

- 1 -

COVERED PROSTHETIC HEART VALVE

FIELD

[001] The present disclosure relates to prosthetic heart valves, and in particular to prosthetic heart valves including a covering that cushions the tissue of a native heart valve in contact with the prosthetic heart valve.

BACKGROUND

[002] In a procedure to implant a transcatheter prosthetic heart valve, the prosthetic heart valve is typically positioned in the annulus of a native heart valve and expanded or allowed to expand to its functional size. In order to retain the prosthetic heart valve at the desired location, the prosthetic heart valve may be larger than the diameter of the native valve annulus such that it applies force to the surrounding tissue in order to prevent the prosthetic heart valve from becoming dislodged. In other configurations, the prosthetic heart valve may be expanded within a support structure that is located within the native annulus and configured to retain the prosthetic heart valve at a selected position with respect to the annulus. Over time, relative motion of the prosthetic heart valve and tissue of the native heart valve (e.g., native valve leaflets, chordae tendineae, etc.) in contact with the prosthetic heart valve may cause damage to the tissue. Accordingly, there is a need for improvements to prosthetic heart valves.

SUMMARY

[003] Certain disclosed embodiments concern coverings for prosthetic heart valves and methods of making and using the same. In a representative embodiment, a prosthetic heart valve comprises a frame comprising a plurality of strut members, and having an inflow end and an outflow end. The prosthetic heart valve further comprises a leaflet structure situated at least partially within the frame, and a covering disposed around the frame. The covering comprises a first layer and a second layer, wherein the second layer has a plush surface. The first layer is folded over a circumferential edge portion of the

- 2 -

second layer to form a protective portion that extends beyond the strut members in a direction along a longitudinal axis of the prosthetic heart valve.

[004] In some embodiments, the protective portion is a first protective portion located adjacent the inflow end of the frame, and the covering further comprises a second protective portion located adjacent the outflow end of the frame.

[005] In some embodiments, the first layer extends along an interior surface of the second layer from the inflow end of the frame to the outflow end of the frame and is folded over a circumferential edge of the second layer at the outflow end of the frame to form the second protective portion.

[006] In some embodiments, the first layer of the first protective portion is configured as a strip member that is folded over the circumferential edge portion of the second layer at the inflow end of the frame.

[007] In some embodiments, a first layer of the second protective portion is configured as a strip member that is folded over a circumferential edge portion of the second layer at the outflow end of the frame.

[008] In some embodiments, the strip member of the first protective portion encapsulates respective apices of the strut members at the inflow end of the frame, and the strip member of the second protective portion encapsulates respective apices of the strut members at the outflow end of the frame.

[009] In some embodiments, the second layer comprises a fabric having a woven layer and a plush pile layer including a plurality of pile yarns.

[010] In some embodiments, the pile yarns are arranged to form a looped pile, or cut to form a cut pile.

[011] In some embodiments, the first layer comprises a tissue layer.

[012] In another representative embodiment, a method comprises securing a first layer to a first surface of a second layer such that a longitudinal edge portion of the first layer extends beyond a longitudinal edge portion of the second layer, the first surface of the

- 3 -

second layer being a plush second surface. The method further comprises securing the attached first and second layers into a cylindrical shape to form a covering, and situating the covering about a frame of a prosthetic heart valve, the frame comprising a plurality of strut members. The method further comprises folding the longitudinal edge portion of the first layer over the longitudinal edge portion of the second layer to form a protective portion such that the protective portion extends beyond apices of the strut members in a direction along a longitudinal axis of the valve.

[013] In some embodiments, situating the covering about the frame further comprises situating the covering about the frame such that the plush first surface of the second layer is oriented radially outward.

[014] In some embodiments, the protective portion is an inflow protective portion adjacent an inflow end of the frame, the first layer of the inflow protective portion is configured as a first strip member, and the method further comprises folding a longitudinal edge portion of a second strip member over a longitudinal edge portion of the second layer to form an outflow protective portion adjacent an outflow end of the frame.

[015] In some embodiments, folding the longitudinal edge portion of the first strip member further comprises folding the longitudinal edge portion of the first strip member such that the inflow protective portion encapsulates respective apices of the strut members at the inflow end of the frame, and folding the longitudinal edge portion of the second strip member further comprises folding the longitudinal edge portion of the second strip member such that the outflow protective portion encapsulates respective apices of the strut members at the outflow end of the frame.

[016] In some embodiments, the second layer comprises a fabric having a woven layer and a plush pile layer including a plurality of pile yarns that form the second surface.

[017] In another representative embodiment, a method comprises positioning a prosthetic heart valve in an annulus of a native heart valve. The prosthetic heart valve is in a radially compressed state, and has a frame including a plurality of strut members and

- 4 -

having an inflow end and an outflow end. The prosthetic heart valve further comprises a leaflet structure situated at least partially within the frame, and a covering disposed around the frame. The covering comprises a first layer and a second layer. The second layer has a plush surface, and the first layer is folded over a circumferential edge portion of the second layer to form a protective portion that extends beyond the strut members in a direction along a longitudinal axis of the prosthetic heart valve. The method further comprises expanding the prosthetic heart valve in the annulus of the native heart valve such that the leaflet structure of the prosthetic heart valve regulates blood flow through the annulus.

[018] In some embodiments, expanding the prosthetic heart valve further comprises expanding the prosthetic heart valve such that the protective portion prevents tissue of the native heart in contact with the protective portion from contacting apices of the strut members.

[019] In some embodiments, expanding the prosthetic heart valve further comprises expanding the prosthetic heart valve such that leaflets of the native heart valve are captured between the plush surface of the second layer and an anchoring device positioned in the heart.

[020] In some embodiments, the protective portion is a first protective portion located adjacent the inflow end of the frame, and the covering further comprises a second protective portion located adjacent the outflow end of the frame.

[021] In some embodiments, the second layer comprises a fabric having a woven layer and a plush pile layer including a plurality of pile yarns that form the plush surface.

[022] In some embodiments, the first layer is folded over the circumferential edge portion of the second layer such that the protective portion encapsulates respective apices of the strut members.

[023] The foregoing and other objects, features, and advantages of the disclosed technology will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

- [024] FIG. 1 shows a schematic cross-sectional view of a human heart.
- [025] FIG. 2 shows a schematic top view of a mitral valve annulus of a heart.
- [026] FIG. 3 is a perspective view of an embodiment of a prosthetic heart valve.
- [027] FIG. 4A is a cross-sectional side view of a ring anchor deployed in a mitral position of the heart, with an implanted valve prosthesis, according to one embodiment.
- [028] FIG. 4B illustrates a cross-sectional side view of a coil anchor deployed in the mitral position of the heart, with an implanted valve prosthesis, according to another embodiment.
- [029] FIG. 4C is a perspective view of a representative embodiment of a helical anchor.
- [030] FIG. 5 is a perspective view of a prosthetic heart valve including a representative embodiment of a covering.
- [031] FIG. 6 is a side-elevation view of the prosthetic heart valve of FIG. 5.
- [032] FIG. 7 is a top plan view of the prosthetic heart valve of FIG. 5.
- [033] FIG. 8 is a cross-sectional side elevation view of the prosthetic heart valve of FIG. 5.
- [034] FIG. 9 is a perspective view of a representative embodiment of a cushioning layer including a plush pile.
- [035] FIG. 10 is a cross-sectional side view of the prosthetic heart valve of FIG. 5 deployed in the mitral position of the heart.
- [036] FIG. 11 is a side elevation view of a prosthetic heart valve including another embodiment of a covering.
- [037] FIG. 12 is a perspective view of a backing layer, a stencil for producing the backing layer, and a cushioning layer, before the backing layer and the cushioning layer are secured together.

- 6 -

[038] FIG. 13 is a cross-sectional side elevation view of a prosthetic heart valve including another embodiment of a covering.

[039] FIG. 14 is a detail view of an inflow protective portion of the covering of FIG. 13.

[040] FIG. 15 is a side elevation view of a prosthetic heart valve including another embodiment of a covering comprising a spacer fabric.

[041] FIG. 16 is a perspective view of a representative embodiment of a spacer cloth including looped pile yarns.

[042] FIG. 17 is a side elevation view of the spacer fabric of FIG. 16.

[043] FIG. 18 is a top plan view of an embodiment of a backing layer after it is cut using a parallelogram stencil.

[044] FIG. 19 is a perspective view of a prosthetic heart valve including another embodiment of a covering.

[045] FIG. 20 is a side elevation view of the prosthetic heart valve of FIG. 19.

[046] FIG. 21 is a plan view of an outflow end of the prosthetic heart valve of FIG. 19.

[047] FIG. 22 is a cross-sectional side elevation view of the prosthetic heart valve of FIG. 19.

[048] FIG. 23 is a top plan view of the covering of FIG. 19 in an unfolded configuration.

[049] FIG. 24 is a perspective view illustrating placement of the prosthetic heart valve of FIG. 19 into the covering after the covering is formed into a cylindrical shape.

[050] FIG. 25 is a perspective view of the inflow end of the prosthetic heart valve of FIG. 19 illustrating attachment of the covering to the strut members of the valve frame.

[051] FIG. 26 is a perspective view of the inflow end of the prosthetic heart valve of FIG. 19 illustrating a strip member of the covering folded over the strut members of the valve frame to form an inflow protective portion.

- 7 -

[052] FIG. 27 is a perspective view of a frame for a prosthetic heart valve including another embodiment of a covering.

[053] FIG. 28 is a cross-sectional side elevation view of the frame and covering of FIG. 27.

[054] FIGS. 29-31A are perspective views illustrating a representative method of making the covering of FIG. 27.

