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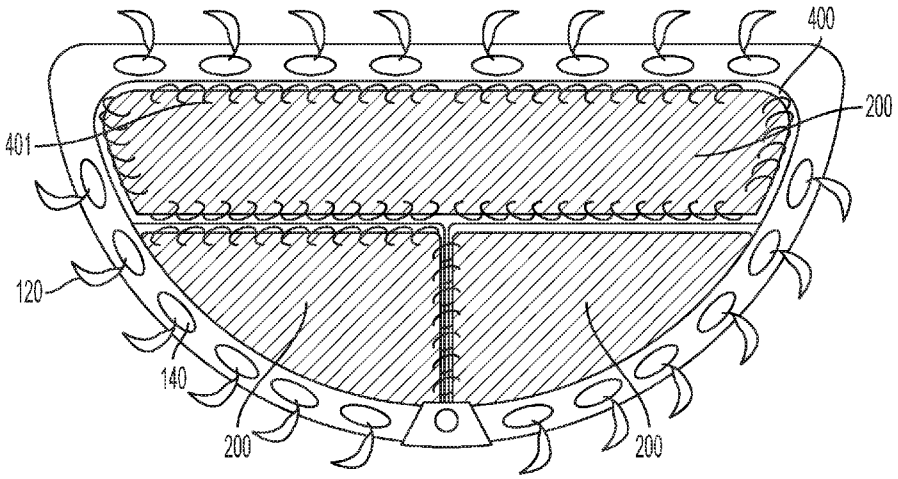

FIG. 7

(57) Abstract: An annuloplasty ring is disclosed. The annuloplasty ring includes an outer tube, a plurality of anchors, and at least one synthetic leaflet. The synthetic leaflets are in mechanical communication with the annuloplasty ring at a plurality of points. The outer tube includes a plurality of windows. The plurality of anchors are positioned inside the outer tube and about a perimeter of the outer tube. The plurality of anchors are configured to be emitted from the plurality of windows in order to anchor the annuloplasty ring to a heart valve of a patient.

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ANNULOPLASTY RING WITH POSTERIOR LEAFLET FOR MINIMALLY INVASIVE TREATMENT

CLAIM OF PRIORITY

[0001] The present application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application No. 62/859,975, filed on June 11, 2019, titled "ANNULOPLASTY RING WITH POSTERIOR LEAFLET FOR MINIMALLY INVASIVE TREATMENT," which is hereby incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] The present disclosure relates to implantable prosthetic devices. More specifically, the disclosure is directed to an improved prosthetic device implantable by catheter for the treatment of mitral or tricuspid regurgitation.

BACKGROUND

[0003] Mitral regurgitation is a valvular dysfunction that causes blood volume to flow during systole (during left ventricular contraction) from the left ventricle to the left atrium as opposed to a healthy heart where this direction of flow is blocked by the mitral valve. The reverse flow during systole causes pressure to rise in the left atrium. Maintaining a normal cardiac output results in an increased left ventricle pressure.

[0004] Treating patients with mitral regurgitation (MR) or tricuspid regurgitation (TR) could require valve replacement in order to reduce or eliminate the regurgitation. For many years, the commonly accepted treatment was surgical repair or replacement of the native valve during open heart surgery. In recent years, a trans-vascular technique has been developed for introducing and implanting a prosthetic heart valve using a flexible catheter in a manner that is less invasive than open heart surgery.

[0005] In the trans-vascular technique, the prosthetic is delivered to the target site (aortic valve, mitral valve, tricuspid valve, or other valve) through a catheter while the device is crimped to a low diameter shaft, and expanded/ deployed to the functional size when it is located in the correct position.

[0006] The catheter can be advanced to the target site: (a) Through the vascular system, where a catheter is advanced from the femoral vein/ artery or any other blood vessel that allows access to the target site; (b) Trans-apically, where a catheter is advanced through a small incision made in the chest wall and then through the apex; or (c) Trans-atrially, where a catheter is advanced through a small incision made in the chest wall and then through the left or right atrium.

SUMMARY

[0007] Some embodiments disclosed herein are directed towards an annuloplasty ring for heart valve repair. In some embodiments, the annuloplasty ring may have a first end and a second end opposite the first end. The annuloplasty ring may be configured to have an elongate insertion geometry and an annular operable geometry. The annuloplasty ring may further comprise a plurality of anchors within the annuloplasty ring. The plurality of anchors may have a deployment configuration in the annular operable geometry. The annuloplasty ring may comprise at least one synthetic leaflet in mechanical communication with the annuloplasty ring at a plurality of points. In some embodiments, the at least one synthetic leaflet may comprise a valve frame having a proximal opening and a synthetic leaflet material mechanically coupled to the valve frame. The synthetic leaflet material may be located within the proximal opening. In some embodiments, the valve frame may comprise a shape memory metal. In further embodiments, the synthetic leaflet material may comprise a polymeric material.

[0008] In some embodiments, the at least one synthetic leaflet of the annuloplasty ring may comprise a plurality of leaflets. In further embodiments, the plurality of leaflets may have a first leaflet positioned adjacent to the first end of the annuloplasty ring and a second leaflet positioned adjacent to the second end of the annuloplasty ring. In some embodiments, at least a portion of the first leaflet and the second leaflet are mechanically coupled.

[0009] In some embodiments, the at least one synthetic leaflet is in mechanical communication with the annuloplasty ring at a plurality of points on a posterior side or an anterior side of a native valve.

[0010] In additional embodiments, the annuloplasty device may further comprise a plurality of anchor windows, a coating, a DACRON (i.e., polyethylene terephthalate) coating, a shape memory metal, or a combination thereof. In some embodiments, the at least one synthetic leaflet may comprise one or more lace holes. In further embodiments, the annuloplasty ring may further comprise at least one snap mechanism configured to connect the first end and the second end.

[0011] Further embodiments disclosed herein are directed towards an anchor device. The anchor device may comprise a leaflet anchor having an anchor body with a first end and a second end. The leaflet anchor may further comprise an anchor portion in mechanical communication with the first end of the leaflet anchor. In some embodiments, the leaflet anchor may further comprise a separating element in mechanical communication with the second end of the leaflet anchor, and a distal portion in mechanical communication with the anchor body between the first end and the second end. In some embodiments, the separating element may be configured to rotate the anchor body. In further embodiments, the anchor portion or the anchor body may comprise a shape memory metal.

[0012] Additional embodiments disclosed herein are directed towards a method of delivering the annuloplasty ring in an elongate insertion geometry, where the delivery of the annuloplasty ring utilizes one of a trans-apical approach, trans-septal approach, a trans-femoral approach, a trans-jugular approach, and a trans-atrial approach.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Aspects, features, benefits and advantages of the embodiments described herein will be apparent with regard to the following description, appended claims, and accompanying drawings where:

[0014] FIG. 1 depicts an annuloplasty ring having at least one synthetic leaflet in accordance with an embodiment.

[0015] FIG. 2 illustrates an annuloplasty ring in an open configuration having at least one synthetic leaflet in accordance with an embodiment.

[0016] FIG. 3 depicts a cross-sectional view of an annuloplasty ring in an elongate insertion geometry in accordance with an embodiment.

[0017] FIG. 4 illustrates a perspective view of an annuloplasty ring having at least one synthetic leaflet in accordance with an embodiment.

[0018] FIG. 5A is a perspective view depicting delivery of an annuloplasty ring having at least one synthetic leaflet in accordance with an embodiment.

[0019] FIG. 5B illustrates a side view of an annuloplasty ring having at least one synthetic leaflet in accordance with an embodiment.

[0020] FIG. 5C is a perspective view depicting delivery of an annuloplasty ring having at least one synthetic leaflet in accordance with an embodiment.

[0021] FIG. 6 is a perspective view of an annuloplasty ring having at least one synthetic leaflet in an open configuration in accordance with an embodiment.

[0022] FIG. 7 depicts an annuloplasty ring having at least one anterior synthetic leaflet and at least one posterior synthetic leaflet in accordance with an embodiment.

[0023] FIG. 8 is a cross-section view of an annuloplasty ring having at least one anterior synthetic leaflet and at least one posterior synthetic leaflet in accordance with an embodiment.

[0024] FIG. 9 is a top view of an annuloplasty ring having at least one anterior synthetic leaflet and at least one posterior synthetic leaflet secured to a native leaflet with a leaflet anchor in accordance with an embodiment.

[0025] FIG. 10 is a side view of an annuloplasty ring having at least one synthetic leaflet in accordance with an embodiment.

[0026] FIG. 11A illustrates a leaflet anchor in accordance with an embodiment.

[0027] FIG. 11B depicts a deployed leaflet anchor in accordance with an embodiment.

[0028] FIG. 11C illustrates a deployed leaflet anchor in accordance with a further embodiment.

[0029] FIG. 12 is a top view of an annuloplasty ring having at least one posterior synthetic leaflet in accordance with an embodiment.

[0030] FIG. 13 depicts an annuloplasty ring having a plurality of synthetic leaflets in accordance with an embodiment.

