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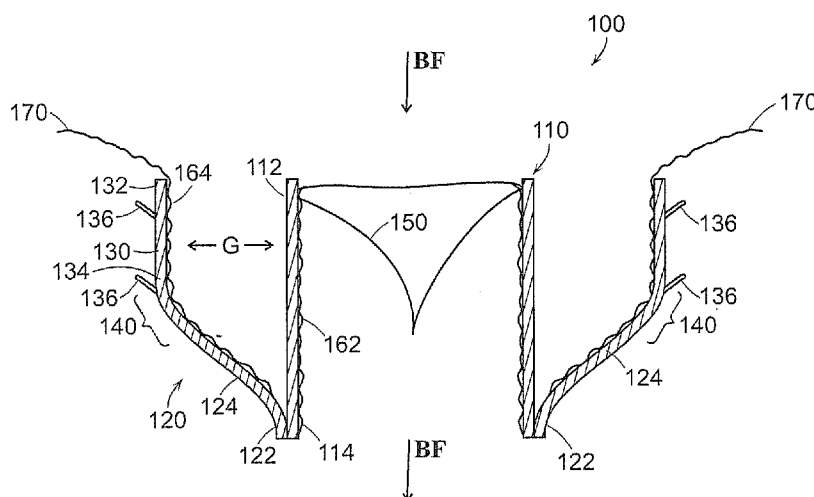


FIG. 6A

(57) Abstract: The present technology is a prosthetic heart valve device, and related systems and methods, for treating a native valve of a human heart having a native annulus and native leaflets. One embodiment comprises a valve support, a prosthetic valve assembly within the valve support, and an anchoring member. The device further includes an extension member coupled to the anchoring member and having an annular first portion coupled to the anchoring member and a second portion coupled to the first portion. The extension member is folded in a delivery configuration such that the first portion overlaps the second portion. When released from the a delivery catheter, the extension member unfolds such that the first portion extends radially outwardly from the anchoring member and the second portion extends radially outwardly from the first portion.



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PROSTHETIC HEART VALVE DEVICES AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] The present application claims priority to U.S. Patent Application No. 15/643,011, filed July 6, 2017, incorporated by reference herein.

[0002] The present application incorporates the subject matter of (1) International Patent Application No. PCT/US2014/029549, filed March 14, 2014, (2) International Patent Application No. PCT/US2012/061219, filed October 19, 2012, (3) International Patent Application No. PCT/US2012/061215, filed October 19, 2012, (4) International Patent Application No. PCT/US2012/043636, filed June 21, 2012. The present application also incorporates the subject matter of U.S. Application No. 15/642,834 (Attorney Docket No. C00013623.USU1), filed concurrently herewith, and U.S. Application No. 15/642,834 (Attorney Docket No. C00013493.USU2), also filed concurrently herewith.

TECHNICAL FIELD

[0003] The present technology relates generally to prosthetic heart valve devices. In particular, several embodiments are directed to prosthetic mitral valves and devices for percutaneous repair and/or replacement of native mitral valves and associated systems and methods.

BACKGROUND

[0004] Heart valves can be affected by several conditions. For example, mitral valves can be affected by mitral valve regurgitation, mitral valve prolapse and mitral valve stenosis. Mitral valve regurgitation is abnormal leaking of blood from the left ventricle into the left atrium caused by a disorder of the heart in which the leaflets of the mitral valve fail to coapt into apposition at peak contraction pressures. The mitral valve leaflets may not coapt sufficiently because heart diseases often cause dilation of the heart muscle, which in turn enlarges the native mitral valve annulus to the extent that the leaflets do not coapt

during systole. Abnormal backflow can also occur when the papillary muscles are functionally compromised due to ischemia or other conditions. More specifically, as the left ventricle contracts during systole, the affected papillary muscles do not contract sufficiently to effect proper closure of the leaflets.

[0005] Mitral valve prolapse is a condition when the mitral leaflets bulge abnormally up in to the left atrium. This can cause irregular behavior of the mitral valve and lead to mitral valve regurgitation. The leaflets may prolapse and fail to coapt because the tendons connecting the papillary muscles to the inferior side of the mitral valve leaflets (chordae tendineae) may tear or stretch. Mitral valve stenosis is a narrowing of the mitral valve orifice that impedes filling of the left ventricle in diastole.

[0006] Mitral valve regurgitation is often treated using diuretics and/or vasodilators to reduce the amount of blood flowing back into the left atrium. Surgical approaches (open and intravascular) for either the repair or replacement of the valve have also been used to treat mitral valve regurgitation. For example, typical repair techniques involve cinching or resecting portions of the dilated annulus. Cinching, for example, includes implanting annular or peri-annular rings that are generally secured to the annulus or surrounding tissue. Other repair procedures suture or clip the valve leaflets into partial apposition with one another.

[0007] Alternatively, more invasive procedures replace the entire valve itself by implanting mechanical valves or biological tissue into the heart in place of the native mitral valve. These invasive procedures conventionally require large open thoracotomies and are thus very painful, have significant morbidity, and require long recovery periods. Moreover, with many repair and replacement procedures, the durability of the devices or improper sizing of annuloplasty rings or replacement valves may cause additional problems for the patient. Repair procedures also require a highly skilled cardiac surgeon because poorly or inaccurately placed sutures may affect the success of procedures.

[0008] Less invasive approaches to aortic valve replacement have been implemented in recent years. Examples of pre-assembled, percutaneous prosthetic valves include, e.g., the CoreValve Revalving® System from Medtronic/Corevalve Inc. (Irvine, CA, USA) and

the Edwards-Sapien® Valve from Edwards Lifesciences (Irvine, CA, USA). Both valve systems include an expandable frame and a tri-leaflet bioprosthetic valve attached to the expandable frame. The aortic valve is substantially symmetric, circular, and has a muscular annulus. The expandable frames in aortic applications have a symmetric, circular shape at the aortic valve annulus to match the native anatomy, but also because tri-leaflet prosthetic valves require circular symmetry for proper coaptation of the prosthetic leaflets. Thus, aortic valve anatomy lends itself to an expandable frame housing a replacement valve since the aortic valve anatomy is substantially uniform, symmetric, and fairly muscular. Other heart valve anatomies, however, are not uniform, symmetric or sufficiently muscular, and thus transvascular aortic valve replacement devices may not be well suited for other types of heart valves.

[0009] The tricuspid valve on the right side of the heart, although it normally has three leaflets, poses similar challenges to less invasive treatment as the mitral valve. Therefore there is a need for a better prosthesis to treat tricuspid valve disease as well.

[0010] Given the difficulties associated with current procedures, there remains the need for simple, effective, and less invasive devices and methods for treating dysfunctional heart valves.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Many aspects of the present disclosure can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale, and instead emphasis is placed on illustrating clearly the principles of the present disclosure. Furthermore, components can be shown as transparent in certain views for clarity of illustration only and not to indicate that the illustrated component is necessarily transparent. For ease of reference, throughout this disclosure identical reference numbers and/or letters are used to identify similar or analogous components or features, but the use of the same reference number does not imply that the parts should be construed to be identical. Indeed, in many examples described herein, identically numbered components refer to different embodiments that are distinct in structure and/or function. The headings provided herein are for convenience only.

[0012] Figure 1 is a schematic, cross-sectional illustration of the heart showing an antegrade approach to the native mitral valve from the venous vasculature in accordance with various embodiments of the present technology.

[0013] Figure 2 is a schematic, cross-sectional illustration of the heart showing access through the inter-atrial septum (IAS) maintained by the placement of a guide catheter over a guidewire in accordance with various embodiments of the present technology.

[0014] Figures 3 and 4 are schematic, cross-sectional illustrations of the heart showing retrograde approaches to the native mitral valve through the aortic valve and arterial vasculature in accordance with various embodiments of the present technology.

[0015] Figure 5 is a schematic, cross-sectional illustration of the heart showing an approach to the native mitral valve using a trans-apical puncture in accordance with various embodiments of the present technology.

[0016] Figure 6A is a cross-sectional side view and Figure 6B is a top view schematically illustrating a prosthetic heart valve device in accordance with an embodiment of the present technology.

[0017] Figure 7 is a top isometric view of a prosthetic heart valve device in accordance with an embodiment of the present technology, shown in a deployed configuration.

[0018] Figure 8A is a schematic cross-sectional view of a portion of a prosthetic heart valve device in accordance with an embodiment of the present technology, shown in a delivery configuration within a delivery catheter.

[0019] Figure 8B is an enlarged view of a portion of the extension member shown in Figure 8A.

[0020] Figure 8C is a cross-sectional view of the portion of the prosthetic heart valve device of Figure 8A, shown as the extension member is being released from the distal end of the delivery catheter and transforming from the delivery configuration to a deployed configuration.

[0021] Figure 8D is a cross-sectional view of the prosthetic heart valve device of Figure 8A, shown in a deployed configuration.

[0022] Figure 9A is a schematic cross-sectional view of a portion of a prosthetic heart valve device shown in a delivery configuration within a delivery catheter in accordance with an embodiment of the present technology.

[0023] Figure 9B is a cross-sectional view of the portion of the prosthetic heart valve device of Figure 9A showing the extension member as it releases from the distal end of the delivery catheter and transforms from the delivery configuration to a deployed configuration.

[0024] Figure 9C is a cross-sectional view of the prosthetic heart valve device of Figure 9A, shown in a deployed configuration.

[0025] Figure 10A is a schematic cross-sectional view of a portion of a prosthetic heart valve device shown in a delivery configuration within a delivery catheter in accordance with an embodiment of the present technology.

[0026] Figure 10B is a cross-sectional view of a portion of a prosthetic heart valve device in accordance with an embodiment of the present technology showing the extension member as it releases from the distal end of the delivery catheter and transforms from the delivery configuration to a deployed configuration.

[0027] Figure 10C is a cross-sectional view of the prosthetic heart valve device of Figure 10A, shown in a deployed configuration.

DETAILED DESCRIPTION

[0028] Specific details of several embodiments of the technology are described below with reference to Figures 1-10C. Although many of the embodiments are described below with respect to prosthetic valve devices, systems, and methods for percutaneous replacement of a native mitral valve, other applications and other embodiments in addition to those described herein are within the scope of the technology. Additionally, several other embodiments of the technology can have different configurations, components, or

procedures than those described herein. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1-10C.

[0029] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a prosthetic valve device and/or an associated delivery device with reference to an operator and/or a location in the vasculature or heart. For example, in referring to a delivery catheter suitable to deliver and position various prosthetic valve devices described herein, "proximal" can refer to a position closer to the operator of the device or an incision into the vasculature, and "distal" can refer to a position that is more distant from the operator of the device or further from the incision along the vasculature (e.g., the end of the catheter). With respect to a prosthetic heart valve device, the terms "proximal" and "distal" can refer to the location of portions of the device with respect to the direction of blood flow. For example, proximal can refer to an upstream position or a location where blood flows into the device (e.g., inflow region), and distal can refer to a downstream position or a location where blood flows out of the device (e.g., outflow region).

