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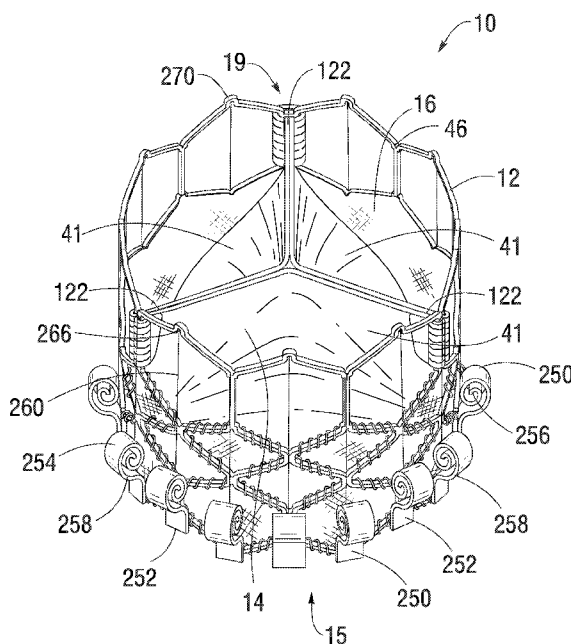
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FIG. 24



(57) Abstract: An implantable prosthetic valve can include a radially expandable and collapsible annular frame having an inflow end and an outflow end. A valvular structure can be positioned within the frame. A plurality of sealing members can be positioned around an outer surface of the frame, wherein the sealing members are configured to transform from an unfurled configuration extending along the outer surface of the frame when the frame is in the radially collapsed configuration to a coiled configuration when the frame is radially expanded to the radially expanded configuration.



## SEALING MEMBER FOR PROSTHETIC HEART VALVE

### CROSS-REFERENCE TO RELATED APPLICATION

[001] The present application claims the benefit of U.S. Provisional Application No. 62/824,904, filed March 27, 2019, which is incorporated herein by reference.

### FIELD

[002] The present disclosure relates to implantable, expandable prosthetic devices, such as prosthetic heart valves.

### BACKGROUND

[003] The human heart can suffer from various valvular diseases. These valvular diseases can result in significant malfunctioning of the heart and ultimately require replacement of the native valve with an artificial valve. There are a number of known artificial valves and a number of known methods of implanting these artificial valves in humans. Because of the drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches are garnering intense attention. In one technique, a prosthetic valve is configured to be implanted in a much less invasive procedure by way of catheterization. For example, collapsible transcatheter prosthetic heart valves can be crimped to a compressed state and percutaneously introduced in the compressed state on a catheter and expanded to a functional size at the desired position by balloon inflation or by utilization of a self-expanding frame or stent.

[004] A prosthetic valve for use in such a procedure can include a radially collapsible and expandable frame to which leaflets of the prosthetic valve can be coupled. For example, U.S. Patent Nos. 6,730,118, 7,393,360, 7,510,575, and 7,993,394, which are incorporated herein by reference, describe exemplary collapsible transcatheter prosthetic heart valves.

[005] A prosthetic valve for use in such a procedure can include a radially collapsible and expandable frame to which leaflets of the prosthetic valve can be coupled, and which can be percutaneously introduced in a collapsed configuration on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent. A challenge in catheter-implanted prosthetic valves is control of perivalvular leakage around the valve, which can occur for a period of time following initial implantation.

## SUMMARY

[006] Embodiments of a radially collapsible and expandable prosthetic valve are disclosed herein that include improved sealing members for reducing perivalvular leakage. In several embodiments, the disclosed prosthetic valves are configured as replacement heart valves for implantation into a subject.

[007] In one representative embodiment, an implantable prosthetic valve comprises an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration; a valvular structure positioned within the frame; and a plurality of sealing members positioned around an outer surface of the frame. The sealing members are configured to transform from an unfurled configuration extending along the outer surface of the frame when the frame is in the radially collapsed configuration to a coiled configuration when the frame is radially expanded to the radially expanded configuration.

[008] In some embodiments, the prosthetic valve further comprises a plurality of tethers, each having a first end portion connected to a respective sealing member and a second end portion connected to or extending around a location on the prosthetic valve axially spaced from the first end portion.

[009] In some embodiments, the tethers are configured to apply axially directed forces to the sealing members that cause the sealing members to transform from the coiled configuration to the unfurled configuration when the frame is radially collapsed to the radially collapsed configuration.

[010] In some embodiments, the tethers are configured to be placed in tension when the when the frame is radially collapsed to the radially collapsed configuration.

[011] In some embodiments, the tethers comprise sutures.

[012] In some embodiments, each sealing member has an inflow end portion retained at a fixed location relative to the frame and an outflow end portion connected to the first end portion of a respective tether.

[013] In some embodiments, the second end portions of the tethers are secured to the frame.

[014] In some embodiments, the second end portions of the tethers are secured to struts of the frame at the outflow end of the frame.

[015] In some embodiments, the tethers loop around struts at the outflow end of the frame and extend inside of the frame toward the inflow end of the frame, and the second end portions of the tethers are secured to struts of the frame spaced from the outflow end of the frame.

[016] In some embodiments, the second end portions of the tethers are secured to struts at the inflow end of the frame.

[017] In some embodiments, the sealing members are secured to the frame at discrete, spaced-apart locations.

[018] In some embodiments, each sealing member comprises a fabric that is shape-set to assume the coiled configuration.

[019] In some embodiments, the sealing members comprises Nitinol wires that are shape-set to assume the coiled configuration.

[020] In some embodiments, the sealing members lie in a flattened state along the outer surface of the frame when in the unfurled configuration.

[021] In another representative embodiment, an implantable prosthetic valve comprises an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration; a valvular structure positioned within the frame; and a plurality of sealing members positioned around an outer surface of the frame. Each sealing member has an inflow end portion and an outflow end portion, wherein the inflow end portion is retained at a fixed location relative to the frame and the outflow end portion is free to move relative to the frame. The sealing members are configured to transform from an unfurled configuration extending along the outer surface of the frame when the frame is in the radially collapsed configuration to a coiled configuration when the frame is expanded to the radially expanded configuration. When the sealing members are in the unfurled configuration, the outflow end

portions are at respective first locations relative to the outflow end of the frame, and when the sealing members are in the coiled configuration, the outflow end portions are at respective second locations closer to the inflow end of the frame than the first locations.

[022] In some embodiments, the prosthetic valve further comprises a plurality of tethers, each having a first end portion connected to the outflow end portion of a respective sealing member and a second end portion connected to or extending around a location on the prosthetic valve axially spaced from the first end portion.

[023] In some embodiments, wherein the tethers are configured to apply axially directed forces to the sealing members that cause the sealing members to transform from the coiled configuration to the unfurled configuration when the frame is radially collapsed to the radially collapsed configuration.

[024] In some embodiments, wherein the inflow end portions of the sealing members are fixed at the inflow end of the frame.

[025] In some embodiments, the tethers are configured to be placed in tension when the when the frame is radially collapsed to the radially collapsed configuration.

[026] In some embodiments, the tethers comprise sutures.

[027] In some embodiments, the second end portions of the tethers are secured to the frame.

[028] In some embodiments, the second end portions of the tethers are secured to struts of the frame at the outflow end of the frame.

[029] In some embodiments, the tethers loop around struts at the outflow end of the frame and extend inside of the frame toward the inflow end of the frame, and the second end portions of the tethers are secured to struts of the frame spaced from the outflow end of the frame.

[030] In some embodiments, the second end portions of the tethers are secured to struts at the inflow end of the frame.

[031] In some embodiments, the sealing members are secured to the frame at discrete, spaced-apart locations.

[032] In some embodiments, each sealing member comprises a fabric that is shape-set to assume the coiled configuration.

[033] In some embodiments, the sealing members comprises Nitinol wires that are shape-set to assume the coiled configuration.

[034] In some embodiments, the sealing members lie in a flattened state along the outer surface of the frame when in the unfurled configuration.

[035] In some embodiments, the prosthetic valve further comprises an inner skirt secured to an inner surface of the frame and wherein the second end portions of the tethers are secured to the inner skirt.

[036] In another representative embodiment, a method of implanting a prosthetic heart valve, comprises inserting into a patient's body, a distal end portion of a delivery apparatus and a prosthetic heart valve that is in a radially compressed configuration and coupled to the distal end portion of the delivery apparatus. The prosthetic valve comprises an annular frame, a valvular structure positioned within the frame, and a plurality of sealing members positioned around an outer surface of the frame, wherein the sealing members are in an unfurled configuration extending along an outer surface of the frame when the prosthetic heart valve is in the radially compressed configuration. The method further comprises positioning the prosthetic heart valve adjacent a native valve of the patient's heart and radially expanding the prosthetic heart valve from the radially compressed configuration to a radially expanded configuration, wherein expanding the prosthetic heart valve causes the sealing members to transform from the unfurled configuration to a coiled configuration engaging surrounding tissue of the native valve.

[037] In some embodiments, the prosthetic heart valve further comprises a plurality of tethers, each having a first end portion connected to a respective sealing member and a second end portion connected to or extending around a location on the prosthetic valve axially spaced from the first end portion. When the prosthetic heart valve is in the radially compressed configuration, the tethers are held in tension and retain the sealing members in the unfurled configuration, and expanding the prosthetic heart valve decreases tension on the tethers, which allow the sealing members to transform to the coiled configuration.

[038] In some embodiments, when the prosthetic heart valve is radially expanded and the sealing members transform from the unfurled configuration to the coiled configuration, free ends of the sealing members move from respective first locations to respective second locations closer to an inflow end of the frame than the first locations.

[039] In some embodiments, the sealing members are shape-set to assume the coiled configuration.

[040] In some embodiments, the tethers comprise sutures.

[041] In some embodiments, each sealing member has an inflow end portion retained at a fixed location relative to the frame and an outflow end portion connected to the first end portion of a respective tether.

[042] In some embodiments, the second end portions of the tethers are secured to the frame.

[043] In some embodiments, the second end portions of the tethers are secured to struts of the frame at the outflow end of the frame.

[044] In some embodiments, the tethers loop around struts at the outflow end of the frame and extend inside of the frame toward the inflow end of the frame, and the second end portions of the tethers are secured to struts of the frame spaced from the outflow end of the frame.

[045] In some embodiments, the second end portions of the tethers are secured to struts at the inflow end of the frame.

[046] In some embodiments, the sealing members are secured to the frame at discrete, spaced-apart locations.

[047] In some embodiments, each sealing member comprises a fabric that is shape-set to assume the coiled configuration.

[048] In some embodiments, the sealing members comprises Nitinol wires that are shape-set to assume the coiled configuration.

[049] In some embodiments, the sealing members lie in a flattened state along the outer surface of the frame when in the unfurled configuration.

[050] In another representative embodiment, an implantable prosthetic valve comprises an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration; a valvular structure positioned within the frame; a plurality of sealing members positioned around an outer surface of the frame; and a plurality of tethers, each having a first end portion connected to a respective sealing member and a second end portion connected to or extending around a location on the prosthetic valve axially spaced from the first end portion. When the frame is radially collapsed from the radially expanded configuration to the radially collapsed configuration, each tether applies an axial force to a respective sealing member to transform the sealing member from a coiled configuration to an unfurled configuration, and when the frame is radially expanded from the radially collapsed configuration to the radially expanded configuration, each tether decreases the applied axial force on a respective sealing member, thereby allowing the sealing member to transform from the unfurled configuration to the coiled configuration.

[051] In some embodiments, the second end portions of the tethers are secured to struts of the frame at the outflow end of the frame.

[052] In some embodiments, the tethers loop around struts at the outflow end of the frame and extend inside of the frame toward the inflow end of the frame, and the second end portions of the tethers are secured to struts of the frame spaced from the outflow end of the frame.

[053] In some embodiments, the second end portions of the tethers are secured to struts at the inflow end of the frame.

[054] In some embodiments, the prosthetic valve further comprises an inner skirt secured to an inner surface of the frame and wherein the second end portions of the tethers are secured to the inner skirt.

[055] In some embodiments, each sealing member comprises a fabric that is shape-set to assume the coiled configuration.

[056] In some embodiments, the sealing members comprises Nitinol wires that are shape-set to assume the coiled configuration.



[057] In some embodiments, the sealing members lie in a flattened state along the outer surface of the frame when in the unfurled configuration.

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

### **BRIEF DESCRIPTION OF THE DRAWINGS**

[059] FIGS. 1-3 show an exemplary embodiment of a prosthetic heart valve.

[060] FIGS. 4-10 show an exemplary frame of the prosthetic heart valve of FIG. 1.

[061] FIGS. 11-12 show an exemplary inner skirt of the prosthetic heart valve of FIG. 1.

[062] FIG. 13 shows another embodiment of a prosthetic heart valve with a deformed frame.

[063] FIG. 14 shows the prosthetic heart valve of FIG. 1 in a collapsed configuration and mounted on an exemplary balloon catheter.

[064] FIGS. 15-17 show the assembly of the inner skirt of FIG. 11 with the frame of FIG. 4.

[065] FIGS. 18-19 show the assembly of an exemplary leaflet structure.

[066] FIG. 20 shows the assembly of commissure portions of the leaflet structure with window frame portions of the frame.

[067] FIGS. 21-22 show the assembly of the leaflet structure with the inner skirt along a lower edge of the leaflets.

[068] FIG. 23 shows a flattened view of an exemplary outer skirt.

[069] FIG. 24 is a perspective view of a prosthetic heart valve having a plurality of coiled sealing members, according to one embodiment.

[070] FIG. 25 is a cross-sectional view of a portion of the frame and one of the sealing members of the prosthetic valve of FIG. 24 with the sealing member shown in a coiled configuration.

[071] FIG. 26 is a cross-sectional view of a portion of the frame and one of the sealing members of the prosthetic valve of FIG. 24 with the sealing member shown in an unfurled configuration.

[072] FIG. 27 shows the prosthetic heart valve of FIG. 24 implanted in the native aortic valve of a patient.

[073] FIG. 28 shows the prosthetic heart valve of FIG. 24 and a docking device implanted in the pulmonary artery of a patient.

[074] FIG. 29 shows the prosthetic heart valve of FIG. 24 and a docking device implanted in the native mitral valve of a patient.

[075] FIGS. 30-31 show an alternative embodiment of a docking device for a prosthetic valve.

[076] FIG. 32 shows the prosthetic heart valve of FIG. 24 and the docking device of FIGS. 30-31 implanted in the inferior vena cava of a patient.

[077] FIG. 33 is a cross-sectional view of a portion of the frame and one of the sealing members of FIG. 24 showing an alternative way of connecting a tether to the frame.

### **DETAILED DESCRIPTION**

[078] FIGS. 1-3 show various views of a prosthetic heart valve 10, according to one embodiment. The illustrated prosthetic valve is adapted to be implanted in the native aortic annulus, although in other embodiments it can be adapted to be implanted in the other native annuluses of the heart (e.g., the pulmonary, mitral, and tricuspid valves). The prosthetic valve can also be adapted to be implanted in other tubular organs or passageways in the body. The prosthetic valve 10 can have four main components: a stent or frame 12, a valvular structure 14, an inner skirt 16, and a perivalvular sealing means or sealing member. The prosthetic valve 10 can have an inflow end portion 15, an intermediate portion 17, and an outflow end portion 19. In the illustrated embodiment, the perivalvular sealing means comprises an outer skirt 18.

[079] The valvular structure 14 can comprise three leaflets 41, collectively forming a leaflet structure, which can be arranged to collapse in a tricuspid arrangement, as best shown in FIG. 2. The lower edge of leaflet structure 14 desirably has an undulating, curved

scalloped shape (suture line 154 shown in FIG. 22 tracks the scalloped shape of the leaflet structure). By forming the leaflets with this scalloped geometry, stresses on the leaflets are reduced, which in turn improves durability of the prosthetic valve. Moreover, by virtue of the scalloped shape, folds and ripples at the belly of each leaflet (the central region of each leaflet), which can cause early calcification in those areas, can be eliminated or at least minimized. The scalloped geometry also reduces the amount of tissue material used to form leaflet structure, thereby allowing a smaller, more even crimped profile at the inflow end of the prosthetic valve. The leaflets 41 can be formed of pericardial tissue (e.g., bovine pericardial tissue), biocompatible synthetic materials, or various other suitable natural or synthetic materials as known in the art and described in U.S. Patent No. 6,730,118, which is incorporated by reference herein.

[080] The bare frame 12 is shown in FIG. 4. The frame 12 can be formed with a plurality of circumferentially spaced slots, or commissure windows, 20 (three in the illustrated embodiment) that are adapted to mount the commissures of the valvular structure 14 to the frame, as described in greater detail below. The frame 12 can be made of any of various suitable plastically-expandable materials (e.g., stainless steel, etc.) or self-expanding materials (e.g., nickel titanium alloy (NiTi), such as nitinol) as known in the art. When constructed of a plastically-expandable material, the frame 12 (and thus the prosthetic valve 10) can be crimped to a radially collapsed configuration on a delivery catheter and then expanded inside a patient by an inflatable balloon or equivalent expansion mechanism. When constructed of a self-expandable material, the frame 12 (and thus the prosthetic valve 10) can be crimped to a radially collapsed configuration and restrained in the collapsed configuration by insertion into a sheath or equivalent mechanism of a delivery catheter. Once inside the body, the prosthetic valve can be advanced from the delivery sheath, which allows the prosthetic valve to expand to its functional size.

[081] Suitable plastically-expandable materials that can be used to form the frame 12 include, without limitation, stainless steel, biocompatible, high-strength alloys (e.g., a cobalt-chromium or a nickel-cobalt-chromium alloys), polymers, or combinations thereof. In particular embodiments, frame 12 is made of a nickel-cobalt-chromium-molybdenum alloy, such as MP35N® alloy (SPS Technologies, Jenkintown, Pennsylvania), which is equivalent to UNS R30035 alloy (covered by ASTM F562-02). MP35N® alloy/UNS R30035 alloy

comprises 35% nickel, 35% cobalt, 20% chromium, and 10% molybdenum, by weight. It has been found that the use of MP35N® alloy to form frame 12 provides superior structural results over stainless steel. In particular, when MP35N® alloy is used as the frame material, less material is needed to achieve the same or better performance in radial and crush force resistance, fatigue resistances, and corrosion resistance. Moreover, since less material is required, the crimped profile of the frame can be reduced, thereby providing a lower profile prosthetic valve assembly for percutaneous delivery to the treatment location in the body.

