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(54) Title: PROSTHETIC VALVE FOR AVOIDING OBSTRUCTION OF OUTFLOW

(57) Abstract: A prosthetic mitral valve may be anchored in a native mitral valve. The prosthetic mitral valve preferably has a large anterior prosthetic leaflet that spans the entire width of the native anterior leaflet and the anterior prosthetic leaflet moves away from left ventricular outflow tract during systole to create a clear unobstructed outflow path.

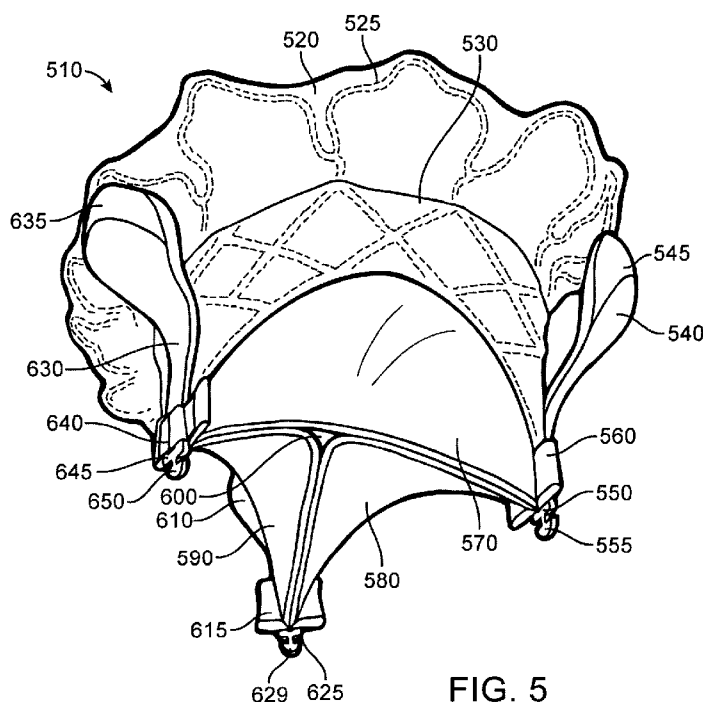


FIG. 5



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PROSTHETIC VALVE FOR AVOIDING OBSTRUCTION OF OUTFLOW

CROSS-REFERENCE

[0001] The present application claims priority to United States Provisional Patent Application Number 62/288,987, filed January 29, 2016.

[0002] The present application is related to: United States Patent Number 8,579,964, filed April 28, 2011; US Patent Publication Number 2015/0216655, filed April 13, 2015; United State Patent Publication Number 2015/0257878, filed April 21, 2015; United States Patent Publication Number 2014/0039611, filed October 4, 2013; United States Patent Publication Number 2013/0211508, filed November 16, 2012; United States Patent Publication Number 2014/0052237, filed February 8, 2013; United States Patent Publication Number 2014/0155990, filed May 5, 2013; United States Patent Publication Number 2014/0257467, filed March 3, 2014; and United States Patent Publication Number 2014/0343669, filed April 1, 2014; the entire contents which are incorporated herein by reference in their entireties for all purposes.

BACKGROUND OF THE INVENTION

[0003] Mitral regurgitation, also known as mitral insufficiency or mitral incompetence, is a heart condition in which the mitral valve does not close properly. This results in abnormal leakage of blood retrograde from the left ventricle through the mitral valve back upstream into the atrium. Persistent mitral regurgitation can result in congestive heart failure. Traditional surgical repair of the valve generally results in a good clinical outcome but requires open heart surgery and a lengthy and costly hospital stay with an extended recovery period. More recently, minimally invasive procedures have been developed to deliver a prosthetic heart valve percutaneously over a catheter through the patient's vasculature to the heart. Alternatively, a transapical procedure is used to introduce the prosthesis through the chest wall and through the apex of the heart. An exemplary prosthesis includes that described in US Patent No. 8,579,964, the entire contents of which are incorporated herein by reference in their entirety for all purposes. These prostheses and delivery procedures appear to be promising, but in certain circumstances they may obstruct blood flow, cause blood flow through the prosthesis to be turbulent, or disrupt the natural flow path, thereby potentially resulting in hemodynamic problems. Therefore, it would be desirable to provide improved devices, systems, and methods that avoid obstructing blood outflow and that maintain the natural flow path and natural hemodynamics. At least some of these objectives may be met by the exemplary embodiments described herein.

SUMMARY OF THE INVENTION

[0004] The present invention generally relates to medical systems, devices, and methods, and more particularly relates to prosthetic heart valves that may be used to repair a valve such as a mitral valve, a heart valve, or any other valve.

[0005] In a first aspect, a prosthetic heart valve for implantation in a native mitral valve of a patient comprises a radially expandable anchor frame having an expanded configuration and a collapsed configuration. The heart valve also comprises a prosthetic valve coupled to the anchor frame. The prosthetic valve comprises a plurality of prosthetic valve leaflets each having a free end and a fixed end, with the fixed end coupled to the anchor frame, and the free ends of the plurality of prosthetic valve leaflets have an open configuration and a closed configuration. In the open configuration, the free ends are disposed away from one another to allow antegrade blood flow therethrough, and in the closed configuration the free ends are disposed adjacent one another to substantially prevent retrograde blood flow therethrough. The prosthetic mitral valve is configured to direct blood flow passing through the prosthetic valve in a non-turbulent manner and circular direction along a posterior wall of the patient's left ventricle towards the apex of the heart and upward along a septal wall until it is ejected out the left ventricular outflow tract during systole.

[0006] The blood flow substantially maintains momentum and conserves energy as it flows through the prosthetic mitral valve and left ventricle and out the left ventricular outflow tract. The blood flow is indirectly directed to the apex of the heart or the septal wall.

[0007] The plurality of prosthetic valve leaflets may comprise an anterior prosthetic leaflet that is sized to span the entire width of the native anterior leaflet. In systole, the anterior prosthetic leaflet may deflect away from the left ventricular outflow tract to provide a clear unobstructed outflow path for the blood flow.

[0008] In another aspect, a prosthetic heart valve for implantation in a native mitral valve of a patient comprises a radially expandable anchor frame having an expanded configuration and a collapsed configuration. The prosthetic heart valve also comprises a prosthetic valve coupled to the anchor frame that comprises a plurality of prosthetic valve leaflets each having a free end and a fixed end. The fixed end is coupled to the anchor frame, and the free ends of the plurality of prosthetic valve leaflets have an open configuration and a closed configuration. In the open configuration the free ends are disposed away from one another to allow antegrade blood flow therethrough, and in the closed configuration the free ends are disposed adjacent one another to substantially prevent retrograde blood flow therethrough. The plurality of prosthetic valve leaflets comprise an anterior prosthetic leaflet sized to span the entire

width of the native anterior leaflet. In systole, the anterior prosthetic leaflet deflects away from the left ventricular outflow tract to provide a clear unobstructed outflow path.

[0009] The prosthetic heart valve may be configured to direct blood flow through the prosthetic valve in a non-turbulent manner and blood flow is preferably directed in a circular direction along a posterior wall of the patient's left ventricle towards the apex of the heart and upward along a septal wall until it is ejected out the left ventricular outflow tract. The blood flow preferably substantially maintains momentum and conserves energy as it flows through the prosthetic heart valve and left ventricle and out the left ventricular outflow tract.

[0010] In any aspect, the anchor frame may comprise an anterior anchoring tab configured to anchor on a fibrous trigone of the native mitral valve or on any tissue anterior of the anterior native leaflet and adjacent thereto. The anchor frame may also comprise a second anterior anchoring tab that is configured to anchor on a second fibrous trigone of the native mitral valve or any tissue anterior of the anterior native leaflet and adjacent thereto. The anchor frame may comprise a D-shaped cross-section having a substantially flat anterior portion and a cylindrically shaped posterior portion. The flat anterior portion prevents impingement of the prosthetic heart valve on the left ventricular outflow tract, and the cylindrically shaped portion engages the posterior portion of the native mitral valve. The anchor frame may also comprise one or more commissure posts, and an anterior anchoring tab. The one or more commissure posts may have a free end and an opposite end coupled to the anchor frame. The plurality of commissure posts may be coupled to the plurality of prosthetic valve leaflets, and the anterior anchoring tab may be configured to anchor on a fibrous trigone of the native mitral valve or on any tissue anterior of the anterior native valve leaflet and adjacent thereto. The anterior anchoring tab and the one or more commissure posts may be nested in one another when the anchor frame is in the collapsed configuration. The anterior anchoring tab may originate from a circumferential position on the anchor frame, and the one or more commissure posts also may originate from the same circumferential position on the anchor frame as the anterior anchoring tab. The anterior anchoring tab may originate from the one or more commissure posts, or the one or more commissure posts may originate from the anchoring tab.

[0011] In another aspect, a method of treating a native mitral valve in a patient's heart comprises providing a prosthetic mitral valve, anchoring the prosthetic mitral valve in the native mitral valve, and directing blood flow in a non-turbulent manner. The blood flow is directed through the prosthetic mitral valve in a circular direction along a posterior wall of the patient's left ventricle towards the apex of the heart and upward along a septal wall until it is ejected out the left ventricular outflow tract.

[0012] The method may further comprise substantially maintaining momentum of the blood flow and conserving energy as the blood flows through the prosthetic mitral valve and left ventricle and out the left ventricular outflow tract. Directing the blood flow may comprise indirectly directing the blood flow to the apex of the heart or the septal wall. The prosthetic mitral valve may comprise an anterior prosthetic leaflet spanning the width of the native anterior valve leaflet, and the method may further comprise deflecting the anterior prosthetic leaflet away from the left ventricular outflow tract to provide a clear unobstructed outflow path during systole. Anchoring the prosthesis may comprise anchoring an anterior anchoring tab disposed on an anterior portion of the prosthetic valve to a fibrous trigone of the native mitral valve or to tissue anterior of the native anterior valve leaflet and adjacent thereto.

[0013] In yet another aspect, a method of treating a native mitral valve in a patient's heart comprises providing a prosthetic mitral valve having an anterior prosthetic leaflet that spans the width of the native anterior valve leaflet, anchoring the prosthetic mitral valve in the native mitral valve, and deflecting the prosthetic anterior leaflet in systole away from the left ventricular outflow tract during systole thereby creating an unobstructed outflow path.

[0014] The method may further comprise directing blood flow in a non-turbulent manner through the prosthetic mitral valve and in a circular direction along a posterior wall of the patient's left ventricle towards the apex of the heart and upward along a septal wall until it is ejected out the left ventricular outflow tract. Anchoring the prosthesis may comprise anchoring an anterior anchoring tab disposed on an anterior portion of the prosthetic valve to a fibrous trigone of the native mitral valve or to tissue anterior of the native anterior leaflet and adjacent thereto.

[0015] In another aspect, a prosthetic heart valve for implantation in a native mitral valve of a patient comprises a radially expandable anchor frame having an expanded configuration and a collapsed configuration; and a prosthetic valve coupled to the anchor frame. The prosthetic valve comprises a plurality of prosthetic valve leaflets each having a free end and a fixed end. The fixed end is coupled to the anchor frame and the free ends of the plurality of prosthetic valve leaflets have an open configuration and a closed configuration. In the open configuration the free ends are disposed away from one another to allow antegrade blood flow therethrough, and in the closed configuration the free ends are disposed adjacent one another to substantially prevent retrograde blood flow therethrough. The plurality of prosthetic valve leaflets comprise an anterior prosthetic leaflet sized to span the entire width of the native anterior leaflet. In systole, the anterior prosthetic leaflet deflects away from the left ventricular outflow tract to provide a clear unobstructed outflow path.

[0016] The anchor frame may comprise an anterior anchoring tab configured to anchor on an anterior portion of the native mitral valve and the anterior portion of the native mitral valve may comprise a

fibrous trigone. The anchor frame may comprise a second anterior anchoring tab configured to anchor on a second anterior portion of the native mitral valve. In some embodiments, the anchor frame can comprise a D-shaped cross-section having a substantially flat anterior portion and a cylindrically shaped posterior portion, wherein the flat anterior portion prevents impingement of the prosthetic heart valve on the left ventricular outflow tract, and the cylindrically shaped posterior portion engages a posterior portion of the native mitral valve. In some examples, the anchor frame can comprise one or more commissure posts, and an anterior anchoring tab, the one or more commissure posts having a free end and an opposite end coupled to the anchor frame, the one or more commissure posts coupled to the plurality of prosthetic valve leaflets.

[0017] The anterior anchoring tab can be configured to anchor on an anterior portion of the native mitral valve. In some embodiments, the anterior anchoring tab and the one or more commissure posts can be nested in one another when the anchor frame is in the collapsed configuration. The anterior anchoring tab originates from a circumferential position on a circumference of the anchor frame, and wherein the one or more commissure posts also originate from the same circumferential position on the circumference of the anchor frame as the anterior anchoring tab. The anterior anchoring tab can originate from the one or more commissure posts, or the one or more commissure posts can originate from the anterior anchoring tab.

[0018] In some examples, the anchor frame can further comprise a plurality of chordal bumper struts originating from the one or more commissure posts. The plurality of chordal bumper struts can be configured to dispose native sub-valvular anatomy away from the LVOT. In some embodiments, the commissure posts can comprise an anchoring element adjacent a free end of the commissure post, the anchoring element configured to engage a delivery system. The anchor frame can further comprise a plurality of wishbone shaped struts originating from the one or more commissure posts. The plurality of wishbone shaped struts can be configured to arcuately span the distance between adjacent commissure posts. Each wishbone shaped strut can be comprised of an anchoring element disposed at an apex of the wishbone shaped strut or adjacent a free end of the wishbone shaped strut. The anchoring element can be configured to engage a delivery catheter. The plurality of wishbone shaped struts can be deformable members and can allow radial compression of the anchor frame upon retraction into the delivery catheter. The anchoring element can comprise a single threaded connector, a plurality of threaded connectors, a buckle connector, or a prong connector.

[0019] In another aspect, a prosthetic heart valve for implantation in a native mitral valve of a patient comprises a radially expandable anchor frame, an anterior anchoring tab coupled to the anchor frame, and a prosthetic valve coupled to the anchor frame. The radially expandable anchor frame has an

expanded configuration and a collapsed configuration and an upstream end and a downstream end. The radially expandable anchor frame comprises one or more commissure posts having a free end and an opposite end coupled to the anchor frame adjacent the downstream end, and an anterior anchoring tab coupled to the anchor frame adjacent the downstream end. The anterior anchoring tab is configured to anchor on an anterior portion of the native mitral valve. The anterior anchoring tab and the one or more commissure posts are nested in one another when the anchor frame is in the collapsed configuration. The prosthetic valve comprises one or more prosthetic valve leaflets each having a free end and a fixed end, wherein the fixed end is coupled to the anchor frame. The one or more commissure posts are coupled to the one or more prosthetic valve leaflets.

[0020] In some embodiments, the free ends of the one or more prosthetic valve leaflets can have an open configuration and a closed configuration. In the open configuration the free ends can be disposed away from one another to allow antegrade blood flow therethrough, and in the closed configuration the free ends can be disposed adjacent one another to substantially prevent retrograde blood flow therethrough. The one or more prosthetic valve leaflets can comprise an anterior prosthetic leaflet sized to span a width of a native anterior valve leaflet between two native fibrous trigones. In systole, the anterior prosthetic leaflet can deflect away from the left ventricular outflow tract to provide a clear unobstructed outflow path. The anterior portion of the native mitral valve can comprise a fibrous trigone.

[0021] In some examples, the anchor frame can comprise a second anterior anchoring tab configured to anchor on a second anterior portion of the native mitral valve. Additionally or in the alternative, the anchor frame can comprise a D-shaped cross-section having a substantially flat anterior portion and a cylindrically shaped posterior portion. The flat anterior portion can prevent impingement of the prosthetic heart valve on the left ventricular outflow tract, and the cylindrically shaped portion can engage the posterior portion of the native mitral valve.

[0022] The anterior anchoring tab can originate from a circumferential position on a circumference of the anchor frame and the one or more commissure posts can also originate from the same circumferential position on the circumference of the anchor frame as the anterior anchoring tab. In some examples, the anterior anchoring tab can originate from the one or more commissure posts, or the one or more commissure posts can originate from the anterior anchoring tab.

[0023] In another aspect, a method of treating a native mitral valve in a patient's heart comprises: providing a prosthetic mitral valve having an anterior prosthetic leaflet that spans a width of a native anterior valve leaflet; anchoring the prosthetic mitral valve in the native mitral valve; and deflecting the prosthetic anterior leaflet in systole away from the left ventricular outflow tract during systole thereby

creating an unobstructed outflow path. Anchoring the prosthetic mitral valve in the native mitral valve can comprise anchoring an anterior anchoring tab disposed on an anterior portion of the prosthetic valve to an anterior portion of the native mitral valve. In some examples, the anterior portion of the native mitral valve can comprise a fibrous trigone.

[0024] The method can comprise radially expanding the prosthetic mitral valve from a collapsed configuration to an expanded configuration, wherein radially expanding the prosthetic mitral valve can comprise expanding one or more anterior anchoring tabs away from nested positions within one or more commissure posts. The method can comprise radially expanding the prosthetic mitral valve from a collapsed configuration to an expanded configuration, wherein radially expanding can comprise expanding one or more posterior anchoring tabs away from nested positions within one or more commissure posts. In some examples, anchoring the prosthetic mitral valve can comprise actuating an actuator mechanism on a delivery system in a first direction, which can comprise moving a sheath catheter away from the prosthetic mitral valve to remove a constraint thereby allowing the prosthetic mitral valve to expand. The method can further comprise actuating the actuator mechanism in a second direction opposite the first direction, which can comprise moving a sheath catheter toward the prosthetic mitral valve to provide a constraint thereby forcing the prosthetic mitral valve to be compressed. In some examples, actuating the actuator mechanism in the first direction can comprise moving a bell catheter away from an anchoring catheter to remove a constraint thereby allowing a commissure anchor to be released. The commissure anchor can comprise an anchoring element that engages a frame of the prosthetic mitral valve to the delivery system. Actuating the actuator mechanism in the second direction can comprise moving the bell catheter toward the anchoring catheter to provide a constraint that captures or restrains the commissure anchor. Providing the constraint that captures or restrains the commissure anchor can comprise releasably sliding a retaining element over the commissure anchor. Moreover, actuating the actuator mechanism can comprise moving a sheath catheter over the anchoring catheter thereby applying a constraint, which can comprise allowing a commissure anchor to be compressed. The commissure anchor can comprise a flexible anchoring element that can engage the frame of the prosthetic mitral valve to the delivery system.

[0025] In another aspect, a method of treating a native mitral valve in a patient's heart comprises: providing a prosthetic mitral valve coupled to a radially expandable anchor frame having an upstream end and a downstream end, expanding the radially expandable anchor frame from a collapsed configuration to an expanded configuration, anchoring the prosthetic mitral valve in the native mitral valve, wherein the anterior anchoring tab anchors on an anterior portion of the native mitral valve, and radially expanding the anterior anchoring tab away from a nested position within the one or more

commissure posts. The radially expandable anchor frame comprises one or more commissure posts having a free end and an opposite end coupled to the anchor frame adjacent the downstream end, and an anterior anchoring tab coupled to the anchor frame adjacent the downstream end. The anterior portion of the native mitral valve can comprise a fibrous trigone. In some examples, radially expanding the anchor frame can comprise expanding the one or more commissure posts away from a nested position within the anterior anchoring tab.

[0026] The prosthetic mitral valve can comprise an anterior prosthetic leaflet and the method can comprise spanning a width of a native anterior valve leaflet between two native fibrous trigones, deflecting the anterior prosthetic leaflet away from a left ventricular outflow tract, and creating an unobstructed outflow path by the deflection of the anterior prosthetic leaflet.

[0027] In another aspect, a delivery system for delivering a prosthesis to a target treatment area comprises: an inner guidewire catheter having a proximal end, a distal end, and a lumen extending therebetween, the lumen sized to slidably receive a guidewire; a flexible dilating tip coupled to the guidewire catheter, the dilating tip having a tapered and flexible self-dilating edge, a sheath catheter slidably disposed over the inner guidewire catheter, the sheath catheter having a proximal end and a distal end; an actuator mechanism operably coupled to the proximal end of the sheath catheter. Actuation of the actuator mechanism in a first direction moves the sheath catheter away from the dilator tip thereby removing a constraint from the prosthesis and allowing the prosthesis to expand. Moreover, actuation of the actuator mechanism in a second direction opposite the first direction moves the sheath catheter into engagement with the dilator tip thereby enclosing the prosthesis therein.

[0028] The system can comprise a stationary anchoring catheter fixedly disposed over the guidewire catheter, the anchoring catheter having an anchor element adjacent a distal end of the anchor catheter and configured to engage the prosthesis. In some examples, a bell catheter can be slidably disposed over the anchoring catheter. The bell catheter can have a bell element disposed adjacent a distal end of the bell catheter and the bell element can constrain the prosthesis into engagement with the anchor catheter. The anchoring catheter can have a flexible prong type anchor element adjacent the distal end of the anchor catheter, configured to engage the prosthesis. The sheath catheter can be slidably disposed over the anchoring catheter. In particular, an advancement of the distal end of the sheath catheter can collapse the flexible prong type anchor elements into engagement with the prosthesis.

[0029] In some embodiments, a stationary bell catheter can be fixedly disposed over the anchoring catheter. The bell catheter can have a bell element disposed adjacent a distal end of the bell catheter, and the bell element can disengage the prosthesis from the anchor catheter. In some embodiments, the system can comprise a bell catheter rotatably disposed over the guidewire catheter. The bell catheter

can have an internally threaded bell element disposed adjacent a distal end of the bell catheter, and the threaded bell element can constrain the prosthesis into engagement. A second actuator mechanism can be operably coupled to a proximal end of the bell catheter. Actuation of the second actuator mechanism in a first direction can couple the prosthesis to the bell catheter, providing a constraint for the prosthesis, and actuation of the second actuator mechanism in a second direction opposite the first direction can de-couple the prosthesis from the bell catheter, removing the constraint from the prosthesis. The system can comprise a rotating torque catheter rotatably disposed over the guidewire catheter. The torque catheter can have a driving gear element adjacent a distal end of the torque catheter and configured to transmit torque. A plurality of rotating thread-connector catheters can be rotatably disposed adjacent the torque catheter. The thread-connector catheters can each have a driven gear element adjacent a distal end of each thread connector catheter, and a threaded socket adjacent to the distal end of each thread connector catheter. The driven gear elements can be sized to enmesh with the driving gear element and receive torque, and the threaded sockets can be configured to constrain the prosthesis into engagement. A second actuator mechanism can be operably coupled to a proximal end of the torque catheter. Actuation of the second actuator mechanism in a first direction can couple the prosthesis to the thread-connector catheters and actuation of the second actuator mechanism in a second direction opposite the first direction can de-couple the prosthesis from the thread-connector catheters.

[0030] In any of the aspects, the method may further comprise radially expanding the prosthetic mitral valve from a collapsed configuration to an expanded configuration. Radially expanding the prosthesis may comprise expanding an anterior anchoring tab away from a nested configuration with a commissure post.

[0031] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

INCORPORATION BY REFERENCE

[0032] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0034] FIG. 1 depicts the anatomical heart in an anterior view.

[0035] FIG. 2 shows a cross-section of FIG. 1, and the interior anatomy of the heart, including the left ventricular outflow tract (LVOT) and a prosthetic mitral valve.

[0036] FIG. 3 depicts the anatomical heart in a posterior view.

[0037] FIG. 4 shows a cross-section of FIG. 3, and the interior anatomy of the heart, particularly, the space inferior to the mitral and aortic valves.

[0038] FIG. 5 illustrates an embodiment of a prosthetic mitral valve configured to avoid LVOT obstruction.

[0039] FIG. 6 depicts an inflow view of a tri-leaflet prosthetic mitral valve configured to avoid LVOT obstruction.

[0040] FIG. 7 depicts an outflow view of a tri-leaflet prosthetic mitral valve configured to avoid LVOT obstruction.

[0041] FIG. 8A shows an outflow view of a mono-leaflet prosthetic mitral valve, in the style of a duck-bill valve.

[0042] FIG. 8B shows an outflow view of a bi-leaflet prosthetic mitral valve.

[0043] FIG. 8C depicts an outflow view of an anterior mono-leaflet prosthetic mitral valve, in the open position.

[0044] FIG. 8D shows an outflow view of an anterior mono-leaflet prosthetic mitral valve, in the closed position.

[0045] FIG. 8E shows an outflow view of a tri-leaflet prosthetic mitral valve, with a large anterior leaflet.

[0046] FIG. 8F shows an outflow view of a tetra-leaflet prosthetic mitral valve.

[0047] FIG. 9 shows a frame flat-pattern of a prosthetic mitral valve frame.

[0048] FIG. 10 shows a frame flat-pattern of a prosthetic mitral valve frame, with chordal bumper struts.

[0049] FIG. 11 shows a frame flat-pattern of a prosthetic mitral valve frame, with chordal bumper struts and wishbone shaped struts.

[0050] FIG. 12 shows a frame flat-pattern of a prosthetic mitral valve frame, with wishbone shaped struts.

[0051] FIG. 13 illustrates an embodiment of a prosthetic mitral valve with wishbone shaped struts, and fashioned to avoid LVOT obstruction.

[0052] FIG. 14 illustrates an embodiment of a prosthetic mitral valve with wishbone shaped struts, anchored to a delivery system.

[0053] FIG. 15A shows an embodiment of a delivery system and wishbone shaped strut anchoring variation, with a plurality of threaded connectors, connected.

[0054] FIG. 15B shows an embodiment of a delivery system and wishbone shaped strut anchoring variation, with a plurality of threaded connectors, disconnected.

[0055] FIG. 16A shows an embodiment of a delivery system and wishbone shaped strut anchoring variation, with a split-threaded connector, connected.

[0056] FIG. 16B shows an embodiment of a delivery system and wishbone shaped strut anchoring variation, with a split-threaded connector, disconnected.

[0057] FIG. 17A shows an embodiment of a delivery system and wishbone shaped strut anchoring method, with a flexing pin connector, connected.

[0058] FIG. 17B shows an embodiment of a delivery system and wishbone shaped strut anchoring method, with a flexing pin connector, disconnected.

[0059] FIG. 18A shows an embodiment of a delivery system and wishbone shaped strut anchoring method, with a flexible buckle connector, connected.

[0060] FIG. 18B shows an embodiment of a delivery system and wishbone shaped strut anchoring method, with an internal view of a flexible buckle connector, connected.

[0061] FIG. 18C shows an embodiment of a delivery system and wishbone shaped strut anchoring method, with an internal view of a flexible buckle connector, disconnected.

[0062] FIG. 19A shows an embodiment of a delivery system and wishbone shaped strut anchoring method, with an internal view of an anchor shaped connector, connected.

[0063] FIG. 19B shows an embodiment of a delivery system and wishbone shaped strut anchoring method, with an anchor shaped connector, unconstrained to allow disconnection.

[0064] FIG. 20A depicts an embodiment of a delivery system in a closed configuration, with a prosthetic mitral valve loaded internally.

[0065] FIG. 20B depicts an embodiment of a delivery system in a partially opened configuration, with a prosthetic mitral valve loaded internally and being deployed.

[0066] FIG. 20C depicts an embodiment of a delivery system in a substantially opened configuration, with a prosthetic mitral valve loaded internally and in mid deployment.

[0067] FIG. 20D depicts an embodiment of a delivery system in a substantially opened configuration, with a prosthetic mitral valve loaded and nearly released.

[0068] FIG. 20E depicts an embodiment of a delivery system in a fully opened configuration, with a prosthetic mitral valve loaded internally, just prior to final deployment.

[0069] FIG. 20F depicts an embodiment of a prosthetic mitral valve, post release.

[0070] FIGS. 21A-C show an embodiment of a delivery system having a slotted anchor mechanism that may accommodate anchored wishbone shaped struts.

[0071] FIG. 22 shows an enlarged view of an embodiment of a delivery system having a slotted anchor mechanism that may accommodate anchored wishbone shaped struts.

[0072] FIG. 23 shows an exploded view of a delivery system having a slotted anchor mechanism that may accommodate anchored wishbone shaped struts.

[0073] FIGS. 24A-C show an embodiment of a delivery system having a flexible connector anchor mechanism that may accommodate pinned wishbone shaped struts.

[0074] FIG. 25 depicts an exploded view of an embodiment of a delivery system having a flexible connector anchor mechanism that may accommodate pinned wishbone shaped struts.

[0075] FIG. 26A depicts an exploded view of an embodiment of a delivery system having a sliding connector anchor mechanism that may accommodate flexible buckle wishbone shaped struts.

[0076] FIG. 26B depicts an enlarged view of an embodiment of a delivery system having a sliding connector anchor mechanism that may accommodate flexible buckle wishbone shaped struts.

[0077] FIG. 27 depicts an exploded view of an embodiment of a delivery system with a singular screw connector anchor mechanism that may accommodate split-threaded wishbone shaped struts.

[0078] FIG. 28 shows an enlarged view of an embodiment of a delivery system with a singular screw connector anchor mechanism that may accommodate split-threaded wishbone shaped struts.

[0079] FIG. 29 shows an exploded view of an embodiment of a delivery system with a plurality of screw connector anchor mechanisms that may accommodate threaded wishbone shaped struts.

[0080] FIG. 30 shows an exploded view of the concentric catheters of an embodiment of a delivery system with a plurality of screw connector anchor mechanisms that may accommodate threaded wishbone shaped struts.

[0081] FIG. 31 shows an enlarged view of the sun-gear and plurality of screw connector anchor mechanisms at the end of an embodiment of a delivery system that may accommodate threaded wishbone shaped struts.

[0082] FIG. 32 shows turbulent blood flow in a heart.

[0083] FIG. 33 shows non-turbulent blood flow in a heart.

[0084] FIG. 34 illustrates a prosthetic mitral valve directing blood in the heart in a non-turbulent manner.

[0085] FIG. 35 illustrates a perspective view of a prosthetic valve.

[0086] FIG. 36A illustrates the atrial skirt of a prosthetic valve.

[0087] FIG. 36B illustrates a top view of a prosthetic valve.

- [0088] FIG. 37 illustrates a flat pattern of a prosthetic valve.
- [0089] FIG. 38 illustrates a perspective view of a prosthetic valve.
- [0090] FIG. 39A illustrates an anterior view of a prosthetic valve.
- [0091] FIG. 39B illustrates a top view of a prosthetic valve.
- [0092] FIG. 40 illustrates deployment of a prosthetic valve.
- [0093] FIG. 41 illustrates a side view of a prosthetic valve.
- [0094] FIG. 42 illustrates a combined commissure post and anchor tab.
- [0095] FIGs. 43A-43B illustrate an unexpanded and expanded anchor tab.
- [0096] FIG. 43C illustrates a flat pattern for an expanded anchor tab.
- [0097] FIG. 44 shows a D-shaped prosthesis.
- [0098] FIG. 45 shows a side view of a prosthetic valve.
- [0099] FIG. 46 shows a top view of a prosthetic valve with four leaflets and four anchors.
- [0100] FIG. 47 shows a top view of a prosthetic valve with three leaflets and three anchors.
- [0101] FIG. 48 shows a flat pattern of a prosthetic valve.
- [0102] FIG. 49 shows native valve leaflets superimposed over anchor tabs.
- [0103] FIG. 50 shows an inversion of the anchor tab with the commissure post nested within.
- [0104] FIG. 51 shows an embodiment with two anchors located adjacent the native anterior leaflet and an expansion region void of similar anchors in the posterior portion.
- [0105] FIG. 52 shows a flat pattern of a prosthetic valve.
- [0106] FIG. 53 shows another flat pattern of a prosthetic valve.
- [0107] FIG. 54 shows a perspective view of a prosthetic valve.
- [0108] FIG. 55 shows a mitral valve adjacent the aortic valve.
- [0109] FIG. 56 shows still another anchor tab nested in a commissure post in the expanded configuration.
- [0110] FIG. 57 shows an anchor tab nested in a commissure post in the expanded configuration.
- [0111] FIG. 58 shows an anchor tab nested in a commissure post in the collapsed configuration.
- [0112] FIG. 59 shows variable strut thickness.