DETAILED DESCRIPTION

[0031] The term "about," as used herein, refers to variations in a numerical quantity that can occur, for example, through measuring or handling procedures in the real world; through inadvertent error in these procedures; through differences in the manufacture, source, or purity of compositions or reagents; and the like. Typically, the term "about" as used herein means greater or lesser than the value or range of values stated by 1/10 of the stated values, e.g., ±10%. The term "about" also refers to variations that would be recognized by one skilled in the art as being

equivalent so long as such variations do not encompass known values practiced by the prior art. Each value or range of values preceded by the term "about" is also intended to encompass the embodiment of the stated absolute value or range of values. Whether or not modified by the term "about," quantitative values recited in the claims include equivalents to the recited values, e.g., variations in the numerical quantity of such values that can occur, but would be recognized to be equivalents by a person skilled in the art.

[0032] The term "patient" and "subject" are interchangeable and may be taken to mean any living organism. As such, the terms "patient" and "subject" may include, but is not limited to, any non-human mammal, primate or human. In some embodiments, the "patient" or "subject" is a mammal, such as mice, rats, other rodents, rabbits, dogs, cats, swine, cattle, sheep, horses, primates, or humans. In some embodiments, the patient or subject is an adult, child or infant. In some embodiments, the patient or subject is a human.

[0033] When implanting a replacement valve (e.g., an aortic valve, mitral valve, tricuspid valve, or other valve), the replacement valve can include a prosthesis attachment. The prosthesis can be configured to secure the replacement valve in a patient's heart. Additional detail related to prosthetic valves for mitral or tricuspid valve replacement can be found in: U.S. Patent Application No. 13/198,582 entitled "Percutaneous Transcatheter Repair of Heart Valves," filed August 4, 2011; U.S. Patent Application No. 13/397,545 entitled "Percutaneous Transcatheter Repair of Heart Valves via Trans-Apical Access," filed February 15, 2012; and U.S. Patent Application No. 13/779,478 entitled "Percutaneous Annuloplasty System with Anterior-Posterior Adjustment," filed February 27, 2013, the contents of which are incorporated herein by reference in their entirety.

[0034] An implant and delivery system for introduction of a semi-rigid ring for treatment of tricuspid or mitral valve regurgitation includes an annuloplasty ring comprising an outer hollow member with a plurality of segments. In a further embodiment, segments may be adjustable and may cooperate with one another in order to change the outer hollow member from an elongated insertion shaped geometry to an annular operable shaped geometry. The tricuspid annuloplasty ring may include one or more zones comprising internal anchor members located at least partially within the outer hollow member. In one non-limiting embodiment, the tricuspid annuloplasty ring may include up to four different anchor zones, which are further discussed herein. In an embodiment, the internal anchor members may be configured to emerge sequentially from windows (i.e., openings) along the hollow tube, thereby engaging the tissue of the tricuspid valve annulus under treatment, potentially in a predetermined sequence.

[0035] Systems and methods are provided for introducing an annuloplasty ring (e.g., while it is housed in a linear shape within the delivery system) in a trans-apical or trans-femoral approach. In an embodiment, the distal tip of the delivery system may be introduced above the annulus. Once the annuloplasty ring is introduced, the plane of the annuloplasty ring may be rotated (e.g., automatically) to be parallel to the plane of the annulus. Once in the proper location, an embodiment may deploy a plurality of anchors. For example, an embodiment may deploy anchors associated with the septal zone, the posterior zone, or the first or second anterior zones.

[0036] The annuloplasty ring may then be snapped into a proper shape (e.g., a "D" shape) and introduced to the stabilization tool. The shape is possible because, as discussed herein, the annuloplasty ring comprises an outer hollow member with a plurality of segments, where the segments may be adjustable and may cooperate with one another in order to change

the outer hollow member from an annular operable shaped geometry to an elongated insertion shaped geometry and vice versa.

[0037] Referring to FIG. 1, a top view of an annuloplasty ring 100, as it relates to various embodiments discussed herein, is shown. As shown, the annuloplasty ring 100 may have an annular operable shaped geometry where a first end and a second end are in mechanical communication through snap mechanism 130. In an embodiment, the annuloplasty ring may have an operable geometry. For example, the hypotube may be annular and/or D-shaped. Additionally, FIG. 1 illustrates a plurality of anchors 120 deployed through a plurality of anchor windows 140 of the annuloplasty ring 100. As shown in FIG. 1, the annuloplasty ring 100 may have at least one synthetic leaflet 200 in mechanical communication with the annuloplasty ring at a plurality of points on the inner surface of the annuloplasty ring 100. In some embodiments, the synthetic leaflet 200 may comprise a valve frame 400 having a proximal opening. The at least one synthetic leaflet may further comprise a synthetic leaflet material mechanically coupled to the valve frame, where the synthetic leaflet material is within the proximal opening. As depicted in FIG. 1, the at least one synthetic leaflet may comprise a plurality of leaflets, where the plurality of leaflets are mechanically coupled.

[0038] The annuloplasty ring may be made of various materials (e.g., a shape memory hypotube (nickel titanium (Ni-Ti) super elastic alloy)) cut to form a plurality of segments. Additionally, the cutting pattern used for laser processing (e.g. the cutting of anchor windows 140 through which anchors 120 may be deployed) of the annuloplasty ring 100 is illustrated in FIG. 1.

[0039] In an embodiment, the valve frame 400 may be made of various materials including, but not limited to, a shape memory metal (e.g. Ni-Ti). The valve frame 400 may have

a diameter in a range of about 0.01 inches to about 0.015 inches. The synthetic leaflet material 200 may be mechanically coupled to the valve frame 400 by suturing (e.g. surgical sutures 401). This configuration may allow the at least one synthetic leaflet to move towards the surface of the annulus upon deployment of the annuloplasty ring. The suture material may be polytetrafluoroethylene (PTFE) or polypropylene sutures. Further embodiments may include a synthetic leaflet material made from a polymeric material (e.g. polyurethane or dried precordium tissue).

[0040] Referring to FIG. 2, a top view of the annuloplasty ring 100, as it relates to various embodiments discussed herein, is shown. As shown, the annuloplasty ring 100 may have an elongate insertion geometry where the first end is opposite the second end. In some embodiments, the first end, the second end, or both may have a snap mechanism 130. In some embodiments, the annuloplasty ring 100 may have a coating 500 (e.g. a DACRON coating) on the inner surface or the outer surface of the annuloplasty ring 100. In further embodiments, the annuloplasty ring 100 may have at least one synthetic leaflet 200. As depicted in FIG. 2, the at least one synthetic leaflet may comprise a plurality of leaflets positioned at the first end or the second end of the annuloplasty ring.

[0041] Illustrated in FIG. 3 is a cross section view of an annuloplasty ring in an elongate insertion geometry within a delivery catheter 600.

[0042] FIG. 4 illustrates a side view of a distal end of the delivery catheter 600 with the annuloplasty ring 100 and the at least one synthetic leaflet 200 partially deployed from the distal end of the delivery catheter. Further illustrated in FIG. 4 is a pull-wire 700 that can be in mechanical communication with the annuloplasty ring 100.

[0043] FIGS. 5A-C depict perspective views of the annuloplasty ring 100 where the plane of the annuloplasty ring 100 (in its annular operable geometry) has been changed to be perpendicular to the longitudinal axis of the delivery catheter 600. As illustrated in FIG. 5A, the at least one synthetic leaflet 200 comprises a plurality of leaflets in mechanical communication. In some embodiments, the plurality of leaflets in mechanical communication are configured to be operably connected to the inner surface of the posterior side 900 of the annuloplasty ring 100. In further embodiments, the plurality of leaflets in mechanical communication are configured to be operably connected to the inner surface of the anterior side 1000 of the annuloplasty ring 100. As illustrated in FIG. 5B, in some embodiments annuloplasty ring 100 may comprise ring element 1100.

[0044] FIG. 5C depicts a further embodiment wherein annuloplasty ring 100 comprises a plurality of leaflets having one or more lace holes 210. The plurality of leaflets may be configured to be in mechanical communication using a suture lace 220 that operably connects the plurality of leaflets through the one or more lace holes 210. In further embodiments, the suture lace 220 can be configured to pass through the snap mechanism 130 and into the delivery catheter 600.

[0045] FIG. 6 depicts the deployed annuloplasty ring 100 and the deployed plurality of anchors 120 with at least one synthetic leaflet 200 tilted toward the annulus and a native posterior leaflet.

[0046] Referring to FIGS. 7-8, the annuloplasty ring 100, as it relates to various embodiments discussed herein, is shown. As shown, the annuloplasty ring 100 in an annular operable geometry (FIG. 7) or an elongate insertion geometry (FIG. 8) may comprise a plurality of leaflets 200. In some embodiments, the inner surface of the posterior side of the annuloplasty

ring 100 may comprise a plurality of leaflets having lace holes that provides mechanical communication for the plurality of leaflets. The plurality of leaflets may be in mechanical communication with the inner surface of the posterior side of the annuloplasty ring 100 at a plurality of points.

[0047] In a further embodiment, as illustrated in FIG. 12, the annuloplasty ring may comprise at least one synthetic leaflet on the inner surface of the posterior side of the annuloplasty ring 100. The at least one synthetic leaflet may be in mechanical communication with the inner surface of the posterior side of the annuloplasty ring 100 at a plurality of points. Further, the snap mechanism 130 can be located on the anterior side of the annuloplasty ring 100.