[082] Referring to FIGS. 4 and 5, the frame 12 in the illustrated embodiment comprises a first, lower row I of angled struts 22 arranged end-to-end and extending circumferentially at the inflow end of the frame; a second row II of circumferentially extending, angled struts 24; a third row III of circumferentially extending, angled struts 26; a fourth row IV of circumferentially extending, angled struts 28; and a fifth row V of circumferentially extending, angled struts 32 at the outflow end of the frame. A plurality of substantially straight axially extending struts 34 can be used to interconnect the struts 22 of the first row I with the struts 24 of the second row II. The fifth row V of angled struts 32 are connected to the fourth row IV of angled struts 28 by a plurality of axially extending window frame portions 30 (which define the commissure windows 20) and a plurality of axially extending struts 31. Each axial strut 31 and each frame portion 30 extends from a location defined by the convergence of the lower ends of two angled struts 32 to another location defined by the convergence of the upper ends of two angled struts 28. FIGS. 6, 7, 8, 9, and 10 are enlarged views of the portions of the frame 12 identified by letters A, B, C, D, and E, respectively, in FIG. 5.

[083] Each commissure window frame portion 30 mounts a respective commissure of the leaflet structure 14. As can be seen each frame portion 30 is secured at its upper and lower ends to the adjacent rows of struts to provide a robust configuration that enhances fatigue resistance under cyclic loading of the prosthetic valve compared to known, cantilevered struts for supporting the commissures of the leaflet structure. This configuration enables a reduction in the frame wall thickness to achieve a smaller crimped diameter of the prosthetic valve. In particular embodiments, the thickness T of the frame 12 (FIG. 4) measured between the inner diameter and outer diameter is about 0.48 mm or less.

[084] The struts and frame portions of the frame collectively define a plurality of open cells of the frame. At the inflow end of the frame 12, struts 22, struts 24, and struts 34 define a lower row of cells defining openings 36. The second, third, and fourth rows of struts 24, 26, and 28 define two intermediate rows of cells defining openings 38. The fourth and fifth rows of struts 28 and 32, along with frame portions 30 and struts 31, define an upper row of cells defining openings 40. The openings 40 are relatively large and are sized to allow portions of the leaflet structure 14 to protrude, or bulge, into and/or through the openings 40 when the frame 12 is crimped in order to minimize the crimping profile.

[085] As best shown in FIG. 7, the lower end of the strut 31 is connected to two struts 28 at a node or junction 44, and the upper end of the strut 31 is connected to two struts 32 at a node or junction 46. The strut 31 can have a thickness S1 that is less than the thicknesses S2 of the junctions 44, 46. The junctions 44, 46, along with junctions 64, prevent full closure of openings 40. FIG. 14 shows the prosthetic valve 10 crimped on a balloon catheter. As can be seen, the geometry of the struts 31, and junctions 44, 46, and 64 assists in creating enough space in openings 40 in the collapsed configuration to allow portions of the prosthetic leaflets to protrude or bulge outwardly through openings. This allows the prosthetic valve to be crimped to a relatively smaller diameter than if all of the leaflet material were constrained within the crimped frame.

[086] The frame 12 is configured to reduce, to prevent, or to minimize possible over-expansion of the prosthetic valve at a predetermined balloon pressure, especially at the outflow end portion of the frame, which supports the leaflet structure 14. In one aspect, the frame is configured to have relatively larger angles 42a, 42b, 42c, 42d, 42e between struts, as shown in FIG. 5. The larger the angle, the greater the force required to open (expand) the frame. As such, the angles between the struts of the frame can be selected to limit radial expansion of the frame at a given opening pressure (e.g., inflation pressure of the balloon). In particular embodiments, these angles are at least 110 degrees or greater when the frame is expanded to its functional size, and even more particularly these angles are up to about 120 degrees when the frame is expanded to its functional size.

[087] In addition, the inflow and outflow ends of a frame generally tend to over-expand more so than the middle portion of the frame due to the “dog-boning” effect of the balloon used to expand the prosthetic valve. To protect against over-expansion of the leaflet structure

14, the leaflet structure desirably is secured to the frame 12 below the upper row of struts 32, as best shown in FIG. 1. Thus, in the event that the outflow end of the frame is over-expanded, the leaflet structure is positioned at a level below where over-expansion is likely to occur, thereby protecting the leaflet structure from over-expansion.

[088] In a known prosthetic valve construction, portions of the leaflets can protrude longitudinally beyond the outflow end of the frame when the prosthetic valve is crimped if the leaflets are mounted too close to the distal end of the frame. If the delivery catheter on which the crimped prosthetic valve is mounted includes a pushing mechanism or stop member that pushes against or abuts the outflow end of the prosthetic valve (for example, to maintain the position of the crimped prosthetic valve on the delivery catheter), the pushing member or stop member can damage the portions of the exposed leaflets that extend beyond the outflow end of the frame. Another benefit of mounting the leaflets at a location spaced away from the outflow end of the frame is that when the prosthetic valve is crimped on a delivery catheter, the outflow end of the frame 12 rather than the leaflets 41 is the proximal-most component of the prosthetic valve 10. As such, if the delivery catheter includes a pushing mechanism or stop member that pushes against or abuts the outflow end of the prosthetic valve, the pushing mechanism or stop member contacts the outflow end of the frame, and not leaflets 41, so as to avoid damage to the leaflets.

[089] Also, as can be seen in FIG. 5, the openings 36 of the lowermost row of openings in the frame are relatively larger than the openings 38 of the two intermediate rows of openings. This allows the frame, when crimped, to assume an overall tapered shape that tapers from a maximum diameter at the outflow end of the prosthetic valve to a minimum diameter at the inflow end of the prosthetic valve. When crimped, the frame 12 has a reduced diameter region extending along a portion of the frame adjacent the inflow end of the frame that generally corresponds to the region of the frame covered by the outer skirt 18. In some embodiments, the reduced diameter region is reduced compared to the diameter of the upper portion of the frame (which is not covered by the outer skirt) such that the outer skirt 18 does not increase the overall crimp profile of the prosthetic valve. When the prosthetic valve is deployed, the frame can expand to the generally cylindrical shape shown in FIG. 4. In one example, the frame of a 26-mm prosthetic valve, when crimped, had a first diameter of 14

French at the outflow end of the prosthetic valve and a second diameter of 12 French at the inflow end of the prosthetic valve.

[090] The main functions of the inner skirt 16 are to assist in securing the valvular structure 14 to the frame 12 and to assist in forming a good seal between the prosthetic valve and the native annulus by blocking the flow of blood through the open cells of the frame 12 below the lower edge of the leaflets. The inner skirt 16 desirably comprises a tough, tear resistant material such as polyethylene terephthalate (PET), although various other synthetic materials or natural materials (e.g., pericardial tissue) can be used. The thickness of the skirt desirably is less than about 0.15 mm (about 6 mil), and desirably less than about 0.1 mm (about 4 mil), and even more desirably about 0.05 mm (about 2 mil). In particular embodiments, the skirt 16 can have a variable thickness, for example, the skirt can be thicker at least one of its edges than at its center. In one implementation, the skirt 16 can comprise a PET skirt having a thickness of about 0.07 mm at its edges and about 0.06 mm at its center. The thinner skirt can provide for better crimping performances while still providing good perivalvular sealing.

[091] The skirt 16 can be secured to the inside of frame 12 via sutures 70, as shown in FIG. 22. Valvular structure 14 can be attached to the skirt via one or more reinforcing sealing members 72 (which collectively can form a sleeve), for example thin, PET reinforcing sealing members, discussed below, which enables a secure suturing and protects the pericardial tissue of the leaflet structure from tears. Valvular structure 14 can be sandwiched between skirt 16 and the thin PET sealing members 72 as shown in FIG. 21. Sutures 154, which secure the PET strip and the leaflet structure 14 to skirt 16, can be any suitable suture, such as Ethibond Excel® PET suture (Johnson & Johnson, New Brunswick, New Jersey). Sutures 154 desirably track the curvature of the bottom edge of leaflet structure 14, as described in more detail below.

[092] Known fabric skirts may comprise a weave of warp and weft fibers that extend perpendicularly to each other and with one set of the fibers extending longitudinally between the upper and lower edges of the skirt. When the metal frame to which the fabric skirt is secured is radially compressed, the overall axial length of the frame increases. Unfortunately, a fabric skirt with limited elasticity cannot elongate along with the frame and therefore tends to deform the struts of the frame and to prevent uniform crimping.

[093] Referring to FIG. 12, in contrast to known fabric skirts, the skirt 16 desirably is woven from a first set of fibers, or yarns or strands, 78 and a second set of fibers, or yarns or strands, 80, both of which are non-perpendicular to the upper edge 82 and the lower edge 84 of the skirt. In particular embodiments, the first set of fibers 78 and the second set of fibers 80 extend at angles of about 45 degrees (e.g., 15-75 degrees or 30-60 degrees) relative to the upper and lower edges 82, 84. For example, the skirt 16 can be formed by weaving the fibers at 45 degree angles relative to the upper and lower edges of the fabric. Alternatively, the skirt 16 can be diagonally cut (cut on a bias) from a vertically woven fabric (where the fibers extend perpendicularly to the edges of the material) such that the fibers extend at 45 degree angles relative to the cut upper and lower edges of the skirt. As further shown in FIG. 12, the opposing short edges 86, 88 of the skirt desirably are non-perpendicular to the upper and lower edges 82, 84. For example, the short edges 86, 88 desirably extend at angles of about 45 degrees relative to the upper and lower edges and therefore are aligned with the first set of fibers 78. Therefore the overall general shape of the skirt is that of a rhomboid or parallelogram.

[094] FIG. 13 shows an example of a crimped prosthetic valve with a skirt having fibers that extend perpendicular to and/or longitudinally between the upper and lower edges of the skirt. During crimping, this fiber orientation can cause the struts to deform non-uniformly. Moreover, when crimped, the fabric tends to bunch or create bulges of excess material in certain locations, which limits the minimum crimping profile and prevents uniform crimping.

[095] FIGS. 15 and 16 show the inner skirt 16 after opposing short edge portions 90, 92 have been sewn together to form the annular shape of the skirt. As shown, the edge portion 90 can be placed in an overlapping relationship relative to the opposite edge portion 92, and the two edge portions can be sewn together with a diagonally extending suture line 94 that is parallel to short edges 86, 88. The upper edge portion of the inner skirt 16 can be formed with a plurality of projections 96 that define an undulating shape that generally follows the shape or contour of the fourth row of struts 28 immediately adjacent the lower ends of axial struts 31. In this manner, as best shown in FIG. 17, the upper edge of the inner skirt 16 can be tightly secured to struts 28 with sutures 70. The inner skirt 16 can also be formed with slits 98 to facilitate attachment of the skirt to the frame. Slits 98 are dimensioned so as to allow an upper edge portion of the inner skirt 16 to be partially wrapped around struts 28 and



to reduce stresses in the skirt during the attachment procedure. For example, in the illustrated embodiment, the inner skirt 16 is placed on the inside of frame 12 and an upper edge portion of the skirt is wrapped around the upper surfaces of struts 28 and secured in place with sutures 70. Wrapping the upper edge portion of the inner skirt 16 around struts 28 in this manner provides for a stronger and more durable attachment of the skirt to the frame. The inner skirt 16 can also be secured to the first, second, and/or third rows of struts 22, 24, and 26, respectively, with sutures 70.

[096] Referring again to FIG. 12, due to the angled orientation of the fibers relative to the upper and lower edges, the skirt can undergo greater elongation in the axial direction (*i.e.*, in a direction from the upper edge 82 to the lower edge 84).

[097] Thus, when the metal frame 12 is crimped (as shown in FIG. 14), the inner skirt 16 can elongate in the axial direction along with the frame and therefore provide a more uniform and predictable crimping profile. Each cell of the metal frame in the illustrated embodiment includes at least four angled struts that rotate towards the axial direction on crimping (*e.g.*, the angled struts become more aligned with the length of the frame). The angled struts of each cell function as a mechanism for rotating the fibers of the skirt in the same direction of the struts, allowing the skirt to elongate along the length of the struts. This allows for greater elongation of the skirt and avoids undesirable deformation of the struts when the prosthetic valve is crimped.

[098] In addition, the spacing between the woven fibers or yarns can be increased to facilitate elongation of the skirt in the axial direction. For example, for a PET inner skirt 16 formed from 20-denier yarn, the yarn density can be about 15% to about 30% lower than in a typical PET skirt. In some examples, the yarn spacing of the inner skirt 16 can be from about 60 yarns per cm (about 155 yarns per inch) to about 70 yarns per cm (about 180 yarns per inch), such as about 63 yarns per cm (about 160 yarns per inch), whereas in a typical PET skirt the yarn spacing can be from about 85 yarns per cm (about 217 yarns per inch) to about 97 yarns per cm (about 247 yarns per inch). The oblique edges 86, 88 promote a uniform and even distribution of the fabric material along inner circumference of the frame during crimping so as to reduce or minimize bunching of the fabric to facilitate uniform crimping to the smallest possible diameter. Additionally, cutting diagonal sutures in a vertical manner may leave loose fringes along the cut edges. The oblique edges 86, 88 help minimize this

from occurring. As noted above, FIG. 13 shows a crimped prosthetic valve with a typical skirt that has fibers that run perpendicularly to the upper and lower edges of the skirt. Compared to the construction of a typical skirt (e.g., FIG. 13), the construction of the inner skirt 16 (e.g., FIG. 14) avoids undesirable deformation of the frame struts and provides more uniform crimping of the frame.

[099] In alternative embodiments, the skirt can be formed from woven elastic fibers that can stretch in the axial direction during crimping of the prosthetic valve. The warp and weft fibers can run perpendicularly and parallel to the upper and lower edges of the skirt, or alternatively, they can extend at angles between 0 and 90 degrees relative to the upper and lower edges of the skirt, as described above.

[0100] The inner skirt 16 can be sutured to the frame 12 at locations away from the suture line 154 so that the skirt can be more pliable in that area. This configuration can avoid stress concentrations at the suture line 154, which attaches the lower edges of the leaflets to the inner skirt 16.

[0101] As noted above, the leaflet structure 14 in the illustrated embodiment includes three flexible leaflets 41 (although a greater or a smaller number of leaflets can be used). Additional information regarding the leaflets, as well as additional information regarding skirt material, can be found, for example, in U.S. Patent Application No. 14/704,861, filed May 05, 2015, which is incorporated by reference in its entirety.

[0102] The leaflets 41 can be secured to one another at their adjacent sides to form commissures 122 of the leaflet structure. A plurality of flexible connectors 124 (one of which is shown in FIG. 18) can be used to interconnect pairs of adjacent sides of the leaflets and to mount the leaflets to the commissure window frame portions 30 (FIG. 5).

[0103] FIG. 18 shows the adjacent sides of two leaflets 41 interconnected by a flexible connector 124. Three leaflets 41 can be secured to each other side-to-side using three flexible connectors 124, as shown in FIG. 19. Additional information regarding connecting the leaflets to each other, as well as connecting the leaflets to the frame, can be found, for example, in U.S. Patent Application Publication No. 2012/0123529, which is incorporated by reference herein in its entirety.

[0104] As noted above, the inner skirt 16 can be used to assist in suturing the leaflet structure 14 to the frame. The inner skirt 16 can have an undulating temporary marking suture to guide the attachment of the lower edges of each leaflet 41. The inner skirt 16 itself can be sutured to the struts of the frame 12 using sutures 70, as noted above, before securing the leaflet structure 14 to the skirt 16. The struts that intersect the marking suture desirably are not attached to the inner skirt 16. This allows the inner skirt 16 to be more pliable in the areas not secured to the frame and minimizes stress concentrations along the suture line that secures the lower edges of the leaflets to the skirt. As noted above, when the skirt is secured to the frame, the fibers 78, 80 of the skirt (see FIG. 12) generally align with the angled struts of the frame to promote uniform crimping and expansion of the frame.

[0105] FIG. 20 shows one specific approach for securing the commissure portions 122 of the leaflet structure 14 to the commissure window frame portions 30 of the frame. The flexible connector 124 (FIG. 19) securing two adjacent sides of two leaflets is folded widthwise and the upper tab portions 112 are folded downwardly against the flexible connector. Each upper tab portion 112 is creased lengthwise (vertically) to assume an L-shape having an inner portion 142 folded against the inner surface of the leaflet and an outer portion 144 folded against the connector 124. The outer portion 144 can then be sutured to the connector 124 along a suture line 146. Next, the commissure tab assembly is inserted through the commissure window 20 of a corresponding window frame portion 30, and the folds outside of the window frame portion 30 can be sutured to portions 144.

[0106] FIG. 20 also shows that the folded down upper tab portions 112 can form a double layer of leaflet material at the commissures. The inner portions 142 of the upper tab portions 112 are positioned flat against layers of the two leaflets 41 forming the commissures, such that each commissure comprises four layers of leaflet material just inside of the window frames 30. This four-layered portion of the commissures can be more resistant to bending, or articulating, than the portion of the leaflets 41 just radially inward from the relatively more-rigid four-layered portion. This causes the leaflets 41 to articulate primarily at inner edges 143 of the folded-down inner portions 142 in response to blood flowing through the prosthetic valve during operation within the body, as opposed to articulating about or proximal to the axial struts of the window frames 30. Because the leaflets articulate at a location spaced radially inwardly from the window frames 30, the leaflets can avoid contact

with and damage from the frame. However, under high forces, the four layered portion of the commissures can splay apart about a longitudinal axis adjacent to the window frame 30, with each inner portion 142 folding out against the respective outer portion 144. For example, this can occur when the prosthetic valve 10 is compressed and mounted onto a delivery shaft, allowing for a smaller crimped diameter. The four-layered portion of the commissures can also splay apart about the longitudinal axis when the balloon catheter is inflated during expansion of the prosthetic valve, which can relieve some of the pressure on the commissures caused by the balloon, reducing potential damage to the commissures during expansion.