Overview

[0030] Several embodiments of the present technology are directed to mitral valve replacement devices that address the unique challenges of percutaneously replacing native mitral valves and are well-suited for navigating through the heart anatomy to the mitral valve annulus. Compared to replacing aortic valves, percutaneous mitral valve replacement faces unique anatomical obstacles that render percutaneous mitral valve replacement significantly more challenging than aortic valve replacement. First, unlike relatively symmetric and uniform aortic valves, the mitral valve annulus has a non-circular D-shape or kidney-like shape, with a non-planar, saddle-like geometry often lacking symmetry. The complex and highly variable anatomy of mitral valves makes it difficult to design a mitral valve prosthesis that conforms well to the native mitral annulus of specific patients. As a result, the prosthesis may not fit well with the native leaflets and/or annulus,

which can leave gaps that allows backflow of blood to occur. For example, placement of a cylindrical valve prosthesis in a native mitral valve may leave gaps in commissural regions of the native valve through which perivalvular leaks may occur.

[0031] Current prosthetic valves developed for percutaneous aortic valve replacement are unsuitable for use in mitral valves. First, many of these devices require a direct, structural connection between the stent-like structure that contacts the annulus and/or leaflets and the prosthetic valve. In several devices, the stent posts which support the prosthetic valve also contact the annulus or other surrounding tissue. These types of devices directly transfer the forces exerted by the tissue and blood as the heart contracts to the valve support and the prosthetic leaflets, which in turn distorts the valve support from its desired cylindrical shape. This is a concern because most cardiac replacement devices use tri-leaflet valves, which require a substantially symmetric, cylindrical support around the prosthetic valve for proper opening and closing of the three leaflets over years of life. As a result, when these devices are subject to movement and forces from the annulus and other surrounding tissues, the prostheses may be compressed and/or distorted causing the prosthetic leaflets to malfunction. Moreover, a diseased mitral annulus is much larger than any available prosthetic aortic valve. As the size of the valve increases, the forces on the valve leaflets increase dramatically, so simply increasing the size of an aortic prosthesis to the size of a dilated mitral valve annulus would require dramatically thicker, taller leaflets, and might not be feasible.

[0032] In addition to its irregular, complex shape, which changes size over the course of each heartbeat, the mitral valve annulus lacks a significant amount of radial support from surrounding tissue. Compared to aortic valves, which are completely surrounded by fibro-elastic tissue that provides sufficient support for anchoring a prosthetic valve, mitral valves are bound by muscular tissue on the outer wall only. The inner wall of the mitral valve anatomy is bound by a thin vessel wall separating the mitral valve annulus from the inferior portion of the aortic outflow tract. As a result, significant radial forces on the mitral annulus, such as those imparted by an expanding stent prostheses, could lead to collapse of the inferior portion of the aortic tract. Moreover, larger prostheses exert more force and

expand to larger dimensions, which exacerbates this problem for mitral valve replacement applications.

[0033] The chordae tendineae of the left ventricle may also present an obstacle in deploying a mitral valve prosthesis. Unlike aortic valves, mitral valves have a maze of cordage under the leaflets in the left ventricle that restrict the movement and position of a deployment catheter and the replacement device during implantation. As a result, deploying, positioning and anchoring a valve replacement device on the ventricular side of the native mitral valve annulus is complicated.

[0034] Embodiments of the present technology provide systems, methods and apparatus to treat heart valves of the body, such as the mitral valve, that address the challenges associated with the anatomy of the mitral valve and provide for improved maneuverability of the device when positioned within the delivery catheter. The apparatus and methods enable a percutaneous approach using a catheter delivered intravascularly through a vein or artery into the heart, or through a cannula inserted through the heart wall. For example, the apparatus and methods are particularly well-suited for trans-septal approaches, but can also be trans-apical, trans-atrial, and direct aortic delivery of a prosthetic replacement valve to a target location in the heart. Additionally, the embodiments of the devices and methods as described herein can be combined with many known surgeries and procedures, such as known methods of accessing the valves of the heart (e.g., the mitral valve or tricuspid valve) with antegrade or retrograde approaches, and combinations thereof.

Access to the Mitral Valve

[0035] To better understand the structure and operation of valve replacement devices in accordance with the present technology, it is helpful to first understand approaches for implanting the devices. The mitral valve or other type of atrioventricular valve can be accessed through the patient's vasculature in a percutaneous manner. By percutaneous it is meant that a location of the vasculature remote from the heart is accessed through the skin, typically using a surgical cut down procedure or a minimally invasive procedure, such as using needle access through, for example, the Seldinger technique. The ability to

percutaneously access the remote vasculature is well known and described in the patent and medical literature. Depending on the point of vascular access, access to the mitral valve may be antegrade and may rely on entry into the left atrium by crossing the inter-atrial septum (e.g., a trans-septal approach). Alternatively, access to the mitral valve can be retrograde where the left ventricle is entered through the aortic valve. Access to the mitral valve may also be achieved using a cannula via a trans-apical approach. Depending on the approach, the interventional tools and supporting catheter(s) may be advanced to the heart intravascularly and positioned adjacent the target cardiac valve in a variety of manners, as described herein.

[0036] Figure 1 illustrates a stage of a trans-septal approach for implanting a valve replacement device. In a trans-septal approach, access is via the inferior vena cava IVC or superior vena cava SVC, through the right atrium RA, across the inter-atrial septum IAS, and into the left atrium LA above the mitral valve MV. As shown in Figure 1, a catheter 1 having a needle 2 moves from the inferior vena cava IVC into the right atrium RA. Once the catheter 1 reaches the anterior side of the inter-atrial septum IAS, the needle 2 advances so that it penetrates through the septum, for example at the fossa ovalis FO or the foramen ovale into the left atrium LA. At this point, a guidewire replaces the needle 2 and the catheter 1 is withdrawn.

[0037] Figure 2 illustrates a subsequent stage of a trans-septal approach in which guidewire 6 and guide catheter 4 pass through the inter-atrial septum IAS. The guide catheter 4 provides access to the mitral valve for implanting a valve replacement device in accordance with the technology.

[0038] In an alternative antegrade approach (not shown), surgical access may be obtained through an intercostal incision, preferably without removing ribs, and a small puncture or incision may be made in the left atrial wall. A guide catheter passes through this puncture or incision directly into the left atrium, sealed by a purse string-suture.

[0039] The antegrade or trans-septal approach to the mitral valve, as described above, can be advantageous in many respects. For example, antegrade approaches will usually enable more precise and effective centering and stabilization of the guide catheter

and/or prosthetic valve device. The antegrade approach may also reduce the risk of damaging the chordae tendinae or other subvalvular structures with a catheter or other interventional tool. Additionally, the antegrade approach may decrease risks associated with crossing the aortic valve as in retrograde approaches. This can be particularly relevant to patients with prosthetic aortic valves, which cannot be crossed at all or without substantial risk of damage.

[0040] Figures 3 and 4 show examples of a retrograde approaches to access the mitral valve. Access to the mitral valve MV may be achieved from the aortic arch AA, across the aortic valve AV, and into the left ventricle LV below the mitral valve MV. The aortic arch AA may be accessed through a conventional femoral artery access route or through more direct approaches via the brachial artery, axillary artery, radial artery, or carotid artery. Such access may be achieved with the use of a guidewire 6. Once in place, a guide catheter 4 may be tracked over the guidewire 6. Alternatively, a surgical approach may be taken through an incision in the chest, preferably intercostally without removing ribs, and placing a guide catheter through a puncture in the aorta itself. The guide catheter 4 affords subsequent access to permit placement of the prosthetic valve device, as described in more detail herein. Retrograde approaches advantageously do not need a trans-septal puncture. Cardiologists also more commonly use retrograde approaches, and thus retrograde approaches are more familiar.

[0041] Figure 5 shows a trans-apical approach via a trans-apical puncture. In this approach, access to the heart is via a thoracic incision, which can be a conventional open thoracotomy or sternotomy, or a smaller intercostal or sub-xyphoid incision or puncture. An access cannula is then placed through a puncture in the wall of the left ventricle at or near the apex of the heart. The catheters and prosthetic devices of the invention may then be introduced into the left ventricle through this access cannula. The trans-apical approach provides a shorter, straighter, and more direct path to the mitral or aortic valve. Further, because it does not involve intravascular access, the trans-apical approach does not require training in interventional cardiology to perform the catheterizations required in other percutaneous approaches.

Selected Embodiments of Prosthetic Heart Valve Devices and Methods

[0042] Embodiments of the present technology can treat one or more of the valves of the heart, and in particular several embodiments advantageously treat the mitral valve. The prosthetic valve devices of the present technology can also be suitable for replacement of other valves (e.g., a bicuspid or tricuspid valve) in the heart of the patient. Examples of prosthetic heart valve devices in accordance with embodiments of the present technology are described in this section with reference to Figures 6A-8B. Specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 6A-8B can be suitably interchanged, substituted or otherwise configured with one another. Furthermore, suitable elements of the embodiments described with reference to Figures 6A-8B can be used as stand-alone and/or self-contained devices.

[0043] Figure 6A is a side cross-sectional view and Figure 6B is a top plan view of a prosthetic heart valve device ("device") 100 in accordance with an embodiment of the present technology. The device 100 includes a valve support 110, an anchoring member 120 attached to the valve support 110, and a prosthetic valve assembly 150 within the valve support 110. Referring to Figure 6A, the valve support 110 has an inflow region 112 and an outflow region 114. The prosthetic valve assembly 150 is arranged within the valve support 110 to allow blood to flow from the inflow region 112 through the outflow region 114 (arrows BF), but prevent blood from flowing in a direction from the outflow region 114 through the inflow region 112.

[0044] In the embodiment shown in Figure 6A, the anchoring member 120 includes a base 122 attached to the outflow region 114 of the valve support 110 and a plurality of arms 124 projecting laterally outward from the base 122. The anchoring member 120 also includes a fixation structure 130 extending from the arms 124. The fixation structure 130 can include a first portion 132 and a second portion 134. The first portion 132 of the fixation structure 130, for example, can be an upstream region of the fixation structure 130 that, in a deployed configuration as shown in Figure 6A, is spaced laterally outward apart from the inflow region 112 of the valve support 110 by a gap G. The second portion 134 of

the fixation structure 130 can be a downstream-most portion of the fixation structure 130. The fixation structure 130 can be a cylindrical ring (e.g., straight cylinder or conical), and the outer surface of the fixation structure 130 can define an annular engagement surface configured to press outwardly against the native annulus. The fixation structure 130 can further include a plurality of fixation elements 136 that project radially outward and are inclined toward an upstream direction. The fixation elements 136, for example, can be barbs, hooks, or other elements that are inclined only in the upstream direction (e.g., a direction extending away from the downstream portion of the device 100).

[0045] Referring still to Figure 6A, the anchoring member 120 has a smooth bend 140 between the arms 124 and the fixation structure 130. For example, the second portion 134 of the fixation structure 130 extends from the arms 124 at the smooth bend 140. The arms 124 and the fixation structure 130 can be formed integrally from a continuous strut or support element such that the smooth bend 140 is a bent portion of the continuous strut. In other embodiments, the smooth bend 140 can be a separate component with respect to either the arms 124 or the fixation structure 130. For example, the smooth bend 140 can be attached to the arms 124 and/or the fixation structure 130 using a weld, adhesive or other technique that forms a smooth connection. The smooth bend 140 is configured such that the device 100 can be recaptured in a capsule or other container after the device 100 has been at least partially deployed.

