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(71) Applicant: **VDYNE, LLC** [US/US]; 10900 73rd Ave. N. Suite 116, Maple Grove, ME 55369 (US).

(72) Inventors: **CHRISTIANSON, Mark**; 10900 73rd Ave. N. #116, Maple Grove, MN 55369 (US). **VIDLUND, Robert**; 10900 73rd Ave. N. #116, Maple Grove, MN 55369 (US). **SAIKRISHNAN, Neelakanatan**; 10900 73rd Ave. N. #116, Maple Grove, MN 55369 (US). **KRAMER, Scott**; 10900 73rd Ave. N. #116, Maple Grove, MN 55369 (US).

(74) Agent: **JUNEAU, Todd**; Juneau & Mitchell, 1727 King Street, Suite 300, Alexandria, VA 22314 (US).

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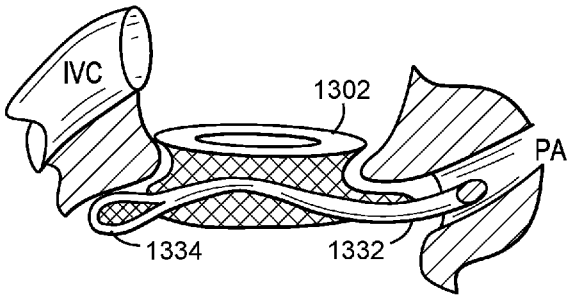


FIG. 14D

(57) Abstract: A prosthetic heart valve includes a valve frame defining an aperture that extends along a central axis and a flow control component mounted within the aperture. The valve frame includes a distal anchoring element and a proximal anchoring element. The valve frame has a compressed configuration to allow the prosthetic heart valve to be delivered to a heart of a patient via a delivery catheter. The valve frame is configured to transition to an expanded configuration when released from the delivery catheter. The prosthetic heart valve is configured to be seated in a native annulus when the valve frame is in the expanded configuration. The distal and proximal anchoring elements configured to be inserted through the native annulus prior to seating the prosthetic heart valve. The proximal anchoring element is ready to be deployed subannularly or is optionally configured to be transitioned from a first configuration to a second configuration after the prosthetic valve is seated.

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PROXIMAL TAB FOR SIDE-DELIVERED TRANSCATHETER HEART VALVES AND METHODS OF DELIVERY

Cross-Reference to Related Applications

[0001] This application claims priority to and the benefit of U.S. Provisional Application Serial No. 62/782,350, entitled "Proximal Tab for Side-Delivered Transcatheter Heart Valve Prosthesis," filed December 20, 2018 and U.S. Application Serial No. 16/445,418, entitled "Proximal Tab for Side-Delivered Transcatheter Heart Valve Prosthesis," filed June 27, 2019, the disclosure of each of which is incorporated herein by reference in its entirety.

Background

[0002] Embodiments are described herein that relate to prosthetic heart valves, and devices and methods for use in the delivery and deployment of such valves.

[0003] Prosthetic heart valves can pose challenges for delivery and deployment within a heart, particularly for delivery by catheters through the patient's vasculature rather than through a surgical approach. Delivery of traditional transcatheter prosthetic valves generally includes compressing the valve in a radial direction and loading the valve into a delivery catheter such that a central annular axis of the valve is parallel to the lengthwise axis of the delivery catheter. The valves are deployed from the end of the delivery catheter and expanded outwardly in a radial direction from the central annular axis. The expanded size (e.g., diameter) of traditional valves, however, can be limited by the internal diameter of the delivery catheter. The competing interest of minimizing delivery catheter size presents challenges to increasing the expanded diameter of traditional valves (e.g., trying to compress too much material and structure into too little space).

[0004] Accordingly, a need exists for prosthetic valves with one or more anchoring features while maintaining a relatively small compressed size that allows for transcatheter delivery of the valve.

Summary

[0005] The embodiments described herein relate generally to transcatheter prosthetic valves and methods for delivering transcatheter prosthetic valves. In some embodiments, a prosthetic heart valve includes a valve frame defining an aperture that extends along a central axis and a flow control component mounted within the aperture. The flow control component is configured to permit blood flow in a first

direction approximately parallel to the central axis from an inflow end to an outflow end of the flow control component and block blood flow in a second direction, opposite the first direction. The valve frame includes a distal anchoring element and a proximal anchoring element. The valve frame has a compressed configuration to allow the prosthetic heart valve to be delivered to a heart of a patient via a delivery catheter. The valve frame is configured to transition from the compressed configuration to an expanded configuration when the prosthetic heart valve is released from the delivery catheter. The prosthetic heart valve is configured to be seated in an annulus of a native valve of the heart when in the expanded configuration. The distal anchoring element and the proximal anchoring element of the valve frame configured to be inserted through the annulus of the native valve prior to the prosthetic heart valve being seated therein. The proximal anchoring element is configured to be transitioned from a first configuration to a second configuration after the prosthetic valve is seated in the annulus of the native valve.

[0006] The embodiments described herein relate generally to transcatheter prosthetic valves configured for side/orthogonal delivery, which can have an increased expanded diameter relative to traditional valves. For example, in side delivery, the valve is compressed and loaded into a delivery catheter such that a central annular axis of the valve is substantially orthogonal to the lengthwise axis of the delivery catheter, which can allow the valve to be compressed laterally and extended longitudinally (e.g., in a direction parallel to the lengthwise axis of the delivery catheter. With traditional and/or orthogonally delivered transcatheter prosthetic valves it is also desirable to provide one or more ways of anchoring the valve in the native annuls without substantially increasing a compressed size of the valve.

Brief Description of the Drawings

[0007] FIGS. 1A-1C are schematic illustrations of a transcatheter prosthetic valve according to an embodiment.

[0008] FIGS. 2-6 are side perspective view illustrations of transcatheter prosthetic valves having distal and proximal anchoring elements, each according to an embodiment.

[0009] FIGS. 7A and 7B are perspective view illustrations of a transcatheter prosthetic valve having a distal and proximal anchoring element according to an embodiment, and shown in a pre-released, anchored configuration and a post-released, extended configuration, respectively.

[0010] FIG. 8 is a cut-away side view illustration of the human heart anatomy.

[0011] FIGS. 9A and 9B are an anterior side perspective view illustration and a septal side perspective view illustration, respectively, of a transcatheter prosthetic valve seated with the native tricuspid annulus of the human heart, according to embodiment.

[0012] FIGS. 10A and 10B are a proximal side view illustration of a transcatheter prosthetic valve showing a proximal anchoring element thereof and a distal side view illustration of the valve showing a distal anchoring element thereof, according to an embodiment.

[0013] FIGS. 11A and 11B are a top anterior view illustration and a top septal view illustration, respectively, of a transcatheter prosthetic valve having a dual anchoring element mechanism according to an embodiment.

[0014] FIG. 12 is a side perspective view illustration of a transcatheter prosthetic valve according to an embodiment, and shown with guide wire coupled to a portion of a distal anchoring element for delivering the valve.

[0015] FIGS. 13A-13D, 14A-14D, 15A-15D, and 16A-16E illustrate a process of deploying a transcatheter prosthetic valve in a native annulus of the human heart each according to a different embodiment.

[0016] FIGS. 17A-17E illustrate a process of deploying a transcatheter prosthetic valve in a native mitral annulus of the human heart according to an embodiment.

[0017] FIG. 18A is an anterior side perspective view illustration of a transcatheter prosthetic valve in a native mitral annulus of the human heart according to an embodiment.

[0018] FIG. 18B is a side view illustration of the transcatheter prosthetic valve of FIG. 18A (shown in dashed line) and disposed in the native mitral annulus (shown in solid line).

[0019] FIGS. 19A and 19B are perspective view illustrations of a proximal anchoring element in a first configuration and a second configuration, respectively, according to an embodiment.

[0020] FIGS. 20A and 20B are perspective view illustrations of a proximal anchoring element in a first configuration and a second configuration, respectively, according to an embodiment.

[0021] FIG. 21A is a top view illustration of a transcatheter prosthetic valve in a native tricuspid annulus of the human heart according to an embodiment.

[0022] FIG. 21B is a top view illustration of the transcatheter prosthetic valve of FIG. 21A (shown in dashed line) and disposed in the native tricuspid annulus (shown in solid line).

[0023] FIG. 22 is a side perspective view illustration of a transcatheter prosthetic valve having multiple subannular anchoring elements according to an embodiment.

[0024] FIGS. 23A and 23B are a side perspective view illustrations of a transcatheter prosthetic valve having a proximal anchoring element being coupled to a tensile member and decoupled from the tensile member, respectively, according to an embodiment.

[0025] FIGS. 24 and 25 are side perspective view illustrations of a portion of a proximal anchoring element of a transcatheter prosthetic valve coupled to a tensile member, each according to a different embodiment.

[0026] FIGS. 26 and 27 are side perspective view illustrations of a portion of a proximal anchoring element of a transcatheter prosthetic valve and a tensile member, each according to a different embodiment.

[0027] FIGS. 28A and 28B are side perspective view illustrations of a portion of a proximal anchoring element of a transcatheter prosthetic valve coupled to a tensile member according to an embodiment, and shown with the tensile member in a first configuration and a second configuration, respectively.

[0028] FIGS. 29A-29D are side perspective view illustrations of a portion of a proximal anchoring element of a transcatheter prosthetic valve being coupled to and decoupled from a tensile member according to an embodiment.

[0029] FIG. 30 is a side perspective view illustration of a portion of a portion of a proximal anchoring element of a transcatheter prosthetic valve coupled to a tensile member according to an embodiment.

[0030] FIGS. 31A-31C are side perspective view illustrations of a portion of a proximal anchoring element of a transcatheter prosthetic valve being coupled to and decoupled from a tensile member according to an embodiment.

[0031] FIG. 32 is a flowchart illustrating a method of delivering a transcatheter prosthetic valve according to an embodiment.

[0032] FIG. 33 is a flowchart illustrating a method of delivering a transcatheter prosthetic valve according to an embodiment.

Detailed Description

[0033] Disclosed embodiments are directed to transcatheter prosthetic heart valves and/or components thereof, and methods of manufacturing, loading, delivering, and/or deploying the transcatheter prosthetic valves and/or components thereof. The transcatheter prosthetic heart valves can have a valve frame and a flow control component mounted within a central lumen or aperture of the valve frame. The flow control component can be configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve. The valves can be compressible and expandable along a long-axis substantially parallel to a lengthwise cylindrical axis of a delivery catheter. The valves can be configured to transition between a compressed configuration for introduction into the body using the delivery catheter, and an expanded configuration for implanting at a desired location in the body.

[0034] In some implementations, the embodiments described herein are directed to a dual-tab prosthetic heart valve that is a low profile, side delivered implantable prosthetic heart valve. The prosthetic heart valves can have at least a ring-shaped or annular valve frame, an inner flow control component (e.g., a 2-leaflet or 3-leaflet sleeve, and/or the like) mounted in the valve frame, a distal anchoring element (e.g., a sub-annular distal anchoring tab or the like) configured to extend into the right ventricular outflow tract (RVOT), and a proximal anchoring element (e.g., a sub-annular proximal anchoring tab) configured to extend into the proximal sub-annular space, preferably between the anterior and the posterior leaflets of the heart.

[0035] Any of the prosthetic heart valves described herein can be configured to transition between an expanded configuration and a compressed configuration. For example, any of the embodiments described herein can be a balloon-inflated prosthetic heart valve, a self-expanding prosthetic heart valve, and/or the like.

[0036] Any of the prosthetic heart valves described herein can be compressible – into the compressed configuration – in a lengthwise or orthogonal direction relative to the central axis of the flow control component that can allow a large diameter valve (e.g., having a height of about 5-60 mm and a diameter of about 20-80 mm) to be delivered and deployed from the inferior vena cava directly into the annulus of a native mitral or tricuspid valve using, for example, a 24-36Fr delivery catheter and without delivery and deployment from the delivery catheter at an acute angle of approach.

[0037] Any of the prosthetic heart valves described herein can have a central axis when in a compressed configuration that is co-axial or at least substantially parallel with blood flow direction through the valve. In some embodiments, the compressed configuration of the valve is orthogonal to the blood flow

direction. In some embodiments, a long-axis is oriented at an intersecting angle of between 45-135 degrees to the first direction when in the compressed configuration and/or the expanded configuration.

[0038] Any of the prosthetic heart valves described herein can include an anchoring element extending from a distal side of the tubular frame, which can be used, for example, as a Right Ventricular Outflow Tract ("RVOT") tab or a Left Ventricular Outflow Tract ("LVOT"). The anchoring element can include and/or can be formed from a wire loop or wire frame, an integrated frame section, and/or a stent, extending from about 10-40 mm away from the tubular frame.

[0039] Any of the prosthetic heart valves described herein can include (i) an upper anchoring element attached to a distal upper edge of the tubular frame, the upper anchoring element can include or be formed from a wire loop or wire frame extending from about 2-20 mm away from the tubular frame, and (ii) a lower anchoring element (e.g., used as a RVOT tab) extending from a distal side of the tubular frame, the lower anchoring element can include and/or can be formed from a wire loop or wire frame extending from about 10-40 mm away from the tubular frame.

[0040] Any of the prosthetic heart valves described herein can include a distal lower anchoring element configured to be positioned into the RVOT of the right ventricle and a proximal lower anchoring element configured to be positioned into a sub-annular position in contact with and/or adjacent to sub-annular tissue of the right ventricle. The catheter prosthetic heart valve can also include a distal upper anchoring element configured to be positioned into a supra-annular position in contact with and/or adjacent to supra-annular tissue of the right atrium. The distal upper anchoring element can provide a supra-annular downward force in the direction of the right ventricle and the distal and proximal lower anchoring elements can provide a sub-annular upward force in the direction of the right atrium.

[0041] Any of the prosthetic heart valves described herein and/or any component, feature, and/or aspect thereof can be similar to and/or substantially the same as the prosthetic heart valves (or components, features, and/or aspects thereof) described in International Patent Application No. PCT/US2019/051957, entitled "Transcatheter Deliverable Prosthetic Heart Valves and Method of Delivery," filed September 19, 2019 (referred to herein as "the '957 PCT"), the disclosure of which is incorporated herein by reference in its entirety.

[0042] Any method for delivering prosthetic heart valves described herein can include side/orthogonal delivery of the prosthetic heart valve to a desired location in the body that includes (i) advancing a delivery catheter to the desired location in the body and (ii) delivering the prosthetic heart valve to the desired location in the body by releasing the valve from the delivery catheter. The valve is in a compressed

configuration when in the delivery catheter and transitions to an expanded configuration when released from the delivery catheter.

[0043] Any method for delivering prosthetic heart valves described herein can include attaching a pulling wire (e.g., a rigid elongated pulling/pushing rod or draw wire) to a sidewall or an anchoring element (e.g., a distal anchoring element) of the prosthetic heart valve and pulling the valve into and/or through a delivery catheter.

[0044] Any method for delivering prosthetic heart valves described herein can include releasing the valve from the delivery catheter by (i) pulling the valve out of the delivery catheter using a pulling wire or rod that is releasably connected to a sidewall or an anchoring element, wherein advancing the pulling wire away from the delivery catheter pulls the compressed valve out of the delivery catheter, or (ii) pushing the valve out of the delivery catheter using a pushing wire or rod that is releasably connected to a sidewall or an anchoring element, wherein advancing the pushing wire or rod out of from the delivery catheter pushes the compressed valve out of the delivery catheter.

[0045] Any method for delivering prosthetic heart valves described herein can include releasing the valve from a delivery catheter while increasing blood flow during deployment of the valve by (i) partially releasing the valve from the delivery catheter to establish blood flow around the partially released valve and blood flow through the flow control component; (ii) completely releasing the valve from the delivery catheter while maintaining attachment to the valve to transition to a state with increased blood flow through the flow control component and decreased blood flow around the valve; (iii) deploying the valve into a final mounted position in a native annulus to transition to a state with complete blood flow through the flow control component and minimal or no blood flow around the valve; and (iv) disconnecting and withdrawing a positioning catheter, pulling or pushing wire or rod, and/or the delivery catheter.

[0046] Any method for delivering prosthetic heart valves described herein can include orthogonal delivery of the prosthetic heart valve to a native annulus of a human heart that includes at least one of (i) advancing the delivery catheter to the tricuspid valve or pulmonary artery of the heart through the inferior vena cava (IVC) via the femoral vein, (ii) advancing to the tricuspid valve or pulmonary artery of the heart through the superior vena cava (SVC) via the jugular vein, or (iii) advancing to the mitral valve of the heart through a trans-atrial approach (e.g., fossa ovalis or lower), via the IVC-femoral or the SVC-jugular approach; and (iv) delivering prosthetic heart valve to the native annulus by releasing the valve from the delivery catheter.

[0047] Any method for delivering prosthetic heart valves described herein and/or any portion thereof can be similar to and/or substantially the same as one or more methods for delivering prosthetic heart valves (or portion(s) thereof) described in the '957 PCT.

[0048] In some embodiments, a prosthetic heart valve includes a valve frame defining an aperture that extends along a central axis and a flow control component mounted within the aperture. The flow control component is configured to permit blood flow in a first direction approximately parallel to the central axis from an inflow end to an outflow end of the flow control component and block blood flow in a second direction, opposite the first direction. The valve frame includes a distal anchoring element and a proximal anchoring element. The valve frame has a compressed configuration to allow the prosthetic heart valve to be delivered to a heart of a patient via a delivery catheter. The valve frame is configured to transition from the compressed configuration to an expanded configuration when the prosthetic heart valve is released from the delivery catheter. The prosthetic heart valve is configured to be seated in an annulus of a native valve of the heart when in the expanded configuration. The distal anchoring element and the proximal anchoring element of the valve frame configured to be inserted through the annulus of the native valve prior to the prosthetic heart valve being seated therein. The proximal anchoring element is configured to be transitioned from a first configuration to a second configuration after the prosthetic valve is seated in the annulus of the native valve.

[0049] In some embodiments, a prosthetic heart valve includes a valve frame having a transannular section and an atrial collar attached around a top edge of the transannular section, a distal anchoring element coupled to the transannular section, a proximal anchoring element coupled to the transannular section, and a flow control component mounted within the valve frame. The flow control component is configured to permit blood flow in a first direction through an inflow end of the prosthetic heart valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the prosthetic heart valve. The prosthetic heart valve has a compressed configuration for introduction into a heart of a patient via a delivery catheter and an expanded configuration when the prosthetic heart valve is released from the delivery catheter within an atrium of the heart. The prosthetic heart valve is configured to be seated in an annulus of a native valve of the heart when in the expanded configuration. The distal anchoring element is configured to be disposed in a ventricular outflow tract when the prosthetic heart valve is seated in the annulus of the native valve and the proximal anchoring element is configured to be transitioned from a first configuration to a second configuration after the prosthetic heart valve is seated in the annulus of the native valve.

[0050] In some embodiments, a method of delivering a prosthetic heart valve to an annulus of a native valve between an atrium and a ventricle of a heart of a patient includes disposing adjacent to the annulus of the native valve a distal end of a delivery catheter having disposed in a lumen thereof the prosthetic heart

valve. The prosthetic heart valve includes a valve frame with a distal anchoring element and a proximal anchoring element, and a flow control component mounted within the valve frame. The prosthetic heart valve is in a compressed configuration within the lumen of the delivery catheter. The prosthetic heart valve is released from the lumen of the delivery catheter. The prosthetic heart valve is configured to transition from the compressed configuration to an expanded configuration in response to being released. A portion of the distal anchoring element is placed on the ventricle side of the annulus of the native valve. The prosthetic heart valve is seated in the annulus when the proximal anchoring element is in a first configuration and the proximal anchoring element is transitioned from the first configuration to a second configuration after the prosthetic heart valve is seated in the annulus.

[0051] In some embodiments, the invention comprises a side delivered transcatheter prosthetic heart valve having a distal anchoring tab and a proximal anchoring tab, having: (i) a self-expanding annular support frame, said annular support frame having a central channel and an outer perimeter wall circumscribing a central vertical axis in an expanded configuration, said annular support frame having a distal side and a proximal side; (ii) a flow control component mounted within the annular support frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve; (iii) a distal anchoring tab mounted on the distal side of the annular support frame; (iv) a proximal anchoring tab mounted on the proximal side of the annular support frame; wherein the valve is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration is oriented along a horizontal axis at an intersecting angle of between 45-135 degrees to the central vertical axis, and expandable to an expanded configuration having a horizontal axis at an intersecting angle of between 45-135 degrees to the central vertical axis; wherein the horizontal axis of the compressed configuration of the valve is substantially parallel to a length-wise cylindrical axis of the delivery catheter; wherein the valve has a height of about 5-60mm and a diameter of about 25-80mm.

[0052] In some embodiments, the proximal tab is fixed or unitary with the outer support frame. In other embodiments, the proximal tab is moveable from a first stowed position, i.e. held against the outer perimeter wall while the valve is positioned in the native annulus, and moveable to a second deployed position that extends away from the outer perimeter wall to provide a subannular anchor.

[0053] In some embodiments, the valve has a lower distal tab and a lower proximal tab. In other embodiments, the valve has a lower distal tab, a lower proximal tab, and an upper distal anchoring tab attached to a distal upper edge of the annular support frame, which may be comprised of wire loop, a wire frame, a laser cut frame, an integrated frame section, or a stent, and may extends from about 2-20mm away from the annular support frame.

[0054] In some embodiments, the annular support frame is comprised of compressible wire cells selected from the group consisting of braided-wire cells, laser-cut wire cells, photolithography produced wire cells, 3D printed wire cells, wire cells formed from intermittently connected single strand wires in a wave shape, a zig-zag shape, or spiral shape, and combinations thereof.

[0055] In some embodiments, the invention provides a method for side delivery of an implantable prosthetic heart valve to a desired location in the body, the method comprising the step of advancing a delivery catheter to the desired location in the body and delivering an expandable prosthetic heart valve to the desired location in the body by releasing the valve from the delivery catheter, wherein the valve comprises an annular support frame having a flow control component mounted within the annular support frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, a distal anchoring tab mounted on a distal side of the annular support frame, and a proximal anchoring tab mounted on a proximal side of the annular support frame, wherein the valve is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, wherein the valve is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration has a height of 8-12mm, a width of 8-12mm, and a length of 25-80mm, and wherein the horizontal axis of the compressed configuration of the valve is substantially parallel to a length-wise cylindrical axis of the delivery catheter, said expanded configuration has a height of about 5-60mm and a diameter of about 25-80mm.

[0056] In some embodiments, the said compressed configuration has a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, and expandable to an expanded configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, wherein the long-axis of the compressed configuration of the valve is substantially parallel to a length-wise cylindrical axis of the delivery catheter.

[0057] In some embodiments, the method includes a step wherein releasing the valve from the delivery catheter is selected from the steps consisting of: (i) pulling the valve out of the delivery catheter using a rigid elongated pushing rod/draw wire that is releasably connected to the distal side of the valve, wherein advancing the pushing rod away from the delivery catheter pulls the compressed valve out of the delivery catheter, or (ii) pushing the valve out of the delivery catheter using a rigid elongated pushing rod that is releasably connected to the proximal side of the valve, wherein advancing the pushing rod out of from the delivery catheter pushes the compressed valve out of the delivery catheter.

[0058] In some embodiments, the method comprises the additional step of anchoring one or more tissue anchors attached to the valve into native tissue.

[0059] In some embodiments, the method comprises the additional step of positioning the distal anchoring tab of the heart valve prosthesis into the right ventricular outflow tract of the right ventricle.

[0060] In some embodiments, the method comprises the additional steps of positioning the distal anchoring tab of the heart valve prosthesis into the right ventricular outflow tract of the right ventricle, and positioning an upper distal anchoring tab into a supra-annular position, and the upper distal anchoring tab providing a supra-annular downward force in the direction of the ventricle and distal anchoring tab providing a sub-annular upward force in the direction of the atrium.

[0061] In some embodiments, the method comprises the additional step of rotating the heart valve prosthesis using a steerable catheter along an axis parallel to the plane of the valve annulus.

[0062] In some embodiments, the invention provides a method for side delivery of implantable prosthetic heart valve in the body, the method comprising the steps: (i) advancing a distal end of a guide wire to a distal location, wherein the distal location is a pulmonary artery or a left ventricle of a heart, wherein the guide wire starts outside of a patient using femoral vein access or brachiocephalic vein access, and extends through an inferior vena cava or a superior vena cava to a right atrium, and extends from the right atrium through the tricupsid valve to the pulmonary artery or extends from the right atrium across the atrial septum in a transeptal access through the mitral valve and into a left ventricle; (ii) advancing a delivery catheter over the guide wire to a target location, where the target location is a right atrium of the tricuspid valve or a left atrium of the mitral valve; (iii) advancing and delivering an orthogonally compressed self-expandable prosthetic heart valve to the target location in the body, wherein a compressed configuration of the valve has a long-axis substantially parallel to a length-wise cylindrical axis of the delivery catheter, wherein the expanded configuration of the valve has a height of about 5-60mm and a diameter of about 25-80mm, wherein the valve comprises an annular support frame having a flow control component mounted within the annular support frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, a distal anchoring tab is mounted on a distal side of the annular support frame, the distal anchoring tab having a length of 10-40mm and a width of 2-10mm, wherein the guide wire is threaded through a threading aperture on or within the distal anchoring tab, at least one proximal anchoring tab is mounted on a proximal side of the annular support frame, the proximal anchoring tab having a length of 2-25mm and a width of 2-10mm, and a valve advancing tool comprising an elongated sheath wherein the guide wire is within a lumen of the sheath, wherein the outer diameter of the sheath is larger than the inner diameter of the threading aperture on the distal anchoring tab, wherein when the sheath is advanced over

the guide wire in a distal direction, and a distal end of the sheath contacts a proximal surface of the threading aperture, the valve is advanced distally through the delivery catheter by the distally-directed pulling force that the sheath imparts to the distal anchoring tab; (iv) partially releasing the valve from the delivery catheter by advancing the sheath over the guide wire, and positioning the distal anchoring tab at a desired anchoring area of the target location, wherein the desired anchoring area is selected from a right ventricular outflow tract (RVOT) of a right ventricle, and a sub-annular area below an A1-P1 antero-lateral commissure of a mitral valve, wherein positioning the distal anchoring tab holds the valve at a raised angle of at least 30 degrees to a localized annular plane relative to the horizontal axis of the valve and the delivery catheter, wherein partially releasing the valve permits blood to flow partially around the prosthetic valve and through the native leaflets, and partially through the flow control component of the prosthetic valve to provide a gradual blood flow transition from flow through native leaflets to complete flow through the prosthetic valve; (v) completing release of the entire valve from the delivery catheter by advancing the sheath over the guide wire, seating the valve in the native annulus by applying a downward force in the direction of the ventricle; and (vi) seating the at least one proximal anchoring tab at a second desired anchoring area.

[0063] In some embodiments, the method comprises the additional step of anchoring one or more tissue anchors attached to the valve into native tissue.

[0064] In some embodiments, the invention provides a method for delivering a prosthetic heart valve to an annulus of a native valve between a ventricle and an atrium of a heart, the method comprising the steps: (i) disposing in the atrium of the heart a distal portion of a delivery catheter having a lumen and a longitudinal axis, with a distal end of the delivery catheter directed towards the annulus of the native valve, the distal portion of the delivery catheter having disposed within the lumen thereof the prosthetic heart valve in a compressed configuration, wherein the compressed configuration of the prosthetic heart valve has a long-axis substantially parallel to a length-wise cylindrical axis of the delivery catheter, wherein the expanded configuration of the prosthetic heart valve has a height of about 5-60mm and a diameter of about 25-80mm, wherein the prosthetic heart valve comprises an annular support frame having a flow control component mounted within the annular support frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, wherein the annular support frame is self-expanding or balloon-expandable, a distal anchoring tab is mounted on a distal side of the annular support frame, the distal anchoring tab having a length of 10-40mm, the distal anchoring tab extending laterally from the annular support frame and is configured to be disposed on a ventricle side of the annulus of the native valve when the annular support frame is disposed within the annulus, at least one proximal anchoring tab is mounted on a proximal side of the annular support frame, the proximal anchoring tab having a length of 2-25mm, the at least one proximal anchoring tab extending laterally from the annular support frame and is configured to

be disposed on the ventricle side of the annulus of the native valve when the annular support frame is disposed within the annulus; (ii) partially releasing the prosthetic heart valve from the delivery catheter, and positioning the distal anchoring tab at a distal subannular anchoring area, wherein the distal subannular anchoring area is a right ventricular outflow tract (RVOT) of a right ventricle or is a sub-annular area below an A1-P1 antero-lateral commissure of a mitral valve; (iii) completing release of the entire prosthetic heart valve from within the lumen of the delivery catheter, and seating the prosthetic heart valve in the native annulus by applying a downward force in the direction of the ventricle; and (iv) seating the proximal anchoring tab at a proximal subannular anchoring area.

