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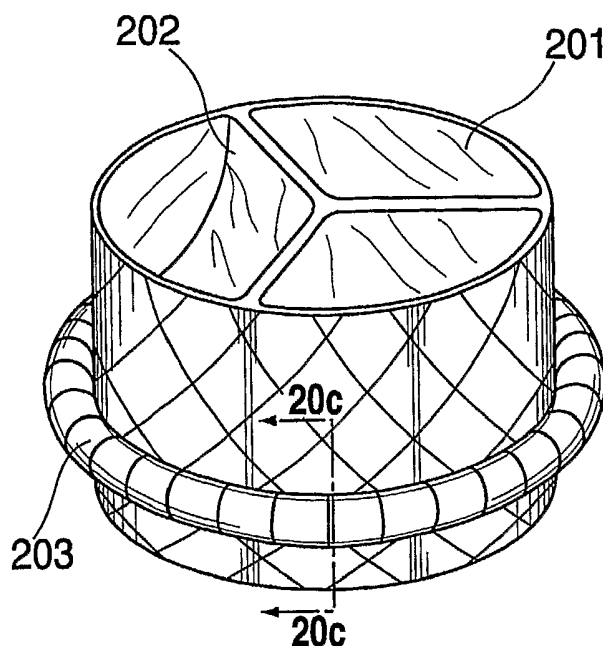
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(54) Title: PARAVALVULAR LEAK DETECTION, SEALING AND PREVENTION



(57) Abstract: The present invention provides a series of new percutaneous concepts of paravalvular repairs including identifying the leak location, several repair techniques and finally built-in means for leak prevention, built on percutaneous valves. A catheter-delivered device locates cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

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PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

FIELD OF THE INVENTION

5 **[0001]** The present invention relates to implantable devices. More particularly it relates to the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses.

BACKGROUND OF THE INVENTION

10 **[0002]** Cardiac valve implantation is well known in the art. Less well addressed is how to detect possible leaks between the valve and surrounding blood vessel, how to seal such leaks, or how to design the valve such that it automatically seals the leaks.

15 **[0003]** Machiraju in U.S. Patent No 5,554,184, entitled "HEART VALVE ", describes a heart valve and a technique for effecting valve replacement or repair, which partially or completely replaces the mitral (or tricuspid) valve with an autologous graft from the pericardium, fascia lata or even the dura mater, or a bovine or porcine pericardial or other synthetic sheet material equivalent thereof, preferably in a configuration which substantially restores the original anatomy of the heart, including
20 chordae tendineae attached to adjacent papillary muscles of the heart. Most preferably, a section of the patient's pericardium is cut to a shape including two leaflets, with each leaflet having a trabeculated tier of chordae tendineae terminating in a spear-shaped tab. The two leaflets are cut out as a single unit, and the two far ends are sutured together to yield a
25 bileaflet valve having appended chordae and tabs.

[0004] Machiraju does not address leaks that can occur around the implanted valve.

[0005] Schreck in U.S. Patent No. 6,454,799, entitled, "MINIMALLY-INVASIVE HEART VALVES AND METHODS OF
5 USE", describes expandable heart valves for minimally invasive valve replacement surgeries. In a first embodiment, an expandable pre-assembled heart valve includes a plastically-expandable annular base having a plurality of upstanding commissure posts. A tubular flexible member including a prosthetic section and a fabric section is provided,
10 with the prosthetic section being connected to the commissure posts and defining leaflets therebetween, and the fabric section being attached to the annular base. In a second embodiment, an expandable heart valve includes an annular tissue-engaging base and a subassembly having an elastic wireform and a plurality of leaflets connected thereto. The annular
15 base and subassembly are separately stored and connected just prior to delivery to the host annulus. Preferably the leaflet subassembly is stored in its relaxed configuration to avoid deformation of the leaflets. The expandable heart valves may be implanted using a balloon catheter. Preferably the leaflets of the heart valves are secured to the commissure
20 regions of the expandable stents using a clamping arrangement to reduce stress.

[0006] Schreck also does not address leaks that can occur around the implanted valve.

[0007] Amplatz in U.S. Patent No. 6,638,257, entitled,
25 "INTRAVASCULAR FLOW RESTRICTOR," describes an intravascular flow restrictor that comprises a braided tubular structure designed to be

placed in the main pulmonary artery for limiting blood pressure in the lungs. The braided structure is designed to be collapsed for placement in a delivery catheter, but when it is ejected from the delivery catheter, it assumes a substantially larger diameter disk shaped device having one or
5 more longitudinal channels or passways therethrough.

[0008] Amplatz also does not address leaks that can occur around the implanted valve. In addition, Amplatz's braided structures are of a shape and size not appropriate for paravalvular leak detection and sealing. Their geometry is designed for the conditions of the transcatheter hole and
10 not appropriate for valve leakage.

[0009] Spenser et al. in U.S. Patent Application No. 20030153974, entitled "IMPLANTABLE PROSTHETIC VALVE", describe a prosthesis device suitable for implantation in body ducts. The device comprises a support stent structure comprised of a deployable construction
15 adapted to be initially crimped in a narrow configuration suitable for catheterization through a body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent structure provided with a plurality of longitudinally rigid support beams
20 of fixed length, and (2) a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet. When flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position,
25 whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly to provide blockage to the reverse flow.

[0010] Spenser et al. also do not address leaks that can occur around the implanted valve.

[0011] With regard to the general topic of prosthetic valves, implantation is currently done either through open heart surgery or by use
5 of newer percutaneous methods, some of which are described in the patents mentioned above. With both methods paravalvular leaks are a known side effect. One way to approach the leak problem is to identify the leak location and repair it. Another approach is to equip the prosthesis with means to prevent the leak ("self-sealing" prosthesis). Both these
10 approaches are encompassed by the present invention.

[0012] Percutaneous introduction of medical devices is a preferred surgical procedure for it involves making only a very small perforation in the patient's skin (usually in the groin or armpit area) under local anesthetic sedation. In contrast, surgical placement involves a large chest
15 surgical incision and requires general anesthesia, to expose a large portion of a patient's thoracic region. Percutaneous introduction is therefore considered safer and less invasive.

[0013] Percutaneous introduction of a leak detection and repair device or of a self-sealing valve resembles other known interventional
20 cardiologic procedures. The percutaneous deployment procedure and device has an impact on several parameters of the product design, some of which are explained hereinafter.

[0014] In summary, the present invention provides new concepts of percutaneous paravalvular repair, including means for identifying the leak
25 location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself.

SUMMARY OF THE INVENTION

[0015] In accordance with a preferred embodiment of the present invention, a catheter-delivered device is provided for locating cavities occurring between a prosthetic valve and the wall of the body vessel
5 where the valve is implanted, the cavities producing paravalvular leaks during diastole. The device comprises at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

10 [0016] Furthermore, in accordance with another preferred embodiment of the present invention, a spacing element is provided to maintain the wires adjacent to the wall of the body vessel.

[0017] There is thus also provided in accordance with a preferred embodiment of the present invention, a catheter-delivered stent for
15 sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The stent, which is delivered via a guidewire to the cavity and held in place in the cavity by friction, comprises a support structure and an impermeable membrane, the
20 membrane preventing the passage of fluids through the stent, thereby sealing the cavity.

[0018] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing stent is balloon-expandable and the membrane comprises a tab spring-hinged to the inside
25 of the stent lumen and sized to occlude the lumen when closed. The tab is

held open by the stent balloon during insertion and springs closed when the balloon is removed after the stent is expanded.

[0019] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing stent is self-expandable,
5 wherein the membrane is a material covering at least one end of the stent.

[0020] Furthermore, in accordance with another preferred embodiment of the present invention, the stent is comprised of shape memory material.

[0021] Furthermore, in accordance with another preferred
10 embodiment of the present invention, the material is nitinol.

[0022] Furthermore, in accordance with another preferred embodiment of the present invention, the stent is covered on its external walls with hooks comprised of shape memory material and which extend, upon insertion of the stent, into adjacent body vessel walls.

15 [0023] Furthermore, in accordance with another preferred embodiment of the present invention, the distal end of the stent-delivery catheter is substantially perpendicular to the wall of the vessel at a point inside the cavity and the stent guidewire terminates in an anchoring mechanism that is inserted through the catheter and into the vessel wall,
20 anchoring itself in the vessel wall and providing greater anchorage for the stent.

[0024] Furthermore, in accordance with another preferred embodiment of the present invention, the anchoring mechanism is a hook comprised of shape memory material that is compressed for catheter

delivery into the vessel wall, whereupon the hook extends out, anchoring the guidewire into the vessel wall.

[0025] Furthermore, in accordance with another preferred embodiment of the present invention, the anchoring mechanism is a threaded point that is threaded into the vessel wall anchoring the guidewire into the vessel wall.

[0026] Also provided in accordance with a preferred embodiment of the present invention, is a device for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The device comprises a first guidewire threaded through the cavity, a second guidewire slidably coupled to the first guidewire and inserted such that the slidable coupling is moved to a desired point in the cavity, a first catheter inserted over the first guidewire to the point in the cavity, a second catheter inserted over the second guidewire to the desired point in the cavity, a first component of a two-component biological adhesive inserted through the first catheter to the desired point, a second component of the two-component adhesive inserted through the second catheter to the desired point, the two components thereby mixing to form a plug that seals the cavity.

[0027] Furthermore, in accordance with another preferred embodiment of the present invention, the device is adapted to apply an adhesive with more than two components.

[0028] Furthermore, in accordance with another preferred embodiment of the present invention, instead of two guidewires and two catheters, a single catheter and guidewire are used for delivery, with the

catheter comprising two lumens, each lumen providing delivery for one of the two-component adhesive components, and the catheter terminates in a mixer that forces the components to mix when they exit the catheter in the cavity, thereby creating the plug that seals the cavity.

5 [0029] Furthermore, in accordance with another preferred embodiment of the present invention, instead of two-component adhesive components being delivered via the catheters, a radiation-cured adhesive is delivered via one of the catheters and a radiation source is delivered via the other catheter, wherein the radiation source is applied to the adhesive
10 to create the plug in the cavity.

[0030] Also provided in accordance with a preferred embodiment of the present invention is a catheter-delivered assembly for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular
15 leaks during diastole. The assembly is delivered via guidewire to the cavity and comprises two sealing stents connected by a suture, the suture running back up the catheter, the sealing stents comprising a stent structure and sealing membrane. One stent of the assembly is inserted underneath the cavity and the other stent is inserted inside the cavity, the
20 membranes preventing the passage of fluids through the stent, thereby sealing the cavity and each stent helping anchor the other in place.

[0031] There is thus also provided in accordance with a preferred embodiment of the present invention, a prosthetic valve with integrated sealing ring attached to the outside wall, the ring having a circumference
25 greater than that of the valve and elastically conforming to seal cavities

between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0032] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a balloon.

5 [0033] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of spring-wire tabs mounted adjacent to one another around the circumference of the valve and covered with an impermeable membrane. The tabs are folded against the body of the valve during catheter delivery,
10 and, upon egress from the catheter, the tabs spring out to form the sealing ring.

[0034] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the
15 circumference of the valve, and further comprises a balloon under the tabs. The tabs are folded down on the deflated balloon during catheter delivery, and, upon egress from the catheter, the balloon is inflated, thereby opening the tabs to form the sealing ring.

[0035] Furthermore, in accordance with another preferred
20 embodiment of the present invention, the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, each tab spring-hinged to the valve. The tabs are folded against the body of the valve during catheter delivery, and, upon egress from the catheter, the tabs spring out to form the sealing ring.

[0036] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

5 [0037] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

[0038] Furthermore, in accordance with another preferred
10 embodiment of the present invention, the sealing ring comprises modified struts of the stent, the modification comprising geometrical constraints that, upon expansion of the stent, cause the struts to bend out from the stent body, thereby creating the sealing ring.

[0039] There is thus also provided in accordance with a preferred
15 embodiment of the present invention, a prosthetic valve with integrated sealing means, the sealing means comprising sutures attached around the perimeter of the valve and extending back out of the body. Patches can be pushed down the sutures and attached to the point where the suture is attached to the valve, thereby sealing any cavity existing between the
20 valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0040] There is thus also provided in accordance with a preferred embodiment of the present invention, a catheter-delivered prosthetic valve with integrated sealing means, the sealing means comprising an elastic
25 stent that is first deployed and inside which the valve is deployed. The elastic stent seals any cavity existing between the valve and the wall of

the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0041] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for locating cavities
5 between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0042] inserting a balloon mounted on a flexible wire next to the valve,

10 [0043] wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

[0044] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel
15 where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0045] inserting an impermeable stent into the cavity,

[0046] whereby the stent seals the cavity.

[0047] There is thus also provided in accordance with a preferred
20 embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0048] inserting a first guidewire into the cavity;

[0049] running a loop attached to a second guidewire over the first guidewire to a point inside the cavity;

[0050] injecting one component of a two-component adhesive through a catheter over the first guidewire to the cavity; and

5 [0051] injecting the second component of the two-component adhesive through a catheter over the second guidewire to the cavity,

[0052] wherein the components combine to create an adhesive plug that seals the cavity.

10 [0053] Furthermore, in accordance with another preferred embodiment of the present invention, instead of the first adhesive component, a radiation-cured adhesive is injected and instead of the second adhesive component a radiation source is applied, thereby creating the adhesive plug.

15 [0054] Furthermore, in accordance with another preferred embodiment of the present invention, only one guidewire is used and the two components are inserted via separate lumens within a single catheter over the guidewire.

20 [0055] In accordance with yet another preferred embodiment, a stented valve is provided wherein a compressible material, such as a clot or fabric, extends around an exterior portion of the stent. The compressible material may be formed of polyethylene terephthalate (PET) and is configured to expand into the gaps. Furthermore, fibers on the material may be configured to encourage coagulation of blood to further fills the gaps and prevent leakage. In one variation, a tissue growth factor

may be disposed on the material to encourage tissue growth between the material and the surrounding tissue.

[0056] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for providing integrated
5 sealing capability in an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0057] providing an expandable elastic ring around the outside of the valve; and

10 [0058] expanding the ring,

[0059] wherein the ring seals any cavities.

[0060] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for sealing cavities
15 between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0061] inserting a sealing stent at the distal end of the cavity; and

[0062] inserting a second sealing stent attached to the first stent into the cavity.

20 BRIEF DESCRIPTION OF THE FIGURES

[0063] To better understand the present invention and appreciate its practical applications, the following Figures are provided and referenced hereafter. It should be noted that the Figures are given as

examples only and in no way limit the scope of the invention as defined in the appended claims. Like components are denoted by like reference numerals.

[0064] Figure 1 illustrates an implanted valve with a cavity
5 creating a paravalvular leak and a device, in accordance with a preferred embodiment of the present invention, comprising a soft guidewire with an inflatable balloon and designed to identify the exact location of the paravalvular leak.