[0046] The device 100 can further include a first sealing member 162 on the valve support 110 and a second sealing member 164 on the anchoring member 120. The first and second sealing members 162, 164 can be made from a flexible material, such as Dacron® or another type of polymeric material. The first sealing member 162 can cover the interior and/or exterior surfaces of the valve support 110. In the embodiment illustrated in Figure 6A, the first sealing member 162 is attached to the interior surface of the valve support 110, and the prosthetic valve assembly 150 is attached to the first sealing member 162 and commissure portions of the valve support 110. The second sealing member 164 is attached to the inner surface of the anchoring member 120. As a result, the outer annular engagement surface of the fixation structure 130 is not covered by the

second sealing member 164 so that the outer annular engagement surface of the fixation structure 130 directly contacts the tissue of the native annulus.

[0047] The device 100 can further include an extension member 170. The extension member 170 can be an extension of the second sealing member 164, or it can be a separate component attached to the second sealing member 164 and/or the first portion 132 of the fixation structure 130. The extension member 170 can be a flexible member that, in a deployed state as shown in Figure 6A, flexes relative to the first portion 132 of the fixation structure 130. In operation, the extension member 170 guides the device 100 during implantation such that the device is located at a desired elevation and centered relative to the native annulus. In some embodiments, one or more components of the extension member 170 can be made of or include a radiopaque material.

[0048] Figure 7 is a top isometric view of an example of the device 100. In this embodiment, the valve support 110 defines a first frame (e.g., an inner frame) and fixation structure 130 of the anchoring member 120 defines a second frame (e.g., an outer frame) that each include a plurality of structural elements. The fixation structure 130, more specifically, includes structural elements 137 arranged in diamond-shaped cells 138 that together form at least a substantially cylindrical ring when freely and fully expanded as shown in Figure 7. The structural elements 137 can be struts or other structural features formed from metal, polymers, or other suitable materials that can self-expand or be expanded by a balloon or other type of mechanical expander.

[0049] Several embodiments of the fixation structure 130 can be a generally cylindrical fixation ring having an outwardly facing engagement surface. For example, in the embodiment shown in Figure 7, the outer surfaces of the structural elements 137 define an annular engagement surface configured to press outwardly against the native annulus in the deployed state. In a fully expanded state without any restrictions, the fixation structure 130 is at least substantially parallel to the valve support 110. However, the fixation structure 130 can flex inwardly (arrow I) in the deployed state when it presses radially outwardly against the inner surface of the native annulus of a heart valve.

[0050] The embodiment of the device 100 shown in Figure 7 includes the first sealing member 162 lining the interior surface of the valve support 110, and the second sealing member 164 along the inner surface of the fixation structure 130. The extension member 170 has a flexible web 172 (e.g., a fabric) and a support member 174 (e.g., metal or polymeric strands) attached to the flexible web 172. The flexible web 172 can extend from the second sealing member 164 without a metal-to-metal connection between the fixation structure 130 and the support member 174. For example, the extension member 170 can be a continuation of the material of the second sealing member 164. Several embodiments of the extension member 170 are thus a floppy structure that can readily flex with respect to the fixation structure 130. The support member 174 can have a variety of configurations and be made from a variety of materials, such as a double-serpentine structure made from Nitinol.

[0051] Figures 8A-8D show one embodiment of a prosthetic heart valve device 200 ("the device 200") having an extension member 270 configured to fold or bend onto itself in the delivery configuration (Figures 8A and 8B) and unfurl to an extended configuration when deployed (Figures 8C and 8D). As such, the collapsible extension member 270 reduces the total length of the device 200 in the delivery configuration without sacrificing the lateral coverage of the extension member 270 in the deployed or extended configuration (as compared to a similar device having a non-folded extension member in the delivery configuration). The reduced length of the device 200 improves the maneuverability of the catheter C when the device 200 is positioned within the catheter lumen, which is especially beneficial when navigating the tortuous intravascular and/or intracardiac path to the mitral valve annulus. Such improved maneuverability, for example, can be particularly advantageous for making the sharp turn towards the mitral valve annulus after crossing the inter-atrial septum IAS during a trans-septal approach (discussed above with reference to Figures 1 and 2).

[0052] The device 200 shown in Figures 8A-8D can include components that are generally similar in structure and function to those of the device 100 in Figures 6A-7. For example, the device 200 can include the valve support 110 (not shown for ease of

illustration), the anchoring member 120 (Figure 8D only), the prosthetic valve assembly 150 (not shown for ease of illustration), and the second sealing member 164 (not shown for ease of illustration), all of which are generally similar to those discussed above with reference to Figures 6A-7. As such, common acts and structures and/or sub-structures are identified by the same reference numbers, and only significant differences in operation and structure are described below.

[0053] Figure 8A shows a distal portion of the device 200 in a delivery configuration within a catheter C. The extension member 270 has a flexible web 272 and a support member 274 attached to the flexible web 272. In the embodiment shown in Figures 8A-8D, the flexible web 272 is a continuation of the material of the second sealing member 164, and the support member 274 is spaced apart from the fixation structure 130 along the second sealing member 164. In other embodiments, the flexible web 272 is not integral with the second sealing member 164 (e.g., the flexible web 272 is a separate piece of fabric), and/or the support member 274 is integral with the fixation structure 130. Moreover, although the embodiment shown in Figure 8A shows the support member 274 disposed at an interior region of the flexible web 272 (e.g., between two layers of fabric), in other embodiments the support member 274 may be positioned at a surface of the web 272. For example, in some embodiments the support member 274 may be positioned on an atrial surface 272a (see Figure 8D) of the web 272, and in other embodiments the support member 274 may be positioned on a ventricular surface 272b (see Figure 8D) of the web 272.

[0054] Figure 8B is an enlarged, isolated view of a portion of the extension member 270 and fixation structure 130 shown in Figure 8A. Referring to Figures 8A and 8B together, the extension member 270 has a longitudinal axis L_E , a first terminus 287 at the fixation structure 130, a free second terminus 288, and a length measured along the longitudinal axis L_E (Figure 8B) between the first and second termini 287, 288. The extension member 270 also has a first portion 282 and a second portion 284 extending along its longitudinal axis L_E (Figure 8B). The first portion 282 meets or is otherwise coupled to the second portion 284 at a joint 286. The first portion 282 has a length

measured between the first terminus 287 of the extension member 270 and the joint 286, and the second portion 284 has a length measured between the joint 286 and the second terminus 288 of the extension member 270. The support member 274 extends along the longitudinal axis L_E from a first location along the first portion 282 to a second location along the second portion 284. As discussed in greater detail below, the support member 274 is configured to preferentially bend at the joint 286 of the extension member 270. In certain embodiments, the support member 274 extends only a portion of the length of the extension member 270, and in some embodiments the support member 274 extends the entire length of the extension member 270. The support member 274 can have a variety of configurations and be made from a variety of materials.

[0055] When positioned in the delivery configuration within the catheter C (e.g., Figure 8A), the extension member 270 may be folded back on itself such that at least a portion of the first portion 282 overlaps at least a portion of the second portion 284 and the extension member 270 includes a folded or bent edge at the joint 286. For example, in the embodiment shown in Figure 8A, the first portion 282 extends distally from the fixation structure 130 and/or first terminus 287 to the joint 286, and the second portion 284 extends proximally from the joint 286 to the second terminus 288. As shown, the extension member 270 may be folded or configured to fold at a single location along the longitudinal axis of the support member 274 and/or extension member 270, thereby dividing the extension member 270 into the first and second portions 282, 284. In other embodiments, the extension member 270 may be folded and/or configured to fold or bend at multiple locations along the longitudinal axis of the support member 274 and/or extension member 270 (e.g., like an accordion), thereby dividing the extension member 270 into more than two portions. Although the second portion 284 is shown positioned radially inward of the first portion 282 in Figures 8A and 8B, in other embodiments the second portion 284 can be positioned radially outward of the first portion 282 in the delivery configuration.

[0056] In the embodiment shown in Figures 8A and 8B, the length of the first portion 282 is greater than the length of the second portion 284 such that the free second

terminus 288 is distal of the first terminus 287 along the longitudinal axis L_D (Figure 8A) of the device 200 when the device 200 is in the delivery configuration. In other embodiments, the length of the first portion 282 is substantially the same as the length of the second portion 284 such that the free second terminus 288 is adjacent or aligned with the first terminus 287 along the longitudinal axis L_D of the device 200 when the device 200 is in the delivery configuration. In yet other embodiments, the length of the first portion 282 can be less than the length of the second portion 284 such that the second terminus 288 is proximal of the first terminus 287 along the longitudinal axis L_D of the device 200 when the device 200 is in the delivery configuration.

[0057] Figure 8C is a cross-sectional view of the extension member 270 as it releases from a distal end of the delivery catheter C and transforms from the delivery configuration to a deployed or extended configuration. Figure 8D is a cross-sectional, isolated view of the anchoring member 120, second sealing member 164, and extension member 270 when the device 200 is in a deployed configuration. Referring to Figures 8C and 8D together, as the extension member 270 releases from the distal end of the delivery catheter C, the first portion 282 rotates radially away from a central longitudinal axis L_D of the device 200 (indicated by arrows A_1 in Figure 8C) around the first terminus 287, while the second portion 284 rotates radially away from the longitudinal axis L_D around the joint 286 (indicated by arrows A_2 in Figure 8C) until the longitudinal axis's of the first and second portions 282, 284 are generally aligned (e.g., the first and second portions 282, 284 are generally within the same plane along their lengths) unless otherwise constrained by the anatomy. As such, in the deployed configuration, the first portion 282 extends radially outwardly from the fixation structure 130, and the second portion 284 extends radially outwardly from the first portion 282. In other embodiments, the extension member 270 may be configured such that the second portion 284 is positioned at an angle with respect to the first portion 282 when the device 200 is in the deployed configuration. In any of the above embodiments, the distance between the first terminus 287 and the second terminus 288 of the extension member 270 is less when the extension member 270 is in the delivery configuration than when the extension member 270 is in the deployed configuration, thereby improving the maneuverability of the

delivery system without sacrificing the lateral coverage of the extension member 270 in the deployed or extended configuration.

[0058] Figures 9A-9C show another embodiment of a prosthetic heart valve device 300 ("the device 300") having an extension member 370 configured to fold or bend onto itself in the deployed configuration (Figure 9C). The device 300 shown in Figures 9A-9C can include components that are generally similar in structure and function to those of the device 100 in Figures 6A-7. For example, the device 300 can include the valve support 110 (not shown for ease of illustration), the anchoring member 120 (Figure 9C only), the prosthetic valve assembly 150 (not shown for ease of illustration), and the second sealing member 164 (not shown for ease of illustration), all of which are generally similar to those discussed above with reference to Figures 6A-7. As such, common acts and structures and/or sub-structures are identified by the same reference numbers, and only significant differences in operation and structure are described below.

[0059] Figure 9A shows a distal portion of the device 300 in a delivery configuration within a catheter C. The extension member 370 has a flexible web 372 and a support member 374 attached to the flexible web 372. In the embodiment shown in Figures 9A-9C, the flexible web 372 is a continuation of the material of the second sealing member 164, and the support member 374 is spaced apart from the fixation structure 130 along the second sealing member 164. In other embodiments, the flexible web 372 is not integral with the second sealing member 164 (e.g., the flexible web 372 is a separate piece of material), and/or the support member 374 is integral with the fixation structure 130. Moreover, although the embodiment shown in Figure 9A shows the support member 374 disposed at an interior region of the flexible web 372 (e.g., between two layers of fabric), in other embodiments the support member 374 may be positioned at a surface of the web 372.

