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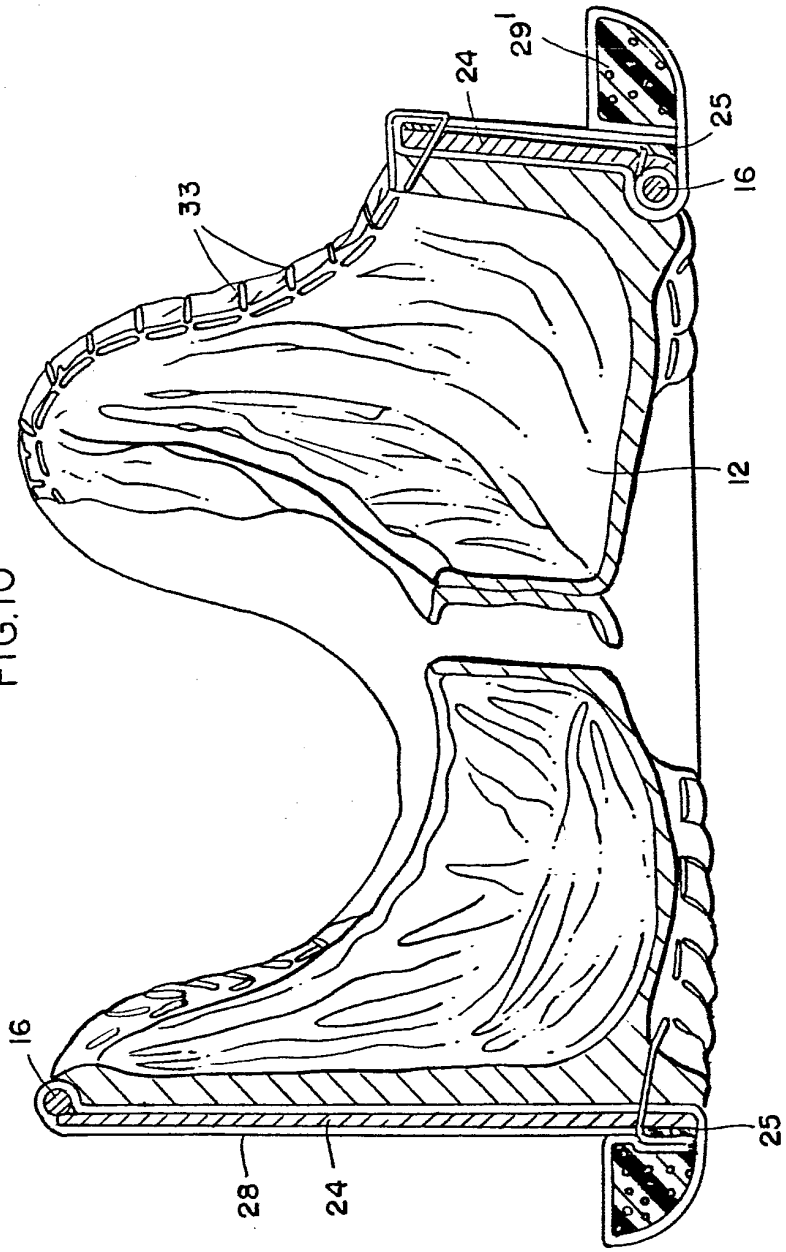


FIG.10

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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

# United States Patent [19]

**Carpentier et al.**

[11] **4,106,129**

[45] **Aug. 15, 1978**


[54] **SUPPORTED BIOPROSTHETIC HEART VALVE WITH COMPLIANT ORIFICE RING**


[75] Inventors: **Alain F. Carpentier,** Paris, France; **Ernest Lane,** Huntington Beach, Calif.

[73] Assignee: **American Hospital Supply Corporation,** Evanston, Ill.



[21] Appl. No.: **827,961**

[22] Filed: **Aug. 26, 1977**

**Related U.S. Application Data**

[63] Continuation of Ser. No. 647,900, Jan. 9, 1976, abandoned.

[51] **Int. Cl.**[2] ..... **A61F 1/22**

[52] **U.S. Cl.** ..... **3/1.5**

[58] **Field of Search** ..... 3/1.5, 1



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| | | | |
|---|---|---|---|
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| | | | |
|---|---|---|---|
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"Fixation of Aortic Valve Homografts with Metal Rings", by A. S. Geha et al., The Journal of Thoracic & Cardiovascular Surgery, vol. 54, No. 5, Nov. 1967, pp. 605–615 & 628–629.



*Primary Examiner*—Ronald L. Frinks

*Attorney, Agent, or Firm*—Tilton, Fallon, Lungmus & Chestnut



[57] **ABSTRACT**

A supported bioprosthetic heart valve in which the supporting stent is capable of annular deformation and also of limited perimetric expansion and contraction during heart operation. The stent includes a wire frame composed of a single flexible wire preformed to define inverted U-shaped commissure supports merging smoothly with arcuate portions connecting such supports.


**29 Claims, 10 Drawing Figures**

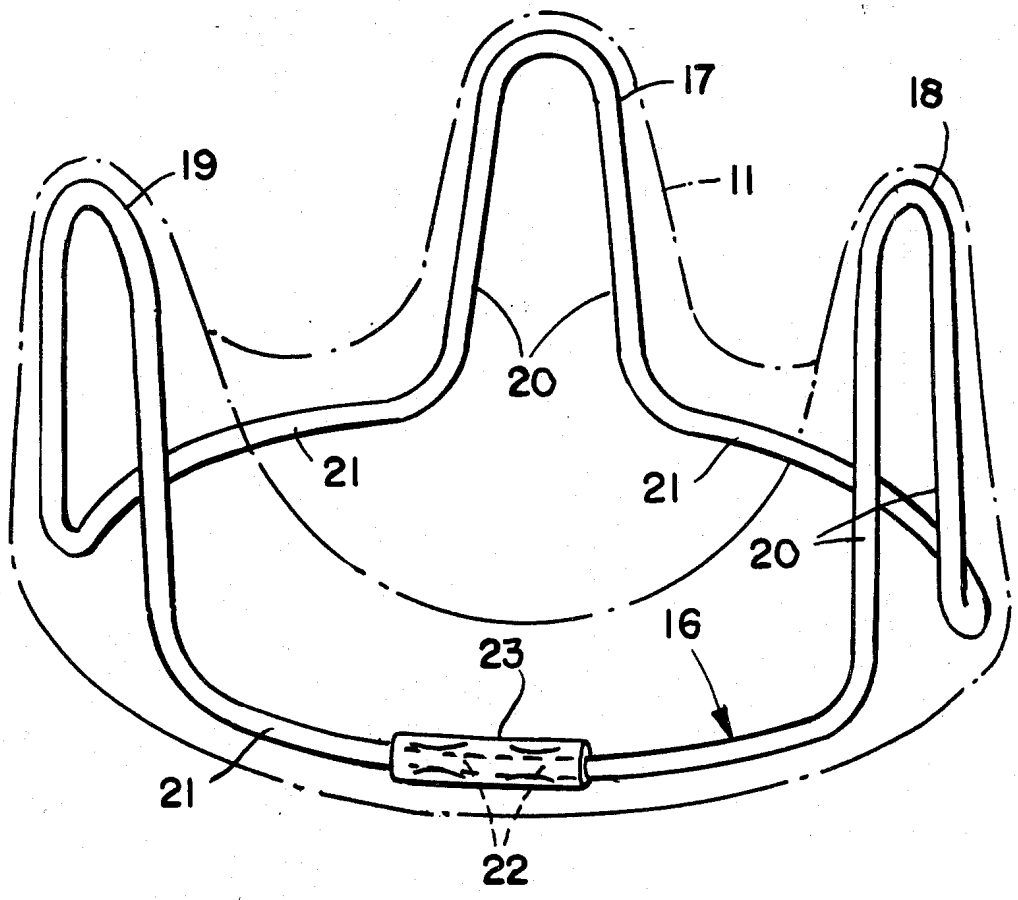

FIG. 1

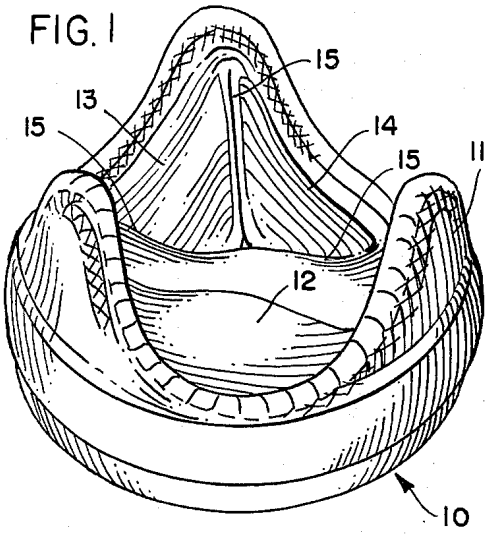


FIG. 2

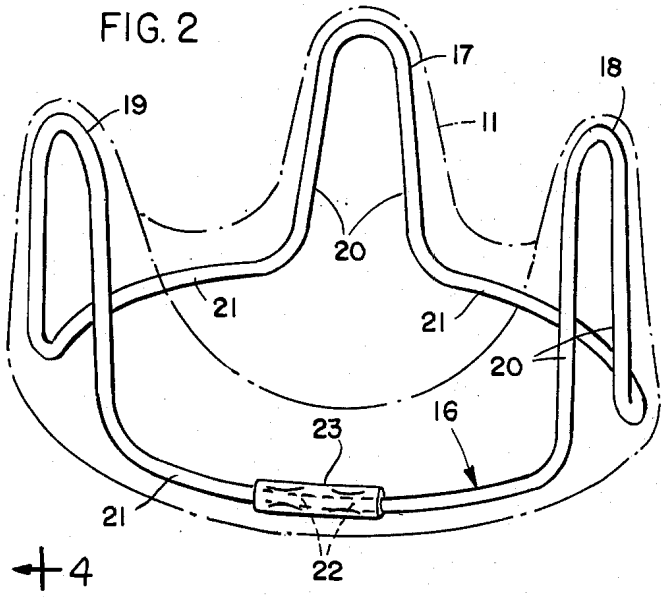


FIG. 3

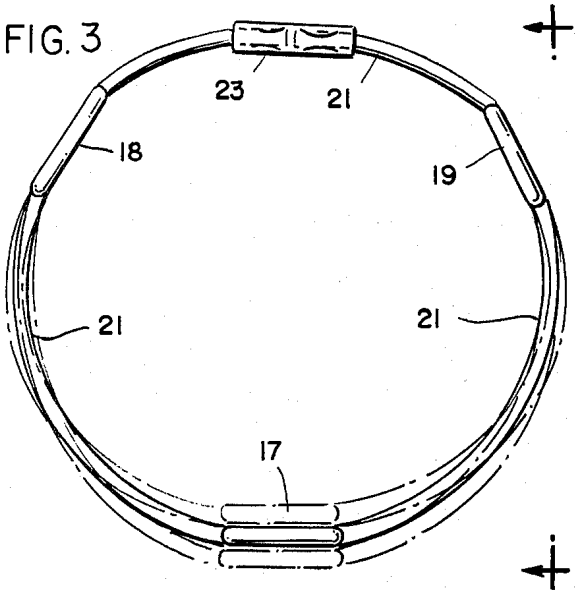


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FIG. 4

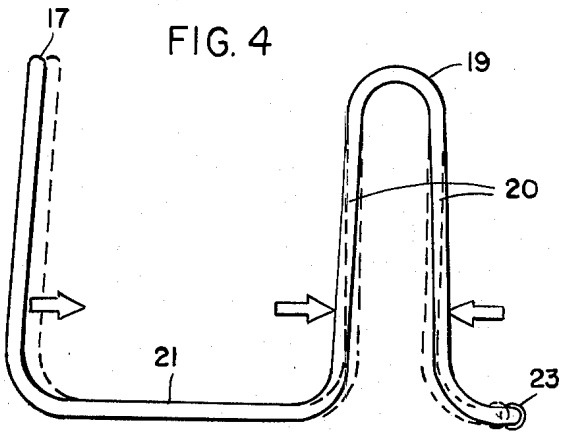


FIG. 5

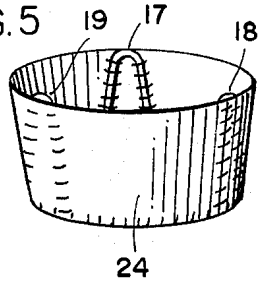


FIG. 6

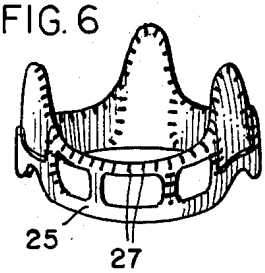


FIG. 7

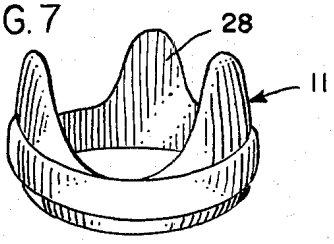


FIG. 8

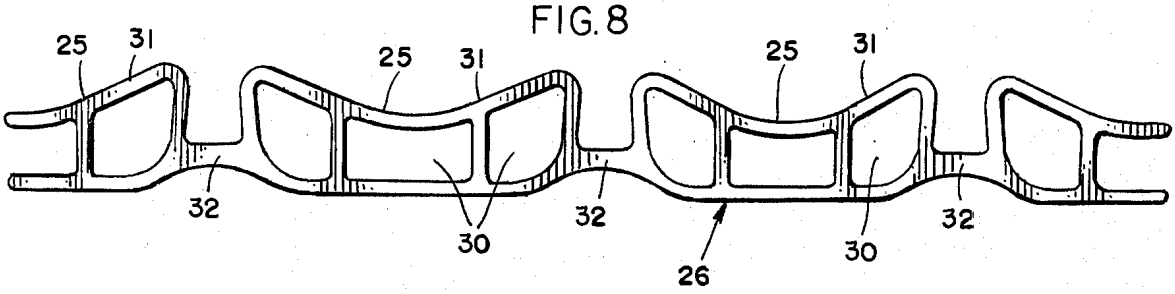


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FIG. 9

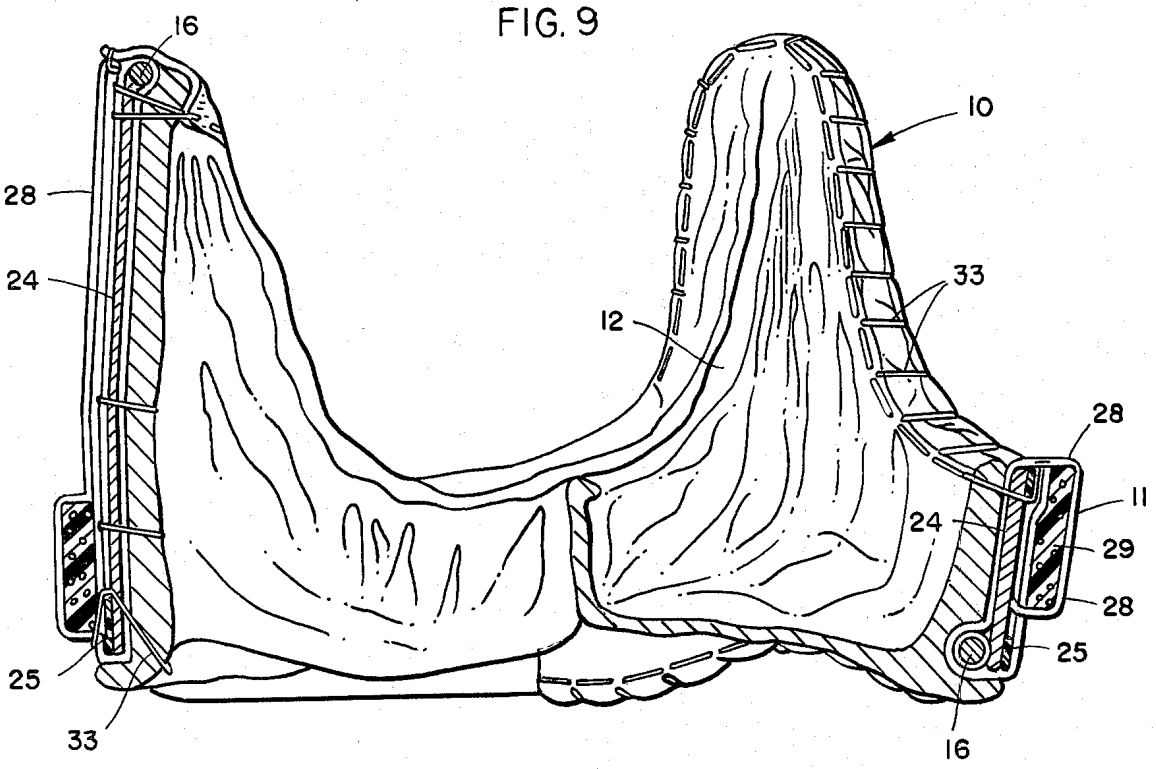
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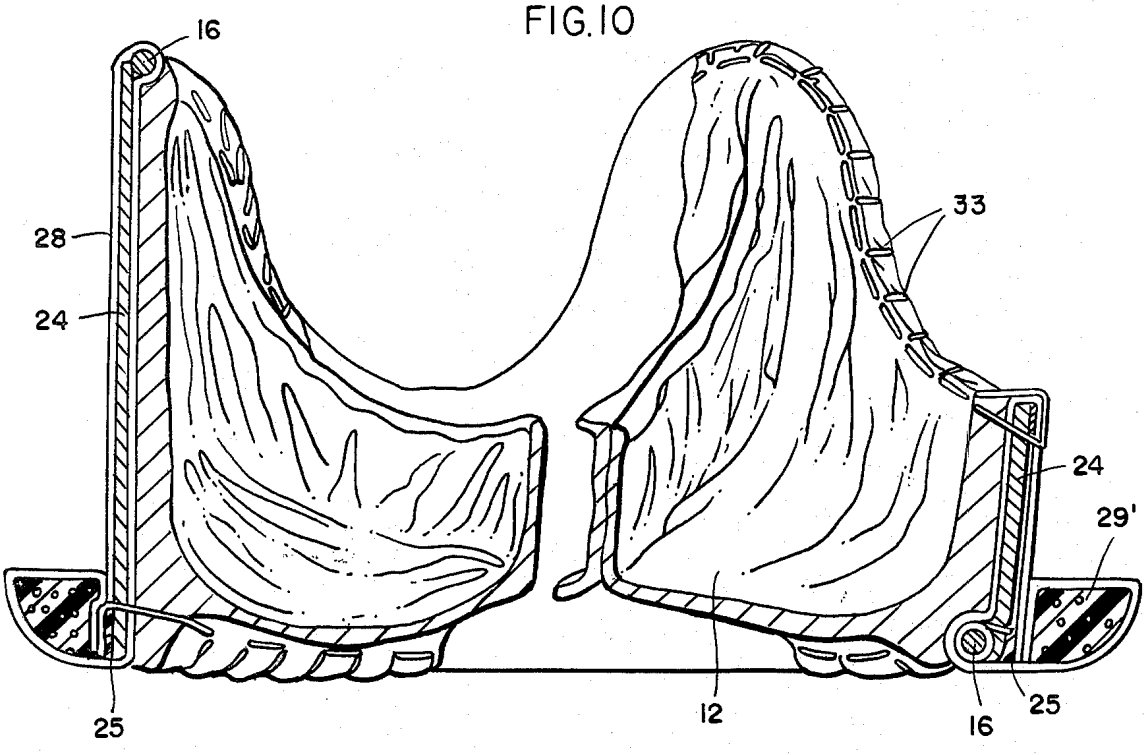
FIG. 10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# SUPPORTED BIOPROSTHETIC HEART VALVE WITH COMPLIANT ORIFICE RING

## RELATED APPLICATION

This application is a continuation of copending application Ser. No. 647,900, filed Jan. 9, 1976, now abandoned.

## BACKGROUND

Stented bioprosthetic valves — that is, supported valvular grafts which may be either xenografts (heterografts) or allografts (homografts) — are believed to have important clinical advantages over mechanical non-tissue prosthetic valves. Reports on the use of xenograft valves indicate that the risks of thromboembolism are lower, the need for long-term anticoagulation is minimized, and the nature of ocassional valve failure is progressive, thereby permitting elective reoperation under optimal conditions. Carpentier et al, J. Thorac. Cardiovasc. Surg. 68:771 (1974); Zuhdi et al, Ann. Thorac. Surg. 17:479 (1974); Horowitz et al, J. Thorac. Cardiovasc. Surg. 67:885 (1974).

In general, such grafts have been mounted on supporting frames which provide rigid orifice rings (see U.S. Pat. Nos. 3,570,014, 3,755,823; Weldon et al J. Surg. Research 6:548 (1966)), even though some stents have included struts capable of flexing inwardly to a limited extent, thereby reducing stresses imposed on the grafts during valve operation and decreasing possible erosion of surrounding tissues of the patient (see Sugie et al, J. Thorac. Cardiovasc. Surg. 57:455 (1969); Hardy, Human Organ Support and Replacement, 338 et. seq. (Thomas, 1971); U.S. Pat. No. 3,755,823). Despite encouraging results in the use of stented valvular grafts, and the significant advantages of bioprosthetic heart valves in contrast to totally artificial prosthetic valves, there is a continuing need for improvement, particularly with regard to the long range durability and reliability of the supported valvular grafts.

## SUMMARY

The present invention is concerned with an improved stent for a bioprosthetic (xenograft or allograft) heart valve which is flexible and, in particular, is capable of yielding to a limited extent in response to forces which tend to alter the configuration and circumference of the orifice ring. Such flexibility and deformability allows the leaflets to close with a sliding type of closure at their free margins which is similar to that observed physiologically, and are believed to be significant in improving long range reliability of the valves.

Conformability of the orifice-defining portion of th prosthetic valve is achieved primarily by utilizing a flexible supporting frame consisting essentially of a single piece or stretch of preformed spring wire. The wire frame is formed to define a triad of axially-projecting circumferentially-spaced commissure supports. Each commissure support has a generally inverted U-shaped configuration with its wire legs merging smoothly at their spaced lower ends with arcuate connecting portions of the wire frame which extend circumferentially between the legs of adjacent commissure supports. Each arcuate connecting portion is capable of being flexed into a condition of greater or lesser curvature, thereby providing limited deformability of the frame's orifice-defining elements. Furthermore, each of the three arcuate connecting portions may be moved to a slight but definite extent independently of the other such portions. Since the wire frame of each commissure support is of inverted U-shaped configuration with the lower ends of the legs thereof normally disposed in spaced-apart relation, the arcuate portions with which the lower ends of the legs smoothly merge may be urged circumferentially towards and away from each other in response to forces occurring during operation of the heart. The result is a flexible frame which is capable of limited changes in dimension and configuration during heart operation.

Insert elements extend between the circumferentially-spaced commissure supports, each of the inserts having an arcuate upper margin sloping upwardly at its ends to merge smoothly with the contour of the commissure supports. The insert elements may be formed integrally as portions of a web of flexible perforated plastic material circumscribing the wire frame. An outer covering of porous fabric extends about the frame and insert elements to provide means for suturing the valve in place and for accommodating tissue ingrowth. A suitable annular cushioning element is also enclosed within the outer covering to promote coaption, the configuration of the cushioning element depending upon the intended use of the valve in a mitral, aortic, or tricuspid position.



## DRAWINGS

FIG. **1** is a perspective view of a bioprosthetic heart valve embodying the present invention.

FIG. **2** is a perspective view illustrating the supporting wire frame for the valve.

FIG. **3** is a top plan view of the wire frame.

FIG. **4** is a side elevational view of the frame.

FIGS **5–7** are reduced perspective views illustrating steps in the fabrication of the stent.

FIG. **8** is a plan view in reduced scale showing the interconnected insert elements of the valve.

FIG. **9** is an enlarged vertical sectional view of a complete bioprosthetic aortic valve embodying the invention.

FIG. **10** is an enlarged sectional view of a mitral valve embodying the invention.

## DESCRIPTION

Referring to FIG. **1**, the numeral **10** generally designates a bioprosthetic valve adapted for implantation in the aortic position. Whether the valve is adapted for replacement of a natural aortic valve, or of a mitral or tricuspid valve, depends largely on the size of the valve and the construction of its suturing cuff or ring. As far as this invention is concerned, all three types of valves have the same essential features and, therefore, an aortic valve has been selected only for purposes of illustration.

Valve **10** comprises a stent **11** and a valvular graft **12**. Typically, the graft would be a preserved porcine xenograft; however, the stent may be used to support grafts from other species and, if desired, may provide support for an allograft (homograft).

Graft **12** has three leaflets **13–15** meeting along commissures **15**. The treatment and preservation of the graft are now well known, as disclosed in Carpentier et al, J. Thorac. Cardiovasc. Surg. 68:771 (1974) and the references cited therein, and need not be discussed in detail here.

Stent **11** consists essentially of a flexible wire frame **16** which is gusseted, padded, and covered with a porous biocompatible fabric so that the completed valve may

be sutured in position within a human heart and will allow the ingrowth of tissue into the fabric covering. Frame **16** is generally annular in configuration and consists essentially of a single piece of spring wire formed to define a triad of axially-projecting and circumferentially-spaced commissure supports **17–19**. As shown in FIG. **2**, each commissure support is generally of inverted U-shaped configuration, having wire legs **20** merging smoothly at their spaced lower ends with arcuate connecting portions **21**. The arcuate connecting portions extend circumferentially and join the adjacent legs of adjoining commissure supports.

The wire from which the frame is formed has its ends **22** joined together along one of the arcuate connecting portions **21** by means of a crimped sleeve or coupling **23**. Both the location and the manner of connection are important if long term durability of the stent is to be achieved. The mid zone of an arcuate connecting portion **21** has been found to be an area of relatively low stress and the use of a coupling sleeve or tube, crimped to each of the end portions, avoids the problems of material degradation, and surprisingly rapid fatigue failure, associated with a welded connection.

The wire is circular in cross section and, except for sleeve **23**, is of substantially uniform diameter throughout its entire extent. Each inverted U-shaped commissure support has a rounded or smoothly-curved upper end. Similarly, the lower ends of legs **20** of the commissure supports curve outwardly to merge smoothly, not abruptly, with the connecting portions **21**. As shown in FIGS. **2** and **4**, the legs **20** of each U-shaped support are straight and generally parallel along substantial portions of their length.

The frame or wireform may be formed of any spring material which is non-corrosive, fatigue resistant, and biocompatible. A particularly effective material is a steel marketed under the name Elgiloy by Elgiloy Company, Elgin, Ill., although other stainless steels or alloys having similar properties might be used.

It will be observed that the arcuate connecting portions **21** in the aggregate define the outline for the orifice ring of the valve. Also, as clearly depicted in FIGS. **2** and **4**, each of the connecting portions or segments **21** has a major part of its length extending along a plane normal to the axis of the valve. Since the connecting portions or segments are interrupted by commissure supports **17–19**, and since the lower ends of each pair of legs **20** are spaced apart, inward flexure of the legs, as depicted in FIG. **4**, reduces the spacing between adjacent connecting segments **21** and thereby decreases the effective perimeter of the orifice ring. Thus, frame **16** is capable of limited contraction and expansion as the spring legs of the commissure supports flex inwardly and outwardly.

In addition, the connecting portions or segments **21** are themselves capable of limited flexure. In particular, the curvature of each arcuate segment **21** may increase or decrease slightly. Such flexure permits slight but significant changes in the positions of the commissure supports relative to each other and to the axis of the valve, as indicated in broken lines in FIG. **3**. In general, the configuration of the orifice ring may be altered in response to forces exerted during each beat of the heart in which the bioprosthetic valve is implanted. The result is a valve stent of limited deformability, one which has the capability of expanding and contracting to a slight but definite extent, during heart operation. Such compliance is believed important not only in achieving improved durability or long-term reliability of the xenograft or allograft, but also in allowing the leaflets to close with a sliding type of closure at their free margins which is more similar to that observed physiologically.

The wireform is covered with a padded, gusseted and porous covering to facilitate attachment, tissue invasion, and encapsulation. FIGS. **5–7** illustrate steps in the fabrication of the final stent. A sleeve **24** of porous biocompatible cloth is fitted about the wireform and is loosely stitched thereto as indicated in FIG. **5**. Thereafter, insert elements which, in the illustration given, are portions **25** of a plastic web **26**, are positioned outside of the sleeve **24** between each of the commissure supports **17–19**. The sleeve is trimmed and secured by stitching **27** to the margins of the insert elements. A covering of porous biocompatible cloth **28** is then fitted about the stent, completely enclosing the wireform and inserts as shown in FIG. **7**. While the cloth may be folded upon itself about the outer periphery of the stent to form a padded suturing rim, it is preferred that such padding be achieved by enclosing an annulus of resilient foam or sponge rubber **29** (FIG. **9**) within the cloth covering **28**. The construction and operation of such padded suturing rims is well known in prosthetic valve construction, being disclosed, for example, in U.S. Pat. Nos. 3,099,016, 3,365,728, and 3,371,352.

The cloth layers **24** and **28** may be formed of porous woven or knitted Teflon, although other materials such as Dacron might be used. The insert elements **25** may be formed from a sheet or sheets of polyglycol terephthalate (Mylar) although other inert biocompatible materials such as polypropylene might be utilized.

The insert elements **25** serve as gussets for increasing the axial dimensions of the stent in the zones between the commissure supports **17–19** and for providing attachment for cloth **24** and for the xenograft or allograft **12**. Each insert element **25** of the connected series illustrated in FIG. **8** is provided with apertures **30** through which stitching **27** is extended during fabrication of the stent. The upper margin **31** of each insert is arcuate or scallop-shaped to define a smooth transition from the outline of the upper portion of each commissure support.

The three insert elements **25** might be separate components individually secured to the cloth-covered wireform but, to facilitate fabrication, it is preferred to form the elements as a continuous web **26**, the successive elements being joined by connecting portions **32** (FIG. **8**). It is to be understood that neither the connecting portions **32** nor the other portions of the insert elements significantly alter the flexing characteristics of the wireform as previously described.

FIG. **9** illustrates details of the completed valve with the graft secured to the stent by sutures **33**. The configuration and location of foam insert **29** are particularly suited for use of the valve as an aortic valve replacement. The valve illustrated in FIG. **10** is adapted for mitral replacement and, accordingly, has somewhat different proportions. The annular foam insert **29'** is positioned and shaped to engage the mitral annulus, all as well known in the art. Except for the obvious differences shown in FIGS. **9** and **10**, differences occasioned by the anatomical characteristics of those portions of the human heart to which the respective valves are to be secured, the valves depicted in these figures are essentially the same, both utilizing wireforms as generally shown in FIGS. **2–4**.

While in the foregoing we have disclosed embodiments of the invention in considerable detail for purposes of illustration, it will be understood by those skilled in the art that many of these details may be varied without departing from the spirit and scope of the invention.

We claim:

1. A supported bioprosthetic heart valve comprising a stent and a valvular graft secured thereto, said stent having an annular frame consisting essentially of a single piece of preformed spring wire, said wire frame being formed to define a triad of axially-projecting circumferentially-spaced commissure supports, each commissure support being of inverted U-shaped configuration having wire legs spaced substantially apart and merging smoothly at their lower ends with arcuate connecting portions extending circumferentially between and joining the legs of adjacent commissure supports, each of said arcuate connecting portions having a major part of the length thereof extending along a plane normal to the axis of said valve.

2. The valve of claim 1 in which each of the commissure supports of said frame is rounded at its upper end and the wire legs thereof are generally parallel along substantial portions of their length.

3. A supported bioprosthetic heart valve comprising a stent and a valvular graft secured thereto, said stent having an annular frame consisting essentially of a single piece of preformed spring wire, said wire frame being formed to define a triad of axially-projecting circumferentially-spaced commissure supports, each commissure support being of inverted U-shaped configuration having wire legs meging smoothly at their lower ends with arcuate connecting portions extending circumferentially between and joining the legs of adjacent commissure supports, said stent including insert elements extending between said commissure supports and having upper margins disposed above said connecting portions of said frame.

4. The valve of claim 3 in which said insert elements are provided with a plurality of apertures.

5. The valve of claim 3 in which said insert elements are integral portions of a web of flexible perforated plastic material circumscribing said frame.

6. The valve of claim 5 in which said web is provided with scalloped upper edge portions between said commissure supports.

7. The valve of claim 3 in which said graft is connected by lines of stitching to said frame and said insert elements.

8. The valve of claim 3 in which said upper margins of said insert elements are arcuate.

9. The valve of claim 3 in which said insert elements extend from the upper margins thereof to said connecting portions of said frame.

10. The valve of claim 3 in which said stent includes a sleeve of cloth between said frame and said insert elements, said cloth sleeve being stitched to said frame and said insert elements being stitched to said cloth sleeve.

11. The valve of claim 3 in which said insert elements are formed integrally from a sheet of flexible perforated polyglycol terephthalate.

12. The valve of claim 5 in which said web is formed from a material of sufficient flexibility that it does not significantly alter the ability of the spaced wire legs of each commissure support to flex towards and away from each other.

13. The valve of claim 5 in which said web is formed from polyglycol terephthalate.

14. A supported bioprosthetic heart valve comprising a stent and a valvular graft secured thereto, said stent having an annular frame consisting essentially of a single piece of preformed spring wire, said wire frame being formed to define a triad of axially-projecting circumferentially-spaced commissure supports, each commissure support being of inverted U-shaped configuration having wire legs merging smoothly at their lower ends with arcuate connecting portions extending circumferentially between and joining the legs of adjacent commissure supports, said wire of said frame having end portions joined together at a point intermediate the length of one of said arcuate connecting portions, said end portion being joined together by a tubular sleeve extending over and joined to both of said end portions.

15. The valve of claim 14 in which said sleeve is crimped tightly about both of said end portions.

16. A flexible stent for supporting a valvular graft, said stent having an annular frame formed of spring wire, said frame including a triad of axially-projecting circumferentially-spaced commissure supports, each commissure support being of inverted U-shaped configuration having wire legs normally spaced substantially apart, the lower end portions of said legs merging smoothly with arcuate connecting segments of said frame extending circumferentially between and joining the adjacent legs of adjoining commissure supports, said U-shaped commissure supports and said connecting segments being formed integrally from the same piece of spring wire, each of said arcuate connecting segments having a major portion of the length thereof extending along a plane normal to the axis of said stent.

17. The stent of claim 16 in which each of the commissure supports of said frame is rounded at its upper end and the wire legs thereof are generally parallel along substantial portions of their length.

18. A flexible stent for supporting a valvular graft, said stent having an annular frame formed of spring wire, said frame including a triad of axially-projecting circumferentially-spaced commissure supports, each commissure support being of inverted U-shaped configuration having wire legs normally spaced apart at their lower end portions, said lower end portions of said legs merging smoothly with arcuate connecting segments of said frame extending circumferentially between and joining the adjacent legs of adjoining commissure supports, said U-shaped commissure supports and said connecting segments being formed integrally from the same piece of spring wire, and insert elements extending between said commissure supports, said insert elements being flexible and having upper margins disposed above said connecting segments of said frame.

19. The stent of claim 18 in which said insert elements are formed of flexible perforated sheet material.

20. The stent of claim 18 in which said insert elements are integral portions of a web of flexible perforated plastic material circumscribing said frame.

21. The stent of claim 18 in which said web is provided with scalloped upper edge portions between said commissure supports.

22. The stent of claim 18 in which the upper margins of said insert elements are arcuate.

23. The stent of claim 18 in which said insert elements extend from the upper margins thereof to the connecting portions of said frame.

24. The stent of claim **18** in which there is a sleeve of cloth between said frame and said insert elements, said cloth sleeve being stitched to said frame and said insert elements being stitched to said cloth sleeve.

25. The stent of claim **18** in which said insert elements are formed integrally from a sheet of flexible perforated polyglycol terephthalate.

26. The stent of claim **20** in which said web is formed from a material of sufficient flexibility that it does not significantly alter the ability of the spaced wire legs of each commissure support to flex towards and away from each other.

27. The stent of claim **20** in which said web is formed from polyglycol terephthalate.

28. A flexible stent for supporting a valvular graft, said stent having an annular frame formed of spring wire, said frame including a triad of axially-projecting circumferentially-spaced commissure supports, each commissure support being of inverted U-shaped configuration having wire legs normally spaced apart at their lower end portions, said lower end portions of said legs merging smoothly with arcuate connecting segments of said frame extending circumferentially between and joining the adjacent legs of adjoining commissure supports, said U-shaped commissure supports and said connecting segments being formed integrally from the same piece of spring wire, said wire of said frame having end portions joined together at a point intermediate the length of one of said arcuate connecting segments, said end portions being joined together by a tubular sleeve extending over and joined to both of said end portions.

29. The stent of claim **28**, in which said sleeve is crimped tightly about both of said end portions.

* * * * *

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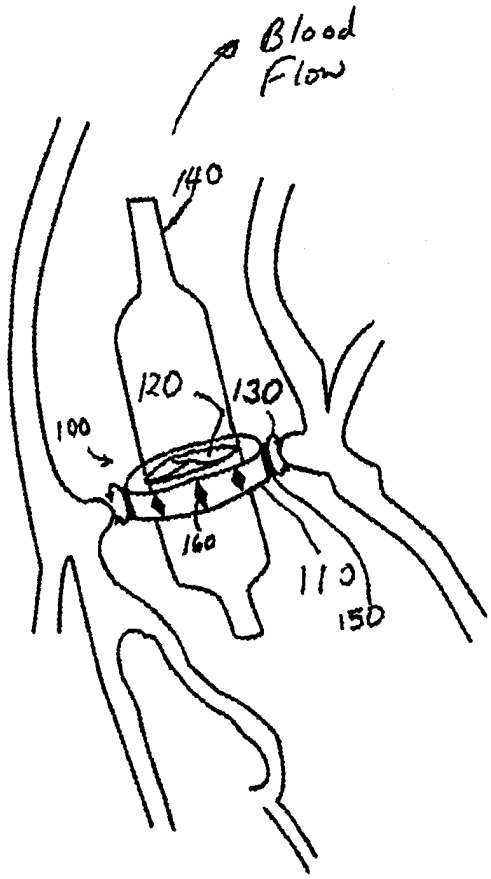
**Published**
*With international search report.*

(54) Title: ARTIFICIAL HEART VALVE ATTACHMENT APPARATUS

(57) Abstract

Heart valve attachment apparatus and methods that significantly reduce attachment times are provided. The apparatus and methods utilize a connector band to form an interface between a unidirectional valve and a tissue annulus. The connector band is secured to the tissue annulus by retention fingers.



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# ARTIFICIAL HEART VALVE ATTACHMENT APPARATUS

## Background of the Invention

This invention relates to apparatus and methods for attaching replacement heart valves.

The replacement of a defective heart valve requires an open heart procedure in which the old, defective, valve is removed and replaced with an artificial valve. Generally, this procedure requires the heart to be placed on a cardiopulmonary bypass (CPB) to allow the heart to be stopped and the new valve to be carefully sewn in place.

This method of valve attachment, commonly known as suturing, is an effective method of attaching the new heart valve to the heart. However, it requires significant time and skill to complete. Therefore, extended CPB time is required. The extended CPB time associated with suturing, in conjunction with the complex nature of the procedure itself, may increase the likelihood of complications, including stroke, heart block and long patient recovery times.

Therefore, it would be desirable to provide heart valve attachment apparatus and methods that significantly reduce attachment times.

Brief Description of the Drawings

The above and other objects and advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout:

FIG. 1 is an elevational view of a preferred embodiment of a heart valve according to the invention.

FIG. 2 is an elevational view of the heart valve of FIG. 1 in a deployed position.

FIG. 3 is an elevational view of another embodiment of a heart valve according to the invention.

FIG. 4 is an elevational view of the heart valve of FIG. 3 in a deployed position.

FIG. 5 is an elevational view of a connector band according to the invention.

FIG. 6 is an elevational view of the heart valve of FIGS. 3 and 4 in a deployed position.

FIG. 7 is an elevational view of another embodiment of a heart valve according to the invention.

FIG. 8 is an elevational view of the heart valve of FIG. 7 in a deployed position.

FIG. 9 is an elevational view of another embodiment of a heart valve according to the invention.

FIG. 10 is an elevational view of the heart valve of FIG. 9 in a deployed position.

FIG. 11 is an elevational view of another connector band according to the invention.

FIG. 12 is an elevational view of another connector band according to the invention.

FIG. 13 is a top view of the connector band in FIG. 12.

FIG. 14 is an elevational view of another embodiment of a heart valve according to the invention.

Summary of the Invention

It is an object of the invention to provide heart valve attachment apparatus and methods that significantly reduce attachment times.

A valve apparatus for deploying in, and securing to, a tissue annulus, includes: a uni-directional valve portion for passing fluid in one direction and obstructing fluid in an opposite direction, a connector band located circumferentially around, and attached to, the valve portion and a plurality of fingers located circumferentially around, and attached to, the band. The fingers are adapted to secure the valve to the tissue annulus.

In an alternative embodiment, a connector band can be deployed separate from the valve portion. After the band is deployed, a valve can be attached to the band by screws, pop rivets or other suitable attachment device or method.

In another alternative embodiment, fingers can be implemented on the valve portion itself, thereby obviating the need for a connector band.

Detailed Description of the Invention

This invention relates to heart valves which are modified so that the valve can be attached to the heart without the need for suturing. Significant technology has been developed related to replacing sutures in bypass grafting -- i.e., attaching a tissue conduit to another with a mechanical connector rather than sewing the conduits to each other to form the anastamosis. Examples of such technology are found in commonly assigned United States Patent No. 5,976,178 and co-pending commonly assigned patent applications 08/839,199, 08/946,742, 09/016,721, 09/187,335, 09/187,361 and 09/186,774, all of which are incorporated by reference herein in their entireties.

These references, at least in part, disclose inventions related to methods and apparatus for attaching synthetic or biological tissue grafts without the need for sutures. Portions of the references deal specifically with methods and apparatus for attaching synthetic or biological tissue grafts to a connector, which is then secured to a blood vessel -- e.g., the aorta -- by using hooked or barbed fingers. In certain embodiments, the fingers are formed from an elastic material -- e.g., nitinol wire. In these embodiments, the fingers may be stretched or otherwise manipulated to pierce the tissue graft and retain the tissue graft with the hooked or barbed ends of the fingers. The elasticity of the fingers then causes the fingers to snap back such that the tissue graft is secured to the connector. The connector is then connected to a blood vessel to complete an anastamosis.

Alternatively, the fingers may be formed from relatively non-elastic stainless steel. In these embodiments, the fingers are deformed to properly engage the tissue graft and then mechanically crimped to seal the connector to the tissue graft.

The present invention provides methods and apparatus for using retention fingers, such as the fingers described above, to attach heart valves to hearts.

FIG. 1 shows an artificial heart valve 100 having a balloon expandable connector band 110 with a one-way valve portion 120 integrated within connector band 110. Valve 100 is positioned for deployment in the left ventricle outflow valve of a heart (this location illustrates only one possible exemplary embodiment of the invention, and is not intended to limit the invention to use only in the left ventricle outflow valve.) Connector band 110 preferably includes a series of retention fingers 130 with barbed ends --

i.e., the ends of the fingers have small projections that secure the fingers to their surface of engagement -- or, alternatively, hooked ends -- i.e., the ends of the fingers are bent --, or a combination of the two, spaced substantially circumferentially around band 110. Each finger preferably is attached adjacent to one end of the length of band 110 and has a corresponding finger that opposes it and is attached to the other end of the length of band 110. Thus, when the length of band 110 is reduced, the ends of each set of corresponding fingers 130 converge and engage the surrounding tissue.

The invention operates as follows: first, valve 100 is positioned for securing to the tissue annulus that surrounded the old valve. Then, balloon 140 is preferably positioned through the orifice of valve 100. Balloon 140 is then expanded. The positioning and expansion of balloon 140 can be accomplished by methods that are known to those in the art and explained in more detail in the references which are incorporated by reference above -- e.g., U.S. Patent No. 5,976,178.

Expansion of balloon 140 increases the circumference of band 110 to conform to, and substantially fill, the tissue annulus. As connector band 110 expands circumferentially, it shortens in length -- i.e., the dimension of band 110 that is substantially parallel to the blood flow. The shortening in length causes the barbed heads on each corresponding pair of retention fingers 130 to converge and engage the surrounding tissue annulus, thereby securing valve 100 to the tissue annulus. When the heads of fingers 130 engage the tissue annulus, they preferably remain there permanently. Valve 120, which may preferably be formed from porcine tissue, or other suitable natural or synthetic tissue, can be pushed out

of the way during expansion and then naturally returns following expansion.

FIG. 2 shows valve 100 after it has been deployed. Band 110 may be formed from expandable metal -- i.e., metal that has been perforated and cut in such a way that it can be expanded in one or more directions by deforming the metal in the vicinity of the cuts and perforations. This type of structure is frequently found in stents used to prevent collapses of tubular body structures; and band 110 could be a converted stent, possibly with some modifications. Alternatively, band 110 may be constructed from an expandable open mesh framework (see mesh 360 in FIG. 3 and 4) -- e.g., a braid of nitinol, stainless steel, tungsten wires or polymer strands -- which may be covered with a rubber-like web -- e.g., of silicone --.

It should be noted that, following expansion of band 110, the diameter of band 110 has increased, while the length of band 110 has decreased. As the length of band 110 is decreased, the barbed heads of axially opposite fingers 130 converge, engage the tissue annulus, and secure valve 100 to the tissue annulus. The broadening and shortening of the black diamonds 160 shown in FIGS. 1 and 2 indicate the circumferential expansion and the lengthwise contraction of the metal. Following deployment, fingers 130 grab the tissue annulus and exert a force joining band 110 to the tissue annulus. The force exerted by the fingers on the tissue annulus forms a substantially leak-proof compression seal between band 110 and the tissue annulus. Thus, the tissue preferably forms a lip which abuts the valve portion 120 of valve 110.

The outer walls of band 110 may include a gasket-like material. In an alternative embodiment, a separate gasket 150 (shown in FIG. 1) may be attached

around band 110. To further enhance the seal between band 110 and valve portion 120 the gasket-like material, or gasket 150, preferably conforms to the existing tissue annulus and seals the new valve to the tissue annulus to protect against leakage around, or through, band 110. Gasket 150 may preferably be formed from a soft, deformable biocompatible material -- e.g., polyurethane, silicone, dacron or other suitable material -- that readily conforms to existing tissue, yet provides a fluid-tight seal around valve 110.

FIG. 3 shows another embodiment of an artificial heart valve 300 according to the principles of the invention. Valve 300 includes fingers 330 that are substantially perpendicular to the length of band 310.

FIG. 4 shows valve 300 after it has been deployed. Fingers 330 are shown secured to the tissue annulus by the barbed heads of fingers 330 and a compression seal is preferably formed between band 310 and the tissue annulus.

FIG. 5 shows one embodiment of an band 510 suitable for deployment to attach to the tissue annulus as shown in FIGS. 3 and 4. At this stage, fingers 530 are parallel to the length of band 510. However, fingers 530 may be redirected radially outward, perpendicular to the length of band 510 by some suitable means. After redirection, fingers 530 may preferably appear similar to fingers 330 shown in FIGS. 3 and 4. Thereafter, band 510 can be further expanded such that fingers 530 engage, and are secured to, the tissue annulus.

One advantage of the embodiment shown in FIG. 5 is that the band can be positioned using suture threads or other suitable devices which can be attached to rings 550. Rings 550 may be linked to the infrastructure of fingers 530.

Band 510 should preferably be expandable. Fingers 530 can be oriented outward before expansion -- e.g., during production of band 510. Then, band 530 is positioned within the tissue annulus. Thereafter, fingers 530 are secured to the tissue annulus upon expansion of band 510.

In an alternative embodiment of the invention, a connector band can also be deployed separate from a valve. In this embodiment, a band, such as band 510, may first be expanded and secured to the tissue annulus at the required implant site. Then, the valve can be incorporated into the band. To facilitate the connection of the band to the valve, the band may contain a number of holes or recesses adapted to receive screws from an implanted valve, or seats for rivets or clips which are used to secure the valve to the previously deployed band. Alternatively, rivets which require no-preformed seats, but are popped through a flat portion of the band may also be used to secure the valve to the band. Examples of recesses 350, 450 are shown in FIGS. 3 and 4. The recesses may preferably be located on the interior side of the band.

FIG. 6 shows an exemplary valve 600 deployed in a left ventricle outflow valve of a complete heart. Valve 600 has fingers 630 similar to the valve shown in FIGS. 3 and 4. Balloon 640 is shown as exiting from a guide catheter 660, as is known in the art. One way to guide balloon 640 is by markers 650 which are implemented on balloon 640, as is known in the art. Markers 650 allow the balloon to be positioned using x-rays or fluoroscopically. Once a desired position for balloon 640 is achieved, balloon 640 is expanded, and valve 600 is secured to the tissue annulus. In one embodiment, the old valve may not require removal, but

may just be compressed out of the way by expanding the new valve.

FIG. 7 shows an embodiment of a non-expanding valve 700 according to the principles of the invention. Valve 700 preferably includes fingers 730 that are oriented in a direction that is substantially parallel to the length of band 710 and are oriented in the direction of the blood flow. The exact orientation of the fingers can be configured before insertion. In this embodiment, once valve 700 is positioned within the tissue annulus, the surrounding tissue can be pulled up and over each retention finger. The tissue can be manipulated using a tweezers or other suitable tool.

The fingers described throughout this application are preferably formed from an elastic material -- e.g., nitinol. The elasticity of the material allows the fingers to be expanded without undesirable deformation. The fingers may be heat-set to be flat against the length of band 710, or to be slightly projecting out from band 710. During deployment through expansion of fingers 730, each flat individual finger 730 may be temporarily erected simultaneous to the tissue from the tissue annulus being pulled up and over the erected fingers. Thereafter, fingers 730 are released. When released, fingers 730 snap back to their original position, compressing and securing the tissue annulus to valve 700.

In an alternative embodiment of valve 700, retention fingers 730 may preferably be formed from relatively non-elastic, preferably annealed, stainless steel. Each finger is erected before deployment. Then, once the tissue annulus is pulled up and over each finger 730 such that the tissue annulus is pierced by each finger 730, the finger is crimped down against

the valve body to secure the tissue annulus to valve 700.

FIG. 8 shows valve 700 after it has been deployed within the tissue annulus. In FIG. 8, fingers 730 secure valve 700 to the tissue annulus.

FIGS. 9 and 10 show a valve 900 with fingers 930 oriented in a direction that is parallel to the length of band 710 but, unlike valve 700, is substantially opposite to the blood flow. One advantage of this embodiment is that fingers 930 are oriented in the direction of insertion which, in the case of the left ventricle outflow valve, is opposite the blood flow. Thus, the orientation of fingers 930 allows the surgeon to more readily advance the valve into the tissue annulus and to engage and secure the valve to the annulus. Another advantage of valve 900 is that the deployment of valve 900 does not require a tool to pull the flesh of the tissue annulus over the finger heads. Rather, valve 900 can be directly engaged to the tissue annulus by applying pressure to valve 900 opposite the direction of the blood flow.

FIG. 11 shows an embodiment of a preferably non-expandable connector band 1110 for use in the valves shown in FIGURES 7-10. When band 1110 is inserted into the tissue annulus. Fingers 1130 and arches 1140 are caused to project outwards from band 1110. Fingers 1130 may be caused to project outwards when they are formed in the production process. When the band is expandable, it may be positioned within the tissue annulus, and, thereafter, the fingers are secured to the tissue annulus upon expansion of the band.

FIG. 12 shows yet another embodiment of a valve 1210 according to the present invention. In valve 1210, fingers 1230 are oriented in a

circumferential direction around the circumference of valve 1210.

Valve 1210 operates as follows: first, valve 1210 is positioned in the tissue annulus. This can be done by rotating valve 1210 into position (in the exemplary valve shown in FIG. 12, this requires a clockwise rotation around central longitudinal axis 1270) so fingers 1230 do not engage the tissue annulus. Then, valve 1210 is rotated in a counterclockwise direction around central longitudinal axis 1270. This rotation causes fingers 1230 to pierce the tissue annulus. Thereafter, fingers 1230 return to their original position (or, in the case of stainless steel fingers, the fingers are mechanically crimped to return to their original position) and the valve 1210 is secured to the tissue annulus. Rotation of valve 1210 can be accomplished using a tool which may be designed to rotate valve 1210 or with another suitable technique.

FIG. 13 shows an end view of valve 1210. In this view, fingers 1230 are shown in a substantially fully expanded state.

FIG. 14 shows another alternative embodiment of the invention wherein the fingers 1430 are preferably placed on the heart valve 1410 directly, without the interface of the connector band. In this embodiment, the fingers are distributed circumferentially around the heart valve, and the heart valve is inserted directly into the tissue annulus. Fingers 1430 may preferably be attached to heart valve 1410 in any of the possible configurations described herein.

In addition, though fingers 1430 are shown as hooked and barbed, they may be either hooked or barbed. As mentioned above, this feature of hooked and/or

barbed fingers may preferably be used in each embodiment of the invention.

Each of the artificial heart valve attachment apparatus described herein preferably allows a replacement valve according to the invention to be implanted surgically or percutaneously.

The diameter of an exemplary expandable valve and/or connector band, like the valves and bands described herein in accordance with the present invention, is preferably between 3 and 5 millimeters before expansion. After expansion, the diameter of the valve and/or band is preferably between 15 and 20 millimeters. The length of the valve and/or band is preferably between .75 and 2 inches before expansion, and, after expansion, is preferably between .5 and 1.5 inches.

Materials that are suitable for use in a connector band according to the invention and as described herein, preferably include stainless steel or tantalum. These materials are relatively easily yieldable under balloon pressure when constructed as described above with either a bio-compatible mesh or with perforations, and are substantially radiopaque. The preferably substantially uni-directional valve element itself is flexible, preferably porcine, tissue (the valve element may allow for a minimal backflow of fluid upon the change in direction of fluid flow). The valve in the embodiment described above in which the connector band is deployed separate from the valve, is preferably a rigid valve formed from a suitable bio-compatible material -- e.g., stainless steel -- which may provide improved connectability with the connector band.

In addition, for the embodiments of the invention described herein, the number of fingers required may preferably be between 10 and 40 barbed or

hooked fingers around the circumference of the valve, and most preferably 24 fingers. As mentioned above, the fingers may be formed from a variety of substances, including, but not limited to, nitinol or stainless steel.

Thus, an artificial heart valve attachment apparatus and methods that significantly reduce attachment times is provided. Persons skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which are presented for purposes of illustration rather than of limitation, and the present invention is limited only by the claims which follow.

WHAT IS CLAIMED IS:

1. A valve apparatus for deploying in, and securing to, a tissue annulus, said valve comprising:

a uni-directional valve portion for passing fluid in one direction and obstructing fluid in an opposite direction;

a connector band located circumferentially around, and attached to, said valve portion; and

a plurality of fingers located circumferentially around, and attached to, said band, said fingers being adapted to secure said valve to said tissue annulus.

2. The valve of claim 1, wherein said fingers are adapted to secure said valve to said tissue annulus upon expansion of said band.

3. The valve of claim 1, wherein said fingers can be expanded from a first position adjacent to said band, engaged to said tissue annulus, and returned to said first position following said engagement, thereby securing said band to said tissue annulus.

4. The valve of claim 1, wherein said fingers are formed from an elastic material.

5. The valve of claim 1, wherein said band comprises a gasket located around an outer circumference of said band, said gasket for sealing between said band and said tissue annulus.

6. The valve of claim 1, wherein said fingers are hooked.

7. The valve of claim 1, wherein said fingers are barbed.

8. The valve of claim 1, wherein said fingers are barbed and hooked.

9. The valve of claim 1, wherein said fingers are substantially parallel to a central longitudinal axis of said band.

10. The valve of claim 1, wherein said fingers are substantially perpendicular to a central longitudinal axis of said band.

11. The valve of claim 1, wherein said band is expandable.

12. A method for attaching a uni-directional valve to a tissue annulus, said valve having a connector band attached circumferentially around said valve, said band having fingers attached circumferentially around said band, said method comprising:

positioning said uni-directional valve within said annulus; and

engaging said fingers to said annulus such that said fingers secure said valve to said annulus and such that said valve controls the flow of fluid through said annulus.

13. The method of claim 12 the engaging further comprising engaging such that said valve permits substantially only uni-directional flow through said annulus.

14. The method of claim 12 wherein said positioning comprises expanding said valve such that said valve substantially fills said annulus and wherein said expanding occurs before said engaging.

15. The method of claim 12 wherein said positioning comprises expanding said valve such that said valve substantially fills said annulus and wherein said expanding occurs before said engaging.

16. The method of claim 12 wherein said engaging is caused by expanding said valve such that said valve substantially fills said annulus.

17. The method of claim 12 wherein said engaging further comprises expanding said fingers for engaging said fingers to said annulus.

18. The method of claim 12 wherein said engaging further comprises expanding said fingers and rotating said valve to engage said fingers to said annulus.

19. The method of claim 12 wherein said engaging said fingers to said annulus comprises repeatedly pulling a single portion of said annulus onto at least a single one of said fingers.

20. A connector band for providing an interface between a uni-directional valve and a tissue annulus, said band comprising:

a wall for location circumferentially around, and attachment to, said valve, said wall having a plurality of recesses for receiving said valve; and

a plurality of fingers located circumferentially around, and attached to, said wall,

said fingers being adapted to secure said band to said tissue annulus.

21. The valve of claim 20, wherein said band is expandable.

22. The band of claim 20, wherein said fingers are adapted to secure said band to said tissue annulus upon expansion of said band.

23. The valve of claim 20, wherein said fingers can be expanded from a first position adjacent to said band, engaged to said tissue annulus, and returned to said first position following said engagement, thereby securing said band to said tissue annulus.

24. The valve of claim 20, wherein said fingers are formed from an elastic material.

25. The valve of claim 20, wherein said band comprises a gasket located around an outer circumference of said band, said gasket for sealing between said band and said tissue annulus.

26. The valve of claim 20, wherein said fingers are hooked.

27. The valve of claim 20, wherein said fingers are barbed.

28. The valve of claim 20, wherein said fingers are hooked and barbed.

29. The valve of claim 20, wherein said fingers are substantially parallel to a central longitudinal axis of said band.

30. The valve of claim 20, wherein said fingers are substantially perpendicular to a central longitudinal axis of said band.

31. The valve of claim 20, wherein said recesses are adapted to receive rivets, said rivets being to attach said valve to said band.

32. The valve of claim 20, wherein said recesses are adapted to receive screws, said screws being to attach said valve to said band.

33. The valve of claim 20, wherein said recesses are for receiving clips, said clips being for attaching said valve to said band.

34. A method for attaching a uni-directional valve to a tissue annulus using a connector band attached circumferentially around said valve, said band having fingers attached circumferentially around said band, said method comprising:

positioning said band within said annulus;

engaging said fingers to said annulus such that said fingers secure said band to said annulus; and

attaching said valve to said band such that said valve controls the flow of fluid through said annulus.

35. The method of claim 34 the engaging further comprising engaging such that said valve

permits substantially only uni-directional flow through said annulus.

36. The method of claim 34 wherein positioning comprises expanding said band such that said band substantially fills said annulus before said engaging.

37. The method of claim 34 wherein positioning comprises expanding said band such that said band substantially fills said annulus simultaneous to said engaging.

38. The method of claim 34 wherein said engaging is caused by expanding said band.

39. The method of claim 34 wherein said engaging further comprises expanding said fingers for engaging said fingers to said annulus.

40. The method of claim 34 wherein said engaging further comprises expanding said fingers and rotating said valve to engage said fingers to said annulus.

41. The method of claim 34 wherein said engaging said fingers to said annulus comprises pulling a portion of said annulus onto one of said fingers.

42. The method of claim 34 said attaching further comprising riveting said valve to said band.

43. The method of claim 34 said attaching further comprising clipping said valve to said band.

44. The method of claim 34 said attaching further comprising screwing said valve to said band.

45. A valve apparatus for deploying in, and securing to, a tissue annulus, said valve comprising:

a uni-directional valve portion for passing fluid in one direction and obstructing fluid in an opposite direction; and

a plurality of fingers located circumferentially around, and attached to, said valve, said fingers being adapted to secure said valve to said tissue annulus.

46. The valve of claim 45, wherein said fingers are adapted to secure said valve to said tissue annulus upon deployment of said valve.

47. The valve of claim 45, wherein said fingers can be expanded from a first position adjacent to said valve, engaged to said tissue annulus, and returned to said first position following said engagement, thereby securing said valve to said tissue annulus.

48. The valve of claim 45, wherein said fingers are formed from an elastic material.

49. The valve of claim 45, wherein said valve comprises a gasket located around an outer circumference of said valve, said gasket for sealing between said valve and said tissue annulus.

50. The valve of claim 45, wherein said fingers are hooked.

51. The valve of claim 45, wherein said fingers are barbed.

52. The valve of claim 45, wherein said fingers are barbed and hooked.

53. The valve of claim 45, wherein said fingers are substantially parallel to a central longitudinal axis of said valve.

54. The valve of claim 45, wherein said fingers are substantially perpendicular to a central longitudinal axis of said valve.

55. A method for attaching a uni-directional valve to a tissue annulus, said valve having fingers attached circumferentially around said valve, said method comprising:

positioning said uni-directional valve within said annulus such that said valve substantially fills said annulus; and

engaging said fingers to said annulus such that said fingers secure said valve to said annulus and such that said valve controls the flow of fluid through said annulus.

56. The method of claim 55 the engaging further comprising engaging such that said valve permits substantially only uni-directional flow through said annulus.

57. The method of claim 55 wherein said engaging further comprises expanding said fingers for engaging said fingers to said annulus.

58. The method of claim 55 wherein said engaging further comprises expanding said fingers and rotating said valve to engage said fingers to said annulus.

59. The method of claim 52 wherein said engaging said fingers to said annulus comprises repeatedly pulling a single portion of said annulus onto at least a single one of said fingers.

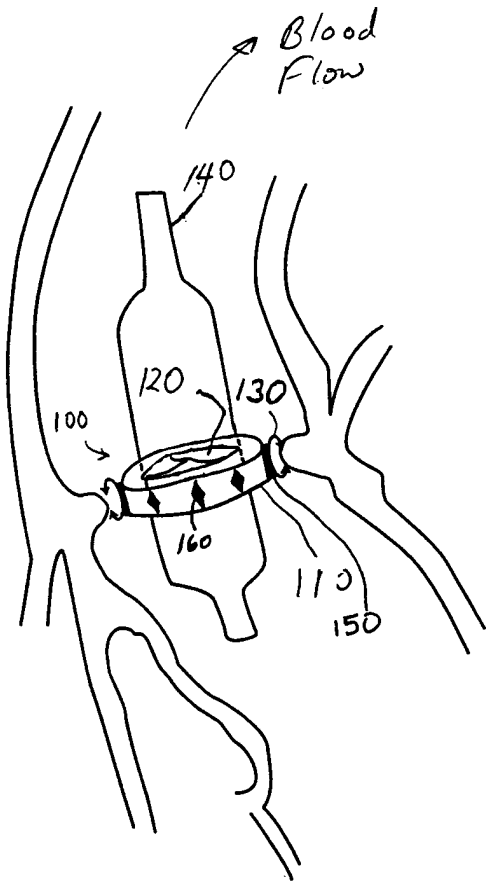


FIG. 1

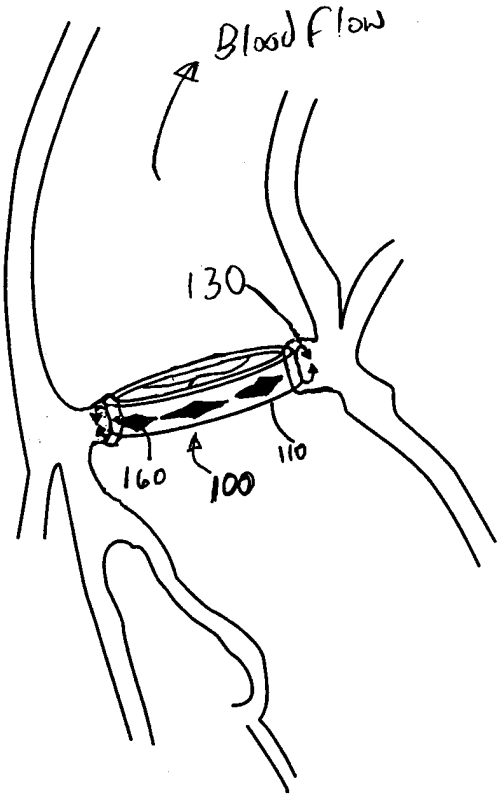


FIG. 2

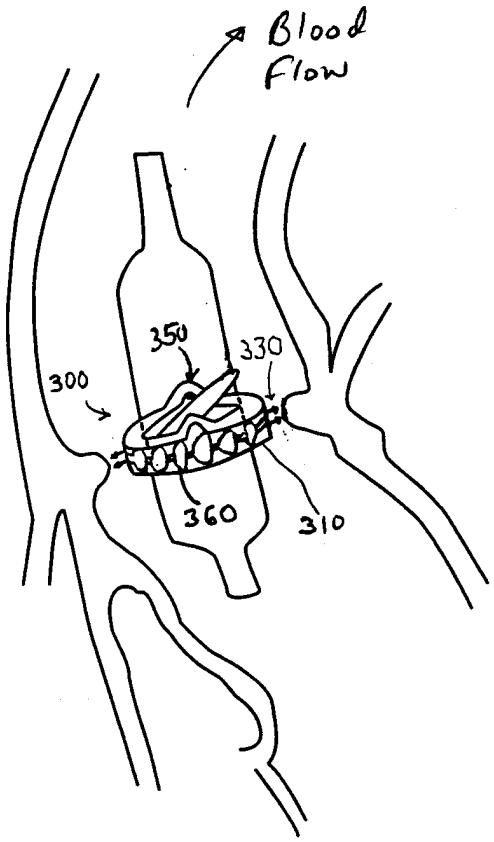


FIG. 3

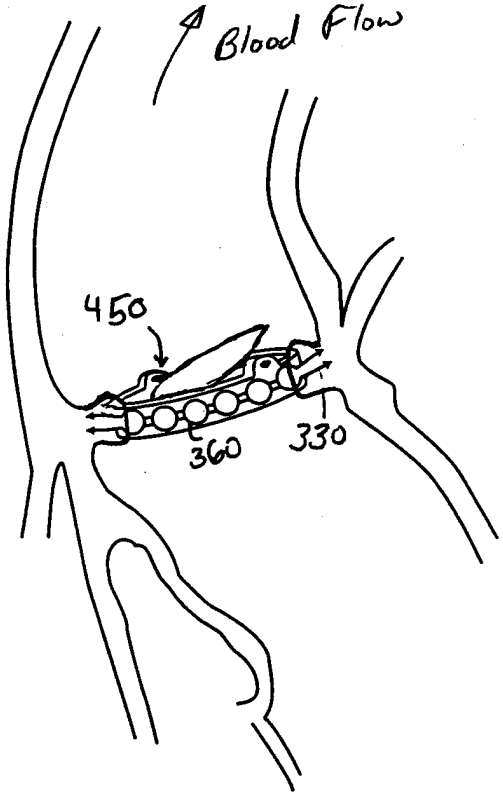


FIG. 4

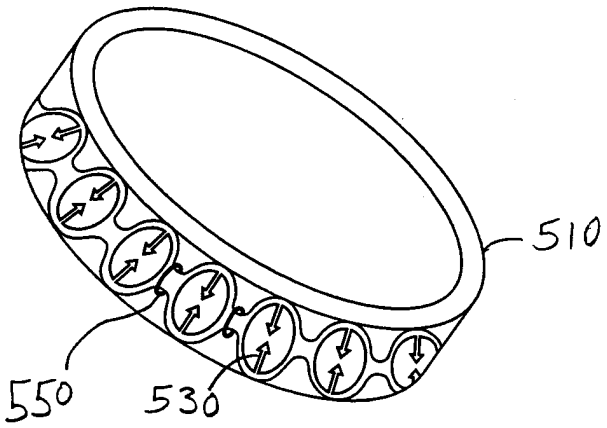


FIG. 5

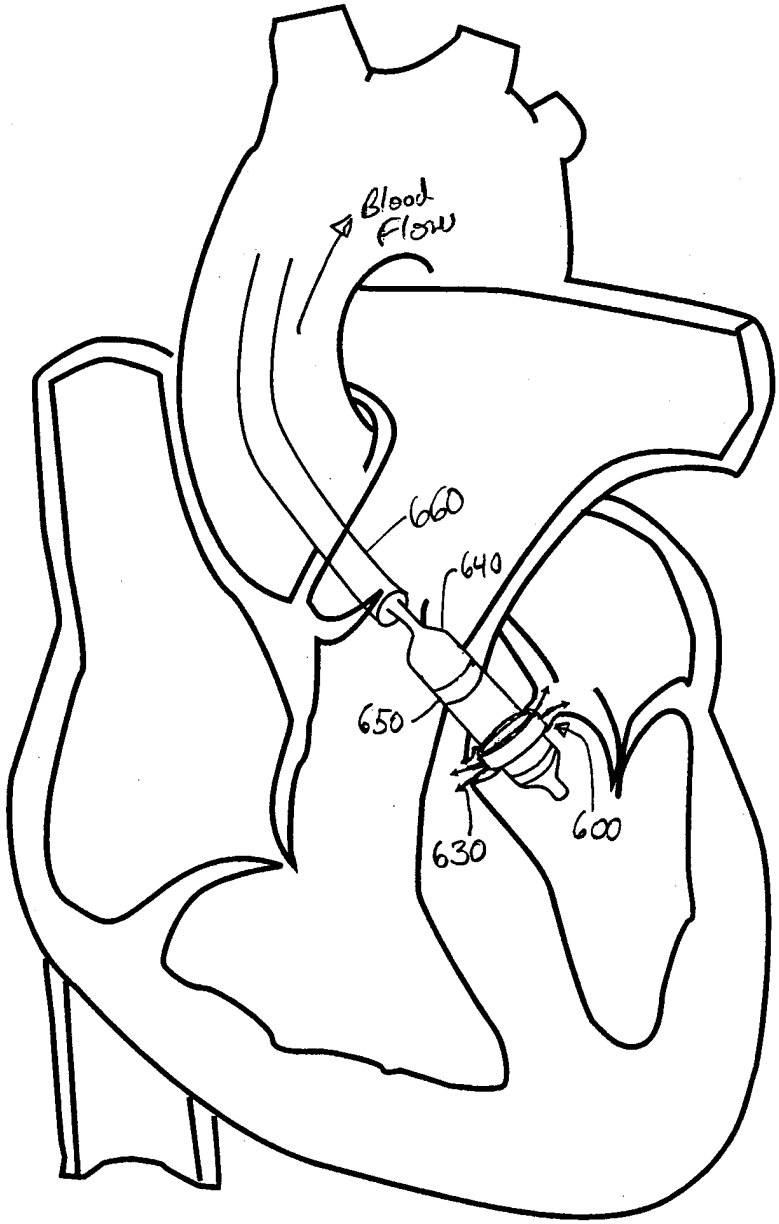


FIG. 6

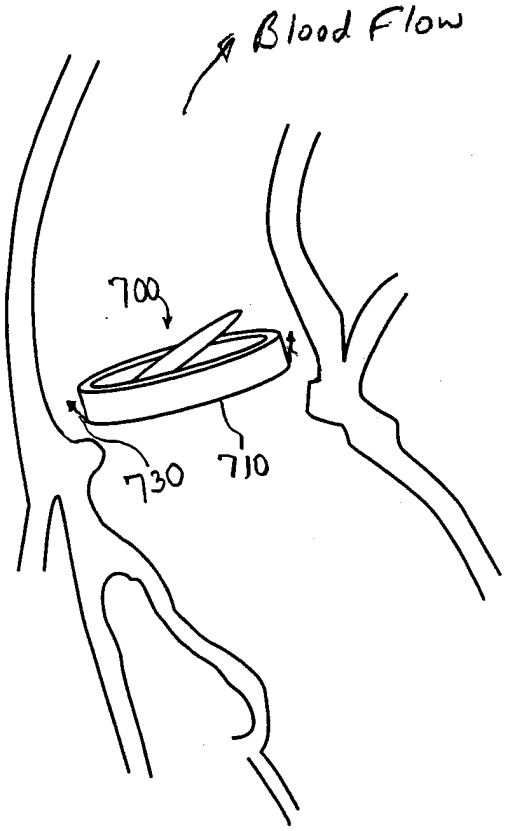


FIG. 7

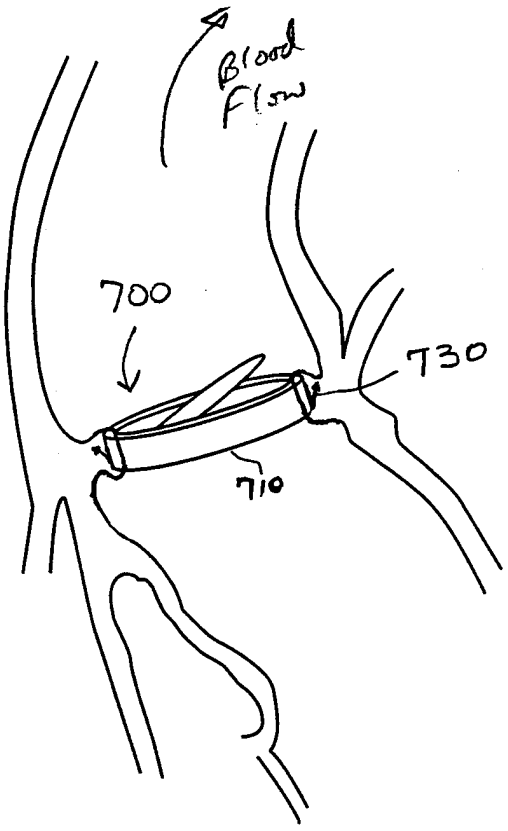


FIG. 8

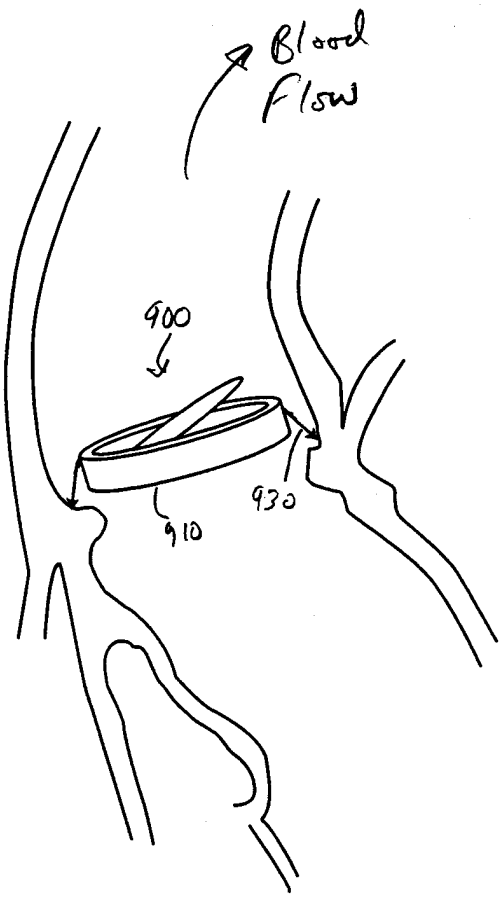


FIG. 9

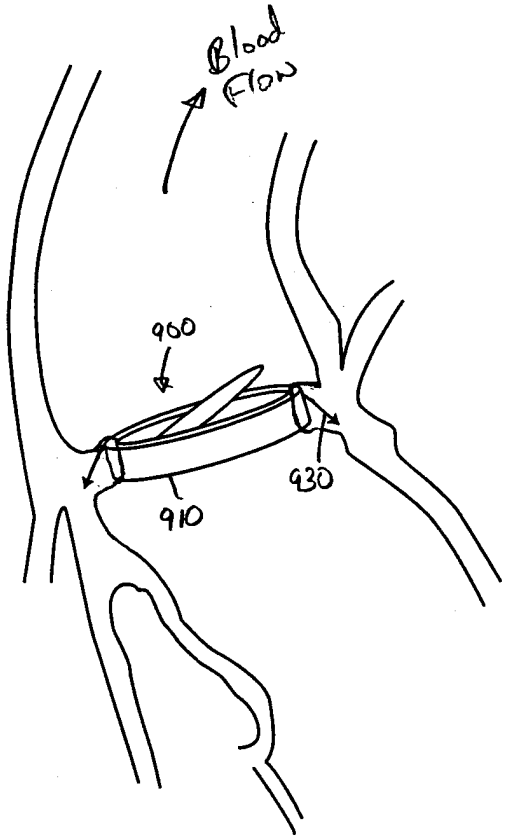


FIG. 10

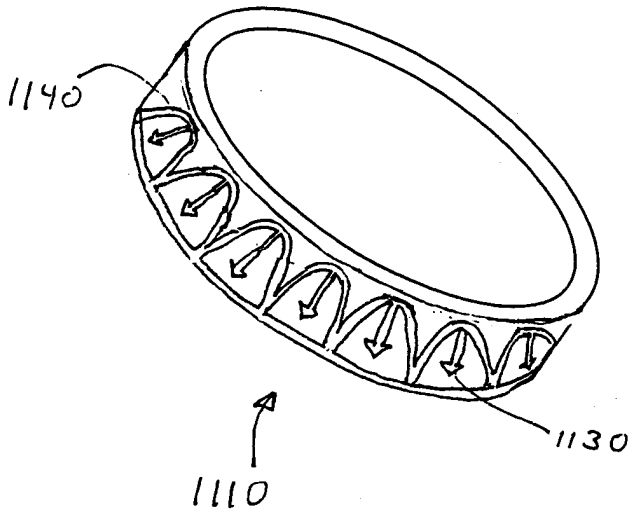


FIG. 11

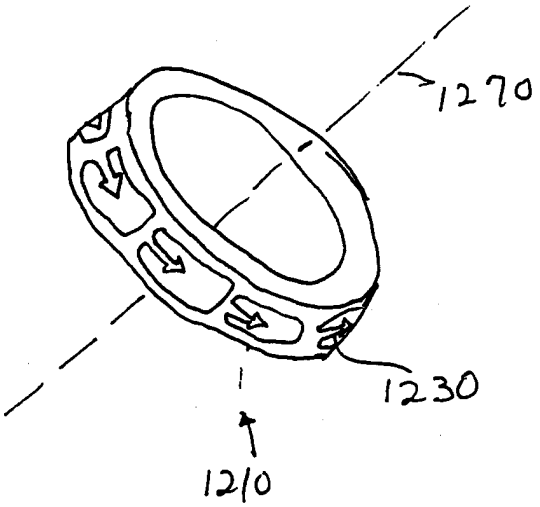


FIG. 12

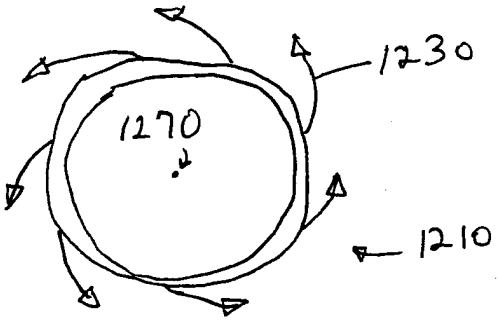


FIG. 13

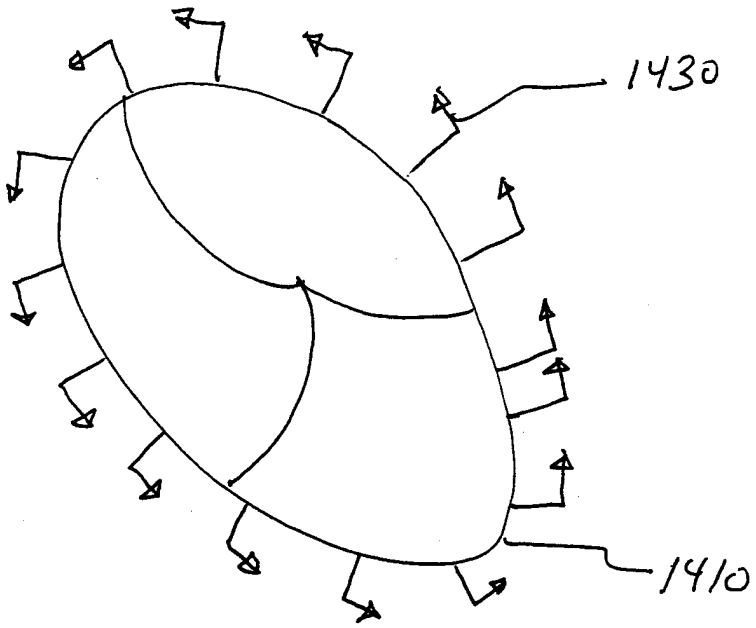


FIG. 14

# INTERNATIONAL SEARCH REPORT

Inter ɔnal Application No
PCT/US 00/10081

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 7 A61F2/24

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)
IPC 7 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 practical, search terms used)
EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 3 686 740 A (D.P. SHILEY)<br>29 August 1972 (1972-08-29) | 1-3,6,<br>10,11,<br>20-23,<br>25,26,<br>29,<br>45-47,<br>49,50,54 |
| Y | column 18, line 1 -column 21, line 17;<br>figures 23-30 | 4,7,8,<br>24,27,<br>28,<br>31-33,<br>48,51,52 |
| | --- | |
| Y | WO 99 04724 A (E.P. STRECKER)<br>4 February 1999 (1999-02-04)<br>abstract; claim 10; figures | 4,24,<br>31-33,48 |
| | --- | |
| | -/-- | |

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 30 June 2000 | 06/07/2000 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Wolf, C |

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Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1246
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

# INTERNATIONAL SEARCH REPORT

Interr nal Application No
PCT/US 00/10081

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication,where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US 5 843 170 A (S.S. AHN)<br>1 December 1998 (1998-12-01)<br>abstract; figure 19 | 7,8,27,<br>28,51,52 |
| P,X | WO 99 56665 A (AXYA MEDICAL,INC.)<br>11 November 1999 (1999-11-11)<br>abstract; figures 1-6 | 1,9,20,<br>29,45,<br>46,53 |
| A | DE 196 05 042 A (H.-R. FIGULLA)<br>15 January 1998 (1998-01-15)<br>the whole document | 4,24,48 |
| A | US 5 824 064 A (S.A. TAHERI)<br>20 October 1998 (1998-10-20)<br>column 2, line 35 - line 44; figures 2A,2B | 1,2,4,<br>10,11,<br>20-22,<br>24,30,<br>45,46,<br>48,54 |
| A | WO 99 18887 A (VASCULAR SCIENCE INC.)<br>22 April 1999 (1999-04-22)<br>cited in the application<br>abstract; figures 21,23<br>page 6, line 25 -page 7, line 7 | 4,7,8,<br>24,27,<br>28,48,<br>51,52 |
| A | WO 97 10757 A (AUTOGENICS)<br>27 March 1997 (1997-03-27) | |

Form PCT/ISA/210 (continuation of second sheet) (July 1992)



Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1247
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/US 00/10081

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| DE 19605042 A | 15-01-1998 | NONE | |
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| WO 9918887 A | 22-04-1999 | US 6074416 A | 13-06-2000 |
| | | AU 9031898 A | 03-05-1999 |
| WO 9710757 A | 27-03-1997 | NONE | |



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Page 2040 - 1248
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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(à n'utiliser que pour les commandes de reproduction)

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(51) Int Cl[7] : **A 61 F 2/24**

# (12) DEMANDE DE BREVET D'INVENTION A1

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(30) **Priorité :**

(43) **Date de mise à la disposition du public de la demande :** 03.05.02 Bulletin 02/18.

(56) **Liste des documents cités dans le rapport de recherche préliminaire :** *Se reporter à la fin du présent fascicule*

(60) **Références à d'autres documents nationaux apparentés :**

(71) **Demandeur(s) :** *SEGUIN JACQUES* — FR.

(72) **Inventeur(s) :** SEGUIN JACQUES.

(73) **Titulaire(s) :**

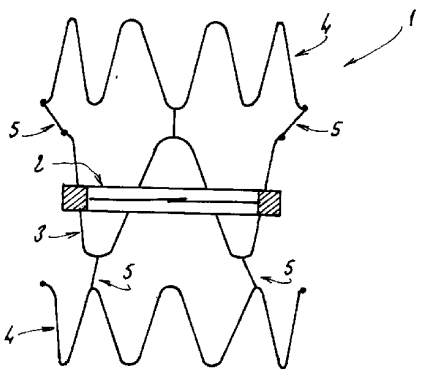
(74) **Mandataire(s) :** GERMAIN ET MAUREAU.

## (54) SUPPORT TUBULAIRE DE MISE EN PLACE, PAR VOIE PERCUTANEE, D'UNE VALVE CARDIAQUE DE REMPLACEMENT.

(57) Ce support (1) comprend une structure susceptible d'être contractée radialement pour permettre l'introduction de l'ensemble support (1) - valve (2) dans le corps du patient, et d'être déployée pour permettre la prise d'appui de cette structure contre la paroi du site à équiper de la valve.

Selon l'invention, la structure du support (1) comprend:

- une portion axiale (3) de support de valve (2), présentant une structure en fil ou en réseau de fils propre à prendre appui contre l'anneau cardiaque (10) subsistant après le retrait de la valve native déficiente;
- au moins une portion axiale de calage (4), présentant une structure en fil ou en réseau de fils distincte de la structure de ladite portion axiale (3) de support de valve, et de diamètre supérieur au diamètre de ladite portion axiale (3) lui permettant de prendre appui contre la paroi bordant ledit anneau cardiaque subsistant (10); et
- au moins un fil (5) reliant ponctuellement lesdites portions (3, 4).




FR 2 815 844 - A1

La présente invention concerne un support tubulaire de mise en place, par voie percutanée, d'une valve cardiaque de remplacement. Elle concerne également un instrument de mise en place de ce support.

La technique classique de remplacement d'une valve cardiaque consiste à opérer à cœur ouvert. Cette technique oblige à une anesthésie générale, à un large abord, et à un arrêt du cœur impliquant la mise du patient sous circulation extracorporelle. Elle est donc particulièrement lourde à mettre en œuvre et induit des risques opératoires importants pour le patient.

Pour remédier à cet inconvénient, il a été envisagé d'opérer l'ablation d'une valve cardiaque déficiente par voie percutanée, avec un abord vasculaire périphérique. La demande de brevet n°FR 99 14462 illustre une technique et un dispositif utilisables à cette fin.

En ce qui concerne la mise en place d'une valve cardiaque de remplacement, il a été envisagé de fixer cette valve sur un support présentant une structure en fil ou en réseau de fils, couramment dénommé "stent". Ce support peut être contracté radialement pour pouvoir être introduit dans le corps du patient par voie percutanée, au moyen d'un cathéter, et peut être déployé radialement une fois positionné au niveau du site à équiper de la valve pour assurer ainsi le montage de cette valve. Le brevet n°US 5 411 552 illustre une technique de ce genre.

Les systèmes de "stent" envisagés à ce jour pour la mise en place d'une valve cardiaque induisent des incertitudes plus ou moins importantes en ce qui concerne leur maintien en position dans les sites à traiter. En particulier, la forme des stents connus n'apparaît pas adaptée à celle de ces sites, dans lesquels la paroi cardiaque s'évase de part et d'autre de l'anneau cardiaque.

En outre, l'anneau cardiaque subsistant après ablation de la valve native peut gêner la mise en place de ces stents.

Ces systèmes connus induisent également, dans certains cas, des problèmes d'étanchéité de la valve de remplacement. En effet, ledit anneau cardiaque subsistant peut présenter une surface plus ou moins irrégulière et plus ou moins calcifiée, qui non seulement amoindrit la qualité de l'appui du stent contre cet anneau mais également peut être à l'origine de fuites entre la valve et cet anneau.

Certains matériels existants présentent par ailleurs des inconvénients en ce qui concerne leur implantation proprement dite. En particulier, ces matériels ne peuvent plus guère être déplacés après déploiement du support même si leur position n'est pas optimale.

La présente invention vise à remédier à ces inconvénients importants.

Son objectif principal est de fournir un support ("stent") procurant une meilleure certitude de maintien en position après implantation.

Un autre objectif de l'invention est de fournir un support permettant d'éliminer la gêne qu'induisent, au moment de la mise en place de la valve de remplacement, les feuillets valvulaires natifs volontiers calcifiés, épaissis et indurés, ou les restes des feuillets valvulaires après résection valvulaire.

Un autre objectif encore de l'invention est de fournir un support permettant une parfaite étanchéité de la valve de remplacement, même en cas d'un anneau cardiaque subsistant qui présente une surface plus ou moins irrégulière et/ou plus ou moins calcifiée.

L'invention a également pour objectif de fournir un support dont la position puisse être adaptée et/ou corrigée le cas échéant au moment de l'implantation.

Le support concerné comprend, de manière connue en soi, une structure en fil ou en réseau de fils susceptible d'être contractée radialement pour permettre l'introduction de l'ensemble support–valve dans le corps du patient, au moyen d'un cathéter, et d'être déployée pour permettre la prise d'appui de cette structure contre la paroi du site à équiper de la valve.

Selon l'invention, cette structure comprend :

- une portion axiale de support de valve, présentant une structure en fil ou en réseau de fils propre à recevoir la valve de remplacement montée sur elle, et propre à prendre appui contre l'anneau cardiaque subsistant après le retrait de la valve native déficiente ;

- au moins une portion axiale de calage, présentant une structure en fil ou en réseau de fils distincte de la structure de ladite portion axiale de support de valve, et dont au moins une partie présente, à l'état déployé, un diamètre supérieur au diamètre à l'état déployé de ladite

portion axiale de support de valve, tel que cette portion axiale de calage est propre à prendre appui contre la paroi bordant ledit anneau cardiaque subsistant ; et

- au moins un fil de liaison desdites portions, ce ou ces fils étant reliés ponctuellement à ces portions, de manière à ne pas faire obstacle au déploiement desdites portions axiales selon leurs diamètres respectifs.

L'invention fournit ainsi un support en au moins deux portions axiales individualisées l'une par rapport à l'autre en ce qui concerne leur structure, qui sont reliées de manière localisée par au moins un fil ; ce ou ces fils ne font pas obstacle à un déploiement différent de la portion axiale comportant la valve et de la ou des portions axiales de calage.

La présence d'une structure en fil ou en réseau de fils au niveau de la portion axiale de support de valve permet un parfait assemblage de cette valve à cette structure, et la forme ainsi que le diamètre de cette portion axiale peuvent être adaptés à une prise d'appui dans les meilleures conditions contre l'anneau cardiaque subsistant. En particulier, cette portion axiale de support de valve peut présenter une force d'expansion radiale telle qu'elle repousse ("impacte") les feuillets valvulaires volontiers calcifiés, ou les restes des feuillets valvulaires après résection valvulaire sur ou dans les tissus sous-jacents, de sorte que ces éléments ne constituent pas une gêne à la mise en place de la valve de remplacement. Cette structure permet également de supporter d'éventuels moyens d'ancrage du support et/ou d'éventuels moyens d'étanchéité de l'espace existant entre l'anneau cardiaque subsistant et la valve de remplacement, comme indiqué plus loin.

La forme et/ou le diamètre de chaque portion axiale de calage peuvent être adaptés à une prise d'appui dans les meilleures conditions contre la paroi cardiaque située aux abords de l'anneau cardiaque subsistant. Notamment, cette portion axiale de calage peut présenter une forme tubulaire de diamètre constant supérieur à celui de la portion axiale de support de valve, ou une forme tronconique dont le diamètre va en augmentant en s'éloignant de la portion axiale de support de valve.

De préférence, le support tubulaire présente une portion axiale de support de valve en au moins deux parties, dont au moins une est adaptée à supporter la valve et dont au moins une autre est adaptée à repousser les feuillets valvulaires natifs ou les restes des feuillets

valvulaires natifs après résection valvulaire, dans ou sur le tissu adjacent afin de rendre cette zone apte à recevoir le support tubulaire.

Cette portion axiale de support de valve élimine la gêne qu'induisent ces éléments valvulaires ou annulaires cardiaques au moment de la mise en place de la valve de remplacement. La force radiale de cette portion axiale de support de valve assure en effet, en impactant tout ou partie du tissu valvulaire dans ou au voisinage de la paroi, une surface plus régulière et plus apte à recevoir l'axe de support de valve. Elle assure également une meilleure solidarisation avec la paroi tout en réduisant le risque de fuite para prothétique.

La portion axiale de support de valve peut notamment comprendre une partie en fil ondulé à larges ondes, pour supporter la valve, et une partie en fil ondulé à ondes réduites, adjacente à ladite partie à larges ondes, présentant une force radiale relativement importante pour permettre de repousser ledit tissu valvulaire contre ou dans la paroi du conduit.

De préférence, le support selon l'invention présente deux portions axiales de calage, l'une étant reliée à une extrémité axiale de ladite portion de support de valve et l'autre à l'autre extrémité axiale de cette même portion de support de valve.

Ces deux portions axiales de calage permettent ainsi un calage du support de part et d'autre de l'anneau cardiaque subsistant, et permettent par conséquent un parfait calage du support dans deux directions opposées par rapport au site traité.

Si nécessaire, par exemple dans le cas où le conduit comprenant la valve présenterait un anévrisme, le support selon l'invention comprend :

- une portion axiale de maintien, propre à prendre appui à l'état déployé contre la paroi du conduit, et

- des fils de liaison tels que précités, reliant ladite portion axiale de support de valve et ladite portion axiale de maintien, ces fils ayant une longueur telle que la portion axiale de maintien soit située après implantation à distance de la portion axiale de support de valve.

Cette distance permet à ladite portion axiale de maintien de prendre appui contre une zone de la paroi du conduit non concernée par une éventuelle affection pouvant exister aux abords de la valve, en particulier un anévrisme. La longueur des fils de liaison peut également être

calculée afin d'éviter que la portion axiale de maintien soit au contact des ostia des artères coronaires.

Les portions axiales précitées (de support de valve, de calage, de maintien) peuvent présenter une structure en fil ondulé, en zig-zag ou, de préférence, une structure en mailles ayant une forme de losange, les mailles étant juxtaposées dans le sens de la circonférence de ces portions.

Cette dernière structure permet une force radiale adaptée, permettant d'assurer une parfaite prise d'appui dedites portions contre la paroi qui les reçoit.

Le support selon l'invention peut être réalisé en un métal plastiquement déformable. L'instrument de mise en place du support comprend alors un ballonnet présentant une portion axiale d'un diamètre prédéterminé, adaptée à réaliser le déploiement de ladite portion axiale de support de valve, et au moins une portion axiale conformée pour présenter, à l'état gonflé, une section supérieure à celle du conduit à traiter, de manière à réaliser le déploiement de la portion axiale de calage placée sur elle jusqu'à ce que cette portion axiale de calage rencontre la paroi contre laquelle elle doit venir en appui.

Le support selon l'invention peut également être réalisé en un matériau à mémoire de forme, tel qu'un alliage nickel–titane du genre dénommé "NITINOL", pouvant être contracté radialement à une température différente de celle du corps du patient et retrouvant une forme originelle lorsque sa température approche ou atteint celle du corps du patient.

Selon une autre possibilité, le support est réalisé en un matériau à mémoire de forme mais susceptible de déformation plastique, ou comprend des parties en un matériau à mémoire de forme et des parties en un matériau susceptible de déformation plastique, et est conformé de manière telle qu'il puisse être amené, par mémoire de forme ou par déformation plastique, d'un état de contraction à un état de déploiement intermédiaire stable entre l'état de contraction et l'état de déploiement total, puis, par déformation plastique ou par mémoire de forme respectivement, dudit état de déploiement intermédiaire audit état de déploiement total ; dans ledit état de déploiement intermédiaire, le support présente des dimensions telles qu'il reste mobile par rapport au site à traiter.

Le support est ainsi amené au niveau du site à traiter puis est déployé dans ledit état intermédiaire ; sa position peut alors éventuellement être adaptée et/ou corrigée puis le support est amené dans son état de déploiement total.

Le matériau à mémoire de forme mais susceptible de déformation plastique précité peut notamment être un alliage nickel–titane du genre dénommé "NITINOL martensitique", susceptible d'être déformé plastiquement au moyen d'un ballonnet.

Avantageusement, le support selon l'invention comprend des moyens d'ancrage propres à s'insérer dans la paroi du site à traiter, conformés de manière à être mobiles entre une position inactive, dans laquelle ils ne font pas obstacle à l'introduction du support dans le corps du patient, et une position active, dans laquelle ils s'insèrent dans la paroi du site à traiter.

Une parfaite immobilisation du support au niveau du site est ainsi obtenue.

En particulier, ces moyens d'ancrage peuvent présenter la forme d'aiguilles et peuvent être montés sur le support entre des positions de rétractation radiale et des positions de saillie radiale.

Avantageusement, la portion axiale de support de valve comporte, au niveau de sa face extérieure, un moyen d'étanchéité conformé de manière à absorber les irrégularités de surface pouvant exister au niveau ou à proximité de l'anneau cardiaque subsistant.

Ce moyen d'étanchéité peut être constitué par une bande périphérique en un matériau compressible ou par une bande périphérique délimitant une chambre et ayant une structure radialement expansible, cette chambre pouvant recevoir un fluide de gonflage propre à se figer dans un délai déterminé après introduction dans ladite chambre. Ce moyen d'étanchéité peut également comprendre un matériau pouvant être appliqué entre l'anneau cardiaque subsistant et la portion axiale de support de valve, ce matériau étant propre à se figer dans un délai déterminé après cette application. Dans ce cas, ce matériau peut notamment être thermoactivable, par exemple au moyen d'un laser, à travers le ballonnet, ou activable par émission de lumière d'une fréquence déterminée, par exemple au moyen d'un laser à ultra-violets, à travers le ballonnet. Ledit moyen d'étanchéité peut également se présenter sous forme d'un insert

gonflable ayant une section transversale en diabolo à l'état gonflé, pouvant être inséré entre l'anneau cardiaque subsistant et la portion axiale de support de valve. Ladite forme en diabolo permet à cet insert de se conformer au mieux aux structures irrégulières adjacentes et d'assurer une meilleure étanchéité.

Pour sa bonne compréhension, l'invention est à nouveau décrite ci-dessous en référence au dessin schématique annexé représentant, à titre d'exemples non limitatifs, plusieurs formes de réalisation possibles du support tubulaire qu'elle concerne.

La figure 1 est une vue en développé de la structure de ce support, selon une première forme de réalisation ;

la figure 2 est une vue en coupe du support à l'état déployé, avec la valve cardiaque qu'il comporte ;

la figure 3 est une vue en bout de ce support à l'état déployé ;

la figure 4 est une vue en bout de ce support à l'état contracté ;

la figure 5 est une vue d'un coeur en coupe partielle, sur lequel une valve cardiaque de remplacement a été mise en place au moyen du support selon l'invention ;

la figure 6 est une vue en développé de la structure du support selon une deuxième forme de réalisation ;

la figure 7 est une vue en développé de la structure du support selon une troisième forme de réalisation ;

la figure 8 est une vue de détail d'une partie de cette structure, à échelle agrandie ;

la figure 9 est une vue du support selon la figure 7, après mise en place dans un conduit corporel présentant un anévrisme ;

la figure 10 est une vue en développé de la structure du support selon une quatrième forme de réalisation ;

la figure 11 est une vue de détail d'une variante de réalisation d'un crochet d'ancrage que comprend le support selon la quatrième forme de réalisation ;

la figure 12 est une vue du même détail, en coupe selon la ligne XII-XII de la figure 11 ;

la figure 13 est une vue similaire à la figure 11, la structure étant dans un état expansé ;

la figure 14 est une vue similaire à la figure 12, la structure étant dans ce même état expansé ;

la figure 15 est une vue partielle d'une portion de structure du support selon une cinquième forme de réalisation ;

la figure 16 est une vue agrandie d'une zone de montage d'une valve prothétique sur cette portion ;

la figure 17 est une vue partielle, en coupe longitudinale, du support selon la première forme de réalisation et d'un anneau cardiaque calcifié ;

la figure 18 est une vue similaire à la figure 17, selon une variante ;

la figure 19 est une vue similaire à la figure 17, selon une autre variante ;

les figures 20 et 21 sont des vues similaires à la figure 17, selon encore une autre variante, dans deux phases de mise en place du support ;

la figure 22 est une vue en coupe longitudinale d'un ballonnet permettant l'expansion de la structure du support représenté aux figures 7 à 9 ;

la figure 23 est une vue en coupe longitudinale d'un ballonnet selon une variante de réalisation, et

la figure 24 est une vue similaire à la figure 5, montrant un coeur sur lequel une valve cardiaque de remplacement a été mise en place au moyen du support selon l'invention, selon une sixième forme de réalisation.

Par simplification, les parties ou éléments de ces différentes formes de réalisation qui sont identiques ou similaires d'une forme de réalisation à une autre sont définis par les mêmes références numériques.Les figures 1 à 4 représentent un support tubulaire 1 de mise en place, par voie percutanée, d'une valve cardiaque 2 de remplacement.

La structure du support 1 comprend une portion médiane 3 comportant la valve 2, deux portions extrémales 4 de calage et des fils 5 de liaison de ces portions 3 et 4. La portion médiane 3 comporte en outre une bande périphérique 6 pourvue d'aiguilles d'ancrage 7 et d'un bandage 8 en matériau compressible.

Ainsi que cela apparaît plus particulièrement sur la figure 1, les portions 3 et 4 sont formées chacune par un fil ondulé, et les fils 5 relient ponctuellement les extrémités des ondulations de la portion 3 à l'extrémité d'une ondulation adjacente d'une portion 4. Les portions 4, vues en développé, ont des longueurs supérieures à la longueur de la portion 3, de sorte que, lorsque les extrémités des fils formant respectivement les portions 3 et 4 sont reliées pour constituer la structure tubulaire du support 1, le diamètre de la portion 3 est inférieur au diamètre des portions 4.

Le diamètre de la portion 3 est tel que cette portion 3 peut, comme le montre la figure 5, prendre appui contre l'anneau cardiaque 10 subsistant après le retrait de la valve native déficiente, tandis que les portions 4 peuvent prendre appui contre les parois 11 bordant l'anneau 10. Ces diamètres respectifs sont de préférence tels que lesdites prises d'appui se font avec une légère contrainte radiale de l'anneau 10 et des parois 11.

La portion 3 présente à l'état déployé un diamètre constant. Les portions 4 peuvent présenter un diamètre constant ou une forme tronconique dont le diamètre va en augmentant en s'éloignant de la portion 3.

L'ensemble de la structure du support 1 est réalisé en un matériau à mémoire de forme, tel qu'un alliage nickel-titane du genre dénommé "NITINOL". Ce matériau permet à cette structure d'être contractée radialement, comme montré sur la figure 4, à une température différente de celle du corps du patient et de retrouver la forme originelle montrée sur les figures 2 et 3 lorsque sa température approche ou atteint celle du corps du patient. L'ensemble de la structure du support 1 peut également être réalisé en un matériau expandable sur ballonnet comme par exemple en acier inoxydable médical (acier 316 L).

La valve 2 peut être en tissu biologique ou synthétique. Elle est reliée à la portion 3 par des sutures ou par tous autres moyens de fixation appropriés. Elle peut également être moulée sur la portion 3.

La bande 6 est en "NITINOL". Elle est reliée aux ondulations de la portion 3, à mi-hauteur de celles-ci, et comporte les aiguilles 7 au niveau de ses zones reliées à ces ondulations.

Les aiguilles 7 sont constituées par des brins de fil métallique acérés à leurs extrémités libres, et font saillie radialement vers l'extérieur de la bande 6.

Cette dernière peut prendre la forme ondulée visible sur la figure 4 à l'état contracté du support 1 et la forme circulaire visible sur la figure 3 à l'état déployé de ce support 1. Dans sa forme ondulée, la bande 6 forme des ondulations 6a faisant saillie radialement sur l'extérieur du support 1, au-delà des aiguilles 7, de sorte que ces aiguilles 7, dans cette position de rétractation, ne gênent pas l'introduction du support 1 dans un cathéter ni, une fois le support 1 introduit dans le coeur à l'aide de ce cathéter, le déploiement de ce support 1. Le retour de la bande 6 dans sa forme circulaire amène les aiguilles 7 dans une position de déploiement, leur permettant de s'insérer dans l'anneau 10 afin de compléter l'ancrage du support 1.

Le bandage 8 est fixé sur la bande 6. Son matériau compressible lui permet d'absorber les irrégularités de surface pouvant exister au niveau ou à proximité de l'anneau 10 et d'assurer ainsi une parfaite étanchéité de la valve 2.

La figure 6 montre une structure du support 1 comprenant une seule portion 4, reliée à la portion 3 par des fils 5. Cette portion 4 est formée par deux fils 14 ondulés reliés entre eux par des fils 15.

La figure 7 montre une structure du support 1 présentant une portion 3 et une portion 4 reliées par des fils de liaison 5.

Ces portions 3 et 4 ont des structures à mailles en forme de losange, ces mailles étant juxtaposées dans le sens de la circonférence de ces portions et étant reliées les unes aux autres au niveau de deux de leurs angles opposés dans le sens de la circonférence de ces portions 3 et 4. Les fils 5 sont reliés à ces structures au niveau de la zone de jonction de deux mailles consécutives. Ces mailles comportent en outre des crochets d'ancrage 7 s'étendant à travers elles à partir de l'un de leurs angles situés dans le sens longitudinal du support 1.

La figure 8 illustre, à échelle agrandie, la structure de cette portion 4 et d'une partie des fils 5, tels que découpés par exemple au laser dans une plaque d'acier inoxydable, et après recourbement des extrémités 7a acérés des crochets 7. Ces derniers ont, vu de profil, une forme telle que montrée sur les figures 12 ou 14.

La structure représentée sur la figure 7 comprend également une portion axiale de maintien 20, ayant une structure identique à celle de la portion 4 mais à maille plus grosses, et trois fils 5 de longueur

importante, reliant cette portion 20 à la portion 3. Ces fils 5 ont, du côté de la portion 20, une suture unitaire 5a et, du côté de la portion 3, une structure double 5b. Leur nombre correspond aux trois commissures que forment les trois valvules de la valve 2, ce qui facilite le montage de la valve 2 sur le support 1 ainsi conformé.

Le support selon la figure 7 est destiné à être utilisé, ainsi cela apparaît sur la figure 9, lorsque le conduit corporel comprenant la valve à remplacer, en particulier l'aorte, présente un anévrisme aux abords de la valve. La longueur des fils 5 reliant les portions 3 et 20 est prévue de manière telle que, après implantation, la portion 20 soit située dans une zone non dilatée dudit conduit corporel, et cette portion 20 est prévue de manière à prendre appui contre la paroi de ce conduit.

La figure 10 montre une structure similaire à la figure 7 mais non expansé, et sinon que les trois fils 5 ont une structure unitaire mais comportent un fil ondulé 21 assurant un appui complémentaire à proximité de la portion 3. Ce fil 21 est conçu pour supporter une valve 2 à trois valvules.

Les figures 11 à 14 montrent une variante de réalisation de la structure des portions 3, 4 ou 20, lorsque cette structure est équipée de crochets 7. Dans ce cas, la structure est en zig-zag et chaque crochet 7 comprend deux branches 7b ; chacune de ces branches 7b est reliée à l'autre branche 7b par une extrémité et à une branche de la structure 1 par son autre extrémité. La zone de jonction des deux branches 7b présente un ergot recourbé 7a d'accrochage.

La figure 15 montre une portion 3 comprenant deux fils ondulés 25, 26 s'étendant l'un à proximité de l'autre et un fil ondulé secondaire 27. Ainsi que le représente la figure 16, les fils 25, 26 peuvent être utilisés pour réaliser l'insertion d'une valve 2 en matériau biologique entre eux et la fixation de cette valve 2 à eux au moyen de sutures 27.

La figure 17 montre une partie du support 1 selon les figures 1 à 5, et la façon dont le matériau compressible constituant le bandage 8 peut absorber les irrégularités de surface pouvant exister au niveau ou à proximité de l'anneau 10, qui résultent de calcifications.

La figure 18 montre un support 1 dont la bande 6 est dépourvue de bandage compressible. Un matériau peut alors être appliqué, au moyen d'une canule appropriée (non représentée), entre l'anneau 10 et cette

bande 6, ce matériau étant propre à se figer dans un délai déterminé après cette application.

La figure 19 montre un support 1 dont la bande 6 présente une section en ligne brisée, délimitant, du côté radialement extérieur, un épaulement inférieur. Dans le redan formé par cet épaulement et la paroi circonférientielle adjacente, est logée une bande périphérique 8, gonflable au moyen d'un cathéter (non représenté). Cette bande 8 délimite une chambre et a une structure radialement expansible, telle qu'elle présente en section transversale, à l'état gonflé, deux extrémités élargies faisant saillie de part et d'autre de la bande 6. Cette chambre peut recevoir un fluide de gonflage propre à se figer dans un délai déterminé après introduction dans ladite chambre. Une fois ce matériau figé, le cathéter de gonflage est sectionné.

Les figures 20 et 21 montrent un support 1 dont la bande 6 reçoit un insert gonflable 8 ayant une section transversale en diabolo à l'état gonflé, cet insert 8 pouvant être gonflé au moyen d'un cathéter 29. L'insert 8 est mis en place à l'état dégonflé (figure 20) aux emplacements dans lesquels il existe un espace entre la bande 6 et l'anneau cardiaque subsistant 10. Sa forme en diabolo permet à cet insert 8 (cf. figure 21) de se conformer au mieux aux structures irrégulières adjacentes et d'assurer une meilleure étanchéité.

La figure 22 montre un ballonnet 30 permettant de déployer le support 1 selon les figures 7 à 9. Ce ballonnet 30 comprend une portion cylindrique 31 dont le diamètre à l'état gonflé permet l'expansion de la portion de maintien 20, une portion cylindrique 32 de diamètre moindre, adaptée à réaliser l'expansion de la portion 3, et une portion tronconique 33, permettant l'expansion de la portion 4.

Ainsi que montre la figure 23, la portion 32 peut être limitée à ce qui est strictement nécessaire pour déployer la portion 3, ce qui permet de réaliser le ballonnet 30 en deux parties au lieu d'une seule, limitant ainsi le volume de ce ballonnet 30.

La figure 24 montre un support 1 dont la portion médiane 3 est en deux parties 3a, 3b. La partie 3a est en fil ondulé à larges ondes, pour supporter la valve 2, et la partie 3b, adjacente à ladite partie 3a et reliée à celle-ci par des ponts 35, est en fil ondulé à ondes réduites. Cette partie 3b, par sa structure, présente une force radiale d'expansion relativement

élevée et est destinée à être placée en regard de l'anneau 10 afin de repousser les feuillets valvulaires natifs volontiers calcifiés, épaissis et indurés, ou les restes des feuillets valvulaires après résection valvulaire contre ou dans la paroi du conduit.

Cette portion axiale 3a, 3b élimine ainsi la gêne qu'induisent ces feuillets ou résidus de feuillets au moment de la mise en place de la valve 2.

Il apparaît de ce qui précède que l'invention fournit un support tubulaire de mise en place, par voie percutanée, d'une valve cardiaque de remplacement procurant, grâce à ses portions 3 et 4, une parfaite certitude de maintien en position après implantation. Ce support permet également une parfaite étanchéité de la valve de remplacement, même en cas d'un anneau cardiaque présentant une surface plus ou moins irrégulière et/ou plus ou moins calcifiée, et sa position peut être adaptée et/ou corrigée le cas échéant au moment de l'implantation.

Il va de soi que l'invention n'est pas limitée à la forme de réalisation décrite ci-dessus à titre d'exemple mais qu'elle en embrasse au contraire toutes les variantes de réalisation couvertes par les revendications ci-annexées.

## REVENDICATIONS

1 - Support tubulaire de mise en place, par voie percutanée, d'une valve cardiaque de remplacement (2), comprenant une structure en fil ou en réseau de fils susceptible d'être contractée radialement pour permettre l'introduction de l'ensemble support (1) – valve (2) dans le corps du patient, au moyen d'un cathéter, et d'être déployée pour permettre la prise d'appui de cette structure contre la paroi du site à équiper de la valve (2) ;

support (1) caractérisé en ce que sa structure comprend :

- une portion axiale (3) de support de valve (2), présentant une structure en fil ou en réseau de fils propre à recevoir la valve de remplacement (2) montée sur elle, et propre à prendre appui contre l'anneau cardiaque (10) subsistant après le retrait de la valve native déficiente ;

- au moins une portion axiale de calage (4), présentant une structure en fil ou en réseau de fils distincte de la structure de ladite portion axiale (3) de support de valve, et dont au moins une partie présente, à l'état déployé, un diamètre supérieur au diamètre à l'état déployé de ladite portion axiale (3) de support de valve, tel que cette portion axiale de calage (4) est propre à prendre appui contre la paroi bordant ledit anneau cardiaque subsistant (10) ; et

- au moins un fil (5) de liaison desdites portions (3, 4), ce ou ces fils (5) étant reliés ponctuellement à ces portions (3, 4), de manière à ne pas faire obstacle au déploiement desdites portions axiales (3, 4) selon leurs diamètres respectifs.

2 - Support tubulaire selon la revendication 1, caractérisé en ce qu'il présente une portion axiale (3) de support de valve en au moins deux parties (3a, 3b), dont au moins une adaptée à supporter la valve (2) et dont au moins une autre adaptée à repousser les feuillets valvulaires natifs ou les restes des feuillets valvulaires natifs après résection valvulaire, dans ou sur le tissu adjacent afin de rendre cette zone apte à recevoir le support tubulaire.

3 - Support tubulaire selon la revendication 1 ou la revendication 2, caractérisé en ce qu'au moins une portion axiale de calage (4) présente

une forme tubulaire de diamètre constant supérieur à celui de la portion axiale (3) de support de valve.

4 - Support tubulaire selon la revendication 1 ou la revendication 2, caractérisé en ce qu'au moins une portion axiale de calage (4) présente une forme tronconique dont le diamètre va en augmentant en s'éloignant de la portion axiale (3) de support de valve.

5 - Support tubulaire selon l'une des revendications 1 à 4, caractérisé en ce qu'il comprend :

- une portion axiale de maintien (20), propre à prendre appui à l'état déployé contre la paroi du conduit comprenant la valve, et
- des fils de liaison (5), reliant ladite portion axiale (3) de support de valve et ladite portion axiale de maintien (20), ces fils (5) ayant une longueur telle que la portion axiale de maintien (20) soit située après implantation à distance de la portion axiale (3) de support de valve.

6 - Support tubulaire selon l'une des revendications 1 à 5, caractérisé en ce que chaque portion axiale de support de valve (3), de calage (4) ou de maintien (20) présente une structure en mailles ayant une forme de losange, les mailles étant juxtaposées dans le sens de la circonférence de cette portion (3, 4, 20).

7 - Support tubulaire selon l'une des revendications 1 à 6, caractérisé en ce qu'il présente deux portions axiales de calage (4), l'une étant reliée à une extrémité axiale de ladite portion (3) de support de valve et l'autre à l'autre extrémité axiale de cette même portion (3) de support de valve.

8 - Support tubulaire selon l'une des revendications 1 à 7, caractérisé en ce qu'il est réalisé en un métal plastiquement déformable.

9 - Support tubulaire selon l'une des revendications 1 à 7, caractérisé en ce qu'il est réalisé en un matériau à mémoire de forme, tel qu'un alliage nickel–titane du genre dénommé "NITINOL", pouvant être contracté radialement à une température différente de celle du corps du patient et retrouvant une forme originelle lorsque sa température approche ou atteint celle du corps du patient.

10 - Support tubulaire selon l'une des revendications 1 à 7, caractérisé en ce qu'il est réalisé en un matériau à mémoire de forme mais susceptible de déformation plastique, ou comprend des parties en un matériau à mémoire de forme et des parties en un matériau susceptible de

déformation plastique, et en ce qu'il est conformé de manière telle qu'il puisse être amené, par mémoire de forme ou par déformation plastique, d'un état de contraction à un état de déploiement intermédiaire stable entre l'état de contraction et l'état de déploiement total, puis, par déformation plastique ou par mémoire de forme respectivement, dudit état de déploiement intermédiaire audit état de déploiement total ; dans ledit état de déploiement intermédiaire, le support présente des dimensions telles qu'il reste mobile par rapport au site à traiter.

11 - Support tubulaire selon l'une des revendications 1 à 10, caractérisé en ce qu'il comprend des moyens d'ancrage (7) propres à s'insérer dans la paroi du site à traiter, conformés de manière à être mobiles entre une position inactive, dans laquelle ils ne font pas obstacle à l'introduction du support (1) dans le corps du patient, et une position active, dans laquelle ils s'insèrent dans la paroi du site à traiter.

12 - Support tubulaire selon l'une des revendications 1 à 11, caractérisé en ce que ladite portion axiale (3) de support de valve comporte, au niveau de sa face extérieure, un moyen d'étanchéité (8) conformé de manière à absorber les irrégularités de surface pouvant exister au niveau ou à proximité de l'anneau cardiaque subsistant (10).

13 - Support tubulaire selon la revendication 12, caractérisé en ce que le moyen d'étanchéité (8) comprend un bandage périphérique en un matériau compressible.

14 - Support tubulaire selon la revendication 12, caractérisé en ce que le moyen d'étanchéité (8) comprend un bandage périphérique délimitant une chambre et ayant une structure radialement expansible, cette chambre pouvant recevoir un fluide de gonflage propre à se figer dans un délai déterminé après introduction dans ladite chambre.

15 - Support tubulaire selon la revendication 12, caractérisé en ce que le moyen d'étanchéité (8) comprend un matériau pouvant être appliqué entre l'anneau cardiaque subsistant (10) et la portion axiale (3) de support de valve, ce matériau étant propre à se figer dans un délai déterminé après cette application.

16 - Support tubulaire selon la revendication 12, caractérisé en ce que le moyen d'étanchéité (8) se présente sous forme d'un insert gonflable ayant une section transversale en diabolo à l'état gonflé, pouvant

être inséré entre l'anneau cardiaque subsistant (10) et la portion axiale (3) de support de valve.

17 - Instrument de mise en place du support selon l'une des revendications 8 ou 10 à 16, caractérisé en ce qu'il comprend un ballonnet (30) présentant une portion axiale (32) d'un diamètre prédéterminé, adaptée à réaliser le déploiement de ladite portion axiale de support de valve, et au moins une portion axiale (31, 33) conformée pour présenter, à l'état gonflé, une section supérieure à celle du conduit à traiter, de manière à réaliser le déploiement de la portion axiale de calage placée sur elle jusqu'à ce que cette portion axiale de calage rencontre la paroi contre laquelle elle doit venir en appui.

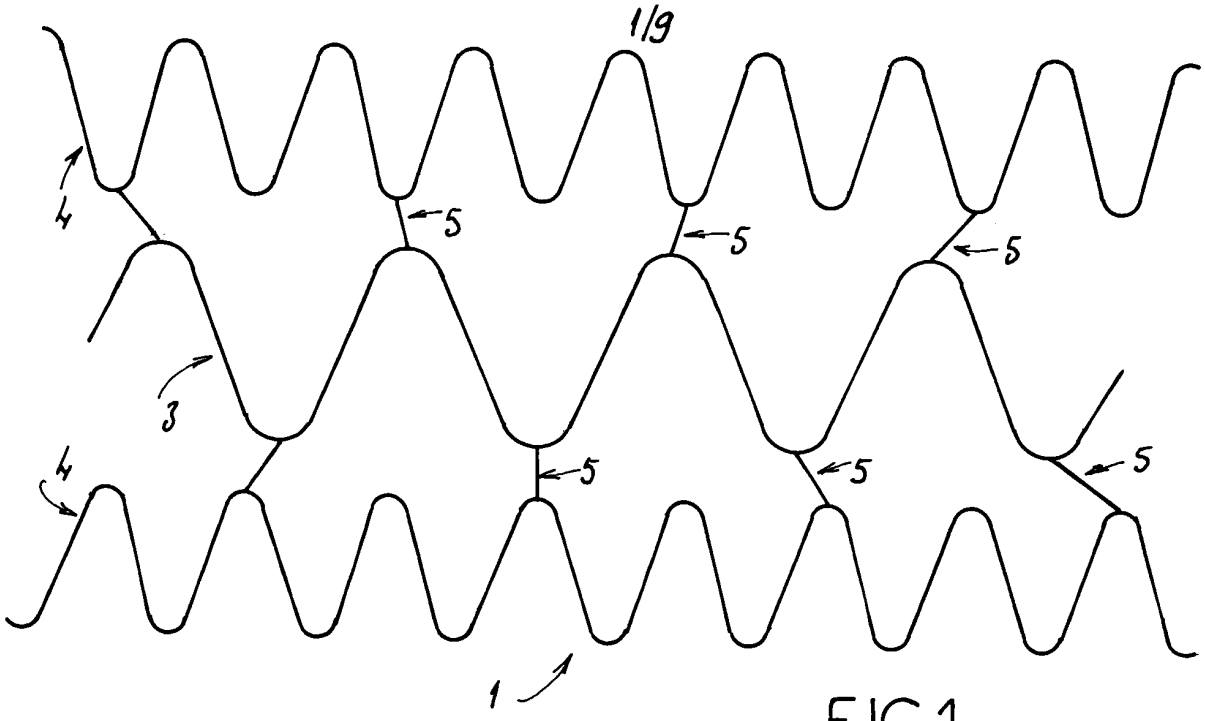



FIG 1

FIG 2

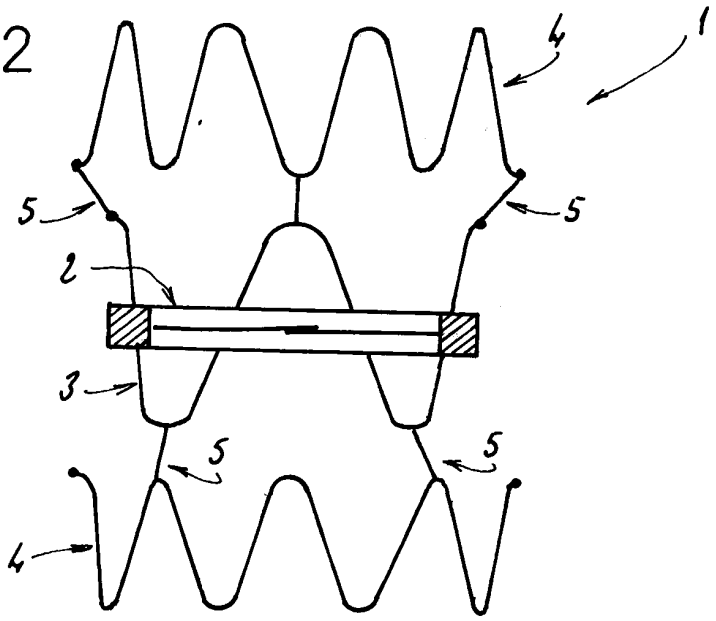


FIG 3

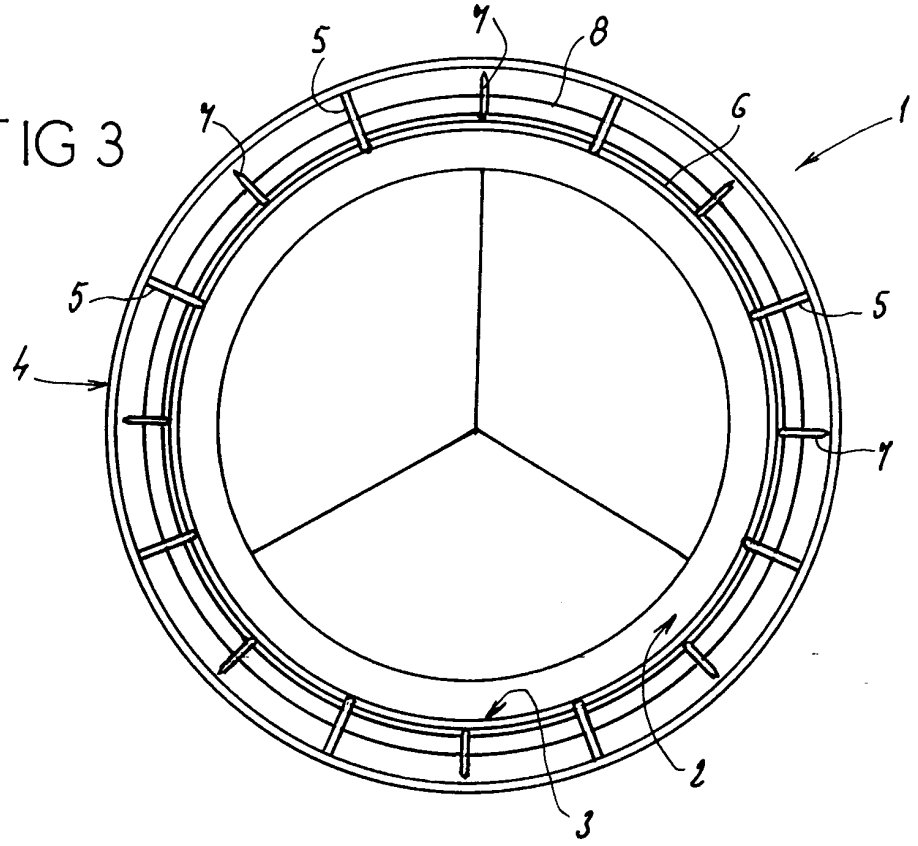



FIG 4

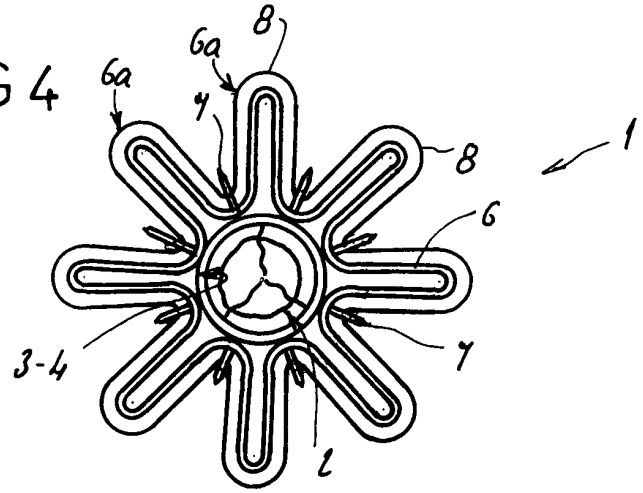


FIG 5

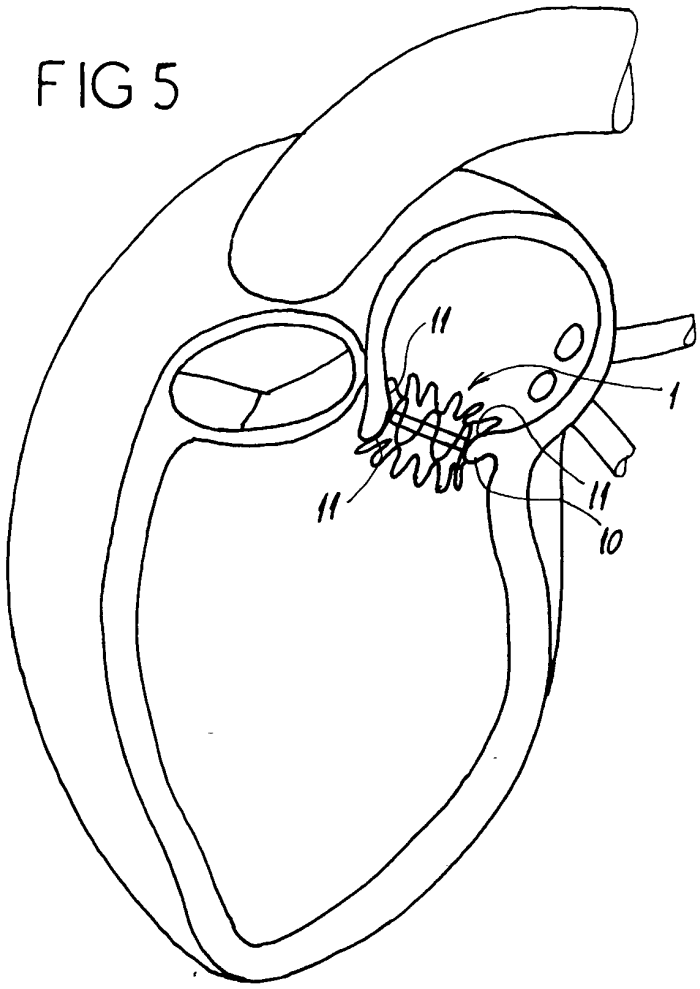



FIG 6

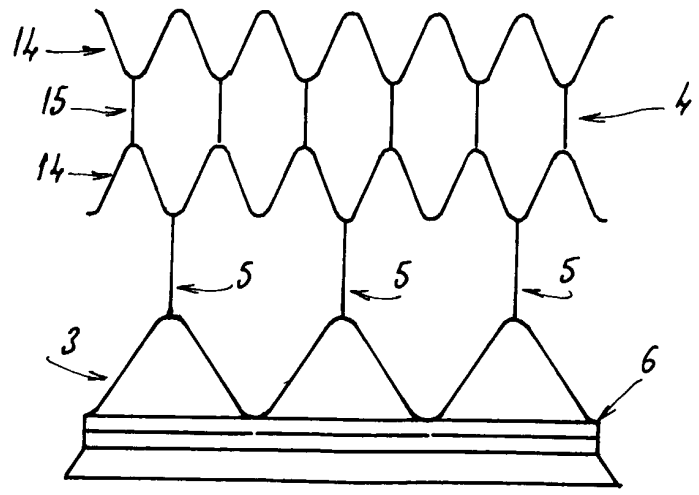


FIG 7

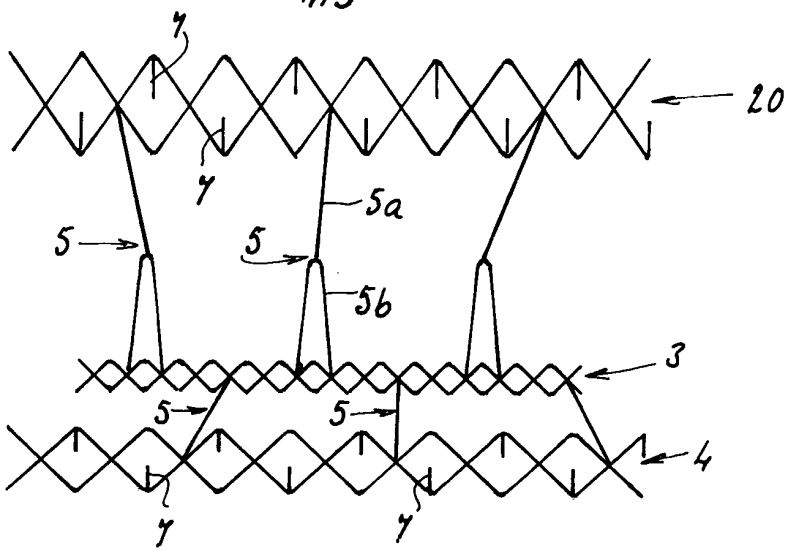



FIG 8

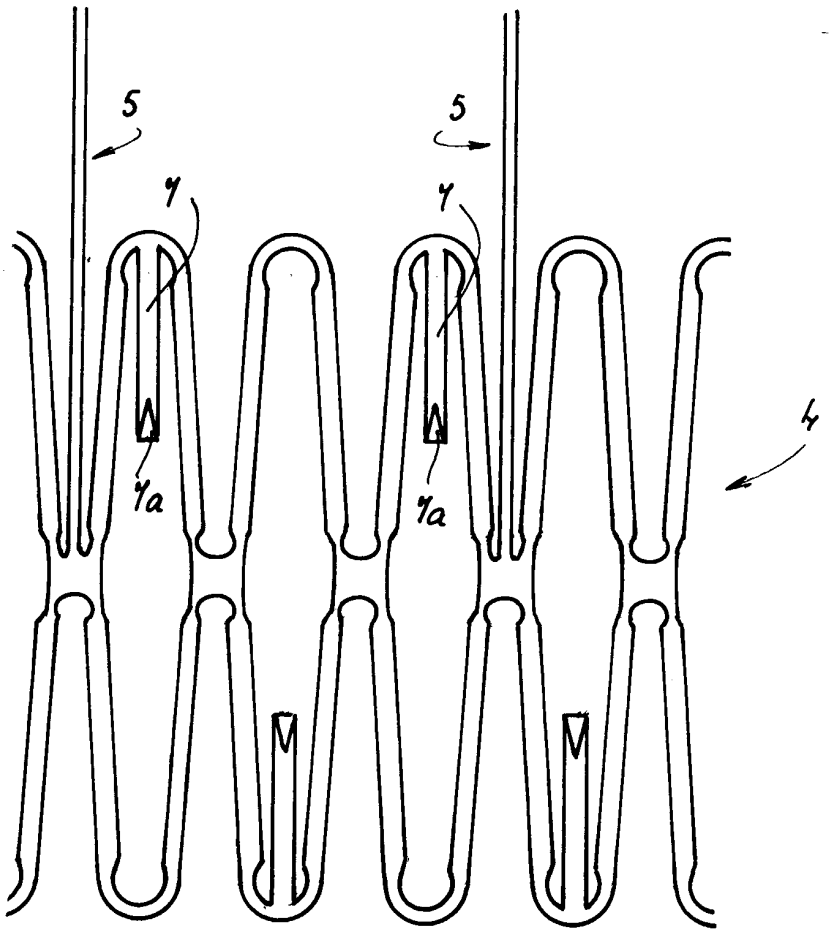



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FIG 9

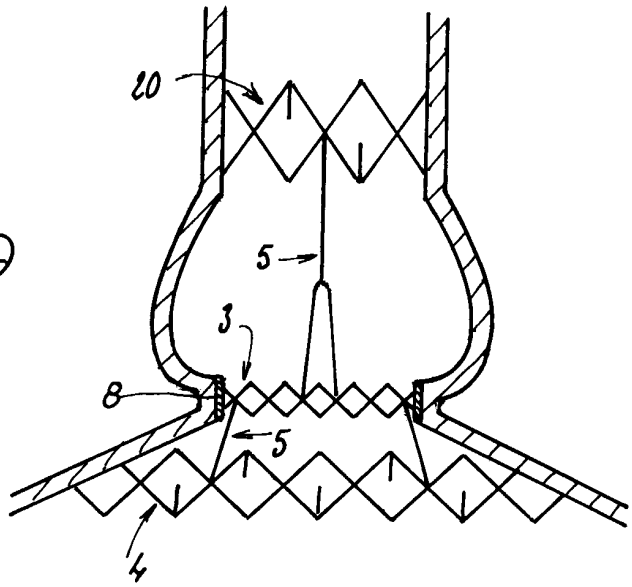



FIG 10

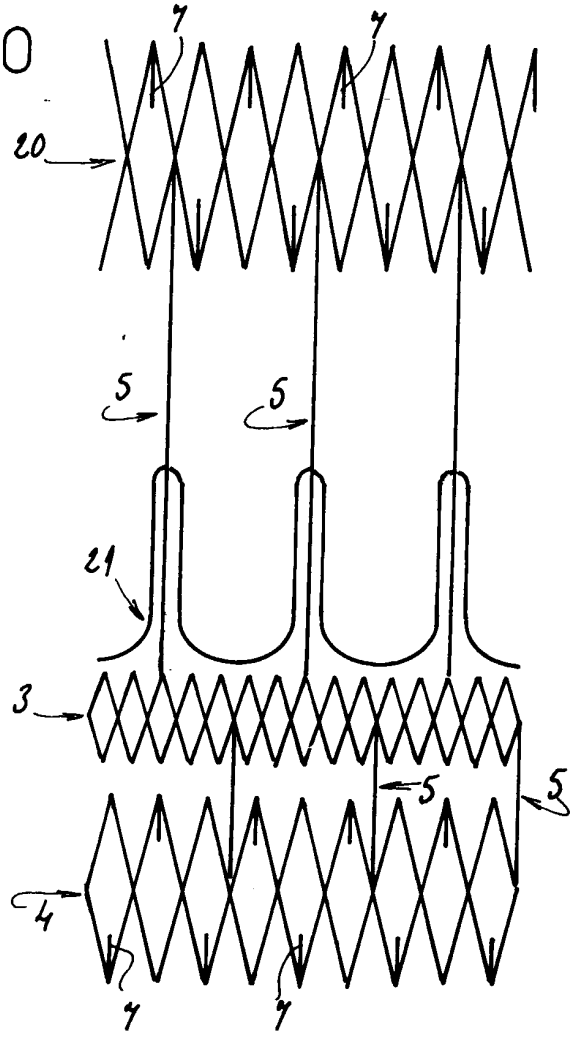


FIG 11

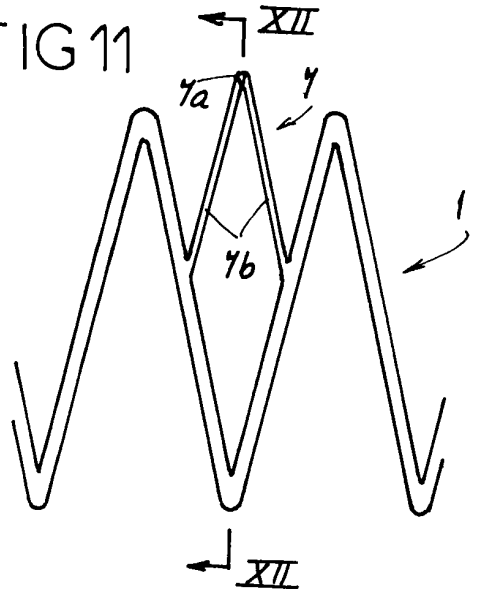
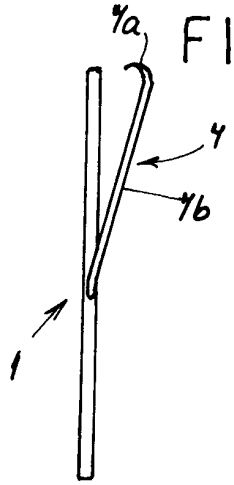



FIG 12



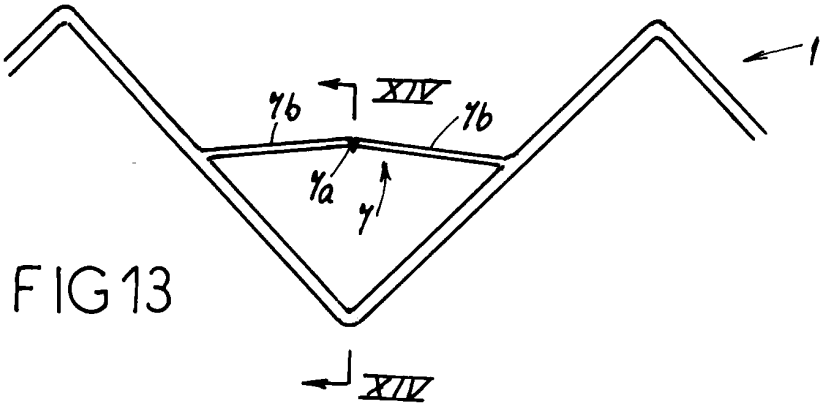




FIG 13

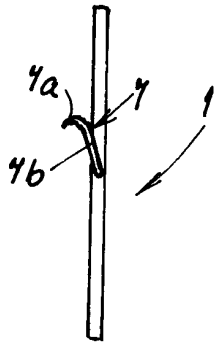



FIG 14

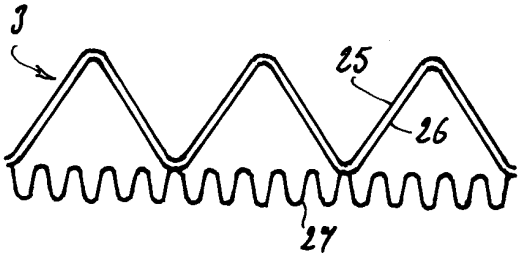



FIG 15

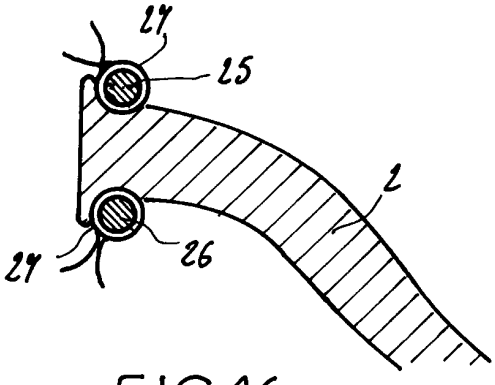



FIG 16

FIG 17

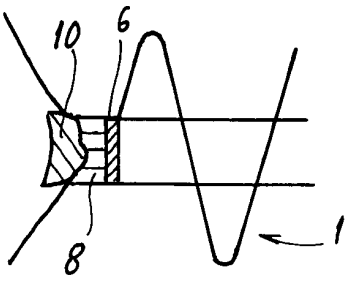



FIG 18

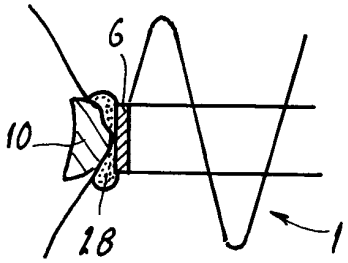



FIG 19

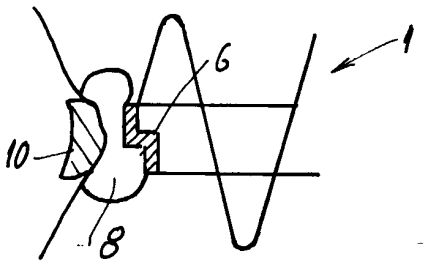



FIG 20

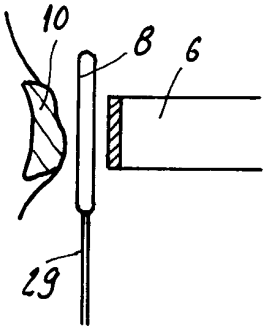



FIG 21

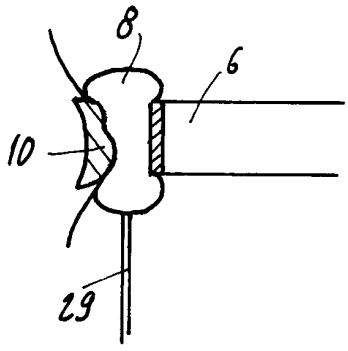


FIG 22

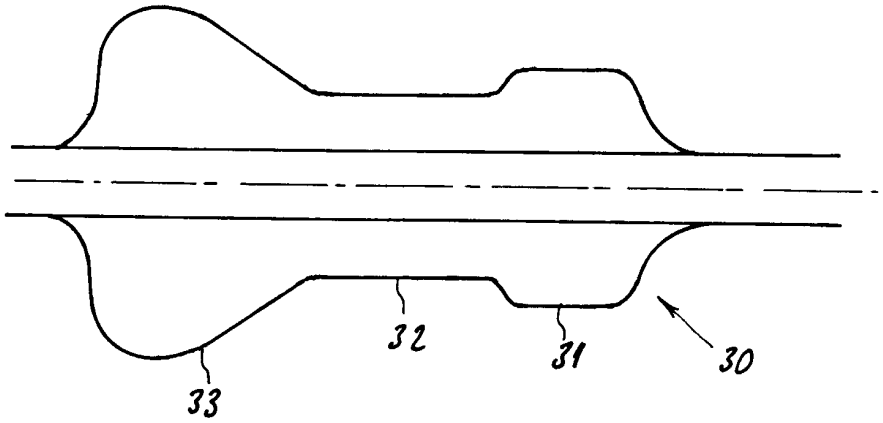



FIG 23

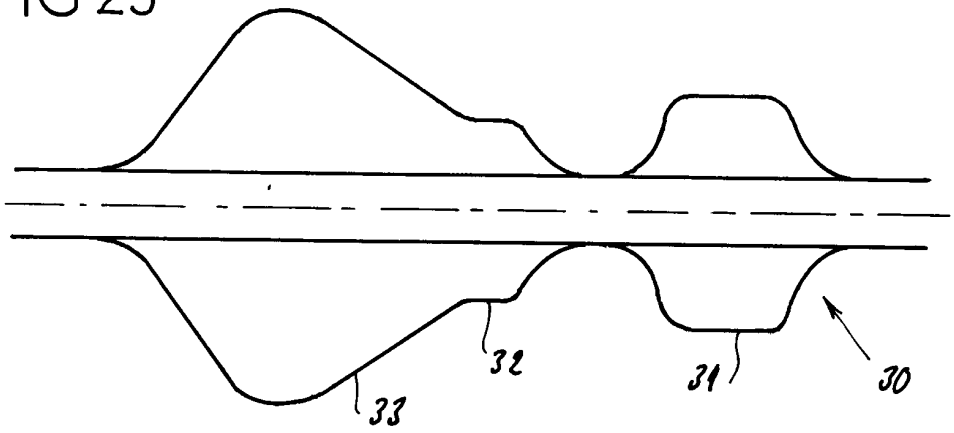
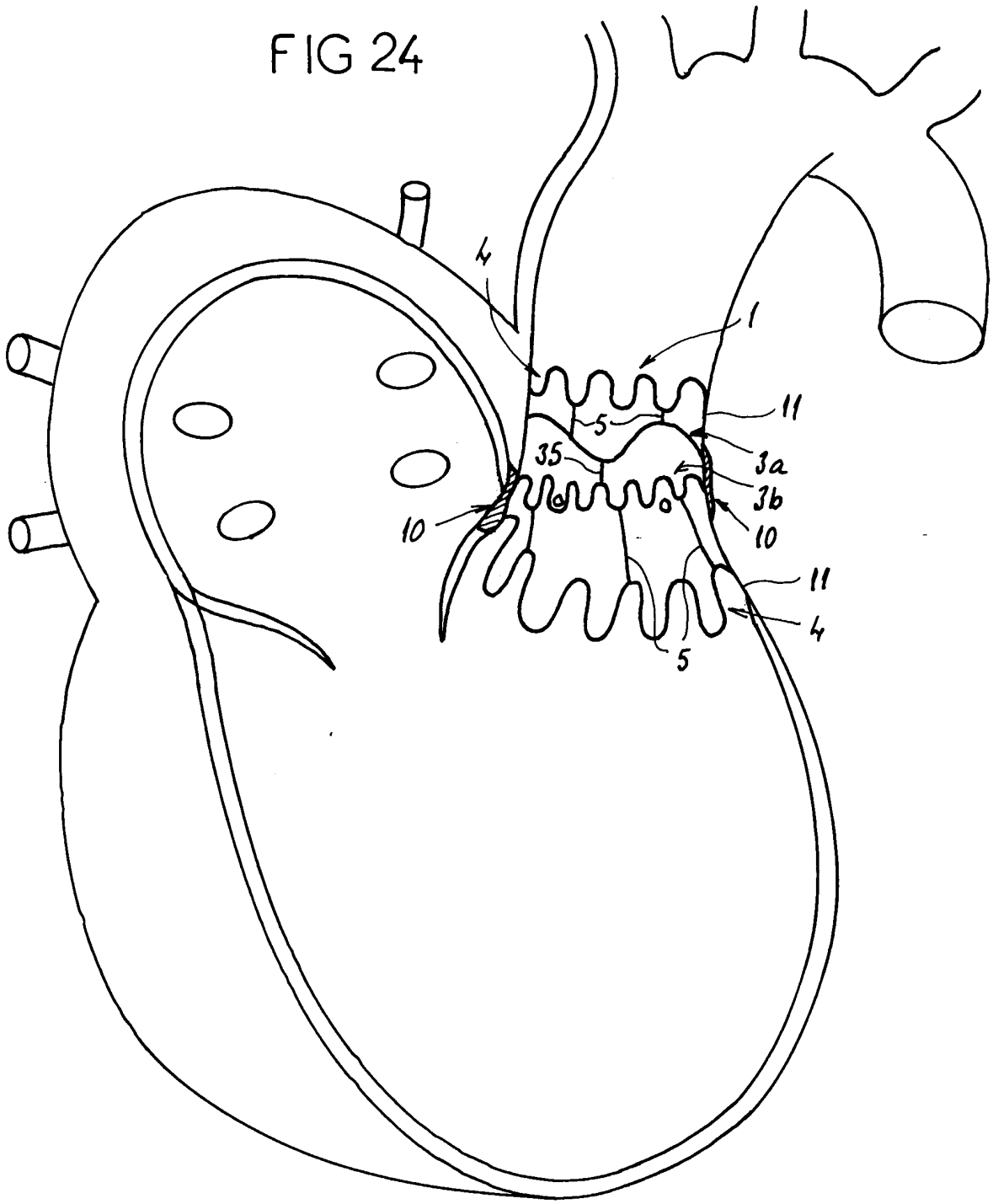


FIG 24



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# RAPPORT DE RECHERCHE PRÉLIMINAIRE

établi sur la base des dernières revendications déposées avant le commencement de la recherche

N° d'enregistrement national

FA 593994
FR 0014028

| DOCUMENTS CONSIDÉRÉS COMME PERTINENTS | | Revendication(s) concernée(s) | Classement attribué à l'invention par l'INPI |
|---|---|---|---|
| Catégorie | Citation du document avec indication, en cas de besoin, des parties pertinentes | | |
| A | US 5 957 949 A (LEONHARDT ET AL)<br>28 septembre 1999 (1999-09-28)<br>* le document en entier *<br>--- | 1,17 | A61F2/24 |
| A | US 5 855 601 A (BESSLER ET AL)<br>5 janvier 1999 (1999-01-05)<br>----- | | |

DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7)

A61F

| Date d'achèvement de la recherche | Examinateur |
|---|---|
| 24 juillet 2001 | Smith, C |

CATÉGORIE DES DOCUMENTS CITÉS

X : particulièrement pertinent à lui seul
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E : document de brevet bénéficiant d'une date antérieure à la date de dépôt et qui n'a été publié qu'à cette date de dépôt ou qu'à une date postérieure.
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## (54) Repositionable heart valve

(57) An apparatus is described for endovascularly replacing a patient's heart valve comprising: a replacement valve; an anchor; and a deployment tool comprising a plurality of anchor actuation elements adapted to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor to reshape the anchor, wherein the anchor actuation elements comprise a plurality of proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

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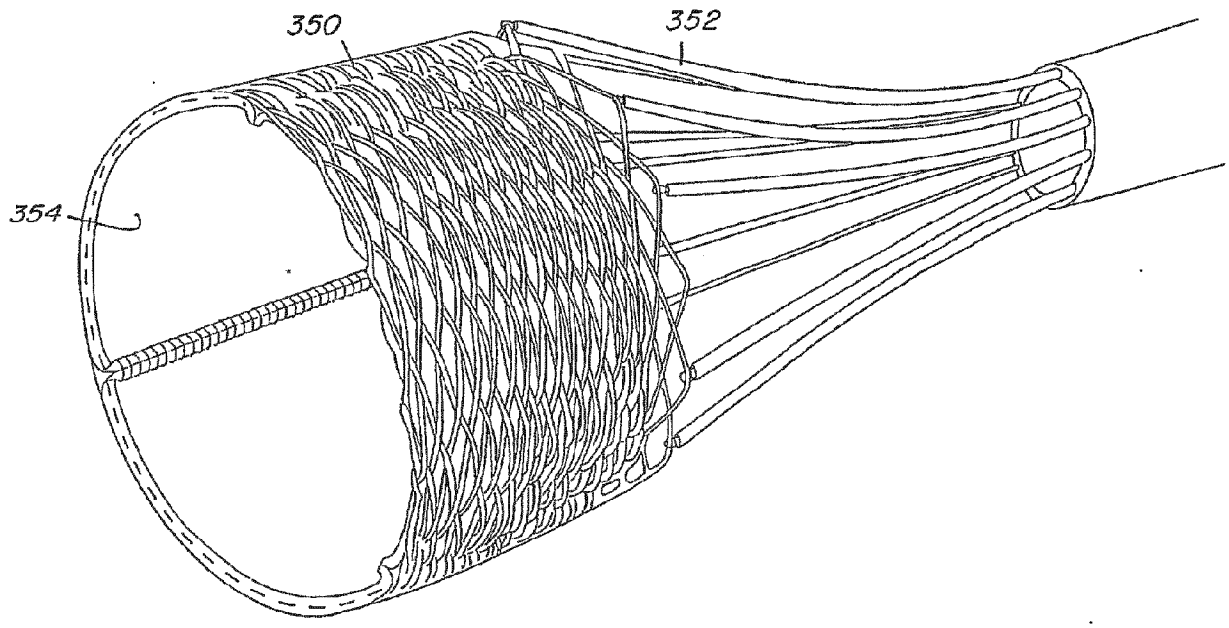


FIG. 24



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## Description

BACKGROUND OF THE INVENTION

**[0001]** The present invention relates to methods and apparatus for endovascularly replacing a heart valve. More particularly, the present invention relates to methods and apparatus for percutaneously replacing a heart valve with a replacement valve using an expandable and retrievable anchor.

**[0002]** Heart valve surgery is used to repair or replace diseased heart valves. Valve surgery is an open-heart procedure conducted under general anesthesia. An incision is made through the patient's sternum (sternotomy), and the patient's heart is stopped while blood flow is rerouted through a heart-lung bypass machine.

**[0003]** Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates.

**[0004]** When replacing the valve, the native valve is excised and replaced with either a biologic or a mechanical valve. Mechanical valves require lifelong anticoagulant medication to prevent blood clot formation, and clicking of the valve often may be heard through the chest. Biologic tissue valves typically do not require such medication. Tissue valves may be obtained from cadavers or may be porcine or bovine, and are commonly attached to synthetic rings that are secured to the patient's heart.

**[0005]** Valve replacement surgery is a highly invasive operation with significant concomitant risk. Risks include bleeding, infection, stroke, heart attack, arrhythmia, renal failure, adverse reactions to the anesthesia medications, as well as sudden death. 2-5% of patients die during surgery.

**[0006]** Post-surgery, patients temporarily may be confused due to emboli and other factors associated with the heart-lung machine. The first 2-3 days following surgery are spent in an intensive care unit where heart functions can be closely monitored. The average hospital stay is between 1 to 2 weeks, with several more weeks to months required for complete recovery.

**[0007]** In recent years, advancements in minimally invasive surgery and interventional cardiology have encouraged some investigators to pursue percutaneous replacement of the aortic heart valve. Percutaneous Valve Technologies ("PVT") of Fort Lee, New Jersey, has developed a balloon-expandable stent integrated with a bioprosthetic valve. The stent/valve device is deployed across the native diseased valve to permanently hold the valve open, thereby alleviating a need to excise the native valve and to position the bioprosthetic valve in place of the native valve. PVT's device is designed for delivery in a cardiac catheterization laboratory under local anesthesia using fluoroscopic guidance, thereby avoiding general anesthesia and open-heart surgery. The device was first implanted in a patient in April of 2002.

**[0008]** PVT's device suffers from several drawbacks. Deployment of PVT's stent is not reversible, and the stent is not retrievable. This is a critical drawback because improper positioning too far up towards the aorta risks blocking the coronary ostia of the patient. Furthermore, a misplaced stent/valve in the other direction (away from the aorta, closer to the ventricle) will impinge on the mitral apparatus and eventually wear through the leaflet as the leaflet continuously rubs against the edge of the stent/valve.

**[0009]** Another drawback of the PVT device is its relatively large cross-sectional delivery profile. The PVT system's stent/valve combination is mounted onto a delivery balloon, making retrograde delivery through the aorta challenging. An antegrade transseptal approach may therefore be needed, requiring puncture of the septum and routing through the mitral valve, which significantly increases complexity and risk of the procedure. Very few cardiologists are currently trained in performing a transseptal puncture, which is a challenging procedure by itself.

**[0010]** Other prior art replacement heart valves use self-expanding stents as anchors. In the endovascular aortic valve replacement procedure, accurate placement of aortic valves relative to coronary ostia and the mitral valve is critical. Standard self-expanding systems have very poor accuracy in deployment, however. Often the proximal end of the stent is not released from the delivery system until accurate placement is verified by fluoroscopy, and the stent typically jumps once released. It is therefore often impossible to know where the ends of the stent will be with respect to the native valve, the coronary ostia and the mitral valve.

**[0011]** Also, visualization of the way the new valve is functioning prior to final deployment is very desirable. Visualization prior to final and irreversible deployment cannot be done with standard self-expanding systems, however, and the replacement valve is often not fully functional before final deployment.

**[0012]** Another drawback of prior art self-expanding replacement heart valve systems is their lack of radial strength. In order for self-expanding systems to be easily delivered through a delivery sheath, the metal needs to flex and bend inside the delivery catheter without being plastically deformed. In arterial stents, this is not a challenge, and there are many commercial arterial stent systems that apply adequate radial force against the vessel wall and yet can collapse to a small enough of a diameter to fit inside a delivery catheter without plastically deforming.

**[0013]** However when the stent has a valve fastened inside it, as is the case in aortic valve replacement, the anchoring of the stent to vessel walls is significantly challenged during diastole. The force to hold back arterial pressure and prevent blood from going back inside the ventricle during diastole will be directly transferred to the stent/vessel wall interface. Therefore the amount of radial force required to keep the self expanding stent/valve in contact with the vessel wall and not sliding will be much



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higher than in stents that do not have valves inside of them. Moreover, a self-expanding stent without sufficient radial force will end up dilating and contracting with each heartbeat, thereby distorting the valve, affecting its function and possibly migrating and dislodging completely. Simply increasing strut thickness of the self-expanding stent is not a practical solution as it runs the risk of larger profile and/or plastic deformation of the self-expanding stent.

**[0014]** U.S. patent application Serial No. 2002/0151-970 to Garrison et al. describes a two-piece device for replacement of the aortic valve that is adapted for delivery through a patient's aorta. A stent is percutaneously placed across the native valve, then a replacement valve is positioned within the lumen of the stent. By separating the stent and the valve during delivery, a profile of the device's delivery system may be sufficiently reduced to allow aortic delivery without requiring a transseptal approach. Both the stent and a frame of the replacement valve may be balloon-expandable or self-expanding.

**[0015]** While providing for an aortic approach, devices described in the Garrison patent application suffer from several drawbacks. First, the stent portion of the device is delivered across the native valve as a single piece in a single step, which precludes dynamic repositioning of the stent during delivery. Stent foreshortening or migration during expansion may lead to improper alignment.

**[0016]** Additionally, Garrison's stent simply crushes the native valve leaflets against the heart wall and does not engage the leaflets in a manner that would provide positive registration of the device relative to the native position of the valve. This increases an immediate risk of blocking the coronary ostia, as well as a longer-term risk of migration of the device post-implantation. FurtherstiU, the stent comprises openings or gaps in which the replacement valve is seated post-delivery. Tissue may protrude through these gaps, thereby increasing a risk of improper seating of the valve within the stent.

**[0017]** In view of drawbacks associated with previously known techniques for percutaneously replacing a heart valve, it would be desirable to provide methods and apparatus that overcome those drawbacks.

## SUMMARY OF THE INVENTION

**[0018]** One aspect of the invention provides a method for endovascularly replacing a heart valve of a patient. In some embodiments the method includes the steps of endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; expanding the anchor to a deployed configuration in which the anchor contacts tissue at an anchor site; repositioning the anchor in the anchor site; and deploying the anchor at the anchor site. The repositioning step may include the step of contracting the anchor and re-expanding the anchor at the anchor site for finer repositioning. The contracting step may include the step of applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

**[0019]** In another aspect of the invention provides a method for endovascularly replacing a heart valve of a patient. In some embodiments the method includes the steps of endovascularly or percutaneously delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; expanding the anchor to a deployed configuration in which the anchor contacts tissue at a first anchor site; repositioning the anchor to a second anchor site; and deploying the anchor at the second anchor site. The repositioning step may include the step of contracting the anchor and reexpanding the anchor at the second anchor site. The contracting step may includes the step of applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

**[0020]** In some embodiments the deploying step includes the step of releasing the anchor from a deployment tool. The delivering step may include the step of delivering the replacement heart valve coupled to the anchor or, alternatively, separate from the anchor, in which case the method further includes the step of attaching the replacement valve to the anchor.

**[0021]** In instances in which the heart valve is an aortic valve, the delivering step may include the step of endovascularly or percutaneously delivering the expandable anchor and replacement valve to the vicinity of the aortic valve along a retrograde approach.

**[0022]** In some embodiments the deploying step may include the step of expanding a balloon within the anchor, and in some embodiments the deploying step may include the step of locking the anchor in an expanded configuration. Proximal and distal regions of the anchor may be expanded separately.

**[0023]** The invention may also include the step of registering the anchor with the first or second anchor site, such as by contacting tissue of the heart valve to resist movement of the anchor in at least a proximal or a distal direction prior to deploying the anchor.

**[0024]** Another aspect of the invention provides a method for percutaneously replacing a heart valve of a patient. The method includes the steps of percutaneously delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; expanding the anchor to an expanded configuration in which the anchor contacts tissue at an anchor site, such as first a force of at least one pound; visually observing the anchor location; and releasing the anchor from a deployment tool. The replacement valve may be delivered coupled to the anchor or separate from the anchor, in which case the method also includes the step of attaching the valve to the anchor.