[0048] In a further embodiment, as illustrated in FIG. 13, the inner surface of the posterior side of the annuloplasty ring 100 may comprise a plurality of leaflets having lace holes that provide mechanical communication for the plurality of leaflets. The plurality of leaflets may be in mechanical communication with the inner surface of the posterior side of the annuloplasty ring 100 at a plurality of points. Further, the inner surface of the anterior side of the annuloplasty ring 100 may comprise at least one synthetic leaflet 200 in mechanical communication with the inner surface of the annuloplasty ring 100. In some embodiments, as depicted in FIG. 13, the inner surface of the annuloplasty ring 100 may comprise a plurality of commissure leaflets 200a,b.

[0049] In some embodiments, as illustrated in FIG. 9, a leaflet anchor 800 may be in mechanical communication with the at least one synthetic leaflet 200 of the annuloplasty ring 100. In some embodiments, the leaflet anchor 800 may mechanically couple one or more native leaflets to the at least one synthetic leaflet 200. This embodiment may allow the one or more synthetic leaflets 200 to co-apt, as illustrated in FIG. 10.

[0050] As illustrated in FIG. 11A-C, the leaflet anchor 800 may have an anchor body 830 with a first end and a second end. The leaflet anchor 800 may further comprise an anchor portion 820 in mechanical communication with the first end of the leaflet anchor. In further embodiments, the leaflet anchor 800 may also include a separating element 850 in mechanical communication with the second end of leaflet anchor. Separating element 850 can be configured to separate the anchor delivery catheter 835 and the leaflet anchor 800. The leaflet anchor 800 may also comprise a disk portion 840, where the disk portion is in mechanical communication with the anchor body 830 between the first end and the second end. As illustrated in FIG. 11B, leaflet anchor 800 can be configured to deploy from delivery catheter 600, from anchor delivery catheter 835, or a combination thereof. In some embodiments, leaflet anchor 800 may be configured to pass through native leaflet 1200 and the at least one synthetic leaflet 200, wherein anchor portion 820 is deployed on a surface of the at least one synthetic leaflet 200. In some embodiments, the disk portion 840 can be configured to fix the anchor portion 820 to the at least one synthetic leaflet 200 and the native leaflet 1200.

[0051] The annuloplasty ring as described above can be designed and shaped for various functions such as mitral valve replacement. A similar annuloplasty ring can be designed and constructed for tricuspid valve replacement as well. However, a tricuspid ring can be designed with additional features, such as a release zone positioned on the ring assembly at a location that will be adjacent to a patient's atrioventricular node or valves. In certain implementations, the release zone does not have any anchors. Rather, the alternate shape and profile of the release zone provides for interference between the annuloplasty ring and the patient's atrioventricular node or valves, thereby securing the ring assembly in position.

[0052] Some embodiments are directed towards a method of delivering the annuloplasty ring as substantially described above. In some embodiments, the annuloplasty ring may be delivered in an elongate insertion geometry, where the delivery of the annuloplasty ring utilizes one of a trans-apical approach, trans-septal approach, trans-femoral approach, trans-jugular approach, or a trans-atrial approach.

[0053] This disclosure is not limited to the particular apparatus, systems, devices and methods described, as these may vary. The terminology used in the description is for the purpose of describing the particular versions or embodiments only, and is not intended to limit the scope.

[0054] As used in this document, the singular forms "a," "an," and "the" include plural references unless the context clearly dictates otherwise. Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art. Nothing in this disclosure is to be construed as an admission that the embodiments described in this disclosure are not entitled to antedate such disclosure by virtue of prior invention. As used in this document, the term "comprising" means "including, but not limited to."

[0055] In the detailed description above, reference is made to the accompanying drawings, which form a part hereof. In the drawings, similar symbols typically identify similar components, unless context dictates otherwise. The illustrative embodiments described in the detailed description, drawings, and claims are not meant to be limiting. Other embodiments may be used, and other changes may be made, without departing from the spirit or scope of the subject matter presented herein. It will be readily understood that various features of the present disclosure, as generally described herein, and illustrated in the Figures, can be arranged,

substituted, combined, separated, and designed in a wide variety of different configurations, all of which are explicitly contemplated herein.

[0056] The present disclosure is not to be limited in terms of the particular embodiments described in this application, which are intended as illustrations of various features. Many modifications and variations can be made without departing from its spirit and scope, as will be apparent to those skilled in the art. Functionally equivalent methods and apparatuses within the scope of the disclosure, in addition to those enumerated herein, will be apparent to those skilled in the art from the foregoing descriptions. Such modifications and variations are intended to fall within the scope of the appended claims. The present disclosure is to be limited only by the terms of the appended claims, along with the full scope of equivalents to which such claims are entitled. It is to be understood that this disclosure is not limited to particular methods, reagents, compounds, compositions or biological systems, which can, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting.

[0057] With respect to the use of substantially any plural and/or singular terms herein, those having skill in the art can translate from the plural to the singular and/or from the singular to the plural as is appropriate to the context and/or application. The various singular/plural permutations may be expressly set forth herein for sake of clarity.

[0058] It will be understood by those within the art that, in general, terms used herein, and especially in the appended claims (for example, bodies of the appended claims) are generally intended as "open" terms (for example, the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," et cetera). While various

compositions, methods, and devices are described in terms of “comprising” various components or steps (interpreted as meaning “including, but not limited to”), the compositions, methods, and devices can also “consist essentially of” or “consist of” the various components and steps, and such terminology should be interpreted as defining essentially closed-member groups. It will be further understood by those within the art that if a specific number of an introduced claim recitation is intended, such an intent will be explicitly recited in the claim, and in the absence of such recitation no such intent is present.

[0059] For example, as an aid to understanding, the following appended claims may contain usage of the introductory phrases "at least one" and "one or more" to introduce claim recitations. However, the use of such phrases should not be construed to imply that the introduction of a claim recitation by the indefinite articles "a" or "an" limits any particular claim containing such introduced claim recitation to embodiments containing only one such recitation, even when the same claim includes the introductory phrases "one or more" or "at least one" and indefinite articles such as "a" or "an" (for example, “a” and/or “an” should be interpreted to mean “at least one” or “one or more”); the same holds true for the use of definite articles used to introduce claim recitations.

[0060] In addition, even if a specific number of an introduced claim recitation is explicitly recited, those skilled in the art will recognize that such recitation should be interpreted to mean at least the recited number (for example, the bare recitation of "two recitations," without other modifiers, means at least two recitations, or two or more recitations). Furthermore, in those instances where a convention analogous to “at least one of A, B, and C, et cetera” is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (for example, “a system having at least one of A, B, and C” would include but not

be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, et cetera). In those instances where a convention analogous to "at least one of A, B, or C, et cetera" is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (for example, "a system having at least one of A, B, or C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, et cetera). It will be further understood by those within the art that virtually any disjunctive word and/or phrase presenting two or more alternative terms, whether in the description, claims, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both terms. For example, the phrase "A or B" will be understood to include the possibilities of "A" or "B" or "A and B."

[0061] In addition, where features of the disclosure are described in terms of Markush groups, those skilled in the art will recognize that the disclosure is also thereby described in terms of any individual member or subgroup of members of the Markush group.

[0062] As will be understood by one skilled in the art, for any and all purposes, such as in terms of providing a written description, all ranges disclosed herein also encompass any and all possible subranges and combinations of subranges thereof. Any listed range can be easily recognized as sufficiently describing and enabling the same range being broken down into at least equal halves, thirds, quarters, fifths, tenths, et cetera. As a non-limiting example, each range discussed herein can be readily broken down into a lower third, middle third and upper third, et cetera. As will also be understood by one skilled in the art all language such as "up to," "at least," and the like include the number recited and refer to ranges that can be subsequently broken down into subranges as discussed above. Finally, as will be understood by one skilled in

the art, a range includes each individual member. Thus, for example, a group having 1-3 cells refers to groups having 1, 2, or 3 cells. Similarly, a group having 1-5 cells refers to groups having 1, 2, 3, 4, or 5 cells, and so forth.

[0063] Various of the above-disclosed and other features and functions, or alternatives thereof, may be combined into many other different devices or applications. Various presently unforeseen or unanticipated alternatives, modifications, variations or improvements therein may be subsequently made by those skilled in the art, each of which is also intended to be encompassed by the disclosed embodiments.

CLAIMS

What is claimed is:

1. An annuloplasty device comprising:

an annuloplasty ring comprising a first end and a second end opposite the first end, the annuloplasty ring configured to transition between an elongate insertion geometry and an annular operable geometry;

a plurality of anchors disposed within the annuloplasty ring, the plurality of anchors configured to assume a deployment configuration when the annuloplasty ring is in the annular operable geometry; and

at least one synthetic leaflet in mechanical communication with the annuloplasty ring at a plurality of points.

2. The annuloplasty device of claim 1, wherein the at least one synthetic leaflet comprises:

a valve frame comprising a proximal opening; and

a synthetic leaflet material mechanically coupled to the valve frame, wherein the synthetic leaflet material is disposed within the proximal opening.

3. The annuloplasty device of claim 2, wherein the valve frame comprises a shape memory metal.

4. The annuloplasty device of claim 2, wherein the synthetic leaflet material comprises a polymeric material.

5. The annuloplasty device of claim 1, wherein the at least one synthetic leaflet comprises a plurality of leaflets.

6. The annuloplasty device of claim 5, wherein the plurality of leaflets comprise:

a first leaflet positioned adjacent to the first end of the annuloplasty ring; and

a second leaflet positioned adjacent to the second end of the annuloplasty ring.