DETAILED DESCRIPTION OF THE INVENTION

- [00113] Specific embodiments of the disclosed device, delivery system, and method will now be described with reference to the drawings. Nothing in this detailed description is intended to imply that any particular component, feature, or step is essential to the invention.
- [00114] As used herein, like numbers refer to like elements.

[00115] FIG. 1 provides an illustration of the anatomical heart, herein represented by an anterior aspect 10 of the heart. Anterior views of various structures of the anatomical heart are also presented. The superior vena cava 50, right atrium 40, and right ventricle 20 are shown on the (viewer's) left side of said anterior aspect 10, with superior and inferior structures being separated by the right coronary artery 120. A cross-section line A-A divides the cardiac anatomy into side sections and is further discussed in FIG. 2. Moving to the (viewer's) right side of the heart, an anterior view of the aorta 60 can be seen in a superior position to the pulmonary trunk 90. Beneath the pulmonary trunk 90 are the left atrium 70 and left atrial appendage 80. Beneath and flanking to the (viewer's) left and right of the left atrial appendage 80 are the left anterior descending coronary artery 100 and the intermediate coronary artery 110, respectively. Finally, inferior to all previously mentioned elements is the left ventricle 30.

[00116] FIG. 2 shows the internal structures of the heart after sectioning the anterior aspect 10 (as shown in FIG. 1) of the heart along cross-section A-A. The cross-section A-A is bounded by a hatched zone 130 that represents the plane of sectioning. Beginning at the superior-most element, the aorta 140 is depicted in a posterior aspect. Below and behind the aorta 140 is the right atrium 180. An interior view of the left atrium 150 is shown, revealing where a prosthetic mitral valve 210 may be located after implantation. The inflow region 220 of the prosthetic mitral valve 210 and the outflow region 230 of the prosthetic mitral valve can also be seen. An anterior aspect 170 of the prosthetic mitral valve 210 may be adjacent to a zone 190 of the left ventricular outflow tract 200 (LVOT). An anterior anchoring tab 240 may be located in a position that avoids blockage of the LVOT 200. As systole occurs, and blood is shunted towards the LVOT 200 from beneath the prosthetic mitral valve 210, there may be a capacious channel leading directly to the aorta 140, due to the large area of the zone 190. This configuration may leave the LVOT 200 free of obstruction from extraneous prosthesis bulkage or projections.

[00117] The prosthetic mitral valve may comprise one or more tabs. The prosthetic mitral valve may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 tabs. A posterior anchoring tab 250 may be located opposite the anterior anchoring tab 240 of the prosthetic mitral valve 210. The posterior anchoring tab 250 may abut the native anatomy and rest against a posterior ventricular shelf region 160, which is formed within the ventricle at the junction of the ventricle and posterior mitral annulus (see FIG. 4 for a clearer depiction). A third anchoring tab is hidden in the depiction of FIG. 2. A valve leaflet 260, typically constructed from chemically-preserved pericardial tissue harvested from various species such as bovine, porcine, or ovine species, may be located between the anterior anchoring tab 240 and the posterior anchoring tab 250. Further details relating to the prosthetic mitral valve 210 are provided beginning with FIG. 5.

[00118] FIG. 3 provides an illustration of the anatomical heart, herein represented by a posterior aspect 265 of the heart. Posterior views of various structures of the anatomical heart are also presented. Beginning with the most superior elements, a posterior aspect of the superior vena cava 380 is adjacent to a posterior aspect of the aorta 370 and above a posterior aspect of the pulmonary trunk 390. Further depicted posteriorly are the right atrium 270, the left atrial appendage 280 (appearing to the viewer's left), the left atrium 340, the right pulmonary veins 350, and the left pulmonary veins 360 (appearing to the viewer's right). A cross-section line B-B divides the presented cardiac anatomy into superior and inferior sections and is further discussed in FIG. 4. The coronary arteries and relevant branches include the left marginal branch 290, the circumflex branch 300, the posterior left ventricular branch 310 of the left coronary artery, and the posterior interventricular branch 320 of the right coronary artery. Finally, in the most inferior position of the elements is the apex of the heart 330.

[00119] FIG. 4 shows the internal structures of the heart after sectioning the posterior aspect 265 (as shown in FIG. 3) of the heart along cross-section B-B. The cross-section B-B is bounded by a hatched zone 400 that represents the plane of sectioning. Beginning at the top of the figure, the posterior ventricular shelf 470 is adjacent to and connected by tissue with the fixed end of the posterior mitral leaflet 450. This shelf may provide a location for a posterior anchoring tab of a prosthetic mitral valve, as described herein. An arcade of posterior chordae tendinae 455 are located adjacent to and connected by tissue with the posterior mitral leaflet 450, finding their insertion points along the free edge of the leaflet. The fixed ends of the chordae 455 find insertion points in both the antero-lateral papillary muscles 430 and postero-medial papillary muscles 440. The papillary muscles 430 and 440 act as muscular support bases for the tethering effect provided by said chordae, spanning the distance between leaflet free edge insertion and papillary muscle insertion while under dynamic tension. Directly opposing the posterior mitral leaflet 450 is an anterior mitral leaflet 460. During systole, the posterior mitral leaflet 450 and the anterior mitral leaflet 460 are brought into communication as their free edges shut against each other, in order to prevent retrograde blood flow into the left atrium. The free edge of the anterior leaflet 460 is also adjacent to and connected by tissue with an arcade of anterior chordae tendinae 465, which also find fixed end insertion points in both the antero-lateral 430 and postero-medial 440 papillary muscles, mirroring the chordal structure of the posterior leaflet.

[00120] The fixed end of the anterior leaflet 460 is directly adjacent and connected by tissue with the inflow of the aortic valve 500. This adjacency is commonly known as the aorto-mitral continuity. It is in this region that a risk for outflow tract obstruction presents itself, necessitating the present invention, which aims to minimize LVOT obstruction. Flanking the fixed end of the anterior leaflet 460 are regions of dense cartilaginous tissue known as the fibrous trigones, which act as skeletal-like structures

for the heart-at-large. The antero-septal fibrous trigone **480** and the antero-lateral fibrous trigone **490** are represented by triangles, which demarcate landing zones on which the anterior anchoring tabs of the prosthetic mitral valve (not shown) may abut during valve deployment. For reference, the tricuspid valve **410** and the aorta **420** are shown at the bottom of the figure.

[00121] **FIG. 5** illustrates the present invention in perspective, showing a prosthetic mitral valve **510** (**210**, as shown in **FIG. 2**) with a large anterior leaflet. The prosthesis may comprise an atrial region, an annular region, a valvular region, and an anchoring region. A frame **525** may provide the structural means on which the entirety of the prosthetic valve may be erected, and is shown by dashed lines in **FIG. 5**. The frame may be a nitinol frame. The frame **525** may be layered within various biocompatible fabrics that provide excellent sealing properties. The biocompatible fabrics may comprise polyester, nylon, or any other biocompatible fabric as is known to one having skill in the art. Medical grade suture may be used to sew the various fabrics onto the frame **525** to construct the prosthesis. The atrial region of the prosthesis may comprise an atrial skirt **520** which acts as a flange and allows the inflow region of the valve (**220**, as shown in **FIG. 2**) to register and seal against the native mitral annulus, upon the floor of the left atrium. The atrial skirt **520** may traverse the entire circumference of the inflow region (**220**, as shown in **FIG. 2**) of the prosthetic valve, and may be in communication with and connected to an annular region **530** that also traverses the circumference of the prosthetic valve. In this representation, the anterior surface of the prosthetic valve is shown facing away and to the right, from the viewer. As such, an anterior leaflet **580** is shown facing away and to the right. One or more valve leaflets may form the valvular region of the prosthesis. The leaflets may comprise the anterior leaflet **580**, a postero-septal leaflet **570**, and a postero-lateral leaflet **590**. The anterior leaflet **580** may comprise an anterior leaflet inflow surface, as described herein. The postero-septal leaflet **570** may comprise a postero-septal leaflet inflow surface, as described herein. The postero-lateral leaflet **590** may comprise a postero-lateral leaflet inflow surface, as described herein.

[00122] One or more of the plurality of leaflets may comprise chemically-preserved pericardial tissue. The chemically-preserved pericardial tissue may be treated with chemical preservatives that promote polymer cross-linking, render the tissue inert and biocompatible to humans, and/or prepare the tissue for further sterilization treatments. The leaflet tissue may be derived from bovine, porcine, or ovine sources, but shall not be limited to the aforementioned species. In the closed configuration, the free ends of each of the anterior leaflet **580**, postero-septal leaflet **570**, and postero-lateral leaflet **590** may meet at a triple-point of leaflet coaptation **600**. Conversely, the fixed end of each leaflet may be sutured to both the annular region of the valve, and to the next adjacent leaflet at a specific location that provides increased structural resilience, as described herein. Although **FIG. 5** shows three leaflets, the prosthetic mitral

valve may comprise any number of leaflets. For instance, the prosthetic mitral valve may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 leaflets.

[00123] Each leaflet may be successively joined to the next adjacent leaflet at a commissure attachment point, through a commissure suture pad. Thus, the prosthetic mitral valve may comprise one or more commissure attachment points and one or more commissure suture pads. Specifically, the postero-septal **570** and anterior **580** leaflets may be joined together and attached to an antero-septal commissure attachment point **550** through an antero-septal commissure suture pad **560**, the anterior **580** and postero-lateral **590** leaflets may be joined together and attached to an antero-lateral commissure attachment point **625** through an antero-lateral commissure suture pad **615**, and the postero-lateral **590** and postero-septal **570** leaflets may be joined together and attached to a posterior commissure attachment point **645** through a posterior commissure suture pad **640**. Although **FIG. 5** shows three commissure attachment points and three commissure suture pads, the prosthetic mitral valve may comprise any number of commissure attachment points. For instance, the prosthetic mitral valve may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 commissure attachment points and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 commissure suture pads.

[00124] One or more commissure anchors may extend away from the valve and into free space from each of the commissure attachment points. For instance, an antero-septal commissure anchor **555** may extend from the antero-septal commissure attachment point **560**, an antero-lateral commissure anchor **620** may extend from the antero-lateral commissure attachment point **625**, and a posterior commissure anchor **650** may extend from the posterior commissure attachment point **645**. Each of the commissure anchors may comprise the means through which the prosthesis may be anchored and connected to an appropriate delivery system, as described herein. The shape of each of the plurality of commissure anchors may generally resemble the shape of an anchor or half-moon, but those skilled in the art will recognize that any shapes that allow the plurality of commissure anchors to be anchored effectively to a potential delivery system may be implied by this element. Although **FIG. 5** shows three commissure anchors, the prosthetic mitral valve may comprise any number of commissure anchors. For instance, the prosthetic mitral valve may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 commissure anchors.

[00125] Extending away from each of the commissure attachment points, in this instance towards the valve, are one or more of anchoring tabs. Each anchoring tab may comprise a fixed end which is in communication with a commissure attachment point, and a free end which extends towards the atrial skirt and provides an anchoring means through which the prosthetic may attach itself to the native anatomy. Anterior anchoring tabs may generally rest against the native fibrous trigones of the mitral valve, while posterior anchoring tabs may generally rest against the posterior ventricular shelf of the

mitral valve. An antero-septal trigonal anchoring tab **540** (**240**, as shown in **FIG. 2**) may be connected at a fixed end to the antero-septal commissure anchor point **560**, and may have a free end **545** that is brought to rest against the antero-septal fibrous trigone (**480**, as shown in **FIG. 4**). An antero-lateral trigonal anchoring tab **610** (**260**, as shown in **FIG. 2**) may be connected at a fixed end to the antero-lateral commissure anchor point **625**, and may have a free end (not shown in this view) that is brought to rest against the antero-lateral fibrous trigone (**490**, as shown in **FIG. 4**). Finally, a posterior anchoring tab **630** (**250**, as shown in **FIG. 2**) may be connected at a fixed end to the posterior commissure anchor point **645**, and may have a free end **635** that is brought to rest against the posterior shelf (**470**, as shown in **FIG. 4**). Although **FIG. 5** shows three anchoring tabs, the prosthetic mitral valve may comprise any number of anchoring tabs. For instance, the prosthetic mitral valve may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 anchoring tabs.

[00126] **FIG. 6** illustrates an inflow view **660** of a prosthetic mitral valve (**510**, as shown in **FIG. 5**). The approximate “D” shape of the prosthetic mitral valve may be fully appreciated by tracing a path from the anterior aspect **690** of the valve inflow (flat side of the D shape) in a clockwise direction until the posterior aspect **700** of the valve inflow (curved portion of the D shape) is reached, and then back again to the anterior aspect **690** of the valve inflow. Adjacent the anterior aspect **690** of the valve inflow is the anterior portion **670** of the atrial skirt (**520**, as shown in **FIG. 5**). Adjacent the posterior aspect **700** of the valve inflow is the posterior portion **680** of the atrial skirt. A plurality of frame struts **740** may encircle the valve inflow circumferentially. The frame struts **740** may provide structural support and attachment means for both the anterior **670** and posterior **680** portions of the atrial skirt to the annular region of the prosthetic mitral valve (**530**, as shown in **FIG. 5**). The postero-lateral leaflet inflow surface **710** (corresponding to the postero-lateral leaflet **590**, as shown in **FIG. 5**), anterior leaflet inflow surface **720** (corresponding to the anterior leaflet **580**, as shown in **FIG. 5**), and postero-septal leaflet inflow surface **730** (corresponding to the postero-septal leaflet **570**, as shown in **FIG. 5**) are also depicted. Also shown are the posterior anchoring tab free end **635**, antero-lateral trigonal anchoring tab free end **610**, and antero-septal trigonal anchoring tab free end **545**.

[00127] **FIG. 7** illustrates an outflow view **750** of a prosthetic mitral valve (**510**, as shown in **FIG. 5**). The triple-point of leaflet coaptation (**600**, as shown in **FIG. 5**) as previously mentioned, may be formed during systole, when a coaptation surface **775** of a postero-septal leaflet **770** (**570**, as shown in **FIG. 5**), a coaptation surface **765** of a postero-lateral leaflet **760** (**590**, as shown in **FIG. 5**), and a coaptation surface **785** of an anterior leaflet **780** (**580**, as shown in **FIG. 5**) are brought into contact with one another through valve closure. The previously described commissures and anchoring tabs are also depicted in this outflow view **750**, and are identified by a posterior anchoring tab **800** (**630**, as shown in

FIG. 5) and associated posterior commissure anchor **805** (**650**, as shown in **FIG. 5**), an antero-septal trigonal anchoring tab **810** (**540**, as shown in **FIG. 5**) and associated antero-septal commissure anchor **815** (**555**, as shown in **FIG. 5**), and an antero-lateral trigonal anchoring tab **790** (**610**, as shown in **FIG. 5**) and associated antero-lateral commissure anchor **795** (**620**, as shown in **FIG. 5**).

[00128] FIG. 8A illustrates an embodiment of a prosthetic mitral valve (**510**, as shown in **FIG. 5**) having a single mono-leaflet **830** that is in the style of a duckbill valve, and is presented in an outflow view **820**. The duckbill style valve may be created by making an incision **840** at approximately the center of the single mono-leaflet **830**, which may create a leaflet coaptation edge on which the resultant valve may function. The prosthetic mitral valve may further comprise one or more of the anterior aspect **690** of the valve inflow, posterior aspect **700** of the valve inflow, the antero-lateral trigonal anchoring tab **790** and associated antero-lateral commissure anchor **795**, the posterior anchoring tab **800** and associated posterior commissure anchor **805**, or the antero-septal trigonal anchoring tab **810** and associated antero-septal commissure anchor **815**.

[00129] FIG. 8B illustrates an embodiment of a prosthetic mitral valve (**510**, as shown in **FIG. 5**) comprising a dual or bi-leaflet configuration, again shown in an outflow view **850**. The bi-leaflet configuration may be realized by way of a pair of leaflets, comprising an anterior leaflet **870** and a posterior leaflet **860**, which may be brought together during systole at a leaflet coaptation edge **880**. The prosthetic mitral valve may further comprise one or more of the anterior aspect **690** of the valve inflow, posterior aspect **700** of the valve inflow, the antero-lateral trigonal anchoring tab **790** and associated antero-lateral commissure anchor **795**, the posterior anchoring tab **800** and associated posterior commissure anchor **805**, and/or the antero-septal trigonal anchoring tab **810** and associated antero-septal commissure anchor **815**.

[00130] FIG. 8C and 8D show an embodiment of a mono-leaflet prosthetic mitral valve (**510**, as shown in **FIG. 5**) seen from the outflow view **890** comprising one large anterior leaflet **900** that may be able to span the entire valve orifice during systole, and seal against the posterior aspect of **700** of the valve inflow. In the open configuration, a posterior outflow region **910** may allow antegrade blood flow through the valve and into the left ventricle, from the left atrium. The prosthetic mitral valve may further comprise one or more of the anterior aspect **690** of the valve inflow, posterior aspect **700** of the valve inflow, the antero-lateral trigonal anchoring tab **790** and associated antero-lateral commissure anchor **795**, the posterior anchoring tab **800** and associated posterior commissure anchor **805**, or the antero-septal trigonal anchoring tab **810** and associated antero-septal commissure anchor **815**.

[00131] FIG. 8D shows that in the closed configuration **920**, the large anterior leaflet **900** has closed and that a posterior covering region **925** of said anterior leaflet **900** has sealed against a leaflet

coaptation edge **930** that appears on the posterior aspect **700** of the valve inflow. The prosthetic mitral valve may further comprise one or more of the anterior aspect **690** of the valve inflow, posterior aspect **700** of the valve inflow, the antero-lateral trigonal anchoring tab **790** and associated antero-lateral commissure anchor **795**, the posterior anchoring tab **800** and associated posterior commissure anchor **805**, or the antero-septal trigonal anchoring tab **810** and associated antero-septal commissure anchor **815**.

[00132] **FIG. 8E** illustrates an embodiment of a prosthetic mitral valve (**510**, as shown in **FIG. 5**) comprising a tri-leaflet configuration **940**, and formed from the plurality of leaflets that are herein described as the large anterior leaflet **960**, the small postero-lateral leaflet **970**, and the small postero-septal leaflet **950**. During systole, said leaflets are forced to close and contact each other along a leaflet coaptation edge **980**. The prosthetic mitral valve may further comprise one or more of the anterior aspect **690** of the valve inflow, posterior aspect **700** of the valve inflow, the antero-lateral trigonal anchoring tab **790** and associated antero-lateral commissure anchor **795**, the posterior anchoring tab **800** and associated posterior commissure anchor **805**, or the antero-septal trigonal anchoring tab **810** and associated antero-septal commissure anchor **815**.

[00133] **FIG. 8F** depicts an embodiment of a prosthetic mitral valve (**510**, as shown in **FIG. 5**), seen from the outflow view and comprising a tetra-leaflet configuration **990**. The valve may be formed from the plurality of leaflets that are herein described as a posterior leaflet **1000**, a septal leaflet **1010**, an anterior leaflet **1020**, and a lateral leaflet **1030**. During systole, the leaflets may be forced to close and contact each other along a leaflet coaptation edge **1040**. of the prosthetic mitral valve may comprise one or more anchoring tabs and commissure anchors. Along with the antero-septal **810**, and antero-lateral trigonal anchoring tabs and corresponding commissure anchors (**815** antero-septal, and **795** antero-lateral), a postero-septal **1060** and a postero-lateral **1050** anchoring tab may be present, as well as the corresponding postero-septal **1065** and postero-lateral **1055** commissure anchors. The prosthetic mitral valve may further comprise one or more of the anterior aspect **690** of the valve inflow, posterior aspect **700** of the valve inflow, the antero-lateral trigonal anchoring tab **790** and associated antero-lateral commissure anchor **795**, the posterior anchoring tab **800** and associated posterior commissure anchor **805**, or the antero-septal trigonal anchoring tab **810** and associated antero-septal commissure anchor **815**.

[00134] **FIG. 9** depicts a frame flat pattern **1070**, which is a representation of a toolpath that a machine-tool (such as a focused laser, router, end mill, or any other machine-tool as is known to one having skill in the art) may follow during the fashioning of a prosthetic valve (**510**, as shown in **FIG. 5**). The frame may be cut from a tubular stock of material. For instance, the frame may be cut from a tubular stock of

nitinol. The device may include several features discussed previously (introduced in **FIG. 5**), such as an antero-lateral commissure anchor **795** (element **620** of **FIG. 5**), an antero-septal commissure anchor **815** (element **555** of **FIG. 5**), and a posterior commissure anchor **805** (element **650** of **FIG. 5**). The phrase “strut format” refers to the elements illustrated in a frame flat pattern, whereupon the elements of the frame may be undeformed (i.e., shapeset through metallurgical heat-treatments that are known to those skilled in the art) and generally resemble rectangular members or “struts.” Additional details regarding the commissure structures and their spatial relationships with the anchoring tabs are depicted in **FIG. 9**. This flat pattern represents an embodiment of the prosthetic mitral valve depicted in **FIG. 5**.

[00135] The prosthetic mitral valve may comprise one or more attachment rails, one or more commissures, one or more commissure attachment holes, one or more commissure slots, and one or more commissure junctions. The prosthetic mitral valve may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 attachment rails, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 commissures, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 commissure attachment holes, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 commissure slots, and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 commissure junctions.

[00136] The antero-lateral commissure anchor **795** may protrude directly from the antero-lateral commissure **1085**. The antero-lateral commissure may be the origin and insertion of the antero-lateral anchoring tab **1110** (**610**, as shown in **FIG. 5**) via an antero-lateral commissural junction **1100**. One or more rows of antero-lateral commissure attachment holes **1090** may be located adjacent to an antero-lateral commissure attachment slot **1095** within the structure of the antero-lateral commissure **1085**. The attachment holes **1090** may provide a location for suture that may be used to sew the antero-lateral commissure suture pads (**615**, as shown in **FIG. 5**) into place. The antero-lateral commissure suture pads may work in conjunction with the antero-lateral commissure attachment holes to help fasten the valve leaflets of the prosthetic mitral valve to the frame. A free end **1111** of the antero-lateral anchoring tab **1110** is also shown, as are a free end **1116** of the antero-septal anchoring tab **1115** and a free end **1121** of the posterior anchoring tab **1120**. A plurality of struts or attachment rails may be used to locate and fasten leaflets onto the frame. Each strut may space a space between successive adjacent commissures. Each strut may have a “u” or arc-shaped form. Specifically, an anterior leaflet attachment rail **1080** may span the space between the antero-lateral commissure **1085** and the antero-septal commissure **1086**. The anterior leaflet attachment-rail **1080** may be used to attach the anterior leaflet (not shown) to the frame. A postero-septal leaflet attachment rail **1130** may span the space between the antero-septal commissure **1086** and the posterior commissure **1087**. The postero-septal leaflet attachment rail **1130** may be used to attach the postero-septal leaflet (not shown) to the frame. The postero-lateral leaflet attachment rail **1125** may span the space between the posterior commissure **1087**

and the antero-lateral commissure **1085**. A postero-lateral leaflet attachment rail **1125** may be used to attach the postero-lateral leaflet (not shown). The posterior commissure anchor **805**, posterior commissure **1087**, posterior anchoring tab **1120**, and the free end **1121** of the posterior anchoring tab **1120** are shown on both sides of **FIG. 9** to emphasize how the prosthetic mitral valve may be laid out in a frame flat configuration.

[00137] Additional structures may support radial compression against the native mitral annulus and/or help to seal the valve inflow against the left atrial floor. A plurality of rows of annular rhomboids **1150** may be located at the annular region **1140** of the frame, traversing the circumference of the frame. A plurality of atrial skirt support struts **1170** may emanate from the annular region **1140** and may act as support beams for a plurality of atrial skirt circumferential struts **1165**. The atrial skirt support struts may be substantially parallel to one another and may extend longitudinally. The atrial skirt circumferential struts may be substantially parallel to one another and may be substantially “v-shaped”. Each atrial skirt support struts may be connected at top and bottom to atrial skirt circumferential struts. The combination of atrial skirt support struts **1170** and atrial skirt circumferential struts **1165** may form the atrial region **1160** of the valve frame and may provide a location for the atrial skirt to be sutured onto the valve frame.

[00138] **FIG. 10** illustrates an embodiment of a frame flat pattern **1180**. The frame flat configuration **1180** may comprise any or all of the elements of **FIG. 9**, with further modifications. The frame flat configuration **1180** may additionally comprise one or more strut features. The configuration may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 strut features. For instance, one or more strut features may be added, each adjacent to two of the leaflet attachment rails. A postero-lateral chordal bumper strut **1190** may run approximately parallel to the postero-lateral leaflet attachment rail **1125**. The postero-lateral chordal bumper strut **1190** may aid in valvular operation by pushing the native chordae away from the prosthetic valve. This may further prevent obstruction in the sub-valvular space and LVOT. The configuration may comprise one or more bumper strut attachment points. The configuration may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 bumper strut attachment points. One or more postero-lateral chordal bumper strut attachment points **1195** may be located at each end of the postero-lateral chordal bumper strut **1190**. Each postero-lateral chordal bumper strut attachment point **1195** may effectively connect an end of the postero-lateral chordal bumper strut **1190** to the adjacent commissure. A postero-septal chordal bumper strut **1210** may run approximately parallel to the postero-septal leaflet attachment rail **1130**. One or more postero-septal chordal bumper strut attachment points **1200** may be located at each end of the postero-septal chordal bumper strut **1210**. Each postero-septal chordal bumper strut attachment point **1200** may effectively connect and end of the postero-septal

chordal bumper strut **1210** to the adjacent commissure. The postero-septal chordal bumper strut **1210** may be functionally equivalent to the postero-lateral chordal bumper strut **1190**. The postero-septal chordal bumper strut attachment points **1200** may be functionally equivalent to the postero-lateral chordal bumper strut attachment points **1195**.

[00139] FIG. 11 shows an embodiment of a frame flat pattern **1220**. The frame flat configuration **1220** may comprise any or all of the elements of **FIG. 10**, with further modifications.. The frame flat configuration **1220** may further comprise one or more wishbone-shaped members and an absence of the previously described commissure anchors. These alterations may provide an alternative method of anchoring the valve frame to a delivery system, as described herein. The configuration may comprise one or more wishbone struts, one or more wishbone anchors, and one or more wishbone attachment points. The configuration may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 wishbone struts, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 wishbone anchors, and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 wishbone attachment points. A postero-lateral wishbone shaped strut **1230** may emanate from a first strut attachment point **1240** on the antero-lateral commissure **1085**. The postero-lateral wishbone shaped strut **1230** may arc upwardly and across the postero-lateral leaflet space until it meets a second strut attachment point **1240** located on the posterior commissure **1087**. At the apex of the postero-lateral wishbone shaped strut **1230** may be a postero-lateral wishbone anchor **1235** which may replace the previously depicted antero-lateral and posterior commissure anchors (**795** and **805** of **FIG. 10**, respectively). The postero-lateral wishbone anchor **1235** may be functionally and structurally equivalent to the antero-lateral and posterior commissure anchors. Additionally, a postero-septal wishbone shaped strut **1250** may emanate from a first strut attachment point **1260** on the antero-septal commissure **1086**. The postero-septal wishbone shaped strut may arc upwardly and across the postero-septal leaflet space until it meets a second strut attachment point **1260** located on the posterior commissure **1087**. At the apex of the postero-septal wishbone shaped strut **1250** may be a postero-septal wishbone anchor **1255** which may replace the previously depicted antero-septal and posterior commissure anchors (**815** and **805** of **FIG. 10**, respectively). The postero-septal wishbone anchor may be functionally and structurally equivalent to the antero-septal and posterior commissure anchors. The wishbone shaped struts may allow the prosthetic mitral valve to be forced into an easily compressible configuration for delivery with a catheter, as described herein. This may result in a more easily retractable and/or repositionable prosthesis. wishbone shaped strut

[00140] FIG. 12 shows yet an embodiment of a frame flat pattern **1270**. The frame flat configuration **1220** may comprise any or all of the elements of **FIG. 11**, with further modification. The frame flat configuration **1270** may lack certain elements of **FIG. 11**. For instance, the postero-lateral chordal

bumper struts (**1190**, as shown in **FIG. 11**) and/or postero-septal chordal bumper struts (**1210**, as shown in **FIG. 11**) may be excluded from the frame flat configuration **1270**. Save for the absence of said bumper struts, the frame flat configuration **1270** may be functionally equivalent to the frame flat configuration **1220** of **FIG. 11**. A perspective view of the prosthetic mitral valve of **FIG. 12** can be seen in **FIG. 13**.

[00141] **FIG. 13** shows a perspective view of the prosthetic mitral valve shown as the frame flat configuration **1270** in **FIG. 12**. Any or all of the features and elements previously described in **FIG. 5** may be present in the embodiment of **FIG. 13**. The embodiment of **FIG. 13** may be functionally and structurally equivalent to the embodiment of **FIG. 5**, save for the addition of one or more wishbone shaped struts and one or more wishbone attachment regions. The embodiment of **FIG. 13** may comprise 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 wishbone shaped struts and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more than 10 wishbone attachment regions. **1330**. A postero-septal wishbone shaped strut **1320** may find a first insertion with the frame at an antero-septal tab wishbone attachment region **1300**, which may be located adjacent to the antero-septal commissure. The postero-septal wishbone shaped strut **1320** may find a second insertion with the frame at a posterior tab wishbone attachment region **1290**, which may be located adjacent to the posterior commissure. A postero-septal wishbone anchor **1255** may be located at the apex of the wishbone, allowing for attachment to a delivery system, as described herein. A postero-lateral wishbone shaped strut **1330** may find a first insertion with the frame at an antero-lateral tab wishbone attachment region **1310**, which may be located adjacent to the antero-lateral commissure. The postero-lateral wishbone shaped strut **1330** may find a second insertion with the frame at a posterior tab wishbone attachment region **1290**, which may be located adjacent to the posterior commissure. A postero-lateral wishbone anchor **1235** may be located at the apex of the wishbone, allowing for attachment to a delivery system, as described herein.

[00142] Prior minimally invasive procedures have been developed to deliver a prosthetic heart valve percutaneously over a delivery catheter through the patient's vasculature to the heart, or through the use of a transapical procedure to introduce the prosthesis through the chest wall and through the apex of the heart (**330** as shown in **FIG. 3**). An exemplary prosthesis includes that described in US Patent No. 8,579,964, the entire contents of which are incorporated herein by reference in their entirety for all purposes. Further embodiments of exemplary delivery catheters and delivery systems are described and illustrated in the following figures.

[00143] **FIG. 14** shows the prosthetic mitral valve with wishbone attachment of **FIG. 13**. The prosthetic mitral valve **1280** may comprise any or all of the elements of **FIG. 13**. The prosthetic mitral valve **1280** may be connected to a delivery system **1340**. The delivery system **1340** may comprise a completely

withdrawn delivery catheter **1350**. It should be readily apparent that the aforementioned postero-septal commissure anchor (**1255**, as shown in **FIG. 13**) and postero-lateral commissure anchor (**1235**, as shown in **FIG. 13**) are presently hidden by an anchoring sleeve member **1360** in **FIG. 14**. The delivery system **1340** is shown in **FIG. 14** as connected to a non-specific anchoring mechanism. Embodiments of the anchoring mechanism are described in **FIGs. 15-19**, as communicated by enlarged detail element **1345**.

[00144] **FIGs. 15A-B** show an embodiment of an anchoring method used to anchor commissure anchors to a delivery system utilizing a plurality of threaded connectors. **FIG. 15A** shows a plurality of threaded connectors **1370** in a connected configuration. In the connected configuration, a first male threaded connector **1390** and a second male threaded connector **1395** may be in threaded connection with a first female threaded connector **1375** and a second female threaded connector **1380**, respectively. The first and second male threaded connectors (**1390** and **1395**, respectively) may each comprise a segment of male threads **1400** appearing at a free end of a wishbone shaped strut **1410**. The wishbone shaped strut may replace the plurality of commissure anchors (**1255** and **1235**, as shown in **FIG. 13**). The male threads may be sized to fasten and mate to similarly threaded first and second segments of female thread **1405**. Arrows **1385** indicate rotation of each of the first and second female threaded connectors (**1375** and **1380**, respectively). Upon rotation in the direction of the arrows **1385**, the connectors may be in the state depicted in **FIG. 15B**.

