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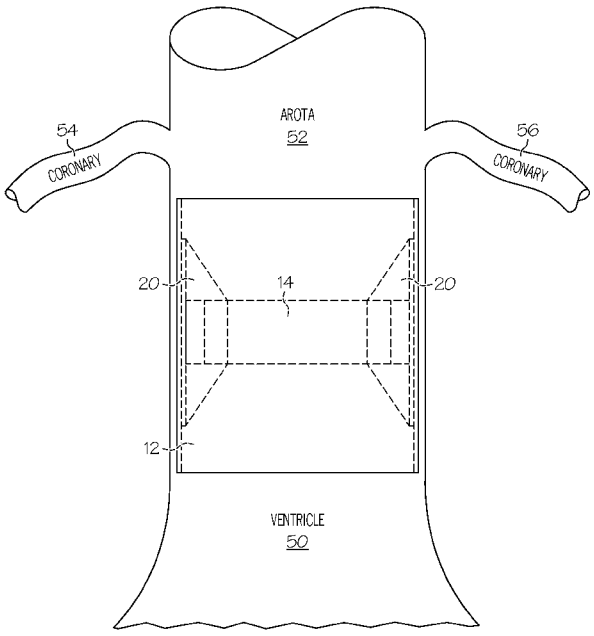
(54) **Title**: VALVE ASSEMBLY WITH A BIOABSORBABLE GASKET AND A REPLACEABLE VALVE IMPLANT



(57) **Abstract**: A percutaneous prosthetic heart valve assembly comprising a radially expandable anchor docking member, the anchor docking member having an unexpanded state and an expanded state, in the expanded state, the anchor docking member comprising a mechanism for receiving and engaging an implantable heart valve and a bioabsorbable gasket member disposed about the anchor docking member, the bioabsorbable gasket member comprising a bioabsorbable polymer material, the bioabsorbable gasket member having an unexpanded and an expanded state.

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VALVE ASSEMBLY WITH A BIOABSORBABLE GASKET AND A REPLACEABLE VALVE IMPLANT

BACKGROUND OF THE INVENTION

[0001] The present invention relates to heart valve implants such as for percutaneous aortic valve implantation in patients having heart disease.

[0002] Valvular heart disease (VHD) is any disease that affects one or more valves of the heart for a large number of patients and often requires elaborate diagnostic procedures, intervention, and long-term management. Heart valve replacement traditionally involved open heart surgery with associated risks including, high mortality, incidence of neurological damage, stroke, and repeated valve replacement.

[0003] Minimally invasive procedures have now been developed for the valve replacement that are much less traumatic and reduce the risks associated with surgical valve replacement.

[0004] Percutaneous valve implantation including percutaneous aortal valve implantation (PAVI) and percutaneous pulmonary valve implantation (PPVI) are less invasive alternatives to open heart surgery for patients in need of heart valve replacement. In percutaneous valve implantation, prosthetic implants are delivered through catheters using transvenous, transarterial, or transapical techniques.

[0005] There are associated risks associated with percutaneous valve implantation including leakage after initial valve replacement which can lead to stroke. This risk is highest in the initial weeks after implantation but continues for up to about three months. Valves typically have a circular or cylindrical circumference while diseased vessels are typically not. Initially after implantation until thrombus fills in gaps that may exist between the valve and the vessel, the chance for leaking is higher.

[0006] There remains a need in the art for a method and device of implanting a valve that will reduce the risk of leakage and stroke.

SUMMARY OF THE INVENTION

[0007] In some embodiments, the present invention relates to a percutaneous prosthetic heart valve assembly including a radially expandable anchor docking member, the anchor docking member having an unexpanded state and an expanded state, in the expanded state, the anchor docking member comprising a mechanism for receiving and engaging an implantable heart valve and a bioabsorbable gasket member disposed about the anchor docking member, the bioabsorbable gasket member comprising a bioabsorbable polymer material, the bioabsorbable gasket member having an unexpanded and an expanded state.

[0008] In some embodiment, the present invention relates to a percutaneous prosthetic heart valve assembly comprising a radially expandable anchor docking member, the anchor docking member having an unexpanded state and an expanded state, in the expanded state, the anchor docking member comprising a mechanism for receiving and engaging an implantable heart valve and a bioabsorbable gasket member disposed about the anchor docking member, the bioabsorbable gasket member comprising a bioabsorbable polymer

material, the bioabsorbable gasket member having an unexpanded and an expanded state; and an annular heart valve, the annular heart valve is received and engaged by the anchor docking member, the heart valve is removable from the anchor docking member.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1 is a side perspective side view of a pre-valve assembly of the invention with an anchor docking system disposed therein shown in dotted lines.

[0010] FIG. 2 is a perspective view of a pre-valve assembly similar to that shown in FIG. 1

[0011] FIG. 3 is a cross-sectional view of a generic implantable prosthetic heart valve in the form of a leaflet valve which may be employed in combination with the pre-valve assembly disclosed herein.

[0012] FIG. 4 is a perspective view of one embodiment of an implantable prosthetic heart valve shown without any leaflets

[0013] FIG. 5 is an end view of a heart valve similar to that shown in FIG. 4.

[0014] FIG. 6 is a perspective view illustrating a valve disposed within a bioabsorbable gasket.

[0015] FIG. 7 is a cross-sectional view taken at section 7-7 in FIG. 6.

[0016] FIG. 8A is a side perspective view of a pre-valve assembly of the invention with an alternative anchor docking member disposed therein shown in dotted lines and a corresponding prosthetic heart valve having a threaded member which is received and engaged by the anchor docking member.

[0017] FIG. 8B is a perspective side view of a pre-valve assembly with the anchor docking system shown in dotted lines and a corresponding prosthetic heart valve disposed in the gasket and engaging the anchor docking member.

[0018] FIGS. 9A and 9B are cross-sectional views taken at section 9A-9A in FIG. 8B.

[0019] FIG. 10 is a partial view of a catheter assembly with an expandable balloon member and an anchor docking system and gasket disposed thereon.

[0020] FIG. 11 illustrates a pre-valve assembly and a valve seated in a patients body vessel.

DETAILED DESCRIPTION OF THE INVENTION

[0021] While embodiments of this invention may take many different forms, there are described in detail herein specific embodiments of the present disclosure. This description is an exemplification of the principles of the present disclosure and is not intended to limit the disclosure to the particular embodiments illustrated.

[0022] The percutaneous heart valve assembly disclosed herein includes, what will be referred to hereinafter, as a pre-valve assembly including an anchor docking member and a bioabsorbable gasket, and an implantable prosthetic heart valve. The anchor docking member is configured and arranged for receiving and engaging the implantable prosthetic heart valve.

