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(54) Title: MULTI-PORTION REPLACEMENT HEART VALVE PROSTHESIS

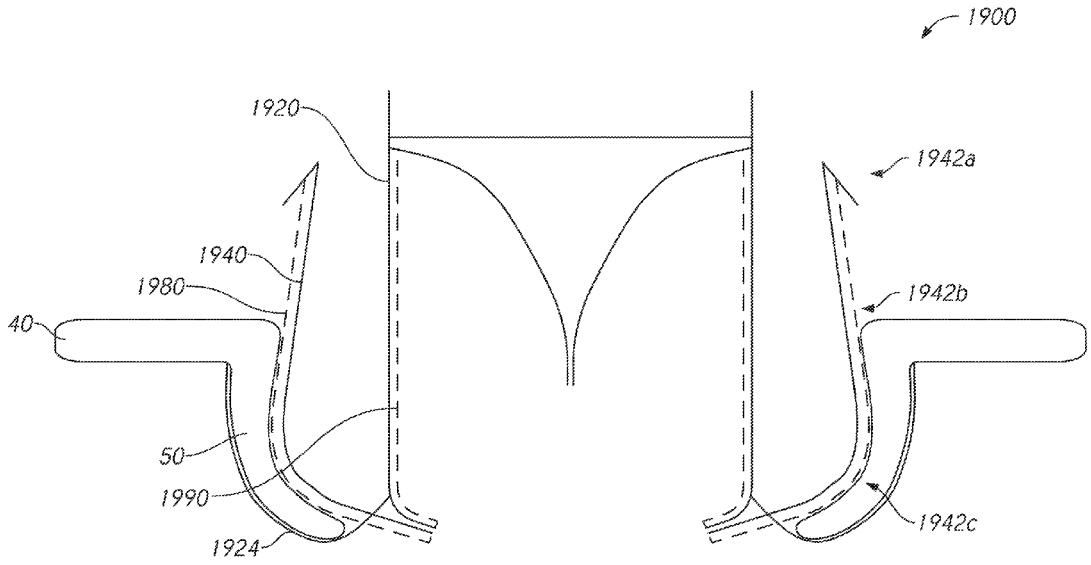

FIG. 38B

(57) Abstract: A replacement mitral valve prosthesis includes a support structure and a valve body having three flexible leaflets. The support structure preferably includes an internal valve frame and an external sealing frame. The valve frame supports the flexible leaflets. The sealing frame is adapted to conform to the shape of the native mitral valve annulus. The sealing frame may be coupled to an inlet end of the valve frame, an outlet end of the valve frame, or both. A plurality of anchors are coupled to the outlet end of the valve frame. The anchors extend radially outwardly for placement behind native leaflets. The prosthesis preferably includes a skirt disposed along an exterior of the external sealing frame. The prosthesis is collapsible for delivery into the heart via a delivery catheter. The prosthesis is configured to self-expand for deployment in the heart when released from the delivery catheter.

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MULTI-PORTION REPLACEMENT HEART VALVE PROSTHESIS

BACKGROUND

Field

[0001] Certain embodiments disclosed herein relate generally to prostheses for implantation within a lumen or body cavity. In particular, certain embodiments relate to expandable prostheses such as replacement heart valves, such as for the mitral valve, that are configured to be secured to intralumenal tissue and prevent paravalvular leakage.

Background

[0002] Human heart valves, which include the aortic, pulmonary, mitral and tricuspid valves, function essentially as one-way valves operating in synchronization with the pumping heart. The valves allow blood to flow downstream, but block blood from flowing upstream. Diseased heart valves exhibit impairments such as narrowing of the valve or regurgitation, which inhibit the valves' ability to control blood flow. Such impairments reduce the heart's blood-pumping efficiency and can be a debilitating and life threatening condition. For example, valve insufficiency can lead to conditions such as heart hypertrophy and dilation of the ventricle. Thus, extensive efforts have been made to develop methods and apparatuses to repair or replace impaired heart valves.

[0003] Prostheses exist to correct problems associated with impaired heart valves. For example, mechanical and tissue-based heart valve prostheses can be used to replace impaired native heart valves. More recently, substantial effort has been dedicated to developing replacement heart valves, particularly tissue-based replacement heart valves that can be delivered with less trauma to the patient than through open heart surgery. Replacement valves are being designed to be delivered through minimally invasive procedures and even percutaneous procedures. Such replacement valves often include a tissue-based valve body that is connected to an expandable frame that is then delivered to the native valve's annulus.

[0004] These replacement valves are often intended to at least partially block blood flow. However, a problem occurs when blood flows around the valve on the

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Outside of the prosthesis. For example, in the context of replacement heart valves, paravalvular leakage has proven particularly challenging. An additional challenge relates to the ability of such prostheses to be secured relative to intralumenal tissue, e.g., tissue within any body lumen or cavity, in an atraumatic manner. Yet another challenge arises when trying to reduce the likelihood of thrombosis within parts of the replacement valves.

SUMMARY

[0004a] It is an object of the present invention to substantially overcome, or at least ameliorate, one or more of the above drawbacks.

[0004b] In an aspect, the present invention provides a replacement heart valve prosthesis the prosthesis comprising:

an expandable frame configured to radially expand and contract for deployment within a native heart valve, the expandable frame having a longitudinal axis between upper and lower ends, the expandable frame comprising:

a first frame portion comprising a first frame body and a first anchoring feature the first frame body comprising a first upper region a first intermediate region and a first lower region,

wherein, when the prosthesis is in an expanded configuration:

the first anchoring feature extends radially outwardly from the first lower region; and

at least a portion of the first anchoring feature extends towards the first upper region; and

a second frame portion positioned radially outward of the first frame body, the second frame portion comprising a second frame body having a second upper region, a second intermediate region, and a second lower region, wherein, when the prosthesis is in an expanded configuration:

at least a portion of the second upper region extends radially outwardly from the first upper region;

the second lower region is positioned radially between the first anchoring feature and the first frame body; and

the second intermediate region is configured such that, when the prosthesis is deployed within the native heart valve, the second intermediate region is positioned within a native valve annulus; and

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a valve body positioned within an interior of the first frame portion, the valve body comprising a plurality of leaflets configured to allow flow in a first direction and prevent flow in a second opposite direction,

wherein

a bend about a circumferential axis is formed at a juncture between the second upper region and the second intermediate region, such that the intermediate region extends in a direction more parallel to the longitudinal axis of the prosthesis than the portion of the second upper region.

[0005] Embodiments of the present disclosure are directed to a prosthesis, such as but not limited to a replacement heart valve.

[0006] In some embodiments, a replacement heart valve prosthesis can include an expandable frame. The expandable frame can radially expand and contract for deployment within a native heart valve. The expandable frame can have a longitudinal axis between upper and lower ends. The expandable frame can include a first frame portion. The first frame portion can include a first frame body. The first frame body can include a first upper region, a first intermediate region, and/or a first lower region. The first frame portion can include a first anchoring feature. When the prosthesis is in an expanded configuration, the first anchoring feature can extend radially outwardly from the first lower region and/or at least a portion of the first anchoring feature can extend towards the first upper region.

[0007] The expandable frame can include a second frame portion positioned radially outward of the first frame body. The second frame portion can include a second frame body. The second frame body can include a second upper region, a second intermediate region, and/or a second lower region. When the prosthesis is in an expanded configuration, at least a portion of the second upper region can extend radially outwardly from the first upper region and/or the second lower region can be positioned radially between the first anchoring feature and the first frame body. When the prosthesis is in an expanded configuration and deployed within the native heart valve, the second intermediate portion can be positioned within a native valve annulus.

[0008] The replacement heart valve prosthesis can include a valve body positioned within an interior of the first frame portion. The valve body can include a plurality of leaflets which can allow flow in a first direction and prevent flow in a second opposite direction.

[0009] When the prosthesis is in an expanded configuration, the second intermediate region can be generally cylindrical. When the prosthesis is in an expanded configuration, the second intermediate region can be generally non-cylindrical. When the prosthesis is in an expanded configuration, a portion of the second intermediate region between the upper and lower ends of the second intermediate region can have a diameter greater than at least one of the upper and lower ends of the second intermediate region. The second intermediate region can be sized such that, when the prosthesis is deployed and expanded within the native heart valve, the second intermediate region can exert a radially outward force on the native valve annulus. When the prosthesis is in an expanded configuration, the second lower region can be inclined and/or curved radially inward towards the longitudinal axis. When the prosthesis is in an expanded configuration, at least a portion of the second upper region can extend towards the first lower region. When the prosthesis is in an expanded configuration, at least a portion of the second upper region can extend towards the first lower region in a direction generally parallel to the longitudinal axis. The second frame portion and the first anchoring feature can be sized such that, when the prosthesis is deployed and expanded within the native heart valve, native valve leaflets and/or the native valve annulus can be pinched between the second frame portion and the first anchoring feature.

[0010] When the prosthesis is in an expanded configuration, at least a portion of the first anchoring feature can extend upwards towards the first upper region. The first anchoring feature can include a first plurality of anchors. When the prosthesis is in an expanded configuration, tips of anchors of the first plurality of anchors can extend in a direction generally parallel to the longitudinal axis. When the prosthesis is in an expanded configuration, tips of anchors of the first plurality of anchors can extend in a direction generally perpendicular to the longitudinal axis. When the prosthesis is in an expanded configuration, at least a portion of tips of anchors of the first plurality of

anchors can extend radially inwardly towards the longitudinal axis. When the prosthesis is in an expanded configuration, at least a portion of tips of anchors of the first plurality of anchors extend radially outwardly away from the longitudinal axis. When the prosthesis is deployed and expanded within a native mitral valve, at least some of the anchors of the first plurality of anchors can contact a native mitral valve annulus on a ventricular side. When the prosthesis is in an expanded configuration, at least a portion of anchors of the first plurality of anchors is angled in a circumferential direction and/or curved in a circumferential direction.

[0011] The second frame portion can include a second anchoring feature. At least a portion of the second anchoring feature can extend from at least one of the second upper region and the second intermediate region. The second anchoring feature can include a second plurality of anchors. Anchors of the second plurality of anchors can be V-shaped. When the prosthesis is in an expanded configuration, anchors of the second plurality of anchors can extend in a direction generally parallel to the second upper region. When the prosthesis transitions from an expanded configuration to a collapsed configuration, ends of the anchors of the second plurality of anchors can move radially outwardly and upwardly. When the prosthesis transitions from an expanded configuration to a collapsed configuration, ends of the anchors of the second plurality of anchors can move radially outwardly and downwardly.

[0012] The prosthesis can include a skirt extending around at least a portion of the prosthesis. At least a portion of the skirt can extend along an exterior of the second frame portion. At least a portion of the skirt can extend along an interior of the second frame portion. At least a portion of the skirt can extend along an interior of the second frame portion is attached to the valve body. At least a portion of the skirt can extend along an exterior of the second intermediate region. At least a portion of the skirt can extend along an exterior of the second upper region. At least a portion of the skirt can extend along an interior of the second upper region. At least a portion of the skirt is spaced apart from the second upper region.

[0013] The valve body can include a liner. The liner can extend from an arcuate edge of the plurality of leaflets towards an upper end of the first frame body. An

upper end of the liner can be positioned at or proximate an upper end of the first frame body. An upper end of the liner can be positioned at or proximate an uppermost end of an arcuate edge of the plurality of leaflets.

[0014] The valve body can include one or more intermediate components. The one or more intermediate components can be positioned between the first frame body and the valve leaflets.

[0015] The first frame portion and the second frame portion can be separate components. The first frame portion can include a plurality of first eyelets. The second frame portion can include a plurality of second eyelets. Each of the plurality of first eyelets can correspond with each of the plurality of second eyelets. The first frame portion and the second frame portion can be coupled at each of the plurality of first and second eyelets. The first and second frame portions can be tautly secured at one or more attachment points such that relative movement at the one or more attachment points is inhibited. The first and second frame portions can be loosely secured at one or more attachment points such that the first and second frame portions are movable relative to each other at the one or more attachment points. The first and second frame portions can be coupled via the skirt.

[0016] The inner frame portion and the outer frame portion form a monolithic component.

[0017] The first frame body can include one or more rows of cells. At least one row of cells can include an upper and lower portion formed from a plurality of undulating struts and a middle portion formed from one or more eyelets. The first frame body can include a foreshortening portion. The second frame body can include one or more rows of cells. The second frame body can include a foreshortening portion. One or more portions of the first frame body can form a cylindrical shape, a bulbous shape, and/or a frustoconical shape.

[0018] In some embodiments, a replacement heart valve prosthesis can include an expandable frame. The expandable frame can radially expand and contract for deployment within a native heart valve. The expandable frame can have a longitudinal axis between upper and lower ends. The expandable frame can include a frame body.

The frame body can include an upper region, an intermediate region, and/or a lower region.

[0019] The expandable frame can include an upper anchoring feature, an intermediate anchoring feature, and/or a lower anchoring feature. The upper anchoring feature can extend from the upper region of the frame body. The intermediate anchoring feature can extend from the intermediate region of the frame body. The lower anchoring feature can extend from the lower region of the frame body. When the frame is in an expanded configuration, at least a portion of the upper anchoring feature can be positioned radially outward of the frame body, at least a portion of the intermediate anchoring feature can be positioned radially outward of the frame body, and/or at least a portion of the lower anchoring feature can be positioned radially outward of the frame body.

[0020] The replacement heart valve prosthesis can include a valve body positioned within an interior of the first frame portion. The valve body can include a plurality of leaflets which can allow flow in a first direction and prevent flow in a second opposite direction.

[0021] The intermediate anchoring feature can be sized such that, when the prosthesis is deployed and expanded within the native heart valve, the second anchoring feature exerts a radially outward force on a native valve annulus. When the prosthesis is in an expanded configuration, at least a portion of the intermediate anchoring feature can be positioned radially between the frame body and the lower anchoring feature. The intermediate anchoring feature and the lower anchoring feature can be sized such that, when the prosthesis is deployed and expanded within the native heart valve, native valve leaflets and/or a native valve annulus can be pinched between the intermediate anchoring feature and the lower anchoring feature. The intermediate anchoring feature can include a braided mesh.

[0022] The frame body and the intermediate anchoring feature can be separate components. The frame body and the intermediate anchoring feature can form a monolithic component.

[0023] When the prosthesis is in an expanded configuration, at least a portion of the upper anchoring feature can extend radially outward away from the longitudinal axis. When the prosthesis is in an expanded configuration, at least a portion of the upper anchoring feature can extend radially inward towards the longitudinal axis. The upper anchoring feature can include an upper plurality of anchors.

[0024] When the prosthesis is in an expanded configuration, at least a portion of the lower anchoring feature can extend radially outward away from the longitudinal axis. When the prosthesis is in an expanded configuration, at least a portion of the lower anchoring feature can extend upwardly towards the upper anchoring feature. The lower anchoring feature can be attached to the frame body above a lower end of the lower region. The lower anchoring feature can include a lower plurality of anchors. When the prosthesis is in an expanded configuration, tips of anchors of the lower plurality of anchors extend in a direction generally parallel to the longitudinal axis. When the prosthesis is in an expanded configuration, tips of anchors of the lower plurality of anchors can extend in a direction generally perpendicular to the longitudinal axis. When the prosthesis is in an expanded configuration, at least a portion of tips of anchors of the lower plurality of anchors can extend radially inwardly towards the longitudinal axis. When the prosthesis is in an expanded configuration, at least a portion of tips of anchors of the lower plurality of anchors can extend radially outwardly away from the longitudinal axis. Anchors of the lower plurality of anchors can be sized such that, when the prosthesis is deployed and expanded within a native mitral valve, at least some of the anchors of the lower plurality of anchors can contact a native mitral valve annulus on a ventricular side. At least a portion of anchors of the lower plurality of anchors can be angled in a circumferential direction and/or curved in a circumferential direction.

[0025] The replacement heart valve prosthesis can include a skirt extending around at least a portion of the prosthesis. At least a portion of the skirt can extend radially outward of an exterior of the upper anchoring feature. At least a portion of the skirt can extend radially inward of an interior of the upper anchoring feature. At least a portion of the skirt can extend radially outward of an exterior of the intermediate anchoring feature. At least a portion of the skirt can extend between the intermediate

anchoring feature and the lower anchoring feature. At least a portion of the skirt can be coupled to the upper region of the frame. At least a portion of the skirt can be coupled to the frame below the intermediate anchoring feature and above the lower anchoring feature. At least a portion of the skirt can be coupled to the valve body. At least a portion of the skirt can be coupled to a liner of the valve body.

[0026] The frame body can include one or more rows of cells. The first frame body can include a foreshortening portion.

[0027] In some embodiments, a replacement heart valve prosthesis can include an expandable frame. The expandable frame can radially expand and contract for deployment within a native heart valve. The expandable frame can have a longitudinal axis between upper and lower ends. The expandable frame can include a frame body. The frame body can include an upper region, an intermediate region, and/or a lower region. The expandable frame can include an anchoring feature. The anchoring feature can extend from the upper region of the frame body. The upper anchoring feature can include an anchor body formed from a wire mesh. When the prosthesis is in an expanded configuration, at least a portion of the anchor body can extend radially outwardly of the frame body.

[0028] The anchor body can be formed from a braided tube. The anchor body can conform to the shape of the native heart valve. When the prosthesis is deployed and expanded within a native mitral valve, at least a portion of the anchor body can be positioned intra-annularly and can exert a radially outward force on a native mitral valve annulus. When the prosthesis is deployed and expanded within a native mitral valve, at least a portion of the anchor body can be positioned in a left atrium and can extend overs an atrial surface of a native valve annulus. When the prosthesis is deployed and expanded within a native mitral valve, at least a portion of the anchor body can be positioned in a left ventricle and can exert a radial outward force on native leaflets. The anchoring feature can include one or more barbs.

[0029] The anchoring feature can include one or more arms extending from the upper region of the frame body and/or the anchor body. The one or more arms can be formed from a wire mesh. When the prosthesis is in an expanded configuration, the one

or more arms can extend radially outwardly from the frame body. When the prosthesis is in an expanded configuration, the one or more arms can extend upwardly away from the frame body. When the prosthesis is deployed and expanded within a native mitral valve, the one or more arms can contact portions of an atrial wall.

[0030] In some embodiments, a replacement heart valve prosthesis can include an expandable frame. The expandable frame can radially expand and contract for deployment within a native heart valve. The expandable frame can have a longitudinal axis between upper and lower ends. The expandable frame can include a first frame portion. The first frame portion can include a first frame body. The first frame body can include a first upper region, a first intermediate region, and/or a first lower region. The first frame portion can include a first anchoring feature. When the prosthesis is in an expanded configuration, the first anchoring feature can be attached to the first frame body at a base along the first distal region and/or at least a portion of the first anchoring feature can extend towards the first upper region.

[0031] The expandable frame can include a second frame portion positioned radially outward of the first frame body. The second frame portion can include a second frame body. The second frame body can include a second upper region, a second intermediate region, and/or a second lower region. When the prosthesis is in an expanded configuration, at least a portion of the second lower region is positioned below the base, at least a portion of the second lower region is positioned radially between the first anchoring feature, and/or the second lower region extends radially outwardly from the first lower region. When the prosthesis is in an expanded configuration and deployed within the native heart valve, the second intermediate portion can be positioned within a native valve annulus.

[0032] The replacement heart valve prosthesis can include a valve body positioned within an interior of the first frame portion. The valve body can include a plurality of leaflets which can allow flow in a first direction and prevent flow in a second opposite direction.

[0033] When the prosthesis is in an expanded configuration, the second intermediate region can be generally cylindrical. When the prosthesis is in an expanded

configuration, the second intermediate region is generally non-cylindrical. The second intermediate region can be sized such that, when the prosthesis is deployed and expanded within the native heart valve, the second intermediate region exerts a radially outward force on the native valve annulus. The second frame portion and the first anchoring feature can be sized such that, when the prosthesis is deployed and expanded within the native heart valve, at least one of native valve leaflets and the native valve annulus are pinched between the second frame portion and the first anchoring feature.

[0034] The first anchoring feature can include a first plurality of anchors. When the prosthesis is in an expanded configuration, tips of anchors of the first plurality of anchors can extend in a direction generally parallel to the longitudinal axis. The first plurality of anchors can be sized such that, when the prosthesis is deployed and expanded within a native mitral valve, at least some of the anchors of the first plurality of anchors contact a native mitral valve annulus on a ventricular side.

[0035] The second frame portion can include a second anchoring feature. The second anchoring feature can include a second plurality of anchors. Anchors of the second plurality of anchors can be V-shaped. When the prosthesis transitions from an expanded configuration to a collapsed configuration, anchors of the second plurality of anchors can extend radially outwardly and upwardly. When the prosthesis transitions from an expanded configuration to a collapsed configuration, anchors of the second plurality of anchors can extend radially outwardly and downwardly.

[0036] The replacement heart valve can include a skirt extending around at least a portion of the prosthesis. At least a portion of the skirt can extend along an exterior of the second frame portion. At least a portion of the skirt can extend along an interior of the second frame portion.

[0037] The valve body can include one or more intermediate components. The one or more intermediate components can be positioned between the first frame body and the valve leaflets.

[0038] The first frame portion and the second frame portion can be separate components. The first frame portion can include a plurality of first eyelets. The second frame portion can include a plurality of second eyelets. Each of the plurality of first

eyelets can correspond with each of the plurality of second eyelets. The first frame portion and the second frame portion can be coupled at each of the plurality of first and second eyelets.

[0039] The first frame portion and the second frame portion can form a monolithic component.

[0040] The first frame body can include one or more rows of cells. One or more portions of the first frame body can form a cylindrical shape, a bulbous shape, and/or a frustoconical shape.

[0041] In some embodiments, a replacement heart valve prosthesis can include a valve body including three flexible leaflets. The flexible leaflets can be made from pericardium. The prosthesis can include a self-expanding, metallic support structure surrounding and supporting the valve body. The support structure can be sized for deployment in a native mitral valve.

[0042] The support structure can include a valve frame having an upper portion, an intermediate portion, and a lower portion. The support structure can include a plurality of anchors which can be coupled to the lower portion of the valve frame. Each of the anchors can extend radially outwardly and/or upwardly.

[0043] The support structure can include a sealing frame. The sealing frame can be coupled to and disposed radially outwardly of the valve frame. The sealing frame can have an upper portion, an intermediate portion and a lower portion. A clearance can be provided between the sealing frame and the valve frame. The plurality of anchors can have ends disposed radially outwardly of the sealing frame.

[0044] The upper portion of the sealing frame can be coupled to the upper portion of the valve frame. The upper portion of the sealing frame can be sutured to the upper portion of the valve frame. The sealing frame can be more flexible than the valve frame for conforming to a mitral valve annulus. The support structure can be adapted to capture native mitral valve leaflets between the sealing frame and the anchors.

[0045] The intermediate portion of the sealing frame can have a diameter in the range of about 35 mm to 55 mm. At least a portion of the sealing frame can be covered by fabric. The lower portion of the sealing frame can have a larger diameter than

the upper portion of the sealing frame. The intermediate portion of the sealing frame can have a larger diameter than the lower portion of the sealing frame.

[0046] The sealing frame can be convex. At least a portion of the sealing frame can be generally frustoconical. For example, the upper portion and/or lower portion of the sealing frame can be generally frustonical. At least a portion of the sealing frame can be generally cylindrical. For example, at least the intermediate portion of the sealing frame can be generally cylindrical.

[0047] The valve frame can be bulbous. The intermediate portion of the valve frame can have a diameter which is less than the diameter of the intermediate portion of the sealing frame. The diameter of the intermediate portion of the valve frame can be in the range of about 28mm to about 32mm.

[0048] The anchoring features can be axially and/or radially biased or compressible. Tips of the anchoring features can be formed from one or more wires. The wires can be looped to form a generally three-dimensional teardrop shape. The wires may be spiraled to form a generally three-dimensional conical shape. Tips of the anchoring features can have a serpentine shape. Tips of the anchoring features can be formed from one or more foreshortening cells.

BRIEF DESCRIPTION OF THE DRAWINGS

[0049] These and other features, aspects and advantages are described below with reference to the drawings, which are intended to illustrate embodiments of prostheses including embodiments of various components of these prostheses.

[0050] FIGURE 1 is a side-oriented cross-sectional schematic view of an embodiment of a prosthesis having an inner frame, an outer frame, a valve body, and a skirt.

[0051] FIGURE 2 is a top-oriented perspective view of another embodiment of a prosthesis having an inner frame, an outer frame, a valve body, and a skirt.

[0052] FIGURE 3 is a bottom-oriented perspective view of the prosthesis of FIGURE 2.

[0053] FIGURE 4 is a top view of the prosthesis of FIGURE 2

[0054] FIGURE 5 is a bottom view of the prosthesis of FIGURE 2.

[0055] FIGURE 6 is a bottom-oriented perspective view of the inner frame and valve body of FIGURE 2.

[0056] FIGURE 7 is a side view of a front-half of another embodiment of an outer frame.

[0057] FIGURE 8 is a top view of the outer frame of FIGURE 2.

[0058] FIGURE 9 is a side view of a front-half of another embodiment of an inner frame.

[0059] FIGURE 10 is a top view of the inner frame of FIGURE 2.

[0060] FIGURES 11A-11K are side-oriented schematic views of other embodiments of a prosthesis having an inner frame and an outer frame.

[0061] FIGURE 12 is a side-oriented schematic view of an embodiment of a prosthesis having a frame body, a mesh anchoring feature, and a valve body.

[0062] FIGURE 13 is a top view of the prosthesis of FIGURE 12.

[0063] FIGURE 14 is a bottom view of the prosthesis of FIGURE 12.

[0064] FIGURE 15 is a side-oriented cross-sectional schematic view of an embodiment of a prosthesis having a frame, a mesh anchoring feature, a valve body, and a skirt.

[0065] FIGURE 16 is a top-oriented perspective view of an embodiment of a prosthesis having a frame, a mesh anchoring feature, a valve body, and a skirt in a partially assembled state.

[0066] FIGURE 17 is an enlarged, side-oriented cross-sectional view of the prosthesis of FIGURE 16.

[0067] FIGURE 18 is a side view of the frame and mesh anchoring feature of FIGURE 16.

[0068] FIGURE 19 is a top-oriented perspective view of the frame of FIGURE 16.

[0069] FIGURE 20 is a side view of an embodiment of another embodiment of a prosthesis having a frame, a valve body, a braided seal, and a skirt in a partially assembled configuration.

[0070] FIGURE 21 is a side view of an embodiment of the prosthesis of FIGURE 20 in an assembled configuration.

[0071] FIGURE 22 is a top-oriented perspective view of another embodiment of the frame of FIGURE 21.

[0072] FIGURE 23 is a side view of an embodiment of a portion of a frame having a circumferentially curved anchoring feature.

[0073] FIGURE 24 is a side-oriented schematic view of the portion of the frame of FIGURE 23 positioned between chordae tendineae of a heart.

[0074] FIGURE 25 is a side view of another embodiment of a portion of a frame having a circumferentially curved anchoring feature.

[0075] FIGURE 26 is a flat, cutting pattern for another embodiment of a frame having a circumferentially curved anchoring feature.

[0076] FIGURE 27 is a side view of a portion of the frame of FIGURE 26 in an expanded configuration.

[0077] FIGURES 28-30 illustrate schematic representations of the prosthesis of Figure 1 positioned within a heart, with FIGURES 28A-B illustrating the prosthesis in situ with distal anchors contacting the ventricular side of a mitral valve annulus, FIGURE 29 illustrating the prosthesis in situ with distal anchors not contacting the ventricular side of the mitral valve annulus, and FIGURE 30 illustrating the prosthesis in situ with distal anchors not extending between the chordae tendineae.

[0078] FIGURE 31 is a cross-sectional view of a distal end of an embodiment of a delivery system loaded with an embodiment of a prosthesis.

[0079] FIGURE 32 is a cross-sectional view of a distal end of another embodiment of a delivery system loaded with another embodiment of a prosthesis.

[0080] FIGURE 33 is a side-oriented cross-sectional schematic view of another embodiment of a prosthesis having an inner frame, an outer frame, a valve body, and a skirt.

[0081] FIGURE 34 is a top-oriented perspective view of another embodiment of a prosthesis having an inner frame, an outer frame, a valve body, and a skirt.

[0082] FIGURE 35 is a bottom view of the prosthesis of FIGURE 34.

[0083] FIGURE 36 is a top-oriented perspective view of another embodiment of an inner frame.

[0084] FIGURE 37 is a top-oriented perspective view of another embodiment of an outer frame.

[0085] FIGURE 38A is a side-oriented cross-sectional schematic view of another embodiment of a prosthesis having an inner frame, an outer frame, a valve body, and a skirt.

[0086] FIGURE 38B is a side-oriented cross-sectional schematic view of the prosthesis of FIGURE 38A in a native mitral valve.

[0087] FIGURE 39 is a top-oriented perspective view of another embodiment of a prosthesis having an inner frame, an outer frame, a valve body, and a skirt.

[0088] FIGURE 40 is a top view of the prosthesis of FIGURE 39.

[0089] FIGURE 41 is a bottom-oriented perspective view of the prosthesis of FIGURE 39.

[0090] FIGURE 42 is a side view of a front-half of the inner frame of FIGURE 39.

[0091] FIGURE 43 is a top-oriented perspective view of another embodiment of an outer frame.

[0092] FIGURE 44 is a top-oriented perspective view of another embodiment of a prosthesis having an inner frame, an outer frame, a valve body, and a skirt.

[0093] FIGURE 45 is a bottom-oriented perspective view of another embodiment of a prosthesis having an inner frame, an outer frame, a valve body, and a skirt.

[0094] FIGURE 46 is a side-oriented cross-sectional schematic view of another embodiment of a prosthesis having an inner frame, an outer frame, a valve body, and a skirt.

[0095] FIGURE 47 is a side-oriented cross-sectional schematic view of the prosthesis of FIGURE 46 illustrating the commissure of a leaflet.

[0096] FIGURE 48 is a side-oriented schematic view of an embodiment of an anchoring feature.

[0097] FIGURE 49 is a side-oriented schematic view of another embodiment of an anchoring feature.

[0098] FIGURE 50 is a side-oriented schematic view of an embodiment of an anchoring feature.

[0099] FIGURE 51 is a side-oriented schematic view of another embodiment of an anchoring feature.

[0100] FIGURE 52 is a side-oriented schematic view of an embodiment of an anchoring feature.

[0101] FIGURE 53 is a side-oriented schematic view of another embodiment of an anchoring feature.

[0102] FIGURES 54A-57H illustrate schematic representations of delivery procedures utilizing embodiments of prostheses and delivery systems described herein.

[0103] FIGURES 58 and 59 illustrate schematic representations of embodiments of prostheses positioned within a heart.

DETAILED DESCRIPTION

[0104] The present specification and drawings provide aspects and features of the disclosure in the context of several embodiments of prostheses, replacement heart valves, and methods that are configured for use in the vasculature of a patient, such as for replacement of natural heart valves in a patient. These embodiments may be discussed in connection with replacing specific valves such as the patient's mitral valve. However, it is to be understood that the features and concepts discussed herein can be applied to replacing other types of valves including, but not limited to, the aortic valve, the pulmonary valve, and the tricuspid valve. Moreover, it is to be understood that the features and concepts discussed herein can be applied to products other than heart valve

implants. For example, the controlled positioning, deployment, and/or securing features described herein can be applied to medical implants, for example other types of expandable prostheses, for use elsewhere in the body, such as within a vein, or the like. In addition, particular features of a prosthesis should not be taken as limiting, and features of any one embodiment discussed herein can be combined with features of other embodiments as desired and when appropriate.

[0105] Certain terminology may be used in the following description for the purpose of reference only, and thus are not intended to be limiting. For example, terms such as "upper", "lower", "upward", "downward", "above", "below", "top", "bottom" and similar terms refer to directions in the drawings to which reference is made. Terms such as "proximal", "distal", "radially outward", "radially inward", "outer", "inner", and "side", describe the orientation and/or location of portions of the components or elements within a consistent but arbitrary frame of reference which is made clear by reference to the text and the associated drawings describing the components or elements under discussion. Such terminology may include the words specifically mentioned above, derivatives thereof, and words of similar import. Similarly, the terms "first", "second", and other such numerical terms referring to structures neither imply a sequence or order unless clearly indicated by the context.

[0106] In some embodiments, the term "proximal" may refer to the parts of the prostheses, or components thereof, which are located closer to the operator of the device and system (e.g., the clinician implanting the prosthesis). The term "distal" may refer to the parts of the prostheses, or components thereof, which are located further from the operator of the device and system (e.g., the clinician implanting the prosthesis). However, it is to be understood that this terminology may be reversed depending on the delivery technique utilized (e.g., a transapical approach as compared to a transseptal approach). In some situations, the prosthesis, or components thereof, may be oriented such that an upper end is a proximal portion and a lower end is a distal portion.

[0107] In some situations, the prosthesis, or components thereof, the upper end may be an inflow end and the lower end may be an outflow end. For example, a valve body used with the prosthesis can allow flow from the upper end to the lower end.

However, it is to be understood that the inflow end and the outflow end may be reversed. For example, the valve body used with the prosthesis can allow flow from the lower end to the upper end.

[0108] A longitudinal axis of the prosthesis, or components thereof, may be defined as the central axis that extends through the center of the prosthesis or component between the upper and lower ends of the prosthesis or component (e.g., the prosthesis, the outer frame, and/or the inner frame). The prostheses described herein may be replacement valves that can be designed to replace a damaged or diseased native heart valve such as a mitral valve, as discussed above. It should be understood that the prostheses are not limited to being a replacement valve.

[0109] As will be described in further detail below, the prostheses can include an inner frame and/or an outer frame. In some embodiments, the inner frame can be a valve frame designed to support a valve body. In some embodiments, the outer frame can be a sealing frame designed to form a seal about a periphery of the outer frame. For example, the outer frame can engage tissue of a body cavity about a periphery of the outer frame and form a seal with said tissue. In some embodiments described herein, the outer frame can be attached to the inner frame at one or more stationary couplings such that the outer frame is fixed to the inner frame at one or more locations. It is to be understood that the outer frame can be attached to the inner frame via one or more movable couplings such as, but not limited to, rails. This can beneficially allow the outer frame to be adjusted relative to the inner frame to better conform to the anatomy of a patient's body cavity.

[0110] The inner frame and/or outer frame may be described as having an upper region, an intermediate region, and a lower region. In some situations, such as those in which the prostheses are positioned within a native mitral valve, the upper region can be generally positioned supra-annularly (i.e., above the plane of the annulus), the intermediate region can be generally positioned intra-annularly (i.e., within the plane of the annulus), and the lower region can be positioned sub-annularly (i.e., below the plane of the annulus). However, it is to be understood that in some situations, the positioning of the inner frame and/or outer frame relative to the annulus can differ.

Moreover, it is to be understood that in some embodiments, the inner frame and/or outer frame can omit one or more of the upper region, the intermediate region, and/or the lower region.

[0111] While certain combinations of inner frames and outer frames are described herein, it is to be understood that the inner frames and outer frames can be interchanged. This can beneficially allow the prosthesis to be configured in a manner which better suits the native anatomy of the patient. Moreover, while the inner frames and outer frames can be attached prior to delivery into the patient, it is to be understood that the inner frames and outer frames can be delivered separately into the patient and subsequently attached in the patient's body. This can beneficially reduce the crimp profile when delivering the frames to the body cavity.The prostheses described herein can be used as a standalone device. For example, the prosthesis can be deployed at a native mitral valve and be sized and shaped appropriately to replace the function of the native mitral valve. However, it is to be understood that the prostheses described herein can be used with other devices. For example, one or more clips can be used to hold together native leaflets of a heart valve. This can advantageously allow a smaller prosthesis to be utilized at the native mitral valve.

Embodiments of Replacement Valves and Frames

[0112] With reference to **Figure 1**, an embodiment of a prosthesis **100** in an expanded configuration is illustrated. The prosthesis **100** can include an inner frame **120**, an outer frame **140**, a valve body **160**, and a skirt **180**. A longitudinal axis **102** of the prosthesis **100** may be defined as the central axis that extends through the center of the prosthesis **100** between the upper and lower ends of the prosthesis **100**. In some situations, the prosthesis **100** may be oriented such that an upper end of the prosthesis **100** is a proximal portion and a lower end of the prosthesis **100** is a distal portion. The illustrated prosthesis **100**, as well as other prostheses described herein, may include components which are self-expanding or balloon expandable. For example, in some embodiments, the inner frame **120** and/or outer frame **140** can be self-expanding. The prosthesis **100**, as well as other prostheses described herein, may be a replacement valve

that can be designed to replace a damaged or diseased native heart valve such as a mitral valve, as discussed above. It should be understood that the prosthesis **100**, as well as other prostheses described herein, are not limited to being a replacement valve.

[0113] With reference first to the inner frame **120** illustrated in **Figure 1**, the inner frame **120** can provide a structure to which various components of the prosthesis **100** can be attached. The inner frame **120** can include an inner frame body **122** and an inner frame anchoring feature **124**. The inner frame body **122** can have an upper region **126**, an intermediate region **128**, and a lower region **130**. As shown, the inner frame body **122** can have a generally cylindrical shape such that the diameters of the upper region **126**, the intermediate region **128**, and the lower region **130** are generally equivalent. However, it is to be understood that the diameters of the upper region **126**, the intermediate region **128**, and/or the lower region **130** can be different. For example, in some embodiments, a diameter of the intermediate region **128** can be larger than the upper region **126** and the lower region **130** such that the frame body **122** has a generally bulbous shape. In some embodiments, the diameter of the lower region **130** can be larger than the diameter of the upper region **126**. In other embodiments, the diameter of the upper region **126** can be larger than the diameter of the lower region **130**. Moreover, although the inner frame body **122** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the inner frame body **122** can have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0114] In some situations, such as those in which the prosthesis **100** is positioned within a native mitral valve, the upper region **126** can be generally positioned supra-annularly (i.e., above the plane of the annulus), the intermediate region **128** can be generally positioned intra-annularly (i.e., within the plane of the annulus), and the lower region **130** can be positioned sub-annularly (i.e., below the plane of the annulus). However, it is to be understood that in some situations, the positioning of the inner frame **120** relative to the annulus can differ. Moreover, it is to be understood that in some embodiments, the inner frame **120** can omit one or more of the upper region **126**, the intermediate region **128**, and/or the lower region **130**.

[0115] As shown in the illustrated embodiment, the inner frame anchoring feature **124** can extend generally downwardly and/or radially outwardly at or proximate a lower end of the lower region **130** of the inner frame body **122**. The inner frame anchoring feature **124** can extend upwardly towards an end of the inner frame anchoring feature **124**. As will be discussed in further detail below, components of the inner frame **120**, such as the inner frame anchoring feature **124**, can be used to attach or secure the prosthesis **100** to a native valve. For example, in some situations, the inner frame anchoring feature **124** can be used to attach or secure the prosthesis **100** to a native mitral valve. In such an embodiment, the inner frame anchoring feature **124** can be positioned to contact or engage a native mitral valve annulus on a ventricular side, tissue beyond the native valve annulus on a ventricular side, native leaflets on a ventricular side, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. When positioned within the native mitral valve, the inner frame anchoring feature **124** can beneficially eliminate, inhibit, or limit upward movement of the prosthesis **100** when subject to upwardly directed forces such as those which are applied on the prosthesis **100** during systole.

[0116] The inner frame **120** can be formed from many different materials including, but not limited to a shape-memory metal such as Nitinol. The inner frame **120** can be formed from a plurality of struts forming open cells. In some embodiments, the inner frame **120** can have a relatively rigid construction as compared to other components of the prosthesis **100** including, but not limited to, the outer frame **140**. This can be achieved, for example, by the dimensions of the struts and by the configuration of the struts. The relatively rigid construction can more strongly resist deformation when subject to stress. This can be beneficial during certain portions of the cardiac cycle, such as systole, during which the inner frame **120** may be subject to significant stresses on the inner frame anchoring feature **124**. The relatively rigid construction can also be beneficial when a valve body **160** is positioned within the inner frame **120** to maintain the shape of the valve body **160**. Moreover, the relatively rigid construction can be beneficial when the inner frame **120** is used for a valve-in-valve procedure wherein a supplemental prosthesis is positioned within the inner frame **120**. However, although the

inner frame **120** has been described as having a relatively rigid construction, it is to be understood that in some embodiments the inner frame **120** can have a construction relatively flexible construction. For example, the inner frame **120** can have a constructions which is about as flexible as, or more flexible than, other components of the prosthesis **100**, such as the outer frame **140**.

[0117] The inner frame **120** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other frames described herein such as, but not limited to, frames **220**, **400**, **520a-k**, **620**, **720**, **820**, **920**, **1000**, **1100**, **1202**, **1520**, **1620**, **1700**, **1920**, **2020**, **2220**, **2320**, **2420**, **2910**, **3010**, **3110**, **3210** discussed below. The inner frame **120**, and any other frame described herein, may include features and concepts similar to those disclosed in U.S. Patent Nos. 8,403,983, 8,414,644, and 8,652,203, U.S. Publication Nos. 2011/0313515, 2014/0277390, 2014/0277427, 2014/0277422, and 2015/0328000, and U.S. Application No. 15/653,390, entitled REPLACEMENT HEART VALVE PROSTHESIS, filed on July 18, 2017, the entireties of each of which are hereby incorporated by reference and made a part of this specification. This is inclusive of the entire disclosure and is not in any way limited to the disclosure of the associated frames. Moreover, although the inner frame **120** has been described as including an inner frame body **122** and an inner frame anchoring feature **124**, it is to be understood that the inner frame **120** need not include all components. For example, in some embodiments, the inner frame **120** can include the inner frame body **122** while omitting the inner frame anchoring feature **124**. Moreover, although the inner frame body **122** and the inner frame anchoring feature **124** have been illustrated as being unitarily or monolithically formed, it is to be understood that in some embodiments the inner frame body **122** and the inner frame anchoring feature **124** can be formed separately. In such embodiments, the separate components can be attached using any of the fasteners and/or techniques described herein. For example, the inner frame anchoring feature **124** can be formed separately from the inner frame body **122** and can be attached to the inner frame body **122**.

[0118] With reference next to the outer frame **140** illustrated in **Figure 1**, the outer frame **140** can provide a structure to which various components of the prosthesis

100 can be attached. The outer frame **140** can be attached to the inner frame **120** using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots which can be on the inner frame **120** and the outer frame **140**), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques. The inner frame **120** and the outer frame **140** can be indirectly attached via an intermediate component, such as the skirt **180**.

[0119] The outer frame **140** can be attached to the inner frame **120** at one or more attachment points. As will be described in further detail, the outer frame **140** can be tautly attached to the inner frame **120** such that little to no relative movement between the outer frame **140** and the inner frame **120** occurs at the one or more attachment points. In other embodiments, the outer frame **140** can be loosely attached to the inner frame **120** such that some relative movement between the outer frame **140** and the inner frame **120** can occur at the one or more attachment points. Although the outer frame **140** is illustrated as a separate component from the inner frame **120**, it is to be understood that the frames **120**, **140** can be unitarily or monolithically formed.

[0120] As shown in the illustrated embodiment, the outer frame **140** can include an outer frame body **142** and an outer frame anchoring feature **144**. The outer frame body **142** can have an upper region **146**, an intermediate region **148**, and a lower region **150**. In some situations, such as those in which the prosthesis **100** is positioned within a native mitral valve, the upper region **146** can be generally positioned supra-annularly, the intermediate region **148** can be generally positioned intra-annularly, and the lower region **150** can be positioned sub-annularly. However, it is to be understood that in some situations, the positioning of the outer frame **140** relative to the annulus can differ. Moreover, it is to be understood that in some embodiments, the outer frame **140** can omit one or more of the upper region **146**, the intermediate region **148**, and/or the lower region **150**.

[0121] When in an expanded configuration such as a fully expanded configuration, the outer frame body **142** can have an enlarged shape with the intermediate region **148** and the lower region **150** being larger than the upper region **146**. The enlarged shape of the outer frame body **142** can advantageously allow the outer frame body **142** to engage a native valve annulus, native valve leaflets, or other tissue of the body cavity, while spacing the upper end from the heart or vessel wall. This can help reduce undesired contact between the prosthesis **100** and the heart or vessel, such as the atrial and ventricular walls of the heart.

[0122] The upper region **146** of the outer frame body **122** can include a generally longitudinally-extending section **146a** and an outwardly-extending section **146b**. The longitudinally-extending section **146a** can be generally concentric with the inner frame body **122**. The outwardly-extending section **146b** can extend radially outwardly away from the longitudinal axis **102** of the prosthesis **100**. The outwardly-extending section **146b** can extend in a direction that is more perpendicular to the longitudinal axis **102** than parallel and/or in a downward direction from the longitudinally-extending section **146a**. However, it is to be understood that the outwardly-extending section **146b** can extend generally perpendicularly to the longitudinal axis **102** and/or in an upward direction from the longitudinally-extending section **146a**. Moreover, it is to be understood that the longitudinally-extending section **146a** can be omitted such that the upper region **146** extends radially outwardly at the upper end of the upper region **146**.

[0123] The intermediate region **148** of the outer frame body **142** can extend generally downwardly from the outwardly-extending section **146b** of the upper region **146**. As shown, the intermediate region **148** can have a generally constant diameter from an upper end of the intermediate region **148** to a lower end of the intermediate region **148** such that the intermediate region **148** forms a generally cylindrical shape. However, it is to be understood that the diameters of the upper end, the lower end, and/or the portion therebetween can be different. For example, a diameter of the portion between the upper end and the lower end can be larger than the upper end and the lower end such that the intermediate region **148** has a generally bulbous shape. In some embodiments, the

diameter of the lower end can be larger than the diameter of the upper end. In other embodiments, the diameter of the upper end can be larger than the diameter of the lower end.

[0124] The lower region **150** of the outer frame body **142** can extend generally downwardly from the lower end of the intermediate region **148**. As shown, the lower region **150** of the outer frame body **142** can have a generally constant diameter from an upper end of the lower region **150** to a lower end of the lower region **150** such that the lower region **150** forms a generally cylindrical shape. However, it is to be understood that the diameters of the upper end, the lower end, and/or the portion therebetween can be different. For example, in some embodiments, the diameter of the upper end of the lower region **150** can be greater than the diameter of the lower end of the lower region **150** such that the lower region **150** extends radially inwardly towards the longitudinal axis **102** of the prosthesis **100**. In some embodiments, the diameter of the lower end can be larger than the diameter of the upper end.

[0125] As shown, the diameters of the intermediate region **148** and the lower region **150** are generally equivalent such that the intermediate region **148** and the lower region **150** together form a generally cylindrical shape. However, it is to be understood that the diameters of the intermediate region **148** and the lower region **150** can be different. For example, the diameter of the lower region **150** can be less than the diameter of the intermediate region **148**. Moreover, although the outer frame body **142** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the outer frame body **142** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0126] With continued reference to the outer frame **140** illustrated in **Figure 1**, the outer frame anchoring feature **144** can extend outwardly relative to the longitudinal axis **102** of the prosthesis **100**. The outer frame anchoring feature **144** can extend at or proximate the juncture between the upper region **146** and the intermediate region **148** of the outer frame body **142**. The outer frame anchoring feature **144** can extend in a direction that is more perpendicular to the longitudinal axis **102** than parallel and/or can

extend in a downward direction from the longitudinally-extending section **146a**. As shown, the outer frame anchoring feature **144** can extend in a direction generally aligned with the outwardly-extending section **146b** of the upper region **146**. However, it is to be understood that the outer frame anchoring feature **144** can extend generally perpendicularly to the longitudinal axis **102** and/or in an upward direction.

[0127] As will be discussed in further detail below, components of the outer frame **140**, such as the outer frame body **142** can be used to attach or secure the prosthesis **100** to a native valve, such as a native mitral valve. For example, the intermediate region **148** of the outer frame body **142** and/or the outer anchoring feature **144** can be positioned to contact or engage a native valve annulus, tissue beyond the native valve annulus, native leaflets, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. In situations where the outer frame body **142** is positioned within a native mitral valve, the outer frame body **142** can beneficially eliminate, inhibit, or limit downwardly directed forces such as those which are applied on the prosthesis **100** during diastole and/or upwardly directed forces such as those which are applied on the prosthesis **100** during systole. As another example, the outer frame body **142** can be sized and positioned relative to the inner frame anchoring feature **124** such that tissue of the body cavity positioned between the outer frame body **142** and the inner frame anchoring feature **124**, such as native valve leaflets and/or a native valve annulus, can be engaged or pinched to further secure the prosthesis **100** to the tissue. For example, the lower region **150** of the outer frame body **142** can be positioned at or proximate a tip or end of the inner frame anchoring feature **124**. As shown, the lower region **150** of the outer frame body **142** is positioned such that at least a portion is positioned radially inward of and below the inner frame anchoring feature **124**. In some embodiments, a portion of the outer frame **140**, such as the lower region **150**, can be attached to the inner frame body **122** via one or more tethers or sutures (as shown in **Figure 45**) to limit the outward extension of the outer frame **140** relative to the inner frame body **122**. This can beneficially maintain a portion of the outer frame **140** between the inner frame body **122** and the inner frame anchoring feature **124**. Although the inner frame anchoring feature

124 is shown extending from the inner frame body **122**, it is to be understood that such an anchoring feature can extend from the outer frame body **140**.

[0128] Use of an inner frame **120** and an outer frame **140** can be beneficial for the design of the prosthesis in that the inner frame **120** can be designed to suit the structure of the valve body **160** and the outer frame **140** can be designed to suit the anatomy of the body cavity in which the prosthesis **100** is to be used. For example, the valve body **160** can be cylindrical and have a smaller diameter than the body cavity. In such an embodiment, the inner frame **120** can advantageously have a smaller shape and/or size to support the valve body **160** while the outer frame **140** can have a larger shape and/or size to secure the prosthesis **100** to the body cavity. Moreover, in embodiments in which the outer frame **140** is larger than the inner frame **120**, the shape of the outer frame **140** can beneficially enhance hemodynamic performance. For example, the shape of the outer frame **140** with a larger, generally cylindrical intermediate region **148** can allow for significant washout on an underside of the valve body **160**. This washout can beneficially reduce the risk of thrombosis or clot formation under and around the valve body **160**.

[0129] The outer frame **140** can be formed from many different materials including, but not limited to, a shape-memory metal such as Nitinol. The outer frame **140** can be formed from a plurality of struts forming open cells. In some embodiments, the outer frame **140** can have a more flexible construction as compared to other components of the prosthesis **100** such as, but not limited to, the inner frame **120**. This can be achieved, for example, by the dimensions of the struts and by the configuration of the struts. For example, fewer struts, thinner struts, and/or a different material for the struts can be used. The more flexible construction can allow the outer frame **140** to better conform to the anatomy of the body cavity, such a native valve annulus and/or native leaflets. This can be beneficial for anchoring against the body cavity and/or forming a seal against the body cavity. However, it is to be understood that in some embodiments the outer frame **140** can have a construction which is about as rigid as, or more rigid than, other components of the prosthesis **100**, such as the inner frame **120**.

[0130] The outer frame **140** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other frames described herein such as, but not limited to, frames **240, 300**, **540a-k**, **560h**, **1204**, **1540**, **1640**, **1800**, **1940**, **2040**, **2100**, **2240**, **2340**, **2440**, **2920**, **3020**, **3120**, **3220** discussed below. The outer frame **140**, and any other frame described herein, may include features and concepts similar to those disclosed in U.S. Patent Nos. 8,403,983, 8,414,644, and 8,652,203, U.S. Publication Nos. 2011/0313515, 2014/0277390, 2014/0277427, 2014/0277422, and 2015/0328000, and U.S. Application No. 15/653,390, entitled REPLACEMENT HEART VALVE PROSTHESIS, filed on July 18, 2017, the entireties of each of which have been incorporated by reference. Moreover, although the outer frame **140** has been described as including an outer frame body **142** and an outer frame anchoring feature **144**, it is to be understood that the outer frame **140** need not include all components. For example, in some embodiments, the outer frame **140** can include the outer frame body **142** while omitting the outer frame anchoring feature **144**. Moreover, although the outer frame body **142** and the outer frame anchoring feature **144** have been illustrated as being unitarily or monolithically formed, it is to be understood that in some embodiments the outer frame body **142** and the outer frame anchoring feature **144** can be formed separately. In such embodiments, the separate components can be attached using any of the fasteners and techniques described herein. For example, the outer frame anchoring feature **144** can be formed separately from the outer frame body **142** and can be attached to the outer frame body **142**.

[0131] With reference next to the valve body **160** illustrated in **Figure 1**, the valve body **160** can be attached to the inner frame **120** within an interior of the inner frame **120**. The valve body **160** can function as a one-way valve to allow blood flow in a first direction through the valve body **160** and inhibit blood flow in a second direction through the valve body **160**. For example, in situations where the upper end of the prosthesis **100** is a proximal end and the lower end of the prosthesis **100** is a distal end, the valve body **160** can allow blood flow in a proximal-to-distal direction and inhibit blood flow in a distal-to-proximal direction. The valve body **160** can include a plurality of valve leaflets **162**, for example three leaflets **162**, which are joined at commissures.

The leaflets **162** can be formed from biocompatible materials including, but not limited to, pericardium and/or synthetic materials.

[0132] The valve body **160** can include a liner **164**. The liner **164** can be used to assist with fluid flow through and/or around the prosthesis **100**, such as through and around the inner frame **120** and the valve leaflets **162**. The liner **164** can surround at least a portion of the valve leaflets **162** and be connected to one or more of the valve leaflets **162**. For example, as shown in the illustrated embodiment, the one or more valve leaflets **162** can be attached to the liner **164** along an arcuate or fixed edge of the valve leaflets **162**. The liner **164** can extend from the arcuate or fixed edge of the leaflet **162** and extend upwardly towards an upper end of the inner frame **120**.

[0133] The valve body **160** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other valve bodies described herein such as, but not limited to, valve bodies **260**, **660**, **760**, **870**, **970**, **1560**, **1660**, **1960**, **2060**, **2260**, **2360**, **2460**, discussed below. Moreover, although the valve body **160** has been described as including a plurality of leaflets **162** and a liner **164**, it is to be understood that the valve body **160** need not include all features. For example, in some embodiments, the valve body **160** can include the plurality of valve leaflets **162** while omitting the liner **164**. It is to be understood that other types of valves can be utilized in conjunction with, or in lieu of, the valve body **160**. For example, the valve can be a mechanical valve such as a ball and cage.

[0134] With continued next to the skirt **180** illustrated in **Figure 1**, the skirt **180** can be attached to the inner frame **120** and/or outer frame **140**. As shown, the skirt **180** can be positioned around and secured to a portion of, or the entirety of, the exterior of the inner frame **120** and/or outer frame **140.** The skirt **180** can also be secured to a portion of the valve body **160**. The skirt **180** can follow the contours of the outer frame **140**, such as the contours of the upper region **146**, the intermediate region **148**, and/or the lower region **150**. In some embodiments, the skirt **180** can be used to attach the outer frame **140** to the inner frame **120**. Although not shown, it is to be understood that the skirt **180** can be positioned around and secured to a portion of, or the entirety of, an interior of the inner frame **120** and/or the outer frame **140**. Moreover, it is to be

understood that while the skirt **180** can follow the contours of portions of the inner frame **120** and the outer frame **140**, at least a portion of the skirt **180** can be spaced apart from at least a portion of both the inner frame **120** and the outer frame **140**. In some embodiments, the skirt **180** can be spaced apart from the upper region **146** of the outer frame **140**. For example, the skirt **180** can be positioned below the upper region **146**. In such an embodiment, the spaced-apart portion of the skirt **180** can be loose such that the skirt **180** is movable relative to the upper region **146** or can be taut such that the skirt **180** is generally fixed in position.

[0135] The skirt **180** can be annular and can extend entirely circumferentially around the inner frame **120** and/or outer frame **140**. The skirt **180** can prevent or inhibit backflow of fluids, such as blood, around the prosthesis **100**. For example, with the skirt **180** positioned annularly around an exterior of the inner frame **120** and/or outer frame **140**, the skirt **180** can create an axial barrier to fluid flow exterior to the inner frame **120** and/or outer frame **140** when deployed within a body cavity such as a native valve annulus. The skirt **180** can encourage tissue in-growth between the skirt **180** and the natural tissue of the body cavity. This may further help to prevent leakage of blood flow around the prosthesis **100** and can provide further securement of the prosthesis **100** to the body cavity. In some embodiments, the skirt **180** can be tautly attached to the inner frame **120** and/or outer frame **140** such that the skirt **180** is generally not movable relative to the inner frame **120** and/or outer frame **140**. In some embodiments, the skirt **180** can be loosely attached to the inner frame **120** and/or outer frame **140** such that the skirt **180** is movable relative to the inner frame **120** and/or outer frame **140**.

[0136] The skirt **180** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other skirts described herein such as, but not limited to, skirts **280**, **780**, **890**, **990**, **1580**, **1590**, **1680**, **1690**, **1980**, **1990**, **2080**, **2280**, **2380**, **2480**, **2490**, discussed below.

[0137] Although the prosthesis **100** has been described as including an inner frame **120**, an outer frame **140**, a valve body **160**, and a skirt **180**, it is to be understood that the prosthesis **100** need not include all components. For example, in some embodiments, the prosthesis **100** can include the inner frame **120**, the outer frame **140**,

and the valve body **160** while omitting the skirt **180**. Moreover, although the components of the prosthesis **100** have been described and illustrated as separate components, it is to be understood that one or more components of the prosthesis **100** can be integrally or monolithically formed. For example, in some embodiments, the inner frame **120** and the outer frame **140** can be integrally or monolithically formed as a single component.

[0138] With reference next to **Figures 2-6**, an embodiment of a prosthesis **200** in an expanded configuration, or components of the prosthesis **200**, are illustrated. The prosthesis **200** can include an inner frame **220**, an outer frame **240**, a valve body **260**, and a skirt **280**. A longitudinal axis of the prosthesis **200** may be defined as the central axis that extends through the center of the prosthesis **200** between the upper and lower ends of the prosthesis **200**. In some situations, the prosthesis **200** may be oriented such that an upper end of the prosthesis **200** is a proximal portion and a lower end of the prosthesis **200** is a distal portion.

[0139] With reference first to the outer frame **240** illustrated in **Figures 2-5**, the outer frame **240** can include an outer frame body **242** and an outer frame anchoring feature **244**. The outer frame **240** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of outer frame **140** described above in connection with **Figure 1**.

[0140] The outer frame body **242** can have an upper region **246**, an intermediate region **248**, and a lower region **250**. As shown, when in an expanded configuration such as the fully expanded configuration, the outer frame body **242** can have an enlarged shape with an intermediate region **248** and a lower region **250** being larger than the upper region **246**. The enlarged shape of the outer frame body **242** can advantageously allow the outer frame body **242** to engage a native valve annulus, native valve leaflets, or other body cavity, while spacing the inlet and outlet from the heart or vessel wall. This can help reduce undesired contact between the prosthesis **200** and the heart or vessel, such as the atrial and ventricular walls of the heart.

[0141] The upper region **246** of the outer frame body **242** can include a generally longitudinally-extending section **246a** and an outwardly-extending section

246b. The longitudinally-extending section **246a** can be generally concentric with the inner frame **220**. The outwardly-extending section **246b** can extend radially outwardly away from the longitudinal axis of the prosthesis **200**. In some embodiments, the outwardly-extending section **246b** can extend in a direction that is more perpendicular to the longitudinal axis **202** than parallel and/or can extend in a downward direction from the longitudinally-extending section **246a**. However, it is to be understood that the outwardly-extending section **246b** can extend generally perpendicularly to the longitudinal axis and/or in an upward direction from the longitudinally-extending section **246a**. Moreover, it is to be understood that the longitudinally-extending section **246a** can be omitted.

[0142] In some embodiments, the outwardly-extending section **246b** can form an angle of between about 20 degrees to about 70 degrees with a plane orthogonal to the longitudinal axis of the prosthesis **200**, an angle of between about 30 degrees to about 60 degrees with a plane orthogonal to the longitudinal axis of the prosthesis **200**, an angle of between about 40 degrees to about 50 degrees with a plane orthogonal to the longitudinal axis of the prosthesis **200**, an angle of about 45 degrees with a plane orthogonal to the longitudinal axis of the prosthesis **200**, any subrange within these ranges, or any other angle as desired. In some embodiments, the outwardly-extending section **246b** can form an angle of less than 70 degrees with a plane orthogonal to the longitudinal axis of the prosthesis **200**, an angle of less than 55 degrees with a plane orthogonal to the longitudinal axis of the prosthesis **200**, an angle of less than 40 degrees with a plane orthogonal to the longitudinal axis of the prosthesis **200**, an angle of less than 25 degrees with a plane orthogonal to the longitudinal axis of the prosthesis **200**, or less than any other angle as desired

[0143] The intermediate region **248** of the outer frame body **242** can extend generally downwardly from the outwardly-extending section **246b** of the upper region **246**. As shown, the intermediate region **248** can have a generally constant diameter from an upper end of the intermediate region **248** to a lower end of the intermediate region **248** such that the intermediate region **248** forms a generally cylindrical shape. However, it is to be understood that the diameters of the upper end, the lower end, and/or the portion

therebetween can be different. For example, in some embodiments, a diameter of the portion between the upper and lower ends can be larger than diameters of the upper and lower ends such that the intermediate region **248** has a generally bulbous shape (as shown, for example, in connection with frame **300** illustrated in **Figures 7-8**). In some embodiments, the diameter of the lower end can be larger than the diameter of the upper end. In other embodiments, the diameter of the upper end can be larger than the diameter of the lower end.

[0144] The general uniformity of the diameter of the intermediate region **248** from the upper end to the lower end, in conjunction with the axial dimension between the upper end and the lower end (i.e., the "height" of the intermediate region **248**), provides for a significantly large circumferential area upon which a native valve annulus, or other body cavity, can be engaged. This can beneficially improve securement of the outer frame **240** to the native valve annulus or other body cavity. This can also improve sealing between the outer frame **240** and the native valve annulus, or other body cavity, thereby reducing paravalvular leakage.

[0145] At the juncture between the upper region **246** and the intermediate region **248**, the outer frame body **242** can include a bend **252**. The bend **252** can be a bend about a circumferential axis such that the intermediate region **248** extends in a direction more parallel to the longitudinal axis of the prosthesis **200** than the outwardly-extending section **246b** of the upper region **246**. In some embodiments, the bend **252** can generally form an arc with an angle between about 20 degrees to about 90 degrees. For example, as shown in the illustrated embodiment, the arc can have an angle of about 45 degrees. In some embodiments, the bend **252** can form an arc with an angle between about 30 degrees to about 60 degrees. The radius of curvature of the arc may be constant such that the bend **252** forms a circular arc or may differ along the length of the bend **252**.

[0146] The lower region **250** of the outer frame body **242** can extend generally downwardly from the lower end of the intermediate region **248**. As shown, the lower region **250** of the outer frame body **242** can have a generally constant diameter from an upper end of the lower region **250** to a lower end of the lower region **250** such

that the lower region **250** forms a generally cylindrical shape. However, it is to be understood that the diameters of the upper end, the lower end, and/or the portion therebetween can be different. For example, in some embodiments, the diameter of the upper end of the lower region **250** can be greater than the diameter of the lower end of the lower region **250** such that the lower region **250** extends radially inwardly towards the longitudinal axis of the prosthesis **200**. In some embodiments, the diameter of the lower end can be larger than the diameter of the upper end.

[0147] As shown, the diameters of the intermediate region **248** and the lower region **250** are generally equivalent such that the intermediate region **248** and the lower region **250** together form a generally cylindrical shape. However, it is to be understood that the diameters of the intermediate region **248** and the lower region **250** can be different. For example, the diameter of the lower region **250** can be less than the diameter of the intermediate region **248**. Moreover, although the outer frame body **242** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the outer frame body **242** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0148] The outer frame body **242** in an expanded configuration can have a diameter at its widest portion of between about 30mm to about 60mm, between about 35mm to about 55mm, about 40mm, any sub-range within these ranges, or any other diameter as desired. The outer frame body **242** in an expanded configuration can have a diameter at its narrowest portion between about 20mm to about 40mm, any sub-range within these ranges, or any other diameter as desired. In some embodiments, in an expanded configuration, the ratio of the diameter of the outer frame body **242** at its widest portion to the diameter of the frame body **242** at its narrowest portion can be about 3:1, about 5:2, about 2:1, about 3:2, about 4:3, any ratio within these ratios, or any other ratio as desired.

[0149] The outer frame body **242** can have an axially compact configuration relative to the radial dimension. The outer frame body **242** in an expanded configuration can have an the axial dimension between the upper and lower ends of the outer frame

body **242** (i.e., the "height" of the outer frame body **242**) of between about 10mm to about 40mm, between about 18mm to about 30mm, about 20mm, any sub-range within these ranges, or any other height as desired. In some embodiments, the ratio of the diameter of the largest portion of the outer frame body **242** to the height of the outer frame body **242** when the frame is in its expanded configuration can be about 3:1, about 5:2, about 2:1, about 3:2, about 4:3, about 13:10, about 5:4, or about 1:1. Thus, in some embodiments the width at the largest portion of the outer frame body **242** can be greater than the height of the outer frame body **242**.

[0150] With continued reference to the outer frame **240** illustrated in **Figures 2-5**, the outer frame body **242** can include a plurality of struts with at least some of the struts forming cells **254a-c**. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes. For reference, the struts in **Figure 2** have been highlighted to show the general configuration of these struts; however, it is to be understood that one or more of the struts may not actually be seen. For example, the skirt **280** can be formed from a non-transparent material and be positioned over the exterior of the outer frame body **242**.

[0151] The upper row of cells **254a** can have an irregular octagonal shape such as a "heart" shape. The cell **254a** can be formed via a combination of struts. As shown in the illustrated embodiment, the upper portion of cells **254a** can be formed from a set of circumferentially-expansible struts **256a** having a zig-zag or undulating shape forming a repeating "V" shape. The circumferentially-expansible struts **256a** can be inclined or curved radially outwardly away from the longitudinal axis of the prosthesis **200** such that an upper portion of the struts **256a** are positioned closer to the longitudinal axis of the prosthesis **200** than the lower portion of the struts **256a**. The middle portion of cells **254a** can be formed from a set of struts **256b** extending downwardly from bottom ends of each of the "V" shapes. The struts **256b** can extend along with a plane parallel to and/or extending through the longitudinal axis of the prosthesis **200**. The portion of the cells **254a** extending upwardly from the bottom end of struts **256b** may be considered to be a substantially non-foreshortening portion of the outer frame **240**. As

will be discussed in further detail below, foreshortening refers to the ability of the frame to longitudinally shorten as the frame radially expands.

[0152] The lower portion of cells **254a** can be formed from a set of circumferentially-expansible struts **256c** having a zig-zag or undulating shape forming a repeating "V" shape. The lower tips or ends of the circumferentially-expansible struts **256c** can be at or proximate the junction of the upper region **246** and the intermediate region **248**. In some embodiments, one or more of the upper ends or tips of the circumferentially-expansible struts **256c** can be a "free" apex which is not connected to a strut. As shown in the illustrated embodiment, every other upper end or tip of circumferentially-expansible struts **256c** is a free apex. However, it is to be understood that other configurations can be used. For example, every upper apex along the upper end can be connected to a strut.

[0153] As shown in the illustrated embodiment, the middle and/or lower rows of cells **254b-c** can have a different shape from the cells **254a** of the first row. The middle row of cells **254b** can have a diamond or generally diamond shape. The cells **254b-c** may be considered to be a substantially foreshortening portion of the outer frame **240**. The diamond or generally diamond shape can be formed via a combination of struts. The upper portion of cells **254b** can be formed from the set of circumferentially-expansible struts **256c** such that cells **254b** share struts with cells **254a**. The lower portion of cells **254b** can be formed from a set of circumferentially-expansible struts **256d**. As shown in the illustrated embodiment, one or more of the circumferentially-expansible struts **256d** can extend generally in a downward direction. The one or more circumferentially-expansible struts **256d** can incorporate the bend **252** such that an upper portion of the struts **256d** can be positioned closer to the longitudinal axis of the prosthesis **200** than the lower portion of the struts **256d** are to the longitudinal axis of the prosthesis **200**. In some embodiments, one or more of the circumferentially-expansible struts **256d** can extend radially outwardly away from the longitudinal axis of the prosthesis **200**. As will be discussed in further detail below, these radially outward portions of struts **256d** can form part of the outer frame anchoring feature **244**.

[0154] The lower row of cells **254c** can have an irregular octagonal shape. The upper portion of cells **254c** can be formed from the set of circumferentially-expansible struts **256d** such that cells **254c** share struts with cells **254b**. The lower portion of cells **254c** can be formed from a set of circumferentially-expansible struts **256e**. Circumferentially-expansible struts **256e** can extend generally in a downward direction. In some embodiments, the circumferentially-expansible struts **256e** can extend radially inwardly towards the longitudinal axis of the prosthesis **200** (as shown, for example, in connection with frame **300** illustrated in **Figures 7-8**). The circumferentially-expansible struts **256e** can be inclined or curved towards the longitudinal axis of the prosthesis **200**.

[0155] While the struts **256a-e** are generally described and illustrated as being straight segments, it is to be understood that some or all of the struts **256a-e** may not form entirely straight segments. For example, the struts **256a-e** can include some curvature such that the upper and/or lower apices are curved.

[0156] As shown in the illustrated embodiment, there can be a row of twelve cells **254a**, a row of twenty-four cells **254b**, and a row of twelve cells **254c**. While each of the cells **254a-c** are shown as having the same shape as other cells **254a-c** of the same row, it is to be understood that the shapes of cells **254a-c** within a row can differ. Moreover, it is to be understood that any number of rows of cells can be used and any number of cells may be contained in the rows. In some embodiments, the number of cells can correspond to the number of anchors or anchor tips forming the outer frame anchoring feature **244**. As shown, the number of cells in the upper row of cells **254a** and the lower row of cells **254c** can have a 1:1 correspondence with the number of anchors in the outer frame anchoring feature **244** (i.e., twelve cells in each row of cells **254a**, **254c** and twelve anchors for the anchoring features **244**). The number of cells in the middle row of cells **254b** can have a 2:1 correspondence with the number of anchors in the outer frame anchoring feature **244** (i.e., twenty-four cells in cells **254b** and twelve anchors for the anchoring features **244**). It is to be understood that other ratios of numbers of cells per row to number of anchors per anchoring feature can be used such as, but not limited to, 3:1, 4:1, 5:1, 6:1, and other ratios as desired. In some embodiments, all three rows of

cells **254a-c** can have the same the number of cells. Moreover, it is to be understood that fewer or greater numbers of rows of cells can be used.

[0157] The geometry of cells **254a-c** can allow the cells **254a-c** to foreshorten as the outer frame **240** is expanded. As such, one or more of cells **254a-c** can allow the outer frame **240** to foreshorten as the outer frame **240** is expanded. Foreshortening of the outer frame **240** can be used to secure the prosthesis to intralumenal tissue in a body cavity such as tissue at or adjacent a native valve including, but not limited to, a native valve annulus and/or leaflets. For example, expansion of the outer frame **240** can allow the outer frame **240** to exert a radially outward force against the tissue at or adjacent the native valve, such as the native valve annulus and/or leaflets.

[0158] With continued reference to the outer frame **240** illustrated in **Figures 2-5**, the outer frame anchoring feature **244** can extend outwardly relative to the longitudinal axis of the prosthesis **200**. The outer frame anchoring feature **244** can extend at or proximate the juncture between the upper region **246** and the intermediate region **248** of the outer frame body **242**. As shown, the outer frame anchoring feature **244** can be formed from one or more anchors extending from the frame body **242** in a direction radially outward from a longitudinal axis of the outer frame **240** and/or in a direction generally toward a lower end of the outer frame **240**. The anchors of the outer frame anchoring feature **244** can be attached to the outer frame body **242** at one or more attachment points. For example, the anchors of the outer frame anchoring feature **244** can be formed from two struts of circumferentially-expansible struts **256d** which are oriented radially outwardly and jointed together at a tip or end **244a**. The individual anchors can form a generally "V" shape.

[0159] In some embodiments, the outer frame anchoring feature **244** can extend in a direction that is more perpendicular to the longitudinal axis of the prosthesis **200** than parallel. As shown, the outer frame anchoring feature **244** can extend in a downward direction generally parallel to the outwardly-extending section **246b**. In some embodiments, the outer frame anchoring feature **144** can extend generally perpendicularly to the longitudinal axis **102** and/or in an upward direction.

[0160] In some embodiments, the lower row of cells **254c** can be omitted. For example, the struts **256e** can extend downwardly along a plane parallel to the longitudinal axis. These struts can extend between anchors of the inner frame anchoring feature **224**. This can advantageously allow the outer frame **240** to extend further downwardly which can beneficially allow a skirt, such as skirt **280**, to extend further downwardly and increase the effective sealing area. For example, in situations where the outer frame **240** is retained in a collapsed configuration and the inner frame anchoring feature **224** is released, the struts would not intersect with the individual anchors of the inner frame anchoring feature **224** regardless of the length of the struts. This can allow the individual anchors of the inner frame anchoring feature **224** to transition from a collapsed configuration to an expanded configuration without contacting the outer frame **240** when the outer frame **240** is retained in a collapsed configuration.

[0161] With reference next to **Figure 6**, the inner frame **220** and valve body **260** of prosthesis **200** are illustrated. The inner frame **220** can include an inner frame body **222** and an inner frame anchoring feature **224**. As shown, the inner frame body **222** can have an upper region **226**, an intermediate region **228**, and a lower region **230**. As shown, the inner frame body **222** can have a generally cylindrical shape such that the diameters of the upper region **226**, the intermediate region **228**, and the lower region **230** are generally equivalent. However, it is to be understood that the diameters of the upper region **226**, the intermediate region **228**, and/or the lower region **230** can be different. For example, in some embodiments, a diameter of the intermediate region **228** can be larger than the upper region **226** and the lower region **230** such that the inner frame body **222** has a generally bulbous shape. In some embodiments, the diameter of the lower region **230** can be larger than the diameter of the upper region **226**. In other embodiments, the diameter of the upper region **226** can be larger than the diameter of the lower region **230**.

[0162] The diameter of the upper region **226**, intermediate region **228**, and/or lower region **230** of the inner frame body **222** may be chosen such that the inner frame body **222** is adequately spaced from the body cavity when the prosthesis **200** is positioned within the body cavity. For example, in embodiments where the prosthesis

200 is positioned within the native mitral valve, the inner frame body **222** may have a diameter which is less than the diameter of the native mitral valve annulus. In situations where the native mitral valve annulus is about 40mm in diameter, the diameter of the inner frame body **222** can be about 30mm. Accordingly, the diameter of the inner frame body **222** may be about 75% of the diameter of the native mitral valve annulus.

[0163] In some embodiments, the diameter of the inner frame body **222** may be between about 40% to about 90% of the diameter of the native valve annulus, between about 60% to about 85%, of the diameter of the native valve annulus, between about 70% to about 80% of the diameter of the native valve annulus, any other sub-range between these ranges, or any other percentage as desired. In some embodiments, the diameter of the inner frame body **222** can be in the range of about 20mm to about 40mm when expanded, in the range of about 25mm to about 35mm when expanded, in the range of about 28mm to about 32mm when expanded, any other sub-range within these ranges when expanded, or any other diameter when expanded as desired. Although the inner frame body **222** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the inner frame body **222** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0164] In other embodiments, the diameter of portions of the inner frame body **222** such as the upper region **226**, intermediate region **228**, and/or lower region **230** may be chosen such that the inner frame body **222** is positioned at the periphery of the body cavity. For example, in embodiments where the prosthesis **200** is positioned within the native mitral valve, the inner frame body **222** may have a diameter which is about equal to the diameter of the native mitral valve annulus.

[0165] With continued reference to the inner frame **220** illustrated in **Figure 6**, the inner frame body **222** can include a plurality of struts with at least some of the struts forming cells **234a-b**. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes.

[0166] The upper row of cells **234a** and the lower row of cells **234b** can have a diamond or generally diamond shape. The rows of cells **234a-b** can be formed via a combination of struts. As shown in the illustrated embodiment, the upper row of cells **234a** can be formed from a first set of circumferentially-expansible struts **236a** and a second set of circumferentially-expansible struts **236b**. The lower row of cells **236b** can be formed from the second set of circumferentially-expansible struts **236b** and a third set of circumferentially-expansible struts **236c**. The first, second, and third sets of struts **236a-c** can have a zig-zag or undulating shape forming a repeating "V" shape. While the struts **236a-c** are generally described and illustrated as being straight segments, it is to be understood that some or all of the struts **236a-c** may not form entirely straight segments. For example, the struts **236a-c** can include some curvature such that the upper and/or lower apices are curved.