[00145] **FIG. 15B** shows a plurality of threaded connectors (**1390** and **1395**) in a disconnected configuration **1420**. It should be apparent that in the state depicted in **FIG. 15B**, the male threaded connectors may be completely disconnected from the female threaded connectors. Upon disconnection, a prosthetic valve that was initially attached to a catheter delivery system through the wishbone connectors may be fully released from its delivery system. A further discussion of the internal mechanisms responsible for the operation of this embodiment of a delivery system begins with the description of **FIG. 29**.

[00146] **FIGs. 16A-B** show an embodiment of an anchoring method used to anchor commissure anchors to a delivery system using a single split-threaded connector. **FIG. 16A** shows a split-threaded connector **1430** in a connected configuration. One or more male split-threaded connectors **1450** may be in threaded connection with one or more female split-threaded connectors **1440**. Each male split-threaded connector **1450** may comprise a segment of male thread **1455** appearing at a free end of a wishbone shaped strut **1460**. The wishbone shaped strut may replace the plurality of commissure anchors (**1255** and **1235**, as shown in **FIG. 13**). The male threads may be sized to fasten and mate to similar threaded segments of female thread **1445** within the female threaded connector **1440**. Arrows

1435 indicate rotation of the individual female threaded connector **1440**. Upon rotation, the connectors may be in the state depicted in **FIG. 16B**.

[00147] **FIG. 16B** shows the split-threaded connector **1455** in a disconnected configuration **1470**. It should be apparent that in the state depicted in **FIG. 16B**, the male split-threaded connector may be completely disconnected from the female threaded connector. Upon disconnection, a prosthetic valve that was initially attached to a catheter delivery system through the wishbone connectors may be fully released from its delivery system. A further discussion of the internal mechanisms responsible for the operation of this embodiment of a delivery system begins with the description of **FIG. 27**.

[00148] **FIGS. 17A-B** show an embodiment of an anchoring method used to anchor commissure anchors to a delivery using a flexing pin-connector type anchoring mechanism. **FIG. 17A** shows a flexing pin-connector type anchoring mechanism **1480** in a connected configuration. One or more flexible sleeves **1490** may be closed about a plurality of pinhole connectors **1530**. The flexible sleeves **1490** may comprise a plurality of flexible sleeve portions **1495** that may be able to snap open and shut when a translating sleeve **1500** is drawn over or off of them. This movement of the translating sleeve may effectively encapsulating the flexible sleeve portions **1495**. The flexible sleeve **1490** may comprise a shape-settable and/or super-elastic nitinol material, as is known to those having skill in the art. Each flexible sleeve portion **1495** may comprise a terminal point **1510**, appearing at the free end of the flexible sleeve **1490**. The terminal points may allow connection of the flexing pin-connector type anchoring mechanism **1480** to wishbone shaped struts **1520**.

[00149] **FIG. 17B** shows the flexing pin-connector type anchoring mechanism **1480** in a disconnected configuration **1540**. The internal surface of each of the terminal points **1510** may comprise a connector pin **1555** which may fit into a complimentary hole for pin connection **1560**. Each of the wishbone shaped struts **1520** of the prosthetic mitral valve may terminate in a pinhole connector **1530**. The pinhole connectors may replace the plurality of commissure anchors (**1255** and **1235**, as shown in **FIG. 13**). Arrows **1550** indicate rotation of each of the individual flexible sleeve portions **1495**. Upon rotation, the connector may be in the state depicted in **FIG. 17B**. Arrow **1545** indicates translation of the translating sleeve **1500** over the flexible sleeve portions **1495**. It should be apparent that in the state depicted in **FIG. 17B**, the connector pins **1555** may be completely disconnected from the holes for pin connection **1560**. Upon disconnection, a prosthetic valve that was initially attached to a catheter delivery system through the wishbone connectors may be fully released from its delivery system. A further discussion of the internal mechanisms responsible for the operation of this embodiment of a delivery system begins with the description of **FIG. 24A**.

[00150] **FIGs. 18A-C** show an embodiment of an anchoring method used to anchor commissure anchors to a delivery system using a plurality of flexible buckle type anchoring mechanisms is employed. **FIG. 18A** shows a plurality of flexible buckle type connectors **1570** in a connected configuration. A plurality of flexible buckles **1580** may be in captured connection with, restrained by, or disposed within an aperture **1575** that is sized to accept and retain the flexible buckles **1580** utilizing opposing tensile forces. The aperture may be fashioned in the side of a translating sleeve **1500**. Each of the flexible buckles may be located adjacent to and protruding from the end of a wishbone shaped strut **1520**, which may replace the plurality of commissure anchors (**1255** and **1235**, as shown in **FIG. 13**). A sheath catheter **1350** may be concentrically positioned over the top of the translating sleeve **1500**. When the translating sleeve **1500** is drawn against the sheath catheter **1350**, the mechanism of action may be achieved.

[00151] **FIG. 18B** depicts the hidden structure of the flexible buckles **1580**, as the translating sleeve **1500** blocks said structure from view in **FIG. 18A**.

[00152] **FIG. 18C** shows the flexible buckle type anchoring mechanisms in a disconnected configuration. When the translating sleeve **1500** is drawn against the sheath catheter **1350**, the flexible buckles **1585** may be forced closed by the inner surface of the sheath catheter **1500**, and released from constraint. It should be apparent that in the state depicted in **FIG. 18C**, the flexible buckle type connectors may be completely disconnected from their aperture **1575** and associated translating sleeve **1500**. Upon disconnection, a prosthetic valve that was initially attached to a catheter delivery system through wishbone connections may be fully released from its delivery system. A further discussion of the internal mechanisms responsible for the operation of this embodiment of a delivery system begins with the description of **FIG. 26A**.

[00153] **FIGs. 19A-B** show an embodiment of an anchoring method used to anchor commissure anchors to a delivery system using a plurality of anchor shaped commissure anchors. **FIG. 19A** shows a plurality of anchor shaped commissure anchors **1630**, adjacent to and connected with the ends of a plurality of wishbone shaped struts **1410**, in a connected configuration. The plurality of commissure anchors **1630** may rest within a complimentary plurality of slots **1615**. The slots may act to retain the anchors and resist tensile forces that may be developed during operation of the delivery system. The slots **1615** may be fashioned on the anchoring end **1610** of an anchoring catheter **1600**. The plurality of commissure anchors **1630** depicted in **FIG. 19A-B** may be identical to the plurality of commissure anchors (**1255** and **1235**, as shown in **FIG. 13**) in design, construction, and function.

[00154] **FIG. 19B** shows the commissure anchors **1640** in an unconstrained configuration that may allow disconnection. Arrow **1620** indicates translation of an anchoring sleeve member **1360**. Upon

translation, the state depicted in **FIG. 19B** may be realized. It should be apparent that in the state depicted in **FIG. 19B**, the commissure anchors **1640** may be unconstrained and capable of being disconnected from the slots **1615** of the anchoring catheter **1600**. Upon disconnection, a prosthetic valve that was initially attached to a catheter delivery system may be released from its delivery system. A further discussion of the internal mechanisms responsible for the operation of this embodiment of a delivery system begins with the description of **FIG. 21A**.

[00155] **FIGs. 20A-20F** depict the successive stages of unsheathing an embodiment of a delivery system and implanting a mitral valve prosthesis. Although the resultant effects of the operation of said delivery system (such as the release of a constrained prosthetic mitral valve) are discussed with reference to the relevant elements necessary for illustration, the mechanical relationships of the various internal components necessary for the physical realization of the delivery system embodiments are not illustrated or discussed until further below, in **FIGs. 21-31**. The deployment process as depicted in **FIGs. 20A-20F** proceeds as follows. A sheath catheter which may constrain a compressed prosthetic valve comprised of tissues, fabrics, sutures and a nitinol frame may be retracted from the valve while in place within the implantation zone. The physiological temperature of the blood in a patient's heart may cause the nitinol material to expand and conform to the space in which it has been implanted. As the prosthesis expands, elements of the invention that are responsible for anchoring to the native anatomy may also expand, allowing the prosthesis to remain in place in order to function as a one-way valve and support proper circulation of blood. It shall be recognized that the relevant anatomy has been previously illustrated in **FIGs. 1-4**, but is not repeated in the following figures, leaving room to focus on the prosthesis and delivery system.

[00156] **FIG. 20A** depicts an embodiment of a fully loaded (sheathed and closed) delivery system **1700**. The delivery system may comprise a prosthetic mitral valve (shown in **FIGs. 20B-20F**) that has been compressed and inserted into a sheath catheter **1350** prior to implantation. A long, tapered and flexible self-dilating dilator tip **1710** may aid the insertion of the delivery system within a small incision that is prepared in the prospective patient (not shown). The incision may be made in the thorax and may lead directly into and through the apex of the heart. The widest end of the dilator tip **1710** may be terminated by an edge **1720** that may register against and fits concentrically within a leading edge **1725** that may appear on the distal end of the sheath catheter **1350**. A lumen **1715** may be formed at the distal-most portion of the dilator tip **1710**, and may extend throughout the entirety of the catheter to which the dilator tip **1710** is attached.

[00157] **FIG. 20B** depicts an embodiment **1730** of a loaded delivery system with the atrial skirt revealed, showing the sheath catheter **1350** previously described in **FIG. 20A** translated a slight distance

away from the dilator tip **1710**. Specifically, the leading edge **1725** of the sheath catheter **1350** may be moved away from the edge **1720** of the dilator tip **1710**, and may thereby reveal a partially constrained atrial skirt **1750**.

[00158] **FIG. 20C** depicts an embodiment **1760** of a loaded delivery system with the anterior trigonal anchoring tabs revealed, showing the sheath catheter **1350** previously described in **FIG. 20B** translated away from the dilator tip **1710** to an even greater extent. Specifically, the leading edge **1725** of the sheath catheter **1350** may be moved further away from the edge **1720** of the dilator tip **1710**, and may thereby reveal most of the structure of the encapsulated prosthetic mitral valve. An atrial skirt **1770** may now be approximately released, yet a still partially constrained annular region **1775** may remain constricted by the sheath catheter **1350**. The configuration of **FIG. 20C** may remove a constraint that may allow the self-expansion of a portion of the prosthetic mitral valve. Adjacent to and directly beneath the constrained annular region **1775** may be a constrained anterior leaflet **1780**, which may remain substantially compressed. Protruding from beneath the leading edge **1725** of the sheath catheter **1350** may be a plurality of trigonal anchoring tabs, such as an antero-lateral trigonal anchoring tab **790** (with an associated free end **1790**), and an antero-septal trigonal anchoring tab **540** (with an associated free end **545**).

[00159] **FIG. 20D** depicts an embodiment **1800** of a loaded delivery system with the anterior trigonal anchoring tabs fully open, showing the sheath catheter **1350** previously described in **FIG. 20C** translated away from the dilator tip **1710** to an advanced extent. Specifically, the leading edge **1725** of the sheath catheter **1350** may be moved further away from the edge **1720** of the dilator tip **1710**, and may thereby reveal all of the structure of the encapsulated prosthetic mitral valve, except for the commissure attachment (not shown). The atrial skirt **1770** may now be completely unconstrained, as may an annular region **1810**. Adjacent to and directly beneath annular region **1810** may be a partially constrained anterior leaflet **1825**, which may be almost completely released. The anterior leaflet **1825** may be operational and able to coapt against any other leaflets present in this embodiment (not shown). The plurality of trigonal anchoring tabs (antero-lateral trigonal anchoring tab **790** and associated free end **1790**, and antero-septal trigonal anchoring tab **540** and associated free end **545**) may be splayed open due to the interaction between the leading edge **1725** of the sheath catheter **1350** and the still-constrained wishbone shaped struts **1820** to which the trigonal anchoring tabs may be directly connected. This opening effect may allow the trigonal anchoring tabs to reach around the native anterior mitral leaflet (**460**, as shown in **FIG. 4**) and through the anterior chordae (**465**, as shown in **FIG. 4**) in order to abut against the trigones after release. Emanating from and concentrically nested within the

sheath catheter **1350** may be a guidewire catheter **1830**, which may be directly connected to and provide support for the dilator tip **1710**.

[00160] **FIG. 20E** shows an embodiment **1840** of a loaded delivery system, just prior to final release, showing the sheath catheter **1350** previously described in **FIG. 20D** translated away from the dilator tip **1710** to an advanced extent. Specifically, the leading edge **1725** of the sheath catheter **1350** may be moved further away from the edge **1720** of the dilator tip **1710**, and may thereby reveal all of the structure of the encapsulated prosthetic mitral valve, such as the fully deployed wishbone shaped struts **1880**, which may be about to be released from the delivery system. The antero-septal **1860** and antero-lateral **1870** trigonal anchoring tabs may be released from their constraint, and may now be in their final position. The anterior leaflet **1850** may be completely freed, and may be in an operable state spanning the native anterior leaflet.

[00161] **FIG. 20E** depicts final deployment **1890** with the delivery system removed. The wishbone shaped struts **1900** and associated commissure anchors **1910** may be entirely released and free from constraint by the delivery system. In this depiction, the prosthesis of the present invention may be fully functional, and free to operate within the native anatomy.

[00162] A thorough discussion of several relevant delivery system embodiments will now be presented, with reference to elements appearing in **FIGs. 21-31**.

[00163] **FIGs. 21A-23** depict an embodiment of a delivery system that corresponds to the description relating to **FIGs. 19A-19B** and that may be compatible with the prosthetic mitral valve embodiment described in **FIG. 13**.

[00164] **FIG. 21A** shows an embodiment of a fully open, extended-length delivery system **1920**. The delivery system may comprise a delivery system handle **1940**. The delivery system handle may comprise a slender, graspable member **1960** that may allow for the housing of various mechanical components, and may provide a location for a family of concentrically nested catheters. The delivery system handle **1940** may also provide an actuation mechanism, such as in the form of a rotatable (see arrow **1950** indicating rotation) thumbwheel **1955**. The thumbwheel may be substantially cylindrical and may have internal threads (not shown) that transform rotational torque applied by a user into linear force. The linear force may be used to translate certain catheters from the family of concentrically nested catheters. The previously discussed sheath catheter **1350** is again present and may be a substantially cylindrical tube with an inner lumen, extending from within the delivery system handle **1940** to a leading edge **1725** that may transit the distance between the edge **1720** of a dilator tip **1710** positioned at the distal-most extremity of the entire device and a set distance proximally away from the edge **1720** that may equate substantially to the constrained length of a prosthetic valve (not shown). An

anchoring sleeve member **1360** may be concentrically nested within the sheath catheter **1350**, which may itself also have an inner lumen that extends from within the delivery system handle **1940** up to and slightly beyond the tip of an anchoring catheter **1930**. The anchoring catheter **1930** may itself be cylindrical and concentrically nested within the anchoring sleeve member **1360**. Further detail regarding the anchoring catheter **1930** is provided in **FIG. 22**. The innermost concentrically nested catheter is the guidewire catheter **1830**, which may be connected to the dilator tip **1710**. There may be an inner lumen extending through the entire length of the delivery system, which may be appropriately sized to receive and transmit a guidewire (not shown) that may be placed within it. An arrow **1925** depicting translation shows how the sheath catheter **1350** may be brought toward the dilator tip **1710** as the thumbwheel **1955** is rotated.

[00165] **FIG. 21B** shows the device introduced in **FIG. 21A** in a configuration **1970**, with the sole differences being the position of the sheath catheter **1350** and the position of the anchoring sleeve member **1360**. The sheath catheter may be translated even further toward the dilator tip **1710** (as depicted by arrow **1975** indicating translation). The anchoring sleeve member **1360** may also be translated. By translating toward the dilator tip **1710**, the anchoring sleeve member **1360** may effectively cover up the anchoring catheter **1930**, **FIG. 21A**. This is the same mechanical relationship depicted in **FIGs. 19A** and **19B**, although in the reverse order.

[00166] **FIG. 21C** shows a closed delivery system **1980**, wherein the thumbwheel **1955** may be rotated to its full extent, and the sheath catheter **1350** may be brought to close against the dilator tip **1710**.

[00167] **FIG. 22** shows the embodiment and configuration of the device as illustrated in **FIG. 21A** with additional detail in the form of an enlarged view **1985**. Specifically, a stabilizer member **1990** may be located between the inner surface of the sheath catheter **1350** and the outer surface of the anchoring sleeve member **1360**. The stabilizer member may take the form of a star shaped cylindrical prism. The stabilizer member may force concentricity between said catheters while still allowing blood and/or saline to flow past. The slotted end of the anchoring catheter **1930** is also portrayed. It may be seen that the anchoring sleeve member **1360** may be positioned concentrically around and in slidable communication with the anchoring catheter **1930**. The guidewire catheter **1830** is again shown exiting the anchoring catheter **1930**.

[00168] **FIG. 23** illustrates an exploded view of the exemplary device of **FIGs. 21A-22B**. The device may comprise a delivery system handle A-side **2140** that may be in mated connection with a delivery system handle B-side **2145**. The device may effectively provide a housing and location for the family of concentrically nested catheters seen to the left side of the handle elements (and described in **FIGs. 22-22**), and the various elements seen to the right side of the handle elements. The device may comprise a

needle hub **2130**, which may be in mated connection with the proximal end **2000** of the guidewire catheter **1830**. The mated connection may be formed using adhesives. The needle hub **2130** may act as a connecting port, through which a syringe (not shown) may be attached to the device and used to flush sterile saline through the innermost lumen to remove air prior to insertion into a patient. A cylindrical anchoring nut **2120** may be in threaded connection with threads on the proximal end **2035** of the anchoring catheter **2010**. The cylindrical anchoring nut may be located within the plurality of handle halves **2140** and **2145** so as to fasten the anchoring catheter **2010** to the delivery system. An inner lumen may run the entirety of the length of the anchoring catheter **2010** and may allow for the concentric nesting of the guidewire catheter **1830** within. A spring **2110** may be mated to and press against a bell slider cap **2100**, which may itself mated to a bell slider **2090**. The spring **2110** may provide a bias force with which the bell slider **2090** may be moved when a leadscrew **2080** is brought out of contact with it. In other words, by rotating the thumbwheel **1955**, the leadscrew **2080** may be translated linearly and may be brought into contact with the distal portion of the bell slider **2090**, which may in turn be biased against the spring **2110**. The bell slider **2090** may act as a carriage for the proximal end **2060** of the bell catheter **2040** (previously referred to as an anchoring sleeve member **1360**) and may allow the distal end **2050** of said bell catheter **2040** to be brought away from the distal end **2020** of the anchoring catheter **2010**, which may be the mechanism responsible for final valve commissure release. The leadscrew **2080** may also be translated in an opposite direction by turning the thumbwheel **1955**, in order to close the delivery system and seal the valve inside. This may be achieved by way of the leadscrew's **2080** connection to a leadscrew cap **2070**, which may itself be mated to the proximal end **2065** of the sheath catheter **1350**. Thus, rotating the thumbwheel **1955** in a first direction may move the leadscrew **2080** towards the dilator tip **1710**, and by extension may also move the sheath catheter **1350** towards said dilator tip **1710** in order to close the device. Rotating the thumbwheel **1955** in a second opposite direction may move the leadscrew **2080** towards the bell slider **2090** and by extension may move both the sheath catheter **1350** and the bell catheter **2040** away from the dilator tip **1710** to open the device and release the prosthetic valve contained within. It should be understood that while both the sheath catheter **1350** and bell catheter **2040** may move synchronously by way of thumbwheel **1955** rotation, there may be a delay in contact provided by the dimensions of the relevant catheters and leadscrew **2080**. The delay may allow some portions of the prosthesis to be uncovered before other portions as the deployment progresses. It should also be understood that the prosthetic valve may ultimately be recaptured or obtained for repositioning or removal by simply closing the sheath catheter **1350** until the leading edge **1725** of said sheath catheter **1350** again contacts the edge **1720** of the dilator tip **1710**.

Finally, a distal end **1995** of the guidewire catheter **1830** may be in mated connection with and anchored to the dilator tip **1710**.

[00169] **FIGs. 24A-25** depict an embodiment of a delivery system corresponding to the description relating to **FIGs. 17A-17B**. In the same manner as the illustrations depicted in **FIGs. 24A-24C**, the relationship between thumbwheel **1955** rotation and sheath catheter **1350** translation is also depicted here. In **FIG. 24A**, a fully open delivery system **2150** may be designed for a flexible connection type of attachment to a prosthetic valve (not shown). An arrow **2190** indicating rotation shows that as the thumbwheel **1955** is rotated, the sheath catheter **1350** may again translate (see arrow **2180** indicating translation) toward the dilator tip **1710**. In this embodiment, a plurality of flexible connector prongs **2160** may be subjected to a camming action due to their inherent arcuate profile and the gradually increasing level of contact between said flexible connector prongs **2160** and the leading edge **1725** of the sheath catheter **1350**. This may bring the flexible connector prongs **2160** into close contact with one another. At the distal tip of each flexible connector prong **2160** may be a connecting element **2170**, which may be a substantially cylindrical boss that may mate with a substantially cylindrical hole or cavity within the commissure element of an associated prosthetic valve (elements **1530**, **1555**, and **1560** show in **FIG. 17B**). **FIGs. 24B** and **24C** show the logical continuation of the sheathing process (**2200** partially open, **FIG. 24B**, and **2210** fully closed, **FIG. 24C**) whereby the leading edge **1725** of the sheath catheter **1350** may be eventually brought into contact with the edge **1720** of the dilator tip **1710**.

[00170] **FIG. 25** shows an exploded view of the delivery system introduced in **FIG. 24A-24C**. The components set forth in this depiction may differ only slightly from the components set forth in **FIG. 23**. The embodiment of a delivery system as shown in **FIG. 25** may not require a bell catheter, as the capturing mechanism may be provided by the relationship between the leading edge **1725** of the sheath catheter **1350** and the plurality of flexible connector prongs **2160**. Therefore, the embodiment of **FIG. 25** may not require a bell slider either. In order to operate the device, a user may only need to draw the sheath catheter **1350** back and forth with the thumbwheel **1955**, directly compressing the plurality of flexible connector prongs **2160**. It should be readily understood that the flexible connector prongs **2160** may be fashioned into the distal end of the flexible prong anchoring catheter **2220**.

[00171] **FIGs. 26A-26B** depict an embodiment of a delivery system corresponding to the description relating to **FIGs. 18A-18C**. **FIG. 26A** shows an exploded view of an embodiment of a delivery system that may be suitable for connecting with a prosthetic valve frame having flexible buckle type anchors. The components set forth in this depiction may differ only slightly from the components set forth in **FIG. 23**. In the embodiment of **FIGs. 26A-26B**, the proximal end **2035** of the anchoring catheter **2010** may be in mated connection with the bell slider **2090** instead of an anchoring nut and may be able to

freely translate along with the bell slider **2090** when contacted by the leadscrew **2080**. The bell slider **2090** may further comprise a plurality of pins **2226** that may transmit the force from the leadscrew **2080** to the bell slider **2090** while also providing clearance for a stationary bell catheter nut **2224** that may anchor and retain the stationary bell catheter **2040** to the delivery system. Thus, by rotating the thumbwheel **1955** the leadscrew **2080** may be brought into contact with the plurality of pins **2226**, forcing the bell slider **2090** and anchoring catheter **2010** proximally away from the dilator tip **1710**. This may effectively retract the anchoring catheter **2010** into the stationary bell catheter **2040**. This relationship is illustrated in greater detail in **FIG. 26B**.

[00172] In **FIG. 26B**, an enlarged view **2228** is provided, which shows in detail the elements that may be present at the distal most end of the translating anchoring catheter **2010** and stationary bell catheter **2040**. When the distal end **2227** of the anchoring catheter **2010** is brought into the distal end **2050** of the bell catheter **2040**, an aperture **2229** that may be formed within the distal end **2227** of the anchoring catheter **2010** may also be brought into said bell catheter distal end **2050**. This action effectively may provide the mechanism behind the embodiment illustrated in **FIGs. 18A-18C**.

[00173] **FIGs. 27** and **28** depict an embodiment of a delivery system corresponding to the description relating to **FIGs. 16A-16B**. **FIG. 27** shows an exploded view **2230** of an embodiment of a delivery system that may be suitable for connecting with a prosthetic valve frame having a single threaded connector anchor. The components set forth in this depiction may differ only slightly from the components set forth in **FIG. 23**. The embodiment may comprise a plurality of stabilizers **1990**. The stabilizers may improve concentricity of the concentrically nested catheters. Again, a plurality of handle halves (A-side **2250**, and B-side **2260**) may provide a location for the various internal components. The delivery system may also comprise a plurality of thumbwheels, such as a first thumbwheel **1955** for actuating the sheath catheter **1350** and a second thumbwheel **2270** for rotating the threaded bell catheter **2040**. The first and second thumbwheels may allow the catheter to connect and disconnect from the related prosthetic valve. Further, the second thumbwheel **2270** may contain a hole **2275** through which the proximal end **2060** of the rotating bell catheter **2040** may be fastened to said second thumbwheel **2270**. An exploded view **2240** of the family of concentrically nested catheters is provided, and further detail regarding the threaded mechanism at the distal end of the family of catheters is provided in **FIG. 28**.

[00174] **FIG. 28** shows an exploded view **2280** focusing on the distal end of the family of nested catheters. Arrow **2300** indicates rotation, which corresponds to the rotation of the threaded and distal end of the bell catheter **2310** in order to connect or disconnect from threaded fasteners that may be present in a valve prosthesis.

[00175] FIGs. 29-31 depict an embodiment of a delivery system corresponding to the description relating to FIGs. 15A-15B. FIG. 29 shows an exploded view of an embodiment of a delivery system that may be suitable for connecting with a prosthetic valve frame having a plurality of threaded type connector anchors (1400, as shown in FIG. 15A). The components set forth in this depiction may be substantially similar to the components set forth in FIG. 23. FIG. 29 shows an exploded view of the delivery handle portion of the delivery system 2320 and an exploded view of the concentrically nested catheters 2330. A slot 2390 may be formed at the proximal end of both delivery system handle A-side 2370, and B-side 2380. The slots may allow for rotational displacement of a level 2420 that may be orthogonal to and originates from a cylindrical torque transmitting member 2410. The torque transmitting member 2410 may be in mated connection with the proximal or driving end 2355 of a torque catheter 2350, and may travel concentrically through a catheter mount 2400, a leadscrew 2080, a plurality of stabilizers 2360, and a sheath catheter 1350 before terminating in a distal or driven end 2352 that may further transmit torque through a geared relationship and that is further described in FIG. 31. The catheter mount 2400 may provide a lateral location and fixation for fixed ends 2345 of a plurality of twisting thread-connector catheters 2340. The thread-connector catheters 2340 may be long, thin, flexible members which may be structurally rigid in compression. The thread-connector catheters may be able to be twisted about their axes when an appropriate torque is applied. In order to maintain the adjacency between the torque catheter 2350 and the plurality of thread-connector catheters 2340, a plurality of stabilizers 2360 may act as journal bearings to both internally retain the placement of the torque catheter 2350 and to externally retain the placement of the plurality of thread-connector catheters 2340. The plurality of thread-connector catheters may be concentrically nested within the sheath catheter 1350. As previously described, by rotating the thumbwheel 1955 the leadscrew 2080 and by extension sheath catheter 1350 may be made to translate, which in turn may cause the leading edge 1725 of the sheath catheter 1350 to advance towards or retreat from the dilator tip 1710.

[00176] FIG. 30 shows the exploded view 2330 of FIG. 29 in greater detail and shows the nesting configuration of the family of catheters.

[00177] FIG. 31 shows an enlarged view 2430, which illustrates in detail the mechanical interaction at the distal end of the delivery system of FIG. 29. As previously described, actuating the lever (2400, as shown in FIG. 29), which may be operably coupled to the driven end 2352 of the torque catheter (2350, as shown in FIG. 29) may cause the torque catheter to rotate, and may further cause a driving gear 2490 to rotate and transmit torque to a plurality of driven gears 2470 that are adjacent to the distal ends 2342 of the plurality of thread-connector catheters 2340 and by extension also adjacent to the threaded socket 2480 of each thread-connector catheter 2340. It should be apparent that rotation of the driving gear 2490

in a first direction (as shown by arrow **2460** indicating rotation) may cause a rotation of each of the driven gears **2470** in a second direction, opposite the first (as shown by arrows **2450** indicating rotation). A mechanical advantage may exist between the driving **2490** and driven **2470** gears. The mechanical advantage may result in an increase in rotational displacement of the driven gears with respect to the driving gears. The mechanical advantage may provide a 4:1 increase in rotational displacement of the driven gears with respect to the driving gears. At the distal end **2342** of each thread-connector catheter **2340** may be a threaded socket (**2480**, as shown in **FIG. 31**) which may be used to connectedly mate to a threaded fastener that may be anchored to an embodiment of the prosthetic valve (**1390** and **1395**, as shown in **FIG. 15A**).

[00178] **FIG. 32** illustrates a prosthetic valve implanted in a mitral valve of a patient's heart. With traditional methods of implantation and traditional devices, the natural blood flow path may be disrupted and blood flow may become turbulent. The blood may flow toward the apex of the heart and towards the septal wall creating turbulence.

[00179] **FIG. 33** illustrates the desired blood flow path through the mitral valve and out the ventricle. The native mitral valve directs the blood to flow along the posterior wall of the ventricle towards the apex of the heart where the blood then continues to flow in a non-turbulent manner up the septal wall and then during heart systole the blood is ejected out of the left ventricular outflow tract (LVOT) and through the aorta to the rest of the body. In this configuration, the blood flow maintains its momentum and conserves its energy resulting in the most efficient flow.

[00180] **FIG. 34** illustrates a prosthetic valve implanted in a native mitral valve. The prosthetic mitral valve has features which preferably avoid obstructing the left ventricular outflow tract and also may help maintain the natural blood flow path so as to conserve momentum of the blood flow and avoid turbulence. For example, the prosthetic valve preferably has a large anterior prosthetic valve leaflet **3410** that spans the width of the native anterior valve leaflet. This will help mimic the size and motion of the native valve leaflet thereby avoiding obstruction of the LVOT. Additionally, the prosthesis has a low profile so that it does not extend too far in to the ventricle, and an atrial flange or skirt helps anchor the prosthesis to the atrial floor. The atrial skirt **3420** also preferably has a low profile. The prosthesis may also include one or preferably two anterior anchoring tabs **3430** that extend behind (anterior of the native leaflet) the native valve leaflets and anchor the prosthesis to the fibrous trigones on the anterior portion of the valve, or anchor on tissue adjacent and anterior of the anterior leaflet. The body **3440** of the valve may direct blood flow to the posterior. Additional details of the anchoring tabs may be found in US Patent No. 8,579,964, the entire contents of which have been previously been incorporated herein by reference. The body of the prosthesis may be designed to avoid LVOT obstruction and this may help

direct blood flow downward along the posterior wall of the heart in a circular manner toward the apex, and then upward along the septum toward the LVOT, thereby maintaining a substantially normal blood flow path that avoids turbulence and maintains momentum of the blood flow. Additional details about these and other features of the prosthesis are discussed in greater detail in this specification.

[00181] FIG. 35 illustrates a ventricular view of the prosthesis which preferably has a large anterior prosthetic leaflet, and two posterior leaflets. Preferably, three commissure posts are used to support the prosthetic valve leaflets and form a tricuspid prosthetic valve. The prosthesis may comprise an atrial skirt **3520**. Additionally, the prosthesis preferably includes two anterior anchor tabs **3510** and optionally one or more posterior anchor tabs **3530**. The anterior anchor tabs may anchor to the fibrous trigones of the valve or they may anchor to tissue that is anterior of the anterior leaflet and adjacent thereto, and in order to avoid interfering with movement of the anterior prosthetic leaflet, the anterior anchor tabs are also preferably at the same circumferential position as the commissure posts. In this exemplary embodiment, the anterior anchor tabs are located approximately at the 10 o'clock and 2 o'clock positions along with two of the commissure posts. The prosthesis is preferably D-shaped in order to conform to the native valve anatomy. Therefore, the anterior portion of the valve is preferably flat and linear so that it does not impinge on the LVOT, and the posterior of the prosthesis is preferably cylindrical so that it conforms to the native valve. In some embodiments, instead of a flat and linear anterior portion, the anterior portion may be concave or slightly convex.