**[0025]** In some embodiments the method further includes the step of repositioning the anchor to a second anchor site after the observing step and before the releasing step. In some embodiments the expanding step includes the step of applying an external non-hydraulic or non-pneumatic actuation force on the anchor, and in



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some embodiments the method further includes the step of expanding a balloon within the anchor after the observing step. The method may include the step of registering the anchor with the anchor site.

**[0026]** One aspect of the present invention provides an apparatus for endovascularly replacing a patient's native heart valve. The apparatus comprises an anchor having an expandable braid and a replacement valve adapted to be secured within the patient. In some embodiments, the expandable braid of the anchor is fabricated from a single strand of wire. In some embodiments, the expandable braid comprises at least one edge feature. The anchor and the replacement valve preferably are configured for endovascular delivery and deployment.

**[0027]** The present invention relates to an apparatus for replacing a patient's native heart valve. The apparatus comprises an anchor having an expandable braid adapted for endovascular delivery. The anchor is further adapted for expansion via active foreshortening at an anchor site within the native valve. The apparatus also includes a replacement valve adapted to be secured within the patient. In some embodiments, the anchor braid is further adapted to remain substantially undeformed in response to a pressure up to 0.5 arm or 2 arm directed substantially radially inward toward the central axis. In some embodiments, the anchor braid comprises a first region and a second region having a diameter larger than a diameter of the first region when the anchor is expanded. In some embodiments, the anchor braid is configured to have an expanded shape that is radially symmetrical, bilaterally symmetrical, or asymmetrical. In some embodiments, the anchor comprises first and second wires, the first wire having a diameter smaller than a diameter of the second wire. In some embodiments, the anchor comprises first and second wires formed from different materials. In some embodiments, the anchor has a collapsed delivery configuration, an at-rest configuration and an expanded deployed configuration.

**[0028]** In some embodiments, the apparatus herein further comprises a lock or a plurality of locks configured to maintain expansion of the braid. In some embodiments, the apparatus herein further comprises a valve support adapted to support the replacement valve within the anchor. In some embodiments, the anchor herein comprises a distal deployment system interface at a distal end of the anchor, the distal deployment system interface being adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor. In some embodiments, the anchor comprises a proximal deployment system interface at a proximal end of the anchor, the proximal deployment system interface being adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor.

**[0029]** One aspect of the present invention provides methods for replacing a native aortic valve. Such methods involve endovascularly delivering a replacement valve and an anchor having an expandable braid. Delivery is preferably made to a site within the native aortic valve. Delivery is preferably made by actively foreshortening the anchor to radially expand the anchor to an expanded shape to secure the anchor at the anchor site. In some embodiments, the methods further include the step of locking the anchor in an expanded shape. In some embodiments, the methods include expanding a first step region of the anchor to a first diameter and a second region of the anchor to a second diameter larger than the first diameter.

**[0030]** In some embodiments, the foreshortening step of the methods herein comprises actively foreshortening the anchor to radially expand the anchor to an expanded shape to secure the anchor at the anchor site while avoiding interference with a mitral valve. In some embodiments, the foreshortening step comprises actively foreshortening the anchor to radially expand the anchor to a radially symmetrical expanded shape, a bilaterally symmetrical expanded shape or an asymmetrical expanded shape.

**[0031]** In some embodiments, the anchor is allowed to self-expand prior to the foreshortening step. In some embodiments, the foreshortening step comprises applying a proximally directed force on a deployment system interface at a proximal end or a distal end of the anchor. In some embodiments, the foreshortening step comprises applying a distally directed force on a deployment system interface at a proximal end of the anchor.

**[0032]** The present invention relates to an apparatus for replacing a native aortic valve, the apparatus includes an expandable anchor adapted to be endovascularly delivered and secured at a site within the native aortic valve. The expandable anchor has a delivery length in a delivery configuration substantially greater than a deployed length in a deployed configuration. The apparatus may also include and a replacement valve configured to be secured within the anchor.

**[0033]** In some embodiments, the delivery length is between about 15 mm and about 150 mm and the deployed length is between about 5 mm and about 40 mm. In some embodiments, the apparatus has a ratio of delivery length to deployed length that is between about 0.05 and about 0.5; between about 0.1 and about 0.35; or between about 0.15 and about 0.25. hi some embodiments, the apparatus herein includes an anchor that has an at-rest configuration and wherein the anchor includes a shape memory material that is heat set in the at-rest configuration. The at-rest configuration may have a length between the delivery length and the deployed length.

**[0034]** In some embodiments, the apparatus herein has an anchor that is configured for active foreshortening during endovascular deployment. The apparatus may also include a lock or a plurality of locks configured to maintain expansion of the anchor. The lock(s) may also be configured to maintain expansion of the anchor at a plurality of amounts of expansion, thereby conferring non cylindrical shapes to the apparatus.

**[0035]** In any of the embodiments herein, the apparatus may further include a valve support adapted to sup-



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port the replacement valve within the anchor. The valve support may also include a lock that is an extension of the valve support.

**[0036]** In any of the embodiments herein, the apparatus may include a distal deployment system interface disposed at a distal end of the anchor, the distal deployment system interface being adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor. The distal deployment system interface may further be adapted to expand radially during application of a proximally directed force on the distal end of the anchor. The distal deployment system interface may further be adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor without passing any portion of a deployment system through a center opening of the replacement valve.

**[0037]** In some embodiments, the apparatus herein may include an anchor, wherein the anchor includes a proximal deployment system interface at a proximal end of the anchor, the proximal deployment system interface being adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor. The proximal deployment system interface may further be adapted to expand radially during application of a distally directed force on the proximal end of the anchor. The proximal deployment system interface may further be adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor through a plurality of deployment system fingers.

**[0038]** The invention provides apparatus and methods for endovascularly replacing a patient's heart valve. One aspect of the invention provides an apparatus including: an expandable anchor with a lip region and a skirt region; and a replacement valve, wherein the lip region and skirt region are configured for percutaneous expansion (e.g., independent expansion or concurrent expansion) to engage leaflets of the heart valve. The lip and/or skirt regions may be adapted to preclude migration of the apparatus post-deployment and expansion. Expansion of the anchor and replacement valve may be by balloon-expansion, self-expansion, and combinations thereof. A locking element may be provided to maintain expansion.

**[0039]** The invention also includes a delivery system that facilitates deployment and expansion of the apparatus to endovascularly replace the heart valve and, in some embodiments, retrieve the apparatus.

**[0040]** Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering apparatus having an anchor having lip and skirt regions, and a replacement valve coupled to the anchor, to a vicinity of the heart valve in a collapsed delivery configuration; and expanding the apparatus such that leaflets of the heart valve are captured between the lip and skirt regions of the anchor. The expanding step of the method may include the step of dynamically repositioning the apparatus relative to the heart valve prior to capturing the leaflets. The expanding step may also include the steps of expanding either the lip region or the skirt region, positively engaging the heart valve with the expanded lip or skirt region, and then expanding the unexpanded region. The apparatus may be retrieved, repositioned and redeployed, and the apparatus may be locked in its expanded configuration.

**[0041]** One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve. The apparatus includes: an expandable anchor and a replacement valve, wherein both are adapted for percutaneous delivery and deployment. The expandable anchor further includes a leaflet engagement element on its proximal end to engage the leaflets of the patient's heart valve. When the leaflets engagement element is engaged, the anchor is substantially distal to the coronary ostia of the patient. Moreover, once engaged, the leaflet engagement element prevents the distal movement of the anchor. In some embodiments, the leaflet engagement element is integral with the anchor or part of the anchor (especially when the anchor is an anchor braid). In other embodiments, the leaflet engagement element is attached to the proximal end of the anchor. In any of the embodiments herein, the anchor may be adapted for active foreshortening during deployment. Active foreshortening can occur by actuating the proximal and/or distal actuation elements of the anchor. The anchor herein may also be configured for locking and may include a locking element. The replacement valve of the apparatus herein is situated within the anchor and is adapted to permit blood flow and prevent blood backflow both during and after deployment.

**[0042]** Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering an anchor comprising a leaflet engagement element on its proximal end and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration; unsheathing the anchor allowing it to take a relaxed configuration intermediate between its sheathed and expanded configurations; expanding the anchor; and, engaging the leaflet engagement element with the native leaflets. The expanding step may further comprise actively foreshortening the anchor. Active foreshortening can include actuating proximal and/or distal actuation elements of the anchor. The method may also include the step of locking the anchor after it is in its deployed configuration. In some embodiments, when the anchor engages the patient's heart, the anchor is substantially distal to the coronary ostia. In any of the embodiments herein, leaflet engagement element prevents the anchor from distally migrating at its proximal end.

**[0043]** One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve. The apparatus includes: an expandable anchor and a replacement valve, wherein both are adapted for percutaneous delivery and deployment. The expandable an-



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chor further includes a leaflet engagement element on its proximal end to engage the leaflets of the patient's heart valve. When the leaflets engagement element is engaged, the anchor is substantially distal to the coronary ostia of the patient. Moreover, once engaged, the leaflet engagement element prevents the distal movement of the anchor. In some embodiments, the leaflet engagement element is integral with the anchor or part of the anchor (especially when the anchor is an anchor braid). In other embodiments, the leaflet engagement element is attached to the proximal end of the anchor. In any of the embodiments herein, the anchor may be adapted for active foreshortening during deployment. Active foreshortening can occur by actuating the proximal and/or distal actuation elements of the anchor. The anchor herein may also be configured for locking and may include a locking element. The replacement valve of the apparatus herein is situated within the anchor and is adapted to permit blood flow and prevent blood backflow both during and after deployment.

**[0044]** Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering an anchor comprising a leaflet engagement element on its proximal end and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration; unsheathing the anchor allowing it to take a relaxed configuration intermediate between its sheathed and expanded configurations; expanding the anchor; and, engaging the leaflet engagement element with the native leaflets. The expanding step may further comprise actively foreshortening the anchor. Active foreshortening can include actuating proximal and/or distal actuation elements of the anchor. The method may also include the step of locking the anchor after it is in its deployed configuration. In some embodiments, when the anchor engages the patient's heart, the anchor is substantially distal to the coronary ostia. In any of the embodiments herein, leaflet engagement element prevents the anchor from distally migrating at its proximal end.

**[0045]** The invention includes methods of and apparatus for endovascularly replacing a heart valve of a patient. One aspect of the invention provides a method including the steps of endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; and applying an external non-hydraulic or non-pneumatic actuation force on the anchor to change the shape of the anchor, such as by applying proximally and/or distally directed force on the anchor using a releasable deployment tool to expand and contract the anchor or parts of the anchor. The method may also include the step of applying a radially outwardly directed force comprises expanding a balloon within the anchor, such as by expanding a balloon. The anchor may be locked in its expanded configuration.

**[0046]** Some embodiments of the method may include the step of registering the anchor with an anatomical landmark in an anchor location and deploying the anchor at the anchor location, such as by contacting tissue of the heart valve (e.g., a native valve leaflet) to resist movement of the anchor in at least a proximal or a distal direction prior to deploying the anchor.

**[0047]** Another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a replacement valve; an anchor; and a deployment tool adapted to apply a non-hydraulic or non-pneumatic actuation force on the anchor to reshape the anchor, such as a proximally or distally directed force to expand or contract regions of the anchor. The deployment tool may be releasable. An anchor lock may be provided to lock the anchor in a deployed configuration, and there may also be a lock prevention element actuatable from outside the patient.

**[0048]** The apparatus may also include a registration element adapted, e.g., to extend radially outward from the anchor to entrap at least part of the heart valve.

**[0049]** Another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: an anchor having a collapsed delivery configuration and an expanded deployed configuration; and a replacement valve coupled to the anchor, wherein the anchor comprises enhanced radial strength in the expanded deployed configuration as compared to the collapsed delivery configuration due to imposed foreshortening. The apparatus may include a locking mechanism for maintaining imposed foreshortening, and it may be configured for retrieval prior to actuation of the locking mechanism. The apparatus may also include a delivery system configured for percutaneous delivery, deployment and foreshortening of the anchor.

**[0050]** In some embodiments the anchor is at least partially covered by a biocompatible film and perhaps an element configured to reduce paravalvular leakage or regurgitation.

**[0051]** Yet another aspect of the invention provides a method for endovascularly replacing a patient's heart valve, h some embodiments the method includes the steps of: providing apparatus comprising an expandable anchor having a replacement valve coupled thereto; endovascularly delivering the apparatus to a vicinity of the heart valve in a collapsed delivery configuration; expanding the apparatus to a partially deployed configuration; and actively foreshortening the anchor to a fully deployed configuration comprising enhanced radial strength, such that the anchor displaces the patient' s heart valve, and the replacement valve regulates blood flow.

**[0052]** Still another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, with the apparatus including: an anchor; a replacement valve coupled to the anchor; and a delivery system, wherein the delivery system is configured to retrieve the anchor and replacement valve post-deployment. The delivery system may also be further configured for percutaneous delivery, deployment and foreshortening of the anchor.



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**[0053]** The invention includes methods of and apparatus for endovascularly replacing a heart valve of a patient. One aspect of the invention provides a method including the steps of" endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; and applying an external non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor through a plurality of anchor actuation elements to change the shape of the anchor, such as by applying a proximally and/or distally directed force on the anchor through anchor actuation elements to change the shape of the anchor. The anchor may be locked in its expanded configuration.

**[0054]** Another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a replacement valve; an anchor; and a deployment tool comprising a plurality of anchor actuation elements adapted to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor to reshape the anchor. An anchor lock may be provided to lock the anchor in a deployed configuration, and there may also be a lock prevention element actuatable from outside the patient. Optionally, the anchor lock may be reversible.

**[0055]** Other aspects of the invention include methods and apparatuses for endovascularly, percutaneously and/or endoscopically delivering and deploying expandable devices in a patient and optionally detaching a deployment tool from the device.

**[0056]** One aspect of the invention provides a method for endovascularly replacing a heart valve of a patient. In some embodiments the method includes the steps of: endovascularly delivering a replacement valve and an expandable anchor in an unexpanded configuration within a catheter to a vicinity of the heart valve; deploying the anchor from the catheter; expanding the anchor to contact tissue at an anchor site; and retrieving the anchor into the catheter. Expansion of the anchor may include application of an actuation force on the anchor, such as a proximally or distally directed force, to expand or contract at least a region of the anchor.

**[0057]** Another aspect of the invention provides an apparatus for endovascularly replacing a heart valve, including: a catheter; a replacement valve configured to be disposed within the catheter for delivery to a vicinity of the heart valve; and an expandable anchor configured to be disposed within the catheter for delivery to a vicinity of the heart valve, to be deployed from the catheter, to be expanded to contact tissue at an anchor site and to be retrieved back into the catheter after having been expanded. The apparatus may also include a deployment tool configured to apply an actuation force to the anchor - such as a proximally or distally directed force - when the anchor is in the vicinity of the heart valve.

**[0058]** The invention includes methods of and apparatus for endovascularly replacing a heart valve of a patient. One aspect of the invention provides a method for endovascularly replacing a patient's heart valve, including the steps of: endovascularly delivering a replacement valve and an expandable anchor in an unexpanded configuration within a sheath to a vicinity of the heart valve; deploying the anchor from the sheath; expanding the anchor with a deployment tool comprising a plurality of actuation elements to contact tissue at an anchor site; and retrieving the anchor into the sheath.

**[0059]** Another aspect of the invention provides apparatus for endovascularly replacing a patient's heart valve, including: a sheath; a deployment tool comprising a plurality of anchor actuation elements; a replacement valve configured to be disposed within the sheath for delivery to a vicinity of the heart valve; and an expandable anchor configured to be disposed within the sheath for delivery to the vicinity of the heart valve, to be deployed from the sheath, to be expanded by the deployment tool to contact tissue at an anchor site and to be retrieved back into the sheath after having been expanded.

**[0060]** Other aspects of the invention include methods and apparatuses for endovascularly, percutaneously and/or endoscopically delivering, deploying and optionally retrieving expandable devices into and from a patient.

**[0061]** One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a delivery catheter having a diameter of 21 french or less; an expandable anchor disposed within the delivery catheter; and a replacement valve disposed within the delivery catheter. The replacement valve may be coupled to the anchor within the catheter, and the catheter may be adapted to deliver the anchor and replacement valve to an aortic valve along a retrograde approach. The apparatus may also include a deployment tool coupled to the anchor within the catheter and an expandable balloon disposed within the delivery catheter, the balloon being adapted to expand the anchor. In some embodiments the balloon is disposed within the catheter apart from the anchor and the replacement valve.

**[0062]** Another aspect of the invention provides a method for endovascularly replacing a heart valve of a patient. In some embodiments the method includes the steps of: inserting a catheter having a diameter no more than 21 french into the patient; endovascularly delivering a replacment valve and an expandable anchor to a vicinity of the heart valve through the catheter; and deploying the anchor and the replacement valve. In embodiments in which the heart valve is an aortic valve, the inserting step may include the step of inserting the catheter to the vicinity of the aortic valve along a retrograde approach. The method's deploying step may include the steps of endovascularly delivering an anchor deployment tool through the catheter and actuating the anchor with the deployment tool, such as by applying proximally or distally directed forces on the anchor. The method may also include the steps of endovascularly delivering an expandable balloon through the catheter to the vicinity of the heart valve and using the balloon to expand the anchor.



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The balloon may be delivered apart from the anchor. The anchor may be retrieved back into the catheter after having been expanded.

**[0063]** One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a replacement valve adapted to be delivered endovascularly to a vicinity of the heart valve; an expandable anchor adapted to be delivered endovascularly to the vicinity of the heart valve; and a lock mechanism configured to maintain a minimum amount of anchor expansion. The lock mechanism may include first and second mating interlocking elements. An actuator may be provided to apply an actuation force on the anchor.

**[0064]** Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; expanding the anchor to a deployed configuration; and locking the anchor in the deployed configuration.

**[0065]** Yet another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: an anchor comprising a lip region and a skirt region; a replacement valve coupled to the anchor; and a lock, wherein the lip region and skirt region are configured for percutaneous expansion to engage the patient's heart valve, and wherein the lock is configured to maintain such expansion.

**[0066]** One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a custom-designed anchor; and a replacement valve, wherein the custom-designed anchor is adapted to engage native leaflets of the heart valve, and wherein the anchor and the valve are adapted for in vivo expansion and coupling to one another to form composite apparatus that endovascularly replaces the heart valve.

**[0067]** Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: providing apparatus comprising an anchor piece and a replacement valve piece; endovascularly delivering the anchor piece to a vicinity of the heart valve in a collapsed delivery configuration; expanding the anchor piece to a deployed configuration; engaging at least one valve leaflet of the heart valve with the anchor piece; endovascularly delivering the replacement valve piece to the vicinity of the heart valve in a collapsed delivery configuration; expanding the replacement valve piece to a deployed configuration; and coupling the valve piece to the anchor piece in vivo to form composite two-piece apparatus that endovascularly replaces the patient's heart valve.

**[0068]** Yet another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: an anchor having a first portion of an alignment/locking mechanism; and a replacement valve having a second portion of the alignment/locking mechanism, wherein the anchor and the valve are adapted for in vivo expansion and coupling to one another to form composite apparatus that endovascularly replaces the patient's heart valve.

**[0069]** Still another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of:

endovascularly delivering an anchor piece having a first portion of an alignment/locking mechanism to a vicinity of the heart valve in a collapsed delivery configuration; expanding the anchor piece to a deployed configuration such that the anchor piece displaces the patient's heart valve; endovascularly delivering a replacement valve piece having a second portion of the alignment/locking mechanism to the vicinity of the heart valve in a collapsed delivery configuration; expanding the replacement valve piece to a deployed configuration; and coupling the valve piece to the anchor piece in vivo by securing the first and second portions of the alignment/locking mechanism to one another, thereby forming composite two-piece apparatus that endovascularly replaces the patient's heart valve.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0070]**

Figures 1A-B are elevational views of a replacement heart valve and anchor according to one embodiment of the invention.

Figures 2A-B are sectional views of the anchor and valve of Figures 1.

Figures 3A-B show delivery and deployment of a replacement heart valve and anchor, such as the anchor and valve of Figures 1 and 2.

Figures 4A-F also show delivery and deployment of a replacement heart valve and anchor, such as the anchor and valve of Figures 1 and 2.

Figures 5 A-I show the use of a replacement heart valve and anchor to replace an aortic valve.

Figures 6A-F show the use of a replacement heart valve and anchor with a positive registration feature to replace an aortic valve.

Figure 7 shows the the use of a replacement heart valve and anchor with an alternative positive registration feature to replace an aortic valve.

Figures 8A-C show another embodiment of a replacement heart valve and anchor according to the invention.

Figures 9A-H show delivery and deployment of the replacement heart valve and anchor of Figures 8.

Figure 10 is a cross-sectional drawing of the delivery system used with the method and apparatus of Figures 8 and 9.

Figures 11A-C show alternative locks for use with replacement heart valves and anchors of this inven-



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tion.

Figures 12 A-C show a vessel wall engaging lock for use with replacement heart valves and anchors of this invention.

Figure 13 demonstrates paravalvular leaking around a replacement heart valve and anchor.

Figure 14 shows a seal for use with a replacement heart valve and anchor of this invention.

Figures 15A-E show alternative arrangements of seals on a replacement heart valve and anchor.

Figures 16 A-C show alternative seal designs for use with replacement heart valves and anchors.

Figures 17 A-B show an alternative anchor lock embodiment in an unlocked configuration.

Figures 18 A-B show the anchor lock of Figure 17 in a locked configuration.

Figure 19 shows an alternative anchor deployment tool attachment and release mechanism for use with the invention.

Figure 20 shows the attachment and release mechanism of Figure 19 in the process of being released.

Figure 21 shows the attachment and release mechanism of Figures 19 and 20 in a released condition.

Figure 22 shows an alternative embodiment of a replacement heart valve and anchor and a deployment tool according to the invention in an undeployed configuration.

Figure 23 shows the replacement heart valve and anchor of Figure 22 in a partially deployed configuration.

Figure 24 shows the replacement heart valve and anchor of Figures 22 and 23 in a more fully deployed configuration but with the deployment tool still attached.

Figure 25 shows yet another embodiment of the delivery and deployment apparatus of the invention in use with a replacement heart valve and anchor.

Figure 26 shows the delivery and deployment apparatus of Figure 25 in the process of deploying a replacement heart valve and anchor.

Figure 27 shows an embodiment of the invention employing seals at the interface of the replacement heart valve and anchor and the patient's tissue.

Figure 28 is a longitudinal cross-sectional view of the seal shown in Figure 27 in compressed form.

Figure 29 is a transverse cross-sectional view of the seal shown in Figure 28.

Figure 30 is a longitudinal cross-sectional view of the seal shown in Figure 27 in expanded form.

Figure 31 is a transverse cross-sectional view of the seal shown in Figure 30.

Figure 32 shows yet another embodiment of the replacement heart valve and anchor of this invention in an undeployed configuration.

Figure 33 shows the replacement heart valve and anchor of Figure 32 in a deployed configuration.

Figure 34 shows the replacement heart valve and anchor of Figures 32 and 33 deployed in a patient's heart valve.

Figures 35A-H show yet another embodiment of a replacement heart valve, anchor and deployment system according to this invention.

Figures 36A-E show more detail of the anchor of the embodiment shown in Figures 35A-H.

Figures 37A-B show further details of the embodiment of Figures 35A-H.

Figures 38A-C illustrate a method for percutaneously replacing a patient's diseased heart valve.

Figures 39A-B show an anchor for use in a two-piece replacement heart valve and anchor embodiment of the invention.

Figures 40A-B show a replacement heart valve for use in a two-piece replacement heart valve and anchor embodiment of the invention.

Figures 41A-D show a method of coupling the anchor of Figures 39 and the replacement heart valve of Figures 40.

Figure 42 shows a delivery system for use with the appartus shown in Figures 39-41.

Figure 43 shows an alternative embodiment of a delivery system for use with the apparatus shown in Figures 39-41.

Figure 44 shows yet another alternative embodiment of a delivery system for use with the apparatus shown in Figures 39-41.

Figures 45 A-I illustrate a method of deliverying and deploying a two-piece replacement heart valve and anchor.

Figures 46A-B shows another embodiment of a two-piece replacement heart valve and anchor according to this invention.

Figure 47 shows yet another embodiment of a two-piece replacement heart valve and anchor according to this invention.

Figure 48 shows yet another embodiment of a two-piece replacement heart valve and anchor according to this invention.

Figures 49A and 49B show replacement valve apparatus in accordance with the present invention. Figure 49 illustrates the apparatus in a collapsed delivery configuration within a delivery system. Figure 49B illustrates the apparatus in an expanded configuration partially deployed from the delivery system.

Figures 50A-50F show an anchor of the apparatus of Figures 49 in the collapsed delivery configuration and the expanded deployed configuration, as well as the full apparatus in the deployed configuration, and optional locking mechanisms for use with the apparatus.

Figure 51 shows a detail view of a variation of an anchor post.

Figures 52A and 52B show an alternative variation of the post having a lock alignment feature.

Figures 53A and 53B show a variation of the post having an alternative lock alignment feature.

Figure 54 shows a variation of the post having an



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expansile element.

Figure 55 shows a variation of the post with an alternative expansile or cable element.

Figures 56A-56C show a variation of the post having an alternative lock alignment feature.

Figure 57 shows the post variation of Figure 51 in combination with an illustrative actuator and release actuator.

Figures 58A-58C show a variation of the post, actuator and release actuator that form an alternative releasable attachment mechanism.

Figures 59A-59C show another variation of the releasable attachment mechanism.

Figures 60A-60C show yet another variation of the releasable attachment mechanism.

Figures 61A and 61B show still another variation of the releasable attachment element.

Figure 62 shows a variation of the post, actuator and anchor lock element having a reversible lock.

Figures 63A-63C show a variation of the actuator, lock actuator and release actuator.

Figure 64 shows a variation of the anchor lock element having a lock alignment feature.

Figures 65A and 65B show expansion, locking and actuation of the releasable attachment mechanism of the apparatus of Figure 64.

Figure 66 shows another variation of the apparatus having an actuable lock prevention mechanism.

Figures 67A and 67B show a variation of the post that is configured to lock against the braid of the anchor.

Figures 68A-68C show actuation and release of a variation of the anchor lock element.

Figures 69A and 69B show another variation of a releasable actuation mechanism having a lock alignment mechanism which can be cut from a tube.

Figures 70A-70D show actuation of a variation of the anchor lock element that may be formed from a cut tube.

Figures 71A-71F show a variation of the post having an unlock actuator.

Figures 72A and 72B show another buckle variation of the anchor lock element.

Figure 73 shows attachment of a variation of the anchor lock element to the anchor.

Figure 74 shows a variation of the post and anchor lock element having a ratcheting lock.

Figures 75A and 75B show variations of the ratcheting lock.

Figures 76A-76H show actuation of another variation of the ratcheting lock.

Figures 77A-77C show a tubular variation of the ratcheting lock element.

Figures 78A-78C show a variation of the anchor lock element of Figures 77.

Figures 79A and 79B show a variation of the apparatus of Figures 78 comprising a lock alignment feature.

Figures 80A-80F show a method of actuating and adjusting the ratcheting lock of the apparatus of Figures 78.

Figures 81A and 81B show a variation of an anchor/actuator.

Figures 82A-82C show detail views of the releasable attachment mechanism of the actuator of Figures 81.

Figures 83A-83C show a variation of the releasable attachment mechanism of Figures 82.

Figures 84A-84C show another variation of the releasable attachment mechanism.

Figures 85A-85C show yet another variation of the releasable attachment mechanism.

Figures 86A-86N show variations of a release actuator used in conjunction with the releasable attachment mechanism of Figures 82.

Figures 87A and 87B show detail views of an embodiment of the delivery system/deployment tool.

Figures 88A and 88B show the delivery system/deployment tool of Figures 87 releaseably attached to apparatus 10, and detached from the apparatus.

Figures 89A and 89B show a variation of the delivery system deployment tool of

Figures 87 and 88 wherein the actuators extend from a unitary structure.

Figures 90A-90C show various ways to connect elements to the anchor of the replacement valve apparatus.

Figure 91 is a schematic top view of an apparatus for fabricating braided anchors in accordance with the present invention.

Figures 92A-92D are schematic top views illustrating a method of using the apparatus of Figure 91 to fabricate a braided anchor of the present invention.

Figures 93A-93O are schematic detail views illustrating features of braid cells at an anchor edge.

Figures 94A-94E illustrate further features of braid cells at an anchor edge.

Figures 95A-95J are schematic detail views terminations for one or more wire strands forming anchors of the present invention.

Figures 96A and 96B are schematic side views of alternative embodiments of the anchor portion of the apparatus of the present invention.

Figures 97A-97E are schematic side views of further alternative embodiments of the of the anchor portion of the apparatus of the present invention.

Figures 98A-98D are schematic views of different weave configurations.

Figures 99A-99E are schematic side views of various braided anchor configurations.

Figures 100A-100E are schematic side views of a deployment process.

Figures 101A and 101B illustrate a braided anchor in the heart.

Figures 102A and 102B illustrate a bilaterally symmetrical anchor and an asymmetric anchor, respectively.



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Figure 103 illustrates a braided anchor of the present invention with closed end turns Tu.
Figures 104A-104E illustrate additional features for end turns of a braided anchor.
Figures 105A-105F illustrate deployment of an anchor with leaflet engagement elements on the deployment system.
Figure 106 illustrates a deployed anchor with leaflet engagement elements on the proximal end of the anchor.
Figures 107A-107C illustrate deployment of an anchor with anchor registration elements and a seal.
Figures 108A-108B illustrate an embodiment of the apparatus with a seal that does not reach the proximal end of the anchor during both systole and diastole.
Figures 109A-109B illustrate an embodiment of the apparatus with a seal that reaches the proximal end of the anchor during both systole and diastole.

DETAILED DESCRIPTION

**[0071]** The present invention relates to apparatus and methods for endovascularly or percutaneously delivering and deploying a prosthesis, e.g., an aortic prosthesis, within and/or across a patient's native heart valve, referred to hereinafter as replacing the patient's heart valve. A delivery system and/or deployment tool is provided including a sheath assembly and a guidewire for placing the prosthetic apparatus endovascularly within the patient and a user control allowing manipulation of the prosthetic apparatus from external to the patient through the application of a non-hydraulically expanding or non-pneumatically expanding force on the anchor. A hydraulically or pneumatically expanding force would be, for example, a force applied to the anchor by a balloon expanded within the anchor. In certain embodiments, the application of a non-hydraulically expanding or non-pneumatically expanding force could include the use of a hydraulic component transmitting a proximally or distally directed force on an anchor.

**[0072]** The apparatus includes an anchor and a replacement valve. The anchor includes an expandable anchor such as a braid. In preferred embodiments, the expandable braid includes closed edges, but the edges may alternatively be open. The replacement valve is adapted to be secured within the anchor, and as such, be delivered endovascularly to the patient's heart to replace one of the patient's native heart valves. More preferably, the apparatus and methods of the present invention contemplate replacement of the patient's aortic valve.

**[0073]** With reference now to Figures 1-4, a first embodiment of replacement heart valve apparatus in accordance with the present invention is described, including a method of actively foreshortening and expanding the apparatus from a delivery configuration and to a deployed configuration. Apparatus 10 comprises replacement valve 20 disposed within and coupled to anchor 30. Figures 1 schematically illustrate individual cells of anchor 30 of apparatus 10, and should be viewed as if the cylindrical anchor has been cut open and laid flat. Figures 2 schematically illustrate a detail portion of apparatus 10 in side-section.

**[0074]** Anchor 30 has a lip region 32, a skirt region 34 and a body region 36. First, second and third posts 38a, 38b and 38c, respectively, are coupled to skirt region 34 and extend within lumen 31 of anchor 30. Posts 38 preferably are spaced 120° apart from one another about the circumference of anchor 30.

**[0075]** Anchor 30 preferably is fabricated by using self-expanding patterns (laser cut or chemically milled), braids, and materials, such as a stainless steel, nickel-titanium ("Nitinol") or cobalt chromium but alternatively may be fabricated using balloon-expandable patterns where the anchor is designed to plastically deform to it's final shape by means of balloon expansion. Replacement valve 20 is preferably from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues, alternatively it can be made from tissue engineered materials (such as extracellular matrix material from Small Intestinal Submucosa (SIS)) but alternatively may be prosthetic from an elastomeric polymer or silicone, Nitinol or stainless steel mesh or pattern (sputtered, chemically milled or laser cut). The leaflet may also be made of a composite of the elastomeric or silicone materials and metal alloys or other fibers such Kevlar or carbon. Annular base 22 of replacement valve 20 preferably is coupled to skirt region 34 of anchor 30, while commissures 24 of replacement valve leaflets 26 are coupled to posts 38.

**[0076]** Anchor 30 may be actuated using external non-hydraulic or non-pneumatic force to actively foreshorten in order to increase its radial strength. As shown below, the proximal and distal end regions of anchor 30 may be actuated independently. The anchor and valve may be placed and expanded in order to visualize their location with respect to the native valve and other anatomical features and to visualize operation of the valve. The anchor and valve may thereafter be repositioned and even retrieved into the delivery sheath or catheter. The apparatus may be delivered to the vicinity of the patient's aortic valve in a retrograde approach in a catheter having a diameter no more than 23 french, preferably no more than 21 french, more preferably no more than 19 french, or more preferably no more than 17 french. Upon deployment the anchor and replacement valve capture the native valve leaflets and positively lock to maintain configuration and position.

**[0077]** A deployment tool is used to actuate, reposition, lock and/or retrieve anchor 30. In order to avoid delivery of anchor 30 on a balloon for balloon expansion, a non-hydraulic or non-pneumatic anchor actuator is used. In this embodiment, the actuator is a deployment tool that includes distal region control actuators 50, control actuators 60 (embodied here as rods or tubes) and proximal region control actuators 62. Locks 40 include posts or



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arms 38 preferably with male interlocking elements 44 extending from skirt region 34 and mating female interlocking elements 42 in lip region 32. Male interlocking elements 44 have eyelets 45. Control actuators 50 pass from a delivery system for apparatus 10 through female interlocking elements 42, through eyelets 45 of male interlocking elements 44, and back through female interlocking elements 42, such that a double strand of wire 50 passes through each female interlocking element 42 for manipulation by a medical practitioner external to the patient to actuate and control the anchor by changing the anchor's shape. Control actuators 50 may comprise, for example, strands of suture or wire.

**[0078]** Actuators 60 are reversibly coupled to apparatus 10 and may be used in conjunction with actuators 50 to actuate anchor 30, e.g., to foreshorten and lock apparatus 10 in the fully deployed configuration. Actuators 60 also facilitate repositioning and retrieval of apparatus 10, as described hereinafter. For example, anchor 30 may be foreshortened and radially expanded by applying a distally directed force on actuators 60 while proximally retracting actuators 50. As seen in Figures 3, control actuators 62 pass through interior lumens 61 of actuators 60. This ensures that actuators 60 are aligned properly with apparatus 10 during deployment and foreshortening. Control actuators 62 can also actuate anchor 60; proximally directed forces on control actuators 62 contacts the proximal lip region 32 of anchor 30. Actuators 62 also act to couple and decouple actuators 60 from apparatus 10. Actuators 62 may comprise, for example, strands of suture or wire.

**[0079]** Figures 1A and 2A illustrate anchor 30 in a delivery configuration or in a partially deployed configuration (e.g., after dynamic self-expansion expansion from a constrained delivery configuration within a delivery sheath). Anchor 30 has a relatively long length and a relatively small width in the delivery or partially deployed configuration, as compared to the foreshortened and fully deployed configuration of Figures IB and 2B.

**[0080]** In Figures 1A and 2A, replacement valve 20 is collapsed within lumen 31 of anchor 30. Retraction of actuators 50 relative to actuators 60 foreshortens anchor 30, which increases the anchor's width while decreasing its length. Such foreshortening also properly seats replacement valve 20 within lumen 31 of anchor 30. Imposed foreshortening will enhance radial force applied by apparatus 10 to surrounding tissue over at least a portion of anchor 30. In some embodiments, the anchor exerts an outward force on surrounding tissue to engage the tissue in such way to prevent migration of anchor caused by force of blood against closed leaflet during diastole. This anchoring force is preferably 1 to 2 lbs, more preferably 2 to 4 lbs, or more preferably 4 to 10 lbs. In some embodiments, the anchoring force is preferably greater than 1 pound, more preferably greater than 2 pounds, or more preferably greater than 4 pounds. Enhanced radial force of the anchor is also important for enhanced crush resistance of the anchor against the surrounding tissue due to the healing response (fibrosis and contraction of annulus over a longer period of time) or to dynamic changes of pressure and flow at each heart beat In an alternative embodiment, the anchor pattern or braid is designed to have gaps or areas where the native tissue is allowed to protrude through the anchor slightly (not shown) and as the foreshortening is applied, the tissue is trapped in the anchor. This feature would provide additional means to prevent anchor migration and enhance long term stability of the device.

**[0081]** Deployment of apparatus 10 is fully reversible until lock 40 has been locked via mating of male interlocking elements 44 with female interlocking elements 42. Deployment is then completed by decoupling actuators 60 from lip section 32 of anchor 30 by retracting one end of each actuator 62 relative to the other end of the actuator, and by retracting one end of each actuator 50 relative to the other end of the actuator until each actuator has been removed from eyelet 45 of its corresponding male interlocking element 44.

**[0082]** As best seen in Figure 2B, body region 36 of anchor 30 optionally may comprise barb elements 37 that protrude from anchor 30 in the fully deployed configuration, for example, for engagement of a patient's native valve leaflets and to preclude migration of the apparatus.

**[0083]** With reference now to Figures 3, a delivery and deployment system for a self-expanding embodiment of apparatus 10 including a sheath 110 having a lumen 112. Self-expanding anchor 30 is collapsible to a delivery configuration within lumen 112 of sheath 110, such that apparatus 10 may be delivered via delivery system 100. As seen in Figure 3A, apparatus 10 may be deployed from lumen 112 by retracting sheath 110 relative to apparatus 10, control actuators 50 and actuators 60, which causes anchor 30 to dynamically self-expand to a partially deployed configuration. Control actuators 50 then are retracted relative to apparatus 10 and actuators 60 to impose foreshortening upon anchor 30, as seen in Figure 3B.

**[0084]** During foreshortening, actuators 60 push against lip region 32 of anchor 30, while actuators 50 pull on posts 3 8 of the anchor. Actuators 62 may be retracted along with actuators 50 to enhance the distally-directed pushing force applied by actuators 60 to lip region 32. Continued retraction of actuators 50 relative to actuators 60 would lock locks 40 and fully deploy apparatus 10 with replacement valve 20 properly seated within anchor 30, as in Figures IB and 2B. Apparatus 10 comprises enhanced radial strength in the fully deployed configuration as compared to the partially deployed configuration of Figure 3A. Once apparatus 10 has been fully deployed, actuators 50 and 62 may be removed from apparatus 10, thereby separating delivery system 100 including actuators 60 from the apparatus.

**[0085]** Deployment of apparatus 10 is fully reversible until locks 40 have been actuated. For example, just prior to locking the position of the anchor and valve and the operation of the valve may be observed under fluoros-



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copy. If the position needs to be changed, by alternately relaxing and reapplying the proximally directed forces exerted by control actuators 50 and/or control actuators 62 and the distally directed forces exerted by actuators 60, expansion and contraction of the lip and skirt regions of anchor 30 may be independently controlled so that the anchor and valve can be moved to, e.g., avoid blocking the coronary ostia or impinging on the mitral valve. Apparatus 10 may also be completely retrieved within lumen 112 of sheath 110 by simultaneously proximally retracting actuators 50 and actuators 60/actuators 62 relative to sheath 110. Apparatus 10 then may be removed from the patient or repositioned for subsequent redeployment.

**[0086]** Referring now to Figures 4, step-by-step deployment of apparatus 10 via delivery system 100 is described. In Figure 4A, sheath 110 is retracted relative to apparatus 10, actuators 50 and actuators 60, thereby causing self-expandable anchor 30 to dynamically self-expand apparatus 10 from the collapsed delivery configuration within lumen 112 of sheath 110 to the partially deployed configuration. Apparatus 10 may then be dynamically repositioned via actuators 60 to properly orient the apparatus, e.g. relative to a patient's native valve leaflets.

**[0087]** In Figure 4B, control actuators 50 are retracted while actuators 60 are advanced, thereby urging lip region 32 of anchor 30 in a distal direction while urging posts 38 of the anchor in a proximal direction. This foreshortens apparatus 10, as seen in Figure 4C. Deployment of apparatus 10 is fully reversible even after foreshortening has been initiated and has advanced to the point illustrated in Figure 4C.

**[0088]** In Figure 4D, continued foreshortening causes male interlocking elements 44 of locks 40 to engage female interlocking elements 42. The male elements mate with the female elements, thereby locking apparatus 10 in the foreshortened configuration, as seen in Figure 4E. Actuators 50 are then pulled through eyelets 45 of male elements 44 to remove the actuators from apparatus 10, and actuators 62 are pulled through the proximal end of anchor 30 to uncouple actuators 60 from the apparatus, thereby separating delivery system 100 from apparatus 10. Fully deployed apparatus 10 is shown in Figure 4F.

**[0089]** Referring to Figures 5, a method of percutaneously replacing a patient's diseased aortic valve with apparatus 10 and delivery system 100 is described. As seen in Figure 5A, sheath 110 of delivery system 100, having apparatus 10 disposed therein, is percutaneously advanced over guide wire G, preferably in a retrograde fashion (although an antegrade or hybrid approach alternatively may be used), through a patient's aorta A to the patient's diseased aortic valve AV. A nosecone 102 precedes sheath 110 in a known manner. In Figure 5B, sheath 110 is positioned such that its distal region is disposed within left ventricle LV of the patient's heart H.

**[0090]** Apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance, such that anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration, as in Figure 5C. Advantageously, apparatus 10 may be retracted within lumen 112 of sheath 110 via actuators 50 - even after anchor 30 has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition apparatus 10 or delivery system 100. As yet another advantage, apparatus 10 may be dynamically repositioned, e.g. via sheath 110 and/or actuators 60, in order to properly align the apparatus relative to anatomical landmarks, such as the patient's coronary ostia or the patient's native valve leaflets L. When properly aligned, skirt region 34 of anchor 30 preferably is disposed distal of the leaflets, while body region 36 is disposed across the leaflets and lip region 32 is disposed proximal of the leaflets.

**[0091]** Once properly aligned, actuators 50 are retracted relative to actuators 60 to impose foreshortening upon anchor 30 and expand apparatus 10 to the fully deployed configuration, as in Figure 5D. Foreshortening increases the radial strength of anchor 30 to ensure prolonged patency of valve annulus An, as well as to provide a better seal for apparatus 10 that reduces paravalvular regurgitation. As seen in Figure 5E, locks 40 maintain imposed foreshortening. Replacement valve 20 is properly seated within anchor 30, and normal blood flow between left ventricle LV and aorta A is thereafter regulated by apparatus 10. Deployment of apparatus 10 advantageously is fully reversible until locks 40 have been actuated.

**[0092]** As seen in Figure 5F, actuators 50 have been pulled from eyelets 45 of male elements 44 of locks 40, actuators 60 are decoupled from anchor 30, e.g. via actuators 62, and delivery system 100 is removed from the patient, thereby completing deployment of apparatus 10. Optional barb elements 37 engage the patient's native valve leaflets, e.g. to further preclude migration of the apparatus and/or reduce paravalvular regurgitation.

**[0093]** Figures 5G and 5H show further details of deployment using a deployment apparatus. Apparatus 10 is deployed from lumen Lu of sheath 110, for example, under fluoroscopic guidance by proximally retracting proximal handle 111 of sheath 110 relative to shaft 108, such that anchor 30 of apparatus 10 dynamically self-expands to the partially deployed configuration of Figure 5C. Advantageously, apparatus 10 may be retracted within lumen Lu of sheath 110 by retracting shaft 108 relative to the sheath, and thereby retracting actuators 106a coupled to anchor 30 relative to sheath 110. In this manner, anchor 30 may be retrieved even after the anchor has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition apparatus 10 or delivery system 100. As yet another advantage, apparatus 10 may be dynamically repositioned, in order to properly align the apparatus relative to anatomical landmarks, such as the patient's coronary ostia or the patient's native valve leaflets L. When properly aligned, a distal region of anchor 30 preferably is disposed distal of the leaflets, while a central region of the anchor is disposed across the leaflets and a proximal



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region is disposed proximal of the leaflets.

**[0094]** Once properly aligned, actuators 106b are proximally retracted relative to actuators 106a, e.g., via knob 126 of handle 120, to impose foreshortening upon anchor 30 and further expand apparatus 10 to the fully deployed configuration, as in Figure 5D. Foreshortening increases the radial strength of anchor 30 to ensure prolonged patency of valve annulus An, as well as to provide a better seal for apparatus 10 that reduces paravalvular regurgitation. Lock 40 formed by engaging post lock elements 44 of posts 32 with anchor lock elements 34 of anchor 30 maintains imposed foreshortening. Replacement valve 20 is properly seated within anchor 30, and normal blood flow between left ventricle LV and aorta A is thereafter completely regulated by apparatus 10, although valve 20 is functional during deployment as well. Deployment of apparatus 10 advantageously is fully reversible until the locks have been actuated. Releasable lock prevention mechanisms may be provided to ensure that the locks are not actuated prematurely. Furthermore, the locks may be reversible, such that apparatus 10 may be retrieved or repositioned even after actuation of the locks.

**[0095]** Once apparatus 10 is fully expanded and locked in the expanded configuration, actuators 106a are decoupled from anchor 30 by actuating releasable attachment mechanisms, e.g., by retracting release actuators 112 relative to the actuators 106a via knob 122 of handle 120. Likewise, actuators 106b are decoupled from posts 32 by actuating releasable attachment mechanisms, e.g., by retracting release actuators 112 relative to the actuators 106b via knob 124 of handle 120. As seen in Figure 5E, delivery system 100 then may be removed from the patient, thereby completing deployment of apparatus 10. Optional barb elements 37 engage the patient's native valve leaflets, e.g. to preclude migration of the apparatus and/or to reduce paravalvular regurgitation.

**[0096]** With reference now to Figures 6, a method of percutaneously replacing a patient's diseased aortic valve with apparatus 10 is provided, wherein proper positioning of the apparatus is ensured via positive registration of a modified delivery system to the patient's native valve leaflets. In Figure 6A, modified delivery system 100' delivers apparatus 10 to diseased aortic valve AV within sheath 110. As seen in Figures 6B and 6C, apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance, such that anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration. As when deployed via delivery system 100, deployment of apparatus 10 via delivery system 100' is fully reversible until locks 40 have been actuated.

**[0097]** Delivery system 100' comprises leaflet engagement element 120, which preferably self-expands along with anchor 30. Engagement element 120 is disposed between actuators 60 of delivery system 100' and lip region 32 of anchor 30. Element 120 releasably engages the anchor. As seen in Figure 6C, the element is initially deployed proximal of the patient's native valve leaflets L. Apparatus 10 arid element 120 then may be advanced/dynamically repositioned until engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus 10. Also delivery system 100' includes filter structure 61 A (e.g., filter membrane or braid) as part of push actuators 60 to act as an embolic protection element. Emboli can be generated during manipulation and placement of anchor from either diseased native leaflet or surrounding aortic tissue and can cause blockage.

**[0098]** Arrows 6 IB in Figure 6E show blood flow through filter structure 61 A where blood is allowed to flow but emboli is trapped in the delivery system and removed with it at the end of the procedure.

**[0099]** Alternatively, foreshortening may be imposed upon anchor 30 while element 120 is disposed proximal of the leaflets, as in Figure 6D. Upon positive registration of element 120 against leaflets L, element 120 precludes further distal migration of apparatus 10 during additional foreshortening, thereby reducing a risk of improperly positioning the apparatus. Figure 6E details engagement of element 120 against the native leaflets. As seen in Figure 6F, once apparatus 10 is fully deployed, element 120, actuators 50 and actuators 60 are decoupled from the apparatus, and delivery system 100' is removed from the patient, thereby completing the procedure.

**[0100]** With reference to Figure 7, an alternative embodiment of the apparatus of Figures 6 is described, wherein leaflet engagement element 120 is coupled to anchor 30 of apparatus 10', rather than to delivery system 100. Engagement element 120 remains implanted in the patient post-deployment of apparatus 10'. Leaflets L are sandwiched between lip region 32 of anchor 30 and element 120 in the fully deployed configuration. In this manner, element 120 positively registers apparatus 10' relative to the leaflets and precludes distal migration of the apparatus over time.

**[0101]** Referring now to Figures 8, an alternative delivery system adapted for use with a balloon expandable embodiment of the present invention is described. In Figure 8A, apparatus 10" comprises anchor 30' that maybe fabricated from balloon-expandable materials. Delivery system 100" comprises inflatable member 130 disposed in a deflated configuration within lumen 31 of anchor 30'. In Figure 8B, optional outer sheath 110 is retracted, and inflatable member 130 is inflated to expand anchor 30' to the fully deployed configuration. As inflatable member 130 is being deflated, as in earlier embodiments, actuators 50 and 62 and actuators 60 maybe used to assist deployment of anchor 30' and actuation of locks 40, as well as to provide reversibility and retrievability of apparatus 10" prior to actuation of locks 40. Next, actuators 50 and 62 and actuators 60 are removed from apparatus 10", and delivery system 100" is removed, as seen in Figure 8C.

**[0102]** As an alternative delivery method, anchor 30' may be partially deployed via partial expansion of inflatable member 130. The inflatable member would then be



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advanced within replacement valve 20 prior to inflation of inflatable member 130 and full deployment of apparatus 10". Inflation pressures used will range from about 3 to 6 arm, or more preferably from about 4 to 5 arm, though higher and lower atm pressures may also be used (e.g., greater than 3 atm, more preferably greater than 4 atm, more preferably greater than 5 atm, or more preferably greater than 6 atm). Advantageously, separation of inflatable member 130 from replacement valve 20, until partial deployment of apparatus 10" at a treatment site, is expected to reduce a delivery profile of the apparatus, as compared to previously known apparatus. This profile reduction may facilitate retrograde delivery and deployment of apparatus 10", even when anchor 30' is balloon-expandable.

**[0103]** Although anchor 30' has illustratively been described as fabricated from balloon-expandable materials, it should be understood that anchor 30' alternatively may be fabricated from self-expanding materials whose expansion optionally may be balloon-assisted. In such a configuration, anchor 30' would expand to a partially deployed configuration upon removal of outer sheath 110. If required, inflatable member 130 then would be advanced within replacement valve 20 prior to inflation. Inflatable member 130 would assist full deployment of apparatus 10", for example, when the radial force required to overcome resistance from impinging tissue were too great to be overcome simply by manipulation of actuators 50 and actuators 60. Advantageously, optional placement of inflatable member 130 within replacement valve 20, only after dynamic self-expansion of apparatus 10" to the partially deployed configuration at a treatment site, is expected to reduce a delivery profile of the apparatus, as compared to previously known apparatus. This reduction may facilitate retrograde delivery and deployment of apparatus 10".

**[0104]** With reference to Figures 9 and 10, methods and apparatus for a balloon-assisted embodiment of the present invention are described in greater detail. Figures 9 and 10 illustratively show apparatus 10' of Figures 7 used in combination with delivery system 100" of Figures 8. Figure 10 illustrates a sectional view of delivery system 100". Inner shaft 132 of inflatable member 130 preferably is about 4 Fr in diameter, and comprises lumen 133 configured for passage of guidewire G, having a diameter of about 0.035", therethrough. Push actuators 60 and pull actuators 50 pass through guidetube 140, which preferably has a diameter of about 15 Fr or smaller. Guide tube 140 is disposed within lumen 112 of outer sheath 110, which preferably has a diameter of about 17 Fr or smaller.

**[0105]** In Figure 9A, apparatus 10' is delivered to diseased aortic valve AV within lumen 112 of sheath 110. In Figure 9B, sheath 110 is retracted relative to apparatus 10' to dynamically self-expand the apparatus to the partially deployed configuration. Also retracted and removed is nosecone 102 which is attached to a pre-slit lumen (not shown) that facilitates its removal prior to loading and advancing of a regular angioplasty balloon catheter over guidewire and inside delivery system 110.

**[0106]** In Figure 9C, pull actuators 50 and push actuators 60 are manipulated from external to the patient to foreshorten anchor 30 and sufficiently expand lumen 31 of the anchor to facilitate advancement of inflatable member 130 within replacement valve 20. Also shown is the tip of an angioplasty catheter 130 being advanced through delivery system 110.

**[0107]** The angioplasty balloon catheter or inflatable member 130 then is advanced within the replacement valve, as in Figure 9D, and additional foreshortening is imposed upon anchor 30 to actuate locks 40, as in Figure 9E. The inflatable member is inflated to further displace the patient's native valve leaflets L and ensure adequate blood flow through, and long-term patency of, replacement valve 20, as in Figure 9F. Inflatable member 130 then is deflated and removed from the patient, as in Figure 9G. A different size angioplasty balloon catheter could be used repeat the same step if deemed necessary by the user. Push actuators 60 optionally may be used to further set leaflet engagement element 120, or optional barbs B along posts 38, more deeply within leaflets L, as in Figure 9H. Then, delivery system 100" is removed from the patient, thereby completing percutaneous heart valve replacement.

**[0108]** As will be apparent to those of skill in the art, the order of imposed foreshortening and balloon expansion described in Figures 9 and 10 is only provided for the sake of illustration. The actual order may vary according to the needs of a given patient and/or the preferences of a given medical practitioner. Furthermore, balloon-assist may not be required in all instances, and the inflatable member may act merely as a safety precaution employed selectively in challenging clinical cases.

**[0109]** Referring now to Figures 11, alternative locks for use with apparatus of the present invention are described. In Figure 11A, lock 40' comprises male interlocking element 44 as described previously. However, female interlocking element 42' illustratively comprises a triangular shape, as compared to the round shape of interlocking element 42 described previously. The triangular shape of female interlocking element 42' may facilitate mating of male interlocking element 44 with the female interlocking element without necessitating deformation of the male interlocking element.

**[0110]** In Figure 11B, lock 40" comprises alternative male interlocking element 44' having multiple in-line arrowheads 46 along posts 38. Each arrowhead comprises resiliently deformable appendages 48 to facilitate passage through female interlocking element 42. Appendages 48 optionally comprise eyelets 49, such that control actuator 50 or a secondary wire may pass therethrough to constrain the appendages in the deformed configuration. To actuate lock 40", one or more arrowheads 46 of male interlocking element 44' are drawn through female interlocking element 42, and the wire is removed from eyelets 49, thereby causing appendages 48 to resiliently expand and actuate lock 40".



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**[0111]** Advantageously, providing multiple arrowheads 46 along posts 38 yields a ratchet that facilitates in-vivo determination of a degree of foreshortening imposed upon apparatus of the present invention. Furthermore, optionally constraining appendages 48 of arrowheads 46 via eyelets 49 prevents actuation of lock 40" (and thus deployment of apparatus of the present invention) even after male element 44' has been advanced through female element 42. Only after a medical practitioner has removed the wire constraining appendages 48 is lock 40" fully engaged and deployment no longer reversible.

**[0112]** Lock 40"' of Figure 11C is similar to lock 40" of Figure 11B, except that optional eyelets 49 on appendages 48 have been replaced by optional overtube 47. Overtube 47 serves a similar function to eyelets 49 by constraining appendages 48 to prevent locking until a medical practitioner has determined that apparatus of the present invention has been foreshortened and positioned adequately at a treatment site. Overtube 47 is then removed, which causes the appendages to resiliently expand, thereby fully actuating lock 40"'.

**[0113]** With reference to Figures 12, an alternative locking mechanism is described that is configured to engage the patient's aorta. Male interlocking elements 44" of locks 40"" comprise arrowheads 46' having sharpened appendages 48'. Upon expansion from the delivery configuration of Figure 12A to the foreshortened configuration of Figure 12B, apparatus 10 positions sharpened appendages 48' adjacent the patient's aorta A. Appendages 48' engage the aortic wall and reduce a risk of device migration over time.

**[0114]** With reference now to Figure 13, a risk of paravalvular leakage or regurgitation around apparatus of the present invention is described. In Figure 13, apparatus 10 has been implanted at the site of diseased aortic valve AV, for example, using techniques described hereinabove. The surface of native valve leaflets L is irregular, and interface I between leaflets L and anchor 30 may comprise gaps where blood B may seep through. Such leakage poses a risk of blood clot formation or insufficient blood flow.

**[0115]** Referring to Figure 14, optional elements for reducing regurgitation or leakage are described. Compliant sacs 200 may be disposed about the exterior of anchor 30 to provide a more efficient seal along irregular interface **I.** Sacs 200 may be filled with an appropriate material, for example, water, blood, foam or a hydrogel. Alternative fill materials will be apparent.

**[0116]** With reference to Figures 15, illustrative arrangements for sacs 200 are provided. In Figure 15A, sacs 200 are provided as discrete sacs at different positions along the height of anchor 30. In Figure 15B, the sacs are provided as continuous cylinders at various heights. In Figure 15C, a single sac is provided with a cylindrical shape that spans multiple heights. The sacs of Figure 15D are discrete, smaller and provided in larger quantities. Figure 15E provides a spiral sac. Alternative sac configurations will be apparent to those of skill in the art.

**[0117]** With reference to Figures 16, exemplary techniques for fabricating sacs 200 are provided. In Figure 16A, sacs 20 comprise 'fish-scale' slots 202 that may be back-filled, for example, with ambient blood passing through replacement valve 20. hi Figure 16B, the sacs comprise pores 204 that may be used to fill the sacs. In Figure 16C, the sacs open to lumen 31 of anchor 30 and are filled by blood washing past the sacs as the blood moves through apparatus 10.

**[0118]** Figures 17 and 18 show yet another alternative embodiment of the anchor lock. Anchor 300 has a plurality of male interlocking elements 302 having eyelets 304 formed therein. Male interlocking elements are connected to braided structure 300 by inter-weaving elements 302 (and 308) or alternatively suturing, soldering, welding, or connecting with adhesive. Valve commissures 24 are connected to male interlocking elements 302 along their length. Replacement valve 20 annular base 22 is connected to the distal end 34 of anchor 300 (or 30) as is illustrated in figures 1A and IB. Male interlocking elements 302 also include holes 306 that mate with tabs 310 extending into holes 312 in female interlocking elements 308. To lock, control actuators 314 passing through eyelets 304 and holes 312 are pulled proximally with respect to the proximal end of braided anchor 300 to draw the male interlocking elements through holes 312 so that tabs 310 engage holes 306 in male interlocking elements 302. Also shown is release actuators 314B that passes through eylet 304B in female interlocking element 308. If needed, during the procedure, the user may pull on release actuators 314B reversing orientation of tabs 310 releasing the anchor and allowing for repositioning of the device or it's removal from the patient. After the desired final position has been attained, release actuator 314B and control actuator 314 be removed from the patient with the delivery system.

**[0119]** Figures 19-21 show an alternative way of releasing the connection between the anchor and its actuating actuators and control actuators. Control actuators 62 (i.e., release actuators) extend through actuators 60 from outside the patient, loop through the proximal region of anchor 30 and extend partially back into tube 60 (i.e., an anchor actuator). The doubled up portion of control actuator 62 creates a force fit within tube 60 that maintains the control actuators's position with respect to tube 60 when all confrol actuators 62 are pulled proximally to place a proximally directed force on anchor 30. When a single half of control actuator 62 is pulled proximally, however, the frictional fit between that control wire and the tube in which it is disposed is overcome, enabling the end 63 of control actuator 62 to pull free of the tube, as shown in Figure 21, thereby releasing anchor 30.

**[0120]** Figures 22-24 show an alternative embodiment of the anchor. Anchor 350 is made of a metal braid, such as Nitinol or stainless steel. A replacement valve 354 is disposed within anchor 350. Anchor 350 is actuated in



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substantially the same way as anchor 30 of Figures 1-4 through the application of proximally and distally directed forces from confrol actuators (not shown) and actuators 352.

**[0121]** Figures 25 and 26 show yet another embodiment of the delivery and deployment apparatus of the invention. As an alternative to the balloon expansion method described with respect to Figures 8, in this embodiment the nosecone (e.g., element 102 of Figures 5) is replaced by an angioplasty balloon catheter 360. Thus, expandable balloon cathether 360 precedes sheath 110 on guidewire G. When anchor 30 and valve 20 are expanded through the operation of actuators 60 and the control actuators (not shown) as described above, balloon cathether 360 is retracted proximally within the expanded anchor and valve and expanded further as described above with respect to Figures 8.

**[0122]** Figures 27-31 show seals 370 that expand over time to seal the interface between the anchor and valve and the patient's tissue. Seals 370 are preferably formed from Nitinol wire surrounded by an expandable foam. As shown in cross-section in Figures 28 and 29, at the time of deployment, the foam 372 is compressed about the wire 374 and held in the compressed form by a time-released coating 376. After deployment, coating 376 dissolves in vivo to allow foam 372 to expand, as shown in Figures 30 and 31.

**[0123]** Figures 32-34 show another way to seal the replacement valve against leakage. A fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery. When deployed, as shown in Figures 33 and 34, fabric seal 3 80 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve.

**[0124]** Figures 35A-H show another embodiment of a replacement heart valve apparatus in accordance with the present invention. Apparatus 450 comprises replacement valve 460 (see Figures 37B and 38C) disposed within and coupled to anchor 470. Replacement valve 460 is preferably biologic, e.g. porcine, but alternatively may be synthetic. Anchor 470 preferably is fabricated from self-expanding materials, such as a stainless steel wire mesh or a nickel-titanium alloy ("Nitinol"), and comprises lip region 472, skirt region 474, and body regions 476a, 476b and 476c. Replacement valve 460 preferably is coupled to skirt region 474, but alternatively may be coupled to other regions of the anchor. As described herein below, lip region 472 and skirt region 474 are configured to expand and engage/capture a patient's native valve leaflets, thereby providing positive registration, reducing paravalvular regurgitation, reducing device migration, etc.

**[0125]** As seen in Figure 35A, apparatus 450 is collapsible to a delivery configuration, wherein the apparatus may be delivered via delivery system 410. Delivery system 410 comprises sheath 420 having lumen 422, as well as actuators 424a and 424b seen in Figures 35D-35G. Actuators 424a are configured to expand skirt region 474 of anchor 470, as well as replacement valve 460 coupled thereto, while actuators 424b are configured to expand lip region 472.

**[0126]** As seen in Figure 35B, apparatus 450 may be delivered and deployed from lumen 422 of catheter 420 while the apparatus is disposed in the collapsed delivery configuration. As seen in Figures 35B-35D, catheter 420 is retracted relative to apparatus 450, which causes anchor 470 to dynamically self-expand to a partially deployed configuration. Actuators 424a are then retracted to expand skirt region 474, as seen in Figures 35E and 35F. Preferably, such expansion may be maintained via locking features described hereinafter.

**[0127]** In Figure 35G, actuators 424b are retracted to expand lip region 472 and fully deploy apparatus 450. As with skirt region 474, expansion of lip region 472 preferably may be maintained via locking features. After both lip region 472 and skirt region 474 have been expanded, actuators 424 may be removed from apparatus 450, thereby separating delivery system 410 from the apparatus. Delivery system 410 then may be removed, as seen in Figure 35H.

**[0128]** As will be apparent to those of skill in the art, lip region 472 optionally may be expanded prior to expansion of skirt region 474. As yet another alternative, lip region 472 and skirt region 474 optionally may be expanded simultaneously, in parallel, in a step-wise fashion or sequentially. Advantageously, delivery of apparatus 450 is fully reversible until lip region 472 or skirt region 474 has been locked in the expanded configuration.

**[0129]** With reference now to Figures 36A-E, individual cells of anchor 470 of apparatus 450 are described to detail deployment and expansion of the apparatus. In Figure 36A, individual cells of lip region 472, skirt region 474 and body regions 476a, 476b and 476c are shown in the collapsed delivery configuration, as they would appear while disposed within lumen 422 of sheath 420 of delivery system 410 of Figures 35. A portion of the cells forming body regions 476, for example, every 'nth' row of cells, comprises locking features.

**[0130]** Body region 476a comprises male interlocking element 482 of lip lock 480, while body region 476b comprises female interlocking element 484 of lip lock 480. Male element 482 comprises eyelet 483. Wire 424b passes from female interlocking element 484 through eyelet 483 and back through female interlocking element 484, such that there is a double strand of wire 424b that passes through lumen 422 of catheter 420 for manipulation by a medical practitioner external to the patient. Body region 476b further comprises male interlocking element 492 of skirt lock 490, while body region 476c comprises female interlocking element 494 of the skirt lock. Wire 424a passes from female interlocking element 494 through eyelet 493 of male interlocking element 492, and back through female interlocking element 494. Lip lock 480 is config-



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ured to maintain expansion of lip region 472, while skirt lock 490 is configured to maintain expansion of skirt region 474.

**[0131]** In Figure 36B, anchor 470 is shown in the partially deployed configuration, e.g., after deployment from lumen 422 of sheath 420. Body regions 476, as well as lip region 472 and skirt region 474, self-expand to the partially deployed configuration. Full deployment is then achieved by refracting actuators 424 relative to anchor 470, and expanding lip region 472 and skirt region 474 outward, as seen in Figures 36C and 36D. As seen in Figure 36E, expansion continues until the male elements engage the female interlocking elements of lip lock 480 and skirt lock 490, thereby maintaining such expansion (lip lock 480 shown in Figure 36E). Advantageously, deployment of apparatus 450 is fully reversible until lip lock 480 and/or skirt lock 490 has been actuated.

**[0132]** With reference to Figures 37A-B, isometric views, partially in section, further illustrate apparatus 450 in the fully deployed and expanded configuration. Figure 37A illustrates the wireframe structure of anchor 470, while Figure 37B illustrates an embodiment of anchor 470 covered in a biocompatible material B. Placement of replacement valve 460 within apparatus 450 may be seen in Figure 37B. The patient's native valve is captured between lip region 472 and skirt region 474 of anchor 470 in the fully deployed configuration (see Figure 38B).

**[0133]** Referring to Figures 38 A-C, in conjunction with Figures 35 and 36, a method for percutaneously replacing a patient's diseased aortic valve with apparatus 450 is described. Delivery system 410, having apparatus 450 disposed therein, is percutaneously advanced, preferably in a retrograde fashion, through a patient's aorta A to the patient's diseased aortic valve AV. Sheath 420 is positioned such that its distal end is disposed within left ventricle LV of the patient's heart H. As described with respect to Figures 35, apparatus 450 is deployed from lumen 422 of sheath 420, for example, under fluoroscopic guidance, such that skirt section 474 is disposed within left ventricle LV, body section 476b is disposed across the patient's native valve leaflets L, and lip section 472 is disposed within the patient's aorta A. Advantageously, apparatus 450 may be dynamically repositioned to obtain proper alignment with the anatomical landmarks. Furthermore, apparatus 450 may be refracted within lumen 422 of sheath 420 via actuators 424, even after anchor 470 has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition sheath 420.

**[0134]** Once properly positioned, elements 424a are retracted to expand skirt region 474 of anchor 470 within left ventricle LV. Skirt region 474 is locked in the expanded configuration via skirt lock 490, as previously described with respect to Figures 36. In Figure 38A, skirt region 474 is maneuvered such that it engages the patient's valve annulus An and/or native valve leaflets L, thereby providing positive registration of apparatus 450 relative to the anatomical landmarks.

**[0135]** Elements 424b are then actuated external to the patient in order to expand lip region 472, as previously described in Figures 35. Lip region 472 is locked in the expanded configuration via lip lock 480. Advantageously, deployment of apparatus 450 is fully reversible until lip lock 480 and/or skirt lock 490 has been actuated. Elements 424 are pulled from eyelets 483 and 493, and delivery system 410 is removed from the patient. As will be apparent, the order of expansion of lip region 472 and skirt region 474 may be reversed, concurrent, etc.

**[0136]** As seen in Figure 38B, lip region 472 engages the patient's native valve leaflets L, thereby providing additional positive registration and reducing a risk of lip region 472 blocking the patient's coronary ostia O. Figure 38C illustrates the same in cross-sectional view, while also showing the position of replacement valve 460. The patient's native leaflets are engaged and/or captured between lip region 472 and skirt region 474. Advantageously, lip region 472 precludes distal migration of apparatus 450, while skirt region 474 precludes proximal migration. It is expected that lip region 472 and skirt region 474 also will reduce paravalvular regurgitation.

**[0137]** With reference to Figures 39-41, a first embodiment of two-piece apparatus of the present invention adapted for percutaneous replacement of a patient's heart valve is described. As seen in Figures 41, apparatus 510 comprises a two-piece device having custom-designed expandable anchor piece 550 of Figures 39 and expandable replacement valve piece 600 of Figures 40. Both anchor piece 550 and valve piece 600 have reduced delivery configurations and expanded deployed configurations. Both may be either balloon expandable (e.g. fabricated from a stainless steel) or self-expanding (e.g. fabricated from a nickel-titanium alloy ("Nitinol") or from a wire mesh) from the delivery to the deployed configurations.

**[0138]** When replacing a patient's aortic valve, apparatus 510 preferably may be delivered through the patient's aorta without requiring a transseptal approach, thereby reducing patient trauma, complications and recovery time. Furthermore, apparatus 510 enables dynamic repositioning of anchor piece 550 during delivery and facilitates positive registration of apparatus 510 relative to the native position of the patient's valve, thereby reducing a risk of device migration and reducing a risk of blocking or impeding flow to the patient's coronary ostia. Furthermore, the expanded deployed configuration of apparatus 510, as seen in Figure 41D, is adapted to reduce paravalvular regurgitation, as well as to facilitate proper seating of valve piece 600 within anchor piece 550.

**[0139]** As seen in Figures 39, anchor piece 550 preferably comprises three sections. Lip section 560 is adapted to engage the patient's native valve leaflets to provide positive registration and ensure accurate placement of the anchor relative to the patient's valve annulus during deployment, while allowing for dynamic repositioning of the anchor during deployment. Lip section 560 also main-



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tains proper positioning of composite anchor/valve apparatus 510 post-deployment to preclude distal migration. Lip section 560 optionally may be covered or coated with biocompatible film B (see Figures 41) to ensure engagement of the native valve leaflets. It is expected that covering lip section 560 with film B especially would be indicated when the native leaflets are stenosed and/or fused together

**[0140]** Groove section 570 of anchor piece 550 is adapted to engage an expandable frame portion, described hereinbelow, of valve piece 600 to couple anchor piece 550 to valve piece 600. As compared to previously known apparatus, groove section 570 comprises additional material and reduced openings or gaps G, which is expected to reduce tissue protrusion through the gaps upon deployment, thereby facilitating proper seating of the valve within the anchor. Groove section 570 optionally may be covered or coated with biocompatible film B (see Figures 41) to further reduce native valve tissue protrusion through gaps G.

**[0141]** Finally, skirt section 580 of anchor piece 550 maintains proper positioning of composite anchor/valve apparatus 510 post-deployment by precluding proximal migration. When replacing a patient's aortic valve, skirt section 580 is deployed within the patient's left ventricle. As with lip section 560 and groove section 570, skirt section 580 optionally may be covered or coated with biocompatible film B (see Figures 41) to reduce paravalvular regurgitation. As will be apparent to those of skill in the art, all, a portion of, or none of anchor piece 50 may be covered or coated with biocompatible film B.

**[0142]** In Figure 39A, a portion of anchor piece 550 has been flattened out to illustrate the basic anchor cell structure, as well as to illustrate techniques for manufacturing anchor piece 550. hi order to form the entire anchor, anchor 550 would be bent at the locations indicated in Figure 39A, and the basic anchor cell structure would be revolved to form a joined 360° structure. Lip section 560 would be bent back into the page to form a lip that doubles over the groove section, groove section 570 would be bent out of the page into a 'C- or 'U'-shaped groove, while skirt section 580 would be bent back into the page. Figure 39B shows the anchor portion after bending and in an expanded deployed configuration.

**[0143]** The basic anchor cell structure seen in Figure 39A is preferably formed through laser cutting of a flat sheet or of a hollow tube placed on a mandrel. When formed from a flat sheet, the sheet would be cut to the required number of anchor cells, bent to the proper shape, and revolved to form a cylinder. The ends of the cylinder would then be joined together, for example, by welding.

**[0144]** If balloon expandable, anchor piece 550 would be formed from an appropriate material, such as stainless steel, and then crimped onto a balloon delivery catheter in a collapsed delivery configuration. If self-expanding and formed from a shape-memory material, such as a nickel-titanium alloy ("Nitinol"), the anchor piece would be heat-set such that it could be constrained within a sheath in the collapsed delivery configuration, and then would dynamically self-expand to the expanded deployed configuration upon removal of the sheath. Likewise, if anchor piece 550 were formed from a wire mesh or braid, such as a spring steel braid, the anchor would be constrained within a sheath in the delivery configuration and dynamically expanded to the deployed configuration upon removal of the sheath.

**[0145]** In Figures 40, valve piece 600 is described in greater detail. Figure 40A illustrates valve piece 600 in a collapsed delivery configuration, while Figure 40B illustrates the valve piece in an expanded deployed configuration. Valve piece 600 comprises replacement valve 610 coupled to expandable frame 620. Replacement valve 610 is preferably biologic, although synthetic valves may also be used. Replacement valve 610 preferably comprises three leaflets 611 coupled to three posts 621 of expandable frame 620. Expandable frame 620 is preferably formed from a continuous piece of material and may comprise tips 622 in the collapsed delivery configuration, which expand to form hoop 624 in the deployed configuration. Hoop 624 is adapted to engage groove section 570 of anchor piece 550 for coupling anchor piece 550 to valve piece 600. As with anchor piece 550, valve piece 600 may be balloon expandable and coupled to a balloon delivery catheter in the delivery configuration. Alternatively, anchor piece 550 may be self-expanding, e.g. Nitinol or wire mesh, and constrained within a sheath in the delivery configuration.

**[0146]** Referring again to Figures 41, a method for deploying valve piece 600 and coupling it to deployed anchor piece 550 to form two-piece apparatus 510 is described, hi Figure 41A, valve piece 600 is advanced within anchor piece 550 in an at least partially compressed delivery configuration. In Figure 41B, tips 622 of frame 620 are expanded such that they engage groove section 570 of anchor piece 550. In Figure 41C, frame 620 continues to expand and form hoop 624. Hoop 624 flares out from the remainder of valve piece 600 and acts to properly locate the hoop within groove section 570. Figure 41D shows valve piece 600 in a fully deployed configuration, properly seated and friction locked within groove section 570 to form composite anchor/valve apparatus 510.

**[0147]** Anchor piece 550 and valve piece 600 of apparatus 510 preferably are spaced apart and releasably coupled to a single delivery catheter while disposed in their reduced delivery configurations. Spacing the anchor and valve apart reduces a delivery profile of the device, thereby enabling delivery through a patient's aorta without requiring a transseptal approach. With reference to Figure 42, a first embodiment of single catheter delivery system 700 for use with apparatus 510 is described. Delivery system 700 is adapted for use with a preferred self-expanding embodiment of apparatus 510.

**[0148]** Delivery system 700 comprises delivery catheter 710 having inner tube 720, middle distal tube 730, and outer tube 740. Inner tube 720 comprises lumen 722



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adapted for advancement over a standard guide wire, per se known. Middle distal tube 730 is coaxially disposed about a distal region of inner tube 720 and is coupled to a distal end 724 of the inner tube, thereby forming proximally-oriented annular bore 732 between inner tube 720 and middle tube 730 at a distal region of delivery catheter 710. Outer tube 740 is coaxially disposed about inner tube 720 and extends from a proximal region of the inner tube to a position at least partially coaxially overlapping middle distal tube 730. Outer tube 740 preferably comprises distal step 742, wherein lumen 743 of outer tube 740 is of increased diameter. Distal step 742 may overlap middle distal tube 730 and may also facilitate deployment of valve piece 600, as described hereinbelow with respect to Figures 45.

**[0149]** Proximally-oriented annular bore 732 between inner tube 720 and middle distal tube 730 is adapted to receive skirt section 580 and groove section 570 of anchor piece 550 in the reduced delivery configuration. Annular space 744 formed at the overlap between middle distal tube 730 and outer tube 740 is adapted to receive lip section 560 of anchor piece 550 in the reduced delivery configuration. More proximal annular space 746 between inner tube 720 and outer tube 740 may be adapted to receive replacement valve 610 and expandable frame 620 of valve piece 600 in the reduced delivery configuration.

**[0150]** Inner tube 720 optionally may comprise retainer elements 726a and 726b to reduce migration of valve piece 600. Retainer elements 726 preferably are fabricated from a radiopaque material, such as platinum-iridium or gold, to facilitate deployment of valve piece 600, as well as coupling of the valve piece to anchor piece 550. Additional or alternative radiopaque elements may be disposed at other locations about delivery system 700 or apparatus 510, for example, in the vicinity of anchor piece 550.

**[0151]** With reference now to Figure 43, an alternative delivery system for use with apparatus of the present invention is described. Delivery system 750 comprises two distinct catheters adapted to deliver the anchor and valve pieces, respectively: anchor delivery catheter 710' and valve delivery catheter 760. hi use, catheters 710' and 760 may be advanced sequentially to a patient's diseased heart valve for sequential deployment and coupling of anchor piece 550 to valve piece 600 to form composite two-piece apparatus 510. Delivery catheter 710' is substantially equivalent to catheter 710 described hereinabove, except that catheter 710' does not comprise retainer elements 726, and annular space 746 does not receive valve piece 600. Rather, valve piece 600 is received within catheter 760 in the collapsed delivery configuration. Catheter 760 comprises inner tube 770 and outer tube 780. Inner tube 770 comprises lumen 772 for advancement of catheter 760 over a guide wire. The inner tube optionally may also comprise retainer elements 774a and 774b, e.g. radiopaque retainer elements 774, to reduce migration of valve piece 600. Outer tube 780 is coaxially disposed about inner tuber 770 and preferably comprises distal step 782 to facilitate deployment and coupling of valve piece 600 to anchor piece 550, as described hereinbelow. Valve piece 600 may be received in annular space 776 between inner tube 770 and outer tube 780, and more preferably may be received within annular space 776 between retainer elements 774.

**[0152]** Referring now to Figure 44, another alternative delivery system is described. As discussed previously, either anchor piece 550 or valve piece 600 (or portions thereof or both) may be balloon expandable from the delivery configuration to the deployed configuration. Delivery system 800 is adapted for delivery of an embodiment of apparatus 510 wherein the valve piece is balloon expandable. Additional delivery systems - both single and multi-catheter - for deployment of alternative combinations of balloon and self-expandable elements of apparatus of the present invention will be apparent to those of skill in the art in view of the illustrative delivery systems provided in Figures 42-44.

**[0153]** In Figure 44, delivery system 800 comprises delivery catheter 710". Delivery catheter 710" is substantially equivalent to delivery catheter 710 of delivery system 700, except that catheter 710" does not comprise retainer elements 726, and annular space 746 does not receive the valve piece. Additionally, catheter 710" comprises inflatable balloon 802 coupled to the exterior of outer tube 740", as well as an inflation lumen (not shown) for reversibly delivering an inflation medium from a proximal region of catheter 710" into the interior of inflatable balloon 802 for expanding the balloon from a delivery configuration to a deployed configuration. Valve piece 600 may be crimped to the exterior of balloon 802 in the delivery configuration, then deployed and coupled to anchor piece 550 in vivo. Delivery catheter 710" preferably comprises radiopaque marker bands 804a and 804b disposed on either side of balloon 802 to facilitate proper positioning of valve piece 600 during deployment of the valve piece, for example, under fluoroscopic guidance.

**[0154]** With reference now to Figures 45, in conjunction with Figures 39-42, an illustrative method of percutaneously replacing a patient's diseased heart valve using apparatus of the present invention is described. In Figure 45A, a distal region of delivery system 700 of Figure 42 has been delivered through a patient's aorta A, e.g., over a guide wire and under fluoroscopic guidance using well-known percutaneous techniques, to a vicinity of diseased aortic valve AV of heart H. Apparatus 510 of Figures 39-41 is disposed in the collapsed delivery configuration within delivery catheter 710 with groove section 570 and skirt section 580 of anchor piece 550 collapsed within annular bore 732, and lip section 560 of anchor piece 550 collapsed within annular space 744. Valve piece 600 is disposed in the collapsed delivery configuration between retainer elements 726 within more proximal annular space 746. Separation of anchor piece 550 and valve piece 600 of apparatus 510 along the longitudinal axis of delivery catheter 710 enables percutaneous aortic de-



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livery of apparatus 510 without requiring a transseptal approach.

**[0155]** Aortic valve AV comprises native valve leaflets L attached to valve annulus An. Coronary ostia O are disposed just proximal of diseased aortic valve AV. Coronary ostia O connect the patient's coronary arteries to aorta A and are the conduits through which the patient's heart muscle receives oxygenated blood. As such, it is critical that the ostia remain unobstructed post-deployment of apparatus 510.

**[0156]** In Figure 45A, a distal end of delivery catheter 710 has been delivered across diseased aortic valve AV into the patient's left ventricle LV. As seen in Figure 45B, outer tube 740 is then retracted proximally relative to inner tube 720 and middle distal tube 730. Outer tube 740 no longer coaxially overlaps middle distal tube 730, and lip section 560 of anchor piece 550 is removed from annular space 744. Lip section 560 self-expands to the deployed configuration. As seen in Figure 45C, inner tube 720 and middle tube 730 (or all of delivery catheter 710) are then distally advanced until lip section 560 engages the patient's native valve leaflets L, thereby providing positive regisfration of anchor piece 550 to leaflets L. Registration may be confirmed, for example, via fluoroscopic imaging of radiopaque features coupled to apparatus 510 or delivery system 700 and/or via resistance encountered by the medical practitioner distally advancing anchor piece 550.

**[0157]** Lip section 560 may be dynamically repositioned until it properly engages the valve leaflets, thereby ensuring proper positioning of anchor piece 550 relative to the native coronary ostia O, as well as the valve annulus An, prior to deployment of groove section 570 and skirt section 580. Such multi-step deployment of anchor piece 550 enables positive registration and dynamic repositioning of the anchor piece. This is in contrast to previously known percutaneous valve replacement apparatus.

**[0158]** As seen in Figure 45D, once leaflets L have been engaged by lip section 560 of anchor piece 550, inner tube 720 and middle distal tube 730 are further distally advanced within left ventricle LV, while outer tube 740 remains substantially stationary. Lip section 560, engaged by leaflets L, precludes further distal advancement/migration of anchor piece 550. As such, groove section 570 and skirt section 580 are pulled out of proximally-oriented annular bore 732 between inner tube 720 and middle distal tube 730 when the tubes are distally advanced. The groove and skirt sections self-expand to the deployed configuration, as seen in Figure 45E. Groove section 570 pushes native valve leaflets L and lip section 560 against valve annulus An, while skirt section 580 seals against an interior wall of left ventricle LV, thereby reducing paravalvular regurgitation across aortic valve AV and precluding proximal migration of anchor piece 550.

**[0159]** With anchor piece 550 deployed and native aortic valve AV displaced, valve piece 600 may be deployed and coupled to the anchor piece to achieve percutaneous aortic valve replacement. Outer tube 740 is further proximally retracted relative to inner tube 720 such that valve piece 600 is partially deployed from annular space 746 between inner tube 720 and outer tube 740, as seen in Figure 45F. Expandable frame 620 coupled to replacement valve 610 partially self-expands such that tips 622 partially form hoop 624 for engagement of groove section 570 of anchor piece 550 (see Figure 41B). A proximal end of expandable frame 620 is engaged by distal step 742 of outer tube 740.

**[0160]** Subsequent re-advancement of outer tube 740 relative to inner tube 720 causes distal step 742 to distally advance valve piece 600 within anchor piece 550 until tips 622 of expandable frame 620 engage groove section 570 of anchor piece 550, as seen in Figure 45G. As discussed previously, groove section 570 comprises additional material and reduced openings or gaps G, as compared to previously known apparatus, which is expected to reduce native valve tissue protrusion through the gaps and facilitate engagement of tips 622 with the groove section. Outer tube 740 then is proximally retracted again relative to inner tube 720, and valve piece 600 is completely freed from annular space 746. Frame 620 of valve piece 600 fully expands to form hoop 624, as seen in Figure 45H.

**[0161]** Hoop 624 friction locks within groove section 570 of anchor piece 550, thereby coupling the anchor piece to the valve piece and forming composite two-piece apparatus 510, which provides a percutaneous valve replacement. As seen in Figure 45I, delivery catheter 710 may then be removed from the patient, completing the procedure. Blood may freely flow from left ventricle LV through replacement valve 610 into aorta A. Coronary ostia O are unobstructed, and paravalvular regurgitation is reduced by skirt section 580 of anchor piece 550.

**[0162]** Referring now to Figures 46, an alternative embodiment of two-piece apparatus 510 is described comprising an alignment/locking mechanism. Such a mechanism may be provided in order to ensure proper radial alignment of the expandable frame of the valve piece with the groove section of the anchor piece, as well as to ensure proper longitudinal positioning of the frame within the hoop. Additionally, the alignment/locking mechanism may provide a secondary lock to further reduce a risk of the anchor piece and the valve piece becoming separated post-deployment and coupling of the two pieces to achieve percutaneous valve replacement.

**[0163]** In Figures 46, apparatus 510' comprises valve piece 600' of Figure 46A and anchor piece 550' of Figure 46B. Anchor piece 550' and valve piece 600' are substantially the same as anchor piece 550 and valve piece 600 described hereinabove, except that anchor piece 550' comprises first portion 652 of illustrative alignment/locking mechanism 650, while valve piece 600' comprises second portion 654 of the alignment/locking mechanism for coupling to the first portion. First portion 652 illustratively comprises three guideposts 653 coupled to



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skirt section 580' of anchor piece 550' (only one guidepost shown in the partial view of Figure 46B), while second portion 654 comprises three sleeves 655 coupled to posts 621' of expandable frame 620' of valve piece 600'.

**[0164]** When anchor piece 550' is self-expanding and collapsed in the delivery configuration, guideposts 653 may be deployed with skirt section 580', in which case guideposts 653 would rotate upward with respect to anchor piece 550' into the deployed configuration of Figure 46B. Alternatively, when anchor piece 550' is either balloon or self-expanding and is collapsed in the delivery configuration, guideposts 653 may be collapsed against groove section 570' of the anchor piece and may be deployed with the groove section. Deploying guideposts 653 with skirt section 580' has the advantages of reduced delivery profile and ease of manufacturing, but has the disadvantage of significant dynamic motion during deployment. Conversely, deploying guideposts 653 with groove section 570' has the advantage of minimal dynamic motion during deployment, but has the disadvantage of increased delivery profile. Additional deployment configurations will be apparent to those of skill in the art. As will also be apparent, first portion 652 of alignment/locking mechanism 650 may be coupled to alternative sections of anchor piece 550' other than skirt section 580'.

**[0165]** Sleeves 655 of second portion 654 of alignment/locking mechanism 650 comprise lumens 656 sized for coaxial disposal of sleeves 655 about guideposts 653 of first portion 652. Upon deployment, sleeves 655 may friction lock to guideposts 653 to ensure proper radial and longitudinal alignment of anchor piece 550' with valve piece 600', as well as to provide a secondary lock of the anchor piece to the valve piece. The secondary lock enhances the primary friction lock formed by groove section 570' of the anchor piece with hoop 624' of expandable frame 620' of the valve piece.

**[0166]** To facilitate coupling of the anchor piece to the valve piece, suture or thread may pass from optional eyelets 651a of guideposts 653 through lumens 656 of sleeves 655 to a proximal end of the delivery catheter (see Figure 47). In this manner, second portion 654 of mechanism 650 may be urged into alignment with first portion 652, and optional suture knots (not shown), e.g. pre-tied suture knots, may be advanced on top of the mechanism post-coupling of the two portions to lock the two portions together. Alternatively, guideposts 653 may comprise optional one-way valves 651b to facilitate coupling of the first portion to the second portion. Specifically, sleeves 655 may be adapted for coaxial advancement over oneway valves 651b in a first direction that couples the sleeves to guideposts 653, but not in a reverse direction that would uncouple the sleeves from the guideposts.

**[0167]** Referring now to Figure 47, an alternative embodiment of apparatus 510' comprising an alternative alignment/locking mechanism is described. Apparatus 510" is illustratively shown in conjunction with delivery system 700 described hereinabove with respect to Figure 42. Valve piece 600" is shown partially deployed from outer tube 740 of catheter 710. For the sake of illustration, replacement valve 610" of valve piece 600", as well as inner tube 720 and middle distal tube 730 of delivery catheter 710, are not shown in Figure 47.

**[0168]** In Figure 47, anchor piece 550" of apparatus 510" comprises first portion 652' of alignment/locking mechanism 650', while valve piece 600" comprises second portion 654' of the alternative alignment/locking mechanism. First portion 652' comprises eyelets 660 coupled to groove section 570" of anchor piece 550". Second portion 654' comprises knotted loops of suture 662 coupled to tips 622" of expandable frame 620" of valve piece 600". Suture 661 extends from knotted loops of suture 662 through eyelets 660 and out through annular space 746 between outer tube 740 and inner tube 720 (see Figure 42) of catheter 710 to a proximal end of delivery system 700. In this manner, a medical practitioner may radially and longitudinally align valve piece 600'' with anchor piece 550" by proximally retracting sutures 661 (as shown by arrows in Figure 47) while distally advancing distal step 742 of outer tube 740 against valve piece 600" until tips 622" of the valve piece engage groove section 570" of anchor piece 550". Proximal retraction of outer tube 740 then causes expandable frame 620" to further expand and form hoop 624" that friction locks with groove section 570" of anchor piece 550", thereby forming apparatus 510" as described hereinabove with respect to apparatus 510. A secondary lock may be achieved by advancing optional suture knots (not shown) to the overlap of eyelets 660 and knotted loops of suture 662. Such optional suture knots preferably are pre-tied.

**[0169]** With reference now to Figure 48, yet another alternative embodiment of apparatus 510', comprising yet another alternative alignment/locking mechanism 650, is described. First portion 652" of alignment/locking mechanism 650" is coupled to anchor piece 550"' of apparatus 510"', while second portion 654" is coupled to valve piece 600"'. The first portion comprises male posts 670 having flared ends 671, while the second portion comprises female guides 672 coupled to tips 622"' of expandable frame 620"' of valve piece 600"'.

**[0170]** Female guides 672 are translatable about male posts 670, but are constrained by flared ends 671 of the male posts. In this manner, anchor piece 550"'; and valve piece 600"' remain coupled and in radial alignment with one another at all times - including delivery -but may be longitudinally separated from one another during delivery. This facilitates percutaneous delivery without requiring a transseptal approach, while mitigating a risk of inadvertent deployment of the anchor and valve pieces in an uncoupled configuration. Additional alignment/locking mechanisms will be apparent in view of the mechanisms described with respect to Figures 46-48.

**[0171]** Prior to implantation of one of the replacement valves described above, it may be desirable to perform a valvoplasty on the diseased valve by inserting a balloon



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into the valve and expanding it using saline mixed with a contrast agent, hi addition to preparing the valve site for implant, fluoroscopic viewing of the valvoplasty will help determine the appropriate size of replacement valve implant to use.

**[0172]** Figures 49A and 49B illustrate one embodiment of a delivery system/deployment tool and apparatus in accordance with the present invention. As seen in Figure 49A, apparatus 10 may be collapsed for delivery within delivery system/deployment tool 100. Delivery system 100 includes guidewire G, nosecone 102, anchor actuation elements 106, multi-lumen shaft or catheter 108 having optional central lumen 109 and a plurality of circumferentially disposed lumens Lu, external sheath 110 having optional proximal handle 111, and confrol handle 120. Nosecone 102 may, for example, be manipulated via a shaft extending through central lumen 109 of multi-lumen catheter 108.

**[0173]** Anchor actuation elements 106 preferably comprise both proximal anchor actuation elements and distal anchor actuation elements. The proximal anchor actuation elements may, for example, comprise actuators 106a that are releasably coupled to a proximal region of anchor 30 of apparatus 10 via releasable attachment mechanisms for manipulating a proximal region of apparatus 10. The distal anchor actuation elements may comprise actuators 106b that are releasably coupled to a distal region of anchor 30 via releasable attachment mechanisms for manipulating the distal region of apparatus 10. h some embodiments, the distal anchor actuation elements may comprise posts or anchor attachment elements 32 of anchor 30 and the releasable attachment mechanisms connecting actuators 106b to posts 32. In an alternative configuration, the proximal anchor actuation elements may be releasably coupled to a proximal region of apparatus 10 through posts and releasable attachment mechanisms for manipulation of a proximal region of the apparatus, while the distal anchor actuation elements may connect to a distal region of anchor 30 via releasable attachment mechanisms to manipulate a distal region of the apparatus. As another alternative, both proximal and distal anchor actuation element may connect to anchor 30 via releasable attachment mechanisms.

**[0174]** In the embodiment shown in Figures 49, actuators 106a may, for example, include stiff finger elements extending from a distal region of multi-lumen shaft 108, while actuators 106b may include control elements (e.g., stands of suture, or metal or polymer wires) which pass through one or more lumens Lu of shaft 108. Release actuators 112 for the releasable attachment mechanisms for both sets of actuators also may pass through one or more lumens Lu of shaft 108. The release actuators may comprise, for example, control elements (e.g., strands of suture, or metal or polymer wires), covers, mandrels, elongated elements, friction surfaces, wrap portions, interference shapes, etc. The release actuators preferably are movable relative to anchor actuation elements 106, e.g., via control handle 120.

**[0175]** Control handle 120 is coupled to multi-lumen shaft 108. Knob 122 disposed in slot 123 may actuate release actuators 112 that couple actuators 106a of anchor actuation elements 106 to apparatus 10. Likewise, knob 124 disposed in slot 125 may actuate release actuators 112 that couple actuators 106b of anchor actuation elements 106 to posts 32 of anchor 30 of apparatus 10. Handle 120 also comprises knob 126 for, e.g., manipulating the actuators 106b to control movement of the distal region of apparatus 10 relative to its proximal region. Conversely, controlled movement of the proximal region of apparatus 10 relative to its distal region may be achieved by holding knob 126 stationary while advancing or retracting handle 120. Knob 126 optionally may move actuators 106b in unison with their concomitant release actuators 112.

**[0176]** Apparatus 10 comprises anchor 30 and replacement valve 20. Anchor 30 preferably comprises a braid. Such braid can have closed ends at either or both its ends. Replacement valve 20 is preferably coupled to the anchor along posts 32, e.g., along a valve attachment structure, such as a tab and/or a plurality of holes. Posts 32, therefore, may function as valve supports and may be adapted to support the replacement valve within the anchor, h the embodiment shown, there are three posts, corresponding to the valve's three commissural attachment points. The posts can be attached to the braid portion of anchor 30. The posts can be attached to the braid's distal end, as shown in Figure 50A, central region, or proximal end. Replacement valve 20 can be composed of a synthetic material and/or may be derived from animal tissue. Replacement valve 20 is preferably configured to be secured within anchor 30.

**[0177]** Anchor 30 comprises a plurality of anchor lock elements 34, e.g., buckles 34, attached to its proximal region, one for each post 32. Posts 32 may comprise a lock element that forms a two-part locking mechanism with anchor lock elements 34 for maintaining anchor 30 in a deployed or expanded configuration (e.g., as illustrated in Figures 49B, 50B and 50C).

**[0178]** In this embodiment, anchor 30 is formed from a collapsible and expandable wire braid. Anchor braid 30 is preferably self-expanding and is preferably formed from a material such as Nitinol, cobalt-chromium steel or stainless steel wire using one or more strands of wire. Delivery and deployment of braided anchor 30 is similar to the delivery and deployment of the anchors described in U.S. Patent Appl. Ser. No. 10/746,120. Specifically, in one embodiment described below, during deployment braided anchor 30 is actively foreshortened by proximally retracting the actuators 106b relative to the actuators 106a to expand and lock the anchor in place. In some embodiments, foreshortening may expand anchor 30 to a radially symmetrical, bilaterally symmetrical, or asymmetrical expanded shape. The foreshortening step can include expanding a first region of the anchor to a first diameter and a second region of the anchor to a second



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diameter larger than the first diameter. A third region may also be expanded to a diameter larger than the first diameter. The expansion of various regions of the anchor (e.g., the distal region) can be especially useful in locating the aortic valve and centering the anchor within it. Preferably, the secured anchor does not interfere with the mitral valve or the ostia. In some embodiments, the anchor is allowed to self-expand prior to the foreshortening step.

**[0179]** As seen in Figures 49, after endovascular delivery through sheath 110 to the vicinity of the patient's native valve (such as the aortic valve), apparatus 10 may be expanded from the collapsed delivery configuration of Figure 49A to the expanded deployed configuration of Figure 49B using delivery system/deployment tool 100. To deploy apparatus 10, external sheath 110 may be retracted relative to apparatus 10 by proximally retracting sheath handle 111 relative to control handle 120. Sheath 110 is thereby removed from the exterior of apparatus 10, permitting the anchor 30 to self-expand. For example, if anchor braid 30 is composed of a shape memory material, it may self-expand to or toward its "at-rest" configuration. This at-rest configuration of the braid can be, for example its expanded configuration, a collapsed configuration, or a partially expanded configuration between the collapsed configuration and the expanded configuration, or some combination. In preferred embodiments, the anchor's at-rest configuration is between the collapsed configuration and the expanded configuration. Depending on the at-rest diameter of the braid and the diameter of the patient's anatomy at the chosen deployment location, the anchor may or may not self-expand to come into contact with the diameter of the patient's anatomy at that location.

**[0180]** In its collapsed configuration, anchor 30 preferably has a collapsed delivery diameter between about 3 to 30 Fr, or more preferably 6 to 28 Fr, or more preferably 12 to 24 Fr. In some embodiments, anchor 30 in its collapsed configuration will have a length ranging from about 5 to about 170 mm, more preferably from about 10 to about 160 mm, more preferably from about 15 to about 150 mm, more preferably from about 20 to about 140 mm, or more preferably from about 25 mm to about 130 mm.

**[0181]** Similarly, in its expanded configuration, anchor 30 preferable has a diameter ranging between about 10 to about 36 mm, or more preferably from about 24 to about 33 mm, or more preferably from about 24 to about 30 mm. In some embodiments, anchor 30 in its expanded configuration will have a length ranging from about 1 to about 50 mm, more preferably from about 2 to about 40 mm, more preferably from about 5 to about 30 mm, or more preferably from about 7 to about 20 mm.

**[0182]** Overall, the ratio of deployed to collapsed/sheathed lengths is preferably between about 0.05 and 0.5, more preferably about 0.1 to 0.35, or more preferably about 0.15 to 0.25. In any of the embodiments herein, anchor 30 in its expanded configuration preferably has a radial crush strength that maintains the anchor substantially un-deformed in response to a pressure of up to about 0.5 atm directed substantially radially inward toward the central axis, or more preferably up to about 2 atm directed substantially radially inward toward the central axis, hi addition, in any of the embodiments herein, the anchor preferably has an axial spring constant of between about 10 to 250 g/cm, more preferably between about 20 to 200 g/cm, or more preferably between about 40 to 160 g/cm. In addition, in any of the embodiments herein, the anchor is preferably adapted to support the replacement valve at the anchor site in response to a differential pressure of up to about 120 mm Hg, more preferably up to about 240 mm Hg, or more preferably up to about 320 mm Hg.

**[0183]** These parameters are not intended to be limiting. Additional parameters within the scope of the present invention will be apparent to those of skill in the art.

**[0184]** As seen in Figure 49B, anchor 30 may be expanded to a fully deployed configuration from a partial deployed configuration (e.g., self-expanded configuration) by actively foreshortening anchor 30 during endovascular deployment. In some embodiments, foreshortening of the apparatus involves applying a distally directed force on the proximal end of the anchor by one or more anchor actuation elements to move the proximal end of the anchor distally while maintaining the position of the distal end of the anchor. For example, the proximal region of anchor 30 may be pushed distally by certain anchor actuation elements 106, e.g., actuators 106a. Alternatively, foreshortening of the apparatus involves applying a proximally directed force on the distal end of the anchor by one or more anchor actuation elements to move the distal end of the anchor proximally while maintaining the position of the proximal end of the anchor. For example, the distal region of anchor 30 may be pulled proximally via a proximally directed force applied by post actuation elements 106b, this force opposed by anchor actuators 106a.

**[0185]** Anchor actuation elements 106 preferably are adapted to expand radially as the anchor expands radially and to contract radially as the anchor contracts radially. Furthermore, proximally or distally directed forces by the anchor actuation elements on one end of the anchor do not diametrically constrain the opposite end of the anchor. In addition, when a proximally or distally directed force is applied on the anchor by the anchor actuation elements, it is preferably applied without passing any portion of a deployment system through a center opening of the replacement valve. This arrangement enables the replacement valve to operate during deployment and before removal of the deployment system.

**[0186]** The distal anchor actuation elements may include, for example, actuators 106b and/or release actuators 112 that are controlled, e.g., by control knobs 124 and 126 of confrol handle 120. Similarly, the proximal regions of anchor 30 may be pushed distally via proximal anchor actuation elements, e.g., actuators 106a, at the



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proximal region of the anchor. The proximal anchor actuation elements facilitate application of a distally directed force to the proximal end of anchor 30 to move or constrain the proximal end of the anchor distally and are controlled through motion of shaft 108 relative to the distal anchor actuation elements. Control knob 122 of control handle 120 may control release actuators 112 for releasing the proximal anchor actuation elements from the braid. The proximal anchor actuation elements may be further adapted to expand as the proximal end of the anchor expands radially during application of a distally directed force on the proximal end of the anchor. Preferably, the proximal anchor actuation elements apply a distally directed force on the proximal end of the anchor system through a plurality of actuators 106a in order to expand the braid of anchor 30. Such braid expansion optionally may be assisted via inflation of a balloon catheter (see Figures 25 and 26) reversibly disposed within apparatus 10, as described in U.S. Patent Appl. Ser. No. 10/746,120.

**[0187]** In the fully deployed configuration, lock elements of posts 32 and anchor lock elements or buckles 34 of anchor 30 may be used to lock and maintain the anchor in the deployed configuration. Apparatus 10 may be repositioned or retrieved from the patient until the lock elements of posts 32 have been interlocked with anchor lock elements 34 of anchor 30 to form lock 40. In one embodiment, actuators 106b and attendant release actuators 112 comprise control elements attached to posts 32 that are threaded through buckles 34 so that the proximally directed force exerted on posts 32 by the control elements during deployment pulls a lock element of posts 32 toward and through buckles 34 to form lock 40. In this manner, the control elements may act as both anchor actuators and lock actuators.

**[0188]** Such lock optionally may be selectively reversible to allow for repositioning and/or retrieval of apparatus 10 during or post-deployment. When the lock is selectively reversible, the apparatus may be repositioned and or retrieved as desired, i.e., even after actuation of lock 40.

**[0189]** Locks used herein may also include a plurality of levels of locking wherein each level of locking results in a different amount of expansion. For example, the anchor lock elements at the proximal end of the post can have multiple configurations for locking within the buckle wherein each configuration results in a different amount of anchor expansion (see, e.g., Figure 50F). Such locking mechanisms may, for example, comprise ratchets having multiple lock locations. Furthermore, lock alignment features may be provided to facilitate alignment of the post and anchor lock elements, such as a hinge or an oversized width of the post or anchor lock elements. FurtherstiU, lock prevention mechanisms may be provided to preclude locking until desired by a medical practitioner.

**[0190]** When apparatus 10 is placed across a patient's diseased heart valve, anchor 30 may be used to displace the patient's native valve leaflets, and replacement valve 20 will thereafter serve in place of the native valve. After final positioning and expansion, apparatus 10 may be decoupled from delivery system 100 by decoupling the proximal and distal anchor actuation elements 106 from the apparatus via releasable attachment mechanisms, e.g., by decoupling proximal actuators 106a from braided anchor 30 and distal actuators 106b from posts 32 of the anchor via the releasable attachment mechanisms. Moving release actuators 112, e.g., using knobs 122 and 124 of handle 120, may, for example, actuate the releasable attachment mechanisms. Preferably, the releasable attachment mechanisms may be actuated by moving the release actuator(s) less than about 1 inch. After decoupling, delivery system/deployment tool 100 may be removed from the patient, thereby completing endovascular replacement of a patient' s heart valve.

**[0191]** Prior to implantation of replacement valve apparatus described herein, it may be desirable to perform a valvuloplasty on the patient's diseased valve by inserting a balloon into the valve and expanding it using, e.g., saline mixed with a contrast agent, hi addition to preparing the valve site for implant, fluoroscopic viewing of the valvuloplasty will help determine the appropriate size of replacement valve implant to use.

**[0192]** Figures 50A-50C show further details of anchor 30 of apparatus 10. Figure 50A shows the apparatus in a collapsed configuration, such as for delivery within a sheath or other lumen or for retrieval and recapture into a sheath or other lumen. Figures 50B and 50C show the anchor and valve in an expanded and locked configuration.

**[0193]** As shown in Figure 50B, anchor 30 illustratively has three posts and three buckles. As seen in Figure 50C, the three leaflets of replacement valve 20 may be, coupled to the three posts 32 along valve support structures. Thus, posts 32 act as valve supports. The posts, unlike the braid, do not collapse or expand. In some embodiments, a post 32 has one or more proximal slots 33, at least one proximal hole 36a and at least one distal hole 36b. Leaflet tissue may, for example, be passed through slot 33 and sutured in place via suture routed through one or more proximal holes 36a. In this manner, slot(s) 33 and hole(s) 36a may form a valve support structure. Alternative valve support structures known in the art for fixing valve leaflets to posts may also be employed.

**[0194]** Posts 32 may be coupled to anchor braid 30 via one or more distal holes 36b. For example, anchor braid 30 may be woven through holes 36b, or a suture or wire may be routed through holes 36b and tied to the braid. Yet another proximal hole (not shown) in post 32 serves as an anchor lock element that interfaces with the anchor lock element provided by buckle 34 to form lock 40. Buckles 34 may likewise be attached to anchor braid 30 via weaving or suturing.

**[0195]** Alternative locks may be used to lock the anchor of the present invention in the foreshortened configuration, as shown, e.g., in Figures 50D-50F. Preferably, a lock of the present invention can have multiple locking



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options such that locking can confer a plurality of amounts of expansion. Furthermore, the locking option can be employed asymmetrically to confer non-cylindrical shapes to the anchor. In Figure 50D, lock 40' comprises male lock element 44 disposed on post 32 and anchor lock element 34 disposed on braided anchor 30. Anchor lock element 34 illustratively comprises triangular protrusion or eyelet 42 of anchor 30. The triangular shape of female lock element 42 may facilitate mating of male lock element 44 with the female lock element without necessitating deformation of the male lock element. One or more holes 45 may be provided through post 32, e.g., for releasably attaching an actuator 106b to the post.

**[0196]** In Figure 50E, lock 40" comprises alternative male lock element 44' having multiple in-line arrowheads 46 along posts 32. Each arrowhead comprises resiliently deformable appendages 48 to facilitate passage through female lock element 42', which illustratively comprises a rounded eyelet. Appendages 48 optionally comprise holes 49, such that releasable lock prevention mechanism 47, illustratively a control wire, may pass through the holes to constrain the appendages in the deformed configuration. To actuate lock 40", one or more arrowheads 46 of male lock element 44' are drawn through female lock element 42', e.g., via a post/lock actuator, and the lock prevention mechanism is removed from holes 49, thereby causing appendages 48 to resiliently expand and actuate lock 40".

**[0197]** Advantageously, providing multiple arrowheads 46 along posts 32 yields a ratchet that facilitates in-vivo determination of a degree of foreshortening and expansion imposed upon anchor 30. Furthermore, optionally constraining appendages 48 of arrowheads 46 via mechanism 47 prevents actuation of lock 40" (and thereby deployment of apparatus 10) even after male element 44' has been advanced through female element 42'. Only after a medical practitioner has removed lock prevention mechanism 47, which constrains appendages 48, is lock 40" fully engaged and is deployment no longer reversible.

**[0198]** Lock 40"' of Figure 50F is similar to lock 40" of Figure 50E, except that holes 49 on appendages 48 have been eliminated, and the lock prevention mechanism comprises overtube or cover 47. Overtube 47 constrains appendages 48 to prevent locking until a medical practitioner has determined that apparatus of the present invention has been foreshortened and positioned adequately at a treatment site. Lock 40"' may, for example, be actuated by applying a proximally-directed force to actuator 106b. Actuator 106b illustratively comprises a control wire releasably disposed through hole 45 in post 32. Lock prevention mechanism 47 then is withdrawn proximally relative to anchor 30, which causes the appendages to resiliently expand, thereby fully actuating lock 40"'.

**[0199]** Referring now to Figure 51, a detail view of a variation of post 32 is described, hi Figure 51, post 32 illustratively comprises actuator attachment element 250 for attaching the post to an actuator 106b; post lock element 252, illustratively a slot, for interlocking post 32 with an anchor lock element 34; valve attachment structure 254, comprising slot 255 and a plurality of holes 256, for attaching replacement valve 20 to the post (a tab of the valve may be passed through slot 255, then sewn to the back of the post through holes 256); and braid attachment element 258 for attaching the post to a distal region of anchor 30. The braid of anchor 30 may, for example, be interwoven through braid attachment element 258. Post 32 may be fabricated from a variety of materials, e.g., metallic materials such as stainless steel, and maybe laser cut, die cast, etc. In this variation of post 32, valve 20 is disposed distal of lock element 252. In alternative variations, the valve may be attached to the post proximal of the lock element or in-line with the lock element (i.e., neither proximal nor distal to the lock).

**[0200]** Figures 52 provide an alternative variation of post 32. In Figures 52, post 32 comprises lock element 260 having lock alignment feature 262, illustratively hinge 263. Hinge 263 allows lock element 260 to rotate from a position in line with post 32, as in Figure 52A, to a position out of alignment with the post, as in Figure 52B, thereby facilitating alignment with an anchor lock element 34. As shown, post 32 further comprises actuator attachment element 264, illustratively an eyelet, valve support structure 266 having slot 267 and a plurality of holes 268, and braid attachment element 269.

**[0201]** Figures 53 illustrate an alternative variation of lock alignment feature 262 comprising spring 270. As with hinge 263, spring 270 facilitates alignment of post lock element 260 with an anchor lock element 34 by allowing the post lock element to rotate from a position in line with post 32, as in Figure 53A, to a position out of alignment with the post, as in Figure 53B. Spring 270 also applies a restoring force that urges post lock element 260 back into alignment with post 32. Furthermore, spring 270 may facilitate dynamic elongation of post 32 in response to axial tension. This elongation may facilitate axial lengthening of anchor 30 in response to radially inward compression applied to the anchor.

**[0202]** With reference to Figure 54, another variation of post 32 is provided comprising expansion zone 280, which may, for example, comprise a laser cut feature along post 32. Expansion zone 280 facilitates dynamic elongation of post 32 in response to axial tension applied to the post, which facilitates axial lengthening of anchor 30 in response to radially inward compression applied to the anchor. Figure 55 illustrates an alternative expansile element 290 comprising a curved wire or rod that may be elongated and straightened through application of axial tension to facilitate axial lengthening of the anchor in response to radially inward compression applied to the anchor (and thereby axial tension applied to post 32 via interaction between post lock element 260 and an anchor lock element 34).

**[0203]** Element 290 additionally or alternatively may serve as a lock alignment feature. In such a configuration,



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element 290 optionally may not be expansile. More generally, post 32 may comprise proximal and distal ends connected by a tensile member.

**[0204]** Figures 56 illustrate another variation of post 32 having another alternative lock alignment feature 262. In Figures 56, actuator 106b applies a proximally-directed force which brings post lock element 260 and anchor lock element 34 proximate to one another allowing the system to lock. Anchor lock element 34 defines a lock width Wi. In this embodiment, lock alignment feature 262 comprises post lock element lock area or width W2 that is substantially wider than the lock width Wi, for example, at least about twice as wide. This increased width enhances the probability of interlocking the post and anchor lock elements, even at sharply misaligned angles. In Figures 56, post 32 and anchor lock element 34 are disposed at an illustrative misalignment angle of about 10°.

**[0205]** Referring now to Figure 57, the variation of post 32 of Figure 51 is shown in combination with an illustrative actuator 106b and release actuator 112. In Figure 57, actuator 106b illustratively comprises rod 300 having post attachment element 302 that mates with actuator attachment element 250 of post 32. Angled camming surfaces 304 and 305 of post attachment element 302 and actuator attachment element 250, respectively, form an interface between post attachment element 302 and actuator attachment element 250. Proximal movement of actuator 106b with respect to post 32 is translated by the camming surfaces into a lateral force between the two elements that acts to separate and release post 32 from actuator 106b,. Release actuator 112, illustratively tube 310, may be advanced over actuator 300 to cover the camming surface interface of the post and the actuator 106b, thereby forming a releasable attachment mechanism for securing the post to the actuator even during application of axial tension to the actuator. To separate post 32 from actuator 106b, e.g., after expansion and locking of anchor 30, release actuator 112 may be retracted relative to actuator 106b to the position shown in Figure 57, thereby removing a constraint from camming surfaces 304 and 305 and allowing the post and actuator to be pulled apart. Release actuator 112 preferably is retracted less than about 1 inch relative to the actuator 106b in order to actuate the releasable attachment mechanism, e.g., to remove constraint from camming surfaces 304 and 305.

**[0206]** Referring now to Figures 58, an alternative releasable attachment mechanism for attaching a variation of post 32 to a variation of actuator 106b is described, hi Figures 58A and 58B, post 32 having actuator attachment element 320, illustratively an enlarged proximal opening within the post, is interference fit with post attachment element 330 of actuator 106b, illustratively an enlarged bulb, knob or other distal protrusion of the actuator. The slope of element 330 provides a camming surface that interfaces with an inside surface of opening 320. The angle of the camming interface between element 330 and opening 320 translates proximal movement of actuator 106b with respect to post 32 into a lateral movement between actuator 106b and post 32, thereby separating these elements. Release actuator 112, illustratively tube 310, covers the interference fit releasable attachment mechanism to preclude lateral movement of the post attachment element relative to the actuator attachment element, thereby releasably attaching the post to the actuator 106b. In Figure 58C, tube 310 is retracted relative to the post and actuator, which permits lateral movement between the post and actuator attachment elements, thereby separating actuator 106b from post 32. If tube 310 has not been refracted, of course, proximal movement of actuator 106b moves post 32 and the distal portion of the anchor proximally.

**[0207]** Figures 59 illustrate a variation of the releasable attachment mechanism of Figures 58. In the variation of Figures 59, actuator attachment element 320 of post 32 is deformable from a substantially round profile to an oval or "figure eight" profile by advancement of release actuator 112 over the attachment element. This forms a releasable attachment mechanism, hi the deformed profile of Figures 59A and 59B, post attachment element 330 of actuator 106b is interference fit with the deformed actuator attachment element of post 32. In Figure 59C, retraction of release actuator 112 relative to the post and actuator allows actuator attachment element 320 to resiliently resume its un-deformed or at-rest configuration, thereby permitting separation of post 32 from actuator 106b. Actuator attachment element 320 may, for example, be fabricated from a shape memory material, such as Nitinol. A camming surface 331 on post attachment element 330 and a corresponding surface on the inner portion of element 320 translate proximal movement of actuator 106b with respect to post 32 into lateral movement of element 330 with respect to element 320 when release actuator 112 has been retracted.

**[0208]** In the variation of Figures 60, post attachment element 330 is deformable (as in Figures 60A and 60B), and anchor attachment element 320 may be interference fit with the post attachment element. Figure 60C shows the post attachment element 330 in its at-rest configuration after tube 310 has been retracted, thereby releasing anchor attachment element 320. As will be apparent, for many or all of the two-part locking or attachment element elements described herein, the position of the elements may be reversed.

**[0209]** In Figures 61, post attachment element 330 comprises wrap portion 332 that may be inserted through anchor attachment element 320, illustratively an eyelet, wrapped backwards, then covered with release actuator tube 310 to constrain the wrap portion 332 in the wrapped configuration, as in Figure 61A. Release actuator tube 310 may be retracted relative to the wrap portion to resiliently or dynamically (e.g., by retracting actuator 106b relative to post 32) reshape the wrap portion to a substantially straight configuration for releasing the attachment between the post and the actuator, as in Figure 61B. Wrap portion 332 preferably is fabricated from a



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shape memory material, such as Nitinol, or a resilient material, such as spring steel.

**[0210]** Figure 62 shows another variation of the post, actuator and anchor lock element. In Figure 62, post 32 comprises post lock element 260 and actuator attachment element 264, illustratively an eyelet, through which actuator 106b is reversibly disposed. Anchor lock element 34 illustratively comprises a buckle, which may, for example, be formed from a cut tube or a bent resilient material. Anchor lock element 34 comprises anchor or braid attachment element 340 for attaching the buckle to anchor 30, and tab 342 for interlocking the buckle with post lock element 260, which illustratively is a slot formed through post 32. Actuator 106b therefore actuates the post (and therefore the distal end of the anchor to which the post is attached) as well as the anchor lock. Actuator 106b may be released from the post (and therefore from the anchor) by pulling one end of the control wire proximally to draw the control wire through and out of opening 264.

**[0211]** Anchor lock element 34 also comprises optional unlock actuator attachment 344, illustratively a pair of eyelets, through which unlock actuator 350 is releasably coupled to anchor lock element 34. Unlock actuator 350 illustratively comprises a control wire. Upon locking of tab 342 of buckle 34 within slot 260 of post 32, a proximally-directed force applied to unlock actuator 350 may remove the tab from the slot, thereby unlocking buckle 34 and post 32 and permitting the anchor to contract and elongate. Unlocking may be utilized, for example, to reposition or retrieve the anchor and valve apparatus even after the apparatus has been locked in the fully deployed configuration, as described previously with respect to Figures 5.

**[0212]** Figures 63 show another variation of the actuator, the lock actuator and the release actuator. As with other anchor lock elements, anchor lock element 34 in this embodiment is attached to a proximal end of the anchor, and the distal end of post 32 is attached to a distal end of the anchor. The anchor is not shown in Figures 63 for ease of illustration. For the purposes of illustration, the unlock actuator also is not shown in Figures 63.

**[0213]** As shown, actuator 106b actuates both post 32 (and therefore the distal end of the anchor to which the post is attached) and the lock formed between post lock element 260 and anchor lock element 34. h Figure 63A, release actuator 112 passes through actuator 106b to actuate the releasable attachment mechanism between post 32 and actuator 106b. Figure 63B provides a detail view of the releasable attachment mechanism. Actuator 106b comprises wrap portion 360 that passes through actuator attachment element 264 and wraps around the end of post 32. Wrap portion 360 may comprise a shape memory material, such as Nitinol, or a deformable material, e.g., a resiliently deformable material.

**[0214]** Wrap portion 360 further comprises first opening 362 for engaging release actuator 112, illustratively a wire or rod that passes through lumen Lu of actuator 106b. The walls of the lumen act a linear bearing and/or motion guide during advancement and retraction of the release actuator relative to the actuator. Actuator 106b also comprises second opening 364, which may be aligned with first opening 362 to engage release actuator 112, as shown. As seen in the cross-sectional view of Figure 63C, wrap portion 360, and especially the curved portion 361 of the wrap portion, acts as a spring element that urges the first opening out of alignment with the second opening. In this manner, release actuator 112 may be interference or friction fit through first opening 362 and second opening 364. Retraction of the release actuator proximal of the first and second openings may actuate the releasable attachment mechanism to resiliently or dynamically unwrap portion 360 and release actuator 106b from post 32. Wrap and/or curved portion 360/361 of actuator 106b illustratively is disposed at a distal end of the actuator.

**[0215]** As will be apparent to those of skill in the art, the releasable attachment mechanism of Figures 63 may also be utilized to attach a actuator 106a to a braided anchor 30. More generally, wrap portion 360 provides an illustrative first shape on an anchor actuation element 106 that is adapted to mate with a second shape on a post or anchor actuator attachment element (such as element 264 in Figures 63, or a wire of the braid of anchor 30) to substantially prevent relative distal or proximal movement between the anchor actuation element and the anchor. The apparatus further comprises a release actuator adapted to actuate the releasable attachment mechanism. The release actuator is adapted to be moved to permit relative movement between the first shape and the second shape. This relative movement may change the first shape and/or the second shape to a third shape that permits relative distal or proximal movement between the anchor actuation element and the anchor or post. Furthermore, this relative movement may separate the anchor actuation element from the anchor or actuator attachment element.

**[0216]** Figure 64 illustrates a variation of the anchor lock element of Figures 63. In Figure 64, anchor lock element 34 comprises lock alignment feature 370. Feature 370 comprises engagement portion 372, illustratively a loop, that is adapted to engage post 32 before engagement of anchor lock element 34 (i.e., before engagement of tab 342 of the anchor lock element) with post lock element 260. Feature 370 ensures alignment of the post and buckle prior to locking. Furthermore, feature 370 adds additional strength to anchor lock element 34 and opposes inwardly-directed forces applied to element 34 when valve 20 of apparatus 10 closes during diastole.

**[0217]** Referring now to Figures 65, actuation of the apparatus of Figure 64 is described. As seen in Figure 65A, anchor lock element 34 is advanced distally relative to post 32, for example, by applying a distally-directed force to the anchor via anchor actuator 106a to move the proximal portion of the anchor distally while maintaining the position of post 32 via actuator 106b. Alternatively or



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additionally, a proximally-directed force may be applied to post 32 via actuator 106b while maintaining the position of the proximal end of the anchor to move the distal portion of the anchor proximally. Lock alignment feature 370 engages the proximal end of the post prior to interlocking of tab 342 of anchor lock element 34 with post lock element 260, thereby ensuring proper alignment. Continued retraction of post 32 relative to buckle 34 locks the post into the buckle, as shown in Figure 65B. This also expands apparatus 10 to the fully deployed configuration of, e.g., Figures 49B and 50C. Next, release actuator 112 is retracted proximally relative to actuator 106b, which causes wrap portion 360 of the actuator to resiliently or dynamically swing outwards, thereby bringing first opening 362 and second opening 364 out of alignment. Proximal retraction of actuator 106b relative to post 32 removes wrap portion 360 from actuator attachment element 264 of post 32.

**[0218]** Figure 66 shows a variation of the apparatus of Figures 64 and 65. In Figure 66, anchor lock element 34 comprises locking hoop 380, while post lock element 260 comprises a wrapped or curved proximal end of post 32. The curved proximal end also forms actuator attachment element 264. Wrap portion 360 of actuator 106b is wrapped about the curved end of post 32. Release actuator 112, passing through first opening 362 and second opening 364 of actuator 106b, releasably secures this attachment. The release actuator further comprises kink 390 that facilitates passage of the actuator through release actuator attachment elements 392 of post 32, illustratively eyelets. When disposed through elements 392, release actuator 112 further acts as a lock prevention mechanism that precludes locking of the curved proximal end of post 32 with hoop 380 of anchor lock element 34.

**[0219]** In use, the proximal end of post 32 may be retracted through hoop 380 of anchor lock element 34. Release actuator 112 then may be refracted relative to anchor actuator 106b and post 32, such that the release actuator is disposed proximal of attachment elements 392 of the post. Next, post 32 may be allowed to distally advance until its curved proximal end catches and locks against hoop 380 of element 34. Continued retraction of release actuator 112 relative to actuator 106b facilitates separation of the actuator from the post, as described previously.

**[0220]** Referring now to Figure 67, an embodiment of post 32 is described that is configured to lock against the braid of anchor 30, as opposed to a separate anchor lock element 34. Post lock element 260 illustratively comprises bent tab 400 that catches against the anchor braid to lock the anchor in a deployed configuration.

**[0221]** Figures 68 illustrate locking and unlocking of a variation of anchor lock element 34. Anchor lock element 34 of Figures 68 is similar to the buckle variation of element 34 described previously with respect to Figures 62 and 63. However, the variation of Figures 68 is fabricated from a strip of material that is bent to form a wrapped or curved portion. Figure 68A illustrates the apparatus prior to locking, Figure 68B illustrates the locked configuration, and Figure 68C illustrates unlocking through application of a proximally-directed unlocking force to unlock actuator 350.

**[0222]** Figures 69 show yet another embodiment of a releasable actuation mechanism. Anchor lock element 34 comprises lock alignment mechanism 410 disposed proximal of locking tab 412. As shown, lock alignment mechanism 410 engages the distal end of post 32 to align the post and the anchor lock element prior to locking of post lock element 260 with tab 412 of anchor lock element 34. Lock alignment mechanism 410 adds additional strength to anchor lock element 34 and opposes inwardly-directed forces applied to element 34 when valve 20 of apparatus 10 closes during diastole. Advantageously, the inwardly-directed forces act to maintain apparatus 10 in the locked configuration. Mechanism 410 optionally may be formed from a cut tube.

**[0223]** Figures 70 illustrate a variation of anchor lock element 34 that may be formed from a cut tube. As seen in Figures 70A and 70B, element 34 comprises tabs 420 for engaging the curved proximal end of post 32 that forms post locking element 260. In order to lock the post to element 34, the curved distal end of the post is retracted proximally of tabs 420 by the action of proximal tension on post 32 by actuator 106b while element 34 is held stationary, as described above. As it enters anchor lock element 34, the curved end of the post is cammed inward by the engagement of the distal edge of element 34 with the outer surface of the curved end. Once proximal of tabs 420, the curved end of the post moves outward, thereby locking the apparatus and preventing subsequent distal movement of post 32 with respect to element 34. To unlock the apparatus, the curved portion of the post is drawn further proximally by actuator 106b until the tip of the curved portion moves into an opening 422 formed in element 34. As seen in Figures 70C and 70D, resilient distal advancement of the post relative to element 34, e.g., via resilient expansion of the braid of anchor 30, deforms and straightens the curved proximal end of post 32 through a camming engagement of the underside of the curved portion of the post with the inner surface of opening 422, thereby allowing actuator 106b to slide off of post 32, unlocking apparatus 10. The curved portion of post 32 optionally may be formed from a shape memory material, such that the post resumes its curved profile for subsequent relocking after unlocking.

**[0224]** Figures 71 illustrate a variation of post 32 and anchor lock element 32. Anchor lock element 34 illustratively comprises a curved portion 35 that engages and enters the slot of post lock element 260 to lock the anchor as post 32 is drawn proximally into element 34 by actuator 106b. After locking, continued proximal retraction of post 32 by actuator 106b engages the distal end of the curved portion of element 34 with a camming surface 430 of post 32. Resilient distal advancement of post 32 (such as by the resilient contraction and elongation of the anchor to its at-rest configuration) then deforms and straightens



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the wrapped end of element 34, thereby permitting anchor lock element 34 to separate from post 32, unlocking the apparatus.

**[0225]** Figures 72 and 73 illustrate additional buckle variations of anchor lock element 34. Proximal movement of post 32 into anchor lock element 34 (by, e.g., actuator 106b) engages a bottom surface 702 of a curved portion 700 of element 34 with the proximal end of post 32. Further proximal movement of post 32 with respect to element 34 cams curved portion 700 forward until the curved end 704 of curved portion 700 meets and resiliently moves into opening 260 in post 32, locking the apparatus. The variation of Figures 73 illustrates attachment to the braid of anchor 30 via sutures or the like passed through openings 340 in element 34. The lock is unlockable via unlock actuator 350.

**[0226]** Referring now to Figure 74, an embodiment of a post 32 and anchor lock element 34 with a ratcheting lock is described. Post 32 comprises previously described actuator attachment element 250 that is releasably secured to post attachment element 302 of actuator 106b. (Other releasable attachment mechanisms may alternatively be used.) Post 32 also comprises braid attachment element 430 and valve attachment structure 432. In the variation of Figure 74, valve attachment structure 432 comprises tab 433 that extends from post 32, as well as a plurality of holes 434 through post 32 and a plurality of holes 435 through tab 433. Replacement valve 20 may be attached to post 32 by sewing the valve to the valve attachment structure through holes 434 and/or 435.

**[0227]** Post 32 further comprises ratcheting locking element 440 having a plurality of inclined planes with camming surfaces 442 and friction surfaces 443. The inclined planes are disposed along either side of tab 433 for ratcheting and locking against ratcheting anchor lock element 34. Anchor lock element 34 comprises ratchet teeth 450 on either side of the valve attachment elements that cam against surface 442 and lock against friction surfaces 443 of element 440 of post 32, as post 32 is proximally retracted through element 34. Advantageously, providing multiple rows of inclined plane ratchets along post 32 facilitates interlocking of the post and the element at multiple discrete locations.

**[0228]** Element 34 comprises proximal and distal slots 452 that receive post 32, as well as central longitudinal slot 453 that facilitate passage of tab 433 (and thereby valve 20) therethrough. Actuator 106b may be disposed through slots 452 prior to approximation and locking of the post to anchor lock element 34 in order to facilitate alignment of the post and the anchor lock element. Element 34 may be ratcheted to any position along ratchet lock element 440 to achieve any desired locking configuration and degree of expansion of apparatus 10. Valve attachment structure 432, and thereby replacement valve 20, may be positioned proximal of the ratchet lock post-deployment or in line with the ratchet lock (i.e., neither proximal nor distal to the ratchet lock). Element 34 further comprises unlock actuator attachment(s) 454 for coupling the element to an unlock actuator, e.g., previously described unlock actuator 350, to unlock element 34 by applying a proximally-directed unlocking force that displaces ratchet teeth 450 from friction surfaces 443.

**[0229]** Figures 75 illustrate variations of the apparatus of Figure 74. Ratchet lock elements 440 of posts 32 in Figures 75 comprise a plurality of ratchet slots 444 in which ratchet tooth 450 of anchor lock element 34 may be locked. Ratchet tooth 450 comprises proximal friction surface 456 and distal camming surface 457 to facilitate proximal retraction of a post 32 through slot 452 for ratcheting of camming surface 457 through ratchet slots 444, but to preclude distal advancement of the post once ratchet tooth 450 is engaged within ratchet slots 444 by locking a ratchet slot against friction surface 456. As with the variation of Figure 74, anchor lock element 34 is unlockable and comprises unlock actuator attachment 454. In contrast to the variation of Figure 74, the ratchet lock is disposed proximally of valve attachment structure 432, and thereby proximally of replacement valve 20. In Figure 75A, valve attachment structure 432 comprises slot 436 instead of tab 433.

**[0230]** Figures 76 illustrate another variation of the ratchet lock of Figure 74. hi Figures 76, ratchet lock elements 440 of post 32 extend along only one edge of the post. Thus, anchor lock element 34 comprises unitary ratchet tooth 450 for camming against surfaces 442 and locking against friction surfaces 443 of elements 440 of post 32, as post 32 is proximally refracted through element 34.

**[0231]** The apparatus of Figures 76 also comprises unlock or adjustment actuator 500 that is releasably attached to anchor lock element 34 along unlock actuator attachment 454. Actuator 500 comprises two independently or concurrently actuable elements: adjustment element 510 and release element 520. Adjustment element 510 comprises elongated member 512 having protrusion 514 with lumen 515, as well as distal extension 516 with notch 518 having optional camming surface 519. Release element 520 comprises elongated member 521, which may, for example, comprise a mandrel, that is configured for passage through lumen 515 of protrusion 514 of adjustment element 510. Elongated members 512 and 521 of actuator 500 preferably extend through delivery system 100 to the exterior of the patient for independent or concurrent advancement and/or retraction by a medical practitioner.

**[0232]** As seen in Figure 76A, notch 518 of adjustment element 510 of actuator 500 maybe positioned within unlock actuator attachment 454 of anchor lock element 34 during deployment of apparatus 10. As seen in Figure 76B, anchor lock element 34 is locked within ratcheting lock elements 440 of post 32 by proximally retracting actuator 106b relative to anchor lock element 34. Release element 520 then may be advanced relative to adjustment element 510 to position elongated member 521 within unlock actuator attachment 454 adjacent distal extension 516 of adjustment element 510. This serves to



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friction lock or interference fit actuator 500 within attachment 454 along notch 518 of adjustment element 510. Thus, concurrent advancement and/or retraction of the adjustment and release elements of actuator 500 by a medical practitioner causes anchor lock element 34 to move in unison with actuator 500. As will be apparent, actuator 500 alternatively may be friction locked with anchor lock element 34 prior to full deployment of apparatus 10. Furthermore, actuator(s) 500 may assist, or be used in place of, actuators 106a to deploy apparatus 10.

**[0233]** As seen in Figure 76C, the lock formed between anchor lock element 34 and post 32 may be unlocked or adjusted, as desired, by applying a lateral unlocking force to ratchet tooth 450 via actuator 500 that pulls the ratchet tooth away from a friction surface 443 of ratcheting lock elements 440. Actuator 500 then may be distally advanced or, as seen in Figure 76D, proximally retracted relative to ratcheting lock elements 440 and post 32 to further expand or partially collapse anchor 30, respectively (further expansion alternatively may be achieved by further ratcheting ratchet tooth 450 along camming surface 442 of ratcheting lock elements 440, e.g., by further proximally retracting actuator 106b, which is not shown in Figures 76C-76F for the sake of clarity). Anchor actuation elements 106 may assist such controlled expansion or collapse anchor 30.

**[0234]** When (re-)positioned at a desired location and/or when a desired degree of locking has been achieved, the lateral unlocking force may be removed from ratchet tooth 450 to again lock anchor lock element 34 to post 32 along ratcheting lock elements 440, as in Figure 76E. To complete deployment of apparatus 10, adjustment actuator 500 and actuator 106b, as well as actuator 106a (not shown), may be separated from the apparatus. In Figure 76F, release element 520 of actuator 500 is proximally refracted relative to adjustment element 510, thereby removing elongated member 521 of release element 520 from unlock actuator attachment 454 of anchor lock element 34. This removes the interference fit between notch 518 and attachment 454. Proximal retraction of actuator 500 relative to anchor lock element 34 detaches adjustment element 510 of actuator 500 from attachment 454 of anchor lock element 34, as in Figure 76G. Optional camming surface 519 along notch 518 may facilitate such detachment. In Figure 76H, actuator 106b is detached from post 32 by retracting release actuator 112 relative to the actuator, as described previously.

**[0235]** Referring now to Figures 77, another variation of an adjustable ratcheting lock element is described. As seen in Figure 77A, post 32 comprises tube 470 having lumen 471 and ratcheting lock element 472, illustratively a plurality of slots that communicate with lumen 471. Post 32 also comprises valve support structure or attachment element 474 and braid attachment element 476.

**[0236]** Anchor lock element 34, which may be fabricated from a cut tube, comprises a substantially cylindrical structure having braid attachment element 480, lumen 482 and tabs 484. As seen in the top view of Figure 77B, tabs 484 of anchor lock element 34 are configured for locking within the slots of ratcheting lock element 472 of post 32. As seen in the top view of Figure 77C, adjustment actuator 490, illustratively mandrel M having tapered distal end 494 that acts as a camming surface, may be advanced through lumen 481 of anchor lock element 34 and lumen 471 of tube 470 of post 32, to displace tabs 484 from the locking slots of post 32, thereby unlocking the post from the anchor lock element. This facilitates, for example, readjustment of a degree of locking/expansion of apparatus 10, repositioning of apparatus 10, retrieval of apparatus 10, etc.

**[0237]** Figures 78 illustrate a variation of anchor lock element 34 wherein tabs 484 are positioned along a different axis. This may provide a more secure lock between post 32 and anchor lock element 34. Figures 79 illustrate a variation of post 32 configured for use with the variation of anchor lock element 34. In Figures 69, post 32 comprises groove 478 that connects the slots of ratcheting lock element 472. Groove 478 does not communicate with lumen 471 of tube 470 of post 32. Rather, the groove may act as a lock alignment mechanism that guides tabs 484 of anchor lock element 34 along post 32 and ratcheting lock element 472, as seen in the top view of Figure 79B.

**[0238]** Referring now to Figures 80, a method of actuating the variation of Figures 78 is described. As seen in Figure 80A, adjustment actuator 490 is initially disposed through lumen 482 of anchor lock element 34 and within lumen 471 of post 32. Post 32 then may be proximally retracted relative to anchor lock element 34, e.g., via actuator 106b (not shown). In Figure 80B, actuator 490 serves as a lock prevention mechanism that precludes locking of tabs 484 within ratcheting lock element 472. In Figure 80C, actuator 490 is retracted relative to post 32 and anchor lock element 34, which opens up lumen 471 of tube 470 and allows tabs 484 to pass through the slots of ratcheting lock element 472, thereby locking the post to the anchor lock element. In Figure 80D, actuator 490 is re-advanced within lumen 471, such that tapered distal end 494 of mandrel M serves as a camming surface that urges tabs 484 out of lumen 471 as the actuator is advanced. This unlocks the post from the anchor lock element to facilitate adjustment, repositioning or retrieval of apparatus 10. In Figure 80E, a degree of locking/expansion of the apparatus is adjusted by repositioning anchor lock element 34 relative to post 32, and thereby tabs 484 relative to ratcheting lock element 472. When properly adjusted, actuator 490 may be removed from lumen 471 of tube 470 of post 32, as in Figure 80F. Tabs 484 resiliently return to the locked configuration within the slots of ratcheting lock element 472.

**[0239]** Referring now to Figures 81, an embodiment of anchor actuator 106a is described. Actuator 106a comprises elongated member 600 having proximal extension 602 that may be attached, for example, to previously described multi-lumen shaft or catheter 108 of delivery sys-



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tem/deployment tool 100 (see Figures 49), e.g., via epoxy, UV curing, etc. Lumen 601 extends through elongated member 600 from proximal extension 602 to releasable attachment mechanism 604. Releasable attachment mechanism 604 releasably attached actuator 106a to the braid of anchor 30. The mechanism comprises release actuator 112 and illustratively is similar to the previously described releasable attachment mechanism of Figures 63-65. Release actuator 112, illustratively a mandrel, passes through a lumen Lu of multi-lumen shaft 108 and then through lumen 601 of actuator 106a to mechanism 604.

**[0240]** Actuator 106a further comprises shaping features 606 that affect a shape of the anchor actuator when an anchor actuation force is applied to anchor 30. These features may comprise, for example, reduced diameter portions of the actuator, reduced wall thickness portions of the actuator and/or slits formed in the anchor actuator. Application of an anchor actuation force may, for example, provide actuator 106a with the profile seen in Figure 81A. This profile may facilitate expansion of anchor 30/apparatus 10. As will be apparent, shaping features may be provided with any anchor actuation elements 106, including any of the previously described variations of actuators 106b.

**[0241]** As seen in Figures 82, releasable attachment mechanism 604 comprises wrap portion 610 that may, for example, pass through the braid of anchor 30 and wrap around the proximal end of the anchor. Wrap portion 610 may comprise a shape memory material, such as Nitinol, or a deformable material, e.g., a resiliently deformable material. The wrap portion comprises first opening 612 for engaging release actuator 112. The walls of lumen 601 of elongated member 600 may act as a linear bearing and/or motion guide during advancement and refraction of the release actuator relative to the actuator. Actuator 106a also comprises second opening 614, which may be aligned with first opening 612 to engage release actuator 112, as shown. Wrap portion 610, and especially curved portion 611 of the wrap portion, acts as a spring element that urges the first opening out of alignment with the second opening to engage and hold release actuator 112 in place.

**[0242]** As seen in Figure 82C, when the release actuator is retracted proximally relative to the actuator, wrap portion 610 resiliently or dynamically swings outwards. Thereafter, proximal retraction of anchor actuator 106a relative to anchor 30 detaches wrap portion 610, and thereby actuator 106a, from the anchor. Surface 616 of wrap portion 610 may act as a camming surface as the inner surface of wrap portion 610 slides along the anchor braid 30 to facilitate such detachment.

**[0243]** In this manner, release actuator 112 may be interference or friction fit through first opening 612 and second opening 614. Retraction of the release actuator proximal of the first and second openings actuates releasable attachment mechanism 604 to resiliently or dynamically unwrap portion 610 and release actuator 106a from anchor 30. Wrap portion 610 of actuator 106a illustratively is disposed at a distal end of the actuator.

**[0244]** With reference to Figures 83, a variation of releasable attachment mechanism 604 is described. In Figures 83, wrap portion 610 illustratively comprises tabs 618 that act as an alignment mechanism for aligning the wrap portion of mechanism 604 with elongated member 600. This may facilitate advancement of release actuator 112 through mechanism 604. Figures 84 illustrate a variation of tabs 618 wherein the tabs are rounded. This may reduce friction, provide an afraumatic surface, etc. Additional shapes for tabs 618 will be apparent. Alternatively, tabs 618 may act as spring elements which are loaded when element 630 is seated, as shown in figure 84B. In this configuration tabs 618 apply a force directed towards element 630 such that 630 will be ejected when element 112 is refracted. In this way tabs 618 apply a restraining force on element 112 which reduces the risk of an early release.

**[0245]** Figures 85 illustrate a variation of wrap portion 610 that comprises a substantially straight distal region in an at-rest configuration, as seen in Figure 85C. It is expected that providing a substantially straight distal region along wrap portion 610 may facilitate detachment of actuator 106a from anchor 30, i.e., may reduce a risk of snagging the wrap portion along the braid of the anchor. The wrap portion may be resiliently deformed for passage of release actuator 112 through first opening 612, as in Figures 85A and 85B.

**[0246]** Referring now to Figures 86, variations of release actuator 112 for use with releasable attachment mechanism 604 are described. In Figure 86A, the release actuator comprises a simple mandrel. In Figures 86B and 86C, the release actuator comprises protrusion 620 having friction surface 621. In Figure 86D, actuator 112 comprises coil 622. In Figures 86E-86H, the actuator comprises kink 624, which may act as a camming surface, as shown. The kink may also provide tactile feedback to a medical practitioner. In Figures 86I and 86J, the release actuator comprises ball or knob 626 disposed proximal of the actuator's distal end. In Figures 86K and 86L, ball 626 is disposed at the distal end of actuator 112. The ball may act as a camming surface. In Figure 86M, actuator 112 comprises protrusion 628 having proximal camming surface 629. In Figure 86N, the actuator comprises oblong protrusion 430 having friction surface 431. Additional variations of actuator 112 will be apparent.

**[0247]** Referring now to Figures 87, an embodiment of delivery system/deployment tool 100 is described. Figure 87A provides a detail view of multi-lumen catheter 108 and sheath 110. As discussed previously catheter 108 comprises central lumen 109 and a plurality of circumferentially-disposed lumens Lu.

**[0248]** As seen in Figure 87B, actuator 106a is coupled to catheter 108 via proximal extension 602, such that lumen 601 is coaxially disposed within a lumen Lu of the catheter. Release actuator 112 extends through lumens Lu and 601. Actuator 106a is distally attached to the braid



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of anchor 30 along releasable attachment mechanism 604. For the sake of clarity, a single actuator 106a is shown in Figure 87B, but multiple such actuators preferably are provided, as in Figures 88 described hereinafter.

**[0249]** Figure 87B also illustrates actuator 106b. The actuator extends through a lumen Lu of catheter 108 and through anchor lock element 34 to post 32 (not shown). Unlock actuator 350 is also provided and extends through a lumen Lu to unlock actuator attachment 344 of anchor lock element 34. Anchor lock element 34 illustratively comprises the variation described previously with respect to Figures 68. The element is attached to the braid of anchor 30 along anchor, attachment elements 340. As with actuator 106a, a single anchor lock element 34 and actuator 106b are shown in Figure 87B. This is only for the sake of clarity, and multiple such actuators may be provided, e.g., three actuators.

**[0250]** Referring now to Figures 88, delivery system/deployment tool 100 is shown with a plurality of actuators 106a and actuators 106b for releasable attachment to anchor 30 of apparatus 10. In Figure 88A, anchor actuation elements 106a are coupled to the anchor. In Figure 88B, the elements are decoupled from the anchor.

**[0251]** With reference now to Figures 89, a variation of the delivery system/deployment tool of Figures 87 and 88 is described comprising a plurality of arms or actuators that extend from a unitary structure. Unitary structure 650, which may extend from a distal region of multi-lumen shaft 108, is preferably fabricated from a laser-cut tube. Structure 650 comprises a plurality of circumferentially disposed arms 652 that serve as actuators. Expansile elements 654 may be disposed between arms 652 and facilitate constraint of the arms radially outward or inward with respect to other arms as the anchor reshapes. Figure 89A shows the arms in a radially collapsed configuration, and Figures 89B shows the arms in a radially expanded configuration. Wrap portions 655 are adapted to wrap around the proximal portion of an anchor braid. Openings 656 and 657 are formed in wrap portions 655 to engage a release actuator, as described in embodiments above.

**[0252]** Referring now to Figures 90, various ways to connect elements to the braid of anchor 30 of replacement valve apparatus 10 are described. In Figure 90A, a post 32 having a single braid attachment hole 660 is attached to anchor 30 along three separate intersections of the braid via suture S. Figure 90B provides a detail view of one exemplary technique for routing the suture between hole 660 and anchor 30. Figure 90C illustrates a variation of the attachment, wherein post 32 comprises multiple braid attachment holes 660. As will be apparent, elements other than posts 32 may be attached to anchor 30 in the manner described, for example, anchor lock elements 34 may be attached in a similar manner.

**[0253]** As described in more detail in U.S. Patent Appl. Ser. No. 10/746,280, the distal region of anchor 30 may be pulled proximally via a proximally directed force applied to posts 32 via a distal deployment system interface. The distal deployment system interface is adapted to expand radially during application of a proximally directed force on the distal end of the anchor.

**[0254]** The distal deployment system interface may include confrol actuators that are controlled, e.g., by control knob 122 of confrol handle 120. Similarly, the proximal regions of anchor 30 may be pushed distally via a proximal deployment system interface at the proximal end of the anchor. The proximal deployment system interface is adapted to permit deployment system to apply a distally directed force to the proximal end of anchor 30 through, e.g., fingers 106, which are controlled by, e.g., Control knob 124 of control handle 120. The proximal deployment system interface may be further adapted to expand radially during application of a distally directed force on the proximal end of the anchor. Preferably, the proximal deployment system interface is adapted to permit deployment system to apply a distally directed force on the proximal end of the anchor system through a plurality of deployment system fingers or actuators 160. Such expansion optionally may be assisted via inflation of a balloon catheter (not shown) reversibly disposed within apparatus 10, as described in U.S. Patent Appl. Ser. No. 10/746,280.

**[0255]** Once anchor 30 is fully deployed, posts 32 and buckles 34 of anchor 30 may be used to lock and maintain the anchor in the deployed configuration. In one embodiment, the control actuators attached to posts 32 are threaded through buckles 34 so that the proximally directed force exerted on posts 32 by the control actuators during deployment pulls the proximal locking end of posts 32 toward and through buckles 34. Such lock optionally may be selectively reversible to allow for repositioning and/or retrieval of apparatus 10 during or post-deployment. Apparatus 10 may be repositioned or retrieved from the patient until the two-part locking mechanism of posts 32 and buckles 34 of anchor 30 have been actuated. When the lock is selectively reversible, the apparatus may be repositioned and/or retrieved as desired, e.g., even after actuation of the two-part locking mechanism. Once again, further details of this and other anchor locking structures may be found in U.S. Patent Appl. Ser. No. 10/746,280. Locking mechanisms used herein may also include a plurality of levels of locking wherein each level of locking results in a different amount of expansion. For example, the proximal end of the post can have multiple configurations for locking within the buckle wherein each configuration results in a different amount of anchor expansion.

**[0256]** Prior to implantation of replacement valve apparatus described herein, it may be desirable to perform a valvuloplasty on the patient's diseased valve by inserting a balloon into the valve and expanding it using, e.g., saline mixed with a contrast agent. In addition to preparing the valve site for implant, fluoroscopic viewing of the valvuloplasty will help determine the appropriate size of replacement valve implant to use.

**[0257]** Figures 50A-F show further details of anchor 30 of apparatus 10. Figure 50A shows the apparatus in a



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collapsed configuration, such as for delivery within a sheath or other lumen or for retrieval and recapture into a sheath or other lumen. Figures 50B and 50C show the anchor and valve in an expanded and locked configuration.

**[0258]** As shown in Figure 50C, anchor 30 has three posts and three buckles. As seen in Figure 50C, the three leaflets of replacement valve 20 may be coupled to the three posts 32 also known as valve supports. The posts, unlike the braid, do not collapse or expand, hi some embodiments a post 32 has one or more proximal slots 33, at least one proximal hole 36a and at least one distal hole 36b. Leaflet tissue may be passed through slot 33 and sutured in place via suture routed through one or more proximal holes 36a. Other means known in the art for fixing valve leaflets to posts may also be employed.

**[0259]** Figure 91 illustrates an exemplary apparatus for fabricating braided anchors. Such apparatus includes a cylindrical braiding fixture 200. The cylindrical braiding fixture 200 comprises proximal circumference of inner posts 202a separated by a distance x from distal circumference of inner posts 202b. x can be, for example, 10 to 60 mm, more preferably 20 to 50 mm, or more preferably 30 to 40 mm. Optionally, the fixture may also comprise proximal and distal circumferences of outer posts 204a and 204b, respectively. 204a and 204b can be situated about 2-10 mm from 202a and 202b, respectively. Posts 202a/b and 204a/b project from fixture 200 and may be used to route wire, e.g., for forming anchor braid 30. Inner posts 202a and 202b generally facilitate formation of a braid, while outer posts 204a and 204b generally facilitate formation of desired features at the ends of the braid, as described hereinafter with respect to Figures 93-96.

**[0260]** In some embodiments, fixture 200 comprises approximately 6-20 posts, more preferably 8-18 posts, or more preferably 10-16 posts around its circumference, though any alternative number of posts may be provided. Likewise, fixture 200 preferably has a diameter of about 2-40mm, more preferably 4-30 mm, or more preferably 6-20mm, though any alternative diameter may be provided. The diameter of fixture 200 preferably is the diameter of the braid in its "at rest" configuration.

**[0261]** Fixture 200 can optionally further comprise circumferential grooves 206 to facilitate interweaving of a first section of wire underneath an adjacent section of wire. The fixture optionally also may comprise localized depressions or holes 208 in addition, or as an alternative, to grooves 206. Depressions 208 may be provided at locations where wire segments cross to act as a visual guide for formation of anchor braid 30, as well as to facilitate the interweaving of a first section of wire beneath an adjacent section of wire.

**[0262]** Referring now to Figures 92A-D, an illustrative method of using fixture 200 to fabricate braided anchors in accordance with the present invention is described. Figure 92A provides a detail view of a proximal front side region of fixture 200 during formation of a braided anchor. Figure 92B shows a detail backside view of a central section of the fixture. Figure 92C shows a full-length front-side view of the fixture and Figure 92D shows the completed braid, hi Figures 92, anchor braid 30 is formed from a single strand of wrapped and interwoven wire W. However, it should be understood that anchor braid 30 alternatively may be formed from multiple strands of wire.

**[0263]** As seen in Figure 92A, formation of anchor braid 30 begins with wire W being routed from starting position P near the proximal end of fixture 200 past outer proximal posts 204a and inner proximal posts 202a. Wire W preferably is formed from a superelastic and/or shape-memory material, such as Nitinol. However, alternative wire materials may be utilized, including Cobalt-Chromium, Steel and combinations thereof, as well as additional materials that will be apparent to those of skill in the art.

**[0264]** After passing inner proximal posts 202a, wire W encircles fixture 200 in a helical spiral while extending towards the distal posts, as seen in Figures 92B and 92C. The wire illustratively encircles fixture 200 a full 360° revolution plus one additional post. However, any alternative degree of winding may be provided (e.g., a full 360° plus 2 additional posts, a full 360° plus 3 additional posts, o a number of posts less than a full 360°) . As will be apparent to those of skill in the art, altering the degree of winding will alter the expansion characteristics of the resultant braid in ways per se known.

**[0265]** At distal inner posts 202b, wire W forms turn Tu and is rerouted back towards proximal imier posts 202a. It should be noted that wire W can form turn Tu in either inner posts 202 or outer posts 204. Turn Tu forms a closed end of the braid. Additional sets of inner and outer posts are also contemplated. The wire once again encircles fixture 200 in a full 360° helical revolution plus one additional post before reaching the proximal inner posts and being rerouted back towards the distal inner posts. This process is repeated with the wire repetitively interwoven at crossing locations between the proximal and distal posts, e.g., via grooves 206 and/or depressions 208, to define the cells of the braid that will provide anchor 30 with desired characteristics. As seen in Figure 92D, wire W turns both proximally and distally in order to complete formation of the braid, hi this embodiment, wire W terminates in the central portion of the braid at T. Termination T may be formed, for example, by welding the wires together, applying a shrink tube about the overlap, using a crimp, braising the wires, etc. Additional techniques will be apparent to those of skill in the art.

**[0266]** When anchor braid 30 is formed from a shape-memory material, the braid may be heat set such that it maintains a desired degree of expansion in an at-rest configuration. The heat set at-rest configuration may comprise, for example, the delivery configuration (e.g., collapsed configuration) of Figure 50A, the deployed configuration (e.g., expanded configuration) of Figures 50B and 50C, or any desired configuration therebetween. In preferred embodiments, the anchor is heat-set in a configuration between the delivery configuration and the de-



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ployed configuration. Anchor braid 30 may be heat set while still disposed on fixture 200 to maintain an at-rest configuration as formed on the fixture, which preferably is a configuration between the delivery and deployed configurations. Alternatively, the braid may be heat set after complete or partial removal from the fixture. As yet another alternative, the braid may be initially heat set while still disposed on the fixture, but thereafter may be additionally heat set in a different shape, for example, a more expanded configuration. It is expected that heat setting anchor braid 30 will provide the braid with desired delivery and/or deployment characteristics.

**[0267]** Referring now to Figures 93A-93O, in conjunction with Figures 50C and 92, an anchor braid 30 may be defined by a set of cells that is different than other cells. Such cells may be formed to provide anchor braid 30 with one or more edge features (for either or both the distal and proximal ends). These edge features can, for example, reduce or relieve sfress within the braid during delivery and deployment, which in turn may reduce the incidence of anchor material fatigue caused by the pulsatile anchor motion of the anchor site. As will be apparent to those of skill in the art, forming braid 31 from a single strand of wire W (or from multiple strands of wire W that form turns or that are joined together) may lead to sfress concentration at turns Tu in the wire where the wire changes direction and extends back towards the opposite end of the braid. Such stress concentration may be most pronounced while the braid is disposed in its extreme configurations, i.e. when the braid is disposed in the collapsed delivery configuration of Figure 50A or the expanded deployed configuration of Figures 50B and 50C.

**[0268]** Stress concentration may increase the rigidity of an anchor braid and/or may impede delivery and deployment, as well as sheathing, of the braid. Thus, in preferred embodiments, a group of cells can be configured to reduce the sheathing force as described herein. Furthermore, to enhance deliverability, sfress concentration may require that anchor braid 30 be fabricated from a relatively thin wire W. However, thin wire may not provide anchor braid 30 with adequate radial strength to displace a patient's diseased native heart valve leaflets and/or to anchor apparatus 10 against a patient's anatomy. Conversely, use of a relatively thick wire W may increase stiffness, thereby precluding retrograde delivery of apparatus 10, as well as a risk of kinking at turns in the braid. Thus, in some embodiments, wires varying in thickness may be used, or multiple wires having different thickness may be woven together. Also, wires made from different materials may be used to form an anchor braid.

**[0269]** It may be desirable to reduce sfress concentration at the edges of anchor 30 where wire W changes direction and/or to reduce the circumferential stiffness of the anchor braid. The edge characteristics of the anchor may be altered by altering the shape of substantially all anchor braid cells at the anchor's edge (e.g., distal edge and/or proximal edge). Wire turns that confrol the shape of the edge cells may be formed within anchor braid 30 by routing wire W around optional outer posts 204 of fixture 200 during formation of the braid. Figure 93A illusfrates a detail view of a standard end turn Tu in an anchor braid resulting in a braid with substantially uniform cell size and shape. Figure 93B illustrates a turn that has been elongated to lengthen the distance over which forces concentrated in the turn may be distributed, resulting in an anchor braid having edge cells that are longer along the anchor axis than the other cells defined by the braid. This elongated turn feature may be formed by routing the wire of braid about outer posts 204 of fixture 200, and then heat setting the wire.

**[0270]** Figure 93C illustrates an alternative anchor edge cell configuration, wherein the tip of the elongated wire turn has been bent out of a cylindrical shape defined by the braid of anchor braid 30. This may be achieved, for example, via a combination of routing of wire W within fixture 200 and heat setting. The out-of-plane bend of turn Tu in the anchor edge cells in Figure 93C may reduce stress in some configurations, and may also provide a lip for engaging the patient's native valve leaflets to facilitate proper positioning of apparatus 10 during deployment.

**[0271]** In Figure 93D, a W-shaped turn feature has been formed at the wire turn, e.g., by routing the wire of anchor braid 30 about a central inner post 202 and two flanking outer posts 204 of fixture 200. As with the elongated braid cells of Figures 93B and 93C, the W-shape may better distribute sfress about turn Tu. The anchor edge cell configuration in Figure 93E includes a loop formed in braid 31 at the turn, which may be formed by looping wire W around an inner or outer post of fixture 200. Figure 93F provides another alternative anchor edge cell configuration having a figure-eight shape. Such a shape may be formed, for example, by wrapping wire W about an inner post 202 and an aligned outer post 204 in a figure-eight fashion, and then heat setting the wire in the resultant shape.

**[0272]** In Figure 93G, the edge cells of braid 31 include a heart-shaped configuration, which may be formed by wrapping the wire about an aligned inner and outer post of fixture 200 in the desired manner. In Figure 93H, the edge cells of braid 31 have an asymmetric loop at turn Tu. The asymmetric loop will affect twisting of braid 31 during expansion and collapse of the braid, in addition to affecting stress concentration, hi Figure 93I, the anchor edge cells have a double-looped turn configuration, e.g. via wrapping about two adjacent inner or outer posts of fixture 200. Additional loops may also be employed. The double loop turn feature may be formed with a smooth transition between the loops, as in Figure 93I, or may be heat set with a more discontinuous shape, as in Figure 93J.

**[0273]** Figure 93K illusfrates that the edge cells of braid 31 may have multiple different configurations about the anchor's circumference. For example, the anchor edge cells shown in Figure 93K have extended length cells as



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in Figure 93B disposed adjacent to standard size edge cells, as in Figure 93A. The anchor edge cells of Figure 93L have an extended turn configuration having an extended loop. The anchor edge cells shown in Figure 93M have an alternative extended configuration with a specified heat set profile. Finally, the anchor edge cells shown in Figure 93N that overlap or are interwoven to be coupled to one another.

**[0274]** In preferred embodiments, the edge cells may be wrapped using wire, string, or sutures, at a location where the wire overlaps after an end turn as is illustrated in Figure 93O. This tied-end turn feature prevents cells from interlocking with each other during deployment.

**[0275]** The edge cell configuration of Figure 93 may be heat set independently of the rest of the braid. The anchor edge cell configurations of Figures 93 are provided only for the sake of illustration and should in no way be construed as limiting. Additional turn features within the scope of the present invention will apparent to those of skill in the art in view of Figures 93. Furthermore, combinations of any such turn features may be provided to achieve desired characteristics of anchor braid 30.

**[0276]** Referring now to Figures 94A-E, additional configurations for reducing sfress concentration and/or circumferential stiffness of anchor braid 30 are illustrated. Such configurations can be used independently or in conjunction with other configurations disclosed herein. Such configurations are preferably used at the anchor's edges to locally reduce the cross-sectional area of substantially all cells or all cells in the anchor braid's edge (e.g., proximal and/or distal). As seen in Figures 94A and 94B, turns Tu in wire W typically may have a substantially continuous (e.g., round) cross-sectional profile. As seen in Figure 94C, modifying the edge cell configuration by locally reducing the thickness or cross-sectional area of wire W at turn(s) Tu will reduce stress concentration within the wire at the turns and facilitate collapse and/or expansion of anchor braid 30 from the delivery to the deployed configurations. Furthermore, it is expected that such localized reduction in thickness or cross-sectional area will reduce a risk of kinking, fatigue or other failure at turns Tu.

**[0277]** Localized reduction may be achieved via a localized etching and/or electropolishing process. Alternatively or additionally, localized grinding of the turns may be utilized. Additional processing techniques will be apparent to those of skill in the art. As seen in Figures 94D-94E, wire W may, for example, comprise an oval or rectangular cross-sectional profile, respectively, after localized reduction. The wire alternatively may comprise a round profile of reduced cross-sectional area (not shown). Additional profiles will be apparent. Localized reduction can take place at any time (e.g., before or after a braid is woven). Preferably, localized reduction occurs after weaving. However, in some embodiments, a wire of a given length may be etched or ground at preset segments and subsequently woven.