[0107] After all three commissure tab assemblies are secured to respective window frame portions 30, the lower edges of the leaflets 41 between the commissure tab assemblies can be sutured to the inner skirt 16. For example, as shown in FIG. 21, each leaflet 41 can be sutured to the inner skirt 16 along suture line 154 using, for example, Ethibond Excel® PET thread. The sutures can be in-and-out sutures extending through each leaflet 41, the inner skirt 16, and each reinforcing strip 72. Each leaflet 41 and respective reinforcing strip 72 can be sewn separately to the inner skirt 16. In this manner, the lower edges of the leaflets are secured to the frame 12 via the inner skirt 16. As shown in FIG. 21, the leaflets can be further secured to the skirt with blanket sutures 156 that extend through each reinforcing strip 72, leaflet 41 and the inner skirt 16 while looping around the edges of the reinforcing sealing members 72 and leaflets 41. The blanket sutures 156 can be formed from PTFE suture material. FIG. 22 shows a side view of the frame 12, leaflet structure 14 and the inner skirt 16 after securing the leaflet structure 14 and the inner skirt 16 to the frame 12 and the leaflet structure 14 to the inner skirt 16.

[0108] FIG. 23 shows a flattened view of the outer skirt 18 prior to its attachment to the frame 12. The outer skirt 18 can be laser cut or otherwise formed from a strong, durable material such as PET or various other suitable synthetic or natural materials configured to restrict and/or prevent blood-flow therethrough. The outer skirt 18 can comprise a substantially straight lower edge 160 and an upper edge portion 162 defining a plurality of alternating projections 164 and notches 166, or castellations. The outer skirt 18 can also comprise a plurality of openings 167 (e.g., 12 in the illustrated embodiment) disposed on an intermediate portion 169 (i.e., the portion between the lower edge 160 and the upper edge portion 162) of the outer skirt 18. The openings 167 are spaced from the lower edge 160 and

the upper edge portion 162 such that the material of the outer skirt 18 separates the openings 167 from the lower edge 160 and the upper edge portion 162.

[0109] As best shown in FIG. 3, a lower edge portion 174 of the outer skirt 18 can be wrapped around the inflow end 15 of the frame 12, and the lower edge 160 of the outer skirt 18 can be attached to the lower edge 84 of the inner skirt 16 and/or the frame 12 at the inflow end of the prosthetic valve 10. In some embodiments, the outer skirt 18 can be attached to the inner skirt 16, for example, with sutures or a suitable adhesive.

[0110] In lieu of or in addition to sutures, the outer skirt 18 can be attached to the inner skirt 16, for example, by ultrasonic welding. Ultrasonic welding can provide several significant advantages. For example, ultrasonic welding can be relatively less time consuming and less expensive compared to suturing, while also providing improved strength.

[0111] As shown in FIG. 1, each projection 164 of the outer skirt 18 can be attached to the third row III of struts 26 (FIG. 5) of the frame 12. The projections 164 can, for example, be wrapped over respective struts 26 of row III and secured with sutures 168.

[0112] As can be seen in FIGS. 1-3, the outer skirt 18 is secured to the frame 12 such that when the frame is in its expanded configuration (e.g., when deployed in a subject), there is excess material between the lower edge 160 and the upper edge portion 162 that does not lie flat against the outer surface of the frame 12. The outer skirt 18 can be secured directly to frame 12 and/or indirectly to frame 12, for example, by securing the outer skirt 18 to the inner skirt 16, which is directly secured to the frame 12. In the expanded configuration of the prosthetic valve, the distance between the upper and lower attachment points of the outer skirt 18 decreases (foreshortens), resulting in radial expansion of the outer skirt 18.

Additionally, the excess material between the lower and upper edges of the outer skirt 18 allows the frame 12 to elongate axially when crimped without any resistance from the outer skirt 18.

[0113] The outer skirt 18 can comprise an axial length or height  $H_s$ , where  $H_s$  is the height of the outer skirt 18, less the lower edge portion 174 that is wrapped around the inflow end 15 of the frame 12, as best shown in FIGS. 1, 3, and 23. In some embodiments, the height  $H_s$  can be substantially the same as the axial length between the upper attachment point of the outer skirt 18 to the frame 12 and the inflow end 15 of the frame 12 when the frame 12 is fully

crimped. In such embodiments, when the frame 12 is fully crimped, the outer skirt 18 can lie flat against the outer surface of the frame 12. In other embodiments, the height  $H_s$  of the outer skirt 18 can exceed the axial length between the upper attachment point of the outer skirt 18 to the frame 12 and the inflow end 15 of the frame 12 when the frame 12 is fully crimped. In such embodiments, the outer skirt 18 can comprise a plurality of creases 170 (e.g., twelve in the illustrated embodiment).

[0114] As best shown in FIG. 3, the creases 170 can extend axially from the lower edge 160 toward the intermediate portion 169 of the outer skirt 18. The creases 170 can be aligned circumferentially with respective projections 164, and the outer skirt 18 can be oriented with respect to the frame 12 such that the creases 170 are circumferentially aligned between a respective pair of apices 22a (FIG. 5) that are formed by the struts 22 at the inflow end 15 of the frame 12. For example, the creases 170 can be circumferentially aligned along a respective vertical line 172 (FIGS. 2 and 5) that is parallel to the longitudinal axis of the frame 12 and bisects the frame 12 at a location equidistant from each apex 22a of a respective pair of apices 22a. In this manner, the creases 170 can cause excess material of the outer skirt 18 to retract radially inwardly between the apices 22a and into the inflow end 15 of the frame 12 when the prosthetic valve 10 is crimped from the expanded configuration. As best shown in FIG. 2, each crease 170 can be circumferentially aligned with a respective opening 167 and projection 164 along a respective line 172.

[0115] In lieu of or in addition to the creases 170 (FIG.1), the outer skirt 18 can be attached and/or positioned relative to the frame 12 such that the lower edge 160 of the outer skirt 18 contacts the inflow end 15 of the frame 12 at locations (e.g., apices 22a) that are offset relative to locations (e.g., the junctions 64) at which the upper edge portion 162 of the outer skirt 18 contacts the outflow end 19 of the frame 12. Configuring the outer skirt 18 and the frame 12 in this manner can cause excess material of the outer skirt 18 to retract inwardly between the apices 22a of the frame 12 when the prosthetic valve 10 is crimped from the expanded configuration to the collapsed configuration.

[0116] This configuration also spreads the deformed fabric of the collapsed outer skirt 18 over a relatively large distance, which reduces the amount of outer skirt material per cross sectional area and flattens the outer skirt 18 around the crimped frame 12, thus reducing the crimped profile of the prosthetic heart valve 10. Reducing the crimped profile of the

prosthetic heart valve 10 can reduce the push force necessary to move the prosthetic heart valve 10 relative to a patient's vasculature or a delivery cylinder of a delivery apparatus. It can also reduce the compression force that is exerted upon the leaflets 41 to achieve a particular crimp profile, which can reduce and/or eliminate damage to the leaflets 41 caused by over compressing the leaflets 41 during crimping and/or delivery of the prosthetic heart valve 10 to an implantation location.

[0117] Retracting the excess material within the frame 12 below the leaflets 41 when the prosthetic valve 10 is crimped advantageously allows the prosthetic valve 10 to have a relatively large outer skirt 18, which can significantly reduce perivalvular leakage, while minimizing the radial crimp profile of the prosthetic valve 10. For example, the height  $H_s$  of the outer skirt 18 can be about 9 mm to about 25 mm or about 13 mm to about 20 mm, with about 19 mm being a specific example. The height  $H_f$  of the frame 12 in the radially expanded state can be about 12 mm to about 27 mm or about 15 mm to about 23 mm, with about 20 mm being a specific example. The outer skirt 18 can be sized such that a ratio  $H_s:H_f$ , where  $H_s$  (FIG. 23) is the height of the outer skirt 18, and  $H_f$  (FIG. 5) is the height of the frame 12 in the expanded state, can be between about 0.75 to about 0.95. In some embodiments, the ratio  $H_s:H_f$  can be between about 0.80 to about 0.90 or about 0.84 to about 0.87. In one particular embodiment, the ratio  $H_s:H_f$  can be 0.86.

[0118] Providing a relatively larger outer skirt 18 allows the prosthetic valve 10 to be positioned in a wider range of positions relative to the native annulus, while providing adequate perivalvular sealing. This improved range can make the prosthetic valve 10 easier to position during the implantation procedure. It also allows the prosthetic valve to adapt to greater variation in native annulus anatomy.

[0119] In addition, the creases 170 can assist the outer skirt 18 in collapsing in a predetermined, uniform manner when the prosthetic valve is crimped. This uniformity can prevent the outer skirt 18 from bunching or wadding when crimping and/or loading the prosthetic valve 10 in a delivery apparatus, which in turn allows the outer skirt 18 to expand to its functional state more quickly and consistently when deploying the prosthetic valve 10, as further described below.

[0120] Each crease 170 can be formed, for example, by overlapping adjacent portions of the outer skirt 18 and securing them together. The creases can then be secured in the overlapped state, for example, by sutures, ultrasonic welding, and/or an adhesive. The creases 170 can be referred to as permanent creases in that the creases are retained when the prosthetic valve 10 is in a radially compressed state and a radially expanded state.

[0121] As best shown in FIG. 23, the openings 167 can be laterally (circumferentially in FIGS. 1-3) spaced apart relative to adjacent openings 167 and be laterally (circumferentially in FIGS. 1-3) aligned with a respective projection 164. The openings 167 can also be circumferentially aligned with respective creases 170, as best shown in FIGS. 1 and 3. For example, the projections 164, the openings 167, and the creases 170 can be aligned along the respective vertical lines 172, as best shown in FIG. 2. Aligning the openings 167 and the creases 170 can, for example, allow blood to quickly enter, and thus expand, the overlapped portions of the outer skirt 18 when the prosthetic valve is initially deployed, as further described below.

[0122] The openings 167 can also advantageously allow back-flowing blood (e.g., retrograde blood) to enter the outer skirt 18 from a different angle or direction than the notches 166, thus improving how quickly the outer skirt 18 initially expands and improving perivalvular sealing. The openings 167 can be provided in lieu of or in addition to the notches 166.

[0123] The openings 167 can comprise various shapes. For example, the openings 167 can comprise a tear-drop shape, as shown in the illustrated embodiment. In other embodiments, the openings can be circular, elliptical, rectangular, etc.

[0124] The prosthetic valve 10 can be configured for and mounted on a suitable delivery apparatus for implantation in a subject. Several catheter-based delivery apparatuses are known; a non-limiting example of a suitable catheter-based delivery apparatus includes that disclosed in U.S. Patent Application Publication No. 2013/0030519, which is incorporated by reference herein in its entirety, and U.S. Patent Application Publication No. 2012/0123529.

[0125] To implant a plastically-expandable prosthetic valve 10 within a patient, the prosthetic valve 10 including the outer skirt 18 can be crimped on an elongated shaft 180 of a delivery apparatus, as best shown in FIG. 14. The prosthetic valve, together with the delivery



apparatus, can form a delivery assembly for implanting the prosthetic valve 10 in a patient's body. The shaft 180 comprises an inflatable balloon 182 for expanding the prosthetic valve within the body. With the balloon 182 deflated, the prosthetic valve 10 can then be percutaneously delivered to a desired implantation location (e.g., a native aortic valve region). Once the prosthetic valve 10 is delivered to the implantation site (e.g., the native aortic valve) inside the body, the prosthetic valve 10 can be radially expanded to its functional state by inflating the balloon 182.

[0126] When the prosthetic valve 10 expands, the notches 166 and the openings 167 allow blood to flow between the outer skirt 18 and the inner skirt 16. This blood-flow causes the excess fabric of the outer skirt 18 to further radially expand and separate from the inner skirt 16.

[0127] The expanded outer skirt 18 can fill-in gaps between the frame 12 and the surrounding native annulus to assist in forming a good, fluid-tight seal between the prosthetic valve 10 and the native annulus. The outer skirt 18 therefore cooperates with the inner skirt 16 to avoid perivalvular leakage after implantation of the prosthetic valve 10. In several embodiments, the prosthetic valve 10 comprising the outer skirt 18 that expands radially outwardly can have reduced perivalvular leakage when implanted in a subject compared to a similar prosthetic valve that has a relatively smaller outer skirt or lacks the outer skirt 18.

[0128] Alternatively, a self-expanding prosthetic valve 10 can be crimped to a radially collapsed configuration and restrained in the collapsed configuration by inserting the prosthetic valve 10, including the outer skirt 18, into a sheath or equivalent mechanism of a delivery catheter. The prosthetic valve 10 can then be percutaneously delivered to a desired implantation location. Once inside the body, the prosthetic valve 10 can be advanced from the delivery sheath, which allows the prosthetic valve to expand to its functional state.

[0129] When the outer skirt 18 is exposed from the delivery sheath, the notches 166 and the openings 167 allow blood to flow between the outer skirt 18 and the inner skirt 16. This blood-flow causes the excess fabric of the outer skirt 18 to further radially expand and separate from the inner skirt 16.

[0130] FIG. 24 shows an embodiment of a prosthetic heart valve 10 with a plurality of sealing members 250 positioned around the outer surface of the frame. The prosthetic heart

valve 10 in this embodiment can include any of the features described above with respect to FIGS. 1-23, and are not repeated here for sake of brevity. As discussed in detail below, the sealing members 250 can move or transform between an unfurled (desirably flattened) configuration extending along the outside of the frame when the prosthetic valve 10 is radially compressed for delivery (FIG. 26) and a coiled, functional configuration when the prosthetic valve 10 is radially expanded (FIGS. 24-25). The prosthetic valve 10 can have any number of sealing members 250, such as two, three, four or more. In particular embodiments, the prosthetic valve 10 includes 24 sealing members. In other embodiments, the prosthetic valve 10 can have a single sealing member 250.

[0131] The sealing members 250 can be coupled to the frame 12 and/or the inner skirt 16 of the prosthetic valve. The sealing members 250 can be secured directly to the frame 12 and/or indirectly to frame 12, for example, by securing the sealing members 250 to the inner skirt 16, which is directly secured to the frame 12 as described above. For example, the sealing members 250 can be attached to the frame 12 and/or the inner skirt 16 of a prosthetic heart valve 10 by sutures and/or ultrasonic welding. In some embodiments, the prosthetic valve 10 may have a plurality of sealing members 250 positioned around the outer surface of the annular frame 12 near the inflow end 15 of the annular frame 12, as depicted in FIG. 24.

[0132] In the embodiment of FIG. 24, the sealing members 250 replace the outer skirt 18. However, in alternative embodiments, a prosthetic valve 10 can include one or more sealing members 250 and an outer skirt, such as outer skirt 18. For example, the outer skirt can be positioned as shown in FIG. 1 and one or more sealing members 250 can be positioned above the outer skirt along the outflow end portion of the frame, or along the outer surface of the outer skirt, so as to at least partially overlap the outer skirt. In some embodiments, one or more sealing members 250 may be located between an outer skirt 18 and the annular frame 12. In some embodiments, an outer skirt 18 may have some features similar to the sealing members 250, such as the ability to assume a coiled conformation when a valve 10 is in a radially expanded configuration.

[0133] In the illustrated embodiment, an inflow edge portion (or inflow end portion) 252 of each sealing member 250 may be secured to or near the inflow end 15 of the annular frame 12, such as with sutures forming stitches that extend through the sealing member and around adjacent strut(s) of the frame. For example, an inflow edge portion 252 of a sealing member

250 may be secured to or near an apex 22a, strut 22, or substantially straight axially extending struts 34, such as with one or more sutures.

[0134] In some embodiments, an inflow edge portion 252 of a sealing member 250 can also be secured to the inner skirt 16 in lieu of or in addition to the frame. For example, an inflow edge portion 252 of a sealing member 250 can be secured to an outer surface of the inner skirt 16 facing away from the longitudinal axis of the valve 10, such as with sutures that extend through the sealing member 250, the inner skirt 16, and optionally around strut(s) of the frame.

[0135] In some embodiments, an inflow edge portion of the inner skirt wraps around the inflow end 15 of the frame 12 and extends at least partially along an outer surface of the frame 12, with the inflow edge portion being secured to the frame 12. The sealing members 250 can be secured to the inflow edge portion of the inner skirt 16 at locations on the inflow edge portion of the inner skirt that extend along an outer surface of the frame 12, such as with sutures.

[0136] All of the sealing members 250 can be located at the same height along the length of the frame. For example, in the illustrated embodiment, all of the sealing members are secured to the inflow end of the frame 12 and have the same overall length when in the unfurled configuration (FIG. 26). In alternative embodiments, the sealing members 250 can be secured to the frame 12 and/or the inner skirt 16 at staggered or varying heights. For example, half of the sealing members 250 can be secured to the lower row I of angled struts 22 and the other half can be secured to the second row II of circumferentially extending, angled struts 24. In another example, the sealing members 250 can alternate where they are attached to the frame such that one set of sealing members are attached at one height and another set of sealing members are attached at another height with each sealing members of the first set being positioned between two sealing members of the second set. Further, in alternative embodiments, the overall length of the sealing members 250 in the unfurled configuration can vary from one sealing member to the next.

[0137] In particular embodiments, as shown in FIGS. 24-25, the sealing members 250 can be configured to assume a coiled shape similar to a snail shell or a flat spiral coil configuration in a fully deployed configuration. As shown in FIG. 25, in the deployed

(coiled) configuration, an outflow edge portion (or outflow end portion) 256 of each sealing member 250 can be located in an innermost part of such a spiral shape, and the sealing member 250 may curve or wrap around itself to form the coiled shape. The coiled shape may be configured to bulge away from the frame 12, as shown in FIG 24. As best shown in FIG. 25, the sealing members can be configured to coil inwardly toward the frame, meaning that the outermost turn or layer of a coil initially curves radially away from the frame 12 and toward the outflow end of the frame starting from where it is connected to the inflow edge portion 252, and then curves radially back toward the frame (in the counterclockwise direction in FIG. 25) to form a flat spiral coil.