[00182] FIG. 36A illustrates more clearly the two anterior anchor tabs which extend upward toward the atrium and away from the commissure posts which extend toward the ventricle, and similarly the posterior anchor also extends upward toward the atrium while the adjacent commissure post extends downward toward the ventricle. Note that in this view, only one of the anterior anchor tabs is visible. The prosthesis may comprise an atrial skirt **3610**.

[00183] FIG. 36B illustrates an outflow view of the prosthesis of **FIG. 36A**, whereby both anterior trigonal anchoring tabs are present, as well as the posterior anchoring tab, and the commissures associated with each of said tabs. It should be apparent that the commissure posts and anchoring tabs are adjacent each other. The prosthesis may comprise an anterior anchor **3620**, an anterior leaflet **3630**, an anterior commissure **3640**, a posterior anchor **3650**, and a posterior commissure **3660**.

[00184] FIG. 37 illustrates two embodiments of structure on the prosthesis for coupling it to a delivery catheter. The figure shows a pattern of the anchor frame after it has been flattened and unrolled. It is formed from numerous interconnected struts which form open or closed cells that can self-expand or that may be balloon expandable. On the left side of **FIG. 37**, a first exemplary embodiment shows a single arcuate strut that forms a closed single cell on the atrial portion of the device. This strut may be

folded radially outward to form a flanged region or atrial skirt which can anchor to the atrial floor. A commissure post with a D-shaped or mushroom head shaped, or anchor shaped portion on the opposite end of the prosthesis may be used to couple and uncouple the device from a delivery catheter as described previously in this specification and in US Patent No. 8,579,964 previously incorporated by reference, and is generally on a ventricular portion of the device. A triangular anchor tab is nested in the single cell between the commissure post and the atrial flange. Thus, the anchor tab is superior to the commissure post. The anchor tab may be formed to flare radially outward during deployment so that the anchor tab may be disposed behind a native leaflet (anterior to the anterior native leaflet, or posterior to a native posterior leaflet) and engage the anterior or posterior native anatomy as described in this specification. The commissure may have suture holes disposed therein in order to allow sutures to attach tissue or other material to the commissure posts. Nesting of the anchor tab adjacent the commissure post helps reduce overall device profile.

[00185] The right-hand side of **FIG. 37** illustrates another exemplary embodiment of an anchor structure that allows the prosthesis to be coupled to the delivery catheter. On the right-hand side, multiple closed cells form the atrial region of the device which may be formed to flare radially outward and create a flanged region that may be secured to the atrial floor of the atrium. Two commissure posts include a slotted region for receiving sutures so that tissue or other material may be coupled to the device. The commissure posts are connected together with a wishbone shaped strut having a central tab that may be coupled to the delivery catheter. The wishbone may extend between two commissures or three commissures, or more commissures. Thus, in this embodiment, only a single connector is used to couple the prosthesis to the delivery catheter. The struts of the frame may be EDM machined or laser cut from tubing (e.g. hypo tube), laser cutting or photo etching a flat sheet and welding the ends together, or by other techniques known in the art.

[00186] **FIG. 38** illustrates a perspective view of the prosthetic mitral valve. An upper portion includes an atrial skirt or atrial flange that generally takes the same form as the atrial skirt or flange described in US Patent No. 8,579,964, previously incorporated herein by reference. The prosthetic valve leaflets are also shown, and preferably include one large anterior leaflet that spans the width of the native anterior mitral valve leaflet, and may include two, or three, or more posterior prosthetic leaflets. Thus, the prosthetic valve may only have two prosthetic leaflets, or three or more prosthetic leaflets in total. Two anterior anchoring tabs also preferably share the same position as the commissure posts. This keeps the anterior commissure posts and the anterior anchor tabs out of the flow path thereby helping to avoid LVOT obstruction, and also helps keep overall profile of the device to a minimum in the collapsed configuration which is desirable during delivery.

[00187] **FIG. 39A** shows an anterior view of the prosthetic valve in the expanded configuration with the anchoring tabs flared outward and in the expanded configuration.

[00188] **FIG. 39B** shows a top view of the prosthetic valve with four prosthetic leaflets including one large anterior leaflet that spans the width of the native anterior leaflet and three posterior leaflets, all coupled together with four commissure posts that may optionally be combined with four anchor tabs. Two of these anchor tabs are preferably anterior anchoring tabs for anchoring the prosthetic valve to the fibrous trigones or any other anatomic location described herein including a region anterior of the anterior leaflet and adjacent thereto, and the two posterior tabs may anchor the prosthetic valve to the posterior shelf of the posterior annulus and posterior to the native posterior leaflet.

[00189] **FIG. 40** shows deployment of the prosthesis by either a transseptal or by a transapical delivery system. In either, preferably an outer sheath catheter constrains the device from self-expanding and when the outer sheath catheter is retracted the device self-expands. Here, the sheath catheter is partially retracted and the anterior **4010** and posterior **4020** anchor tabs are partially deployed.

[00190] **FIG. 41** shows a partial perspective view of the prosthetic valve with an upper saddle shaped atrial skirt for atrial anchoring along with the combined large anterior leaflet and two or three posterior leaflets and combined anchor tabs/commissure posts.

[00191] **FIG. 42** shows a flat pattern of the combined anterior or posterior anchor tab that is nested in the commissure post. The anchors in alternative embodiments may be cut above the commissure posts and bent backward during heat treating and shape setting so they can anchor to the native heart valve anatomy as described in this specification. This may require the anchors to be deployed first, before other portions of the prosthesis, as seen in **FIG. 40**. This may also involve anchoring of the prosthesis to the delivery catheter on both the inflow end and the outflow ends of the prosthesis for successful delivery.

[00192] **FIG. 43A** shows the unexpanded anchor tabs which may be triangular in the collapsed configuration and have a horizontal paddle shape in the expanded configuration in order to increase the contact area and thereby minimize tissue trauma, tissue piercing during anchoring, as illustrated in **FIG. 43B**. Alternatively, the anchors may have pointed tips which pierce or embed in tissue to help anchor the device.

[00193] **FIG. 43C** shows an exemplary cut pattern of the prosthesis that provides the results seen in **FIGS. 43A-43B**.

[00194] **FIG. 44** illustrates a top view of the prosthetic valve with a large anterior leaflet that spans the width of the native anterior leaflet, and two posterior prosthetic leaflets. The prosthetic leaflets are coupled together with three commissure posts.

[00195] FIG. 45 shows portions of the prosthesis including the upper atrial skirt, an annular region and the anchor tabs which may be combined with commissure posts. The anchor tabs are preferably 10 mm – 50 mm long, more preferably 20 mm – 30 mm long to allow adequate length to go under and behind the native valve leaflets to reach the fibrous trigones and/or posterior annulus or to anchor on other anatomic locations described herein including regions that are anterior of the native leaflet and adjacent thereto. Optionally, the prosthetic valve may not include a posterior anchoring tab. The annular section which is preferably D-shaped may be radially expanded into engagement with the native valve annulus and thus the radial force may be adequate to prevent the posterior portion of the prosthesis from tilting or otherwise pivoting upward into the atrium. Or teeth may be used to engage and/or penetrate the posterior annulus.

[00196] In any embodiment, the prosthesis may be recaptured and resheathed if needed in order to either abort the delivery procedure or to reposition the device.

[00197] Preferred embodiments are formed from nitinol or any other biocompatible material that is self-expanding. Preferred target sizes and profiles may be dependent on patient anatomy, but are estimated to be approximately 30 mm – 50 mm x 40 mm – 50 mm D-shaped prosthesis that may be delivered in a delivery system that is less than 45 French in size. More preferably, the prosthesis is 35 mm – 45 mm x 40 mm – 50 mm D-shaped and delivered with a delivery system less than 40 French in size. Smaller sizes are preferred, and nominally, the prosthesis is 40mm x 45mm D-shaped and delivered with a delivery system less than 40 French.

[00198] In some embodiments, tethers may be used to help couple the prosthesis to the delivery system for controlling delivery.

[00199] FIG. 46 shows a top view of a prosthetic valve with four prosthetic leaflets and four commissure posts. Optionally, four anchoring tabs may also be co-located with the four commissure posts.

[00200] FIG. 47 shows a top view of prosthetic valve with three prosthetic leaflets and three commissure posts. Optionally, three anchoring tabs may also be co-located with the three commissure posts.

[00201] FIG. 48 shows the prosthesis unrolled and flattened out and having three commissure posts with three prosthetic leaflets and three anchoring tabs. The atrial skirt is also illustrated below the commissure posts and anchor tabs.

[00202] FIG. 49 shows the native anterior and posterior leaflet unrolled and flattened and superimposed over the three anchoring tabs.

[00203] FIG. 50 shows an embodiment where the anchor tabs (triangular shaped cells) are connected to the commissure posts configured for deployment as depicted in FIG. 40, where the anchor tabs are deployed first as an outer sheath when the delivery system is retracted. Alternative catheter attachment methods are depicted for this embodiment. Either the use of mushroom shaped anchor tabs at the atrial aspect of the device or a central wishbone style attachment can be used to secure the device to the catheter.

[00204] FIG. 51 shows a large anterior leaflet superimposed over two anterior anchor tabs and a posterior section of diamond shaped cells which may engage or pierce the posterior annulus in an exemplary embodiment that does not use a posterior anchor tab.

[00205] FIG. 52 illustrates another exemplary embodiment showing two anterior anchoring tabs formed and nested within the anterior commissure posts and a series of expandable diamond shaped cells which may anchor against the posterior annulus or may pierce into the posterior annulus thereby avoiding the need for a posterior anchoring tab. This embodiment includes four commissure posts.

[00206] FIG. 53 illustrates another exemplary flat pattern of a prosthetic valve having two anterior anchor tabs nested in two anterior commissure posts and two posterior commissure posts. The atrial flange is shown below the commissure posts.

[00207] FIG. 54 shows a perspective view of a prosthetic valve with four commissure posts and a large anterior prosthetic leaflet coupled to two anterior commissure posts.

[00208] FIG. 55 shows a native mitral valve adjacent the aortic valve and preferably the anterior leaflet moves well away from the LVOT during systole. Preferably a prosthetic anterior leaflet would have similar motion to maintain natural flow dynamics such as maintaining blood flow momentum and reducing or eliminating turbulence.

[00209] FIG. 56 shows another exemplary embodiment of a section of prosthetic valve having an anchoring tab nested within the commissure post and the adjacent closed cells of the frame are also shown.

[00210] FIG. 57 illustrates still another exemplary embodiment of a prosthetic valve having a commissure post and an anchoring tab nested with the commissure post.

[00211] FIG. 58 shows yet another variation of a prosthetic valve having an anchoring tab nested within the commissure post.

[00212] FIG. 59 shows how variable strut thickness (e.g. thicker 5910 and thinner 5920 regions) may be used to control the material properties of the prosthesis to create stiffer regions and less stiff regions.

[00213] While preferred embodiments of the present invention have been illustrated and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of

example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. A prosthetic heart valve for implantation in a native mitral valve of a patient, said heart valve comprising:

a radially expandable anchor frame having an expanded configuration and a collapsed configuration; and

a prosthetic valve coupled to the anchor frame, the prosthetic valve comprising a plurality of prosthetic valve leaflets each having a free end and a fixed end, wherein the fixed end is coupled to the anchor frame, and wherein the free ends of the plurality of prosthetic valve leaflets have an open configuration and a closed configuration, in the open configuration the free ends are disposed away from one another to allow antegrade blood flow therethrough, and in the closed configuration the free ends are disposed adjacent one another to substantially prevent retrograde blood flow therethrough, and

wherein the plurality of prosthetic valve leaflets comprise an anterior prosthetic leaflet sized to span the entire width of the native anterior leaflet, and

wherein in systole, the anterior prosthetic leaflet deflects away from the left ventricular outflow tract to provide a clear unobstructed outflow path.

2. The valve of claim 1, wherein the anchor frame comprises an anterior anchoring tab configured to anchor on an anterior portion of the native mitral valve.

3. The valve of claim 2, wherein the anterior portion of the native mitral valve comprises a fibrous trigone.

4. The valve of claim 2, wherein the anchor frame comprises a second anterior anchoring tab configured to anchor on a second anterior portion of the native mitral valve.

5. The valve of claim 1, wherein the anchor frame comprises a D-shaped cross-section having a substantially flat anterior portion and a cylindrically shaped posterior portion, wherein the flat anterior portion prevents impingement of the prosthetic heart valve on the left ventricular outflow tract, and the cylindrically shaped posterior portion engages a posterior portion of the native mitral valve.

6. The valve of claim 1, wherein the anchor frame comprises one or more commissure posts, and an anterior anchoring tab, the one or more commissure posts having a free end and an opposite end coupled to the anchor frame, the one or more commissure posts coupled to the plurality of prosthetic valve leaflets, and

wherein the anterior anchoring tab is configured to anchor on an anterior portion of the native mitral valve.

7. The valve of claim 6, wherein the anterior anchoring tab and the one or more commissure posts are nested in one another when the anchor frame is in the collapsed configuration.

8. The valve of claim 6, wherein the anterior anchoring tab originates from a circumferential position on a circumference of the anchor frame, and wherein the one or more commissure posts also originate from the same circumferential position on the circumference of the anchor frame as the anterior anchoring tab.

9. The valve of claim 6, wherein the anterior anchoring tab originates from the one or more commissure posts, or wherein the one or more commissure posts originate from the anterior anchoring tab.

10. The valve of claim 9, wherein the anchor frame further comprises a plurality of chordal bumper struts originating from the one or more commissure posts, wherein the plurality of chordal bumper struts are configured to dispose native sub-valvular anatomy away from the LVOT.

11. The valve of claim 9, wherein the commissure posts further comprise an anchoring element adjacent a free end of the commissure post, the anchoring element configured to engage a delivery system.

12. The valve of claim 9, wherein the anchor frame further comprises a plurality of wishbone shaped struts originating from the one or more commissure posts, wherein the plurality of wishbone shaped struts are configured to arcuately span the distance between adjacent commissure posts, and wherein each wishbone shaped strut is comprised of an anchoring element adjacent a free end of the wishbone shaped strut, the anchoring element configured to engage a delivery catheter.

13. The valve of claim 12, wherein the plurality of wishbone shaped struts are deformable members and allow radial compression of the anchor frame upon retraction into the delivery catheter.

14. The valve of claim 12, wherein the anchoring element comprises a single threaded connector, a buckle connector, or a prong connector.

15. A prosthetic heart valve for implantation in a native mitral valve of a patient, said heart valve comprising:

a radially expandable anchor frame having an expanded configuration and a collapsed configuration and an upstream end and a downstream end, the radially expandable anchor frame comprising one or more commissure posts having a free end and an opposite end coupled to the anchor frame adjacent the downstream end, and an anterior anchoring tab coupled to the anchor frame adjacent the downstream end, wherein the anterior anchoring tab is configured to anchor on an anterior portion of the native mitral valve, and wherein the anterior anchoring tab and the one or more commissure posts are nested in one another when the anchor frame is in the collapsed configuration; and

a prosthetic valve coupled to the anchor frame, the prosthetic valve comprising one or more prosthetic valve leaflets each having a free end and a fixed end, wherein the fixed end is coupled to the anchor frame, and

wherein the one or more commissure posts are coupled to the one or more prosthetic valve leaflets.

16. The valve of claim 15, wherein the free ends of the one or more prosthetic valve leaflets have an open configuration and a closed configuration, wherein in the open configuration the free ends are disposed away from one another to allow antegrade blood flow therethrough, and in the closed configuration the free ends are disposed adjacent one another to substantially prevent retrograde blood flow therethrough, wherein the one or more prosthetic valve leaflets comprise an anterior prosthetic leaflet sized to span a width of a native anterior valve leaflet between two native fibrous trigones, and wherein in systole, the anterior prosthetic leaflet deflects away from the left ventricular outflow tract to provide a clear unobstructed outflow path.

17. The valve of claim 15, wherein the anterior portion of the native mitral valve comprises a fibrous trigone.

18. The valve of claim 15, wherein the anchor frame comprises a second anterior anchoring tab configured to anchor on a second anterior portion of the native mitral valve.

19. The valve of claim 15, wherein the anchor frame comprises a D-shaped cross-section having a substantially flat anterior portion and a cylindrically shaped posterior portion, wherein the flat anterior portion prevents impingement of the prosthetic heart valve on the left ventricular outflow tract, and the cylindrically shaped portion engages the posterior portion of the native mitral valve.

20. The valve of claim 15, wherein the anterior anchoring tab originates from a circumferential position on a circumference of the anchor frame, and wherein the one or more commissure posts also originate from the same circumferential position on the circumference of the anchor frame as the anterior anchoring tab.

21. The valve of claim 15, wherein the anterior anchoring tab originates from the one or more commissure posts, or wherein the one or more commissure posts originate from the anterior anchoring tab.

22. A method of treating a native mitral valve in a patient's heart, said method comprising:
providing a prosthetic mitral valve having an anterior prosthetic leaflet that spans a width of a native anterior valve leaflet;

anchoring the prosthetic mitral valve in the native mitral valve; and

deflecting the prosthetic anterior leaflet in systole away from the left ventricular outflow tract during systole thereby creating an unobstructed outflow path.

23. The method of claim 22, wherein anchoring comprises anchoring an anterior anchoring tab disposed on an anterior portion of the prosthetic valve to an anterior portion of the native mitral valve.

24. The method of claim 23, wherein the anterior portion of the native mitral valve comprises a fibrous trigone.

25. The method of claim 22, comprising radially expanding the prosthetic mitral valve from a collapsed configuration to an expanded configuration, wherein radially expanding the prosthetic mitral valve comprises expanding one or more anterior anchoring tabs away from nested positions within one or more commissure posts.

26. The method of claim 22, comprising radially expanding the prosthetic mitral valve from a collapsed configuration to an expanded configuration, wherein radially expanding comprises expanding one or more posterior anchoring tabs away from nested positions within one or more commissure posts.

27. The method of claim 22, wherein anchoring the prosthetic mitral valve comprises actuating an actuator mechanism on a delivery system in a first direction, wherein actuating the actuator mechanism in the first direction comprises moving a sheath catheter away from the prosthetic mitral valve to remove a constraint thereby allowing the prosthetic mitral valve to expand, and actuating the actuator mechanism in a second direction opposite the first direction, wherein actuating the actuator mechanism in the second direction comprises moving a sheath catheter toward the prosthetic mitral valve to provide a constraint thereby forcing the prosthetic mitral valve to be compressed.

28. The method of claim 27, wherein actuating the actuator mechanism in the first direction further comprises moving a bell catheter away from an anchoring catheter to remove a constraint thereby allowing a commissure anchor to be released, wherein the commissure anchor comprises an anchoring element that engages a frame of the prosthetic mitral valve to the delivery system, and wherein actuating the actuator mechanism in the second direction comprises moving the bell catheter toward the anchoring catheter to provide a constraint that captures or restrains the commissure anchor.

29. The method of claim 28, wherein providing the constraint comprises releasably sliding a retaining element over the commissure anchor.

30. The method of claim 27, wherein actuating the actuator mechanism comprises moving a sheath catheter over the anchoring catheter thereby applying a constraint, wherein applying the constraint comprises allowing a commissure anchor to be compressed, wherein the commissure anchor

comprises a flexible anchoring element that engages the frame of the prosthetic mitral valve to the delivery system.

31. A method of treating a native mitral valve in a patient's heart, said method comprising:
providing a prosthetic mitral valve coupled to a radially expandable anchor frame having an upstream end and a downstream end, the radially expandable anchor frame comprising one or more commissure posts having a free end and an opposite end coupled to the anchor frame adjacent the downstream end, and an anterior anchoring tab coupled to the anchor frame adjacent the downstream end,

expanding the radially expandable anchor frame from a collapsed configuration to an expanded configuration,

anchoring the prosthetic mitral valve in the native mitral valve, wherein the anterior anchoring tab anchors on an anterior portion of the native mitral valve, and

radially expanding the anterior anchoring tab away from a nested position within the one or more commissure posts.

32. The method of claim 31, wherein the anterior portion of the native mitral valve comprises a fibrous trigone.

33. The method of claim 31, wherein radially expanding the anchor frame comprises expanding the one or more commissure posts away from a nested position within the anterior anchoring tab.

34. The method of claim 31, wherein the prosthetic mitral valve comprises an anterior prosthetic leaflet, the method comprising:

spanning a width of a native anterior valve leaflet between two native fibrous trigones, deflecting the anterior prosthetic leaflet away from a left ventricular outflow tract, and creating an unobstructed outflow path by the deflection of the anterior prosthetic leaflet.

35. A delivery system for delivering a prosthesis to a target treatment area, said system comprising:

an inner guidewire catheter having a proximal end, a distal end, and a lumen extending therebetween, the lumen sized to slidably receive a guidewire;

a flexible dilating tip coupled to the guidewire catheter, the dilating tip having a tapered and flexible self-dilating edge,

a sheath catheter slidably disposed over the inner guidewire catheter, the sheath catheter having a proximal end and a distal end;

an actuator mechanism operably coupled to the proximal end of the sheath catheter, wherein actuation of the actuator mechanism in a first direction moves the sheath catheter away from the dilator tip thereby removing a constraint from the prosthesis and allowing the prosthesis to expand, and wherein actuation of the actuator mechanism in a second direction opposite the first direction moves the sheath catheter into engagement with the dilator tip thereby enclosing the prosthesis therein.

36. The system of claim 35, further comprising a stationary anchoring catheter fixedly disposed over the guidewire catheter, the anchoring catheter having an anchor element adjacent a distal end of the anchor catheter and configured to engage the prosthesis.

37. The system of claim 36, further comprising a bell catheter slidably disposed over the anchoring catheter, the bell catheter having a bell element disposed adjacent a distal end of the bell catheter, wherein the bell element constrains the prosthesis into engagement with the anchor catheter.

38. The system of claim 36, wherein the anchoring catheter has a flexible prong type anchor element adjacent the distal end of the anchor catheter, configured to engage the prosthesis.

39. The system of claim 38, wherein the sheath catheter is slidably disposed over the anchoring catheter, wherein an advancement of the distal end of the sheath catheter collapses the flexible prong type anchor elements into engagement with the prosthesis.

40. The system of claim 36, further comprising a stationary bell catheter fixedly disposed over the anchoring catheter, the bell catheter having a bell element disposed adjacent a distal end of the bell catheter, wherein the bell element disengages the prosthesis from the anchor catheter.

41. The system of claim 35, further comprising a bell catheter rotatably disposed over the guidewire catheter, the bell catheter having an internally threaded bell element disposed adjacent a distal end of the bell catheter, wherein the threaded bell element constrains the prosthesis into engagement.

42. The system of claim 41, further comprising a second actuator mechanism operably coupled to a proximal end of the bell catheter, wherein actuation of the second actuator mechanism in a first direction couples the prosthesis to the bell catheter, providing a constraint for the prosthesis, and wherein actuation of the second actuator mechanism in a second direction opposite the first direction decouples the prosthesis from the bell catheter, removing the constraint from the prosthesis.

43. The system of claim 35, further comprising a rotating torque catheter rotatably disposed over the guidewire catheter, the torque catheter having a driving gear element adjacent a distal end of the torque catheter and configured to transmit torque.

44. The system of claim 43, further comprising a plurality of rotating thread-connector catheters rotatably disposed adjacent the torque catheter, the thread-connector catheters each having a driven gear element adjacent a distal end of each thread connector catheter, and a threaded socket adjacent to the distal end of each thread connector catheter, the driven gear elements sized to enmesh with the driving gear element and receive torque, and the threaded sockets configured to constrain the prosthesis into engagement.

45. The system of claim 44, further comprising a second actuator mechanism operably coupled to a proximal end of the torque catheter, wherein actuation of the second actuator mechanism in a first direction couples the prosthesis to the thread-connector catheters, and wherein actuation of the second actuator mechanism in a second direction opposite the first direction de-couples the prosthesis from the thread-connector catheters.

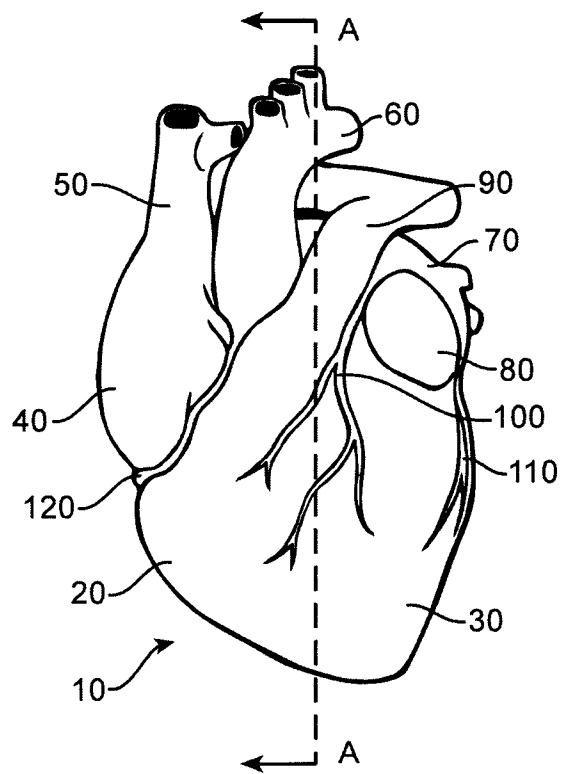
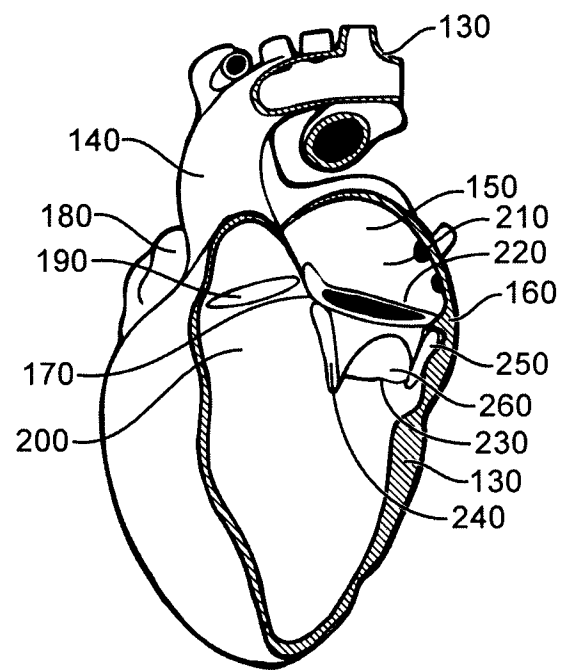
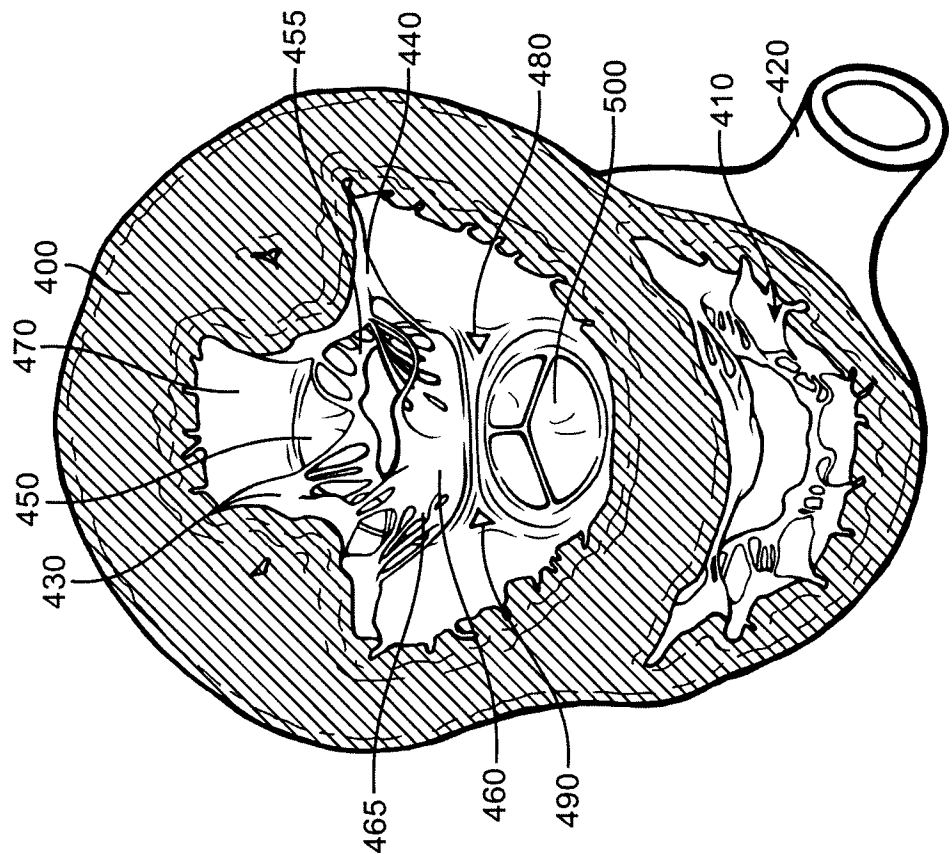


