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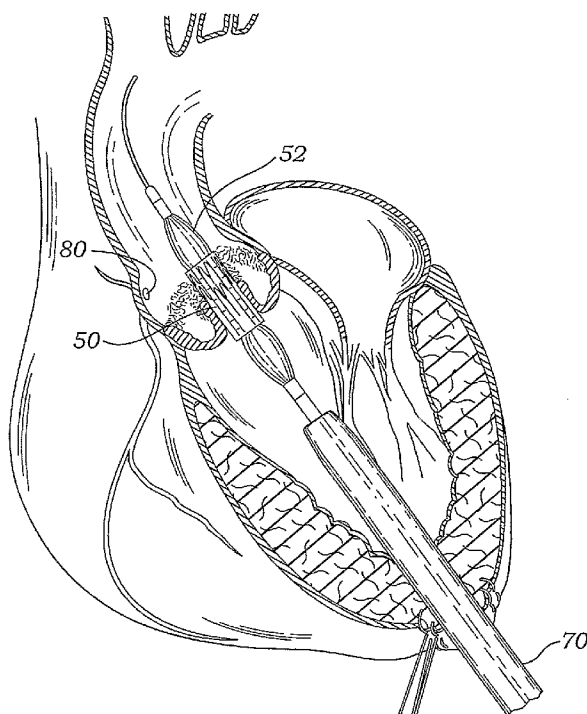
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[Continued on next page]

(54) Title: TRANSAPICAL HEART VALVE DELIVERY SYSTEM AND METHOD



(57) Abstract: A delivery system and method for delivering a prosthetic heart valve to the aortic valve annulus. The system includes a balloon catheter (54) having a steering mechanism thereon for delivering a balloon-expandable prosthetic heart valve (50) through an introducer (70) in an antegrade fashion to the aortic annulus. The balloon catheter passes through an introducer that accesses the left ventricle through its apex and a small incision in the chest wall. The balloon catheter includes a deflecting segment (164) just proximal to the distal balloon (52) to facilitate positioning of the prosthetic heart valve in the proper orientation within the aortic annulus. A slider in a deflection handle (154) may be coupled to a deflection wire that actuates the deflecting segment. The method includes using two concentric rings of purse-string sutures (44) around the puncture in the left ventricular apex to maintain a good seal around instruments passed therethrough. The prosthetic heart valve may be installed over the existing calcified leaflets, and a pre-dilation valvuloplasty procedure may also be utilized.

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## TRANSAPICAL HEART VALVE DELIVERY SYSTEM AND METHOD

### Field of the Invention

[0001] The present invention relates to methods and systems used to  
5 deliver a prosthetic valve to a heart. More specifically, the present invention  
relates to methods and apparatus for surgically replacing a heart valve without  
opening the chest cavity and with or without placing the patient on bypass, the  
latter being termed “off-pump.”

### Background of the Invention

10 [0002] Heart valve replacement may be indicated when there is a  
narrowing of the native heart valve, commonly referred to as stenosis, or when  
the native valve leaks or regurgitates, such as when the leaflets are calcified.  
When replacing the valve, the native valve may be excised and replaced with  
either a biologic or a mechanical valve. Mechanical valves require lifelong  
15 anticoagulant medication to prevent blood clot formation, and clicking of the  
valve often may be heard through the chest. Biologic tissue valves typically do  
not require such medication. Tissue valves may be obtained from cadavers or  
may be porcine or bovine, and are commonly attached to synthetic rings that  
are secured to the patient’s heart valve annulus.

20 [0003] Conventional heart valve surgery is an open-heart procedure  
conducted under general anesthesia. An incision is made through the patient’s  
sternum (sternotomy), and the patient’s heart is stopped while blood flow is  
rerouted through a heart-lung “cardiopulmonary” bypass machine. Valve  
replacement surgery is a highly invasive operation with significant  
25 concomitant risks include bleeding, infection, stroke, heart attack, arrhythmia,  
renal failure, adverse reactions to the anesthesia medications, as well as  
sudden death. Fully 2-5% of patients die during surgery. Post-surgery,  
patients temporarily may be confused due to emboli and other factors  
associated with the heart-lung machine. The first 2-3 days following surgery

are spent in an intensive care unit where heart functions can be closely monitored. The average hospital stay is between 1 to 2 weeks, with several more weeks to months required for complete recovery.

[0004] In recent years, advancements in “minimally-invasive” surgery and interventional cardiology have encouraged some investigators to pursue percutaneous replacement of the aortic heart valve. Percutaneous Valve Technologies (“PVT”), formerly of Fort Lee, N.J. and now part of Edwards Lifesciences of Irvine, CA, has developed a balloon-expandable stent integrated with a bioprosthetic valve. The stent/valve device is deployed across the native diseased valve to permanently hold the valve open, thereby alleviating a need to excise the native valve. PVT’s device is designed for delivery in a cardiac catheterization laboratory under local anesthesia using fluoroscopic guidance, thereby avoiding general anesthesia and open-heart surgery.

[0005] Other prior art minimally-invasive heart valves use self-expanding stents as anchors. In the percutaneous/endovascular aortic valve replacement procedure, accurate placement of the prosthetic valve relative to the coronary ostia is critical. Though the proximal end of the stent is not released from the delivery system until accurate placement is verified by fluoroscopy, the self-expanding stent may still jump once released. It is therefore often difficult to know where the ends of the stent will be with respect to the native valve and surrounding structures.

[0006] U.S. Patent Publication No. 2002/0151970 to Garrison et al. describes a two-piece device for replacement of the aortic valve that is adapted for delivery through a patient’s aorta. A stent is endovascularly placed across the native valve, then a replacement valve is positioned within the lumen of the stent and connected thereto. By separating the stent and the valve during delivery, a so-called “two-stage” approach, the profile of the delivery system can be reduced. Both the stent and a frame of the replacement valve may be balloon- or self-expandable.

[0007] Some researchers propose implanting prosthetic heart valves at the aortic annulus through a ventricular approach. For instance, Christoph H. Huber of the Brigham and Women's Hospital of Harvard Medical School, and others, have proposed a procedure in which a self-expanding valve stent is  
5 implanted at the aortic position using a direct-access transapical approach. (E.g., Huber, et al. Direct-access valve replacement a novel approach for off-pump valve implantation using valved stents. J Am Coll Cardiol 2005; 46:366-70). The clinical studies by Huber, et al. recommend use of the procedure only for animals with normal, noncalcified leaflets. More recently,  
10 Bergheim in U.S. Patent Publication No. 2005/0240200 discloses another transapical approach in which either a balloon- or self-expanding valve may be implanted, and also proposes removing or decalcifying stenotic valves.

[0008] In view of drawbacks associated with previously known techniques for replacing a heart valve without open-heart surgery or  
15 cardiopulmonary bypass, i.e., minimally-invasive procedures, improved methods and apparatuses that are more robust and less invasive are needed.

#### Summary of the Invention

[0009] Preferred embodiments of the present invention provide a heart valve delivery system for delivery of a prosthetic (i.e., replacement) heart  
20 valve to a native valve site without an open chest procedure. The delivery system includes a valve delivery catheter having a steerable section to facilitate positioning of the valve.

[0010] In accordance with one aspect, the present invention provides an off-pump, minimally-invasive surgical method of implanting a prosthetic  
25 heart valve to an aortic valve annulus of a patient while the patient's heart remains beating. The method includes providing a balloon-expandable prosthetic heart valve mounted over a balloon on a distal end of a balloon catheter. The physician creates a puncture through the ventricle wall at or near the apex of the left ventricle of the patient and inserts an introducer sheath  
30 through the puncture. A balloon catheter passes through the introducer sheath

into the left ventricle. The distal end of the balloon advances so that the prosthetic heart valve is positioned within the aortic annulus. Finally, the balloon inflates to expand the prosthetic heart valve at the aortic annulus.

[0011] The method may also include placing a first line of purse-string  
5 sutures generally in a first circle in one direction defining a perimeter at or near the apex of the left ventricle of the patient, and then placing a second line of purse-string sutures generally in a circle concentric to the first circle but in an opposite direction. The puncture is created within the perimeter, and after the introducer sheath is inserted through the puncture, the purse-string sutures  
10 are cinched to create a seal therearound.

[0012] Desirably, the balloon catheter incorporates a steering mechanism, and the method further includes steering the balloon catheter within the left ventricle to facilitate positioning the prosthetic heart valve within the aortic annulus. The balloon catheter may also include a deflecting  
15 segment located just proximal to the balloon which bends so as to angle the balloon and prosthetic heart valve mounted thereon. The balloon catheter may also have a pusher with a distal sleeve mounted over the deflecting segment and engaging a proximal end of the balloon. The method therefore includes using the pusher and sleeve to advance the balloon and prosthetic heart valve  
20 mounted thereon, and proximally displacing the pusher and sleeve with respect to the deflecting segment prior to inflating the balloon. Desirably, the pusher and sleeve are proximally displaced before the deflecting segment bends.

[0013] The exemplary method may further include leaving the native  
25 aortic valve leaflets in place such that inflating the balloon expands the prosthetic heart valve into contact therewith. Furthermore, a pre-dilation balloon catheter may be inserted prior to the introducer sheath and a balloon thereon inflated to pre-dilate the aortic annulus. Alternatively, the method may include expanding the prosthetic heart valve into contact with a prosthetic  
30 heart valve that was previously implanted at the aortic annulus

[0014] Another off-pump, minimally-invasive surgical method of delivering a prosthetic heart valve to an aortic valve annulus of a patient while the patient's heart remains beating includes providing an expandable prosthetic heart valve in an expanded state and a delivery catheter having a distal end. The heart valve is crimped to a contracted state over the delivery catheter distal end. An intercostal access opening is created to expose the left ventricular apex of the patient, and a puncture formed at or near the apex of the left ventricle. An introducer sheath inserts through the puncture, and the delivery catheter passes through the introducer sheath and into the left ventricle. The distal end of the delivery catheter is advanced and steered so that the prosthetic heart valve is properly positioned and oriented within the aortic annulus. Finally, the prosthetic heart valve expands at the aortic annulus into contact therewith.

[0015] The delivery catheter desirably includes a balloon on its distal end, and the prosthetic heart valve includes a balloon-expandable stent, wherein the step of expanding includes injecting fluid into the balloon to expand the prosthetic heart valve outward into contact with the aortic annulus. The native aortic valve leaflets may be left in place such that inflating the balloon expands the prosthetic heart valve into contact therewith. Preferably, prior to inserting the introducer sheath, a pre-dilation balloon catheter having a balloon on a distal end is inserted through the puncture and inflated to pre-dilate the aortic annulus.

[0016] The present invention further encompasses a minimally-invasive prosthetic heart valve delivery system, including an introducer sheath having a lumen therethrough of no greater than 24 French and a balloon catheter having a balloon on a distal end, the balloon catheter further including a steering mechanism for deflecting the distal end. The system includes a balloon-expandable prosthetic heart valve crimped over the balloon, wherein the outer dimension of the balloon catheter with the prosthetic heart valve crimped thereon is small enough to pass through the introducer sheath lumen.

[0017] Desirably, the steering mechanism includes a deflecting segment on the balloon catheter located just proximal to the balloon. A deflection wire may be attached to a distal end of the deflecting segment and extend through the balloon catheter to a proximal deflection handle. The system preferably has a pusher with a distal sleeve sized to encompass the deflecting segment and a proximal end of the balloon, the pusher being longitudinally movable with respect to the deflecting segment.

[0018] In one embodiment, the balloon catheter further includes inner and outer balloon inflation tubes attached to opposite ends of the balloon and arrange to concentrically slide with respect one another to alternately elongate and shorten the balloon. An inner tube handle displaces the inner balloon inflation tube. A balloon inflation connector through which the inner balloon inflation tube passes attaches to a proximal end of the outer balloon inflation tube. A side port opens to a space defined within the balloon inflation connector, the side port facilitating introduction of an inflation fluid into the space and into a tubular space between the inner and outer balloon inflation tubes for inflating the balloon. A deflection handle through which the outer balloon inflation tube passes may be attached just distal to the balloon inflation connector. The outer balloon inflation tube includes a first lumen for passage of the inner balloon inflation tube, and a second lumen. A deflection wire connects to an actuator on the deflection handle and passes through the second lumen of the outer balloon inflation tube to a distal end of the balloon catheter.

[0019] The system is desirably relatively short, such that the balloon catheter has a working length sized to fit into the introducer of no more than about 24 inches (61 cm). At the same time, the introducer preferably has a total length of no more than about 13 inches (33 cm).

[0020] A further understanding of the nature and advantages of the present invention are set forth in the following description and claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.