[0060] As shown in Figure 9A, the extension member 370 has a first terminus 387 at the fixation structure 130, a free second terminus 388, and a length measured along its longitudinal axis L_E between the first and second termini 387, 388. The extension member 370 also has a first portion 382 and a second portion 384 extending along its

longitudinal axis L_E . The first portion 382 meets or is otherwise coupled to the second portion 384 at a joint 386. The first portion 382 has a length measured between the first terminus 387 of the extension member 370 and the joint 386, and the second portion 384 has a length measured between the joint 386 and the second terminus 388 of the extension member 370. The support member 374 extends along the longitudinal axis L_E of the extension member 370 from a first location along the first portion 382 to a second location along the second portion 384, and the support member 374 is configured to preferentially bend at the joint 386 of the extension member 370, as discussed in greater detail below. In certain embodiments the support member 374 extends only a portion of the length of the extension member 370, but in other embodiments the support member 374 extends the entire length of the extension member 370. The support member 374 can have a variety of configurations and be made from a variety of materials.

[0061] As shown in Figure 9A, in the delivery configuration, the extension member 370 can be generally straight such that the first portion 382 extends distally from the fixation structure 130, and the second portion 384 extends distally from the joint 386. As such, the free second terminus 388 is spaced apart from the first terminus 387 by a distance measured along a longitudinal axis L_E of the extension member 370 that is at least the combined lengths of the first portion 382 and the second portion 384. Advantageously, the joint 386 of extension member 370 provides an articulation and/or flexing point that improves the flexibility of the distal portion of the delivery system (i.e., delivery catheter C and device 300 loaded therein), at least as compared to an extension member that does not include a joint along its length. As such, the joint 386 improves the maneuverability of the catheter C when the device 200 is positioned within the catheter lumen, which is especially beneficial when navigating the tortuous intravascular and/or intracardiac path to the mitral valve annulus, as discussed above with reference to Figures 8A-D. The joint 386 additionally improves the flexibility of the extension member 370 when the device 300 is positioned at the annulus, thereby allowing the device 300 to better adapt and conform to the local anatomy.

[0062] Figure 9B is a cross-sectional view of the extension member 370 as it releases from a distal end of the delivery catheter C and transforms from the delivery configuration to a deployed or folded configuration, and Figure 9C is a cross-sectional, isolated view of the anchoring member 120, second sealing member 164, and extension member 370 when the device 300 is in a deployed configuration. Referring to Figures 9B and 9C together, when the extension member 370 is released from a distal end of the delivery catheter C, the extension member 370 folds back on itself such that the first portion 382 rotates radially away from the central longitudinal axis L_D of the device 300 (indicated by arrows A_1 in Figure 9B) about the first terminus 387, and the second portion 384 rotates radially toward the central longitudinal axis L_D (indicated by arrows A_3 in Figure 9B) about the joint 386. As such, in the deployed configuration, at least a portion of the second portion 384 overlaps at least a portion of the first portion 382 and the joint 386 therebetween forms a folded or bent edge.

[0063] In the illustrated embodiment, the second portion 384 rotates towards the fixation structure 130 in an upstream direction (indicated by arrows A_3 in Figure 9B) such that the second portion 384 is positioned upstream of the first portion 382 in the expanded configuration. In other embodiments, such as the device 300' shown in Figures 10A-10C, the second portion 384 rotates towards the fixation structure 130 in a downstream direction (indicated by arrows A_4 in Figure 10B) such that the second portion 384 is positioned downstream of the first portion 382 in the expanded configuration. Moreover, in the embodiment shown in Figures 9B and 9C, the extension member 370 is folded or configured to fold at a single location along the longitudinal axis of the support member 374, thereby dividing the extension member 370 into the first and second portions 382, 384. In other embodiments, the extension member 370 may be folded and/or configured to fold or bend at multiple locations along the longitudinal axis of the support member 374 (e.g., like an accordion), thereby dividing the extension member 370 into more than two portions.

[0064] In any of the embodiments disclosed herein, the length of the first portion 382 is substantially the same as the length of the second portion 384 such that the second free

terminus 388 is adjacent or aligned with the first terminus 387 along a line L (Figure 9C) substantially parallel to the longitudinal axis of the first portion 382 when the device 300 is expanded. In such embodiments, the distance between the second terminus 388 and the first terminus 387 along the line L is substantially zero. In other embodiments, the length of the first portion 382 can be greater than the length of the second portion 384 such that the second terminus 388 is radially outward of and spaced apart from the first terminus 387 along the line L when the device 300 is expanded. In yet other embodiments, the length of the first portion 382 can be less than the length of the second portion 384 such that the second terminus 388 is radially inward of and spaced apart from the first terminus 387 along the line L when the device 300 is expanded.

[0065] In any of the foregoing embodiments, the extension member may include one or more impedance sensors for detecting or otherwise assessing contact between the extension member and adjacent tissue (e.g., the leaflets, the atrial floor, etc.) while the prosthetic heart valve device is being positioned within the mitral annulus. For example, in some embodiments the support member may be formed of a metal wire coated or otherwise surrounded by an insulative material. The support member can include one or more impedance sensors comprising portions of the metal wire exposed through corresponding openings in the insulative material. The wire may be electrically coupled to a conductive member that extends proximally from the prosthetic heart valve device to a proximal portion (e.g., a handle) of the delivery system. For example, in some embodiments the metal wire may be directly coupled to the conductive member (i.e., in direct contact), and in other embodiments the metal wire may be indirectly coupled to the conductive member via the anchoring member and/or another conductive component of the device.

Examples

[0066] The following examples are illustrative of several embodiments of the present technology:

1. A prosthetic heart valve device comprising:
an anchoring member having an annular fixation structure with an upstream portion and a downstream portion;
a tubular valve support having a first portion coupled to the upstream portion of the anchoring member and a second portion spaced radially inward from the upstream portion of the anchoring member;
a valve assembly coupled to the valve support and having at least one leaflet movable from a closed position in which blood flow is blocked through the valve support and an open position in which blood flow is allowed through the valve support in a downstream direction; and
an extension member having an annular first portion coupled to the fixation structure and a second portion coupled to the first portion, wherein—
the extension member folds back on itself in a delivery configuration such that the first portion extends distally from the fixation structure and the second portion extends back proximally from the first portion, and
when the extension member is in a deployed configuration, the first portion extends radially outwardly from the fixation structure and the second portion extends radially outwardly from the first portion.
2. The device of example 1 wherein the second portion is positioned radially inwardly of the first portion in the delivery configuration.
3. The device of example 1 wherein the second portion is positioned radially outwardly of the first portion in the delivery configuration.
4. The device of any one of examples 1-3 wherein the extension member has a first terminus at the anchoring member and a free second terminus, wherein a length of the first portion is substantially the same as a length of the second portion such that, when the device is in the delivery configuration, the free second terminus is axially aligned with the first terminus along a line substantially parallel to the longitudinal axis of the device.

5. The device of any one of examples 1-3 wherein the extension member has a first terminus at the anchoring member and a free second terminus, and wherein a length of the first portion is greater than a length of the second portion such that, when the device is in the delivery configuration, the second terminus is distal of the first terminus along a line substantially parallel to the longitudinal axis of the device.

6. The device of any one of examples 1-3 wherein the extension member has a first terminus at the anchoring member and a free second terminus, and wherein a length of the first portion is less than a length of the second portion such that, when the device is in the delivery configuration, the second terminus is proximal of a first terminus along a line substantially parallel to the longitudinal axis of the device.

7. The device of any one of examples 1-6 wherein, in the expanded configuration, the first portion and the second portion have a straight configuration such that the first portion is not at an angle with respect to the second portion.

8. The device of any one of examples 1-7 wherein the extension member includes one or more impedance sensors.

9. A prosthetic heart valve device comprising:

an anchoring member having a radially expandable frame with an interior and having an upstream portion and a downstream portion, wherein the upstream portion includes a tissue fixation portion configured to press outwardly against tissue located at and/or downstream of a native annulus of a heart valve in a subject and configured to be at least partially deformable to conform to a shape of the tissue;

a valve positioned relative to the anchoring member and having at least one leaflet movable from a closed position in which blood flow is blocked through the interior and an open position in which blood flow is allowed through the interior in a flow direction from the upstream portion toward the downstream

portion, wherein the valve is spaced inwardly apart from the tissue fixation portion of the anchoring member such that the valve remains competent when the tissue fixation portion is deformed to conform to the shape of the tissue; and

an extension member having a first terminus at the anchoring member and a second, free terminus, wherein—

the extension member has a delivery configuration in which the extension member extends distally from the anchoring member, has an inverted distal portion, and the second, free terminus is spaced apart from the first terminus by a first distance, and

the extension member has a deployed configuration in which the extension member extends laterally away from the anchoring member such that the second, free terminus is spaced apart from the first terminus by a second distance greater than the first distance.

10. The device of example 9 wherein the second free terminus is distal of the first terminus when the extension member is in the delivery configuration.

11. The device of example 9 wherein the second free terminus is proximal of the first terminus when the extension member is in the delivery configuration.

12. The device of any one of examples 9-11 wherein the extension member includes a flexible web and a support member extending along at least a portion of the length of the extension member, the support member attached to the web.

13. The device of any one of examples 9-11 wherein the extension member includes a flexible web and a superelastic material attached to the web.

14. The device of any one of examples 9-13 wherein the extension member has joint, a first portion extending between the first terminus and the joint, and a second portion

extending between the joint and the second terminus, and wherein at least a portion of the first portion overlaps at least a portion of the second portion when the extension member is in a delivery configuration.

15. The device of any one of examples 9-14 wherein the extension member includes one or more impedance sensors.

16. A method for deploying a prosthetic heart valve device, the method comprising:

positioning a distal portion of a delivery catheter at a native heart annulus;

delivering a prosthetic heart valve device to the distal portion of the delivery

catheter, the prosthetic heart valve device having a brim configured to be

positioned at an upstream side of the annulus when the device is deployed,

and wherein the brim is folded into a first portion and an overlapping second portion during delivery; and

withdrawing the delivery catheter proximally thereby allowing the brim to unfold

such that the brim extends laterally away from a central longitudinal axis of the prosthetic heart valve device.

17. The method of example 16 wherein withdrawing the delivery catheter proximally allows the brim to unfold such that (a) a distal end of the first portion moves radially away from the central longitudinal axis of the device, and (b) a distal end of the second portion moves radially towards the central longitudinal axis of the device.

18. The method of example 16 wherein—

the brim includes a joint and the first portion and the second portion are coupled at

the joint, and wherein a proximal terminus of the first portion is coupled to an upstream region of an anchoring member of the device; and

withdrawing the delivery catheter proximally allows the brim to unfold such that (a)

the first portion rotates away from the central longitudinal axis of the device

about the proximal terminus, and (b) the second portion rotates radially away from the central longitudinal axis of the device about the joint.