FIG. 1



SECTION A-A

FIG. 2



SECTION B-B

FIG. 4

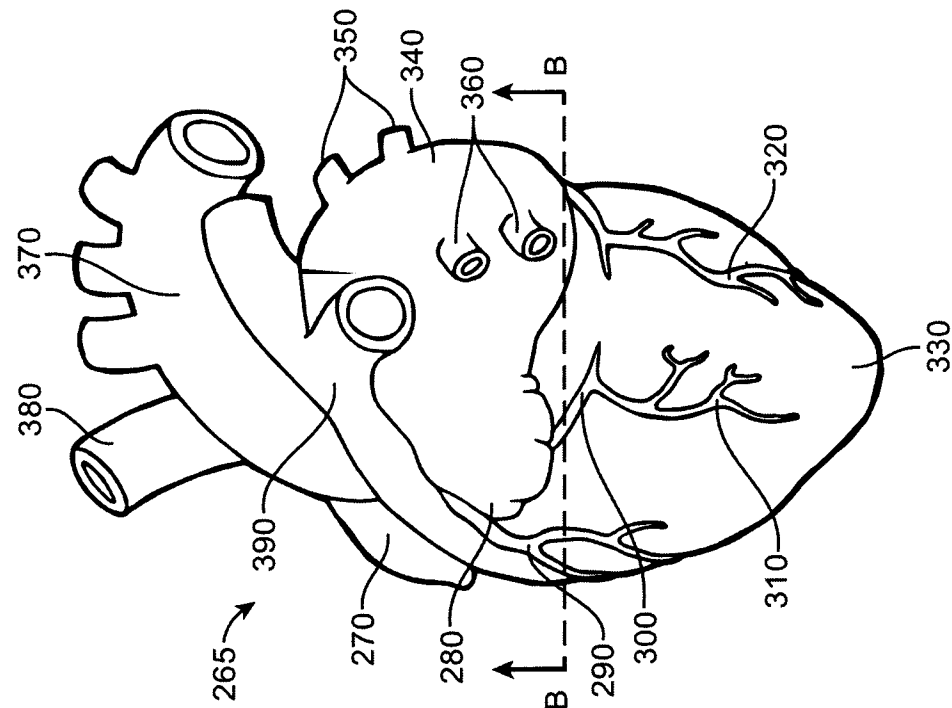
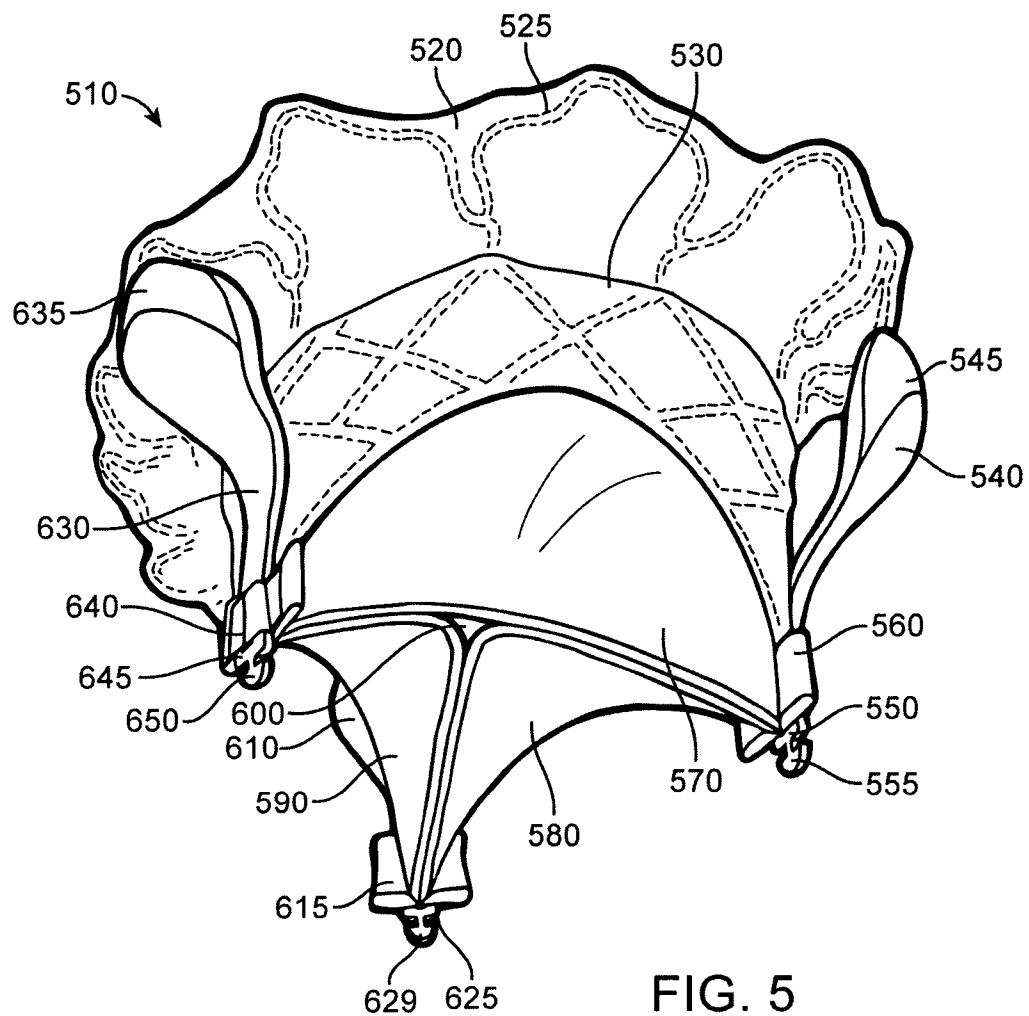
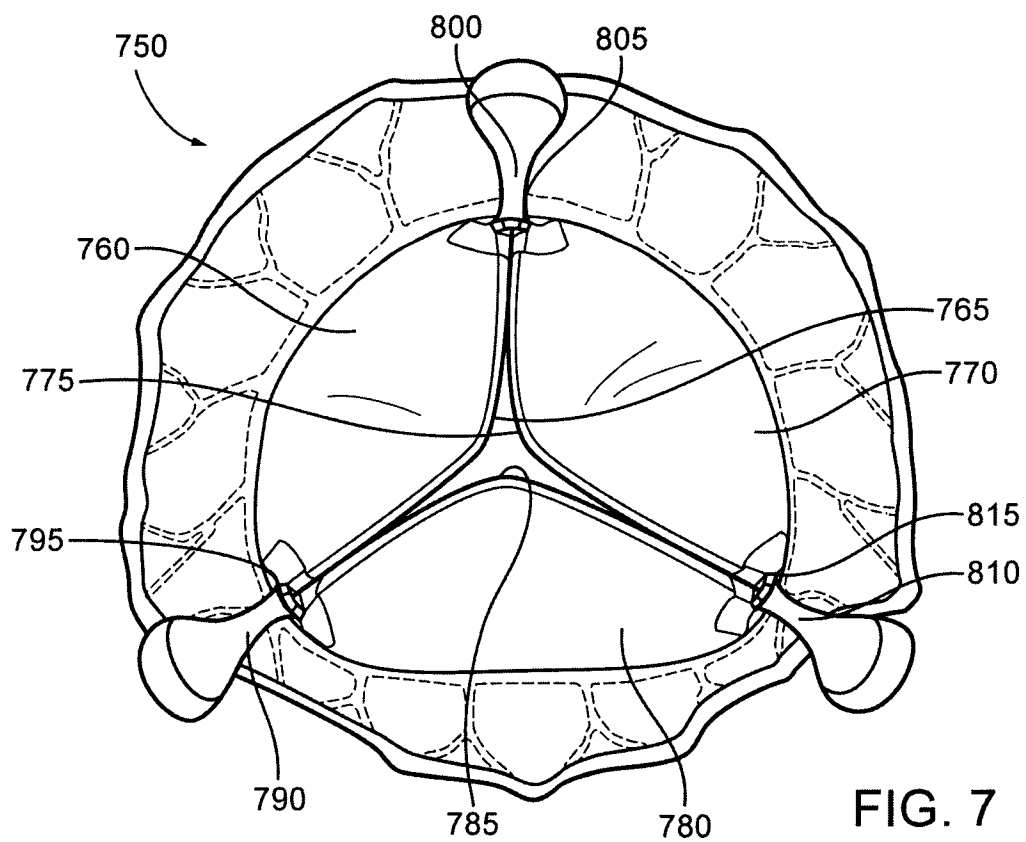
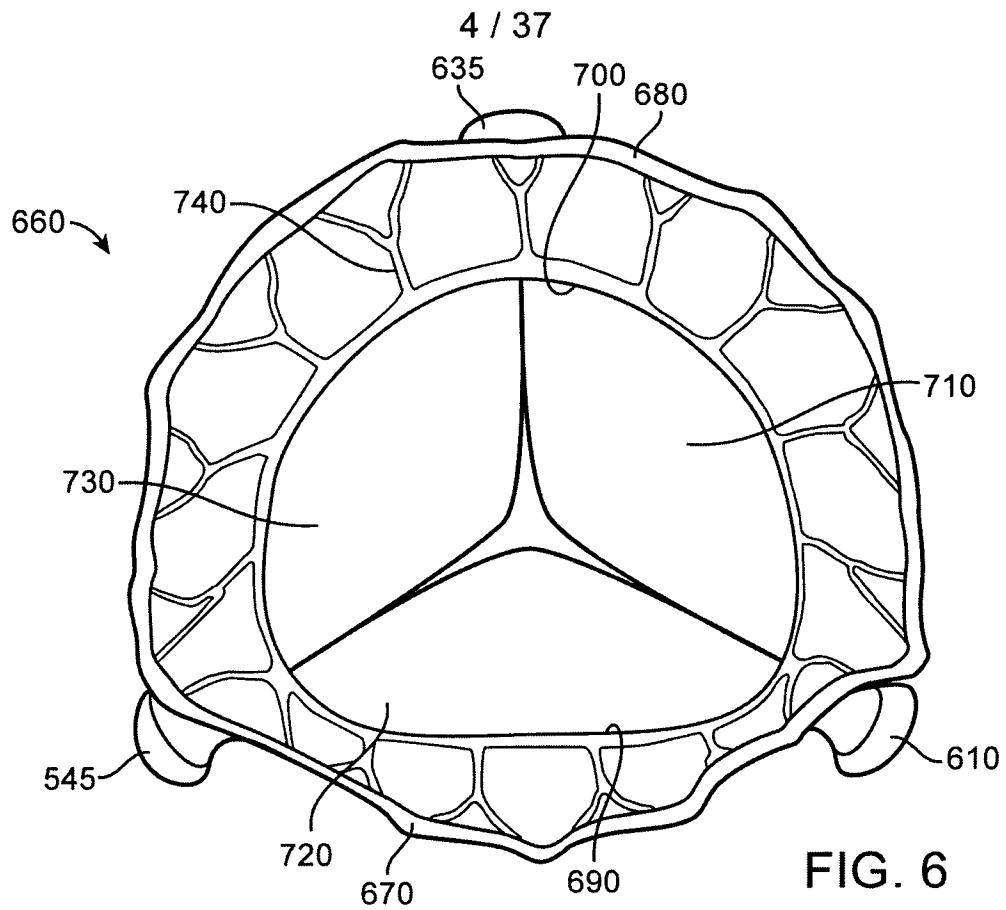
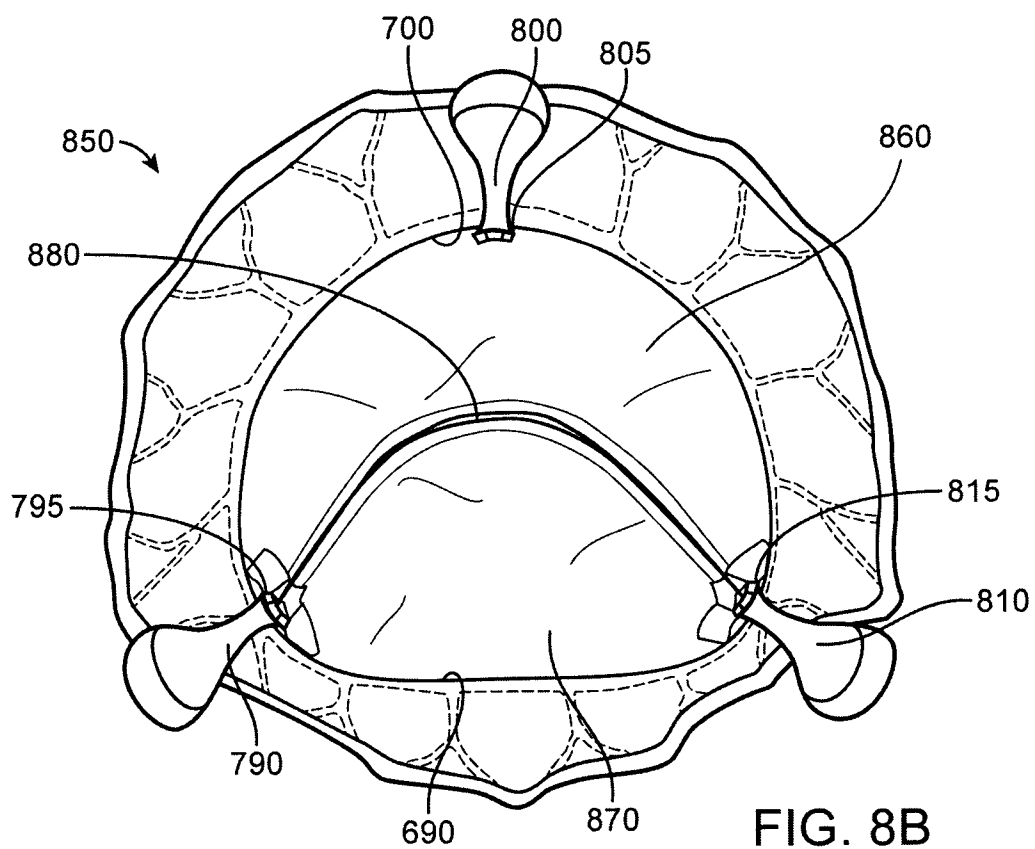
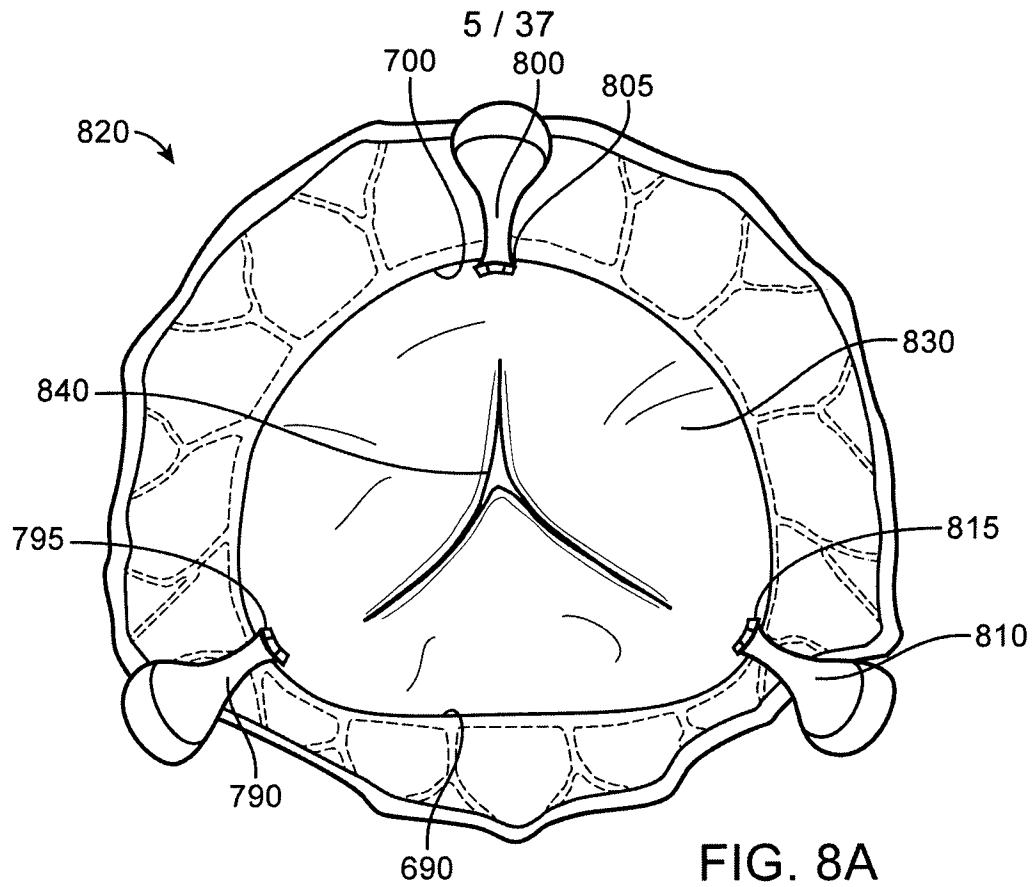
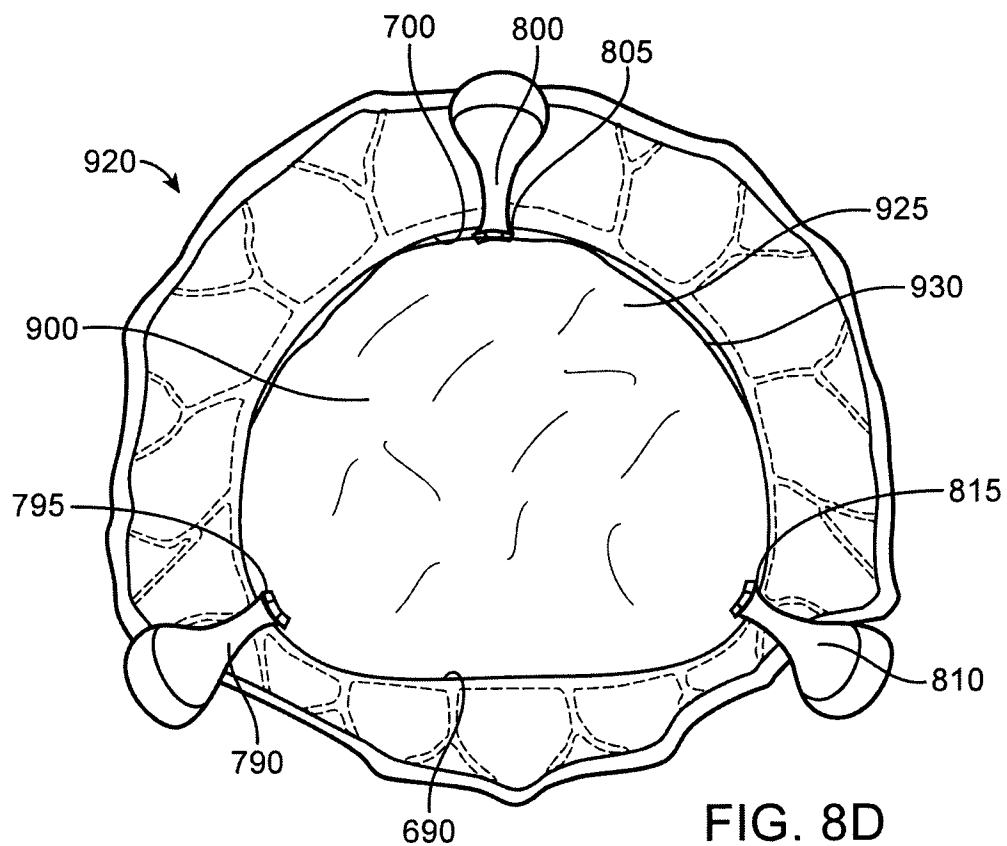
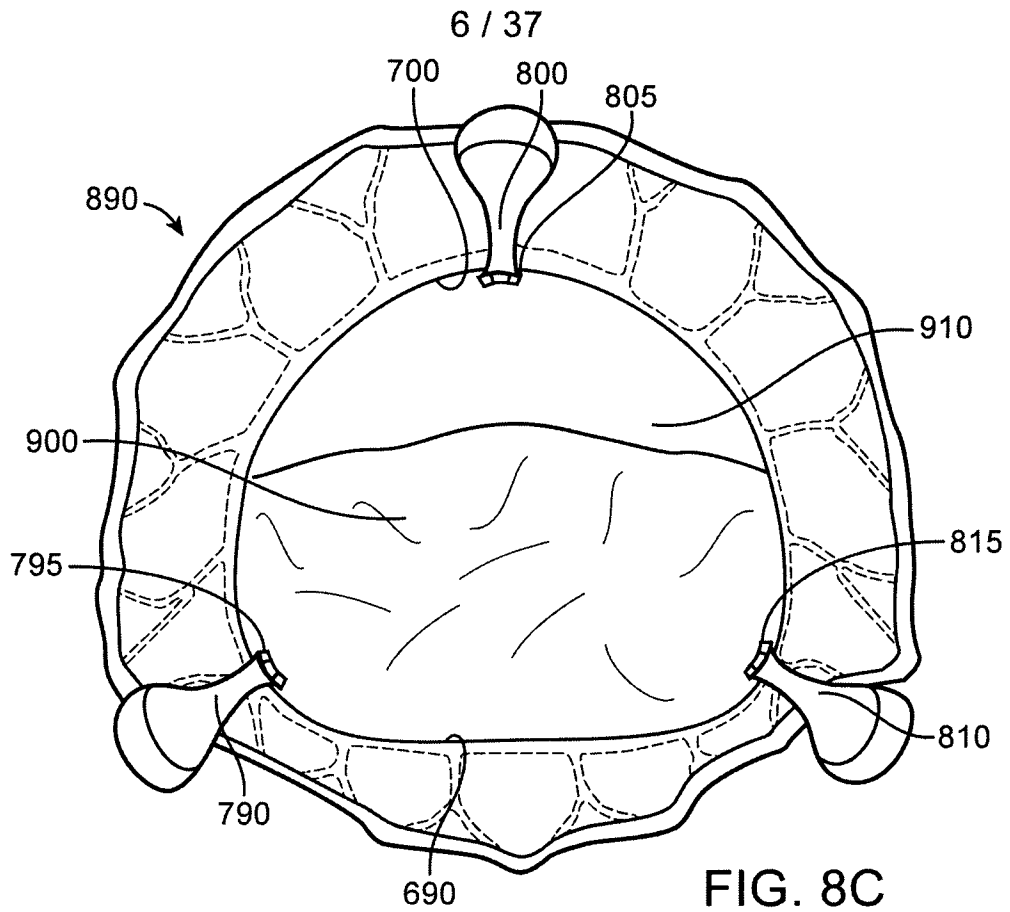


