place it on the delivery system with the inflow (fabric cuff end) of the THV proximally towards the pusher if accessing antegrade. If accessing retrograde, place the THV on the delivery system with the inflow (fabric cuff end) of the THV towards the distal end away from the pusher. Ensure that the THV is aligned between the radiopaque markers.

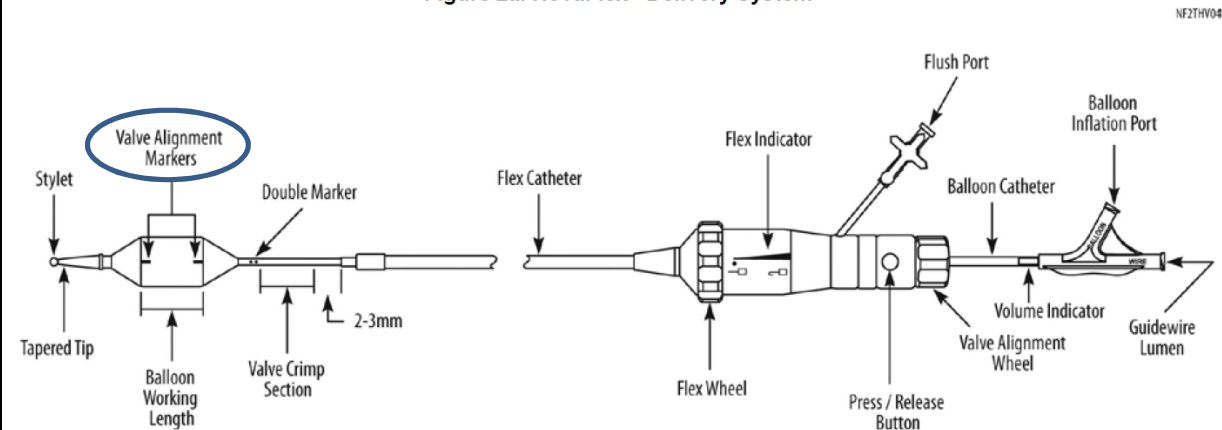
Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 8 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.

Certitude:

On information and belief, the Certitude has marker bands positioned proximally and distally of the stent, as will be demonstrated with further discovery.

NovaFlex:

Figure 2a. NovaFlex+ Delivery System



Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.

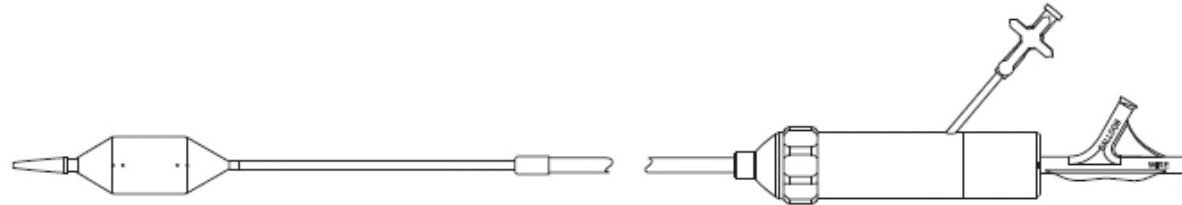
Use the Valve Alignment Wheel to position the THV between the valve alignment markers.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System: Instructions for Use at 9 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S037d.pdf.

RetroFlex:

Figure 2. RetroFlex 3 Delivery System

THV112



Black dots indicate position of radiopaque markers.

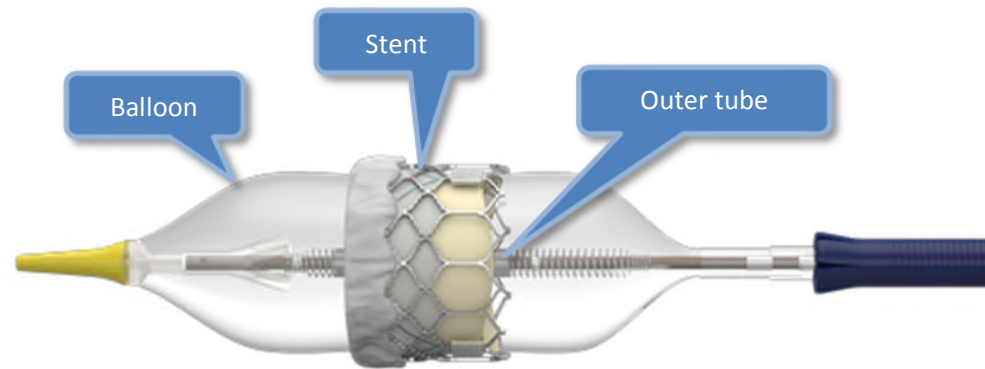
Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf>.

[1c]
an outer tube disposed between the inner tube and the balloon as an intermediate layer, wherein the intermediate layer substantially covers the longitudinal space on the inner tube between the image

Each of the Sapien products includes an outer tube disposed between the inner tube and the balloon as an intermediate layer. The intermediate layer substantially covers the longitudinal space on the inner tube between the image sensitive marking sleeves. The outer diameter of the intermediate layer is substantially constant between the pair of marking sleeves. For example:

sensitive marking sleeves, the intermediate layer having an outer diameter, wherein the outer diameter of the intermediate layer is substantially constant between the pair of marking sleeves.

Commander:



Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

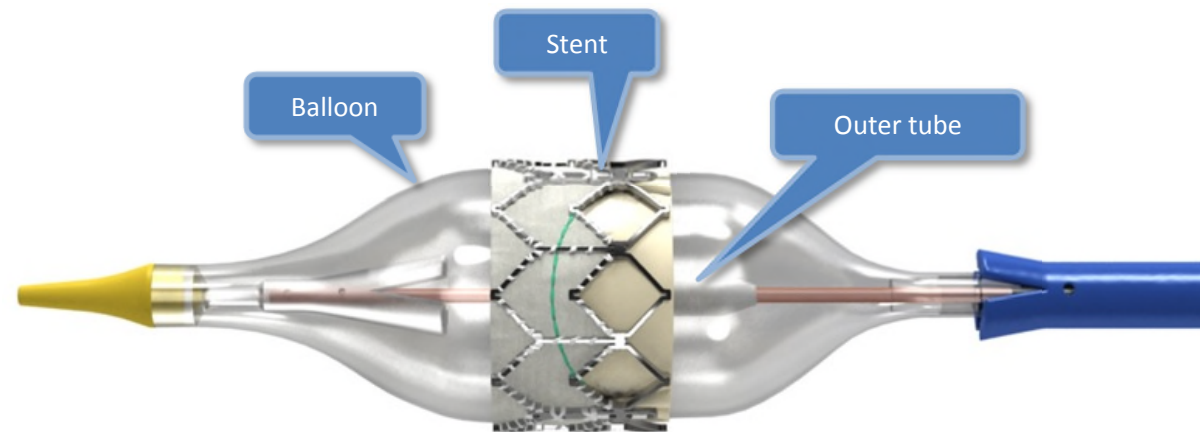
Ascendra:

On information and belief, the Ascendra has an outer tube disposed between the inner tube and the balloon as an intermediate layer, as will be demonstrated with further discovery.

Certitude:

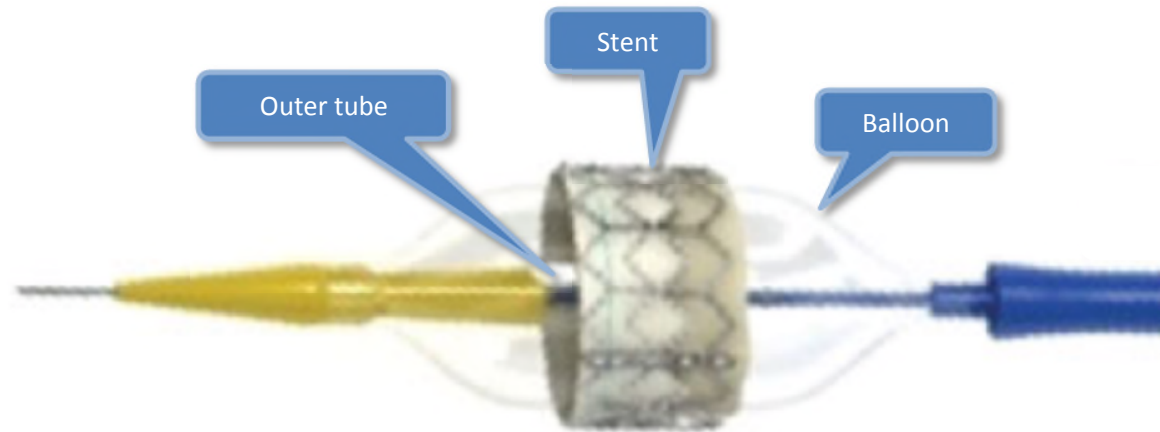
On information and belief, the Certitude has an outer tube disposed between the inner tube and the balloon as an intermediate layer, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 available at <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:



Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, Catheter Cardiovasc Interv 2010;75:295–300 at 298.

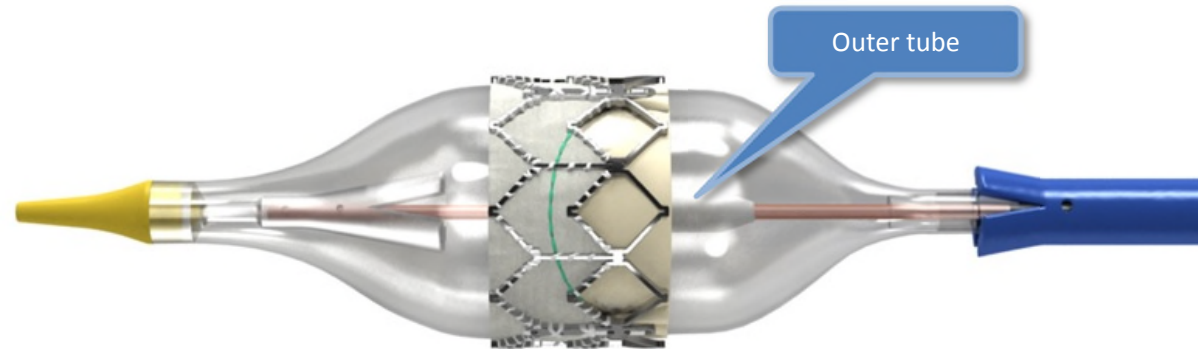
Claim 2

Element	Accused Products
[2 preamble] A balloon catheter as set forth in claim 1,	See claim chart for claim 1 above.
[2a] wherein the inner tube, the balloon, the outer tube forming the intermediate layer and the deformable	Upon information and belief, the inner tube, the balloon, the outer tube forming the intermediate layer and the deformable stent which is crimped onto the catheter form a pre-assembled unit.

stent which is crimped onto said catheter form a pre-assembled unit.	
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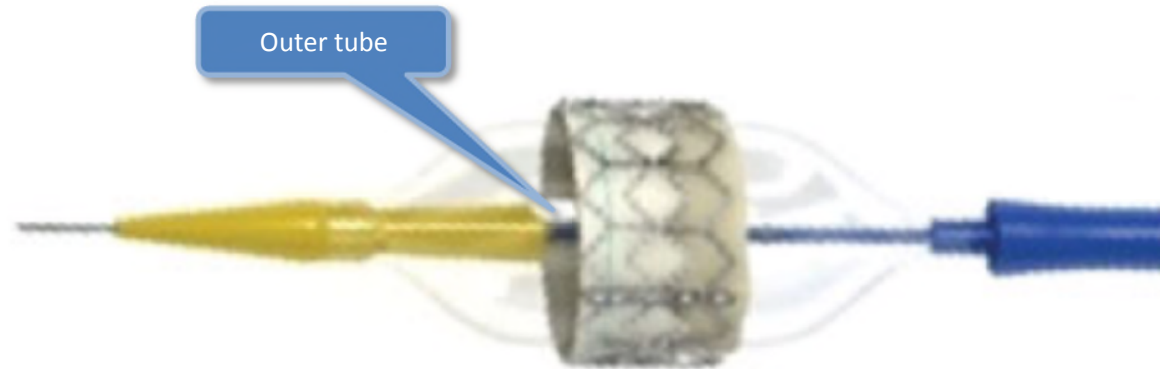
Claim 3	
Element	Accused Products
[3 preamble] A balloon catheter as set forth in claim 1,	<i>See claim chart for claim 1 above.</i>
[3a] wherein the outer tube comprises an elastic material into which the deformable stent is pressed in the crimping operation.	<p>The outer tubes of the Ascendra, Certitude, NovaFlex, and RetroFlex comprise elastic materials into which the deformable stent is pressed in the crimping operation.</p> <p><u>Ascendra:</u></p> <p>On information and belief, the Ascendra has an outer tube comprising an elastic material into which the deformable stent is pressed in the crimping operation, as will be demonstrated with further discovery.</p> <p><u>Certitude:</u></p> <p>On information and belief, the Certitude has an outer tube comprising an elastic material into which the deformable stent is pressed in the crimping operation, as will be demonstrated with further discovery.</p>

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 available at <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

RetroFlex:



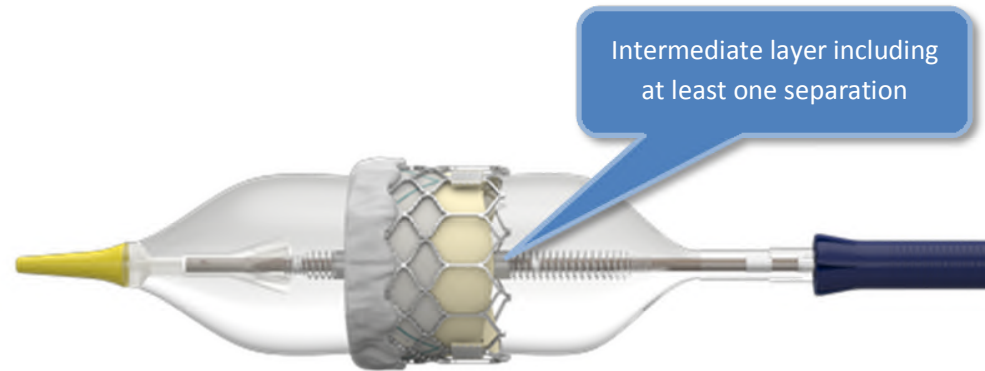
Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, *Catheter Cardiovasc Interv* 2010;75:295–300 at 298.

Claim 5

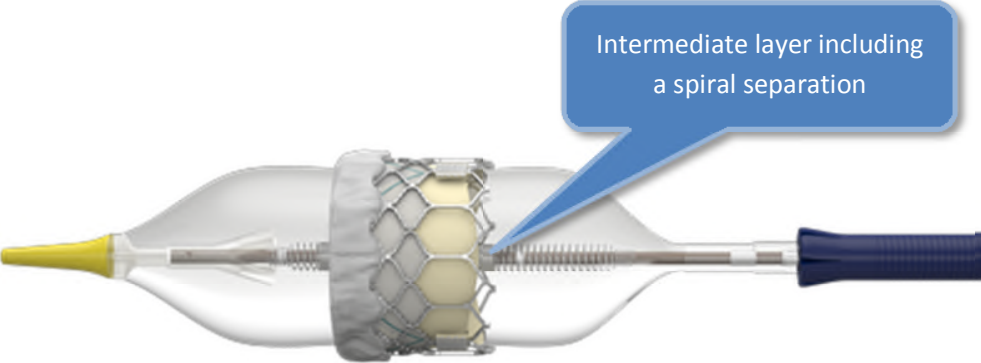
Element	Accused Products
[5 preamble] A balloon catheter as set forth in claim 1,	<i>See claim chart for claim 1 above.</i>
[5a] wherein the intermediate layer includes at least one	The intermediate layer of the Commander includes a coil having at least one separation. For example:

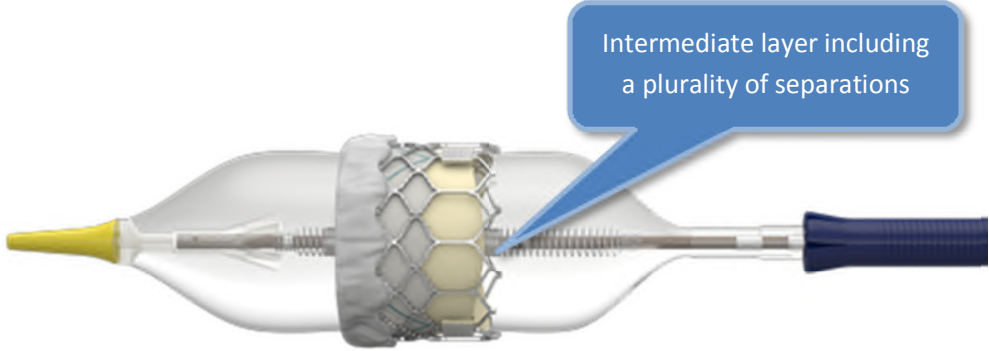
separation whereby the flexibility of the body and catheter is increased.

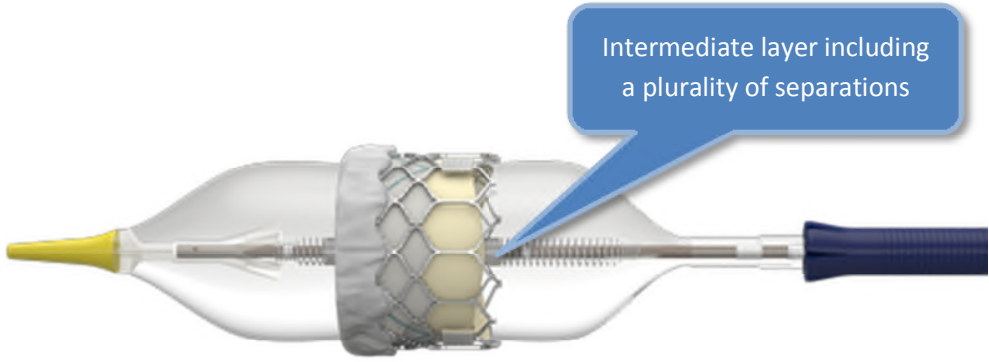
Commander:

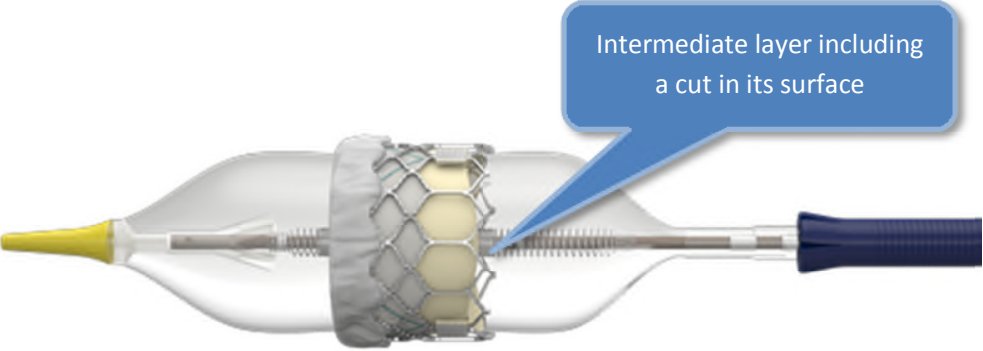


Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

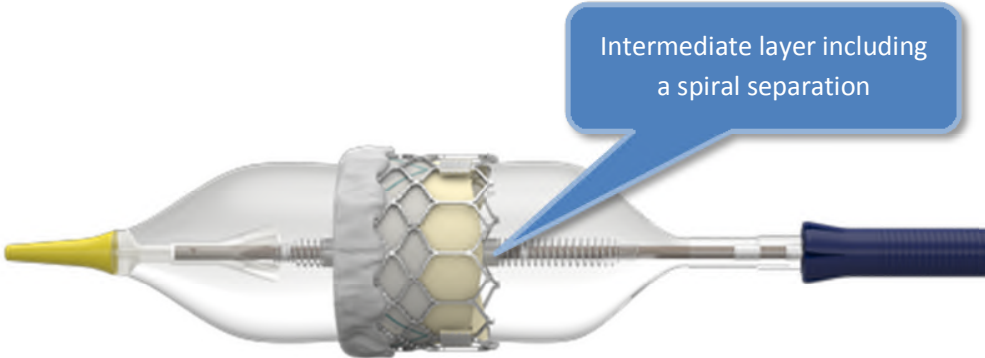
Claim 6	
Element	Accused Products
[6 preamble] A balloon catheter as set forth in claim 1,	See claim chart for claim 1 above.
[6a] wherein the separation is a spiral separation.	<p>The intermediate layer of the Commander includes a coil having at least one spiral separation. For example:</p> <p><u>Commander:</u></p> <div style="text-align: center;">  </div> <p>Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/.</p>

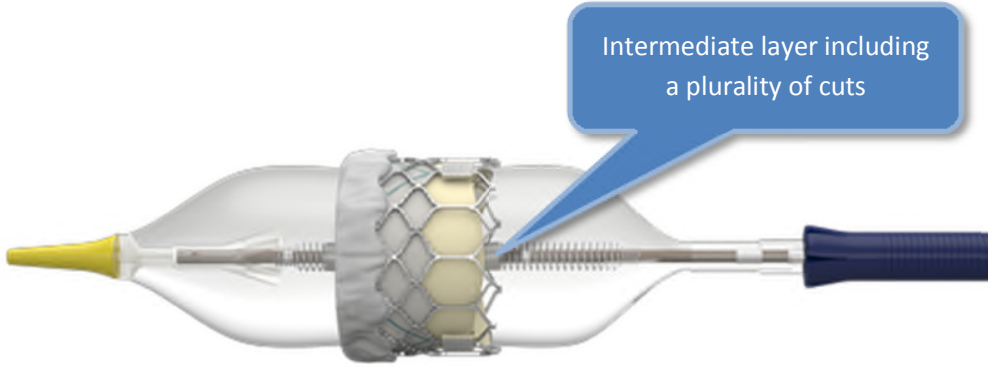
Claim 7	
Element	Accused Products
[7 preamble] A balloon catheter as set forth in claim 5,	<i>See claim chart for claim 5 above.</i>
[7a] wherein there are a plurality of separations.	<p>The intermediate layer of the Commander includes a separation between each coil winding. For example:</p> <p><u>Commander:</u></p>  <p>Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/.</p>

Claim 8	
Element	Accused Products
[8 preamble] A balloon catheter as set forth in claim 7,	<i>See claim chart for claim 7 above.</i>
[8a] wherein the plurality of separations are substantially parallel.	<p>The plurality of separations in the intermediate layer of the Commander are substantially parallel. For example:</p> <p><u>Commander:</u></p>  <p>Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/.</p>


Claim 9	
Element	Accused Products
[9 preamble] A balloon catheter as set forth in claim 1,	See claim chart for claim 1 above.
[9a] wherein the intermediate layer includes at least one cut in its surface.	<p>The intermediate layer of the Commander includes a coil having at least one cut in its surface. For example:</p> <p><u>Commander:</u></p> <div style="text-align: center;">  </div> <p>Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/.</p>

Claim 10

Element	Accused Products
[10 preamble] A balloon catheter as set forth in claim 9,	<i>See claim chart for claim 9 above.</i>
[10a] wherein the cut is a spiral separation.	<p>The separations in the intermediate layer of the Commander is a spiral separation. For example:</p> <p><u>Commander:</u></p>  <p>Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/.</p>

Claim 11	
Element	Accused Products
[11 preamble] A balloon catheter as set forth in claim 9,	<i>See</i> claim chart for claim 9 above.
[11a] wherein the plurality of cuts are circumferential cuts and are substantially parallel.	<p>The intermediate layer of the Commander includes a coil having cuts between each of its windings. For example:</p> <p><u>Commander:</u></p>  <p>Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/.</p>

Claim 12	
Element	Accused Products
[12 preamble] A balloon catheter as set forth in claim 11,	<i>See</i> claim chart for claim 11 above.
[12a] wherein the plurality of cuts are circumferential cuts and are substantially parallel.	The cuts of the Commander coil are circumferential and substantially parallel.

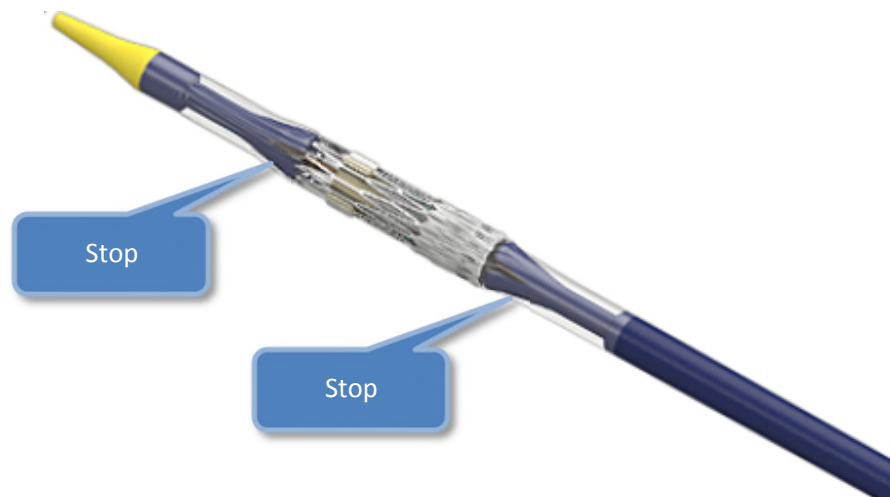
Claim 13	
Element	Accused Products
[13 preamble] A balloon catheter as set forth in claim 1,	<i>See</i> claim chart for claim 1 above.
[13a] further including a stop carried by the inner tube inside the balloon..	<p>Each of the Sapien products includes a stop carried by the inner tube inside the balloon. For example:</p> <p><u>Commander:</u></p>  <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx.</p>

Ascendra:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>.

Certitude:



Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>.

NovaFlex:



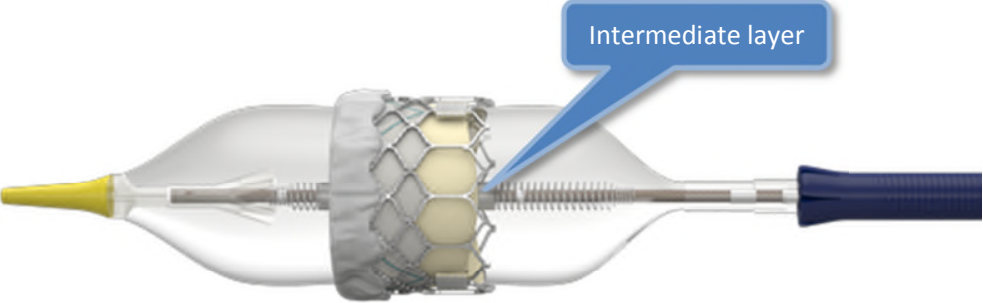
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>.

RetroFlex:



Source: Webb J, Altwegg L, Masson J, Al Bugami S, Al Ali A, Boone R, *A New Transcatheter Aortic Valve and Percutaneous Valve Delivery System*, J Am Coll Cardiol. 2009;53(20):1855-1858 at 1858.

Claim 14

Element	Accused Products
[14 preamble] A balloon catheter as set forth in claim 1,	<i>See claim chart for claim 1 above.</i>
[14a] wherein the intermediate layer is generally cylindrical in shape.	<p>The intermediate layers of each of the Sapien products are cylindrical in shape. For example:</p> <p><u>Commander:</u></p>  <p>Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/.</p>

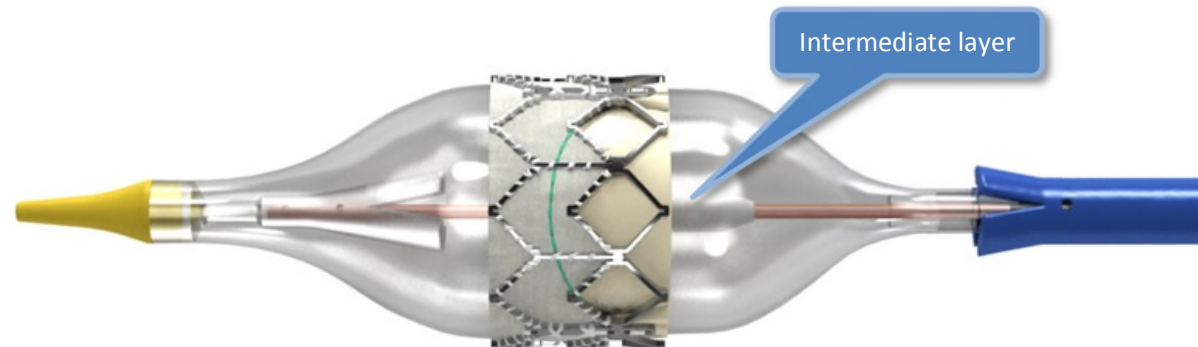
Ascendra:

On information and belief, the Ascendra has an intermediate layer that is cylindrical in shape, as will be demonstrated with further discovery.

Certitude:

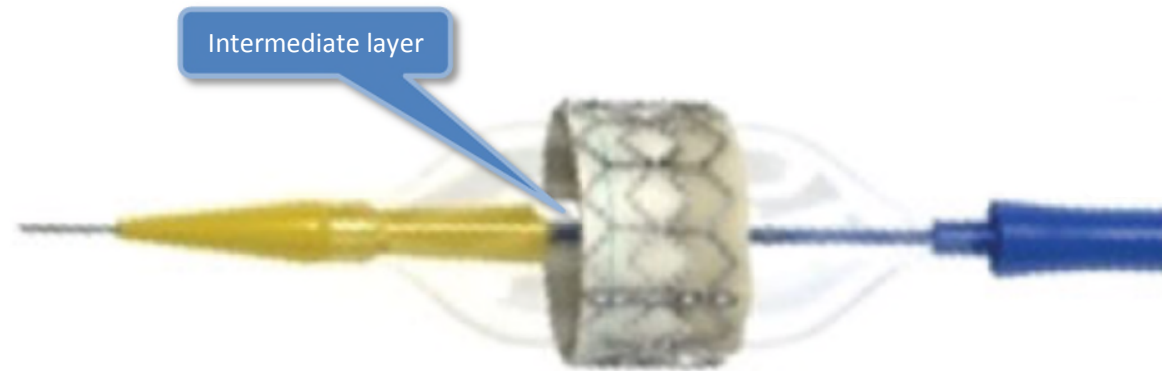
On information and belief, the Certitude has an intermediate layer that is cylindrical in shape, as will be demonstrated with further discovery.

NovaFlex:



Source: The Edwards Transcatheter Heart Valve (THV) Newsletter Europe/May 2010 at 7 available at <http://ht.edwards.com/scin/edwards/de/sitecollectionimages/products/transcathetervalves/tavitalk3.pdf>.

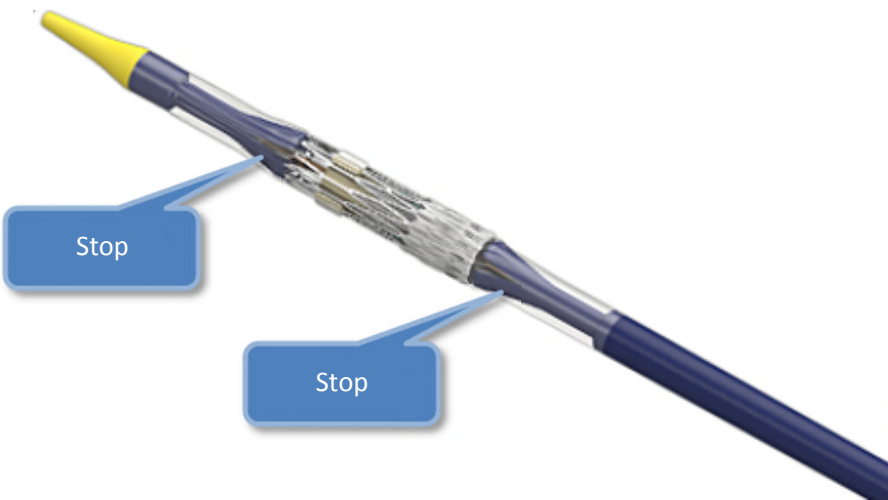
RetroFlex:



Source: Nietlispach F, Wijesinghe N, Wood D, Carere RG, Webb JG., *Current balloon-expandable transcatheter heart valve and delivery systems*, *Catheter Cardiovasc Interv* 2010;75:295–300 at 298.

Claim 15

Element	Accused Products
[15 preamble] A balloon catheter as set forth in claim 1,	See claim chart for claim 1 above.

<p>[15a] Including a pair of stops, each of which is respectively positioned at opposite ends of the deformable stent and carried by the inner tube inside the balloon.</p>	<p>The Certitude includes a pair of stops positioned at opposite ends of the stent and carried by the inner tube inside the balloon. For example:</p> <p><u>Certitude:</u></p>  <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx.</p>
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Claim 16	
Element	Accused Products
<p>[16a] Balloon catheter for expansion of vessel stenoses and for simultaneous</p>	<p>See claim chart for claim [1 preamble] above.</p>

introduction of a deformable stent,	
[16b] the deformable stent being expandable from an unexpanded condition to an expanded condition, into the vessel which is to be expanded in order to stabilize it in the expanded condition,	See claim chart for claim [1 preamble] above.
[16c] whereby the distal area of the catheter which is provided for receiving the deformable stent has an interior tube which is surrounded by the unexpanded deformable stent, a balloon is arranged between the deformable stent and the interior tube,	See claim chart for claim [1a] above.
[16d] and the interior tube has at its ends two sleeves applied to it as image sensitive markers which are composed of material opaque to X rays and are provided within the balloon on the interior tube,	See claim chart for claim [1b] above.
[16e] the catheter further comprising a intermediate tube which forms an additional plateau and which	See claim chart for claim [1c] above.

<p>is composed of a flexible material is provided between interior tube and exterior balloon as an intermediate layer in such manner that it extends in longitudinal direction to the sleeves which form the image sensitive markers, the intermediate layer having an outer diameter, wherein the outer diameter of the intermediate layer is substantially constant between the pair of image sensitive markers.</p>	
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Claim 17	
Element	Accused Products
<p>[17 preamble] A balloon catheter for introducing a stent, the stent being expandable, into a vessel comprising</p>	<p>See claim chart for claim [1 preamble] above.</p>
<p>[17a] an inner tube that is surrounded and crimped onto by the stent; a balloon arranged between the stent and the inner tube;</p>	<p>See claim chart for claim [1a] above.</p>

<p>[17b] a first marking sleeve having a distal end and a proximal end and a second marking sleeve having a distal end, wherein the sleeves are longitudinally spaced from one another along the inner tube, the second marking sleeve being distal to the first marking sleeve along the inner tube, and are image sensitive, the sleeves being carried on the inner tube within the balloon, such that there is a longitudinal space on the inner tube extending between the pair of marking sleeves and such that the stent is substantially centered there-between,</p>	<p>See claim chart for claim [1b] above.</p>
<p>[17c] an intermediate layer disposed between the inner tube and the balloon, the intermediate layer having a proximal portion and a distal portion, wherein the proximal portion covers the inner tube and is positioned immediately distal to the distal end of the first marking sleeve and wherein</p>	<p>See claim chart for claim [1c] above.</p>

the distal portion covers the inner tube and is positioned immediately proximal to the proximal end of the second marking sleeve.	
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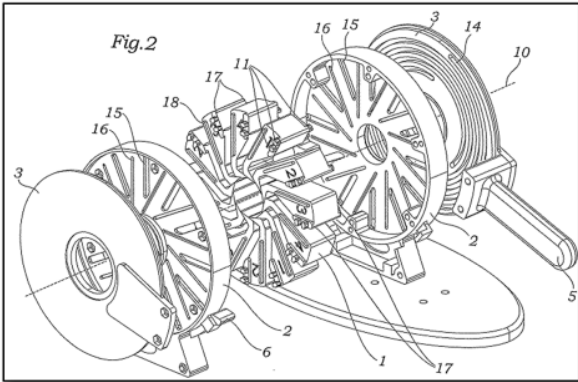
Claim 18	
Element	Accused Products
[18 preamble] The balloon catheter of claim 17,	<i>See claim chart for claim 17 above.</i>
[18a] wherein the intermediate layer extends from the distal end of the first marking sleeve to the proximal end of the second marking sleeve.	<i>See claim chart for claim [1b] above. See claim chart for claim [1c] above.</i>

Claim 19	
Element	Accused Products
[19 preamble] The balloon catheter of claim 17,	<i>See claim chart for claim 17 above.</i>
[19a] the first marking sleeve having an outer diameter and the intermediate layer having an inner diameter, wherein	<i>For each of the Ascendra, Certitude, NovaFlex, and RetroFlex, the inner diameter of the intermediate layer is equal to or less than the outer diameter of the first marking sleeve.</i>

<p>the inner diameter of the intermediate layer is equal to or less than the outer diameter of the first marking sleeve.</p>	
--	--

<p style="text-align: center;">Claim 20</p>	
<p style="text-align: center;">Element</p>	<p style="text-align: center;">Accused Products</p>
<p>[20 preamble] The balloon catheter of claim 18,</p>	<p><i>See claim chart for claim 18 above.</i></p>
<p>[20a] the intermediate layer having an outer diameter, wherein the outer diameter of the intermediate layer is substantially constant between the pair of marking sleeves.</p>	<p><i>See claim chart for claim [1c] above.</i></p>

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

Claim 1	
Element	Accused Products
<p>[1 preamble¹] A stent crimper comprising:</p>	<p>To the extent the preamble is deemed a limitation, the Edwards Crimper (“Crimper”) is a stent crimper.² For example:</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p align="center">Edwards Crimper</p> <p>http://www.edwards.com/eu/products/transcatheter valves/pages/pulmonicmodels.aspx; WO2007/030825</p> <p>See, also http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 (“The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation” using the Edwards Commander Delivery System, among other catheter delivery systems.)</p>

¹ The designations in square brackets before the claim language in each row is added to permit convenient reference to specific claim language. These added designations are not part of the claim language and are not intended to limit the claims in any way. No interpretation is intended to be conveyed by the words grouped together with each designation.

² On information and belief, unless otherwise noted, any differences between various versions or models of the Crimper identified herein are immaterial to the assertions set forth herein

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

2.2 Crimper

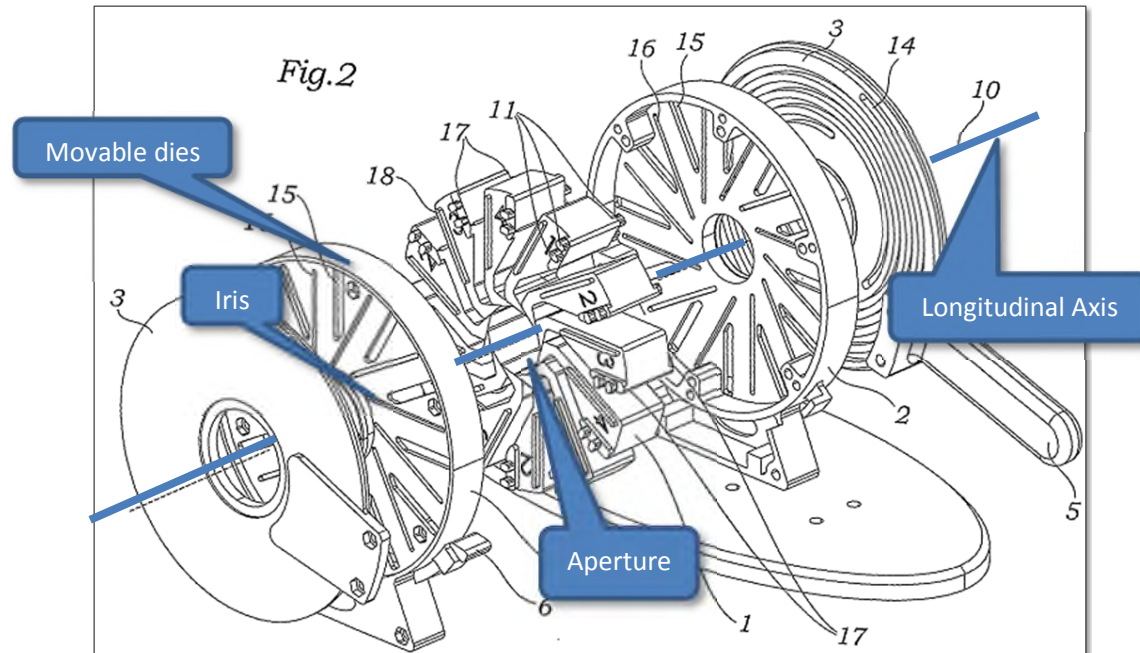
The crimper (Models 9100CR23 and 9100CR26) is a single-use non-patient contacting, compression device (Figure 2) that symmetrically reduces the overall diameter of the bioprosthesis from its expanded size to its collapsed (mounted) size, effectively mounting the bioprosthesis to its delivery balloon catheter. The crimper is comprised of a housing and a compression mechanism (creating the aperture). The aperture is closed by means of a handle located on the housing. The crimper is equipped with two measuring gauges:

- o A crimp gauge to verify that the bioprosthesis/balloon assembly has been suitably collapsed.
- o A balloon gauge to verify the bioprosthesis/balloon assembly catheter diameter when inflated.

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM307365.pdf>

[1a]
a plurality of movable dies arranged to form an iris having a longitudinal axis,

The Crimper's plurality of movable dies are arranged to form an iris having a longitudinal axis. For example:



**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

[1b]
the iris defining an
aperture,

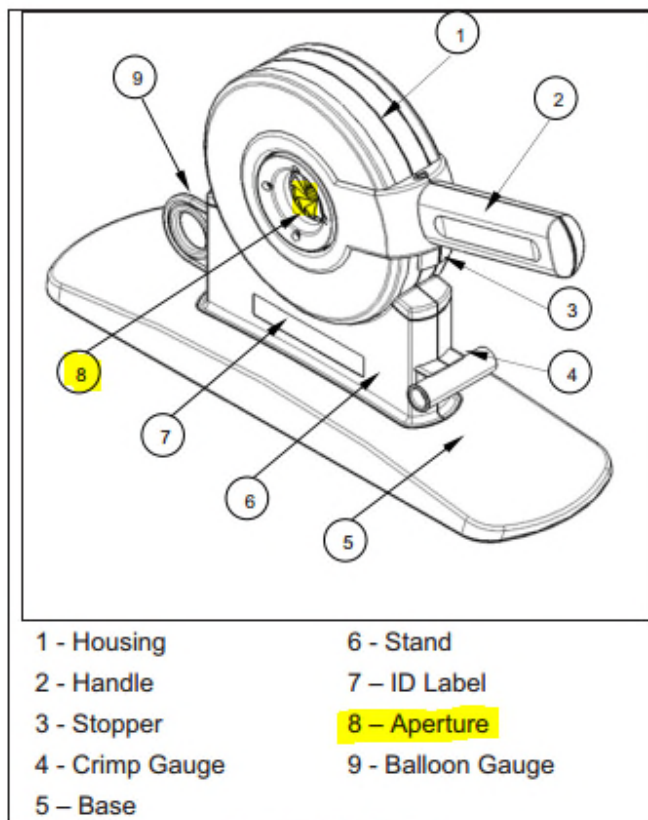
The iris formed by the dies defines an aperture, as illustrated above.

See also:

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM307365.pdf>

**The PARTNER-US IDE Trial
with Continued Access and Post-Approval Study**

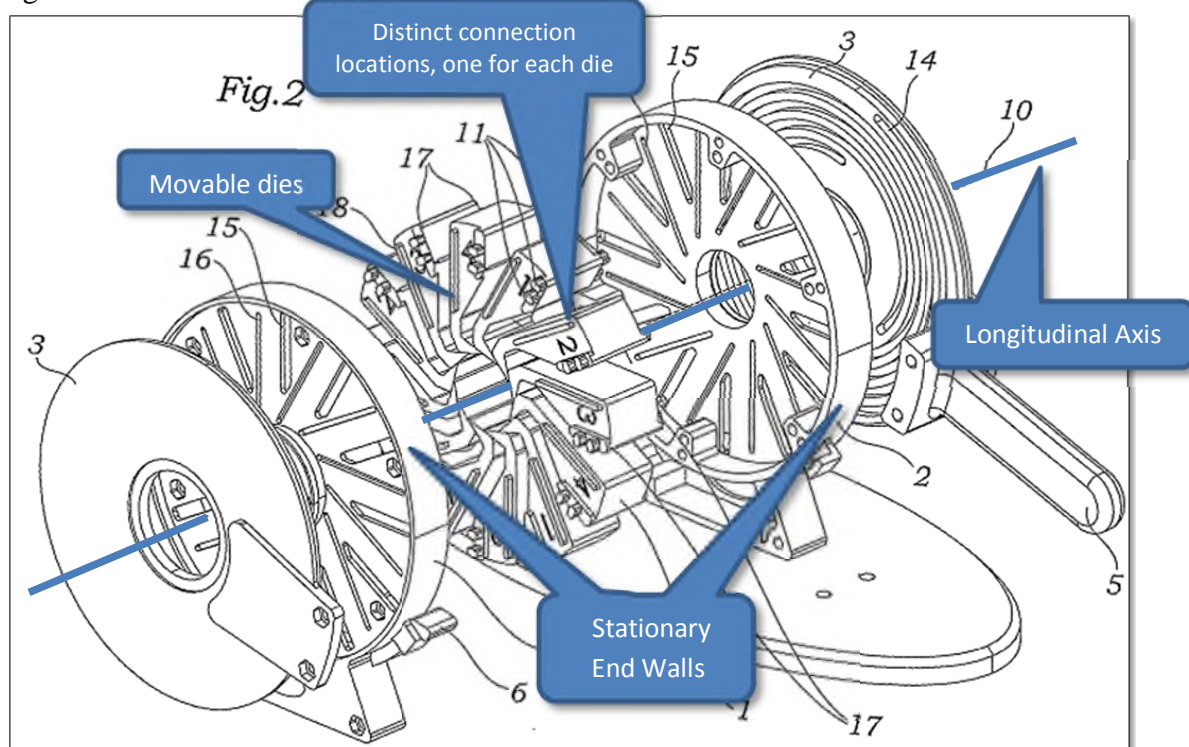
Edwards Lifesciences



**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

[1c]
the dies disposed about the aperture and between stationary end-walls which are disposed about the longitudinal axis,

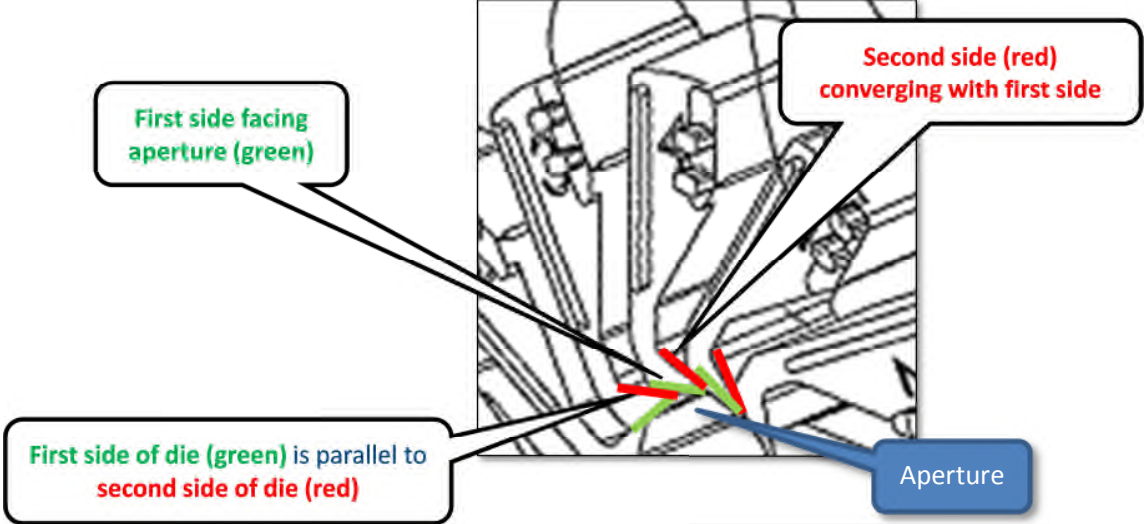
The Crimper's dies are disposed about the aperture and between stationary end-walls which are disposed about the longitudinal axis: For example:



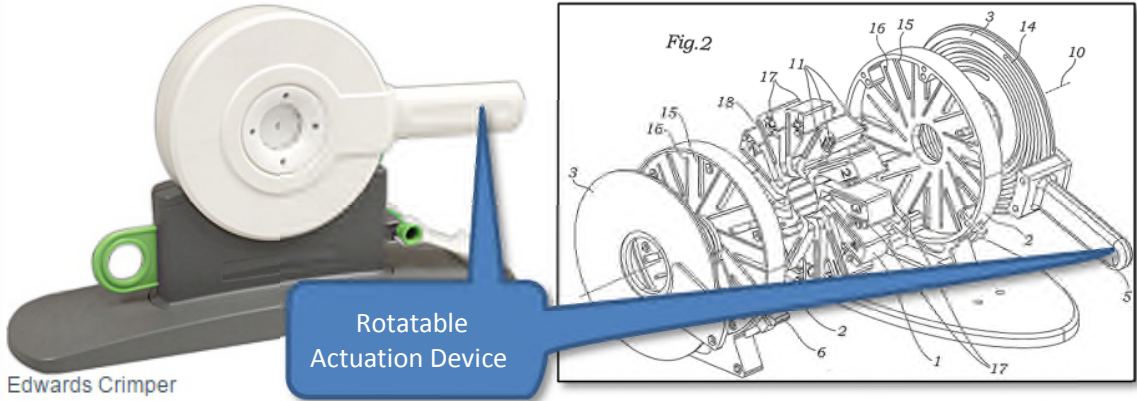
[1d]
at least one of the stationary end-walls operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same;

As shown above, each die has a distinct connection location at which it operatively engages to the stationary end wall.