### Brief Description of the Drawings

[0021] Features and advantages of the present invention will become appreciated as the same become better understood with reference to the specification, claims, and appended drawings wherein:

[0022] Fig. 1 is a schematic frontal view of a patient showing the location of an intercostal incision providing access to the apex of the left ventricle of the heart;

[0023] Figs. 2A-2B are cross-sectional views through the left side of a patient's heart showing a procedure for dilating a calcified aortic annulus prior to implantation of a prosthetic heart valve in accordance with the present invention;

[0024] Figs. 3A-3E are cross-sectional views through the left side of a patient's heart showing several steps in a procedure for implanting a prosthetic heart valve in accordance with the present invention;

[0025] Fig. 4A is a side elevational view of an introducer used in the minimally-invasive heart valve implantation procedure of the present invention;

[0026] Fig. 4B is an exploded view of the introducer of Fig. 4A;

[0027] Fig. 5 is a perspective view of an exemplary balloon catheter for implanting a prosthetic heart valve in accordance with the present invention;

[0028] Fig. 5A is a perspective view of a loader that provides an interface between the introducer of Fig. 4A and the balloon catheter of Fig. 5;

[0029] Fig. 6A is an enlarged broken plan view of the balloon catheter of Fig. 5;

[0030] Fig. 6B is an enlarged broken sectional view of the balloon catheter of Fig. 5 taken along a vertical plane;

[0031] Fig. 7 is an enlarged broken portion of the proximal end of the balloon catheter as seen in Fig. 6B;

[0032] Fig. 8 is an isolated side view of a tube segment having an anti-rotation block on one end that forms part of the balloon catheter of Fig. 5;

[0033] Fig. 9 is an isolated side view of a proximal end of an outer balloon inflation tube that forms part of the balloon catheter of Fig. 5;

5 [0034] Fig. 10 is an enlarged sectional view of a pusher handle that forms part of the balloon catheter as seen in Fig. 6B;

[0035] Fig. 11 is an enlarged sectional view of a distal deflecting segment of the balloon catheter as seen in Fig. 6B;

10 [0036] Fig. 12 is an enlarged sectional view of the distal balloon of the balloon catheter of the present invention in its expanded state;

[0037] Fig. 13 is an enlarged sectional view of a distal soft tip of the balloon catheter;

[0038] Fig. 14 is an enlarged elevational view of the distal end of the balloon catheter showing the balloon in its deflated state partly encompassed  
15 by a pusher sleeve; and

[0039] Fig. 15 is an enlarged elevational view of the distal end of the balloon catheter showing a protective sheath around the deflated balloon.

#### Detailed Description of the Preferred Embodiments

20 [0040] The heart is a hollow muscular organ of a somewhat conical form; it lies between the lungs in the middle mediastinum and is enclosed in the pericardium. The heart rests obliquely in the chest behind the body of the sternum and adjoining parts of the rib cartilages, and projects farther into the left than into the right half of the thoracic cavity so that about one-third is situated on the right and two-thirds on the left of the median plane. The heart  
25 is subdivided by septa into right and left halves, and a constriction subdivides each half of the organ into two cavities, the upper cavity being called the atrium, the lower the ventricle. The heart therefore consists of four chambers; the right and left atria, and right and left ventricles.

30 [0041] As seen in Fig. 1, the left ventricular apex LVA is directed downward, forward, and to the left (from the perspective of the patient). The

apex typically lies behind the fifth left intercostal space (or between the fourth and fifth), 8 to 9 cm from the mid-sternal line, and about 4 cm below and 2 mm to the medial side of the left mammary papilla. Access to the left ventricle may therefore be attained through an intercostal incision 20 as shown in dashed line, positioned over the fifth left intercostal space. Such an approach is often termed a “mini-thoracotomy.”

[0042] In a preferred embodiment of the present invention, a surgeon implants a prosthetic heart valve over the existing native leaflets, which are typically calcified. There are procedures and devices for removing calcified leaflets, but the risks associated therewith, including a release of calcific material into the bloodstream, are not insignificant. Therefore, a heart valve replacement procedure that installs the prosthetic heart valve directly over and contains the native leaflets is preferred.

[0043] Those skilled in the art will recognize that it may be necessary to pre-dilate the leaflets and annulus of the stenotic aortic valve before deploying a prosthetic valve within the aortic valve. Figs. 2A and 2B are two snapshots of a valvuloplasty procedure that may be initially performed to compress the native aortic heart valve leaflets outward against the sinuses and ascending aorta. As mentioned above, the native aortic valve leaflets may be substantially calcified, and the valvuloplasty may be necessary to crack and otherwise force apart hardened tissue. Pre-dilation increases the flow area through the aortic valve and creates an opening in the leaflets of sufficient size to receive the prosthetic valve. Pre-dilatation is preferably achieved using an expandable member, such as a dilatation balloon catheter. One example of pre-dilation of a valve annulus is seen in U.S. Patent No. 6,908,481 to Cribier, issued June 21, 2005 and expressly incorporated by reference herein.

[0044] Fig. 2A illustrates introduction of a guidewire 30 through an apical puncture 32 in the left ventricle LV. A distal tip 34 of the guidewire 30 extends through the native aortic valve AV and into the ascending aorta AA. The distal tip 34 may extend further over the aortic arch, as seen in Fig. 2B, but the minimum extension is across the aortic valve AV.

[0045] Fig. 2B illustrates a balloon catheter 40 having a dilatation balloon 42 on a distal end passed over the guidewire 30 and through the apical puncture 32. It should be noted at this point that one or more purse-string sutures 44 are threaded through the tissue of the left ventricular apex surrounding the puncture 32. These sutures 44 are pre-implanted prior to formation of the initial puncture. In a preferred embodiment, the surgeon places a first line of purse-string sutures generally in a first circle in one direction, and then places a second line of purse-string sutures generally in a circle concentric to the first circle but in an opposite direction. The result is two concentric circles of separate purse-string sutures 44 defining a periphery within which the puncture is formed. The purse-string sutures 44 can therefore be pulled to cinch the ventricular tissue around whatever object passes through the puncture. In particular, the purse-string sutures 44 are tightened around both the guidewire 30 and balloon catheter 40. Installing the separate lines of purse-string sutures 44 in opposite directions helps prevent tearing of the ventricular tissue and provides a more uniform compression about whatever elongated object passes through the puncture.

[0046] As indicated in Fig. 2B, the dilatation balloon 42 expands radially outward into contact with the native aortic valve leaflets. With information concerning the size of the particular aortic valves, the balloon 42 is chosen so that it expands outward and nominally compresses the aortic valve leaflets against the surrounding aortic walls. There are various means for assessing the size of the particular patient's aortic valve, including ultrasound, which will not be described herein. Suffice it to say that following the valvuloplasty procedure seen in Fig. 2B, the native aortic valve leaflets are compressed outward against the aortic wall and a substantially circular orifice results. Additional details regarding pre-dilatation and valve replacement can be found in Applicant's co-pending U.S. Patent Publication No. 20030014104, filed May 2, 2002, and expressly incorporated by reference herein.

[0047] With reference now to Figs. 3A-3E, a preferred method of deploying and implanting a prosthetic heart valve of the present invention

using a transapical approach will now be described in more detail. The devices and methods disclosed herein are particularly well-suited for replacing a stenotic aortic valve, and as such that the pre-dilation procedure seen in Figs. 2A-2B typically precedes the valve implantation so as to smooth out the contours of the annulus and leaflets. It should be noted, however, that the procedure described herein may be performed without valve pre-dilation.

[0048] Furthermore, the present procedure may be performed as a first time valve implant or to supplement a previous implant. A relatively large proportion of recipients of prosthetic heart valves are older, typically older than 60. Over time, prosthetic heart valves have been known to show reduced performance and even failure. Re-operating on septagenarians and even octogenarians is problematic. However, a minimally-invasive procedure such as disclosed herein eliminates open-heart surgery and potentially cardiopulmonary bypass, and is therefore more desirable for the aging patient. Therefore, the present invention contemplates transapical implantation of a prosthetic heart valve over an existing prosthetic valve implant. In such a case, a pre-dilation step is typically not necessary, though it is conceivable.

[0049] Prior to a discussion of the procedure itself, it should be noted that a preferred delivery system of the present invention will be described in greater detail below with reference to Figs. 4-15. The workings of the present delivery system may be more easily understood after an explanation of the steps taken to ultimately implant the valve in the aortic annulus.

[0050] The prosthetic heart valve implantation procedure described herein may be performed in conjunction with cardiopulmonary bypass, or without in a so-called off-pump procedure. The necessity for bypass depends on a number of factors, including the patient's age, vulnerability to such a procedure, and viability of the native leaflets. Ideally, the implantation procedure is performed off-pump.

[0051] The surgeon or cardiologist first sizes the aortic valve using a physical sizer, or echocardiography. The physician or operating room staff then crimps an expandable prosthetic valve 50 over the balloon 52 of a balloon

catheter 54 (some of the elements presently described can be seen in the procedure drawings of Figs. 3A-3E, while others can be seen in the system drawings of the Figs. 4-15). The surgeon advances the balloon catheter 54 over a guidewire 60 (that might be the same guidewire 30 used in a pre-dilation procedure), through an introducer sheath 70 that has been inserted  
5 through the left ventricular apex puncture 32.

[0052] The same purse-string sutures 44 that were used for the pre-dilation procedure may also be used to seal the ventricular tissue around the introducer sheath 70. In the absence of the pre-dilation procedure, the purse-string sutures 44 are pre-implanted prior to formation of the initial puncture.  
10 As before, the surgeon places a first line of purse-string sutures generally in a first circle in one direction, and then places a second line of purse-string sutures generally in a circle concentric to the first circle but in an opposite direction. The result is two concentric circles of separate purse-string sutures  
15 44 defining a periphery within which the puncture is formed, and which seal around the introducer sheath 70.

[0053] Furthermore, a dilator (not shown) that expands the inner diameter of the puncture 32 and rides over the guidewire 60 may be inserted prior to the introducer sheath 70. Preferred dilator diameters range between  
20 12 and 22 French. The introducer sheath 70 comprises the distal end of an introducer that will be described below. Introducer sheath diameters of no greater than 24 French, and desirably 22 or 24 Fr are preferred.

[0054] Fig. 3A shows the introducer sheath 70 passing into the left ventricle through the puncture 32 and over the guidewire 60 that extends  
25 upward through the calcified aortic valve AV. The surgeon locates a distal tip 72 of the introducer sheath 70 just to the inflow side of the aortic valve AV, as seen in Fig. 3A. At this point, it should be understood by those of skill in the art that the position of the introducer sheath 70 relative to the aortic valve AV, as well as the position of other elements of the system, is monitored using  
30 radiopaque markers and fluoroscopy, or using other imaging systems such as

transesophageal echo, transthoracic echo, intravascular ultrasound imaging (IVUS), or an injectable dye that is radiopaque.

[0055] Fig. 3B shows the advancement of the balloon catheter 54 over the guidewire 60 and through the introducer sheath 70. Ultimately, as seen in Fig. 3C, the prosthetic heart valve 50 is located at the aortic annulus and between the native aortic leaflets. Fig. 3C also illustrates retraction of the introducer sheath 70 from its more forward position in Fig. 3B. Radiopaque markers may be provided on the distal end of the introducer sheath 72 more accurately determine its position relative to the valve 50 and balloon 52.

[0056] Again, the precise positioning of the prosthetic heart valve 50 may be accomplished by locating radiopaque markers on its distal and proximal ends. Desirably, the surgeon can adjust the position of the valve 50 by actuating a steering or deflecting mechanism within the balloon catheter 54, as will be described below. Furthermore, the rotational orientation of the valve 50 can be adjusted relative to the cusps and commissures of the native aortic valve by twisting the balloon catheter 54 from its proximal end and observing specific markers on the valve (or balloon catheter) under fluoroscopy. One of the coronary ostia 80 opening into one of the sinuses of the ascending aorta is shown, and those of skill in the art will understand that it is important not to occlude the two coronary ostia with the prosthetic valve 50. It should also be noted that although the native leaflets of the aortic valve AV are shown coapting in Fig. 3A, and being flexibly displaced by the balloon catheter 54 in Figs. 3B and 3C, they may actually be compressed further outward against the aortic annulus from a pre-dilation procedure.

[0057] Fig. 3C shows the prosthetic heart valve 50 in its contracted or unexpanded state crimped around the balloon 52. When the surgeon is satisfied of the proper positioning and rotational orientation of the valve 50, the balloon 52 is expanded as seen in Fig. 3D. Proper size measurement of the native aortic valve AV enables the surgeon to select an optimum-sized valve 50 such that it expands outward into good contact with the aortic annulus. The term "good contact" implies sufficient contact to ensure that the prosthetic

heart valve 50 does not migrate after implant. Excessive expansion of the valve, however, may damage surrounding tissue or interfere with the performance of adjacent valves.

5 [0058] A number of devices are available to assist in anchoring the prosthetic valve 50 into the aortic annulus, such as barbs and the like. A preferred configuration of prosthetic heart valve 50 for use with the present invention is disclosed in co-pending U.S. patent application Serial No. 10/883,575, filed June 30, 2004, which disclosure is expressly incorporated herein by reference. Of course, the valve 50 can take a variety of different  
10 forms but generally comprises an expandable stent portion that supports a valve structure. The stent portion has sufficient radial strength to hold the valve at the treatment site and resist recoil of the stenotic valve leaflets. Additional details regarding preferred balloon expandable valve embodiments can be found in U.S. Patent Nos. 6,730,118 and 6,893,460, both of which are  
15 expressly incorporated herein by reference. The preferred prosthetic heart valve 50 includes sufficient irregularity on its outer surface such that it may be anchored in the aortic annulus without the use of barbs or other tissue piercing structure.

[0059] Once the valve 50 is properly implanted, as seen in Fig. 3D, the  
20 balloon 52 is deflated, and the entire delivery system including the balloon catheter 54 is withdrawn over the guidewire 60. The guidewire 60 is then withdrawn, followed by the introducer sheath 70. Ultimately, the purse-string sutures 44 previously described are cinched tight and tied to close the puncture 32, as seen in Fig. 3E

25 [0060] It is important to recognize that the heart valve delivery system of the present invention is particularly well-suited for the antegrade, left ventricular apex, "transapical," approach. More particularly, the mini-thoracotomy approach requires relatively short instruments. Therefore, the portion of the introducer sheath 70 that extends into the body is desirably no  
30 more than about 8 inches (20 cm) long, and the length of the balloon catheter 54 that may extend into the introducer sheath 70, i.e., the "working length," is



desirably no more than about 24 inches (61 cm). Further specifics on the relatively short length of the balloon catheter 54 and introducer sheath 70 will be provided below. The short length of the prosthetic heart valve delivery system described herein is also well-suited for other anatomical approaches, including through the carotid or subclavian arteries. The short length of the system is desirable because it enhances controllability and steerability of the distal end, relative to longer systems, which helps improve accuracy and reduced time for valve positioning.