[0065] Figures 2a and 2b depict a plurality of balloons on soft
10 guidewires, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

[0066] Figure 3 illustrates a plurality of balloons on soft guidewires and kept along the perimeter of the blood vessel by a ring, in accordance
15 with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

[0067] Figures 4a to 4c depict the process, in accordance with another preferred embodiment of the present invention, of inserting a sealing stent over a guidewire to close a paravalvular leak.

20 [0068] Figures 5a to 5d depict several types of sealing stents, in accordance with another preferred embodiment of the present invention.

[0069] Figures 6a to 6d illustrate blocking a paravalvular leak with a sealing device, in accordance with another preferred embodiment of the present invention, assisted by anchors, which attach the device to the
25 aortic wall (or annulus).

[0070] Figure 7 illustrates an anchoring apparatus, in accordance with another preferred embodiment of the present invention, for achieving sealing as shown in Figure 6, in this case by use of a screw, which is embedded into to the aortic wall (or annulus).

- 5 [0071] Figures 8a and 8b depict a leak repair done, in accordance with another preferred embodiment of the present invention, using a two-component biological glue.

[0072] Figures 9a to 9c depict a leak repair done, in accordance with another preferred embodiment of the present invention, using an
10 ultra-violet light-cured biological glue.

[0073] Figure 10 illustrates a catheter, in accordance with another preferred embodiment of the present invention, that inserts a two-component biological glue into a balloon in order to block a paravalvular leak.

- 15 [0074] Figures 11a to 11f illustrate a device and procedure, in accordance with another preferred embodiment of the present invention, for blocking a paravalvular leak using two connected sealing stents.

[0075] Figures 12 depicts a valve, in accordance with another preferred embodiment of the present invention, with a built-in inflatable
20 portion allowing to fill gaps between the valve stent and the aortic wall in order to prevent paravalvular leaks.

[0076] Figures 13a to 13d illustrate a valve, in accordance with another preferred embodiment of the present invention, having a flexible and self-expanding portion for blocking possible leaks around the stent.

[0077] Figures 14a to 14c illustrate a valve, in accordance with another preferred embodiment of the present invention, having a having a flexible and self-expanding portion for blocking possible leaks around the stent..

5 [0078] Figures 15a to 15c illustrate a valve, in accordance with another preferred embodiment of the present invention, having a plurality of flexible and expanding segments on its proximal side for blocking possible leaks around the stent.

[0079] Figures 16a and 16b illustrate a valve device, in accordance
10 with another preferred embodiment of the present invention, comprising an additional portion for blocking possible leaks around the stent.

[0080] Figures 17a to 17e illustrate a valve device, in accordance with another preferred embodiment of the present invention, where the stent is adapted such that when expanded, a portion of the stent is forced
15 to protrude radially, thereby blocking possible leaks.

[0081] Figures 18a to 18e illustrate a valve, in accordance with another preferred embodiment of the present invention, constructed with additional sutures attached to the proximal side, allowing attachment of extra pieces of pericardium or artificial fabric for blocking paravalvular
20 leaks.

[0082] Figures 19a to 19d depict a procedure, in accordance with another preferred embodiment of the present invention, the procedure comprising two stages: first, insertion of a stent that includes an outer sealing layer; and second, insertion of a prosthetic valve through the stent.

[0083] Figures 20a to 20g illustrate a valve, in accordance with another preferred embodiment of the present invention, having a sealing element made of a flexible and expandable material for blocking leaks around the stent.

5 [0084] Figure 21 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein the sealing element is attached to the valve in a sealing line for providing an improved crimped profile.

10 [0085] Figure 22 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve.

DETAILED DESCRIPTION OF THE INVENTION

15 [0086] The present invention provides methods and apparatuses for substantially reducing or effectively eliminating the deleterious effects of paravalvular leaks in prosthetic valves. More specifically, it enables locating, sealing, and preventing paravalvular leaks using both dedicated and integrated (with the valve) means.

20 [0087] While the present invention is particularly suited for prosthetic heart valve leaks, such as a prosthetic aortic valve, it can also be applied to other leakage problems such as in other blood vessels, a septum, or other body lumens. Similarly, while the prosthetic valve described herein is a tricuspid valve, it could be another type of valve as well.

[0088] A main aspect of the present invention is the introduction of several novel designs and methods for locating paravalvular leaks in prosthetic valves.

[0089] Another main aspect of the present invention are several
5 novel designs for sealing paravalvular leaks detected in prosthetic valves.

[0090] Another main aspect of the present invention are several novel designs for modifying percutaneous prosthetic valves to automatically seal paravalvular leaks when the valve is implanted.

[0091] Another main aspect of the present invention is a novel
10 design that automatically seals paravalvular leaks when the valve is implanted without requiring valve modification.

[0092] Another main aspect of the present invention is the disclosure of several novel designs for modifying percutaneous prosthetic valves to enable sealing of paravalvular leaks after the valve is implanted.

[0093] For locating paravalvular leaks, the present invention
15 provides several designs comprising catheter-delivered balloons mounted on flexible guidewires. The balloons are delivered to a point near the valve. When regurgitation (leaking) occurs during diastole, the balloons are drawn into the leak-producing cavities occurring between the valve
20 and the wall of the blood vessel, thereby providing a means to deliver means for sealing the leak.

[0094] For sealing paravalvular leaks, the present invention provides several designs including sealing stents, and multi-component and radiation-cured adhesive compounds.

[0095] Sealing stents are crimped stents that are delivered to the leak location, expanded, and anchored in place. The stents are designed to block flow, thereby sealing the leak. Several innovations are provided for these operations.

- 5 [0096] Delivery of the sealing stent is via a guidewire that is anchored in the wall of the blood vessel at the leak location. The anchoring means can be a hook, for example a multi-headed hook composed of a shape memory alloy, such as nickel titanium (also known as nitinol), which is crimped at low temperature for delivery. The
10 anchoring means expands back to its original shape due to the higher temperature of the blood vessel wall at its deployment point, thereby anchoring itself into the blood vessel wall.

[0097] Another anchoring means is for the guidewire to be terminated in a screw, which can be threaded into the blood vessel wall.

- 15 [0098] Once delivered to the leak location via the guidewire, the sealed stent is expanded. This can be done by another agent, such as a balloon, or by making the stent self-expanding. In the case of balloon inflation, the stent is crimped around the deflated balloon prior to insertion in the delivery catheter. Upon delivery the balloon is inflated,
20 thereby expanding the stent, and then the balloons can be deflated and withdrawn. In the case of the self-expanding stent, the stent is preferably built from a shape memory alloy, such as nickel titanium (also known as nitinol), which can be crimped at low temperature for delivery, expanding back to its original shape due to the higher body temperature at the
25 deployment site. Alternatively the self-expanding stent can be a metallic stent comprised of a physiologically acceptable metal such as stainless

steel or an alloy such as nitinol, which is compressed or wound on a delivery, catheter or device. When the stent is released from the delivery catheter or device, it expands.

[0099] The sealing stent is held in place by friction. Additional
5 holding force can be obtained by adding hooks around the perimeter of the stent, such as self-expanding hooks made of shape memory alloy.

[00100] The expanded stent includes an internal element that seals the stent's own lumen, preventing flow through the stent and thereby sealing the cavity causing the leak. Examples of internal sealing elements
10 include a spring-hinged flap inside the stent lumen that opens upon stent expansion or, in the case of the self-expanding stent, a membrane covering one or both openings of the stent.

[00101] In some cases, it may be preferred to use two sealing stents. In this embodiment, the two stents are connected in series by a suture.
15 The delivery catheter is extended through the top of the cavity and out the bottom of the cavity to deploy one of the sealing stents and then, together with the stents' guide wire, retracted. This pulls the deployed stent back until it catches in the bottom of the cavity. The catheter is further retracted, and the second stent is deployed into the cavity. The catheter is
20 further retracted and the second stent is pulled back, catching it (from the bottom) in the top of the cavity.

[00102] An alternative sealing element to the sealing stent is a biological adhesive compound that can be delivered to the cavity via catheterization. In such a case, two catheters are brought to the leak
25 location. The catheters are used in one of the following ways: to deliver two adhesive components that, when mixed, harden to form an adhesive

sealing plug, or to deliver a radiation-cured adhesive and the cure source, for example an ultra-violet light source, to produce an adhesive sealing plug.

[00103] In both sealing element designs there is a need to bring the
5 distal catheter ends in close proximity to one another, for proper mixing
or curing, at the leak point. This is accomplished as follows: a first
catheter is used to insert the leak detector guidewire mentioned above.
A second guidewire is fitted with a loop, and the loop is run over the first
guidewire until it reaches the leak location. The respective cathethers are
10 then slid over their guidewires to meet at the leak location, thereby
providing egress for applying the bi-component adhesive or radiation-
cured adhesive.

[00104] Another delivery design for a bi-component adhesive
utilizes a single catheter run over the leak detection guidewire. The
15 catheter has three lumens: one to track the guidewire and one for each
adhesive component. A mixing means at the distal end of the catheter
mixes the components at the leak location to form the sealing plug.

[00105] In other embodiments of the present invention, leak sealing
means are integrated into the valve as an impermeable ring that, when the
20 valve is implanted, adaptively seals any gaps between the valve and the
surrounding lumen.

[00106] In one embodiment of such a self-sealing valve, the ring is
deflated for delivery and then inflated for sealing.

[00107] In another self-sealing valve embodiment, the ring is a sponge-like material that is compressed for delivery and then expands for sealing.

[00108] In another self-sealing valve embodiment, the ring
5 comprises a set of flaps that are closed for delivery and are opened either by balloon inflation, by the geometry of their connection to the valve, or by spring-action.

[00109] In another self-sealing valve embodiment, the ring comprises a set of self-expanding tubes.

10 [00110] In another self-sealing valve embodiment, the ring comprises struts of the valve's stent that are geometrically constrained to bend and enlarge their final diameter in respect to the main stent geometry when expanded from the crimped form

[00111] In another embodiment where sealing means are built into
15 the valve, a set of filament pairs are attached around the valve and feed back to the delivery catheter ingress. When a paravalvular leak is detected, impermeable patches of a material such as pericardium are threaded onto the local filament pair and pushed down to the leak location where they are tied off in place.

20 [00112] In another embodiment of the present invention, a sealing stent is first inserted into the lumen, and then the valve is inserted inside the sealing stent.

[00113] The aforementioned embodiments as well as other
embodiments, manufacturing methods, different designs and different
25 types of devices are discussed with reference to the drawings. Note that

the drawings are only given for the purpose of understanding the present invention and presenting some preferred embodiments of the present invention. The drawings are not meant to limit the scope of the present invention as defined in the appended claims.

5 [00114] Figure 1 illustrates a simple leak detector 27 in accordance with a preferred embodiment of the present invention. Leak detector 27 detects a leak between general tricuspid implantable prosthesis valve 20 and the aortic annulus 22. Leak detector 27 will typically be used together with leak sealing devices, like those described later in this specification.

10 [00115] A cavity 24 exists between the perimeter of valve 20 and aortic annulus 22. The cavity could have any number of causes, including calcification or other irregularities in the aortic annulus 22 that prevent proper sealing between the valve 20 and the annulus 22. The cavity will cause regurgitation (leaking) during diastole, characterized by blood
15 flowing 25 from the aorta into the left ventricle. Leak detector 27, is delivered through catheter 21 to a position above valve 20. Leak detector 27 comprises a soft guide wire 28 on which is mounted inflatable balloon 29, which is inflated after leak detector 27 has been passed through catheter 21. Guidewire 28 is soft enough that during diastole inflated
20 balloon 29 is drawn into the regurgitation flow and lodges in cavity 24 in between valve 20 and annulus 22.

[00116] Figures 2a and 2b depict a multiple leak detector 228 that is similar to leak detector 27 of Figure 1 but which comprises a plurality of soft guidewires 31 rather than just the single guidewire 28 of detector 27.
25 On each guidewire 31 is mounted a balloon 35. Figure 2b is a top view showing valve 20 during diastole. Two cavities 24 cause a flow of blood,

which pulls the balloon 35 closest to each cavity 24 into that cavity while remaining balloons 35 stay stationary. At this point, cavity 24 locations can be determined and marked and the cavities repaired.

[00117] Figure 3 illustrates an annular-configured leak detector 229,
5 which incorporates an adaptation that can be used to force wire(s) 40 of leak detector 27 or multiple-leak detector 228 (implementation shown) to remain close to aortic wall 45 rather than being allowed to drift to the center of the aorta. The advantage of this adaptation is that, in the case of detectors 27 and 228, if there is a central leak in valve 20, a balloon near
10 the center of the aorta might be drawn into the central leak instead of to the paravalvular cavity, thereby indicating a false paravalvular leak. Spacing ring 40 is a compressible wire ring that pops open after catheter 21 delivery. Guidewire(s) 42 are distributively attached to the external edge of ring 40 and are thereby held by the ring against the aortic wall 45.

15 [00118] Figures 4a to 4c depict an implantable valve 49 deployed in the native aortic valve position, creating a cavity 24, which causes paravalvular regurgitation (leak) during diastole. In Figure 4a, guidewire 46, which can be a leak detection device like those shown in Figures 1, 2, and 3, is inserted through cavity 24. Balloon 33 is deflated. In Figure 4b,
20 a balloon-expandable sealing stent (stent with an impermeable membrane that prevents the passage of fluids through the stent), is catheter-deployed over guidewire 46. Balloon 33 is inflated, causing balloon-expandable sealing stent 47 to be expanded, thereby sealing cavity 24 and stopping the paravalvular leak. Figure 4c shows a similar leak repair with the
25 difference that a self-expanding sealing stent 48 is used, and therefore balloon inflation is not required. The sealing stents 47 and 48 are anchored by friction between themselves and the surrounding aortic

annulus. Means for providing stronger anchoring for sealing stents are described later in this specification.

[00119] Figures 5a and 5b illustrate an embodiment of a balloon-expandable sealing stent (such as that used in Figure 4b) in accordance with another preferred embodiment of the present invention. The outer part 51 of the stent is made of a material that can be reshaped by plastic deformation. Sealing element 52, comprising an impermeable membrane, is connected to the inside wall of outer part 51 by spring hinge 53. The balloon-expandable sealing stent 47 is crimped on balloon 55. Once balloon 55 has reached cavity 24, the balloon is inflated, thereby expanding the sealing stent (Figure 5a). Balloon 33 is then deflated, whereupon (Figure 5b) sealing element 52 is forced by spring 53 to close and seal the lumen of the stent.

[00120] Figures 5c and 5d show a self-expanding sealing stent (such as that used in Figure 4c) in accordance with another preferred embodiment of the present invention. One way to implement the self-expanding sealing stent is to build stent framework 56 from a shape memory material such as nitinol 56 and cover it with a layer of impermeable material 58. The self-expanding sealing stent is catheter-delivered to the cavity, whereupon the stent opens, its shape adjusting to the shape of the cavity and its impermeable covering 58 sealing the cavity, to prevent the paravalvular regurgitation. To anchor the self-expanding sealing stent in place, hooks 59 can be included on framework 56. Hooks 59 are attached to framework 56 and extend through sealing material 58 and into the wall of the aortic annulus. The hooks are self-extending. One way to implement them is to make them from a shape memory material such as nitinol.