**[0278]** Referring now to Figures 95 A- J, instead of terminating the beginning and end of wire W of braid 31 at an overlap within the braid, as discussed previously, the two ends of the wire may be terminated at the anchor's edge. Likewise, when braid 31 is fabricated from multiple wires W, the wires (or a subset of the wires) optionally may be joined together or terminated at turn(s) of the braid. In Figure 95A, wire termination T at the ends of wire(s) W comprises a hinged termination with hinge post 38. In Figure 95B termination T comprises a clipped or crimped termination with end cap 39. In Figure 95C, cap 39 is wrapped about the ends of wire W to form wrapped termination T.

**[0279]** In Figure 95D, cap 39 is placed over the wire ends, which are then bent to provide a swivel termination, hi Figure 95E, the wire ends are potted within cap 39 at termination T. In Figure 95F, cap 39 is swaged about the wire ends. In Figure 95G, the wire ends are welded or glued together, hi Figure 95G, the wire ends are spot welded together. Alternatively, the wire ends may be braised to form termination T, as in Figure 95H. As yet another alternative, cap 39 may be placed about the wire ends, and kinks K may be formed in wire W to provide the ends of the wire with an 'over-center' bias that maintains termination T, e.g., swivel termination T. Additional terminations will be apparent to those of skill in the art.

**[0280]** With reference now to Figures 96A-B, alternative anchors of the present invention are described having anchor edge features that facilitate sheathing of the apparatus and reduce the sheathing force. In Figure 96A, the edge cells of anchor 30 have inwardly canted configurations at the wire turns Tu about a proximal circumference of the anchor. These edge cell configurations provide the proximal circumference with a conical profile that facilitates sheathing of the apparatus within a delivery system, e.g., previously described delivery system 100, by allowing collapse of anchor 30 to proceed in a more gradual and/or continuous manner, and tunneling the anchor into the sheath.

**[0281]** Figure 96B illusfrates another alternative anchor 30 having edge cell configurations formed by wire turns Tu about its proximal circumference that first cant outward, and then cant inward. The inward cant provides the proximal circumference with a conical profile and may facilitate sheathing, while the outward cant may facilitate anchoring at a treatment site, e.g., may engage a patient's native valve leaflets. As will be apparent, the edge cell configurations of Figures 8, as well as those of Figures 93-95, optionally may be provided at either the proximal or distal ends of the anchor, or both. The edge cell configurations of Figures 96, as well as those of Figures 93 and 95, may, for example, be formed by heat setting braid 31 in the desired configuration.

**[0282]** Referring now to Figures 97, further alternative anchors are described having edge cell configurations adapted to lock the anchor in the deployed configuration to maintain expansion. In Figure 97A, anchor 30 comprises elongated, hooked edge cells formed from wire turns Tu that are configured to snag braid 31 and maintain the anchor in the deployed configuration, as shown, hi



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Figure 97B, the hooked turn features have been elongated, such that the hooks are configured to snag the opposing end of anchor 30 to maintain expansion.

**[0283]** In Figure 97C, anchor edge cells defined by wire turns TuP and distal turn features TuD are configured to interlock between the ends of anchor braid 30 in order to maintain the deployed configuration of anchor 30. The proximal edge cells form a hook adapted to engage elongated turns of the distal turn features. As will be apparent, the disposition of all or a portion of the proximal and distal edge cell configurations optionally may be reversed, i.e. the proximal edge cells may form hooks and the distal edge cells may be configured as elongated turns. Figure 97D illusfrates interlocking proximal and distal edge cell configurations of more complex geometry. Figure 97E illustrates interlocking proximal and distal edge cell configurations while anchor 30 is disposed in the collapsed delivery configuration. The locking turn features of Figures 97 may, for example, be formed by heat setting anchor braid 30 (or locking features only) in the desired configuration. Additional locking turn features will be apparent to those of skill in the art. In preferred embodiments, the anchor locking mechanism can be set to have alternative locking options that allow for various amounts of expansion.

**[0284]** Figures 98A-98D illustrate various embodiments of anchor braids. An anchor braid can be made of one or more wire and can be used to form various density braids. The density of the braid can be assessed by the size of cells formed by the weave. In some embodiments, two or more different density braids may be woven together. For example, Figure 98A illusfrates two groups of cells or two braids interwoven in the center. The top group of cells forms a more open weave than the bottom group of cells, which forms a denser weave. Figure 98B illusfrates another embodiment of an anchor braid having three groups of cells. The top and bottom (proximal and distal) edges of the anchor braid have denser cells than the central portion of the anchor. Also, the edges of the anchor are woven from a thinner filament than the central portion. In another embodiment illustrated by Figure 98C, all three sections of an anchor valve are woven by more than one wire. The wires of each section are made of a different material and/or thickness. Wires at the sectional boundaries may or may not interconnect with wires from a different section. Each of the sections of the braid anchor may be composed of a different number of wires. Figure 98D illustrates another embodiment of a braided anchor having three sections, i this embodiment, all sections are composed of a single wire. The proximal and distal sections/edges of the braided anchor have the same pitch. The central region of the braided anchor has a different pitch than the edge sections.

**[0285]** Figures 99A-99E illustrate side views of braided anchor having more than one braid pitch. Varying pitch within the anchor allows localized variations in foreshortening across the anchor, as greater foreshortening is achieved by higher pitch of the braid. Moreover, the localized foreshortening features allow for the design of a braid which incorporates various diameters depending upon the amount of foreshortening. (The greater the foreshortening, the greater the diameter increase upon deployment.)

**[0286]** Figure 99A, for example, is a side view representation of braided anchor of Figure 98D. On the left side of the figure, the expanded anchor is illustrated having a denser weave (shorter pitch) at the distal and proximal ends; hence the dots are located closer to each other. The middle section of the anchor is composed of a looser weave that is generated by a higher pitch braid and is represented by dots that are farther away from each other. On the right side of the figure, the braided anchor is foreshortened and the dots are collapsed closer to each other. In this case, the central portion of the anchor foreshortened more than the proximal and distal edges. Figure 99B illustrates a side view of a foreshortened braided anchor that is created by low pitch at the edges and high pitch in the middle. Figure 99C illustrates a side view of a foreshortened braided anchor that is created by high pitch edges and low pitch middle section. Figure 99D illusfrates a side view of a foreshortened braided anchor that includes a sealing feature or space filling feature at both ends. This type of anchor can be created by a high pitch braid at edges, low pitch braid in the middle and heat setting the edges to curl upon unsheathing. This end feature is useful in facilitating anchoring by functioning as a locator and sealing. Figure 99E illustrates a side view of a foreshortened braided anchor that is associated with an everting valve or locational features.

**[0287]** In preferred embodiments, the middle section of the anchor may be composed of thicker wire(s) than edge section(s)

**[0288]** Figures 100A-100C illustrate an example of the process of deploying the anchor, such as the one illustrated in Figure 99B above. Figure 100A illusfrates a braided anchor 30 in its expanded configuration. The anchor is composed of three sections. The distal and proximal sections of the anchor are made of a fine weave (low pitch) braid. The middle section of the anchor is made of a higher pitch braid and are preferably heat set to roll upon unsheathing. Furthermore, in preferred embodiments, the filaments of the distal and proximal sections may be thinner (e.g..005 in thickness) than the filaments of the middle section (e.g., .010 in thickness). Posts 32 are coupled to the middle section of the anchor. For deployment, proximal actuators 106 are coupled to the anchor's middle section. Figure 100B illusfrates the process of deployment. As the anchor is pushed distally by the proximal actuators and pulled proximally by the distal actuators, it is unsheathed and begins foreshortening. The distal section rolls up and can act as a locator, assisting the operator in locating the aortic valve. It then functions as a seal preventing leakage. The proximal section may optionally also roll up. hi Figure 100C, the device may be configured such that the middle section of the



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valve may form an hour glass shape or a round shape. The actuators may subsequently be removed as described before. Figure 100D is another illustration of the braided anchor in its elongated configuration. Figure 100E is another illustration of the braided anchor in its foreshortened configuration.

**[0289]** Figures 101A-101B illustrate another embodiment of a braided anchor. In this embodiment, the anchor includes two sections - a distal section made of a fine weave and a higher pitch braid than the proximal section. In Figure 101A the device is deployed such that the distal section made of the fine weave is distal to the aortic valve. In Figure 101B, the distal section is foreshortened, either by heat set memory or actively. The foreshortening of the distal section allows the operator to locate the valve and situate the anchor prior to release.

**[0290]** The anchors described herein can be, for example, radially symmetrical, bilaterally symmetrical, or asymmetrical. A radially symmetrical anchor is one for which symmetry exists across any diameter. A bilaterally symmetrical anchor is one for which symmetry exists across a finite number if diameters). An asymmetrical anchor is one for which there exists no diameter across which a symmetry may be found. Figure 50B illustrates one embodiment of a radially symmetrical anchor. Figure 102A illustrates one embodiment of a bilaterally symmetrical anchor. Figure 102B illusfrates two embodiments (side and top views) of asymmetrical anchors. The benefits of bilaterally symmetrical an asymmetrical anchors is their ability to avoid interfering with anatomical features, such as, for example the coronary ostial and/or mitral valve. Thus, in preferred embodiments, a braided anchor includes a region adapted to prevent expansion of the anchor into the mitral valve, as is illustrated in Figure 102A.

**[0291]** In preferred embodiments, the anchor includes a leaflet engagement element and/or a seal inverting element situated on its proximal end. The leaflet engagement element is adapted for engaging the native leaflets of the patient's heart, or more preferably the proximal edge and/or the commissural attachments of the native leaflets. The leaflet engagement v element need not extend all the way into the pocket or the distal end of the native leaflet. Preferred embodiments of the apparatus herein are depicted in Figures 32-34, 49, 50, 93 and 98-109, which are discussed in more detail below.

**[0292]** Figure 103 provides a detail view of a front side region of anchor braid 30 with closed end turns Tu. Anchor braid 30 includes various cells, some having an end turn (Tu). End turns can serve various functions. For example, end turns can be configured to reduce the sheathing force, to reduce stress within the braid during delivery and deployment, to prevent distal migration during expansion of the anchor, and/or to positively register the anchor against the native valve during deployment. In preferred embodiments, an end turn feature functions to prevent distal migration and to register the anchor by engaging the native leaflets. In preferred embodiments, the proximal end of an anchor comprises embodiments (Tu).

**[0293]** Figures 93A-93N provide multiple examples of edge cells having end turn feature. The end turn features disclosed and others known in the art may be used as leaflet engagement elements to engage the native heart leaflets with the anchor. The leaflet engagement elements are preferably integral with the anchor, or more preferably part of a braided anchor. The end turn features can occur at the proximal end, the distal end, or both proximal and distal ends of the anchor.

**[0294]** For example, Figure 93 A illustrates a detail view of a standard end turn Tu in an anchor braid resulting in a braid with substantially uniform cell size and shape.

**[0295]** Figure 93B illusfrates a turn that has been elongated to lengthen the distance over which forces concentrated in the turn may be distributed, resulting in an anchor braid having edge cells that are longer along the anchor axis than the other cells defined by the braid. This elongated turn feature may be formed by routing the wire of braid about outer posts and then heat setting the wire.

**[0296]** Figure 93 C illustrates an alternative anchor edge cell configuration, wherein the tip of the elongated wire turn may be bent out of a cylindrical shape defined by the braid of anchor braid 30. This may be achieved, for example, via a combination of routing of wire W within a fixture and then heat setting. Such a turn Tu in the anchor edge cells in Figure 93 C may reduce stress in some configurations without increasing height, and may also provide a lip for engaging the patient's native valve leaflets to facilitate proper positioning of apparatus 10 during deployment.

**[0297]** In Figure 93D, a W-shaped turn feature has been formed at the wire turn, e.g., by routing the wire of anchor braid 30 about a central inner post and two flanking outer posts. As with the elongated braid cells of Figures 93B and 93C, the W-shape may better distribute stress about turn Tu.

**[0298]** The anchor edge cell configuration in Figure 93E includes a loop formed in braid 30 at the turn, which may be formed by looping wire W around an inner or outer post.

**[0299]** Figure 93F provides another alternative anchor edge cell configuration having a figure-eight shape. Such a shape may be formed, for example, by wrapping wire W about an inner post and an aligned outer post in a figure-eight fashion, and then heat setting the wire in the resultant shape.

**[0300]** In Figure 93G, the edge cells of braid 30 include a heart-shaped configuration, which may be formed by wrapping the wire about an aligned inner and outer post in the desired mamier.

**[0301]** In Figure 93H, the edge cells of braid 30 have an asymmetric loop at turn Tu. The asymmetric loop will affect twisting of braid 30 during expansion and collapse of the braid, in addition to affecting stress concentration.

**[0302]** In Figure 93I, the anchor edge cells have a double-looped turn configuration, e.g. via wrapping about two



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adjacent inner or outer posts. Additional loops may also be employed.

**[0303]** The double loop turn feature may be formed with a smooth transition between the loops, as in Figure 93I, or may be heat set with a more discontinuous shape, as in Figure 93J.

**[0304]** Figure 93K illustrates that the edge cells of braid 30 may have multiple different configurations about the anchor's circumference. For example, the anchor edge cells shown in Figure 93K have extended length cells as in Figure 93B disposed adjacent to standard size edge cells, as in Figure 93A.

**[0305]** The anchor edge cells of Figure 93L have an extended turn configuration having an extended loop.

**[0306]** The anchor edge cells shown in Figure 93M have an alternative extended configuration with a specified heat set profile.

**[0307]** In Figure 93N, some or all anchor edge cells are interwoven. When interwoven, one or more edge cells may be shorter or longer than an adjacent edge cell. This permits one or more edge cells to extend into one or more leaflet pocket(s). For example, in Figure 93N the middle Tu may be taller than the two adjacent edge cells thus permitting the edge cell to be situated within a leaflet pocket.

**[0308]** In any of the embodiments herein, edge cells may be wrapped using wire, string, or sutures, at a location where the wire overlaps after an end turn as is illustrated in Figure 93O. This tied-end turn feature prevents cells from interlocking with each other during deployment.

**[0309]** The anchor and any of its features may be heat set at different configurations. For example, the anchor may be heat set ay its "at rest" configuration such that upon unsheathing it expands radially. The end turn features/leaflet engagement elements may be heat set at a different "at rest" configuration than the rest of the anchor. In preferred embodiment, end turn features are heat set to "flower" and then "evert" upon unsheathing.

**[0310]** The end turn features of Figures 93 are provided only for the sake of illustration and should in no way be construed as limiting. Additional turn features within the scope of the present invention will apparent to those of skill in the art in view of Figures 93. Furthermore, combinations of any such end turn features may be provided to achieve the desired characteristics of anchor 30.

**[0311]** Referring now to Figures 104A-E, additional configurations for reducing and/or circumferential stiffness of an anchor braid and/or leaflet engagement elements are illustrated. Such configurations can be used independently or in conjunction with other configurations disclosed herein. Such configurations are preferably used at the anchor's edges to locally reduce the cross-sectional area of substantially all cells or all cells in the anchor braid's edge (e.g., proximal and/or distal). As seen in Figures 104A and 104B, turns Tu in wire W typically may have a substantially continuous (e.g., round) cross-sectional profile. As seen in Figure 104C, modifying the edge cell configuration by locally reducing the thickness or cross-sectional area of wire W at turn(s) Tu will reduce stress concentration within the wire at the turns and facilitate collapse and/or expansion of anchor braid 30 from the delivery to the deployed configurations. Furthermore, it is expected that such localized reduction in thickness or cross-sectional area will reduce a risk of kinking, fatigue or other failure at turns Tu.

**[0312]** In any of the embodiments herein, localized reduction of an anchor wire may be achieved via a localized etching and/or electropolishing process. Alternatively or additionally, localized grinding of the turns may be utilized. Additional processing techniques will be apparent to those of skill in the art. As seen in Figures 104D-104E, wire W may, for example, comprise an oval or rectangular cross-sectional profile, respectively, after localized reduction. The wire alternatively may comprise a round profile of reduced cross-sectional area (not shown). Additional profiles will be apparent. Localized reduction can take place at any time (e.g., before or after a braid is woven). Preferably, localized reduction occurs after weaving. However, in some embodiments, a wire of a given length may be etched or ground at preset segments and subsequently woven.

**[0313]** With reference now to Figures 105A-F, a method of endovascularly replacing a patient's diseased aortic valve is provided. The method involves endovascularly delivering an anchor/valve apparatus and properly positioning such apparatus via positive registration with the patient's native valve leaflets. Regisfration with the native valve leaflet preferably occurs using the leaflet engagement elements.

**[0314]** In Figure 105 A, modified delivery system 100' delivers apparatus 10 to diseased aortic valve AV within sheath 110. Apparatus 10 is delivered in a collapsed delivery configuration.

**[0315]** As seen in Figures 105B and 105C, apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance. Sheath 110 includes at its distal end leaflet engagement elements 120. Upon deployment, anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration. This causes elements 60 to also dynamically expand, as well as membrane filter (or braid) 61 A and leaflet engagement elements 120. As when deployed via delivery system 100, deployment of apparatus 10 via delivery system 100' is fully reversible until locks 40 have been actuated.

**[0316]** Thus, delivery system 100' comprises leaflet engagement element 120, which preferably self-expands along with anchor 30. hi preferred embodiments, the distal end of leaflet engagement elements 120 expands a greater radial distance than anchor 30. Moreover, engagement elements 120 maybe disposed between elements 60 of delivery system 100' and lip region 32 of anchor 30. However, leaflet engagement elements 120 may also be disposed on the proximal end of an anchor (as is illustrated in Figure 106). Leaflet engagement elements 120 releasably engage the anchor. As seen in



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Figure 105C, the leaflet engagement elements 120 are initially deployed proximal of the patient's native valve leaflets L. Apparatus 10 and element 120 then may be advanced/dynamically repositioned until engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus 10. The leaflet engagement element engages with the proximal edges of the native valve leaflets and/or the commissural attachments. The leaflet engagement element need not extend all the way to the distal edge of the native leaflets (the leaflet pockets). In preferred embodiments, a leaflet engagement element length is less than about 20 mm, more preferably less than about 15 mm, or more preferably less than about 10 mm. Once leaflet engagement element 120 is registered against the native valve leaflets and/or commissural attachments, apparatus 10 deploys substantially distal to the coronary ostia of the heart.

**[0317]** In any of the embodiments herein, delivery system 100' can include filter structure 61A (e.g., filter membrane or braid) as part of push elements 60 to act as an embolic protection element. Emboli can be generated during manipulation and placement of anchor from either diseased native leaflet or surrounding aortic tissue and can cause blockage. Arrows 61B in Figure 105C show blood flow through filter structure 61A where blood is allowed to flow but emboli is trapped in the delivery system and removed with it at the end of the procedure.

**[0318]** Active foreshortening may be imposed upon anchor 30 while element 120 is disposed proximal of the leaflets, as is illustrated in Figure 105D. Active foreshortening can be accomplished by actuating distal anchor actuation elements (e.g., elements 50) and/or proximal anchor actuation elements (e.g., elements 60). Upon positive registration of element 120 against leaflets L, element 120 precludes further distal migration of apparatus 10 during additional foreshortening, thereby reducing a risk of improperly positioning the apparatus. Figure 105E details engagement of element 120 against the native leaflets.

**[0319]** As seen in Figure 105F, once apparatus 10 is fully deployed, anchor 30 may be locked (reversibly or irreversibly). Subsequently, structure 61A leaflet engagement, elements 120, elements 50 and/or elements 60 may be decoupled from the apparatus, and delivery system 100' may be removed from the patient, thereby completing the procedure.

**[0320]** Figure 106 illustrates an alternative embodiment of the apparatus of Figures 105A-F described above, wherein leaflet engagement elements 120 are coupled to anchor 30 of apparatus 10' rather than to delivery system 100. In the embodiment illustrated in Figure 106, leaflet engagement elements 120 remain implanted near the patient's native heart valve after the deployment of apparatus 10' and removal of delivery system 100. Leaflets L may be sandwiched between the proximal region of anchor 30 and leaflet engagement element 120 in the fully deployed configuration. In this manner, element 120 positively registers apparatus 10' relative to the leaflets L and precludes distal migration of the apparatus over time.

**[0321]** Figures 107A-107C illustrate another embodiment for endovascularly delivering an apparatus of the present invention. In Figure 107A, a catheter 600 is delivered percutaneously in a retrograde fashion to the aortic valve. The catheter passes through the native aortic valve before an operator actuates the unseathing of the anchor/valve apparatus. As the sheathing catheter is pulled proximally out of the native valve, anchor 30 and replacement valve 20 become unsheathed. Immediately the portion of the unsheathed anchor 30 dynamically self-expands to its "at rest" position, and replacement valve 20 within the anchor regains an uncollapsed structure, allowing it to begin to function. In preferred embodiments in its "at rest" position, anchor 30 presses against the native leaflets limiting blood from flowing in between the anchor and leaflet. Also, in preferred embodiments, anchor 30 portions relatively adjacent to the valve is externally covered by a seal 60, more preferably the entire exterior contour of anchor 30 excluding the leaflet engagement elements is externally covered by a seal, or more preferably the entire contour of anchor 30 including the external face of the leaflet engagement elements is externally covered by a seal. A seal can be composed of any material that prevents or limits the flow of blood through the anchor. In preferred embodiments, a seal is composed of a thin, elastic polymer or any other type of fabric. The seal can be attached by any means known in the art to the anchor and, in some embodiments, to the distal end of the valve. In preferred embodiments, a seal is attached to the anchor by suturing.

**[0322]** In Figure 107B, as the catheter is further pulled proximally, the proximal end of anchor 30 and fingers 50 are unsheathed. In this embodiment, it is possible to visualize that the seal covers the entire contour of the anchor including the external face of the leaflet engagement element 70. As soon as the proximal end of the anchor is exposed, it also dynamically expands. Furthermore, when fingers 50 become exposed, replacement valve 20 begins to function permitting blood to flow through replacement valve 20, between fingers 50, and around the catheter 600. This also permits blood to flow into the coronary ostias. In other embodiments where the seal does not cover the proximal end of the anchor, the replacement valve can begin to function as soon as the unsealed portion of the anchor is unsheathed. This causes the leaflet engagement elements 70 to radially expand to their heat set position and engage with the native heart leaflets.

**[0323]** Next, Figure 107C, as the apparatus is actively foreshortened using proximal (e.g., fingers) and/or distal actuators (e.g., elements 55), the leaflet engagement elements positively register with the native valve leaflets. Foreshortening can cause seal 60 to bunch up and create pleats. These pleats can then fill pockets thereby improving the paravalvular seal. In preferred embodiments, wherein the leaflet engagement elements are covered with a seal, at least a portion of the seal is also positioned



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between the native valve leaflets and the aortic wall. Once the anchor is fully compressed within the aortic valve, the anchor is locked, the fingers and post mandrels are disengaged, and the seal is adapted to further limit blood flow around the replacement valve. The catheter is subsequently'withdrawn, leaving behind valve 20, seal 60 and anchor 70. When fully deployed, the anchor is substantially distal to the coronary ostia of the patient such that it will not interfere with blood flow through the ostia.

**[0324]** Figures 108A-108B illustrate an embodiment wherein only a distal portion anchor 30 is covered by seal 60 and wherein anchor 30 is only partially deployed since the blood can escape through the proximal end of the anchor braid. As anchor 30 in this embodiment is unsheathed, it presses against the native valve leaflets. At this point replacement valve 20 is functional even though anchor 30 is not fully deployed since blood can escape through the proximal end of the anchor braid. This allows blood to flow through replacement valve 20 and out of holes in the distal end of anchor 30 during systole (Figure 108A) while preventing backflow during diastole (Figure 108B).

**[0325]** Figures 109A-109B illustrate a similar embodiment wherein seal 60 around anchor 30 surrounds the entire contour of anchor 30. In this embodiment, valve 20 does not become functional until both anchor 30 and a portion of fingers 50 are unsheathed. As soon as a portion of fingers 50 is unsheathed, replacement valve 20 is fully functional. This allows blood to flow through replacement valve 20 and anchor 30, out of fingers 50, and around catheter 60 into the aorta and coronary ostias during systole. Similarly, during diastole, replacement valve 20 closes preventing blood backflow from entering the chamber.

**[0326]** In any of the embodiments herein the anchor is preferably a self-expanding anchor braid. Anchor braid of the present invention can be made from one or more wires, more preferably 2-20 wires, more preferably 3-15 wires, or more preferably 4-10 wires. Moreover, the density of the braid can be modified by various forms of weave used.

**[0327]** Figures 32-34 illustrate the process of forming a pleated seal around a replacement valve to prevent leakage. Figure 32 illusfrates a fabric seal 380 prior to deployment and foreshortening of the anchor/valve apparatus. In Figure 32, the fabric seal 380 extends from the distal end of valve 20 proximally over anchor 30 during delivery. During deployment, as illustrated in Figure 33, anchor 30 foreshortens and the fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382. The bunched up fabric or pleats occur, in particular, when the pockets are filled with blood in response to backflow blood pressure. The pleating can create a seal around the replacement valve. Figure 34 illustrates anchor 30, surrounded by fabric seal 380 in between native valve leaflets 382. In preferred embodiments, at least a portion of a seal is captured between the leaflets and the wall of the heart when the anchor is fully deployed.

EMBODIMENTS

**[0328]** Although the present invention is defined in the attached claims, it should be understood that the present invention can also (alternatively) be defined in accordance with the following embodiments:

1. Apparatus for replacing a native aortic valve, the apparatus comprising: an anchor comprising an expandable braid with closed ends, the anchor being adapted to be endovascularly delivered and secured at an anchor site within the native aortic valve; and a replacement valve configured to be secured within the anchor.
2. The apparatus of embodiment 1 wherein the anchor comprises a central axis, the anchor being further adapted to remain substantially undeformed in response to a pressure up to 0.5 atm directed substantially radially inward toward the central axis.
3. The apparatus of embodiment 2 wherein the anchor is further adapted to remain substantially undeformed in response to a pressure up to 2 atm directed substantially radially inward toward the central axis.
4. The apparatus of embodiment 1 wherein the anchor is adapted to support the replacement valve at the anchor site in response to differential pressure across the replacement valve of up to about 200 mm Hg.
5. The apparatus of embodiment 4 wherein the anchor is adapted to support the replacement valve at the anchor site in response to differential pressure across the replacement valve of up to about 80 mm Hg.
6. The apparatus of embodiment 1 wherein the anchor comprises sfress reduction elements adapted to reduce the incidence of anchor material fatigue caused by pulsatile motion of the anchor site.
7. The apparatus of embodiment 6 wherein the braid comprises a plurality of cells, the stress reduction elements comprising a set of cells at a distal or proximal edge of the anchor.
8. The apparatus of embodiment 1 wherein the braid comprises sheathing features adapted to reduce sheathing force.
9. The apparatus of embodiment 8 wherein the braid comprises a plurality of cells, the sheathing features comprising a set of cells at a proximal edge of the anchor.
10. The apparatus of embodiment 1 wherein the braid comprises a first region and a second region having a diameter larger than a diameter of the first region when the anchor is expanded.
11. The apparatus of embodiment 10 wherein the braid defines a plurality of cells, at least a first set of the cells in the first region each being of a substan-



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tially different configuration than a second set of the cells in the second region.

12. The apparatus of embodiment 11 wherein the braid further comprises a third region having a diameter larger than the first region diameter when the anchor is expanded.

13. The apparatus of embodiment 12 wherein the first, second and third regions are adapted to center the anchor within the native aortic valve.

14. The apparatus of embodiment 12 wherein the braid defines a plurality of cells, at least a first set of the cells in the first region each being of a substantially different configuration than a second set of the cells in the second region and a third set of cells in the third region.

15. The apparatus of embodiment 1 wherein the anchor is further adapted to avoid interference with coronary ostia.

16. The apparatus of embodiment 1 wherein the anchor is further adapted to avoid interference with a mitral valve.

17. The apparatus of embodiment 16 wherein the braid comprises a region adapted to prevent expansion of the anchor into the mitral valve.

18. The apparatus of embodiment 1 wherein the braid is configured to have an expanded shape that is radially symmetrical.

19. The apparatus of embodiment 1 wherein the braid is configured to have an expanded shape that is bilaterally symmetrical.

20. The apparatus of embodiment 1 wherein the braid is configured to have an expanded shape that is asymmetrical.

21. The apparatus of embodiment 1 wherein the braid is configured to have distal fine mesh section with a higher pitch than the proximal section.

22. The apparatus of embodiment 1 wherein the braid defines a plurality of cells, at least a first set of the cells each being of a substantially different configuration than a second set of the cells.

23. The apparatus of embodiment 22 wherein the anchor comprises distal and proximal edges, the first set of cells being disposed at at least the distal edge or the proximal edge.

24. The apparatus of embodiment 23 wherein each cell in the first set of cells is longer in a first direction than the cells in the second set of cells.

25. The apparatus of embodiment 24 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

26. The apparatus of embodiment 23 wherein each cell in the first set of cells has a portion bent out of a cylindrical shape defined by the braid and each cell in the second set of cells does not have a portion bent out of the cylindrical shape defined by the braid.

27. The apparatus of embodiment 26 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

28. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises an inward bend to form a W shape along one side of the cell and each cell in the second set of cells does not.

29. The apparatus of embodiment 28 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

30. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises a loop and each cell in the second set of cells does not.

31. The apparatus of embodiment 30 wherein the loop is disposed asymmetrically within each cell of the first set of cells.

32. The apparatus of embodiment 30 each cell in the first set of cells comprises a plurality of loops and each cell in the second set of cells does not.

33. The apparatus of embodiment 30 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

34. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises a figure 8 shaped loop and each cell in the second set of cells does not.

35. The apparatus of embodiment 34 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

36. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises a heart shaped loop and each cell in the second set of cells does not.

37. The apparatus of embodiment 36 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

38. The apparatus of embodiment 23 wherein a wire section of each cell of the first set of cells comprises a reduced cross-sectional diameter in at least one location and each cell in the second set of cells does not.

39. The apparatus of embodiment 38 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

40. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises an inward cant with respect to the second set of cells.

41. The apparatus of embodiment 40 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

42. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises an inward cant and an outward cant with respect to the second set of cells.

43. The apparatus of embodiment 42 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

44. The apparatus of embodiment 23 wherein each cell of the first set of cells comprises a lock adapted to lock the anchor in an expanded configuration.

45. The apparatus of embodiment 44 wherein the braid further comprises a third set of cells each being of a substantially different configuration than the sec-



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ond set of cells, each of the third set of cells being adapted to interact with the first set of cells to lock the anchor in the expanded configuration.

46. The apparatus of embodiment 22 further comprising a third set of cells having a substantially different configuration than a second set of the cells.

47. The apparatus of embodiment 46 wherein the first set of cells is disposed at a distal end of the anchor and the third set of cells is disposed at a proximal end of the anchor.

48. The apparatus of embodiment 1 wherein the anchor comprises first and second wires, the first wire having a diameter smaller than a diameter of the second wire.

49. The apparatus of embodiment 1 wherein the anchor comprises first and second wires formed from different materials.

50. The apparatus of embodiment 1 wherein the anchor has a collapsed delivery configuration, an at-rest configuration and an expanded deployed configuration.

51. The apparatus of embodiment 50 wherein the braid comprises a shape memory material that is heat set in the at-rest configuration.

52. The apparatus of embodiment 50 wherein the at-rest configuration is between the collapsed delivery configuration and expanded deployed configuration.

53. The apparatus of embodiment 1 wherein the braid is configured for active foreshortening during endovascular deployment.

54. The apparatus of embodiment 1 further comprising a lock configured to maintain expansion of the braid.

55. The apparatus of embodiment 1 further comprising a plurality of locks configured to maintain expansion of the braid.

56. The apparatus of embodiment 55 wherein the plurality of locks are further configured to maintain expansion of the braid at a plurality of amounts of expansion.

57. The apparatus of embodiment 1 further comprising a valve support adapted to support the replacement valve within the anchor.

58. The apparatus of embodiment 57 further comprising a lock configured to maintain expansion of the braid.

59. The apparatus of embodiment 58 wherein the lock comprises an extension of the valve support.

60. The apparatus of embodiment 1 wherein the anchor comprises a distal deployment system interface disposed at a distal end of the anchor, the distal deployment system interface being adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor.

61. The apparatus of embodiment 60 wherein the distal deployment system interface is further adapted to expand radially during application of a proximally directed force on the distal end of the anchor.

62. The apparatus of embodiment 61 wherein the distal deployment system interface is further adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor without passing any portion of a deployment system through a center opening of the replacement valve.

63. The apparatus of embodiment 1 wherein the anchor comprises a proximal deployment system interface at a proximal end of the anchor, the proximal deployment system interface being adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor.

64. The apparatus of embodiment 63 wherein the proximal deployment system interface is further adapted to expand radially during application of a distally directed force on the proximal end of the anchor.

65. The apparatus of embodiment 63 wherein the proximal deployment system interface is further adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor through a plurality of deployment system fingers.

66. The apparatus of embodiment 1 wherein the delivery length is between about 15 mm and about 150 mm and the deployed length is between 5 mm and about 40 mm.

67. Apparatus for replacing a native aortic valve, the apparatus comprising:

an expandable anchor adapted to be endovascularly delivered and secured at an anchor site within the native aortic valve, the expandable anchor having a delivery length in a delivery configuration substantially greater than a deployed length in a deployed configuration; and

a replacement valve configured to be secured within the anchor.

68. The apparatus of embodiment 67 wherein the delivery length is between about 15 mm and about 150 mm and the deployed length is between about 2 mm and about 40 mm.

69. The apparatus of embodiment 68 wherein the delivery length is between about 20 mm and about 140 mm and the deployed length is between about 5 mm and about 30 mm.

70. The apparatus of embodiment 68 wherein the delivery length is between about 25 mm and about 130 mm and the deployed length is between about 7 mm and about 20 mm.

71. The apparatus of embodiment 67 wherein ratio of delivery length to deployed length is between about 0.05 and about 0.5.

72. The apparatus of embodiment 71 wherein ratio of delivery length to deployed length is between about 0.1 and about 0.35.



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73. The apparatus of embodiment 72 wherein ratio of delivery length to deployed length is between about 0.15 and about 0.25.

74. The apparatus of embodiment 67 wherein the anchor has an at-rest configuration and wherein the anchor comprises a shape memory material that is heat set in the at-rest configuration.

75. The apparatus of embodiment 74 wherein the at-rest configuration has a length between the delivery length and the deployed length.

76. The apparatus of embodiment 67 wherein the anchor is configured for active foreshortening during endovascular deployment.

77. The apparatus of embodiment 67 further comprising a lock configured to maintain expansion of the anchor.

78. The apparatus of embodiment 67 further comprising a plurality of locks configured to maintain expansion of the anchor.

79. The apparatus of embodiment 78 wherein the plurality of locks are further configured to maintain expansion of the anchor at a plurality of amounts of expansion.

80. The apparatus of embodiment 67 further comprising a valve support adapted to support the replacement valve within the anchor.

81. The apparatus of embodiment 80 further comprising a lock configured to maintain expansion of the anchor.

82. The apparatus of embodiment 81 wherein the lock comprises an extension of the valve support.

83. The apparatus of embodiment 67 wherein the anchor comprises a distal deployment system interface disposed at a distal end of the anchor, the distal deployment system interface being adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor.

84. The apparatus of embodiment 83 wherein the distal deployment system interface is further adapted to expand radially during application of a proximally directed force on the distal end of the anchor.

85. The apparatus of embodiment 84 wherein the distal deployment system interface is further adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor without passing any portion of a deployment system through a center opening of the replacement valve.

86. The apparatus of embodiment 67 wherein the anchor comprises a proximal deployment system interface at a proximal end of the anchor, the proximal deployment system interface being adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor.

87. The apparatus of embodiment 86 wherein the proximal deployment system interface is further adapted to expand radially during application of a distally directed force on the proximal end of the anchor.

88. The apparatus of embodiment 86 wherein the proximal deployment system interface is further adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor through a plurality of deployment system fingers.

89. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an expandable anchor comprising a lip region and a skirt region; and
a replacement valve,
wherein the lip region and skirt region are configured for percutaneous expansion to engage leaflets of the heart valve.

90. The apparatus of embodiment 89 wherein the lip region and skirt region are configured for independent expansion.

91. The apparatus of embodiment 89 wherein the lip region and skirt region are configured for concurrent expansion.

92. The apparatus of embodiment 89 wherein the lip region is adapted to preclude distal migration of the apparatus post-deployment and expansion.

93. The apparatus of embodiment 89 wherein the skirt section is adapted to preclude proximal migration of the apparatus post-deployment and expansion.

94. The apparatus of embodiment 89 wherein the anchor is at least partially covered by a biocompatible film.

95. The apparatus of embodiment 89 wherein the replacement valve is configured to be coupled to the anchor during percutaneous delivery.

96. The apparatus of embodiment 89 wherein the anchor and the replacement valve are adapted for expansion from the delivery to the deployed configurations via a mechanism chosen from the group consisting of balloon-expansion, self-expansion, and combinations thereof.

97. The apparatus of embodiment 89 further comprising a delivery system configured for percutaneous advancement of the apparatus to a vicinity of the patient's diseased valve while the anchor is disposed in a collapsed delivery configuration.

98. The apparatus of embodiment 97 wherein the delivery system facilitates deployment and expansion of the apparatus to endovascularly replace the heart valve.

99. The apparatus of embodiment 98 wherein the delivery system is configured to retrieve the apparatus.

100. The apparatus of embodiment 89 further comprising at least one locking element configured to maintain expansion of the lip region and the skirt region.

101. Apparatus for endovascularly replacing a pa-



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tient' s heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage leaflets of the patient's heart valve.

102. The apparatus of embodiment 101 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is fully deployed.

103. The apparatus of embodiment 101 wherein the anchor is further adapted to be actively foreshortened during deployment.

104. The apparatus of embodiment 103 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

105. The apparatus of embodiment 103 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

106. The apparatus of embodiment 103 further comprising a lock adapted to lock the anchor in a deployed shape.

107. The apparatus of embodiment 101 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.

108. The apparatus of embodiment 101 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.

109. The apparatus of embodiment 101 wherein the leaflet engagement elements are integral with the anchor.

110. The apparatus of embodiment 109 wherein the anchor comprises a braid, the leaflet engagement elements being part of the braid.

111. The apparatus of embodiment 101 wherein the anchor and the replacement valve are further adapted to permit blood flow from a chamber of the heart through the replacement valve and to prevent blood flow to the chamber of the heart through the replacement valve during deployment of the anchor and replacement valve.

112. The apparatus of embodiment 101 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

113. The apparatus of embodiment 112 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter but before the anchor completely exits the catheter.

114. The apparatus of embodiment 112 wherein the anchor comprises a self-expanding anchor.

115. The apparatus of embodiment 112 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

116. The apparatus of embodiment 112 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

117. The apparatus of embodiment 112 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

118. The apparatus of embodiment 112 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

119. The apparatus of embodiment 101 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

120. The apparatus of embodiment 119 wherein the seal comprises a pleated seal.

121. The apparatus of embodiment 119 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

122. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising a braid, the braid comprising leaflet engagement elements adapted to engage leaflets of the patient's heart valve.

123. The apparatus of embodiment 122 wherein the leaflet engagement elements extend from a proximal end of the anchor.

124. The apparatus of embodiment 122 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is



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fully deployed.

125. The apparatus of embodiment 122 wherein the anchor is further adapted to be actively foreshortened during deployment.

126. The apparatus of embodiment 125 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

127. The apparatus of embodiment 125 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

128. The apparatus of embodiment 125 further comprising a lock adapted to lock the anchor in a deployed shape.

129. The apparatus of embodiment 123 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.

130. The apparatus of embodiment 123 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.

131. The apparatus of embodiment 123 wherein the anchor and the replacement valve are further adapted to permit blood flow from a chamber of the heart through the replacement valve and to prevent blood flow through the replacement valve during deployment of the anchor and replacement valve.

132. The apparatus of embodiment 123 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

133. The apparatus of embodiment 132 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before the anchor completely exits the catheter.

134. The apparatus of embodiment 132 wherein the anchor comprises a self-expanding anchor.

135. The apparatus of embodiment 132 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

136. The apparatus of embodiment 132 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

137. The apparatus of embodiment 132 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

138. The apparatus of embodiment 132 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

139. The apparatus of embodiment 123 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

140. The apparatus of embodiment 139 wherein the seal comprises a pleated seal.

141. The apparatus of embodiment 139 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

142. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve and a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor and the replacement valve being further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

143. The apparatus of embodiment 142 wherein the anchor comprises a self-expanding anchor.

144. The apparatus of embodiment 142 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

145. The apparatus of embodiment 142 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

146. The apparatus of embodiment 142 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment



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of the anchor.

147. The apparatus of embodiment 142 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

148. The apparatus of embodiment 142 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

149. The apparatus of embodiment 148 wherein the seal comprises a pleated seal.

150. The apparatus of embodiment 148 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

151. Apparatus for endovascularly replacing a patient's heart valve comprising:

a replacement valve;
an anchor; and
a deployment tool adapted to apply a non-hydraulic or non-pneumatic actuation force on the anchor to reshape the anchor.

152. The apparatus of embodiment 151 wherein the deployment tool is adapted to deliver a proximally directed actuation force on the anchor.

153. The apparatus of embodiment 152 wherein the deployment tool comprises a control member adapted to move a distal end of the anchor proximally.

154. The apparatus of embodiment 152 wherein at least a portion of the anchor is adapted to expand in response to application of the proximally directed actuation force.

155. The apparatus of embodiment 152 wherein the deployment tool comprises a control member adapted to move a proximal end of the anchor proximally.

156. The apparatus of embodiment 152 wherein at least a portion of the anchor is adapted to contract in response to application of the proximally directed actuation force.

157. The apparatus of embodiment 151 wherein the deployment tool is adapted to deliver a distally directed actuation force on the anchor.

158. The apparatus of embodiment 157 wherein the deployment tool comprises a control member adapted to move a proximal end of the anchor distally.

159. The apparatus of embodiment 157 wherein at least a portion of the anchor is adapted to contract in response to application of the distally directed actuation force.

160. The apparatus of embodiment 151 further comprising a releasable connection between the deployment tool and the anchor.

161. The apparatus of embodiment 151 wherein the anchor comprises self-expanding shape memory material.

162. The apparatus of embodiment 151 wherein further comprising an anchor lock adapted to lock the anchor in a deployed configuration.

163. The apparatus of embodiment 162 further comprising a lock prevention element actuatable from outside the patient.

164. The apparatus of embodiment 151 wherein the anchor comprises barbs adapted to penetrate tissue when the anchor is in an expanded configuration.

165. The apparatus of embodiment 151 further comprising a registration element adapted to determine a position of the replacement valve with respect to the heart valve.

166. The apparatus of embodiment 165 further comprising a catheter adapted to deliver the anchor and the replacement valve to a vicinity of the heart valve, the registration element being disposed on the catheter.

167. The apparatus of embodiment 165 wherein the registration element is disposed on the anchor.

168. The apparatus of embodiment 165 wherein the registration element is adapted to extend radially outward from the anchor to entrap at least part of the heart valve.

169. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor having a collapsed delivery configuration and an expanded deployed configuration; and
a replacement valve coupled to the anchor,
wherein the anchor comprises enhanced radial strength in the expanded deployed configuration as compared to the collapsed delivery configuration due to imposed foreshortening.

170. The apparatus of embodiment 169 further comprising a locking mechanism for maintaining imposed foreshortening.

171. The apparatus of embodiment 170, wherein the apparatus is configured for retrieval prior to actuation of the locking mechanism.

172. The apparatus of embodiment 170, wherein the locking mechanism is configured to maintain a degree of imposed foreshortening selected in vivo.

173. The apparatus of embodiment 169 further comprising a delivery system configured for percutaneous delivery, deployment and foreshortening of the anchor.

174. The apparatus of embodiment 173 further comprising a leaflet engagement element coupled to the delivery system to provide positive registration of the apparatus relative to an anatomical landmark.

175. The apparatus of embodiment 173, wherein the delivery system is releasably coupled to the anchor in a manner facilitating dynamic repositioning and



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retrieval of the anchor post-deployment.

176. The apparatus of embodiment 169, wherein the anchor is at least partially covered by a biocompatible film.

177. The apparatus of embodiment 169, wherein the replacement valve comprises a valve chosen from the group consisting of mechanical valves, biologic valves, and combinations thereof.

178. The apparatus of embodiment 169, wherein the anchor is fabricated from materials chosen from the group consisting of self-expanding materials, balloon-expandable materials, and combinations thereof.

179. The apparatus of embodiment 169, wherein the anchor further comprises barbs adapted to engage tissue at the heart valve when the anchor is disposed in the expanded deployed configuration.

180. The apparatus of embodiment 169 further comprising a leaflet engagement element coupled to the anchor to provide positive registration of the apparatus relative to anatomical landmarks.

181. The apparatus of embodiment 169, wherein the anchor further comprises an element configured to reduce paravalvular leakage or regurgitation.

182. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor;
a replacement valve coupled to the anchor; and
a delivery system,
wherein the delivery system is configured to retrieve the anchor and replacement valve post-deployment.

183. The apparatus of embodiment 182, wherein the delivery system is further configured for percutaneous delivery, deployment and foreshortening of the anchor.

184. Apparatus for endovascularly replacing a patient's heart valve comprising:

a replacement valve;
an anchor; and a deployment tool comprising a plurality of anchor actuation elements adapted to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor to reshape the anchor.

185. The apparatus of embodiment 184 wherein the anchor actuation elements comprise a plurality of proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

186. The apparatus of embodiment 184 wherein the anchor actuation elements comprise a plurality of distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

187. The apparatus of embodiment 184 wherein the anchor actuation elements each comprise a first member attached to the anchor and a second member releasably attached to the first member.

188. The apparatus of embodiment 187 wherein the first members each comprise a post adapted to support the valve within the anchor.

189. The apparatus of embodiment 188 wherein at least one post comprises valve attachment structure, the replacement valve being attached to the post via the valve attachment structure.

190. The apparatus of embodiment 189 wherein the valve attachment structure comprises a plurality of holes formed in the post.

191. The apparatus of embodiment 190 wherein the valve attachment structure comprises a tab extending from the post.

192. The apparatus of embodiment 187 wherein the first members each comprise a lock element adapted to lock the anchor in a deployed shape.

193. The apparatus of embodiment 192 wherein the lock element is further adapted to engage an anchor element to lock the anchor in the deployed shape.

194. The apparatus of embodiment 192 wherein the apparatus further comprises anchor lock elements attached to the anchor and adapted to mate with the lock element of each first member to lock the anchor in the deployed shape.

195. The apparatus of embodiment 194 wherein the anchor lock elements each comprise a camming surface adapted to engage the first member and to move at least a portion of the anchor lock element in response to a lock actuation force.

196. The apparatus of embodiment 194 further comprising a lock actuator adapted to apply a locking force to move at least a portion of the anchor lock element.

197. The apparatus of embodiment 194 wherein at least one first member lock element and at least one anchor lock element are adapted to mate at a plurality of mating configurations.

198. The apparatus of embodiment 197 wherein the at least one first member lock element comprises a plurality of ratchets adapted to engage a tooth portion of the at least one anchor lock element.

199. The apparatus of embodiment 198 wherein the at least one first member further comprises valve support structure, at least a portion of the plurality of ratchets being disposed distal to the valve support structure.

200. The apparatus of embodiment 198 wherein the at least one first member further comprises valve support structure, at least a portion of the plurality of ratchets being disposed neither distal to nor proximal to the valve support structure.

201. The apparatus of embodiment 198 wherein the at least one first member further comprises valve support structure, substantially all of the plurality of ratchets being disposed proximal to the valve sup-



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port structure.

202. The apparatus of embodiment 194 wherein the anchor lock elements each comprise a buckle.

203. The apparatus of embodiment 202 wherein the buckle is formed from a cut tube.

204. The apparatus of embodiment 202 wherein the buckle is formed from bent resilient material.

205. The apparatus of embodiment 194 wherein the first member lock element further comprises a lock alignment feature adapted to align the first member lock element with the anchor lock element.

206. The apparatus of embodiment 205 wherein the lock alignment feature comprises a hinge.

207. The apparatus of embodiment 205 wherein the lock alignment feature comprises an engagement portion of the anchor lock element adapted to engage the first member before engagement of the anchor lock element with the first member lock element.

208. The apparatus of embodiment 205 wherein the first member lock element and the anchor lock element define a lock width, the lock alignment feature comprising a first member lock element lock area substantially wider than the lock width.

209. The apparatus of embodiment 192 further comprising a lock actuator adapted to apply a locking force to lock the anchor in the deployed shape.

210. The apparatus of embodiment 209 wherein the distal anchor actuation element comprises the lock actuator.

211. The apparatus of embodiment 209 further comprising an unlocking actuator adapted to unlock the anchor.

212. The apparatus of embodiment 211 wherein the lock actuator comprises the unlocking actuator.

213. The apparatus of embodiment 211 wherein the unlocking actuator comprises a proximal pull actuator.

214. The apparatus of embodiment 211 wherein the unlocking actuator comprises a distal push actuator.

215. The apparatus of embodiment 209 further comprising a lock prevention mechanism.

216. The apparatus of embodiment 192 wherein the first members each comprise a spring adapted to permit axial lengthening of the anchor in response to radially inward compression.

217. The apparatus of embodiment 184 wherein the anchor actuation elements are adapted to apply a distally directed force on the anchor.

218. The apparatus of embodiment 184 wherein the anchor actuation elements are adapted to apply a proximally directed force on the anchor.

219. The apparatus of embodiment 184 wherein the anchor actuation elements are adapted to apply distally directed and proximally directed forces on the anchor.

220. The apparatus of embodiment 184 further comprising a releasable attachment mechanism adapted to releasably attach at least one anchor actuation element to the anchor.

221. The apparatus of embodiment 220 further comprising a movable release actuator adapted to actuate the releasable attachment mechanism.

222. The apparatus of embodiment 221 wherein the movable release actuator is adapted to prevent a release movement of the anchor attachment mechanism in a first position and to permit a release movement of the anchor attachment mechanism in a second position.

223. The apparatus of embodiment 222 wherein the release actuator comprises a cover covering at least a portion of the releasable attachment mechanism.

224. The apparatus of embodiment 221 wherein the release actuator comprises an elongated element movable within at least part of the releasable attachment mechanism.

225. The apparatus of embodiment 224 wherein the release actuator further comprises a camming surface adapted to resist actuation of the releasable attachment mechanism.

226. The apparatus of embodiment 224 wherein a distal portion of the elongated element is adapted to engage the anchor.

227. The apparatus of embodiment 221 wherein the release actuator comprises a friction surface.

228. The apparatus of embodiment 221 wherein the release actuator is adapted to move less than one inch to release the attachment mechanism.

229. The apparatus of embodiment 220 wherein the releasable attachment mechanism comprises a wrap portion adapted to wrap at least part way around an anchor element.

230. The apparatus of embodiment 229 wherein at least the wrap portion comprises shape memory material.

231. The apparatus of embodiment 229 wherein the wrap portion comprises an opening adapted to engage a release actuator.

232. The apparatus of embodiment 231 wherein the opening comprises a first opening, the releasable attachment mechanisms each comprising a second opening adapted to be aligned with the first opening and to engage the release actuator.

233. The apparatus of embodiment 232 wherein the releasable attachment mechanisms each comprise a spring element adapted to urge the first opening out of alignment with the second opening.

234. The apparatus of embodiment 220 wherein the releasable attachment mechanism comprises a first shape on an anchor actuation element adapted to mate with a second shape on an anchor attachment element to substantially prevent relative distal or proximal movement between the anchor actuation element and the anchor.

235. The apparatus of embodiment 234 further comprising a release actuator adapted to actuate the releasable attachment mechanism.



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236. The apparatus of embodiment 235 wherein the release actuator is adapted to be moved to permit relative movement between the first shape and the second shape.
237. The apparatus of embodiment 235 wherein the release actuator is adapted to be moved to permit the first shape to change to a third shape permitting relative distal or proximal movement between the anchor actuation element and the anchor.
238. The apparatus of embodiment 235 wherein the release actuator is adapted to be moved to permit the second shape to change to a third shape permitting relative distal or proximal movement between the anchor actuation element and the anchor.
239. The apparatus of embodiment 234 wherein the anchor actuation element is adapted to separate from the anchor attachment element in response to relative movement between the anchor actuation element and the anchor attachment element.
240. The apparatus of embodiment 239 wherein the first shape comprises a camming surface.
241. The apparatus of embodiment 239 wherein the second shape comprises a camming surface.
242. The apparatus of embodiment 184 wherein the anchor actuation elements each comprise a curved portion.
243. The apparatus of embodiment 242 wherein the curved portion of each anchor actuation element is at a distal end of the anchor actuation element.
244. The apparatus of embodiment 184 wherein the anchor actuation elements comprise shaping features adapted to affect a shape of the anchor actuation elements when an anchor actuation force is applied.
245. The apparatus of embodiment 244 wherein the shaping features comprise reduced diameter portions of the anchor actuation elements.
246. The apparatus of embodiment 244 wherein the shaping features comprise reduced wall thickness portions of the anchor actuation elements.
247. The apparatus of embodiment 244 wherein the shaping features comprise slits formed in the anchor actuation elements.
248. The apparatus of embodiment 184 wherein the anchor actuation elements comprise a plurality of arms extending from a unitary structure.
249. The apparatus of embodiment 248 wherein each arm is adapted to move radially outward and radially inward with respect to other arms as the anchor reshapes.
250. The apparatus of embodiment 248 wherein the anchor actuation elements comprise a cut tube.
251. The apparatus of embodiment 184 wherein the deployment tool further comprises a catheter adapted to percutaneously communicate the anchor actuation elements with an operator exterior to the patient.
252. The apparatus of embodiment 251 wherein the catheter comprises a plurality of lumens, at least part of each anchor actuation element being disposed in one of the lumens.
253. The apparatus of embodiment 251 wherein the deployment tool further comprises a handle adapted to actuate the anchor actuation elements.
254. The apparatus of embodiment 184 wherein the deployment tool is further adapted to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor without passing any portion of the deployment tool through a central opening in the replacement valve.
255. Apparatus for endovascularly replacing a heart valve comprising:

a catheter;
a replacement valve configured to be disposed within the catheter for delivery to a vicinity of the heart valve; and
an expandable anchor configured to be disposed within the catheter for delivery to a vicinity of the heart valve, to be deployed from the catheter, to be expanded to contact tissue at an anchor site and to be retrieved back into the catheter after having been expanded.

256. The apparatus of embodiment 255 further comprising a deployment tool configured to apply an actuation force to the anchor when the anchor is in the vicinity of the heart valve.
257. The apparatus of embodiment 256 wherein the deployment tool is adapted to deliver a proximally directed actuation force on the anchor.
258. The apparatus of embodiment 257 wherein the deployment tool comprises a control member adapted to move a distal end of the anchor proximally.
259. The apparatus of embodiment 257 wherein at least a portion of the anchor is adapted to expand in response to application of the proximally directed actuation force.
260. The apparatus of embodiment 257 wherein the deployment tool comprises a control member adapted to move a proximal end of the anchor proximally.
261. The apparatus of embodiment 257 wherein at least a portion of the anchor is adapted to contract in response to application of the proximally directed actuation force.
262. The apparatus of embodiment 256 wherein the deployment tool is adapted to deliver a distally directed actuation force on the anchor.
263. The apparatus of embodiment 262 wherein the deployment tool comprises a control member adapted to move a proximal end of the anchor distally.
264. The apparatus of embodiment 262 wherein at least a portion of the anchor is adapted to contract in response to application of the distally directed actuation force.
265. The apparatus of embodiment 256 further com-



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prising a releasable connection between the deployment tool and the anchor.

266. The apparatus of embodiment 255 wherein the replacement valve is coupled to the anchor.

267. The apparatus of embodiment 255 wherein the catheter comprises a catheter having a diameter no more than 21 french.

268. Apparatus for endovascularly replacing a patient's heart valve comprising:

a sheath;

a deployment tool comprising a plurality of anchor actuation elements;

a replacement valve configured to be disposed within the sheath for delivery to a vicinity of the heart valve; and

an expandable anchor configured to be disposed within the sheath for delivery to the vicinity of the heart valve, to be deployed from the sheath, to be expanded by the deployment tool to contact tissue at an anchor site and to be retrieved back into the sheath after having been expanded.

269. The apparatus of embodiment 268 wherein the anchor actuation elements comprise a plurality of proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

270. The apparatus of embodiment 268 wherein the anchor actuation elements comprise a plurality of distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

271. The apparatus of embodiment 270 wherein the distal anchor actuation elements each comprises a first member attached to the distal portion of the anchor and a second member releasably attached to the first member.

272. The apparatus of embodiment 271 wherein the first members each comprise a post adapted to support the valve within the anchor.

273. The apparatus of embodiment 272 wherein at least one post comprises valve attachment structure, the replacement valve being attached to the post via the valve attachment structure.

274. The apparatus of embodiment 273 wherein the valve attachment structure comprises a plurality of holes formed in the post.

275. The apparatus of embodiment 274 wherein the valve attachment structure comprises a tab extending from the post.

276. The apparatus of embodiment 271 wherein the first members each comprise a lock element adapted to lock the anchor in a deployed shape.

277. The apparatus of embodiment 276 wherein the lock element is further adapted to engage an anchor element to lock the anchor in the deployed shape.

278. The apparatus of embodiment 276 wherein the apparatus further comprises anchor lock elements attached to the anchor and adapted to mate with the lock element of each first member to lock the anchor in the deployed shape.

279. The apparatus of embodiment 278 wherein the anchor lock elements each comprise a camming surface adapted to engage the first member and to move at least a portion of the anchor lock element in response to a lock actuation force.

280. The apparatus of embodiment 278 further comprising a lock actuator adapted to apply a locking force to move at least a portion of the anchor lock element.

281. The apparatus of embodiment 278 wherein at least one first member lock element and at least one anchor lock element are adapted to mate at a plurality of mating configurations.

282. The apparatus of embodiment 281 wherein the at least one first member lock element comprises a plurality of ratchets adapted to engage a tooth portion of the at least one anchor lock element.

283. The apparatus of embodiment 282 wherein the at least one first member further comprises valve support structure, at least a portion of the plurality of ratchets being disposed distal to the valve support structure.

284. The apparatus of embodiment 282 wherein the at least one first member further comprises valve support structure, at least a portion of the plurality of ratchets being disposed neither distal to nor proximal to the valve support structure.

285. The apparatus of embodiment 282 wherein the at least one first member further comprises valve support structure, substantially all of the plurality of ratchets being disposed proximal to the valve support structure.

286. The apparatus of embodiment 278 wherein the anchor lock elements each comprise a buckle.

287. The apparatus of embodiment 286 wherein the buckle is formed from a cut tube.

288. The apparatus of embodiment 286 wherein the buckle is formed from bent resilient material.

289. The apparatus of embodiment 278 wherein the first member lock element further comprises a lock alignment feature adapted to align the first member lock element with the anchor lock element.

290. The apparatus of embodiment 289 wherein the lock alignment feature comprises a hinge.

291. The apparatus of embodiment 289 wherein the lock alignment feature comprises an engagement portion of the anchor lock element adapted to engage the first member before engagement of the anchor lock element with the first member lock element.

292. The apparatus of embodiment 289 wherein the first member lock element and the anchor lock element define a lock width, the lock alignment feature comprising a first member lock element lock area substantially wider than the lock width.



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293. The apparatus of embodiment 276 further comprising a lock actuator adapted to apply a locking force to lock the anchor in the deployed shape.
294. The apparatus of embodiment 293 wherein the distal anchor actuation element comprises the lock actuator.
295. The apparatus of embodiment 293 further comprising an unlocking actuator adapted to unlock the anchor.
296. The apparatus of embodiment 295 wherein the lock actuator comprises the unlocking actuator.
297. The apparatus of embodiment 295 wherein the unlocking actuator comprises a proximal pull actuator.
298. The apparatus of embodiment 295 wherein the unlocking actuator comprises a distal push actuator.
299. The apparatus of embodiment 293 further comprising a lock prevention mechanism.
300. The apparatus of embodiment 276 wherein the first members each comprise a spring adapted to permit axial lengthening of the anchor in response to radially inward compression.
301. The apparatus of embodiment 268 wherein the anchor actuation elements are adapted to apply a distally directed force on the anchor.
302. The apparatus of embodiment 268 wherein the anchor actuation elements are adapted to apply a proximally directed force on the anchor.
303. The apparatus of embodiment 302 wherein the anchor actuation elements are further adapted to retrieve the anchor into the sheath.
304. The apparatus of embodiment 268 wherein the anchor actuation elements are adapted to apply distally directed and proximally directed forces on the anchor.
305. The apparatus of embodiment 268 further comprising a releasable attachment mechanism adapted to releasably attach at least one anchor actuation element to the anchor.
306. The apparatus of embodiment 305 further comprising a movable release actuator adapted to actuate the releasable attachment mechanism.
307. The apparatus of embodiment 306 wherein the movable release actuator is adapted to prevent a release movement of the anchor attachment mechanism in a first position and to permit a release movement of the anchor attachment mechanism in a second position.
308. The apparatus of embodiment 306 wherein the release actuator comprises a cover covering at least a portion of the releasable attachment mechanism.
309. The apparatus of embodiment 306 wherein the release actuator comprises an elongated element movable within at least part of the attachment mechanism.
310. The apparatus of embodiment 309 wherein the release actuator further comprises a camming surface adapted to resist actuation of the attachment mechanism.
311. The apparatus of embodiment 309 wherein a distal portion of the elongated element is adapted to engage the anchor.
312. The apparatus of embodiment 306 wherein the release actuator comprises a friction surface.
313. The apparatus of embodiment 306 wherein the release actuator is adapted to move less than one inch to release the attachment mechanism.
314. The apparatus of embodiment 305 wherein the releasable attachment mechanism comprises a wrap portion adapted to wrap at least part way around an anchor element.
315. The apparatus of embodiment 314 wherein at least the wrap portion comprises shape memory material.
316. The apparatus of embodiment 314 wherein the wrap portion comprises an opening adapted to engage a release actuator.
317. The apparatus of embodiment 316 wherein the opening comprising a first opening, the releasable attachment mechanisms each comprising a second opening adapted to be aligned with the first opening and to engage the release actuator.
318. The apparatus of embodiment 317 wherein the releasable attachment mechanisms each comprise a spring element adapted to urge the first opening out of alignment with the second opening.
319. The apparatus of embodiment 305 wherein the releasable attachment mechanisms each comprise a first shape on an anchor actuation element adapted to mate with a second shape on an anchor attachment element to substantially prevent relative distal or proximal movement between the anchor actuation element and the anchor.
320. The apparatus of embodiment 319 further comprising a release actuator adapted to actuate the releasable attachment mechanism.
321. The apparatus of embodiment 320 wherein the release actuator is adapted to be moved to permit relative movement between first shape and second shape.
322. The apparatus of embodiment 320 wherein the release actuator is adapted to be moved to permit the first shape to change to a third shape permitting relative distal or proximal movement between the anchor actuation element and the anchor.
323. The apparatus of embodiment 328 wherein the release actuator is adapted to be moved to permit the second shape to change to a third shape permitting relative distal or proximal movement between the anchor actuation element and the anchor.
324. The apparatus of embodiment 319 wherein the anchor actuation element is adapted to separate from the anchor attachment element in response to relative movement between the anchor actuation element and the anchor attachment element.
325. The apparatus of embodiment 324 wherein the



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first shape comprises a camming surface.

326. The apparatus of embodiment 324 wherein the second shape comprises a camming surface.

327. The apparatus of embodiment 268 wherein the anchor actuation elements each comprise a curved portion.

328. The apparatus of embodiment 327 wherein the curved portion of each anchor actuation element is at a distal end of the anchor actuation element.

329. The apparatus of embodiment 268 wherein the anchor actuation elements comprise shaping features adapted to affect a shape of the anchor actuation elements when an anchor actuation force is applied.

330. The apparatus of embodiment 329 wherein the shaping features comprise reduced diameter portions of the anchor actuation elements.

331. The apparatus of embodiment 329 wherein the shaping features comprise reduced wall thickness portions of the anchor actuation elements.

332. The apparatus of embodiment 329 wherein the shaping features comprise slits formed in the anchor actuation elements.

333. The apparatus of embodiment 268 wherein the anchor actuation elements comprise a plurality of arms extending from a unitary structure.

334. The apparatus of embodiment 333 wherein each arm is adapted to move radially outward and radially inward with respect to other arms as the anchor reshapes.

335. The apparatus of embodiment 333 wherein the anchor actuation elements comprise a cut tube.

336. The apparatus of embodiment 268 wherein the deployment tool further comprises a deployment tool catheter adapted to percutaneously communicate the anchor actuation elements with an operator exterior to the patient.

337. The apparatus of embodiment 336 wherein the deployment tool catheter comprises a plurality of lumens, at least part of each anchor actuation element being disposed in one of the lumens.

338. The apparatus of embodiment 336 wherein the deployment tool further comprises a handle adapted to actuate the anchor actuation elements.

339. The apparatus of embodiment 268 wherein the deployment tool is configured to expand the anchor without passing any portion of the deployment tool through a center opening of the replacement valve.

340. Apparatus for endovascularly replacing "a patient's heart valve comprising:

a delivery catheter having a diameter of 21 french or less;
an expandable anchor disposed within the delivery catheter; and
a replacement valve disposed within the delivery catheter.

341. The apparatus of embodiment 340 wherein the replacement valve is coupled to the anchor within the catheter.

342. The apparatus of embodiment 340 wherein the catheter is adapted to deliver the anchor and replacement valve to an aortic valve along a retrograde approach.

343. The apparatus of embodiment 340 further comprising a sheath covering the anchor and the replacement valve within the catheter.

344. The apparatus of embodiment 340 further comprising a deployment tool coupled to the anchor within the catheter.

345. The apparatus of embodiment 344 wherein the deployment tool comprises a plurality of flexible control elements.

346. The apparatus of embodiment 344 wherein the deployment tool comprises a plurality of stiff control rods.

347. The apparatus of embodiment 344 further comprising a releasable connection between the deployment tool and the anchor.

348. The apparatus of embodiment 340 further comprising an expandable balloon disposed within the delivery catheter, the balloon being adapted to expand the anchor.

349. The apparatus of embodiment 348 wherein the balloon is disposed within the catheter apart from the anchor and the replacement valve.

350. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve adapted to be delivered endovascularly to a vicinity of the heart valve;
an expandable anchor adapted to be delivered endovascularly to the vicinity of the heart valve; and
a lock mechanism configured to maintain a minimum amount of anchor expansion.

351. The apparatus of embodiment 350 wherein the lock mechanism comprises an arm extending from a first anchor region toward a second anchor region.

352. The apparatus of embodiment 351 wherein the arm comprises a first interlocking element.

353. The apparatus of embodiment 352 wherein the second anchor region comprises a second interlocking element adapted to mate with the first interlocking element.

354. The apparatus of embodiment 352 wherein the first interlocking element comprises a locking configuration and a lock prevention configuration.

355. The apparatus of embodiment 352 wherein the arm comprises a plurality of first interlocking elements having substantially the same shape, the plurality of first interlocking elements extending along the arm in a spaced-apart relationship.

356. The apparatus of embodiment 355 wherein the



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second anchor region comprises a second interlocking element adapted to mate with one of the plurality of first interlocking elements.

357. The apparatus of embodiment 350 wherein the lock mechanism comprises first and second interlocking elements adapted to mate with each other.

358. The apparatus of embodiment 357 wherein the first and second interlocking elements are associated with first and second anchor regions, respectively.

359. The apparatus of embodiment 350 further comprising an anchor actuator adapted to change the anchor's shape.

360. The apparatus of embodiment 359 wherein the actuator is further adapted to move a first anchor region toward a second anchor region.

361. The apparatus of embodiment 360 wherein the anchor is adapted to radially expand when the first anchor region moves toward the second anchor region.

362. The apparatus of embodiment 360 wherein the actuator is further adapted to move the first anchor region away from the second anchor region.

363. The apparatus of embodiment 362 wherein the anchor is adapted to radially contract when the first anchor region moves away from the second anchor region.

364. The apparatus of embodiment 359 wherein the lock mechanism comprises first and second interlocking elements adapted to mate with each other to prevent the first anchor region and second anchor region from moving away from each other.

365. The apparatus of embodiment 359 further comprises an actuator release mechanism.

366. The apparatus of embodiment 350 wherein the replacement valve is adapted to be coupled to the anchor during delivery of the anchor and replacement valve through a catheter to the vicinity of the heart valve.

367. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor comprising a lip region and a skirt region;
a replacement valve coupled to the anchor; and
a lock,
wherein the lip region and skirt region are configured for percutaneous expansion to engage the patient's heart valve, and
wherein the lock is configured to maintain such expansion.

368. A replacement heart valve system comprising:

an anchor having a collapsed endovascular delivery configuration and an expanded deployed configuration;
a replacement valve support secured to the anchor in the anchor's delivery and deployed configurations, the replacement valve support having a length that is substantially the same in the anchor's delivery and deployed configurations; and
a replacement valve supported by the replacement valve support.

369. The system of embodiment 368 wherein the replacement valve support comprises a base portion and a commissure support portion, the base portion being adapted to be radially expandable.

370. The system of embodiment 368 wherein the replacement valve support comprises a base portion and a commissure support portion axially separated from the base portion.

371. The system of embodiment 368 wherein the replacement valve support comprises a base portion and a commissure support portion, the replacement valve support being secured to the anchor solely at the base portion.

372. The system of embodiment 371 where the replacement valve support is secured to the anchor at the base portion and at the commissure support portion.

373. The system of embodiment 368 wherein the replacement valve support comprises an anchor actuator interface.

374. The system of embodiment 373 wherein the replacement valve support comprises a commissure support portion, the commissure support portion comprising the anchor actuator interface.

375. The system of embodiment 373 wherein the anchor actuator interface comprises a first anchor actuator interface, the anchor further comprising a second anchor actuator interface.

376. The system of embodiment 375 wherein the first anchor actuator interface is adapted to actuate a distal portion of the anchor and the second anchor actuator interface is adapted to actuate a proximal portion of the anchor.

377. The system of embodiment 373 wherein the replacement valve support comprises a plurality of anchor actuator interfaces.

378. The system of embodiment 377 wherein thp anchor actuator interfaces are adapted to actuator a distal portion of the anchor, the system further comprising a plurality of proximal anchor actuator interfaces adapted to actuate a proximal portion of the anchor.

379. The system of embodiment 368 further comprising an anchor lock adapted to lock the anchor in the deployed configuration.

380. The system of embodiment 379 wherein the replacement valve support comprises the anchor lock.

381. The system of embodiment 380 wherein the replacement valve support comprises a base portion and a commissure support portion, the commissure



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support portion comprising the anchor lock.

382. The system of embodiment 381 wherein the anchor lock comprises first and second locking elements, the commissure support comprising the first locking element, the anchor supporting the second locking element.

383. The system of embodiment 380 wherein the anchor lock is adapted to lock the anchor in a plurality of expanded configurations.

384. The system of embodiment 368 wherein the replacement valve support comprises a plurality of commissure supports.

385. The system of embodiment 368 wherein the replacement valve support is adapted to have the same configuration in the anchor's delivery and deployed configurations.

386. The system of embodiment 368 wherein the anchor comprises a braid.

387. A replacement heart valve system comprising:

an anchor having a collapsed delivery configuration and an expanded deployed configuration; and

a replacement valve having a valve height and being supported within the anchor such that the valve height is substantially the same in the anchor's delivery and

deployed configurations.

388. The system of embodiment 387 wherein the anchor comprises a braid.

389. The system of embodiment 387 further comprising a replacement valve support secured to the anchor, the replacement valve support being adapted to support the replacement valve within the anchor.

390. The system of embodiment 389 wherein the replacement valve support comprises a base portion and a commissure support portion, the base portion being adapted to be expandable.

391. The system of embodiment 389 wherein the replacement valve support comprises a base portion and a commissure support portion axially separated from the base portion.

392. The system of embodiment 389 wherein the replacement valve support comprises a base portion and a commissure support portion, the replacement valve support being secured to the anchor solely at the base portion.

393. The system of embodiment 389 wherein the replacement valve support comprises an anchor actuator interface.

394. The system of embodiment 393 wherein the replacement valve support comprises a commissure support portion, the commissure support portion comprising the anchor actuator interface.

395. The system of embodiment 393 wherein the anchor actuator interface comprises a first anchor actuator interface, the anchor further comprising a second anchor actuator interface.

396. The system of embodiment 395 further comprising an anchor lock adapted to lock the anchor in the deployed configuration.

397. The system of embodiment 389 wherein the replacement valve support is adapted to have the same configuration in the anchor's delivery and deployed configurations.

398. The system of embodiment 387 further comprising an anchor lock adapted to lock the anchor in the deployed configuration.

399. The system of embodiment 398 wherein the replacement valve support comprises the anchor lock.

400. The system of embodiment 399 wherein the replacement valve support comprises a base portion and a commissure support portion, the commissure support portion comprising the anchor lock.

401. The system of embodiment 400 wherein the anchor lock comprises first and second locking elements, the commissure support comprising the first locking element, the anchor supporting the second locking element.

402. The system of embodiment 399 wherein the anchor lock is adapted to lock the anchor in a plurality of expanded configurations.

403. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a custom-designed anchor; and

a replacement valve,

wherein the custom-designed anchor is adapted to engage native leaflets of the heart valve, and wherein the anchor and the valve are adapted for in vivo expansion and coupling to one another to form composite apparatus that endovascularly replaces the heart valve.

404. The apparatus of embodiment 403, wherein the anchor comprises a lip section adapted to engage valve leaflets of the heart valve and to preclude distal migration of the composite apparatus.

405. The apparatus of embodiment 404, wherein the anchor comprises a groove section adapted to couple the anchor to the replacement valve to form the composite apparatus.

406. The apparatus of embodiment 405, wherein the groove section is adapted to reduce impingement of tissue from the valve leaflets within the groove section, thereby facilitating formation of the composite apparatus.

407. The apparatus of embodiment 403, wherein the anchor comprises a skirt section adapted to preclude proximal migration of the composite apparatus.

408. The apparatus of embodiment 403, wherein the anchor is at least partially covered by a biocompatible film.



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409. The apparatus of embodiment 403, wherein the anchor comprises a lip section, a groove section and a skirt section.

410. The apparatus of embodiment 409, wherein the replacement valve comprises a valve and an expandable frame.

411. The apparatus of embodiment 410, wherein the expandable frame of the replacement valve is adapted to engage the groove section of the anchor to form the composite apparatus.

412. The apparatus of embodiment 403, wherein the replacement valve comprises a valve chosen from the group consisting of mechanical valves, biologic valves, and combinations thereof.

413. The apparatus of embodiment 412, wherein the replacement valve further comprises an expandable frame coupled to the valve.

414. The apparatus of embodiment 413, wherein the expandable frame is adapted to couple the replacement valve to the anchor to form the composite apparatus.

415. The apparatus of embodiment 403, wherein the apparatus is fabricated from a material chosen from the group consisting of stainless steel, spring steel, shape-memory polymers, shape-memory alloys, nickel-titanium alloys, and combinations thereof.

416. The apparatus of embodiment 403, wherein both the anchor and the replacement valve have collapsed delivery configurations and expanded deployed configurations.

417. The apparatus of embodiment 416, wherein the anchor and the replacement valve are adapted for expansion from the delivery to the deployed configurations via a mechanism chosen from the group consisting of balloon-expansion, self-expansion, and combinations thereof.

418. The apparatus of embodiment 416 further comprising a delivery system for endovascularly advancing the anchor and the replacement valve to a vicinity of the patient's valve while the anchor and the replacement valve are disposed in the collapsed delivery configuration.

419. The apparatus of embodiment 418, wherein the delivery system comprises a single catheter.

420. The apparatus of embodiment 418, wherein the delivery system comprises multiple catheters.

421. The apparatus of embodiment 418, wherein the delivery system is adapted to facilitate expansion of the anchor and the replacement valve to the deployed configuration and to facilitate coupling of the anchor to the replacement valve to form the composite apparatus.

422. The apparatus of embodiment 403, wherein the apparatus comprises at least one radiopaque feature adapted to facilitate deployment and in vivo coupling of the anchor to the replacement valve under fluoroscopic guidance.

423. The apparatus of embodiment 418, wherein the delivery system comprises at least one radiopaque feature adapted to facilitate deployment and in vivo coupling of the anchor to the replacement valve under fluoroscopic guidance.

424. The apparatus of embodiment 403, wherein the apparatus is adapted to facilitate dynamic repositioning of the apparatus during delivery.

425. The apparatus of embodiment 403, wherein engagement of the native leaflets is adapted to facilitate positive registration of the anchor relative to the patient's heart valve and the patient's coronary ostia.

426. The apparatus of embodiment 403, wherein the composite apparatus is adapted to reduce paravalvular regurgitation.

427. The apparatus of embodiment 403, wherein the apparatus is configured for percutaneous delivery through the patient's aorta without necessitating a transseptal puncture.

428. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor having a first portion of an alignment/locking mechanism; and

a replacement valve having a second portion of the alignment/locking mechanism, wherein the anchor and the valve are adapted for in vivo expansion and coupling to one another to form composite apparatus that endovascularly replaces the patient's heart valve.

429. The apparatus of embodiment 428, wherein the first and second portions of the alignment/locking mechanism are configured to lockingly form the composite apparatus.

430. The apparatus of embodiment 428, wherein the anchor comprises a lip section, a groove section and a skirt section.

431. The apparatus of embodiment 430, wherein the lip section is adapted to engage valve leaflets of the heart valve and preclude distal migration of the composite apparatus.

432. The apparatus of embodiment 430, wherein the groove section is adapted to couple the anchor to the replacement valve to form the composite apparatus.

433. The apparatus of embodiment 430, wherein the skirt section is adapted to preclude proximal migration of the composite apparatus.

434. The apparatus of embodiment 428, wherein the anchor is at least partially covered by a biocompatible film.

435. The apparatus of embodiment 428, wherein the replacement valve comprises a valve chosen from the group consisting of mechanical valves, biologic valves, and combinations thereof.

436. The apparatus of embodiment 428, wherein the replacement valve further comprises an expandable frame coupled to the valve.



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437. The apparatus of embodiment 428, wherein both the anchor and the replacement valve have collapsed delivery configurations and expanded deployed configurations.

438. The apparatus of embodiment 437, wherein the anchor and the replacement valve are adapted for expansion from the delivery to the deployed configurations via a mechanism chosen from the group consisting of balloon-expansion, self-expansion, and combinations thereof.

439. The apparatus of embodiment 437 further comprising a delivery system for endovascularly advancing the anchor and the replacement valve to a vicinity of the patient's valve while the anchor and the replacement valve are disposed in the collapsed delivery configuration.

440. The apparatus of embodiment 439, wherein the apparatus comprises at least one radiopaque feature adapted to facilitate deployment and in vivo coupling of the anchor to the replacement valve under fluoroscopic guidance.

441. The apparatus of embodiment 428, wherein the apparatus is at least partially fabricated from a material chosen from the group consisting of stainless steel, spring steel, shape-memory polymers, shape-memory alloys, nickel-titanium alloys, and combinations thereof.

## Claims

1. Apparatus for endovascularly replacing a patient's heart valve comprising:

   a replacement valve;
   an anchor; and
   a deployment tool comprising a plurality of anchor actuation elements adapted to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor to reshape the anchor,
   wherein the anchor actuation elements comprise a plurality of proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

2. The apparatus of claim 1, wherein the anchor actuation elements comprise a plurality of distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

3. The apparatus of claim 1 or 2, wherein the anchor actuation elements each comprise a first member attached to the anchor and a second member releasably attached to the first member.

4. The apparatus of one of the preceding claims, wherein the first members each comprise a post adapted to support the valve within the anchor.

5. The apparatus of claim 4, wherein at least one post comprises valve attachment structure, the replacement valve being attached to the post via the valve attachment structure.

6. The apparatus of one of claims 3 to 5, wherein the first members each comprise a lock element adapted to lock the anchor in a deployed shape.

7. The apparatus of claim 6, wherein the lock element is further adapted to engage an anchor element to lock the anchor in the deployed shape.

8. The apparatus of claims 6 or 7, wherein the apparatus further comprises anchor lock elements attached to the anchor and adapted to mate with the lock element of each first member to lock the anchor in the deployed shape.

9. The apparatus of one of claims 6 to 8, further comprising a lock actuator adapted to apply a locking force to lock the anchor in the deployed shape.

10. The apparatus of one of claims 6 to 9, further comprising an unlocking actuator adapted to unlock the anchor.

11. The apparatus of claim 10, wherein the lock actuator comprises the unlocking actuator.

12. The apparatus of claim 11, wherein the unlocking actuator comprises a proximal pull actuator.

13. The apparatus of one of claims 6 to 12, further comprising a lock prevention mechanism.

14. The apparatus of one of the preceding claims, further comprising a releasable attachment mechanism adapted to releasably attach at least one anchor actuation element to the anchor.

15. The apparatus of claim 14, wherein the releasable attachment mechanism comprises a first shape on an anchor actuation element adapted to mate with a second shape on an anchor attachment element to substantially prevent relative distal or proximal movement between the anchor actuation element and the anchor.



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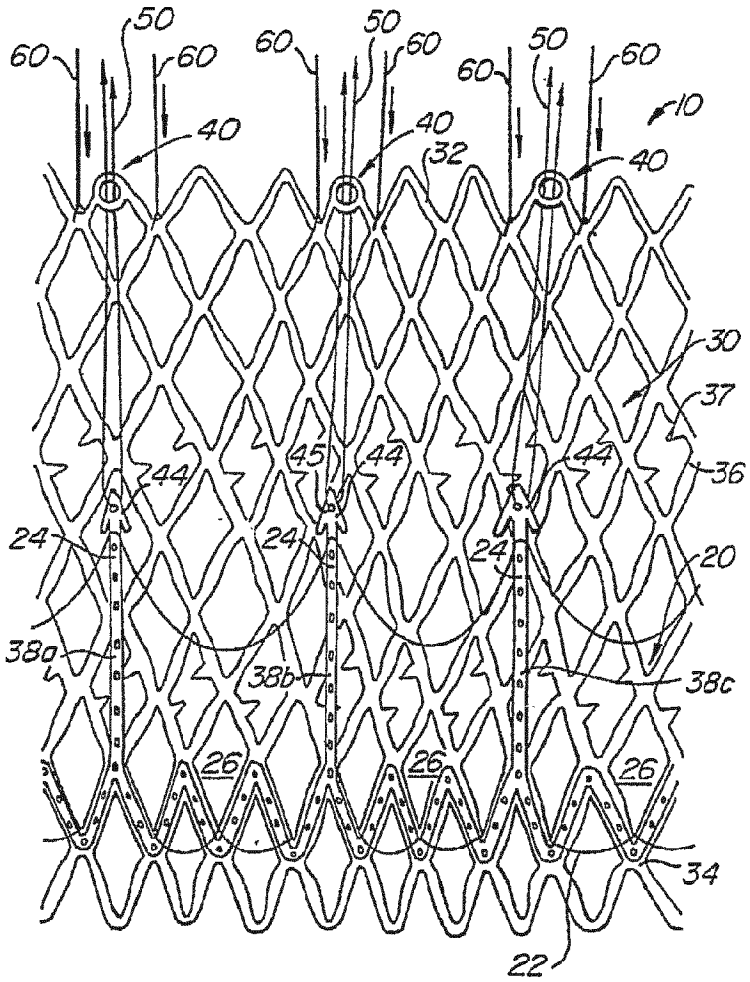


FIG. 1A

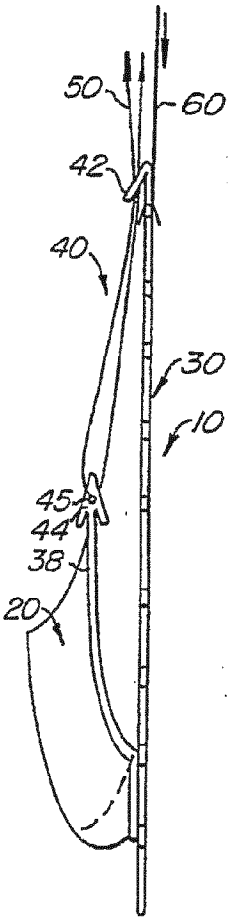


FIG. 2A



Aortic Innovations, LLC, Exhibit 2040
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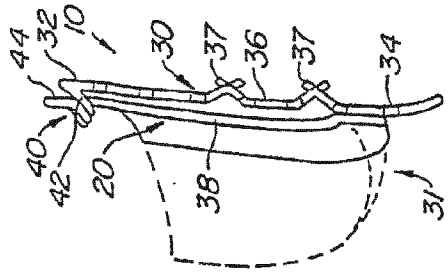


FIG. 2B

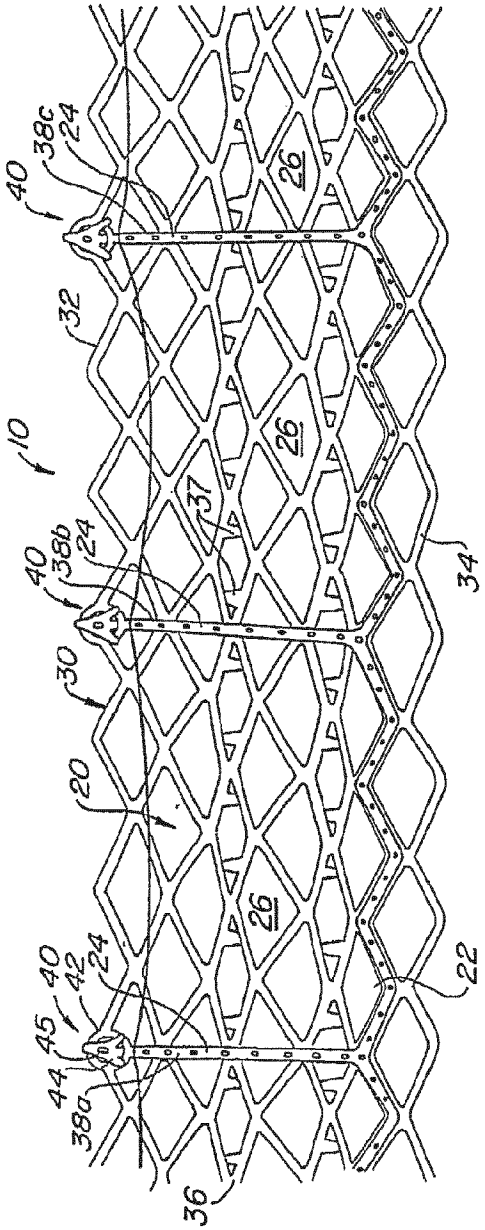


FIG. 1B



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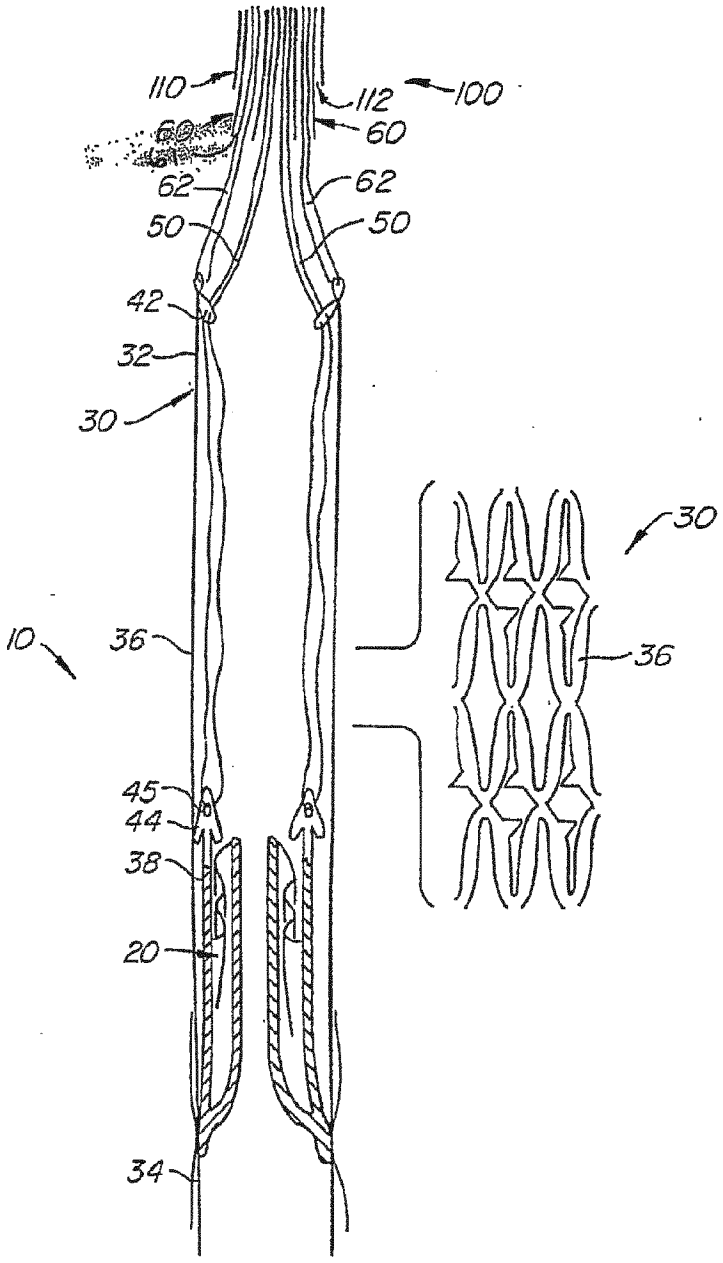


FIG. 3A



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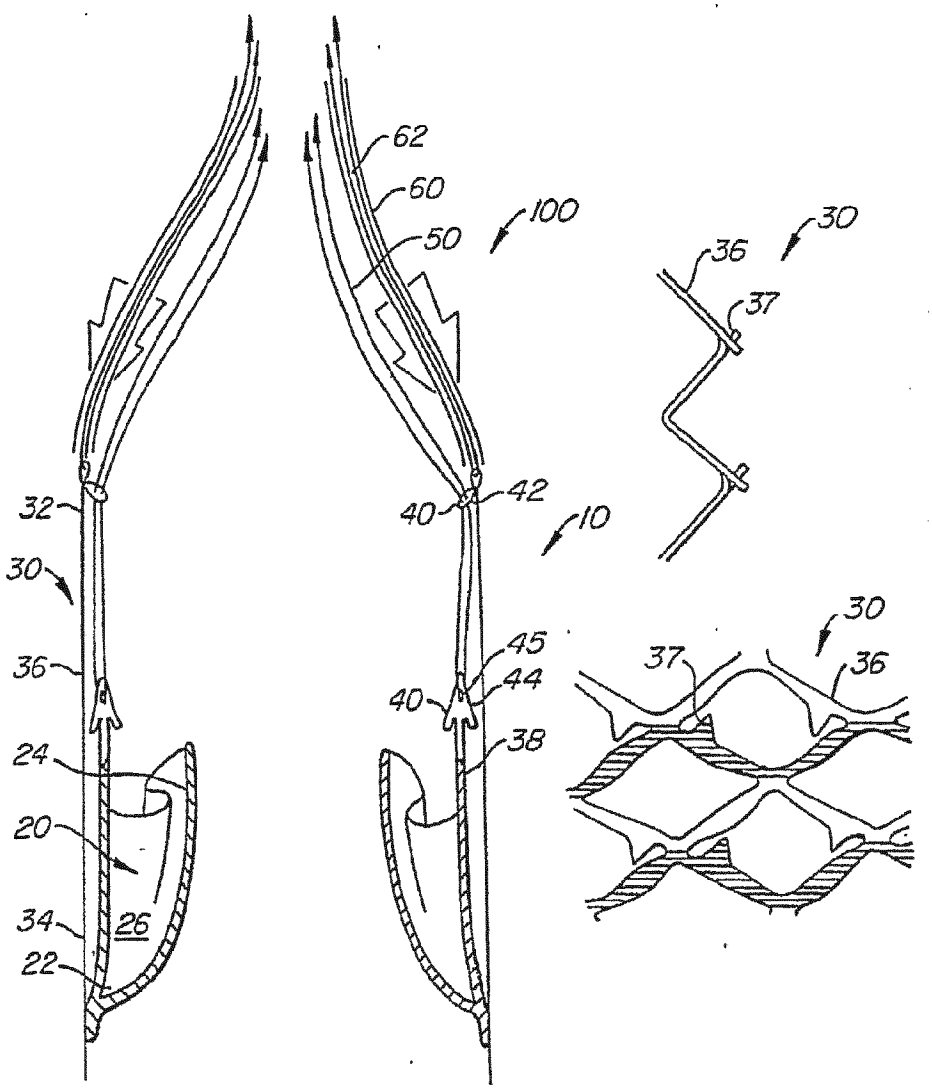


FIG. 3B



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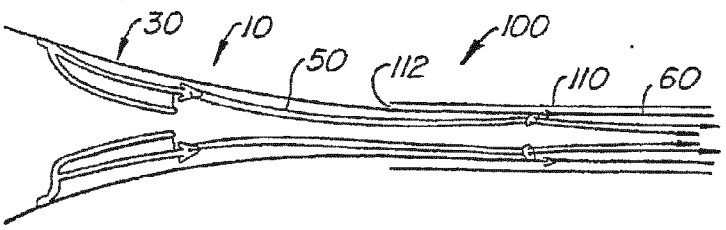


FIG. 4A

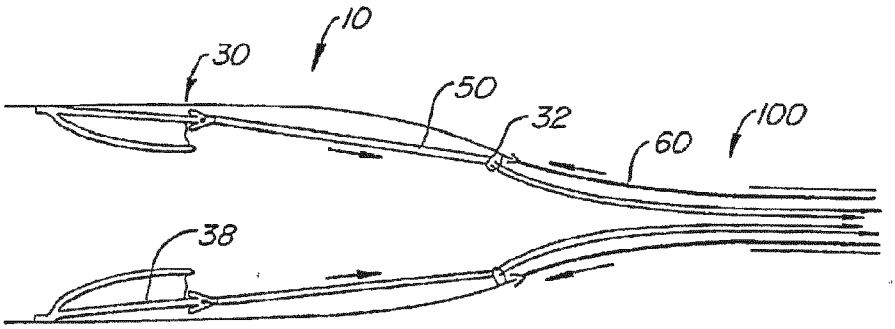


FIG. 4B

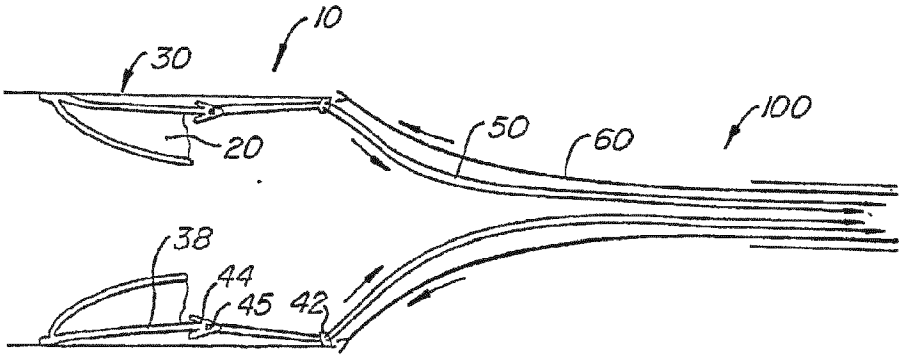


FIG. 4C



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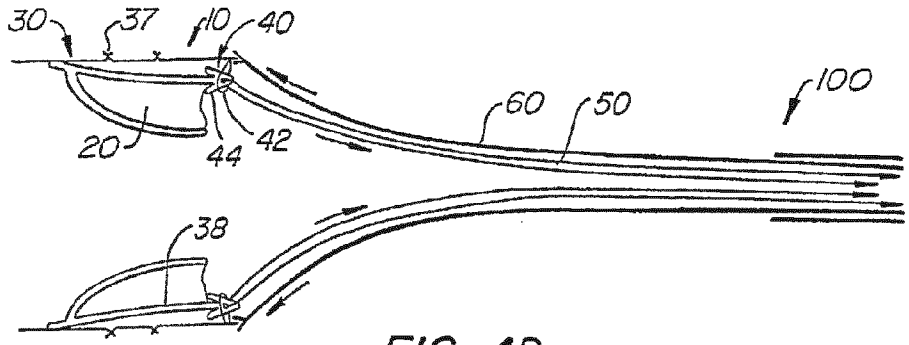


FIG. 4D

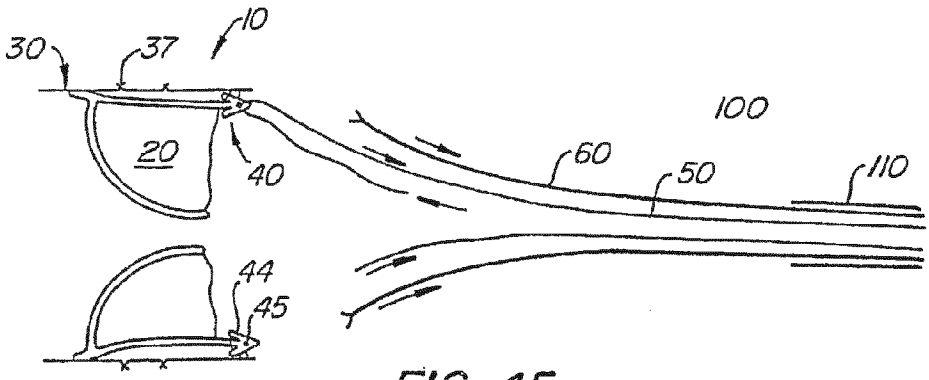


FIG. 4E

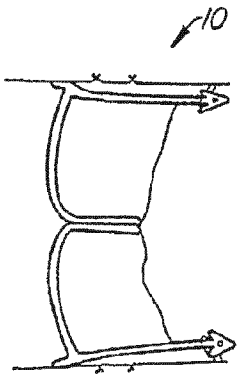


FIG. 4F



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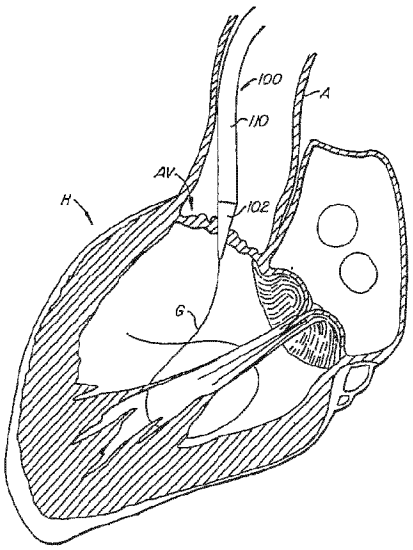


FIG. 5A

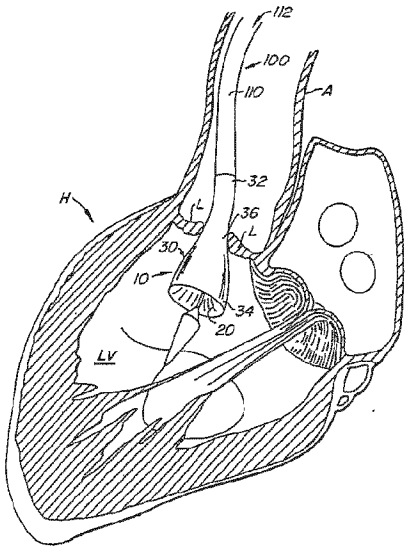


FIG. 5B

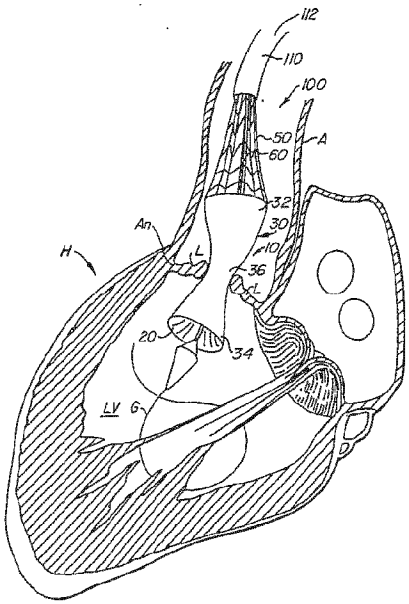


FIG. 5C

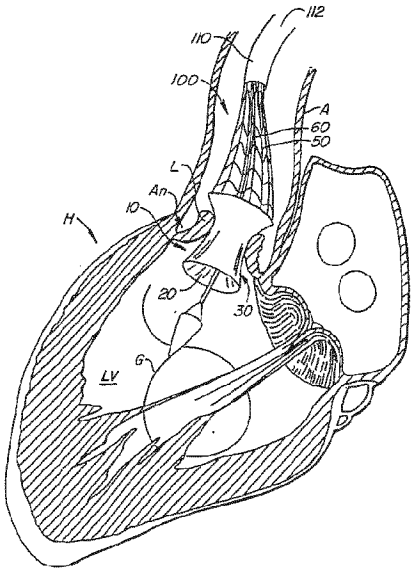


FIG. 5D



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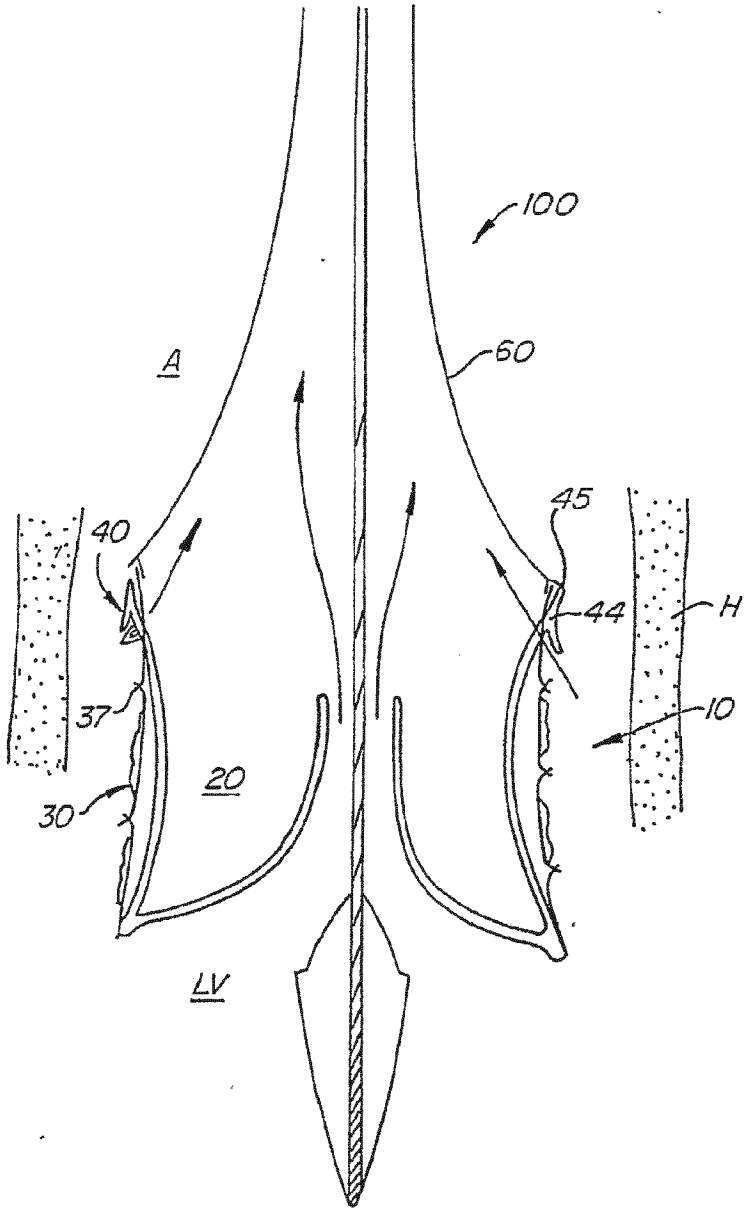


FIG. 5E



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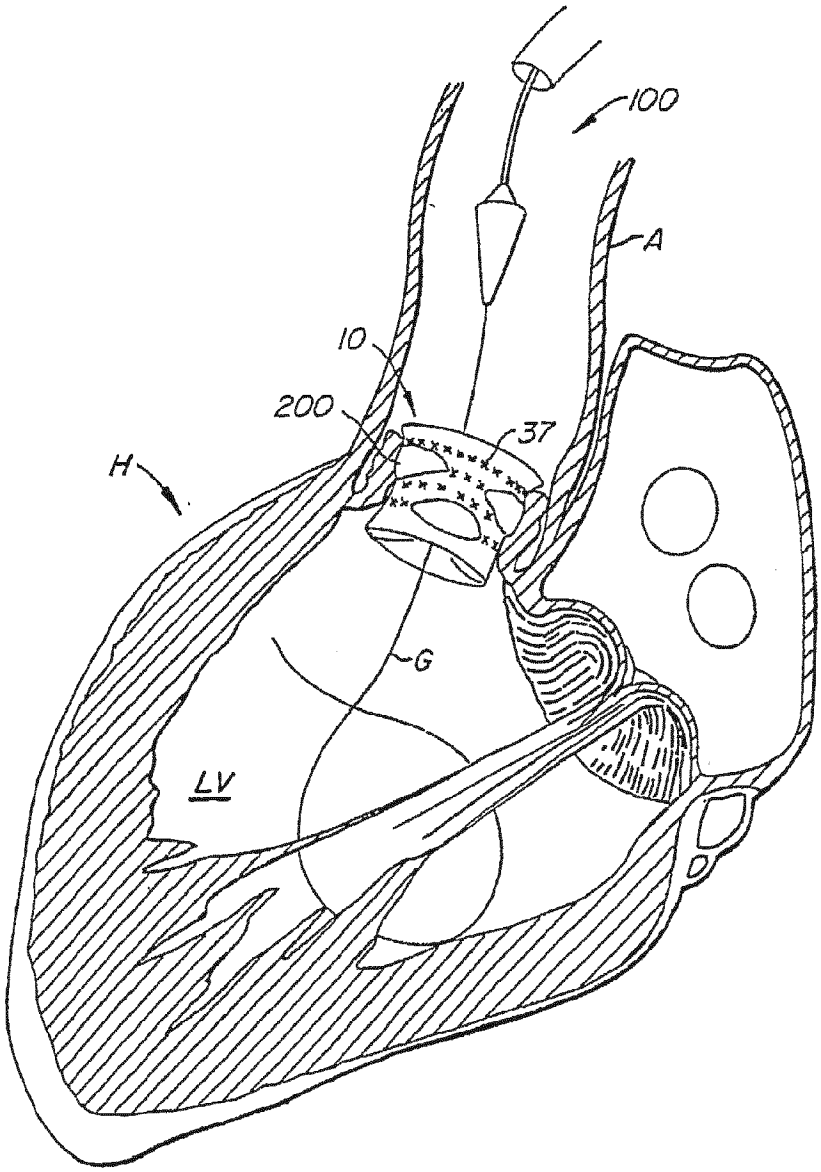


FIG. 5F



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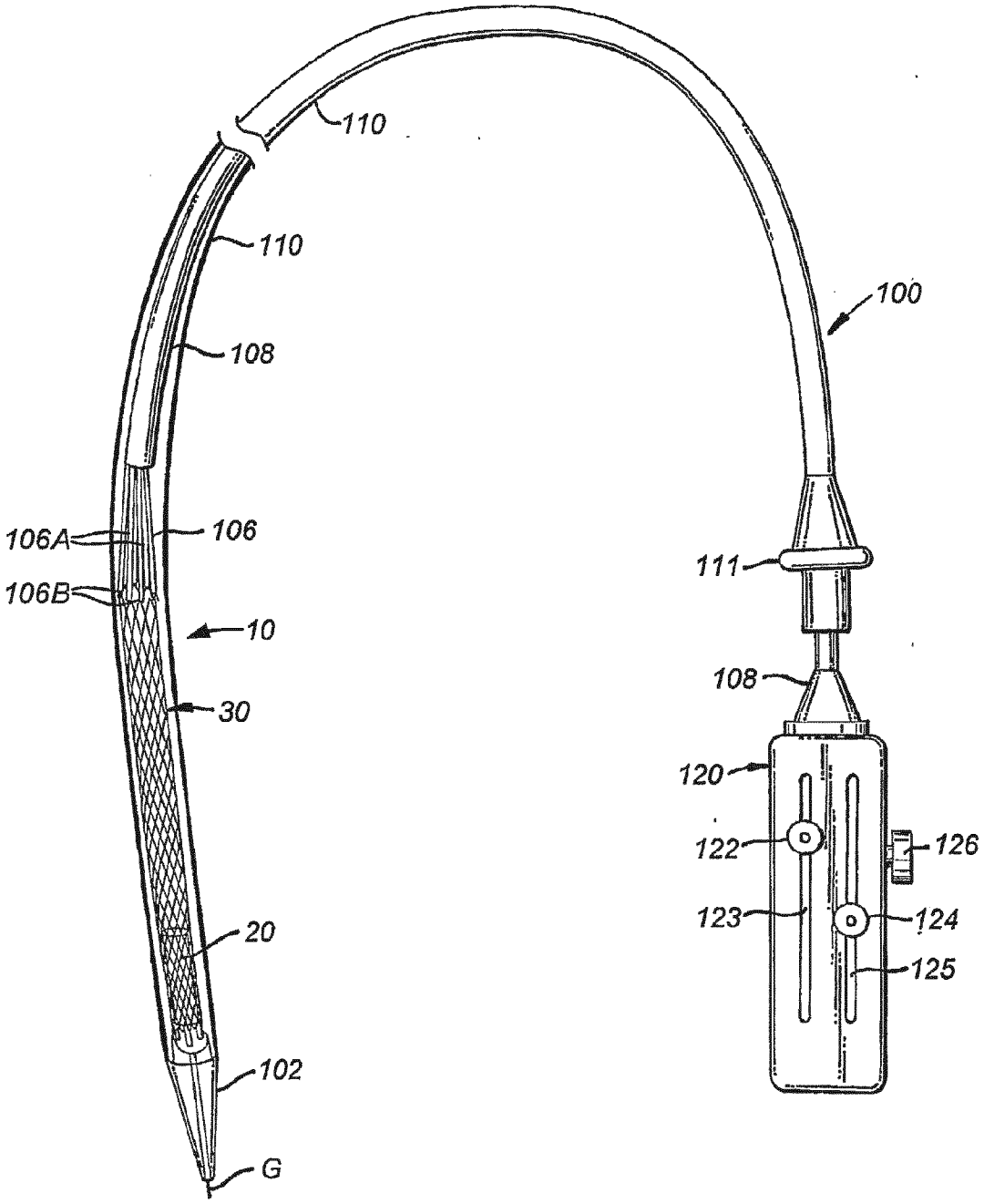


FIG. 5G



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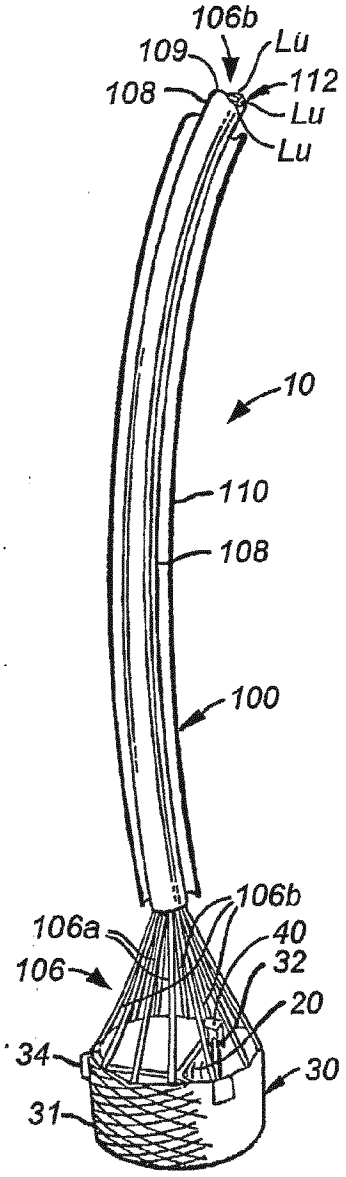


FIG. 5H

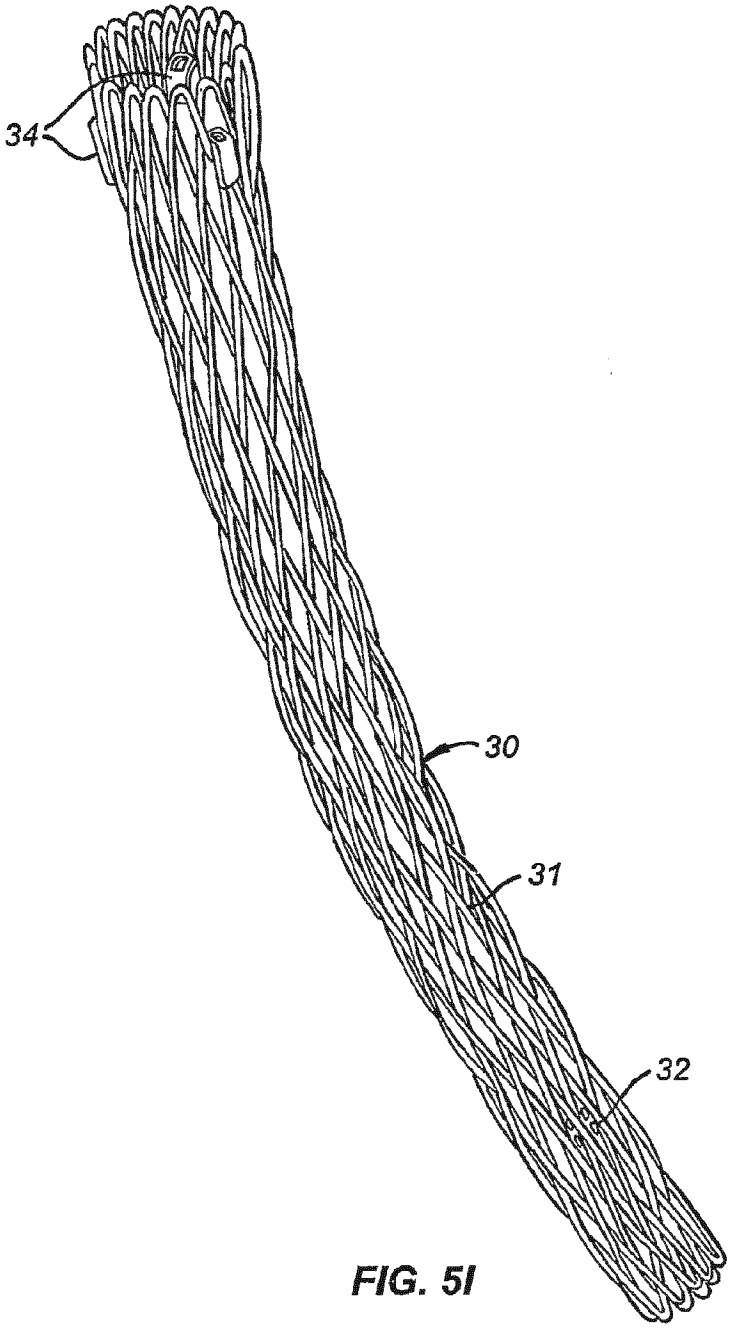


FIG. 5I



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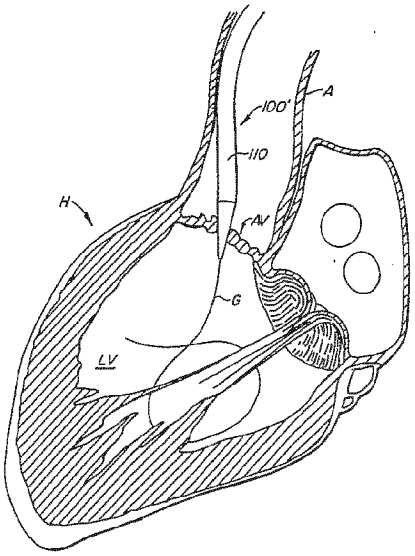


FIG. 6A

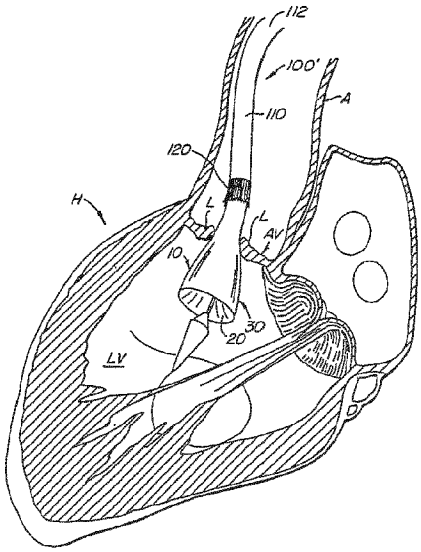


FIG. 6B

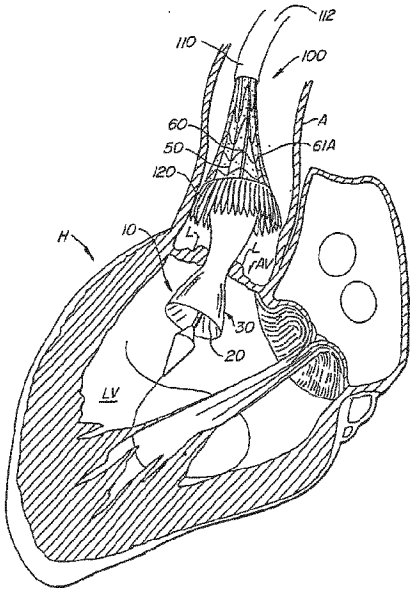


FIG. 6C

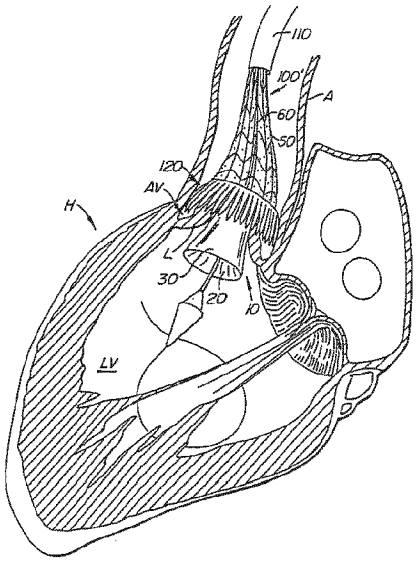


FIG. 6D



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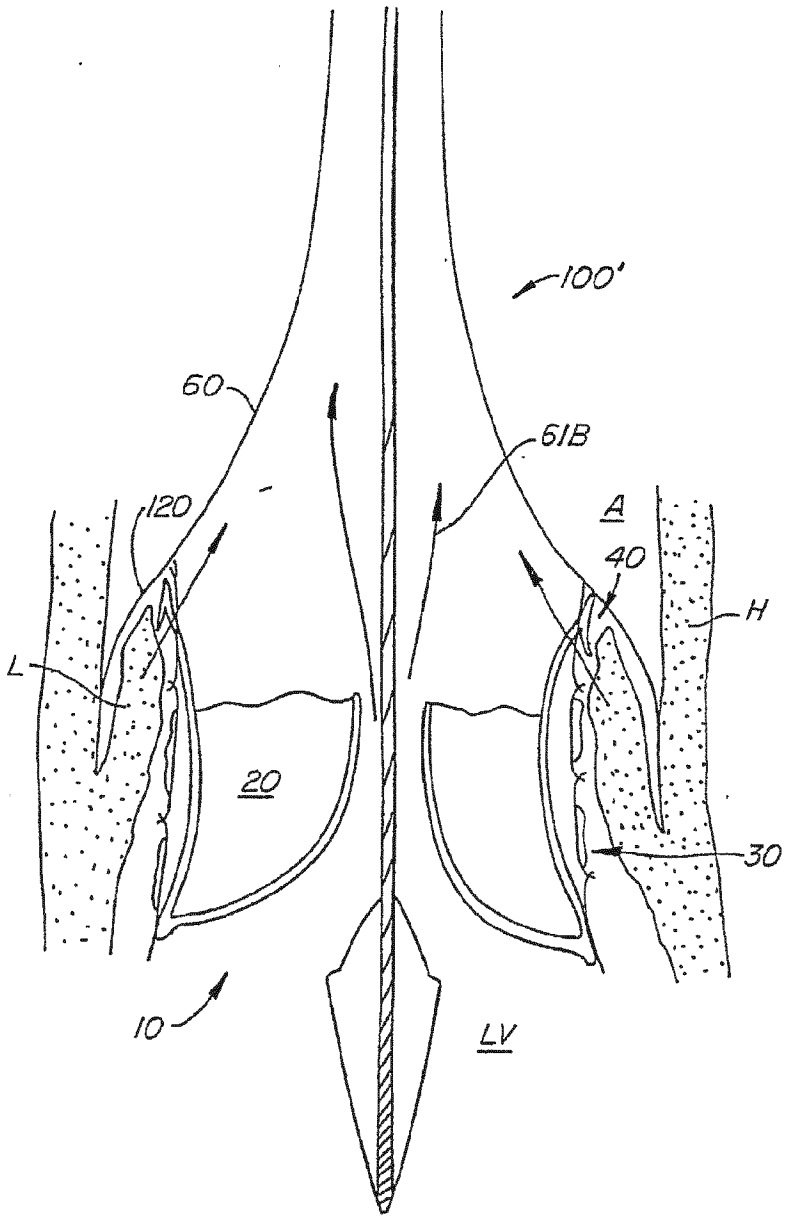


FIG. 6E



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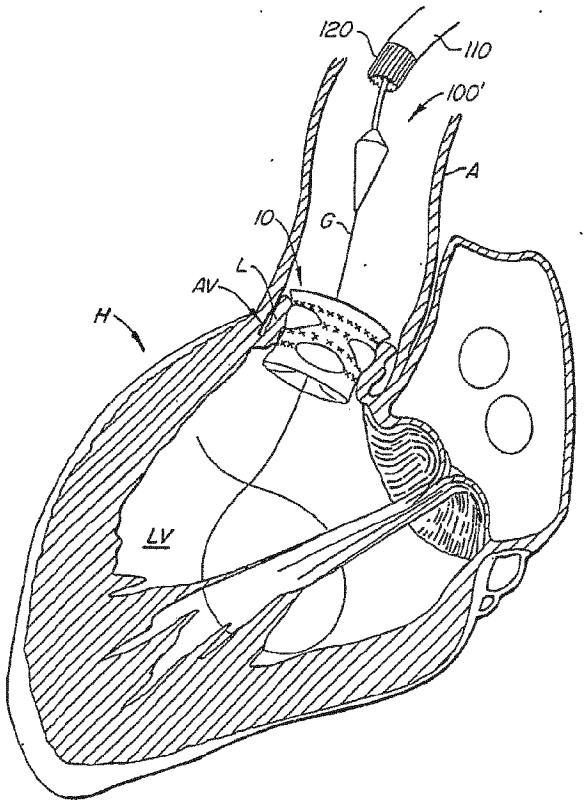


FIG. 6F

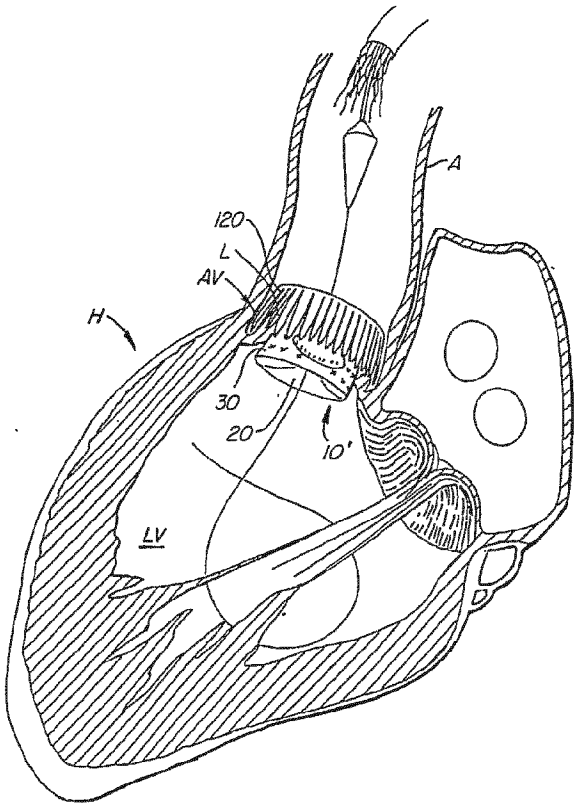


FIG. 7



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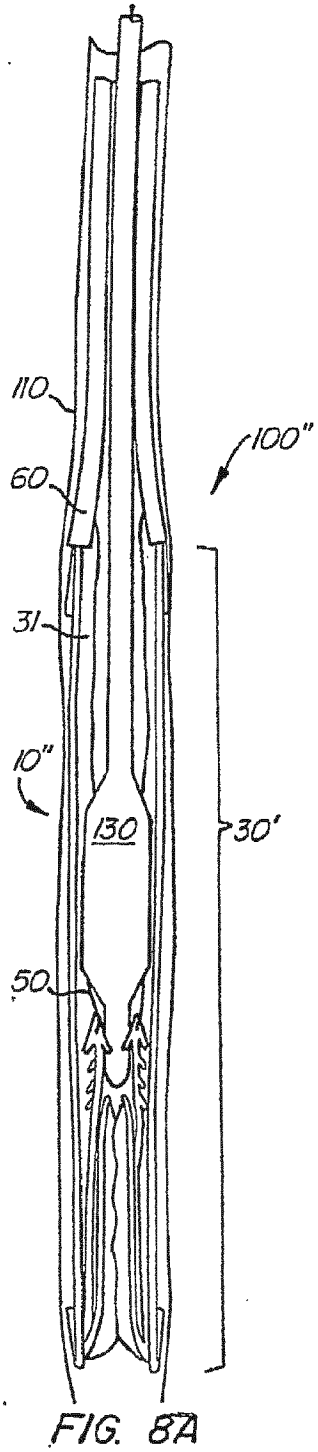


FIG. 8A

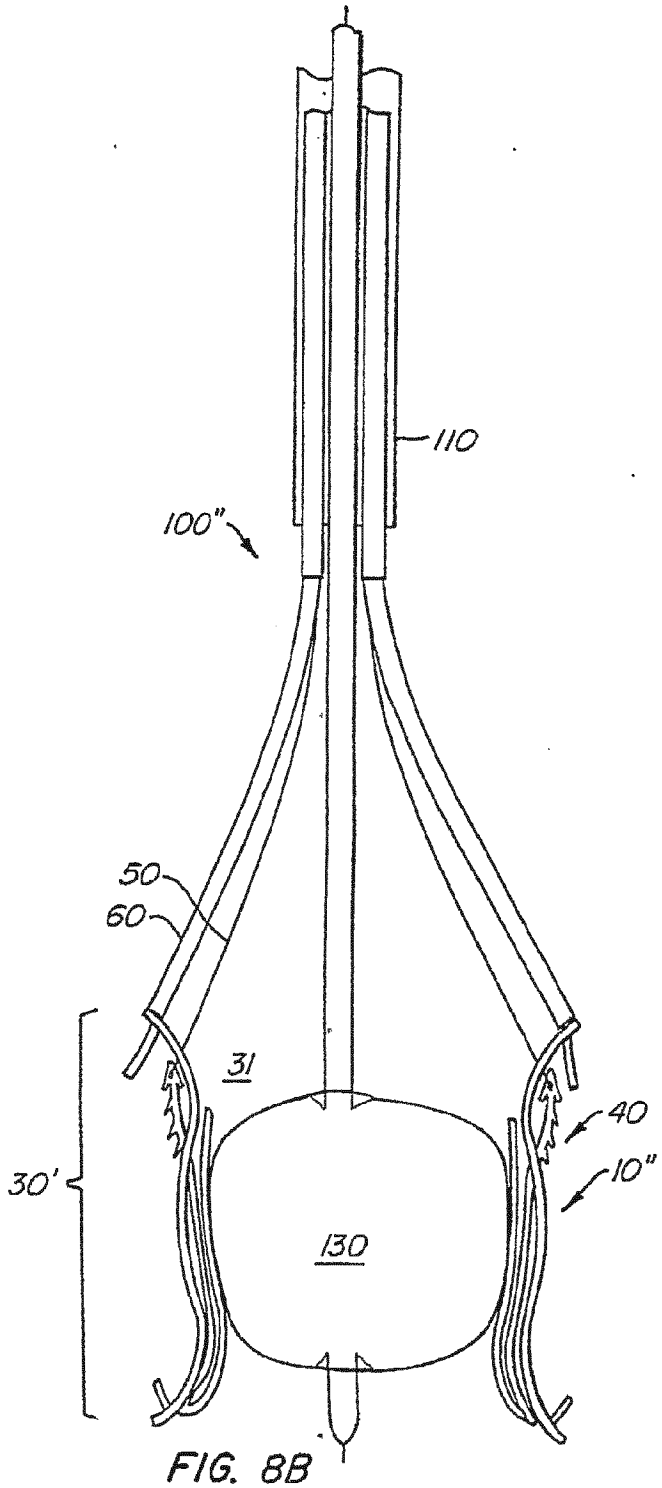


FIG. 8B



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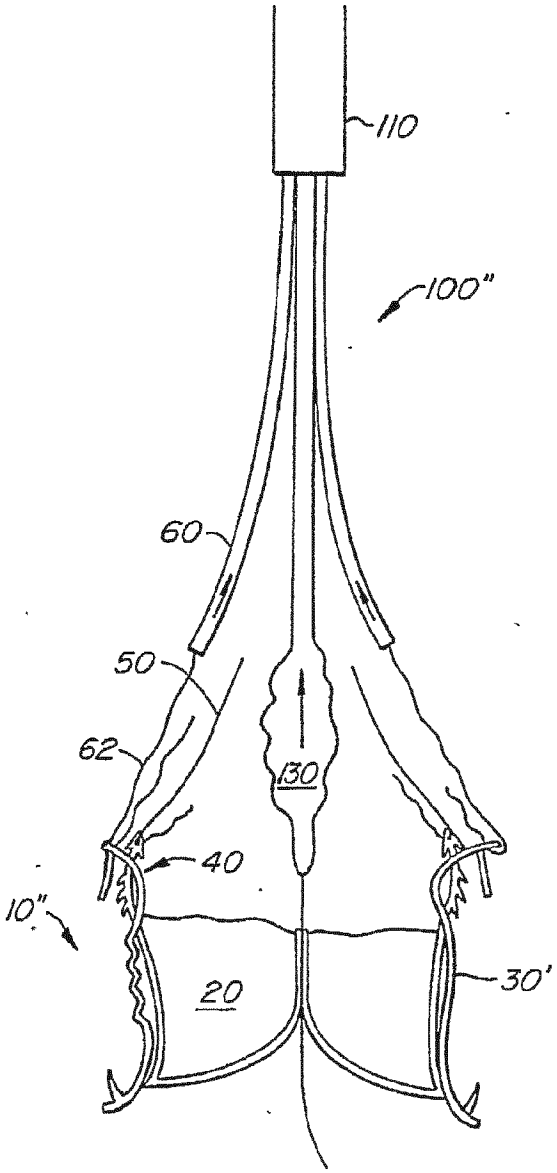


FIG. 8C



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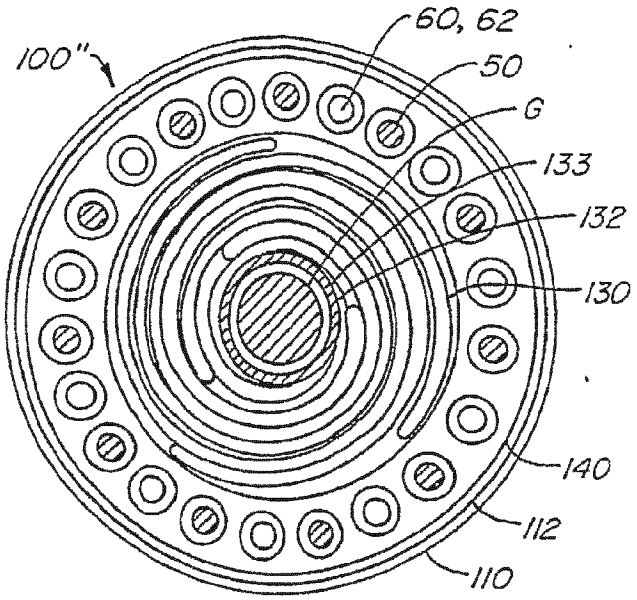


FIG. 10

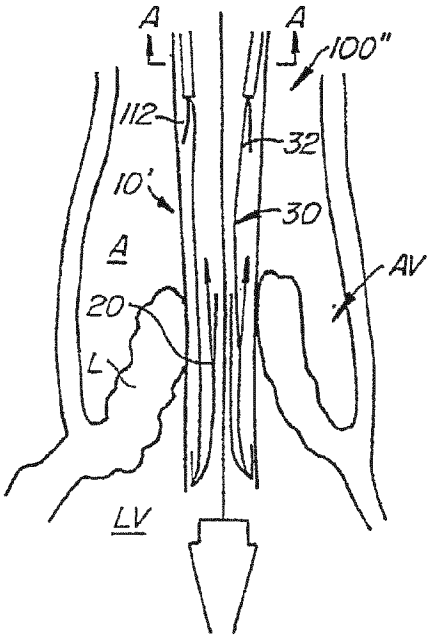


FIG. 9A

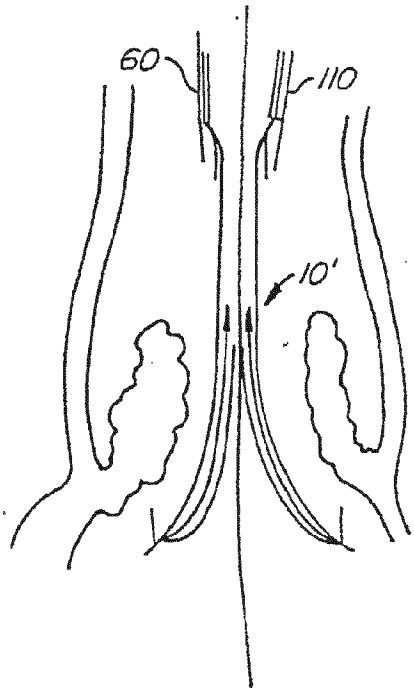


FIG. 9B



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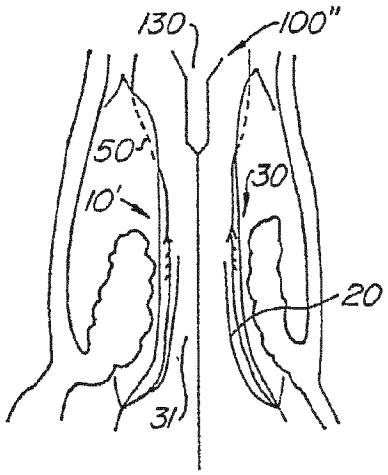


FIG. 9C

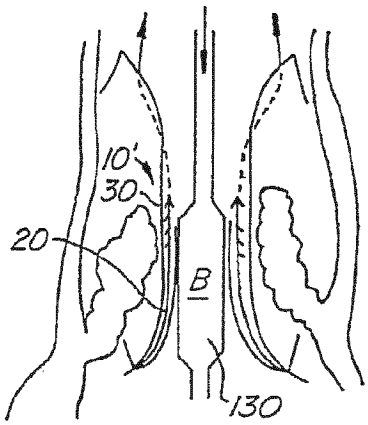


FIG. 9D

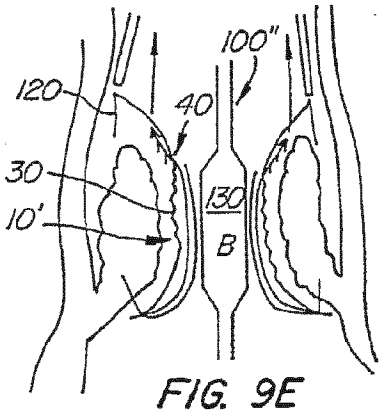


FIG. 9E

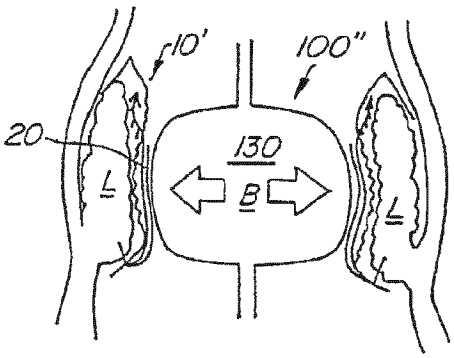


FIG. 9F

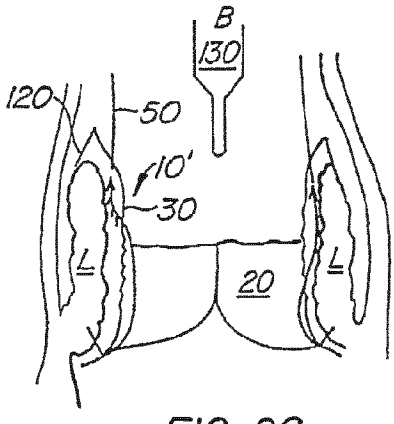


FIG. 9G

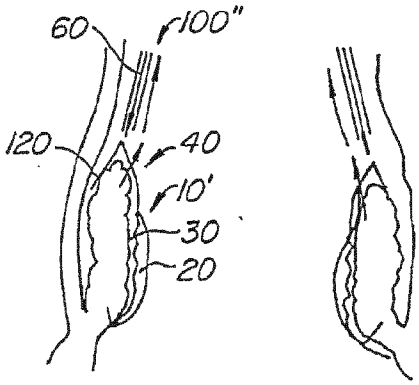


FIG. 9H



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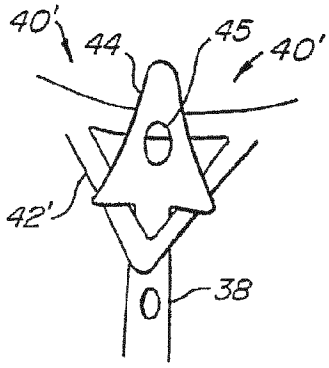


FIG. 11A

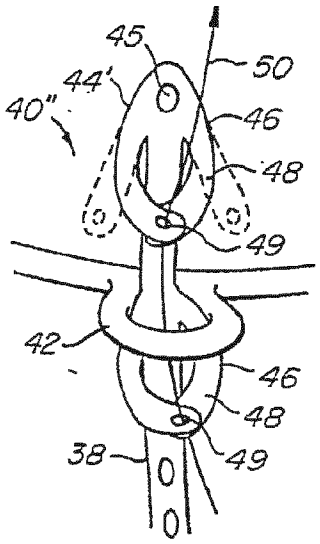


FIG. 11B

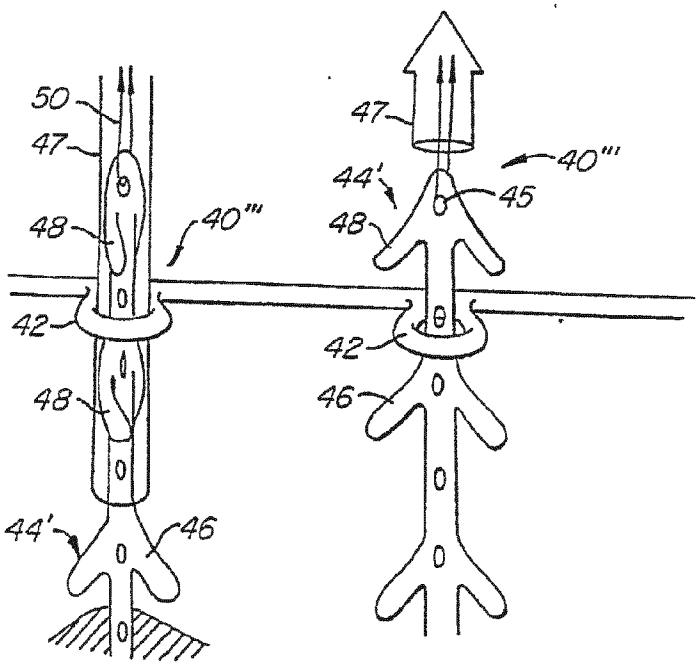


FIG. 11C



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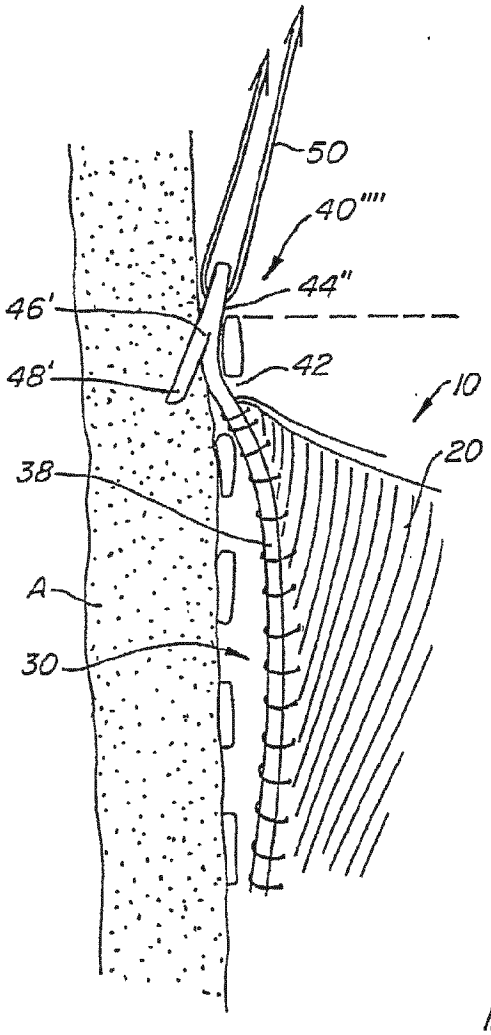


FIG. 12C

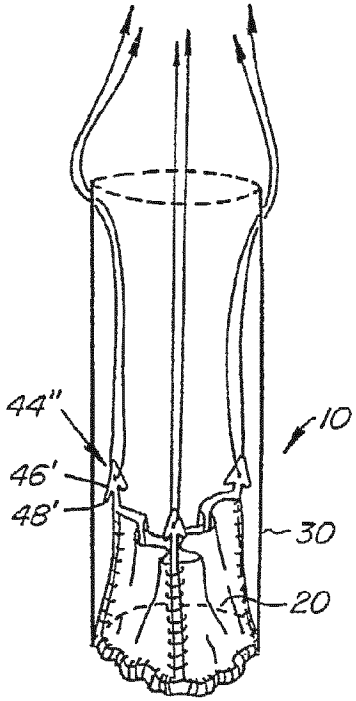


FIG. 12A

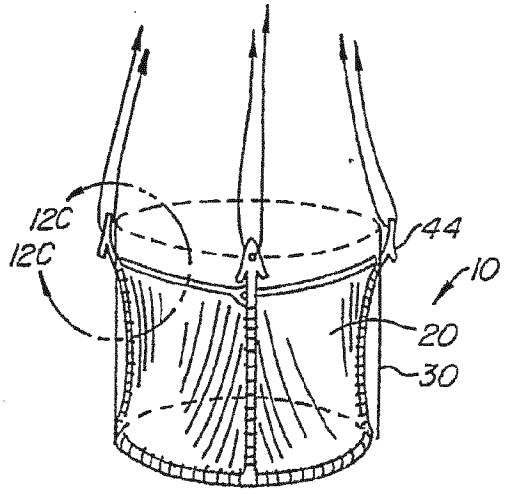


FIG. 12B



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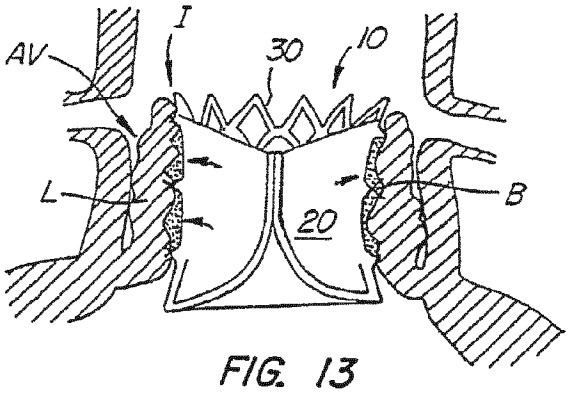


FIG. 13

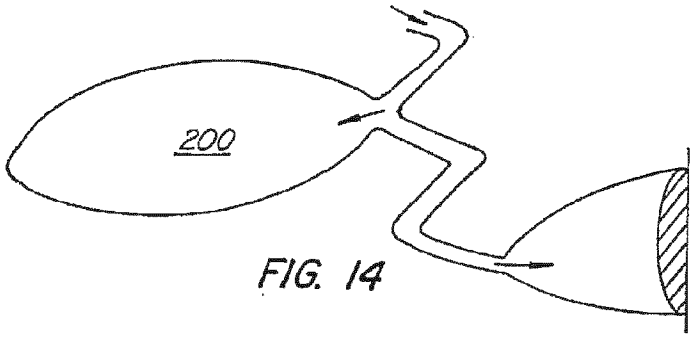


FIG. 14

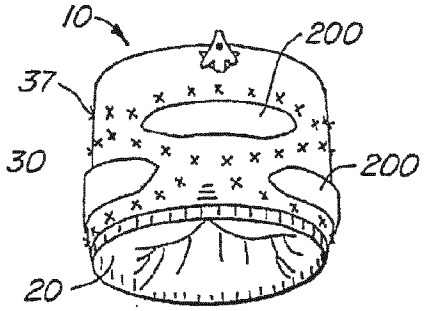


FIG. 15A

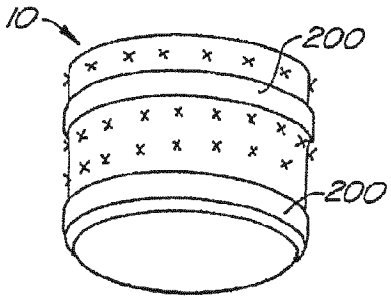


FIG. 15B

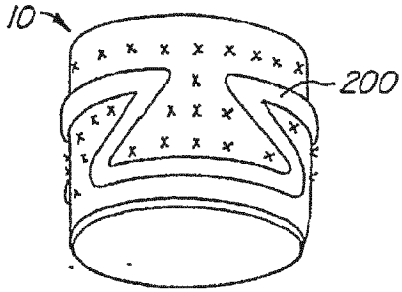


FIG. 15C



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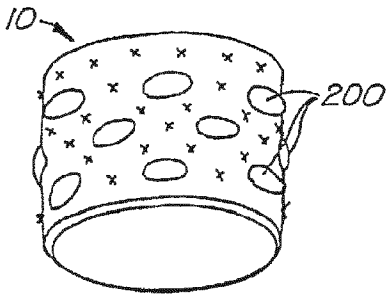


FIG. 15D

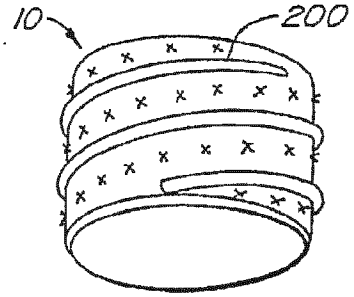


FIG. 15E

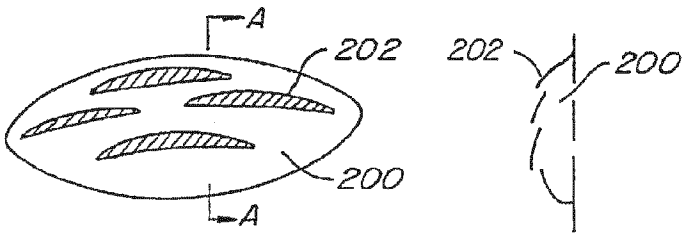


FIG. 16A

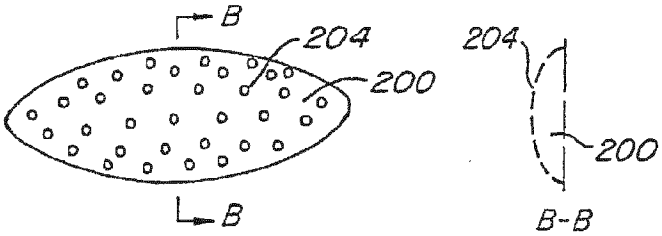


FIG. 16B

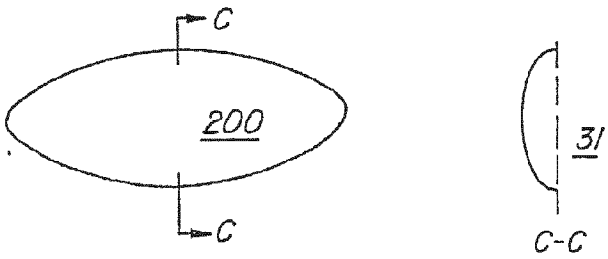


FIG. 16C



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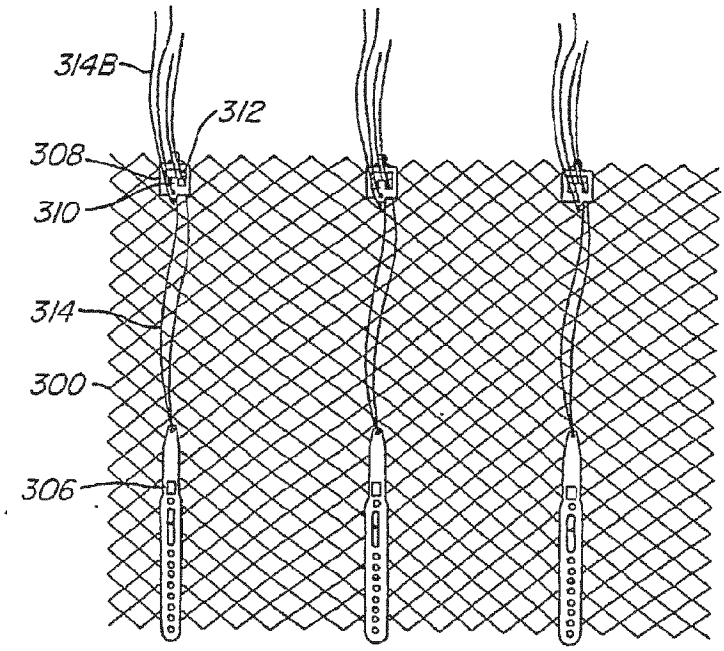


FIG. 17A

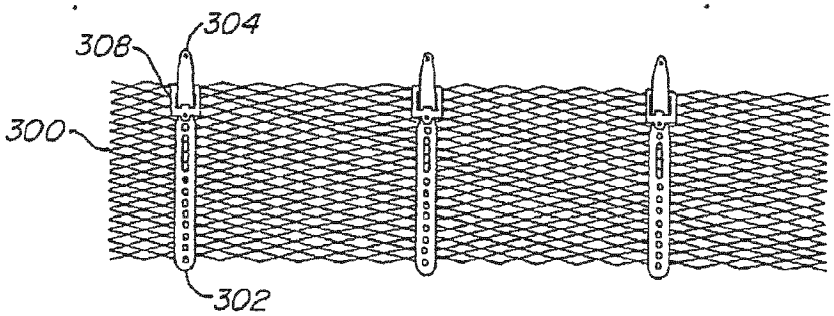


FIG. 18A



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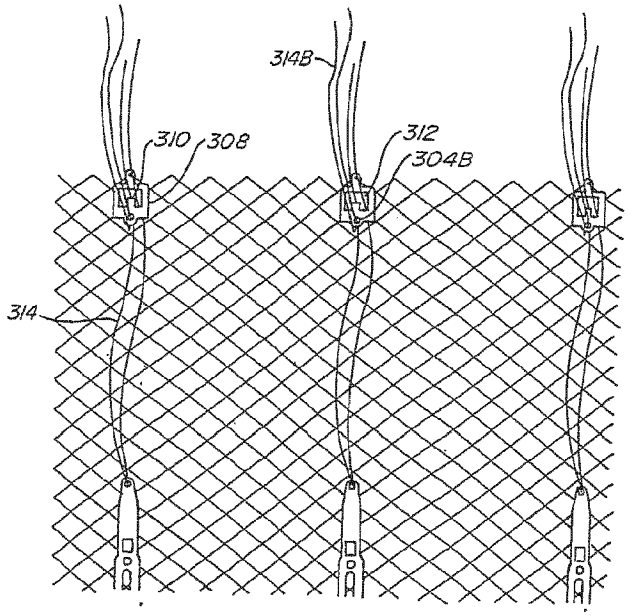


FIG. 17B

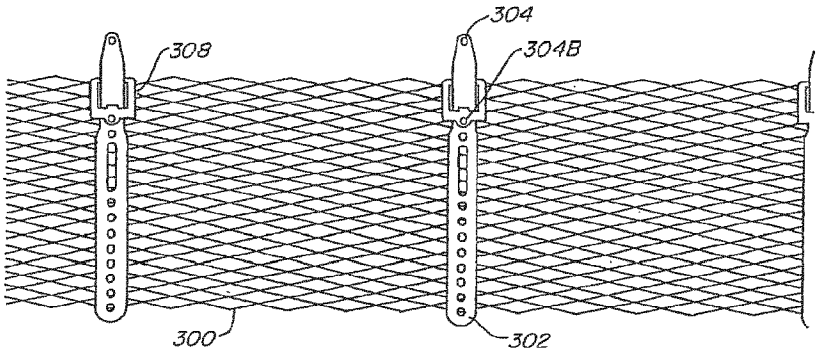


FIG. 18B



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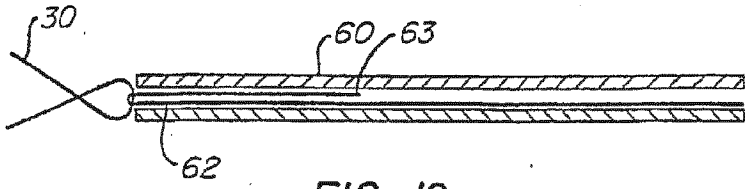


FIG. 19

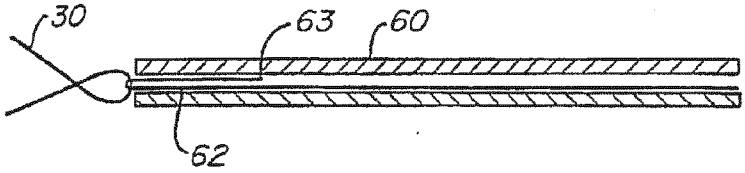


FIG. 20

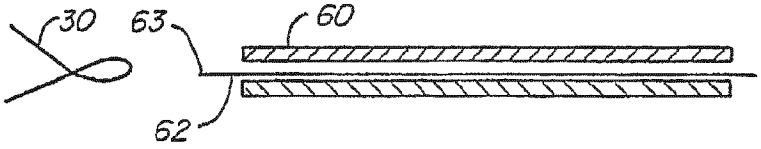


FIG. 21



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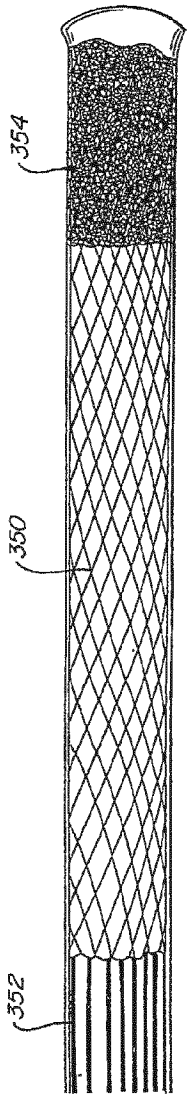


FIG. 22

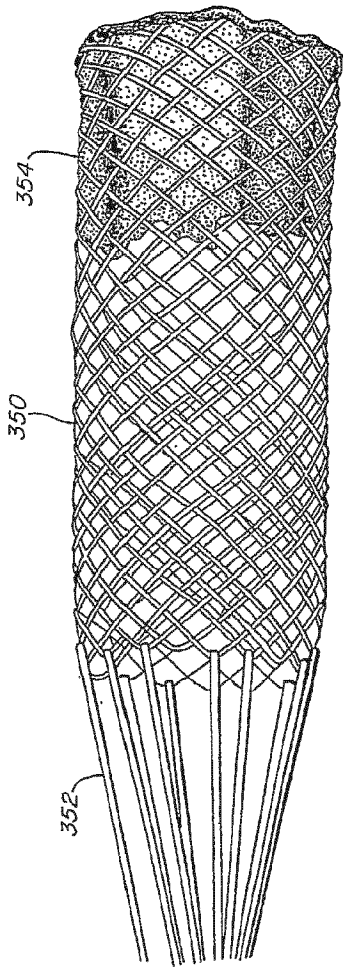


FIG. 23



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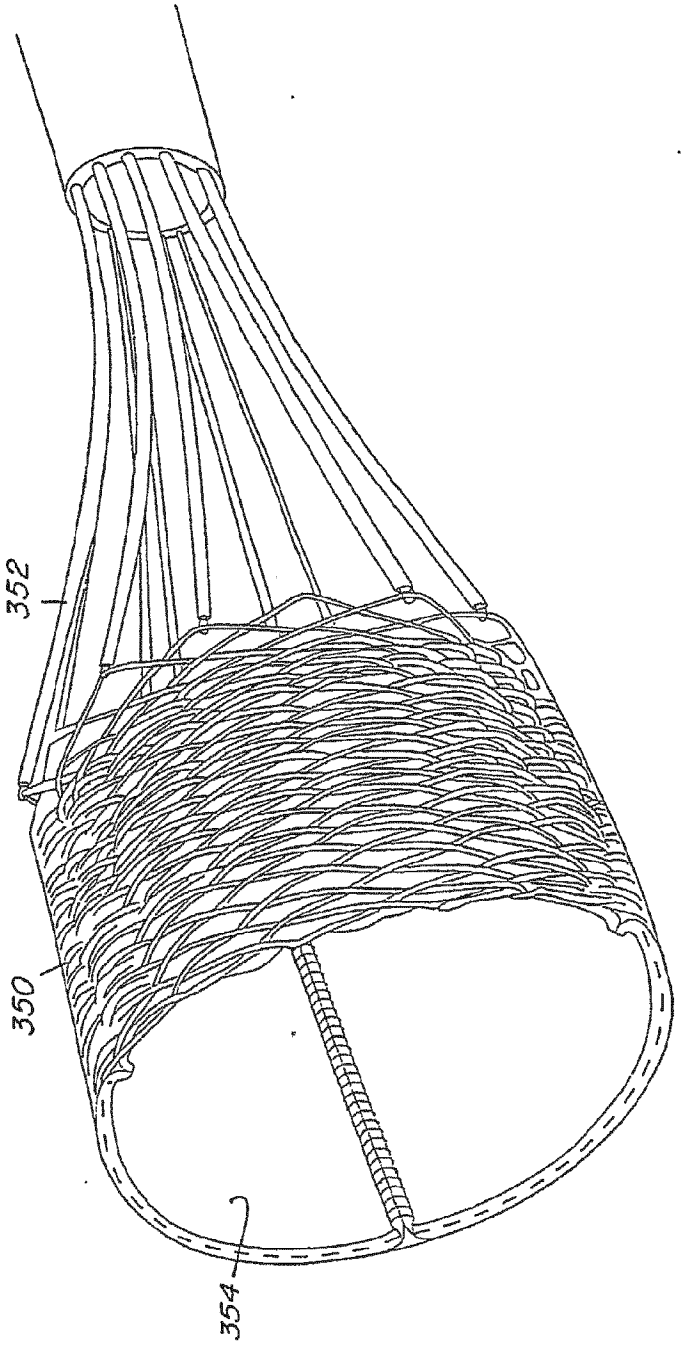


FIG. 24



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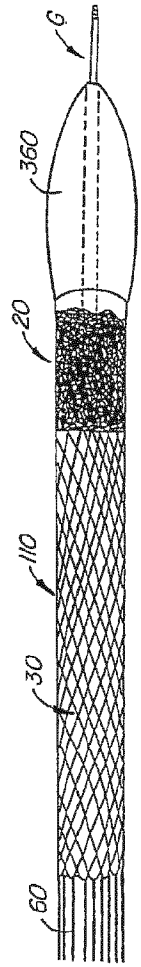