[0167] As shown in the illustrated embodiment, the upper row of cells **234a** and the lower row of cells **234b** extend in a direction generally parallel to the longitudinal axis of the prosthesis **200**. There can be a row of twelve cells **234a** and a row of twelve cells **234b**. While each of the cells **234a-b** are shown as having the same shape as other cells **234a-b** of the same row, it is to be understood that the shapes of cells **234a-b** within a row can differ. Moreover, it is to be understood that any number of rows of cells can be used and any number of cells may be contained in the rows. In some embodiments, the number of cells can correspond to the number of anchors or anchor tips forming the inner frame anchoring feature **224**. As shown, the number of cells in the upper row of cells **234a** and the lower row of cells **234b** can have a 1:1 correspondence with the number of anchors in the outer frame anchoring feature **224** (i.e., twelve cells in each row of cells **234a-b** and twelve anchors for the anchoring features **224**). It is to be understood that other ratios of numbers of cells per row to number of anchors per anchoring feature can be used such as, but not limited to, 3:1, 4:1, 5:1, 6:1, and other ratios as desired. In some embodiments, both rows of cells **234a-b** can have different numbers of cells. Moreover, it is to be understood that fewer or greater numbers of rows of cells can be used.

[0168] The geometry of cells **234a-b** can allow the cells **234a-b** to foreshorten as the inner frame **220** is expanded. As such, one or more of cells **234a-b** can allow the inner frame **220** to foreshorten as the inner frame **220** is expanded. As will be discussed in further detail, foreshortening of the inner frame **220** can be used to secure the prosthesis to intralumenal tissue in a body cavity such as tissue at or adjacent a native valve including, but not limited to, a native valve annulus and/or leaflets. For example, expansion of the inner frame **220** can allow the inner frame anchoring feature **224** to extend radially outward and draw closer to tissue of the body cavity, such as a native valve annulus and/or leaflets, to engage tissue of the body cavity.

[0169] With continued reference to the inner frame **220** illustrated in **Figure 6**, the inner frame anchoring feature **224** can have ends or tips **224a** positioned radially outwardly relative to the longitudinal axis of the prosthesis **200**. The inner frame anchoring feature **224** can extend at or proximate a lower end of the lower region **230** of the inner frame body **222**. As shown, the inner frame anchoring feature **224** can be formed from a plurality of individual anchors extending from the frame body **222**. The anchors can extend downwardly from one or more attachment points to the frame body **222** including, but not limited to, lower apices of cells **234b**. The anchors can bend to extend generally radially outwardly of the longitudinal axis of the prosthesis **200**. As shown in the illustrated embodiment, the anchors can extend upwardly towards an end or tip **224a**.

[0170] As shown in the illustrated embodiment, the tips or ends **224a** extend upwardly in a direction generally parallel to the longitudinal axis of the prosthesis **200**. In some embodiments, the tip or end **224a** of anchoring feature **224** can extend generally perpendicular to the longitudinal axis of the prosthesis **200**. This can beneficially increase the tissue contact area of the tip **224a** of the anchor. This increased tissue contact area can beneficially reduce the stress applied by the tip **224a** to tissue thereby reducing the amount of pressure and potential for trauma to the tissue. In some embodiments, the tip or ends **224a** of the anchoring feature **224** extend radially inward towards the longitudinal axis and/or radially outward away from the longitudinal axis.

[0171] The tips or ends **224a**, **244a** as described above can advantageously provide atraumatic surfaces that may be used to contact or engage intralumenal tissue without causing unnecessary or undesired trauma to tissue. For example, the tips or ends **224a**, **244a** can form flat, substantially flat, curved or other non-sharp surfaces to allow the tips to engage and/or grasp tissue, without necessarily piercing or puncturing through tissue. A looped end or looped anchor may assist the frame in not getting caught up on structures at or near the treatment location. For example, each loop can be configured so that when the prosthesis **200** is deployed in-situ and the anchoring features **224, 244** expands away from the frame bodies **222**, **242**, the movement of each loop from a delivered position to a deployed position avoids getting caught on the papillary muscles. As shown in the illustrated embodiment, the inner frame anchoring feature **224** can include a lacrosse-head-shaped tip or end **224a**. The outer frame anchoring feature **244** can include tips or ends **244a** having a "U" shape or rounded shape.

[0172] As shown in the illustrated embodiment, the anchoring features **224**, **244** can include twelve individual anchors; however, it is to be understood that a greater number or lesser number of individual anchors can be used. For example, the number of individual anchors can be chosen as a multiple of the number of commissures for the valve body **260**. As such, for a prosthesis **200** with a valve body **260** having three commissures, the inner frame anchoring feature **224** and/or the outer frame anchoring feature **244** can have three individual anchors (1:1 ratio), six individual anchors (2:1 ratio), nine individual anchors (3:1 ratio), twelve individual anchors (4:1 ratio), fifteen individual anchors (5:1 ratio), or any other multiple of three. It is to be understood that the number of individual anchors need not correspond to the number of commissures of the valve body **260**. Moreover, while the prosthesis **200** includes anchoring features **224**, **244** with twelve anchors each, it is to be understood that a greater number of anchors or a lesser number of anchors can be used. In some embodiments, instead of a 1:1 correspondence between the number of anchors in the inner frame anchoring feature **224** and the outer frame anchoring feature **244** (i.e., twelve anchors each), other ratios can be used. For example, a 1:2 or a 1:3 correspondence between the anchors, are possible such

that the inner frame anchoring feature **224** or the outer frame anchoring feature **244** have fewer anchors than the other anchoring feature.

[0173] With continued reference to the inner frame **220** illustrated in **Figure 6**, the inner frame anchoring feature **224** can include covers and/or cushions **238** to surround or partially surround at least a portion of the inner frame anchoring feature **224**, such as the tips or ends **224a**. The covers and/or cushions **238** can be similar to those described in U.S. Publication No. 2015/0328000, which has been incorporated by reference in its entirety. The covers and/or cushions **238** can either fit snuggly around the tips **224a** of the inner frame anchoring feature **224** or can have extra padding so that the covers extend radially away from the inner frame body **222**. As shown in the illustrated embodiment, covers and/or cushions **238** are attached to a subset of anchors of the inner frame anchoring feature **224** such that a cover and/or cushion **238** is used on every third anchor. In some embodiments, the outer frame anchoring feature **244** can include covers and/or cushions to surround or partially surround at least a portion of the outer frame anchoring feature **244**, such as the tips or ends **244a**.

[0174] It is to be understood that greater or fewer numbers of covers and/or cushions **238** can be used with anchors of the inner frame anchoring feature **224** and/or the outer frame anchoring feature **244**. For example, a cover and/or cushion **238** can be used on every other anchor such that there is a 1:2 ratio of covers and/or cushions **238** to anchors. As another example, a cover and/or cushion **238** can be used on every anchor (as shown in **Figures 2-5**). In some embodiments, all of the anchors can have the covers and/or cushions with some of the anchors having less cushioning than others. In some embodiments, all of the anchors can have the padded covers. In other embodiments, all of the anchors can have the snuggly fitting cushions. In other embodiments, the configuration of the covers and/or cushions can differ between the inner frame anchoring feature **224** and the outer frame anchoring feature **244**.

[0175] The cover and/or cushion **238** can be formed from a deformable material. When the top portion of the cover and/or cushion **238** is subject to pressure due to a downwardly directed force, the cover and/or cushion **238** can compress and expand laterally outward. Such a force may be exerted upon the cover and/or cushion **238** when

the cover and/or cushion **238**, for example, when the cover and/or cushion **238** contacts a ventricular side of the mitral valve annulus during systole. The compression and lateral expansion of cover and/or cushion **238** can increase the surface area of the cover and/or cushion **238** in contact with the tissue, thereby exerting less pressure on the tissue and reducing the potential for trauma.

[0176] With continued reference to the anchoring features **224**, **244** illustrated in **Figures 2-6**, the tips or ends **224a** of the inner frame anchoring feature **224** can be generally circumferentially aligned with respect to the tips or ends **244a** of the outer frame anchoring feature **244** meaning that the tips or ends **224a** of the inner frame anchoring feature **224** are aligned, in a circumferential direction, with the tips or ends **244a** of the outer frame anchoring feature **244**. In other embodiments (not shown), the tips or ends **224a** of the inner frame anchoring feature **224** and the tips or ends **244a** of the outer frame anchoring feature **244** can be circumferentially offset or staggered meaning that the tips or ends **224a** of the inner frame anchoring feature **224** are not aligned, in a circumferential direction, with the tips or ends **244a** of the outer frame anchoring feature **244**.

[0177] Preferably, each of the anchoring features **224**, **244** are positioned or extend generally radially outwardly from the prosthesis **200** so that the anchor tips or ends **224a**, **244a** are generally spaced away or radially outward from the rest of the frame bodies **222**, **242** and from the one or more attachment points or bases of the anchors of the anchoring features **224**, **244**. For example, the anchor tips **224a**, **244a** may be located radially outward from the intermediate region **248** and/or lower region **250** of the outer frame body **242**, with the tips **224a**, **244a** being axially spaced from one another.

[0178] As shown in the illustrated embodiment, at least some of the anchoring features, such as anchoring feature **244**, can extend to a radial distance from an exterior surface of the intermediate region **248** and/or lower region **250** of the outer frame body **242** that is about 110% or more of the expanded diameter of the intermediate region **248** of the outer frame body **242** at the plane of tips **244a**. At least some of the anchoring features, such as anchoring feature **224**, can extend to a radial distance from an exterior surface of the intermediate region **248** of the outer frame body **242** that is

slightly greater than the expanded diameter of the intermediate region **248** and/or the lower region **250** of the outer frame body **242** at the plane of tips **224a**. As shown, the tips **224a** can be positioned such that the tips **224a** contact an exterior of the outer frame body **242**. As will be discussed in further detail below, this can beneficially pinch or grasp tissue of the body cavity therebetween. For example, in instances where the prosthesis **200** is used at a native mitral valve, native leaflets and/or portions of the native mitral valve annulus can be pinched or grasped between the anchoring feature **224** and the intermediate region **248** and/or lower region **250** of the outer frame body **242**.

[0179] In some embodiments, all of the anchors of the inner frame anchoring feature **224** and/or all of the anchors of the outer frame anchoring feature **244** extend at least to this radial distance. In other embodiments, fewer than all of the anchors of the inner frame anchoring feature **224** and/or all of the anchors of the outer frame anchoring feature **244** extend to this radial distance. The outermost diameter of the inner frame anchoring feature **224** and/or the outer frame anchoring feature **244** may be greater than the diameter of frame bodies **222**, **224** as described above and may be in the range of about 35mm to about 70mm when expanded, in the range of about 35mm to about 60mm when expanded, in the range of about 40mm to about 60mm when expanded, in the range of about 45mm to about 50mm when expanded, any sub-range within these ranges when expanded, or any other diameter as desired.

[0180] As shown, the inner frame anchoring feature **224** can be positioned to be not as far radially outward as the outer frame anchoring feature **244**. However, it is to be understood that in other embodiments, the inner frame anchoring feature **224** and the outer frame anchoring feature **244** can extend radially outward from the longitudinal axis of the prosthesis **200** to about the same radial dimension or the outer frame anchoring feature **244** can be positioned to be not as far radially outward as the inner frame anchoring feature **224**. Such configurations may be advantageous in positioning and securing the prosthesis in a native valve annulus or other body location.

[0181] In some embodiments, individual anchors can extend radially outwardly from the frame at an anchor base and terminate at an anchor tip. The individual anchors can be connected to the frame at one of many different locations

including apices, junctions, other parts of struts, etc. Moreover, the anchors forming the anchoring features **224**, **244** can comprise first, second, third, or more spaced apart bending stages along the length of each anchor. Further details that may be incorporated and/or interchanged with the features described herein are disclosed in U.S. Publication Nos. 2014/0277422, 2014/0277427, 2014/0277390, and 2015/0328000, and U.S. Application No. 15/653,390, entitled REPLACEMENT HEART VALVE PROSTHESIS, filed on July 18, 2017, which have been incorporated by reference herein.

[0182] One or both anchoring features **224**, **244** can contact or engage a native valve annulus, such as the native mitral valve annulus, tissue beyond the native valve annulus, native leaflets, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. In some embodiments, one or both anchoring features **224**, **244** do not contact or engage, or only partially contact or engage, a native valve annulus, such as the native mitral valve annulus, tissue beyond the native valve annulus, native leaflets, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. However, it is to be understood that in some embodiments, when the prosthesis **200** is used for a replacement mitral valve prosthesis, during diastole and/or systole, both the inner frame anchoring feature **224** and the outer frame anchoring feature **244** can be sized to contact or engage the native mitral valve annulus.

[0183] The anchoring features **224**, **244** and anchor tips **224a**, **244a** are preferably located along the prosthesis **200** with at least part of the foreshortening portion positioned between the anchoring features **224**, **244** so that a portion of the anchoring features **224**, **244** will move closer together with expansion of the prosthesis **200**. This can allow the anchoring features **224**, **244** to close in on opposite sides of the native mitral annulus to thereby secure the prosthesis at the mitral valve. In some embodiments, the anchoring features **224**, **244** can be positioned such that the anchoring features **224**, **244** do not contact opposing portions of the native mitral annulus at the same time. For example, when the prosthesis **200** is used for a replacement mitral valve prosthesis, during at least systole, in some embodiments the inner frame anchoring feature **224** is sized to contact or engage the native mitral valve annulus whereas the outer frame

anchoring feature **244** is sized to be spaced from the native mitral valve annulus. This can be beneficial when outer frame anchoring feature **244** is used to provide stabilization and help align the prosthesis. In some embodiments, the anchoring features **224**, **244** can be positioned such that the anchoring features **224**, **244** grasp opposite side of the native mitral annulus.

[0184] While the anchoring features **224**, **244** have been illustrated as extending from the lower end of the lower region **230** of the inner frame body **222** and at a junction between the upper region **246** and the intermediate region **248** of the outer frame body **242** respectively, it is to be understood that the anchoring features **224**, **244** can be positioned along any other portion of the prosthesis **200** as desired. Moreover, while two anchoring features **224**, **244** have been included in the illustrated embodiment, it is to be understood that a greater number or lesser number of sets of anchoring features can be utilized.

[0185] With reference back to the inner frame **220** illustrated in **Figure 6**, the inner frame **220** can include a set of locking tabs **232** extending the at or proximate an upper end of the upper region **226** of the inner frame body **222** such as upper apices of cells **234a**. As shown, the inner frame **220** can include twelve locking tabs **232**, however, it is to be understood that a greater number or lesser number of locking tabs can be used. The locking tabs **232** can extend generally upwardly from the upper region **226** of the inner frame body **222** in a direction generally aligned with the longitudinal axis of the prosthesis **200**. As shown in the illustrated embodiment, the locking tabs **232** can include a longitudinally-extending strut **232a**. At an upper end of the strut **232a**, the locking tab **232** can include an enlarged head **232b**. As shown, the enlarged head **232b** can have a semi-circular or semi-elliptical shape forming a "mushroom" shape with the strut **232a**. The locking tab **232** can include an eyelet **232c** which can be positioned through the enlarged head **232b**. It is to be understood that the locking tab **232** can include an eyelet at other locations, or can include more than a single eyelet.

[0186] The locking tab **232** can be advantageously used with multiple types of delivery systems. For example, the shape of the struts **232a** and the enlarged head **232b** can be used to secure the inner frame **220** to a "slot" based delivery system. The

eyelets **232c** can be used to secure the inner frame **220** to a "tether" based delivery system such as those which utilize sutures, wires, or fingers to control delivery of the inner frame **220** and the prosthesis **200**. This can advantageously facilitate recapture and repositioning of the inner frame **220** and the prosthesis **200** in situ. In some embodiments, the prosthesis **220** can be used with the delivery systems described herein, including but not limited to, those described in U.S. Patent Nos. 8,414,644 and 8,652,203 and U.S. Publication Nos. 2015/0238315, the entireties of each of which are hereby incorporated by reference and made a part of this specification.

[0187] While the locking tabs **232** have been described as being attached to the inner frame body **222**, it is to be understood that the locking tabs **232** can be attached to other portions of the prosthesis **200** such as, but not limited to, the outer frame body **242**. For example, in some embodiments, the locking tabs **232** can extend from an upper end of an upper region **246** of the outer frame body **242**. Moreover, it is to be understood that portions of, or the entirety of, the locking tabs **232** can be omitted. For example, in some embodiments, the strut **232a** can be omitted such that the enlarged head **232b** and eyelet **232c** are positioned at an upper end of the upper region **226** of the inner frame body **222**, such as at upper apices of cell **234a**.

[0188] With reference next to the valve body **260** illustrated in **Figure 6**, the valve body **260** can be positioned within the inner frame **220**. The valve body **260** can be a replacement heart valve which includes a plurality of valve leaflets **262**. The valve leaflets **262** can include a first edge **264**, second edge **266**, and tabs **268** (as shown in **Figure 5**) for attaching the valve leaflets **262** together at commissures of the valve body **260**. The tabs **268** can be used to secure the valve leaflets **262** to the inner frame **220**. The first edge **264** can be an arcuate edge and can be generally fixed in position relative to the frame **220**. The second edge **266** can be a freely moving edge which can allow the valve body **260** to open and close.

[0189] The plurality of valve leaflets **262** can function in a manner similar to the native mitral valve, or to any other valves in the vascular system as desired. The plurality of valve leaflets **262** can open in a first position and then engage one another to close the valve in a second position. The plurality of valve leaflets **262** can be made to

function as a one way valve such that flow in one direction opens the valve and flow in a second direction opposite the first direction closes the valve. For example, as shown in the illustrated embodiment, the valve body **260** can open allow to blood to flow through the valve body **260** in a direction from an upper end to a lower end. The valve body **260** can close to inhibit blood flow through the valve body **260** in a direction from the lower end to the upper end. In situations where the prosthesis **200** is oriented such that an upper end is a proximal end and a lower end is a distal end, the valve body **260** can be positioned such that the valve body **260** can open to allow blood to flow through the valve body **260** in a proximal-to-distal direction and close to inhibit blood flow in a distal-to-proximal direction. The valve body **260** can be constructed so as to open naturally with the beating of the heart. For example, the valve body **260** can open during diastole and close during systole. The valve body **260** can replace a damaged or diseased native heart valve such as a diseased native mitral valve.

[0190] The valve body **260** can include a liner **270**. The liner **270** can be used to assist with fluid flow through and/or around the prosthesis **200**, such as through and around the inner frame **220** and the valve leaflets **262**. The liner **270** can surround at least a portion of the valve leaflets **262** and be connected to one or more of the valve leaflets **262**. For example, as shown in the illustrated embodiment, the one or more valve leaflets **262** can be attached to the liner **270** along the first edge **264** of the valve leaflets **262**.

[0191] As shown in the illustrated embodiment, the liner **270** can be positioned within the interior of the inner frame **220** and can form an inner wall of the prosthesis **200**. For example, the liner **270** can be positioned such that the liner **270** is radially inward, relative to the longitudinal axis of the prosthesis **200**, from the struts **236a-c** of the inner frame **220**. In this manner, the fluid pathway towards the valve leaflets **262** can be relatively smooth. It is also contemplated that the liner **270** can at least be partially positioned along an exterior of the inner frame **220** and/or outer frame **240** such that at least a portion of the liner **270** is radially outward, relative to the longitudinal axis of the prosthesis **200**, from struts of the inner frame **220** and/or outer frame **240**. As shown in the illustrated embodiment, the liner **270** can be positioned along an upper or inlet side of the inner frame **220**. The liner **270** can extend from the first

edge **264** of the valve leaflets **262** towards the upper end of the inner frame **220**. The liner **270** can also extend below the first edge **264** of the valve leaflet **262** towards the lower end of the inner frame **220**. The liner **270** can also be made to move with foreshortening portions of the inner frame **220**.

[0192] In some embodiments, the liner **270** can extend the entire length of the inner frame **220** or the inner frame body **222**. In other embodiments, it can extend along only part of the length of the inner frame body **222** as shown. In some embodiments, the ends of the valve leaflets **262** can coincide with ends of the liner **270**. In addition, one or more of the ends of the inner frame body **222** can coincide with the ends of the liner **270**. As shown in the illustrated embodiment, an end **272** of the liner **270** can be positioned between the upper end of the inner frame **220** and the valve leaflets **262**. The end **272** of the liner **270** can extend above an upper end of the inner frame body **222** and extend along a portion of the locking tabs **232**. In some embodiments, the end **272** of the liner **270** can be positioned at or proximate an uppermost portion of the first or arcuate edge **264** of the valve leaflet **262** below the upper end of the inner frame body **222**.

[0193] Other shapes and configurations can also be used for the valve body **260**. In some embodiments, the liner **270** may extend along the length of the leaflets, but is not connected to them. In the illustrated embodiment, the liner **270** is attached to the inner frame **220** and at least a portion of the leaflets **262**, such as the first or arcuate edge **264**, is attached to the liner **270**. Portions of the valve leaflets **262**, such as the portions of the first edge **264** and/or tabs **268**, can also be attached to the inner frame **220**. The liner **270** and/or the valve leaflets **262** can be attached to the inner frame **220** or to each other using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques.

[0194] The liner **270** can be constructed in multiple different ways. The liner **270** can be made a layer of resilient material, such as such as knit polyester (e.g.,

polyethylene terephthalate (PET), polyvalerolactone (PVL)) or any other biocompatible material such as those which are wholly or substantially fluid impermeable, flexible, stretchable, deformable, and/or resilient. In some embodiments, the liner **270** can be made from a material that is more flexible than the valve leaflet material. The upper and/or lower end, such as end **272**, of the liner **270** can be straight, curved, or have any other desired configuration. For example, as shown in the illustrated embodiment, the liner **270** can have a straight edge forming the end **272**. In other embodiments, the end **272** can be patterned to generally correspond to the undulations at one end of the inner frame **220**. The liner **270** can be formed of one piece or multiple pieces.E

[0195] In another embodiment of the liner **270**, the end can extend past the inner frame **220** and can be wrapped around it. Thus, the liner **270** can extend from the interior of the inner frame **220** to the exterior of the inner frame **220**. The liner **270** can extend completely around the inner frame **220** for 1/4, 1/3, 1/2, or more of the length of inner frame **220**.

[0196] With reference next to the skirt **280** illustrated in **Figures 2-5**, the skirt **280** can be positioned around and secured to at least a portion of the exterior of the prosthesis **200** such as, but not limited to, the inner frame **220** and/or the outer frame **240**. The skirt **280** can be annular and can extend entirely circumferentially around the prosthesis **200**. The skirt **280** can prevent or inhibit backflow of fluids around the prosthesis **200**. For example, with the skirt **280** positioned annularly around an exterior of the prosthesis **200**, the skirt **280** can create an axial barrier to fluid flow exterior to the prosthesis **200** when deployed within a body cavity. As shown, the skirt **280** can seal against at least a portion of tissue surrounding the body cavity. In addition, the skirt **280** can encourage tissue in-growth between the flap assembly **280** and natural tissue of the body cavity. This may further help to prevent leakage of blood flow around the prosthesis **200**.

[0197] The skirt **280** can have an upper region **282**, an intermediate region **284**, and a lower region **286**. The upper region **282** of the skirt **280** can extend along a portion of the exterior of the outer frame **240** such as the upper region **246** of the outer frame **240**. The intermediate region **284** of the skirt **280** can extend along a portion of

the exterior of the outer frame **240** such as the intermediate region **248** of the outer frame **240**. The lower region **286** of the skirt **280** can extend along a portion of the exterior of the outer frame **240** such as the lower region **250** of the outer frame **240**. While the skirt **280** is shown extending along the exterior of the outer frame **240**, it is to be understood that portions of, or the entirety of, the skirt **280** can extend along an interior of the outer frame. It is also to be understood that while the skirt **280** is shown tautly attached to the outer frame **240**, a portion of, or the entirety of, the skirt **280** can be loosely attached such that a portion of, or the entirety of, the skirt **280** is movable relative to the outer frame **240**.

[0198] The upper end of the skirt **280** can be positioned at or proximate an upper end of the outer frame body **242** and/or an upper end of the inner frame body **222**. In some embodiments, the upper end of the skirt **280** can be attached to the end **272** of the liner **270** using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques. The lower end of the lower region **286** of the skirt **280** can be positioned at or proximate a lower end of the lower region **250** of the outer frame body **242**. The skirt **280** may be attached to the outer frame **240** and/or inner frame **220** using any fasteners and/or techniques described herein. For example, portions of the skirt **280** can be attached to struts and/or anchoring features of the outer frame **240** and/or inner frame **220** via sutures.

[0199] As shown in the illustrated embodiment, the lower end of the lower region **286** of the skirt **280** can be provided with a generally straight edge with extends circumferentially around the outer frame body **242** and/or inner frame body **222**. It is to be understood that other configurations, such as a curved edge, can also be used as desired. In some embodiments, the lower end of the lower region **286** of the skirt **280** can follow the shape of the struts along the lower end of the lower region **250** of the outer frame body **242**.

[0200] In some embodiments, the skirt **280** can be formed from a material such as knit polyester (e.g., polyethylene terephthalate (PET), polyvalerolactone (PVL)) or any other biocompatible material such as those which are wholly or substantially fluid impermeable, flexible, stretchable, deformable, and/or resilient. The skirt **280** and/or the liner **270** may be made from the same or similar materials. As shown in the illustrated embodiment, the skirt **280** can be formed as separate components. The components can be attached together using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques. For example, the upper region **282** can be a first component and the intermediate region **284** and/or lower region **286** can be a second component. In other embodiments, skirt **280** can be integrally or monolithically formed. For example, in some embodiments, the upper region **282** of the skirt **280** and the intermediate region **284** and/or lower region **286** can be integrally or monolithically formed as a single component.

[0201] In some embodiments, the outer frame **240** can be attached to the inner frame **220** at one or more attachment points using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots which can be on the inner frame **220** and the outer frame **240**), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques.

[0202] The outer frame **240** can be attached to the inner frame **220** by attaching the skirt **280** to the inner frame **220** and/or portions of the valve body **260**, such as the liner **270** using any mechanism or technique described herein. In some embodiments, the outer frame **240** can be tautly attached to the inner frame **220** such that

little to no relative movement between the outer frame **240** and the inner frame **220** occurs at the one or more attachment points of the outer frame **240** to the inner frame **220**. For example, the outer frame **240** can be tautly attached to the inner frame **220** and/or the skirt **280** can be attached to the inner frame **220** and/or valve body **260** with little to no slack. In other embodiments, the outer frame **240** can be loosely attached to the inner frame **220** such that some relative movement between the outer frame **240** and the inner frame **220** occurs at the one or more attachment points of the outer frame **240** to the inner frame **220**. For example, the outer frame **240** can be loosely attached to the inner frame **220** and/or the skirt **280** can be attached to the inner frame **220** and/or valve body **260** with slack to permit relative movement between the outer frame **240** and the inner frame **240**.

[0203] With reference next to **Figures 7-8**, an embodiment of an outer frame **300** in an expanded configuration is illustrated. The outer frame **300** can include an outer frame body **302**. A longitudinal axis of the outer frame **300** may be defined as the central axis that extends through the center of the outer frame **300** between the upper and lower ends of the outer frame **300**. As shown, the outer frame body **302** can have an upper region **304**, an intermediate region **306**, and a lower region **308**.

[0204] When in an expanded configuration such as in a fully expanded configuration, the outer frame body **302** can have a bulbous shape with the intermediate region **306** being larger than the upper region **304** and the lower region **308**. The bulbous shape of the outer frame body **302** can advantageously allow the outer frame body **302** to engage a native valve annulus, native valve leaflets, or other body cavity, while spacing the inlet and outlet from the heart or vessel wall. This can help reduce undesired contact between the prosthesis in which the outer frame **300** is used and the heart or vessel, such as the atrial and ventricular walls of the heart. The bulbous shape can further enhance securement of the outer frame body **302** to the body cavity. For example, in some embodiments, the bulbous shape can allow the intermediate region **306** to extend further radially outward compared to an anchoring feature, such as lower frame anchoring features **124**, **224**. In this manner, the intermediate region **306** can exert a greater radial

force on tissue of the body cavity and/or can more completely conform to the tissue of the body cavity, such as the native valve annulus and/or native leaflets.

[0205] The upper region **304** of the outer frame body **302** can include a generally longitudinally-extending section **304a** and an outwardly-extending section **304b**. The outwardly-extending section **304b** can extend radially outwardly away from the longitudinal axis of the outer frame **300**. In some embodiments, the outwardly-extending section **246b** can extend in a direction that is more perpendicular to the longitudinal axis **202** than parallel and/or in a downward direction from the longitudinally-extending section **304a**. However, it is to be understood that the outwardly-extending section **304b** can extend generally perpendicularly to the longitudinal axis and/or in an upward direction from the longitudinally-extending section **304a**. Moreover, it is to be understood that the longitudinally-extending section **304a** can be omitted.

[0206] At the juncture between the longitudinally-extending section **304a** and the outwardly-extending section **304b**, the outer frame body **302** can include a bend **310**. The bend **310** can be about a circumferential axis such that the outwardly-extending section **304b** extends in a direction more perpendicular to the longitudinal axis of the outer frame **300** than the longitudinally-extending section **304a**. In some embodiments, the bend **310** can generally form an arc with an angle between about 20 degrees to about 90 degrees. For example, as shown in the illustrated embodiment, the arc can have an angle of about 60 degrees. In some embodiments, the bend **310** can form an arc with an angle between about 30 degrees to about 60 degrees. The radius of curvature of the arc may be constant such that the bend **310** forms a circular arc or may differ along the length of the bend **310**.

[0207] In some embodiments, the outwardly-extending section **304b** can form an angle of between about 20 degrees to about 70 degrees with a plane orthogonal to the longitudinal axis of the outer frame **300**, an angle of between about 30 degrees to about 60 degrees with a plane orthogonal to the longitudinal axis of the outer frame **300**, an angle of between about 40 degrees to about 50 degrees with a plane orthogonal to the longitudinal axis of the outer frame **300**, an angle of about 30 degrees with a plane

orthogonal to the longitudinal axis of the outer frame **300**, any subrange within these ranges, or any other angle as desired. In some embodiments, the outwardly-extending section **304b** can form an angle of less than 70 degrees with a plane orthogonal to the longitudinal axis of the outer frame **200**, an angle of less than 55 degrees with a plane orthogonal to the longitudinal axis of the outer frame **300**, an angle of less than 40 degrees with a plane orthogonal to the longitudinal axis of the outer frame **300**, an angle of less than 25 degrees with a plane orthogonal to the longitudinal axis of the outer frame **300**, or less than any other angle as desired.

[0208] The intermediate region **306** of the outer frame body **302** can extend generally downwardly from the outwardly-extending section **304b** of the upper region **304**. As shown, the intermediate region **306** can have a generally bulbous shape with a greater diameter along a portion between the upper and lower ends of the intermediate region **306**. However, it is to be understood that the diameters of the upper end, the lower end, and/or the portion therebetween can be the same such that the intermediate region **306** forms a generally cylindrical shape. In some embodiments, the diameter of the lower end can be larger than the diameter of the upper end. In other embodiments, the diameter of the upper end can be larger than the diameter of the lower end.

[0209] Although the outer frame body **302** has been described and illustrated as having a circular cross-sections, it is to be understood that all or a portion of the outer frame body **302** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0210] At the juncture between the upper region **304** and the intermediate region **306**, the outer frame body **302** can include a bend **312**. The bend **312** can be about a circumferential axis such that the intermediate region **306** extends in a direction more parallel to the longitudinal axis of the outer frame **300** than the outwardly-extending section **304b** of the upper region **304**. In some embodiments, the bend **312** can generally form an arc with an angle between about 20 degrees to about 90 degrees. For example, as shown in the illustrated embodiment, the arc can have an angle of about 60 degrees. In some embodiments, the bend **312** can form an arc with an angle between about 30 degrees to about 60 degrees. The radius of curvature of the arc may be constant

such that the bend **312** forms a circular arc or may differ along the length of the bend **312**.

[0211] The lower region **308** of the outer frame body **302** can extend generally downwardly from the lower end of the intermediate region **306**. As shown, the lower region **308** of the outer frame body **302** can have a decreasing diameter from an upper end of the lower region **308** to a lower end of the lower region **308** such that the lower region **308** is inclined or curved radially inwards towards the longitudinal axis of the outer frame **300**. This radially inward incline or curve of the lower region **308** can facilitate capture of native valve leaflets between the outer frame **300** and other portions, such as an anchoring feature, of the prosthesis in which the outer frame **300** is used. Moreover, this radially inward inclined or curve of the lower region **308** can reduce or inhibit potential trauma to tissue of the body cavity, such as the native leaflets and/or native valve annulus. For example, the curvature and/or inclination of the lower region **308** can be chosen to better conform to the curvature of tissue positioned between the outer frame **300** and an anchoring feature of another portion of a prosthesis in which the outer frame **300** is used.

[0212] The lower region **308** can be curved and/or inclined towards the longitudinal axis of the frame **300** such that the lower ends of the lower region **308** can extend in a direction that is between about 20 degrees to about 80 degrees with respect to a plane parallel to the longitudinal axis of the frame **300**, between about 25 degrees to about 70 degrees with respect to a plane parallel to the longitudinal axis of the frame **300** between about 30 degrees to about 60 degrees with respect to a plane parallel to the longitudinal axis of the frame **300,** about 30 degrees with respect to a plane parallel to the longitudinal axis of the frame **300**. The lower region **308** can be curved and/or inclined towards the longitudinal axis of the frame **300** such that the lower ends of the lower region **308** can extend in a direction generally perpendicular to the longitudinal axis of the frame **300**.

[0213] In some embodiments, the outer frame body **302** in an expanded configuration can have a diameter at its widest portion of between about 30mm to about 60mm, between about 35mm to about 55mm, about 40mm, any sub-range within these

ranges, or any other diameter as desired. In some embodiments, the outer frame body **302** in an expanded configuration can have a diameter at its narrowest portion between about 20mm to about 40mm, any sub-range within these ranges, or any other diameter as desired. In some embodiments, the outer frame body **302** in an expanded configuration can have a diameter at a lower end of the lower region **308** between about 20mm to about 40mm, any sub-range within these ranges, or any other diameter as desired. In some embodiments, in an expanded configuration, the ratio of the diameter of the outer frame body **302** at its widest portion to the diameter of the frame body **302** at its narrowest portion can be about 3:1, about 5:2, about 2:1, about 3:2, about 4:3, any ratio within these ratios, or any other ratio as desired.

[0214] The outer frame body **302** can have an axially compact configuration relative to the radial dimension. In some embodiments, the outer frame body **302** in an expanded configuration can have an the axial dimension between the upper and lower ends of the outer frame body **302** (i.e., the "height" of the outer frame body **302**) of between about 10mm to about 40mm, between about 18mm to about 30mm, about 20mm, any sub-range within these ranges, or any other height as desired. For example, the ratio of the diameter of the largest portion of the outer frame body **302** to the height of the outer frame body **302** when the frame is in its expanded configuration can be about 3:1, about 5:2, about 2:1, about 3:2, about 4:3, about 13:10, about 5:4, or about 1:1. Thus, in some embodiments the width at the largest portion of the outer frame body **302** can be greater than the height of the outer frame body **302**.

[0215] With continued reference to the outer frame **300** illustrated in **Figures 7-8**, the outer frame body **302** can include a plurality of struts with at least some of the struts forming cells **314a-c**. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes.

[0216] The upper row of cells **314a** can have an irregular hexagonal shape such as the illustrated "heart" shape. The cell **314a** can be formed via a combination of struts. As shown in the illustrated embodiment, the upper portion of cells **314a** can be formed from a set of circumferentially-expansible struts **316a** having a zig-zag or

undulating shape forming a repeating "V" shape. The circumferentially-expansible struts **316a** can be inclined or curved radially outwards away from the longitudinal axis of the outer frame **300** such that an upper portion of the struts **316a** is positioned closer to the longitudinal axis of the outer frame **300** than the lower portion of the struts **316a**. As shown in the illustrated embodiment, the circumferentially-expansible struts can incorporate bend **310** of the outer frame body **302**.

[0217] The lower portion of cells **314a** can be formed from a set of circumferentially-expansible struts **316b** having a zig-zag or undulating shape forming a repeating "V" shape. The lower tips or ends of the circumferentially-expansible struts **316b** can be at or proximate the junction of the upper region **304** and the intermediate region **306**. As shown in the illustrated embodiment, the circumferentially-expansible struts can incorporate part of bend **312** of the outer frame body **302**. One or more of the upper ends or tips of the circumferentially-expansible struts **316b** can be a "free" apex which is not connected to a strut. For example, as shown in the illustrated embodiment, every other upper end or tip of circumferentially-expansible struts **316b** is a free apex. However, it is to be understood that other configurations can be used. For example, every upper apex along the upper end can be connected to a strut.

[0218] The middle and/or lower rows of cells **314b-c** can have a different shape from the cells **314a** of the first row. The middle row of cells **314b** and the lower row of cells **314c** can have a diamond or generally diamond shape. The diamond or generally diamond shape can be formed via a combination of struts. The upper portion of cells **314b** can be formed from the set of circumferentially-expansible struts **316b** such that cells **314b** share struts with cells **314a**. The lower portion of cells **314b** can be formed from a set of circumferentially-expansible struts **316c**. As shown in the illustrated embodiment, one or more of the circumferentially-expansible struts **316c** can extend generally in a downward direction and can incorporate part of bend **312** of the outer frame body **302**. For example, the one or more circumferentially-expansible struts **316c** can be curved such that an upper portion of the struts **316c** are positioned closer to the longitudinal axis of the outer frame **300** than a portion of the struts **316c** positioned between the upper and lower ends of the struts **316c**. In some embodiments, one or more

of the circumferentially-expansible struts **316c** can extend radially outward from the longitudinal axis of the outer frame **300**.

[0219] The upper portion of cells **314c** can be formed from the set of circumferentially-expansible struts **316c** such that cells **314c** share struts with cells **314b**. The lower portion of cells **314c** can be formed from a set of circumferentially-expansible struts **316d**. Circumferentially-expansible struts **316d** can extend generally in a downward direction. As shown in the illustrated embodiment, the circumferentially-expansible struts **316e** can be inclined or curved towards the longitudinal axis of the outer frame **300** such that an upper portion of the struts **316d** can be positioned closer to the longitudinal axis of the outer frame **300** than the lower portion of the struts **316d**. In some embodiments, the circumferentially-expansible struts **316d** can extend in a direction generally parallel to the longitudinal axis of the outer frame **300**.

[0220] As shown in the illustrated embodiment, there can be a row of twelve cells **314a**, a row of twenty-four cells **314b**, and a row of twenty-four cells **314c**. While each of the cells **314a-c** are shown as having the same shape as other cells **314a-c** of the same row, it is to be understood that the shapes of cells **314a-c** within a row can differ. Moreover, it is to be understood that any number of rows of cells can be used and any number of cells may be contained in the rows. In some embodiments, the number of cells can correspond to the number of anchors or anchor tips forming the anchoring features of the prosthesis in which the outer frame **300** is used such as, but not limited to, a 1:1 correspondence, a 2:1 correspondence, a 3:1 correspondence, a 4:1 correspondence, a 5:1 correspondence, a 6:1 correspondence, and other ratios as desired. In some embodiments, all three rows of cells **314a-c** can have the same the number of cells. Moreover, it is to be understood that fewer or greater numbers of rows of cells can be used.

[0221] The geometry of cells **314a-c** can allow the cells **314a-c** to foreshorten as the outer frame **300** is expanded. As such, one or more of cells **314a-c** can allow the outer frame **300** to foreshorten as the outer frame **300** is expanded. Foreshortening of the outer frame **300** can be used to secure the prosthesis to intralumenal tissue in a body cavity such as a native valve including, but not limited to, a native valve annulus and/or

leaflets. For example, expansion of the outer frame **300** can allow the outer frame **300** to exert a radially outward force against the tissue at or adjacent the native valve, such as the native valve annulus and/or leaflets.

[0222] As shown in the illustrated embodiment, the outer frame **300** can include tabs **318** extending from a portion of the frame **300** such as an upper end of the frame body **302**. The tabs **318** can include an eyelet **320**. The tab **318** can be advantageously used to couple the outer frame **300** to an inner frame, such as inner frames **120**, **220**, of the prosthesis in which the outer frame **300** is used. For example, a suture can be passed through the eyelet **320** for coupling to an inner frame. In some embodiments, the tabs **318** can be used to couple to other components of a prosthesis in which the outer frame **300** is used such as, but not limited to, a valve body and/or a skirt.

[0223] In some embodiments, the tab **318** can be advantageously used to couple the outer frame **300** with multiple types of delivery systems. For example, the shape of the tab **318** can be used to secure the outer frame **300** to a "slot" based delivery system. The eyelets **320** can be used to secure the outer frame **300** to a "tether" based delivery system such as those which utilize sutures, wires, or fingers to control delivery of the outer frame **300** and the prosthesis. This can advantageously facilitate recapture and repositioning of the outer frame **300** and the prosthesis in situ. In some embodiments, the outer frame **300** and prosthesis can be used with the delivery systems described herein, including but not limited to, those described in U.S. Patent Nos. 8,414,644 and 8,652,203 and U.S. Publication Nos. 2015/0238315, the entireties of each of which have been incorporated by reference herein. In some embodiments, a tab can be positioned at an end of a strut similar to locking tabs **232**.

[0224] With reference next to **Figures 9-10**, an embodiment of an inner frame **400** in an expanded configuration is illustrated. The inner frame **400** can include an inner frame body **402**. The inner frame **400** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of inner frame **220** described above in connection with **Figures 2-6**. As such, reference should be made to the description of inner frame **220** above.

[0225] As shown in the illustrated embodiment, the inner frame **400** can include tabs **404** extending from a portion of the inner frame **400**, such as an upper end of the frame body **402**. The inner frame **400** can include an eyelet **406**. The eyelet **406** can be advantageously used to couple the inner frame **400** to an outer frame, such as outer frames **120**, **220**, **300**, of the prosthesis in which the inner frame **400** is used. For example, a suture can be passed through the eyelet **406** for coupling to an eyelet **320** of the outer frame **300**. In some embodiments, the eyelet **406** can be used to couple to other components of a prosthesis in which the inner frame **400** is used such as, but not limited to, a valve body and/or a skirt.

[0226] In some embodiments, the tab **404** can be advantageously used to couple the inner frame **400** with multiple types of delivery systems. For example, the shape of the tab **404** can be used to secure the inner frame **400** to a "slot" based delivery system. The eyelets **406** can be used to secure the inner frame **400** to a "tether" based delivery system such as those which utilize sutures, wires, or fingers to control delivery of the inner frame **400** and the prosthesis. This can advantageously facilitate recapture and repositioning of the inner frame **400** and the prosthesis in situ. In some embodiments, the inner frame **400** and prosthesis can be used with the delivery systems described herein, including but not limited to, those described in U.S. Patent Nos. 8,414,644 and 8,652,203 and U.S. Publication Nos. 2015/0238315, the entireties of each of which have been incorporated by reference herein. In such embodiments, the tab **404** may be omitted to advantageously the axial dimension between the upper end and the lower end of the inner frame **400** (i.e., the "height" of the inner frame **400**).

[0227] With reference next to **Figure 33**, an embodiment of a prosthesis **1500** in an expanded configuration is illustrated. The prosthesis **1500** can include an inner frame **1520**, an outer frame **1540**, a valve body **1560**, and one or more skirts, such as an outer skirt **1580** and an inner skirt **1590**. The prosthesis **1500** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other prostheses described herein such as, but not limited to prosthesis **100**.

[0228] With reference first to the inner frame **1520**, the inner frame **1520** can include an inner frame body **1522** and an inner frame anchoring feature **1524**. The inner

frame body **1522** can have an upper region **1522a**, an intermediate region **1522b**, and a lower region **1522c**. As shown, the inner frame body **1522** can have a generally bulbous shape such that the diameters of the upper region **1522a** and the lower region **1522c** are less than the diameter of the intermediate region **1522b**. The diameter of the upper region **1522a** can be less than the diameter of the lower region **1522c**. This can beneficially allow the use of a smaller valve body **1560** within the inner frame **1520** while allowing the inner frame body **1522** to have a larger diameter proximate the connection between the inner frame body **1522** and the inner frame anchoring feature **1524**. This larger diameter can reduce the radial distance between the connection and the tip or end of the inner frame anchoring feature **1524**. This can beneficially enhance fatigue resistance of the inner frame anchoring feature **1524** by reducing the length of the cantilever.

[0229] While the illustrated inner frame body **1522** is bulbous, it is to be understood that the diameters of the upper region **1522a**, the intermediate region **1522b**, and/or the lower region **1522c** can be the same such that the inner frame body **1522** is generally cylindrical along one or more regions. Moreover, while the illustrated embodiment includes a lower region **1522a** having a greater diameter than the upper region **1522c**, it is to be understood that the diameters of the upper and lower regions **1522a, 1522c** can be the same or the diameter of the upper region **1522a** can be greater than the diameter of the lower region **1522c**. Moreover, although the inner frame body **1522** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the inner frame body **1522** can have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0230] With reference next to the outer frame **1540** illustrated in **Figure 33**, the outer frame **1540** can be attached to the inner frame **1520** using any of the fasteners and/or techniques described herein. Although the outer frame **1540** is illustrated as a separate component from the inner frame **1520**, it is to be understood that the frames **1520**, **1540** can be unitarily or monolithically formed.

[0231] As shown in the illustrated embodiment, the outer frame **1540** can include an outer frame body **1542** and an outer frame anchoring feature **1544**. The outer frame body **1542** can have an upper region **1542a**, an intermediate region **1542b**, and a lower region **1542c**. When in an expanded configuration such as a fully expanded configuration, the outer frame body **1542** can have an enlarged shape with the intermediate region **1542b** and the lower region **1542c** being larger than the upper region **1542a**. The enlarged shape of the outer frame body **1542** can advantageously allow the outer frame body **1542** to engage a native valve annulus, native valve leaflets, or other tissue of the body cavity, while spacing the upper end from the heart or vessel wall.

[0232] The upper region **1542a** of the outer frame body **1542** can include a first section **1546a** and a second section **1546b**. The first section **1546a** can be sized and/or shaped to generally match the size and/or shape of the inner frame **1520**. For example, the first section **1546a** can have a curvature which matches a curvature of the upper region **1522a** of the inner frame body **1522**. The second section **1546b** can extend radially outwardly away from the inner frame **1520**. As shown in the illustrated embodiment, the transition between the first section **1546a** and the second section **1546b** can incorporate a bend such that the second section **1546b** extends radially outwardly at a greater angle relative to the longitudinal axis.

[0233] The intermediate region **1542b** of the outer frame body **1542** can extend generally downwardly from the outwardly-extending section **1546b** of the upper region **1542a**. As shown, the intermediate region **1542b** can have a generally constant diameter from an upper end to a lower end such that the intermediate region **1542b** forms a generally cylindrical shape. The lower region **1542c** of the outer frame body **1542** can extend generally downwardly from the lower end of the intermediate region **1542b**. As shown, the lower region **1542c** of the outer frame body **1542** can have a generally constant diameter from an upper end to a lower end such that the lower region **1542c** forms a generally cylindrical shape. As shown, the diameters of the intermediate region **1542b** and the lower region **1542c** are generally equivalent such that the intermediate region **1542b** and the lower region **1542c** together form a generally cylindrical shape.

[0234] While the intermediate and lower regions **1542b**, **1542c** have been described as cylindrical, it is to be understood that the diameters of the upper end, the lower end, and/or the portion therebetween can be different. For example, a diameter of the portion between the upper end and the lower end can be larger than the upper end and the lower end such that the intermediate region **1542b** and/or lower region **1542c** forms a generally bulbous shape. In some embodiments, the diameter of the lower end can be larger than the diameter of the upper end. In other embodiments, the diameter of the upper end can be larger than the diameter of the lower end. Moreover, although the outer frame body **1542** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the outer frame body **1542** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0235] With continued reference to the outer frame **1540** illustrated in **Figure 33**, the outer frame anchoring feature **1544** can extend outwardly relative to the longitudinal axis of the prosthesis **1500**. As shown in the illustrated embodiment, the outer frame anchoring feature **1544** is attached to the outer frame body **1542** along the upper region **1542a**. The outer frame anchoring feature **1544** can be attached to the outer frame body **1542** such that, when transitioning from a collapsed configuration to an expanded configuration, the tip or end of the outer frame anchoring feature **1544** moves radially outwardly and upwardly.

[0236] In some embodiments, the outer frame anchoring feature **1544** can be attached to the outer frame body **1542** along a portion having a larger diameter, such as the intermediate region **1542b** and/or the second section **1546b**. This can beneficially increase the radial extent of the outer frame anchoring feature **1544** while maintaining the same anchor length. Moreover, in some embodiments, the outer frame anchoring feature **1544** can be attached to the outer frame body **1542** such that, when transitioning from a collapsed configuration to an expanded configuration, the tip or end of the outer frame anchoring feature **1544** moves radially outwardly and downwardly. This can beneficially facilitate alignment of the prosthesis **1500**. For example, in the event that a portion of the prosthesis **1500** is positioned too far into the ventricle, the outer frame anchoring

features **1544** can contact tissue of the native mitral valve and exert a force to elevate at least that portion of the prosthesis **1500**. In some embodiments, the outer frame anchoring feature **1544** can include one or more individual anchors to allow the individual anchors to operate independently of other anchors. In some embodiments, the outer frame anchoring feature **1544** can be relatively flexible. For example, the outer frame anchoring feature **1544** can incorporate anchors having the serpentine shape of anchoring feature **2600** described in connection with **Figure 50**.

[0237] The outer frame **1540**, such as the outer frame body **1542** can be used to attach or secure the prosthesis **1500** to a native valve, such as a native mitral valve. For example, the intermediate region **1542b** of the outer frame body **1542** and/or the outer anchoring feature **1544** can be positioned to contact or engage a native valve annulus, tissue beyond the native valve annulus, native leaflets, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. As another example, the outer frame body **1542** can be sized and positioned relative to the inner frame anchoring feature **1524** such that tissue of the body cavity positioned between the outer frame body **1542** and the inner frame anchoring feature **1524**, such as native valve leaflets and/or a native valve annulus, can be engaged or pinched to further secure the prosthesis **1500** to the tissue.

[0238] With continued reference to the prosthesis **1500** illustrated in **Figure 33**, the valve body **1560** is attached to the inner frame **1520** within an interior of the inner frame body **1522**. The valve body **1560** functions as a one-way valve to allow blood flow in a first direction through the valve body **1560** and inhibit blood flow in a second direction through the valve body **1560**.

[0239] The valve body **1560** can include a plurality of valve leaflets **1562**, for example three leaflets **1562**, which are joined at commissures. The valve body **1560** can include one or more intermediate components **1564**. The intermediate components **1564** can be positioned between a portion of, or the entirety of, the leaflets **1562** and the inner frame **1520** such that at least a portion of the leaflets **1542** are coupled to the frame **1520** via the intermediate component **1564**. In this manner, a portion of, or the entirety of, the portion of the valve leaflets **1562** at the commissures and/or an arcuate edge of the valve

leaflets **1562** are not directly coupled or attached to the inner frame **1520** and are indirectly coupled or "float" within the inner frame **1520**. For example, a portion of, or the entirety of, the portion of the valve leaflets **1562** proximate the commissures and/or the arcuate edge of the valve leaflets **1562** can be spaced radially inward from an inner surface of the inner frame **1520**. By using one or more intermediate components **1564**, the valve leaflets **1562** can be attached to non-cylindrical frames **1520** and/or frames **1520** having a diameter larger than that of the diameter of the valve leaflets **1562**. Further details on floating valve concepts can be found in U.S. Application No. 15/653,390, entitled REPLACEMENT HEART VALVE PROSTHESIS, filed on July 18, 2017, the entirety of which has been incorporated herein by reference.

[0240] With reference next to the outer skirt **1580** illustrated in **Figure 33**, the outer skirt **1580** can be attached to the inner frame **1520** and/or outer frame **1540**. As shown, the outer skirt **1580** can be positioned around and secured to a portion of, or the entirety of, the exterior of the outer frame **1540.** The skirt **1580** can also be secured to a portion of the valve body **1560** such as, but not limited to, the intermediate components **1564**. For example, the skirt **1580** can be attached to an inflow region of the intermediate components **1564**. As shown, the outer skirt **1580** can follow the contours of the outer frame **1540**; however, it is to be understood that at least a portion of the skirt **1580** can be spaced apart from at least a portion of both the inner frame **1520** and the outer frame **1540**.

[0241] With reference next to the inner skirt **1590** illustrated in **Figure 33**, the inner skirt **1590** can be attached to the valve body **1560** and the outer skirt **1580**. As shown, a first end of the inner skirt **1590** can be coupled to the valve body **1560** along portions of the valve body **1560** which are proximate the inner frame **1520**. A second end of the inner skirt **1590** can be attached to the lower region of the outer skirt **1580**. In so doing, a smooth surface can be formed under each of the leaflets. This can beneficially enhance hemodynamics by allowing blood to more freely circulate and reducing areas of stagnation. In some embodiments, the inner skirt **1590** can beneficially reduce contact between the outer frame body **1542** and the inner frame body **1522**.

[0242] Although the prosthesis **1500** has been described as including an inner frame **1520**, an outer frame **1540**, a valve body **1560**, and skirts **1580**, **1590,** it is to be understood that the prosthesis **1500** need not include all components. For example, in some embodiments, the prosthesis **1500** can include the inner frame **1520**, the outer frame **1540**, and the valve body **1560** while omitting the skirt **1580**. Moreover, although the components of the prosthesis **1500** have been described and illustrated as separate components, it is to be understood that one or more components of the prosthesis **1500** can be integrally or monolithically formed. For example, in some embodiments, the inner frame **1520** and the outer frame **1540** can be integrally or monolithically formed as a single component.

[0243] With reference next to **Figures 34-35**, an embodiment of a prosthesis **1600** in an expanded configuration is illustrated. The prosthesis **1600** can include an inner frame **1620**, an outer frame **1640**, a valve body **1660**, and one or more skirts, such as an outer skirt **1680** and an inner skirt **1690**. The prosthesis **1600** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other prostheses described herein such as, but not limited to prostheses **100**, **1500**.

[0244] With reference first to the outer frame **1640** illustrated in **Figures 34-35**, the outer frame **1640** can be attached to the inner frame **1620** using any of the fasteners and/or techniques described herein. Although the outer frame **1640** is illustrated as a separate component from the inner frame **1620**, it is to be understood that the frames **1620**, **1640** can be unitarily or monolithically formed.

[0245] As shown in the illustrated embodiment, the outer frame **1640** can include an outer frame body **1642** and an outer frame anchoring feature **1644**. The outer frame body **1642** can have an upper region **1642a**, an intermediate region **1642b**, and a lower region **1642c**. At least a portion of the upper region **1642a** of the outer frame body **1642** can be sized and/or shaped to generally match the size and/or shape of an upper region **1622a** the inner frame **1620**. As shown in the illustrated embodiment, the upper region **1642a** of the outer frame body **1642** can include one or more struts which generally match the size and/or shape of struts of the inner frame **1620**. This can locally

reinforce a portion of the prosthesis **1600** by effectively increasing the wall thickness of the combined struts. Further details on reinforcing portions of the prosthesis can be found in U.S. Application No. 15/653,390, entitled REPLACEMENT HEART VALVE PROSTHESIS, filed on July 18, 2017, the entirety of which has been incorporated herein by reference.

[0246] When in an expanded configuration such as in a fully expanded configuration, the outer frame body **1642** can have a shape similar to that of outer frame body **1542** described above in connection with **Figure 33**. As shown, the intermediate region **1642b** and the lower region **1642c** can have a diameter which is larger than the diameter of the upper region **1642a**. The upper region **1642a** of the outer frame body **1642** can have a decreasing diameter from a lower end to an upper end such that the upper region **1642a** is inclined or curved radially inwards towards the longitudinal axis of the prosthesis **1600**. Although the outer frame body **1642** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the outer frame body **1642** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0247] With continued reference to the outer frame **1600** illustrated in **Figure 34**, the outer frame body **1642** can include a plurality of struts with at least some of the struts forming cells **1646a-c**. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes.

[0248] The upper row of cells **1646a** can have an irregular octagonal shape such as a "heart" shape. This larger shape can provide additional space for outer frame anchoring feature **1644**. This additional space can beneficially allow the outer frame **1640** to retain a smaller profile when crimped. The cell **1646a** can be formed via a combination of struts. As shown in the illustrated embodiment, the upper portion of cells **1646a** can be formed from a set of circumferentially-expansible struts **1648a** having a zig-zag or undulating shape forming a repeating "V" shape. The struts **1648a** can extend

radially outwardly from an upper end to a lower end. These struts can generally match the size and/or shape of struts of the inner frame **1620**.

[0249] The middle portion of cells **1646a** can be formed from a set of struts **1648b** extending downwardly from bottom ends of each of the "V" shapes. The struts **1648b** can extend radially outwardly from an upper end to a lower end. The portion of the cells **1646a** extending upwardly from the bottom end of struts **1648b** may be considered to be a substantially non-foreshortening portion of the outer frame **1640**.

[0250] The lower portion of cells **1646a** can be formed from a set of circumferentially-expansible struts **1648c** having a zig-zag or undulating shape forming a repeating "V" shape. As shown in the illustrated embodiment, the struts **1648c** can incorporate a curvature such that the lower end of struts **1648c** extend more parallel with the longitudinal axis than the upper end of the struts **1648c**. One or more of the upper ends or tips of the circumferentially-expansible struts **1648c** can be a "free" apex which is not connected to a strut. For example, as shown in the illustrated embodiment, every other upper end or tip of circumferentially-expansible struts **1648b** is a free apex. However, it is to be understood that other configurations can be used. For example, every upper apex along the upper end can be connected to a strut.

[0251] The middle and/or lower rows of cells **1646b-c** can have a different shape from the cells **1646a** of the first row. The middle row of cells **1646b** and the lower row of cells **1646c** can have a diamond or generally diamond shape. The diamond or generally diamond shape can be formed via a combination of struts.

[0252] The upper portion of cells **1646b** can be formed from the set of circumferentially-expansible struts **1648c** such that cells **1646b** share struts with cells **1646a**. The lower portion of cells **1646b** can be formed from a set of circumferentially-expansible struts **1648d**. As shown in the illustrated embodiment, one or more of the circumferentially-expansible struts **1648d** can extend generally in a downward direction generally parallel to the longitudinal axis of the outer frame **1640**.

[0253] The upper portion of cells **1646c** can be formed from the set of circumferentially-expansible struts **1648d** such that cells **1646c** share struts with cells **1646b**. The lower portion of cells **1646c** can be formed from a set of circumferentially-

expansible struts **1648e**. Circumferentially-expansible struts **1648e** can extend generally in a downward direction.

[0254] As shown in the illustrated embodiment, there can be a row of nine cells **1646a** and a row of eighteen cells **1646b-c**. While each of the cells **1646a-c** are shown as having the same shape as other cells **1646a-c** of the same row, it is to be understood that the shapes of cells **1646a-c** within a row can differ. Moreover, it is to be understood that any number of rows of cells can be used and any number of cells may be contained in the rows.

[0255] With continued reference to **Figures 34-35**, the outer frame **1640** can include an outer frame anchoring feature **1644**. The outer frame anchoring feature **1644** can include one or more individual anchors **1644a** having tips or ends **1644b**. As shown, the outer frame anchoring feature **1644** includes nine anchors; however, it is to be understood that a fewer or greater number of anchors can be used. For example, the outer frame anchoring feature **1644** can include three anchors **1644a**.

[0256] As shown, the anchors **1644a** extend from an upper portion of cells **1646a**, such as an upper apex of cells **1646a**. The anchors **1644a** can extend downwardly. The anchors **1644a** can be attached to the outer frame body **1642** such that, when transitioning from a collapsed configuration to an expanded configuration, the tip or end **1644b** of the anchors **1644a** moves radially outwardly and upwardly.

[0257] In some embodiments, one or more anchors **1644a** can be attached to the outer frame body **1642** along struts **1648c**. For example, the anchors **1644a** can extend from one or more of the free apices. The anchors **1644a** can be attached to the outer frame body **1642** such that, when transitioning from a collapsed configuration to an expanded configuration, the tip or end **1644b** of the anchors **1644a** moves radially outwardly and downwardly. This can beneficially facilitate alignment of the prosthesis **1600**.

[0258] As shown in the illustrated embodiment, the outer frame **1600** can include a set of eyelets **1650**. The upper set of eyelets **1650** can extend from an upper region **1642a** of the outer frame body **1642**. As shown, the upper set of eyelets **1650** can extend from an upper portion of cells **1646a**, such as the upper apices of cells **1646a**.

The upper set of eyelets **1650** can be used to attach the outer frame **1640** to the inner frame **1620**. For example, in some embodiments, the inner frame **1620** can include one or more eyelets which correspond to the eyelets **2150**. In such embodiments, the inner frame **1620** and outer frame **1640** can be attached together via eyelets **1650** and corresponding eyelets on the inner frame **1620**. For example, the inner frame **1620** and outer frame **1640** can be sutured together through said eyelets or attached via other means, such as mechanical fasteners (e.g., screws, rivets, and the like).

[0259] As shown, the set of eyelets **1650** can include two eyelets extending in series from each "V" shaped strut. This can reduce the likelihood that the outer frame **1640** twists along an axis of the eyelet. However, it is to be understood that some "V" shaped struts may not include an eyelet. Moreover, it is to be understood that a fewer or greater number of eyelets can extend from a "V" shaped strut.

[0260] The outer frame **1640** can include a set of locking tabs **1652** extending from at or proximate an upper end of the upper region **1642a**. As shown, the locking tabs **1652** can extend upwardly from the set of eyelets **1650**. The outer frame **1640** can include twelve locking tabs **1652**, however, it is to be understood that a greater number or lesser number of locking tabs can be used. The locking tabs **1652** can include a longitudinally-extending strut **1652a**. At an upper end of the strut **1652a**, the locking tab **1652** can include an enlarged head **1652b**. As shown, the enlarged head **1652b** can have a semi-circular or semi-elliptical shape forming a "mushroom" shape with the strut **1652a**. The locking tab **1652** can include an eyelet **1652c** which can be positioned through the enlarged head **1652b**. It is to be understood that the locking tab **1652** can include an eyelet at other locations, or can include more than a single eyelet.

[0261] The locking tab **1652** can be advantageously used with multiple types of delivery systems. For example, the shape of the struts **1652a** and the enlarged head **1652b** can be used to secure the outer frame **1640** to a "slot" based delivery system. The eyelets **1652c** and/or eyelets **1650** can be used to secure the outer frame **1640** to a "tether" based delivery system such as those which utilize sutures, wires, or fingers to control delivery of the outer frame **1640** and the prosthesis **1600**. This can advantageously facilitate recapture and repositioning of the outer frame **1640** and the

prosthesis **1600** in situ. In some embodiments, the prosthesis **1600** can be used with the delivery systems described herein, including but not limited to, those described in U.S. Patent Nos. 8,414,644 and 8,652,203 and U.S. Publication Nos. 2015/0238315, the entireties of each of which are hereby incorporated by reference and made a part of this specification.

[0262] The outer frame **1640**, such as the outer frame body **1642** can be used to attach or secure the prosthesis **1600** to a native valve, such as a native mitral valve. For example, the intermediate region **1642b** of the outer frame body **1642** and/or the outer anchoring feature **1644** can be positioned to contact or engage a native valve annulus, tissue beyond the native valve annulus, native leaflets, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. As another example, the outer frame body **1642** can be sized and positioned relative to the inner frame anchoring feature **1624** such that tissue of the body cavity positioned between the outer frame body **1642** and the inner frame anchoring feature **1624**, such as native valve leaflets and/or a native valve annulus, can be engaged or pinched to further secure the prosthesis **1600** to the tissue. As shown, the inner frame anchoring feature **1624** includes nine anchors; however, it is to be understood that a fewer or greater number of anchors can be used. In some embodiments, the number of individual anchors can be chosen as a multiple of the number of commissures for the valve body **1660**. For example, for a valve body **1660** have three commissures, the inner frame anchoring feature **1624** can have three individual anchors (1:1 ratio), six individual anchors (2:1 ratio), nine individual anchors (3:1 ratio), twelve individual anchors (4:1 ratio), fifteen individual anchors (5:1 ratio), or any other multiple of three. In some embodiments, the number of individual anchors does not correspond to the number of commissures of the valve body **1660**.

[0263] With continued reference to the prosthesis **1600** illustrated in **Figures 34-35**, the valve body **1660** is attached to the inner frame **1620** within an interior of the inner frame body **1622**. The valve body **1660** functions as a one-way valve to allow blood flow in a first direction through the valve body **1660** and inhibit blood flow in a second direction through the valve body **1660**.

[0264] The valve body **1660** can include a plurality of valve leaflets **1662**, for example three leaflets **1662**, which are joined at commissures. The valve body **1660** can include one or more intermediate components **1664**. The intermediate components **1664** can be positioned between a portion of, or the entirety of, the leaflets **1662** and the inner frame **1620** such that at least a portion of the leaflets **1642** are coupled to the frame **1620** via the intermediate component **1664**. In this manner, a portion of, or the entirety of, the portion of the valve leaflets **1662** at the commissures and/or an arcuate edge of the valve leaflets **1662** are not directly coupled or attached to the inner frame **1620** and are indirectly coupled or "float" within the inner frame **1620**. Further details on floating valve concepts can be found in U.S. Application No. 15/653,390, entitled REPLACEMENT HEART VALVE PROSTHESIS, filed on July 18, 2017, the entirety of which is incorporated herein by reference.

[0265] With reference next to the outer skirt **1680** illustrated in **Figure 34**, the outer skirt **1680** can be attached to the inner frame **1620** and/or outer frame **1640**. As shown, the outer skirt **1680** can be positioned around and secured to a portion of, or the entirety of, the exterior of the outer frame **1640.** The inner skirt **1690** can be attached to the valve body **1660** and the outer skirt **1680**. As shown, a first end of the inner skirt **1690** can be coupled to the valve body **1660** along portions of the valve body **1660** which are proximate the inner frame **1620**. A second end of the inner skirt **1690** can be attached to the lower region of the outer skirt **1680**. In so doing, a smooth surface can be formed along under each of the leaflets. This can beneficially enhance hemodynamics by allowing blood to more freely circulate and reducing areas of stagnation.

[0266] Although the prosthesis **1600** has been described as including an inner frame **1620**, an outer frame **1640**, a valve body **1660**, and skirts **1680**, **1690,** it is to be understood that the prosthesis **1600** need not include all components. For example, in some embodiments, the prosthesis **1600** can include the inner frame **1620**, the outer frame **1640**, and the valve body **1660** while omitting the skirt **1680**. Moreover, although the components of the prosthesis **1600** have been described and illustrated as separate components, it is to be understood that one or more components of the prosthesis **1600** can be integrally or monolithically formed. For example, in some embodiments, the

inner frame **1620** and the outer frame **1640** can be integrally or monolithically formed as a single component.

[0267] With reference next to **Figure 36**, an embodiment of an inner frame **1700** in an expanded configuration is illustrated. The inner frame **1700** can include an inner frame body **1702**, an inner frame anchoring feature **1704** and/or a set of locking tabs **1712**. The locking tabs **1812** can include features similar to other locking tabs described herein. As shown in the illustrated embodiment, the tips or ends of the inner frame anchoring feature **1704** can incorporate two or more prongs which extend in different directions. This can beneficially increase a tissue contact surface for the tips or ends particularly when used with a cover or cushion.

[0268] The inner frame body **1702** can have an upper region **1702a**, an intermediate region **1702b**, and a lower region **1702c**. The inner frame body **1702** can have a shape similar to that described above in connection with inner frame bodies **1520** and **1620**. As shown, the inner frame body **1702** can have a generally bulbous shape such that the diameters of the upper region **1702a** and the lower region **1702c** are less than the diameter of the intermediate region **1702b**. The diameter of the upper region **1702a** can be less than the diameter of the lower region **1702c**.

[0269] While the illustrated inner frame body **1702** is bulbous, it is to be understood that the diameters of the upper region **1702a**, the intermediate region **1702b**, and/or the lower region **1702c** can be the same such that the inner frame body **1702** is generally cylindrical along one or more regions. Moreover, while the illustrated embodiment includes a lower region **1702a** having a greater diameter than the upper region **1702c**, it is to be understood that the diameters of the lower and upper regions **1702a, 1702c** can be the same or the diameter of the upper region **1702a** can be greater than the diameter of the lower region **1702c**. Moreover, although the inner frame body **1702** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the inner frame body **1702** can have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0270] The inner frame body **1702** can include a plurality of struts with at least some of the struts forming cells **1706a-c**. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes.

[0271] The upper row of cells **1706a** can have an elongated hexagonal shape. The cell **1706a** can be formed via a combination of struts. As shown in the illustrated embodiment, the upper portion of cells **1706a** can be formed from a set of circumferentially-expansible struts **1708a** having a zig-zag or undulating shape forming a repeating "V" shape. The struts **1708a** can extend radially outwardly from an upper end to a lower end.

[0272] The middle portion of cells **1706a** can be formed from a set of eyelets **1710** extending downwardly from bottom ends of each of the "V" shapes. The eyelets **1710** can extend radially outwardly from an upper end to a lower end. The eyelets **1710** can be used to attach various components to the inner frame **1700**. In some embodiments, the eyelets **1710** can be used to attach the inner frame **1700** to an outer frame. For example, the outer frame may be similar to outer frame **1640** having eyelets **1650.** Such an attachment location can be lower than that illustrated in connection with prosthesis **1600**. This can allow the use of a more axially compact outer frame. In some embodiments, the eyelets **1710** can be utilized to attach a valve body to the inner frame **1700**.

[0273] The portion of the cells **1706a** extending upwardly from the bottom end of eyelets **1710** may be considered to be a substantially non-foreshortening portion of the inner frame **1700**. Although eyelets **1710** are used, it is to be understood that a strut can be utilized in lieu of or in combination with eyelets **1710**.

[0274] The lower portion of cells **1706a** can be formed from a set of circumferentially-expansible struts **1708b** having a zig-zag or undulating shape forming a repeating "V" shape. As shown in the illustrated embodiment, the struts **1708b** can incorporate a curvature such that the lower end of struts **1708b** extend more parallel with the longitudinal axis than the upper end of the struts **1708b**.

[0275] The middle and/or lower rows of cells **1706b-c** can have a different shape from the cells **1706a** of the first row. The middle row of cells **1706b** and the lower row of cells **1706c** can have a diamond or generally diamond shape. The diamond or generally diamond shape can be formed via a combination of struts.

[0276] The upper portion of cells **1706b** can be formed from the set of circumferentially-expansible struts **1708b** such that cells **1706b** share struts with cells **1706a**. The lower portion of cells **1706b** can be formed from a set of circumferentially-expansible struts **1708c**. As shown in the illustrated embodiment, one or more of the circumferentially-expansible struts **1708c** can extend generally in a downward direction generally parallel to the longitudinal axis of the outer frame **1640**.

[0277] The upper portion of cells **1706c** can be formed from the set of circumferentially-expansible struts **1708c** such that cells **1706c** share struts with cells **1706b**. The lower portion of cells **1706c** can be formed from a set of circumferentially-expansible struts **1708d**. Circumferentially-expansible struts **1708d** can extend generally in a downward direction and/or radially inward direction..

[0278] As shown in the illustrated embodiment, there can be nine cells in each row of cells **1706a-c**. While each of the cells **1706a-c** are shown as having the same shape as other cells **1706a-c** of the same row, it is to be understood that the shapes of cells **1706a-c** within a row can differ. Moreover, it is to be understood that any number of rows of cells can be used and any number of cells may be contained in the rows.

[0279] With reference next to **Figure 37**, an embodiment of an outer frame **1800** in an expanded configuration is illustrated. The outer frame **1800** can include an outer frame body **1802** and/or locking tabs **1812**. The locking tabs **1812** can include features similar to other locking tabs described herein.

[0280] When in an expanded configuration such as in a fully expanded configuration, the outer frame body **1802** can have a shape similar to that of outer frames **1540** and **1640** described above in connection with **Figures 33 and 34-35**. As shown, the intermediate region **1802b** and the lower region **1802c** can have a diameter which is larger than the diameter of the upper region **1802a**. The upper region **1802a** of the outer frame body **1802** can increase in diameter from an upper end to a lower end such that the

upper region **1802a** is inclined or curved radially outwards away from the longitudinal axis of the outer frame **1800**. Although the outer frame body **1802** has been illustrated as having a circular cross-sections, it is to be understood that all or a portion of the outer frame body **1802** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0281] The outer frame body **1802** can include a plurality of struts with at least some of the struts forming cells **1804a-b**. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes.

[0282] The upper region **1802a** can include an elongate strut **1806a**. The elongate strut **1806a** can extend radially outwardly from the longitudinal axis of the outer frame **1802**. The elongate strut **1806a** can incorporate a bend **1808** to orient an upper portion of the strut **1806a** in a direction more parallel with the longitudinal axis. The use of an elongate strut **1806a** can reduce the change in axial length when the outer frame **1800** transitions from a collapsed configuration to an expanded configuration.

[0283] In some embodiments, the elongate strut **1806a** can beneficially dampen radial displacements and/or forces experienced by other portions of the outer frame body **1800**. For example, the elongate strut **1806a** can dampen radial displacements and/or forces due to compression of the intermediate and/or lower regions **1802b**, **1802c** during phases of the cardiac cycle. In situations where the outer frame **1800** is positioned within a native mitral valve, these compressive forces can be cyclically imparted by the native mitral valve annulus during phases of the cardiac cycle. Dampening of such displacements and/or forces by the elongate strut **1806a** can reduce forces applied on an inner frame which may cause undesirable movement and/or deformation of the inner frame. The amount of dampening can be chosen by adjusting the width, length, taper, materials, and other characteristics of the elongate strut **1806a**.

[0284] The upper row of cells **1804a** can have a diamond or generally diamond shape. As shown in the illustrated embodiment, the upper portion of cells **1804a** can be formed from a set of circumferentially-expansible struts **1806b** having a zig-zag or undulating shape forming a repeating "V" shape. One or more of the upper

ends or tips of the circumferentially-expansible struts **1806b** can be a "free" apex which is not connected to a strut. For example, as shown in the illustrated embodiment, every other upper end or tip of circumferentially-expansible struts **1806b** is a free apex. However, it is to be understood that other configurations can be used. For example, every upper apex along the upper end can be connected to a strut. The lower portion of cells **1804a** can be formed from a set of circumferentially-expansible struts **1806c** having a zig-zag or undulating shape forming a repeating "V" shape. Although the outer frame **1800** is shown without an anchoring feature, it is to be understood that an anchoring feature may be incorporated into the outer frame **1800** in a manner similar to those described in connection with other outer frames described herein. For example, an anchoring feature may extend from one or more of the free apices of the circumferentially-expansible struts **1806b**.

[0285] The upper portion of cells **1804b** can be formed from the set of circumferentially-expansible struts **1806c** such that cells **1804b** share struts with cells **1804a**. The lower portion of cells **1804b** can be formed from a set of circumferentially-expansible struts **1806d**.

[0286] As shown in the illustrated embodiment, there can be a row of eighteen cells **1804a-b**. While each of the cells **1804a-b** are shown as having the same shape as other cells **1804a-b** of the same row, it is to be understood that the shapes of cells **1804a-b** within a row can differ. Moreover, it is to be understood that any number of rows of cells can be used and any number of cells may be contained in the rows.

[0287] As shown in the illustrated embodiment, the outer frame **1800** can include a set of eyelets **1810**. The eyelets **1810** can extend from an upper region **1802a** of the outer frame body **1802**. As shown, the eyelets **1810** can extend from an upper end of struts **1806a**. In some embodiments, the eyelets **1810** can be used to attach the outer frame **1800** to an inner frame. For example, the inner frame may be similar to inner frame **1620** and/or **1700** having eyelets **1710.** This can allow the use of a more axially compact outer frame. In some embodiments, the eyelets **1710** can be utilized to attach a valve body to the inner frame **1700**. In some embodiments, the upper set of eyelets **1810**

can be used to attach the outer frame **1800** to a delivery system. For example, sutures or tethers of a delivery system can be attached or passed through the eyelets **1810**.

[0288] With reference next to **Figure 38A**, an embodiment of a prosthesis **1900** in an expanded configuration is illustrated. The prosthesis **1900** can include an inner frame **1920**, an outer frame **1940**, a valve body **1960**, and one or more skirts, such as outer skirt **1980** and inner skirt **1990**. The prosthesis **1900** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other prostheses described herein.

[0289] With reference first to the inner frame **1920**, the inner frame **1920** can include an inner frame body **1922** and an inner frame anchoring feature **1924**. The inner frame body **1922** can have an upper region **1922a**, an intermediate region **1922b**, and a lower region **1922c**. As shown, the inner frame body **1922** can have a generally cylindrical shape. The inner frame body **1922** can include a bend **1926** along a lower region **1922c** of the inner frame body **1920** such that a region **1928** of the inner frame body **1920** tapers radially inwardly towards the longitudinal axis of the prosthesis **1900**. The shape of region **1928** can match the shape of a portion of the outer frame **1940**.

