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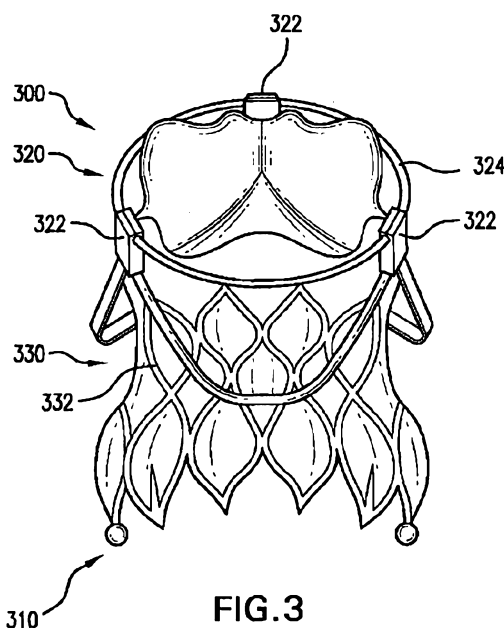
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[Continued on next page]

(54) Title: PROSTHETIC VALVE SUPPORT STRUCTURE



(57) Abstract: The present invention is directed to prosthe-
ses including a support structure (100) having a proximal
end and a distal end, and a motion limiting member (324)
attached to the distal end of the support structure, wherein
the motion limiting member is configured to restrict radial
expansion of the distal end of the support structure. Meth-
ods for delivering the prosthesis are also provided.

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PROSTHETIC VALVE SUPPORT STRUCTURE

RELATED APPLICATION DATA

[0001] This application claims priority to U.S. Provisional Patent Application No. 61/379,115, filed September 1, 2010.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present invention relates to prosthetic valves and methods for their implantation. More particularly, the present invention provides for prosthetic valve support structures configured for transcatheter delivery.

Background

[0003] Aortic valve replacement in patients with severe valve disease is a common surgical procedure. The replacement is conventionally performed by open heart surgery, in which the heart is usually arrested and the patient is placed on a heart bypass machine. Prostheses including prosthetic heart valves have been developed that are implanted using minimally invasive procedures such as transapical or percutaneous approaches. These methods involve compressing the prosthesis radially to reduce its diameter, inserting the prosthesis into a delivery tool, such as a catheter, and advancing the delivery tool to the correct anatomical position in the heart. Once properly positioned, the prosthesis is deployed by radial expansion within the native valve annulus.

[0004] Such a prosthesis can include a support structure to maintain the prosthetic heart valve in place. The inflow section of the prosthesis can be subject to radial interference from a body lumen, such as the left ventricular outflow tract (LVOT), that can exert circumferential radial pressure on the prosthesis. Such radial interference at an inflow section of the prosthesis can result in radial movement at an outflow section of the prosthesis. Such movement may be undesirable.

[0005] Moreover, a prosthesis can be subject to radial movement at an inflow section, due to, for example, valve function and cardiac contraction. Such radial movement can cause the diameter of the inflow section to experience cyclical contraction and expansion. Such contraction and expansion can subject the prosthesis to unnecessary fatigue.

- [0006] Additionally, due to less than perfect conformance between the geometries of a patient's anatomy and the prosthesis, paravalvular leakage can occur. For example, a major cause of leakage between a prosthesis and the LVOT wall is due to spaces created between scalloped leaflets called inter-leaflet triangles.
- [0007] Accordingly, there is a need for a prosthesis that provides decoupled radial motion of the outflow section and the inflow section, and that better conforms to a patient's anatomy.
- [0008] PCT Publication No. WO 05/002466 to Schwammenthal et al., which is incorporated herein by reference in its entirety, describes prosthetic devices for treating aortic stenosis.
- [0009] PCT Publication No. WO 06/070372 to Schwammenthal et al., which is incorporated herein by reference in its entirety, describes a prosthetic device having a single flow field therethrough, adapted for implantation in a subject, and shaped so as to define a fluid inlet, and a diverging section, distal to the fluid inlet.
- [0010] US Patent Application Publication No. 2006/0149360 to Schwammenthal et al., which is incorporated herein by reference in its entirety, describes a prosthetic device including a valve-orifice attachment member attachable to a valve in a blood vessel and including a fluid inlet, and a diverging member that extends from the fluid inlet, the diverging member including a proximal end near the fluid inlet and a distal end distanced from the proximal end. A distal portion of the diverging member has a larger cross-sectional area for fluid flow therethrough than a proximal portion thereof.
- [0011] US Patent Application Publication No. 2006/0259136 to Nguyen et al., which is incorporated herein by reference, describes a heart valve prosthesis having a self-expanding multi-level frame that supports a valve body including a skirt and plurality of coapting leaflets. The frame transitions between a contracted delivery configuration that enables percutaneous transluminal delivery, and an expanded deployed configuration having an asymmetric hourglass shape. The valve body skirt and leaflets are constructed so that the center of coaptation can be selected to reduce horizontal forces applied to the commissures of the valve, and to efficiently distribute and transmit forces along the leaflets and to the frame. Alternatively, the valve body can be used as a surgically implantable replacement valve prosthesis.

BRIEF SUMMARY OF THE INVENTION

- [0012] The present invention provides a valve prosthesis support structure that limits radial motion at a distal end thereof.
- [0013] The present invention also provides a valve prosthesis support structure that limits radial motion at a proximal end thereof.
- [0014] The present invention also provides a valve prosthesis support structure that includes sealing members to prevent paravalvular leakage.
- [0015] The present invention provides a prosthesis including a support structure having a proximal end and a distal end, and a motion limiting member attached to the distal end of the support structure, wherein the motion limiting member is configured to restrict radial expansion of the distal end of the support structure.
- [0016] The present invention also provides a valve prosthesis support structure, including a collapsible and expandable support structure including a plurality of posts at a distal end thereof and a flared portion extending in a proximal direction from the plurality of posts, and a motion limiting member attached to a proximal end of the proximal skirt, wherein the motion limiting member is configured to restrict radial movement of the proximal end of the collapsible support structure.
- [0017] The present invention also provides a method of delivering a prosthesis to a desired location in a body. One such method includes introducing a sheath of a delivery system into a subject's vasculature, wherein a distal tip of the sheath contains the prosthesis, advancing the distal tip of the sheath to the desired location in the body, and releasing the prosthesis within the body, wherein the prosthesis includes a support structure having a proximal end and a distal end, and a motion limiting member attached to the distal end of the support structure.
- [0018] Additional features of the invention will be set forth in the description that follows. Both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the invention as claimed.
- [00018A] The present invention provides a valve prosthesis comprising: a support structure having a proximal end and a distal end; a motion limiting member attached to the distal end of the support structure, wherein the motion limiting member is configured to restrict radial expansion of the distal end of the support structure.