[055] FIG. 31B is a detail view of the electrospun layer of the inflow end portion of the covering of FIG. 31A.

[056] FIG. 32 is a perspective view of a prosthetic heart valve including a main covering and a second covering extending over the apices of the frame.

[057] FIG. 33 is a side elevation view of the prosthetic heart valve of FIG. 32.

[058] FIG. 34 is a plan view of a portion of the frame of the prosthetic valve of FIG. 32 in a laid-flat configuration.

[059] FIG. 35 is a perspective view of the prosthetic heart valve of FIG. 32 without the main outer covering.

[060] FIG. 36 is a perspective view of the prosthetic heart valve of FIG. 32 illustrating how the second covering is wrapped around the apices of the frame.

[061] FIG. 37 is a perspective view illustrating the frame of the prosthetic valve of FIG. 32 including the second covering crimped onto a shaft of a delivery apparatus.

[062] FIG. 38A is a side elevation view of the prosthetic valve of FIG. 19 including an outer covering, according to another embodiment.

[063] FIG. 38B is a detail view of the fabric of the outer covering of FIG. 38A.

[064] FIG. 39A is a plan view illustrating the prosthetic heart valve of FIG. 38A crimped onto a shaft of a delivery device.

[065] FIG. 39B is a detail view of the outer covering of the prosthetic heart valve in FIG. 39A.

- 8 -

[066] FIG. 40A is a cross-sectional side elevation view of the fabric of the outer covering of FIG. 38A in a relaxed state,

[067] FIG. 40B is a cross-sectional side elevation view of the fabric of the outer covering of FIG. 38A in a tensioned state.

[068] FIG. 41A is a plan view of another embodiment of a fabric outer covering for a prosthetic valve in a laid-flat configuration and including an outer surface defined by a pile layer.

[069] FIG. 41B is a magnified view of the outer covering of FIG. 41A.

[070] FIG. 42A is a plan view of a base layer of the outer covering of FIG. 41A.

[071] FIG. 42B is a magnified view of the base layer of FIG. 42A.

DETAILED DESCRIPTION

[072] The present disclosure concerns embodiments of implantable prosthetic heart valves and methods of making and using such devices. In one aspect, a prosthetic heart valve includes an outer covering having a backing layer and a main cushioning layer disposed on the backing layer such that the cushioning layer is oriented radially outward about the circumference of the valve. The cushioning layer can be soft and compliant in order to reduce damage to native tissues of the heart valve and/or of the surrounding anatomy at the implantation site due to, for example, relative movement or friction between the prosthetic valve and the tissue as the heart expands and contracts. The covering can also include an inflow protective portion and an outflow protective portion to cushion the surrounding anatomy and prevent the native tissue of the heart valve from contacting the apices of the strut members of the frame, thereby protecting the surrounding tissue. In another embodiment, the covering can include an inflow strip member and an outflow strip member secured to the cushioning layer and folded over the apices of the strut members to form the inflow and outflow protective portions.

[073] Embodiments of the disclosed technology can be used in combination with various prosthetic heart valves configured for implantation at various locations within the

- 9 -

heart. A representative example is a prosthetic heart valve for replacing the function of the native mitral valve. FIGS. 1 and 2 illustrate the mitral valve of the human heart. The mitral valve controls the flow of blood between the left atrium and the left ventricle. After the left atrium receives oxygenated blood from the lungs via the pulmonary veins, the mitral valve permits the flow of the oxygenated blood from the left atrium into the left ventricle. When the left ventricle contracts, the oxygenated blood that was held in the left ventricle is delivered through the aortic valve and the aorta to the rest of the body. Meanwhile, the mitral valve closes during ventricular contraction to prevent any blood from flowing back into the left atrium.

[074] When the left ventricle contracts, the blood pressure in the left ventricle increases substantially, which urges the mitral valve closed. Due to the large pressure differential between the left ventricle and the left atrium during this time, a possibility of prolapse, or eversion of the leaflets of the mitral valve back into the atrium, arises. A series of chordae tendineae therefore connect the leaflets of the mitral valve to papillary muscles located on the walls of the left ventricle, where both the chordae tendineae and the papillary muscles are tensioned during ventricular contraction to hold the leaflets in the closed position and to prevent them from extending back towards the left atrium. This generally prevents backflow of oxygenated blood back into the left atrium. The chordae tendineae are schematically illustrated in both the heart cross-section of FIG. 1 and the top view of the mitral valve of FIG. 2.

[075] A general shape of the mitral valve and its leaflets as viewed from the left atrium is shown in FIG. 2. Various complications of the mitral valve can potentially cause fatal heart failure. One form of valvular heart disease is mitral valve leak or mitral regurgitation, characterized by abnormal leaking of blood from the left ventricle through the mitral valve back into the left atrium. This can be caused by, for example, dilation of the left ventricle, which can cause incomplete coaptation of the native mitral leaflets resulting in leakage through the valve. Mitral valve regurgitation can also be caused by damage to the native leaflets. In these circumstances, it may be desirable to repair the

- 10 -

mitral valve, or to replace the functionality of the mitral valve with that of a prosthetic heart valve, such as a transcatheter heart valve.

[076] Some transcatheter heart valves are designed to be radially crimped or compressed to facilitate endovascular delivery to an implant site at a patient's heart. Once positioned at a native valve annulus, the replacement valve is then expanded to an operational state, for example, by an expansion balloon, such that a leaflet structure of the prosthetic heart valve regulates blood flow through the native valve annulus. In other cases, the prosthetic valve can be mechanically expanded or radially self-expand from a compressed delivery state to the operational state under its own resiliency when released from a delivery sheath. One embodiment of a prosthetic heart valve is illustrated in FIG. 3. A transcatheter heart valve with a valve profile similar to the prosthetic valve shown in FIG. 3 is the Edwards Lifesciences SAPIEN XT™ valve. The prosthetic valve 1 in FIG. 3 has an inflow end 2 and an outflow end 3, includes a frame or stent 10, and a leaflet structure 20 supported inside the frame 10. In some embodiments, a skirt 30 can be attached to an inner surface of the frame 10 to form a more suitable attachment surface for the valve leaflets of the leaflet structure 20.

[077] The frame 10 can be made of any body-compatible expandable material that permits both crimping to a radially collapsed state and expansion back to the expanded functional state illustrated in FIG. 3. For example, in embodiments where the prosthetic valve is a self-expandable prosthetic valve that expands to its functional size under its own resiliency, the frame 10 can be made of Nitinol or another self-expanding material. In other embodiments, the prosthetic valve can be a plastically expandable valve that is expanded to its functional size by a balloon or another expansion device, in which case the frame can be made of a plastically expandable material, such as stainless steel or a cobalt chromium alloy. Other suitable materials can also be used.

[078] The frame 10 can comprise an annular structure having a plurality of vertically extending commissure attachment posts 11, which attach and help shape the leaflet structure 20 therein. Additional vertical posts or strut members 12, along with circumferentially extending strut members 13, help form the rest of the frame 10. The

- 11 -

strut members 13 of the frame 10 zig-zag and form edged crown portions or apices 14 at the inflow and outflow ends 2, 3 of the valve 1. Furthermore, the attachment posts 11 can also form edges at one or both ends of the frame 10.

[079] In prosthetic valve 1, the skirt 30 is attached to an inner surface of the valve frame 10 via one or more threads 40, which generally wrap around to the outside of various struts 11, 12, 13 of the frame 10, as needed. The skirt 30 provides a more substantive attachment surface for portions of the leaflet structure 20 positioned closer to the inflow end 2 of the valve 1.

[080] FIGS. 4A and 4B show side cross-sectional views of embodiments of different anchors that can be used to facilitate implantation of the valve 1 at the mitral position of a patient's heart. As shown in FIGS. 4A and 4B, a left side of a heart 80 includes a left atrium 82, a left ventricle 84, and a mitral valve 86 connecting the left atrium 82 and the left ventricle 84. The mitral valve 86 includes anterior and posterior leaflets 88 that are connected to an inner wall of the left ventricle 84 via chordae tendineae 90 and papillary muscles 92.

[081] In FIG. 4A, a first anchoring device includes a flexible ring or halo 60 that surrounds the native leaflets 88 of the mitral valve 86 and/or the chordae tendineae 90. The ring 60 pinches or urges portions of the leaflets inwards, in order to form a more circular opening at the mitral position, for more effective implantation of the prosthetic valve 1. The valve prosthesis 1 is retained in the native mitral valve annulus 86 by the ring anchor 60, and can be delivered to the position shown, for example, by positioning the valve 1 in the mitral annulus 86 while the valve 1 is crimped, and then expanding the valve 1 once it is positioned as shown in FIG. 4A. Once expanded, the valve 1 pushes outwardly against the ring anchor 60 to secure the positions of both the valve 1 and the ring anchor 60. In some embodiments, an undersized ring anchor 60 with an inner diameter that is slightly smaller than the diameter of the prosthetic valve 1 in its expanded state can be used, to provide stronger friction between the parts, leading to more secure attachment. As can be seen in FIG. 4A, at least a portion of the native mitral valve leaflets 88 and/or a portion of the chordae tendineae 90 are pinched or

- 12 -

sandwiched between the valve 1 and the ring anchor 60 to secure the components to the native anatomy.

[082] FIG. 4B is similar to FIG. 4A, except instead of a ring anchor 60, a helical anchor 70 is utilized instead. The helical anchor 70 can include more coils or turns than the ring anchor 60, and can extend both upstream and downstream of the mitral valve annulus 86. The helical anchor 70 in some situations can provide a greater and more secure attachment area against which the valve 1 can abut. Similar to the ring anchor 60 in FIG. 4A, at least a portion of the native mitral valve leaflets 88 and/or the chordae 90 are pinched between the valve 1 and the helical anchor 70. Methods and devices for implanting helical anchors and prosthetic valves are described in U.S. Application No. 15/682,287, filed on August 21, 2017, and U.S. Application No. 15/684,836, filed on August 23, 2017.