[0023] The pre-valve assembly is first delivered and deployed at the treatment site such as with a balloon catheter having an expandable balloon member disposed about the distal end of a catheter shaft. The pre-valve assembly is disposed about the deflated balloon member by first crimping an expandable anchor docking member onto the deflated balloon. The bioabsorbable gasket can then be disposed about the balloon member. The catheter

assembly is then inserted into and guided through a patient's vasculature to the site of treatment of a diseased natural valve wherein the balloon can be expanded thereby expanding the anchor docking member which simultaneously expands the bioabsorbable gasket which is suitably formable to the patient's diseased valve. The implantable prosthetic heart valve is then inserted into the bioabsorbable gasket and is received and engaged by the anchor docking member. The bioabsorbable gasket is suitably degraded and absorbed by the body in a period of months leaving behind the anchor docking member and prosthetic heart valve. This valve assembly is described in more detail hereinafter.

[0024] The prosthetic heart valve disclosed herein allows for repositioning and/or removal of the prosthetic heart valve during the percutaneous delivery of the prosthetic heart valve to a treatment site. In addition, the prosthetic heart valve of the present disclosure is designed to prevent migration of the prosthetic heart valve once it is deployed in a body lumen.

[0025] Turning now the drawings, FIG. 1 is a side perspective view of a pre-valve assembly 10 including a bioabsorbable gasket 14 and an anchor docking member 14 disposed within the bioabsorbable gasket 14 and represented by dotted lines. In this embodiment, the anchor docking system 14 is shown as a in the form of an expandable ring.

[0026] FIG. 2 is a perspective view of a pre-valve assembly 10 similar to that shown in FIG 1 wherein the anchor docking member 14 is clearly seen disposed within the bioabsorbable gasket 12.

[0027] Prosthetic heart valves are well known and the invention is not limited by the type of heart valve employed herein. Any number of various embodiments of a prosthetic heart valve can employed herein. Valves are selected so as to provide hemodynamic performance that approximates the natural state with a reduced risk of thrombogenicity. Preferably, the

device complies with the natural motion of the tissue with which it is in contact so that hemodynamics of the treatment site are maintained during the treatment period. The valve can be designed to allow blood flow in a physiologic direction (that is, forward flow of the blood through the biological passage), block back flow (also referred to as retrograde flow) of blood through the device, and collapse sufficiently to allow the catheter to be passed through the vasculature to the treatment site. Preferably, the components of the valve, for example, leaflets, are sufficiently flexible to open and close smoothly, with minimal pressure drop across the valve and without creating undue turbulence or hemolytically damaging the blood cells.

[0028] As an example, the valve can be, can be provided in the form of a conventional flexible leaflet valve well known to those of ordinary skill in the art. These valves may be tricuspid valves and can be used to mimic the aortic valve, for example. Valves that mimic a mitral valve might be biscupid. These flexible leaflet valves may comprise a generally arcuate center portion comprising three leaflets. It is understood, however, that there could be any desired number of leaflets in the flexible valve, preferably, two to four leaflets.

[0029] The leaflets are often fixed to an outer portion such as a sheath or cuff such as by suturing or with a biocompatible adhesive. However, any suitable attachment means can be employed. The prosthetic valve is sized to expand and fit within a body lumen that is to be treated. Once the valve is expanded, it spans the circumference of the lumen.

[0030] For prosthetic heart valves of this type, please refer to US Patent No. 7,244,242, the entire content which is incorporated by reference herein. See also US Patent No. 5,928,281, the entire content of which is incorporated by reference herein.

[0031] Valves can be composed of a synthetic material and/or may be derived from animal tissue such as bovine tissue.

[0032] Turning back to the figures, a cross-sectional view of a generic leaflet valve is depicted by FIG. 3 illustrating three leaflets 22 attached to a cuff 24. Cuff 24 may be formed from the same material or a different material from that of the valve, for example, a flexible polymer or fabric, for example.

[0033] In some embodiments, the outer portion of the valve may be formed from a shape memory metal such as nitinol and be in the form of a braided mesh.

[0034] FIG. 4 is a perspective view of another embodiment of a prosthetic heart valve 20. In this embodiment heart valve 20 is in the form of a braided mesh which may be formed from a shape memory polymer or shape memory metal for example, nitinol. Valve 20 comprises a band 26 disposed about the middle portion of the valve 20. Prosthetic heart valve has reduced diameter or unexpanded configuration and an expanded configuration. Band 26 may be disposed on the braided mesh tube 24 when it is in a reduced diameter with the diameter of the band 26 similar to that of the reduced diameter of the braided mesh tube 24. However, other ways of forming the prosthetic heart valve are contemplated herein.

[0035] For example, a bi-stable heart valve formed from either metal or polymer may be employed herein. One example is a self-expandable metallic structure made from stainless steel filaments woven in a criss-cross pattern to form a tubular mesh configuration similar to the construction of the Wallstent®. The valve may further include a polymeric membrane on the luminal surface. Bi-stable heart valves are known in the art and have two positions, open and closed. These valves are crimped down into a reduced diameter state and can be folded into a catheter delivery device for delivery through a patient's body lumen for

positioning in the diseased valve. Once in position, the heart valve is forced from the catheter and elastically unfolds to a stable unfolded position wherein the valve is open to about 30 or 40% of its fully expanded diameter. The valve then either self expands to a fully open position or can be forced into the fully expanded second stable position.

[0036] Another suitable heart valve has a radial expanding slide and lock mechanism similar to that described for an implantable stent in US Patent No. 7,947,071, the entire content of which is incorporated by reference herein. The valve comprises radial elements wherein a backbone of a first radial element can be configured to comprise a series of slots formed along the backbone for facilitating interconnection of the first radial backbone assembly with another second radial backbone assembly via corresponding elongate members along the second backbone assembly. Additionally, each elongate member can comprise a locking member such as a tooth, deflectable tooth or a stop. The corresponding slots can also comprise a stop inside the cavity of the slot. This functions similar to a "zip tie" wherein the device ratchets and clicks to lock the device into place but wherein the device is in a circular rather than an elongate form.

[0037] The valve 20 is radially expandable and is delivered through the vasculature in its crimped, reduced diameter configuration such as within the interior of a sheath of a delivery catheter. This is well known in the art. An example of a delivery catheter and sheath can be found in FIG. 1A of US Patent Pub. No. 2005/0137692 and 2008/0125859, the entire content of each is incorporated by reference herein.

[0038] In FIGS. 4 and 5, the leaflets of the valve 20 are not shown. However, leaflets 20 may be sutured to the braided mesh 24 of the valve.

[0039] The prosthetic heart valve 20 is positioned within the gasket 12 of pre-valve assembly 10 so that the band 26 is aligned with anchor docking member 14. When the prosthetic heart valve 20 is expanded, either end 28, 30 of the valve 20 expands to a larger diameter than that of the band 26 thus locking the valve 20 into position over the anchor docking member 14.

[0040] Alternatively, band 26 can be secured to two tubular members rather than one continuous member using any suitable method known in the art such as by welding or adhesively sealing them together.