[00018B] The present invention provides a valve prosthesis, comprising a collapsible and expandable support structure including a plurality of posts at a distal end thereof and a flared portion extending in a proximal direction from the plurality of posts; and a motion limiting member attached to a proximal end of the support structure wherein the motion limiting member is configured to restrict radial movement of the proximal end of the support structure.

[00018C] Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present disclosure as it existed before the priority date of each claim of this application.

[00018D] Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

BRIEF DESCRIPTION OF THE FIGURES

[0019] The accompanying figures, which are incorporated herein, form part of the specification and illustrate exemplary embodiments of the present invention. Together

with the description, the figures further serve to explain the principles of and to enable a person skilled in the relevant art(s) to make and use the exemplary embodiments described herein. In the drawings like reference characters indicate identical or functionally similar elements.

- [0020] FIG. 1 is a perspective view of a valve prosthesis subject to radial interference at a proximal end.
- [0021] FIG. 2 is a perspective view of a valve prosthesis not subject to radial interference at a proximal end.
- [0022] FIG. 3 is a perspective view of a valve prosthesis according to an embodiment of the present invention.
- [0023] FIG. 4 is a top schematic view of the valve prosthesis of FIG. 3.
- [0024] FIG. 5 is a perspective view of a valve prosthesis according to an embodiment of the present invention.
- [0025] FIG. 6 is a side schematic view of the valve prosthesis of FIG. 5.
- [0026] FIG. 7 is a perspective view of a valve prosthesis according to an embodiment of the present invention.
- [0027] FIG. 8 is a top schematic view of the valve prosthesis of FIG. 7.
- [0028] FIG. 9 is a perspective view of a valve prosthesis according to an embodiment of the present invention.
- [0029] FIG. 10 is a side schematic view of the valve prosthesis of FIG. 10.
- [0030] FIG. 11 is a perspective view of a valve prosthesis according to an embodiment of the present invention.
- [0031] FIG. 12 is a perspective view of a valve prosthesis according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

- [0032] The following detailed description of the present invention refers to the accompanying figures that illustrate exemplary embodiments. Other embodiments are possible and may fall within the scope of the present invention. Modifications can be made to the exemplary embodiments described herein without departing from the spirit and scope of the present invention. Therefore, the following detailed description is not meant to be limiting. The operation and behavior of the exemplary embodiments

presented are described with the understanding that various modifications and variations of the exemplary embodiments may be within the scope of the present invention.

[0033] FIG. 1 is a perspective view of a valve prosthesis 100 subject to radial interference at a proximal end. Radial interference can constrain or cause a change in the diameter of a portion of valve prosthesis 100. FIG. 2 is a perspective view of valve prosthesis 100 not subject to radial interference at a proximal end. Valve prosthesis 100 includes an inflow section 110 at a proximal end thereof, and an outflow section 120 at a distal end thereof. Valve prosthesis 100 also includes a valve prosthesis support structure 130.

[0034] Valve prosthesis support structure 130 includes posts 122 (also referred to as commissural posts) proximate to outflow section 120, and a proximal skirt 132 extending from inflow section 110 toward posts 122.

[0035] Valve prosthesis 100 is preferably collapsible in order to facilitate transcatheter delivery. Preferably, valve prosthesis 100 can be delivered via a transfemoral approach. Valve prosthesis 100 can also be delivered, however, by other transvascular approach methods or a transapical approach. Valve prosthesis 100 can also be implanted by open heart surgery or related methods. The valve prosthesis 100 can expand radially upon delivery at a target site. The target site is preferably the native aortic annulus of a subject, but it is understood that valves according to the present invention could be implanted at other positions in a subject (e.g., a native mitral or pulmonary annulus).

[0036] For example, distal tip of a catheter sheath containing prosthesis 100 can be inserted into a patient's vasculature (e.g., via a body lumen such as a femoral artery) and advanced (along a guide wire, if provided) to the position of a native annulus. The native leaflets of the annulus can be in place at the time of implantation of prosthesis 100, or can be partially or completely removed prior to implantation. An outer tube of the catheter can be withdrawn some distance to expose a proximal portion of proximal skirt 132. The proximal portion can be positioned so as to abut against the ventricular side of the aortic annulus. If provided, barbs 134 can be primary contact points of prosthesis 100 with an interior of a valve retaining sleeve, thereby reducing friction that could be caused by the inner surface of the valve retaining sleeve sliding over prosthesis 100 while prosthesis 100 moves with respect to the catheter sheath. Once it is determined that prosthesis 100 is properly positioned in the annulus, the outer tube can be fully withdrawn, releasing valve prosthesis 100 and allowing radial expansion of valve prosthesis 100 to engage the

annulus. If, after partial release, it is determined that the prosthesis is not properly positioned, the inflow section 110 can be recaptured into the outer tube for repositioning.

[0037] Prosthesis support structure 130 can be made of a self-expanding material, e.g., nitinol, thus tending toward a fully expanded position that is sufficient to securely engage the native annulus. When in position within a patient, this tendency creates a radial force between prosthesis support structure 130 and the patient's anatomy, thus helping to hold valve prosthesis 100 in place. The pressure applied by the prosthesis support structure 130, however, need not be sufficient by itself to anchor the prosthesis 100 in the native annulus. Further inhibiting migration of valve prosthesis 100 can be axial support arms 128, which protrude over the tips of the native leaflets to provide axial support to valve prosthesis 100 and to prevent valve prosthesis 100 from being forced into the ventricle through the native leaflets during the cardiac cycle. Support arms 128 can take on a variety of configurations. Further, as detailed above, inflow section 110 can engage the ventricle below the inflow end of the native annulus, providing additional anchoring.

[0038] Support arms 128 can, for example, be configured to be at least partially disposed within aortic sinuses of the subject, and, for some applications, to engage and/or rest against floors of the aortic sinuses, and to apply an axial force directed toward a left ventricle of the subject. Support arms 128 can meet one another at junctures. For applications in which each of support arms 128 is fabricated as a separate piece, the support arms can be mechanically engaged to one another where they meet at the junctures. For some applications, support arms 128 meet one another without actually touching one another, and instead meet via an area defined at each juncture. Typically, the support arms are configured to define peaks at the junctures, and troughs between adjacent peaks. U.S. Application No. 11/728,253, filed March 23, 2007, and U.S. Application No. 11/726,889, filed March 23, 2007 detail various support arm configurations, and each is incorporated by reference herein in its entirety.

[0039] In some exemplary embodiments, valve prosthesis 100 includes three posts 122, arranged circumferentially around a central longitudinal axis of valve prosthesis 100, and a flared portion extending in a proximal direction from posts 122. In some exemplary embodiments, valve prosthesis 100 includes more or fewer than three posts 122, such as, for example, two posts 122, or four posts 122. Approximately 90% of humans have exactly three aortic sinuses. The three posts 122 provided in some exemplary

embodiments correspond to these three aortic sinuses. For implantation in the approximately 10% of patients that have exactly two aortic sinuses, valve prosthesis 100 can include only two posts 122.