[0138] In alternative embodiments, the sealing members can be configured to coil outwardly from the frame, meaning that the outermost turn or layer of a coil initially extends along the outer surface of the frame starting from where it is connected to the inflow edge portion 252, curves away from the frame 12 and toward the inflow end of the frame, and then curves back toward the frame toward the outflow end of the frame (in the clockwise direction in FIG. 25) to form a flat spiral coil.

[0139] In the illustrated embodiment, each sealing member 250 can be positioned around the exterior of the frame 12 in such an orientation that opposing longitudinal side edges 258 of each sealing member 250 are configured to face the side edges 258 of adjacent sealing members 250. In the illustrated embodiment, the sealing members 250 are positioned relative to each other such that they are circumferentially spaced apart from each other around the outer surface of the frame 12 when the prosthetic valve is in the radially expanded configuration. As shown, the sealing members 250 are uniformly spaced apart at regular intervals around the circumference of the annular frame 12. In other embodiments, the spacing between adjacent sealing members 250 can vary around the frame.

[0140] When prosthetic valve is in the radially compressed configuration, the spacing between adjacent sealing members 250 decreases. In some embodiments, the side edges 258 are brought into contact with or into close proximity with side edges 258 of adjacent sealing members 250 when the prosthetic valve is in the radially compressed configuration.

[0141] In alternative embodiments, the sealing members 250 can be configured such that the side edges 258 of neighboring sealing members 250 touch each other or are otherwise very

close to each other when the prosthetic valve 10 is in the radially expanded configuration. In other embodiments, the sealing members 250 can partially overlap each other when the prosthetic valve is in the radially expanded configuration. For example, the sealing members can be sized and positioned relative to each other such that each sealing member partially overlaps an adjacent sealing member in the circumferential direction when the prosthetic valve is in the radially expanded configuration.

[0142] As shown in FIG. 24, the sealing members 250 may be positioned on the frame 12 in a configuration such that one coiled strip is positioned over and circumferentially centered on a respective vertical line 172 or 173. (*See* FIG 2). In another embodiment, the sealing members 250 can be circumferentially centered at respective locations between vertical lines 172, 173. In other embodiments, the sealing members 250 may be sized to extend over more than one respective vertical line 172 or 173 at the same time.

[0143] The sealing members 250 can extend axially from near the inflow end portion 15 of the valve 10 toward the outflow end portion 19 of the valve. Each of the plurality of sealing members 250 can be aligned circumferentially between a respective pair of apices 22a (FIG. 5) that are formed by the struts 22 at the inflow end 15 of the frame 12. For example, the sealing members 250 can be circumferentially aligned along respective vertical lines 172 (FIGS. 2 and 5) that are parallel to the longitudinal axis of the frame 12 and intersect the frame 12 at locations equidistant from respective pairs of apices 22a.

[0144] The sealing members 250 can be formed from any of various suitable materials described above with respect to the inner skirt 16 and the outer skirt 18, and include, without limitation, various fabric and non-fabric materials made of PET, PTFE, ePTFE, polyurethane, polyester, and/or other suitable materials configured to restrict and/or prevent blood-flow therethrough. In particular embodiments, the sealing members 250 are made of PET fabric.

[0145] The sealing members 250 can have any of various shapes. In the illustrated embodiment, the sealing members 250 are rectangular in shape when in a flattened configuration and have a constant width or substantially constant width along the length of the sealing member (the width being measured between side edges 258). In other embodiments, the sealing members 250 can be wider near their inflow edge portions 252, and narrower near their outflow edge portions 256. In other embodiments, the sealing members

250 can be narrower near their inflow edge portions 252, and wider near their outflow edge portions 256.

[0146] The coiled shaped of the sealing members can be formed using various techniques or mechanism. In some embodiments, a sealing member 250 can be formed by weaving a fabric in a coiled shape. In other embodiments, a sealing member 250 can be initially formed in a flattened configuration, such as by cutting a piece of fabric, and then shape-setting the material to a desired configuration (*e.g.*, the coiled shape shown in FIG. 24). In lieu of or in addition to these techniques, the sealing members 250 can comprise wires or threads formed from a shape-memory metal or alloy (*e.g.*, Nitinol) that are trained to assume a coiled shape when the prosthetic valve is radially expanded. For example, a sealing member 250 can include one or more shape-memory wires or threads that extend along the length of the sealing member and which can be woven into the fabric that forms sealing member.

[0147] In the illustrated embodiment, when each sealing member 250 is in a coiled configuration, the inflow end portion 252 can remain straight or flattened while the coiled portion is at a location between the first and second rows of struts of the frame. As shown in FIG. 24, the coiled portions of some of the sealing members are aligned with the centers of cells formed from the first and second rows of struts I, II of the frame, while others are aligned with the struts 34. In alternative embodiments, the sealing members 250 can be sized and shaped such that the coiled portions are located at other locations along the length of the frame, such as between the second and third rows of struts II, III, or between the third and fourth rows of struts III, IV.

[0148] In some embodiments, the position of the coiled portions of the sealing members along the height of the frame can vary from one sealing member to the next. In one embodiment, for example, all of the sealing members 250 can have the same overall length in the unfurled configuration (FIG. 26) and the inflow end portions 252 can be connected to the same location on the frame (*e.g.*, the inflow end of the frame), but the portion of each sealing member that forms the coil can vary from one sealing member to the next. For example, some sealing members can form coils located closer to the inflow end of the frame and some sealing members can form coils located closer to the outflow end of the frame.

[0149] In particular embodiments, the prosthetic valve 10 can further comprise a plurality of tethers 260 to facilitate unfurling of the sealing members when the prosthetic valve is radially compressed. Each tether 260 has a first end portion 262 (the inflow end portion of the tether in the illustrated embodiment) connected to a respective sealing member 250 and a second end portion 266 (the outflow end portion of the tether in the illustrated embodiment) connected to the frame 12 or to another component of the prosthetic valve at a location axially spaced from the sealing member. In this manner, each tether 260 is configured to apply an axially directed force to a respective sealing member 250 upon radial compression of the prosthetic valve due to the axial elongation of the frame 12. The axial force applied to sealing member facilitates unfurling of the sealing member to an unfurled configuration (FIG. 26), as further described below.

[0150] As best shown in FIGS. 24 and 25, the first end portion 262 of each tether 260 can be secured to a respective sealing member 250 at or near an outflow edge portion 256 of the sealing member 250. Alternatively, the first end portion 262 of each tether 260 can be secured to a respective sealing member 250 at an intermediate portion 254 of the sealing member 250. The second end portions 266 of the tethers 260 can be secured to the frame 12 (or another component of the prosthetic valve) at any convenient locations axially spaced from the outflow edge portions 256 of the sealing members 250 when the sealing members are in their unfurled configuration. (FIG. 26). For example, instead of being secured to the frame, the second end portions 266 can be connected to the inner skirt 16 at locations axially spaced from the outflow edge portions 256 of the sealing members 250 when the sealing members are in their unfurled configuration (in which case the inner skirt 16 extends closer to the outflow end of the frame 12 than the outflow ends of the sealing members in their unfurled configuration).

[0151] In particular embodiments, the second end portion 266 of each tether 260 can be secured at or near the outflow end 19 of the annular frame 12. In the illustrated embodiment, for example, the second end portions 266 of the tethers 260 are secured at or near the apices 270 of the frame at the outflow end (the convergence of the upper ends of two angled struts 32). Alternatively, the second end portions 266 of the tethers 260 can be secured at or near the convergence of the lower ends of two angled struts 32. The convergence of the lower

ends of two angled struts 32 may be either at or near a node or junction 46 or at or near the axially extending window frame portions 30.

[0152] In the illustrated embodiment, one tether 260 is secured to each sealing member. In alternative embodiments, more than one tether 260 can be secured to each sealing member 250, such as two, three, or more tethers, with each tether having a first end 262 secured to the same sealing member and a second end 266 secured to the frame or another component of the prosthetic valve. In some embodiments, more than one sealing member 250 can be secured to each tether 260.

[0153] The tethers 260 can be formed from any of various suitable materials such as PET, PTFE, ePTFE, polyurethane, polyester, and/or other suitable materials. In particular embodiments, the tethers 260 can be sutures (e.g., single filament sutures, or multi-filament sutures, such as multi-filament, braided sutures). In other embodiments, the tethers (or portions thereof) can be formed from less flexible materials. For example, the tethers 260 (or portions thereof) can be formed from polymers, metals, metal alloys, or combinations thereof. For example, the tethers can be in the form of wires made of such materials. In some embodiments, a portion of a tether 260, such as the second end portion 266 or the intermediate portion 264 may comprise a less flexible material, such as a polymer metal or metal alloy, such as stainless steel.

[0154] In alternative embodiments, the tethers 260 can be elastic such that they can stretch longitudinally when the prosthetic valve is radially compressed and contract longitudinally when the prosthetic valve is radially expanded. For example, the tethers can be made of any of various elastomers and can be provided in the form of elastomeric cords or bands.

[0155] The first and second end portions of the tethers 260 can be secured to the sealing members 250 and to the frame using a variety of techniques and/or mechanisms. In one implementation, for example, the tethers 260 comprise sutures and each suture can be stitched at one end to a respective sealing member 250 and tied off around a strut of the frame 12 at the other end of the suture. If the second (upper) end of the suture is secured to the inner skirt 16 (instead of being secured to the frame), the upper end of the suture can be stitched to the inner skirt. In other embodiments, the tethers 260 can be secured at their first



and second end portions using mechanical connectors, welding, adhesives, or combinations thereof.

[0156] As discussed above, the sealing members 250 can move or transform between an unfurled (desirably flattened or straightened) configuration when the prosthetic valve is radially compressed for delivery and a coiled, functional configuration when the prosthetic valve is radially expanded. When the prosthetic valve 10 is radially compressed, causing the frame 12 to elongate axially, each tether 260 applies a pulling force to a respective sealing member 250, which causes the sealing member to unfurl along the outer surface of the frame. The tethers desirably have a length selected such that they are placed in tension when the frame is radially compressed to help keep the sealing members in a flattened or substantially flattened configuration against the frame until the prosthetic valve is expanded. Also, in the unfurled configuration, the sealing members are desirably straight or substantially straight along their length, but may be curved in the direction of their width to conform to the outer surface of the frame.

[0157] When the prosthetic valve 10 is radially expanded at a desired implantation location within the body (*e.g.*, within the native aortic valve), tension on the tethers 260 decreases and the sealing members 250 can revert to their coiled shape. As discussed above, the sealing members can be shape-set such that they “self-expand” and move to their coiled shape under their own resiliency in the absence of pulling forces from the tethers. In some embodiments, as discussed above, the sealing members 250 can include Nitinol threads or wires (or threads or wires made of other types of shape memory alloys or materials) to facilitate movement of the sealing members to their coiled shape. Once sealing members move to the coiled configuration, they extend radially outwardly from the frame into contact with surrounding tissue. In this manner, the sealing members 250 can reduce and/or eliminate perivalvular leakage between the frame of the prosthetic heart valve 10 and the native annulus. As a result, the sealing members 250 can improve the functionality of the prosthetic heart valve 10 and thus improve functionality of a patient’s heart.

[0158] FIG. 33 shows an alternative way of connecting a tether 260 to the frame 12. In this embodiment, the first end portion 262 of the tether is connected to a respective sealing member 250, as in the embodiment of FIG. 25. Instead of being fixed to the outflow end of the frame, the tether 260 wraps or loops around the outflow end of the frame, extends along

the inner surface of the frame to the inflow end of the frame where the second end portion 266 of the tether 260 is secured to the frame, such as by tying off the second end portion 266 to one or more struts of the frame. Upon radial compression and corresponding foreshortening of the frame 12, the tether 260 can slide relative to the outflow end of the frame as the tether pulls the sealing member 250 toward the outflow end of the frame, causing sealing member to unfurl as previously described. Because the tether 260 passes over more struts of the frame as compared to FIG. 25, a greater pulling force can be applied to the sealing member. Alternatively, the second end portions 266 of the tethers 260 can be secured to another component of the prosthetic valve, such as to an inner skirt 16 of the prosthetic valve. For example, the second end portions 266 can be stitched to the inner skirt 16 or tied off around a portion of the inner skirt.

[0159] In another representative embodiment, an assembly for implanting a prosthetic heart valve 10 in a patient's body is provided. The assembly can comprise a delivery apparatus comprising an elongate shaft, and a prosthetic heart valve 10 mounted on the shaft in a radially collapsed configuration for delivery into the body. In particular embodiments, the delivery apparatus can be the delivery apparatus shown in FIG. 14, which includes a balloon catheter having a balloon 182 for deploying the prosthetic valve.

[0160] In another representative embodiment, a method of implanting the prosthetic heart valve 10 of FIG. 24 in a patient's body is provided. The method can comprise coupling the prosthetic heart valve 10 to the distal end of a delivery apparatus (such as by crimping the prosthetic valve on the balloon 182), inserting the distal end portion of the delivery apparatus and the prosthetic heart valve 10 into a patient's body, positioning the prosthetic heart valve 10 adjacent a native valve of the patient's heart (*e.g.*, the native aortic valve), and radially expanding the prosthetic heart valve 10 so that it engages the native valve. When the prosthetic heart valve is radially expanded, the sealing members 250 revert to the coiled configuration and engage surrounding tissue to help seal the prosthetic valve within the native annulus.

[0161] In the embodiments described above, the sealing members 250 are fixed at their inflow end portions and their outflow end portions are free to curl up to form the sealing coils upon expansion of the prosthetic valve. However, in alternative embodiments, the sealing members 250 can be fixed relative to the frame (*e.g.*, sutured to the frame, such as to the

struts at the outflow end of the frame) at their outflow end portions 256 and their inflow end portions 252 are free to curl up to form the sealing coils upon expansion of the prosthetic valve. In such embodiments, each tether 260 can have a first end portion fixed relative to the frame (*e.g.*, at the inflow end of the frame) and a second end portion fixed to the inflow end portion 252 of a respective sealing member.

[0162] FIGS. 27-32 show various implantation positions for the prosthetic heart valve 10 of FIG. 24. FIG. 27 shows the prosthetic heart valve 10 of FIG. 24 implanted in the native aortic valve of a patient.

[0163] FIG. 28 shows the prosthetic heart valve 10 of FIG. 24 implanted in the pulmonary artery of a patient for replacing or enhancing the function of a diseased pulmonary valve. Due to the variations in the size and shape of the native pulmonary valve and the pulmonary artery, the prosthetic valve 10 can be implanted within a radially expandable outer docking device 600. The docking device 600 can comprise a radially expandable and compressible annular stent 602 and a sealing member 604 that covers all or a portion of the stent and can extend across the inner surface and/or outer surface of the stent. The docking device 600 is configured to engage the inner wall of the pulmonary artery and can accommodate variations in patient anatomy. The docking device 600 also can compensate for the expanded prosthetic heart valve 10 being much smaller than the vessel in which it is placed. The docking device 600 also can be used to support a prosthetic valve in other areas of the patient's anatomy, such as, the inferior vena cava, superior vena cava, or the aorta. Further details of the docking device 600 and methods for implanting the docking device and a prosthetic valve are disclosed in U.S. Patent Publication No. 2017/0231756, which is incorporated herein by reference.

[0164] FIG. 29 shows the prosthetic heart valve 10 of FIG. 24 implanted in the native mitral valve of a patient using a docking device in the form of a helical anchor 700. The helical anchor 700 can include one or more coils 702 deployed in left atrium and one or more coils 704 deployed in the left ventricle and radially outside of the native mitral valve leaflets 706. When the prosthetic valve 10 is deployed within the native valve, the native leaflets are compressed or pinched between the prosthetic valve 10 and the anchor 700 to retain the prosthetic valve in place. Further details of the helical anchor 700 and methods for

implanting the anchor and a prosthetic valve are disclosed in U.S. Patent Publication No. 2018/0055628, which is incorporated herein by reference.

[0165] FIGS. 30 and 31 show a docking device 800 for a prosthetic heart valve, according to another embodiment. The docking device 800 can include a radially expandable and compressible frame 802 having an outer portion 804, an inner portion 806 disposed coaxially within one end portion of the outer portion 804, and a curved transition portion 808 extending between and connecting the inner portion 806 and the outer portion 804. The docking device 800 can further include a sealing member 810 extending over the inner surface of the inner portion 806, a portion of the outer surface of the outer portion 804 adjacent the inner portion 806, and the transition portion 808.

[0166] FIG. 32 shows the docking device 800 implanted in a vessel 820, which can be, for example, the inferior vena cava, superior vena cava, or the ascending aorta. As shown, the prosthetic valve 10 of FIG. 24 can be deployed within the inner portion 806 of the docking device 800. Similar to the docking device 600, the docking device 800 can compensate for the expanded prosthetic heart valve 10 being much smaller than the vessel in which it is placed. The docking device 800 is particularly suited for implanting a prosthetic valve in the inferior vena cava for replacing or enhancing the function of the native tricuspid valve. Further details of the docking device 800 and methods for implanting the docking device and a prosthetic valve are disclosed in U.S. Patent Publication No. 2018/0000615, which is incorporated herein by reference.

#### General Considerations

[0167] It should be understood that the disclosed embodiments can be adapted to deliver and implant prosthetic devices in any of the native annuluses of the heart (*e.g.*, the aortic, pulmonary, mitral, and tricuspid annuluses), and can be used with any of various approaches (*e.g.*, retrograde, antegrade, transseptal, transventricular, transatrial, etc.). The disclosed embodiments can also be used to implant prostheses in other lumens of the body. Further, in addition to prosthetic valves, the delivery assembly embodiments described herein can be adapted to deliver and implant various other prosthetic devices such as stents and/or other prosthetic repair devices.