[0041] This valve 20 can be removed from the pre-valve assembly by using a snare and pulling the valve back into a sheath as is known in the art.

[0042] FIG. 6 is a perspective view of a valve 20 positioned within bioabsorbable gasket 12.

[0043] FIG. 7 is a cross-sectional taken at section 7-7 in FIG. 6 showing valve 20 disposed over anchor docking member 14 and within bioabsorbable gasket 12.

[0044] The leaflets 22 are shown closed in FIGS. 6 and 7 and would not be visible in an open state.

[0045] FIGS. 8A-10B illustrate an alternative embodiment of a pre-valve and valve assembly wherein a 270° twist lock mechanism is employed to secure the valve 20 to the anchor docking member 14.

[0046] FIG. 8A is a side perspective view of a bioabsorbable gasket 12 showing a 270° twist lock member 14 in dotted line along with a valve 20 having a corresponding twist lock thread 15 disposed thereon for insertion into the gasket 12 and engaging with the twist lock anchor docking member 14.

[0047] FIG. 8B illustrates the anchor docking member 14 engaging the twist lock thread 15 of the valve 20 which is disposed within gasket 12.

[0048] FIGS. 9A and 9B are radial cross-sectional views taken at section 9A-9A in FIG. 8B showing twist lock thread 15 of valve 20 and anchor docking member 14 prior to twisting and engaging of the members 14, 15. FIG. 9B simply illustrates that the members 14, 15 are engaged upon a twisting motion. This embodiment includes a conventional threaded fastener mechanism similar to a bolt/nut or key way/slot mechanism.

[0049] As previously discussed, the pre-valve assembly 10 will first be delivered to the treatment site in the vasculature. In some embodiments, the anchor docking member 14 is first crimped onto deflated expandable balloon member disposed on the distal end of a delivery catheter. As is known in the art, the deflated expandable balloon member is often in a folded and wrapped state about a shaft of a delivery catheter.

[0050] In some embodiments, the bioabsorbable gasket 12 is in the form of a sheet of a bioabsorbable polymeric material. In some embodiments, the bioabsorbable material is a soft tacky material. A sheet of the bioabsorbable material is wrapped over the anchor docking member 14 and about the deflated balloon member. The bioabsorbable material suitably sticks to itself. The bioabsorbable sheet is sized so that upon expansion and unwrapping in a patient's body lumen, the diameter of the sheet in the unwrapped state is sufficient to completely cover the vessel in which it is disposed.

[0051] Alternatively, the bioabsorbable gasket is in the form of an extruded tube.

[0052] FIG. 11 is a partial perspective view of the bioabsorbable gasket 12 in the form of a sheet wrapped about, or a tube or sleeve crimped onto an expandable balloon member 40 disposed about the distal end of a catheter shaft 42.

[0053] The anchor docking member and valve can be equipped with alternative mechanisms for the anchor docking system to receive and engage the valve. Examples include, but are not limited to, a prosthetic heart valve that includes threads which are compatible with the threads of the anchor docking member similar to that of a nut and bolt, one of the anchor docking member and the prosthetic heart valve includes detents while the other member comprises a spring, snap-fit designs such as an annular snap fit design, a ball and socket design, a cantilever snap fit design and tongue and groove, and so forth.

[0054] The anchor docking member may be formed from a variety of suitable materials including, but not limited to, shape memory polymers, elastomeric polymers such as an elastomeric polyurethane, shape memory metals such as nitinol, and stainless steel.

[0055] Materials suitable for use in forming the bioabsorbable gasket include, but are not limited to, biodegradable polymers, bioerodible hydrogels, and proteins.

[0056] Suitable classes of biodegradable polymer materials include, but are not limited to, poly(amides) such as poly(amino acids) and poly(peptides), poly(esters) such as polylactide including poly(DL-lactide) and polyglycolide, poly(caprolactone), poly(anhydrides), poly(orthoesters), poly(carbonates) including tyrosine derived polycarbonates, and chemical derivatives thereof (substitutions, additions of chemical groups, for example, alkyl, alkylene, hydroxylations, oxidations, and other modifications routinely made by those skilled in the art), copolymers and mixtures thereof.

[0057] Copolymers of these materials are also suitable for use herein. Examples include, but are not limited to, polylactide-co-glycolide including poly(DL-lactide-co-glycolide) and poly(L-lactide-co-glycolide), polylactide-co-caprolactone including poly(DL-lactide-co-caprolactone and poly(L-lactide-co-caprolactone), tyrosine derived polycarbonates,

collagen, protein and mixtures thereof. This list is intended for illustrative purposes only, and not as a limitation on the scope of the present invention.

[0058] Suitable examples of bioerodable hydrogels include, but are not limited to, poly(ethers) such as poly(ethylene oxide), poly(ethylene glycol), and poly(tetramethylene oxide), vinyl polymers including but not limited to, poly(acrylates) and poly(methacrylates) such as methyl, ethyl, other alkyl, hydroxyethyl methacrylate, acrylic and methacrylic acids, poly(vinyl alcohol), poly(vinyl pyrrolidone), and poly(vinyl acetate), poly(urethanes), cellulose and its derivatives such as alkyl, hydroxyalkyl, ethers, esters, nitrocellulose, and various cellulose acetates, poly(siloxanes), collagen, and any chemical derivatives thereof (substitutions, additions of chemical groups, for example, alkyl, alkylene, hydroxylations, oxidations, and other modifications routinely made by those skilled in the art).

[0059] Copolymers and mixtures of these materials are also suitable for use herein.

[0060] These lists are intended for illustrative purposes only and not as a limitation on the scope of the invention. One of ordinary skill in the art would understand that there are suitable substitutes not listed herein.

[0061] FIG. 11 illustrates the pre-valve assembly including the anchor docking member 14 shown in dotted lines and the bioabsorbable sleeve 12 and valve 20 shown in dotted lines positioned in a patient's vessel between the ventricle 50 and the aorta 52. Suitably, the assembly sits approximately one inch below the right 54 and left 56 coronary arteries.

[0062] The gasket is flexible and conforms to the vessel wall to reduce the possibility of leakage around the valve during the initial period after implantation such as from zero days up to about 3 months where the likelihood of stroke is much higher due to the possibility of leakage. A prosthetic heart valve is spherical whereas a diseased valve is not.

Consequently, before thrombus can fill in any gaps between the natural diseased valve and the prosthetic heart valve chances of leakage are higher.

[0063] The description provided herein is not to be limited in scope by the specific embodiments described which are intended as single illustrations of individual aspects of certain embodiments. The methods, compositions and devices described herein can comprise any feature described herein either alone or in combination with any other feature(s) described herein. Indeed, various modifications, in addition to those shown and described herein, will become apparent to those skilled in the art from the foregoing description and accompanying drawings using no more than routine experimentation. Such modifications and equivalents are intended to fall within the scope of the appended claims.