FIG. 25

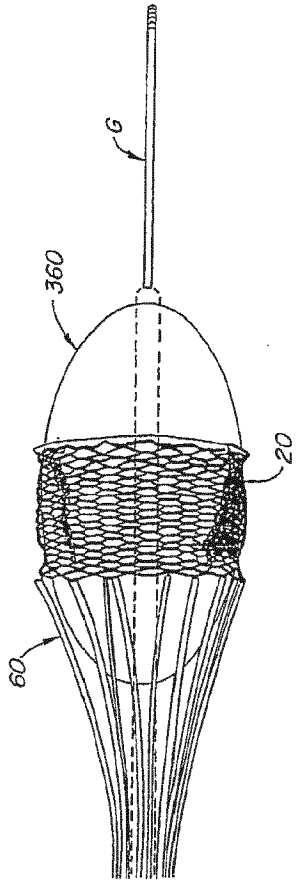


FIG. 26



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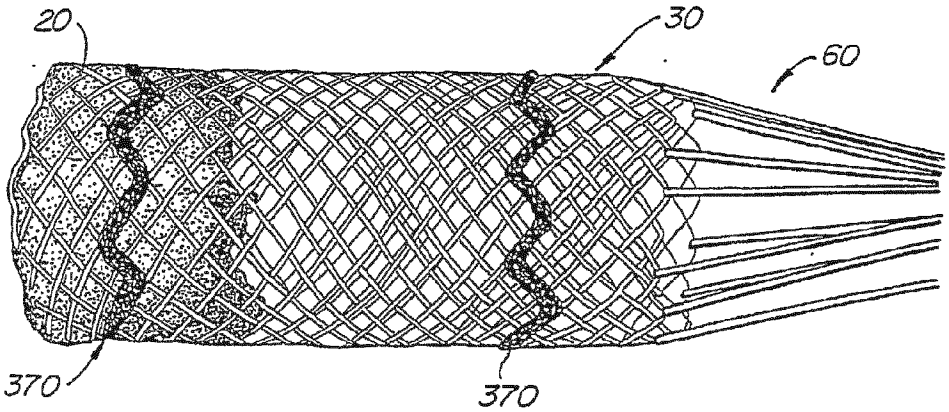


FIG. 27

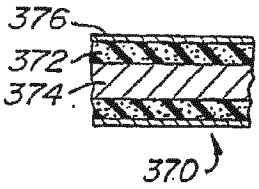


FIG. 28

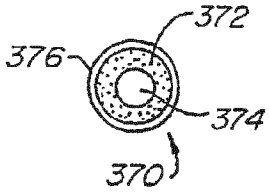


FIG. 29

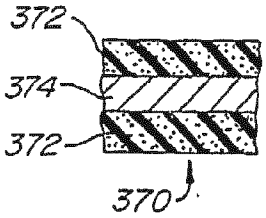


FIG. 30

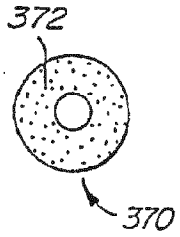


FIG. 31



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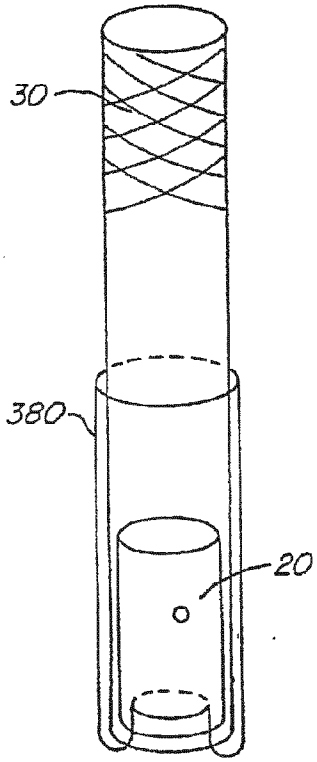


FIG. 32

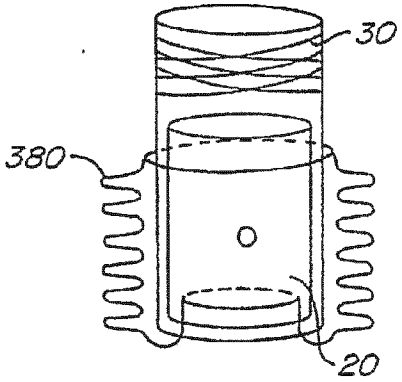


FIG. 33

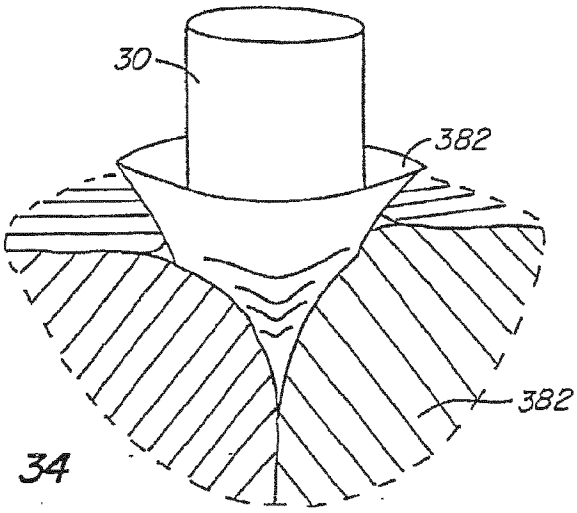


FIG. 34



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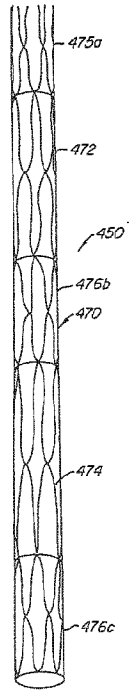


FIG. 35A

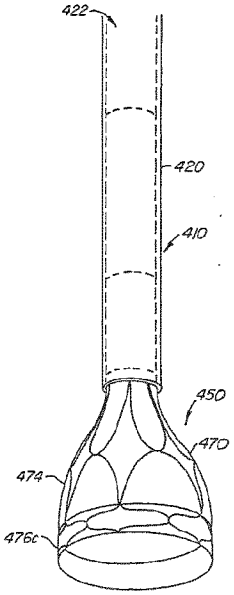


FIG. 35B

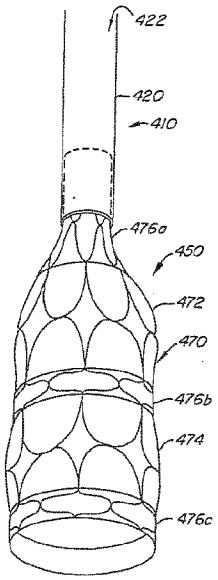


FIG. 35C

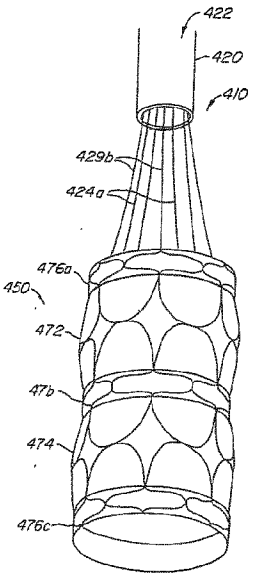


FIG. 35D

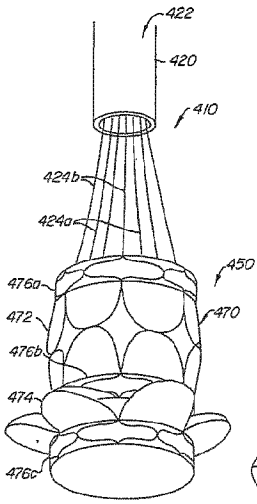


FIG. 35E

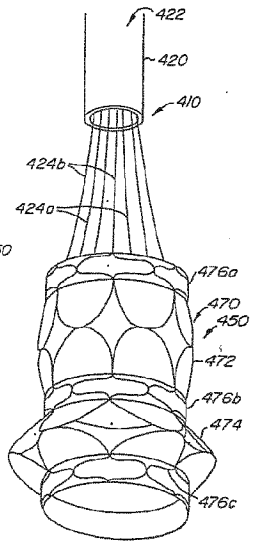


FIG. 35F

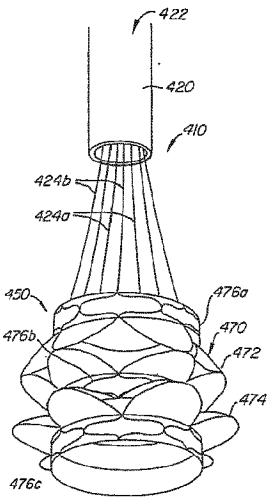


FIG. 35G

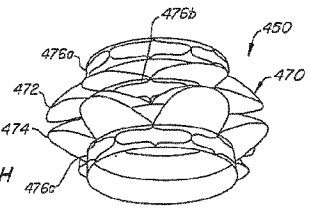


FIG. 35H



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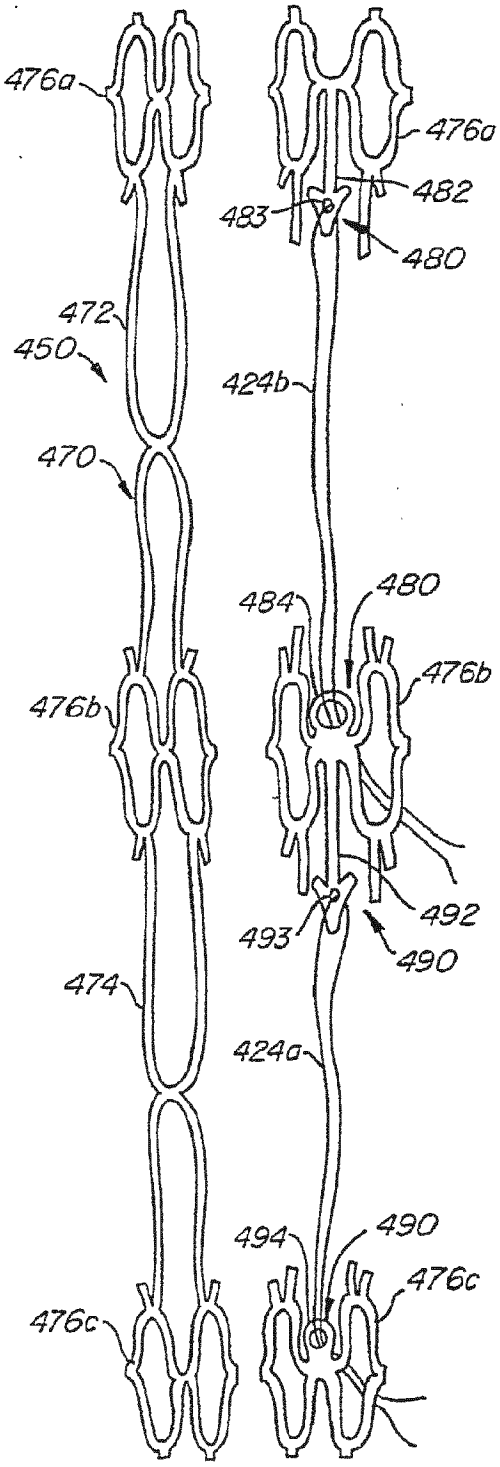


FIG. 36A

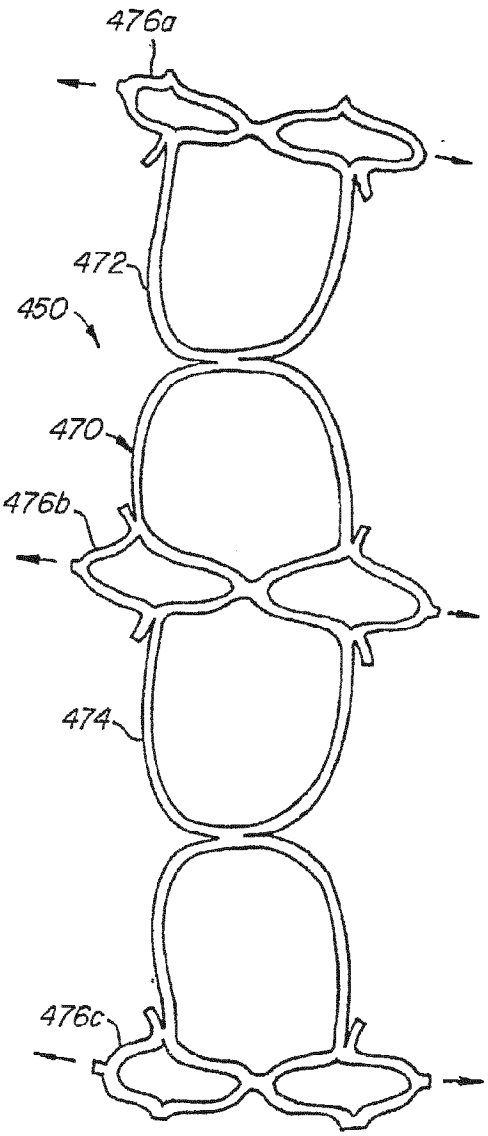


FIG. 36B



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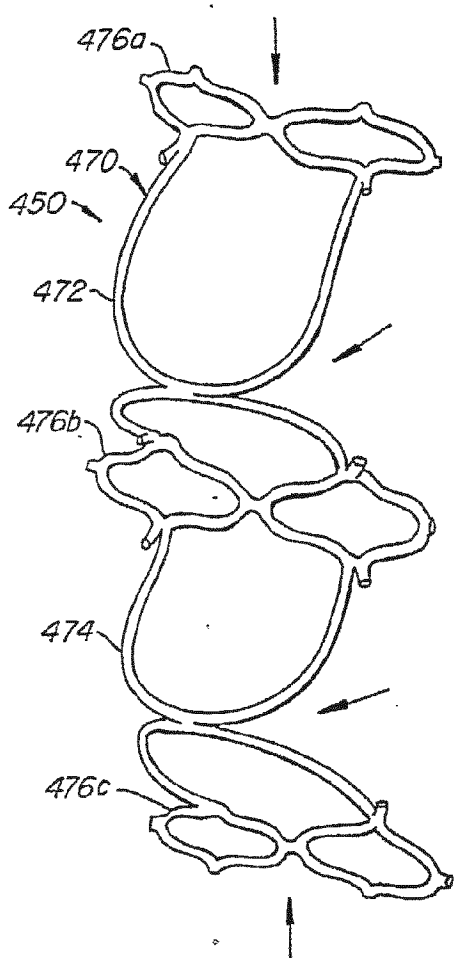


FIG. 36C

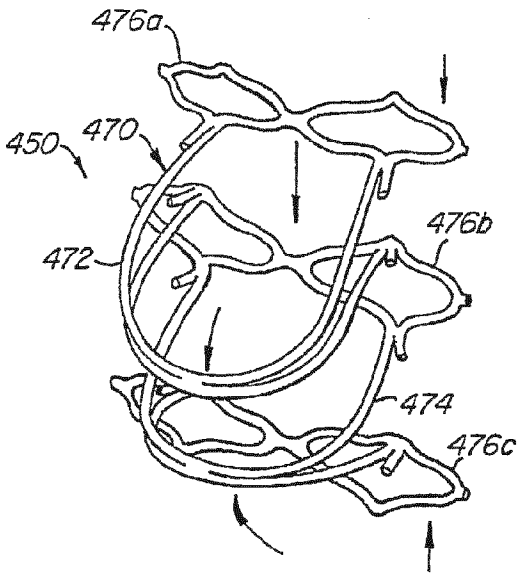


FIG. 36D

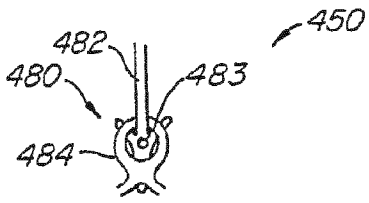


FIG. 36E



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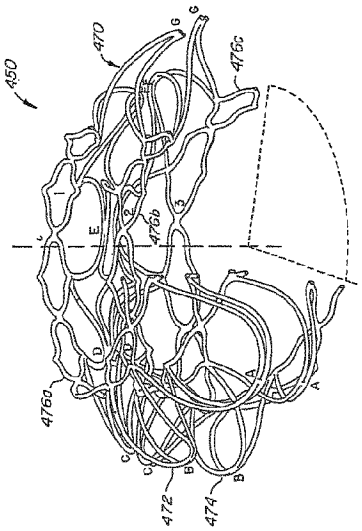


FIG. 37A

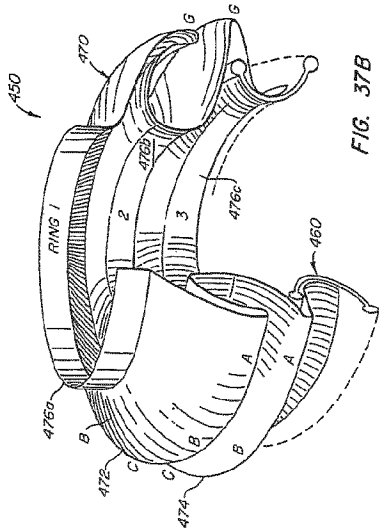


FIG. 37B

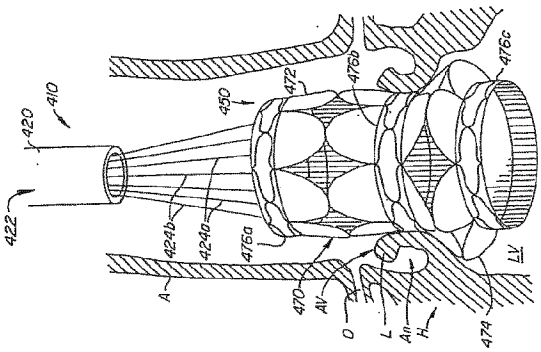


FIG. 38A

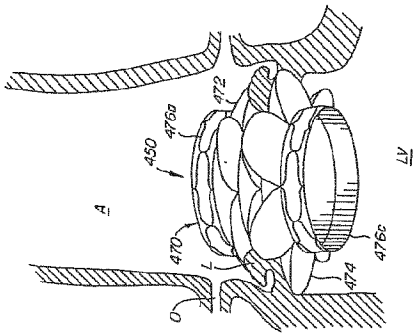


FIG. 38B



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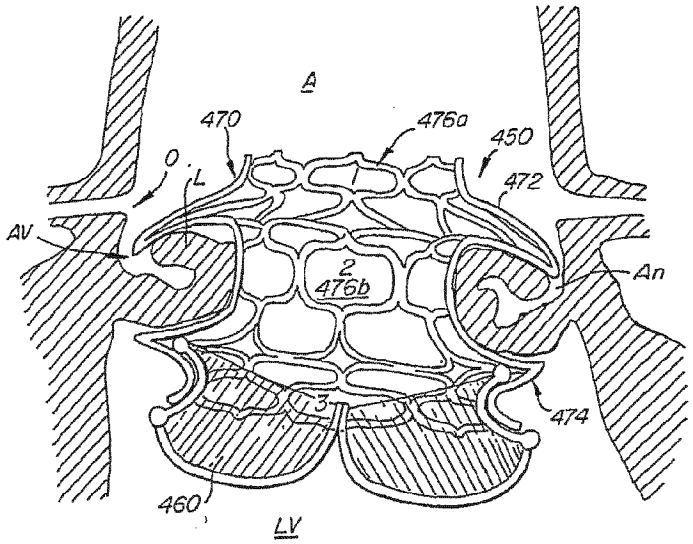


FIG. 38C

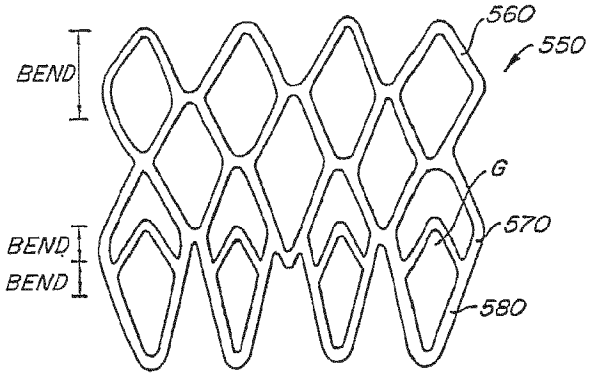


FIG. 39A

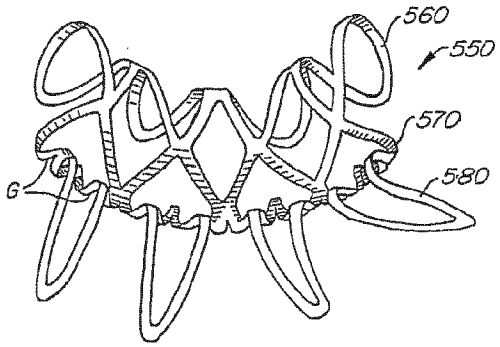


FIG. 39B



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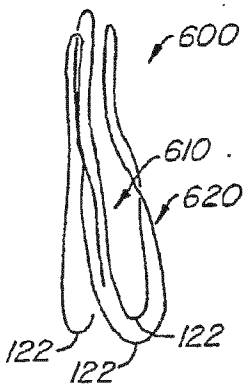


FIG. 40A

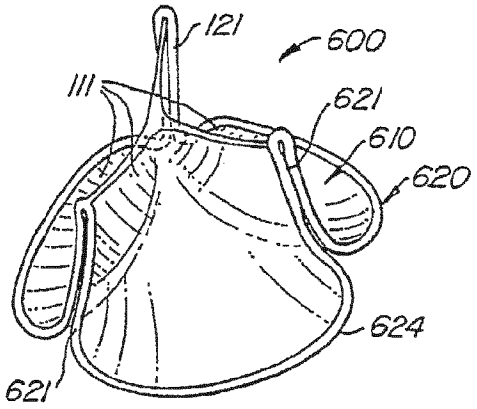


FIG. 40B

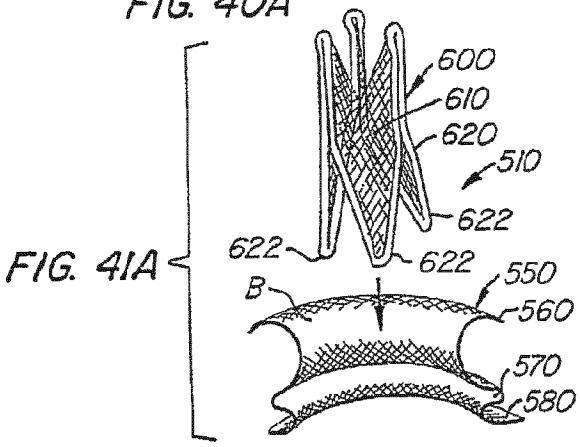


FIG. 41A

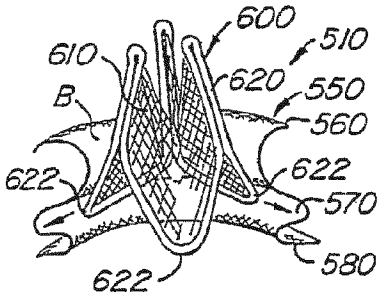


FIG. 41B

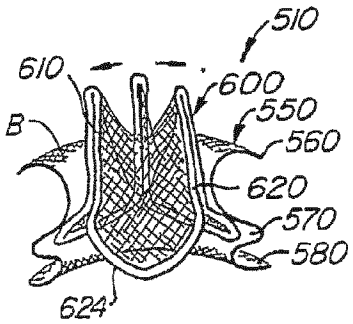


FIG. 41C

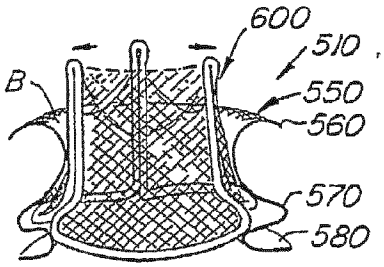


FIG. 41D



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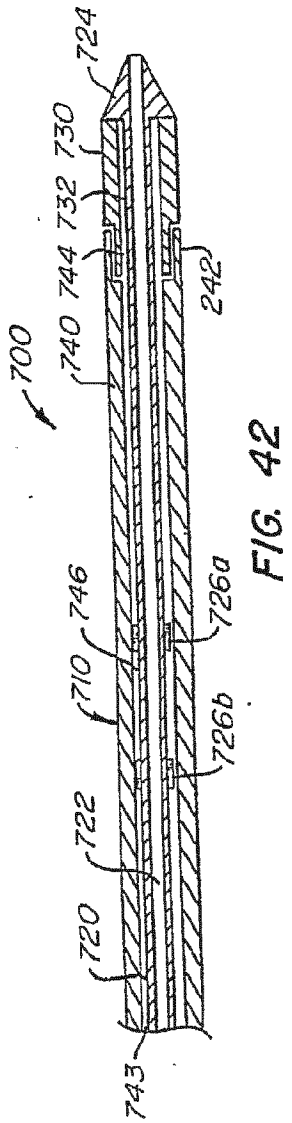


FIG. 42

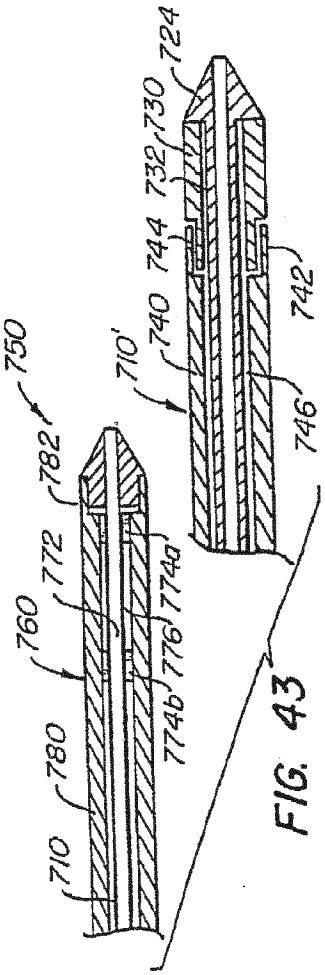


FIG. 43

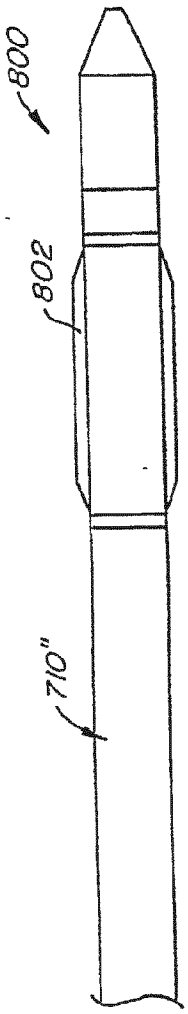


FIG. 44



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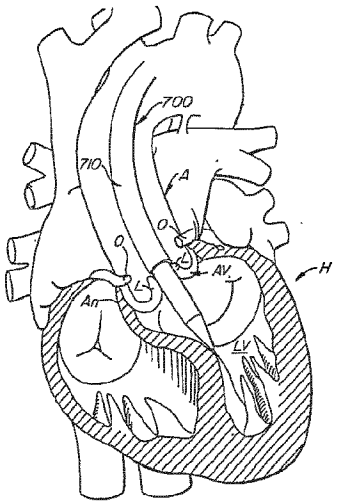


FIG. 45A

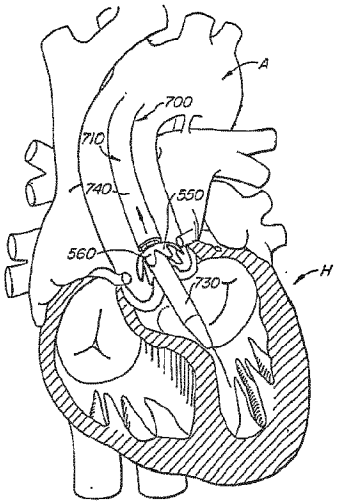


FIG. 45B

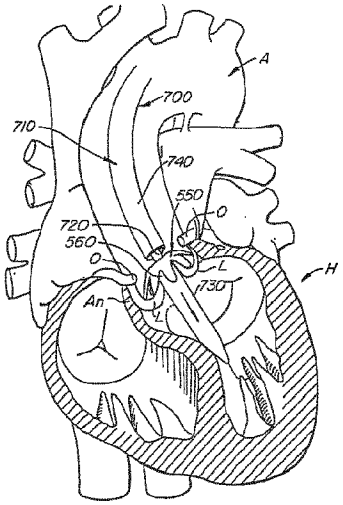


FIG. 45C

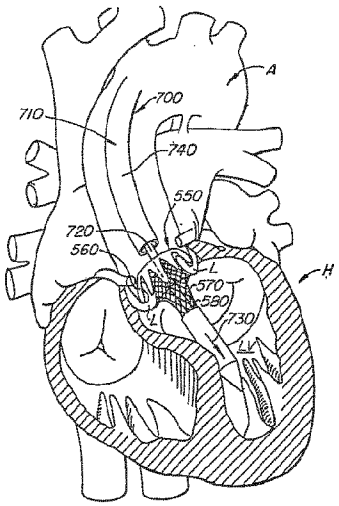


FIG. 45D



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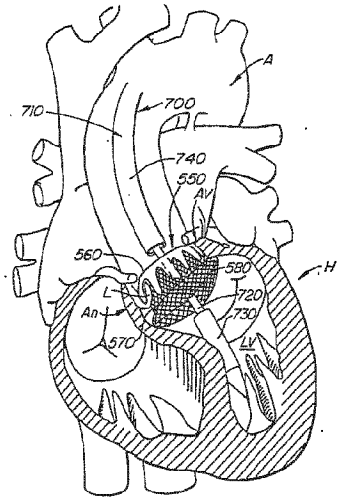


FIG. 45E

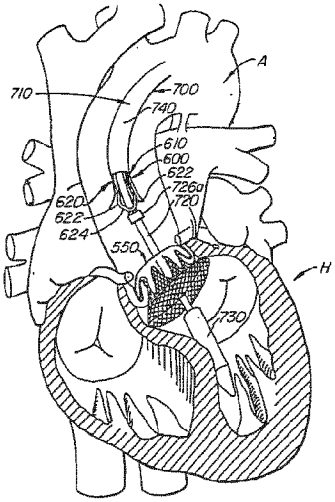


FIG. 45F

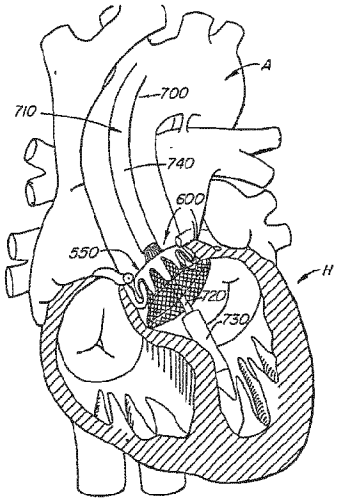


FIG. 45G

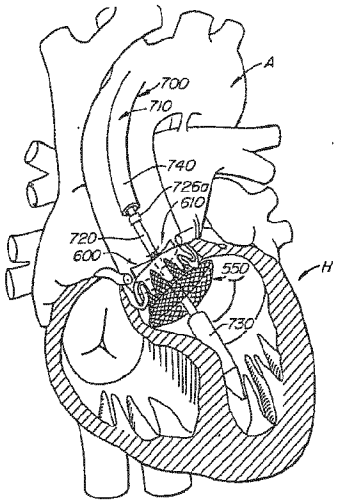


FIG. 45H



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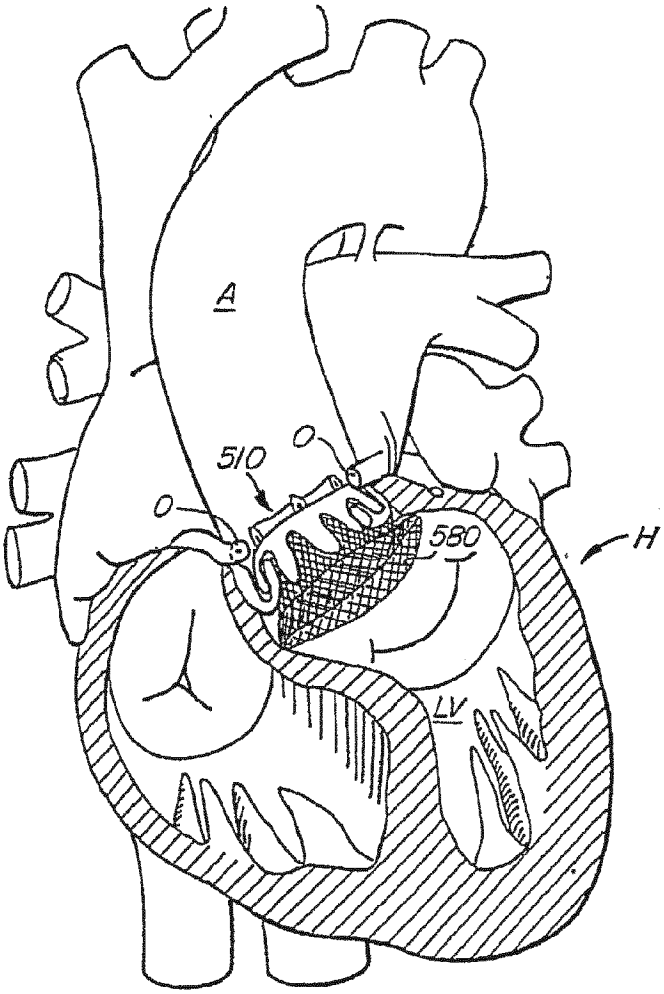


FIG. 45I



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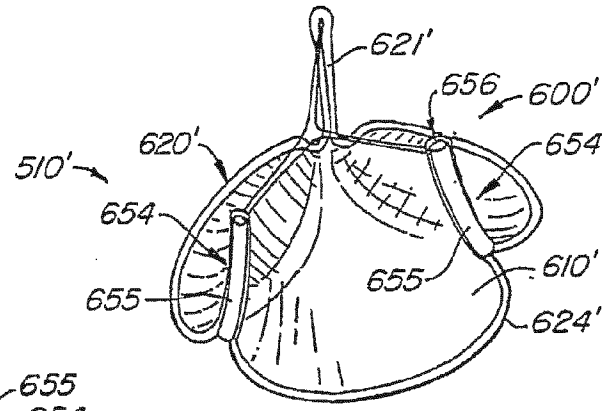


FIG. 46A

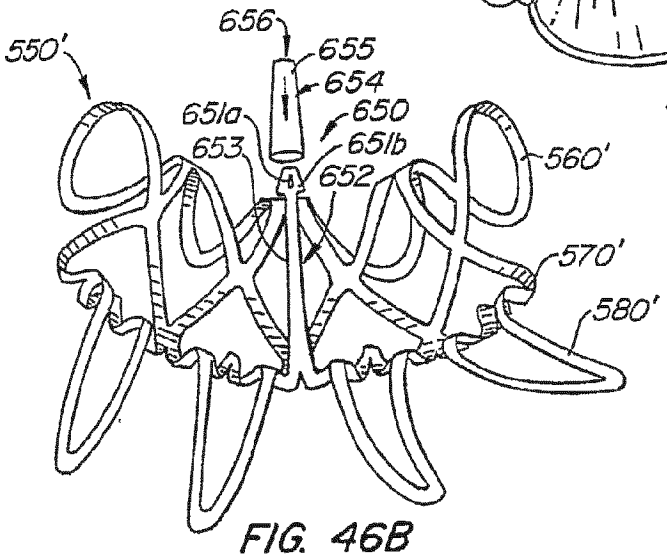


FIG. 46B

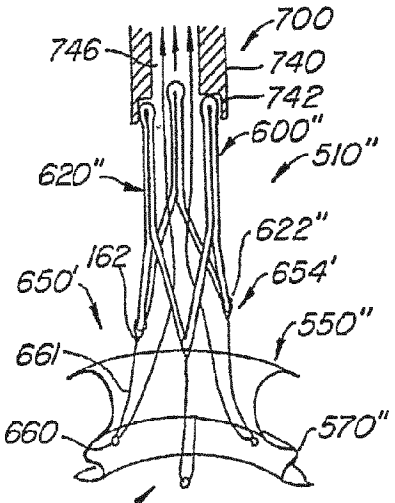


FIG. 47

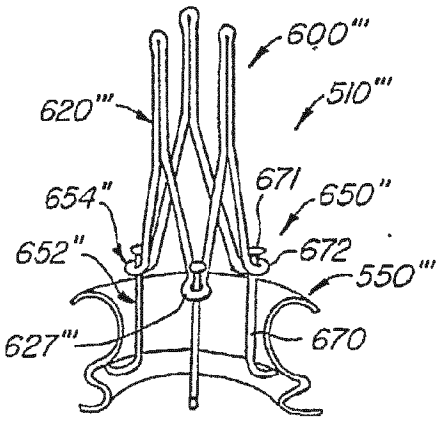


FIG. 48



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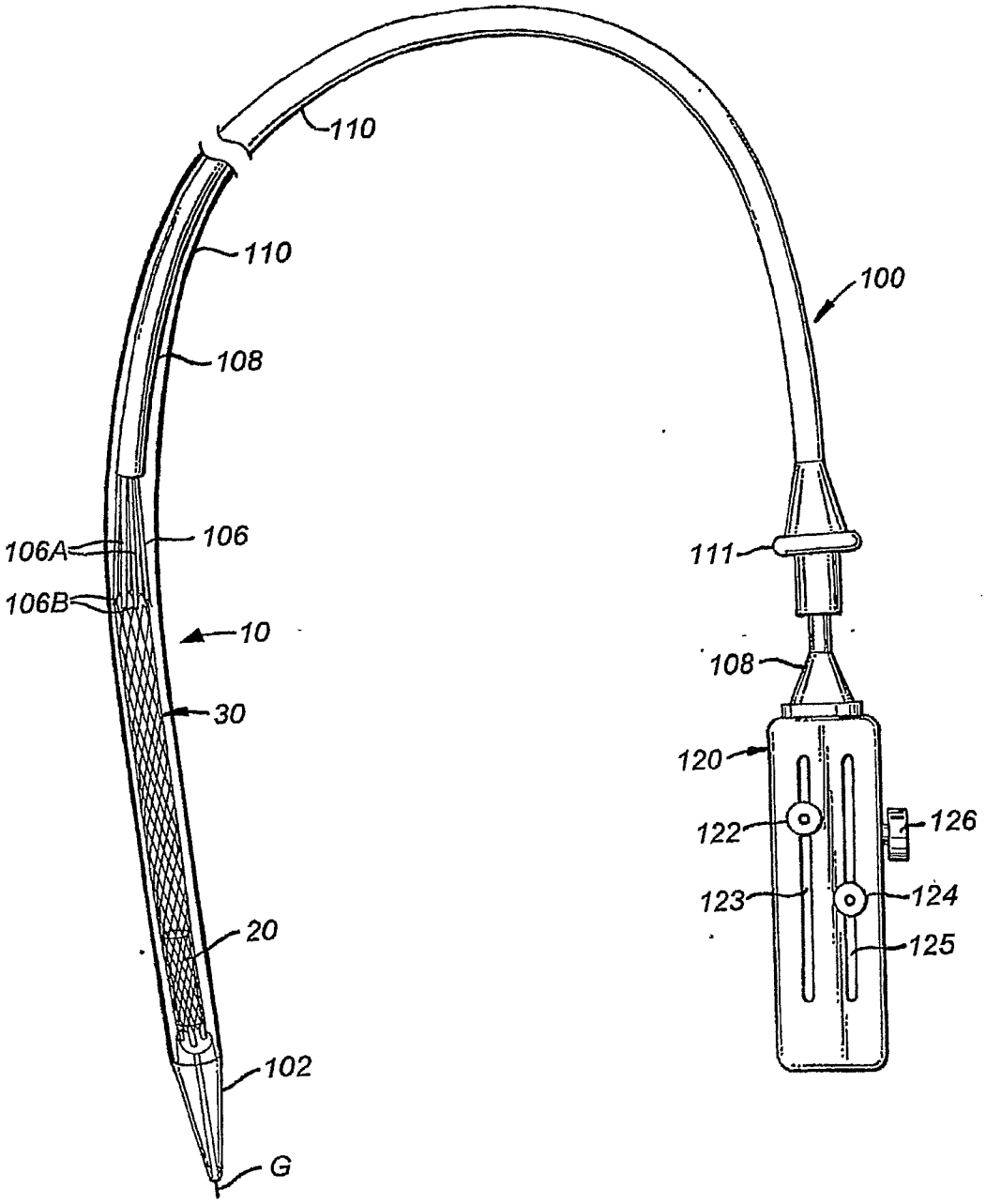


FIG. 49A



Aortic Innovations, LLC, Exhibit 2040
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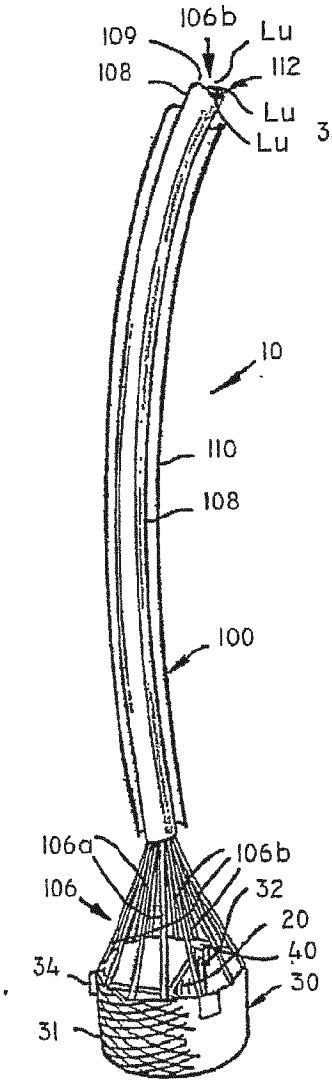


FIG. 49B

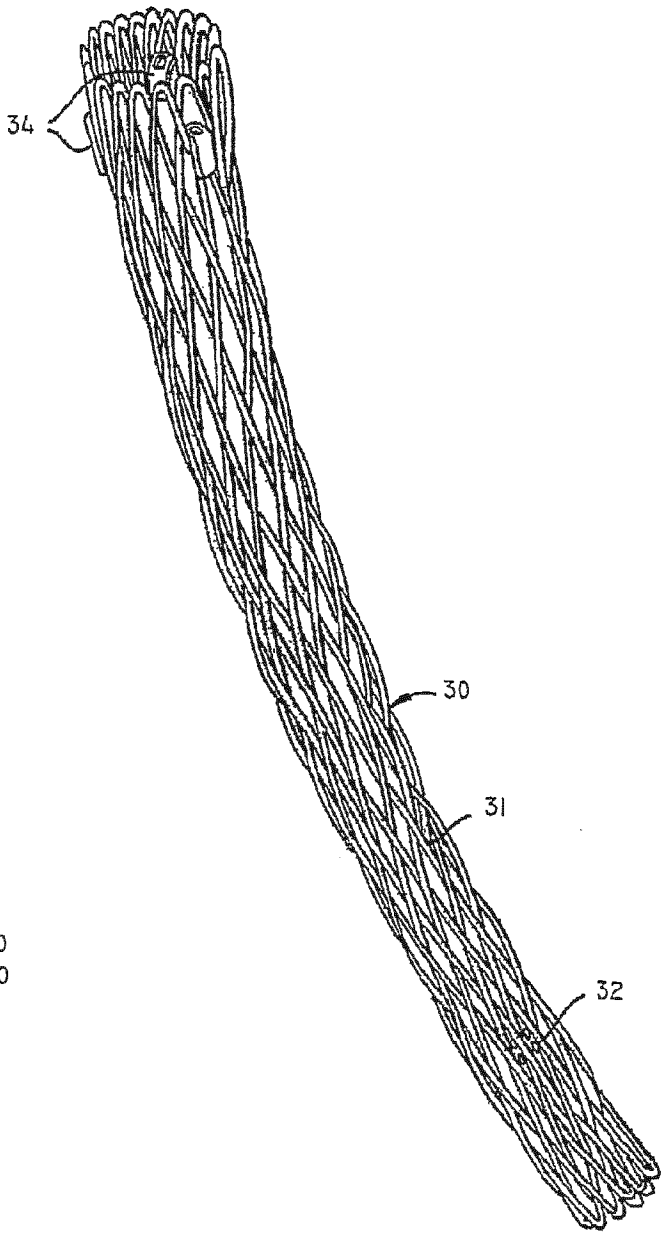


FIG. 50A



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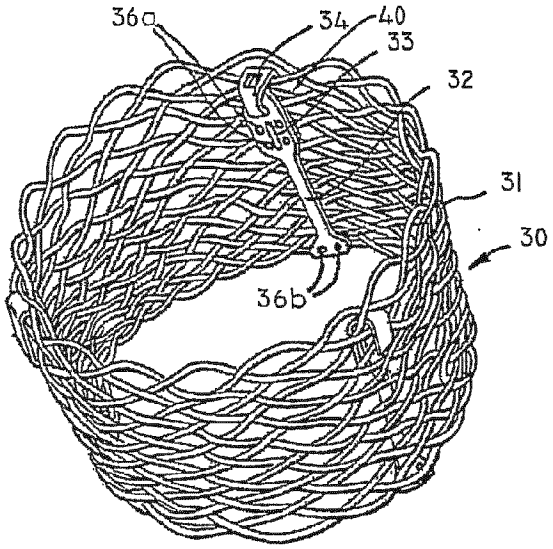


FIG. 50B

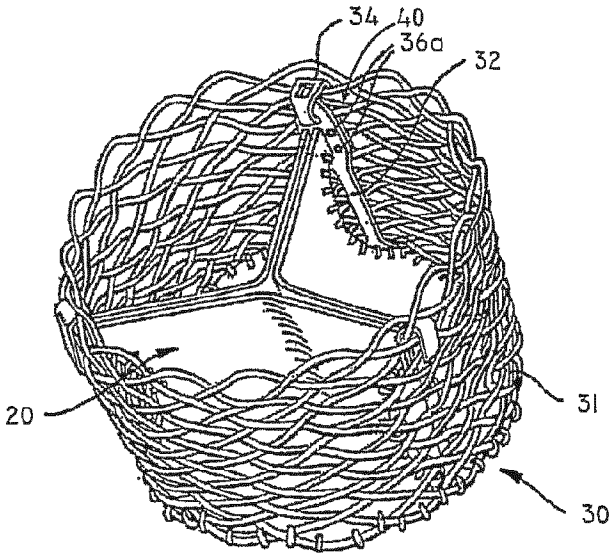


FIG. 50C



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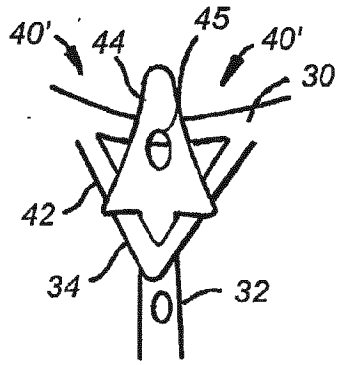


FIG. 50D

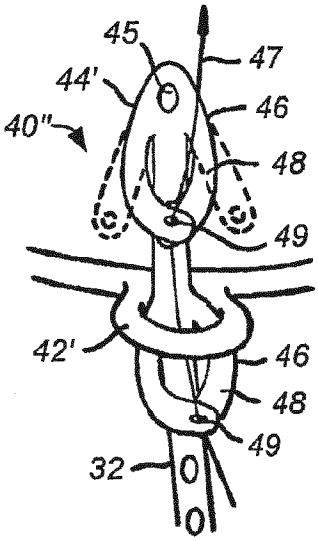


FIG. 50E

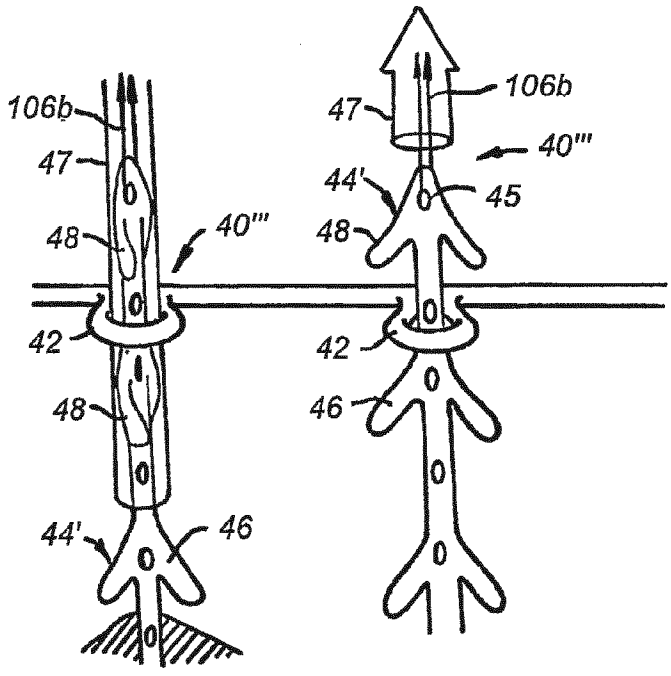


FIG. 50F



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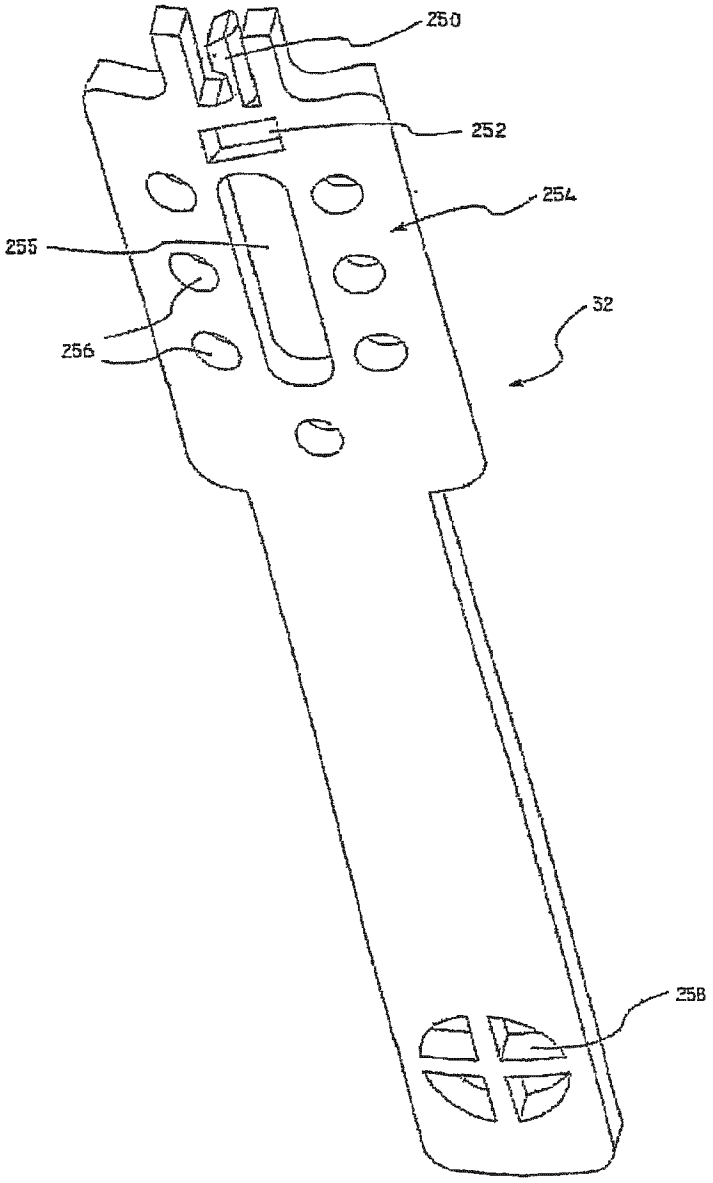


FIG. 51



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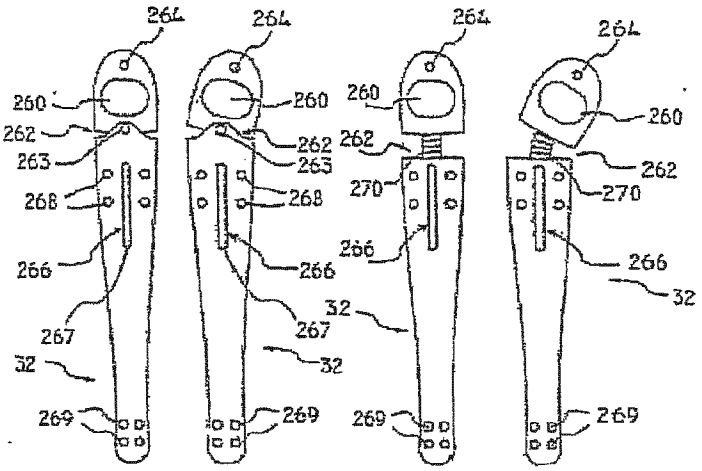


FIG. 52A FIG. 52B FIG. 53A FIG. 53B

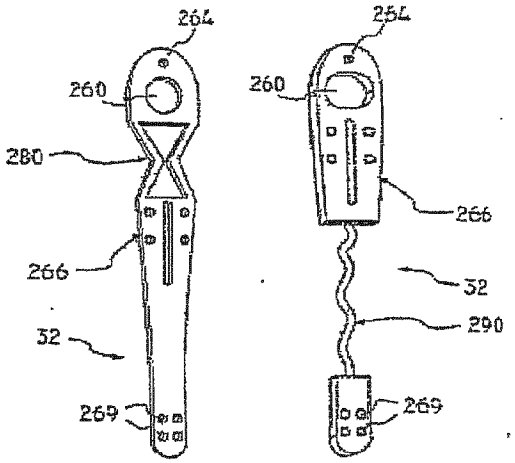


FIG. 54 FIG. 55



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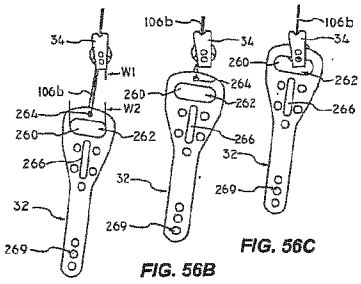


FIG. 56A FIG. 56B FIG. 56C

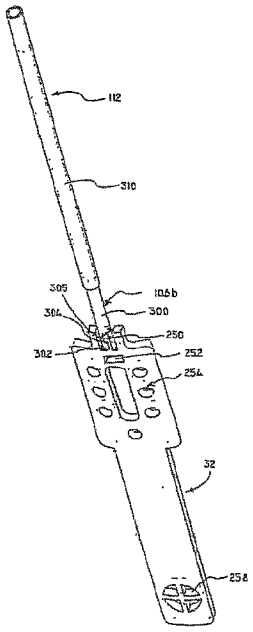


FIG. 57

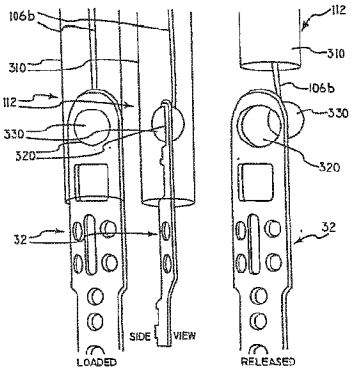


FIG. 58A FIG. 58B FIG. 58C

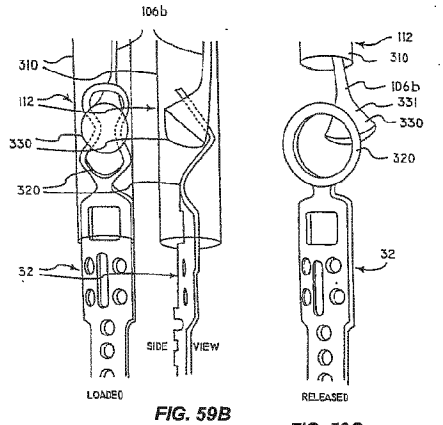


FIG. 59A FIG. 59B FIG. 59C



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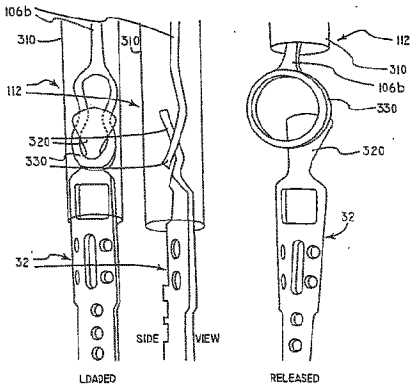


FIG. 60A FIG. 60B FIG. 60C

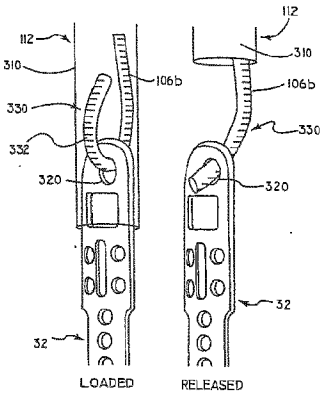


FIG. 61A FIG. 61B

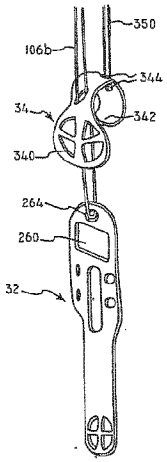


FIG. 62

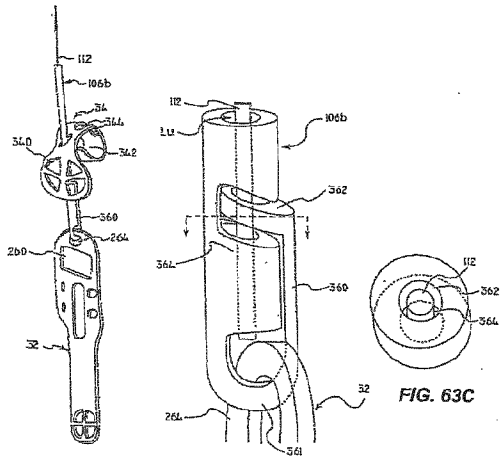


FIG. 63A FIG. 63B FIG. 63C



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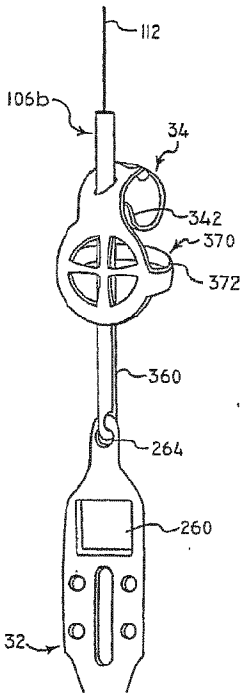


FIG. 64

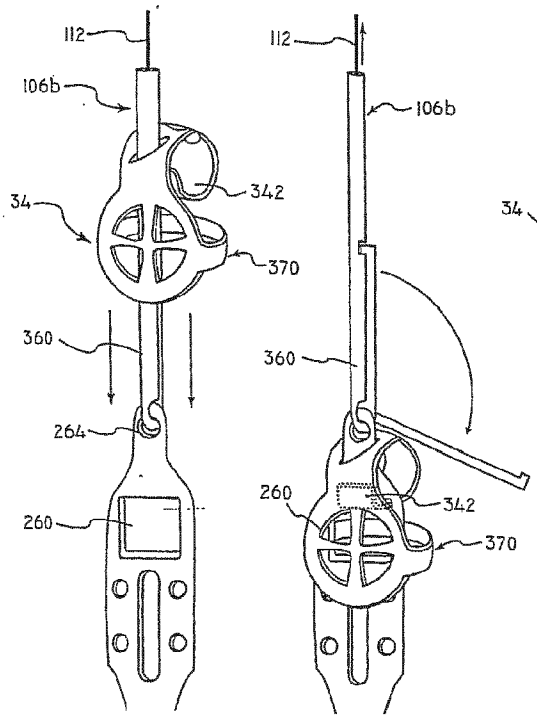


FIG. 65A FIG. 65B FIG. 66



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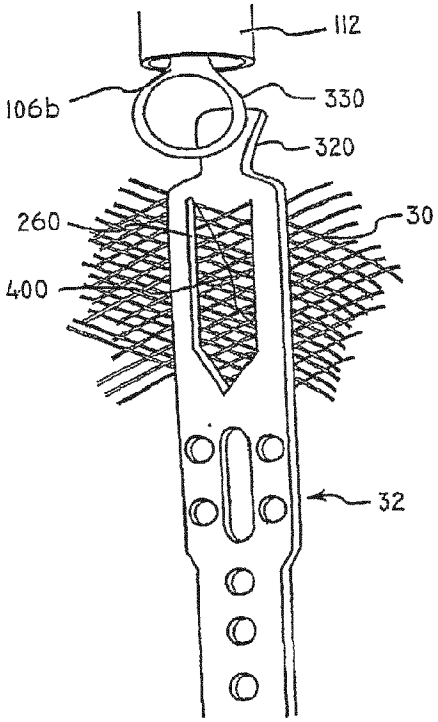


FIG. 67A

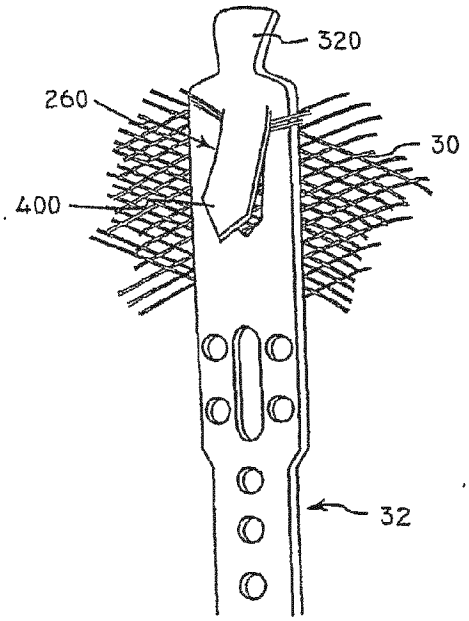


FIG. 67B



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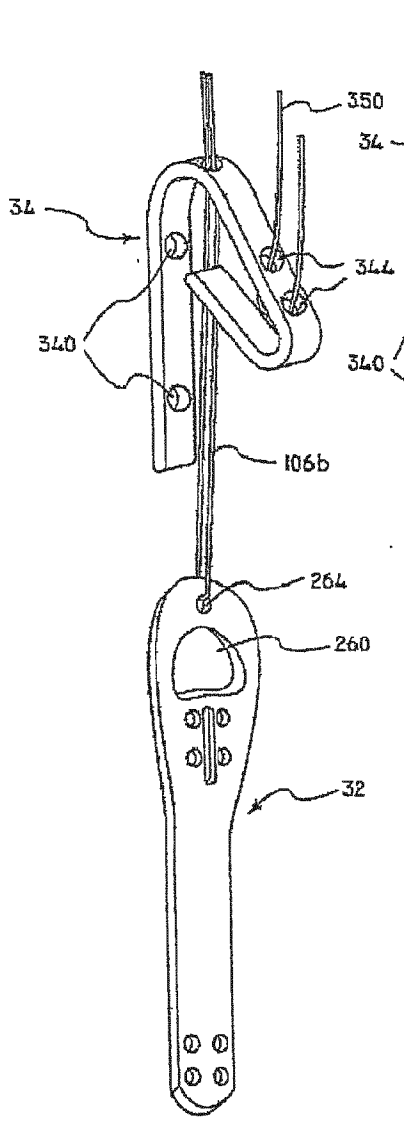


FIG. 68A

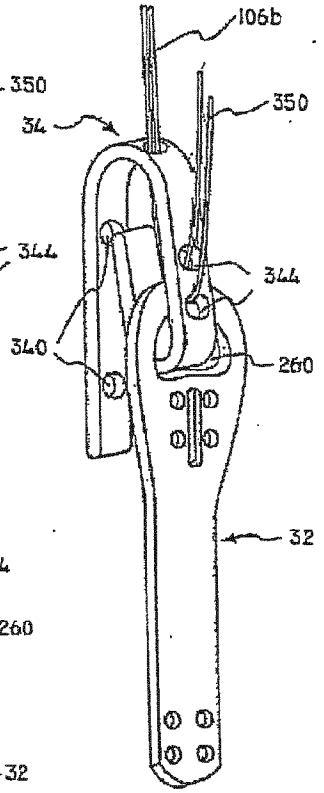


FIG. 68B

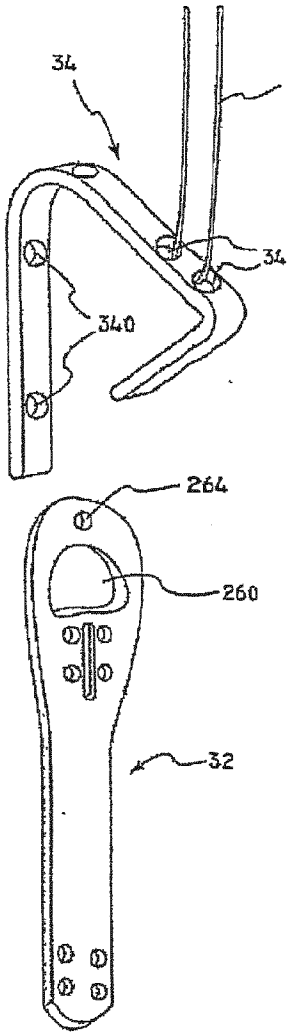


FIG. 68C



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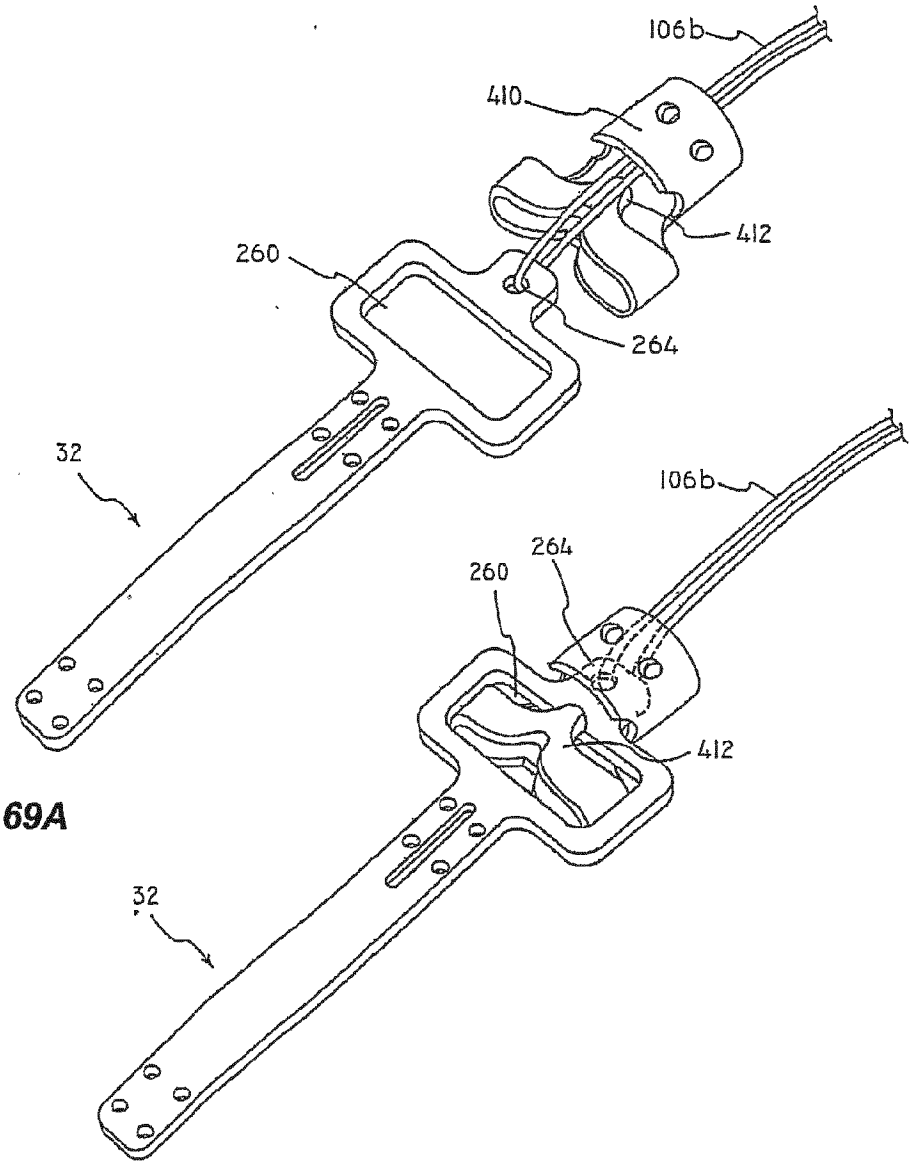


FIG. 69A

FIG. 69B



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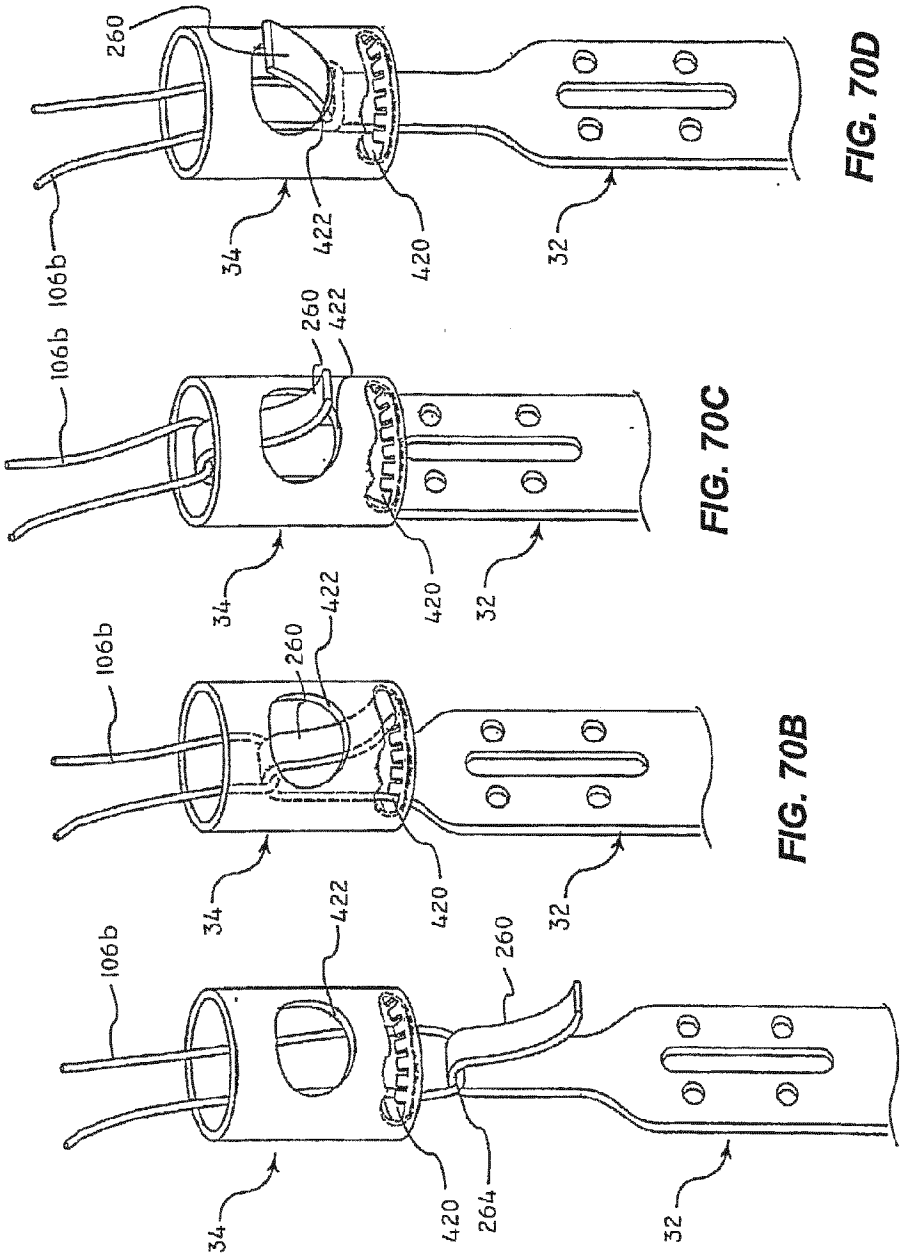


FIG. 70D

FIG. 70C

FIG. 70B

FIG. 70A



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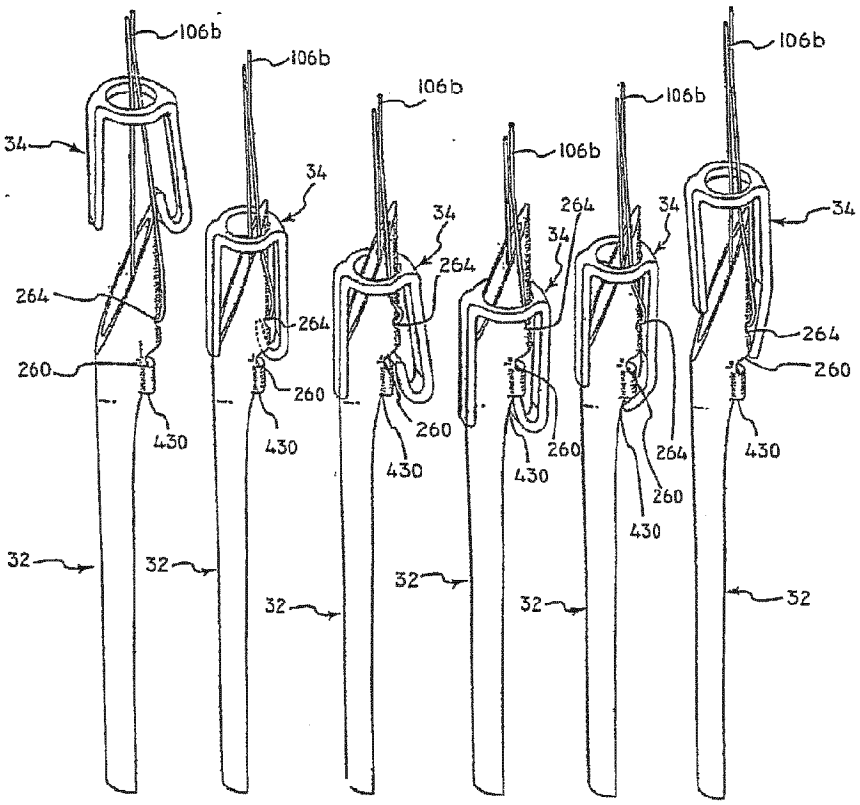


FIG. 71A FIG. 71B FIG. 71C FIG. 71D FIG. 71E FIG. 71F



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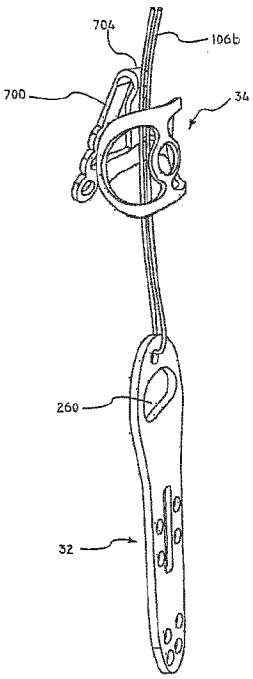


FIG. 72A

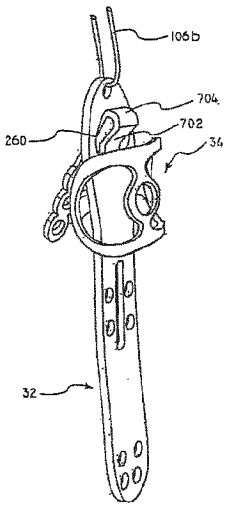


FIG. 72B

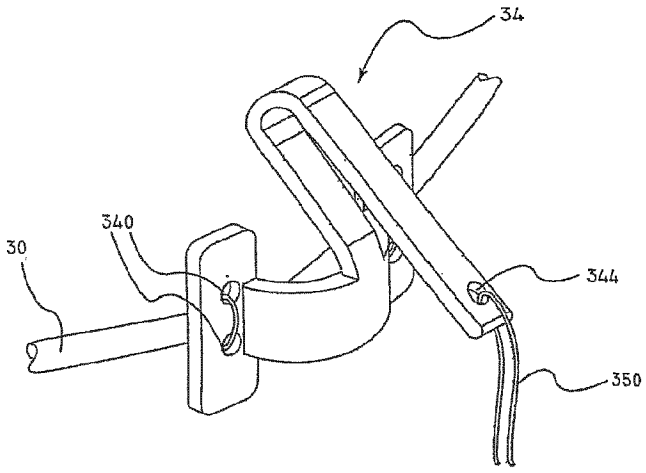


FIG. 73



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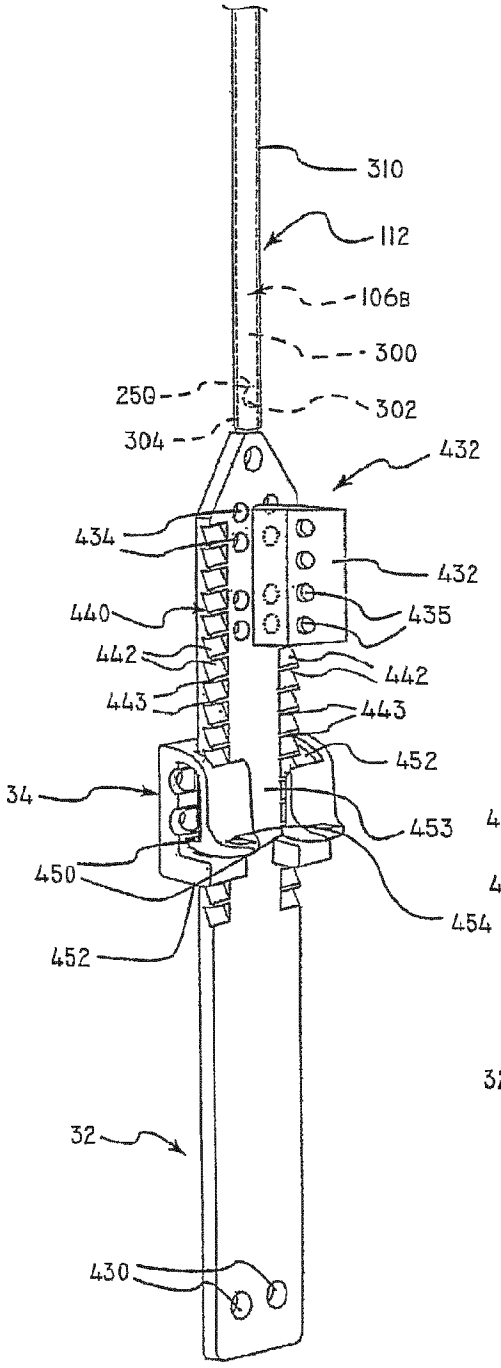


FIG. 74

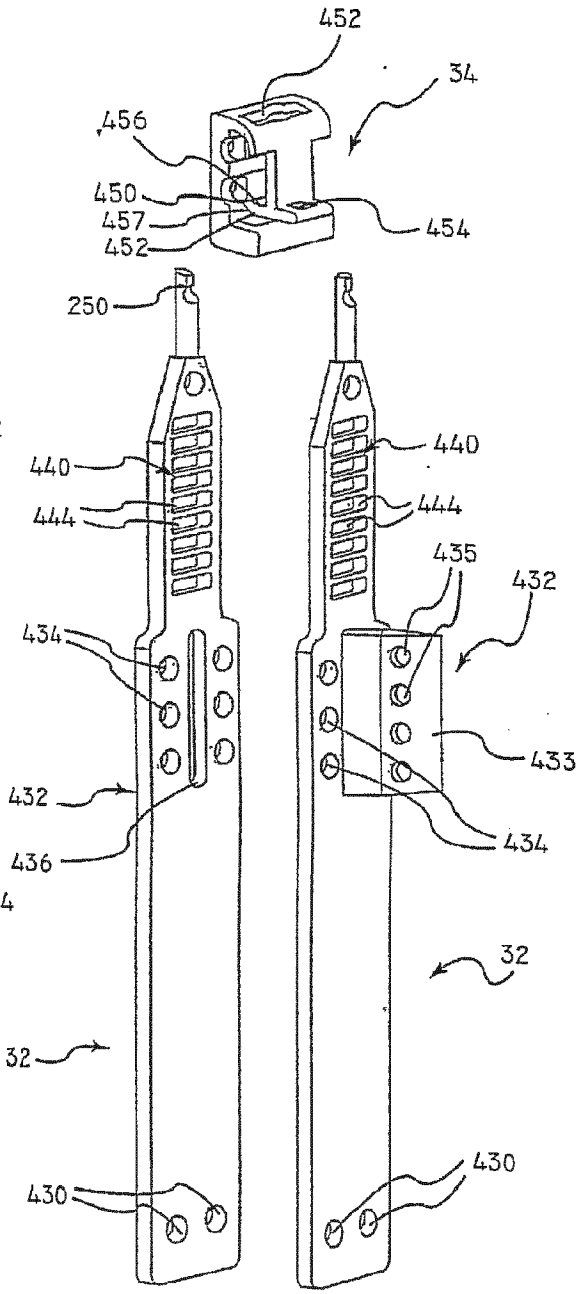


FIG. 75A




FIG. 75B



Aortic Innovations, LLC, Exhibit 2040
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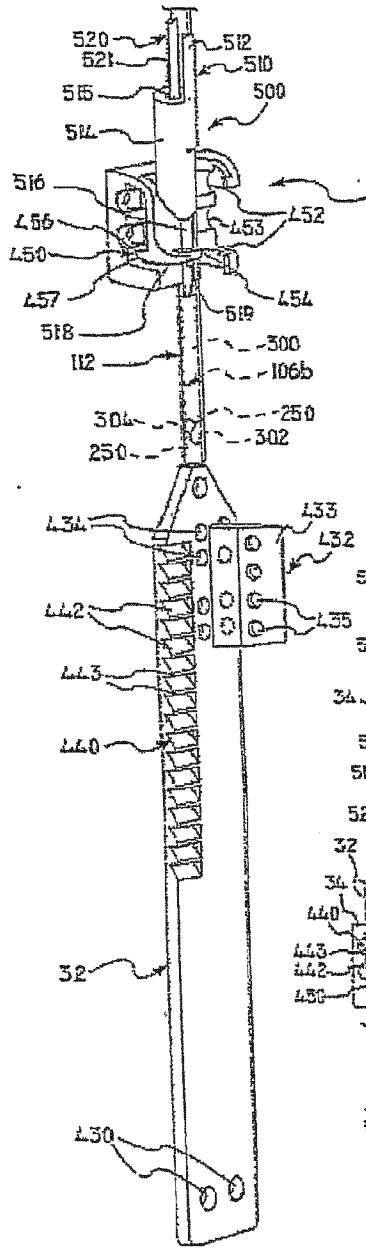


FIG. 76A

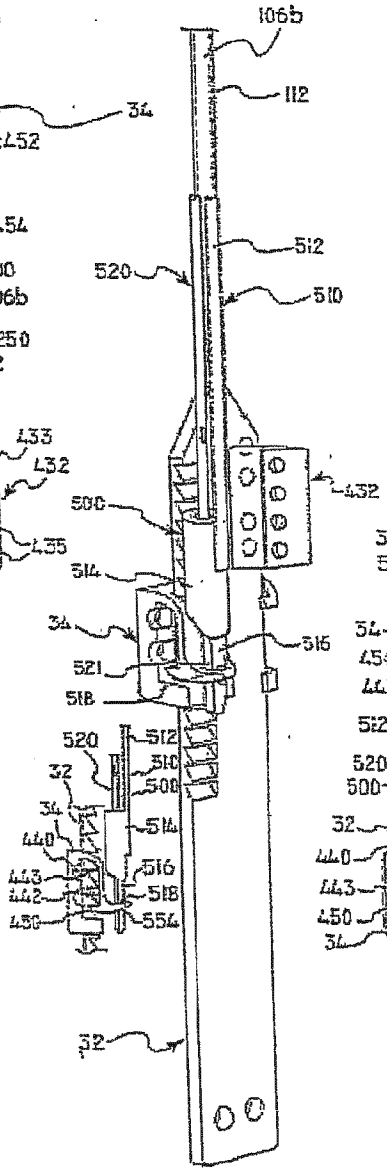


FIG. 76B

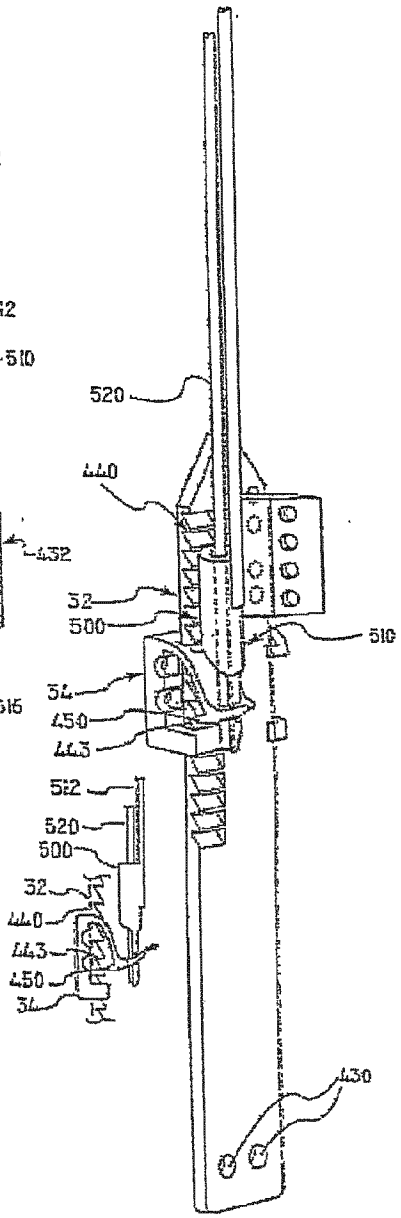


FIG. 76C



Aortic Innovations, LLC, Exhibit 2040
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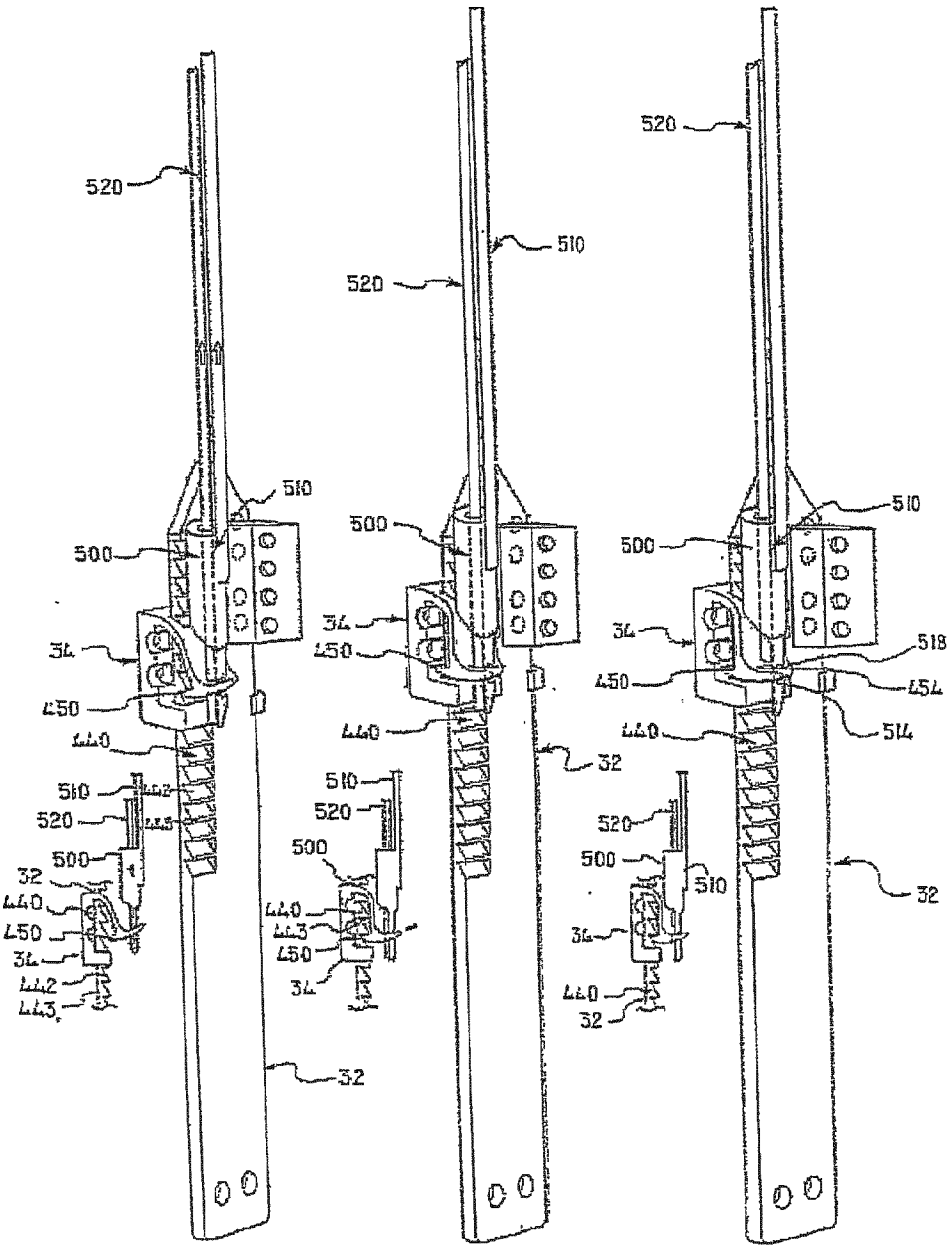


FIG. 76D FIG. 76E FIG. 76F



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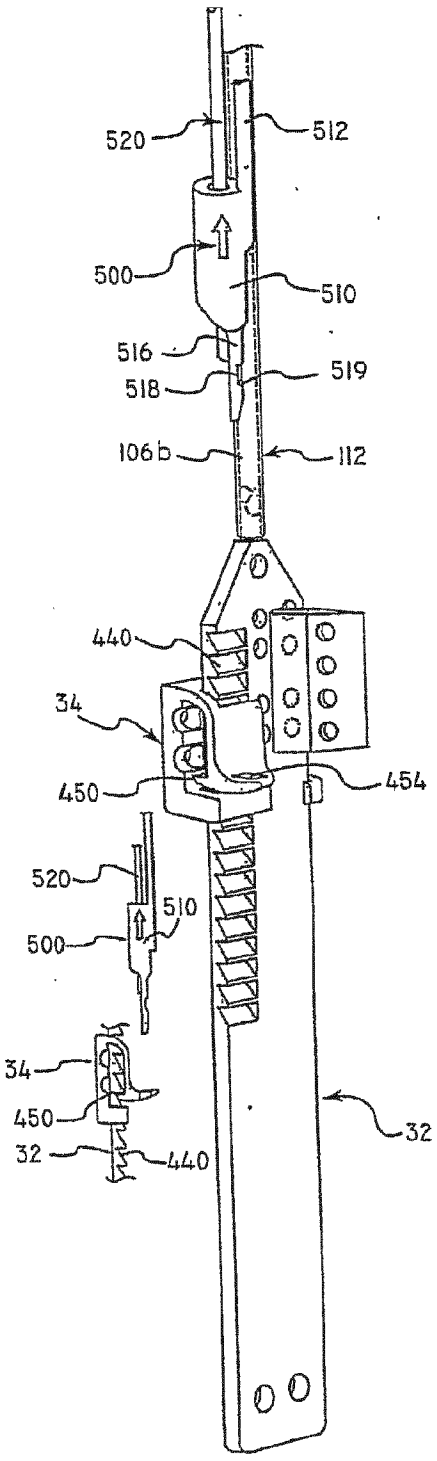


FIG. 76G

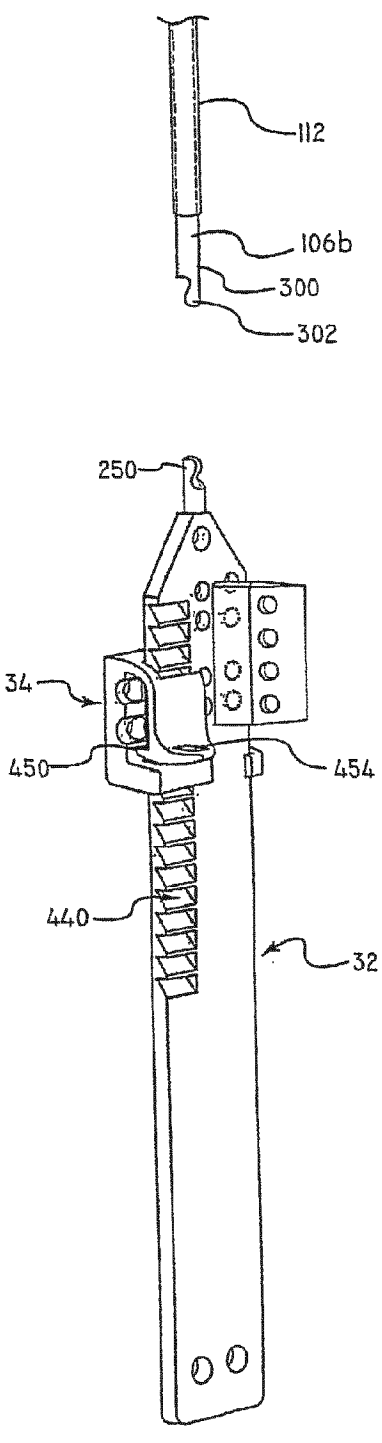


FIG. 76H



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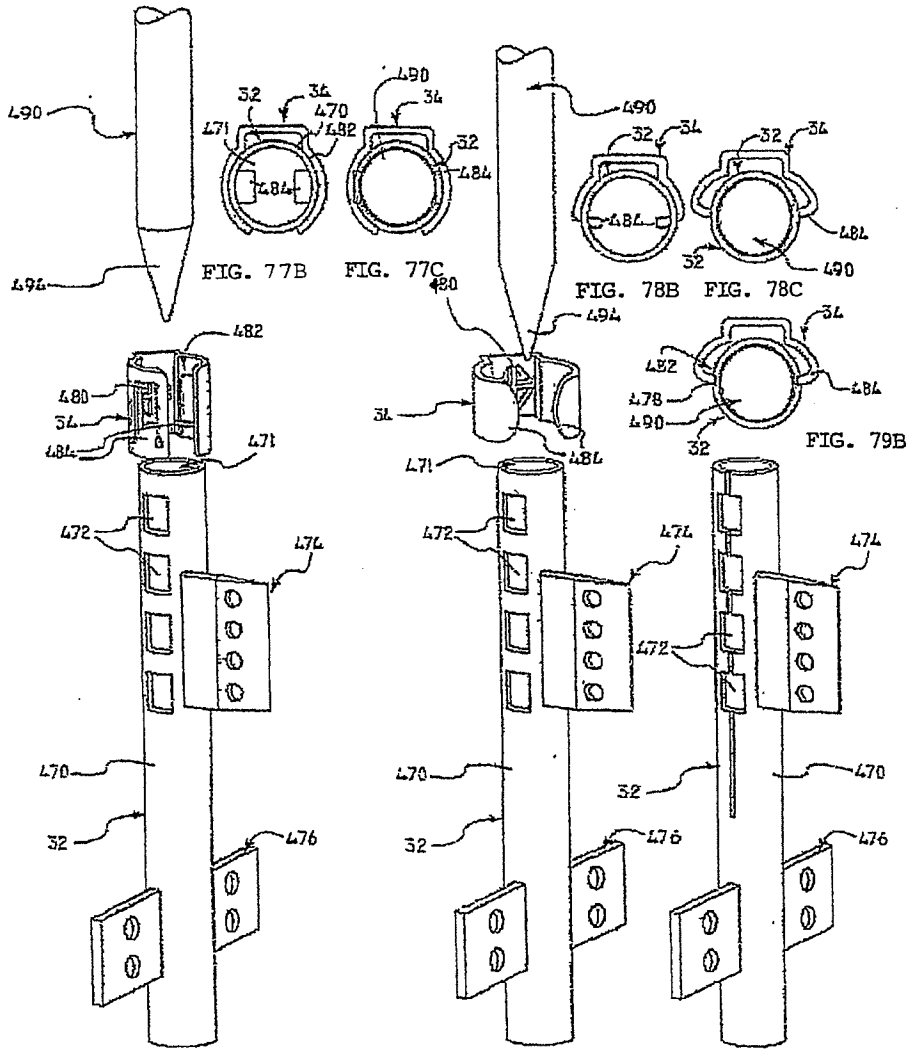




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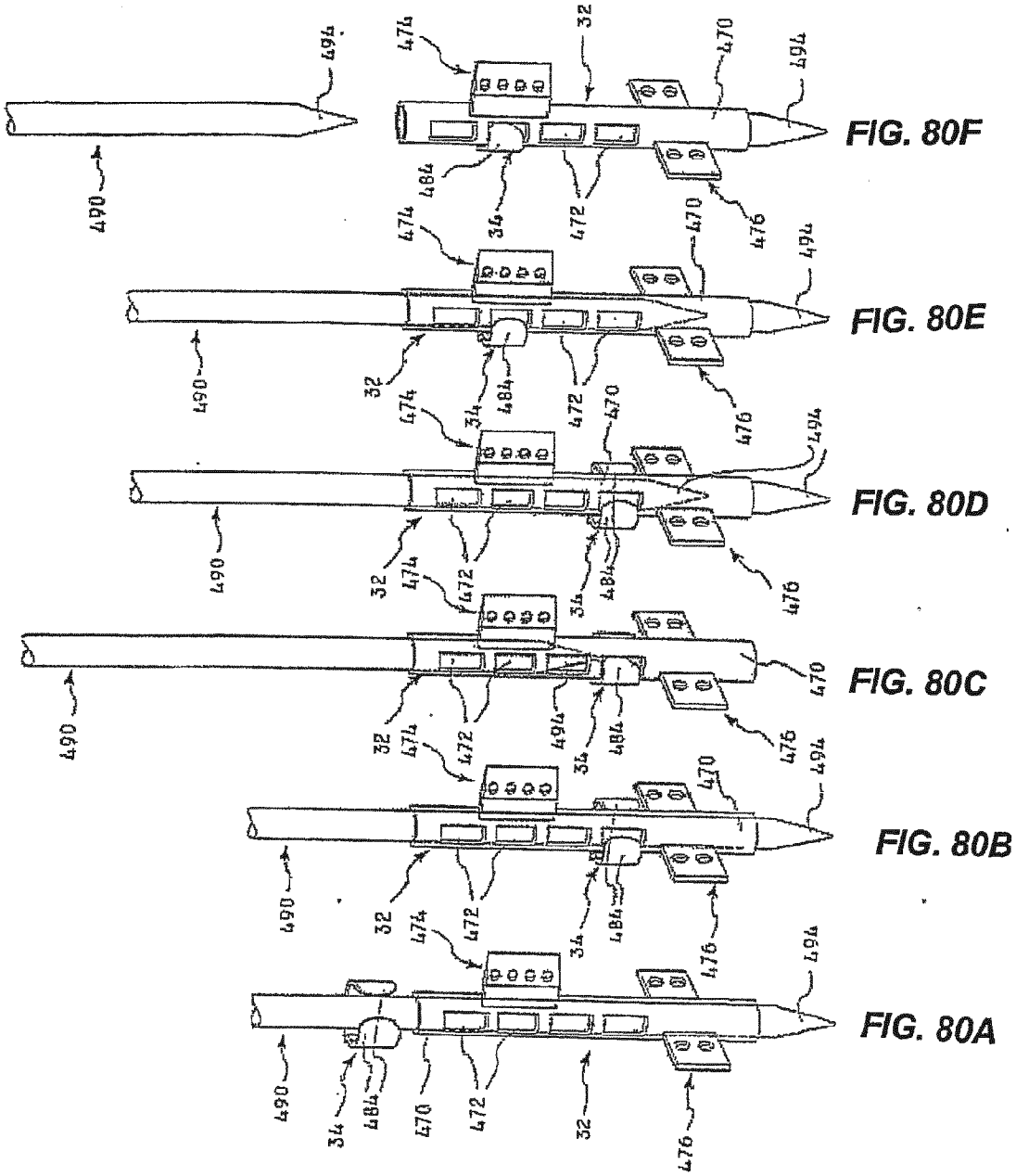




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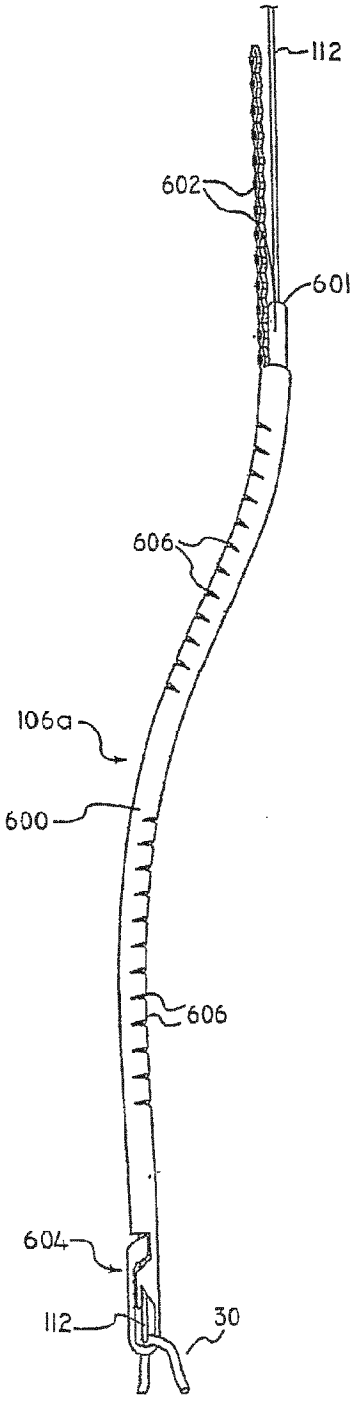


FIG. 81A

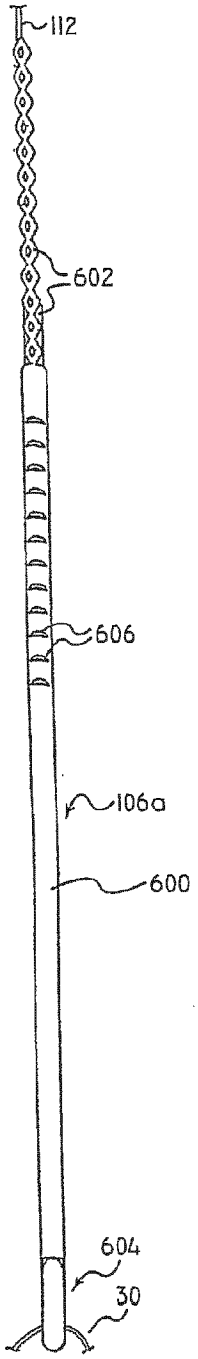


FIG. 81B



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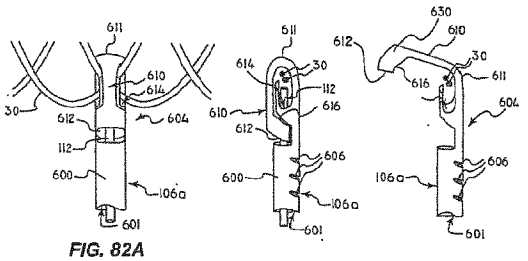


FIG. 82A FIG. 82B FIG. 82C

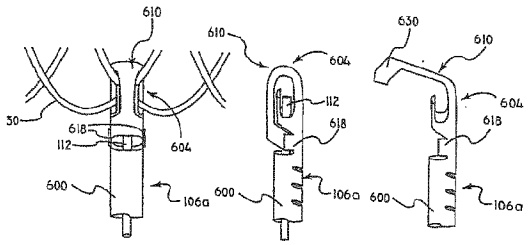


FIG. 83A FIG. 83B FIG. 83C

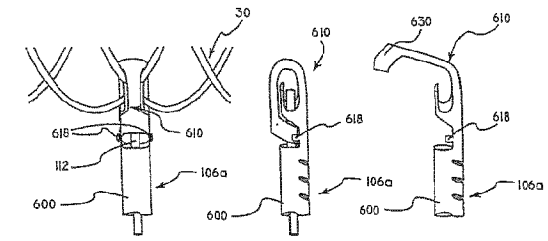


FIG. 84A FIG. 84B FIG. 84C

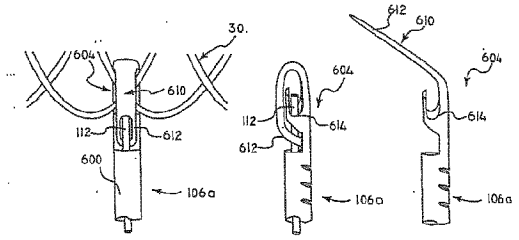


FIG. 85A FIG. 85B FIG. 85C



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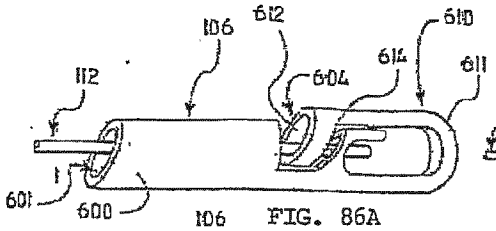


FIG. 86A

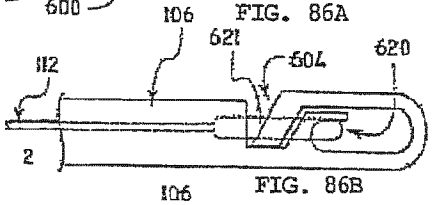


FIG. 86B

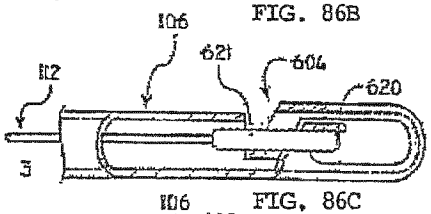


FIG. 86C

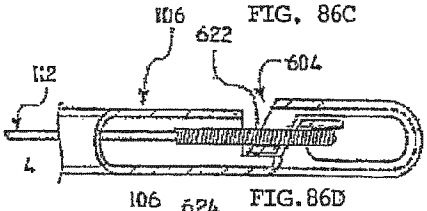


FIG. 86D

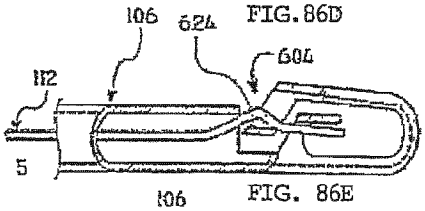


FIG. 86E

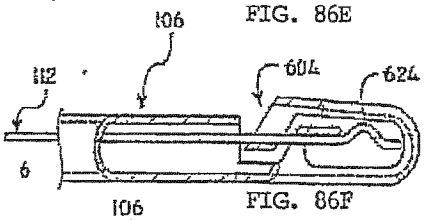


FIG. 86F

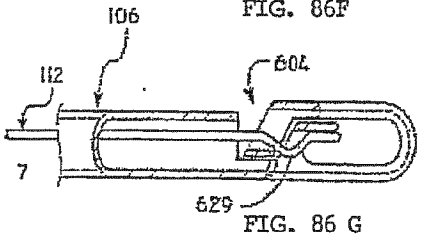


FIG. 86 G

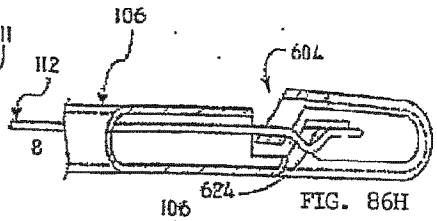


FIG. 86H

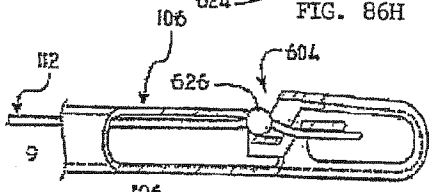


FIG. 86I

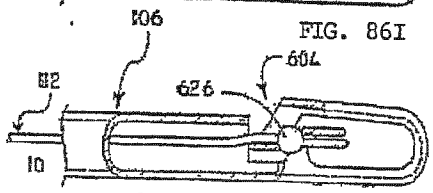


FIG. 86J

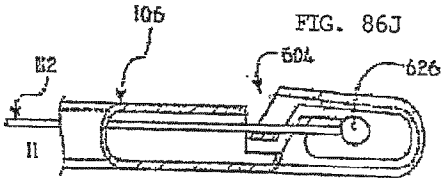


FIG. 86K

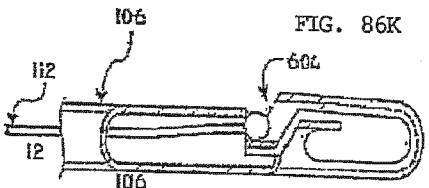


FIG. 86L

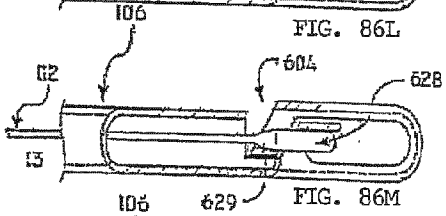


FIG. 86M

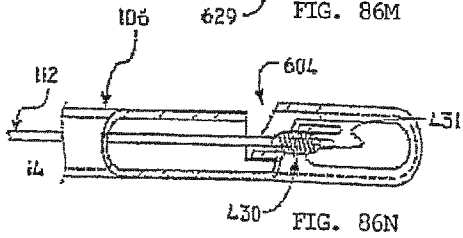


FIG. 86N



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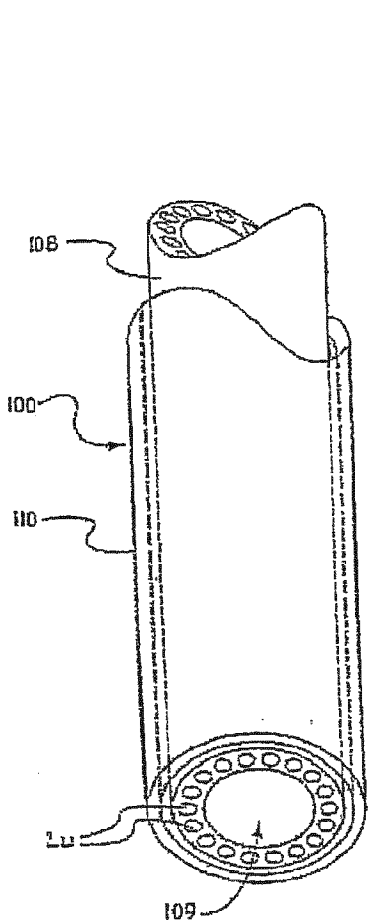


FIG. 87A

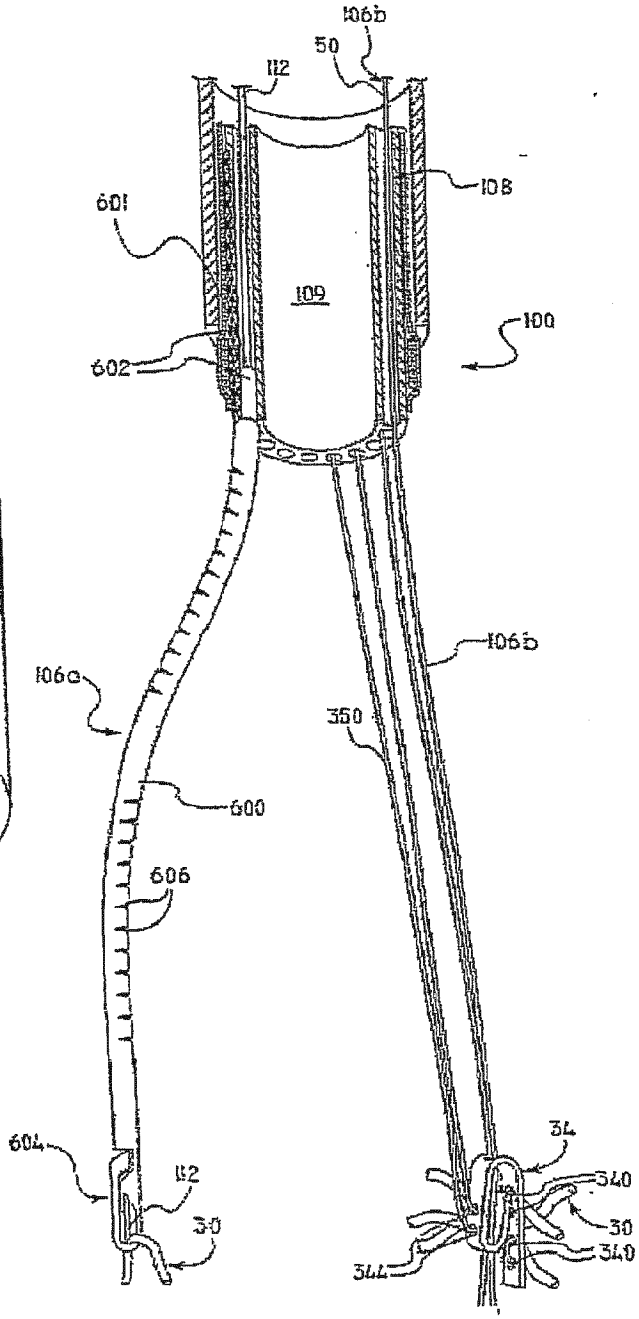


FIG. 87B



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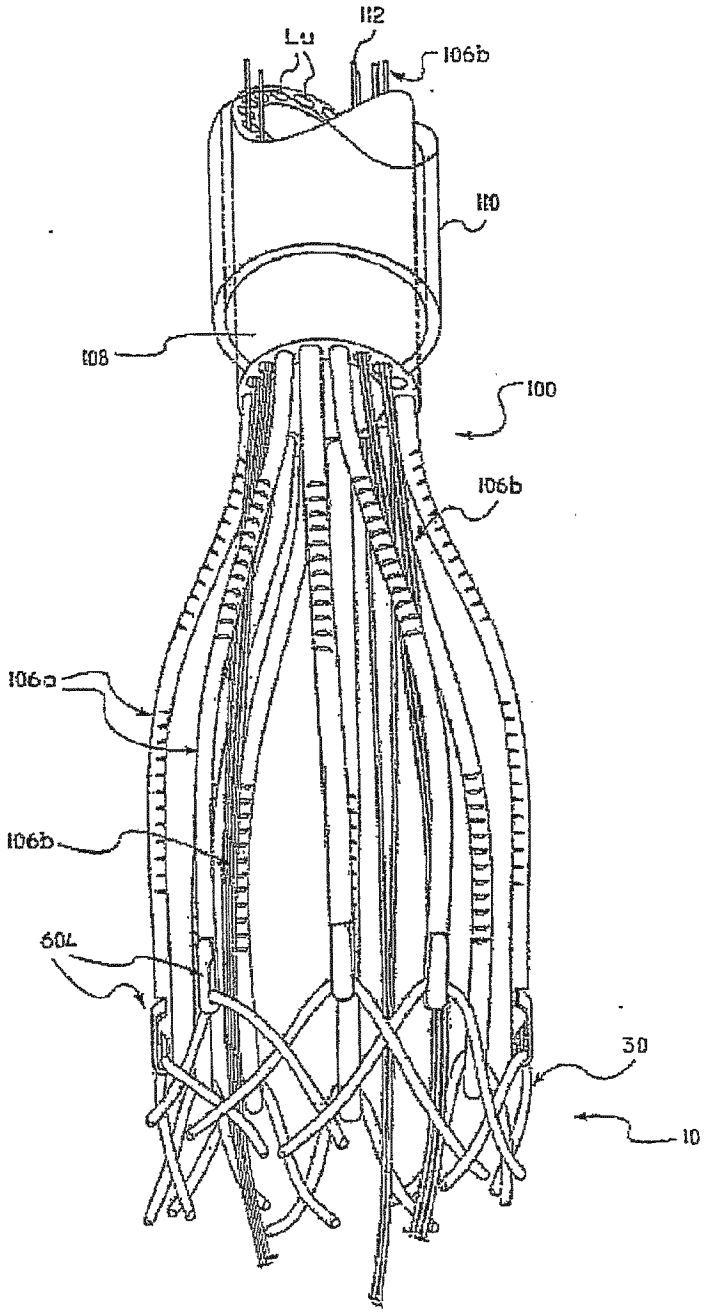


FIG. 88A



Aortic Innovations, LLC, Exhibit 2040
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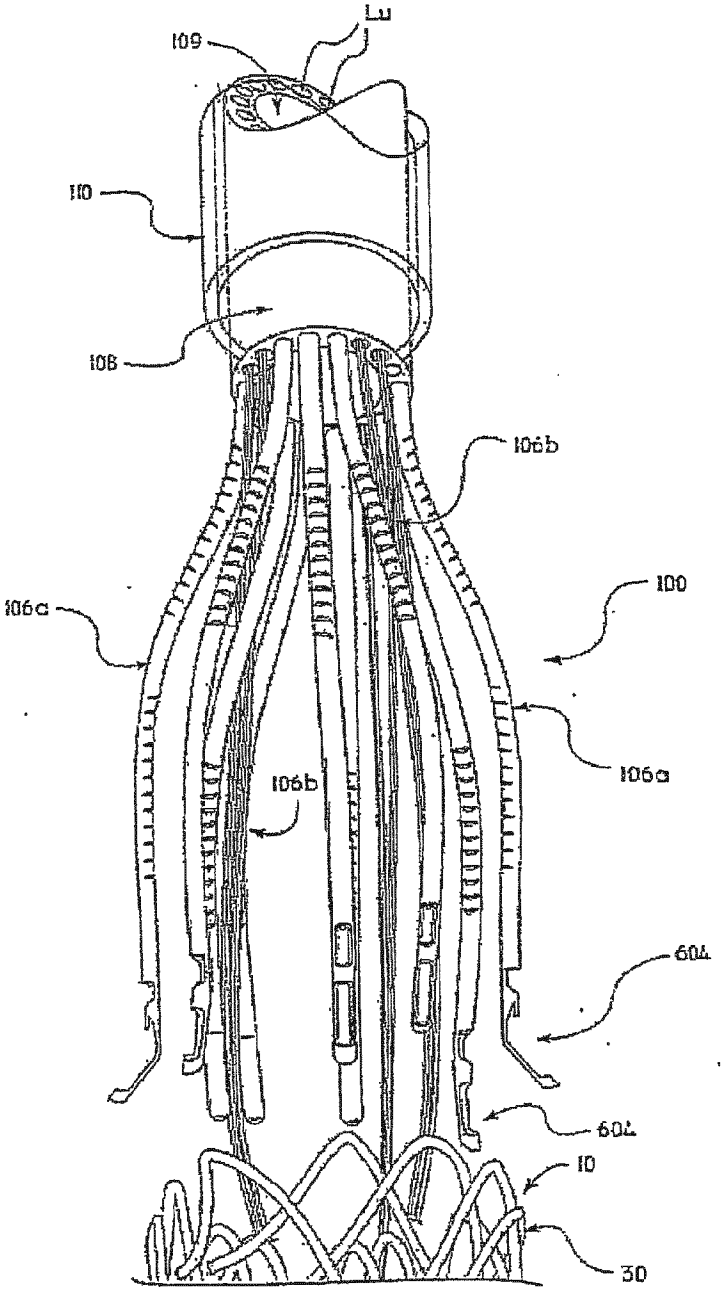


FIG. 88B



Aortic Innovations, LLC, Exhibit 2040
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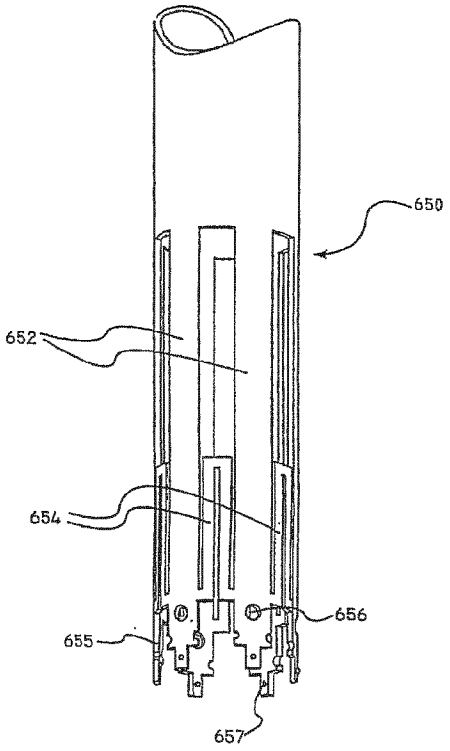


FIG. 89A

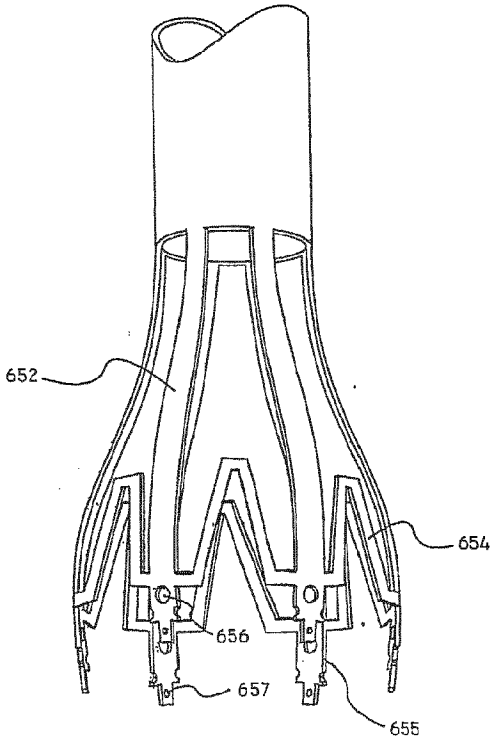


FIG. 89B



Aortic Innovations, LLC, Exhibit 2040
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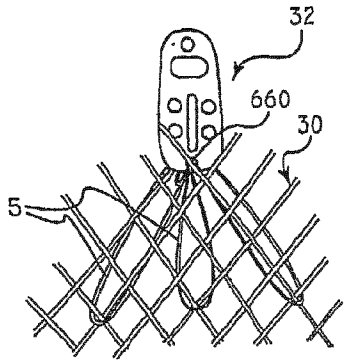


FIG. 90A

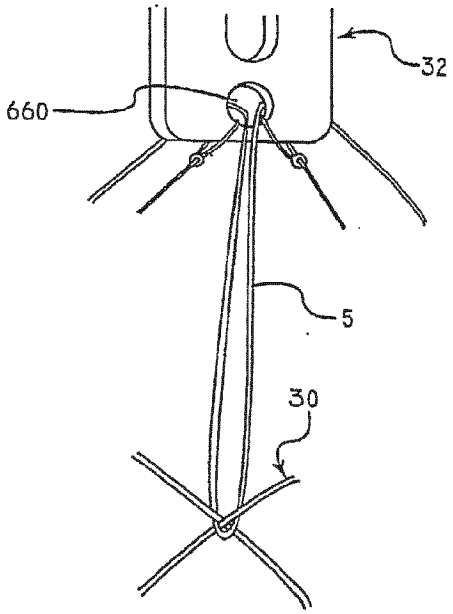


FIG. 90B

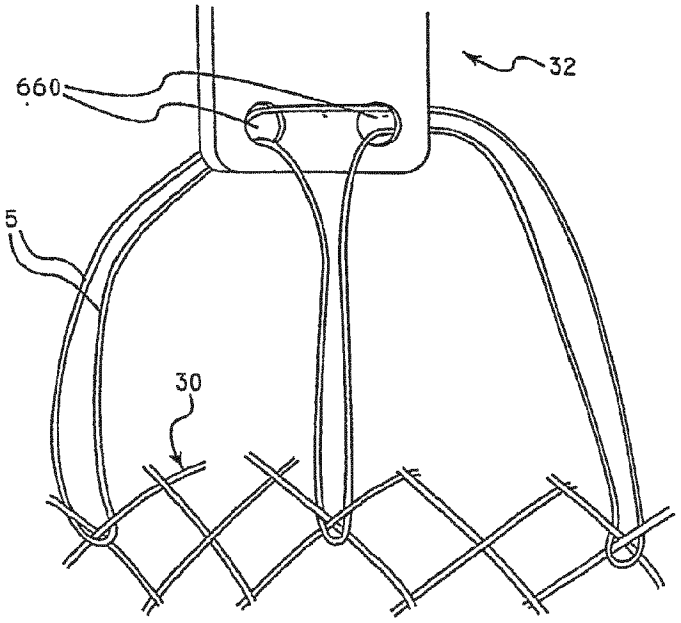


FIG. 90C



Aortic Innovations, LLC, Exhibit 2040
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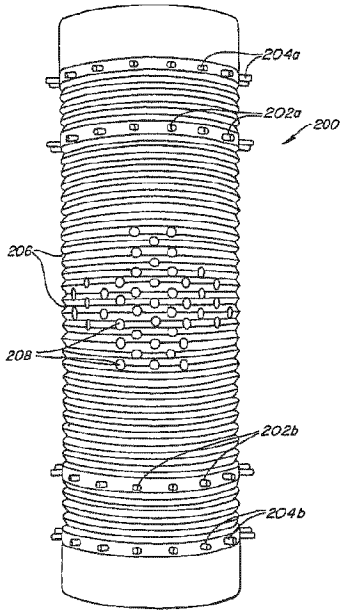


FIG. 91

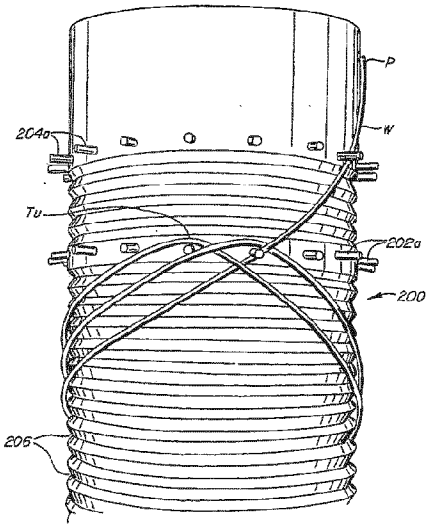


FIG. 92A

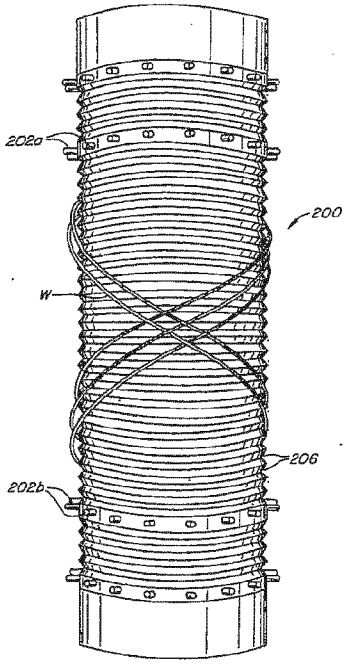


FIG. 92B

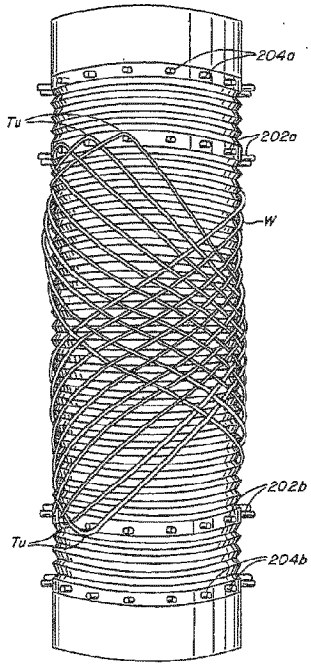


FIG. 92C

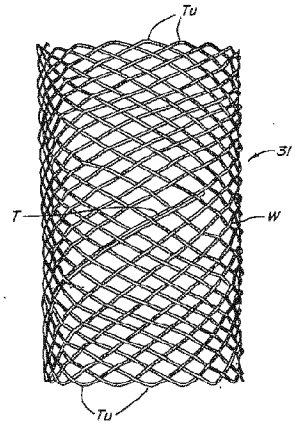


FIG. 92D



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FIG. 93A

FIG. 93D

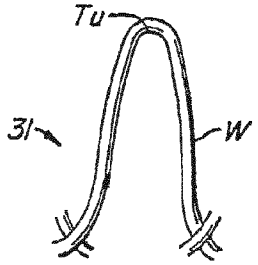


FIG. 93B

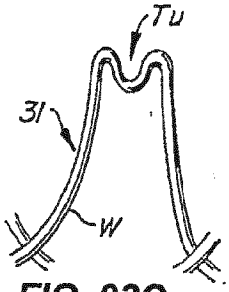


FIG. 93C

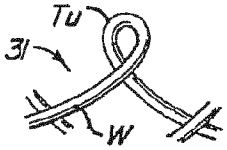


FIG. 93E

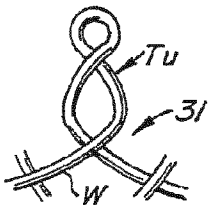


FIG. 93F

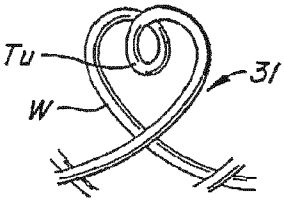


FIG. 93G

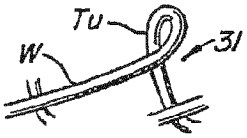


FIG. 93H

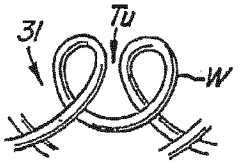


FIG. 93I

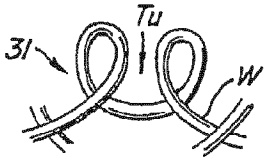


FIG. 93J

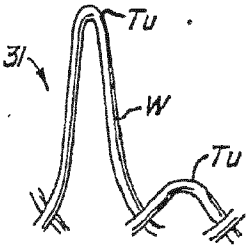


FIG. 93K

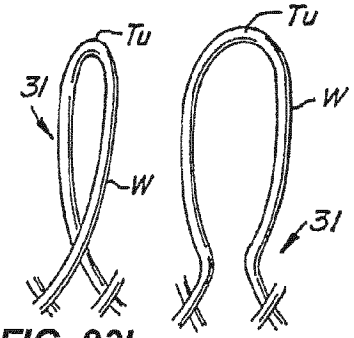


FIG. 93L FIG. 93M



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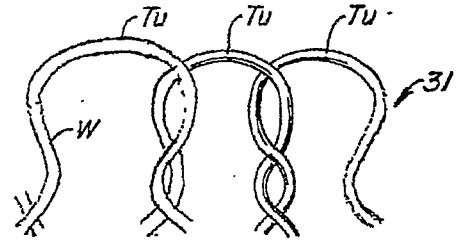


FIG. 93N

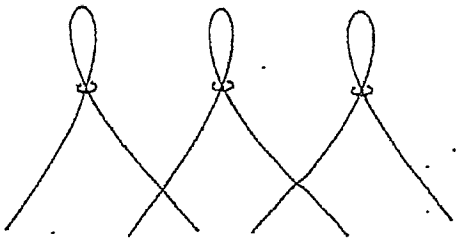

FIG. 93O

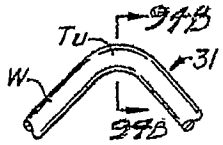


FIG. 94A

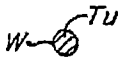


FIG. 94B

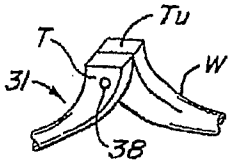


FIG. 95A

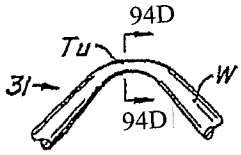


FIG. 94C

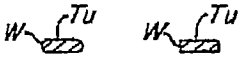


FIG. 94D FIG. 94E

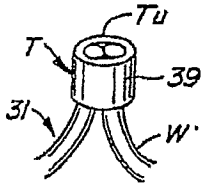


FIG. 95B

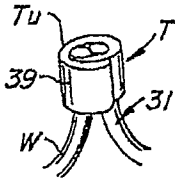


FIG. 95C

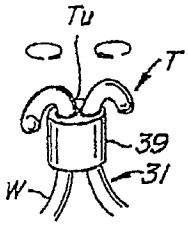


FIG. 95D

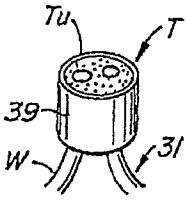


FIG. 95E

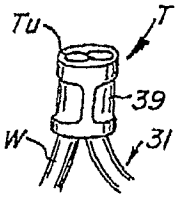


FIG. 95F



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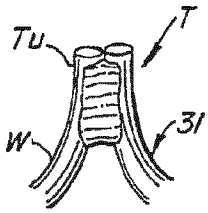


FIG. 95G

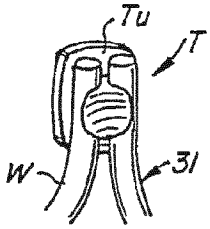


FIG. 95H

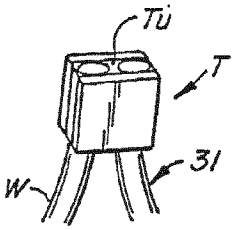


FIG. 95I

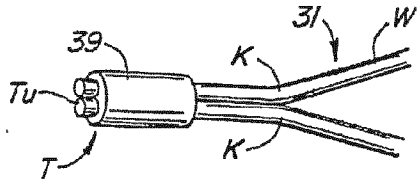


FIG. 95J

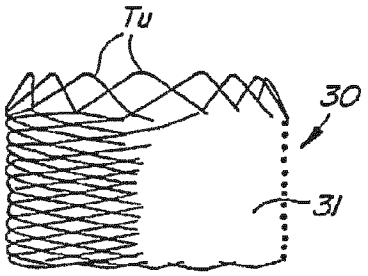


FIG. 96A

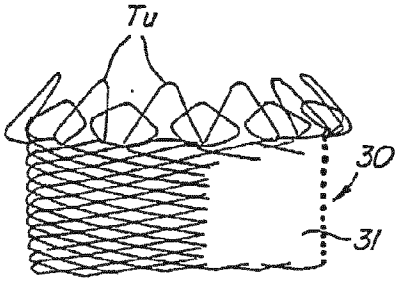


FIG. 96B

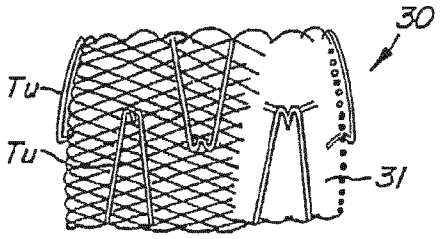


FIG. 97A

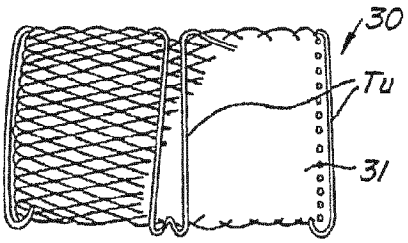


FIG. 97B



Aortic Innovations, LLC, Exhibit 2040
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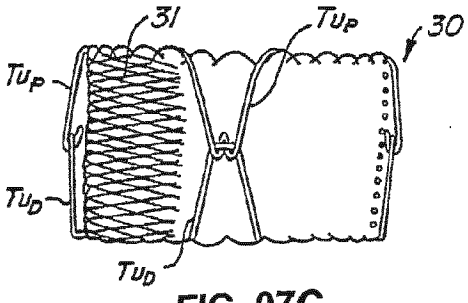


FIG. 97C

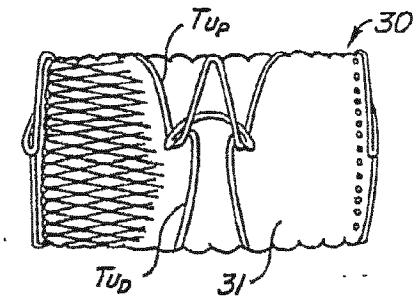


FIG. 97D

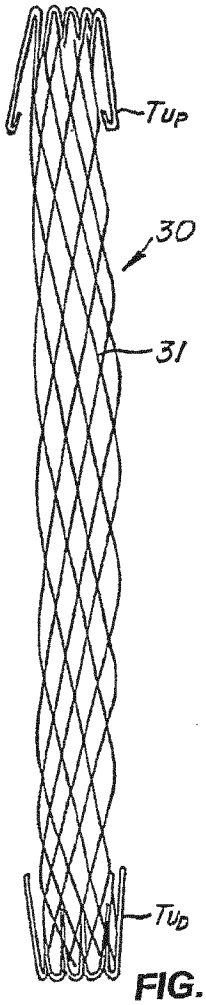


FIG. 97E

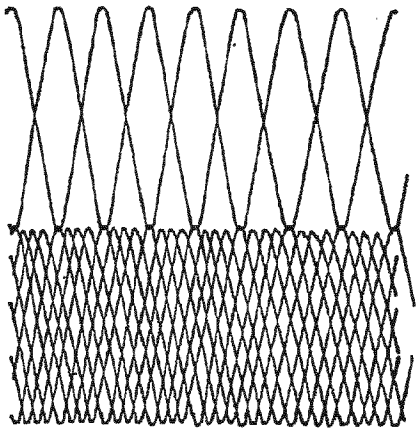

FIG. 98A



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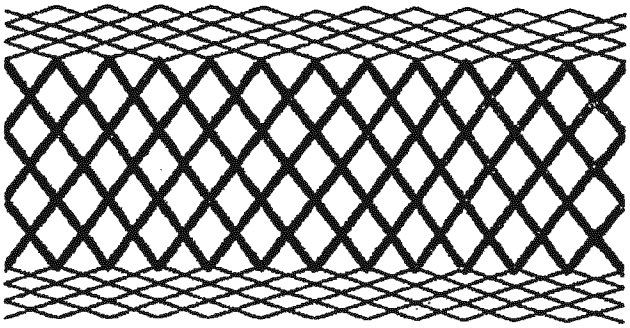

FIG. 98B

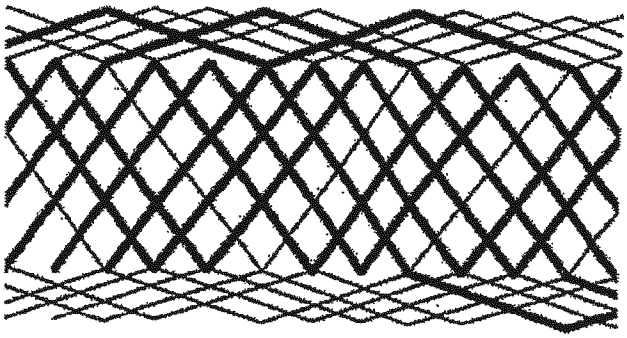

FIG. 98C

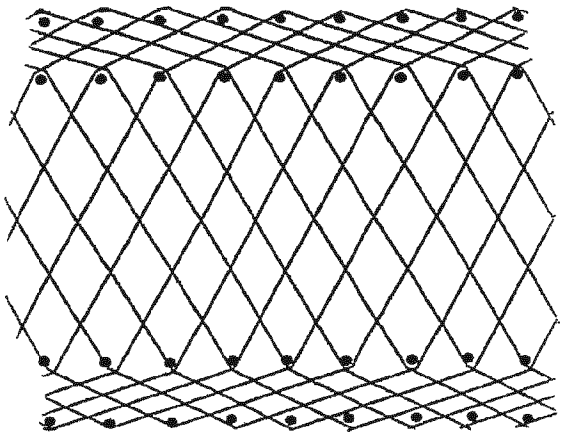

FIG. 98D



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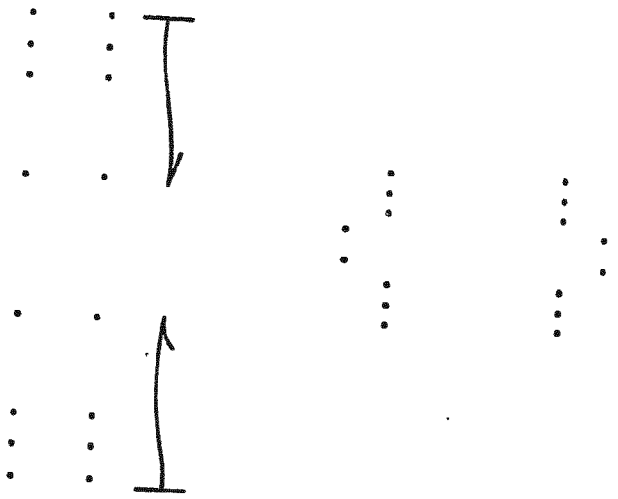

FIG. 99A

FIG. 99B

FIG. 99C

FIG. 99D

FIG. 99E



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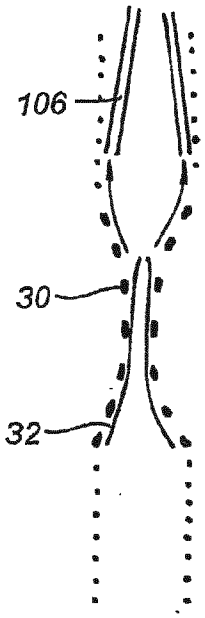


FIG. 100A

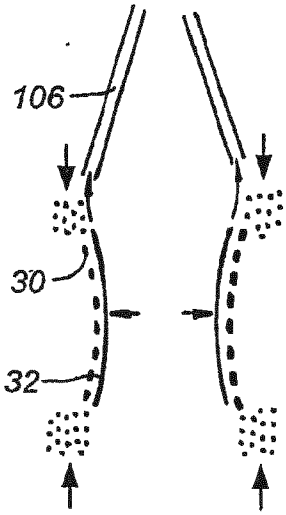


FIG. 100B

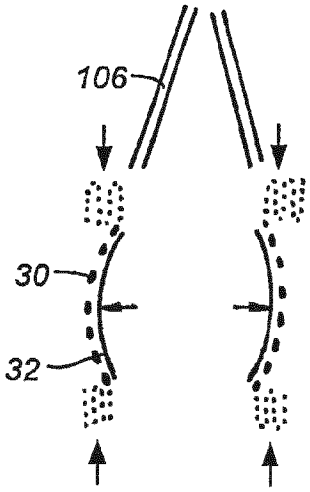


FIG. 100C

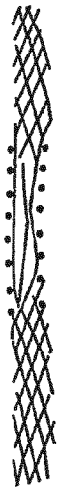

FIG. 100D

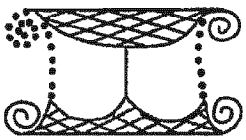

FIG. 100E



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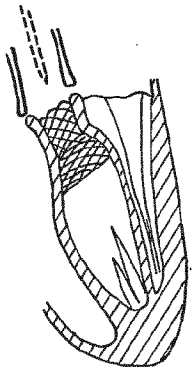

FIG. 101A

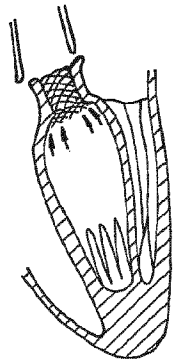

FIG. 101B

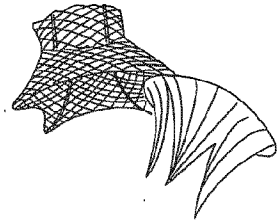

FIG. 102A

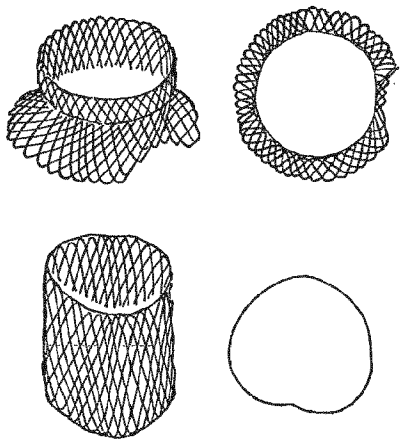

FIG. 102B

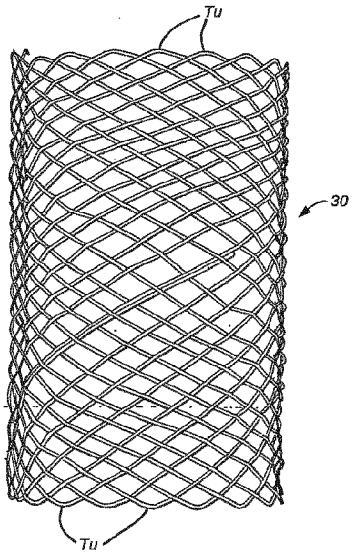


FIG. 103



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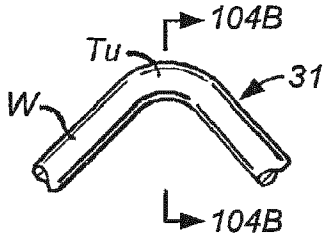


FIG. 104A

FIG. 104B

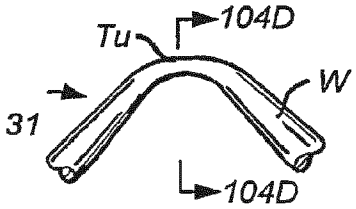


FIG. 104C

FIG. 104D

FIG. 104E



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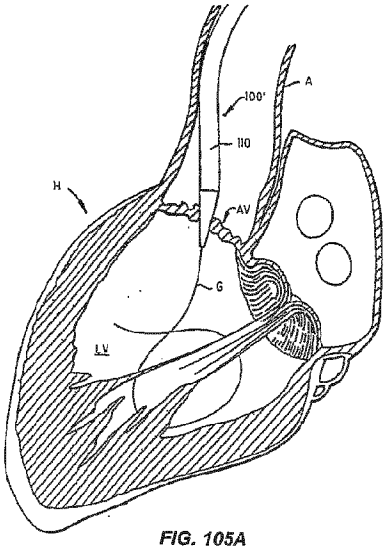


FIG. 105A

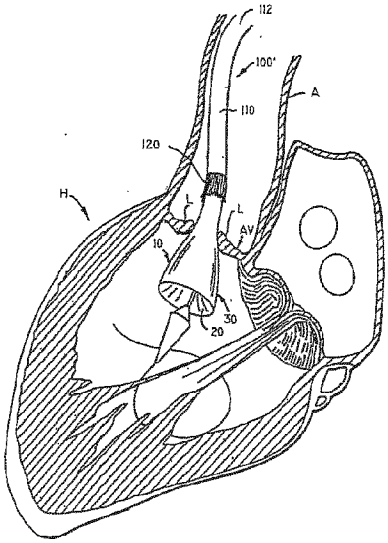


FIG. 105B

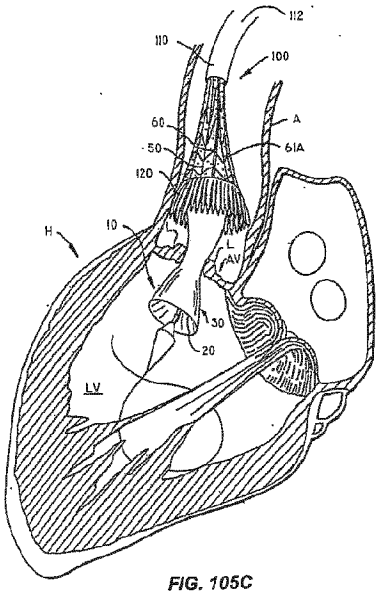


FIG. 105C

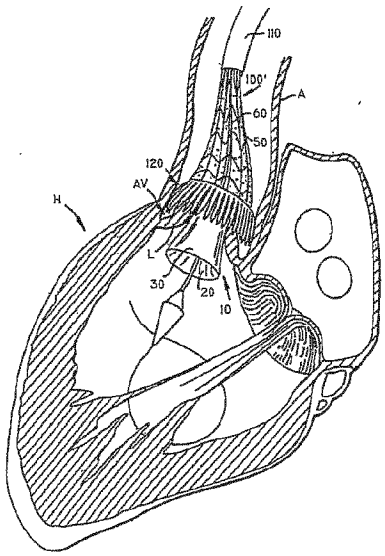


FIG. 105D



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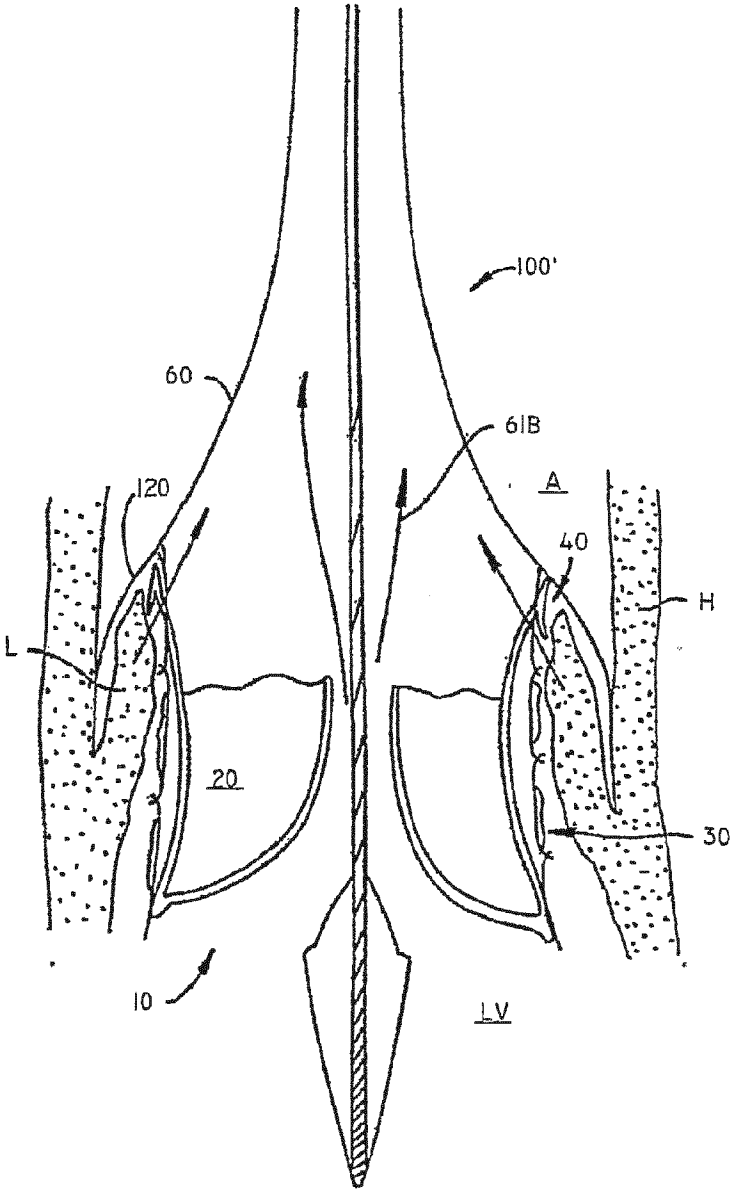


*FIG. 105E*



Aortic Innovations, LLC, Exhibit 2040
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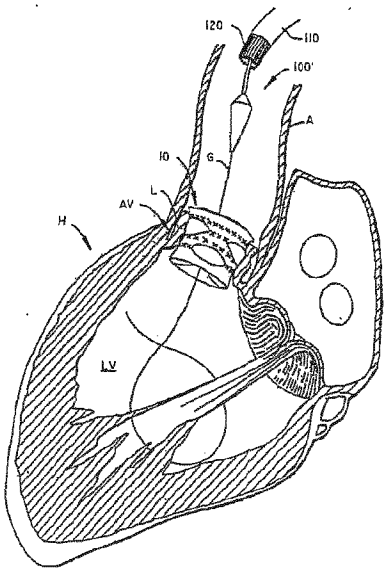


FIG. 105F

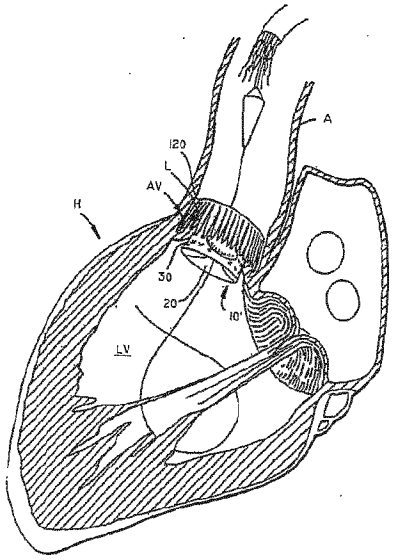


FIG. 106

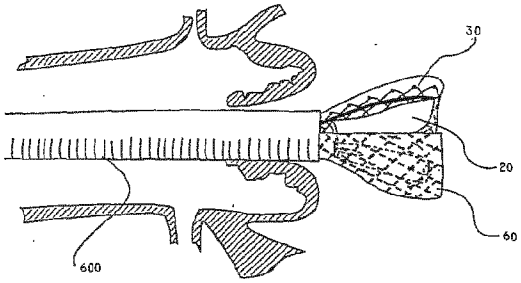


FIG. 107A

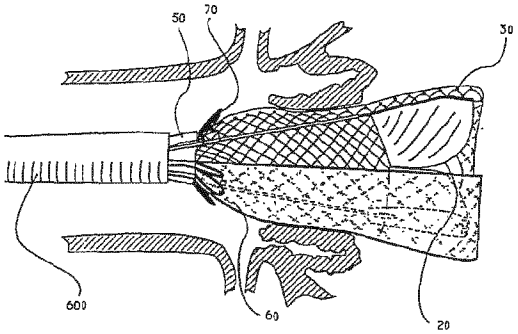


FIG. 107B

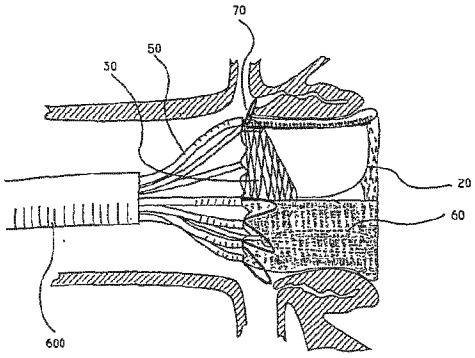


FIG. 107C



Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1417
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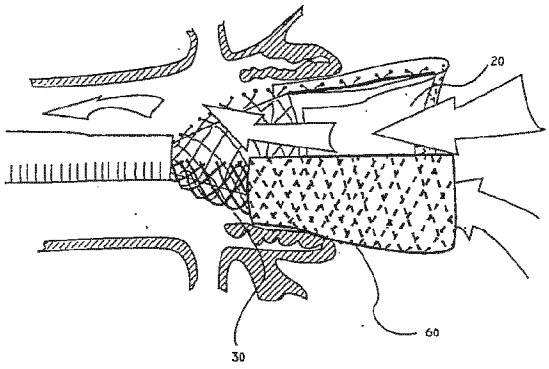


FIG. 108A

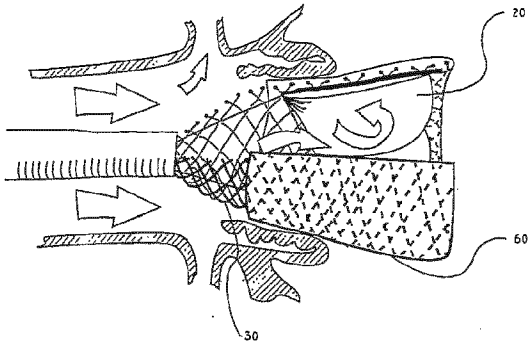


FIG. 108B

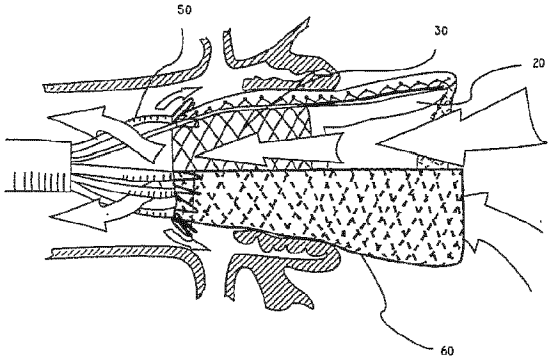


FIG. 109A

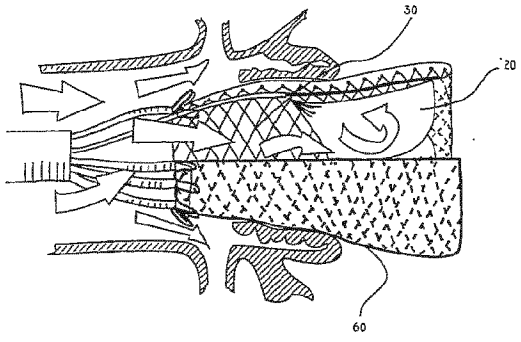


FIG. 109B



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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Europäisches Patentamt
European Patent Office
Office européen des brevets

# EUROPEAN SEARCH REPORT

Application Number
EP 12 17 9330

## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (IPC) |
|---|---|---|---|
| A | US 2002/123802 A1 (SNYDERS ROBERT V [US]) 5 September 2002 (2002-09-05) * paragraphs [0056] - [0064]; figures 8,9,16-18 * | 1-15 | INV. A61F2/01 A61F2/24 |
| A | US 5 957 949 A (LEONHARDT HOWARD J [US] ET AL) 28 September 1999 (1999-09-28) * column 9, line 6 - line 24 * * figures 7A,B * | 1-15 | |
| A,D | WO 00/47139 A1 (HEARTPORT INC [US]) 17 August 2000 (2000-08-17) * page 7, line 18 - line 25 * * figures 9,10 * | 1-15 | |

TECHNICAL FIELDS SEARCHED (IPC)

A61F

The present search report has been drawn up for all claims

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| The Hague | 29 October 2012 | Geuer, Melanie |

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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D : document cited in the application
L : document cited for other reasons

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EPO FORM 1503 03.82 (P04C01)

2



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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

## ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 12 17 9330

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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29-10-2012

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| | | US 2002151970 A1 | 17-10-2002 |
| | | WO 0047139 A1 | 17-08-2000 |

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82



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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

## REFERENCES CITED IN THE DESCRIPTION

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- US 746120 A **[0178] [0186]**
- US 746280 A **[0253] [0254] [0255]**




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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

US 20050137688A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2005/0137688 A1**

**Salahieh et al.** (43) **Pub. Date: Jun. 23, 2005**

(54) **REPOSITIONABLE HEART VALVE AND METHOD**

(75) Inventors: **Amr Salahieh**, Saratoga, CA (US); **Brian D. Brandt**, Santa Clara, CA (US); **Dwight P. Morejohn**, Davis, CA (US); **Ulrich R. Haug**, Campbell, CA (US); **Jean-Pierre Dueri**, Stockton, CA (US); **Hans F. Valencia**, Berkeley, CA (US); **Robert A. Geshlider**, San Francisco, CA (US); **Jeff Krolik**, Campbell, CA (US)

Correspondence Address:
**WILSON SONSINI GOODRICH & ROSATI**
**650 PAGE MILL ROAD**
**PALO ALTO, CA 943041050**

(73) Assignee: **Sadra Medical, a Delaware Corporation**, Saratoga, CA (US)

(21) Appl. No.: **10/746,280**

(22) Filed: **Dec. 23, 2003**

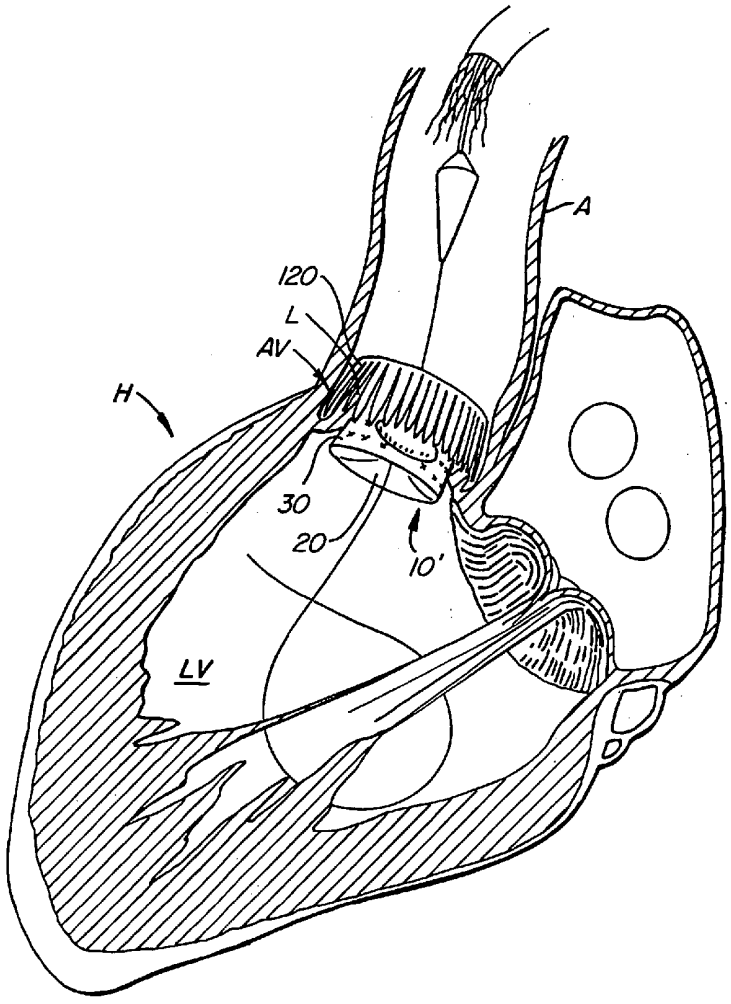
**Publication Classification**

(51) **Int. Cl.**[7] ..... **A61F 2/24**

(52) **U.S. Cl.** ..... **623/2.11**; 623/904; 623/2.18

(57) **ABSTRACT**

A method for percutaneously replacing a heart valve of a patient. In some embodiments the method includes the steps of percutaneously delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; expanding the anchor to a deployed configuration in which the anchor contacts tissue at a first anchor site; repositioning the anchor to a second anchor site; and deploying the anchor at the second anchor site.