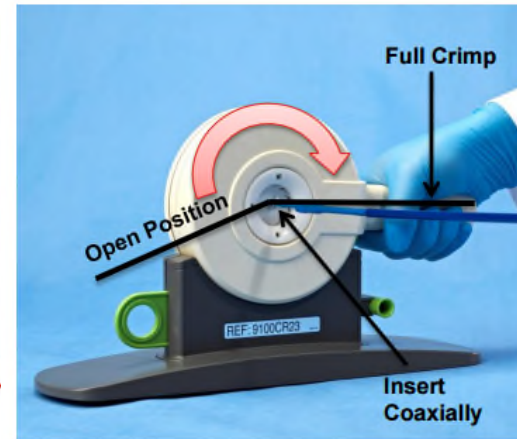
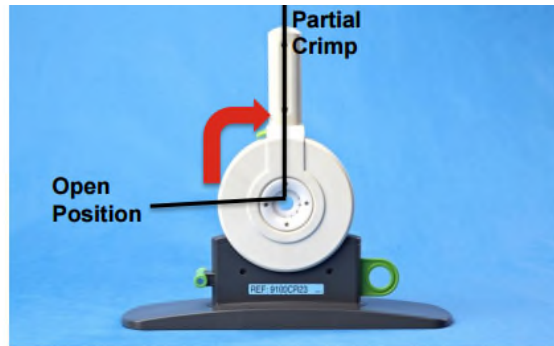
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

<p>[1e] each die having a first straight side and a second straight side,</p>	<p>For example, each of the Crimper's dies has a first straight side (shown in green) and a second straight side (shown in red):</p>  <p>The diagram shows a cross-section of a die assembly. A central blue callout points to the 'Aperture'. A green callout points to the 'First side facing aperture (green)'. A red callout points to the 'Second side (red) converging with first side'. A larger callout at the bottom states 'First side of die (green) is parallel to second side of die (red)'.</p>
<p>[1f] the first straight side and the second straight side converging to form a tip;</p>	<p>As shown above, the first straight side (green) and the second straight side (red) converge to form a tip.</p>
<p>[1g] wherein a portion of the first straight side of each die faces the aperture,</p>	<p>As shown above, a portion of the first straight side of each die (green) faces the aperture.</p>
<p>[1h] each first straight side parallel to the second side of an adjacent die.</p>	<p>As shown above, each first straight side (red) is parallel to the second side of an adjacent die (green).</p>

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

Claim 2	
Element	Accused Products
[2 preamble] The stent crimper of claim 1	As shown in connection with claim 1, the Crimper includes all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[2a] having a rotatable actuation device coupled to the dies,	<p>The Crimper has a rotatable actuation device coupled to the dies. For example:</p>  <p>Edwards Crimper</p>
[2b] rotation of the actuation device causing the dies to move inward and reduce the size of the aperture	Rotation of the Crimper's actuation device causes the dies to move inward, thereby reducing the size of the aperture. <i>See</i> http://market360online.com/sqlimages/1246/129856.pdf

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

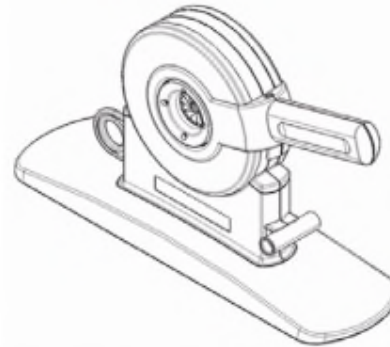


EDWARDS LIFESCIENCES CONFIDENTIAL
SOP4408EL28 Rev: B Issued: 5/16/2013 ECN094263

See also: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm262934.pdf>, p. 2

The Crimper, shown in Figure 4, is comprised of a housing and a compression mechanism, creating an aperture that is opened and closed by means of a handle located on the housing. The crimper includes a balloon gauge to verify diameter of an inflated balloon catheter and a crimp gauge to verify collapsed diameter of the device.

Figure 4: Crimper



**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

[2c]
or outward so as to
increase the size of the
aperture.

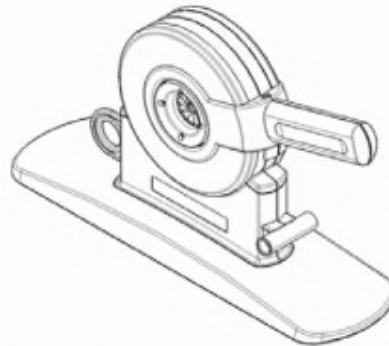
Rotation of the Crimper's actuation device cause in the opposite direction causes the dies to move outward, thereby increasing the size of the aperture. For example:



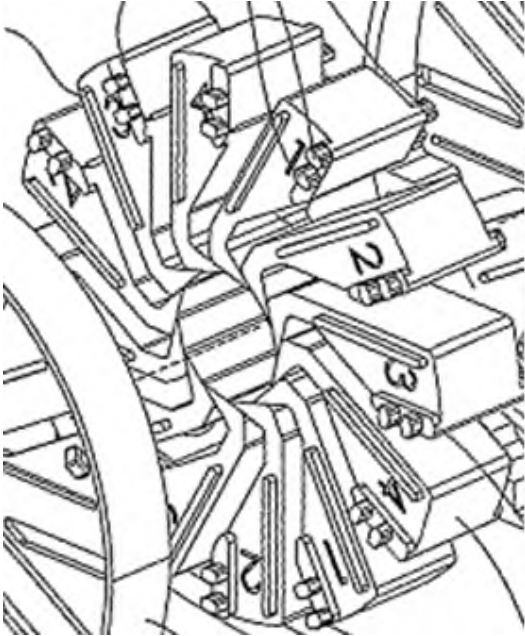

See also: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm262934.pdf>, p. 2

The Crimper, shown in Figure 4, is comprised of a housing and a compression mechanism, creating an aperture that is opened and closed by means of a handle located on the housing. The crimper includes a balloon gauge to verify diameter of an inflated balloon catheter and a crimp gauge to verify collapsed diameter of the device.


Figure 4: Crimper




**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

Claim 6	
Element	Accused Products
[6 preamble] The stent crimper of claim 1	As shown in connection with claim 1, the Crimper includes all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[6a] wherein at least 8 dies are provided.	<p>The Crimper has 12 dies. For example:</p>  


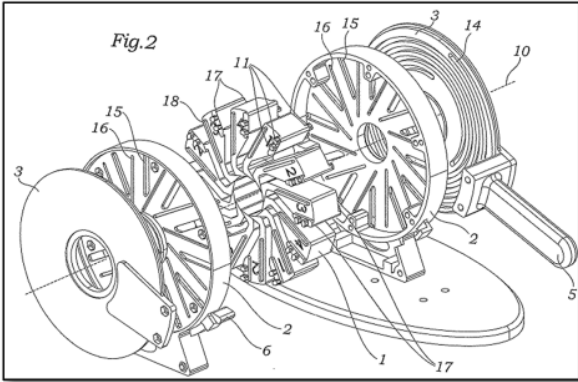
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

Claim 8	
Element	Accused Products
[8 preamble] The stent crimper of claim 1	As shown in connection with claim 1, the Crimper includes all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[8a] wherein the dies are moved cooperatively inward during the moving step.	The Crimper's dies move cooperatively inward during the moving step. For example: 

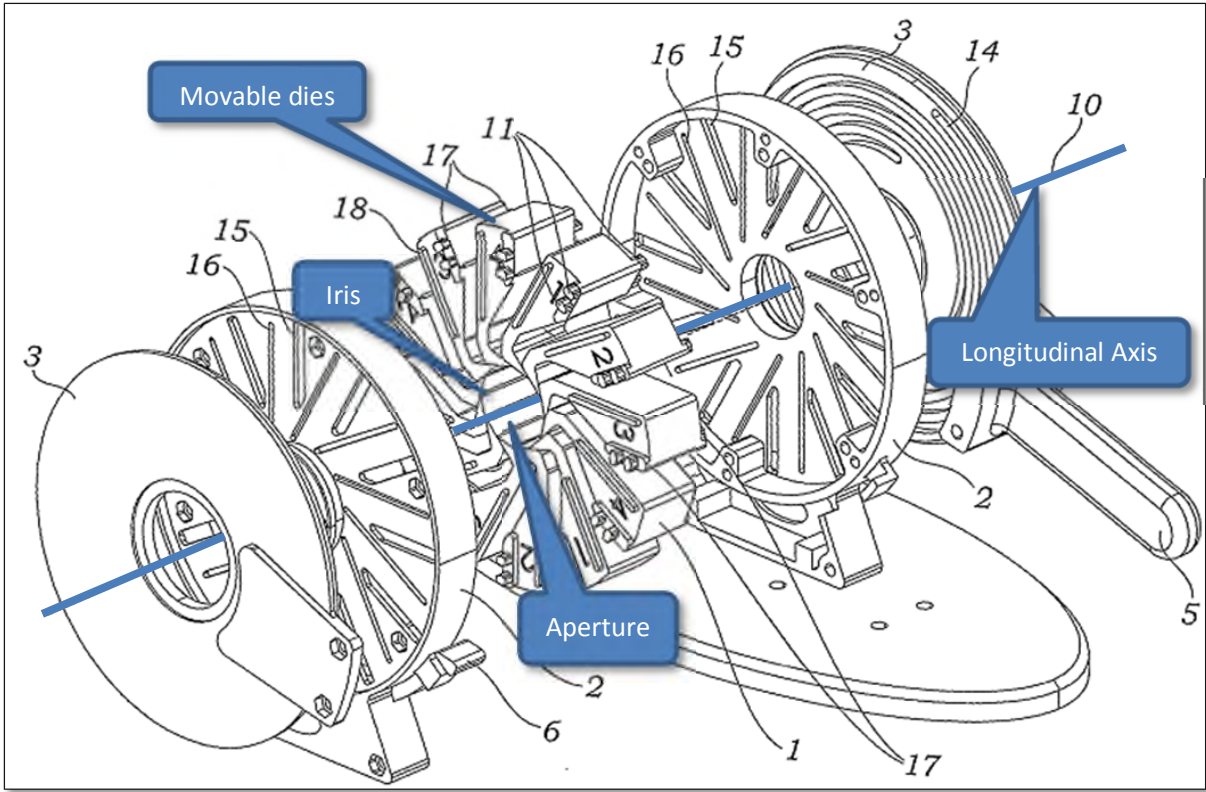
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

Claim 9	
Element	Accused Products
[9 preamble] The stent crimper of claim 1	As shown in connection with claim 1, the Crimper includes all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[9a] wherein the dies are wedge shaped.	The Crimper's dies are wedge shaped. For example: 

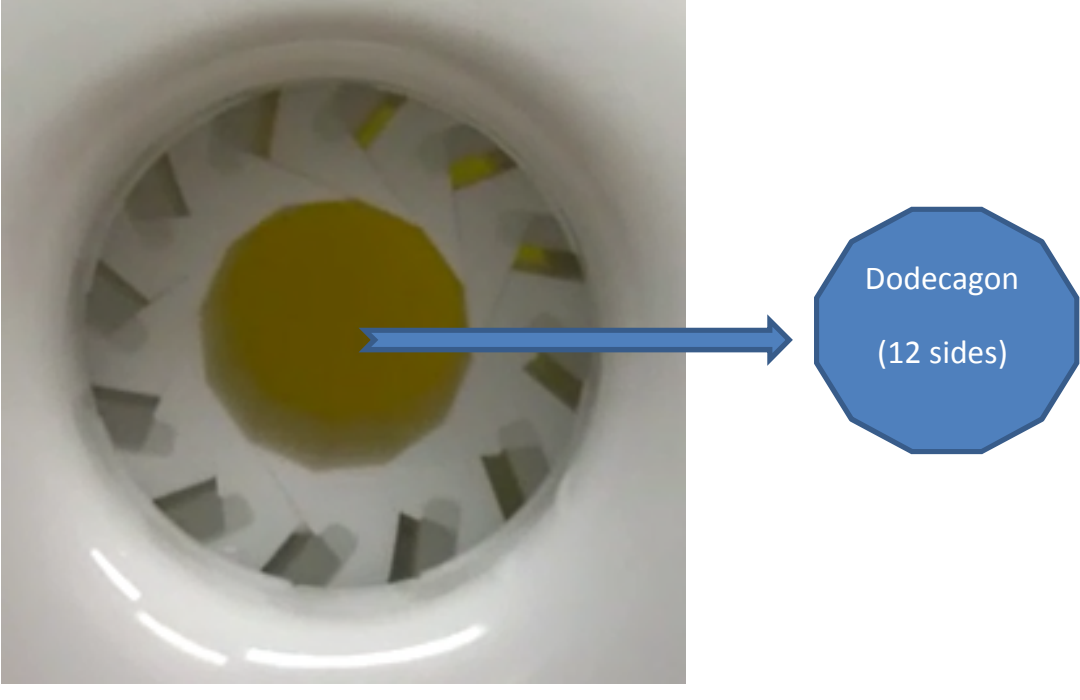
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

Claim 10	
Element	Accused Products
<p>[10 preamble] A stent crimper comprising:</p>	<p>To the extent the preamble is deemed a limitation, the Crimper is a stent crimper.</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p align="center">Edwards Crimper</p> <p>http://www.edwards.com/eu/products/transcathetervalves/pages/pulmonicmodels.aspx; WO2007/030825</p> <p>See, also http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 (“The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation.”)</p>
<p>[10a] a plurality of movable dies arranged to form an iris,</p>	<p>The Crimper’s plurality of movable dies are arranged to form an iris. For example:</p>

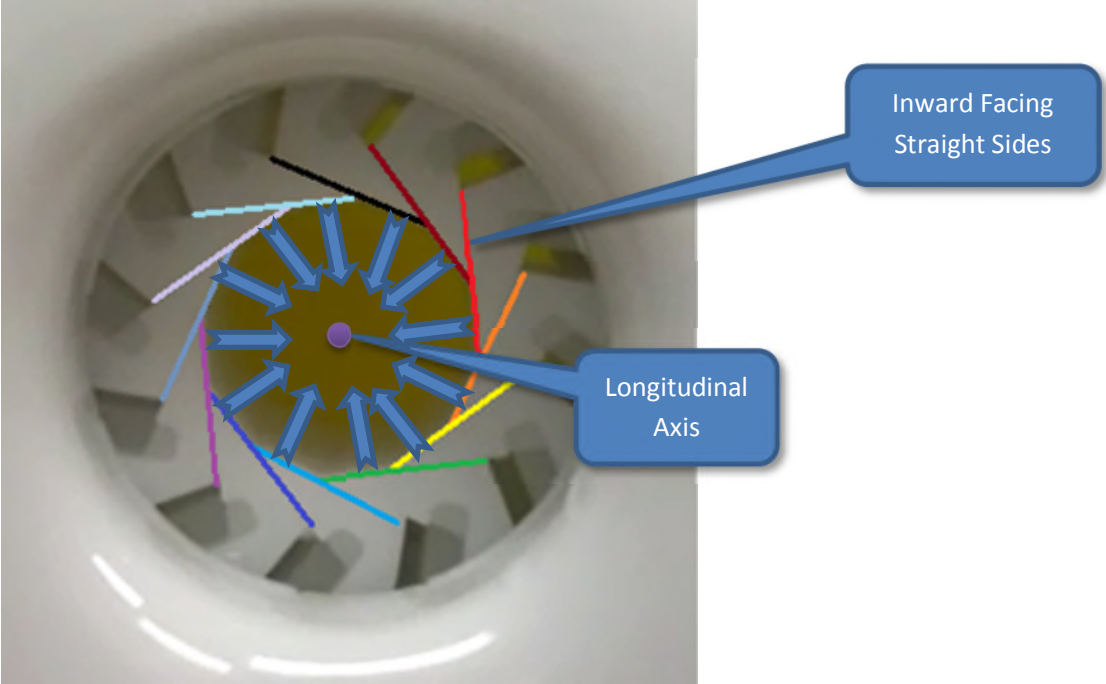

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

	
<p>[10b] the dies disposed about an aperture,</p>	<p>The iris formed by the dies defines an aperture about which the dies are disposed, as illustrated above.</p>
<p>[10c] the aperture having a longitudinal axis and a substantially regular polygonal shape,</p>	<p>The aperture has a longitudinal axis and a substantially regular polygonal shape as shown above. <i>See also:</i></p>

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

	
<p>[10d] each of the dies having an inward facing straight side which faces the longitudinal axis of the aperture,</p>	<p>Each of the Crimper's dies has an inward facing straight side which faces the longitudinal axis of the aperture. For example:</p>

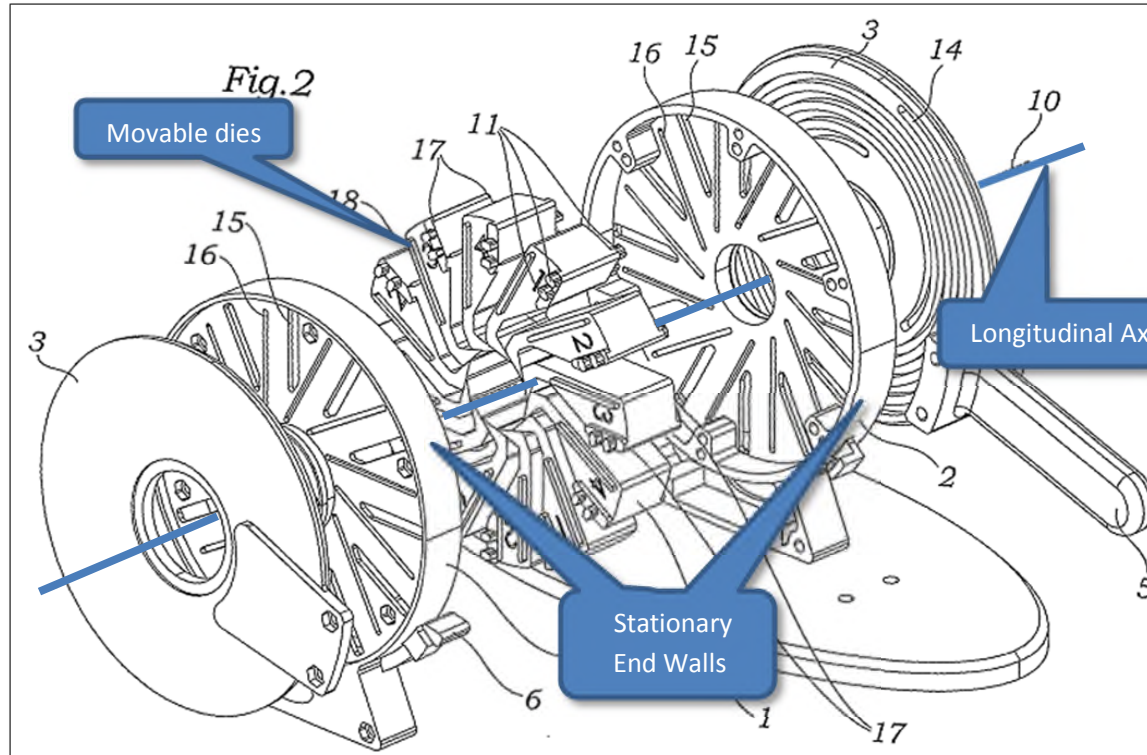
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

	
<p>[10e] both when the dies move to maximize the aperture and when the dies move to minimize the aperture,</p>	<p>The inward facing straight sides of the Crimper's dies face the longitudinal axis of the aperture both when the dies move to minimize and maximize the aperture. For example:</p> 

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

[10f]
the dies between two stationary end-walls disposed about the longitudinal axis,

The Crimper's dies are between two stationary end-walls and are disposed about the longitudinal axis. For example:



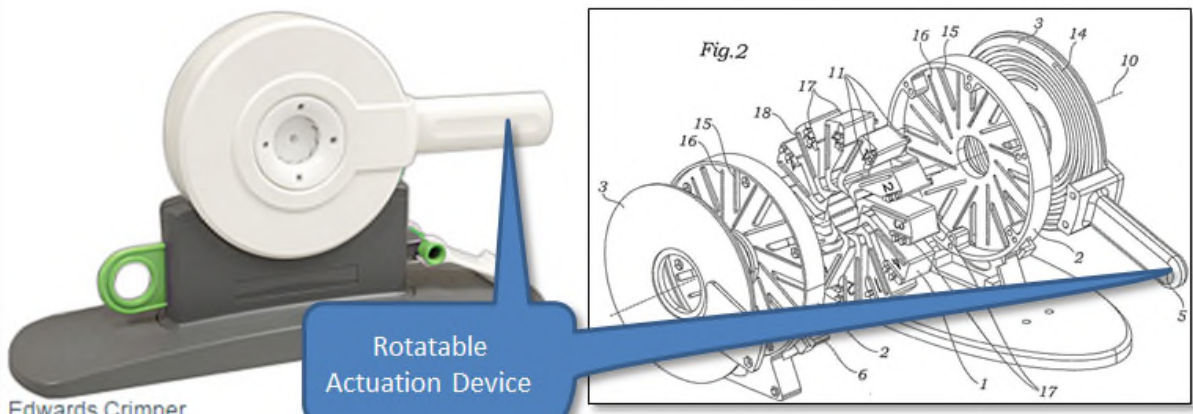
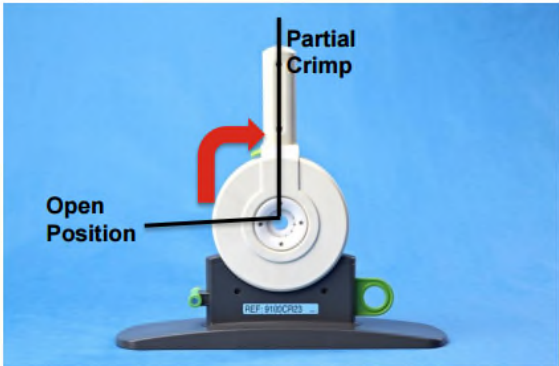
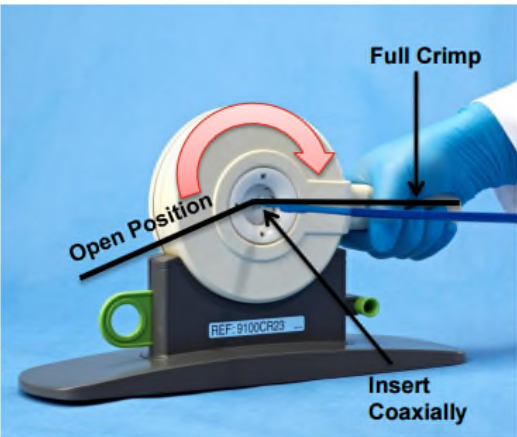
[10g]
the longitudinal axis passing through a point substantially centered on the end-walls,

As shown above, the Crimper's longitudinal axis passes through a point substantially centered on the stationary end-walls.

[10h]
a rotatable actuation device coupled to the dies,

The Crimper has a rotatable actuation device coupled to the dies. For example:

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

	 <p>Edwards Crimper</p> <p>Rotatable Actuation Device</p> <p>Fig. 2</p>
<p>[10i] rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture</p>	<p>The rotation of the Crimper's actuation device causes the inward facing straight sides of the dies to move inward and reduce the size of the aperture. For example:</p> <div style="display: flex; justify-content: space-around;"> <div data-bbox="622 753 1178 1120">  <p>Open Position</p> <p>Partial Crimp</p> </div> <div data-bbox="1205 762 1720 1200">  <p>Open Position</p> <p>Full Crimp</p> <p>Insert Coaxially</p> </div> </div> <p>EDWARDS LIFESCIENCES CONFIDENTIAL SOP4408EL28 Rev: B Issued: 5/16/2013 ECN094263</p>

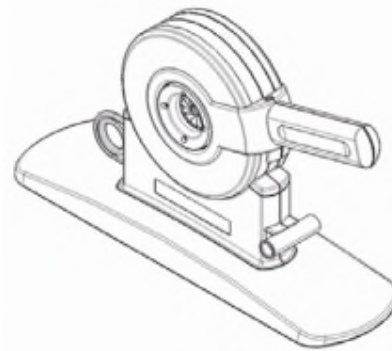
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**



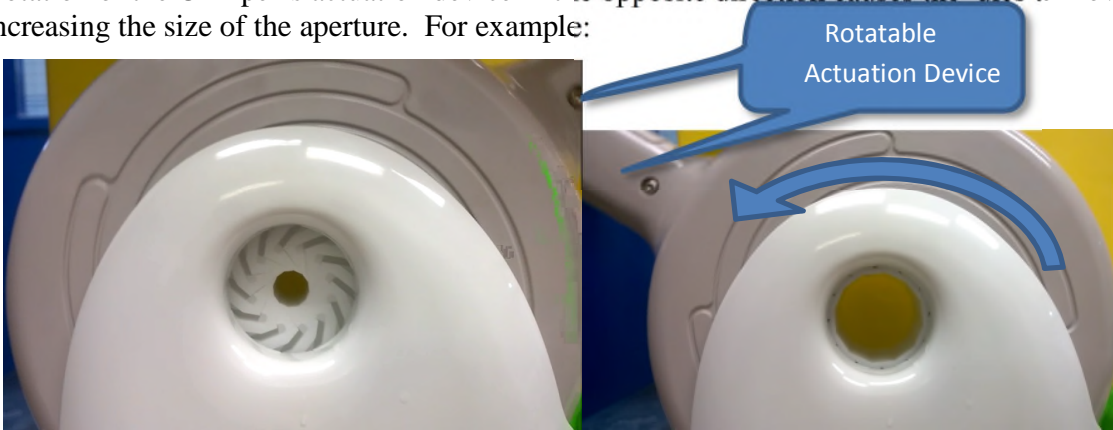
See also: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm262934.pdf>, p. 2

The Crimper, shown in Figure 4, is comprised of a housing and a compression mechanism, creating an aperture that is opened and closed by means of a handle located on the housing. The crimper includes a balloon gauge to verify diameter of an inflated balloon catheter and a crimp gauge to verify collapsed diameter of the device.

Figure 4: Crimper

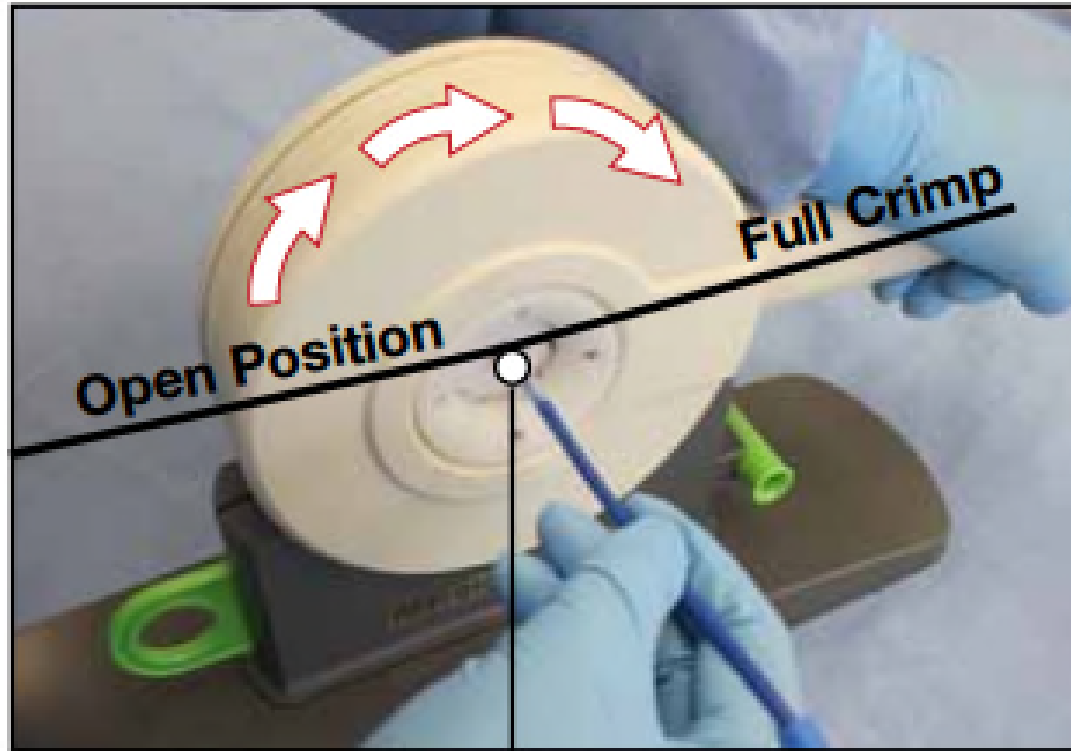


**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

<p>[10j] or outward so as to increase the size of the aperture.</p>	<p>Rotation of the Crimper's actuation device in the opposite direction causes the dies to move outward, thereby increasing the size of the aperture. For example:</p> 
---	---

Claim 11	
Element	Accused Products
<p>[11 preamble] The stent crimper of claim 10</p>	<p>As shown in connection with claim 10, the Crimper includes all elements of claim 10. <i>See</i> claim chart for claim 10, above.</p>
<p>[11a] wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.</p>	<p>For example, the “Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation” using the Edwards Commander Delivery System, among other catheter delivery systems. It is also used to prepare other Sapien products. <i>See</i> http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 http://market360online.com/sqlimages/1246/128634.pdf, p. 22:</p>

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**



Insert Coaxially

Each of the Sapien products comprises a balloon-expandable stent.

The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

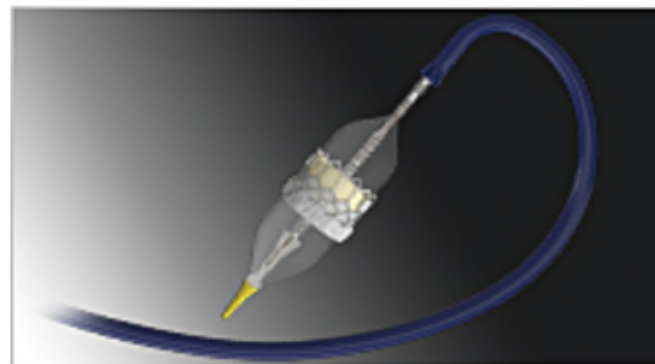
The Edwards SAPIEN XT transcatheter heart valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and a polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.

The Edwards SAPIEN transcatheter heart valve (bioprosthesis) is comprised of a balloon-expandable, radiopaque, stainless steel (316 L) frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) fabric. The bioprosthesis is treated according to the Carpentier-Edwards ThermaFix process, packaged, and terminally sterilized in glutaraldehyde

Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/Adviso...orySystemDevicesPanel/UCM262938.pdf>.


The Edwards Commander Delivery System includes a stent disposed about a medical balloon, the medical balloon disposed about a catheter.



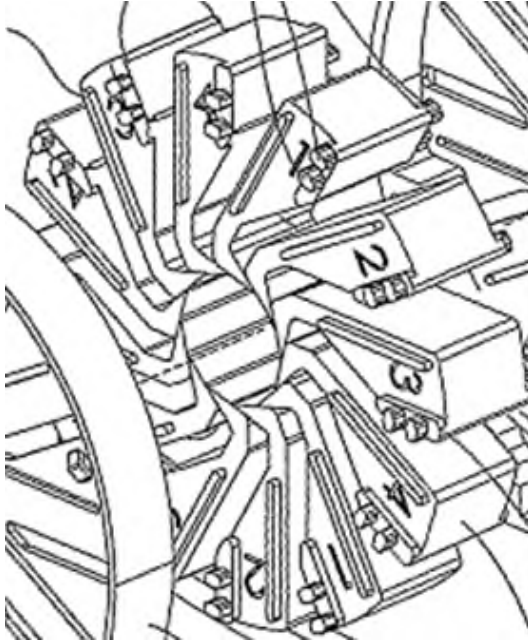

Edwards Commander System

<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>

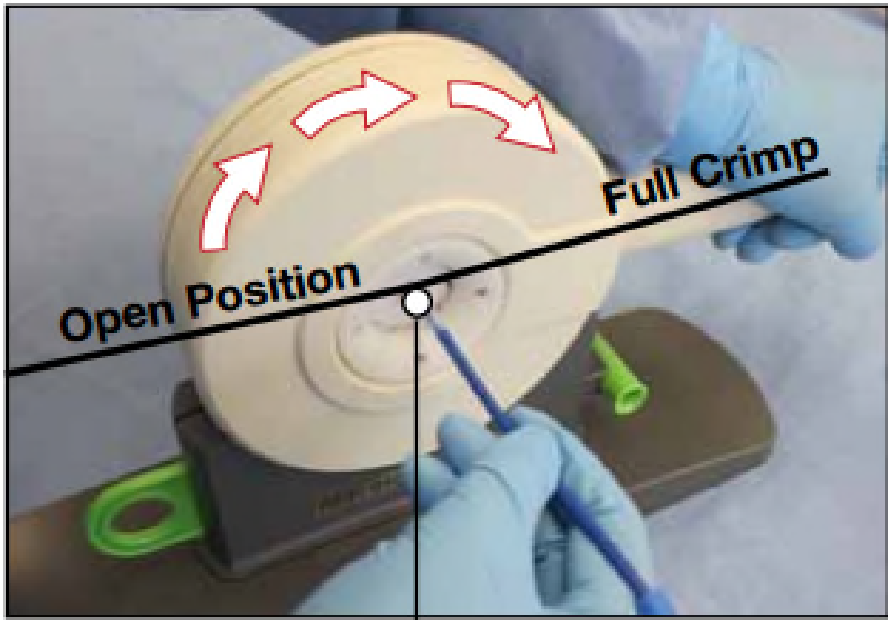
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

Claim 14	
Element	Accused Products
[14 preamble] The stent crimper of claim 10	As shown in connection with claim 10, the Crimper includes all elements of claim 10. <i>See</i> claim chart for claim 10, above.
[14a] wherein the dies are wedge shaped.	The Crimper's dies are wedge shaped. For example: 


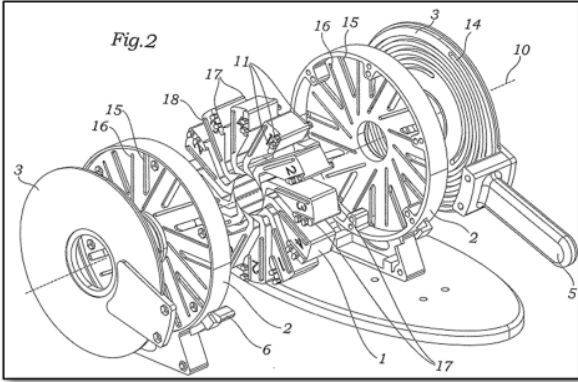
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

Claim 15	
Element	Accused Products
[15 preamble] The stent crimper of claim 10	As shown in connection with claim 10, the Crimper includes all elements of claim 10. <i>See</i> claim chart for claim 10, above.
[15a] wherein at least 8 dies are provided.	<p>The Crimper has 12 dies. For example:</p>  

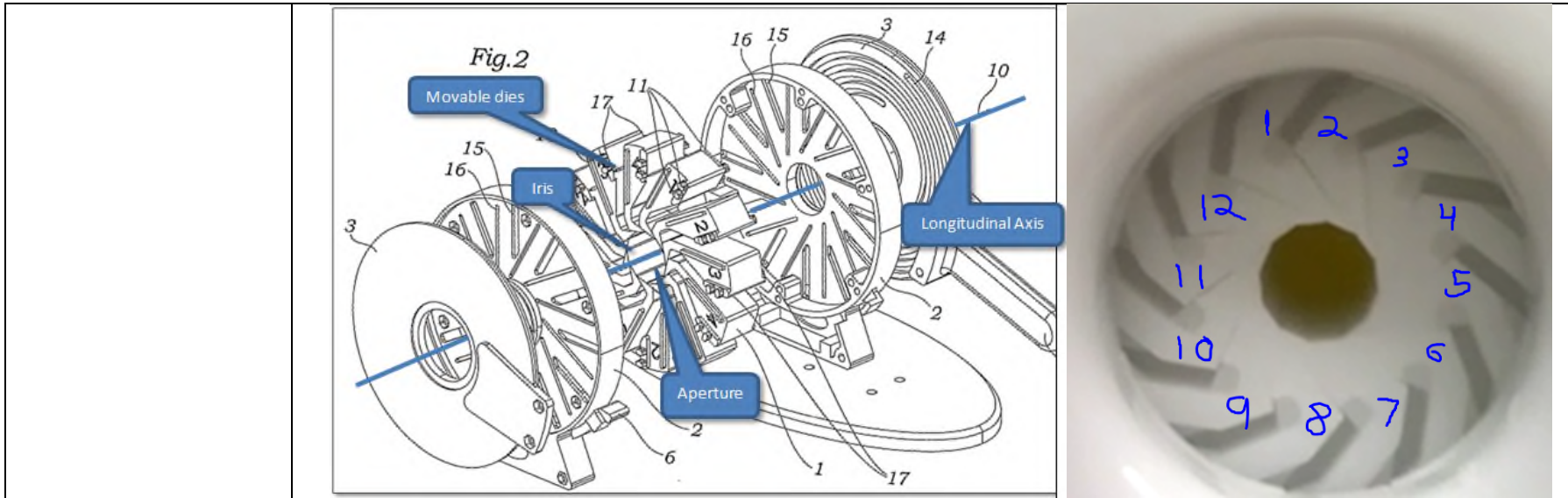
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

Claim 17	
Element	Accused Products
[17 preamble] The stent crimper of claim 10	As shown in connection with claim 10, the Crimper includes all elements of claim 10. <i>See</i> claim chart for claim 10, above.
[17a] wherein an entire stent is disposed in the aperture.	<p>During the crimping process, the entire stent is disposed in the aperture. For example: <i>See</i> http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 http://market360online.com/sqlimages/1246/128634.pdf, p. 22:</p> <div style="text-align: center;">  <p>Insert Coaxially</p> </div>

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

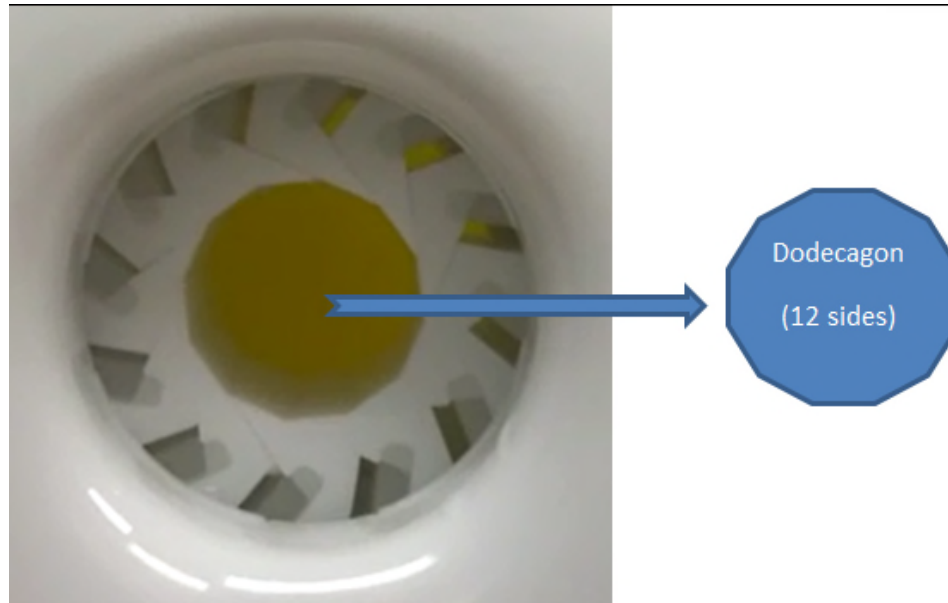
Claim 18	
Element	Accused Portion
<p>[18 preamble] A stent crimper comprising:</p>	<p>To the extent the preamble is deemed a limitation, the Crimper is a stent crimper. For example:</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p align="center">Edwards Crimper</p> <p>http://www.edwards.com/eu/products/transcathetervalves/pages/pulmonicmodels.aspx; WO2007/030825</p> <p>See, also http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 (“The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation” using the Edwards Commander Delivery System, among other catheter delivery systems.)</p>
<p>[18a] eight or more movable dies arranged to form an iris,</p>	<p>The Crimper has 12 movable dies arranged to form an iris. For example:</p>

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[18b]
the iris defining an
aperture of a
substantially regular
polygonal shape,

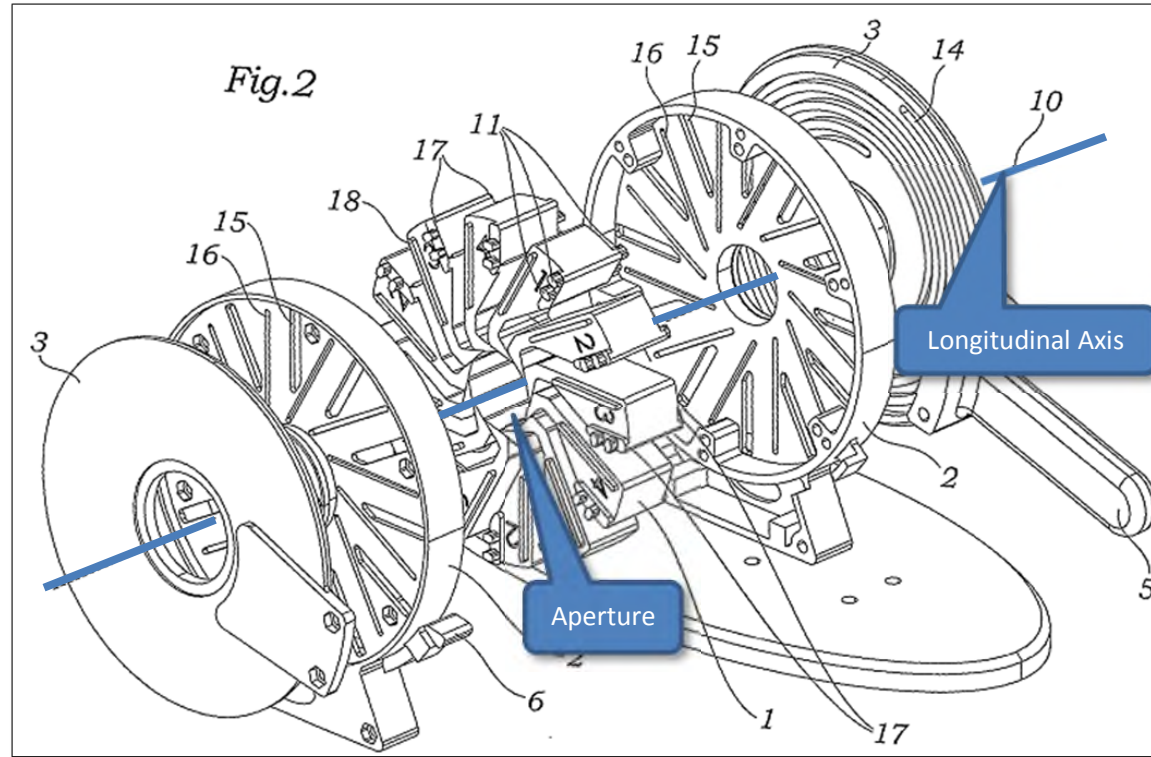
The Crimper's iris defines an aperture of a substantially regular polygonal shape - a dodecagon. For example:



**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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[18c]
the aperture having a
longitudinal axis,

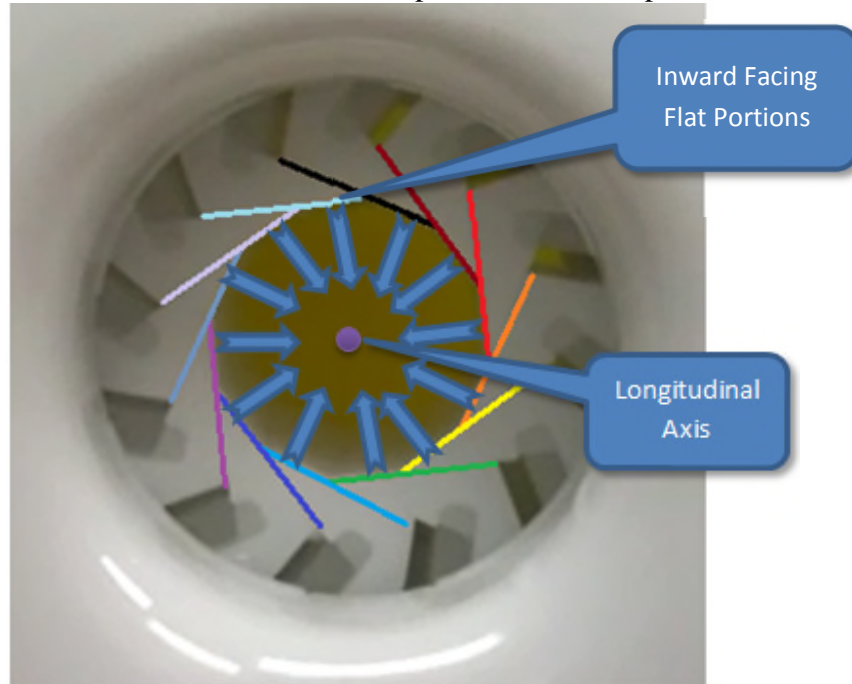
The Crimper's aperture has a longitudinal axis. For example:



**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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[18d]
each die having an inward facing flat portion which faces the longitudinal axis of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture,

Each of the Crimper's dies has an inward facing flat portion which faces the longitudinal axis of the aperture both when the dies move to maximize and minimize the aperture. For example:





[18e]
the dies between stationary end walls and operatively engaged to at least one of the stationary end-walls,

The Crimper's dies are between and operatively engaged to at least one of the stationary end-walls. For example:

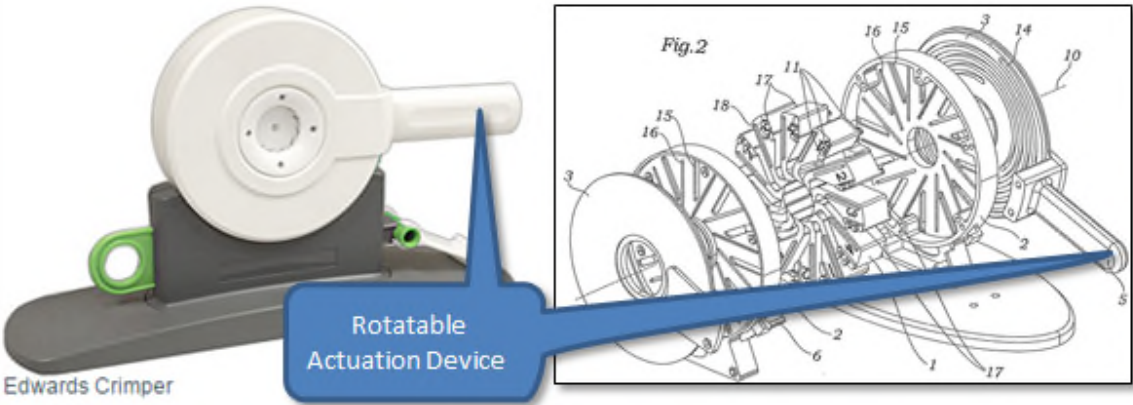
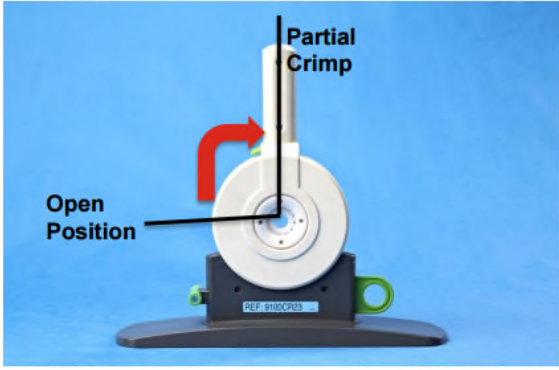
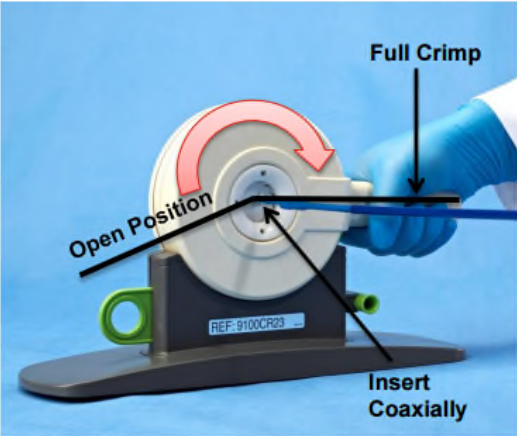
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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	<p><i>Fig. 2</i></p> <p>Movable dies</p> <p>Connection locations to engage with end wall (one for each die)</p> <p>Stationary End Walls</p> <p>Longitudinal Axis</p>
<p>[18f] the stationary end-walls disposed about the longitudinal axis,</p>	<p>As shown above, the Crimper's stationary end-walls are disposed about the longitudinal axis.</p>
<p>[18g] the iris comprising at least eight of the inward facing flat portions,</p>	<p>The Crimper's iris comprises twelve of the inward facing flat portions. For example:</p>

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<p>[18i] the aperture being reducible in size by moving the inward facing flat portions toward the longitudinal axis of the aperture,</p>	<p>The Crimper's aperture is reducible in size by moving the inward facing flat portions toward the longitudinal axis of the aperture. For example:</p> 
<p>[18j] a rotatable actuation device coupled to the dies,</p>	<p>The Crimper has a rotatable actuation device coupled to the dies. For example:</p>

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<p>[18k] rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture</p>	<p>Rotation of the Crimper's actuation device causes the inward facing straight sides of the dies to move inward, thereby reducing the size of the aperture. See http://market360online.com/sqlimages/1246/129856.pdf</p> <div style="display: flex; justify-content: space-around;"> <div data-bbox="622 746 1178 1117">  </div> <div data-bbox="1205 756 1720 1193">  </div> </div> <p>EDWARDS LIFESCIENCES CONFIDENTIAL SOP4408EL28 Rev: B Issued: 5/16/2013 ECN094263</p>

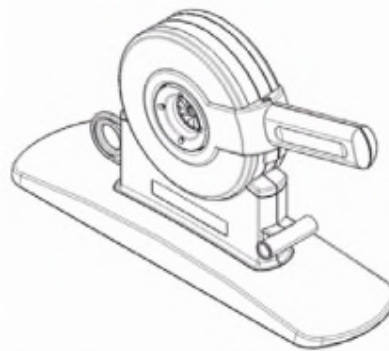
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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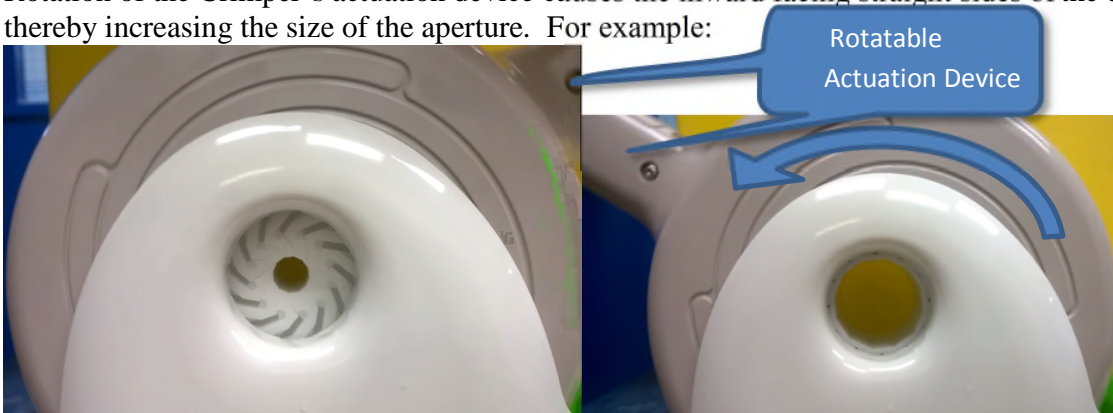
See also: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm262934.pdf>, p. 2

The Crimper, shown in Figure 4, is comprised of a housing and a compression mechanism, creating an aperture that is opened and closed by means of a handle located on the housing. The crimper includes a balloon gauge to verify diameter of an inflated balloon catheter and a crimp gauge to verify collapsed diameter of the device.

Figure 4: Crimper

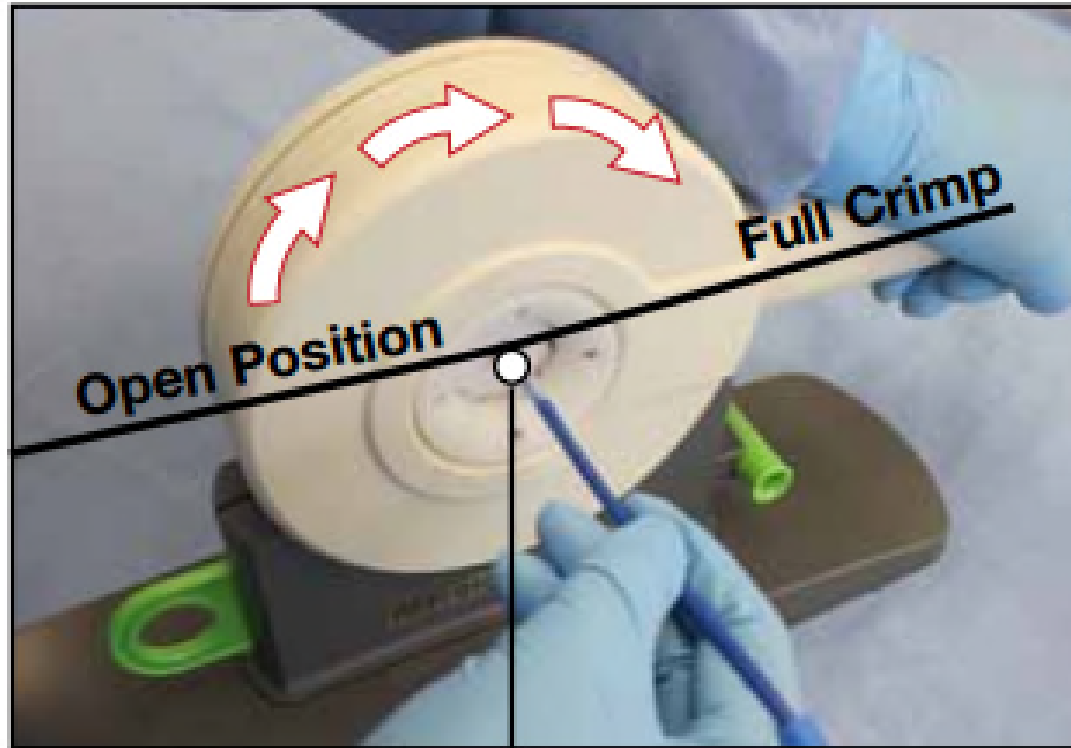


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<p>[18l] or outward so as to increase the size of the aperture.</p>	<p>Rotation of the Crimper's actuation device causes the inward facing straight sides of the dies to move outward, thereby increasing the size of the aperture. For example:</p> 
---	---

Claim 19	
Element	Accused Products
<p>[19 preamble] The stent crimper of claim 18</p>	<p>As shown in connection with claim 18, the Crimper includes all elements of claim 18. See claim chart for claim 18, above.</p>
<p>[19a] wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.</p>	<p>For example, the “Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation” using the Edwards Commander Delivery System, among other catheter delivery systems. It is also used to prepare other Sapein products.</p> <p>See http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 http://market360online.com/sqlimages/1246/128634.pdf, p. 22:</p>

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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Insert Coaxially

Each of the Sapien products comprises a balloon-expandable stent.

The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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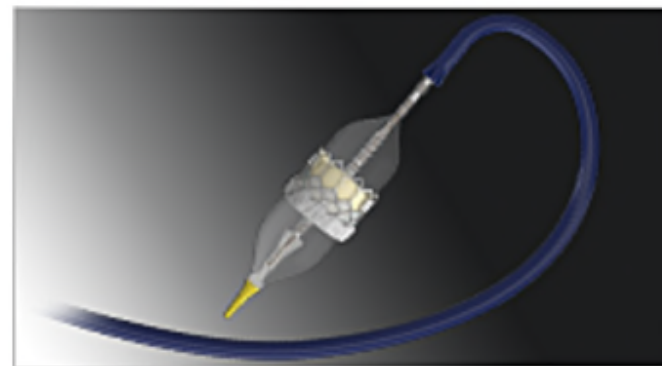
The Edwards SAPIEN XT transcatheter heart valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and a polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.

The Edwards SAPIEN transcatheter heart valve (bioprosthesis) is comprised of a balloon-expandable, radiopaque, stainless steel (316 L) frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) fabric. The bioprosthesis is treated according to the Carpentier-Edwards ThermaFix process, packaged, and terminally sterilized in glutaraldehyde

Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/Adviso...orySystemDevicesPanel/UCM262938.pdf>.


The Edwards Commander Delivery System includes a stent disposed about a medical balloon, the medical balloon disposed about a catheter.




Edwards Commander System

<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>

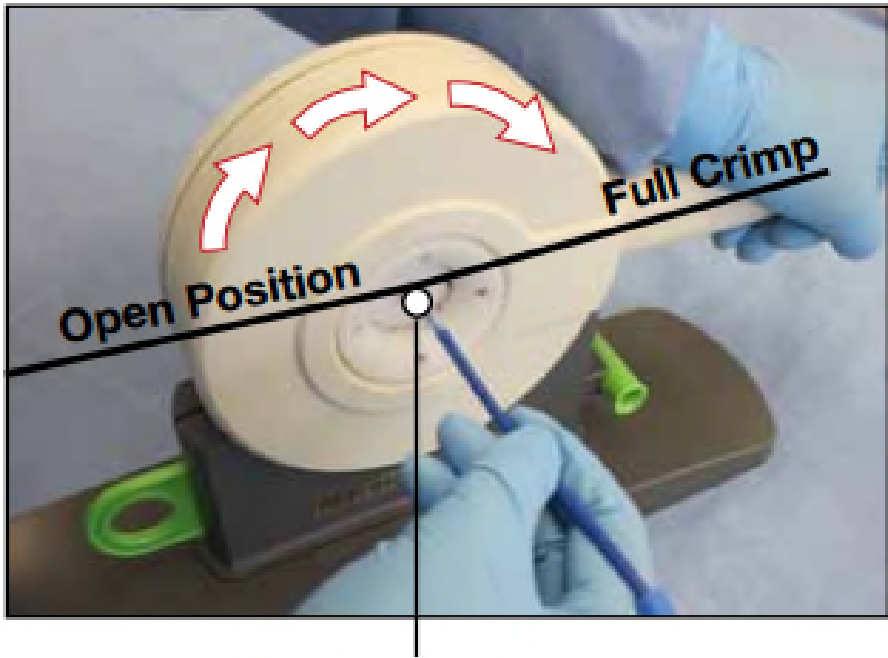
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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Claim 23	
Element	Accused Products
[23 preamble] The stent crimper of claim 18	As shown in connection with claim 18, the Crimper includes all elements of claim 18. <i>See</i> claim chart for claim 18, above.
[23a] wherein the dies are wedge shaped.	The Crimper's dies are wedge shaped. For example: 


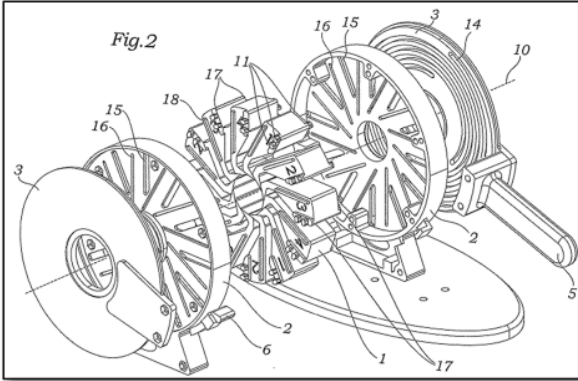
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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Claim 25	
Element	Accused Products
[25 preamble] The stent crimper of claim 18	As shown in connection with claim 18, the Crimper includes all elements of claim 18. <i>See</i> claim chart for claim 18, above.
[25a] wherein the dies are moved cooperatively inward during the moving step.	The Crimper's dies move cooperatively inward during the moving step. For example: 

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Claim 26	
Element	Accused Products
[26 preamble] The stent crimper of claim 18	As shown in connection with claim 18, the Crimper includes all elements of claim 18. <i>See</i> claim chart for claim 18, above.
[26a] wherein an entire stent is disposed in the aperture.	<p>During the crimping process, the entire stent is disposed in the aperture. <i>See</i> http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 http://market360online.com/sqlimages/1246/128634.pdf, p. 22:</p> <div style="text-align: center;">  <p>Insert Coaxially</p> </div>

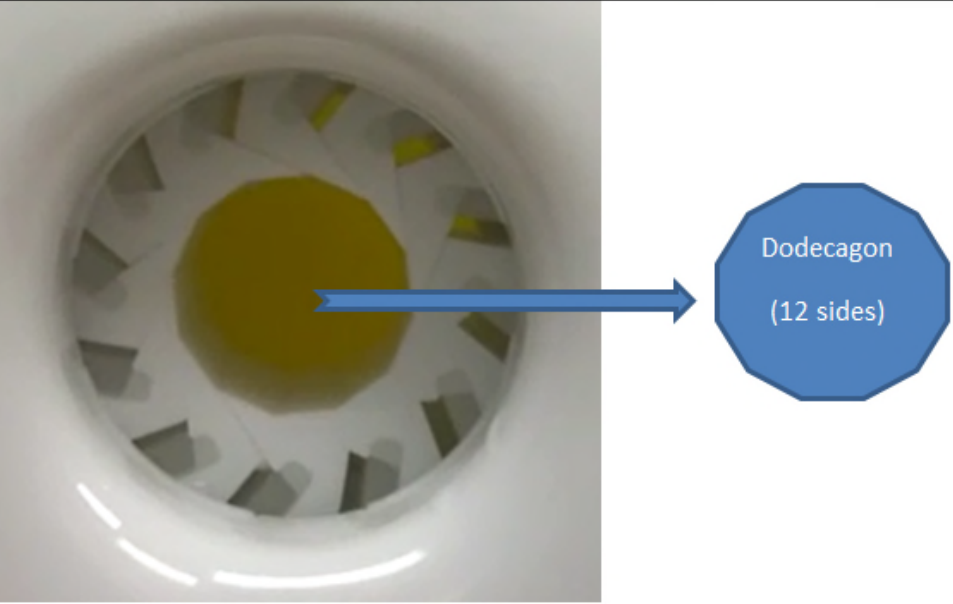
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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Claim 27	
Element	Accused Portion
<p>[27 preamble] A stent crimper comprising:</p>	<p>To the extent the preamble is deemed a limitation, the Crimper is a stent crimper.</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p align="center"><small>Edwards Crimper</small></p> <p>http://www.edwards.com/eu/products/transcathetervalves/pages/pulmonicmodels.aspx; WO2007/030825</p> <p>See, also http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 (“The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation” using the Edwards Commander Delivery System, among other catheter delivery systems.)</p>
<p>[27a] an aperture with a plurality of movable blades disposed thereabout,</p>	<p>The Crimper’s has an aperture with a plurality of movable blades disposed thereabout. For example:</p>



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<p>[27b] the aperture having a longitudinal axis and being substantially polygonal,</p>	<p>As shown above, the Crimper's aperture has a longitudinal axis. The aperture is polygonal (a dodecagon). For example:</p>

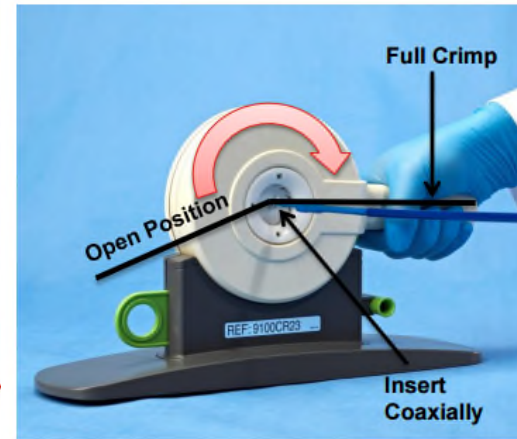
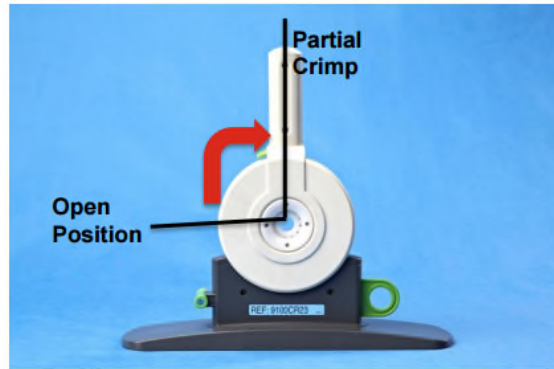
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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<p>[27c] the blades between stationary end-walls substantially centered about the longitudinal axis,</p>	<p>As shown above, the Crimper's blades are between stationary end-walls and substantially centered on the longitudinal axis.</p>
<p>[27d] the blades coupled to one another so as to be movable inward or outward simultaneously,</p>	<p>The Crimper's blades are coupled to one another so as to be movable inward or outward simultaneously.</p>

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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<p>[27e] movement of the blades outward increasing the size of the aperture,</p>	<p>Rotation of the Crimper's actuation device in a counter-counterclockwise direction causes the dies to move outward, thereby increasing the size of the aperture. For example:</p> 
<p>[27f] movement of the blades inward decreasing the size of the aperture,</p>	<p>Rotation of the Crimper's actuation device clockwise causes the dies to move inward, thereby reducing the size of the aperture. See http://market360online.com/sqlimages/1246/129856.pdf</p>

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U.S. PATENT NO. 6,915,560 By Edwards**



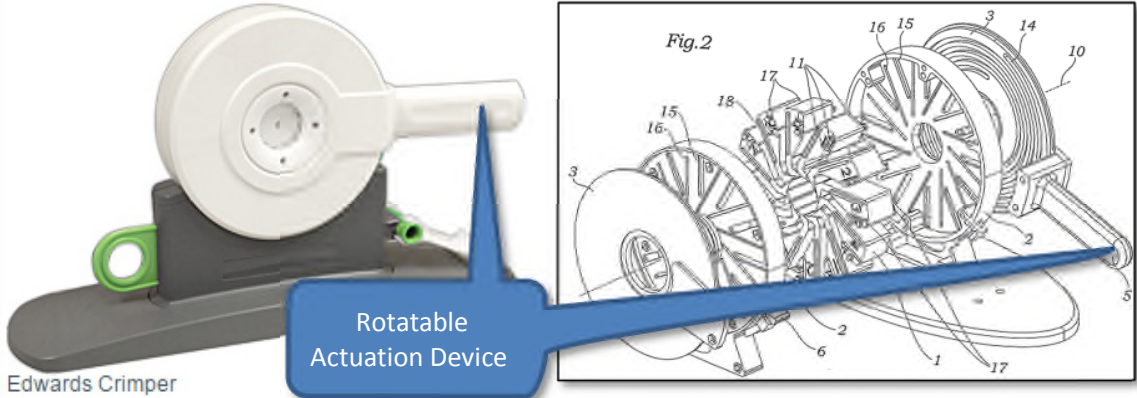
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SOP4408EL28 Rev: B Issued: 5/16/2013 ECN094263



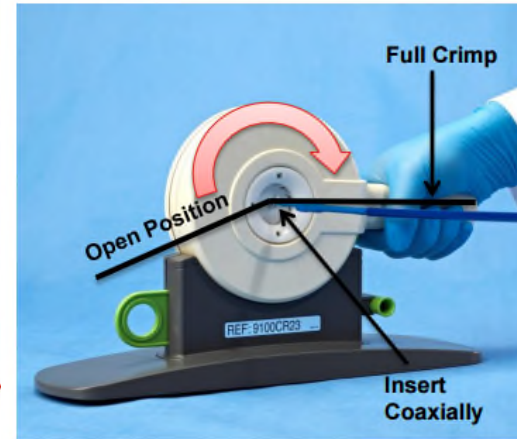
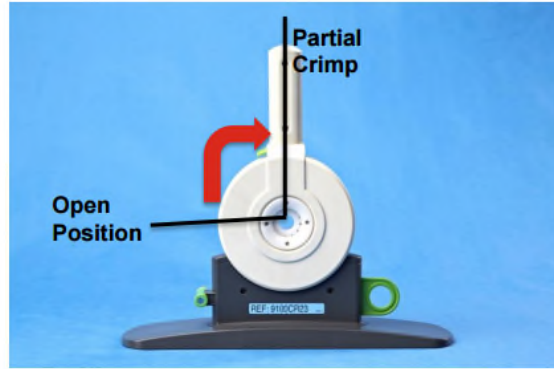
[27g]
the aperture remaining substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture.

As shown above, the Crimper's aperture remains a regular polygon when it is sized to receive a stent therein and when the blades minimize the aperture.

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Claim 28	
Element	Accused Products
[28 preamble] The stent crimper of claim 27	As shown in connection with claim 27, the Crimper includes all elements of claim 27. <i>See</i> claim chart for claim 27, above.
[28a] further comprising a rotatable actuation device coupled to the blades,	<p>The Crimper has a rotatable actuation device coupled to the blades. For example:</p>  <p style="text-align: center;">Edwards Crimper</p>
[28b] rotation of the actuation device causing the blades to move inward or outward.	<p>For example, rotation of the Crimper's actuation device causes the dies to move inward, thereby reducing the size of the aperture, and outward, thereby increasing the size of the aperture.</p> <p><i>See</i> http://market360online.com/sqlimages/1246/129856.pdf</p>

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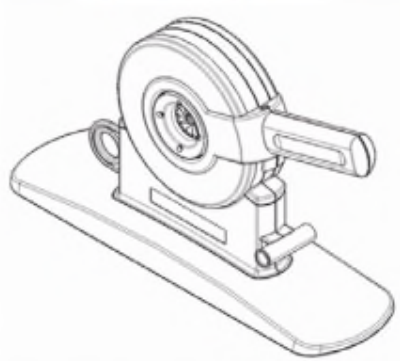


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SOP4408EL28 Rev: B Issued: 5/16/2013 ECN094263



See also: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm262934.pdf>, p. 2

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	<p>The Crimper, shown in Figure 4, is comprised of a housing and a compression mechanism, creating an aperture that is opened and closed by means of a handle located on the housing. The crimper includes a balloon gauge to verify diameter of an inflated balloon catheter and a crimp gauge to verify collapsed diameter of the device.</p> <p align="center">Figure 4: Crimper</p> 
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Claim 31	
Element	Accused Products
[31 preamble] The stent crimper of claim 28	As shown in connection with claim 28, the Crimper includes all elements of claim 28. See claim chart for claim 28, above.
[31a] wherein the dies are wedge shaped.	The Crimper's dies are wedge shaped. For example:

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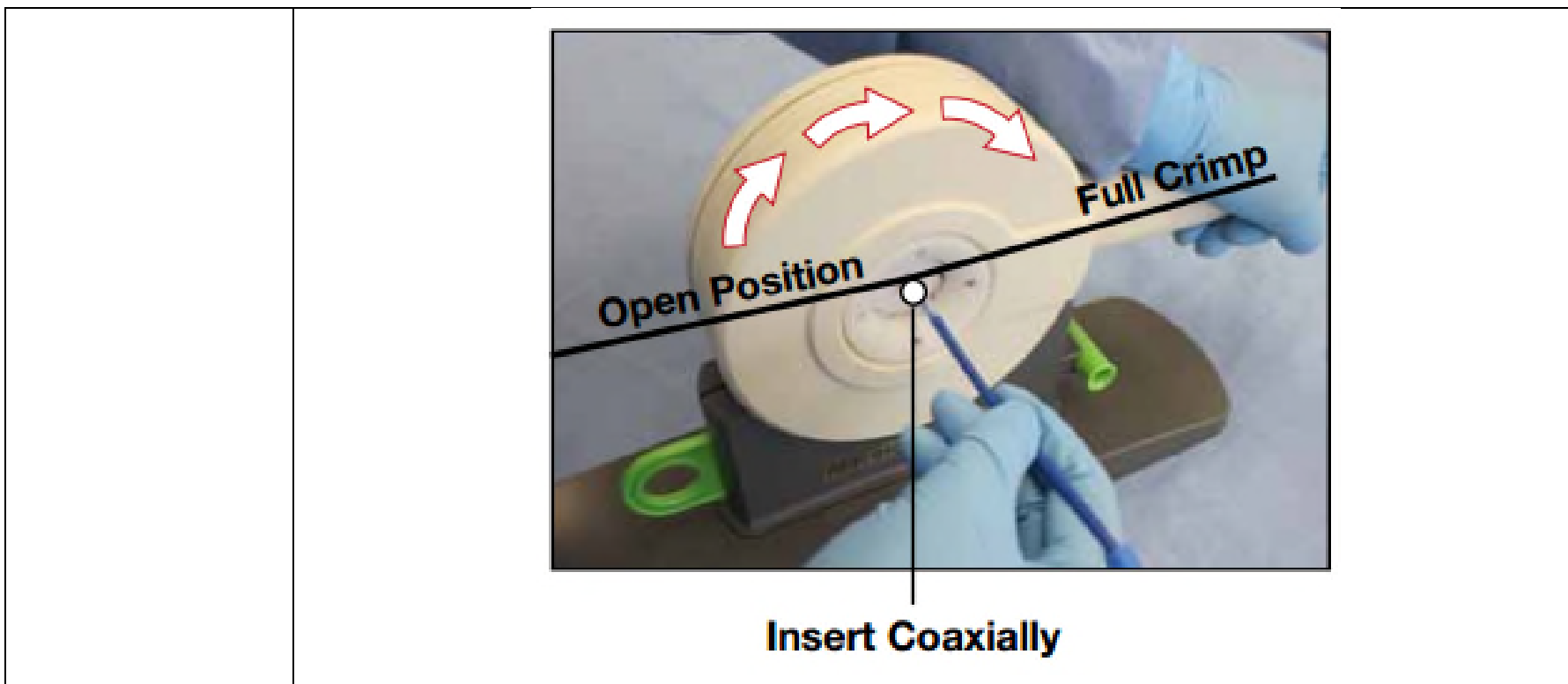
Claim 33	
Element	Accused Products
[33 preamble] The stent crimper of claim 28	As shown in connection with claim 28, the Crimper includes all elements of claim 28. <i>See</i> claim chart for claim 28, above.

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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<p>[33a] wherein the dies are moved cooperatively inward during the moving step.</p>	<p>The Crimper's dies move cooperatively inward during the moving step. For example:</p> 
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Claim 34	
Element	Accused Products
<p>[34 preamble] The stent crimper of claim 28</p>	<p>As shown in connection with claim 28, the Crimper includes all elements of claim 28. <i>See</i> claim chart for claim 28, above.</p>
<p>[34a] wherein an entire stent is disposed in the aperture.</p>	<p>During the crimping process, the entire stent is disposed in the aperture. <i>See</i> http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 http://market360online.com/sqlimages/1246/128634.pdf, p. 22:</p>

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Claim 35	
Element	Accused Portion
[35 preamble] The stent crimper of claim 27	As shown in connection with claim 27, the Crimper includes all elements of claim 27. <i>See</i> claim chart for claim 27, above.
[35a] wherein a stent is disposed about a	For example, the “Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation” using the Edwards Commander Delivery System, among other catheter delivery systems. It is also

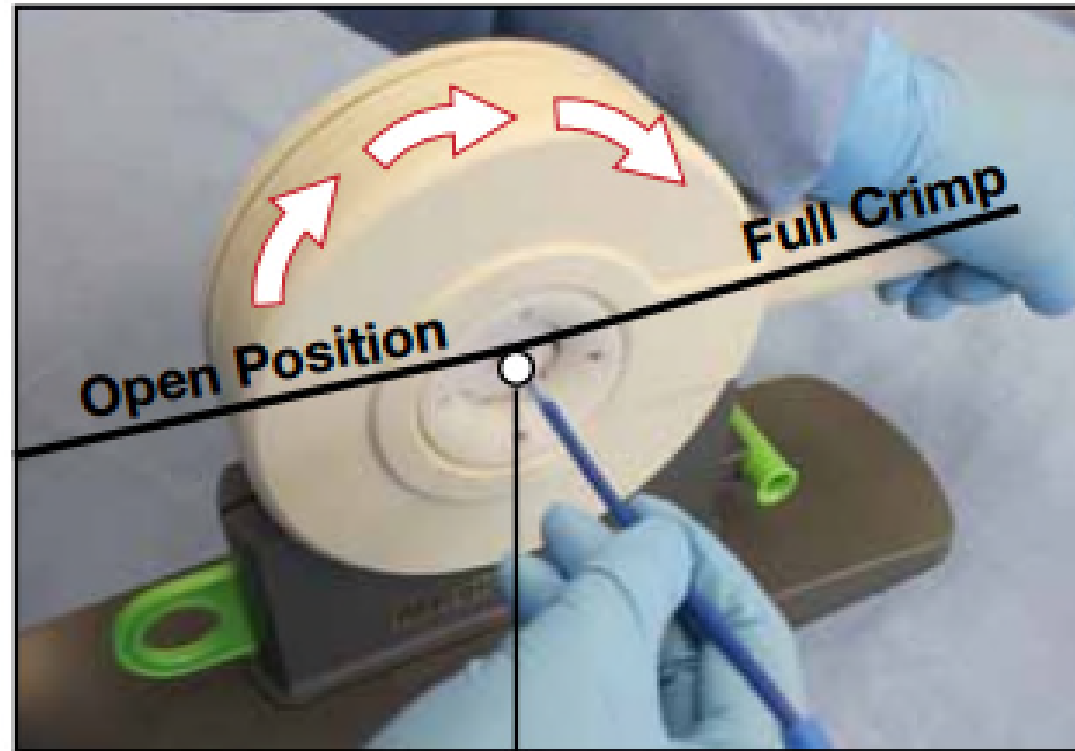
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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medical balloon, the
medical balloon
disposed about a
catheter.

used to prepare other Sapien products.

See <http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3>

<http://market360online.com/sqlimages/1246/128634.pdf>, p. 22:



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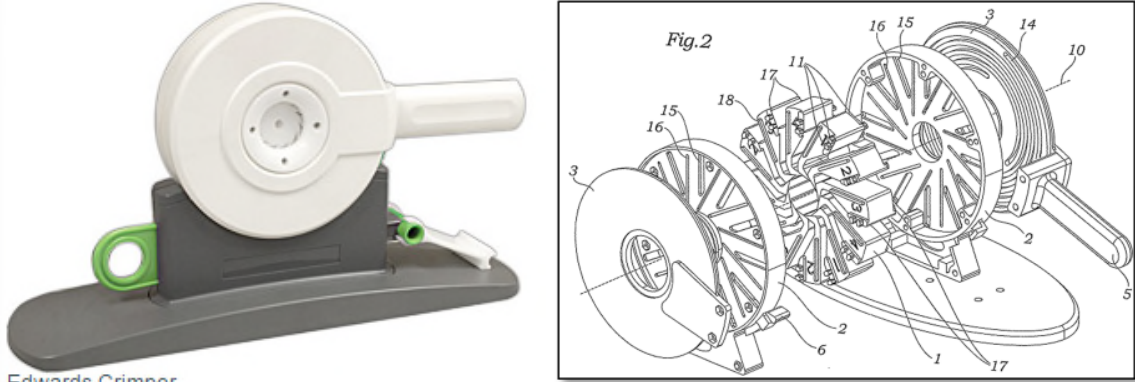
Each of the Sapien products comprises a balloon-expandable stent.

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	<p>The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p>The Edwards SAPIEN XT transcatheter heart valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and a polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.</p> <p>The Edwards SAPIEN transcatheter heart valve (bioprosthesis) is comprised of a balloon-expandable, radiopaque, stainless steel (316 L) frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) fabric. The bioprosthesis is treated according to the Carpentier-Edwards ThermaFix process, packaged, and terminally sterilized in glutaraldehyde</p> <p>Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf.</p> <p>The Edwards Commander Delivery System includes a stent disposed about a medical balloon, the medical balloon disposed about a catheter.</p>
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	 <p align="center">Edwards Commander System</p> <p>http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx</p>
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Claim 37	
Element	Accused Products
<p>[37 preamble] A stent crimper comprising:</p>	<p>To the extent the preamble is deemed a limitation, the Crimper is a stent crimper. For example:</p>  <p>Edwards Crimper</p>

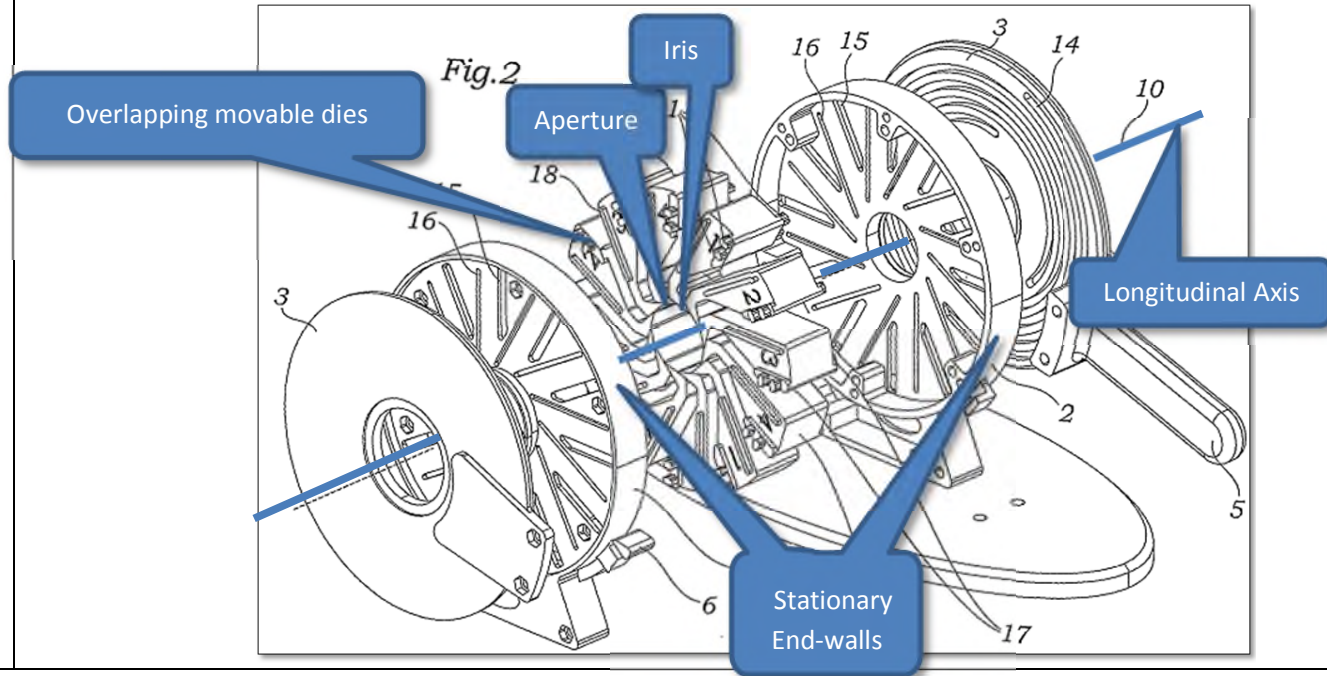
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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<http://www.edwards.com/eu/products/transcatheter valves/pages/pulmonicmodels.aspx>; WO2007/030825


See, also <http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3> (“The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation” using the Edwards Commander Delivery System, among other catheter delivery systems.)

[37a]
a plurality of overlapping movable dies arranged to form an iris,

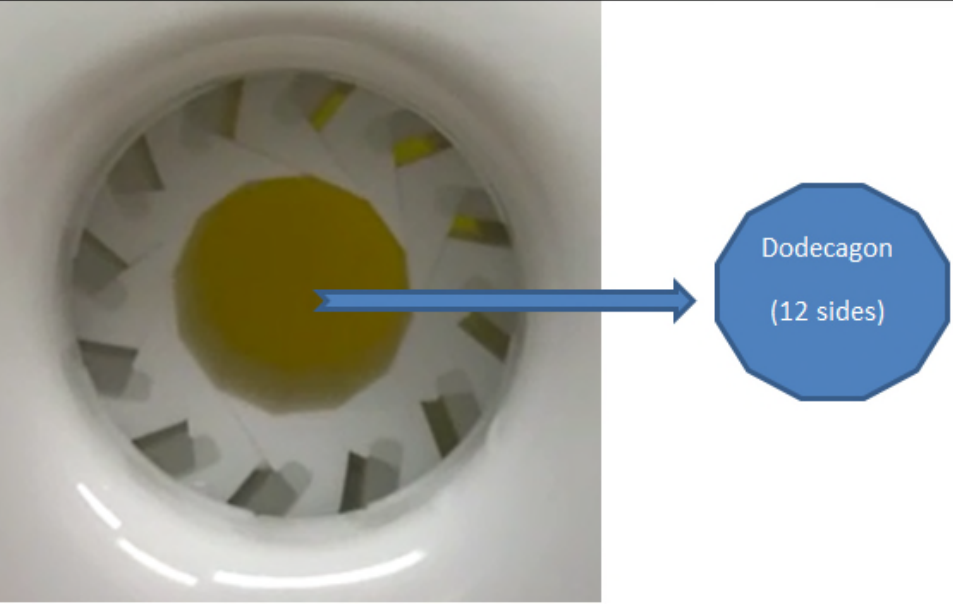
The Crimper has multiple overlapping movable dies arranged to form an iris. For example:



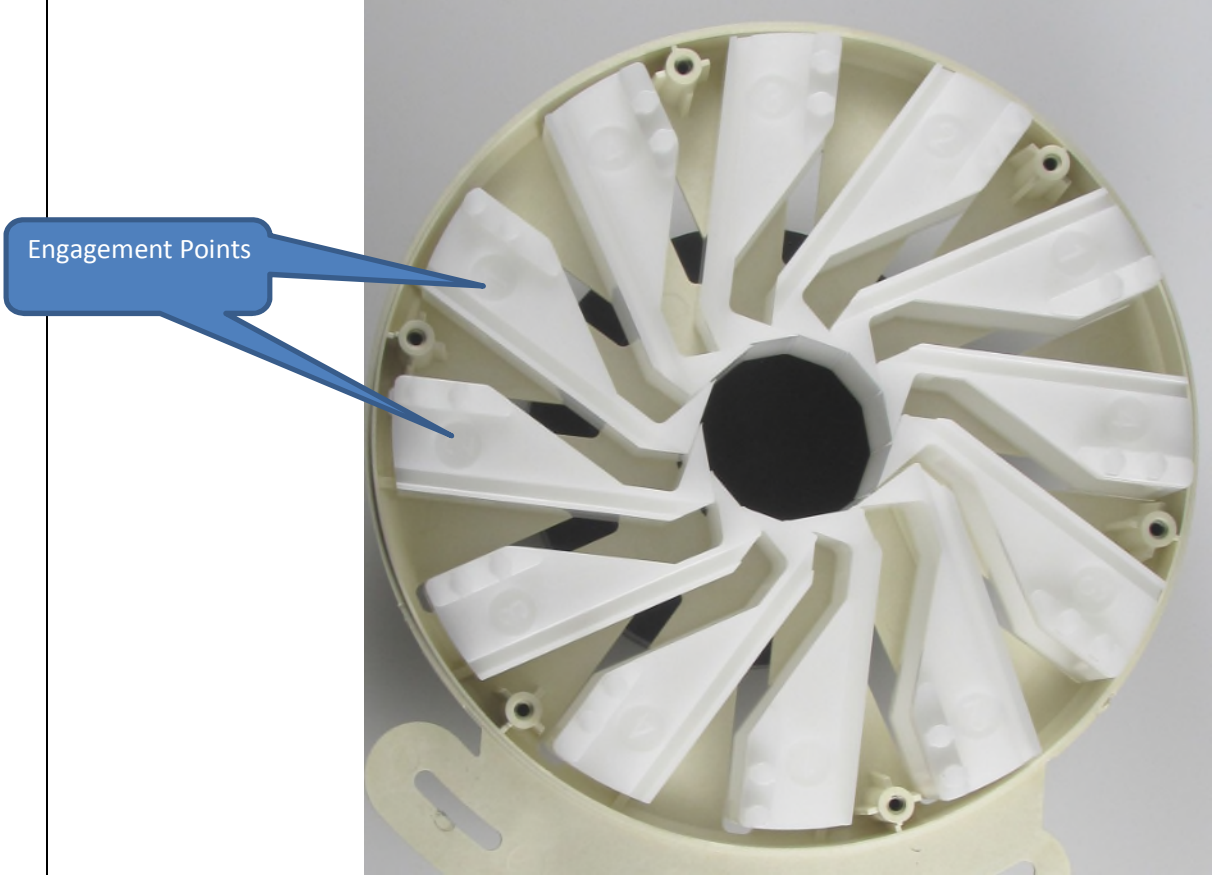
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
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<p>[37b] the dies disposed about an aperture, the aperture having a longitudinal axis,</p>	<p>As shown above, the Crimper's dies are disposed about an aperture having a longitudinal axis. For example:</p>

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<p>[37c] the dies between stationary end-walls disposed about the longitudinal axis,</p>	<p>As shown above, the Crimper's dies are between stationary end-walls disposed about the longitudinal axis.</p>
<p>[37d] he dies operatively engaged to at least one of the stationary end-walls;</p>	<p>The Crimper's dies are operatively engaged to at least one of the stationary end walls. For example:</p>

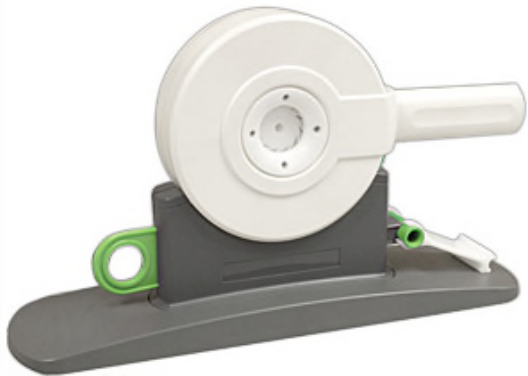
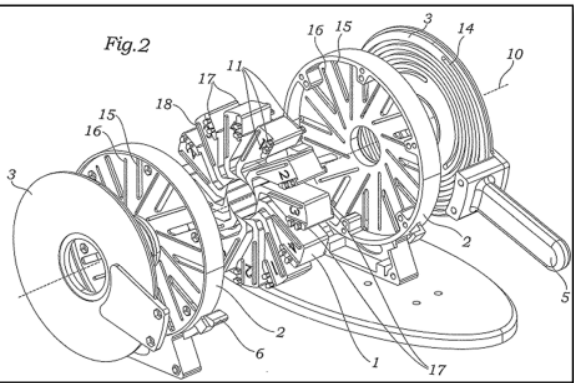
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

	
<p>[37e] each die having a first straight side and a second straight side, the first straight side and the second straight side converging to form a tip;</p>	<p>Each of the Crimper's dies has a first straight side (shown in green) and a second straight side (shown in red), which converge to form a tip. For example:</p>