[0064] All publications, patents and patent applications mentioned in this specification are herein incorporated by reference in their entirety into the specification to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. Citation or discussion of a reference herein shall not be construed as an admission that such is prior art.

CLAIMS:

1. A percutaneous prosthetic heart valve assembly comprising:

a radially expandable anchor docking member, the anchor docking member having an unexpanded state and an expanded state, in the expanded state, the anchor docking member comprising a mechanism for receiving and engaging an implantable heart valve; and

a bioabsorbable gasket member disposed about the anchor docking member, the bioabsorbable gasket member comprising a bioabsorbable polymer material, the bioabsorbable gasket member having an unexpanded and an expanded state.

2. The heart valve assembly of claim 1 in combination with an annular heart valve having two opposing ends, one the two opposing ends is configured to engage the mechanism of the anchor docking member.

3. The heart valve assembly of claim 2 wherein said anchor docking member comprises threads and the implantable heart valve having two opposing ends, one of the ends comprising threads which are compatible with the threads of the anchor docking member.

4. The heart valve assembly of claim 2 wherein one of said anchor docking member and said implantable heart valve comprises detents and one of anchor docking member and said implantable heart valve comprises a spring.

5. The heart valve assembly of claim 2 wherein said mechanism for engaging said heart valve is a snap fit design comprising one of an annular snap fit design, a ball and socket design, a cantilever snap fit and tongue and groove.

6. The heart valve assembly of claim 2 wherein said mechanism comprises a 270 twist lock design.

7. The heart valve assembly of claim 1 wherein said bioabsorbable gasket comprises at least one member selected from the group consisting of polylactide, polylactide-co-glycolide copolymers, polycaprolactone, polylactide-co-caprolactone, polyethylene glycol, tyrosine derived polycarbonates, collagen and proteins.

8. The heart valve assembly of claim 7 wherein said bioabsorbable gasket comprises a polylactide-co-glycolide block copolymer.

9. The heart valve assembly of claim 1 wherein said anchor docking member comprises a shape memory polymer, an elastomeric polymer, a shape memory metal or stainless steel.

10. The heart valve assembly of claim 9 wherein said shape memory metal is nitinol.

11. The heart valve assembly of claim 1 wherein said anchor docking member is a ring comprising a substantially cylindrical shape.

12. The heart valve assembly of claim 1 wherein said anchor docking member comprises

13. The heart valve assembly of claim 1 wherein said bioabsorbable gasket is in the form of a sheet of tube.

14. The heart valve assembly of claim 13 further in combination with an expandable balloon member, the balloon having a deflated and an expanded state, the anchor docking member is crimped about the balloon in the deflated state, the bioabsorbable gasket comprising a sheet that is wrapped around the balloon and the anchor docking member.

15. The heart valve assembly of claim 14 wherein said bioabsorbable gasket in the expanded state is sized to cover the circumference of an inner surface of a heart valve.

16. A percutaneous heart valve assembly comprising:

a radially expandable anchor docking member, the anchor docking member having an unexpanded state and an expanded state, in the expanded state, the anchor docking member comprising a mechanism for receiving and engaging an implantable heart valve;

a bioabsorbable gasket member disposed about the anchor docking member, the bioabsorbable gasket member comprising a bioabsorbable polymer material, the bioabsorbable gasket member having an unexpanded and an expanded state; and

an annular heart valve, the annular heart valve is received and engaged by the anchor docking member, the heart valve is removable from the anchor docking member.

17. The heart valve assembly of claim 16 wherein said bioabsorbable gasket comprises a member selected from the group consisting of polylactide-co-glycolide copolymers, collagen and protein.

18. The heart valve assembly of claim 16 wherein said anchor docking member comprises a shape memory metal or stainless steel.

19. The heart valve assembly of claim 16 wherein said mechanism is threaded, or comprises a detent or spring.

20. The heart valve assembly of claim 16 wherein said mechanism for engaging said heart valve is a snap fit design comprising one of an annular snap fit design, a ball and socket design, a cantilever snap fit and tongue and groove.