[0168] For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The disclosed methods, apparatus, and systems should not be construed as being limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another. The methods, apparatus, and systems are not limited to any specific aspect or feature or combination thereof, nor do the disclosed embodiments require that any one or more specific advantages be present or problems be solved.

[0169] Although the operations of some of the disclosed embodiments are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth below. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be used in conjunction with other methods. Additionally, the description sometimes uses terms like “provide” or “achieve” to describe the disclosed methods. These terms are high-level abstractions of the actual operations that are performed. The actual operations that correspond to these terms may vary depending on the particular implementation and are readily discernible by one of ordinary skill in the art.

[0170] As used in this application and in the claims, the singular forms “a,” “an,” and “the” include the plural forms unless the context clearly dictates otherwise. Additionally, the term “includes” means “comprises.” Further, the terms “coupled” and “associated” generally mean electrically, electromagnetically, and/or physically (*e.g.*, mechanically or chemically) coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items absent specific contrary language.

[0171] As used herein, the term “proximal” refers to a position, direction, or portion of a device that is closer to the user and further away from the implantation site. As used herein, the term “distal” refers to a position, direction, or portion of a device that is further away from the user and closer to the implantation site. Thus, for example, proximal motion of a device is motion of the device toward the user, while distal motion of the device is motion of

the device away from the user. The terms “longitudinal” and “axial” refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined.

[0172] As used herein, the terms “integrally formed” and “unitary construction” refer to a construction that does not include any welds, fasteners, or other means for securing separately formed pieces of material to each other.

[0173] As used herein, the term “coupled” generally means physically coupled or linked and does not exclude the presence of intermediate elements between the coupled items absent specific contrary language.

[0174] As used herein, operations that occur “simultaneously” or “concurrently” occur generally at the same time as one another, although delays in the occurrence of one operation relative to the other due to, for example, spacing, play or backlash between components in a mechanical linkage such as threads, gears, etc., are expressly within the scope of the above terms, absent specific contrary language.

[0175] In view of the many possible embodiments to which the principles of the disclosed invention may be applied, it should be recognized that the illustrated embodiments are only preferred examples of the invention and should not be taken as limiting the scope of the invention. Rather, the scope of the invention is defined by the following claims. I therefore claim as my invention all that comes within the scope and spirit of these claims.

We claim:

1. An implantable prosthetic valve comprising:  
an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration;  
a valvular structure positioned within the frame; and  
a plurality of sealing members positioned around an outer surface of the frame;  
wherein the sealing members are configured to transform from an unfurled configuration extending along the outer surface of the frame when the frame is in the radially collapsed configuration to a coiled configuration when the frame is radially expanded to the radially expanded configuration.
2. The prosthetic valve of claim 1, further comprising a plurality of tethers, each having a first end portion connected to a respective sealing member and a second end portion connected to or extending around a location on the prosthetic valve axially spaced from the first end portion.
3. The prosthetic valve of claim 2, wherein the tethers are configured to apply axially directed forces to the sealing members that cause the sealing members to transform from the coiled configuration to the unfurled configuration when the frame is radially collapsed to the radially collapsed configuration.
4. The prosthetic valve of claim 3, wherein the tethers are configured to be placed in tension when the when the frame is radially collapsed to the radially collapsed configuration.
5. The prosthetic valve of any of claims 2-4, wherein the tethers comprise sutures.

6. The prosthetic valve of any of claims 2-5, wherein each sealing member has an inflow end portion retained at a fixed location relative to the frame and an outflow end portion connected to the first end portion of a respective tether.
7. The prosthetic valve of any of claims 2-6, wherein the second end portions of the tethers are secured to the frame.
8. The prosthetic valve of claim 7, wherein the second end portions of the tethers are secured to struts of the frame at the outflow end of the frame.
9. The prosthetic valve of claim 7, wherein the tethers loop around struts at the outflow end of the frame and extend inside of the frame toward the inflow end of the frame, and the second end portions of the tethers are secured to struts of the frame spaced from the outflow end of the frame.
10. The prosthetic valve of claim 9, wherein the second end portions of the tethers are secured to struts at the inflow end of the frame.
11. The prosthetic valve of any previous claim, wherein the sealing members are secured to the frame at discrete, spaced-apart locations.
12. The prosthetic valve of any previous claim, wherein each sealing member comprises a fabric that is shape-set to assume the coiled configuration.
13. The prosthetic valve of any previous claim, wherein the sealing members comprises Nitinol wires that are shape-set to assume the coiled configuration.
14. The prosthetic valve of any previous claim, wherein the sealing members lie in a flattened state along the outer surface of the frame when in the unfurled configuration.
15. An implantable prosthetic valve comprising:



an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration;

a valvular structure positioned within the frame; and

a plurality of sealing members positioned around an outer surface of the frame, each sealing member having an inflow end portion and an outflow end portion, wherein the inflow end portion is retained at a fixed location relative to the frame and the outflow end portion is free to move relative to the frame;

wherein the sealing members are configured to transform from an unfurled configuration extending along the outer surface of the frame when the frame is in the radially collapsed configuration to a coiled configuration when the frame is expanded to the radially expanded configuration;

wherein when the sealing members are in the unfurled configuration, the outflow end portions are at respective first locations relative to the outflow end of the frame, and when the sealing members are in the coiled configuration, the outflow end portions are at respective second locations closer to the inflow end of the frame than the first locations.

16. The prosthetic valve of claim 15, further comprising a plurality of tethers, each having a first end portion connected to the outflow end portion of a respective sealing member and a second end portion connected to or extending around a location on the prosthetic valve axially spaced from the first end portion.

17. The prosthetic valve of claim 16, wherein the tethers are configured to apply axially directed forces to the sealing members that cause the sealing members to transform from the coiled configuration to the unfurled configuration when the frame is radially collapsed to the radially collapsed configuration.

18. The prosthetic valve of any of claims 15-17, wherein the inflow end portions of the sealing members are fixed at the inflow end of the frame.

19. The prosthetic valve of any of claims 16-18, wherein the tethers are configured to be placed in tension when the when the frame is radially collapsed to the radially collapsed configuration.
20. The prosthetic valve of any of claims 16-19, wherein the tethers comprise sutures.
21. The prosthetic valve of any of claims 16-20, wherein the second end portions of the tethers are secured to the frame.
22. The prosthetic valve of claim 21, wherein the second end portions of the tethers are secured to struts of the frame at the outflow end of the frame.
23. The prosthetic valve of claim 21, wherein the tethers loop around struts at the outflow end of the frame and extend inside of the frame toward the inflow end of the frame, and the second end portions of the tethers are secured to struts of the frame spaced from the outflow end of the frame.
24. The prosthetic valve of claim 23, wherein the second end portions of the tethers are secured to struts at the inflow end of the frame.
25. The prosthetic valve of any of claims 15-24, wherein the sealing members are secured to the frame at discrete, spaced-apart locations.
26. The prosthetic valve of any of claims 15-25, wherein each sealing member comprises a fabric that is shape-set to assume the coiled configuration.
27. The prosthetic valve of any of claims 15-26, wherein the sealing members comprises Nitinol wires that are shape-set to assume the coiled configuration.
28. The prosthetic valve of any of claims 15-27, wherein the sealing members lie in a flattened state along the outer surface of the frame when in the unfurled configuration.

29. The prosthetic valve of any of claims 16-20 and 25-28, further comprising an inner skirt secured to an inner surface of the frame and wherein the second end portions of the tethers are secured to the inner skirt.

30. A method of implanting a prosthetic heart valve, comprising:  
inserting into a patient's body, a distal end portion of a delivery apparatus and a prosthetic heart valve that is in a radially compressed configuration and coupled to the distal end portion of the delivery apparatus, wherein the prosthetic valve comprises an annular frame, a valvular structure positioned within the frame, and a plurality of sealing members positioned around an outer surface of the frame, wherein the sealing members are in an unfurled configuration extending along an outer surface of the frame when the prosthetic heart valve is in the radially compressed configuration;

positioning the prosthetic heart valve adjacent a native valve of the patient's heart;  
and

radially expanding the prosthetic heart valve from the radially compressed configuration to a radially expanded configuration;

wherein expanding the prosthetic heart valve causes the sealing members to transform from the unfurled configuration to a coiled configuration engaging surrounding tissue of the native valve.

31. The method of claim 30, wherein:

the prosthetic heart valve further comprises a plurality of tethers, each having a first end portion connected to a respective sealing member and a second end portion connected to or extending around a location on the prosthetic valve axially spaced from the first end portion;

when the prosthetic heart valve is in the radially compressed configuration, the tethers are held in tension and retain the sealing members in the unfurled configuration; and

expanding the prosthetic heart valve decreases tension on the tethers, which allow the sealing members to transform to the coiled configuration.

32. The method of any of claims 30-31, wherein when the prosthetic heart valve is radially expanded and the sealing members transform from the unfurled configuration to the coiled configuration, free ends of the sealing members move from respective first locations to respective second locations closer to an inflow end of the frame than the first locations.

33. The method of any of claims 30-32, wherein the sealing members are shape-set to assume the coiled configuration.

34. The method of any of claims 30-33, wherein the tethers comprise sutures.

35. The method of any of claims 30-34, wherein each sealing member has an inflow end portion retained at a fixed location relative to the frame and an outflow end portion connected to the first end portion of a respective tether.

36. The method of any of claims 30-35, wherein the second end portions of the tethers are secured to the frame.

37. The method of claim 36, wherein the second end portions of the tethers are secured to struts of the frame at the outflow end of the frame.

38. The method of claim 36, wherein the tethers loop around struts at the outflow end of the frame and extend inside of the frame toward the inflow end of the frame, and the second end portions of the tethers are secured to struts of the frame spaced from the outflow end of the frame.

39. The method of claim 38, wherein the second end portions of the tethers are secured to struts at the inflow end of the frame.

40. The method of any of claims 30-39, wherein the sealing members are secured to the frame at discrete, spaced-apart locations.

41. The method of any of claims 30-40, wherein each sealing member comprises a fabric that is shape-set to assume the coiled configuration.

42. The method of any of claims 30-41, wherein the sealing members comprises Nitinol wires that are shape-set to assume the coiled configuration.

43. The method of any of claims 30-42, wherein the sealing members lie in a flattened state along the outer surface of the frame when in the unfurled configuration.

44. An implantable prosthetic valve comprising:  
an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration;  
a valvular structure positioned within the frame;  
a plurality of sealing members positioned around an outer surface of the frame; and  
a plurality of tethers, each having a first end portion connected to a respective sealing member and a second end portion connected to or extending around a location on the prosthetic valve axially spaced from the first end portion;  
wherein when the frame is radially collapsed from the radially expanded configuration to the radially collapsed configuration, each tether applies an axial force to a respective sealing member to transform the sealing member from a coiled configuration to an unfurled configuration, and wherein when the frame is radially expanded from the radially collapsed configuration to the radially expanded configuration, each tether decreases the applied axial force on a respective sealing member, thereby allowing the sealing member to transform from the unfurled configuration to the coiled configuration.

45. The prosthetic valve of claim 44, wherein the second end portions of the tethers are secured to struts of the frame at the outflow end of the frame.

46. The prosthetic valve of claim 44, wherein the tethers loop around struts at the outflow end of the frame and extend inside of the frame toward the inflow end of the frame,

and the second end portions of the tethers are secured to struts of the frame spaced from the outflow end of the frame.

47. The prosthetic valve of claim 46, wherein the second end portions of the tethers are secured to struts at the inflow end of the frame.

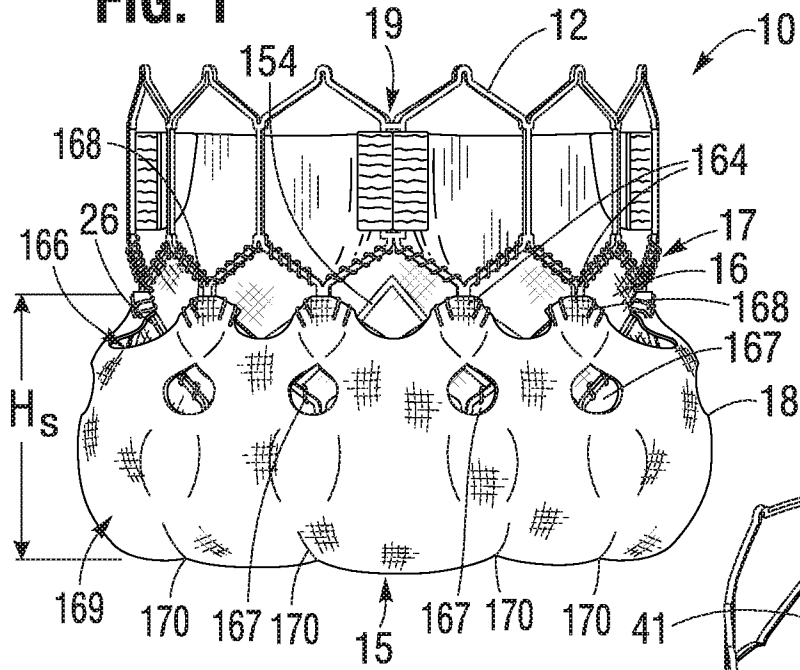
48. The prosthetic valve of claim 44, further comprising an inner skirt secured to an inner surface of the frame and wherein the second end portions of the tethers are secured to the inner skirt.

49. The prosthetic valve of any of claims 44-48, wherein each sealing member comprises a fabric that is shape-set to assume the coiled configuration.

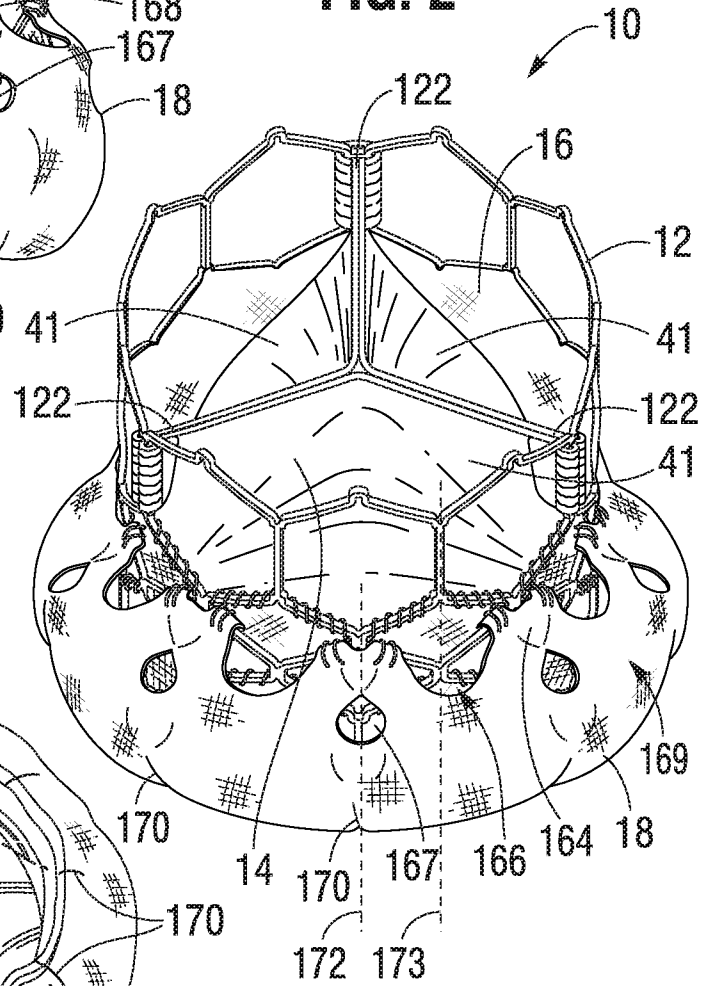
50. The prosthetic valve of any of claims 44-49, wherein the sealing members comprises Nitinol wires that are shape-set to assume the coiled configuration.

51. The prosthetic valve of any of claims 44-50, wherein the sealing members lie in a flattened state along the outer surface of the frame when in the unfurled configuration.