[00121] Figures 6a to 6d illustrate a technique for anchoring a sealing stent 66 (such as balloon-expandable sealing stent 47 or self-expanding sealing stent 48) into an open cavity 24, which is situated between aortic annulus 63 and prosthetic valve 20, and which creates paravalvular regurgitation. In Figure 6a, a guidewire 61 is led through cavity 24 by balloon 29 (this can be done with a device such as those disclosed in Figures 1 to 3). Guiding catheter 603 is fed over the guidewire, and the guidewire is removed. In Figure 6b an additional wire, anchoring wire 67, which terminates in anchoring apparatus 65, is inserted through catheter 63 to the anchoring location in cavity 24. Anchor 65 is a hook with one or more hook heads that can be compressed for delivery and will spring back to their original position when the delivery compression is removed (in other words, when the device emerges from the delivery catheter). Anchor 65 could be composed of flexible metal or a shape memory compound. Anchor 65 penetrates the aortic annulus at an approximately perpendicular angle due to the angled tip of guiding catheter 603. Figure 6c shows sealing stent 66 inserted via anchoring wire 67 and expanded to seal the cavity by one of the methods described in Figure 4 or 5. In the case shown in Figure 6c, a self expandable sealing stent as described in Figure 4 is shown. This method enables improved anchoring forces in comparison to friction alone, which is the sole anchoring for the embodiments shown Figures 4 and 5. Figure 6d shows the final step of the procedure, where the wire is detached from the anchor at detaching point 68.

[00122] Figure 7 depicts an apparatus that is similar to that illustrated in Figure 6, only here anchor 65 is implemented as a screw tip 69. The anchoring is accomplished by rotating anchoring wire 67, thereby threading tip 69 into aortic annulus 22.

[00123] Figures 8a to 8d demonstrate an apparatus for repairing a paravalvular leak by means of biological bi-component adhesive material (such as an epoxy resin), the components of which are in liquid form and turn to solid when mixed, in accordance with another preferred embodiment of the present invention. The leak is caused by an open cavity between valve 20 and annulus 22. A leak detector, such as those shown in Figures 1 to 3, is used to run guidewire 83 through cavity 24. A second guidewire 84 with a slide element 85 is slid over the first guidewire 83. Slide element 85 enables second guidewire 84 to slide over first guidewire 28 and can be a ring at the end of second wire 84. In Figure 8b, when slide element 85 and first guidewire 83 reach a point approximately midway through cavity 24, catheters 86 and 87 are slid over guidewires 28 and 84, respectively, until the catheters meet at meeting point 75.

[00124] In Figure 8c one of the components of a biological bi-component adhesive material is injected via catheter 86, and the other component is injected via catheter 87. The liquid adhesive components meet at the catheter outlets at meeting point 75, mixing to create the adhesive blocking element 89, which repairs the paravalvular leak by closing cavity 24. Figure 8d depicts a top view of the final result of the repaired cavity showing that adhesive blocking element has been formed to seal cavity 24 between valve 20 and annulus 22.

[00125] Figure 9 illustrates another apparatus for blocking a leak by means of biological adhesive in accordance with another preferred embodiment of the present invention. Again, two guidewires meet at meeting point 75, and catheters, in this case 91 and 93, are fed over the guidewires to meeting point 75. However, in this case the blocking adhesive material comprises one liquid component that is solidified by the

presence of ultra-violet light or another radiation cure. The liquid adhesive material is inserted into cavity 24 at catheter meeting point 75 via catheter 91. Active wave 96 shining through light probe catheter 93 hardens the material, creating sealing block 95, which closes the leak
5 caused by cavity 24.

[00126] Figures 10a to 10e illustrate another apparatus for repairing a paravalvular leak using a bi-component adhesive material in accordance with another preferred embodiment of the present invention. Figure 10a shows a multiple-lumen catheter 100 that can be slid over guidewire 99 to
10 the desired location, inside cavity 24 between aorta 82 and prosthetic valve 81. Figure 10b is a cross-section of the catheter 100's multiple-lumen shaft. Lumens 102 and 103 provide means of approach for the separate components of the adhesive. Lumen 104 provides means for catheter to be fed over guidewire 28. Figure 10c shows a bi-component
15 adhesive infusion chamber 100 in the form of a double syringe connected to the end of catheter 100 that is proximal to the medical operator. Figure 10d illustrates a mixing element 105 located at the distal end of catheter 100 (its location can be seen in Figure 10a). Mixing element 105 serves to mix the two adhesive components as they emerge from distal end of
20 catheter 100 after being forced out of chamber 101, thereby ensuring that they will solidify and cure inside cavity 24. Figure 10e shows the adhesive components after they have been infused by chamber 101 via multiple-lumen catheter 100 and mixing element 105 into cavity 24 to form a plug. The cured adhesive fills the cavity and blocks the leak. Also
25 shown in Figure 10e is an optional flexible mesh bag 106, which receives and holds the adhesive mix. The bag prevents possible migration of adhesive material during insertion and prevents the adhesive from passing through stent struts 108 in cases where such valve designs are present.

[00127] Figures 11a to 11f illustrate an apparatus for repairing a paravalvular leak in accordance with another preferred embodiment of the present invention. Two self-expanding sealing stents 110 are connected by suture 112 and pushed into insertion catheter 111 (Figure 11b). At this stage, insertion into the catheter has reduced the stents' diameter, enabling them to enter a cavity 24 between a prosthetic valve and surrounding blood vessel. Figures 11c and 11d depict an implanted valve 115 where two large calcifications 116 create cavity 117, which causes regurgitation and must be repaired. (The calcification is just one example of a condition that creates a cavity that must be repaired. The cavity could equally have been caused by other factors, the cause is not determinant for the embodiment.) Figure 11e depicts insertion catheter 111 inserted over guidewire 28 to a point where the distal (delivery) end of the catheter has passed through the bottom of cavity 117. A first sealing stent 110 is deployed below the bottom of cavity 117. Catheter 111 is withdrawn and suture 112 is partially retracted, pulling the first sealing stent 110 into the bottom of the cavity, where it lodges. With reference to Figure 11f, insertion catheter 111 is withdrawn until its distal end is near the top of cavity 24, whereupon a second sealing stent 110 is deployed. Suture 112 is further retracted, pulling the second stent into the top of the cavity, where it lodges. The final step of the procedure is to disconnect the proximal part of the suture at point 119.

[00128] Figure 12 depicts a valve adapted to seal paravalvular leaks in accordance with a preferred embodiment of the present invention. Valve 121 is held in holder stent 124 with sealing element 120 attached circumferentially around stent 124's outer surface. When valve 121 is implanted, sealing element 120 is expanded to seal any peripheral paravalvular leaks. Several means can be used to implement expansion of

sealing element 120. In the implementation shown in Figure 12, sealing element 120 is inflated by operator application of syringe 123, and it constitutes a balloon-like portion, made of a pliant physiologically acceptable polymeric material such as polyurethane. The inflation media
5 can be saline solution, the patient's blood, or another physiologically acceptable fluid.

[00129] Alternatively, the sealing portion can be made of a material that, on contact with a fluid, soaks up the fluid and swells up. Once inserted into the body, the sealing portion comes into contact with the
10 blood, causing it to swell and seal the cavity.

[00130] Figures 13a to 13d depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. Figure 13a depicts an implantable valve 124. Stent 125 has a sealing component 126 connected to its inlet. Sealing
15 component 126 is comprised of a plurality of flaps 127 and expands to a larger diameter than the principal diameter of the stent 125, creating an extra sealing line to prevent paravalvular leaks. Figure 13b depicts a top view of valve 124. Sealing component 126 comprises a plurality of flaps 127 that, independent of one another, are connected to the valve stent 125.
20 Each flap 127 is made of spring wire 131, which, after the valve is deployed, causes flap 127 to extend out. Flaps 127 are covered with impermeable sealing material 128. Flaps 127 are arranged such that they are substantially perpendicular to the longitudinal axis of stent 124 and overlap one another, ensuring a full seal.

25 [00131] Figure 13c shows stent-mounted valve 124 in its crimped configuration. Introducing sheath tube 130 holds stent 125 and sealing

component 126 crimped on balloon 129. After deployment, flaps 127 of sealing component 126 open to their final diameter.

[00132] Figure 13d shows a cross-section of a self-expanding sealing flap 127. Stent strut 133 is attached to spring wire ring 131 by
5 mechanical attachment means 134, which can be a rivet, a screw, etc. Spring wire ring 131 can be folded into introducing sheath tube 130 shown in Figure 13c and, when released from tube 130, springs back to its shape as shown in Figure 13d.

[00133] Figure 14 illustrates a valve adapted to seal paravalvular
10 leaks in accordance with another preferred embodiment of the present invention. This design includes balloon-inflatable stent 140 (containing a prosthetic valve) and balloon-inflated sealing ring 145, which is similar to sealing component 126 of Figure 13, only here balloon-inflatable wire 145 is used instead of spring wire ring 131. Stent 140 is inflated using a
15 double balloon. First balloon section 142 inflates stent 140 to the desired diameter, and then second balloon section 143 inflates sealing flaps 145 perpendicular to stent 140, creating a larger diameter and thus sealing any cavities around the stent.

[00134] Figures 15a and 15b depict a valve adapted to seal
20 paravalvular leaks in accordance with another preferred embodiment of the present invention. In this embodiment the sealing ring comprises flexible sealing elements 150. Each sealing element 150 is independently spring-actuated. When the valve is crimped, sealing elements 150 fold, enabling valve to be reduced to a small diameter for insertion. When
25 valve is expanded to its final diameter, sealing elements 150 open to a larger diameter 154 to seal cavities around the valve, preventing

paravalvular leaks. Since each sealing element 150 is independent, sealing elements adjacent to native valve tissue 152 remain closed. These closed elements provide a further benefit of adding compressive forces that improve the anchoring of the valve.

5 [00135] Figures 16a to 16c depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. Here the sealing ring 165 comprises at least one of a plurality of flexible, self-expanding sealing elements 165 connected to the outer surface of stent 160. Similar to the embodiment shown in Figure
10 15, when stent 160 is pressed against the native tissue, sealing element 165 will stay compressed against the wall. But where there is a gap between stent 160 and the surrounding tissue, sealing element 165 will expand and block any possible leak. With reference to Figure 16b, sealing element 165 is made of self-expanding mesh 166 covered with PET
15 (polyethylene terephthalate) mesh 167 or other impermeable material.

[00136] Figures 17a to 17e depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention, wherein the sealing component is built into a ring 172 of the stent struts. In the figure the ring of struts 172 is located at the
20 stent's inlet; however, the ring of struts can equally be implemented at another point along the stent. The modified struts 173 comprising ring of struts 172 are designed so that they are geometrically constrained such that, upon expansion of the stent from crimped state (Figure 17a) to expanded state (Figure 17b), ring of struts 172 bend to a final diameter
25 169 substantially larger than the final diameter 168 of the rest of the expanded stent, thereby sealing paravalvular cavities and associate leaks.

[00137] Figures 17c and 17d show front and side views of the geometrical restriction in modified strut 173 that causes the displacement of point 175, creating enlarged diameter 169. Figure 17c shows modified strut 173 before stent expansion and in line with the rest of the stent wall.

5 Figure 17d shows modified strut 173 after stent expansion, which has caused modified strut 173 to rise up and out, creating the sealing ring. Figure 17e details the operation of the geometric restriction: when stent 170 is crimped, the strut legs are relatively close to each other 176, making strut height relatively large 177. After expansion, the strut legs

10 are spaced further apart 176a, leading to displacement of point 175, and lessening of strut height 177a. The result of the movement of point 175 is shown in Figures 17c, 17d, and 17e. When the stent is crimped, as shown in Figure 17c and the left side of Figure 17e, point 175 is low. When the stent is expanded, as shown in the right side of Figure 17e, point 175

15 moves up, pulling the stent to the shape shown in 17d .

[00138] Figures 18a to 18e depict a valve adapted to include means for sealing paravalvular leaks in accordance with another preferred embodiment of the present invention. In Figure 18a percutaneous valve 180 crimped on balloon 182 is shown being advanced toward the stenotic

20 aortic valve 175. At least one of a plurality of sutures 181 are connected to valve 180 at inlet end 187. The sutures spread back along the balloon's shaft 183 and continue back along the deployment path and out of the patient's body as shown in Figure 18b.

[00139] Inflating balloon 183, as shown in Figure 18c, anchors

25 valve 185 in annulus 179 with sutures 181 arranged around it. In cases where paravalvular cavities 178 are present, it is possible to repair them assisted by sutures 181. Figure 18d shows a patch 189 made of

pericardium (or other suitable patch material) inserted on sutures 181 and pushed to the leaking cavity by means of a pushing catheter 190. After the patch is in place, a knot or clip 191 is used to secure it, thereby repairing the leak (18e).

5 **[00140]** Figures 19a to 19d depict a valve adapted to include means for sealing paravalvular leaks in accordance with another preferred embodiment of the present invention. First elastic sealing stent 195 is inserted in the desired location. Then, valve 196 is inserted into sealing stent 195. Figure 19a shows inserting catheter 191 with sealing stent 195
10 and valve 196 mounted on it. Sealing stent 195 and valve 196 can be either balloon inflated as shown in this figure, or self-expanding which would then require an introducing sheath.

[00141] Figure 19b shows the two stents placed in the native aortic valve. Sealing stent 195 compensates for irregular shapes, while the
15 stented valve 196, which is mounted inside sealing stent 195, can be absolutely round. Sealing stent 195 is able to avoid leaks caused by cavities or irregularities caused by pieces of calcification as described earlier in this patent. The sealing component of sealing stent 195 can be self-expandable hydrophilic sponge 197 (Figure 19c) or other suitable
20 material. Sealing stent 195 can include hooks 198 that open when the stent is inserted, improving the anchoring of the stent in the annulus as well as improving sealing around the stent by blocking blood (Figure 19d).

[00142] Figure 20a depicts a stented valve 201 having a valvular
25 structure 202 along an interior region and a mechanism along an exterior region for sealing paravalvular leaks in accordance with yet another

preferred embodiment. In this embodiment, a flexible sealing element 203 provides a sealing ring. The sealing element 203 may be formed of any material suitable for implantation in the human body, such as, for example, a sponge material. When the stented valve 201 is crimped to a smaller diameter, sealing element 203 is also crimped, thereby enabling valve to be easily advanced to a treatment site. For purposes of illustration, figure 20f illustrates sealing element 203 before crimping, while Figure 20g illustrates sealing element in a crimped condition. When the valve is expanded to its final diameter, sealing element 203 expands to its original size diameter by internal spring forces and/or by absorbing blood. Expansion of the sealing element seals cavities around the valve and thereby prevents paravalvular leaks. In addition to the mechanical effect of blocking cavities, blood protein preferably adheres to the sealing element, thereby causing coagulation for further leak prevention. Figures 20c and 20d provide cross-sectional views of preferred sealing elements. A tubular form 203a shown in figure 20c is configured to be crimped to a smaller size than a rod form 203b shown in figure 20d. Figure 20e illustrates the sealing element with additional fibers 206, which increase the active surface, thus increasing the effect of protein adhesion and enhancing coagulation and sealing. Figure 20e also illustrates a suture 207 as one preferred means for attachment to the valve body. Figure 20b is a perspective view illustrating another preferred embodiment of a valve 210 having a sealing mechanism. In this variation, two sealing elements 204, 205 are provided along an exterior region.