[0290] While the illustrated inner frame body **1922** is generally cylindrical, it is to be understood that the diameters of the upper region **1922a**, the intermediate region **1922b**, and/or the lower region **1922c** can be different. For example, in some embodiments, a diameter of the intermediate region **1922a** can be larger than the upper region **1922b** and the lower region **1922c** such that the frame body **1922** has a generally bulbous shape. Moreover, although the inner frame body **1922** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the inner frame body **1922** can have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0291] With reference next to the outer frame **1940** illustrated in **Figure 38A**, the outer frame **1940** can be attached to the inner frame **1920** using any of the fasteners and/or techniques described herein. Although the outer frame **1940** is illustrated as a

separate component from the inner frame **1920**, it is to be understood that the frames **1920**, **1940** can be unitarily or monolithically formed.

[0292] As shown in the illustrated embodiment, the outer frame **1940** can include an outer frame body **1942** and an outer frame anchoring feature **1944**. The outer frame body **1942** can have an upper region **1942a**, an intermediate region **1942b**, and a lower region **1942c**. When in an expanded configuration such as a fully expanded configuration, the outer frame body **1942** can have an enlarged shape with the upper region **1942a** and the intermediate region **1942b** being larger than the lower region **1942c**. The enlarged shape of the outer frame body **1942** can advantageously allow the outer frame body **1942** to engage a native valve annulus, native valve leaflets, or other tissue of the body cavity, while spacing the upper end from the heart or vessel wall.

[0293] As shown in the illustrated embodiment, the lower region **1942c** of the outer frame body **1942** can be attached to the lower region **1922c** of the inner frame body **1922**. This can provide significant advantages particularly with respect to the geometry of the prosthesis **1900** when the prosthesis **1900** is in a crimped or collapsed configuration. For example, in embodiments where the outer frame body **1942** is capable of foreshortening, any increase in the axial length of the outer frame body **1942** as the outer frame body **1942** is crimped occurs upwardly relative to the lower regions **1922c**, **1942c** from which the frame bodies are attached. In this manner, regardless of the axial length of the outer frame body **1942** in the crimped or collapsed configuration, the outer frame body **1942** can be prevented from extending over the inner frame anchoring features **1922** when crimped or collapsed.

[0294] The lower region **1942c** of the outer frame body **1942** can include a region **1946**. The region **1946** can extend radially inwardly towards the longitudinal axis of the prosthesis **1900.** As shown in the illustrated embodiment, a portion of region **1946** can be sized and/or shaped to generally match the size and/or shape of the region **1928** of inner frame **1920**. This can advantageously enhance securement of the outer frame **1940** to the inner frame **1920** by providing a greater area over which the outer frame **1940** can be attached to the inner frame **1920**. Moreover, by bending the region **1928** of inner frame **1920** to match the shape of region **1946** of the outer frame **1940**, the fatigue

resistance of the outer frame **1940** can be enhanced as the lower end of outer frame **1940** need not be significantly bent to match the geometry of the inner frame **1920**.

[0295] The intermediate region **1942b** of the outer frame body **1942** can extend generally upwardly from the lower region **1942c**. As shown, the intermediate region **1942b** can have a generally constant diameter from an upper end to a lower end such that the intermediate region **1942b** forms a generally cylindrical shape. The upper region **1942a** of the outer frame body **1942** can extend generally upwardly from the lower end of the intermediate region **1942b**. As shown, the upper region **1942a** of the outer frame body **1942** can have a generally constant diameter from an upper end to a lower end such that the upper region **1942a** forms a generally cylindrical shape. While, the diameters of the intermediate region and the upper region **1942a** are generally equivalent such that the intermediate region and the upper region **1942b**, **1942a** together form a generally cylindrical shape, it is to be understood that the diameters of the upper end, the lower end, and/or the portion therebetween can be different.

[0296] For example, a diameter of the portion between the upper end and the lower end can be larger than the upper end and the lower end such that the intermediate region and/or lower region **1942b**, **1942a** forms a generally bulbous shape. In some embodiments, the diameter of the lower end can be larger than the diameter of the upper end. In other embodiments, the diameter of the upper end can be larger than the diameter of the lower end.

[0297] As another example, the diameter of the upper end of the upper region **1942a** can be greater than the diameter of the lower end of the upper region **1942a** such that the upper region **1942a** extends radially outwardly away from the longitudinal axis of the prosthesis **1900**. This can advantageously enhance securement and/or stability when the prosthesis **1900** is positioned within a native valve, such as the native mitral valve. For example, when the prosthesis **1900** is positioned within a native mitral valve, the upper region **1942a** can extend radially outwardly over an atrial side of the native mitral valve annulus. This can inhibit movement of the prosthesis **1900** into the left ventricle during phases of the cardiac cycle (e.g., diastole). In some embodiments, the upper end can increase to a diameter which is similar to, or greater than, a diameter

formed around the tips or ends **1924b** of inner frame anchoring feature **1924**. In some embodiments, the upper region **1942a** can extend generally perpendicularly to the intermediate region **1942b** to form a flange.

[0298] Moreover, although the outer frame body **1942** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the outer frame body **1942** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0299] With continued reference to the outer frame **1940** illustrated in **Figure 38A**, the outer frame anchoring feature **1944** can extend outwardly relative to the longitudinal axis of the prosthesis **1900**. As shown in the illustrated embodiment, the outer frame anchoring feature **1944** is attached to the outer frame body **1942** along the upper region **1942a**. The outer frame anchoring feature **1944** can be attached to the outer frame body **1942** such that, when transitioning from a collapsed configuration to an expanded configuration, the tip or end of the outer frame anchoring feature **1944** moves radially outwardly and downwardly; however, it is to be understood that the outer frame anchoring feature **1944** can be attached to the outer frame body **1942** such that, when transitioning from a collapsed configuration to an expanded configuration, the tip or end of the outer frame anchoring feature **1944** moves radially outwardly and upwardly. The radial extent of the outer frame anchor feature **1944** can be generally the same as the radial extend of the inner frame anchoring feature **1924**. Although the anchoring feature **1944** is shown attached to the outer frame body **1942**, it is to be understood that the anchoring feature **1944** can be attached to the inner frame body **1922**. Moreover, it is to be understood that the anchoring feature **1944** can be one or more barbs or penetrating structures. The barbs may be angled upwardly, angled downwardly, and/or perpendicular. Although shown extending along an upper region of the outer frame body **1942**, it is to be understood that such barbs or other penetrating structures may extend along other regions of the outer frame body **1942**.

[0300] Similar to other prostheses described herein, components of the outer frame **1940**, can be used to attach or secure the prosthesis **1900** to a native valve, such as

a native mitral valve. For example, the intermediate region **1942b** of the outer frame body **1942** and/or the outer anchoring feature **1944** can be positioned to contact or engage a native valve annulus, tissue beyond the native valve annulus, native leaflets, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. As another example, the outer frame body **1942** can be sized and positioned relative to the inner frame anchoring feature **1924** such that tissue of the body cavity positioned between the outer frame body **1942** and the inner frame anchoring feature **1924**, such as native valve leaflets and/or a native valve annulus, can be engaged or pinched to further secure the prosthesis **1900** to the tissue. As shown in the illustrated embodiment, the profile of the outer frame **1940** can generally match the profile of the inner frame anchoring feature **1924**. This can beneficially enhance sealing along the outer frame **1940** when tissue, such as a leaflet, is captured between the outer frame **1940** and the inner frame anchoring feature **1924**. This can also beneficially enhance sealing along the outer frame **1940** even if tissue, such as a leaflet, is not captured between the outer frame **1940** and the inner frame anchoring feature.

[0301] The shape of the illustrated outer frame body **1942** can enhance securement of the prosthesis **1900**. For example, as shown in **Figure 38B**, in some instances where the prosthesis **1900** is positioned within the native mitral valve, the outer frame **1940** can compress in a manner such that the region above the annulus **40** bends further radially inwardly than a region below the annulus **40**. This can allow the outer frame **1940** to impart a force on the native leaflets and/or native mitral valve annulus **40** in at least a direction towards the atrium. This application of force can result in a counter-force which can tend to push the outer frame **1940**, and the prosthesis **1900**, towards the ventricle. In embodiments where the inner frame anchoring feature **1924** contacts the annulus **40**, this can reduce the systolic loads applied to the inner frame anchoring feature **1924** during systole. This can beneficially reduce and distribute fatigue loads on the inner frame anchoring feature **1924**. Moreover, this counter-force can reduce the likelihood that the prosthesis **1900** shifts towards the atrium during systole.

[0302] However, it is to be understood that the outer frame **1900** can take on other shapes. For example, in some instances where the prosthesis **1900** is positioned

within the native mitral valve, the outer frame **1940** can compress in a manner such that the region below the annulus **40** bends further radially inwardly than a region above the annulus **40**. This can allow the outer frame **1940** to impart a force on the native leaflets and/or native mitral valve annulus **40** in at least a direction towards the ventricle. This application of force can result in a counter-force which can tend to push the outer frame **1940**, and the prosthesis **1900**, towards the atrium. In embodiments where the inner frame anchoring feature **1924** contacts the annulus, this can increase the force applied by the inner frame anchoring feature **1924** to the annulus. Moreover, this counter-force can reduce the likelihood that the prosthesis **1900** shifts towards the left ventricle during stages of the cardiac cycle.

[0303] The shape of the illustrated outer frame body **1942** can facilitate positioning of the inner frame anchoring feature **1924** during partial deployment of the prosthesis **1900**. During this stage of deployment, the inner frame anchoring feature **1924** can be released while the upper end of the outer frame body **1942** is retained within the delivery system. Since the larger diameter portion of the outer frame body **1942** is proximate the upper region **1942a** of the outer frame body **1942** and the lower region **1942c** is attached to the inner frame **1920**, the outer frame body **1942** can be substantially constrained from expanding. In this manner, the outer frame body **1942** can be maintained in a smaller profile during partial deployment. The smaller profile of the outer frame body **1942** can increase the gap between the inner frame anchoring feature **1924** and the outer frame body **1942** during partial deployment which can facilitate placement of the inner frame anchoring feature **1924** at a target tissue location and/or capture of native valve tissue between the inner frame anchoring feature **1924** and the outer frame body **1942**.

[0304] With continued reference to the prosthesis **1900** illustrated in **Figure 38A**, the valve body **1960** is attached to the inner frame **1920** within an interior of the inner frame body **1922**. The valve body **1960** functions as a one-way valve to allow blood flow in a first direction through the valve body **1960** and inhibit blood flow in a second direction through the valve body **1960**. As shown in the illustrated embodiment, the valve body **1960** can include a plurality of leaflets **1962** and/or a liner **1964**. The

liner **1964** can be positioned between at least the upper edges of the leaflets **1962** to an inflow end of the inner frame **1960**. In some instances, the leaflets **1962** can be attached to the liner **1964** which is attached to the inner frame **1960**.

[0305] With reference next to the skirts **1980**, **1990** illustrated in **Figure 38A**, the outer skirt **1980** can be attached to the inner frame **1920** and/or outer frame **1940**. As shown, the outer skirt **1980** can be positioned around and secured to a portion of, or the entirety of, the exterior of the outer frame **1940.** As shown, the outer skirt **1980** can follow the contours of the outer frame **1940**; however, it is to be understood that at least a portion of the skirt **1980** can be spaced apart from at least a portion of both the inner frame **1920** and the outer frame **1940**. The inner skirt **1990** can be attached to the valve body **1960** and the outer skirt **1980**. As shown, a first end of the inner skirt **1990** can be coupled to the valve body **1960** along portions of the valve body **1960** which are proximate the inner frame **1920**. A second end of the inner skirt **1990** can be attached to the lower region of the outer skirt **1980**. Although described as separate structures, it is to be understood that the outer skirt **1980** and the inner skirt **1990** can be monolithically formed. Moreover, it is to be understood that the liner **1964** and the inner skirt **1990** can be monolithically formed.

[0306] The outer skirt **1980** can extend to a location below the connection between the inner frame body **1922** and the inner frame anchoring feature **1924**. This can advantageously provide a greater surface area upon which the outer skirt **1980** can form a seal with tissue of the native valve, such as the native mitral valve. Moreover, the inward taper of the outer skirt **1980** can better conform to the native anatomy, such as the native mitral valve leaflets, when parts of the native anatomy are positioned between the inner frame anchoring feature **1924** and the outer frame **1940**. This can further enhance sealing along the outer skirt **1980**.

[0307] Although the outer skirt **1980** is shown extending along an exterior of the outer frame body **1942**, it is to be understood that the outer skirt **1980** can extend along an interior of the outer frame body **1942**. This can allow the outer frame body **1942** to directly contact tissue of the body cavity. In embodiments where the outer frame body **1942** includes struts and/or cells, the tissue can extend between the struts and/or

cells. This can beneficially enhance securement of the prosthesis **1900** to the body cavity.

[0308] As shown in the illustrated embodiment, a cavity **1992** can be formed between the outer skirt **1980** and the inner skirt **1990** which opens upwardly. In instances where the prosthesis **1900** is positioned within the native mitral valve, the cavity **1992** can open towards the atrium. Accordingly, during systole, the cavity **1992** can be at a lower pressure than the ventricle. This can beneficially enhance sealing outer skirt **1980** since the native tissue, such as the native mitral valve leaflets, are forced towards the outer skirt **1980** due to a pressure differential between the ventricle and the cavity **1992**.

[0309] In some embodiments, the cavity **1992** can be filed with material such as, but not limited to, silicone, saline, foam, hydrogel, knit polyesters such as polyethylene terephthalate (PET) and/or polyvalerolactone (PVL), other materials, and/or a combination of such materials. The filler material can be included in the cavity **1992** prior to the prosthesis **1900** being deployed. In some embodiments, the filler material can be added after the prosthesis **1900** has been at least partially deployed. For example, the filler material can be pre-formed into a cylindrical shape or ring can subsequently positioned within the cavity **1992** after the prosthesis **1900** has been deployed.

[0310] The filler material can be used to fill the cavity **1992** to reduce the open volume. In some embodiments, the filler material can promote tissue growth within the cavity. In some embodiments, the filler material can promote healing of tissue surrounding the prosthesis **1900**. In some embodiments, the filler material can beneficially alter the structural characteristics of the outer frame **1940** and/or inner frame **1920**. For example, the filler material can be used to reduce the compliancy of the outer frame **1940** along certain portions of the outer frame and/or to transmit forces applied to the outer frame **1940** to the inner frame **1920**. This can beneficially allow the outer frame **2040** to exert a greater force along these regions.

[0311] In some embodiments, the cavity **1992** can include a cover (not shown) to partially or fully close the cavity **1992**. An upper end of the outer skirt **1980** can be attached to the upper end of the inner skirt **1990** and/or liner **1964** such that the

cover extends generally perpendicular to the longitudinal axis. However, it is to be understood that the cover can take other shapes. In some embodiments, the cover can extend downwardly and radially inwardly to funnel blood towards the inflow end of the inner frame **1920**. In some embodiments, the cover can extend upwardly and radially inwardly. This can form a tapered shape which can facilitate recapture of the device.

[0312] In some embodiments, the cover can be at least partially permeable to allow the flow of blood into the cavity **1992** and/or sufficiently impermeable to inhibit larger particulates such as clots. For example, the cover can be formed from a mesh such as a cloth or wire mesh, a woven material, and/or a perforated material. This can facilitate the growth of tissue within the cavity **1992** and/or on the cover. For example, the cover can allow for endothelialization. This tissue growth can be enhanced in combination with the filler material noted above. In some embodiments, the cover can be formed from a substantially impermeable material to inhibit the flow of fluids into the cavity **1992**. In some embodiments, this material can be the same material forming the skirt **2080** and/or the inner skirt **1990**.

[0313] Although the prosthesis **1900** has been described as including an inner frame **1920**, an outer frame **1940**, a valve body **1960**, and skirts **1980**, **1990,** it is to be understood that the prosthesis **1900** need not include all components. For example, in some embodiments, the prosthesis **1900** can include the inner frame **1920**, the outer frame **1940**, the valve body **1960**, and the outer skirt **1980** while omitting the inner skirt **1990**, particularly in instances where a cover is used. Moreover, although the components of the prosthesis **1900** have been described and illustrated as separate components, it is to be understood that one or more components of the prosthesis **1900** can be integrally or monolithically formed. For example, in some embodiments, the inner frame **1920** and the outer frame **1940** can be integrally or monolithically formed as a single component.

[0314] With reference next to **Figures 39-42**, an embodiment of a prosthesis **2000** in an expanded configuration, or components of the prosthesis **2000**, are illustrated. The prosthesis **2000** can include an inner frame **2020**, an outer frame **2040**, a valve body **2060**, and a skirt **2080**. The prosthesis **1900** can share characteristics, such as structure

and/or functionality, which are the same as, or at least similar to, those of other prostheses described herein such as prosthesis **1900**.

[0315] With reference first to the outer frame **2040** illustrated in **Figures 39-41**, the outer frame **2040** can include an outer frame body **2042**. The outer frame body **2042** can have an upper region **2042a**, an intermediate region **2042b**, and a lower region **2042c**. As shown, when in an expanded configuration such as the fully expanded configuration, the outer frame body **2042** can have an enlarged shape with an upper region **2042a** and an intermediate region **2042b** being larger than the lower region **2042c**. The enlarged shape of the outer frame body **2040** can advantageously allow the outer frame body to engage a native valve annulus, native valve leaflets, or other body cavity, while spacing the inlet and outlet from the heart or vessel wall.

[0316] The lower region **2042c** of the outer frame body **2042** can extend radially outwardly away from the longitudinal axis of the prosthesis **2000** and/or in an upward direction towards the upper region. As shown in the illustrated embodiment, the lower region **2042c** can incorporate a bend or curve such that the angle of the lower region **2042c** relative to the longitudinal axis decreases towards an upper end of the lower region **2042c**. However, it is to be understood that in some embodiments, the lower region **2042c** can extend substantially linearly.

[0317] The intermediate region **2042b** of the outer frame body **2042** can extend generally upwardly from the lower region **2042c**. As shown, the intermediate region **2042b** can have a generally constant diameter from a lower end to an upper end such that the intermediate region **2042b** forms a generally cylindrical shape. The upper region **2042a** of the outer frame body **2042** can extend generally upwardly from the upper end of the intermediate region **2042b**. As shown, the upper region **2042a** of the outer frame body **2042** can have a generally constant diameter from a lower end to an upper end such that the upper region **2042a** forms a generally cylindrical shape. However, it is to be understood that the diameters of the upper end, the lower end, and/or the portion therebetween of the intermediate region and/or upper region **2042b**, **2042a** can be different. For example, in some embodiments, a diameter of the portion between the upper and lower ends can be larger than diameters of the upper and lower ends such that

the intermediate region and/or upper region **2042b**, **2042a** form a generally bulbous shape (as shown, for example, in connection with frame **300** illustrated in **Figures 7-8**). In some embodiments, the diameter of the lower end can be larger than the diameter of the upper end. In other embodiments, the diameter of the upper end can be larger than the diameter of the lower end.

[0318] Moreover, although the outer frame body **2042** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the outer frame body **2042** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0319] With continued reference to the outer frame **2040** illustrated in **Figures 39-41**, the outer frame body **2042** can include a plurality of struts with at least some of the struts forming cells **2044a-d**. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes.

[0320] As shown in the illustrated embodiment, the cells **2044a-d** can have a diamond or generally diamond shape. The cells **2044a-d** can be considered to be a substantially foreshortening portion of the outer frame **2040**. While the struts forming cells **2044a-d** are generally illustrated as being straight segments, it is to be understood that some or all of the struts may not form entirely straight segments. For example, the struts can include some curvature such that the upper and/or lower apices are curved.

[0321] As shown in the illustrated embodiment, there can be three rows of eighteen cells **2044a-c** and a row of nine cells **2044d**. While each of the cells **2044a-d** are shown as having the same shape as other cells **2044a-d** of the same row, it is to be understood that the shapes of cells **2044a-d** within a row can differ. Moreover, it is to be understood that any number of rows of cells can be used and any number of cells may be contained in the rows.

[0322] With reference next to **Figure 42**, the inner frame **2020** of prosthesis **2000** is illustrated. The inner frame **2020** can include an inner frame body **2022** and an inner frame anchoring feature **2024**. As shown, the inner frame body **2022** can have an

upper region **2022a**, an intermediate region **2022b**, and a lower region **2022c**. As shown, the inner frame body **2022** can have a generally cylindrical shape such that the diameters of the upper region **2022a**, the intermediate region **2022b**, and the lower region **2022c** are generally equivalent. However, it is to be understood that the diameters of the upper region **2022a**, the intermediate region **2022b**, and/or the lower region **2022c** can be different. For example, in some embodiments, a diameter of the lower region **2022c** can be larger than the upper region **2022a**. In other embodiments, the diameter of the upper region **2022a** can be larger than the diameter of the lower region **2022c**.

[0323] The diameter of the upper region **2022a**, intermediate region **2022b**, and/or lower region **2022c** of the inner frame body **2022** may be chosen such that the inner frame body **2022** is adequately spaced from the body cavity when the prosthesis **2000** is positioned within the body cavity. For example, in embodiments where the prosthesis **2000** is positioned within the native mitral valve, the inner frame body **2022** may have a diameter which is less than the diameter of the native mitral valve annulus. Although the inner frame body **2022** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the inner frame body **2022** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0324] The inner frame body **2022** can be substantially non-foreshortening. This can advantageously allow the inner frame body **2022** to retain its axial length when the inner frame body **2022** transitions from a collapsed configuration to an expanded configuration. This can reduce the crimp length of the inner frame body **2022** which can facilitate positioning within a delivery system. As shown in the illustrated embodiment, the inner frame body **2022** can include longitudinally-extending struts **2026**. The longitudinally-extending struts **2026** can extend in a direction generally parallel to the longitudinal axis of the prosthesis **2000**. The longitudinally-extending struts **2026** can extend from an upper region **2022a** of the inner frame body **2022** to a lower region **2022c** of the inner frame body **2022**. Although the longitudinally-extending struts **2026** extend in a direction generally parallel to the longitudinal axis of the prosthesis **2000**, it is to be

understood that at least a portion of these struts **2026** can extend in a direction transverse to the longitudinal axis.

[0325] As shown in the illustrate embodiment, the inner frame body **2022** can include nine longitudinally-extending struts **2026**. It is to be understood that a fewer or greater number of struts can be used. The number of struts can be a multiple of the number of commissures of the valve body. For example, in instances where a valve body having three commissures is used, the inner frame body **2022** can include three, six, twelve, fifteen, or more struts.

[0326] A plurality of undulating struts can extend between the longitudinally-extending struts **2026**. In some embodiments, the inner frame body **2022** can include one or more sets of struts which extend circumferentially around the inner frame body **2022**. As shown, the inner frame body **2022** can include a first, second, and third set of struts **2028a-c** extending circumferentially around the inner frame body **2022**. Each of the sets of struts **2028a-c** can have a zig-zag or undulating shape forming a repeating "V" shape. The tips of these "V" shapes can form a "U" shape. This can facilitate transitioning of the inner frame body **2022** between a collapsed configuration and an expanded configuration.

[0327] As shown, the first and second sets of struts **2028a-b** can extend in a direction generally parallel to the longitudinal axis of the prosthesis **2000**. As such, the first and second sets of struts **2028a-b** can form a generally cylindrical shape. The third set of struts **2028c** can extend radially inwardly towards the longitudinal axis of the prosthesis **2000**. This radially inward shape can correspond to the shape of the lower region **2042c** of the outer frame body **2042.** This can advantageously facilitate attachment of the outer frame body **2042** to the inner frame body **2022** along the lower regions **2022c**, **2042c**.

[0328] The inner frame **2020** can include one or more eyelets to facilitate attachment of one or more components of the prosthesis **2000** to the inner frame **2020**. As shown in the illustrated embodiment, the inner frame **2020** can include an upper and/or lower set of eyelets **2030a-b**. The upper set of eyelets **2030a** can be positioned along the upper region **2022a** of the inner frame body **2022**. As shown, the eyelets **2030a**

can be positioned at or proximate an upper end of the longitudinally-extending struts **2026**.

[0329] The eyelets **2030a** can be used to attach the inner frame **2020** to a delivery instrument, such as a suture or tether-based delivery instrument. For example, sutures or tethers can be attached to the eyelets **2030a**. In some embodiments, the outer frame **2040** can include an upper set of eyelets (not shown) in lieu of, or in combination with, the upper eyelets **2030a**. In embodiments with eyelets on both the inner frame **2020** and the outer frame **2040**, a tether or suture can be passed through corresponding eyelets of the inner frame **2020** and the outer frame **2040**. This tether or suture can draw the inner frame **2020** and the outer frame **2040** closer together when tightened. This can facilitate recapture of the prosthesis **2000**.

[0330] The lower set of eyelets **2030b** can be positioned along the lower region **2022c** of the inner frame body **2022**. As shown in the illustrated embodiment, the lower set of eyelets **2030b** can be positioned along the lower row of struts **2028c**. The eyelets **2030b** can be utilized to facilitate securement of the outer frame **2040** to the inner frame **2020**. For example, in some embodiments, the outer frame **2040** can include one or more eyelets which correspond to the eyelets **2030b**. The inner frame **2020** and outer frame **2040** can be attached together via eyelets **2030b** and corresponding eyelets on the outer frame **2040**. For example, the inner frame **2020** and outer frame **2040** can be sutured together through said eyelets or attached via other means, such as mechanical fasteners (e.g., screws, rivets, and the like).

[0331] Although a single eyelet **2030b** is shown extending from each "V" shaped strut, it is to be understood that some "V" shaped struts may not include an eyelet. Moreover, it is to be understood that multiple eyelets can extend from a "V" shaped strut. For example, two eyelets can extend in series. This can enhance the stability of the coupling between the inner frame **2020** and the outer frame **2040** by allowing a suture to pass through two adjacent eyelets. For example, this can reduce the likelihood that the outer frame **2040** twists along an axis of the eyelet.

[0332] With continued reference to the inner frame **2020** illustrated in **Figure 42**, the inner frame anchoring feature **2024** can extend at or proximate a lower end of the

lower region **2022c** of the inner frame body **2022**. The inner frame anchoring feature **2024** can be formed from a plurality of individual anchors **2024a** extending from the frame body **2022**. The anchors **2024a** can extend downwardly from one or more attachment points to the inner frame body **2022** including, but not limited to, longitudinally-extending struts **2026**. As shown, the anchors **2024a** can be an extension of the longitudinally-extending struts **2026**. This can beneficially enhance the structural integrity of the anchors **2024a**. The anchors **2024a** can bend to extend generally radially outwardly of the longitudinal axis of the prosthesis **2000**. Although the anchors **2024a** are shown extending from longitudinally-extending struts **2026**, it is to be understood that the anchors **2024a** can be connected to the inner frame body **2022** frame at one of many different locations including apices, junctions, other parts of struts, etc.

[0333] The anchors **2024a** can extend upwardly towards an end or tip **2024b**. The ends or tips **2024b** can be positioned radially outwardly relative to the longitudinal axis of the prosthesis **2000**. As shown, the ends or tips **2024b** can extend upwardly in a direction generally parallel to the longitudinal axis of the prosthesis **2000**; however, it is to be understood that the ends or tips **2024b** can have other geometries as described herein. For example, the ends or tips can extend generally perpendicular to the longitudinal axis of the prosthesis **2000**. Although the anchors **2024a** are shown with a single bend, it is to be understood that one or more anchors can comprise first, second, third, or more spaced apart bending stages along the length of each anchor. Further details that may be incorporated and/or interchanged with the features described herein are disclosed in U.S. Publication Nos. 2014/0277422, 2014/0277427, 2014/0277390, and 2015/0328000, and U.S. Application No. 15/653,390, entitled REPLACEMENT HEART VALVE PROSTHESIS, filed on July 18, 2017, which have been incorporated by reference herein.

[0334] As shown in the illustrated embodiment, the inner frame anchoring feature **2024** can include nine individual anchors; however, it is to be understood that a greater number or lesser number of individual anchors can be used. For example, the number of individual anchors can be chosen as a multiple of the number of commissures for the valve body **2060**. As such, for a prosthesis **2000** with a valve body **2060** having

three commissures, the inner frame anchoring feature **2024** can have three individual anchors (1:1 ratio), six individual anchors (2:1 ratio), nine individual anchors (3:1 ratio), twelve individual anchors (4:1 ratio), fifteen individual anchors (5:1 ratio), or any other multiple of three. It is to be understood that the number of individual anchors need not correspond to the number of commissures of the valve body **2060**.

[0335] With reference back to **Figures 39-41**, the inner frame anchoring feature **2024** can include covers and/or cushions **2032** to surround or partially surround at least a portion of the inner frame anchoring feature **2024**, such as the tips or ends **2024b**. The covers and/or cushions **2032** can be similar to cushions **238** and/or those described in U.S. Publication No. 2015/0328000, which has been incorporated by reference in its entirety. As shown in the illustrated embodiment, covers and/or cushions **2032** are attached to all anchors **2024a**; however, it is to be understood that the covers and/or cushions **2032** can be utilized on a subset of anchors **2024a**.

[0336] As shown in the illustrated embodiment, the radial extent of the tips or ends **2024b** of the inner frame anchoring feature **2024** can be greater than the radial extent of the outer frame body **2042** at the plane of the tips or ends **2024b**. The tips or ends **2024b** can be positioned such that the tips or ends **2024b** are spaced apart from an exterior of the outer frame body **2042**. This can provide a gap in which tissue of the body cavity can be retained. For example, in instances where the prosthesis **2000** is positioned within a native mitral valve, the native mitral valve leaflets can be positioned between these gaps. It is to be understood that this gap between the tips or ends **2024b** and the outer frame body **2042** can be reduced. For example, in some embodiments, the tips or ends **2024b** can be positioned proximate, or contact, the exterior of the outer frame body **2042**. This can beneficially increase the force applied by the prosthesis **2000** to pinch or grasp tissue of the body cavity therebetween.

[0337] With continued reference to **Figures 39-41**, the valve body **2060** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other valve bodies described herein. The valve body **2060** can include one or more leaflets **2062** and/or a liner **2064**. The liner **2064** can be used to assist with fluid flow through and/or around the prosthesis **2000**, such as through and

around the inner frame **2020** and the valve leaflets **2062**. The liner **2062** can surround at least a portion of the valve leaflets **2062** and be connected to one or more of the valve leaflets **2062**. For example, as shown in the illustrated embodiment, the one or more valve leaflets **2062** can be attached to the liner **2064** along an upper edge of the valve leaflets **2062**.

[0338] As shown in the illustrated embodiment, the liner **2064** can be positioned within the interior of the inner frame **2020** and can form an inner wall of the prosthesis **2000**. It is also contemplated that the liner **2064** can at least be partially positioned along an exterior of the inner frame **2020** and/or outer frame **2040** such that at least a portion of the liner **2064** is radially outward, relative to the longitudinal axis of the prosthesis **2000**, from struts of the inner frame **2020** and/or outer frame **2040**. As shown in the illustrated embodiment, the liner **2064** can be positioned along an upper or inlet side of the inner frame **2020**. The liner **2064** can extend above the upper edge of the valve leaflets **2062** towards the upper end of the inner frame **2020**. As shown, the liner **2064** can also extend below the upper edge of the valve leaflet **2062** towards the lower end of the inner frame **2020**.

[0339] With continued reference to **Figures 39-41**, the skirt **2080** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other skirts described herein. The skirt **2080** can be positioned around and secured to at least a portion of the exterior of the prosthesis **2000** such as, but not limited to, the inner frame **2020** and/or the outer frame **2040**. The skirt **2080** can be annular and can extend entirely circumferentially around the prosthesis **2000**. The skirt **2080** can prevent or inhibit backflow of fluids around the prosthesis **2000**. For example, with the skirt **2080** positioned annularly around an exterior of the prosthesis **2000**, the skirt **2080** can create an axial barrier to fluid flow exterior to the prosthesis **2000** when deployed within a body cavity. As shown, the skirt **2080** can seal against at least a portion of tissue surrounding the body cavity. In addition, the skirt **2080** can encourage tissue in-growth between the flap assembly **2080** and natural tissue of the body cavity. This may further help to prevent leakage of blood flow around the prosthesis **2000**.

[0340] As shown in the illustrated embodiment, the skirt **2080** can extend along an exterior of the outer frame body **2042**. This can increase the contact area between tissue of the body cavity and the skirt **2080**. This can beneficially enhance sealing around the prosthesis **2000** by providing smooth, continuous contact along the periphery of the outer frame **2040** and the skirt **2080**. In embodiments where the skirt **2080** is formed from a material which encourages tissue in-growth, this increased contact area can be beneficial.

[0341] While the skirt **2080** is shown extending along the exterior of the outer frame body **2042**, it is to be understood that portions of, or the entirety of, the skirt **2080** can extend along an interior of the outer frame. This can allow tissue of the body cavity to contact and/or extend between struts forming the outer frame body **2042**. For example, tissue of the body cavity can contact and/or extend between struts forming one or more of cells **2044a-d.** This can beneficially enhance stability and/or securement of the prosthesis **2000** to tissue of the body cavity. It is also to be understood that while the skirt **2080** is shown tautly attached to the outer frame **2040**, a portion of, or the entirety of, the skirt **2080** can be loosely attached such that a portion of, or the entirety of, the skirt **2080** is movable relative to the outer frame **2040**.

[0342] The upper end of the skirt **2080** can be positioned at or proximate an upper end of the outer frame body **2042** and/or an upper end of the inner frame body **2022**. The lower end of the skirt **2080** can be positioned at or proximate a lower end of the outer frame body **2042**. The skirt **2080** may be attached to the outer frame **2040** and/or inner frame **2020** using any fasteners and/or techniques described herein. For example, portions of the skirt **2080** can be attached to struts and/or anchoring features of the outer frame **2040** and/or inner frame **2020** using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques.

[0343] With reference back to the inner frame **2020** illustrated in **Figure 42**, the inner frame **2020** can include a set of locking tabs **2034** extending at or proximate an upper end of the upper region **2022a** of the inner frame body **2022**. As shown, the locking tabs **2034** can extend at or proximate an upper end of the longitudinal struts **2030** and/or the upper set of eyelets **2030a**. The locking tabs **2034** can extend upwardly in a direction generally aligned with the longitudinal axis of the prosthesis **2000**. As shown in the illustrated embodiment, the locking tabs **2034** can include a longitudinally-extending strut **2034a**. At an upper end of the strut **2034a**, the locking tab **2034** can include an enlarged head **2034b**. As shown, the enlarged head **2034b** can have a semi-circular or semi-elliptical shape forming a "mushroom" shape with the strut **2034a**. As shown, the inner frame **2020** can include nine locking tabs **2034**; however, it is to be understood that a greater number or lesser number of locking tabs can be used. Moreover, it is to be understood that portions of, or the entirety of, the locking tabs **2034** can be omitted.

[0344] The locking tabs **2034** can be advantageously used with multiple types of delivery systems. For example, the shape of the locking tabs **2034** can allow the prosthesis **2000** to be used with multiple delivery systems such as, but not limited to, a "slot" based delivery system and a "tether" based delivery system such as those which utilize sutures, wires, or fingers to control delivery. In some embodiments, the prosthesis **2000** can be used with the delivery systems described herein, including but not limited to, those described in U.S. Patent Nos. 8,414,644 and 8,652,203 and U.S. Publication Nos. 2015/0238315, the entireties of each of which are hereby incorporated by reference and made a part of this specification.

[0345] Although the locking tabs **2034** are shown extending from the inner frame **2020**, it is to be understood that locking tabs can extend from the outer frame **2040** in lieu of, or in addition to, the locking tabs **2034**. Moreover, although the locking tabs are shown extending generally parallel to the longitudinal axis, it is to be understood that locking tabs, such as locking tabs **2034** or those on the outer frame, can extend at an angle relative to the longitudinal axis. This can beneficially allow the locking tabs to

function as an upper set of anchors (similar to upper anchors **1944** discussed in connection with **Figure 38A**).

[0346] With reference next to **Figure 43**, an embodiment of an outer frame **2100** in an expanded configuration is illustrated. The outer frame **2100** can include an outer frame body **2102** and/or an outer frame anchoring feature **2104**. The outer frame **2100** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other outer frames described herein such as outer frames **1940** and **2040** described above in connection with **Figures 38 and 39-41**.

[0347] When in an expanded configuration such as in a fully expanded configuration, the outer frame body **2102** can have a shape similar to that of outer frame **1940** and **2040**. As shown, the upper region **2102a** and the intermediate region **2102b** can have a diameter which is larger than the diameter of the lower region **2102c**. The lower region **2102c** of the outer frame body **2102** can have a decreasing diameter from an upper end of the lower region **2102c** to a lower end of the lower region **2102c** such that the lower region **2102c** is inclined or curved radially inwards towards the longitudinal axis of the outer frame **2100**. This radially inward incline or curve of the lower region **2102c** can facilitate capture of native valve leaflets between the outer frame **2100** and other portions, such as an anchoring feature, of the prosthesis in which the outer frame **2100** is used. Moreover, this radially inward inclined or curve of the lower region **2102c** can reduce or inhibit potential trauma to tissue of the body cavity, such as the native leaflets and/or native valve annulus. For example, the curvature and/or inclination of the lower region **2102c** can be chosen to better conform to the curvature of tissue positioned between the outer frame **2100** and an anchoring feature of another portion of a prosthesis in which the outer frame **2100** is used.

[0348] Although the outer frame body **2102** has been illustrated as having circular cross-sections, it is to be understood that all or a portion of the outer frame body **2102** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0349] With continued reference to the outer frame **2100** illustrated in **Figure 43**, the outer frame body **2102** can include a plurality of struts with at least some of the

struts forming cells **2106a-c**. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes.

[0350] The upper row of cells **2106a** can have an irregular octagonal shape such as a "heart" shape. This larger shape can provide additional space for outer frame anchoring feature **2104**. This additional space can beneficially allow the outer frame **2100** to retain a smaller profile when crimped. The cell **2106a** can be formed via a combination of struts. As shown in the illustrated embodiment, the upper portion of cells **2106a** can be formed from a set of circumferentially-expansible struts **2108a** having a zig-zag or undulating shape forming a repeating "V" shape.

[0351] The middle portion of cells **2106a** can be formed from a set of struts **2108b** extending downwardly from bottom ends of each of the "V" shapes. The struts **2108b** can extend along with a plane parallel to and/or extending through the longitudinal axis of the prosthesis **2100**. The portion of the cells **2106a** extending upwardly from the bottom end of struts **2108b** may be considered to be a substantially non-foreshortening portion of the outer frame **2100**.

[0352] The lower portion of cells **2106a** can be formed from a set of circumferentially-expansible struts **2108c** having a zig-zag or undulating shape forming a repeating "V" shape. One or more of the upper ends or tips of the circumferentially-expansible struts **2108c** can be a "free" apex which is not connected to a strut. For example, as shown in the illustrated embodiment, every other upper end or tip of circumferentially-expansible struts **2108b** is a free apex. However, it is to be understood that other configurations can be used. For example, every upper apex along the upper end can be connected to a strut.

[0353] The middle and/or lower rows of cells **2106b-c** can have a different shape from the cells **2106a** of the first row. The middle row of cells **2106b** and the lower row of cells **2106c** can have a diamond or generally diamond shape. The diamond or generally diamond shape can be formed via a combination of struts.

[0354] The upper portion of cells **2106b** can be formed from the set of circumferentially-expansible struts **2108c** such that cells **2106b** share struts with cells

2106a. The lower portion of cells **2106b** can be formed from a set of circumferentially-expansible struts **2108d**. As shown in the illustrated embodiment, one or more of the circumferentially-expansible struts **2108d** can extend generally in a downward direction and extend radially inwardly towards the longitudinal axis of the outer frame **2100**. For example, the one or more circumferentially-expansible struts **2108d** can be curved such that an upper portion of the struts **2108d** is positioned further from the longitudinal axis of the outer frame **2100** than the lower portion of the struts **2108d**.

[0355] The upper portion of cells **2106c** can be formed from the set of circumferentially-expansible struts **2108d** such that cells **2106c** share struts with cells **2106b**. The lower portion of cells **2106c** can be formed from a set of circumferentially-expansible struts **2108e**. Circumferentially-expansible struts **2108e** can extend generally in a downward direction. As shown in the illustrated embodiment, the circumferentially-expansible struts **2108e** can be inclined or curved towards the longitudinal axis of the outer frame **2100** such that an upper portion of the struts **2108e** is positioned further from the longitudinal axis of the outer frame **2100** than the lower portion of the struts **2108e**. In some embodiments, the circumferentially-expansible struts **2108d** can extend in a direction generally parallel to the longitudinal axis of the outer frame **2100**.

[0356] As shown in the illustrated embodiment, there can be a row of nine cells **2106a**, a row of eighteen cells **2106b**, and a row of nine cells **2106c**. While each of the cells **2106a-c** are shown as having the same shape as other cells **2106a-c** of the same row, it is to be understood that the shapes of cells **2106a-c** within a row can differ. Moreover, it is to be understood that any number of rows of cells can be used and any number of cells may be contained in the rows.

[0357] With continued reference to **Figure 43**, the outer frame **2100** can include an outer frame anchoring feature **2104**. The outer frame anchoring feature **2104** can include one or more individual anchors **2104a** having tips or ends **2104b**. As shown, the outer frame anchoring feature **2104** includes three anchors; however, it is to be understood that a fewer or greater number of anchors can be used. For example, the outer frame anchoring feature **2104** can include nine anchors **2104a**.

[0358] As shown, the anchors **2104a** extend from an upper portion of cells **2106a**, such as an upper apex of cells **2106a**. The anchors **2104a** can extend downwardly. The anchors **2104a** can be attached to the outer frame body **2102** such that, when transitioning from a collapsed configuration to an expanded configuration, the tip or end **2104b** of the anchors **2104a** moves radially outwardly and upwardly.

[0359] In some embodiments, one or more anchors **2104a** can be attached to the outer frame body **2102** along struts **2108c**. For example, the anchors **2104a** can extend from one or more of the free apices. The anchors **2104a** can be attached to the outer frame body **2102** such that, when transitioning from a collapsed configuration to an expanded configuration, the tip or end **2104b** of the anchors **2104a** moves radially outwardly and downwardly. This can beneficially facilitate alignment of the prosthesis **2104a**. Moreover, it is to be understood that the anchors **2104a** and/or the tips or ends **2104b** can be barbs or penetrating structures. The barbs may be angled upwardly, angled downwardly, and/or perpendicular. Although shown extending along an upper region of the outer frame body **2102**, it is to be understood that such barbs or other penetrating structures may extend along other regions of the outer frame body **2102**.

[0360] As shown in the illustrated embodiment, the outer frame **2100** can include an upper set of eyelets **2110a** and/or a lower set of eyelets **2110b**. The upper set of eyelets **2110a** can extend from an upper region **2102a** of the outer frame body **2102**. As shown, the upper set of eyelets **2110a** can extend from an upper portion of cells **2106a**, such as the upper apices of cells **2106a**. The upper set of eyelets **2110a** can be used to attach the outer frame **2100** to a delivery system. For example, sutures or tethers of a delivery system can be attached or passed through the upper set of eyelets **2110a**.

[0361] The lower set of eyelets **2110b** can be positioned along the lower region **2102c** of the outer frame body **2102**. As shown, the lower set of eyelets **2110b** can extend from an upper portion of cells **2106c**, such as the lower apices of cells **2106c**. The lower set of eyelets **2110b** can be used to attach the outer frame **2100** to an inner frame of a prosthesis. For example, in some embodiments, the inner frame can include one or more eyelets which correspond to the eyelets **2110b**. The inner frame and outer frame **2100** can be attached together via these eyelets. For example, the inner frame and

outer frame **2040** can be sutured together through said eyelets or attached via other means, such as mechanical fasteners (e.g., screws, rivets, and the like).

[0362] As shown, the lower set of eyelets **2110b** can include two eyelets extending in series from each "V" shaped strut. This can reduce the likelihood that the outer frame **2040** twists along an axis of the eyelet. However, it is to be understood that some "V" shaped struts may not include an eyelet. Moreover, it is to be understood that a fewer or greater number of eyelets can extend from a "V" shaped strut.

[0363] With reference next to **Figure 44**, an embodiment of a prosthesis **2200** in an expanded configuration, or components of the prosthesis **2200**, are illustrated. The prosthesis **2200** can include an inner frame **2220**, an outer frame **2240**, a valve body **2260**, and a skirt **2280**. The prosthesis **2200** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of prostheses described herein such as prosthesis **1900** and **2000**.

[0364] The prosthesis **2200** can include a cover **2290** to close the gap between the upper regions of the inner frame **2220** and the outer frame **2240**. The cover **2290** can extend between the upper end of the outer skirt **2280** and the upper end of the leaflets **2262** and/or liner **2264** of the valve body **2260**. As shown, the cover **2290** extends generally perpendicular to the longitudinal axis; however, it is to be understood that the cover **2290** can be transverse to the longitudinal axis. In some embodiments, the cover **2290** can extend downwardly and radially inwardly to funnel blood towards the inflow end of the inner frame **2220** and towards the leaflets. In some embodiments, the cover **2290** can extend upwardly and radially inwardly. This can form a tapered shape which can facilitate recapture of the device. As shown, the cover **2290** can be integrally formed with the skirt **2280**; however, it is to be understood that the cover **2290** can be formed separately from the shirt **2280**.

[0365] The prosthesis **2200** can include a cushion **2224** extending along the length of the inner frame anchoring feature **2222**. The cushion **2224** can include a first section **2224a** extending along a portion of an individual anchor and a second section **2224b** extending along a tip or end of an individual anchor. The cushion **2224** can beneficially reduce trauma to tissue of the body cavity.

[0366] With reference next to **Figure 45**, an embodiment of a prosthesis **2300** in an expanded configuration, or components of the prosthesis **2300**, are illustrated. The prosthesis **2300** can include an inner frame **2320**, an outer frame **2340**, a valve body **2360**, and a skirt **2380**. The prosthesis **2300** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of prostheses described herein.

[0367] The prosthesis **2300** can include sutures **2390** extending between the inner frame **2320** and the outer frame **2340**. In some embodiments, the sutures **2390** can extend between the lower portion of the outer frame **2340** and the lower portion of the inner frame body **2322** and/or inner frame anchoring feature **2324**. The sutures **2390** can be tensioned such that a radially inward force is applied on the outer frame **2340** and a radially outward force is applied on the inner frame **2320**. This can beneficially enhance the structural integrity of the prosthesis **2300** by maintaining the outer frame **2340** and inner frame **2320** with an initial amount of strain. In embodiments utilizing materials with a generally linear modulus of elasticity, the pre-strained frame components can require a greater degree of force to further strain the frame components.

[0368] Moreover, the structural integrity of the prosthesis **2300** can be enhanced by tying movement of the outer frame **2340** and the inner frame **2320** together. For example, application of a downwardly-oriented force on anchoring feature **2342** can tend to move the inner frame anchoring feature **2342** in a downward and/or radially inward direction. By tying the outer frame **2340** and the inner frame **2320** together, the inner frame **2320** can pull the outer frame **2340** in the same direction. As such, the forces required to move the inner frame anchoring feature **2342** would be higher than if the inner frame anchoring feature **2342** moved independently of the outer frame **2340**.

[0369] With reference next to **Figures 46-47**, an embodiment of a prosthesis **2400** in an expanded configuration is illustrated. The prosthesis **2400** can include an inner frame **2420**, an outer frame **2440**, a valve body **2460**, and one or more skirts, such as outer skirt **2480** and inner skirt **2490**. The prosthesis **2400** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other prostheses described herein such as prostheses **1900, 2000,** and **2200**.

[0370] With reference first to the inner frame **2420**, the inner frame **2420** can include an inner frame body **2422** and an inner frame anchoring feature **2424**. As shown, the inner frame body **2422** can have a generally bulbous shape and/or frustoconical shape. The diameter of the upper region **2422a** can be less than the diameter of the lower region **2422c**. This can beneficially allow the use of a smaller valve body **2460** within the inner frame **2420** while allowing the inner frame body **2422** to have a larger diameter proximate the connection between the inner frame body **2422** and the inner frame anchoring feature **2424**. This larger diameter can reduce the radial distance between the connection and the tip or end of the inner frame anchoring feature **2424**. This can beneficially enhance fatigue resistance of the inner frame anchoring feature **2424** by reducing the length of the cantilever. Moreover, this can allow the inner frame anchoring feature **2424** to more closely match the geometry of the outer frame **2440**. The larger diameter can also facilitate valve-in-valve functionality by providing a larger diameter portion in which a subsequent replacement valve may be received.

[0371] As shown in the illustrated embodiment, the intermediate region **2422b** can have a frustoconical shape such that the diameter increases linearly from an upper end to a lower end of the intermediate region **2422b**. However, it is to be understood that the intermediate region **2422b** can incorporate a curvature. For example, the intermediate region **2422b** can include a geometry similar to that of inner frame body **1522b** described in connection with **Figure 33**. The inner frame body **2422** can include a bend **2426** along a lower region **2422c** of the inner frame body **2420** such that a region **2428** of the inner frame body **2420** tapers radially inwardly towards the longitudinal axis of the prosthesis **2400**. The shape of region **2428** can match the shape of a portion of the outer frame **2440**.

[0372] The radially inward bend can enhance the durability of the valve body **2460**. As shown in **Figure 47**, an intermediate component **2464** of the valve body **2460** can couple a commissure formed by leaflets **2464** to the inner frame body **2422**. The intermediate component **2464** can extend from below the leaflets **2464**. As such, when the valve body **2460** closes due to a flow of fluid in the upward direction, the intermediate component **2464** is pulled upwardly into tension as opposed to shear. This

can be beneficial in instances where the intermediate component **2464** is more resistant to tension than shear as it can reduce the likelihood of the intermediate component **2464** tearing.

[0373] With continued reference to the prosthesis **2400** illustrated in **Figure 46**, the valve body **2460** is attached to the inner frame **2420** within an interior of the inner frame body **2422**. The valve body **2460** functions as a one-way valve to allow blood flow in a first direction through the valve body **2460** and inhibit blood flow in a second direction through the valve body **2460**.

[0374] The valve body **2460** can include a plurality of valve leaflets **2462**, for example three leaflets **2462**, which are joined at commissures. The valve body **2460** can include one or more intermediate components **2464**. The intermediate components **2464** can be positioned between a portion of, or the entirety of, the leaflets **2462** and the inner frame **2420** such that at least a portion of the leaflets **2462** are coupled to the frame **2420** via the intermediate component **2464**. In this manner, a portion of, or the entirety of, the portion of the valve leaflets **2462** at the commissures and/or an arcuate edge of the valve leaflets **2462** are not directly coupled or attached to the inner frame **2420** and are indirectly coupled or "float" within the inner frame **2420**. For example, a portion of, or the entirety of, the portion of the valve leaflets **2462** proximate the commissures and/or the arcuate edge of the valve leaflets **2462** can be spaced radially inward from an inner surface of the inner frame **2420**. By using one or more intermediate components **2464**, the valve leaflets **2462** can be attached to non-cylindrical frames **2420** and/or frames **2420** having a diameter larger than that of the diameter of the valve leaflets **2462**. Further details on floating valve concepts can be found in U.S. Application No. 15/653,390, entitled REPLACEMENT HEART VALVE PROSTHESIS, filed on July 18, 2017, the entirety of which is incorporated herein by reference.

[0375] With reference next to the skirts **2480**, **2490** illustrated in **Figure 46**, the outer skirt **2480** can be attached to the inner frame **2420** and/or outer frame **2440**. As shown, the outer skirt **2480** can be positioned around and secured to a portion of, or the entirety of, the exterior of the outer frame **2440.** As shown, the outer skirt **2480** can follow the contours of the outer frame **2440**; however, it is to be understood that at least a

portion of the skirt **2480** can be spaced apart from at least a portion of both the inner frame **2420** and the outer frame **2440**.

[0376] The inner skirt **2490** can be attached to the valve body **2460** and the outer skirt **2480**. As shown, a first end of the inner skirt **2490** can be coupled to the valve body **2460** along portions of the valve body **2460** which are proximate the inner frame **2420**. A second end of the inner skirt **2490** can be attached to the lower region of the outer skirt **2480**. As shown, the inner skirt **2490** can be positioned radially outwardly of the inner frame **2420**. The inner skirt **2490** can be detached from the inner frame **2490** along portions between the upper end and the lower end such that the inner skirt **2490**. This can allow the inner skirt **2490** to form a shape which facilitate fluid flow around the underside of the valve body **2460**. This can improve washout on the underside of the valve thereby beneficially reducing the risk of thrombosis or clot formation under and around the valve body **2460**.

[0377] Although the inner skirt **2490** is shown positioned radially outwardly from the inner frame **2420**, it is to be understood that the inner skirt **2490** can follow the contours of the inner frame **2420** and/or be positioned along an interior surface of the inner skirt **2490**. In some embodiments, the inner frame **2490** can incorporate the shape of the illustrated inner skirt **2490**.

[0378] Although the prosthesis **2400** has been described as including an inner frame **2420**, an outer frame **2440**, a valve body **2460**, and skirts **2480**, **2490,** it is to be understood that the prosthesis **2400** need not include all components. For example, in some embodiments, the prosthesis **2400** can include the inner frame **2420**, the outer frame **2440**, and the valve body **2460** while omitting the skirt **2480**. Moreover, although the components of the prosthesis **2400** have been described and illustrated as separate components, it is to be understood that one or more components of the prosthesis **2400** can be integrally or monolithically formed. For example, in some embodiments, the inner frame **2420** and the outer frame **2440** can be integrally or monolithically formed as a single component.

[0379] With reference next to **Figures 11A-K**, embodiments of prostheses **500a-k** in expanded configurations are illustrated. The prostheses **500a-k** can include

inner frames **520a-k** and outer frames **540a-k**. The inner frames **520a-k** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of the inner frames described herein such as inner frames **120**, **220**, **400**. The outer frames **540a-k** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of the outer frames described herein such as outer frames **140**, **240**, **300**.

[0380] With reference first to the prosthesis **500a** illustrated in **Figure 11A**, outer frame **540a** can include an upper region **542a**, an intermediate region **544a**, and a lower region **546a**. The upper region **542a** can include a longitudinally-extending section **548a** and an outwardly-extending section **550a**. The intermediate region **544a** can extend from the outwardly-extending section **550a**. As shown in the illustrated embodiment, the intermediate region **544a** can extend in a direction generally parallel to a longitudinal axis of the prosthesis **500a**. The lower region **546a** can extend from the intermediate region **544a**. The lower region **546a** can bend to extend radially inward towards the longitudinal axis of the prosthesis **500a**. In some embodiments, the lower region **546a** can extend in a direction more perpendicular to the longitudinal axis of the prosthesis **500a** than parallel. For example, the lower region **546a** can extend in a direction generally perpendicular to the longitudinal axis of the prosthesis **500a**.

[0381] Portions of the outer frame **540a**, such as the upper region **542a**, can be attached to the inner frame **520a** at or proximate an upper region **522a** of the inner frame **520a**. As shown in the illustrated embodiment, the outer frame **540a** can be sized such that a lower end of the outer frame **540a** is at or proximate an upper end or tip **526a** of anchoring feature **524a**.

[0382] With reference next to the prosthesis **500b** illustrated in **Figure 11B**, outer frame **540b** can include an upper region **542b**, an intermediate region **544b**, and a lower region **546b**. The upper region **542b** can include a longitudinally-extending section **548b** and an outwardly-extending section **550b**. The regions **542b**, **544b**, **546b** and sections **548b**, **550b** can be similar, or the same, as regions **542a**, **544a**, **546a** and sections **548a**, **550a** described above in connection with prosthesis **500a** illustrated in **Figure 11A**. Portions of the outer frame **540b**, such as the upper region **542b**, can be

attached to the inner frame **520b** at or proximate an upper region **522b** of the inner frame **520b**. As shown in the illustrated embodiment, the outer frame **540b** can be sized such that a lower end of the outer frame **540b** is above an upper end or tip **526b** of anchoring feature **524b**.

[0383] With reference next to the prosthesis **500c** illustrated in **Figure 11C**, outer frame **540c** can include an upper region **542c**, an intermediate region **544c**, and a lower region **546c**. Portions of the outer frame **540c**, such as the upper region **542c**, can be attached to the inner frame **520c** at or proximate an upper region **522c** of the inner frame **520c**. The upper region **542c** can include a longitudinally-extending section **548c** and an outwardly-extending section **550c**. The intermediate region **544c** can extend from the outwardly-extending section **550c**. As shown in the illustrated embodiment, the intermediate region **544c** can extend in a direction generally parallel to a longitudinal axis of the prosthesis **500c**. The lower region **546c** can extend from the intermediate region **544c**. As shown in the illustrated embodiment, the lower region **546c** can bend to extend radially outwardly away from the longitudinal axis of the prosthesis **500c**. The lower region **546c** can continue to bend such that a tip or end **552c** of the lower region **546c** extends upwardly. For example, the tip or end **552c** of the lower region **546c** can extend upwardly in a direction generally parallel to the longitudinal axis of the prosthesis **500c**.

[0384] In some embodiments, the lower region **546c** can function similarly to anchoring features described herein such as, but not limited to, anchoring features **124**, **224**. The tips or ends **552c** as described above can be positioned to contact or engage a native mitral valve annulus on a ventricular side, tissue beyond the native valve annulus on a ventricular side, native leaflets on a ventricular side, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. For example, the tips or ends **552c** can be positioned to contact a ventricular side of the native mitral valve annulus and/or tissue beyond the ventricular side of the native valve annulus. In some embodiments, the tips or ends **552c** can advantageously provide atraumatic surfaces that may be used to contact or engage intralumenal tissue without causing unnecessary or undesired trauma to tissue. For

example, the tips or ends **552c** can form flat, substantially flat, curved or other non-sharp surfaces to allow the tips to engage and/or grasp tissue, without necessarily piercing or puncturing through tissue. A looped end or looped anchor may assist the frame in not getting caught up on structures at or near the treatment location.

[0385] With reference next to the prosthesis **500d** illustrated in **Figure 11D**, outer frame **540d** can include an upper region **542d**, an intermediate region **544d**, and a lower region **546d**. As shown in the illustrated embodiment, the outer frame **540d** can have a generally bulbous shape with a diameter of the intermediate region **544d** being greater than the diameter of the upper region **542d** and the diameter of the lower region **546d**. Moreover, as shown in the illustrated embodiment, the diameter of the upper region **542d** can be larger than the diameter of the lower region **546d**.

[0386] Portions of the outer frame **540d**, such as the lower region **546d**, can be attached to the inner frame **520d** at or proximate a lower region **522d** of the inner frame **520d**. As shown in the illustrated embodiment, the outer frame **540d** can be sized such that an upper end of the outer frame **540d** is at or proximate a plane orthogonal to the longitudinal axis of the prosthesis **500d** which passes through the upper end of the inner frame **520d**. The outer frame **540d** can be sized such that a lower end of the outer frame **540d** is axially below the tips or ends **526d** of the inner frame anchoring feature **524d**. The outer frame **540d** can be sized such that a diameter of the widest portion of the outer frame **540d** is greater than a widest portion of the inner frame anchoring feature **524d**.

[0387] With reference next to the prosthesis **500e** illustrated in **Figure 11E**, outer frame **540e** can include an upper region **542e**, an intermediate region **544e**, and a lower region **546e**. As shown in the illustrated embodiment, the outer frame **540e** can have a generally bulbous shape with a diameter of the intermediate region **544e** being greater than the diameter of the upper region **542e** and the diameter of the lower region **546e**. Moreover, as shown in the illustrated embodiment, the diameter of the upper region **542e** can be larger than the diameter of the lower region **546e**.

[0388] Portions of the outer frame **540e**, such as the lower region **546e**, can be attached to the inner frame **520e** at or proximate a lower region **522e** of the inner

frame **520e**. As shown in the illustrated embodiment, the outer frame **540e** can be sized such that an upper end of the outer frame **540e** is below a plane orthogonal to the longitudinal axis of the prosthesis **500e** which passes through the upper end of the inner frame **520e**. The outer frame **540e** can be sized such that a lower end of the outer frame **540e** is axially below the tips or ends **526e** of the inner frame anchoring feature **524e**. The outer frame **540e** can be sized such that a diameter of the widest portion of the outer frame **540e** is less than a widest portion of the inner frame anchoring feature **524e**. As shown in the illustrated embodiment, the tips **526e** of the inner anchoring feature **524e** can be at or proximate an intermediate region **544e** of the outer frame **540e**.

[0389] With reference next to the prosthesis **500f** illustrated in **Figure 11F**, outer frame **540f** can include an upper region **542f**, an intermediate region **544f**, and a lower region **546f**. Portions of the outer frame **540f**, such as the intermediate region **544f** and/or lower region **546f**, can be attached to the inner frame **520f** at or proximate an intermediate region **522f** of the inner frame **520f**.

[0390] The upper region **542f** can extend downwardly in a direction generally parallel to a longitudinal axis of the prosthesis **500f**. The intermediate region **544f** can extend from the upper region **542f**. As shown in the illustrated embodiment, the intermediate region **544f** can extend in a direction radially inward towards the longitudinal axis of the prosthesis **500f**. The lower region **546f** can extend from the intermediate region **544f**. As shown in the illustrated embodiment, the lower region **546f** can bend to extend radially outwardly away from the longitudinal axis of the prosthesis **500f**. In some embodiments, the lower region **546f** can continue to bend such that a tip or end **548f** of the lower region **546f** extends upwardly. For example, the tip or end **548f** of the lower region **546f** can extend upwardly in a direction generally parallel to the longitudinal axis of the prosthesis **500f**. In some embodiments, the tip or end **548f** of the lower region **546f** can extend axially such that it is positioned at or proximate the intermediate region **544f**.

[0391] In some embodiments, the lower region **546f** can function similarly to anchoring features described herein such as, but not limited to, anchoring features **124**, **224**. The tips or ends **548f** as described above can be positioned to contact or engage a

native mitral valve annulus on a ventricular side, tissue beyond the native valve annulus on a ventricular side, native leaflets on a ventricular side, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. For example, the tips or ends **548f** can be positioned to contact a ventricular side of the native mitral valve annulus and/or tissue beyond the ventricular side of the native valve annulus. In some embodiments, the tips or ends **548f** can advantageously provide atraumatic surfaces that may be used to contact or engage intralumenal tissue without causing unnecessary or undesired trauma to tissue. For example, the tips or ends **548f** can form flat, substantially flat, curved or other non-sharp surfaces to allow the tips to engage and/or grasp tissue, without necessarily piercing or puncturing through tissue. A looped end or looped anchor may assist the frame in not getting caught up on structures at or near the treatment location.

[0392] With reference next to the prosthesis **500g** illustrated in **Figure 11G**, outer frame **540g** can include an upper region **542g**, an intermediate region **544g**, and a lower region **546g**. Portions of the outer frame **540f**, such as the upper region **544g**, can be attached to the inner frame **520g** at or proximate an upper region **522g** of the inner frame **520g**. As shown in the illustrated embodiment, the outer frame **540g** can loosely attached to the inner frame **520g** via a coupling **560g** such that the entirety of the outer frame **540g** is generally movable relative to the entirety of the inner frame **520g**. For example, the coupling **560g** can be a portion of a skirt attached to both the outer frame **540g** and the inner frame **520g**.

[0393] The upper region **542g** can extend downwardly in a direction generally parallel to a longitudinal axis of the prosthesis **500g**. The intermediate region **544g** can extend from the upper region **542g**. As shown in the illustrated embodiment, the intermediate region **544g** can extend in a direction generally downwards such that the intermediate region **544g** and the upper region **542g** form a generally cylindrical portion. The lower region **546g** can extend from the intermediate region **544g**. As shown in the illustrated embodiment, the lower region **546g** can bend to extend radially inward towards the longitudinal axis of the prosthesis **500g**. In some embodiments, the lower region **546g** can extend in a direction more perpendicular to the longitudinal axis of the

prosthesis **500g** than parallel. For example, the lower region **546g** can extend in a direction generally perpendicular to the longitudinal axis of the prosthesis **500g**.

[0394] With reference next to the prosthesis **500h** illustrated in **Figure 11H**, the prosthesis **500h** can include a lower outer frame **540h** and an upper outer frame **560h**. The prosthesis **500h** can be similar to other prostheses described herein, such as prosthesis **500e** described in connection with **Figure 11E**. For example, the lower outer frame **540h** can be similar to outer frame **540e** described in connection with **Figure 11E**. As shown in the illustrated embodiment, the lower and upper outer frames **540h**, **560h** can form a generally bulbous shape with a diameter of an intermediate region being greater than the diameter of the upper region and the diameter of the lower region. The lower outer frame **540h** can be attached to the inner frame **520h** along a lower region of the lower outer frame **540h**. The upper outer frame **560h** can be attached to the inner frame **520h** along an upper region of the upper outer frame **540h**.

[0395] The upper outer frame **560h** can extend downwardly and extend radially outwardly. As shown, the upper end of the upper outer frame **560h** can have a diameter which is less than the upper end of the lower outer frame **560h**. The lower end of the upper outer frame **560h** can have a diameter which is greater than the upper end of the lower outer frame **560h**. As shown, the upper outer frame **560h** can overlap with a portion of the lower outer frame **540h** when at least when the prosthesis **500h** is in a partially or fully expanded state.

[0396] The shape of the upper outer frame **560h** can facilitate recapture of the prosthesis **500h**. In some embodiments, the prosthesis **500h** is sequentially deployed with the lower region of the prosthesis **500h** being deployed before the upper region of the prosthesis **500h**. For example, a sheath (not shown) maintaining the prosthesis **500h** in a collapsed or crimped configuration can be retracted upwardly. The upper region of the prosthesis **500h** can be retained in a collapsed or crimped configuration while the remaining portions of the prosthesis **500h** are allowed to expand as shown, for example, in **Figure 56F**. Should a user decide to recapture the prosthesis **500h** to re-position or remove the prosthesis **500h**, the user may advance the sheath downwardly over the prosthesis **500h**. This process can be facilitated due to the shape and/or attachment of

the upper end of the upper outer frame **560h.** Moreover, as the sheath is advanced downwardly, the upper outer frame **560h** can crimp or collapse over the lower outer frame **540h** thereby crimping the lower outer frame **540h**.

[0397] With reference next to the prosthesis **500i** illustrated in **Figure 11I**, the prosthesis **500i** can include a lower outer frame **540i** and an upper outer frame **560i**. The prosthesis **500i** can be similar to other prostheses described herein, such as prosthesis **500h** described in connection with **Figure 11H**. As shown, the upper outer frame **560i** and the lower outer frame **540i** can be formed from structures, such as struts, which do not overlap.

[0398] With reference next to the prosthesis **500j** illustrated in **Figure 11J**, outer frame **540j** can include an upper region **542j**, an intermediate region **544j**, and a lower region **546j**. As shown in the illustrated embodiment, the outer frame **540j** can have a generally bulbous shape with a diameter of the intermediate region **544j** being greater than the diameter of the upper region **542j** and the diameter of the lower region **546j**. Portions of the outer frame **540j** such as the upper region **542j** and/or the lower region **546j**, can be attached to the inner frame **520j** at or proximate an upper region **522j** and/or lower region **524j** of the inner frame **520j**. The outer frame **540j** may be formed from a plurality of struts and/or cells which can allow the outer frame to be crimped or collapsed to a configuration which generally matches the size and/or shape of the inner frame **520j**. For example, when the outer frame **540j** is in a collapsed configuration, the length of the outer frame **540j** can generally match that of the inner frame **520j**. When expanded, differences in cell structure between the upper region **542j**, intermediate region **544j**, and the lower region **546j** can allow the regions to expand to different extents as shown. For example, in some embodiments, the intermediate region **544j** can have a strut geometry which differs from the strut geometry of the upper and/or lower regions **542j**, **546j**.

[0399] The shape of the outer frame **540j** can facilitate recapture of the prosthesis **500j**. In some embodiments, the prosthesis **500j** is sequentially deployed with the lower region of the prosthesis **500h** being deployed before the upper region of the prosthesis **500h**. For example, the upper region of the prosthesis **500j** can be retained in

a collapsed or crimped configuration while the remaining portions of the prosthesis **500j** are allowed to expand as shown, for example, in **Figure 56F**. Should a user decide to recapture the prosthesis **500j** to re-position or remove the prosthesis **500j**, the user may advance the sheath downwardly over the prosthesis **500j**. This process can be facilitated due to the shape and/or attachment of the upper end of the outer frame **540j.**

[0400] With reference next to the prosthesis **500k** illustrated in **Figure 11k**, outer frame **540k** can include an upper region **542k**, an intermediate region **544k**, and a lower region **546k**. As shown in the illustrated embodiment, the outer frame **540k** can have a generally bulbous shape with a diameter of the intermediate region **544k** being greater than the diameter of the upper region **542k** and the diameter of the lower region **546k**. The shape of the outer frame **540k** can facilitate recapture of the prosthesis **500k** for reasons similar to those described in connection with prosthesis **500j** shown in **Figure 11J**.

[0401] Portions of the outer frame **540k** such as the upper region **542k** and/or the lower region **546k**, can be attached to the inner frame **520k** at or proximate an upper region **522k** and/or lower region **524k** of the inner frame **520k**. As shown, the coupling between the upper region **542k** of the outer frame **540k** and inner frame **520k** can be movable. This can facilitate crimping of the outer frame **540k** since the upper region **542k** can move independently of the inner frame **520k**. In some embodiments, the upper region **542k** of the outer frame **540k** can be coupled to the inner frame **520k** via a track or rail to allow the upper region **542k** to slide relative to the inner frame **520k**. This can beneficially maintain the upper end of the outer frame **540k** at a diameter which matches the diameter of the inner frame **520k**. In some embodiments, the upper region **542k** of the outer frame **540k** can be coupled to the inner frame **520k** via a coupling similar to the coupling **560g** discussed in connection with **Figure 11G**. For example, the coupling **560g** can be a portion of a skirt. Although the coupling between the upper region **542k** of the outer frame **540k** and inner frame **520k** has been described as movable, it is to be understood that the coupling between the lower region **546k** of the outer frame **540k** can be movably coupled to the inner frame **520k** in lieu of, or in combination with, the movable coupling between the upper region **542k** and the inner frame **520k**.

Embodiments of Mesh Anchoring Features

[0402] In some embodiments, the prostheses described herein can incorporate a mesh or braided anchoring feature. It is to be understood that the mesh or braided anchoring features can be used in combination with other anchoring features described herein or as a replacement for one or more of the anchoring features described herein.

[0403] With reference next to **Figures 12-14**, an embodiment of a prosthesis **600** in an expanded configuration is illustrated. The prosthesis **600** can include a frame **620** and a valve body **660**. A longitudinal axis of the prosthesis **600** may be defined as the central axis that extends through the center of the prosthesis **600** between the upper and lower ends of the prosthesis **600**. In some situations, the prosthesis **600** may be oriented such that an upper end of the prosthesis **600** is a proximal portion and a lower end of the prosthesis **600** is a distal portion. The valve body **660** can be similar to, or the same as, other valve bodies described herein such as, but not limited to, valve bodies **160**, **260**, **760**, **870**, **970**. Accordingly, reference should be made to the discussion of such valve bodies.

[0404] As shown in the illustrated embodiment, the frame **620** can include a frame body **622** and an anchoring feature **624**. The frame body **622** can include an upper region **626**, an intermediate region **628**, and a lower region **630**. As shown, the frame body **622** can have a generally cylindrical shape such that the diameters of the upper region **626**, the intermediate region **628**, and the lower region **620** are generally constant. However, it is to be understood that the diameters of the upper region **626**, the intermediate region **628**, and/or the lower region **630** can be different. For example, in some embodiments, a diameter of the intermediate region **628** can be larger than the upper region **626** and the lower region **630** such that the frame body **622** has a generally bulbous shape. In some embodiments, the diameter of the lower region **630** can be larger than the diameter of the upper region **626**. In other embodiments, the diameter of the upper region **626** can be larger than the diameter of the lower region **630**. In some situations, the frame **620** may be oriented such that the upper region **626** is a proximal portion and the lower region **630** is a distal portion. Moreover, although the frame body **622** has been described and illustrated as being cylindrical, it is to be understood that all

or a portion of the frame body **622** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape. The frame body **622** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of frames described herein such as, but not limited to, inner frames **120**, **220**, **400**, **520a-g**.

[0405] As shown, the anchoring feature **624** can be positioned at or proximate the upper region **626** of the frame body **622**. However, it is to be understood that the anchoring feature **624** can be positioned along other regions of the frame body **622** such as the intermediate region **630** and/or the lower region **628** based on the configuration of the prosthesis **600** and the implantation location. The anchoring feature **624** can include a body portion **632** formed from a wire mesh. The body portion **632** can be positioned such that it is radially outward of the frame body **622**. The body portion **632** can be relatively flexible, resilient, and/or malleable. For example, the construction of the body portion **632**, such as the materials used and/or the geometry of the mesh, can be chosen to provide this flexibility, resilience, and/or flexibility. In some embodiments, the body portion **632** can be formed from a metal including, but not limited to, a shape memory metal such as Nitinol. The body portion **632** can take the form of a braided tube. In some embodiments, the body portion **632** can be formed separately from the other portions of the frame **620**. The body portion **632** can be attached to the frame **620** using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots which can be on the frame **620** and the body portion **632**), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques. The frame **620** and the body portion **632** can be indirectly attached via an intermediate component, such as a skirt. In other embodiments, the body portion **632** can be integrally or monolithically formed with other portions of the frame **620**.

[0406] The flexibility, resiliency, and/or malleability of the body portion **632** can beneficially allow the body portion **632** to conform to the anatomy of the body cavity in which it is positioned, such as tissue of a native heart wall, a native valve annulus, and/or leaflets. In some situations, such as when the body portion **632** is positioned within a native mitral valve, the body portion **632** can conform to the shape of the mitral valve annulus such that an upper region of the body portion **632** extends over an atrial side of the native mitral valve annulus, an intermediate region of the body portion **632** conforms to the inner periphery of the native mitral valve annulus, and/or the lower region of the body portion **632** contacts portions of the leaflets. Moreover, the flexibility, resiliency, and/or malleability can beneficially allow the body portion **632** to be crimped to a smaller diameter during the delivery process, thereby allowing for the use of a smaller gauge delivery device.

[0407] The anchoring feature **624** can include one or more protrusions or barbs **634**. The one or more protrusions **634** can be positioned along the body portion **632**. As shown in the illustrated embodiment, the one or more protrusions **634** can advantageously enhance securement of the anchoring feature **624** to tissue of the body cavity in which the anchoring feature **624** is positioned, such as tissue of a native heart wall, a native valve annulus, and/or native leaflets. In some instances, the protrusions **634** can be oriented to inhibit or limit upward movement of the prosthesis **600**. For example, in situations where the prosthesis **600** is positioned within a native mitral valve, the protrusions **634** can be oriented to inhibit or limit upward movement of the prosthesis **600** during systole. Moreover, the one or more protrusions **634** can beneficially encourage tissue ingrowth by activating the fibroblasts and inducing tissue proliferation. The length and directionality of the protrusions **634** can be chosen to reduce trauma yet provide adequate engagement with tissue and adequate tissue ingrowth.

[0408] The anchoring feature **624** can include one or more arms or paddles **636**. As shown, the anchoring feature **624** can include eight arms or paddles **636**, however, it is to be understood that the anchoring feature **624** can include a greater or fewer number of arms or paddles. The arms or paddles **636** can be attached at or proximate an upper region **626** of the frame body **622.** The arms or paddles **638** can

extend radially outward relative to the longitudinal axis of the prosthesis **600**. As shown in the illustrated embodiment, the arms or paddles **636** can be positioned to extend above the body portion **632**. The arms or paddles **636** can be formed from a wire mesh. The arms or paddles **636** can be relatively flexible, resilient, and/or malleable. For example, the construction of the arms or paddles **636**, such as the materials used and/or the geometry of the mesh, can be chosen to provide this flexibility, resilience, and/or flexibility. The construction of the arms or paddles **636** can be chosen to provide adequate engagement with tissue while is use while reducing the forces exerted by the prosthesis **600** while in a collapsed or crimped configuration.

[0409] In some embodiments, the arms or paddles **636** can be formed from a metal including, but not limited to, a shape memory metal such as Nitinol. The arms or paddles **636** can be braided. In some embodiments, the arms or paddles **636** can be formed separately from the other portions of the frame **620** such as the body portion **632**. The arms or paddles **636** can be attached to other portions of the frame **620** such as the body portion **632** using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots which can be on the arms or paddles **636** and other portions of the frame **620**), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques. The arms or paddles **636** and other portions of the frame **620** can be indirectly attached via an intermediate component, such as a skirt. In other embodiments, the arms or paddles **636** can be integrally or monolithically formed with other portions of the frame **620** and/or body portion **632**.

[0410] The flexibility, resiliency, and/or malleability of the arms or paddles **636** can beneficially allow the arms or paddles **636** to conform to the anatomy of the body cavity in which it is positioned, such as tissue of a native heart wall, a native valve annulus, and/or leaflets. In some situations, such as when the arms or paddles **636** are positioned within a native mitral valve, the arms or paddles **636** can conform to the shape

of the atrial wall. Moreover, the flexibility, resiliency, and/or malleability can beneficially allow the body portion **632** to be crimped to a smaller diameter during the delivery process, thereby allowing for the use of a smaller gauge delivery device.