19. A prosthetic heart valve device comprising:
an anchoring member having an annular fixation structure with an upstream portion and a downstream portion;
a tubular valve support having a first portion coupled to the upstream portion of the anchoring member and a second portion spaced radially inward from the upstream portion of the anchoring member;
a valve assembly coupled to the valve support and having at least one leaflet movable from a closed position in which blood flow is blocked through the valve support and an open position in which blood flow is allowed through the valve support in a downstream direction; and
an extension member having an annular first portion coupled to the fixation structure and a second portion coupled to the first portion, wherein—
the extension member is generally linear in a delivery configuration such that the first portion extends distally from the fixation structure and the second portion extends distally from the first portion, and
the extension member folds back on itself in a deployed configuration such that the first portion extends radially outwardly from the fixation structure and the second portion extends back towards the fixation structure.

20. The device of example 19 wherein the second portion extends back towards the fixation structure in an upstream direction such that the second portion is positioned upstream of the first portion in the deployed configuration.

21. The device of example 18 wherein the second portion extends back towards the fixation structure in a downstream direction such that the second portion is positioned downstream of the first portion in the deployed configuration.

22. The device of any one of examples 19-21 wherein the extension member has a first terminus at the anchoring member and a free second terminus, wherein a length of the first portion is substantially the same as a length of the second portion such that, when the device is expanded, the second terminus is axially aligned with the first terminus along a line substantially parallel to the longitudinal axis of the first portion.

23. The device of any one of examples 19-21 wherein the extension member has a first terminus at the anchoring member and a free second terminus, and wherein a length of the first portion is greater than a length of the second portion such that, when the device is expanded, the second terminus is radially outward of and spaced apart from the first terminus along a line substantially parallel to the longitudinal axis of the first portion.

24. The device of any one of examples 19-21 wherein the extension member has a first terminus at the anchoring member and a free second terminus, and wherein a length of the first portion is less than a length of the second portion such that, when the device is expanded, the second terminus is radially inward of and spaced apart from the first terminus along a line substantially parallel to the longitudinal axis of the first portion.

25. The device of any one of examples 19-24 wherein, in the expanded configuration, the first portion and the second portion have a straight configuration such that the first portion is not at an angle with respect to the second portion.

26. A prosthetic heart valve device comprising:
an anchoring member having a radially expandable frame with an interior and having an upstream portion and a downstream portion, wherein the upstream portion includes a tissue fixation portion configured to press outwardly against tissue located at and/or downstream of a native annulus of a heart valve in a subject and configured to be at least partially deformable to conform to a shape of the tissue;

a valve positioned relative to the anchoring member and having at least one leaflet movable from a closed position in which blood flow is blocked through the interior and an open position in which blood flow is allowed through the interior in a flow direction from the upstream portion toward the downstream portion, wherein the valve is spaced inwardly apart from the tissue fixation portion of the anchoring member such that the valve remains competent when the tissue fixation portion is deformed to conform to the shape of the tissue; and

an extension member having a first terminus at the anchoring member and a second, free terminus, wherein—

the extension member has a delivery configuration in which the extension member extends in a generally straight configuration and the second, free terminus is spaced apart from the first terminus by a first distance, and

wherein the extension member has a deployed configuration in which the extension member extends laterally away from the anchoring member, has an inverted distal portion, and the second, free terminus is spaced apart from the first terminus by a second distance less than the first distance.

27. The device of example 26 wherein the extension member includes a flexible web and a support member extending along at least a portion of the length of the extension member, the support member attached to the web.

28. A method for deploying a prosthetic heart valve device, the method comprising:

positioning a distal portion of a delivery catheter at a native heart annulus;

delivering a prosthetic heart valve device to the distal portion of the delivery catheter, the prosthetic heart valve device having a brim configured to be positioned at an upstream side of the annulus when the device is deployed,

and wherein the brim has a first portion and a second portion positioned distal to the first portion during delivery; and withdrawing the delivery catheter proximally thereby allowing the brim to fold back on itself such that (a) a distal end of the first portion moves in a first direction relative to a central longitudinal axis of the deployed device, and (b) a distal end of the second portion moves in a second direction relative to the central longitudinal axis that is opposite the first direction.

29. The method of example 28 wherein withdrawing the delivery catheter proximally allows the brim to fold back on itself such that (a) a distal end of the first portion moves away from the central longitudinal axis of the deployed device, and (b) a distal end of the second portion moves toward the central longitudinal axis.

30. The method of example 29 wherein withdrawing the delivery catheter proximally allows the brim to fold back on itself such that (a) a distal end of the first portion moves toward the central longitudinal axis of the deployed device, and (b) a distal end of the second portion moves away from the central longitudinal axis.

[0067] From the foregoing, it will be appreciated that specific embodiments of the invention have been described herein for purposes of illustration, but that various modifications may be made without deviating from the scope of the invention. For example, several individual components can be interchange with each other in the different embodiments. Accordingly, the invention is not limited except as by the appended claims.

CLAIMS

I/We claim:

1. A prosthetic heart valve device comprising:
an anchoring member having an annular fixation structure with an upstream portion and a downstream portion;
a tubular valve support having a first portion coupled to the upstream portion of the anchoring member and a second portion spaced radially inward from the upstream portion of the anchoring member;
a valve assembly coupled to the valve support and having at least one leaflet movable from a closed position in which blood flow is blocked through the valve support and an open position in which blood flow is allowed through the valve support in a downstream direction; and
an extension member having an annular first portion coupled to the fixation structure and a second portion coupled to the first portion, wherein—
the extension member folds back on itself in a delivery configuration such that the first portion extends distally from the fixation structure and the second portion extends back proximally from the first portion, and
when the extension member is in a deployed configuration, the first portion extends radially outwardly from the fixation structure and the second portion extends radially outwardly from the first portion.
2. The device of claim 1 wherein the second portion is positioned radially inwardly of the first portion in the delivery configuration.
3. The device of claim 1 wherein the second portion is positioned radially outwardly of the first portion in the delivery configuration.

4. The device of claim 1 wherein the extension member has a first terminus at the anchoring member and a free second terminus, wherein a length of the first portion is substantially the same as a length of the second portion such that, when the device is in the delivery configuration, the free second terminus is axially aligned with the first terminus along a line substantially parallel to the longitudinal axis of the device.

5. The device of claim 1 wherein the extension member has a first terminus at the anchoring member and a free second terminus, and wherein a length of the first portion is greater than a length of the second portion such that, when the device is in the delivery configuration, the second terminus is distal of the first terminus along a line substantially parallel to the longitudinal axis of the device.

6. The device of claim 1 wherein the extension member has a first terminus at the anchoring member and a free second terminus, and wherein a length of the first portion is less than a length of the second portion such that, when the device is in the delivery configuration, the second terminus is proximal of a first terminus along a line substantially parallel to the longitudinal axis of the device.

7. The device of claim 1 wherein, in the expanded configuration, the first portion and the second portion have a straight configuration such that the first portion is not at an angle with respect to the second portion.

8. The device of claim 1 wherein the extension member includes one or more impedance sensors.

9. A prosthetic heart valve device comprising:
an anchoring member having a radially expandable frame with an interior and having an upstream portion and a downstream portion, wherein the upstream portion includes a tissue fixation portion configured to press outwardly against tissue located at and/or downstream of a native annulus of a heart

- valve in a subject and configured to be at least partially deformable to conform to a shape of the tissue;
- a valve positioned relative to the anchoring member and having at least one leaflet movable from a closed position in which blood flow is blocked through the interior and an open position in which blood flow is allowed through the interior in a flow direction from the upstream portion toward the downstream portion, wherein the valve is spaced inwardly apart from the tissue fixation portion of the anchoring member such that the valve remains competent when the tissue fixation portion is deformed to conform to the shape of the tissue; and
- an extension member having a first terminus at the anchoring member and a second, free terminus, wherein—
- the extension member has a delivery configuration in which the extension member extends distally from the anchoring member, has an inverted distal portion, and the second, free terminus is spaced apart from the first terminus by a first distance, and
- the extension member has a deployed configuration in which the extension member extends laterally away from the anchoring member such that the second, free terminus is spaced apart from the first terminus by a second distance greater than the first distance.
10. The device of claim 9 wherein the second free terminus is distal of the first terminus when the extension member is in the delivery configuration.
11. The device of claim 9 wherein the second free terminus is proximal of the first terminus when the extension member is in the delivery configuration.
12. The device of claim 9 wherein the extension member includes a flexible web and a support member extending along at least a portion of the length of the extension member, the support member attached to the web.

13. The device of claim 9 wherein the extension member includes a flexible web and a support member extending along at least a portion of the length of the extension member, the support member attached to the web.

14. The device of claim 9 wherein the extension member has joint, a first portion extending between the first terminus and the joint, and a second portion extending between the joint and the second terminus, and wherein at least a portion of the first portion overlaps at least a portion of the second portion when the extension member is in a delivery configuration.

15. The device of claim 9 wherein the extension member includes one or more impedance sensors.

16. A method for deploying a prosthetic heart valve device, the method comprising:

- positioning a distal portion of a delivery catheter at a native heart annulus;
- delivering a prosthetic heart valve device to the distal portion of the delivery catheter, the prosthetic heart valve device having a brim configured to be positioned at an upstream side of the annulus when the device is deployed, and wherein the brim is folded into a first portion and an overlapping second portion during delivery; and
- withdrawing the delivery catheter proximally thereby allowing the brim to unfold such that the brim extends laterally away from a central longitudinal axis of the prosthetic heart valve device.

17. The method of claim 16 wherein withdrawing the delivery catheter proximally allows the brim to unfold such that (a) a distal end of the first portion moves radially away from the central longitudinal axis of the device, and (b) a distal end of the second portion moves radially towards the central longitudinal axis of the device.

18. The method of claim 16 wherein—
the brim includes a joint and the first portion and the second portion are coupled at the joint, and wherein a proximal terminus of the first portion is coupled to an upstream region of an anchoring member of the device; and
withdrawing the delivery catheter proximally allows the brim to unfold such that (a) the first portion rotates away from the central longitudinal axis of the device about the proximal terminus, and (b) the second portion rotates radially away from the central longitudinal axis of the device about the joint.
19. A prosthetic heart valve device comprising:
an anchoring member having an annular fixation structure with an upstream portion and a downstream portion;
a tubular valve support having a first portion coupled to the upstream portion of the anchoring member and a second portion spaced radially inward from the upstream portion of the anchoring member;
a valve assembly coupled to the valve support and having at least one leaflet movable from a closed position in which blood flow is blocked through the valve support and an open position in which blood flow is allowed through the valve support in a downstream direction; and
an extension member having an annular first portion coupled to the fixation structure and a second portion coupled to the first portion, wherein—
the extension member is generally linear in a delivery configuration such that the first portion extends distally from the fixation structure and the second portion extends distally from the first portion, and
the extension member folds back on itself in a deployed configuration such that the first portion extends radially outwardly from the fixation structure and the second portion extends back towards the fixation structure.

20. The device of claim 19 wherein the second portion extends back towards the fixation structure in an upstream direction such that the second portion is positioned upstream of the first portion in the deployed configuration.

21. The device of claim 19 wherein the second portion extends back towards the fixation structure in a downstream direction such that the second portion is positioned downstream of the first portion in the deployed configuration.