[0065] In some embodiments, the method includes wherein positioning the distal anchoring tab holds the prosthetic heart valve at a raised angle of at least 30 degrees to a localized annular plane relative to a horizontal axis of the valve, and wherein partially releasing the prosthetic heart valve permits blood to flow partially around the prosthetic heart valve and through the native leaflets, and partially through the flow control component of the prosthetic valve to provide a gradual blood flow transition from flow through native leaflets to complete flow through the prosthetic valve.

[0066] In some embodiments, the method includes wherein seating the proximal anchoring tab comprises releasing the proximal anchoring tab from a compressed pre-release configuration to an expanded post-release configuration with the proximal anchoring tab extending into the proximal subannular anchoring area.

[0067] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to limit the full scope of the claims. As used herein, the singular forms “a”, “an” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise. With respect to the use of substantially any plural and/or singular terms herein, those having skill in the art can translate from the plural to the singular and/or from the singular to the plural as is appropriate to the context and/or application. The various singular/plural permutations may be expressly set forth herein for sake of clarity.

[0068] In general, terms used herein, and especially in the appended claims (e.g., bodies of the appended claims) are generally intended as “open” terms (e.g., the term “including” should be interpreted as “including but not limited to,” the term “having” should be interpreted as “having at least,” etc.). Similarly, the terms “comprises” and/or “comprising,” when used in this specification, specify the presence of stated features, integers (or fractions thereof), steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers (or fractions thereof), steps, operations, elements, components, and/or groups thereof. As used in this document, the term “comprising” means “including, but not limited to.”

[0069] As used herein the term “and/or” or the phrase “selected from” or the phrase “selected from thr group consisting of” or the phrase “selected from one or more of” includes any and all combinations of one or more of the associated listed items. It should be understood that virtually any disjunctive word and/or phrase presenting two or more alternative terms, whether in the description, claims, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both/all terms. For example, the phrase “A or B” will be understood to include the possibilities of “A” or “B” or “A and B”, and the phrase “selected from A, B, and C” will be understood to include the possibilities of “A”, “B”, “C”, “A and B”, “B and C”, “A and C”, and “A and B and C”.

[0070] All ranges disclosed herein also encompass any and all possible subranges and combinations of subranges thereof unless expressly stated otherwise. Any listed range should be recognized as sufficiently describing and enabling the same range being broken down into at least equal subparts unless expressly stated otherwise. As will be understood by one skilled in the art, a range includes each individual member.

[0071] Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art. Nothing in this disclosure is to be construed as an admission that the embodiments described in this disclosure are not entitled to antedate such disclosure by virtue of prior invention.

[0072] The term “valve prosthesis,” “prosthetic heart valve,” and/or “prosthetic valve” can refer to a combination of a frame and a leaflet or flow control structure or component, and can encompass both complete replacement of an anatomical part (e.g., a new mechanical valve replaces a native valve), as well as medical devices that take the place of and/or assist, repair, or improve existing anatomical parts (e.g., the native valve is left in place).

[0073] The disclosed valves include a member (e.g., a frame) that can be seated within a native valve annulus and can be used as a mounting element for a leaflet structure, a flow control component, or a flexible reciprocating sleeve or sleeve-valve. It may or may not include such a leaflet structure or flow control component, depending on the embodiment. Such members can be referred to herein as an “annular support frame,” “tubular frame,” “wire frame,” “valve frame,” “flange,” “collar,” and/or any other similar terms.

[0074] The term “flow control component” can refer in a non-limiting sense to a leaflet structure having 2-, 3-, 4-leaflets of flexible biocompatible material such a treated or untreated pericardium that is sewn or joined to a annular support frame, to function as a prosthetic heart valve. Such a valve can be a heart valve, such as a tricuspid, mitral, aortic, or pulmonary, that is open to blood flowing during diastole from atrium to ventricle, and that closes from systolic ventricular pressure applied to the outer surface. Repeated

opening and closing in sequence can be described as "reciprocating." The flow control component is contemplated to include a wide variety of (bio)prosthetic artificial heart valves, including ball valves (e.g., Starr-Edwards), bileaflet valves (St. Jude), tilting disc valves (e.g., Bjork-Shiley), stented pericardium heart-valve prosthesis' (bovine, porcine, ovine) (Edwards line of bioprostheses, St. Jude prosthetic valves), as well as homograft and autograft valves. Bioprosthetic pericardial valves can include bioprosthetic aortic valves, bioprosthetic mitral valves, bioprosthetic tricuspid valves, and bioprosthetic pulmonary valves.

[0075] Any of the disclosed valve embodiments may be delivered by a transcatheter approach. The term "transcatheter" is used to define the process of accessing, controlling, and/or delivering a medical device or instrument within the lumen of a catheter that is deployed into a heart chamber (or other desired location in the body), as well as an item that has been delivered or controlled by such as process. Transcatheter access is known to include cardiac access via the lumen of the femoral artery and/or vein, via the lumen of the brachial artery and/or vein, via lumen of the carotid artery, via the lumen of the jugular vein, via the intercostal (rib) and/or sub-xiphoid space, and/or the like. Transcatheter can be synonymous with transluminal and is functionally related to the term "percutaneous" as it relates to delivery of heart valves. As used herein, the term "lumen" can refer to the inside of a cylinder or tube. The term "bore" can refer to the inner diameter of the lumen.

[0076] The mode of cardiac access can be based at least in part on "body channel" may be used to define a blood conduit or vessel within the body, the particular application of the disclosed embodiments of prosthetic valves determines the body channel at issue. An aortic valve replacement, for example, would be implanted in, or adjacent to, the aortic annulus. Likewise, a tricuspid or mitral valve replacement would be implanted at the tricuspid or mitral annulus. Certain features are particularly advantageous for one implantation site or the other. However, unless the combination is structurally impossible, or excluded by claim language, any of the valve embodiments described herein could be implanted in any body channel.

[0077] The term "expandable" as used herein may refer to a component of the heart valve capable of expanding from a first, delivery diameter to a second, implantation diameter. An expandable structure, therefore, does not mean one that might undergo slight expansion from a rise in temperature, or other such incidental cause. Conversely, "non-expandable" should not be interpreted to mean completely rigid or a dimensionally stable, as some slight expansion of conventional "non-expandable" heart valves, for example, may be observed.

[0078] Any of the disclosed valve embodiments may be delivered via traditional transcatheter delivery techniques or via orthogonal delivery techniques. For example, traditional delivery of prosthetic valves can be such that a central cylinder axis of the valve is substantially parallel to a length-wise axis of the delivery catheter. Typically, the valves are compressed in a radial direction relative to the central cylinder axis and

advanced through the lumen of the delivery catheter. The valves are deployed from the end of the delivery catheter and expanded outwardly in a radial direction from the central cylinder axis.

[0079] Side or orthogonal delivery of prosthetic valves can be such that the central cylinder axis of the valve is substantially orthogonal to the length-wise axis of the delivery catheter. With orthogonal delivery, the valves are compressed (or otherwise reduced in size) in a direction substantially parallel to the central cylinder axis and/or in a lateral direction relative to the central cylinder axis. As such, a length-wise axis of an orthogonally delivered valve is substantially parallel to the length-wise axis of the delivery catheter. In other words, an orthogonally delivered prosthetic valve is compressed and/or delivered at a roughly 90 degree angle compared to traditional processes of compressing and delivering transcatheter prosthetic valves. Moreover, prosthetic valves configured to be orthogonally delivered and the processes of delivering such valves are described in detail in the '957 PCT incorporated by reference hereinabove. As used herein the terms "side-delivered," "side-delivery," "orthogonal delivery," "orthogonally delivered," and/or so forth can be used interchangeably to such a delivery method and/or a valve delivered using such a method.

[0080] Mathematically, the term "orthogonal" refers to an intersecting angle of 90 degrees between two lines or planes. As used herein, the term "substantially orthogonal" refers to an intersecting angle of 90 degrees plus or minus a suitable tolerance. For example, "substantially orthogonal" can refer to an intersecting angle ranging from 75 to 105 degrees.

[0081] In some embodiments, components may be fabricated from a synthetic material(s) such a polyurethane or polytetrafluoroethylene (PTFE). Where a thin, durable synthetic material is contemplated (e.g., for a covering) synthetic polymer materials such expanded PTFE or polyester may optionally be used. Other suitable materials may optionally include thermoplastic polycarbonate urethane, polyether urethane, segmented polyether urethane, silicone polyether urethane, polyetheretherketone (PEEK), silicone-polycarbonate urethane, polypropylene, polyethylene, low-density polyethylene, high-density polyethylene, and ultra-high molecular weight polyethylene. Additional biocompatible polymers may optionally include elastomers, polyolefins, polyethylene-glycols, polyethersulphones, polysulphones, polyvinylpyrrolidones, polyvinylchlorides, other fluoropolymers, polyesters, polyethylene-terephthalate (PET) (e.g., Dacron), Poly-L-lactic acids (PLLA), polyglycolic acid (PGA), poly(D, L-lactide/glycolide) copolymer (PDLA), silicone polyesters, polyamides (Nylon), PTFE, elongated PTFE, expanded PTFE, polyurethanes, siloxane polymers and/or oligomers, and/or polylactones, and block co-polymers using the same.

[0082] In some embodiments, a valve frame and/or components thereof may be fabricated from biocompatible metals, metal alloys, polymer coated metals, and/or the like. Suitable biocompatible metals and/or metal alloys can include stainless steel (e.g., 316 L stainless steel), cobalt chromium (Co-Cr) alloys, nickel-titanium alloys (e.g., Nitinol®), and/or the like. Suitable polymer coatings can include polyethylene

vinyl acetate (PEVA), poly-butyl methacrylate (PBMA), translute Styrene Isoprene Butadiene (SIBS) copolymer, polylactic acid, polyester, polylactide, D-lactic polylactic acid (DLPLA), and/or the like.

[0083] Any of the valve frames and/or portions or components thereof can be internally or externally covered, partially or completely, with a biocompatible material such as pericardium. A valve frame may also be optionally externally covered, partially or completely, with a second biocompatible material such as polyester or Dacron®. Disclosed embodiments may use tissue, such as a biological tissue that is a chemically stabilized pericardial tissue of an animal, such as a cow (bovine pericardium), sheep (ovine pericardium), pig (porcine pericardium), or horse (equine pericardium). Preferably, the tissue is bovine pericardial tissue. Examples of suitable tissue include that used in the products Duraguard®, Peri-Guard®, and Vascu-Guard®, all products currently used in surgical procedures, and which are marketed as being harvested generally from cattle less than 30 months old.

[0084] The embodiments herein and the various features and advantageous details thereof are explained more fully with reference to the non-limiting embodiments that are illustrated in the accompanying drawings and detailed in the following description. Descriptions of well-known components and processing techniques are omitted so as to not unnecessarily obscure the embodiments herein. The examples used herein are intended merely to facilitate an understanding of ways in which the embodiments herein may be practiced and to further enable those of skill in the art to practice the embodiments herein. Accordingly, the examples should not be construed as limiting the scope of the embodiments herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the inventive concepts to those skilled in the art. Like numbers refer to like elements throughout.

[0085] FIGS. 1A-1C are various schematic illustrations of a transcatheter prosthetic valve 102 according to an embodiment. The transcatheter prosthetic valve 102 is configured to deployed in a desired location within a body (e.g., of a human patient) and to permit blood flow in a first direction through an inflow end of the transcatheter prosthetic valve 102 and to block blood flow in a second direction, opposite the first direction, through an outflow end of the transcatheter prosthetic valve 102. For example, the transcatheter prosthetic valve 102 can be a transcatheter prosthetic heart valve configured to be deployed within the annulus of a native tricuspid valve or native mitral valve of a human heart to supplement and/or replace the functioning of the native valve.

[0086] The transcatheter prosthetic valve 102 (also referred to herein as “prosthetic valve” or simply “valve”) is compressible and expandable in at least one direction relative to a long-axis 111 of the valve 102 (also referred to herein as “horizontal axis,” “longitudinal axis,” or “lengthwise axis”). The valve 102 is configured to compressible and expandable between an expanded configuration (FIG. 1A and 1C) for

implanting at a desired location in a body (e.g., a human heart) and a compressed configuration (FIG. 1B) for introduction into the body using a delivery catheter 172.

[0087] In some embodiments, the valve 102 can be centric, or radially symmetrical. In other embodiments, the valve 102 can be eccentric, or radially (y-axis) asymmetrical. In some eccentric embodiments, the valve 102 (or an outer frame thereof) may have a D-shape (viewed from the top) so the flat portion can be matched to the anatomy in which the valve 102 will be deployed. For example, in some instances, the valve 102 may be deployed in the tricuspid annulus and may have a complex shape determined by the anatomical structures where the valve 102 is being mounted. In the tricuspid annulus, the circumference of the tricuspid valve may be a rounded ellipse, the septal wall is known to be substantially vertical, and the tricuspid is known to enlarge in disease states along the anterior-posterior line. In other instances, the valve 102 may be deployed in the mitral annulus (e.g., near the anterior leaflet) and may have a complex shape determined by the anatomical structures where the valve 102 is being mounted. For example, in the mitral annulus, the circumference of the mitral valve may be a rounded ellipse, the septal wall is known to be substantially vertical, and the mitral is known to enlarge in disease states.

[0088] As shown, the valve 102 generally includes an annular support frame 110 and a flow control component 150. In addition, the valve 102 and/or at least the annular support frame 110 of the valve 102 includes one or more anchoring element. For example, in the embodiment shown in FIGS. 1A-1C, the annular support frame 110 includes at least a distal anchoring element 132 and a proximal anchoring element 134. In some implementations, the distal anchoring element 132 and the proximal anchoring element 134 can be lower anchoring elements and the valve 102 and/or the annular support frame 110 can include a distal upper anchoring element and a proximal upper anchoring element (not shown). In some implementations, the valve 102 and/or aspects or portions thereof can be similar to and/or substantially the same as the valves (and/or the corresponding aspects or portions thereof) described in detail in the ‘957 PCT incorporated by reference hereinabove. Accordingly, certain aspects, portions, and/or details of the valve 102 may not be described in further detail herein.

[0089] The annular support frame 110 (also referred to herein as “tubular frame,” “valve frame,” “wire frame,” or “frame”) can have or can define an aperture 114 that extends along a central axis 113. The aperture 114 (e.g., a central axial lumen) can be sized and configured to receive the flow control component 150 across a diameter of the aperture 114. The frame 110 may have an outer circumferential surface for engaging native annular tissue that may be tensioned against an inner aspect of the native annulus to provide structural patency to a weakened native annular ring.

[0090] The frame 110 includes a cuff or collar 120 and a tubular or transannular section 112. The cuff or collar 120 (referred to herein as "collar") can be attached to and/or can form an upper edge of the frame 110. When the valve 102 is deployed within a human heart, the collar 120 can be an atrial collar. The collar 120 can be shaped to conform to the native deployment location. In a mitral replacement, for example, the collar 120 will be configured with varying portions to conform to the native valve. In one embodiment, the collar 120 will have a distal and proximal upper collar portion. The distal collar portion can be larger than the proximal upper collar portion to account for annular geometries, supra-annular geometries, and/or subannular geometries.

[0091] The frame 110 may optionally have a separate atrial collar attached to the upper (atrial) edge of the frame 110, for deploying on the atrial floor that is used to direct blood from the atrium into the flow control component 150 and to seal against blood leakage (perivalvular leakage) around the frame 110. The frame 110 may also optionally have a separate ventricular collar attached to the lower (ventricular) edge of the frame 110, for deploying in the ventricle immediately below the native annulus that is used to prevent regurgitant leakage during systole, to prevent dislodging of the valve 102 during systole, to sandwich or compress the native annulus or adjacent tissue against the atrial collar or collar 120, and/or optionally to attach to and support the flow control component 150. Some embodiments may have both an atrial collar and a ventricular collar, whereas other embodiments either include a single atrial collar, a single ventricular collar, or have no additional collar structure.

[0092] The frame 110 can be a ring, or cylindrical or conical tube, but may also have a side profile of a flat-cone shape, an inverted flat-cone shape (narrower at top, wider at bottom), a concave cylinder (walls bent in), a convex cylinder (walls bulging out), an angular hourglass, a curved, graduated hourglass, a ring or cylinder having a flared top, flared bottom, or both. The frame 110 may have a height in the range of about 5-60 mm, may have an outer diameter dimension, R, in the range of about 20-80 mm, and may have an inner diameter dimension in the range of about 21-79 mm, accounting for the thickness of the frame 110 (e.g., a wire material forming the frame 110).

[0093] The frame 110 is compressible for delivery and when released it is configured to return to its original (uncompressed) shape. The frame 110 may be compressed for transcatheter delivery and may be expandable using a transcatheter expansion balloon. In other implementations, the frame 110 can include and/or can be formed of a shape-memory element allowing the frame 110 to be self-expanding. In some instances, suitable shape-memory materials can include metals and/or plastics that are durable and biocompatible. For example, the frame 110 can be made from super elastic metal wire, such as a Nitinol wire or other similarly functioning material. The frame 110 may be constructed as a braid, wire, or laser cut wire frame. The frame 110 may also have and/or form additional functional elements (e.g., loops, anchors, etc.) for attaching accessory components such as biocompatible covers, tissue anchors, releasable

deployment and retrieval control guides, knobs, attachments, rigging, and so forth. In some implementations, the frame 110 (or aspects and/or portions thereof) can be structurally and/or functionally similar to the frames (or corresponding aspects and/or portions thereof) described in detail in the '957 PCT.

[0094] As described above, the frame 110 and/or the valve 102 can include at least a distal anchoring element 132 and a proximal anchoring element 134. The distal and proximal anchoring elements 132 and 134 can be, for example, lower anchoring elements (e.g., coupled to and/or included in a lower portion of the frame 110). In some embodiments, the frame 110 and/or the valve 102 can also optionally include one or more of a distal upper anchoring element and a proximal upper anchoring element. The anchoring elements of the valve 102 can be configured to engage a desired portion of the annular tissue to mount the frame 110 to the annulus of the native valve in which the valve 102 is deployed, as described in further detail herein. The anchoring elements of the valve 102 and/or the frame 110 can be any suitable shape, size, and/or configuration such as any of those described in detail in the '957 PCT. Moreover, certain aspects, features, and/or configurations of at least the distal and proximal anchoring elements 132 and 134 are described below reference to specific embodiments.

[0095] As shown in FIGS. 1A and 1B, the distal anchoring element 132 can include a guidewire collar 145 configured to selectively engage and/or receive a portion of a guidewire 185 or a portion of a guidewire assembly and/or can have any suitable configuration as described below with respect to specific embodiments. For example, in some embodiments, a portion of the guidewire 185 can extend through an aperture (not shown) of the guidewire collar 145, thereby allowing the valve 102 to be advanced over or along the guidewire 185. The guidewire collar 145 can be any suitable element that selectively allows the guidewire 185 to be advanced therethrough while blocking or preventing other elements and/or components such as a pusher or the like. In certain embodiments, the distal lower anchoring element 132 can form and/or can include a feature that forms the guidewire collar 145. In other implementations, the guidewire collar 145 can be attached to any suitable portion of the frame 110, to the proximal anchoring element 134, and/or to any other anchoring elements and/or features of the frame 110 (e.g., a distal or proximal upper anchoring element).

[0096] The proximal anchoring element 134 can be any suitable shape, size, and/or configuration such as any of those described herein with respect to specific embodiments. The proximal anchoring element 134 can be, for example, a proximal lower anchoring element and can be configured to engage subannular tissue of the ventricle to aid in the securement of the valve 102 in the annulus. In some implementations, the proximal anchoring element 134 can be configured to transition between a first configuration in which the proximal anchoring element 134 is maintained in a compressed, undeployed, and/or restrained state, to a second configuration in which the proximal anchoring element 134 is expanded, extended, deployed, and/or unrestrained. More specifically, the proximal anchoring element 134 when in

the first configuration can be maintained in a first position that is in contact with, adjacent to, and/or otherwise near the transannular section 112 of the valve frame 110, and when in the second configuration, can be released to a second position that extends away from the transannular section 112 of the frame 110. Said another way, the second position proximal anchoring element 134 can be further from the transannular section 112 than the first position of the proximal anchoring element 134.

[0097] In some embodiments, the valve 102 and/or the frame 110 can include a feature, member, mechanism, etc. configured to at least temporarily retain the proximal anchoring element 134 in the first configuration. For example, as shown in FIGS. 1A and 1B, the valve 102 and/or the frame 110 can include a tensile member 135 configured to selectively engage the proximal anchoring element 134 to temporarily maintain the proximal anchoring element 134 in the first configuration. The tensile member 135 can be any suitable shape, size, and/or configuration. For example, the tensile member 135 can be an anchor, loop, tab, latch, hook, tether, elastomeric band, threaded coupler, ball and cup mechanism, and/or any other suitable removable attachment. The tensile member 135 can removably couple to a portion of the proximal anchoring element 134 and can exert a force (e.g., a tensile or compression force) operable in maintaining the proximal anchoring element 134 in the first configuration. The tensile member 135 can be reconfigurable allowing the tensile member 135 to be disengaged from the proximal anchoring element 134, which in turn, can allow the proximal anchoring element 134 to transition from its first configuration to its second configuration, as described in further detail herein with reference to specific embodiments.

[0098] The valve 102 can be delivered to the desired location in the body via a procedure generally including advancing a delivery catheter 172 over the guide wire 185 to place a distal end of the delivery catheter 172 at or near the desired location. The guidewire 185, therefore, may be disposed within a lumen 174 of the delivery catheter 172. The valve 102 can be disposed within the lumen 174 of the delivery catheter 172 (e.g., in the compressed configuration) such that the guidewire collar 145 is engaged with and/or receives a portion of the guidewire 185, thereby allowing the valve 102 to be advanced over and/or along the guidewire 185 through the delivery catheter 172.

[0099] The flow control component 150 can refer in a non-limiting sense to a device for controlling fluid flow therethrough. In some embodiments, the flow control component 150 can be a leaflet structure having 2-leaflets, 3-leaflets, 4-leaflets, or more, made of flexible biocompatible material such a treated or untreated pericardium. The leaflets can be sewn or joined to a support structure and/or can be sewn or joined to the frame 110. The flow control component 150 can be mounted within the frame 110 and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve. For example, the flow control component 150 can be configured such that the valve 102 functions, for example, as a heart valve, such as a tricuspid valve, mitral valve, aortic valve, or pulmonary valve, that can open to blood flowing

during diastole from atrium to ventricle, and that can close from systolic ventricular pressure applied to the outer surface. Repeated opening and closing in sequence can be described as "reciprocating."

[0100] The flow control component 150 is contemplated to include a wide variety of (bio)prosthetic artificial valves, including ball valves (e.g., Starr-Edwards), bileaflet valves (St. Jude), tilting disc valves (e.g., Bjork-Shiley), stented pericardium heart-valve prosthesis' (bovine, porcine, ovine) (Edwards line of bioprostheses, St. Jude prosthetic valves), as well as homograft and autograft valves. Bioprosthetic pericardial valves can include bioprosthetic aortic valves, bioprosthetic mitral valves, bioprosthetic tricuspid valves, and bioprosthetic pulmonary valves. In some implementations, a suitable commercially available valve (flow control component 150) can be received or accepted by and/or otherwise mounted in the frame 110. Commercially available valves (flow control components 150) may include, for example, a Sapien, Sapien 3, or Sapien XT from Edwards Lifesciences, an Inspiris Resilia aortic valve from Edwards Lifesciences, a Masters HP 15 mm valve from Abbott, a Lotus Edge valve from Boston Scientific, a Crown PRT leaflet structure from Livanova/Sorin, a valve from the Carbomedics family of valves from Sorin, or other flow control component(s), or a flexible reciprocating sleeve or sleeve-valve. In some implementations, the flow control component 150 can be similar to or substantially the same as any of the flow control components described in detail in the '957 PCT.

[0101] The valve 102 is compressible and expandable between the expanded configuration and the compressed configuration. The valve 102 is compressed during delivery of the valve 102 and is configured to expand once released from the deliver catheter 172. The valve 102 is in the expanded configuration when deployed or implanted (or ready to be deployed or implanted) at the desired location in the body. When in the expanded configuration shown in FIGS. 1A and 1B, the valve 102 has an extent in any direction along or lateral to the central axis 113 that is larger than a diameter of the lumen 174 of the delivery catheter 172 used to deliver the valve 102. Said another way, the valve 102 has an extent in any direction perpendicular to the longitudinal axis 111 of the valve 102 that is larger than the diameter of the lumen 174 of the delivery catheter 172.

[0102] In some embodiments, the valve 102 can have an expanded height (y-axis) of 5-60 mm. In some embodiments, the valve 102 can have an expanded diameter length and width of about 20-80 mm and more particularly, 40-80 mm. In certain embodiments, the valve 102 can have a length and/or width including, for example, 20 mm, 25 mm, 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, 55 mm, 60 mm, 65 mm, 70 mm, 75 mm, and 80 mm, and/or any size or fraction of a size therebetween.

[0103] The valve 102 is in the compressed configuration when being delivered to the desired location in the body via the delivery catheter 172. When in the compressed configuration, the valve 102 can have a size that allows the valve 102 to be disposed within the lumen 174 of the delivery catheter 172. In some

implementations, the valve 102 is configured for transcatheter orthogonal delivery to the desired location in the body (e.g., the annulus of a native valve), in which the valve 102 is compressed in a lateral direction relative to the dimensions of the valve 102 in the expanded configuration (e.g., along the central axis 113) and can be elongated in a longitudinal direction (e.g., along the longitudinal axis 111). In other implementations, the valve 102 is configured to traditional transcatheter delivery to the desired location in the body, in which the central axis 113 is coaxial with the longitudinal axis 111. Aspects, features, and/or processes of traditional transcatheter delivery are not described in further detail herein.

[0104] During delivery, the longitudinal axis 111 of the valve 102 is substantially parallel to a longitudinal axis 175 of the delivery catheter 172. In orthogonal delivery, the longitudinal axis 111 is oriented at an intersecting angle between 45 and 135 degrees relative to the central axis 113 (e.g., perpendicular or at about 90 degrees). In some embodiments, the horizontal x-axis (e.g., the longitudinal axis 111) of the valve 102 is orthogonal or substantially orthogonal to (e.g., 75-105 degrees), or substantially oblique to (45-135 degrees) the central vertical y-axis (e.g., the central axis 113) when in an expanded configuration. In some embodiments, the horizontal x-axis (e.g., the longitudinal axis 111) of the valve 102 in the compressed configuration is substantially parallel to a lengthwise cylindrical axis 175 of the delivery catheter 172.

[0105] As used herein, the terms “intersecting angle” and/or “orthogonal angle” can refer to both (i) the relationship between the lengthwise cylindrical axis (e.g., the longitudinal axis 175) of the delivery catheter 174 and the long-axis 111 of the compressed valve 102, where the long-axis 111 is perpendicular to the central axis 113 of traditional valves, and (ii) the relationship between the long-axis 111 of the compressed or expanded valve 102 and the axis defined by the blood flow through the prosthetic valve 102 where the blood is flowing (e.g., from one part of the body or chamber of the heart to another downstream part of the body or chamber of the heart, such as from an atrium to a ventricle through a native annulus).