[0061] The delivery system of the present invention essentially comprises an introducer 100, the balloon catheter 54, and attendant couplers and operating structures, including a loader 140 between the introducer and balloon catheter as seen in Fig. 5A. The introducer 100 is illustrated in Figs. 4A and 4B, while the balloon catheter 54 and loader 140 are shown in Figs. 5-15. It should be noted that the delivery system is similar to another system used to percutaneously implant a prosthetic aortic valve, which is disclosed in co-pending U.S. patent application Serial No. 11/152,288 filed June 13, 2005, and expressly incorporated herein by reference. The present system differs in several aspects that make it more suitable for a transapical approach, although some features are common.

[0062] As seen in Figs. 4A and 4B, the introducer 100 comprises the aforementioned distal sheath 70 coupled to an introducer housing 102 containing a series of valves. The exploded view of Fig. 4B shows an end cap 104 detached from the introducer housing 102. The end cap 104 includes a flanged nipple 105 for mating with the loader 140, as will be explained below. The end cap 104 threads or otherwise attaches to the housing 102 and retains therein, in series from proximal to distal, a cross-slit valve 106, a spacer 108, a disk valve 110, and a duck-bill valve 112. These three valves function to provide a seal when no instruments pass through the introducer 100, and when several different sizes of instruments pass therethrough. For example, the valves seal around both the guidewire 60 and the balloon catheter 54 as previously shown. The introducer sheath 70 extends into the body vessel, with

the introducer housing 102 located outside the body vessel. In a preferred embodiment, the introducer sheath 70 possesses an external hydrophilic coating and has a length of about 8 inches so that it may extend through the access incision 20 (see Fig. 1), into the left ventricle and reach the aortic annulus.

[0063] The introducer sheath 70 attaches to the housing 102 via an intermediate section of tubing 120. The tubing 120 is desirably size slightly larger than the sheath 70 such that it can be shrunk around a proximal end thereof. The proximal end of the tubing 120 includes a sealing flange 122 that mates with a distal nipple 124 extending from the housing 102. Preferably adhesive is used between these two mating sections. A nut housing 126 rides over the tubing 120 and couples to threading 128 provided on the housing 102 just proximal to the nipple 124. In this way, the various components can be manufactured (typically molded or extruded) separately and easily coupled together during assembly.

[0064] A side port tube 130 extends at an angle away from the introducer housing 102 and terminates in a three-way stopcock 132. This permits the user to infuse medicaments or other fluids through the lumen of the introducer 100 even if devices such as the balloon catheter 54 are present therein.

[0065] Fig. 5 illustrates in perspective the balloon catheter 54, which comprises an assembly of interrelated components commencing on a proximal end with a luer fitting 142 and terminating at a distal end in a soft tip 144. The loader 140 shown in perspective in Fig. 5A will be described in more detail below and provides a coupling between the balloon catheter 54 and the above-described introducer 100. The balloon catheter 54 is also shown in plan, sectional, and isolated views in Figs. 6-15 and comprises, from proximal to distal, an inner tube handle 150 having the luer fitting 142, a balloon inflation connector 152, a deflection handle 154, an outer balloon inflation tube 156, a pusher handle 158, a pusher body 160, a pusher sleeve 162, a deflecting segment 164, and an expandable balloon 52 located just proximal to the soft

tip 144. An internally threaded loader cap 170 fits over the pusher body 160 and couples to the loader 140.

[0066] Prior to a detailed description of the exemplary balloon catheter 54, its interaction with the introducer 100 via the loader 140 will be explained.

5 The loader 140 has a tube-shaped body with exterior threading 172 at a proximal end for connection with internal threading on the loader cap 170, and a slightly externally tapered distal nose 174 that fits within the introducer 100. The loader 140 includes a pair of attached cantilevered fingers 176 extending parallel thereto with internally facing snap ridges 178 for securing the loader  
10 140 to the introducer 100. An annular loader seal 180, seen better in Figs. 6A and 6B, is positioned within the loader cap 170. The annular loader seal 180 comprises a pair of annular washers 182, preferably nylon, that sandwich therebetween an annular resilient seal 184, preferably silicone.

[0067] The loader 140 facilitates introduction of the balloon catheter  
15 54 into the introducer 100. As described above, the introducer housing 102 contains the series of valves 106, 110, 112 that in aggregate provide an effective fluid seal against egress of blood through the introducer 100 in the absence or presence of different sized medical implements. The distal nose 174 of the loader 140 extends through the introducer housing 102 and through  
20 these valves 106, 110, 112 to hold them open and provide a smooth internal lumen which matches the size of the lumen of the introducer sheath 70. In this way, the somewhat irregular contours of the balloon catheter 54 having a prosthetic valve 50 crimped around the balloon 52 may smoothly pass into the introducer sheath 70.

25 [0068] Prior to balloon expansion as seen in Fig. 5, the loader 140 couples over the distal extent of the balloon catheter 54 and is displaced proximally until it can be coupled with the loader cap 170. Screwing the loader cap 170 onto the external threats 172 of the loader 140 axially compresses the loader seal 180 to provide a fluid tight fit and lock the loader  
30 140 with respect to the balloon catheter 54. At this point, the distal extremity of the balloon catheter 54, including the balloon 160, is located within the

tubular body of the loader 140. The distal nose 174 inserts into the introducer housing 102 and the cantilevered loader fingers 176 mate with the flanged nipple 105 of the end cap 104 (Fig. 4A). The balloon catheter 54 is thus coupled to the introducer 100. The loader cap 170 is then loosened, permitting  
5 axial displacement of the balloon catheter 54 with respect to the loader 140. Sliding the entire balloon catheter 54 distally permits the irregular contours of the distal extremity thereof to pass safely across the valves 106, 110, 112 and into the introducer sheath 70. The loader 140 remains coupled to the introducer 100 during the valve implant procedure, and the loader cap 170 can  
10 be re-tightened if necessary to secure the relative positions of the balloon catheter 54 and introducer 100.

[0069] The various components of the balloon catheter 54 will now be described with respect to Fig. 5, and the more detailed views of Figs. 6-15. With reference to the Figs. 6A and 6B, the balloon inflation connector 152  
15 comprises a main body 186 having a proximal section 188 and a distal section 190. Extending longitudinally through the proximal section 188 is a first bore 192, while extending longitudinally through the distal section 190 is a second bore 194 which communicates with the first bore 192. The first bore 192 has a non-circular cross-sectional configuration for reasons which will be discussed  
20 in more detail below. Disposed on the distal end of the distal section 190 is a distal connector nut 196, while disposed on the proximal end of the proximal section 188 is an inflation cap 198 that retains an inflation seal 199 within the inflation connector 152. The second bore 194 widens at its distal end into an enlarged opening that receives a connector nipple 200 also attached within the  
25 deflection handle 154.

[0070] The balloon catheter 54 of the present invention desirably incorporates relatively sliding concentric inner and outer balloon inflation tubes that attach to opposite ends of the balloon 52. Without going into great detail, the concentric tubes permit the balloon 52 to be shortened or  
30 lengthened depending on the relative movement therebetween. This provides the ability to axially extend the balloon 52 after it has been deflated so that its

radial profile is reduced and it may be easily removed from the surrounding structures, anatomical or otherwise. Inflation fluid, preferably saline, passes in a tubular space provided between the concentric balloons. In the present invention, the balloon 52 expands the prosthetic heart valve 52 to implant it in the annulus, after which the balloon is deflated and axially elongated before being removed from within the valve. A detailed discussion of the structure and function of this concentric tube configuration may be found in U.S. Patent No. 5,968,068, the disclosure of which is expressly incorporated by reference herein.

10           [0071] An inner balloon inflation tube 210 is seen at its proximal end extending into the inner tube handle 150 in Fig. 6B, and also in the enlarged view of Fig. 7. The tube 210 fixes concentrically within a tube segment 212 (seen isolated in Fig. 8), a proximal end of which, in turn, is fixed within a bore of the tube handle 150. An anti-rotation block 214 fixed on the distal end of the tube segment 212 axially slides within the first bore 192 of the inflation connector body 186. The first bore 192 and anti-rotation block 214 are non-circular in radial cross-section to prevent relative rotation therebetween. Preferably, these elements are square. This also prevents rotation between the inner tube 210 and the inflation connector 152.

20           [0072] The proximal end of the outer balloon inflation tube 156 is seen in Figs. 6B and 7 extending into the deflection handle 154 to be fixedly received within the connector nipple 200. As seen in isolation in Fig. 9, the outer balloon inflation tube 156 has a larger cross-section at the distal end of the deflection handle 154 than it does at its termination in the connector nipple 200. An outer portion of the tube 156 fastens within a connector at the distal end of the hollow body 230 of the deflection handle 154, while a smaller diameter fluid-carrying tube 215 extends through the deflection handle to the connector nipple 200. The fluid-carrying tube 215 receives the inner balloon inflation tube 210, while another lumen defined within the outer balloon inflation tube 156 receives a deflection wire, as described below. The connector nipple 200 is fixed (e.g., adhered or similarly secured) with respect

to both the inflation connector 152 and deflection handle 154, rendering these two elements essentially contiguous. It can therefore be seen, as in Fig. 6B, that displacement of the inner tube handle 150 with respect to the inflation connector 152 also displaces the inner tube 210 with respect to the outer tube 156.

[0073] A Y-port 216 in the distal section 190 of the balloon inflation connector main body 186 leads to a side tube and a stop-cock valve 218. The valve 218 provides a connection point for a source of saline for inflating the balloon 52. The second bore 194 in the main body 186 is open to the first bore 192 which is, in turn, sealed at the inflation cap 198 on the proximal end of the inflation connector 152. Saline thus passes in a distal direction past the connector nipple 200 through a tubular space outside of the inner tube 210 and inside the fluid-carrying tube 215 of the outer tube 156. The concentric space between the tubes 210, 215 provides a pathway for the saline into the distal balloon 152.

[0074] Still with reference to Fig. 7, the inner tube handle 150 features a pair of opposed cantilevered clips 220 that serve to temporarily attach the tube handle to the inflation cap 198 on the proximal end of the inflation connector 152. By squeezing the proximal ends of the clips 220 their distal ends open up and the inner tube handle 150 can be displaced in a proximal direction with respect to the inflation cap 198. After a short distance of travel, typically between 1-2 cm, the distal ends of the clips 220 are located over a short flanged nipple 222 on the inflation cap 198 and can be released so that inwardly facing teeth on the clips 220 engaged the flange. This operation displaces the inner balloon inflation tube 210 with respect to the outer balloon inflation tube 156, which in turn causes the opposite axial ends of the balloon 52 to move apart. As mentioned above, this movement facilitates the reduction in profile of the deflated balloon. The interaction between the teeth on the clips 220 and the flanged nipple 222 holds the relative position of the outer and inner tubes 156, 210 such that the balloon 52 remains locked in its extended configuration for ease of removal.

[0075] The luer fitting 142 on the proximal end of the inner tube handle 150 provides an entry point for injection of radiographic contrast medium. The luer fitting 142 opens to the lumen of the inner balloon inflation tube 210 which continues to the distal end of the balloon catheter 54 where an egress port is provided. Contrast medium is useful to check for perivalvular leaks after the prosthetic valve is implanted.

[0076] With reference both to Figs. 6B and 7, the deflection handle 154 includes a generally hollow body 230 having an axial slot on one side that receives a slider 232, seen in Fig. 6A. The hollow body 230 defines a series of partial external circumferential ribs 234 opposite the slider 232 to facilitate gripping by the user. Although it is not readily apparent from the cross-sectional view of Fig. 7, the slider 232 attaches within the handle body 230 to a deflection wire 236 that passes into one of the lumens provided within the larger portion of the outer balloon inflation tube 156. The enlarged view of Fig. 11 illustrates a distal end of the outer tube 156 and shows the deflection wire 236 extending therefrom. Specifics of the attachment of the deflection wire 236 to the distal end of the balloon catheter 54 will be given below. Suffice it to say that axial movement of the slider 232 translates into axial movement of the deflection wire 236.

[0077] With reference to Figs. 6A-6B and 10, the pusher handle 158 comprises a tubular body 240 having a longitudinally extending lumen 242 that slidably receives the outer tube 156 therethrough. A pair of connector nuts 244, 246 couple to respective proximal and distal ends of the body 240, and in particular mate with external threads provided thereon. A tubular side arm 248 extends angularly from the body 240 and communicates with the lumen 242 therein. The proximal end of the pusher body 160 desirably bonds within the distal end of the body 240, and a lumen defined within the pusher body fluidly communicates with the lumen 242 of the pusher handle body 240. Since the side arm 248 opens into the lumen 242, which surrounds the outer balloon inflation tube 156, fluid introduced through the side arm enters the concentric space between the outer tube 156 and the pusher body 160. The

side arm 248 provides a multi-function port for introduction of angiography fluid, heparin, or other such therapeutic substances. The proximal connector nut 244 axially compresses a sealing member 252 to both secure the pusher handle 158 to the outer balloon inflation tube 156, and provide a fluid seal therebetween.