[0411] Although not shown, the frame body **622** can include an anchoring feature positioned below the anchoring feature **624**. The anchoring feature can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of anchoring features described herein including, but not limited to, inner frame anchoring features **124**, **224**, **524d**, **524e** and lower frame anchoring features **726**, **826**, **926**, **1106**, **1220**.

[0412] With reference next to **Figure 15**, an embodiment of a prosthesis **700** in an expanded configuration is illustrated. The prosthesis **700** can include a frame **720**, a valve body **760**, and a skirt **780**. A longitudinal axis of the prosthesis **700** may be defined as the central axis that extends through the center of the prosthesis **700** between the upper and lower ends of the prosthesis **700**. In some situations, the prosthesis **700** may be oriented such that an upper end of the prosthesis **700** is a proximal portion and a lower end of the prosthesis **700** is a distal portion. The valve body **760** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other valve bodies described herein such as, but not limited to, valve bodies **160**, **260**, **660**, **870**, **970**.

[0413] The frame **720** can include a frame body **722**, an upper anchoring feature **724**, a lower anchoring feature **726**, and an intermediate anchoring feature **728**. The frame body **722** can include an upper region **730**, an intermediate region **732**, and a lower region **734**. As shown, the frame body **722** can have a generally cylindrical shape such that the diameters of the upper region **730**, the intermediate region **732**, and the lower region **734** are generally constant. However, it is to be understood that the diameters of the upper region **730**, the intermediate region **732**, and/or the lower region **734** can be different. For example, in some embodiments, a diameter of the intermediate region **732** can be larger than the upper region **730** and the lower region **734** such that the frame body **722** has a generally bulbous shape. In some embodiments, the diameter of the lower region **734** can be larger than the diameter of the upper region **730**. In other

embodiments, the diameter of the upper region **730** can be larger than the diameter of the lower region **734**. Moreover, although the frame body **722** has been described and illustrated as being cylindrical, it is to be understood that all or a portion of the frame body **722** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape. The frame body **722** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of frame such as inner frames **120**, **220**, **400**, **520a-g**.

[0414] The upper anchoring feature **724** can extend radially outward from the longitudinal axis of the prosthesis **700**. In this manner, upper anchoring feature **724** can create a flared or shoulder portion **736** of the frame **720**. As shown in the illustrated embodiment, a portion of the upper anchoring feature **724** can extend radially outward via a bend **738** beginning at or proximate the upper end of the upper region **730** of the frame body **722**. The bend **738** can be about a circumferential axis such that the upper anchoring feature **724** extends in a direction more perpendicular to the longitudinal axis of the prosthesis **700** than the frame body **722**. In some embodiments, the bend **738** can generally form an arc with an angle between about 20 degrees to about 90 degrees. For example, as shown in the illustrated embodiment, the arc can have an angle of about 60 degrees. In some embodiments, the bend **738** can form an arc with an angle between about 30 degrees to about 70 degrees. The radius of curvature of the arc may be constant such that the bend **738** forms a circular arc or may differ along the length of the bend **738**.

[0415] The upper anchoring feature **724** can include a second bend **740** above the bend **738**. The bend **740** can be about a circumferential axis such that the portion of the upper anchoring feature **724** above the second bend **740** extends in a direction less perpendicular to the longitudinal axis of the prosthesis **700** than the portion of the upper anchoring feature **724** below the second bend **740**. In some embodiments, the bend **740** can continue such that the end of the upper anchoring feature **724** extends in a direction radially towards the longitudinal axis of the prosthesis **700**. In some embodiments, the second bend **740** can generally form an arc with an angle between about 20 degrees to about 90 degrees. For example, as shown in the illustrated embodiment, the arc can have

an angle of about 90 degrees. In some embodiments, the second bend **740** can form an arc with an angle between about 45 degrees to about 135 degrees. The radius of curvature of the arc may be constant such that the second bend **740** forms a circular arc or may differ along the length of the second bend **740**.

[0416] With continued reference to the frame **720** illustrated in **Figure 15**, the lower anchoring feature **726** can extend generally downwardly from above a lower end of the lower region **734** of the inner frame body **722** and/or generally radially outward of the longitudinal axis of the prosthesis **700**. As shown in the illustrated embodiment, the lower anchoring feature **726** can also extend upwardly towards an end **742** of the lower anchoring feature **726**. As will be discussed in further detail below, components of the frame **120**, such as the lower anchoring feature **726**, can be used to attach or secure the prosthesis **700** to a native valve. For example, in some embodiments, the lower anchoring feature **726** can be used to attach or secure the prosthesis **700** to a native valve, such as a native mitral valve. In such an embodiment, the lower anchoring feature **726** can be positioned to contact or engage a native mitral valve annulus on a ventricular side, tissue beyond the native valve annulus on a ventricular side, native leaflets on a ventricular side, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. The lower anchoring feature **726** can beneficially eliminate, inhibit, or limit upward movement of the prosthesis **700** when subject to upwardly directed forces such as those which are applied on the prosthesis **700** during systole.

[0417] The intermediate anchoring feature **728** can be positioned at or proximate the intermediate region **732** of the frame body **722**. The intermediate anchoring feature **728** can be positioned such that it is radially outward of the frame body **722**. The intermediate anchoring feature **728** can be relatively flexible, resilient, and/or malleable. For example, the construction of the intermediate anchoring feature **728**, such as the materials used and/or the geometry of the mesh, can be chosen to provide this flexibility, resilience, and/or flexibility. In some embodiments, the intermediate anchoring feature **728** can be formed from a metal such as, but not limited to, stainless steel, cobalt-chrome, and a shape memory metal such as Nitinol. The intermediate

anchoring portion **728** can take the form of a wire mesh. In some embodiments, the intermediate anchoring portion **728** can be formed separately from the other portions of the frame **720**. The intermediate anchoring portion **728** can be attached to other portions of the frame **720** using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots which can be on the frame **720** and the intermediate anchoring feature **728**), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques. The frame **720** and the intermediate anchoring feature **728** can be indirectly attached via an intermediate component, such as the skirt **780**. In some embodiments, the intermediate anchoring feature 728 can be maintained in position by wrapping the skirt **780** over the intermediate anchoring feature **728** and attaching ends of the skirt **780** to the frame **720**. In some embodiments, the intermediate anchoring portion **728** can be integrally or monolithically formed with other portions of the frame **720**.

[0418] The flexibility, resiliency, and/or malleability of the intermediate anchoring feature **728** can beneficially allow the intermediate anchoring feature **728** to conform to the anatomy of the body cavity in which it is positioned, such as tissue of a native heart wall, a native valve annulus, and/or leaflets. In some situations, such as when the intermediate anchoring feature **728** is positioned within a native mitral valve, the intermediate anchoring feature **728** can conform to the shape of the mitral valve annulus such that the anchoring feature **728** contacts or extends over one or more of: an atrial side of the native mitral valve annulus, an inner periphery of the native mitral valve annulus, and portions of the leaflets. Moreover, the flexibility, resiliency, and/or malleability can beneficially allow the intermediate anchoring feature **728** to be crimped to a smaller diameter during the delivery process, thereby allowing for the use of a smaller gauge delivery device.

[0419] As shown in the illustrated embodiment, at least a portion of the intermediate anchoring feature **728** can be positioned radially between the lower

anchoring feature **726** and the frame body **722**. In this manner, tissue of the body cavity can be positioned between the lower anchoring feature **726** and the intermediate anchoring feature **728**. In some embodiments, portions of the lower anchoring feature **726** and the intermediate anchoring feature **728** are sufficiently proximate each other such that tissue of the body cavity positioned therebetween are pinched or engaged. For example, in situations where the prosthesis **700** is positioned within a native mitral valve, the native mitral valve annulus and/or leaflets can be pinched or engaged between the lower anchoring feature **726** and the intermediate anchoring feature **728**. This can beneficially enhance securement of the prosthesis **700** to the body cavity. As shown in the illustrated embodiment, a diameter of the intermediate anchoring feature **728** can be greater at or proximate tips or ends of the lower anchoring feature **726** and can have a reduced diameter near a lower end of the intermediate anchoring feature **728**. This can beneficially allow for a greater degree of pinching or clamping force at or proximate the tips of the lower anchoring feature **726** while providing substantial space for tissue of the body cavity, such as native leaflets, positioned between the frame body **722**, the lower anchoring feature **728**, and the intermediate anchoring feature **728**.

[0420] As noted above, one or more of anchoring features **724**, **726**, **728** can contact or engage a native valve annulus, such as the native mitral valve annulus, tissue beyond the native valve annulus, native leaflets, and/or other tissue at or around the implantation location. In instances where the prosthesis **700** is positioned within a native mitral valve, the upper anchoring feature **724** can be positioned on an atrial side of the native mitral valve annulus, the lower anchoring feature **726** can be positioned on a ventricular side of the native mitral valve annulus, and the intermediate anchoring feature **728** can be positioned intra-annularly. While the anchoring features **724**, **726**, **728** have been illustrated as extending from the upper region **730,** the lower region **734**, and the intermediate region **732** of the frame body **722** respectively, it should be understood that the anchoring features **724**, **726**, **728** can be positioned along any other portion of the frame body **722** as desired. Moreover, while three anchoring features **724**, **726**, **728** have been included in the illustrated embodiment, it is contemplated that fewer or greater sets of anchoring features can be utilized.

[0421] The anchoring features **724**, **726**, **728** are preferably located along the prosthesis **700** with at least part of the foreshortening portion positioned between the anchoring features **724**, **726**, **728** so that a portion of the anchoring features **724**, **726**, **728** will move closer together with expansion of the prosthesis **700**. As one example, this can allow the anchoring features **724**, **726**, **728** to close in on opposite sides of the native mitral annulus to thereby secure the prosthesis at the mitral valve. In some embodiments, the anchoring features **724**, **726**, **728** can be positioned such that the anchoring features **724**, **726**, **728** do not contact opposing portions of the native mitral annulus at the same time. For example, in some situations, the intermediate anchoring feature **726** and the upper anchoring feature **728** may contact the native mitral annulus while the upper anchoring feature **724** may not contact the native mitral annulus. This can be beneficial when upper anchoring feature **724** is used to provide stabilization and help align the prosthesis. In some embodiments, the anchoring features **724**, **726**, **728** can be positioned such that the anchoring features **724**, **726** grasp opposite side of the native mitral annulus.

[0422] With reference next to the skirt **780** illustrated in **Figure 15**, the skirt **780** can be attached to frame **720** and/or the valve body **760**. The skirt **780** can be positioned around and secured to a portion of, or the entirety of, the exterior and/or interior of the frame **720**. As shown, the skirt **780** can extend from the valve body **760** and extend along an interior of the upper anchoring feature **724**. This can beneficially serve as a collector or funnel to direct blood into the inlet of the valve body **760**. The skirt **780** can wrap around the ends of the upper anchoring feature **724** and extend downwardly. As shown, the skirt **780** can extend between the lower anchoring feature **726** and the intermediate anchoring feature **728**. The skirt **780** can be attached to the frame **720** and/or the valve body **760** below the intermediate anchoring feature **728**.

[0423] The skirt **780** can be annular and can extend entirely circumferentially around the frame **720**. The skirt **780** can prevent or inhibit backflow of fluids, such as blood, around the prosthesis **700**. For example, with the skirt **780** positioned annularly around an exterior of the frame **720**, the skirt **780** can create an axial barrier to fluid flow exterior to the frame **720** when deployed within a body cavity such as a native valve

annulus. The skirt **780** can encourage tissue in-growth between the skirt **780** and the natural tissue of the body cavity. This may further help to prevent leakage of blood flow around the prosthesis **700** and can provide further securement of the prosthesis **700** to the body cavity. In some embodiments, the skirt **780** can be tautly attached to the frame **720** such that the skirt **780** is generally not movable relative to the frame **720**. In some embodiments, the skirt **780** can be loosely attached to the frame **720** such that the skirt **780** is movable relative to the frame **720**. In some embodiments, blood may be allowed to flow into the skirt **780**.

[0424] Although the prosthesis **700** has been described as including a frame **720**, a valve body **760**, and a skirt **780**, it is to be understood that the prosthesis **700** need not include all components. For example, in some embodiments, the prosthesis **700** can include the frame **720** and the valve body **760** while omitting the skirt **780**. Moreover, although the components of the prosthesis **700** have been described and illustrated as separate components, it is to be understood that one or more components of the prosthesis **700** can be integrally or monolithically formed.

[0425] With reference next to **Figures 16-19**, an embodiment of a prosthesis **800** in an expanded configuration, or components of the prosthesis **800**, are illustrated. The prosthesis **800** can include a frame **820**, a valve body **870**, and a skirt **890**. A longitudinal axis of the prosthesis **800** may be defined as the central axis that extends through the center of the prosthesis **800** between the upper and lower ends of the prosthesis **800**. In some situations, the prosthesis **800** may be oriented such that an upper end of the prosthesis **800** is a proximal portion and a lower end of the prosthesis **800** is a distal portion.

[0426] With reference first to the frame **820** illustrated in **Figures 18-19**, the frame **820** can include a frame body **822**, an upper anchoring feature **824**, a lower anchoring feature **826**, and an intermediate anchoring feature **828**. The frame body **822** can include an upper region **830**, an intermediate region **832**, and a lower region **834**. As shown, the frame body **822** can have a generally cylindrical shape such that the diameters of the upper region **830**, the intermediate region **832**, and the lower region **834** are

generally constant. However, it is to be understood that the diameters of the upper region **830**, the intermediate region **832**, and/or the lower region **834** can be different.

[0427] In some embodiments, the diameter of the frame body **822** may be between about 40% to about 90% of the diameter of the native valve annulus, between about 60% to about 85%, of the diameter of the native valve annulus, between about 70% to about 80% of the diameter of the native valve annulus, any other sub-range between these ranges, or any other percentage as desired. In some embodiments, the diameter of the frame body **822** can be in the range of about 20mm to about 40mm when expanded, in the range of about 25mm to about 35mm when expanded, in the range of about 28mm to about 32mm when expanded, about 29mm when expanded, any other sub-range within these ranges when expanded, or any other diameter when expanded as desired. Although the frame body **822** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the frame body **822** can be have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0428] In other embodiments, the diameter of portions of the frame body **822** such as the upper region **830**, intermediate region **832**, and/or lower region **834** may be chosen such that the frame body **822** is positioned at the periphery of the body cavity. For example, in embodiments where the prosthesis **800** is positioned within the native mitral valve, the inner frame body **822** may have a diameter which is about equal to the diameter of the native mitral valve annulus.

[0429] The frame **822** can include a plurality of struts with at least some of the struts forming cells **836a-b**. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes.

[0430] The upper and lower row of cells **836a-b** can have a diamond or generally diamond shape. The rows of cells **836a-b** can be formed via a combination of struts. As shown in the illustrated embodiment, the upper row of cells **836a** can be formed from a first set of circumferentially-expansible struts **838a** and a second set of circumferentially-expansible struts **838b**. The lower row of cells **836b** can be formed

from the second set of circumferentially-expansible struts **838b** and a third set of circumferentially-expansible struts **838c**. The first, second, and third sets of struts **838a-c** can have a zig-zag or undulating shape forming a repeating "V" shape. It is to be understood that some or all of the struts **838a-c** may not form entirely straight segments. For example, the struts **838a-c** can include some curvature such that the upper and/or lower apices are curved.

[0431] As shown in the illustrated embodiment, the upper and lower row of cells **836a-b** extend in a direction generally parallel to the longitudinal axis of the prosthesis **800**. There can be a row of nine cells **836a** and a row of nine cells **836b**. While each of the cells **836a-b** are shown as having the same shape as other cells **836a-b** of the same row, it is to be understood that the shapes of cells **836a-b** within a row can differ. Moreover, it is to be understood that any number of rows of cells can be used and any number of cells may be contained in the rows. In some embodiments, the number of cells can correspond to the number of anchors or anchor tips forming the upper anchoring feature **824** and/or the lower anchoring feature **826**. The number of cells in the upper and lower row of cells **836a-b** can have a 1:1 correspondence with the number of anchors in the upper anchoring feature **824** and/or the lower anchoring feature **826** (i.e., nine cells in each row of cells **836a-b** and nine anchors for the anchoring features **824**, **826**). It is to be understood that other ratios of numbers of cells per row to number of anchors per anchoring feature can be used such as, but not limited to, 3:1, 4:1, 5:1, 6:1, and other ratios as desired. In some embodiments, all three rows of cells **836a-b** can have different numbers of cells. Moreover, it is to be understood that fewer or greater numbers of rows of cells can be used.

[0432] The geometry of cells **836a-b** can allow the cells **836a-b** to foreshorten as the frame **820** is expanded. As such, one or more of cells **836a-b** can allow the frame **820** to foreshorten as the frame **820** is expanded. As described herein, foreshortening of the frame **820** can be used to secure the prosthesis to intralumenal tissue in a body cavity, for example tissue at or adjacent a native valve, such as a native valve annulus and/or leaflets. For example, expansion of the frame **820** can allow the upper frame anchoring feature **824,** the lower anchoring feature **826**, and/or the

intermediate anchoring feature **828** to extend radially outward and draw closer to tissue of the body cavity, such as a native valve annulus and/or leaflets, to engage tissue of the body cavity.

[0433] The frame **820** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of frames such as inner frames **120**, **220**, **400**, **520a-g**, **720**.

[0434] As shown in the illustrated embodiment, the upper anchoring feature **824** can extend radially outwardly from the longitudinal axis of the prosthesis **800**. In this manner, upper anchoring feature **824** can create a flared or shoulder portion **840** of the frame **820**. As shown in the illustrated embodiment, the upper anchoring feature **824** can include one or more anchors **842a-b**. The anchors **842a-b** can extend from below an upper end of the frame body **822**. For example, the anchors **842a-b** can extend from a portion of the frame body **822** between the upper row of cells **836a**. However, it is to be understood that the anchors **842a-b** can extend from other portions of the frame body **822**, such as upper apices of the upper row of cells **836a**.

[0435] The anchors **842a-b** can extend upwardly from the frame body **822**. The anchors **842a-b** can then extend radially outwardly via a bend **844**. The bend **844** can be about a circumferential axis such that the anchors **842a-b** extend in a direction more perpendicular to the longitudinal axis of the prosthesis **800** than the frame body **822**. The bend **844** can be similar to the bend **738** discussed above in connection with prosthesis **700** illustrated in **Figure 15**.

[0436] As shown, anchors **842a**, **842b** can include a second bend **846** above the bend **844**. The bend **846** can be a clockwise bend about a circumferential axis such that the portion of the anchors **842a**, **842b** above the second bend **846** extends in a direction less perpendicular to the longitudinal axis of the prosthesis **800** than the portion of the anchors **842a**, **842b** below the second bend **846**. The bend **846** can be similar to the bend **740** discussed above in connection with prosthesis **700** illustrated in **Figure 15**.

[0437] Some anchors of the upper anchoring feature **824**, such as anchors **842b**, can have a greater length than other anchors of the upper anchoring feature **824**, such as anchors **842a**. As shown, anchors **842b** can include a third bend **848** above the

bend **846**. The bend **848** can be about a circumferential axis such that the portion of the anchors **842b** above the third bend **848** extends in a direction radially towards the longitudinal axis of the prosthesis **800**. This can beneficially reduce the likelihood that the anchors **842b** contact tissue of the body cavity. For example, in situations where the prosthesis **800** is positioned within a native mitral valve, the radially inward bend can reduce the likelihood of anchors **842b** contacting the atrial wall.

[0438] In some embodiments, portions of anchors **842b** can form part of a locking tab **850** having a strut **850a** and an enlarged head **850b**. The locking tab **850** can advantageously be used with multiple types of delivery systems. For example, the shape of the strut **850a** and the enlarged head **850b** can be used to secure the frame **850** to a "slot" based delivery system. The locking tabs **850** can include eyelets which can be used to secure the frame **820** to a "tether" based delivery system such as those which utilize sutures, wires, or fingers to control delivery of the frame **820**. This can advantageously facilitate recapture and repositioning of the frame **820** in situ. In some embodiments, the frame **820** can be used with the delivery systems described herein, including but not limited to, those described in U.S. Patent Nos. 8,414,644 and 8,652,203 and U.S. Publication Nos. 2015/0238315, the entireties of each of which are hereby incorporated by reference and made a part of this specification.

[0439] With continued reference to the frame **820** illustrated in **Figures 18-19**, the lower anchoring feature **826** can include one or more anchors **854**. The anchors **854** can extend generally downwardly from above a lower end of the lower region **814** of the frame body **822**. For example, the anchors **854** can extend from a portion of the frame body **822** between the lower row of cells **836b**. However, it is to be understood that the anchors **854** can extend from other portions of the frame body **822**, such as lower apices of the lower row of cells **836b**. The anchors **854** can bend to extend generally radially outward of the longitudinal axis of the prosthesis **800**. The anchors can extend upwardly towards an end or tip **856**.

[0440] The anchors **854** can be used to attach or secure the prosthesis **800** to a native valve. For example, in some embodiments, the anchors **854** can be used to attach or secure the prosthesis **800** to a native valve, such as a native mitral valve. In such an

embodiment, the anchors **854** can be positioned to contact or engage a native mitral valve annulus on a ventricular side, tissue beyond the native valve annulus on a ventricular side, native leaflets, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. The anchors **854** can beneficially eliminate, inhibit, or limit upward movement of the prosthesis **800** when subject to upwardly directed forces such as those which are applied on the prosthesis **800** during systole.

[0441] The tips or ends of the anchors **842a-b**, **854** can advantageously provide atraumatic surfaces that may be used to contact or engage intralumenal tissue without causing unnecessary or undesired trauma to tissue. For example, the tips or ends can form flat, substantially flat, curved or other non-sharp surfaces to allow the tips to engage and/or grasp tissue, without necessarily piercing or puncturing through tissue. A looped end or looped anchor may assist the frame in not getting caught up on structures at or near the treatment location. For example, each loop can be configured so that when the prosthesis **800** is deployed in-situ and the anchors **842a-b**, **854** expand away from the frame body **822**, the movement of each loop from a delivered position to a deployed position avoids getting caught on the papillary muscles. As shown in the illustrated embodiment, the anchors **854** can include eyelets or holes **858** at or proximate the tips or ends. The eyelets or holes **858** can facilitate attachment of component, such as a cover and/or cushion, the tips or ends **856** of the anchors **842a-b**, **854**.

[0442] As shown in the illustrated embodiment, the upper and lower anchoring features **824**, **826** can include twelve individual anchors; however, it is to be understood that a greater number or lesser number of individual anchors can be used. For example, the number of individual anchors can be chosen as a multiple of the number of commissures for the valve body **870**. As such, for a prosthesis **800** with a valve body **870** having three commissures, the upper anchoring feature **824** and/or the lower anchoring feature **826** can have three individual anchors (1:1 ratio), six individual anchors (2:1 ratio), nine individual anchors (3:1 ratio), twelve individual anchors (4:1 ratio), fifteen individual anchors (5:1 ratio), or any other multiple of three. It is to be

understood that the number of individual anchors need not correspond to the number of commissures of the valve body **870**.

[0443] Moreover, while the prosthesis **800** includes anchoring features **824**, **826** with twelve anchors each, it is to be understood that a greater number of anchors or a lesser number of anchors can be used. In some embodiments, instead of a 1:1 correspondence between the number of anchors in the upper frame anchoring feature **824** and the lower anchoring feature **826** (i.e., twelve anchors each), other ratios can be used. For example, a 1:2 or a 1:3 correspondence between the anchors, are possible such that the upper anchoring feature **824** or the lower anchoring feature **826** have fewer anchors than the other anchoring feature.

[0444] The intermediate anchoring feature **828** can be positioned at or proximate the intermediate region **832** of the frame body **822**. The intermediate anchoring feature **828** can be positioned such that it is radially outward of the frame body **822**. The intermediate anchoring feature **828** can be relatively flexible, resilient, and/or malleable. For example, the construction of the intermediate anchoring feature **828**, such as the materials used and/or the geometry of the mesh, can be chosen to provide this flexibility, resilience, and/or flexibility. In some embodiments, the intermediate anchoring feature **828** can be formed from a metal such as, but not limited to, stainless steel, cobalt-chrome, and a shape memory metal such as Nitinol. The intermediate anchoring portion **828** can take the form of a wire mesh. In some embodiments, the intermediate anchoring portion **828** can be formed separately from the other portions of the frame **820**. The intermediate anchoring portion **828** can be attached to other portions of the frame **820** using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots which can be on the frame **820** and the intermediate anchoring feature **828**), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques. For example, in embodiments having a braided mesh with loops, sutures can be used to

connect the edge loops to the frame body **822**. The frame **820** and the intermediate anchoring feature **828** can be indirectly attached via an intermediate component, such as the skirt **890**. In some embodiments, the intermediate anchoring feature **828** can be maintained in position by wrapping the skirt **890** over the intermediate anchoring feature **828** and attaching ends of the skirt **890** to the frame **820**. In some embodiments, the intermediate anchoring portion **828** can be integrally or monolithically formed with other portions of the frame **820**.

[0445] The flexibility, resiliency, and/or malleability of the intermediate anchoring feature **828** can beneficially allow the intermediate anchoring feature **828** to conform to the anatomy of the body cavity in which it is positioned, such as tissue of a native heart wall, a native valve annulus, and/or leaflets. In some situations, such as when the intermediate anchoring feature **828** is positioned within a native mitral valve, the intermediate anchoring feature **828** can conform to the shape of the mitral valve annulus such that an upper region of the intermediate anchoring feature **828** extends over an atrial side of the native mitral valve annulus, an intermediate region of the intermediate anchoring feature **828** conforms to the inner periphery of the native mitral valve annulus, and/or the lower region of the intermediate anchoring feature **828** contacts portions of the leaflets. Moreover, the flexibility, resiliency, and/or malleability can beneficially allow the intermediate anchoring feature **828** to be crimped to a smaller diameter during the delivery process, thereby allowing for the use of a smaller gauge delivery device.

[0446] As shown in the illustrated embodiment, at least a portion of the intermediate anchoring feature **828** can be positioned radially between the lower anchoring feature **826** and the frame body **822**. In this manner, tissue of the body cavity can be positioned between the lower anchoring feature **826** and the intermediate anchoring feature **828**. In some embodiments, portions of the lower anchoring feature **826** and the intermediate anchoring feature **828** are sufficiently proximate each other such that tissue of the body cavity positioned therebetween are pinched or engaged. For example, in situations where the prosthesis **800** is positioned within a native mitral valve, the native mitral valve annulus and/or leaflets can be pinched or engaged between the

lower anchoring feature **826** and the intermediate anchoring feature **828**. This can beneficially enhance securement of the prosthesis **800** to the body cavity.

[0447] As shown in the illustrated embodiment, the intermediate anchoring feature **828** can have a generally triangular, cross-sectional shape along a plane parallel to and extending through the longitudinal axis of the prosthesis **800**. The intermediate anchoring feature **828** can have a greater diameter at or proximate tips or ends of the lower anchoring feature **826** and a reduced diameter near a lower end of the intermediate anchoring feature **828**. This can beneficially allow for a greater degree of pinching or clamping force at or proximate the tips of the lower anchoring feature **826** while providing substantial space for tissue of the body cavity, such as native leaflets, positioned between the frame body **822**, the lower anchoring feature **826**, and the intermediate anchoring feature **828**. However, it is to be understood that other cross-sectional shapes along a plane parallel to and extending through the longitudinal axis of the prosthesis **800**. For example, the cross-section can be circular, semi-circular, elliptical, semi-elliptical, rectangular, and the like.

[0448] As noted above, one or more of anchoring features **824**, **826**, **828** can contact or engage a native valve annulus, such as the native mitral valve annulus, tissue beyond the native valve annulus, native leaflets, and/or other tissue at or around the implantation location. In instances where the prosthesis **800** is positioned within a native mitral valve, the upper anchoring feature **824** can be positioned on an atrial side of the native mitral valve annulus, the lower anchoring feature **826** can be positioned on a ventricular side of the native mitral valve annulus, and the intermediate anchoring feature **828** can be positioned intra-annularly. While the anchoring features **824**, **826**, **828** have been illustrated as extending from the upper region **830,** the lower region **834**, and the intermediate region **832** of the frame body **822** respectively, it should be understood that the anchoring features **824**, **826**, **828** can be positioned along any other portion of the frame body **822** as desired. Moreover, while three anchoring features **824**, **826**, **828** have been included in the illustrated embodiment, it is contemplated that fewer or greater sets of anchoring features can be utilized.

[0449] With reference back to the prosthesis **800** illustrated in **Figures 16-17**, covers **860** and/or cushions **862** can be used to surround or partially surround at least a portion of the anchoring features **824**, **826**, **828**, such as anchors of the lower anchoring feature **826**. As shown in the illustrated embodiment, a cover **860** can be positioned around portions of the anchors **854** preceding the tips or ends **856**. A cushion **862** can be positioned to around the tips or ends **856**. The covers **860** and/or cushions **862** can be similar to those described in U.S. Publication No. 2015/032800, which has been incorporated by reference in its entirety. It is to be understood that greater or fewer numbers of covers **860** and/or cushions **862** can be used with anchors **854**. For example, a cover **860** and/or cushion **862** can be used on every other anchor such that there is a 1:2 ratio of covers **860** and/or cushions **862** to anchors

[0450] The tips or ends **856** of the anchors **854** can be generally circumferentially offset with respect to the tips or ends of the anchors **842a**, **842b**. In other embodiments (not shown), the tips or ends **856** of the anchors **854** can be generally circumferentially aligned with respect to the tips or ends of the anchors **842a**, **842b**.

[0451] Preferably, each of the anchoring features **824**, **826**, **828** are positioned or extend generally radially outwardly from the prosthesis **800** so that the tips or ends of the anchoring features **824**, **826**, **828** are generally spaced away or radially outward from the rest of the frame body **822**. As shown in the illustrated embodiment, at least some of the anchoring features, such as lower anchoring feature **826**, can extend to a radial distance from an exterior surface of the frame body **822** that is about 120% or more of the expanded diameter of the frame body **822**, that is about 130% or more of the expanded diameter of the frame body **822,** that is about 140% or more of the expanded diameter of the frame body **822,** that is about 150% or more of the expanded diameter of the frame body **822**.

[0452] In some embodiments, all of the anchors of the lower anchoring feature **826** and/or all of the anchors of the upper frame anchoring feature **824** extend at least to this radial distance. In other embodiments, fewer than all of the anchors of the lower anchoring feature **826** and/or all of the anchors of the upper anchoring feature **824** extend to this radial distance. The outermost diameter of the anchoring features **824**, **826**,

828 may be greater than the diameter of frame body **822** as described above and may be in the range of about 35mm to about 70mm when expanded, in the range of about 35mm to about 60mm when expanded, in the range of about 40mm to about 60mm when expanded, in the range of about 45mm to about 50mm when expanded, any sub-range within these ranges when expanded, or any other diameter as desired. In some embodiments, the upper anchoring feature **824** can have a diameter of about 49mm while the lower anchoring feature **826** and the intermediate anchoring feature **828** can have a diameter of about 46mm.

[0453] Moreover, as will be discussed in further detail below, the anchoring features **824**, **826**, **828** are preferably located along the prosthesis **800** with at least part of the foreshortening portion positioned between the anchoring features **824**, **826**, **828** so that a portion of the anchoring features **824**, **826**, **828** will move closer together with expansion of the prosthesis **800**. As one example, this can allow the anchoring features **824**, **826**, **828** to close in on opposite sides of the native mitral annulus to thereby secure the prosthesis at the mitral valve. In some embodiments, the anchoring features **824**, **826**, **828** can be positioned such that the anchoring features **824**, **826**, **828** do not contact opposing portions of the native mitral annulus at the same time. For example, in some situations, the intermediate anchoring feature **826** and the upper anchoring feature **828** may contact the native mitral annulus while the upper anchoring feature **824** may not contact the native mitral annulus. This can be beneficial when upper anchoring feature **824** is used to provide stabilization and help align the prosthesis. In some embodiments, the anchoring features **824**, **826**, **828** can be positioned such that the anchoring features **824**, **826** grasp opposite side of the native mitral annulus.

[0454] With reference next to the valve body **870** illustrated in **Figures 16-17**, the valve body **870** can be positioned within the frame **820**. The valve body **870** can be a replacement heart valve which includes a plurality of valve leaflets **872**. The valve leaflets **872** can include a first edge **874**, second edge (not shown), and tabs **878** for attaching the valve leaflets **872** together at commissures of the valve body **870**. The tabs **878** can be used to secure the valve leaflets **872** to the frame **820**. The first edge **874** can be an arcuate edge and can be generally fixed in position relative to the frame **820**. The

second edge can be a freely moving edge which can allow the valve body **870** to open and close.

[0455] The plurality of valve leaflets **872** can function in a manner similar to the native mitral valve, or to any other valves in the vascular system as desired. The plurality of valve leaflets **872** can open in a first position and then engage one another to close the valve in a second position. The plurality of valve leaflets **872** can be made to function as a one-way valve such that flow in one direction opens the valve and flow in a second direction opposite the first direction closes the valve. For example, as shown in the illustrated embodiment, the valve body **870** can open allow to blood to flow through the valve body **870** in a direction from an upper end to a lower end. The valve body **870** can close to inhibit blood flow through the valve body **870** in a direction from the lower end to the upper end. In situations where the prosthesis **800** is oriented such that an upper end is a proximal end and a lower end is a distal end, the valve body **870** can be positioned such that the valve body **870** can open to allow blood to flow through the valve body **870** in a proximal-to-distal direction and close to inhibit blood flow in a distal-to-proximal direction. The valve body **870** can be constructed so as to open naturally with the beating of the heart. For example, the valve body **870** can open during diastole and close during systole. The valve body **870** can replace a damaged or diseased native heart valve such as a diseased native mitral valve.

[0456] With continued reference to the valve body **870** illustrated in **Figures 16-17**, the valve body **870** can include a liner **880**. The liner **880** can be used to assist with fluid flow through and/or around the prosthesis **880**, such as through and around the inner frame **880** and the valve leaflets **872**. The liner **880** can surround at least a portion of the valve leaflets **872** and be connected to one or more of the valve leaflets **872**. For example, as shown in the illustrated embodiment, the one or more valve leaflets **872** can be attached to the liner **880** along the first edge **874** of the valve leaflets **872**.

[0457] As shown in the illustrated embodiment, the liner **880** can be positioned within the interior of the inner frame **880** and can form an inner wall of the prosthesis **800**. For example, the liner **880** can be positioned such that the liner **880** is radially inward, relative to the longitudinal axis of the prosthesis **800**, from the struts of

the frame **820**. In this manner, the fluid pathway towards the valve leaflets **872** can be relatively smooth. It is also contemplated that the liner **880** can at least be partially positioned along an exterior of the frame **820** such that at least a portion of the liner **880** is radially outward, relative to the longitudinal axis of the prosthesis **800**, from struts of the frame **820**. As shown in the illustrated embodiment, the liner **880** can be positioned along an upper or inlet side of the frame **820**. The liner **880** can extend from the first edge **874** of the valve leaflets **872** towards the upper end of the frame **820**. The liner **880** can also extend below the first edge **874** of the valve leaflet **872** towards the lower end of the frame **820**. The liner **880** can also be made to move with foreshortening portions of the frame **820**.

[0458] In some embodiments, the liner **880** can extend the entire length of the frame **820** or the frame body **822**. In other embodiments, it can extend along only part of the length of the frame body **822** as shown. In some embodiments, the ends of the valve leaflets **872** can coincide with ends of the liner **880**. In addition, one or more of the ends of the frame body **822** can coincide with the ends of the liner **880**. As shown in the illustrated embodiment, an end **882** of the liner **880** can be positioned between the upper end of the frame **820** and the valve leaflets **872**. The end **882** of the liner **880** can extend above an upper end of the frame body **822**. In some embodiments, the end **882** of the liner **880** can be positioned at or proximate an uppermost portion of the first or arcuate edge **874** of the valve leaflet **872**.

[0459] Other shapes and configurations can also be used for the valve body **870**. In some embodiments, the liner **880** may extend along the length of the leaflets, but is not connected to them. In the illustrated embodiment, the liner **880** is attached to the frame **820** and at least a portion of the leaflets **872**, such as the first or arcuate edge **874**, is attached to the liner **880**. Portions of the valve leaflets **872**, such as the portions of the first edge **874** and/or tabs **878**, can also be attached to the frame **820**. The liner **880** and/or the valve leaflets **872** can be attached to the frame **820** or to each other using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots), and any other type of mechanical fastener as desired, chemical fasteners

such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques.

[0460] The liner **880** can be constructed in multiple different ways. The liner **880** can be made a layer of resilient material, such as such as knit polyester (e.g., polyethylene terephthalate (PET), polyvalerolactone (PVL)) or any other biocompatible material such as those which are wholly or substantially fluid impermeable, flexible, stretchable, deformable, and/or resilient. In some embodiments, the liner **880** can be made from a material that is more flexible than the valve leaflet material. The upper and/or lower end, such as end **882**, of the liner **880** can be straight, curved, or have any other desired configuration. For example, as shown in the illustrated embodiment, the liner **880** can have one or more straight edges **884** and one or more slots **886** forming the end **882**. It is to be understood that the liner **880**, such as the straight edges **884**, can be folded over a top end of the frame body **822**. In other embodiments, the end **882** can be patterned to generally correspond to the undulations at one end of the frame **820**. The liner **880** can be formed of one piece or multiple pieces.

[0461] In another embodiment of the liner **880**, the end can extend past the frame **820** and can be wrapped around it. Thus, the liner **880** can extend from the inside of the frame **820** to the outside of the frame **820**. The liner **880** can extend completely around the frame **820** for 1/4, 1/3, 1/2, or more of the length of frame **820**.

[0462] With reference next to the skirt **890** illustrated in **Figures 16-17**, the skirt **890** can be attached to frame **820** and/or the valve body **870**. The skirt **890** can be positioned around a portion of, or the entirety of, the exterior of the frame **820** and/or the interior of the frame **820**. As shown, the skirt **890** can extend from the valve body **870** and extend along an interior of the upper anchoring feature **824**. The skirt **890** can wrap around the ends of the upper anchoring feature **870**, or a portion thereof, and extend downwardly. For example, the skirt **890** can extend up to and wrap around the ends of the anchors **842a** but not the ends of anchors **842b**. This can advantageously allow the locking tabs **848** to remain uncovered to facilitate use with a delivery system. As shown, the skirt **890** can extend between the lower anchoring feature **826** and the intermediate

anchoring feature **828**. The skirt **890** can be attached to the frame **820** and/or the valve body **870** below the intermediate anchoring feature **828**.

[0463] The skirt **890** can be annular and can extend entirely circumferentially around the frame **890**. The skirt **890** can prevent or inhibit backflow of fluids, such as blood, around the prosthesis **800**. For example, with the skirt **890** positioned annularly around an exterior of the frame **820**, the skirt **890** can create an axial barrier to fluid flow exterior to the frame **820** when deployed within a body cavity such as a native valve annulus. The skirt **890** can encourage tissue in-growth between the skirt **890** and the natural tissue of the body cavity. This may further help to prevent leakage of blood flow around the prosthesis **800** and can provide further securement of the prosthesis **800** to the body cavity. In some embodiments, the skirt **890** can be tautly attached to the frame **820** and/or valve body **870**. In some embodiments, the skirt **890** can be loosely attached around the frame **820** and/or valve body **870**. In some embodiments, blood may be allowed to flow into the skirt **890**.

[0464] As shown in the illustrated embodiment, the skirt **890** can have a first portion **892**, a second portion **894**, and a third portion **896**. The first portion **892** can extend along an interior portion of the frame **820**. For example, the first portion **892** can extend from the liner **880** of the valve body **870** and extend along an interior of the frame body **882** and/or the upper anchoring feature **824**. The first portion **892** can extend up to the ends of the anchors **842a**. The first portion **892** can also extend up to the ends of anchors **842b**.

[0465] The second portion **894** can extend downwardly from an upper end of the first portion **892**. The second portion **894** can extend along an exterior portion of the frame **820**. For example, the second portion **894** can extend along an exterior of the upper anchoring feature **824** and/or the intermediate anchoring feature **828**. The second portion **894** can be attached to the frame **820** at a position between the intermediate anchoring feature **828** and the lower anchoring feature **826**.

[0466] The third portion **896** can extend along an exterior portion of the frame **820**. For example, the third portion **896** can extend along an exterior of the frame body **822**. The third portion **896** can extend upwardly from a lower end of the frame

body **822**. The third portion **896** can extend upwardly towards a lower end of the liner **880**. In some embodiments, the third portion **896** can extend up to, or beyond, the lower end of the liner **880**. As shown in the illustrated embodiment, the third portion **896** can be positioned between the frame body **822** and the intermediate anchoring feature **828**.

[0467] The first portion **892**, second portion **894**, and third portions **896** can be formed from separate components. The components can be attached using any of the fasteners and/or techniques described herein including, but not limited to, mechanical fasteners, such as sutures, staples, screws, rivets, interfacing members (e.g., tabs and slots), and any other type of mechanical fastener as desired, chemical fasteners such as adhesives and any other type of chemical fastener as desired, fastening techniques such as welding, soldering, sintering, and any other type of fastening technique as desired, and/or a combination of such fasteners and techniques. In some embodiments, the skirt **890** can be formed from additional components. For example, the second portion **894** can be formed from an upper component and a lower component. In some embodiments, two or more portions of the skirt **890** can be integrally or monolithically formed.

[0468] Although the prosthesis **800** has been described as including a frame **820**, a valve body **870**, and a skirt **890**, it is to be understood that the prosthesis **800** need not include all components. For example, in some embodiments, the prosthesis **800** can include the frame **820** and the valve body **870** while omitting the skirt **890**. Moreover, although the components of the prosthesis **800** have been described and illustrated as separate components, it is to be understood that one or more components of the prosthesis **800** can be integrally or monolithically formed.

[0469] With reference next to **Figures 20-22**, an embodiment of a prosthesis **900** in an expanded configuration, or components of the prosthesis **900**, are illustrated. The prosthesis **900** can include a frame **920**, a valve body **970**, and a skirt **990**. A longitudinal axis of the prosthesis **900** may be defined as the central axis that extends through the center of the prosthesis **900** between the upper and lower ends of the prosthesis **900**. The prosthesis **900** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of prosthesis **800** described in connection with **Figures 16-19**.

[0470] The frame **920** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of frame **820** described in connection with **Figures 16-19**. The frame **920** can include a frame body **922**, an upper anchoring feature **924**, a lower anchoring feature **926**, and an intermediate anchoring feature **928**. As shown in the illustrated embodiment, the upper anchoring feature **924** can be formed from a row of circumferentially expansible struts **930**. The circumferentially-expansible struts **930** can be attached to the frame body **922** via one or more struts **932**. The intermediate anchoring feature **928** can be formed from a braided structure.

[0471] The skirt **990** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of skirt **890** described in connection with **Figures 16-19**. Accordingly, reference should be made to the discussion of skirt **890** for further details pertaining to the skirt **990**. As shown in **Figure 20**, the skirt **990** can be formed from multiple components which can be attached together (as shown in **Figure 21**).

Embodiments of Circumferentially Curved Anchoring Features

[0472] In some embodiments, the prostheses described herein can incorporate a circumferentially curved or inclined anchoring feature. In some situations, such as those in which the prostheses are implanted at a native mitral valve, the circumferential curve and/or incline can allow a greater number of chordae tendineae to be positioned between a frame body and the curved or inclined anchors. This can beneficially enhance securement of the frame to the native mitral valve. It is to be understood that the circumferentially curved or inclined anchoring feature can be used in combination with other anchoring features described herein or as a replacement for one or more of the anchoring features described herein.

[0473] With reference next to **Figures 23-25**, a portion of an embodiment of a frame **1000** is illustrated. The frame **1000** can include a frame body **1002** and an anchoring feature **1004**. A longitudinal axis of the frame **1000** may be defined as the central axis that extends through the center of the frame **1000** between the upper and

lower ends of the frame **1000**. Features of the frame **1000** can be incorporated in any of the prostheses described herein.

[0474] The frame body **1002** can include an upper region **1006**, an intermediate region **1008**, and a lower region **1010**. As shown, the frame body **1002** can include a plurality of struts with at least some of the struts forming cells **1012a-c**. The cells **1012a-c** can have a diamond or generally diamond shape. However, it is to be understood that the cells **1012a-c** can have different shapes such as those described in connection with other frames herein. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes. For example, the frame body **1002** can be formed from circumferentially-expansible elements **1014a-d**. While the struts **1014a-d** are generally described and illustrated as being straight segments, it is to be understood that some or all of the struts **1014a-d** may not form entirely straight segments. For example, the struts **1014a-d** can include some curvature such that the upper and/or lower apices are curved.

[0475] The anchoring feature **1004** can include one or more anchors **1016**. The anchors **1016** can extend from a lower region **1010** of the frame body **1002**. For example, the anchors **1016** can extend downwardly and/or radially outwardly from a lower end of the lower region **1010**. The anchors **1016** can also extend upwardly towards a tip or end **1018**. As shown in the illustrated embodiment, at least a portion of the anchors **1016**, such as the strut **1020** and/or the tip or end **1018**, can be curved and/or inclined in a circumferential direction about the longitudinal axis of the frame **1000**. For example, the portion of the strut **1020** which extends upwardly as well as the tip or end **1018** can be curved as shown in **Figures 23** and **24**. As another example, the entirety of the strut **1020a**, including both portions which extend downwardly and upwardly, as well as the tip or end **1018a** can be curved as shown in **Figure 25**.

[0476] As discussed above, some of the anchoring features described herein can be positioned on a ventricular side of the native mitral valve annulus and/or tissue beyond the ventricular side of the annulus. The anchoring features may be positioned in this manner by extending around the native mitral valve leaflets, which include chordae

tendineae **60** that connect a downstream end of the native mitral leaflets to the papillary muscle of the left ventricle. As shown in **Figure 24**, the circumferential curve and/or incline can allow a greater number of chordae tendineae **60** to be positioned between the frame body **1002** and the anchors **1016**. This can beneficially enhance securement of the frame **1000** to the native mitral valve.

[0477] With reference next to **Figures 26** and **27**, an embodiment of a frame **1100** is illustrated. The frame **1100** can include a frame body **1102**, an upper anchoring feature **1104**, and a lower anchoring feature **1106**. A longitudinal axis of the frame **1100** may be defined as the central axis that extends through the center of the frame **1100** between the upper and lower ends of the frame **1100**. Features of the frame **1100** can be incorporated in any of the prostheses described herein.

[0478] The frame body **1102** can include an upper region **1108**, an intermediate region **1110**, and a lower region **1112**. As shown, the frame body **1102** can include a plurality of struts with at least some of the struts forming cells **1114a-b**. The sides of cells **1114a-b** can have a "bell-curve" shape. As shown in the illustrated embodiment, an upper portion of the first row of cells **1114a** can be formed from circumferentially expansible struts **1116a** and a lower portion of the first row of cells **1114a** can be formed from circumferentially-expansible struts **1116b**. The upper portion of the second row of cells **1114b** can be formed from circumferentially expansible struts **1116b** and a lower portion of the second row of cells **1114b** can be formed from circumferentially-expansible struts **1116c**. The frame body **1102** can include a plurality of interconnecting struts **1118a-d**. The struts **1118a-d** can be straight segments extending in a circumferential direction about the longitudinal axis of the frame **1100**. These struts **1118a-d** can form a flat upper end and lower end of the frame body **1102**.

[0479] The upper anchoring feature **1104** can be similar to upper anchoring feature **924** described in connection with prosthesis **900** illustrated in **Figures 20-22**. The upper anchoring feature **1104** can be formed from a row of circumferentially expansible struts **1120**. The circumferentially-expansible struts **1120** can be attached to the frame body **1102** via one or more struts **1122**. The struts **1122** can be attached to the frame body **1102** at struts **1118b**. However, it is to be understood that struts **1122** can extend

from other portions of the frame body **1102**, such as the upper and/or uppermost ends of cells **1102**. The upper anchoring feature **1104** can include tips or ends **1124.** The tips or ends can include eyelets **1126** which can allow other components of a prosthesis to be attached thereto, such as a skirt. Moreover, the eyelets **1126** can allow the prosthesis to be coupled to a delivery system.

[0480] The lower anchoring feature **1106** can include one or more anchors **1128**. The anchors **1128** can include a strut **1130** and extend to a tip or end **1132**. The anchors **1128** can extend from above a lower end of a lower region **1112** of the frame body **1002**. For example, the anchors **1128** can extend downwardly and/or radially outwardly from struts **1118c**. The anchors **1128** can also extend upwardly towards the tip or end **1132**. As shown in the illustrated embodiment, at least a portion of the anchors **1016**, such as a segment **1130b** of strut **1130** and the tip or end **1132**, can be curved and/or inclined in a circumferential direction about the longitudinal axis of the frame **1100**. For example, the strut **1130** can incorporate a bend about an axis perpendicular to and/or passing through the longitudinal axis of the frame **1100**. The bend can orient a second portion **1130b** of the strut **1130** such that it is more inclined in a circumferential direction relative to the first portion **1130a** of the strut **1130**. As shown, the second portion **1130b** can be inclined at an angle of about 30 degrees with respect to a plane parallel to and/or passing through the longitudinal axis of the frame **1100**. In some embodiments, the second portion can be curved and/or inclined at an angle of between about 10 degrees to about 80 degrees relative to a plane parallel to and/or passing through the longitudinal axis of the frame **1100**, about 15 degrees to about 60 degrees relative to a plane parallel to and/or passing through the longitudinal axis of the frame **1100**, about 20 degrees to about 40 degrees relative to a plane parallel to and/or passing through the longitudinal axis of the frame **1100**, about 30 degrees relative to a plane parallel to and/or passing through the longitudinal axis of the frame **1100**, any sub-range within these ranges, and any other angle as desired.

Embodiments of Biased or Compressible Anchoring Features

[0481] In some embodiments, the prostheses described herein can incorporate a biased or compressible anchoring feature. The anchoring feature can be axially and/or radially biased or compressible. This can beneficially allow the anchoring feature to shift when subjected to forces, such as those which may be applied to an implanted anchoring feature during the cardiac cycle. This can significantly reduce the impact applied to tissue in contact with the anchor by spreading the applied force over a longer duration of time thereby reducing trauma to such tissue. In some embodiments, the biased or compressible anchoring features can be combined with cushions and/or covers described herein to further reduce trauma.

[0482] For example, tips or ends of an anchoring feature can be generally parallel to a longitudinal axis of the prosthesis and be in contact with a ventricular side of the native mitral valve annulus. Axial biasing or compression of such an anchoring feature can allow the anchoring feature to shift and apply the force over an extended duration of time to the ventricular side of the native mitral valve annulus. This can be particularly beneficial during systole in which the prosthesis is subject to a force tending to move the prosthesis towards the atrium. As another example, tips or ends of an anchoring feature can be generally perpendicular to a longitudinal axis of the prosthesis (e.g., a flange) and be in contact with an atrial side of the native mitral valve annulus. Radial biasing or compression of such an anchoring feature can allow the anchoring feature to shift and apply the force over an extended duration of time to the atrial side of the native mitral valve annulus.

[0483] Axial and/or radial biasing or compressibility can also the anchoring feature to better conform to tissue of the body cavity in which the anchoring feature is positioned. For example, similar to other prostheses described herein, the anchoring feature can include a plurality of individual anchors extending around a periphery of a frame. Each of the tips or ends of the anchors can independently shift to conform to the native anatomy, such as a native mitral annulus.

[0484] The axial and/or radially biasing or compressibility of the anchoring feature can also facilitate positioning within a delivery system. For example, the

anchoring feature can shift to a position which better conforms to the shape of the delivery system, such as a sheath of the delivery system. As another example, the anchoring feature can radially compress to reduce the crimp profile of the anchoring feature.

[0485] It is to be understood that the biased or compressible anchoring features can be used in combination with other anchoring features described herein or as a replacement for one or more of the anchoring features described herein.

[0486] With reference to **Figure 48**, an embodiment of a frame **2500** is illustrated. The frame **2500** can include a frame body **2502** and/or an anchoring feature **2504**. The anchoring feature **2504** can include a strut **2504a** connected to the frame body **2502**. The strut **2504a** can extend to a tip or end **2504b**. As shown, the tip or end **2504b** can be formed from a plurality of wires. These wires may be looped to form a generally three-dimensional teardrop shape. The wires may be compliant such that the tip or end **2504b** can be axially and/or radially biased or compressed.

[0487] With reference next to **Figure 49**, an embodiment of a frame **2550** is illustrated. The frame **2550** can include a frame body **2552** and/or an anchoring feature **2554**. The anchoring feature **2554** can include a strut **2554a** connected to the frame body **2552**. The strut **2554a** can extend to a tip or end **2554b**. As shown, the tip or end **2554b** can be formed from one or more wires. The one or more wires may be spiraled to form a generally three-dimensional conical shape. The wires may be compliant such that the tip or end **2554b** can axially and/or radially biased or compressed.

[0488] With reference to **Figure 50**, an embodiment of an anchoring feature **2600** is illustrated. The anchoring feature **2600** can include a strut **2602** which can be connected to a frame body (not shown). The strut **2602** can extend to a tip or end **2604**. As shown, the tip or end **2604** can have a serpentine shape. The serpentine shape can allow the tip or end **2604** to axially compress as represented by arrow **2606**. The serpentine shape can allow the tip or end **2604** to radially compress as represented by arrows **2608**. In some embodiments, the tip or end **2604** can be biased radially outward (e.g., out-of-plane movement). This can be achieved by forming the material of the tip or end **2604** out of a thinner or more compliant material. In some embodiments, such as the

anchoring feature **2650** illustrated in **Figure 51**, the anchoring feature can include multiple prongs **2654a**, **2654b** having a serpentine shape.

[0489] With reference to **Figure 52**, an embodiment of an anchoring feature **2700** is illustrated. The anchoring feature **2700** can include a strut **2702** which can be connected to a frame body (not shown). The strut **2702** can extend to a tip or end **2704**. As shown, the tip or end **2704** can be formed from a plurality of cells. The cells can be foreshortening cells such as the illustrated diamond-shaped cells. The cells can allow the tip or end **2704** to axially compress as represented by arrow **2706**. The cells can allow the tip or end **2704** to radially compress as represented by arrows **2708**. In some embodiments, the tip or end **2704** can be biased radially outward (e.g., out-of-plane movement). This can be achieved by forming the material of the tip or end **2704** out of a thinner or more compliant material.

[0490] With reference to **Figure 53**, an embodiment of an anchoring feature **2800** is illustrated. The anchoring feature **2800** can include a strut **2802** which can be connected to a frame body (not shown). The strut **2802** can extend to a tip or end **2804**. As shown, the tip or end **2804** can be formed from one or more prongs **2806a**, **2806a**. The tip or end **2804** can include a component such as a plate **2808**. The plate **2808** can advantageously increase the surface area of the tip or end **2804** thereby reducing pressures applied to tissue. The plate **2808** can be flexible to allow the plate **2808** to deform when subjected to forces. In some embodiments, the plate **2808** can be retained in a collapsed configuration prior to delivery. For example, the plate **2808** may be retained in a collapsed configuration via a suture. The suture may be biodegradable such that the plate **2808** expands after implantation.

[0491] In some embodiments, the tips or ends can be covered with a biodegradable material. This can allow the tips or ends to be retained in a compressed configuration when initially implanted into a body cavity. Over time, the material can biodegrade and allow the tips or ends to expand into the shapes illustrated above. In some embodiments, the entire anchoring feature can be formed from a biodegradable or resorbable material. In some implementations, the entire anchoring features can be resorbed after a duration of time sufficient to allow tissue ingrowth around the prosthesis.

In some embodiments, the anchoring features can be removable. It is to be understood that other geometries and structures can be implemented with respect to the anchoring features described herein. Further details on such geometries and structures can be found in U.S. Application No. 15/653,390, entitled REPLACEMENT HEART VALVE PROSTHESIS, filed on July 18, 2017, the entirety of which has been incorporated herein by reference.

[0492] Other anchoring mechanisms are also contemplated. In some embodiments, the inner and/or outer frames can include one or more barbs to facilitate securement to tissue of a body cavity in which the prosthesis is positioned. In some embodiments, the inner and/or outer frames can include a tether which can be attached tissue of the body cavity. For example, the tether may be attached to a portion of the heart wall, such as an apex of the heart wall.

Exemplary Placement of Replacement Valves

[0493] Reference is now made to **Figures 28A-30** which illustrate schematic representations of an embodiment of a prosthesis **1200** in an expanded configuration, having an inner frame portion **1202** and an outer frame portion **1204**, positioned within a native mitral valve of a heart **10**. As noted above, in some embodiments the prostheses described herein can be positioned within a native mitral valve. A portion of the native mitral valve is shown schematically and represents typical anatomy, including a left atrium **20** positioned above an annulus **40** and a left ventricle **30** positioned below the annulus **40**. The left atrium **20** and left ventricle **30** communicate with one another through a mitral annulus **40**. Also shown schematically in **Figures 28A-30** is a native mitral leaflet **50** having chordae tendineae **60** that connect a downstream end of the mitral leaflet **50** to the papillary muscle of the left ventricle **30**. The portion of the prosthesis **1200** disposed upstream of the annulus **40** (toward the left atrium) can be referred to as being positioned supra-annularly. The portion generally within the annulus **40** can be referred to as positioned intra-annularly. The portion downstream of the annulus **40** can be referred to as being positioned sub-annularly (toward the left ventricle). In the illustrated embodiment, only a part of the foreshortening portion is

positioned intra-annularly or sub-annularly, and the rest of the prosthesis **1200** is supra-annular.

[0494] As shown in the situations illustrated in **Figures 28A-30**, the prosthesis **1200** can be disposed so that the mitral annulus **40** is between the upper or atrial anchoring feature **1210** and the lower or ventricular anchoring feature **1220** with a portion of the outer frame portion **1204** contacting the mitral annulus **40** along an inner edge or periphery. As shown in **Figures 28A-29**, portions of the mitral annulus **40** and/or the mitral leaflet **50** can be positioned between the outer frame portion **1204** and the lower anchoring feature **1220**. The mitral annulus **40** and/or the mitral leaflet **50** can be pinched between the outer frame portion **1204** and the lower anchoring feature **1220**. As shown, the outer frame portion **1204** is oriented radially inward to conform to the shape of mitral annulus **40** and/or the mitral leaflet **50**. In an expanded configuration, the outer frame portion **1204** can be positioned radially outward in a natural, unbiased state. Accordingly, with the mitral annulus **40** and/or the mitral leaflet **50** positioned therebetween, the outer frame portion **1204** can be biased outward to apply a pinching force on the mitral annulus **40** and/or the mitral leaflet **50**.

[0495] In some situations, the prosthesis **1200** can be positioned such that ends or tips **1222** of the lower anchoring feature **1220** can contact the ventricular side of the annulus **40** as shown, for example, in **Figures 28A-B**. In some situations, the prosthesis **1200** can be positioned such that ends or tips **1222** of the lower anchoring feature **1220** do not contact the annulus **40** as shown, for example, in **Figure 29**, and may just contact a downstream side of the leaflet **50**. In some situations, the prosthesis **1200** can be positioned such that the lower anchoring feature **1220** does not extend around the leaflet **50** as illustrated, but rather are positioned radially inward of the leaflet **50** as shown, for example, in **Figure 30**. While **Figures 28A-30** are described separately below, it should be understood that one or more of the situations illustrated in **Figures 28A-30** may be present when the prosthesis **1200** is positioned at the implantation location, such as a native mitral valve. For example, in some situations the prosthesis **1200** may be positioned such that some portion of the anchoring feature **1220** may contact the annulus **40** while another portion of the lower anchoring feature **1220** may

not. Moreover, it may be contemplated some in some situations, some portion of the anchoring feature **1220** may be positioned

[0496] With reference first to the situations illustrated in **Figures 28A-29**, the prosthesis **1200** can be positioned so that the ends or tips **1222** of the lower anchoring feature **1220** are on a ventricular side of the mitral annulus **40** and the ends or tips **1212** of the upper anchoring feature **1210** are on an atrial side of the mitral annulus **40**. The lower anchoring feature **1220** can be positioned such that the ends or tips **1222** of the lower anchoring feature **1220** are on a ventricular side of the native leaflets radially outwardly beyond a location where chordae tendineae **60** connect to free ends of the native leaflets **50**. The lower anchoring feature **1220** may extend between at least some of the chordae tendineae **60** and, in some situations such as those shown in **Figures 28A-B**, can contact or engage a ventricular side of the annulus **40**. It is also contemplated that in some situations, such as those shown in **Figure 29**, the lower anchoring feature **1220** may not contact the annulus **40**, though the lower anchoring feature **1220** may still contact the native leaflet **50**. In some situations, the lower anchoring feature **1220** can contact tissue of the left ventricle **30** beyond the annulus **40** and/or a ventricular side of the leaflets **50**.

[0497] During delivery, the lower anchoring feature **1220** (along with the inner frame portion **1202** and outer frame portion **1204**) can be moved toward the ventricular side of the annulus **40** with the lower anchoring feature **1220** extending between at least some of the chordae tendineae **60** to provide tension on the chordae tendineae **60** after the prosthesis **1200** is finally delivered. The degree of tension provided on the chordae tendineae **60** can differ. For example, little to no tension may be present in the chordae tendineae **60** as shown in **Figure 28B** where the leaflet **50** is shorter than or similar in size to the lower anchoring feature **1220**. A greater degree of tension may be present in the chordae tendineae **60** as shown in **Figure 28A** where the leaflet **50** is longer than the lower anchoring feature **1220** and, as such, takes on a compacted form and is pulled proximally. An even greater degree of tension may be present in the chordae tendineae **60** as shown in **Figure 29** where the leaflets **50** are even longer relative to the lower anchoring feature **1220**. As shown in **Figure 29**, the leaflet **50** is

sufficiently long such that the lower anchoring feature **1220** does not contact the annulus **40**.

[0498] The upper anchoring feature **1210** can be positioned such that the ends or tips **1212** of the upper anchoring feature **1210** are on or adjacent the atrial side of the annulus **40** and/or tissue of the left atrium **20** beyond the annulus **40**. In some situations, some portion or all of the upper anchoring feature **1210** may only occasionally contact or engage atrial side of the annulus **40** and/or tissue of the left atrium **20** beyond the annulus **40**. For example, as shown in **Figures 28A-30**, the upper anchoring feature **1210** may be spaced from the atrial side of the annulus **40** and/or tissue of the left atrium **20** beyond the annulus **40**. The upper anchoring feature **1210** may be utilized to provide axial stability for the prosthesis **1200** and prevent off-axis orientation. Further, the upper anchoring feature **1210** can act as a safety feature without utilizing them for axial stability and off-axis orientation. For example, if the prosthesis **1200** is improperly deployed so that the prosthesis **1200** is deployed too low toward the left ventricle **30**, the upper anchoring feature **1210** can prevent the prosthesis **1200** from falling into the left ventricle **30**. It is to be understood that some or all of the upper anchoring feature **1210** may contact the atrial side of the annulus **40** and/or tissue of the left atrium **20** beyond the annulus **40**.

[0499] In some situations such as that shown in **Figure 30**, the leaflet **50** may not be captured between the frame portions **1202**, **1204** and a portion of the lower anchoring feature **1220**. As shown, the portion of the lower anchoring feature **1220** may be positioned along an atrial surface of the leaflet **50**. The portion of the lower anchoring feature **1220** may also be positioned along an inner surface of the annulus **40**. It is also contemplated that the portion of the lower anchoring feature **1220** may exert a force against the leaflet **50** such that the leaflet **50** is pushed radially outward, relative to the longitudinal axis of the frame **1202**, towards a wall of the heart **10**. In such situations, the outer frame portion **1204** can still anchor intra-annularly and/or along an atrial side of the leaflet **50**. In alternative situations (not shown), the outer frame portion **1204** can still anchor along a ventricular side of the annulus **40**.

[0500] As noted above, although the in vivo situations of **Figure 28A-30** have been described separately, it should be understood that one or more of these situations may be present when a prosthesis is positioned at the implantation location, such as a native mitral valve. For example, a portion of the lower anchoring feature **1220** may not capture the leaflet **50** whereas the remaining portion may capture the leaflet **50**.

Delivery of Prosthesis

[0501] The prostheses described herein can be delivered to a patient's native heart valve in various ways, such as by open surgery, minimally-invasive surgery, and percutaneous or transcatheter delivery through the patient's vasculature. In some embodiments, the prosthesis can be delivered to a patient's native mitral valve through procedure such as, but not limited to, a transapical procedure and a transseptal procedure. As noted above, the prostheses can be used with a variety of delivery systems such as "slot"-based and/or "tether"-based systems. For purposes of **Figures 31 and 32**, it is to be understood that the distal direction is towards the right of the drawing.

[0502] With reference first to the system **1300** of **Figure 31**, the system **1300** can include a delivery device **1310** with a prosthesis **1380** (illustrated schematically) contained within the delivery device **1310**. A first end **1382** of the prosthesis **1380** can be placed in a compressed state such that the first end **1382** of the prosthesis **1380** is retained between a nose cone **1320** and an inner retention member **1322** when the inner retention member **1322** is received within and covered by the nose cone **1320**. The inner retention member **1322** can include one or more slots which interface with locking tabs **1384**. The interface between the locking tabs **1384** and slots of the inner retention member **1322** can inhibit axial movement of the prosthesis **1380** relative to the inner retention member **1322**. When the first end **1382** of the prosthesis **1380** is uncovered, such as by moving the nose cone **1320** distally relative to the inner retention member **1322** or by moving the inner retention member **1322** proximally relative to the nose cone **1320**, the first end **1382** of the prosthesis **1380** can be released. This release can be caused by the prosthesis **1380** transitioning from a collapsed configuration to an

expanded configuration when the prosthesis **1380** is formed from a self-expanding material.

[0503] At least a second end **1386** of the prosthesis **1380** can be placed in a compressed state such that the second end **1386** of the prosthesis **1380** is retained within a hollow shaft member **1330**. When the second end **1386** is uncovered, such as by moving the hollow shaft member **1330** proximally relative to the prosthesis **1380** or by moving the prosthesis **1380** distally relative to the hollow shaft member **1330**, the second end **1386** of the prosthesis **1380** can be released. This release can be caused by the prosthesis **1380** transitioning from a collapsed configuration to an expanded configuration when the prosthesis **1380** is formed from a self-expanding material. In some embodiments, the delivery system **1310** can include a tether **1340** which can wrap around a portion of the prosthesis **1380**, such as an anchoring feature on the second end **1386**. The tether **1340** can be used to control expansion of a portion of the prosthesis **1380**, such as the second end **1386**, when the portion of the prosthesis **1380** is uncovered. For example, in some embodiments, the tether **1340** can be used to control the rate at which anchors positioned at the second end **1386** flip from the collapsed configuration to the expanded configuration such that the anchors extend towards the first end **1382**.

[0504] In some embodiments, the system **1300** can be used in connection with a transapical procedure to access a native mitral valve. During such a procedure, the system **1300** can access a mitral valve through the apex of the heart. The anchoring feature on a ventricular side of the prosthesis **1380**, such as the second end **1386**, can be released on a ventricular side of the native mitral valve annulus. During delivery, the anchoring feature on a ventricular side of the annulus (along with the prosthesis **1380**) can be moved toward the ventricular side of the annulus with the ventricular anchors extending between at least some of the chordae tendineae to provide tension on the chordae tendineae. The degree of tension provided on the chordae tendineae can differ. For example, little to no tension may be present in the chordae tendineae if the leaflet is shorter than or similar in size to the ventricular anchors. A greater degree of tension may be present in the chordae tendineae where the leaflet is longer than the ventricular anchors and, as such, takes on a compacted form and is pulled toward the native valve

annulus. An even greater degree of tension may be present in the chordae tendineae where the leaflets are even longer relative to the ventricular anchors. The leaflet can be sufficiently long such that the ventricular anchors do not contact the annulus. After the anchoring feature on a ventricular side of the annulus is positioned, the remainder of the prosthesis **1380** can be deployed from the delivery system **1310**.

[0505] Reference is now made to **Figures 54A-54H** which illustrate schematic representations of an embodiment of a prosthesis **2900** and a delivery system **2950** during various stages of deployment within a native mitral valve of a heart **10**. The prosthesis **2900** can include an inner frame **2910** and an outer frame **2920**. The inner frame **2910** can include an inner frame body **2912** and an inner frame anchoring feature **2914**. The prosthesis **2900** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other prostheses described herein, such as prostheses **100**, **200**, **1500**, **1600**.

[0506] The delivery system **2950** can include a nose cone **2960** and an inner retention member **2962** at a first end of the delivery system **2950**. The nose cone **2960** and inner retention member **2970** can retain an upper end of the prosthesis **2900**. The delivery system **2950** can include a hollow shaft member **2980** and a tether **2990**. The hollow shaft member **2980** can retain portions of the prosthesis **2900** therein. The tether **2990** can be tensioned to retain portions of the prosthesis **2900** in a collapsed state. The delivery system **2950** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other delivery systems described herein, such as delivery system **1310**.

[0507] With reference first to **Figure 54A**, the prosthesis **2900** and delivery system **2950** can be introduced with the prosthesis **2900** in a fully collapsed configuration. As shown, the prosthesis **2900** and the delivery system **2950** can be introduced in a direction from the ventricle to the atrium (e.g., a transapical delivery procedure).

[0508] With reference next to **Figure 54B**, the hollow shaft member **2980** can be retracted downwardly or proximally to expose the prosthesis **2900**. This can allow the inner frame anchoring feature **2914** to transition to an expanded configuration. In some

instances, a portion of the outer frame **2920** can also expand. As shown, the nose cone **2960** can be sized to retain at least a portion, or the entirety, of an upper region of the prosthesis **2900** in a collapsed or crimped configuration. This can beneficially reduce radial expansion of the prosthesis **2900** during this step of delivery. As shown in the illustrated embodiment, the inner frame anchoring feature **2914** can be positioned generally above the annulus **40** prior to allowing the inner frame anchoring feature **2914** to expand; however, it is to be understood that this step can occur while the inner frame anchoring feature **2914** is positioned within the annulus **40**, below the annulus **40**, or below the leaflets **50**. Although the inner frame **2910** is shown in a fully collapsed configuration via tether **2990**, it is to be understood that the inner frame **2910** can at least partially expand during this stage.

[0509] With reference next to in **Figure 54C**, the prosthesis **2900** can be moved such that the inner frame anchoring feature **2914** is positioned below the annulus **40**. As shown, the inner frame anchoring feature **2914** can be positioned below free edges of the leaflets **50**. With reference next to **Figure 54D**, the tether **2990** can be loosened to allow the inner frame **2910** to expand further radially outward. In some embodiments, the nose cone **2960** can be advanced upwardly or proximally relative to the inner retention member **2970** to allow the inner frame **2910** and/or outer frame **2920** to expand further. The prosthesis **2900** may be moved during this process to seat the inner frame anchoring feature **2914** against the annulus **40**.

[0510] In some situations, a user may determine that the prosthesis **2900** should be repositioned. The prosthesis **2900** may be recaptured reversing the previous steps as shown in **Figure 54E**. The inwardly tapered shape of the outer frame **2920** can facilitate the process of recapturing the device. For example, the inwardly tapered shape can function as a funnel which draws the outer frame **2920** and/or inner frame **2910** together when advancing the hollow shaft member **2980** over the outer frame **2920**. The user may then re-expand the prosthesis **2900** as shown in **Figure 54F**.

[0511] With reference next to **Figure 54G**, the prosthesis **2900** can be fully deployed by advancing the nose cone **2960** further upwardly or proximally relative to the inner retention member **2970**. As shown, the inner frame anchoring feature **2914** can be

positioned between chordae tendineae **60** and contact a ventricular side of the annulus **40**. Moreover, the annulus **40** and/or leaflets **50** can be engaged between the inner frame anchoring feature **2914** and the outer frame **2920**. With reference next to **Figure 54H**, the prosthesis **2900** is illustrated with the delivery system **2950** removed from the heart **10**. As shown, prosthesis **2900** includes one or more flexible valve leaflets **2930** (e.g., three leaflets) which allow blood to flow in a direction from the left atrium **20** to the left ventricle **30**. The inner frame **2910**, inner frame anchoring feature **2914**, and/or outer frame **2920** of prosthesis **2900** can be positioned similarly to the inner frame **3310**, inner frame anchoring feature **3314**, and/or outer frame **3320** of prosthesis **3300** shown in **Figure 58**.

[0512] Reference is now made to **Figures 55A-55H** which illustrate schematic representations of an embodiment of a prosthesis **3000** and a delivery system **3050** during various stages of deployment within a native mitral valve of a heart **10**. These steps can be similar to those described above in connection with **Figures 54A-54F**. The prosthesis **3000** can include an inner frame **3010** and an outer frame **3020**. The inner frame **3010** can include an inner frame body **3012** and an inner frame anchoring feature **3014**. The prosthesis **3000** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other prostheses described herein, such as prostheses **1900**, **2000**, **2200**, **2400**.

[0513] The delivery system **3050** can include a nose cone **3060** and an inner retention member **3062** at a first end of the delivery system **3050**. The delivery system **3050** can include a hollow shaft member **3080** and a tether **3090**. The delivery system **3050** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other delivery systems described herein, such as delivery system **1310**.

[0514] With reference first to **Figure 55A**, the prosthesis **3000** and delivery system **3050** can be introduced with the prosthesis **3000** in a fully collapsed configuration. With reference next to **Figure 55B**, the hollow shaft member **3080** can be retracted downwardly or proximally to expose the prosthesis **2900**. As shown in the illustrated embodiment, the inner frame anchoring feature **2914** can be positioned

generally above the annulus **40** prior to allowing the inner frame anchoring feature **2914** to expand; however, it is to be understood that this step can occur while the inner frame anchoring feature **2914** is positioned within the annulus **40**, below the annulus **40**, or below the leaflets **50**. Although the inner frame **2910** is shown in a fully collapsed configuration via tether **2990**, it is to be understood that the inner frame **2910** can at least partially expand during this stage.

[0515] With reference next to in **Figure 55C**, the prosthesis **3000** can be moved such that the inner frame anchoring feature **3014** is positioned below the annulus **40**. As shown, the inner frame anchoring feature **3014** can be positioned below free edges of the leaflets **50**. As shown in the illustrated embodiment, the geometry of the outer frame **3020** can advantageously increase a gap between the outer frame **3020** and the inner frame anchoring feature **3014**. This can facilitate positioning the prosthesis **3000** such that the leaflets **50** are positioned between the outer frame **3020** and the inner frame anchoring feature **3014**.

[0516] With reference next to **Figure 55D**, the tether **3090** can be loosened to allow the inner frame **3010** to expand further radially outward. The prosthesis **3000** may be moved during this process to seat the inner frame anchoring feature **3014** against the annulus **40**.

[0517] In some situations, a user may determine that the prosthesis **3000** should be repositioned. The prosthesis **3000** may be recaptured reversing the previous steps as shown in **Figure 55E**. The user may then re-expand the prosthesis **3000** as shown in **Figure 55F**. With reference next to **Figure 55G**, the prosthesis **3000** can be fully deployed by advancing the nose cone **3060** further upwardly or proximally relative to the inner retention member **3070**. With reference next to **Figure 55H**, the prosthesis **3000** is illustrated with the delivery system **3050** removed from the heart **10**. As shown, prosthesis **3000** includes one or more flexible valve leaflets **3030** (e.g., three leaflets) which allow blood to flow in a direction from the left atrium **20** to the left ventricle **30**. The inner frame **3010**, inner frame anchoring feature **3014**, and/or outer frame **3020** of prosthesis **3000** can be positioned similarly to the inner frame **3410**, inner frame anchoring feature **3414**, and/or outer frame **3420** of prosthesis **3400** shown in **Figure 59**.

[0518] With reference next to the system **1400** of **Figure 32**, the system **1400** can include a delivery device **1410** with a prosthesis **1480** (illustrated schematically) contained within the delivery device **1410**. A first end **1482** of the prosthesis **1480** can be placed in a compressed state such that the first end **1482** of the prosthesis **1480** is retained between an inner retention member **1420** and another portion of the delivery device, such as an outer retention member **1422**, when the inner retention member **1420** is received within and covered by the outer retention member **1422**. The interface between the locking tabs **1484** and slots of the inner retention member **1420** can inhibit axial movement of the prosthesis **1480** relative to the inner retention member **1420**. When the first end **1482** of the prosthesis **1480** is uncovered, such as by moving the outer retention member **1422** proximally relative to the inner retention member **1420** or by moving the inner retention member **1420** distally relative to the outer retention member **1422**, the first end **1482** of the prosthesis **1480** can be released from the inner retention member **1422**. If the inner retention member **1420** is fully uncovered, the first end **1482** of the prosthesis **1480** can be released from the delivery device **1410**. This release can be caused by the prosthesis **1480** transitioning from a collapsed configuration to an expanded configuration when the prosthesis **1480** is formed from a self-expanding material.