[0040] Valve prosthesis 100 can also include a valve 150 coupled to posts 122. Valve 150 can be formed of a pliant material configured to collapse inwardly (i.e., towards the central longitudinal axis of valve prosthesis 100) during diastole, in order to inhibit retrograde blood flow, and to open outwardly during systole, to allow blood flow through valve prosthesis 100. Valve 150 can be formed of artificial or natural tissue. For example, valve 150 can be formed of bovine or porcine pericardium, or of any suitable synthetic material.

[0041] FIG. 2 is a perspective view of valve prosthesis 100 in an expanded state, wherein no inward radial pressure or interference is applied to inflow section 110. In this expanded state, inflow section 110 has a diameter ID2, and outflow section 120 has an outflow diameter OD2. FIG. 1 is a perspective view of a valve prosthesis 100 that is subject to inward radial pressure or interference at inflow section 110. Depending on the geometry of a particular subject's annulus, inflow section 110 will often be in at least a somewhat compressed position as shown in FIG. 1 due to the radial interference at inflow section 110. In this position, outflow section 120 has an outflow diameter OD1 that is larger than OD2, causing posts 122 to be positioned farther from one another than in a relaxed state. In other words, the outflow diameter of valve prosthesis 100 at outflow section 120 and the positioning of posts 122 are affected by radial interference on valve prosthesis 100 at inflow section 110, which can result in decreased performance characteristics of valve prosthesis 100.

[0042] Decoupling of radial motion of outflow section 120 from radial interference at inflow section 110 can produce significant benefits by providing more predictable and stable valve geometry regardless of patient-specific anatomy.

[0043] FIG. 3 is a perspective view of a valve prosthesis 300 according to an embodiment of the present invention. FIG. 4 is a top schematic view of valve prosthesis 300. The basic structure of valve prosthesis 300 is generally similar to valve prosthesis 100. Valve prosthesis 300 includes an inflow section 310 at a proximal end thereof, and an outflow section 320 at a distal end thereof. Valve prosthesis support structure 330 includes posts 322 proximate to outflow section 320, and a proximal skirt 332 extending from inflow

section 310 towards posts 322. Valve prosthesis 300 also includes a valve prosthesis support structure 330.

[0044] Valve prosthesis 300 further includes a motion limiting member 324. Motion limiting member 324 includes a substantially rigid circular frame disposed around outflow section 320. The substantially rigid circular frame preferably substantially maintains its shape even when subjected to outside forces such as can be present within a body lumen of a patient. The substantially rigid circular frame can be made of, for example, the types of surgical steel traditionally used for making stent devices. Motion limiting member 324 can be mounted to valve prosthesis support structure 330 by being attached to distal ends of posts 322. In such a configuration, motion limiting member 324 prevents divergence of posts 322 by limiting the maximum diameter of outflow section 320, thereby preventing motion of posts 322 beyond the limits imposed by motion limiting member 324. Motion limiting member 324 can be constructed of a variety of materials, for example, nitinol.

[0045] The rigid circular frame of motion limiting member 324 can, however, be sufficiently flexible to be compatible with collapse of valve prosthesis 300 during an insertion process.

[0046] The rigid circular frame of motion limiting member 324 can alternately or additionally be mounted to valve prosthesis support structure 330 by being attached to proximal ends of posts 322, or at intermediate positions of posts 322, in between proximal and distal ends.

[0047] Because the diameter of outflow section 320 is limited by motion limiting member 324, the diameter of outflow section 320 is not substantially affected by changes in the diameter of inflow section 310, thereby decoupling radial motion of outflow section 320 from radial interference at inflow section 310. Thus, valve prosthesis 300 maintains predictable and stable valve geometry regardless of patient-specific anatomy.

[0048] FIG. 5 is a perspective view of a valve prosthesis 500 according to an exemplary embodiment of the present invention. FIG. 6 is a side schematic view of valve prosthesis 500. Description of elements of the embodiment depicted in FIGS. 5 and 6 that are the same or operate similarly as the embodiments described above may be omitted or abbreviated.

- [0049] Valve prosthesis 500 includes an inflow section 510 at a proximal end thereof, and an outflow section 520 at a distal end thereof. Valve prosthesis 500 also includes a valve prosthesis support structure 530, and a motion limiting member 524. Valve prosthesis support structure 530 includes posts 522 proximate to outflow section 520, and a proximal skirt 532 extending from inflow section 510 toward posts 522.
- [0050] Motion limiting member 524 includes rigid arches disposed proximate to outflow section 520. Each rigid arch is mounted to valve prosthesis support structure 530 by being attached to proximal ends of two adjacent posts 522. In this way, the rigid arches of the motion limiting member 524 together extend around outflow section 520. In such a configuration, motion limiting member 524 prevents divergence of posts 522 by limiting the diameter of outflow section 520, thereby preventing motion of posts 522 beyond the limits imposed by motion limiting member 524.
- [0051] In some embodiments, the rigid arches of motion limiting member 524 can together form a circular shape, or can form another shape, such as, for example, a series of linked "humps" connecting around outflow section 520.
- [0052] In some embodiments, the rigid arches of motion limiting member 524 are sufficiently flexible to collapse with valve prosthesis 500 during an insertion process.
- [0053] In some embodiments, the rigid arches of motion limiting member 524 are mounted to valve prosthesis support structure 530 by being attached to distal ends of posts 522, or at intermediate positions of posts 522, in between proximal and distal ends.
- [0054] In some embodiments, the rigid arches of motion limiting member 524 can extend out from valve prosthesis support structure 530 at a 90 degree angle with respect to a longitudinal axis extending through valve prosthesis 500. Alternatively, the rigid arches of motion limiting member 524 can extend from valve prosthesis support structure 530 at an angle other than 90 degrees, such as, for example, approximately 30 degrees, approximately 45 degrees, or approximately 120 degrees. Moreover, each rigid arch need not extend out from valve prosthesis support structure 530 at the same angle as other rigid arches.
- [0055] In some embodiments multiple rigid arches can extend between adjacent posts 522. Intermediate connections can be formed between adjacent rigid arches such that the rigid arches extending between adjacent posts 522 are connected in series.