FIG. 3









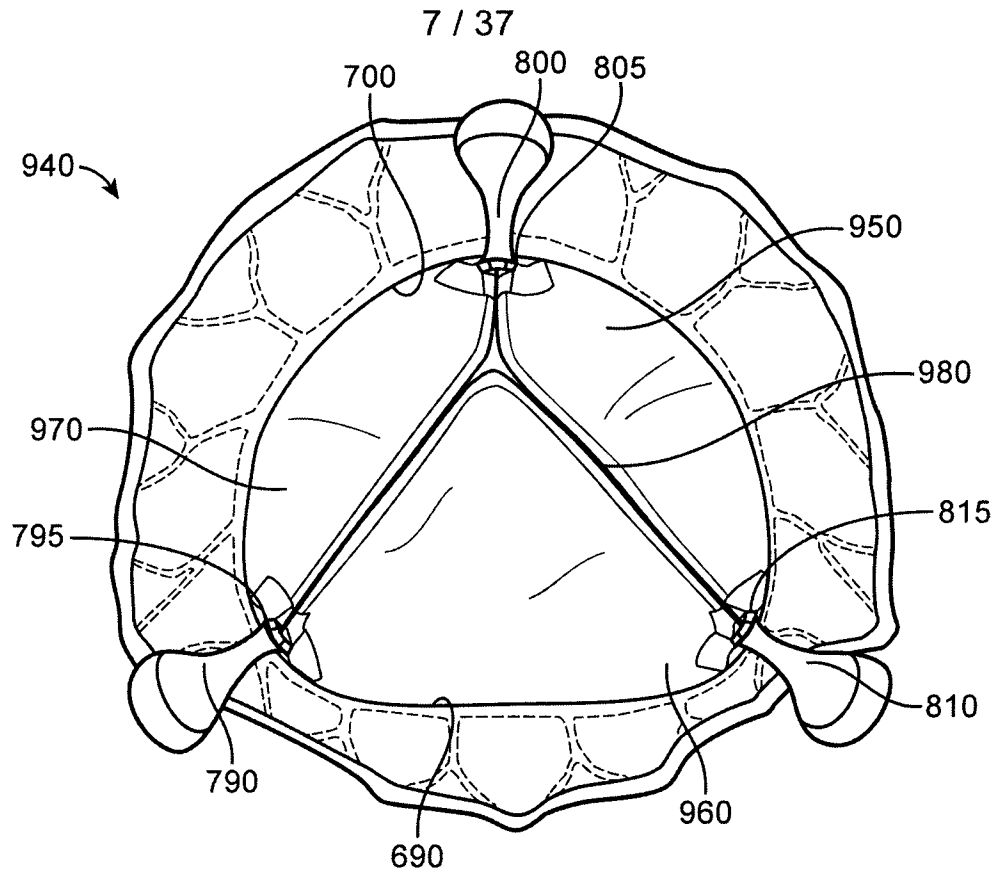


FIG. 8E

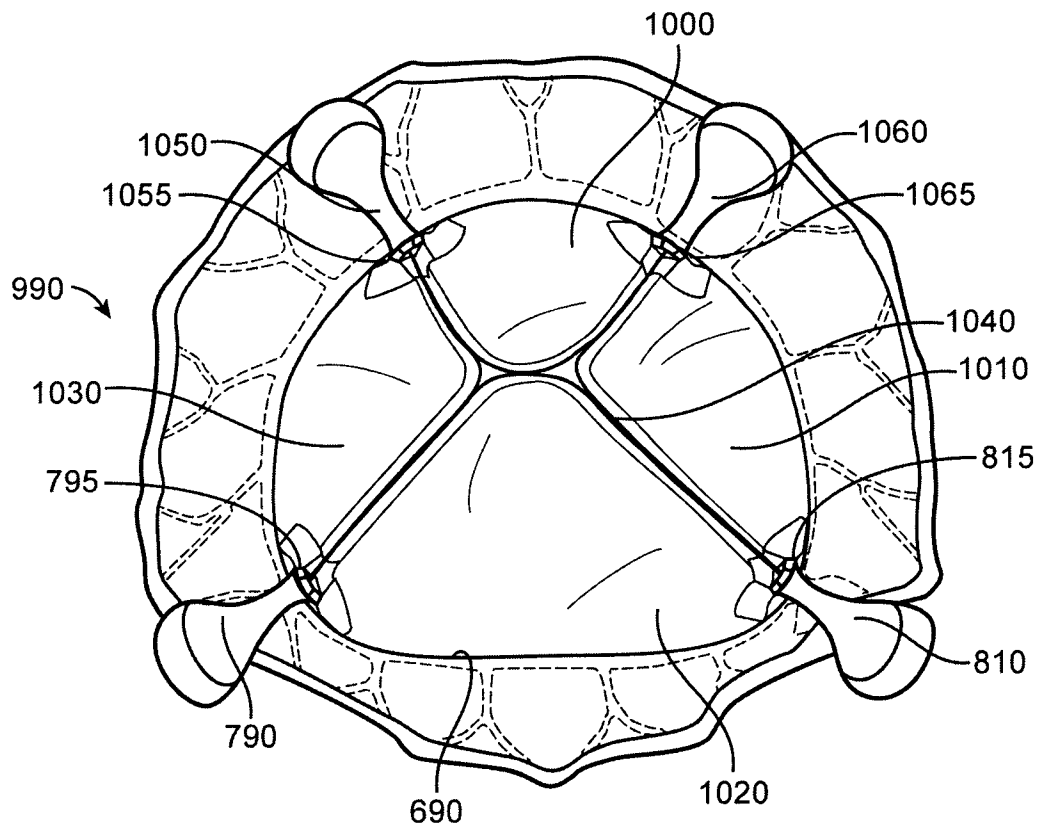


FIG. 8F

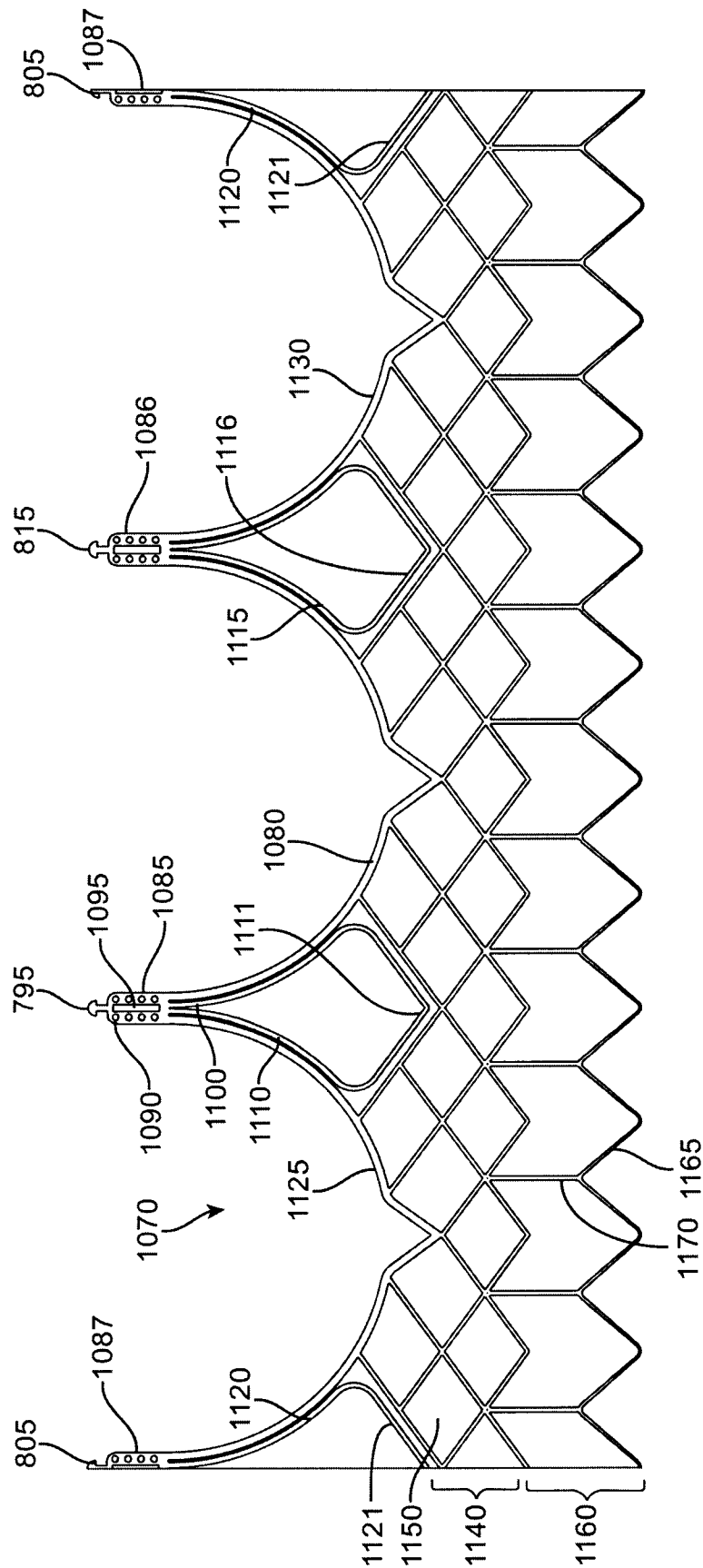


FIG. 9

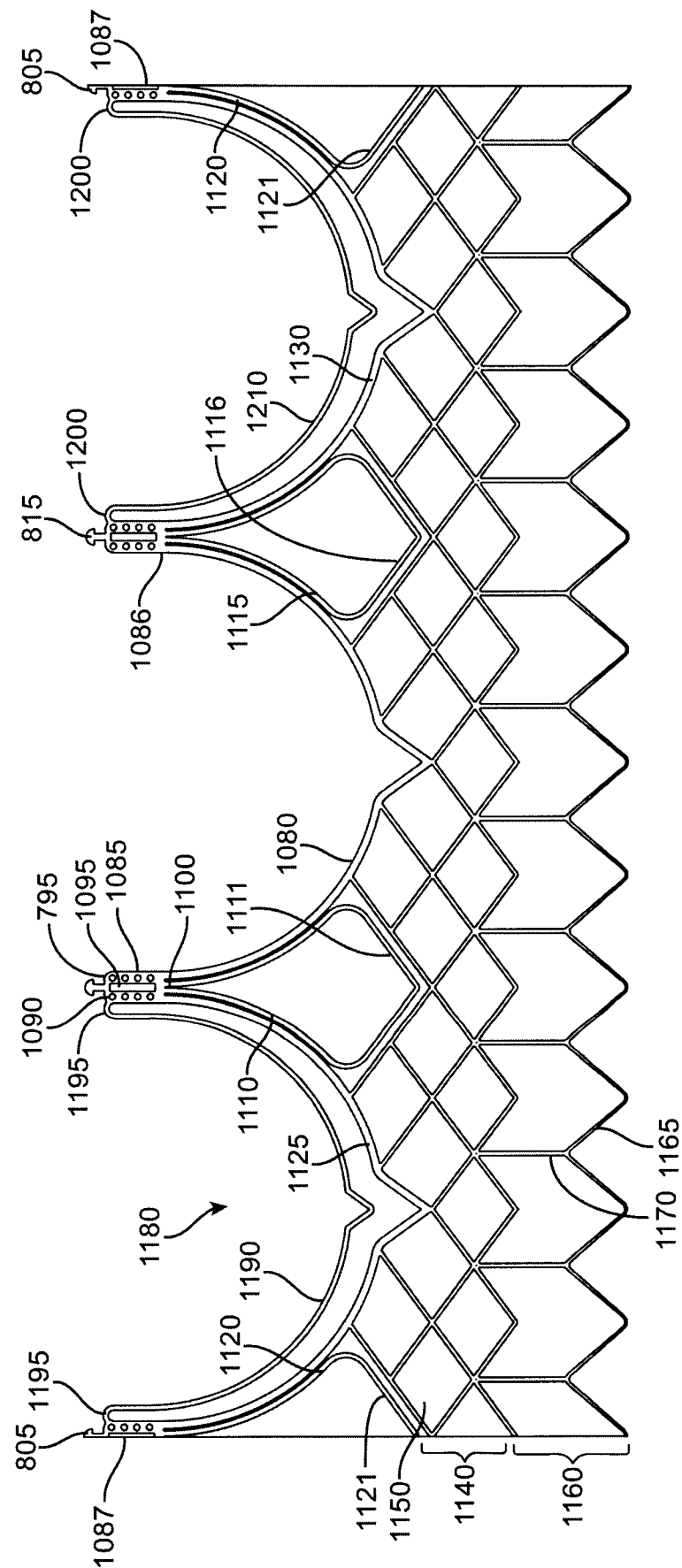


FIG. 10

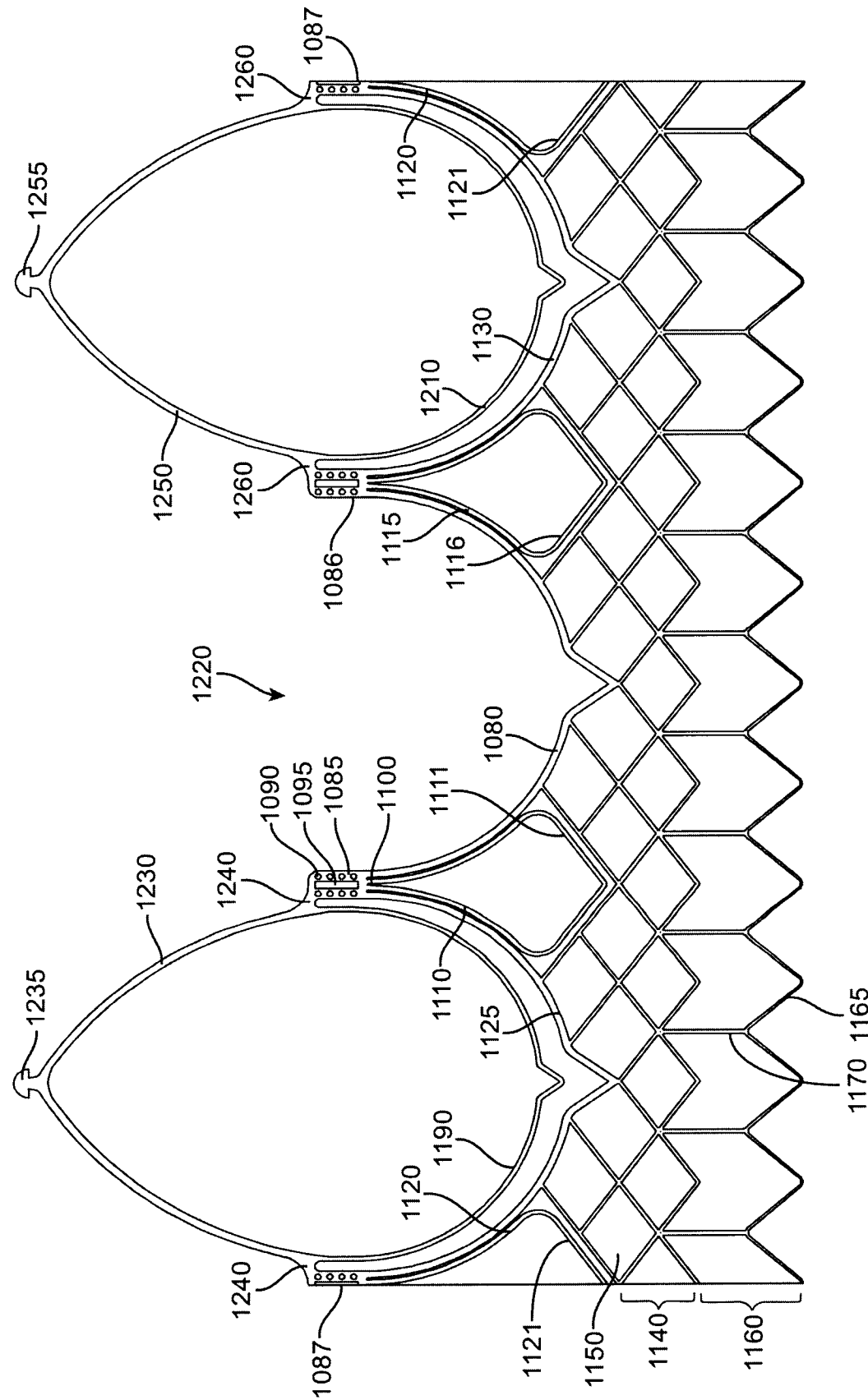


FIG. 11

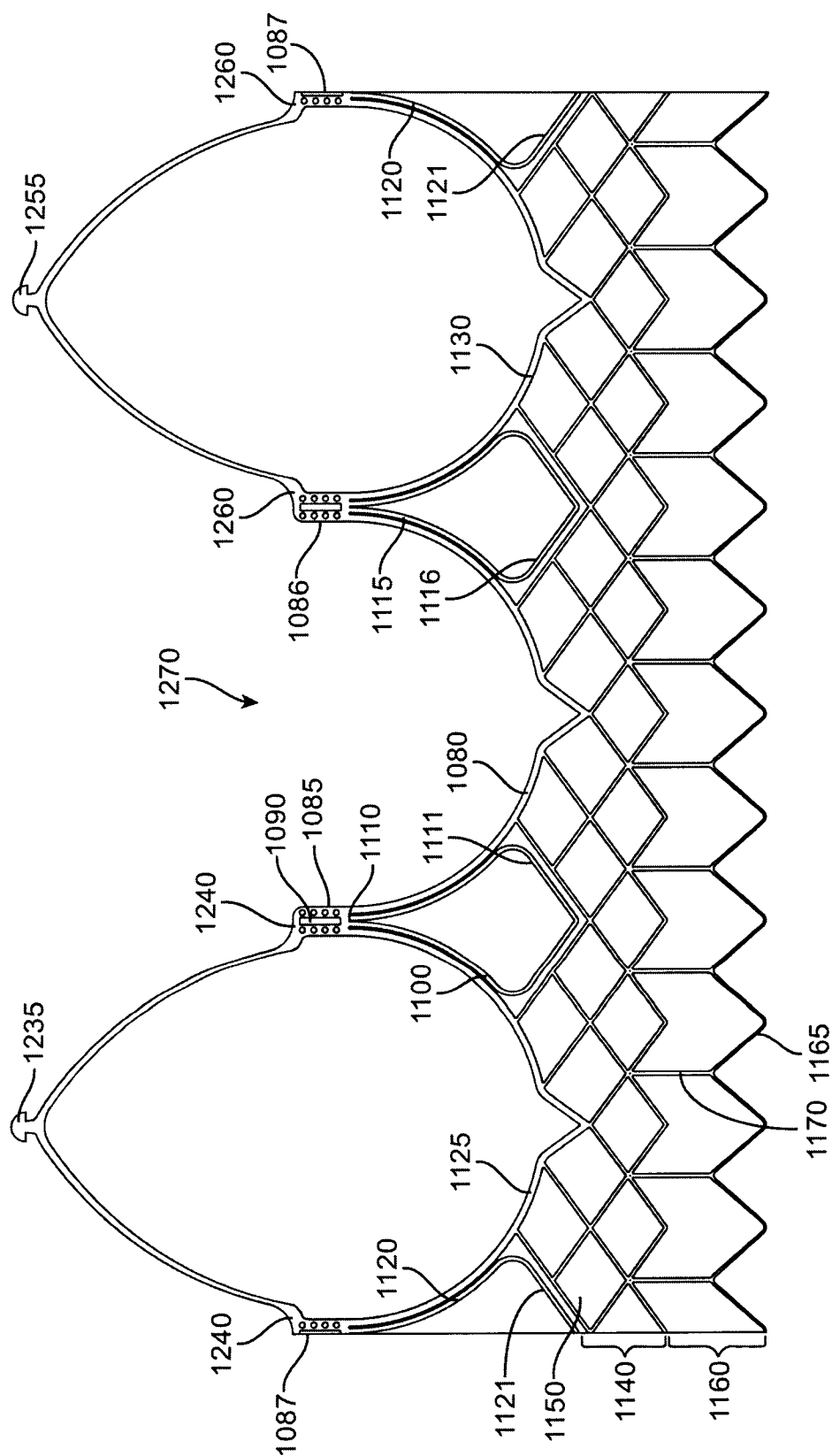


FIG. 12

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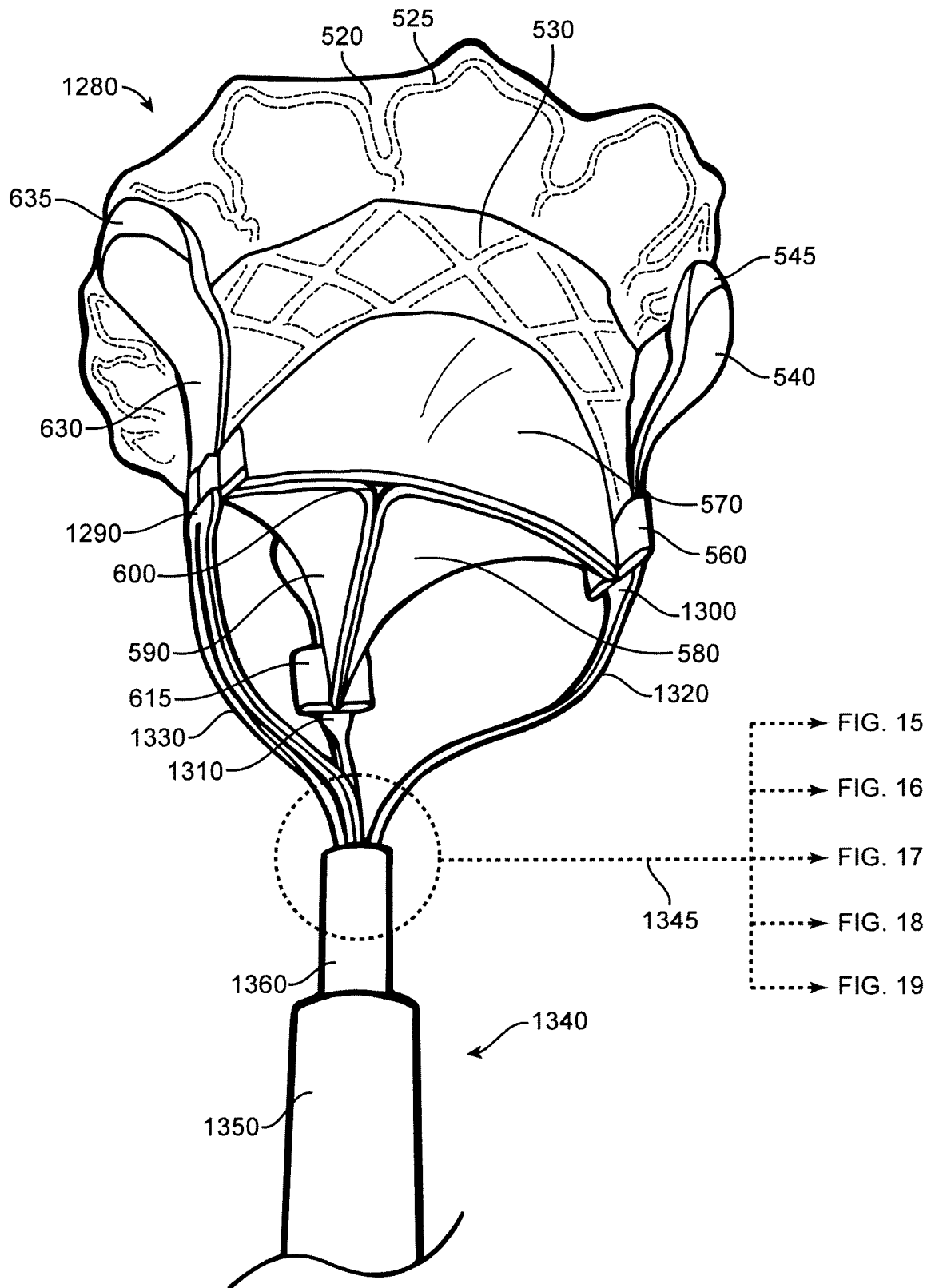