[083] FIG. 4C illustrates another representative embodiment of a helical anchor 300 that can be used in combination with any of the prosthetic valves described herein. The anchor 300 can be configured as a coil having a central region 302, a lower region 304, and an upper region 306. The lower region 304 includes one or more turns in a helical arrangement that can be configured to encircle or capture the chordae tendineae and/or the leaflets of the mitral valve. The central region 302 includes a plurality of turns configured to retain the prosthetic valve in the native annulus. The upper region 306 includes one or more turns, and can be configured to keep the anchor from being dislodged from the valve annulus prior to implantation of the prosthetic valve. In some embodiments, the upper region 306 can be positioned over the floor of the left atrium, and can be configured to keep the turns of the central region 302 positioned high within the mitral apparatus.

[084] The anchor 300 also includes an extension portion 308 positioned between the central region 302 and the upper region 306. In other embodiments, the extension portion 308 can instead be positioned, for example, wholly in the central region 302 (e.g., at an upper portion of the central region) or wholly in the upper region 306. The extension portion 308 includes a part of the coil that extends substantially parallel to a

- 13 -

central axis of the anchor. In other embodiments, the extension portion 308 can be angled relative to the central axis of the anchor. The extension portion 308 can serve to space the central region 302 and the upper region 306 apart from one another in a direction along the central axis so that a gap is formed between the atrial side and the ventricular side of the anchor.

[085] The extension portion 308 of the anchor is intended to be positioned through or near the native valve annulus, in order to reduce the amount of the anchor that passes through, pushes, or rests against the native annulus and/or the native leaflets when the anchor is implanted. This can reduce the force applied by the anchor on the native mitral valve and reduce abrasion of the native leaflets. In one arrangement, the extension portion 308 is positioned at and passes through one of the commissures of the native mitral valve. In this manner, the extension portion 308 can space the upper region 306 apart from the native leaflets of the mitral valve to prevent the upper region 306 from interacting with the native leaflets from the atrial side. The extension portion 308 also elevates the upper region 306 such that the upper region contacts the atrial wall above the native valve, which can reduce the stress on and around the native valve, as well as provide for better retention of the anchor.

[086] In the illustrated embodiment, the anchor 300 can further include one or more openings configured as through holes 310 at or near one or both of the proximal and distal ends of the anchor. The through holes 310 can serve, for example, as suturing holes for attaching a cover layer over the coil of the anchor, or as an attachment site for delivery tools such as a pull wire for a pusher or other advancement device. In some embodiments, a width or thickness of the coil of the anchor 300 can also be varied along the length of the anchor. For example, a central portion of the anchor can be made thinner than end portions of the anchor. This can allow the central portion to exhibit greater flexibility, while the end portions can be stronger or more robust. In certain examples, making the end portions of the coil relatively thicker can also provide more surface area for suturing or otherwise attaching a cover layer to the coil of the anchor.

- 14 -

[087] In certain embodiments, the helical anchor 300 can be configured for insertion through the native valve annulus in a counter-clockwise direction. For example, the anchor can be advanced through commissure A3P3, commissure A1P1, or through another part of the native mitral valve. The counter-clockwise direction of the coil of the anchor 300 can also allow for bending of the distal end of the delivery catheter in a similar counter-clockwise direction, which can be easier to achieve than to bend the delivery catheter in the clockwise direction. However, it should be understood that the anchor can be configured for either clockwise or counter-clockwise insertion through the valve, as desired.

[088] Returning to the prosthetic valve of FIG. 3, the prosthetic valve 1 generally includes a metal frame 10 that forms a number of edges. In addition, many frames 10 are constructed with edged crowns or apices 14 and protruding commissure attachment posts 11, as well as threads 40 that can be exposed along an outer surface of the frame 10. These features can cause damage to the native mitral tissue, such as tissue lodged between the prosthetic valve 1 and the anchor 60, 70, for example, by movement or friction between the native tissue and the various abrasive surfaces of the prosthetic valve 1. In addition, other native tissue in close proximity to the prosthetic valve 1, such as the chordae tendinae, can also potentially be damaged.

[089] FIGS. 5-7 illustrate a representative embodiment of a prosthetic heart valve 100 similar to the Edwards Lifesciences SAPIEN™ 3 valve, which is described in detail in U.S. Patent No. 9,393,110. The prosthetic valve 100 includes a frame 102 formed by a plurality of angled strut members 104, and having an inflow end 106 and an outflow end 108. The prosthetic valve 100 also includes a leaflet structure comprising three leaflets 110 situated at least partially within the frame 102 and configured to collapse in a tricuspid arrangement similar to the aortic valve, although the prosthetic valve can also include two leaflets configured to collapse in a bicuspid arrangement in the manner of the mitral valve, or more than three leaflets, as desired. The strut members 104 can form a plurality of apices 124 arranged around the inflow and outflow ends of the frame.

- 15 -

[090] The prosthetic heart valve can include an outer covering 112 configured to cushion (protect) native tissue in contact with the prosthetic valve after implantation, and to reduce damage to the tissue due to movement or friction between the tissue and surfaces of the valve. The covering 112 can also reduce paravalvular leakage. In the embodiment of FIG. 5, the covering 112 includes a first layer configured as a backing layer 114 (see, e.g., FIG. 8), and a second layer configured as a cushioning layer 116. The cushioning layer 116 can be disposed on the backing layer 114, and can comprise a soft, plush surface 118 oriented radially outward so as to protect tissue or objects in contact with the cushioning layer. In the illustrated configuration, the covering 112 also includes an atraumatic inflow protective portion 120 extending circumferentially around the inflow end 106 of the frame, and an atraumatic outflow protective portion 122 extending circumferentially around the outflow end 108 of the frame. The portion of the cushioning layer 116 between the inflow and outflow protective portions 120, 122 can define a main cushioning portion 136.

[091] FIG. 8 is a cross-sectional view schematically illustrating the prosthetic valve 100 with the leaflet structure removed for purposes of illustration. The covering 112 extends around the exterior of the frame 102, such that an interior surface of the backing layer 114 is adjacent or against the exterior surfaces of the strut members 104. As illustrated in FIG. 8, the cushioning layer 116 can have a length that is greater than the length of the frame as measured along a longitudinal axis 126 of the frame. Thus, the covering 112 can be situated such that the cushioning layer 116 extends distally (e.g., in the upstream direction) beyond the apices 124 of the strut members at the inflow end 106 of the frame, with the portion of the cushioning layer extending beyond the apices being referred to herein as distal end portion 128. At the opposite end of the valve, the cushioning layer 116 can extend proximally (e.g., in the downstream direction) beyond the apices 124 of the strut members, with the portion located beyond the apices being referred to as proximal end portion 130. The distances by which the proximal and distal end portions 128, 130 of the cushioning layer 116 extend beyond the apices at the respective end of

- 16 -

the valve can be the same or different depending upon, for example, the dimensions of the valve, the particular application, etc.

[092] The backing layer 114 can have sufficient length in the axial direction such that a proximal end portion or flap 132 of the backing layer 114 can be folded over the proximal end portion 130 of the cushioning layer 116 in the manner of a cuff to form the outflow protective portion 122. Meanwhile, a distal end portion or flap 134 of the backing layer 114 can be folded over the distal end portion 128 of the cushioning layer 116 to form the inflow protective portion 120. The proximal and distal flaps 132, 134 of the backing layer 116 can be secured to the underlying section of the backing layer by, for example, sutures 136. In this manner, the inflow and outflow protective portions 120, 122 are constructed such that the proximal and distal end portions 130, 128 of the cushioning layer 116 are at least partially enclosed by the flaps 132, 134 of the backing layer 116. This construction provides sufficient strength and resistance to bending to the inflow and outflow protective portions 120, 122 so that they extend along the longitudinal axis 126 of the valve without bending or otherwise protruding into the inner diameter of the valve (e.g., by bending under their own weight, by blood flow, or by blood pressure). In this manner, the inflow and outflow protective portions 120, 122 minimally impact flow through the prosthetic valve and avoid interfering with the prosthetic valve leaflets, reducing flow disturbances and the risk of thrombus.

[093] In the illustrated configuration, the inflow protective portion 120 can extend beyond the apices 124 of the strut members at the inflow end of the frame by a distance d_1 , and the outflow protective portion 122 can extend beyond the apices 124 of the strut members at the outflow end of the frame by a distance d_2 . The distances d_1 and d_2 can be the same or different, depending upon the type of prosthetic valve, the treatment location, etc. For example, for a 29 mm prosthetic valve, the distances d_1 and d_2 can be from about 0.5 mm to about 3 mm. In a representative embodiment, the distances d_1 and d_2 can be from about 1 mm to about 2 mm. Because the inflow and outflow protective portions 120, 122 extend beyond the apices 124 of the respective ends of the frame, the

- 17 -

inflow and outflow protective portions can shield adjacent tissue and/or another implant adjacent the prosthetic valve from contacting the apices 124 of the frame.