- [0056] Because the diameter of outflow section 520 is limited by motion limiting member 524, it is not substantially affected by radial interference (i.e., changes in diameter) at inflow section 510, thereby achieving decoupling of radial motion of outflow section 520 from radial interference at inflow section 510. Thus, valve prosthesis 500 maintains predictable and stable valve geometry regardless of patient-specific anatomy.
- [0057] FIG. 7 is a perspective view of a valve prosthesis 700 according to an embodiment of the present invention. FIG. 8 is a side schematic view of valve prosthesis 700. Description of elements of the embodiment depicted in FIGS. 7 and 8 that are the same or operate similarly as the embodiments described above may be omitted or abbreviated.
- [0058] Valve prosthesis 700 includes an inflow section 710 at a proximal end thereof, and an outflow section 720 at a distal end thereof. Valve prosthesis 700 also includes a valve prosthesis support structure 730, and a motion limiting member 724.
- [0059] Valve prosthesis support structure 730 includes posts 722 proximate to outflow section 720, and a proximal skirt 732 extending from posts 722 toward inflow section 710.
- [0060] Motion limiting member 724 includes linear support elements disposed proximate to outflow section 720. Each linear support element is mounted to valve prosthesis support structure 730 by being attached to distal ends of two adjacent posts 722. In this way, the linear support elements of motion limiting member 724 together link posts 722. In such a configuration, motion limiting member 724 prevents divergence of posts 722 by limiting the diameter of outflow section 720, thereby preventing motion of posts 722 beyond the limits imposed by motion limiting member 724.
- [0061] In some embodiments the linear support elements of motion limiting member 724 are non-rigid and act only in tension. For example, such linear support elements can be made of string, wire, sutures, or the like.
- [0062] In some embodiments, the linear support elements of motion limiting member 724 are rigid.
- [0063] In some embodiments, the linear support elements of motion limiting member 724 are mounted to valve prosthesis support structure 730 by being attached to proximal ends of posts 722, or at intermediate positions of posts 722, in between proximal and distal ends.

- [0064] In some embodiments multiple linear support sub-elements can extend between adjacent posts 722, with intermediate connections between adjacent linear support sub-elements such that the linear support sub-elements extending between adjacent posts 722 are connected in series.
- [0065] Because the diameter of outflow section 720 is limited by motion limiting member 724, it is preferably not substantially affected by radial interference (i.e., changes in diameter) at inflow section 710, thereby achieving decoupling of radial motion of outflow section 720 from radial interference at inflow section 710. Thus, valve prosthesis 700 maintains predictable and stable valve geometry regardless of patient-specific anatomy.
- [0066] FIG. 9 is a perspective view of a valve prosthesis 900 according to an embodiment of the present invention. FIG. 10 is a side schematic view of valve prosthesis 900. Description of elements of the embodiment depicted in FIGS. 9 and 10 that are the same or operate similarly as the embodiments described above may be omitted or abbreviated.
- [0067] Valve prosthesis 900 includes an inflow section 910 at a proximal end thereof, and an outflow section 920 at a distal end thereof. Valve prosthesis 900 also includes a valve prosthesis support structure 930, and a motion limiting member 926.
- [0068] Valve prosthesis support structure 930 includes posts 922 proximate to outflow section 920, and a proximal skirt 932 extending from inflow section 910 toward posts 922.
- [0069] Motion limiting member 926 includes strut support elements disposed proximate to inflow section 910. Each strut support element is mounted to a proximal end of inflow section 910, and extends between adjacent endpoints of proximal skirt 932. In this way, the strut support elements of motion limiting member 926 together link endpoints of inflow section 910. In such a configuration, motion limiting member 926 prevents divergence of the endpoints of proximal skirt 932 by limiting the diameter of inflow section 910, thereby preventing motion of the endpoints of proximal skirt 932 beyond the limits imposed by motion limiting member 926.
- [0070] In some embodiments, multiple strut support elements can extend between adjacent endpoints of proximal skirt 932, with intermediate connections between adjacent endpoints of proximal skirt 932 such that the strut support elements extending between adjacent endpoints of proximal skirt 932 are connected in series.

- [0071] In some embodiments, the strut support members of motion limiting member 926 are incorporated in and form a part of proximal skirt 932 such that motion limiting member 926 and proximal skirt 932 are formed together monolithically.
- [0072] In some embodiments, the strut support members of motion limiting member 926 are rigid. In some embodiments, the strut support members of motion limiting member are non-rigid.
- [0073] Because the diameter of inflow section 910 is limited by motion limiting member 926, its motion due to valve function and cardiac contraction can be confined to within limits necessary for proper functioning, thereby eliminating or reducing unnecessary radial movement. Reducing this unnecessary radial movement in turn reduces the fatigue that valve prosthesis 900 is subject to, thereby extending its useful life, and eliminating the need for subsequent replacement of valve prosthesis 900 or reducing the frequency with which valve prosthesis 900 must be replaced to maintain proper functionality. Additionally, because motion limiting member 926 limits the diameter of inflow section 910, valve prosthesis 900 maintains more predictable and stable valve motion and valve geometry regardless of patient-specific anatomy. Further, stabilizing the diameter of inflow section 910 results in less deformation (i.e., changes in diameter) of outflow section 920.
- [0074] FIG. 11 is a perspective view of a valve prosthesis 1100 according to an embodiment of the present invention. Description of elements of the embodiment depicted in FIG. 11 that are the same or operate similarly as those described above may be omitted or abbreviated.
- [0075] Valve prosthesis 1100 includes an inflow section 1110 at a proximal end thereof, and an outflow section 1120 at a distal end thereof. Valve prosthesis 1100 also includes a valve prosthesis support structure 1130, and sealing members 1142.
- [0076] Valve prosthesis support structure 1130 includes posts 1122 proximate to outflow section 1120, and a proximal skirt 1132 extending from posts 1122 toward inflow section 1110.
- [0077] Sealing members 1142 can be disposed proximate to inflow section 1110, and can be positioned to correspond radially with posts 1122. Such positioning corresponds to native commissures, and aligns sealing members 1142 with a patient's inter-leaflet triangles. Sealing members 1142 can be shaped so as to fit into the inter-leaflet triangles,

or can be formed of a material that conforms to the shape of the inter-leaflet triangles upon being placed in contact with the inter-leaflet triangles. In this way, sealing members 1142 help valve prosthesis 1100 attain a high level of conformance to the patient's annular anatomy, thereby preventing or reducing the chance and severity of paravalvular leakage. U.S. Application No. 13/091,765, filed April 21, 2011, discusses sealing members for use with prosthetic valves, and is incorporated by reference herein in its entirety.

[0078] FIG. 12 is a perspective view of a valve prosthesis 1200 according to an embodiment of the present invention. Description of elements of the embodiment depicted in FIG. 12 that are the same or operate similarly as those described above may be omitted or abbreviated.

[0079] Valve prosthesis 1200 includes an inflow section 1210 at a proximal end thereof, and an outflow section 1220 at a distal end thereof. Valve prosthesis 1200 also includes a valve prosthesis support structure 1230, and a sealing member 1242.

[0080] Valve prosthesis support structure 1230 includes posts 1222 proximate to outflow section 1220, and a proximal skirt 1232 extending from posts 1222 toward inflow section 1210.