FIG. 14

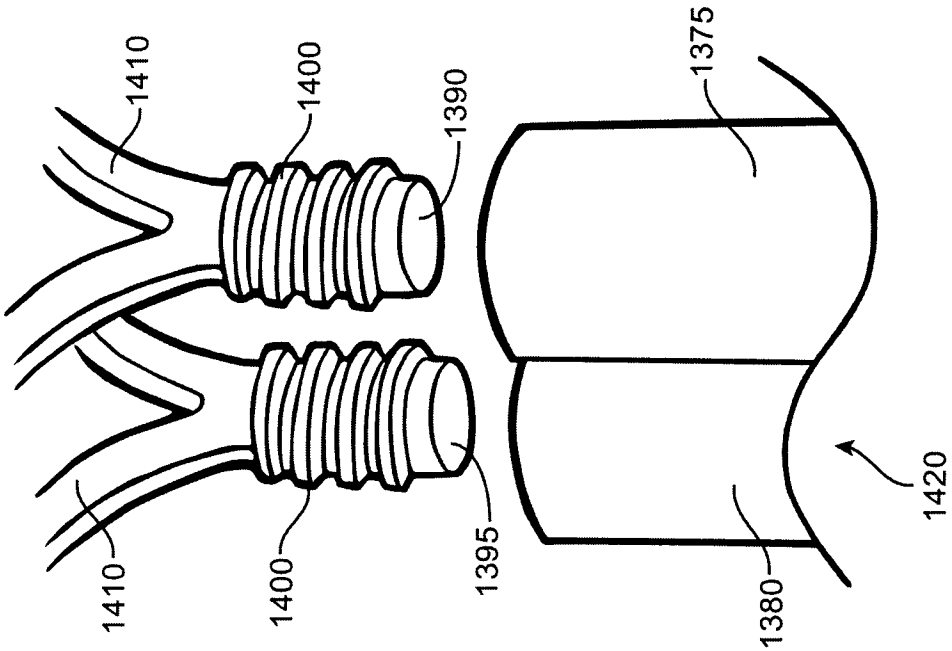


FIG. 15B

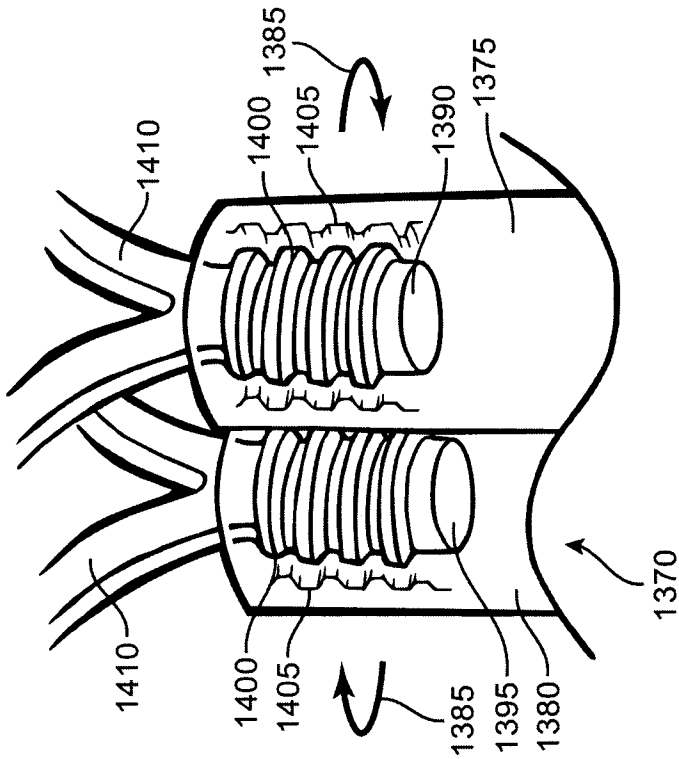


FIG. 15A

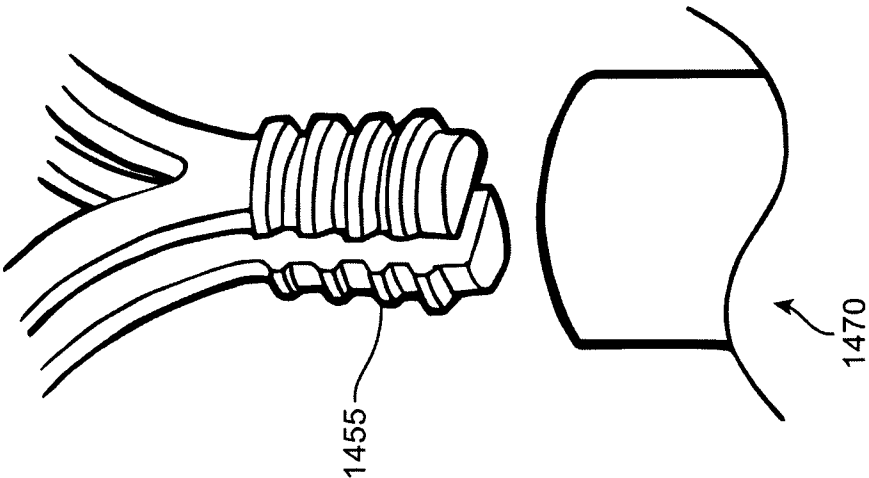


FIG. 16B

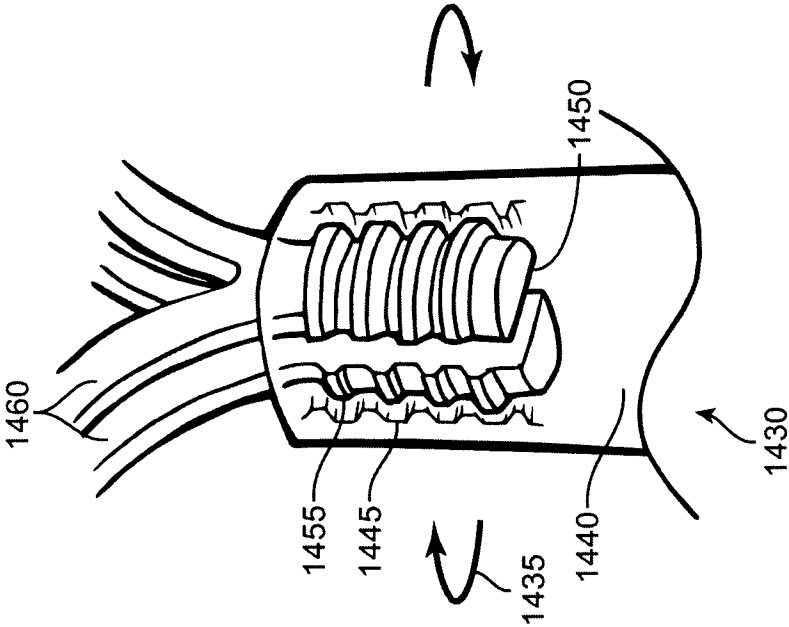


FIG. 16A

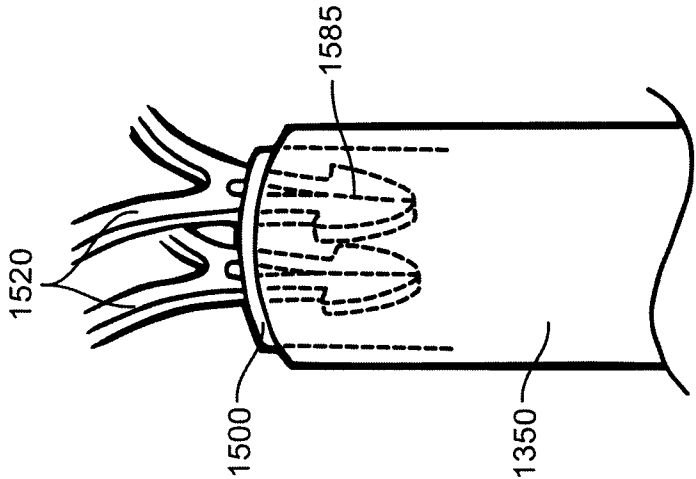


FIG. 18C

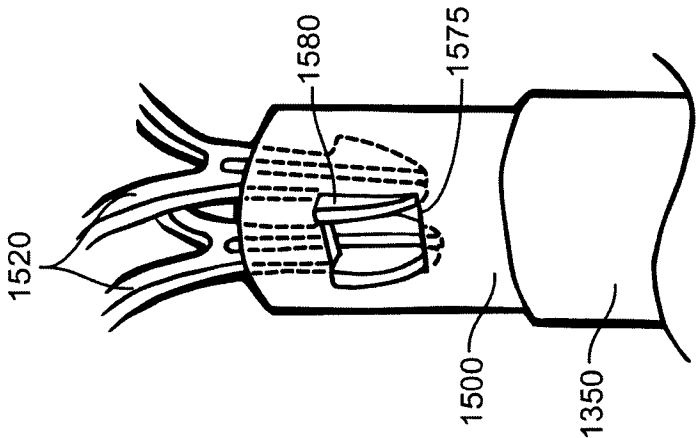


FIG. 18B

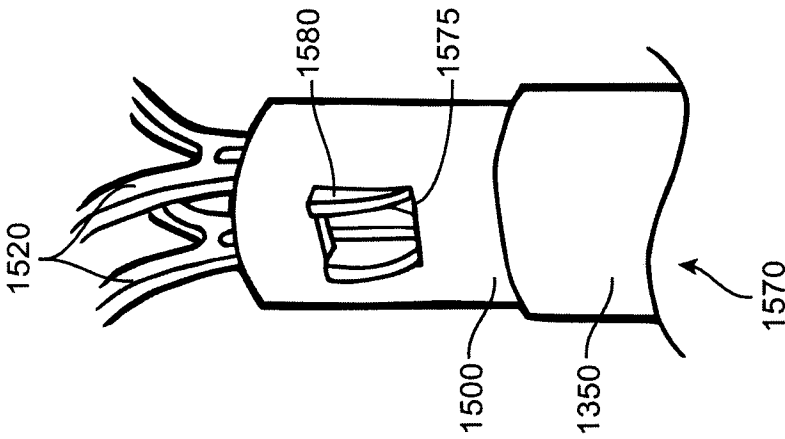


FIG. 18A

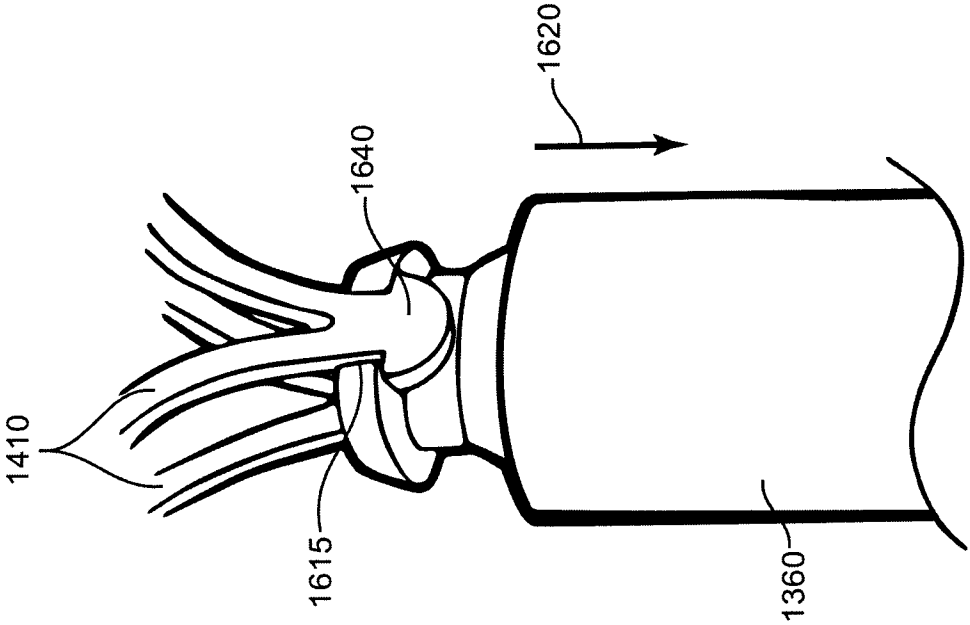


FIG. 19B

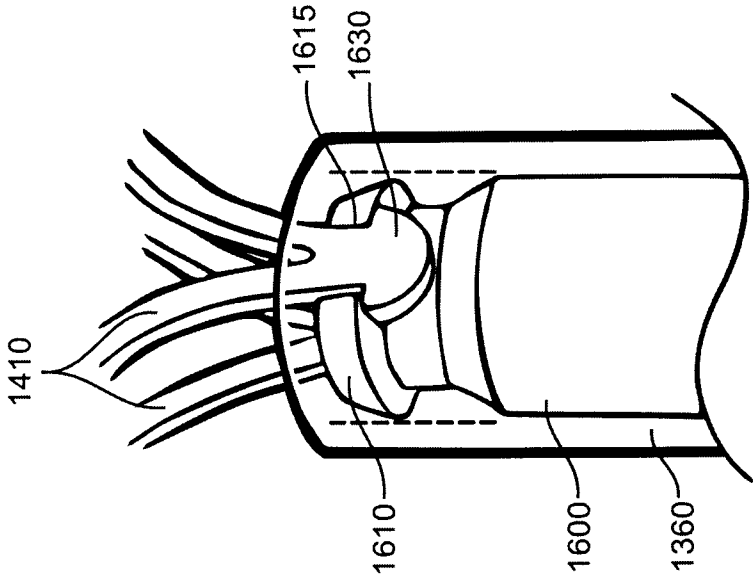


FIG. 19A

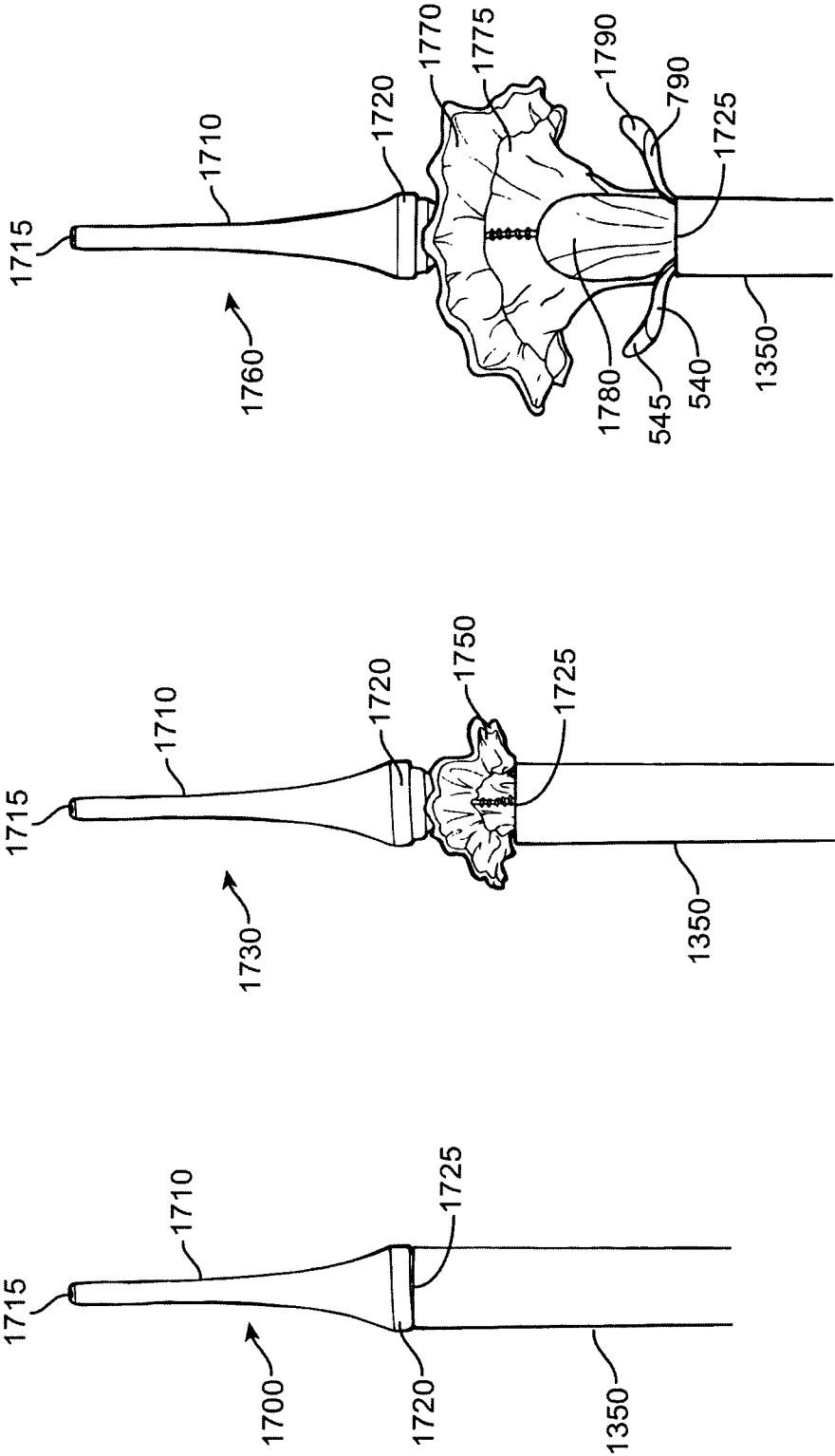


FIG. 20C

FIG. 20B

FIG. 20A

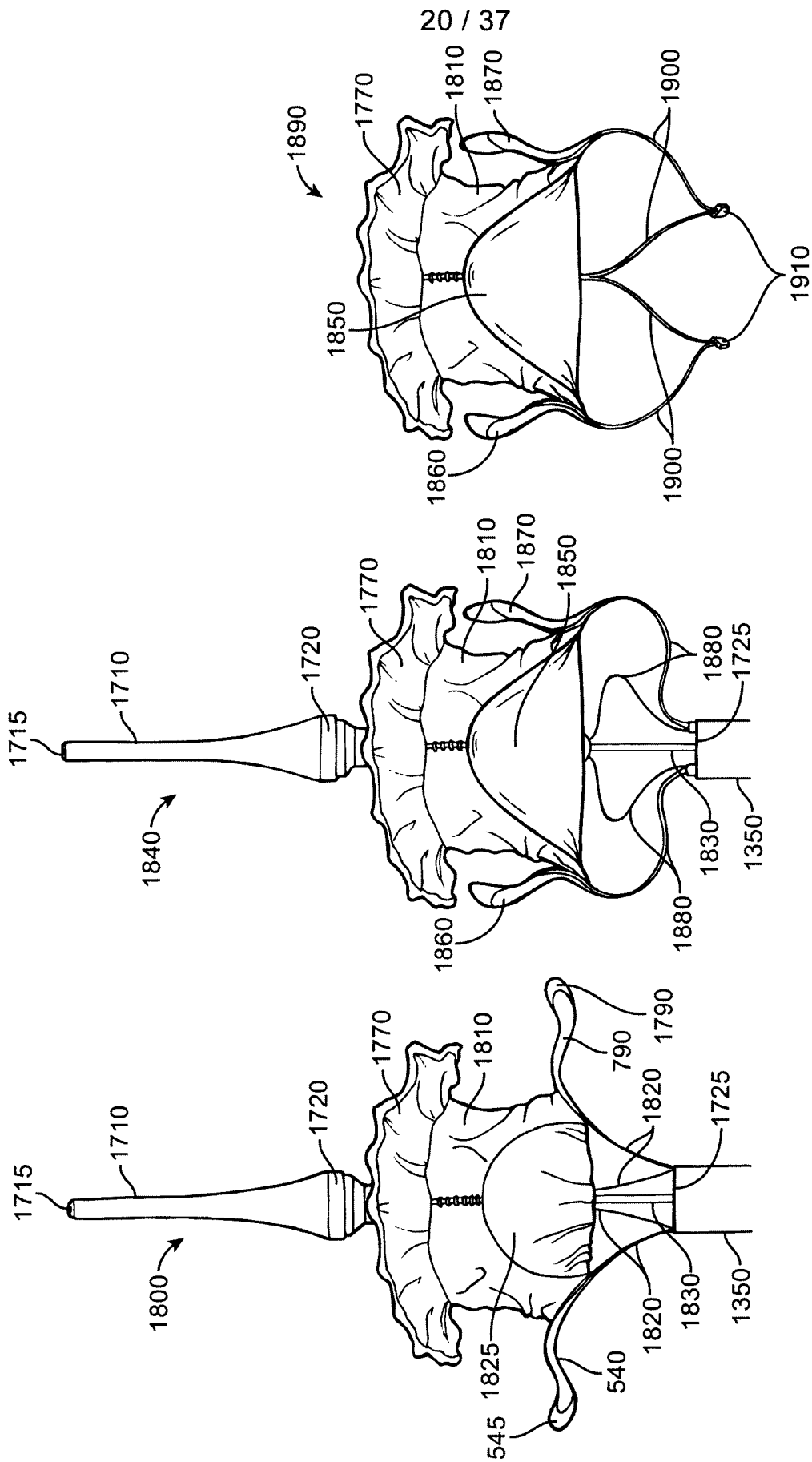
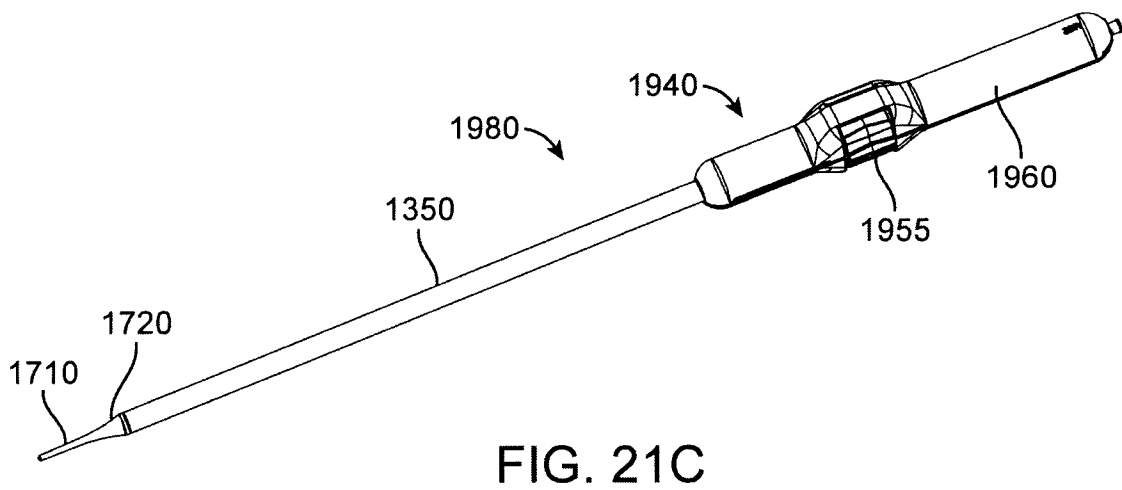
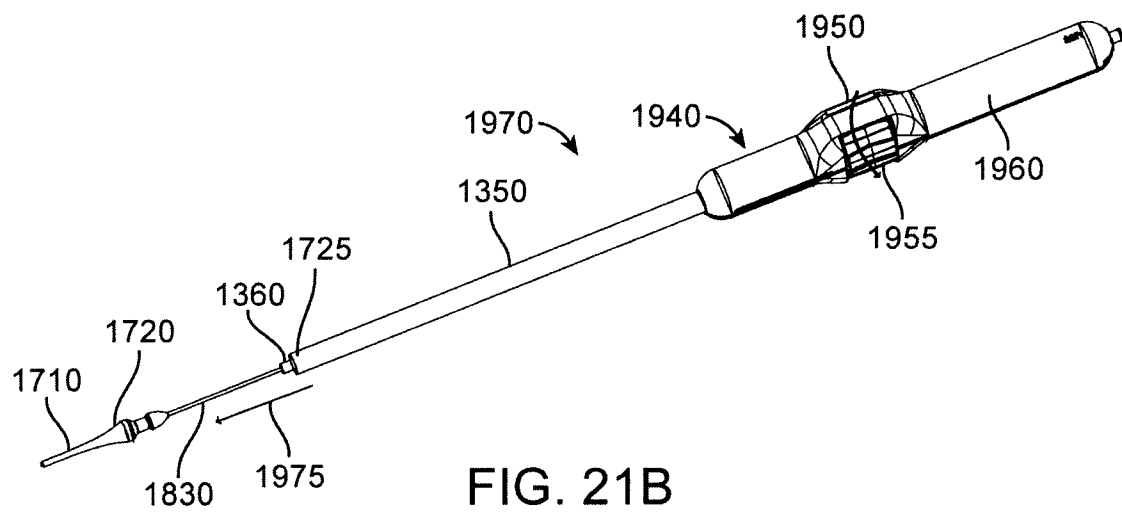
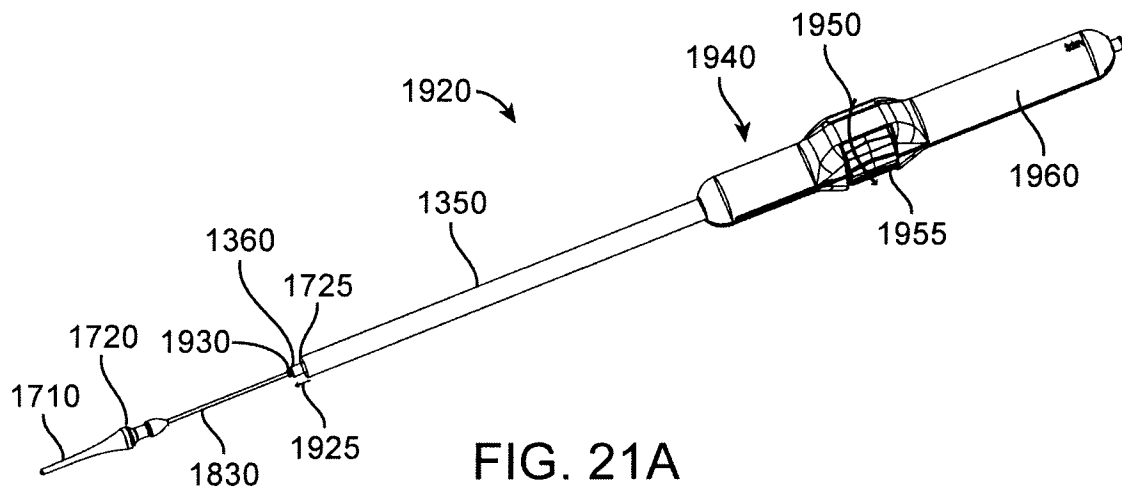


FIG. 20D

FIG. 20E

FIG. 20F

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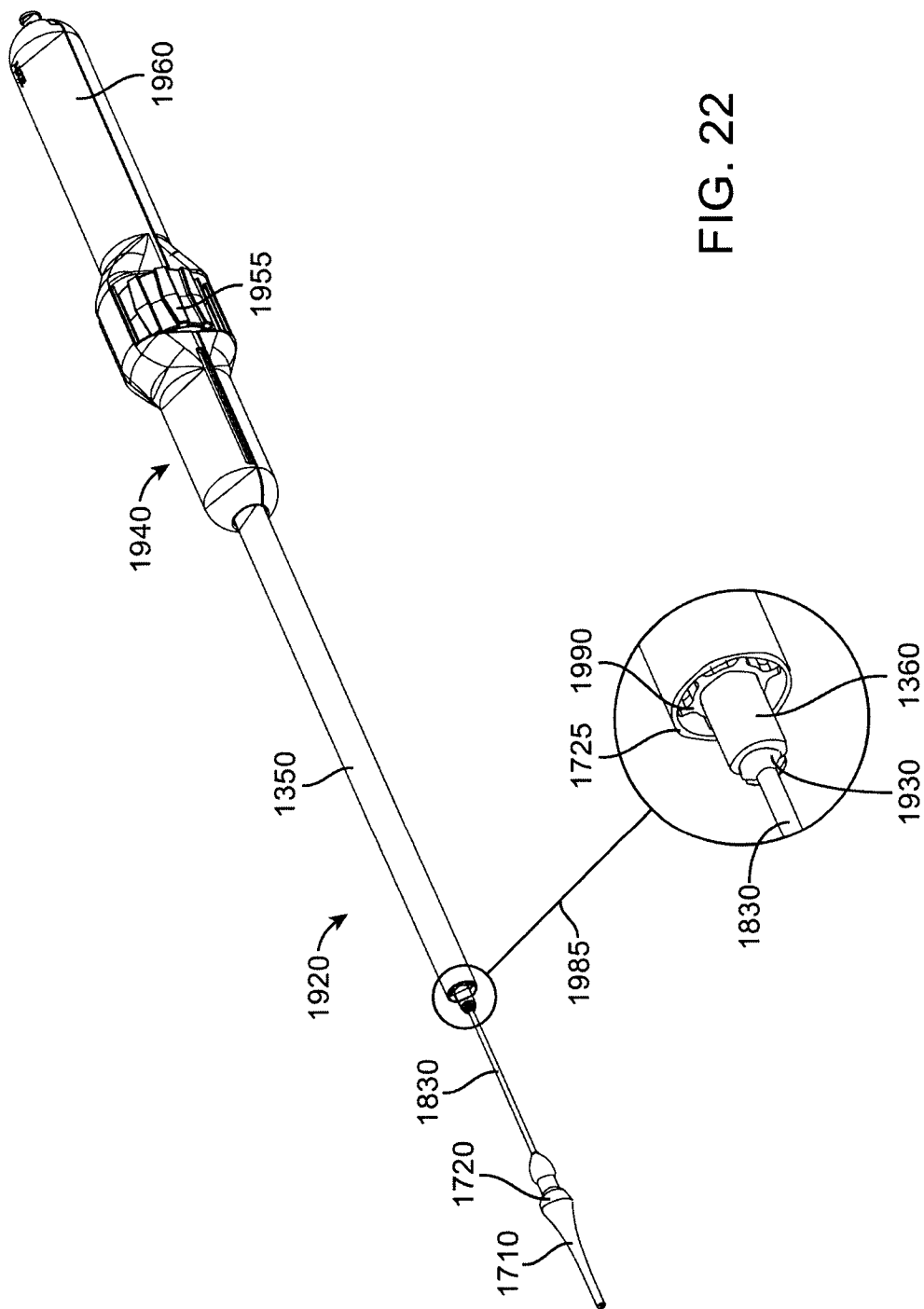


FIG. 22

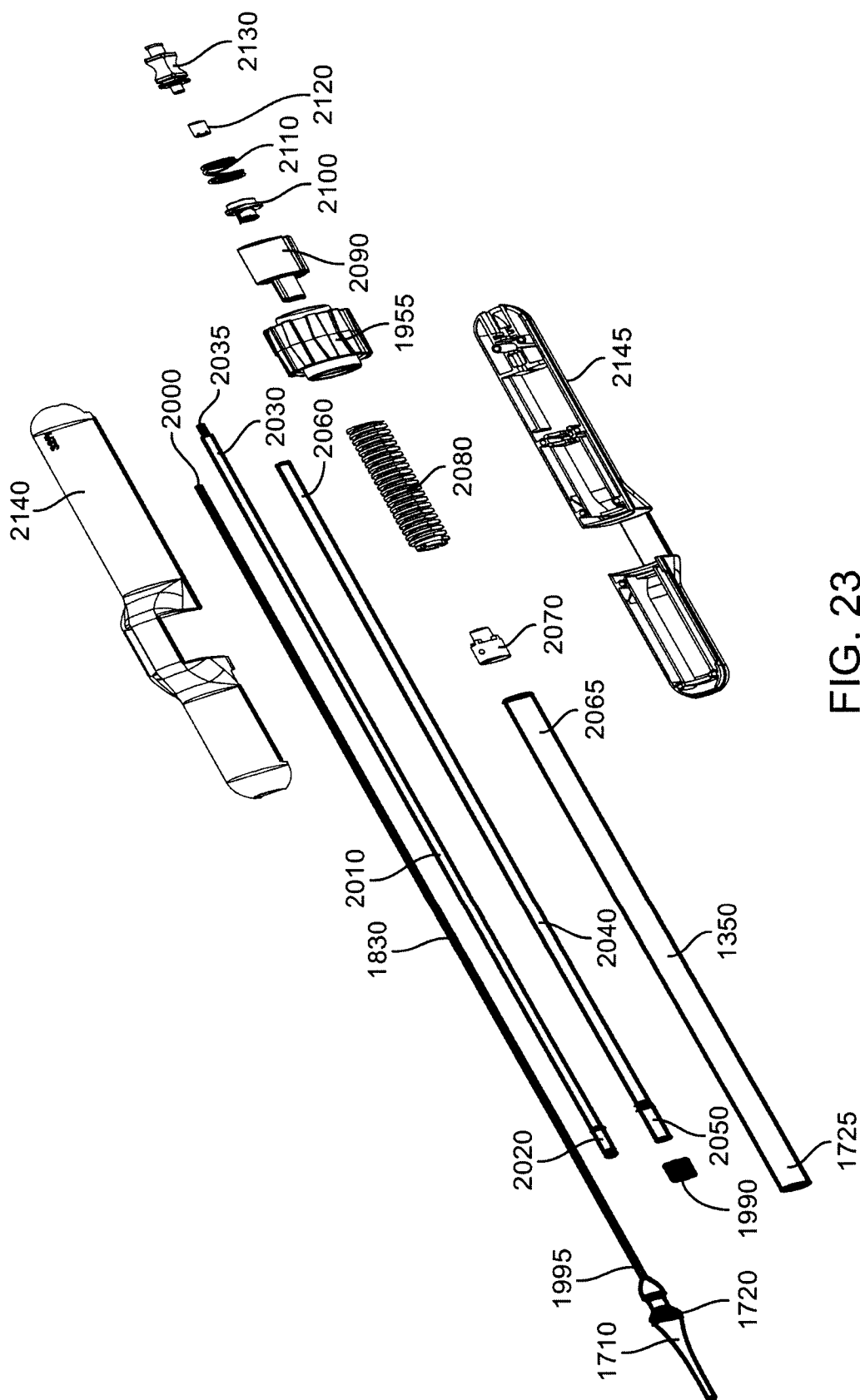


FIG. 23

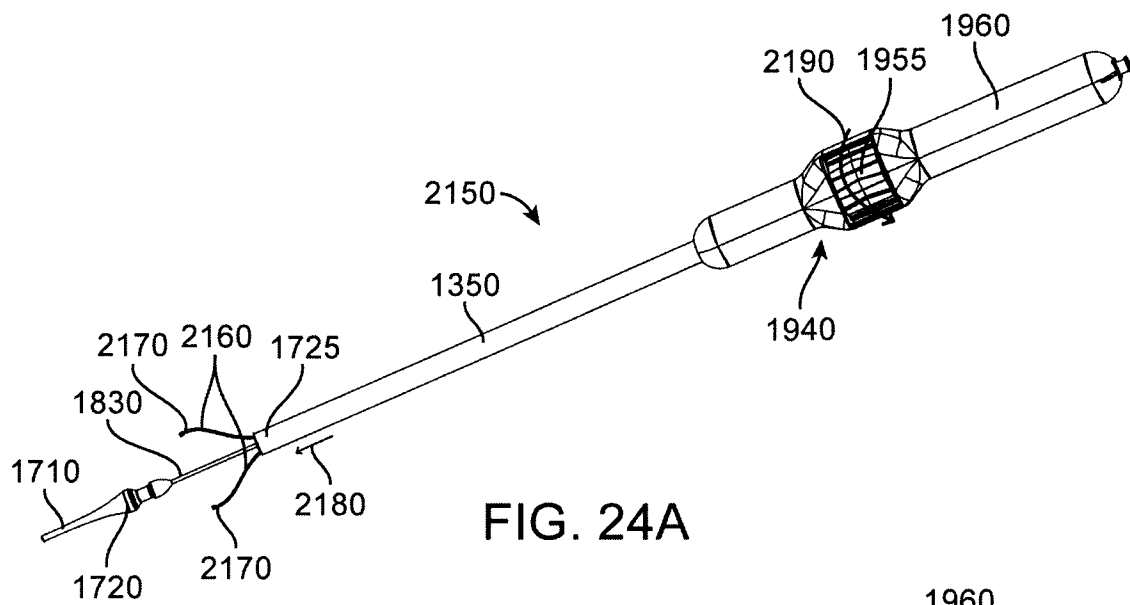


FIG. 24A

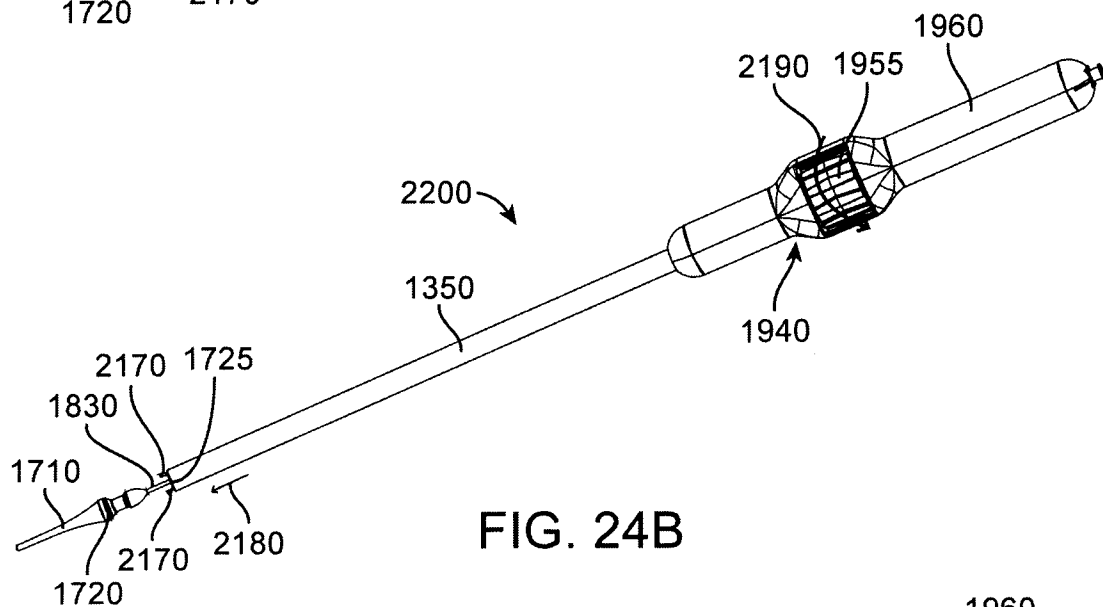


FIG. 24B

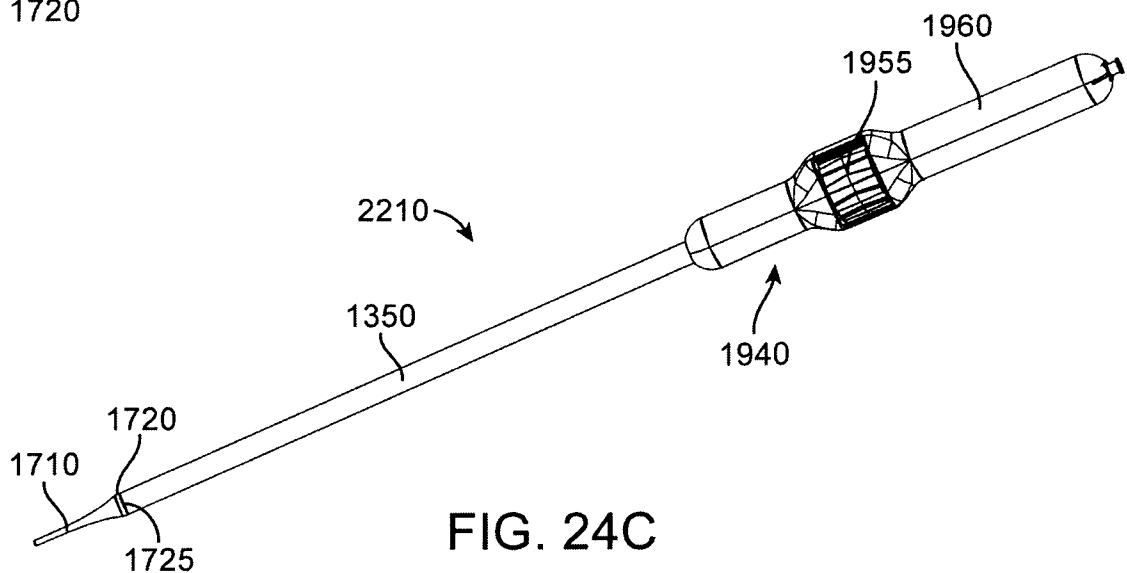


FIG. 24C

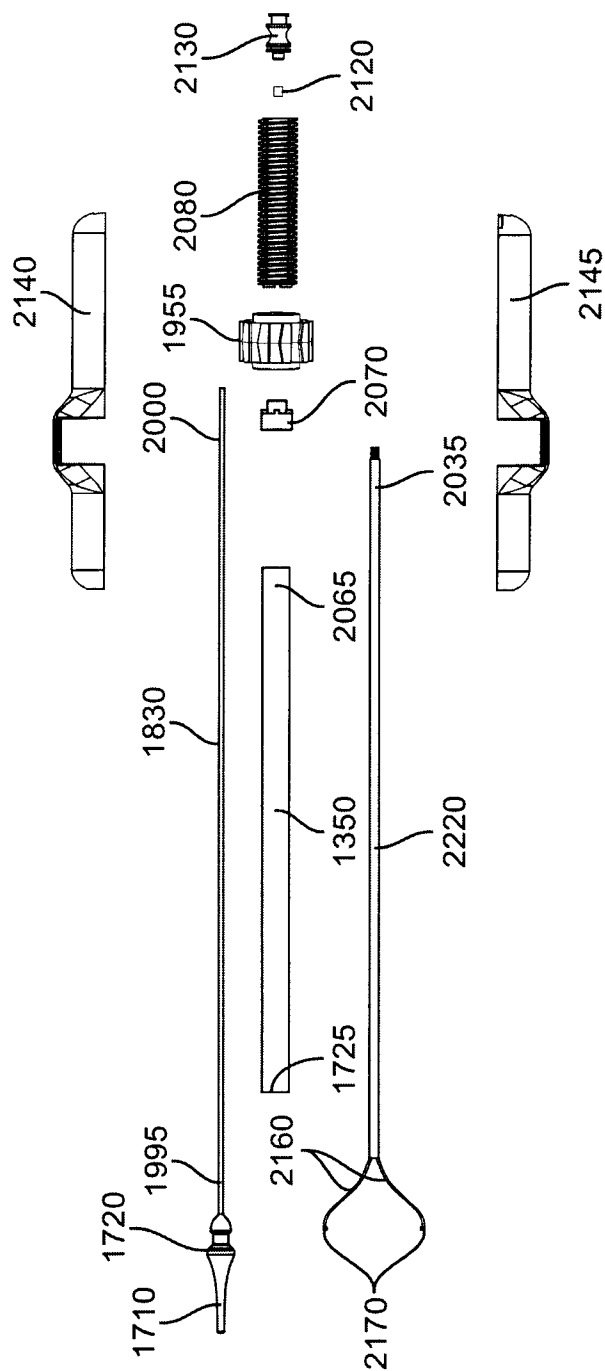


FIG. 25

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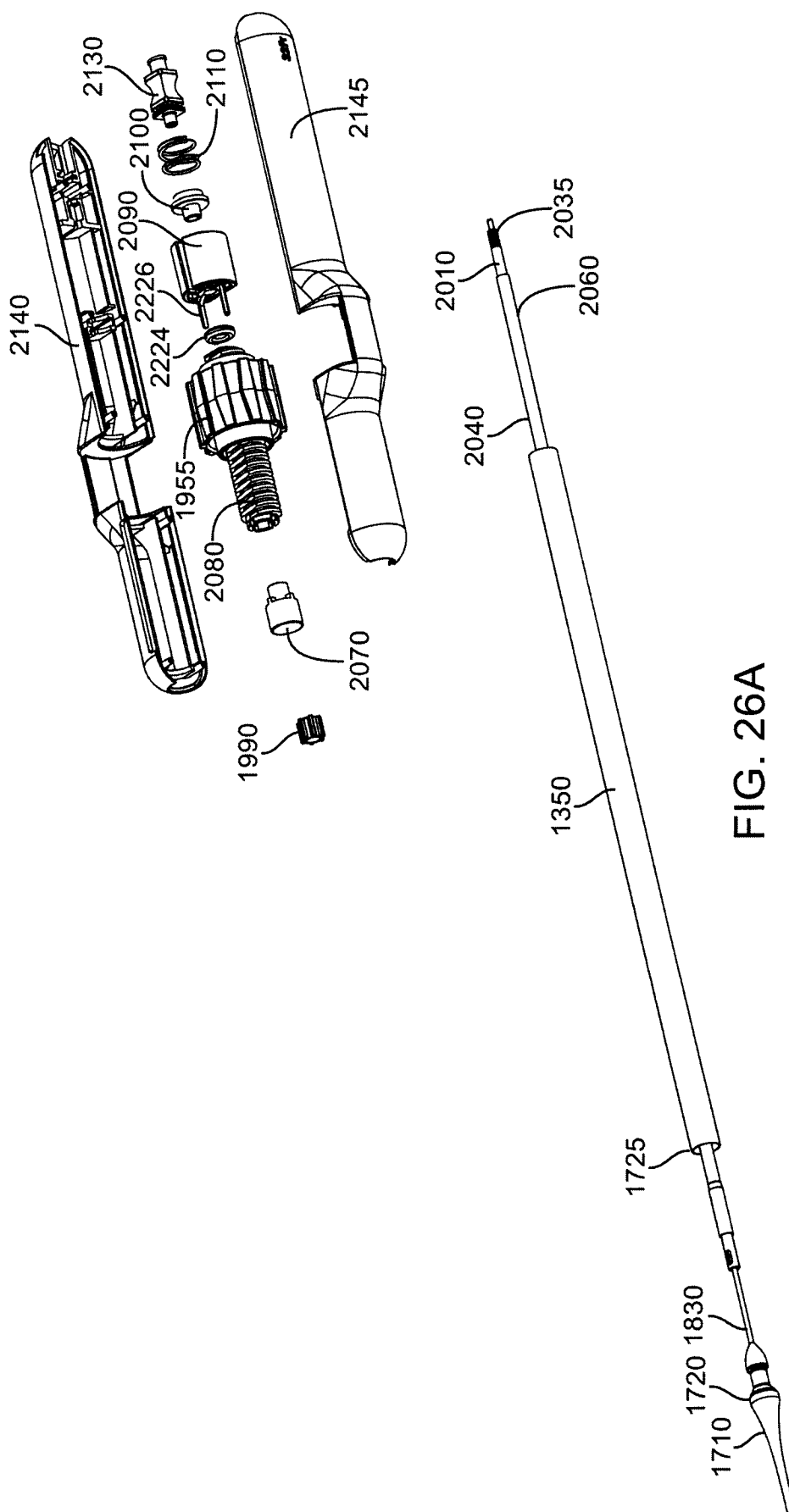


FIG. 26A

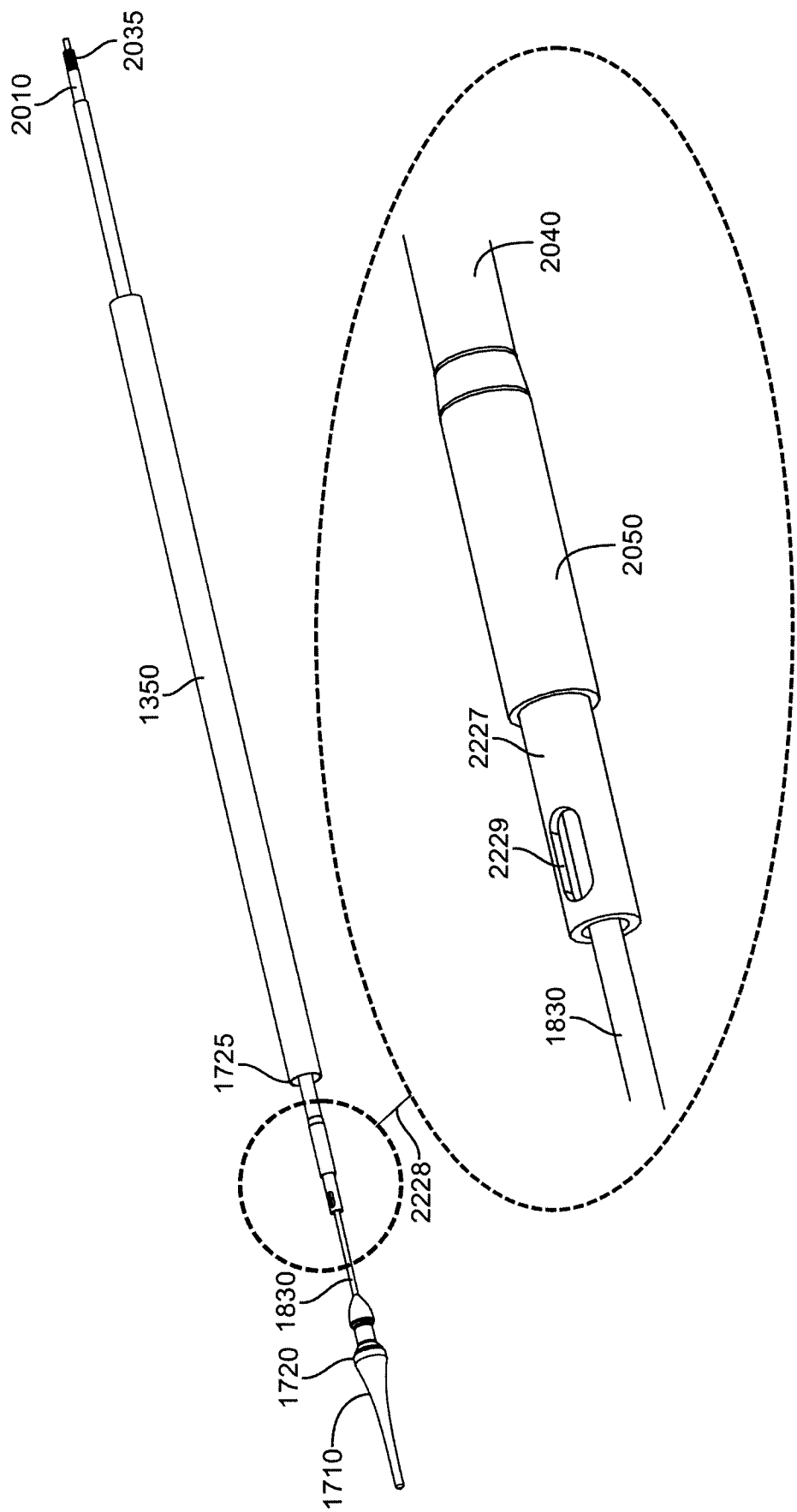
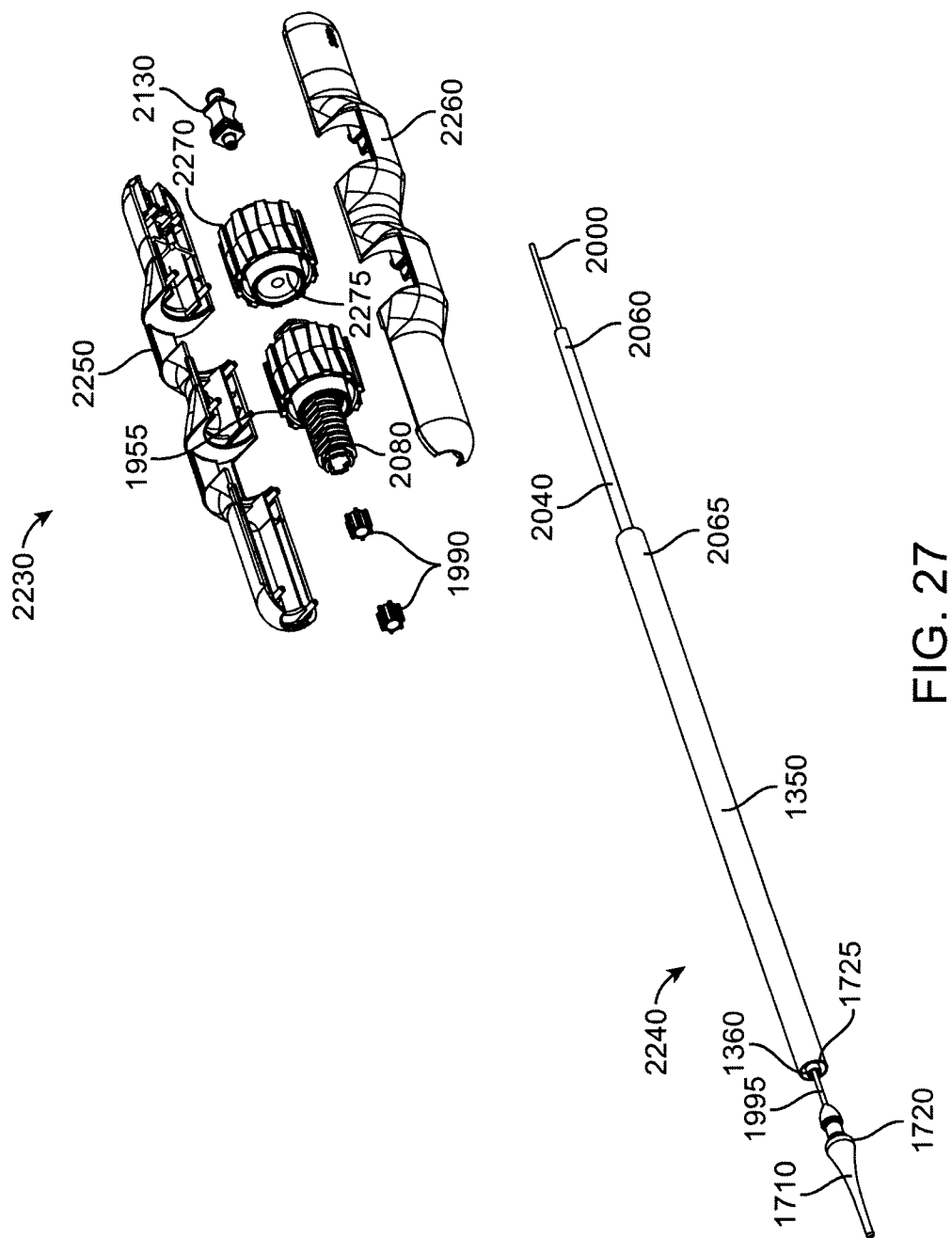