[0078] Reference now to Fig. 11, the pusher body 160 attaches on its distal end to a flared pusher sleeve 162. Although shown separated, the pusher sleeve 162 surrounds the deflecting segment 164 and a proximal portion of the balloon 52 during passage through the introducer sheath 70. The deflecting segment 164 generally comprises an outer flexible cover 262 surrounding an inner coil spring 264. The pusher body 160 and pusher sleeve 162 facilitate advancement of the deflecting segment 164 and attached balloon 52 having the valve 50 crimped thereon through the introducer sheath 70. Proximal retraction of the pusher body 160 relative to the outer balloon inflation tube 156 frees the deflecting segment 164 and the balloon 52. As seen best in Fig. 5, the pusher handle 158 may slide proximally over the balloon inflation tube 156 by loosening the proximal connector nut 244, thus pulling the pusher body 160 back with respect to the tube 156.

[0079] As mentioned above, the deflection handle 154 supports the slider 232 (Fig. 6A) which is connected to the deflection wire 236, seen extending through the deflecting segment 164 in Fig. 11. In this regard, the deflection wire 236 extends from the deflection handle 154 along one of the lumens in the outer balloon inflation tube 156. The tube 156 terminates just within the flexible cover 262 of the deflecting segment 164, and more particularly is fastened within a rigid proximal tube segment 274 to which the flexible cover 262 also attaches, such as with adhesives. The coil spring 264 desirably includes tightly wound sections 270, 272 at both ends, a proximal one of which is secured within the distal end of the tube 156. The deflection wire 236 exits the outer tube 156 and passes around the outside of the coil spring 264, finally fastening to a distal tube segment 276 of the deflecting



segment 164. The tube segment 276 provides a rigid anchor for the flexible cover 262, coil spring 264, and the proximal end of the balloon 52.

5       [0080] Tension in the deflection wire 236 pulls on one side of the distal tube segment 276 which causes the distal end of the deflecting segment 164 to bend in that direction. Of course by rotating the entire balloon catheter 54 about its axis the deflecting segment 164 may be steered in any direction. The coil spring 264 provides both flexibility and resiliency such that release of tension on the deflection wire 236 permits the deflecting segment 164 to return to a straight orientation. Because the balloon 52 attaches to the distal end of  
10       the deflecting segment 164, the prosthetic heart valve 50 crimped thereon may be oriented precisely within the native annulus.

      [0081] With reference again to Figs. 6A and 6B and 12, the balloon 52 includes a first cone portion 288, a main cylindrical portion 290, and a second cone portion 292. The prosthetic heart valve 50 desirably crimps around the  
15       main cylindrical portion 290, such as shown in phantom in Fig. 12. The balloon 52 can be formed of nylon, and is rated at a burst pressure of 6-8 atm. In preferred embodiments, the expanded diameter of the balloon ranges from about 20 to 28 mm, the particular size depending on the size of the heart valve 50 being implanted.

20       [0082] The inner balloon inflation tube 210 passes through the balloon 52 and terminates at a distal end that is capped by the aforementioned soft tip 144, best seen in Fig. 13. The soft tip 144 facilitates introduction of the balloon catheter 54 and reduces trauma to surrounding tissue. This is particularly important in the preferred procedure of the present invention  
25       where the catheter enters the apex of the left ventricle and travels through the aortic valve into the ascending aorta. As was seen in Fig. 3D, the distal tip of the catheter may extend far enough to enter the aortic arch, and the soft tip 144 thus prevents rupture or other abrasion to the surrounding vascular tissue. Fig. 13 also illustrates the open distal end of the inner tube 210 and soft tip 144  
30       through which radiographic contrast medium may be injected to test valve sufficiency after implant.

[0083] Fig. 14 is an elevational view of the distal end of the balloon catheter 54 showing the balloon 52 deflated and its proximal end encompassed by the pusher sleeve 162. This view also shows a series of inflation holes 298 provided in the inner tube 210 through which saline passes to inflate the balloon 52.

[0084] Figure 15 shows the distal end of the balloon catheter 54 as it is delivered in its packaging. Specifically, a protective sheath 300 is provided surrounding the balloon 52 which is removed in the operating room prior to the implantation procedure.

[0085] In use, the present invention provides a novel and effective way for implanting a prosthetic heart valve 50 in the aortic annulus. The steps of the procedure have been described above with respect to Figs. 1-3, at least as far as the final implantation steps. A description of the advantageous use of the exemplary balloon catheter 54 in performing the entire procedure will now be provided.

[0086] First, as mentioned above, the physician determines the size of the patient's annulus. This can be done physically by creating the incision 20 and puncture 32 in the left ventricular apex, and inserting a sizing tool into the aortic annulus. However, the puncture 32 may not be large enough to pass a conventional sizer, and an alternative technique such as echocardiography or other such imaging system may be utilized.

[0087] Next, the balloon catheter 54, introducer 100, loader 140, and prosthetic heart valve 50 are selected, and prepared for use by removing them from any packaging and rinsing or sterilizing as needed. A pre-dilation step as described above with respect to Figs. 2A-2B may be performed to enlarge or crack existing calcification in the aortic annulus.

[0088] The process of crimping the prosthetic heart valve 50 over the balloon 52 may be accomplished in a number of ways, and there are suitable devices on the market for crimping balloon-expanding stents over balloons. In a preferred embodiment, a device having a compressing mechanism that works like the aperture iris of a camera is utilized. In such a device, multiple

continuous segments around the periphery of the prosthetic heart valve 50 close separately but in concert so that uniform inward pressure is exerted on the heart valve. The devices typically operate manually.

[0089] Subsequently, the aforementioned pusher body 160 and flared sleeve 162 are advanced distally over the proximal end of the balloon 52, such as seen in Fig. 14. The pusher handle 158 is secured in this position by screwing tight the connector nut 244. The loader 140 is then secured over the distal end of the balloon catheter 54, including the assembly of the deflecting segment 164, balloon 52 and prosthetic valve 50. The loader 140 fastens in this position through engagement of the loader cap 170 with the proximal threads 172 of the loader body.

[0090] At this point, or at the same time as balloon catheter preparation, the introducer 100 is positioned within the left ventricle as seen in Fig. 3A. Again, the purse-string sutures 44 maintain a fluid tight seal around the introducer sheath 70. During the entire procedure the heart may continue beating. The physician inserts the distal nose 174 of the loader 140 into the proximal opening of the introducer housing 102 and bottoms the loader out such that the cantilevered fingers 176 engage the flanged nipple 105 of the introducer. At this point, the balloon catheter 54 is ready for introduction in the body.

[0091] Loosening the loader cap 170 permits distal advancement of the balloon catheter 54 with respect to the loader 140 and introducer 100. The physician then retracts the pusher sleeve 164 from the deflecting segment 164 and the proximal portion of the balloon 52 by loosening the connector nut 244 (Fig. 10) and pulling back the pusher handle 158 over the outer balloon inflation tube 156. The physician advances the catheter 54 until it reaches the position shown in Fig. 3C, which also involves retraction of the introducer sheath 70. The entire operation is visualized using radiographic markers and fluoroscopy, and the precise positioning of the balloon 52 and prosthetic valve 50 mounted thereon is accomplished by axial movement and rotation of the catheter 54 coupled with angular changes of the deflecting segment 164.

Specifically, as the prosthetic valve 54 advances it is aligned as much as possible along the flow axis of the native aortic valve AV by gross movement of the catheter 54 and slight changes in its angular orientation by tensioning the deflecting wire 236 with the slider 232 (Fig. 6A).

5           **[0092]** Ultimately, the valve 50 is positioned correctly as in Fig. 3C taking care that the valve 50 is not liable to block either of the coronary ostia 80 when expanded. Saline is then injected through the stopcock 218 (Fig. 6B) which passes through the Y-port 216 and into the tubular space between the outer and inner balloon inflation tubes 156, 210. Saline continues distally  
10 through fluid passages in the balloon catheter 54 and fills the balloon 52. The balloon 52 is of a type that has a maximum expanded diameter which has previously been selected to properly expand the prosthetic heart valve 52 to its optimum diameter in contact with the surrounding aortic valve AV, and calcified leaflets if they remain in place. The step is illustrated in Fig. 3D.

15           **[0093]** Subsequently, saline pressure is reduced within the balloon 52 permitting it to deflate. The deflation may be assisted by axially extending the opposite ends of the balloon 52 by moving the inner tube handle 150 distally toward the inflation handle 152 (see Fig. 6B). Radiographic contrast medium may be injected from the proximal lure 142 of the balloon catheter 54 to  
20 egress through the distal soft tip 144 and test the efficacy of the just-implanted prosthetic valve 50. If the valve is properly functioning, the balloon catheter 54 is withdrawn into the introducer sheath 70, which is removed from the puncture 32. The purse-string sutures 44 are closed up to seal the puncture 32.

**[0094]** Once again, the delivery system described herein is particularly  
25 well-suited for an antegrade, transapical approach, partly because of its relatively short length. With reference to Fig. 4A, the entire length of the introducer 100 is approximately 13 inches (33 cm), while the length of the sheath 70 that may extend within the body is about 8 inches. The portion of the balloon catheter 54 that extends into the introducer 100 (that is, the portion  
30 of the balloon catheter from the distal soft tip 144 to approximately the deflection handle 154) is no more than about 24 inches (61 cm), which permits

about 11 inches (28 cm) of the balloon catheter to extend beyond the introducer distal tip 72 (see Fig. 4). It should be noted that the relatively short length of the delivery system is unsuited for a longer, more circuitous approach through the peripheral vasculature, such as shown in co-pending

5 U.S. patent application Serial No. 11/152,288. Also, the steering mechanism is provided on the balloon catheter 54 itself, rather than on a secondary catheter used for guiding the balloon catheter, as is done in application Serial No. 11/152,288. The short length of the balloon catheter and the ability to directly manipulate it greatly enhances successful positioning of the prosthetic

10 heart in the aortic annulus.

[0095] While the invention has been described in its preferred embodiments, it is to be understood that the words which have been used are words of description and not of limitation. Therefore, changes may be made within the appended claims without departing from the true scope of the

15 invention.

WHAT IS CLAIMED IS:

1. An off-pump, minimally-invasive surgical method of implanting a prosthetic heart valve to an aortic valve annulus of a patient, comprising, while the patient's heart remains beating:

providing a balloon catheter that includes a balloon on its distal end and a movable pusher having a distal sleeve engaging a proximal end of the balloon

providing a balloon-expandable prosthetic heart valve mounted over the balloon on the distal end of the balloon catheter;

creating a puncture through the ventricle wall at or near the apex of the left ventricle of the patient;

inserting an introducer sheath through the puncture;

passing the balloon catheter through the introducer sheath into the left ventricle;

using the pusher and sleeve to advance the balloon and prosthetic heart valve mounted thereon so that the prosthetic heart valve is positioned within the aortic annulus;

proximally displacing the pusher and sleeve with respect to the balloon; and

inflating the balloon to expand the prosthetic heart valve at the aortic annulus.

2. The method of claim 1, further comprising:

placing a first line of purse-string sutures generally in a first circle in one direction defining a perimeter at or near the apex of the left ventricle of the patient, and then placing a second line of purse-string sutures generally in a circle concentric to the first circle but in an opposite direction;

creating a puncture within the perimeter; and

after inserting the introducer sheath through the puncture, cinching the purse-string sutures to create a seal therearound.

3. The method of claim 1, wherein the balloon catheter includes a steering mechanism therein, and further comprising:

steering the balloon catheter with the steering mechanism within the left ventricle to facilitate positioning the prosthetic heart valve within the aortic annulus.

4. The method of claim 3, wherein the balloon catheter comprises a deflecting segment located just proximal to the balloon, the step of steering comprising:

bending the deflecting segment so as to angle the balloon and prosthetic heart valve mounted thereon.

5. The method of claim 4, wherein the pusher sleeve mounts over the deflecting segment, the method further including:

proximally displacing the pusher and sleeve with respect to the deflecting segment prior to inflating the balloon.

6. The method of claim 5, further comprising:

proximally displacing the pusher and sleeve with respect to the deflecting segment prior to bending the deflecting segment.

7. The method of claim 1, further comprising:

leaving the native aortic valve leaflets in place such that inflating the balloon expands the prosthetic heart valve into contact therewith.

8. The method of claim 1, further comprising:

expanding the prosthetic heart valve into contact with a prosthetic heart valve that was previously implanted at the aortic annulus.

9. An off-pump, minimally-invasive surgical method of delivering a prosthetic heart valve to an aortic valve annulus of a patient, comprising, while the patient's heart remains beating:

- providing an expandable prosthetic heart valve in an expanded state;

- providing a delivery catheter having a distal end;

- crimping the expandable prosthetic heart valve to a contracted state over the delivery catheter distal end;

- creating an intercostal access opening and exposing the left ventricular apex of the patient;

- creating a puncture at or near the apex of the left ventricle;

- inserting an introducer sheath through the puncture;

- passing the delivery catheter through the introducer sheath and into the left ventricle;

- advancing and steering the distal end of the delivery catheter so that the prosthetic heart valve is properly positioned and oriented within the aortic annulus; and

- expanding the prosthetic heart valve at the aortic annulus into contact therewith.

10. The method of claim 9, wherein the delivery catheter includes a balloon on its distal end, and the prosthetic heart valve includes a balloon-expandable stent, the step of expanding including:

- injecting fluid into the balloon to expand the prosthetic heart valve outward into contact with the aortic annulus.

11. The method of claim 9, further including:

- leaving the native aortic valve leaflets in place such that inflating the balloon expands the prosthetic heart valve into contact therewith.



12. The method of claim 9, wherein the delivery catheter comprises a deflecting segment located just proximal to its distal end, the step of steering comprising:

bending the deflecting segment so as to angle the prosthetic heart valve mounted at its distal end thereon.