7. The annuloplasty device of claim 6, wherein at least a portion of each of the first leaflet and the second leaflet are mechanically coupled.

8. The annuloplasty device of claim 1, wherein the at least one synthetic leaflet is in mechanical communication with the annuloplasty ring at a plurality of points on a posterior side of a native valve.

9. The annuloplasty device of claim 1, wherein the at least one synthetic leaflets is in mechanical communication with the annuloplasty ring at a plurality of points on an anterior side of the native valve.

10. The annuloplasty device of claim 1, wherein the annuloplasty ring further comprises a plurality of anchor windows through which the plurality of anchors are deployable.

11. The annuloplasty device of claim 1, wherein the annuloplasty ring comprises a coating.

12. The annuloplasty device of claim 11, wherein the coating comprises a polyethylene terephthalate coating.

13. The annuloplasty device of claim 1, wherein the annuloplasty ring comprises a shape memory metal.

14. The annuloplasty device of claim 1, wherein the at least one synthetic leaflet comprises one or more lace holes configured to receive a suture therethrough.

15. The annuloplasty device of claim 1, wherein the annuloplasty ring further comprises at least one snap mechanism configured to connect the first end and the second end.

16. An anchor device, comprising:

a leaflet anchor comprising an anchor body comprising a first end and a second end;

an anchor portion in mechanical communication with the first end of the leaflet anchor;

a separating element in mechanical communication with the second end of the leaflet anchor; and

a disk portion in mechanical communication with the anchor body between the first end and the second end.

17. The anchor device of claim 16, wherein the anchor portion comprises a shape memory metal.

18. The anchor device of claim 16, wherein the anchor body comprises a shape memory metal.

19. The anchor device of claim 16, wherein the separating element is configured to rotate the anchor body.

20. A method of implanting an annuloplasty device within a patient, the method comprising:

delivering, into the patient, an annuloplasty ring in an elongate insertion geometry, the annuloplasty ring comprising at least one synthetic leaflet in mechanical communication with an annuloplasty ring at a plurality of points; and

positioning the annuloplasty ring parallel to a plane of a valve annulus of the patient.

21. The method of claim 20, wherein the annuloplasty ring is delivered using one of a trans-apical approach, a trans-septal approach, a trans-femoral approach, a trans-jugular approach, or a trans-atrial approach.