[0081] Sealing member 1242 can be disposed proximate to inflow section 1210, and can extend around the circumference of proximal skirt 1232. Sealing member 1242 can include sealing tips 1244 positioned to correspond radially with posts 1222. Such positioning corresponds to native commissures, and aligns sealing tips 1244 with a patient's inter-leaflet triangles. Sealing tips 1244 can be shaped so as to fit into the inter-leaflet triangles, or can be formed of a material that conforms to the shape of the inter-leaflet triangles upon being placed in contact with the inter-leaflet triangles. In this way, sealing member 1242, including sealing tips 1244, helps valve prosthesis 1200 attain a high level of conformance to the patient's annular anatomy, thereby preventing or reducing the chance and severity of paravalvular leakage.

[0082] In some embodiments, sealing member 1242 including sealing tips 1244 is formed of a single material. In some embodiments, sealing tips 1244 are formed of a material different from the balance of sealing member 1242. For example, sealing tips 1244 can be formed of a soft material capable of conforming to the patient's inter-leaflet triangles, while the balance of sealing member 1242 can be formed of a more rigid material.

- [0083] In some embodiments, sealing member 1242 acts as a motion limiting member, and limits the diameter of inflow section 1210, thereby preventing motion of endpoints of proximal skirt 1232 beyond limits imposed by sealing member 1242. In this way, sealing member 1242 is similar to motion limiting member 926.
- [0084] While various embodiments of the present invention have been described above, they have been presented by way of example only, and not limitation. The elements of the embodiments presented above are not necessarily mutually exclusive, but can be interchanged to meet various needs as would be appreciated by one of skill in the art.
- [0085] It therefore will be apparent to one skilled in the art that various changes in form and detail can be made to the embodiments disclosed herein without departing from the spirit and scope of the present invention. The phraseology or terminology herein is used for description and not for limitation. Thus, it is intended that the present invention cover modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents.

WHAT IS CLAIMED IS:

1. A valve prosthesis comprising:

a support structure having a proximal end and a distal end; and

a motion limiting member attached to the distal end of the support structure,

wherein the motion limiting member is configured to restrict radial expansion of the distal end of the support structure such that the diameter of the distal end does not substantially change when the diameter of the proximal end changes.
2. The prosthesis of claim 1, wherein the motion limiting member comprises a substantially rigid circular frame.
3. The prosthesis of claim 2, wherein:

the support structure comprises a plurality of posts at a distal portion thereof, and

wherein the rigid circular frame is attached to a distal end of each of the plurality of posts.
4. The prosthesis of any one of claims 1 to 3, wherein the motion limiting member comprises a plurality of rigid arches, each rigid arch extending between adjacent posts.
5. The prosthesis of claim 4, wherein:

each rigid arch is attached to proximal ends of the adjacent posts or,

the rigid arches together form a substantially circular shape or,

the rigid arches are sufficiently flexible to collapse and expand during a prosthesis insertion process or,

the rigid arches each form an angle with respect to a longitudinal axis extending through the support structure, and wherein the angle is within the range of approximately 30 to approximately 120 degrees.

6. The prosthesis of claim 1, wherein the support structure comprises a plurality of posts at a distal portion thereof, and

wherein the motion limiting member comprises a plurality of linear support elements, each linear support element extending between adjacent posts.
7. The prosthesis of claim 6, wherein:

each linear support element is attached to distal ends of the adjacent posts or,
each linear support element is formed of a non-rigid material or,
each linear support element is formed of a rigid material or,
each linear support element comprises a plurality of linear support sub-elements connected in series.
8. The prosthesis of claim 3 or claim 6, wherein the motion limiting member is configured to limit radial movements of the plurality of posts.
9. The prosthesis of any one of the preceding claims, further comprising a sealing member attached to the proximal end of the support structure, wherein the sealing member is shaped and configured to conform to interleaflet triangles of a patient's heart.
10. The prosthesis of claim 9, wherein the support structure comprises a plurality of posts at a distal portion thereof, and wherein the sealing member comprises a plurality of sealing elements, each sealing element being positioned so as to align with a corresponding post.
11. The prosthesis of claim 9, wherein the sealing member extends around the proximal end of the support structure.
12. The prosthesis of claim 9, wherein the support structure comprises a plurality of posts at a distal portion thereof, and wherein the sealing member comprises a plurality of sealing

tips, and wherein the sealing member is oriented so as to align each sealing tip with a corresponding post.

13. A valve prosthesis, comprising:

a collapsible and expandable support structure including a plurality of posts at a distal end thereof and a flared portion extending in a proximal direction from the plurality of posts; and

a motion limiting member attached to a proximal end of the support structure,

wherein the motion limiting member is configured to restrict radial movement of the proximal end of the support structure such that the proximal end does not substantially radially move when the distal end radially moves.

14. The valve prosthesis of claim 13, wherein the flared portion comprises a bulging proximal portion comprising a plurality of endpoints, and wherein the motion limiting member comprises a plurality of struts, each strut linking adjacent endpoints.

15. The valve prosthesis of claim 13, wherein the flared portion comprises a bulging proximal portion comprising a plurality of endpoints,
wherein the motion limiting member comprises a plurality of struts, and
wherein a plurality of struts link adjacent endpoints.

16. The valve prosthesis of any one of claims 13 to 15, wherein the motion limiting member is monolithic with the support structure.

17. The valve prosthesis of any one of claims 13 to 16, further comprising a sealing member attached to the support structure, wherein the sealing member is shaped and configured to conform to interleaflet triangles of a patient's heart.

18. The valve prosthesis of claim 17, wherein the sealing member comprises a plurality of sealing elements, each sealing element being positioned at a proximal end of the support structure so as to align with a corresponding post.
19. The valve prosthesis of claim 17, wherein the sealing member is positioned at a proximal end of the support structure and extends around the proximal end of the support structure.
20. The valve prosthesis of claim 17, wherein the sealing member comprises a plurality of sealing tips, and wherein the sealing member is oriented so as to align each sealing tip with a corresponding post.