[0106] The valve 102 can have a first height or size along the central axis 113 when in the expanded configuration and can have a second height or size, less than the first height or size, along the central axis 113 when in the compressed configuration. The second height or size of the valve 102 when in the compressed configuration is smaller than the diameter of the lumen 174 of the delivery catheter 175, allowing the valve 102 to be delivered therethrough. The valve 102 can also be compressed in additional directions. For example, the valve 102 can be compressed along a lateral axis (not shown) that is perpendicular to both the longitudinal axis 111 and the central axis 113. The valve 102, when in the expanded configuration, has an extent in any direction along or parallel to the lateral axis that is larger than a diameter of the lumen 174 of the delivery catheter 172. In other words, the valve 102 can have a first width or size along the lateral axis when in the expanded configuration and can have a second width or size, less than the first width or size, along the lateral axis when in the compressed configuration, as described in detail in the ‘957 PCT.

[0107] The valve 102 may be compressed (as described above) and delivered in a sideways or orthogonal manner such that the longitudinal axis 111 is substantially parallel to a delivery axis (e.g., the lengthwise axis 175 of the delivery catheter 172). The shape of the expanded valve 102 can be that of a large diameter shortened cylinder with an extended collar (e.g., the collar 120). The valve 120 can be compressed, in some embodiments, where the central axis 113 of the valve 102 is roughly perpendicular to (orthogonal to) the lengthwise axis 175 of the delivery catheter 172. In some embodiments, the valve 102 can be compressed vertically (e.g., along the central axis 113) and/or can be compressed laterally (e.g., along the lateral axis, not shown). In some embodiments, the valve 102 can have a compressed height (y-axis) and/or width (z-axis) of about 6-15 mm, about 8-12 mm, or more particularly, 9-10 mm. In some embodiments, the length of the valve 102 (x-axis) does not require compression since it can extend along the length of the lumen 174 of the delivery catheter 172. In some embodiments, the length of the valve 102 (x-axis) is increased in response to compression of the height (y-axis) and/or width (z-axis). The valve 102 can be compressed by compressing, rolling, folding, and/or any other suitable manner, or combinations thereof, as described in detail in the '957 PCT.

[0108] In some implementations, a delivery system can include one or more features or components configured to deliver the valve 102 to a desired location in the body (e.g., the annulus of a native valve) – either via traditional delivery techniques or via orthogonal delivery techniques. For example, a delivery system 170 suitable for at least orthogonal delivery is shown in FIG. 1B. The delivery system 170 includes the delivery catheter 172, a secondary catheter 180, and the guidewire 185. The delivery system 170 can be configured to orthogonally deliver the compressed valve 102 and/or portions of the valve 102 (e.g., the compressed frame 110 or the compressed flow control component 150) to a desired location in the body such as, for example, the annulus of a native tricuspid valve and/or the annulus of a native mitral valve of the human heart. For example, the delivery catheter 172 can be 12-34 Fr, with any suitable corresponding internal lumen diameter and/or an internal lumen diameter sufficient to receive the prosthetic valve 102 in the compressed configuration. In some implementations, the delivery system 170 and/or aspects or portions thereof can be similar to and/or substantially the same as those described in detail in the '957 PCT.

[0109] The guidewire 185 extends or threads through the secondary catheter 180, the guidewire collar 145 of or connected to the distal anchoring element 132, and the delivery catheter 172. The guidewire 185 can be, for example, a sheathed guidewire at least partially sheathed by the secondary catheter 180. The guidewire 185 is configured to be advanced through the anatomy of the body and placed in a desired position relative to native tissue (e.g., a native valve). In some instances, the guidewire 185 can be advanced to provide a wire path (e.g., for the delivery catheter 172, the valve 102, the secondary catheter 180, etc.) to the outflow tract of the ventricle (e.g., the RVOT or the LVOT depending on the native valve). The guidewire 185 extends through the guidewire collar 145 of the valve 102 to provide a wire path along

which the valve 102 is advanced (e.g., through the delivery catheter 172 and/or at least a portion of the atrium or ventricle of the heart).

[0110] As shown in FIG. 1B, at least a portion of the secondary catheter 180 can be disposed in the lumen 174 of the delivery catheter 172. The secondary catheter 180 can be disposed over and/or advanced along the guidewire 185. The secondary catheter 180 can be a sheath, tube, annular rod or wire, and/or the like. In some embodiments, the secondary catheter 180 is a hypotube sheath disposed about a portion of the guidewire 185 (e.g., the secondary catheter 180 and the guidewire 185 collectively form a sheathed guidewire or sheathed guidewire assembly). The secondary catheter 180 can have a relatively small size allowing the secondary catheter 180 to be advanced through the delivery catheter 172 and/or at least partially disposed in or otherwise engaged with the guidewire collar 145. The secondary catheter 180 has a lumen with an internal diameter that is greater than the guidewire 185, allowing the guidewire 185 to pass therethrough.

[0111] The pusher 181 is also disposed within the secondary catheter 180 and is configured to push on a portion of the valve 102 to advance the valve 102 through and/or out of the delivery catheter 172. In some implementations, the pusher 181 is configured to push against a portion of the guidewire collar 145 and/or the distal anchoring element 132. For example, the guidewire collar 145 can allow the guidewire 185 to be advanced through the guidewire collar 145 and can block and/or substantially prevent the pusher 181 from being advanced beyond the guidewire collar 145 (or at least a portion thereof). The guidewire collar 145 can be and/or can include a feature that defines an aperture or lumen that is sufficiently large to allow the guidewire 185 to pass through but is not sufficiently large to allow other components to be advanced therethrough (e.g., the pusher 181). As such, the secondary catheter 180 and/or the pusher 181 can be stopped against the guidewire collar 145 by the larger circumference of the secondary catheter 180 and/or pusher 181 relative to the aperture or lumen of the guidewire collar 145. Such an arrangement allows the secondary catheter 180 and/or pusher 181 to push on the guidewire collar 145 and thus, the distal anchoring element 132 to which it is attached. When the guidewire collar 145 is attached to the distal anchoring element 132, the pushing on the guidewire collar 145 is operative to pull the valve 102 through and/or out of the delivery catheter 172.

[0112] While the pusher 181 is shown disposed in the secondary catheter 180, in some embodiments, the secondary catheter 180 can be used as the pusher 181. In such embodiments, the delivery system 170 need not include a separate pusher 181. Moreover, while the pusher 181 is described above as engaging, for example, the distal anchoring element 132, in other implementations, the pusher 181 can be configured to engage any suitable portion of the valve 102 such as the proximal anchoring element 134, and/or the like. Although not shown in FIGS. 1A-1C, the guidewire collar 145, the secondary catheter 180, and/or the pusher 181 can include a release mechanism or feature configured to release the guidewire 185,

the secondary catheter 180, and/or the pusher 181 from the guidewire collar 145, for example, after deployment of the valve 102.

[0113] As shown in FIG. 1C, the valve 102 can be delivered, for example, to an atrium of the human heart and disposed within an annulus of a native valve such as, for example, the pulmonary valve (PV), the mitral valve (MV), the aortic valve (AV), and/or the tricuspid valve (TV). As described above, the valve 102 can be in the compressed configuration and delivered to the annulus via the delivery system 170 – either via traditional delivery techniques or via orthogonal delivery techniques – and can be released from the delivery system 170 and allowed to expand to the expanded configuration. For example, the valve 102 can be delivered to the atrium of the human heart and released from the delivery catheter 172 via any of the delivery systems, devices, and/or methods described in detail in the '957 PCT.

[0114] The deployment of the valve 102 can include placing the distal anchoring element 132 (e.g., the distal lower anchoring element 132) in the ventricle (RV, LV) below the annulus while the remaining portions of the valve 102 are in the atrium (RA, LA). In some instances, the distal anchoring element 132 can be positioned in an outflow tract of the ventricle (e.g., the distal anchoring element 132 can be advanced over and/or along the guidewire 185). For example, in some implementations, the valve 102 can be delivered to the annulus of the native tricuspid valve (TV) and at least a portion of the distal anchoring element 132 can be positioned in a right ventricular outflow tract (RVOT). In other implementations, the valve 102 can be delivered to the annulus of the native mitral valve (MV) and at least a portion of the distal anchoring element 132 can be positioned in a left ventricular outflow tract (LVOT). In some instances, the distal anchoring element 134 can engage subannular tissue to at least partially secure the distal end portion of the valve 102 to the native annular tissue while the remainder of the valve 102 is maintained in a supra-annular position within the atrium side of the annulus.

[0115] In some implementations, the prosthetic valve 102 can be temporarily maintained in a partially deployed state. For example, the valve 102 can be partially inserted into the annulus and held at an angle relative to the annulus to allow blood to flow from the atrium to the ventricle partially through the native valve annulus around the valve 102, and partially through the valve 102, which can allow for assessment of the valve function.

[0116] The valve 102 can be placed or seated in the annulus (PVA, MVA, AVA, and/or TVA) of the native valve (PV, MV, AV, and/or TV) such that the transannular section 112 of the valve frame 110 extends through the annulus and into the ventricle while the collar remains in the atrium in a supra-annular position. For example, in some embodiments, the secondary catheter 180 and/or the pusher 181 can be used to push at least the proximal end portion of the valve 102 into the annulus. In some implementations, the proximal anchoring element 134 can be maintained in its first configuration as the valve 102 is seated in

the annulus. For example, as described above, the proximal anchoring element 134 can be in contact with, adjacent to, and/or near the transannular section 112 of the frame 110 while in the first configuration, which in turn, can limit an overall circumference of a lower portion of the frame 110, thereby allowing the transannular section 112 of the frame 110 to be inserted through the annulus.

[0117] Once seated, the proximal anchoring element 134 can be transitioned from its first configuration to its second configuration. For example, in some implementations, a tensile force can be exerted on, along, and/or through the tensile member 135 that can be operable in maintaining the proximal anchoring element 134 in its first configuration. The tensile member 135 can be manipulated to disengage from the proximal anchoring element 135 thereby allowing the proximal anchoring element 134 to transition to its second configuration. In some implementations, the secondary catheter 180, the pusher 181, and/or any suitable member or feature of the delivery system 170 can be configured to disengage the tensile member 135 from the proximal anchoring element 134. In some implementations, a portion of the tensile member 135 can be actuated to disengage from the proximal anchoring element 134. Accordingly, once the valve 102 is seated in the annulus, the proximal anchoring element 134 can be placed in its second configuration in which the proximal anchoring element 134 contacts, engages, and/or is otherwise disposed adjacent to subannular tissue. Moreover, in some implementations, the distal anchoring element 132, the proximal anchoring element 134, and the collar 120 (or any other upper anchoring elements) can exert a compressive force on the annular tissue separating the atrium from the ventricle, thereby placing the valve 102 in a fully deployed state. While not shown in FIGS. 1A-1C, in some implementations, the valve 102 and/or the delivery system 170 can include one or more tissue anchors that can be used to anchor one or more portions of the valve 102 to the annular tissue, as described in detail in the ‘957 PCT.

[0118] Provided below is a discussion of certain aspects or embodiments of transcatheter prosthetic valves (e.g., prosthetic heart valves). The transcatheter prosthetic valves (or aspects or portions thereof) described below with respect to specific embodiments can be substantially similar in at least form and/or function to the valve 102 and/or corresponding aspects or portions of the valve 102 described above with reference to FIGS. 1A-1C. Similarly, the valves described below (or aspects or portions thereof) can be similar in at least form and/or function to the valves described in detail in the ‘957 PCT. Thus, certain aspects and/or portions of the specific embodiments may not described in further detail herein.

[0119] FIG. 2 is an illustration of a side perspective view of a side delivered transcatheter prosthetic heart valve 202 according to an embodiment. The valve 202 and/or aspects or portions thereof can be substantially similar to the valve 102 shown in FIGS. 1A-1C. The valve 202 has a wire frame 210 that includes a distal anchoring element 232 and a proximal anchoring element 234. In the embodiment shown in FIG. 2, each of the distal anchoring element 232 and the proximal anchoring element 234 is formed of or from a superelastic wire loop (e.g., formed by Nitinol wire or the like).

[0120] FIG. 3 is an illustration of a side perspective view of a side delivered transcatheter prosthetic heart valve 302 according to an embodiment. The valve 302 has a laser cut frame 310 with a laser cut distal anchoring element 332 and a laser cut proximal anchoring element 334.

[0121] FIG. 4 is an illustration of a side perspective view of a side delivered transcatheter prosthetic heart valve 402 according to an embodiment. The valve 402 has a laser cut frame 410 with a laser cut distal anchoring element 432 and a superelastic wire loop proximal anchoring element 434.

[0122] FIG. 5 is an illustration of a side perspective view of a side delivered transcatheter prosthetic heart valve 502 according to an embodiment. The valve 502 has a laser cut frame 510 with a superelastic wire loop distal anchoring element 532 and a laser cut proximal anchoring element 534.

[0123] FIG. 6 is an illustration of a side perspective view of a side delivered transcatheter prosthetic heart valve 602 according to an embodiment. The valve 602 has a laser cut frame 610 with a superelastic wire loop distal anchoring element 632 and a superelastic wire loop proximal anchoring element 634.

[0124] FIGS. 7A and 7B illustrate side perspective views of a side delivered transcatheter prosthetic heart valve 702 according to an embodiment. The valve 702 has a laser cut frame 710 with a superelastic wire loop distal anchoring element 732 and a superelastic wire loop proximal anchoring element 734. The valve 702 shown in FIG. 7A has a frame 710 and a flow control component 750. The frame 710 has a transannular section 712 and an atrial collar 720 disposed around and/or coupled to a top edge of the transannular section 712. The flow control component 750 is disposed within an aperture 714 of the frame 710. The flow control component 750 can have any number of prosthetic leaflets 753 (e.g., two, three, four, or more) mounted within the flow control component 750. The leaflets 753 can define a channel for blood flow in a single direction from an inflow side of the valve 702 to an outflow side of the valve 702.

[0125] FIG. 7A shows a tensile member 735 of the frame 710 and/or valve 702 in a first or initial state in which the tensile member 735 engages the proximal anchoring element 734 to maintain the proximal anchoring element 734 in its first configuration (e.g., a pre-release configuration). The proximal anchoring element 734 can be in its first configuration before and during deployment of the valve 702 and/or seating of the valve 702 in an annulus). FIG. 7B shows the tensile member 735 in a second state in which the tensile member 735 is disengaged from the proximal anchoring element 734. The proximal anchoring element 734 is allowed to transition from its first configuration to its second configuration, as indicated by the arrow in FIG. 7B. The proximal anchoring element 734 can be transitioned to the second configuration after the valve 702 is seated in the annulus.

[0126] FIG. 8 is an illustration of a side view of human heart anatomy, with an inset showing the geometric relationship between the inferior vena cava (IVC), superior vena cava (SVC), the right atrium

(RA), the left atrium (LA), the right ventricle (RV), the left ventricle (LV), and the pulmonary artery (PA). A three leaflet tricuspid valve – having anterior, posterior, and septal cusps – is shown between the RA and the RV. A two leaflet mitral valve is shown between the LA and the LV.

[0127] FIGS. 9A and 9B illustrate an anterior side perspective view and a posterior side perspective view, respectively, of a side delivered valve 802 seated with the native tricuspid annulus. A collar 820 of the valve 802 is laying atrially above the tricuspid annulus and leaflets, a transannular section 812 of the valve 802 extending into and through the annulus to provide corrective hemodynamic flow from the flow control component 850, a distal anchoring element 832 at least partially disposed in a right ventricular outflow tract (e.g., the pulmonary artery (PA)), and a proximal anchoring element 134 in a released configuration engaging subannular tissue.

[0128] FIGS. 10A and 10B illustrate side perspective views of a side delivered transcatheter prosthetic heart valve 902 according to an embodiment. FIG. 10A is a proximal side perspective view of the valve 902 and shows a proximal anchoring element 934 extending away from a wire frame 910. FIG. 10B is a distal side perspective view of the valve 902 and shows a distal anchoring element 932 extending away from the wire frame 910.

[0129] FIGS. 11A and 11B illustrate a top anterior view and a top septal view, respectively, of a side delivered transcatheter prosthetic heart valve 1002 according to an embodiment. The valve 1002 can have a wire frame that includes a wire loop distal anchoring element 1032 and a wire loop proximal anchoring element 1034 attached around the circumference of the frame, beneath a collar 1020 of the valve 1002.

[0130] FIG. 12 is an illustration of a side perspective view of a side delivered transcatheter prosthetic heart valve 1102 according to an embodiment. The valve 1102 has a distal anchoring element 1132 and a proximal anchoring element 1134. The distal anchoring element 1132 has a guidewire collar 1145 coupled thereto. The guidewire collar 1145 can be a threaded tip element or the like that can receive a portion of a guidewire 1185. The valve 1102 can be delivered to a native annulus via a delivery catheter 1172. More particularly, the guidewire 1185 can be advanced into a human heart and through an annulus of a native valve. The delivery catheter 1172 can be advanced over the guidewire 1172 to place the distal end of the delivery catheter 1172 on an atrial side of the annulus. The guidewire collar 1145 can be threaded or otherwise positioned over the guidewire 1145. A pusher 1110 can be threaded or otherwise positioned over the guidewire 1145 proximal to the guidewire collar 1145. The guidewire collar 1145 can allow the guidewire 1180 to pass therethrough but can prevent the pusher 1180 from passing through the guidewire collar 1145, thereby providing a mechanism for pushing on the distal anchoring element 1132. The valve 1102 can be advanced through the delivery catheter 1172 with the guidewire collar 1145 being distal to the remaining portion of the valve 1102. Thus, pushing on the guidewire collar 1145 (or distal anchoring

element 1132) pulls the valve 1102 through and out of the delivery catheter 1172 from the distal side to avoid damaging compressive pushing forces that may otherwise attend a process of delivering a valve.

[0131] FIGS. 13A-13D illustrate septal side views of a side delivered transcatheter prosthetic heart valve 1202 showing a process of delivering the valve 1202 according to an embodiment. FIG. 13A shows the valve 1202 in a compressed configuration and disposed within a delivery catheter 1272. In some instances, the process can include extending at least a distal end of the delivery catheter 1272 into an atrium of the human heart via the inferior vena cava (IVC). A pusher 1280 or other member can be used to advance the compressed valve 1202 through the delivery catheter 1272 toward the distal end. FIG. 13B shows the valve 1202 partially ejected from the delivery catheter 1272. A distal anchoring element 1232 extends through the annulus and into a ventricular outflow tract such as the pulmonary artery (PA). FIG. 13C shows the valve 1202 ejected from the delivery catheter 1272 and in an uncompressed or expanded configuration. In some implementations, the pusher 1280 can be used to exert a force on a proximal side of the valve 1202 to seat the valve 1202 in the native annulus. A proximal anchoring element 1234 of the valve 1202 can be in a first, compressed, and/or pre-released state as the valve 1202 is seated in the annulus. FIG. 13D shows the valve 1202 seated in the annulus and the proximal anchoring element 1234 in a second, uncompressed, and/or post-released state. For example, a tensile member (not shown) can be manipulated after the valve 1202 is seated in the annulus to allow the proximal anchoring element 1234 to transition to its second state.

[0132] FIGS. 14A-14D illustrate anterior side views of a side delivered transcatheter prosthetic heart valve 1302 showing a process of delivering the valve 1302 according to an embodiment. The valve 1302 can have a wire frame that includes a wire loop distal anchoring element 1332 and a wire loop proximal anchoring element 1334. FIG. 14A shows a portion of a delivery catheter 1372 extending through the IVC having disposed within a lumen thereof the valve 1302 in a compressed configuration. A pusher 1380 or other member can be used to advance the compressed valve 1302 through the delivery catheter 1372. FIG. 14B shows the valve 1302 partially ejected from the delivery catheter 1372 and the distal anchoring element 1332 extending through the annulus and into a ventricular outflow tract such as the PA. FIG. 14C shows the expanded valve 1302 ejected from the delivery catheter 1372 and seated in the annulus of the native valve, while the proximal anchoring element 1334 of the valve 1302 is in a first, compressed, and/or pre-released state. FIG. 14D shows the valve 1302 seated in the annulus and the proximal anchoring element 1334 in a second, uncompressed, and/or post-released state.

[0133] FIGS. 15A-15D illustrate septal side views of a side delivered transcatheter prosthetic heart valve 1402 showing a process of delivering the valve 1402 according to an embodiment. The valve 1402 has a laser cut frame with a laser cut distal anchoring element 1432 and a laser cut proximal anchoring element 1434. FIG. 15A shows a portion of a delivery catheter 1472 extending through the IVC having

disposed within a lumen thereof the valve 1402 in a compressed configuration. A pusher 1480 or other member can be used to advance the compressed valve 1402 through the delivery catheter 1472. FIG. 15B shows the valve 1402 partially ejected from the delivery catheter 1472 and the distal anchoring element 1432 extending through the annulus and into a ventricular outflow tract such as the PA. FIG. 15C shows the expanded valve 1402 ejected from the delivery catheter 1472 and seated in the annulus of the native valve, while the proximal anchoring element 1434 of the valve 1402 is in a first, compressed, and/or pre-released state. FIG. 15D shows the valve 1402 seated in the annulus and the proximal anchoring element 1434 in a second, uncompressed, and/or post-released state. For example, the proximal anchoring element 1434 can be unhinged, unfolded, uncompressed, and/or otherwise reconfigured to the second configuration.

[0134] FIGS. 16A-16E illustrate septal side views of a side delivered transcatheter prosthetic heart valve 1502 showing a process of delivering the valve 1502 according to an embodiment. FIG. 16A shows a guidewire 1585 advanced through the IVC, the native annulus, and into a ventricular outflow tract such as the PA. FIG. 16B shows a delivery catheter 1572 being advanced over the guidewire 1585 and through the IVC. In addition, a distal anchoring element 1532 of the valve 1502 can receive and/or can allow the guidewire 1585 to extend through a portion thereof. A pusher 1580 can be used to push on the distal anchoring element 1532 to advance the distal anchoring element 1532 along the guidewire 1585 and through the delivery catheter 1572. FIG. 16C shows the valve 1302 ejected from the delivery catheter 1372 and partially expanded. The distal anchoring element 1332 extends through the annulus and into the PA. FIG. 16D shows the at least partially expanded valve 1502 being temporarily held at an angle relative to the native annulus to allow blood to flow through the native annulus around the valve 1502 as well as through the flow control component (not shown) of the valve 1502. FIG. 16E shows the valve 1502 seated in the annulus. A proximal anchoring element 1534 can be in a first, compressed, and/or pre-released state as the valve 1502 is seated in the annulus and can be allowed to transition to a second, uncompressed, and/or post-released state after the valve 1502 is seated.

[0135] FIGS. 17A-17E illustrate side views of a side delivered transcatheter prosthetic heart valve 1602 showing a process of delivering the valve 1602 to an annulus of a native mitral valve according to an embodiment. FIG. 17A shows a delivery catheter 1672 having the compressed valve 1602 disposed therein. A distal anchoring element 1632 of the valve 1602 is threaded and/or otherwise disposed on a guidewire 1685 that can extend, for example, through the femoral vein and the IVC, transeptally from the right atrium to the left atrium, through the annulus of the mitral valve, and into the left ventricle. A pusher 1680 or other valve advancing tool can be used to advance the compressed valve 1602 through the delivery catheter 1672. FIG. 17B shows the delivery catheter 1672 extending transeptally into the left atrium from the femoral/IVC access, and the pusher 1680 expelling the valve 1602 out of the delivery catheter 1672

such that the distal anchoring element 1632 extends through the annulus and into or near a subannular mitral anterolateral commissure anchoring area. FIG. 17C shows the valve 1602 in an expanded configuration and seated in the annulus of the mitral valve. A proximal anchoring element 1634 is in a released state allowing the proximal anchoring element 1634 to engage a subannular commissure anchoring area. FIG. 17D shows a top view of the valve 1602 positioned relative to the native mitral annulus and shows how the distal anchoring element 132 and the proximal anchoring element 134 provide anchoring in the A1-P1 and A3-P3 commissural anchoring areas. FIG. 17E is a top view of the native mitral valve annulus shown in solid line and the valve 1602 seated therein shown in dashed line.

[0136] FIGS. 18A and 18B illustrate anterior side views of a side delivered transcatheter prosthetic heart valve 1702 seated in an annulus of a native mitral valve according to an embodiment. FIG. 18A shows how a distal anchoring element 1732 and a proximal anchoring element 1734 provide anchoring in the A1-P1 and A3-P3 commissural anchoring areas (shown in dashed line). FIG. 18B is a side view of the native mitral valve annulus shown in solid line and the valve 1702 seated therein shown in dashed line.

[0137] FIG. 19A and 19B are illustrations of a proximal anchoring element 1834 included in a transcatheter prosthetic heart valve according to an embodiment and shown in a first configuration and a second configuration, respectively. The proximal anchoring element 1834 can include, for example, a mechanical hinge or similar mechanism allowing at least an end portion of the proximal anchoring element 1834 to rotate relative to the remaining portion of the proximal anchoring element 1834. Although not shown, in some implementations, the end portion of the proximal anchoring element 1834 can be engaged by a tensile member and/or the like configured to retain the proximal anchoring element 1834 in the first configuration prior to seating the valve in an annulus.

[0138] FIG. 20A and 20B are illustrations of a proximal anchoring element 1934 included in a transcatheter prosthetic heart valve according to an embodiment and shown in a first configuration and a second configuration, respectively. The proximal anchoring element 1934 can include, for example, a fold and/or release region or mechanism formed of shape memory or superelastic material such as Nitinol. The proximal anchoring element 1934 can be in a folded state when in the first configuration and an unfolded or expanded state when in the second configuration. Although not shown, in some implementations, the end portion of the proximal anchoring element 1934 can be engaged by a tensile member and/or the like configured to retain the proximal anchoring element 1934 in the first configuration prior to seating the valve in an annulus.

[0139] FIGS. 21A and 21B illustrate top views of a side delivered transcatheter prosthetic heart valve 2002 seated in an annulus of a native tricuspid according to an embodiment. FIG. 21A shows how a distal anchoring element 2032 and a proximal anchoring element 2034 provide anchoring in the RVOT and

proximal anchoring area (adjacent the IVC), respectively. FIG. 21B is a top view of the native valve annulus shown in solid line with the valve 1702 seated therein shown in dashed line.

[0140] FIG. 24 is an illustration of a side perspective view of a side delivered transcatheter prosthetic heart valve 2102 according to an embodiment. The valve 2102 can include a wire or laser cut frame having any suitable number of subannular anchoring elements. For example, in this embodiment, the valve 2102 includes three subannular anchoring elements, such as a distal anchoring element 2132, a proximal anchoring element 2134, and a medial anchoring element 2137.

[0141] Any of the valves described herein can include a proximal anchoring element that can be transitioned from a first state or configuration to a second state or configuration after the valve has been inserted or seated in an annulus of a native valve. For example, a proximal anchoring element can be configured to transition between a compressed, undeployed, restrained, and/or pre-released state (e.g., the first configuration) and an expanded, extended, deployed, unrestrained, and/or post-released state. When in the first configuration, a proximal anchoring element can be in contact with, adjacent to, and/or otherwise near a body or transannular section of the valve. When in the second configuration, the proximal anchoring element (or at least an end portion thereof) can extend away from the body or transannular section of the valve. That is to say, at least the end portion of the proximal anchoring element in the second configuration can be farther from the body or transannular section of the valve compared to the end portion of the proximal anchoring element in the first configuration. Such an arrangement can result in a size, circumference, and/or perimeter of at least a portion of the body or transannular section of the valve being smaller when the proximal anchoring element is in the first configuration than when the proximal anchoring element is in the second configuration, which in turn, can allow the body or transannular section of the valve (or a portion thereof) to be inserted through the annulus. Once the valve is seated and the proximal anchoring element is transitioned to its second configuration, the larger size, circumference, and/or perimeter of the body or transannular section can act to secure and/or anchor the valve in the annulus.

[0142] In some embodiments, a valve can include a feature, member, mechanism, etc. configured to at least temporarily retain a proximal anchoring element in its first configuration. For example, a valve can include a tensile member that can selectively engage a proximal anchoring element to temporarily maintain the proximal anchoring element in the first configuration. In some implementations, the tensile member can removably couple to a portion of the proximal anchoring element and can exert a force (e.g., a tensile or compression force) operable in maintaining the proximal anchoring element in the first configuration. The tensile member can be reconfigurable allowing the tensile member to be disengaged from the proximal anchoring element, which in turn, can allow the proximal anchoring element to transition from its first configuration to its second configuration, as described in further detail herein with reference to specific embodiments.