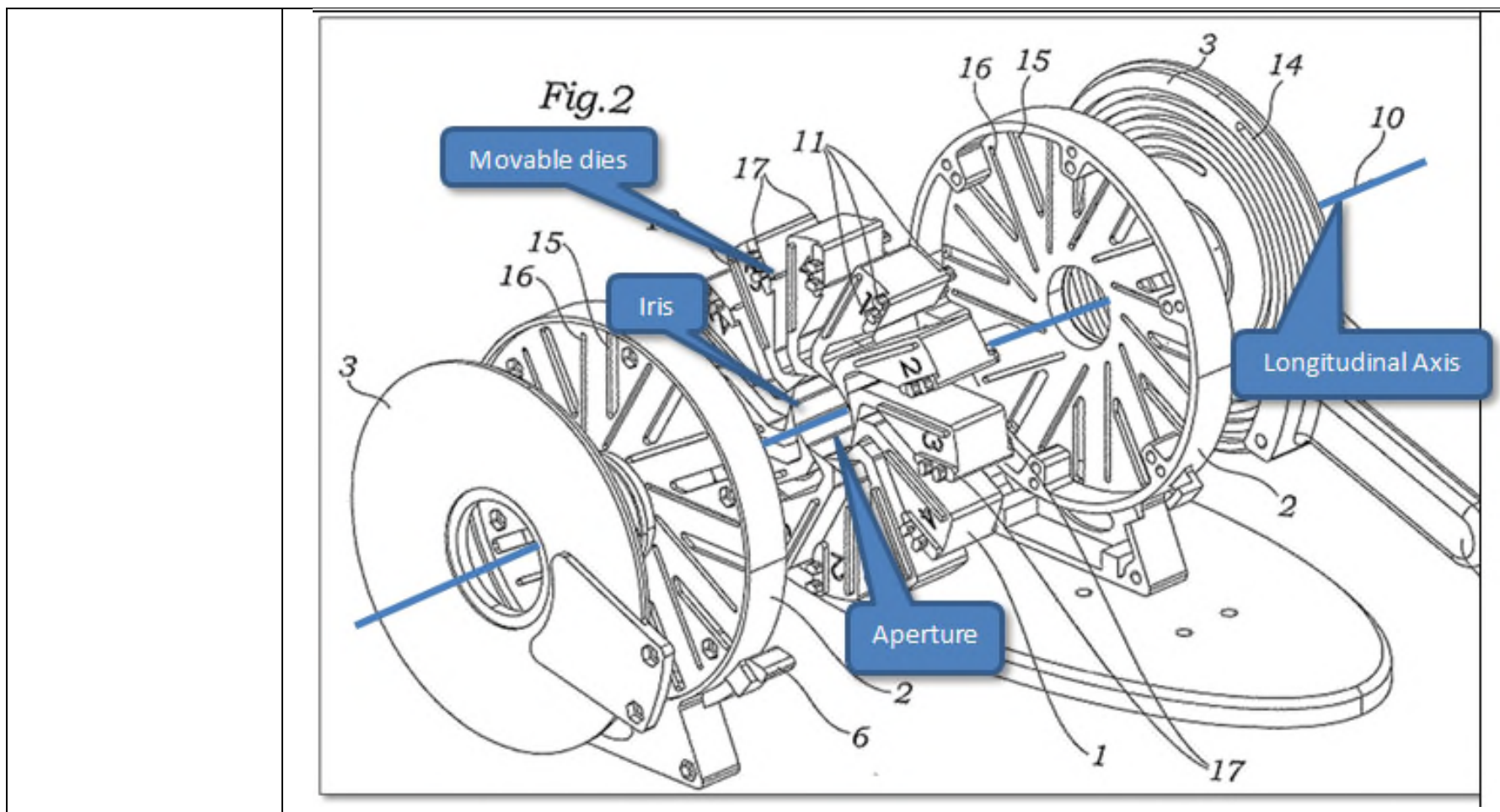
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

<p>[37f] wherein a portion of the first straight side of each die faces the aperture,</p>	<p>As shown above, a portion of the first straight side of each die (green) faces the aperture.</p>
<p>[37g] each first straight side parallel to the second side of an adjacent die.</p>	<p>As shown above, each first straight side (red) is parallel to the second side of an adjacent die (green).</p>

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

Claim 40	
Element	Accused Products
<p>[40 preamble] A stent crimper comprising:</p>	<p>To the extent the preamble is deemed a limitation, the Crimper is a stent crimper. For example:</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p align="center"><small>Edwards Crimper</small></p> <p>http://www.edwards.com/eu/products/transcathetervalves/pages/pulmonicmodels.aspx; WO2007/030825</p> <p>See, also http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 (“The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation” using the Edwards Commander Delivery System, among other catheter delivery systems.)</p>
<p>[40a] a plurality of movable dies arranged to form an iris disposed about an aperture</p>	<p>The Crimper has a plurality of movable dies arranged to form an iris disposed about an aperture. For example:</p>

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**



[40b]
the aperture having a longitudinal axis,

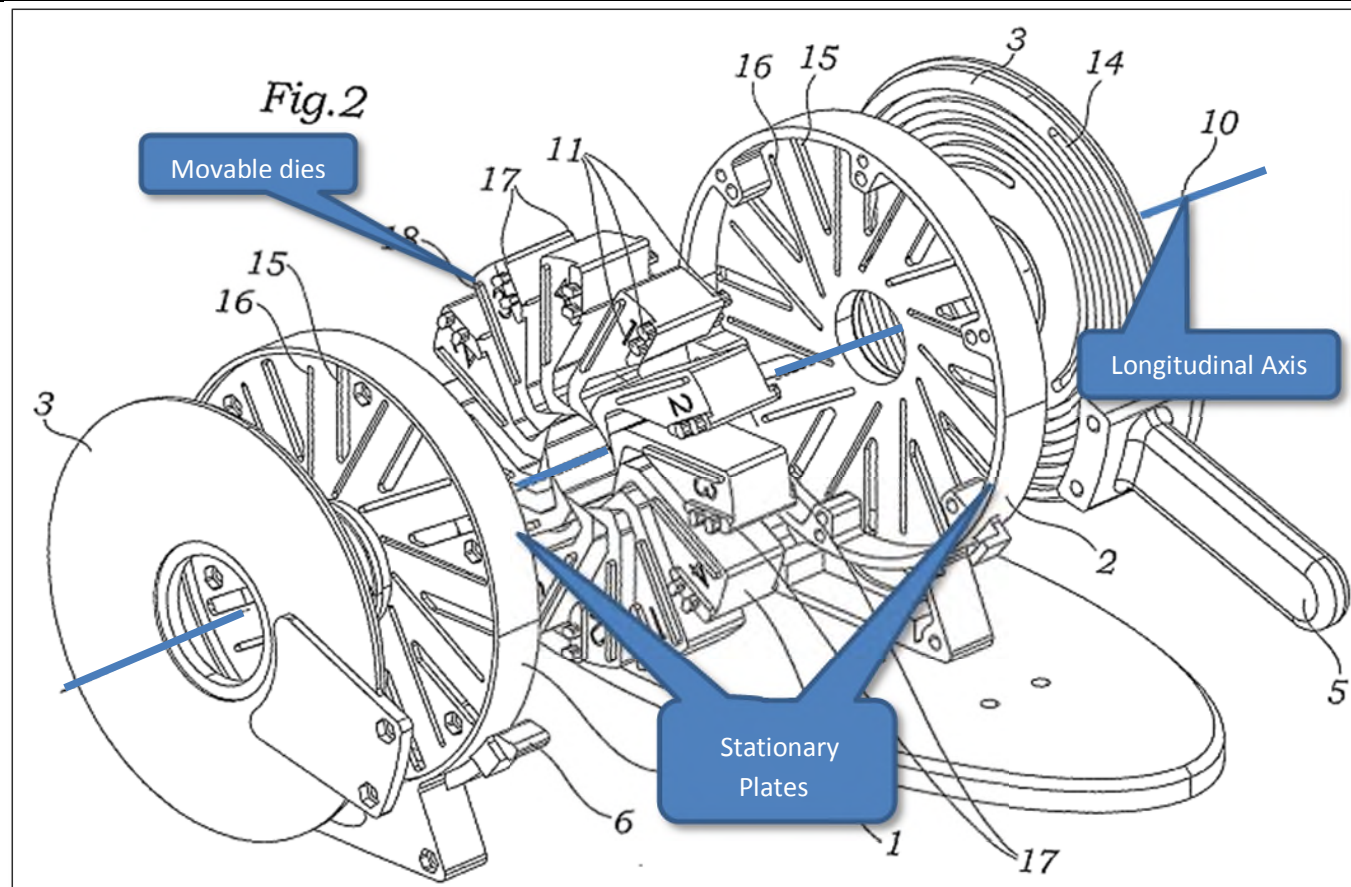
As illustrated above, the Crimper's aperture has a longitudinal axis.

[40c]
the plurality of movable dies between

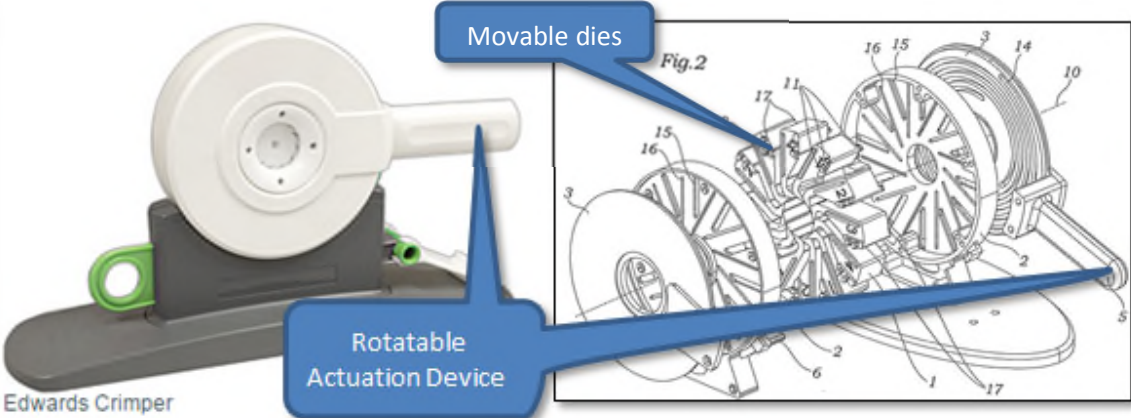
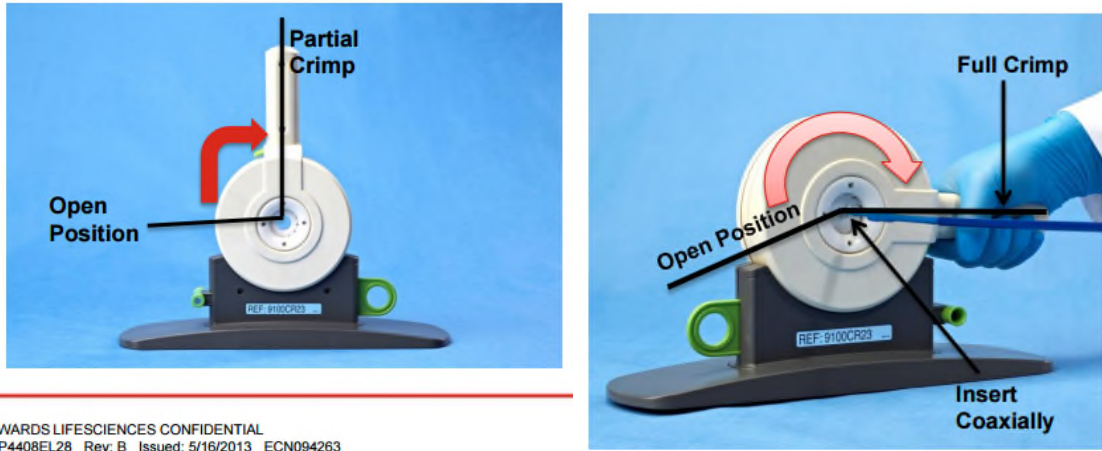
The Crimper's plurality of movable dies are between stationary plates disposed about the longitudinal axis. For example:

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

stationary plates
disposed about the
longitudinal axis,



**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

<p>[40d] each die in communication with an actuation device,</p>	<p>Each of the Crimper's dies is in communication with the Crimper's actuation device. For example:</p> 
<p>[40e] the actuation device constructed and arranged such that rotational motion of the actuation device opens or closes the aperture,</p>	<p>The Crimper's actuation device is constructed and arranged such that rotational motion of the actuation device opens or closes the aperture. See http://market360online.com/sqlimages/1246/129856.pdf</p>  <p>EDWARDS LIFESCIENCES CONFIDENTIAL SOP4408EL28 Rev. B Issued: 5/16/2013 ECN094263</p>

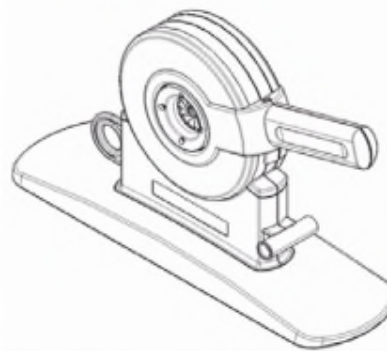
**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**



See also: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm262934.pdf>, p. 2

The Crimper, shown in Figure 4, is comprised of a housing and a compression mechanism, creating an aperture that is opened and closed by means of a handle located on the housing. The crimper includes a balloon gauge to verify diameter of an inflated balloon catheter and a crimp gauge to verify collapsed diameter of the device.

Figure 4: Crimper



**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

<p>[40f] the dies operatively engaged to at least one of the stationary plates;</p>	<p>Each of the Crimper's dies are operatively engaged to at least one of the stationary plates. For example:</p>
<p>[40g] each die having a first straight side and a second straight side,</p>	<p>Each of the Crimper's dies has a first straight side and a second straight side. For example:</p>

**Ex. E CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 6,915,560 By Edwards**

<p>[40h] the first straight side and the second straight side converging to form a tip;</p>	<p>As shown above, the first straight side (green) and the second straight side (red) converge to form a tip.</p>
<p>[40i] wherein a portion of the first straight side of each die faces the aperture,</p>	<p>As shown above, a portion of the first straight side of each die (green) faces the aperture.</p>
<p>[40j] each first straight side parallel to the second side of an adjacent die.</p>	<p>As shown above, each first straight side (red) is parallel to the second side of an adjacent die (green).</p>

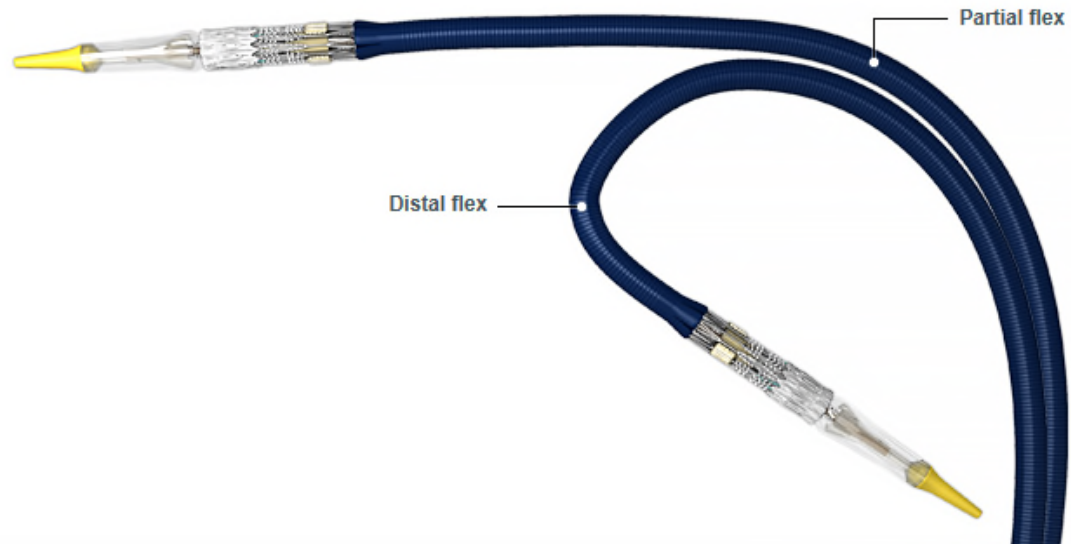
**Ex. F: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,749,234 By Edwards**

Claim 1	
Element	Accused Products
<p>[1 preamble¹] A stent delivery catheter comprising:</p>	<p>To the extent the preamble is deemed a limitation, on information and belief, Edwards made, used, offered to sell, and/or sold in the United States, and/or imported into the United States the balloon catheter used in its Commander Delivery System (“Commander”) for delivery and deployment of its Sapien 3 product. For example:</p> <p><u>Commander:</u></p> <p>The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

¹ The designations in square brackets before the claim language in each row is added to permit convenient reference to specific claim language. These added designations are not part of the claim language and are not intended to limit the claims in any way. No interpretation is intended to be conveyed by the words grouped together with each designation.

Edwards Commander Delivery System

Dual articulation for coaxiality even in challenging anatomies



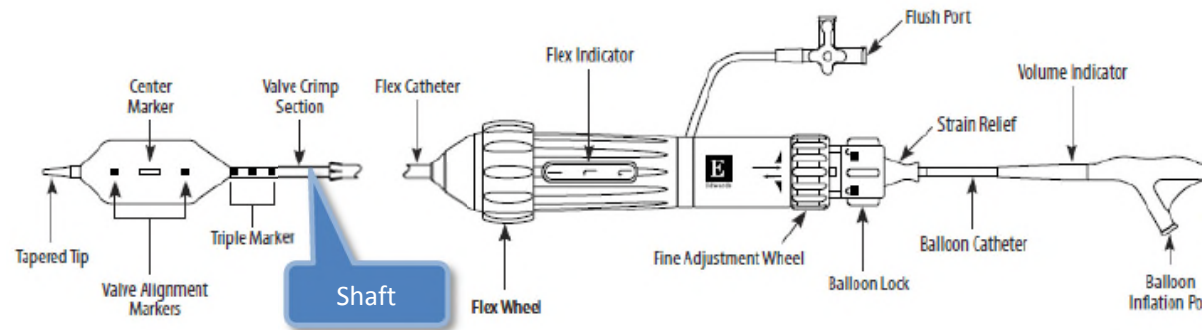
Source: <http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>.

[1a]
an inner shaft, the inner shaft having a proximal portion and a distal portion and a center axis,

The Commander includes a catheter having an inner shaft having a proximal portion and a distal portion and a center axis. For example:

Commander:

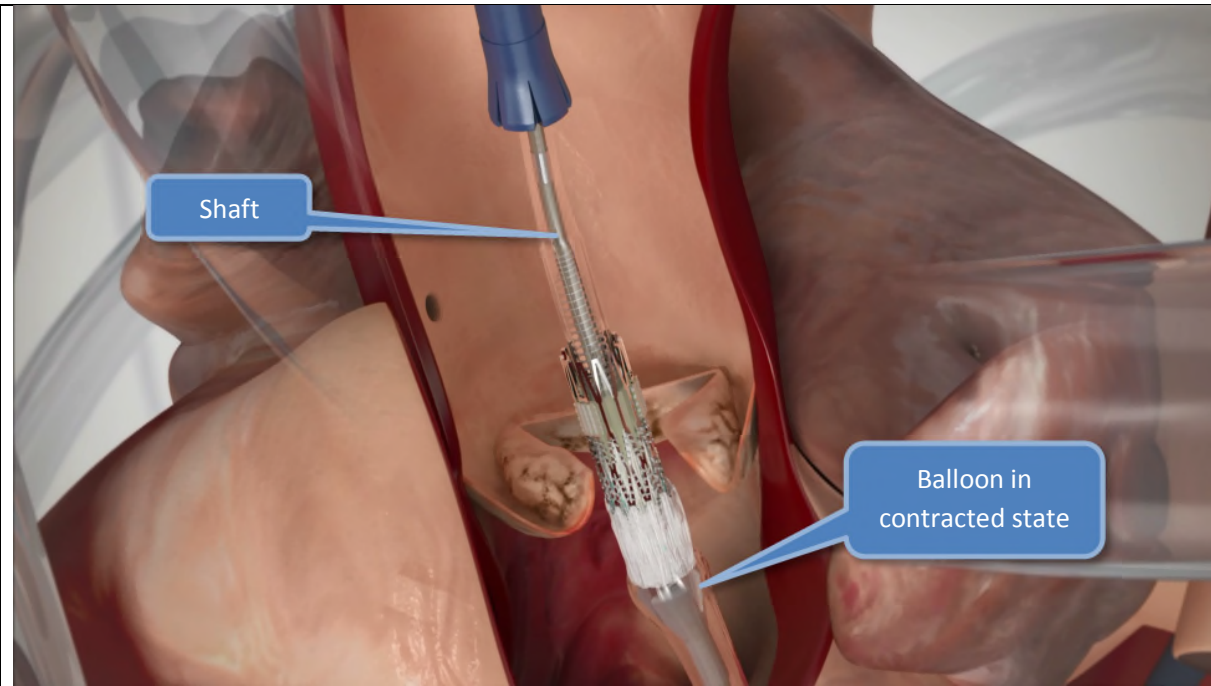
Figure 2 Edwards Commander Delivery System



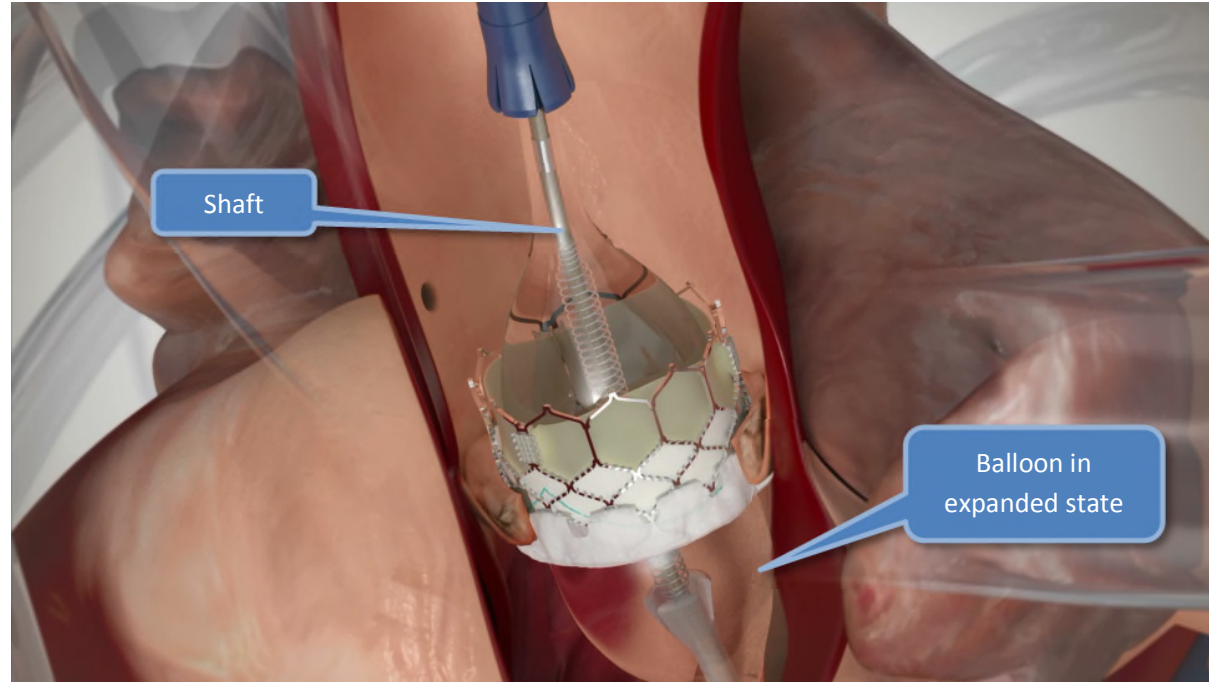
Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 3 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

[1b]
an inflatable medical balloon positioned about the distal portion of the inner shaft, the medical balloon having an expanded state, a contracted state, a proximal end and a distal end, wherein the medical balloon can be expanded from its contracted state to its expanded state, and

The Commander includes an inflatable medical balloon positioned about the distal portion of the inner shaft, the medical balloon having an expanded state, a contracted state, a proximal end and a distal end, wherein the medical balloon can be expanded from its contracted state to its expanded state. For example:



Source: "thv_commander.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN 3 Valve" hyperlink; then follow "Transfemoral Procedural Animation" hyperlink)



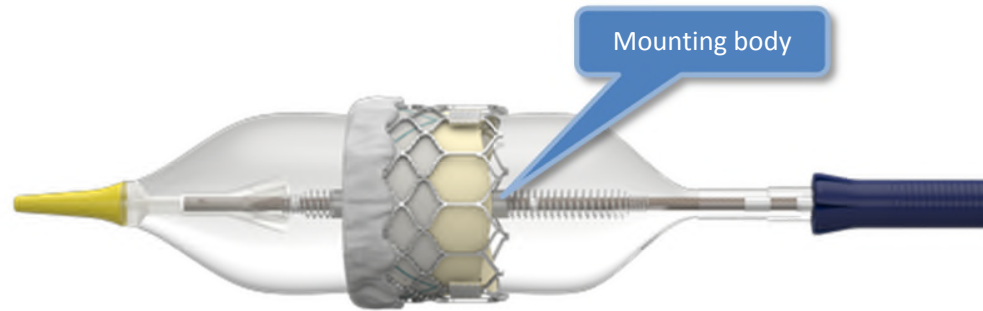
Source: “thv_commander.mp4” available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow “Edwards SAPIEN 3 Valve” hyperlink; then follow “Transfemoral Procedural Animation” hyperlink)

[1c]
 at least one mounting body secured to the inner shaft, inside the medical balloon and around the center axis, the mounting body having a length, a circumferential surface, wherein the

The Commander includes mounting body secured to the inner shaft, inside the medical balloon and around the center axis. The mounting body is in the form of a coil having a length and a circumferential surface that is outermost relative to the center axis and that faces radially away from the center axis and toward the medical balloon. The coil has a separation in the form of a spiral.

circumferential surface is a surface of the mounting body that is outermost relative to the center axis and that faces radially away from the center axis and toward the medical balloon, and having at least one separation in the circumferential surface,

Commander:



Source: “635907831022739465-EdwardsCommander-Distal.Expand.Valve.png” available at <http://www.app.com/story/news/health/cardiac/2016/02/11/heart-research-stem-cell/80054246/>.

[1d]
wherein the at least one separation is exposed to a portion of the medical balloon which is located

The at least one separation of the Commander coil is exposed to a portion of the balloon. The at least one separation is a circumferential separation.

along a radial line which extends from the center axis and through the separation, the at least one separation being a circumferential separation,	
[1e] wherein the mounting body is formed of a material which resiliently deforms under radial pressure.	The coil of the Commander is capable resiliently deforming under radial pressure.

Claim 2	
Element	Accused Products
[2 preamble] The stent delivery catheter of claim 1,	<i>See</i> claim chart for claim 1 above.
[2a] wherein the mounting body has a plurality of separations, the plurality of separations being distinct from one another and being linearly aligned with one another relative to the center axis and the plurality of separations being exposed to the medical balloon.	The spiral windings of the Commander coil comprise a plurality of separations.

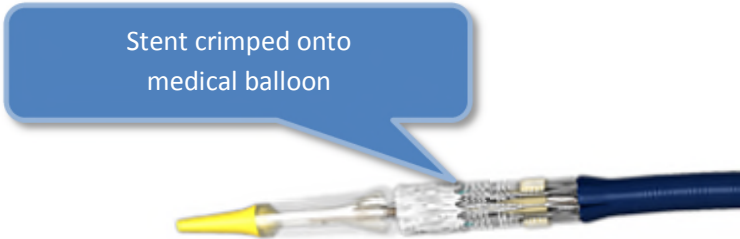
Claim 3	
Element	Accused Products
[3 preamble] The stent delivery catheter of claim 2,	<i>See</i> claim chart for claim 2 above.
[3a] wherein the plurality of separations are substantially parallel and substantially circumferentially positioned around the mounting body.	The spiral windings of the Commander coil are substantially parallel and substantially circumferentially positioned around the mounting body.

Claim 5	
Element	Accused Products
[5 preamble] The stent delivery catheter of claim 2,	<i>See</i> claim chart for claim 2 above.
[5a] wherein the plurality of separations form a plurality of linearly positioned separate rings, the separate rings being linearly aligned with one another and non-overlapping relative to the center axis.	The spiral windings of the Commander coil form a plurality of linearly positioned separate rings, the separate rings being linearly aligned with one another and non-overlapping relative to the center axis..

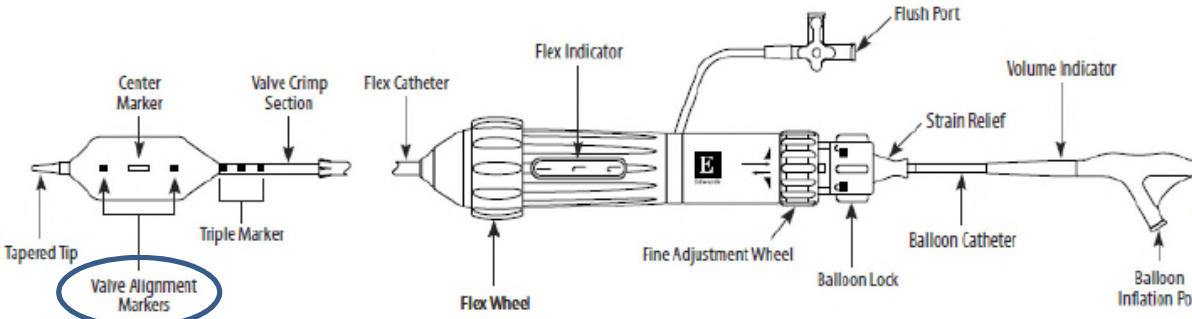
Claim 6	
Element	Accused Products
[6 preamble] The stent delivery catheter of claim 1,	<i>See claim chart for claim 1 above.</i>
[6a] wherein the separation is substantially along the entire length of the mounting body.	The spiral windings of the Commander coil comprise a separation substantially along the entire length of the mounting body.

Claim 7	
Element	Accused Products
[7 preamble] The stent delivery catheter of claim 1,	<i>See claim chart for claim 1 above.</i>
[7a] wherein the separation is in the form of a spiral, the separate rings being linearly aligned with one another and non-overlapping relative to the center axis.	The Commander coil is in the form of a spiral.

Claim 8	
Element	Accused Products
[8 preamble] The stent delivery catheter of claim 7,	<i>See claim chart for claim 7 above.</i>
[8a] wherein the separation is substantially along the entire length of the mounting body.	The spiral windings of the Commander coil comprise a separation substantially along the entire length of the mounting body.

Claim 13	
Element	Accused Products
[13 preamble] The stent delivery catheter of claim 1,	<i>See claim chart for claim 1 above.</i>
[13a] further comprising a stent crimped onto the medical balloon.	<p>The Commander and the Sapien 3 comprise a stent crimped onto a medical balloon. For example:</p> <div style="text-align: center;">  <p><u>Commander:</u></p> </div> <p>Source: http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx.</p>

Claim 15

Element	Accused Products
<p>[15 preamble] The stent delivery catheter of claim 13,</p>	<p>See claim chart for claim 13 above.</p>
<p>[15a] further including marker bands positioned proximally and distally of the stent.</p>	<p>The Commander includes marker bands positioned proximally and distally of the stent. For example:</p> <p>Commander:</p> <p align="center">Figure 2 Edwards Commander Delivery System</p>  <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 3 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

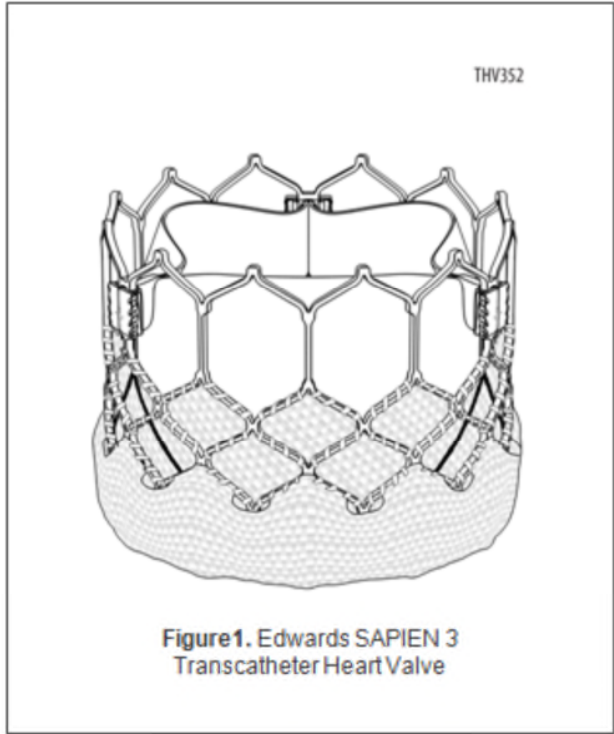
	<p>Before deployment, ensure that the THV is correctly positioned between the Valve Alignment Markers and the Flex Catheter tip is over the Triple Marker.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 11 <i>available at</i> http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>
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Claim 18	
Element	Accused Products
[18 preamble] The stent delivery catheter of claim 13,	<i>See claim chart for claim 13 above.</i>
[18a] wherein the mounting body is substantially the same length as the stent.	The portion of the Commander coil that comprises the mounting body is substantially the same length as the stent.

Claim 19	
Element	Accused Products
[19 preamble] The stent delivery catheter of claim 1,	<i>See claim chart for claim 1 above.</i>
[19a] the mounting body having an outer diameter, wherein the outer diameter of the mounting body is	The portion of the Commander coil that comprises the mounting body is substantially constant along its length.

substantially constant along its length.	
--	--

Claim 20	
Element	Accused Products
[20 preamble] The stent delivery catheter of claim 1,	<i>See claim chart for claim 1 above.</i>
[20a] further comprising a tubular medical device,	The Sapien 3 is a tubular medical device.

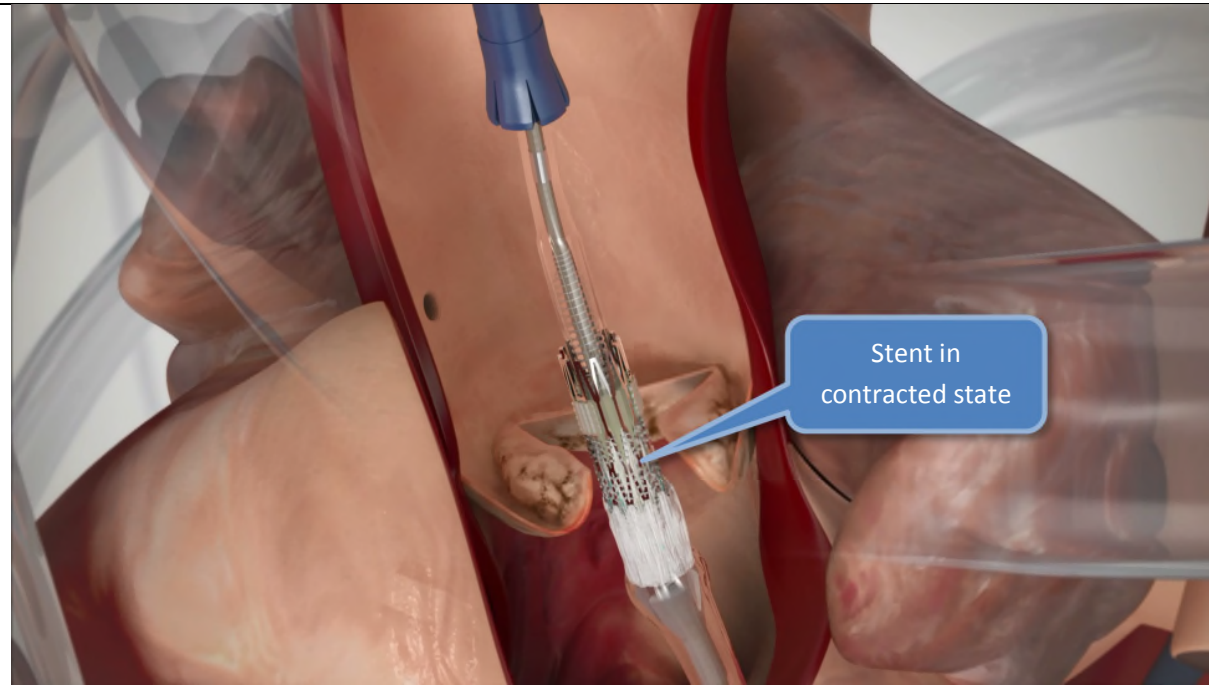


Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

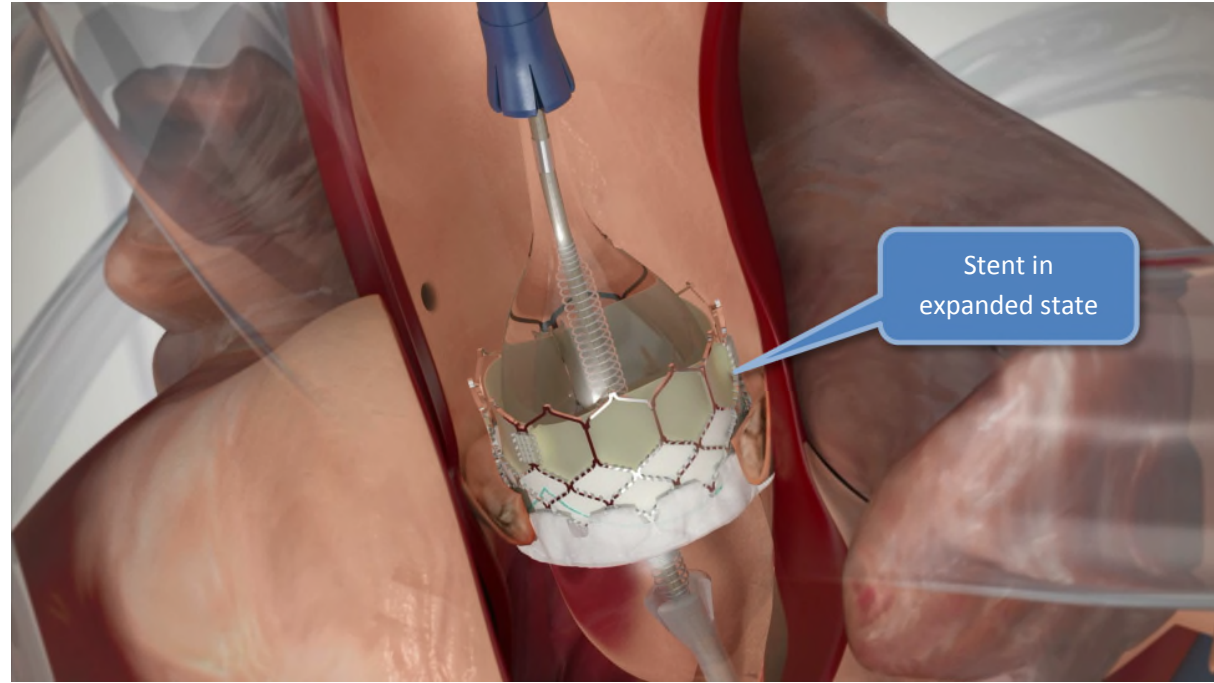
[20b]
the tubular medical device
being about the medical
balloon and at least a portion
of the mounting body and
having an expanded state and

The Sapien 3 has a contracted state and an expanded state.

a contracted state.

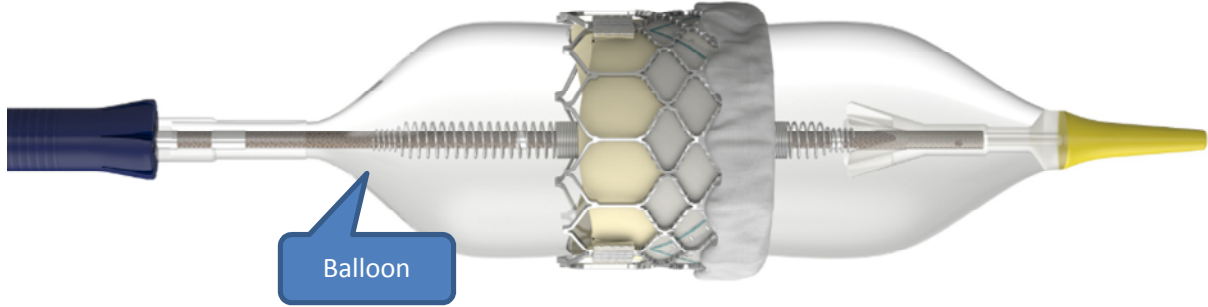


Source: "thv_commander.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN 3 Valve" hyperlink; then follow "Transfemoral Procedural Animation" hyperlink)



Source: "thv_commander.mp4" available at <http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx> (follow "Edwards SAPIEN 3 Valve" hyperlink; then follow "Transfemoral Procedural Animation" hyperlink)

**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

Claim 5	
Element	Accused Products
<p>[5 preamble¹] A method for making a balloon catheter comprising:</p>	<p>On information and belief, Edwards made and/or makes each of the balloon catheters used in its Commander Delivery System (“Commander”), Ascendra Delivery System (“Ascendra”), Certitude Delivery System (“Certitude”), NovaFlex Delivery System (“NovaFlex”), and RetroFlex Delivery System (“RetroFlex”) using the patented method detailed herein. On information and belief, unless otherwise noted, any differences between various versions or models of the delivery systems identified herein are immaterial to the assertions set forth herein.</p>
<p>[5a] providing a balloon cylinder,</p>	<p>Edwards provides a balloon cylinder in each of the accused products.</p> <p><u>Commander:</u></p>  <p>http://www.healthwellnesscolorado.com/wpcontent/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

¹ The designations in square brackets before the claim language in each row is added to permit convenient reference to specific claim language. These added designations are not part of the claim language and are not intended to limit the claims in any way. No interpretation is intended to be conveyed by the words grouped together with each designation.