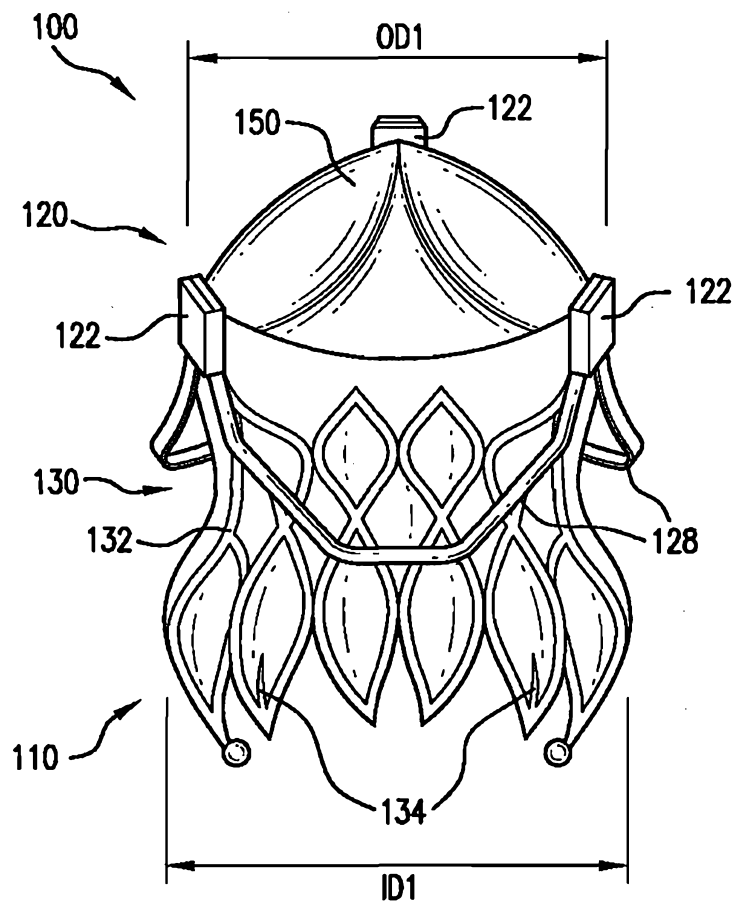


FIG. 1

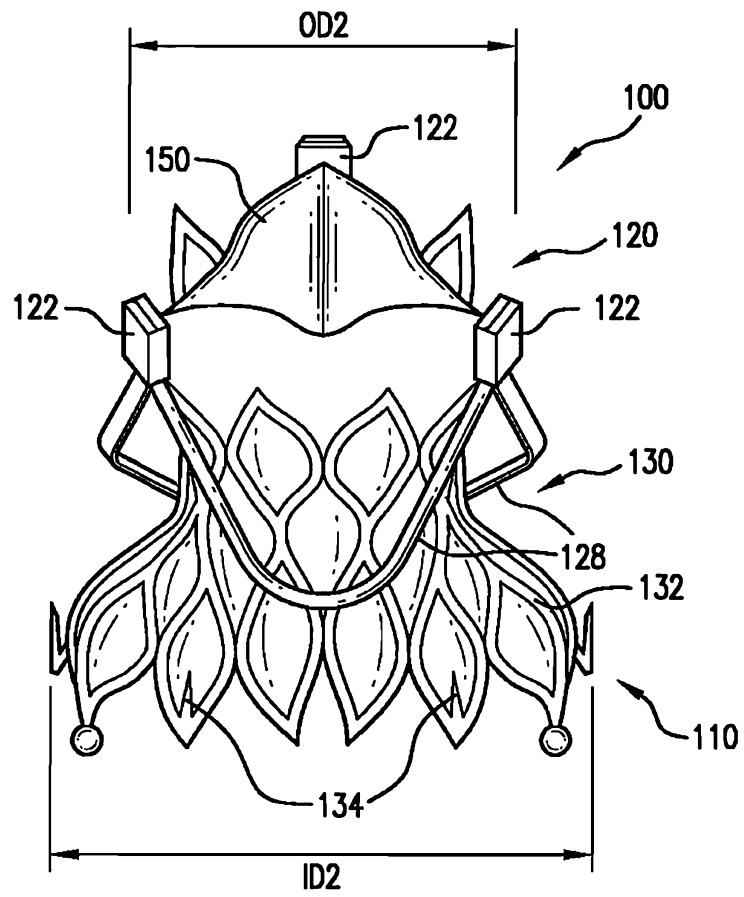
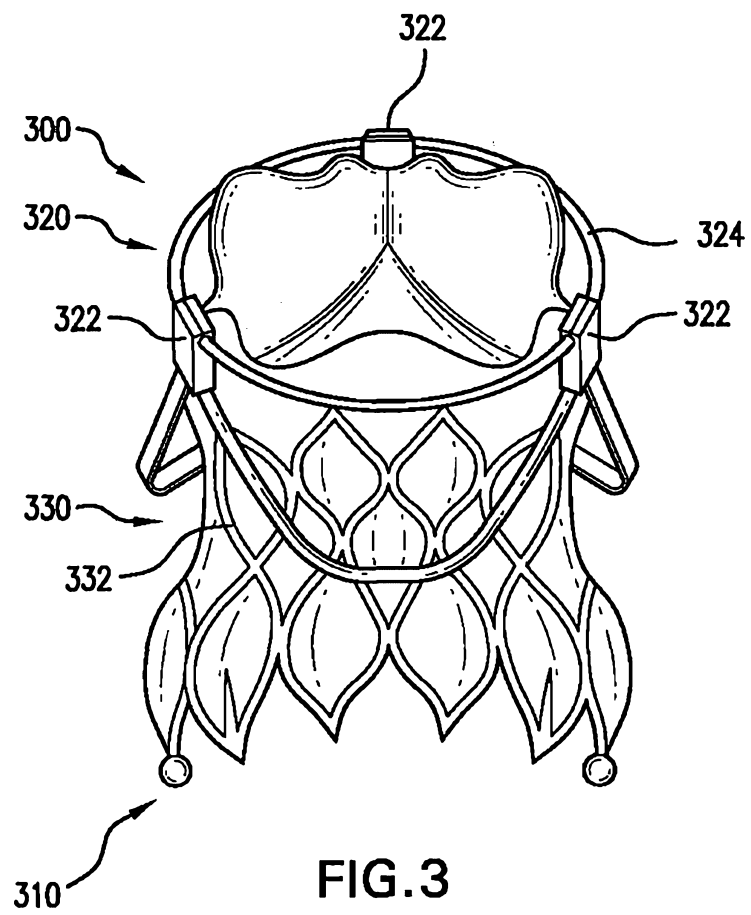