[0143] Provided below is a discussion of certain aspects, embodiments, and/or methods of removably coupling a tensile member to a proximal anchoring element of a transcatheter prosthetic valve. The proximal anchoring elements (or aspects or portions thereof) described below with respect to specific embodiments can be substantially similar in at least form and/or function to any of the proximal anchoring elements described herein. Similarly, the tensile members described below (or aspects or portions thereof) can be similar in at least form and/or function to any of the tensile members described herein. Thus, certain aspects and/or portions of the specific embodiments may not described in further detail herein.

[0144] FIGS. 23A and 23B illustrate side perspective views of a side delivered transcatheter prosthetic heart valve 2202 and a tensile member 2235 according to an embodiment. The valve 2202 has a frame 2210 with a distal anchoring element 2232 and a proximal anchoring element 2234 (e.g., wire loop anchoring elements and/or any other suitable type of anchoring element). The tensile member 2235 can be and/or can include any suitable coupler, attachment device, and/or the like configured to be at least temporarily coupled to the proximal anchoring element 2234. In some embodiments, the tensile member 2235 can be a tether that can be advanced through a delivery catheter as the valve is advanced therethrough. In some embodiments, the tensile member 2235 can be and/or can include a pusher that can be used to advance the valve through the delivery catheter.

[0145] FIG. 23A shows the tensile member 2235 coupled to the proximal anchoring element 2234. Although not shown, the proximal anchoring element 2234 and/or the tensile member 2235 can include one or more features allowing tensile member 2235 to temporarily couple to the proximal anchoring element 2234. The tensile member 2235 is at least partially disposed within the valve 2202. An end portion of the tensile member 2235 is shown extending through a waypoint 2221 defined by a portion of the valve 2202 (e.g., a portion of the frame 2210). The waypoint 2221 can be, for example, an opening, an aperture, a slot, a cut, self-healing port, etc. Such an arrangement can result in the end portion of the tensile member 2235 substantially forming a U-bend, where a distal end surface of the tensile member 2235 is oriented and/or faces a proximal direction. Accordingly, applying a tensile force along the tensile member 2235 can act to pull the proximal anchoring element 2234 toward a body or transannular section of the valve 2202. Said another way, a user can pull on a proximal end portion of the tensile member 2235 (e.g., an end disposed outside of the body) to place the tensile member 2235 in tension that pulls the proximal anchoring element 2234 toward the body of the valve 2202 – i.e., its first configuration.

[0146] FIG. 23B shows the tensile member 2235 decoupled from the proximal anchoring element 2234 and withdrawn through the waypoint 2201 and the valve 2202. Although not shown, the tensile member 2235, the proximal anchoring element 2234, and/or any suitable member or element of a delivery system can include a release mechanism that can release the proximal anchoring element 2234 from the tensile member 2235. Once decoupled, the tensile member 2235 can be retracted from the valve 2202.

The decoupling allows the proximal anchoring element 2234 to transition from its first configuration to its second configuration. In some implementations, the tensile member 2235 can remain coupled to the proximal anchoring element 2234 as the valve 2202 is placed in the annulus of the native valve and can be released or decoupled after the valve 2202 is placed or seated. As described above, the proximal anchoring element 2234 is configured to engage subannular tissue such as, for example, the septal-posterior and/or anterior-septal commissures bridging the posterior and anterior leaflets of the native valve.

[0147] FIG. 24 is an illustration of a side perspective view of a portion of a proximal anchoring element 2334 included in a transcatheter prosthetic heart valve and a tensile member 2335 according to an embodiment. The proximal anchoring element 2334 includes an attachment point 2336 (e.g., an eyelet, hole, loop, hook, aperture, etc.) to which the tensile member 2335 is removably coupled. The tensile member 2335 is shown, for example, as a continuous tether, cable, suture, wire, and/or the like. A portion of the tensile member 2335 is threaded through a delivery system, a portion of the valve (e.g., a waypoint thereof), looped around or through the attachment point 2336 of the proximal anchoring element 2334, and threaded back through the delivery system. Pulling on both ends of the tensile member 2335 places the tensile member 2335 in tension, which in turn, maintains the proximal anchoring element 2334 in its first configuration. After the valve has been deployed, one end of the tensile member 2335 is pulled to remove the tensile member 2335 from the attachment point 2336 of the proximal anchoring element 2334.

[0148] FIG. 25 is an illustration of a side perspective view of a portion of a proximal anchoring element 2434 included in a transcatheter prosthetic heart valve and a tensile member 2435 according to an embodiment. The proximal anchoring element 2434 includes an attachment point 2436 (e.g., a threaded eyelet, opening, or coupler) to which the tensile member 2435 is removably coupled. The tensile member 2435 is shown, for example, as a continuous cable with a threaded distal end portion. The tensile member 2435 can extend through a delivery system and a portion of the valve (e.g., a waypoint thereof), and can form a threaded coupling with the attachment point 2436 of the proximal anchoring element 2434. Pulling on an end of the tensile member 2435 places the tensile member 2435 in tension, which in turn, maintains the proximal anchoring element 2434 in its first configuration. After the valve has been deployed, the tensile member 2435 is twisted to unthread the threaded distal end portion from attachment point 2436 and removed from the delivery system.

[0149] FIG. 26 is an illustration of a side perspective view of a portion of a proximal anchoring element 2534 included in a transcatheter prosthetic heart valve and a tensile member 2535 according to an embodiment. The proximal anchoring element 2534 includes an attachment point 2536 such as an eyelet or loop to which a lead 2537 of the tensile member 2535 is coupled. The lead 2537 can be configured to remain coupled to the valve after deployment. In some implementations, a first end of the lead 2537 can be coupled to the attachment point 2536 and a second end of the lead 2537 opposite the first end can

extend through a portion of the valve (e.g., the waypoint and any other suitable portion). Such an arrangement can result in the second end of the lead 2537 being disposed, for example, outside of and/or above a collar of the valve, which can be more accessible than the attachment point 2536 of the proximal anchoring element 2334.

[0150] The tensile member 2535 is shown, for example, as a continuous tether, cable, suture, wire, and/or the like that can be threaded through a delivery system, looped around or through the second end of the lead 2537, and threaded back through the delivery system. Pulling on both ends of the tensile member 2535 places the tensile member 2535 in tension, which in turn, places the lead 2537 in tension. Thus, the lead 2537 maintains the proximal anchoring element 2534 in its first configuration. After the valve has been deployed, one end of the tensile member 2535 is pulled to remove the tensile member 2535 from the second end of the lead 2536. The tensile member 2535 is removed from the delivery system while the lead 2537 remains coupled to the proximal anchoring element 2534.

[0151] FIG. 27 is an illustration of a side perspective view of a portion of a proximal anchoring element 2634 included in a transcatheter prosthetic heart valve and a tensile member 2635 according to an embodiment. The proximal anchoring element 2634 includes an attachment point 2636 to which a lead 2637 of the tensile member 2635 is coupled. A first end of the lead 2637 can be coupled to the attachment point 2636 and a second end of the lead 2637 opposite the first end can extend through a portion of the valve (e.g., the waypoint and any other suitable portion). The tensile member 2635 is shown, for example, as a continuous cable with a threaded distal end portion, which can form a removable threaded coupling with the second end of the lead 2637. Pulling on an end of the tensile member 2635 places the tensile member 2635 in tension, which in turn, places the lead 2637 in tension. Thus, the lead 2637 maintains the proximal anchoring element 2634 in its first configuration. After the valve has been deployed, the tensile member 2635 is twisted to unthread the threaded distal end portion from the second end of the lead 2637 and removed from the delivery system while the lead 2637 remains coupled to the proximal anchoring element 2634.

[0152] FIGS. 28A and 28B illustrate a side perspective view of a portion of a proximal anchoring element 2734 included in a transcatheter prosthetic heart valve and a tensile member 2735 according to an embodiment. The proximal anchoring element 2734 includes an attachment point 2736 to which an end portion 2738 of the tensile member 2735 is removably coupled. The tensile member 2735 is shown, for example, as a continuous tether, cable, suture, wire, and/or the like with a coupling feature 2739 (e.g., a ball, knob, protrusion, etc.) included in and/or formed at the distal end. The tensile member 2735 includes a receiving member 2740 (e.g., a cup or the like) configured to removably receive the end of the tensile member 2735 (e.g., the coupling feature 2739). For example, the coupling feature 2739 can be disposed or snapped into a recessed feature of the receiving member 2740, which can be coaxial with an outer

sleeve member. The outer sleeve member can be slid (e.g., in a distal direction) to cover the coupling feature 2739 and to form a friction fit that maintains the coupling feature 279 in the recessed feature of the receiving member 2740 while covered by the sleeve member.

[0153] FIG. 28A shows the end portion 2738 of the tensile member 2735 threaded through a portion of the valve (e.g., a waypoint thereof), looped around or through the attachment point 2736 of the proximal anchoring element 2734, and threaded back through the portion of the valve (e.g., back through the waypoint) to allow the coupling feature 2739 at the end of the tensile member 2735 to be coupled to the receiving member 2740. Pulling on a proximal end of the tensile member 2735 places the tensile member 2735 in tension, which in turn, maintains the proximal anchoring element 2734 in its first configuration. FIG. 28B shows the sleeve member in a position that allows the coupling feature 2739 at the end of the tensile member 2735 to be removed from the receiving member 2740. After the valve has been deployed and the coupling feature 2739 is released from the receiving member 2740, the tensile member 2735 is pulled to remove the tensile member 2735 from the attachment point 2736 of the proximal anchoring element 2734 and the delivery system.

[0154] FIGS. 29A-29D illustrate a side perspective view of a portion proximal anchoring element 2834 included in a transcatheter prosthetic heart valve and one or more portions of a tensile member 2835 according to an embodiment. The proximal anchoring element 2834 includes an attachment point 2836 to which a lead 2841 of the tensile member 2835 is coupled. Each end of the lead 2841 includes a coupling feature 2842 (e.g., a ball or the like) and is configured to at least temporarily couple to a receiving member 2843 of the tensile member 2835.

[0155] FIG. 29A shows the lead 2841 threaded through a portion of the valve (e.g., a waypoint thereof), looped around or through the attachment point 2836 of the proximal anchoring element 2834, and threaded back through the portion of the valve (e.g., back through the waypoint) such that each end of the lead 2841 is outside of the valve. FIGS. 29B and 29C show the coupling features 2842 disposed at each end of the lead 2841 being coupled to the receiving member 2843 of the tension member 2835. For example, the receiving member 2843 can define two recessed features and two sleeve members. Each coupling feature 2842 can be disposed in a corresponding recessed feature and each sleeve member can be transitioned to cover each coupling feature 2842, thereby coupling the lead 2841 to the tensile member 2835. Pulling on an end of the tensile member 2835 places the tensile member 2835 in tension, which in turn, places the lead 2841 in tension. Thus, the lead 2841 maintains the proximal anchoring element 2834 in its first configuration.

[0156] FIG. 29D shows one of the sleeve members of the receiving member 2843 (e.g., a proximal sleeve member) transitioned to a position that allows the corresponding coupling feature 2842 to be

removed from the corresponding recessed feature of the receiving member 2843. After the valve has been deployed and the coupling feature 2842 is released from the receiving member 2843, the tensile member 2835 is pulled to remove the tensile member 2835. Moreover, one of the coupling features 2842 can remain coupled to the receiving member 2843 such that the lead 2841 is removed from the attachment point 2836 of the proximal anchoring element 2834, allowing the tensile member 2835 and the lead 2841 to be removed from the delivery system.

[0157] FIG. 30 is an illustration of a side perspective view of a portion of a proximal anchoring element 2934 included in a transcatheter prosthetic heart valve and a tensile member 2935 according to an embodiment. The proximal anchoring element 2934 includes an attachment point 2936 to which a lead 2941 of the tensile member 2935 is coupled. Each end of the lead 2941 includes a coupling feature 2942 (e.g., a loop or the like) and is configured to at least temporarily couple to the tensile member 2835. An end of the lead 2941 is threaded through a portion of the valve (e.g., a waypoint thereof), looped around or through the attachment point 2936 of the proximal anchoring element 2934, and threaded back through the portion of the valve (e.g., back through the waypoint) such that the coupling feature 2944 at each end of the lead 2941 is outside of the valve.

[0158] The tensile member 2935 is shown, for example, as a continuous suture and/or the like that can be threaded through the coupling features 2944 at each end of the lead 2941, thereby coupling the tensile member 2935 to the lead 2941. Pulling on both ends of the tensile member 2935 places the tensile member 2935 in tension, which in turn, places the lead 2941 in tension. Thus, the lead 2941 maintains the proximal anchoring element 2934 in its first configuration. After the valve has been deployed, a portion of the tensile member 2935 can be severed allowing at least the tensile member 2935 to be removed from the delivery system. In some implementations, the severing of the tensile member 2935 can include cutting the tensile member 2935 and/or otherwise breaking apart a portion of the tensile member 2935 at a breakpoint 2946. For example, the breakpoint 2946 can include and/or can form a frangible portion of the tensile member 2935, a magnetic coupler, a threaded coupler, a ball and cup coupler, and/or any other suitable coupler. Moreover, the severing of the tensile member 2935 can result in one end portion of the lead 2941 remaining coupled to the tensile member 2935, which in turn, can allow the lead 2941 to be removed within the tensile member 2935.

[0159] FIGS. 31A-31C illustrate side perspective views of a side delivered transcatheter prosthetic heart valve 3002 and a tensile member 3035 according to an embodiment. The valve 3002 has a frame 3010 with a collar 3020, a distal anchoring element 3032, and a proximal anchoring element 3034 (e.g., wire loop anchoring elements and/or any other suitable type of anchoring element). The frame 3010 defines a waypoint 3021. The collar 3020 includes and/or forms a coupler 3022. While the waypoint 3021 is shown along a body of the frame 3010, in other embodiments, the collar 3020 and/or any other suitable portion of

the valve 3002 can form and/or define the waypoint 3021. Similarly, while the coupler 3022 is shown along the collar 3020, in other embodiments, the body of the frame 3010 and/or any other suitable portion of the valve 3020 can include the coupler 3022.

[0160] The tensile member 3035 includes a lead 3041 configured to be coupled to and/or threaded through an attachment point 3036 of the proximal anchoring element 3034. The lead 3041 includes a first end that has and/or forms a first coupling feature 3044 and a second end that has and/or forms a second coupling feature 3044. The coupling features can be any suitable configuration. For example, in this embodiment, the first coupling feature 3044 is and/or forms a loop, eyelet, opening, and/or the like, and the second coupling feature 3042 is and/or forms a ball, protrusion, knob, knot, and/or the like. The tensile member 3035 can be and/or can include any suitable cable, tether, wire, catheter, conduit, etc. In some implementations, the tensile member 3035 can be used, for example, as a pusher or the like configured to push and/or otherwise advance the valve 3002 through a delivery system.

[0161] In this embodiment, the tensile member 3035 includes a first cable 3047 with an end portion that forms a threaded coupler configured to engage and/or couple to the coupler 3022 formed by the collar (e.g., a threaded nut or the like). The tensile member 3035 includes a second cable 3048 with an end portion that forms a receiving member configured to receive and/or removably couple to the second end of the lead 3041. For example, the receiving member of the second cable 3048 and the coupling feature 3042 formed by the second end of the lead 3041 can be a ball and cup coupling mechanism as described above with reference to the tensile members 2735 and 2835. Moreover, the tensile member 3035 can include and/or can form an outer sheath or catheter configured to at least partially house the first cable 3047 and the second cable 3048.

[0162] FIG. 31A shows the tensile member 3035 prior to coupling to the valve 3002 and/or the lead 3041. The lead 3041 is shown threaded through a portion of the valve 3002 and the waypoint 3021, looped around or through the attachment point 3036 of the proximal anchoring element 3034, and threaded back through the waypoint 3021 and portion of the valve 3002 such that the first end 3044 and the second end 3042 are each outside of the valve 3002 and/or above or proximal to the collar 3020.

[0163] FIG. 31B shows, the end portion of the first cable 3047 of the tensile member 3035 coupled to the coupler 3022 of the collar 3020, for example, via a threaded coupling. The first coupling feature 3044 of the lead 3041 is coupled to the first cable 3047 (e.g., the first coupling feature 3044 can be a loop that is disposed on or about the first cable 3047). In some implementations, the tensile member 3035 can be used as a proximal pusher by virtue of the first cable 3047 being coupled to the coupler 3022 formed by the collar 3020. For example, a substantially fixed portion of the first cable 3047 can extend from the tensile member 3035 (e.g., the outer sheath) such that a distal or pushing force applied to the tensile member 3035, via the

first cable 3047, pushes the valve 3002. With the first coupling feature 3044 coupled to the first cable 3047, the first end of the lead 3041 is maintained in a relatively fixed position relative to the valve 3002. The second cable 3048 of the tensile member 3035 is shown coupled to the second coupling feature 3042 of the lead 3041 (e.g., via a ball and cup coupling mechanism and/or the like). Thus, while the tensile member 3035 and/or the first cable 3047 can be used to push the valve 3002, a tensile or pulling force can be applied to the second cable 3048, which can pull the second end of the lead 3041 in a proximal direction, thereby placing the lead in tension. Accordingly, the lead 3041 can maintain the proximal anchoring element 3034 in its first configuration during deployment.

[0164] FIG. 31C shows the first cable 3047 decoupled from the coupler 3022 of the collar 3020 and the first coupling feature 3044 at the first end of the lead 3041. The second coupling feature 3042 at the second end of the lead 3041 can remain coupled to the second cable 3048. After the valve has been deployed, the tensile member 3035 is pulled to remove the tensile member 3035 and the lead 3041 from the valve 3002 and the delivery system. With the tensile member 3035 removed, the proximal anchoring element 3034 is allowed to transition to its second configuration.

[0165] FIG. 32 is a flowchart illustrating a method of delivering a transcatheter prosthetic valve according to an embodiment. In some instances, the method for delivery can include the steps of: (i) advance a guidewire through a femoral vein or brachiocephalic vein, an inferior vena cava (IVC) or superior vena cava (SVC), and into a pulmonary artery or left ventricle; (ii) advance a delivery catheter over the guide wire to a right atrium proximate to a native tricuspid valve or a left atrium proximate to a native mitral valve; (iii) advance and deliver an orthogonally compressed prosthetic heart valve to the right atrium or the left atrium, where the delivering includes partially releasing the valve from the delivery catheter, positioning a distal anchoring element of the valve in the pulmonary artery (e.g., a right ventricular outflow tract (RVOT)) or a subannular area below an anterolateral commissure of a mitral valve, and holding the valve at a raised angle of about 30 degrees or more relative to a localized horizontal annular plane of the native valve to permit blood flow around and through the prosthetic valve, allowing a gradual blood flow transition from a flow through native leaflets to a complete flow through the prosthetic valve; (iv) completely release of the valve from delivery catheter and seat the valve in the native annulus by applying a downward force in the direction of the ventricle (e.g., on a proximal side of the prosthetic valve); and (v) transition at least one proximal anchoring element to a second configuration in which the proximal anchoring element engages a subannular proximal anchoring area.

[0166] FIG. 33 is a flowchart illustrating a method 10 of delivering a transcatheter prosthetic valve according to an embodiment. The method 10 includes disposing adjacent to an annulus of a native valve of the heart, a distal portion of a delivery catheter having disposed in a lumen thereof the prosthetic valve in a compressed configuration, at 11. The prosthetic valve can be any of the valves disclosed herein. For

example, the valve can be a valve having (i) a frame with at least a distal anchoring element and a proximal anchoring element, and (ii) a flow control component mounted within the frame configured to permit blood flow in a single direction through an inflow end of the valve and to block blood flow in an opposite direction through an outflow end of the valve. The valve can be delivered via a traditional delivery process or an orthogonal delivery process. For example, the valve can be delivered via any of the processes and/or methods described in detail herein and/or in the '957 PCT.

[0167] The valve is released from the lumen of the delivery catheter such that the valve transitions from the compressed configuration to an expanded configuration, at 12. As described in detail above with respect to specific embodiments, releasing the valve from the delivery catheter allows the prosthetic valve to expanded from the compressed configuration within the delivery catheter to the expanded configuration outside of the delivery catheter and suitable for deployment into the annulus of the native valve.

[0168] A portion of the distal anchoring element is placed on a ventricle side of the annulus of the native valve, at 13. In some implementations, the distal anchoring element can be a distal lower anchoring element that can be placed on the ventricle side of the annulus while the rest of the valve remains on the atrium side of the annulus. In some implementations, the distal anchoring element can be placed within a ventricular outflow tract. For example, the distal anchoring element can be placed within a right ventricular outflow tract (e.g., the pulmonary artery) when the native valve is a native tricuspid valve. In some instances, the distal anchoring element can engage subannular tissue to at least partially secure a distal end portion of the valve to the annular tissue while the remainder of the valve is maintained in a supra-annular position within the atrium side of the heart.

[0169] In some implementations, the method 10 optionally may include holding the prosthetic valve at an angle relative to the annulus of the native valve. The angle can be, for example, an oblique angle relative to the annulus. In some instances, holding the valve at an angle relative to the annulus can allow blood to flow from the atrium to the ventricle partially through the native valve annulus and around the prosthetic valve, as well as partially through the prosthetic valve, which can allow for assessment of the prosthetic valve function.

[0170] The prosthetic valve is seated in the annulus of the native valve while the proximal anchoring element is in a first configuration, at 14. The proximal anchoring element can have a first configuration and a second configuration. As described in detail above with reference to specific embodiments, the proximal anchoring element can be maintained in a compressed, restrained, tethered, and/or otherwise pre-released state when in the first configuration (e.g., via a tensile member or the like). When the proximal anchoring element is in the first configuration, a lower portion of the valve (e.g., a subannular portion) can have a size that allows the valve to extend through the annulus of the native valve.

[0171] After seating the prosthetic valve in the annulus, the proximal anchoring element is transitioned from its first configuration to its second configuration, at 15. As described in detail above with reference to specific embodiments, the proximal anchoring element can extend away from a body or transannular section of the valve. The proximal anchoring element can engage subannular tissue on a proximal side of the annulus that can at least partially secure the proximal side of the prosthetic valve to the proximal annular tissue. In some implementations, an atrial collar or the like of the valve and the distal and proximal anchoring elements can exert opposing forces on the annular tissue that can secure the prosthetic valve the annulus of the native valve. In some implementations, the valve can include one or more additional anchors or the like that can provide additional securement, as described in the '957 PCT.

[0172] Many modifications and variations can be made without departing from its spirit and scope, as will be apparent to those skilled in the art. Functionally equivalent methods and apparatuses within the scope of the disclosure, in addition to those enumerated herein, will be apparent to those skilled in the art from the foregoing descriptions. Such modifications and variations are intended to fall within the scope of the appended claims. The present disclosure is to be limited only by the terms of the appended claims, along with the full scope of equivalents to which such claims are entitled. It is to be understood that this disclosure is not limited to particular methods, reagents, compounds, compositions or biological systems, which can, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting.

[0173] While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods described above indicate certain events occurring in certain order, the ordering of certain events may be modified. Additionally, certain of the events may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above.

[0174] Where schematics and/or embodiments described above indicate certain components arranged in certain orientations or positions, the arrangement of components may be modified. While the embodiments have been particularly shown and described, it will be understood that various changes in form and details may be made. Any portion of the apparatus and/or methods described herein may be combined in any combination, except mutually exclusive combinations. The embodiments described herein can include various combinations and/or sub-combinations of the functions, components, and/or features of the different embodiments described.

What is claimed is:

1. A prosthetic heart valve, comprising:

a valve frame having a central axis and defining an aperture extending along the central axis, the valve frame including a distal anchoring element and a proximal anchoring element; and

a flow control component mounted within the aperture and configured to permit blood flow in a first direction approximately parallel to the central axis from an inflow end to an outflow end of the flow control component and block blood flow in a second direction, opposite the first direction,

the valve frame having a compressed configuration to allow the prosthetic heart valve to be delivered to a heart of a patient via a delivery catheter, the valve frame configured to transition from the compressed configuration to an expanded configuration when the prosthetic heart valve is released from the delivery catheter,

the prosthetic heart valve configured to be seated in an annulus of a native valve of the heart when in the expanded configuration, the distal anchoring element and the proximal anchoring element configured to be inserted through the annulus of the native valve prior to the prosthetic heart valve being seated therein, the proximal anchoring element configured to be transitioned from a first configuration to a second configuration after the prosthetic heart valve is seated in the annulus of the native valve.

2. The prosthetic heart valve of claim 1, wherein the valve frame, when in the expanded configuration, has a first height along the central axis, a first lateral width along a lateral axis perpendicular to the central axis, and a longitudinal length along a longitudinal axis perpendicular to the central axis and the lateral axis, and

when in the compressed configuration, the valve frame has a second height along the central axis less than the first height and a second lateral width along the lateral axis less than the first lateral width.

3. The prosthetic heart valve of claims 1 or 2, wherein seating the prosthetic heart valve in the annulus of the native valve includes positioning the distal anchoring element in a ventricular outflow tract before the prosthetic heart valve is seated in the annulus of the native valve.

4. The prosthetic heart valve of any of the preceding claims, wherein the distal anchoring element is at least one of a wire loop, a wire frame, an integrated frame section, or a stent.

5. The prosthetic heart valve of any of the preceding claims, wherein the proximal anchoring element is at least one of a wire loop, a wire frame, an integrated frame section, or a stent.

6. The prosthetic heart valve of any of the preceding claims, wherein the proximal anchoring element is in the first configuration as the prosthetic heart valve is seated in the annulus of the native valve.

7. The prosthetic heart valve of any of the preceding claims, wherein the distal anchoring element is configured to be temporarily coupled to a guidewire.

8. The prosthetic heart valve of any of the preceding claims, further comprising:

a tensile member coupled to the valve frame, the tensile member having a first configuration in which the tensile member is engaged with the proximal anchoring element to maintain the proximal anchoring element in the first configuration, and a second configuration in which the tensile member is disengaged from the proximal anchoring element to allow the proximal anchoring element to transition to the second configuration.

9. The prosthetic heart valve of claim 8, wherein at least a portion of the tensile member extends through a waypoint defined by the valve frame.

10. The prosthetic heart valve of claims 8 or 9, wherein the tensile member is removably coupled to the proximal anchoring element.

11. The prosthetic heart valve of any one of claims 8-10, wherein the tensile member is one of a suture, a cable, a wire.

12. The prosthetic heart valve of any one of claims 8-11, wherein the tensile member has a connector configured to operably couple at least a portion of the tensile member to the proximal anchoring element.

13. The prosthetic heart valve of claim 12, wherein the connector is in a first configuration when the tensile member is engaged within the proximal anchoring element, the connector configured to be transitioned to a second configuration to allow at least the portion of the tensile member to be disengaged from the proximal anchoring element.

14. The prosthetic heart valve of claims 12 or 13, wherein the connector is at least one of a threaded connector or a ball and cup connector.

15. A prosthetic heart valve, comprising:

a valve frame having a transannular section and an atrial collar attached around a top edge of the transannular section;

a distal anchoring element coupled to the transannular section of the valve frame;

a proximal anchoring element coupled to the transannular section of the valve frame; and

a flow control component mounted within the valve frame and configured to permit blood flow in a first direction through an inflow end of the prosthetic heart valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the prosthetic heart valve,

the prosthetic heart valve having a compressed configuration for introduction into a heart of a patient via a delivery catheter and an expanded configuration when the prosthetic heart valve is released from the delivery catheter within an atrium of the heart,

the prosthetic heart valve configured to be seated in a annulus of a native valve of the heart when in the expanded configuration, the distal anchoring element configured to be disposed in a ventricular outflow tract when the prosthetic heart valve is seated in the annulus of the native valve, the proximal anchoring element configured to be transitioned from a first configuration to a second configuration after the prosthetic heart valve is seated in the annulus of the native valve.

16. The prosthetic heart valve of claim 15, wherein the native valve is a native mitral valve and the ventricular outflow tract is a left ventricular outflow track (LVOT).

17. The prosthetic heart valve of claim 15, wherein the native valve is a native tricuspid valve and the ventricular outflow tract is a right ventricular outflow track (RVOT).