[0519] At least a second end **1486** of the prosthesis **1480** can be placed in a compressed state such that the second end **1486** of the prosthesis **1480** is retained within an outer sheath assembly **1430**. When the second end **1486** is uncovered, such as by moving the outer sheath assembly **1430** proximally relative to the prosthesis **1480** or by moving the prosthesis **1480** distally relative to the outer sheath assembly **1430**, the second end **1486** of the prosthesis **1480** can be released. This release can be caused by the prosthesis **1480** transitioning from a collapsed configuration to an expanded configuration when the prosthesis **1480** is formed from a self-expanding material. In some embodiments, anchors positioned at the second end **1486** can flip from the collapsed configuration to the expanded configuration such that they extend towards the first end **1482**.

[0520] In some embodiments, the system **1400** can be used in connection with a transseptal procedure to access a native mitral valve. During such a procedure, the system **1400** can access a mitral valve through a septal puncture. The anchoring feature on a ventricular side of the prosthesis **1480**, such as the second end **1486**, can be released on a ventricular side of the native mitral valve annulus. During delivery, the anchoring feature on a ventricular side of the annulus (along with the prosthesis **1480**) can be moved toward the ventricular side of the annulus with the ventricular anchors extending between at least some of the chordae tendineae to provide tension on the chordae tendineae. The degree of tension provided on the chordae tendineae can differ. For example, little to no tension may be present in the chordae tendineae if the leaflet is shorter than or similar in size to the ventricular anchors. A greater degree of tension may be present in the chordae tendineae where the leaflet is longer than the ventricular anchors and, as such, takes on a compacted form and is pulled toward the native valve annulus. An even greater degree of tension may be present in the chordae tendineae where the leaflets are even longer relative to the ventricular anchors. The leaflet can be sufficiently long such that the ventricular anchors do not contact the annulus. After the anchoring feature on a ventricular side of the annulus is positioned, the remainder of the prosthesis **1480** can be deployed from the delivery device **1410**.

[0521] Reference is now made to **Figures 56A-56H** which illustrate schematic representations of an embodiment of a prosthesis **3100** and a delivery system **3150** during various stages of deployment within a native mitral valve of a heart **10**. The prosthesis **3100** can include an inner frame **3110** and an outer frame **3120**. The inner frame **3110** can include an inner frame body **3112** and an inner frame anchoring feature **3114**. The prosthesis **3100** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other prostheses described herein, such as prostheses **100**, **200**, **1500**, **1600**.

[0522] The delivery system **3150** can include an inner retention member **3160** and a sheath **3170**. The inner retention member **3160** and sheath **3170** can retain an upper end of the prosthesis **3100**. The delivery system **3150** can share characteristics,

such as structure and/or functionality, which are the same as, or at least similar to, those of other delivery systems described herein, such as delivery system **1410**.

[0523] With reference first to **Figure 56A**, the prosthesis **3100** and delivery system **3150** can be introduced with the prosthesis **3100** in a fully collapsed configuration. As shown, the prosthesis **3100** and the delivery system **3150** can be introduced in a direction from the atrium to the ventricle (e.g., a transseptal delivery procedure).

[0524] With reference next to **Figure 56B**, the sheath **3170** can be retracted upwardly or proximally to expose the prosthesis **3100**. This can allow the inner frame anchoring feature **3114** to transition to an expanded configuration. As shown in the illustrated embodiment, the inner frame anchoring feature **3114** can be positioned generally above the annulus **40** prior to allowing the inner frame anchoring feature **3114** to expand; however, it is to be understood that this step can occur while the inner frame anchoring feature **3114** is positioned within the annulus **40**, below the annulus **40**, or below the leaflets **50**.

[0525] With reference next to in **Figure 56C**, the prosthesis **3100** can be moved such that the inner frame anchoring feature **3114** is positioned below the annulus **40**. As shown, the inner frame anchoring feature **3114** can be positioned below free edges of the leaflets **50**. With reference next to **Figure 56D**, the sheath **3170** can be further retracted to allow the inner frame **3110** and/or outer frame **3120** to expand further radially outward. The prosthesis **3100** may be moved during this process to seat the inner frame anchoring feature **3114** against the annulus **40**.

[0526] In some situations, a user may determine that the prosthesis **3100** should be repositioned. The prosthesis **3100** may be recaptured reversing the previous steps as shown in **Figure 56E**. The inwardly tapered shape of the outer frame **3120** can facilitate the process of recapturing the device. For example, the inwardly tapered shape can function as a funnel which draws the outer frame **3120** and/or inner frame **3110** together when advancing the sheath **3170** over the outer frame **3120**. The user may then re-expand the prosthesis **3100** as shown in **Figure 56F**.

[0527] With reference next to **Figure 56G**, the prosthesis **3100** can be fully deployed by further retracting the sheath **3170**. As shown, the inner frame anchoring feature **3114** can be positioned between chordae tendineae **60** and contact a ventricular side of the annulus **40**. Moreover, the annulus **40** and/or leaflets **50** can be engaged between the inner frame anchoring feature **3114** and the outer frame **3120**. With reference next to **Figure 56H**, the prosthesis **3100** is illustrated with the delivery system **3150** removed from the heart **10**. As shown, prosthesis **3100** includes one or more flexible valve leaflets **3130** (e.g., three leaflets) which allow blood to flow in a direction from the left atrium **20** to the left ventricle **30**. The inner frame **3110**, inner frame anchoring feature **3114**, and/or outer frame **3120** of prosthesis **3100** can be positioned similarly to the inner frame **3310**, inner frame anchoring feature **3314**, and/or outer frame **3320** of prosthesis **3300** shown in **Figure 58**.

[0528] Reference is now made to **Figures 57A-57F** which illustrate schematic representations of an embodiment of a prosthesis **3200** and a delivery system **3250** during various stages of deployment within a native mitral valve of a heart **10**. These steps can be similar to those described above in connection with **Figures 56A-56F**. The prosthesis **3200** can include an inner frame **3210** and an outer frame **3220**. The inner frame **3210** can include an inner frame body **3212** and an inner frame anchoring feature **3214**. The prosthesis **3200** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other prostheses described herein, such as prostheses **1900**, **2000**, **2200**, **2400**.

[0529] The delivery system **3250** can include an inner retention member **3260** and a sheath **3270**. The delivery system **3250** can share characteristics, such as structure and/or functionality, which are the same as, or at least similar to, those of other delivery systems described herein, such as delivery system **1310**.

[0530] With reference first to **Figure 57A**, the prosthesis **3200** and delivery system **3250** can be introduced with the prosthesis **3200** in a fully collapsed configuration. With reference next to **Figure 57B**, the sheath **3270** can be retracted upwardly or proximally to expose the prosthesis **3200**. As shown in the illustrated embodiment, the inner frame anchoring feature **3214** can be positioned generally above

the annulus **40** prior to allowing the inner frame anchoring feature **3214** to expand; however, it is to be understood that this step can occur while the inner frame anchoring feature **3214** is positioned within the annulus **40**, below the annulus **40**, or below the leaflets **50**.

[0531] With reference next to in **Figure 57C**, the prosthesis **3200** can be moved such that the inner frame anchoring feature **3214** is positioned below the annulus **40**. With reference next to **Figure 55D**, the sheath **3270** can be further retracted to allow the inner frame **3210** and/or outer frame **3220** to expand further radially outward. The prosthesis **3200** may be moved during this process to seat the inner frame anchoring feature **3214** against the annulus **40**. As shown, the inner frame anchoring feature **3214** can be positioned below free edges of the leaflets **50**. As shown in the illustrated embodiment, the geometry of the outer frame **3220** can advantageously increase a gap between the outer frame **3220** and the inner frame anchoring feature **3214**. This can facilitate positioning the prosthesis **3200** such that the leaflets **50** are positioned between the outer frame **3220** and the inner frame anchoring feature **3214**.

[0532] In some situations, a user may determine that the prosthesis **3200** should be repositioned. The prosthesis **3200** may be recaptured reversing the previous steps as shown in **Figure 57E**. The user may then re-expand the prosthesis **3200** as shown in **Figure 57F**. With reference next to **Figure 57G**, the prosthesis **3200** can be fully deployed by further retracting the sheath **3170.** With reference next to **Figure 57H**, the prosthesis **3200** is illustrated with the delivery system **3250** removed from the heart **10**. As shown, prosthesis **3200** includes one or more flexible valve leaflets **3230** which allow blood to flow in a direction from the left atrium **20** to the left ventricle **30**. The inner frame **3210**, inner frame anchoring feature **3214**, and/or outer frame **3220** of prosthesis **3200** can be positioned similarly to the inner frame **3410**, inner frame anchoring feature **3414**, and/or outer frame **3420** of prosthesis **3400** shown in **Figure 59**.

Other Embodiments

[0533] While certain embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of

the disclosure. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms. Furthermore, various omissions, substitutions and changes in the systems and methods described herein may be made without departing from the spirit of the disclosure. The accompanying claims and their equivalents are intended to cover such forms or modifications as would fall within the scope of the disclosure. Accordingly, the scope of the present disclosure is defined only by reference to the claims presented herein or as presented in the future.

[0534] Features, materials, characteristics, or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described in this section or elsewhere in this specification unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0535] Furthermore, certain features that are described in this disclosure in the context of separate implementations can also be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation can also be implemented in multiple implementations separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations, one or more features from a claimed combination can, in some cases, be excised from the combination, and the combination may be claimed as a subcombination or variation of a subcombination.

[0536] For purposes of this disclosure, certain aspects, advantages, and novel features are described herein. Not necessarily all such advantages may be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art

will recognize that the disclosure may be embodied or carried out in a manner that achieves one advantage or a group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein.

[0537] Conditional language, such as "can," "could," "might," or "may," unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements, and/or steps. Thus, such conditional language is not generally intended to imply that features, elements, and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements, and/or steps are included or are to be performed in any particular embodiment.

[0538] Conjunctive language such as the phrase "at least one of X, Y, and Z," unless specifically stated otherwise, is otherwise understood with the context as used in general to convey that an item, term, etc. may be either X, Y, or Z. Thus, such conjunctive language is not generally intended to imply that certain embodiments require the presence of at least one of X, at least one of Y, and at least one of Z.

[0539] Language of degree used herein, such as the terms "approximately," "about," "generally," and "substantially" as used herein represent a value, amount, or characteristic close to the stated value, amount, or characteristic that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", "generally," and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount. As another example, in certain embodiments, the terms "generally parallel" and "substantially parallel" refer to a value, amount, or characteristic that departs from exactly parallel by less than or equal to 15 degrees, 10 degrees, 5 degrees, 3 degrees, 1 degree, or 0.1 degree.

[0540] The scope of the present disclosure is not intended to be limited by the specific disclosures of preferred embodiments in this section or elsewhere in this specification, and may be defined by claims as presented in this section or elsewhere in

this specification or as presented in the future. The language of the claims is to be interpreted broadly based on the language employed in the claims and not limited to the examples described in the present specification or during the prosecution of the application, which examples are to be construed as non-exclusive.

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CLAIMS

1. A replacement heart valve prosthesis the prosthesis comprising:

an expandable frame configured to radially expand and contract for deployment within a native heart valve, the expandable frame having a longitudinal axis between upper and lower ends, the expandable frame comprising:

a first frame portion comprising a first frame body and a first anchoring feature the first frame body comprising a first upper region a first intermediate region and a first lower region,

wherein, when the prosthesis is in an expanded configuration:

the first anchoring feature extends radially outwardly from the first lower region; and

at least a portion of the first anchoring feature extends towards the first upper region; and

a second frame portion positioned radially outward of the first frame body, the second frame portion comprising a second frame body having a second upper region, a second intermediate region, and a second lower region, wherein, when the prosthesis is in an expanded configuration:

at least a portion of the second upper region extends radially outwardly from the first upper region;

the second lower region is positioned radially between the first anchoring feature and the first frame body; and

the second intermediate region is configured such that, when the prosthesis is deployed within the native heart valve, the second intermediate region is positioned within a native valve annulus; and

a valve body positioned within an interior of the first frame portion, the valve body comprising a plurality of leaflets configured to allow flow in a first direction and prevent flow in a second opposite direction,

wherein

a bend about a circumferential axis is formed at a juncture between the second upper region and the second intermediate region, such that the intermediate region extends in a direction more parallel to the longitudinal axis of the prosthesis than the portion of the second upper region.

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2. The replacement heart valve prosthesis of claim 1, wherein the first anchoring feature comprises a plurality of anchors.

3. The replacement heart valve prosthesis of claim 1 or 2, wherein, when the prosthesis is in an expanded configuration, the second intermediate region is generally non-cylindrical.

4. The replacement heart valve prosthesis of any one of claims 1 to 3, wherein the second frame portion and the first anchoring feature are sized such that, when the prosthesis is deployed and expanded within the native heart valve, at least native valve leaflets are pinched between the second frame portion and the first anchoring feature.

5. The replacement heart valve prosthesis of any one of claims 1 to 4, wherein the second upper region is coupled to the first upper region using mechanical fasteners, chemical fasteners, fastening techniques and/or a combination of such fasteners and techniques.

6. The replacement heart valve prosthesis of any one of claims 1 to 5, wherein the second frame portion is more flexible than the first frame portion for conforming to a native valve annulus.

7. The replacement heart valve prosthesis of any one of claims 1 to 6, wherein the widest region of the second frame portion has a diameter in the range of about 35 mm to 55 mm.

8. The replacement heart valve prosthesis of any one of claims 1 to 7, wherein the second intermediate region has a larger diameter than the second lower region and the second upper region.

9. The replacement heart valve prosthesis of any one of claims 1 to 8, wherein the first anchoring feature is sized such that, when the prosthesis is deployed and expanded within a native mitral valve, at least a portion of the first anchoring feature contacts a native mitral valve annulus on a ventricular side.

10. The replacement heart valve prosthesis of any one of claims 1 to 9, wherein the second frame portion comprises a second anchoring feature.

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11. The replacement heart valve prosthesis of claim 10, wherein the second anchoring feature is configured such that, when the prosthesis transitions from an expanded configuration to a collapsed configuration, ends of the second anchoring feature move radially outwardly and downwardly.

12. The replacement heart valve prosthesis of any one of claims 1 to 11, further comprising a skirt extending around at least a portion of the prosthesis.

13. The replacement heart valve prosthesis of claim 12, wherein the skirt is formed from fabric.

14. The replacement heart valve prosthesis of claim 12 or 13, wherein the skirt extends around a portion of the second frame portion.

15. The replacement heart valve prosthesis of any one of claims 12 to 14, wherein at least a portion of the skirt extends along an exterior of the second frame portion and at least a portion of the skirt extends between the first frame portion and the second frame portion.

16. The replacement heart valve prosthesis of claim 15, wherein the portion extending between the first frame portion and the second frame portion is attached to the valve body.

17. The replacement heart valve prosthesis of any one of claims 1 to 16, wherein the valve body comprises one or more intermediate components, the one or more intermediate components positioned between the first frame body and the valve leaflets.

18. The replacement heart valve prosthesis of any one of claims 1 to 17, wherein the first frame body forms a bulbous shape.

Edwards Lifesciences Corporation

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON

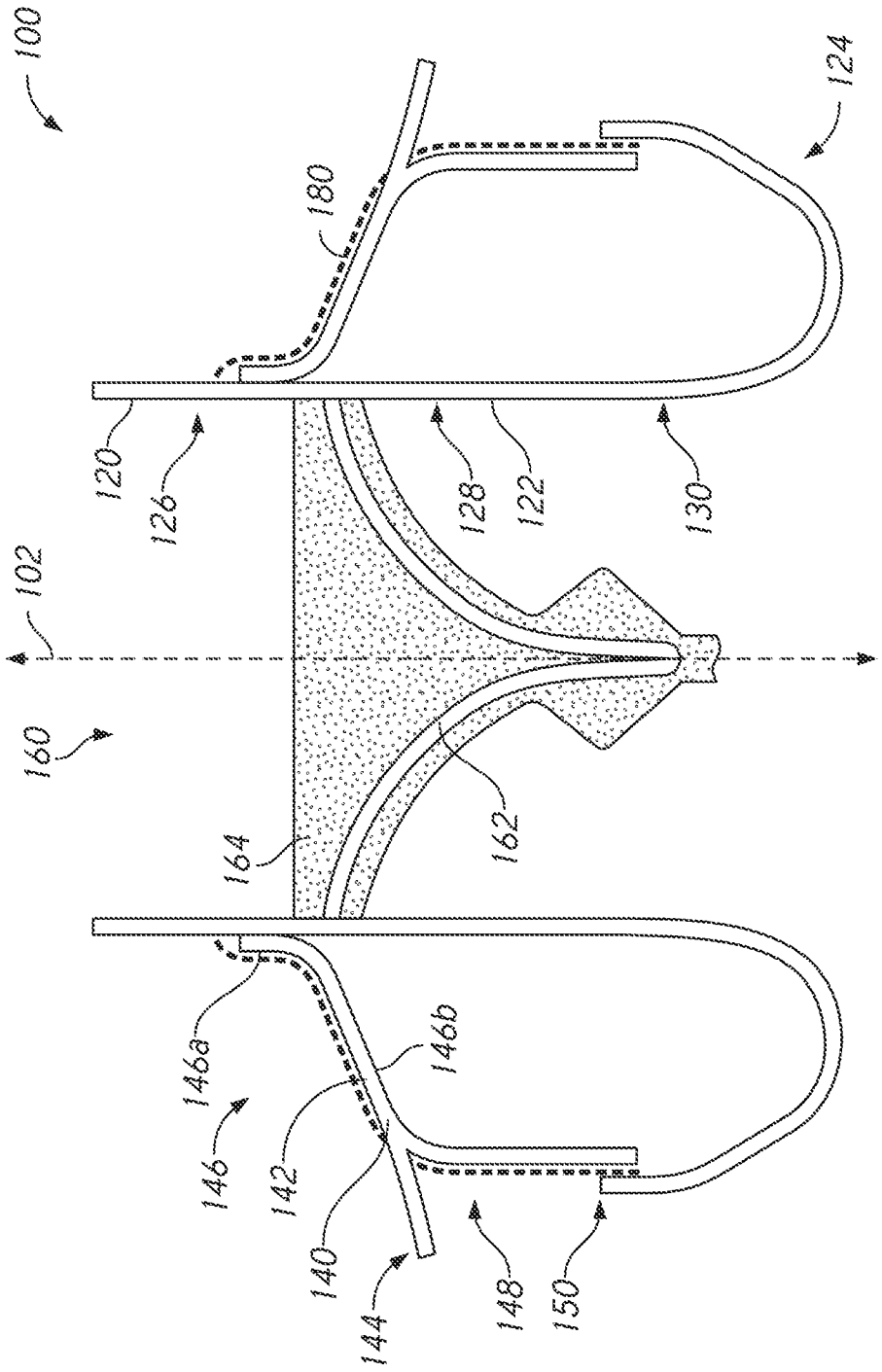
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FIG. 1

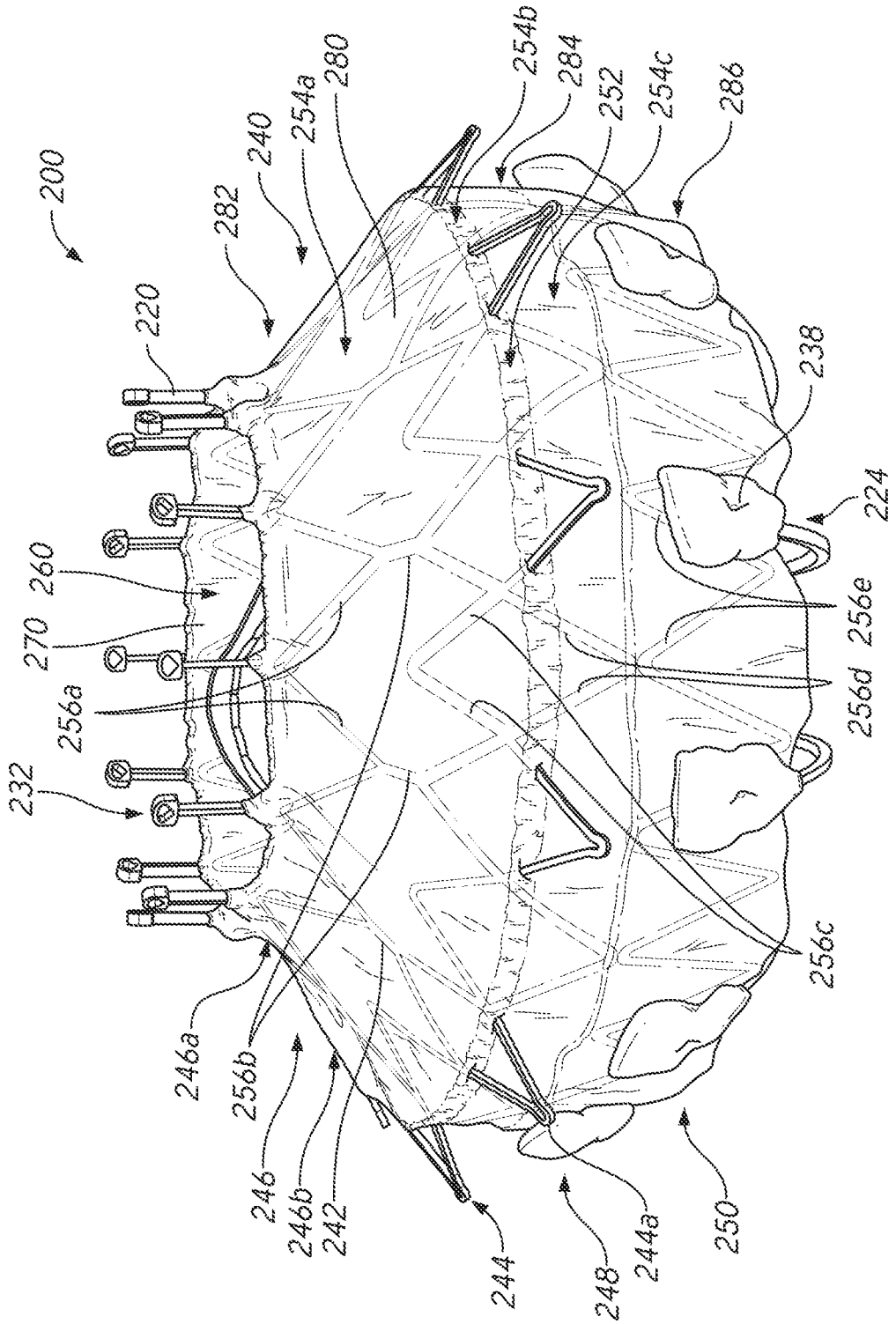
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FIG. 2

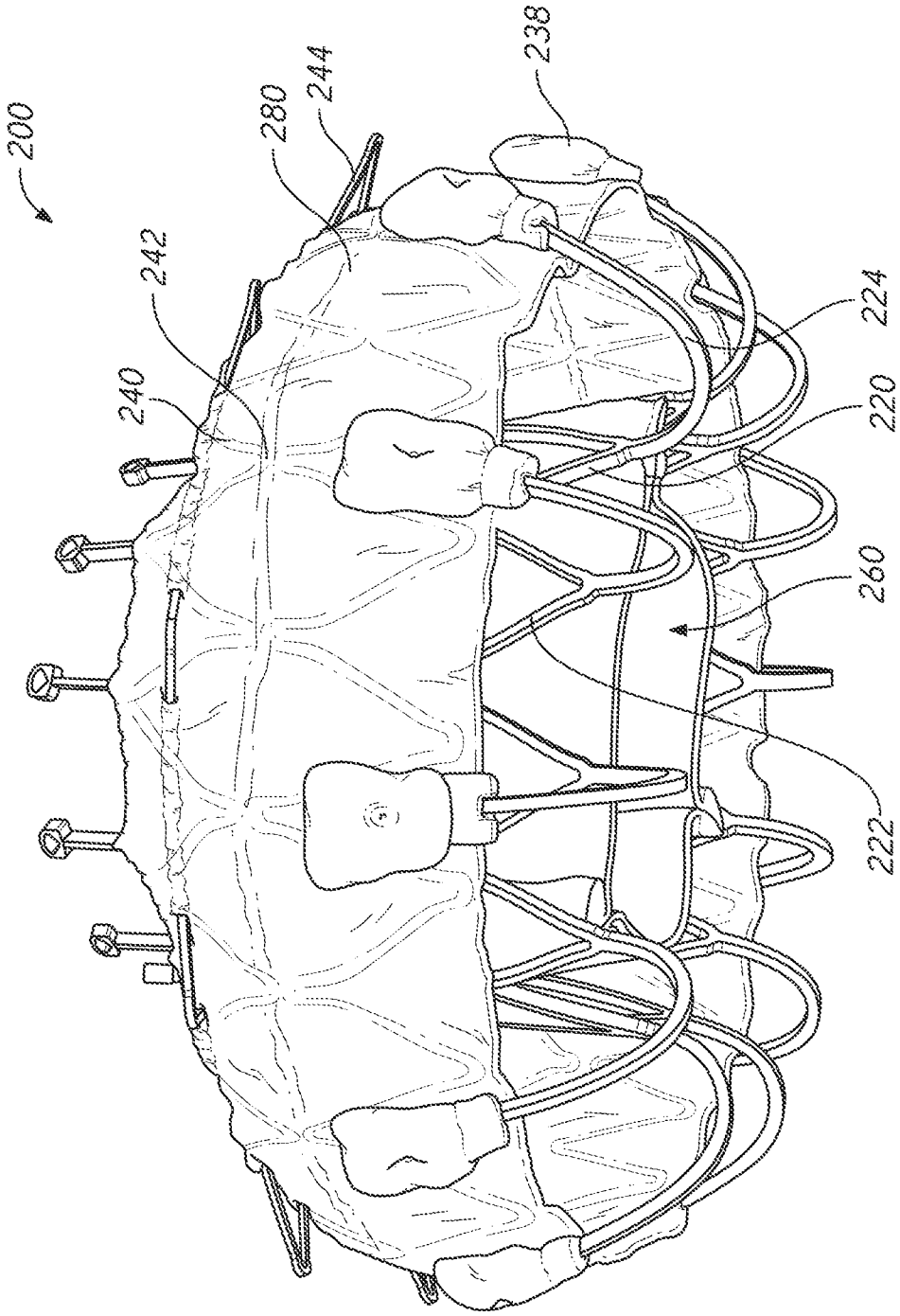

FIG. 3

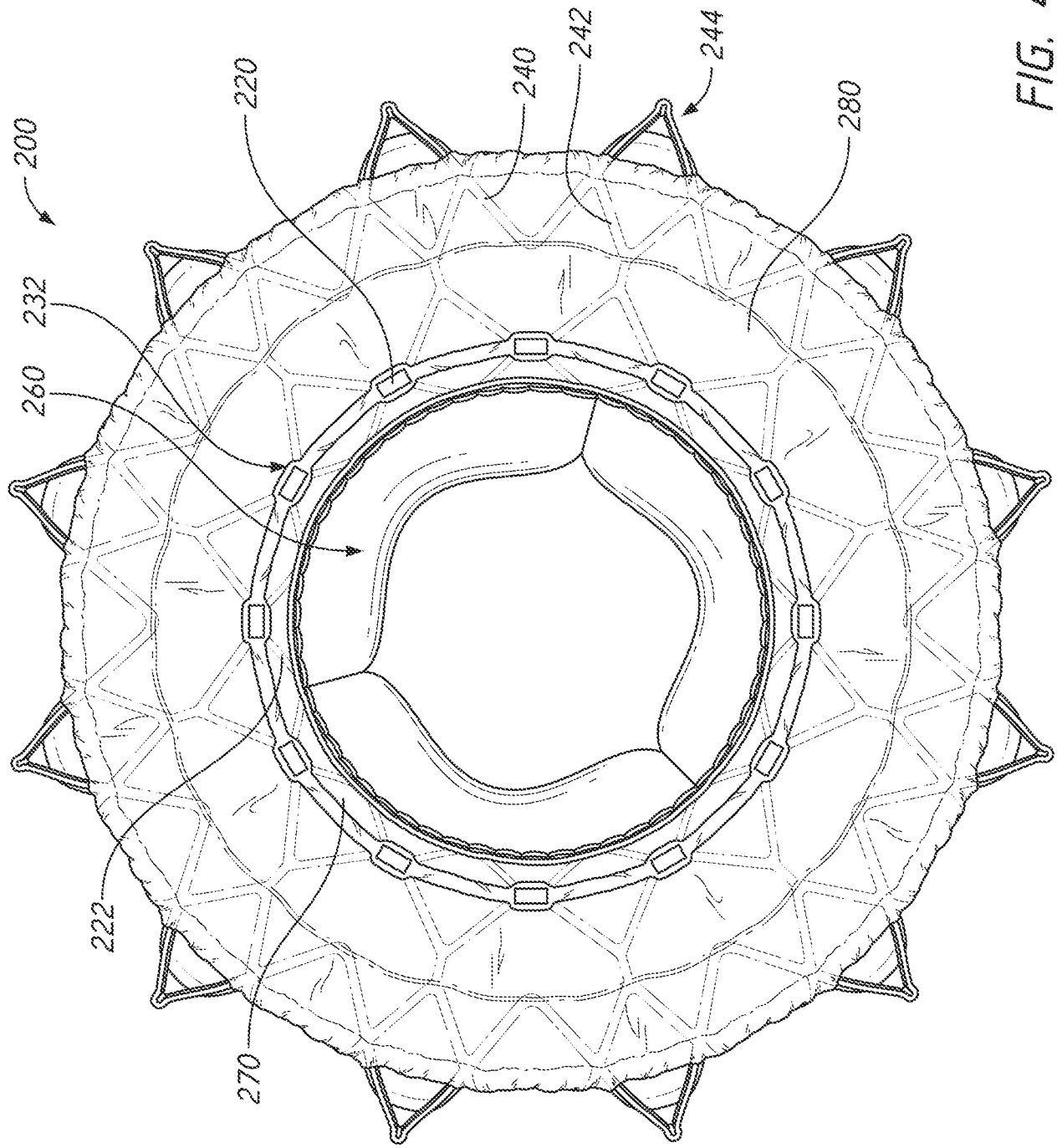

FIG. 4

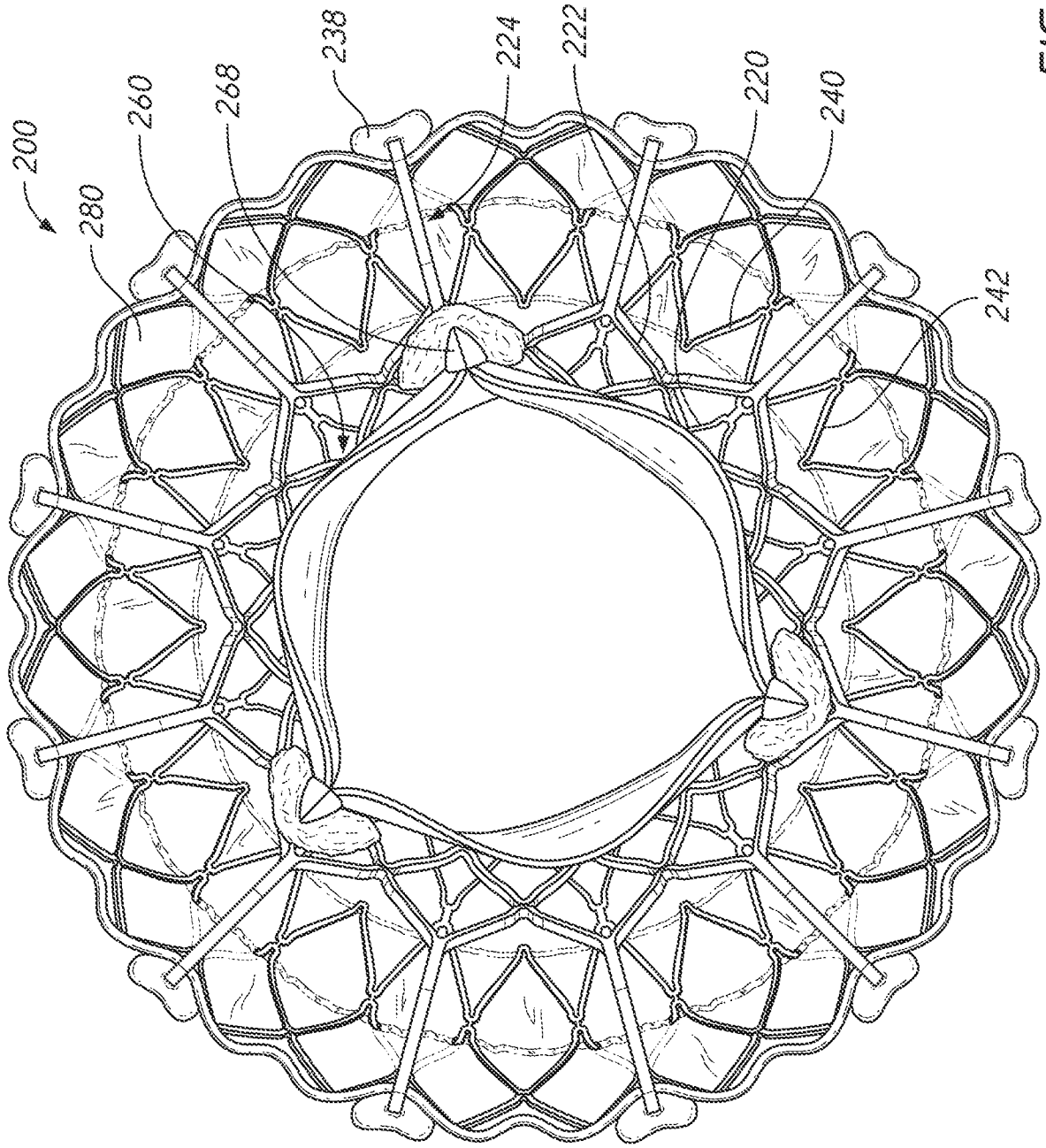

FIG. 5

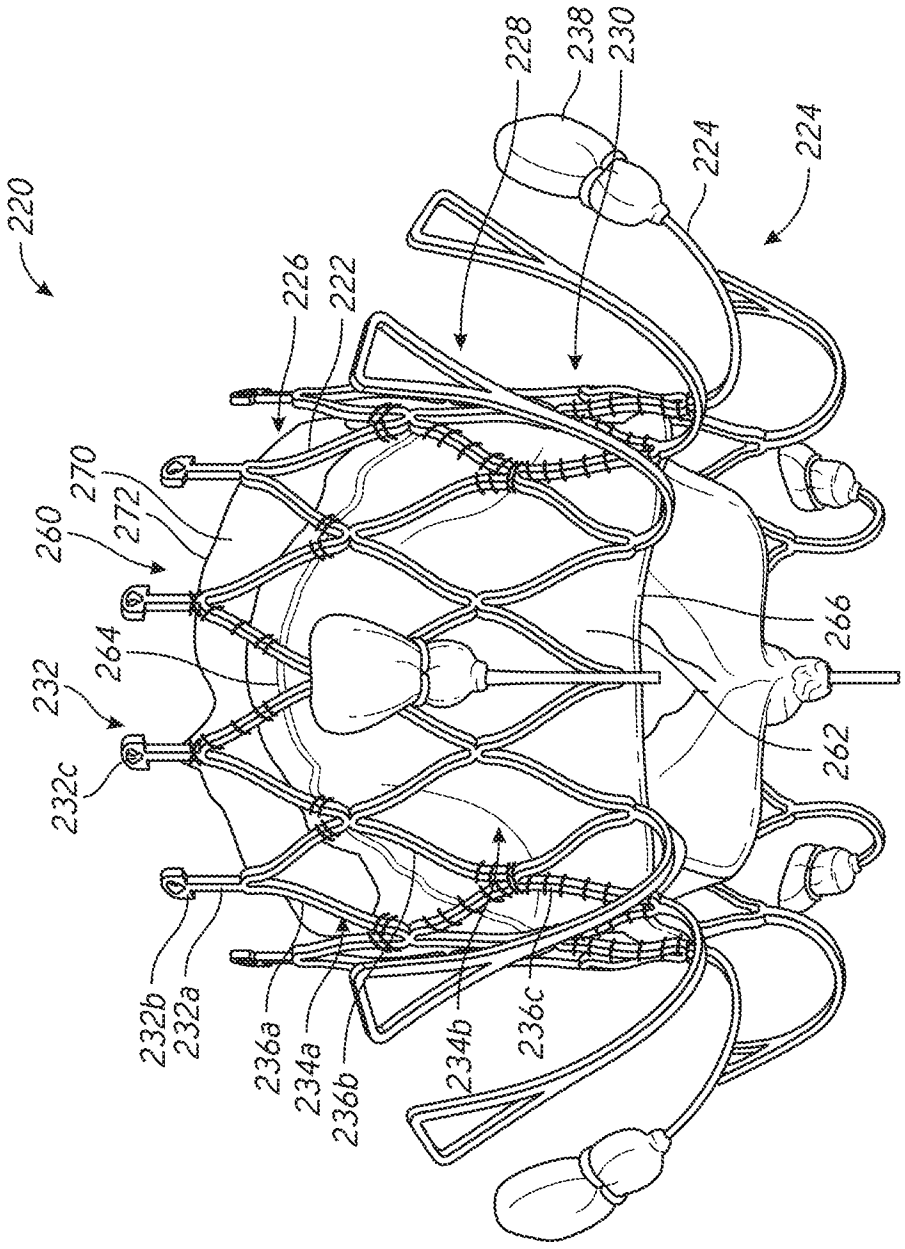
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FIG. 6

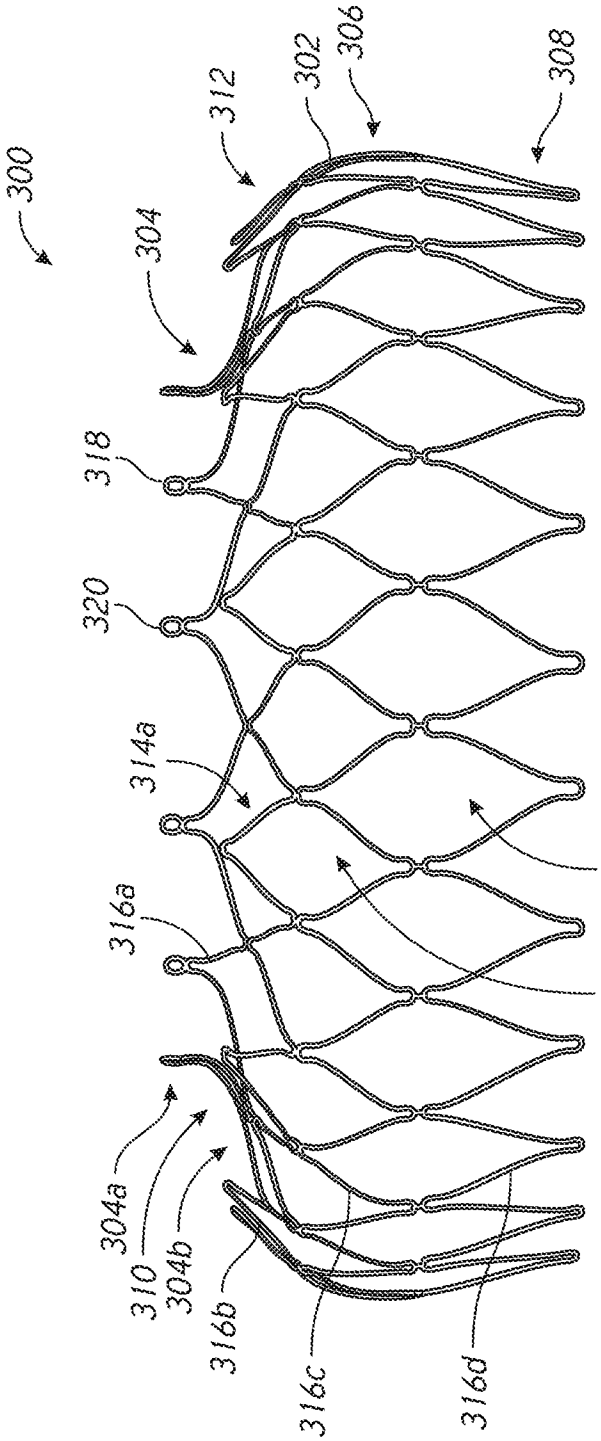
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FIG. 7