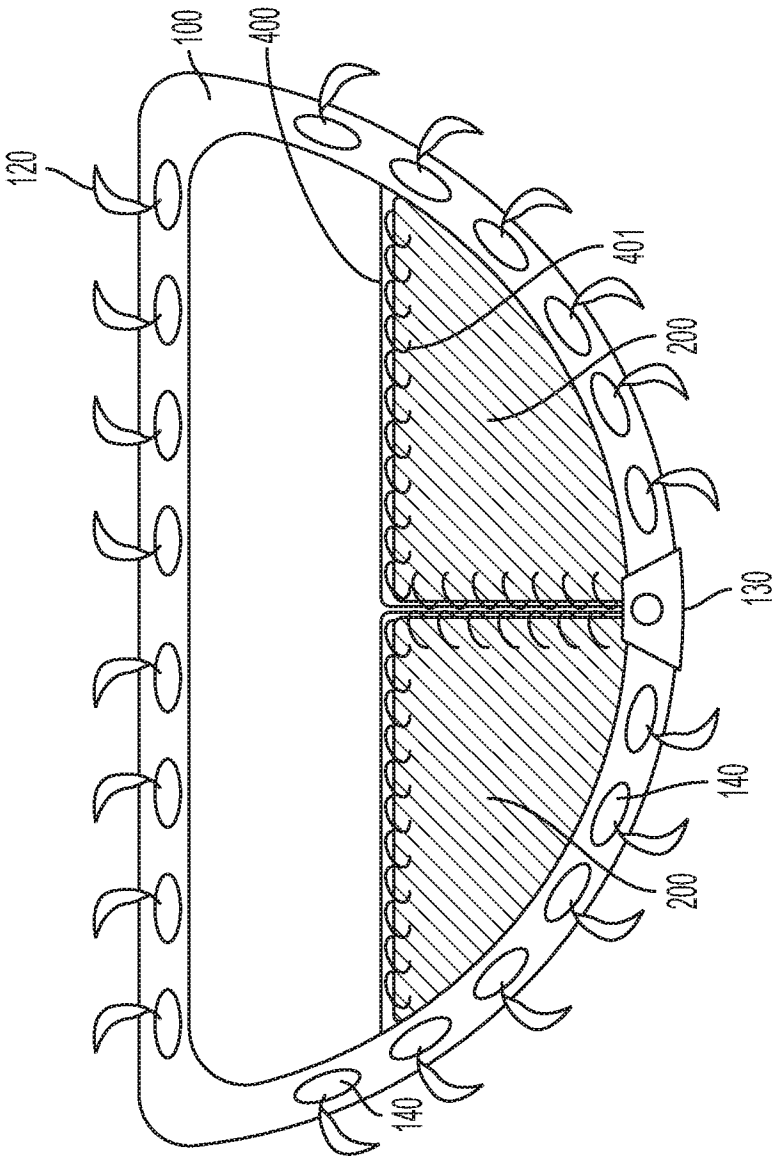

FIG. 1

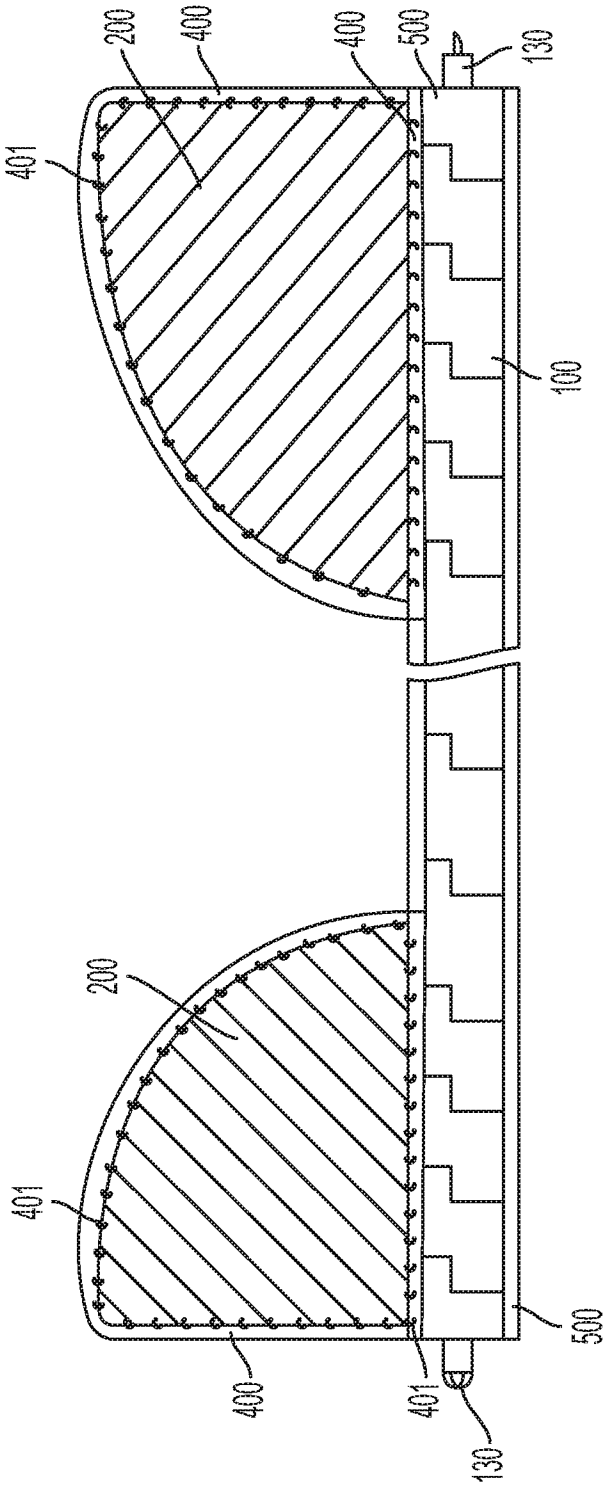

FIG. 2

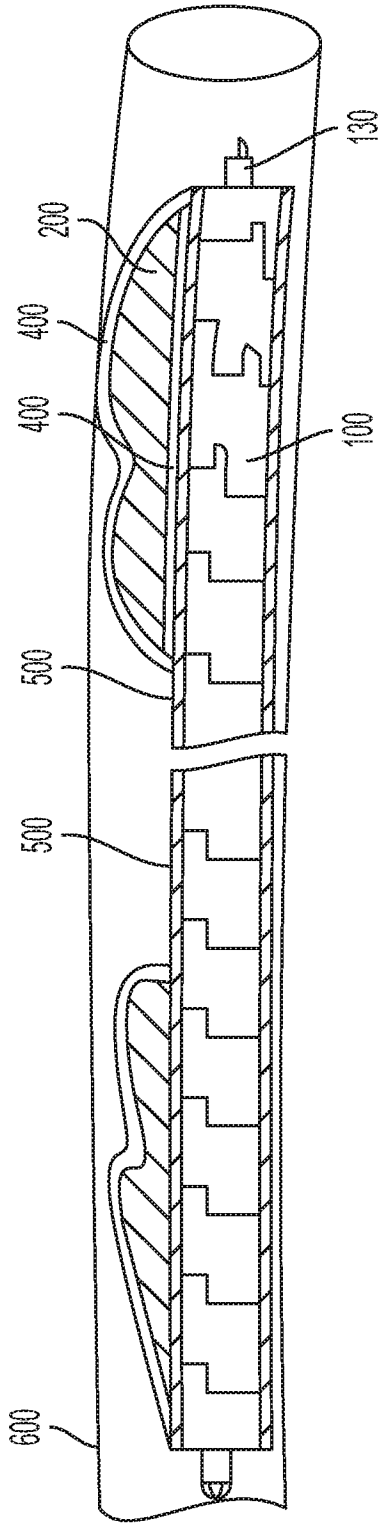

FIG. 3

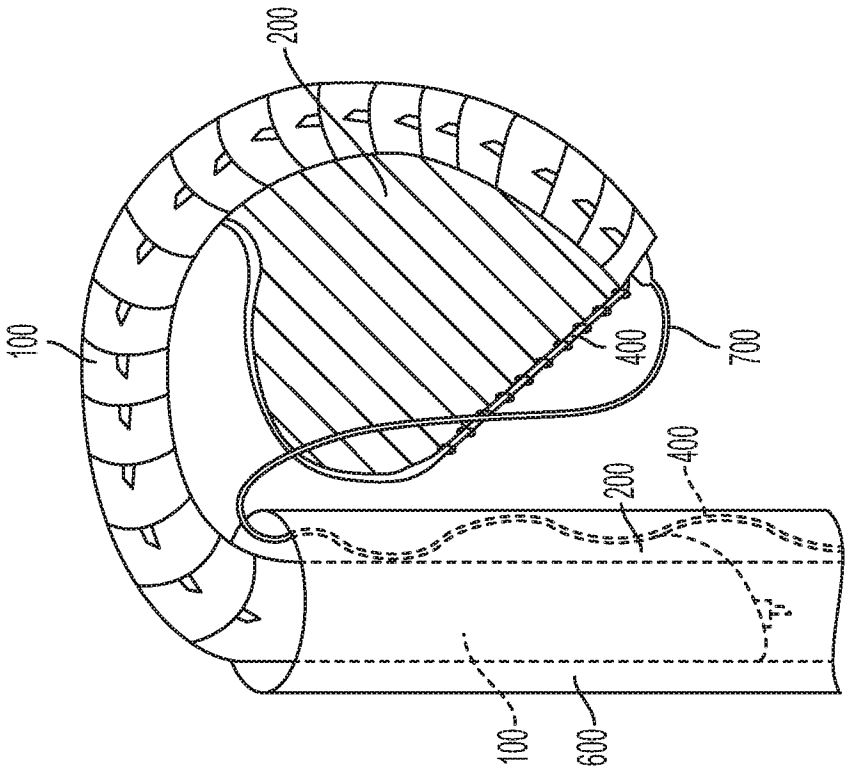

FIG. 4

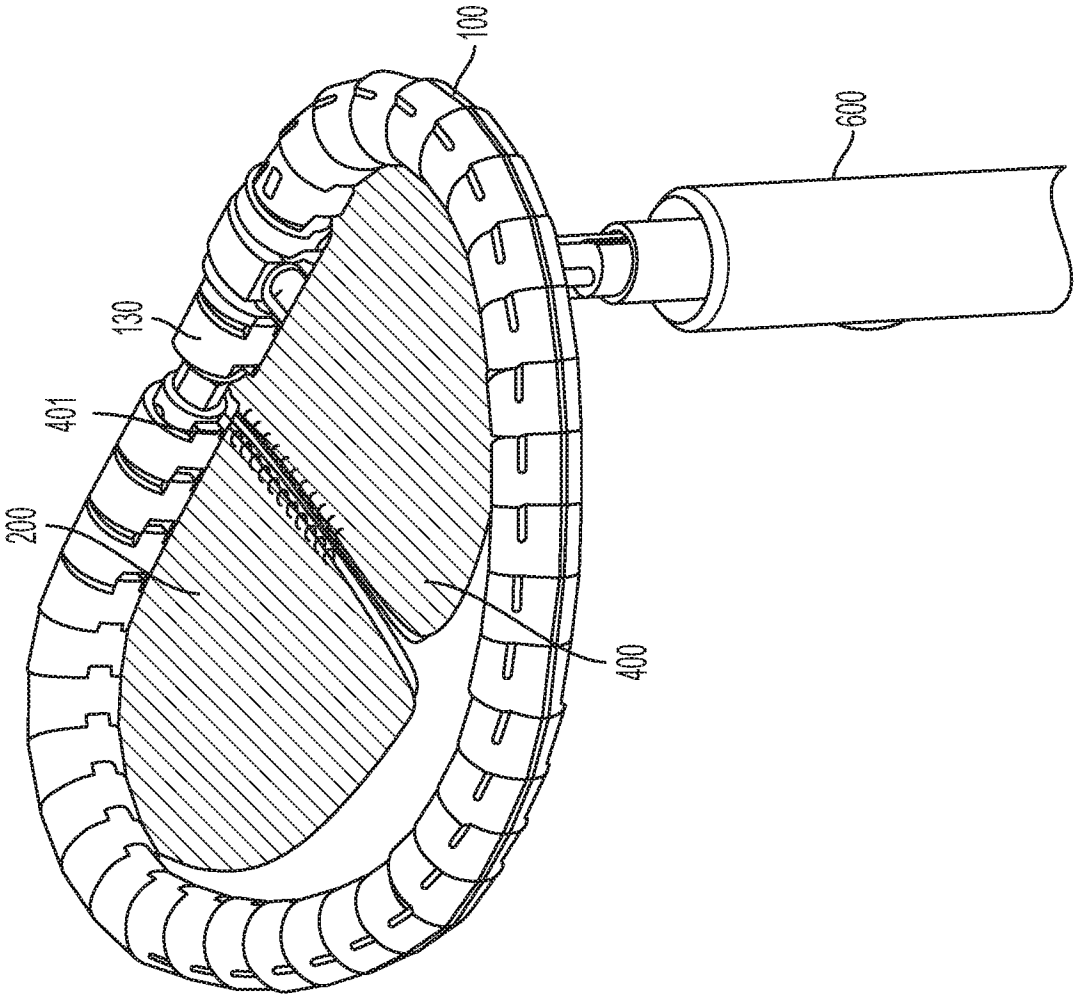

FIG. 5A

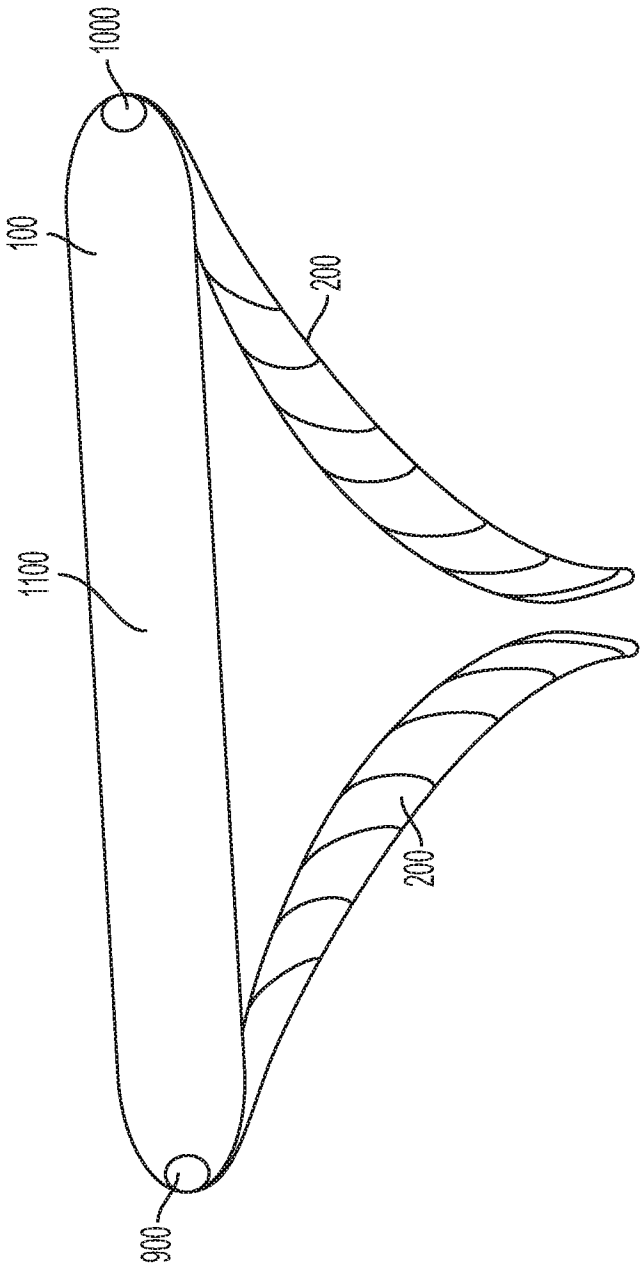

FIG. 5B

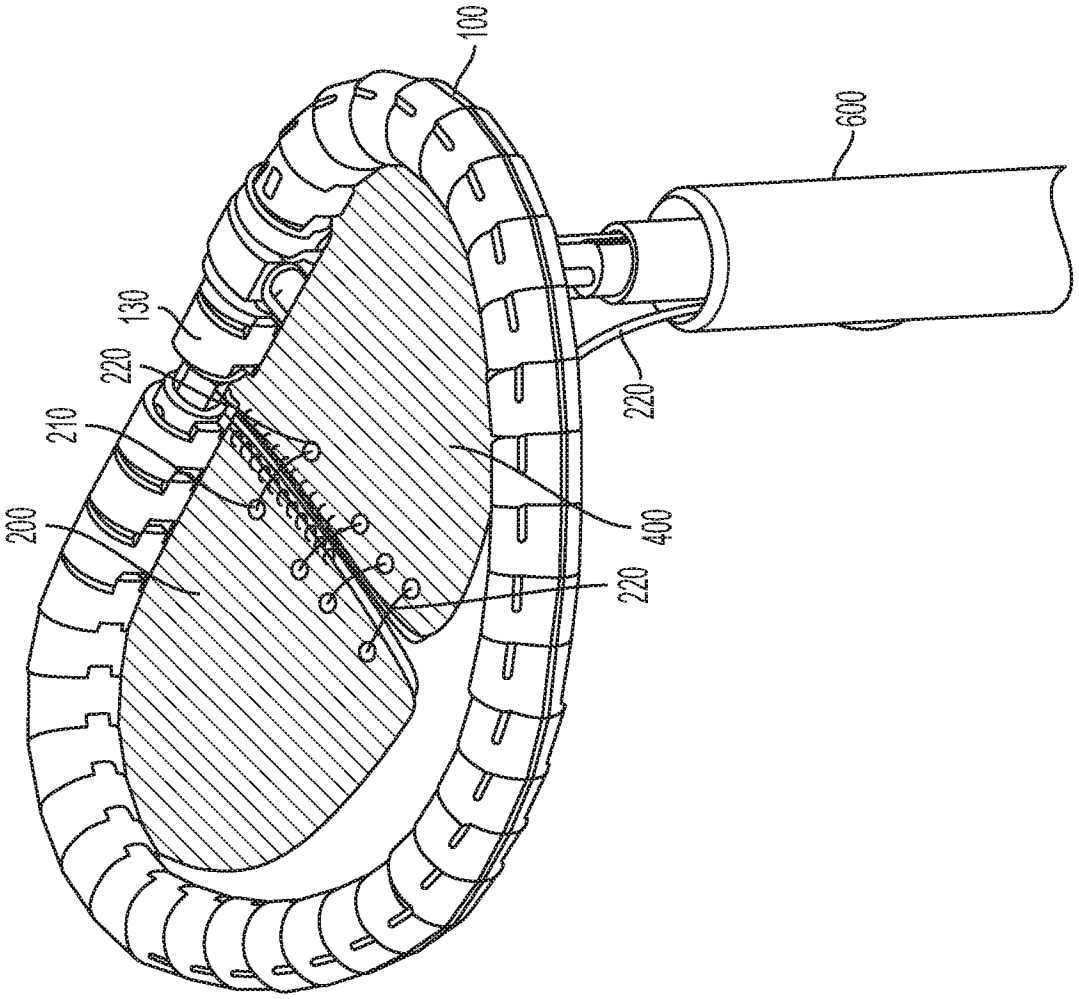

FIG. 5C

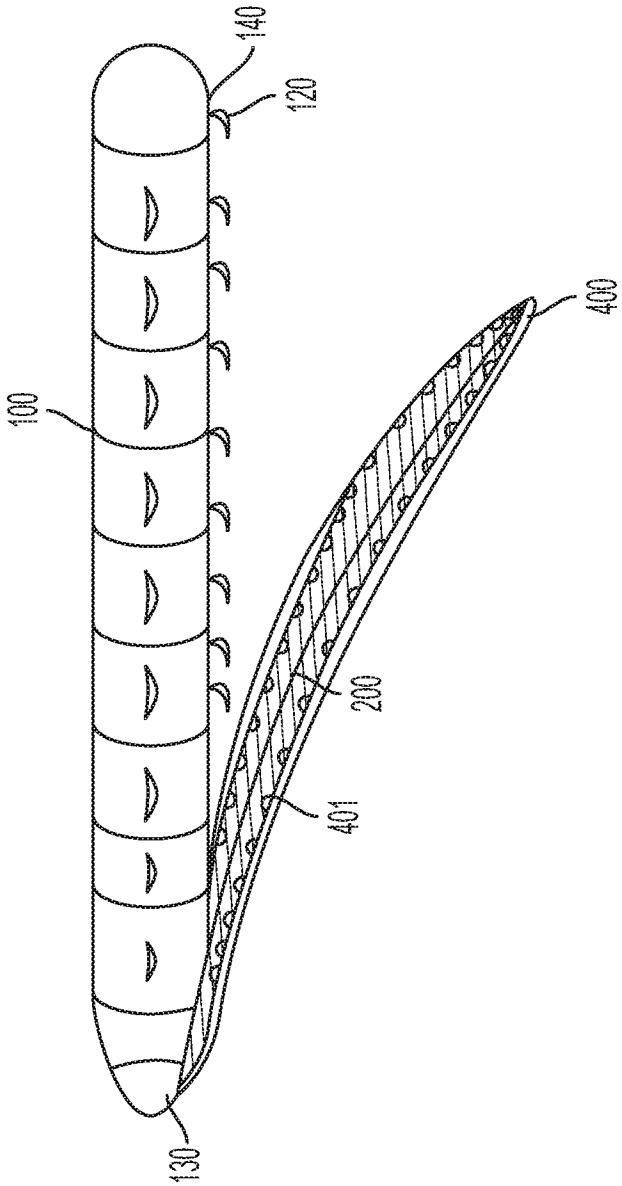

FIG. 6

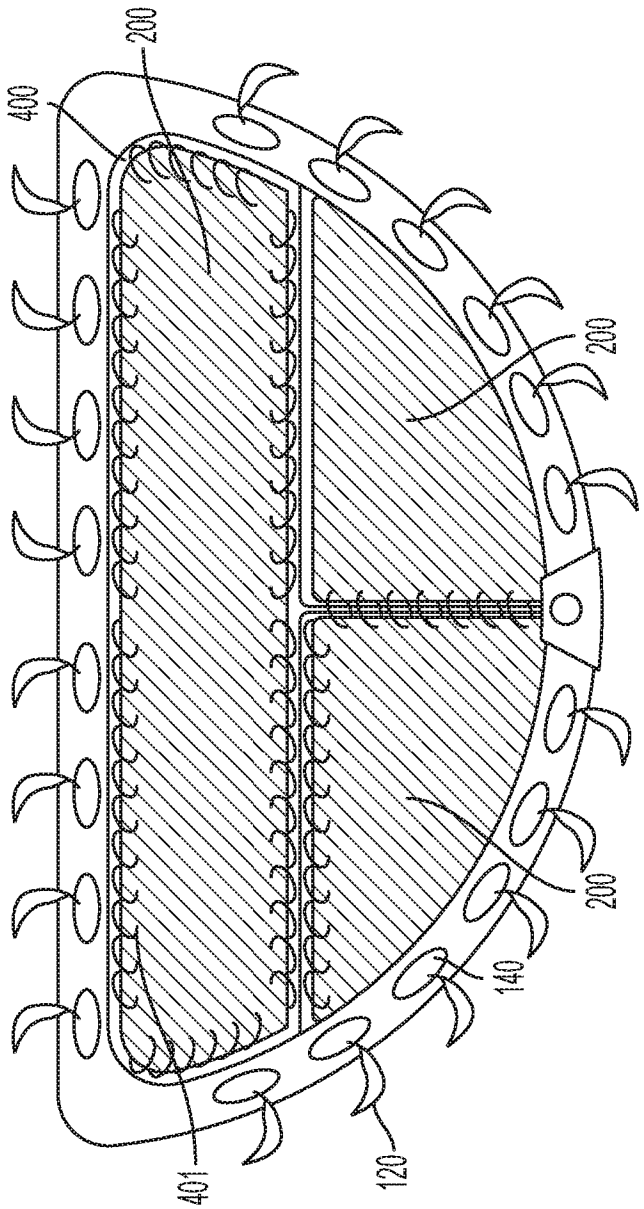