22. The device of claim 19 wherein the extension member has a first terminus at the anchoring member and a free second terminus, wherein a length of the first portion is substantially the same as a length of the second portion such that, when the device is expanded, the second terminus is axially aligned with the first terminus along a line substantially parallel to the longitudinal axis of the first portion.

23. The device of claim 19 wherein the extension member has a first terminus at the anchoring member and a free second terminus, and wherein a length of the first portion is greater than a length of the second portion such that, when the device is expanded, the second terminus is radially outward of and spaced apart from the first terminus along a line substantially parallel to the longitudinal axis of the first portion.

24. The device of claim 19 wherein the extension member has a first terminus at the anchoring member and a free second terminus, and wherein a length of the first portion is less than a length of the second portion such that, when the device is expanded, the second terminus is radially inward of and spaced apart from the first terminus along a line substantially parallel to the longitudinal axis of the first portion.

25. The device of claim 19 wherein, in the expanded configuration, the first portion and the second portion have a straight configuration such that the first portion is not at an angle with respect to the second portion.

26. A prosthetic heart valve device comprising:

an anchoring member having a radially expandable frame with an interior and having an upstream portion and a downstream portion, wherein the upstream portion includes a tissue fixation portion configured to press outwardly against tissue located at and/or downstream of a native annulus of a heart valve in a subject and configured to be at least partially deformable to conform to a shape of the tissue;

a valve positioned relative to the anchoring member and having at least one leaflet movable from a closed position in which blood flow is blocked through the interior and an open position in which blood flow is allowed through the interior in a flow direction from the upstream portion toward the downstream portion, wherein the valve is spaced inwardly apart from the tissue fixation portion of the anchoring member such that the valve remains competent when the tissue fixation portion is deformed to conform to the shape of the tissue; and

an extension member having a first terminus at the anchoring member and a second, free terminus, wherein—

the extension member has a delivery configuration in which the extension member extends in a generally straight configuration and the second, free terminus is spaced apart from the first terminus by a first distance, and

wherein the extension member has a deployed configuration in which the extension member extends laterally away from the anchoring member, has an inverted distal portion, and the second, free terminus is spaced apart from the first terminus by a second distance less than the first distance.

27. The device of claim 26 wherein the extension member includes a flexible web and a support member extending along at least a portion of the length of the extension member, the support member attached to the web.

28. A method for deploying a prosthetic heart valve device, the method comprising:

positioning a distal portion of a delivery catheter at a native heart annulus;
delivering a prosthetic heart valve device to the distal portion of the delivery catheter, the prosthetic heart valve device having a brim configured to be positioned at an upstream side of the annulus when the device is deployed, and wherein the brim has a first portion and a second portion positioned distal to the first portion during delivery; and
withdrawing the delivery catheter proximally thereby allowing the brim to fold back on itself such that (a) a distal end of the first portion moves in a first direction relative to a central longitudinal axis of the deployed device, and (b) a distal end of the second portion moves in a second direction relative to the central longitudinal axis that is opposite the first direction.

29. The method of claim 28 wherein withdrawing the delivery catheter proximally allows the brim to fold back on itself such that (a) a distal end of the first portion moves away from the central longitudinal axis of the deployed device, and (b) a distal end of the second portion moves toward the central longitudinal axis.

30. The method of claim 28 wherein withdrawing the delivery catheter proximally allows the brim to fold back on itself such that (a) a distal end of the first portion moves toward the central longitudinal axis of the deployed device, and (b) a distal end of the second portion moves away from the central longitudinal axis.