**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

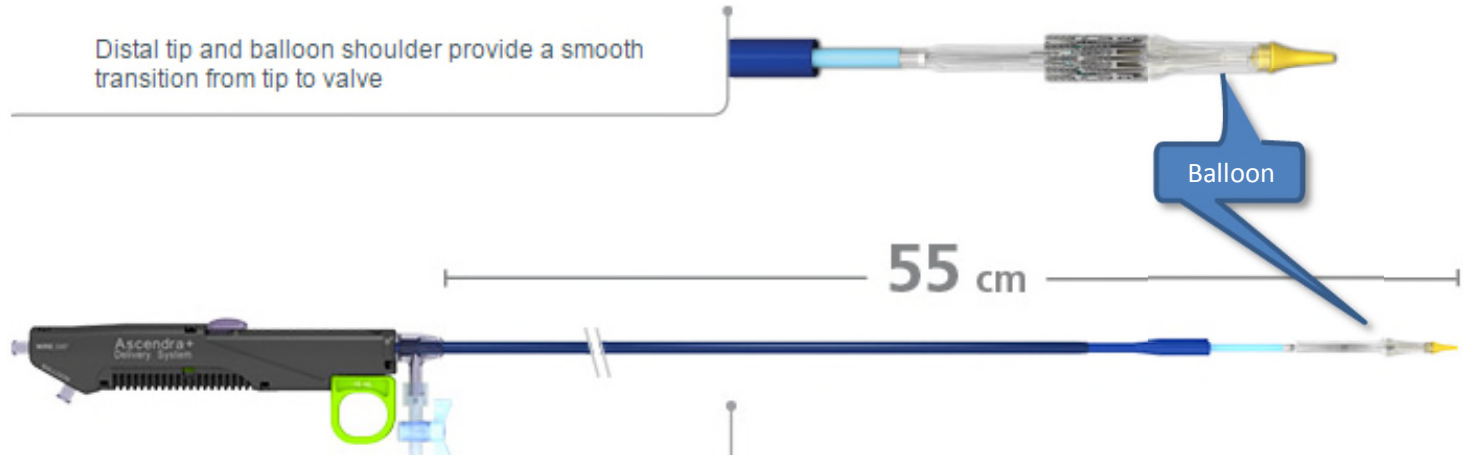
Ascendra:

Ascendra+ System

Expanding delivery options

- Designed for transapical and transaortic delivery
- The same easy-to-use system for all 3 valve sizes

Distal tip and balloon shoulder provide a smooth transition from tip to valve



**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

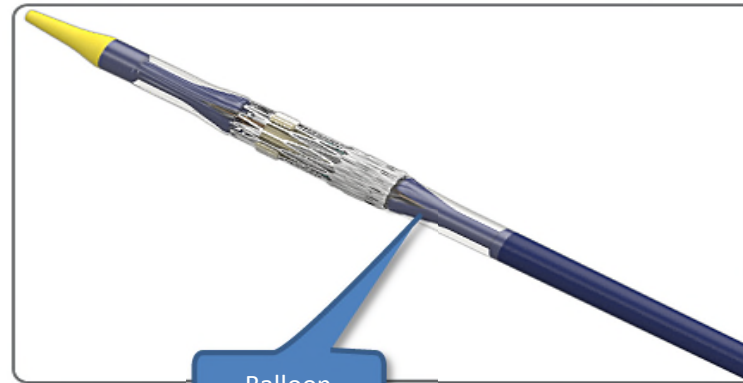
Certitude:

Edwards Certitude Delivery System
designed for seamless deployment

Ultra-low profile system – 18F Certitude sheath compatible*

Integrated pusher

- Streamlines procedure



Articulation feature

- For ease of coaxial positioning



**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

NovaFlex:

NovaFlex+ Transfemoral System

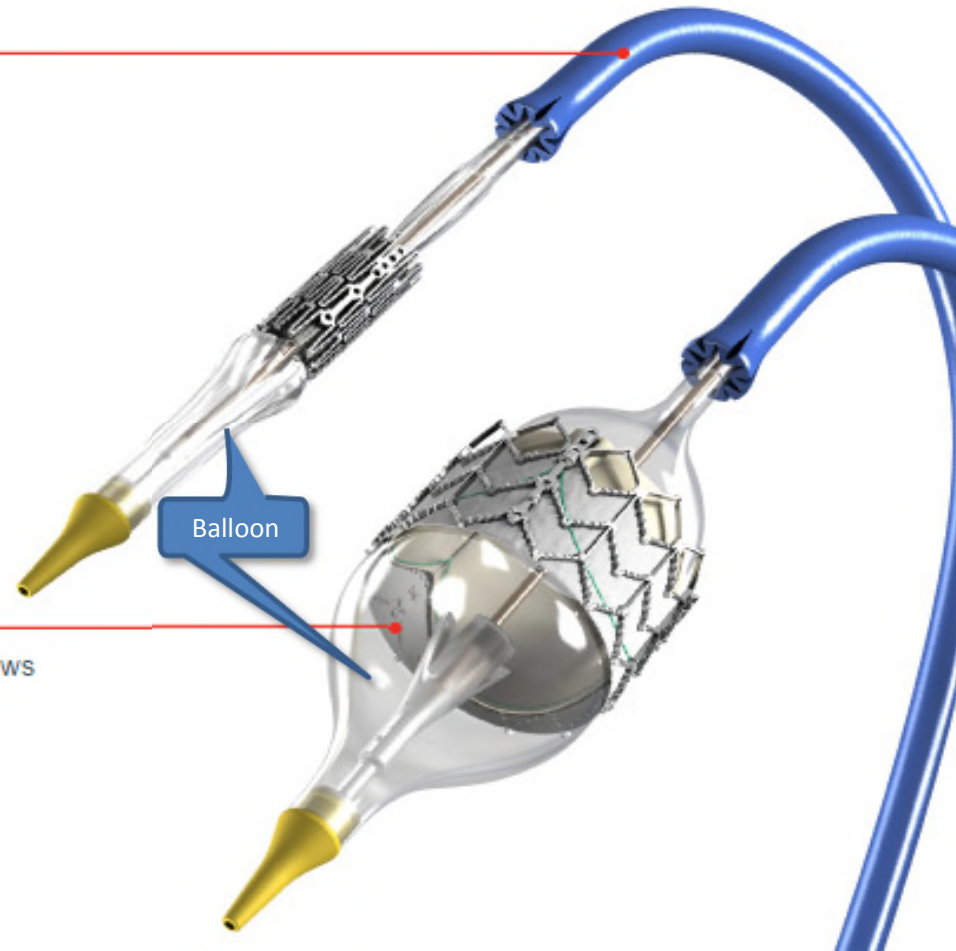
Control

Flex catheter stabilizes balloon shaft during deployment



Precision

Balloon-expandable design allows for user-controlled inflation and precise delivery



Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards

RetroFlex:



RetroFlex 1-3

RetroFlex 1™



Balloon catheter and steerable pusher catheter

RetroFlex 2™



Coaxial nose cone facilitating crossing of the aortic arch and native valve

Moveable nose cone

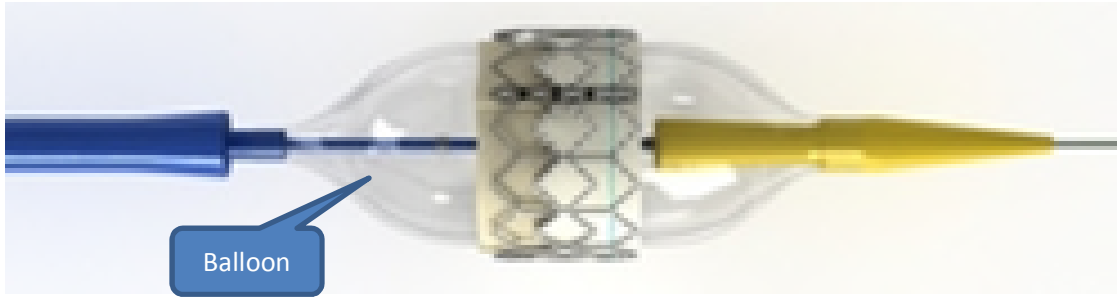
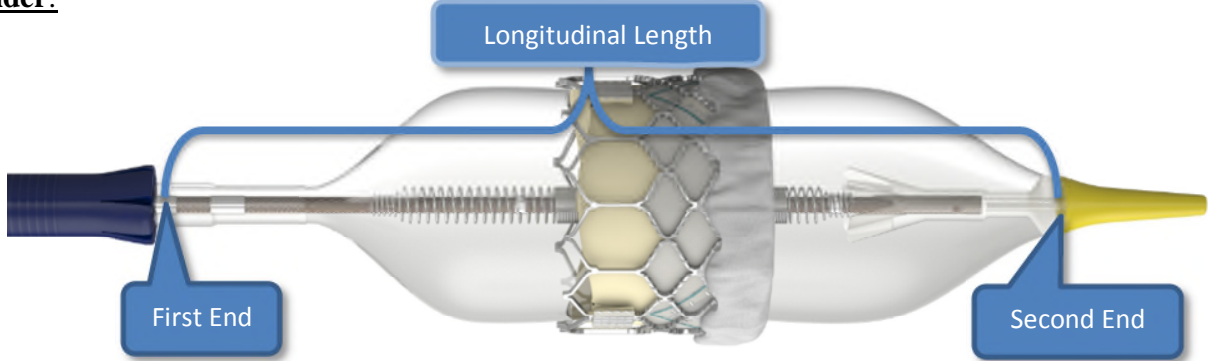
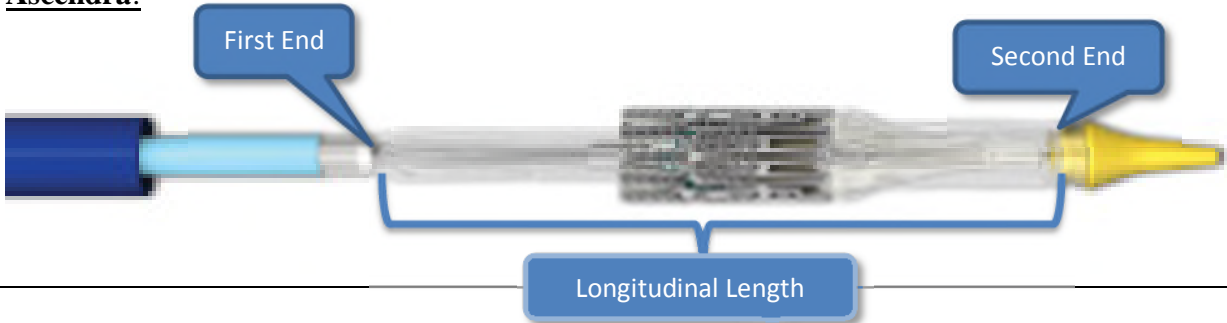
RetroFlex 3™



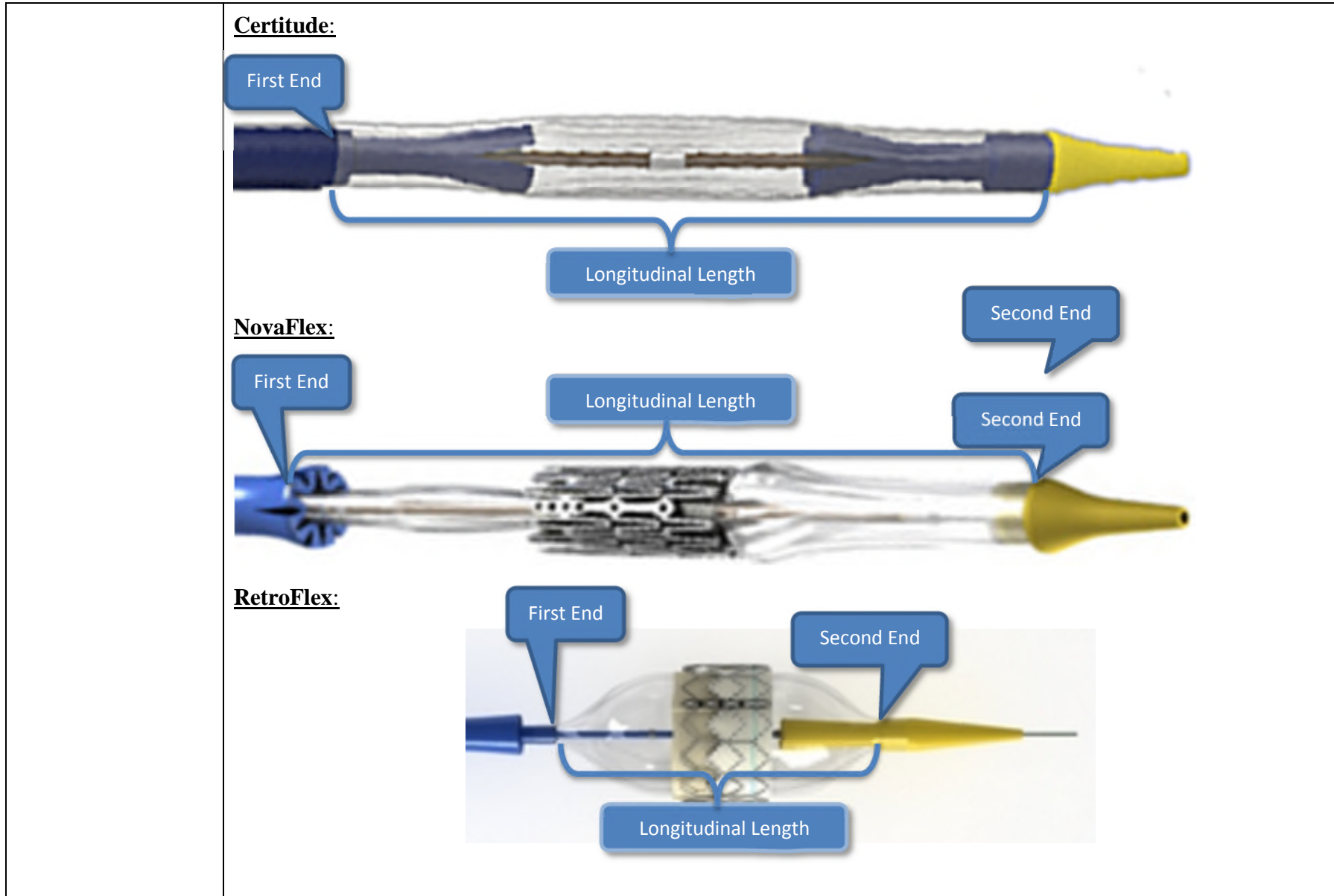
Fixed nose cone

<http://www.pcronline.com/Lectures/2009/Retroflex-3-a-new-percutaneous-valve-delivery-system-initial-experience-and-outcome-data>

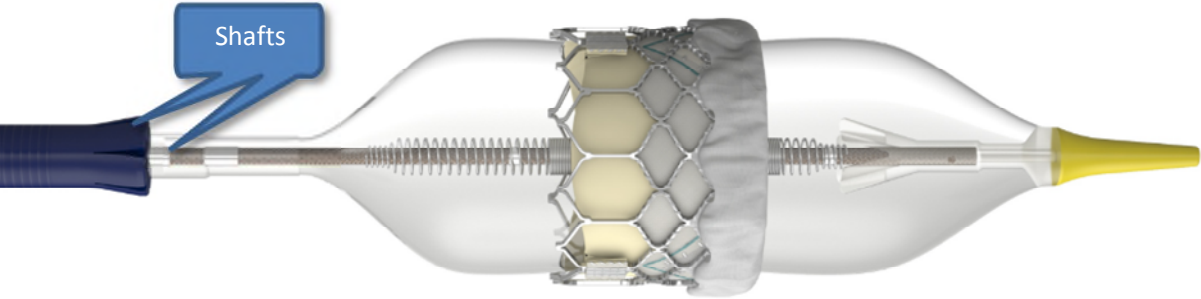

**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

	 <p align="center">http://www.edwards.com/eu/newsroom/Pages/showpr.aspx?PageGuid=%7B1981375d-3f20-4ada-9bb3-69aa519b1d81%7D</p>
<p>[5b] the balloon cylinder having a first end and a second end,</p>	<p>The provided balloon cylinder in each of the accused products has a first end and a second end. For example:</p> <p><u>Commander:</u></p>  <p align="center">http://www.healthwellnesscolorado.com/wpcontent/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p> <p><u>Ascendra:</u></p> 

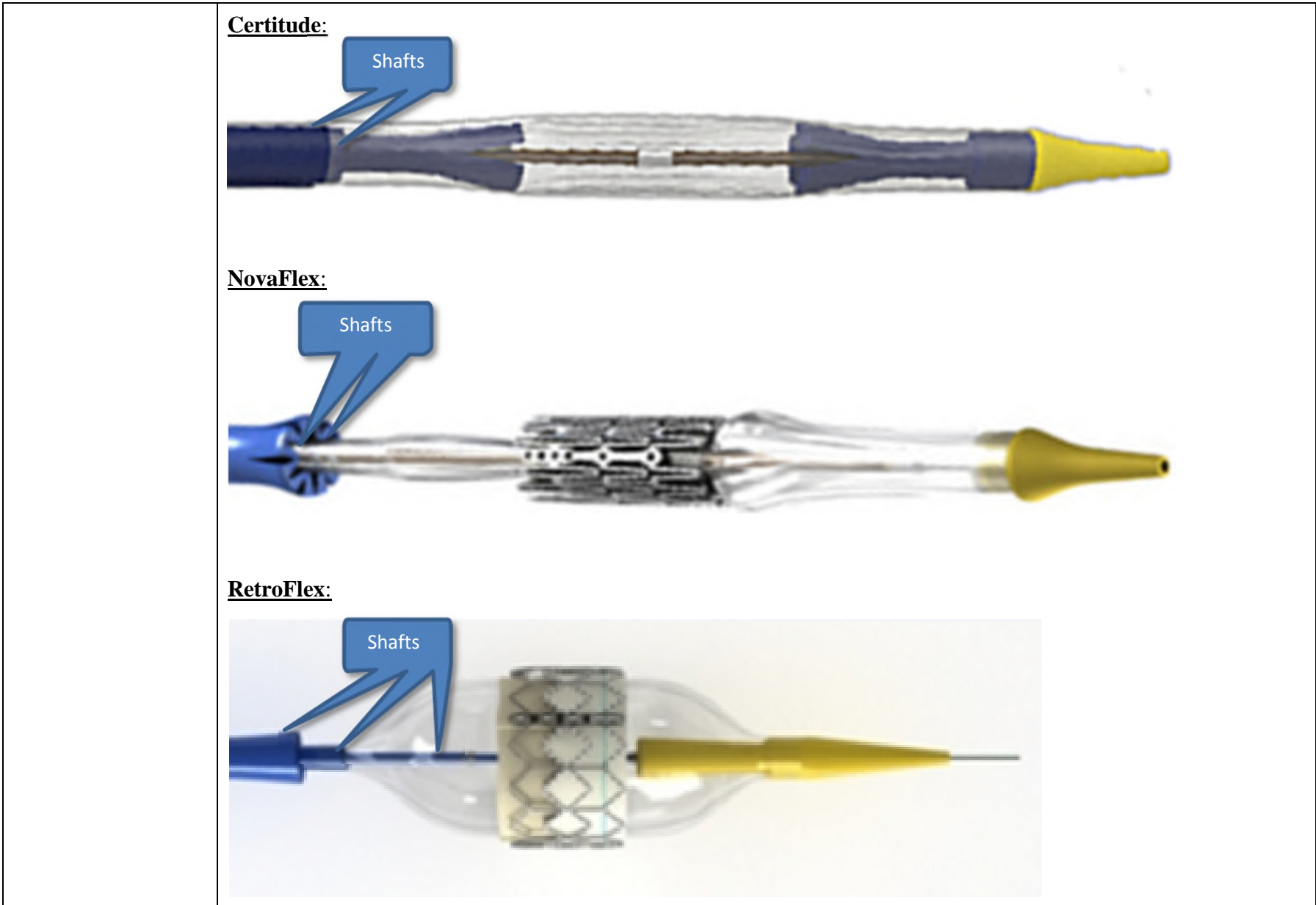
**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**



**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

<p>[5c] the first end and the second end separated by a longitudinal length;</p>	<p>As shown above, the first and second end of the provided balloon cylinder in each of the accused products is separated by a longitudinal length.</p>
<p>[5d] providing a catheter comprising at least one shaft;</p>	<p>Edwards provides a catheter comprising at least one shaft in each of the accused products, including, but not limited to, transition tubes.</p> <p><u>Commander:</u></p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p> <p><u>Ascendra:</u></p> 

**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

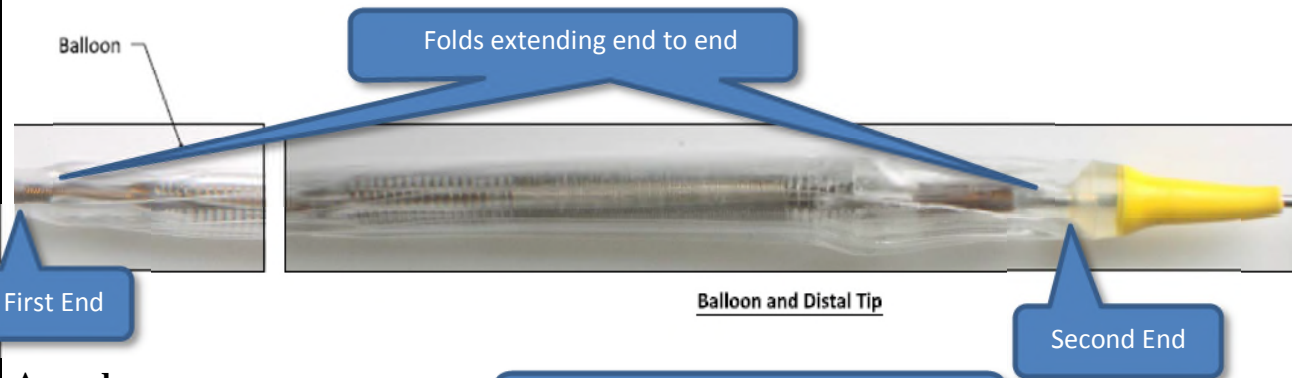


**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

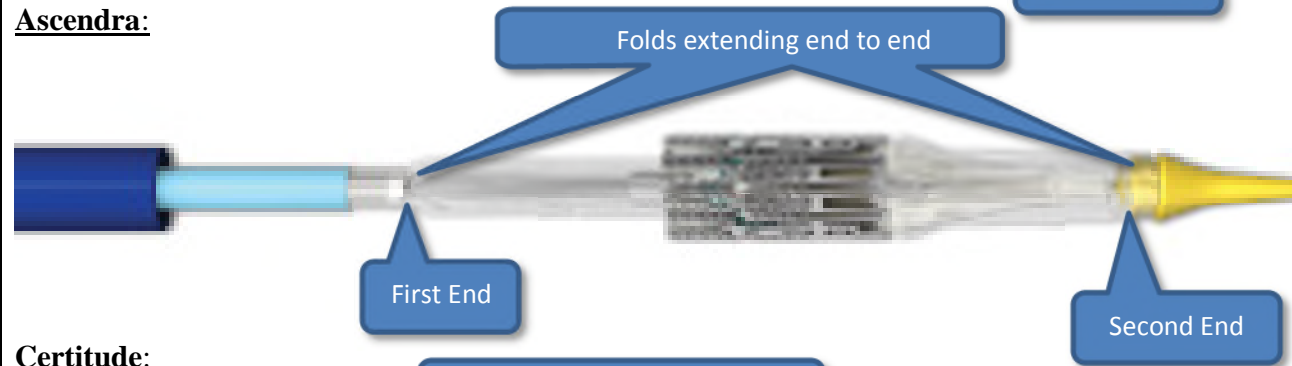
[5e]
incorporating at least one fold, the at least one fold extending from the first end to the second end of the balloon cylinder; and

The provided balloon cylinder in each of the accused products incorporates at least one fold extending from the first end to the second end of the balloon cylinder. For example:

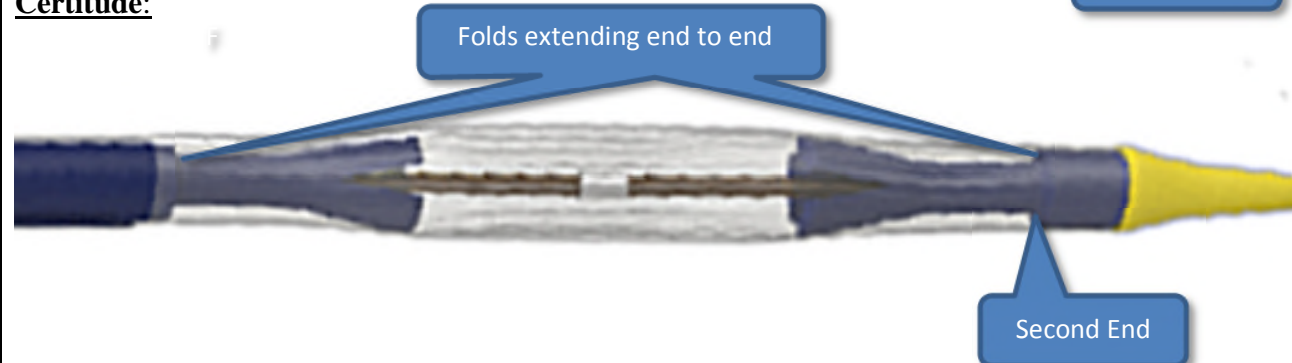
Commander:



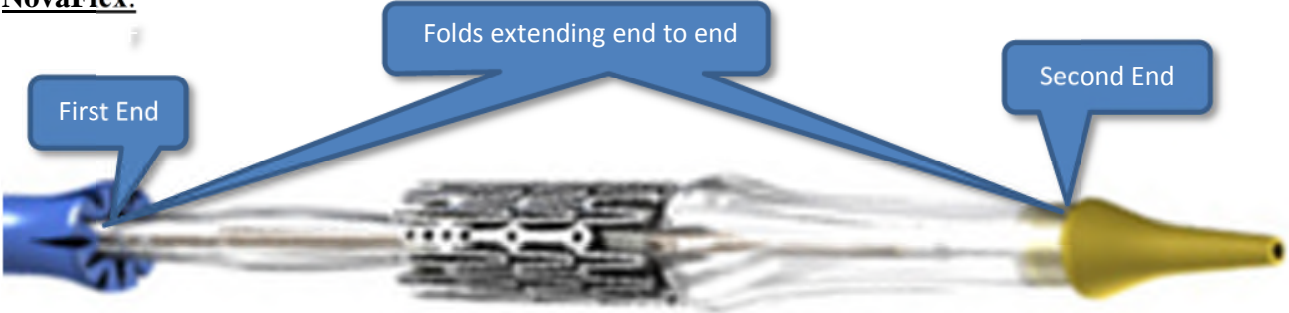
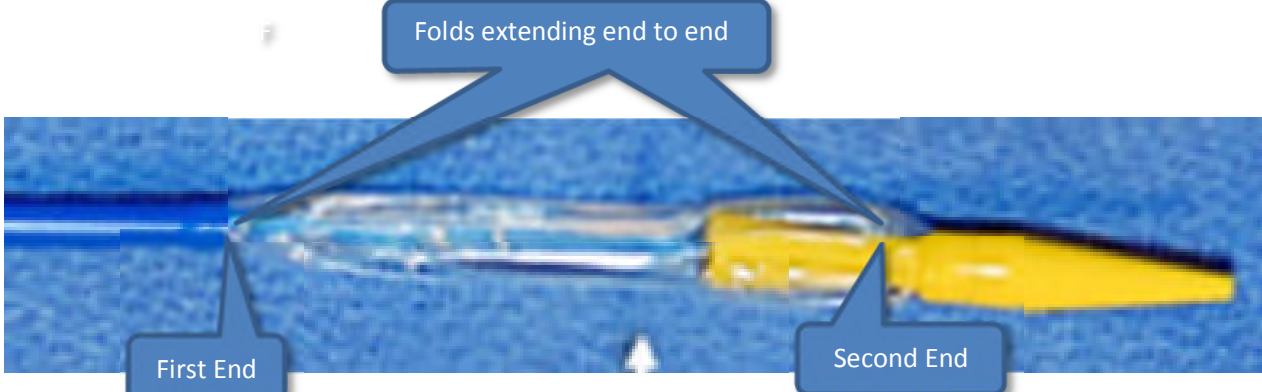
Ascendra:



Certitude:



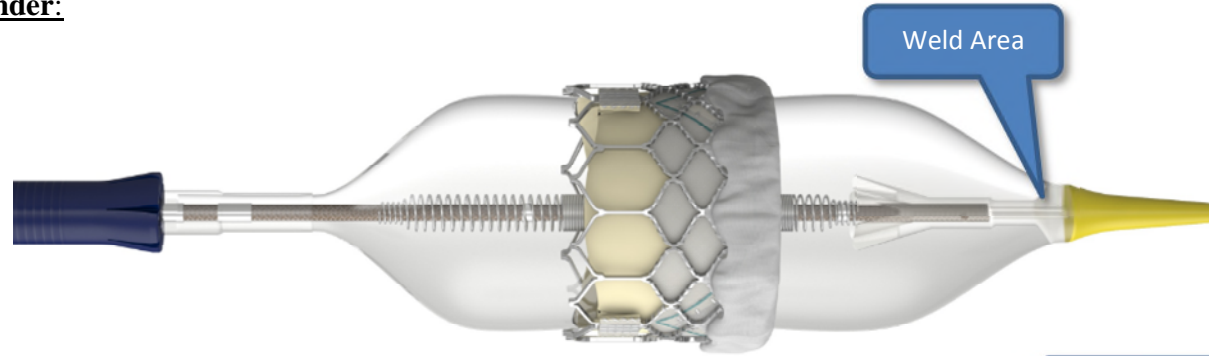
**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

	<p><u>NovaFlex:</u></p>  <p><u>RetroFlex:</u></p>  <p>https://www.researchgate.net/publication/257809371 The Edwards SAPIEN Transcatheter Heart Valve for Calcific Aortic Stenosis A Review of the Valve Procedure and Current Literature</p>
<p>[5f] welding the balloon cylinder with the at least one fold to the at least one shaft of</p>	<p>On informaiton and belief, Edwards welds the folded balloon cylinder to at least one shaft of the catheter. For example</p>

**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

the catheter.

Commander:



Ascendra:



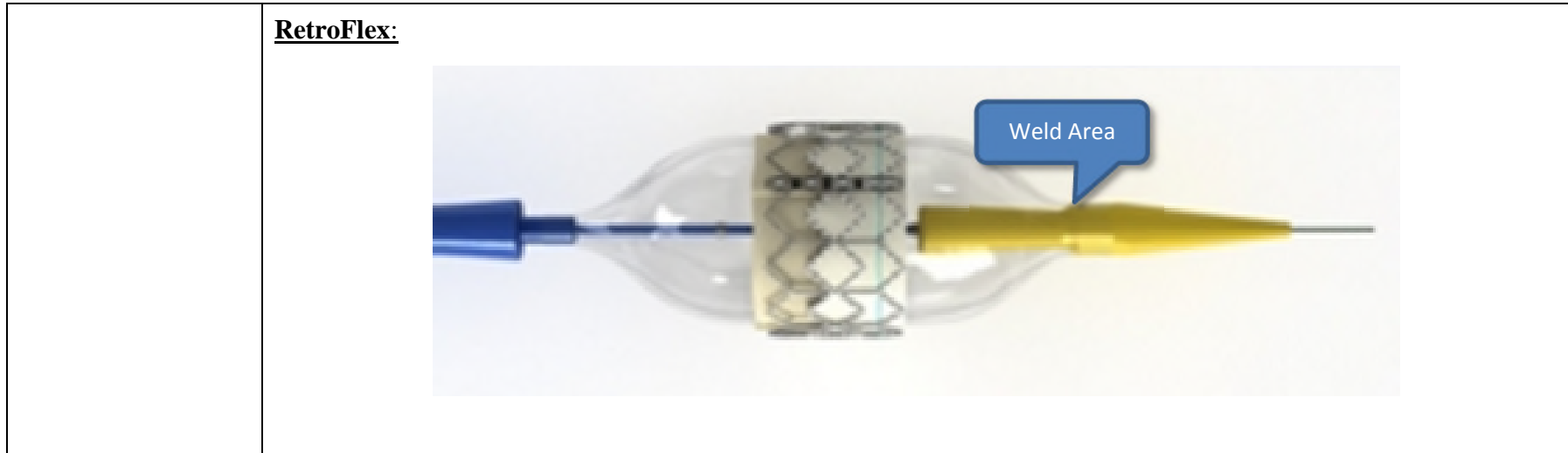
Certitude:



NovaFlex:

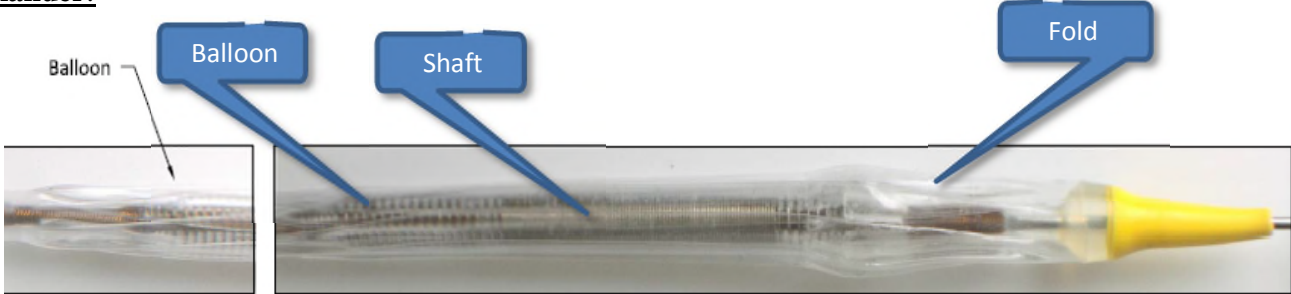
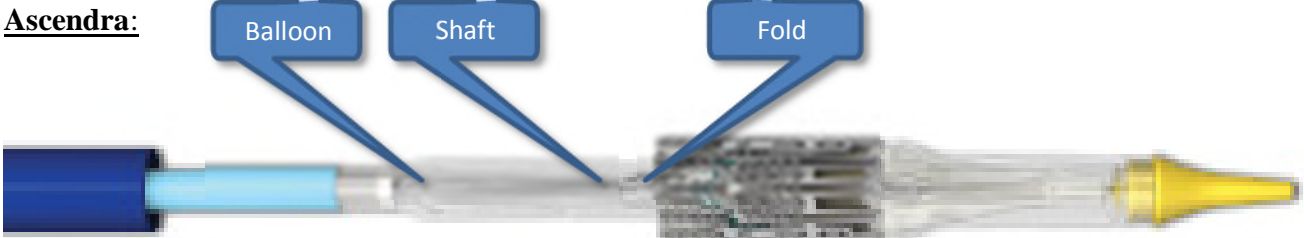


**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

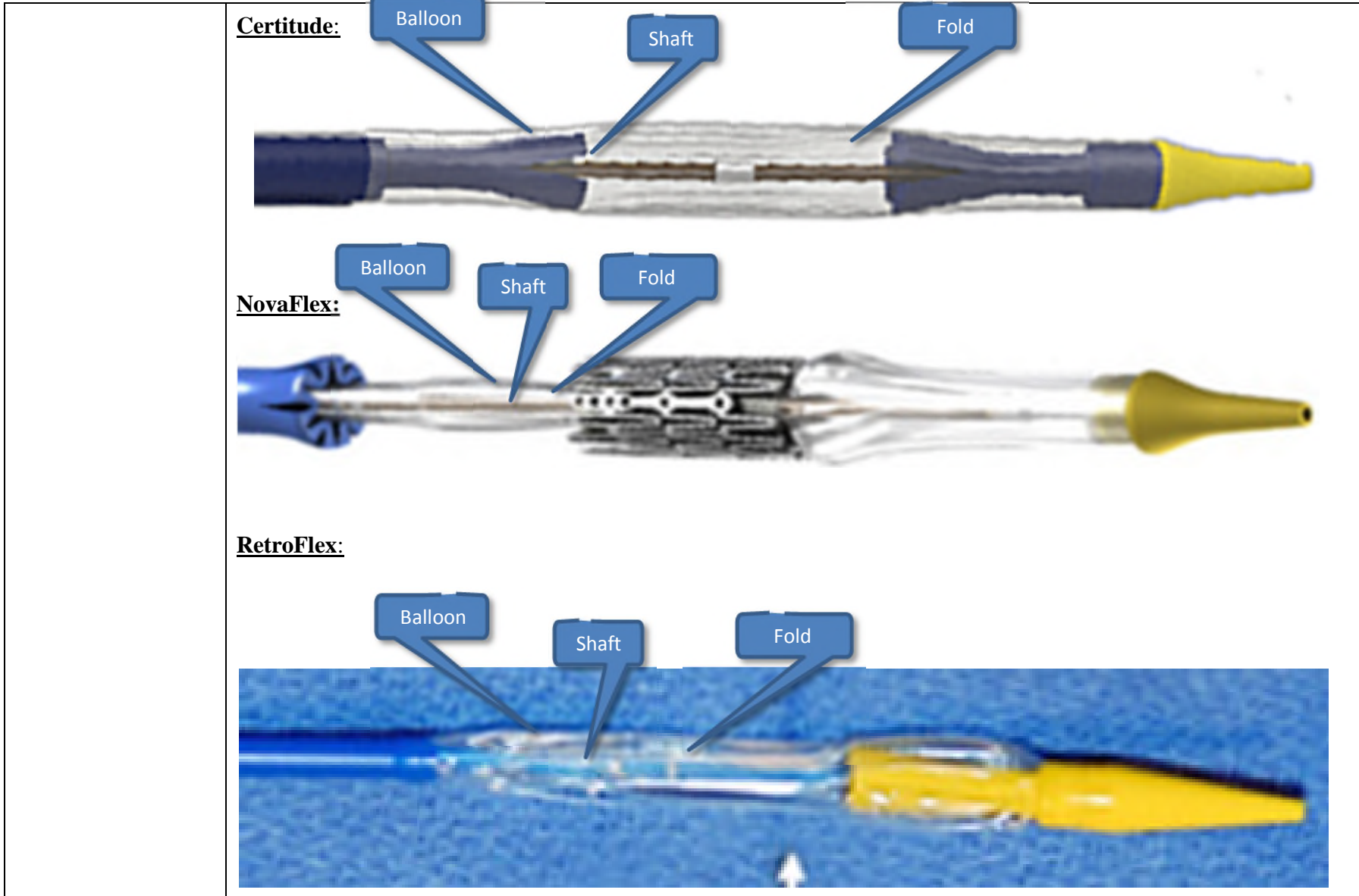


Claim 6	
Element	Accused Products
<p>[6 preamble] The method of claim 5,</p>	<p>As shown in connection with claim 5, Edwards made and/or makes each of the accused products using the patented method detailed in claim 5. <i>See</i> claim chart for claim 5, above.</p>
<p>[6a] wherein a laser is used to weld the balloon cylinder to the catheter.</p>	<p>On information and belief, a laser is used to weld the balloon cylinder to the catheter in each of the accused products.</p>

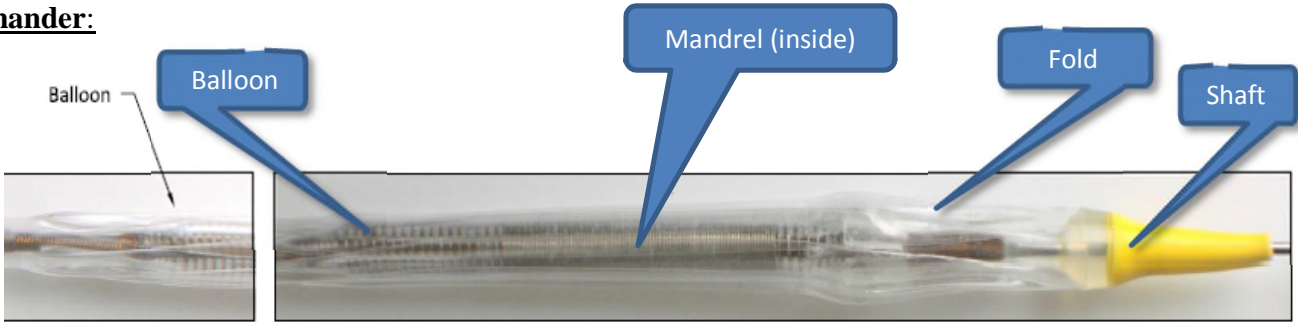
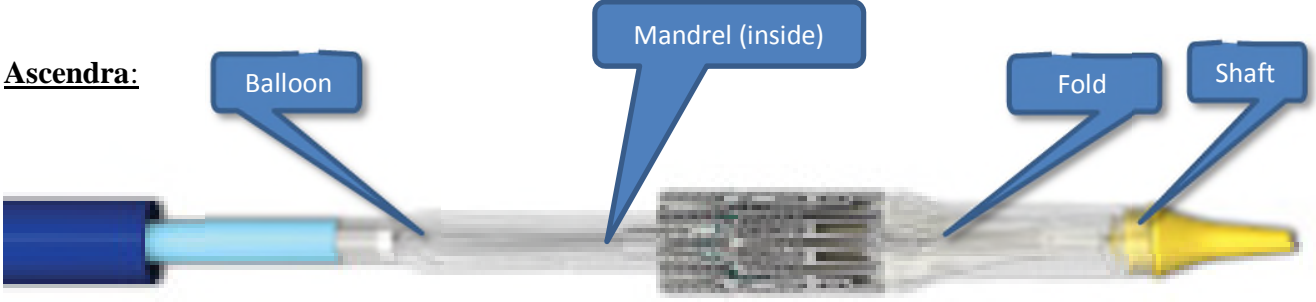
**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

Claim 9	
Element	Accused Products
[9 preamble] The method of claim 5,	As shown in connection with claim 5, Edwards made and/or makes each of the accused products using the patented method detailed in claim 5. <i>See</i> claim chart for claim 5, above.
[9a] wherein the balloon cylinder is disposed about the at least one shaft when incorporating the at least one fold.	<p>In each of the accused products, Edwards provides a balloon cylinder disposed about at least one shaft when incorporating the at least one fold.</p> <p><u>Commander:</u></p>  <p align="center">Balloon and Distal Tip</p> <p><u>Ascendra:</u></p> 

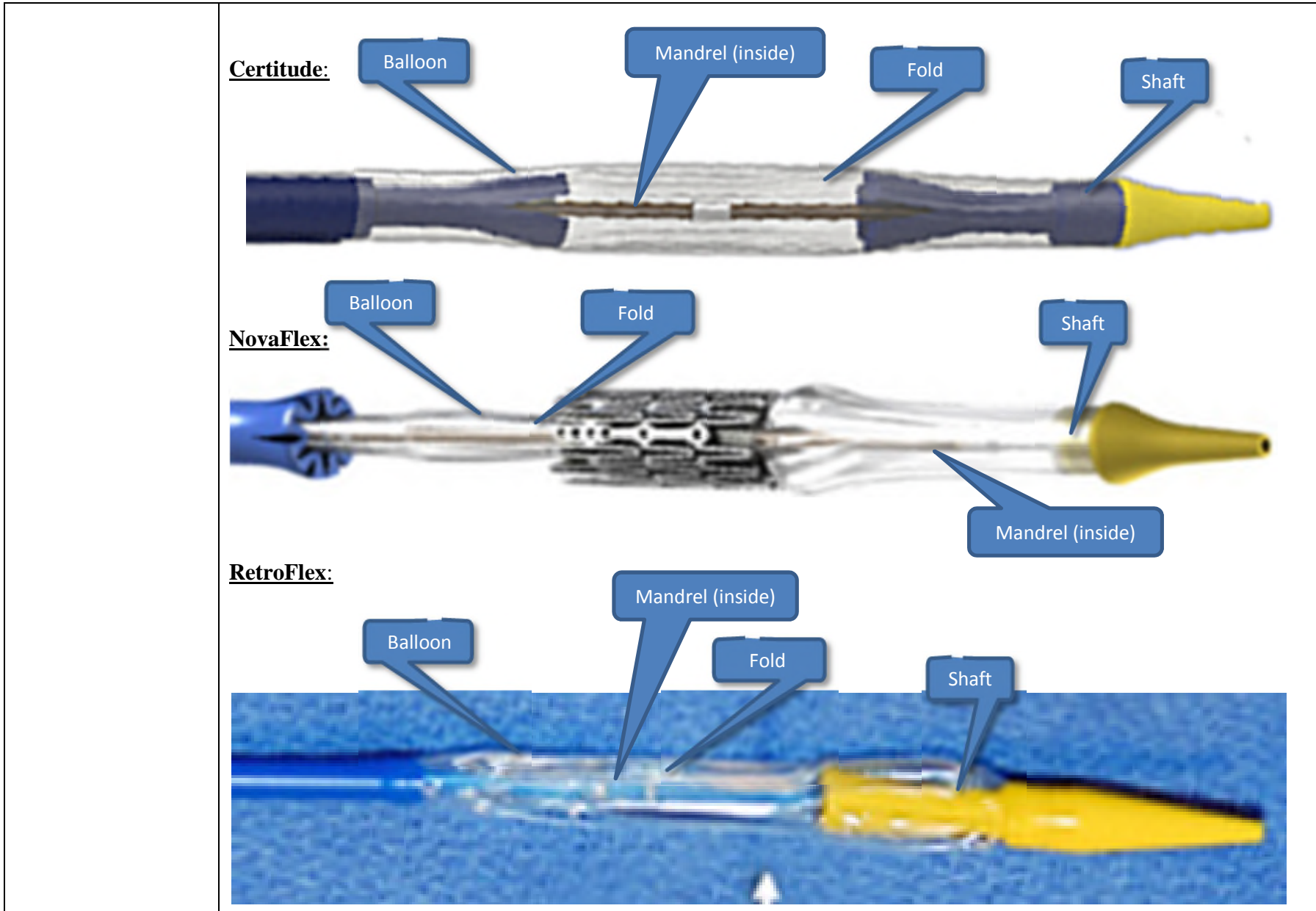
**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**



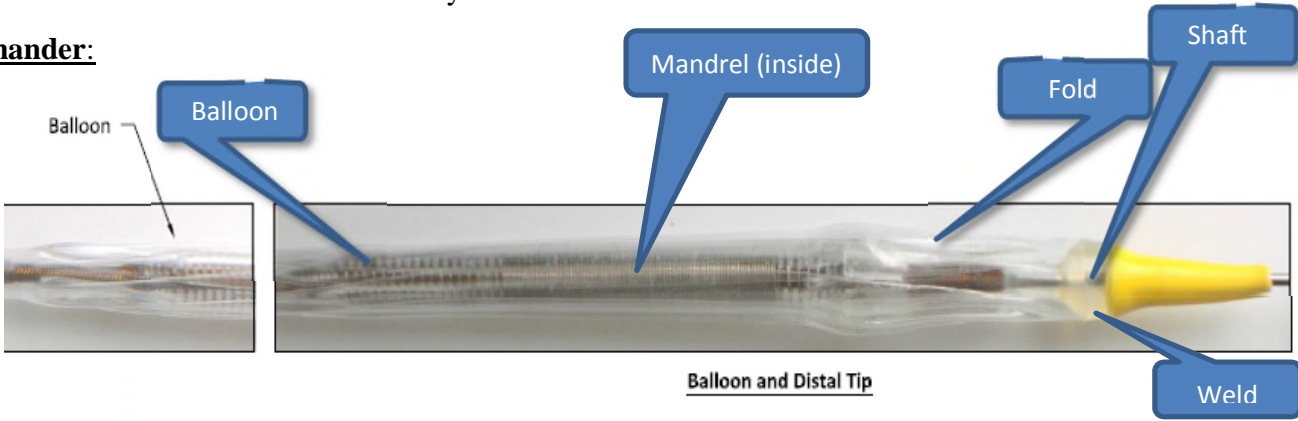
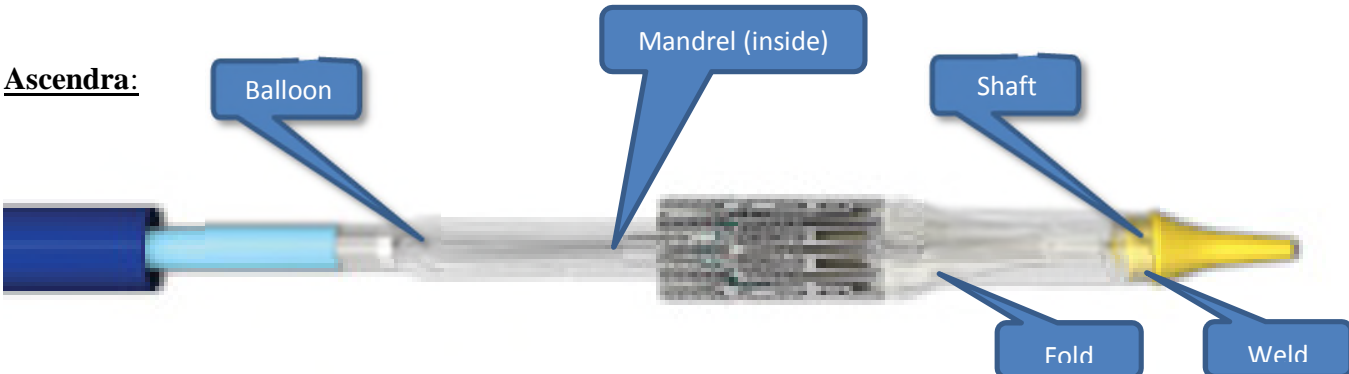
**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

Claim 10	
Element	Accused Products
<p>[10 preamble] The method of claim 9,</p>	<p>As shown in connection with claim 9, Edwards made and/or makes each of the accused products using the patented method detailed in claim 9. <i>See</i> claim chart for claim 9, above.</p>
<p>[10a] further comprising providing a mandrel, the balloon cylinder being disposed about the at least one shaft which is disposed about the mandrel when incorporating the at least one fold.</p>	<p>In each of the Accused Products, Edwards provides a mandrel inside the catheter, and a balloon cylinder disposed about at least one shaft which is disposed about the mandrel when incorporating the at least one fold.</p> <p><u>Commander:</u></p>  <p align="center"><u>Balloon and Distal Tip</u></p> <p><u>Ascendra:</u></p> 

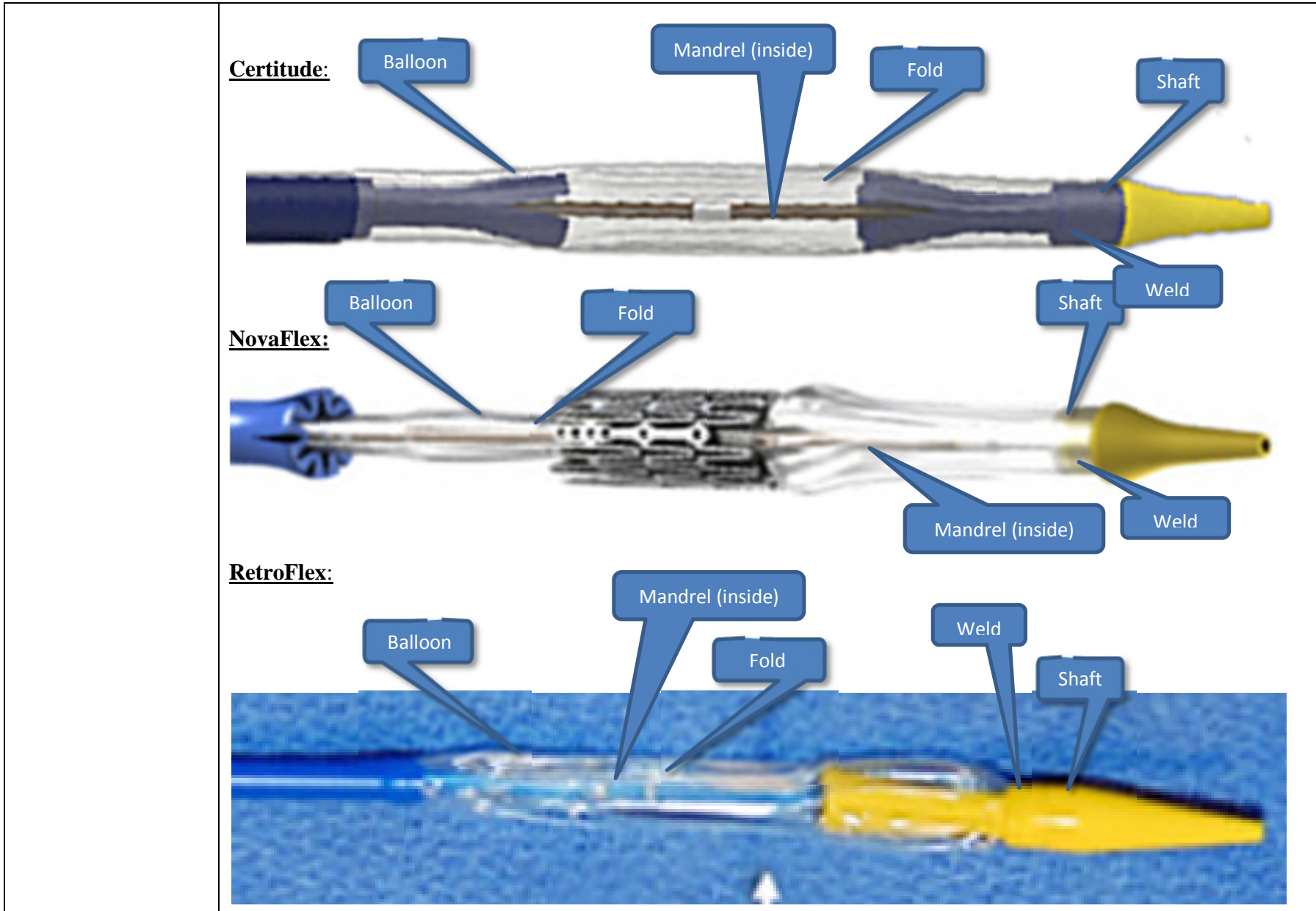
**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**