[094] For example, FIG. 10 illustrates the prosthetic valve 100 implanted within a helical anchor 70 in the native mitral valve 86, similar to FIGS. 4A and 4B above. In the illustrated example, the inflow end portion of the prosthetic valve is positioned above the superior surface of the native mitral valve annulus and spaced from surrounding tissue. However, in other implementations, depending on the axial positioning of the prosthetic valve, the inflow protective portion 120 can contact the native leaflets 88 and prevent them from directly contacting the apices 124 at the inflow end of the frame. Depending on the diameter of the prosthetic valve at the inflow end, the inflow protective portion 120 can serve to prevent the atrium wall from directly contacting the apices 124 at the inflow end of the frame.

[095] As shown in FIG. 10, the anchor 70 can also rest against the compliant inflow protective portion 120. Meanwhile, the portions of the native leaflets 88 captured between the anchor 70 and the prosthetic valve 100 can be cushioned by the plush surface 118 of the main cushioning portion 136. In certain embodiments, the soft, compliant nature and texture of the cushioning layer 116 can increase friction between the native leaflets and the prosthetic valve. This can reduce relative movement of the native leaflets and the prosthetic valve as the left ventricle expands and contracts, reducing the likelihood of damage to the native leaflets and the surrounding tissue. The cushioning layer 116 can also provide increased retention forces between the anchor 70 and the prosthetic valve 100. The plush, compressible nature of the cushioning layer 116 can also reduce penetration of the covering 112 through the openings in the frame 102 caused by application of pressure to the covering, thereby reducing interference with the hemodynamics of the valve. Additionally, the outflow cushioning portion 122 can protect the chordae tendineae 90 from contacting the strut members of the frame, and in particular the apices 124 at the outflow end of the frame, thereby reducing the risk of injury or rupture of the chordae.

- 18 -

[096] The backing layer 114 can comprise, for example, any of various woven fabrics, such as gauze, polyethylene terephthalate (PET) fabric (e.g., Dacron), polyester fabric, polyamide fabric, or any of various non-woven fabrics, such as felt. In certain embodiments, the backing layer 114 can also comprise a film including any of a variety of crystalline or semi-crystalline polymeric materials, such as polytetrafluorethylene (PTFE), PET, polypropylene, polyamide, polyetheretherketone (PEEK), etc. In this manner, the backing layer 114 can be relatively thin and yet strong enough to allow the covering 112 to be sutured to the frame, and to allow the prosthetic valve to be crimped, without tearing.

[097] As stated above, the cushioning layer 116 can comprise at least one soft, plush surface 118. In certain examples, the cushioning layer 116 can be made from any of a variety of woven or knitted fabrics wherein the surface 116 is the surface of a plush nap or pile of the fabric. Exemplary fabrics having a pile include velour, velvet, velveteen, corduroy, terrycloth, fleece, etc. FIG. 9 illustrates a representative embodiment of the cushioning layer 116 in greater detail. In the embodiment of FIG. 9, the cushioning layer 116 can have a base layer 162 (a first layer) from which the pile 158 (a second layer) extends. The base layer 162 can comprise warp and weft yarns woven or knitted into a mesh-like structure. For example, in a representative configuration, the yarns of the base layer 162 can be flat yarns with a denier range of from about 7 dtex to about 100 dtex, and can be knitted with a density of from about 20 to about 100 wales per inch and from about 30 to about 110 courses per inch. The yarns can be made from, for example, biocompatible thermoplastic polymers such as PET, Nylon, ePTFE, etc., other suitable natural or synthetic fibers, or soft monolithic materials.

[098] The pile 158 can comprise pile yarns 164 woven or knitted into loops. In certain configurations, the pile yarns 164 can be the warp yarns or the weft yarns of the base layer 162 woven or knitted to form the loops. The pile yarns 164 can also be separate yarns incorporated into the base layer, depending upon the particular characteristics desired. In certain embodiments, the loops can be cut such that the pile 158 is a cut pile in the manner of, for example, a velour fabric. FIGS. 5-8 illustrate a representative

- 19 -

embodiment of the cushioning layer 116 configured as a velour fabric. In other embodiments, the loops can be left intact to form a looped pile in the manner of, for example, terrycloth. FIG. 9 illustrates a representative embodiment of the cushioning layer 116 in which the pile yarns 164 are knitted to form loops 166. FIG. 11 illustrates an embodiment of the covering 112 incorporating the cushioning layer 116 of FIG. 9.

[0099] In some configurations, the pile yarns 164 can be textured yarns having an increased surface area due to, for example, a wavy or undulating structure. In configurations such as the looped pile embodiment of FIG. 11, the loop structure and the increased surface area provided by the textured yarn of the loops 166 can allow the loops to act as a scaffold for tissue growth into and around the loops of the pile. Promoting tissue growth into the pile 158 can increase retention of the valve at the implant site and contribute to long-term stability of the valve.

[0100] The cushioning layer embodiments described herein can also contribute to improved compressibility and shape memory properties of the covering 112 over known valve coverings and skirts. For example, the pile 158 can be compliant such that it compresses under load (e.g., when in contact with tissue, implants, or the like), and returns to its original size and shape when the load is relieved. This can help to improve sealing between the cushioning layer 116 and, for example, support structures or other devices such as the helical anchor 70 in which the prosthetic valve is deployed, or between the cushioning layer and the walls of the native annulus. The compressibility provided by the pile 158 of the cushioning layer 116 is also beneficial in reducing the crimp profile of the prosthetic valve. Additionally, the covering 112 can prevent the leaflets 110 or portions thereof from extending through spaces between the strut members 104 as the prosthetic valve is crimped, thereby reducing damage to the prosthetic leaflets due to pinching of the leaflets between struts.

[0101] In alternative embodiments, the cushioning layer 116 be made of non-woven fabric such as felt, or fibers such as non-woven cotton fibers. The cushioning layer 116 can also be made of porous or spongy materials such as, for example, any of a variety of compliant polymeric foam materials, or woven or knitted fabrics, such as woven or

- 20 -

knitted PET. In further alternative embodiments, the proximal and distal end portions of the cushioning layer 116 of the embodiment of FIG. 11 can be free of loops 166, and the inflow and outflow protective portions 120, 122 can be formed by folding the base layer 162 back on itself to form cuffs at the inflow and outflow ends of the valve.

[0102] In a representative example illustrated in FIG. 12, the covering 112 of FIGS. 5-8 can be made by cutting a fabric material (e.g., a PET fabric) with a stencil 138 to form the backing layer 114. In the illustrated embodiment, the stencil 138 is shaped like a parallelogram, although other configurations are possible. The angles of the corners of the stencil 138 can be shaped such that the fabric material is cut at about a 45 degree angle relative to the direction of the fibers of the fabric. This can improve the crimpability of the resulting backing layer 114 by, for example, allowing the backing layer to stretch along a direction diagonal to the warp and weft yarns. FIG. 18 illustrates a plan view of a representative example of the backing layer 114 after being cut using the parallelogram stencil 138.

[0103] The cushioning layer 116 can be attached (e.g., by sutures, adhesive, etc.) to the backing layer 114. In FIG. 12, the location of the proximal and distal ends of the frame 102 when the covering is attached to the frame are represented as dashed lines 140, 141 on the backing layer 114. Meanwhile, dashed lines 142, 144 represent the location of the proximal and distal edges of the cushioning layer 116 once the cushioning layer is secured to the backing layer. For example, the cushioning layer 116 can be sutured to the backing layer 114 along the proximal and distal edges at or near lines 142, 144. As shown in FIG. 12, line 142 representing the proximal edge of the cushioning layer 116 can be offset from the proximal edge 146 of the backing layer 114 by a distance d_3 to create the proximal flap 132. Meanwhile, line 144 representing the distal edge of the cushioning layer 116 can be offset from the distal edge 148 of the backing layer 114 by a distance d_4 to create the distal flap 134. The distances d_3 and d_4 can be the same or different, as desired. For example, depending upon the size of the valve and the size of the inflow and outflow cushioning portions, the distances d_3 and d_4 can be, for example, about 3-5 mm. In some embodiments, the distances d_3 and d_4 can be about 3.5 mm.

[0104] Once the cushioning layer 116 is secured to the backing layer 114, the resulting swatch can be folded and sutured into a cylindrical shape. The flaps 132, 134 of the backing layer 114 can be folded over the edges of the cushioning layer 116 and sutured to form the inflow and outflow protective portions 120, 122. The resulting covering 112 can then be secured to the frame 102 by, for example, suturing it the strut members 104.

[0105] FIGS. 13 and 14 illustrate another embodiment of the covering 112 in which the inflow and outflow protective portions 120, 122 are formed with separate pieces of material that wrap around the ends of the cushioning layer 116 at the inflow and outflow ends of the valve. For example, the proximal end portion 130 of the cushioning layer 116 can be covered by a member configured as a strip 150 of material that wraps around the cushioning layer from the interior surface 170 (e.g., the surface adjacent the frame) of the cushioning layer 116, over the circumferential edge of the proximal end portion 130, and onto the exterior surface 118 of the cushioning layer to form the outflow protective portion 122. Likewise, a material strip member 152 can extend from the interior surface 170 of the cushioning layer, over the circumferential edge of the distal end portion 128, and onto the exterior surface of the cushioning layer to form the inflow protective portion 120. The strip members 150, 152 can be sutured to the cushioning layer 116 along the proximal and distal edge portions 130, 128 of the cushioning layer at suture lines 154, 156, respectively.

[0106] In certain configurations, the strip members 150, 152 can be made from any of various natural materials and/or tissues, such as pericardial tissue (e.g., bovine pericardial tissue). The strip members 150, 152 can also be made of any of various synthetic materials, such as PET and/or expanded polytetrafluoroethylene (ePTFE). In some configurations, making the strip members 150, 152 from natural tissues such as pericardial tissue can provide desirable properties such as strength, durability, fatigue resistance, and compliance, and cushioning and reduced friction with materials or tissues surrounding the implant.