[00143] Figure 21 depicts yet another stented valve 220 adapted to seal paravalvular leaks. In this embodiment, a sealing element 223, which is preferably made of the same materials described above with

respect to figures 20a through 20g, is attached to the stent in a non-linear sealing line. In preferred configurations, the line can be adjacent to the connection of a valvular structure 222 to the stent or according to the lines of the stent structure. In one feature, an improved crimped profile may be achieved using the illustrated attachment line.

[00144] Figure 22 depicts yet another stented valve 250 configured to reduce or prevent paravalvular leaks. The stented valve generally comprises an expandable stent structure 252 which supports a valvular structure 254. The stent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter. The valvular structure 254 forms three leaflets and is illustrated in the open configuration.

[00145] To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252. The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve. In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm. In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped. The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage. In addition, the compressible material, and especially the fibers, may be adapted to encourage

coagulation of blood to further fill the gaps and prevent leakage. In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps. Any suitable tissue growth
5 factor may be used. In various preferred methods, the growth factor may be applied along the outer surface of the compressible material or the material may be soaked or dipped in the growth factor before use.

[00146] In yet another embodiment, a biocompatible hydrogel may be applied to the outside surface of a prosthetic valve. After deployment,
10 the hydrogel absorbs fluids from the blood and expands to fill the gaps between the valve and surrounding tissue (e.g., host annulus). In preferred methods, the hydrogel may be applied to the surface of the stented valve before deployment or may be applied after deployment.

[00138] The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other
15 expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention or the scope of the appended claims.

CLAIMS

1. A catheter-delivered device for locating cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks
5 during diastole, the device comprising at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.
2. The device of Claim 1 further comprising a spacing
10 element to maintain the wires adjacent to the wall of the body vessel.
3. A catheter-delivered stent for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the stent delivered via guide wire to the cavity, held in
15 place in the cavity by friction, and comprising a support structure and an impermeable membrane, the membrane preventing the passage of fluids through the stent, thereby sealing the cavity.
4. The device of Claim 3, wherein the sealing stent is balloon-expandable type and the membrane comprises a tab spring-
20 hinged to the inside of the stent lumen and sized to occlude the lumen when closed, the tab being held open by the stent balloon during insertion and springing closed when the balloon is removed after the stent is expanded.

5. The device of Claim 3, wherein the sealing stent is self-expandable, wherein the membrane is a material covering at least one end of the stent.

6. The device of Claim 5, wherein the stent is
5 comprised of shape memory material.

7. The device of Claim 6, wherein the material is
nitinol.

8. The device of Claim 5 further covered on its external walls with hooks comprised of shape memory material and which extend,
10 upon insertion of the stent, into adjacent body vessel walls.

9. The device of Claim 3, wherein the distal end of the stent-delivery catheter is substantially perpendicular to the wall of the vessel at a point inside the cavity and the stent guidewire terminates in an anchoring mechanism that is inserted through the catheter and into the
15 vessel wall, anchoring itself in the vessel wall and providing greater anchorage for the stent.

10. The device of Claim 9, wherein the anchoring mechanism is a hook comprised of shape memory material that is compressed for catheter delivery into the vessel wall whereupon the hook
20 extends out, anchoring the guide wire into the vessel wall.

11. The device of Claim 10, wherein the anchoring mechanism is a threaded point that is threaded into the vessel wall anchoring the guide wire into the vessel wall.

12. A device for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising a first guidewire threaded through the cavity, a second
5 guidewire slidably coupled to the first wire and inserted such that the slidable coupling is moved to a point in the cavity, a first catheter inserted over the first guidewire to the point in the cavity, a second catheter inserted over the second guidewire to the point in the cavity, a first component of a two-component biological adhesive inserted through the
10 first catheter to the point, a second component of the two-component adhesive inserted through the second catheter to the point, and the two components thereby mixing to form a plug that seals the cavity.

13. The device of Claim 12 adapted to apply an adhesive with more than two components.

14. The device of Claim 12, wherein, instead of two
15 guidewires and two catheters, a single catheter and guidewire are used for delivery, with the catheter comprising two lumens, each lumen providing delivery for one of the two-component adhesive components, the catheter terminating in a mixer that forces the components to mix when the exit
20 the catheter in the cavity, thereby creating the plug that seals the cavity.

15. The device of Claim 12, wherein, instead of two-component adhesive components being delivered via the catheters, a radiation-cured adhesive is delivered via one of the catheters and a radiation source is delivered via the other catheter, wherein the radiation
25 source is applied to the adhesive to create the plug in the cavity.

16. A catheter-delivered assembly for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the assembly delivered via guidewire to the cavity and comprising two sealing stents connected by a suture, the suture running back up the catheter, the sealing stents comprising a stent structure and sealing membrane, one stent of the assembly inserted underneath the cavity and the other stent inserted inside the cavity, the membranes preventing the passage of fluids through the stent, thereby sealing the cavity and each stent helping anchor the other in place.

17. A prosthetic valve with integrated sealing ring attached to the outside wall, the ring having a circumference greater than that of the valve and elastically conforming to seal cavities between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

18. The device of Claim 17, wherein the ring comprises a balloon.

19. The device of Claim 17, wherein the ring comprises a plurality of spring-wire tabs mounted adjacent to one another around the circumference of the valve and covered with an impermeable membrane and wherein the tabs are folded against the body of the valve during catheter delivery and where, upon egress from the catheter, the tabs spring out to form the sealing ring.

20. The device of Claim 17, wherein the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, and further comprising a balloon under

the tabs and wherein the tabs are folded down on the deflated balloon during catheter delivery and wherein, upon egress from the catheter, the balloon is inflated, thereby opening the tabs to form the sealing ring.

21. The device of Claim 17, wherein the ring comprises
5 a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, each tab spring-hinged to the valve and wherein the tabs are folded against the body of the valve during catheter delivery and wherein, upon egress from the catheter, the tabs spring out to form the sealing ring.

10 22. The device of Claim 17, wherein the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

15 23. The device of Claim 17, wherein the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

20 24. The device of Claim 17, wherein the sealing ring comprises modified struts of the stent, the modification comprising geometrical constraints that, upon expansion of the stent, cause the struts to bend out from the stent body, thereby creating the sealing ring.

25 25. A prosthetic valve with integrated sealing means, the sealing means comprising sutures attached around the perimeter of the valve and extending back out of the body and wherein patches can be pushed down the sutures and attached to the point where the suture is

attached to the valve, thereby sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

26. A catheter-delivered prosthetic valve with integrated
5 sealing means, the sealing means comprising an elastic stent that is first deployed and inside which the valve is deployed, the elastic stent sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

10 27. A prosthetic valve for implantation in a body channel, comprising:

a substantially cylindrical stent structure configured for radial expansion;

15 a valvular structure providing a flexible conduit having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

a layer of compressible material disposed along an outer surface of the stent structure, the compressible material being adapted for expansion after deployment to fill gaps between the prosthetic valve and
20 the body channel.

28. The prosthetic valve of claim 27, wherein the compressible material is formed of polyethylene terephthalate.

29. The prosthetic valve of claim 28, further comprising a tissue growth factor disposed along the compressible material and

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

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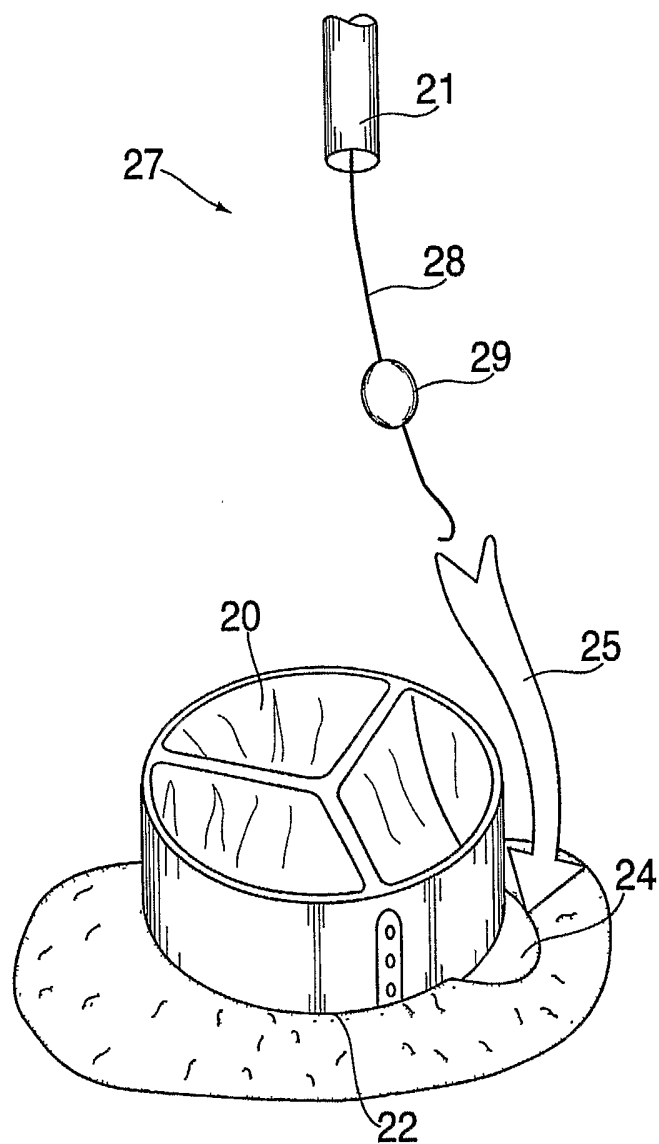


FIG. 1

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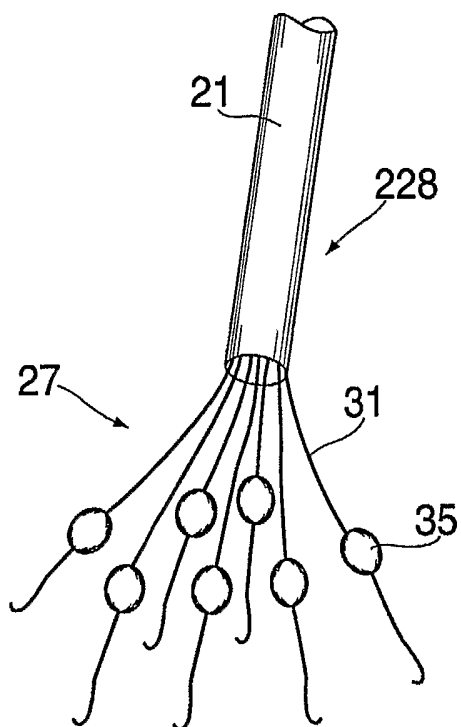


FIG. 2a

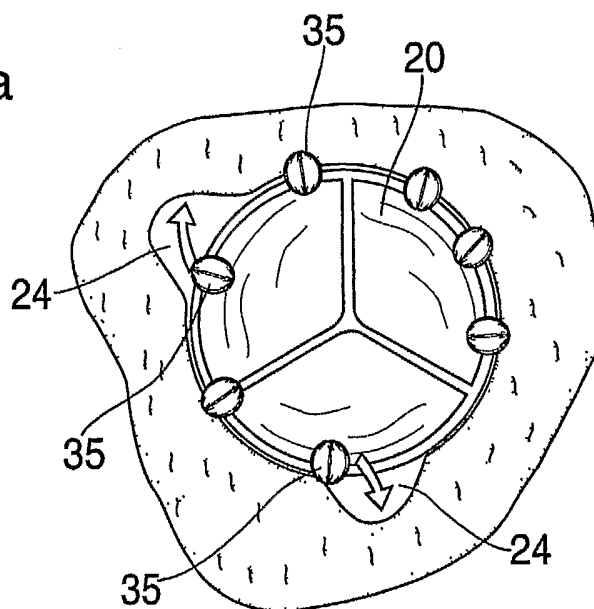


FIG. 2b

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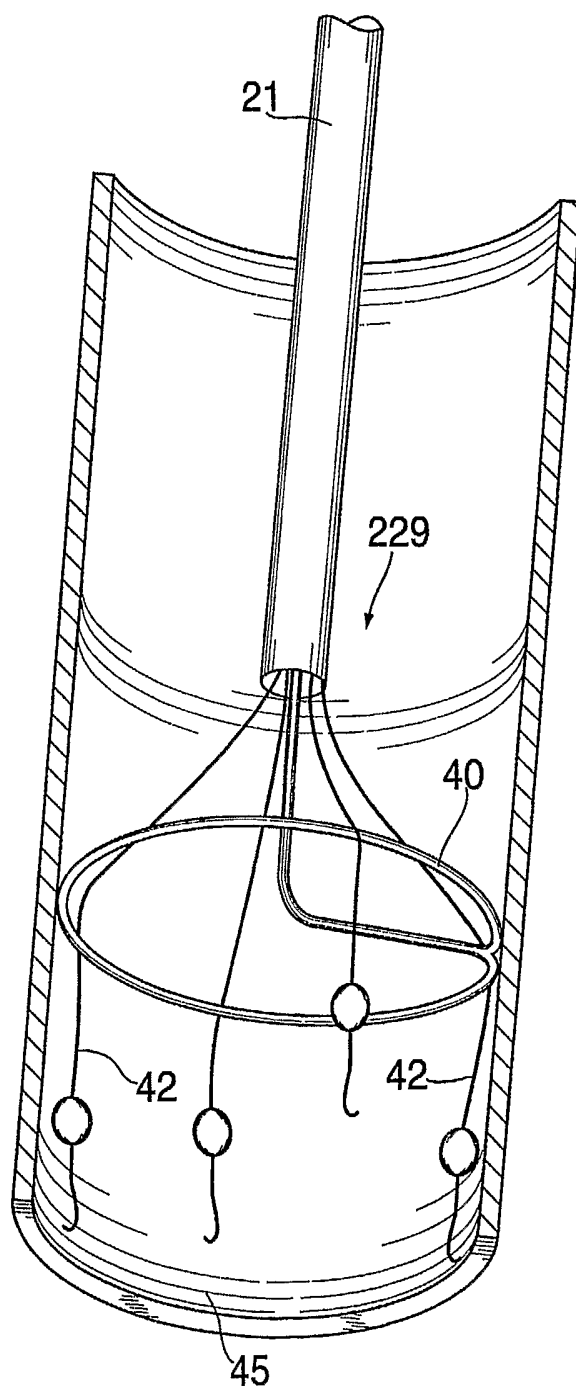