FIG. 2



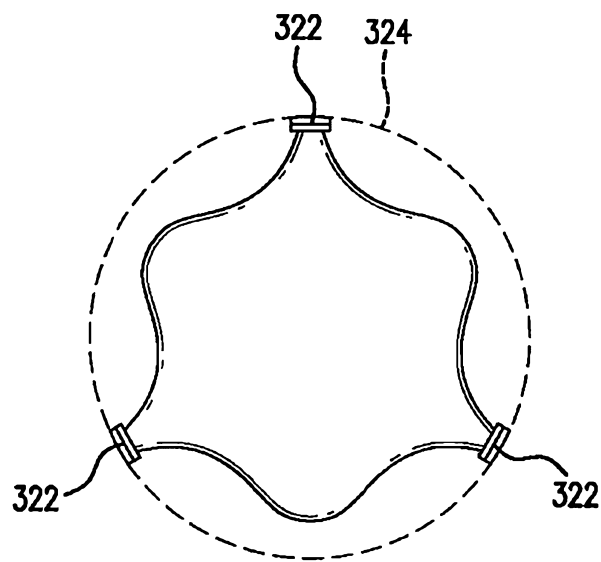
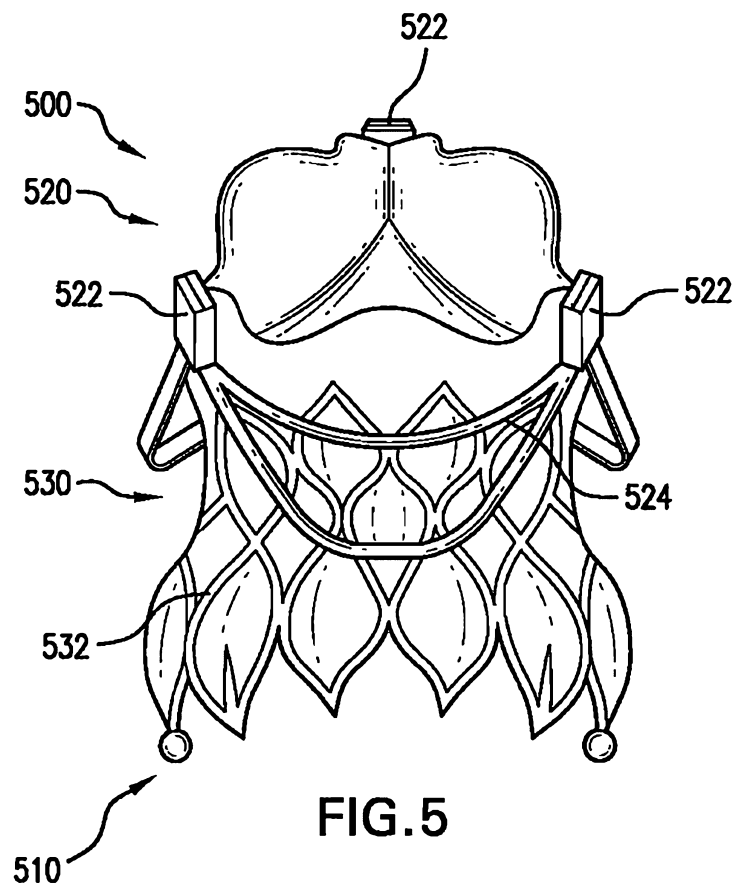


FIG. 4



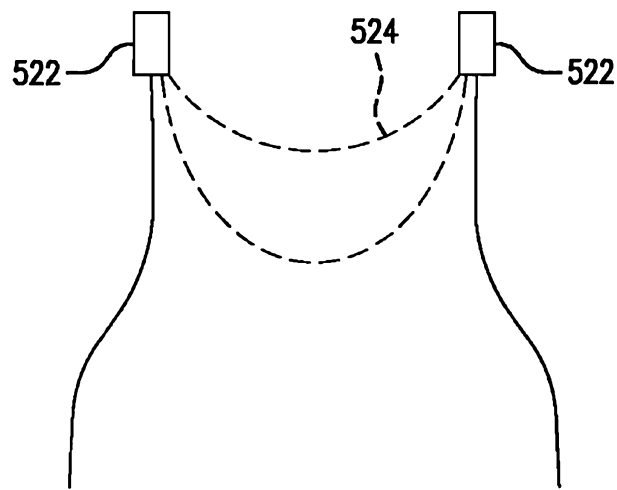
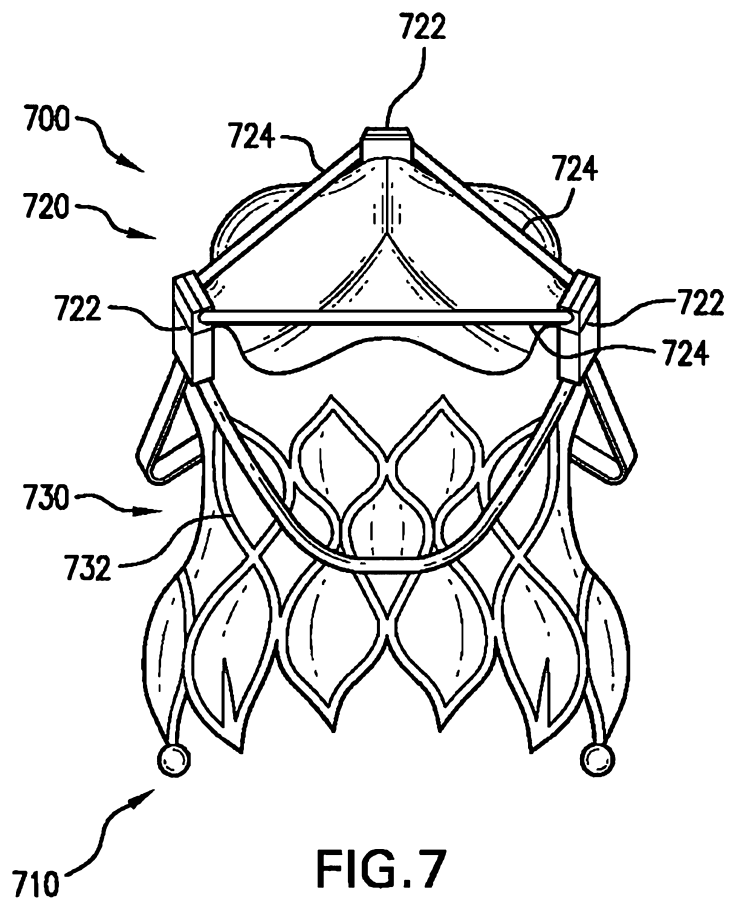