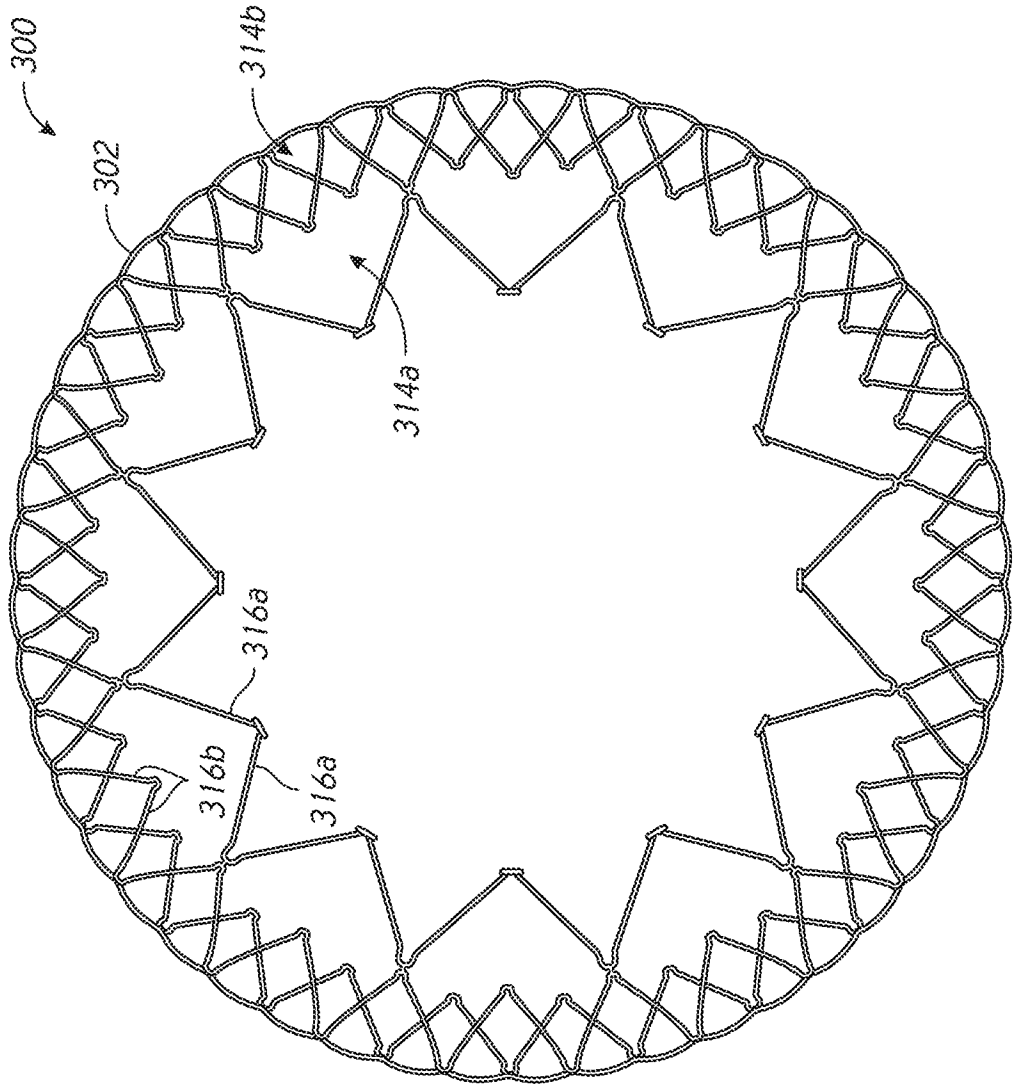


FIG. 8

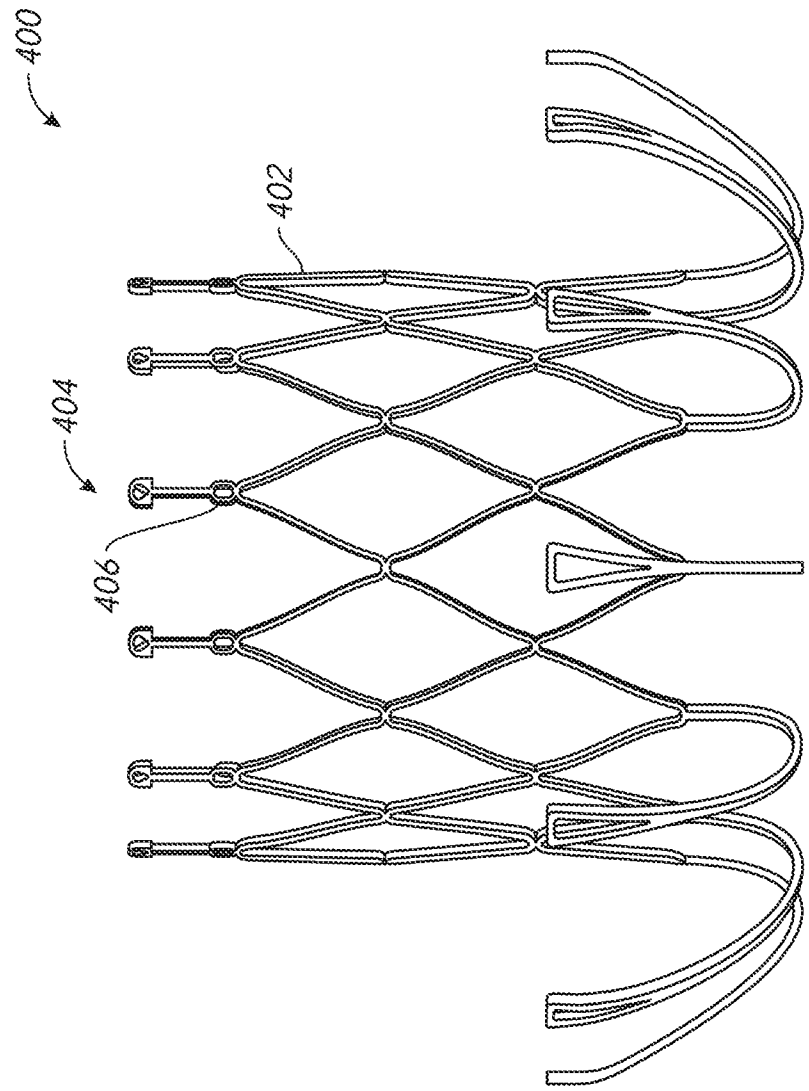


FIG. 9

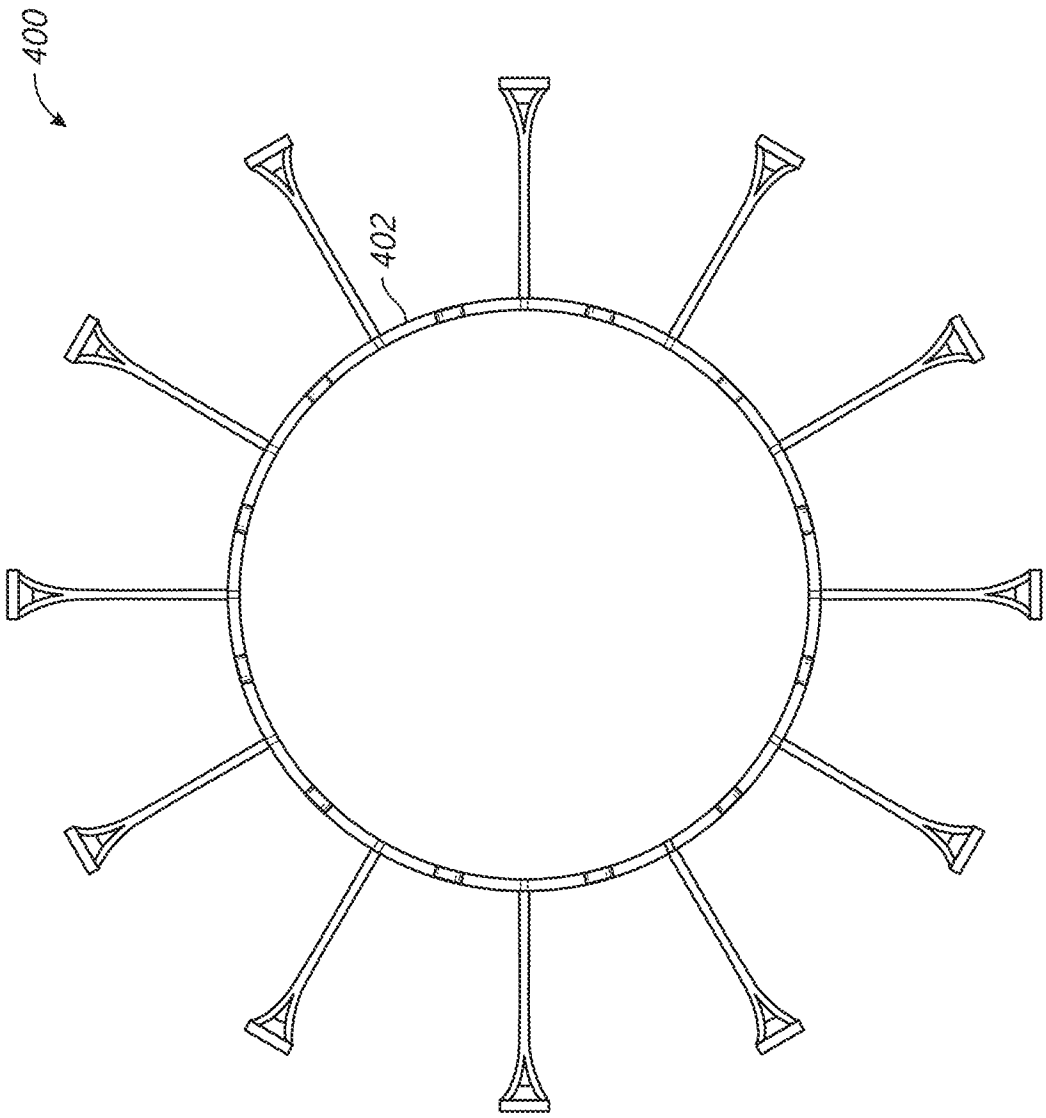


FIG. 10

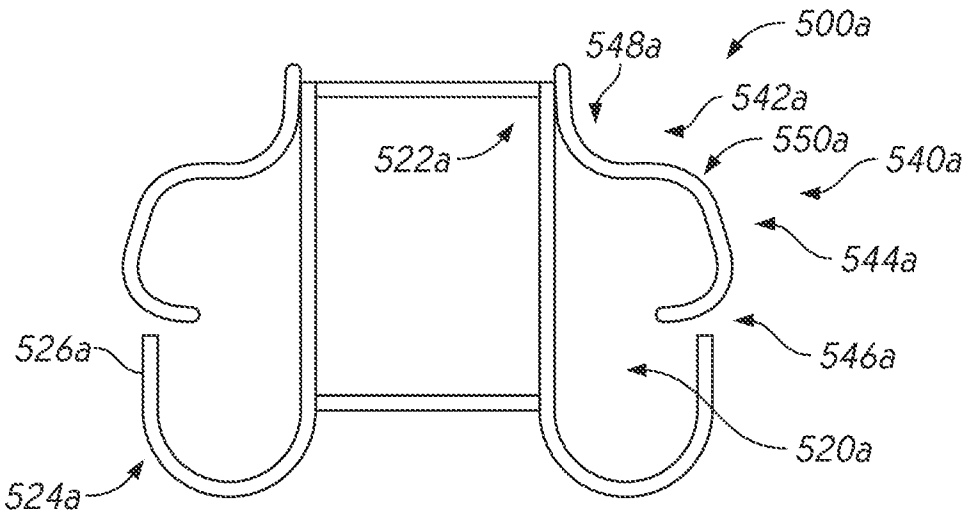


FIG. 11A

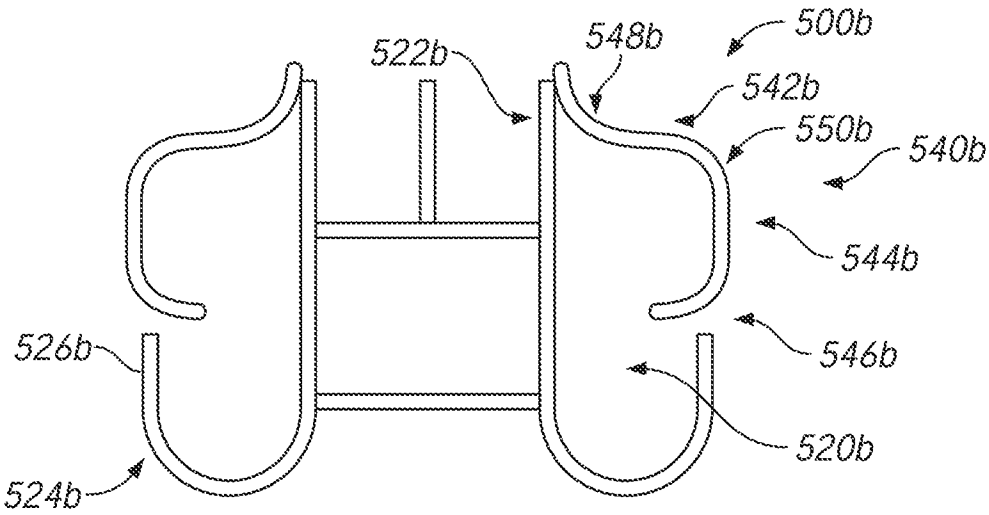


FIG. 11B

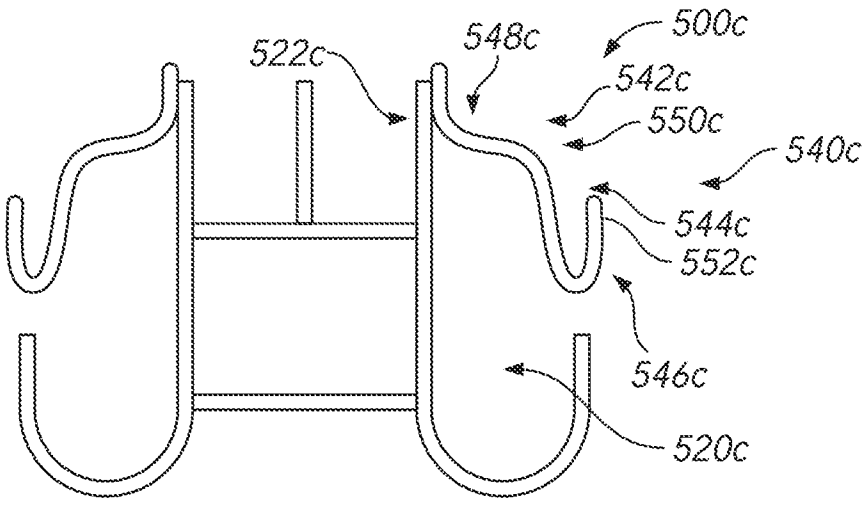


FIG. 11C

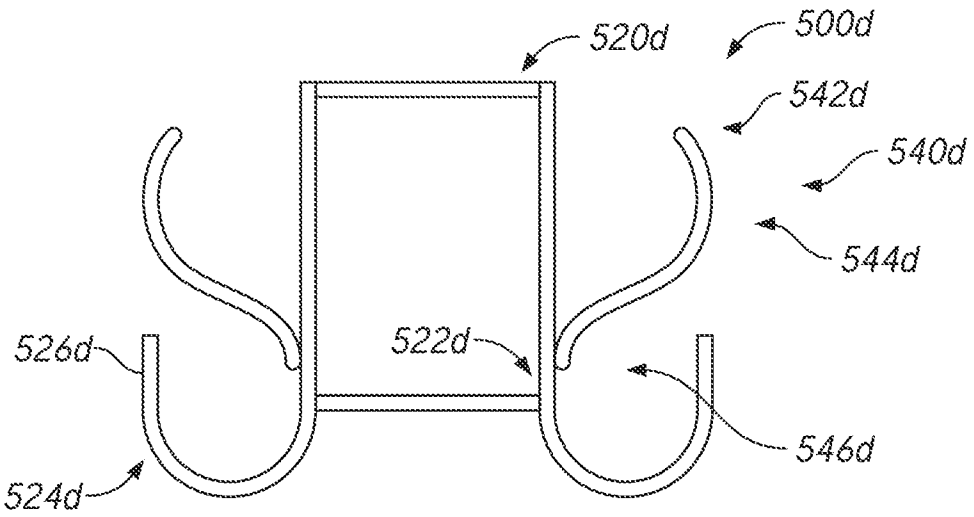


FIG. 11D

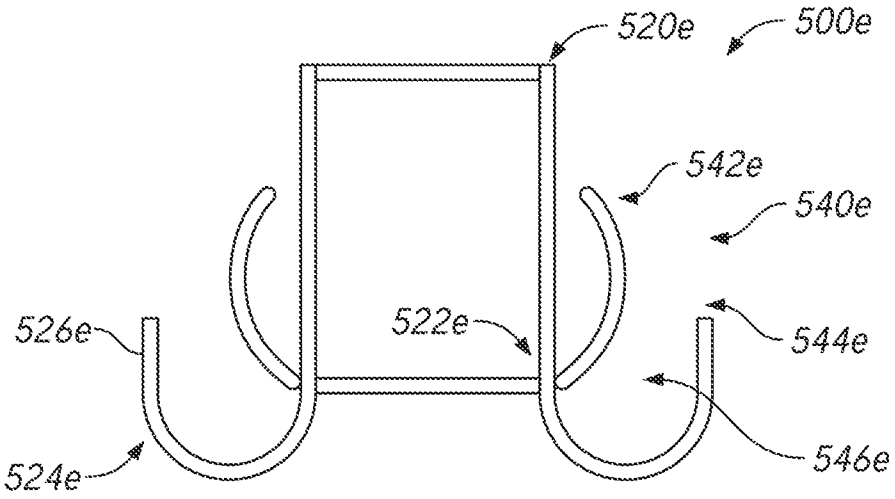


FIG. 11E

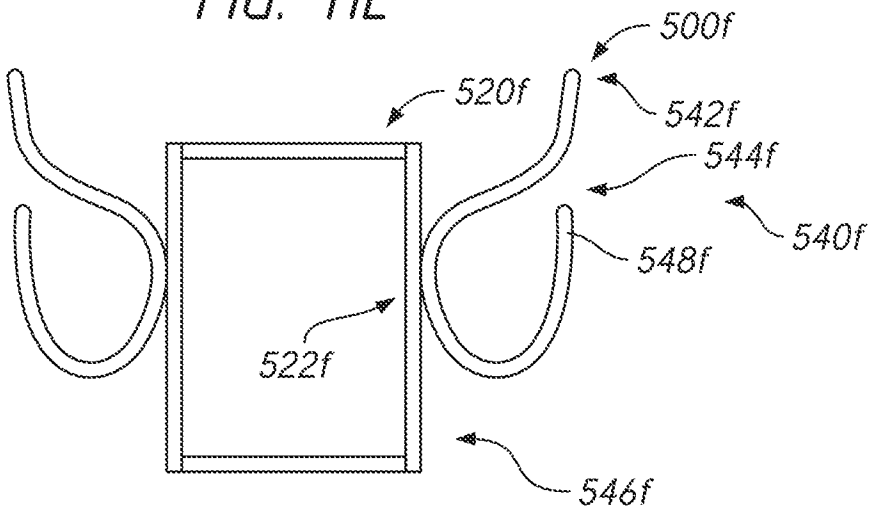


FIG. 11F

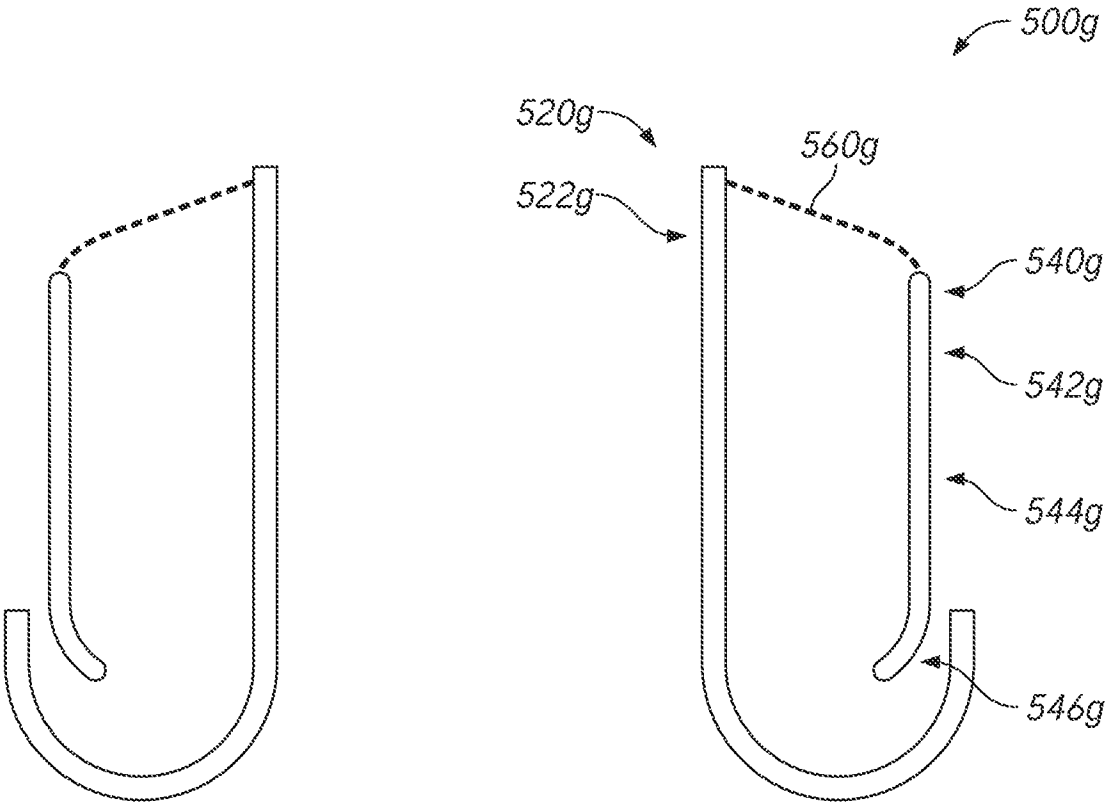


FIG. 11G

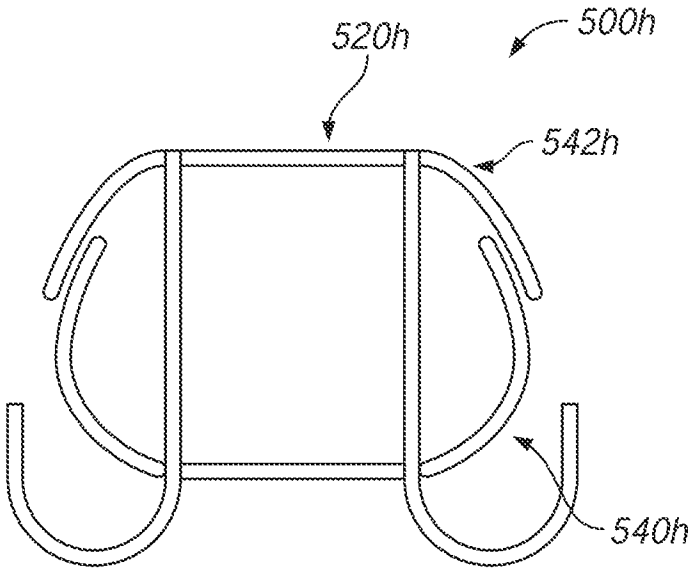


FIG. 11H

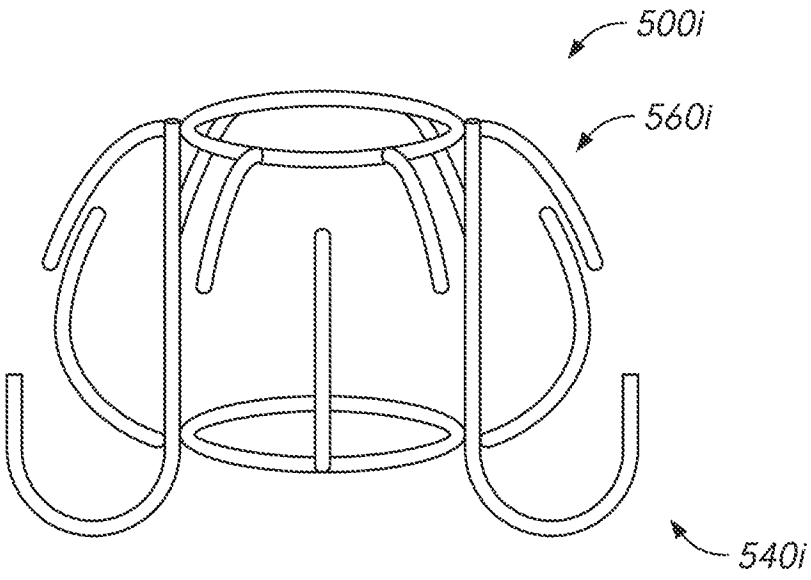


FIG. 11I

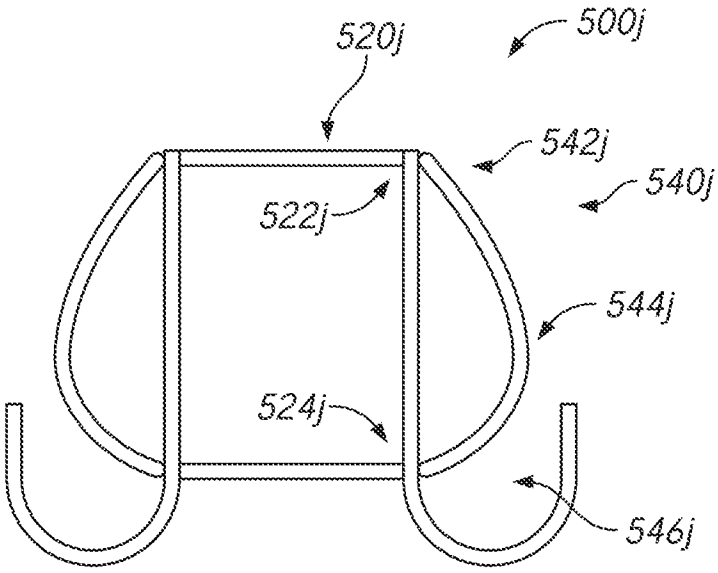


FIG. 11J

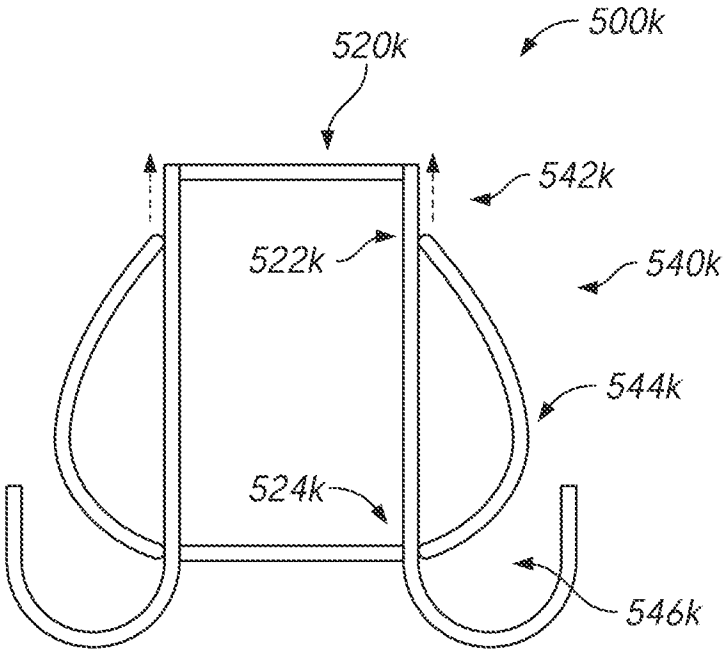


FIG. 11K

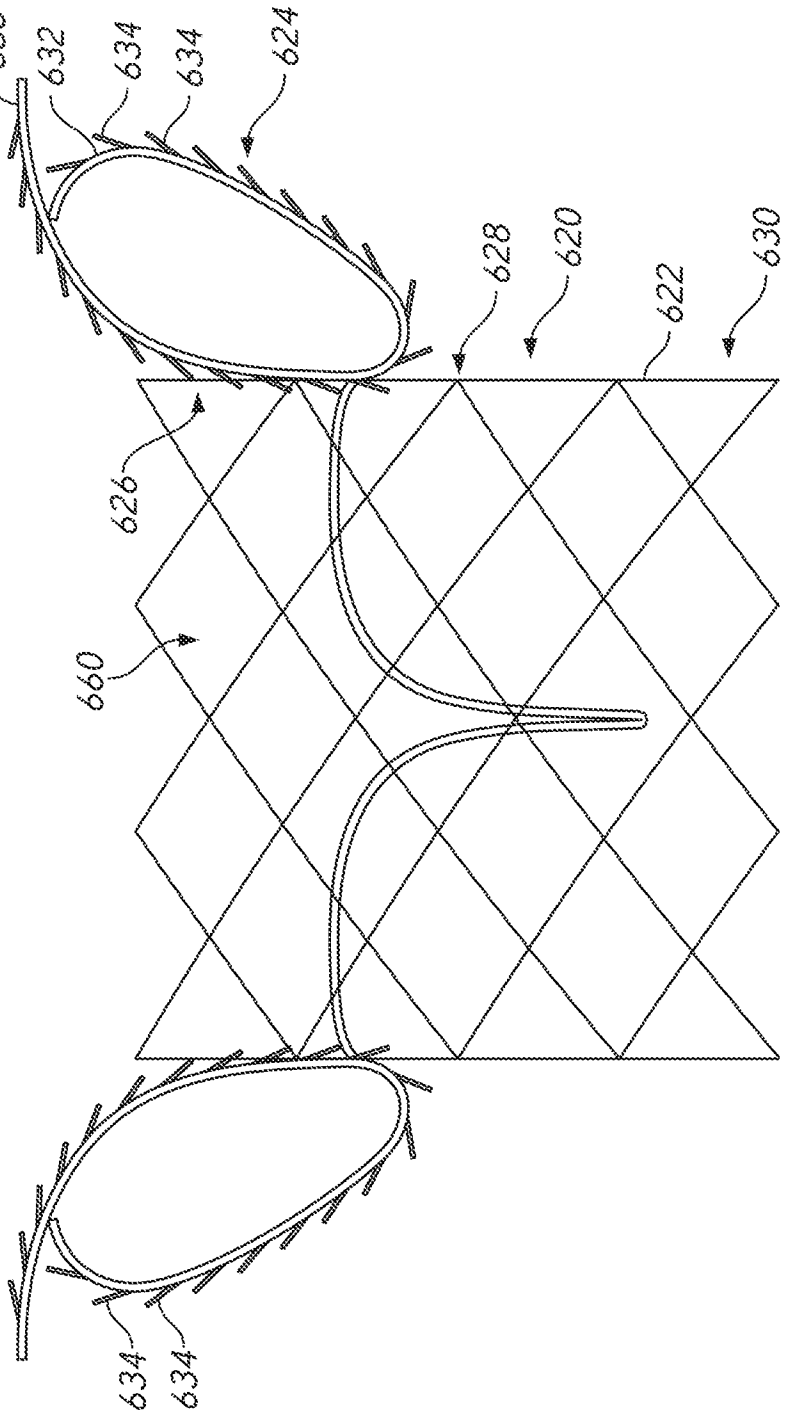


FIG. 12

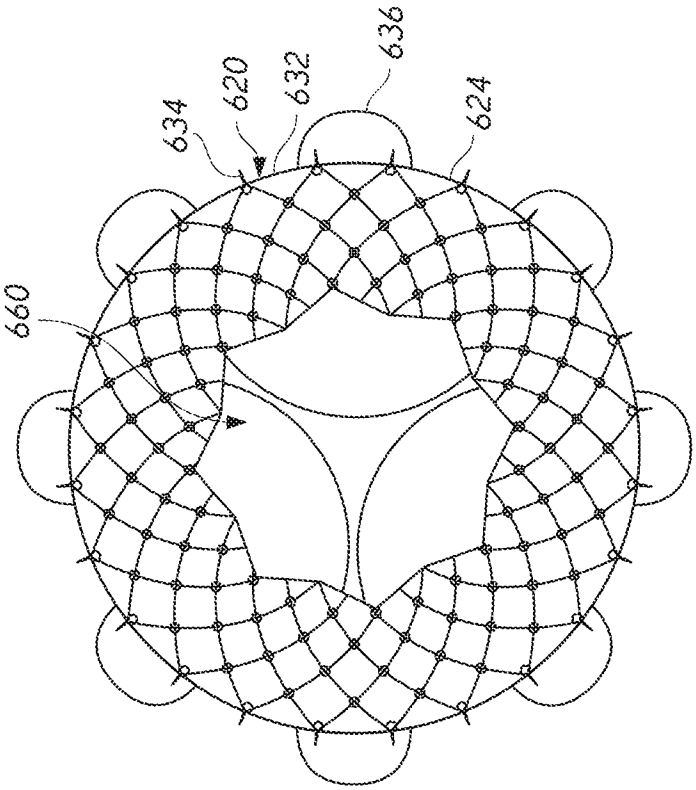


FIG. 14

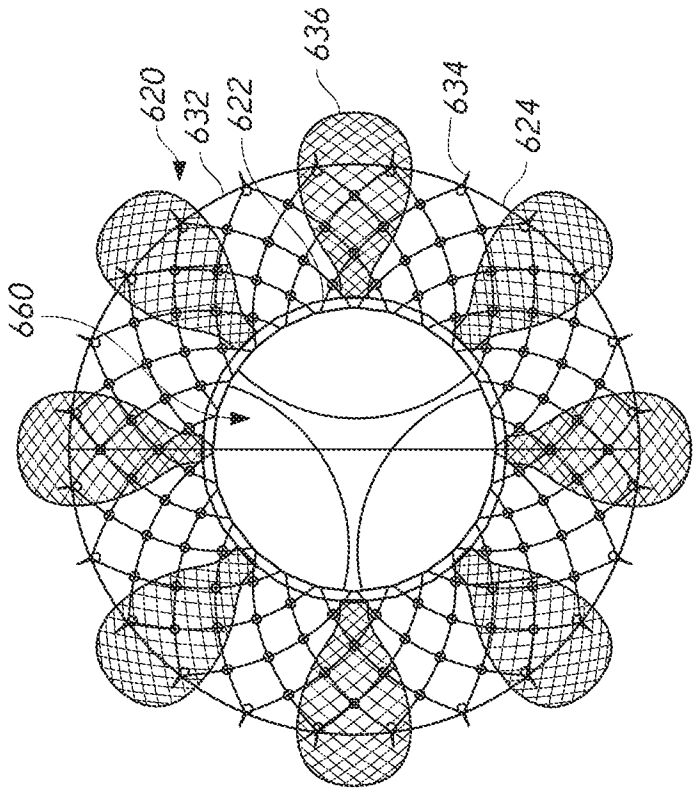


FIG. 13

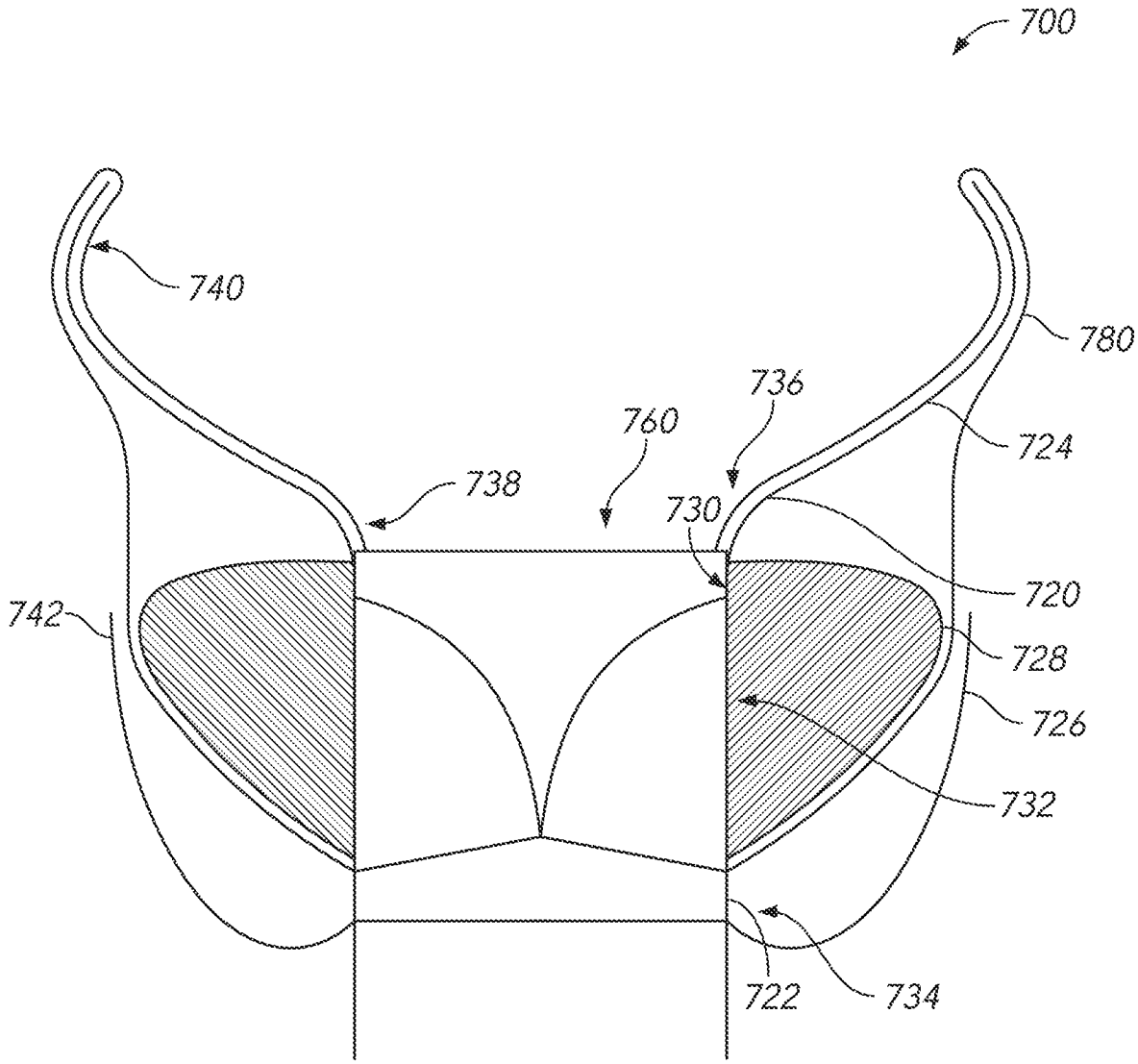


FIG. 15

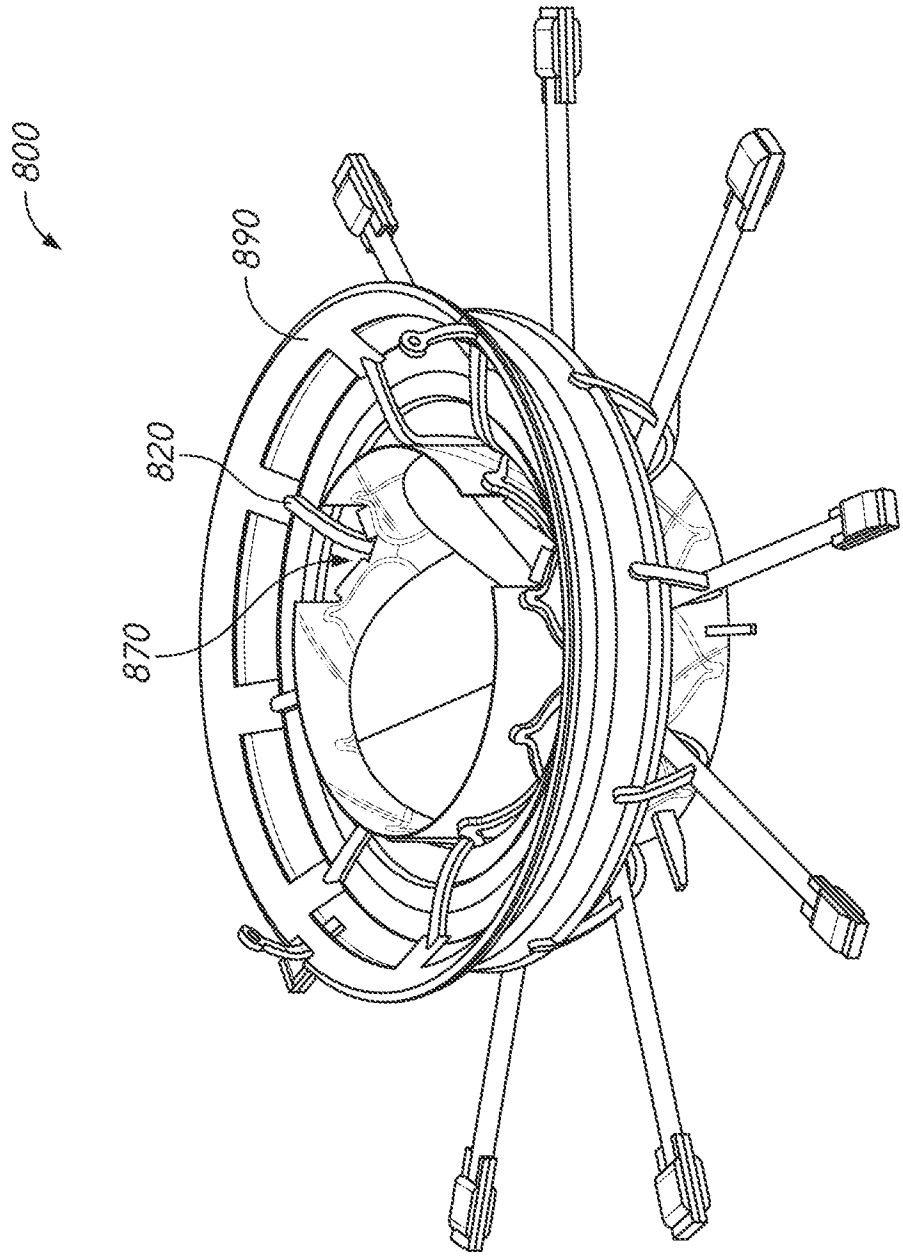


FIG. 16

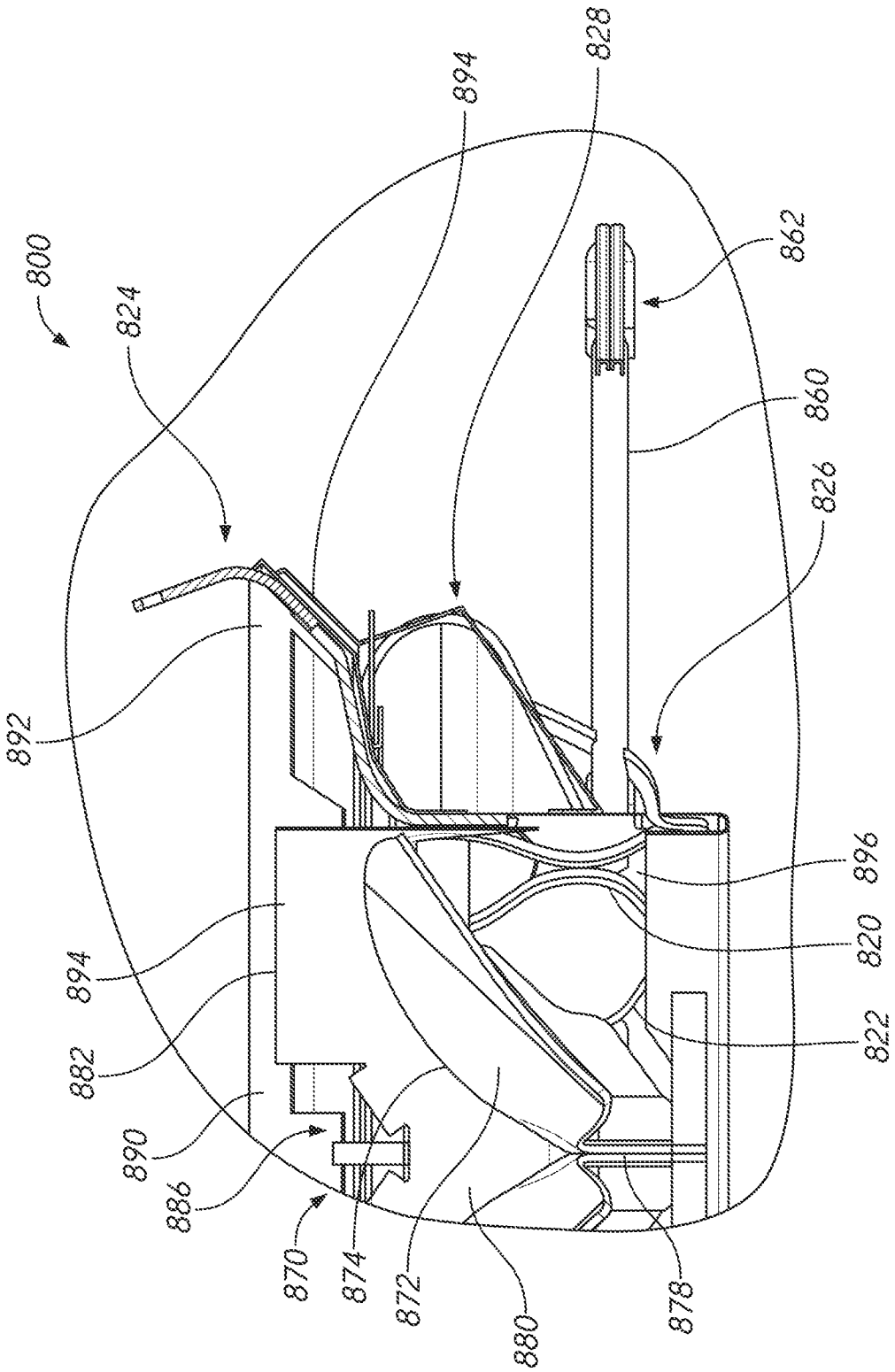

800
824
894
828
862
860
826
892
896
820
822
894
882
890
886
870
874
872
880
878

FIG. 17

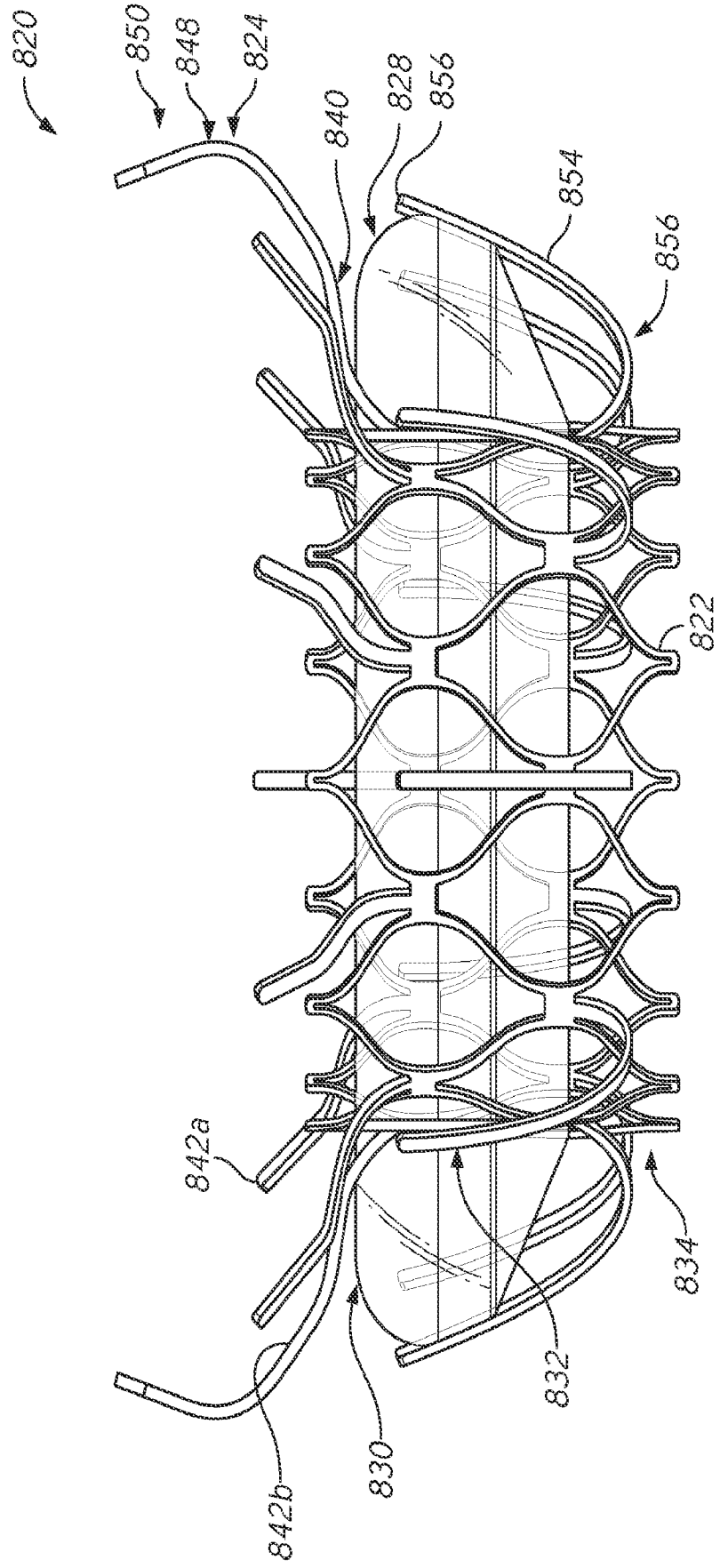


FIG. 18

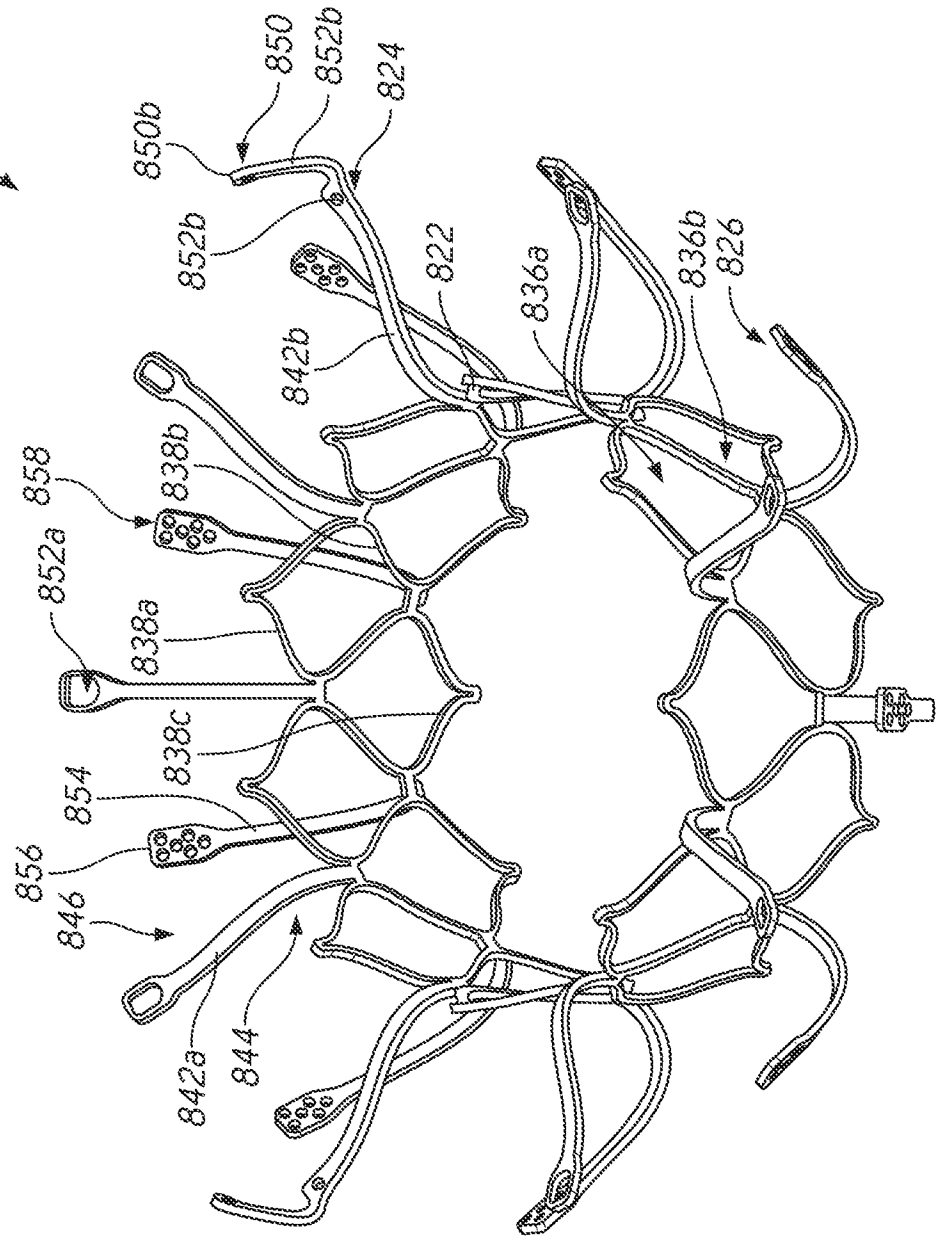

820
850
852b
824
850b
852b
822
836a
836b
826
842b
838b
858
852a
838a
838c
854
856
846
842a
844

FIG. 19

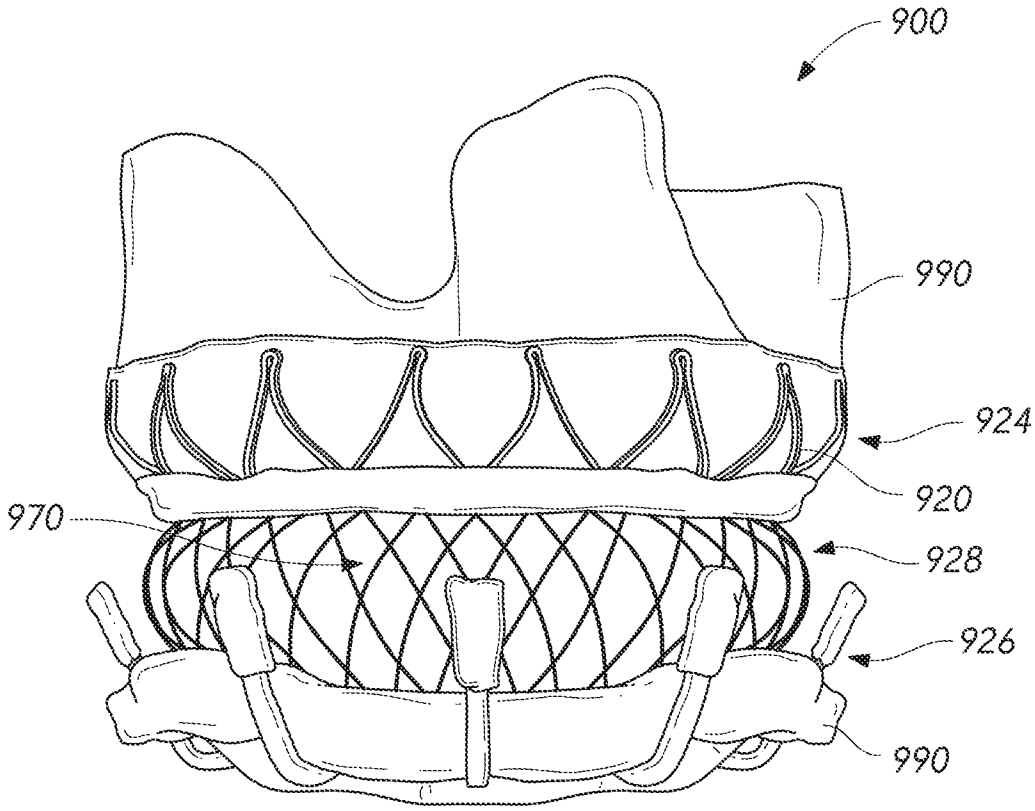


FIG. 20

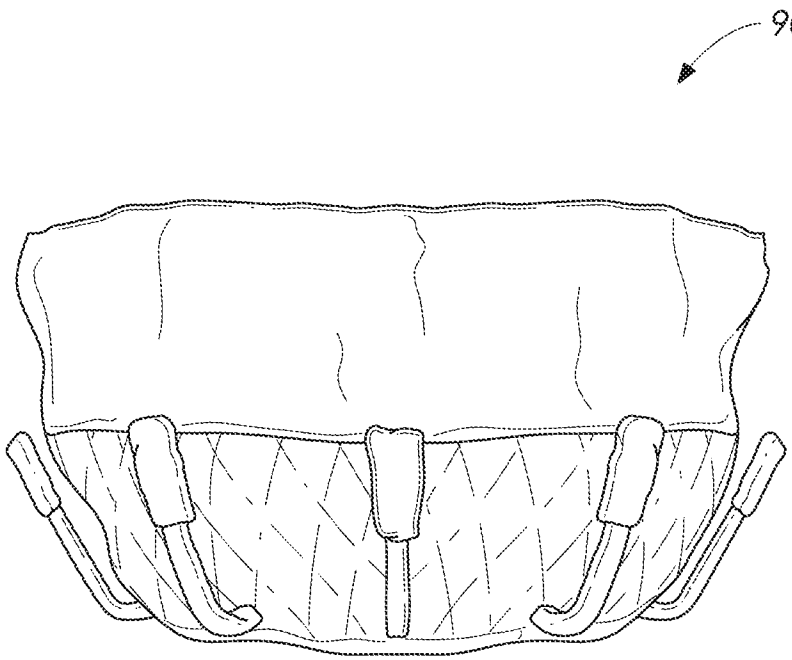


FIG. 21

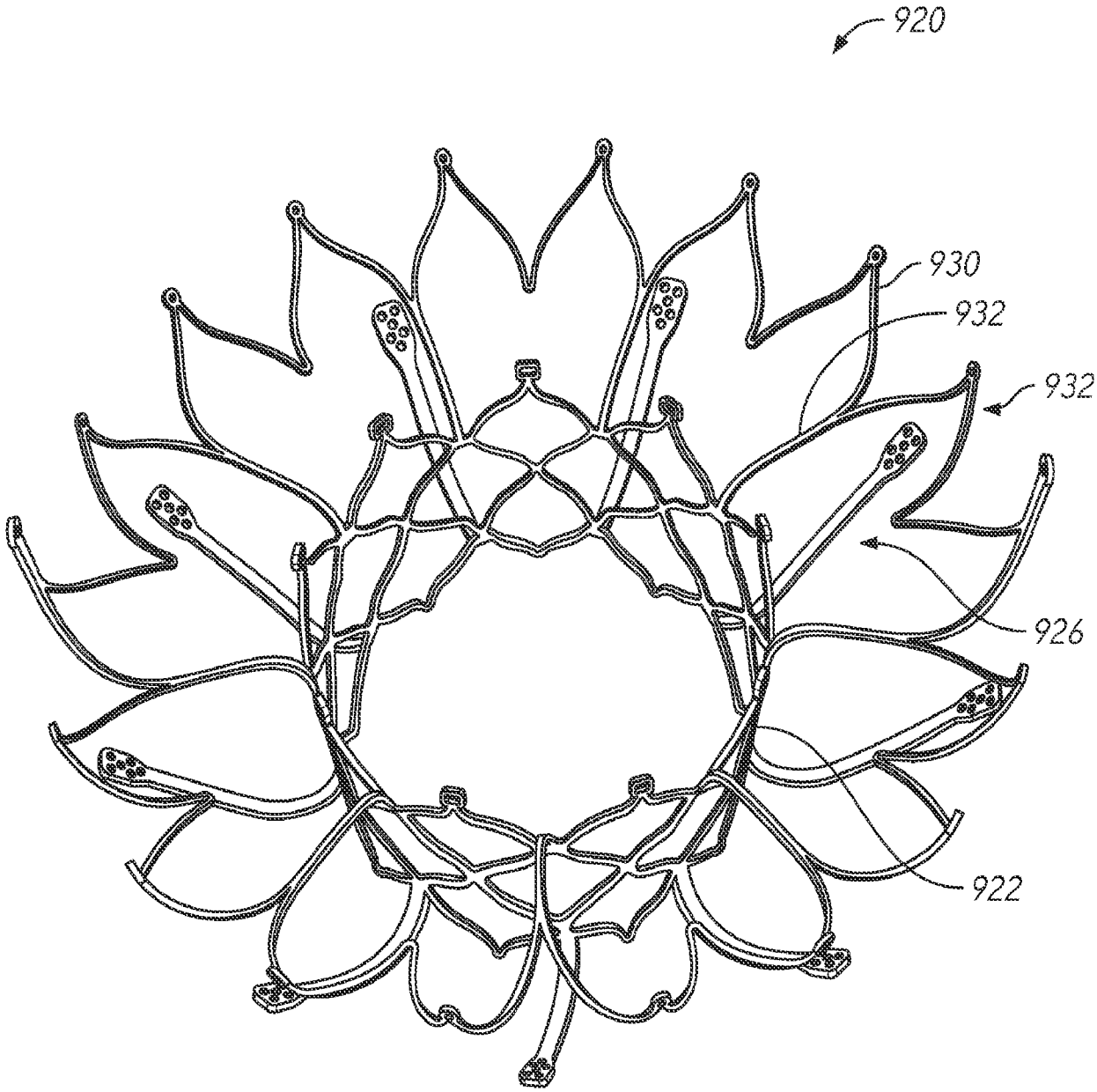


FIG. 22

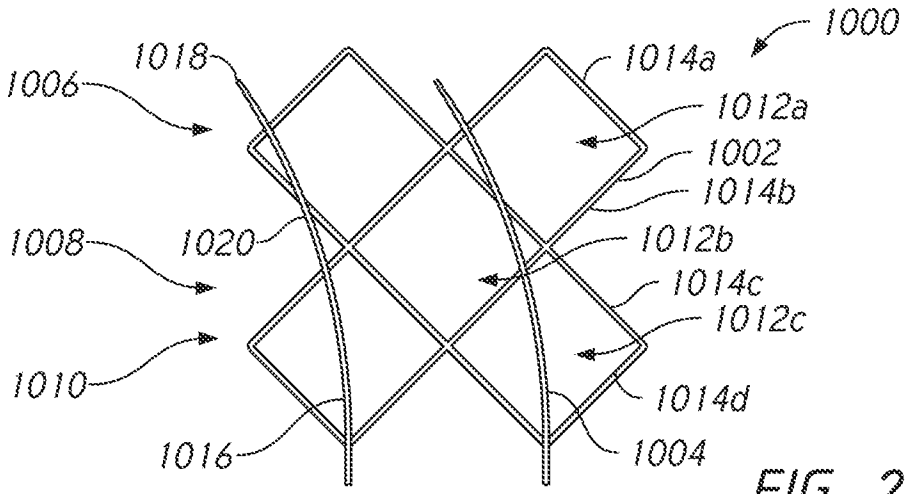


FIG. 23

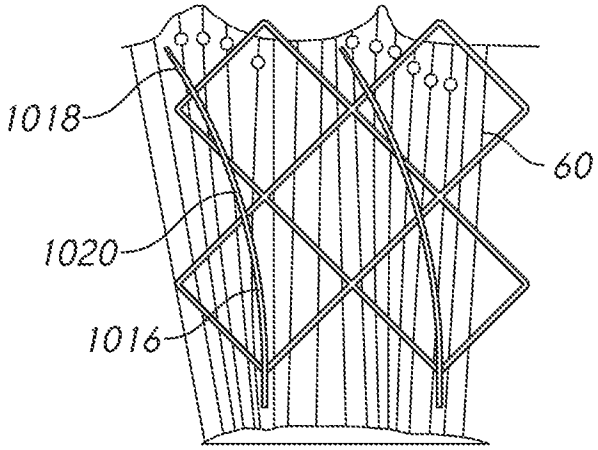


FIG. 24

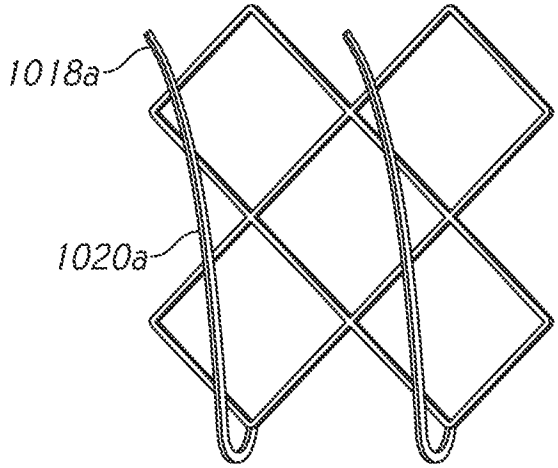


FIG. 25

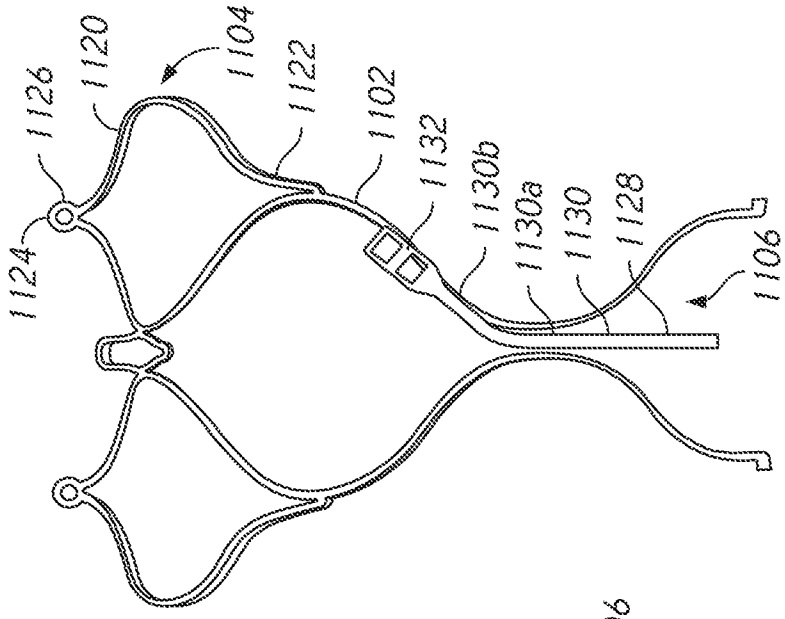

1100
1126
1120
1104
1122
1102
1132
1130b
1130a
1130
1128
1124
1106

FIG. 27

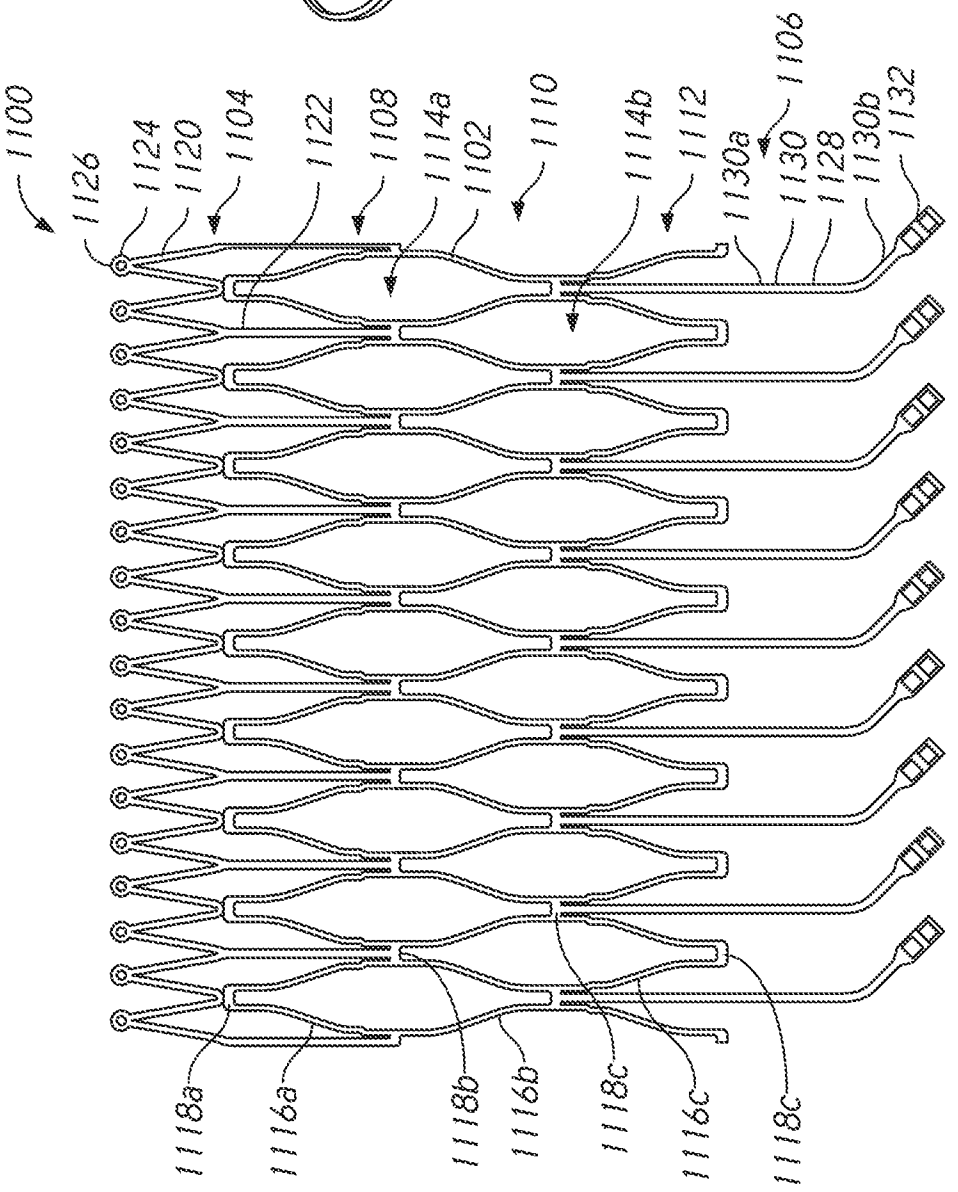

1100
1126
1124
1120
1104
1122
1108
1114a
1102
1110
1114b
1112
1130a
1106
1130
1128
1130b
1132
1118a
1116a
1118b
1116b
1118c
1116c
1118c

FIG. 26

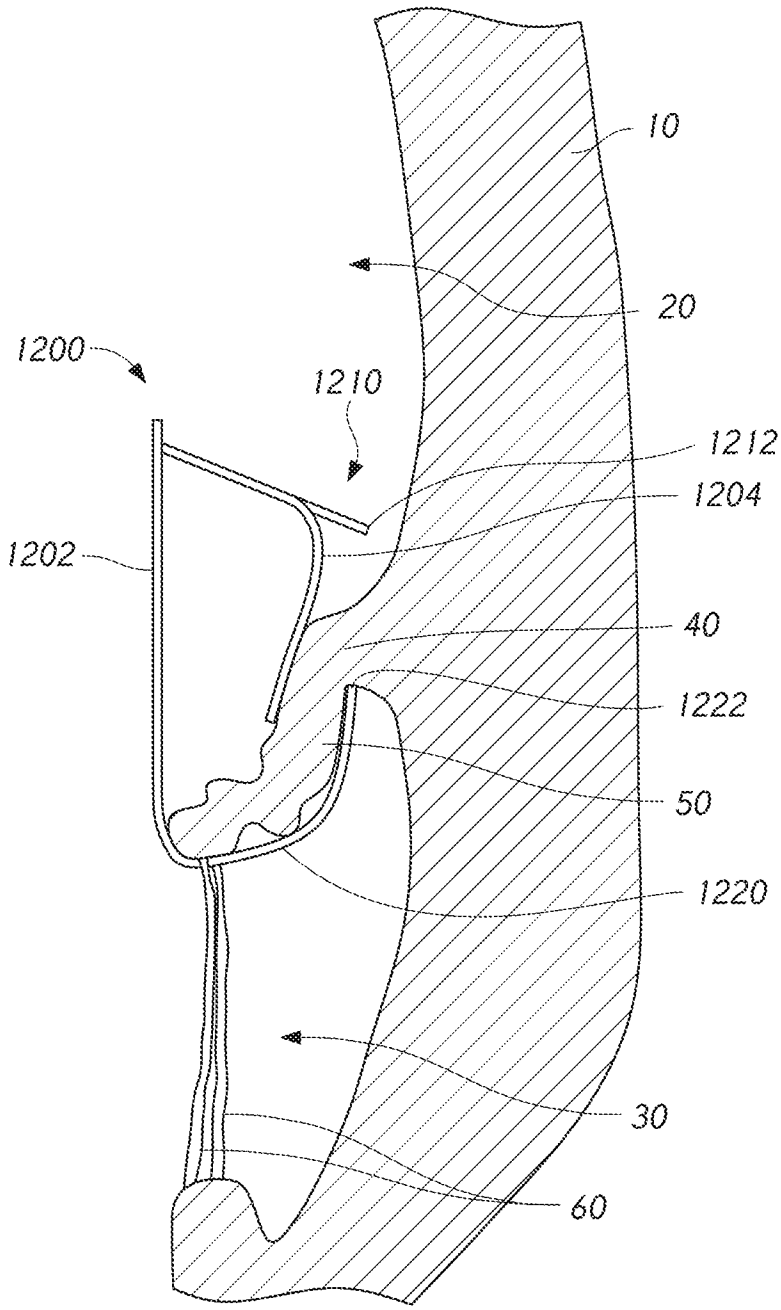


FIG. 28A

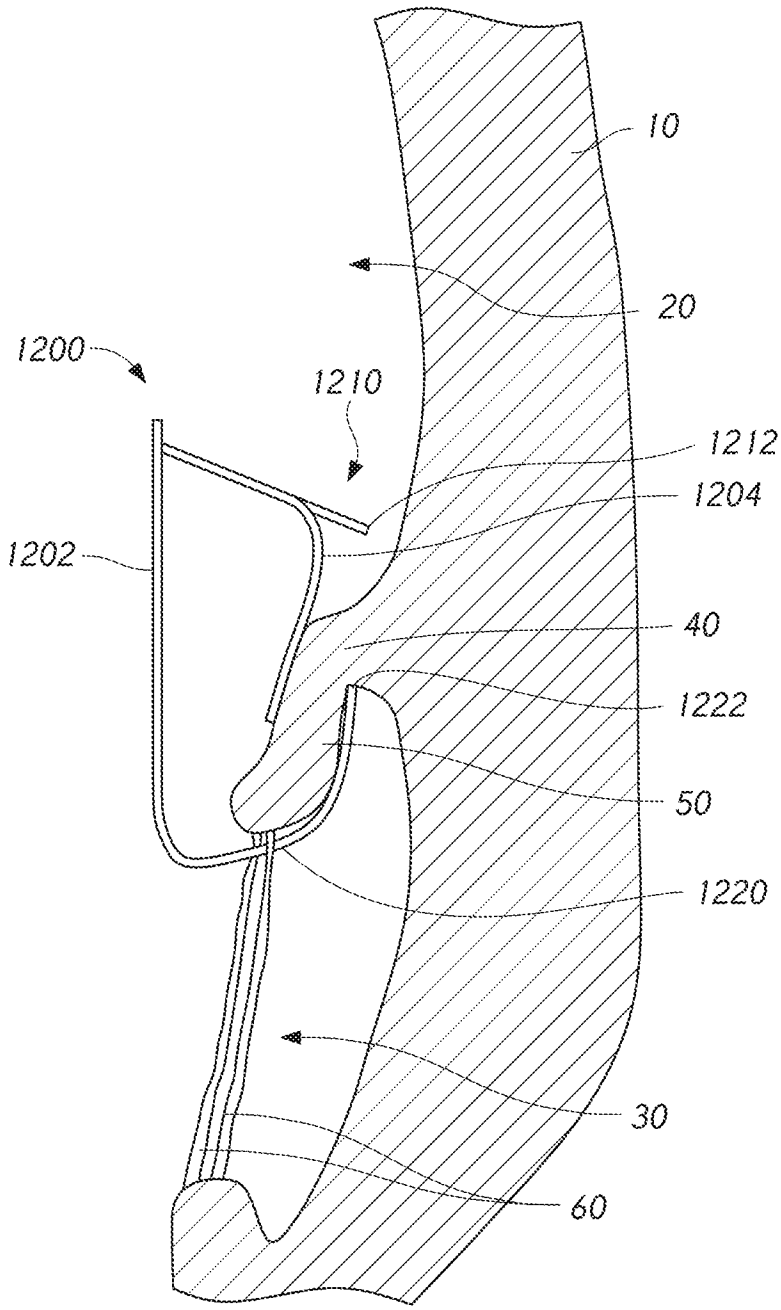


FIG. 28B

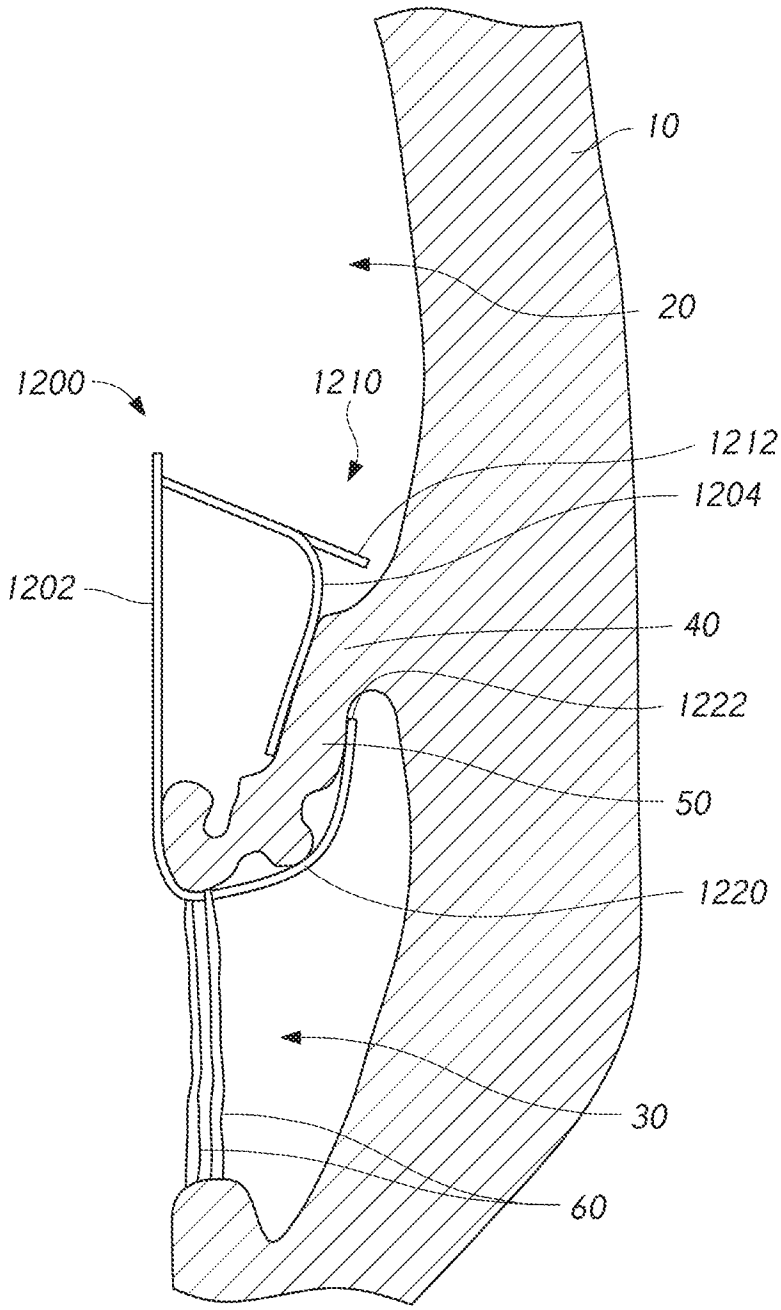


FIG. 29

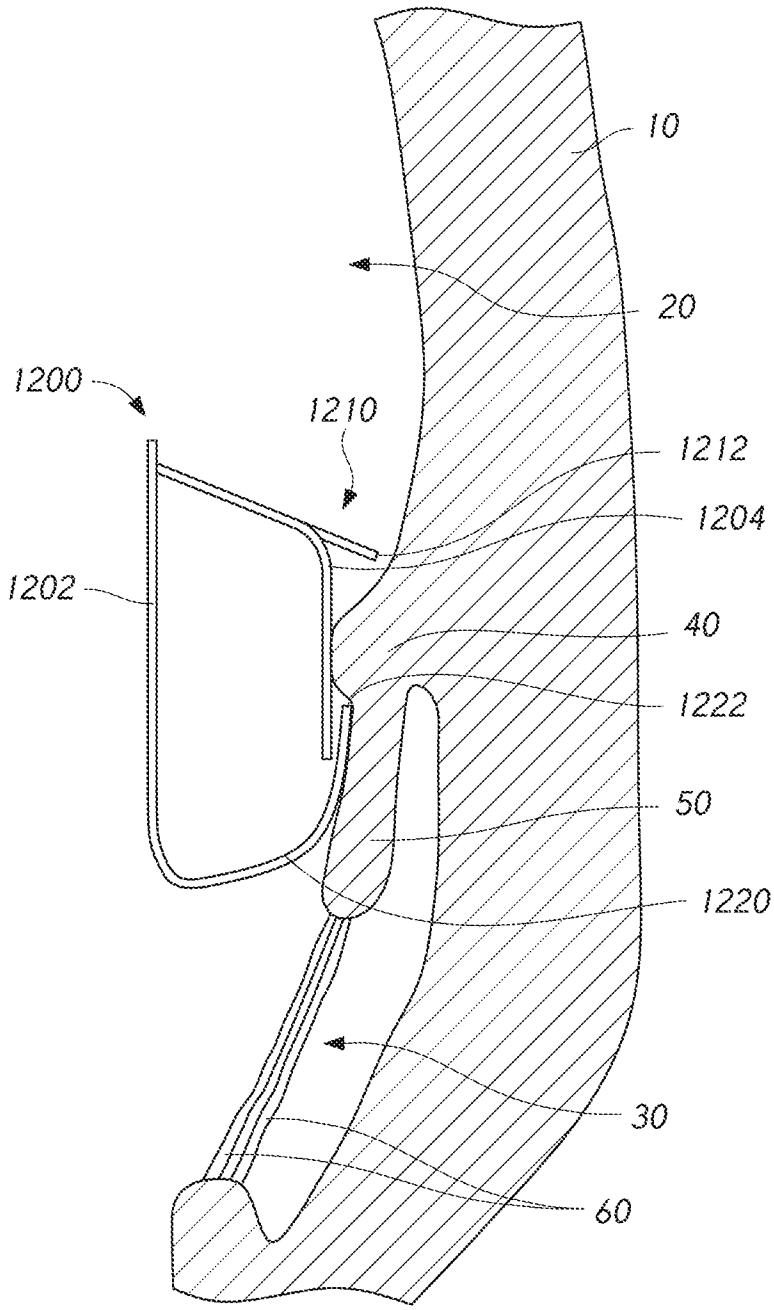


FIG. 30

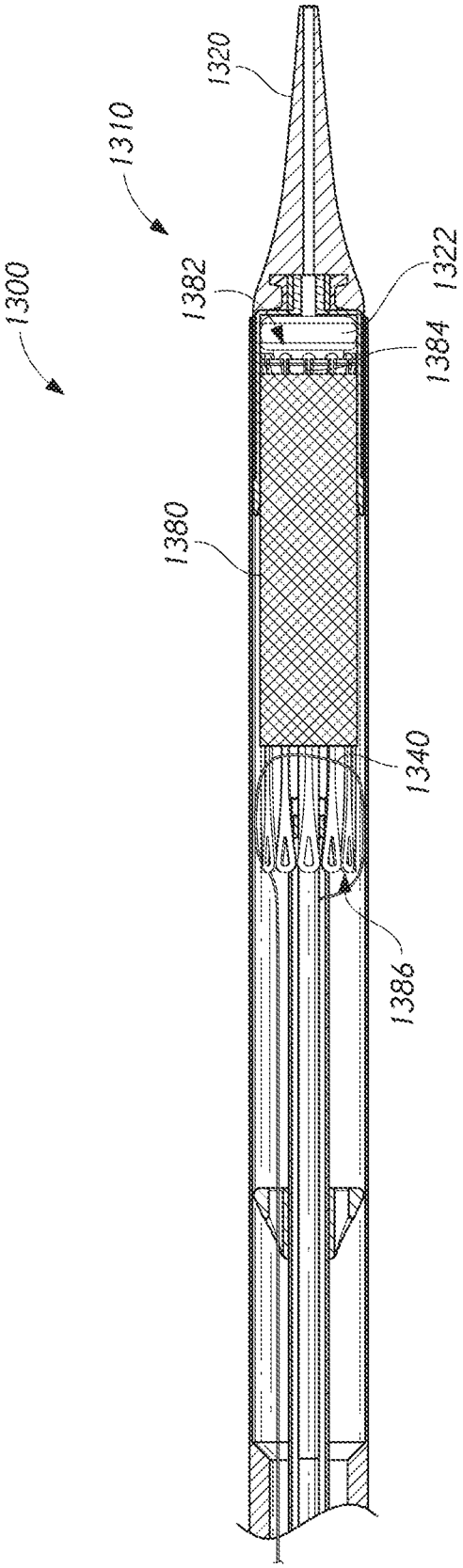


FIG. 31

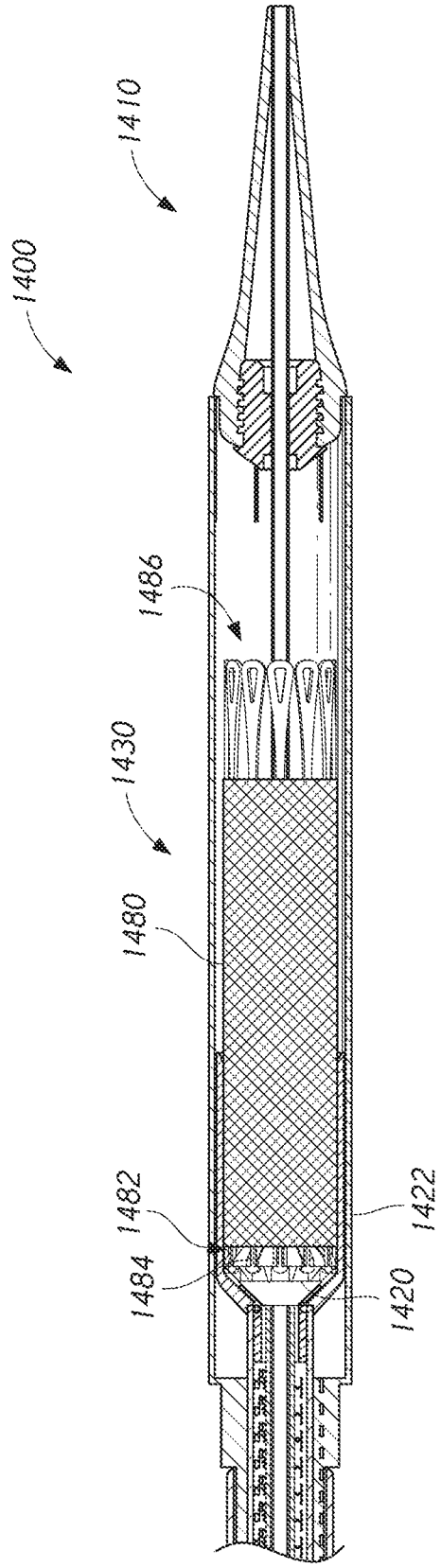


FIG. 32

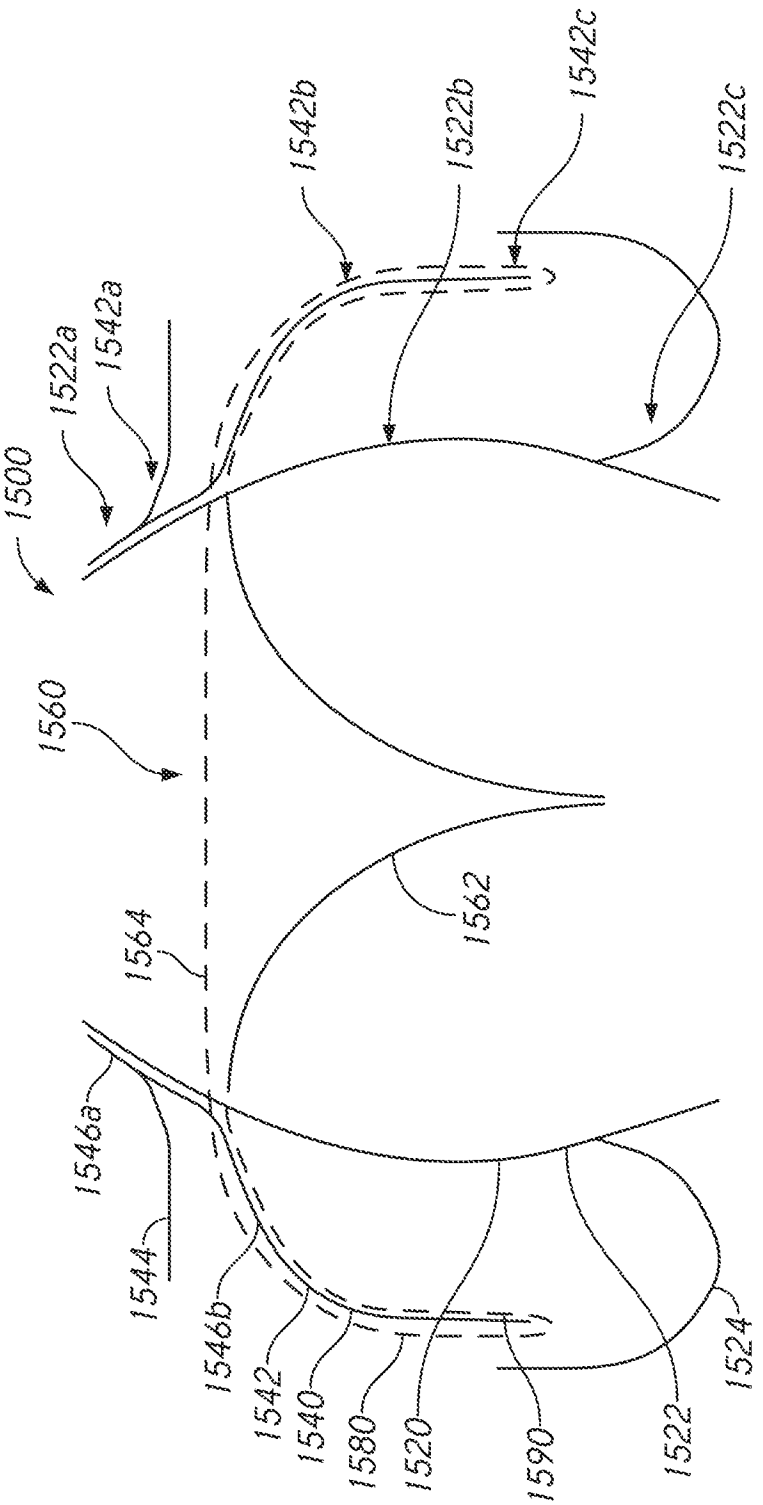

1500
1522a
1542a
1542b
1522b
1542c
1522c
1560
1562
1564
1546a
1544
1546b
1542
1540
1580
1520
1590
1522
1524

FIG. 33

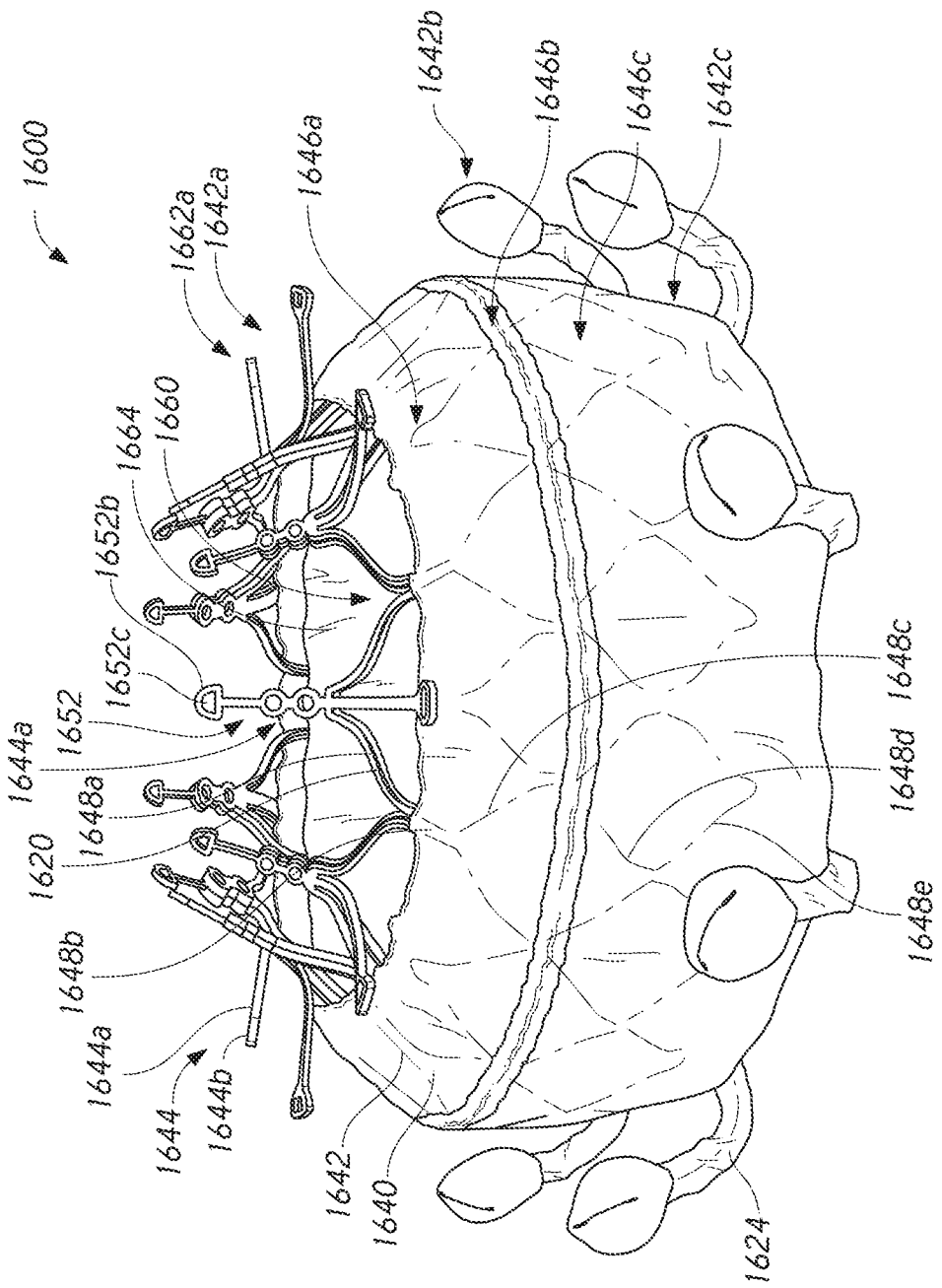

1600
1662a
1642a
1646a
1642b
1646b
1646c
1642c
1660
1664
1652b
1652c
1652
1644a
1620
1648a
1648b
1644a
1644
1644b
1642
1640
1624
1648c
1648d
1648e

FIG. 34

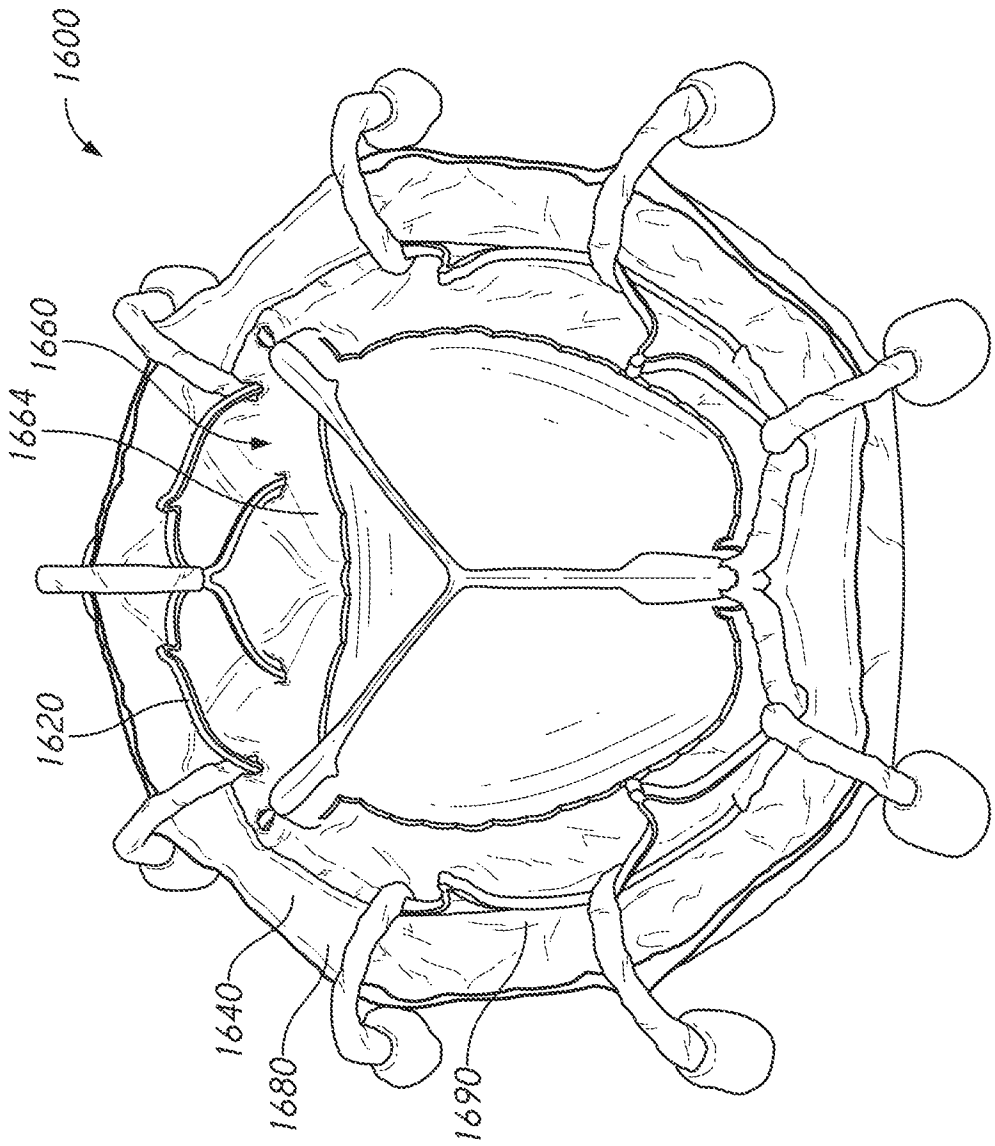


FIG. 35

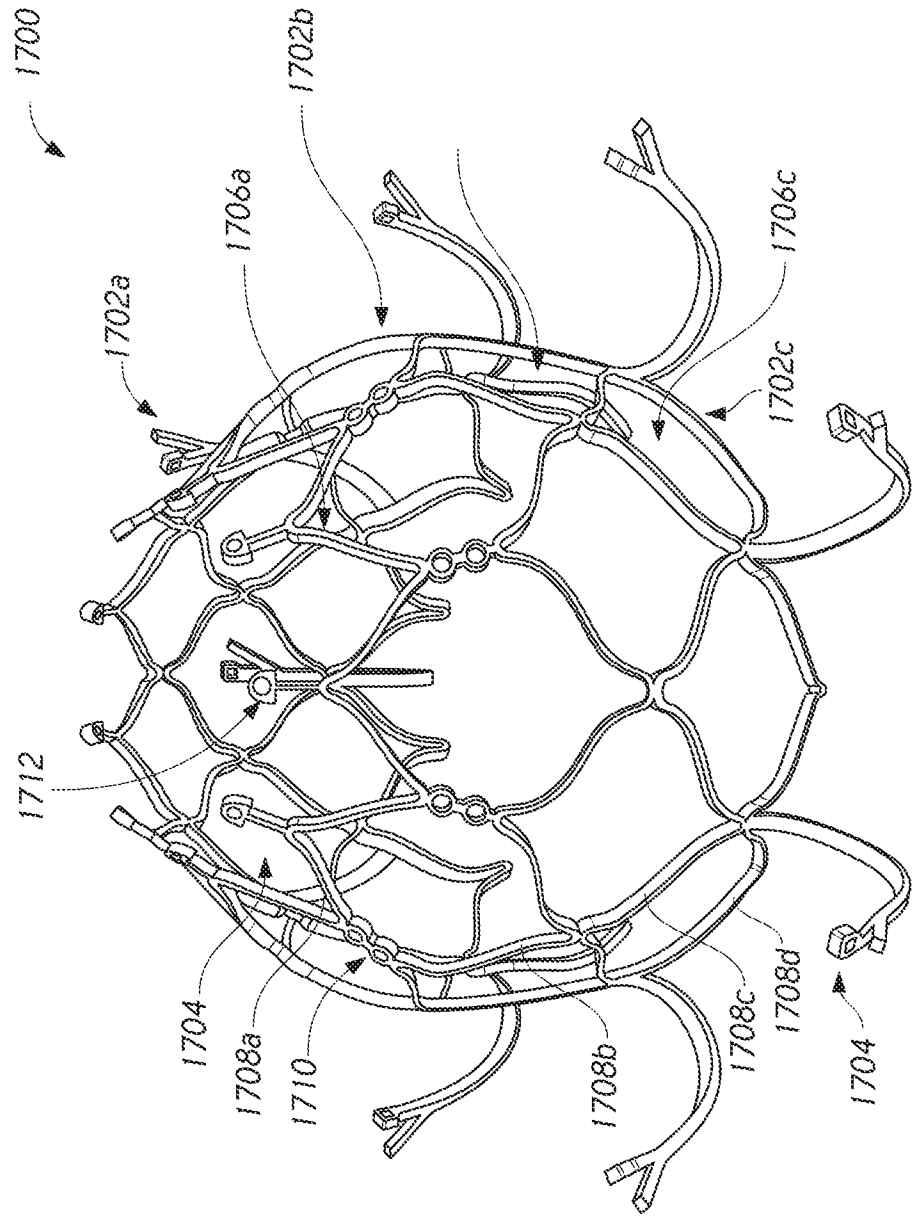

1700
1702b
1706a
1702a
1706c
1702c
1712
1704
1708a
1710
1708b
1708c
1708d
1704

FIG. 36

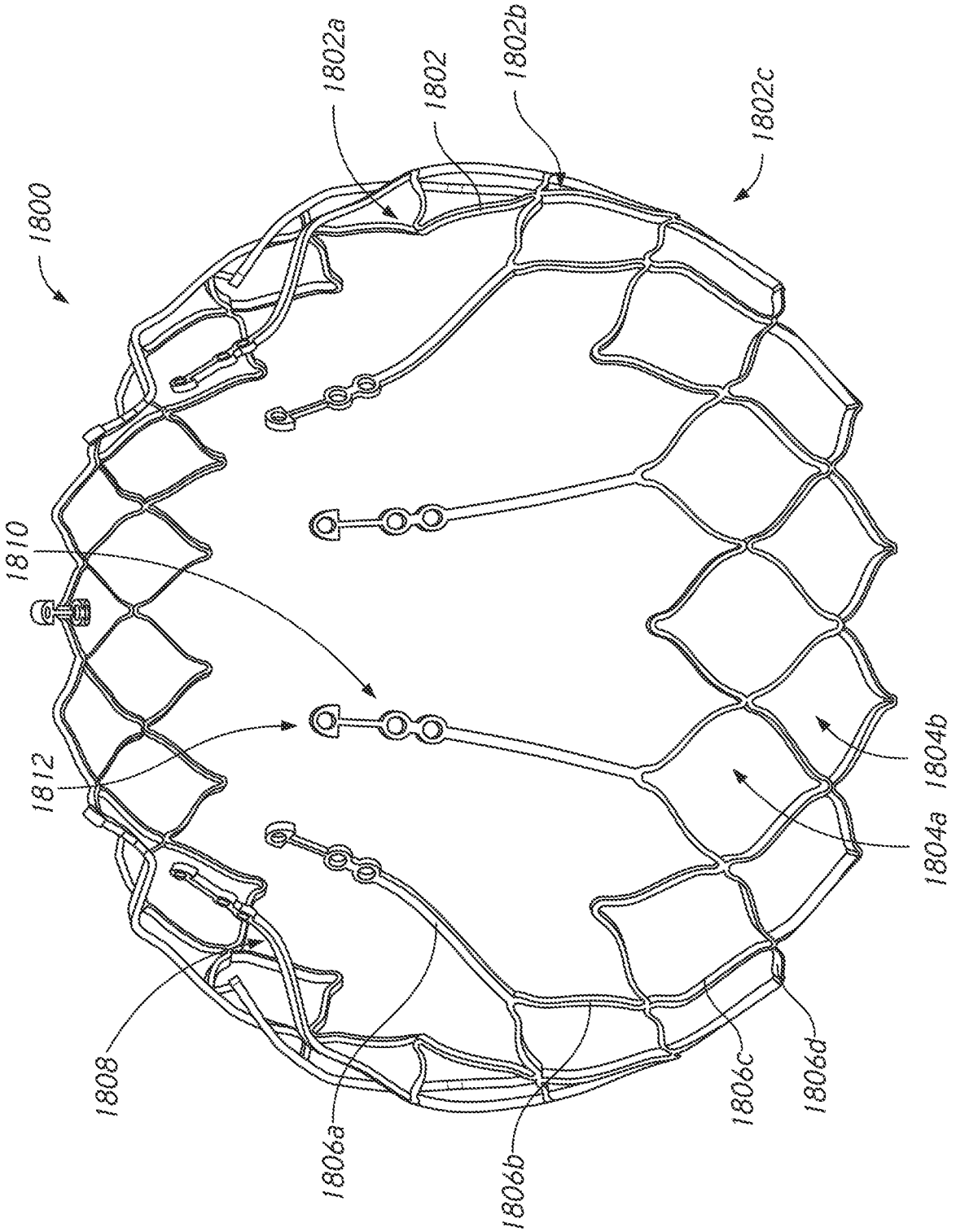

1800
1802a
1802
1802b
1802c
1810
1812
1808
1806a
1806b
1806c
1806d
1804a
1804b

FIG. 37

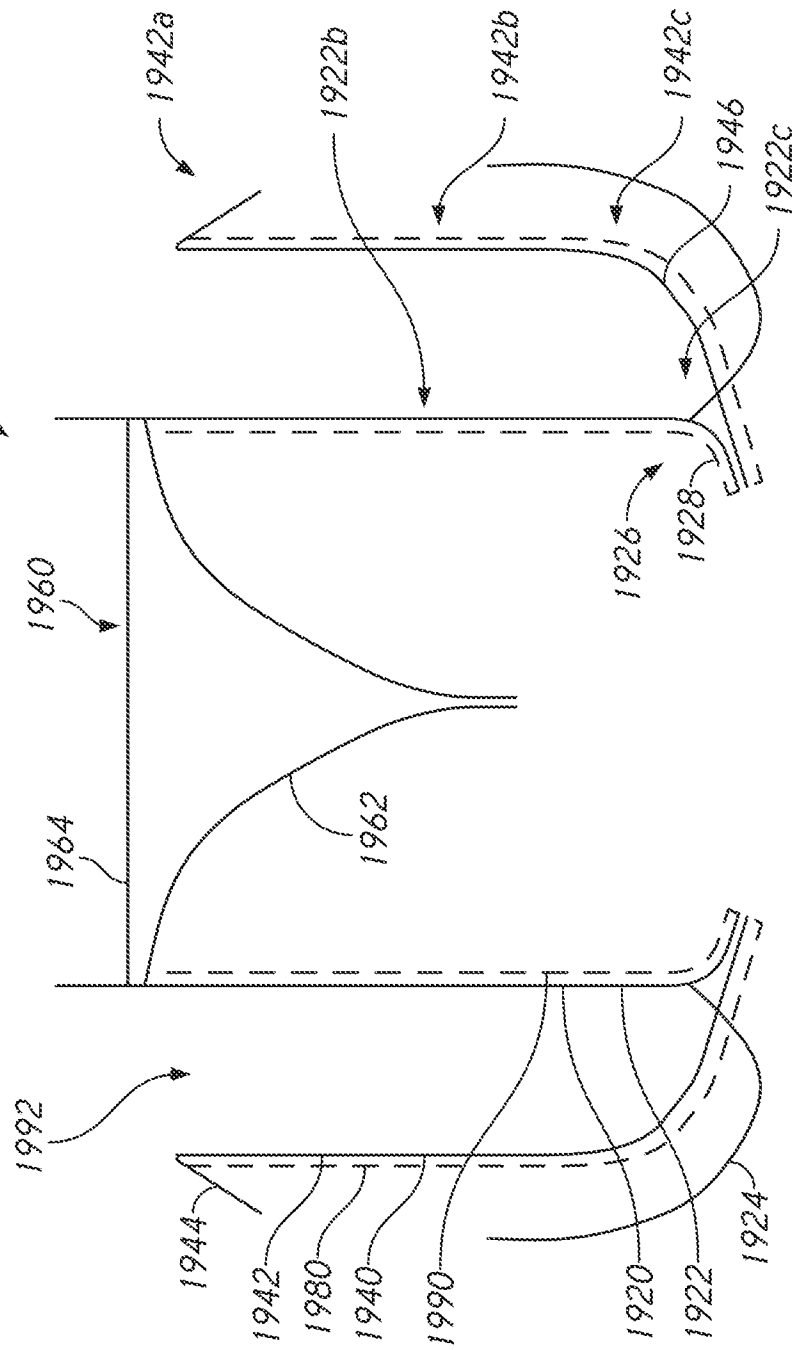

1900
1960
1964
1962
1992
1942a
1922b
1942b
1942c
1946
1922c
1926
1928
1944
1942
1980
1940
1990
1920
1922
1924