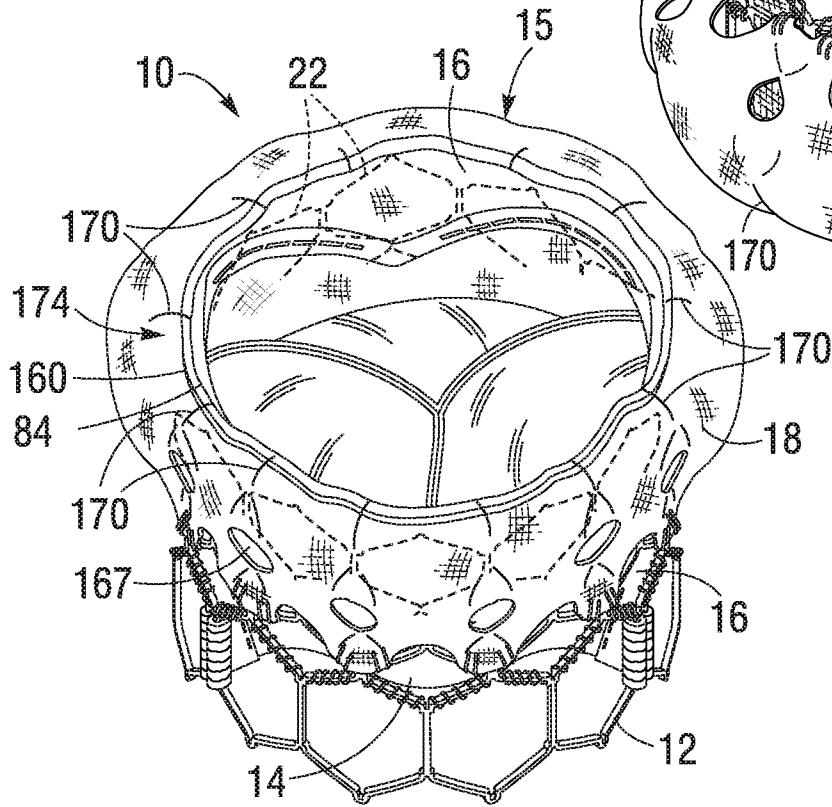
**FIG. 1**

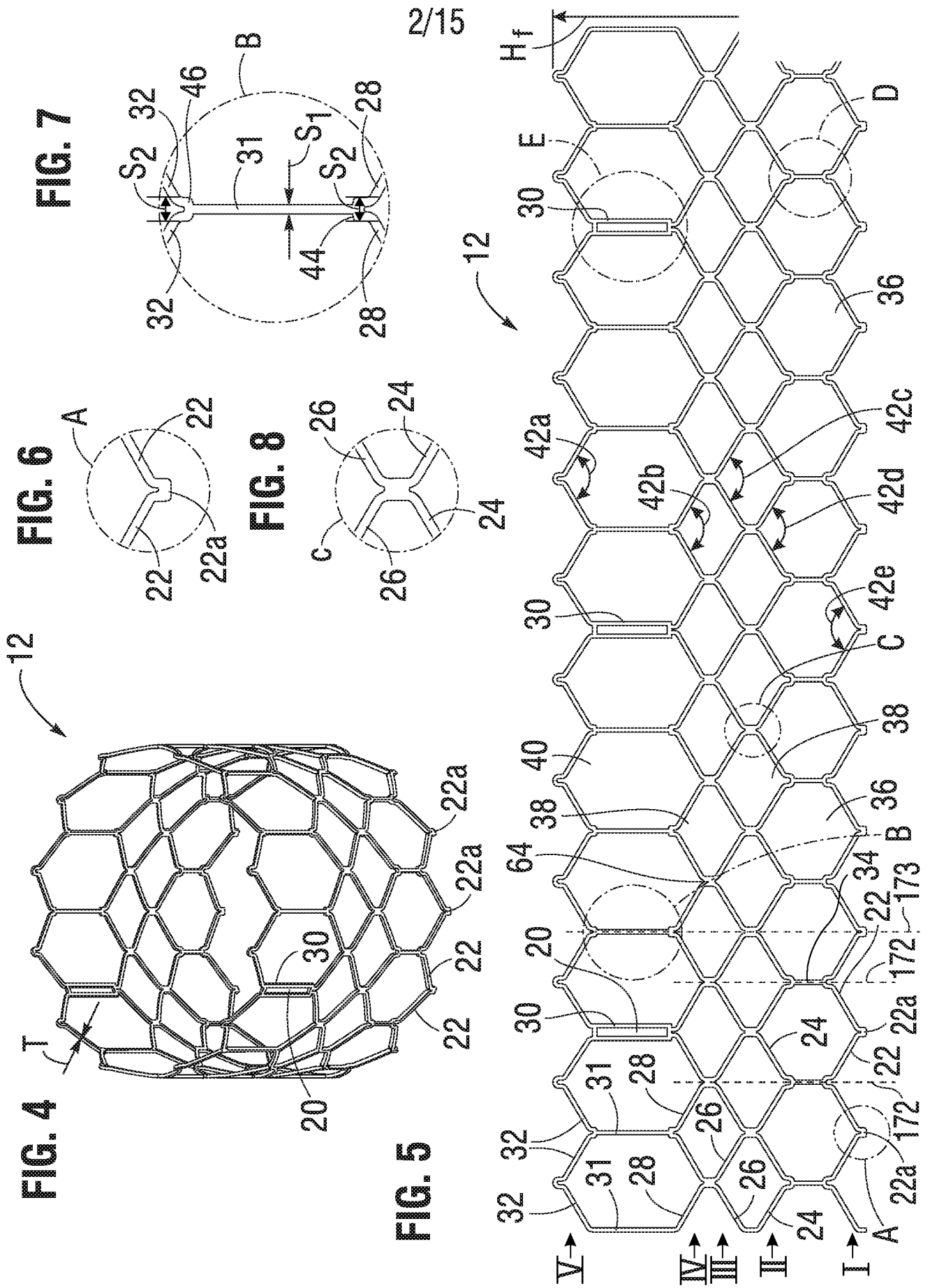


**FIG. 2**



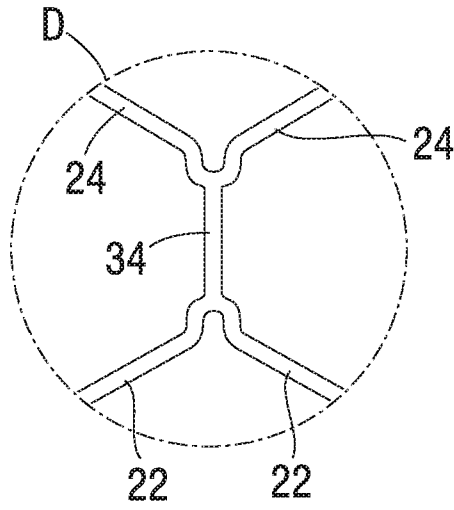
**FIG. 3**







**FIG. 9**



**FIG. 10**

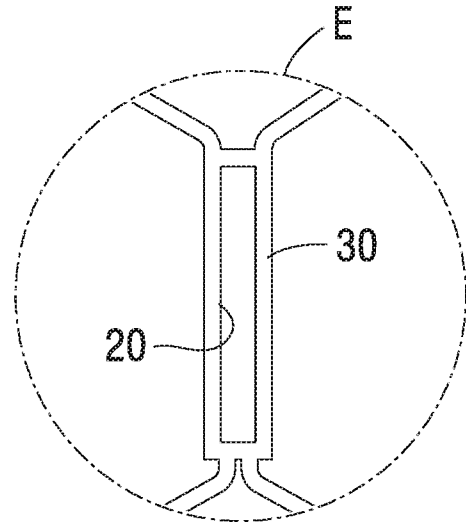


FIG. 11

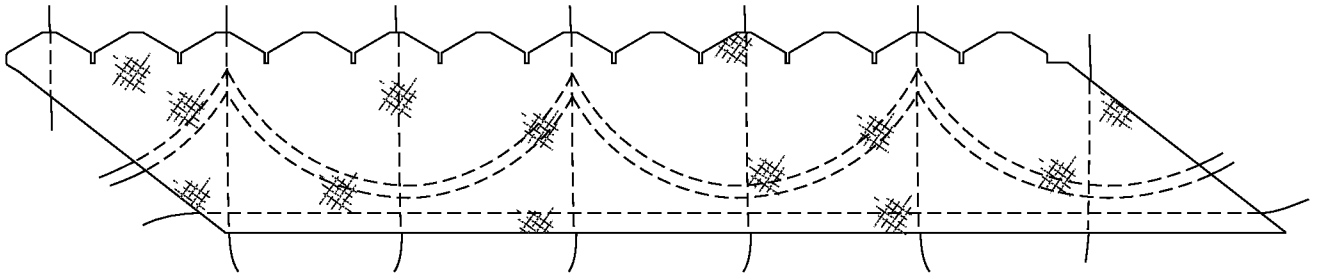


FIG. 12

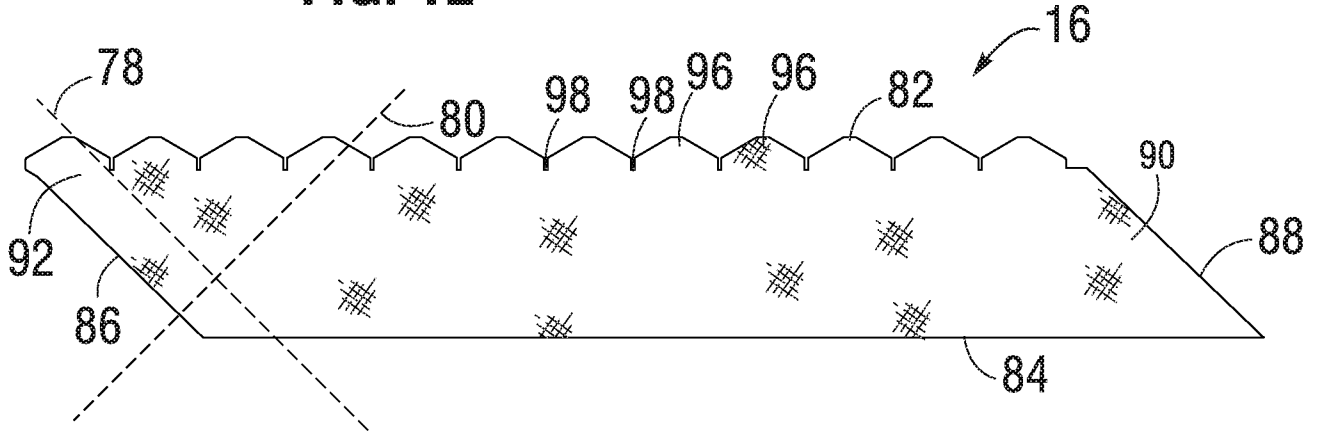


FIG. 13

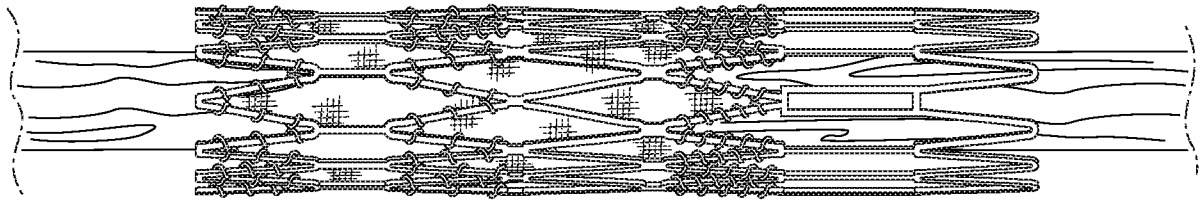
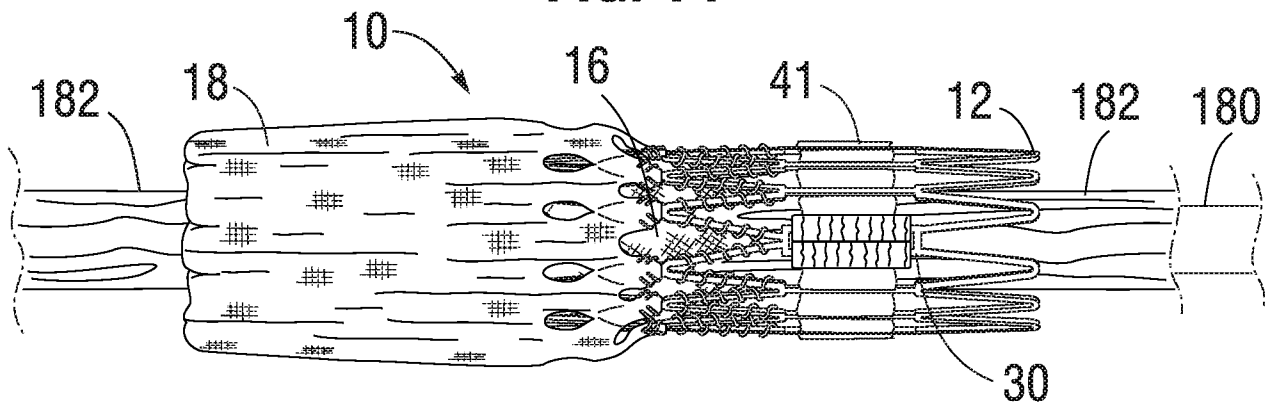
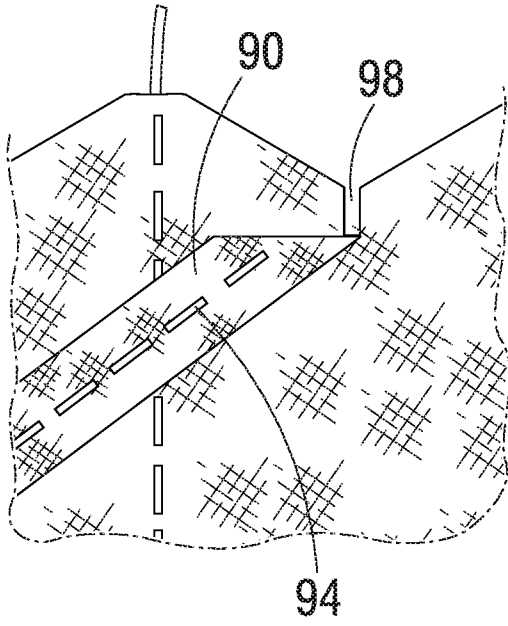