13. The method of claim 12, wherein the delivery catheter further includes a pusher having a distal sleeve mounted over the deflecting segment, the method further including:

using the pusher and sleeve to advance the distal end of the delivery catheter and prosthetic heart valve mounted thereon; and

proximally displacing the pusher and sleeve with respect to the deflecting segment prior to bending the deflecting segment.

14. A minimally-invasive prosthetic heart valve delivery system, comprising:

an introducer sheath having a lumen therethrough of no greater than 24 French;

a balloon catheter having a balloon on a distal end, the balloon catheter further including a steering mechanism for deflecting the distal end; and

a balloon-expandable prosthetic heart valve crimped over the balloon,

wherein the outer dimension of the balloon catheter having the prosthetic heart valve thereon is small enough to pass through the introducer sheath lumen.

15. The system of claim 14, wherein the steering mechanism includes:

a deflecting segment on the balloon catheter located just proximal to the balloon.

16. The system of claim 15, further including:

a deflection wire attached to a distal end of the deflecting segment and extending through the balloon catheter to a proximal deflection handle.

17. The system of claim 15, further including:

a pusher having a distal sleeve sized to encompass the deflecting segment and a proximal end of the balloon, the pusher being longitudinally movable with respect to the deflecting segment.

18. The system of claim 14, wherein the balloon catheter further includes:

inner and outer balloon inflation tubes attached to opposite ends of the balloon and arranged to concentrically slide with respect to one another to alternately elongate and shorten the balloon;

an inner tube handle for displacing the inner balloon inflation tube;

a balloon inflation connector through which the inner balloon inflation tube passes and to which a proximal end of the outer balloon inflation tube attaches; and

a side port opening to a space defined within the balloon inflation connector, the side port adapted for introducing an inflation fluid into the space and into a tubular space between the inner and outer balloon inflation tubes for inflating the balloon.

19. The system of claim 18, further including:

a deflection handle attached just distal to the balloon inflation connector and through which the outer balloon inflation tube passes,

the outer balloon inflation tube including a first lumen for passage of the inner balloon inflation tube, and a second lumen; and

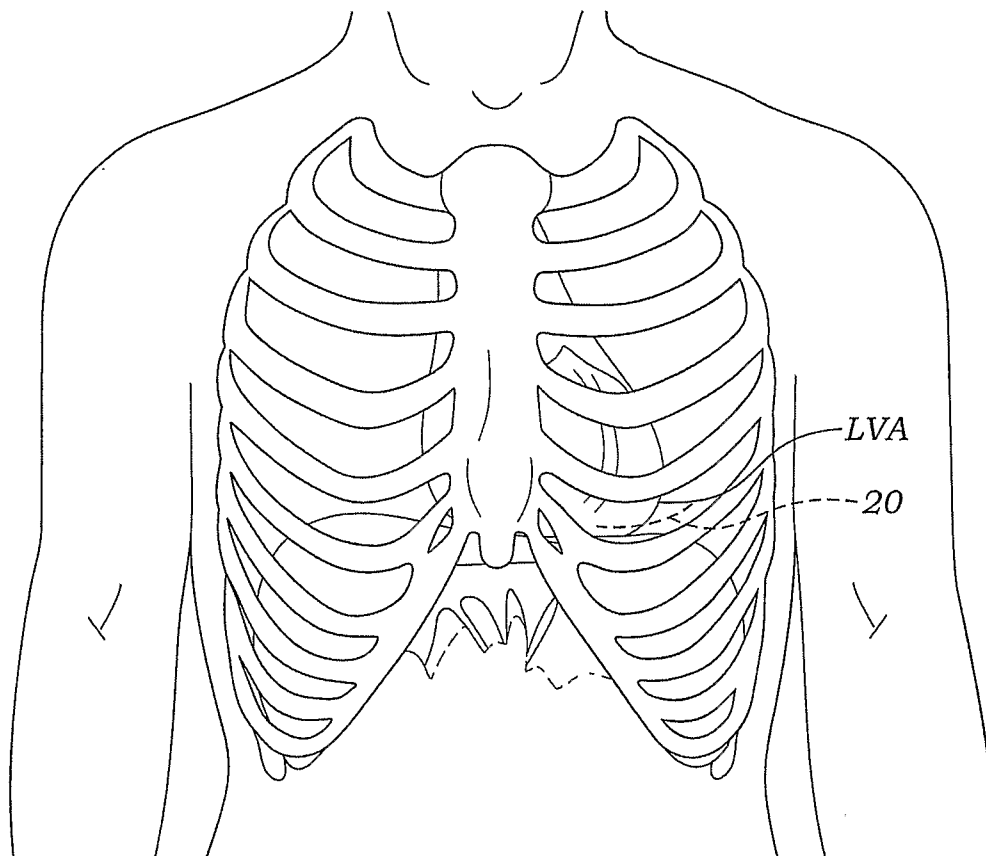
a deflection wire connected to an actuator on the deflection handle and passing through the second lumen of the outer balloon inflation tube to a distal end of the balloon catheter.

20. The system of claim 14, wherein the balloon catheter has a working length sized to fit into the introducer of no more than about 24 inches (61 cm).

21. The system of claim 20, wherein the introducer has a total length of no more than about 13 inches (33 cm).

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*Fig. 1*



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Fig. 2B

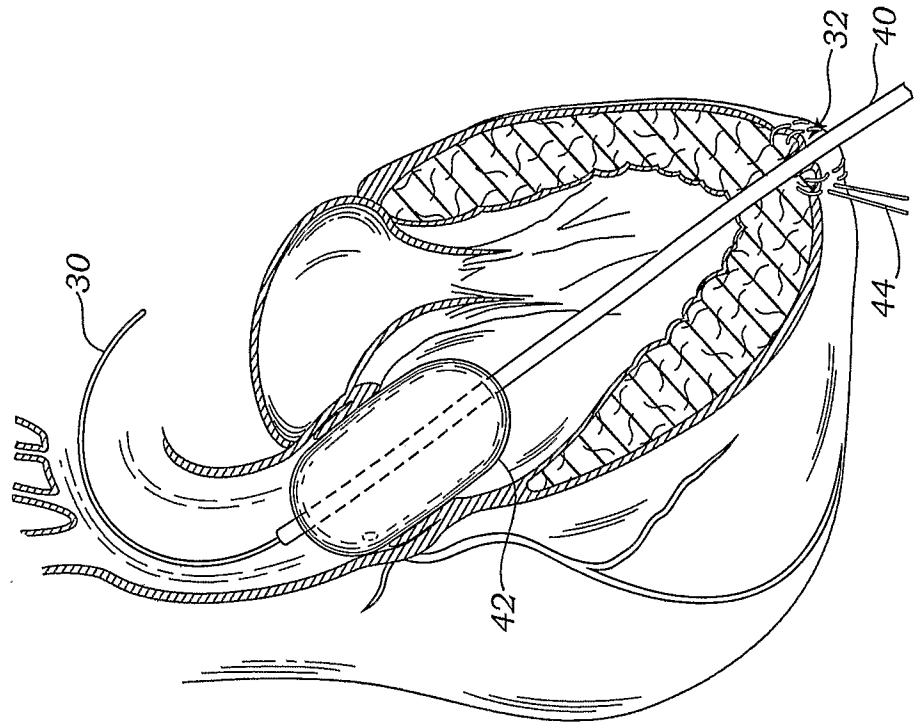


Fig. 2A

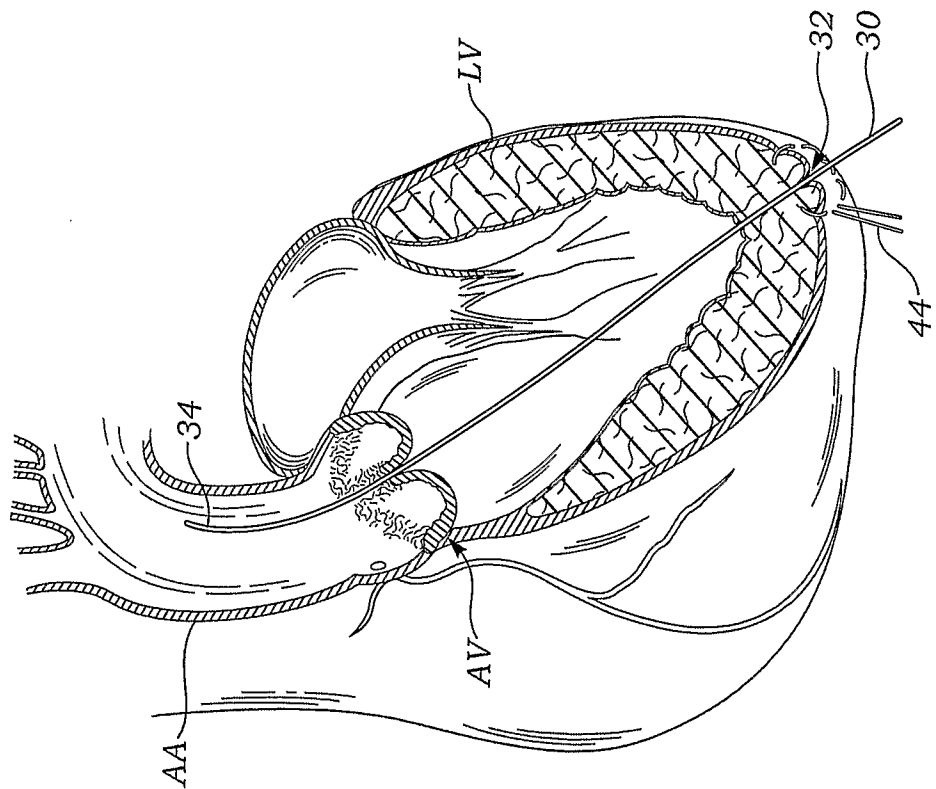
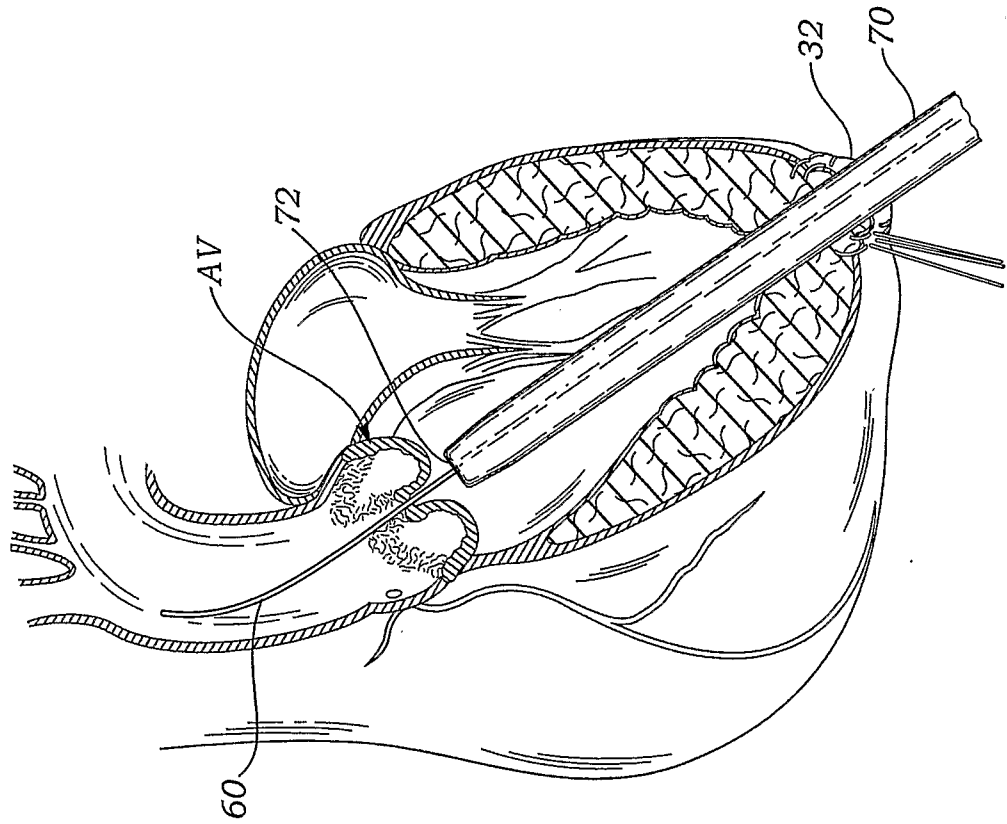