FIG. 3

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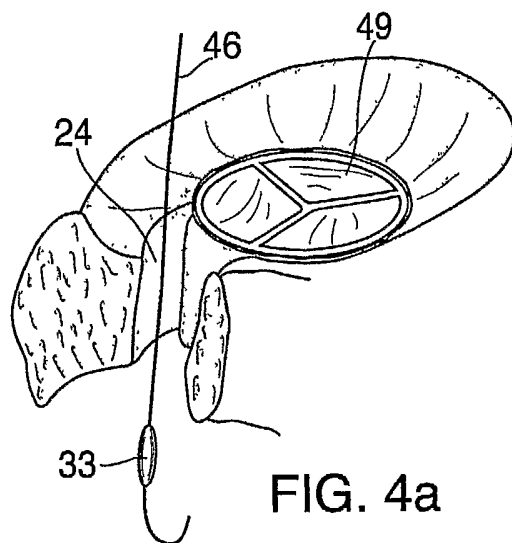


FIG. 4a

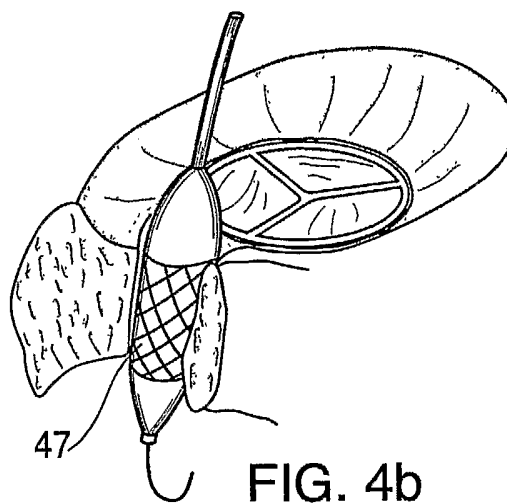


FIG. 4b

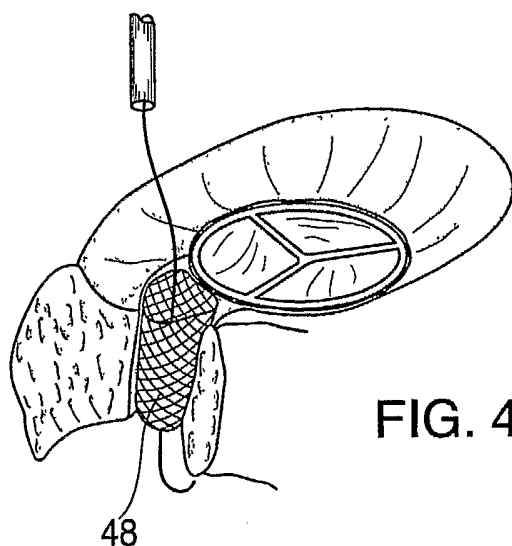


FIG. 4c

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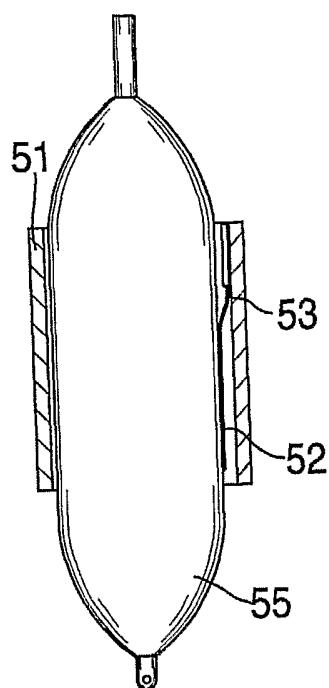


FIG. 5a

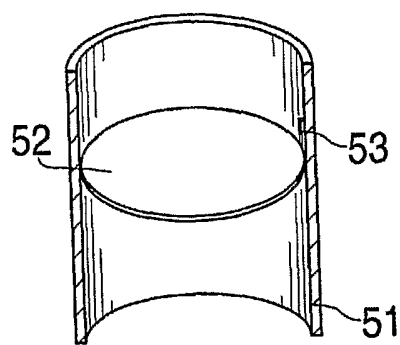


FIG. 5b

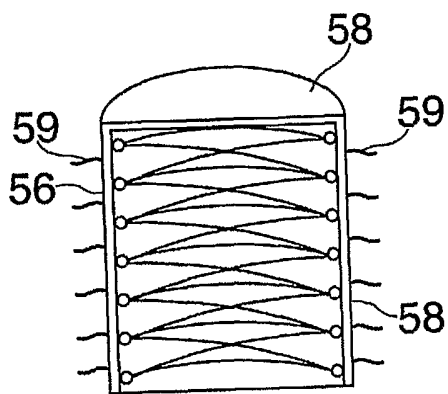


FIG. 5c

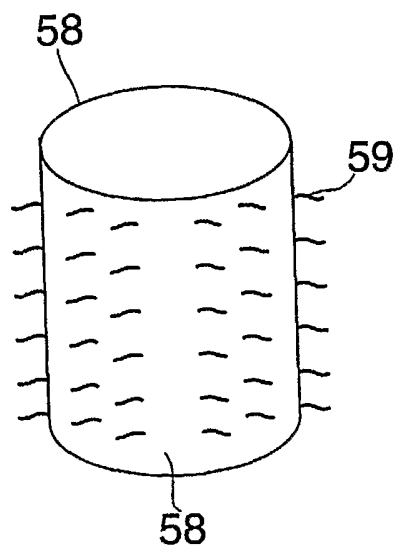


FIG. 5d

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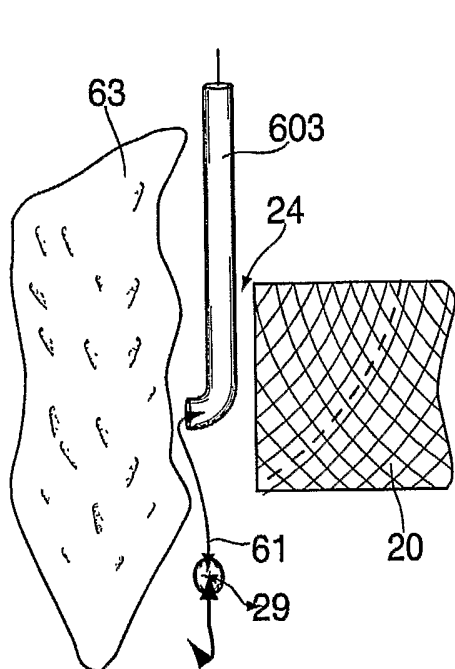


FIG. 6a

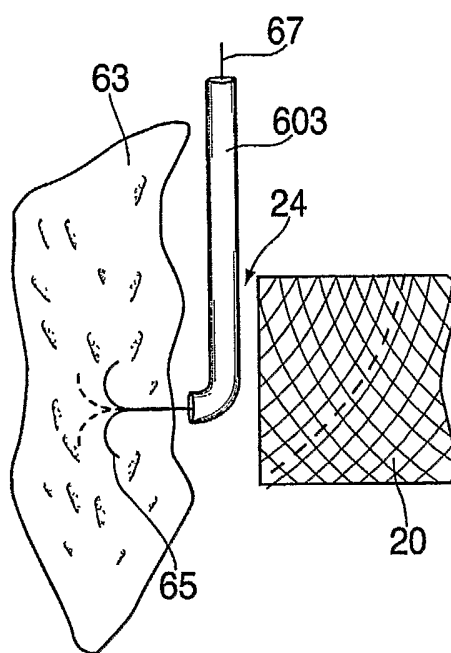


FIG. 6b

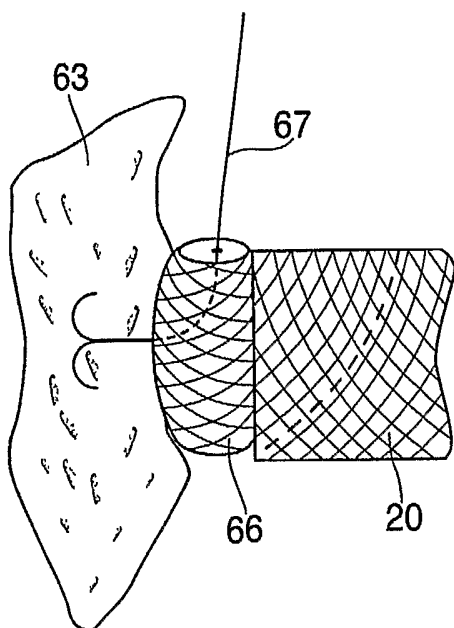


FIG. 6c

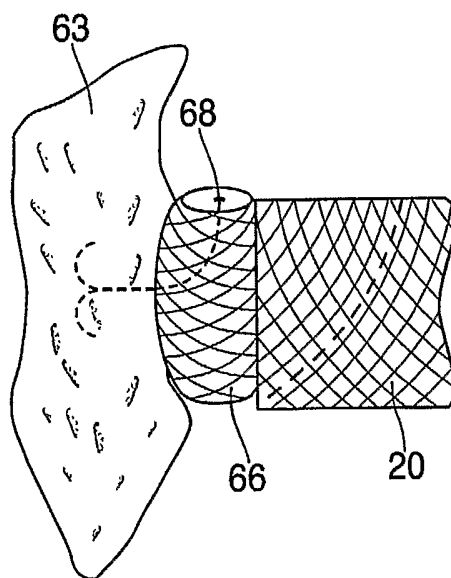


FIG. 6d

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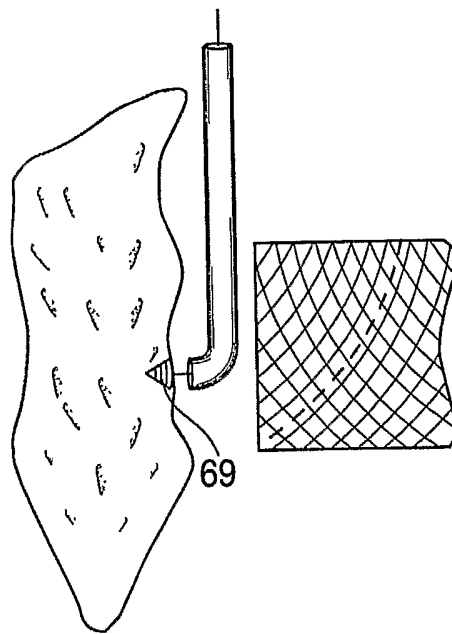
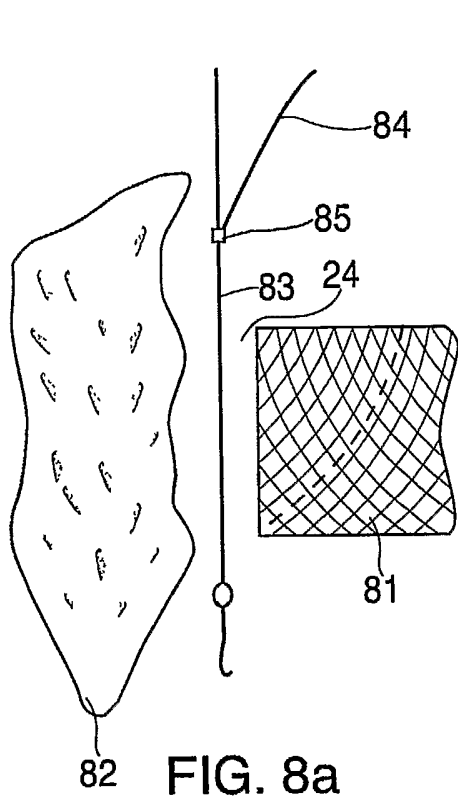
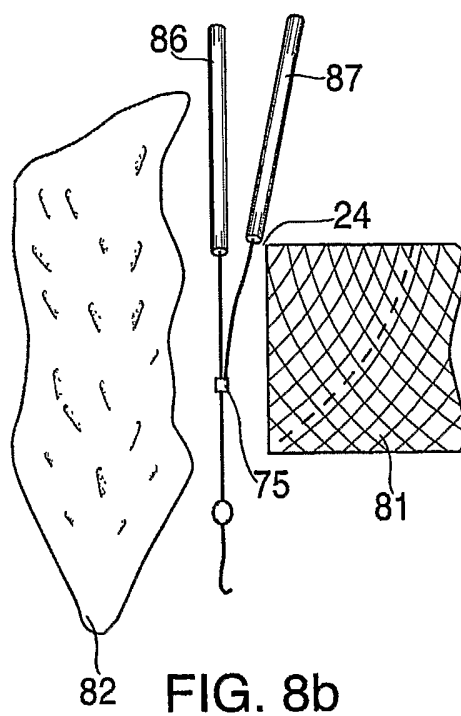
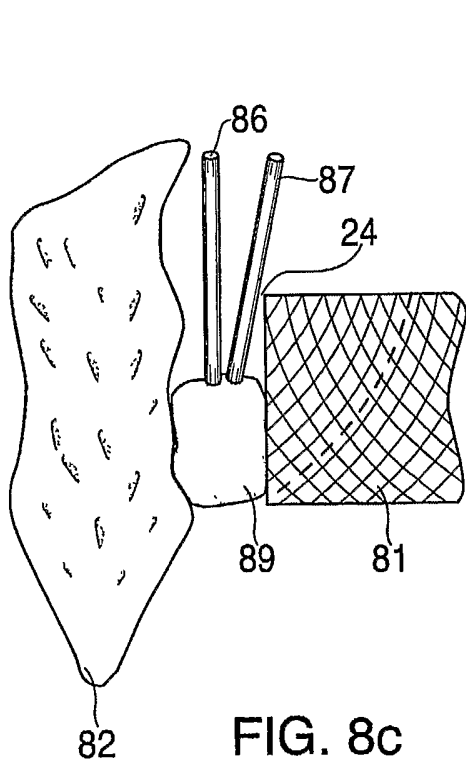
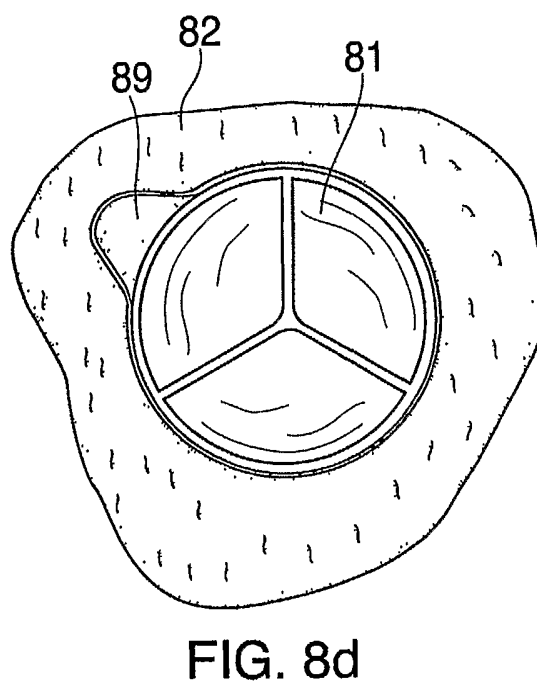
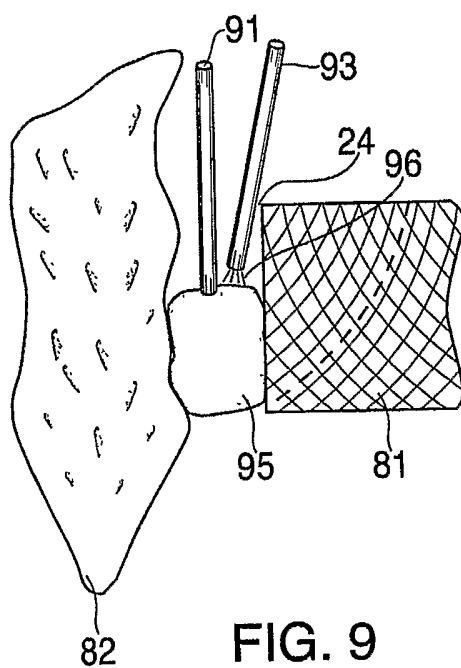