[0107] FIG. 15 illustrates a prosthetic valve 200 including another embodiment of an outer covering 202 comprising a cushioning layer 204 made of a spacer fabric. In the

- 22 -

illustrated embodiment, the outer covering 202 is shown without inflow and outflow protective portions, and with the cushioning layer 204 extending along the full length of the frame from the inflow end to the outflow end of the valve. However, the outer covering 202 may also include inflow and/or outflow protective portions, as described elsewhere herein.

[0108] Referring to FIGS. 16 and 17, the spacer fabric cushioning layer can comprise a first layer 206, a second layer 208, and a spacer layer 210 extending between the first and second layers to create a three-dimensional fabric. The first and second layers 206, 208 can be woven fabric or mesh layers. In certain configurations, one or more of the first and second layers 206, 208 can be woven such that they define a plurality of openings 212. In some examples, openings such as the openings 212 can promote tissue growth into the covering 202. In other embodiments, the layers 206, 208 need not define openings, but can be porous, as desired.

[0109] The spacer layer 210 can comprise a plurality of pile yarns 214. The pile yarns 214 can be, for example, monofilament yarns arranged to form a scaffold-like structure between the first and second layers 206, 208. For example, FIGS. 16 and 17 illustrate an embodiment in which the pile yarns 214 extend between the first and second layers 206, 208 in a sinusoidal or looping pattern.

[0110] In certain examples, the pile yarns 214 can have a rigidity that is greater than the rigidity of the fabric of the first and second layers 206, 208 such that the pile yarns 214 can extend between the first and second layers 206, 208 without collapsing under the weight of the second layer 208. The pile yarns 214 can also be sufficiently resilient such that the pile yarns can bend or give when subjected to a load, allowing the fabric to compress, and return to their non-deflected state when the load is removed.

[0111] The spacer fabric can be warp-knitted, or weft-knitted, as desired. Some configurations of the spacer cloth can be made on a double-bar knitting machine. In a representative example, the yarns of the first and second layers 206, 208 can have a denier range of from about 10 dtex to about 70 dtex, and the yarns of the monofilament pile yarns 214 can have a denier range of from about 2 mil to about 10 mil. The pile

- 23 -

yarns 214 can have a knitting density of from about 20 to about 100 wales per inch, and from about 30 to about 110 courses per inch. Additionally, in some configurations (e.g., warp-knitted spacer fabrics) materials with different flexibility properties may be incorporated into the spacer cloth to improve the overall flexibility of the spacer cloth.

[0112] FIGS. 19-21 illustrate another embodiment of a prosthetic heart valve 400 including an outer covering with inflow and outflow protective portions that encapsulate the apices of the strut members. For example, the prosthetic valve can include a frame 402 formed by a plurality of strut members 404 defining apices 420 (FIGS. 22 and 24), and can have an inflow end 406 and an outflow end 408. A plurality of leaflets 410 can be situated at least partially within the frame 402.

[0113] The prosthetic valve can include an outer covering 412 situated about the frame 402. The outer covering 412 can include a main cushioning layer 414 including a plush exterior surface 432 (e.g., a first surface), similar to the cushioning layer 116 of FIG. 13 above. The covering 412 can also include an inflow protective portion 416 extending circumferentially around the inflow end 406 of the valve, and an outflow protective portion 418 extending circumferentially around the outflow end 408 of the valve. The inflow and outflow protective portions 416, 418 can be formed with separate pieces of material that are folded around the circumferential ends of the cushioning layer 414 at the inflow and outflow ends of the valve such that the protective portions encapsulate the apices 420 of the strut members.

[0114] For example, with reference to FIG. 22, the inflow protective portion 416 can comprise a member configured as a strip 424 of material including a first circumferential edge portion 426 and a second circumferential edge portion 428. The strip member 424 of material can be folded such that the first circumferential edge portion 426 is adjacent (e.g., contacting) an inner skirt 430 disposed within the frame 402. The first circumferential edge portion 426 thereby forms a first or inner layer of the inflow protective portion 416. The strip member 424 can extend over the apices 420 of the strut members, and over an inflow end portion 422 of the cushioning layer 414 such that the second circumferential edge portion 428 is disposed on the exterior surface 432 of the

- 24 -

cushioning layer 414. In this manner, the inflow end portion 422 of the cushioning layer 414 can form a second layer of the inflow protective portion 414, and the second circumferential edge portion 428 can form a third or outer layer of the inflow protective portion. The first and second circumferential edge portions 426, 428 of the strip member 424 can be secured to the strut members 404 (e.g., the rung of struts nearest the inflow end 406) with sutures 434, 435. Thus, the strip member 424 can encapsulate the apices 420, along with the inflow end portion 422 of the cushioning layer 414, between the first and second circumferential edge portions 426, 428.

[0115] In the illustrated configuration, the inflow protective portion 416 can extend beyond the apices 420 of the frame, similar to the embodiments above. In particular, the inflow end portion 422 of the cushioning layer 414 can extend beyond the apices 420 of the frame and into the inflow protective portion 416 within the folded strip 424. In this manner, the inflow end portion 422 of the cushioning layer 414, together with the strip member 424, can impart a resilient, cushioning quality to the inflow protective portion 416. This can also allow the inflow protective portion 416 to resiliently deform to accommodate and protect, for example, native tissue, other implants, etc., that come in contact with the inflow protective portion.

[0116] In the illustrated embodiment, the inflow end portion 422 can extend beyond the apices 420 by a distance d_I . The distance d_I can be configured such the inflow end portion 422 can extend over or cover the apices 420 when the inflow protective portion 416 comes in contact with, for example, native tissue at the treatment site. The strip member 424 can also form a dome over the edge of the of the inflow end portion 422 such that the edge of the inflow end portion 422 is spaced apart from the domed portion of the strip member 424. In other embodiments, the strip member 424 can be folded such that it contacts the edge of the inflow edge portion 422, similar to the embodiment of FIG. 13.

[0117] The outflow protective portion 418 can include a member configured as a strip 436 of material folded such that a first circumferential edge portion 438 is adjacent (e.g., contacting) inner surfaces 440 of the strut members, and a second circumferential edge

- 25 -

portion 442 is disposed on the exterior surface 432 of the cushioning layer 414, similar to the inflow protective portion 416. An outflow end portion 444 of the cushioning layer 414 can extend beyond the apices 420 by a distance d_2 , and can be encapsulated by the strip member 436 together with the apices 420 between the first and second circumferential edge portions 438, 442. The distance d_2 can be the same as distance d_1 or different, as desired. The strip member 436 can be secured to the strut members 404 with sutures 446, 447. The strip member 436 can also form a domed shape similar to the strip member 424.

[0118] In certain configurations, the cushioning layer 414 can be a fabric including a plush pile, such as a velour fabric, or any other type of plush knitted, woven, or non-woven material, as described above. In some embodiments, the cushioning layer 414 may also comprise a relatively low thickness woven fabric without a plush pile. In certain configurations, the strip members 424, 436 can be made of resilient natural tissue materials such as pericardium. Alternatively, the strip members can also be made from fabric or polymeric materials such as PTFE or ePTFE.

[0119] FIGS. 23-26 illustrate a representative method of making the outer covering 412 and attaching the covering to the prosthetic valve 400 to form the inflow and outflow protective portions 416, 418. FIG. 23 illustrates the outer covering 412 in an unfolded configuration prior to securing the covering to the frame 402. As illustrated in FIG. 23, the second circumferential edge portion 428 of the strip member 424 can be sutured to the plush surface 432 (e.g., the first surface) of the cushioning layer 414 at the inflow end portion 422 of the cushioning layer. The second circumferential edge portion 442 of the strip member 436 can be sutured to the plush surface 432 of the cushioning layer 414 at the outflow end portion 444 of the cushioning layer.

[0120] In the illustrated configuration, the cushioning layer 414 and the strip members 424, 436 can have a length dimension L corresponding to a circumference of the frame 402. In a representative example, the length dimension L can be about 93 mm. The strip members 424, 436 can also have respective width dimensions W_1 , W_2 . Referring to width dimension W_1 for purposes of illustration, the width dimension W_1 can be

- 26 -

configured such that the strip member 424 extends from the interior of the valve to the exterior of the valve without contacting the apices 420 of the strut members, as shown in FIG. 22. For example, the width dimension W_1 can be configured such that the strip member 424 extends from adjacent the rung of strut members 404 at the inflow end 406 of the frame to the exterior of the valve adjacent the same rung of strut members and forms a domed shape over the apices 420. In certain configurations, the width dimension W_1 can be about 6 mm. The width dimension W_2 can be the same as W_1 or different, as desired.

[0121] Referring to FIG. 24, the outer covering 412 can be folded and sutured into a cylindrical shape. The outer covering 412 can then be situated around the frame 402 such that a second or interior surface 454 of the cushioning layer 414 is oriented toward the frame. In certain configurations, the frame 402 can already include the inner skirt 430 and the leaflet structure 410, as shown in FIG. 24.

[0122] Referring to FIGS. 25 and 26, the outer covering 412 can then be sutured to the frame. For example, as illustrated in FIG. 25, the strip member 424 can be aligned with an adjacent rung of strut members 404 (e.g., the rung of strut members nearest the inflow end of the frame). The cushioning layer 414 and/or the strip member 424 can then be sutured to the strut members 404 at suture line 434. The strip member 424 can then be folded over the apices 420 at the inflow end of the frame, and the first and second circumferential edge portions 426, 428 can be sutured to each other at suture line 435 to form the inflow protective portion 416. In other embodiments, the strip member 424 can be folded and sutured to form the inflow protective portion 416 before the outer covering 412 is sutured to the frame.