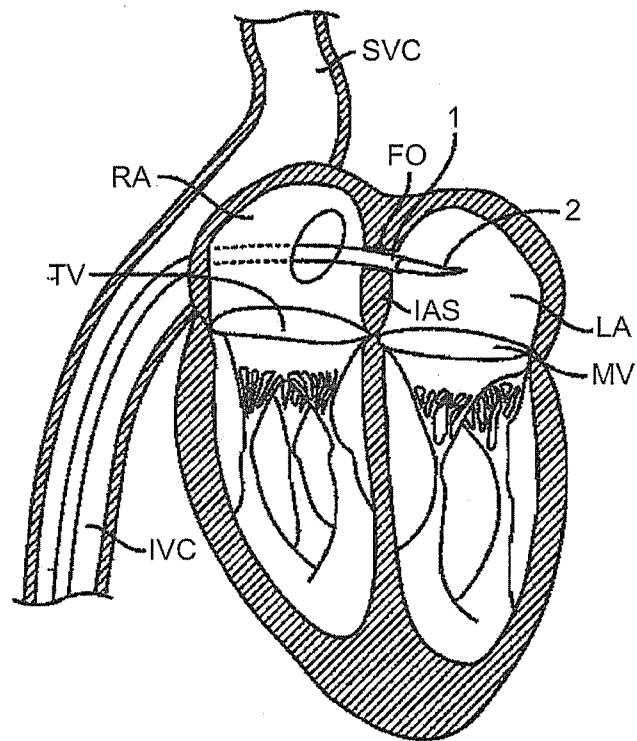


FIG. 1

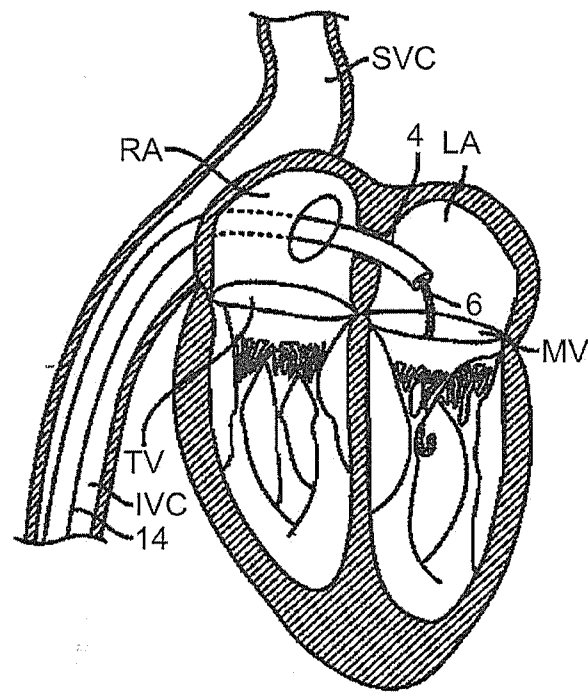


FIG. 2

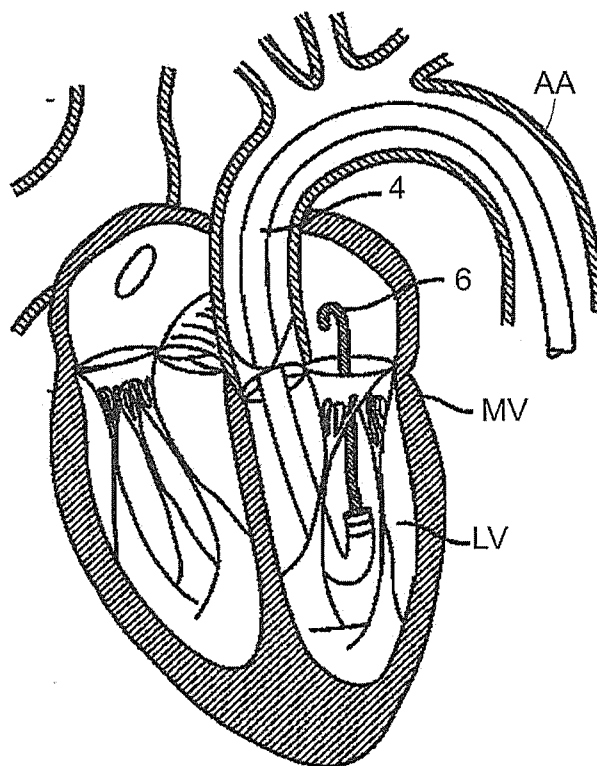


FIG. 3

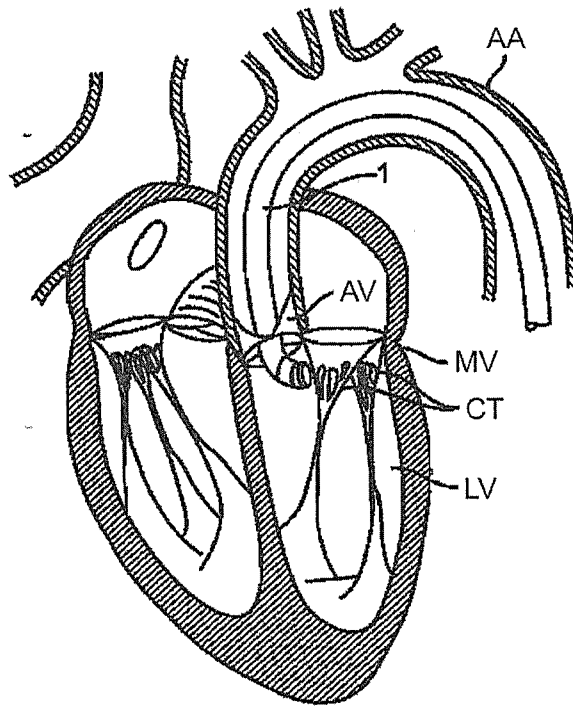


FIG. 4

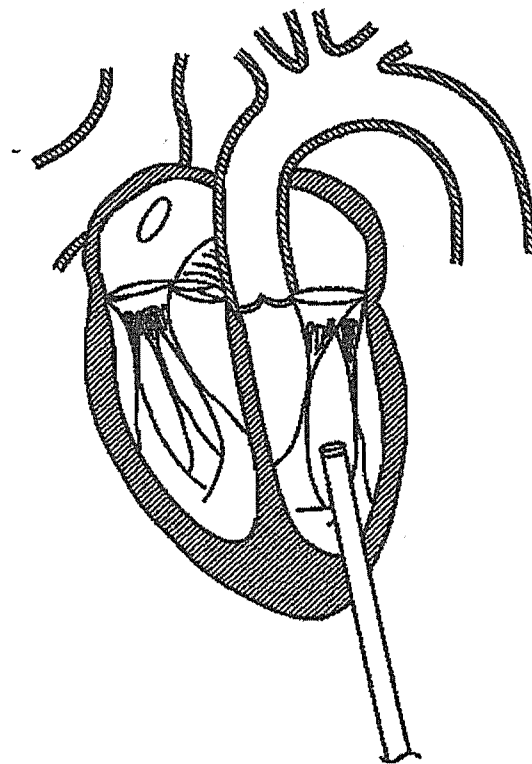


FIG. 5

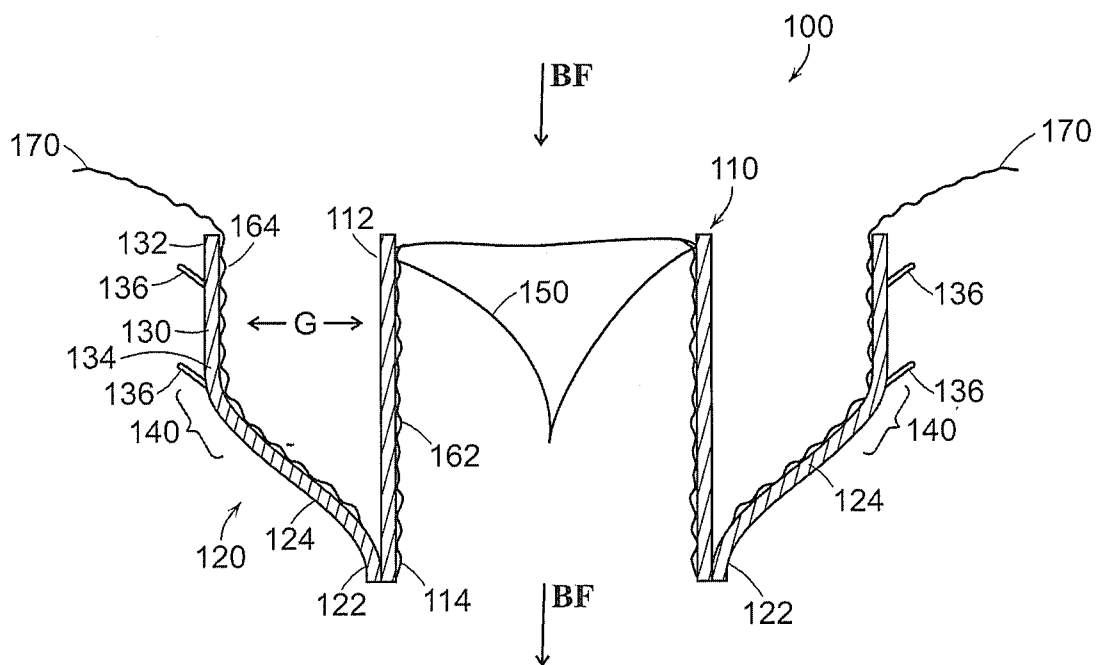


FIG. 6A

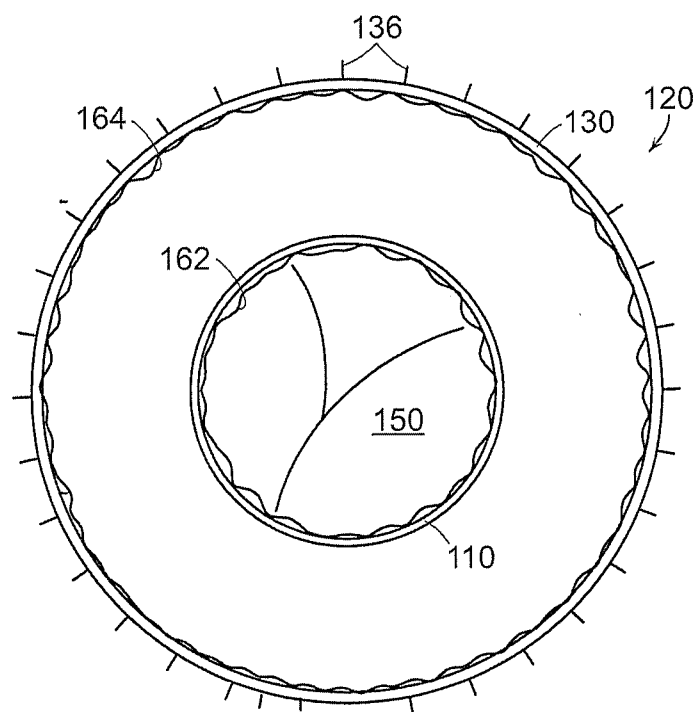


FIG. 6B

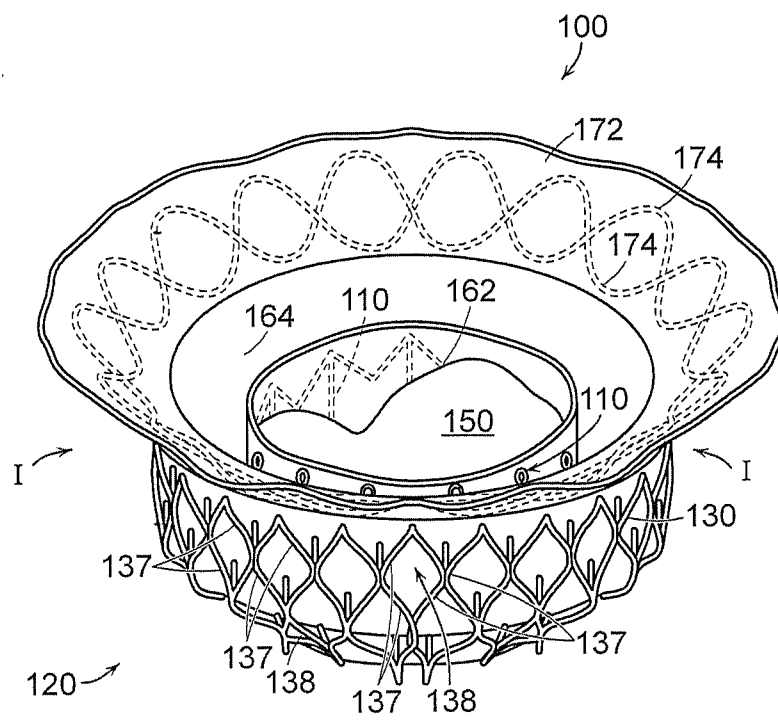


FIG. 7

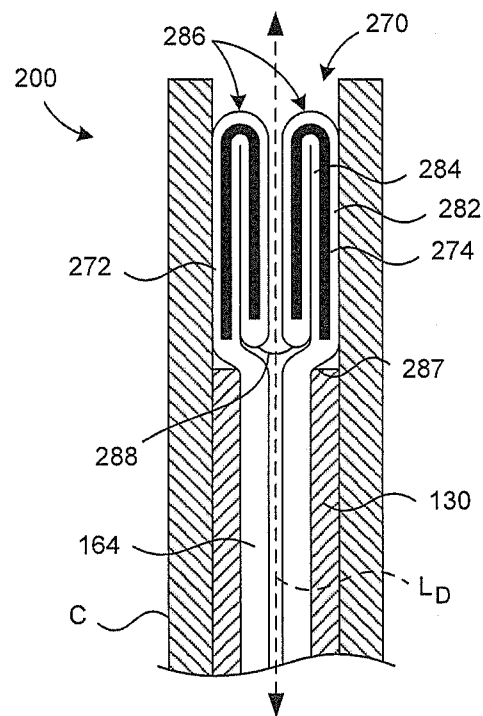


FIG. 8A

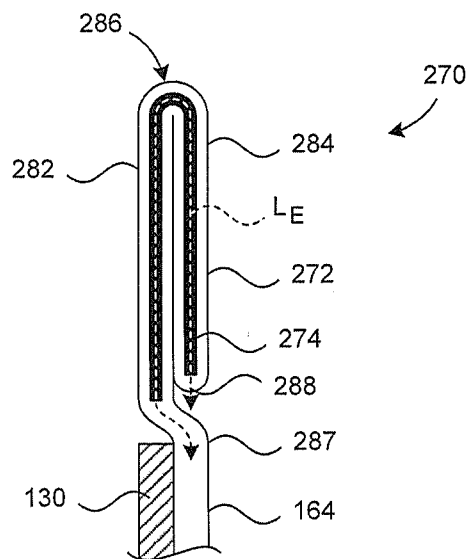


FIG. 8B

FIG. 8C

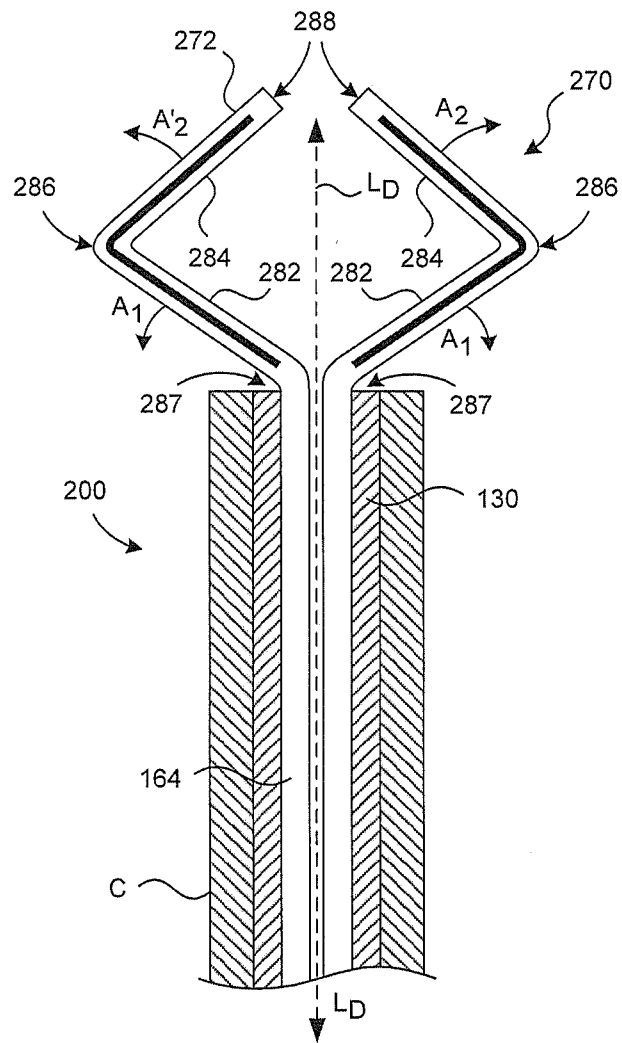
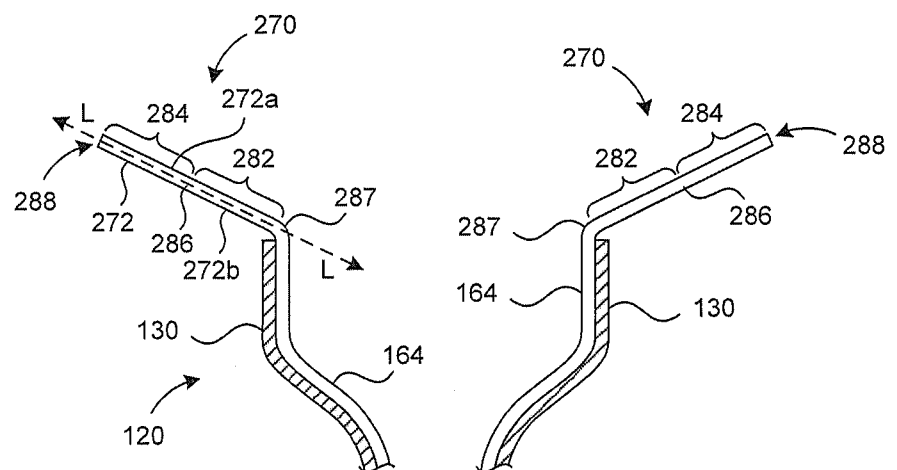