18. The prosthetic heart valve of any of the preceding claims, wherein the proximal anchoring element is in the first configuration as the prosthetic heart valve is seated in the annulus of the native valve.

19. The prosthetic heart valve of any of the preceding claims, wherein a proximal end portion of the proximal anchoring element is disposed in a first position relative to the transannular section when in the first configuration and a second position relative to the transannular section when in the second configuration, the second position being farther from the transannular section than the first position.

20. The prosthetic heart valve of any of the preceding claims, wherein the proximal anchoring element when in the second configuration is configured to contact sub-annular tissue on a proximal side of the annulus of the native valve.

21. The prosthetic heart valve of any of the preceding claims, further comprising:

a tensile member coupled to the valve frame, the tensile member having a first configuration in which the tensile member is engaged with the proximal anchoring element to maintain the proximal anchoring element in the first configuration, and a second configuration in which the tensile member is disengaged from the proximal anchoring element to allow the proximal anchoring element to transition to the second configuration.

22. The prosthetic heart valve of claim 21, wherein at least a portion of the tensile member extends through a waypoint defined by the transannular section of the valve frame.

23. The prosthetic heart valve of claims 21 or 22, wherein the tensile member is removably coupled to the proximal anchoring element.

24. The prosthetic heart valve of any one of claims 21-23, wherein the tensile member is one of a suture, a cable, a wire.

25. The prosthetic heart valve of any one of claims 21-24, wherein the tensile member has a connector configured to operably couple at least a portion of the tensile member to the proximal anchoring element.

26. The prosthetic heart valve of claim 25, wherein the connector is in a first configuration when the tensile member is engaged within the proximal anchoring element, the connector configured to be transitioned to a second configuration to allow at least the portion of the tensile member to be disengaged from the proximal anchoring element.

27. The prosthetic heart valve of claims 25 or 26, wherein the connector is at least one of a threaded connector or a ball and cup connector.

28. A method of delivering a prosthetic heart valve to an annulus of a native valve between an atrium and a ventricle of a heart of a patient, the method comprising:

disposing adjacent to the annulus of the native valve a distal end of a delivery catheter having disposed in a lumen thereof the prosthetic heart valve, the prosthetic heart valve having a valve frame with a distal anchoring element and a proximal anchoring element, and a flow control component mounted within the valve frame, the prosthetic heart valve being in a compressed configuration within the lumen of the delivery catheter;

releasing the prosthetic heart valve from the lumen of the delivery catheter, the prosthetic heart valve configured to transition from the compressed configuration to an expanded configuration in response to the releasing;

placing a portion of the distal anchoring element on the ventricle side of the annulus of the native valve;

seating the prosthetic heart valve in the annulus of the native valve when the proximal anchoring element is in a first configuration; and

transitioning the proximal anchoring element from the first configuration to a second configuration after the seating the prosthetic heart valve in the annulus.

29. The method of claim 26, wherein the native valve is a native mitral valve, the placing the portion of the distal anchoring element on the ventricle side of the annulus includes placing the portion of the distal anchoring element in a left ventricular outflow track (LVOT).

30. The method of claim 26, wherein the native valve is a native tricuspid valve, the placing the portion of the distal anchoring element on the ventricle side of the annulus includes placing the portion of the distal anchoring element in a right ventricular outflow track (RVOT).

31. The method of any of the preceding claims, wherein the proximal anchoring element when in the second configuration is configured to contact sub-annular tissue on a proximal side of the annulus of the native valve.

32. The method of any of the preceding claims, wherein the prosthetic heart valve includes a tensile member coupled to the valve frame, the method further comprising:

transitioning, after the seating the prosthetic heart valve in the annulus, the tensile member from a first configuration in which the proximal anchoring element is in its first configuration to a second configuration in which the proximal anchoring element is allowed to transition to the second configuration.

33. The method of claim 32, wherein at least a portion of the tensile member extends through a waypoint defined by the valve frame.

34. The method of claims 32 or 33, wherein the first configuration of the proximal anchoring element is in a compressed configuration and the second configuration of the proximal anchoring element is an expanded configuration.

35. The method of any one of claims 32-34, wherein the transitioning the tensile member from the first configuration to the second configuration include decoupling the tensile member from the proximal anchoring element.

36. The method of any one of claims 32-35, wherein the tensile member is one of a suture, a cable, a wire.

37. The method of any one of claims 32-36, wherein the tensile member has a connector configured to operably couple at least a portion of the tensile member to the proximal anchoring element.

38. The method of claim 37, wherein the connector is in a first configuration when the tensile member is in its first configuration, the method further comprising:

transitioning the connector from the first configuration to a second configuration to place the tensile member in its second configuration.

39. The method of claims 37 or 38, wherein the connector is at least one of a threaded connector or a ball and cup connector.

40. A side delivered transcatheter prosthetic heart valve having a distal anchoring tab and a proximal anchoring tab, comprising: (i) a self-expanding annular support frame, said annular support frame having a central channel and an outer perimeter wall circumscribing a central vertical axis in an expanded configuration, said annular support frame having a distal side and a proximal side; (ii) a flow control component mounted within the annular support frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve; (iii) a distal subannular anchoring tab mounted on the distal side of the annular support frame; (iv) a proximal subannular anchoring tab mounted on the proximal side of the annular support frame; wherein the valve is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration has a height of 8-12mm, a width of 8-12mm, and a length of 25-80mm, and wherein the horizontal axis of the compressed configuration of the valve is substantially parallel to a length-wise cylindrical axis of the delivery catheter, said expanded configuration has a height of about 5-60mm and a diameter of about 25-80mm.

41. The valve of claim 40, wherein the proximal tab is fixed or unitary with the outer support frame.

42. The valve of claim 40, wherein the proximal tab is moveable from a first stowed position, held against the outer perimeter wall, and moveable to a second deployed position that extends away from the outer perimeter wall to provide a subannular anchor.

43. The valve of claim 40, comprising a tensile member coupled to the valve frame, the tensile member having a first configuration in which the tensile member is engaged with the proximal anchoring element to maintain the proximal anchoring element in the first configuration, and a second configuration in which the tensile member is disengaged from the proximal anchoring element to allow the proximal anchoring element to transition to the second configuration.

44. The valve of claim 43, wherein at least a portion of the tensile member extends through a waypoint defined by the valve frame.

45. The valve of claim 43, wherein the tensile member is removably coupled to the proximal anchoring element.

46. The valve of claim 43, wherein the tensile member is one of a suture, a cable, a wire.

47. The valve of claim 40, wherein the valve has an upper distal anchoring tab attached to a distal upper edge of the annular support frame, which may be comprised of wire loop, a wire frame, a laser cut frame, an integrated frame section, or a stent, and extends from about 2-20mm away from the annular support frame.

48. The valve of claim 40, wherein the annular support frame is comprised of compressible wire cells selected from the group consisting of braided-wire cells, laser-cut wire cells, photolithography produced wire cells, 3D printed wire cells, wire cells formed from intermittently connected single strand wires in a wave shape, a zig-zag shape, or spiral shape, and combinations thereof.

49. A method for side delivery of an implantable prosthetic heart valve to a desired location in the body, the method comprising: advancing a delivery catheter to the desired location in the body and delivering an expandable prosthetic heart valve to the desired location in the body by releasing the valve from the delivery catheter, wherein the valve comprises an annular support frame having a flow control component mounted within the annular support frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, a distal anchoring tab mounted on a distal side of the annular support frame, and a proximal anchoring tab mounted on a proximal side of the annular support frame, wherein the valve

is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration has a height of 8-12mm, a width of 8-12mm, and a length of 25-80mm, and wherein the horizontal axis of the compressed configuration of the valve is substantially parallel to a length-wise cylindrical axis of the delivery catheter, said expanded configuration has a height of about 5-60mm and a diameter of about 25-80mm.

50. The method of claim 49, wherein releasing the valve from the delivery catheter is selected from the steps consisting of: (i) pulling the valve out of the delivery catheter using a rigid elongated pushing rod/draw wire that is releasably connected to the distal side of the valve, wherein advancing the pushing rod away from the delivery catheter pulls the compressed valve out of the delivery catheter, or (ii) pushing the valve out of the delivery catheter using a rigid elongated pushing rod that is releasably connected to the proximal side of the valve, wherein advancing the pushing rod out of from the delivery catheter pushes the compressed valve out of the delivery catheter.

51. The method of claim 49, wherein the method comprises the additional step of anchoring one or more tissue anchors attached to the valve into native tissue.

52. The method of claim 49, wherein the method comprises the additional step of positioning the distal anchoring tab of the heart valve prosthesis into the right ventricular outflow tract of the right ventricle.

53. The method of claim 49, wherein the method comprises the additional steps of positioning the distal anchoring tab of the heart valve prosthesis into the right ventricular outflow tract of the right ventricle, and positioning an upper distal anchoring tab into a supra-annular position, and the upper distal anchoring tab providing a supra-annular downward force in the direction of the ventricle and distal anchoring tab providing a sub-annular upward force in the direction of the atrium.

54. The method of claim 49, wherein the method comprises the additional step of rotating the heart valve prosthesis using a steerable catheter along an axis parallel to the plane of the valve annulus.

55. A method for side delivery of implantable prosthetic heart valve in the body, the method comprising the steps: (i) advancing a distal end of a guide wire to a distal location, wherein the distal location is a pulmonary artery or a left ventricle of a heart, wherein the guide wire starts outside of a patient using femoral vein access or brachiocephalic vein access, and extends through an inferior vena cava or a superior vena cava to a right atrium, and extends from the right atrium through the tricupsid valve to the pulmonary artery or extends from the right atrium across the atrial septum in a transeptal access through the mitral valve and into a left ventricle; (ii) advancing a delivery catheter over the guide wire to a target

location, where the target location is a right atrium of the tricuspid valve or a left atrium of the mitral valve; (iii) advancing and delivering an orthogonally compressed self-expandable prosthetic heart valve to the target location in the body, wherein a compressed configuration of the valve has a long-axis substantially parallel to a length-wise cylindrical axis of the delivery catheter, wherein the expanded configuration of the valve has a height of about 5-60mm and a diameter of about 25-80mm, wherein the valve comprises an annular support frame having a flow control component mounted within the annular support frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, a distal anchoring tab is mounted on a distal side of the annular support frame, the distal anchoring tab having a length of 10-40mm, wherein the guide wire is threaded through a threading aperture on or within the distal anchoring tab, at least one proximal anchoring tab is mounted on a proximal side of the annular support frame, the proximal anchoring tab having a length of 2-25mm, and a valve advancing tool comprising an elongated sheath wherein the guide wire is within a lumen of the sheath, wherein the outer diameter of the sheath is larger than the inner diameter of the threading aperture on the distal anchoring tab, wherein when the sheath is advanced over the guide wire in a distal direction, and a distal end of the sheath contacts a proximal surface of the threading aperture, the valve is advanced distally through the delivery catheter by the distally-directed pulling force that the sheath imparts to the distal anchoring tab; (iv) partially releasing the valve from the delivery catheter by advancing the sheath over the guide wire, and positioning the distal anchoring tab at a desired anchoring area of the target location, wherein the desired anchoring area is selected from a right ventricular outflow tract (RVOT) of a right ventricle, and a sub-annular area below an A1-P1 antero-lateral commissure of a mitral valve, wherein positioning the distal anchoring tab holds the valve at a raised angle of at least 30 degrees to a localized annular plane relative to the horizontal axis of the valve and the delivery catheter, wherein partially releasing the valve permits blood to flow partially around the prosthetic valve and through the native leaflets, and partially through the flow control component of the prosthetic valve to provide a gradual blood flow transition from flow through native leaflets to complete flow through the prosthetic valve; (v) completing release of the entire valve from the delivery catheter by advancing the sheath over the guide wire, seating the valve in the native annulus by applying a downward force in the direction of the ventricle; and (vi) seating the at least one proximal anchoring tab at a second desired anchoring area.

56. The method of claim 55, wherein the method comprises the additional step of anchoring one or more tissue anchors attached to the valve into native tissue.

57. A method for delivering a prosthetic heart valve to an annulus of a native valve between a ventricle and an atrium of a heart, the method comprising the steps: (i) disposing in the atrium of the heart a distal portion of a delivery catheter having a lumen and a longitudinal axis, with a distal end of the delivery

catheter directed towards the annulus of the native valve, the distal portion of the delivery catheter having disposed within the lumen thereof the prosthetic heart valve in a compressed configuration, wherein the compressed configuration of the prosthetic heart valve has a long-axis substantially parallel to a length-wise cylindrical axis of the delivery catheter, wherein the expanded configuration of the prosthetic heart valve has a height of about 5-60mm and a diameter of about 25-80mm, wherein the prosthetic heart valve comprises an annular support frame having a flow control component mounted within the annular support frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, wherein the annular support frame is self-expanding or balloon-expandable, a distal anchoring tab is mounted on a distal side of the annular support frame, the distal anchoring tab having a length of 10-40mm, the distal anchoring tab extending laterally from the annular support frame and is configured to be disposed on a ventricle side of the annulus of the native valve when the annular support frame is disposed within the annulus, at least one proximal anchoring tab is mounted on a proximal side of the annular support frame, the proximal anchoring tab having a length of 2-25mm, the at least one proximal anchoring tab extending laterally from the annular support frame and is configured to be disposed on the ventricle side of the annulus of the native valve when the annular support frame is disposed within the annulus; (ii) partially releasing the prosthetic heart valve from the delivery catheter, and positioning the distal anchoring tab at a distal subannular anchoring area, wherein the distal subannular anchoring area is a right ventricular outflow tract (RVOT) of a right ventricle or is a sub-annular area below an A1-P1 antero-lateral commissure of a mitral valve; (iii) completing release of the entire prosthetic heart valve from within the lumen of the delivery catheter, and seating the prosthetic heart valve in the native annulus by applying a downward force in the direction of the ventricle; and (iv) seating the proximal anchoring tab at a proximal subannular anchoring area.

58. The method of claim 57, wherein positioning the distal anchoring tab holds the prosthetic heart valve at a raised angle of at least 30 degrees to a localized annular plane relative to a horizontal axis of the valve, and wherein partially releasing the prosthetic heart valve permits blood to flow partially around the prosthetic heart valve and through the native leaflets, and partially through the flow control component of the prosthetic valve to provide a gradual blood flow transition from flow through native leaflets to complete flow through the prosthetic valve.

59. The method of claim 57, wherein seating the proximal anchoring tab comprises releasing the proximal anchoring tab from a compressed pre-release configuration to an expanded post-release configuration with the proximal anchoring tab extending into the proximal subannular anchoring area.

FIG. 1A

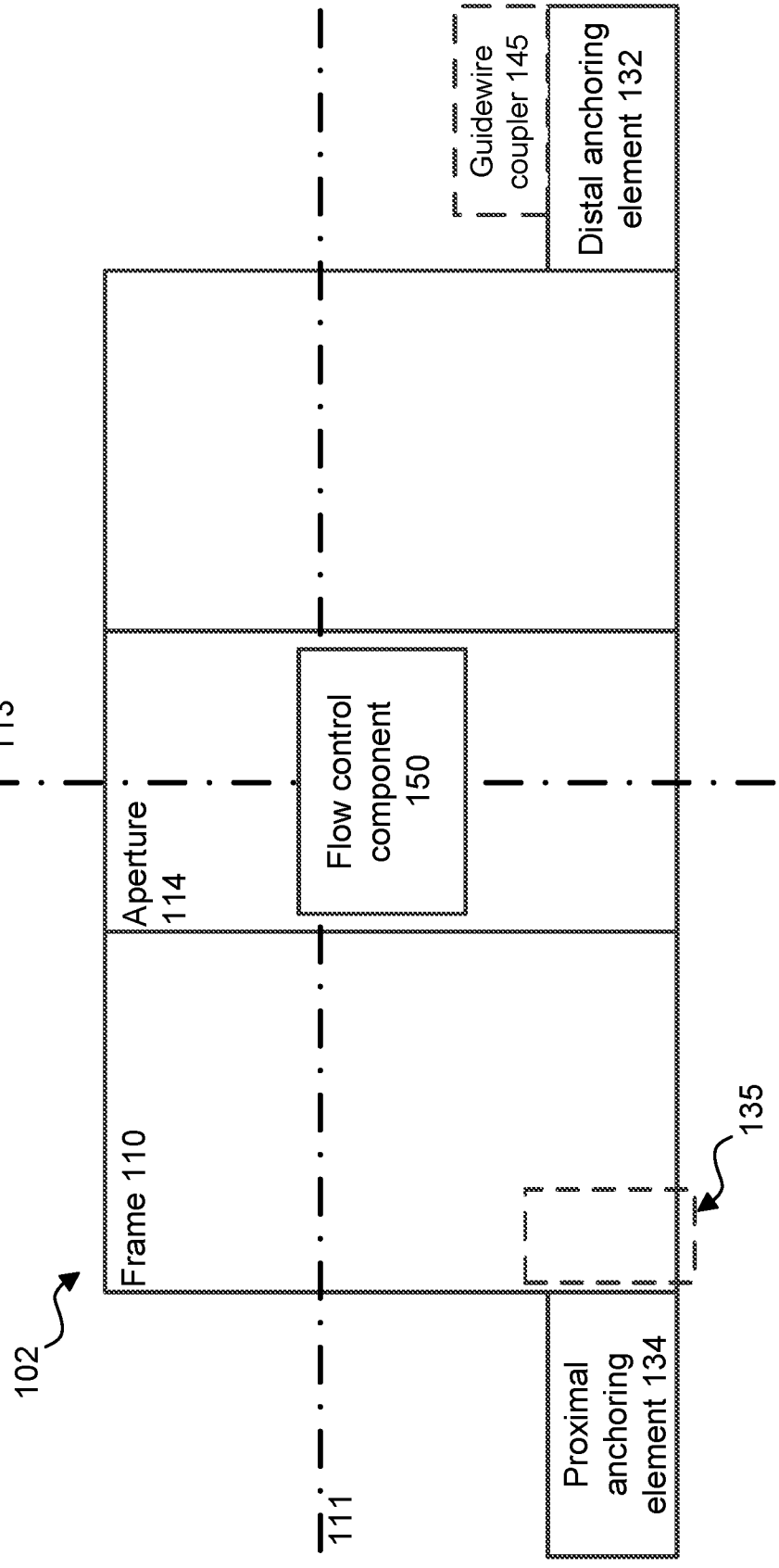

113
Aperture 114
Flow control component 150
Guidewire coupler 145
Distal anchoring element 132
Frame 110
135
102
Proximal anchoring element 134
111

FIG. 1B

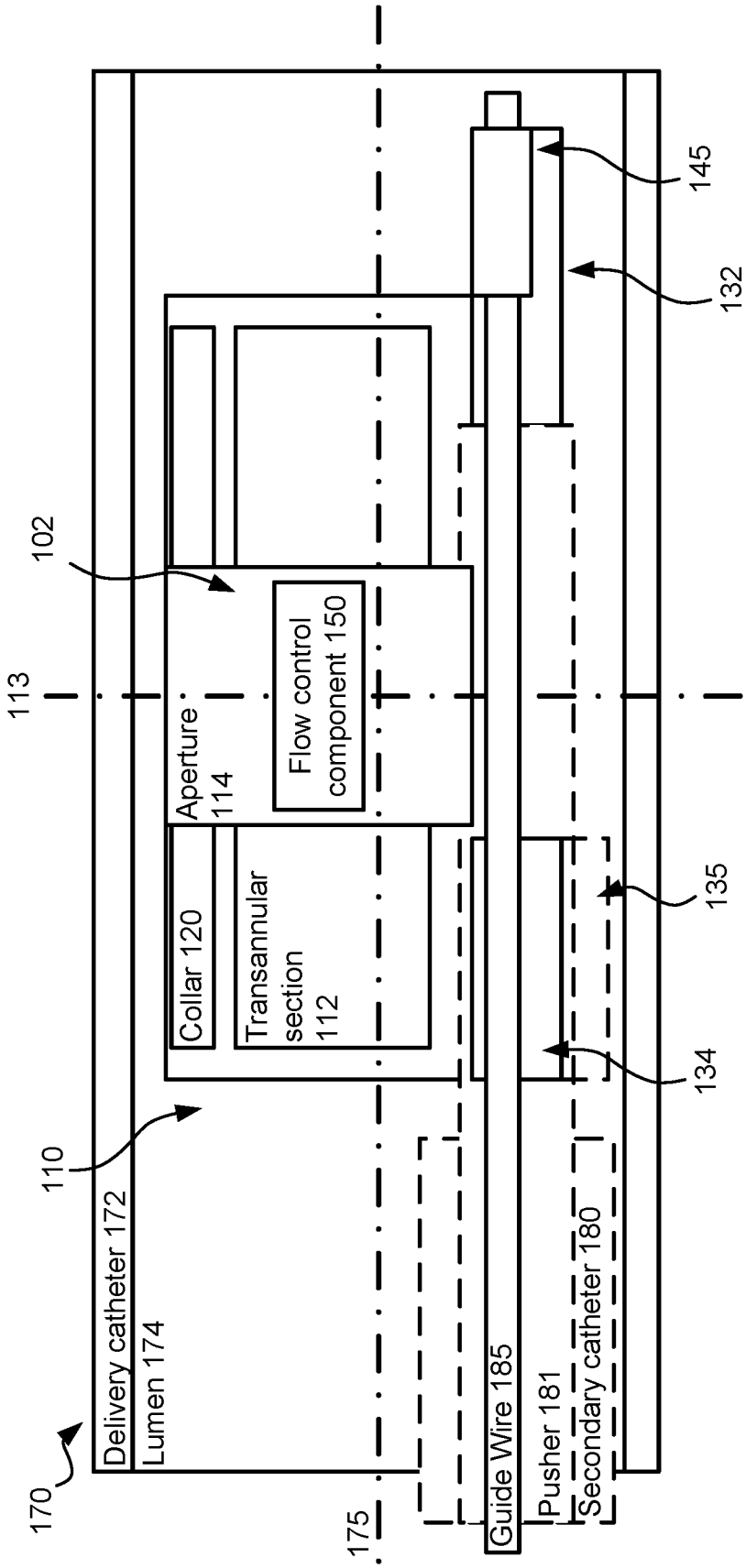

Delivery catheter 172
Lumen 174
Collar 120
Transannular section 112
Aperture 114
Flow control component 150
Guide Wire 185
Pusher 181
Secondary catheter 180
102
110
113
132
134
135
145
170
175

FIG. 1C

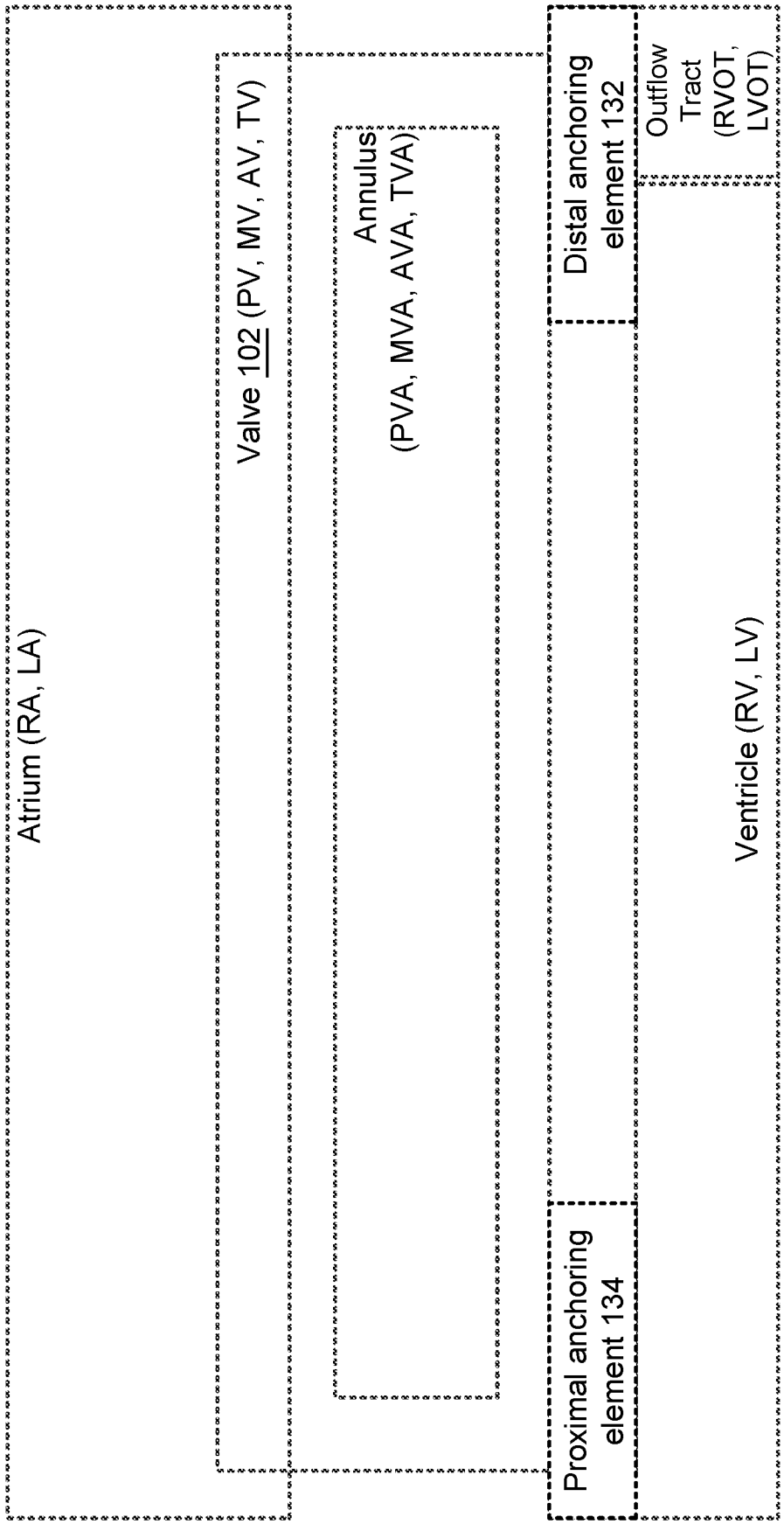

Atrium (RA, LA)
Valve 102 (PV, MV, AV, TV)
Annulus
(PVA, MVA, AVA, TVA)
Proximal anchoring element 134
Distal anchoring element 132
Outflow Tract (RVOT, LVOT)
Ventricle (RV, LV)