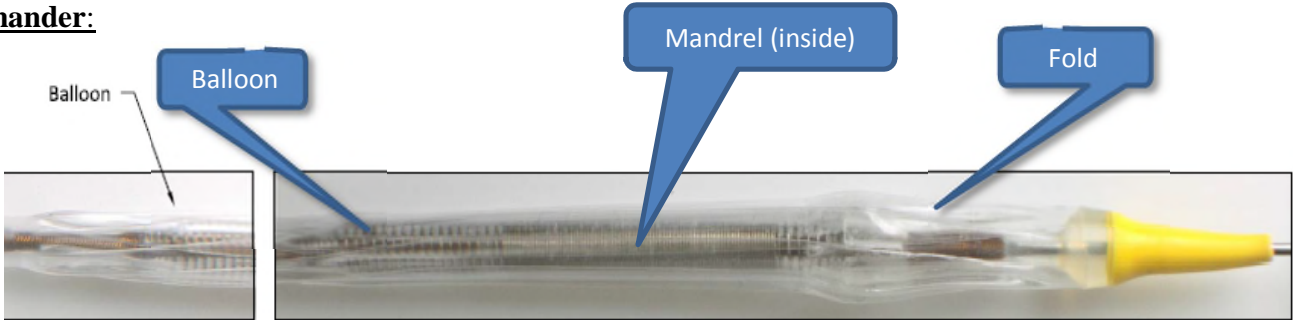
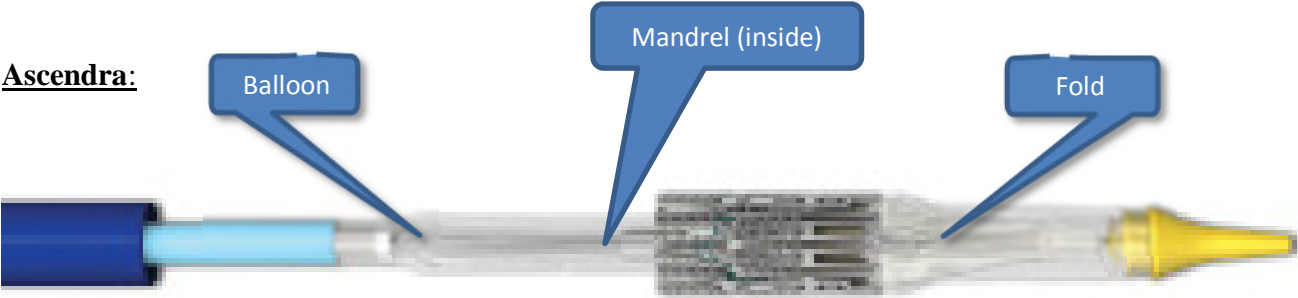
**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

Claim 11	
Element	Accused Products
[11 preamble] The method of claim 10,	As shown in connection with claim 10, Edwards made and/or makes each of the accused products using the patented method detailed in claim 10. <i>See</i> claim chart for claim 10, above.
[11a] wherein the balloon cylinder is disposed about the at least one shaft which is disposed about the mandrel when the balloon cylinder is welded to the at least one shaft of the catheter.	<p>In each of the accused products, Edwards provides a mandrel inside the catheter, and a balloon cylinder disposed about at least one shaft when the balloon cylinder is welded to a shaft of the catheter.</p> <p><u>Commander:</u></p>  <p align="center"><u>Balloon and Distal Tip</u></p> <p><u>Ascendra:</u></p> 

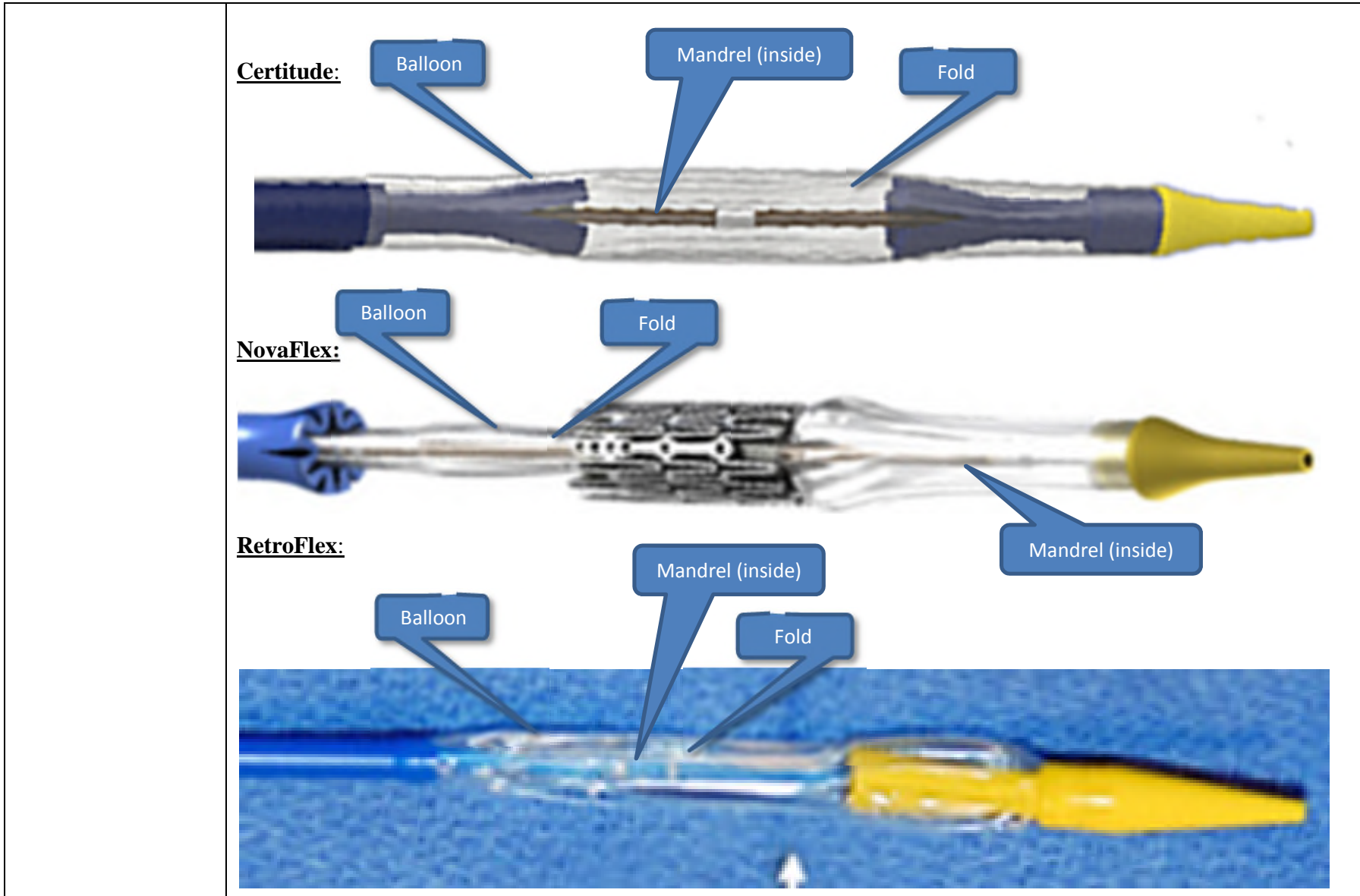
**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**



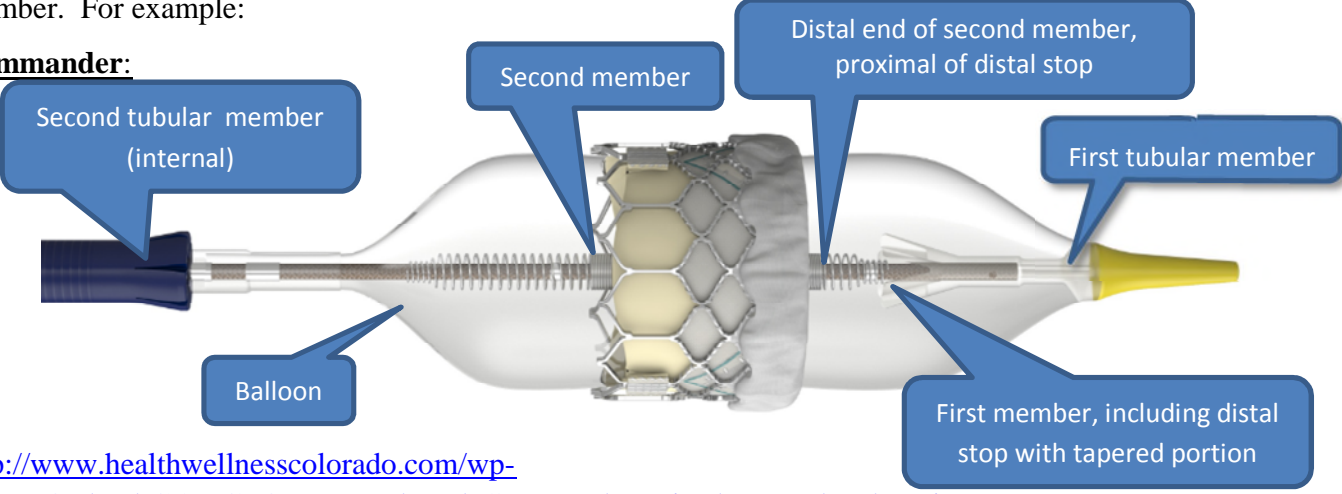
**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**

Claim 12	
Element	Accused Products
[12 preamble] The method of claim 5,	As shown in connection with claim 5, Edwards made and/or makes each of the accused products using the patented method detailed in claim 5. <i>See</i> claim chart for claim 5, above.
[12a] further comprising providing a mandrel, the balloon cylinder being disposed about the mandrel while incorporating the at least one fold.	<p>In each of the accused products, Edwards provides a mandrel inside the catheter, and a balloon cylinder disposed about the mandrel when incorporating the at least one fold.</p> <p><u>Commander:</u></p>  <p align="center"><u>Balloon and Distal Tip</u></p> <p><u>Ascendra:</u></p> 

**Ex. G: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 7,828,767 By Edwards**



**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

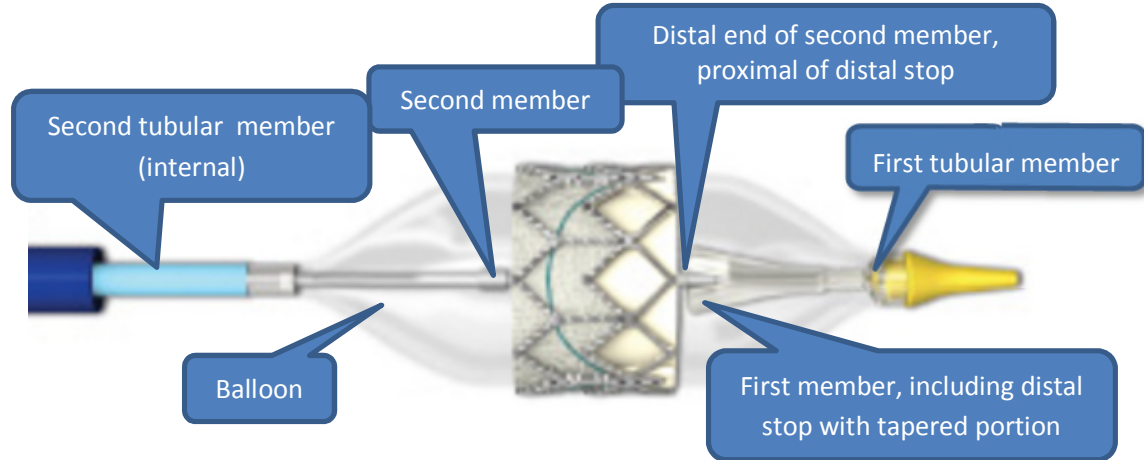
Claim 1	
Element	Accused Products
<p>[1 preamble¹] A medical device, comprising:</p>	<p>To the extent the preamble is deemed a limitation, on information and belief, Edwards made, used, offered to sell, and/or sold in the United States, and/or imported into the United States its Commander Delivery System (“Commander”), Ascendra Delivery System (“Ascendra”), Certitude Delivery System (“Certitude”), NovaFlex Delivery System (“NovaFlex”), and RetroFlex Delivery System (“RetroFlex”), each of which are medical devices for delivery and deployment of its Sapien 3, and/or Sapien XT products.²</p>
<p>[1a] an elongate shaft including a first tubular member and a second tubular member;</p>	<p>Each of the accused products have an elongate shaft including a first tubular member and a second tubular member. For example:</p> <p>Commander:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

¹ The designations in square brackets before the claim language in each row is added to permit convenient reference to specific claim language. These added designations are not part of the claim language and are not intended to limit the claims in any way. No interpretation is intended to be conveyed by the words grouped together with each designation.

² The Sapien 3, Sapien XT, and Sapien, and their corresponding delivery systems, are collectively referred to herein as the “Sapien products.” On information and belief, unless otherwise noted, any differences between various versions or models of the delivery systems identified herein or between the Sapien 3, Sapien XT, and Sapien are immaterial to the assertions set forth herein.

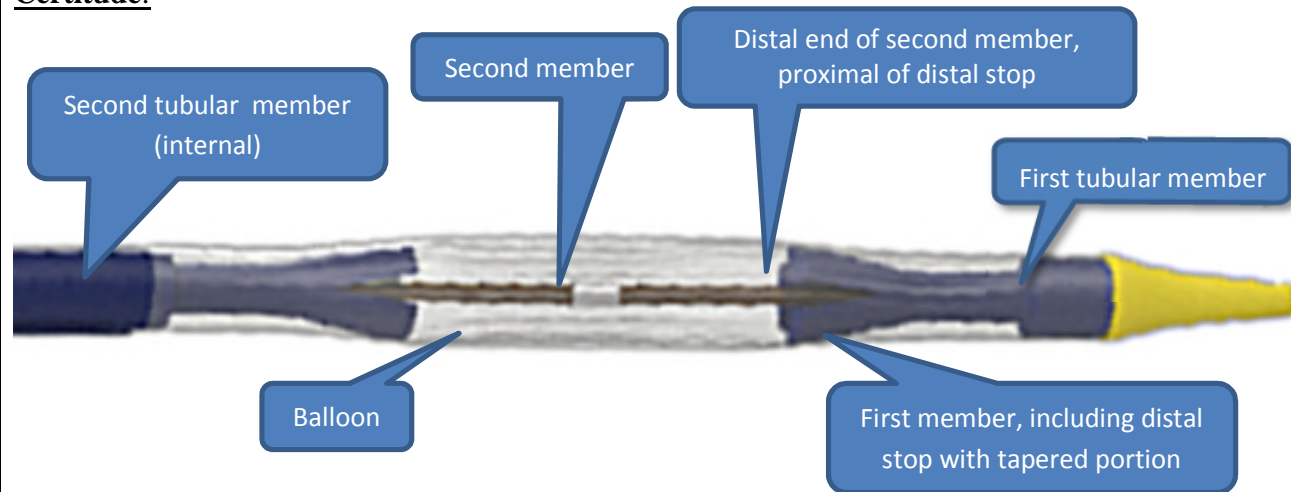
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Ascendra:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>

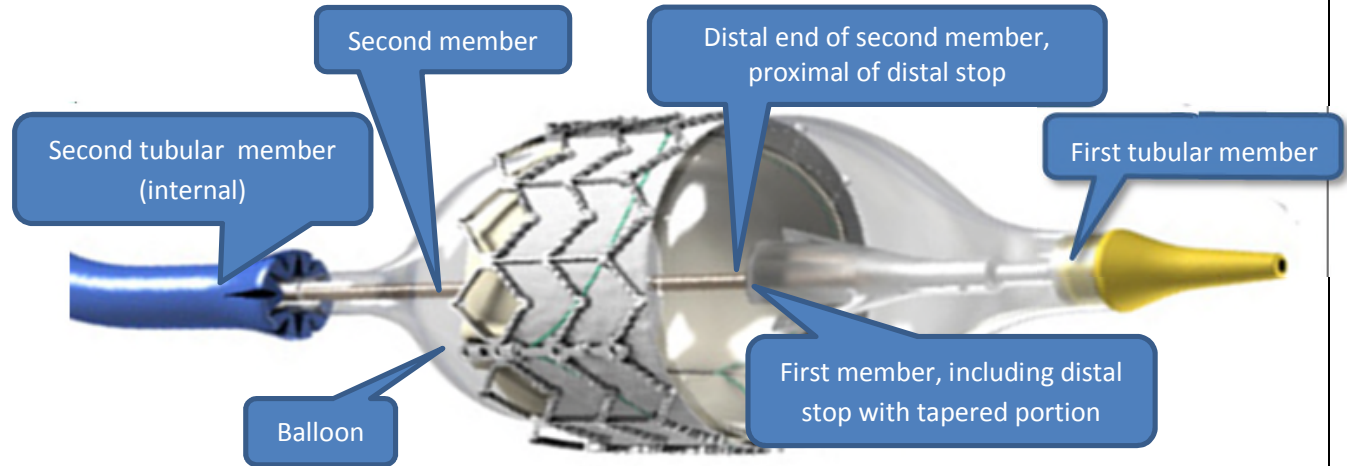
Certitude:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>

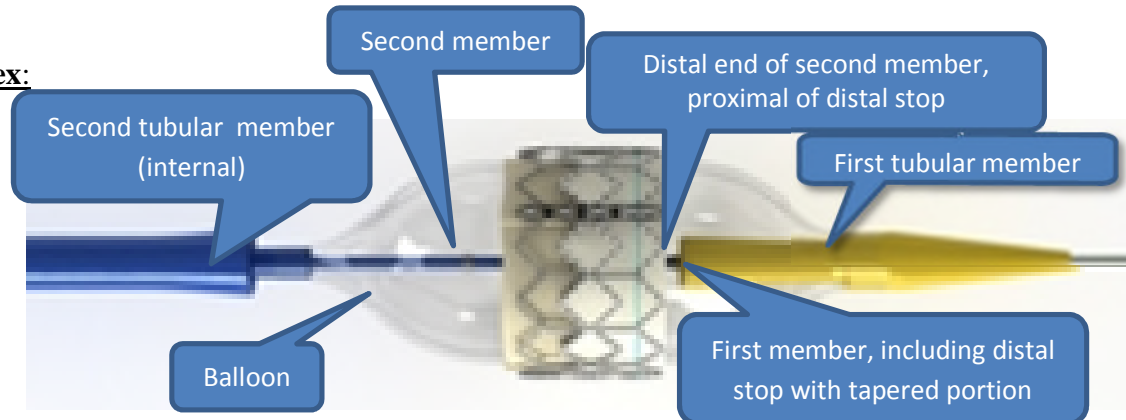
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

NovaFlex:



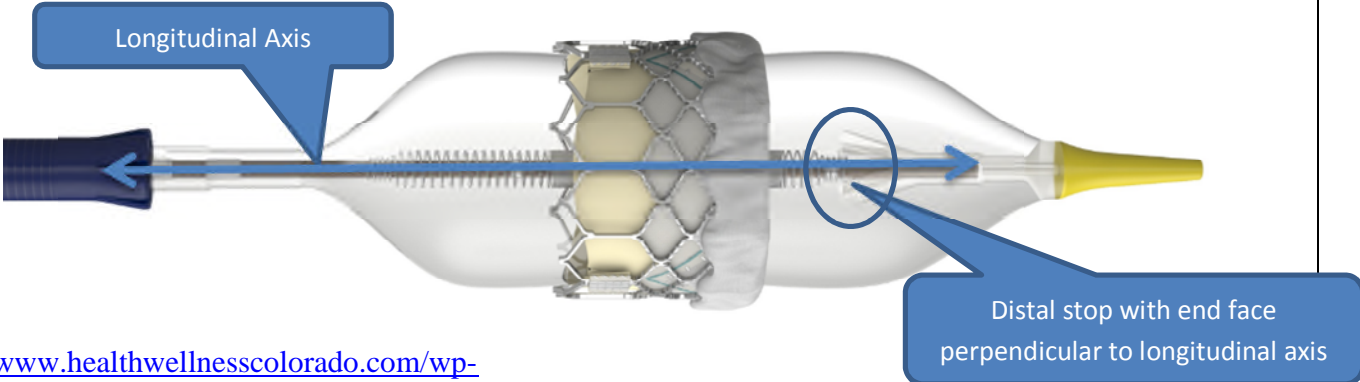
<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>

RetroFlex:



<http://www.edwards.com/eu/newsroom/Pages/showpr.aspx?PageGuid=%7B1981375d-3f20-4ada-9bb3-69aa519b1d81%7D>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

<p>[1b] a balloon coupled to the shaft;</p>	<p>As shown above, each of the accused products has a balloon coupled to the shaft.</p>
<p>[1c] a first member coupled to the first tubular member and positioned within the balloon, the first member including a distal stop with a tapered distal portion;</p>	<p>As shown above, each of the accused products has a first member, including a distal stop with a tapered distal portion, coupled to the first tubular member and positioned within the balloon.</p>
<p>[1d] wherein the distal stop includes a proximal end face extending substantially perpendicular to a longitudinal axis of the elongate shaft;</p>	<p>The distal stop on each of the accused products includes a proximal end face that is substantially perpendicular to the longitudinal axis of the elongate shaft. For example:</p> <p><u>Commander:</u></p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

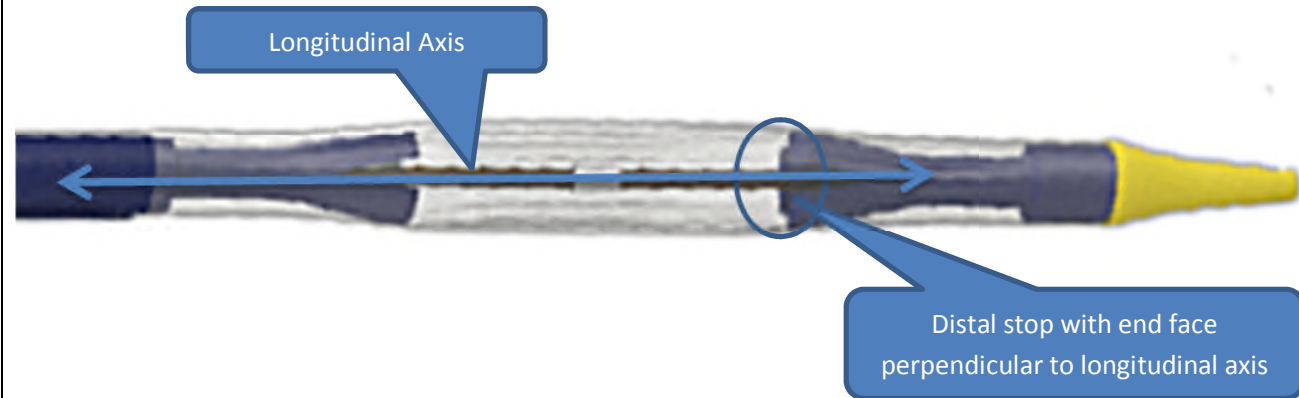
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Ascendra:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>

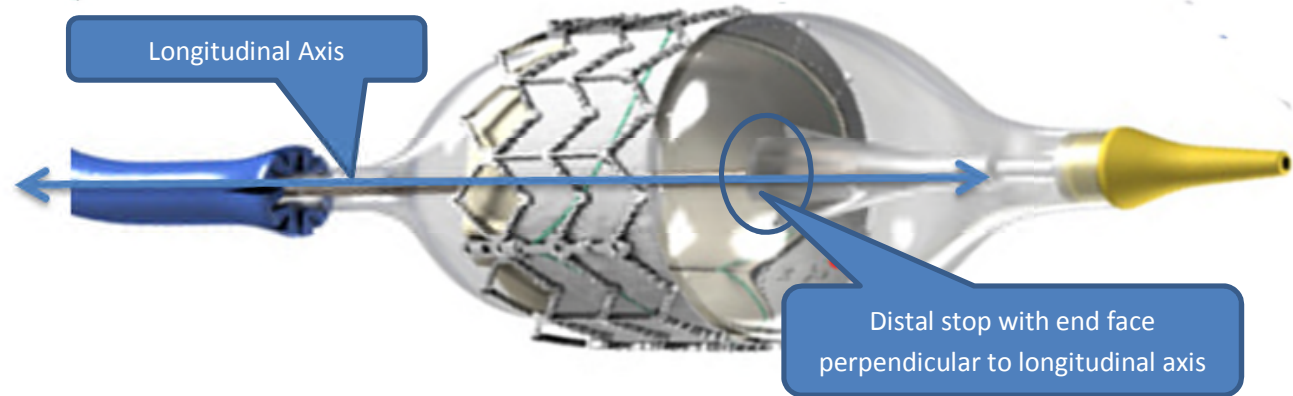
Certitude:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>

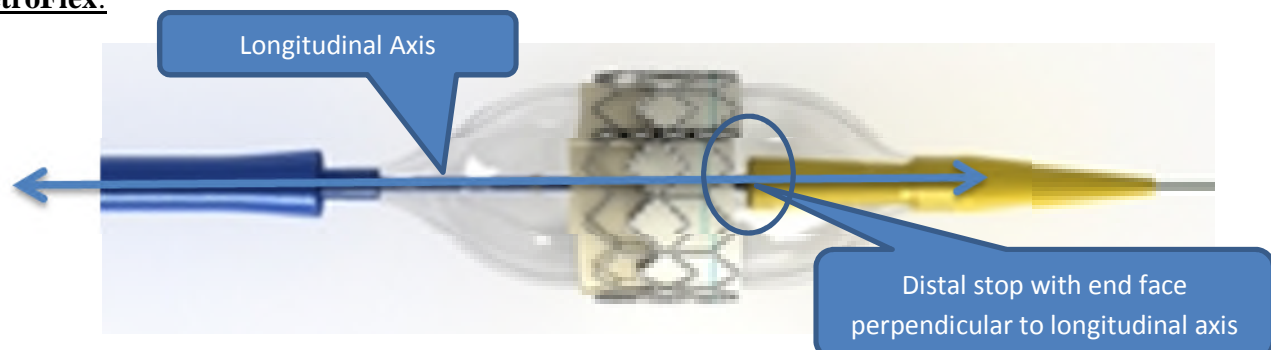
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

NovaFlex:




<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>

RetroFlex:



<http://www.edwards.com/eu/newsroom/Pages/showpr.aspx?PageGuid=%7B1981375d-3f20-4ada-9bb3-69aa519b1d81%7D>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
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<p>[1e] a second member coupled to the first tubular member and positioned within the balloon, the second member having a distal end disposed proximal of the distal stop; and,</p>	<p>As shown above (<i>see</i> [1a]), each of the accused products has second member with a distal end disposed proximal of the distal stop, coupled to the first tubular member, and positioned within the balloon.</p>
<p>[1f] a medical implant coupled to the shaft and positioned adjacent to the balloon.</p>	<p>Each accused product has a medical implant (such as the Sapien 3 or Sapien XT products) coupled to the shaft and positioned adjacent to the balloon. For example:</p> <p><u>Commander:</u></p>  <p>Edwards Commander System</p> <p>http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx</p>

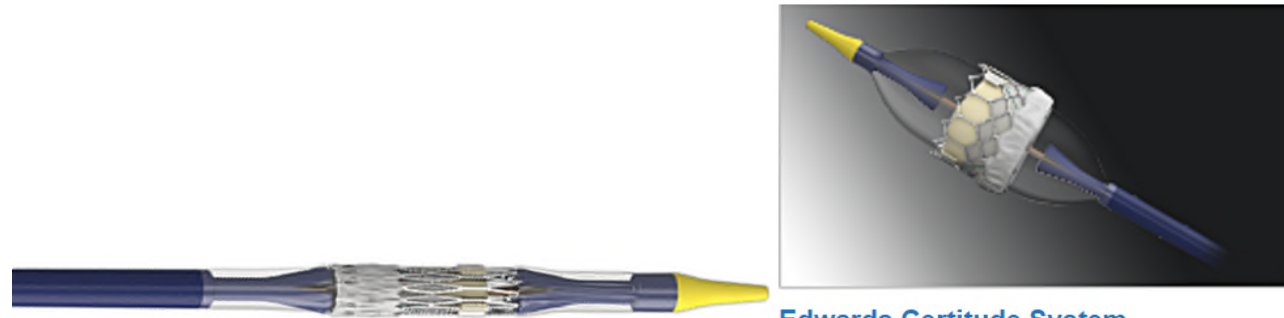
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Ascendra:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>

Certitude:



Edwards Certitude System

<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>

<http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

NovaFlex:

NovaFlex+ Transfemoral System

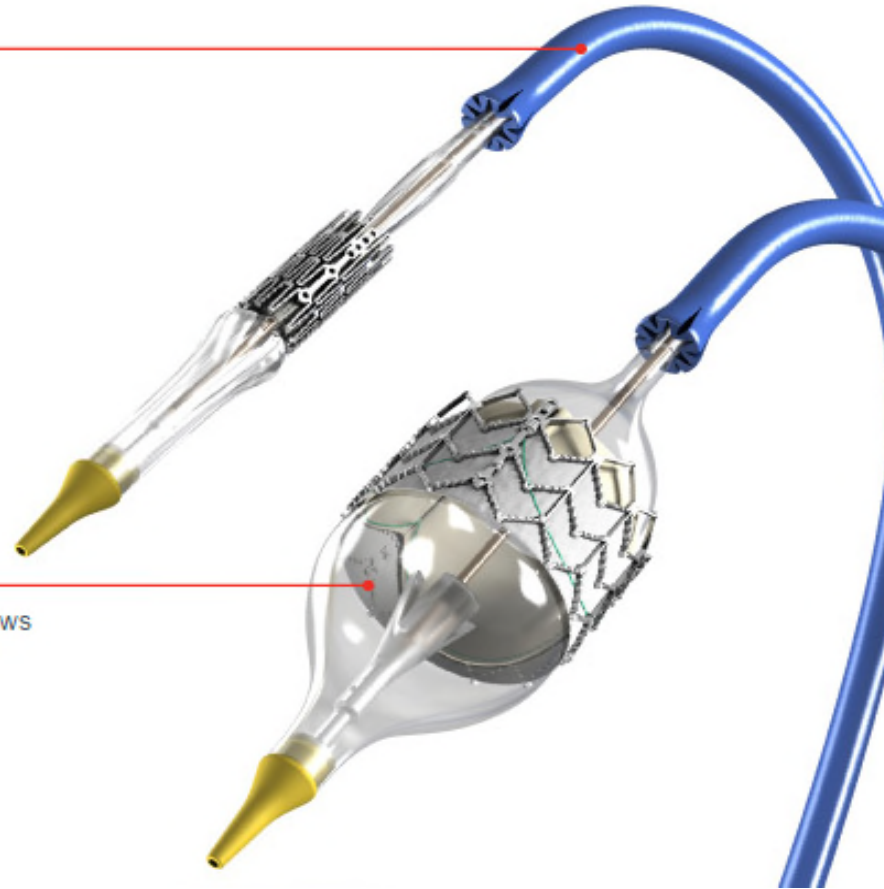
Control

Flex catheter stabilizes balloon shaft during deployment



Precision

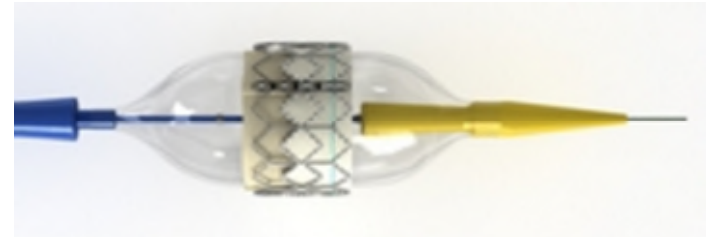
Balloon-expandable design allows for user-controlled inflation and precise delivery



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>

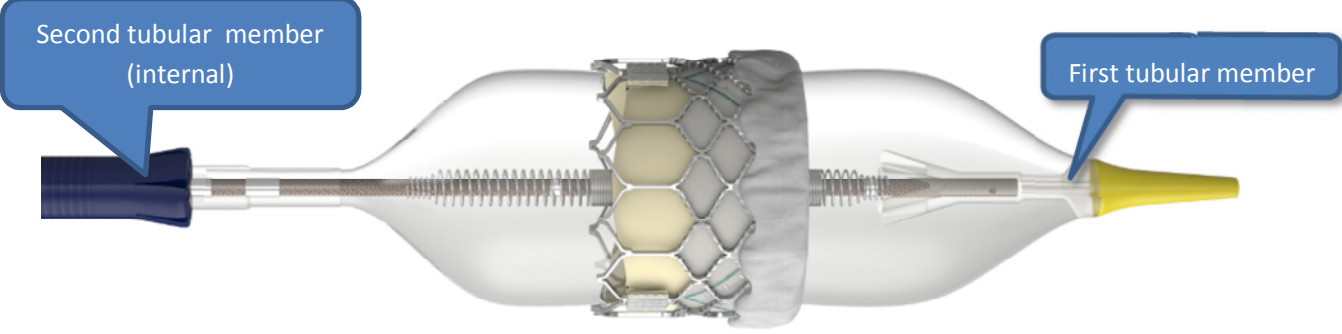

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

RetroFlex:



<http://www.edwards.com/eu/newsroom/Pages/showpr.aspx?PageGuid=%7B1981375d-3f20-4ada-9bb3-69aa519b1d81%7D>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Claim 2	
Element	Accused Products
[2 preamble] The medical device of claim 1:	As shown in connection with claim 1, each of the accused products include all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[2a] wherein the first tubular member is an inner tubular member and wherein the second tubular member is an outer tubular member.	<p>Each of the accused products has an inner first tubular member and an outer second tubular member. For example:</p> <p>Commander:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p> <p>Ascendra:</p>  <p>http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx</p>

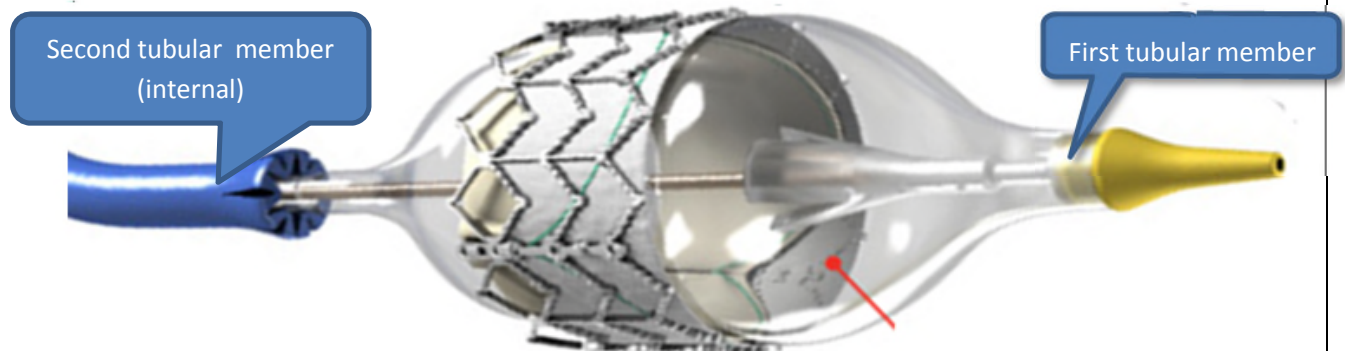
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Certitude:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>

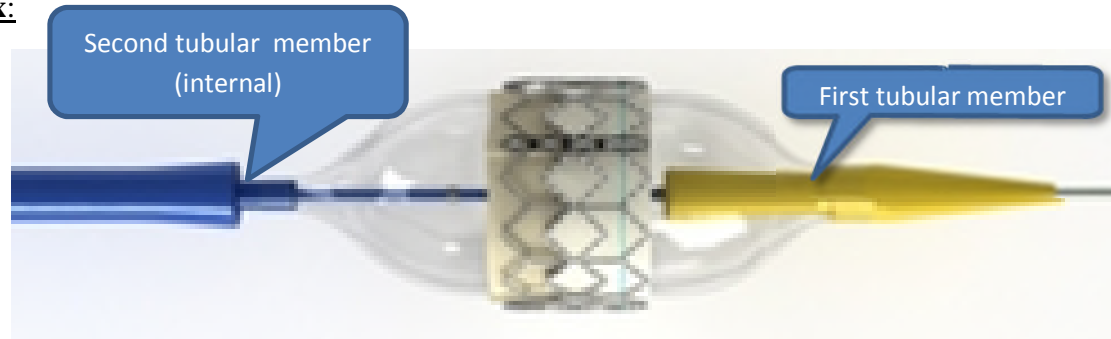
NovaFlex:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>

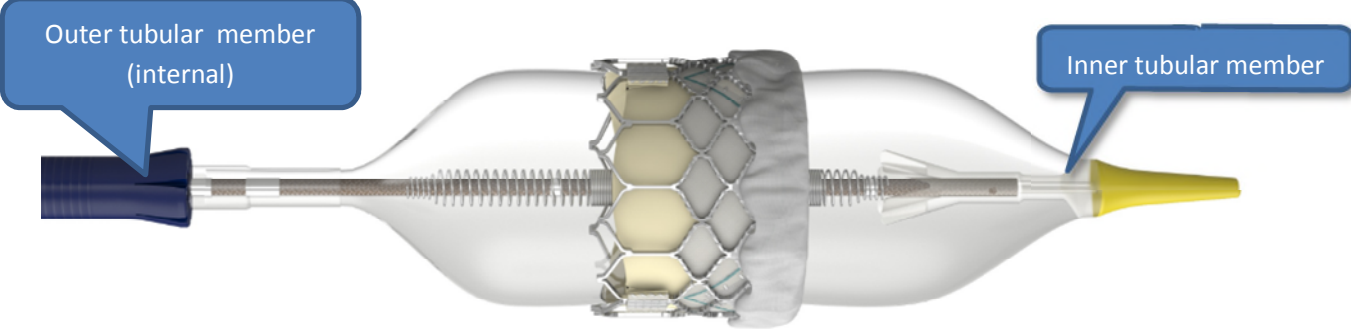

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
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RetroFlex:



<http://www.edwards.com/eu/newsroom/Pages/showpr.aspx?PageGuid=%7B1981375d-3f20-4ada-9bb3-69aa519b1d81%7D>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Claim 3	
Element	Accused Products
[3 preamble] The medical device of claim 1:	As shown in connection with claim 1, each of the accused products include all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[3a] wherein an inflation lumen is defined between the inner tubular member and the outer tubular member, the inflation lumen being in fluid communication with the balloon.	<p>In each of the accused products, an inflation lumen is defined between the inner and outer tubular members and is in fluid communication with the balloon. For example:</p> <p>Commander:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p> <p>Ascendra:</p>  <p>http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx</p>

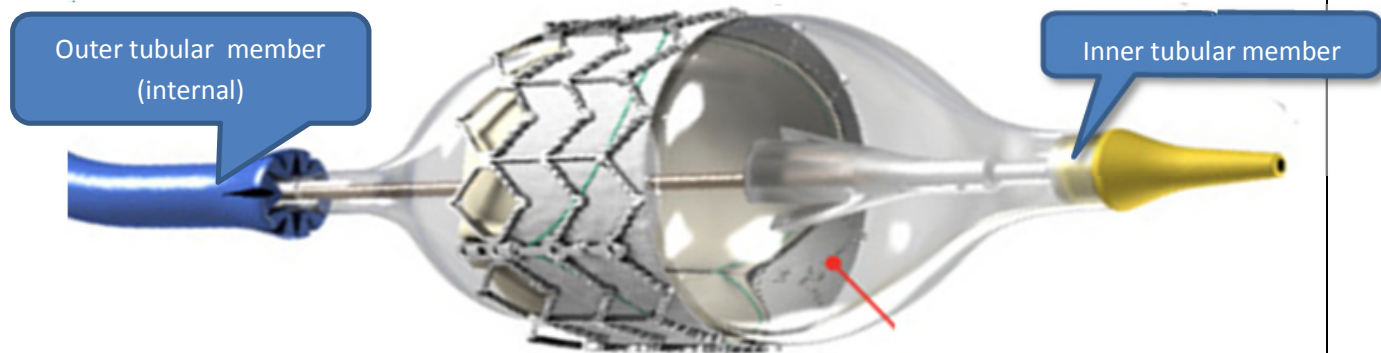
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Certitude:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>

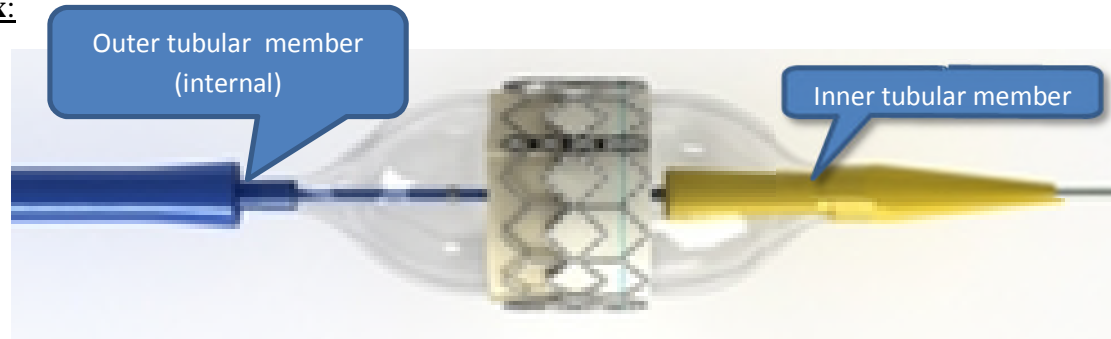
NovaFlex:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>

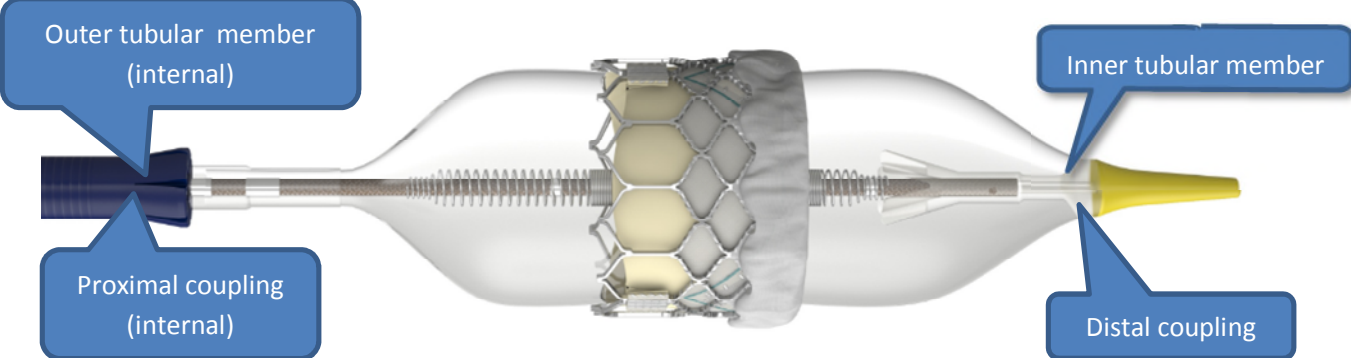
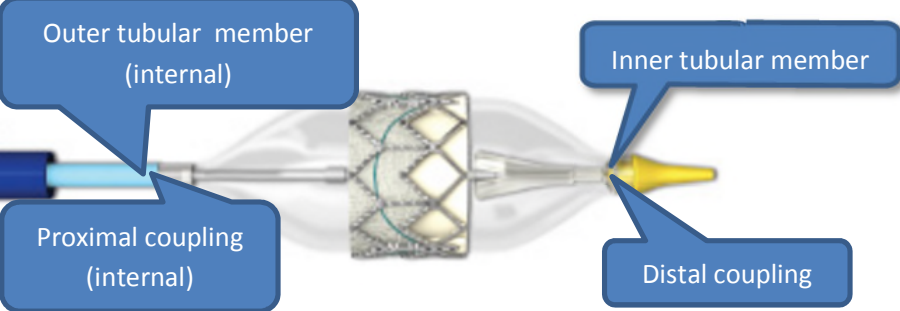
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

RetroFlex:



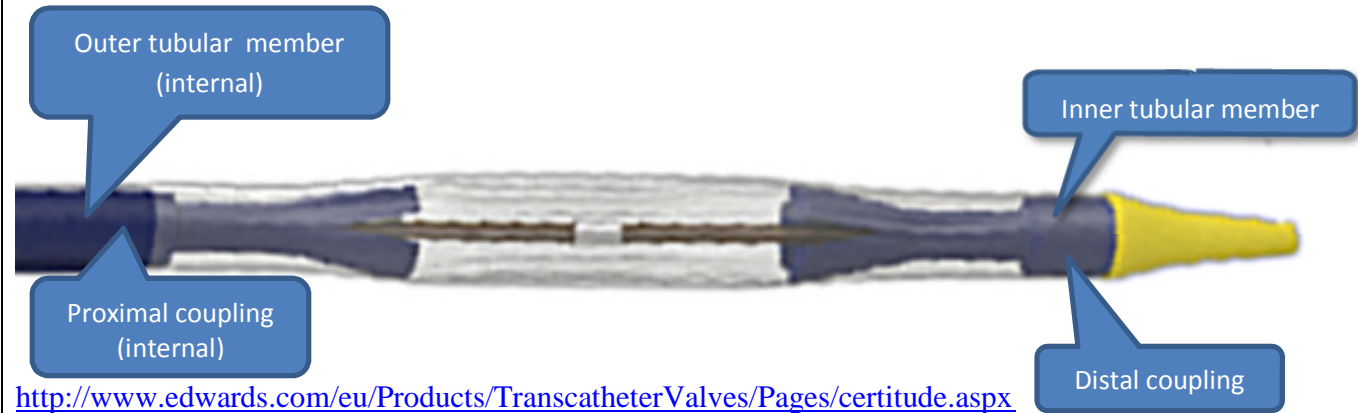
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**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