Fig. 3A



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Fig. 3C

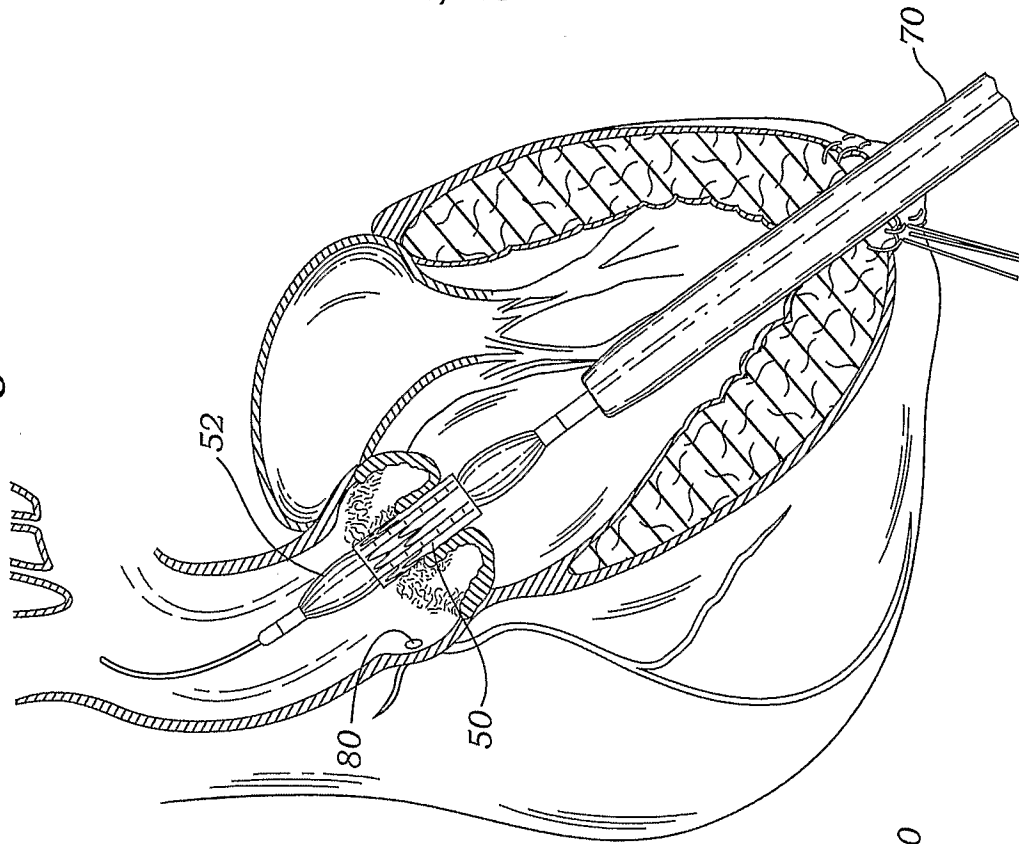
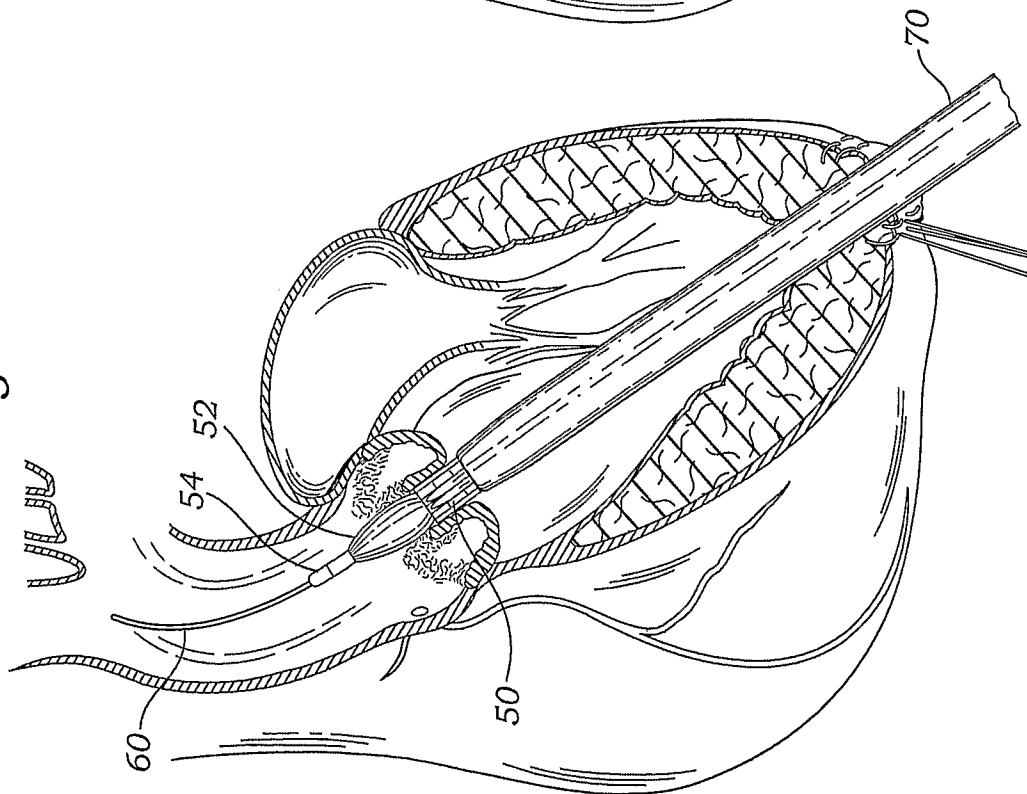


Fig. 3B



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Fig. 3E

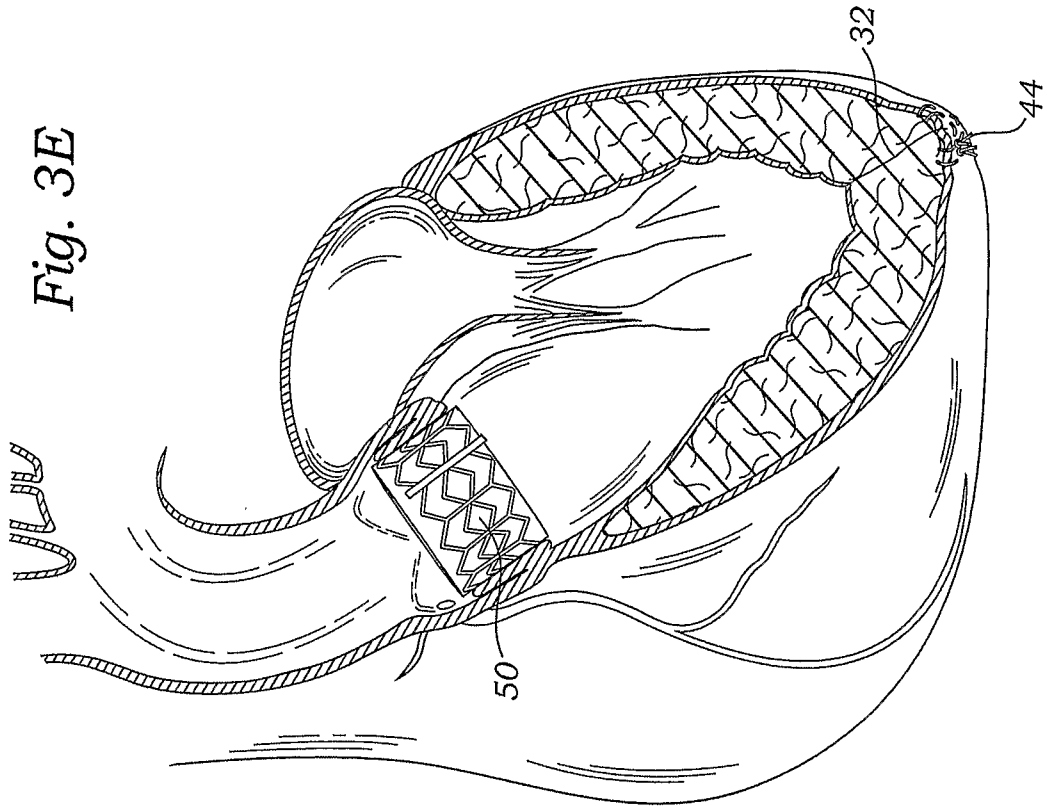
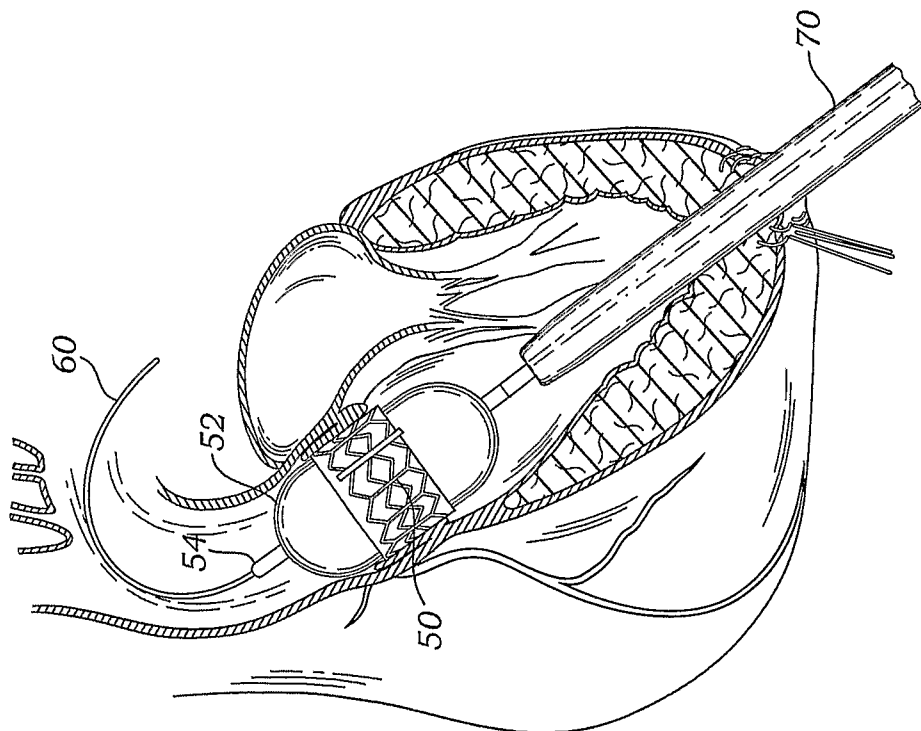
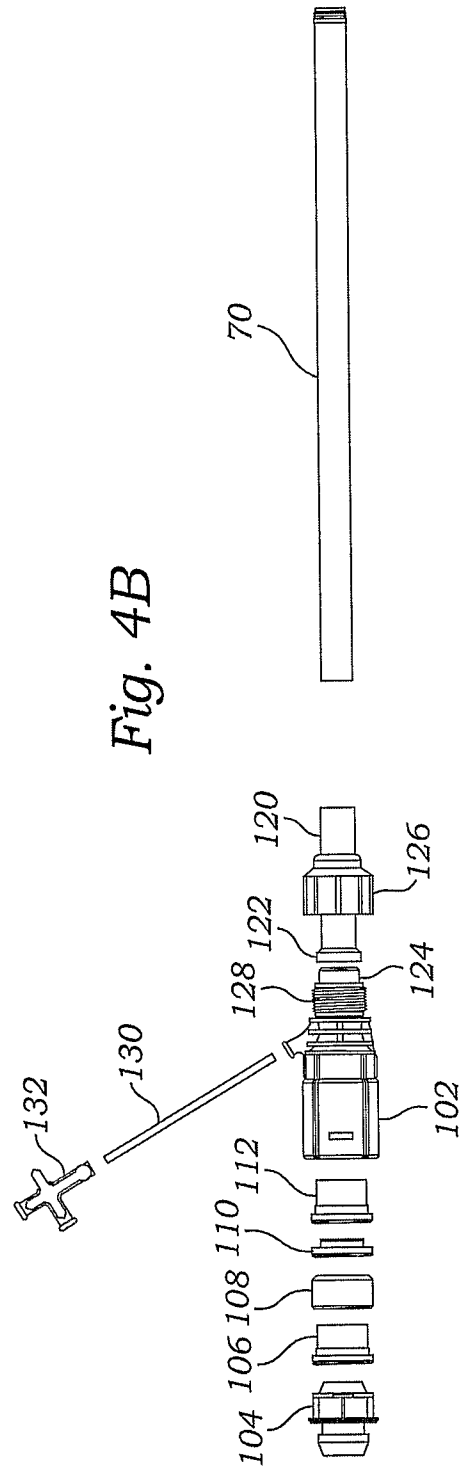
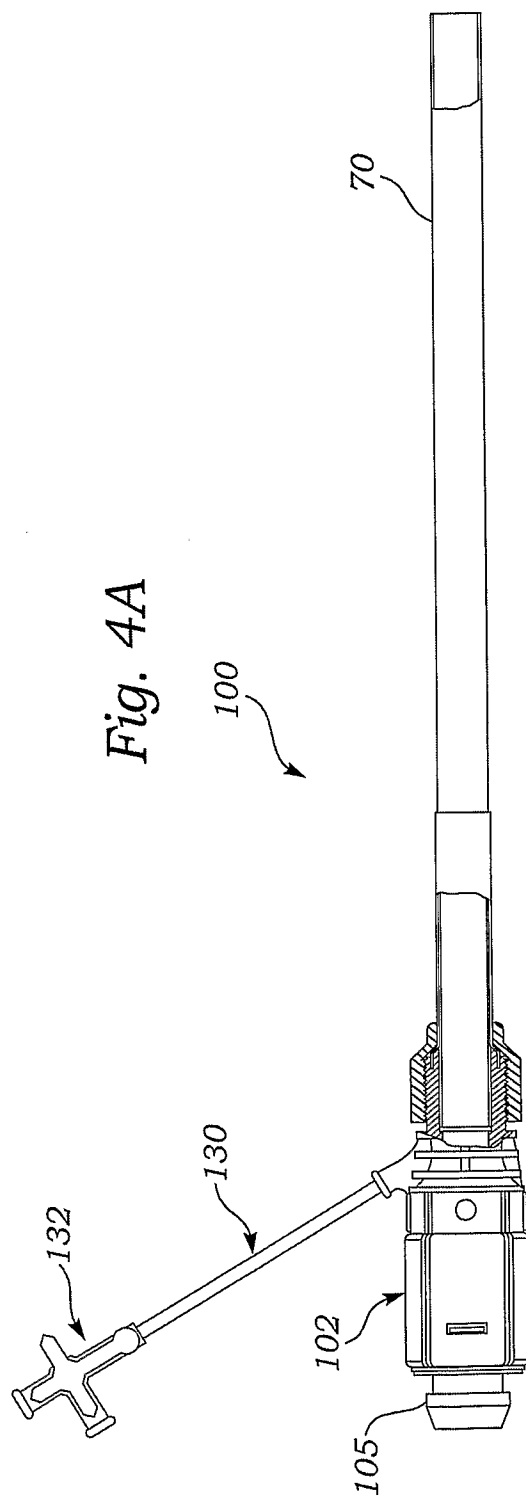