FIG. 7

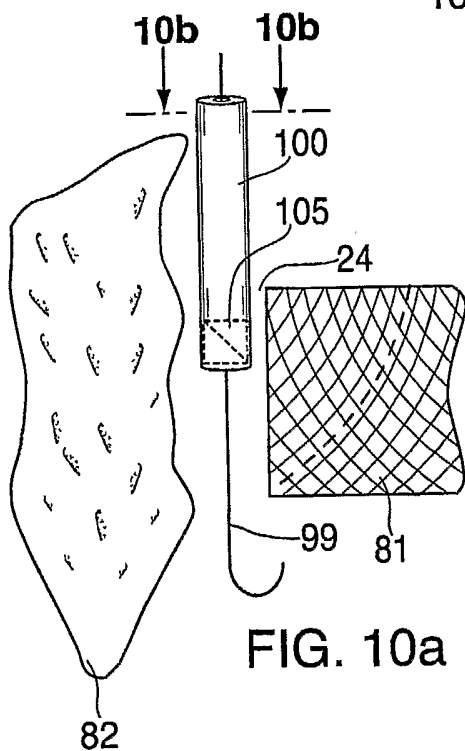
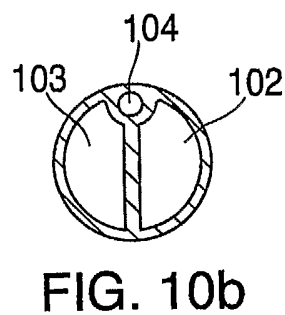
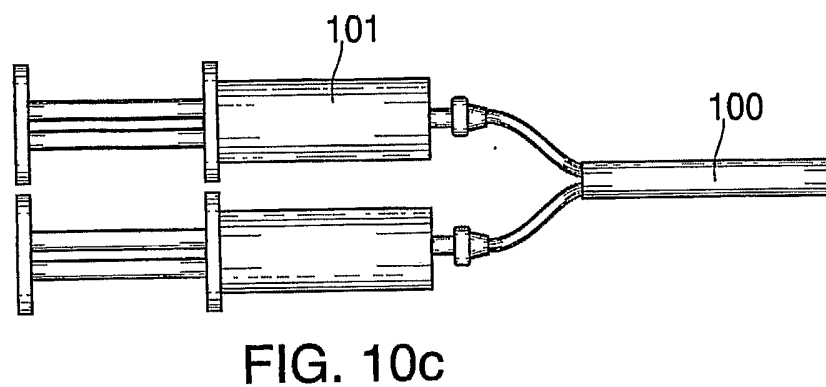
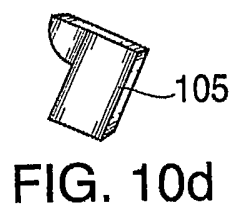
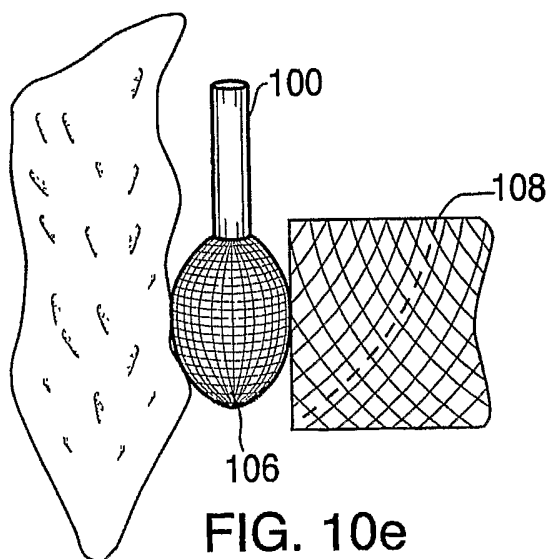
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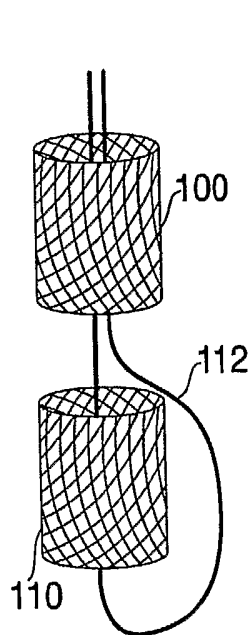


FIG. 11a

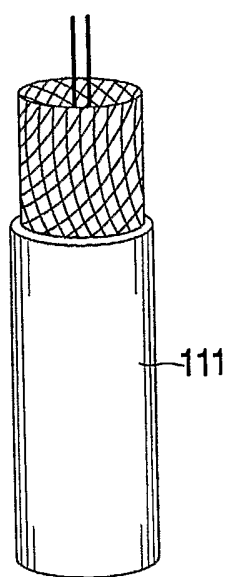


FIG. 11b

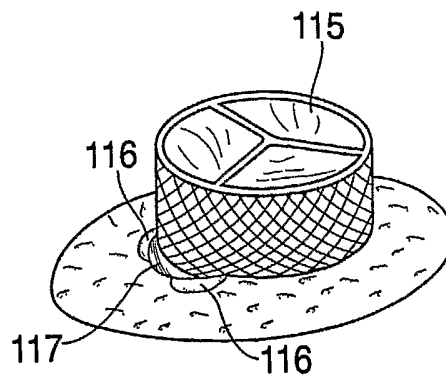


FIG. 11c

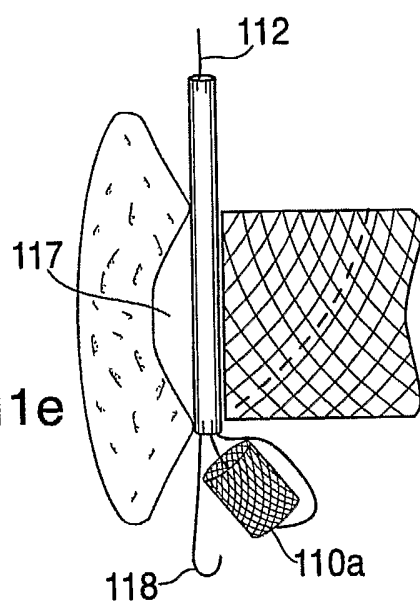


FIG. 11e

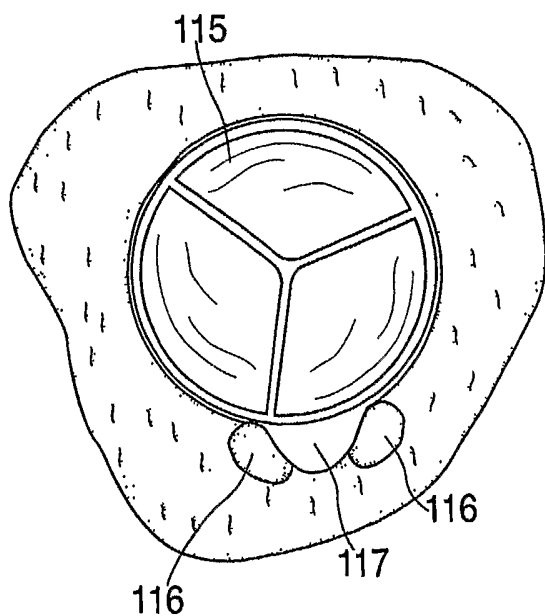


FIG. 11d

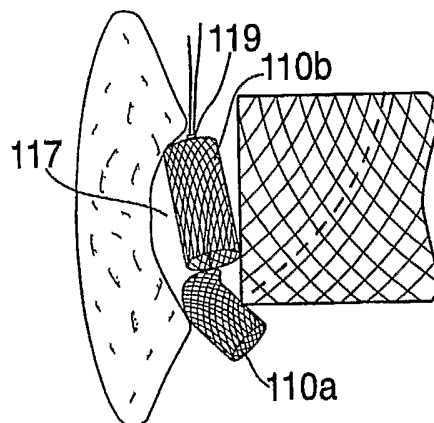


FIG. 11f

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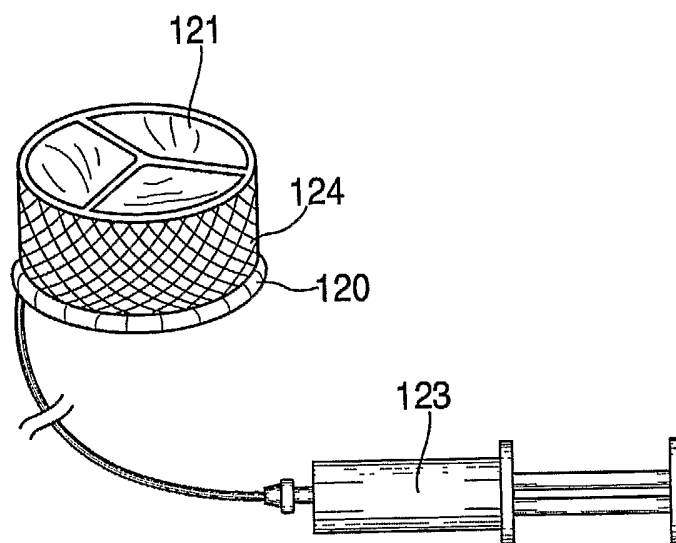


FIG. 12

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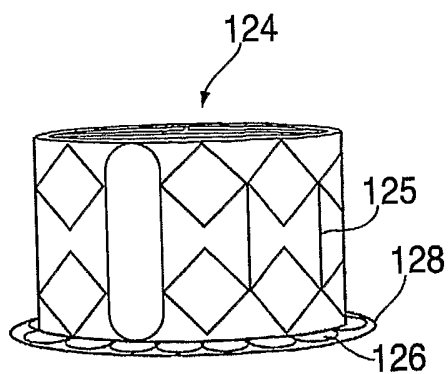


FIG. 13a

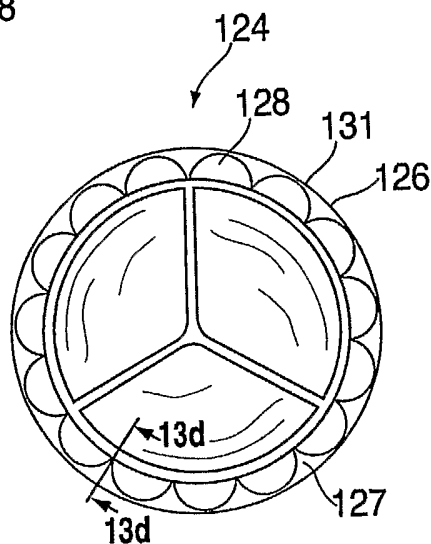


FIG. 13b

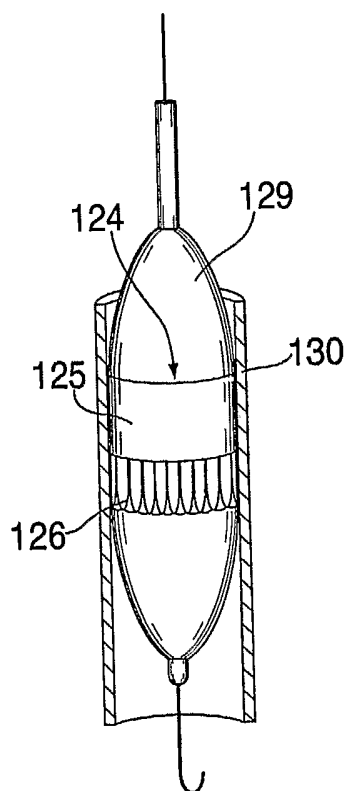


FIG. 13c

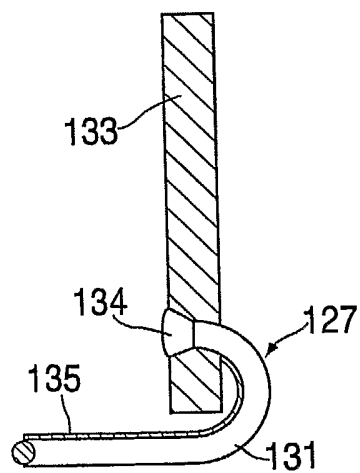


FIG. 13d

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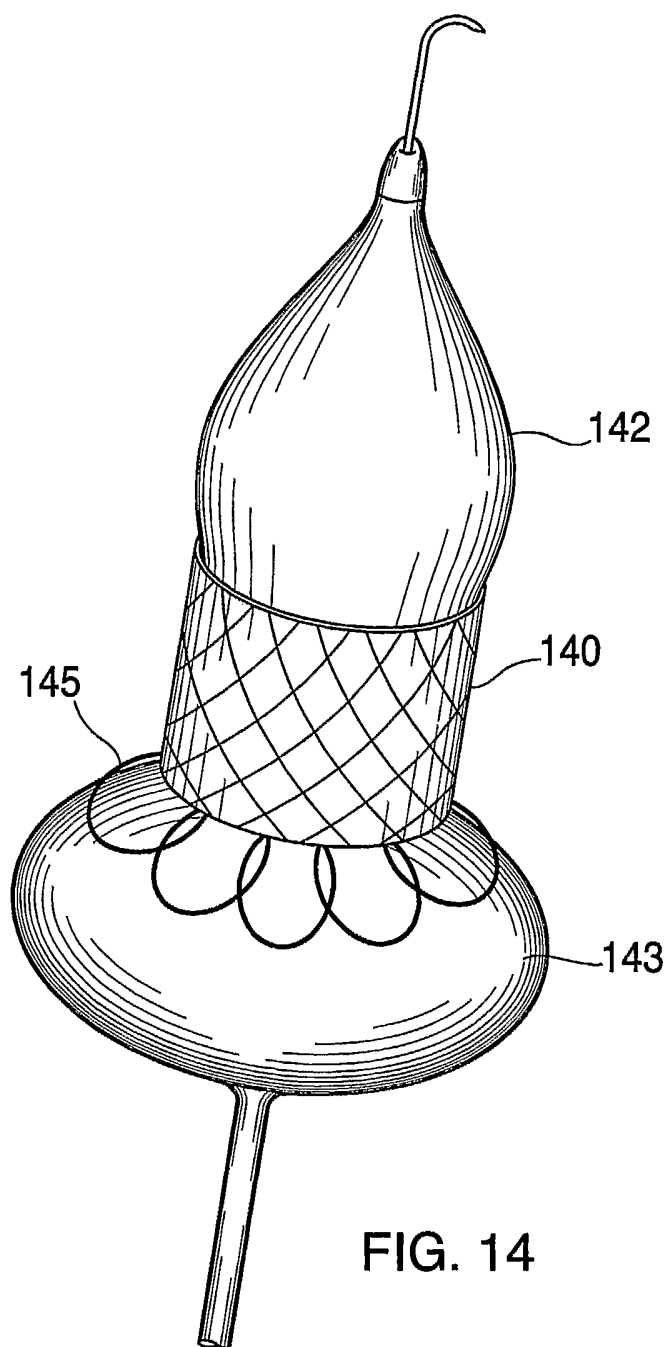