FIG. 2

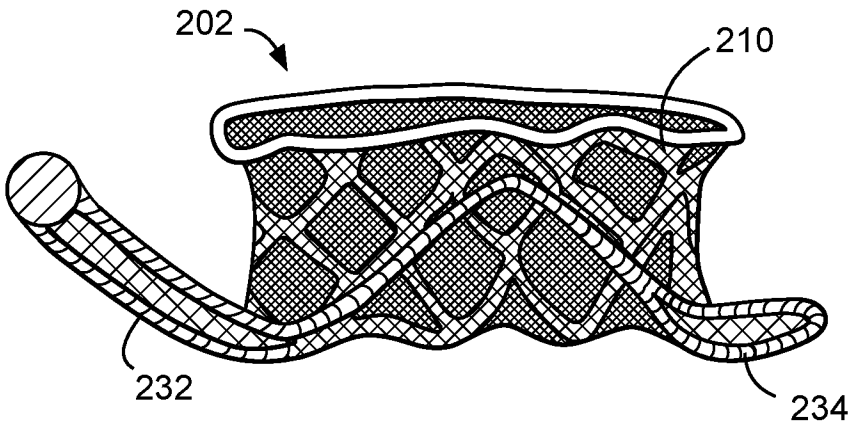


FIG. 3

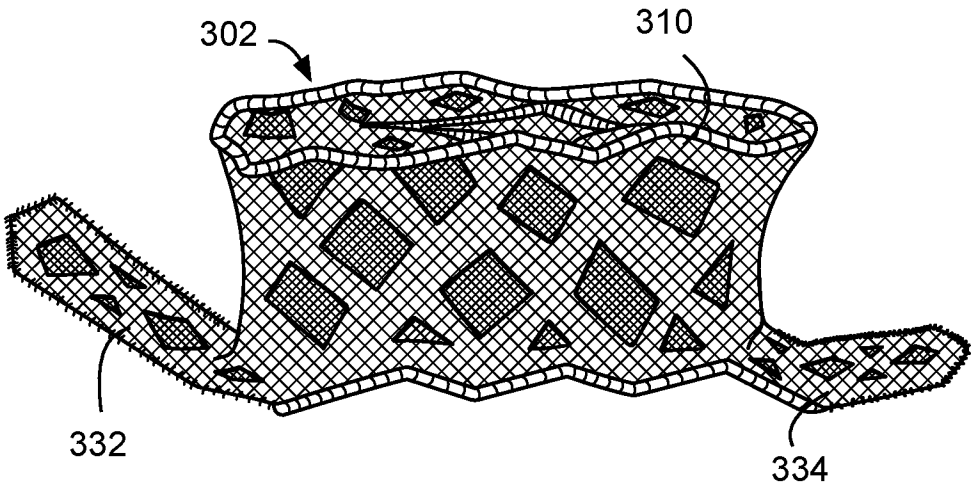


FIG. 4

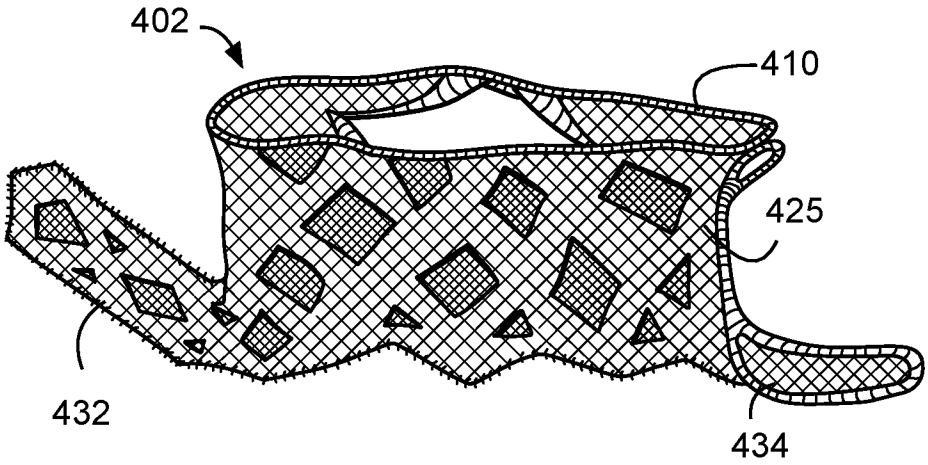


FIG. 5

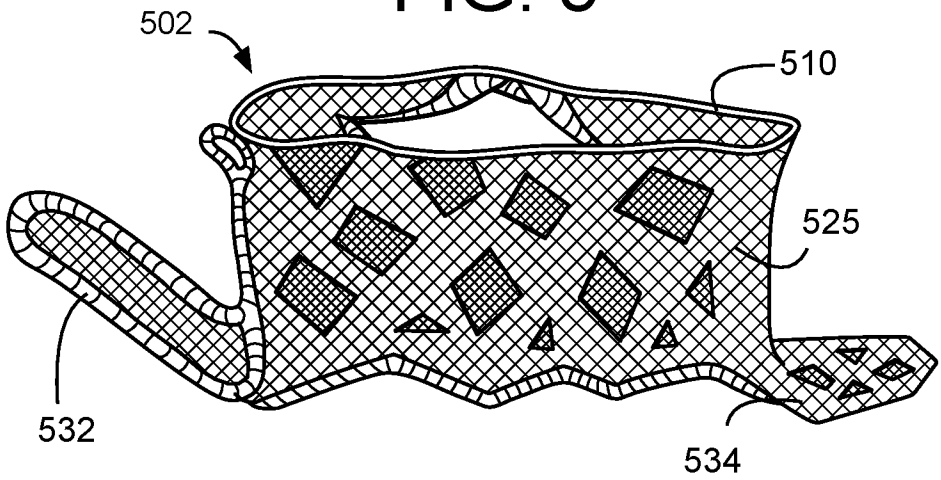


FIG. 6

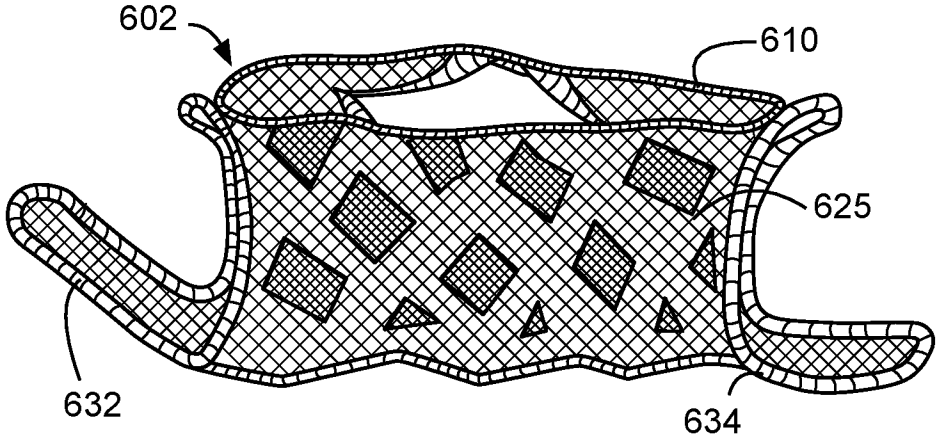


FIG. 7A

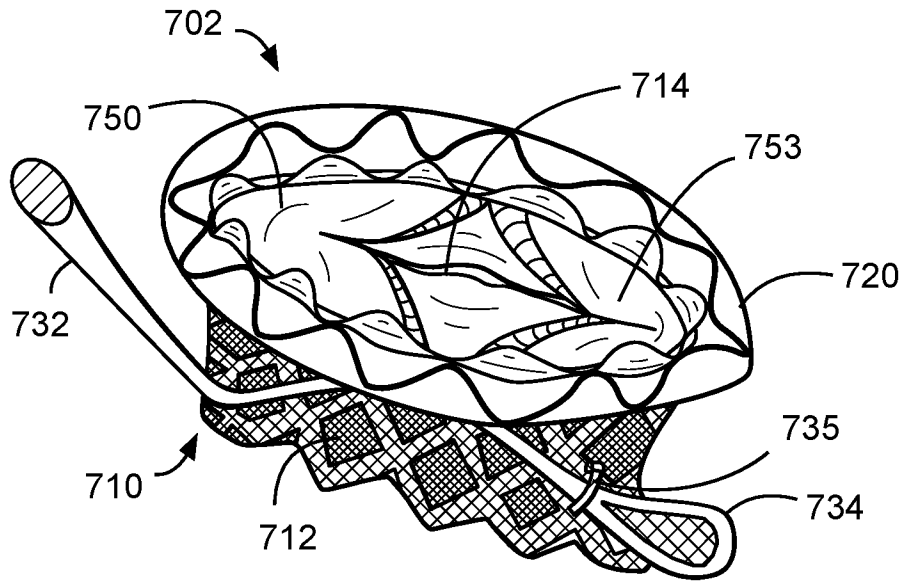


FIG. 7B

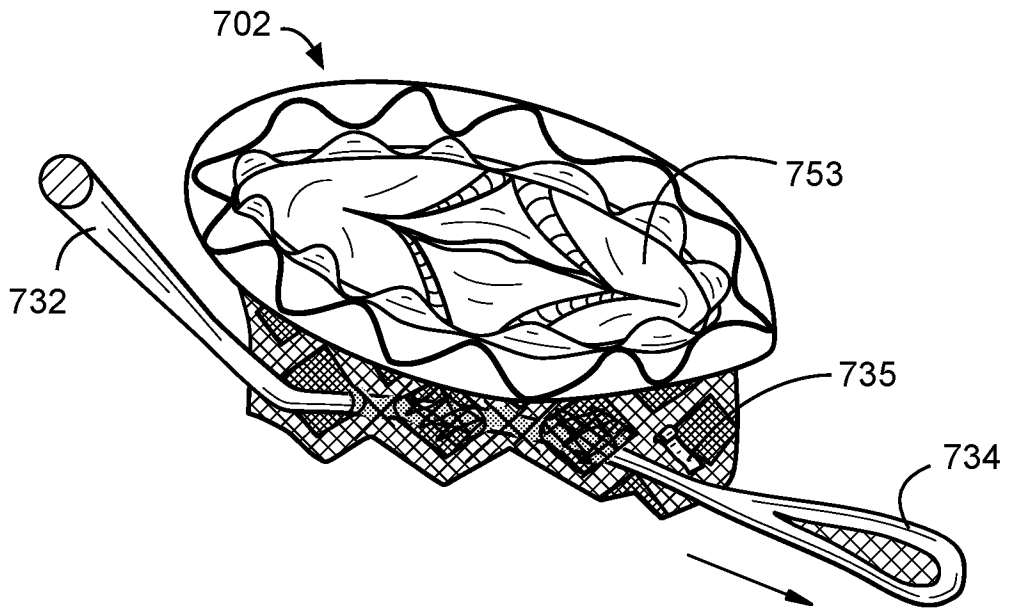


FIG. 8

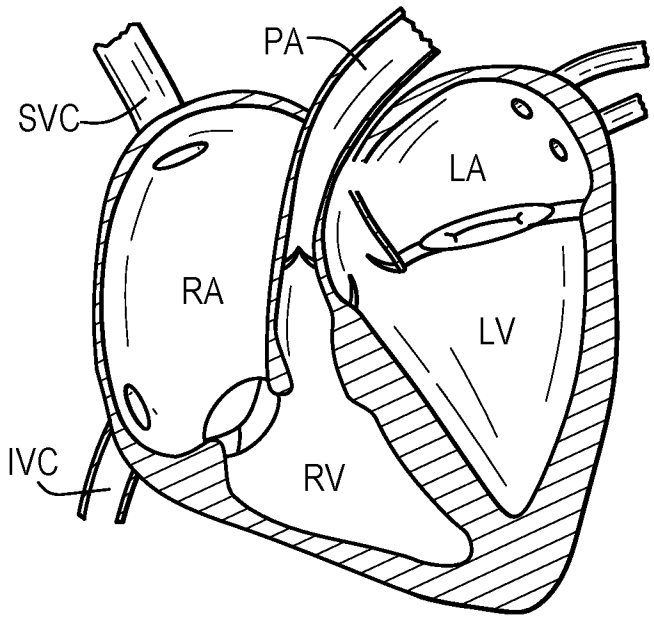


FIG. 9A

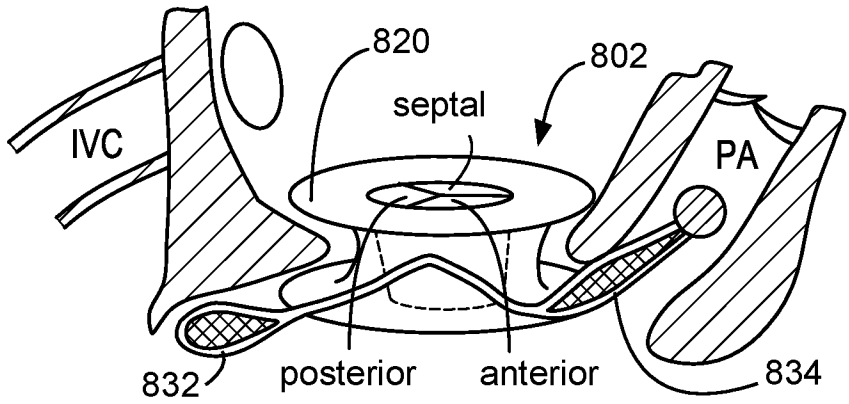


FIG. 9B

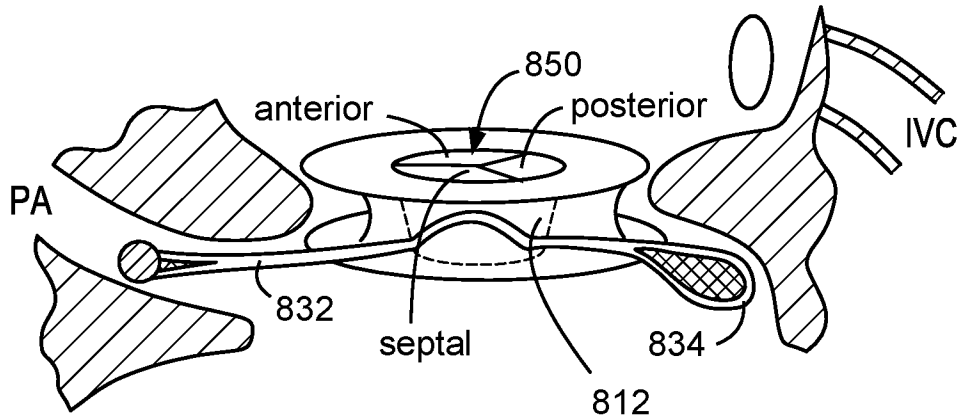


FIG. 10A

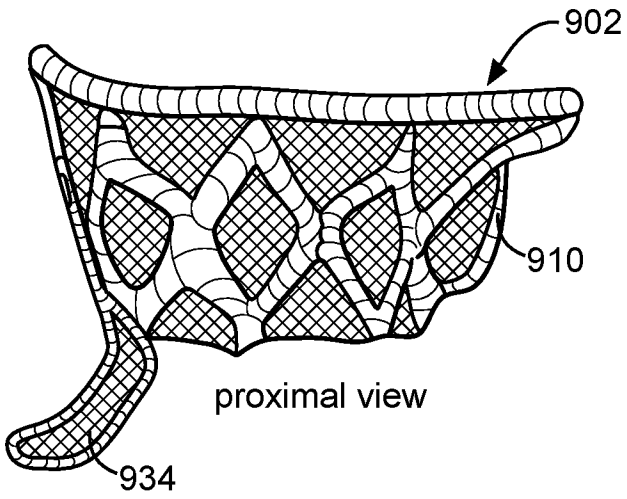


FIG. 10B

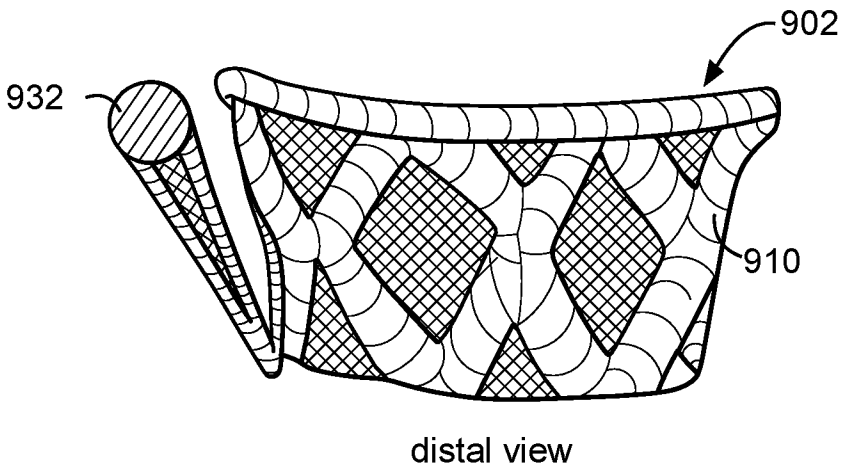


FIG. 11A

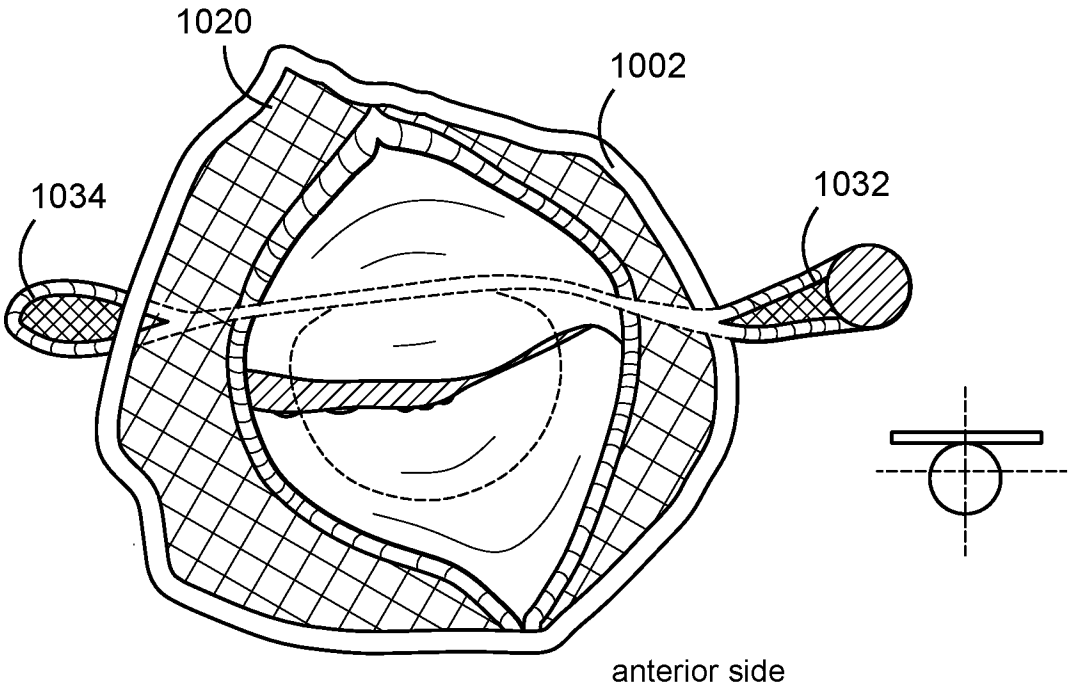


FIG. 11B

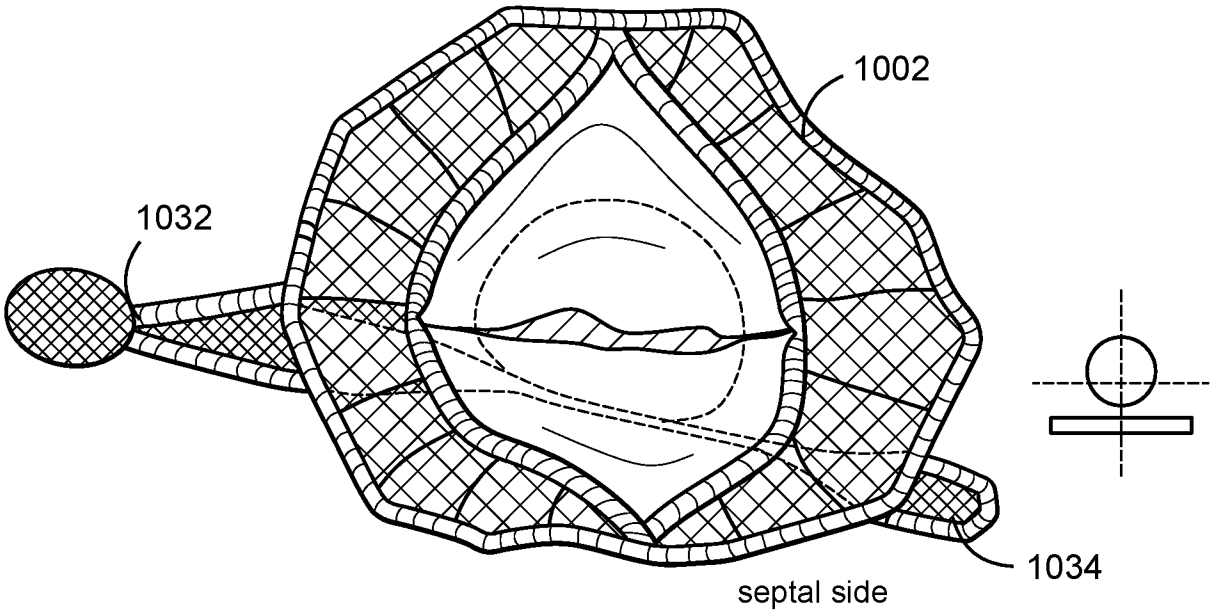


FIG. 12

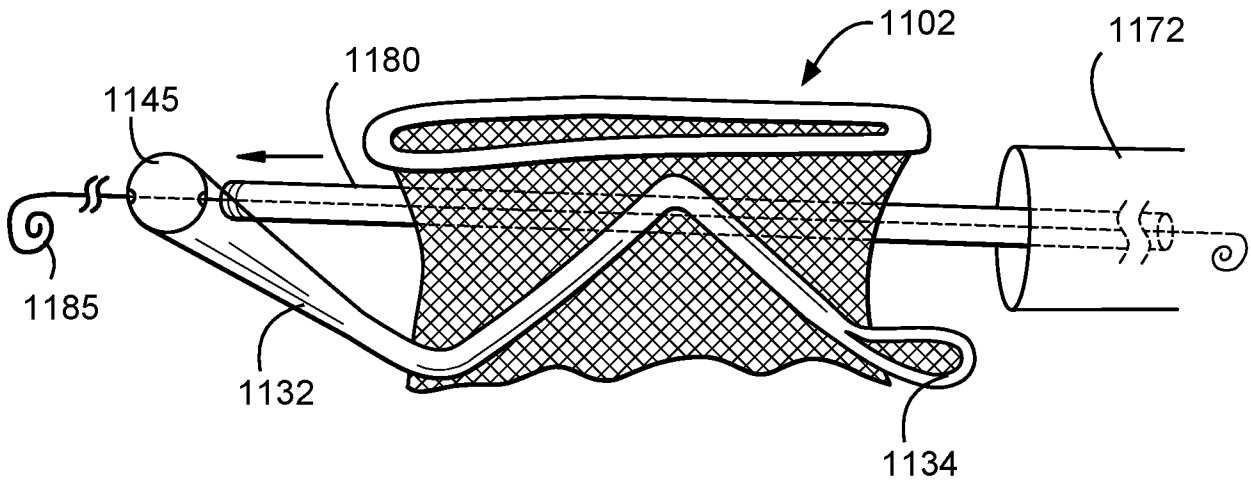


FIG. 13A

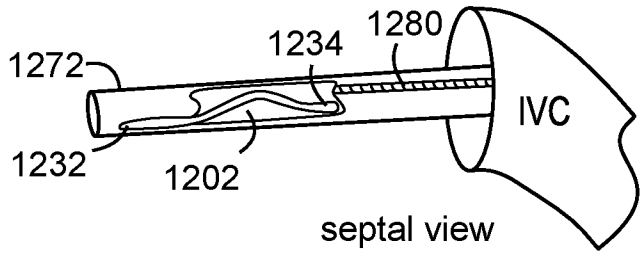


FIG. 13B

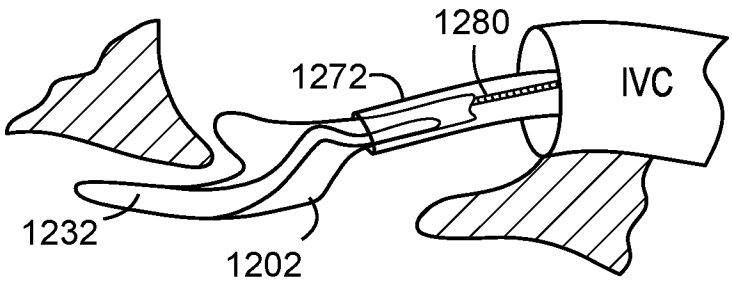


FIG. 13C

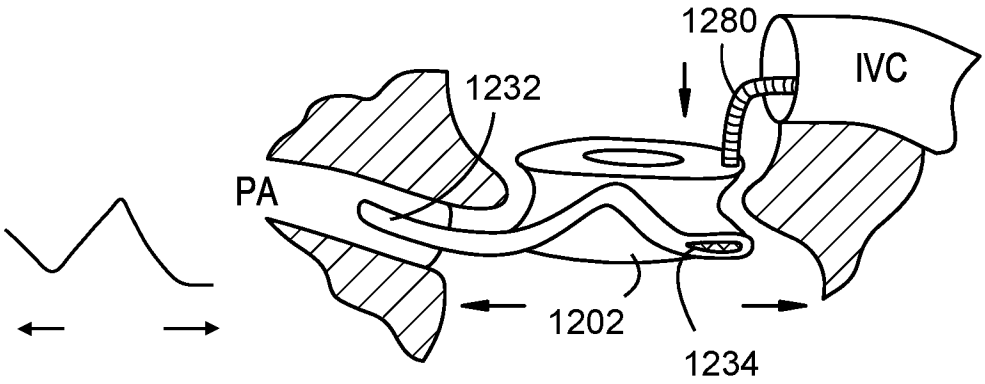


FIG. 13D

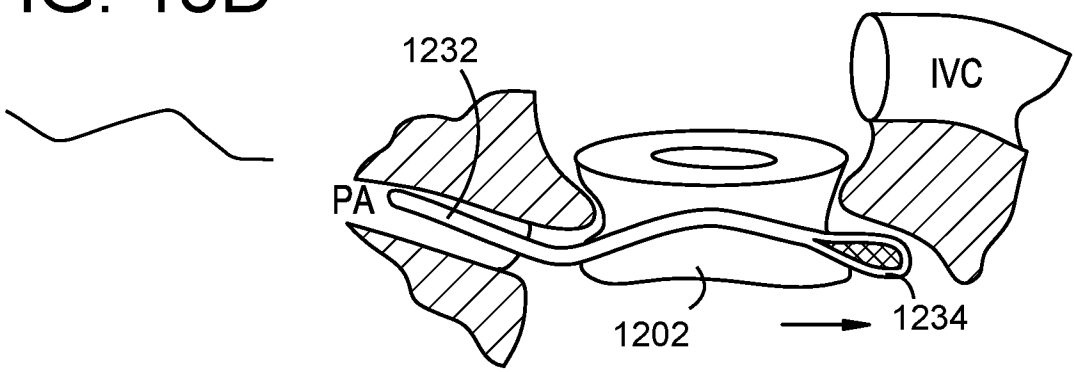


FIG. 14A

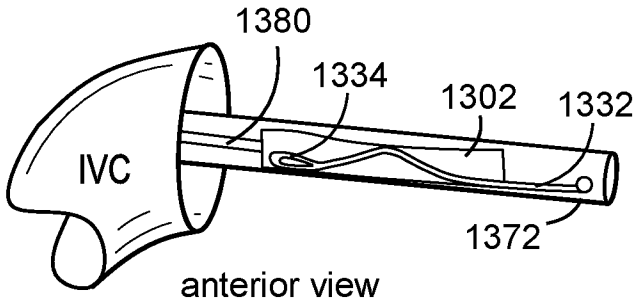


FIG. 14B

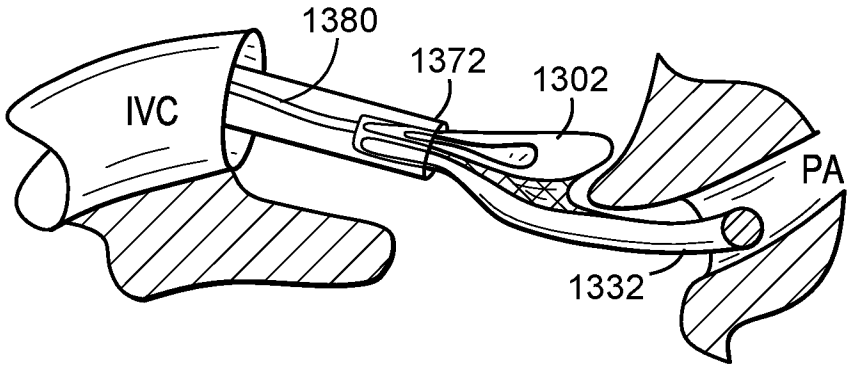


FIG. 14C

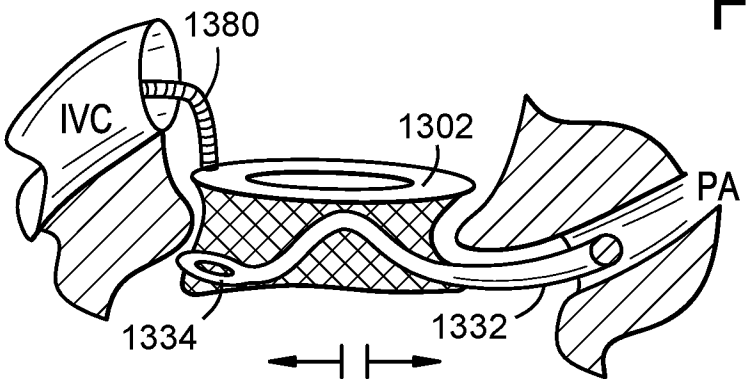


FIG. 14D

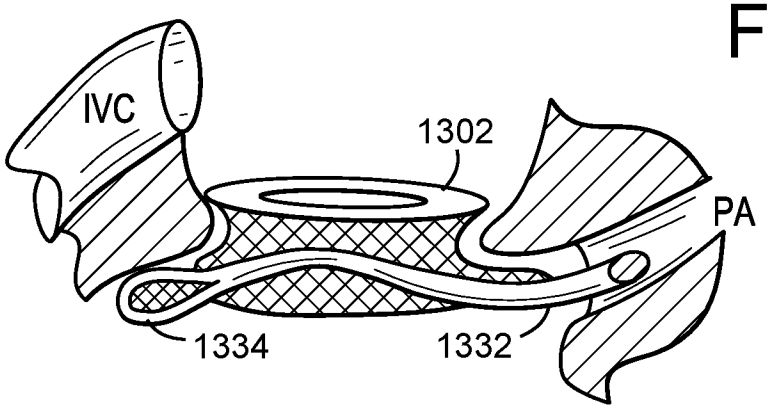


FIG. 15A

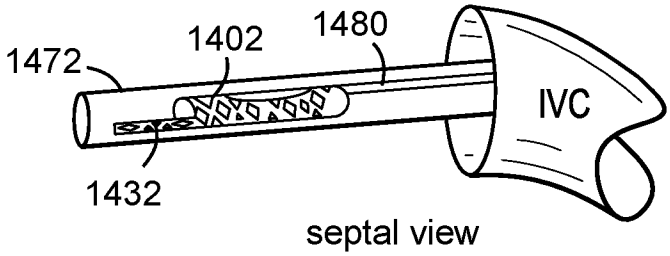


FIG. 15B

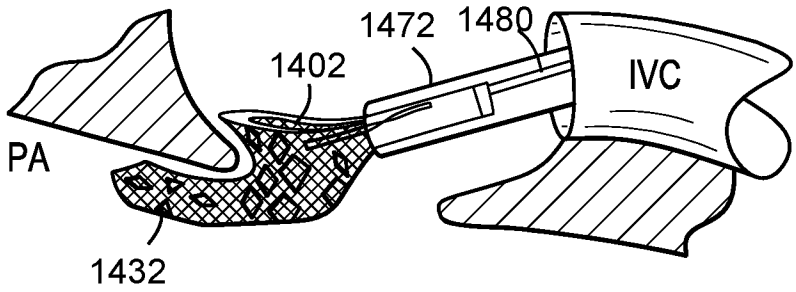


FIG. 15C

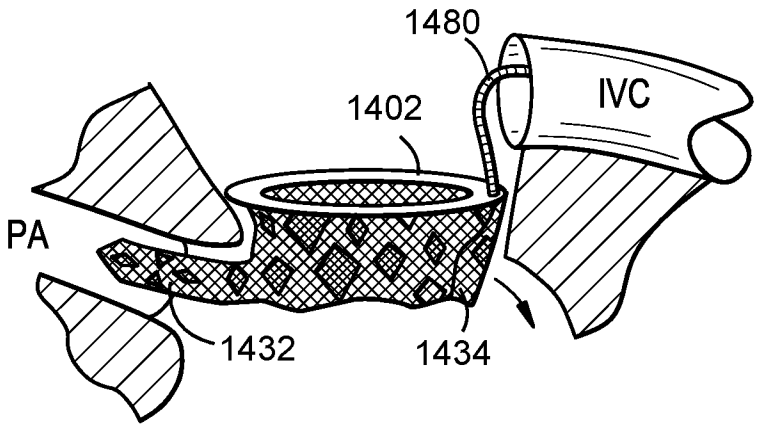


FIG. 15D

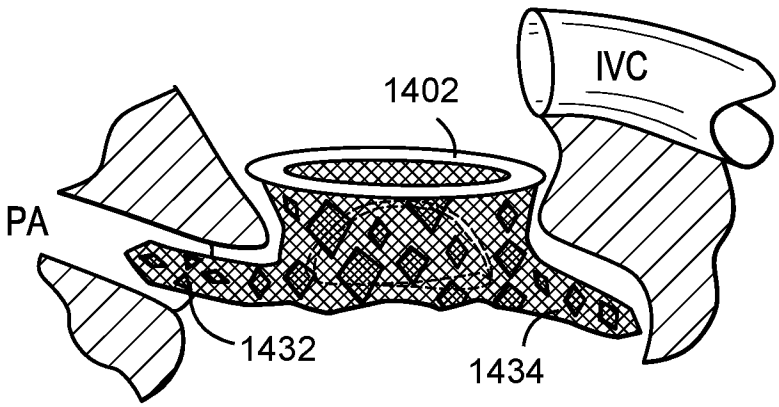


FIG. 16A

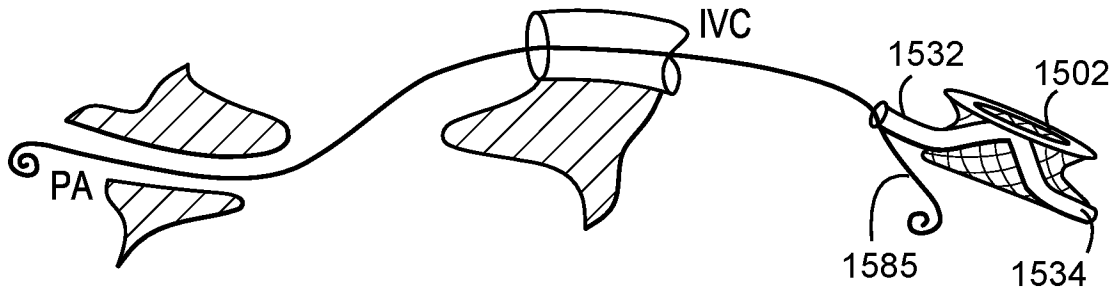


FIG. 16B

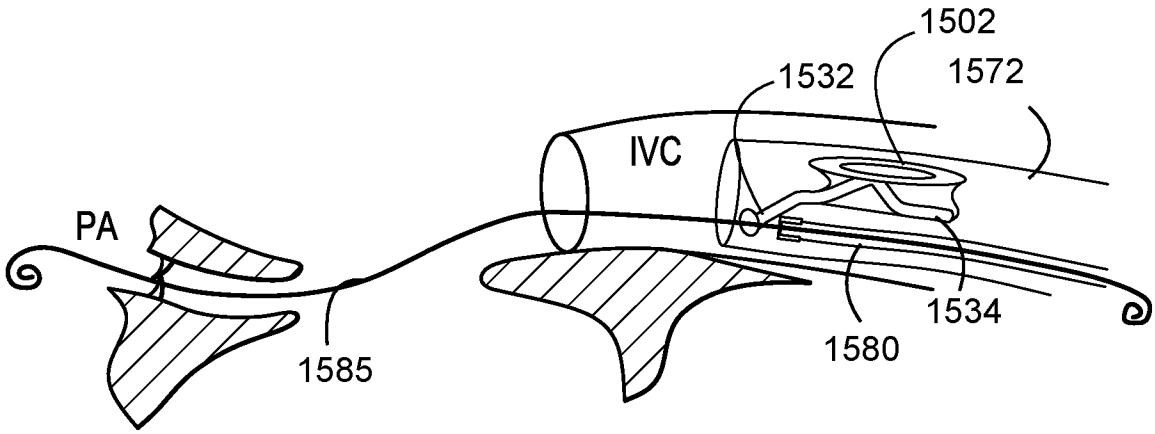


FIG. 16C

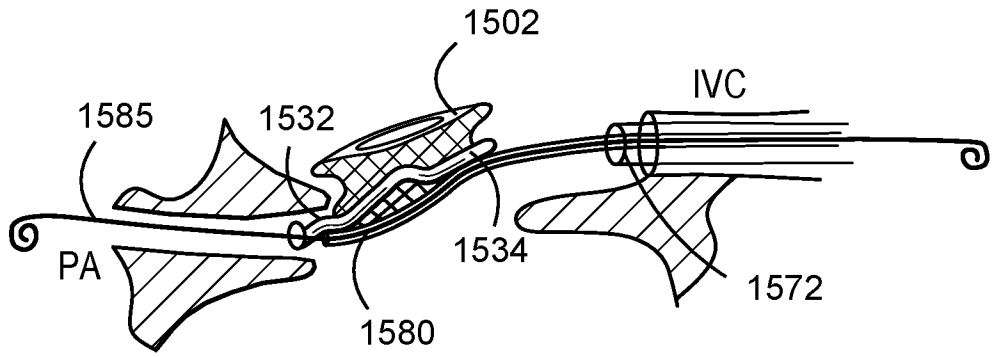


FIG. 16D

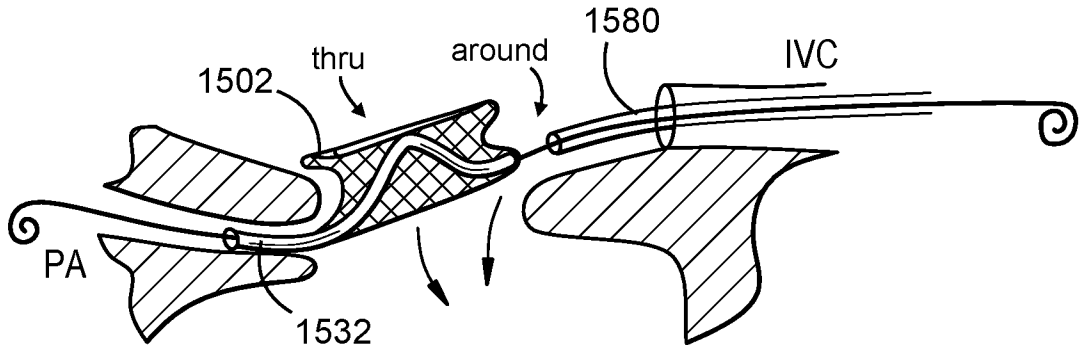


FIG. 16E

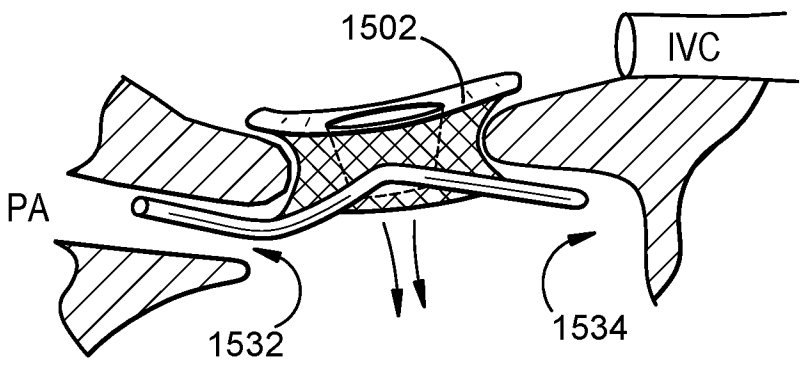


FIG. 17A

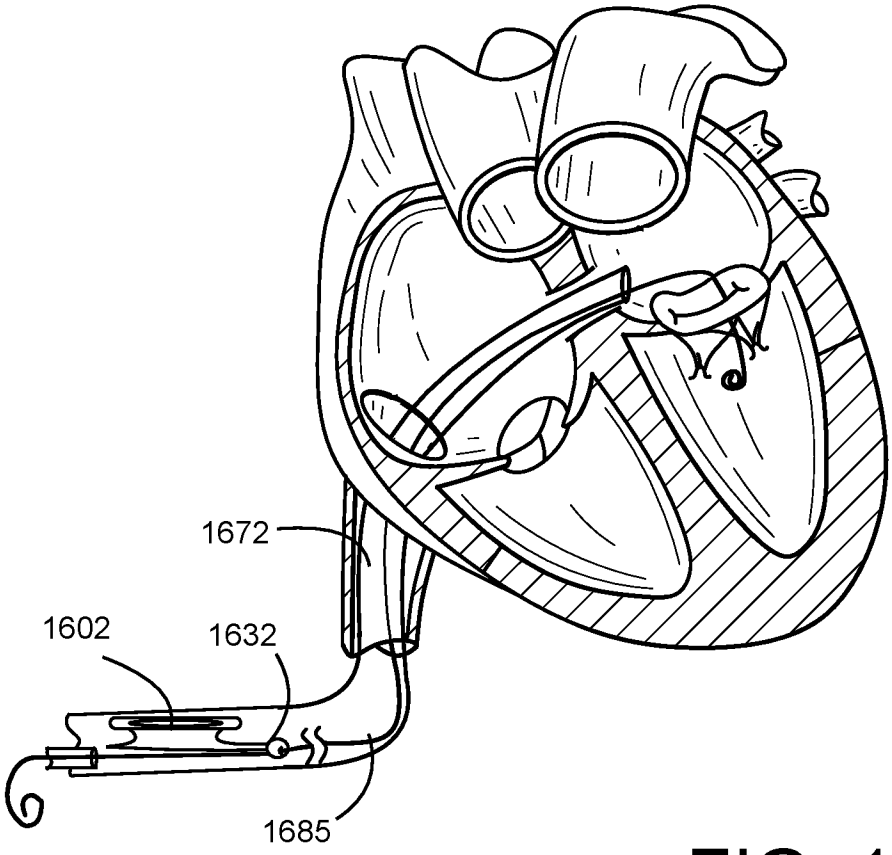


FIG. 17B

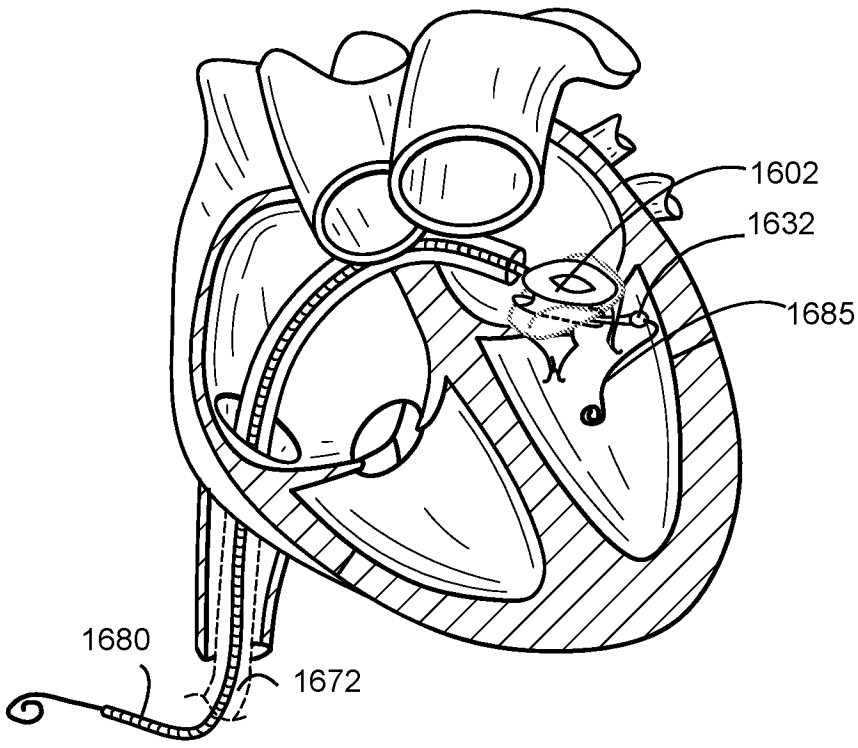


FIG. 17C

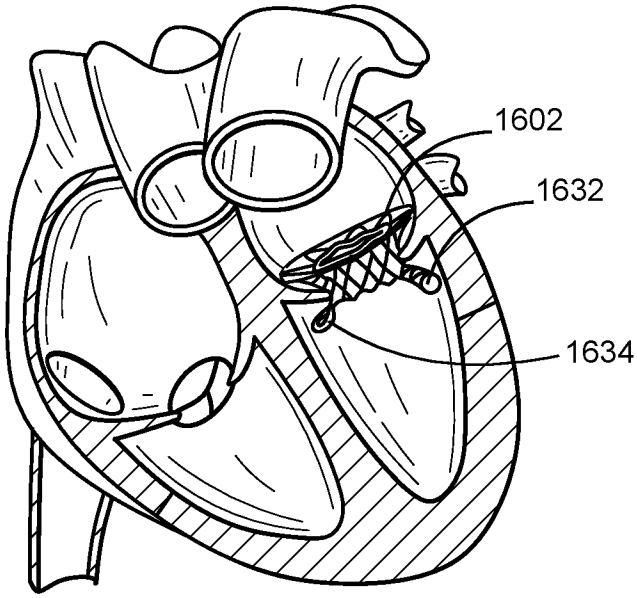


FIG. 17D

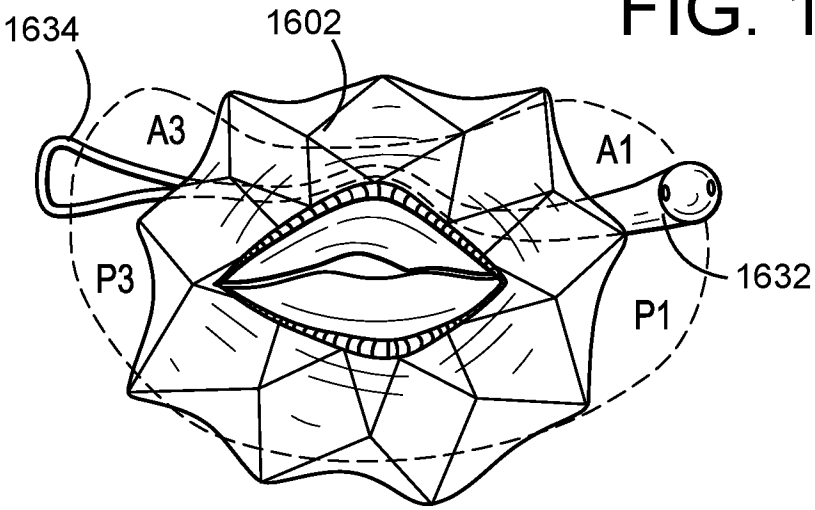


FIG. 17E

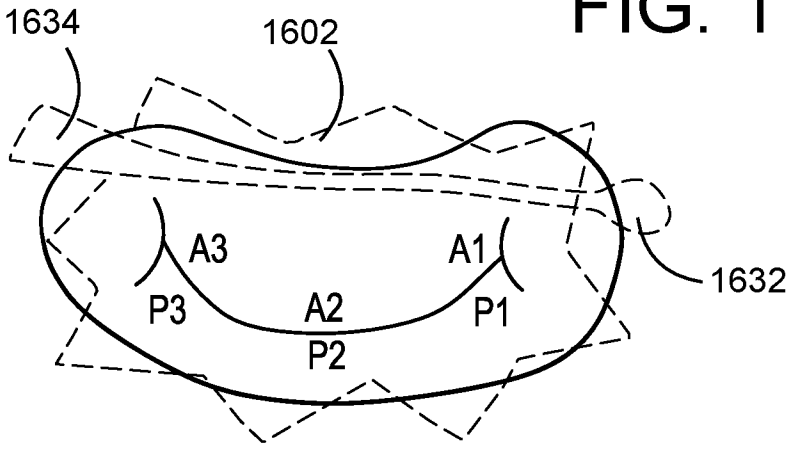


FIG. 18A

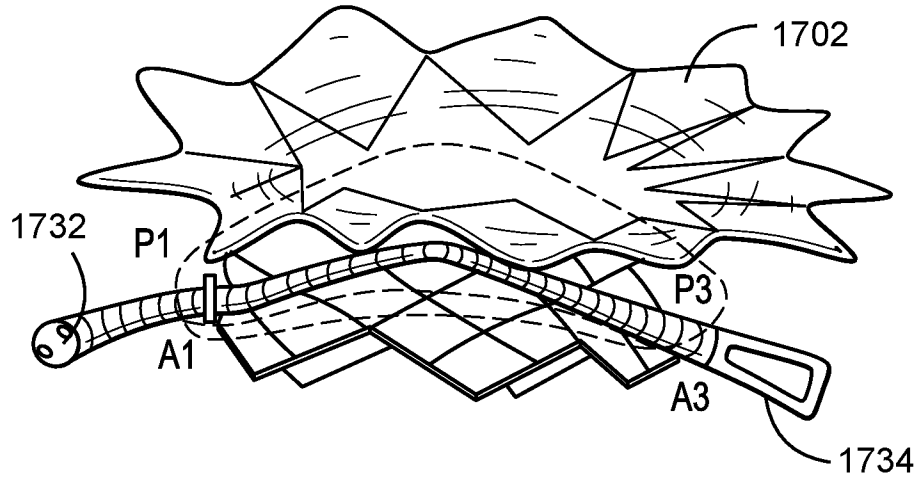


FIG. 18B

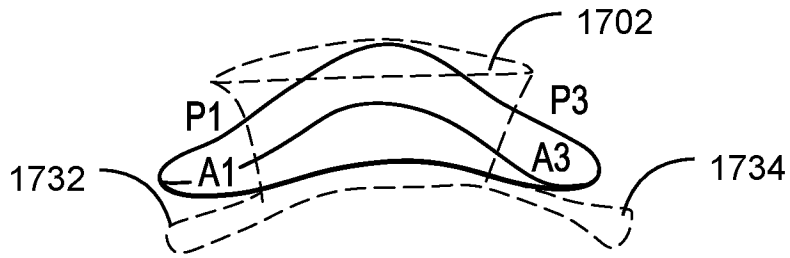


FIG. 19A

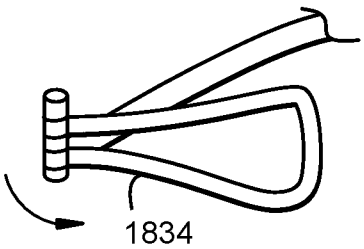