Fig. 3D





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Fig. 5

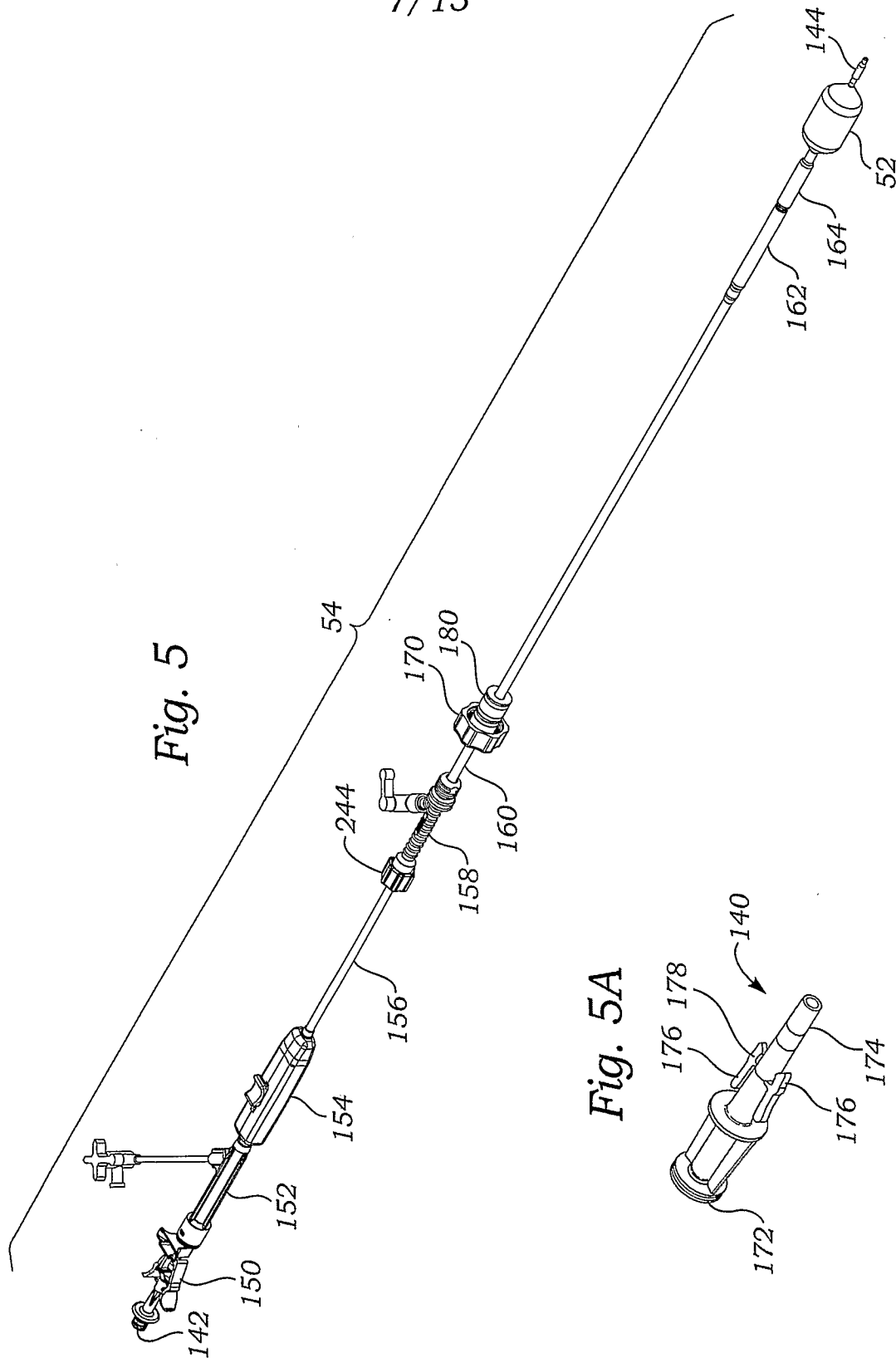
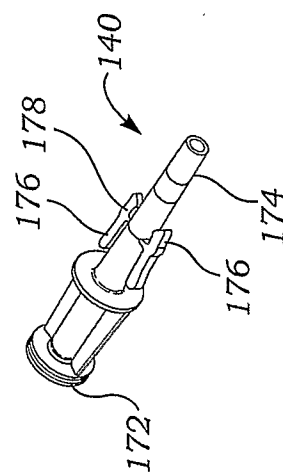
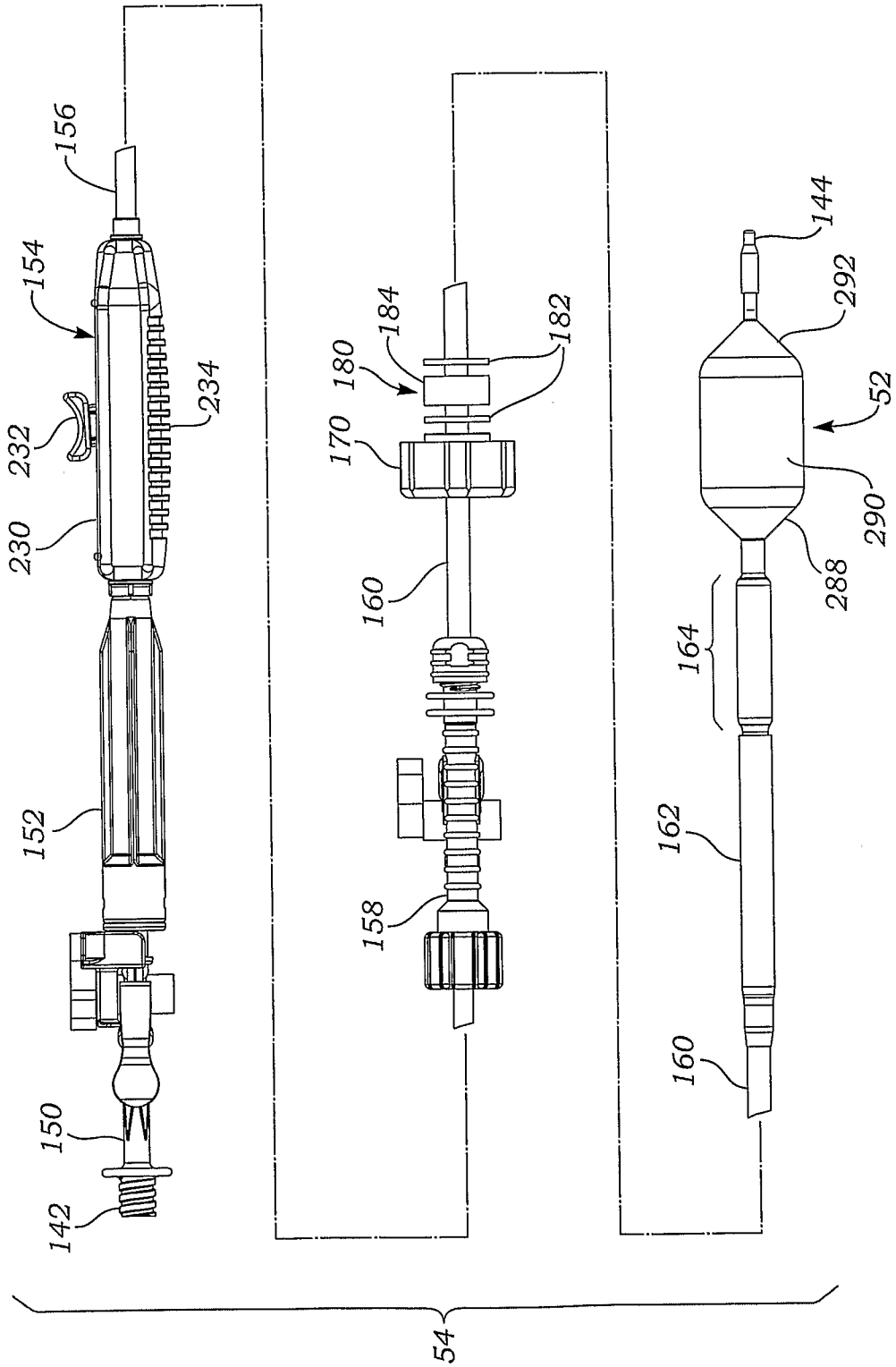


Fig. 5A



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Fig. 6A



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Fig. 6B

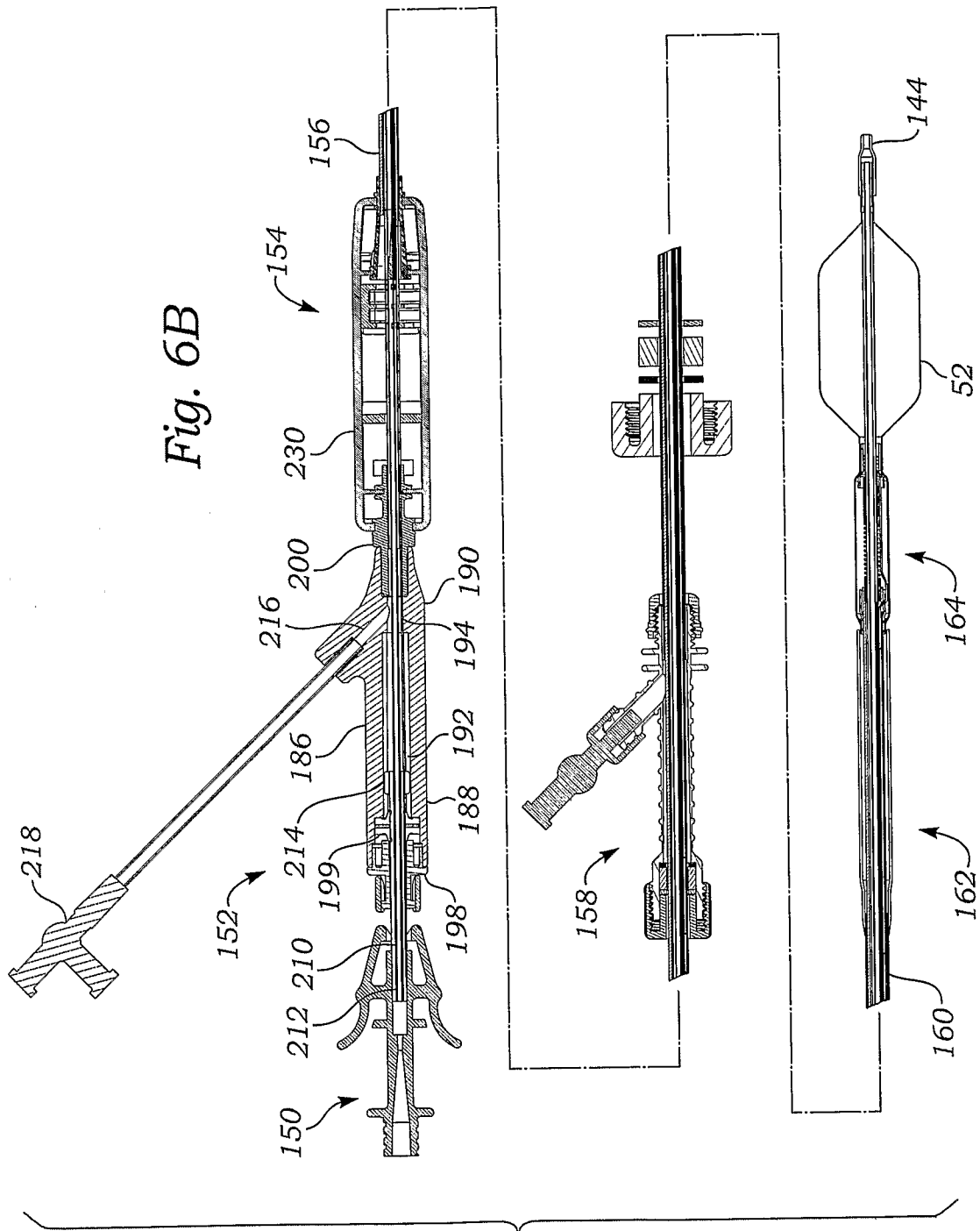


Fig. 7

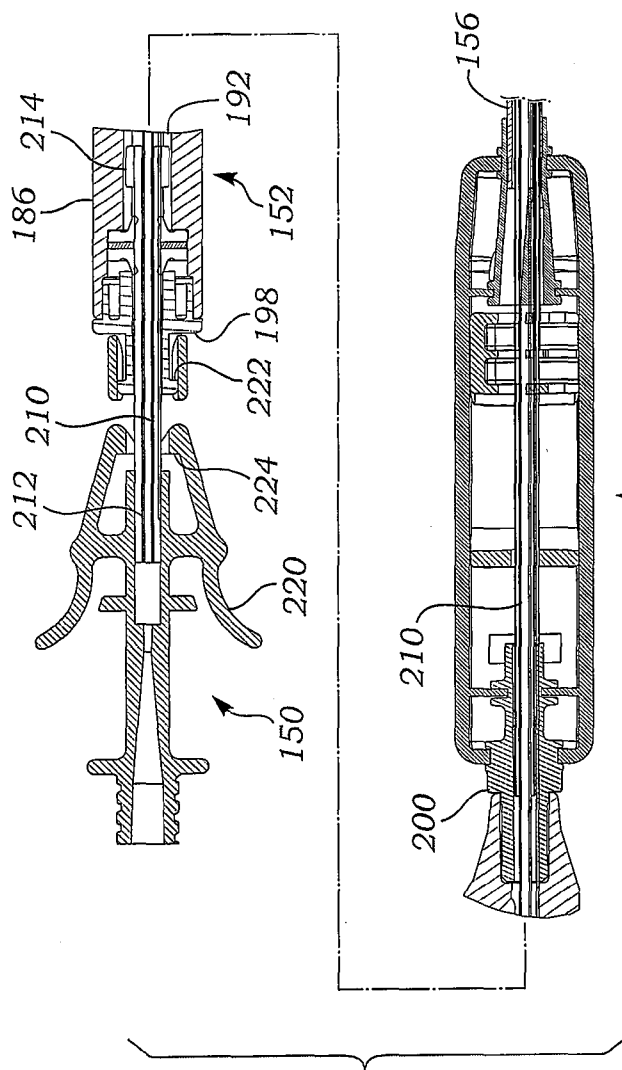


Fig. 9

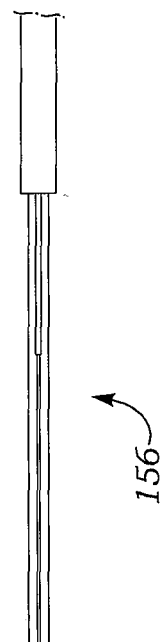
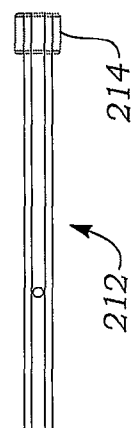