FIG. 8D



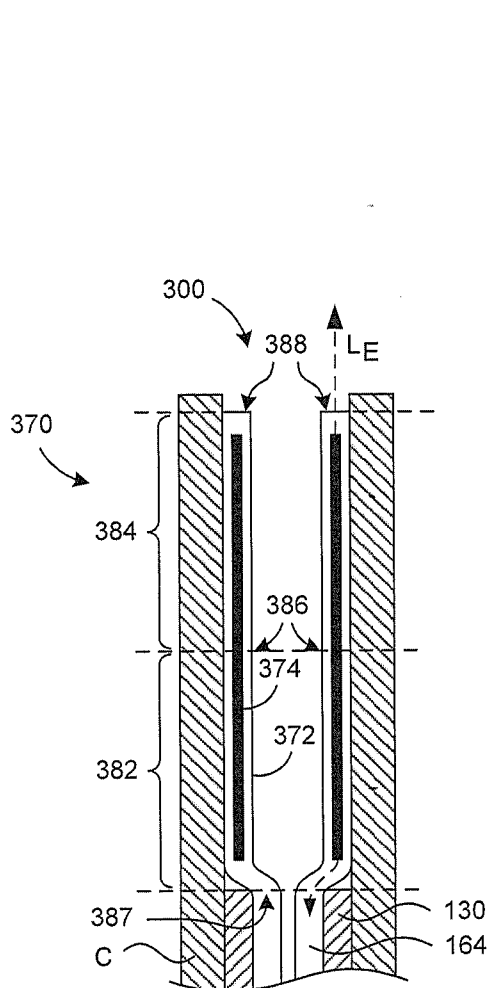


FIG. 9A

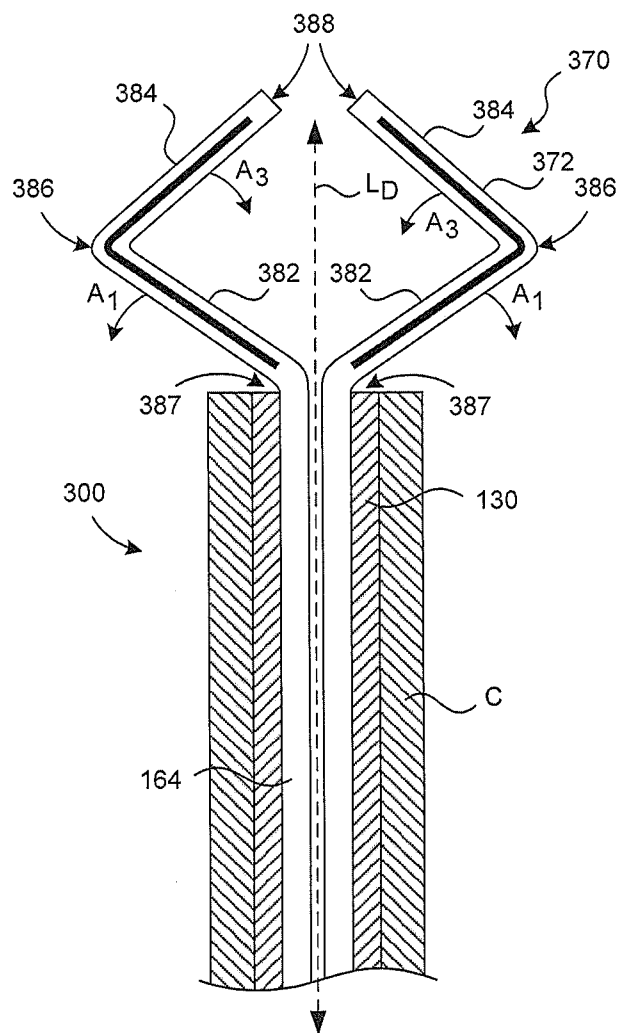


FIG. 9B

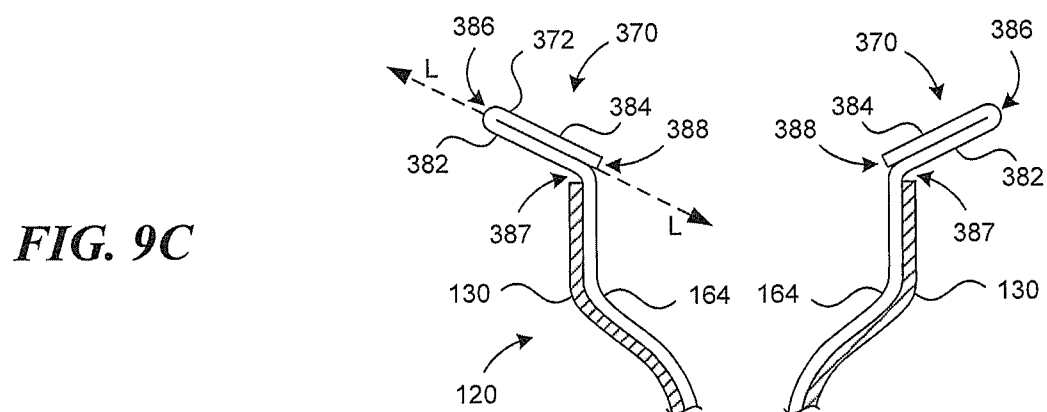


FIG. 9C

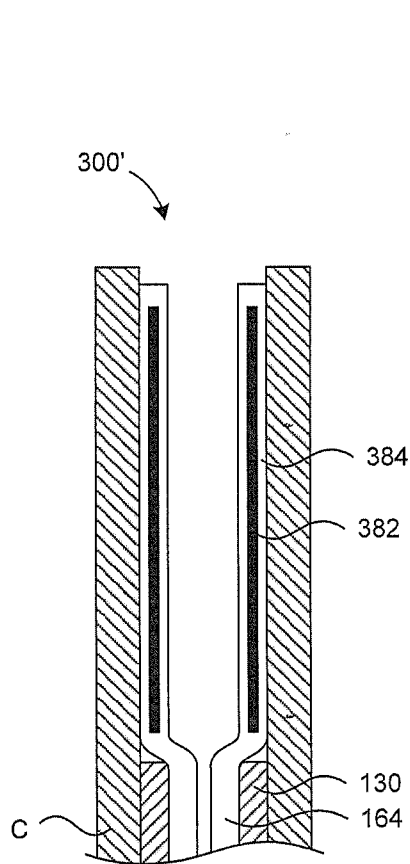


FIG. 10A

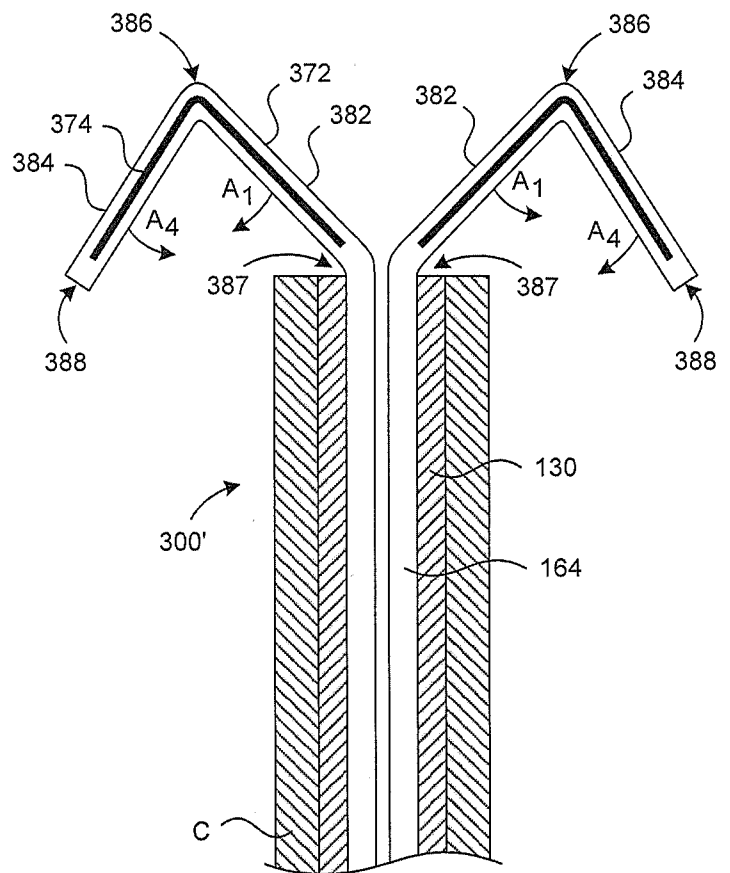
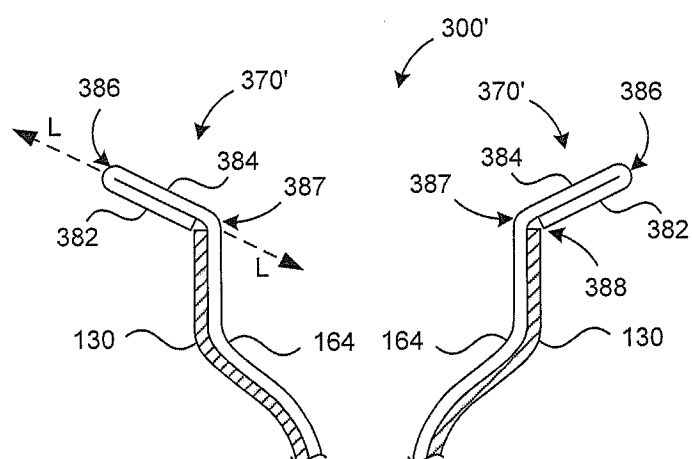


FIG. 10B

FIG. 10C



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/038847

Box No. 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.: 16-18, 28-30
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 No. 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 fees, this Authority did not invite payment of additional fees.
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 and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2018/038847

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/24

ADD.

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 practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2014/144937 A2 (TWELVE INC [US]) 18 September 2014 (2014-09-18)	19-27
A	paragraph [0363]; figures 66a, 66d paragraph [0426] - paragraph [0441]; figures 84a-88c	1-15
X,P	----- WO 2018/029680 A1 (MITRALTECH LTD [IL]) 15 February 2018 (2018-02-15) page 57, line 19 - page 60, line 10; figures 9a-10	19-27
X	----- EP 2 695 586 A1 (SORIN GROUP ITALIA SRL [IT]) 12 February 2014 (2014-02-12)	26
A	paragraph [0117] - paragraph [0133]; figures 23-26	1-15, 19-25
	----- -/-	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

31 August 2018

Date of mailing of the international search report

11/09/2018

Name and mailing address of the ISA/

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Authorized officer

Mary, Céline

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2018/038847

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2016/209970 A1 (EDWARDS LIFESCIENCE CARDIAQ LLC [US]; VERSO HV LLC [US]; GREENE JAMES) 29 December 2016 (2016-12-29) page 23, line 25 - page 30, line 2; figures 1-13 -----	1-15, 19-27

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2018/038847

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2014144937 A2	18-09-2014	AU 2014233505 A1	03-09-2015
		CA 2901008 A1	18-09-2014
		CN 105101911 A	25-11-2015
		EP 2967858 A2	20-01-2016
		JP 2016512753 A	09-05-2016
		JP 2018086571 A	07-06-2018
		WO 2014144937 A2	18-09-2014

WO 2018029680 A1	15-02-2018	US 9987132 B1	05-06-2018
		WO 2018029680 A1	15-02-2018

EP 2695586 A1	12-02-2014	EP 2695586 A1	12-02-2014
		US 2014046434 A1	13-02-2014

WO 2016209970 A1	29-12-2016	CA 2990872 A1	29-12-2016
		US 2016367360 A1	22-12-2016
		WO 2016209970 A1	29-12-2016