FIG. 7

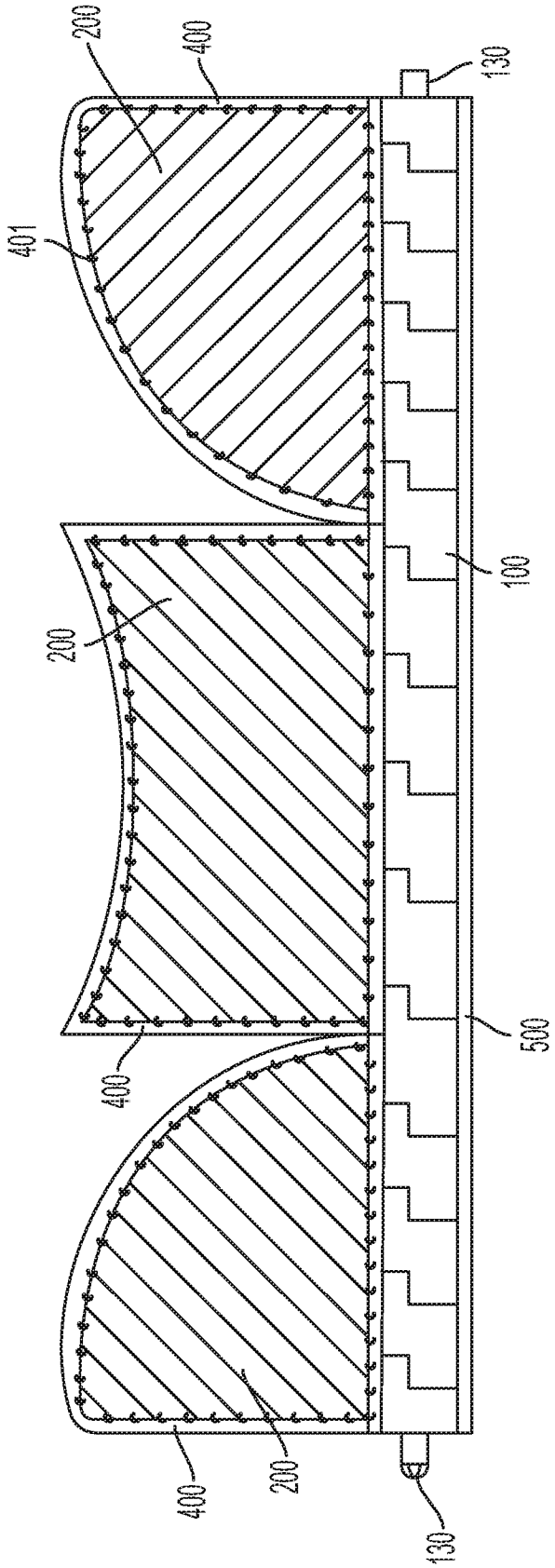

FIG. 8

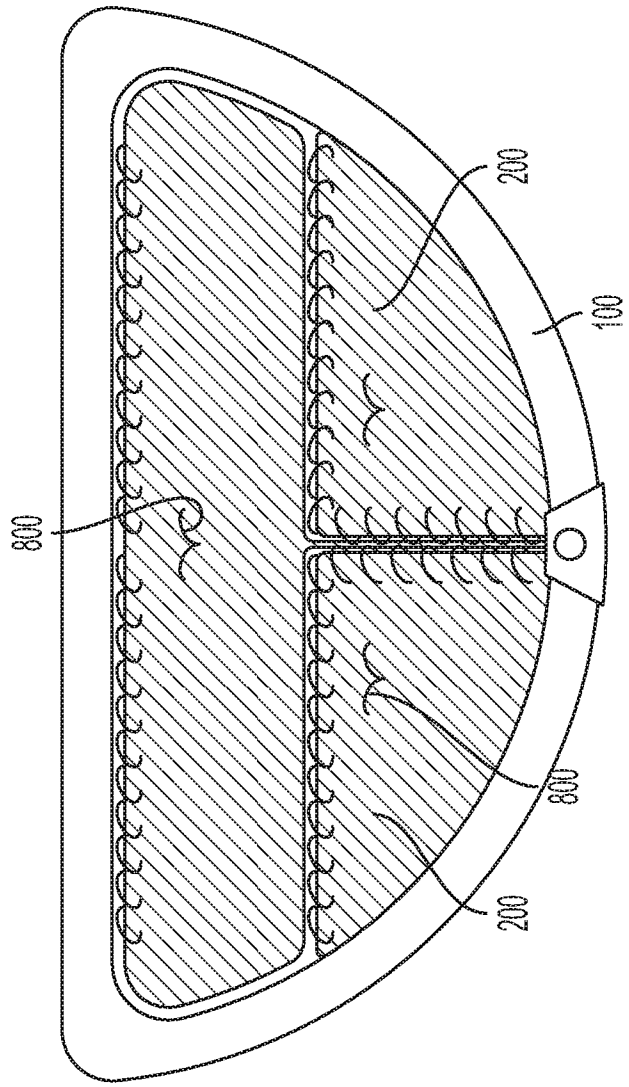

FIG. 9

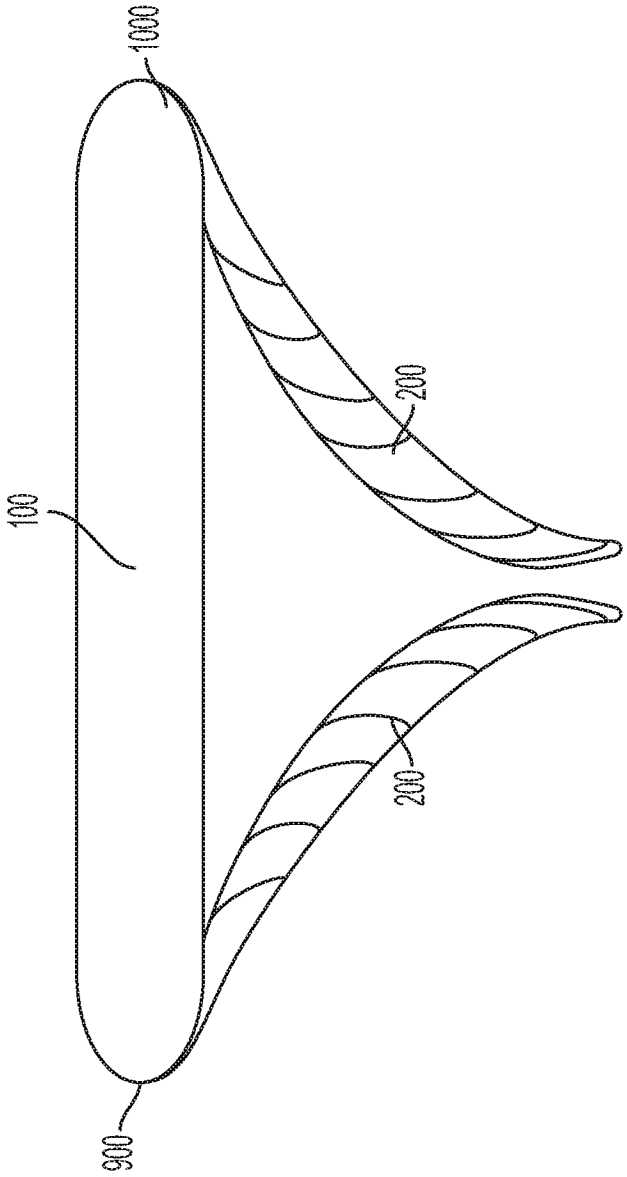

FIG. 10

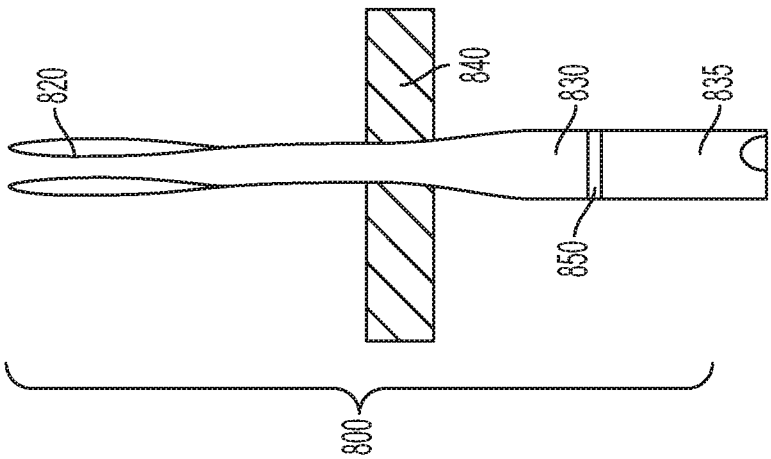

FIG. 11A

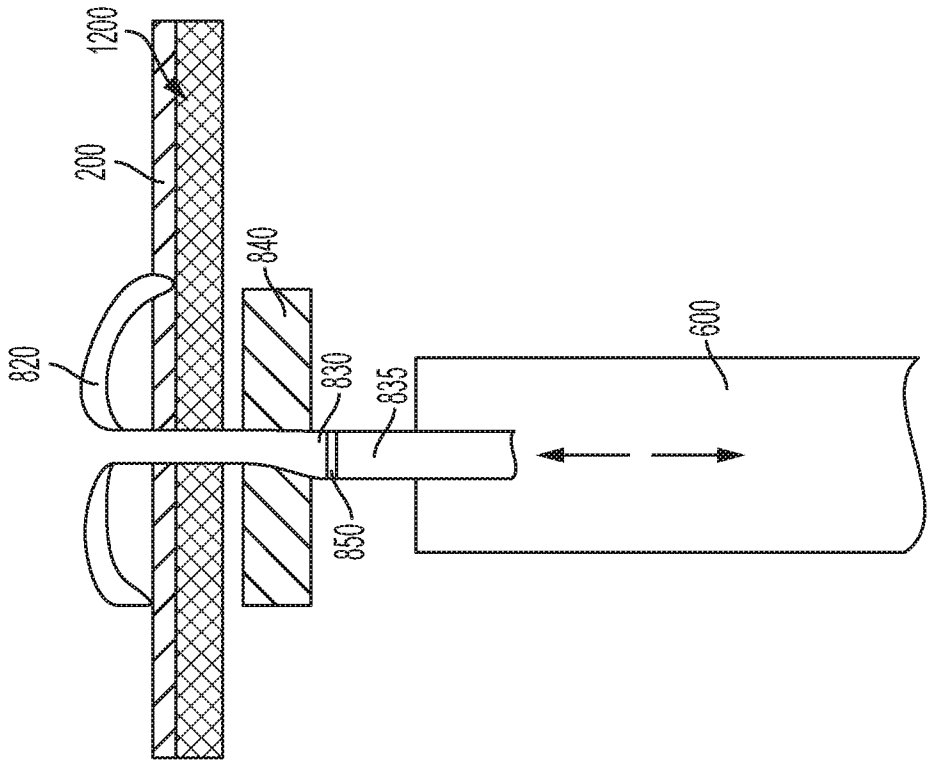

FIG. 11B

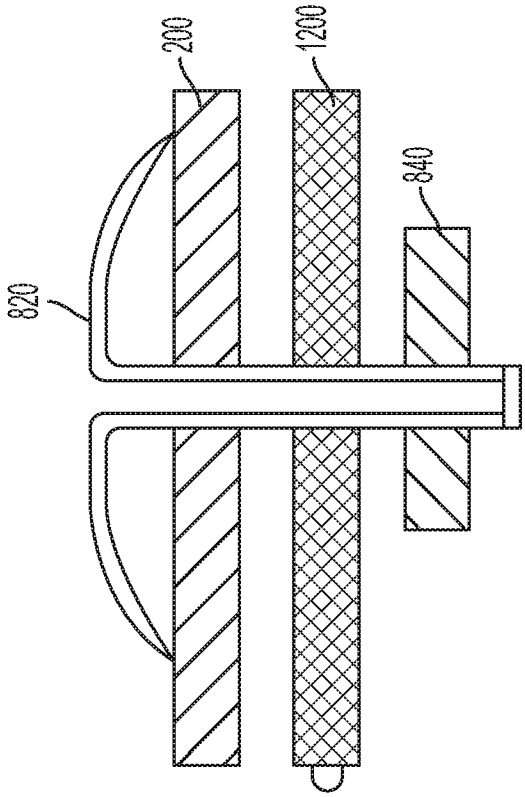

FIG. 11C

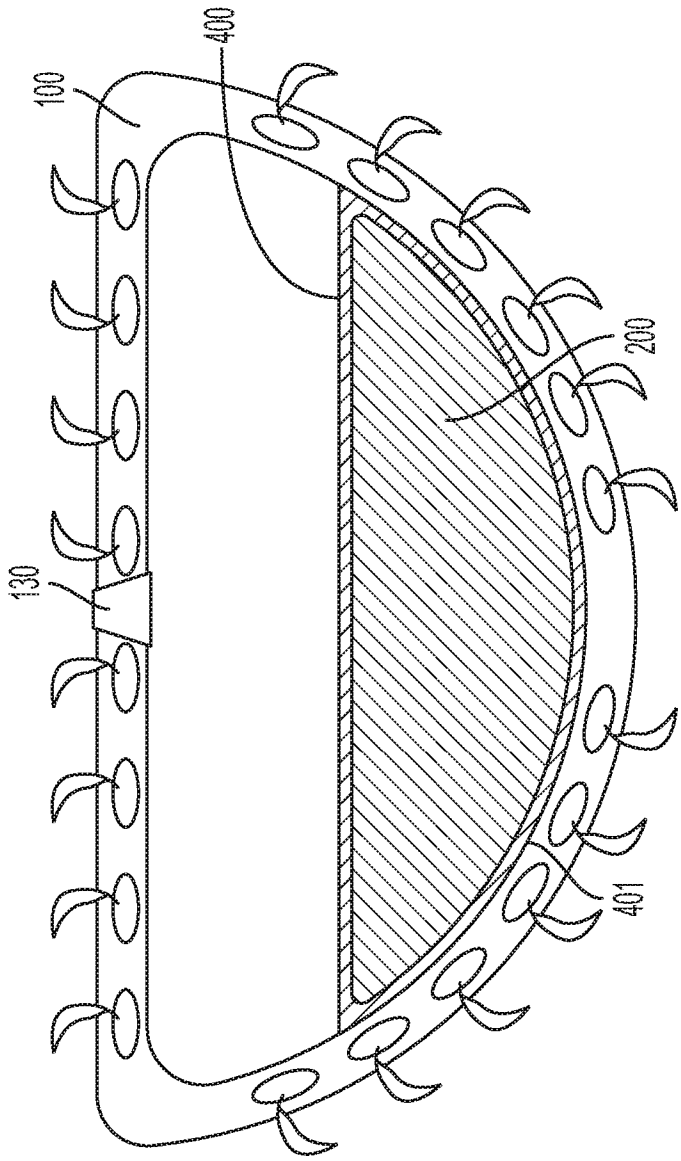

FIG. 12

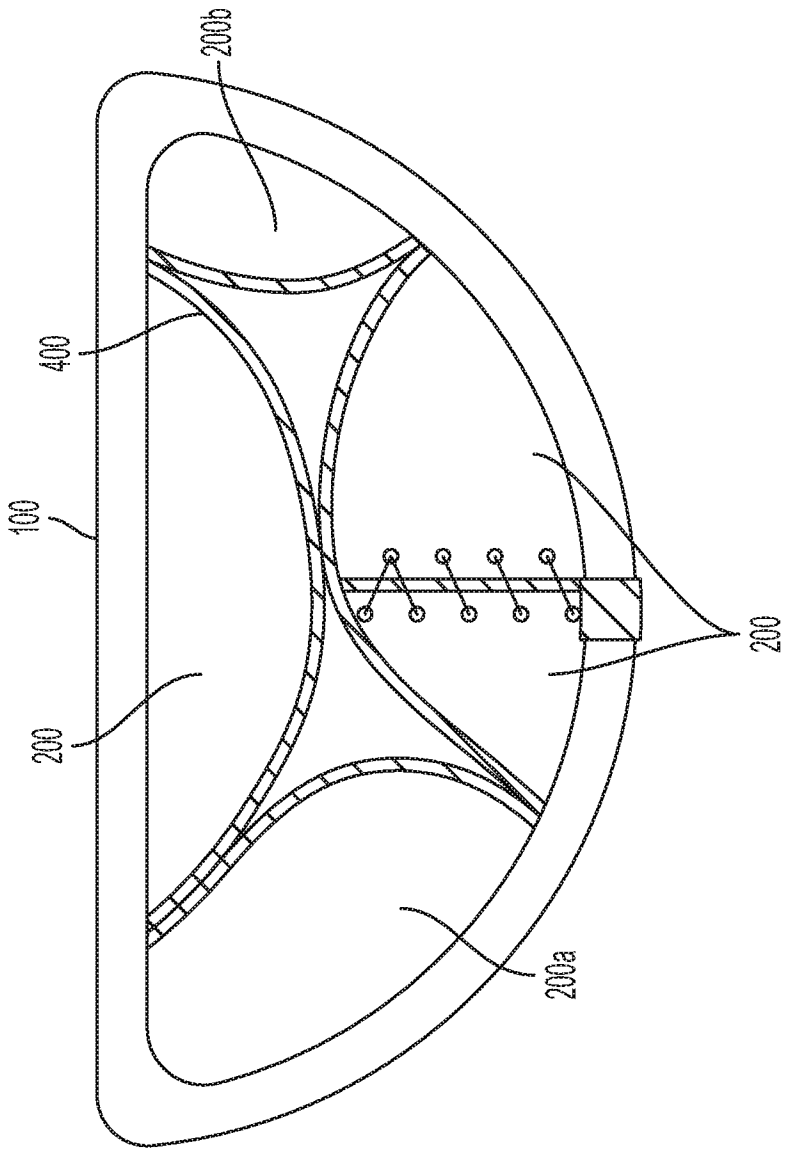

FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/037294

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/24; A61F 2/00; A61F 2/02; A61M 39/00 (2020.01)
CPC - A61F 2/24; A61F 2/00; A61F 2/02; A61M 39/00 (2020.08)

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/0235758 A1 (XELTIS, BV) 23 August 2018 (23.08.2018) entire document	16-18
Y	US 6,869,444 B2 (GABBAY) 22 March 2005 (22.03.2005) entire document	1-5, 8-13, 15, 20, 21
Y	US 2019/0083240 A1 (VALCARE, INC.) 21 March 2019 (21.03.2019) entire document	1-5, 8-13, 15, 20, 21
Y	US 2014/0025163 A1 (PADALA et al) 23 January 2014 (23.01.2014) entire document	4, 5
Y	US 2008/0215145 A1 (MOADDEB et al) 04 September 2008 (04.09.2008) entire document	11, 12

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
10 August 2020	28 AUG 2020
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver Telephone No. PCT Helpdesk: 571-272-4300