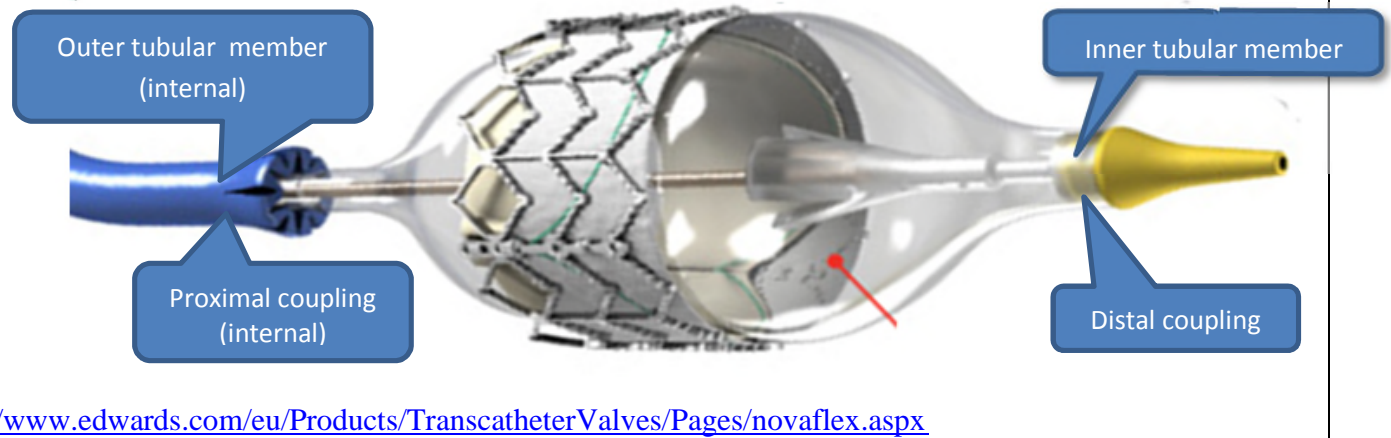
Claim 4	
Element	Accused Products
[4 preamble] The medical device of claim 3:	As shown in connection with claim 3, each of the accused products include all elements of claim 3. <i>See</i> claim chart for claim 3, above.
[4a] wherein the balloon has a proximal portion coupled to the outer tubular member and wherein the balloon has a distal portion coupled to the inner tubular member.	<p>In each of the accused products, the proximal portion of the balloon is coupled to the outer tubular member and the distal portion of the balloon is coupled to the inner tubular member. For example:</p> <p>Commander:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p> <p>Ascendra:</p>  <p>http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx</p>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

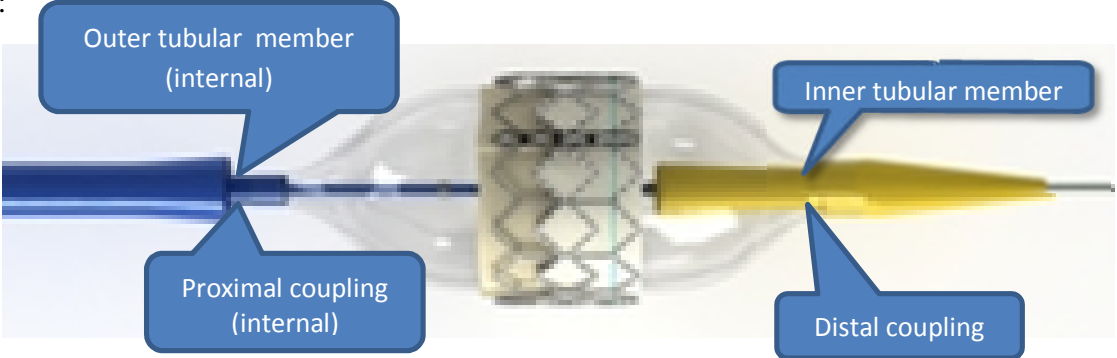
Certitude:



NovaFlex:



**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

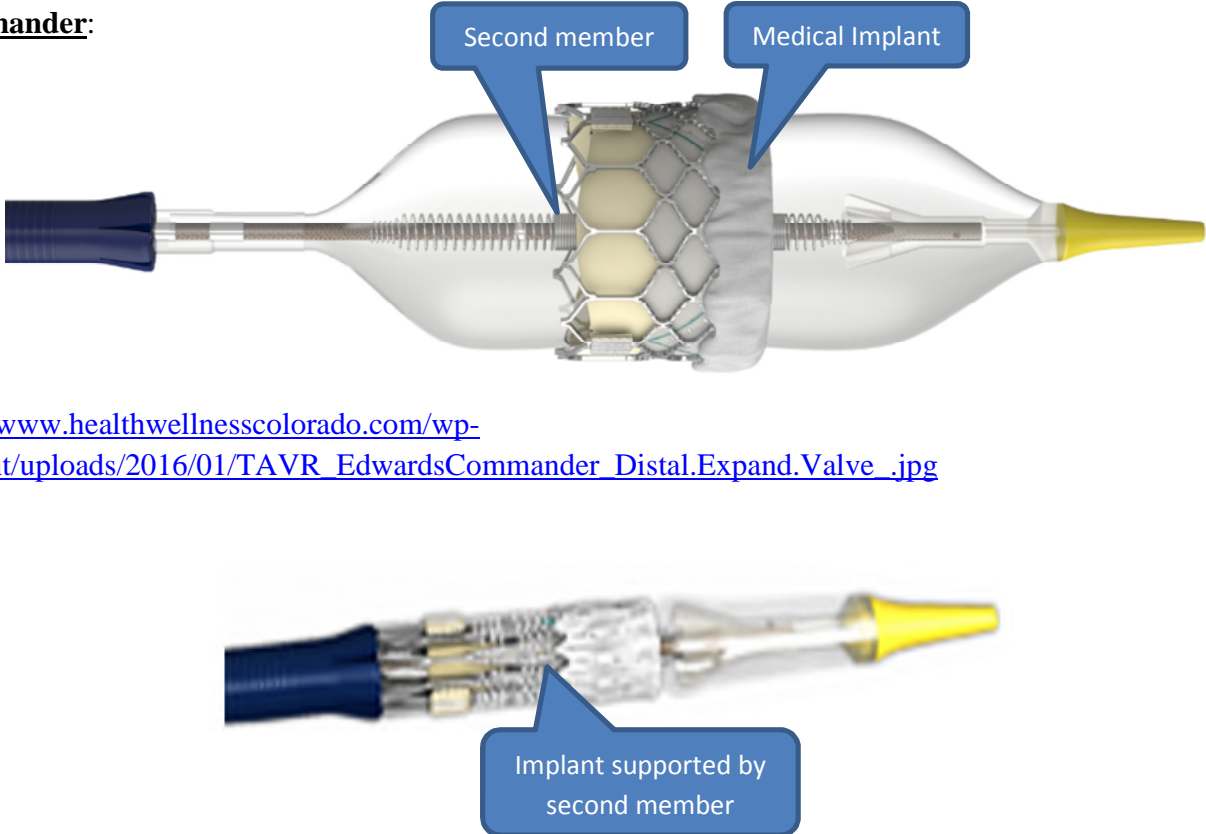
	<p><u>RetroFlex:</u></p>  <p>http://www.edwards.com/eu/newsroom/Pages/showpr.aspx?PageGuid=%7B1981375d-3f20-4ada-9bb3-69aa519b1d81%7D</p>
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Claim 5	
Element	Accused Products
[5 preamble] The medical device of claim 4:	As shown in connection with claim 4, each of the accused products include all elements of claim 4. <i>See</i> claim chart for claim 4, above.
[5a] wherein the proximal portion of the balloon is adhesively bonded to the outer tubular member.	On information and belief, in each of the accused products, the proximal portion of the balloon is adhesively bonded to the outer tubular member.

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

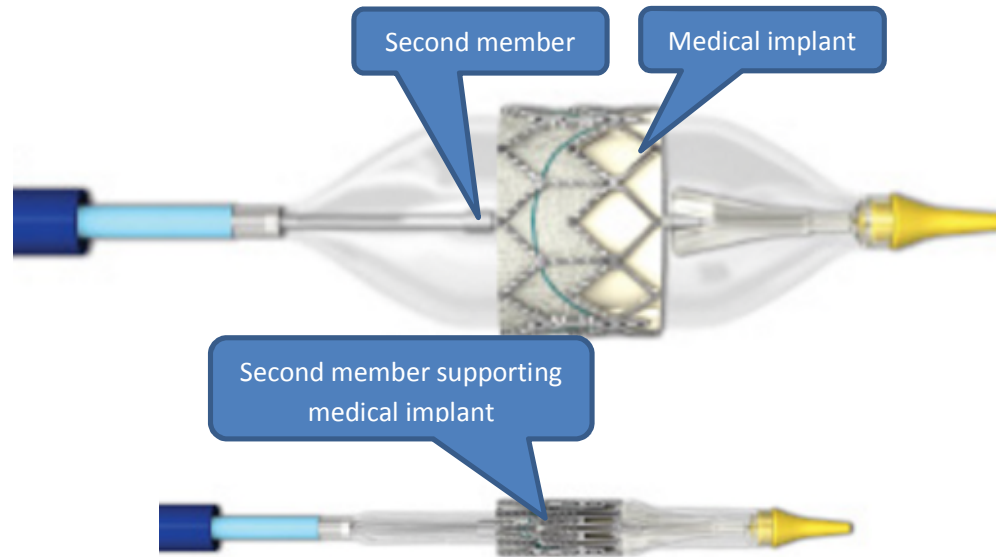
Claim 6	
Element	Accused Products
[6 preamble] The medical device of claim 4:	As shown in connection with claim 4, each of the accused products include all elements of claim 4. <i>See</i> claim chart for claim 4, above.
[6a] wherein the distal portion of the balloon is adhesively bonded to the inner tubular member.	On information and belief, in each of the accused products, the distal portion of the balloon is adhesively bonded to the inner tubular member.

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Claim 7	
Element	Accused Products
[7 preamble] The medical device of claim 1:	As shown in connection with claim 1, each of the accused products include all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[7a] wherein the second member is a support member configured to support the medical implant.	<p>Each of the accused products have a second member configured to support the medical implant. For example:</p> <p><u>Commander:</u></p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p> <p>http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx</p>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

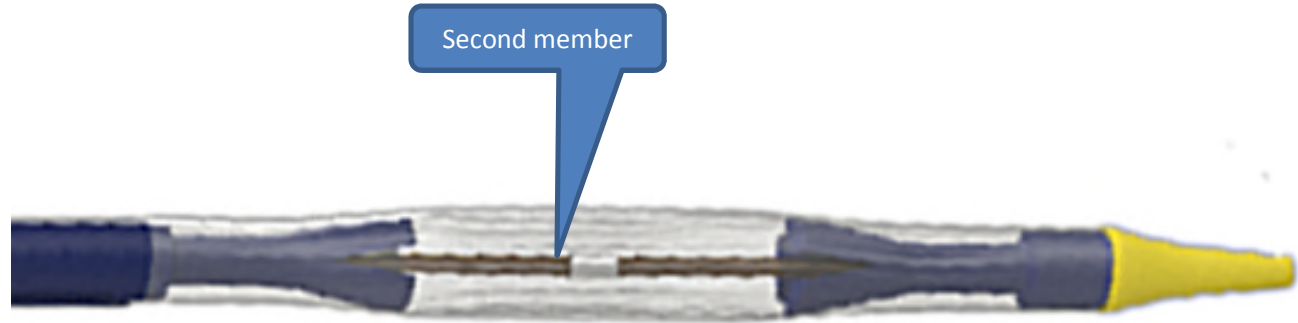
Ascendra:



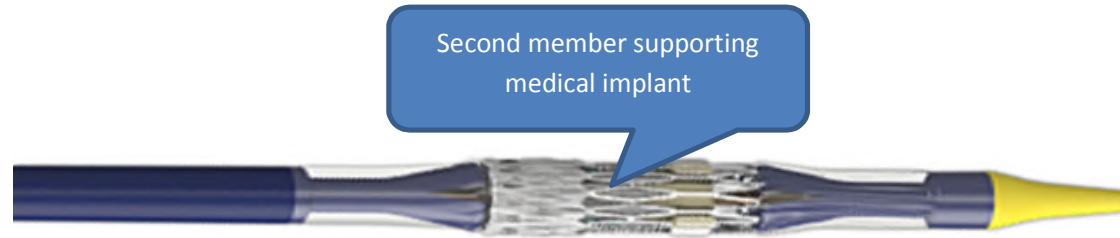
<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Certitude:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>



<http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx>

Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards

NovaFlex:

NovaFlex+ Transfemoral System

Control

Flex catheter stabilizes balloon shaft during deployment

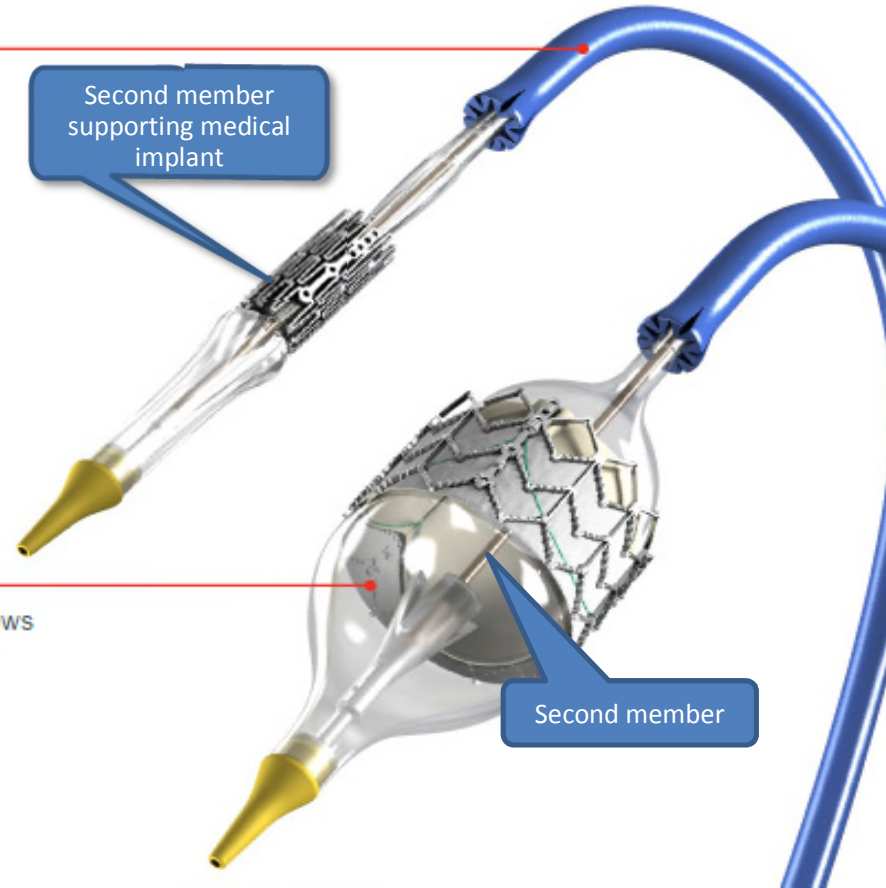


Second member supporting medical implant

Precision

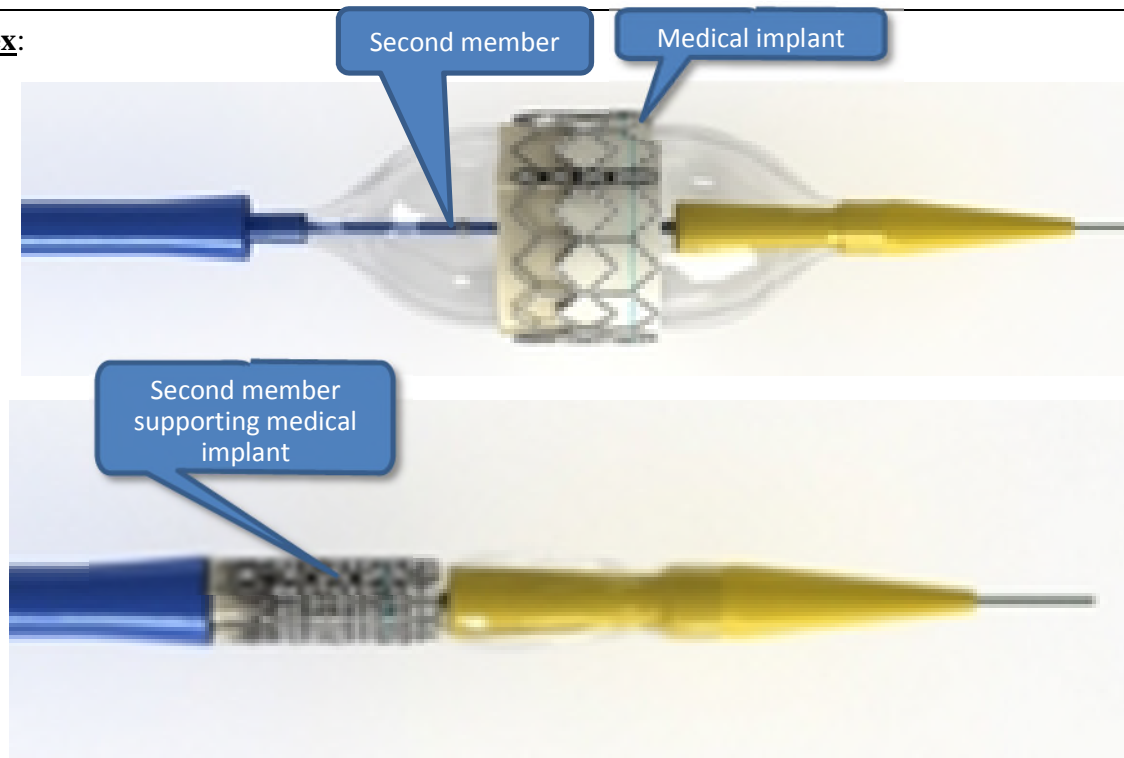
Balloon-expandable design allows for user-controlled inflation and precise delivery

Second member



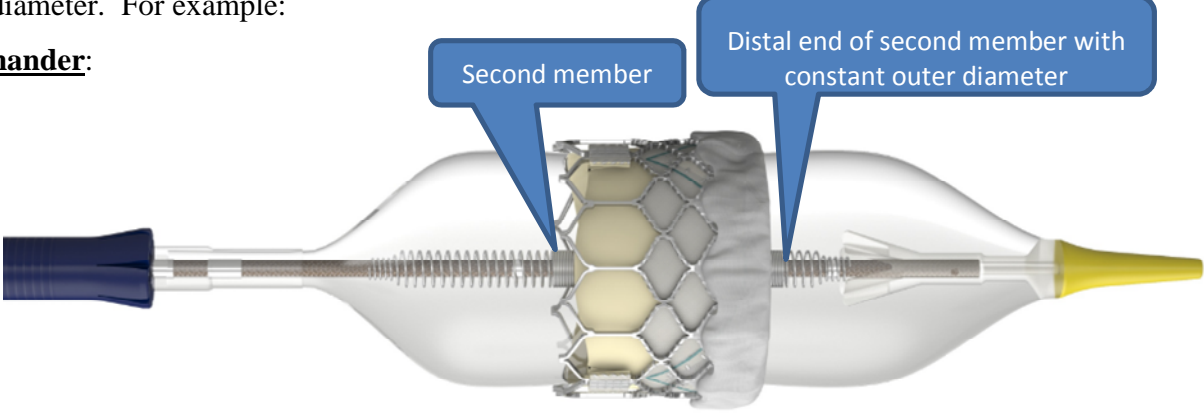
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

RetroFlex:



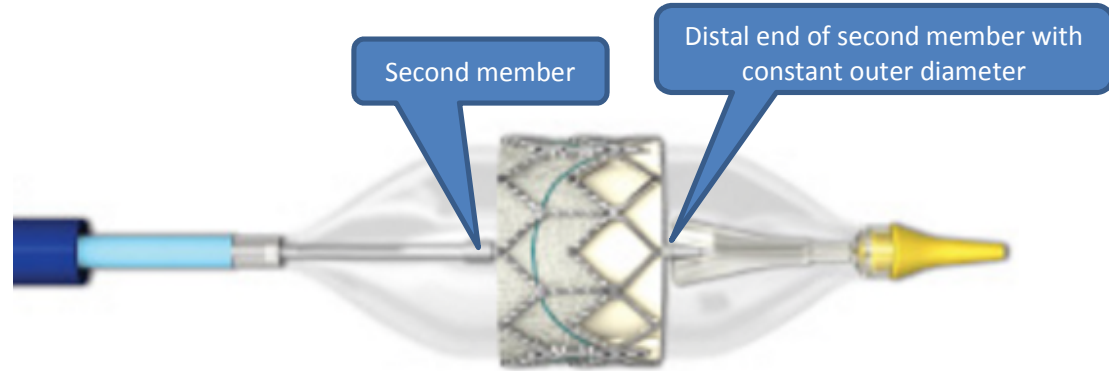
<http://www.edwards.com/eu/newsroom/Pages/showpr.aspx?PageGuid=%7B1981375d-3f20-4ada-9bb3-69aa519b1d81%7D>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Claim 8	
Element	Accused Products
[8 preamble] The medical device of claim 1:	As shown in connection with claim 1, each of the accused products include all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[8a] wherein the second member includes a distal portion having a substantially constant outer diameter.	<p>Each of the accused products have a second member, the distal portion of which has a substantially constant outer diameter. For example:</p> <p><u>Commander:</u></p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

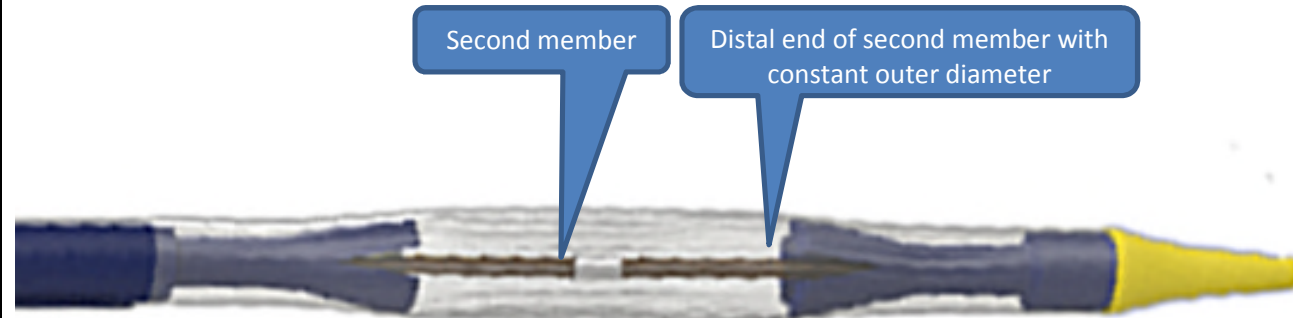
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
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Ascendra:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>

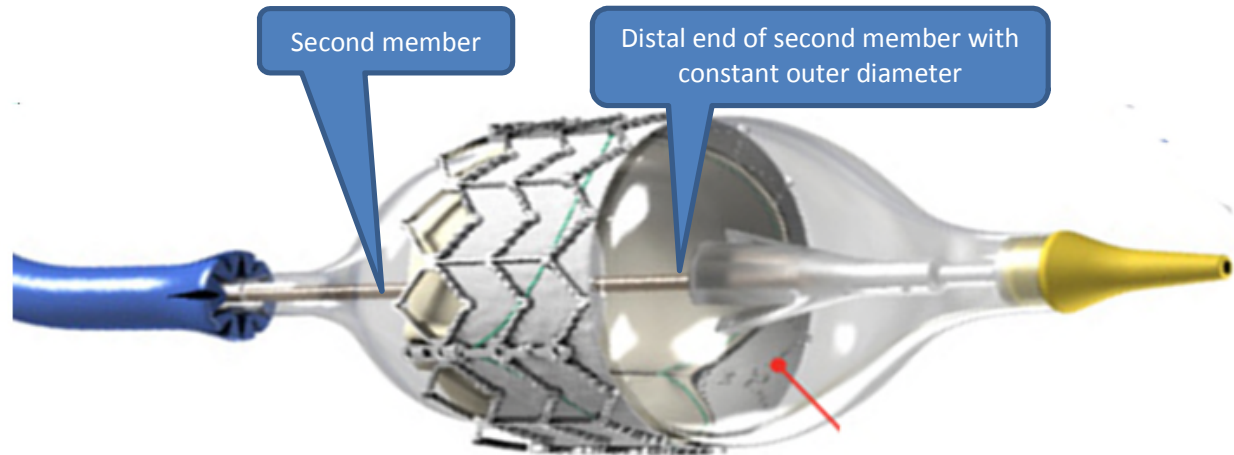
Certitude:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>

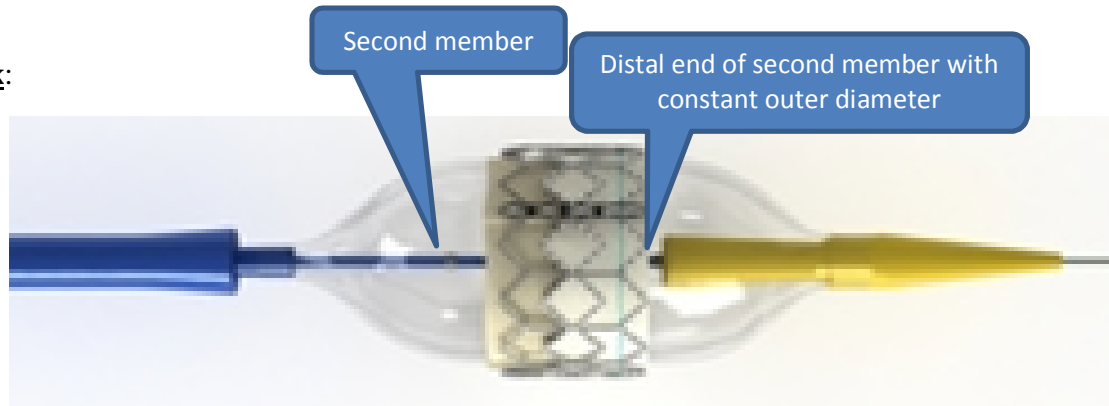
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

NovaFlex:



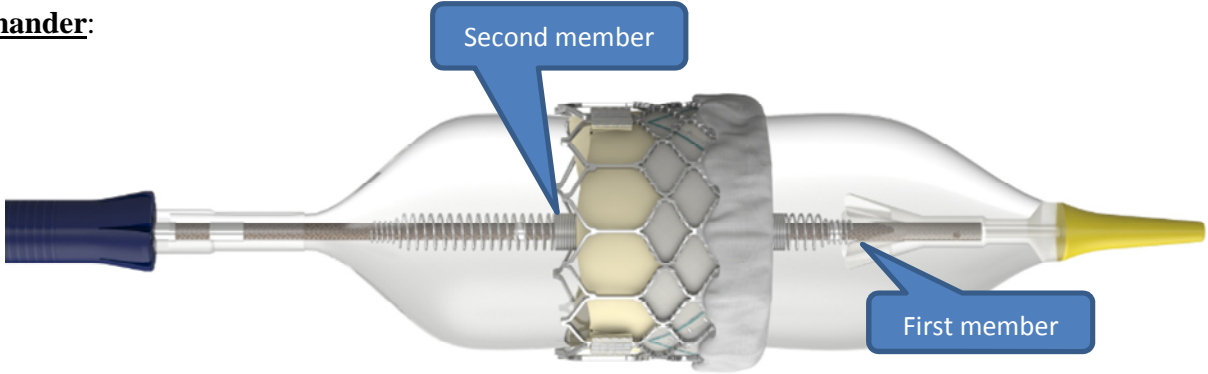
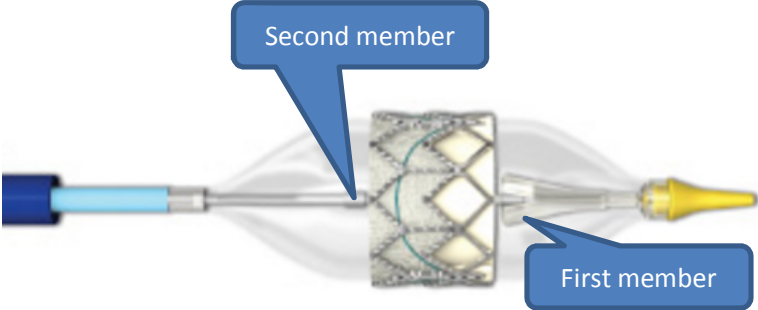
<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>

RetroFlex:



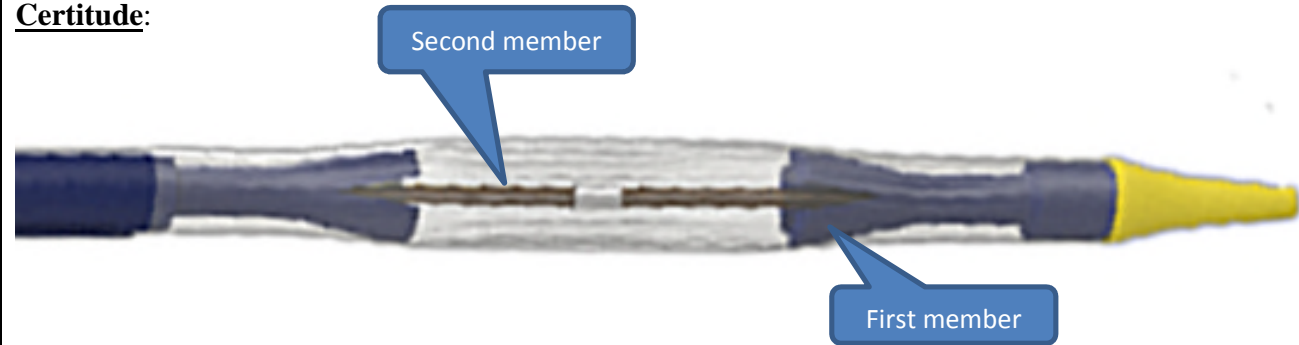
<http://www.edwards.com/eu/newsroom/Pages/showpr.aspx?PageGuid=%7B1981375d-3f20-4ada-9bb3-69aa519b1d81%7D>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Claim 9	
Element	Accused Products
[9 preamble] The medical device of claim 1:	As shown in connection with claim 1, each of the accused products include all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[9a] wherein the first member and the second member are longitudinally spaced from each other.	<p>In each of the accused products, the first member and second member are longitudinally spaced from each other. For example:</p> <p><u>Commander:</u></p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p> <p><u>Ascendra:</u></p>  <p>http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx</p>

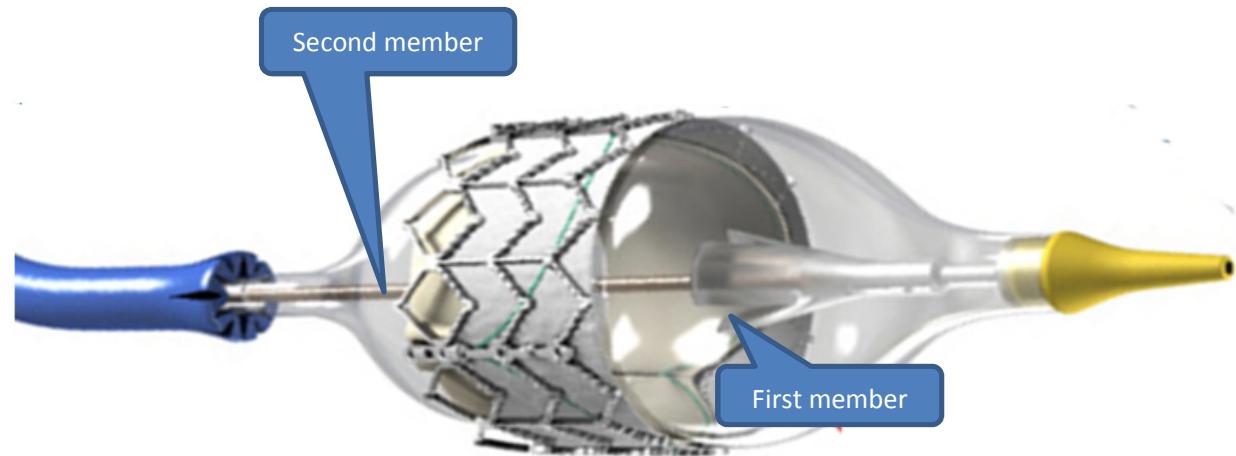
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Certitude:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>

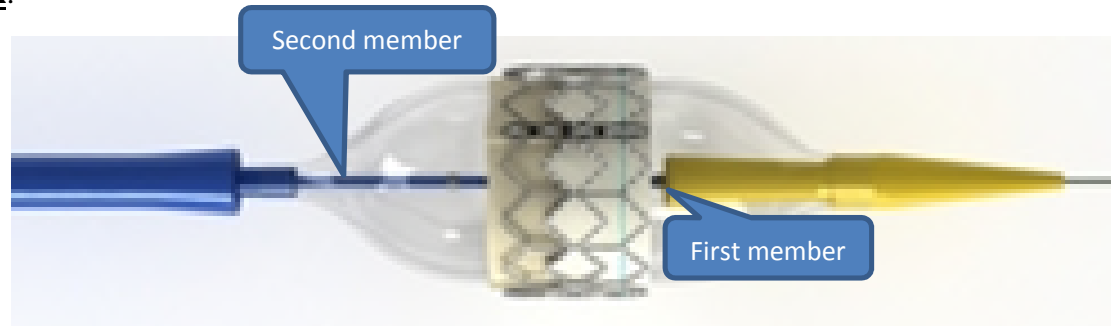
NovaFlex:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

RetroFlex:



<http://www.edwards.com/eu/newsroom/Pages/showpr.aspx?PageGuid=%7B1981375d-3f20-4ada-9bb3-69aa519b1d81%7D>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Claim 10	
Element	Accused Products
[10 preamble] The medical device of claim 1:	As shown in connection with claim 1, each of the accused products include all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[10a] wherein the medical implant includes a stent.	<p>As shown in connection with claim 1 above, each accused product has a medical implant (such as the Sapien 3 or Sapien XT products) coupled to the shaft and positioned adjacent to the balloon. <i>See</i> claim chart for claim 1f, above. For example:</p> <p>Each of the Sapien products comprises a stent. For example:</p> <p style="padding-left: 40px;">The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 <i>available at</i> http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p style="padding-left: 40px;">The Edwards SAPIEN XT transcatheter heart valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and a polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 <i>available at</i> http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.</p> <p style="padding-left: 40px;">The Edwards SAPIEN transcatheter heart valve (bioprosthesis) is comprised of a balloon-expandable, radiopaque, stainless steel (316 L) frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) fabric. The bioprosthesis is treated according to the Carpentier-Edwards ThermaFix process, packaged, and terminally sterilized in glutaraldehyde</p> <p>Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 <i>available at</i> http://www.fda.gov/downloads/Adviso...orySystemDevicesPanel/UCM262938.pdf.</p>

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

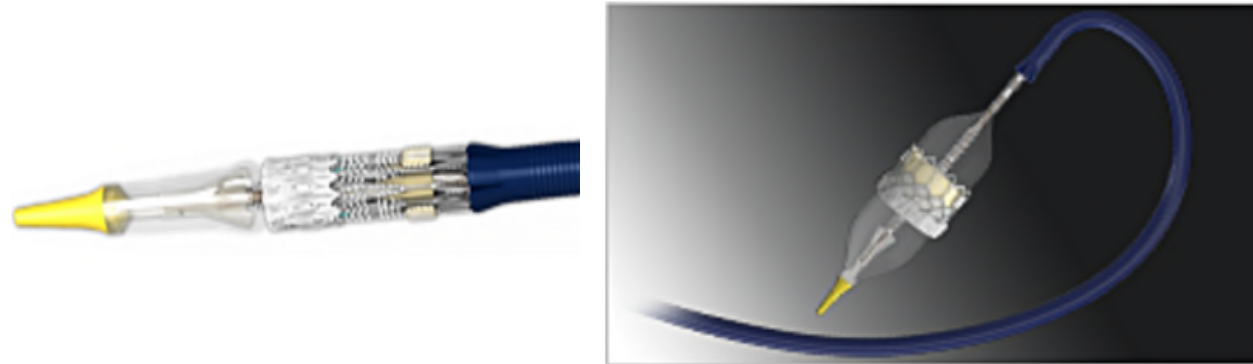
Claim 11	
Element	Accused Products
[11 preamble] The medical device of claim 1:	As shown in connection with claim 1, each of the accused products include all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[11a] wherein the medical implant is configured to be expanded by expanding the balloon.	<p>As shown in connection with claim 1 above, each accused product has a medical implant (such as the Sapien 3 or Sapien XT products) coupled to the shaft and positioned adjacent to the balloon. <i>See</i> claim chart for claim 1f, above.</p> <p>Each of the Sapien products comprises a balloon-expandable stent. For example:</p> <p style="padding-left: 40px;">The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p style="padding-left: 40px;">The Edwards SAPIEN XT transcatheter heart valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and a polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.</p> <p style="padding-left: 40px;">The Edwards SAPIEN transcatheter heart valve (bioprosthesis) is comprised of a balloon-expandable, radiopaque, stainless steel (316 L) frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) fabric. The bioprosthesis is treated according to the Carpentier-Edwards ThermaFix process, packaged, and terminally sterilized in glutaraldehyde</p>

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Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf>.

Each of the Accused Products uses a balloon to expand the stent. For example:

Commander:



Edwards Commander System

<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>

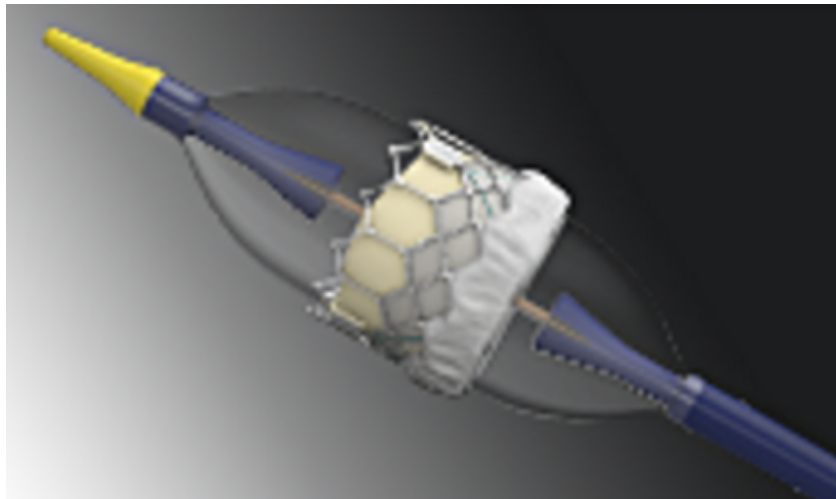
Ascendra:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/ascendraplus.aspx>

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Certitude:



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/certitude.aspx>

<http://www.edwards.com/eu/products/transcathetervalves/Pages/thvhome.aspx>

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NovaFlex:

NovaFlex+ Transfemoral System

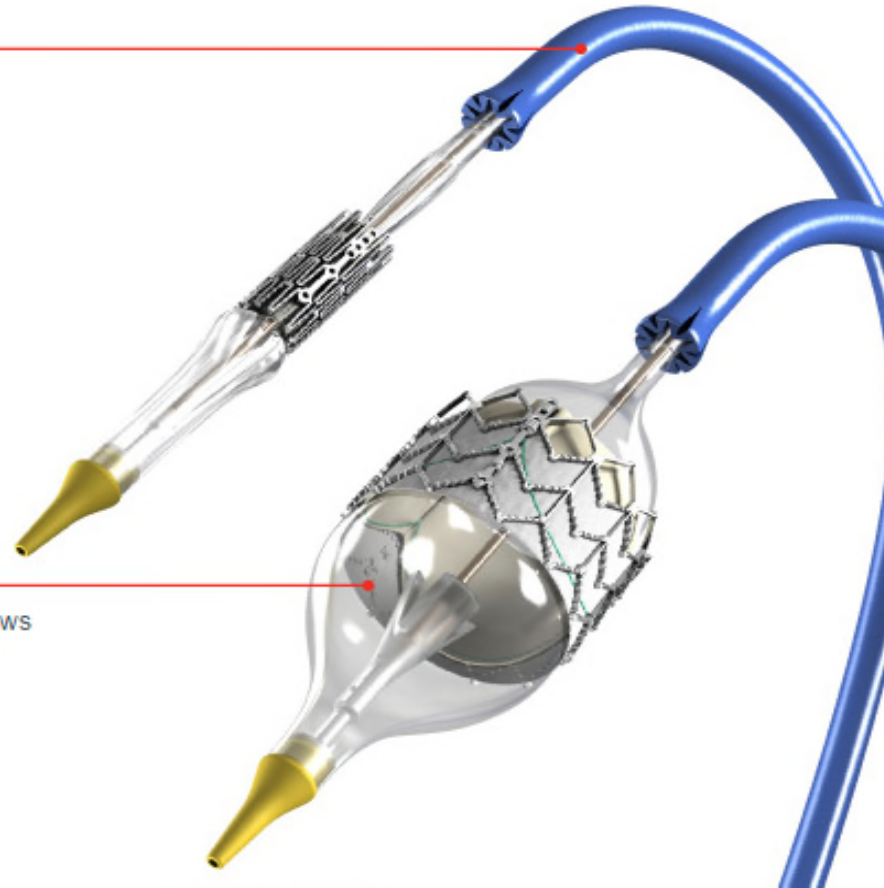
Control

Flex catheter stabilizes balloon shaft during deployment



Precision

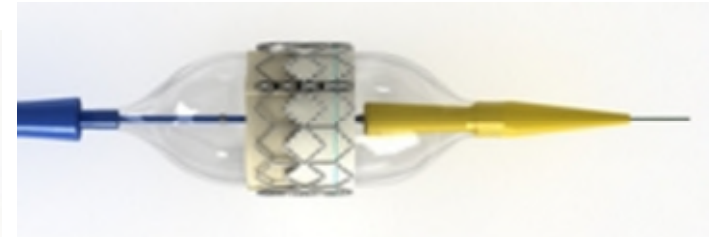
Balloon-expandable design allows for user-controlled inflation and precise delivery



<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx>

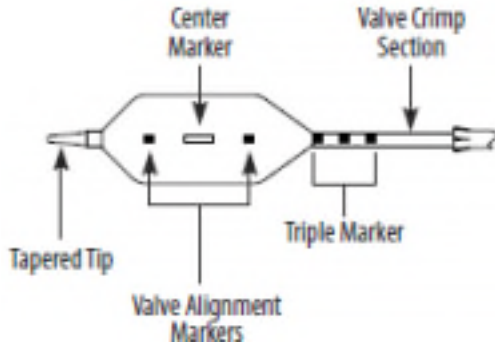
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

RetroFlex:



<http://www.edwards.com/eu/newsroom/Pages/showpr.aspx?PageGuid=%7B1981375d-3f20-4ada-9bb3-69aa519b1d81%7D>

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U.S. PATENT NO. 8,709,062 By Edwards**

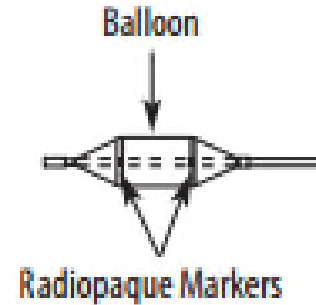
Claim 12	
Element	Accused Products
[12 preamble] The medical device of claim 1:	As shown in connection with claim 1, each of the accused products include all elements of claim 1. <i>See</i> claim chart for claim 1, above.
[12a] wherein the first member, the second member, or both include a radiopaque marker.	<p>Each of the accused products contains radiopaque markers on either the first or second members. For example:</p> <p><u>Commander:</u></p> <ul style="list-style-type: none"> • Edwards Commander Delivery System (Figure 2) <p>The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <div style="text-align: center;">  <p>The diagram shows a cross-section of the delivery system. From left to right: a tapered tip, a central marker, two valve alignment markers, a triple marker, and a valve crimp section. Arrows point from labels to each of these components.</p> </div> <p>Commander Instructions for Use, pp. 2, 3 - http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf</p>

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Ascendra:

1.0 Device Description

The Ascendra Balloon Aortic Valvuloplasty Catheter (Figure 1 on page 2) consists of a shaft and balloon with radiopaque marker bands indicating working length of the balloon. At the proximal end of the device, there is a standard "Y-connector" for balloon inflation and the guidewire lumen. An extension tubing is supplied for use with the balloon valvuloplasty catheter during inflation. The inflation parameters are as follows:



Instructions for Use, pp. 36-37

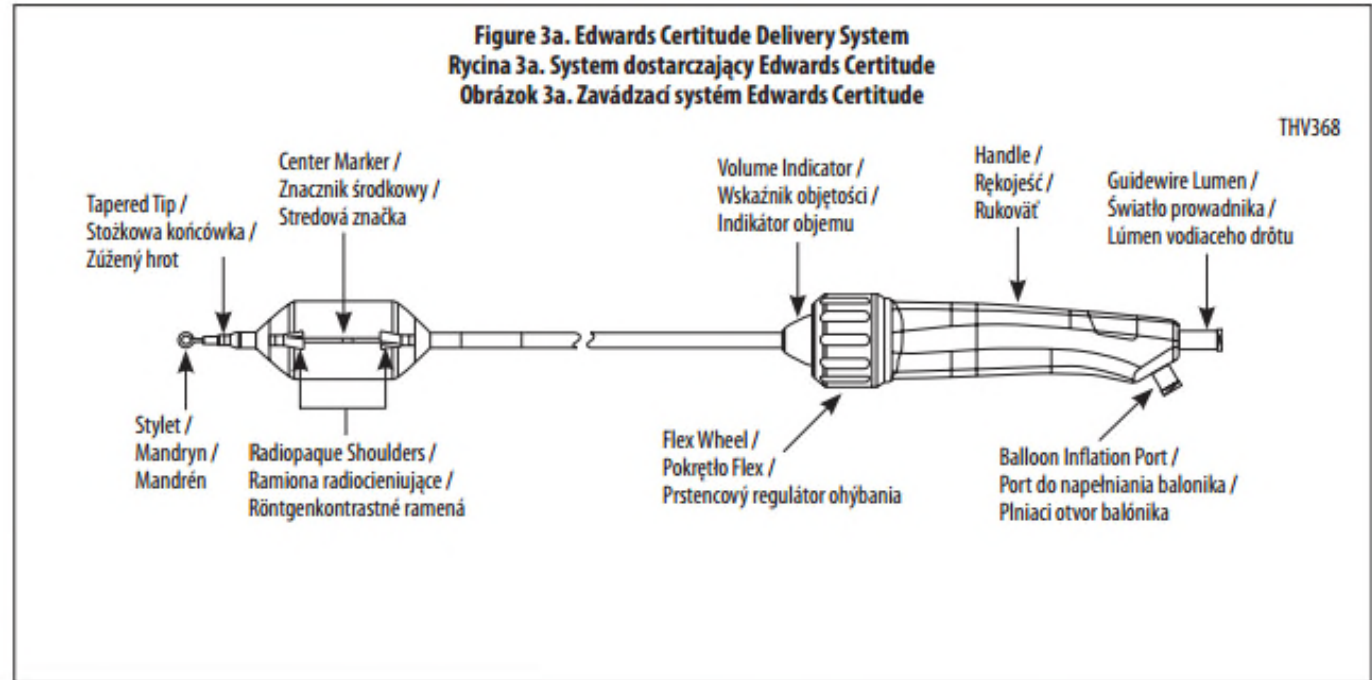
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM307362.pdf>

Certitude:

• Edwards Certitude Delivery System (Figures 3a, 3b, & 3c)

The Edwards Certitude delivery system includes a handle with a Flex Wheel for articulation of the Balloon Catheter and a Loader. The loader allows for the delivery of the crimped THV through the hemostasis valves of the sheath. Three radiopaque indicators on the catheter shaft define the position on the balloon where the THV should be crimped and also provide visualization of the balloon. The THV is crimped between the two radiopaque shoulders on the distal and proximal ends of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. An inflation and guidewire hub is housed in the handle assembly. The Qualcrimp crimping accessory (packaged with the Edwards Certitude delivery system) is used during crimping of the THV.