FIG. 38A

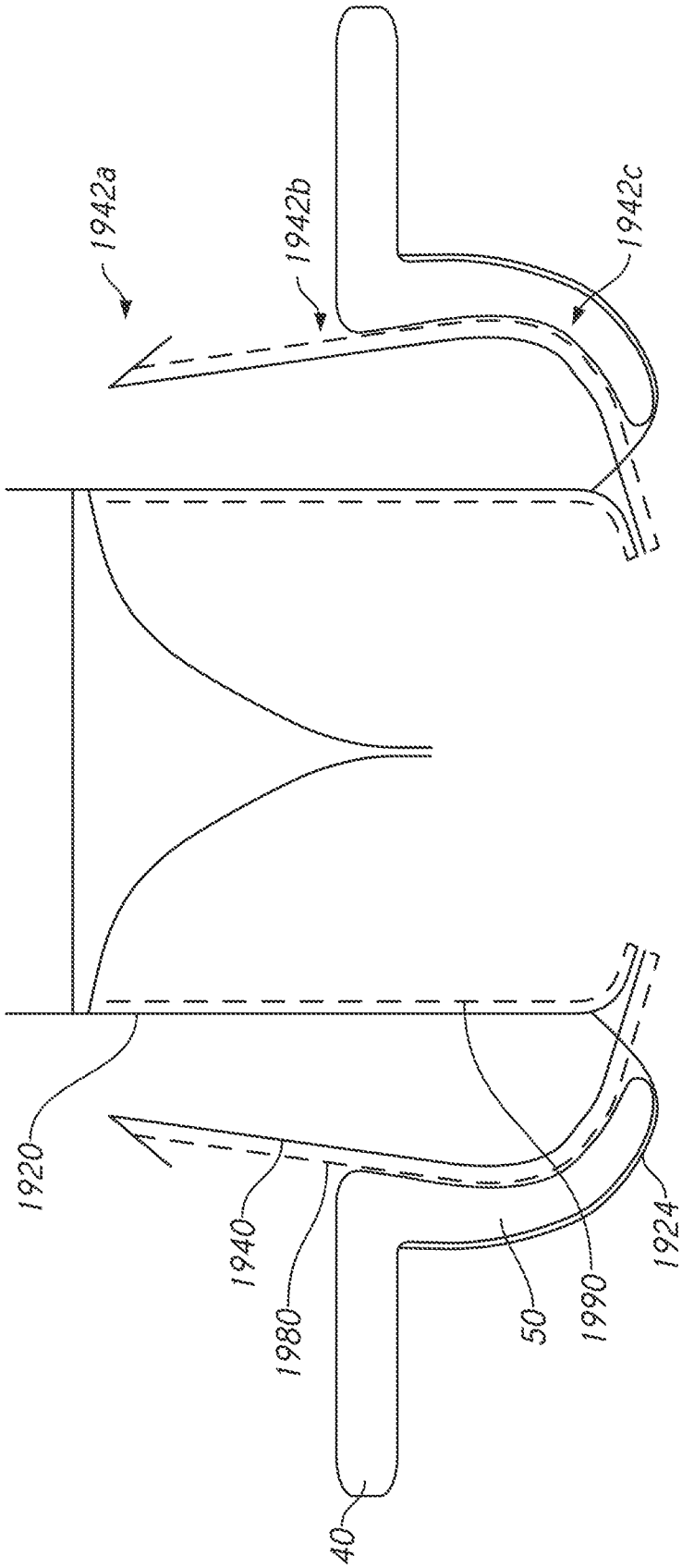


FIG. 38B

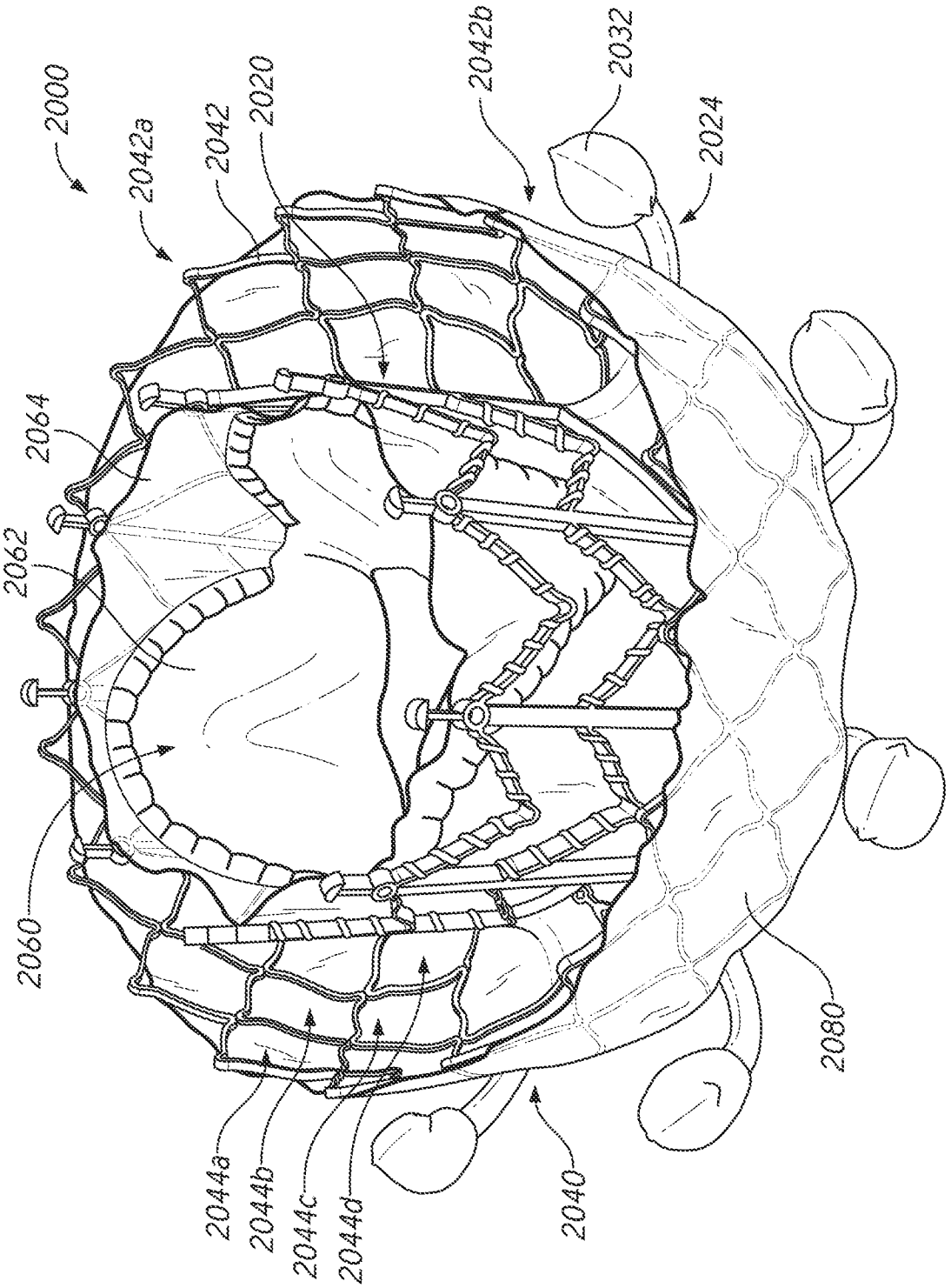

2000
2042a
2042
2020
2042b
2032
2024
2064
2062
2060
2044a
2044b
2044c
2044d
2040
2080

FIG. 39

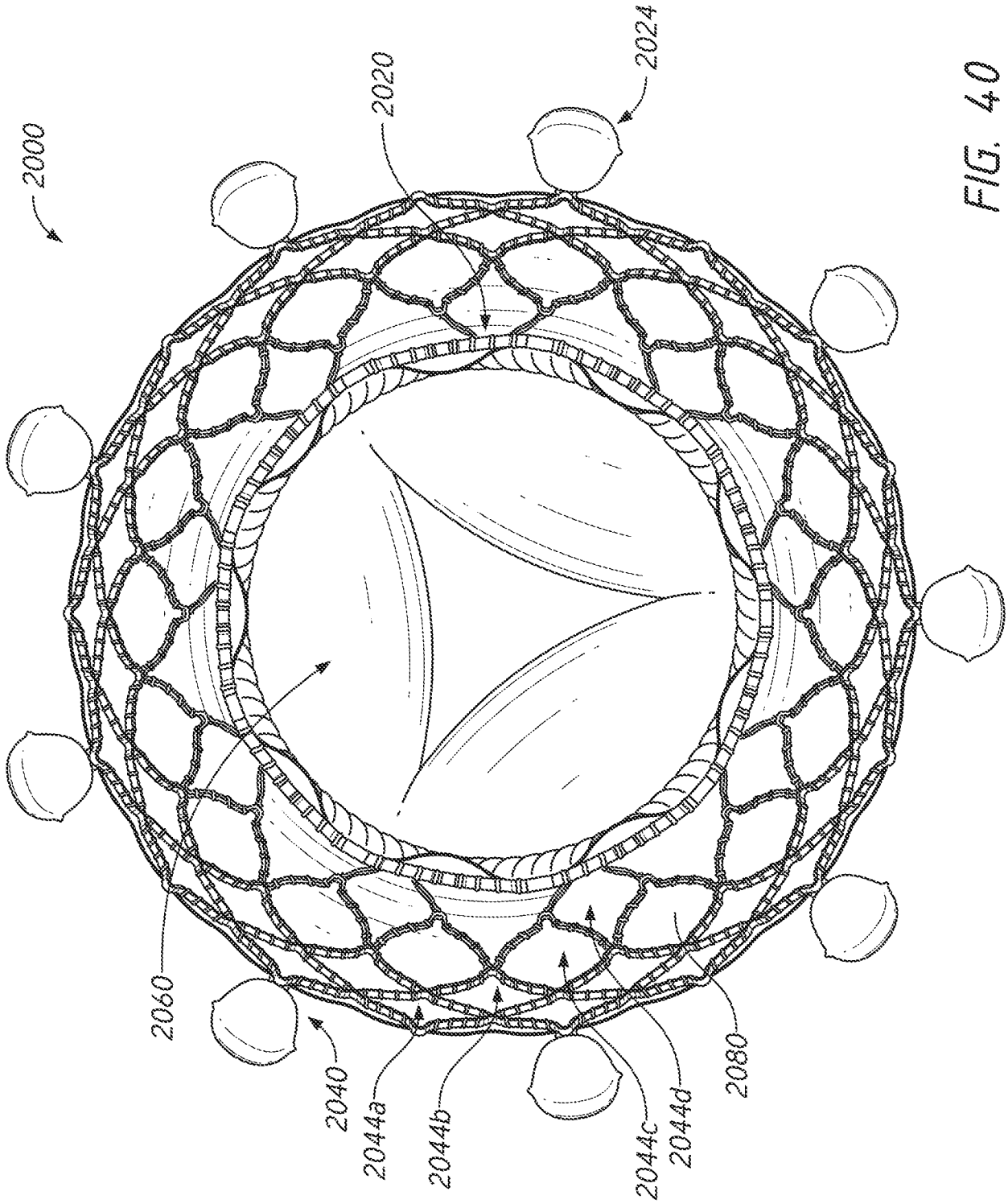


FIG. 40

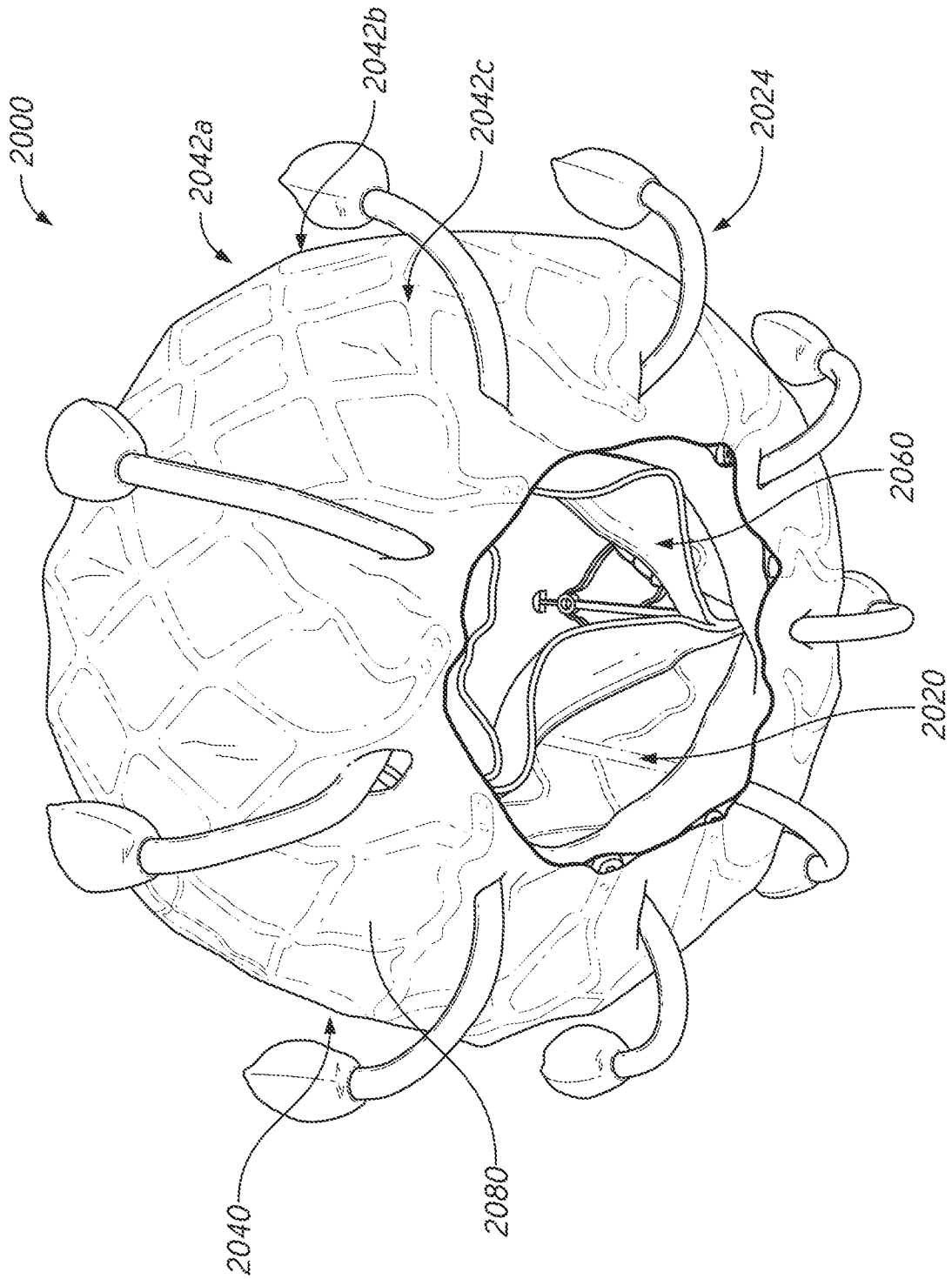


FIG. 41

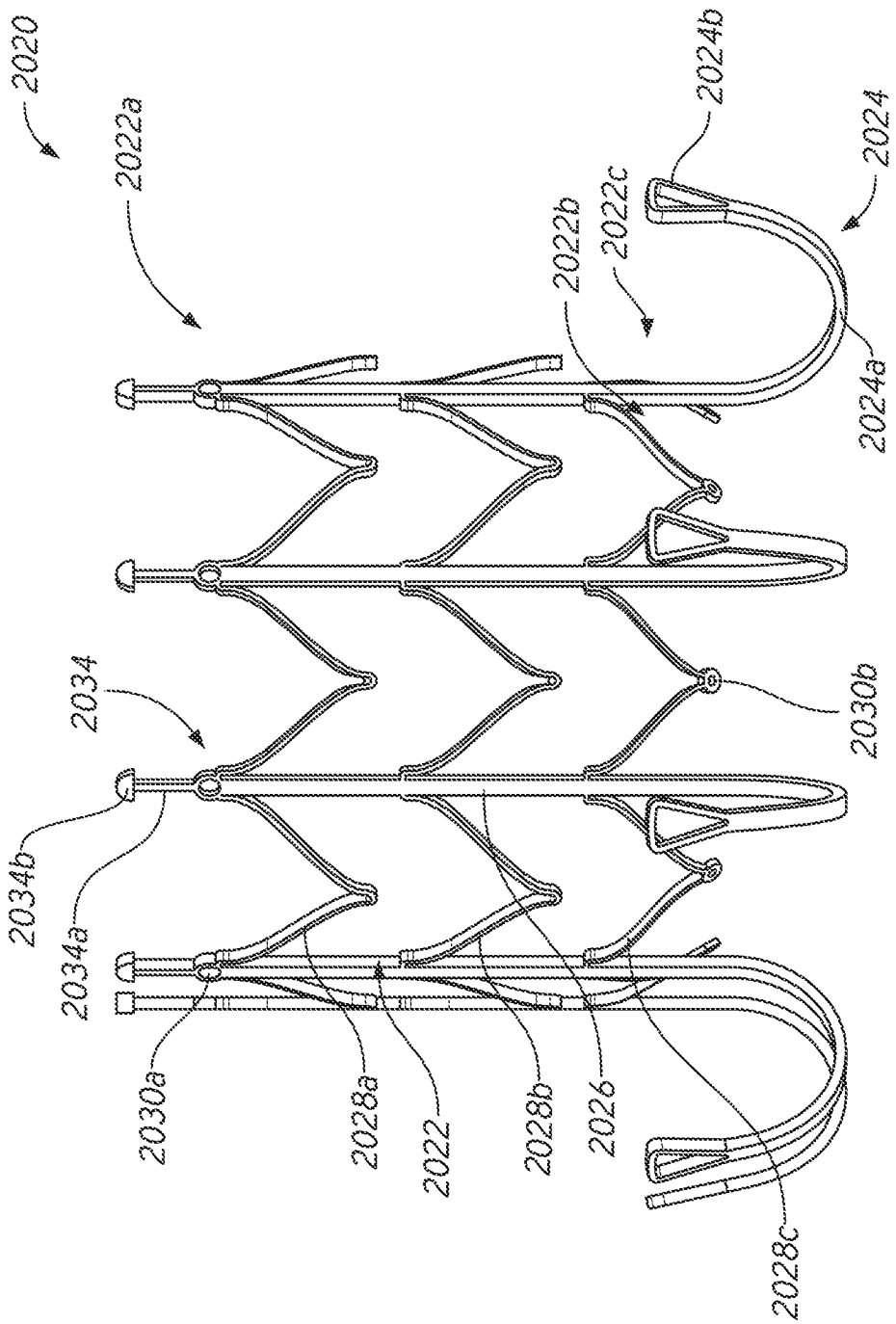

2020
2022a
2024b
2024
2022c
2022b
2024a
2034
2030b
2034b
2034a
2030a
2028a
2022
2028b
2026
2028c

FIG. 42

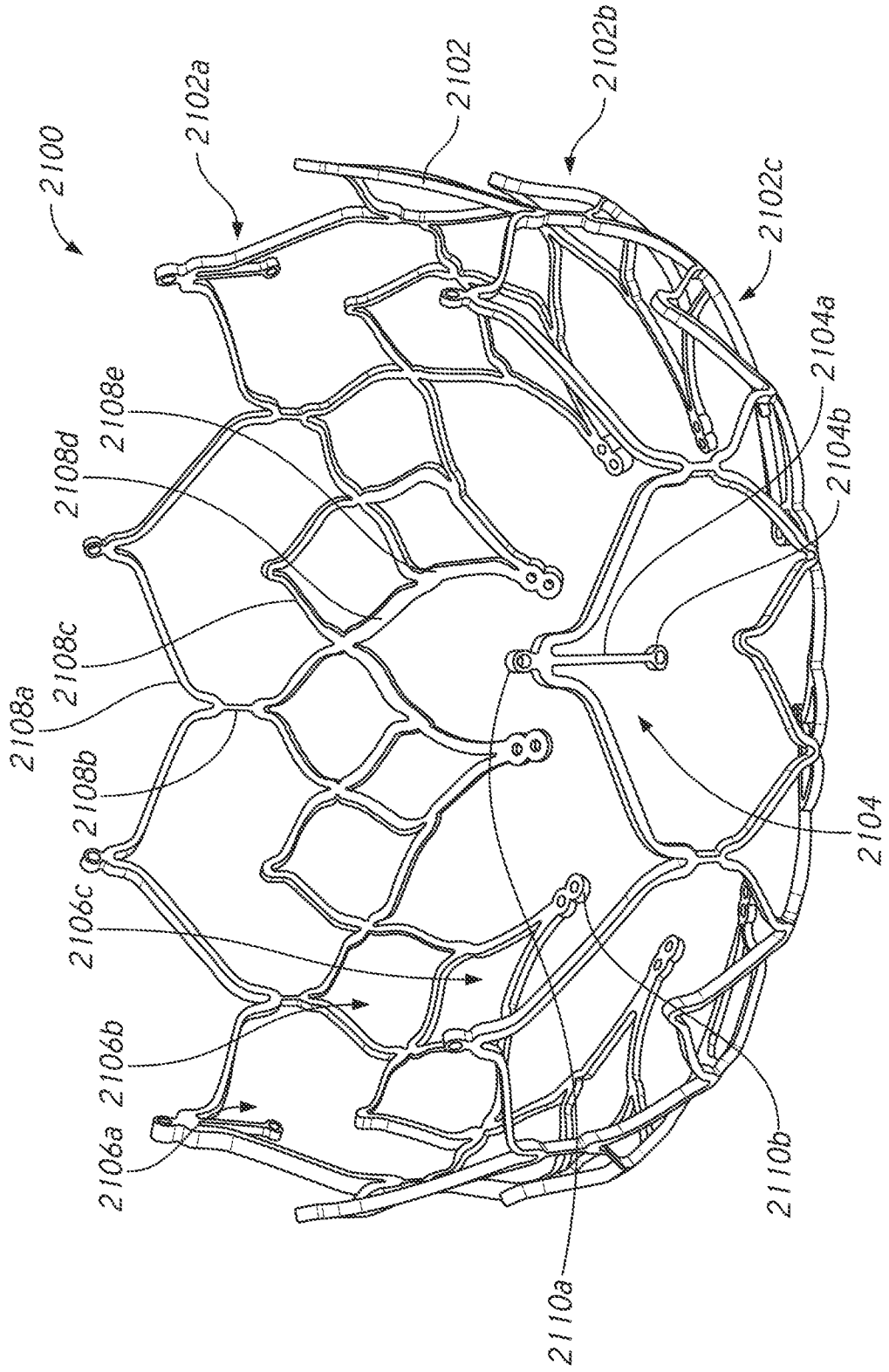

2100
2102a
2102
2102b
2102c
2104a
2104b
2104
2108e
2108d
2108c
2108b
2108a
2106c
2106b
2106a
2110a
2110b

FIG. 43

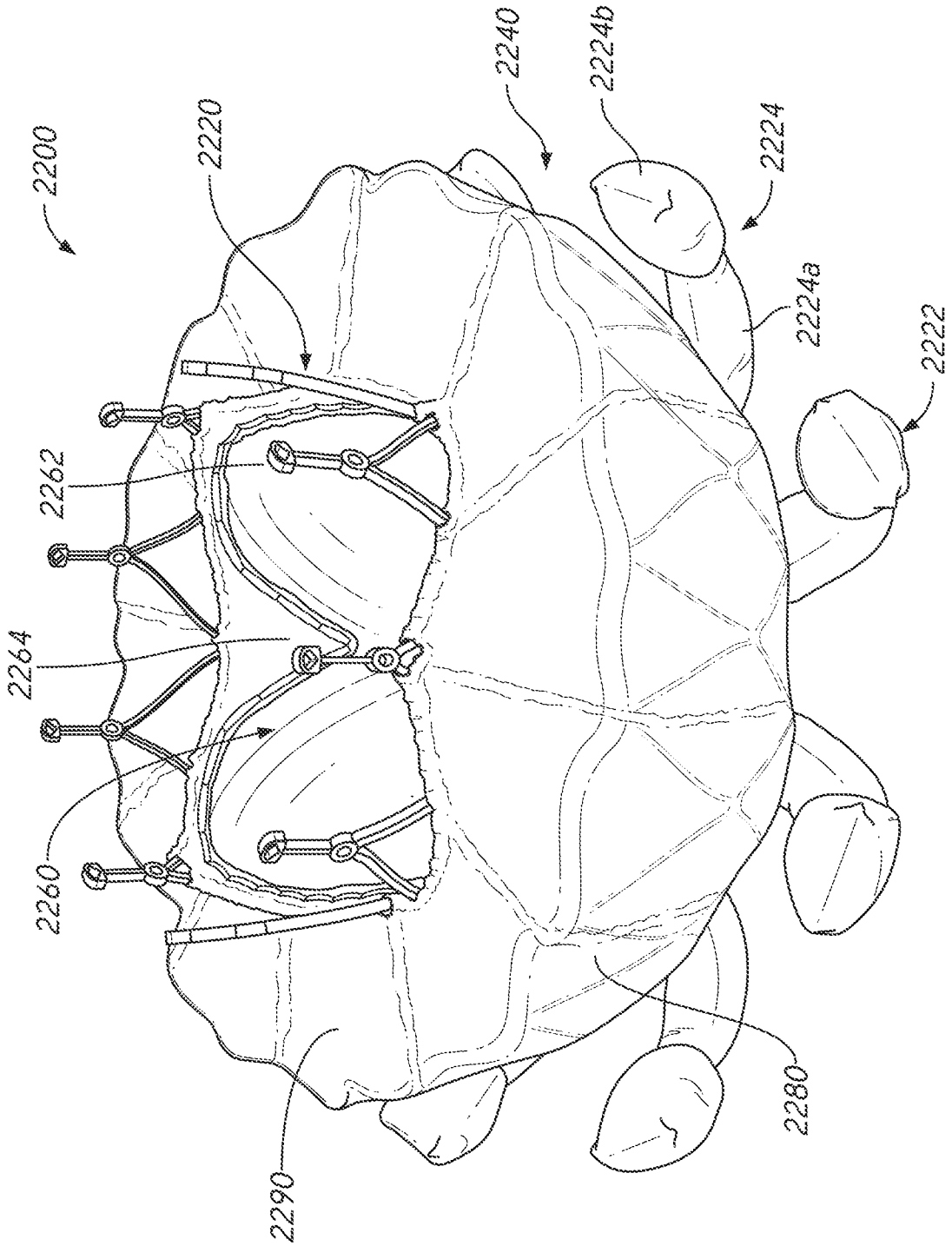

2200
2220
2240
2224b
2224
2224a
2222
2262
2264
2260
2290
2280

FIG. 44

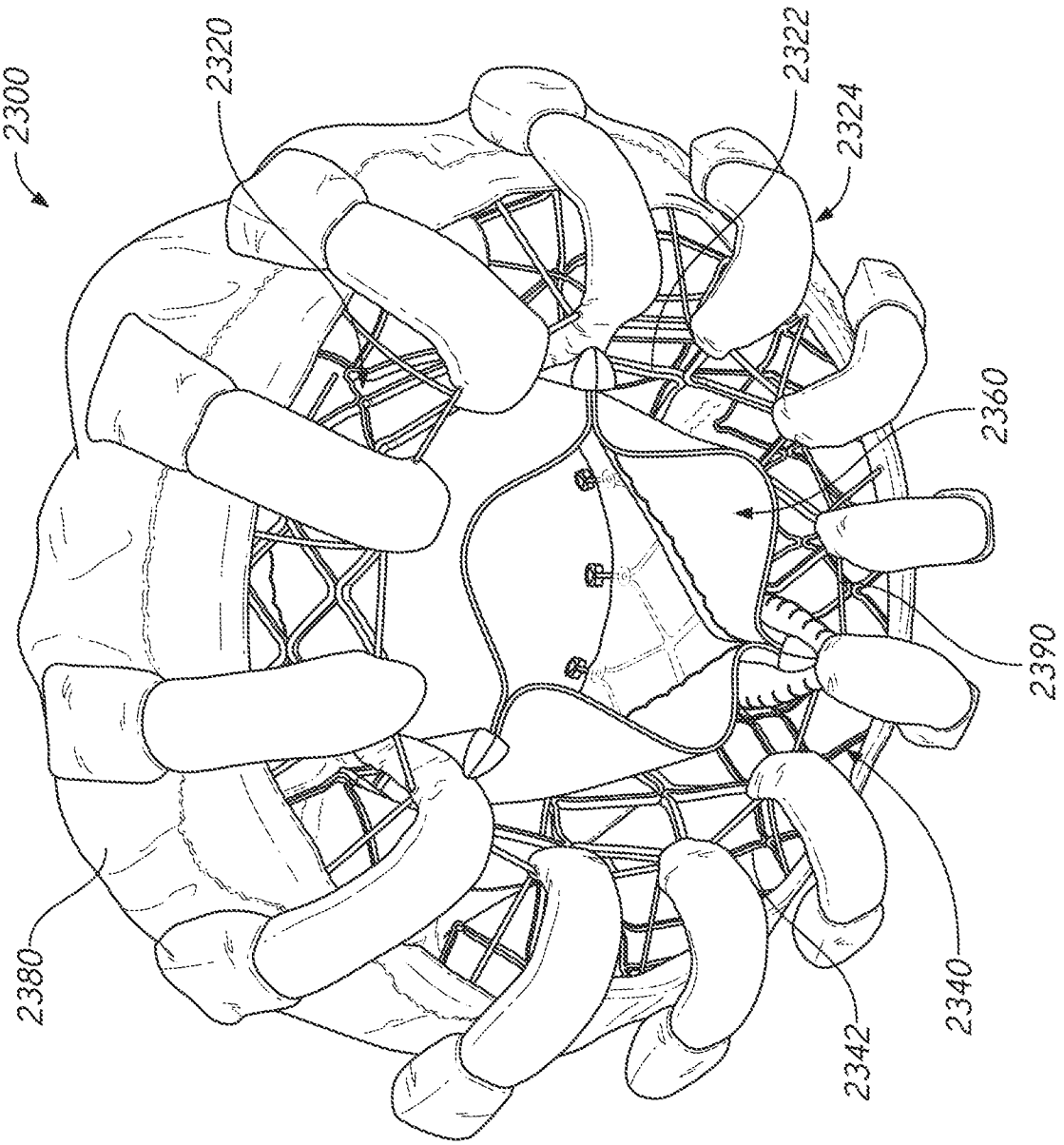


FIG. 45

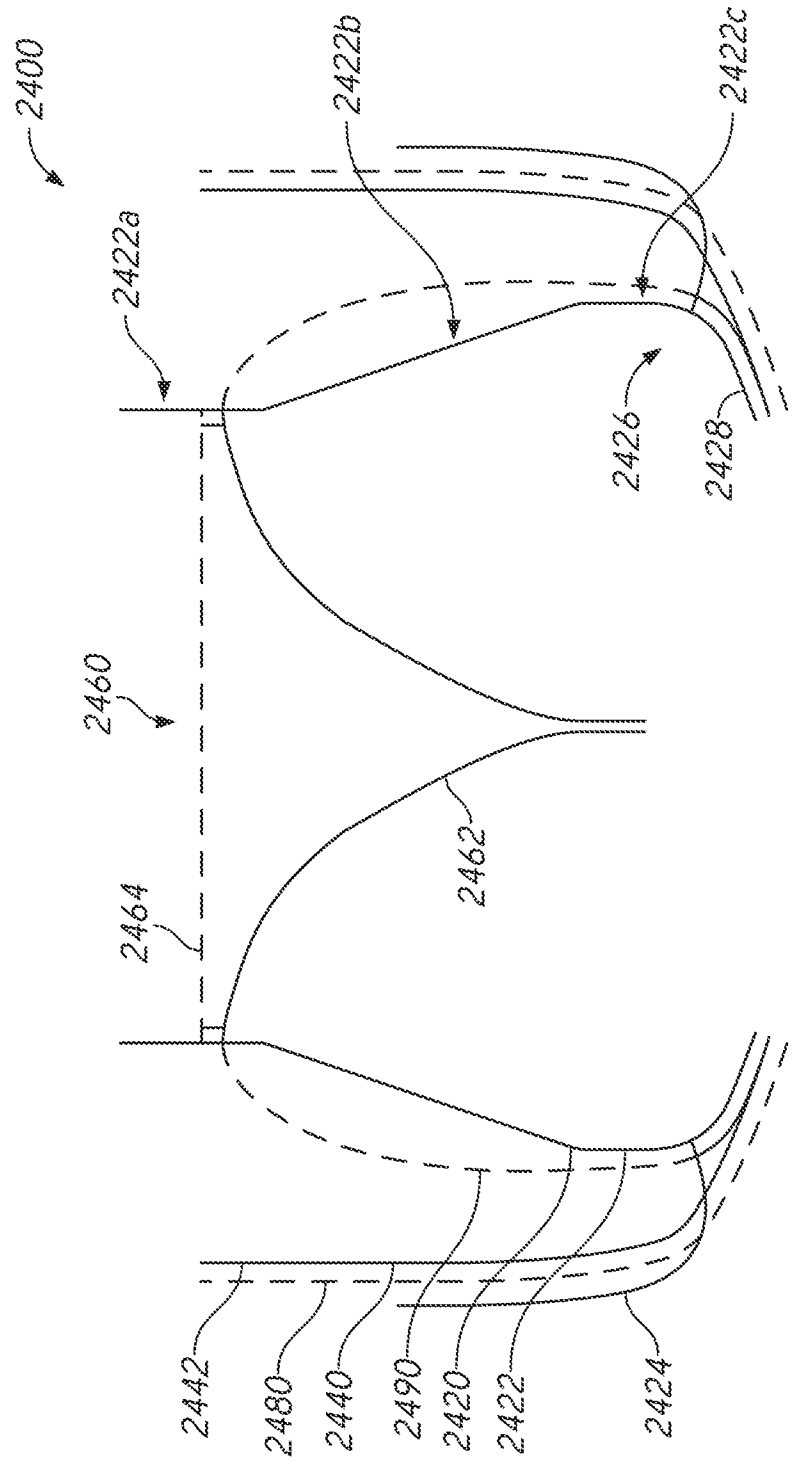

2400
2422a
2422b
2422c
2426
2428
2460
2462
2464
2442
2480
2440
2490
2420
2422
2424

FIG. 46

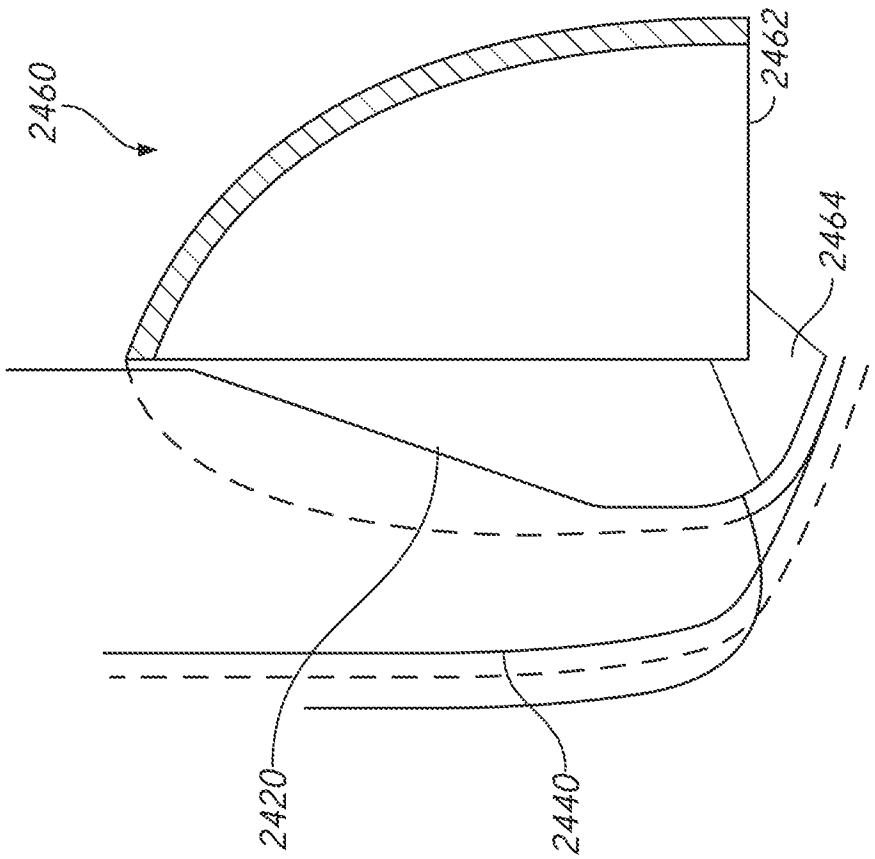


FIG. 47

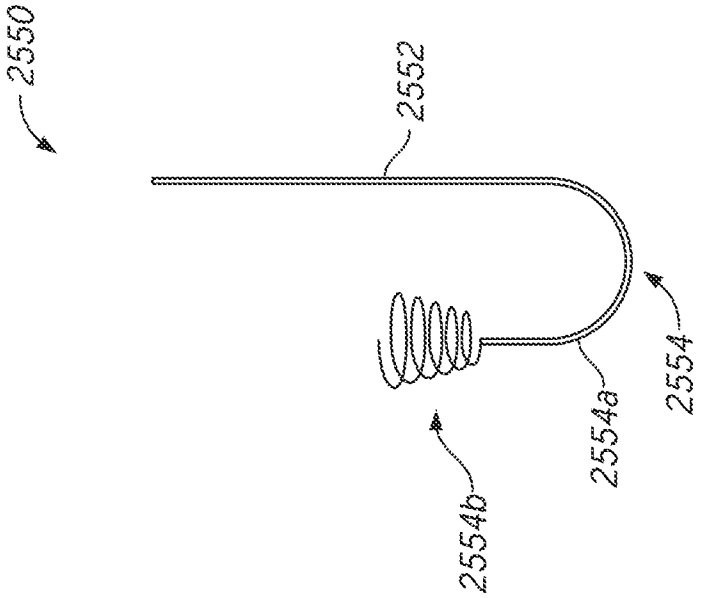


FIG. 49

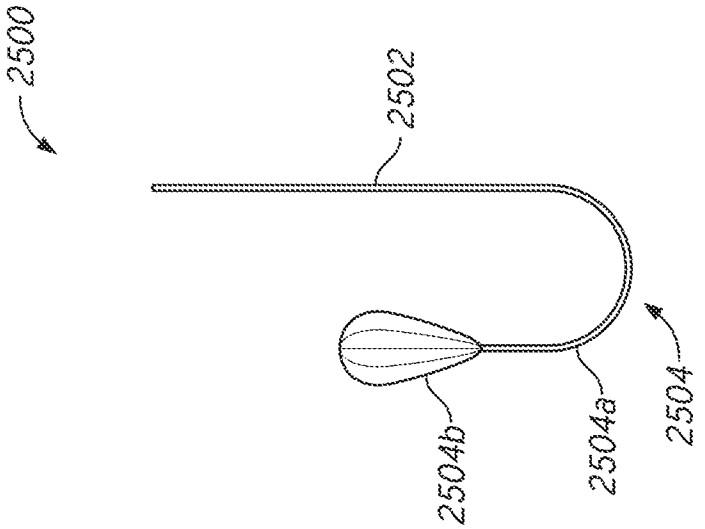


FIG. 48

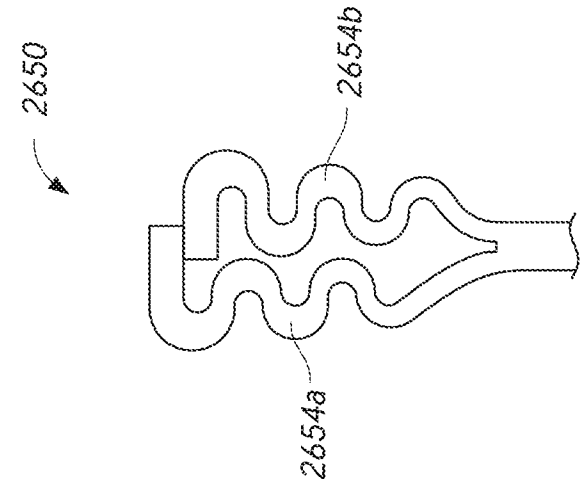


FIG. 51

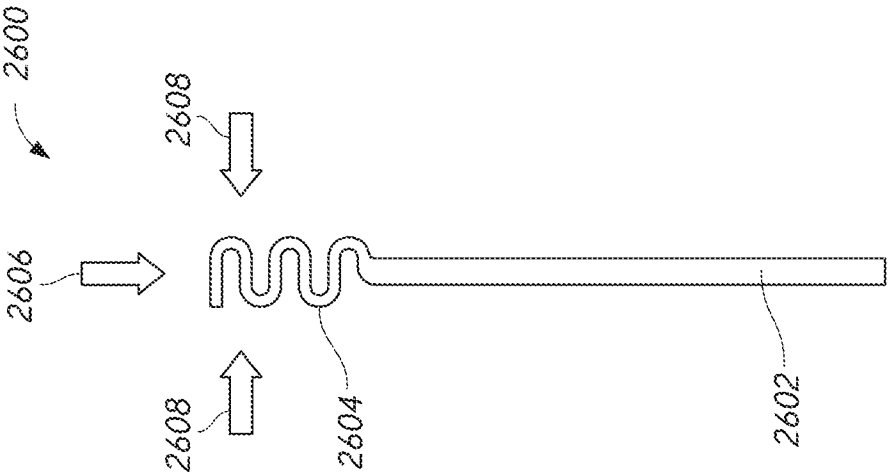


FIG. 50

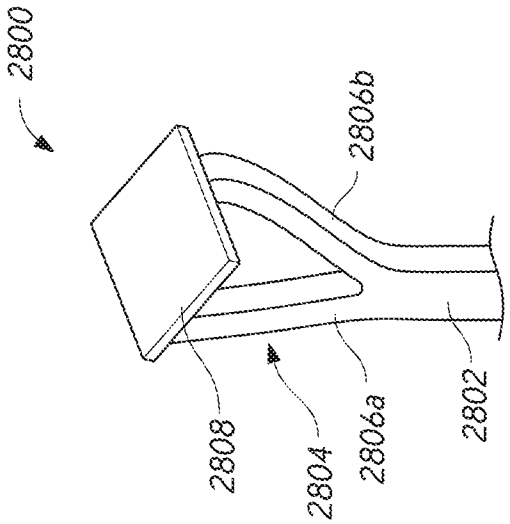

2800
2806b
2808
2804
2806a
2802

FIG. 53

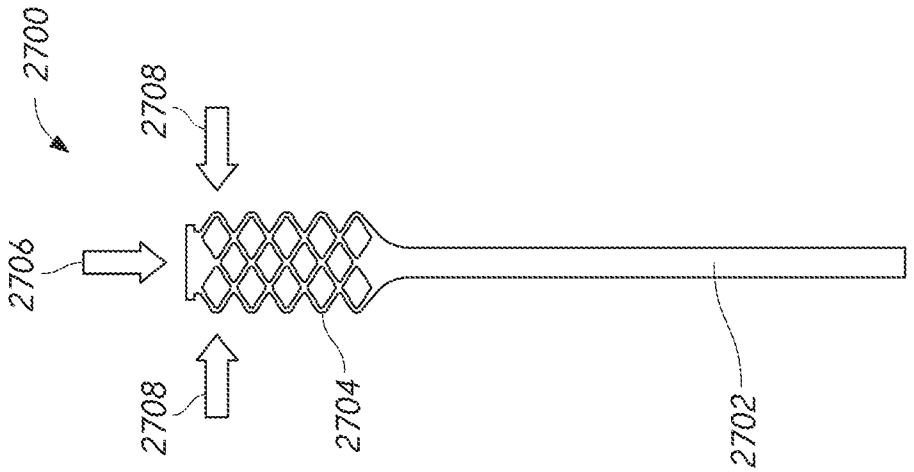
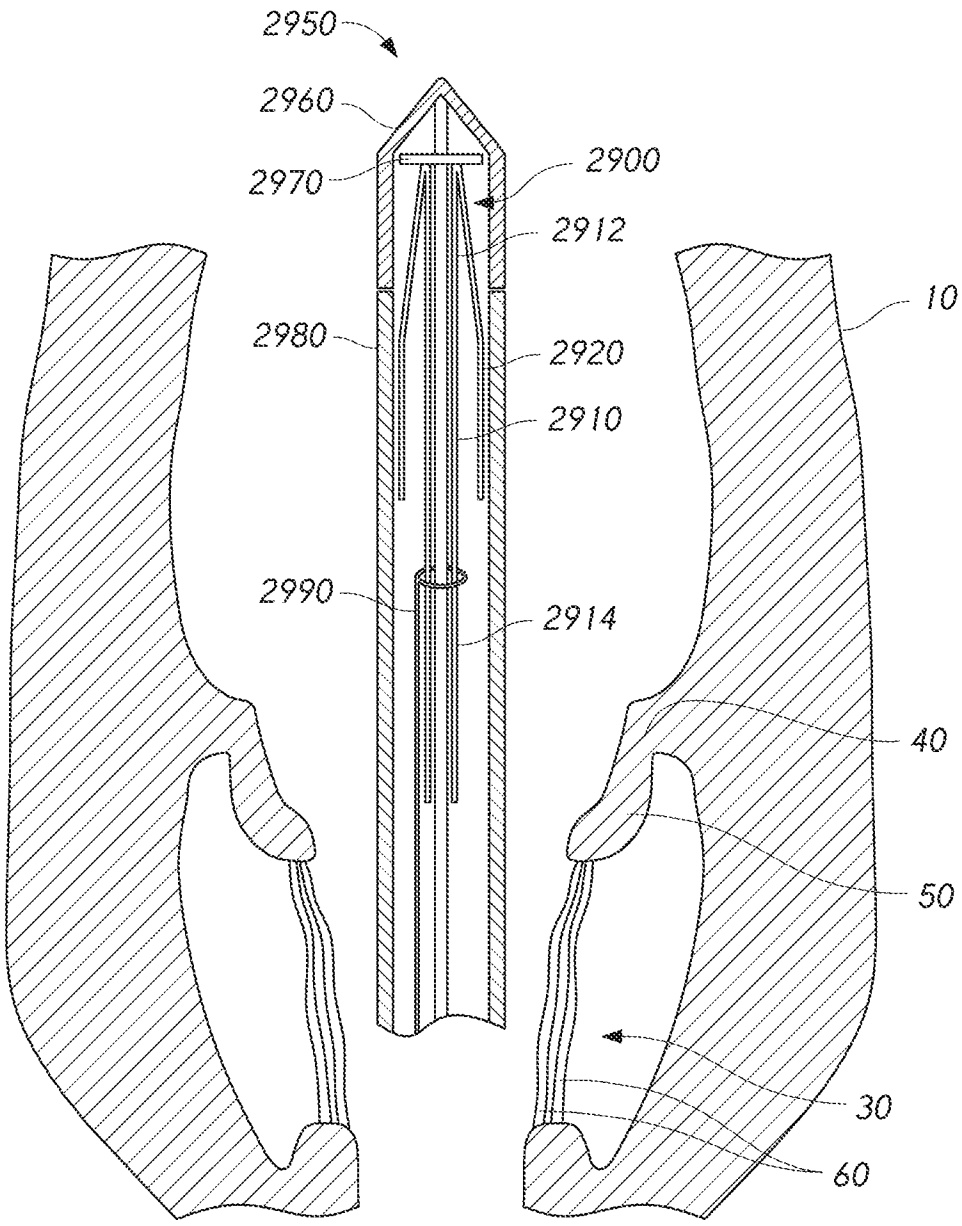

2700
2708
2706
2708
2704
2702

FIG. 52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2960
2970
2900
2912
10
2980
2920
2910
2990
2914
40
50
30
60

FIG. 54A

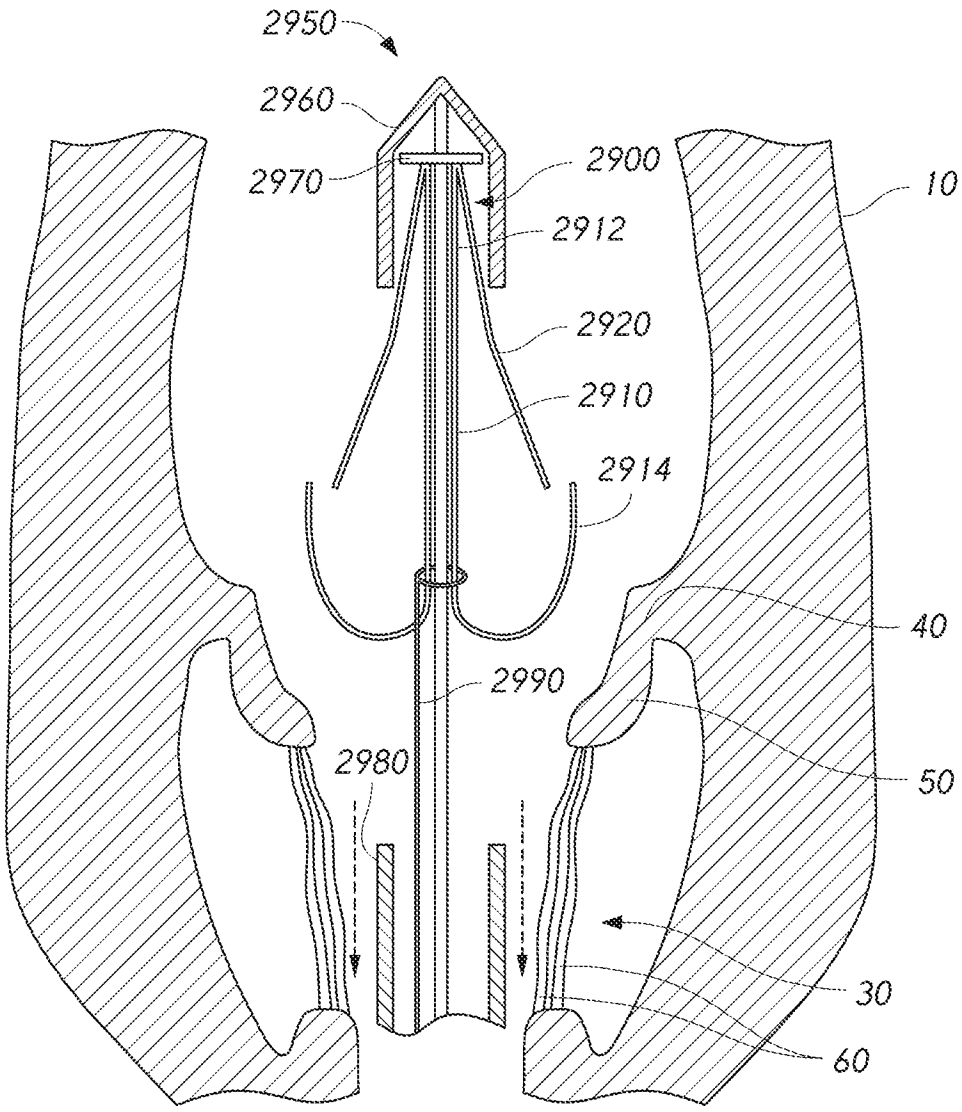
2950
2960
2970
2900
2912
2920
2910
2914
10
40
2990
2980
50
30
60

FIG. 54B

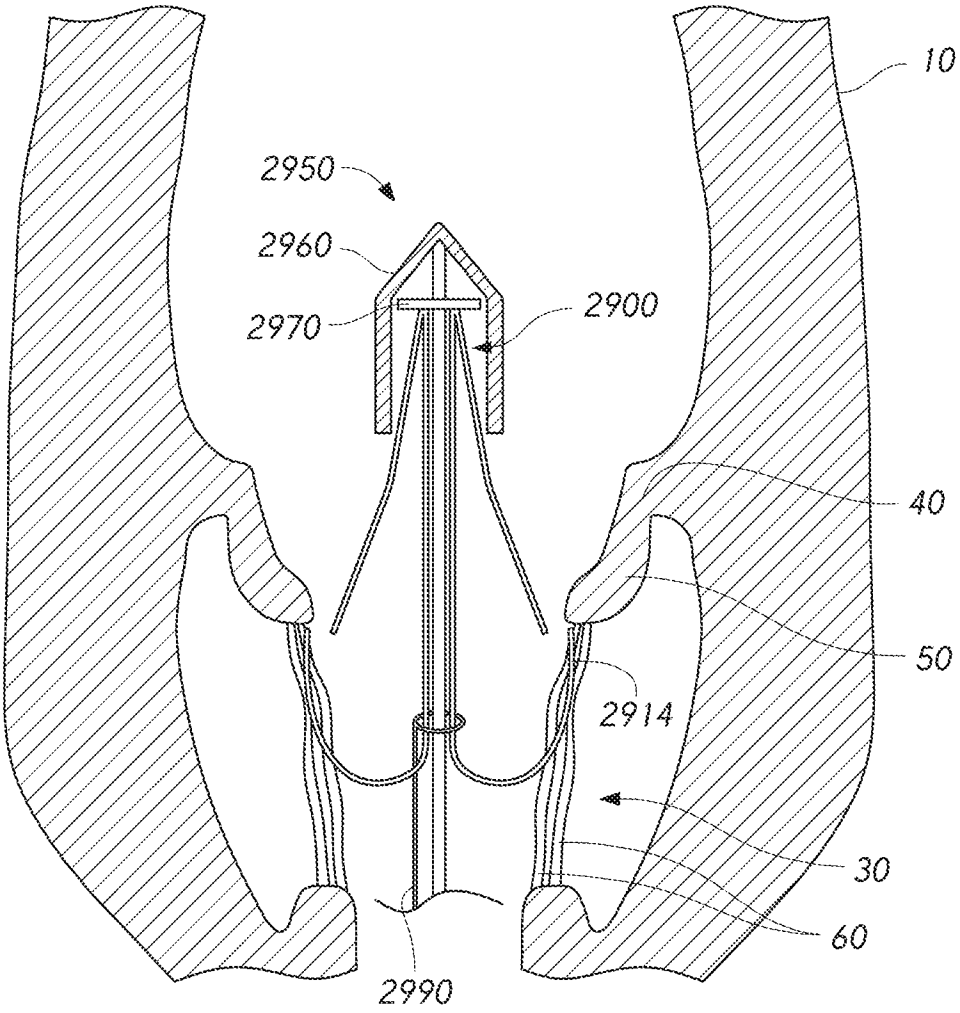

FIG. 54C

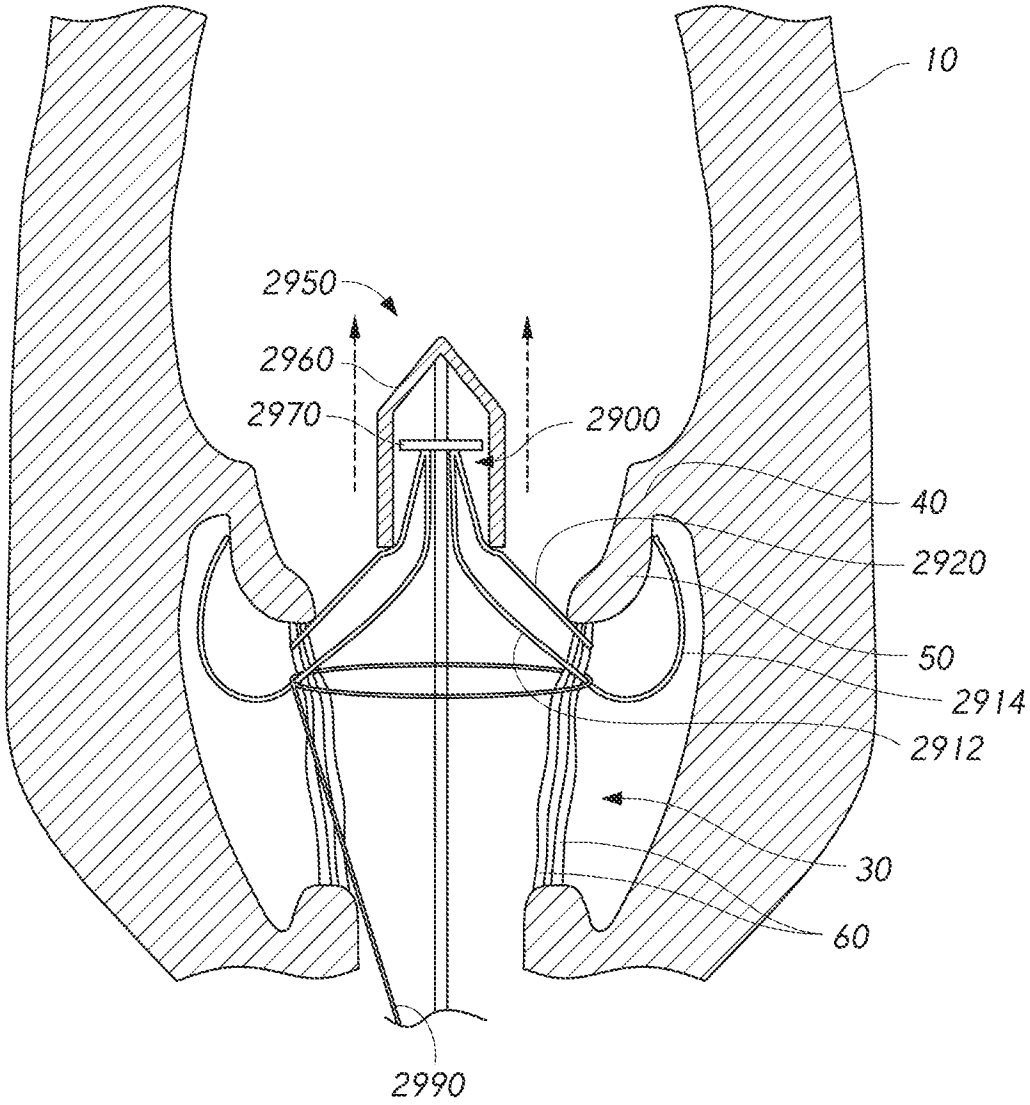

FIG. 54D

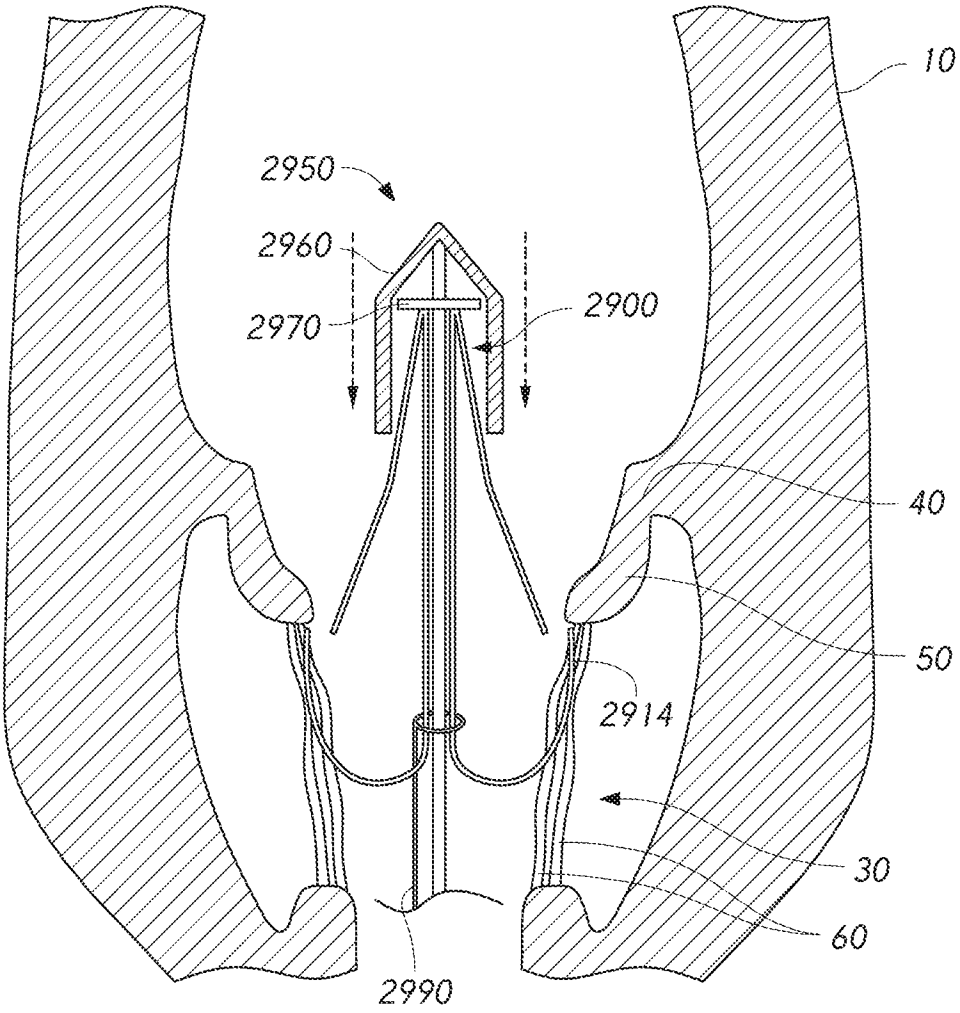

FIG. 54E

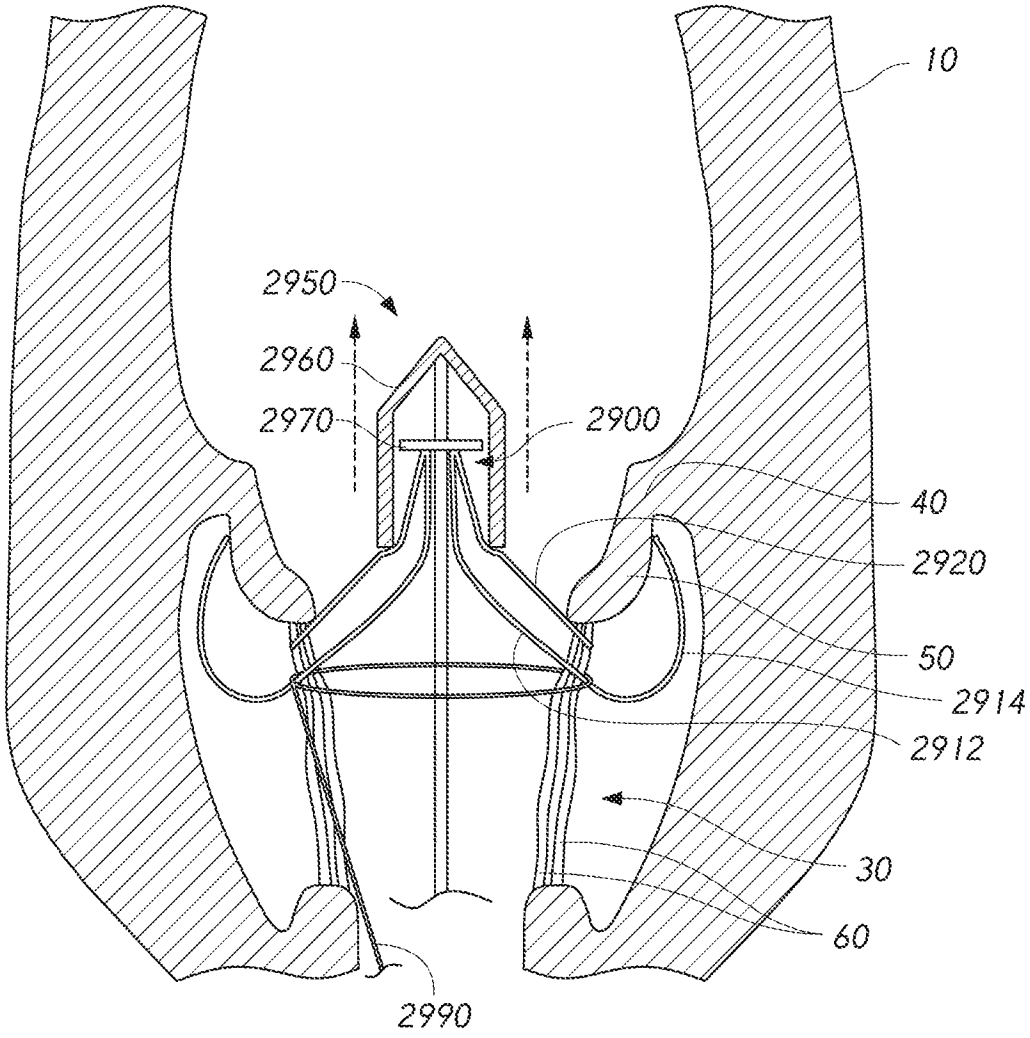

FIG. 54F

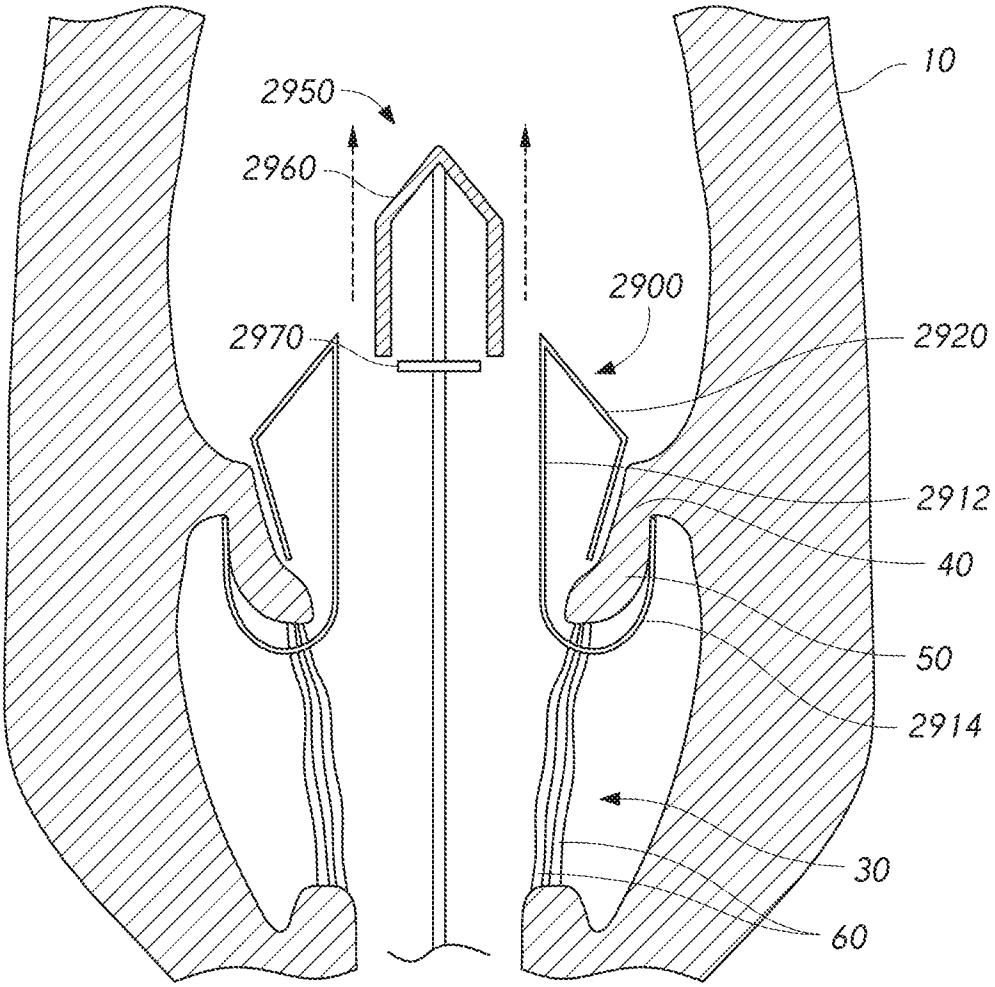

FIG. 54G

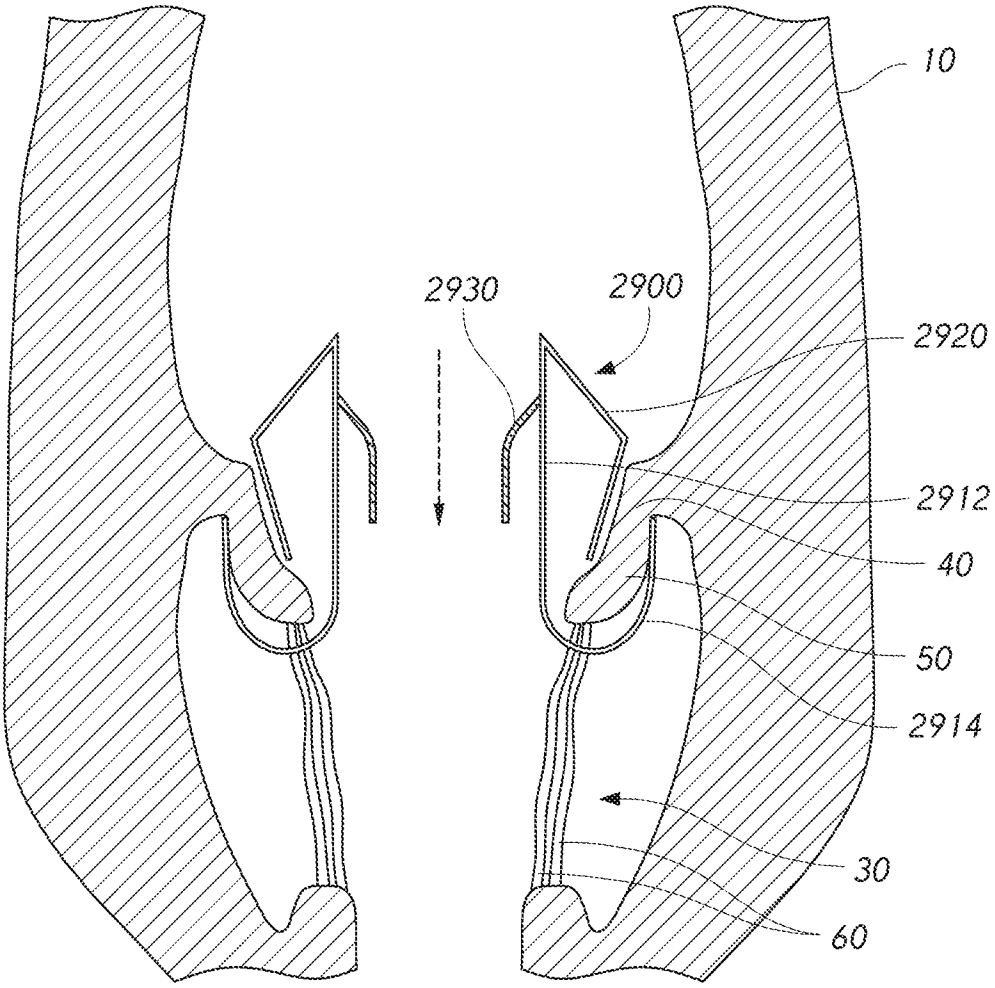

FIG. 54H

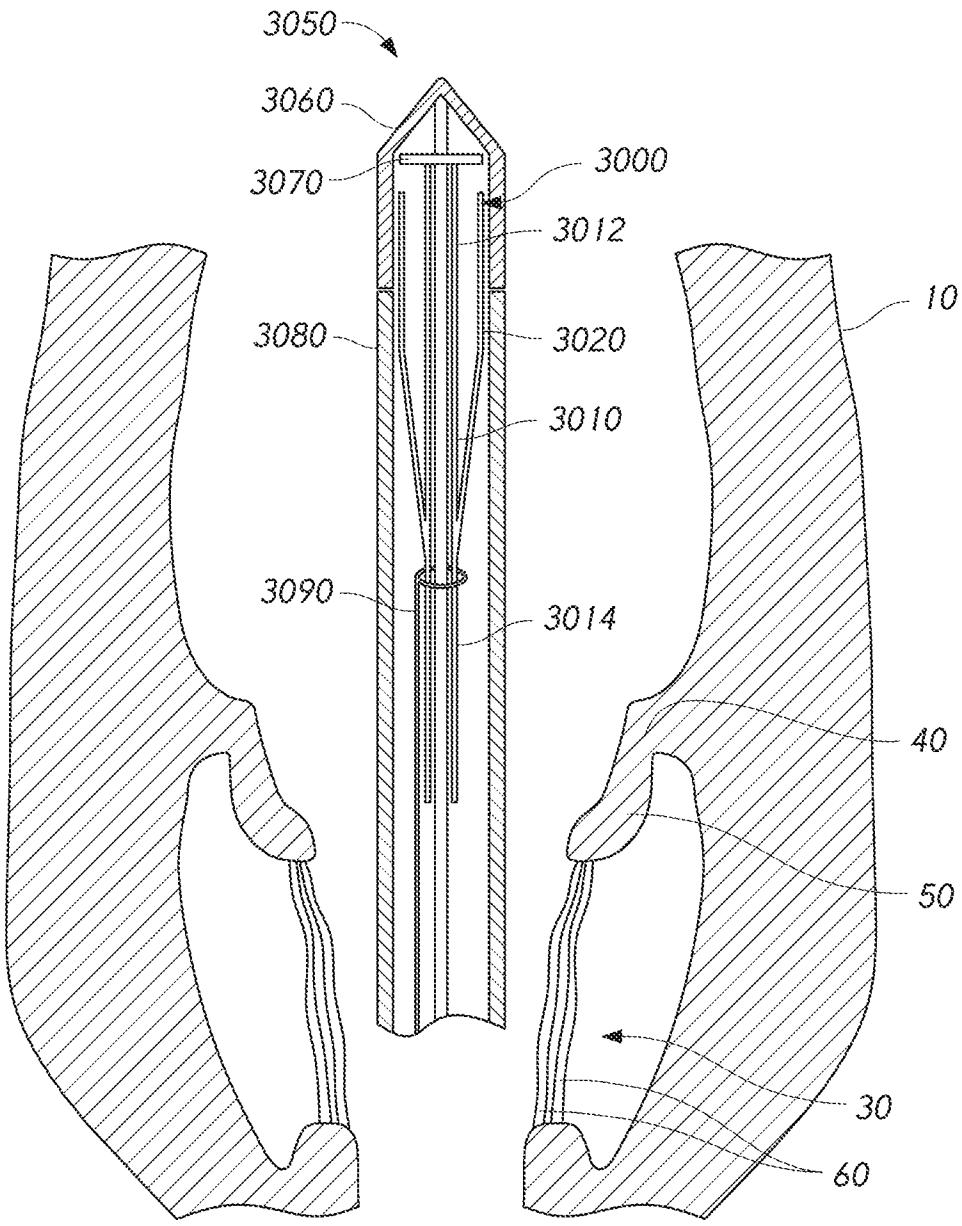
3050
3060
3070
3000
3012
3080
3020
3010
3090
3014
10
40
50
30
60

FIG. 55A

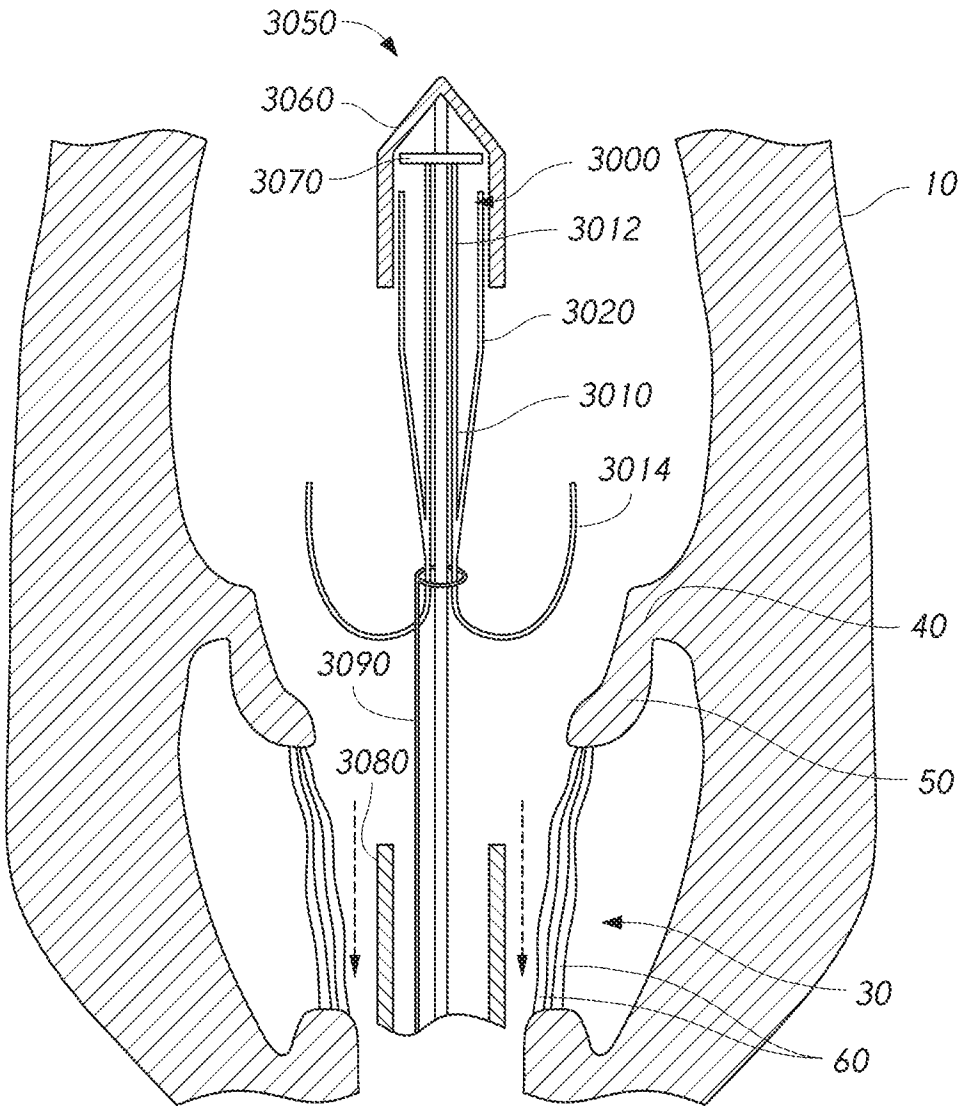
3050
3060
3070
3000
3012
3020
3010
3014
10
40
3090
3080
50
30
60