FIG. 20A

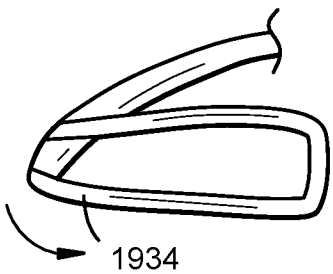


FIG. 19B

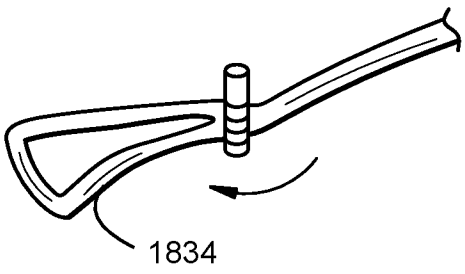


FIG. 20B

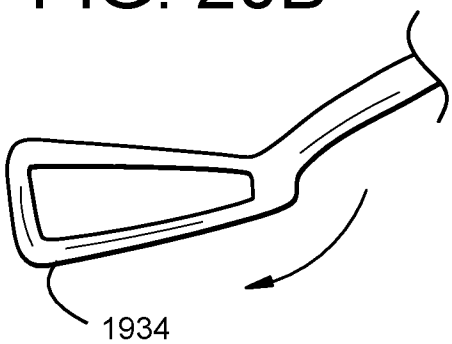


FIG. 21A

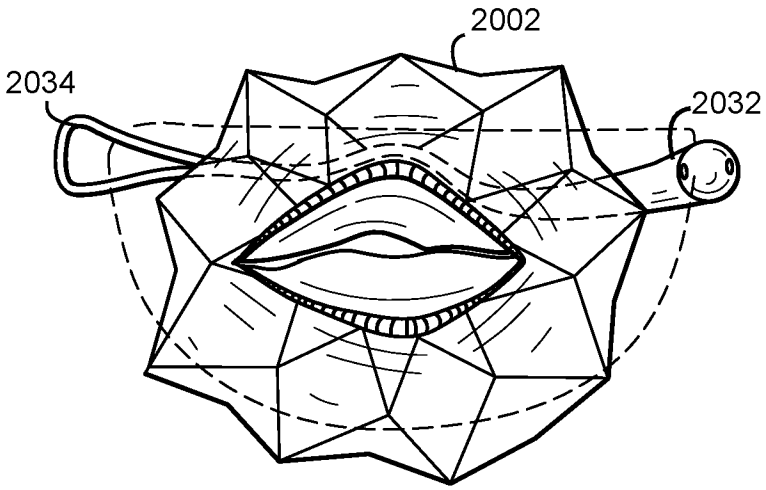


FIG. 21B

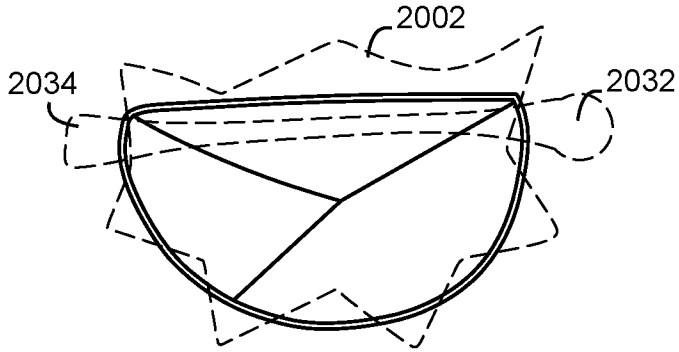


FIG. 22

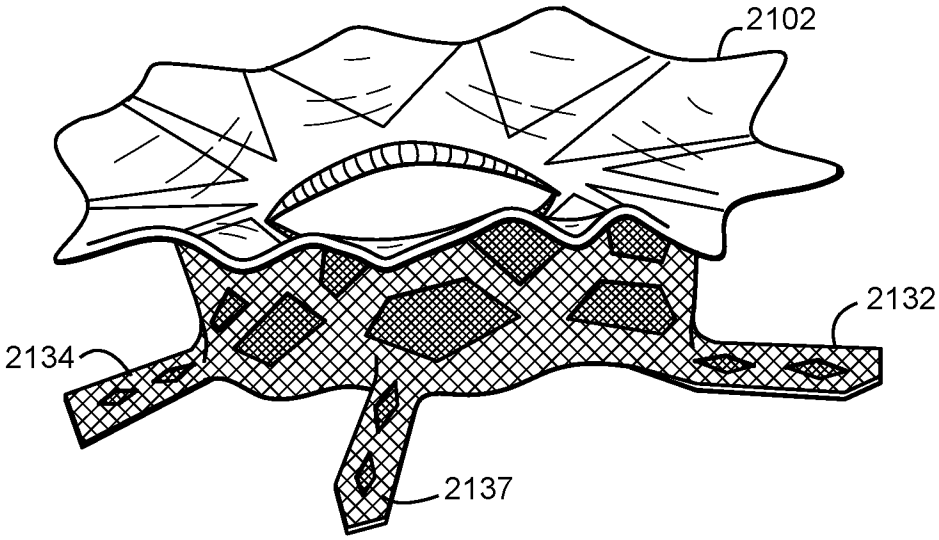


FIG. 23A

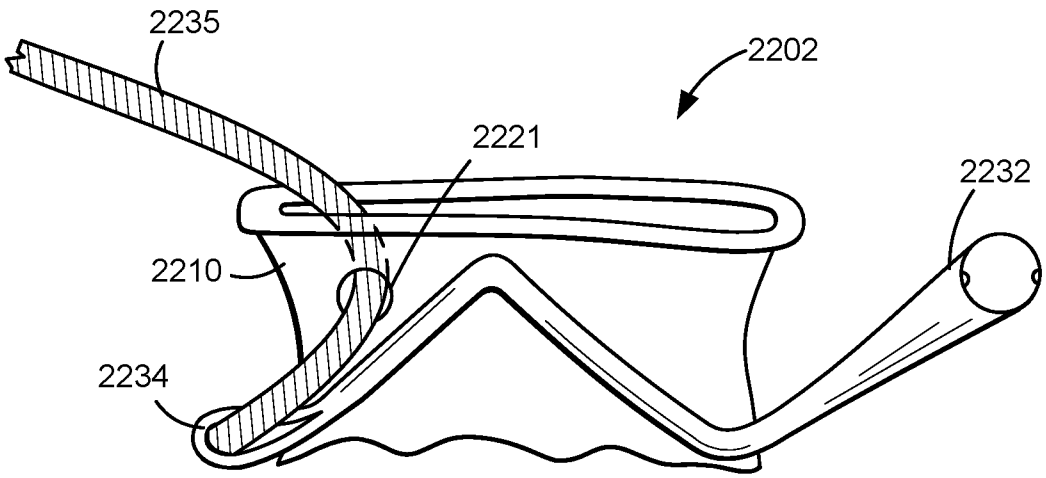


FIG. 23B

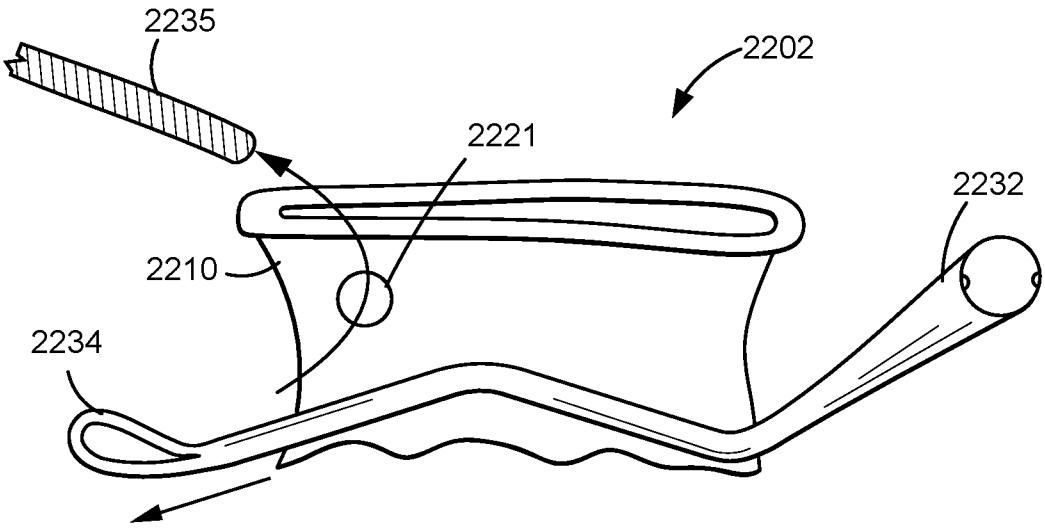


FIG. 24

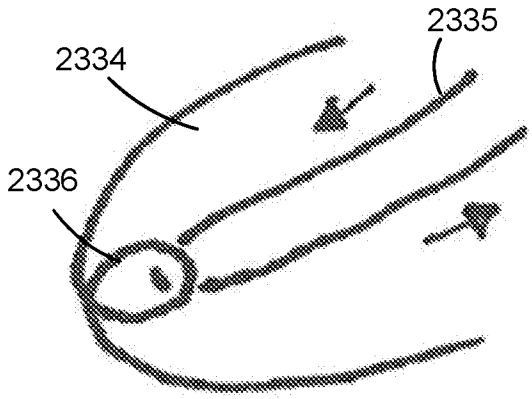


FIG. 25

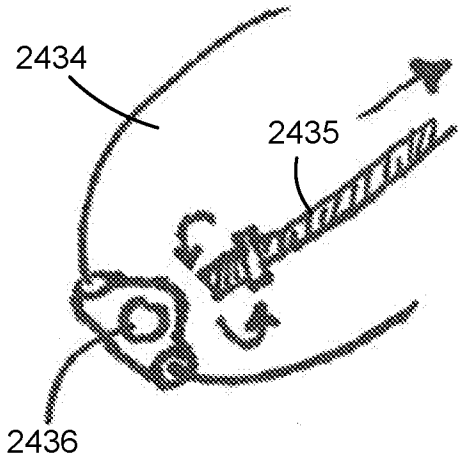


FIG. 26

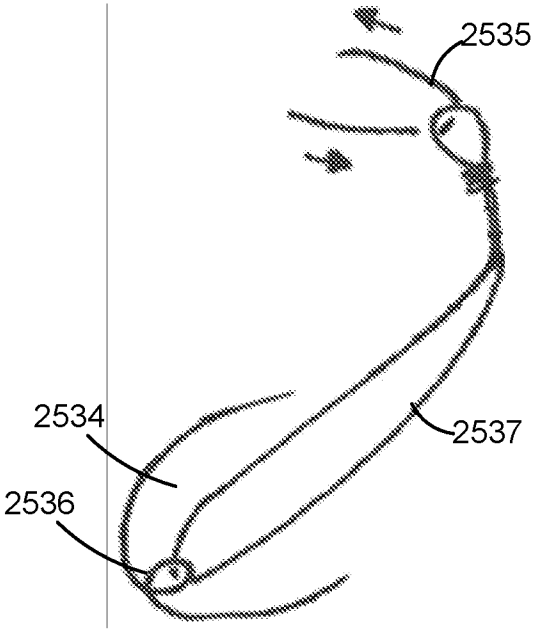


FIG. 27

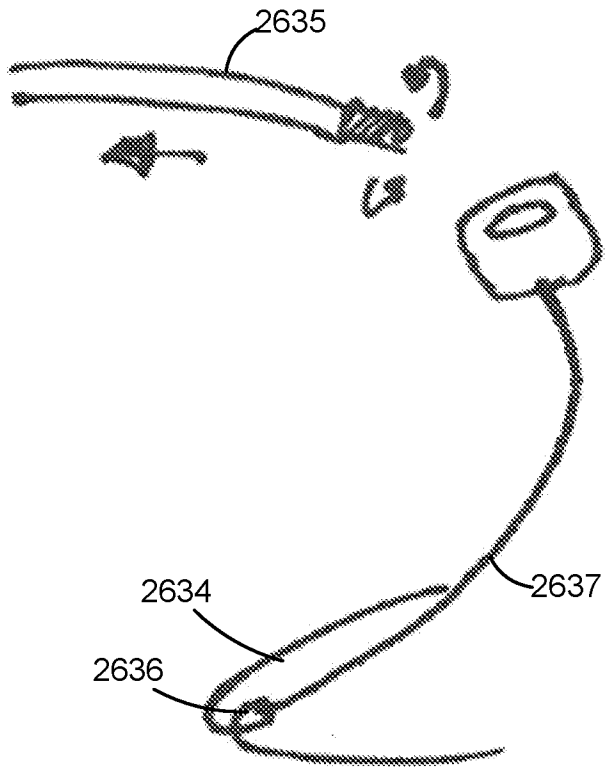


FIG. 28A

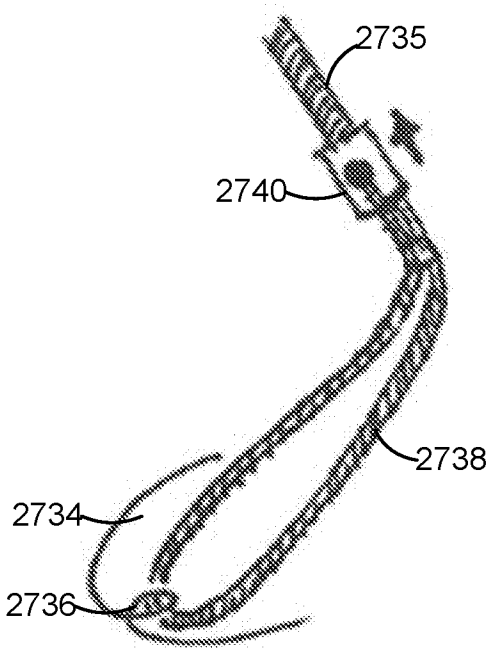
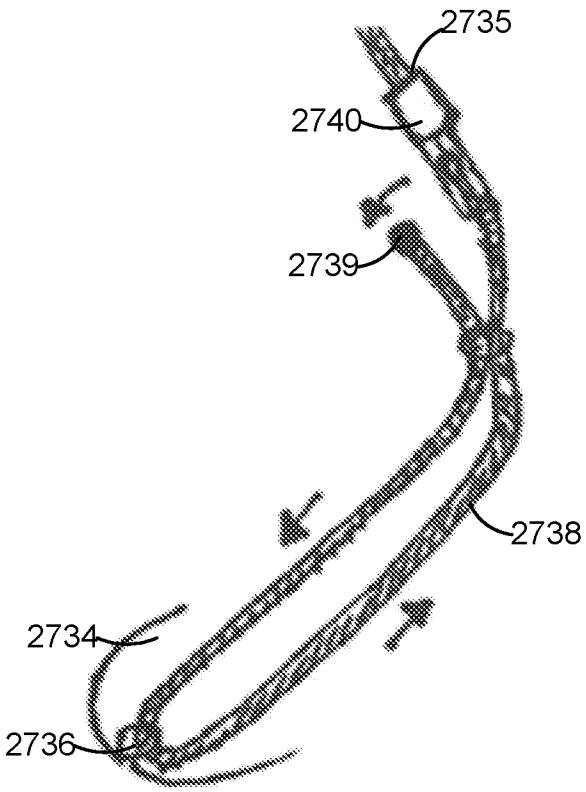


FIG. 28B



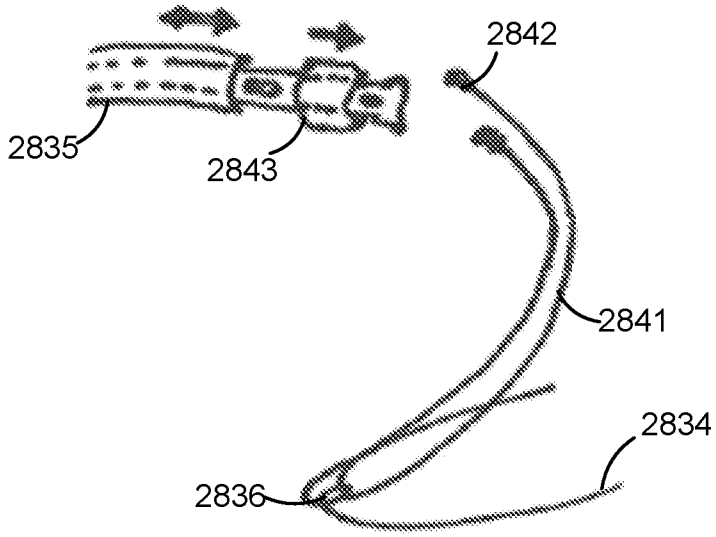


FIG. 29A

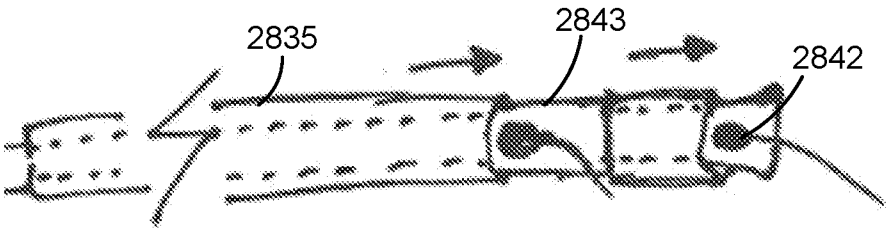


FIG. 29B

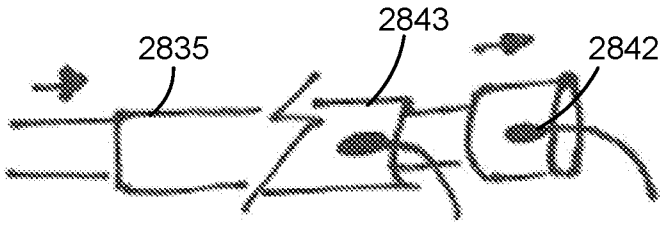


FIG. 29C

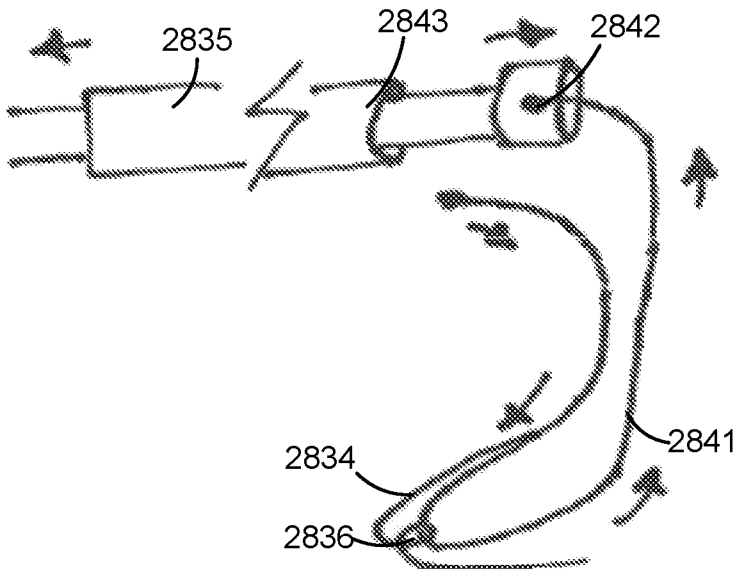


FIG. 29D

FIG. 30

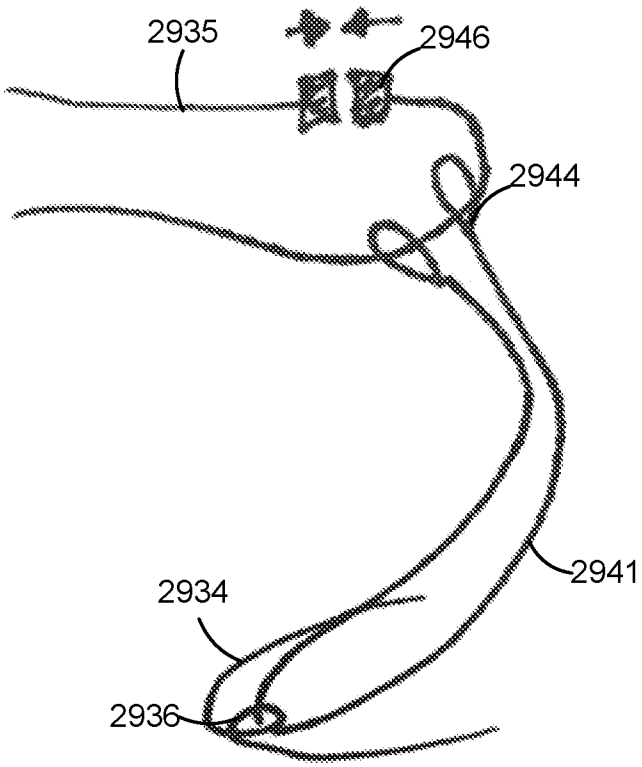


FIG. 31A

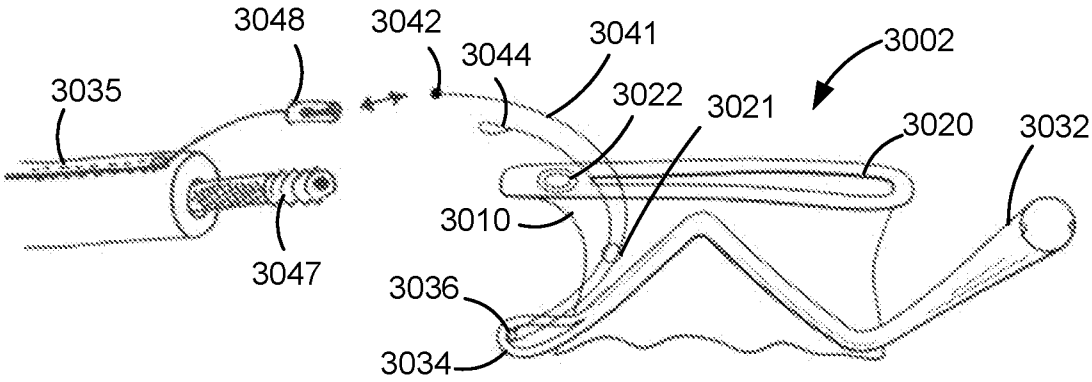


FIG. 31B

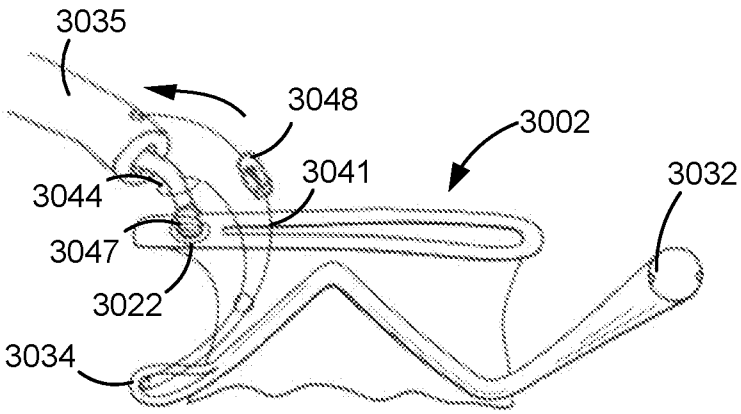


FIG. 31C

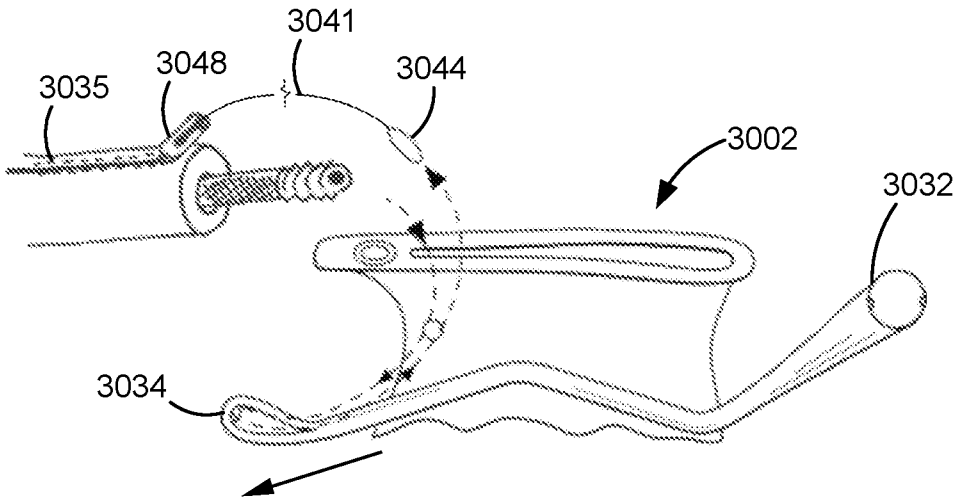


FIG. 32

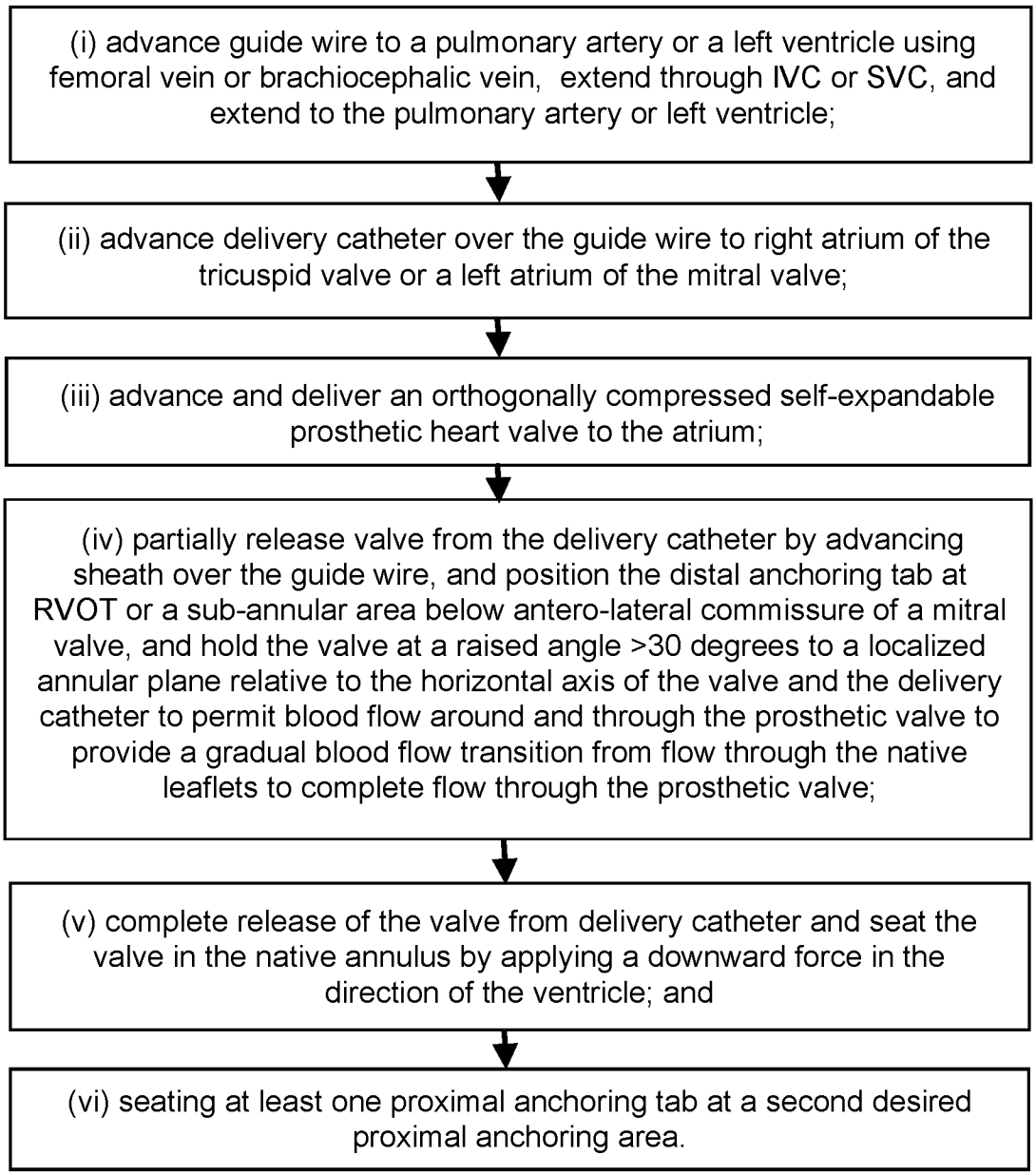
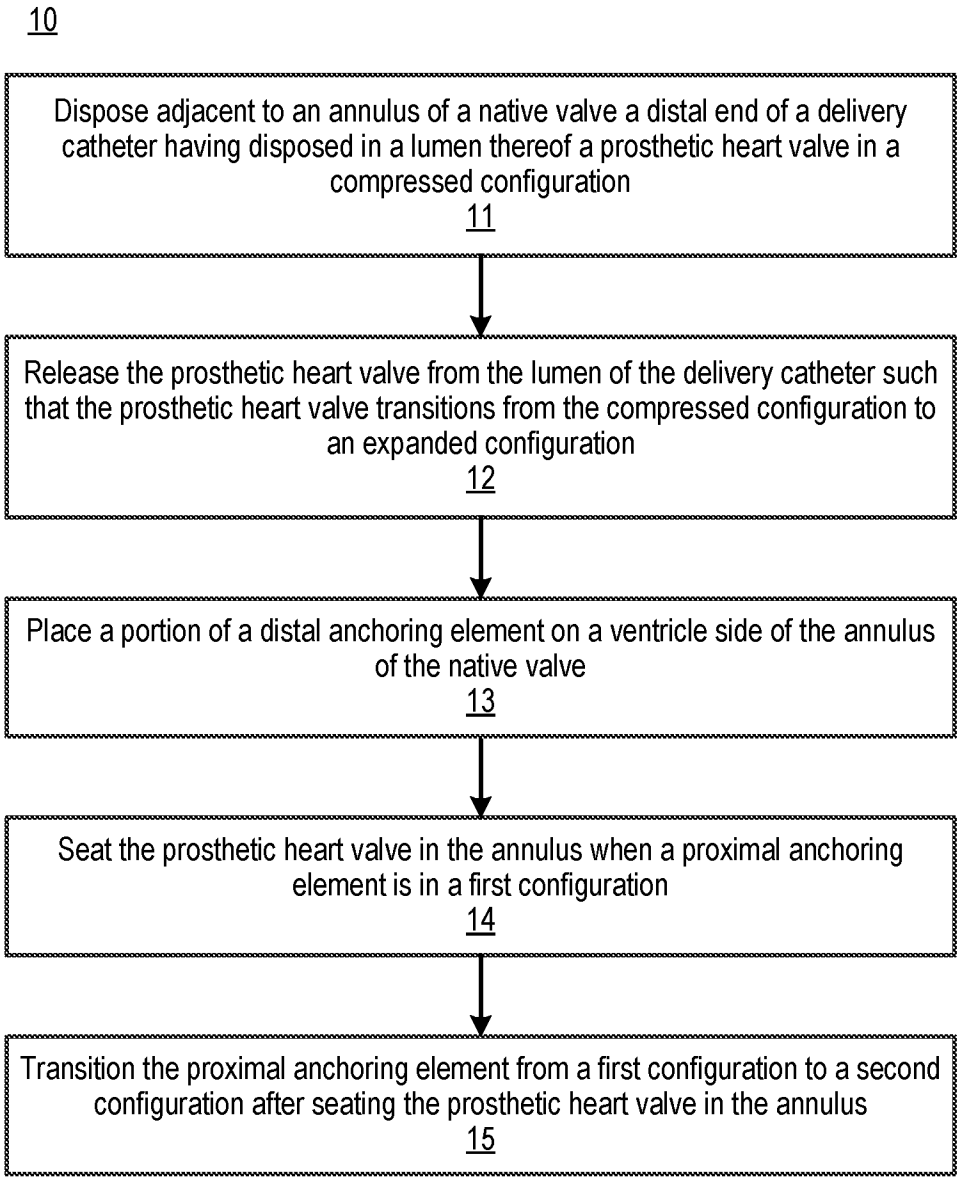

(i) advance guide wire to a pulmonary artery or a left ventricle using femoral vein or brachiocephalic vein, extend through IVC or SVC, and extend to the pulmonary artery or left ventricle;
(ii) advance delivery catheter over the guide wire to right atrium of the tricuspid valve or a left atrium of the mitral valve;
(iii) advance and deliver an orthogonally compressed self-expandable prosthetic heart valve to the atrium;
(iv) partially release valve from the delivery catheter by advancing sheath over the guide wire, and position the distal anchoring tab at RVOT or a sub-annular area below antero-lateral commissure of a mitral valve, and hold the valve at a raised angle >30 degrees to a localized annular plane relative to the horizontal axis of the valve and the delivery catheter to permit blood flow around and through the prosthetic valve to provide a gradual blood flow transition from flow through the native leaflets to complete flow through the prosthetic valve;