FIG. 14

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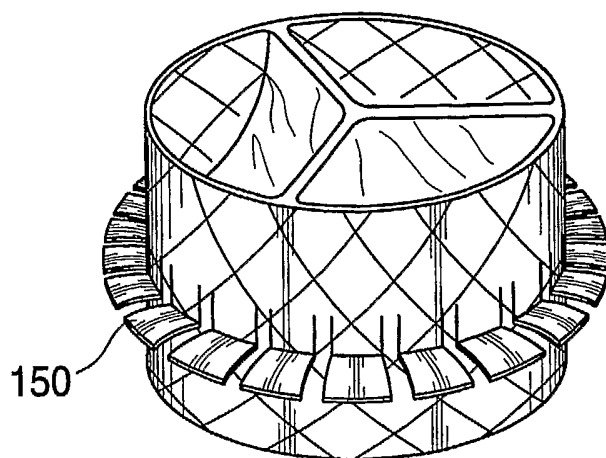


FIG. 15a

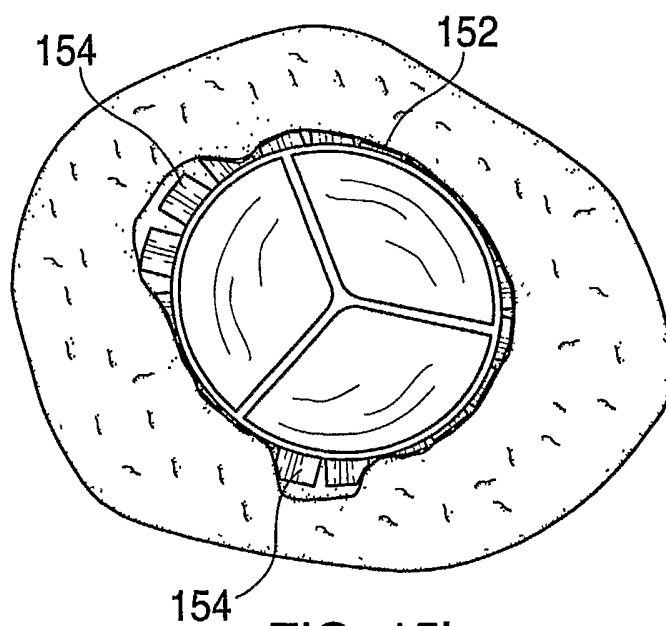


FIG. 15b

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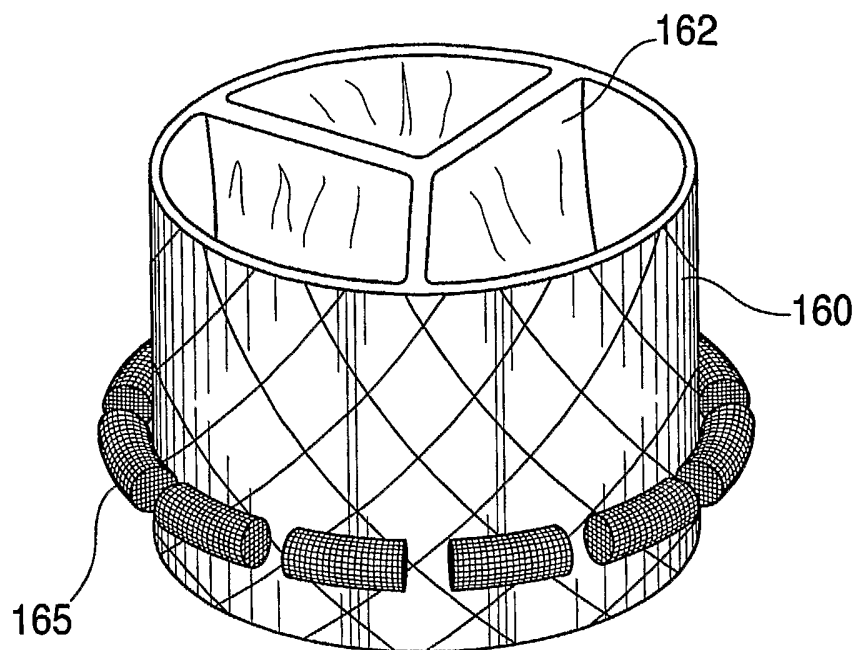


FIG. 16a

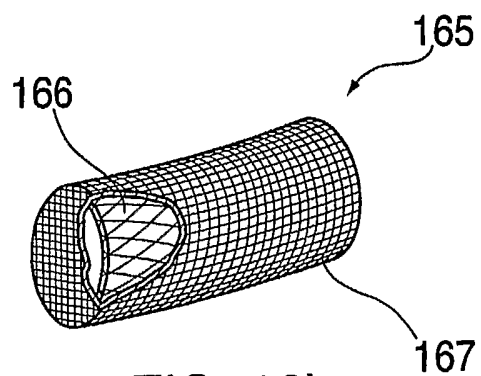


FIG. 16b

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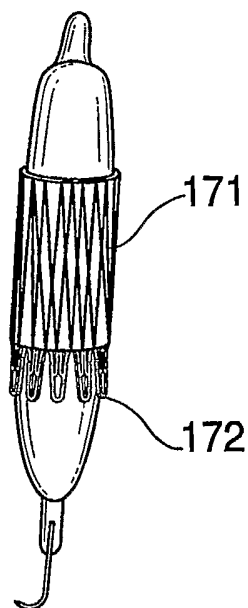


FIG. 17a

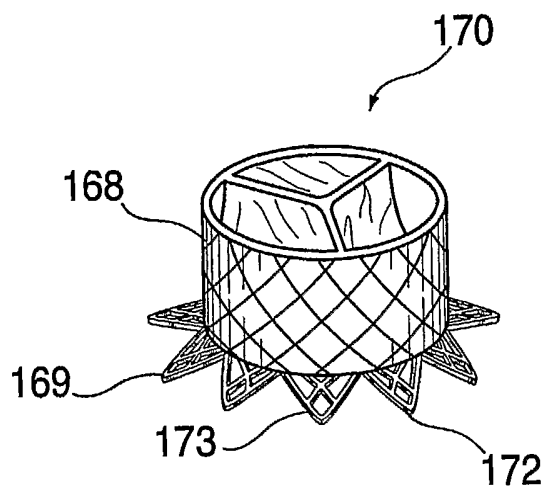


FIG. 17b

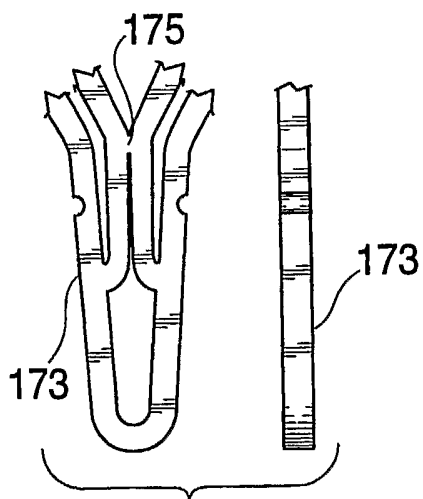


FIG. 17c

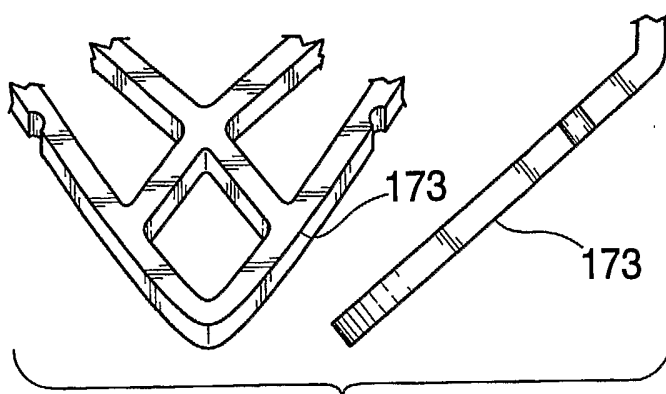


FIG. 17d

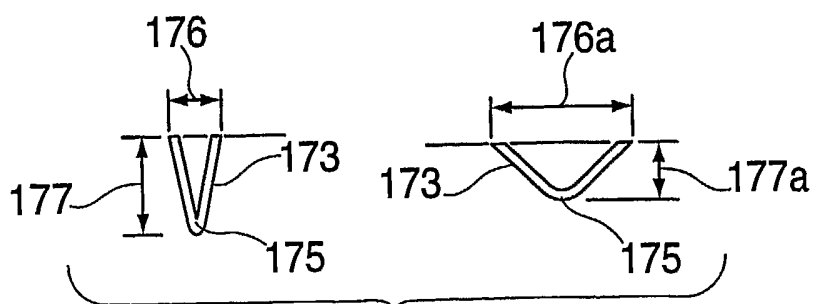


FIG. 17e

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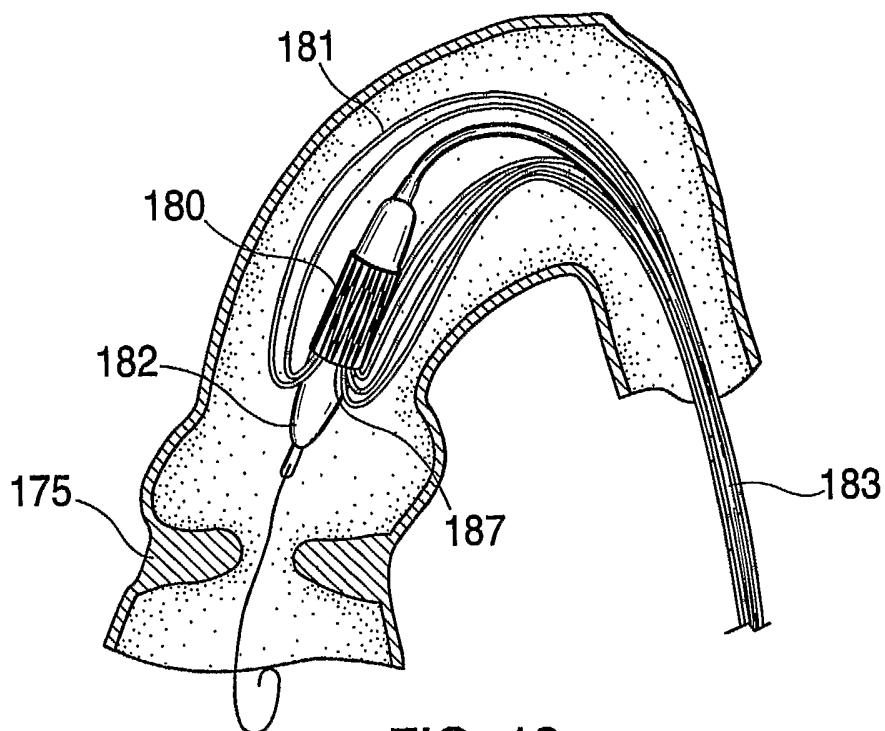