[0123] The outflow protective portion 418 can be formed in a similar manner. For example, the strip member 426 can be aligned with the rung of strut members 404 adjacent the outflow end 408 of the frame, and the strip member 426 and/or the cushioning layer 414 can be sutured to the strut members. The strip member 436 can then be folded over the apices 420 and the cushioning layer 414 at the outflow end of the frame, and the first and second circumferential edge portions 438, 442 can be sutured

- 27 -

together, and to the rung of strut members 404 adjacent the outflow end of the frame, to form the outflow protective portion 418. The covering 412 can also be sutured to the frame at one or more additional locations, such as at suture lines 448 and 450, as shown in FIG. 22.

[0124] FIGS. 27 and 28 illustrates another embodiment of a prosthetic heart valve 500 including a frame 502 formed by a plurality of strut members 504 defining apices 506 (FIG. 28), similar to the frame 102 described above and in U.S. Patent No. 9,393,110. The prosthetic valve 500 can have an inflow end 508 and an outflow end 510, and can include a leaflet structure (not shown) situated at least partially within the frame.

[0125] The prosthetic valve can include an outer covering 514 situated about the frame 502. The outer covering 514 can include a main cushioning layer 516 (also referred to as a main layer) having a cylindrical shape, and made from a woven, knitted, or braided fabric (e.g., a PET fabric, an ultra-high molecular weight polyethylene (UHMWPE) fabric, a PTFE fabric, etc.). In some embodiments, the fabric of the main cushioning layer 516 can include a plush pile. In some embodiments, the fabric of the main cushioning layer 516 can comprise texturized yarns in which the constituent fibers of the yarns have been bulked by, for example, being twisted, heat set, and untwisted such that the fibers retain their deformed, twisted shape and create a voluminous fabric. The volume contributed by the texturized yarns can improve the cushioning properties of the covering, as well as increase friction between the fabric and the surrounding anatomy and/or an anchoring device into which the valve is deployed.

[0126] The outer covering 514 can include an inflow protective portion 518 extending circumferentially around the inflow end 508 of the frame, and an outflow protective portion 520 extending circumferentially around the outflow end 510 of the frame. In certain embodiments, the inflow and outflow protective portions 518 and 520 can be formed on the fabric of the main cushioning layer 516 such that the outer covering 514 is a one-piece, unitary construction, as described further below.

[0127] Referring to FIG. 28, the main cushioning layer 516 can include a first circumferential edge portion 522 (also referred to as an inflow edge portion) located

- 28 -

adjacent the inflow end 508 of the valve, which can form a part of the inflow protective portion 518. The cushioning layer 516 can further include a second circumferential edge portion 524 (also referred to as an outflow edge portion) located adjacent the outflow end 510 of the valve, and which can form a part of the outflow protective portion 520.

Referring still to FIG. 28, the first circumferential edge portion 522 can comprise an edge 526, and the second circumferential edge portion 524 can comprise an edge 528. The first circumferential edge portion 522 can be folded or wrapped over the apices 506 of the strut members 504 such that the edge 526 is disposed on the inside of the frame 502. The second circumferential edge portion 524 can be folded around the apices 506 at the outflow end 510 of the frame in a similar fashion such that the edge 528 is also disposed on the inside of the frame opposite the edge 522.

[0128] In the illustrated configuration, the inflow protective portion 518 can include a second or outer layer configured as a lubricious layer 530 of material disposed on an outer surface 532 of the main cushioning layer 516. The outflow protective portion 520 can also include a second or outer lubricious layer 534 of material disposed on the outer surface 532 of the main cushioning layer 516. In some embodiments, the layers 530 and 534 can be smooth, low-thickness coatings comprising a low-friction or lubricious material. For example, in certain configurations one or both of the layers 530, 534 can comprise PTFE or ePTFE.

[0129] In the illustrated configuration, the lubricious layer 530 can have a first circumferential edge 536 (FIG. 27) and a second circumferential edge 538 (FIG. 28). The lubricious layer 530 can extend from the outer surface 532 of the main cushioning layer 516 and over the apices 506 such that the first circumferential edge 536 is disposed on the outside of the frame and the second circumferential edge 538 is disposed on the inside of the frame. The lubricious layer 534 can be configured similarly, such that a first circumferential edge 540 (FIG. 27) is disposed outside the frame, the layer 534 extends over the apices 506 of the outflow end 510 of the frame, and a second circumferential edge 542 (FIG. 28) is disposed inside the frame. Once implanted in a native heart valve, the protection portions 518 and 520 can prevent direct contact

- 29 -

between the apices 506 and the surrounding anatomy. The lubricious material of the layers 530 and 534 can also reduce friction with tissue of the native valve (e.g., chordae) in contact with the inflow and outflow ends of the prosthetic valve, thereby preventing damage to the tissue. In other embodiments, the entire outer surface 532 of the main cushioning layer 516, or a portion thereof, can be covered with a lubricious coating such as ePTFE in addition to the inflow and outflow protective portions 518 and 520 such that the lubricious coating extends axially from the inflow end to the outflow end of the covering. In yet other embodiments, the cushioning layer 516 can be formed from woven, knitted, braided, or electrospun fibers of lubricious material, such as PTFE, ePTFE, etc., and can form the inflow and outflow protective portions.

[0130] FIGS. 29-31B illustrate a representative method of making the covering 514. FIG. 29 illustrates the main cushioning layer 516 formed into a cylindrical, tubular body. Referring to FIG. 30, the first circumferential edge portion 522 of the cushioning layer 516 can then be folded over (e.g., inward toward the interior surface of the tubular body) in the direction of arrows 544 such that the lower edge 526 is inside the tubular body and disposed against the interior surface of the tubular body. The edge portion 524 can be folded in a similar manner as indicated by arrows 546 such that the top edge 528 is inside the tubular body and disposed against the interior surface.

[0131] Referring to FIGS. 31A and 31B, the lubricious layers 530, 534 can then be applied to the main layer 516 to form the inflow and outflow protection portions 518 and 520. In certain embodiments, the lubricious layers 530, 534 can be formed by electrospinning a low-friction material (e.g., PTFE, ePTFE, etc.) onto the first and second circumferential edge portions 522 and 524. In certain embodiments, forming the layers 530, and 534 by electrospinning can provide a smooth, uniform surface, and keep the thickness of the layers within strictly prescribed specifications.

[0132] For example, the layers 530 and 534 can be made relatively thin, which can reduce the overall crimp profile of the valve. In certain embodiments, a thickness of the layers 530 and 534 can be from about 10 μm to about 500 μm , about 100 μm to about 500 μm , about 200 μm to about 300 μm , about 200 μm , or about 300 μm . In other

- 30 -

embodiments, the layer 530 and/or 534 can be made by dip-coating, spray-coating, or any other suitable method for applying a thin layer of lubricious material to the main cushioning layer 516. The finished outer covering 514 can then be situated about and secured to the frame 502 using, for example, sutures, ultrasonic welding, or any other suitable attachment method. In other embodiments, the main cushioning layer 516 can be situated about the frame 502 before the edges are folded, and/or before the lubricious layers 530 and 534 are applied. In yet other embodiments, one or both of the lubricious layers 530 and/or 534 can be omitted from the first and second circumferential edge portions 522 and 524. In yet other embodiments, one or both of the first and second circumferential edge portions 522, 524 need not be folded inside the frame, but may extend to the respective inflow or outflow end of the frame, or beyond the ends of the frame on the exterior of the frame, as desired.

[0133] In addition to covering the frame 502 and the apices 506, the outer covering 514 can provide a number of other significant advantages. For example, the covering 514 can be relatively thin, allowing the prosthetic valve to achieve a low crimp profile (e.g., 23 Fr or below). The one-piece, unitary construction of the outer covering 514 and the protective portions 518 and 520 can also significantly reduce the time required to produce the covering and secure it to the frame, and can increase production yield.

[0134] In some embodiments, one or both of the inflow and outflow protection portions can be configured as separate coverings that are spaced apart from the main outer covering, and may or may not be coupled to the main outer covering. For example, FIGS. 32-36 illustrate another embodiment of a prosthetic heart valve 600 including a frame 602 formed by a plurality of strut members 604 defining apices 606, similar to the frame 102 described above and in U.S. Patent No. 9,393,110. The prosthetic valve 600 can have an inflow end 608 and an outflow end 610, and can include a plurality of leaflets 612 situated at least partially within the frame.

[0135] FIG. 34 illustrates a portion of the frame 602 in a laid-flat configuration for purposes of illustration. The strut members 604 can be arranged end-to-end to form a plurality of rows or rungs of strut members that extend circumferentially around the

- 31 -

frame 602. For example, with reference to FIG. 34, the frame 602 can comprise a first or lower row I of angled strut members forming the inflow end 608 of the frame; a second row II of strut members above the first row; a third row III of strut members above the second row; a fourth row IV of strut members above the third row, and a fifth row V of strut members above the fourth row and forming the outflow end 610 of the frame. At the outflow end 610 of the frame, the strut members 604 of the fifth row V can be arranged at alternating angles in a zig-zag pattern. The strut members 604 of the fifth row V can be joined together at their distal ends (relative to the direction of implantation in the mitral valve) to form the apices 606, and joined together at their proximal ends at junctions 630, which may form part of the commissure windows 638. Additional structure and characteristics of the rows I-V of strut members 604 are described in greater detail in U.S. Patent No. 9,393,110.