FIG. 55B

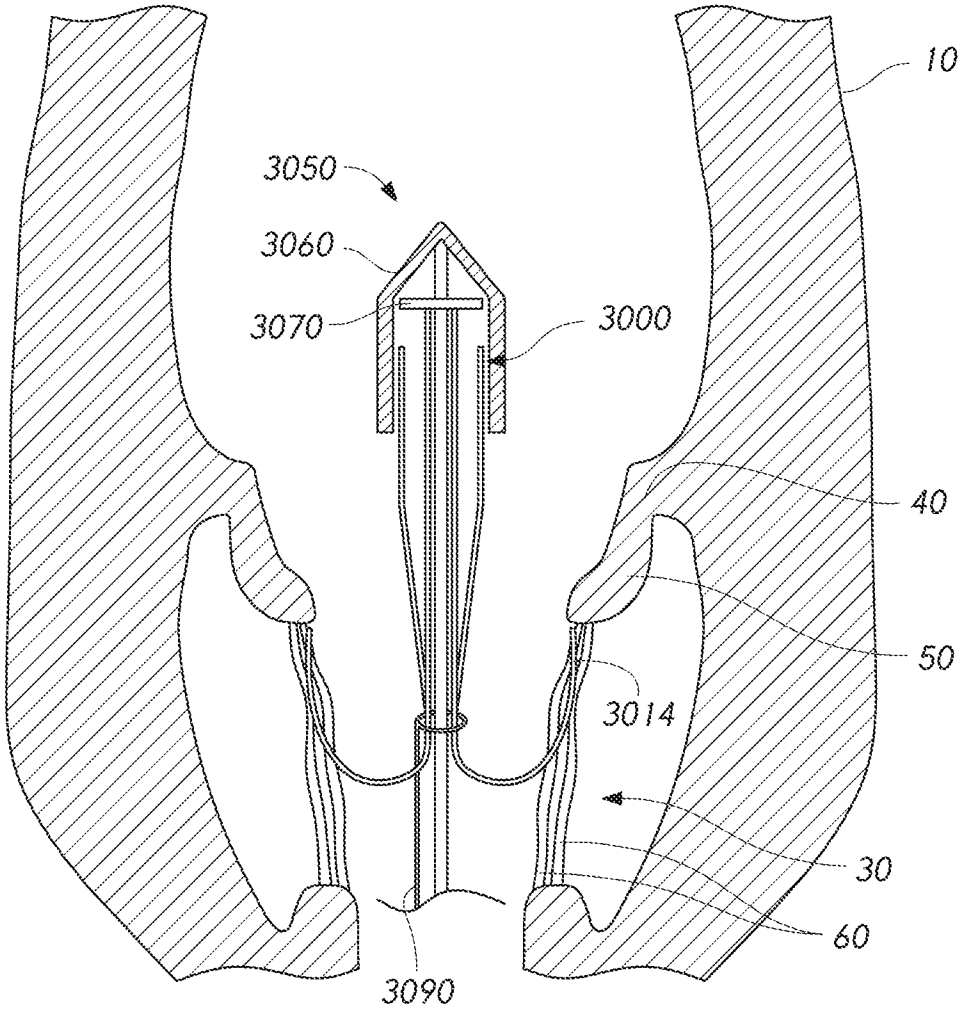

FIG. 55C

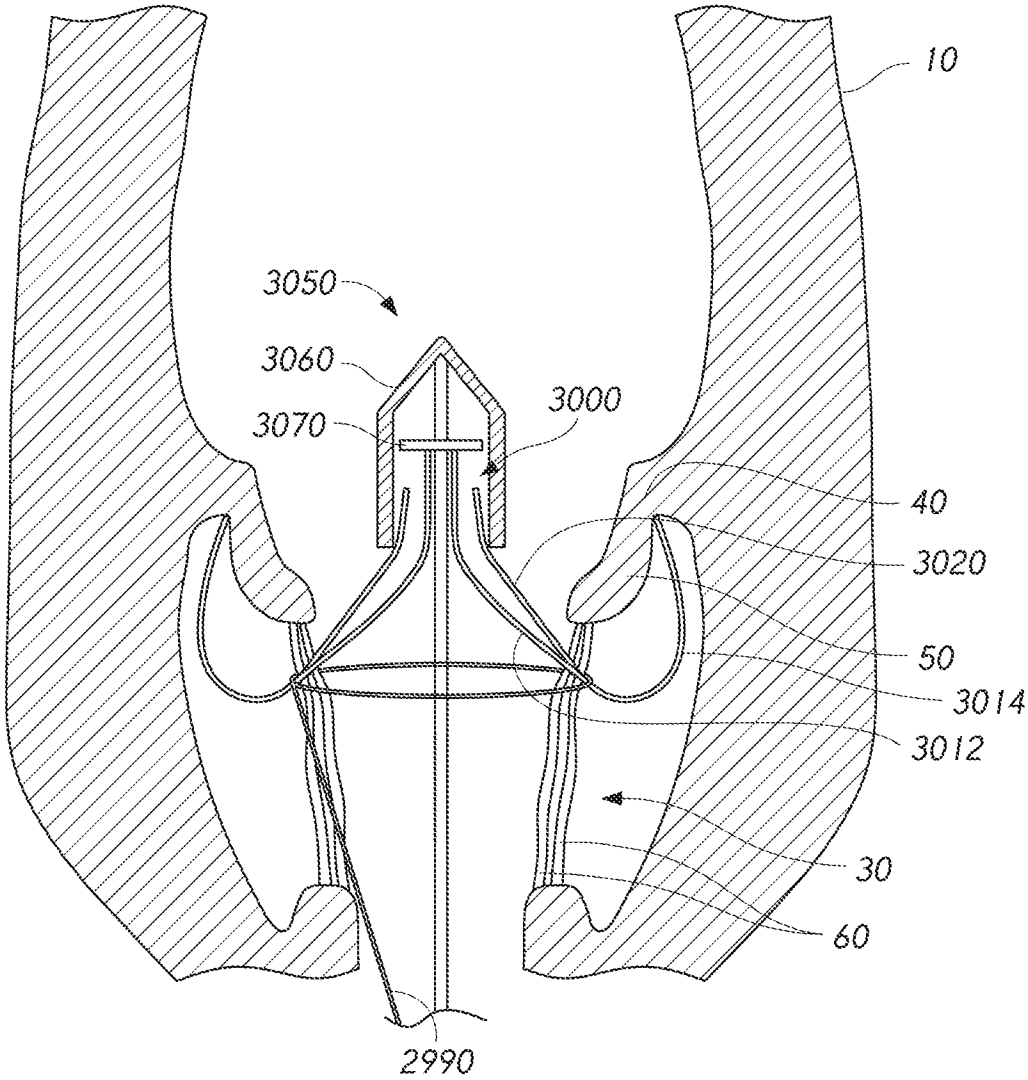

FIG. 55D

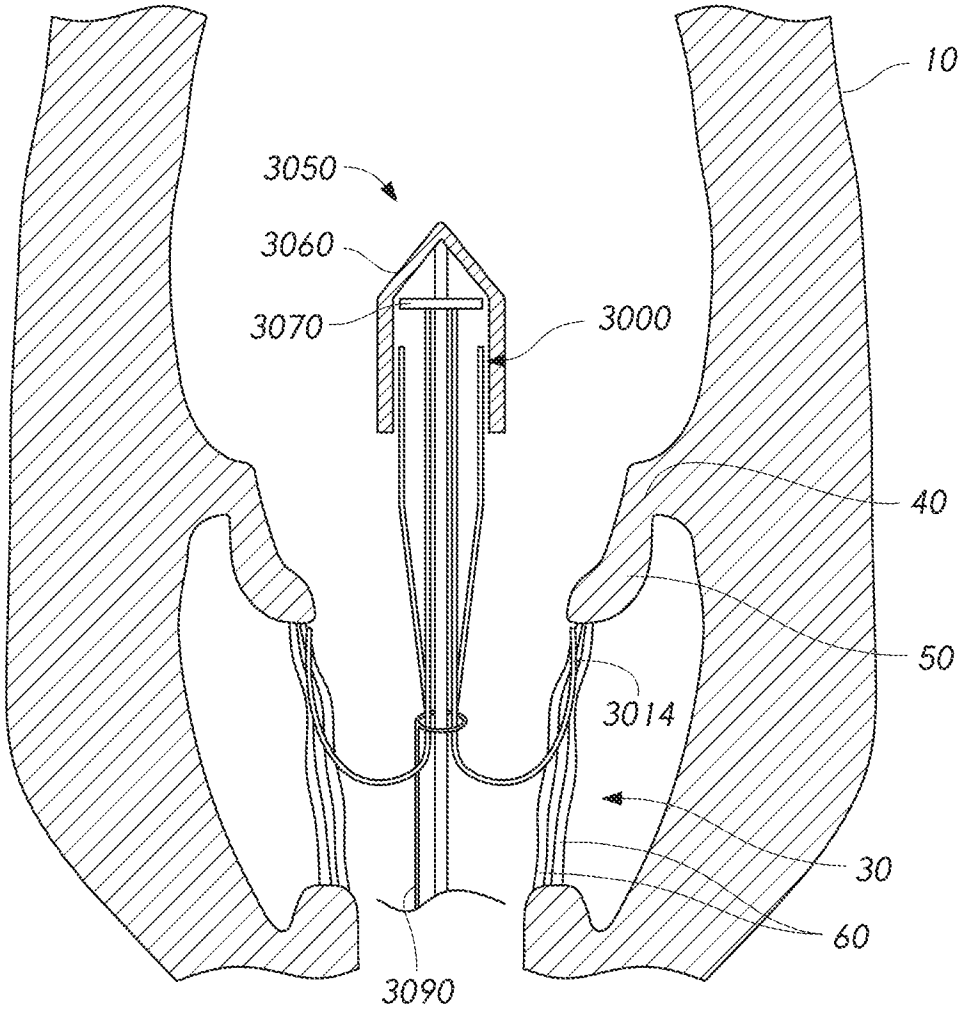

FIG. 55E

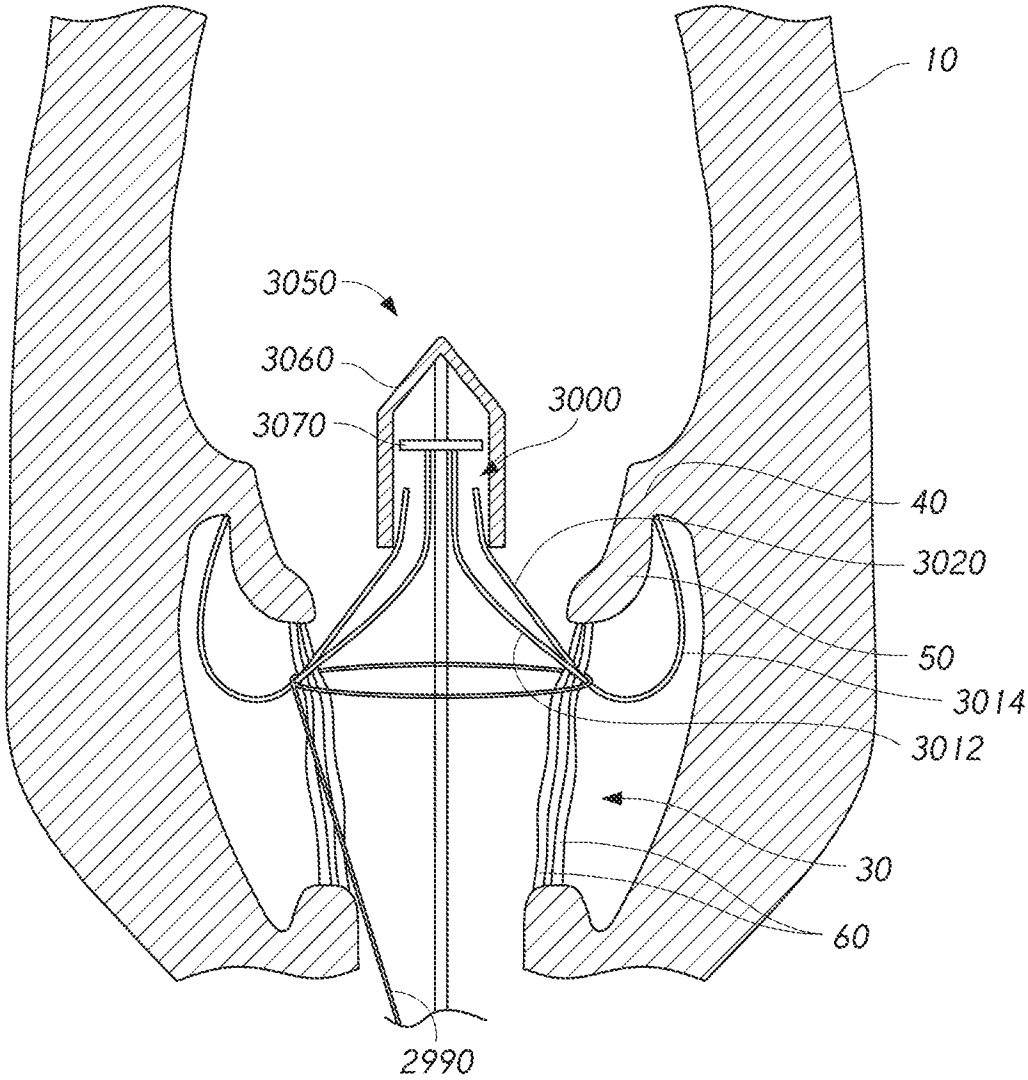

FIG. 55F

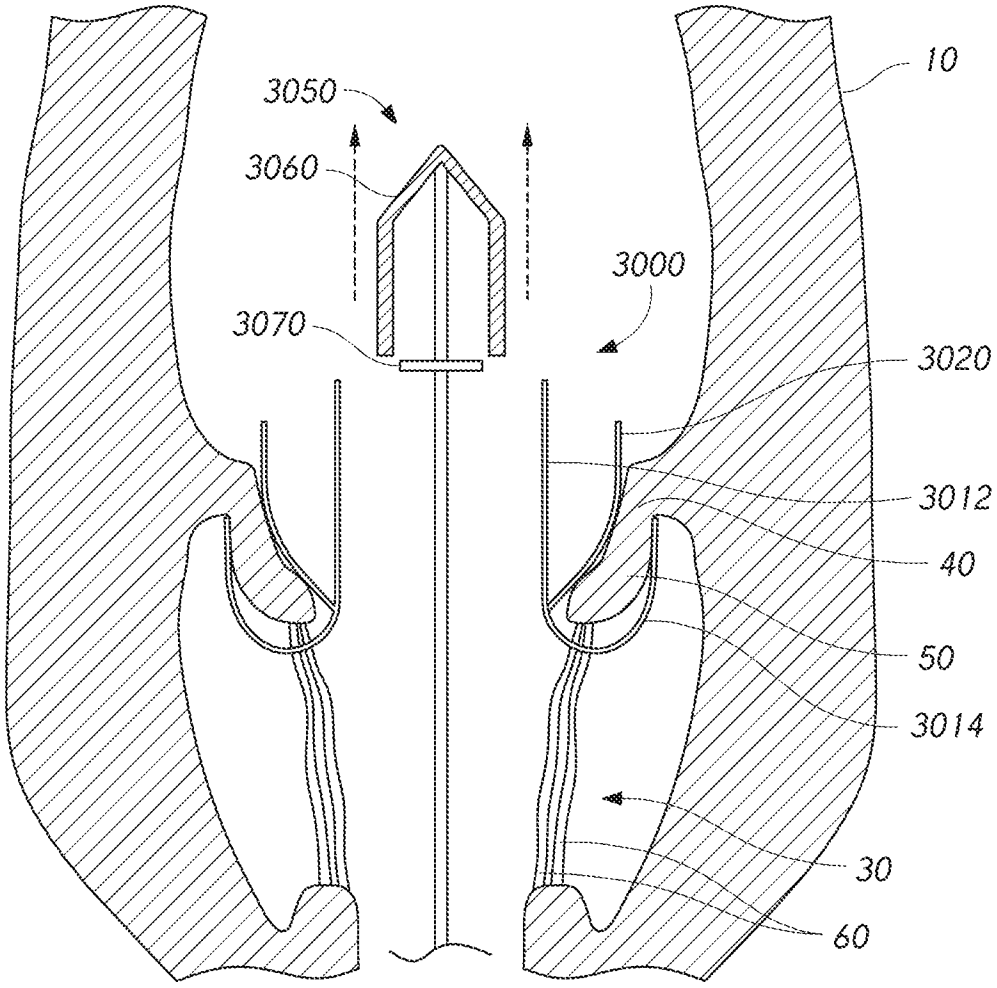

FIG. 55G

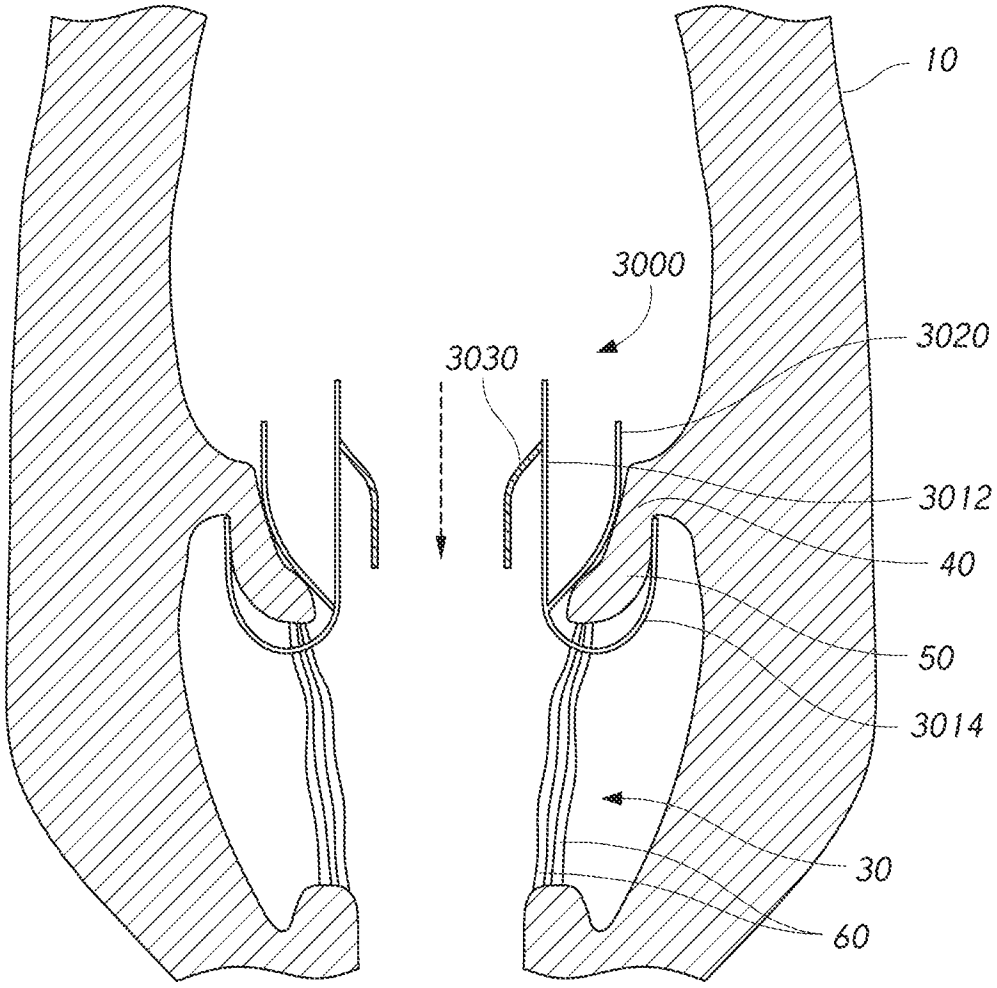

FIG. 55H

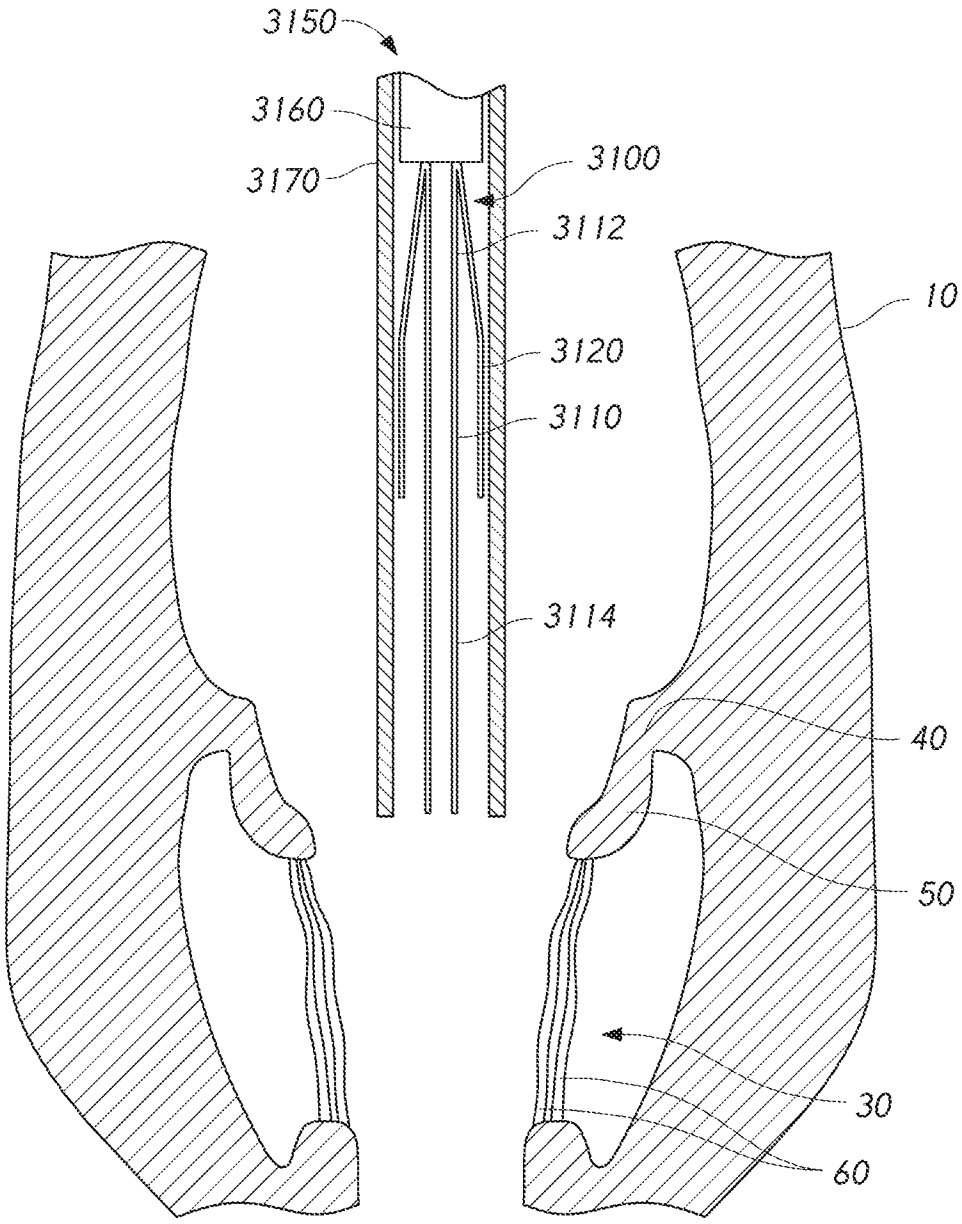

FIG. 56A

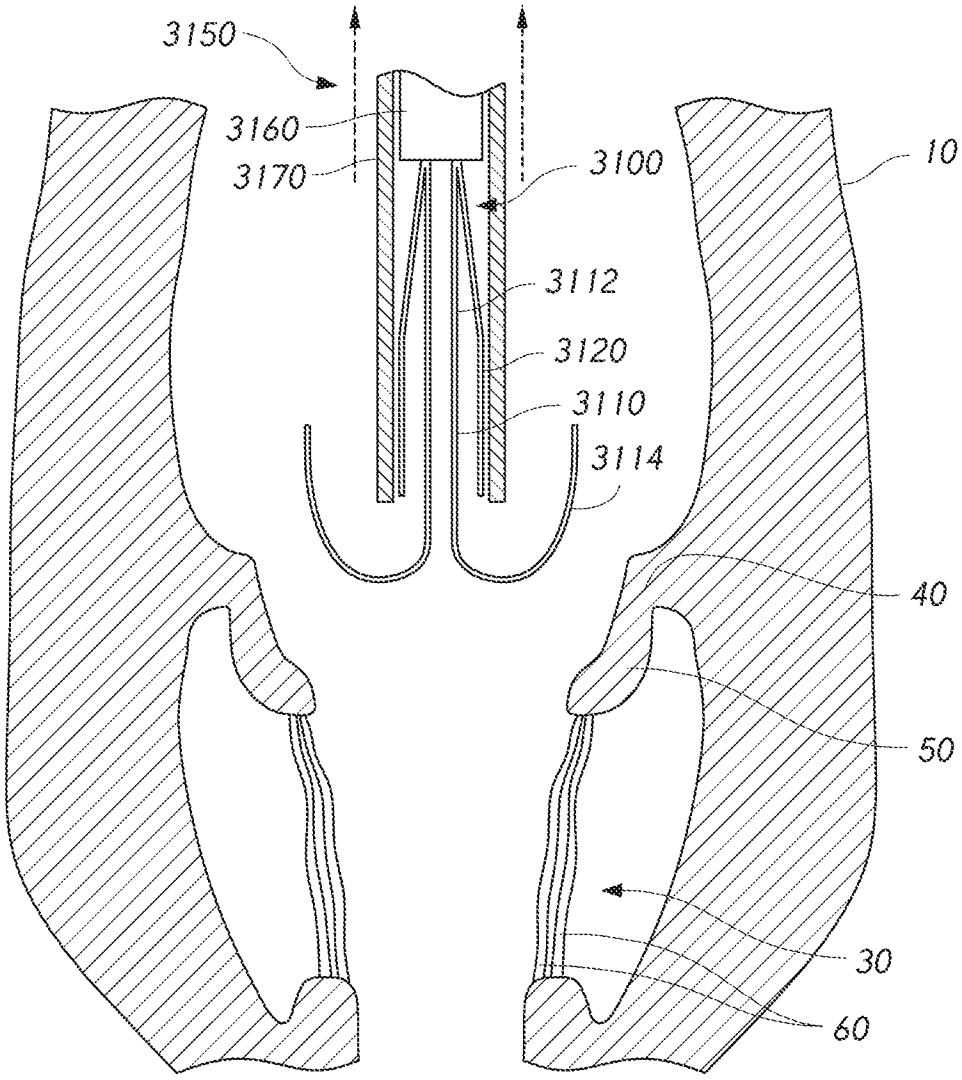

FIG. 56B

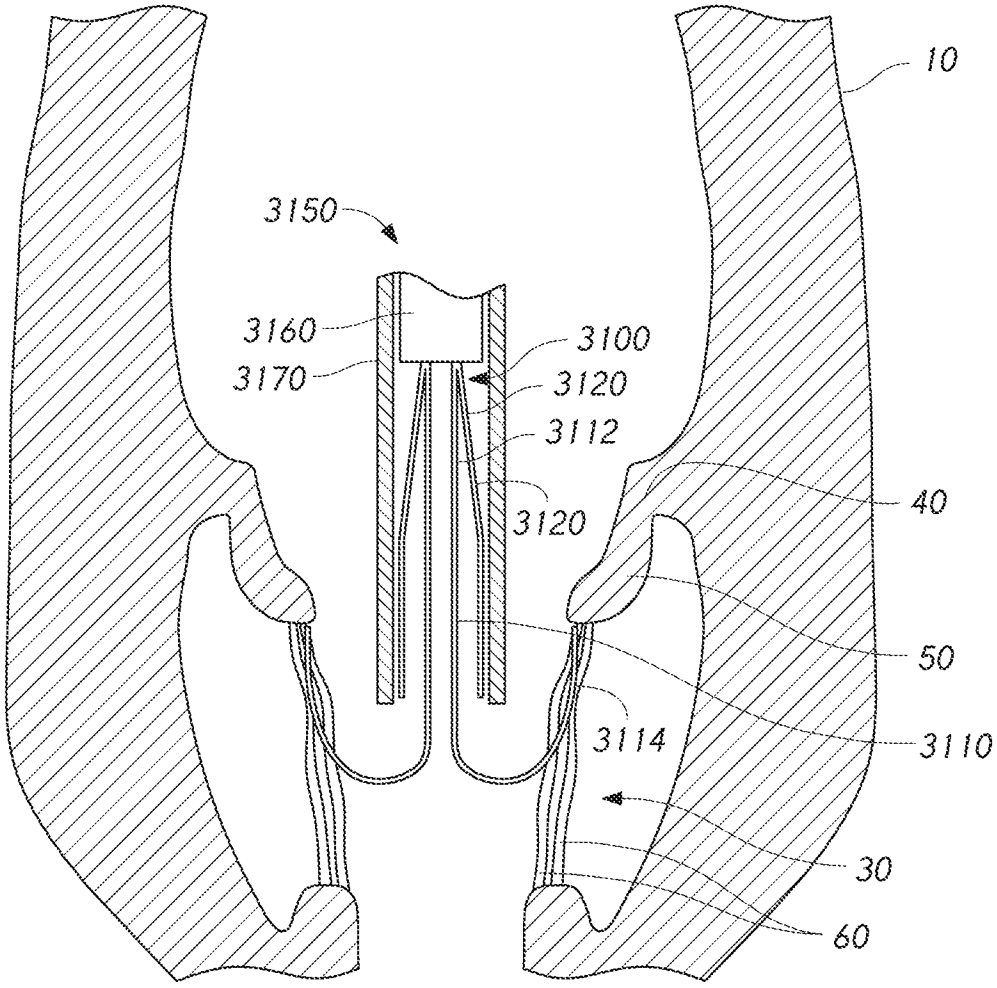

FIG. 56C

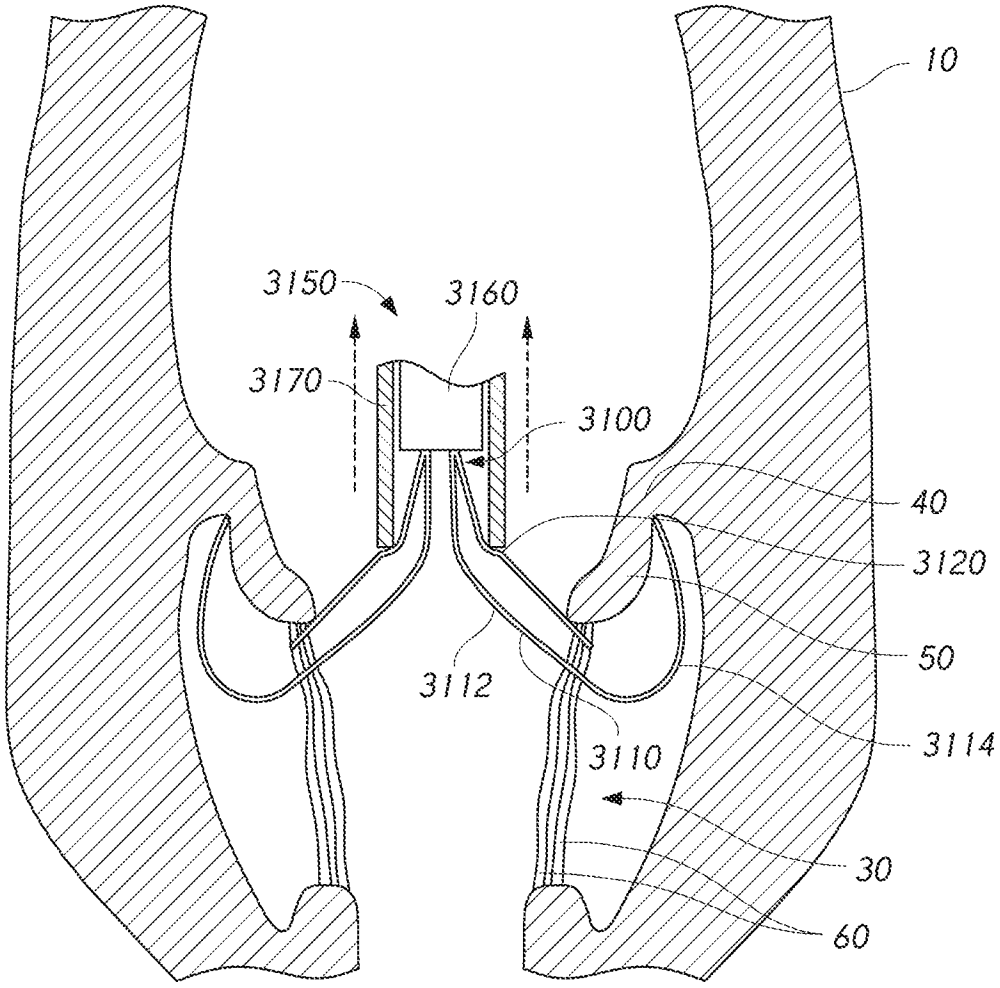

FIG. 56D

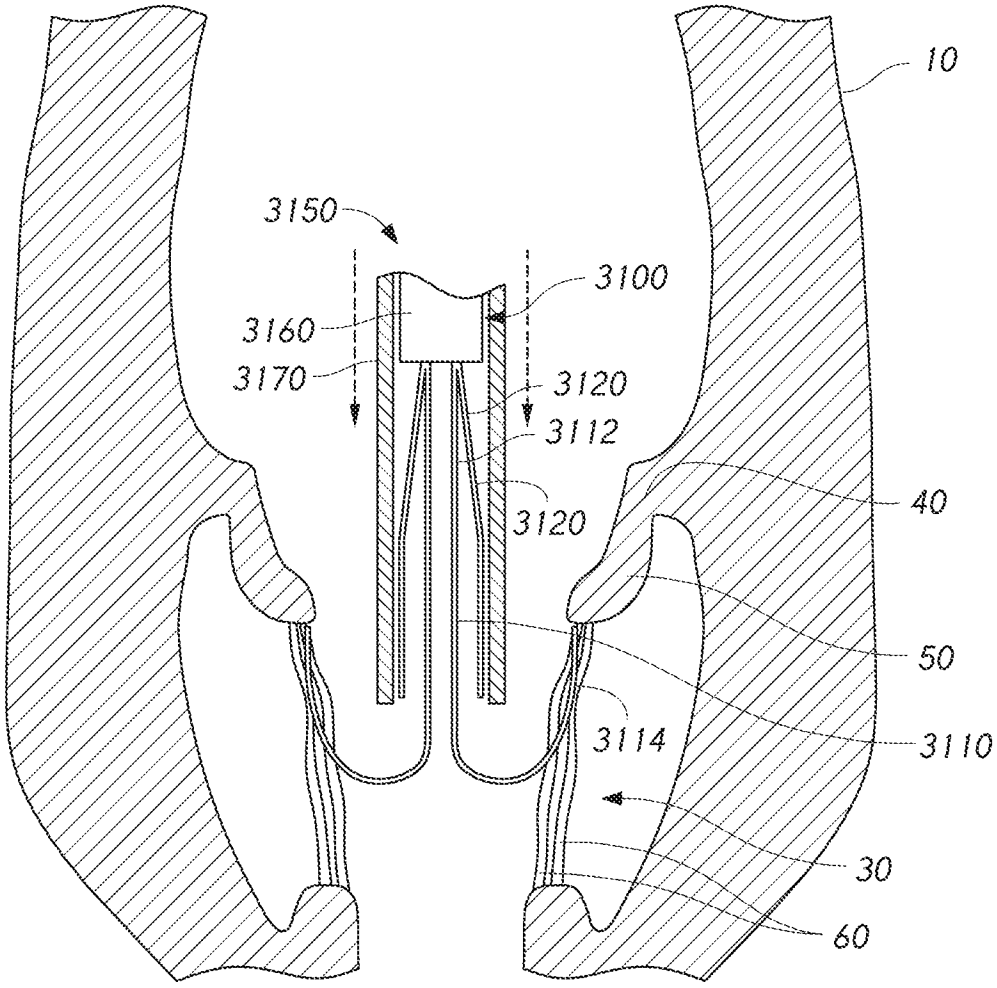

FIG. 56E

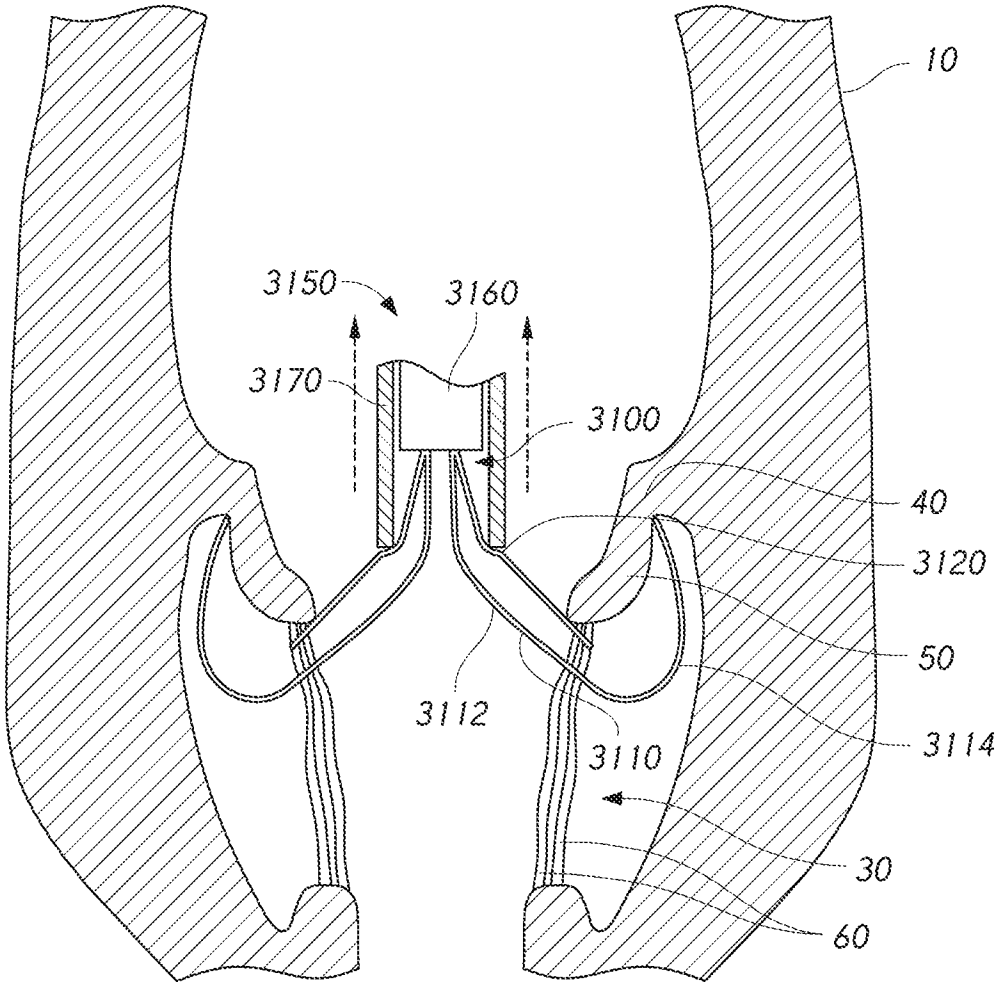

FIG. 56F

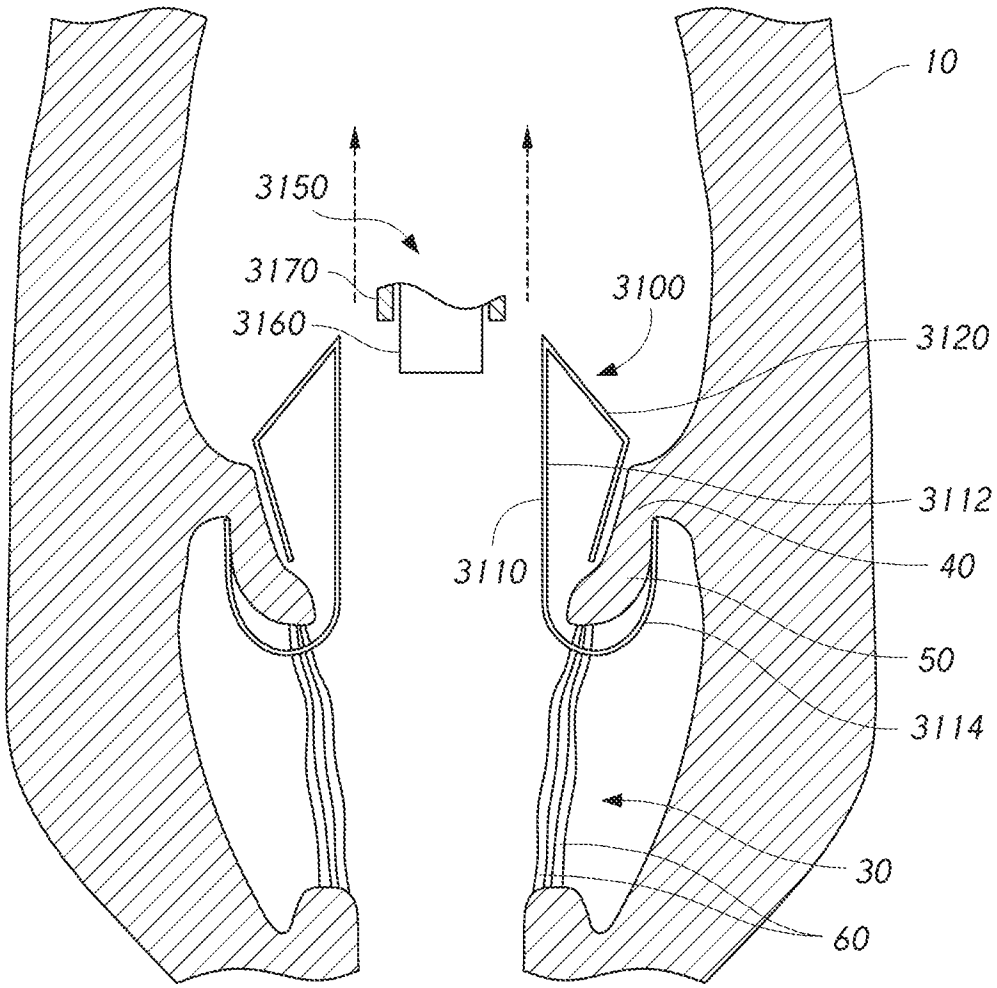

FIG. 56G

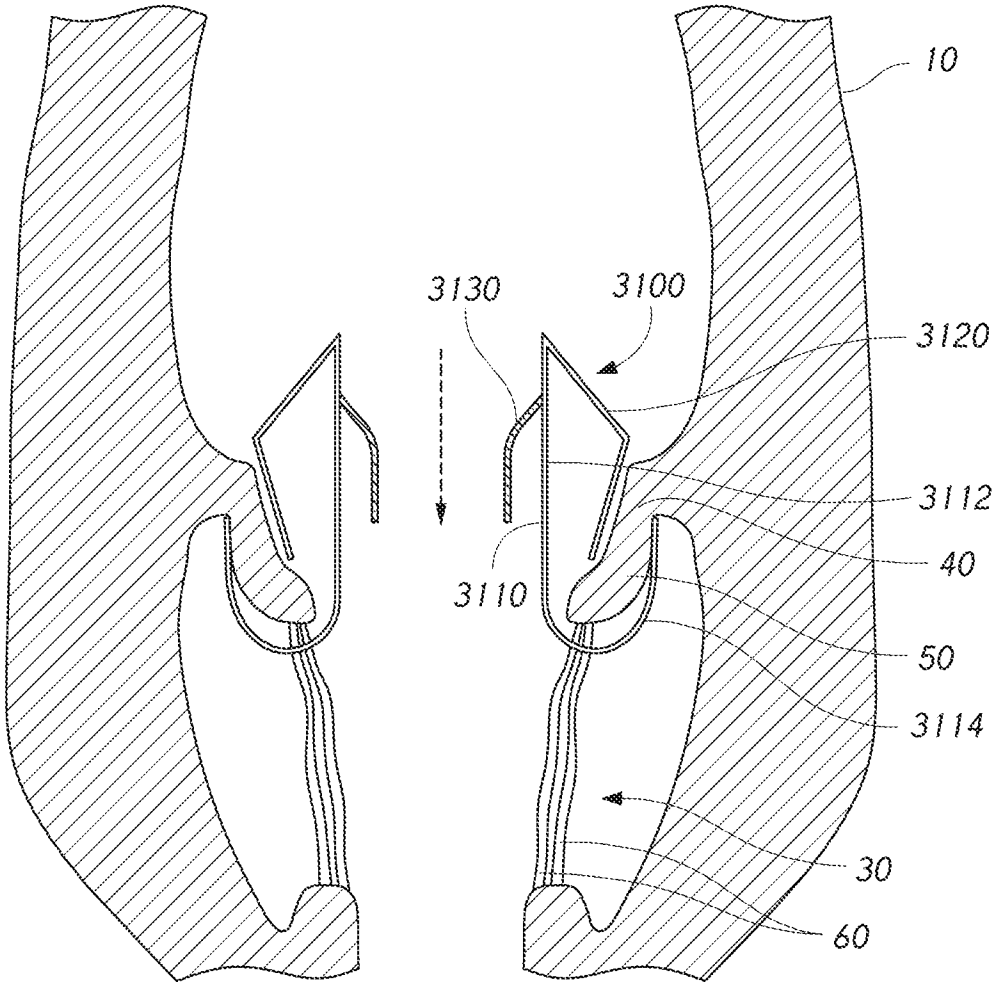

FIG. 56H

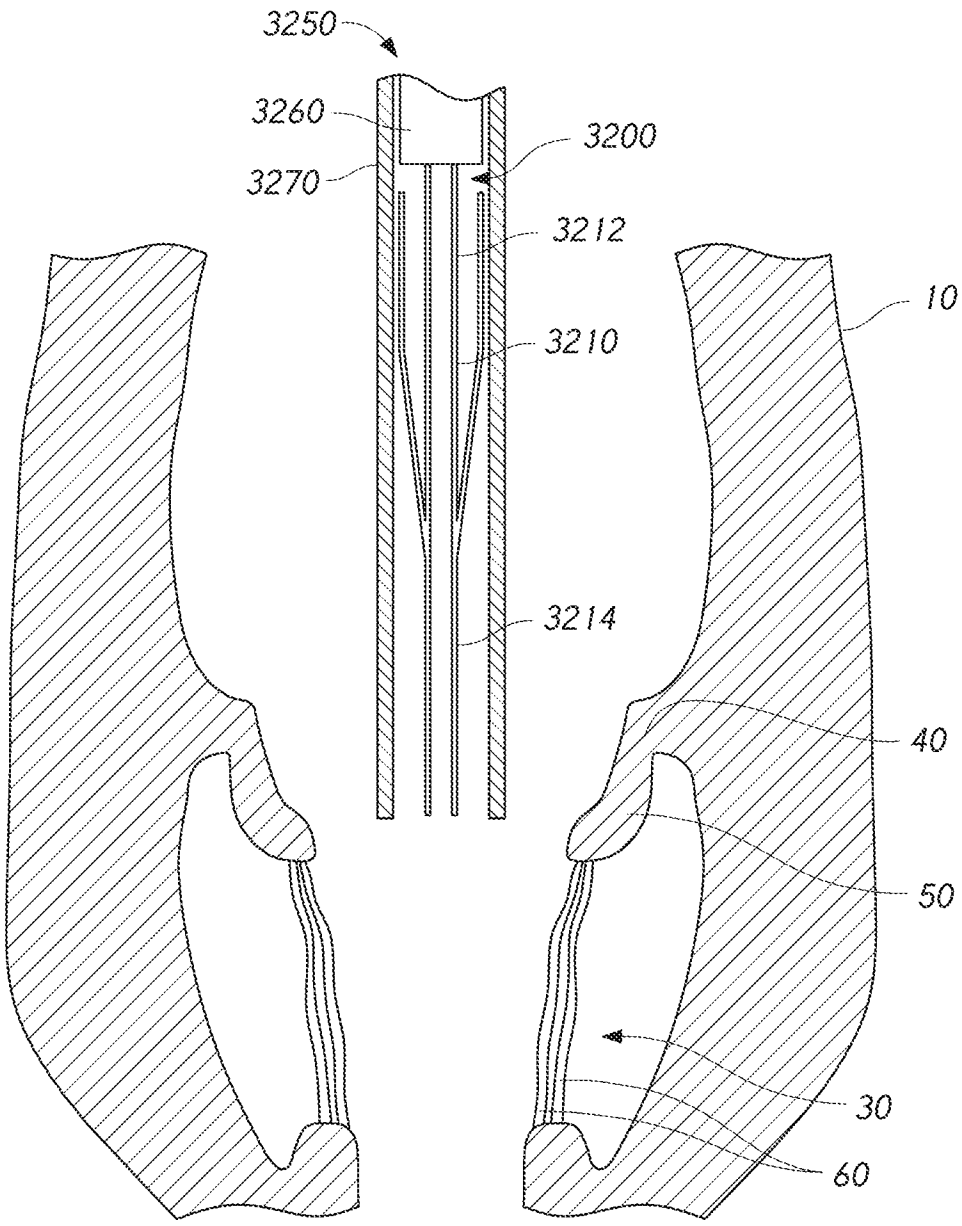

FIG. 57A

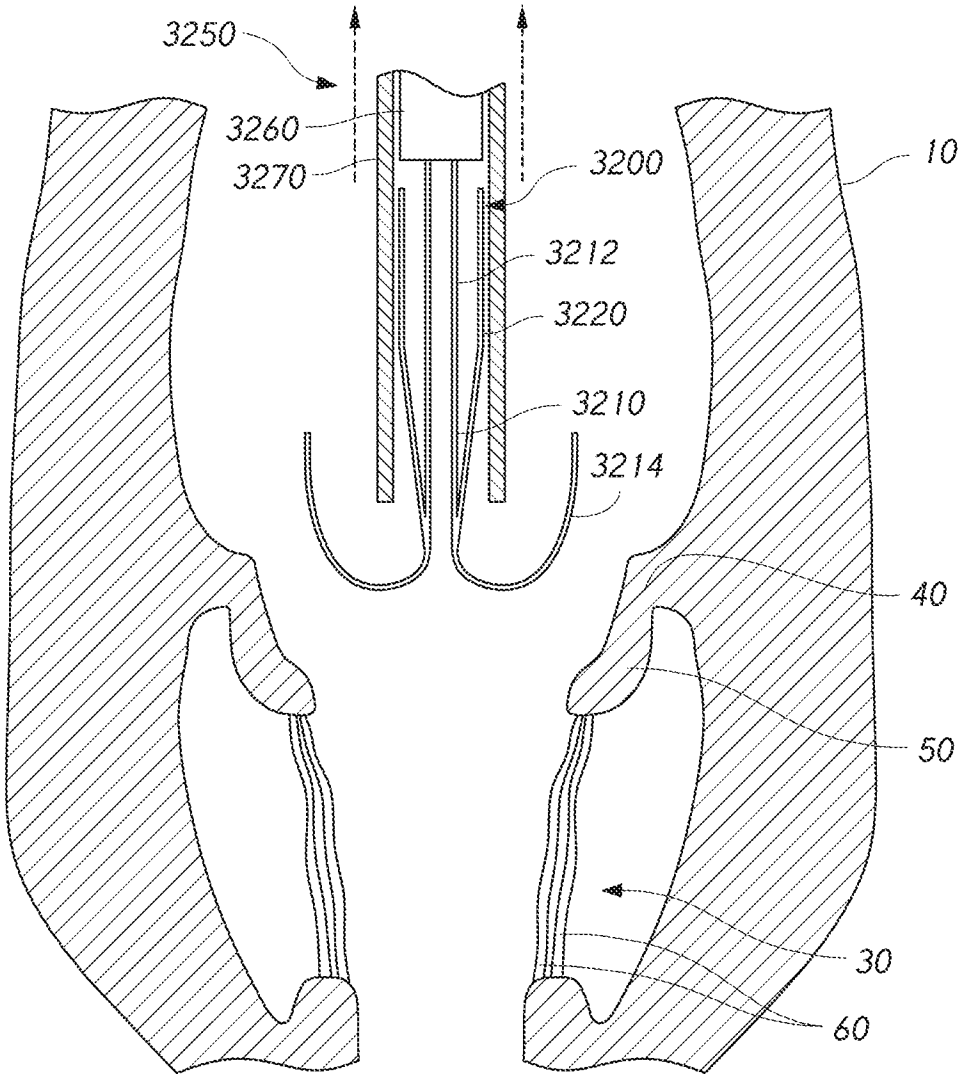

FIG. 57B

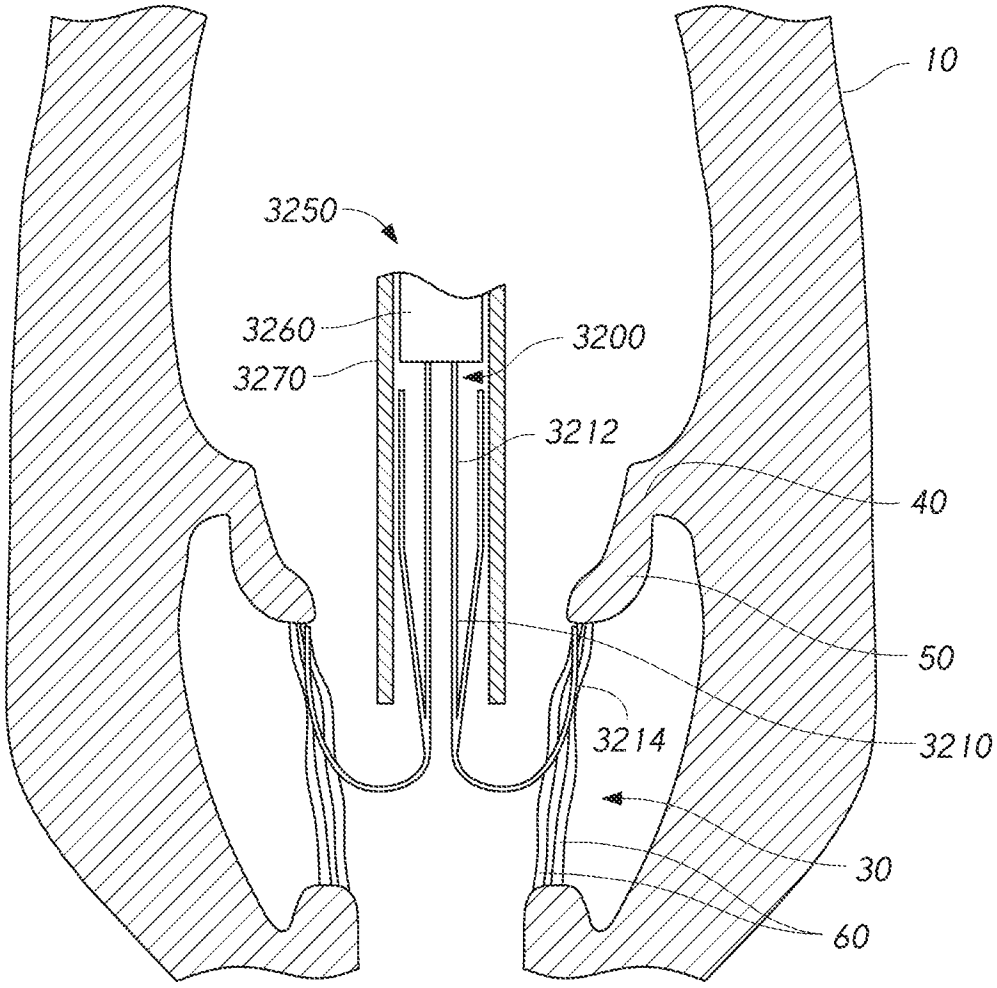

FIG. 57C

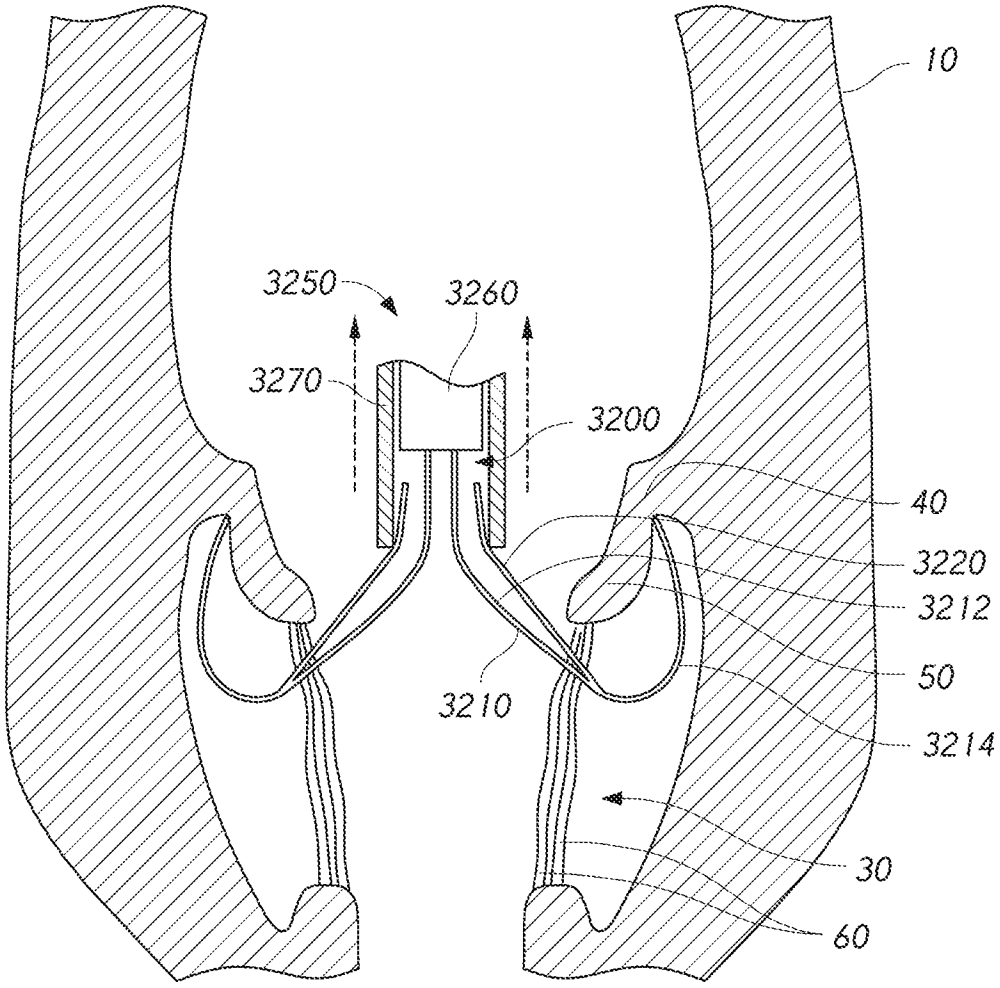

FIG. 57D

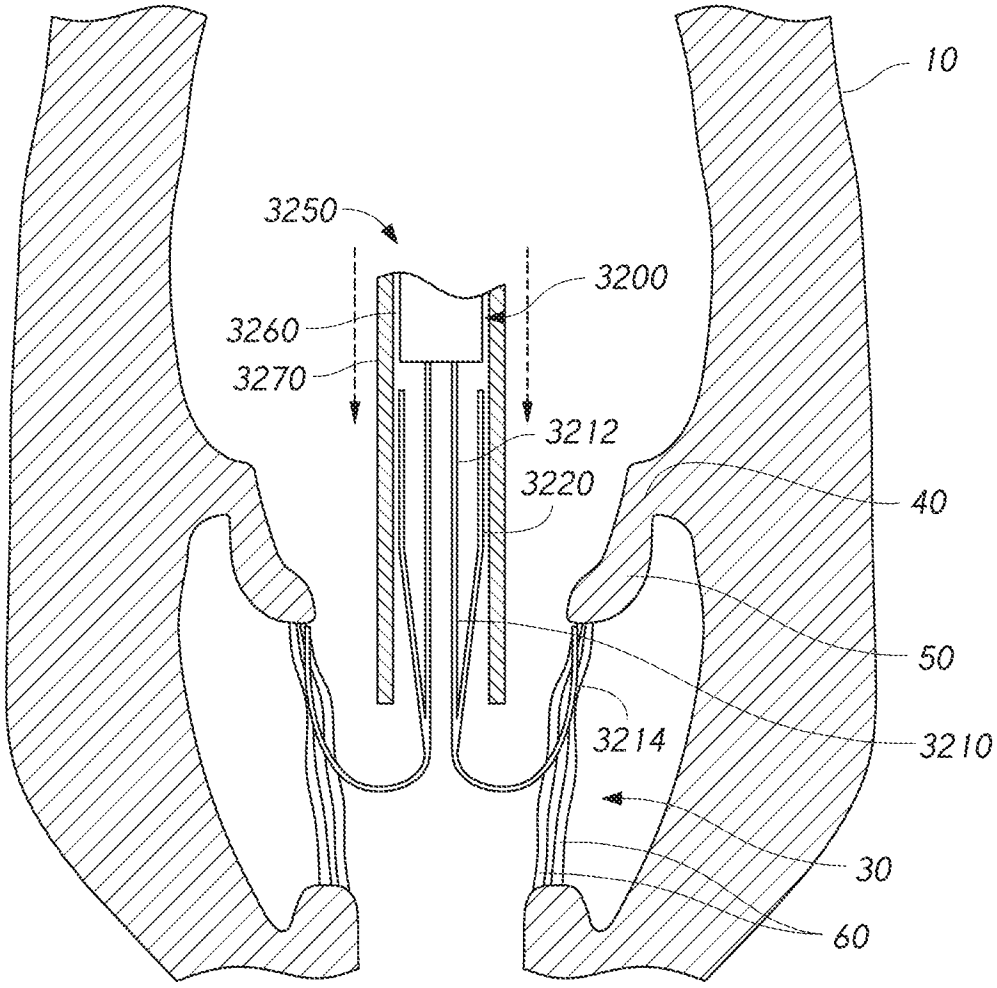

FIG. 57E

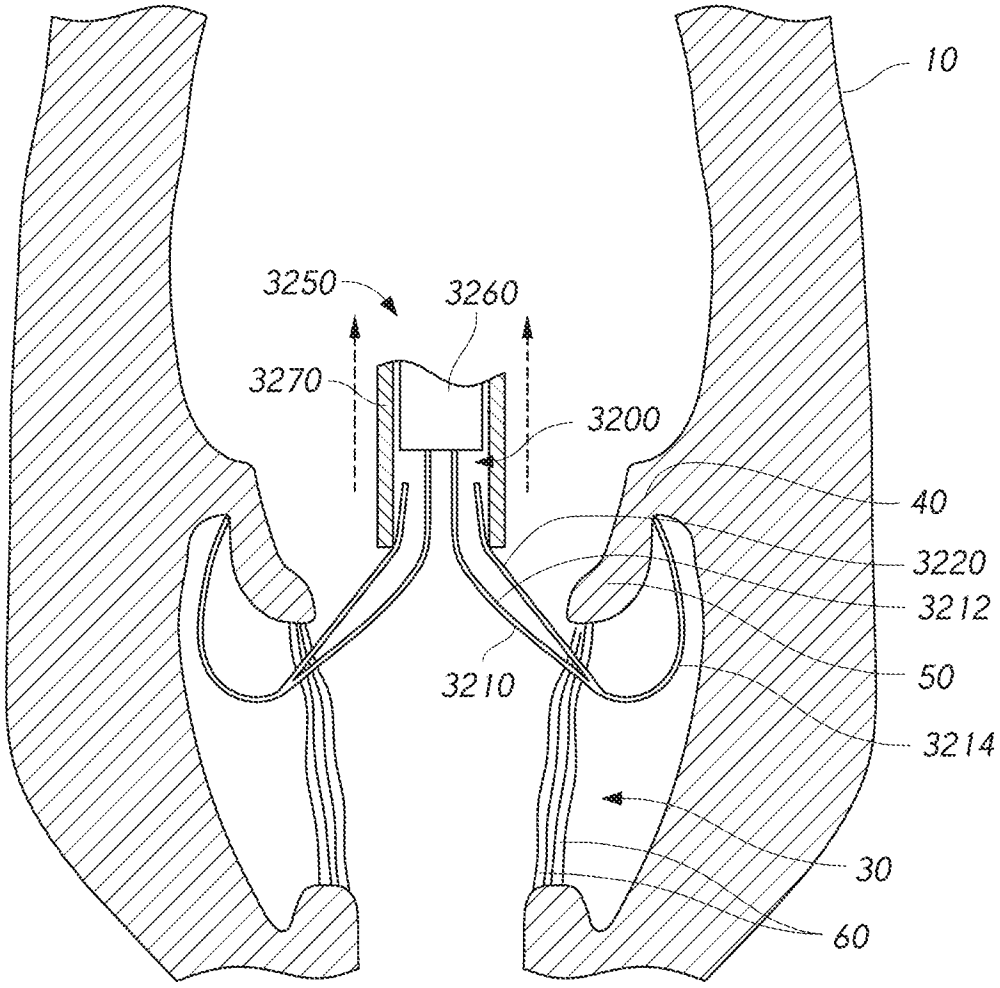

FIG. 57F

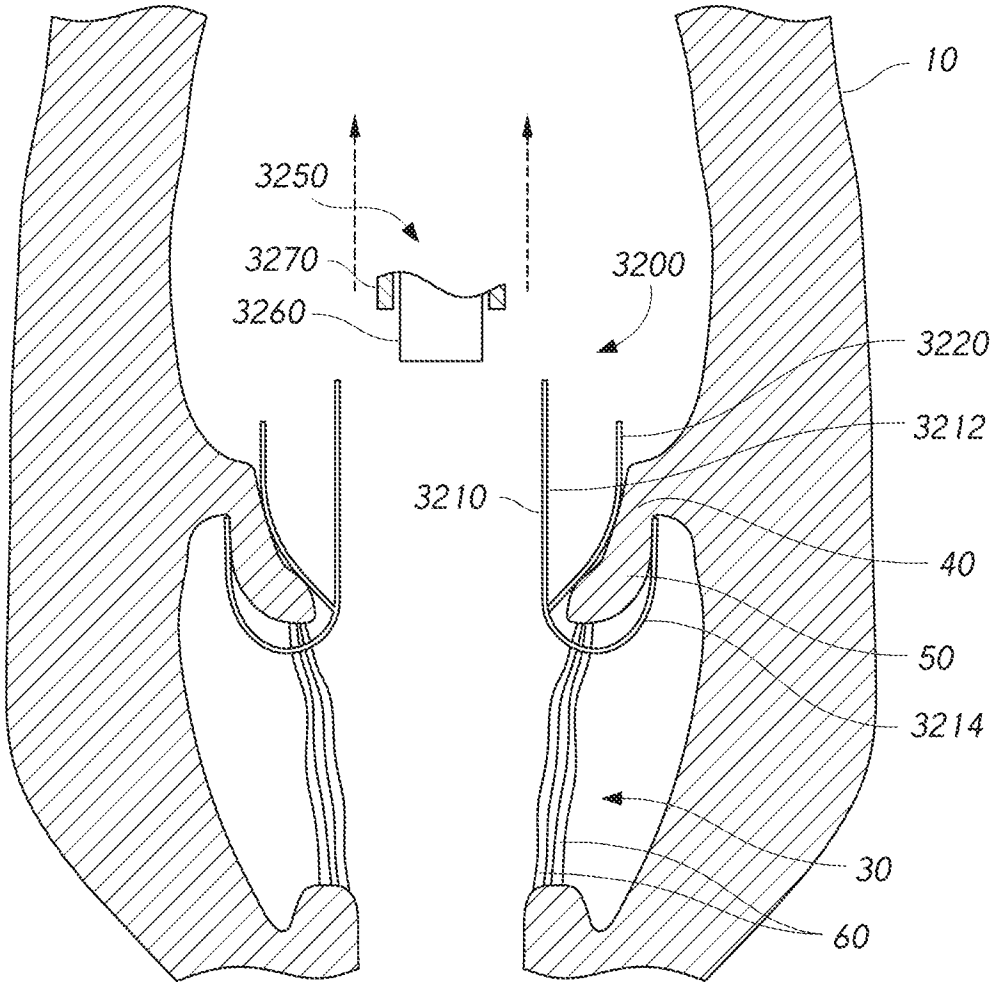

FIG. 57G

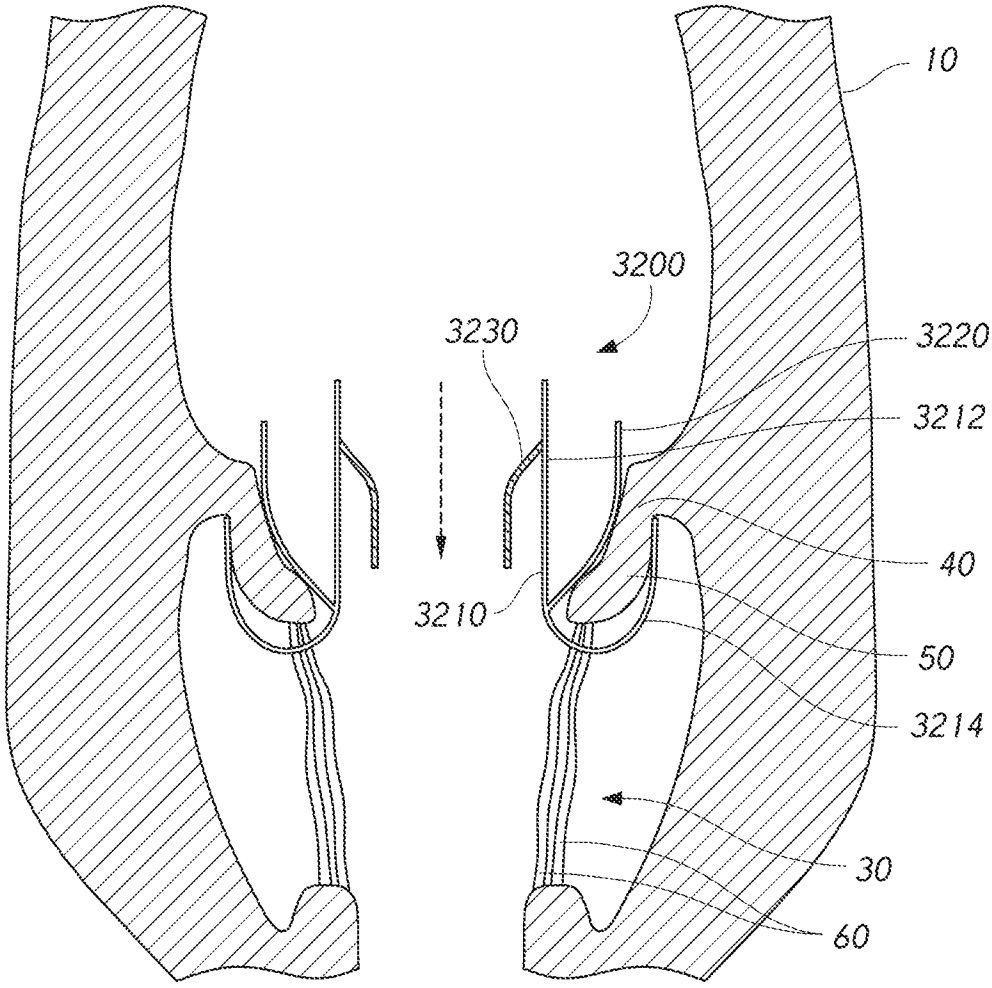

FIG. 57H

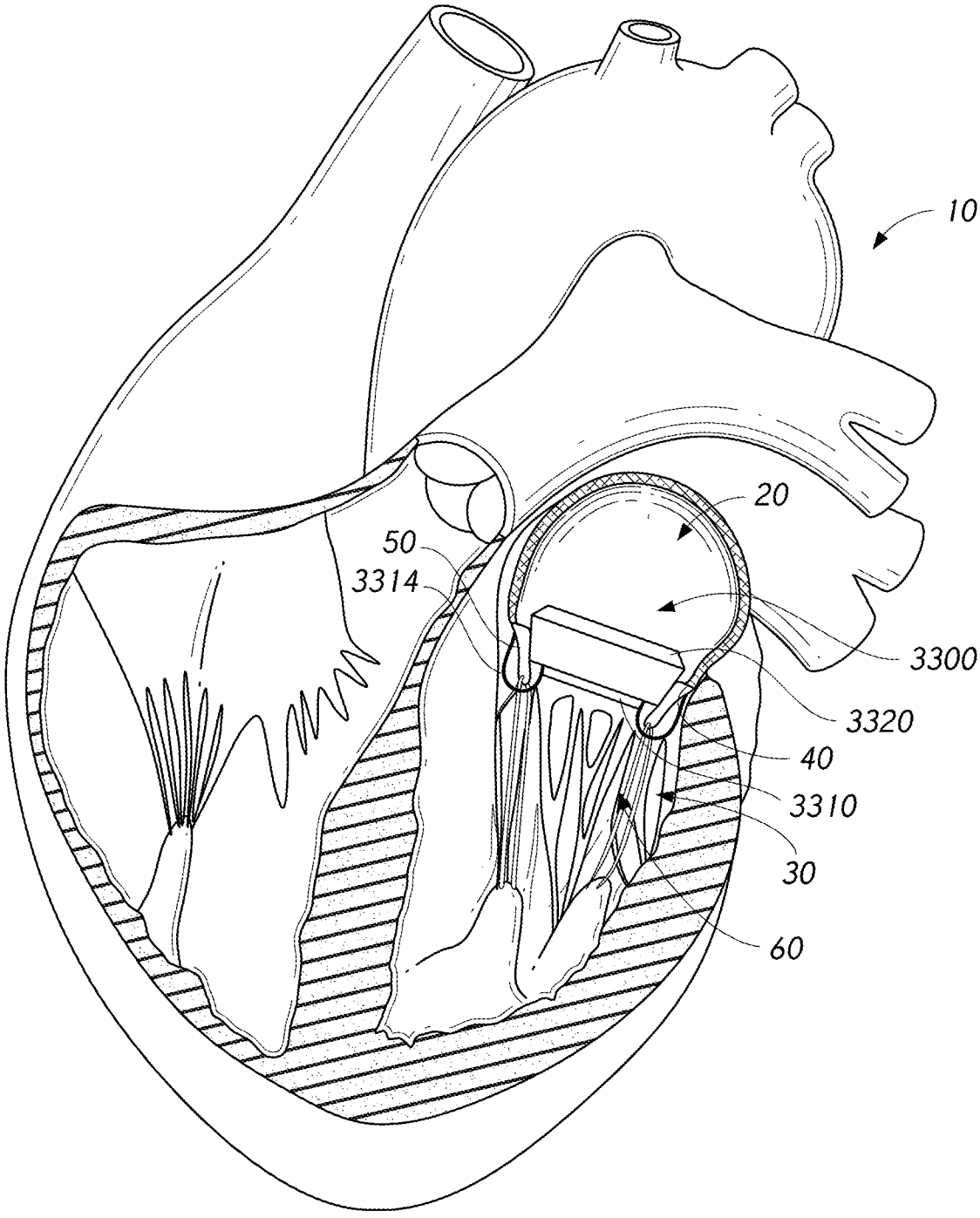

FIG. 58

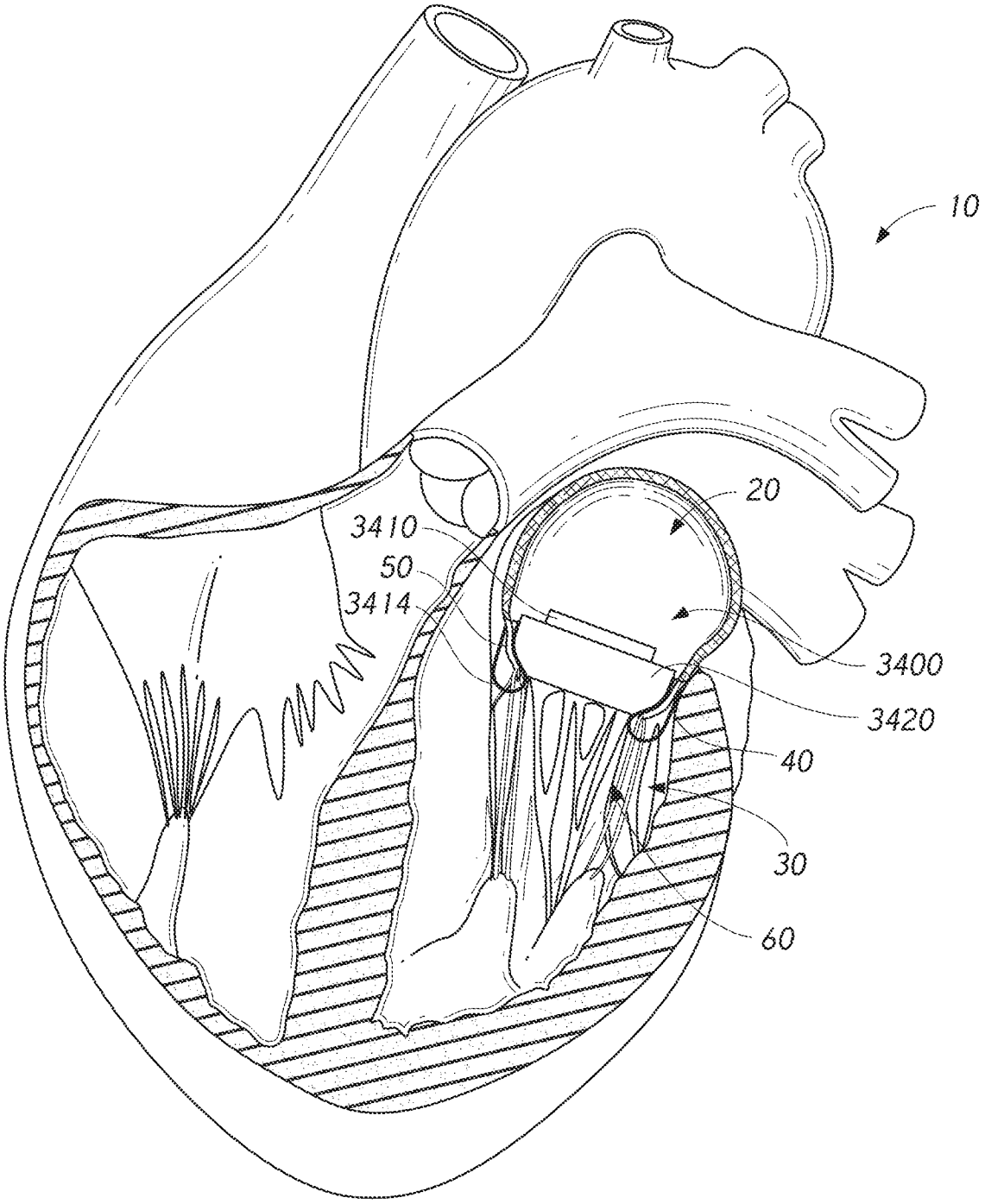

FIG. 59