FIG. 18a

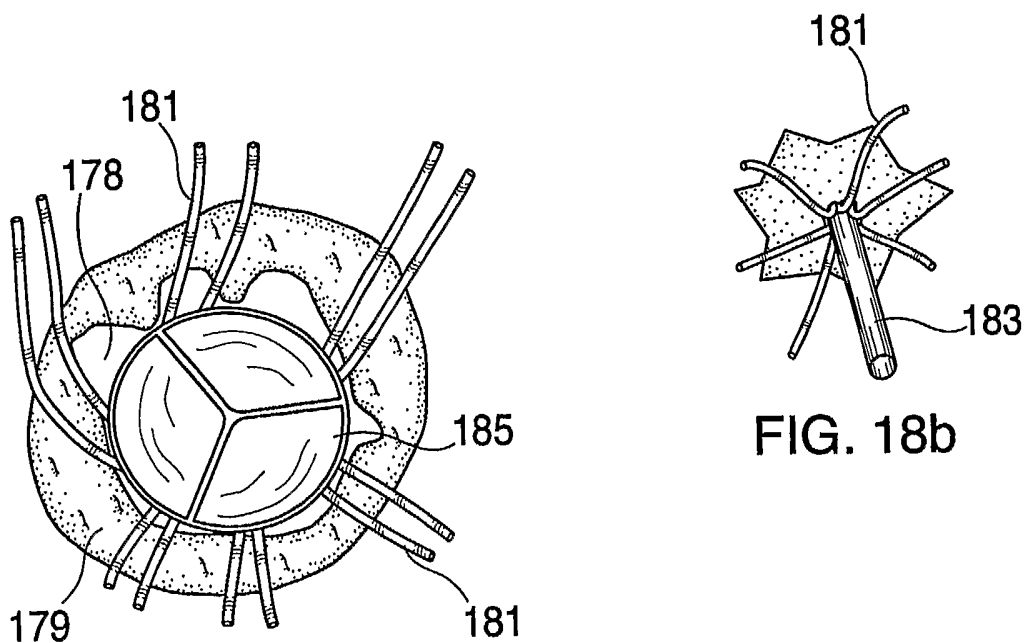


FIG. 18b

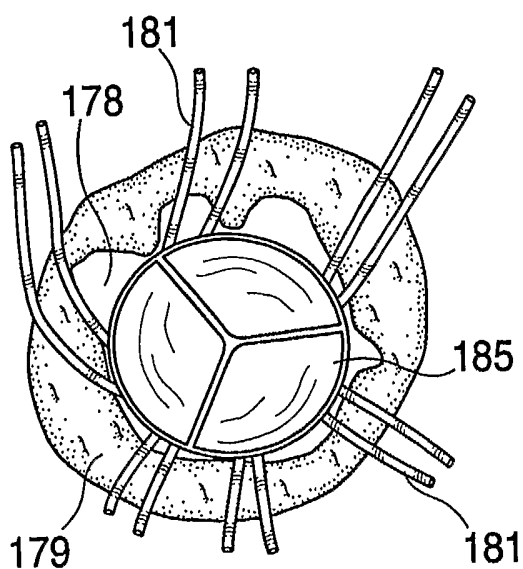


FIG. 18c

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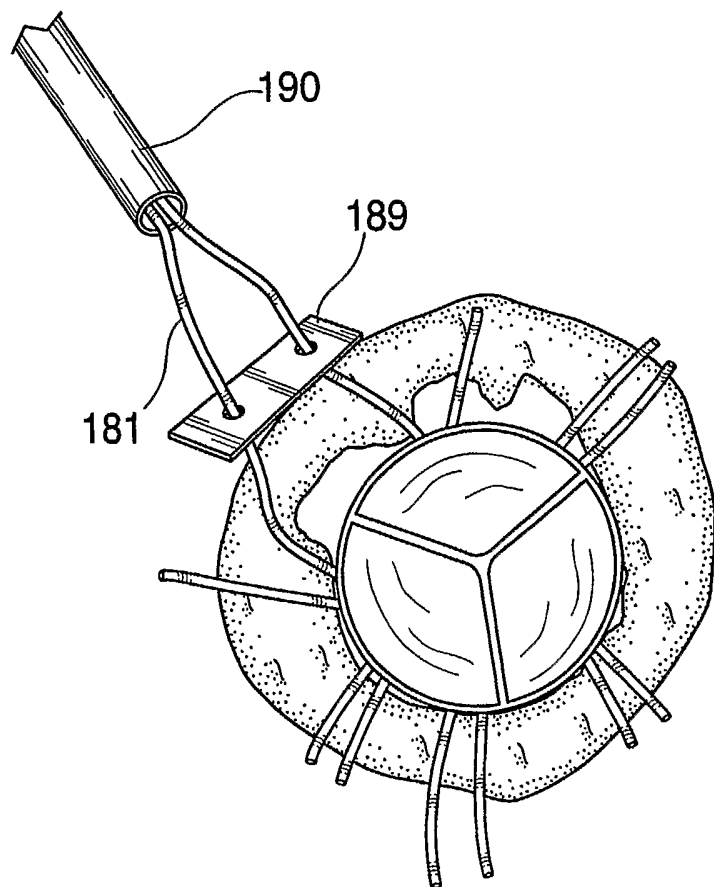


FIG. 18d

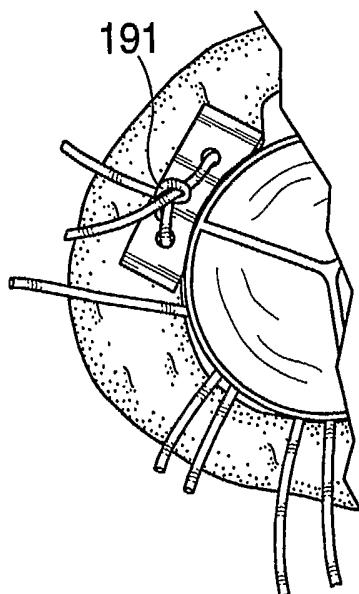


FIG. 18e

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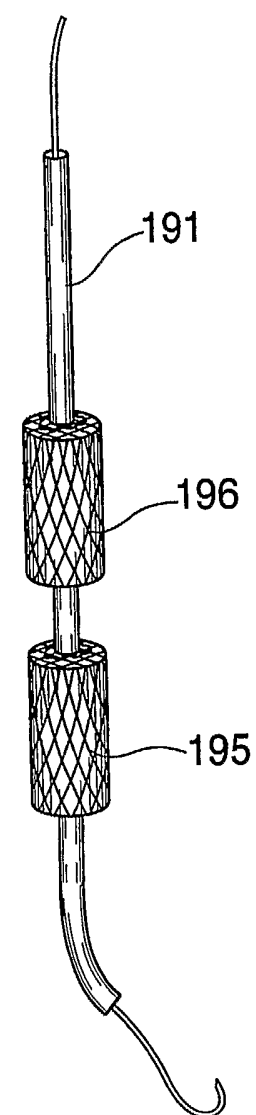


FIG. 19a

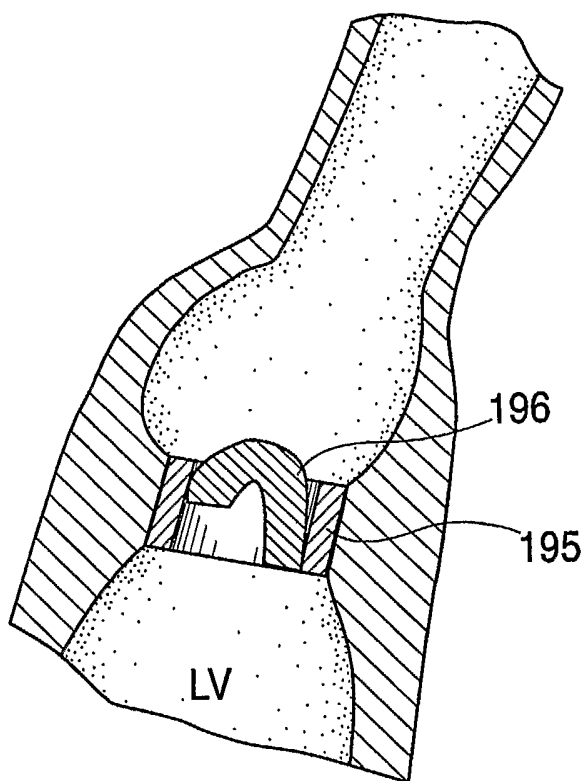


FIG. 19b

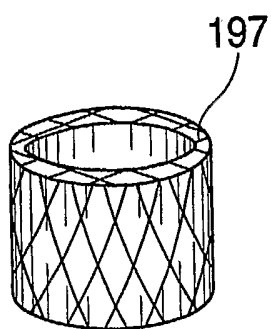


FIG. 19c

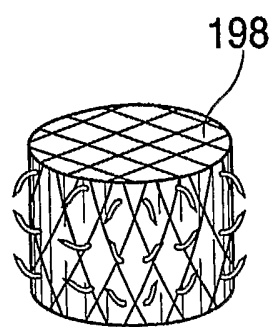


FIG. 19d

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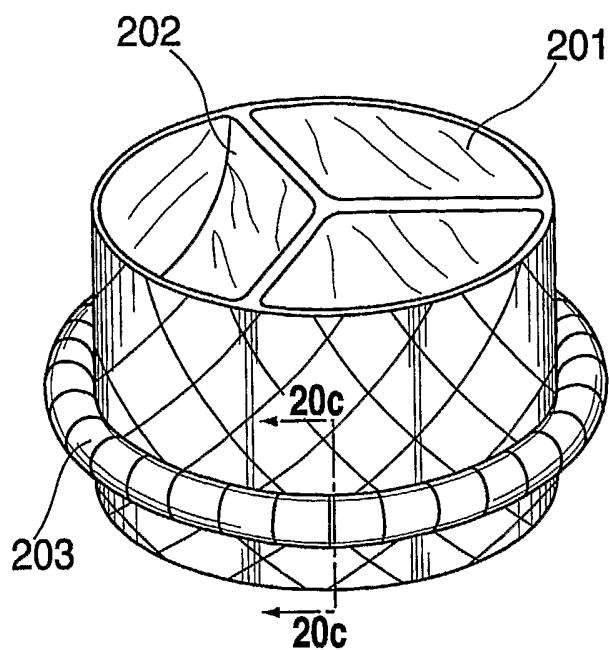


FIG. 20a

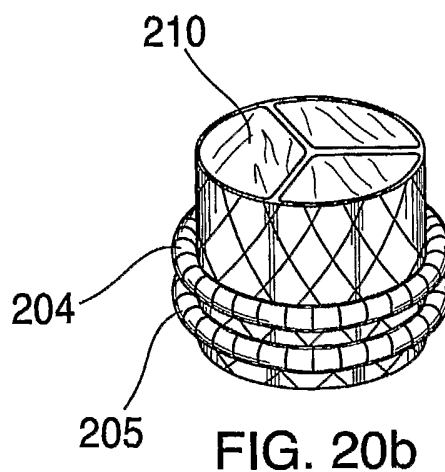


FIG. 20b

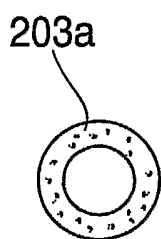


FIG. 20c

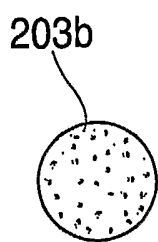


FIG. 20d

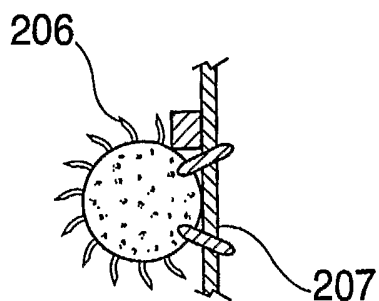


FIG. 20e

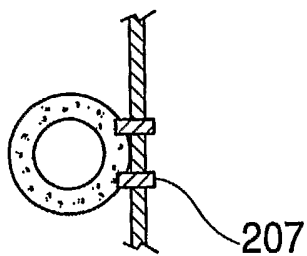


FIG. 20f



FIG. 20g

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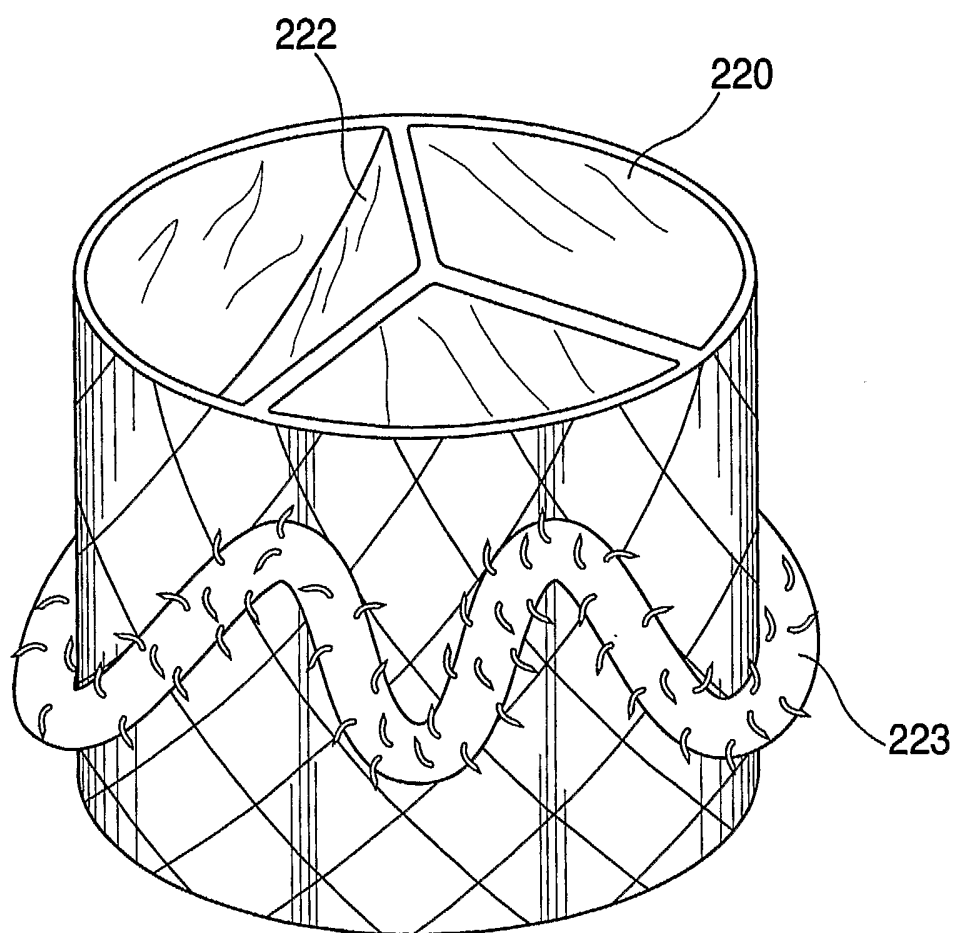


FIG. 21

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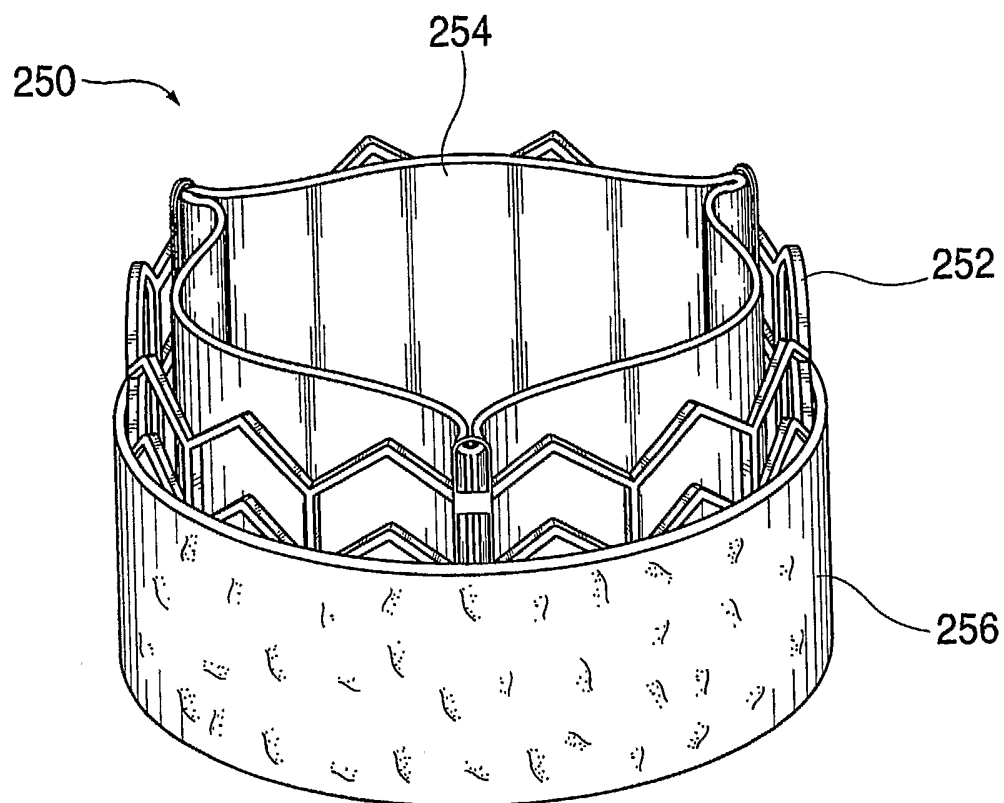


FIG. 22