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Instructions for Use, pp. 1, 23

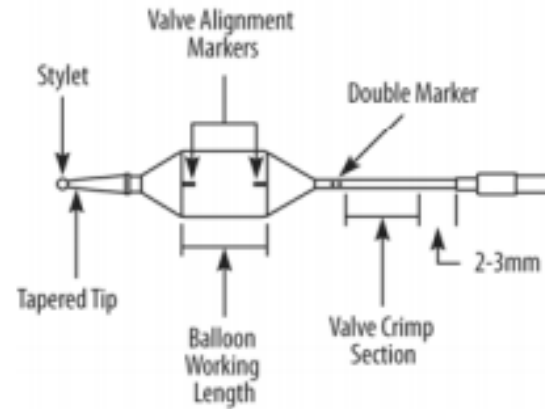
https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=0ahUKEwjRjqW00ZHOAhWTCD4KHYocC1IQFgg7MAQ&url=https%3A%2F%2Fkategorizacia.mzsr.sk%2FPomocky%2FDownload%2FRequestAttachment%2F42973&usg=AFQjCNEiQREydPqWAsSHf13pO5WFDW22tA&sig2=_3239z7hSK1BUVhfrgZ7Q&bvm=bv.127984354,d.cWw

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NovaFlex:

• **NovaFlex+ Delivery System (Figures 2a, 2b, 2c)**

The NovaFlex+ delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN XT transcatheter heart valve. The delivery system includes a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system to facilitate crossing the valve, and a balloon catheter for deployment of the THV. The handle also contains a flex indicator depicting articulation of the flex catheter, a valve alignment wheel for fine adjustment of the THV during valve alignment, a button that enables movement between handle positions, and a flush port to flush the flex catheter. The balloon catheter has radiopaque markers defining the valve alignment position and the working length of the balloon. A radiopaque double marker proximal to the balloon indicates flex catheter position during deployment. The inflation parameters for THV deployment are:



Instructions for Use, pp. 2, 3

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf

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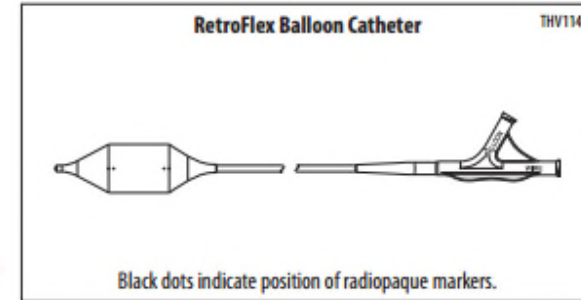
RetroFlex:

1.0 Device Description

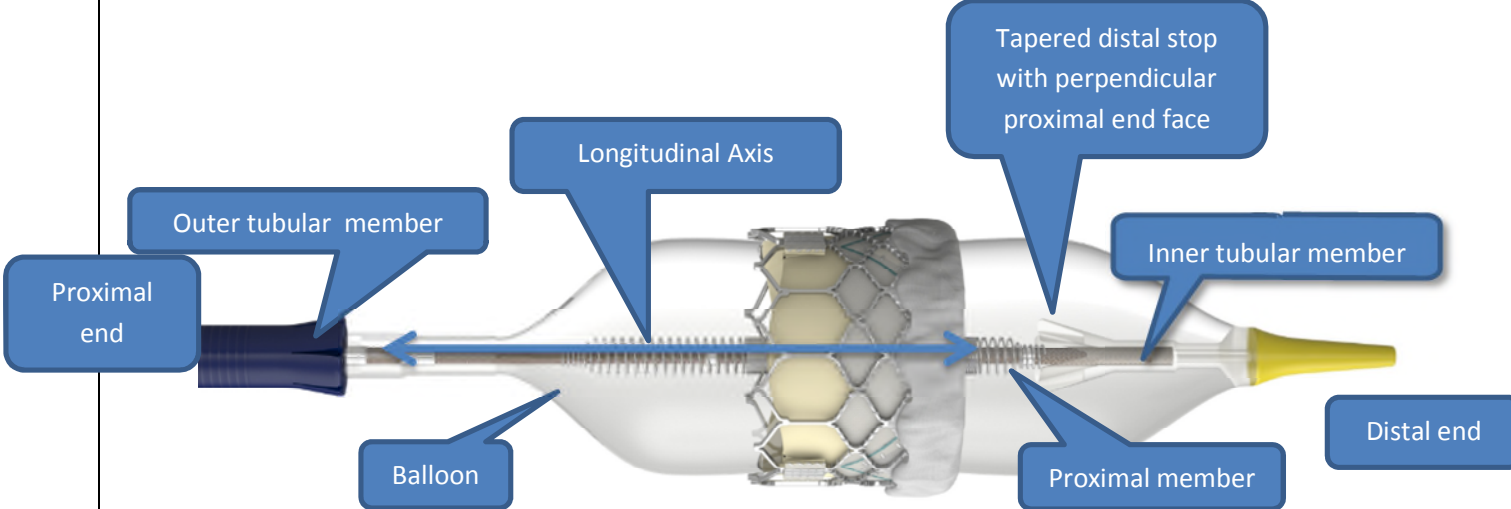
The RetroFlex Balloon Catheter consists of a shaft and balloon with radiopaque markers indicating working length of the balloon. At the proximal end of the device, there is a standard "Y-connector" for balloon inflation and the guidewire lumen. The inflation parameters are as follows:

Instructions for Use, p. 76.

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM307362.pdf> at p. 76



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Claim 13	
Element	Accused Products
[13 preamble] A system for delivering an implantable medical device, the system comprising:	As detailed above, the Commander is a catheter system for delivering implantable medical devices, such as the Sapien products.
[13a] a catheter shaft, the catheter shaft including an inner tubular member and an outer tubular member;	<p>The Commander has a catheter shaft including an inner tubular member and an outer tubular member. For example:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>
[13b] a balloon coupled to the catheter shaft;	As shown above, a balloon is coupled to the catheter shaft of the Commander.
[13c] a distal stop including a	As shown above, the Commander has a tapered distal stop attached to the inner tubular member and positioned

**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

<p>tapered distal portion attached to the inner tubular member and positioned at least partially underneath the balloon;</p>	<p>within the balloon.</p>
<p>[13d] wherein the distal stop includes a proximal end face extending substantially perpendicular to a longitudinal axis of the catheter shaft;</p>	<p>As shown above, the distal stop in the Commander includes a proximal end face perpendicular to the longitudinal axis of the catheter shaft.</p>
<p>[13e] a proximal member attached to the inner tubular member and positioned underneath the balloon, the proximal member having a distal end disposed proximal of the distal stop; and</p>	<p>As shown above, the Commander has a proximal member attached to the inner tubular member and positioned underneath the balloon, with the distal end of the proximal member disposed proximal of the distal stop.</p>
<p>[13f] a cardiovascular implant disposed along the catheter shaft, the cardiovascular implant being configured to shift between a first configuration and an expanded configuration.</p>	<p>The Commander has a cardiovascular implant (such as the Sapien products) disposed along the catheter shaft and configured to shift between a first configuration (for deployment) and an expanded configuration.</p> <p>The Commander comprises a balloon-expandable stent. For example:</p> <p style="padding-left: 40px;">The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards TheraFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

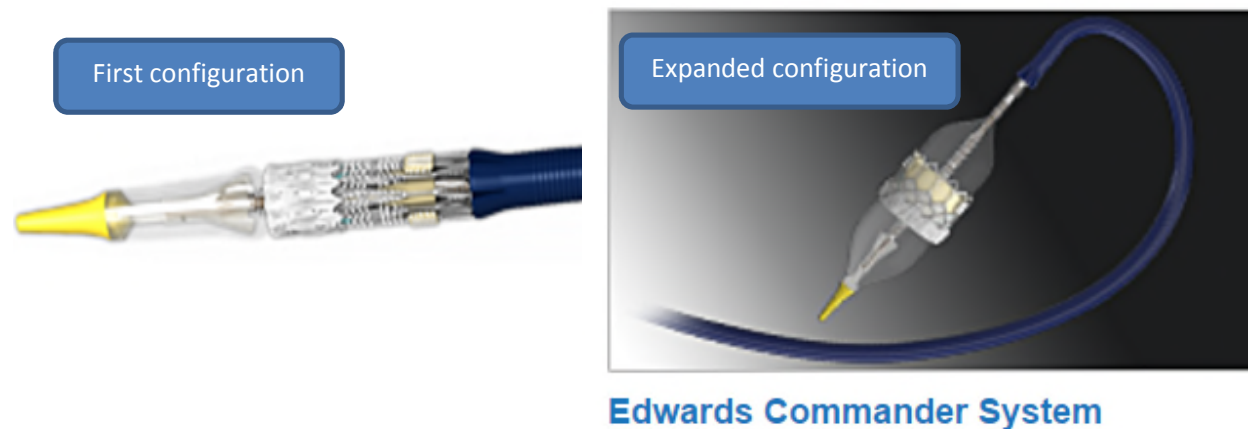
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

The Commander is used to deliver cardiovascular implants such as the Sapien products.

The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:

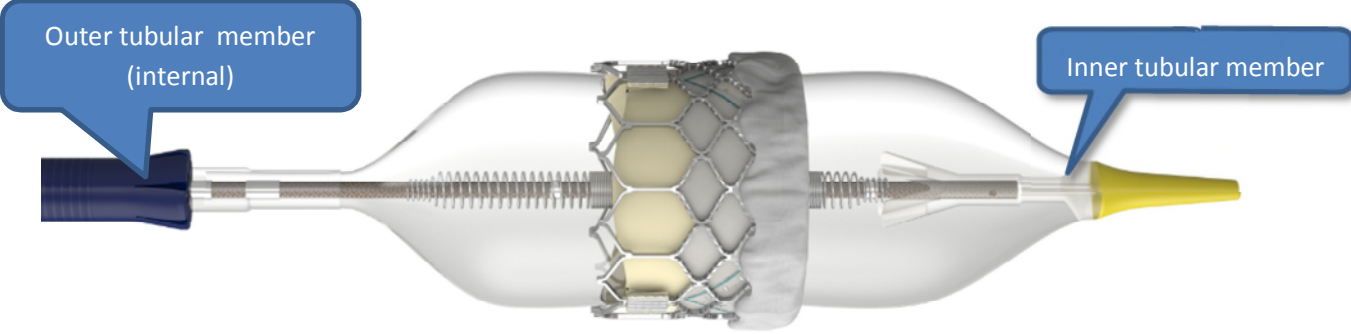
Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

The Commander uses a balloon to expand the cardiovascular implant.

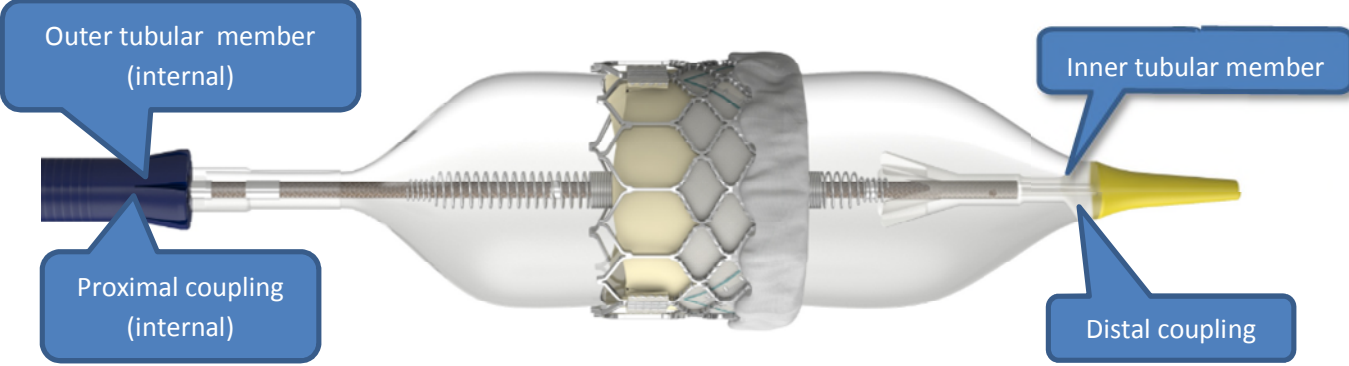


<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>

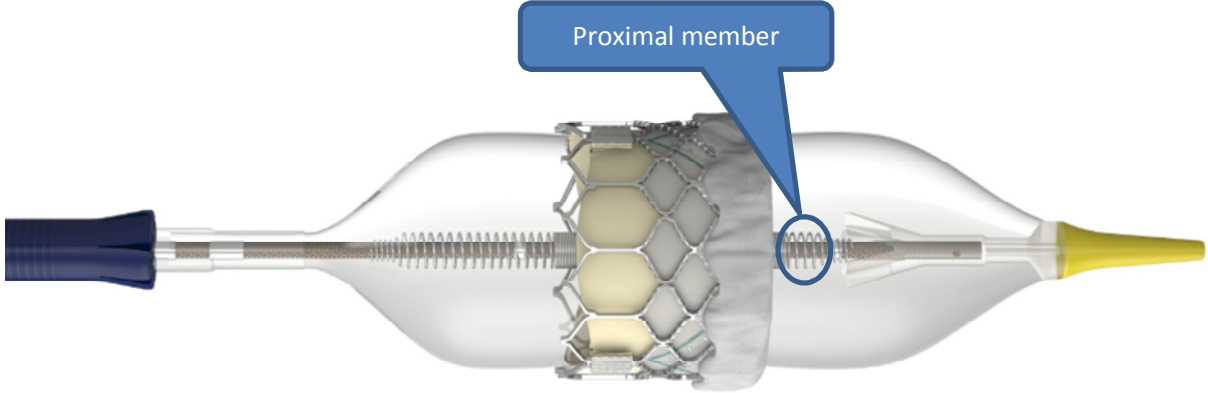
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Claim 14	
Element	Accused Products
[14 preamble] The system of claim 13:	As shown in connection with claim 13, the Commander includes all elements of claim 13. <i>See</i> claim chart for claim 13, above.
[14a] wherein an inflation lumen is defined between the inner tubular member and the outer tubular member, the inflation lumen being in fluid communication with the balloon.	<p>In the Commander, an inflation lumen is defined between the inner and outer tubular members and is in fluid communication with the balloon. For example:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

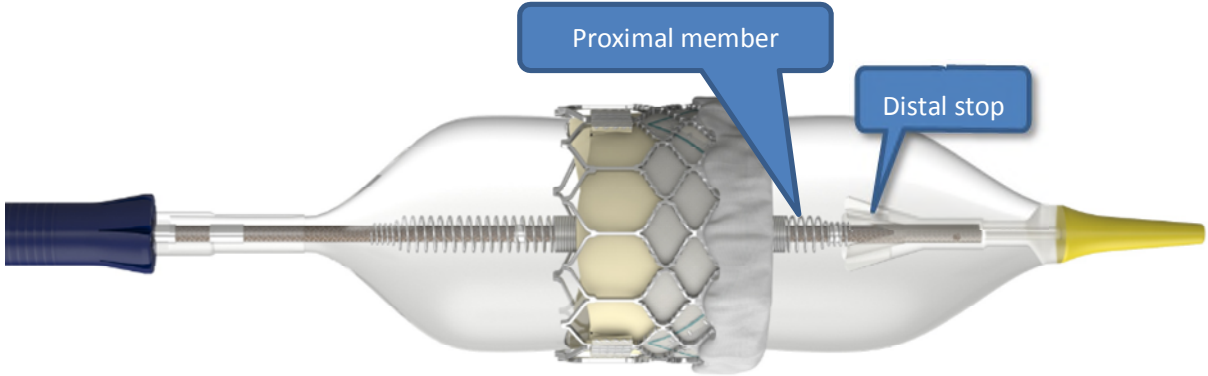
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
U.S. PATENT NO. 8,709,062 By Edwards**

Claim 15	
Element	Accused Products
[15 preamble] The system of claim 14:	As shown in connection with claim 14, the Commander includes all elements of claim 14. <i>See</i> claim chart for claim 14, above.
[15a] wherein the balloon has a proximal portion coupled to the outer tubular member and wherein the balloon has a distal portion coupled to the inner tubular member.	<p>In the Commander, the proximal portion of the balloon is coupled to the outer tubular member and the distal portion of the balloon is coupled to the inner tubular member. For example:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

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Claim 16	
Element	Accused Products
[16 preamble] The system of claim 13:	As shown in connection with claim 13, the Commander includes all elements of claim 13. <i>See</i> claim chart for claim 13, above.
[16a] wherein the proximal member includes a distal region having a substantially constant outer diameter.	<p>In the Commander, the proximal member includes a distal region having a substantially consistent outer diameter. For example:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

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Claim 17	
Element	Accused Products
[17 preamble] The system of claim 13:	As shown in connection with claim 13, the Commander includes all elements of claim 13. <i>See</i> claim chart for claim 13, above.
[17a] wherein the distal stop and the proximal member are longitudinally spaced from each other.	<p>In the Commander, the distal stop is longitudinally spaced from the proximal member. For example:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

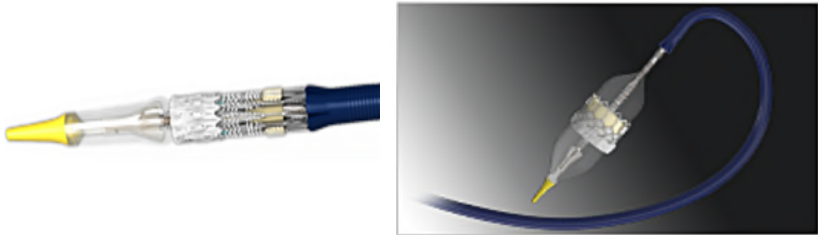
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
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Claim 18	
Element	Accused Products
[18 preamble] The system of claim 13:	As shown in connection with claim 13, the Commander includes all elements of claim 13. <i>See</i> claim chart for claim 13, above.
[18a] wherein the cardiovascular implant includes a stent.	<p>The Commander is used to deliver cardiovascular implants such as the Sapien products. For example:</p> <p style="padding-left: 40px;">The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p>The Commander comprises a balloon-expandable stent.</p> <p style="padding-left: 40px;">The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

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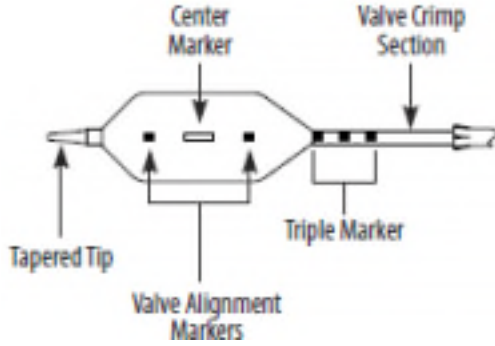
Claim 19	
Element	Accused Products
[19 preamble] The system of claim 13:	As shown in connection with claim 13, the Commander includes all elements of claim 13. <i>See</i> claim chart for claim 13, above.
[19a] Wherein the cardiovascular implant is configured to be expanded by the balloon.	<p>The Commander is used to deliver cardiovascular implants such as the Sapien products. For example:</p> <p style="padding-left: 40px;">The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p>The Commander comprises a balloon-expandable stent. For example:</p> <p style="padding-left: 40px;">The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p style="padding-left: 40px;">The Edwards SAPIEN XT transcatheter heart valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and a polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.</p>

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	<p>The Edwards SAPIEN transcatheter heart valve (bioprosthesis) is comprised of a balloon-expandable, radiopaque, stainless steel (316 L) frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) fabric. The bioprosthesis is treated according to the Carpentier-Edwards ThermaFix process, packaged, and terminally sterilized in glutaraldehyde</p> <p>Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf.</p> <p>The Commander uses a balloon to expand the cardiovascular implant.</p> <div style="text-align: center;">  <p>Edwards Commander System</p> </div> <p>http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx</p>
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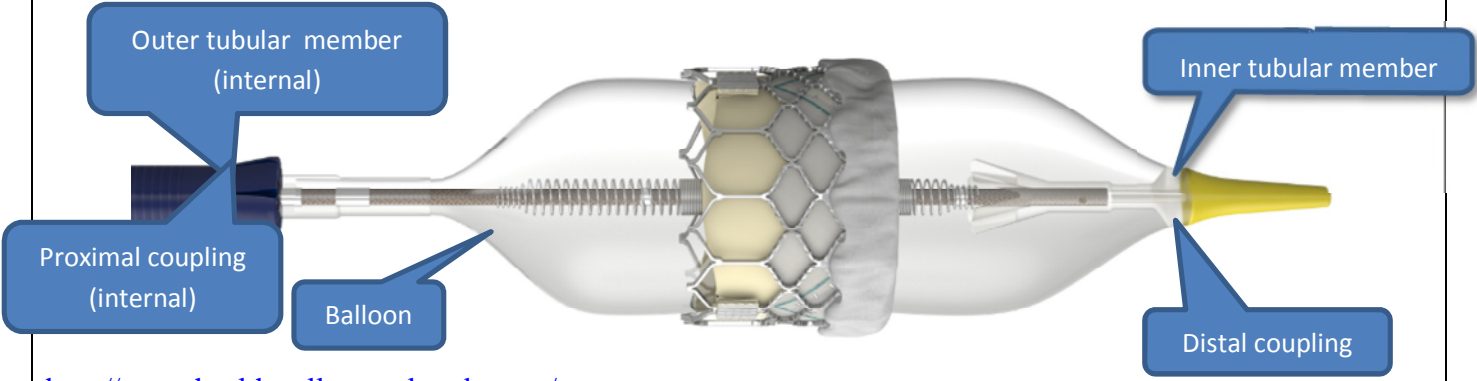
Claim 20	
Element	Accused Products
<p>[20 preamble] The system of claim 13:</p>	<p>As shown in connection with claim 13, the Commander includes all elements of claim 13. <i>See</i> claim chart for claim 13, above.</p>
<p>[20a] wherein the distal stop, the proximal member, or both</p>	<p>The Commander has multiple radiopaque markers. On information and belief, the distal stop, the proximal member, or both include a radiopaque marker. For example:</p>

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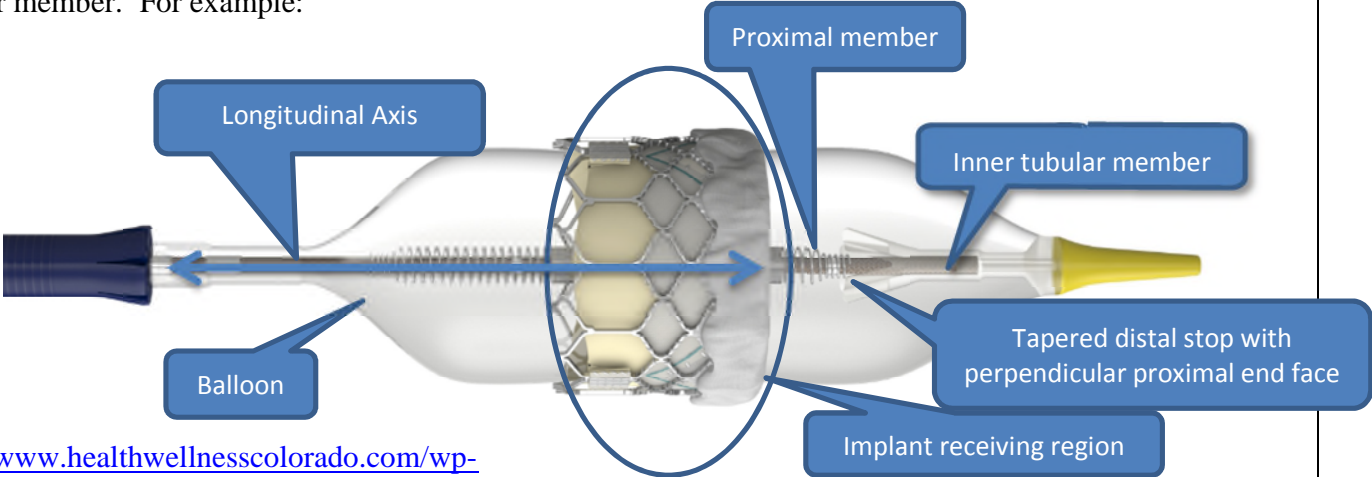
<p>include a radiopaque marker.</p>	<p>• Edwards Commander Delivery System (Figure 2)</p> <p>The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <div align="center">  <p>The diagram shows a cross-section of the delivery system. From left to right: a tapered tip, a balloon section containing a center marker and valve alignment markers, a triple marker, and a valve crimp section. Arrows point from labels to each of these components.</p> </div> <p>Commander Instructions for Use, pp. 2, 3 - http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf</p>
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<p align="center">Claim 21</p>	
<p align="center">Element</p>	<p align="center">Accused Products</p>
<p>[21 preamble] A medical device for implanting a medical implant, the medical device comprising:</p>	<p>As detailed above, the Commander is a medical device for implanting medical implants, such as the Sapien products.</p>

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<p>[21a] a catheter shaft, the catheter shaft including an inner tubular member and an outer tubular member;</p>	<p>The Commander has an catheter shaft including an inner tubular member and an outer tubular member. For example:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>
<p>[21b] a balloon attached to the catheter shaft;</p>	<p>As shown above, the Commander has a balloon attached to the catheter shaft.</p>
<p>[21c] wherein a proximal portion of the balloon is coupled to the outer tubular member and a distal portion of the balloon is coupled to the inner tubular member;</p>	<p>As shown above, in the Commander, the proximal portion of the balloon is coupled to the outer tubular member and the distal portion of the balloon is coupled to the inner tubular member.</p>
<p>[21d] wherein an inflation lumen is defined between the inner tubular member and the outer tubular member, the inflation lumen being in fluid communication with the</p>	<p>As shown above, in the Commander, the inflation lumen is defined between the inner tubular member and the outer tubular member and is in fluid communication with the balloon.</p>

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<p>balloon;</p> <p>[21e] wherein a body portion of the balloon extends over an implant receiving region of the inner tubular member;</p>	<p>A body portion of the balloon in the Commander extends over an implant receiving region of the inner tubular member. For example:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>
<p>[21f] a distal stop including a tapered distal portion attached to the inner tubular member adjacent to the implant receiving region;</p>	<p>As shown above, the Commander has a tapered distal stop attached to the inner tubular member at a position adjacent to the implant receiving region.</p>
<p>[21g] wherein the distal stop includes a proximal end face extending substantially perpendicular to a longitudinal axis of the catheter shaft;</p>	<p>As shown above, the distal stop in the Commander has a proximal end face extending perpendicular to the longitudinal axis of the catheter shaft.</p>
<p>[21h] wherein at least a portion of the distal stop is disposed within the balloon;</p>	<p>As shown above, the Commander has a distal stop disposed within the balloon.</p>

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<p>[21i] a proximal member attached to the implant receiving region and positioned between the implant receiving region and the body portion of the balloon, the proximal member having a distal end disposed proximal of the distal stop; and</p>	<p>As show above, the Commander has a proximal member attached to the implant receiveing region, positioned between the implant receiving region and the body portion of the balloon, and having its distal end disposed proximal of the distal stop.</p>
<p>[21j] an implantable endoprosthesis disposed along the catheter shaft, the implantable endoprosthesis being configured to be received along the implant receiving region.</p>	<p>The commander has implantable endoprosthesis (such as the Sapien products) disposed along the catheter shaft and configured to be received along the implant receiving region.</p> <p>Each of the Sapien products comprises an implantable endoprosthesis. For example:</p> <p style="padding-left: 40px;">The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p style="padding-left: 40px;">The Edwards SAPIEN XT transcatheter heart valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and a polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System: Instructions for Use at 1 available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009d.pdf.</p>

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The Edwards SAPIEN transcatheter heart valve (bioprosthesis) is comprised of a balloon-expandable, radiopaque, stainless steel (316 L) frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) fabric. The bioprosthesis is treated according to the Carpentier-Edwards ThermaFix process, packaged, and terminally sterilized in glutaraldehyde

Source: Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System: Instructions for Use at 1 available at <http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262938.pdf>.

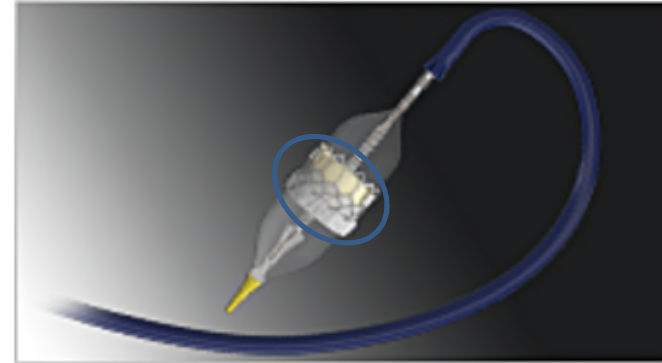
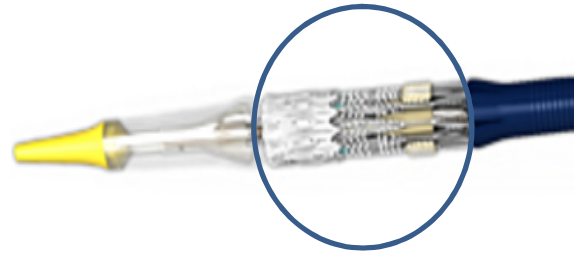
The Commander is used to deliver implantable endoprosthesis such as the Sapien products.

The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:

Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

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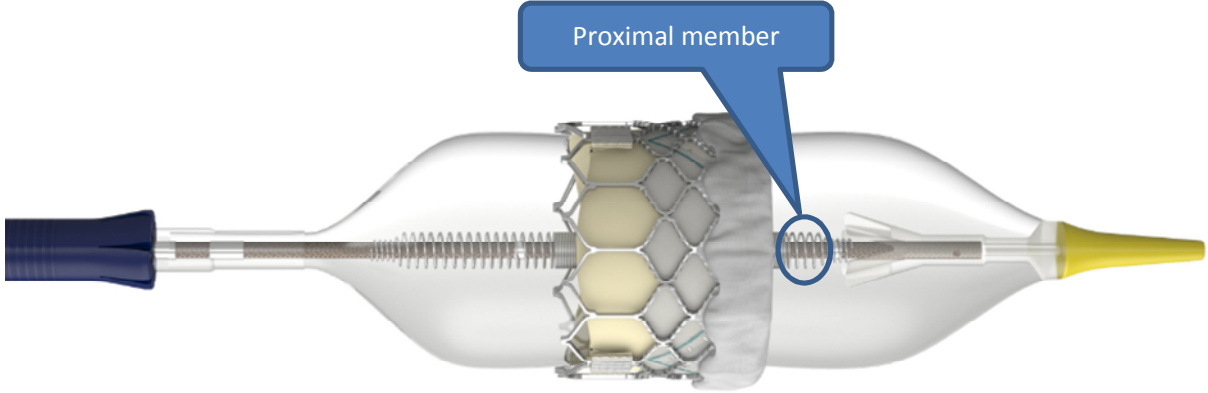
The implantable endoprosthesis is received along the implant receiving region of the Commander



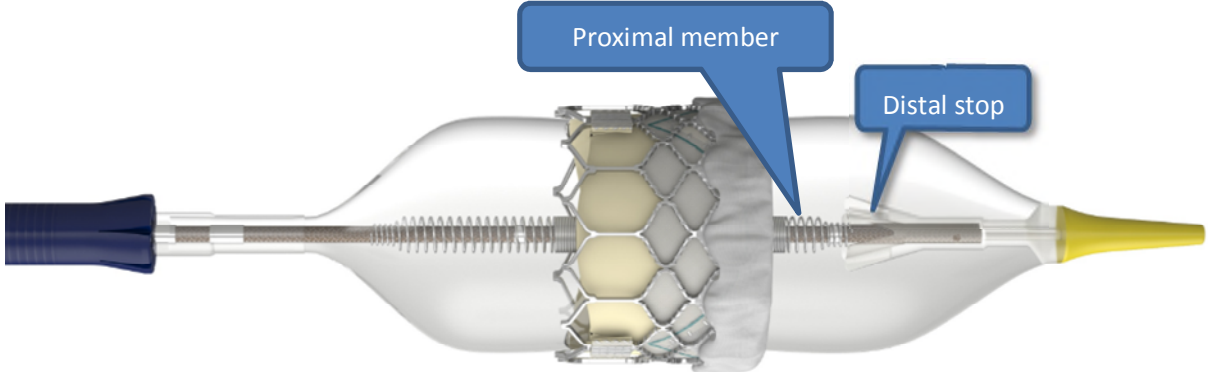
Edwards Commander System

<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>

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Claim 22	
Element	Accused Products
[22 preamble] The medical device of claim 21:	As shown in connection with claim 21, the Commander includes all elements of claim 21. <i>See</i> claim chart for claim 21, above.
[22a] wherein the proximal member includes a distal region having a substantially constant outer diameter.	<p>In the Commander, the proximal member includes a distal region having a substantially consistent outer diameter. For example:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

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Claim 23	
Element	Accused Products
[23 preamble] The medical device of claim 21:	As shown in connection with claim 21, the Commander includes all elements of claim 21. <i>See</i> claim chart for claim 21, above.
[23a] wherein the distal stop and the proximal member are longitudinally spaced from each other.	<p>In the Commander, the distal stop is longitudinally spaced from the proximal member. For example:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>

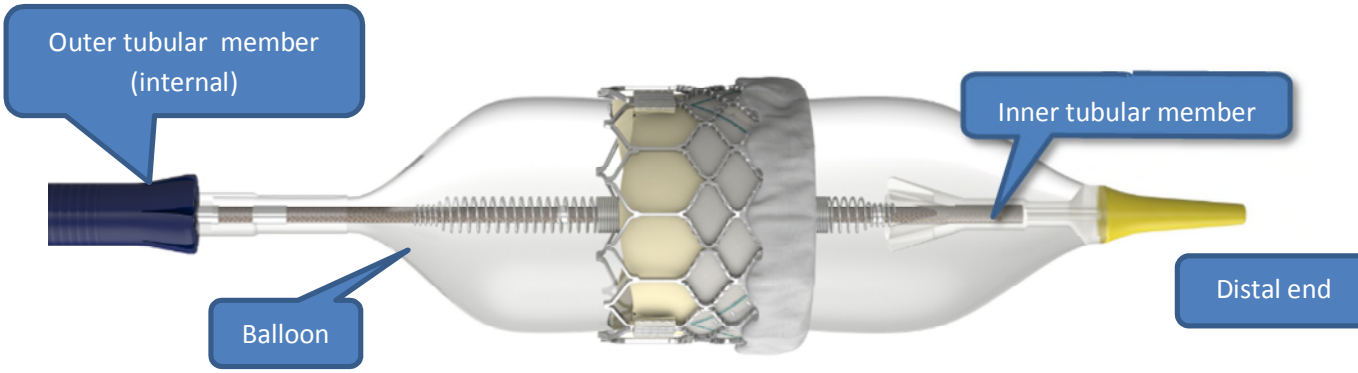
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
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Claim 24	
Element	Accused Products
[24 preamble] The medical device of claim 21:	As shown in connection with claim 21, the Commander includes all elements of claim 21. <i>See</i> claim chart for claim 21, above.
[24a] wherein the implantable endoprosthesis includes a stent.	<p>The Commander is used to deliver implantable endoprosthesis such as the Sapien products. For example:</p> <p style="padding-left: 40px;">The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p> <p>Each of the Sapien products comprises a balloon-expandable stent.</p> <p style="padding-left: 40px;">The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

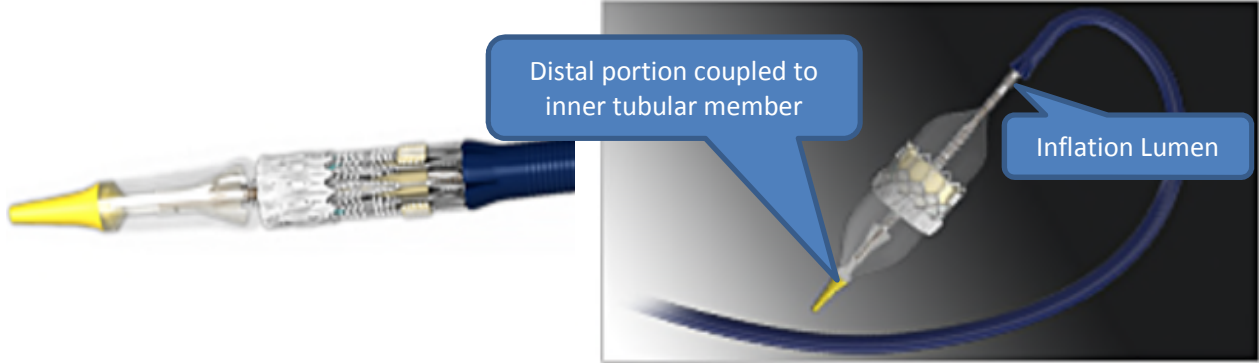
**Ex. H: CLAIM CHART FOR INFRINGEMENT OF
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Claim 25	
Element	Accused Products
[25 preamble] The medical device of claim 21:	As shown in connection with claim 21, the Commander includes all elements of claim 21. <i>See</i> claim chart for claim 21, above.
[25a] further comprising a radiopaque marker coupled to the inner tubular member.	<p>The Commander has multiple radiopaque markers, including at least one coupled to the inner tubular member. For example:</p> <ul style="list-style-type: none"> Edwards Commander Delivery System (Figure 2) <p>The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <div style="text-align: center;"> <p>The diagram shows a cross-section of the delivery system. From left to right: a tapered tip, a balloon section containing a center marker and two valve alignment markers, a triple marker, and a valve crimp section. Arrows point from labels to each of these components.</p> </div> <p>Commander Instructions for Use, pp. 2, 3 - http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf</p>

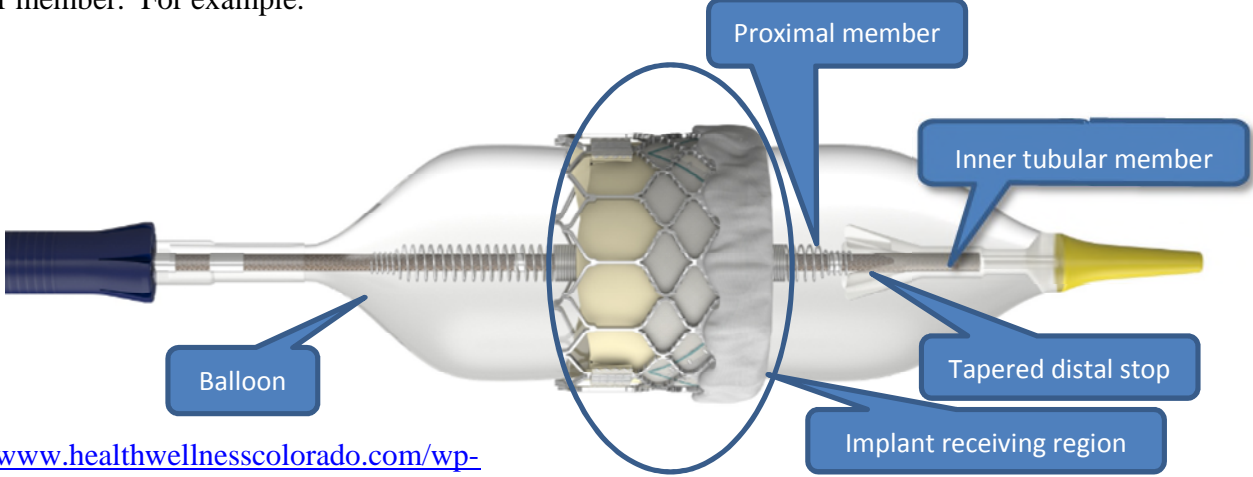
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Claim 26	
Element	Accused Products
[26 preamble] A system for delivering an implantable medical device, the system comprising:	As detailed above, the Commander is a catheter system for delivering implantable medical devices, such as the Sapien products.
[26a] a catheter shaft, the catheter shaft including an inner tubular member and an outer tubular member;	<p>The Commander has a catheter shaft including an inner tubular member and an outer tubular member.</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>
[26b] wherein the inner tubular member has a distal end that extends distally beyond a distal end of the outer tubular member;	As shown above, the inner tubular member of the Commander has a distal end that extends distally beyond a distal end of the outer tubular member.
[26c] wherein the inner tubular member defines a guidewire	The inner tubular member in the Commander defines a guidewire lumen.

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<p>lumen;</p>	<p>• Edwards Commander Delivery System (Figure 2)</p> <p>The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p> <p>Instructions for Use, p. 2 - http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf</p>
<p>[26d] a balloon attached to the catheter shaft, the balloon being configured to shift between a collapsed configuration and an expanded configuration;</p>	<p>The Commander has a balloon attached to the catheter shaft and configured to shift between a collapsed configuration and an expanded configuration. For example:</p>  <p align="center">Edwards Commander System</p> <p>http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx</p>
<p>[26e] wherein a proximal portion of the balloon is coupled to the outer tubular member and</p>	<p>As shown above, in the Commander, the proximal portion of the balloon is coupled to the outer tubular member and the distal portion of the balloon is coupled to the inner tubular member.</p>

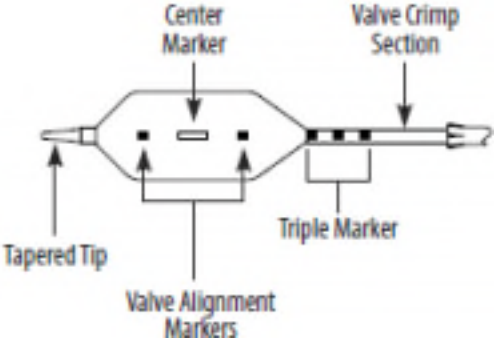
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<p>a distal portion of the balloon is coupled to the inner tubular member;</p>	
<p>[26f] wherein an inflation lumen is defined between the inner tubular member and the outer tubular member, the inflation lumen being in fluid communication with the balloon;</p>	<p>As shown above, in the Commander, the inflation lumen is defined between the inner tubular member and the outer tubular member and is in fluid communication with the balloon.</p>
<p>[26g] wherein a body portion of the balloon extends over an implant receiving region of the inner tubular member;</p>	<p>A body portion of the balloon in the Commander extends over an implant receiving region of the inner tubular member. For example:</p>  <p>http://www.healthwellnesscolorado.com/wp-content/uploads/2016/01/TAVR_EdwardsCommander_Distal.Expand.Valve_.jpg</p>
<p>[26h] a distal stop attached to the inner tubular member at a position adjacent to the implant receiving region, the distal stop being disposed at</p>	<p>As shown above, the Commander has a distal stop attached to the inner tubular member at a position adjacent to the implant receiving region and disposed between the balloon and the inner tubular member.</p>

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<p>least partially between the balloon and the inner tubular member;</p>	
<p>[26i] wherein at least a section of the distal stop is tapered;</p>	<p>As shown above, the distal stop in the Commander is tapered.</p>
<p>[26j] a proximal member attached to the implant receiving region and being positioned between the implant receiving region and the body portion of the balloon;</p>	<p>As described above, the Commander has a proximal member attached to the implant receiving region and positioned between the implant receiving region and the body portion of the balloon.</p>
<p>[26k] wherein the distal stop is axially spaced from the proximal member;</p>	<p>As shown above, the distal stop in the Commander is axially spaced from the proximal member.</p>
<p>[26l] a first radiopaque marker disposed along the implant receiving region and positioned adjacent to the distal stop;</p>	<p>The Commander has multiple radiopaque markers. On information and belief, the Commander has a first marker disposed along the implant receiving region and positioned adjacent to the distal stop. For example:</p> <ul style="list-style-type: none"> • Edwards Commander Delivery System (Figure 2) <p>The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:</p>

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	 <p>Commander Instructions for Use, pp. 2, 3 - http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf</p>
<p>[26m] a second radiopaque marker disposed along the implant receiving region and positioned adjacent to the proximal member;</p>	<p>As shown immediately above, the Commander has multiple radiopaque markers. On information and belief, the Commander has a radiopaque marker disposed along the implant receiving region and positioned adjacent to the proximal member.</p>
<p>[26n] wherein the first radiopaque marker is axially spaced from the second radiopaque marker; and</p>	<p>As described above, the first radiopaque marker in the Commander is axially spaced from the second radiopaque marker.</p>
<p>[26o] an implantable endoprosthesis disposed along the catheter shaft and configured to be received along the implant receiving region, the implantable endoprosthesis being configured to be expandable by the balloon.</p>	<p>The Commander has implantable endoprosthesis (such as the Sapien products) disposed along the catheter shaft and configured to be received along the implant receiving region and expanded by the balloon.</p> <p>The Commander comprises a balloon-expandable implantable endoprosthesis.</p> <p>The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.</p> <p>Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.</p>

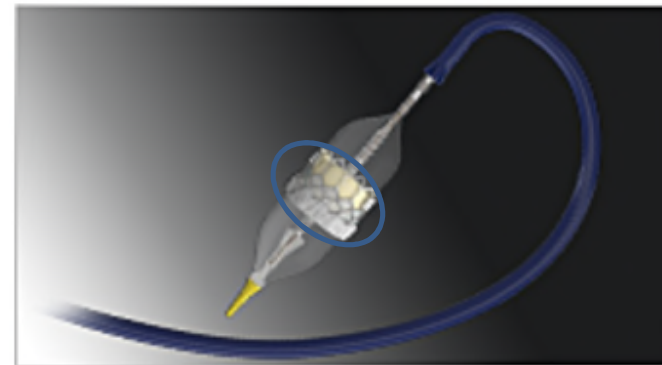
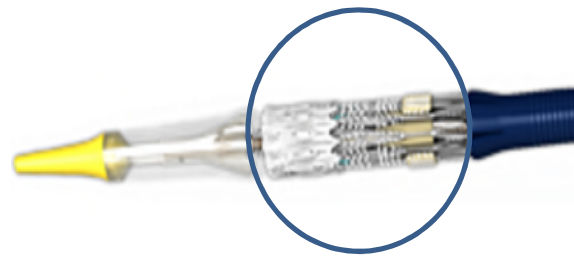
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The Commander is used to deliver an implantable endoprosthesis such as the Sapien products.

The Edwards Commander delivery system (usable length 105 cm) is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve and consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the native valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the native annulus. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for THV deployment are:

Source: Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System: Instructions for Use at 2 available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031c.pdf.

The Commander uses a balloon to expand the implantable endoprosthesis, which is received along the implant receiving region.



Edwards Commander System

<http://www.edwards.com/eu/Products/TranscatheterValves/Pages/commander.aspx>