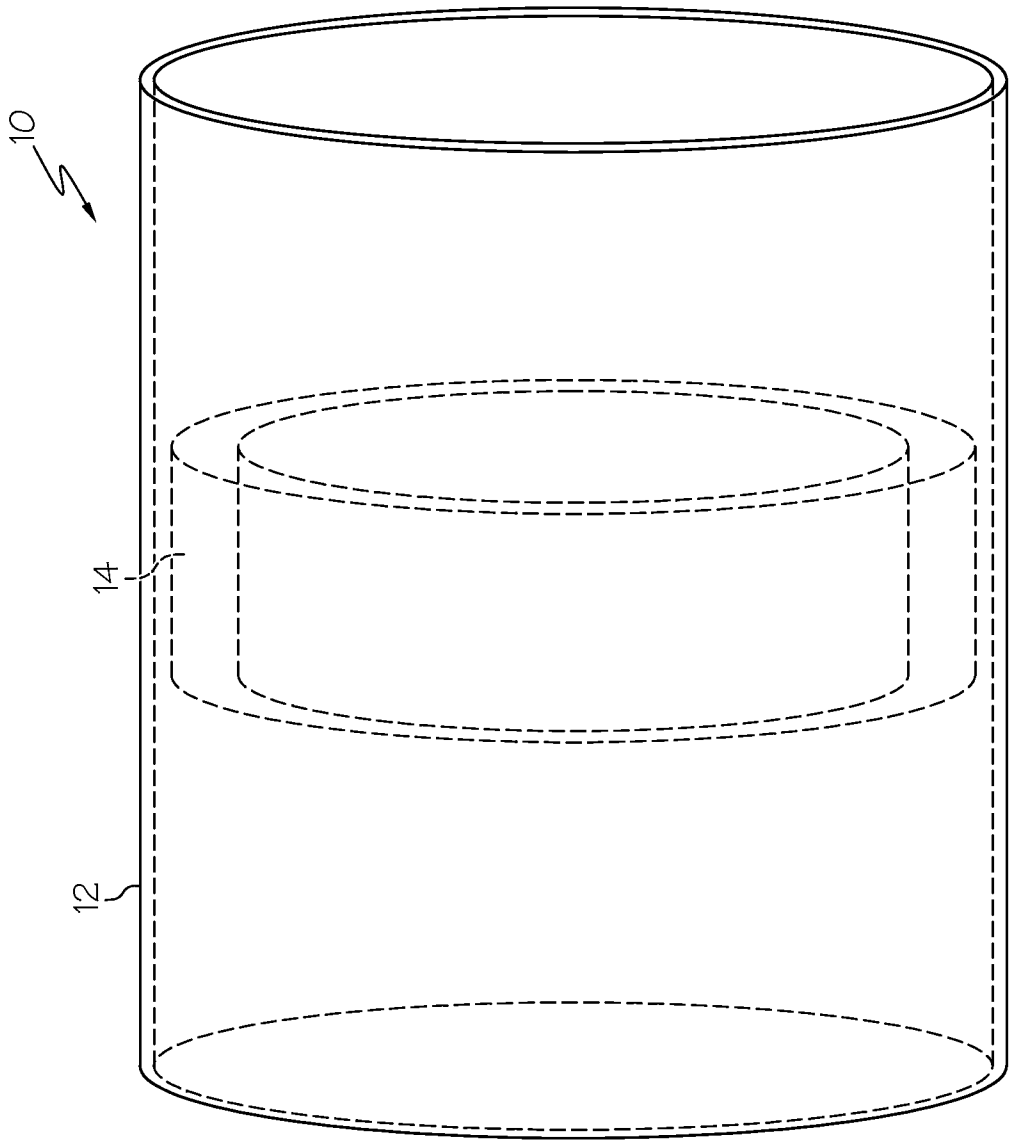

FIG. 1

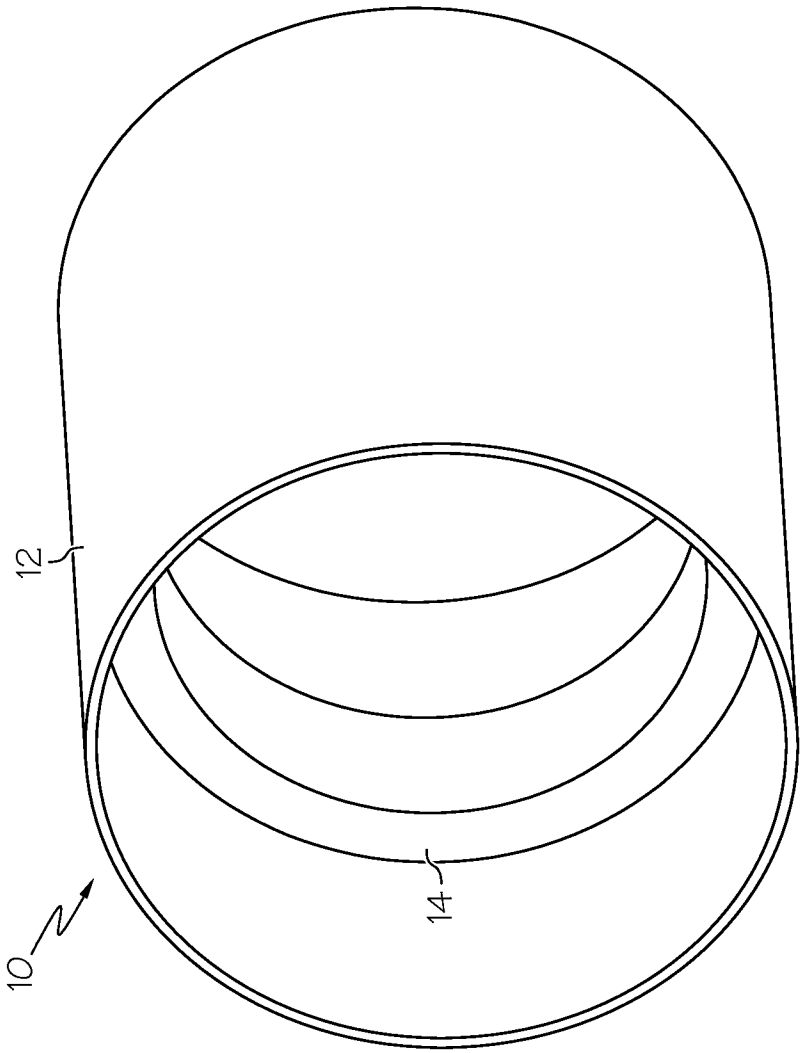

FIG. 2

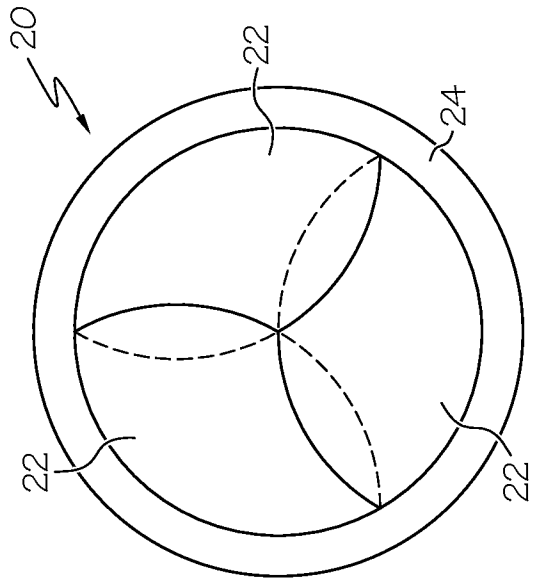

FIG. 3

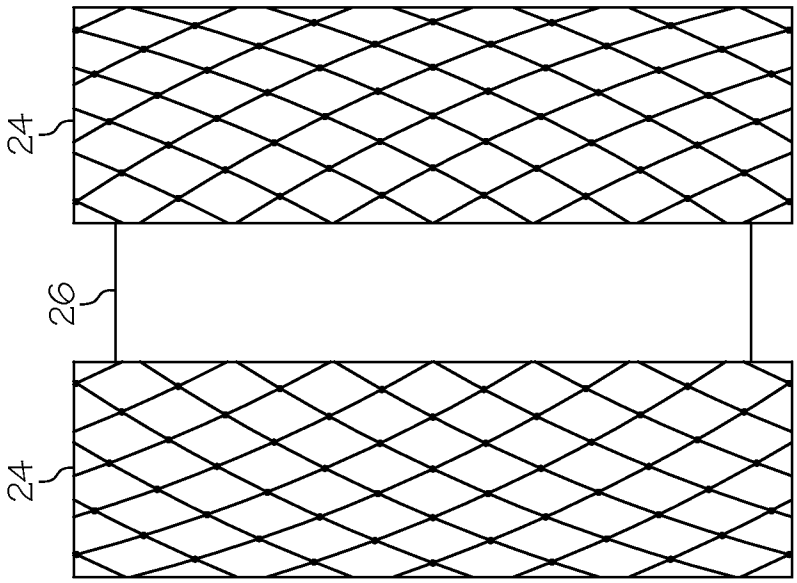

FIG. 5

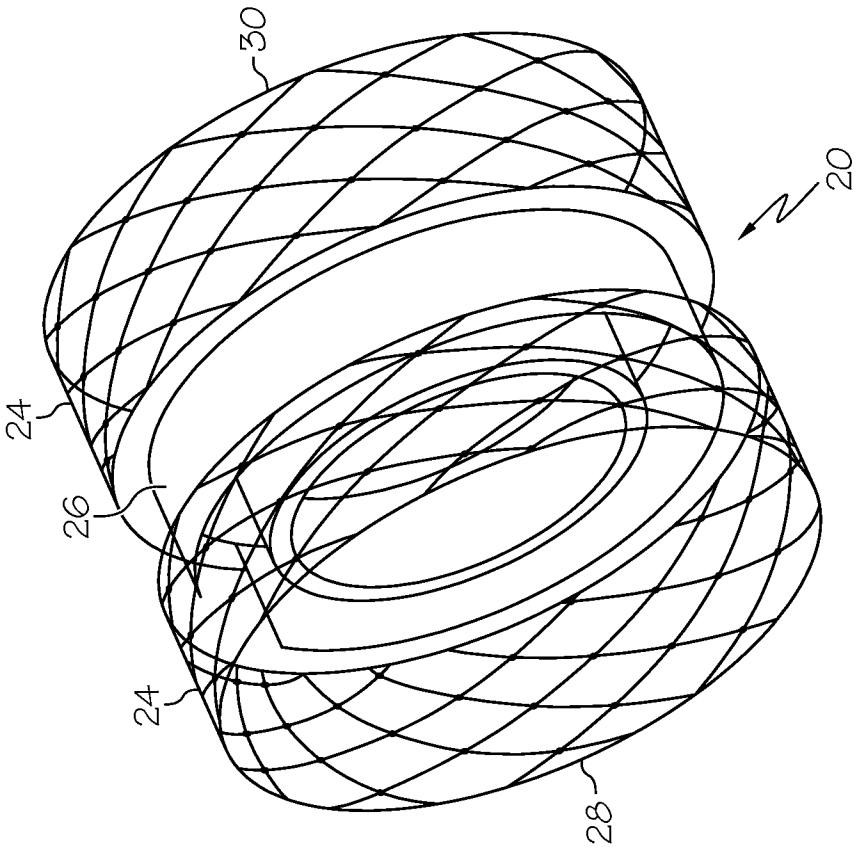

FIG. 4

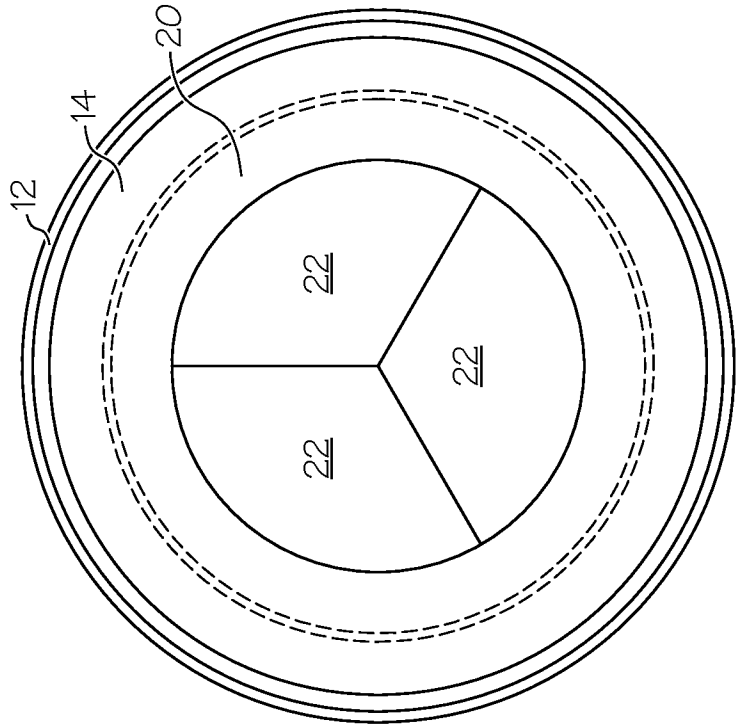

FIG. 7

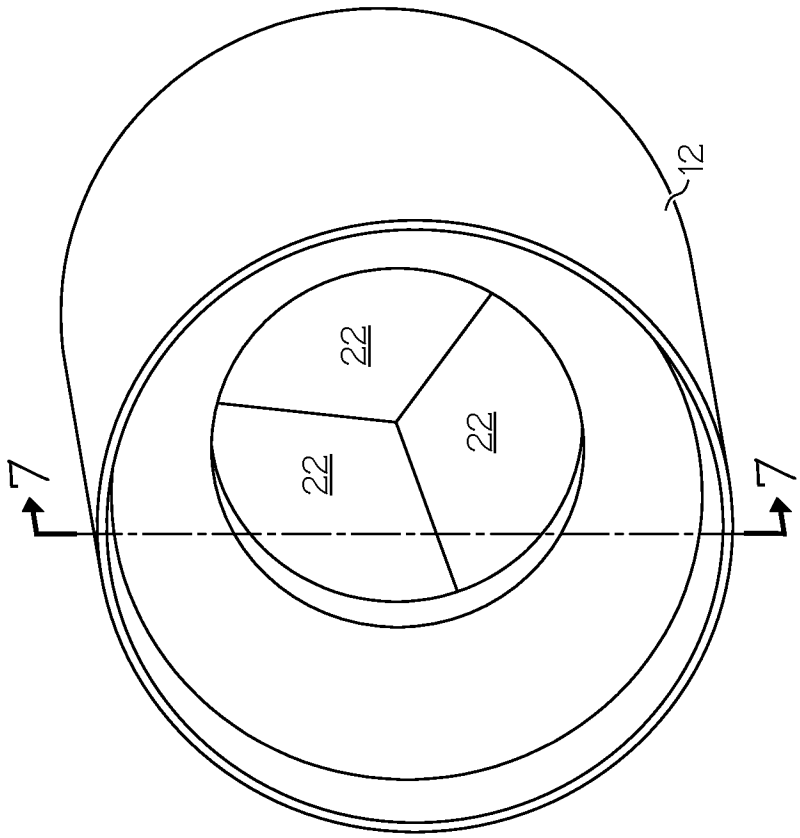

FIG. 6