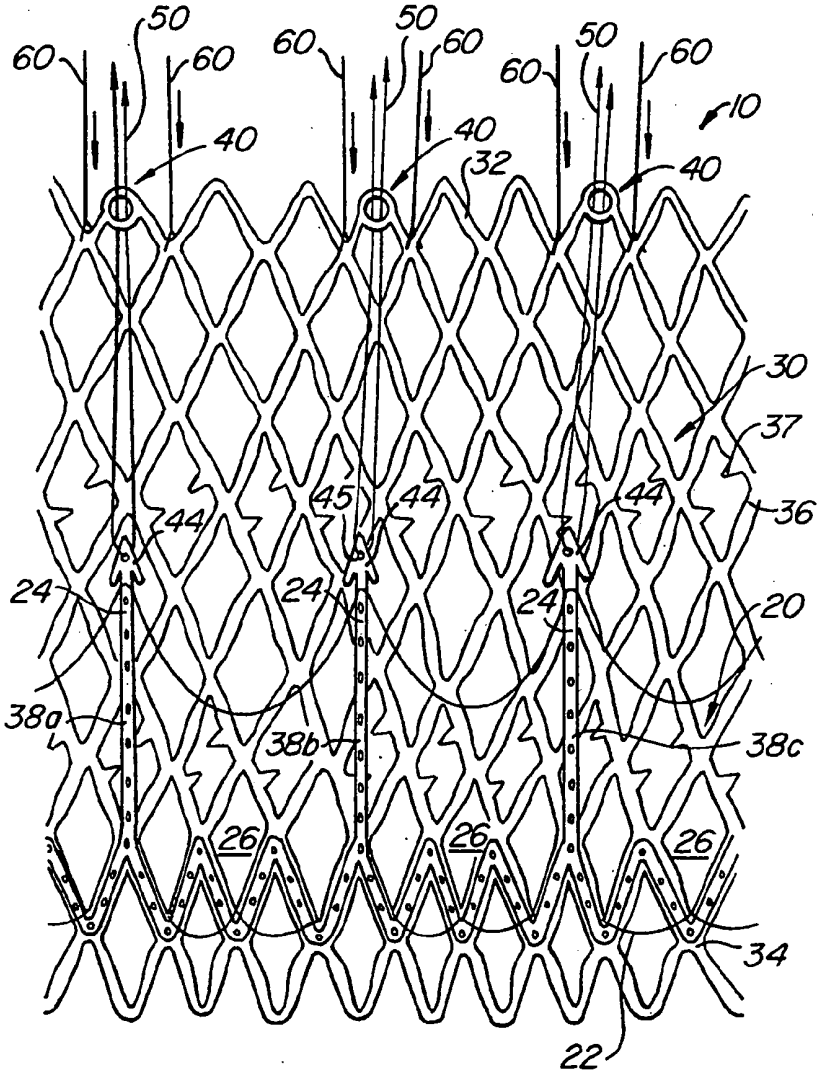

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FIG. 1A

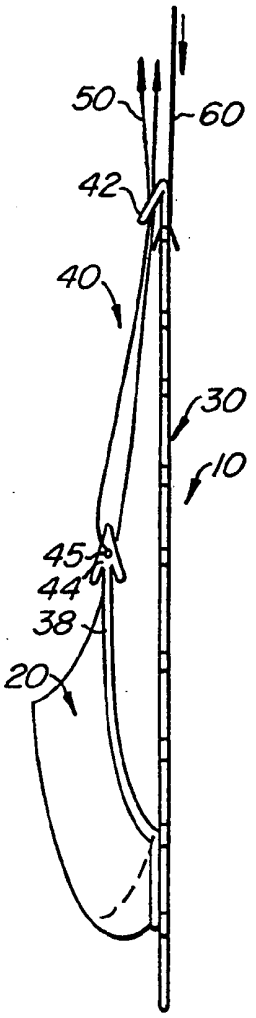
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FIG. 2A

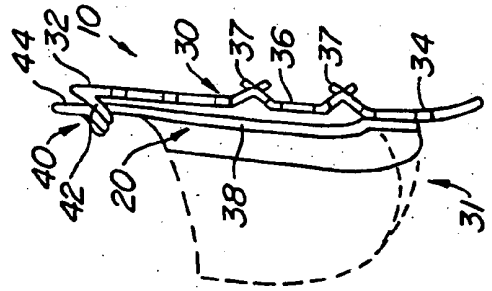
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FIG. 2B

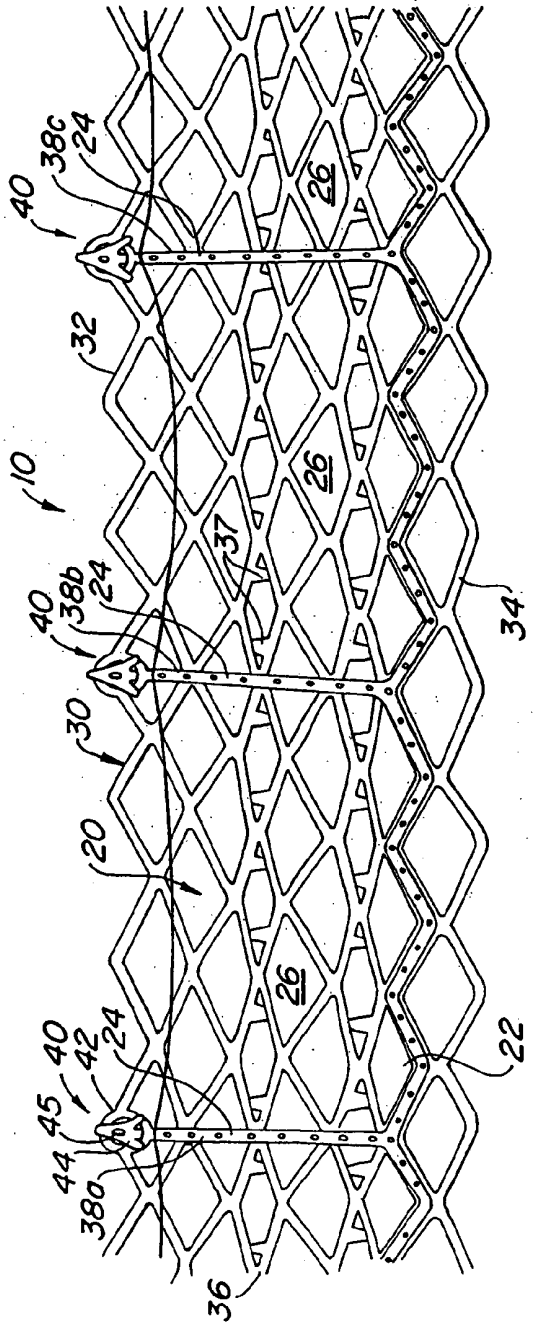
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FIG. 1B

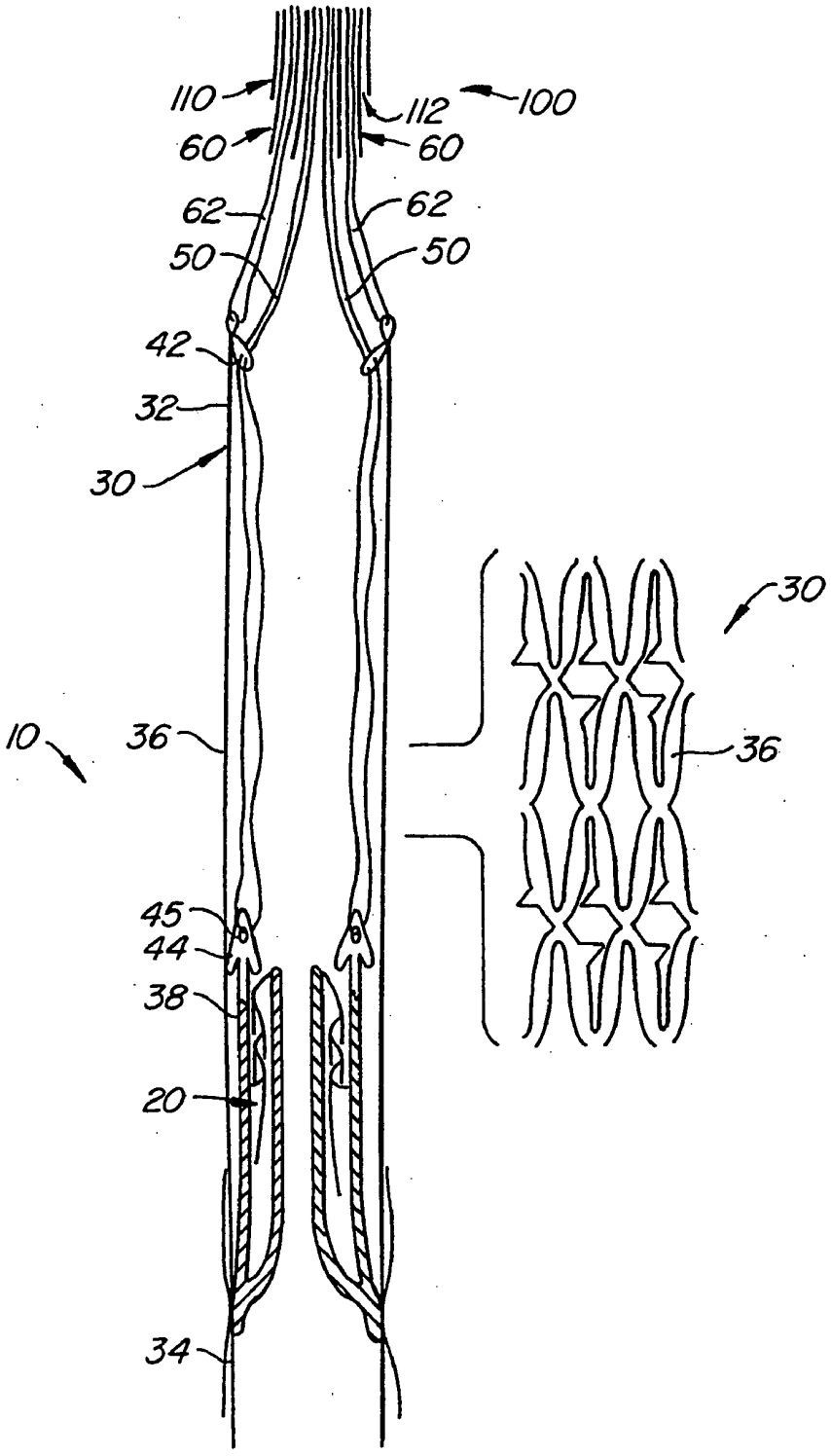


FIG. 3A

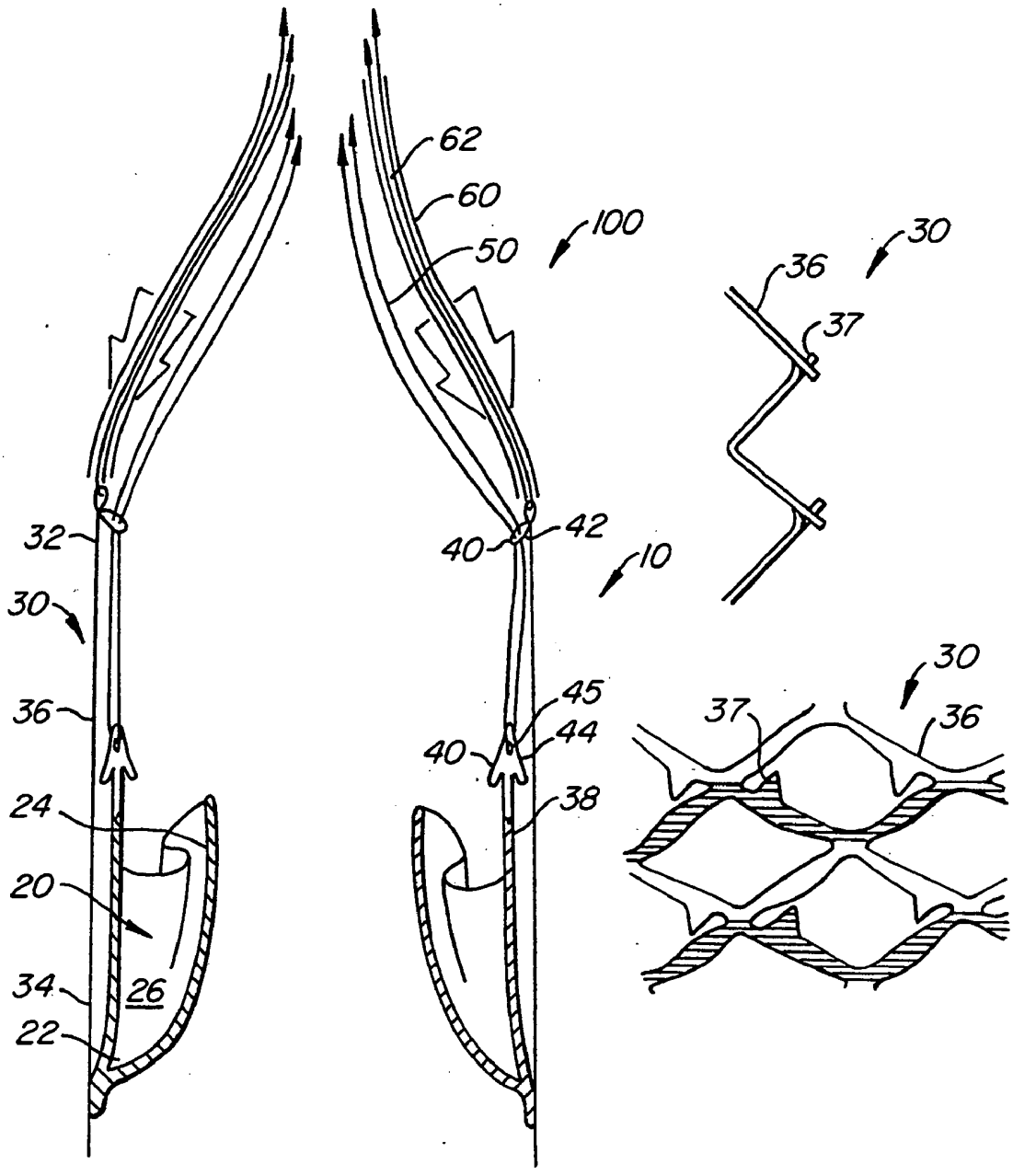
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FIG. 3B

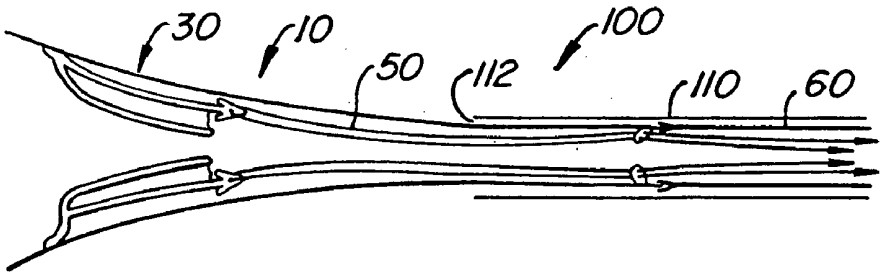



FIG. 4A

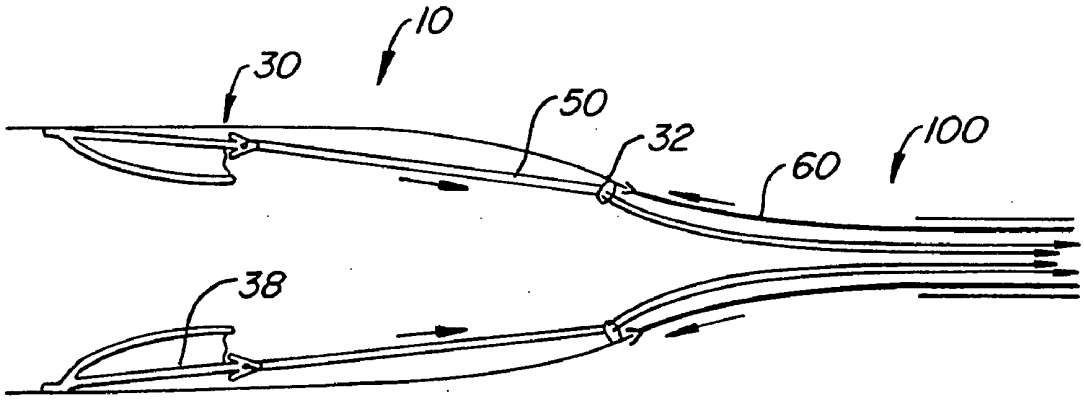



FIG. 4B

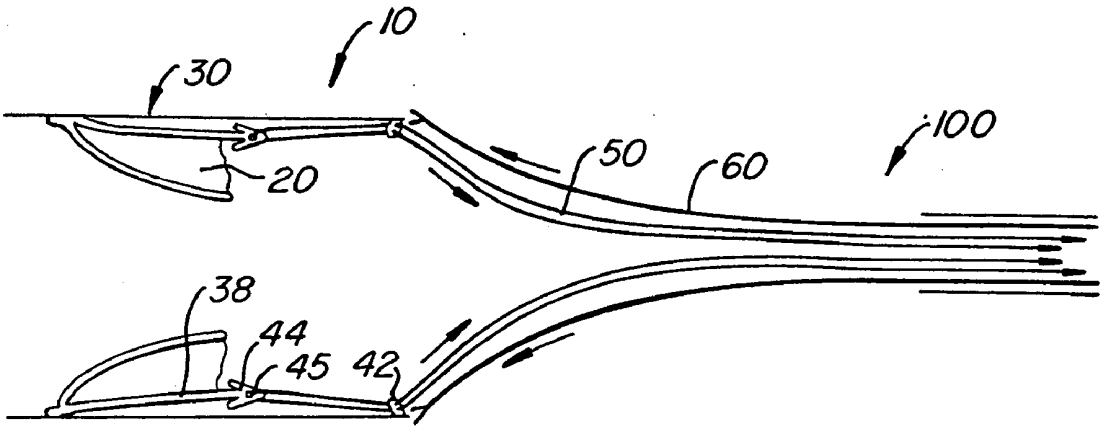



FIG. 4C

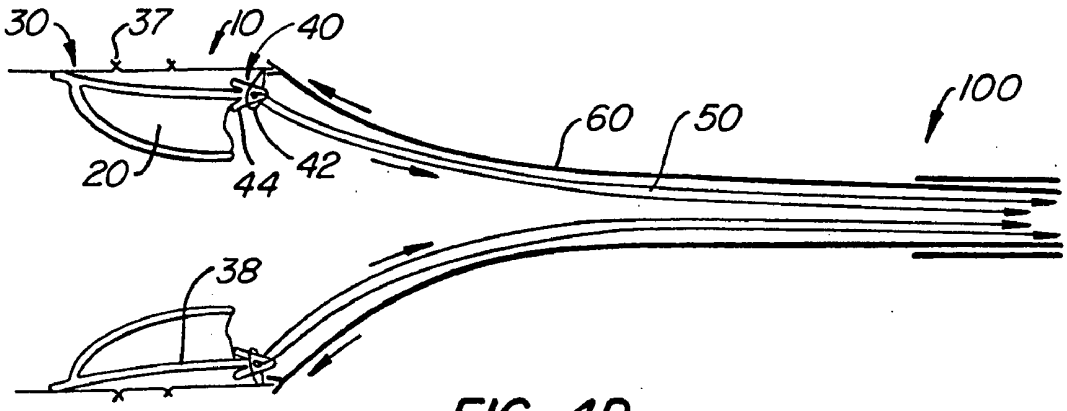



FIG. 4D

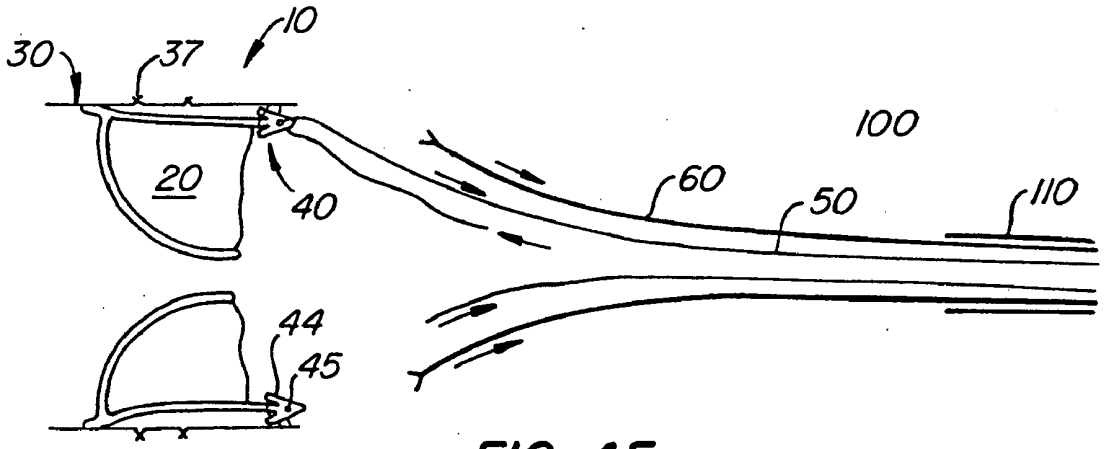



FIG. 4E

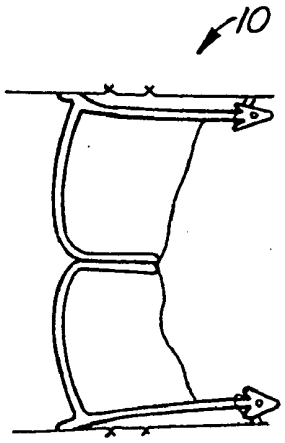



FIG. 4F

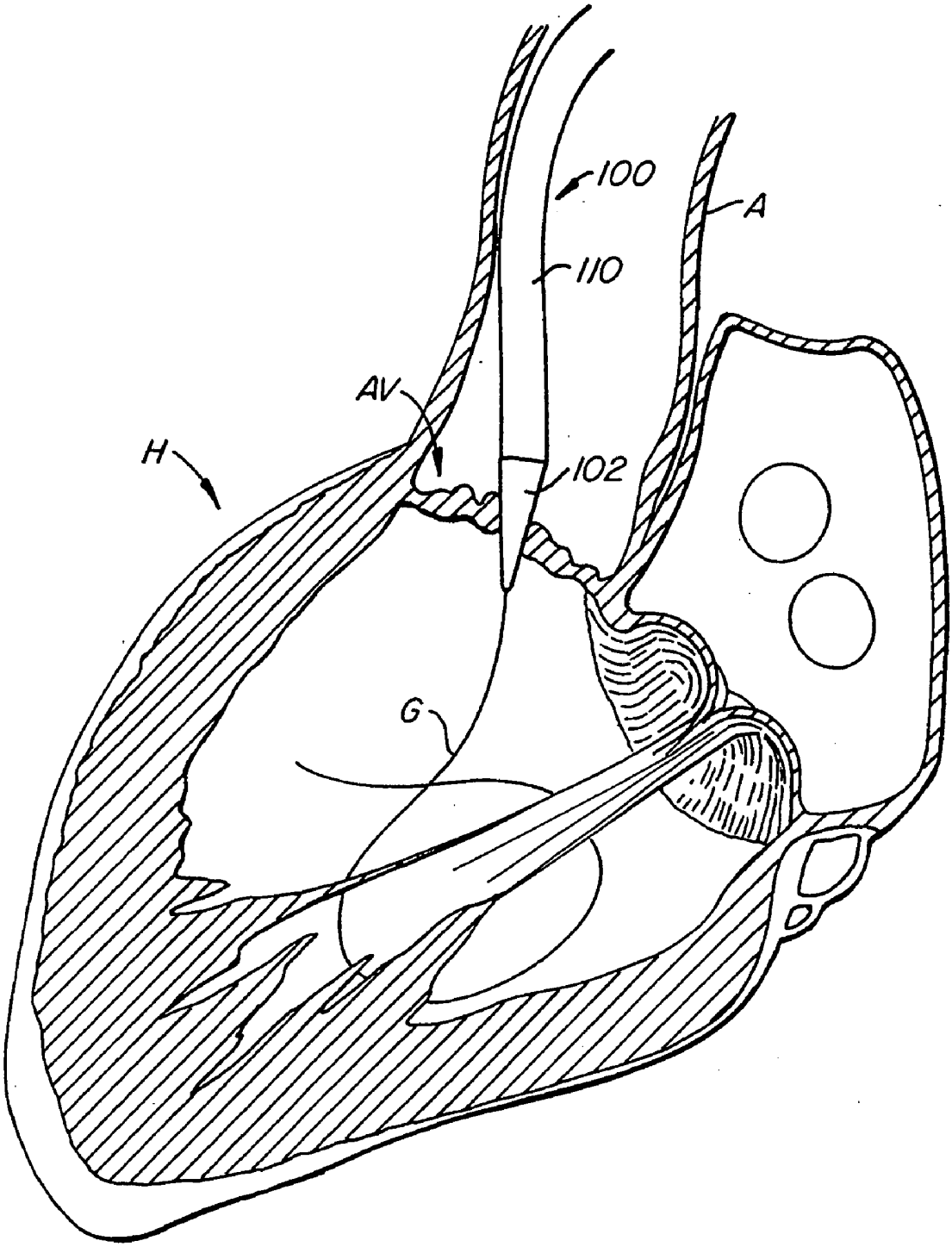



FIG. 5A

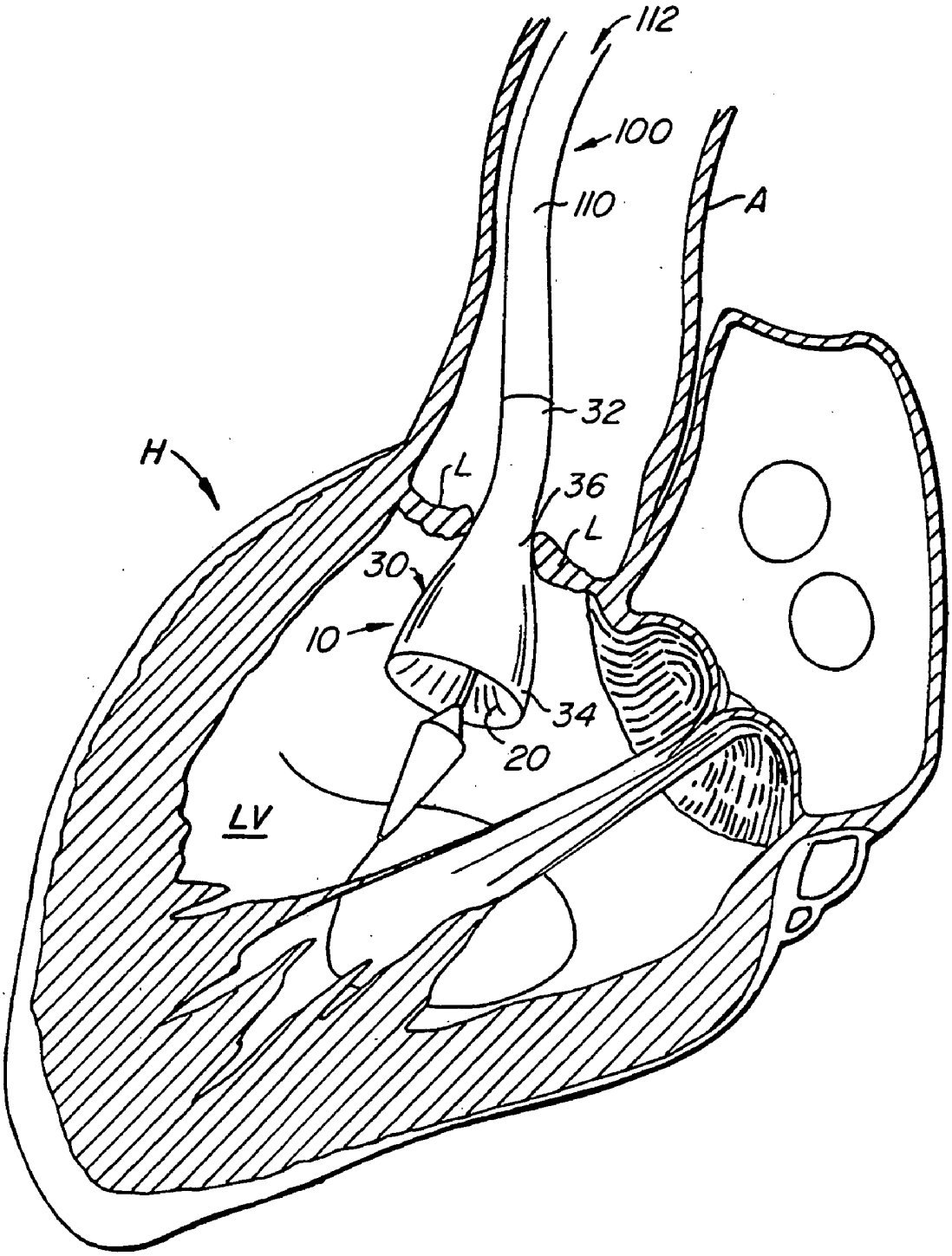



FIG. 5B

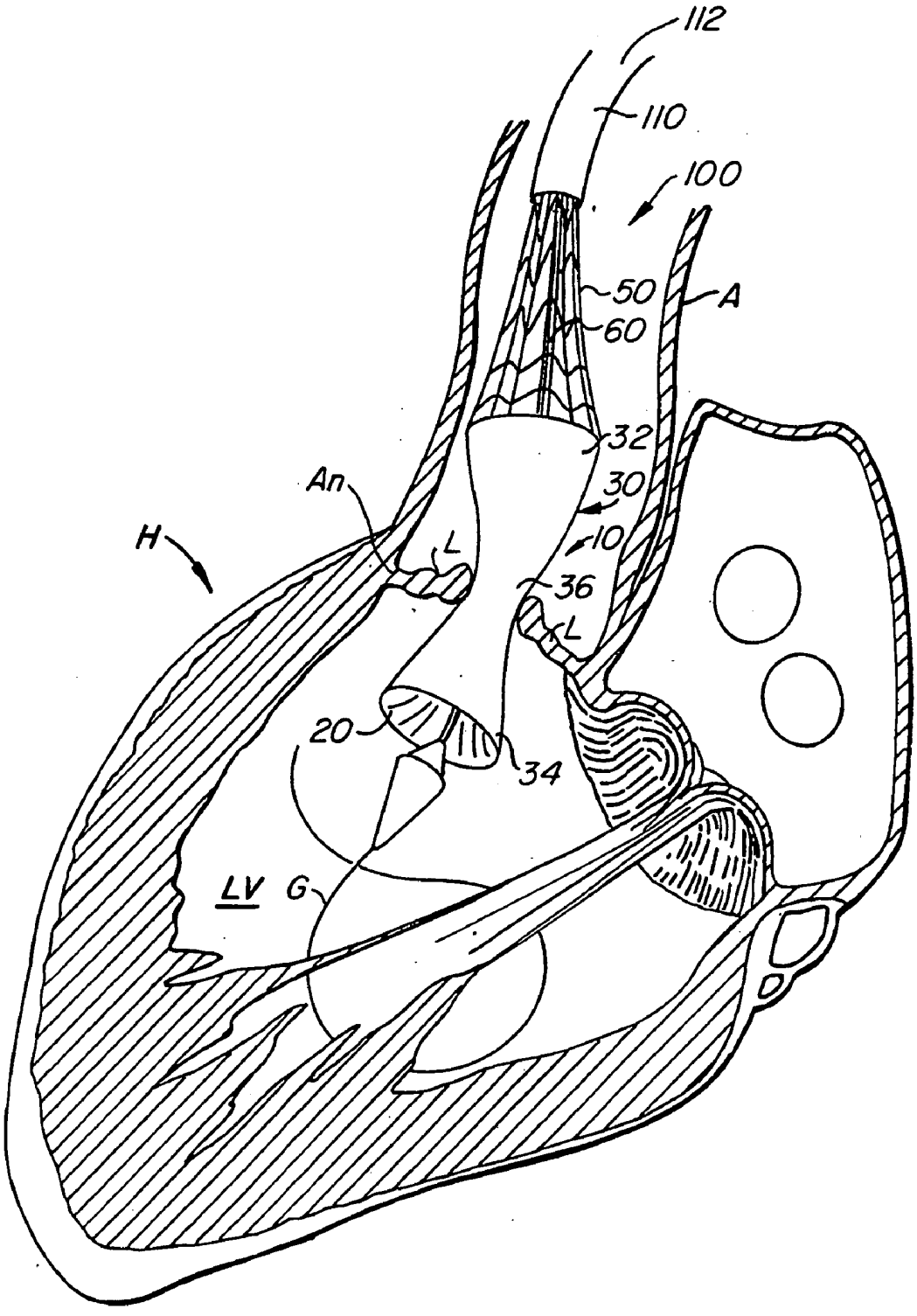



FIG. 5C

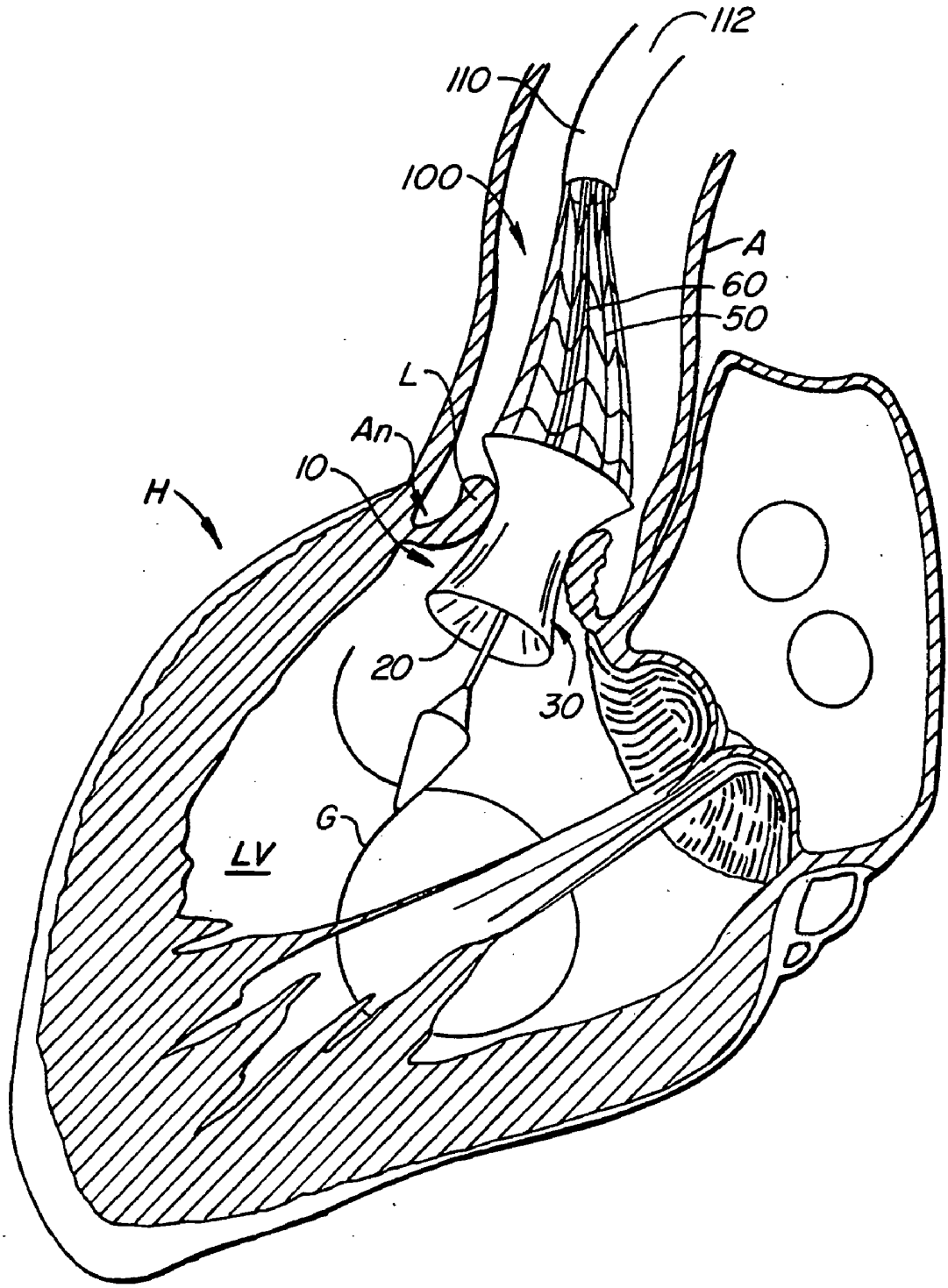



FIG. 5D

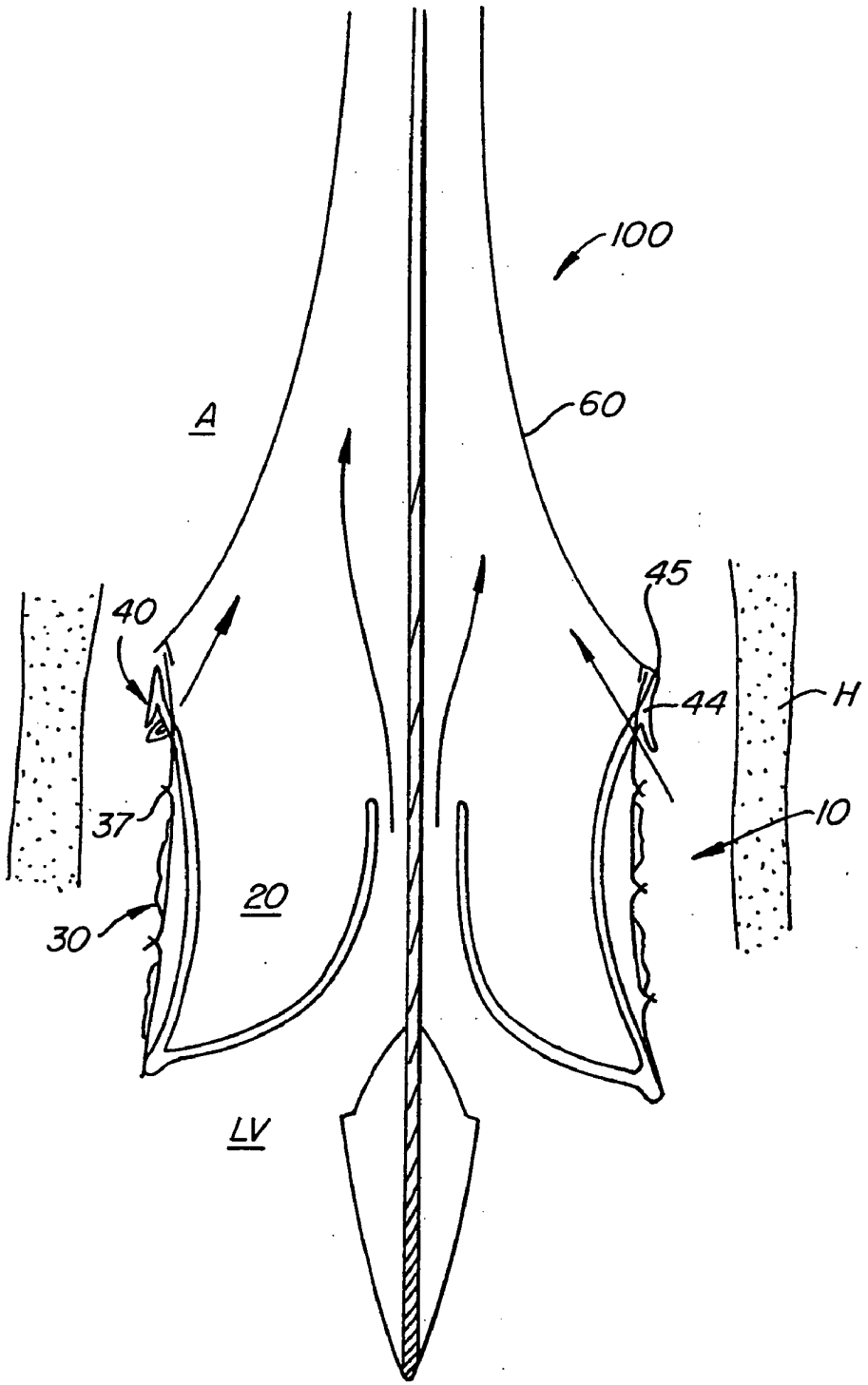
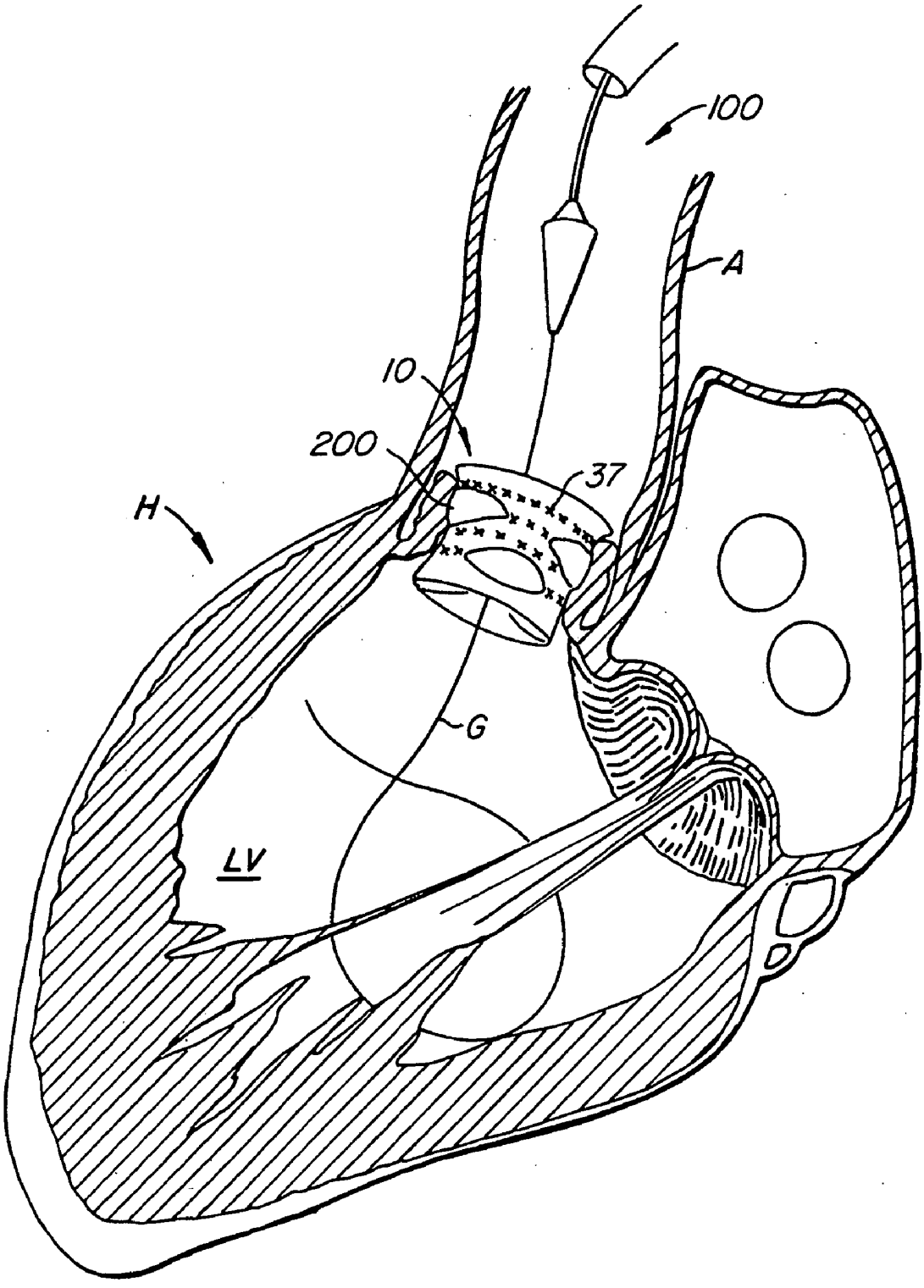



FIG. 5E

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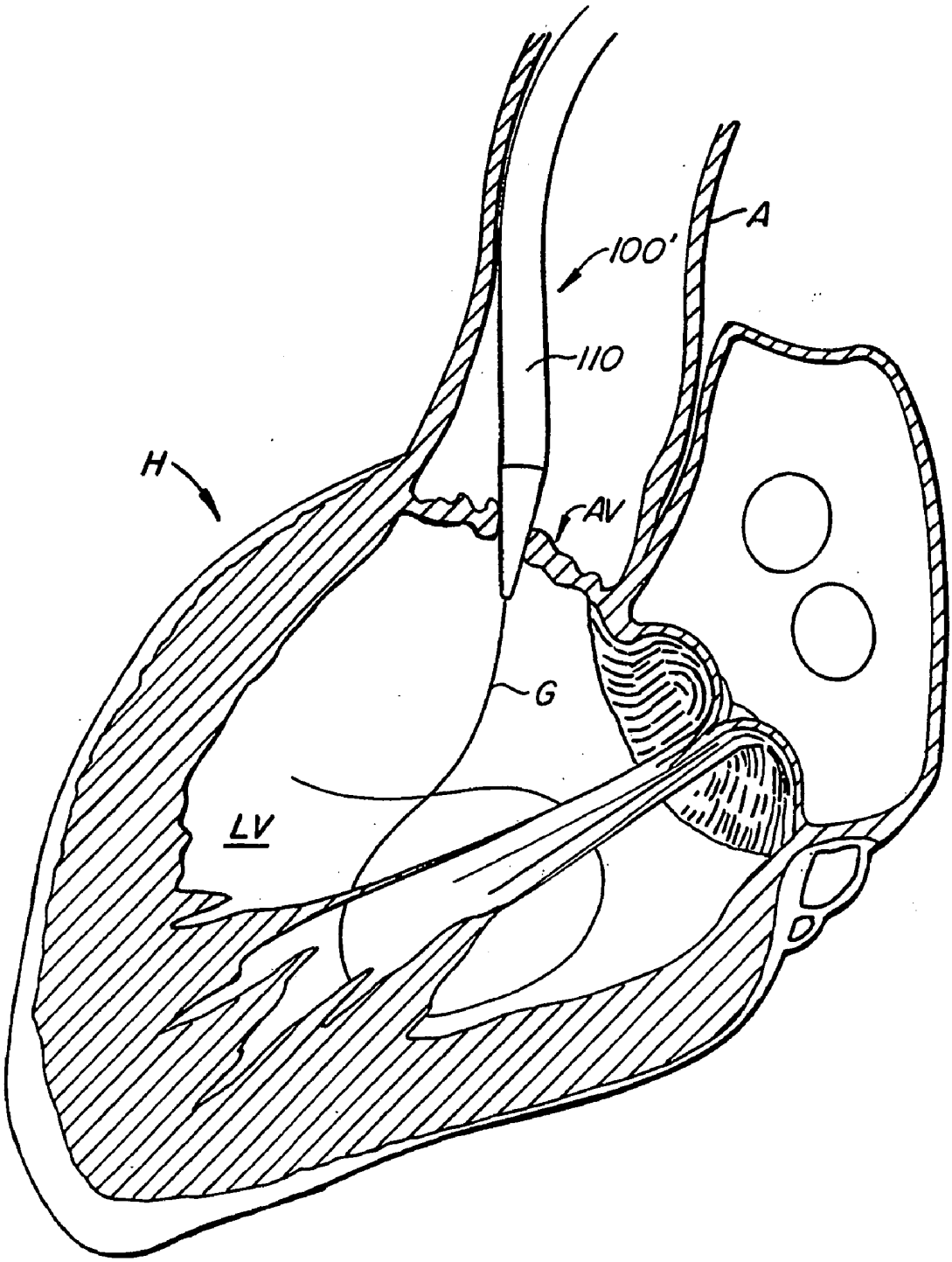



FIG. 6A

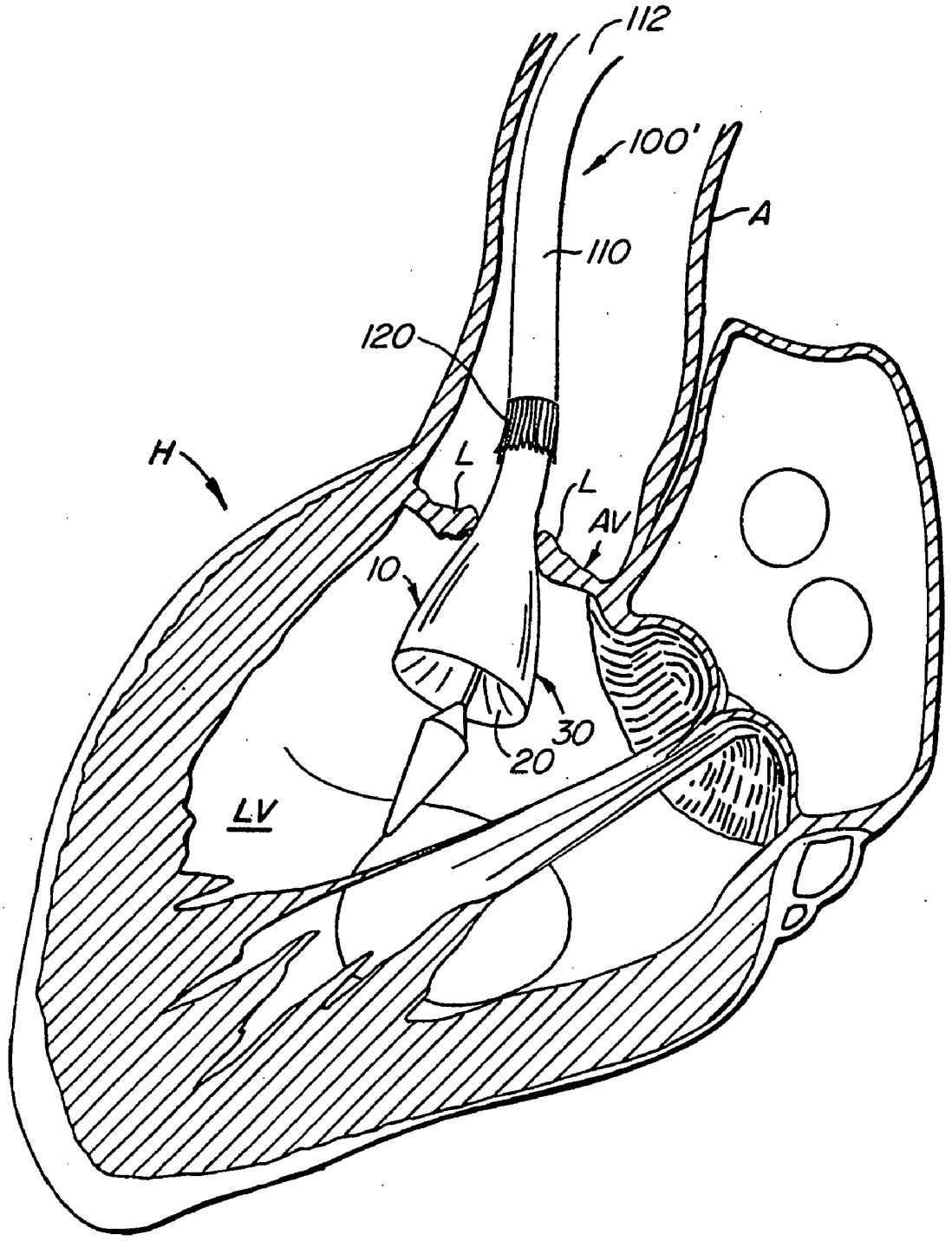



FIG. 6B

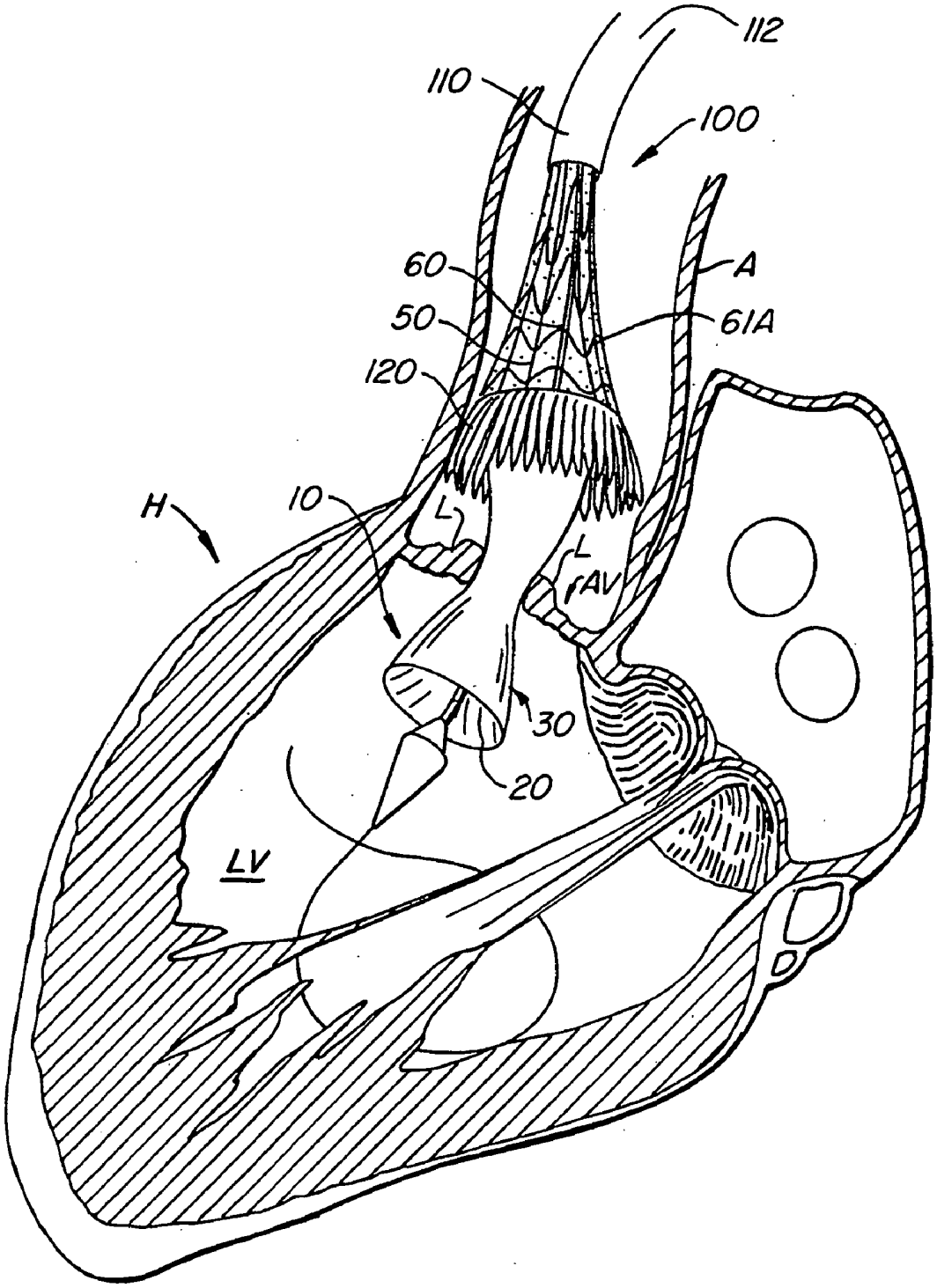
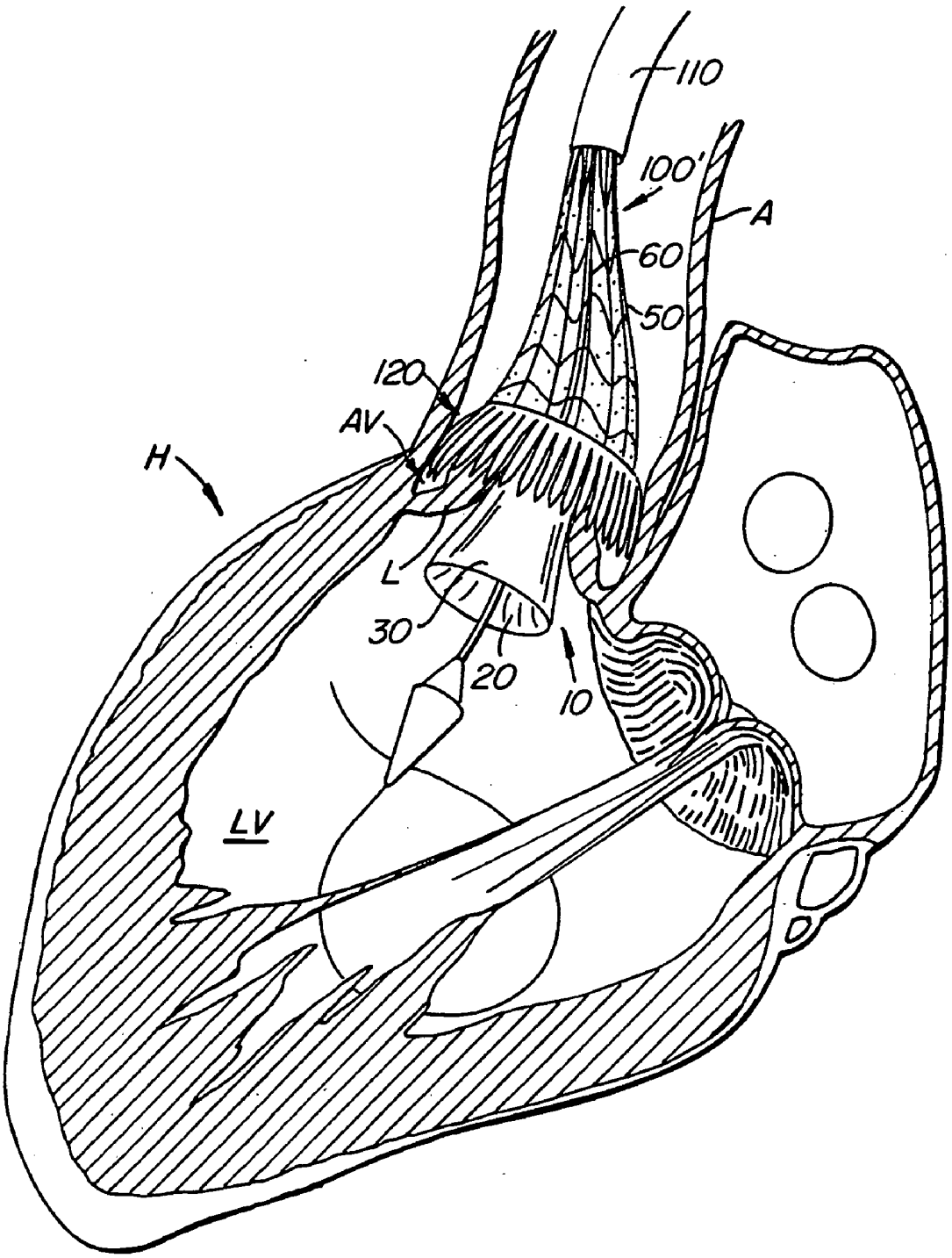



FIG. 6C

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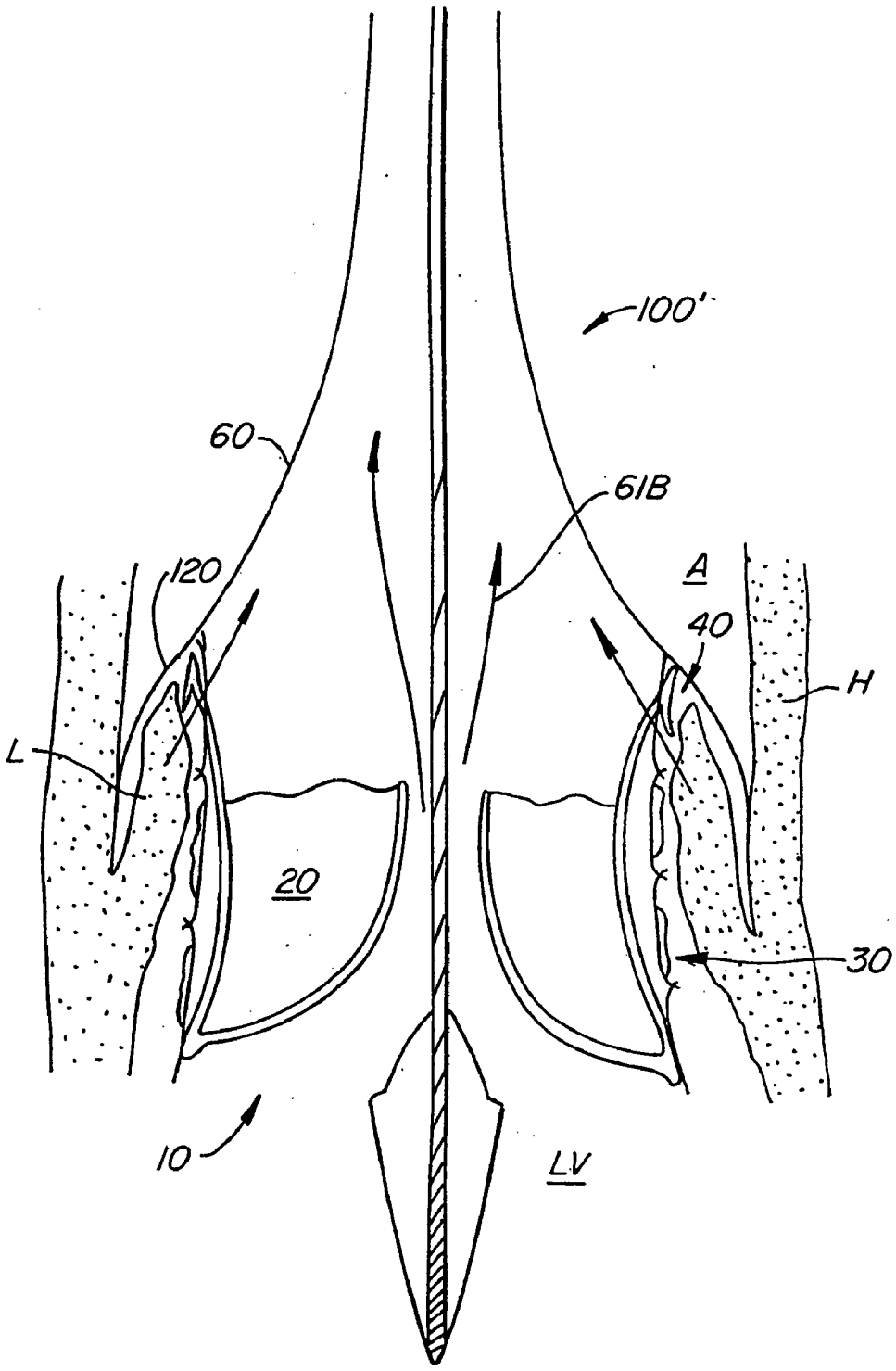



FIG. 6E

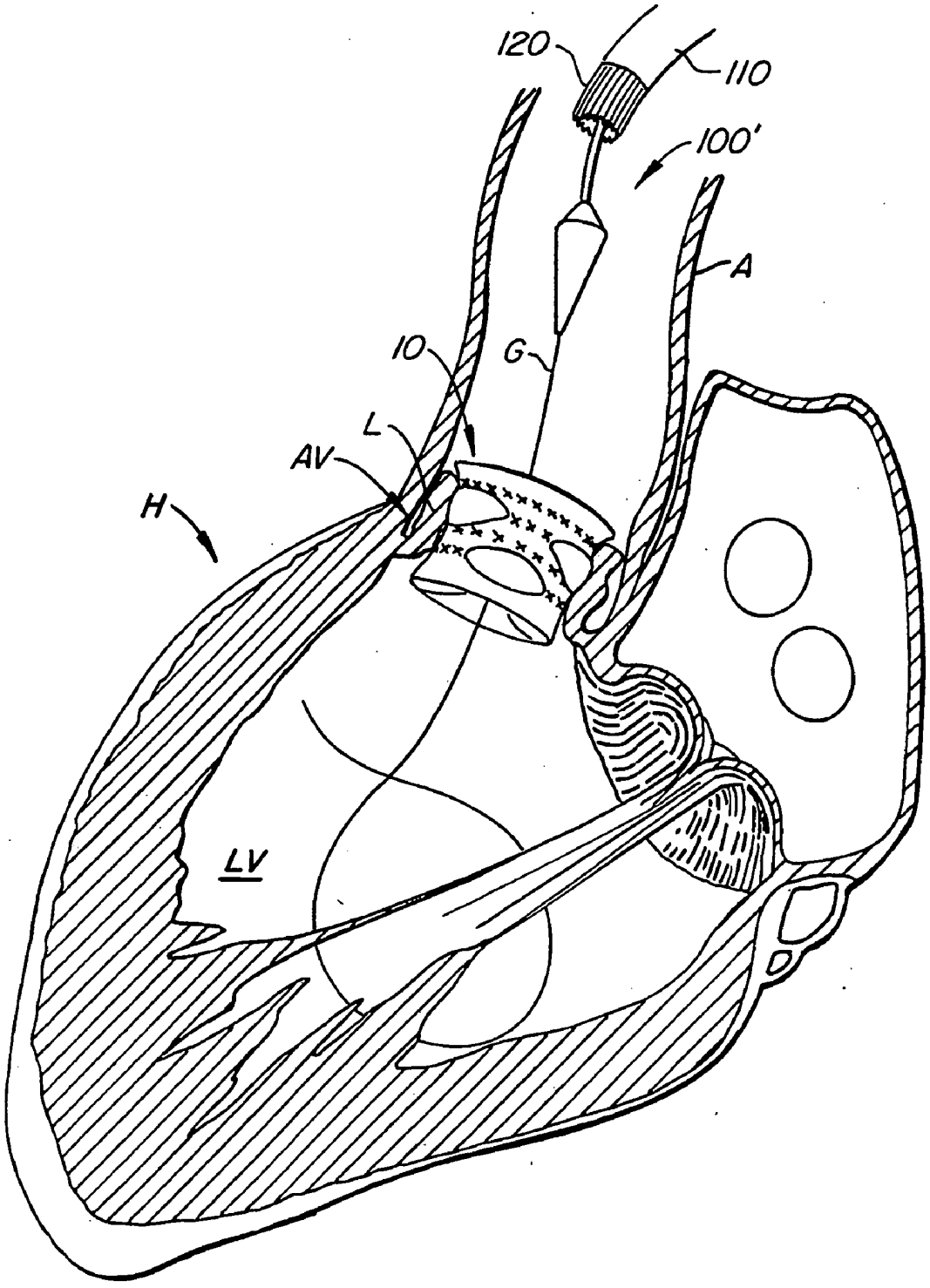



FIG. 6F

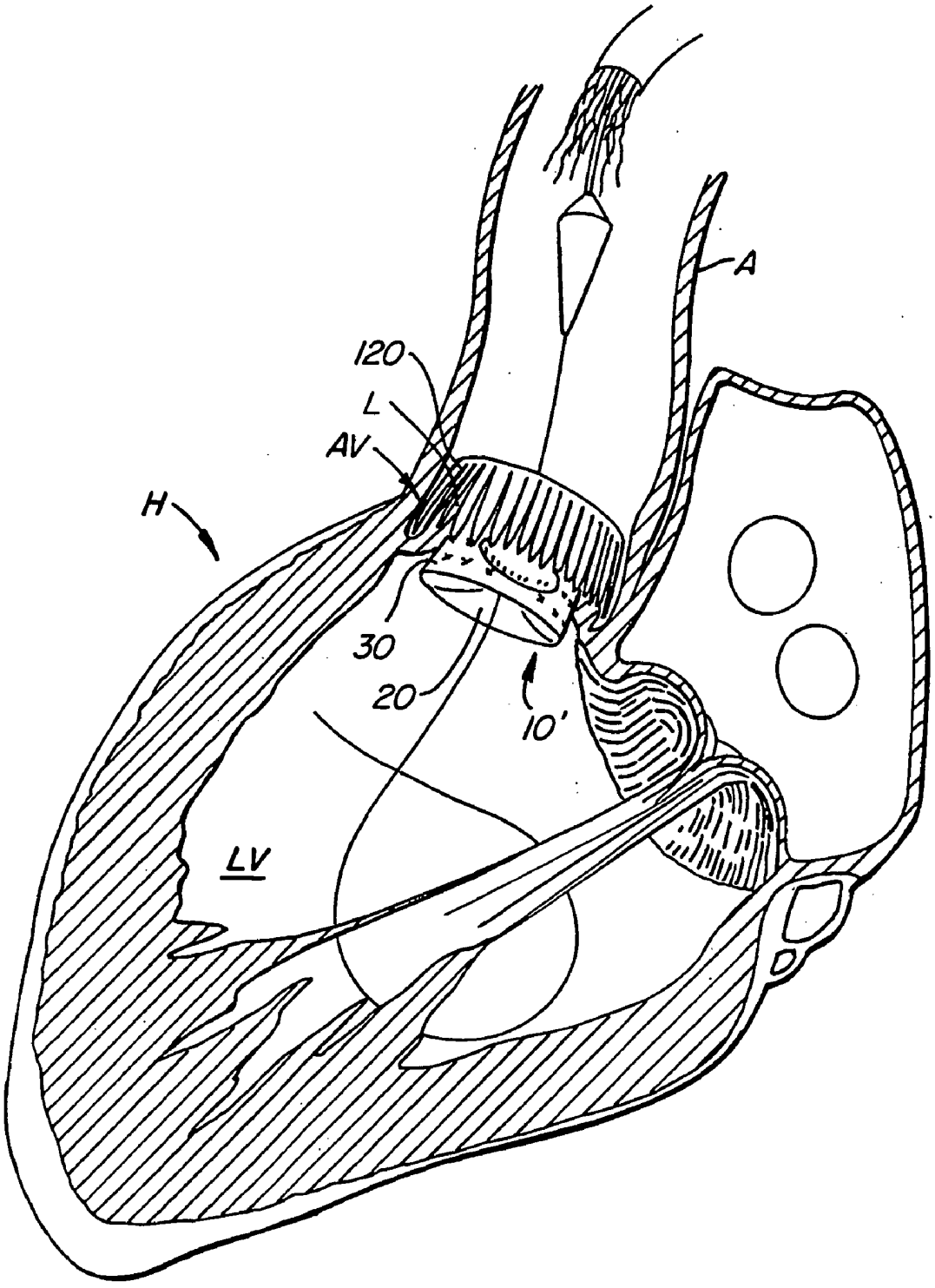



FIG. 7

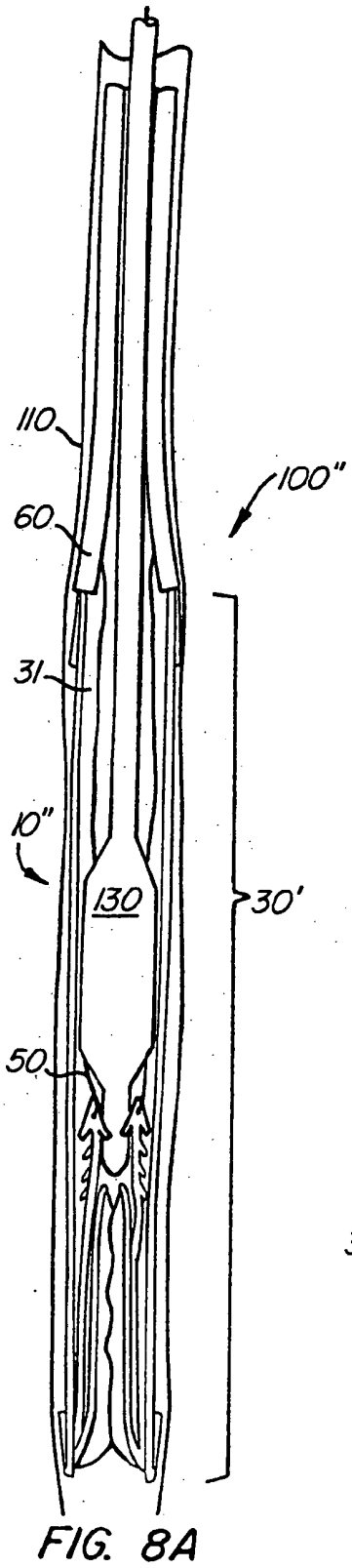



FIG. 8A

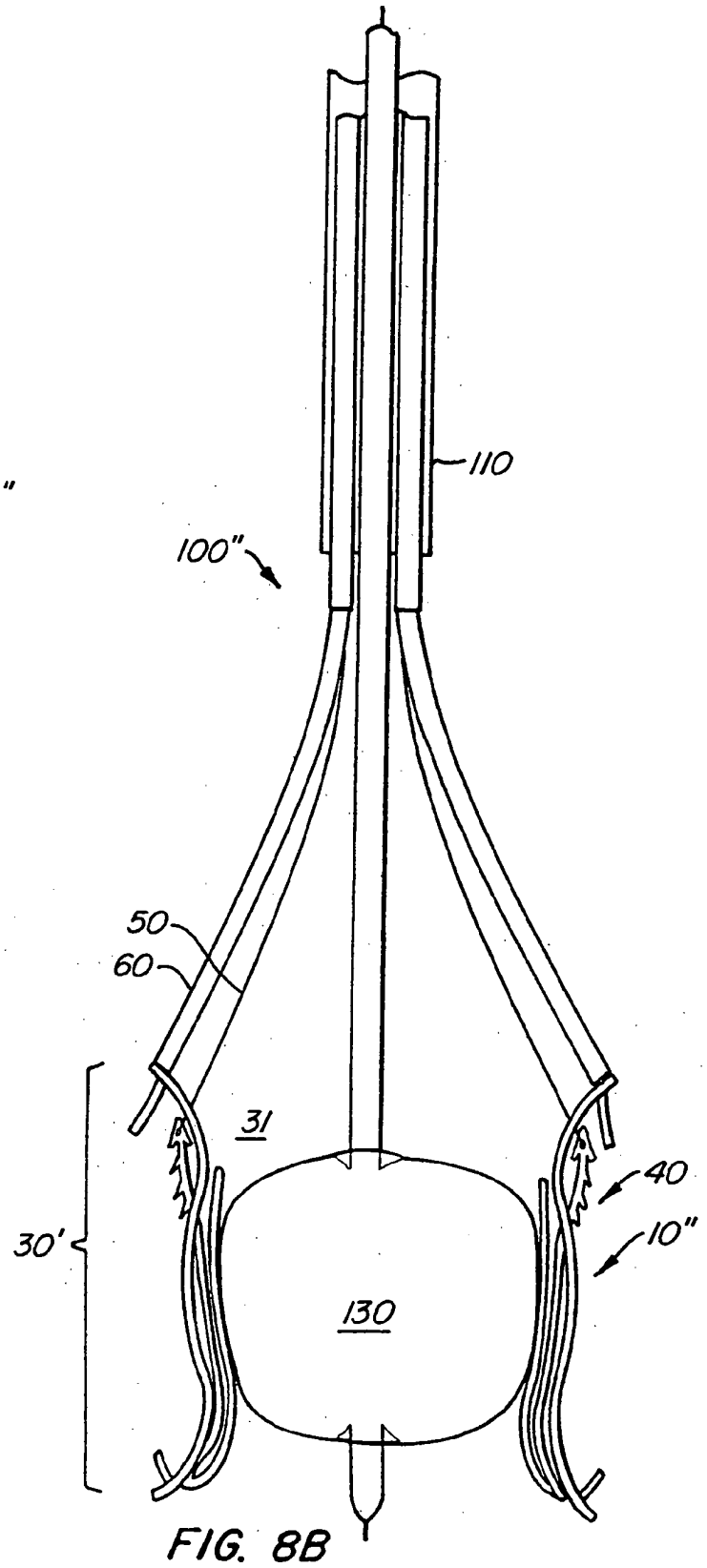



FIG. 8B

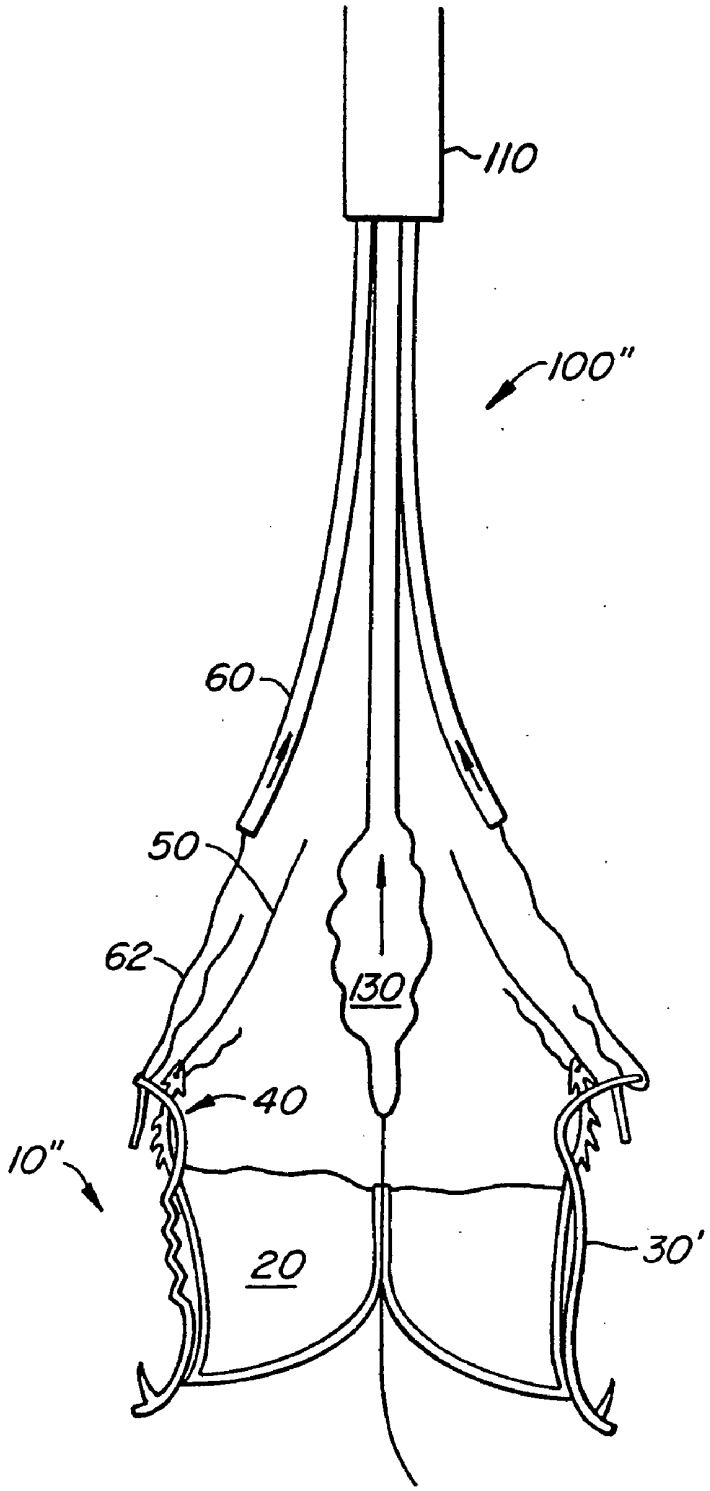



FIG. 8C

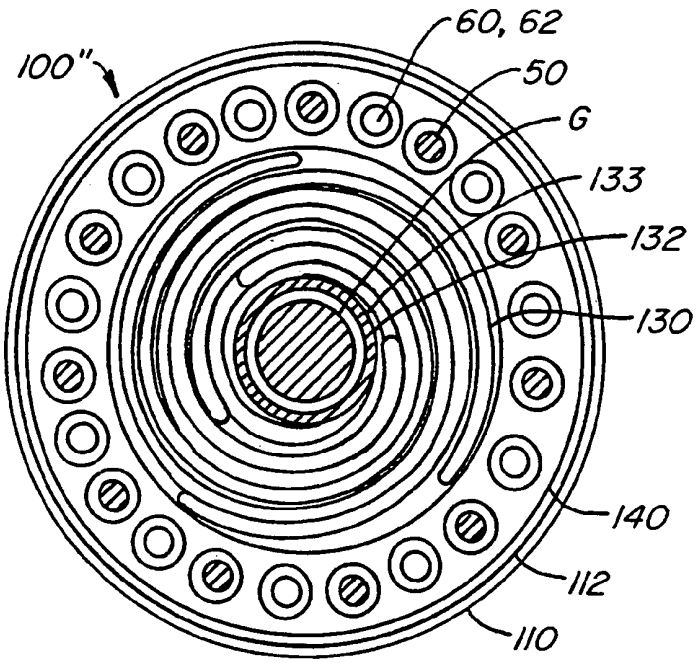



FIG. 10

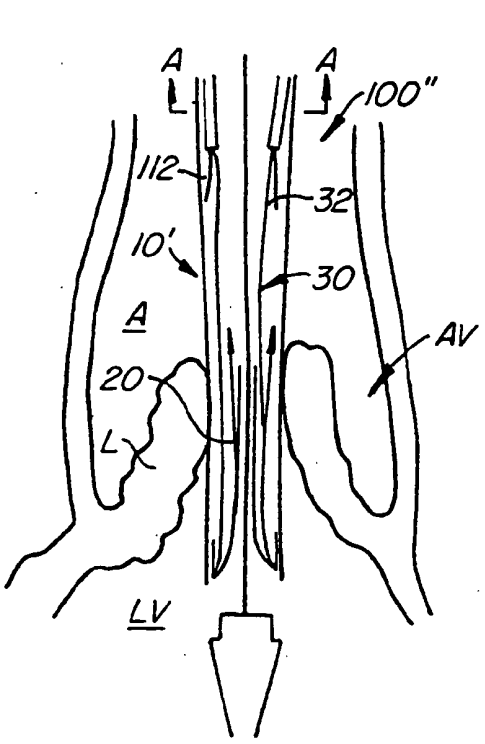



FIG. 9A

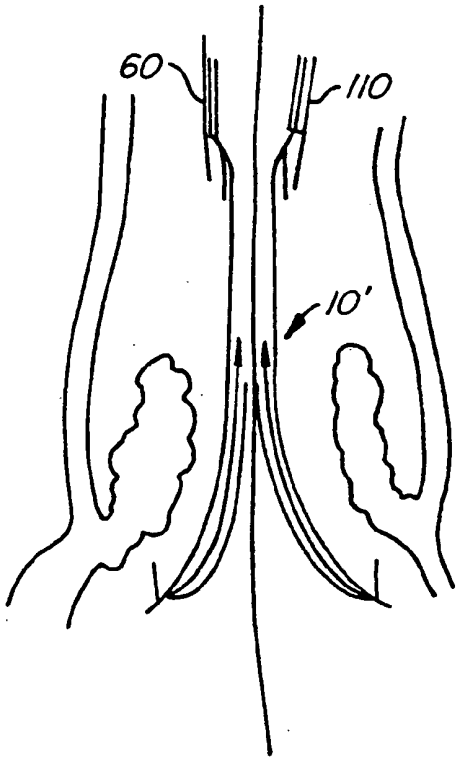



FIG. 9B

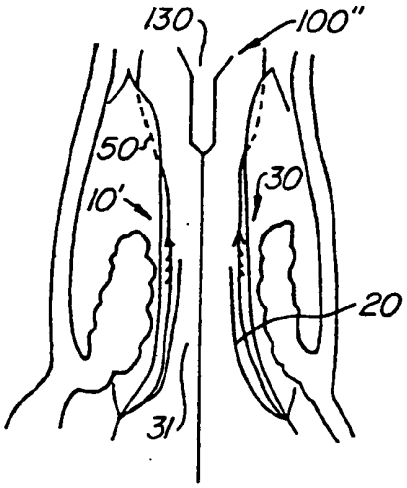



FIG. 9C

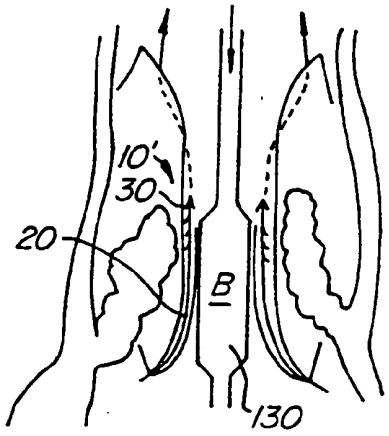



FIG. 9D

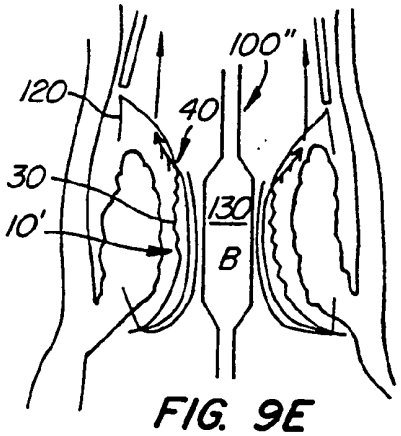



FIG. 9E

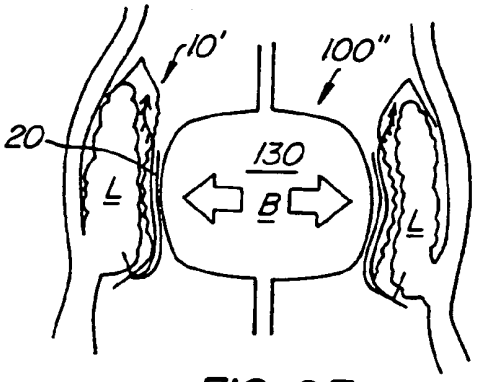



FIG. 9F

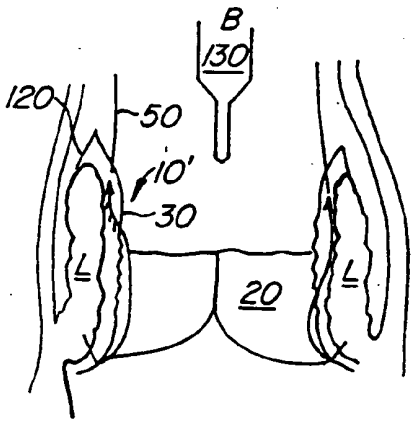



FIG. 9G

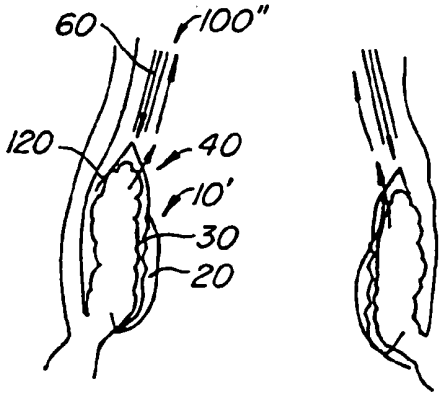



FIG. 9H

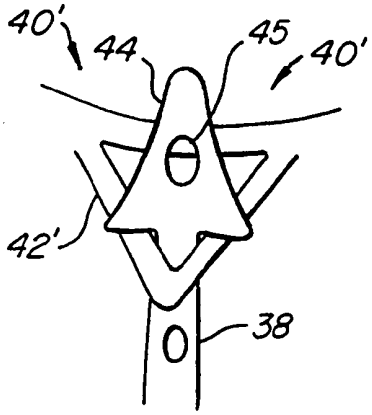



FIG. IIA

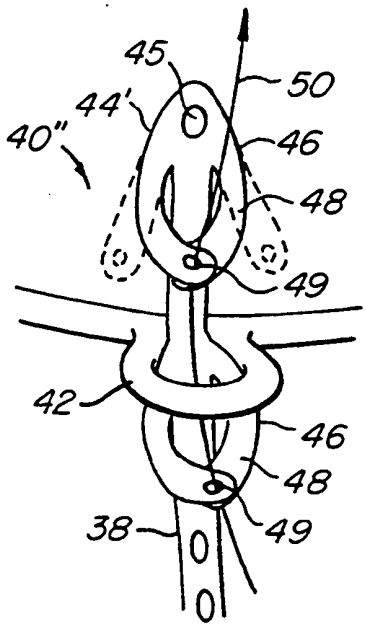



FIG. IIB

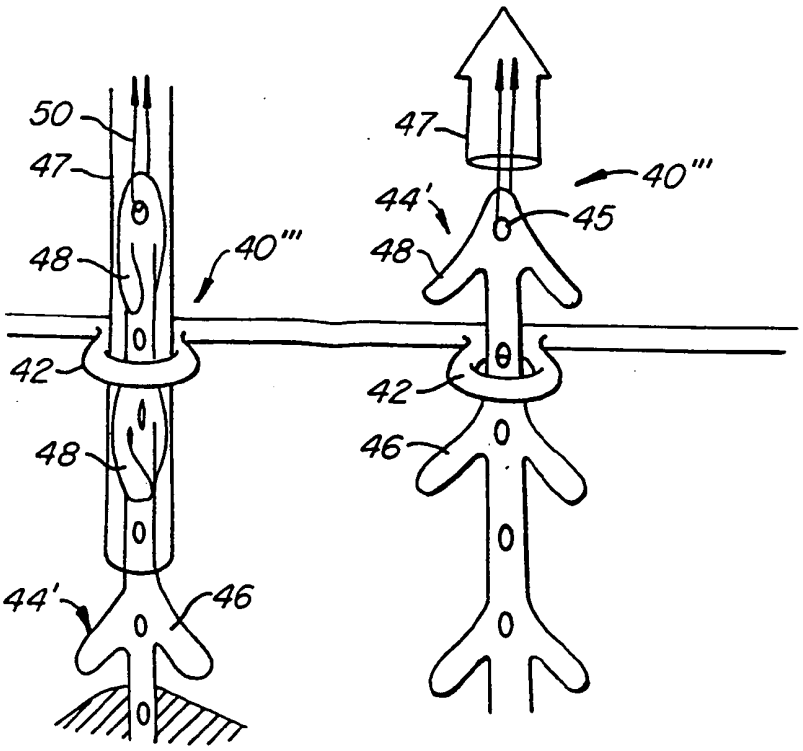



FIG. IIC

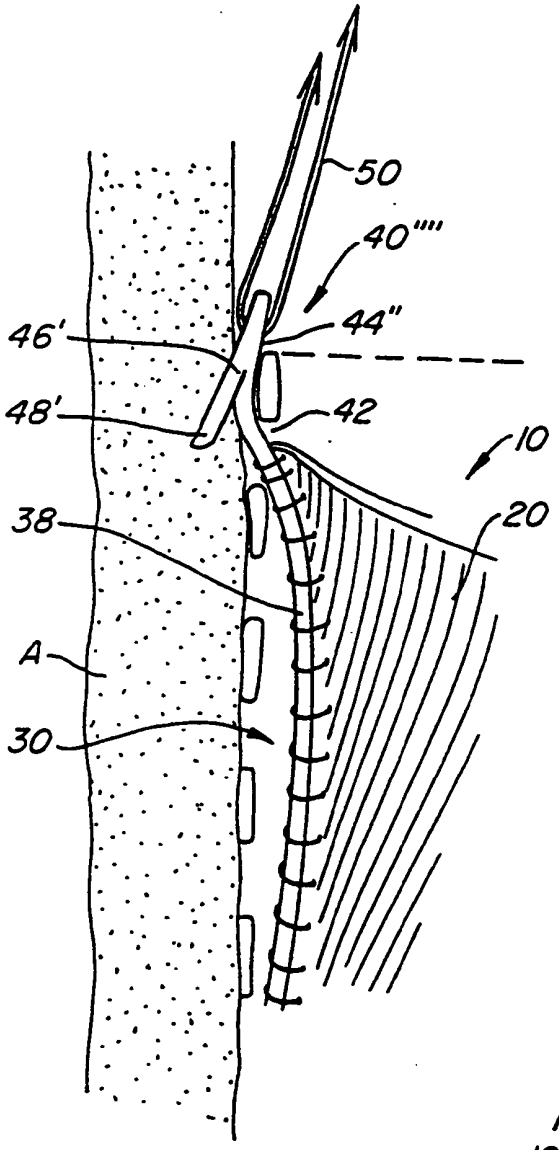



FIG. 12C

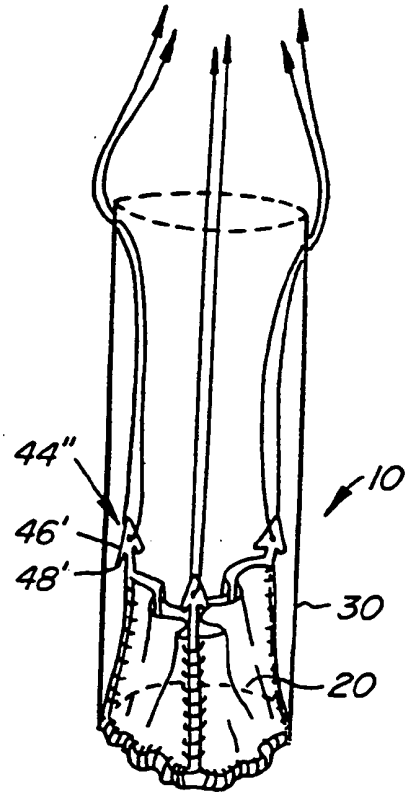



FIG. 12A

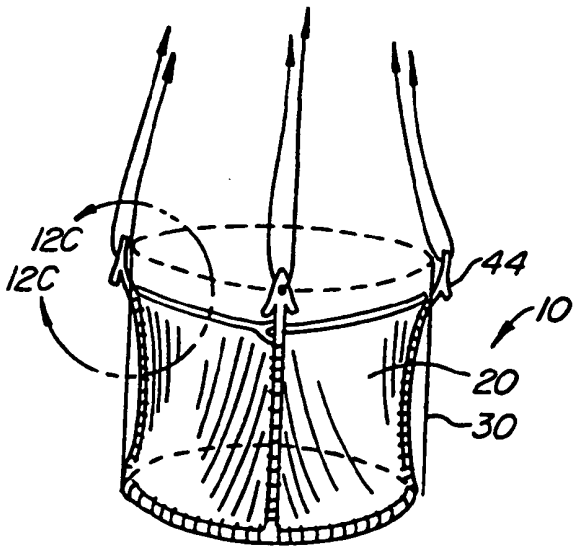



FIG. 12B

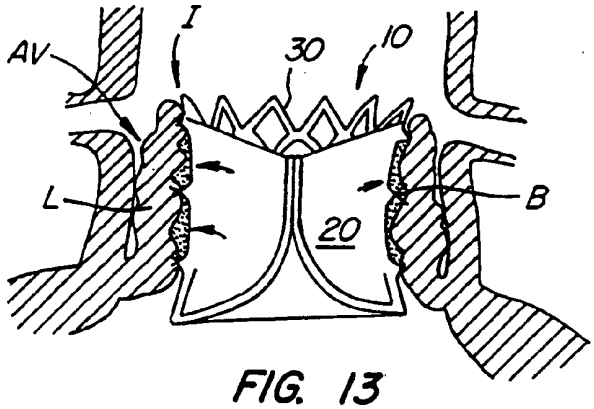



FIG. 13

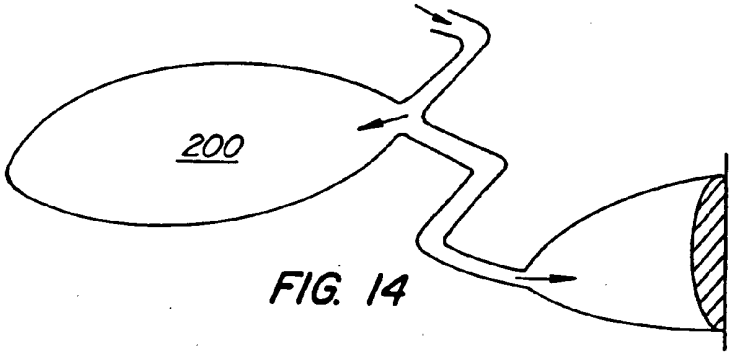



FIG. 14

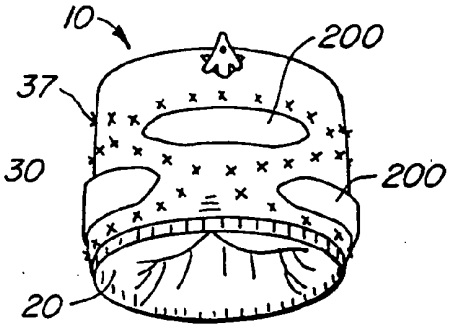



FIG. 15A

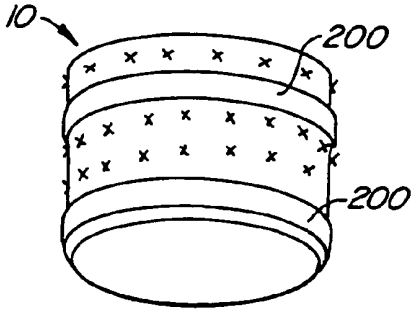



FIG. 15B

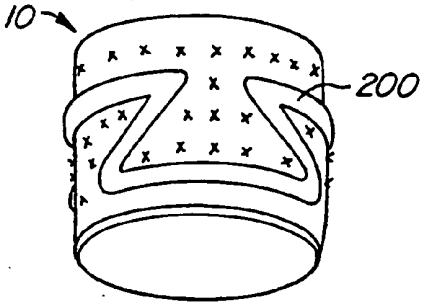



FIG. 15C

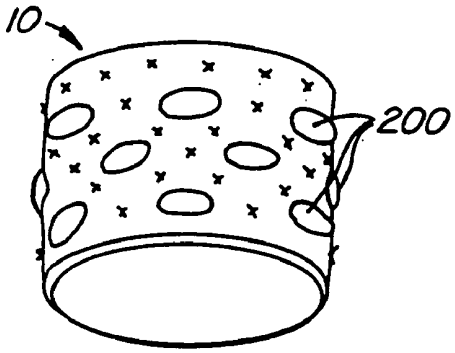



FIG. 15D

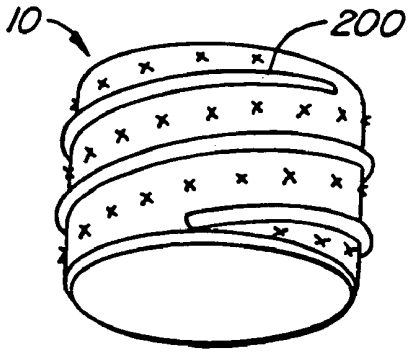



FIG. 15E

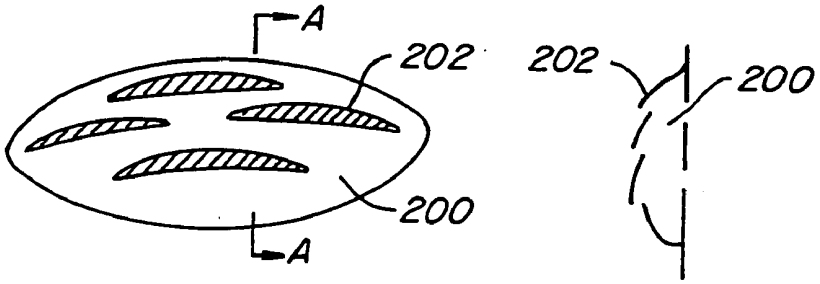



FIG. 16A

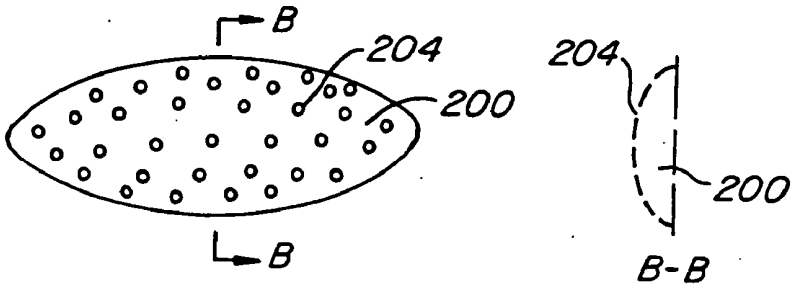



FIG. 16B

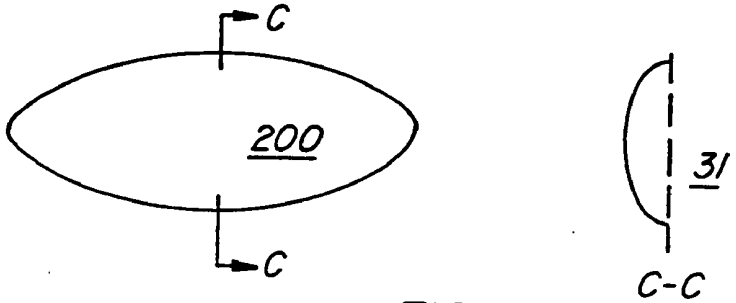



FIG. 16C

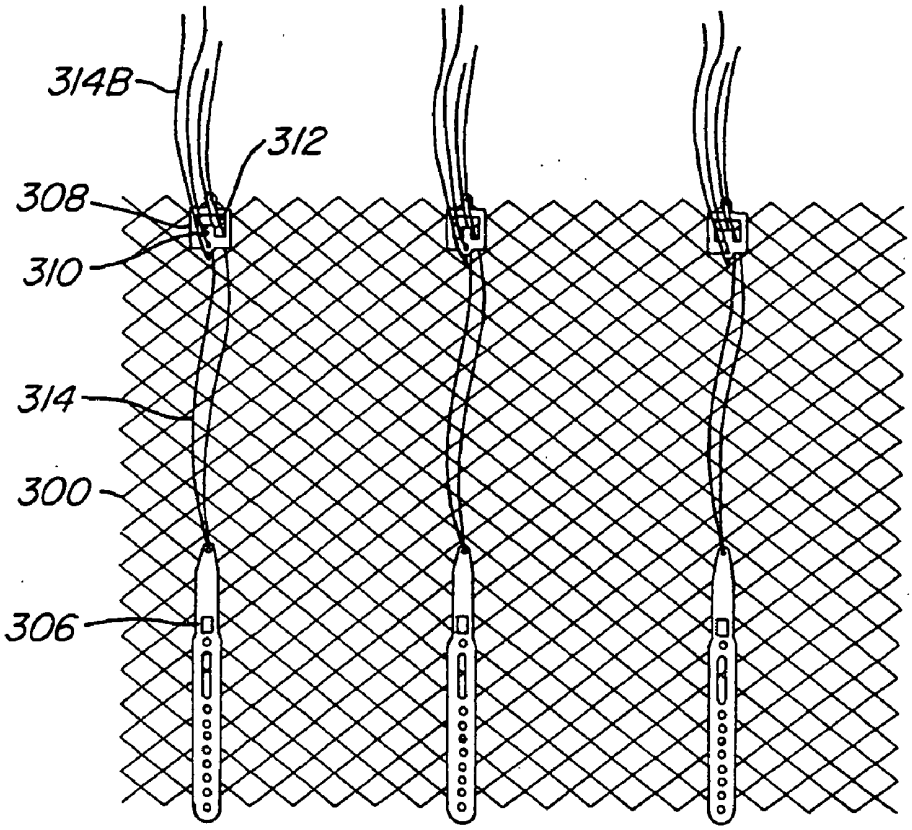



FIG. 17A

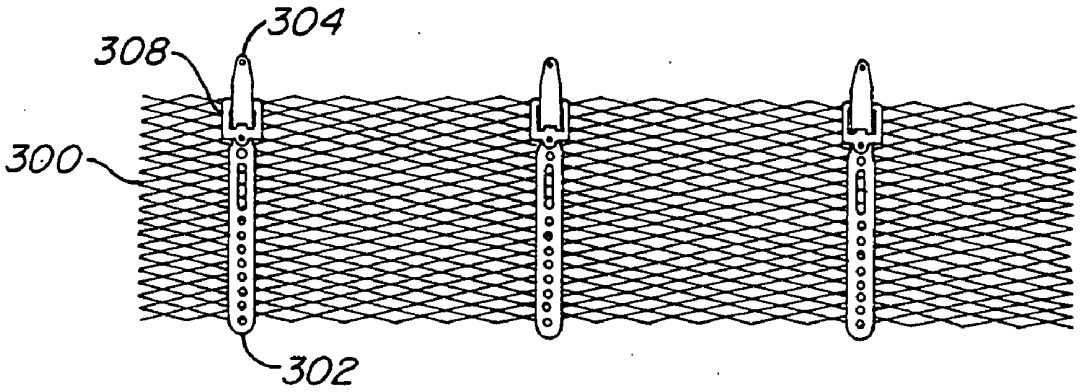



FIG. 18A

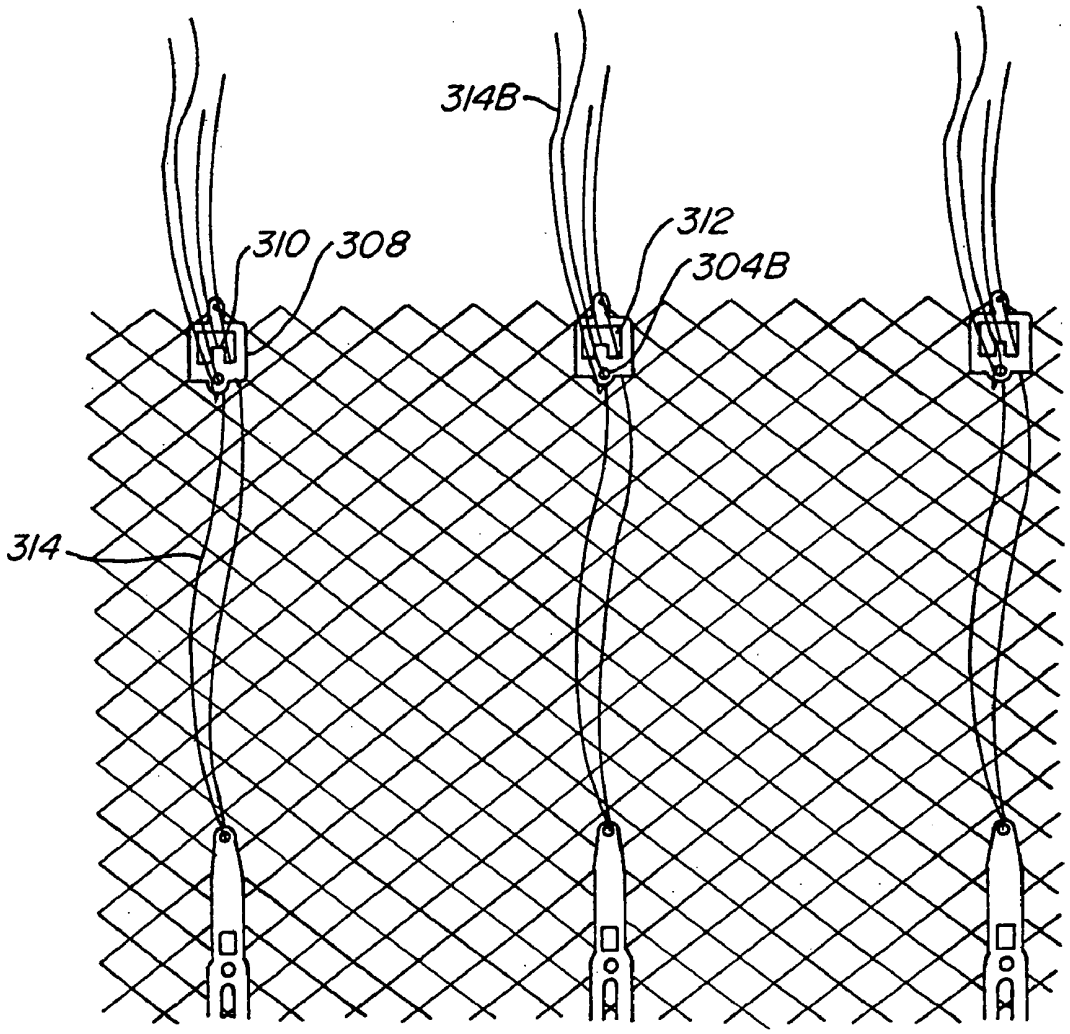



FIG. 17B

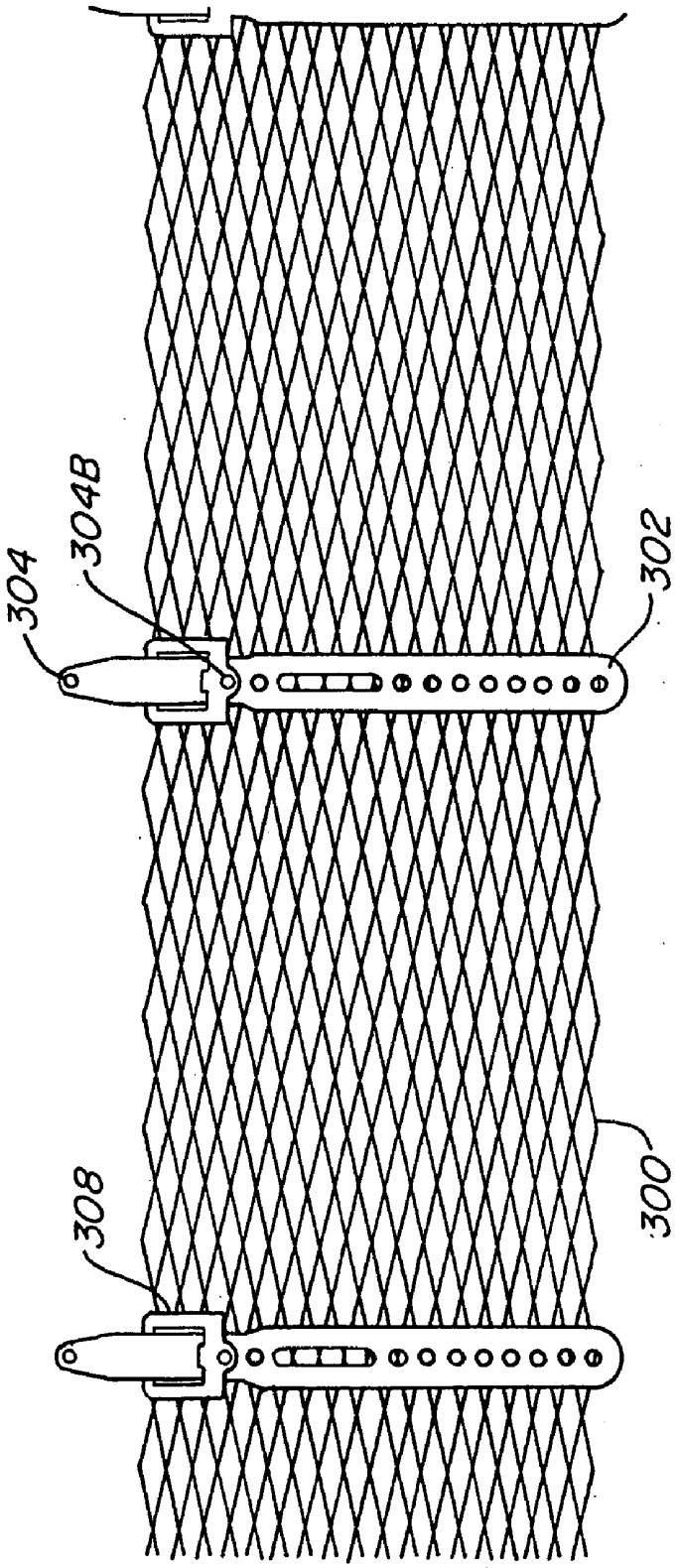



FIG. 18B

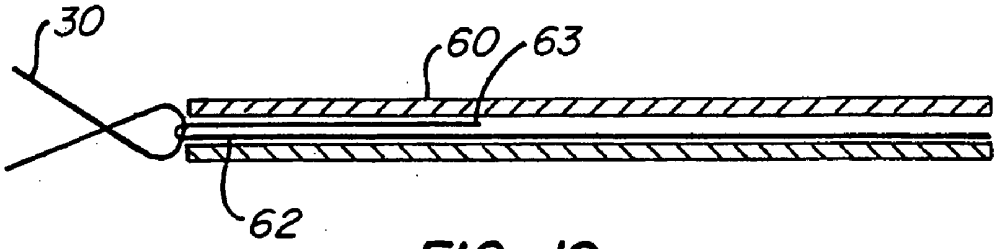



FIG. 19

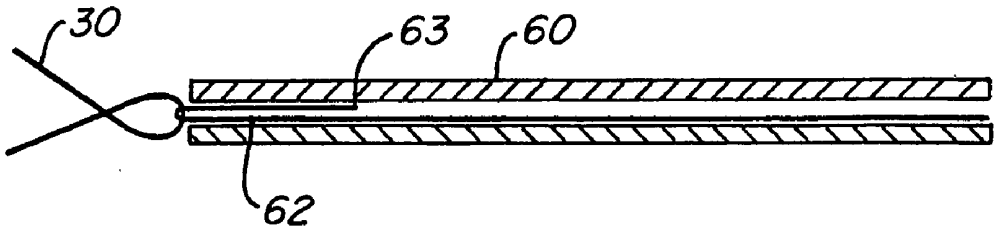



FIG. 20

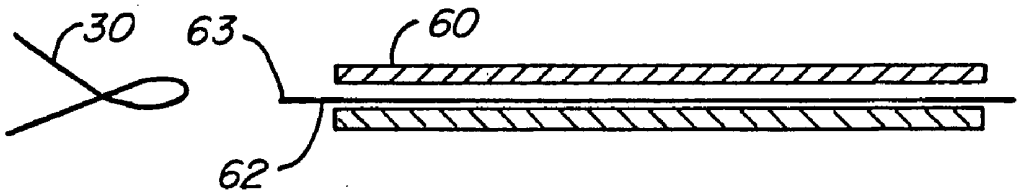



FIG. 21

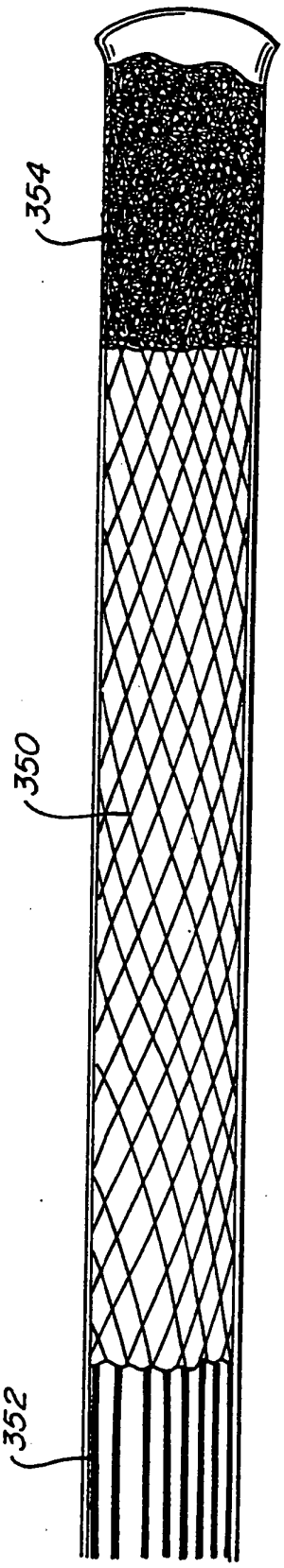



FIG. 22

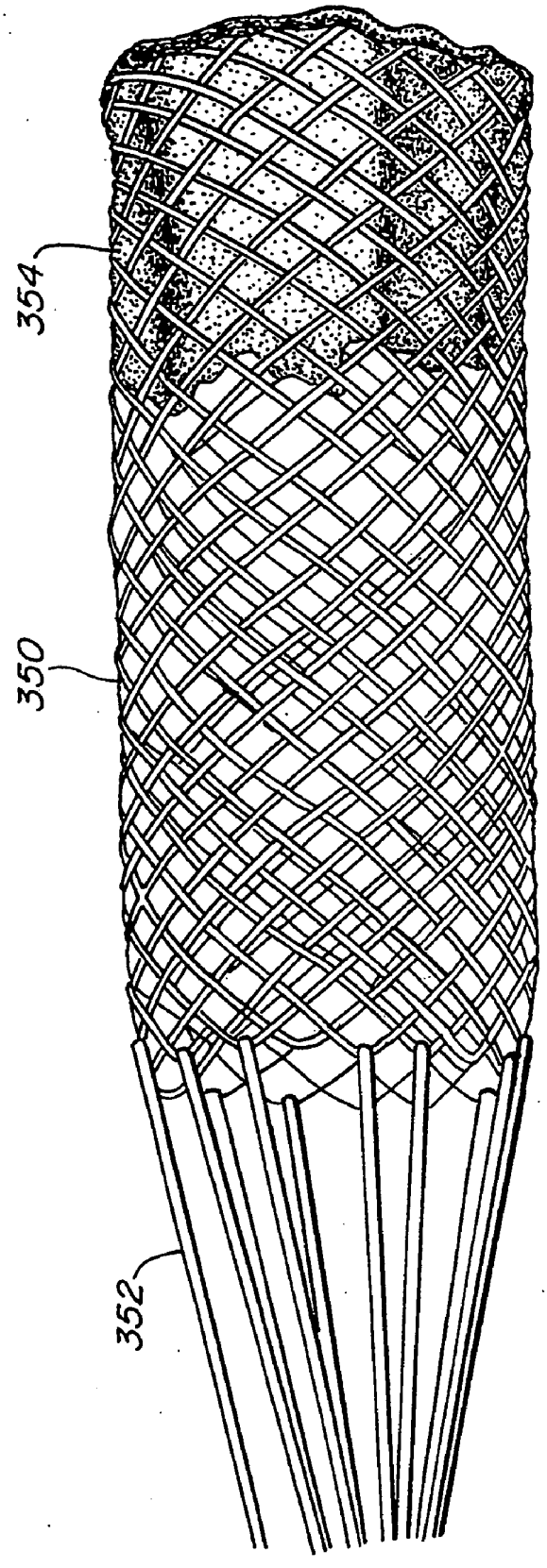



FIG. 23

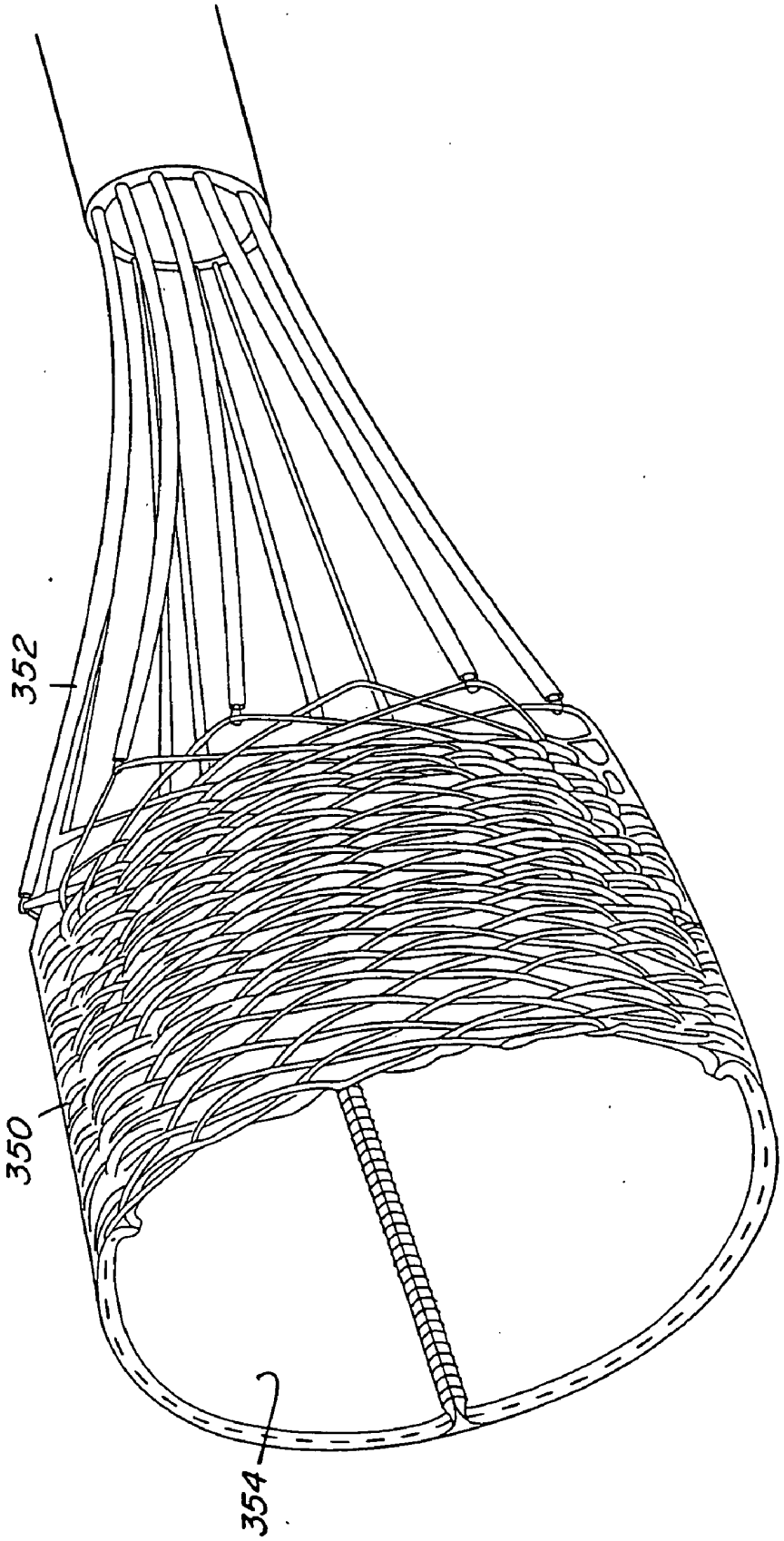



FIG. 24

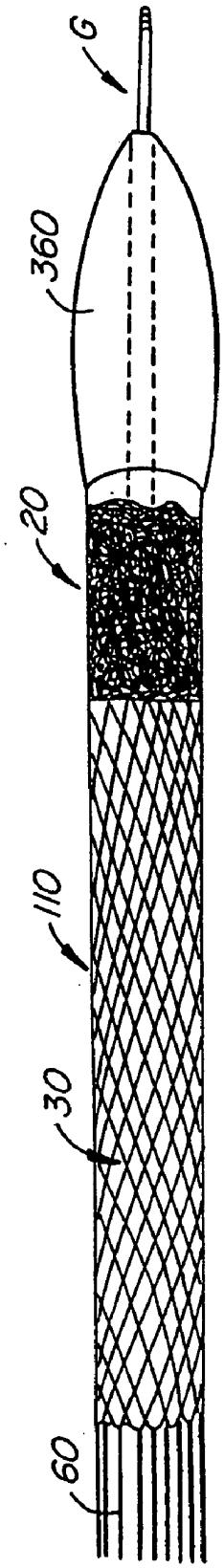



FIG. 25

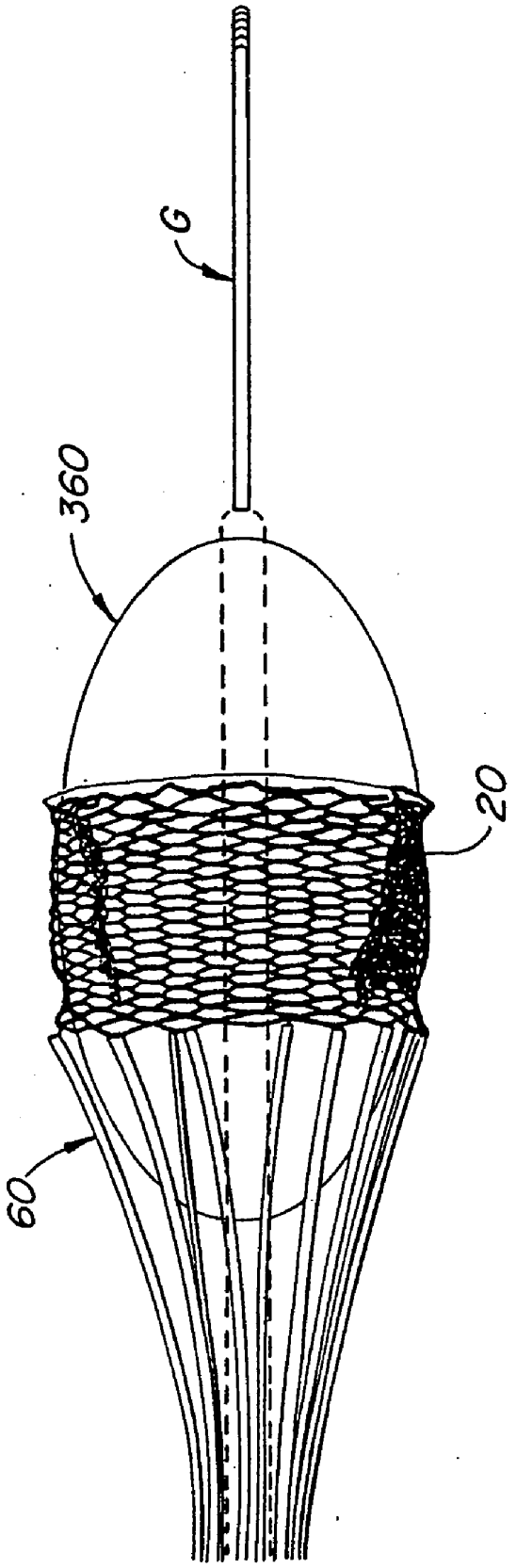



FIG. 26

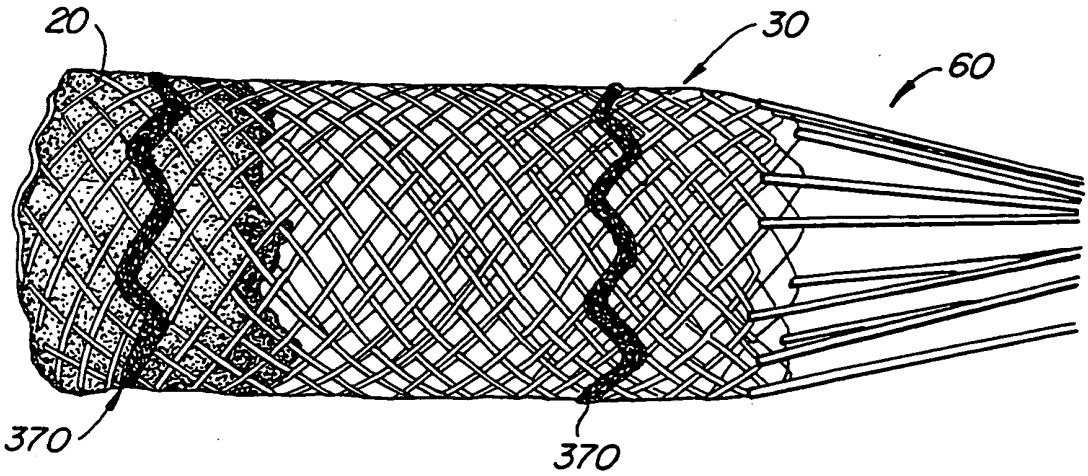



FIG. 27

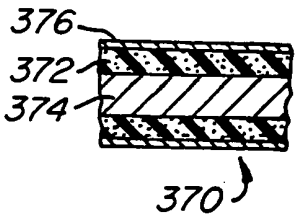



FIG. 28

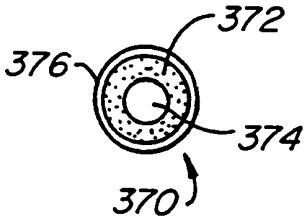



FIG. 29

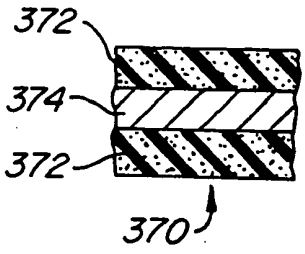



FIG. 30

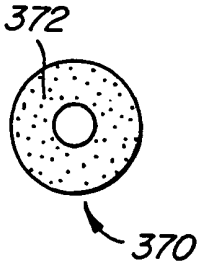



FIG. 31

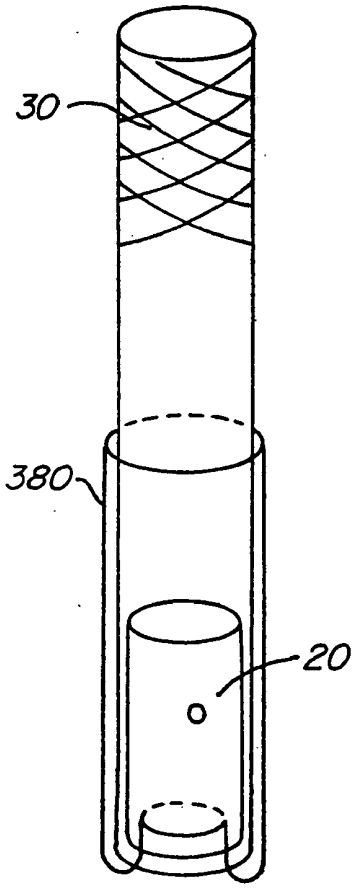



FIG. 32

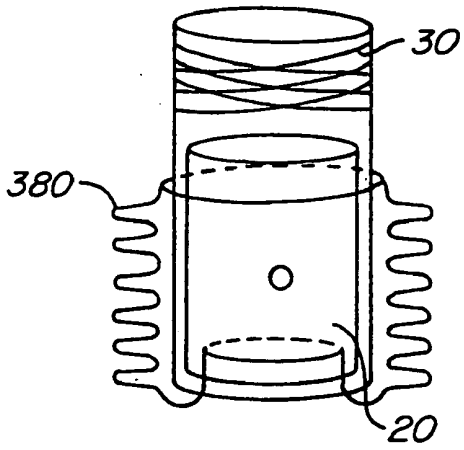



FIG. 33

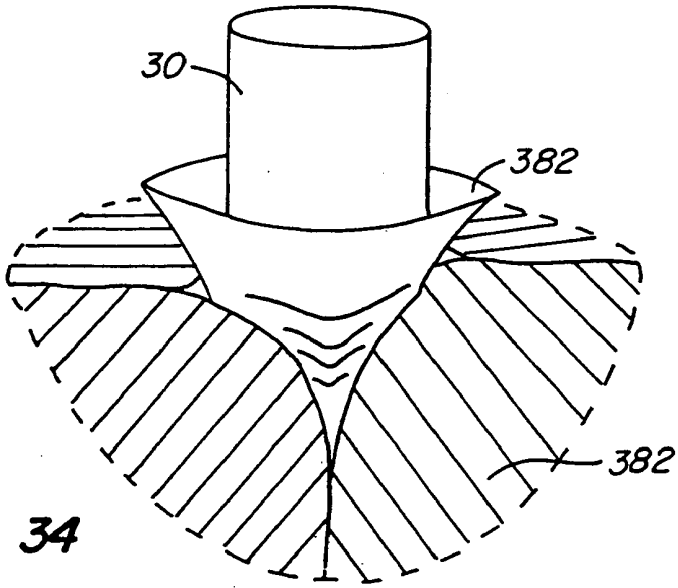



FIG. 34

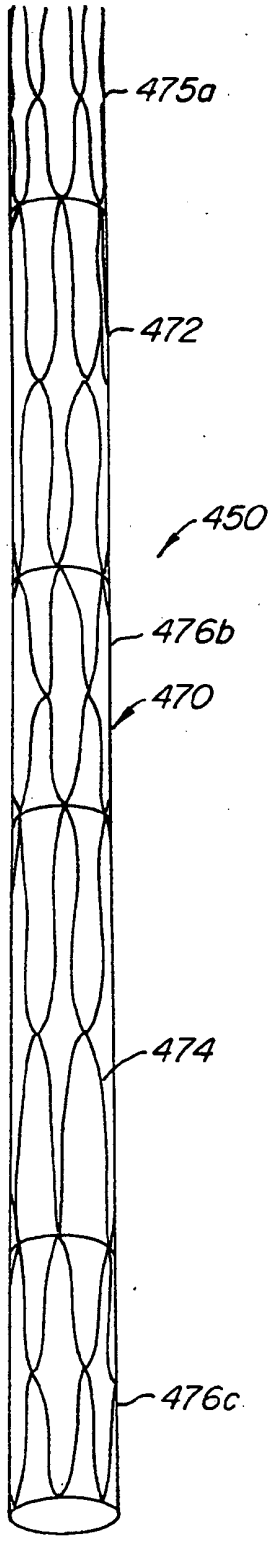



FIG. 35A

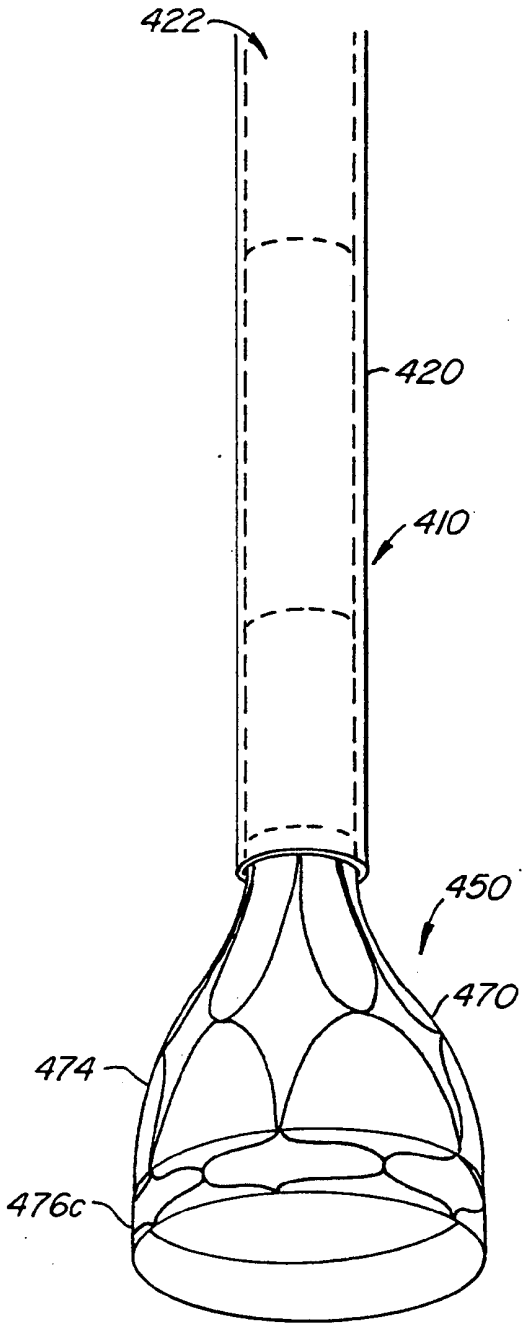



FIG. 35B

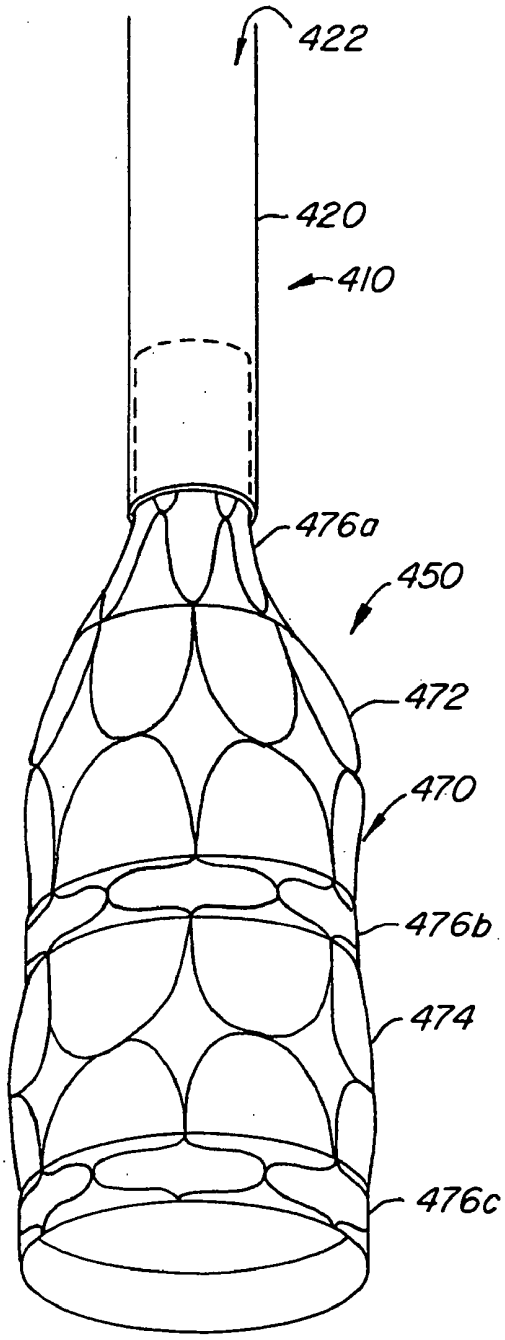



FIG. 35C

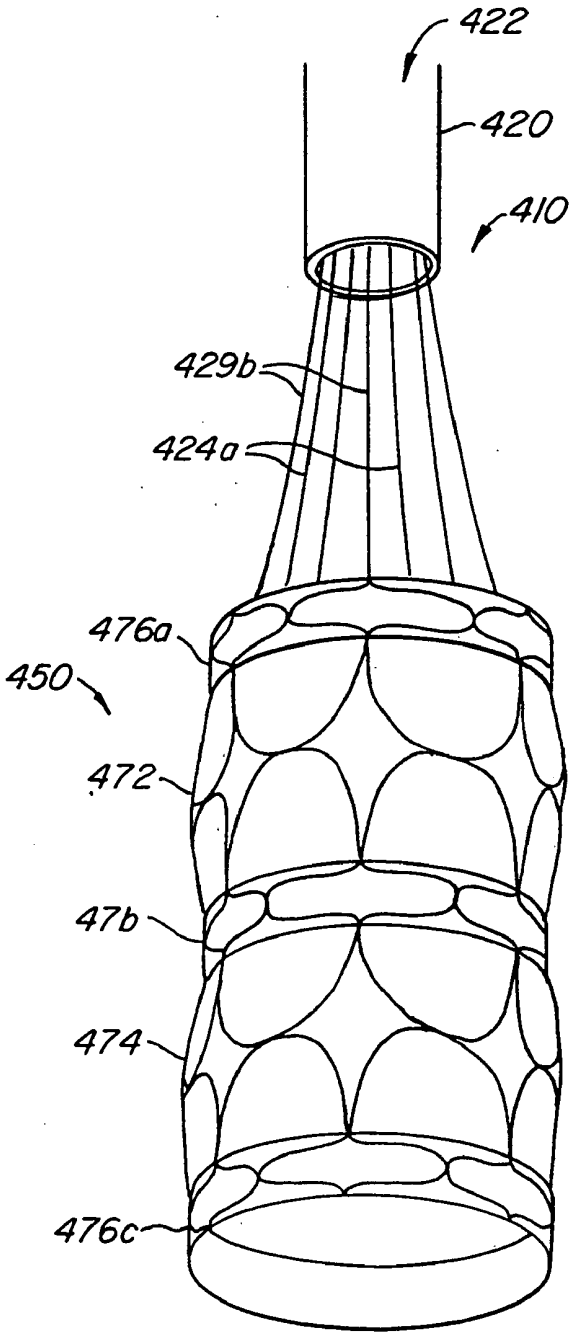



FIG. 35D

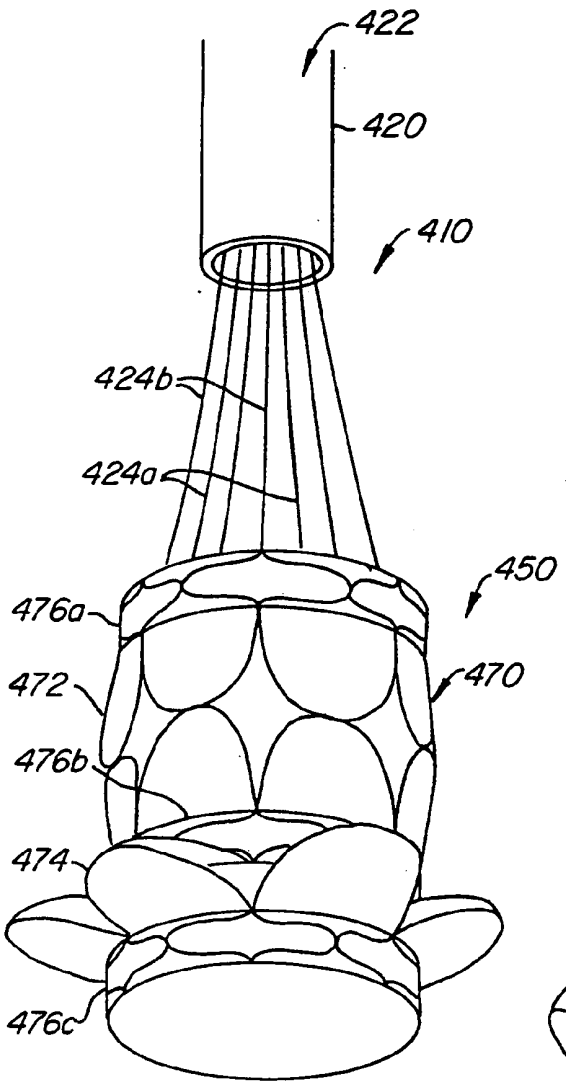



FIG. 35E

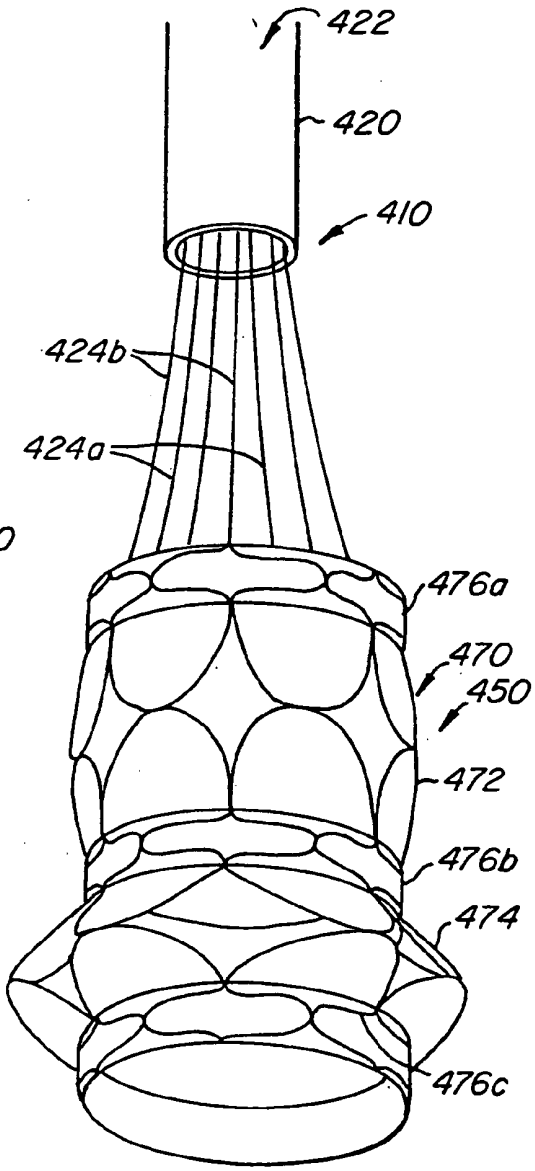



FIG. 35F

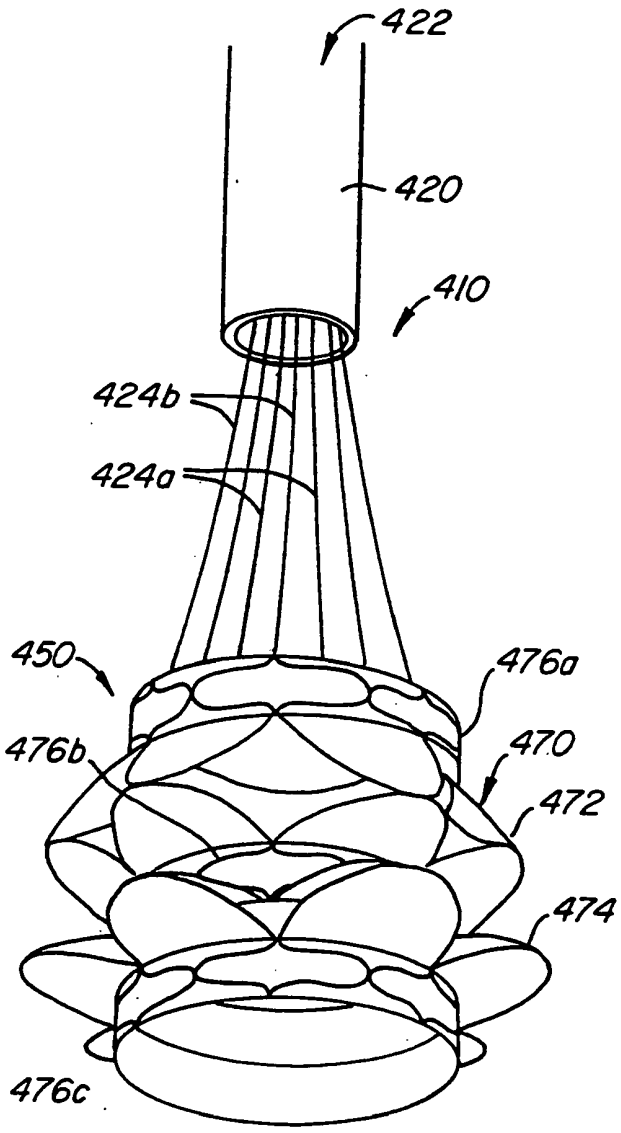



FIG. 35G

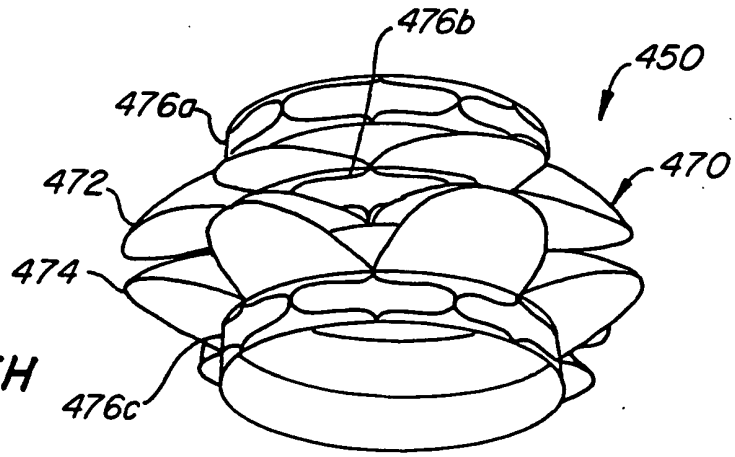



FIG. 35H

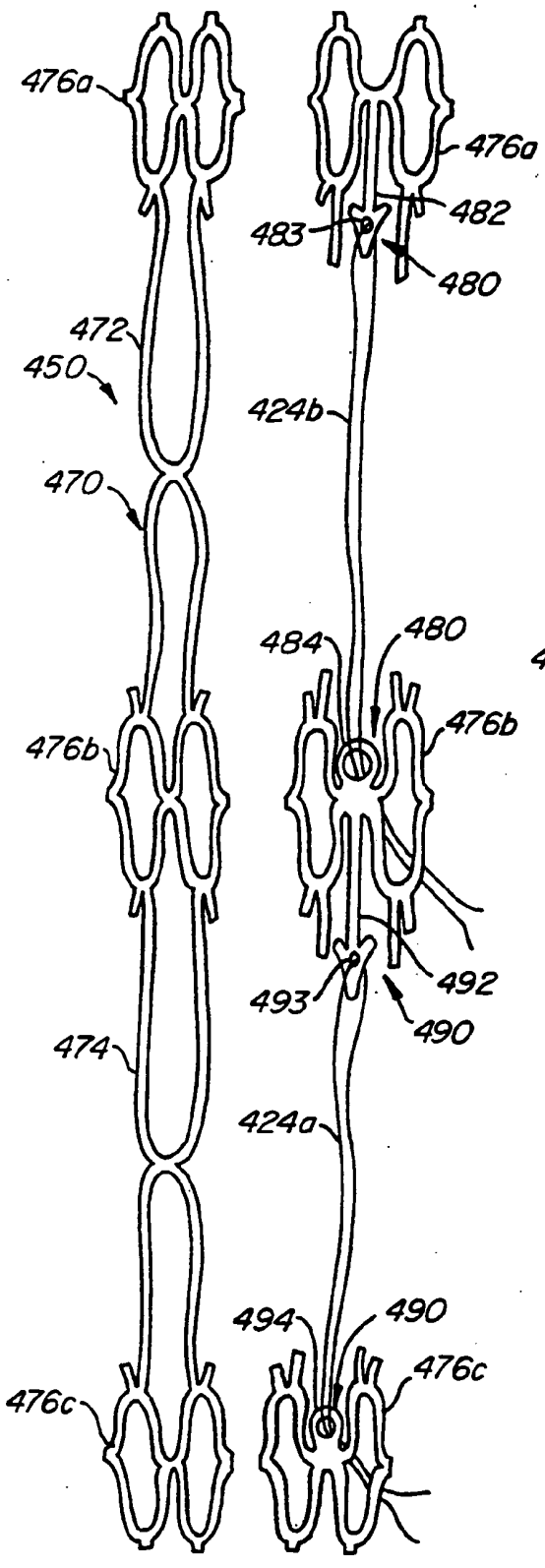



FIG. 36A

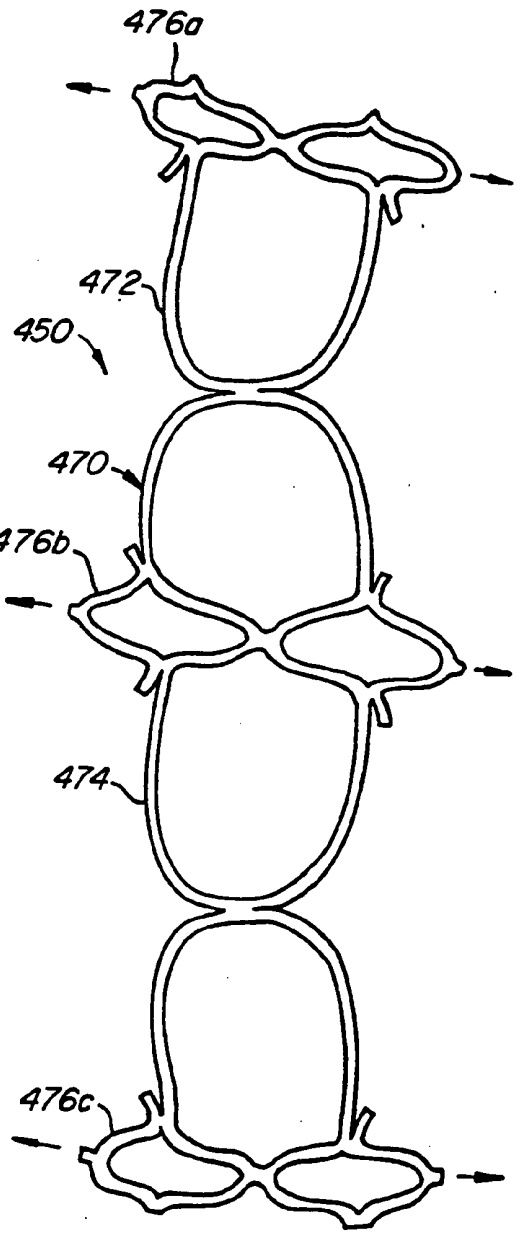



FIG. 36B

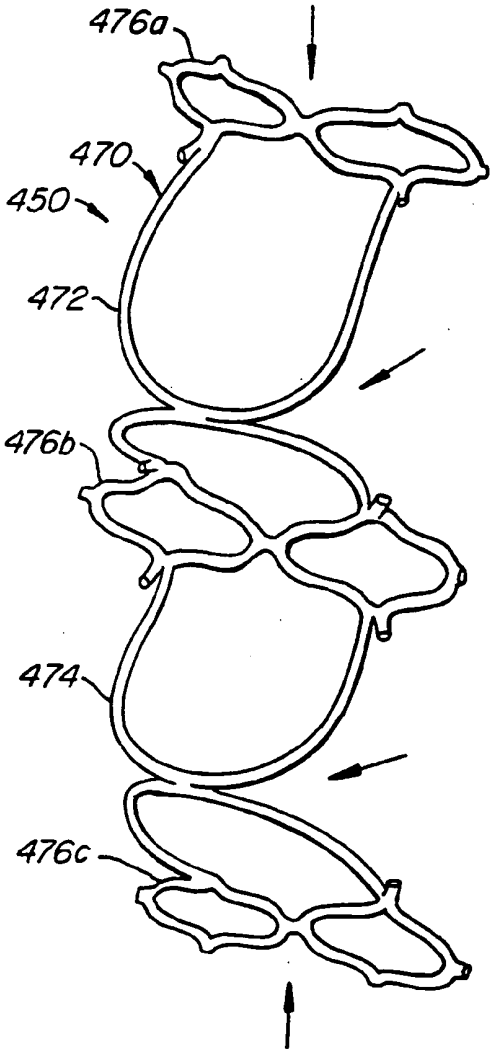



FIG. 36C

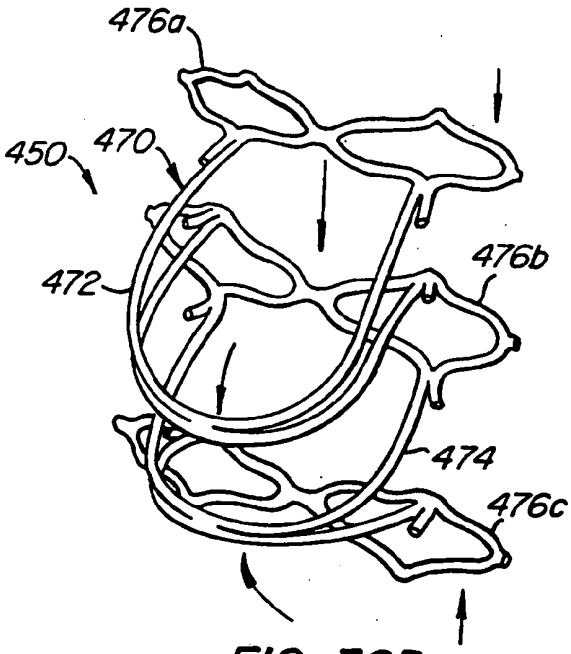



FIG. 36D

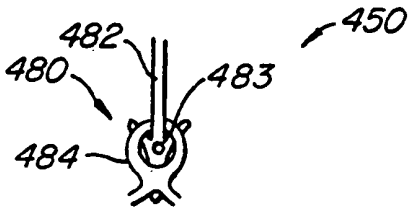



FIG. 36E

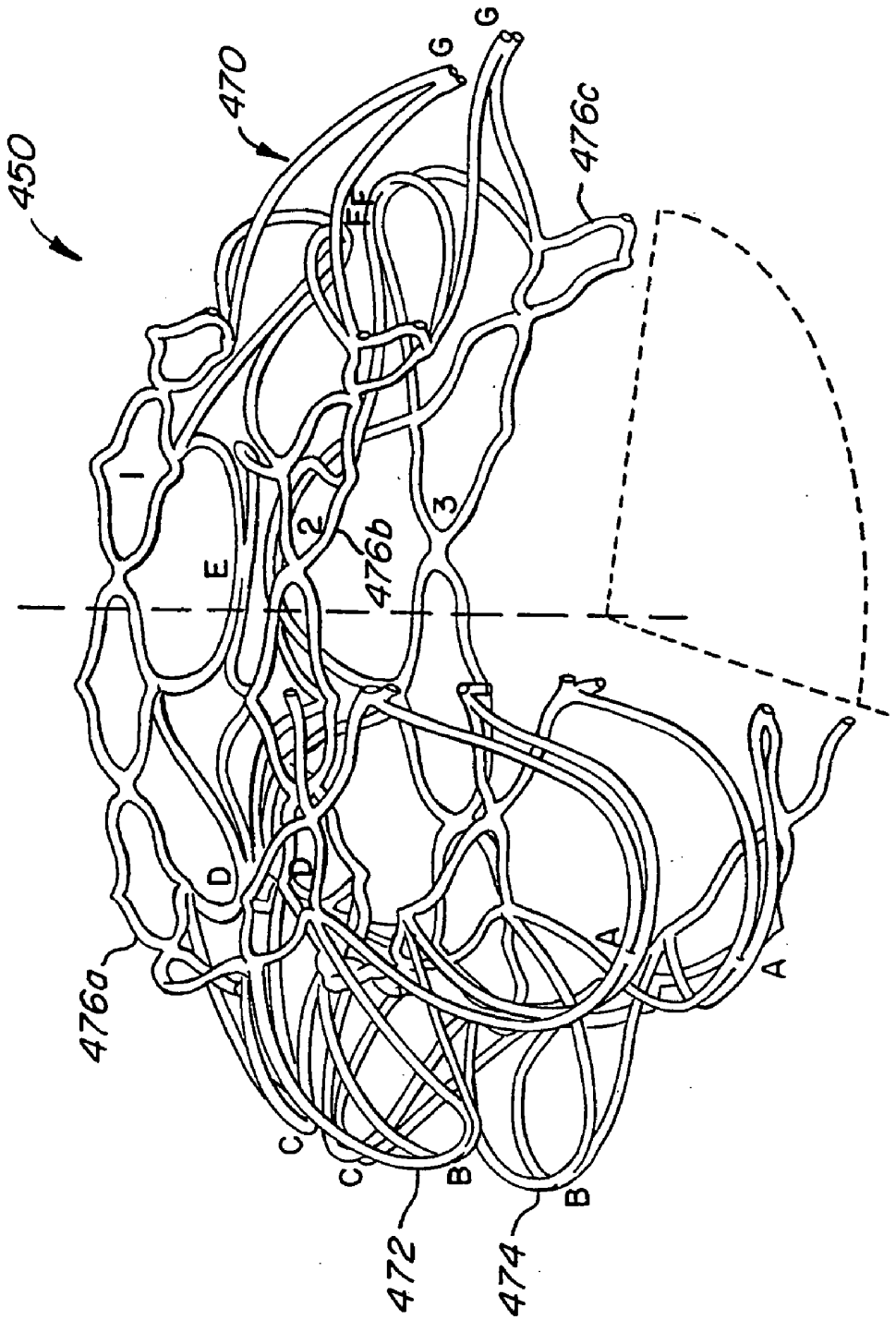



FIG. 37A

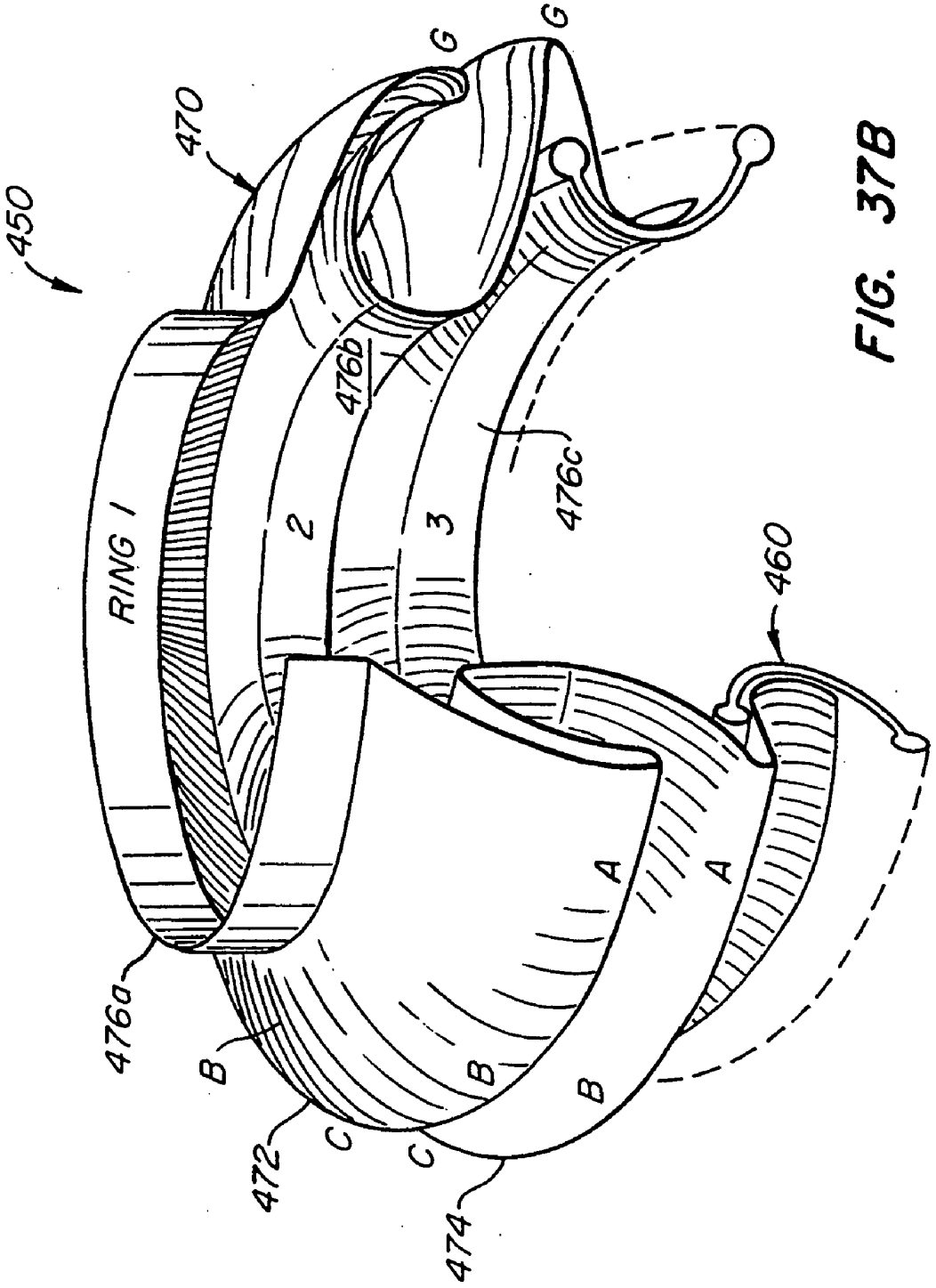
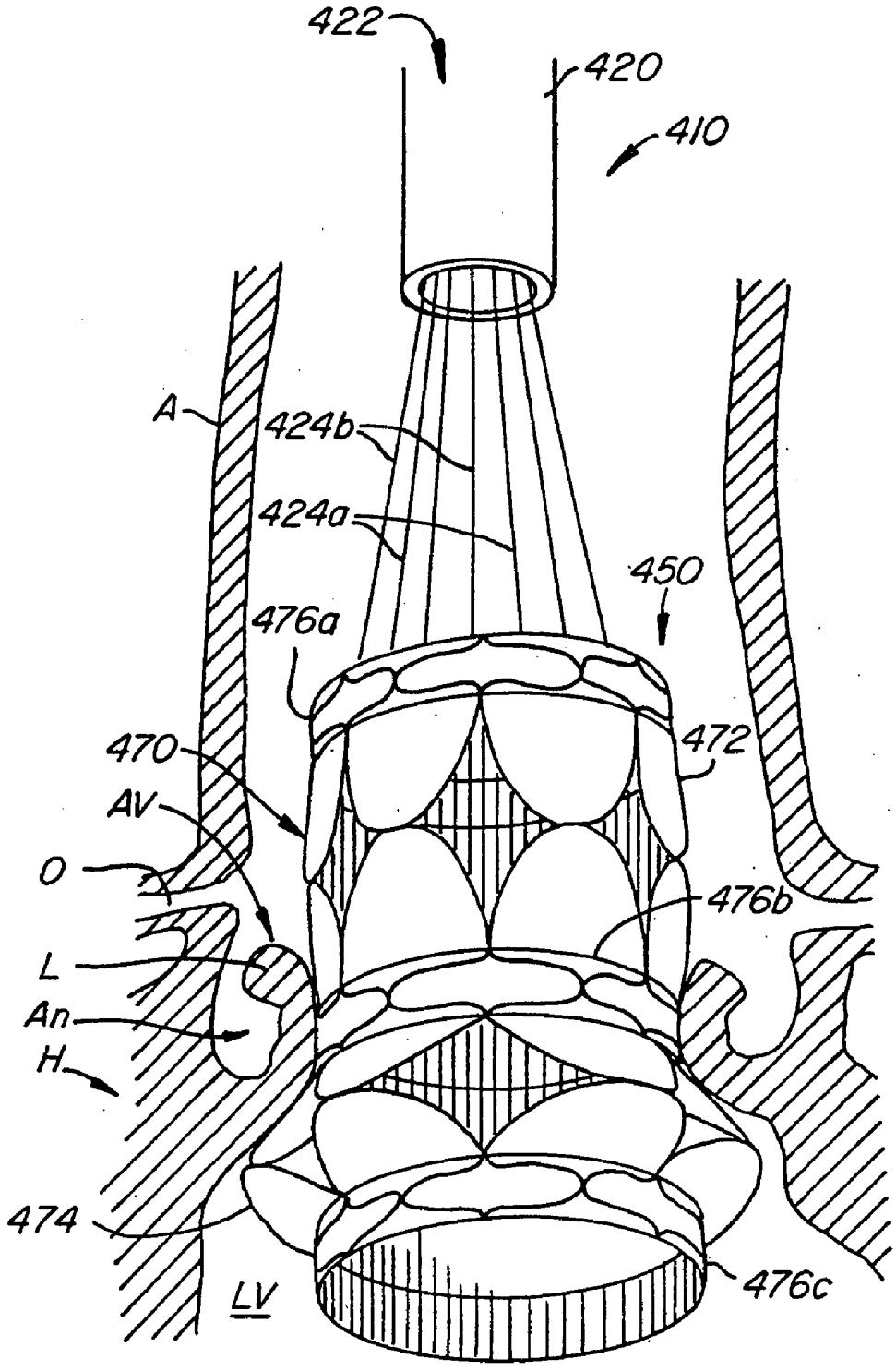