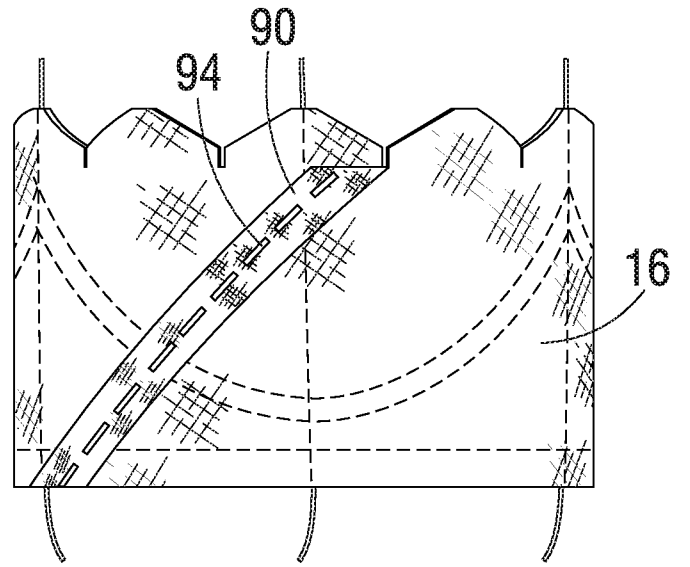
FIG. 14



**FIG. 15**



**FIG. 16**



**FIG. 17**

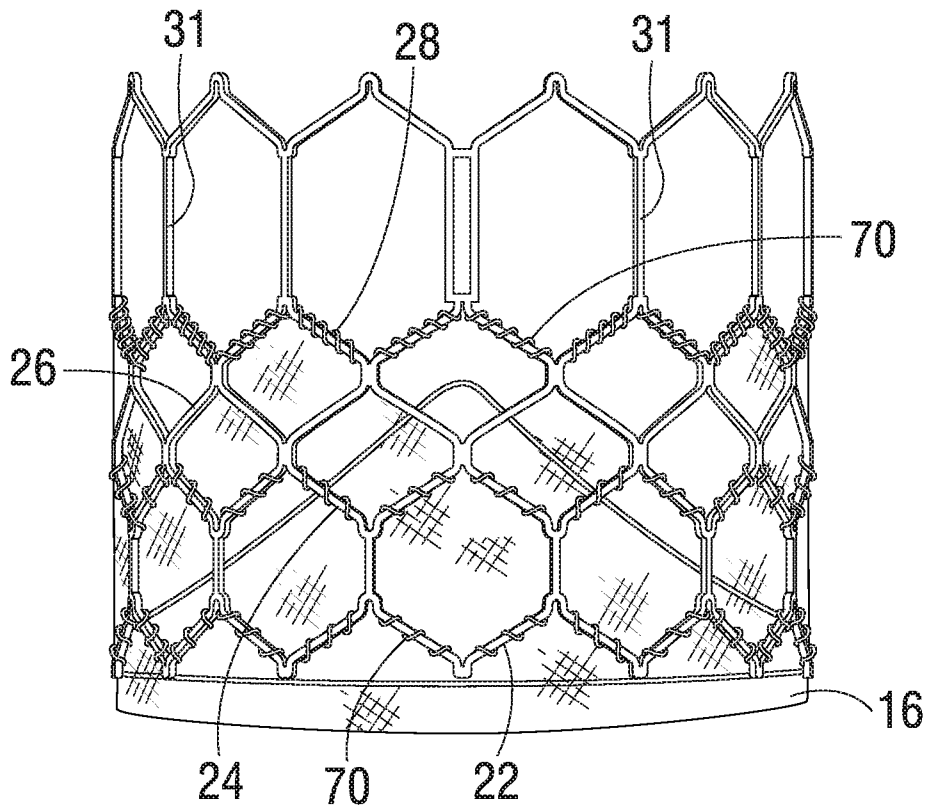


FIG. 18

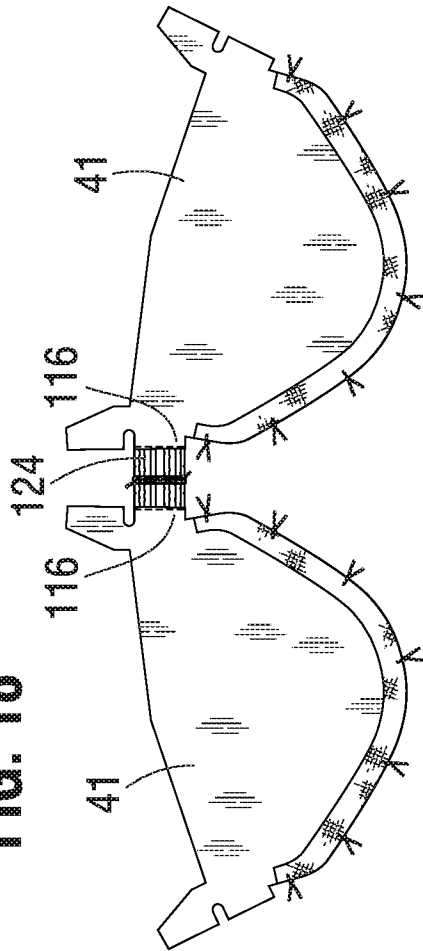


FIG. 19

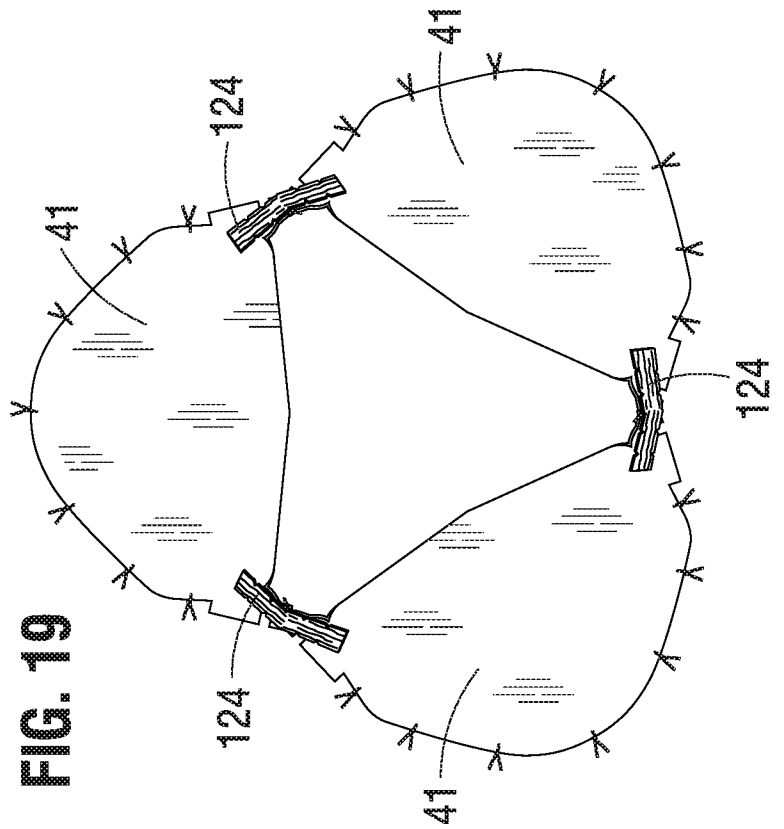
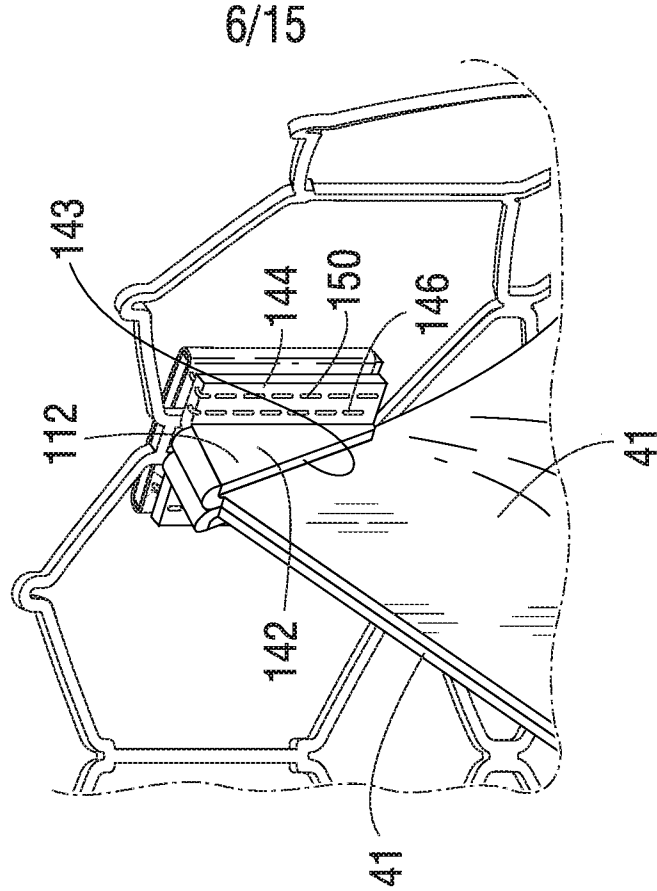
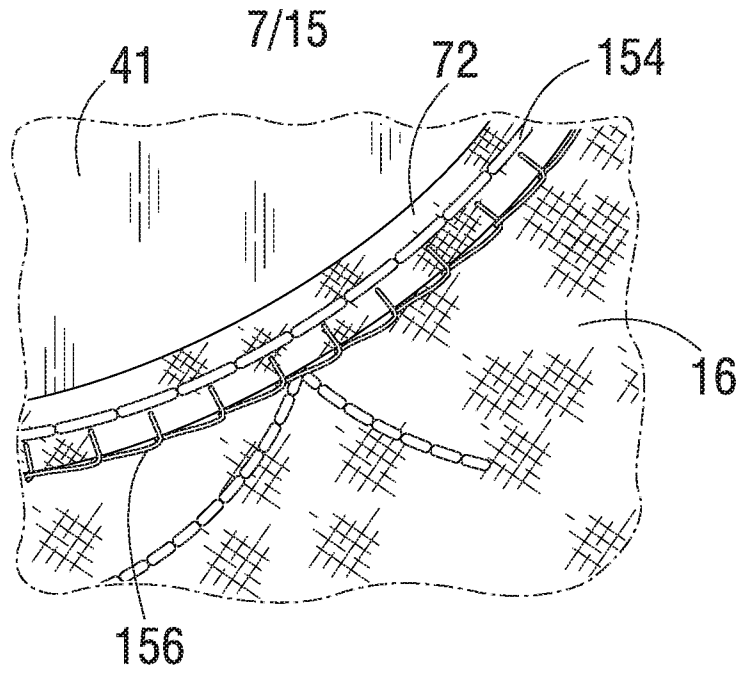


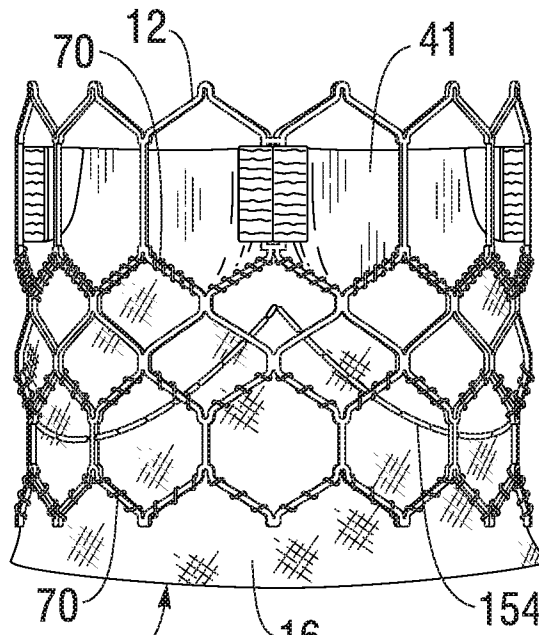
FIG. 20



**FIG. 21**



**FIG. 22**



**FIG. 23**

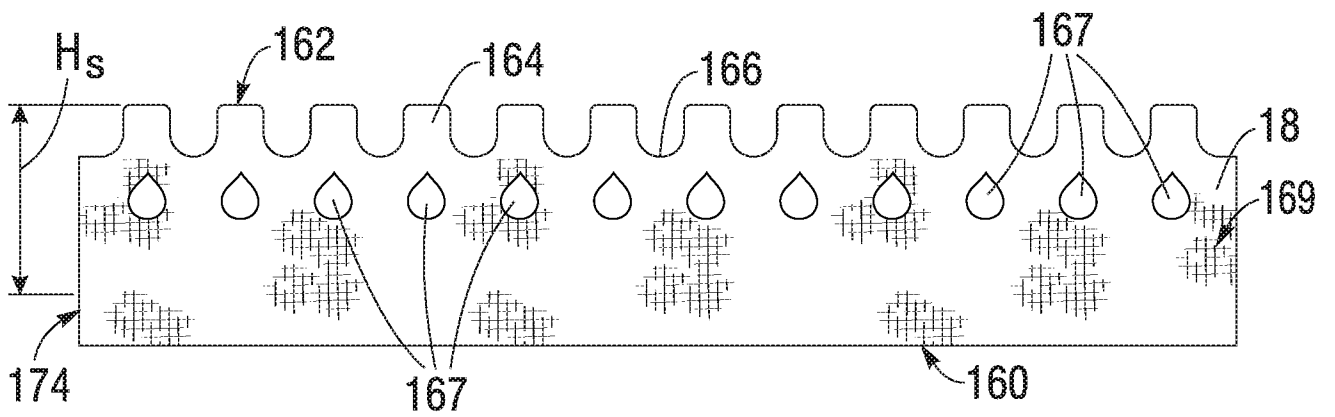
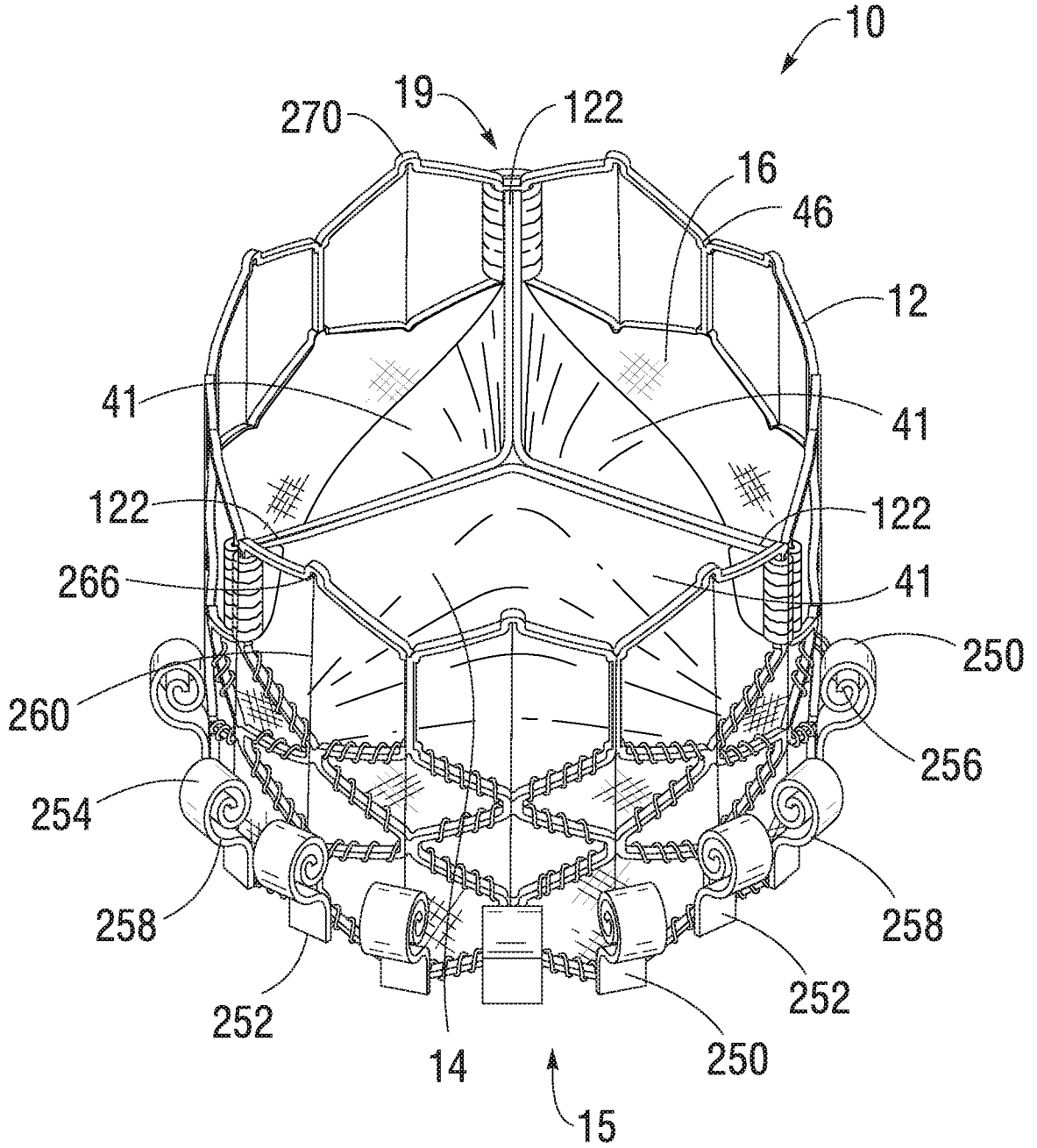
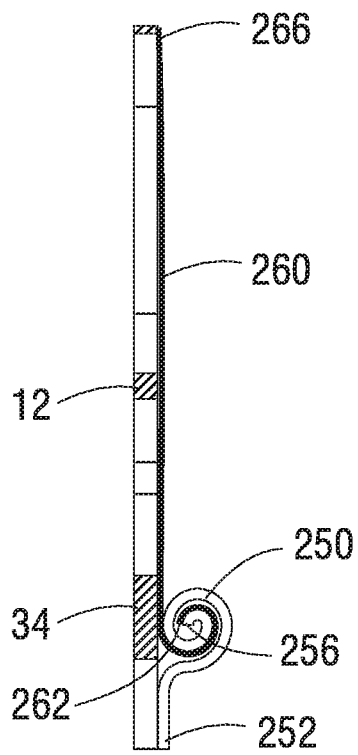