[0136] Returning to FIGS. 32 and 33, the prosthetic valve can include a first covering 614 (also referred to as a main covering) situated about the frame 602. The valve can also include an outflow protective portion configured as a second covering 616 disposed about the strut members 604 and the apices 606 of the fifth row V of strut members at the outflow end 610 of the frame. The first covering 616 can comprise a woven or knitted fabric made from, for example, PET, UHMWPE, PTFE, etc. Referring to FIG. 33, the first covering 614 can include an inflow end portion 618 located at the inflow end 608 of the valve, and an outflow end portion 620 located at the outflow end 610 of the valve. In the illustrated embodiment, the outflow end portion 620 of the first covering 614 can be offset toward the inflow end of the frame (e.g., in the upstream direction) from the fifth row V of strut members 604. Stated differently, the strut members 604 of the fifth row V can extend beyond an uppermost circumferential edge 622 of the first covering 614 (e.g., distally beyond the edge 622 when the prosthetic valve is implanted in the mitral valve). A lowermost circumferential edge 624 of the main covering 614 can be disposed adjacent the first row I of strut members 604 at the inflow end 608 of the valve. In some embodiments, the first covering 614 can extend over and cover the apices 606 at the inflow end 608 of the frame.

- 32 -

[0137] FIG. 35 illustrates the frame 602 including the second covering 616 and an inner skirt 640, and without the first covering 614 for purposes of illustration. In certain embodiments, the second covering 616 can be configured as a wrapping that extends around the circumference of the frame 602 and surrounds the fifth row V of strut members 604. For example, with reference to FIG. 36, the covering 616 can be configured as one or more straps or strips 626 of material that are helically wrapped around the struts 604 and the apices 606 of the fifth row V of strut members at the outflow end 610 of the frame in the direction such as indicated by arrow 632. In certain configurations, second covering 616 can be made of a lubricious or low-friction polymeric material, such as PTFE, ePTFE, UHMWPE, polyurethane, etc. In this manner, the second covering 616 can reduce friction between the second covering and native tissue that is in contact with the outflow end 610 of the valve. The covering 616 can also prevent injury to native tissue by preventing it from directly contacting the apices 606.

[0138] In some embodiments, the strip 626 can be relatively thick to improve the cushioning characteristics of the second covering 616. For example, in some embodiments, the strip 626 can be a PTFE strip having a thickness of from about 0.1 mm to about 0.5 mm, and a width of from about 3 mm to about 10 mm. In a representative embodiment, the strip 626 can have a thickness of about 0.25 mm, and a width of about 6 mm. The second covering 616 can also include one or multiple layers. For example, the second covering 616 can include a single layer (e.g., a single strip 626) wrapped around a row of struts of the frame. The second covering may also include two layers, three layers, or more of strips wrapped around a row of struts of the frame. In some embodiments, the second covering 616 can comprise multiple layers made of different materials. In certain configurations, the second covering 616 can also be porous, and can have a pore size and pore density configured to promote tissue ingrowth into the material of the second covering.

[0139] In some embodiments, the first covering 614 and/or the second covering 616 can be secured to the frame by, for example, suturing. In some embodiments, the first and

- 33 -

second coverings 614, 616 can also be secured to each other. For example, with reference to FIGS. 32 and 33, the first covering 614 can include one or more sutures 628 extending circumferentially around the outflow end portion 620 of the first covering in, for example, a running stitch. At or near the junctions 630 (FIG. 34) of the fifth row V of strut members 604, the suture 628 can extend out of the stitch line (e.g., from the radially outward surface of the covering 614), and loop over the second covering 616. The suture 628 can then reenter the covering 614 (e.g., on the radially inward surface of the covering 614) and resume the running stitch. In the illustrated embodiment, the suture 628 can loop over the second covering 616 at the junctions 630. The loops of suture 628 thereby rest in “valleys” between the apices 606, and can serve to hold the second covering 616 in place on the strut members 602. The suture 628 can also hold the first covering 614 in place while the valve is being crimped.

[0140] Still referring to FIGS. 32 and 33, the circumferential edge 622 of the first covering 614 can be relatively straight, while the second covering 616 can conform to the angled or zig-zag pattern of the fifth row V of strut members 604. In this manner, the first and second coverings 614 and 616 can define a plurality of gaps or openings 634 through the frame 602 between the first and second coverings. In the illustrated embodiment, the openings 634 have a triangular shape, with the base of the triangle being defined by the edge 622 of the first covering 614, and the sides being defined by the second covering 616. The openings 634 can be configured such that after the valve 600 is implanted, blood can flow in and/or out of the frame 602 through the openings. In this manner, the space between the interior of the frame 602 and the ventricular surfaces 638 of the leaflets 612 can be flushed or washed by blood flowing into and out of the openings 634 during operation of the prosthetic valve. This can reduce the risk of thrombus formation and left ventricular outflow tract obstruction.

[0141] FIG. 37 illustrates the frame 602 including the second covering 616 in a radially collapsed or crimped delivery configuration on a shaft 636 of a delivery apparatus. As shown in FIG. 37, the second covering 616 can conform to the closely-packed, serpentine shape of the strut members 604 as they move to the radially collapsed

- 34 -

configuration. In certain configurations, the second covering 616 can closely mimic the shape and direction of the strut members 604 without bulging, pleating, creasing, or bunching to maintain a low crimp profile. In other embodiments, the inflow end of the frame can also include a separate covering similar to the covering 616.

[0142] FIGS. 38A, 38B, 39A, and 39B illustrate the prosthetic valve 400 of FIGS. 19-26 including an outer covering 700, according to another embodiment. The outer covering 700 can include a main cushioning layer 702 having a plush exterior surface 704. The covering 700 can also include an inflow protection portion 706 extending circumferentially around the inflow end 406 of the valve, and an outflow protection portion 708 extending circumferentially around the outflow end 408 of the valve. As in the embodiment of FIGS. 19-26, the inflow and outflow protection portions 706, 708 can be formed with separate pieces of material that are folded around the circumferential ends of the main layer 702 such that the cushioning portions encapsulate the apices 420 of the strut members at the inflow and outflow ends of the valve. For example, the inflow and outflow protection portions 706, 708 can be constructed from strips of material (e.g., polymeric materials such as PTFE, ePTFE, etc., or natural tissues such as pericardium, etc.) folded such that one circumferential edge of the strips is disposed against the interior of the frame 402 (or an inner skirt within the frame), and the other circumferential edge is disposed against the outer surface of the main layer 702. The outer covering 700 can be secured to the frame 402 using, for example, sutures, ultrasonic welding, or any other suitable attachment method.

[0143] The main layer 702 of the outer covering 700 can comprise a woven or knitted fabric. The fabric of the main layer 702 can be resiliently stretchable between a first, natural, or relaxed configuration (FIGS. 38A and 38B), and a second, elongated, or tensioned configuration (FIGS. 39A and 39B). When disposed on the frame 402, the relaxed configuration can correspond to the radially expanded, functional configuration of the prosthetic valve, and the elongated configuration can correspond to the radially collapsed delivery configuration of the valve. Thus, with reference to FIG. 38A, the outer covering 700 can have a first length L_1 when the prosthetic valve is in the expanded

- 35 -

configuration, and a second length L_2 (FIG. 39A) that is longer than L_1 when the valve is crimped to the delivery configuration, as described in greater detail below.

[0144] The fabric can comprise a plurality of circumferentially extending warp yarns 712 and a plurality of axially extending weft yarns 714. In some embodiments, the warp yarns 712 can have a denier of from about 1 D to about 300 D, about 10 D to about 200 D, or about 10 D to about 100 D. In some embodiments, the warp yarns 712 can have a thickness t_1 (FIG. 40A) of from about 0.01 mm to about 0.5 mm, about .02 mm to about 0.3 mm, or about 0.03 mm to about 0.1 mm. In some embodiments, the warp yarns 712 can have a thickness t_1 of about 0.03 mm, about 0.04 mm, about 0.05 mm, about 0.06 mm, about 0.07 mm, about 0.08 mm, about 0.09 mm, or about 0.1 mm. In a representative embodiment, the warp yarns 712 can have a thickness of about 0.06 mm.

[0145] The weft yarns 714 can be texturized yarns comprising a plurality of texturized filaments 716. For example, the filaments 716 of the weft yarns 714 can be bulked, wherein, for example, the filaments 716 are twisted, heat set, and untwisted such that the filaments retain their deformed, twisted shape in the relaxed, non-stretched configuration. The filaments 716 can also be texturized by crimping, coiling, etc. When the weft yarns 714 are in a relaxed, non-tensioned state, the filaments 716 can be loosely packed and can provide compressible volume or bulk to the fabric, as well as a plush surface. In some embodiments, the weft yarns 714 can have a denier of from about 1 D to about 500 D, about 10 D to about 400 D, about 20 D to about 350 D, about 20 D to about 300 D, or about 40 D to about 200 D. In certain embodiments, the weft yarns 714 can have a denier of about 150 D. In some embodiments, a filament count of the weft yarns 714 can be from 2 filaments per yarn to 200 filaments per yarn, 10 filaments per yarn to 100 filaments per yarn, 20 filaments per yarn to 80 filaments per yarn, or about 30 filaments per yarn to 60 filaments per yarn. Additionally, although the axially-extending textured yarns 714 are referred to as weft yarns in the illustrated configuration, the fabric may also be manufactured such that the axially-extending textured yarns are warp yarns and the circumferentially-extending yarns are weft yarns.