Fig. 8



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Fig. 10

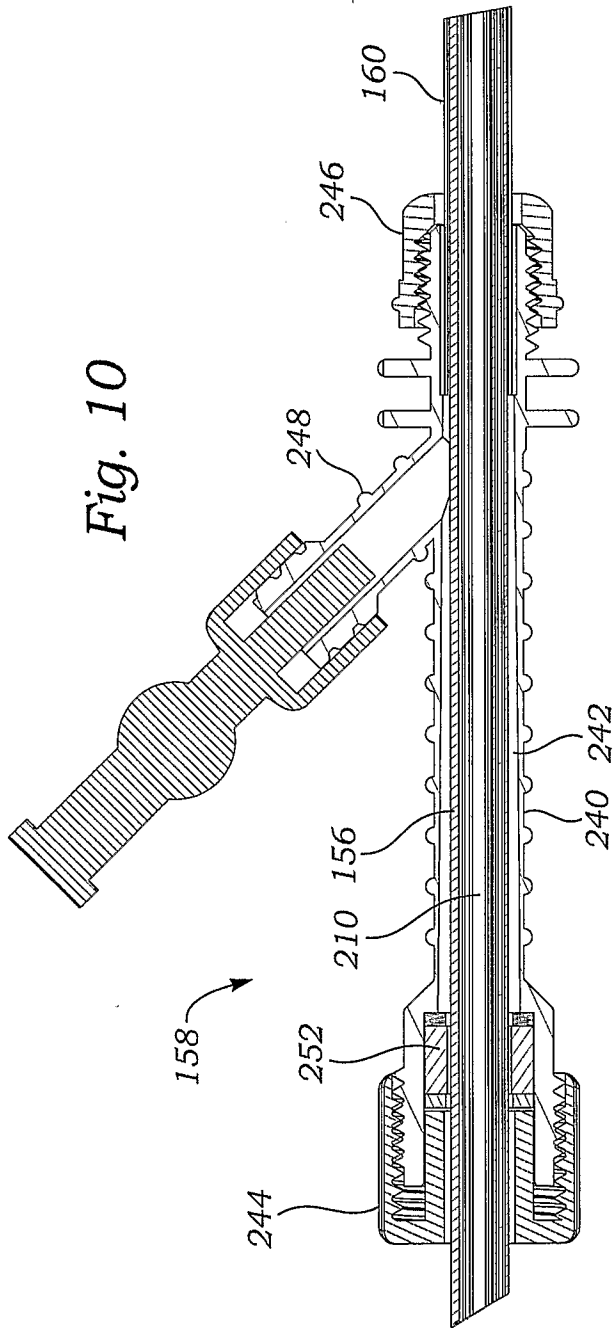
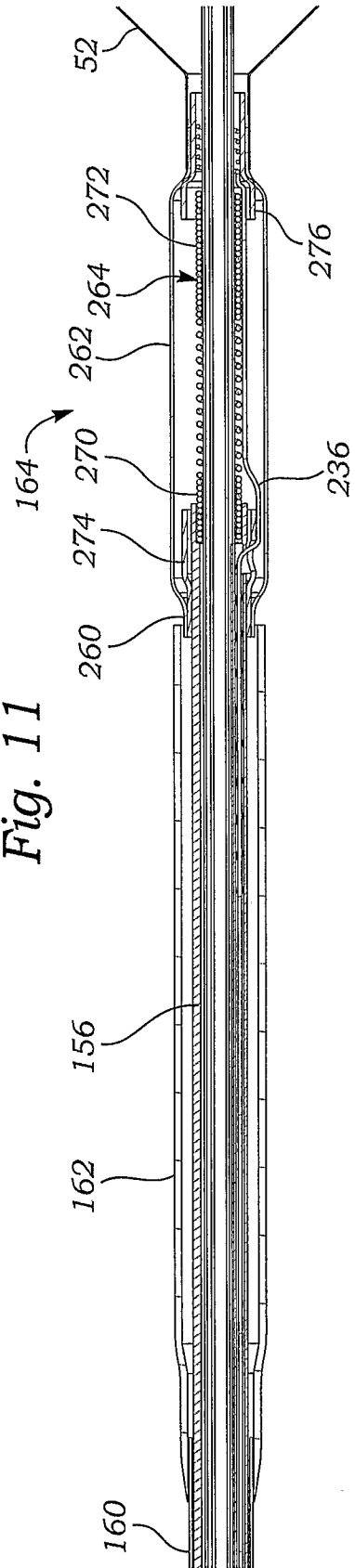


Fig. 11



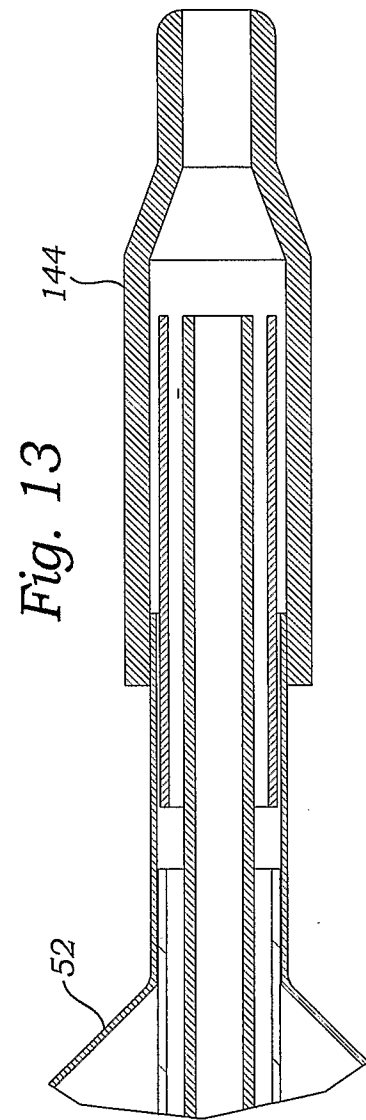
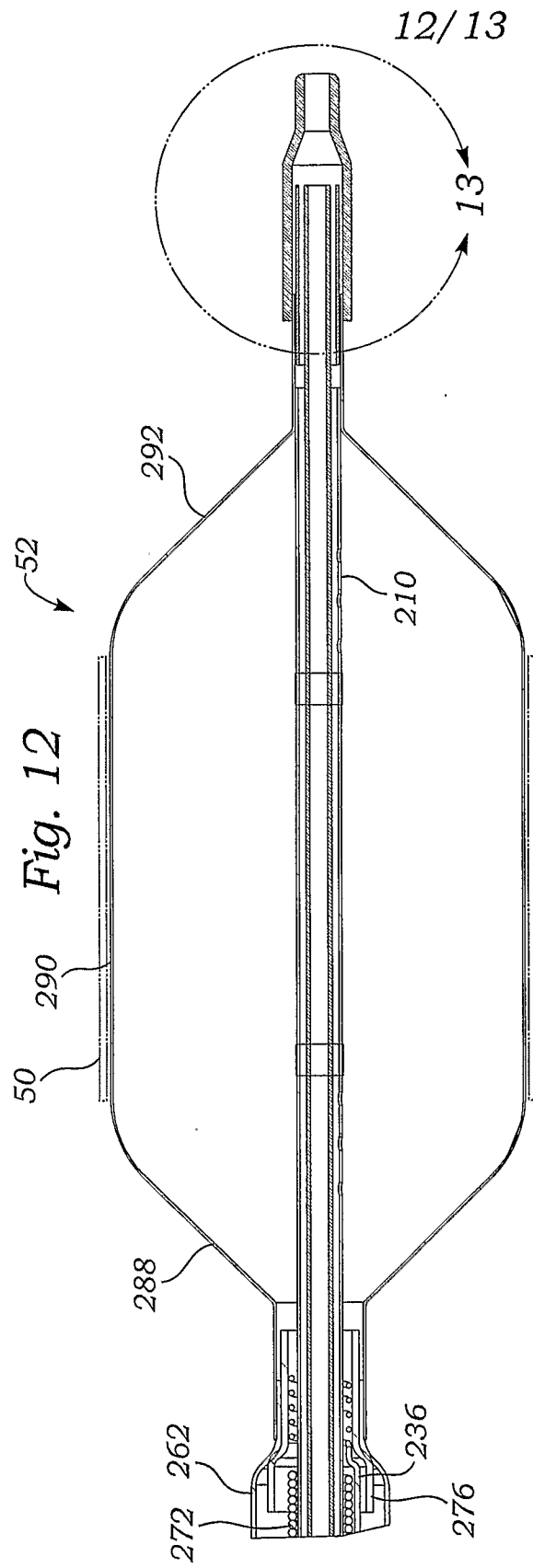


Fig. 14

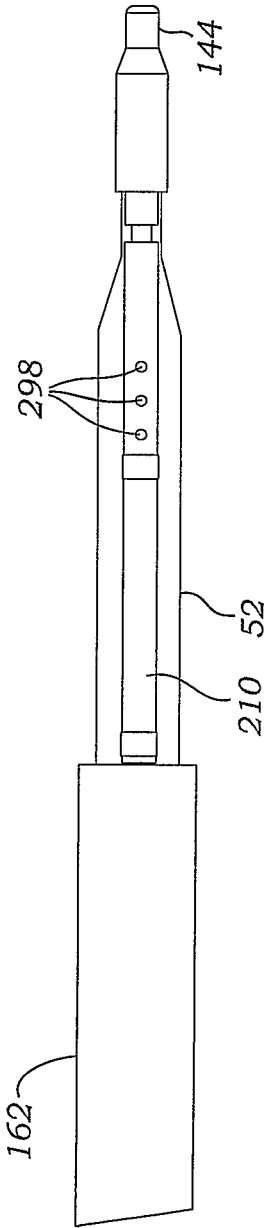
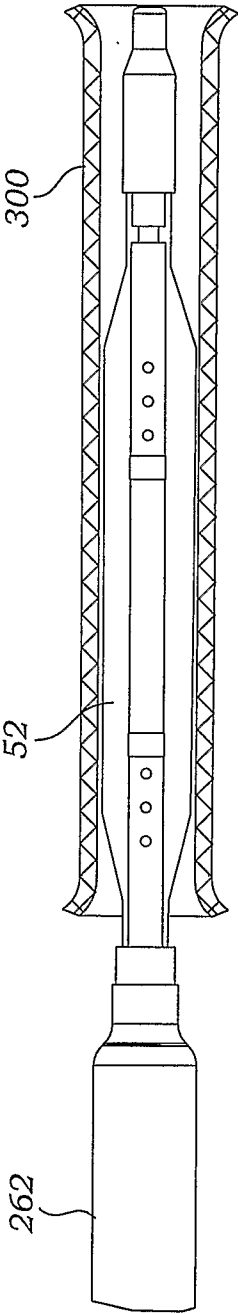


Fig. 15





# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/044422

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61F2/84 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 356 793 A2 (NUMED INC [US]) 29 October 2003 (2003-10-29)	14
Y	the whole document	16, 20, 21
Y	US 2005/070844 A1 (CHOW MINA [US] ET AL) 31 March 2005 (2005-03-31) the whole document	16
Y	EP 1 447 111 A (MEDTRONIC VASCULAR INC [US]) 18 August 2004 (2004-08-18) paragraph [0013]	20, 21
A	US 2005/148997 A1 (VALLEY KIRSTEN L [US] ET AL) 7 July 2005 (2005-07-07) the whole document	14
	----- -/-	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search

12 February 2007

Date of mailing of the international search report

23/02/2007

Name and mailing address of the ISA/

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Steiner, Bronwen

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/044422

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 379 372 B1 (DEHDASHTIAN MARK [US] ET AL) 30 April 2002 (2002-04-30) the whole document -----	14
A	EP 0 815 805 A2 (CORDIS CORP [US]) 7 January 1998 (1998-01-07) the whole document -----	14
E	WO 2006/138173 A (EDWARDS LIFESCIENCES CORP [US]; TAYLOR DAVID M [US]) 28 December 2006 (2006-12-28) the whole document -----	14
E	WO 2006/127765 A (COREVALVE INC [US]; SEGUIN JACQUES [GB]; BORTLEIN GEORG [FR]; NGUYEN T) 30 November 2006 (2006-11-30) the whole document -----	14

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2006/044422

### Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-13  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/044422

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WO 2006127765	A	30-11-2006	NONE	