FIG. 37B


422
420
410
A
424b
424a
450
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470
AV
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476b
L
An
H
474
LV
476c

FIG. 38A

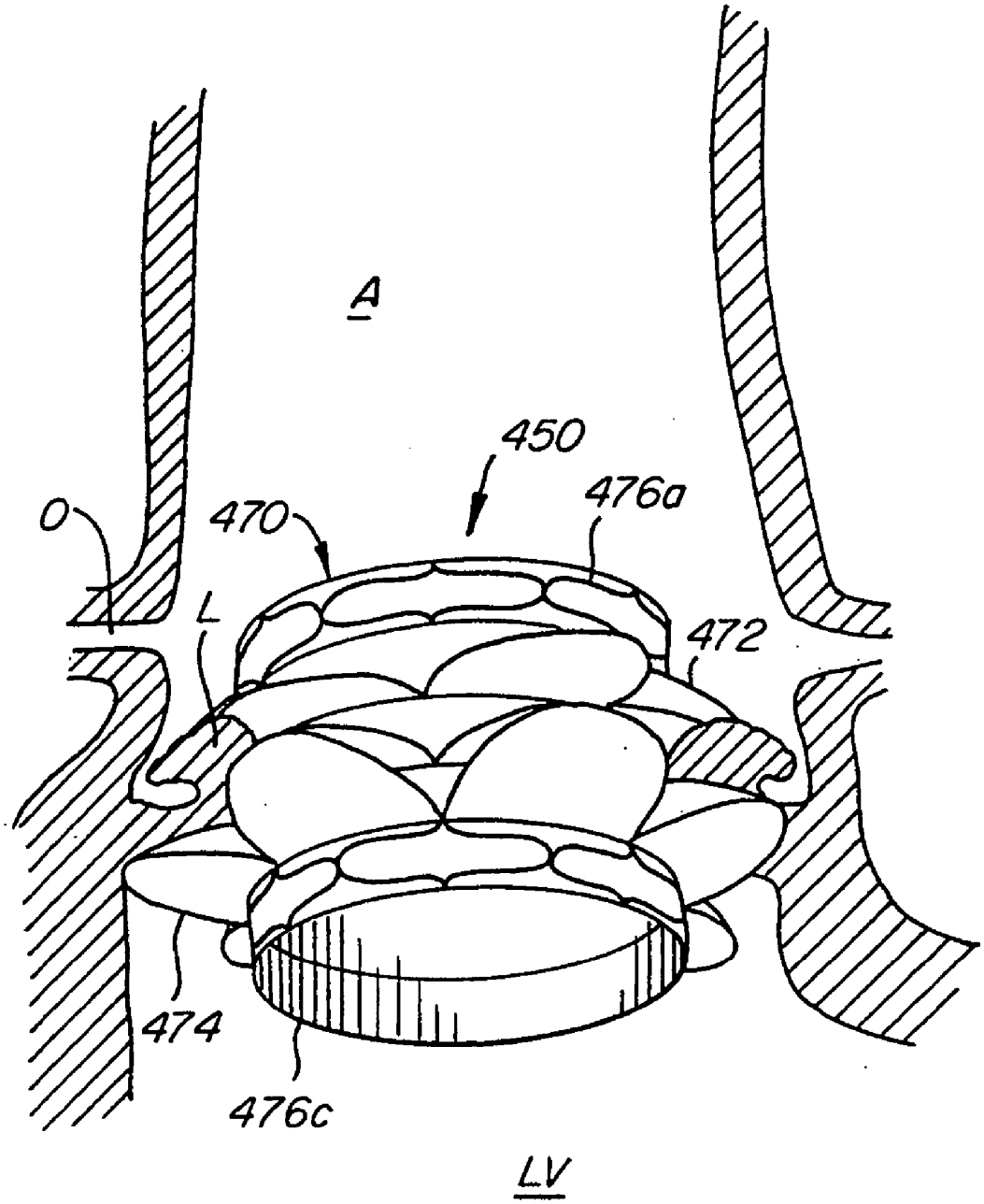



FIG. 38B

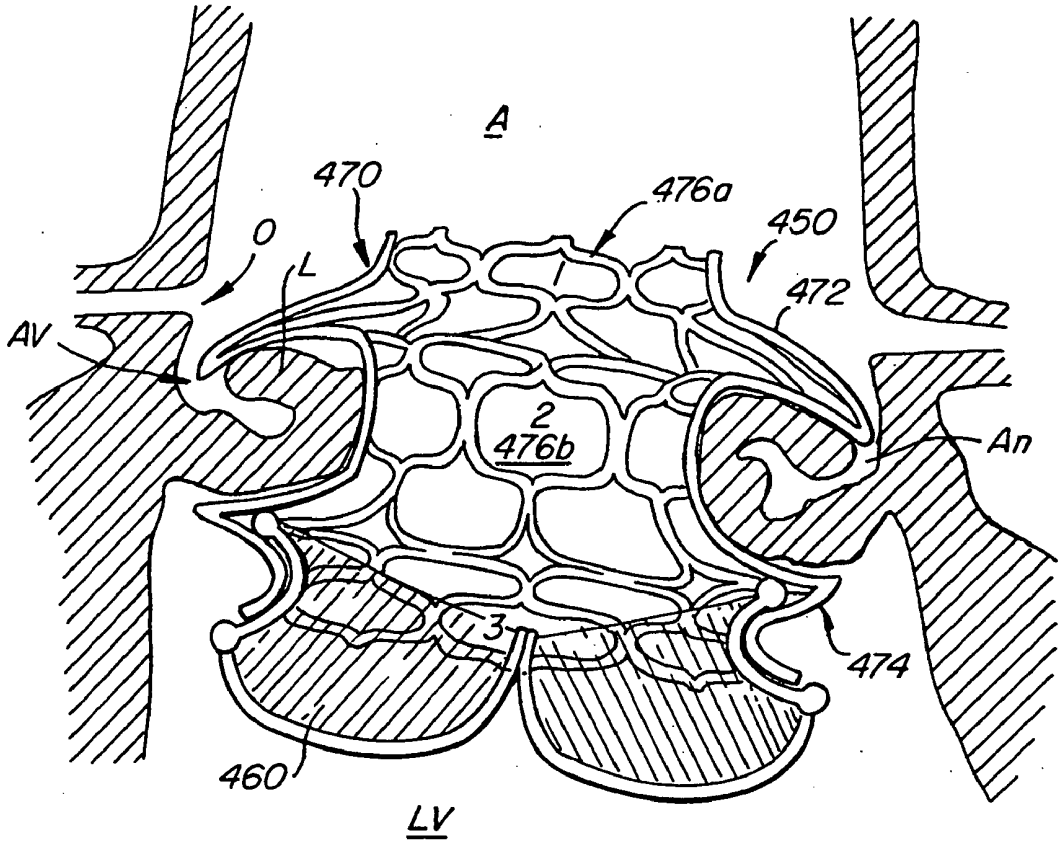



FIG. 38C

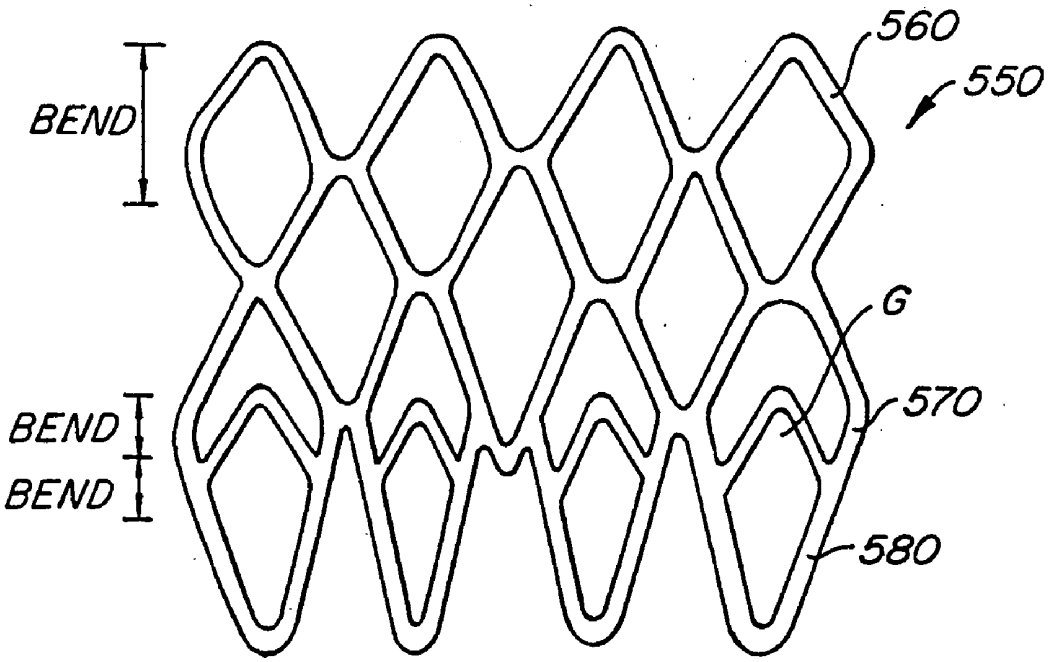



FIG. 39A

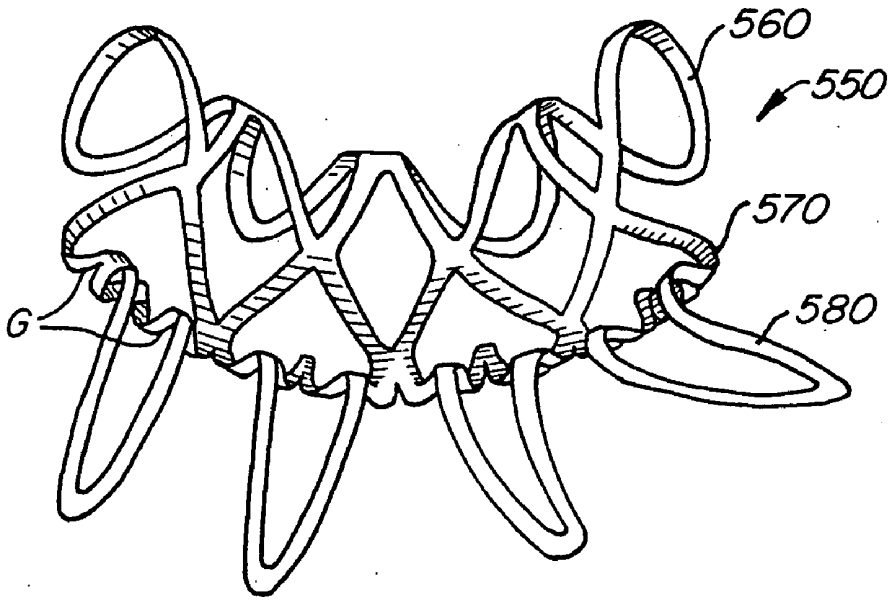



FIG. 39B

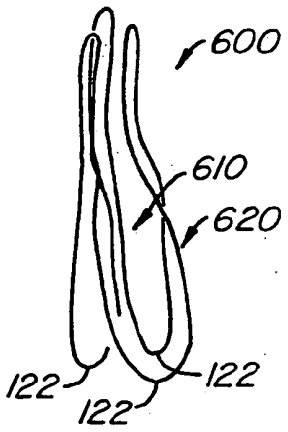



FIG. 40A

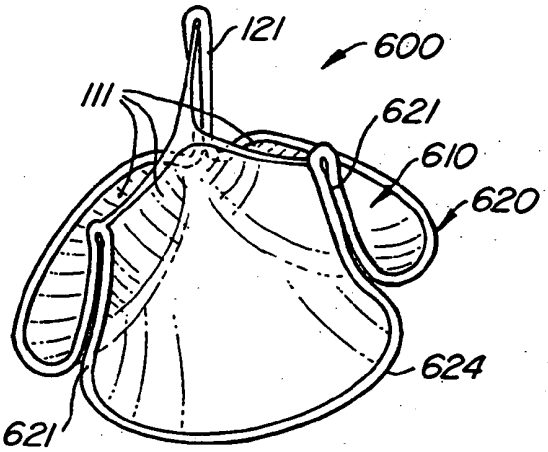
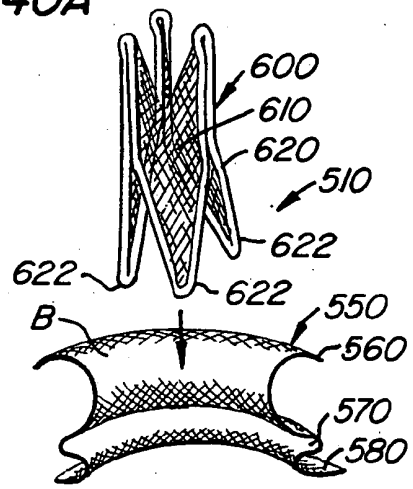



FIG. 40B

FIG. 41A



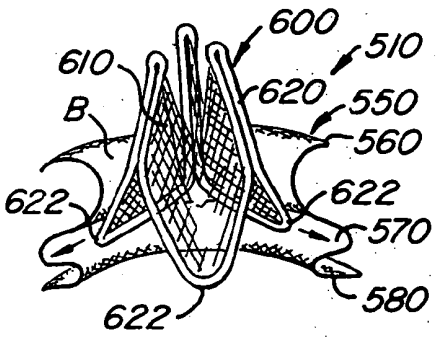




FIG. 41B

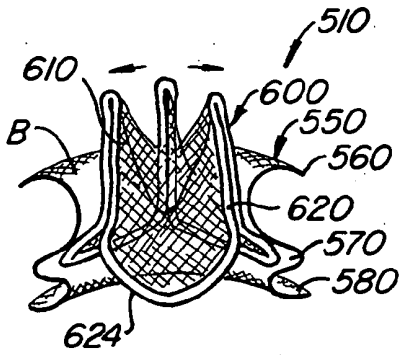



FIG. 41C

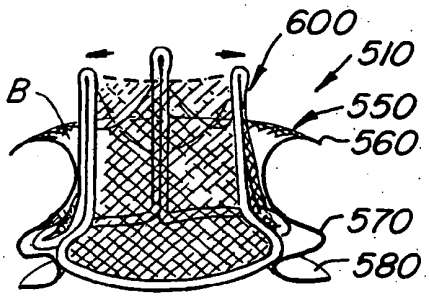



FIG. 41D

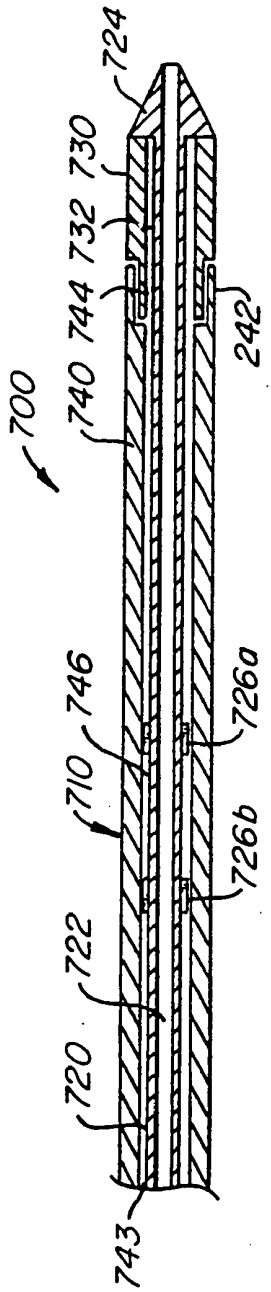



FIG. 42

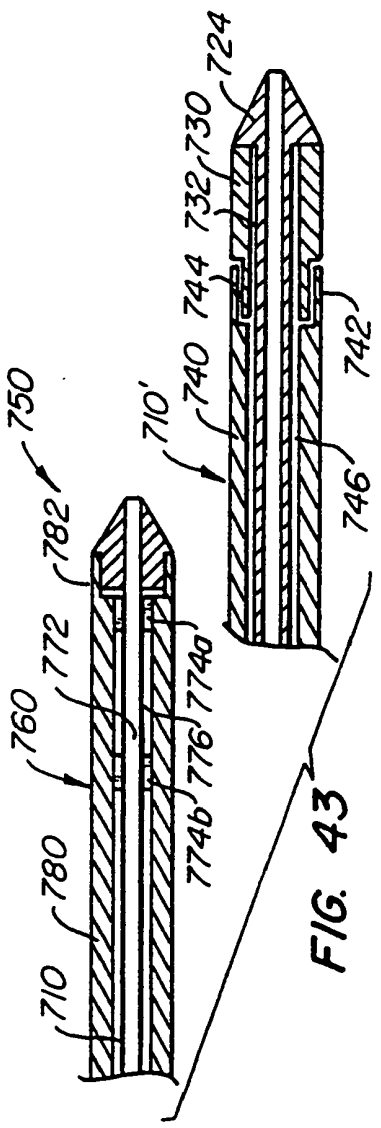



FIG. 43

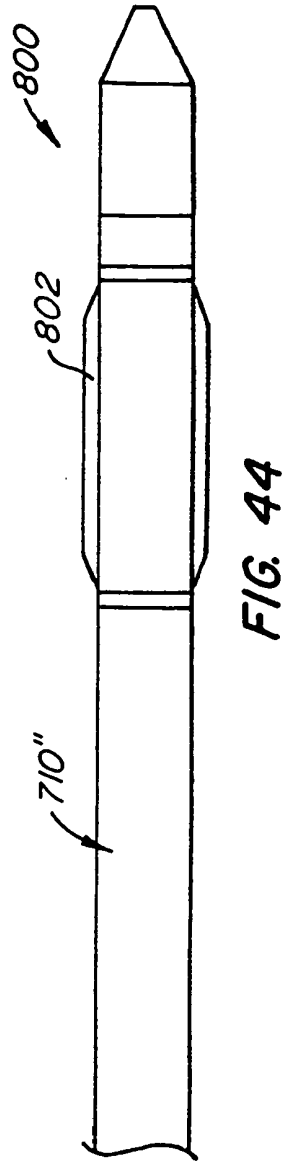



FIG. 44

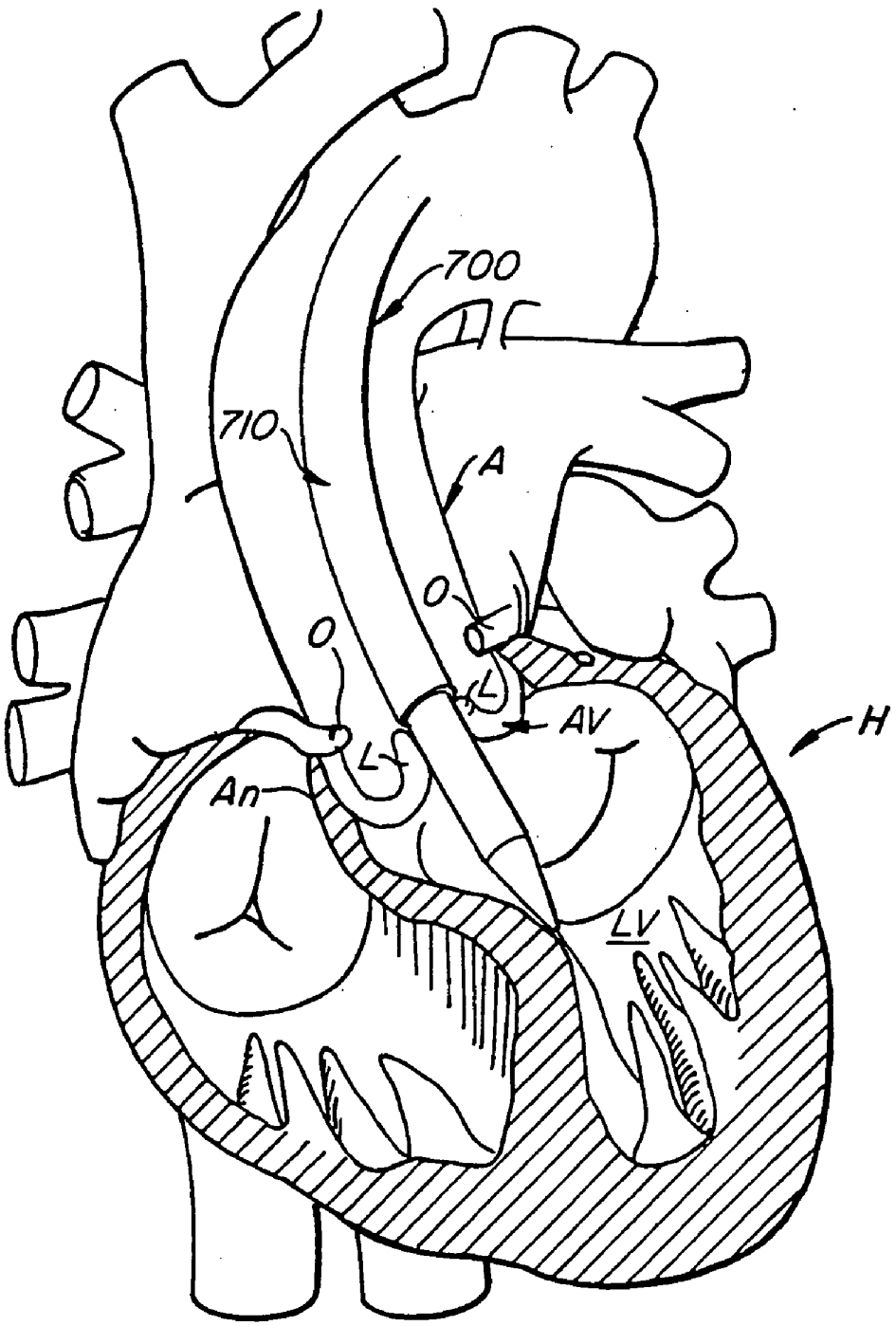



FIG. 45A

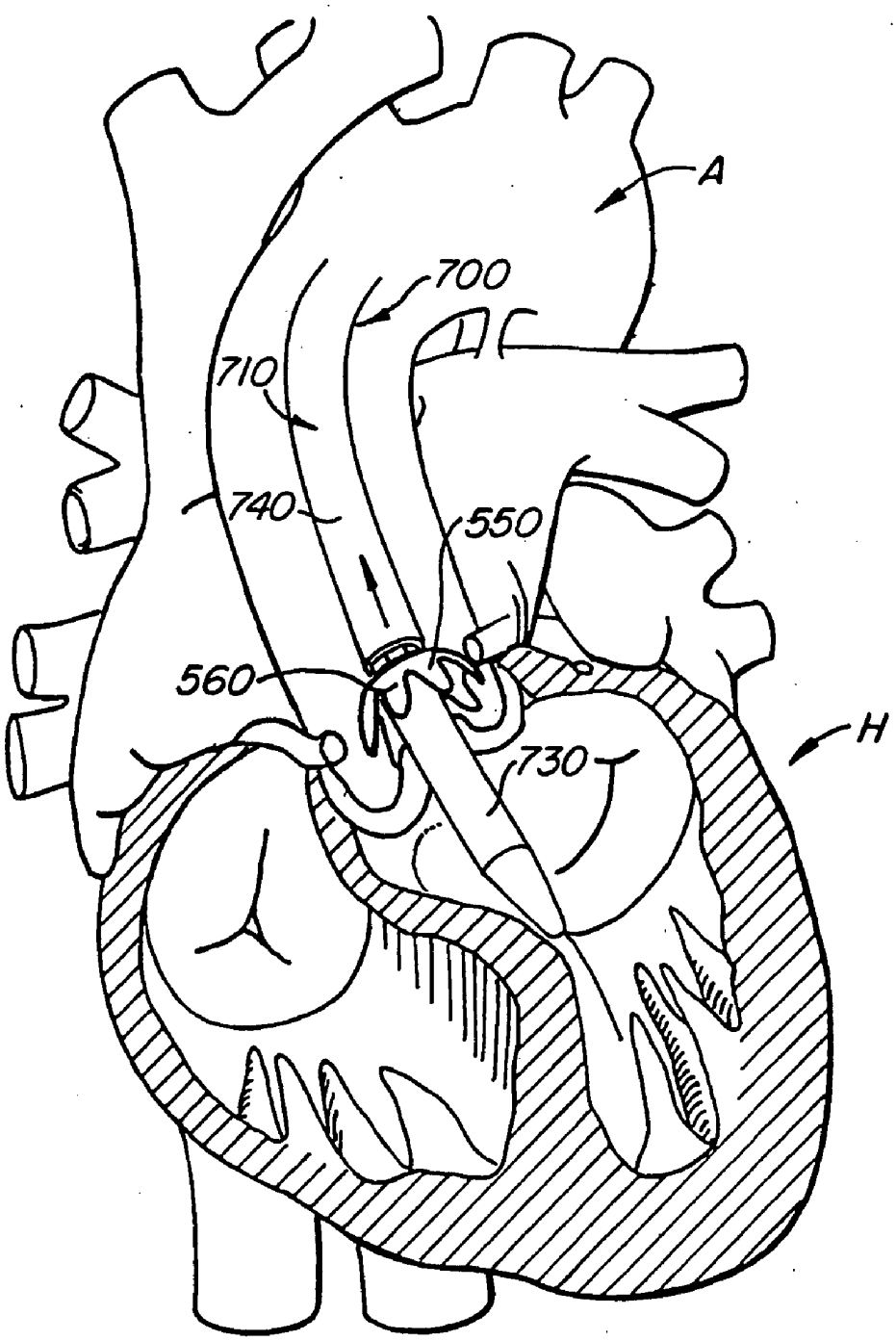



FIG. 45B

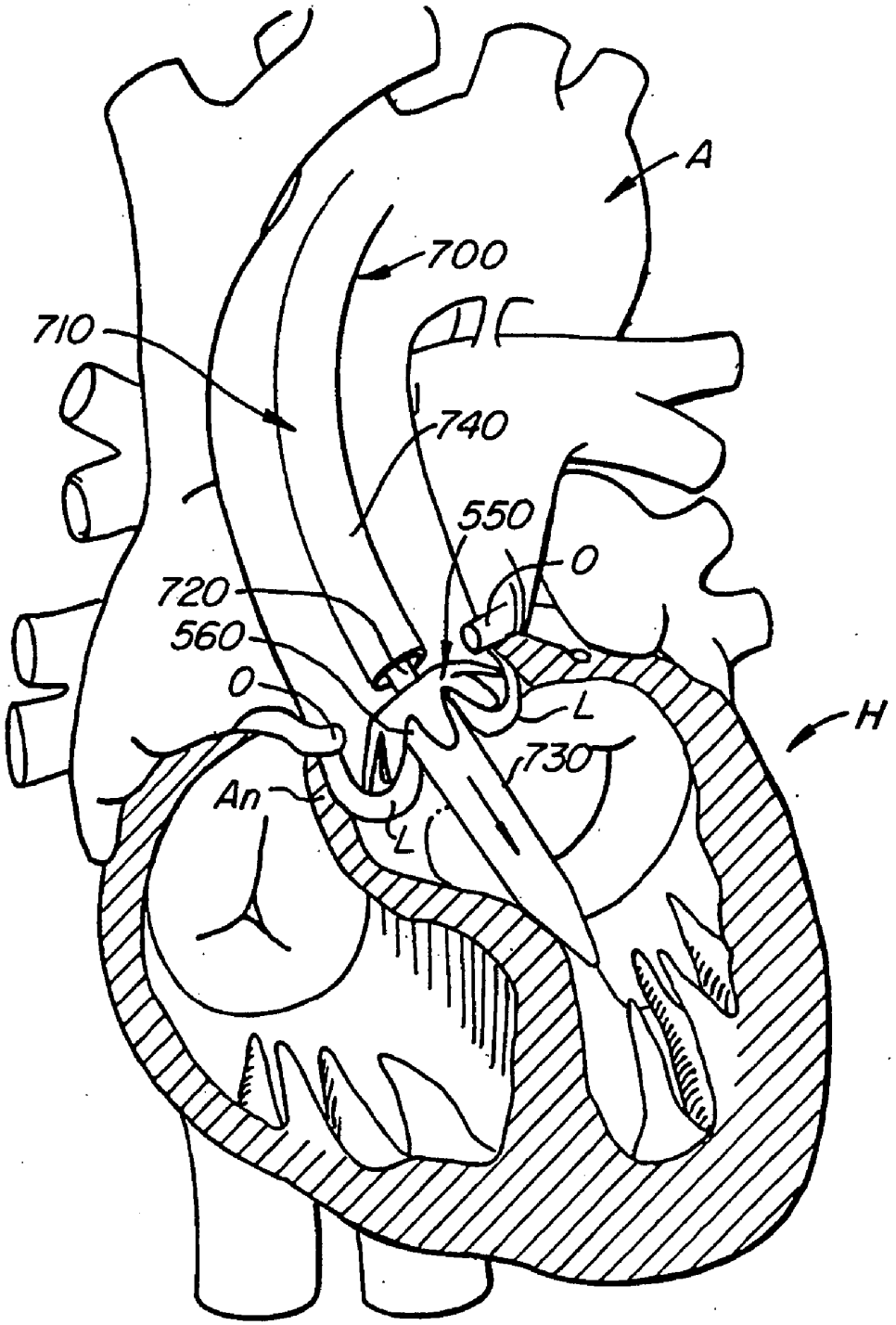



FIG. 45C

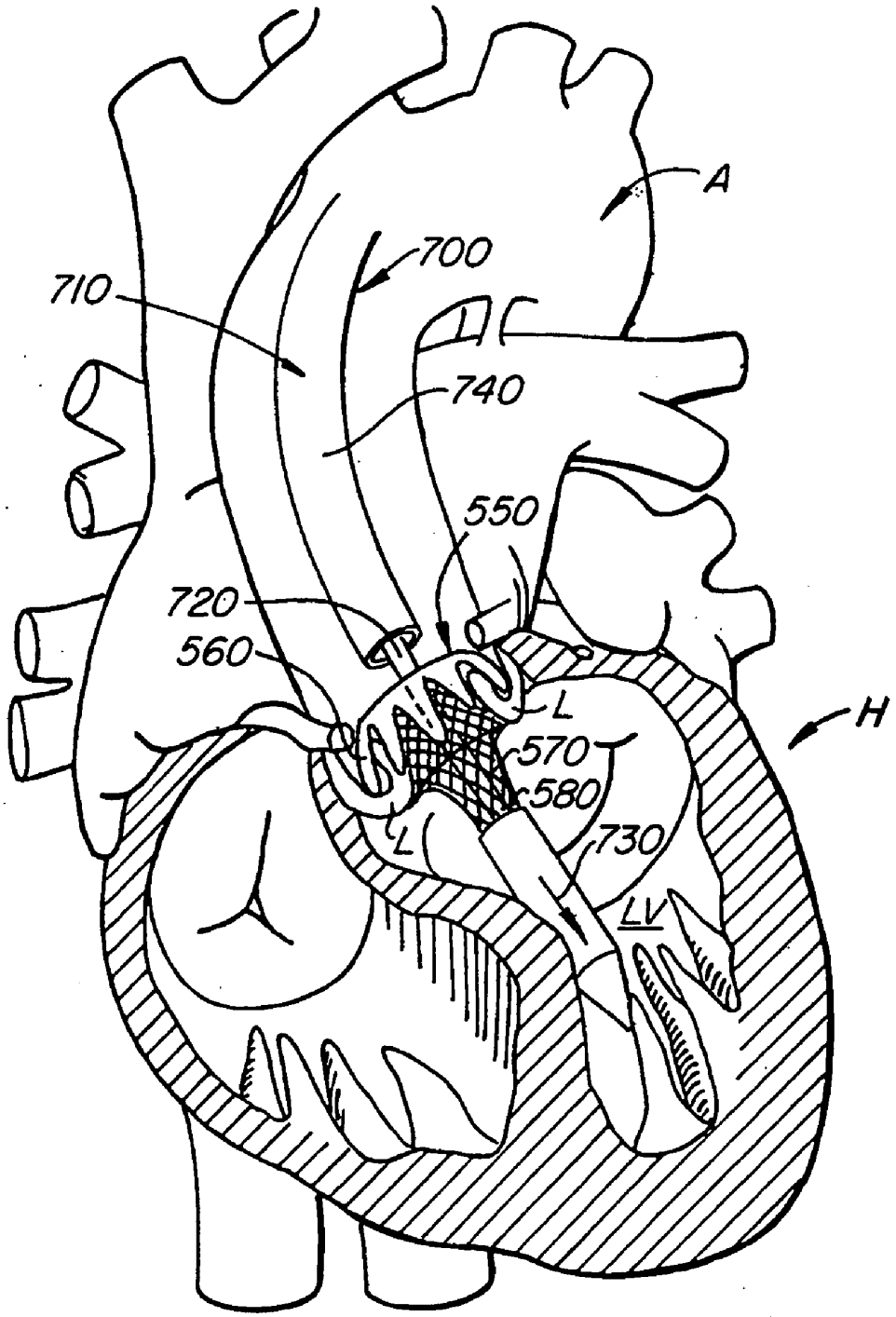



FIG. 45D

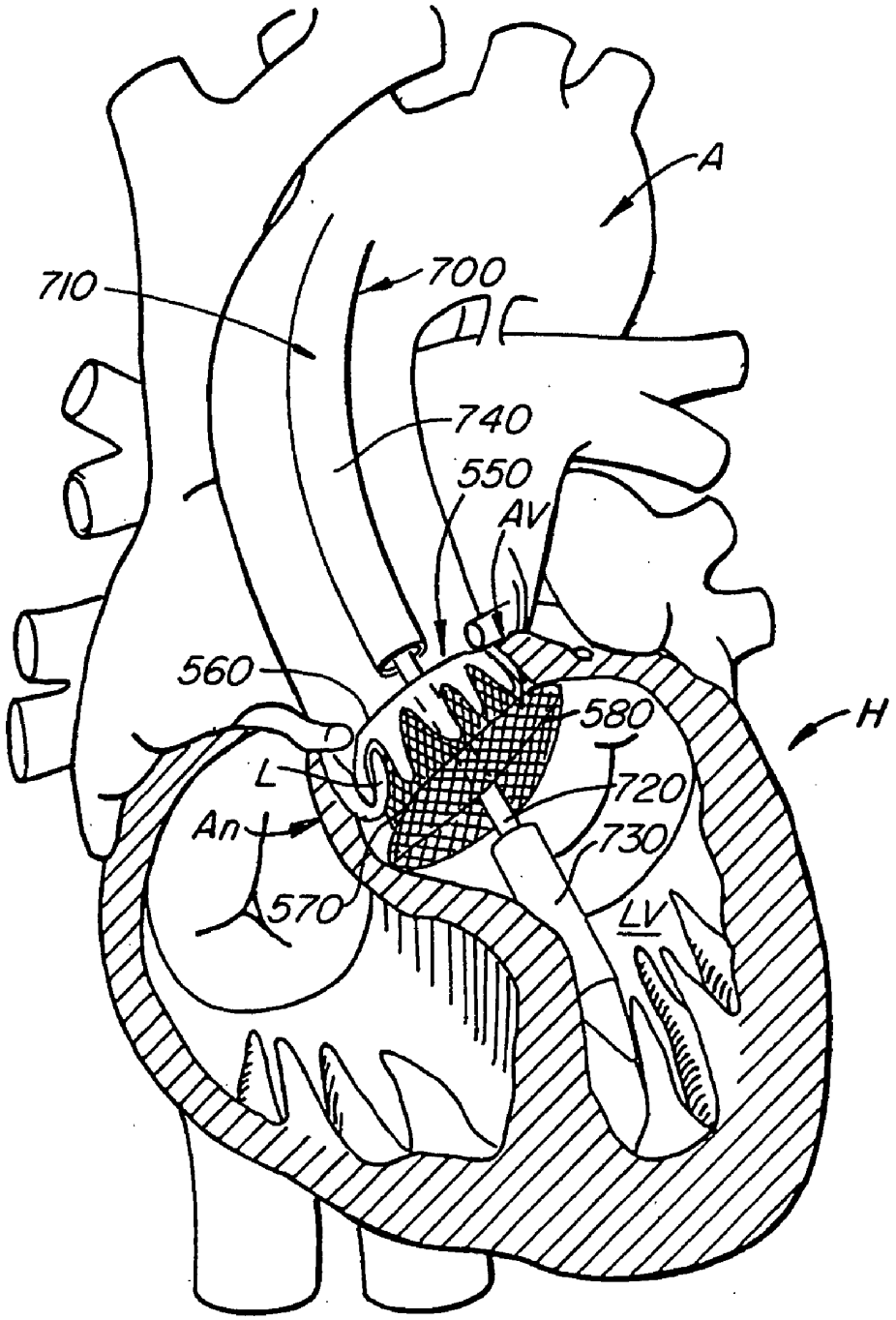



FIG. 45E

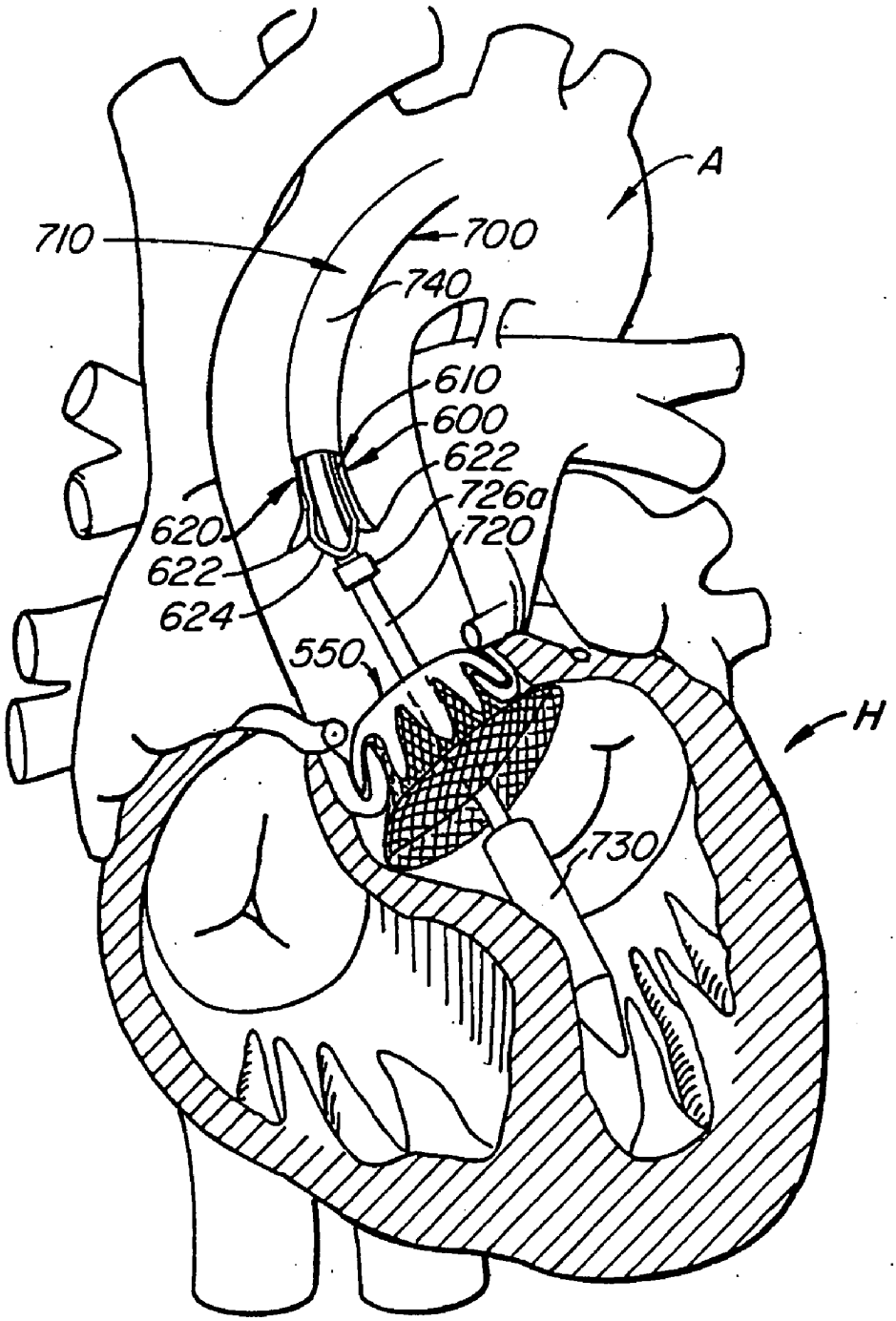



FIG. 45F

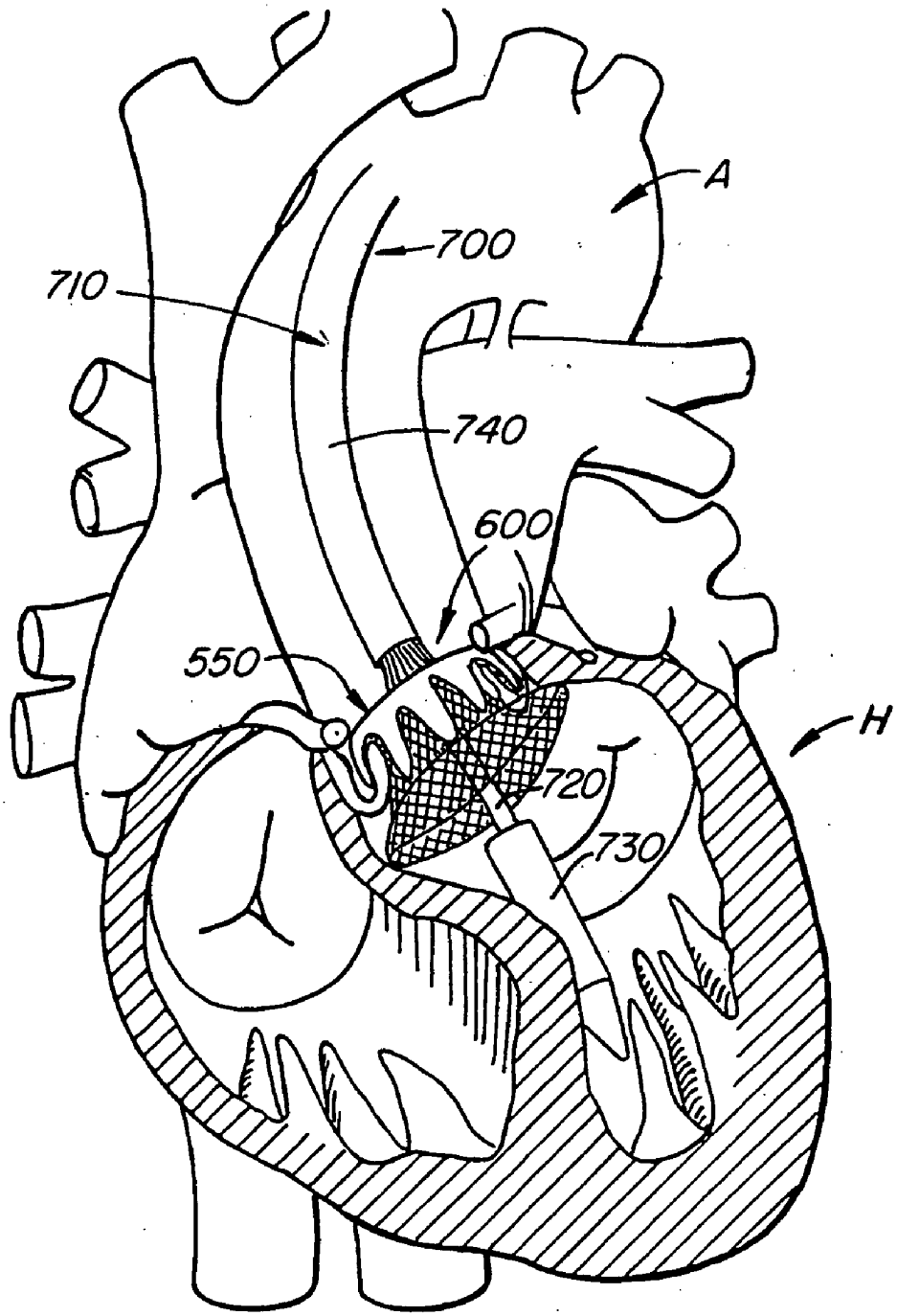



FIG. 45G

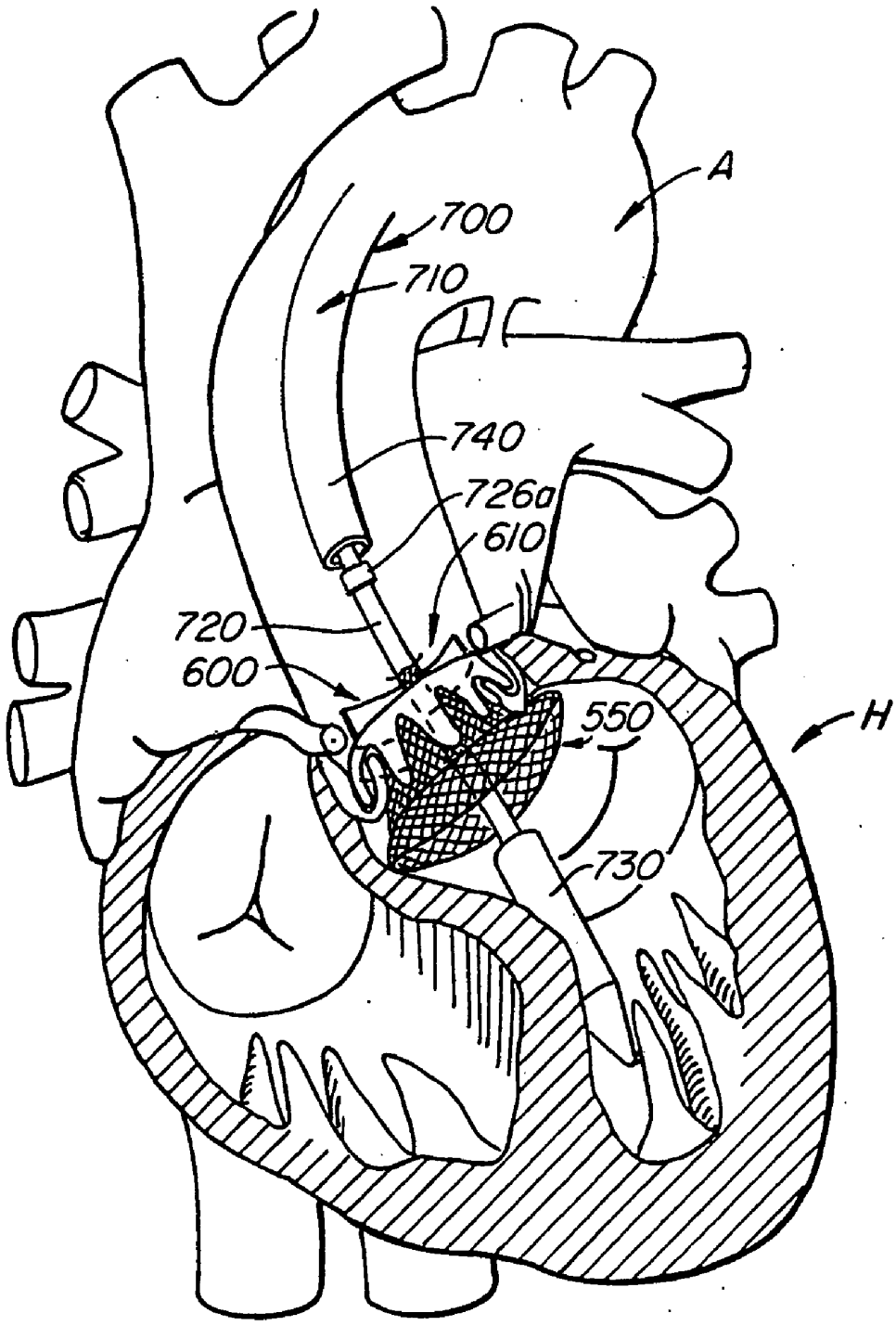



FIG. 45H

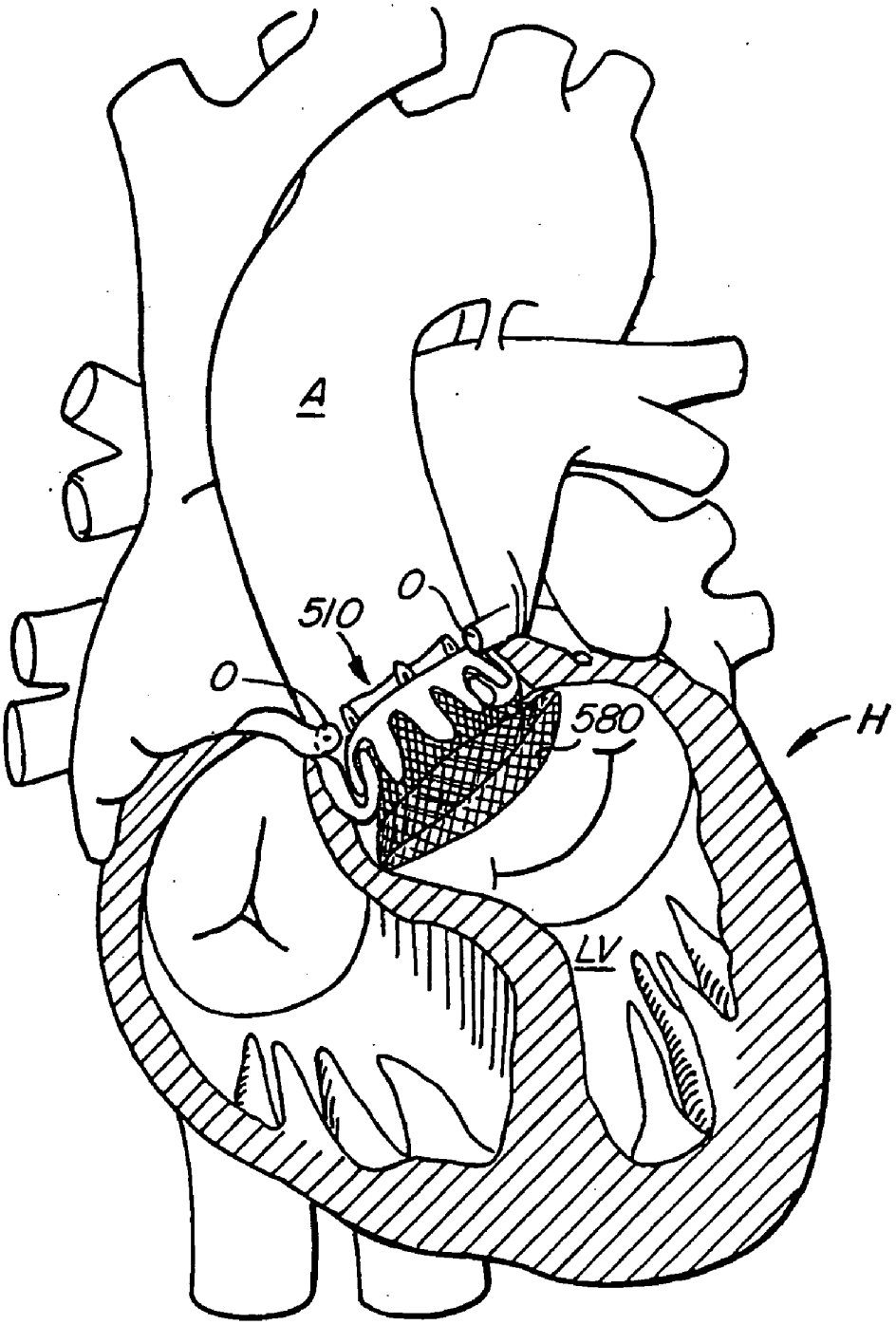



FIG. 451

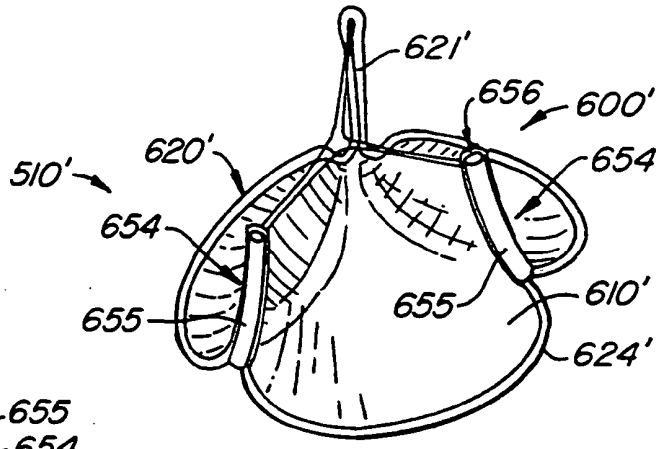



FIG. 46A

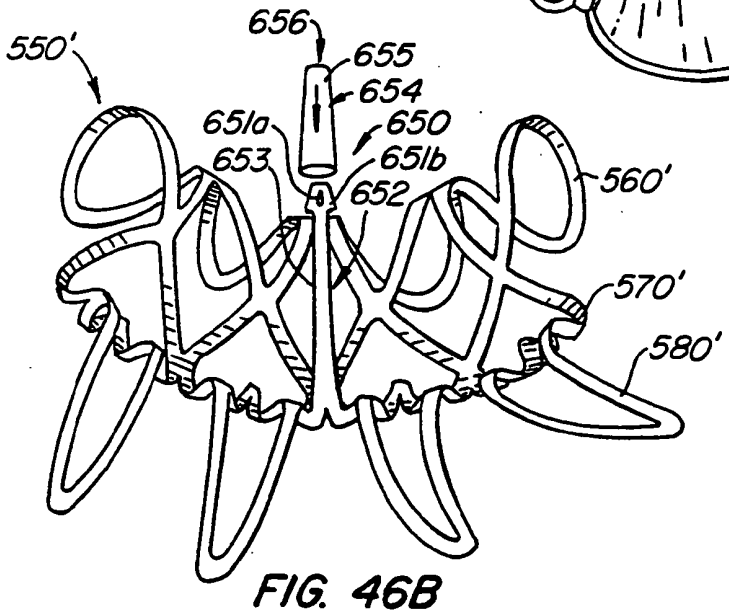



FIG. 46B

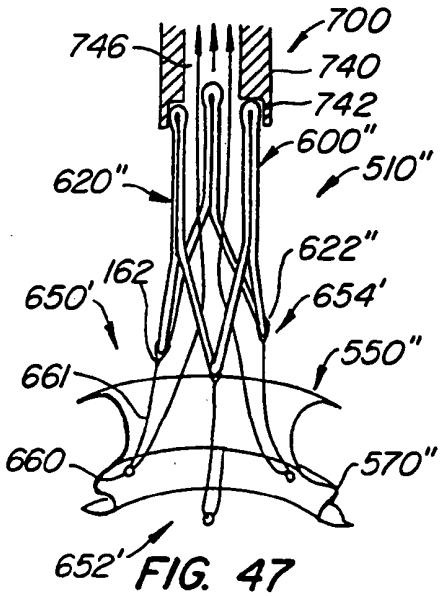



FIG. 47

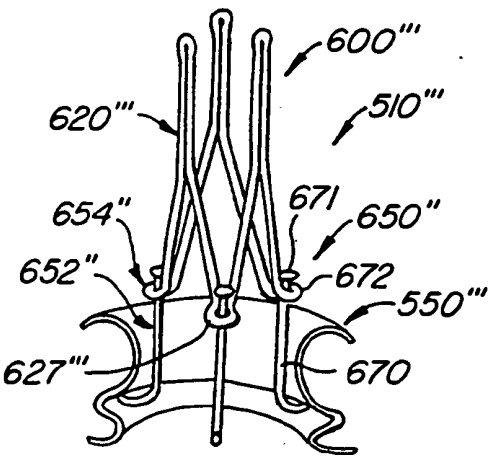



FIG. 48

# REPOSITIONABLE HEART VALVE AND METHOD

## BACKGROUND OF THE INVENTION

[0001] The present invention relates to methods and apparatus for endovascularly replacing a heart valve. More particularly, the present invention relates to methods and apparatus for percutaneously replacing a heart valve with a replacement valve using an expandable and retrievable anchor.

[0002] Heart valve surgery is used to repair or replace diseased heart valves. Valve surgery is an open-heart procedure conducted under general anesthesia. An incision is made through the patient's sternum (stemotomy), and the patient's heart is stopped while blood flow is rerouted through a heart-lung bypass machine.

[0003] Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates. When replacing the valve, the native valve is excised and replaced with either a biologic or a mechanical valve. Mechanical valves require lifelong anticoagulant medication to prevent blood clot formation, and clicking of the valve often may be heard through the chest. Biologic tissue valves typically do not require such medication. Tissue valves may be obtained from cadavers or may be porcine or bovine, and are commonly attached to synthetic rings that are secured to the patient's heart.

[0004] Valve replacement surgery is a highly invasive operation with significant concomitant risk. Risks include bleeding, infection, stroke, heart attack, arrhythmia, renal failure, adverse reactions to the anesthesia medications, as well as sudden death. 2-5% of patients die during surgery.

[0005] Post-surgery, patients temporarily may be confused due to emboli and other factors associated with the heart-lung machine. The first 2-3 days following surgery are spent in an intensive care unit where heart functions can be closely monitored. The average hospital stay is between 1 to 2 weeks, with several more weeks to months required for complete recovery.

[0006] In recent years, advancements in minimally invasive surgery and interventional cardiology have encouraged some investigators to pursue percutaneous replacement of the aortic heart valve. Percutaneous Valve Technologies ("PVT") of Fort Lee, N.J., has developed a balloon-expandable stent integrated with a bioprosthetic valve. The stent/valve device is deployed across the native diseased valve to permanently hold the valve open, thereby alleviating a need to excise the native valve and to position the bioprosthetic valve in place of the native valve. PVT's device is designed for delivery in a cardiac catheterization laboratory under local anesthesia using fluoroscopic guidance, thereby avoiding general anesthesia and open-heart surgery. The device was first implanted in a patient in April of 2002.

[0007] PVT's device suffers from several drawbacks. Deployment of PVT's stent is not reversible, and the stent is not retrievable. This is a critical drawback because improper positioning too far up towards the aorta risks blocking the coronary ostia of the patient. Furthermore, a misplaced stent/valve in the other direction (away from the aorta, closer to the ventricle) will impinge on the mitral apparatus and eventually wear through the leaflet as the leaflet continuously rubs against the edge of the stent/valve.

[0008] Another drawback of the PVT device is its relatively large cross-sectional delivery profile. The PVT system's stent/valve combination is mounted onto a delivery balloon, making retrograde delivery through the aorta challenging. An antegrade transseptal approach may therefore be needed, requiring puncture of the septum and routing through the mitral valve, which significantly increases complexity and risk of the procedure. Very few cardiologists are currently trained in performing a transseptal puncture, which is a challenging procedure by itself.

[0009] Other prior art replacement heart valves use self-expanding stents as anchors. In the endovascular aortic valve replacement procedure, accurate placement of aortic valves relative to coronary ostia and the mitral valve is critical. Standard self-expanding systems have very poor accuracy in deployment, however. Often the proximal end of the stent is not released from the delivery system until accurate placement is verified by fluoroscopy, and the stent typically jumps once released. It is therefore often impossible to know where the ends of the stent will be with respect to the native valve, the coronary ostia and the mitral valve.

[0010] Also, visualization of the way the new valve is functioning prior to final deployment is very desirable. Visualization prior to final and irreversible deployment cannot be done with standard self-expanding systems, however, and the replacement valve is often not fully functional before final deployment.

[0011] Another drawback of prior art self-expanding replacement heart valve systems is their lack of radial strength. In order for self-expanding systems to be easily delivered through a delivery sheath, the metal needs to flex and bend inside the delivery catheter without being plastically deformed. In arterial stents, this is not a challenge, and there are many commercial arterial stent systems that apply adequate radial force against the vessel wall and yet can collapse to a small enough of a diameter to fit inside a delivery catheter without plastically deforming. However when the stent has a valve fastened inside it, as is the case in aortic valve replacement, the anchoring of the stent to vessel walls is significantly challenged during diastole. The force to hold back arterial pressure and prevent blood from going back inside the ventricle during diastole will be directly transferred to the stent/vessel wall interface. Therefore the amount of radial force required to keep the self expanding stent/valve in contact with the vessel wall and not sliding will be much higher than in stents that do not have valves inside of them. Moreover, a self-expanding stent without sufficient radial force will end up dilating and contracting with each heartbeat, thereby distorting the valve, affecting its function and possibly migrating and dislodging completely. Simply increasing strut thickness of the self-expanding stent is not a practical solution as it runs the risk of larger profile and/or plastic deformation of the self-expanding stent.

[0012] U.S. patent application Ser. No. 2002/0151970 to Garrison et al. describes a two-piece device for replacement of the aortic valve that is adapted for delivery through a patient's aorta. A stent is percutaneously placed across the native valve, then a replacement valve is positioned within the lumen of the stent. By separating the stent and the valve

during delivery, a profile of the device's delivery system may be sufficiently reduced to allow aortic delivery without requiring a transseptal approach. Both the stent and a frame of the replacement valve may be balloon-expandable or self-expanding.

[0013] While providing for an aortic approach, devices described in the Garrison patent application suffer from several drawbacks. First, the stent portion of the device is delivered across the native valve as a single piece in a single step, which precludes dynamic repositioning of the stent during delivery. Stent foreshortening or migration during expansion may lead to improper alignment.

[0014] Additionally, Garrison's stent simply crushes the native valve leaflets against the heart wall and does not engage the leaflets in a manner that would provide positive registration of the device relative to the native position of the valve. This increases an immediate risk of blocking the coronary ostia, as well as a longer-term risk of migration of the device post-implantation. Furtherstill, the stent comprises openings or gaps in which the replacement valve is seated post-delivery. Tissue may protrude through these gaps, thereby increasing a risk of improper seating of the valve within the stent.

[0015] In view of drawbacks associated with previously known techniques for percutaneously replacing a heart valve, it would be desirable to provide methods and apparatus that overcome those drawbacks.

## SUMMARY OF THE INVENTION

[0016] One aspect of the invention provides a method for endovascularly replacing a heart valve of a patient. In some embodiments the method includes the steps of endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; expanding the anchor to a deployed configuration in which the anchor contacts tissue at an anchor site; repositioning the anchor in the anchor site; and deploying the anchor at the anchor site. The repositioning step may include the step of contracting the anchor and re-expanding the anchor at the anchor site for finer repositioning. The contracting step may include the step of applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

[0017] In another aspect of the invention provides a method for endovascularly replacing a heart valve of a patient. In some embodiments the method includes the steps of endovascularly or percutaneously delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; expanding the anchor to a deployed configuration in which the anchor contacts tissue at a first anchor site; repositioning the anchor to a second anchor site; and deploying the anchor at the second anchor site. The repositioning step may include the step of contracting the anchor and reexpanding the anchor at the second anchor site. The contracting step may includes the step of applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

[0018] In some embodiments the deploying step includes the step of releasing the anchor from a deployment tool. The delivering step may include the step of delivering the replacement heart valve coupled to the anchor or, alternatively, separate from the anchor, in which case the method further includes the step of attaching the replacement valve to the anchor.

[0019] In instances in which the heart valve is an aortic valve, the delivering step may include the step of endovascularly or percutaneously delivering the expandable anchor and replacement valve to the vicinity of the aortic valve along a retrograde approach.

[0020] In some embodiments the deploying step may include the step of expanding a balloon within the anchor, and in some embodiments the deploying step may include the step of locking the anchor in an expanded configuration. Proximal and distal regions of the anchor may be expanded separately.

[0021] The invention may also include the step of registering the anchor with the first or second anchor site, such as by contacting tissue of the heart valve to resist movement of the anchor in at least a proximal or a distal direction prior to deploying the anchor.

[0022] Another aspect of the invention provides a method for percutaneously replacing a heart valve of a patient. The method includes the steps of percutaneously delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; expanding the anchor to an expanded configuration in which the anchor contacts tissue at an anchor site, such as first a force of at least one pound; visually observing the anchor location; and releasing the anchor from a deployment tool. The replacement valve may be delivered coupled to the anchor or separate from the anchor, in which case the method also includes the step of attaching the valve to the anchor.

[0023] In some embodiments the method further includes the step of repositioning the anchor to a second anchor site after the observing step and before the releasing step. In some embodiments the expanding step includes the step of applying an external non-hydraulic or non-pneumatic actuation force on the anchor, and in some embodiments the method further includes the step of expanding a balloon within the anchor after the observing step. The method may include the step of registering the anchor with the anchor site.

## INCORPORATION BY REFERENCE

[0024] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0026] FIGS. 1A-B are elevational views of a replacement heart valve and anchor according to one embodiment of the invention.

[0027] FIGS. 2A-B are sectional views of the anchor and valve of **FIG. 1**.

[0028] FIGS. 3A-B show delivery and deployment of a replacement heart valve and anchor, such as the anchor and valve of **FIGS. 1 and 2**.

[0029] FIGS. 4A-E also show delivery and deployment of a replacement heart valve and anchor, such as the anchor and valve of **FIGS. 1 and 2**.

[0030] FIGS. 5A-F show the use of a replacement heart valve and anchor to replace an aortic valve.

[0031] FIGS. 6A-F show the use of a replacement heart valve and anchor with a positive registration feature to replace an aortic valve.

[0032] **FIG. 7** shows the the use of a replacement heart valve and anchor with an alternative positive registration feature to replace an aortic valve.

[0033] FIGS. 8A-C show another embodiment of a replacement heart valve and anchor according to the invention.

[0034] FIGS. 9A-H show delivery and deployment of the replacement heart valve and anchor of **FIG. 8**.

[0035] **FIG. 10** is a cross-sectional drawing of the delivery system used with the method and apparatus of **FIGS. 8 and 9**.

[0036] FIGS. 11A-C show alternative locks for use with replacement heart valves and anchors of this invention.

[0037] FIGS. 12A-C show a vessel wall engaging lock for use with replacement heart valves and anchors of this invention.

[0038] **FIG. 13** demonstrates paravalvular leaking around a replacement heart valve and anchor.

[0039] **FIG. 14** shows a seal for use with a replacement heart valve and anchor of this invention.

[0040] FIGS. 15A-E show alternative arrangements of seals on a replacement heart valve and anchor.

[0041] FIGS. 16A-C show alternative seal designs for use with replacement heart valves and anchors.

[0042] **FIG. 17** shows an alternative anchor lock embodiment in an unlocked configuration.

[0043] **FIG. 18** shows the anchor lock of **FIG. 17** in a locked configuration.

[0044] **FIG. 19** shows an alternative anchor deployment tool attachment and release mechanism for use with the invention.

[0045] **FIG. 20** shows the attachment and release mechanism of **FIG. 19** in the process of being released.

[0046] **FIG. 21** shows the attachment and release mechanism of **FIGS. 19 and 20** in a released condition.

[0047] **FIG. 22** shows an alternative embodiment of a replacement heart valve and anchor and a deployment tool according to the invention in an undeployed configuration.

[0048] **FIG. 23** shows the replacement heart valve and anchor of **FIG. 22** in a partially deployed configuration.

[0049] **FIG. 24** shows the replacement heart valve and anchor of **FIGS. 22 and 23** in a more fully deployed configuration but with the deployment tool still attached.

[0050] **FIG. 25** shows yet another embodiment of the delivery and deployment apparatus of the invention in use with a replacement heart valve and anchor.

[0051] **FIG. 26** shows the delivery and deployment apparatus of **FIG. 25** in the process of deploying a replacement heart valve and anchor.

[0052] **FIG. 27** show an embodiment of the invention employing seals at the interface of the replacement heart valve and anchor and the patient's tissue.

[0053] **FIG. 28** is a longitudinal cross-sectional view of the seal shown in **FIG. 27** in compressed form.

[0054] **FIG. 29** is a transverse cross-sectional view of the seal shown in **FIG. 28**.

[0055] **FIG. 30** is a longitudinal cross-sectional view of the seal shown in **FIG. 27** in expanded form.

[0056] **FIG. 31** is a transverse cross-sectional view of the seal shown in **FIG. 30**.

[0057] **FIG. 32** shows yet another embodiment of the replacement heart valve and anchor of this invention in an undeployed configuration.

[0058] **FIG. 33** shows the replacement heart valve and anchor of **FIG. 32** in a deployed configuration.

[0059] **FIG. 34** shows the replacement heart valve and anchor of **FIGS. 32 and 33** deployed in a patient's heart valve.

[0060] FIGS. 35A-H show yet another embodiment of a replacement heart valve, anchor and deployment system according to this invention.

[0061] FIGS. 36A-E show more detail of the anchor of the embodiment shown in FIGS. 35A-H.

[0062] FIGS. 37A-B show other embodiments of the replacement heart valve and anchor of the invention.

[0063] FIGS. 38A-C illustrate a method for percutaneously replacing a patient's diseased heart valve.

[0064] FIGS. 39A-B show an anchor for use in a two-piece replacement heart valve and anchor embodiment of the invention.

[0065] FIGS. 40A-B show a replacement heart valve for use in in a two-piece replacement heart valve and anchor embodiment of the invention.

[0066] FIGS. 41A-D show a method of coupling the anchor of **FIG. 39** and the replacement heart valve of **FIG. 40**.

[0067] **FIG. 42** shows a delivery system for use with the appartus shown in **FIGS. 39-41**.

[0068] **FIG. 43** shows an alternative embodiment of a delivery system for use with the apparatus shown in **FIGS. 39-41**.

[0069] **FIG. 44** shows yet another alternative embodiment of a delivery system for use with the apparatus shown in **FIGS. 39-41**.

[0070] FIGS. **45**A-I illustrate a method of deliverying and deploying a two-piece replacement heart valve and anchor.

[0071] FIGS. **46**A-B shows another embodiment of a two-piece replacement heart valve and anchor according to this invention.

[0072] **FIG. 47** shows yet another embodiment of a two-piece replacement heart valve and anchor according to this invention.

[0073] **FIG. 48** shows yet another embodiment of a two-piece replacement heart valve and anchor according to this invention.

## DETAILED DESCRIPTION OF THE INVENTION

[0074] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

[0075] With reference now to **FIGS. 1-4**, a first embodiment of replacement heart valve apparatus in accordance with the present invention is described, including a method of actively foreshortening and expanding the apparatus from a delivery configuration and to a deployed configuration. Apparatus **10** comprises replacement valve **20** disposed within and coupled to anchor **30**. **FIG. 1** schematically illustrate individual cells of anchor **30** of apparatus **10**, and should be viewed as if the cylindrical anchor has been cut open and laid flat. **FIG. 2** schematically illustrate a detail portion of apparatus **10** in side-section.

[0076] Anchor **30** has a lip region **32**, a skirt region **34** and a body region **36**. First, second and third posts **38***a*, **38***b* and **38***c*, respectively, are coupled to skirt region **34** and extend within lumen **31** of anchor **30**. Posts **38** preferably are spaced 120° apart from one another about the circumference of anchor **30**.

[0077] Anchor **30** preferably is fabricated by using self-expanding patterns (laser cut or chemically milled), braids and materials, such as a stainless steel, nickel-titanium ("Nitinol") or cobalt chromium but alternatively may be fabricated using balloon-expandable patterns where the anchor is designed to plastically deform to it's final shape by means of balloon expansion. Replacement valve **20** is preferably from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues, alternatively it can be made from tissue engineered materials (such as extracellular matrix material from Small Intestinal Submucosa (SIS)) but alternatively may be prosthetic from an elastomeric polymer or silicone, Nitinol or stainless steel mesh or pattern (sputtered, chemically milled or laser cut). The leaflet may also be made of a composite of the elastomeric or silicone materials and metal alloys or other fibers such Kevlar or carbon. Annular base **22** of replacement valve **20** preferably is coupled to skirt region **34** of anchor **30**, while commissures **24** of replacement valve leaflets **26** are coupled to posts **38**.

[0078] Anchor **30** may be actuated using external non-hydraulic or non-pneumatic force to actively foreshorten in order to increase its radial strength. As shown below, the proximal and distal end regions of anchor **30** may be actuated independently. The anchor and valve may be placed and expanded in order to visualize their location with respect to the native valve and other anatomical features and to visualize operation of the valve. The anchor and valve may thereafter be repositioned and even retrieved into the delivery sheath or catheter. The apparatus may be delivered to the vicinity of the patient's aortic valve in a retrograde approach in a catheter having a diameter no more than 23 french, preferably no more than 21 french, more preferably no more than 19 french, or more preferably no more than 17 french. Upon deployment the anchor and replacement valve capture the native valve leaflets and positively lock to maintain configuration and position.

[0079] A deployment tool is used to actuate, reposition, lock and/or retrieve anchor **30**. In order to avoid delivery of anchor **30** on a balloon for balloon expansion, a non-hydraulic or non-pneumatic anchor actuator is used. In this embodiment, the actuator is a deployment tool that includes distal region control wires **50**, control rods or tubes **60** and proximal region control wires **62**. Locks **40** include posts or arms **38** preferably with male interlocking elements **44** extending from skirt region **34** and mating female interlocking elements **42** in lip region **32**. Male interlocking elements **44** have eyelets **45**. Control wires **50** pass from a delivery system for apparatus **10** through female interlocking elements **42**, through eyelets **45** of male interlocking elements **44**, and back through female interlocking elements **42**, such that a double strand of wire **50** passes through each female interlocking element **42** for manipulation by a medical practitioner external to the patient to actuate and control the anchor by changing the anchor's shape. Control wires **50** may comprise, for example, strands of suture.

[0080] Tubes **60** are reversibly coupled to apparatus **10** and may be used in conjunction with wires **50** to actuate anchor **30**, e.g., to foreshorten and lock apparatus **10** in the fully deployed configuration. Tubes **60** also facilitate repositioning and retrieval of apparatus **10**, as described hereinafter. For example, anchor **30** may be foreshortened and radially expanded by applying a distally directed force on tubes **60** while proximally retracting wires **50**. As seen in **FIG. 3**, control wires **62** pass through interior lumens **61** of tubes **60**. This ensures that tubes **60** are aligned properly with apparatus **10** during deployment and foreshortening. Control wires **62** can also actuate anchor **60**; proximally directed forces on control wires **62** contacts the proximal lip region **32** of anchor **30**. Wires **62** also act to couple and decouple tubes **60** from apparatus **10**. Wires **62** may comprise, for example, strands of suture.

[0081] **FIGS. 1A and 2A** illustrate anchor **30** in a delivery configuration or in a partially deployed configuration (e.g., after dynamic self-expansion expansion from a constrained delivery configuration within a delivery sheath). Anchor **30** has a relatively long length and a relatively small width in the delivery or partially deployed configuration, as compared to the foreshortened and fully deployed configuration of **FIGS. 1B and 2B**.

[0082] In **FIGS. 1A and 2A**, replacement valve **20** is collapsed within lumen **31** of anchor **30**. Retraction of wires **50** relative to tubes **60** foreshortens anchor **30**, which increases the anchor's width while decreasing its length. Such foreshortening also properly seats replacement valve **20** within lumen **31** of anchor **30**. Imposed foreshortening will enhance radial force applied by apparatus **10** to surrounding tissue over at least a portion of anchor **30**. In some embodiments, the anchor exerts an outward force on surrounding tissue to engage the tissue in such way to prevent migration of anchor caused by force of blood against closed leaflet during diastole. This anchoring force is preferably 1 to 2 lbs., more preferably 2 to 4 lbs., or more preferably 4 to 10 lbs. In some embodiments, the anchoring force is preferably greater than 1 pound, more preferably greater than 2 pounds, or more preferably greater than 4 pounds. Enhanced radial force of the anchor is also important for enhanced crush resistance of the anchor against the surrounding tissue due to the healing response (fibrosis and contraction of annulus over a longer period of time) or to dynamic changes of pressure and flow at each heart beat In an alternative embodiment, the anchor pattern or braid is designed to have gaps or areas where the native tissue is allowed to protrude through the anchor slightly (not shown) and as the foreshortening is applied, the tissue is trapped in the anchor. This feature would provide additional means to prevent anchor migration and enhance long term stability of the device.

[0083] Deployment of apparatus **10** is fully reversible until lock **40** has been locked via mating of male interlocking elements **44** with female interlocking elements **42**. Deployment is then completed by decoupling tubes **60** from lip section **32** of anchor **30** by retracting one end of each wire **62** relative to the other end of the wire, and by retracting one end of each wire **50** relative to the other end of the wire until each wire has been removed from eyelet **45** of its corresponding male interlocking element **44**.

[0084] As best seen in **FIG. 2B**, body region **36** of anchor **30** optionally may comprise barb elements **37** that protrude from anchor **30** in the fully deployed configuration, for example, for engagement of a patient's native valve leaflets and to preclude migration of the apparatus.

[0085] With reference now to **FIG. 3**, a delivery and deployment system for a self-expanding embodiment of apparatus **10** including a sheath **110** having a lumen **112**. Self-expanding anchor **30** is collapsible to a delivery configuration within lumen **112** of sheath **110**, such that apparatus **10** may be delivered via delivery system **100**. As seen in **FIG. 3A**, apparatus **10** may be deployed from lumen **112** by retracting sheath **110** relative to apparatus **10**, control wires **50** and tubes **60**, which causes anchor **30** to dynamically self-expand to a partially deployed configuration. Control wires **50** then are retracted relative to apparatus **10** and tubes **60** to impose foreshortening upon anchor **30**, as seen in **FIG. 3B**.

[0086] During foreshortening, tubes **60** push against lip region **32** of anchor **30**, while wires **50** pull on posts **38** of the anchor. Wires **62** may be retracted along with wires **50** to enhance the distally-directed pushing force applied by tubes **60** to lip region **32**. Continued retraction of wires **50** relative to tubes **60** would lock locks **40** and fully deploy apparatus **10** with replacement valve **20** properly seated within anchor **30**, as in **FIGS. 1B and 2B**. Apparatus **10** comprises enhanced radial strength in the fully deployed configuration as compared to the partially deployed configuration of **FIG. 3A**. Once apparatus **10** has been fully deployed, wires **50** and **62** may be removed from apparatus **10**, thereby separating delivery system **100** and tubes **60** from the apparatus.

[0087] Deployment of apparatus **10** is fully reversible until locks **40** have been actuated. For example, just prior to locking the position of the anchor and valve and the operation of the valve may be observed under fluoroscopy. If the position needs to be changed, by alternately relaxing and reapplying the proximally directed forces exerted by control wires **50** and/or control wires **62** and the distally directed forces exerted by tubes **60**, expansion and contraction of the lip and skirt regions of anchor **30** may be independently controlled so that the anchor and valve can be moved to, e.g., avoid blocking the coronary ostia or impinging on the mitral valve. Apparatus **10** may also be completely retrieved within lumen **112** of sheath **110** by simultaneously proximally retracting wires **50** and tubes **60**/wires **62** relative to sheath **110**. Apparatus **10** then may be removed from the patient or repositioned for subsequent redeployment.

[0088] Referring now to **FIG. 4**, step-by-step deployment of apparatus **10** via delivery system **100** is described. In **FIG. 4A**, sheath **110** is retracted relative to apparatus **10**, wires **50** and tubes **60**, thereby causing self-expandable anchor **30** to dynamically self-expand apparatus **10** from the collapsed delivery configuration within lumen **112** of sheath **110** to the partially deployed configuration. Apparatus **10** may then be dynamically repositioned via tubes **60** to properly orient the apparatus, e.g. relative to a patient's native valve leaflets.

[0089] In **FIG. 4B**, control wires **50** are retracted while tubes **60** are advanced, thereby urging lip region **32** of anchor **30** in a distal direction while urging posts **38** of the anchor in a proximal direction. This foreshortens apparatus **10**, as seen in **FIG. 4C**. Deployment of apparatus **10** is fully reversible even after foreshortening has been initiated and has advanced to the point illustrated in **FIG. 4C**.

[0090] In **FIG. 4D**, continued foreshortening causes male interlocking elements **44** of locks **40** to engage female interlocking elements **42**. The male elements mate with the female elements, thereby locking apparatus **10** in the foreshortened configuration, as seen in **FIG. 4E**. Wires **50** are then pulled through eyelets **45** of male elements **44** to remove the wires from apparatus **10**, and wires **62** are pulled through the proximal end of anchor **30** to uncouple tubes **60** from the apparatus, thereby separating delivery system **100** from apparatus **10**. Fully deployed apparatus **10** is shown in **FIG. 4F**.

[0091] Referring to **FIG. 5**, a method of percutaneously replacing a patient's diseased aortic valve with apparatus **10** and delivery system **100** is described. As seen in **FIG. 5A**, sheath **110** of delivery system **100**, having apparatus **10** disposed therein, is percutaneously advanced over guide wire G, preferably in a retrograde fashion (although an antegrade or hybrid approach alternatively may be used), through a patient's aorta A to the patient's diseased aortic valve AV. A nosecone **102** precedes sheath **110** in a known manner. In **FIG. 5B**, sheath **110** is positioned such that its distal region is disposed within left ventricle LV of the patient's heart H.

[0092] Apparatus **10** is deployed from lumen **112** of sheath **110**, for example, under fluoroscopic guidance, such that anchor **30** of apparatus **10** dynamically self-expands to a partially deployed configuration, as in **FIG. 5C**. Advantageously, apparatus **10** may be retracted within lumen **112** of sheath **110** via wires **50**—even after anchor **30** has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition apparatus **10** or delivery system **100**. As yet another advantage, apparatus **10** may be dynamically repositioned, e.g. via sheath **110** and/or tubes **60**, in order to properly align the apparatus relative to anatomical landmarks, such as the patient's coronary ostia or the patient's native valve leaflets L. When properly aligned, skirt region **34** of anchor **30** preferably is disposed distal of the leaflets, while body region **36** is disposed across the leaflets and lip region **32** is disposed proximal of the leaflets.

[0093] Once properly aligned, wires **50** are retracted relative to tubes **60** to impose foreshortening upon anchor **30** and expand apparatus **10** to the fully deployed configuration, as in **FIG. 5D**. Foreshortening increases the radial strength of anchor **30** to ensure prolonged patency of valve annulus An, as well as to provide a better seal for apparatus **10** that reduces paravalvular regurgitation. As seen in **FIG. 5E**, locks **40** maintain imposed foreshortening. Replacement valve **20** is properly seated within anchor **30**, and normal blood flow between left ventricle LV and aorta A is thereafter regulated by apparatus **10**. Deployment of apparatus **10** advantageously is fully reversible until locks **40** have been actuated.

[0094] As seen in **FIG. 5F**, wires **50** are pulled from eyelets **45** of male elements **44** of locks **40**, tubes **60** are decoupled from anchor **30**, e.g. via wires **62**, and delivery system **100** is removed from the patient, thereby completing deployment of apparatus **10**. Optional barb elements **37** engage the patient's native valve leaflets, e.g. to preclude migration of the apparatus and/or reduce paravalvular regurgitation.

[0095] With reference now to **FIG. 6**, a method of percutaneously replacing a patient's diseased aortic valve with apparatus **10** is provided, wherein proper positioning of the apparatus is ensured via positive registration of a modified delivery system to the patient's native valve leaflets. In **FIG. 6A**, modified delivery system **100'** delivers apparatus **10** to diseased aortic valve AV within sheath **110**. As seen in **FIGS. 6B and 6C**, apparatus **10** is deployed from lumen **112** of sheath **110**, for example, under fluoroscopic guidance, such that anchor **30** of apparatus **10** dynamically self-expands to a partially deployed configuration. As when deployed via delivery system **100**, deployment of apparatus **10** via delivery system **100'** is fully reversible until locks **40** have been actuated.

[0096] Delivery system **100'** comprises leaflet engagement element **120**, which preferably self-expands along with anchor **30**. Engagement element **120** is disposed between tubes **60** of delivery system **100'** and lip region **32** of anchor **30**. Element **120** releasably engages the anchor. As seen in **FIG. 6C**, the element is initially deployed proximal of the patient's native valve leaflets L. Apparatus **10** and element **120** then may be advanced/dynamically repositioned until engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus **10**. Also delivery system **100'** includes filter structure **61A** (e.g., filter membrane or braid) as part of push tubes **60** to act as an embolic protection element. Emboli can be generated during manipulation and placement of anchor from either diseased native leaflet or surrounding aortic tissue and can cause blockage. Arrows **61B** in **FIG. 6E** show blood flow through filter structure **61A** where blood is allowed to flow but emboli is trapped in the delivery system and removed with it at the end of the procedure.

[0097] Alternatively, foreshortening may be imposed upon anchor **30** while element **120** is disposed proximal of the leaflets, as in **FIG. 6D**. Upon positive registration of element **120** against leaflets L, element **120** precludes further distal migration of apparatus **10** during additional foreshortening, thereby reducing a risk of improperly positioning the apparatus. **FIG. 6E** details engagement of element **120** against the native leaflets. As seen in **FIG. 6F**, once apparatus **10** is fully deployed, element **120**, wires **50** and tubes **60** are decoupled from the apparatus, and delivery system **100'** is removed from the patient, thereby completing the procedure.

[0098] With reference to **FIG. 7**, an alternative embodiment of the apparatus of **FIG. 6** is described, wherein leaflet engagement element **120** is coupled to anchor **30** of apparatus **10'**, rather than to delivery system **100**. Engagement element **120** remains implanted in the patient post-deployment of apparatus **10'**. Leaflets L are sandwiched between lip region **32** of anchor **30** and element **120** in the fully deployed configuration. In this manner, element **120** positively registers apparatus **10'** relative to the leaflets and precludes distal migration of the apparatus over time.

[0099] Referring now to **FIG. 8**, an alternative delivery system adapted for use with a balloon expandable embodiment of the present invention is described. In **FIG. 8A**, apparatus **10"** comprises anchor **30'** that may be fabricated from balloon-expandable materials. Delivery system **100"** comprises inflatable member **130** disposed in a deflated configuration within lumen **31** of anchor **30'**. In **FIG. 8B**, optional outer sheath **110** is retracted, and inflatable member **130** is inflated to expand anchor **30'** to the fully deployed configuration. As inflatable member **130** is being deflated, as in earlier embodiments, wires **50** and **62** and tubes **60** may be used to assist deployment of anchor **30'** and actuation of locks **40**, as well as to provide reversibility and retrievability of apparatus **10"** prior to actuation of locks **40**. Next, wires **50** and **62** and tubes **60** are removed from apparatus **10"**, and delivery system **100"** is removed, as seen in **FIG. 8C**.

[0100] As an alternative delivery method, anchor **30'** may be partially deployed via partial expansion of inflatable member **130**. The inflatable member would then be advanced within replacement valve **20** prior to inflation of inflatable member **130** and full deployment of apparatus **10"**. Inflation pressures used will range from about 3 to 6 atm, or more preferably from about 4 to 5 atm, though higher and lower atm pressures may also be used (e.g., greater than 3 atm, more preferably greater than 4 atm, more preferably greater than 5 atm, or more preferably greater than 6 atm). Advantageously, separation of inflatable member **130** from replacement valve **20**, until partial deployment of apparatus **10"** at a treatment site, is expected to reduce a delivery profile of the apparatus, as compared to previously known apparatus. This profile reduction may facilitate retrograde

delivery and deployment of apparatus **10"**, even when anchor **30'** is balloon-expandable.

[**0101**] Although anchor **30'** has illustratively been described as fabricated from balloon-expandable materials, it should be understood that anchor **30'** alternatively may be fabricated from self-expanding materials whose expansion optionally may be balloon-assisted. In such a configuration, anchor **30'** would expand to a partially deployed configuration upon removal of outer sheath **110**. If required, inflatable member **130** then would be advanced within replacement valve **20** prior to inflation. Inflatable member **130** would assist full deployment of apparatus **10"**, for example, when the radial force required to overcome resistance from impinging tissue were too great to be overcome simply by manipulation of wires **50** and tubes **60**. Advantageously, optional placement of inflatable member **130** within replacement valve **20**, only after dynamic self-expansion of apparatus **10"** to the partially deployed configuration at a treatment site, is expected to reduce a delivery profile of the apparatus, as compared to previously known apparatus. This reduction may facilitate retrograde delivery and deployment of apparatus **10"**.

[**0102**] With reference to **FIGS. 9 and 10**, methods and apparatus for a balloon-assisted embodiment of the present invention are described in greater detail. **FIGS. 9 and 10** illustratively show apparatus **10'** of **FIG. 7** used in combination with delivery system **100"** of **FIG. 8**. **FIG. 10** illustrates a sectional view of delivery system **100"**. Inner shaft **132** of inflatable member **130** preferably is about 4 Fr in diameter, and comprises lumen **133** configured for passage of guidewire G, having a diameter of about 0.035", therethrough. Push tubes **60** and pull wires **50** pass through guidetube **140**, which preferably has a diameter of about 15 Fr or smaller. Guide tube **140** is disposed within lumen **112** of outer sheath **110**, which preferably has a diameter of about 17 Fr or smaller.

[**0103**] In **FIG. 9A**, apparatus **10'** is delivered to diseased aortic valve AV within lumen **112** of sheath **110**. In **FIG. 9B**, sheath **110** is retracted relative to apparatus **10'** to dynamically self-expand the apparatus to the partially deployed configuration. Also retracted and removed is nosecone **102** which is attached to a pre-slit lumen (not shown) that facilitates its removal prior to loading and advancing of a regular angioplasty balloon catheter over guidewire and inside delivery system **110**.

[**0104**] In **FIG. 9C**, pull wires **50** and push tubes **60** are manipulated from external to the patient to foreshorten anchor **30** and sufficiently expand lumen **31** of the anchor to facilitate advancement of inflatable member **130** within replacement valve **20**. Also shown is the tip of an angioplasty catheter **130** being advanced through delivery system **110**.

[**0105**] The angioplasty balloon catheter or inflatable member **130** then is advanced within the replacement valve, as in **FIG. 9D**, and additional foreshortening is imposed upon anchor **30** to actuate locks **40**, as in **FIG. 9E**. The inflatable member is inflated to further displace the patient's native valve leaflets L and ensure adequate blood flow through, and long-term patency of, replacement valve **20**, as in **FIG. 9F**. Inflatable member **130** then is deflated and removed from the patient, as in **FIG. 9G**. A different size angioplasty balloon catheter could be used repeat the same step if deemed necessary by the user. Push tubes **60** optionally may be used to further set leaflet engagement element **120**, or optional barbs B along posts **38**, more deeply within leaflets L, as in **FIG. 9H**. Then, delivery system **100"** is removed from the patient, thereby completing percutaneous heart valve replacement.

[**0106**] As will be apparent to those of skill in the art, the order of imposed foreshortening and balloon expansion described in **FIGS. 9 and 10** is only provided for the sake of illustration. The actual order may vary according to the needs of a given patient and/or the preferences of a given medical practitioner. Furthermore, balloon-assist may not be required in all instances, and the inflatable member may act merely as a safety precaution employed selectively in challenging clinical cases.

[**0107**] Referring now to **FIG. 11**, alternative locks for use with apparatus of the present invention are described. In **FIG. 11A**, lock **40'** comprises male interlocking element **44** as described previously. However, female interlocking element **42'** illustratively comprises a triangular shape, as compared to the round shape of interlocking element **42** described previously. The triangular shape of female interlocking element **42'** may facilitate mating of male interlocking element **44** with the female interlocking element without necessitating deformation of the male interlocking element.

[**0108**] In **FIG. 11B**, lock **40"** comprises alternative male interlocking element **44'** having multiple in-line arrowheads **46** along posts **38**. Each arrowhead comprises resiliently deformable appendages **48** to facilitate passage through female interlocking element **42**. Appendages **48** optionally comprise eyelets **49**, such that control wire **50** or a secondary wire may pass therethrough to constrain the appendages in the deformed configuration. To actuate lock **40"**, one or more arrowheads **46** of male interlocking element **44'** are drawn through female interlocking element **42**, and the wire is removed from eyelets **49**, thereby causing appendages **48** to resiliently expand and actuate lock **40"**.

[**0109**] Advantageously, providing multiple arrowheads **46** along posts **38** yields a ratchet that facilitates in-vivo determination of a degree of foreshortening imposed upon apparatus of the present invention. Furthermore, optionally constraining appendages **48** of arrowheads **46** via eyelets **49** prevents actuation of lock **40"** (and thus deployment of apparatus of the present invention) even after male element **44'** has been advanced through female element **42**. Only after a medical practitioner has removed the wire constraining appendages **48** is lock **40"** fully engaged and deployment no longer reversible.

[**0110**] Lock **40'"** of **FIG. 11C** is similar to lock **40"** of **FIG. 11B**, except that optional eyelets **49** on appendages **48** have been replaced by optional overtube **47**. Overtube **47** serves a similar function to eyelets **49** by constraining appendages **48** to prevent locking until a medical practitioner has determined that apparatus of the present invention has been foreshortened and positioned adequately at a treatment site. Overtube **47** is then removed, which causes the appendages to resiliently expand, thereby fully actuating lock **40'"**.

[**0111**] With reference to **FIG. 12**, an alternative locking mechanism is described that is configured to engage the patient's aorta. Male interlocking elements **44"** of locks **40""**

comprise arrowheads **46'** having sharpened appendages **48'**. Upon expansion from the delivery configuration of **FIG. 12A** to the foreshortened configuration of **FIG. 12B**, apparatus **10** positions sharpened appendages **48'** adjacent the patient's aorta A. Appendages **48'** engage the aortic wall and reduce a risk of device migration over time.

[**0112**] With reference now to **FIG. 13**, a risk of paravalvular leakage or regurgitation around apparatus of the present invention is described. In **FIG. 13**, apparatus **10** has been implanted at the site of diseased aortic valve AV, for example, using techniques described hereinabove. The surface of native valve leaflets L is irregular, and interface I between leaflets L and anchor **30** may comprise gaps where blood B may seep through. Such leakage poses a risk of blood clot formation or insufficient blood flow.

[**0113**] Referring to **FIG. 14**, optional elements for reducing regurgitation or leakage are described. Compliant sacs **200** may be disposed about the exterior of anchor **30** to provide a more efficient seal along irregular interface I. Sacs **200** may be filled with an appropriate material, for example, water, blood, foam or a hydrogel. Alternative fill materials will be apparent.

[**0114**] With reference to **FIG. 15**, illustrative arrangements for sacs **200** are provided. In **FIG. 15A**, sacs **200** are provided as discrete sacs at different positions along the height of anchor **30**. In **FIG. 15B**, the sacs are provided as continuous cylinders at various heights. In **FIG. 15C**, a single sac is provided with a cylindrical shape that spans multiple heights. The sacs of **FIG. 15D** are discrete, smaller and provided in larger quantities. **FIG. 15E** provides a spiral sac. Alternative sac configurations will be apparent to those of skill in the art.

[**0115**] With reference to **FIG. 16**, exemplary techniques for fabricating sacs **200** are provided. In **FIG. 16A**, sacs **20** comprise 'fish-scale' slots **202** that may be back-filled, for example, with ambient blood passing through replacement valve **20**. In **FIG. 16B**, the sacs comprise pores **204** that may be used to fill the sacs. In **FIG. 16C**, the sacs open to lumen **31** of anchor **30** and are filled by blood washing past the sacs as the blood moves through apparatus **10**.

[**0116**] **FIGS. 17 and 18** show yet another alternative embodiment of the anchor lock. Anchor **300** has a plurality of male interlocking elements **302** having eyelets **304** formed therein. Male interlocking elements are connected to braided structure **300** by inter-weaving elements **302** (and **308**) or alternatively suturing, soldering, welding, or connecting with adhesive. Valve commissures **24** are connected to male interlocking elements **302** along their length. Replacement valve **20** annular base **22** is connected to the distal end **34** of anchor **300** (or **30**) as is illustrated in **FIGS. 1A and 1B**. Male interlocking elements **302** also include holes **306** that mate with tabs **310** extending into holes **312** in female interlocking elements **308**. To lock, control wires **314** passing through eyelets **304** and holes **312** are pulled proximally with respect to the proximal end of braided anchor **300** to draw the male interlocking elements through holes **312** so that tabs **310** engage holes **306** in male interlocking elements **302**. Also shown is release wires **314**B that passes through eylet **304**B in female interlocking element **308**. If needed, during the procedure, the user may pull on release wires **314**B reversing orientation of tabs **310** releasing the anchor and allowing for repositioning of the device or it's removal from the patient. Only when final positioning as desired by the operating physician, would release wire **314**B and control wire **314** are cut and removed from the patient with the delivery system.

[**0117**] **FIGS. 19-21** show an alternative way of releasing the connection between the anchor and its actuating tubes and control wires. Control wires **62** extend through tubes **60** from outside the patient, loop through the proximal region of anchor **30** and extend partially back into tube **60**. The doubled up portion of control wire **62** creates a force fit within tube **60** that maintains the control wire's position with respect to tube **60** when all control wires **62** are pulled proximally to place a proximally directed force on anchor **30**. When a single control wire **62** is pulled proximally, however, the frictional fit between that control wire and the tube in which it is disposed is overcome, enabling the end **63** of control wire **62** to pull free of the tube, as shown in **FIG. 21**, thereby releasing anchor **30**.

[**0118**] **FIGS. 22-24** show an alternative embodiment of the anchor. Anchor **350** is made of a metal braid, such as Nitinol or stainless steel. A replacement valve **354** is disposed within anchor **350**. Anchor **350** is actuated in substantially the same way as anchor **30** of **FIGS. 1-4** through the application of proximally and distally directed forces from control wires (not shown) and tubes **352**.

[**0119**] **FIGS. 25 and 26** show yet another embodiment of the delivery and deployment apparatus of the invention. As an alternative to the balloon expansion method described with respect to **FIG. 8**, in this embodiment the nosecone (e.g., element **102** of **FIG. 5**) is replaced by an angioplasty balloon catheter **360**. Thus, expandable balloon cathether **360** precedes sheath **110** on guidewire G. When anchor **30** and valve **20** are expanded through the operation of tubes **60** and the control wires (not shown) as described above, balloon cathether **360** is retracted proximally within the expanded anchor and valve and expanded further as described above with respect to **FIG. 8**.

[**0120**] **FIGS. 27-31** show seals **370** that expand over time to seal the interface between the anchor and valve and the patient's tissue. Seals **370** are preferably formed from Nitinol wire surrounded by an expandable foam. As shown in cross-section in **FIGS. 28 and 29**, at the time of deployment, the foam **372** is compressed about the wire **374** and held in the compressed form by a time-released coating **376**. After deployment, coating **376** dissolves in vivo to allow foam **372** to expand, as shown in **FIGS. 30 and 31**.

[**0121**] **FIGS. 32-34** show another way to seal the replacement valve against leakage. A fabric seal **380** extends from the distal end of valve **20** and back proximally over anchor **30** during delivery. When deployed, as shown in **FIGS. 33 and 34**, fabric seal **380** bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets **382**, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve.

[**0122**] FIGS. **35**A-H show another embodiment of a replacement heart valve apparatus in accordance with the present invention. Apparatus **450** comprises replacement valve **460** (see **FIGS. 37B and 38C**) disposed within and coupled to anchor **470**. Replacement valve **460** is preferably biologic, e.g. porcine, but alternatively may be synthetic.

Anchor **470** preferably is fabricated from self-expanding materials, such as a stainless steel wire mesh or a nickel-titanium alloy ("Nitinol"), and comprises lip region **472**, skirt region **474**, and body regions **476***a*, **476***b* and **476***c*. Replacement valve **460** preferably is coupled to skirt region **474**, but alternatively may be coupled to other regions of the anchor. As described hereinbelow, lip region **472** and skirt region **474** are configured to expand and engage/capture a patient's native valve leaflets, thereby providing positive registration, reducing paravalvular regurgitation, reducing device migration, etc.

[**0123**] As seen in **FIG. 35A**, apparatus **450** is collapsible to a delivery configuration, wherein the apparatus may be delivered via delivery system **410**. Delivery system **410** comprises sheath **420** having lumen **422**, as well as wires **424***a* and **424***b* seen in **FIGS. 35D-35G**. Wires **424***a* are configured to expand skirt region **474** of anchor **470**, as well as replacement valve **460** coupled thereto, while wires **424***b* are configured to expand lip region **472**.

[**0124**] As seen in **FIG. 35B**, apparatus **450** may be delivered and deployed from lumen **422** of catheter **420** while the apparatus is disposed in the collapsed delivery configuration. As seen in **FIGS. 35B-35D**, catheter **420** is retracted relative to apparatus **450**, which causes anchor **470** to dynamically self-expand to a partially deployed configuration. Wires **424***a* are then retracted to expand skirt region **474**, as seen in **FIGS. 35E and 35F**. Preferably, such expansion may be maintained via locking features described hereinafter.

[**0125**] In **FIG. 35G**, wires **424***b* are retracted to expand lip region **472** and fully deploy apparatus **450**. As with skirt region **474**, expansion of lip region **472** preferably may be maintained via locking features. After both lip region **472** and skirt region **474** have been expanded, wires **424** may be removed from apparatus **450**, thereby separating delivery system **410** from the apparatus. Delivery system **410** then may be removed, as seen in **FIG. 35H**.

[**0126**] As will be apparent to those of skill in the art, lip region **472** optionally may be expanded prior to expansion of skirt region **474**. As yet another alternative, lip region **472** and skirt region **474** optionally may be expanded simultaneously, in parallel, in a step-wise fashion or sequentially. Advantageously, delivery of apparatus **450** is fully reversible until lip region **472** or skirt region **474** has been locked in the expanded configuration.

[**0127**] With reference now to FIGS. **36**A-E, individual cells of anchor **470** of apparatus **450** are described to detail deployment and expansion of the apparatus. In **FIG. 36A**, individual cells of lip region **472**, skirt region **474** and body regions **476***a*, **476***b* and **476***c* are shown in the collapsed delivery configuration, as they would appear while disposed within lumen **422** of sheath **420** of delivery system **410** of **FIG. 35**. A portion of the cells forming body regions **476**, for example, every 'nth' row of cells, comprises locking features.

[**0128**] Body region **476***a* comprises male interlocking element **482** of lip lock **480**, while body region **476***b* comprises female interlocking element **484** of lip lock **480**. Male element **482** comprises eyelet **483**. Wire **424***b* passes from female interlocking element **484** through eyelet **483** and back through female interlocking element **484**, such that there is a double strand of wire **424***b* that passes through lumen **422** of catheter **420** for manipulation by a medical practitioner external to the patient. Body region **476***b* further comprises male interlocking element **492** of skirt lock **490**, while body region **476***c* comprises female interlocking element **494** of the skirt lock. Wire **424***a* passes from female interlocking element **494** through eyelet **493** of male interlocking element **492**, and back through female interlocking element **494**. Lip lock **480** is configured to maintain expansion of lip region **472**, while skirt lock **490** is configured to maintain expansion of skirt region **474**.

[**0129**] In **FIG. 36B**, anchor **470** is shown in the partially deployed configuration, e.g., after deployment from lumen **422** of sheath **420**. Body regions **476**, as well as lip region **472** and skirt region **474**, self-expand to the partially deployed configuration. Full deployment is then achieved by retracting wires **424** relative to anchor **470**, and expanding lip region **472** and skirt region **474** outward, as seen in **FIGS. 36C and 36D**. As seen in **FIG. 36E**, expansion continues until the male elements engage the female interlocking elements of lip lock **480** and skirt lock **490**, thereby maintaining such expansion (lip lock **480** shown in **FIG. 36E**). Advantageously, deployment of apparatus **450** is fully reversible until lip lock **480** and/or skirt lock **490** has been actuated.

[**0130**] With reference to FIGS. **37**A-B, isometric views, partially in section, further illustrate apparatus **450** in the fully deployed and expanded configuration. **FIG. 37A** illustrates the wireframe structure of anchor **470**, while **FIG. 37B** illustrates an embodiment of anchor **470** covered in a biocompatible material B. Placement of replacement valve **460** within apparatus **450** may be seen in **FIG. 37B**. The patient's native valve is captured between lip region **472** and skirt region **474** of anchor **470** in the fully deployed configuration (see **FIG. 38B**).

[**0131**] Referring to FIGS. **38**A-C, in conjunction with **FIGS. 35 and 36**, a method for percutaneously replacing a patient's diseased aortic valve with apparatus **450** is described. Delivery system **410**, having apparatus **450** disposed therein, is percutaneously advanced, preferably in a retrograde fashion, through a patient's aorta A to the patient's diseased aortic valve AV. Sheath **420** is positioned such that its distal end is disposed within left ventricle LV of the patient's heart H. As described with respect to **FIG. 35**, apparatus **450** is deployed from lumen **422** of sheath **420**, for example, under fluoroscopic guidance, such that skirt section **474** is disposed within left ventricle LV, body section **476***b* is disposed across the patient's native valve leaflets L, and lip section **472** is disposed within the patient's aorta A. Advantageously, apparatus **450** may be dynamically repositioned to obtain proper alignment with the anatomical landmarks. Furthermore, apparatus **450** may be retracted within lumen **422** of sheath **420** via wires **424**, even after anchor **470** has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition sheath **420**.

[**0132**] Once properly positioned, wires **424***a* are retracted to expand skirt region **474** of anchor **470** within left ventricle LV. Skirt region **474** is locked in the expanded configuration via skirt lock **490**, as previously described with respect to **FIG. 36**. In **FIG. 38A**, skirt region **474** is maneuvered such that it engages the patient's valve annulus An and/or native

valve leaflets L, thereby providing positive registration of apparatus **450** relative to the anatomical landmarks.

[**0133**] Wires **424***b* are then actuated external to the patient in order to expand lip region **472**, as previously described in **FIG. 35**. Lip region **472** is locked in the expanded configuration via lip lock **480**. Advantageously, deployment of apparatus **450** is fully reversible until lip lock **480** and/or skirt lock **490** has been actuated. Wires **424** are pulled from eyelets **483** and **493**, and delivery system **410** is removed from the patient. As will be apparent, the order of expansion of lip region **472** and skirt region **474** may be reversed, concurrent, etc.

[**0134**] As seen in **FIG. 38B**, lip region **472** engages the patient's native valve leaflets L, thereby providing additional positive registration and reducing a risk of lip region **472** blocking the patient's coronary ostia O. **FIG. 38C** illustrates the same in cross-sectional view, while also showing the position of replacement valve **460**. The patient's native leaflets are engaged and/or captured between lip region **472** and skirt region **474**. Advantageously, lip region **472** precludes distal migration of apparatus **450**, while skirt region **474** precludes proximal migration. It is expected that lip region **472** and skirt region **474** also will reduce paravalvular regurgitation.

[**0135**] With reference to **FIGS. 39-41**, a first embodiment of two-piece apparatus of the present invention adapted for percutaneous replacement of a patient's heart valve is described. As seen in **FIG. 41**, apparatus **510** comprises a two-piece device having custom-designed expandable anchor piece **550** of **FIG. 39** and expandable replacement valve piece **600** of **FIG. 40**. Both anchor piece **550** and valve piece **600** have reduced delivery configurations and expanded deployed configurations. Both may be either balloon expandable (e.g. fabricated from a stainless steel) or self-expanding (e.g. fabricated from a nickel-titanium alloy ("Nitinol") or from a wire mesh) from the delivery to the deployed configurations.

[**0136**] When replacing a patient's aortic valve, apparatus **510** preferably may be delivered through the patient's aorta without requiring a transseptal approach, thereby reducing patient trauma, complications and recovery time. Furthermore, apparatus **510** enables dynamic repositioning of anchor piece **550** during delivery and facilitates positive registration of apparatus **510** relative to the native position of the patient's valve, thereby reducing a risk of device migration and reducing a risk of blocking or impeding flow to the patient's coronary ostia. Furthermore, the expanded deployed configuration of apparatus **510**, as seen in **FIG. 41D**, is adapted to reduce paravalvular regurgitation, as well as to facilitate proper seating of valve piece **600** within anchor piece **550**.

[**0137**] As seen in **FIG. 39**, anchor piece **550** preferably comprises three sections. Lip section **560** is adapted to engage the patient's native valve leaflets to provide positive registration and ensure accurate placement of the anchor relative to the patient's valve annulus during deployment, while allowing for dynamic repositioning of the anchor during deployment. Lip section **560** also maintains proper positioning of composite anchor/valve apparatus **510** post-deployment to preclude distal migration. Lip section **560** optionally may be covered or coated with biocompatible film B (see **FIG. 41**) to ensure engagement of the native valve leaflets. It is expected that covering lip section **560** with film B especially would be indicated when the native leaflets are stenosed and/or fused together

[**0138**] Groove section **570** of anchor piece **550** is adapted to engage an expandable frame portion, described hereinbelow, of valve piece **600** to couple anchor piece **550** to valve piece **600**. As compared to previously known apparatus, groove section **570** comprises additional material and reduced openings or gaps G, which is expected to reduce tissue protrusion through the gaps upon deployment, thereby facilitating proper seating of the valve within the anchor. Groove section **570** optionally may be covered or coated with biocompatible film B (see **FIG. 41**) to further reduce native valve tissue protrusion through gaps G.

[**0139**] Finally, skirt section **580** of anchor piece **550** maintains proper positioning of composite anchor/valve apparatus **510** post-deployment by precluding proximal migration. When replacing a patient's aortic valve, skirt section **580** is deployed within the patient's left ventricle. As with lip section **560** and groove section **570**, skirt section **580** optionally may be covered or coated with biocompatible film B (see **FIG. 41**) to reduce paravalvular regurgitation. As will be apparent to those of skill in the art, all, a portion of, or none of anchor piece **50** may be covered or coated with biocompatible film B.

[**0140**] In **FIG. 39A**, a portion of anchor piece **550** has been flattened out to illustrate the basic anchor cell structure, as well as to illustrate techniques for manufacturing anchor piece **550**. In order to form the entire anchor, anchor **550** would be bent at the locations indicated in **FIG. 39A**, and the basic anchor cell structure would be revolved to form a joined 360° structure. Lip section **560** would be bent back into the page to form a lip that doubles over the groove section, groove section **570** would be bent out of the page into a 'C'- or 'U'-shaped groove, while skirt section **580** would be bent back into the page. **FIG. 39B** shows the anchor portion after bending and in an expanded deployed configuration.

[**0141**] The basic anchor cell structure seen in **FIG. 39A** is preferably formed through laser cutting of a flat sheet or of a hollow tube placed on a mandrel. When formed from a flat sheet, the sheet would be cut to the required number of anchor cells, bent to the proper shape, and revolved to form a cylinder. The ends of the cylinder would then be joined together, for example, by heat welding.

[**0142**] If balloon expandable, anchor piece **550** would be formed from an appropriate material, such as stainless steel, and then crimped onto a balloon delivery catheter in a collapsed delivery configuration. If self-expanding and formed from a shape-memory material, such as a nickel-titanium alloy ("Nitinol"), the anchor piece would be heat-set such that it could be constrained within a sheath in the collapsed delivery configuration, and then would dynamically self-expand to the expanded deployed configuration upon removal of the sheath. Likewise, if anchor piece **550** were formed from a wire mesh or braid, such as a spring steel braid, the anchor would be constrained within a sheath in the delivery configuration and dynamically expanded to the deployed configuration upon removal of the sheath.

[**0143**] In **FIG. 40**, valve piece **600** is described in greater detail. **FIG. 40A** illustrates valve piece **600** in a collapsed

delivery configuration, while **FIG. 40B** illustrates the valve piece in an expanded deployed configuration. Valve piece **600** comprises replacement valve **610** coupled to expandable frame **620**. Replacement valve **610** is preferably biologic, although synthetic valves may also be used. Replacement valve **610** preferably comprises three leaflets **611** coupled to three posts **621** of expandable frame **620**. Expandable frame **620** is preferably formed from a continuous piece of material and may comprise tips **622** in the collapsed delivery configuration, which expand to form hoop **624** in the deployed configuration. Hoop **624** is adapted to engage groove section **570** of anchor piece **550** for coupling anchor piece **550** to valve piece **600**. As with anchor piece **550**, valve piece **600** may be balloon expandable and coupled to a balloon delivery catheter in the delivery configuration. Alternatively, anchor piece **550** may be self-expanding, e.g. Nitinol or wire mesh, and constrained within a sheath in the delivery configuration.

[**0144**] Referring again to **FIG. 41**, a method for deploying valve piece **600** and coupling it to deployed anchor piece **550** to form two-piece apparatus **510** is described. In **FIG. 41A**, valve piece **600** is advanced within anchor piece **550** in an at least partially compressed delivery configuration. In **FIG. 41B**, tips **622** of frame **620** are expanded such that they engage groove section **570** of anchor piece **550**. In **FIG. 41C**, frame **620** continues to expand and form hoop **624**. Hoop **624** flares out from the remainder of valve piece **600** and acts to properly locate the hoop within groove section **570**. **FIG. 41D** shows valve piece **600** in a fully deployed configuration, properly seated and friction locked within groove section **570** to form composite anchor/valve apparatus **510**.

[**0145**] Anchor piece **550** and valve piece **600** of apparatus **510** preferably are spaced apart and releasably coupled to a single delivery catheter while disposed in their reduced delivery configurations. Spacing the anchor and valve apart reduces a delivery profile of the device, thereby enabling delivery through a patient's aorta without requiring a transseptal approach. With reference to **FIG. 42**, a first embodiment of single catheter delivery system **700** for use with apparatus **510** is described. Delivery system **700** is adapted for use with a preferred self-expanding embodiment of apparatus **510**.

[**0146**] Delivery system **700** comprises delivery catheter **710** having inner tube **720**, middle distal tube **730**, and outer tube **740**. Inner tube **720** comprises lumen **722** adapted for advancement over a standard guide wire, per se known. Middle distal tube **730** is coaxially disposed about a distal region of inner tube **720** and is coupled to a distal end **724** of the inner tube, thereby forming proximally-oriented annular bore **732** between inner tube **720** and middle tube **730** at a distal region of delivery catheter **710**. Outer tube **740** is coaxially disposed about inner tube **720** and extends from a proximal region of the inner tube to a position at least partially coaxially overlapping middle distal tube **730**. Outer tube **740** preferably comprises distal step **742**, wherein lumen **743** of outer tube **740** is of increased diameter. Distal step **742** may overlap middle distal tube **730** and may also facilitate deployment of valve piece **600**, as described hereinbelow with respect to **FIG. 45**.

[**0147**] Proximally-oriented annular bore **732** between inner tube **720** and middle distal tube **730** is adapted to receive skirt section **580** and groove section **570** of anchor piece **550** in the reduced delivery configuration. Annular space **744** formed at the overlap between middle distal tube **730** and outer tube **740** is adapted to receive lip section **560** of anchor piece **550** in the reduced delivery configuration. More proximal annular space **746** between inner tube **720** and outer tube **740** may be adapted to receive replacement valve **610** and expandable frame **620** of valve piece **600** in the reduced delivery configuration.

[**0148**] Inner tube **720** optionally may comprise retainer elements **726***a* and **726***b* to reduce migration of valve piece **600**. Retainer elements **726** preferably are fabricated from a radiopaque material, such as platinum-iridium or gold, to facilitate deployment of valve piece **600**, as well as coupling of the valve piece to anchor piece **550**. Additional or alternative radiopaque elements may be disposed at other locations about delivery system **700** or apparatus **510**, for example, in the vicinity of anchor piece **550**.

[**0149**] With reference now to **FIG. 43**, an alternative delivery system for use with apparatus of the present invention is described. Delivery system **750** comprises two distinct catheters adapted to deliver the anchor and valve pieces, respectively: anchor delivery catheter **710'** and valve delivery catheter **760**. In use, catheters **710'** and **760** may be advanced sequentially to a patient's diseased heart valve for sequential deployment and coupling of anchor piece **550** to valve piece **600** to form composite two-piece apparatus **510**.

[**0150**] Delivery catheter **710'** is substantially equivalent to catheter **710** described hereinabove, except that catheter **710'** does not comprise retainer elements **726**, and annular space **746** does not receive valve piece **600**. Rather, valve piece **600** is received within catheter **760** in the collapsed delivery configuration. Catheter **760** comprises inner tube **770** and outer tube **780**. Inner tube **770** comprises lumen **772** for advancement of catheter **760** over a guide wire. The inner tube optionally may also comprise retain elements **774***a* and **774***b*, e.g. radiopaque retainer elements **774**, to reduce migration of valve piece **600**. Outer tube **780** is coaxially disposed about inner tuber **770** and preferably comprises distal step **782** to facilitate deployment and coupling of valve piece **600** to anchor piece **550**, as described hereinbelow. Valve piece **600** may be received in annular space **776** between inner tube **770** and outer tube **780**, and more preferably may be received within annular space **776** between retainer elements **774**.

[**0151**] Referring now to **FIG. 44**, another alternative delivery system is described. As discussed previously, either anchor piece **550** or valve piece **600** (or portions thereof or both) may be balloon expandable from the delivery configuration to the deployed configuration. Delivery system **800** is adapted for delivery of an embodiment of apparatus **510** wherein the valve piece is balloon expandable. Additional delivery systems—both single and multi-catheter—for deployment of alternative combinations of balloon and self-expandable elements of apparatus of the present invention will be apparent to those of skill in the art in view of the illustrative delivery systems provided in **FIGS. 42-44**.

[**0152**] In **FIG. 44**, delivery system **800** comprises delivery catheter **710"**. Delivery catheter **710"** is substantially equivalent to delivery catheter **710** of delivery system **700**, except that catheter **710"** does not comprise retainer elements **726**, and annular space **746** does not receive the valve

piece. Additionally, catheter **710**" comprises inflatable balloon **802** coupled to the exterior of outer tube **740**", as well as an inflation lumen (not shown) for reversibly delivering an inflation medium from a proximal region of catheter **710**" into the interior of inflatable balloon **802** for expanding the balloon from a delivery configuration to a deployed configuration. Valve piece **600** may be crimped to the exterior of balloon **802** in the delivery configuration, then deployed and coupled to anchor piece **550** in vivo. Delivery catheter **710**" preferably comprises radiopaque marker bands **804***a* and **804***b* disposed on either side of balloon **802** to facilitate proper positioning of valve piece **600** during deployment of the valve piece, for example, under fluoroscopic guidance.

[**0153**] With reference now to **FIG. 45**, in conjunction with **FIGS. 39-42**, an illustrative method of percutaneously replacing a patient's diseased heart valve using apparatus of the present invention is described. In **FIG. 45A**, a distal region of delivery system **700** of **FIG. 42** has been delivered through a patient's aorta A, e.g., over a guide wire and under fluoroscopic guidance using well-known percutaneous techniques, to a vicinity of diseased aortic valve AV of heart H. Apparatus **510** of **FIGS. 39-41** is disposed in the collapsed delivery configuration within delivery catheter **710** with groove section **570** and skirt section **580** of anchor piece **550** collapsed within annular bore **732**, and lip section **560** of anchor piece **550** collapsed within annular space **744**. Valve piece **600** is disposed in the collapsed delivery configuration between retainer elements **726** within more proximal annular space **746**. Separation of anchor piece **550** and valve piece **600** of apparatus **510** along the longitudinal axis of delivery catheter **710** enables percutaneous aortic delivery of apparatus **510** without requiring a transseptal approach.

[**0154**] Aortic valve AV comprises native valve leaflets L attached to valve annulus An. Coronary ostia O are disposed just proximal of diseased aortic valve AV. Coronary ostia O connect the patient's coronary arteries to aorta A and are the conduits through which the patient's heart muscle receives oxygenated blood. As such, it is critical that the ostia remain unobstructed post-deployment of apparatus **510**.

[**0155**] In **FIG. 45A**, a distal end of delivery catheter **710** has been delivered across diseased aortic valve AV into the patient's left ventricle LV. As seen in **FIG. 45B**, outer tube **740** is then retracted proximally relative to inner tube **720** and middle distal tube **730**. Outer tube **740** no longer coaxially overlaps middle distal tube **730**, and lip section **560** of anchor piece **550** is removed from annular space **744**. Lip section **560** self-expands to the deployed configuration. As seen in **FIG. 45C**, inner tube **720** and middle tube **730** (or all of delivery catheter **710**) are then distally advanced until lip section **560** engages the patient's native valve leaflets L, thereby providing positive registration of anchor piece **550** to leaflets L. Registration may be confirmed, for example, via fluoroscopic imaging of radiopaque features coupled to apparatus **510** or delivery system **700** and/or via resistance encountered by the medical practitioner distally advancing anchor piece **550**.

[**0156**] Lip section **560** may be dynamically repositioned until it properly engages the valve leaflets, thereby ensuring proper positioning of anchor piece **550** relative to the native coronary ostia O, as well as the valve annulus An, prior to deployment of groove section **570** and skirt section **580**. Such multi-step deployment of anchor piece **550** enables positive registration and dynamic repositioning of the anchor piece. This is in contrast to previously known percutaneous valve replacement apparatus.

[**0157**] As seen in **FIG. 45D**, once leaflets L have been engaged by lip section **560** of anchor piece **550**, inner tube **720** and middle distal tube **730** are further distally advanced within left ventricle LV, while outer tube **740** remains substantially stationary. Lip section **560**, engaged by leaflets L, precludes further distal advancement/migration of anchor piece **550**. As such, groove section **570** and skirt section **580** are pulled out of proximally-oriented annular bore **732** between inner tube **720** and middle distal tube **730** when the tubes are distally advanced. The groove and skirt sections self-expand to the deployed configuration, as seen in **FIG. 45E**. Groove section **570** pushes native valve leaflets L and lip section **560** against valve annulus An, while skirt section **580** seals against an interior wall of left ventricle LV, thereby reducing paravalvular regurgitation across aortic valve AV and precluding proximal migration of anchor piece **550**.

[**0158**] With anchor piece **550** deployed and native aortic valve AV displaced, valve piece **600** may be deployed and coupled to the anchor piece to achieve percutaneous aortic valve replacement. Outer tube **740** is further proximally retracted relative to inner tube **720** such that valve piece **600** is partially deployed from annular space **746** between inner tube **720** and outer tube **740**, as seen in **FIG. 45F**. Expandable frame **620** coupled to replacement valve **610** partially self-expands such that tips **622** partially form hoop **624** for engagement of groove section **570** of anchor piece **550** (see **FIG. 41B**). A proximal end of expandable frame **620** is engaged by distal step **742** of outer tube **740**.

[**0159**] Subsequent re-advancement of outer tube **740** relative to inner tube **720** causes distal step **742** to distally advance valve piece **600** within anchor piece **550** until tips **622** of expandable frame **620** engage groove section **570** of anchor piece **550**, as seen in **FIG. 45G**. As discussed previously, groove section **570** comprises additional material and reduced openings or gaps G, as compared to previously known apparatus, which is expected to reduce native valve tissue protrusion through the gaps and facilitate engagement of tips **622** with the groove section. Outer tube **740** then is proximally retracted again relative to inner tube **720**, and valve piece **600** is completely freed from annular space **746**. Frame **620** of valve piece **600** fully expands to form hoop **624**, as seen in **FIG. 45H**.

[**0160**] Hoop **624** friction locks within groove section **570** of anchor piece **550**, thereby coupling the anchor piece to the valve piece and forming composite two-piece apparatus **510**, which provides a percutaneous valve replacement. As seen in **FIG. 45I**, delivery catheter **710** may then be removed from the patient, completing the procedure. Blood may freely flow from left ventricle LV through replacement valve **610** into aorta A. Coronary ostia O are unobstructed, and paravalvular regurgitation is reduced by skirt section **580** of anchor piece **550**.

[**0161**] Referring now to **FIG. 46**, an alternative embodiment of two-piece apparatus **510** is described comprising an alignment/locking mechanism. Such a mechanism may be provided in order to ensure proper radial alignment of the expandable frame of the valve piece with the groove section of the anchor piece, as well as to ensure proper longitudinal positioning of the frame within the hoop. Additionally, the

alignment/locking mechanism may provide a secondary lock to further reduce a risk of the anchor piece and the valve piece becoming separated post-deployment and coupling of the two pieces to achieve percutaneous valve replacement.

[0162] In **FIG. 46**, apparatus **510'** comprises valve piece **600'** of **FIG. 46A** and anchor piece **550'** of **FIG. 46B**. Anchor piece **550'** and valve piece **600'** are substantially the same as anchor piece **550** and valve piece **600** described hereinabove, except that anchor piece **550'** comprises first portion **652** of illustrative alignment/locking mechanism **650**, while valve piece **600'** comprises second portion **654** of the alignment/locking mechanism for coupling to the first portion. First portion **652** illustratively comprises three guideposts **653** coupled to skirt section **580'** of anchor piece **550'** (only one guidepost shown in the partial view of **FIG. 46B**), while second portion **654** comprises three sleeves **655** coupled to posts **621'** of expandable frame **620'** of valve piece **600'**.

[0163] When anchor piece **550'** is self-expanding and collapsed in the delivery configuration, guideposts **653** may be deployed with skirt section **580'**, in which case guideposts **653** would rotate upward with respect to anchor piece **550'** into the deployed configuration of **FIG. 46B**. Alternatively, when anchor piece **550'** is either balloon or self-expanding and is collapsed in the delivery configuration, guideposts **653** may be collapsed against groove section **570'** of the anchor piece and may be deployed with the groove section. Deploying guideposts **653** with skirt section **580'** has the advantages of reduced delivery profile and ease of manufacturing, but has the disadvantage of significant dynamic motion during deployment. Conversely, deploying guideposts **653** with groove section **570'** has the advantage of minimal dynamic motion during deployment, but has the disadvantage of increased delivery profile. Additional deployment configurations will be apparent to those of skill in the art. As will also be apparent, first portion **652** of alignment/locking mechanism **650** may be coupled to alternative sections of anchor piece **550'** other than skirt section **580'**.

[0164] Sleeves **655** of second portion **654** of alignment/locking mechanism **650** comprise lumens **656** sized for coaxial disposal of sleeves **655** about guideposts **653** of first portion **652**. Upon deployment, sleeves **655** may friction lock to guideposts **653** to ensure proper radial and longitudinal alignment of anchor piece **550'** with valve piece **600'**, as well as to provide a secondary lock of the anchor piece to the valve piece. The secondary lock enhances the primary friction lock formed by groove section **570'** of the anchor piece with hoop **624'** of expandable frame **620'** of the valve piece.

[0165] To facilitate coupling of the anchor piece to the valve piece, suture or thread may pass from optional eyelets **651***a* of guideposts **653** through lumens **656** of sleeves **655** to a proximal end of the delivery catheter (see **FIG. 47**). In this manner, second portion **654** of mechanism **650** may be urged into alignment with first portion **652**, and optional suture knots (not shown), e.g. pre-tied suture knots, may be advanced on top of the mechanism post-coupling of the two portions to lock the two portions together. Alternatively, guideposts **653** may comprise optional one-way valves **651***b* to facilitate coupling of the first portion to the second portion. Specifically, sleeves **655** may be adapted for coaxial advancement over one-way valves **651***b* in a first direction that couples the sleeves to guideposts **653**, but not in a reverse direction that would uncouple the sleeves from the guideposts.

[0166] Referring now to **FIG. 47**, an alternative embodiment of apparatus **510'** comprising an alternative alignment/locking mechanism is described. Apparatus **510"** is illustratively shown in conjunction with delivery system **700** described hereinabove with respect to **FIG. 42**. Valve piece **600"** is shown partially deployed from outer tube **740** of catheter **710**. For the sake of illustration, replacement valve **610"** of valve piece **600"**, as well as inner tube **720** and middle distal tube **730** of delivery catheter **710**, are not shown in **FIG. 47**.

[0167] In **FIG. 47**, anchor piece **550"** of apparatus **510"** comprises first portion **652'** of alignment/locking mechanism **650'**, while valve piece **600"** comprises second portion **654'** of the alternative alignment/locking mechanism. First portion **652'** comprises eyelets **660** coupled to groove section **570"** of anchor piece **550"**. Second portion **654'** comprises knotted loops of suture **662** coupled to tips **622"** of expandable frame **620"** of valve piece **600"**. Suture **661** extends from knotted loops of suture **662** through eyelets **660** and out through annular space **746** between outer tube **740** and inner tube **720** (see **FIG. 42**) of catheter **710** to a proximal end of delivery system **700**. In this manner, a medical practitioner may radially and longitudinally align valve piece **600"** with anchor piece **550"** by proximally retracting sutures **661** (as shown by arrows in **FIG. 47**) while distally advancing distal step **742** of outer tube **740** against valve piece **600"** until tips **622"** of the valve piece engage groove section **570"** of anchor piece **550"**. Proximal retraction of outer tube **740** then causes expandable frame **620"** to further expand and form hoop **624"** that friction locks with groove section **570"** of anchor piece **550"**, thereby forming apparatus **510"** as described hereinabove with respect to apparatus **510**. A secondary lock may be achieved by advancing optional suture knots (not shown) to the overlap of eyelets **660** and knotted loops of suture **662**. Such optional suture knots preferably are pre-tied.

[0168] With reference now to **FIG. 48**, yet another alternative embodiment of apparatus **510'**, comprising yet another alternative alignment/locking mechanism **650**, is described. First portion **652"** of alignment/locking mechanism **650"** is coupled to anchor piece **550'"** of apparatus **510'"**, while second portion **654"** is coupled to valve piece **600'"**. The first portion comprises male posts **670** having flared ends **671**, while the second portion comprises female guides **672** coupled to tips **622'"** of expandable frame **620'"** of valve piece **600'"**.

[0169] Female guides **672** are translatable about male posts **670**, but are constrained by flared ends **671** of the male posts. In this manner, anchor piece **550'"** and valve piece **600'"** remain coupled and in radial alignment with one another at all times—including delivery—but may be longitudinally separated from one another during delivery. This facilitates percutaneous delivery without requiring a transseptal approach, while mitigating a risk of inadvertent deployment of the anchor and valve pieces in an uncoupled configuration. Additional alignment/locking mechanisms will be apparent in view of the mechanisms described with respect to **FIGS. 46-48**.

[0170] Prior to implantation of one of the replacement valves described above, it may be desirable to perform a valvoplasty on the diseased valve by inserting a balloon into the valve and expanding it using saline mixed with a contrast agent. In addition to preparing the valve site for implant, fluoroscopic viewing of the valvoplasty will help determine the appropriate size of replacement valve implant to use.

What is claimed is:

**1**. A method for endovascularly replacing a heart valve of a patient, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration;

expanding the anchor to a deployed configuration in which the anchor contacts tissue at a first anchor site;

repositioning the anchor to a second anchor site; and

deploying the anchor at the second anchor site.

**2**. The method of claim 1 wherein the repositioning step comprises contracting the anchor and re-expanding the anchor at the second anchor site.

**3**. The method of claim 2 wherein the contracting step comprises applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

**4**. The method of claim 1 wherein the deploying step comprises releasing the anchor from a deployment tool.

**5**. The method of claim 1 wherein the delivering step comprises delivering the replacement heart valve coupled to the anchor.

**6**. The method of claim 1 wherein the delivering step comprises delivering the replacement valve separate from the anchor, the method further comprising attaching the replacement valve to the anchor.

**7**. The method of claim 1 wherein the heart valve comprises an aortic valve and wherein the delivering step comprises endovascularly delivering the expandable anchor and replacement valve to the vicinity of the aortic valve along a retrograde approach.

**8**. The method of claim 1 wherein the expanding step comprises applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

**9**. The method of claim 1 wherein the deploying step comprises expanding a balloon within the anchor.

**10**. The method of claim 1 wherein the deploying step comprises locking the anchor in an expanded configuration.

**11**. The method of claim 1 further comprising registering the anchor with the first or second anchor site.

**12**. The method of claim 11 wherein the registering step comprises contacting tissue of the heart valve to resist movement of the anchor in at least a proximal or a distal direction prior to deploying the anchor.

**13**. The method of claim 1 wherein the anchor comprises a proximal region and a distal region and wherein the expanding step comprises expanding the proximal and distal regions separately.

**14**. A method for endovascularly replacing a heart valve of a patient, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration;

expanding the anchor to an expanded configuration in which the anchor contacts tissue at an anchor site;

visually observing the anchor location; and

releasing the anchor from a deployment tool.

**15**. The method of claim 14 wherein the expanding step comprises expanding the anchor to contact the tissue with a force of about 2 to 4 pounds.

**16**. The method of claim 14 wherein the anchor site comprises a first anchor site, the method further comprising repositioning the anchor to a second anchor site after the observing step and before the releasing step.

**17**. The method of claim 14 wherein the expanding step comprises applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

**18**. The method of claim 14 further comprising expanding a balloon within the anchor after the observing step.

**19**. The method of claim 14 further comprising registering the anchor with the anchor site.

**20**. The method of claim 14 wherein the delivering step comprises delivering the replacement heart valve coupled to the anchor.

**21**. The method of claim 14 wherein the delivering step comprises delivering the replacement valve separate from the anchor, the method further comprising attaching the replacement valve to the anchor.

**22**. A method for endovascularly replacing a heart valve of a patient, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration;

expanding the anchor to a deployed configuration in which the anchor contacts tissue at an anchor site at the vicinity of the heart valve;

repositioning the anchor in the anchor site; and

deploying the anchor at the anchor site.

**23**. The method of claim 22 wherein the reposition step comprises contacting the anchor and re-expanding the anchor at the anchor site.

**24**. The method of claim 23 wherein the contacting step comprises applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

**25**. The method of claim 22 wherein the deploying step comprises releasing the anchor from a deployment tool.

**26**. The method of claim 22 wherein the delivering step comprises delivering the replacement heart valve coupled to the anchor.

**27**. The method of claim 22 wherein the delivering step comprises delivering the replacement valve separate from the anchor, wherein the method further comprised attaching the replacement valve to the anchor.

**28**. The method of claim 22 wherein the heart valve comprises an aortic valve and wherein the delivering step comprises endovascularly delivering the expandable anchor and replacement valve to the vicinity of the aortic valve along a retrograde approach.

**29**. The method of claim 22 wherein the expanding step comprises applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

**30**. The method of claim 22 wherein the deploying step comprises expanding a balloon within the anchor.

**31**. The method of claim 22 wherein the deploying step comprises locking the anchor in an expanded configuration.

**32**. The method of claim 22 further comprising registering the anchor with the anchor site.

**33**. The method of claim 32 wherein the registering step comprises contacting tissue of the heart valve to resist movement of the anchor in at least a proximal or a distal direction prior to deploying the anchor.

**34**. The method of claim 22 wherein the anchor comprises a proximal region and a distal region and wherein the expanding step comprises expanding the proximal and distal regions separately.

**35**. The method of claim 22 further comprising visually observing the anchor location.

**36**. The method of claim 35 wherein the step of observing occurs prior to locking the anchor.

**37**. The method of claim 1 wherein the deploying step comprises unlocking the anchor and adjusting its position in an expanded configuration before locking the anchor and releasing the anchor from a deployment tool.

**38**. The method of claim 1 wherein the deployment step comprises unlocking the anchor and adjusting its position in an expanded configuration.

**39**. The method of claim 1 wherein the deployment step comprises unlocking the anchor.

**40**. The method of claim 22 wherein the deploying step comprises unlocking the anchor and adjusting its position in an expanded configuration before locking the anchor and releasing the anchor from a deployment tool.

**41**. The method of claim 22 wherein the deployment step comprises unlocking the anchor and adjusting its position in an expanded configuration.

**42**. The method of claim 22 wherein the deployment step comprises unlocking the anchor.

* * * * *

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**Salahieh et al.** (43) **Pub. Date: Jun. 23, 2005**

(54) **LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF**

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(21) Appl. No.: **10/972,287**

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**Related U.S. Application Data**

(63) Continuation-in-part of application No. 10/746,240, filed on Dec. 23, 2003.

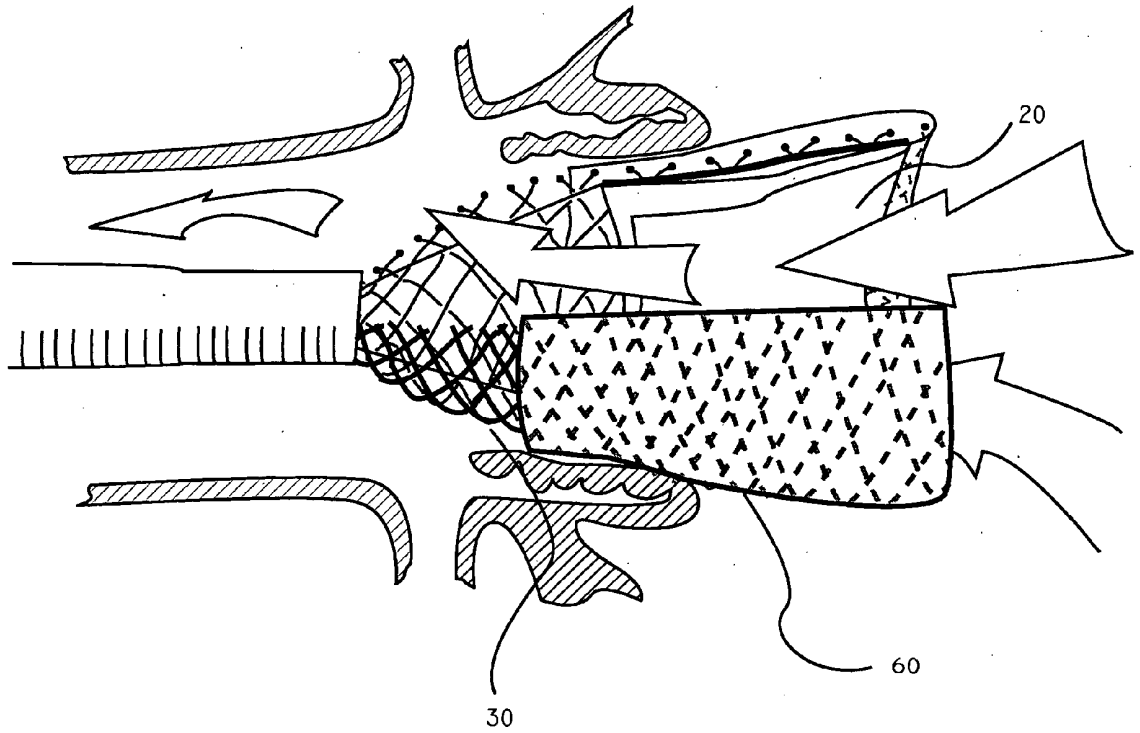
**Publication Classification**

(51) **Int. Cl.**[7] ..... **A61F 2/24**

(52) **U.S. Cl.** ..... **623/2.11**; 623/2.18; 623/2.38

(57) **ABSTRACT**

The present invention relates to apparatus for methods for endovascularly replacing a patient's heart valve. The apparatus includes an expandable anchor with leaflet engagement elements on the proximal end of the anchor and a replacement valve. The leaflet engagement elements can be used to prevent distal migration and insure proper positioning of the apparatus.