(v) complete release of the valve from delivery catheter and seat the valve in the native annulus by applying a downward force in the direction of the ventricle; and
(vi) seating at least one proximal anchoring tab at a second desired proximal anchoring area.

FIG. 33


10
Dispose adjacent to an annulus of a native valve a distal end of a delivery catheter having disposed in a lumen thereof a prosthetic heart valve in a compressed configuration
11
Release the prosthetic heart valve from the lumen of the delivery catheter such that the prosthetic heart valve transitions from the compressed configuration to an expanded configuration
12
Place a portion of a distal anchoring element on a ventricle side of the annulus of the native valve
13
Seat the prosthetic heart valve in the annulus when a proximal anchoring element is in a first configuration
14
Transition the proximal anchoring element from a first configuration to a second configuration after seating the prosthetic heart valve in the annulus
15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/67010

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61F 2/24, A61F 2/07 (2020.01)

CPC - A61F 2/2427, A61F 2/2412, A61F 2/2418, A61F 2/2409, A61F 2/0401, A61F 2/2427, A61B 17/0401

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017/0325948 A1 (WALLACE, D et al.) 16 November 2017; paragraph [0072]	1-3
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A		40-59
X	US 2018/0147055 A1 (TENDYNE HOLDINGS, INC.) 31 May 2018; paragraph [0392]	15-17, 28-30
---		---
A		40-59
A	US 2014/0121763 A1 (MEDTRONIC VASCULAR GALWAY LIMITED) 01 May 2014; paragraph [0028]	40-59

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 February 2020 (17.02.2020)	10 MAR 2020
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/67010

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-14, 18-27, 31-39
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.