FIG. 26B



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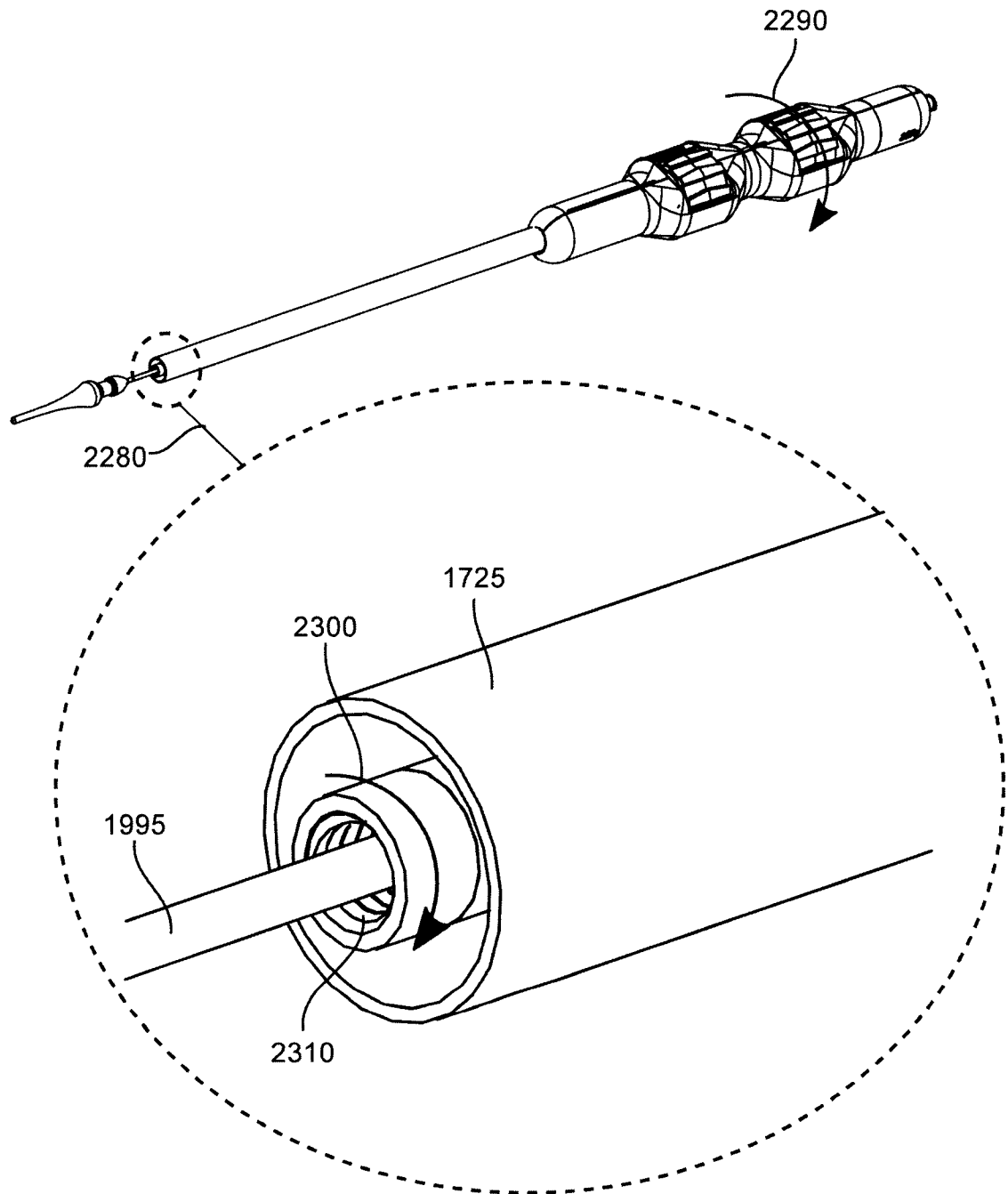
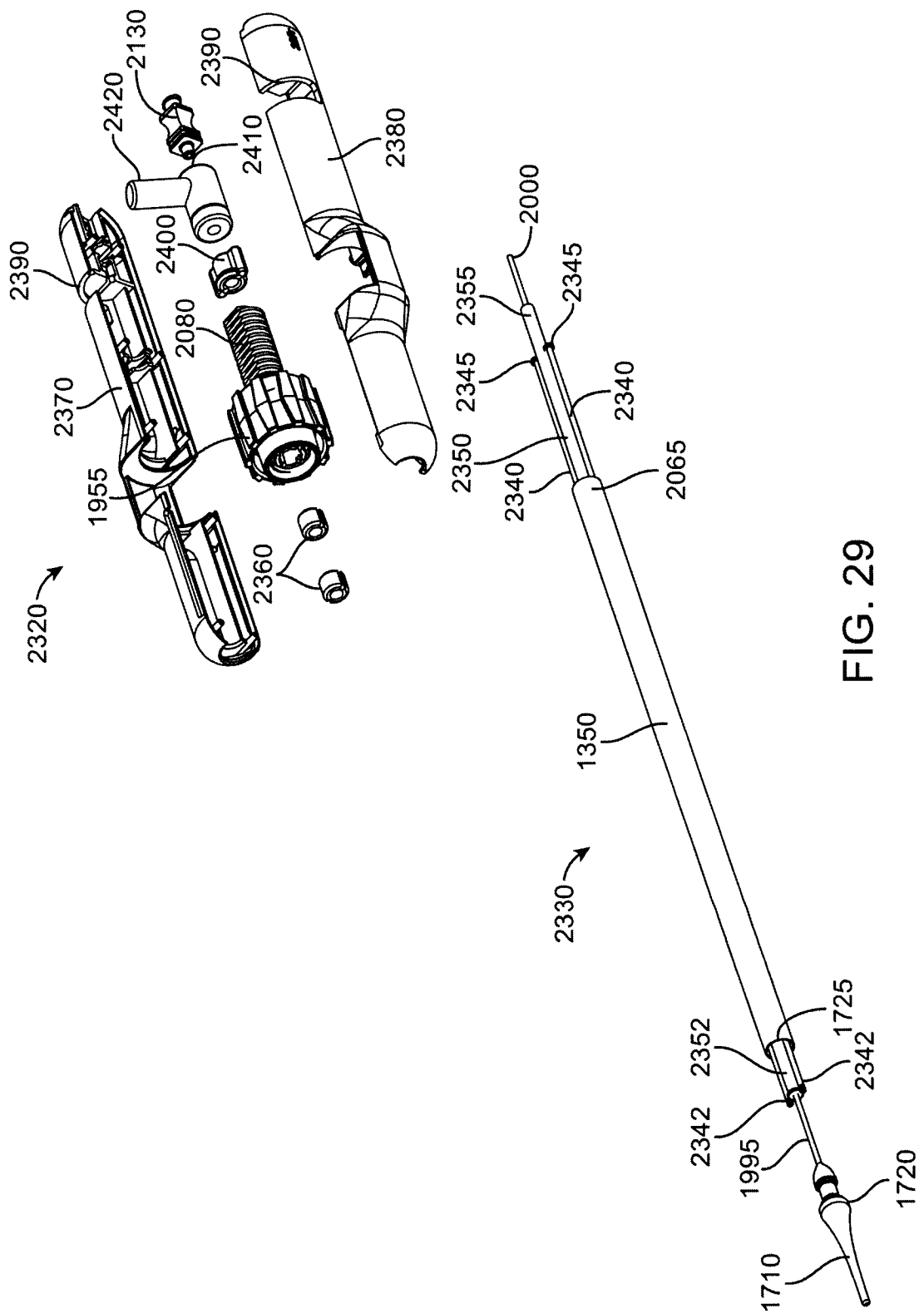


FIG. 28



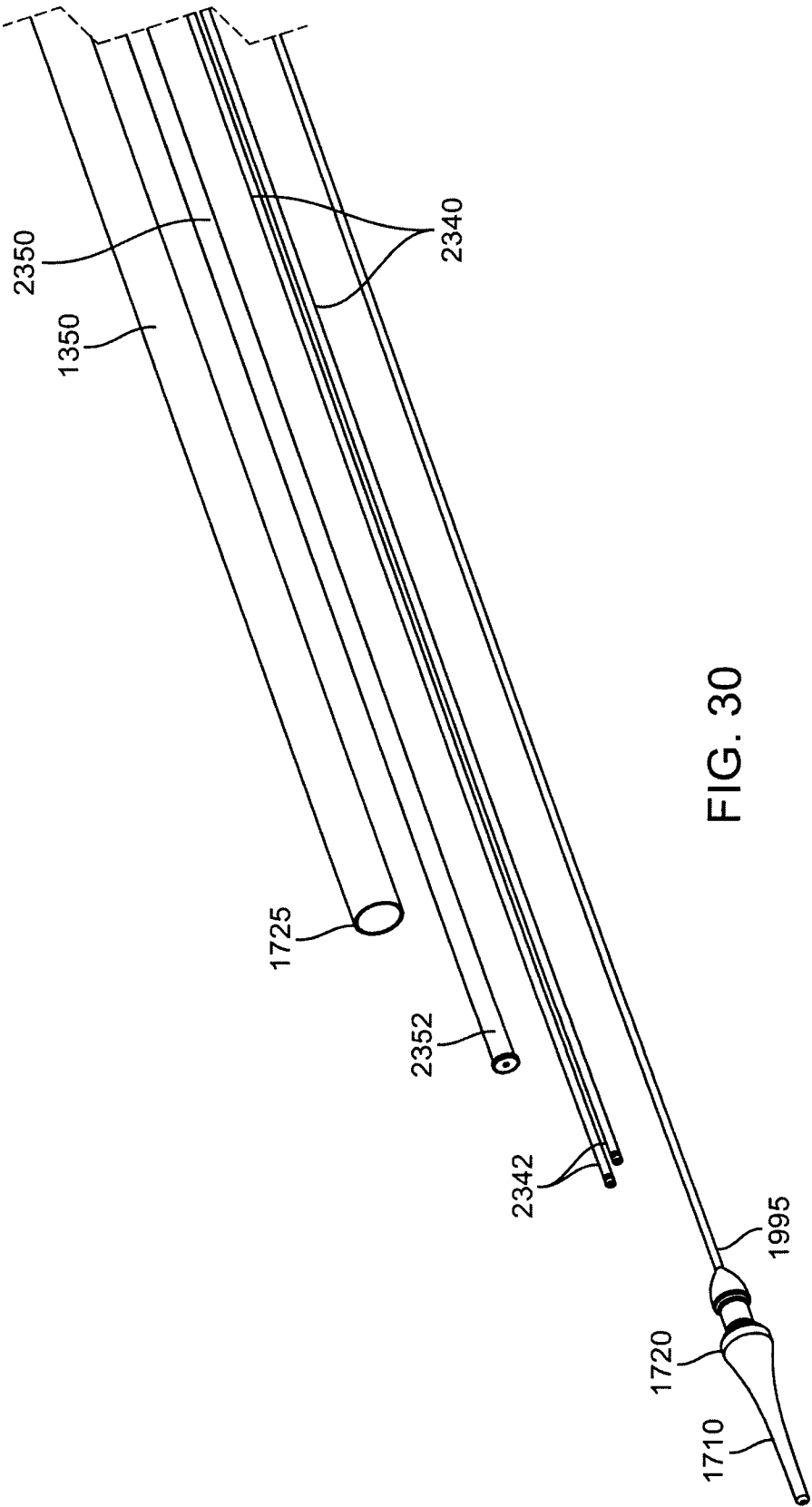


FIG. 30

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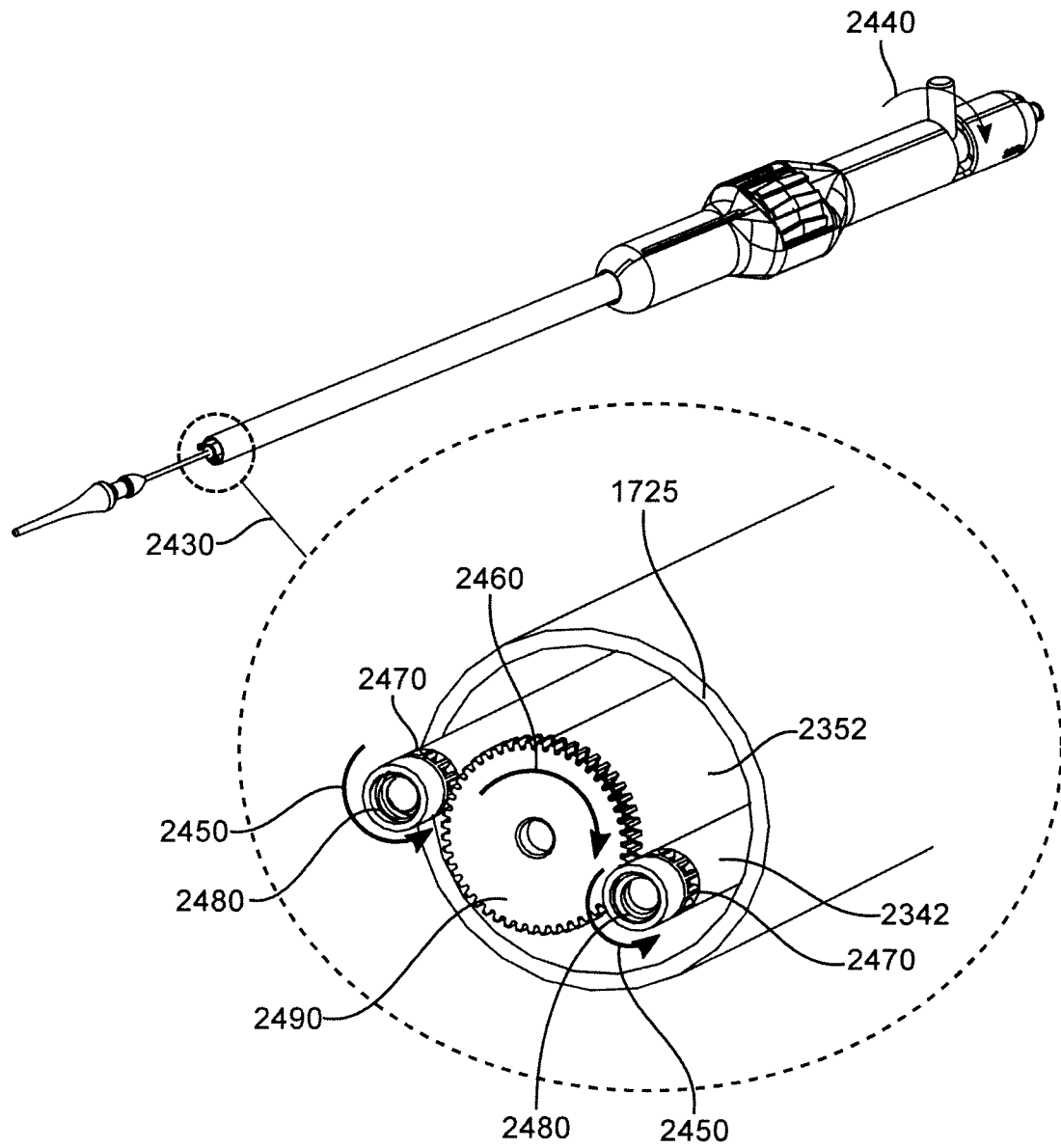


FIG. 31

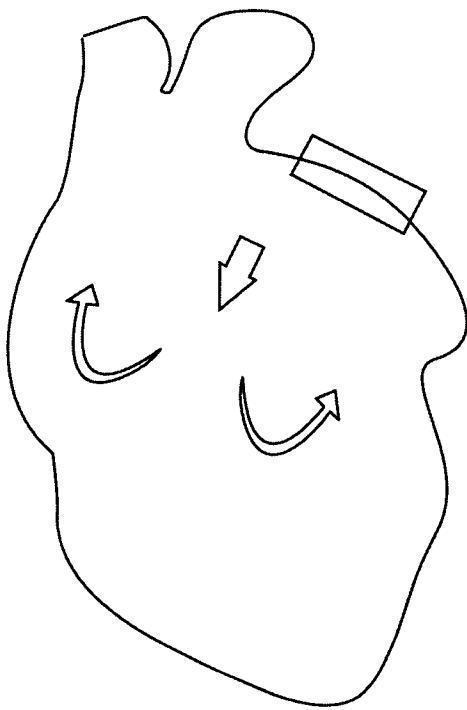


FIG. 32

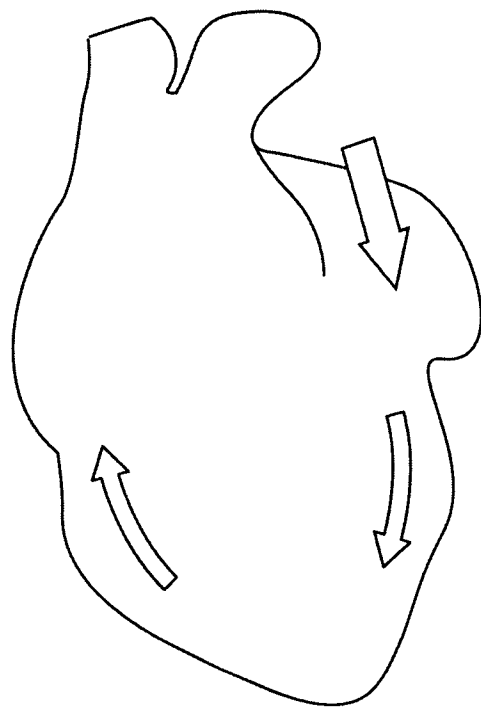


FIG. 33

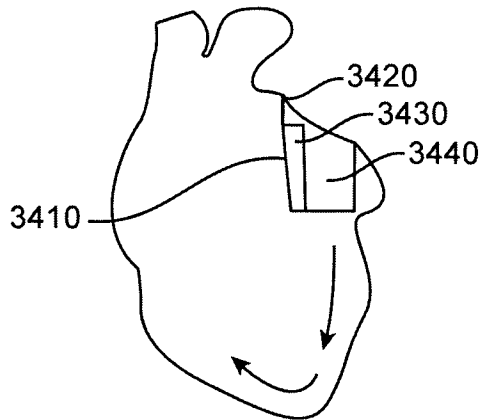


FIG. 34

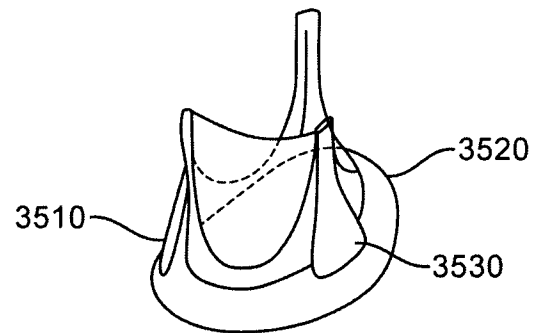


FIG. 35

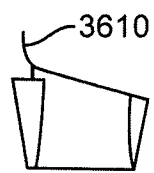


FIG. 36A

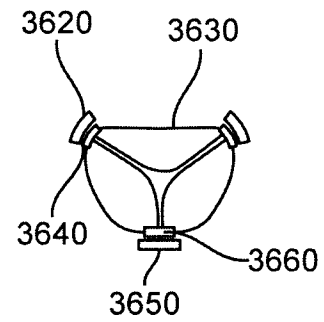


FIG. 36B

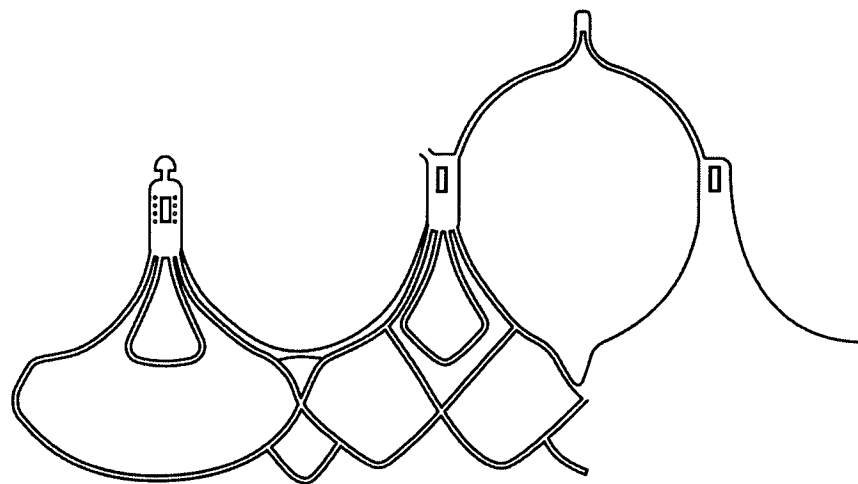
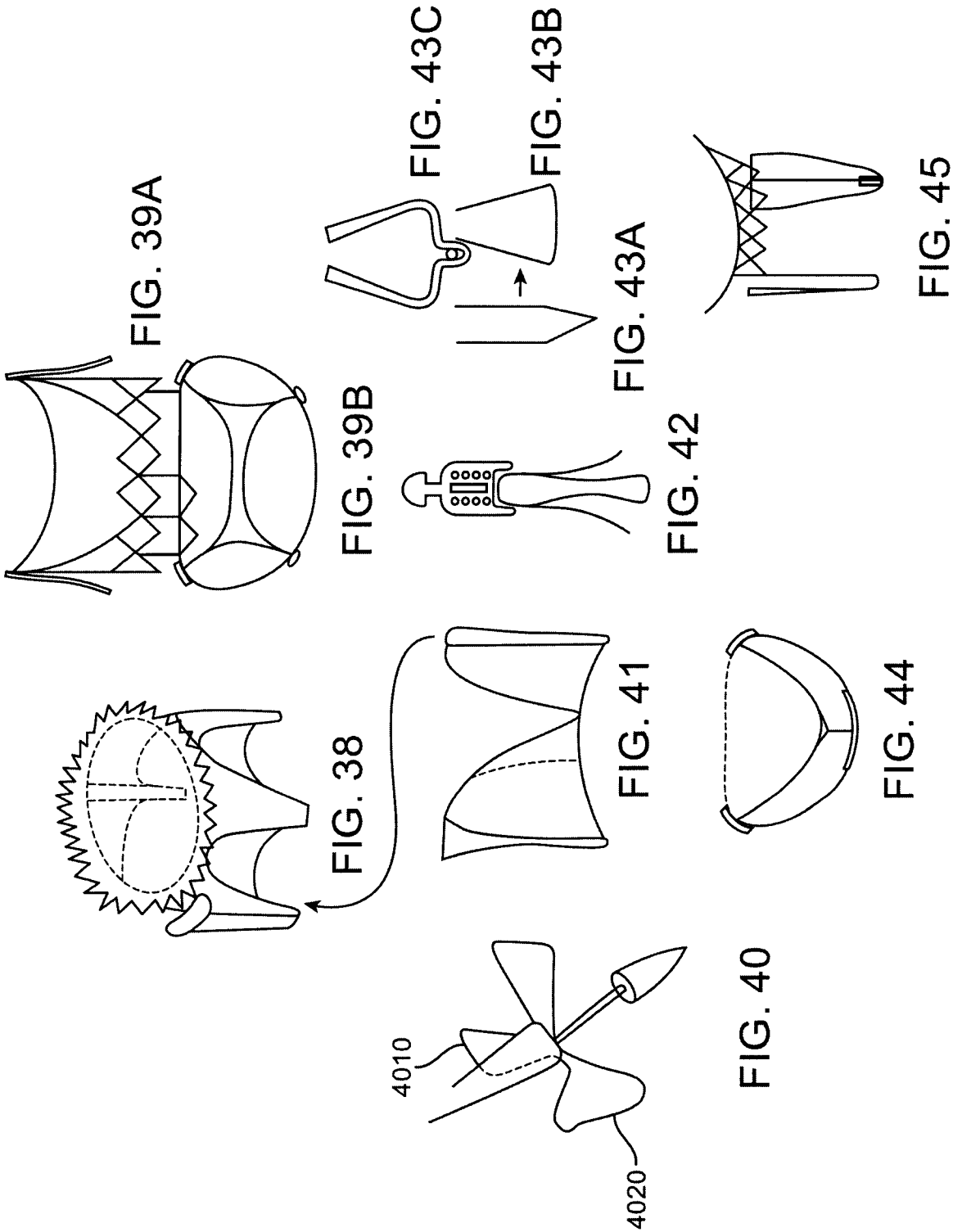


FIG. 37



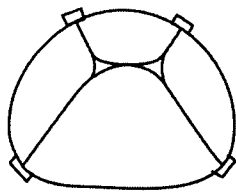


FIG. 46

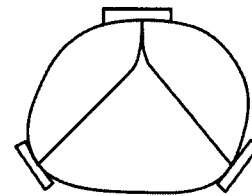


FIG. 47

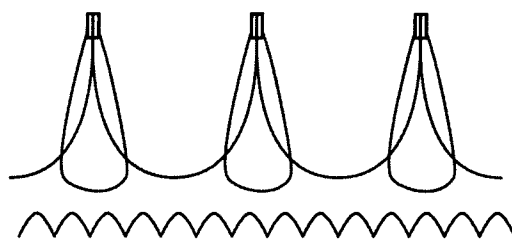


FIG. 48

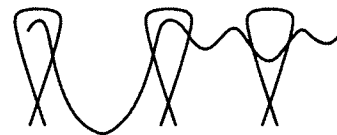


FIG. 49

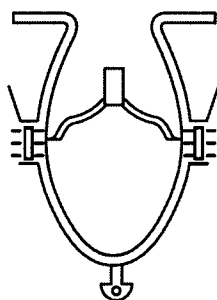


FIG. 50

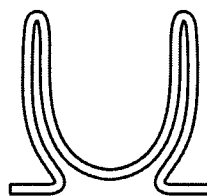


FIG. 51

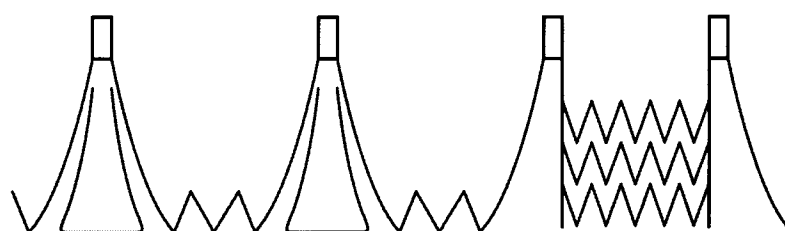


FIG. 52

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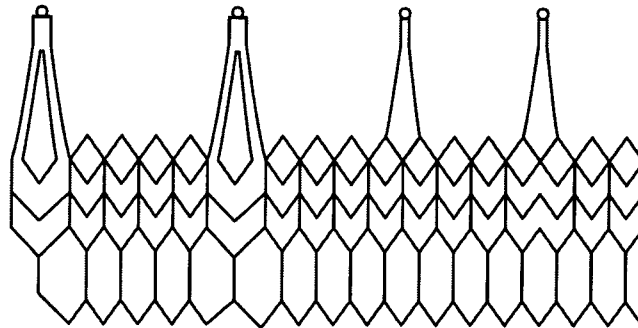


FIG. 53



FIG. 54



FIG. 55

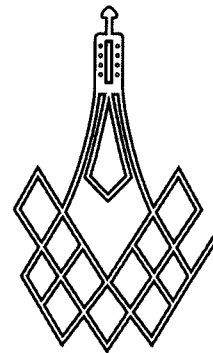


FIG. 56

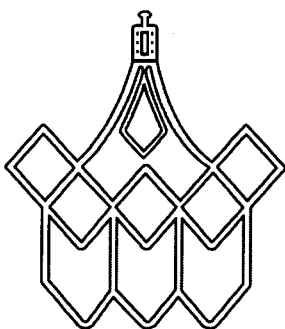


FIG. 57

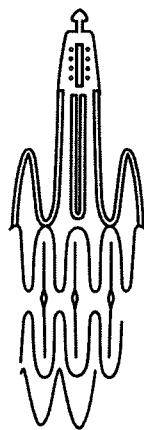


FIG. 58

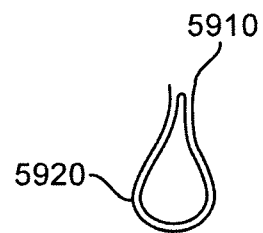


FIG. 59

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2017/050097

A. CLASSIFICATION OF SUBJECT MATTER

IPC: *A61F 2/24* (2006.01), *A61F 2/00* (2006.01), *A61M 25/01* (2006.01), *A61M 25/04* (2006.01)

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)

IPC: *A61F 2/24* (2006.01), *A61F 2/00* (2006.01), *A61M 25/01* (2006.01), *A61M 25/04* (2006.01)

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

Questel-Orbit

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 7871435 B2 (Carpentier, A. F. et al) 18 January 2011 (18-01-2011) entire document	1, 5
Y		2-4, 6-21
Y	US 8579964 B2 (Lane, R. M. et al) 12 November 2013 (12-11-2013) entire document	2-4, 6-21
A	US 2004/0117009 A1 (Cali, D. S. et al.) 17 June 2004 (17-06-2004) entier document	1-21
A	WO 2011/069048 A2 (Chau, M. et al) 9 June 2011 (09-06-2011) entier document	1-21

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

* "A" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance earlier application or patent but published on or after the international filing date 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) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" "X" "Y" "&"	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 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 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
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Date of the actual completion of the international search
08 June 2017 (08-06-2017)Date of mailing of the international search report
12 June 2017 (12-06-2017)Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, C114 - 1st Floor, Box PCT
50 Victoria Street
Gatineau, Quebec K1A 0C9
Facsimile No.: 819-953-2476

Authorized officer

George Carpinisan (819) 953-8628

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2017/050097**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the 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. ☒ Claim Nos.: **22 to 34**
because they relate to subject matter not required to be searched by this Authority, namely:
Claims **22 to 34** are directed to a method for treatment of the human or animal body by surgery or therapy, which the International Searching Authority is not required to search under PCT Rule 39.1(iv).
2. ☐ Claim 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. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

Group A – Claims **1 to 21** are directed to a prosthetic heart valve for implantation in a native mitral valve comprising a radially expandable anchor frame having commissure posts and an anterior anchoring tab to anchor on an anterior portion of the native mitral valve, and a prosthetic valve coupled to the anchor frame and comprising a plurality of prosthetic leaflets including an anterior leaflet sized to span the entire width of a native anterior leaflet; and

Group B – Claims **35 to 45** are directed to a delivery system for delivering a prosthesis to a target treatment area.

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 claim 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 claim Nos.: **1 to 21**

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2017/050097

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