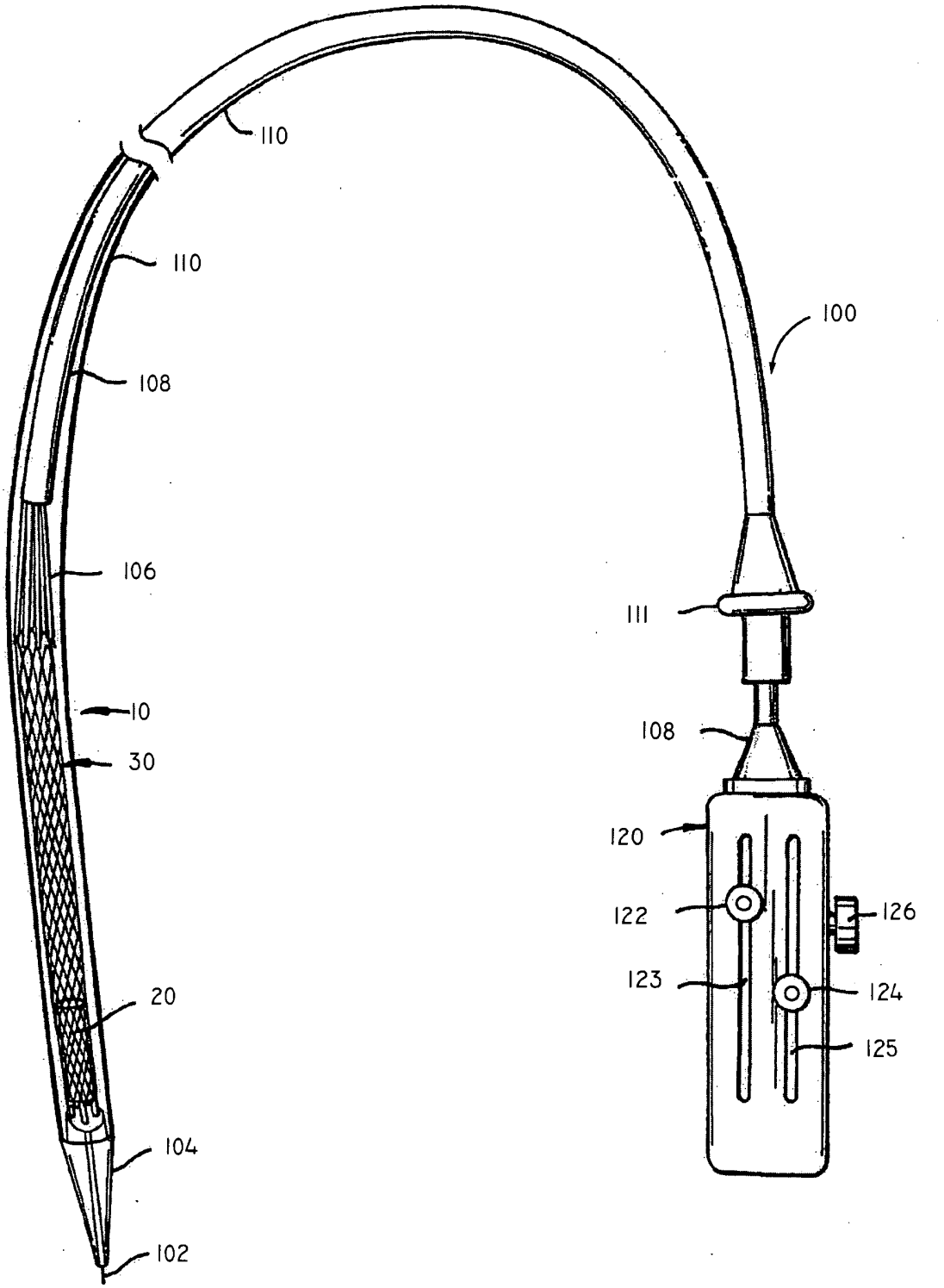

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FIG 1A

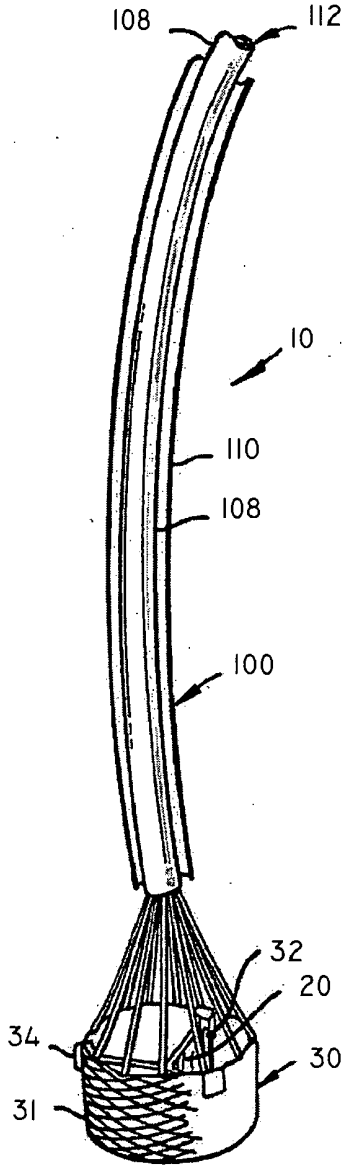


FIG 1B

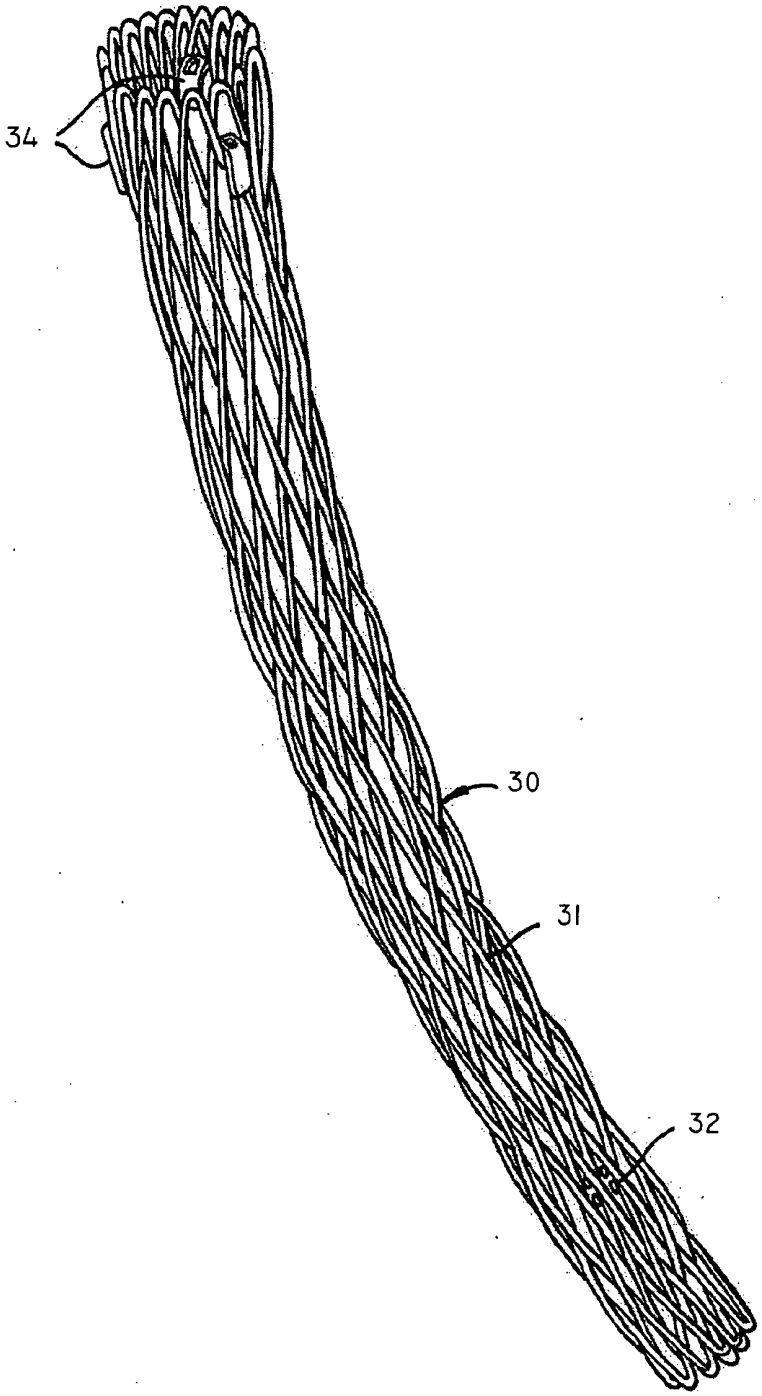


FIG 2

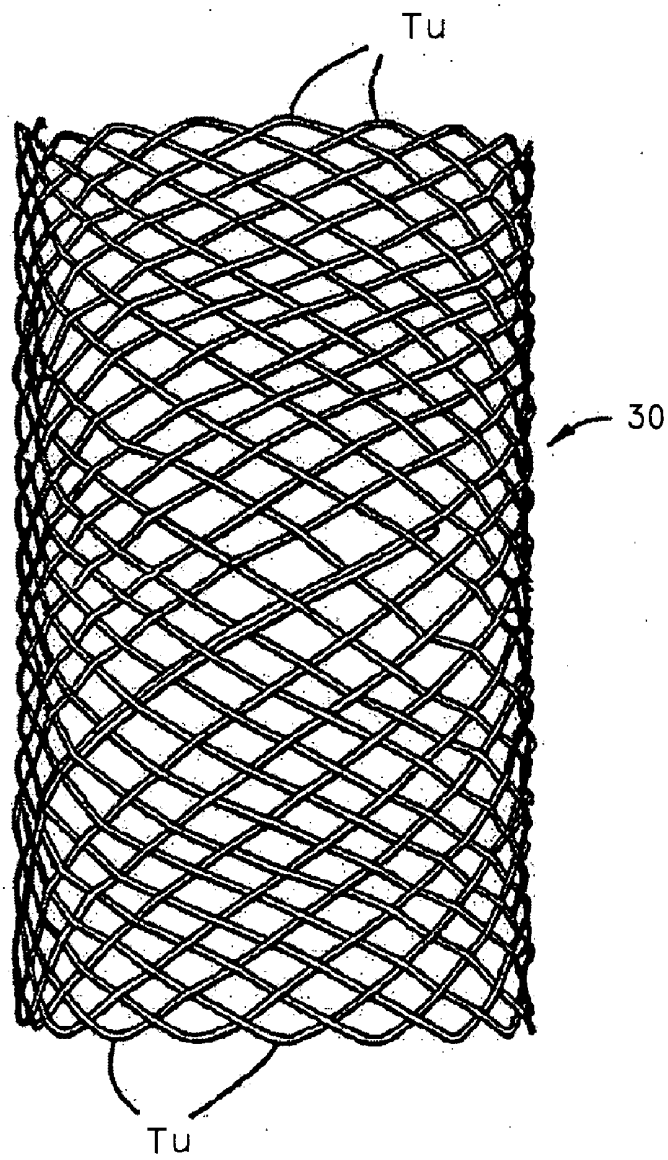


FIG 3

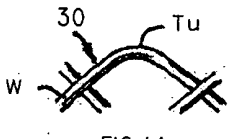


FIG 4A

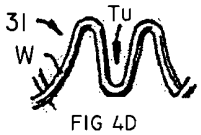


FIG 4D

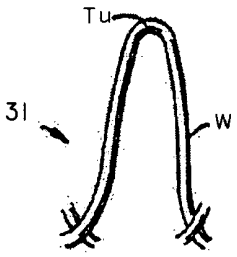


FIG 4B

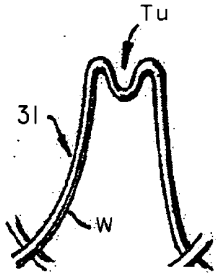


FIG 4C

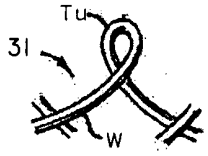


FIG 4E

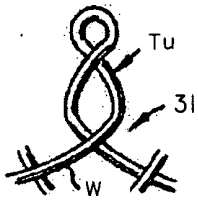


FIG 4F

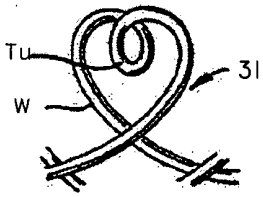


FIG 4G

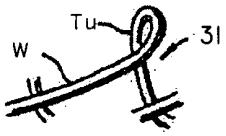


FIG 4H

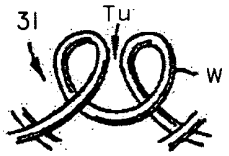


FIG 4I

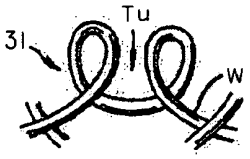


FIG 4J

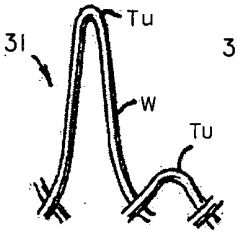


FIG 4K

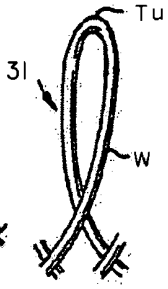


FIG 4L

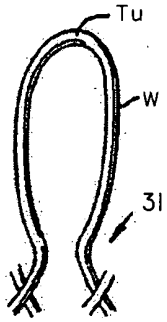


FIG 4M

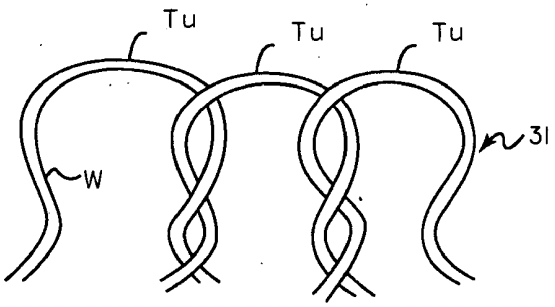


FIG 4N

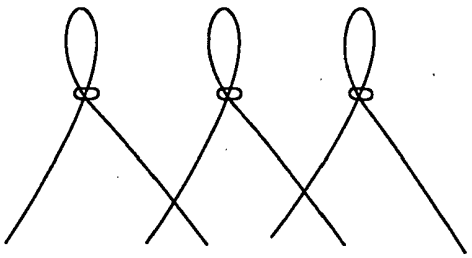

FIG 4O

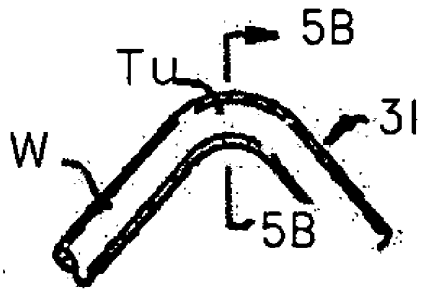


FIG 5A

FIG 5B

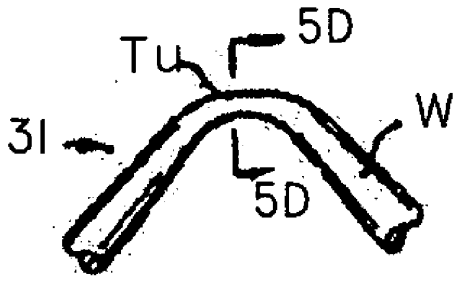


FIG 5C

FIG 5D

FIG 5E

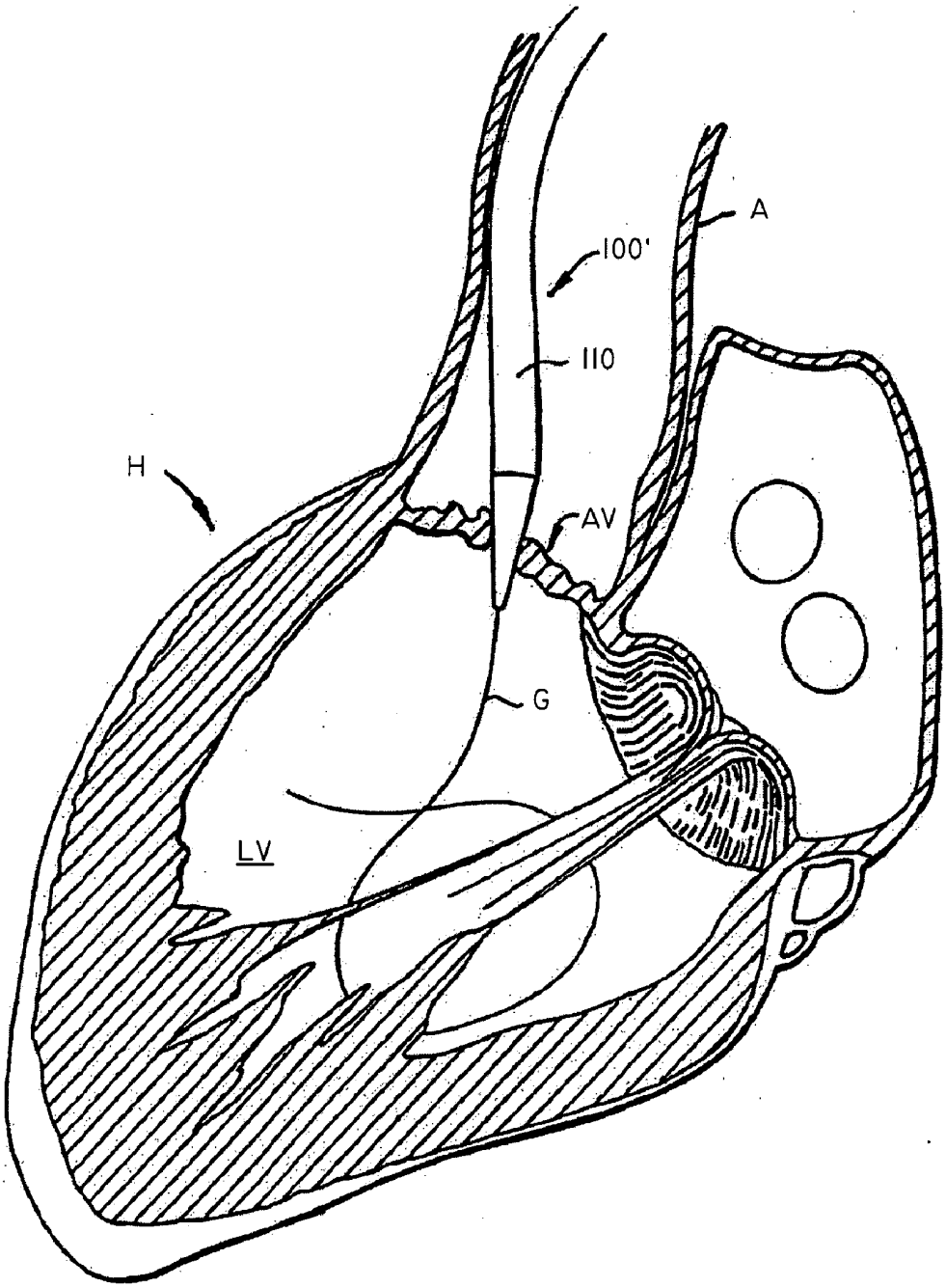


FIG 6A

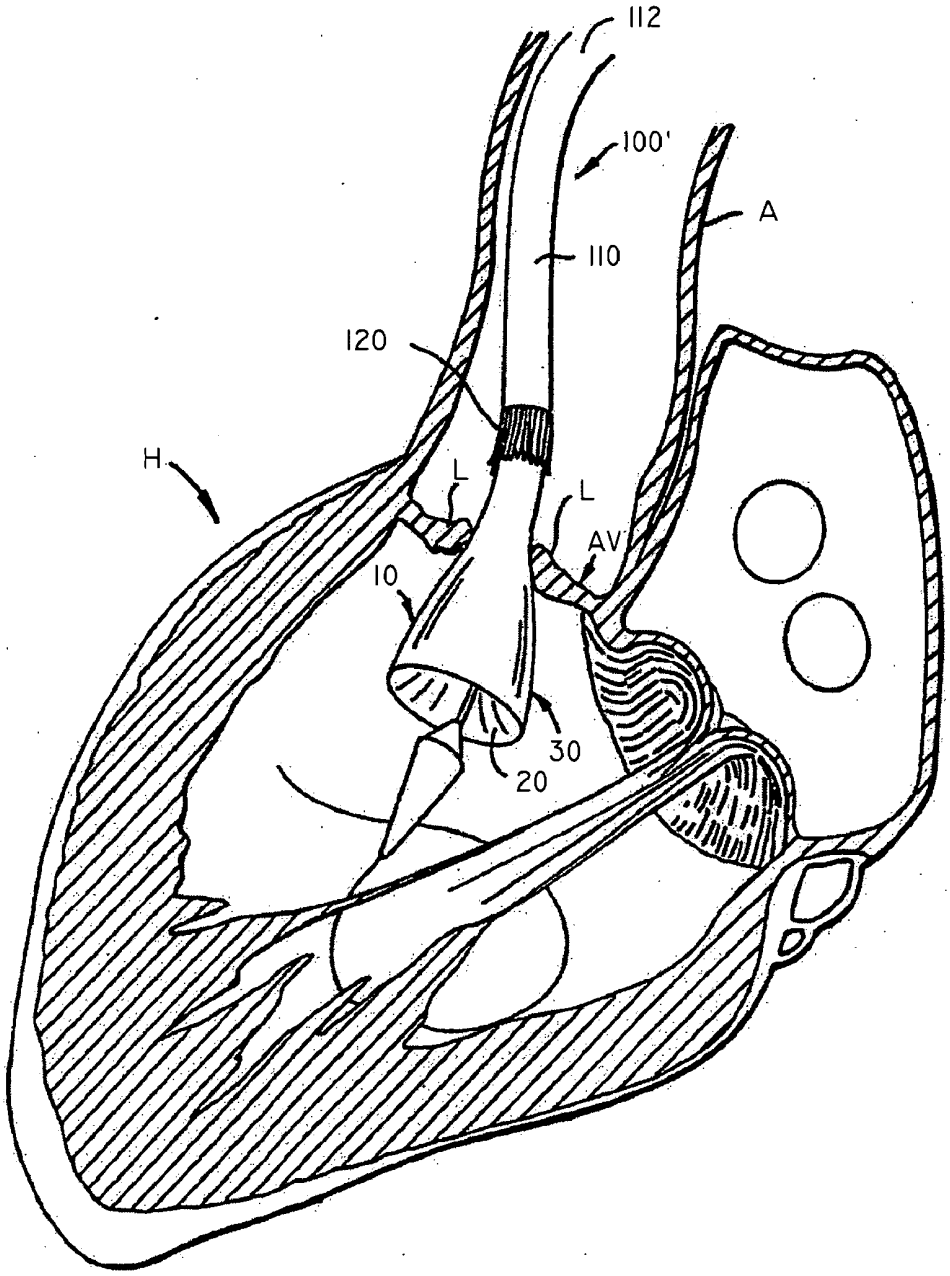


FIG 6B

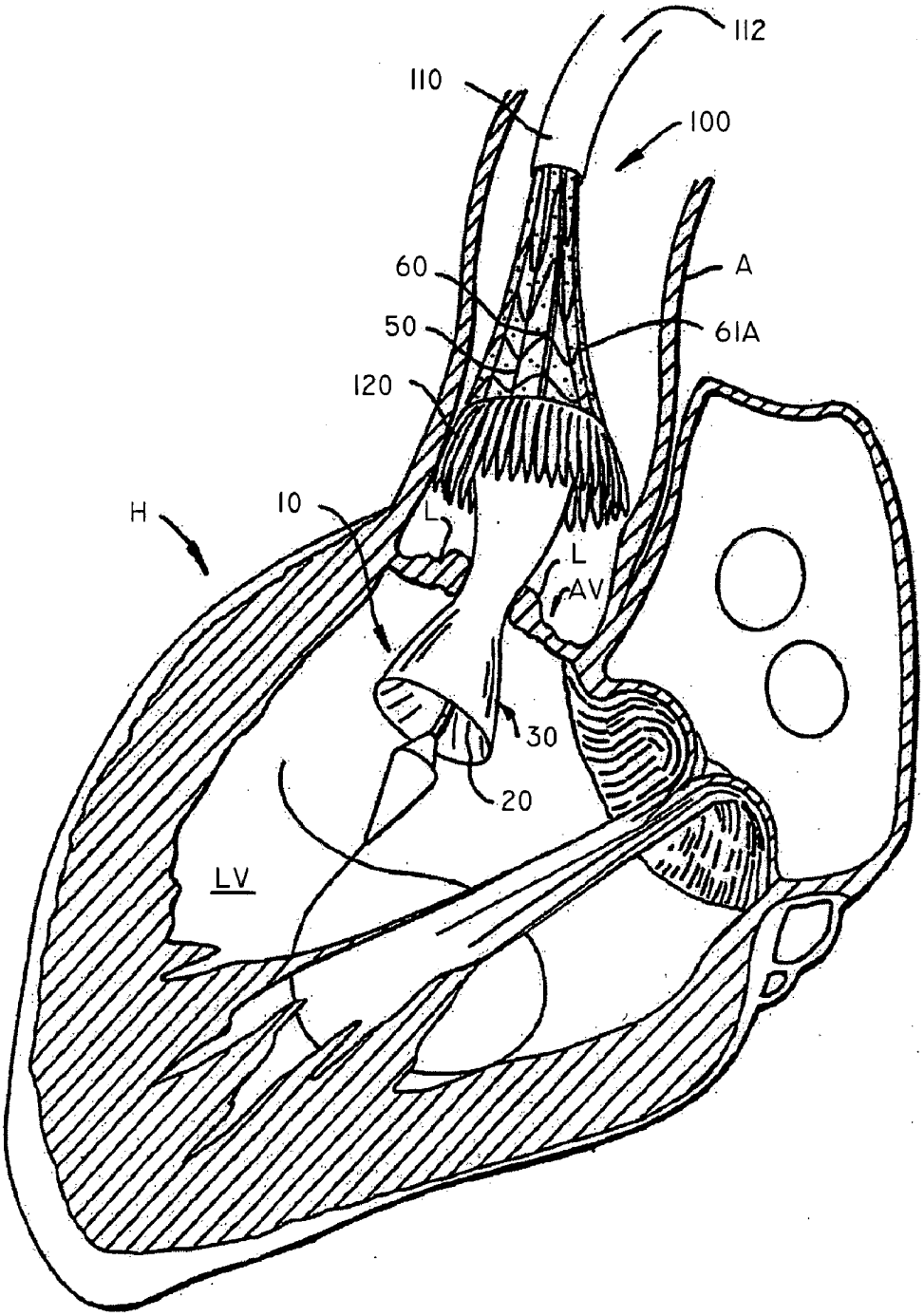


FIG 6C

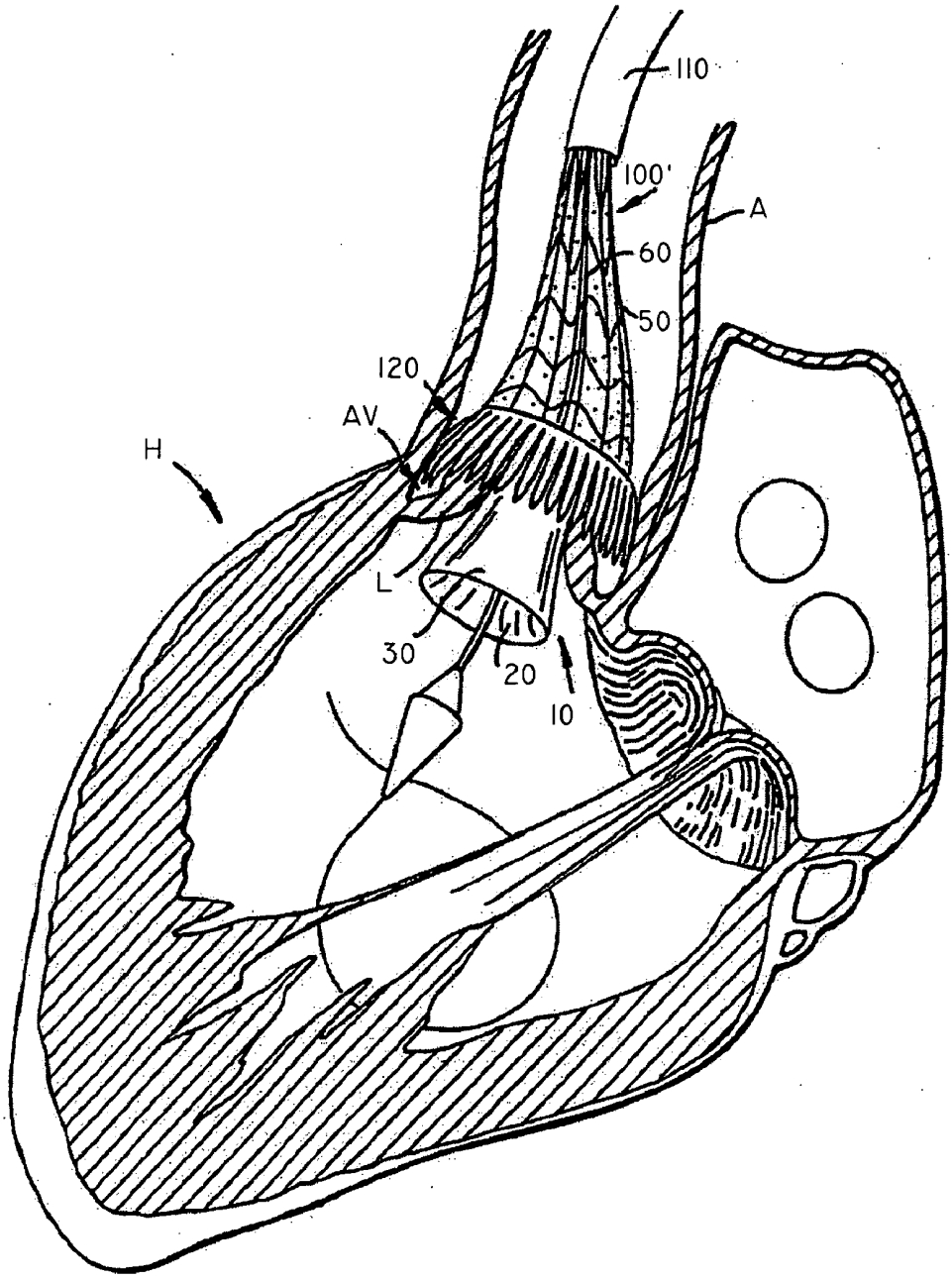


FIG 6D

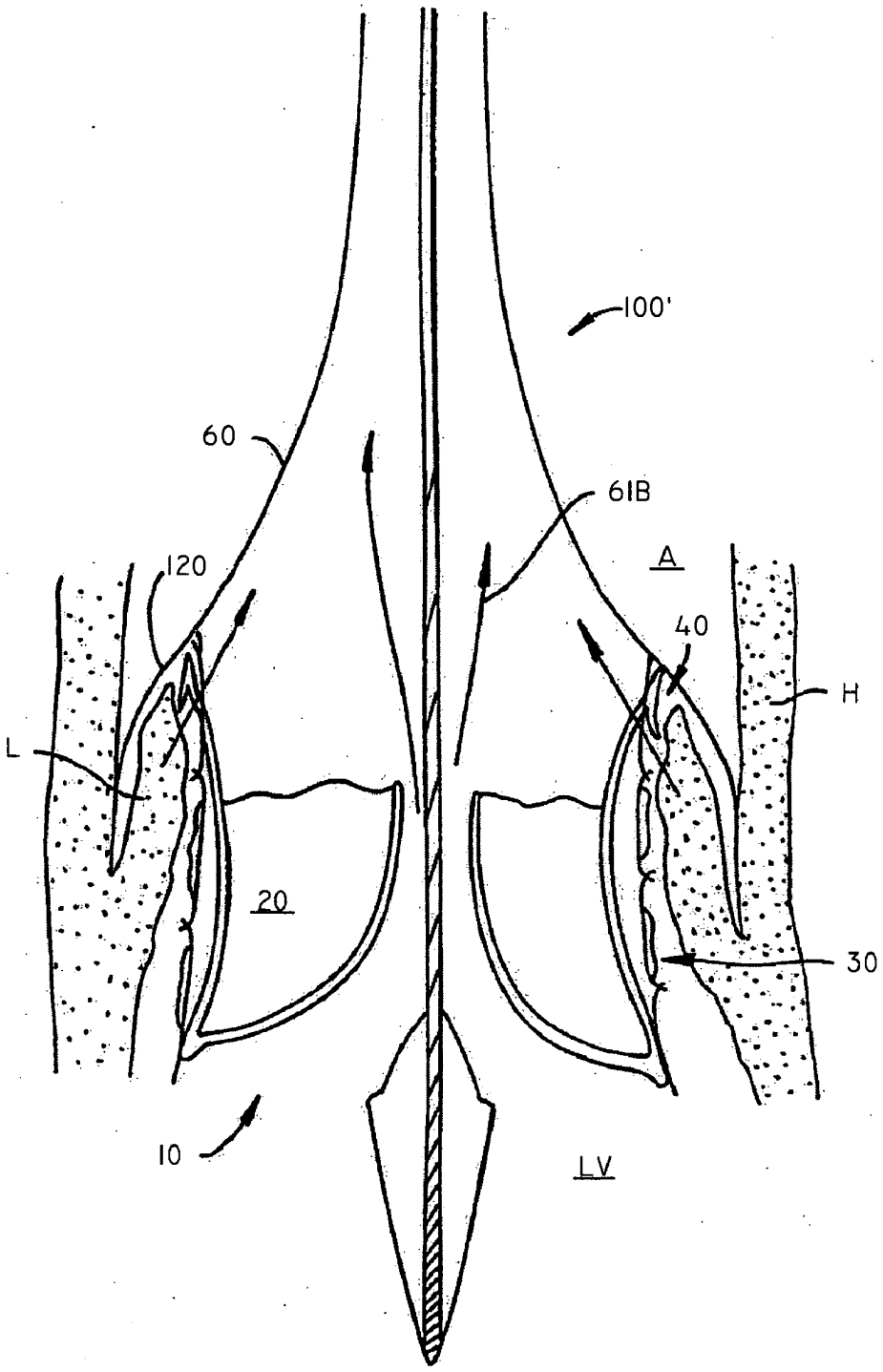


FIG 6E

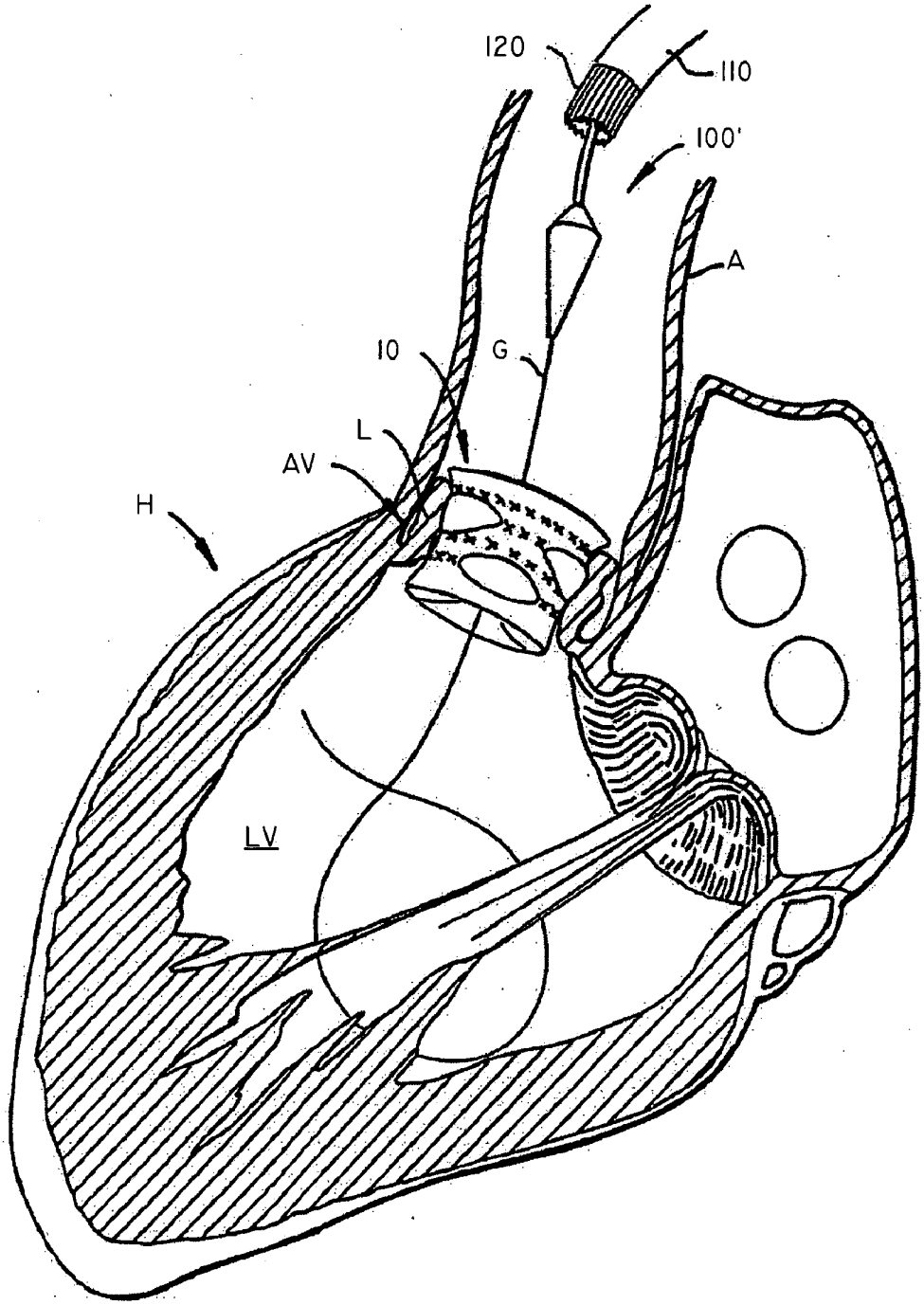


FIG 6F

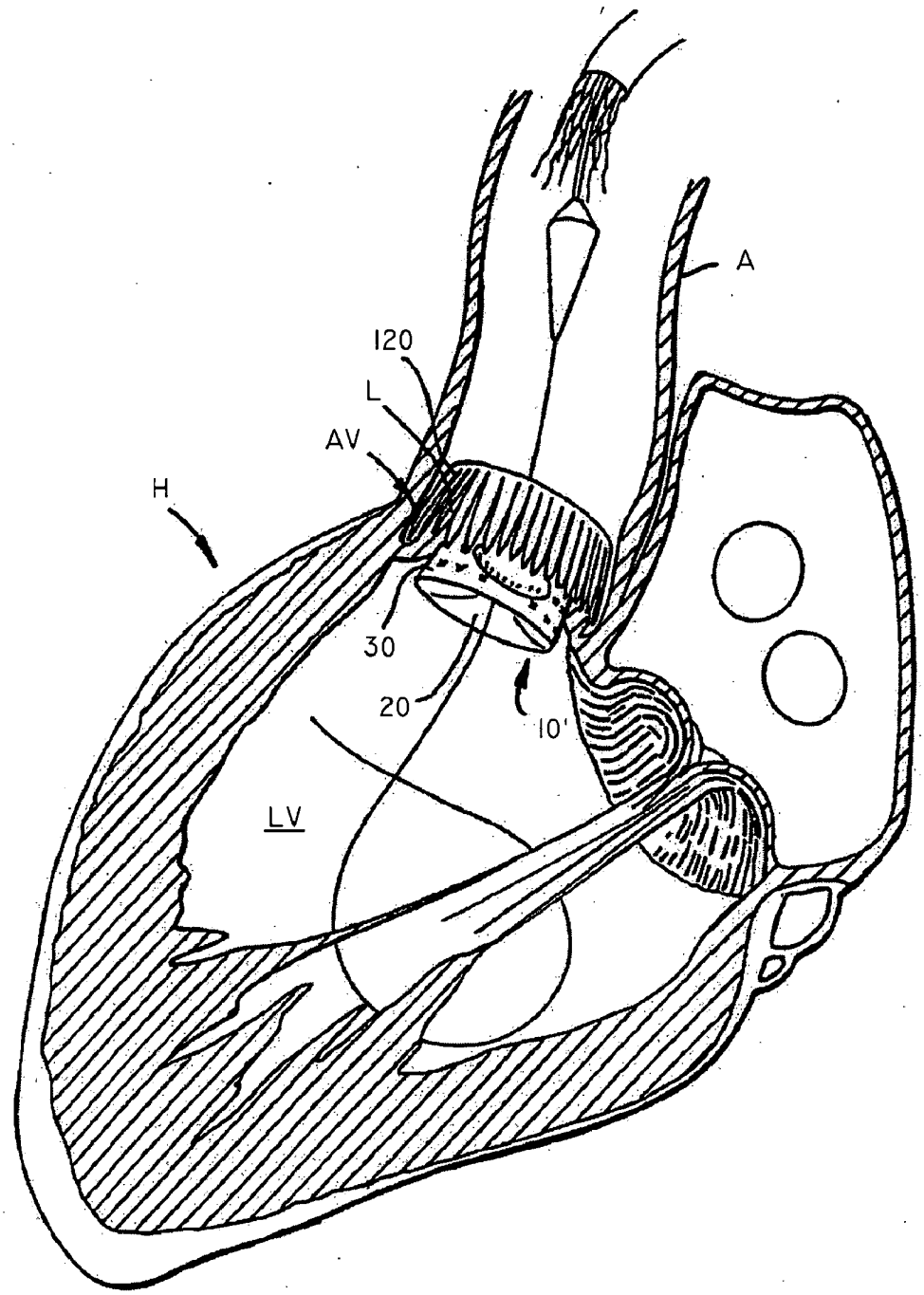


FIG 7

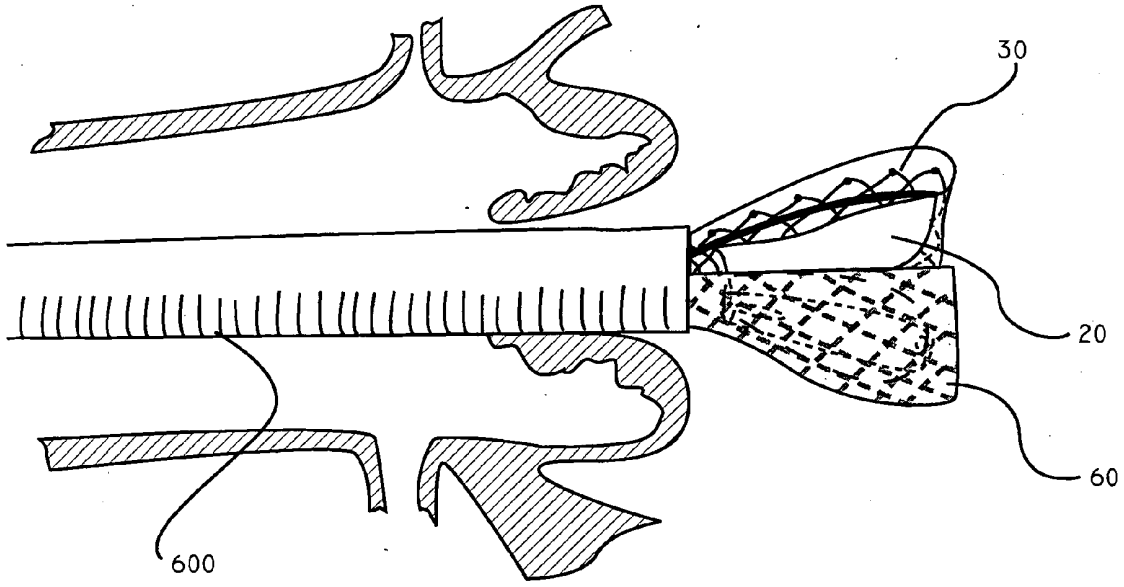


FIG 8A

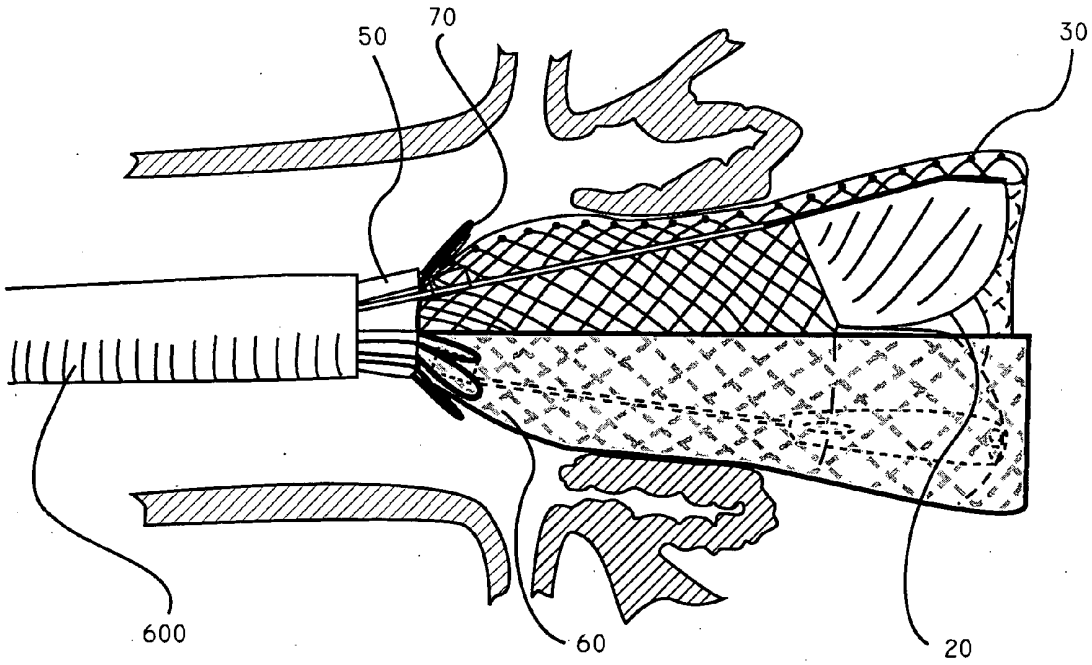


FIG 8B

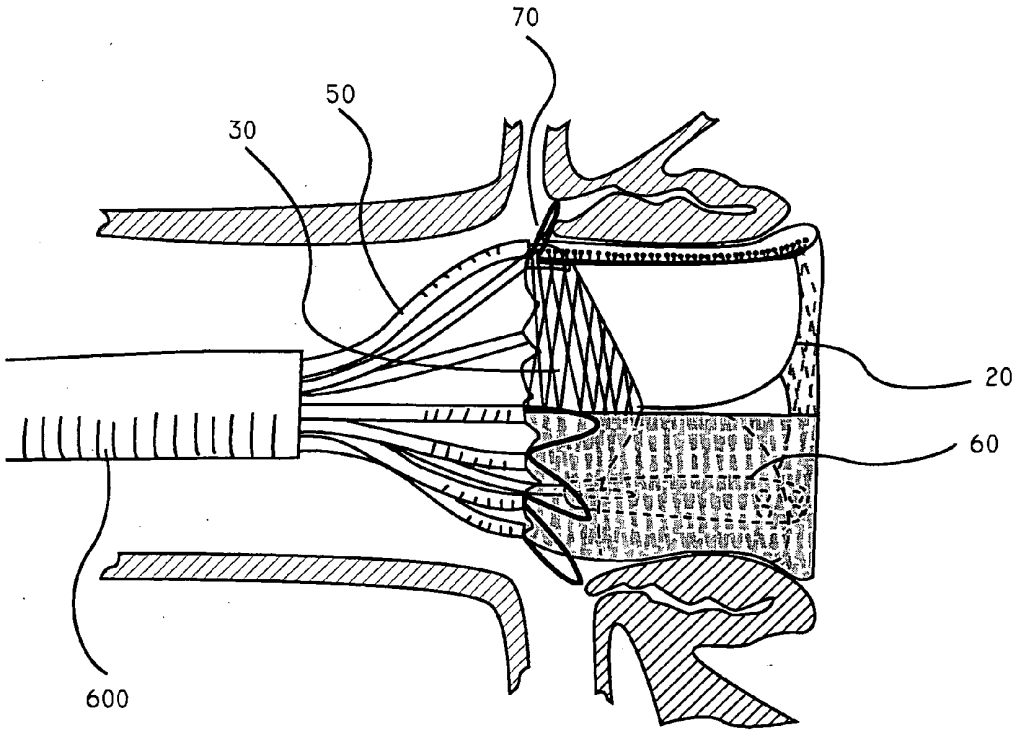


FIG 8C

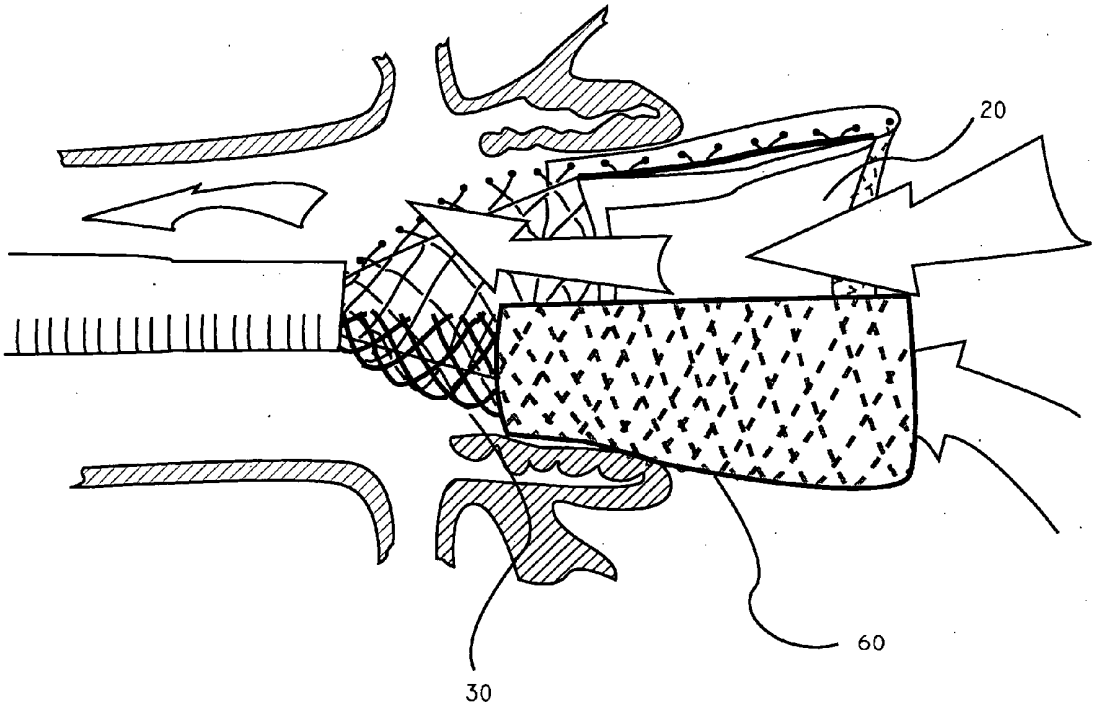


FIG 9A

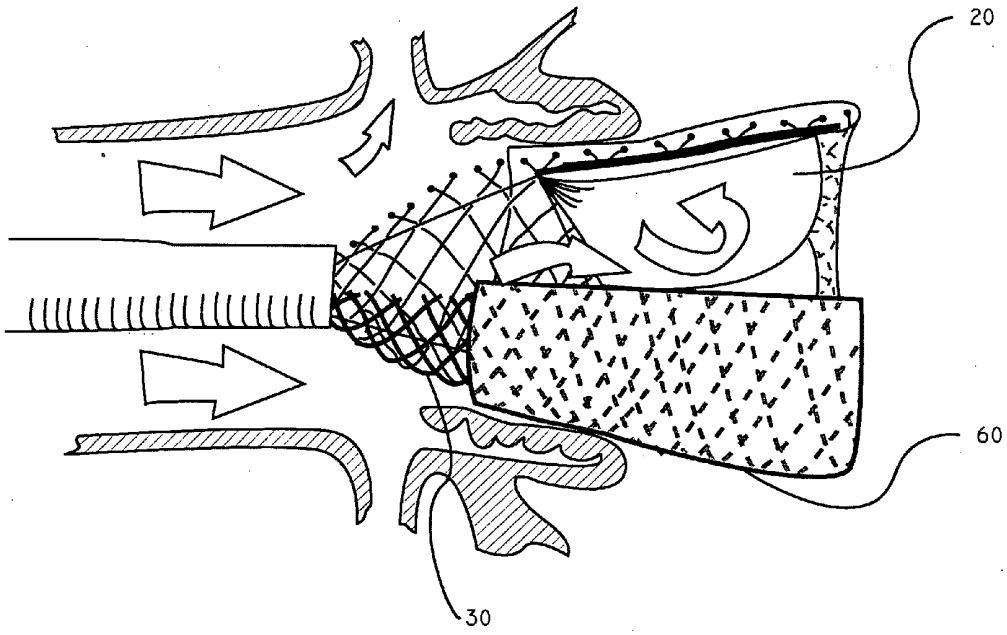


FIG 9B

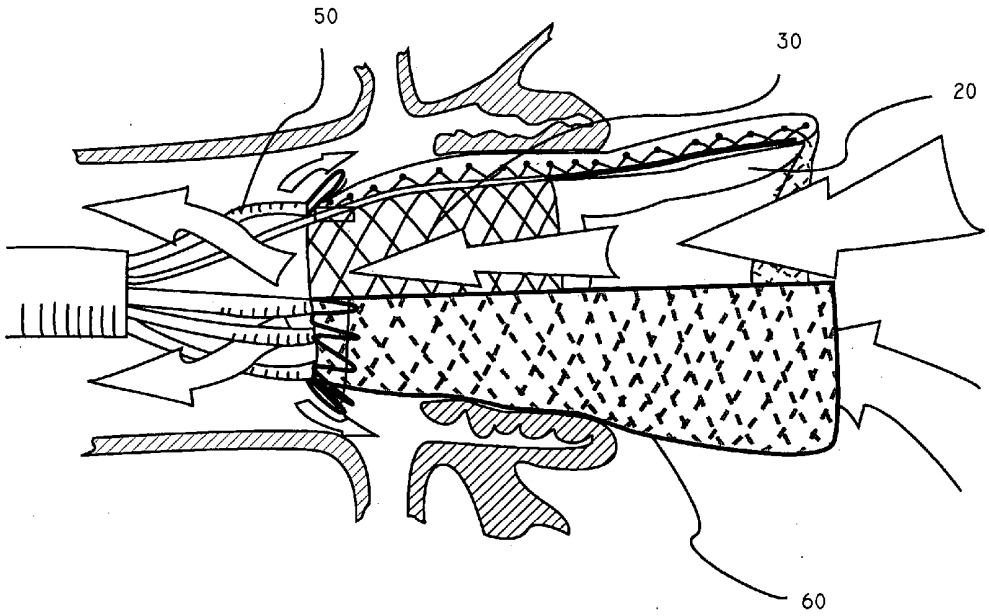


FIG 10A

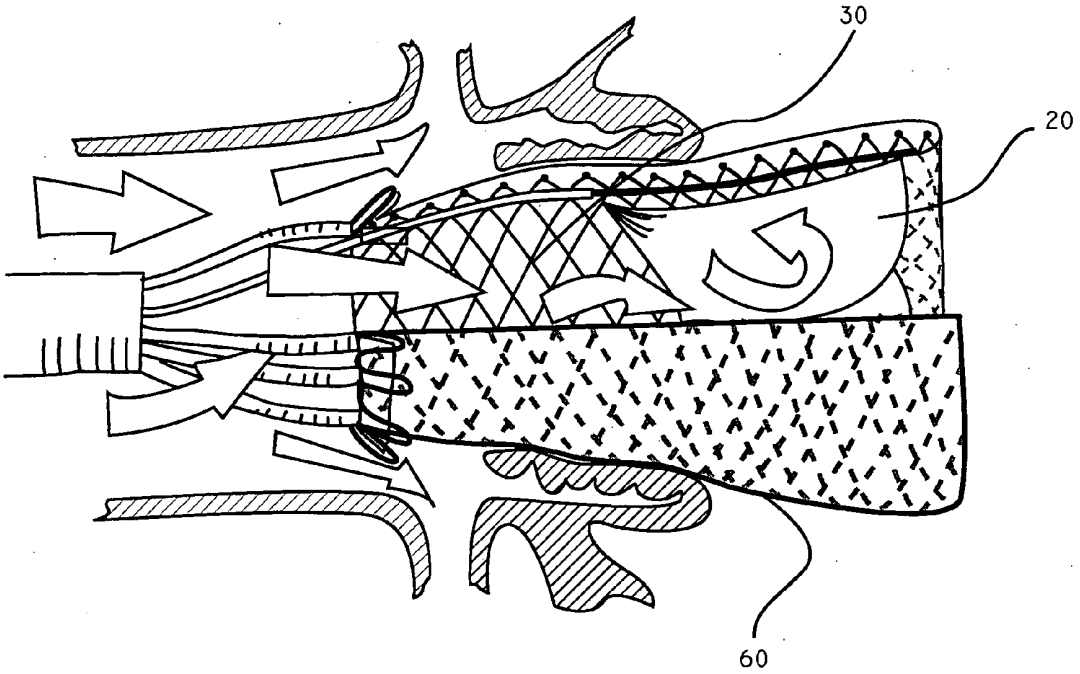


FIG10B

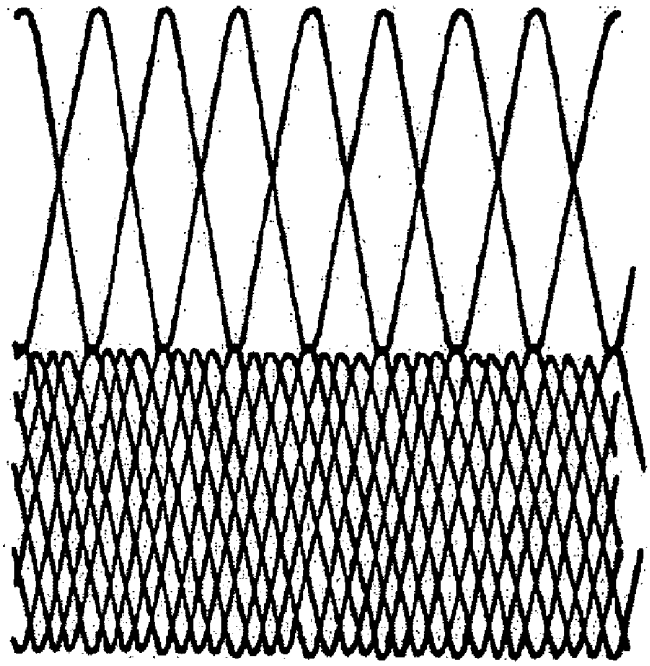

FIG IIA

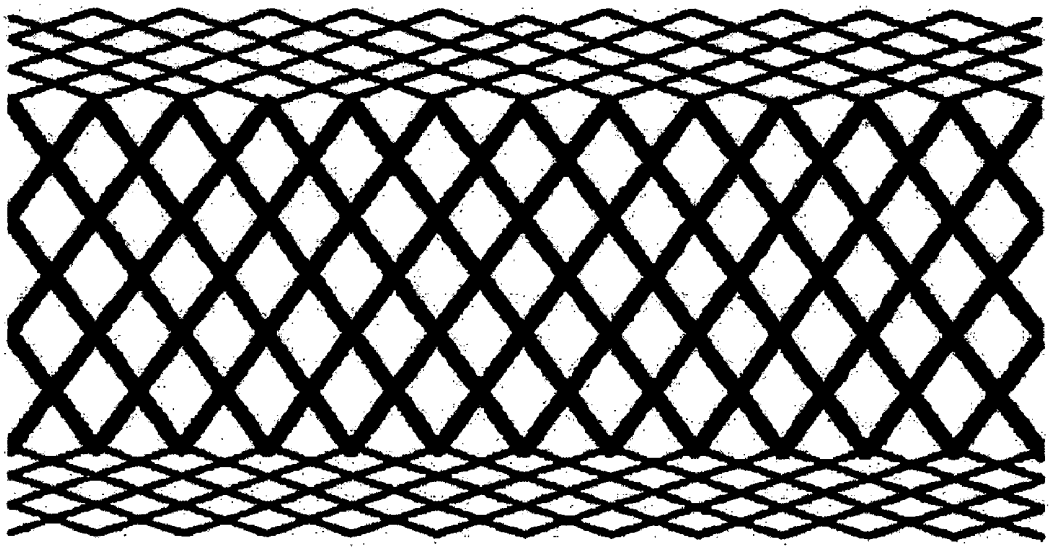

FIG 11B

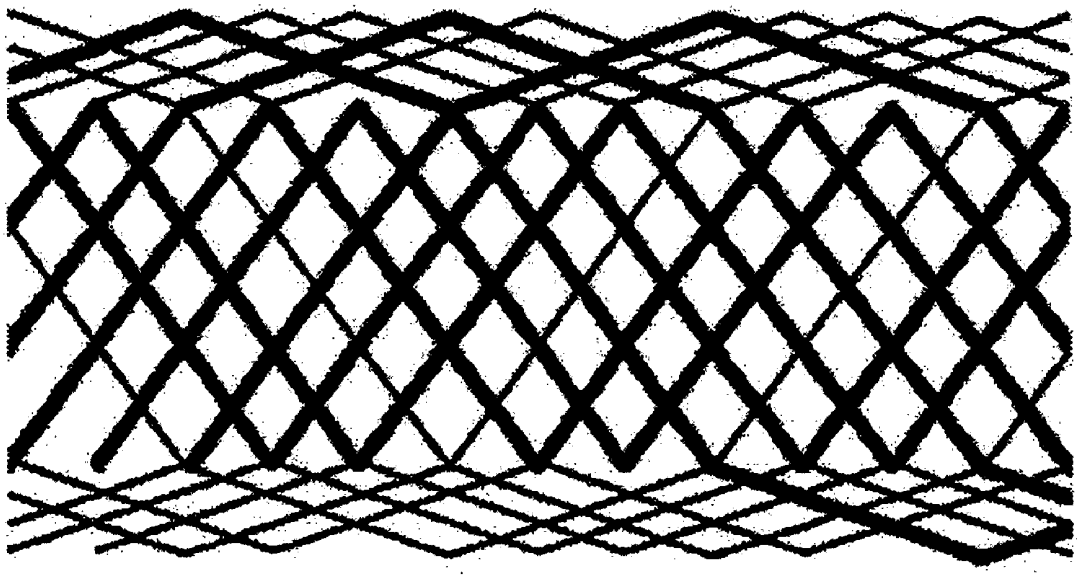

FIG IIC

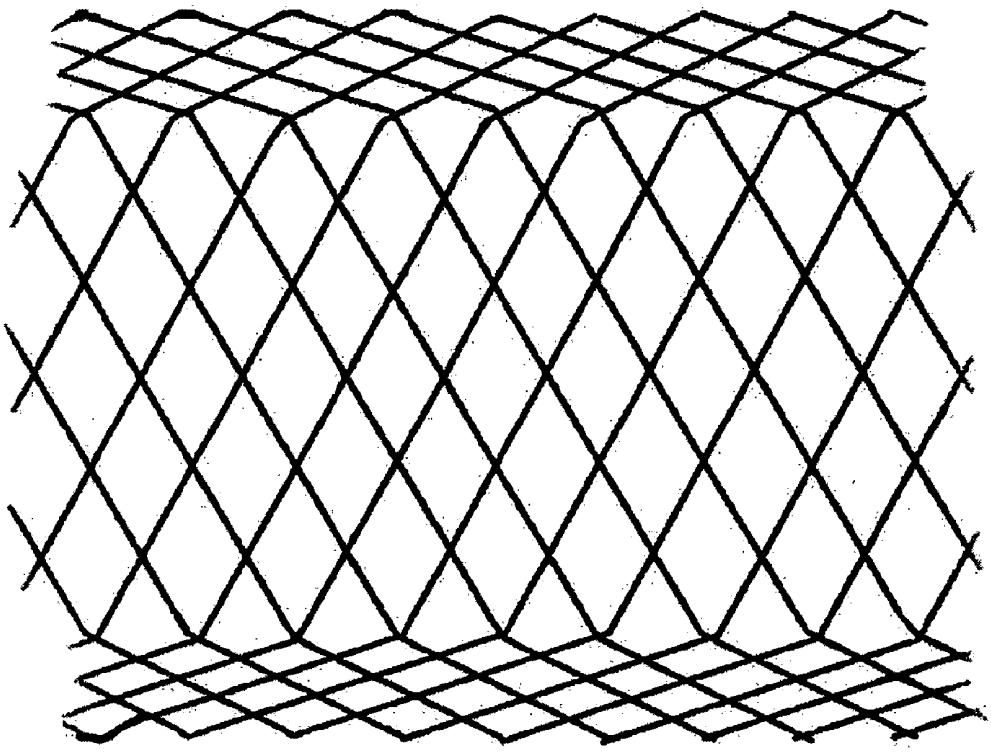

FIG IID

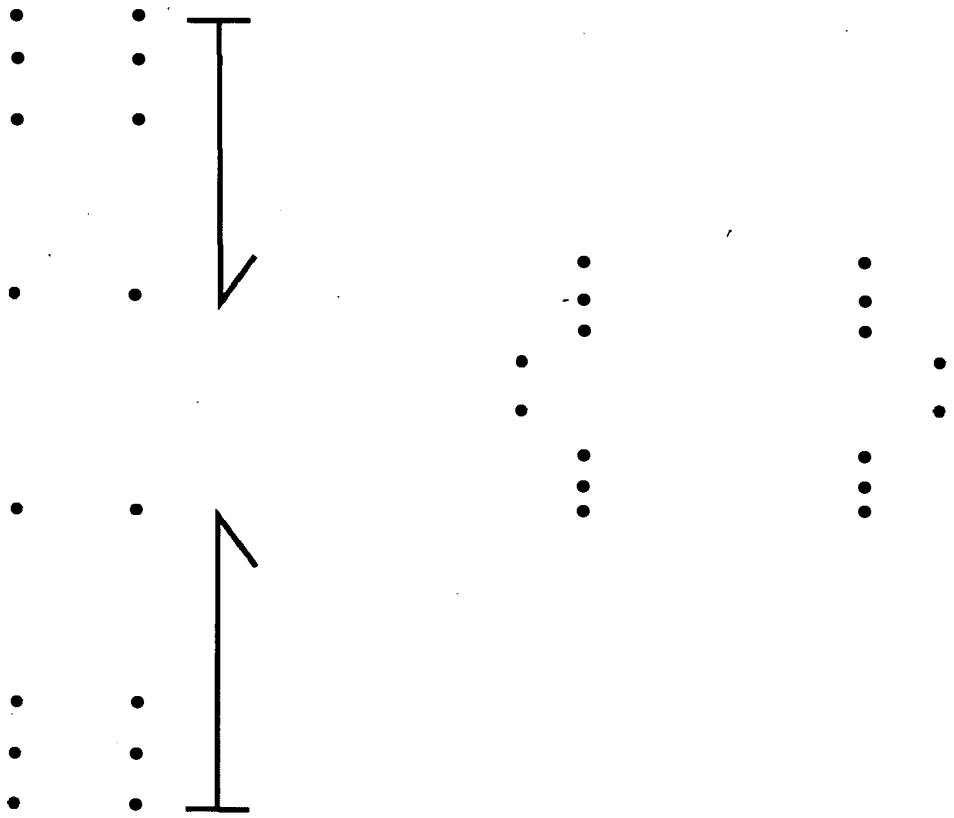

FIG 12A

FIG 12B

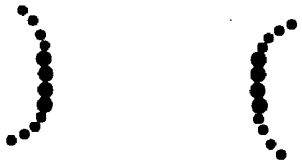

FIG 12C

FIG 12D

FIG 12E

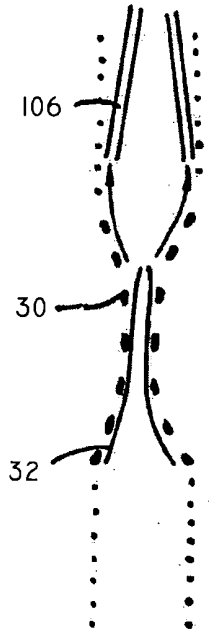


FIG 13A

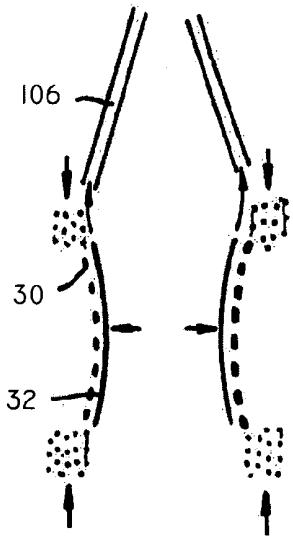


FIG 13B

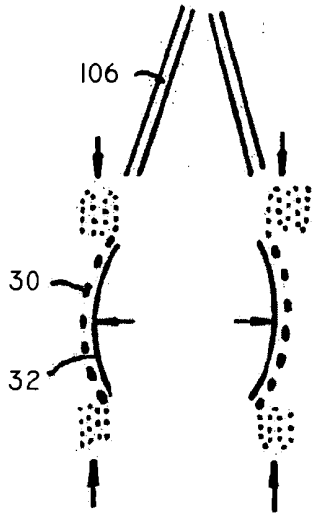


FIG 13C

FIG 13D

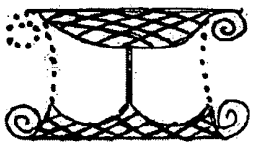

FIG 13E

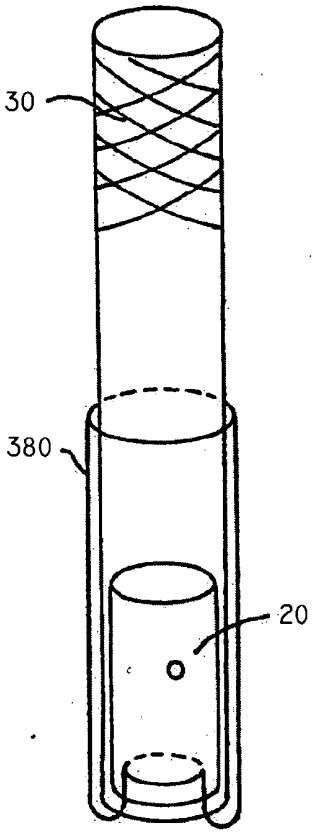


FIG 14A

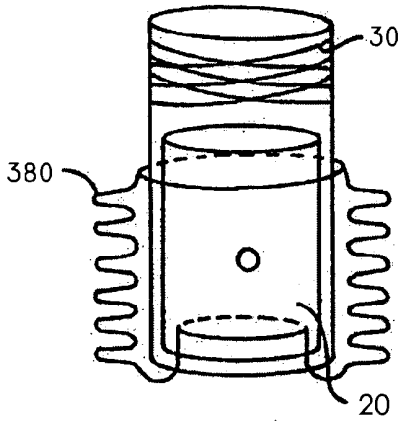


FIG 14B

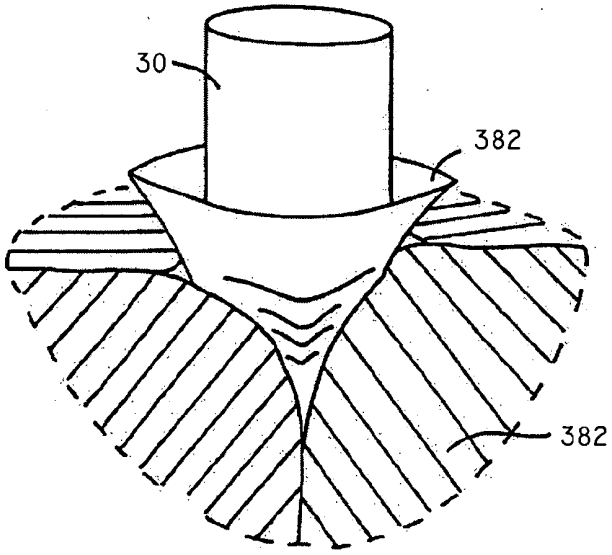


FIG 14C

# LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF

## CROSS-REFERENCE

[0001] This application is a continuation-in-part application of application Ser. No. 10/746,240, filed Dec. 23, 2003, which is incorporated herein by reference in its entirety and to which application we claim priority under 35 USC § 120.

## BACKGROUND OF THE INVENTION

[0002] The present invention relates to methods and apparatus for endovascularly replacing a heart valve. More particularly, the present invention relates to methods and apparatus for endovascularly replacing a heart valve with a replacement valve using an expandable and retrievable anchor.

[0003] Heart valve surgery is used to repair or replace diseased heart valves. Valve surgery is an open-heart procedure conducted under general anesthesia. An incision is made through the patient's sternum (sternotomy), and the patient's heart is stopped while blood flow is rerouted through a heart-lung bypass machine.

[0004] Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates. When replacing the valve, the native valve is excised and replaced with either a biologic or a mechanical valve. Mechanical valves require lifelong anticoagulant medication to prevent blood clot formation, and clicking of the valve often may be heard through the chest. Biologic tissue valves typically do not require such medication. Tissue valves may be obtained from cadavers or may be porcine or bovine, and are commonly attached to synthetic rings that are secured to the patient's heart.

[0005] Valve replacement surgery is a highly invasive operation with significant concomitant risk. Risks include bleeding, infection, stroke, heart attack, arrhythmia, renal failure, adverse reactions to the anesthesia medications, as well as sudden death. 2-5% of patients die during surgery.

[0006] Post-surgery, patients temporarily may be confused due to emboli and other factors associated with the heart-lung machine. The first 2-3 days following surgery are spent in an intensive care unit where heart functions can be closely monitored. The average hospital stay is between 1 to 2 weeks, with several more weeks to months required for complete recovery.

[0007] In recent years, advancements in minimally invasive surgery and interventional cardiology have encouraged some investigators to pursue percutaneous replacement of the aortic heart valve. However, the current devices suffer from several drawbacks.

[0008] First, many of the devices available today can become mispositioned with respect to the native valve. This is a critical drawback because improper positioning too far up towards the aorta risks blocking the coronary ostia of the patient. Furthermore, a misplaced stent/valve in the other direction (away from the aorta, closer to the ventricle) will impinge on the mitral apparatus and eventually wear through the leaflet as the leaflet continuously rubs against the edge of the stent/valve.

[0009] Moreover, some stent/valve devices simply crush the native valve leaflets against the heart wall and do not engage the leaflets in a manner that would provide positive registration of the device relative to the native position of the valve. This increases an immediate risk of blocking the coronary ostia, as well as a longer-term risk of migration of the device post-implantation.

[0010] Another drawback of the devices known today is that during implantation they may still require the patient to be on life support as the valve does not function for a portion of the procedure. This further complicates the implantation procedure.

[0011] Furtherstill, the stent comprises openings or gaps, thereby increasing a risk of improper seating of the valve within the stent and increasing the risk of paravalvular leaks. The interface between the stent and the native valve may additionally comprise gaps which again would increase the risks of paravalvular leaks.

[0012] In view of drawbacks associated with previously known techniques for endovascularly replacing a heart valve, it would be desirable to provide methods and apparatus that overcome those drawbacks.

## SUMMARY OF THE INVENTION

[0013] One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve. The apparatus includes: an expandable anchor and a replacement valve, wherein both are adapted for percutaneous delivery and deployment. The expandable anchor further includes a leaflet engagement element on its proximal end to engage the leaflets of the patient's heart valve. When the leaflets engagement element is engaged, the anchor is substantially distal to the coronary ostia of the patient. Moreover, once engaged, the leaflet engagement element prevents the distal movement of the anchor. In some embodiments, the leaflet engagement element is integral with the anchor or part of the anchor (especially when the anchor is an anchor braid). In other embodiments, the leaflet engagement element is attached to the proximal end of the anchor. In any of the embodiments herein, the anchor may be adapted for active foreshortening during deployment. Active foreshortening can occur by actuating the proximal and/or distal actuation elements of the anchor. The anchor herein may also be configured for locking and may include a locking element. The replacement valve of the apparatus herein is situated within the anchor and is adapted to permit blood flow and prevent blood backflow both during and after deployment.

[0014] Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering an anchor comprising a leaflet engagement element on its proximal end and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration; unsheathing the anchor allowing it to take a relaxed configuration intermediate between its sheathed and expanded configurations; expanding the anchor; and, engaging the leaflet engagement element with the native leaflets. The expanding step may further comprise actively foreshortening the anchor. Active foreshortening can include actuating proximal and/or distal actuation elements of the anchor. The method may also include the step of locking the anchor after it is in its

deployed configuration. In some embodiments, when the anchor engages the patient's heart, the anchor is substantially distal to the coronary ostia. In any of the embodiments herein, leaflet engagement element prevents the anchor from distally migrating at its proximal end.

## INCORPORATION BY REFERENCE

[0015] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0017] **FIGS. 1A and 1B** are schematic views of an anchor and valve apparatus in accordance with the present invention. **FIG. 1A** illustrates the apparatus in a collapsed delivery configuration within a delivery system. **FIG. 1B** illustrates the apparatus in an expanded configuration partially deployed from the delivery system.

[0018] **FIG. 2** illustrates an anchor of **FIG. 1** in the collapsed delivery configuration with locking elements separated.

[0019] **FIG. 3** illustrates a braided anchor of the present invention with closed end turns Tu.

[0020] **FIGS. 4A-4O** are schematic detail views illustrating end turns for a braided anchor.

[0021] **FIGS. 5A-5E** illustrate additional features for end turns of a braided anchor.

[0022] **FIGS. 6A-6F** illustrate deployment of an anchor with leaflet engagement elements on the deployment system.

[0023] **FIG. 7** illustrates a deployed anchor with leaflet engagement elements on the proximal end of the anchor.

[0024] **FIGS. 8A-8C** illustrate deployment of an anchor with anchor registration elements and a seal.

[0025] **FIGS. 9A-9B** illustrate an embodiment of the apparatus with a seal that does not reach the proximal end of the anchor during both systole and diastole.

[0026] **FIGS. 10A-10B** illustrate an embodiment of the apparatus with a seal that reaches the proximal end of the anchor during both systole and diastole.

[0027] **FIGS. 11A-11D** are schematic side views of various braided anchor configurations.

[0028] **FIGS. 12A-12E** are schematic side views of a deployment process for an anchor braid.

[0029] **FIGS. 13A-13E** are schematic views of different weave configurations for an anchor braid.

[0030] **FIGS. 14A-14C** illustrate an embodiment of a replacement heart valve and anchor in the undeployed and deployed configurations.

## DETAILED DESCRIPTION OF THE INVENTION

[0031] The present invention relates to an apparatus and methods for endovascularly delivering and deploying an aortic prosthesis within a patient's native heart valve, referred to here out as "replacing" a patient's heart valve. The delivery system includes a sheath assembly, a multi-lumen shaft, and a guide wire for placing the apparatus endovascularly within a patient and a user control allowing manipulation of the aortic prosthesis. The apparatus includes an anchor and a replacement valve. The anchor and the replacement valve are adapted for percutaneous delivery and deployment within a patient's heart valve. In preferred embodiments, the anchor includes a leaflet engagement element and/or a seal inverting element situated on its proximal end. The leaflet engagement element is adapted for engaging the native leaflets of the patient's heart, or more preferably the proximal edge and/or the commissural attachments of the native leaflets. The leaflet engagement element need not extend all the way into the pocket or the distal end of the native leaflet. Preferred embodiments of the apparatus herein are depicted in **FIGS. 1-14**, which are discussed in more detail below.

[0032] **FIGS. 1A and 1B** illustrate one embodiment of a delivery system and the apparatus of the present invention.

[0033] As illustrated by **FIG. 1A**, apparatus **10** may be collapsed for delivery within a delivery system **100**. Delivery system **100** includes a guidewire **102**, a nosecone **104**, anchor actuation elements **106** (in this case fingers) coupled to a multi-lumen shaft **108**, an external sheath **110** having a proximal handle **111**, and a control handle **120**. Delivery system **100** further comprises distal region control elements (not shown), comprised of or actuated by control wires **112**, which pass through one or more lumens of shaft **108** and are reversibly coupled to posts **32** of anchor **30** for manipulating a distal region of apparatus **10**. Thus, the distal region control elements may function as a distal actuation element.

[0034] The delivery system also comprises proximal region control elements comprised of or actuated by control wires **112** that pass through one or more lumens of shaft **108** and anchor actuation elements **106** to reversibly couple the control tubes to a proximal region of anchor **30**. The control wires may comprise, for example, strands of suture, or metal or polymer wires. Control handle **120** is coupled to multi-lumen shaft **108**. In some embodiments, these fingers and wires may be referred to as proximal actuation elements. A knob **122** disposed in slot **123** is coupled to the distal region control wires for controlling movement of the distal region of apparatus **10**. Likewise, a knob **124** disposed in slot **125** is coupled to proximal region control wires **112** for control of the proximal region of apparatus **10**. Handle **120** may also have a knob **126** for, e.g., decoupling the proximal and/or distal region control wires from apparatus **10**, or for performing other control functions.

[0035] As illustrated by **FIG. 1B**, apparatus **10** comprises an anchor **30** and a replacement valve **20**. Anchor **30** preferably comprises a braid. Such braid can have closed ends at either or both of its ends but preferably at least in its

proximal end. Replacement valve **20** is preferably coupled to the anchor at posts **32** attached at distal region of the anchor. Post **32** therefore, may function as valve support and may be adapted to support the replacement valve within the anchor. In the embodiment shown, there are three posts, corresponding to the valve's three commissure attachments. The posts can be attached to braid portion of anchor **30**. The posts can be attached to the braid's distal end, as shown in **FIG. 2**, central region, or proximal end. Replacement valve **20** can be composed of a metal, a synthetic material and/or may be derived from animal tissue. Replacement valve **20** is preferably configured to be secured within anchor **30**.

[**0036**] In preferred embodiments, anchor **30** is collapsible and/or expandable and is formed from material such as Nitinol™, cobalt-chromium steel or stainless steel wire. More preferably, an anchor **30** is self-collapsing and/or self-expanding and is made out of shape memory material, such as Nitinol™. An anchor composed of shape memory material may self-expand to or toward its "at-rest" configuration. This "at rest" configuration of an anchor can be, for example its expanded configuration, its collapsed configuration, or a partially expanded configuration (between the collapsed configuration and the expanded configuration). In preferred embodiments, an anchor's at-rest configuration is between its collapsed configuration and its expanded configuration. Depending on the "at rest" diameter of the anchor and the diameter of the patient's anatomy at the chosen deployment location, the anchor may or may not self-expand to come into contact with the diameter of the patient's anatomy at that location.

[**0037**] Anchor **30** may be expanded to a fully deployed configuration from a partial deployed configuration (e.g., self-expanded configuration) by actively foreshortening anchor **30** during endovascular deployment. Active foreshortening is described in more detail in U.S. patent application Ser. No. 10/746,280, which is incorporated herein by reference in its entirety. During active foreshortening, the distal region of anchor **30** may be pulled proximally via a proximally directed force applied to posts **32** via a distal deployment system interface comprised of the distal system control elements. The distal deployment system interface is adapted to expand radially during application of a proximally directed force on the distal end of the anchor when opposed by a distally directed force applied to the proximal end of the anchor.

[**0038**] In some embodiments, actuating foreshortening of the apparatus involves applying a proximally directed force on a deployment system interface at the distal end of the anchor, while maintaining the proximal end of the anchor in the same location. In other embodiments, foreshortening of the apparatus involves applying a distally directed force on proximal end of the anchor (e.g., by applying a distally directed force on the anchor actuation elements).

[**0039**] Anchor actuation elements **106** (e.g., fingers, tubes, posts, and control wires connecting to posts) are preferably adapted to expand radially as the anchor expands radially and to contract radially as the anchor contracts radially. Furthermore, proximally or distally directed forces by the anchor actuation elements on one end of the anchor do not diametrically constrain the opposite end of the anchor. In addition, when a proximally or distally directed force is applied on the anchor by the anchor actuation elements, it is preferably applied without passing any portion of a deployment system through a center opening of the replacement valve. This arrangement enables the replacement valve to operate during deployment and before removal of the deployment system.

[**0040**] The distal deployment system interface may include control wires that are controlled, e.g., by control knob **122** of control handle **120**. Similarly, the proximal regions of anchor **30** may be pushed distally via a proximal deployment system interface at the proximal end of the anchor. The proximal deployment system interface is adapted to permit deployment system to apply a distally directed force to the proximal end of anchor **30** through, e.g., fingers, which are controlled by, e.g., control knob **124** of control handle **120**. The proximal deployment system interface may be further adapted to expand radially during application of a distally directed force on the proximal end of the anchor. Preferably, the proximal deployment system interface is adapted to permit deployment system to apply a distally directed force on the proximal end of the anchor system through a plurality of deployment system fingers or tubes **160**. Such expansion optionally may be assisted via inflation of a balloon catheter (not shown) reversibly disposed within apparatus **10**, as described in U.S. patent application Ser. No. 10/746,280.

[**0041**] Once anchor **30** is fully deployed, posts **32** and buckles **34** of anchor **30** may be used to lock and maintain the anchor in the deployed configuration. In one embodiment, the control wires attached to posts **32** are threaded through buckles **34** so that the proximally directed force exerted on posts **32** by the control wires during deployment pulls the proximal locking end of posts **32** toward and through buckles **34**. Such lock optionally may be selectively reversible to allow for repositioning and/or retrieval of apparatus **10** during or post-deployment. Apparatus **10** may be repositioned or retrieved from the patient until the two-part locking mechanism of posts **32** and buckles **34** of anchor **30** have been actuated. When the lock is selectively reversible, the apparatus may be repositioned and/or retrieved as desired, e.g., even after actuation of the two-part locking mechanism. Once again, further details of this and other anchor locking structures may be found in U.S. patent application Ser. No. 10/746,280. Locking mechanisms used herein may also include a plurality of levels of locking wherein each level of locking results in a different amount of expansion. For example, the proximal end of the post can have multiple configurations for locking within the buckle wherein each configuration results in a different amount of anchor expansion. **FIG. 2** illustrates a braided anchor of **FIG. 1** in the collapsed delivery configuration with locking elements separated.

[**0042**] **FIG. 3** provides a detail view of a front side region of anchor braid **30** with closed end turns Tu. Anchor braid **30** includes various cells, some having an end turn (Tu). End turns can serve various functions. For example, end turns can be configured to reduce the sheathing force, to reduce stress within the braid during delivery and deployment, to prevent distal migration during expansion of the anchor, and/or to positively register the anchor against the native valve during deployment. In preferred embodiments, an end turn feature functions to prevent distal migration and to

register the anchor by engaging the native leaflets. In preferred embodiments, the proximal end of an anchor comprises embodiments (Tu).

[0043] **FIGS. 4A-4N** provide multiple examples of edge cells having end turn feature. The end turn features disclosed and others known in the art may be used as leaflet engagement elements to engage the native heart leaflets with the anchor. The leaflet engagement elements are preferably integral with the anchor, or more preferably part of a braided anchor. The end turn features can occur at the proximal end, the distal end, or both proximal and distal ends of the anchor.

[0044] For example, **FIG. 4A** illustrates a detail view of a standard end turn Tu in an anchor braid resulting in a braid with substantially uniform cell size and shape.

[0045] **FIG. 4B** illustrates a turn that has been elongated to lengthen the distance over which forces concentrated in the turn may be distributed, resulting in an anchor braid having edge cells that are longer along the anchor axis than the other cells defined by the braid. This elongated turn feature may be formed by routing the wire of braid about outer posts and then heat setting the wire.

[0046] **FIG. 4C** illustrates an alternative anchor edge cell configuration, wherein the tip of the elongated wire turn may be bent out of a cylindrical shape defined by the braid of anchor braid **30**. This may be achieved, for example, via a combination of routing of wire W within a fixture and then heat setting. Such a turn Tu in the anchor edge cells in **FIG. 4C** may reduce stress in some configurations without increasing height, and may also provide a lip for engaging the patient's native valve leaflets to facilitate proper positioning of apparatus **10** during deployment.

[0047] In **FIG. 4D**, a W-shaped turn feature has been formed at the wire turn, e.g., by routing the wire of anchor braid **30** about a central inner post and two flanking outer posts. As with the elongated braid cells of **FIGS. 4B and 4C**, the W-shape may better distribute stress about turn Tu.

[0048] The anchor edge cell configuration in **FIG. 4E** includes a loop formed in braid **30** at the turn, which may be formed by looping wire W around an inner or outer post.

[0049] **FIG. 4F** provides another alternative anchor edge cell configuration having a figure-eight shape. Such a shape may be formed, for example, by wrapping wire W about an inner post and an aligned outer post in a figure-eight fashion, and then heat setting the wire in the resultant shape.

[0050] In **FIG. 4G**, the edge cells of braid **30** include a heart-shaped configuration, which may be formed by wrapping the wire about an aligned inner and outer post in the desired manner.

[0051] In **FIG. 4H**, the edge cells of braid **30** have an asymmetric loop at turn Tu. The asymmetric loop will affect twisting of braid **30** during expansion and collapse of the braid, in addition to affecting stress concentration.

[0052] In **FIG. 4I**, the anchor edge cells have a double-looped turn configuration, e.g. via wrapping about two adjacent inner or outer posts. Additional loops may also be employed.

[0053] The double loop turn feature may be formed with a smooth transition between the loops, as in **FIG. 4I**, or may be heat set with a more discontinuous shape, as in **FIG. 4J**.

[0054] **FIG. 4K** illustrates that the edge cells of braid **30** may have multiple different configurations about the anchor's circumference. For example, the anchor edge cells shown in **FIG. 4K** have extended length cells as in **FIG. 4B** disposed adjacent to standard size edge cells, as in **FIG. 4A**.

[0055] The anchor edge cells of **FIG. 4L** have an extended turn configuration having an extended loop.

[0056] The anchor edge cells shown in **FIG. 4M** have an alternative extended configuration with a specified heat set profile.

[0057] In **FIG. 4N**, some or all anchor edge cells are interwoven. When interwoven, one or more edge cells may be shorter or longer than an adjacent edge cell. This permits one or more edge cells to extend into one or more leaflet pocket(s). For example, in **FIG. 4N** the middle Tu may be taller than the two adjacent edge cells thus permitting the edge cell to be situated within a leaflet pocket.

[0058] In any of the embodiments herein, edge cells may be wrapped using wire, string, or sutures, at a location where the wire overlaps after an end turn as is illustrated in **FIG. 4O**. This tied-end turn feature prevents cells from interlocking with each other during deployment.

[0059] The anchor and any of its features may be heat set at different configurations. For example, the anchor may be heat set ay its "at rest" configuration such that upon unsheathing it expands radially. The end turn features/leaflet engagement elements may be heat set at a different "at rest" configuration than the rest of the anchor. In preferred embodiment, end turn features are heat set to "flower" and then "evert" upon unsheathing.

[0060] The end turn features of **FIG. 4** are provided only for the sake of illustration and should in no way be construed as limiting. Additional turn features within the scope of the present invention will apparent to those of skill in the art in view of **FIG. 4**. Furthermore, combinations of any such end turn features may be provided to achieve the desired characteristics of anchor **30**.

[0061] Referring now to FIGS. **5**A-E, additional configurations for reducing stress concentration and/or circumferential stiffness of an anchor braid and/or leaflet engagement elements are illustrated. Such configurations can be used independently or in conjunction with other configurations disclosed herein. Such configurations are preferably used at the anchor's edges to locally reduce the cross-sectional area of substantially all cells or all cells in the anchor braid's edge (e.g., proximal and/or distal). As seen in **FIGS. 5A and 5B**, turns Tu in wire W typically may have a substantially continuous (e.g., round) cross-sectional profile. As seen in **FIG. 5C**, modifying the edge cell configuration by locally reducing the thickness or cross-sectional area of wire W at turn(s) Tu will reduce stress concentration within the wire at the turns and facilitate collapse and/or expansion of anchor braid **30** from the delivery to the deployed configurations. Furthermore, it is expected that such localized reduction in thickness or cross-sectional area will reduce a risk of kinking, fatigue or other failure at turns Tu.

[0062] In any of the embodiments herein, localized reduction of an anchor wire may be achieved via a localized etching and/or electropolishing process. Alternatively or additionally, localized grinding of the turns may be utilized.

Additional processing techniques will be apparent to those of skill in the art. As seen in **FIGS. 5D-5E**, wire W may, for example, comprise an oval or rectangular cross-sectional profile, respectively, after localized reduction. The wire alternatively may comprise a round profile of reduced cross-sectional area (not shown). Additional profiles will be apparent. Localized reduction can take place at any time (e.g., before or after a braid is woven). Preferably, localized reduction occurs after weaving. However, in some embodiments, a wire of a given length may be etched or ground at preset segments and subsequently woven.

[**0063**] With reference now to FIGS. **6**A-F, a method of endovascularly replacing a patient's diseased aortic valve is provided. The method involves endovascularly delivering an anchor/valve apparatus and properly positioning such apparatus via positive registration with the patient's native valve leaflets. Registration with the native valve leaflet preferably occurs using the leaflet engagement elements.

[**0064**] In **FIG. 6A**, modified delivery system **100'** delivers apparatus **10** to diseased aortic valve AV within sheath **110**. Apparatus **10** is delivered in a collapsed delivery configuration.

[**0065**] As seen in **FIGS. 6B and 6C**, apparatus **10** is deployed from lumen **112** of sheath **110**, for example, under fluoroscopic guidance. Sheath **110** includes at its distal end leaflet engagement elements **120**. Upon deployment, anchor **30** of apparatus **10** dynamically self-expands to a partially deployed configuration. This causes tubes **60** to also dynamically expand, as well as membrane filter (or braid) **61**A and leaflet engagement elements **120**. As when deployed via delivery system **100**, deployment of apparatus **10** via delivery system **100'** is fully reversible until locks **40** have been actuated.

[**0066**] Thus, delivery system **100'** comprises leaflet engagement element **120**, which preferably self-expands along with anchor **30**. In preferred embodiments, the distal end of leaflet engagement elements **120** expands a greater radial distance than anchor **30**. Moreover, engagement elements **120** may be disposed between tubes **60** of delivery system **100'** and lip region **32** of anchor **30**. However, leaflet engagement elements **120** may also be disposed on the proximal end of an anchor (as is illustrated in **FIG. 7**). Leaflet engagement elements **120** releasably engage the anchor. As seen in **FIG. 6C**, the leaflet engagement elements **120** are initially deployed proximal of the patient's native valve leaflets L. Apparatus **10** and element **120** then may be advanced/dynamically repositioned until engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus **10**. The leaflet engagement element engages with the proximal edges of the native valve leaflets and/or the commissural attachments. The leaflet engagement element need not extend all the way to the distal edge of the native leaflets (the leaflet pockets). In preferred embodiments, a leaflet engagement element length is less than about 20 mm, more preferably less than about 15 mm, or more preferably less than about 10 mm. Once leaflet engagement element **120** is registered against the native valve leaflets and/or commissural attachments, apparatus **10** deploys substantially distal to the coronary ostia of the heart.

[**0067**] In any of the embodiments herein, delivery system **100'** can include filter structure **61**A (e.g., filter membrane or braid) as part of push tubes **60** to act as an embolic protection element. Emboli can be generated during manipulation and placement of anchor from either diseased native leaflet or surrounding aortic tissue and can cause blockage. Arrows **61**B in **FIG. 6C** show blood flow through filter structure **61**A where blood is allowed to flow but emboli is trapped in the delivery system and removed with it at the end of the procedure.

[**0068**] Active foreshortening may be imposed upon anchor **30** while element **120** is disposed proximal of the leaflets, as is illustrated in **FIG. 6D**. Active foreshortening can be accomplished by actuating distal anchor actuation elements (e.g., wires **50**) and/or proximal anchor actuation elements (e.g., tubes **60**). Upon positive registration of element **120** against leaflets L, element **120** precludes further distal migration of apparatus **10** during additional foreshortening, thereby reducing a risk of improperly positioning the apparatus. **FIG. 6E** details engagement of element **120** against the native leaflets.

[**0069**] As seen in **FIG. 6F**, once apparatus **10** is fully deployed, anchor **30** may be locked (reversibly or irreversibly). Subsequently, structure **61**A leaflet engagement, elements **120**, wires **50** and/or tubes **60** may be decoupled from the apparatus, and delivery system **100'** may be removed from the patient, thereby completing the procedure.

[**0070**] **FIG. 7** illustrates an alternative embodiment of the apparatus of FIGS. **6**A-F described above, wherein leaflet engagement elements **120** are coupled to anchor **30** of apparatus **10'** rather than to delivery system **100**. In the embodiment illustrated in **FIG. 7**, leaflet engagement elements **120** remain implanted near the patient's native heart valve after the deployment of apparatus **10'** and removal of delivery system **100**. Leaflets L may be sandwiched between the proximal region of anchor **30** and leaflet engagement element **120** in the fully deployed configuration. In this manner, element **120** positively registers apparatus **10'** relative to the leaflets L and precludes distal migration of the apparatus over time.

[**0071**] **FIGS. 8A-8C** illustrate another embodiment for endovascularly delivering an apparatus of the present invention. In **FIG. 8A**, a catheter **600** is delivered percutaneously in a retrograde fashion to the aortic valve. The catheter passes through the native aortic valve before an operator actuates the unseathing of the anchor/valve apparatus. As the sheathing catheter is pulled proximally out of the native valve, anchor **30** and replacement valve **20** become unsheathed. Immediately the portion of the unsheathed anchor **30** dynamically self-expands to its "at rest" position, and replacement valve **20** within the anchor regains an uncollapsed structure, allowing it to begin to function. In preferred embodiments in its "at rest" position, anchor **30** presses against the native leaflets limiting blood from flowing in between the anchor and leaflet. Also, in preferred embodiments, anchor **30** portions relatively adjacent to the valve is externally covered by a seal **60**, more preferably the entire exterior contour of anchor **30** excluding the leaflet engagement elements is externally covered by a seal, or more preferably the entire contour of anchor **30** including the external face of the leaflet engagement elements is externally covered by a seal. A seal can be composed of any material that prevents or limits the flow of blood through the anchor. In preferred embodiments, a seal is composed of a thin, elastic polymer or any other type of fabric. The seal can

be attached by any means known in the art to the anchor and, in some embodiments, to the distal end of the valve. In preferred embodiments, a seal is attached to the anchor by suturing.

[0072] In **FIG. 8B**, as the catheter is further pulled proximally, the proximal end of anchor **30** and fingers **50** are unsheathed. In this embodiment, it is possible to visualize that the seal covers the entire contour of the anchor including the external face of the leaflet engagement element **70**. As soon as the proximal end of the anchor is exposed, it also dynamically expands. Furthermore, when fingers **50** become exposed, replacement valve **20** begins to function permitting blood to flow through replacement valve **20**, between fingers **50**, and around the catheter **600**. This also permits blood to flow into the coronary ostias. In other embodiments where the seal does not cover the proximal end of the anchor, the replacement valve can begin to function as soon as the unsealed portion of the anchor is unsheathed. This causes the leaflet engagement elements **70** to radially expand to their heat set position and engage with the native heart leaflets.

[0073] Next, **FIG. 8C**, as the apparatus is actively foreshortened using proximal (e.g., fingers) and/or distal actuators (e.g., wires **55**), the leaflet engagement elements positively register with the native valve leaflets. Foreshortening can cause seal **60** to bunch up and create pleats. These pleats can then fill pockets thereby improving the paravalvular seal. In preferred embodiments, wherein the leaflet engagement elements are covered with a seal, at least a portion of the seal is also positioned between the native valve leaflets and the aortic wall. Once the anchor is fully compressed within the aortic valve, the anchor is locked, the fingers and post mandrels are disengaged, and the seal is adapted to further limit blood flow around the replacement valve. The catheter is subsequently withdrawn, leaving behind valve **20**, seal **60** and anchor **70**. When fully deployed, the anchor is substantially distal to the coronary ostia of the patient such that it will not interfere with blood flow through the ostia.

[0074] **FIGS. 9A-9B** illustrate an embodiment wherein only a distal portion anchor **30** is covered by seal **60** and wherein anchor **30** is only partially deployed since the blood can escape through the proximal end of the anchor braid. As anchor **30** in this embodiment is unsheathed, it presses against the native valve leaflets. At this point replacement valve **20** is functional even though anchor **30** is not fully deployed since blood can escape through the proximal end of the anchor braid. This allows blood to flow through replacement valve **20** and out of holes in the distal end of anchor **30** during systole (**FIG. 9A**) while preventing backflow during diastole (**FIG. 9B**).

[0075] **FIGS. 10A-10B** illustrate a similar embodiment wherein seal **60** around anchor **30** surrounds the entire contour of anchor **30**. In this embodiment, valve **20** does not become functional until both anchor **30** and a portion of fingers **50** are unsheathed. As soon as a portion of fingers **50** is unsheathed, replacement valve **20** is fully functional. This allows blood to flow through replacement valve **20** and anchor **30**, out of fingers **50**, and around catheter **60** into the aorta and coronary ostias during systole. Similarly, during diastole, replacement valve **20** closes preventing blood backflow from entering the chamber.

[0076] In any of the embodiments herein the anchor is preferably a self-expanding anchor braid. Anchor braid of the present invention can be made from one or more wires, more preferably 2-20 wires, more preferably 3-15 wires, or more preferably 4-10 wires. Moreover, the density of the braid can be modified by various forms of weave used.

[0077] **FIGS. 11A-11D** illustrate various anchor braid embodiments contemplated by the present invention.

[0078] **FIG. 11A** illustrates two groups of cells or two braids interwoven in the center. The top group of cells forms a more open weave than the bottom group of cells, which forms a denser weave.

[0079] **FIG. 11B** illustrates another embodiment of an anchor braid having three groups of cells. The top and bottom (proximal and distal) edges of the anchor braid have denser cells than the central portion of the anchor. Also, the edges of the anchor are woven from a thinner filament than the central portion.

[0080] In another embodiment illustrated by **FIG. 11C**, all three sections of an anchor valve are woven by more than one wire. The wires of each section are made of a different material and/or thickness. Wires at the sectional boundaries may or may not interconnect with wires from a different section. Each of the sections of the braid anchor may be composed of a different number of wires.

[0081] **FIG. 11D** illustrates another embodiment of a braided anchor having three sections. In this embodiment, all sections are composed of a single wire. The proximal and distal sections/edges of the braided anchor have the same pitch. The central region of the braided anchor has a different pitch than the edge sections.

[0082] **FIGS. 12A-12E** illustrate side views of braided anchor having more than one braid pitch. Varying pitch within the anchor allows localized variations in foreshortening across the anchor, as greater foreshortening is achieved by higher pitch of the braid. Moreover, the localized foreshortening features allow for the design of a braid which incorporates various diameters depending upon the amount of foreshortening. (The greater the foreshortening, the greater the diameter increase upon deployment.)

[0083] **FIG. 12A**, is a side view representation of the braided anchor of **FIG. 11D**. On the left side of the figure, the expanded anchor is illustrated having a denser weave (shorter pitch) at the distal and proximal ends; hence the dots are located closer to each other. The middle section of the anchor is composed of a looser weave that is generated by a higher pitch braid and is represented by dots that are farther away from each other. On the right side of the figure, the braided anchor is foreshortened and the dots are collapsed closer to each other. In this case, the central portion of the anchor foreshortened more than the proximal and distal edges.

[0084] **FIG. 12B** illustrates a side view of a foreshortened braided anchor that is created by low pitch at the edges and high pitch in the middle.

[0085] **FIG. 12C** illustrates a side view of a foreshortened braided anchor that is created by high pitch edges and low pitch middle section.

[0086] **FIG. 12D** illustrates a side view of a foreshortened braided anchor that includes a sealing feature or space filling feature at both ends. This type of anchor can be created by

a high pitch braid at edges, low pitch braid in the middle and heat setting the edges to curl upon unsheathing. These end features can be useful in facilitating anchoring by functioning as a locator and/or sealing. In preferred embodiment the curled ends of the anchor in **FIG. 12D** can be used as leaflet engagement elements.

[**0087**] **FIG. 12E** illustrates a side view of a foreshortened braided anchor that is associated with an everting valve or locational features. In preferred embodiments, the middle section of the anchor may be composed of thicker wire(s) than edge section(s). The everting feature at the proximal end can function as a leaflet engagement element as disclosed herein.

[**0088**] **FIGS. 13A-13E** illustrate an example of the process of deploying an anchor, such as the one illustrated in **FIG. 12B** above.

[**0089**] **FIG. 13A** illustrates a braided anchor **30** in its expanded or elongated configuration. The anchor is composed of three sections. The distal and proximal sections of the anchor are made of a fine weave, low pitch braid and the middle section of the anchor is made of a thicker thread and higher pitch braid. The distal and proximal section are preferably heat set to roll upon unsheathing, though some rolling may occur simply from active for shortening of the fine weave braid. In preferred embodiments, the filaments of the fine weave braid are less than 0.01 cm, or more preferably less than 0.005 cm in thickness. On the other hand, thicker filaments of the middle section are preferably 0.01 cm or greater in thickness or more preferably 0.015 cm or greater in thickness. Posts **32** are coupled to the middle section of the anchor. For deployment, tubes (or fingers) **106** are coupled to the anchor's middle section.

[**0090**] **FIG. 13B** illustrates an anchor during the process of deployment after the anchor is unsheathed. The anchor is pushed distally by tubes and pulled proximally by wires and begins foreshortening. In some embodiment the distal section rolls up and can act as a locator, assisting the operator in locating the aortic valve, or as a seal preventing leakage. In some embodiments, the proximal section may roll down and be used as a leaflet engagement element to prevent distal migration or as a proximal seal.

[**0091**] In **FIG. 13C**, the device may be configured such that the middle section of the valve may form an hour glass shape or a round shape. The tubes may subsequently be removed as described before.

[**0092**] **FIG. 13D** is another illustration of the braided anchor in its elongated configuration.

[**0093**] **FIG. 13E** is another illustration of the braided anchor in its foreshortened configuration.

[**0094**] **FIGS. 14A-14C** illustrate the process of forming a pleated seal around a replacement valve to prevent leakage. **FIG. 14A** illustrates a fabric seal **380** prior to deployment and foreshortening of the anchor/valve apparatus. In **FIG. 14A**, the fabric seal **380** extends from the distal end of valve **20** proximally over anchor **30** during delivery. During deployment, as illustrated in **FIG. 14B**, anchor **30** foreshortens and the fabric seal **380** bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets **382**. The bunched up fabric or pleats occur, in particular, when the pockets are filled with blood in response to backflow blood pressure. The pleating can create a seal around the replacement valve. **FIG. 14C** illustrates anchor **30**, surrounded by fabric seal **380** in between native valve leaflets **382**. In preferred embodiments, at least a portion of a seal is captured between the leaflets and the wall of the heart when the anchor is fully deployed.

What is claimed is:

**1**. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage leaflets of the patient's heart valve.

**2**. The apparatus of claim 1 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is fully deployed.

**3**. The apparatus of claim 1 wherein the anchor is further adapted to be actively foreshortened during deployment.

**4**. The apparatus of claim 3 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

**5**. The apparatus of claim 3 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

**6**. The apparatus of claim 3 further comprising a lock adapted to lock the anchor in a deployed shape.

**7**. The apparatus of claim 1 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.

**8**. The apparatus of claim 1 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.

**9**. The apparatus of claim 1 wherein the leaflet engagement elements are integral with the anchor.

**10**. The apparatus of claim 9 wherein the anchor comprises a braid, the leaflet engagement elements being part of the braid.

**11**. The apparatus of claim 1 wherein the anchor and the replacement valve are further adapted to permit blood flow from a chamber of the heart through the replacement valve and to prevent blood flow to the chamber of the heart through the replacement valve during deployment of the anchor and replacement valve.

**12**. The apparatus of claim 1 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

**13**. The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter but before the anchor completely exits the catheter.

**14**. The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor.

**15**. The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration,

the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

**16**. The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

**17**. The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

**18**. The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

**19**. The apparatus of claim 1 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

**20**. The apparatus of claim 19 wherein the seal comprises a pleated seal.

**21**. The apparatus of claim 19 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

**22**. A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering an anchor and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage native valve leaflets;

expanding the anchor; and

engaging the leaflet engagement elements with native valve leaflets.

**23**. The method of claim 22 further comprising expanding the anchor into engagement with the patient's heart such that the anchor is substantially distal to coronary ostia of the heart.

**24**. The method of claim 23 wherein the expanding step comprises actively foreshortening the anchor.

**25**. The method of claim 24 wherein the actively foreshortening step comprises actuating distal anchor actuation elements.

**26**. The method of claim 24 wherein the actively foreshortening step comprises actuating proximal anchor actuation elements.

**27**. The method of claim 24 further comprising locking the anchor in a deployed configuration.

**28**. The method of claim 22 further comprising resisting distal movement of the proximal end of the anchor after the engaging step.

**29**. The method of claim 22 further comprising moving the leaflet engagement elements further apart radially during the anchor expanding step.

**30**. The method of claim 22 further comprising permitting blood flow through the replacement valve and preventing blood backflow through the replacement valve during deployment of the anchor and replacement valve.

**31**. The method of claim 22 further comprising:

delivering the anchor and replacement valve to a vicinity of the heart in a delivery catheter;

removing the anchor and the replacement valve from the catheter; and

permitting blood flow through the replacement valve and preventing blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

**32**. The method of claim 31 wherein the permitting and preventing steps are performed before the anchor completely exits the catheter.

**33**. The method of claim 31 wherein the permitting step comprises allowing the anchor to self-expand.

**34**. The method of claim 31 wherein the permitting step comprises permitting blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

**35**. The method of claim 31 wherein the permitting step comprises permitting blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

**36**. The method of claim 22 further comprising sealing between the replacement valve and the heart.

**37**. The method of claim 36 wherein the sealing step comprises pleating a seal.

**38**. The method of claim 36 wherein the sealing step comprises capturing at least a portion of a seal between the leaflets and a wall of the heart.

**39**. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising a braid, the braid comprising leaflet engagement elements adapted to engage leaflets of the patient's heart valve.

**40**. The apparatus of claim 39 wherein the leaflet engagement elements extend from a proximal end of the anchor.

**41**. The apparatus of claim 39 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is fully deployed.

**42**. The apparatus of claim 39 wherein the anchor is further adapted to be actively foreshortened during deployment.

**43**. The apparatus of claim 42 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

**44**. The apparatus of claim 42 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

**45**. The apparatus of claim 42 further comprising a lock adapted to lock the anchor in a deployed shape.

**46**. The apparatus of claim 40 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.

**47**. The apparatus of claim 40 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.

**48**. The apparatus of claim 40 wherein the anchor and the replacement valve are further adapted to permit blood flow

from a chamber of the heart through the replacement valve and to prevent blood flow through the replacement valve during deployment of the anchor and replacement valve.

**49**. The apparatus of claim 40 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

**50**. The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before the anchor completely exits the catheter.

**51**. The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor.

**52**. The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

**53**. The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

**54**. The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

**55**. The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

**56**. The apparatus of claim 40 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

**57**. The apparatus of claim 56 wherein the seal comprises a pleated seal.

**58**. The apparatus of claim 56 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

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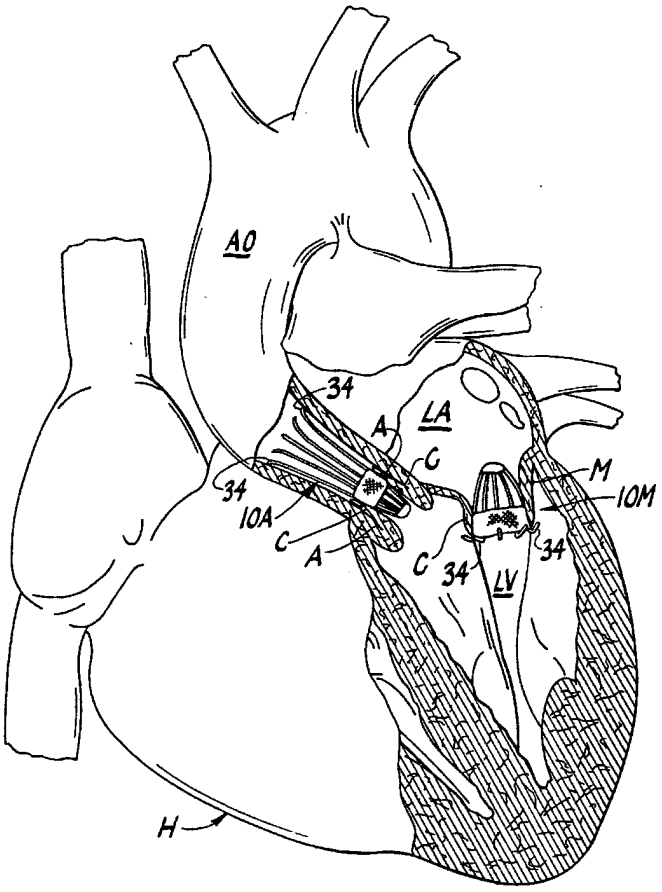


(57) Abstract: An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region. The artificial valve includes a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region. The frame has a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors. The valve also includes a flexible valve element attached to the frame and to the central portion of the frame having an upstream side facing the upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing the downstream region when the frame is anchored in the position between the upstream region and the downstream region. The valve element moves to an open position when fluid pressure in the upstream region is greater than fluid pressure in the downstream region to permit downstream flow from the upstream region to the downstream region. The valve element moves to a closed position when fluid pressure in the downstream region is greater than fluid pressure in the upstream region to prevent flow reversal from the downstream region to the upstream region.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# ARTIFICIAL HEART VALVE

## Cross-reference to Related Application

This application claims benefit of Provisional Patent Application No. 60/179,853 filed February 2, 2000, which is hereby incorporated by reference.

## Background of the Invention

The present invention relates generally to valve implants, and more particularly to artificial heart valves for repairing damaged heart valves.

A human heart has four chambers which alternately expand and contract to pump blood through the vessels of the body. The heart also includes a check valve at the upstream end of each chamber to ensure that blood flows in the correct direction through the body as the heart chambers expand and contract. These valves sometimes become damaged resulting in their inability to close when the downstream chamber contracts. When the valves do not close, blood flows backward through the valve resulting in diminished blood flow and lower blood pressure. The valves can also become damaged so they do not open sufficiently thereby resulting in diminished downstream blood flow.

Although replacement valves and surgical procedures have been developed to alleviate these conditions, they have significant drawbacks. Many earlier valves require invasive implantation techniques in which the chest is opened, the ribs are spread, the heart is paralyzed, and following cardio-pulmonary bypass, the heart is cut open to implant the valve. These invasive techniques are stressful on the patient, increase the opportunity for infection and slow recovery. As a result, valves which may be implanted with non-invasive techniques have been developed. These valves are implanted by transluminal or endothoracoscopic techniques which reduce many of the drawbacks associated

with invasive surgery. However, many of these valves also require the damaged native heart valve be removed prior to implanting the artificial valve. Removing the native valve increases the risk that a portion of the valve will migrate through the body and block vessels downstream from the heart.

Many mechanical and bioprosthetic valves have been developed to replace native heart valves. See C.A. Hufnagel, Basic Concepts in the Development of Cardiovascular Prostheses, 137 Am. J. of Surg. at 285-300 (1972). See also D.E. Harken et al., Partial and Complete Prosthesis in Aortic Insufficiency, 40 J. Thorac & Cdvsc Surg., no. 6., at 744-62 (1960). These valves include ball-valve prostheses, flap-valve prostheses, polymeric trileaflet synthetic valves, and bioprosthetic valves made from animal allograft tissues such as pig valves and preserved heterologous bovine and porcine pericardial tissue valves. See H.B. Lo et al., A Tricuspid Polyurethane Heart Valve as an Alternative to Mechanical Prostheses or Bioprostheses, 34 Trans. Am. Soc. of Art. Int. Organs at 839-44 (1988); and S.L. Hilbert et al., Evaluation of Explanted Polyurethane Trileaflet Cardiac Valve Prostheses, 94 J. Thorac & Cdvsc Surg. at 419-29 (1987). Most of the aforementioned valves require open chest surgery and cardio-pulmonary bypass for implantation.

More recently percutaneous and transluminal implantation have been suggested. See Steven R. Bailey, Percutaneous Expandable Prosthetic Valves Textbook of Interventional Cardiology, chap. 75 (1995)(referencing work of Andersen et al.) See also Knudsen et al., Catheter-implanted Prosthetic Heart Valves, 6 Int'l J. of Art. Organs, no. 5, at 253-62 (1993); Knudsen et al. Transluminal Implantation of Artificial Heart Valves. Description of New Expandable Aortic Valve and Initial Results With Implantation by Catheter Technique in Closed Chest Pigs, 13 European Heart J. at 704-08 (1992); and

U.S. Patent No. 5,411,552 (Andersen). The Andersen device includes a heterologous pig valve mounted in an annular ring. Due to the size of this device, it must be implanted by direct abdominal aortic incision and entry. Further, the Andersen device requires a separate inflating balloon for its deployment. U.S. Patent No. 5,397,351 (Pavcnik) describes an expandable caged poppet for percutaeuous implantation in an aortic valve site. However, the size of the Pavcnik device makes percutaneous implantation difficult. U.S. Patent No. 5,885,601 (Bessler) describes a transluminal valve implantation but does not describe the specific valve construction. The Bessler procedure includes excision, vacuum removal of the native valve, cardio-pulmonary bypass and backflushing of the coronary arterial tree.

Summary of the Invention

Among the several objects and features of the present invention may be noted the provision of an artificial heart valve which accommodates implantation without removing the damaged native heart valve; the provision of a valve which may be implanted using non-invasive surgery; the provision of a valve which permits implantation without the need for cardio-pulmonary bypass; and the provision of a valve which permits implantation by conventional open chest surgery and cardio-pulmonary bypass.

Briefly, apparatus of this invention is an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region. The artificial valve comprises a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region. The frame has a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the anchors.

In addition, the artificial valve includes a flexible valve element attached to the frame and to the central portion of the frame. The valve element has an upstream side facing the upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing the downstream region when the frame is anchored in the position between the upstream region and the downstream region. The valve element moves in response to a difference between fluid pressure in the upstream region and fluid pressure in the downstream region between an open position in which the element permits downstream flow between the upstream region and the downstream region and a closed position in which the element blocks flow reversal from the downstream region to the upstream region. The valve element moves to the open position when fluid pressure in the upstream region is greater than fluid pressure in the downstream region to permit downstream flow from the upstream region to the downstream region, and the valve element moves to the closed position when fluid pressure in the downstream region is greater than fluid pressure in the upstream region to prevent flow reversal from the downstream region to the upstream region.

In another aspect of the invention, the artificial valve comprises a flexibly resilient frame and a flexible valve element attached to the frame. The valve element has a convex upstream side facing the upstream region when the frame is anchored in the position between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing the downstream region when the frame is anchored in the position between the upstream region and the downstream region. The valve element moves in response to a difference between fluid pressure in the upstream region and the downstream region between an open position and a closed position.

In yet another aspect of the present invention, the artificial valve comprises a plurality of U-shaped frame elements sized and shaped for insertion in the heart in the position between the upstream region and the downstream region. Each of the plurality of frame elements has opposite ends. The elements are joined together generally midway between their respective ends at a junction of the elements. In addition, the artificial valve includes a band extending between each frame element and an adjacent frame element to limit spacing between the frame elements. Further, the artificial valve includes a flexible valve element attached to the junction of the frame elements. The valve element has a convex upstream side facing the upstream region when the frame elements are inserted in the position between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing the downstream region when the frame elements are inserted in the position between the upstream region and the downstream region. The valve element moves in response to a difference between fluid pressure in the upstream region and fluid pressure in the downstream region between an open position and a closed position.

In still another aspect, the invention includes the artificial valves described above having a frame which is collapsible to a configuration having a maximum width less than about 18 mm in combination with an instrument for inserting the artificial valve in the position between the upstream region and the downstream region. The instrument includes a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration. In addition, the instrument includes an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region and an ejector mounted in the hollow interior of the holder

for ejecting the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

Still further, the invention includes an endothoracoscopic method of inserting an artificial valve between a plurality of cusps of a damaged heart valve. The method comprises the steps of making an opening in a chest wall, making an incision in a heart and inserting an end of an elongate instrument through the opening made in the chest wall and incision made in the heart. In addition, the method includes positioning the inserted end of the instrument adjacent the cusps of the damaged heart valve and ejecting an artificial valve from the end of the instrument into a position between the cusps of the damaged heart valve without removing the damaged heart valve from the heart.

Moreover, the invention includes a transluminal method of inserting an artificial valve between a plurality of cusps of a damaged heart valve comprising the steps of making an incision in a vessel leading to the heart and inserting an end of an elongate flexible instrument through the incision made in the vessel. In addition, the method includes pushing the end of the instrument through the vessel until the end is adjacent the cusps of the damaged heart valve and ejecting an artificial valve from the end of the instrument into a position between the cusps of the damaged heart valve without removing the damaged heart valve from the heart.

Other objects and features of the present invention will be in part apparent and in part pointed out hereinafter.

Brief Description of the Drawings

Fig. 1 is a front elevation of a heart in partial section showing two artificial valves of the present invention;

Fig. 2 is a vertical cross section of an artificial valve;

Fig. 3 is a cross section of the valve taken in the plane of line 3-3 of Fig. 2;

Fig. 4 is a vertical cross section of an instrument for implanting a valve using an endothoracoscopic procedure of the present invention;

Fig. 5 is a vertical cross section of an introducer for implanting a valve using a transluminal procedure of the present invention; and

Fig. 6 is a front elevation of a heart in partial section showing artificial valves of the present invention.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

Detailed Description of the Preferred Embodiment

Referring now to the drawings and in particular to Fig. 1, artificial heart valves of the present invention are designated in their entireties by the reference numbers 10A and 10M. The artificial valve 10A is specifically configured for repairing a damaged aortic valve A of a heart, generally designated by H. The artificial valve 10M is specifically configured for repairing a damaged mitral valve M. In addition, an artificial valve having a configuration similar to valve 10A may be used to repair a damaged pulmonary heart valve (not shown), and a valve having a configuration similar to valve 10M may be used to repair a damaged tricuspid heart valve (not shown). Each native heart valve (e.g., mitral valve M) normally has two cusps C (or three cusps in the case of the tricuspid valve) separating an upstream region (e.g., the left atrium LA) of the heart H from a downstream region (e.g., the left ventricle LV) of the heart positioned downstream from the upstream region. In use, the artificial heart valves (e.g., the

artificial heart valve 10M) are positioned between the upstream region and the downstream region, preferably between the cusps C of the respective native valve (e.g., the mitral valve M), to ensure blood flows through the heart H in the appropriate direction as will be explained in greater detail below.

As illustrated in Fig. 2, the artificial valve 10M comprises a flexibly resilient external frame, generally designated by 20, and a flexible valve element, generally designated by 22. The frame 20 includes a plurality of U-shaped stenting elements 30. Each of the U-shaped elements 30 has a length extending between opposite ends. Although the elements 30 may have other lengths without departing from the scope of the present invention, the elements of the preferred embodiment have approximately equal lengths. Further, the elements 30 are joined generally midway between their respective ends at a junction 32 of the elements. Although four frame elements 30 are shown in Figs. 2 and 3, the valve 10M may have fewer or more elements without departing from the scope of the present invention. Preferably, the stenting elements 30 are sufficiently compressible to permit the valve 10M to be compressed to a configuration such as shown in Fig. 4 during implantation in the respective heart valve as will be explained below. Still further, the stenting elements 30 preferably are sufficiently resilient to hold the artificial valve 10M in position between the cusps C of the native valve M after implantation and to hold the cusps of the native valve open. As used herein, the term "stenting" is intended to convey that the element 30 holds the cusps of the native valve at least partially open. Moreover, although the elements 30 of the preferred embodiment are made of nickel alloy wire such as nitinol wire, other materials may be made without departing from the scope of the present invention. Further, although the wire of the preferred embodiment has a rectangular cross section with

dimensions of about 0.508 mm (0.02 inch) by about 0.762 mm (0.03 inch), wires having other shapes and sizes may be used without departing from the scope of the present invention.

A peripheral anchor 34 is formed at each end of the frame elements 30. As illustrated in Fig. 1, these anchors 34 are used to attach the frame 20 between the plurality of cusps C of the damaged valve (e.g., the mitral valve M) in a position between an upstream region and a downstream region. Although other conventional anchor formations may be used without departing from the scope of the present invention, the anchors 34 of the preferred embodiment are hooks. It is envisioned the anchors 34 may also include conventional barbs (not shown) for preventing the hooks from being dislodged from the heart H after implantation. Further, as illustrated in Fig. 2, in the most preferred embodiment the hooks form an angle B of between about 55 degrees and about 80 degrees with the ends of the frame elements 30. In addition, the frame 20 includes a central portion, generally designated by 36, located between the plurality of peripheral anchors 34.

As further shown in Fig. 2, a band, generally designated by 40, extends around the frame 20 between each of the frame elements 30. The band 40 extends between each frame element 30 and an adjacent frame element to limit maximum spacing S between the frame elements. The band 40 permits the frame elements 30 to be pushed together so the flexibly resilient frame 20 can be collapsed to a collapsed configuration as shown in Figs. 4 and 5. Depending upon the procedure which is intended to be used when implanting the valve, the frame 20 collapses to configurations having different maximum widths X. For instance, if the artificial valve (e.g., 10M) is implanted using endothoracoscopic methods, the maximum width X is less than about 18 mm and more preferably between about 12 mm and about 18 mm. However,

if the valve (e.g., the artificial valve 10A) is implanted through a blood vessel, the maximum width X must be smaller. For instance, the maximum width X must be about 6 mm or more preferably between about 4 mm and about 6 mm. Thus, the frame 20 is sized and shaped for insertion between the plurality of cusps C of the damaged heart valve in a position between an upstream region and a downstream region. Further, because the frame 20 is resilient, it expands to an expanded configuration as shown in Fig. 2 when not collapsed. When in the expanded configuration, the frame 20 has different sizes depending upon which native valve it is intended to replace. For instance, if the artificial valve is intended to repair a damaged mitral valve M or a tricuspid valve, the opposite ends of the frame elements 30 are spaced by a distance D of between about 3 cm and about 5 cm. If the artificial valve is intended to repair a damaged aortic valve A or a pulmonary valve, preferably the opposite ends of the frame elements 30 are spaced by a distance D of between about 2 cm and about 3 cm.

Although the band 40 may be made of other materials, such as heterologous animal pericardium (e.g., bovine or porcine pericardium) or autologous tissue engineered substrates, without departing from the scope of the present invention, the band of the preferred embodiment is made of a biocompatible, radiopaque, elastic material such as silicone rubber, polyurethane or ePTFE. Further, although the band 40 may have other constructions without departing from the scope of the present invention, the band of the preferred embodiment comprises an internal strip 42 and an external strip 44 joined in face-to-face relation. Although the band 40 may be attached to the frame elements 30 by other means, in the most preferred embodiment, the internal and external strips 42, 44, respectively, are adhesively bonded to the frame elements and to each other. Further, although the band 40 illustrated in Fig. 2 is

substantially cylindrical, it is envisioned the band may have other shapes without departing from the scope of the present invention. For example, it is envisioned the band 40 may include a rim or flange (not shown) surrounding the valve adjacent the hooks for engaging the cusps C. It is also envisioned that an exterior surface of the band 40 may include a continuous or interrupted sheath of Dacron® velour material, porous PTFE felt or the like to provide sites for vascular connective tissue ingrowth to enhance stability of the device after its implantation. (Dacron is a U.S. federally registered trademark of E.I. duPont de Nemours and Company of Wilmington Delaware.)

The flexible valve element 22 is disposed within the frame 20 and attached to the central portion 36 of the frame. The valve element 22 has a convex upstream side 50 facing an upstream region (e.g., the left atrium LA) when the frame 20 is anchored between the cusps C of the damaged heart valve (e.g., mitral valve M) in a position between the upstream region and a downstream region; and a concave downstream side 52 opposite the upstream side facing the downstream region (e.g., the left ventricle LV) when the frame 20 is anchored between the cusps of the damaged heart valve in a position between the upstream region and the downstream region. The valve element 22 moves in response to differences between fluid pressure in the upstream region and the downstream region between an open position (as shown in phantom lines in Fig. 3) and a closed position (as shown in solid lines in Fig. 3). When the valve element 22 is in the open position, it permits flow between the upstream region and the downstream region. When in the closed position, the element 22 blocks flow between the upstream and downstream regions. The valve element 22 moves to the open position when fluid pressure in the upstream region is greater than fluid pressure in the downstream region to permit downstream flow from the

upstream region to the downstream region. The valve element 22 moves to the closed position when fluid pressure in the downstream region is greater than fluid pressure in the upstream region to prevent flow reversal from the downstream region to the upstream region. Although the valve element 22 may be made of other materials without departing from the scope of the present invention, the valve element of the preferred embodiment is made of a biocompatible elastic material such as silicone rubber, polyurethane, ePTFE, heterologous animal pericardium (e.g., bovine or porcine pericardium), or autologous tissue engineered substrates. Further, although the valve element 22 may have other thicknesses without departing from the scope of the present invention, the valve element of the preferred embodiment has a thickness of between about 0.127 mm (0.005 inch) and about 0.381 mm (0.015 inch). In addition, it is envisioned the valve element 22 may be longitudinally pleated without departing from the scope of the present invention. Without wishing to be bound by any particular theory, it is envisioned that longitudinal pleats may encourage laminar flow through the valve when in the open position.

The upstream side 50 of the flexible valve element 22 has an apex 54 which is attached to the frame 20 at the junction 32 of the elements 30. As illustrated in Fig. 3, the flexible valve element 22 is attached to the central portion 36 of the frame 20 at a position substantially centered between the anchors 34. Although the valve element 22 may be attached to the frame 20 by other means without departing from the scope of the present invention, the valve element of the preferred embodiment is attached to the frame by adhesive bonding. Further, the flexible valve element 22 is attached to the frame 20, and more particularly to the band 40, at several attachment points 56 around the frame. Thus, the valve element 22 forms flaps 58 extending between

adjacent attachment points 56. Each of the flaps 58 and a corresponding portion of the band 40 extending between adjacent attachment points 56 defines an opening 60 through the valve when the valve element 22 moves to the open position. Although the valve element 22 may be attached to the band 40 using other means, the valve element of the preferred embodiment is attached to the band by adhesive bonding.

As illustrated in Figs. 4 and 5, the artificial valves 10M, 10A, respectively, are used in combination with instruments, generally designated by 70M, 70A, for inserting the artificial valve between the cusps C of damaged heart valves M, A. The instrument 70M shown in Fig. 4 is intended for use when implanting the valve 10M using an endothoracoscopic procedure. It is envisioned this instrument would be used primarily when implanting an artificial valve in the mitral valve M, however similar instruments could be used to implant artificial valves in other native valves of the heart H such as the tricuspid valve. When used to implant an artificial valve in a tricuspid valve, the instrument could be introduced through a jugular vein. The endothoracoscopic instrument 70M comprises a tubular holder 72, and an elongate tubular manipulator 74 attached to the holder for manipulating the holder into position. Further, the instrument 70M includes an ejector, generally designated by 76, positioned in a hollow interior 78 of the holder 72 for ejecting the artificial heart valve 10M from the holder. The hollow interior 78 of the holder 72 is sized for holding the artificial valve 10M when the frame 20 is in the collapsed configuration (e.g., less than 18 mm). Further, the hollow interior 78 may have axial grooves (not shown) for receiving the anchors 34 of the valve to prevent the anchors from being tangled during valve implantation. The manipulator 74 is a semi-rigid tube attached to the holder 72 for manipulating the holder through an incision made in the heart and into position

adjacent the plurality of cusps C of the damaged heart valve. The ejector 76 includes a flat plunger tip 80 which engages the valve 10M, a push rod 82 attached to the tip for moving the tip forward in the holder 72 for ejecting the valve from the holder, and a handle 84 attached to the push rod opposite the plunger tip for gripping the ejector when ejecting the valve from the holder.

To implant an artificial valve 10M using the endothoracoscopic instrument 70M, a small opening is made in a chest wall of a patient and a small incision is made in a heart of the patient. The holder end 86 of the instrument 70M is inserted through the opening made in the chest wall and the incision made in the heart. The inserted end 86 of the instrument 70M is positioned adjacent the cusps C of the damaged heart valve M and the artificial valve 10M is ejected from the end of the instrument into a position between the cusps of the damaged valve as shown in Fig. 1. When ejecting the valve 10M from the end 86 of the instrument 70M, it is envisioned that the handle 84 of the ejector 76 will be held in place while the manipulator 74 and holder 72 are withdrawn to push the valve out of the holder. Once the valve 10M is in position, the instrument 70M is withdrawn from the chest before the opening and incision are closed using conventional procedures. As will be appreciated by those skilled in the art, the valve 10M may be implanted using this procedure with minimal trauma to the heart and without removing the damaged heart valve from the heart.

The instrument 70A shown in Fig. 5 is intended for use when implanting the valve 10A by a transluminal procedure through a vessel. It is envisioned this instrument 70A would be used when implanting an artificial valve in the pulmonary valve or the aortic valve. When used to implant an artificial valve in a pulmonary valve, the instrument could be introduced through a jugular vein, and when used to implant an

artificial valve in an aortic valve, the instrument could be introduced through a femoral artery. The instrument 70A comprises a holder 90 having a hollow interior 92 sized for holding the artificial valve 10A when the frame 20 is in the collapsed configuration (e.g., less than 6 mm) and an elongate flexible manipulator 94 attached to the holder for manipulating the holder through a vessel and into position adjacent the plurality of cusps C of the damaged heart valve A. Further, the instrument 70A has a flexible ejector, generally designated by 96, mounted in the hollow interior 92 of the holder 90 for ejecting the artificial heart valve 10A from the hollow interior of the holder into position between the cusps C of the damaged heart valve A. The manipulator 94 is used to manipulate the instrument 70A through the vessel. The ejector 96 includes a flat plunger tip 100 which engages the valve 10A, a push rod 102 attached to the tip for moving the tip forward in the holder 90 for ejecting the valve from the holder, and a handle 104 attached to the push rod opposite the plunger tip for gripping the ejector when ejecting the valve from the holder. In contrast to the manipulator 74 of the endothorascopic instrument 70M, the manipulator 94 of the transluminal instrument 70A is longer and flexible so it can be pushed or pulled through a vessel and/or over a conventional guide wire (not shown).

In an alternate embodiment (not shown), it is envisioned that the apex 54 of the flexible valve element 22 and the junction 32 of the frame elements 30 may include an opening to allow the guide wire to pass through the valve. Although this opening may have other dimensions without departing from the scope of the present invention, in one embodiment the opening has a diameter of between about 0.5 mm and about 1 mm. After removal of the guide wire, it is envisioned that this opening may provide surface washing to reduce a potential for blood to coagulate adjacent the downstream side of

the valve element 22. It is further envisioned that an opening may be used even where a guide wire is not needed to reduce potential for blood to coagulate adjacent the valve element 22.

To implant an artificial valve 10A using the transluminal instrument 70A, a small incision is made in a vessel (e.g., the femoral artery) leading to a heart H. An end 106 of the instrument 70A having the holder 90 is inserted through the incision made in the vessel and the end is pushed through the vessel and over a guide wire until the end is adjacent the cusps C of the damaged heart valve A. Once in position, the artificial valve 10A is ejected from the end 106 of the instrument 70A between the cusps C of the damaged heart valve A. As with the endothorascopic procedure described above, the transluminal procedure may be performed with minimal trauma to the heart and without removing the damaged heart valve from the heart and without cardiopulmonary bypass or heart arrest.

A second embodiment of the aortic valve is generally designated by 10A' in Fig. 6. This second embodiment is identical to the aortic valve of the first embodiment except that it includes a second band 110 surrounding the frame 20 downstream from the first band 40. The second band 110 permits the frame elements 30 to be pushed together so the frame 20 can be collapsed to the collapsed configuration, but limits the maximum spacing between adjacent frame elements. It is envisioned that the second band 110 may be constructed similarly to the first band 40 and may be made from similar materials to the first band. As will be appreciated by those skilled in the art, the second band 100 of the aortic valve 10A' supports the tissue surrounding the downstream region (i.e., the ascending aorta) and prevents the tissue from distending. An opening 112 provided between the first and second bands 40, 110, respectively, corresponds to openings of the

right and left coronary arteries (designated by RC, LC, respectively) which enter the aorta immediately above the cusps of the native valve so the replacement valve does not obstruct blood flow through these openings. Although the opening 112 may have other widths O without departing from the scope of the present invention, in one embodiment the opening has a width of between about 5 mm and about 1 cm. Although the second band 110 may have other lengths L without departing from the scope of the present invention, in one embodiment the second band 110 has a length of between about 6 cm and about 12 cm. It is further envisioned that hooks (not shown) may be provided along the frame elements 30 adjacent the second band 110 to engage the tissue to further prevent distention of the tissue.

As will be appreciated by those skilled in the art, the valves and instruments described above permit "beating heart" procedures (i.e., without cardiopulmonary bypass or cardioplegic arrest) in part due to the relatively small size of the valves and instruments. Further, the valves described above permit implantation without removal of the native valves. The valves also permit some correction of valvular stenosis along with correction of regurgitant valvular disease. It is further envisioned that the valves described above may be coated with heparin or other protective coatings and immune suppressant coatings (e.g., rapamycin coating) to reduce coagulation or immune inflammatory response initiation.

It is envisioned that the valves of the present invention may be suitable for implant in pediatric patients due to their small size and substantially unrestricted flow characteristics. Further, because the valves adaptively expand, they are capable of expanding to fit the growing child.

It is further envisioned that rapidly implanting the valves of the present invention using an

endothoracoscopic technique may provide a suitable remedy of acute papillary muscle dysfunction due to major chordal rupture or frank papillary muscle infarction.

In heavily calcified native valves, implantation of the valve described above could remedy regurgitant disease without disturbing the calcific deposits.

When used in the mitral site, the valve described above avoids problems associated with valve cusp stents and fabric arms present in prior art bioprosthetic valves. Also use of the valve described above at the mitral site eliminates removal of or damage to papillary muscles and most of the chordae tendinae thereby preserving systolic apical movement. Still further, the valve described above is compliant and capable of regurgitant control in cases of ischemic mitral regurgitation.

When used in the aortic valve site, placement of the valve may be controlled using fluoroscopic guidance to ensure the native cusps are positioned in the valve sinuses and the coronary openings above the valve site are not obstructed. It is envisioned that a conventional dye injection technique may be used to identify the coronary openings.

In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results attained.

When introducing elements of the present invention or the preferred embodiment(s) thereof, the articles "a", "an", "the" and "said" are intended to mean that there are one or more of the elements. The terms "comprising", "including" and "having" are intended to be inclusive and mean that there may be additional elements other than the listed elements.

As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in

the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

Claims

WHAT IS CLAIMED IS:

1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:

a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors; and

a flexible valve element attached to the central portion of the frame having an upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region, said valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region.

2. An artificial valve as set forth in claim 1 wherein said flexibly resilient frame is collapsible to a configuration having a maximum width less than about 18 mm.

3. An artificial valve as set forth in claim 2 wherein said flexibly resilient frame is collapsible to a configuration having a maximum width between about 12 mm and about 18 mm.

4. An artificial valve as set forth in claim 2 wherein said flexibly resilient frame is collapsible to a configuration having a maximum width less than about 6 mm.

5. An artificial valve as set forth in claim 4 wherein said flexibly resilient frame is collapsible to a configuration having a maximum width between about 4 mm and about 6 mm.

6. An artificial valve as set forth in claim 1 wherein said flexible valve element is attached to the central portion of the frame at a position substantially centered between said plurality of anchors.

7. An artificial valve as set forth in claim 6 wherein said flexible valve element is attached to the frame at a plurality of attachment points around the frame thereby forming flaps, each of said flaps extending between adjacent attachment points of said plurality of attachment points and at least partially defining an opening through the valve when the valve element moves to the open position.

8. An artificial valve as set forth in claim 1 wherein said flexibly resilient frame comprises a plurality of U-shaped elements joined together at a junction of the elements.

9. An artificial valve as set forth in claim 8 wherein said upstream side of the flexible valve element is convex and has an apex which is attached to the frame at the junction of the elements.

10. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:

a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region; and

a flexible valve element attached to the frame having a convex upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region, said valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region

to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region.

11. An artificial valve as set forth in claim 10 wherein said flexibly resilient frame is collapsible to a configuration having a maximum width less than about 18 mm.

12. An artificial valve as set forth in claim 11 wherein said flexibly resilient frame is collapsible to a configuration having a maximum width less than about 6 mm.

13. An artificial valve as set forth in claim 10 wherein said flexibly resilient frame comprises a plurality of U-shaped elements having opposite ends, said elements being joined together generally midway between their respective ends at a junction of the elements.

14. An artificial valve as set forth in claim 13 wherein said convex upstream side of the flexible valve element has an apex which is attached to the frame at the junction of the elements.

15. An artificial valve as set forth in claim 13 further comprising a band surrounding the frame and extending between adjacent elements of said plurality of U-shaped elements to limit spacing between said adjacent elements.

16. An artificial valve as set forth in claim 15 wherein said band comprises an internal strip and an external strip joined in face-to-face relation.

17. An artificial valve as set forth in claim 15 wherein said band is radiopaque.

18. An artificial valve as set forth in claim 15 wherein said band is a first band and said artificial valve further comprises a second band surrounding the frame downstream from said first band for supporting tissue defining said downstream region to reenforce said tissue and prevent distention thereof.

19. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:

a plurality of U-shaped frame elements sized and shaped for insertion in the heart in a position between the upstream region and the downstream region, each of said plurality of frame elements having opposite ends, said elements being joined together generally midway between their respective ends at a junction of the elements;

a band surrounding the frame and extending between adjacent elements of said plurality of frame elements to limit spacing between said adjacent elements; and

a flexible valve element attached to the junction of the frame elements having a convex upstream side facing said upstream region when said plurality of frame elements is inserted in the position between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing said downstream region when said plurality of frame elements is inserted in the position between the upstream region and the downstream region, said valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element

permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region.

20. An artificial valve as set forth in claim 19 wherein each end of said plurality of frame elements has an anchor for anchoring the respective frame element in the position between the upstream region and the downstream region.

21. An artificial valve as set forth in claim 20 wherein each of said anchors comprises a hook for anchoring the respective frame element in the position between the upstream region and the downstream region.

22. An artificial valve as set forth in claim 19 wherein each of said frame elements is flexibly resilient and collapsible to a configuration having a maximum width less than about 18 mm.

23. An artificial valve as set forth in claim 22 wherein each of said frame elements is collapsible to a configuration having a maximum width less than about 6 mm.

24. An artificial valve as set forth in claim 19 wherein said band comprises an internal strip and an external strip joined in face-to-face relation.

25. An artificial valve as set forth in claim 19 wherein said flexible valve element is attached to the band at a plurality of attachment points around the band thereby forming flaps extending between adjacent attachment points of said plurality of attachment points, and wherein each of said flaps and a corresponding portion of the band define an opening through the valve when the valve element moves to the open position.

26. An artificial valve as set forth in claim 19 wherein each of said frame elements has a distance between its respective opposite ends of between about 3 cm and about 5 cm.

27. An artificial valve as set forth in claim 19 wherein each of said frame elements has a distance between its respective opposite ends of between about 2 cm and about 3 cm.

28. An artificial valve as set forth in claim 19 wherein said band is a first band and said artificial valve further comprises a second band surrounding the frame downstream from said first band for supporting tissue defining said downstream region to reenforce said tissue and prevent distention thereof.

29. In combination, an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, and an instrument for inserting the artificial valve between the upstream region and the downstream region, said combination comprising:

an artificial valve including

a flexibly resilient frame sized and shaped for insertion between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame between the upstream

region and the downstream region and a central portion located between the plurality of peripheral anchors, the frame being collapsible to a configuration having a maximum width less than about 18 mm, and

a flexible valve element attached to the frame and to the central portion of the frame having an upstream side facing said upstream region when the frame is anchored between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored between the upstream region and the downstream region, said valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region; and

an instrument including

a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration;

an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region; and

an ejector mounted in the hollow interior of the holder for ejecting the artificial heart valve from

the hollow interior of the holder into position between the upstream region and the downstream region.

30. In combination, an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, and an instrument for inserting the artificial valve between the upstream region and the downstream region, said combination comprising:

an artificial valve including:

a flexibly resilient frame sized and shaped for insertion between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region, the frame being collapsible to a configuration having a maximum width less than about 18 mm, and

a flexible valve element attached to the frame having a convex upstream side facing said upstream region when the frame is anchored between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing said downstream region when the frame is anchored between the upstream region and the downstream region, said valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said

upstream region to prevent flow reversal from said downstream region to said upstream region; and

an instrument including

a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration,

an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region, and

an ejector mounted in the hollow interior of the holder for ejecting the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

31. An endothoracoscopic method of inserting an artificial valve between a plurality of cusps of a damaged heart valve, said method comprising the steps of:

making an opening in a chest wall of a patient;

making an incision in a heart of the patient;

inserting an end of an elongate instrument through the opening made in the chest wall and the incision made in the heart;

positioning the inserted end of the instrument adjacent the plurality of cusps of the damaged heart valve; and

ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

32. A transluminal method of inserting an artificial valve between a plurality of cusps of a damaged heart valve, said method comprising the steps of:

making an incision in a vessel leading to the heart;

inserting an end of an elongate flexible instrument through the incision made in the vessel;

pushing the end of the instrument through the vessel until the end is adjacent the plurality of cusps of the damaged heart valve; and

ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

FIG. 1

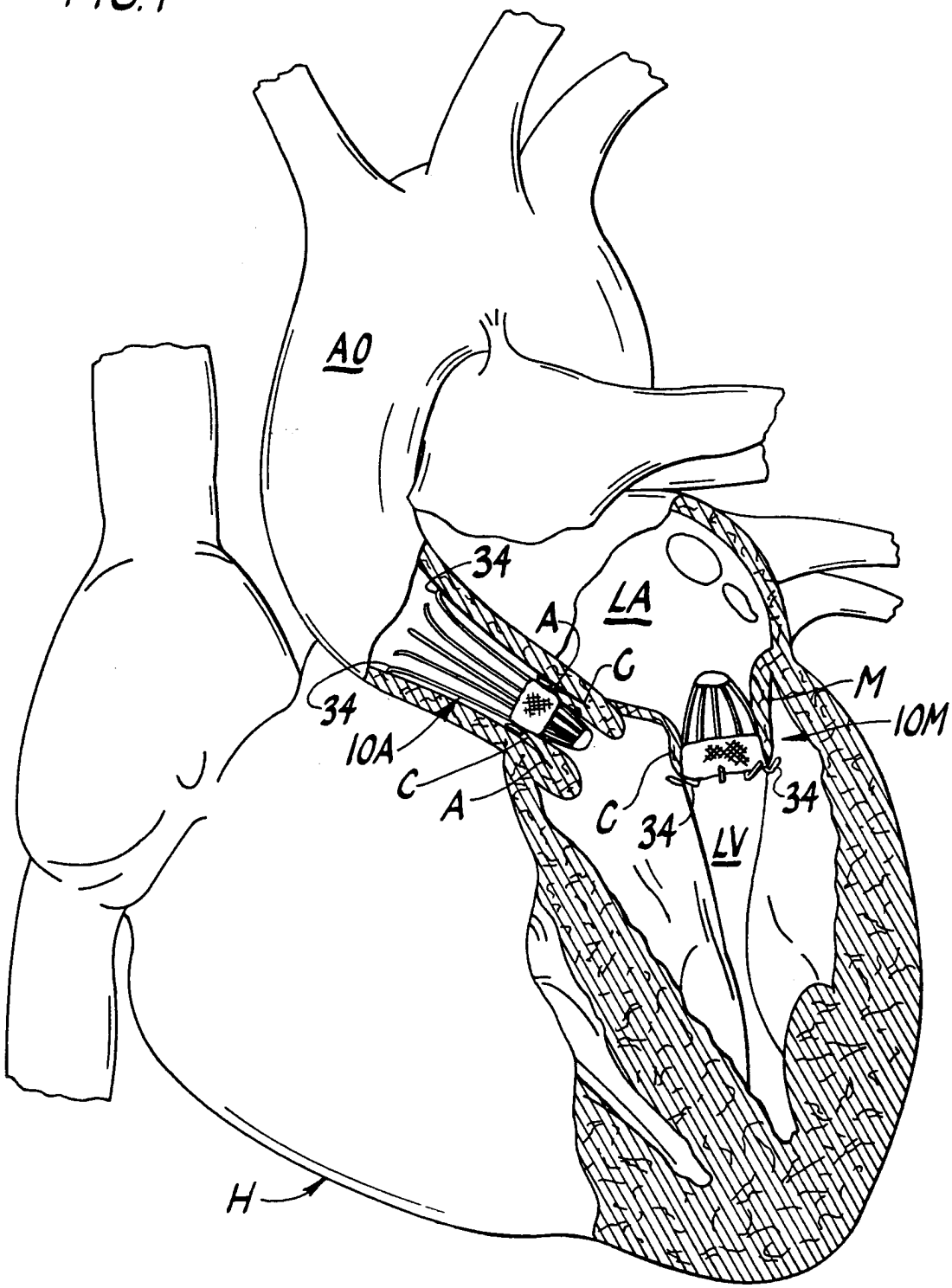

FIG. 2

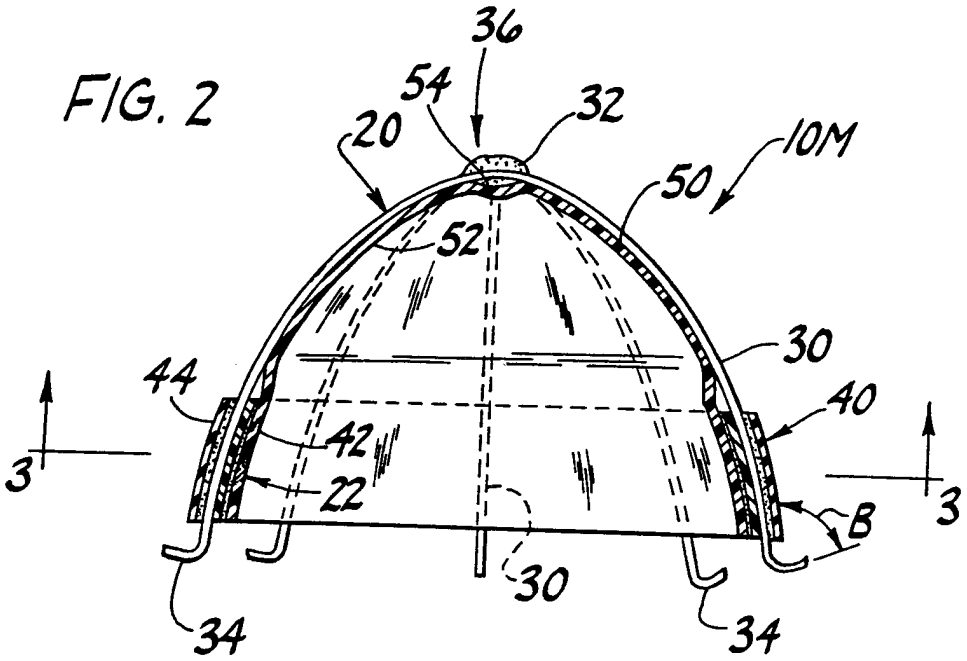
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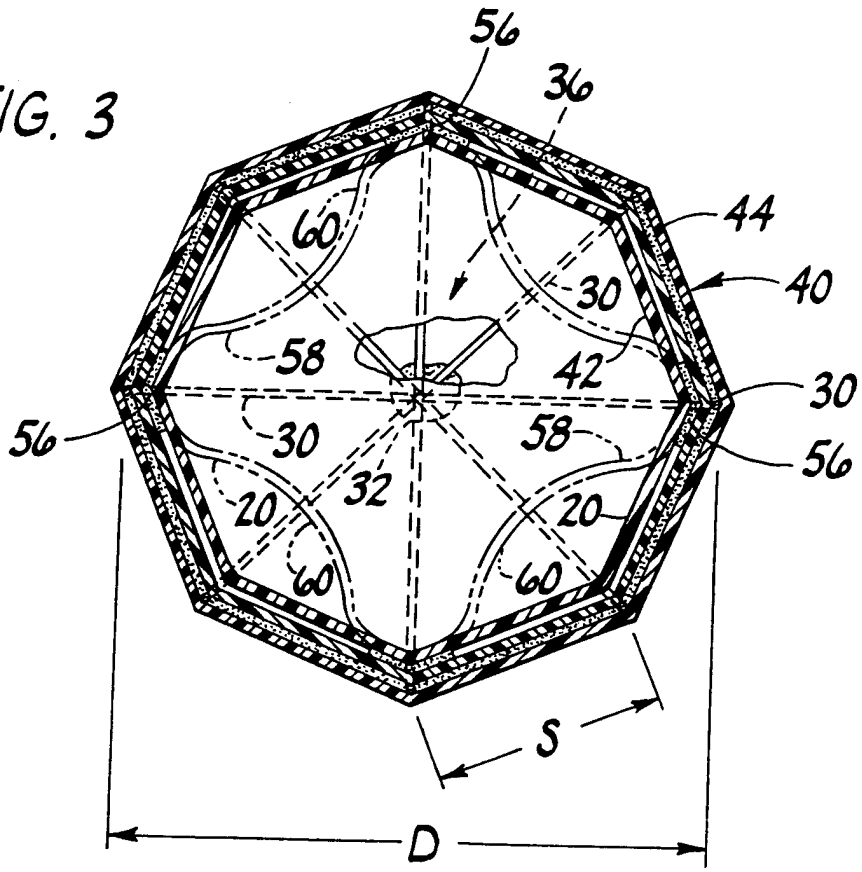
FIG. 3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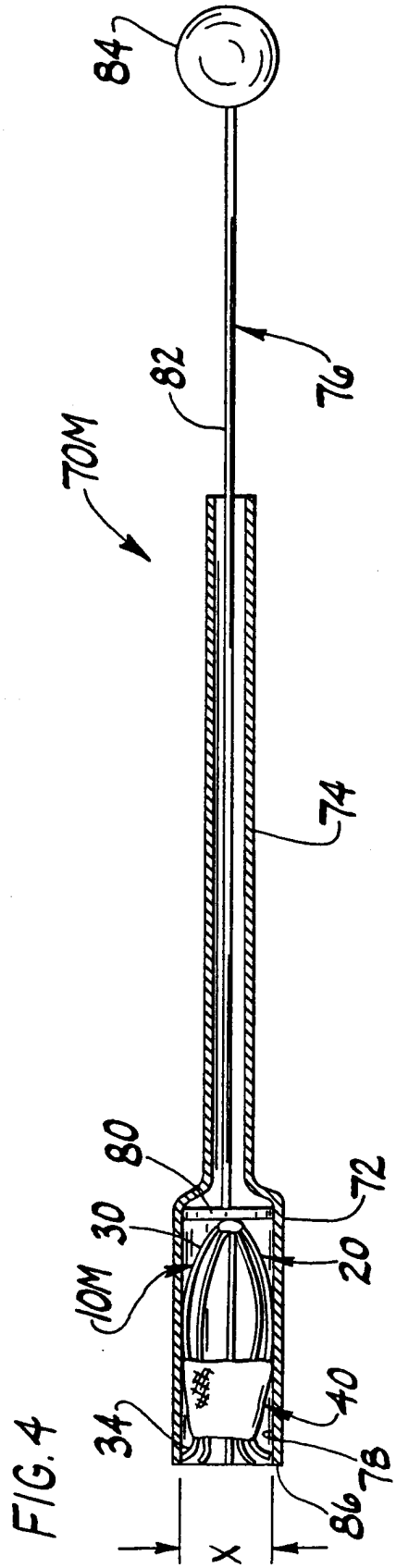


FIG. 4

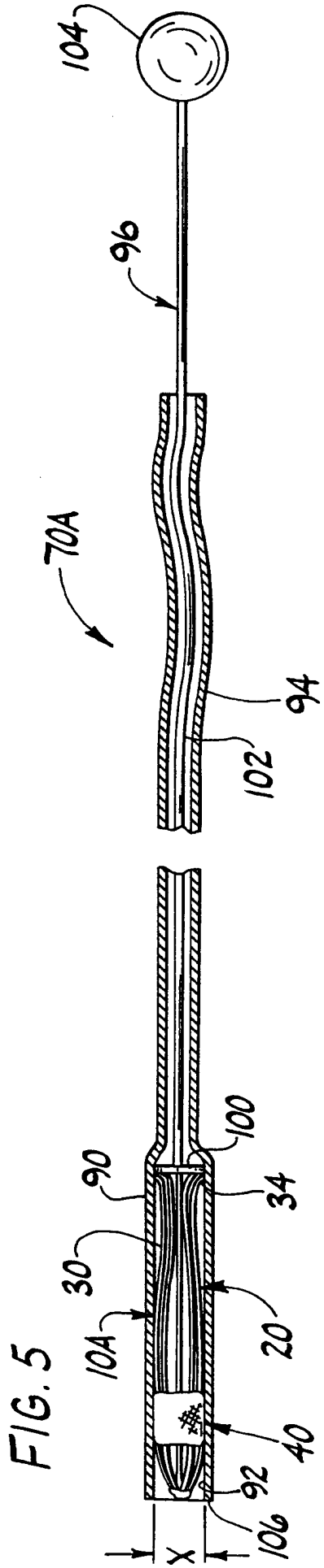


FIG. 5

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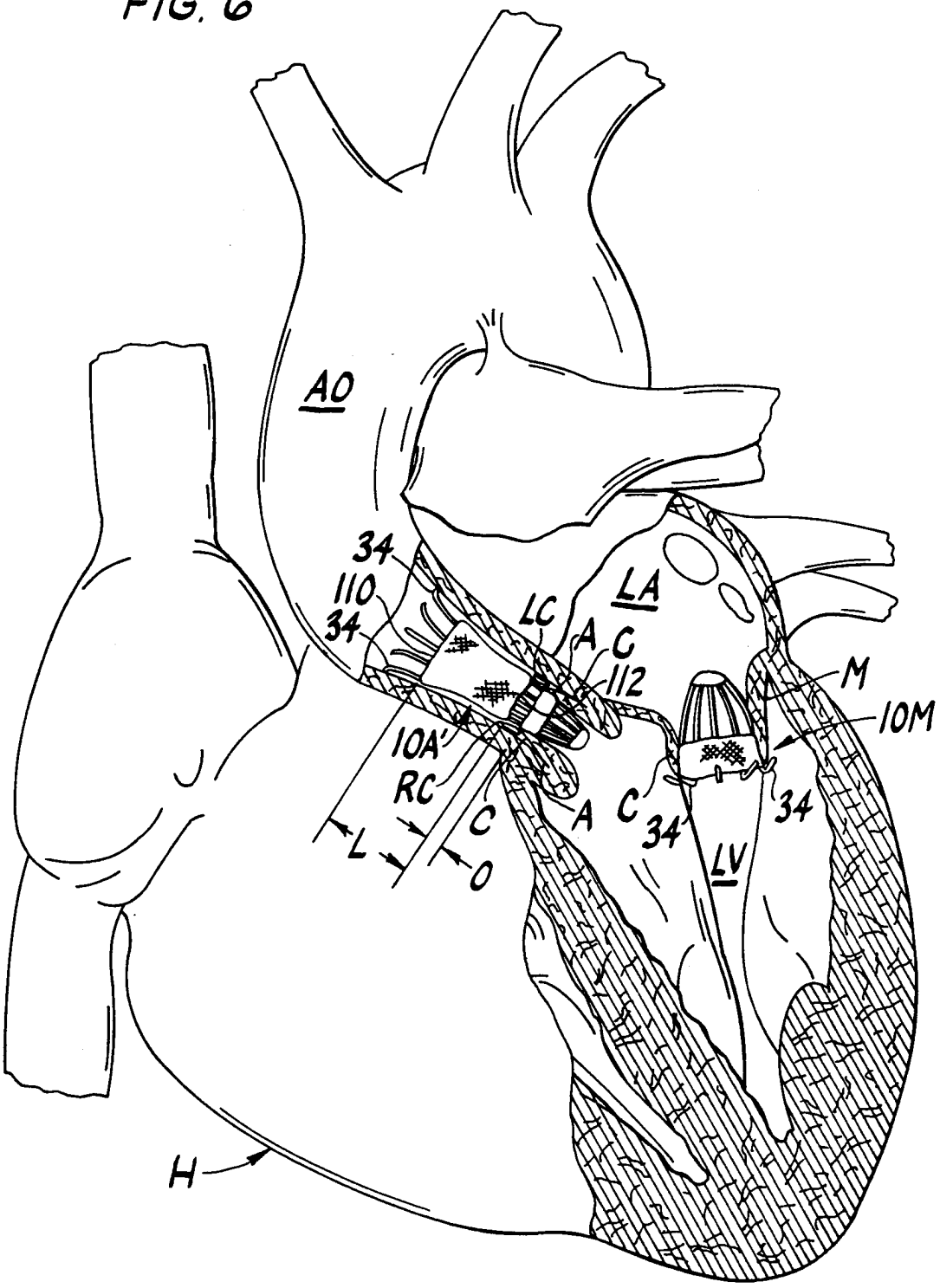
Page 2040 - 1571
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

FIG. 6



# INTERNATIONAL SEARCH REPORT

Ir. ational Application No
PCT/US 01/03353

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

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)
IPC 7 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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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| Date of the actual completion of the international search | Date of mailing ot the international search report |
|---|---|
| 6 June 2001 | 12/06/2001 |

| Name and mailing address of the ISA | Authorized officer |
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US006454799B1

(12) **United States Patent**
**Schreck**

(10) **Patent No.: US 6,454,799 B1**
(45) **Date of Patent: Sep. 24, 2002**

(54) **MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE**

(75) Inventor: **Stefan Schreck**, Vista, CA (US)

(73) Assignee: **Edwards Lifesciences Corporation**, Irvine, CA (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/549,413**

(22) Filed: **Apr. 6, 2000**

(51) **Int. Cl.**[7] ..... **A61F 2/24**

(52) **U.S. Cl.** ..... **623/2.18**; 623/2.1; 623/2.14; 623/2.17; 623/2.28; 623/2.33

(58) **Field of Search** ..... 623/2.1, 2.14, 623/2.17, 2.18, 2.38, 2.33, 2.23, 2.28

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*Primary Examiner*—Corrine McDermott
*Assistant Examiner*—Cheryl L. Miller
(74) *Attorney, Agent, or Firm*—Debra D. Condino; John Christopher James; Guy L. Cumberbatch

(57) **ABSTRACT**

Expandable heart valves for minimally invasive valve replacement surgeries are disclosed. In a first embodiment, an expandable pre-assembled heart valve includes a plastically-expandable annular base having plurality of upstanding commissure posts. A tubular flexible member including a prosthetic section and a fabric section is provided, 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 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 regions of the expandable stents using a clamping arrangement to reduce stress.