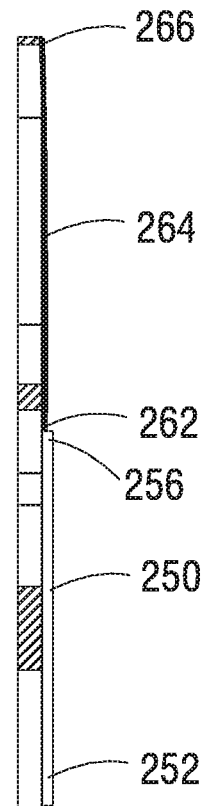
FIG. 24

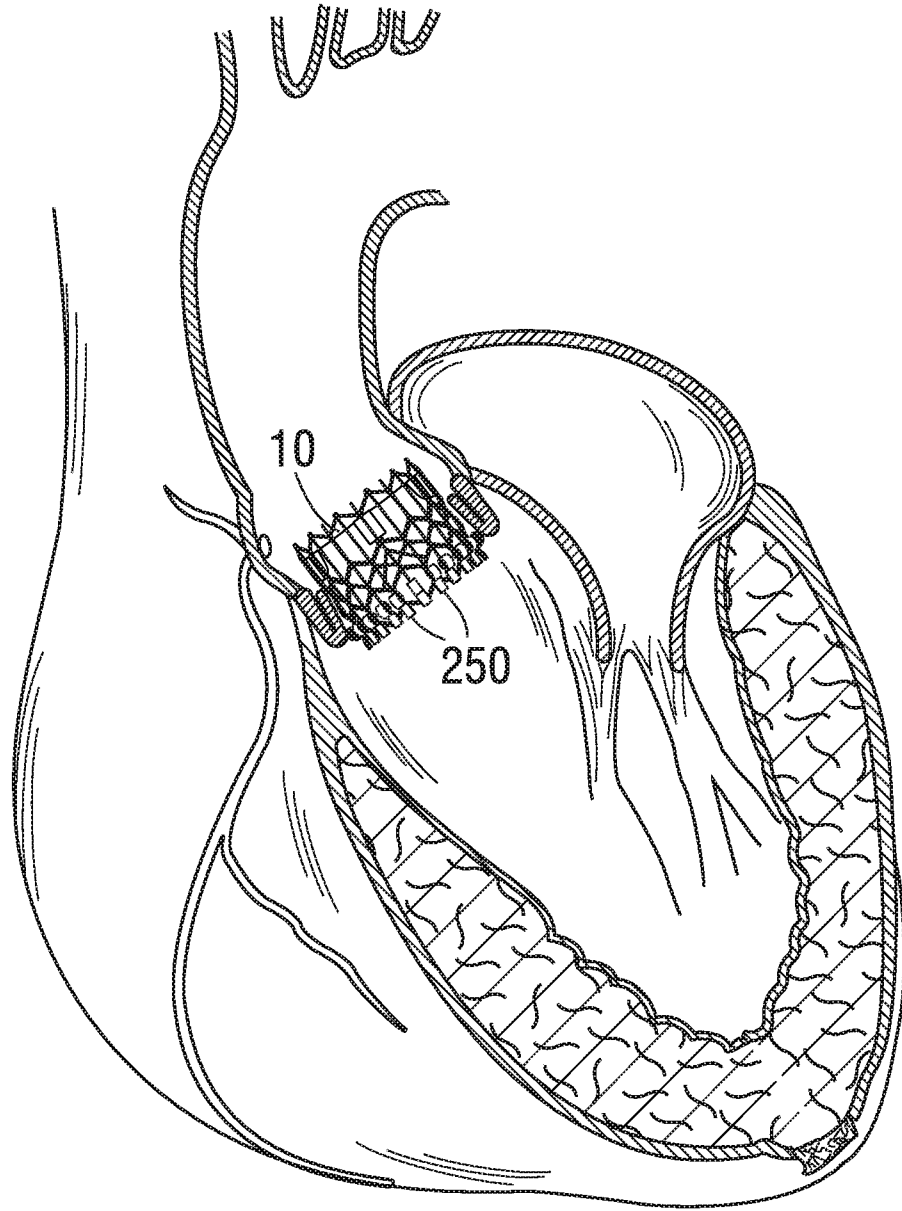


**FIG. 25**



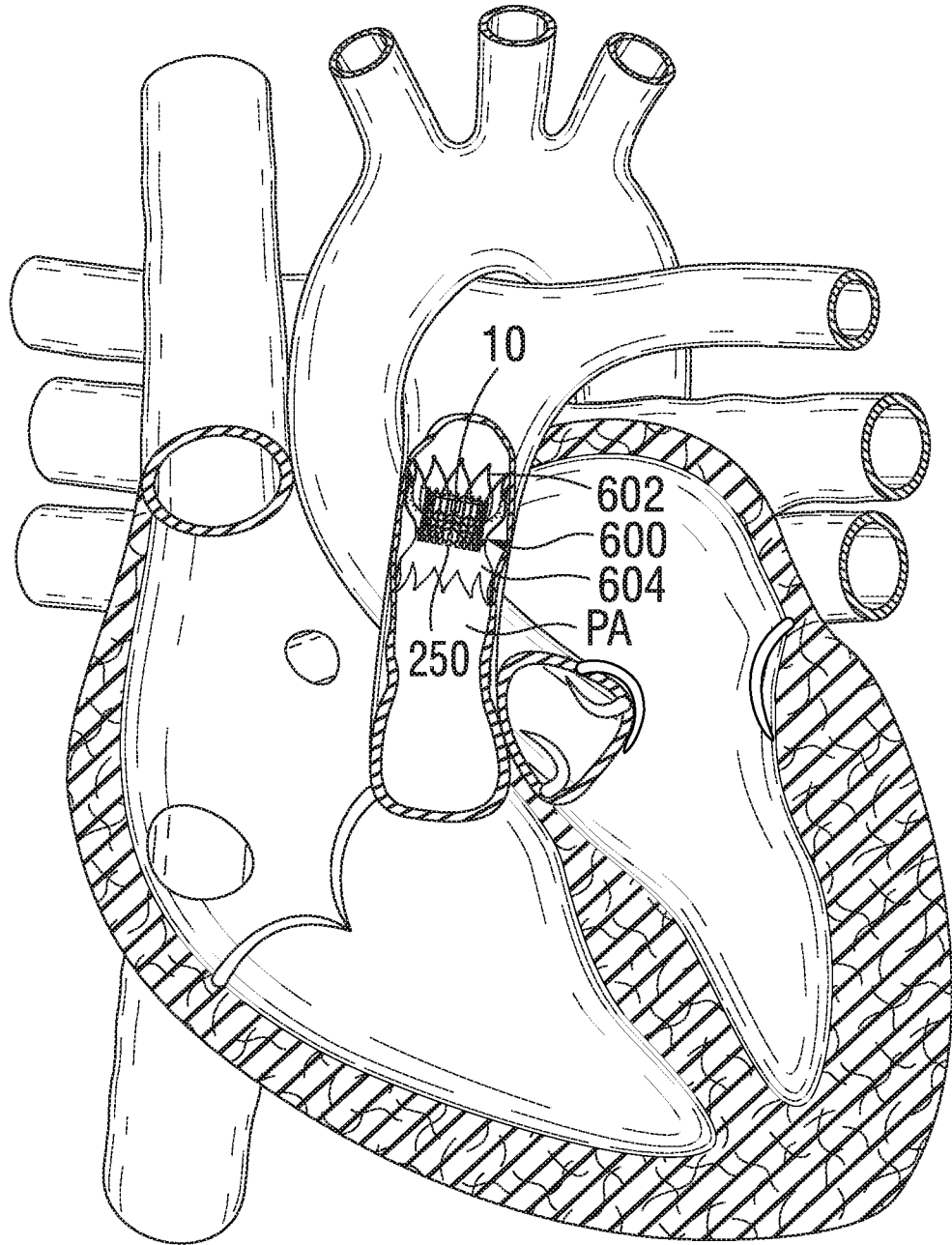
**FIG. 26**



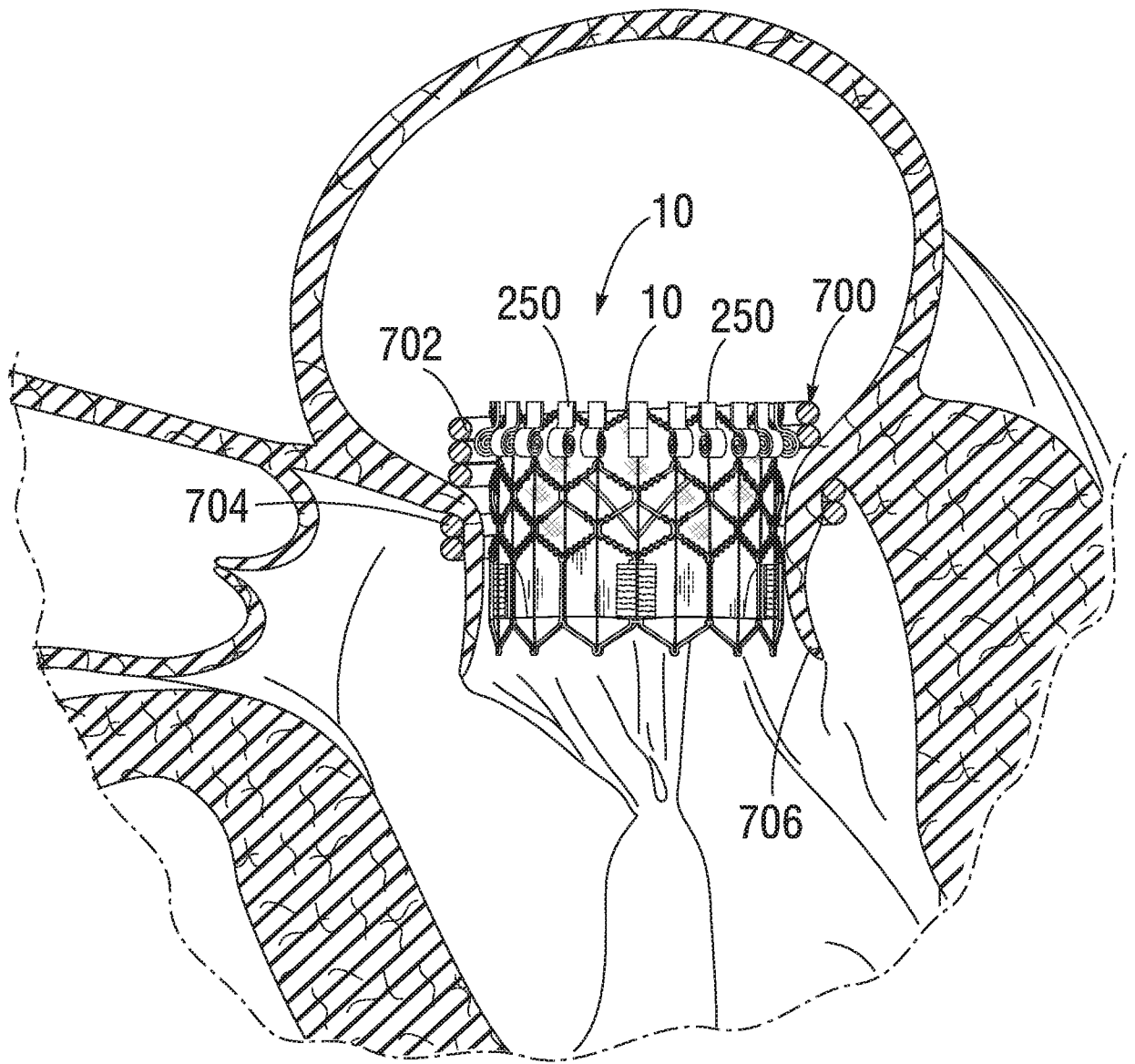


**FIG. 27**

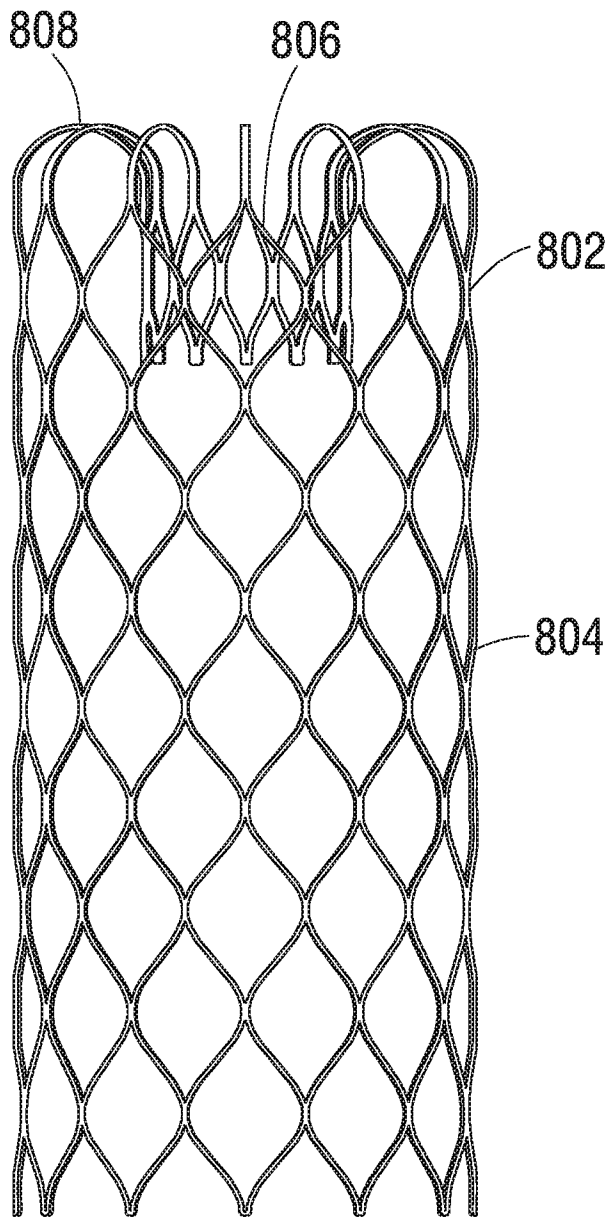




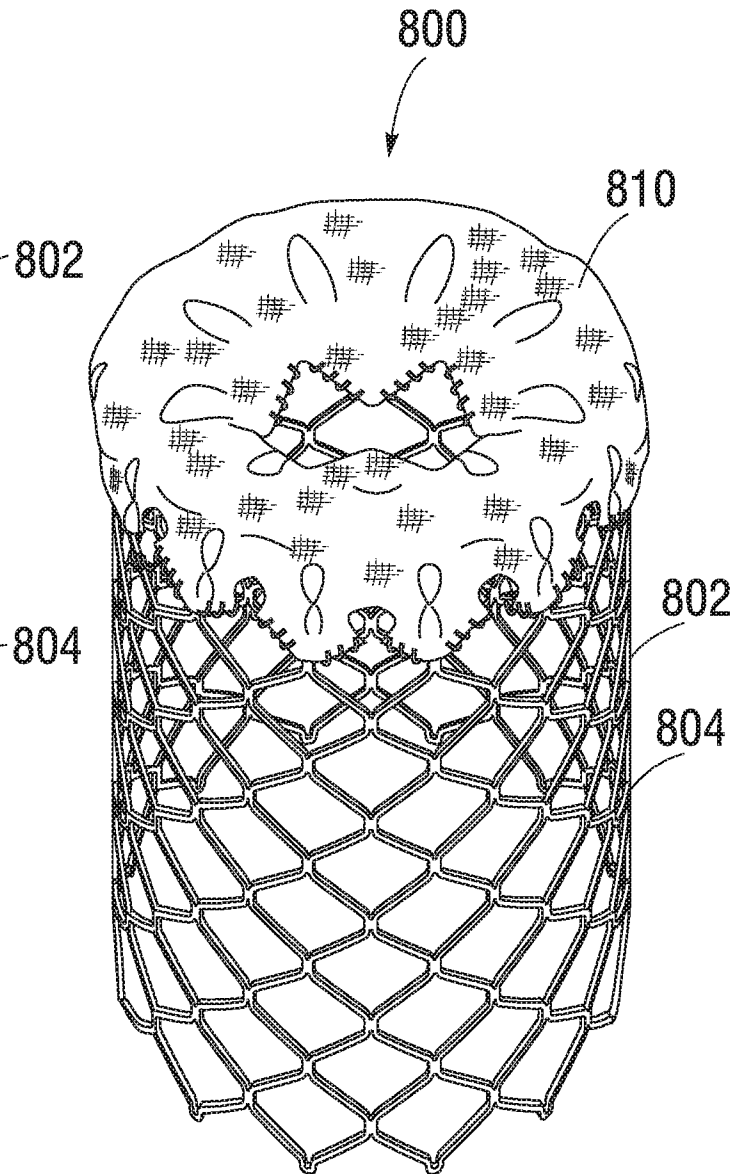
**FIG. 28**



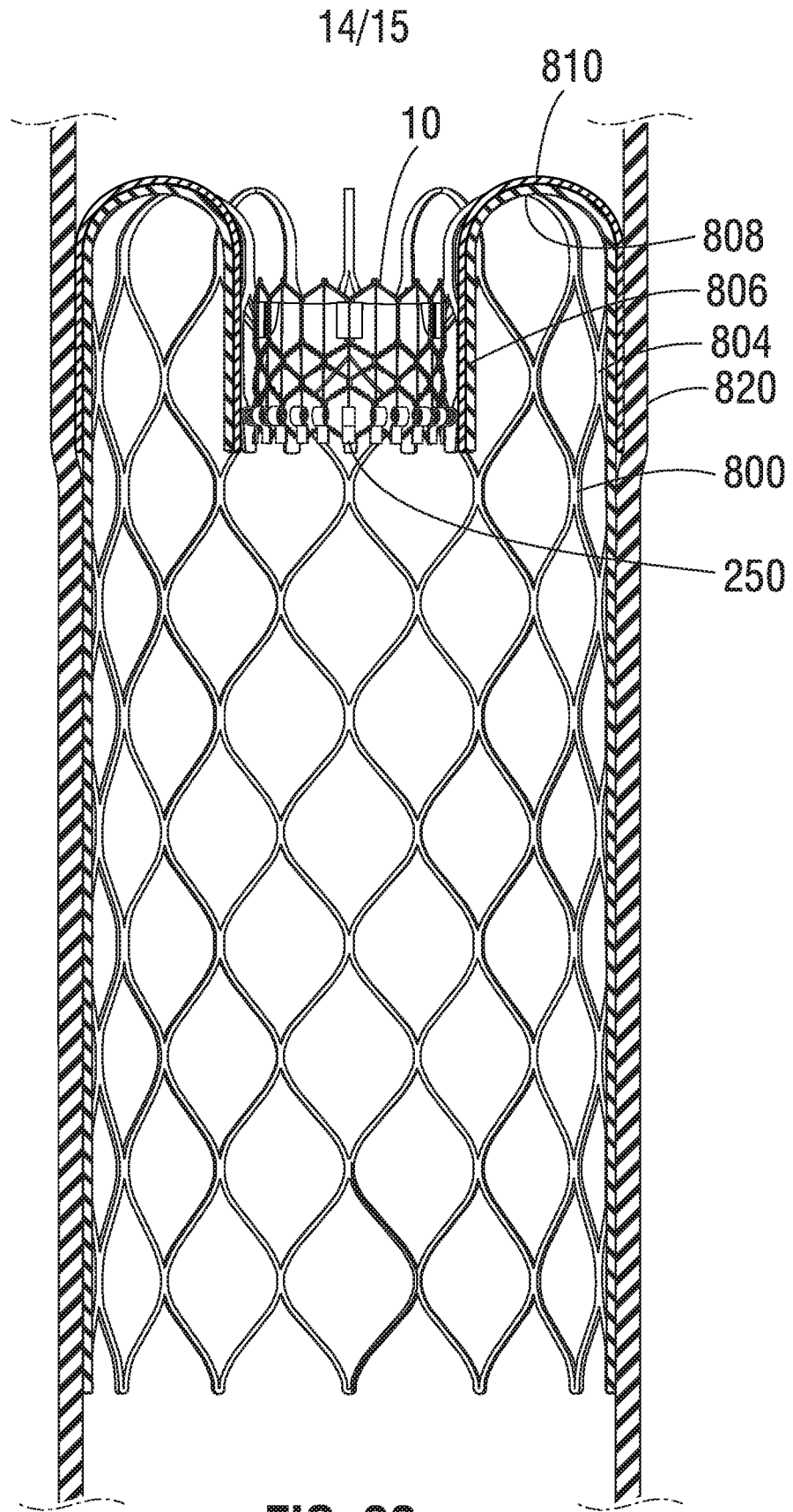
**FIG. 29**



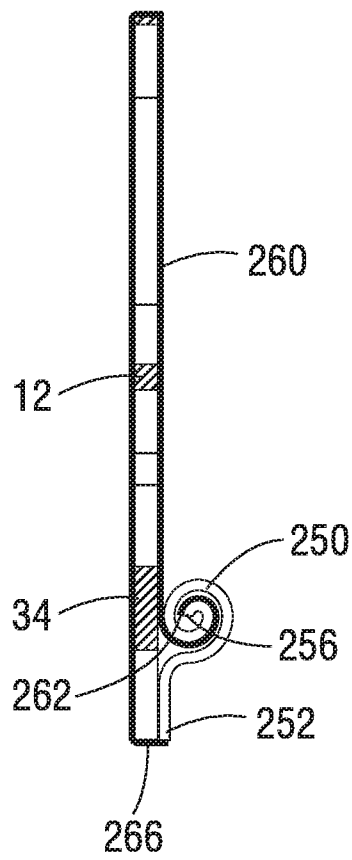
**FIG. 30**



**FIG. 31**



**FIG. 33**



**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/US2020/024574

**A. CLASSIFICATION OF SUBJECT MATTER**  
 INV. A61F2/24  
 ADD.

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

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
 A61F

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
 EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 2015/152980 A1 (ST JUDE MEDICAL CARDIOLOGY DIV [US]) 8 October 2015 (2015-10-08) paragraphs [0162] - [0166]; figures 9A,9B	1,11-15, 18,25-28  2-10,16, 17, 19-24, 29,44-51
A	----- WO 2017/151566 A1 (SPENCE PAUL A [US]) 8 September 2017 (2017-09-08) paragraphs [0143], [0144]; figures 9A-10B -----	1-29, 44-51

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

\* Special categories of cited documents :

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

Date of the actual completion of the international search  18 June 2020	Date of mailing of the international search report  29/06/2020
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  Geuer, Melanie
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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2020/024574

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

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

1.  Claims Nos.: 30-43  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

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

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No

PCT/US2020/024574

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
WO 2015152980	A1	08-10-2015	EP 3125826 A1	08-02-2017
			US 2017189174 A1	06-07-2017
			US 2019060065 A1	28-02-2019
			WO 2015152980 A1	08-10-2015
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			EP 3423005 A1	09-01-2019
			US 2020121454 A1	23-04-2020
			WO 2017151566 A1	08-09-2017
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