FIG. 6



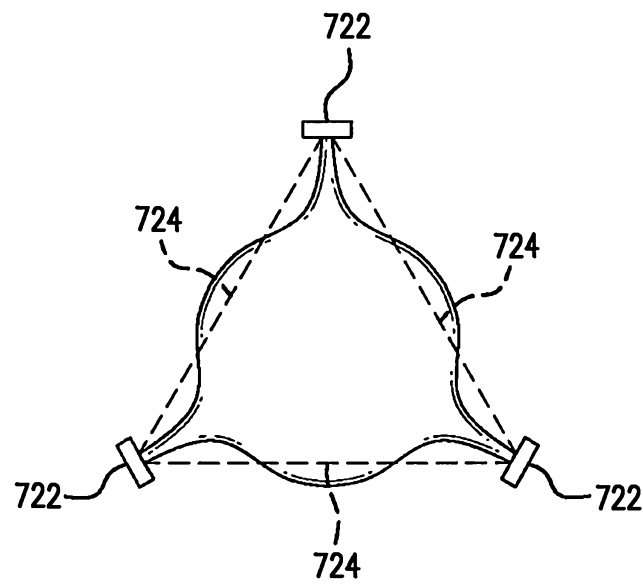


FIG. 8

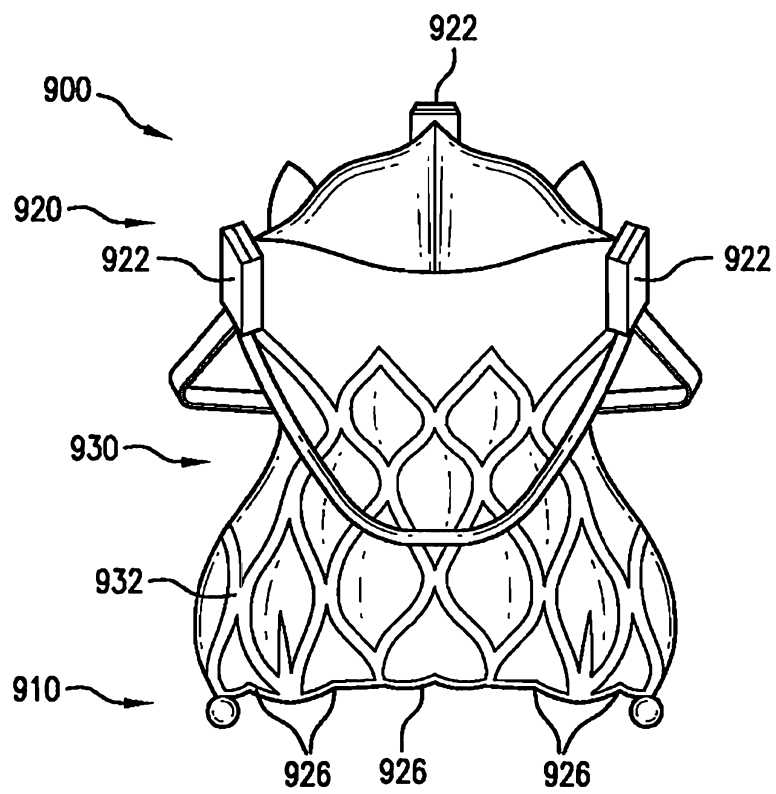


FIG. 9

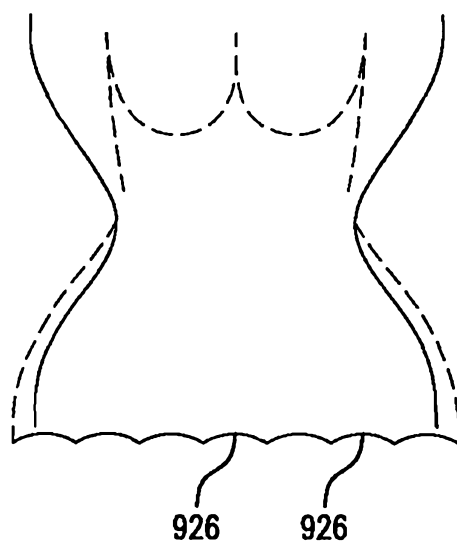


FIG. 10

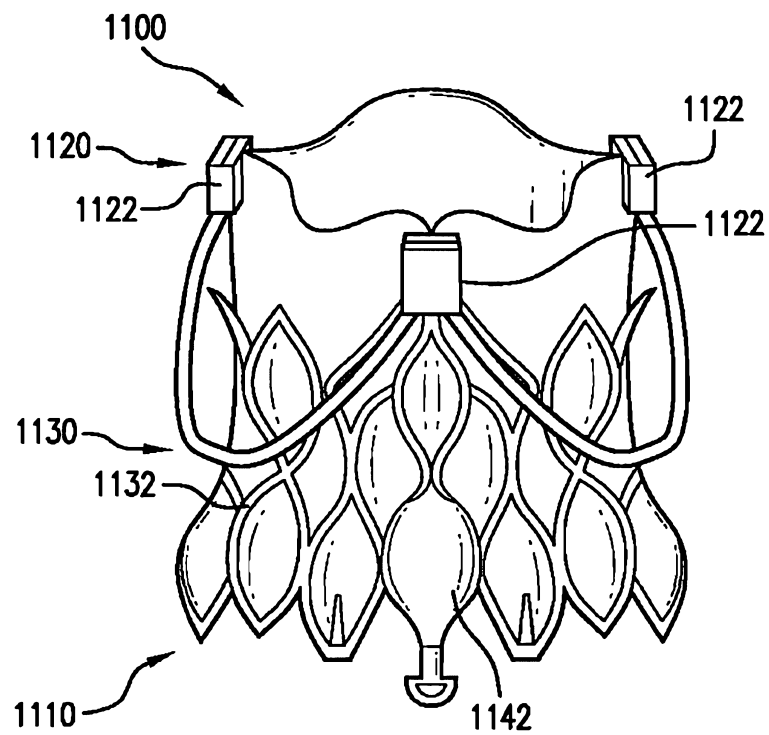
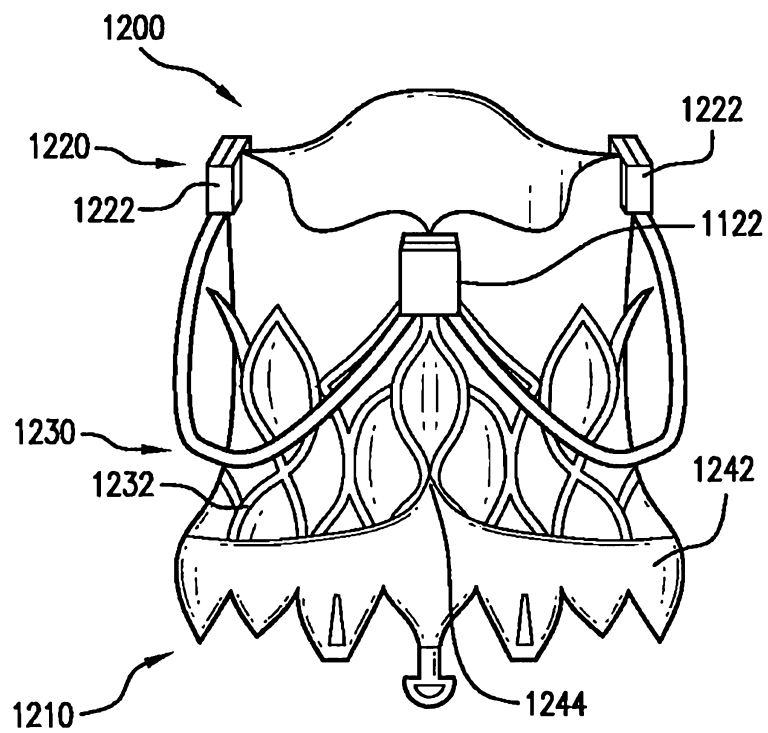


FIG. 11

**FIG. 12**