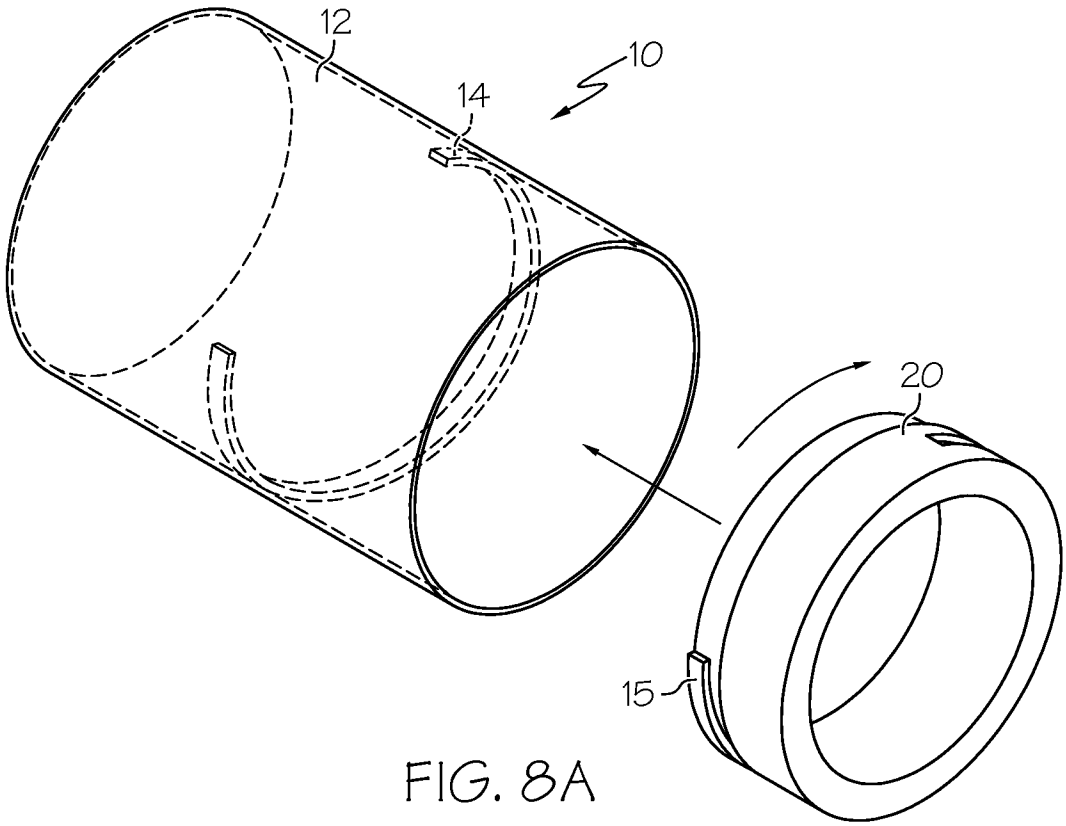

FIG. 8A

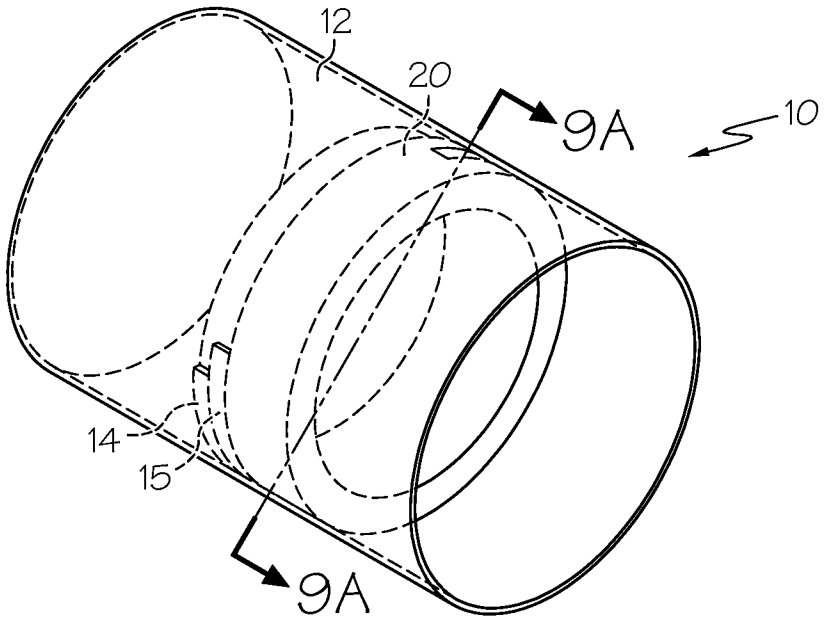

FIG. 8B

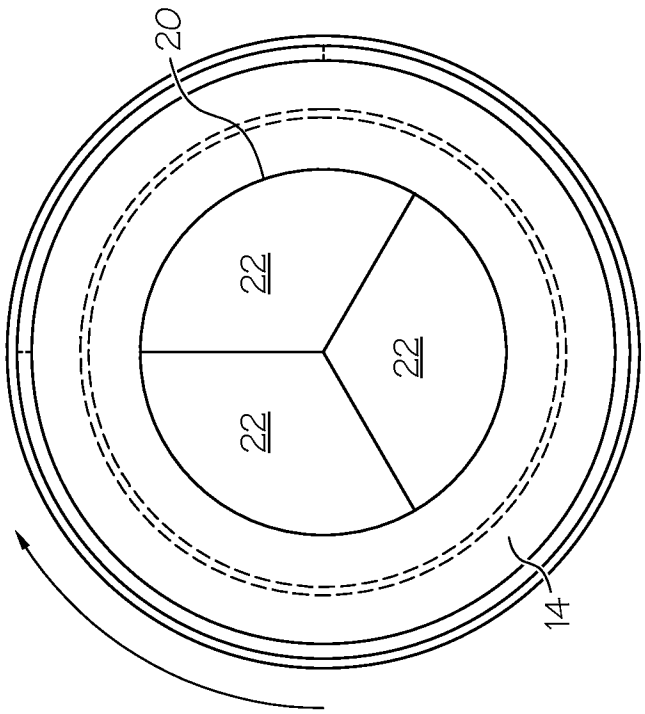

FIG. 9B

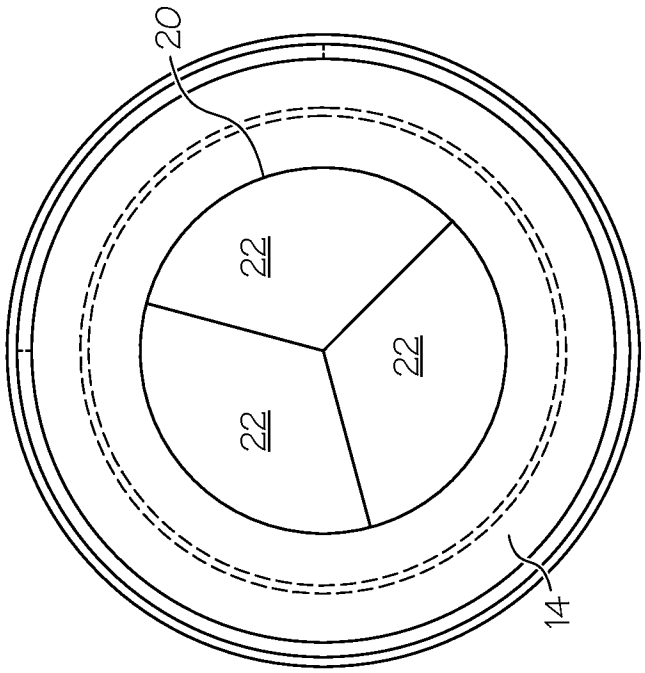

FIG. 9A

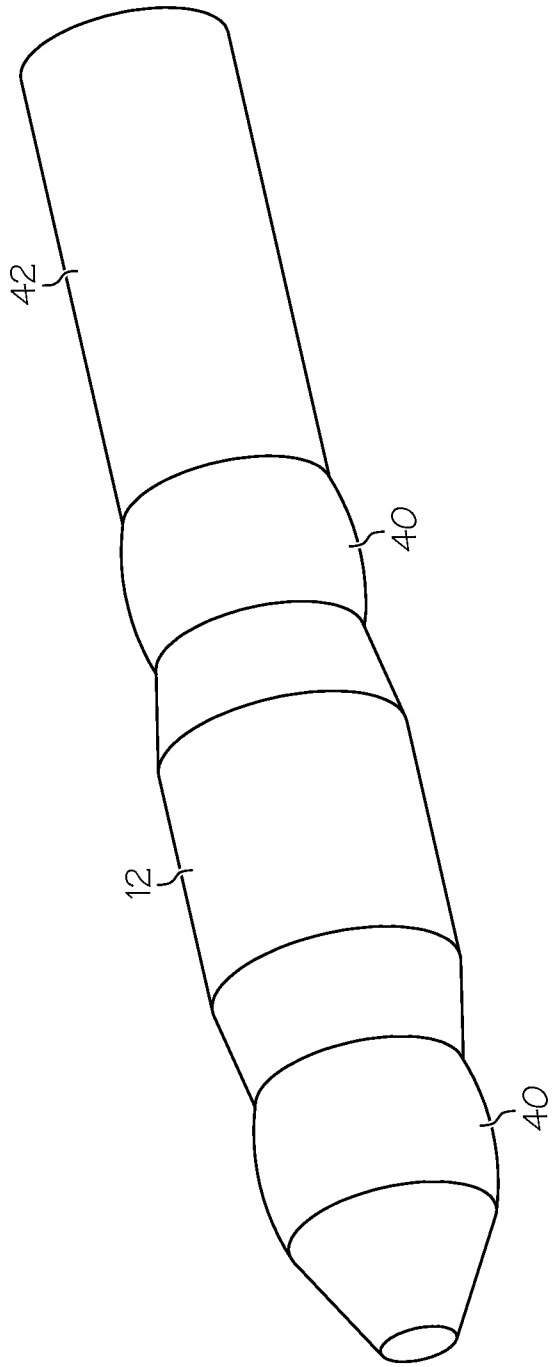

FIG. 10

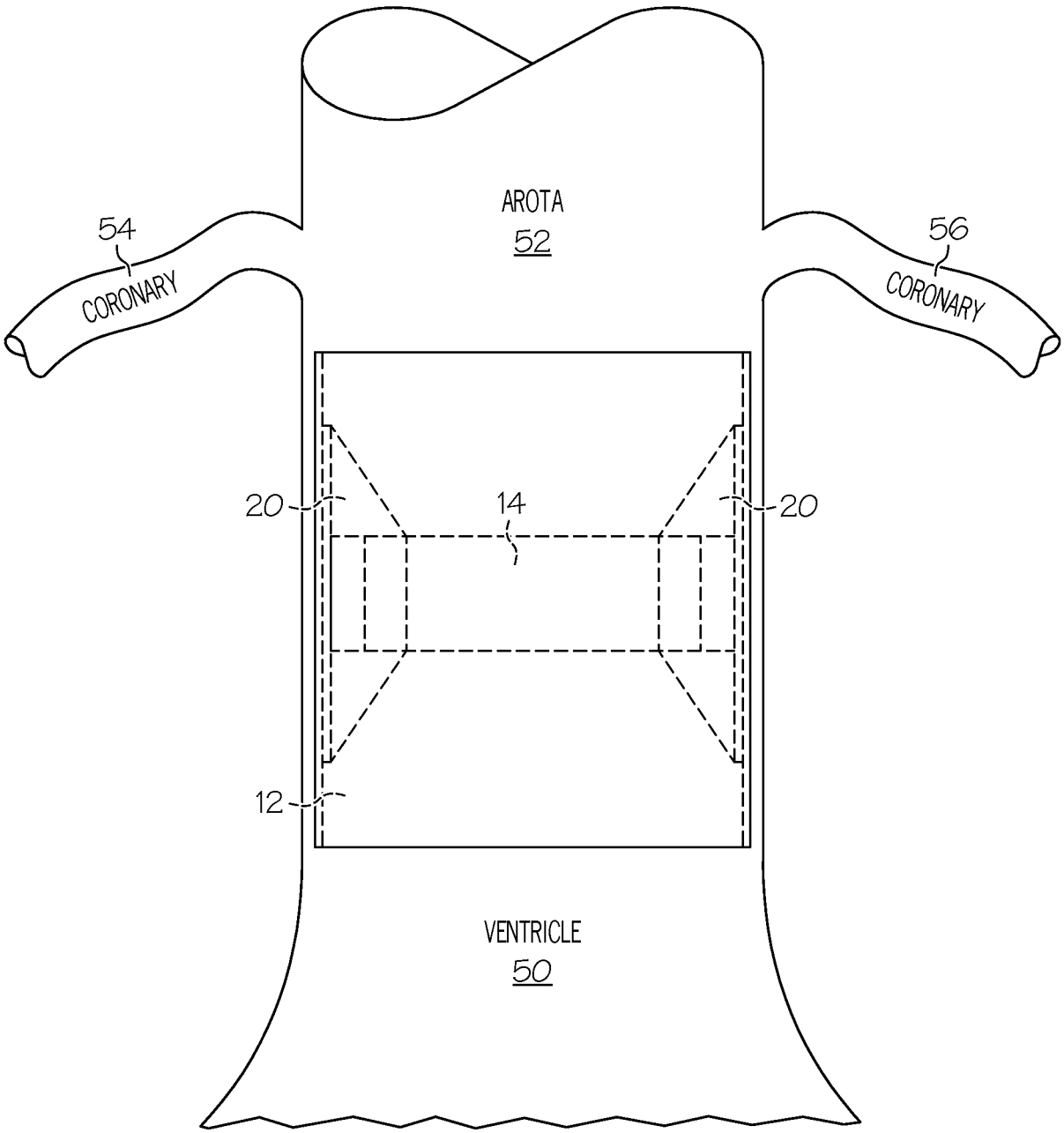

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/022694

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.
A	US 2006/287717 A1 (ROWE STANTON J [US] ET AL) 21 December 2006 (2006-12-21) paragraphs [0065], [0067], [0079], [0080], [0107], [0111]; figures 1-22B	1-20
A	WO 96/40012 A1 (ST JUDE MEDICAL [US]) 19 December 1996 (1996-12-19) page 4, line 18 - page 5, line 17 figures 1-3	1-20
A	US 2008/033541 A1 (GELBART DANIEL [CA] ET AL) 7 February 2008 (2008-02-07) paragraph [0021]	1-20

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
15 May 2013	23/05/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Geuer, Melanie

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2013/022694

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US 2008033541 A1	07-02-2008	NONE	