- 36 -

[0146] FIGS. 40A and 40B illustrate a cross-sectional view of the main layer 702 in which the weft yarns 712 extend into the plane of the page. With reference to FIG. 40A, the fabric of the main layer 702 can have a thickness t_2 of from about 0.1 mm to about 10 mm, about 1 mm to about 8 mm, about 1 mm to about 5 mm, about 1 mm to about 3 mm, about 0.5 mm, about 1 mm, about 1.5 mm, about 2 mm, about 2.5 mm, or about 3 mm when in a relaxed state and secured to a frame. In some embodiments, the main layer 702 can have a thickness of about 0.1 mm, about 0.2 mm, about 0.3 mm, about 0.4 mm, or about 0.5 mm as measured in a relaxed state with a weighted drop gauge having a presser foot. In a representative example, the main layer 702 can have a thickness of about 1.5 mm when secured to a prosthetic valve frame in the relaxed state. This can allow the fabric of the main layer 702 to cushion the leaflets between the valve body and an anchor or ring into which the valve is implanted, as well as to occupy voids or space in the anatomy. The texturized, loosely packed filaments 716 of the weft yarns 714 in the relaxed state can also promote tissue growth into the main layer 702.

[0147] When the fabric is in the relaxed state, the textured filaments 716 of the weft yarns 714 can be widely dispersed such that individual weft yarns are not readily discerned, as in FIGS. 38A and 38B. When tensioned, the filaments 716 of the weft yarns 714 can be drawn together as the weft yarns elongate and the kinks, twists, etc., of the filaments are pulled straight such that the fabric is stretched and the thickness decreases. In certain embodiments, when sufficient tension is applied to the fabric in the axial (e.g., weft) direction, such as when the prosthetic valve is crimped onto a delivery shaft, the textured fibers 716 can be pulled together such that individual weft yarns 714 become discernable, as best shown in FIGS. 39B and 40B.

[0148] Thus, for example, when fully stretched, the main layer 702 can have a second thickness t_3 , as shown in FIG. 40B that is less than the thickness t_2 . In certain embodiments, the thickness of the tensioned weft yarns 714 may be the same or nearly the same as the thickness t_1 of the warp yarns 712. Thus, in certain examples, when stretched the fabric can have a thickness t_3 that is the same or nearly the same as three times the thickness t_1 of the warp yarns 712 depending upon, for example, the amount of

- 37 -

flattening of the weft yarns 714. Accordingly, in the example above in which the warp yarns 712 have a thickness of about 0.06 mm, the thickness of the main layer 702 can vary between about 0.2 mm and about 1.5 mm as the fabric stretches and relaxes. Stated differently, the thickness of the fabric can vary by 750% or more as the fabric stretches and relaxes.

[0149] Additionally, as shown in FIG. 40A, the warp yarns 712 can be spaced apart from each other in the fabric by a distance y_1 when the outer covering is in a relaxed state. As shown in FIGS. 39B and 40B, when tension is applied to the fabric in the direction perpendicular to the warp yarns 712 and parallel to the weft yarns 714, the distance between the warp yarns 712 can increase as the weft yarns 714 lengthen. In the example illustrated in FIG. 40B, in which the fabric has been stretched such that the weft yarns 714 have lengthened and narrowed to approximately the diameter of the warp yarns 712, the distance between the warp yarns 712 can increase to a new distance y_2 that is greater than the distance y_1 .

[0150] In certain embodiments, the distance y_1 can be, for example, about 1 mm to about 10 mm, about 2 mm to about 8 mm, or about 3 mm to about 5 mm. In a representative example, the distance y_1 can be about 3 mm. In some embodiments, when the fabric is stretched as in FIGS. 39B and 40B, the distance y_2 can be about 6 mm to about 10 mm. Thus, in certain embodiments, the length of the outer covering 700 can vary by 100% or more between the relaxed length L_1 and the fully stretched length (e.g., L_2). The fabric's ability to lengthen in this manner can allow the prosthetic valve to be crimped to diameters of, for example, 23 Fr, without being limited by the outer covering's ability to stretch. Thus, the outer covering 700 can be soft and voluminous when the prosthetic valve is expanded to its functional size, and relatively thin when the prosthetic valve is crimped to minimize the overall crimp profile of the prosthetic valve.

[0151] FIGS. 41A, 41B, 42A, and 42B show an outer sealing member or covering 800 for a prosthetic heart valve (e.g., such as the prosthetic heart valve 400), according to another embodiment. The sealing member 800 can be a dual-layer fabric comprising a base layer 802 and a pile layer 804. FIG. 41A shows the outer surface of the sealing

- 38 -

member 800 defined by the pile layer 804. FIG. 42A shows the inner surface of the sealing member 800 defined by the base layer 802. The base layer 802 in the illustrated configuration comprises a mesh weave having circumferentially extending rows or stripes 806 of higher-density mesh portions interspersed with rows or stripes 808 of lower-density mesh portions.

[0152] In particular embodiments, the yarn count of yarns extending in the circumferential direction (side-to-side or horizontally in FIGS. 42A and 42B) is greater in the higher-density rows 806 than in the lower-density rows 808. In other embodiments, the yarn count of yarns extending in the circumferential direction and the yarn count of yarns extending in the axial direction (vertically in FIGS. 42A and 42B) is greater in the higher-density rows 806 than in the lower-density rows 808.

[0153] The pile layer 804 can be formed from yarns woven into the base layer 802. For example, the pile layer 804 can comprise a velour weave formed from yarns incorporated in the base layer 802. Referring to FIG. 41B, the pile layer 804 can comprise circumferentially extending rows or stripes 810 of pile formed at axially-spaced locations along the height of the sealing member 800 such that there are axial extending gaps between adjacent rows 810. In this manner, the density of the pile layer varies along the height of the sealing member. In alternative embodiments, the pile layer 804 can be formed without gaps between adjacent rows of pile, but the pile layer can comprise circumferentially extending rows or stripes of higher-density pile interspersed with rows or stripes of lower-density pile.

[0154] In alternative embodiments, the base layer 802 can comprise a uniform mesh weave (the density of the weave pattern is uniform) and the pile layer 804 has a varying density.

[0155] In alternative embodiments, the density of the sealing member 800 can vary along the circumference of the sealing member. For example, the pile layer 804 can comprise a plurality of axially-extending, circumferentially-spaced, rows of pile yarns, or alternatively, alternating axially-extending rows of higher-density pile interspersed with axially-extending rows of lower-density pile. Similarly, the base layer 802 can comprise

- 39 -

a plurality axially-extending rows of higher-density mesh interspersed with rows of lower-density mesh.

[0156] In other embodiments, the sealing member 800 can include a base layer 802 and/or a pile layer 804 that varies in density along the circumference of the sealing member and along the height of the sealing member.

[0157] Varying the density of the pile layer 804 and/or the base layer 802 along the height and/or the circumference of the sealing member 800 is advantageous in that it reduces the bulkiness of the sealing member in the radially collapsed state and therefore reduces the overall crimp profile of the prosthetic heart valve.

[0158] In certain embodiments, the outer covering 800 can include inflow and/or outflow protective portions similar to the protective portions 416 and 418 above. However, in other embodiments, the outer covering 800 need not include protective portions and can extend between the top and bottom row of strut members of a frame, or between intermediate rows of strut members, depending upon the particular application.

[0159] Although the prosthetic valve covering embodiments described herein are presented in the context of mitral valve repair, it should be understood that the disclosed coverings can be used in combination with any of various prosthetic heart valves for implantation at any of the valves in the heart. For example, the prosthetic valve coverings described herein can be used in combination with transcatheter heart valves, surgical heart valves, minimally-invasive heart valves, etc. The covering embodiments can be used in valves intended for implantation at any of the native annuluses of the heart (e.g., the aortic, pulmonary, mitral, and tricuspid annuluses), and include valves that are intended for implantation within existing prosthetics valves (so called “valve-in-valve” procedures). The covering embodiments can also be used in combination with other types of devices implantable within other body lumens outside of the heart, or heart valves that are implantable within the heart at locations other than the native valves, such as trans-atrial or trans-ventricle septum valves.

- 40 -

[0160] General Considerations

[0161] For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The disclosed methods, apparatus, and systems should not be construed as being limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another. The methods, apparatus, and systems are not limited to any specific aspect or feature or combination thereof, nor do the disclosed embodiments require that any one or more specific advantages be present or problems be solved.

[0162] Although the operations of some of the disclosed embodiments are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth below. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be used in conjunction with other methods. Additionally, the description sometimes uses terms like “provide” or “achieve” to describe the disclosed methods. These terms are high-level abstractions of the actual operations that are performed. The actual operations that correspond to these terms may vary depending on the particular implementation and are readily discernible by one of ordinary skill in the art.

[0163] As used in this application and in the claims, the singular forms “a,” “an,” and “the” include the plural forms unless the context clearly dictates otherwise. Additionally, the term “includes” means “comprises.” Further, the terms “coupled” and “associated” generally mean electrically, electromagnetically, and/or physically (*e.g.*, mechanically or chemically) coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items absent specific contrary language.

- 41 -

[0164] In the context of the present application, the terms “lower” and “upper” are used interchangeably with the terms “inflow” and “outflow”, respectively. Thus, for example, the lower end of the valve is its inflow end and the upper end of the valve is its outflow end.

[0165] As used herein, the term “proximal” refers to a position, direction, or portion of a device that is closer to the user and further away from the implantation site. As used herein, the term “distal” refers to a position, direction, or portion of a device that is further away from the user and closer to the implantation site. Thus, for example, proximal motion of a device is motion of the device toward the user, while distal motion of the device is motion of the device away from the user. The terms “longitudinal” and “axial” refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined.

[0166] In view of the many possible embodiments to which the principles of the disclosed technology may be applied, it should be recognized that the illustrated embodiments are only preferred examples and should not be taken as limiting the scope of the disclosure. Rather, the scope of the disclosure is at least as broad as the following claims.