**20 Claims, 10 Drawing Sheets**

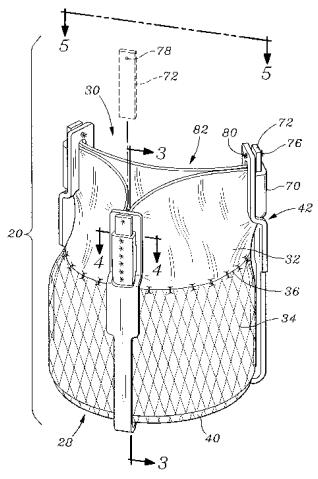

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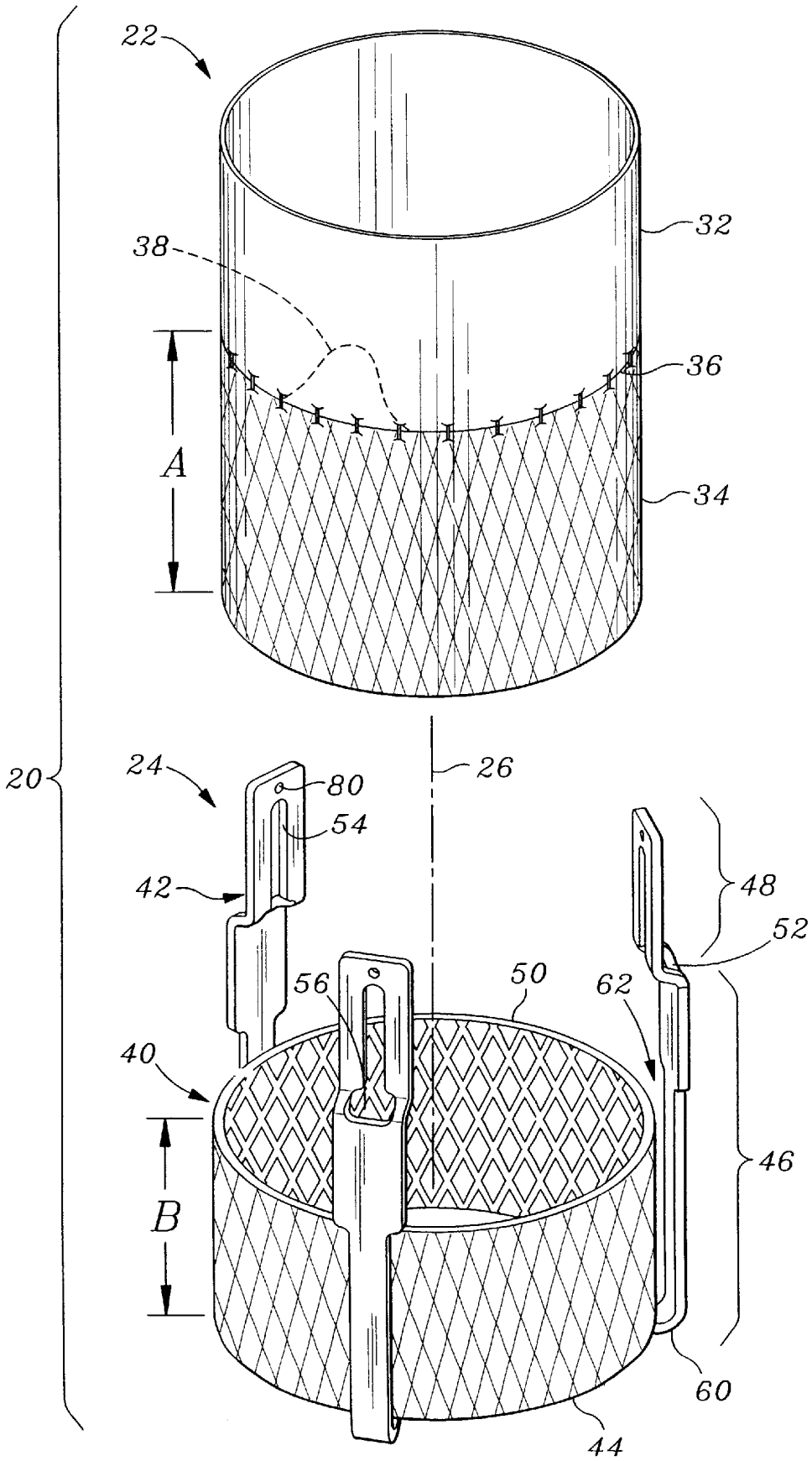
Fig. 1



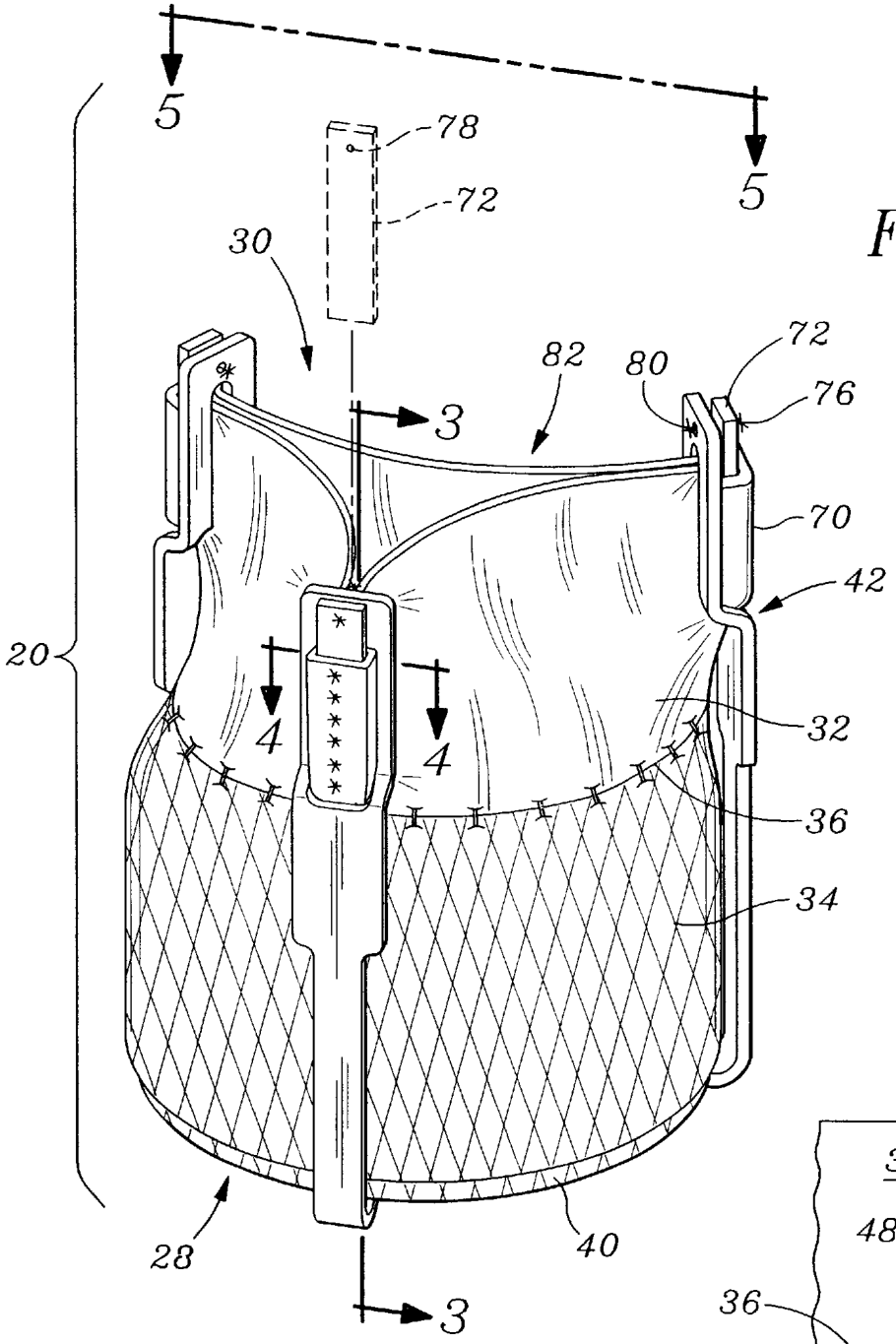

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Fig. 2

Fig. 3

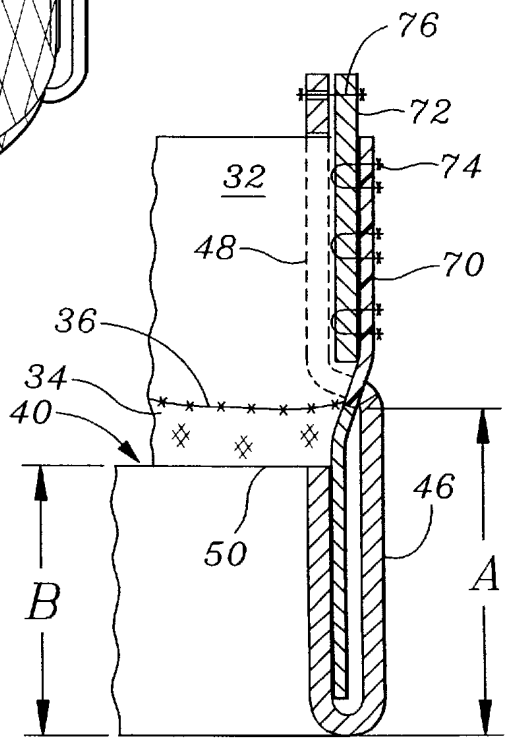
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*Fig. 4*

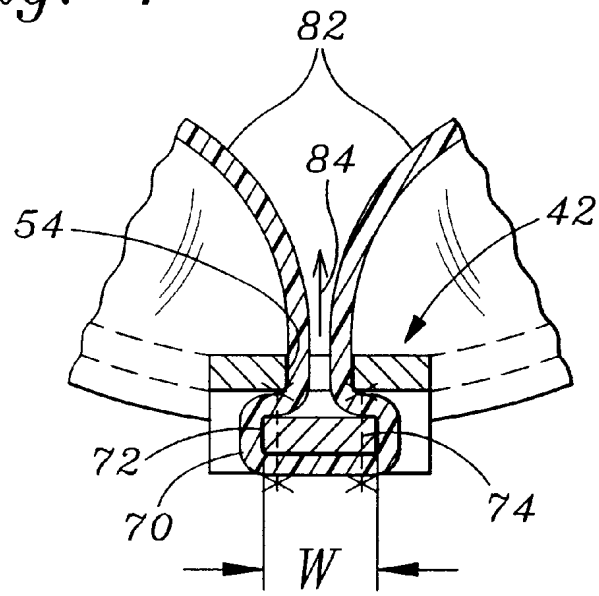


*Fig. 5*

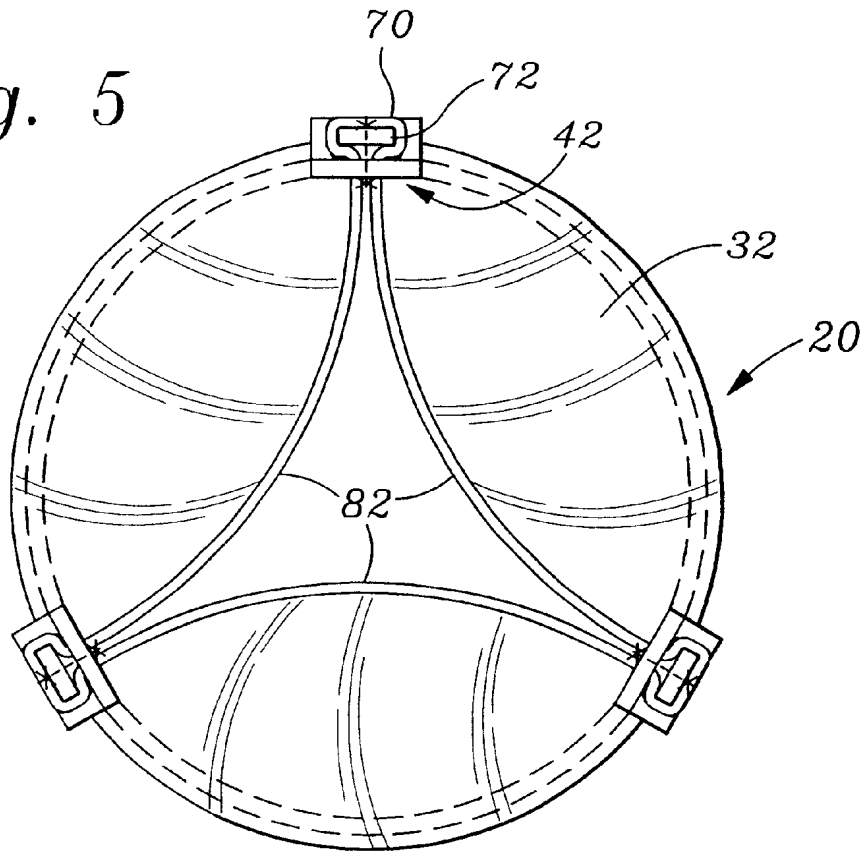

Fig. 6

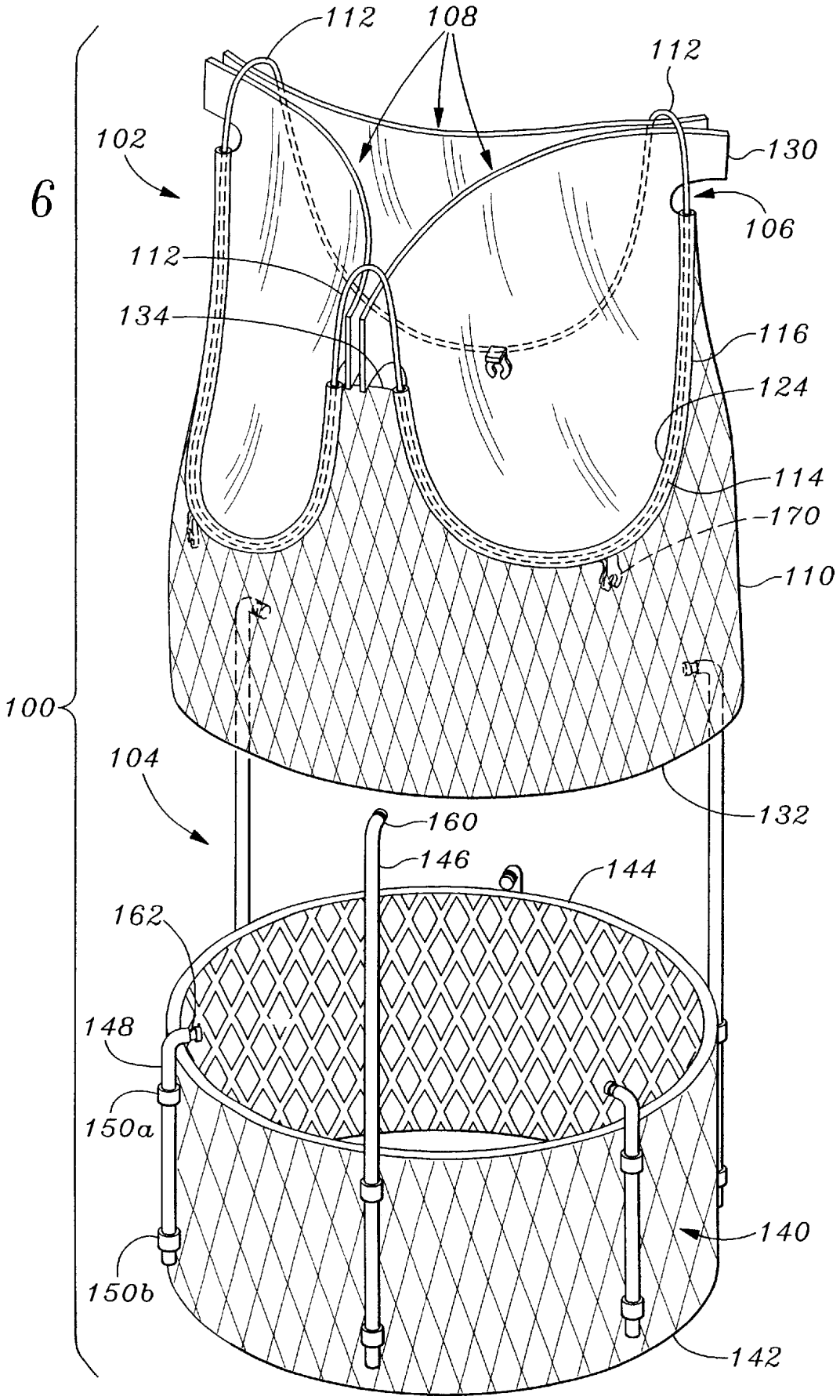
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Fig. 9

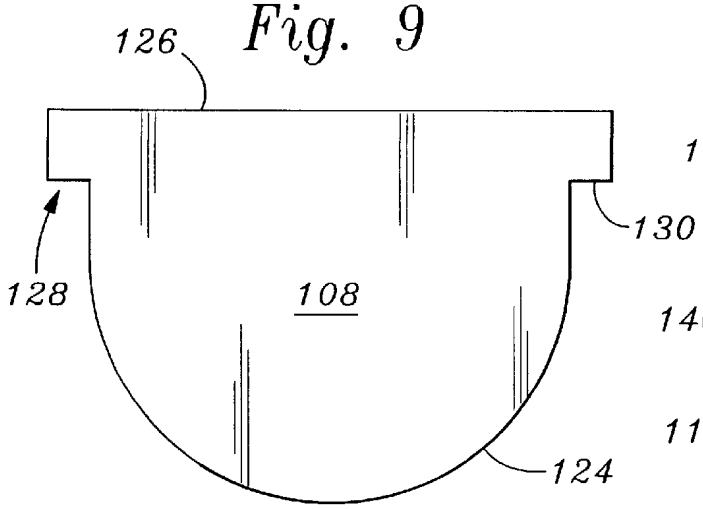
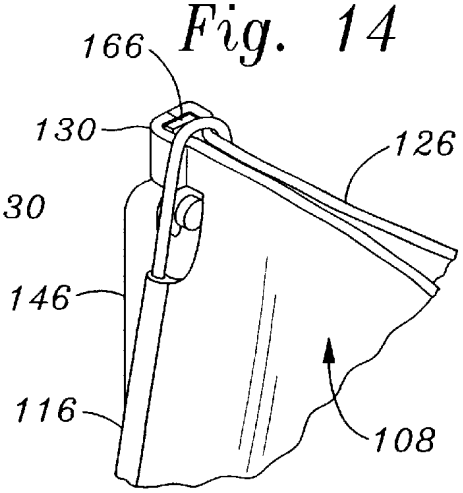



Fig. 14



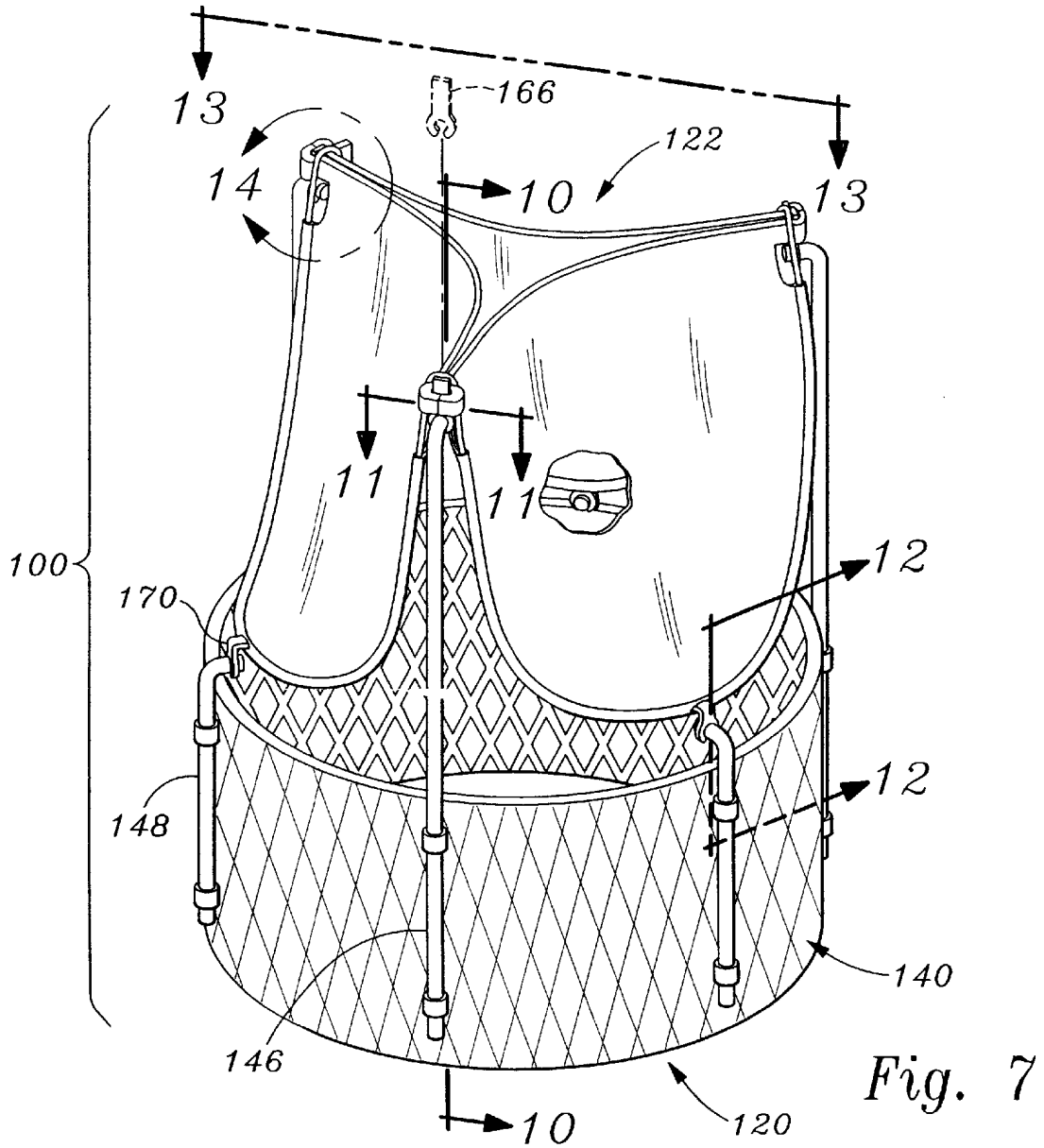




Fig. 7

Fig. 12

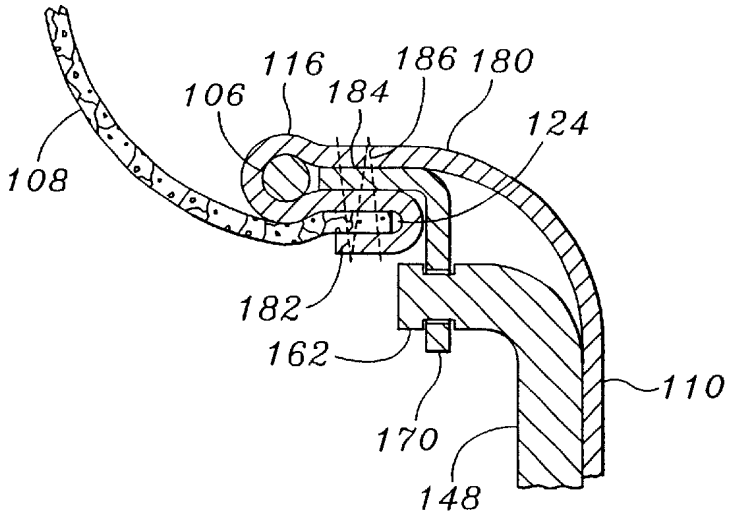



Fig. 8

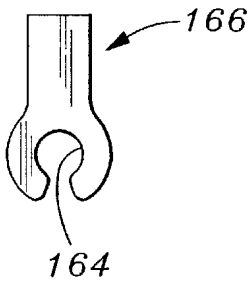



Fig. 10

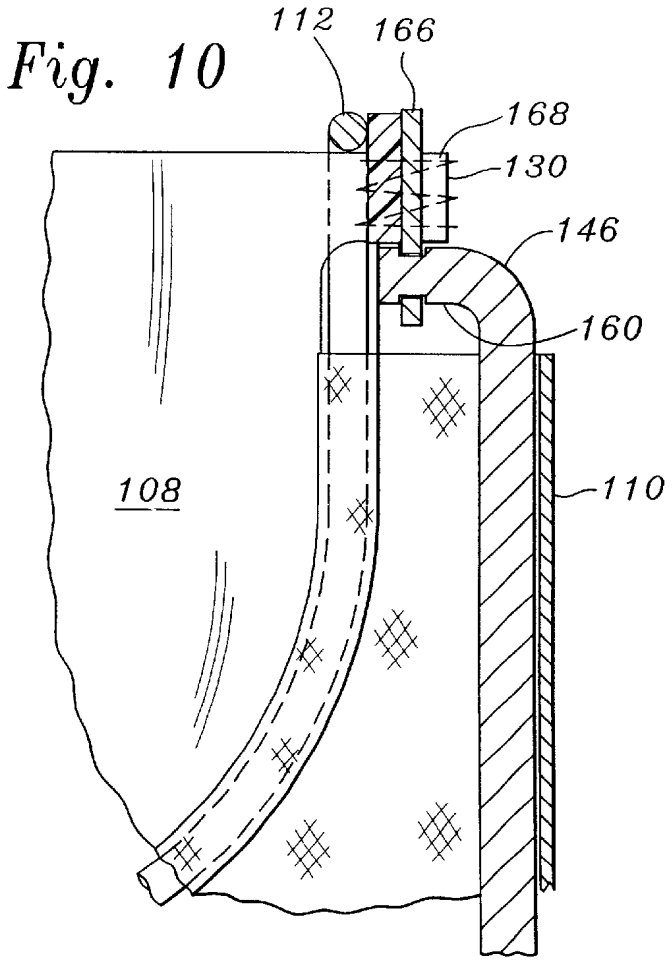



Fig. 11

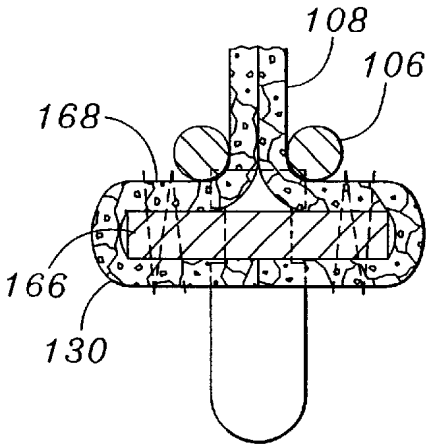


Fig. 15

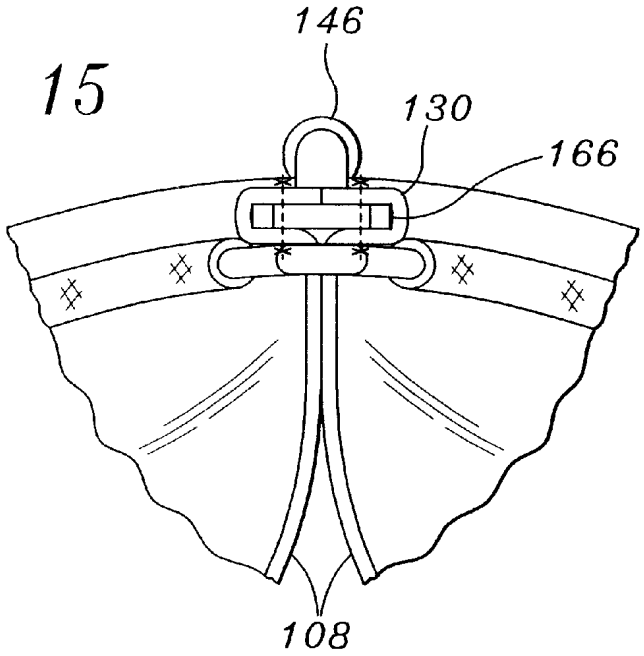
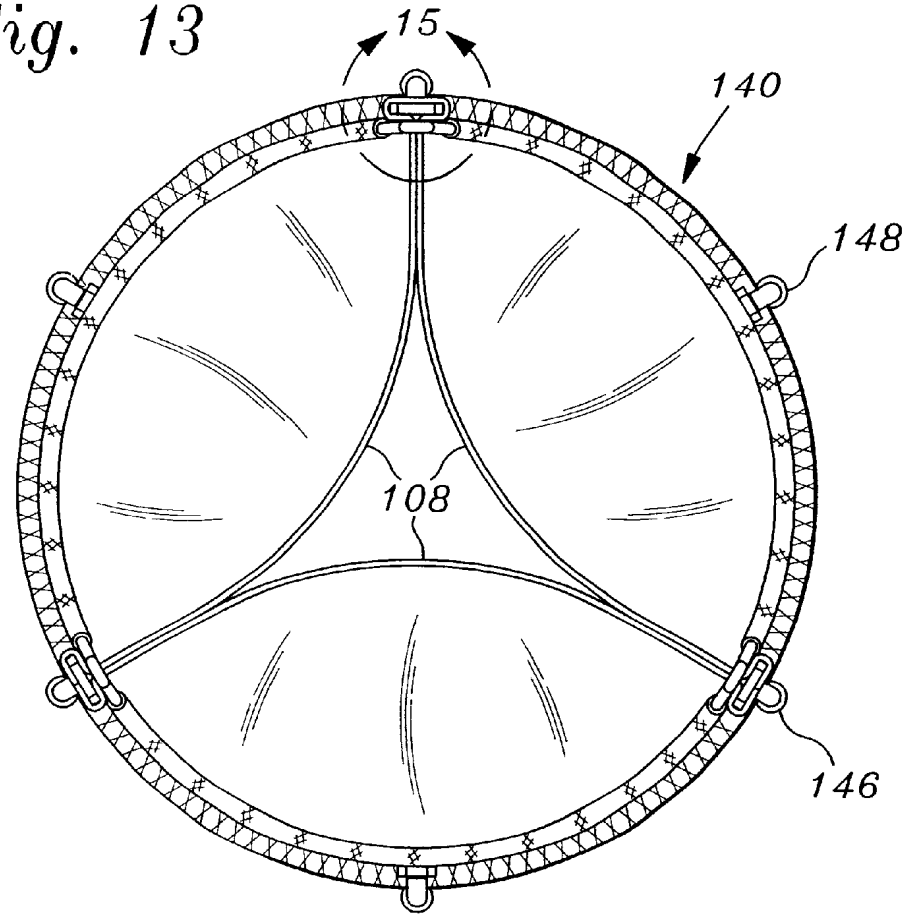



Fig. 13



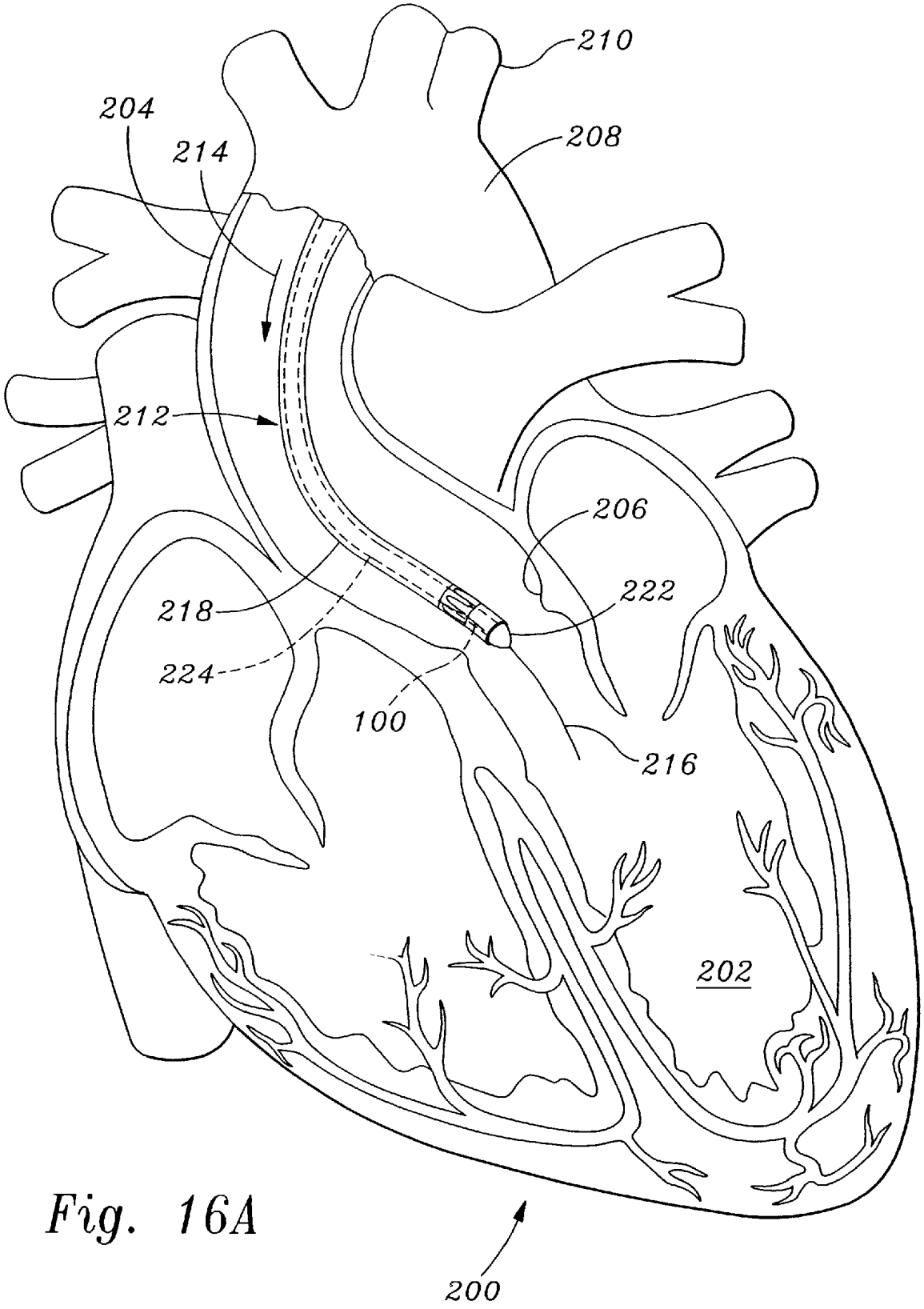



Fig. 16A

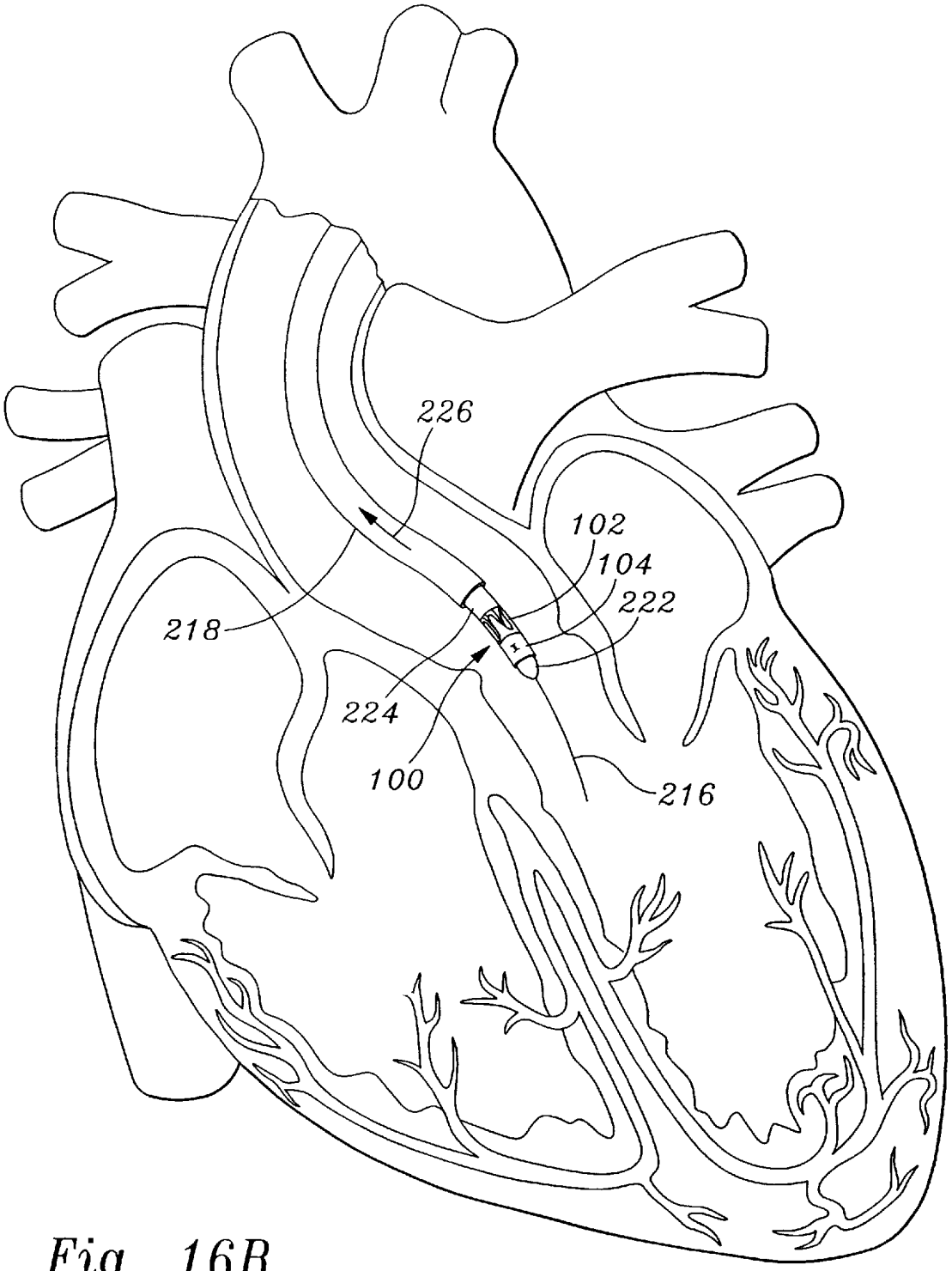



*Fig. 16B*

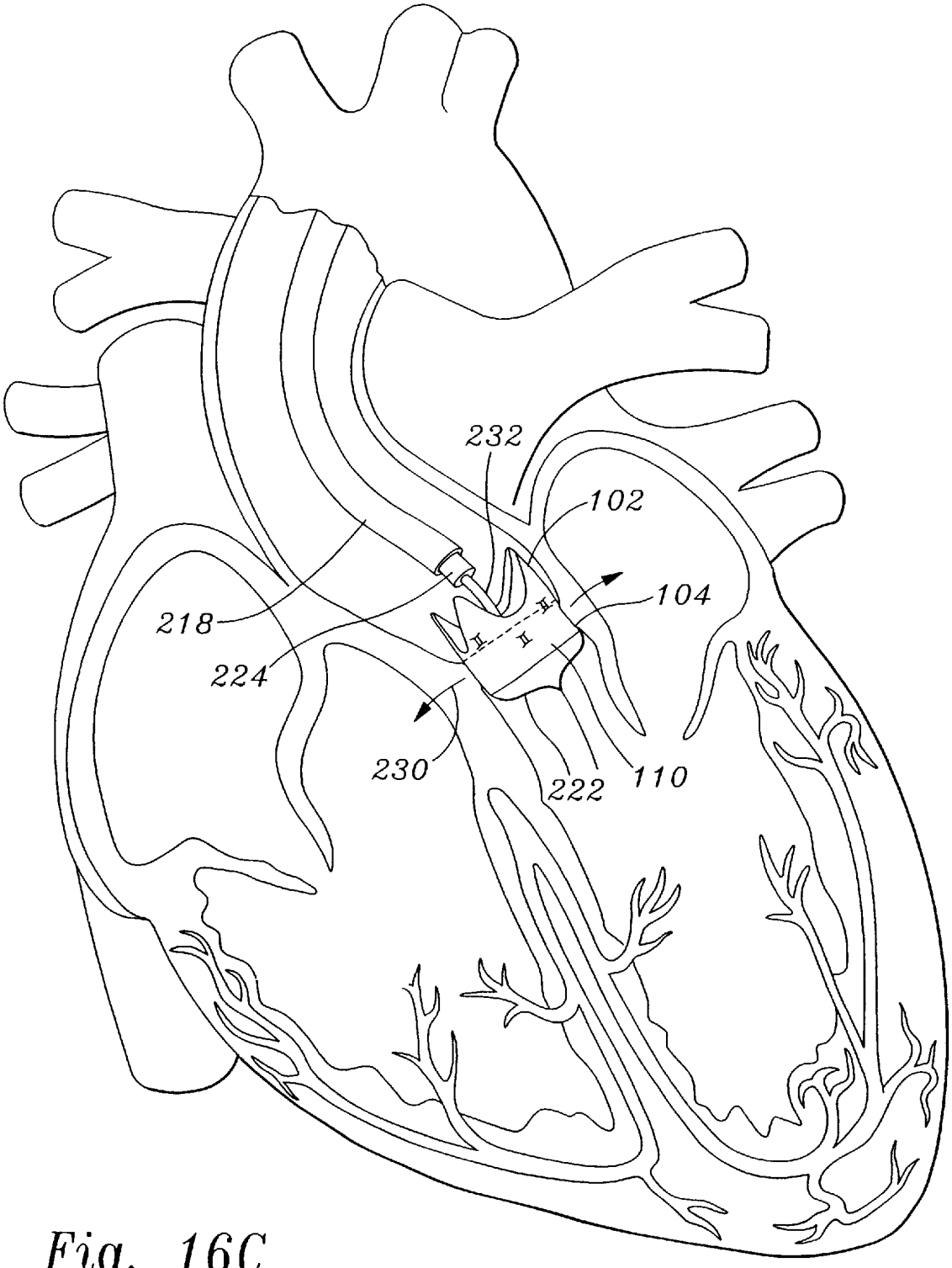



Fig. 16C

# MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE

## FIELD OF THE INVENTION

The present invention relates generally to medical devices and particularly to expandable heart valve prostheses especially for use in minimally-invasive surgeries.

## BACKGROUND OF THE INVENTION

Prosthetic heart valves are used to replace damaged or diseased heart valves. In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left and right atria and the left and right ventricles, each provided with its own one-way valve. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. Prosthetic heart valves can be used to replace any of these naturally occurring valves, although repair or replacement of the aortic or mitral valves is most common because they reside in the left side of the heart where pressures are the greatest.

Where replacement of a heart valve is indicated, the dysfunctional valve is typically cut out and replaced with either a mechanical valve, or a tissue valve. Tissue valves are often preferred over mechanical valves because they typically do not require long-term treatment with anticoagulants. The most common tissue valves are constructed with whole porcine (pig) valves, or with separate leaflets cut from bovine (cow) pericardium. Although so-called stentless valves, comprising a section of porcine aorta along with the valve, are available, the most widely used valves include some form of stent or synthetic leaflet support. Typically, a wireform having alternating arcuate cusps and upstanding commissures supports the leaflets within the valve, in combination with an annular stent and a sewing ring. The alternating cusps and commissures mimic the natural contour of leaflet attachment. Importantly, the wireform provides continuous support for each leaflet along the cusp region so as to better simulate the natural support structure.

A conventional heart valve replacement surgery involves accessing the heart in the patient's thoracic cavity through a longitudinal incision in the chest. For example, a median sternotomy requires cutting through the sternum and forcing the two opposing halves of the rib cage to be spread apart, allowing access to the thoracic cavity and heart within. The patient is then placed on cardiopulmonary bypass which involves stopping the heart to permit access to the internal chambers. Such open heart surgery is particularly invasive and involves a lengthy and difficult recovery period.

Recently, a great amount of research has been done to reduce the trauma and risk associated with conventional open heart valve replacement surgery. In particular, the field of minimally invasive surgery (MIS) has exploded since the early to mid-1990s, with devices now being available to enable valve replacements without opening the chest cavity. MIS heart valve replacement surgery still requires bypass, but the excision of the native valve and implantation of the prosthetic valve are accomplished via elongated tubes or cannulas, with the help of endoscopes and other such visualization techniques.

Some examples of MIS heart valves are shown in U.S. Pat. No. 5,980,570 to Simpson, U S. Pat. No. 5,984,959 to Robertson, et al., and PCT Publication No. WO 99/334142 to Vesely. Although these and other such devices provide various ways for collapsing, delivering, and then expanding a "heart valve" per se, none of them disclose an optimum structure for tissue valves. For instance, the publication to



Vesely shows a tissue leaflet structure of the prior art in FIG. **1**, and an expandable inner frame of the invention having stent posts in FIGS. **3**A–**3**C. The leaflets are "mounted to the stent posts **22** in a manner similar to that shown in FIG. **1**." Such a general disclosure stops short of explaining how to construct an optimum valve. In particular, the means of attaching the leaflets to the MIS stent is critical to ensure the integrity and durability of the valve once implanted. All of the prior art MIS valves fall short in this regard.

In view of the foregoing, it is evident that an improved sewing ring that addresses the apparent deficiencies in existing expandable heart valves is necessary and desired.

## SUMMARY OF THE INVENTION

The present invention provides an expandable prosthetic heart valve for placement in a host heart valve annulus, comprising an expandable stent system adapted to be delivered in a collapsed state to an implantation site and expanded, and a plurality of prosthetic leaflets attached to the stent system. Each leaflet has an approximately semicircular cusp edge terminating at each end in commissure portions, and a coapting edge extending between the commissure portions. Each leaflet is attached to the stent system substantially entirely along the cusp edge and at both commissure portions, with a coapting edge remaining unattached. The stent system may comprise an expandable generally annular tissue-engaging base and an elastic generally annular wireform attached thereto. The base is adapted to be delivered in a radially collapsed state and expanded into contact with the host annulus. The annular wireform defines a plurality of upstanding commissures and a plurality of arcuate cusps between adjacent commissures, and the prosthetic leaflets are attached to the wireform along the cusps and commissures, wherein the wireform and leaflets are configured to be radially compressed.

In one embodiment, the heart valve includes a plurality of upstanding posts attached to one of the tissue-engaging base and elastic wireform, each post having a connector. A plurality of mating connectors are provided on the other of the tissue-engaging base and elastic wireform for mating with the post connectors. The posts and mating connectors may be provided for each commissure and each cusp of the elastic wireform so that the valve includes a number of posts and mating connectors equal to the number of commissures plus the number of cusps. Further, the expandable stent system may include an undulating wireform defining a plurality of commissures and a plurality of cusps between adjacent commissures. The cusp edge of each of the prosthetic leaflets attaches along a wireform cusp, and the commissure portions of each leaflet terminate in outwardly extending tabs that each attach to a wireform commissure, wherein tabs from adjacent leaflets are attached together at each of the wireform commissures.

In another aspect of the invention, an expandable prosthetic heart valve for placement in a host heart valve annulus is provided. The heart valve comprises an expandable stent portion and an elastic leaflet portion connectable to the stent portion. The stent portion defines an inflow end of the valve and is adapted to be delivered in a collapsed state and expanded into contact with the host annulus. The leaflet portion forms a one-way flow occluder on an outflow end of the valve and includes an elastic wireform defining alternating cusps and commissures and prosthetic tissue attached substantially entirely therealong. The stent portion desirably includes a tubular member and a plurality of connectors, and wherein a plurality of connectors are provided on the elastic

wireform for mating with the tubular member connectors. The wireform connectors may be provided on each commissure and on each cusp of the wireform so that the valve includes a number of mating connectors equal to the number of commissures plus the number of cusps. In a preferred embodiment, the prosthetic tissue comprises a plurality of individual leaflets secured along the alternating cusps and commissures of the elastic wireform. Additionally, the wireform may have a fabric covering, wherein the individual leaflets are stitched along the fabric covering. The fabric covering continues toward an inflow end of the valve in a skirt that surrounds the stent portion and is adapted to be captured between the expanded stent portion and the host annulus. A plurality of posts rigidly may connect to the stent portion and extend upward within the skirt into mating connection with the elastic wireform.

In a still further aspect, the present invention provides a two-part expandable prosthetic heart valve for placement in a host heart valve annulus, comprising:

a leaflet subassembly having a wireform defining a plurality of upstanding commissures and a plurality of arcuate cusps extending between adjacent commissures, a midpoint of each cusp being located approximately equidistant from the adjacent commissures;

a generally annular tissue-engaging base defining an axis; and

a system for connecting the leaflet subassembly and the tissue-engaging base, including a plurality of mating connectors on the leaflet subassembly and on the tissue-engaging base, wherein one connector each is provided at each commissure, and one at each cusp midpoint.

In the two-part heart valve, the tissue-engaging base preferably comprises an expandable tubular member that is deliverable to the host annulus in a collapsed state and expandable into contact with the host annulus to secure the valve therein. Furthermore, the tissue-engaging base forms an inflow end of the valve, and the system for connecting the leaflet subassembly and tissue-engaging base includes a plurality of posts coupled to the tubular member and having varying lengths extending away from the inflow end of the valve. A first plurality of posts each having a first length connects with the wireform commissures, and a second plurality of posts each having a second length connects with the wireform cusps shorter than the first length. The mating connectors may be configured to be joined together by axial compression, preferably with a snap-fit configuration.

A further aspect of the invention includes a prosthetic heart valve having a support stent and a flexible tubular member. The support stent includes a tubular base along an inflow end a plurality of generally axially-extending commissure posts disposed evenly around the tubular base on an outflow end thereof. The flexible tubular member has a prosthetic section attached to the commissure posts so as to define a plurality of the prosthetic valve leaflets between the posts, and a fabric section connected to the base. The prosthetic section and fabric section are desirably both generally tubular and attached together at a seam, wherein the seam is spaced from the outflow end of the tubular base so that only the fabric section of the flexible tubular member contacts the tubular base. The commissure posts each may have an axial slot, wherein the tubular member is primarily located within the posts except for a plurality of loops that extend outward through each slot on each post. A plurality of inserts sized larger than the slots may be provided, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot. In a preferred embodiment, the commissure posts are integrally formed with the base, the base and commissure posts being initially formed from a flat section of material, wherein the commissure posts initially extend from the inflow end of the base and are bent 180° to extend alongside the base and project beyond the base at the outflow end thereof.

A prosthetic heart valve of the present invention has a support stent including a tubular base along an inflow end. A plurality of generally axially-extending commissure posts each having an axial slot is disposed evenly around the tubular base on an outflow end thereof. A flexible tubular member having an outflow edge is primarily located within the posts except for a plurality of loops that extend outward through each slot on each post. Further, a plurality of inserts sized larger than the slots are provided, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot, the outflow edge of the tubular member defining a plurality of valve leaflets. The tubular base may be plastically-expandable from a first size adapted for minimally invasive delivery, to a second, functional size that fits within a heart valve annulus.

A method of minimally-invasive heart valve replacement surgery on a patient is also provided by the present invention. The method includes the steps of:

providing an annular tissue-engaging base, the base being expandable from a collapsed state;

providing a generally annular elastic wireform subassembly having a plurality of prosthetic leaflets connected thereto, the elastic wireform subassembly having a relaxed, expanded size and a compressed, reduced size;

connecting the wireform and leaflets to the base to form a heart valve;

delivering the heart valve with the connected base in its collapsed state and wireform subassembly in its reduced size to an annulus of the patient's heart valve being replaced; and

expanding the base into its expanded state in contact with the annulus.

The step of delivering the heart valve to the annulus may be accomplished by passing the valve through the patient's vasculature or via a minimally-invasive port in the patient's chest. The tissue-engaging base may plastically-expandable from its collapsed state to its expanded state, and the step of expanding the plastically-expandable base comprises inflating a balloon within the annular base.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded perspective view of a first embodiment of an expandable heart valve of the present invention, including a support stent and a flexible tubular member;

FIG. **2** is an assembled perspective view of the expandable heart valve of FIG. **1**;

FIG. **3** is a longitudinal cross-sectional view taken along line **3**—**3** through a commissure of the expandable heart valve of FIG. **2**;

FIG. **4** is a transverse cross-sectional view taken along line **4**—**4** through the commissure of the expandable heart valve of FIG. **2**;

FIG. **5** is a top plan view of the expandable heart valve of FIG. **2**;

FIG. **6** is an exploded perspective view of a second embodiment of an expandable heart valve of present inven-

tion having two detachable components designed to be assembled post-storage, including a tissue-engaging base and a wireform-supported leaflet subassembly;

FIG. **7** is an assembled perspective view of the expandable heart valve of FIG. **6**, with a fabric skirt removed to illustrate details of a connecting system between the base and leaflet subassembly;

FIG. **8** is a plan view of an insert used to both attach individual leaflets to commissures of the wireform, and connect the commissures of the leaflet subassembly to the tissue-engaging base of the expandable heart valve of FIG. **6**;

FIG. **9** is a plan view of an individual leaflet for use in the expandable heart valve of FIG. **6**;

FIG. **10** is a longitudinal cross-sectional view taken along line **10**—**10** of FIG. **7**;

FIG. **11** is a transverse cross-sectional view taken along line **11**—**11** of FIG. **7**;

FIG. **12** is a longitudinal cross-sectional view taken along line **12**—**12** of FIG. **7**;

FIG. **13** is a top plan view of the expandable heart valve taken along line **13**—**13** of FIG. **7**;

FIG. **14** is an enlarged perspective view of a commissure region of the expandable heart valve taken within the circle **14** of FIG. **7**;

FIG. **15** is an enlarged plan view of the commissure region of the expandable heart valve taken within the circle **15** of FIG. **13**; and

FIGS. **16**A–C illustrate a heart in section and several steps in a delivery and implantation procedure of the expandable valve of the present invention.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention discloses two different expandable heart valves for implantation in a host annulus, or host tissue adjacent the annulus. The valves may be implanted in any of the four valve positions within the heart, but are more likely to be used in replacing the aortic valve because of the circular shape of the annulus.

It should also be noted that the specific constructional details, including materials and shapes, may be varied from those shown. For example, an expandable tubular base is used in both valve embodiments, and is described as being a plastically-expandable structure that radially expands into contact with the annulus tissue. Alternatively, the tubular base may be elastically- or self-expandable, or expandable on the application of heat (i.e., using shape memory material). Further, various means are known for plastically or elastically expanding structures into contact with anatomical passageways, and though the present invention illustrates and describes only one such structure, others may be used to practice the invention. For example, any plastically- or elastically-expandable structure may be modified so as to have a suitable diameter for heart valves and used to practice the present invention. In addition, barbs, flanges, staples, and the like may be added to the tubular base for the purpose of greater attachment to the host tissue. In short, the present invention should not be construed to be limited to the particular structures and materials disclosed, the scope of the invention being solely defined by the appended claims.

With reference to FIGS. **1**–**5**, a first embodiment of an expandable prosthetic heart valve **20** is shown and described. The prosthetic heart valve **20** is assembled prior to storage. In a second embodiment, shown in FIGS. **6**–**15**, a second embodiment of an expandable heart valve is shown and described. Detachable components of the expandable heart valve in the second embodiment are separately stored, and assembled just prior to insertion and delivery to the host annulus, which provides certain advantages to be described.

Pre-Assembled Expandable Heart Valve

FIG. **1** illustrates the first embodiment of the expandable heart valve **20** exploded, with a flexible tubular member **22** separated from a support stent **24** along a central axis **26**. FIG. **2** illustrates the flexible tubular member **22** attached to the support stent **24** to form the assembled heart valve **20**. The heart valve **20** has an inflow end **28** (the lower end in the figure) and an outflow end **30** (the upper end in the figure).

The flexible tubular member **22** comprises a leaflet section **32** connected to a fabric section **34** at a seam **36**. As illustrated, both the leaflet section **32** and fabric section **34** are desirably formed as tubes, such that the seam **36** defines a circle therebetween. Alternatively, the seam **36** may be other than circular if areas of the leaflet section **32** or fabric section **34** need to be expanded around their circumferential juncture. For example, the fabric section **34** may need to be increased in the commissure region of the valve **20**, such as indicated by the dashed line **38** in FIG. **1**. Whatever the configuration, the fabric section **34** has a minimum axial height indicated at A.

Desirably, the leaflet section **32** is formed from pericardial tissue, such as bovine or equine pericardium, suitably treated to render it biocompatible. Of course, any suitable leaflet material, including synthetics, may be used. The fabric section **34** is desirably a woven polyester, such as polyethylene terepthalate. Alternatively, the fabric section **34** may be formed of polytetrafluoroethylene (PTFE), or other suitable biocompatible sheet material. Still further, the leaflet section **32** may extend the entire axial height of the flexible tubular member **22**, with the fabric section **34** being wrapped around and attached to the inflow end.

As seen in FIG. **1**, the support stent **24** comprises a tubular base **40** and a plurality of upstanding commissure posts **42** distributed evenly around the periphery thereof. That is, the tubular base **40** is provided at the inflow end **28** of the support stent **24**, with the commissure posts **42** extending in the outflow direction. Desirably, there are three such commissure posts **42** disposed at 120° intervals about the circumference of the stent **24**. The tubular base **40** has an axial height indicated at B, which height is less than the axial height A of the fabric section **34** of the flexible tubular member **22**. The commissure posts **42** extending upward a sufficient distance such that the entire axial dimension of the support stent **24** is slightly greater than the axial dimension of the flexible tubular member **22**, as indicated in the assembled view of FIG. **2**.

The tubular base **40** comprises a plastically-expandable material that can be expanded into the configuration shown in the figures from a radially compressed configuration (not shown). In this regard, the illustrated tubular base **40** essentially comprises a non-self expanding stent that can be expanded from its compressed state using a balloon inflated from within the base, for example. Numerous configurations of such plastically-expandable tubes are available in the prior art, and as mentioned above, the present invention should not be considered limited to any one configuration. Moreover, in other configurations the base **40** may be self- or heat-expandable.

With reference to FIG. **1**, each commissure post **42** attaches to or extends from an inflow rim **44** of the tubular

base **40**, continuing on the outside of the tubular base toward the outflow end in an elongated axially-extending lower section **46**, and terminating in an axially extending upper section **48**. The upper section **48** commences at a predetermined distance above an outflow rim **50** of the tubular base **40** and is stepped radially inward from the lower section **46** at a transition region **52**. An axial slot **54** is provided in the upper section **48** and in the transition region **52**. The width of the axial slot **54** is desirably constant in the upper section **48**, but increases at a relief region **56** in the transition region **52**.

In a preferred embodiment, the commissure posts **42** are formed of a biocompatible, elastic material, preferably metallic. For example, each commissure post **42** may be formed of stainless-steel, titanium, or Elgiloy. Alternatively, the commissure posts **42** may be a biocompatible polymer, such as Delrin or polyacetyl.

In a preferred embodiment, the support stent **24** is formed from a single piece of flat material. Specifically, the tubular base **40** initially comprises a flat, narrow strip of uniform width material with the commissure posts **42** extending from one long side thereof. Using conventional means, the narrow strip of material is then rolled into the tubular shape shown in the figures, and the juxtaposed narrow ends joined by, for example, crimping. Each of the commissure posts **42** is then bent 180° outward to project in the opposite direction from their original direction. FIG. **1** illustrates such a configuration in which a 180° bend **60** joins each commissure post **42** to the inflow rim **44**. The radius of the bend **60** is such that a narrow space **62** is defined between the lower section **46** of each commissure post **42** and the exterior of the tubular base **40**.

The flexible tubular member **22** attaches to the support stent **24** as seen in FIG. **2**,with the leaflet section **32** connected to the commissure posts **42**, and the fabric section **34** connected to the tubular base **40**. More specifically, the fabric section **34** surrounds the tubular base **40** and extends toward the inflow rim **44** in the spaces **62** created inboard of each commissure post **42**. Although not shown, the fabric section **34** may be attached to the exterior of the tubular base **40**, such as by sutures passed through the fabric and through openings in the tubular base. Because the axial dimension A of the fabric section **34** is greater than the axial dimension B of the tubular base **40**, the seam **36** is disposed above the outflow rim **50** (FIG. **1**) of the base. This is more clearly shown in the cross-section of FIG. **3**.

The leaflet section **32** is disposed substantially between the commissure posts **42**, except for a number of loops **70** threaded outward through the axial slots **54**. As seen FIGS. **2–3**, the loops **70** comprises regions of the tubular leaflet section **32** pinched and threaded through the axial slots **54**. A plurality of inserts **72** are used to secure the loops **70** to the exterior of the commissure posts **42**. That is, as seen FIG. **4**, the inserts **72** each have a width W that is greater than the circumferential width of the axial slots, **54**. Because the inserts **72** are disposed within the loops **70**, they prevent the loops from pulling inward again through the axial slot **54**. A plurality of stitches **74** are preferably provided to secure the leaflet section **32** to the inserts **72**. In addition, as seen in FIG. **3**, stitching **76** passes through an aperture **78** in each insert **72**, and through an aperture **80** provided in the outflow end of each commissure post **42**. In this manner, each insert **72** is secured with respect to the support stent **24**.

With reference to FIGS. **2** and **5**, a plurality of leaflets **82**, are defined between the support stents **24** by the leaflet section **32**. Specifically, where there are three stent post **24**, a generally triangular arrangement of leaflets **82** remains unconstrained in the middle portion of the valve **20** and opens and closes depending on blood flow forces. Furthermore, the continuous flexible tubular member **22** provides a flow channel for blood through the valve **20**. When the pressure differential is such that blood flows into the inflow end **28** of the valve **20**, the leaflets **82** spread apart and the valve opens. Conversely, when the pressure differential reverses, the leaflets **82** come together, or coapt, to close the valve **20**.

When the pressures are such that the valve closes, radially inward forces are imposed on the free edge of the leaflet section **32**, which may tend to cantilever the support stents **24** inward a slight amount. Localized stresses on the leaflet section **32** are reduced at the connection with the stent supports **24**, however, because of the use of the inserts **72** within the loops **70**. That is, as best seen in FIG. **4**, radially inward forces on the leaflets **82** as indicated by the arrow **84**, pull the inserts **72** inward such that the leaflet material is clamped between each insert and the respective commissure post **42**. Although stitching **74** through the leaflet section **32** is provided, such stitching is not subjected to direct tensile stresses, and thus is less likely to tear through the leaflet tissue.

Certain features of the valve **20** reduce wear typically associated with stent-leaflet dynamic contact. First, because the axial dimension A of the fabric section **34** is greater than the dimension B of the tubular base **40**, any contact between the flexible tubular member **22** and the tubular base **40** (at the outflow rim **50**) is between fabric and the base. That is, the leaflet section **32** is not placed in contact with the base **40**, thus increasing the life of the valve. Additionally, the enlarged relief region **56** of the slot **54** in the transition region **52** helps reduce the rubbing that might otherwise occur between the commissure posts **42** and the leaflets **80**. That is, the leaflet section **32** continues substantially axially downward from the loops **70**, as seen in FIG. **3**, and the relief region **56** provides a small gap in the transition region **52** between the leaflet tissue and the sides of the slot **54** to help prevent rubbing therebetween.

In use, the assembled heart valve **20** as seen in FIG. **2** is initially provided in a radially compacted configuration (not shown). Preferably, the valve **20** is loaded about a balloon catheter and within a delivery cannula. The balloon catheter with the valve **20** loaded thereon is than passed through the patient's vasculature (or through an access port in the chest) into proximity with the host annulus. Alternatively, where the chest of the patient is opened, the reduced size valve **20** is inserted into position using a holder.

Once in position within the annulus of the valve being replaced, the balloon (or other expanding means) causes the tubular base **40** to expand into contact with the annulus. Actually, because the commissure posts **42** and fabric section **34** surround tubular base **40**, these elements are compressed against the host annulus. Because the tubular base **40** is plastically-expandable, it substantially retains its expanded shape. A slight over-expansion of the tubular base **40** may be required to compensate for any elastic spring-back character of the material used. Again, barbs or staples may also be utilized to further secure the valve **20** and in place. Ultimately, the balloon catheter is deflated and removed from within the valve **20**.

Expandable Heart Valve Assembled Post-Storage

FIGS. **6–15** illustrate an expandable prosthetic heart valve **100** including, as best seen in FIG. **6**, a leaflet subassembly **102** adapted to connect to a tissue-engaging base **104**. The two components are both shown in FIG. **6** in their radially expanded configurations, though both are designed to be

radially compressed and delivered through a catheter or cannula, for example. In contrast with the first embodiment, however, the two components are stored separately, and connected just prior to delivery into the body of the patient. In general, the two components provide a tissue-engagement ring and a relatively more flexible valve member having fluid occluding surfaces. It should be understood that configurations of these two connectable components other than those specifically shown may be encompassed by the appended claims.

As seen in FIG. **6**, the leaflet subassembly **102** comprises an elastic wireform **106** supporting a plurality of prosthetic leaflets **108**, and a fabric skirt **110**. The wireform **106** comprises a continuous undulating pattern of alternating commissures **112** and cusps **114**. Preferably, the valve **100** is a tri-leaflet type, such that the wireform **106** has three commissures **112** and three cusps **114**, with three leaflets **108** support thereby. In particular, each leaflet **108** is desirably attached to adjacent commissures **112**, and along the entire arcuate cusp **114** therebetween. As will be described in more detail below, the leaflets **108** each attach to a fabric covering **1 16** around the wireform cusps **114**. In a preferred embodiment, the elastic wireform **106** is formed of a biocompatible, elastic material, preferably metallic. For example, the elastic wireform **106** may be formed of stainless-steel, titanium, or Elgiloy. Alternatively, the elastic wireform **106** may be formed from a biocompatible polymer, such as Delrin or polyacetyl. In this sense, therefore, the term "wire" in wireform should not be construed as limiting the material to metallic.

FIG. **7** illustrates an assembled valve **100** with the fabric skirt **110** shown in FIG. **6** removed for clarity. That is, the fabric skirt **119** is sized to drape outside of and surround the tissue-engaging base **104**, but is removed in FIG. **7** to show the connection details between the base and the leaflet subassembly **102**. The valve **100** defines an inflow end **120** and an outflow end **122**.

FIG. **9** illustrates an exemplary leaflet **108** having an arcuate cusp edge **124** opposite a linear coapting edge **126**. The cusp edge **124** is generally semi-circular, and terminates at commissure portions **128**. A pair of oppositely-directed tabs **130** extend outward from both ends of the coapting edge **126**, and are seen in FIG. **6** prior to attachment to the wireform **106**. That is, the tabs **130** from adjacent leaflets **108** join together and pass through the inverted U-shaped commissures **112** of the elastic wireform **106**. In a preferred embodiment, each leaflet **108** is formed from pericardial tissue, such as bovine or equine pericardium, or a synthetic material, that has been suitably treated to render it biocompatible.

With reference again to FIG. **6**, the cusp edge **124** of each leaflet **108** is shaped so as to follow a cusp **114** of the elastic wireform **106**. The fabric skirt **110** extends to an inflow edge **132** from each of the cusps **114**, and when the skirt is assembled to the tissue-engaging base **104**, the inflow edge extends substantially to the inflow end **120** (FIG. **7**) of the valve. The fabric skirt **110** further terminates at outflow edges **134** between adjacent wires of the wireform commissures **112**, below the leaflet tabs **130** extending therethrough. The skirt **110** may be made of a biocompatible fabric such as polyester, or of other suitable biocompatible sheet material.

The leaflet subassembly **102** attaches to the tissue-engaging base **104** at discrete locations, securely coupling each of the commissures **112** and cusps **114** of the elastic wireform **106** to the base. As seen best in FIG. **6**, the tissue-engaging base **104** comprises a tubular plastically-expandable member **140** having an inflow rim **142** and outflow rim **144**. A plurality of commissure posts **146** are either rigidly attached to, or securely coupled to, the tubular member **140** so as to extend generally axially beyond the outflow rim **144** in the outflow direction. Likewise, a plurality of cusp posts **148** are rigidly attached to, or securely coupled to, the tubular member **140** so as to extend beyond the outflow rim **144**. Because the commissure posts **146** couple to the wireform commissures **112**, they are longer than the cusp posts **148** that couple to the wireform cusps **114**.

As illustrated, both the commissure posts **146** and cusp posts **148** extend through upper and lower sleeves **150***a*, **150***b*, respectively provided on the exterior of the tubular member **140**, and are desirably axially secured therein. It should be noted that this is only one of numerous possible ways to rigidly couple upstanding posts to a plastically-expandable tubular member. However, the posts **146,148** are desirably located on the outside of the tubular member **140** so as not to interfere with a balloon for expanding the tubular member from the inside, nor to interfere with blood flowing through the valve. It should also be noted that in a reverse configuration, the posts **146, 148** may be initially attached to the wireform commissures **112** and cusps **114**, respectively, as part of the leaflet subassembly **102** and subsequently connected to mating structures (not shown) provided on the tissue-engaging base **104**.

A plurality of connectors are provided for attaching the elastic wireform **106** to the posts **146, 148** of the tissue-engaging base **104**. In particular, as seen in FIG. **6**, each commissure post **146** provides a lower commissure connector **160** thereon. Likewise, each cusp posts **148** provides a lower cusp connector **162**. In the illustrate embodiment, the outflow end of each of the posts **146, 148** is bent 90° to face radially inward and a groove formed therein defines the respective connectors **160,162**.

FIGS. **9–11** illustrate the configuration of the connection between the leaflet subassembly **102** and tissue-engaging base **104** at the commissures of the valve. With specific reference to FIG. **10**, the lower commissure connector **160** of the commissure post **146** mates with an upper commissure connector **164** of an insert **166** (isolated in FIG. **8**) secured to the wireform is commissure **112**. As seen in FIG. **11**, adjacent leaflets **130** extend radially outward between spaced wires of the wireform **106** and wrap around the insert **166** to be connected on an outer side thereof with a plurality of stitches **168**. FIG. **8** illustrates one form of the insert **166** wherein the upper commissure connector **164** comprises a downwardly opening partial circle which mates with the groove of the lower commissure connector **160**, as seen in FIG. **10**. In this manner, the commissures **112** are securely fastened with respect to the tissue-engaging base **104** by virtue of the interaction between the lower commissure connector **160** and upper commissure connector **164**.

With reference again to FIGS. **6** and **7**, a plurality of upper cusp connectors **170** attach to the approximate midpoint of each of the cusps **114** of the wireform **106**. Each upper cusp connectors **170** is configured and positioned to mate with the lower cusp connector **162** formed on each of the cusp posts **140**. Again, the upper cusp connector **170** may be provided with a downwardly opening partial circle that mates with the groove of the lower cusp connector **162**.

With specific reference to FIG. **12**, certain constructional details of the valve cusps are further illustrated. The fabric covering **116** of the wireform **106** is shown as a tube having an upper fabric extension **180** and a lower fabric extension **182** sandwiched around a radial portion **184** of the upper

cusp connector **170**. The upper cusp connector **170** extends outward and bends 90° downward to mate with the lower cusp connector **162**. The upper fabric extension **180** continues outward and downward in the fabric skirt **110**. The lower fabric extension **182** bends 180° underneath the cusp edge **124** of the respective leaflet **108**. Stitching **186** secures the combined layers of the upper extension **180**, radial portion **184**, first part of the lower extension **182**, leaflet cusp **124**, and wrapped-around portion of the lower extension **182**.

Desirably, both the insert **166** and upper cusp connector **170** are made from a suture-permeable material having sufficient strength to maintain the connections between the leaflet subassembly **102** and tissue-engaging base **104**. For example, the insert **166** and connector **170** may be made of Delrin, or other suitable polymer. As illustrated, each of the connectors **164** and **170** are partial circles that fit around tubular grooves in the respective posts **146**,**148**. Of course, other arrangements are possible, and the present invention should not be considered limited to those connectors illustrated.

As with the earlier embodiment, the valve **100** utilizes a low-stress connection between the leaflets **108** and the elastic wireform **106**. In particular, as seen in FIG. **11**, the provision of the insert **166** provides a clamping force during diastole between the insert and the wireform **106** against the portion of the leaflets **108** therebetween. The stitching **168** is not subjected to direct tensile stresses, and there is thus less chance for tearing.

Leaflet subassembly **102** is desirably stored in its expanded state, as seen in FIG. **6** (which, as mentioned, does not illustrate the commissure attachment structure). That is, the wireform **106** and leaflets **108** may be stored immersed in a preservative such as glutaraldehyde in a sterile container until needed. In this regard, the prosthetic leaflets **108** remain in their functional shape during storage. This greatly reduces adverse wrinkling or other permanent or semi-permanent damage to the leaflets over time, and improves the quality of the valve **100**. At the same time, the base **104** desirably does not include any bioprosthetic or otherwise perishable components, and thus may be stored in a separate dry sterile container. This method also permits the combination of different bases with any one leaflet subassembly **102**, or visa versa. For example, the type of attachment mechanism (i.e., staples, barbs, sutures, etc.) of the base **104** to the annulus may be selected by the surgeon, with different bases being attached in different ways, and all being combinable with a particular leaflet subassembly **102**. Also, the type of base may be selected based on patient indications; with a self-expanding base being preferred in some situations and a balloon-expanded base in others.

In use, the leaflet subassembly **102** is compressed from its expanded configuration to a size corresponding to the tissue-engaging base **104** in its compressed state (not shown). If the tissue-engaging base **104** is plastically deformable then it is initially supplied in its compressed state. Alternatively, a self-expandable base **104** will have to be compressed either before or after connection to the similarly configured leaflet subassembly **102**. Compression of the leaflet subassembly **102** (and base if necessary) may be accomplished using a tapered mandrel through which the subassembly is passed, or with a cinch or other direct constricting means. The two components are then connected together, just prior to insertion into the patient's body, and the valve **100** delivered simultaneously to the host annulus site. To connect the two components, the fabric skirt **110** is passed around the outside of the commissure posts **146** and around the tubular member **140**. Each of the upper connectors **164** and **170** are caused to mate with the lower connectors **160**, **162**. In the illustrated embodiment, such a mating operation simply requires forcing each of the partial circles defining the upper connectors over the grooves defining the lower connectors. The partial circles open slightly, but then spring inward when the connectors snap together and the groove is fully seated.

There are a number of ways to deliver the valve **100** to the aortic annulus. For one, the tubular member **140** may be mounted around a balloon catheter and inserted via an introducer or other cannula into the patient's vasculature and to the aorta. Alternatively, an open-heart procedure or less-invasive port procedure may be utilized, with the tissue-engaging base **104** being delivered to the host annulus using a holder or other such means.

FIG. **16A** depicts a sectional view of a heart **200** having a left ventricle chamber **202** opening to an ascending aorta **204** through an aortic annulus **206**. The ascending aorta **204** continues over an aortic arch **208**, and branches off into several upper body arteries **210** before descending to the abdominal aorta (not shown). As mentioned above, the expandable valves of the present invention can be delivered into proximity of the aortic annulus **206** in several ways, including through the patient's vasculature as shown.

In particular, a valve delivery catheter **212** is shown in the cutaway portion of the ascending aorta **204**, having been introduced along the direction of the arrow **214** so that a distal end thereof lies adjacent the aortic annulus **206**. The catheter **212** can be introduced percutaneously into the patient's arterial system (e.g. into a peripheral artery such as the fermeral artery) and advanced to the ascending aorta **204**. The catheter shaft preferably has a length of at least about 80 cm, usually about 90–100 cm, to allow transluminal positioning of the shaft from the femoral and iliac arteries to the ascending aorta. Alternatively, the shaft may have a shorter length, e.g. 20–60 cm, for introduction through the iliac artery, through the brachial artery, through the carotid or subclavian arteries, or through a penetration in the aorta itself. In the femoral approach, the catheter is long enough and flexible enough to traverse the path through the femoral artery, iliac artery, descending aorta and aortic arch. At the same time, the catheter has sufficient pushability to be advanced to the ascending aorta by pushing on the proximal end, and has sufficient axial, bending, and torsional stiffness to allow the physician to control the position of the distal end, even when the catheter is in a tortuous vascular structure. Alternatively, the catheter **212** may be passed through a port between ribs in the patient's thorax above the heart and through an incision in the aortic arch **208**, in a so-called minimally-invasive procedure.

Techniques for introducing catheters into the human vasculature are well-known, and typically involve the introduction of a guidewire **216** first, followed by an obturator or dilator (not shown) within a sheath **218**. The dilator facilitates introduction of the catheter sheath **218** into the vasculature, and is then removed, though the guidewire **216** typically remains in place. Subsequently, a valve of the present invention, such as valve **100** seen in FIGS. **6–15**, is delivered over the guidewire **216** and to the distal end of the sheath **218**. In accordance with one aspect of the present invention, the valve **100** includes a balloon-expandable portion and thus is mounted over an expansion balloon **222**. To facilitate passage of the valve **100** through the sheath **218**, a pusher **224** may be used.

FIG. **16B** illustrates a second step in the exemplary valve delivery procedure in which the sheath **218** is retracted in a proximal direction as indicated by arrow **226**. Retraction of the sheath **218** exposes the valve **100**, which is positioned

within the aortic annulus **206** with the assistance of fluoroscopy and radiopaque markers, ultrasonic imaging, or the like. If the valve **100** includes self-expanding components, retraction of the sheath **218** releases the outer restraint on the valve and permits it to expand into contact with the annulus **206**. In the illustrated embodiment, however, the tubular member **140** of the tissue-engaging base **104** is plastically-deformable and retains its radially constricted configuration after retraction of the sheath **218**. Because of the rigid connections between the leaflet subassembly **102** and the base **104**, the subassembly also remains in its constricted configuration.

Finally, in FIG. **16**C, the balloon **222** is inflated to cause the tissue-engaging base **104** to radially expand into contact with the aortic annulus **206**, as indicated by the arrows **230**. Simultaneously, the leaflet subassembly **102** radially expands by virtue of the rigid connection with the base **104**, and by virtue of its spring bias. A balloon inflation catheter **232** is seen projecting from the pusher **224** and through the leaflet subassembly **102**. With reference back to FIG. **6**, the fabric skirt **110** is captured between the tubular member **140** and the surrounding tissue, and is in direct contact therewith. Therefore, by virtue of the continuous connection between the cusp edges **124** of the leaflets **108** and the fabric skirt **110**, the skirt forms a flow channel for blood entering the inflow end **120** of the valve **100**. Again, the plastically-expandable tubular member **140** may be slightly over-expanded to account for any spring-back in the material. Further, as mentioned above, the tubular member **140** may include staples or barbs or other such attachment structure for securely locating the valve **100** within the annulus **206**.

Once the valve **100** is fully expanded and securely attached to the annulus **206**, the balloon **222** is deflated and removed. Such an operation may include elongating the balloon **222** in the distal direction and reducing its radial dimension by, for example, twisting. Care must be taken so as not to damage the leaflets within the subassembly **102** during retraction of the balloon **222** therethrough. After the balloon **222** has been retracted within the sheath **218**, the entire catheter **212** is removed from the patient.

The fully formed valve **100** has a number of distinct advantages over prior expandable valves. For example, as mentioned above, the prosthetic leaflets **108** may be stored in the final, uncompressed implantation shape. This is in contrast to prior expandable valves where the entire valve may be initially compressed such that the leaflets are stored in a compressed state. Consequently, valves of the prior art can be stored for years prior to use, and permanent wrinkling of the compressed leaflets may be a real problem.

Furthermore, each of the leaflets **108** is supported substantially entirely around the undulating wireform **106**, which has proven to provide optimal valve performance. Also, separate leaflets are used as opposed to a continuous tube, as in the first embodiment. Additionally, the advantageous low-stress attachment structure of the leaflet tabs **130** to the wireform commissures **112** further increases the durability of the valve.

While the foregoing is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Moreover, it will be obvious that certain other modifications may be practiced within the scope of the appended claims.

What is claimed is:

**1**. A prosthetic heart valve, comprising:

a support stent including a tubular base along an inflow end and a plurality of generally axially-extending commissure posts disposed evenly around the tubular base on an outflow end thereof, each commissure post having an axial slot, wherein the base is plastically-expandable from a first size adapted for minimally invasive delivery, to a second, functional size that fits within a heart valve annulus; and

a flexible tubular member having a prosthetic section attached to the commissure posts so as to define a plurality of prosthetic valve leaflets between the posts, and a fabric section connected to the base, and wherein the tubular member is primarily located within the posts except for a plurality of loops that extend outward through each slot on each post, and further including a plurality of inserts sized lager than the slots, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot.

**2**. The heart valve of claim **1**, wherein the prosthetic section and fabric section are both generally tubular and attached together at a seam.

**3**. The heart valve of claim **2**, wherein the seam is spaced from the outflow end of the tubular base so that only the fabric section of the flexible tubular member contacts the tubular base.

**4**. The heart valve of claim **2**, wherein the seam is other than circular.

**5**. The heart valve of claim **1**, wherein the fabric section of the flexible tubular member attaches along a seam to the outflow end of the tubular base.

**6**. The heart valve of claim **1**, wherein the prosthetic section of the flexible tubular member is pericardial tissue.

**7**. The heart valve of claim **1**, wherein the commissure posts are integrally formed with the base, the base and commissure posts being initially formed from a flat section of material, wherein the commissure posts initially extend from the inflow end of the base and are bent 180° to extend alongside the base and project beyond the base at the outflow end thereof.

**8**. The heart valve of claim **7**, wherein the fabric section of the flexible tubular member extends around the exterior of the tubular base and within spaces created between each of the commissure posts and the tubular base.

**9**. The heart valve of claim **1**, wherein the commissure posts each comprise:

a first axial section extending from the inflow end of the base and spaced radially therefrom;

a second axial section defining the outflow extent of the post and a portion of the axial slot, the second section being radially inwardly offset from the first section; and

a transition region between the first and second sections, wherein an enlarged portion of the axial slot is defined in the transition region.

**10**. The heart valve of claim **1**, further including a plurality of stitches securing each loop of the flexible tubular member to the corresponding insert.

**11**. The heart valve of claim **10**, further including stitching securing each insert to the corresponding commissure post of the base.

**12**. A prosthetic heart valve, comprising:

a support stent including a tubular base along an inflow end and a plurality of generally axially-extending commissure posts each having an axial slot and being disposed evenly around the tubular base on an outflow end thereof; and

a flexible tubular member having an outflow edge,

wherein the tubular member is primarily located within the posts except for a plurality of loops that extend

outward through each slot on each post, and further including a plurality of inserts sized larger than the slots, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot, the outflow edge of the tubular member defining a plurality of valve leaflets.

**13**. The heart valve of claim **12**, wherein the tubular base is plastically-expandable from a first size adapted for minimally invasive delivery, to a second, functional size that fits within a heart valve annulus.

**14**. The heart valve of claim **12**, wherein the commissure posts are integrally formed with the base, the base and commissure posts being initially formed from a flat section of material, wherein the commissure posts initially extend from the inflow end of the base and are bent 180 degrees to extend alongside the base and project beyond the base at the outflow end thereof.

**15**. The heart valve of claim **12**, wherein the flexible tubular member has a prosthetic section attached to the commissure posts and a fabric section connected to the base at a seam.

**16**. The heart valve of claim **15**, wherein the seam is other than circular.

**17**. The heart valve of claim **15**, wherein the fabric section of the flexible tubular member extends around the exterior of the tubular base and attaches along a seam to the outflow end of the tubular base.

**18**. The heart valve of claim **15**, wherein the prosthetic section of the flexible tubular member is pericardial tissue.

**19**. The heart valve of claim **12**, further including a plurality of stitches securing each loop of the flexible tubular member to the corresponding insert.

**20**. The heart valve of claim **19**, further including stitching securing each insert to the corresponding commissure post of the base.

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(54) IMPLANTABLE PROSTHETIC VALVE

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(52) **U.S. Cl.** ..... **623/2.11**; 623/1.13; 623/2.18

(57) **ABSTRACT**

A valve prosthesis device is disclosed suitable for implantation in body ducts. The device comprises support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the 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 provided with a plurality of longitudinally rigid support beams of fixed length; 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, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.

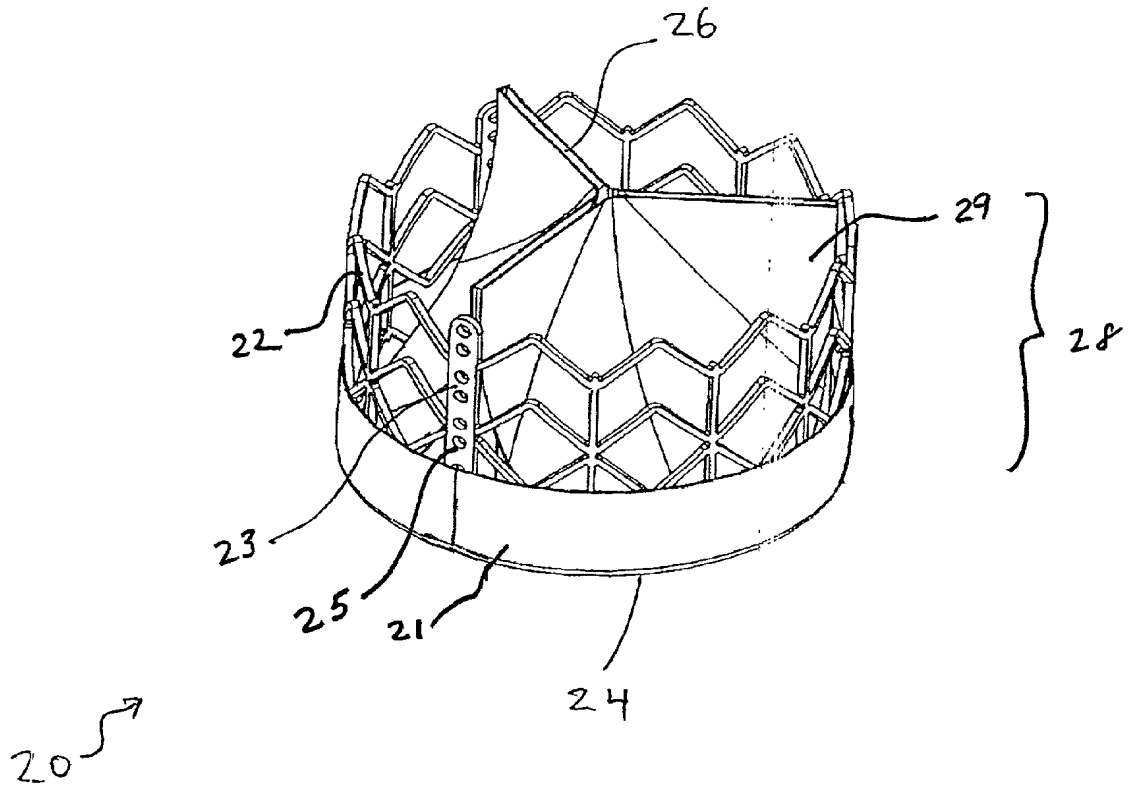


FIG. 1

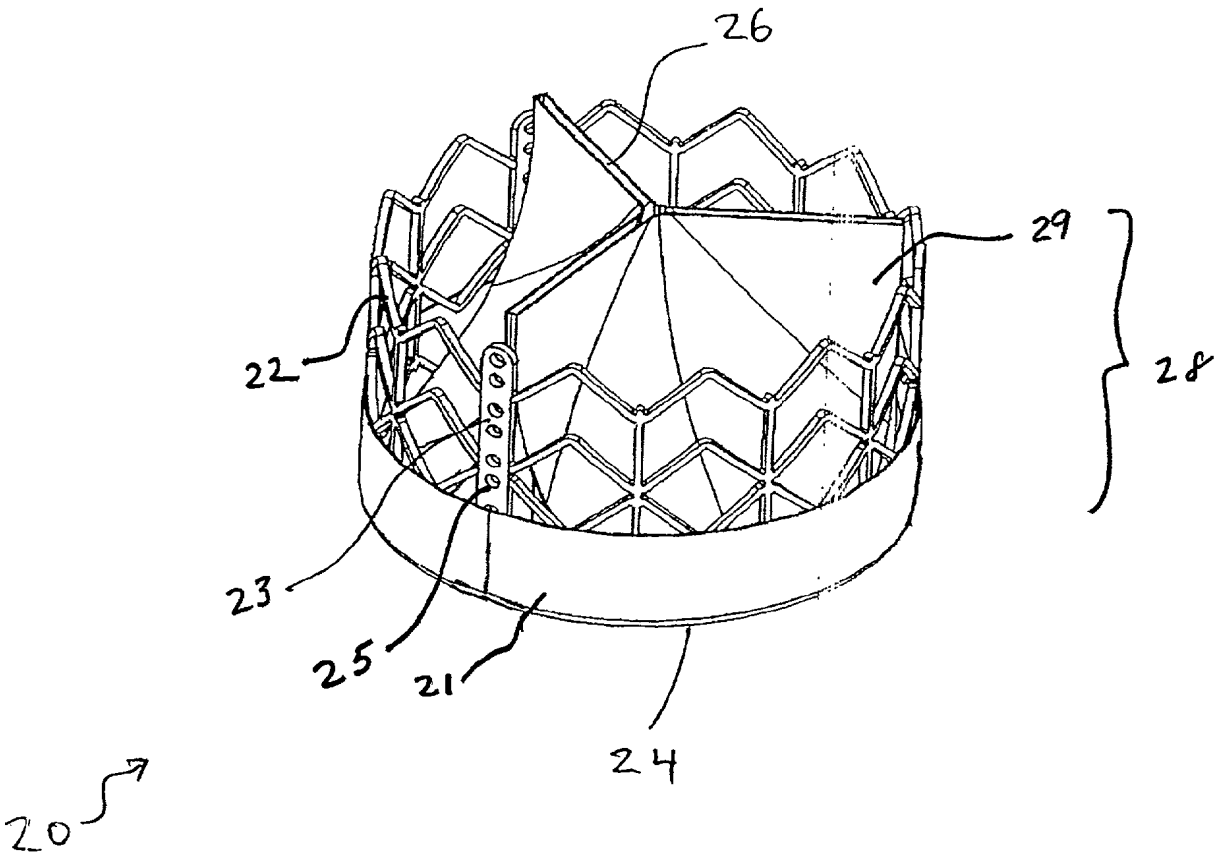


FIG. 2

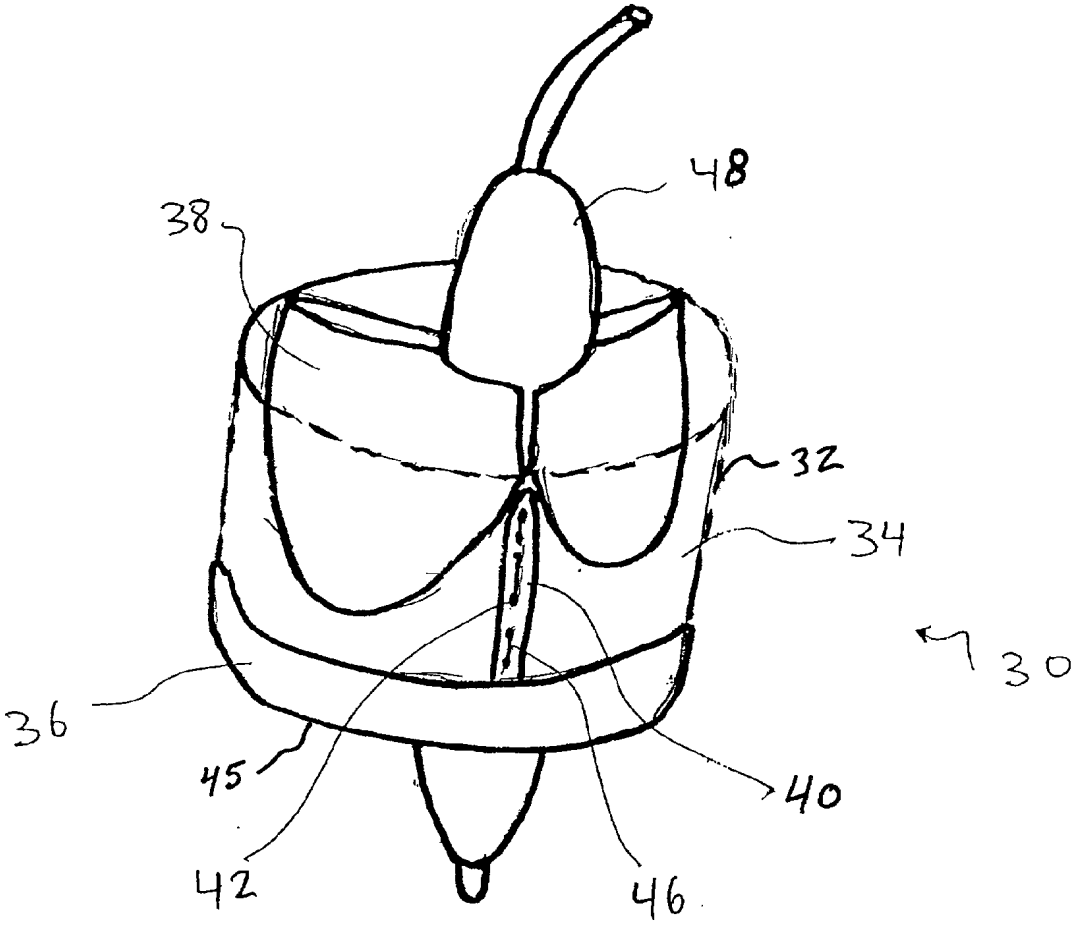


FIG. 3

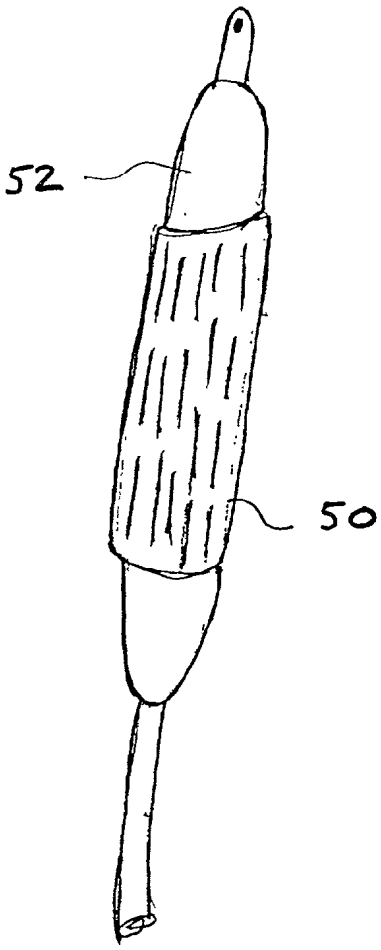



FIG. 4

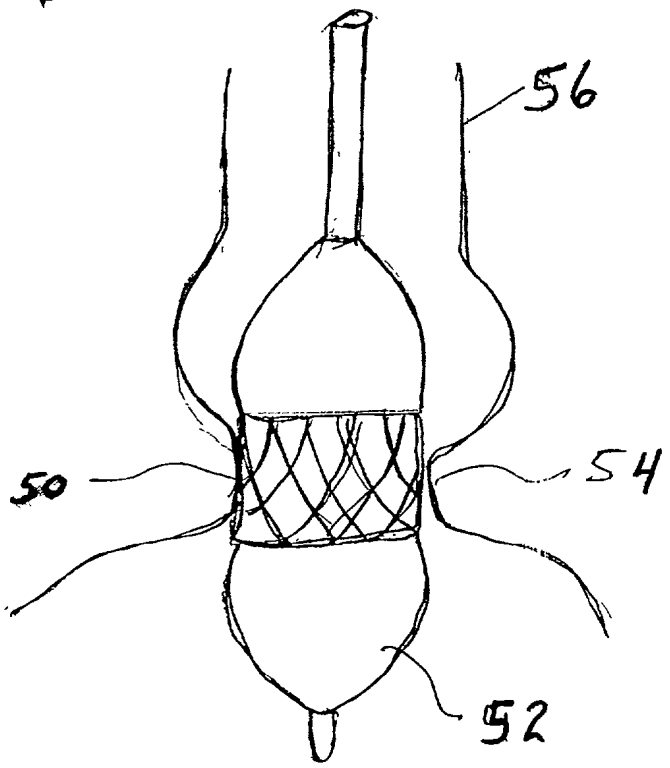
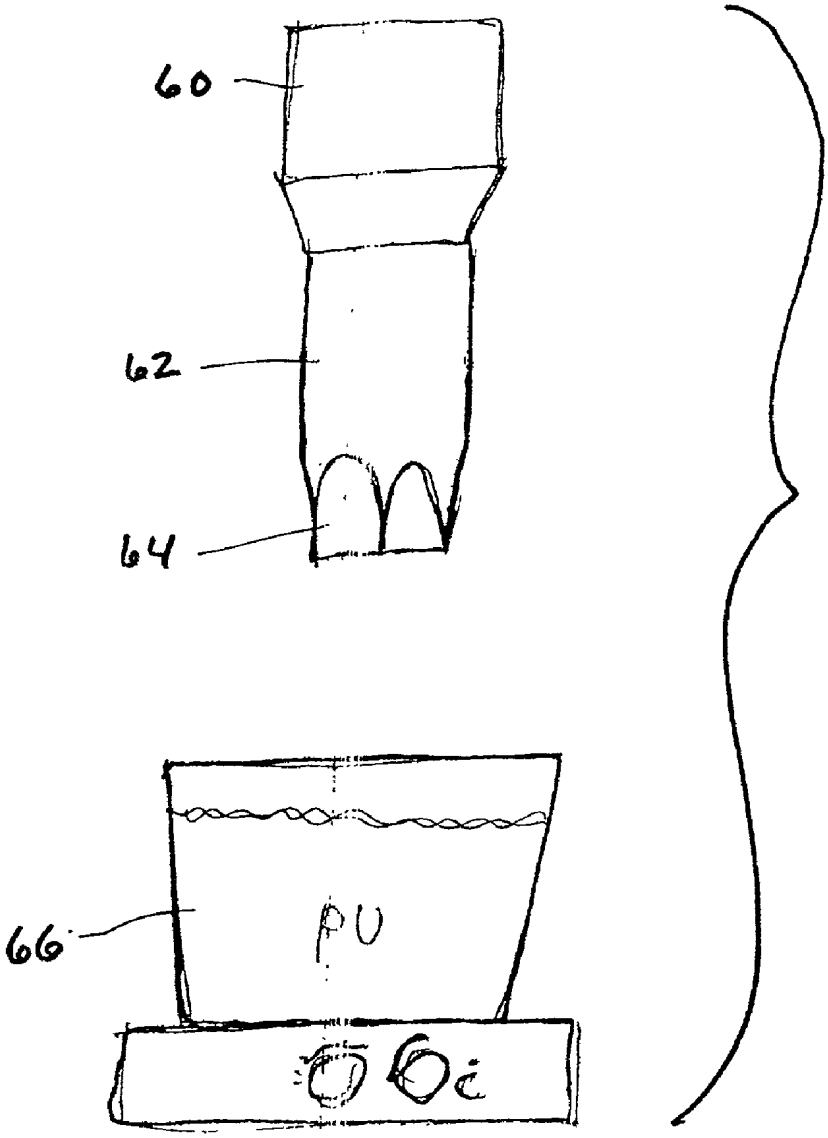


FIG. 5



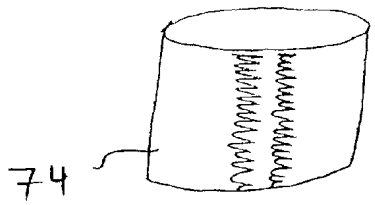



Fig. 6a

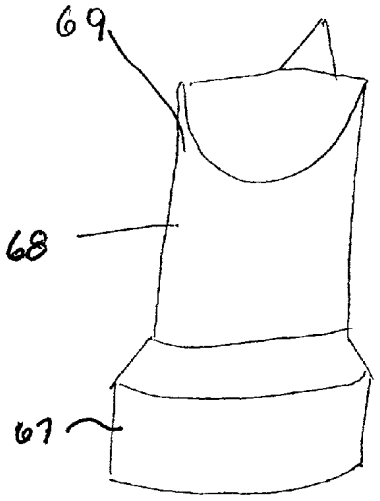



Fig. 6b

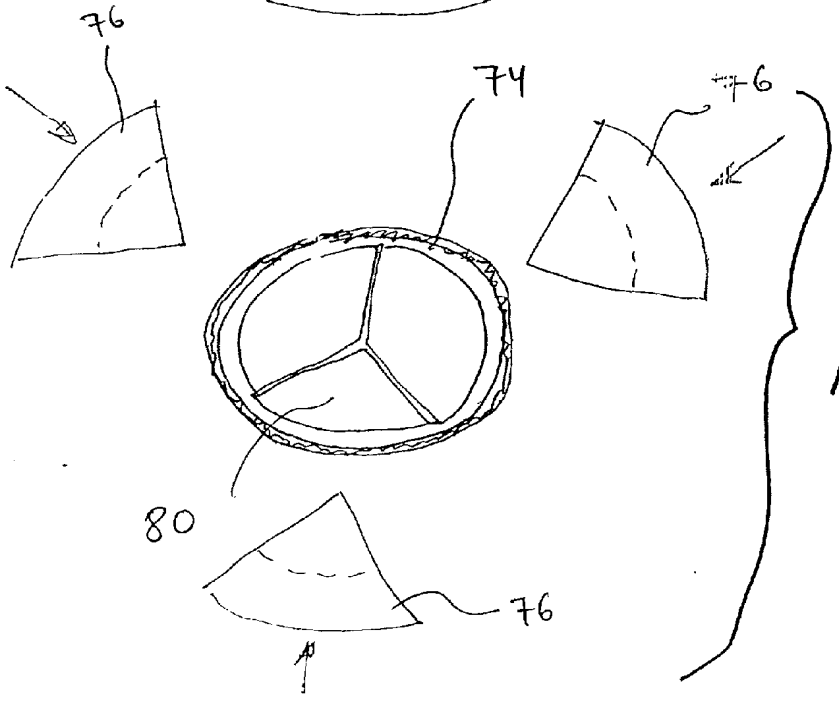



Fig. 6c

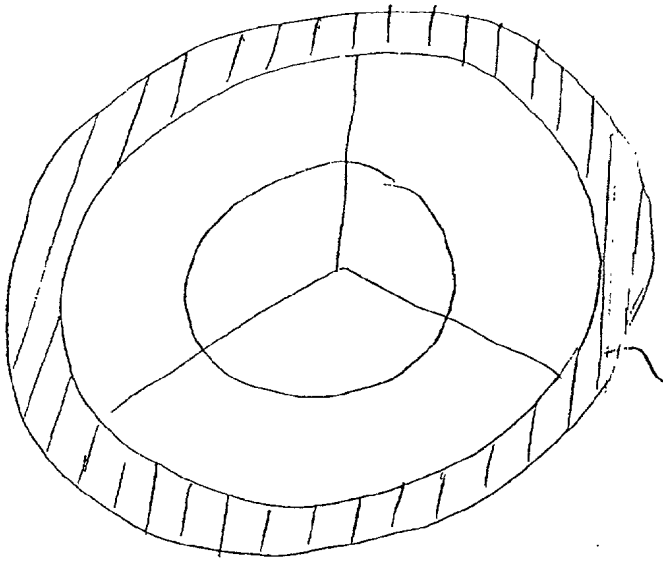



Fig. 6d

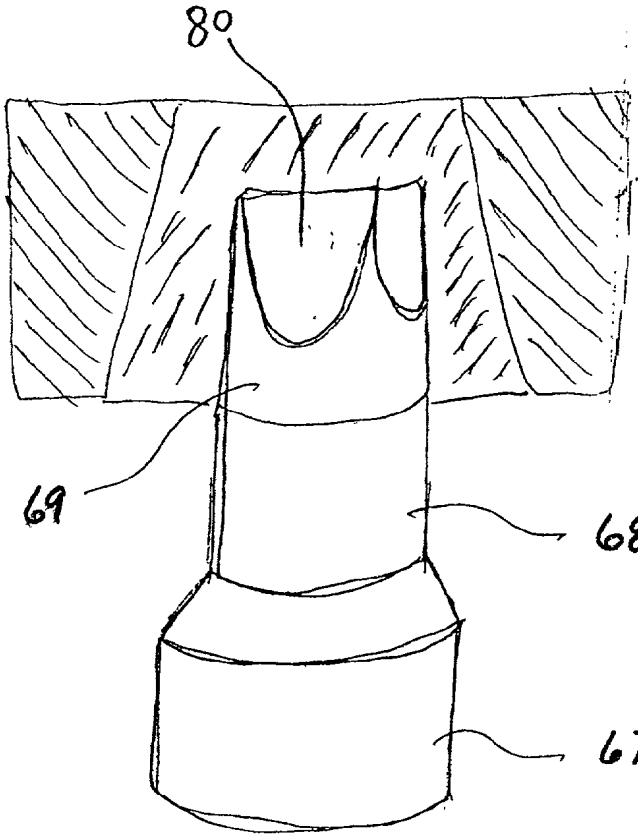



Fig. 6e

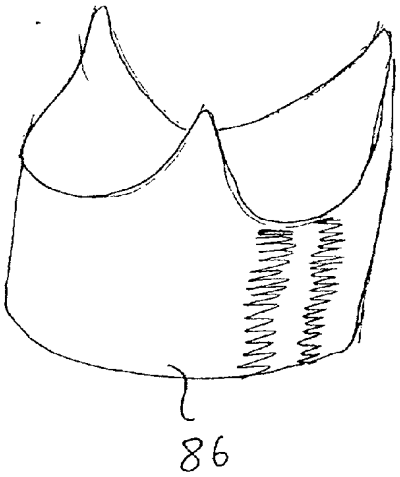



FIG. 7a

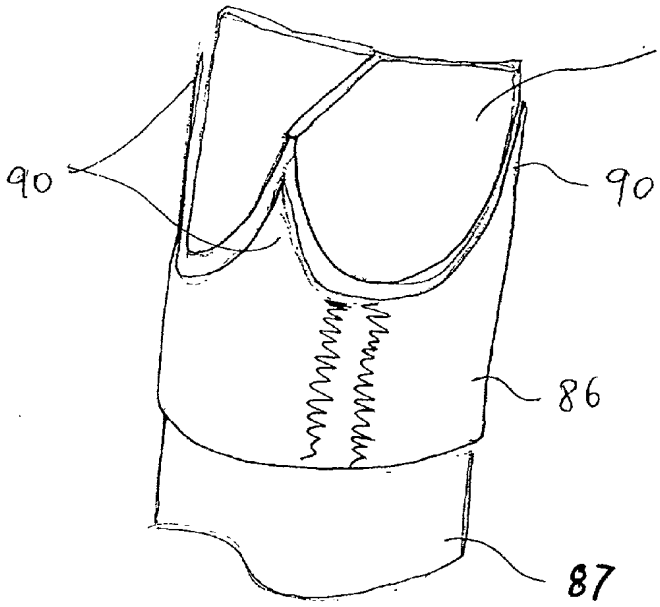



Fig. 7b

FIG 8a

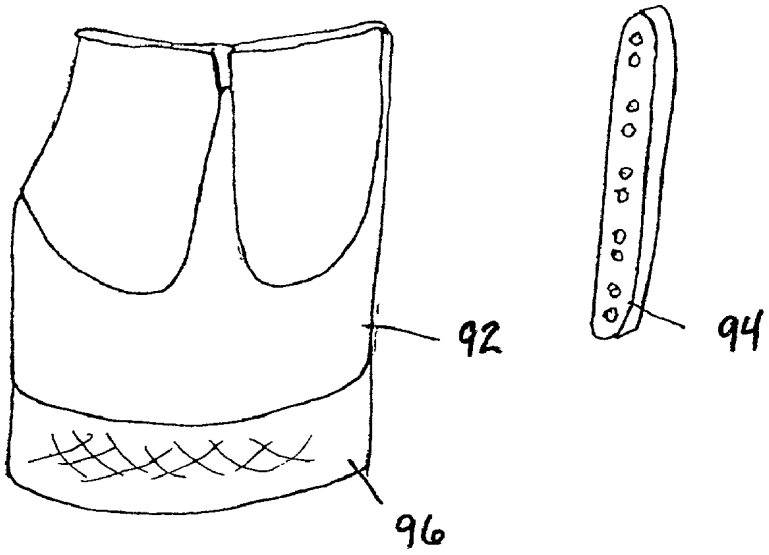



Fig. 8b

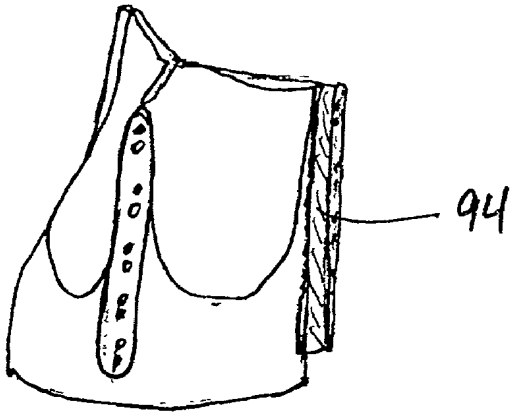
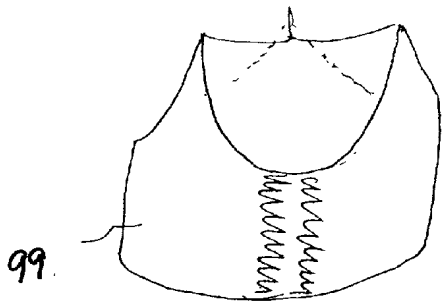


FIG. 9



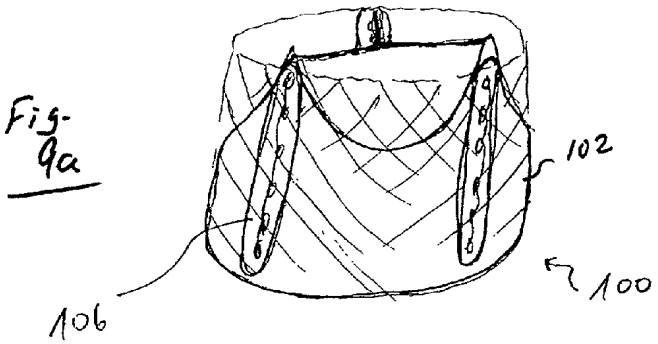




Fig. 9a

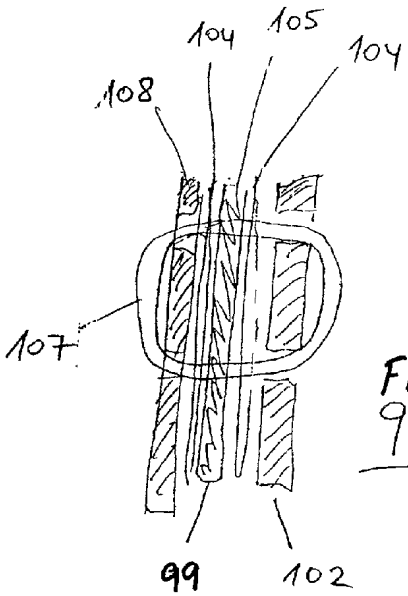



Fig. 9b

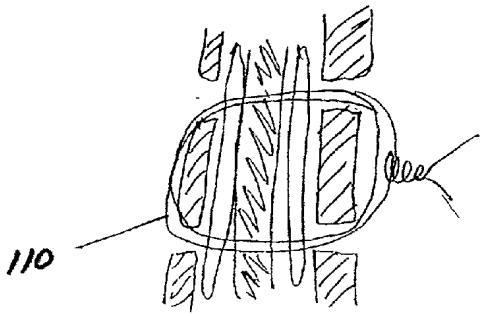



Fig. 9d

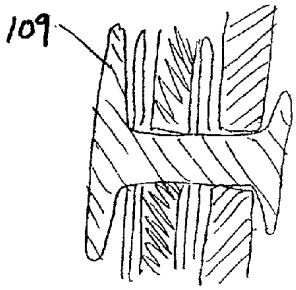



Fig. 9c

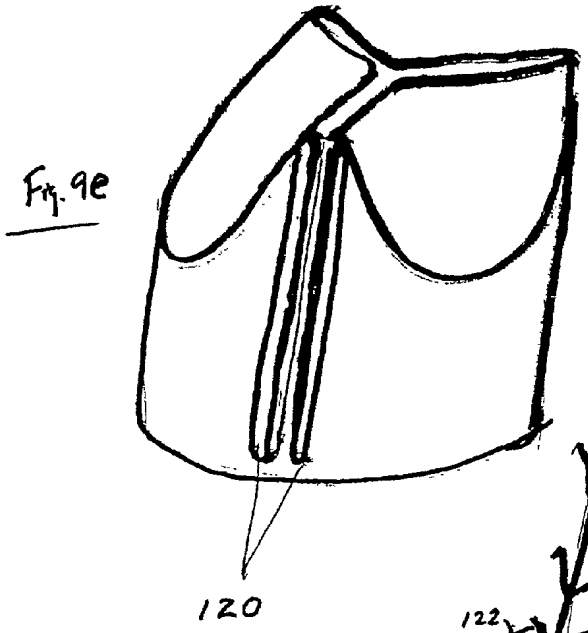



Fig. 9e

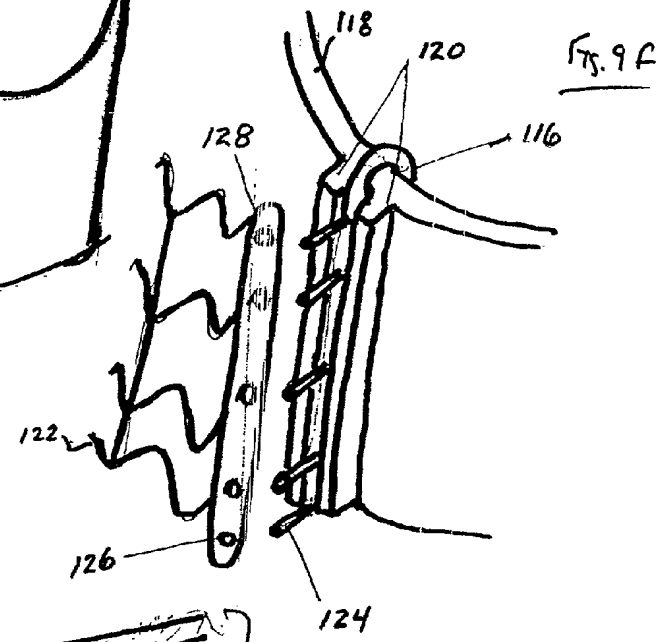



Fig. 9f

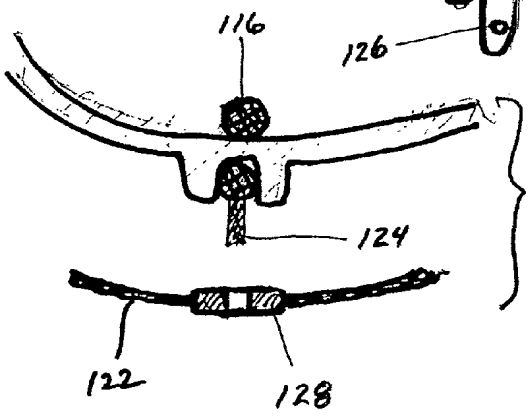



Fig. 9g

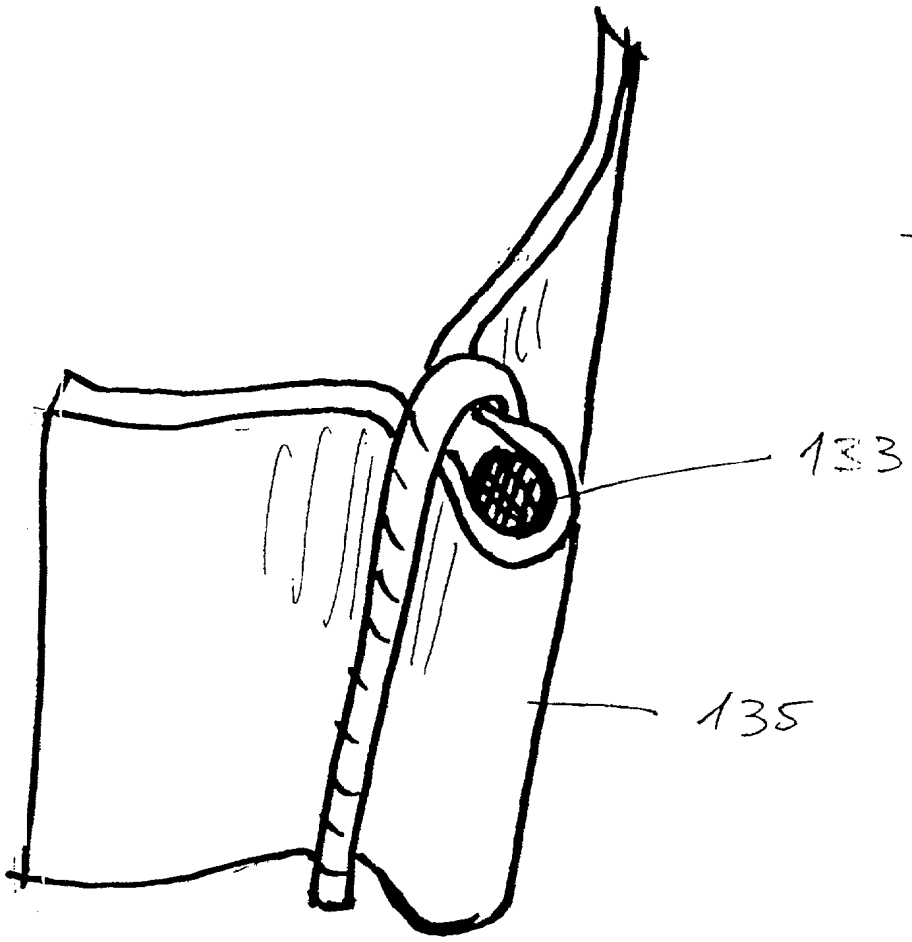



Fig. 9h

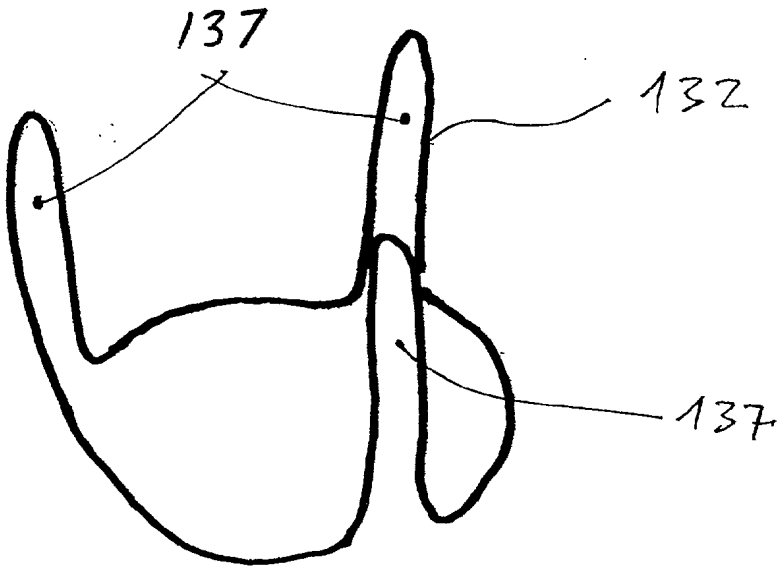
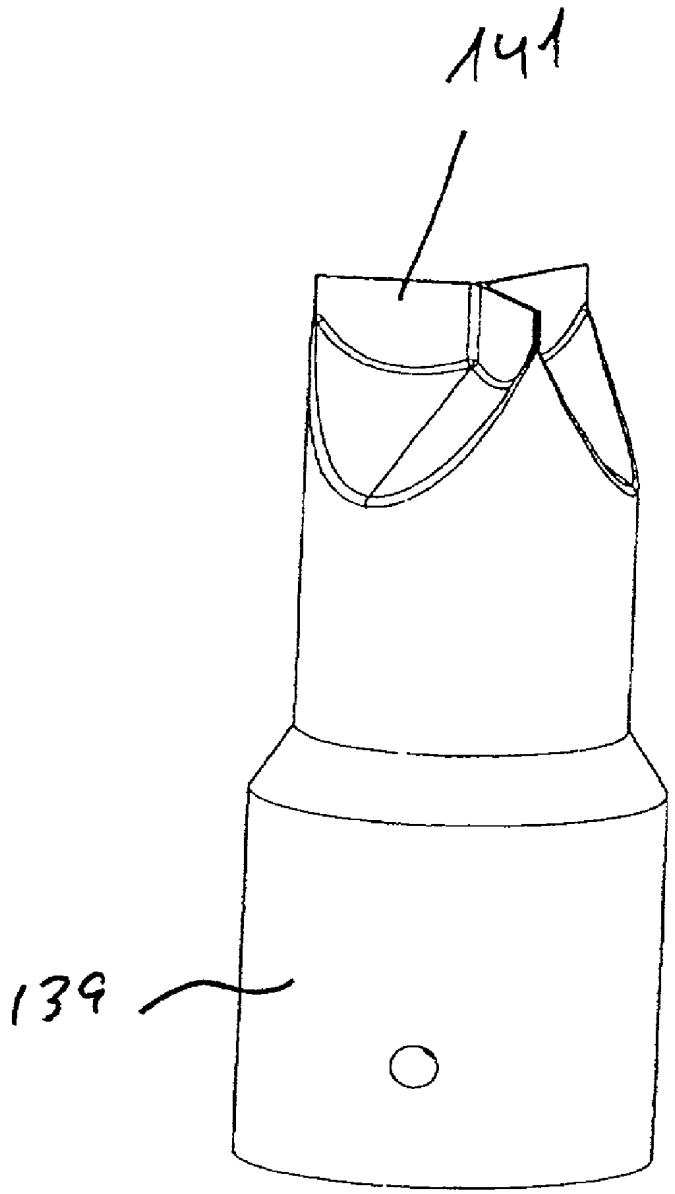



Fig. 9i

FIG 10



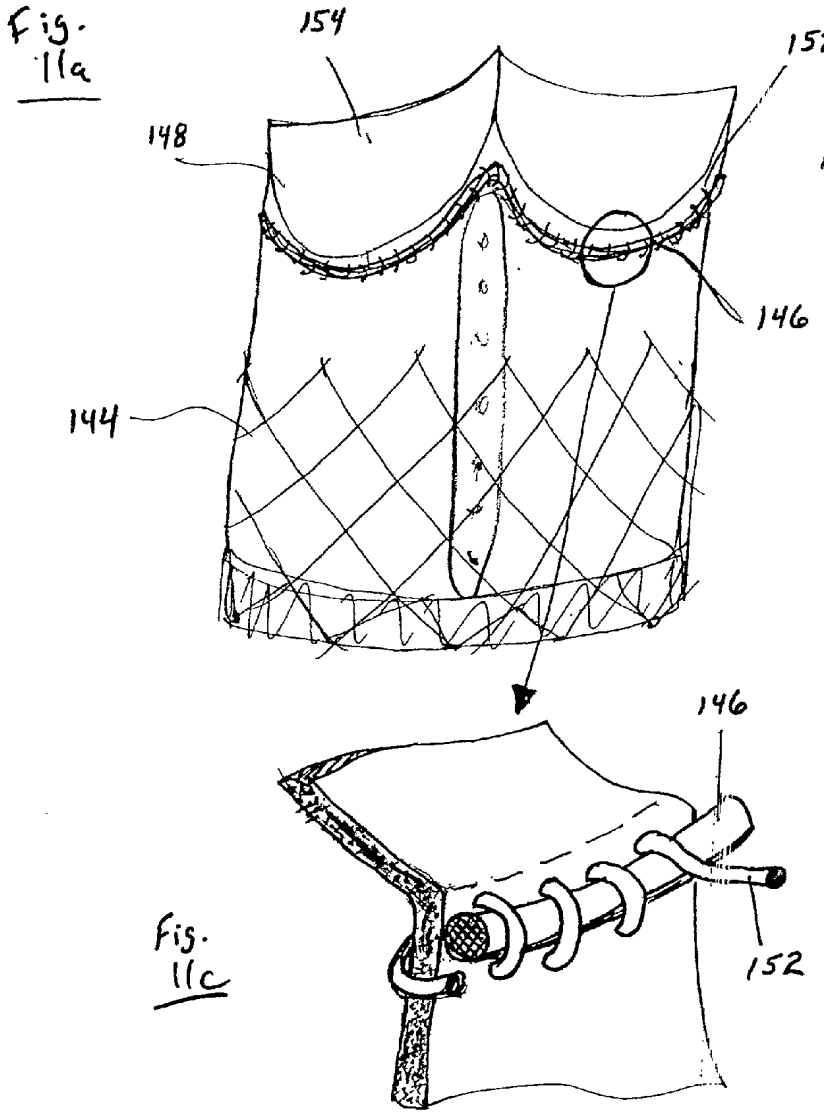



Fig. 11a

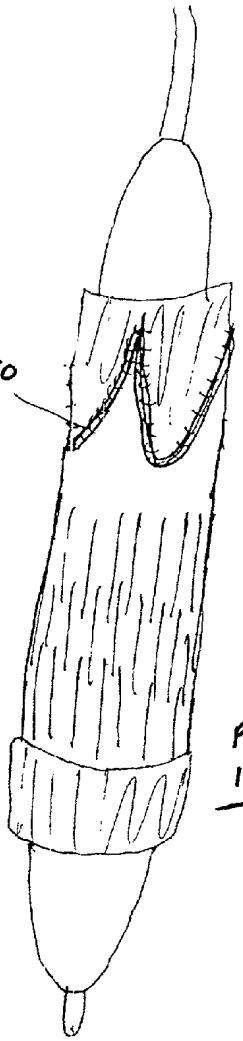



Fig. 11b




Fig. 11c

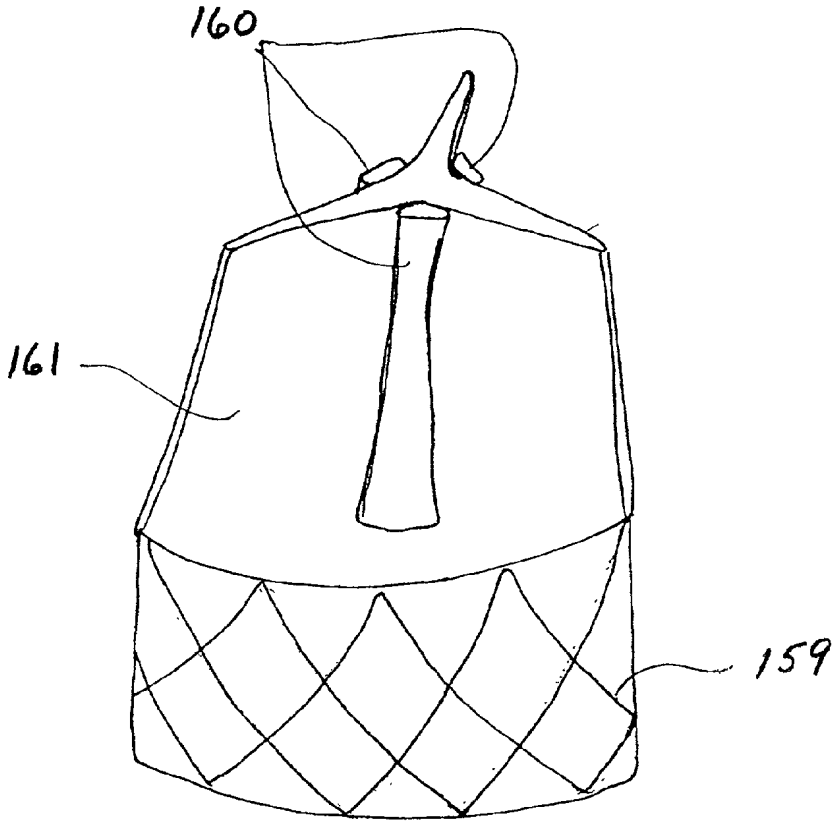
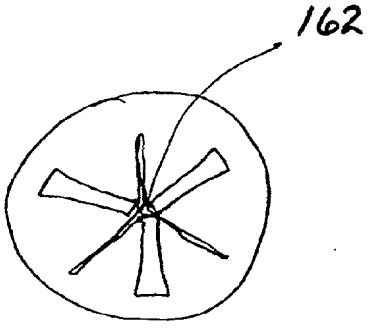
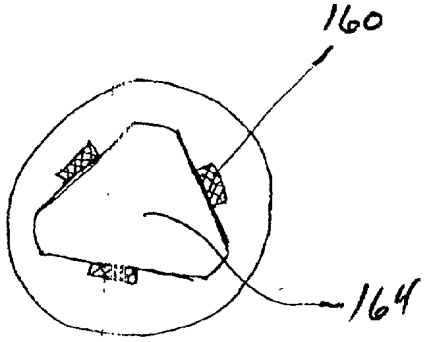



Fig. 12a




closed

Fig. 12b




open

Fig. 12c

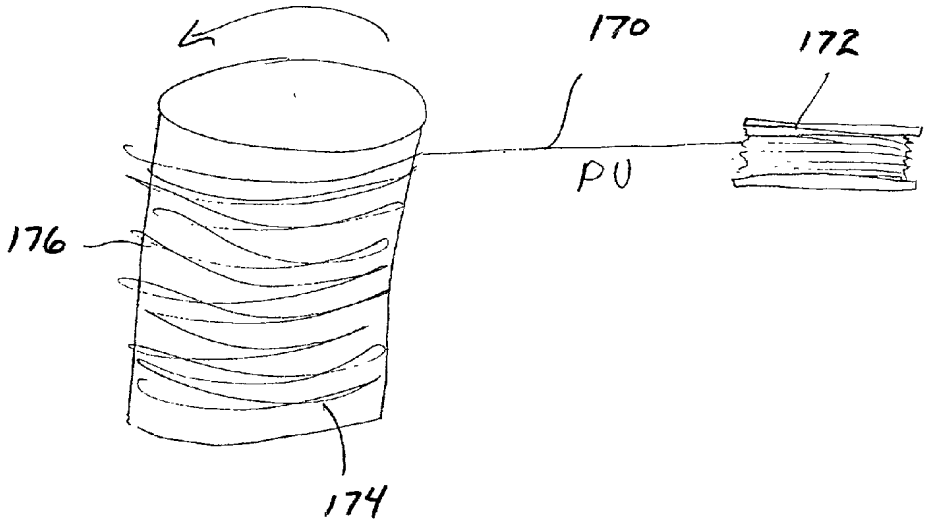



Fig. 13a

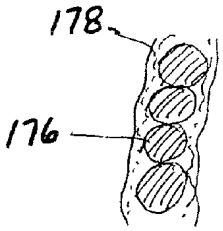



Fig. 13c

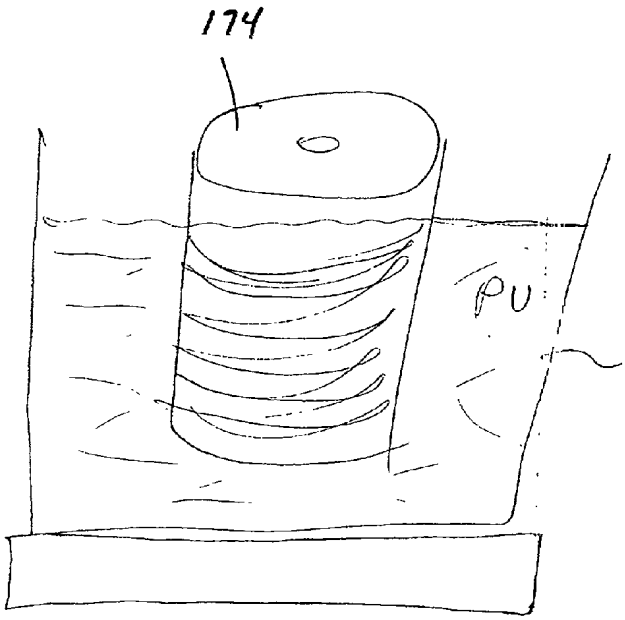



Fig. 13b

FIG 14

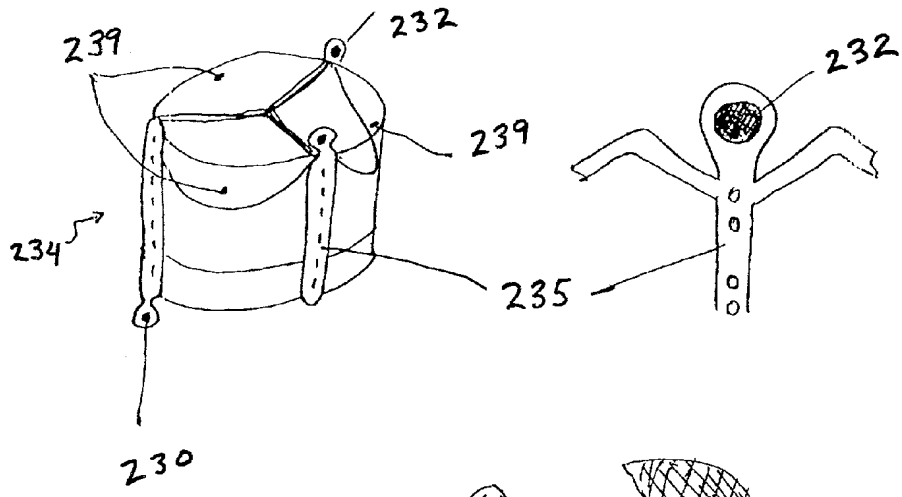



Fig. 14a

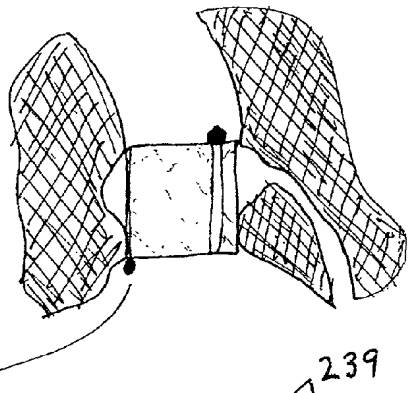



Fig. 14b

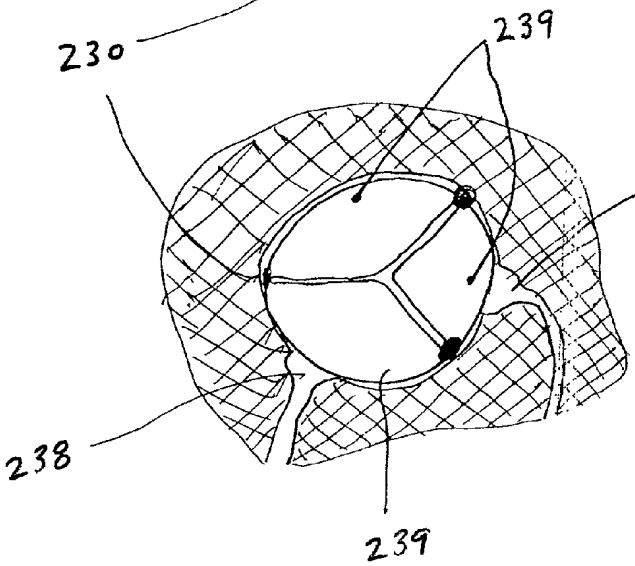



Fig. 14c

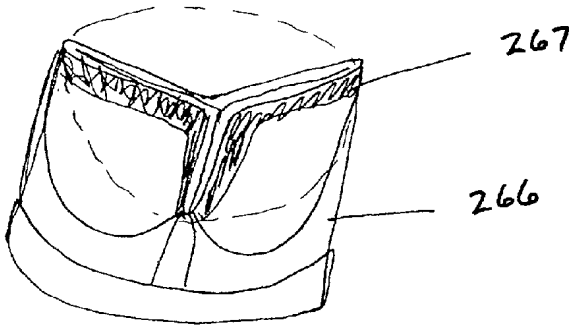



Fig. 15a

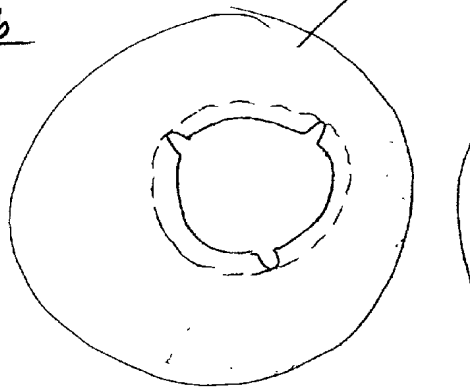



Fig. 15b

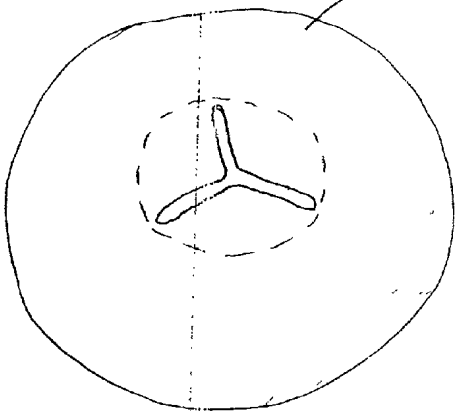



Fig. 15c

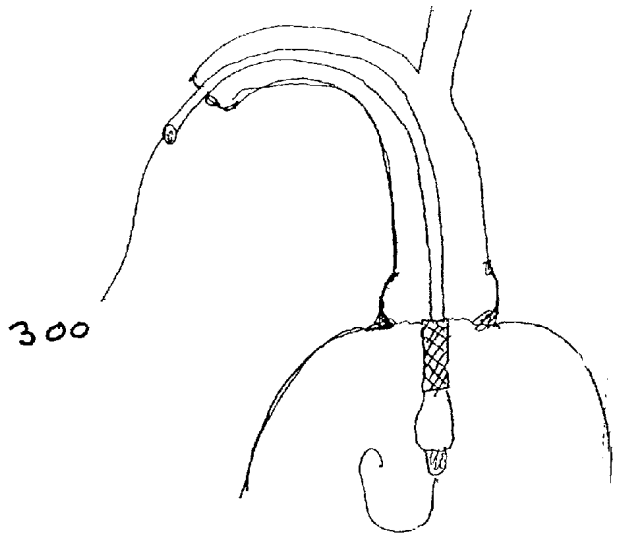



Fig. 16a

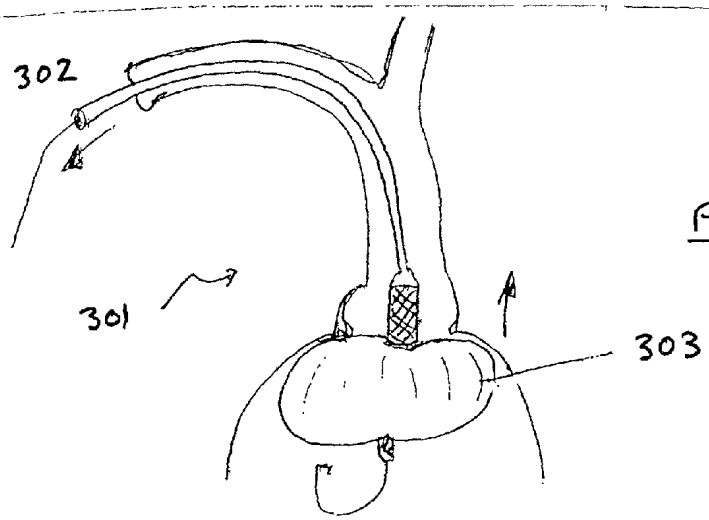



Fig. 16b

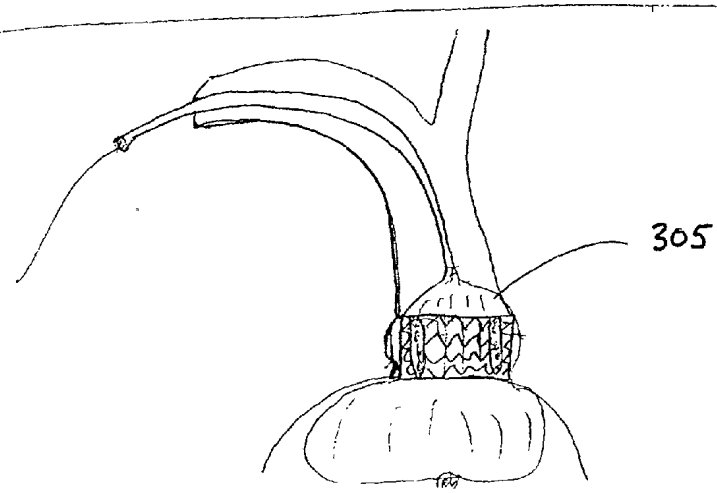



Fig. 16c

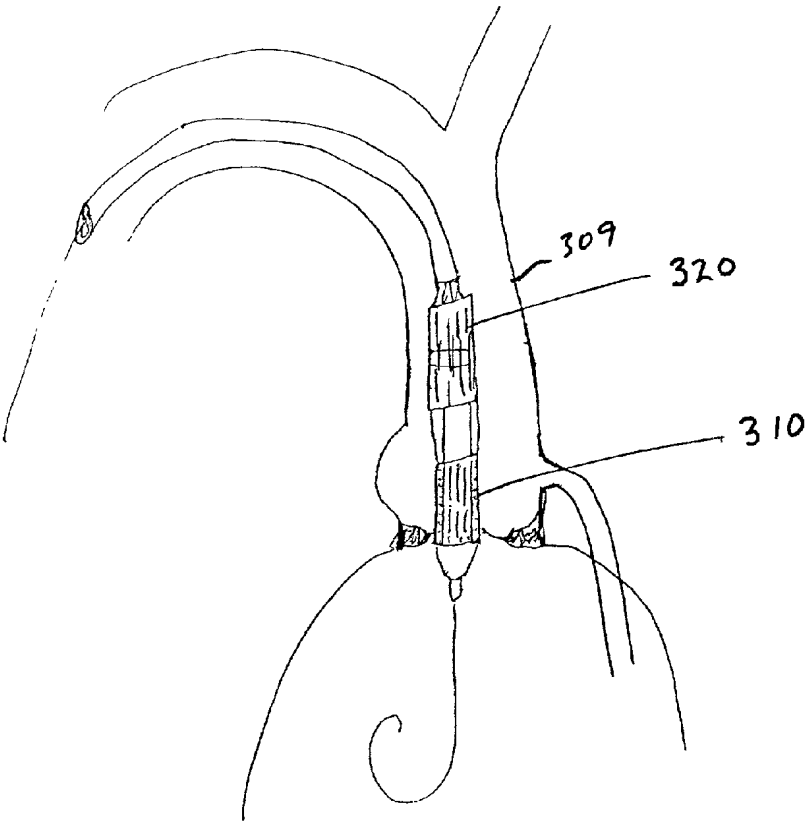



Fig. 17a

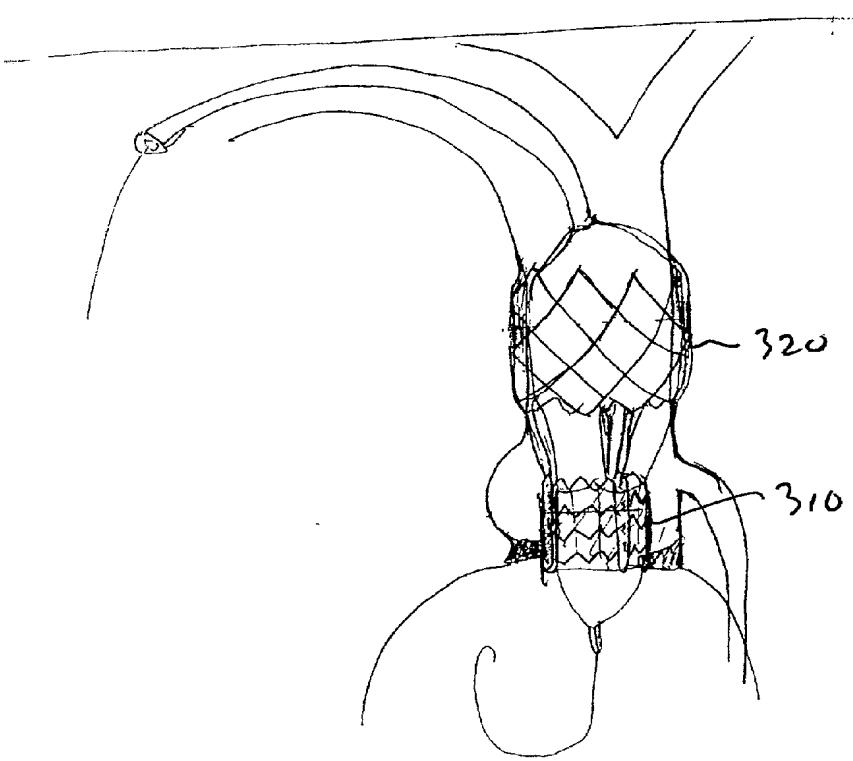



Fig. 17b

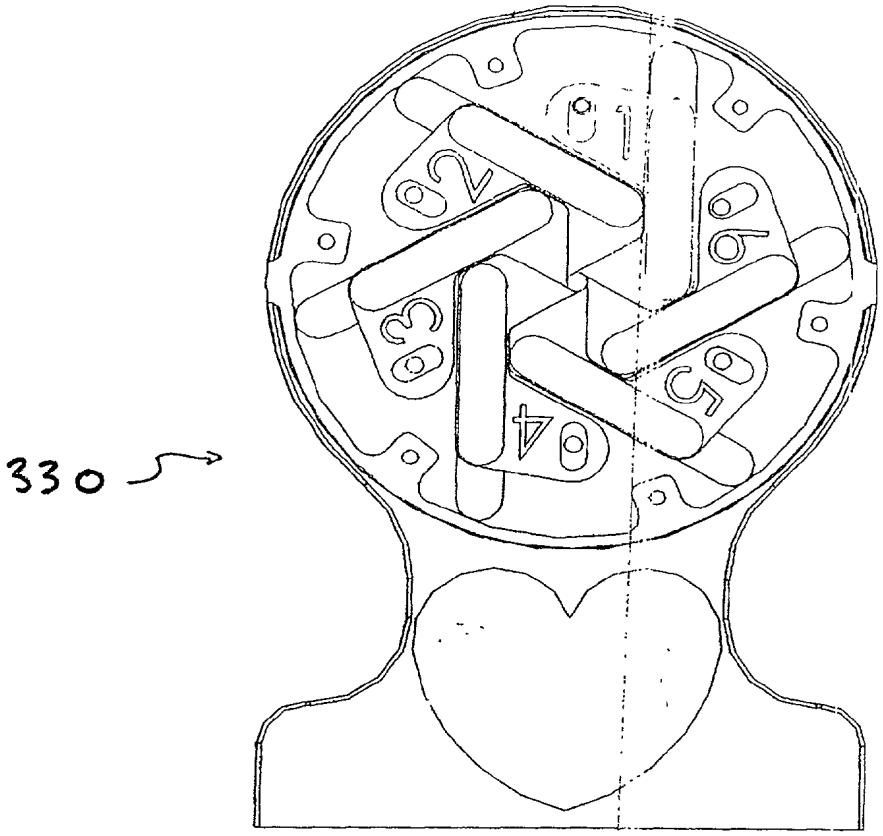



Fig. 18b

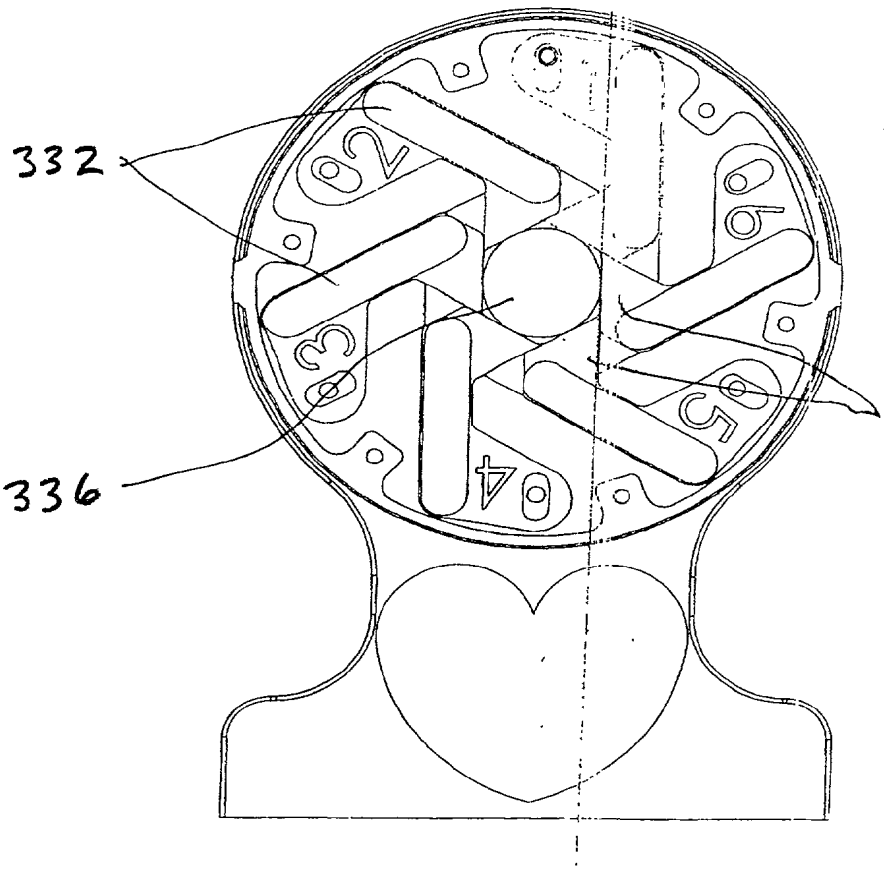



Fig. 18a

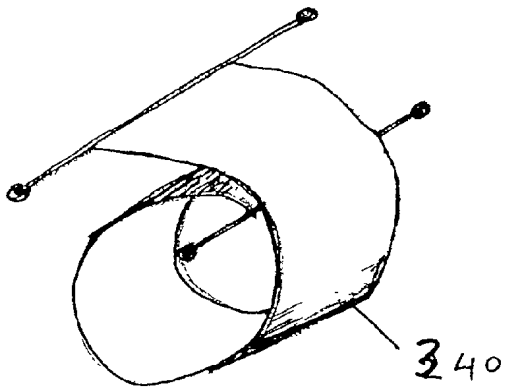



Fig. 19a

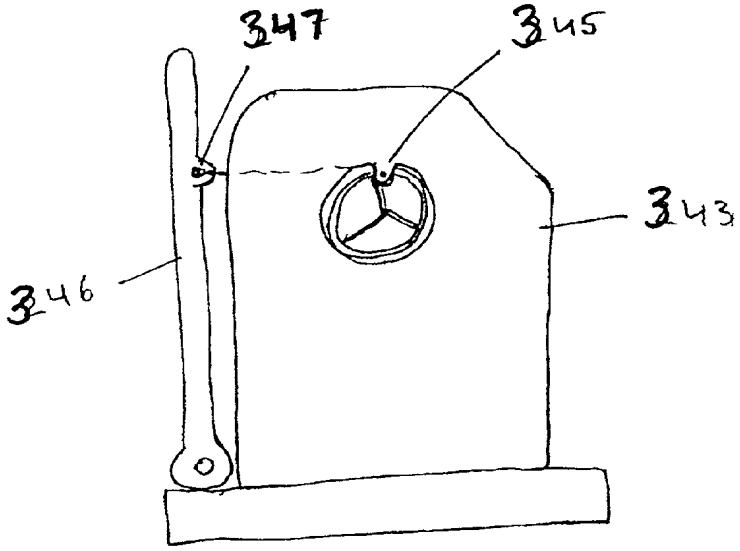



Fig. 19b

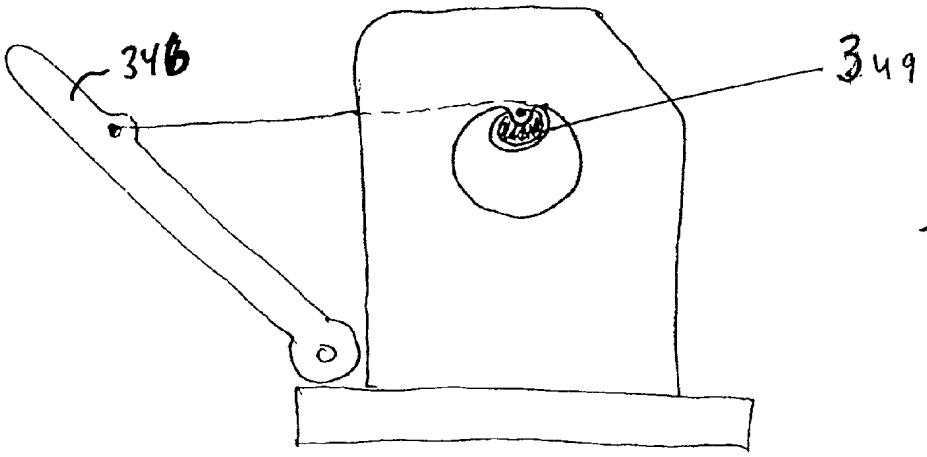



Fig. 19c

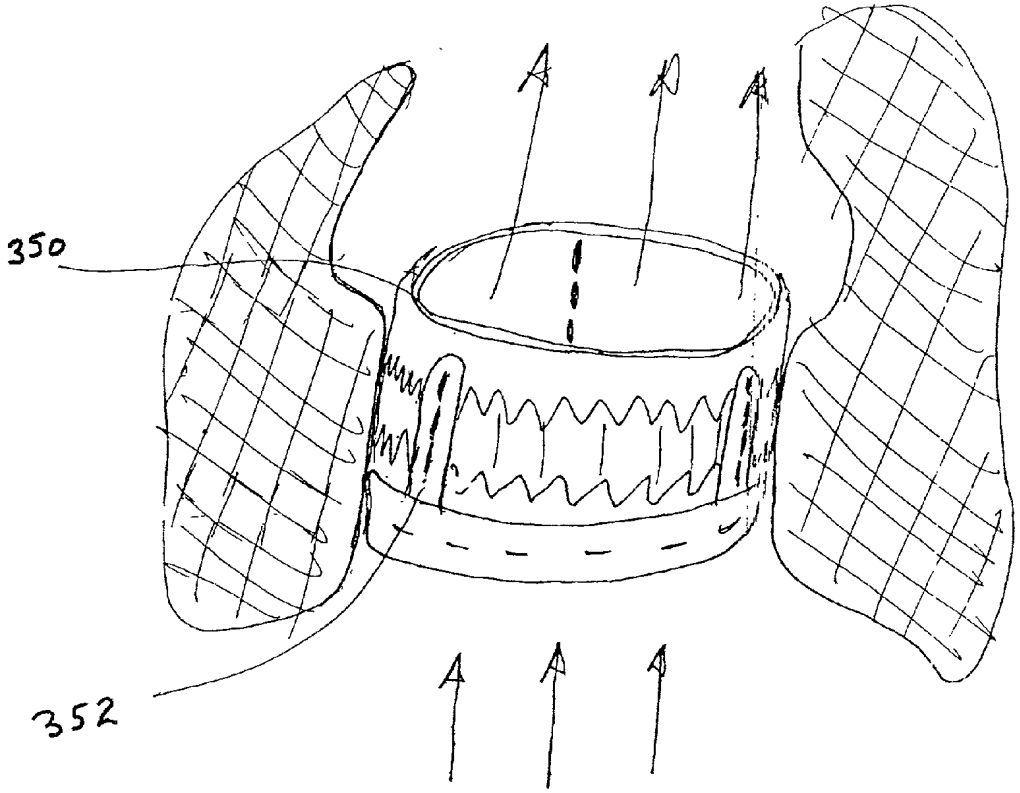



Fig. 20a

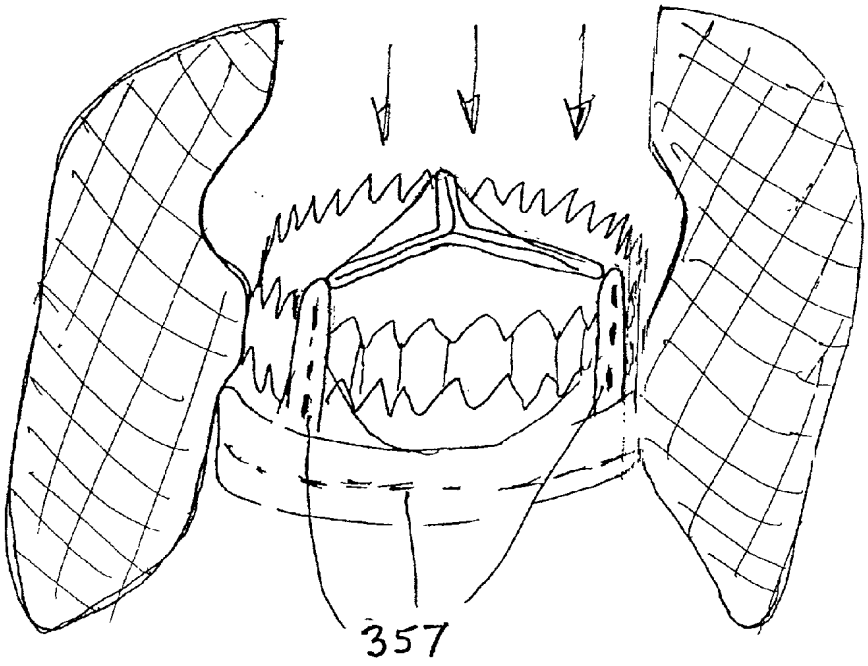



Fig. 20b

FIG 21

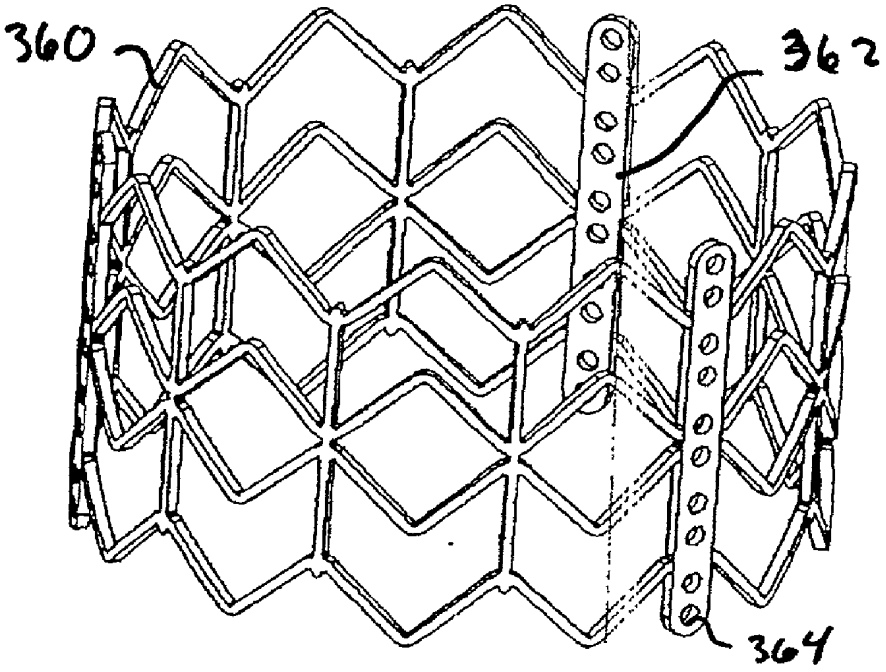
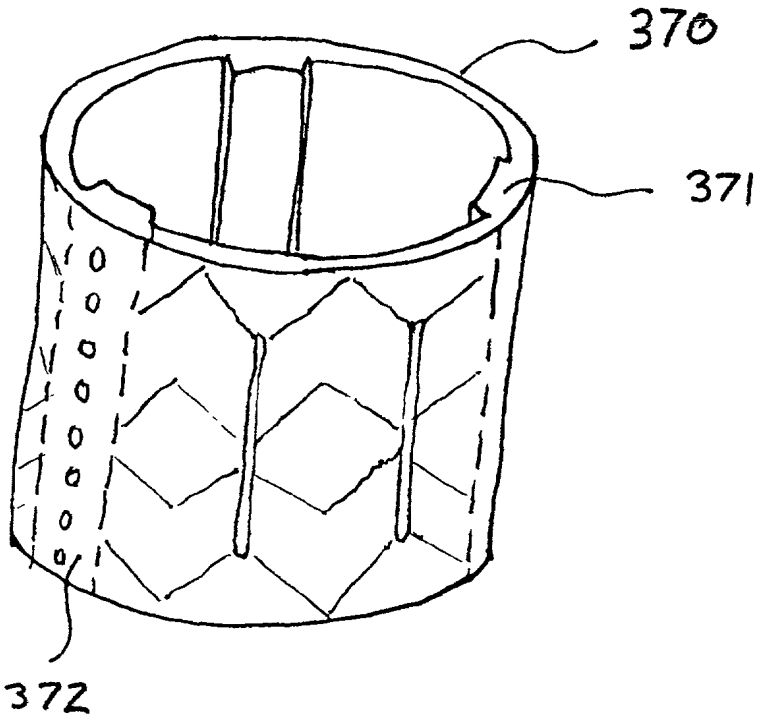


FIG 22



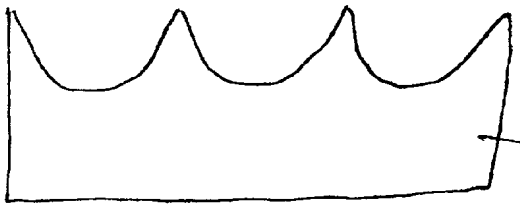



Fig. 23a

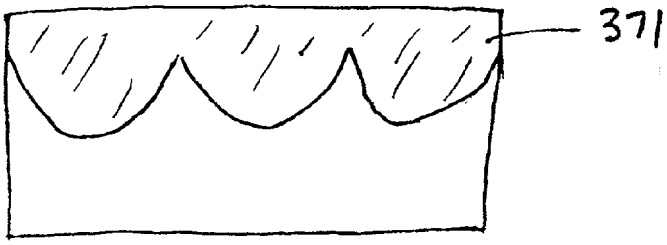



Fig. 23b

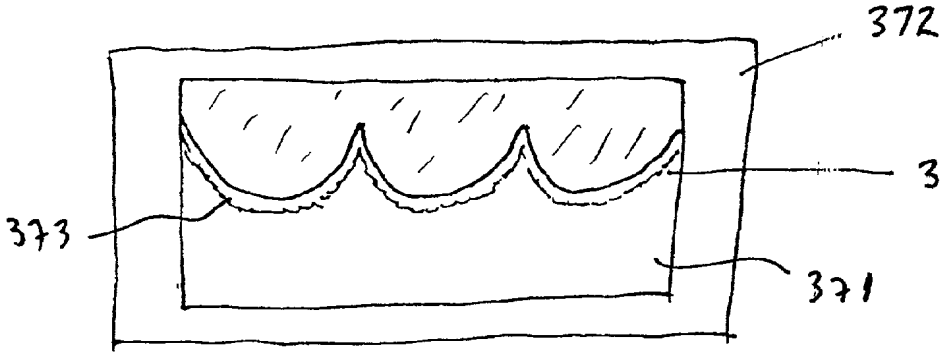



Fig. 23c

Fig. 23d

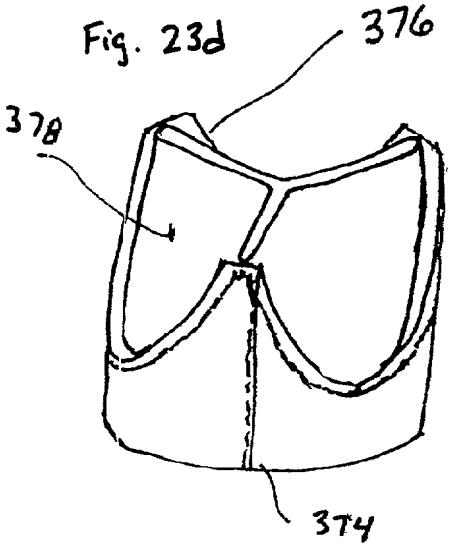
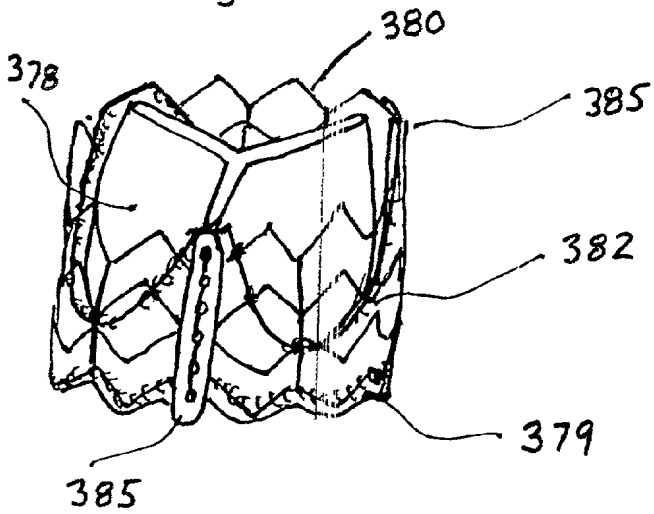



Fig. 23e



# IMPLANTABLE PROSTHETIC VALVE

## FIELD OF THE INVENTION

[0001] The present invention relates to implantable devices. More particularly, it relates to a valve prosthesis for cardiac implantation or for implantation in other body ducts.

## BACKGROUND OF THE INVENTION

[0002] There are several known prosthesis valves that have been previously described. U.S. Pat. No. 5,411,552 (Andersen et al.), entitled VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS, discloses a valve prosthesis comprising a stent made from an expandable cylinder-shaped thread structure comprising several spaced apices. The elastically collapsible valve is mounted on the stent with the commissural points of the valve secured to the projecting apices, which prevents the valve from turning inside out. Deployment of the valve can be achieved by using an inflatable balloon which in its deflated state is used to carry about it the valve structure to its position and, when inflated, deploys the stent in position to its final size. See, also, U.S. Pat. No. 6,168,614 (Andersen et al.) entitled VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY and U.S. Pat. No. 5,840,081 (Andersen et al.), titled SYSTEM AND METHOD FORIMPLANTING CARDIAC VALVES.

[0003] In PCT/EP97/07337 (Letac, Cribier et al.), published as WO 98/29057, entitled VALVE PROSTHESIS FOR IMPLANTATION IN BODY CHANNELS, there is disclosed a valve prosthesis comprising a collapsible valve structure and an expandable frame on which the valve structure is mounted. The valve structure is composed of a valvular tissue compatible with the human body and blood, the valvular tissue being sufficiently supple and resistant to allow the valve structure to be deformed from a closed state to an opened state. The valvular tissue forms a continuous surface and is provided with guiding means formed or incorporated within, the guiding means creating stiffened zones which induce the valve structure to follow a patterned movement in its expansion to its opened state and in its turning back to its closed state. The valve structure can be extended to an internal cover which is fastened to the lower part of the valve structure to prevent regurgitation.

[0004] There are several known methods currently used for replacing aortic valves and several types of artificial prosthetic devices. Mechanical valves are commonly used in several different designs (single and double flap) manufactured by well-known companies such as St. Jude, Medtronic, Sulzer, and others. Some of the main disadvantages of these devices are: a need for permanent treatment of anticoagulants, noisy operation, and a need for a large-scale operation to implant.

[0005] There is a wide range of biologically based valves made of natural valves or composed of biological materials such as pericardial tissue. These too are made and marketed by well-known companies such as Edwards Lifesciences, Medtronic, Sulzer, Sorin, and others.

[0006] Polymer valves are new and are not yet in use, but several companies are in the process of developing such products. A new type of prosthesis is being considered, based on artificial polymer materials such as polyurethane.

[0007] The present invention introduces several novel structural designs for implantable valves. An aspect of the present invention deals with the possibility of implanting the valve percutaneously, i.e., inserting the valve assembly on a delivery device similar to a catheter, then implanting the valve at the desired location via a large blood vessel such as the femoral artery, in a procedure similar to other known interventional cardiovascular procedures. The percutaneous deployment procedure and device has an impact on the product design in several parameters, some of which are explained hereinafter.

[0008] The percutaneous implantation of medical devices, and particularly prosthetic valves, is a preferred surgical procedure for it involves making a very small perforation in the patient's skin (usually in the groin or armpit area) under local anesthetic sedation, as opposed to a large chest surgery incision, which requires general anesthesia, opening a large portion of the chest, and cardiopulmonary bypass. This percutaneous procedure is therefore considered safer.

[0009] The present invention provides a series of new concepts in the field of aortic valves and other human valves.

## SUMMARY OF THE INVENTION

[0010] It is therefore thus provided, in accordance with a preferred embodiment of the present invention, a valve prosthesis device suitable for implantation in body ducts, the device comprising:

[0011] a support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the 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 provided with a plurality of longitudinally rigid support beams of fixed length; and

[0012] 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,

[0013] whereby 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, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.

[0014] Furthermore, in accordance with another preferred embodiment of the present invention, the support stent comprises an annular frame.

[0015] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly has a tricuspid configuration.

[0016] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is made from biocompatible material.

[0017] Furthermore, in accordance with another preferred embodiment of the present invention, the valve assembly is made from pericardial tissue, or other biological tissue.

[0018] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is made from biocompatible polymers.

[0019] Furthermore, in accordance with another preferred embodiment of the present invention, the valve assembly is made from materials selected from the group consisting of polyurethane and polyethylene terphthalane.

[0020] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly comprises a main body made from polyethylene terphthalane and leaflets made from polyurethane.

[0021] Furthermore, in accordance with another preferred embodiment of the present invention, said support stent is made from nickel titanium.

[0022] Furthermore, in accordance with another preferred embodiment of the present invention, the support beams are substantially equidistant and substantially parallel so as to provide anchorage for the valve assembly.

[0023] Furthermore, in accordance with another preferred embodiment of the present invention, the support beams are provided with bores so as to allow stitching or tying of the valve assembly to the beams.

[0024] Furthermore, in accordance with another preferred embodiment of the present invention, the support beams are chemically adhered to the support stent.

[0025] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is riveted to the support beams.

[0026] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is stitched to the support beams.

[0027] Furthermore, in accordance with another preferred embodiment of the present invention, said beams are manufactured by injection using a mold, or by machining.

[0028] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is rolled over the support stent at the inlet.

[0029] Furthermore, in accordance with another preferred embodiment of the present invention, said valve device is manufactured using forging or dipping techniques.

[0030] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly leaflets are longer than needed to exactly close the outlet, thus when they are in the collapsed state substantial portions of the leaflets fall on each other creating better sealing.

[0031] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is made from coils of a polymer, coated by a coating layer of same polymer.

[0032] Furthermore, in accordance with another preferred embodiment of the present invention, said polymer is polyurethane.

[0033] Furthermore, in accordance with another preferred embodiment of the present invention, the support stent is provided with heavy metal markers so as to enable tracking and determining the valve device position and orientation.

[0034] Furthermore, in accordance with another preferred embodiment of the present invention, the heavy metal markers are selected from gold, platinum, iridium, or tantalum.

[0035] Furthermore, in accordance with another preferred embodiment of the present invention, the valve assembly leaflets are provided with radio-opaque material at the outlet, so as to help tracking the valve device operation in vivo.

[0036] Furthermore, in accordance with another preferred embodiment of the present invention, said radio-opaque material comprises gold thread.

[0037] Furthermore, in accordance with another preferred embodiment of the present invention, the diameter of said support stent, when fully deployed is in the range of from about 19 to about 25 mm.

[0038] Furthermore, in accordance with another preferred embodiment of the present invention, the diameter of said support stent may be expanded from about 4 to about 25 mm.

[0039] Furthermore, in accordance with another preferred embodiment of the present invention, the support beams are provided with bores and wherein the valve assembly is attached to the support beams by means of U-shaped rigid members that are fastened to the valve assembly and that are provided with extruding portions that fit into matching bores on the support beams.

[0040] Furthermore, in accordance with another preferred embodiment of the present invention, the support beams comprise rigid support beams in the form of frame construction, and the valve assembly pliant material is inserted through a gap in the frame and a fastening rod is inserted through a pocket formed between the pliant material and the frame and holds the valve in position.

[0041] Furthermore, in accordance with another preferred embodiment of the present invention, the main body of the valve assembly is made from coiled wire coated with coating material.

[0042] Furthermore, in accordance with another preferred embodiment of the present invention, the coiled wire and the coating material is made from polyurethane.

[0043] Furthermore, in accordance with another preferred embodiment of the present invention, a strengthening wire is interlaced in the valve assembly at the outlet of the conduit so as to define a fault line about which the collapsible slack portion of the valve assembly may flap.

[0044] Furthermore, in accordance with another preferred embodiment of the present invention, the strengthening wire is made from nickel titanium alloy.

[0045] Furthermore, in accordance with another preferred embodiment of the present invention, there is provided a valve prosthesis device suitable for implantation in body ducts, the device comprising a main conduit body having an inlet and an outlet and pliant leaflets attached at the outlet so that when a flow passes through the conduit from the inlet to the outlet the leaflets are in an open position allowing the flow to exit the outlet, and when the flow is reversed the leaflets collapse so as to block the outlet, wherein the main body is made from polyethylene terphtalate and collapsible leaflets are made form polyurethane.

[0046] Furthermore, in accordance with another preferred embodiment of the present invention, support beams made from polyurethane are provided on the main body and wherein the leaflets are attached to the main body at the support beams.

[0047] Furthermore, in accordance with another preferred embodiment of the present invention, said support beams are chemically adhered to the main body.

[0048] Furthermore, in accordance with another preferred embodiment of the present invention, there is provided a valve prosthesis device suitable for implantation in body ducts, the device comprising:

[0049] a support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the 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 provided with a plurality of longitudinally rigid support beams of fixed length;

[0050] 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; and

[0051] substantially equidistant rigid support beams interlaced or attached to the slack portion of the valve assembly material, arranged longitudinally.

[0052] Furthermore, in accordance with another preferred embodiment of the present invention, there is provided a crimping device for crimping the valve device described above or in claim 1, the crimping device comprising a plurality of adjustable plates that resemble a typical SLR (Single Lens Reflex) camera variable restrictor, each provided with a blade, that are equally dispersed in a radial symmetry but each plate moves along a line passing off an opening in the center, all plates equidistant from that center opening.

[0053] Furthermore, in accordance with another preferred embodiment of the present invention, the multiple plates are adapted to move simultaneously by means of a lever and transmission.

[0054] Furthermore, in accordance with another preferred embodiment of the present invention, there is provided a method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, the method comprising the steps of:

[0055] (a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

[0056] (b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

[0057] (c) providing a deployable implantable valve prosthesis device adapted to be mounted on the second inflatable portion of the balloon catheter;

[0058] (d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the second inflatable portion of the balloon catheter until the first inflatable portion of the balloon catheter is inserted into the left ventricle, whereas the second inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

[0059] (e) inflating the first inflatable portion of the balloon catheter so as to substantially block blood flow through the natural aortic valve and anchor the distal end of the balloon catheter in position;

[0060] (f) inflating the second inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

[0061] (g) deflating the first and second inflatable portions of the balloon catheter; and

[0062] (h) retracting the balloon catheter and removing it from the patient's body.

[0063] Furthermore, in accordance with another preferred embodiment of the present invention, the guiding tool comprises a guide wire.

[0064] Finally, in accordance with another preferred embodiment of the present invention, there is provided a method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, the method comprising the steps of:

[0065] (a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

[0066] (b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

[0067] (c) providing a deployable implantable valve prosthesis device adapted to be mounted on the first inflatable portion of the balloon catheter, and a deployable annular stent device adapted to be mounted over the second inflatable portion of the balloon catheter, the deployable implantable valve prosthesis device and the deployable annular stent kept at a predetermined distant apart;

[0068] (d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the first inflatable portion of the balloon catheter and the deployable annular stent mounted over the second inflatable portion of the balloon catheter, until the first inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

[0069] (e) inflating the second inflatable portion of the balloon catheter so that the deployable stent device is deployed within the aorta thus anchoring the deployable annular stent and the coupled valve device in position;

[0070] (f) inflating the first inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

[0071] (g) deflating the first and second inflatable portions of the balloon catheter; and

[0072] (h) retracting the balloon catheter and removing it from the patient's body.

## BRIEF DESCRIPTION OF THE FIGURES

[0073] 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.

[0074] **FIG. 1** illustrates an implantable prosthetic tricuspid valve in accordance with a preferred embodiment of the present invention, suitable for percutaneous deployment using a stent or similar deploying means, in its deployed-inflated position;

[0075] **FIG. 2** depicts an implantable valve according to the present invention mounted over a deploying stent with an inflatable balloon;

[0076] **FIG. 3** illustrates an implantable valve according to the present invention mounted over a stent with an inflatable balloon, in a crimped position;

[0077] **FIG. 4** depicts implantable valve deployment in a natural aortic valve position in accordance with the present invention;

[0078] **FIG. 5** demonstrates manufacturing a polyurethane implantable valve in a dipping technique according with the present invention;

[0079] **FIGS. 6***a* to **6***e* illustrate manufacturing of an implantable valve by forging according to the present invention;

[0080] **FIGS. 7***a* and **7***b* demonstrate composite valve, which has polyurethane (PU) leaflets and Polyethylene terphthalate (PET) tubular-crown shaped construction, according to the present invention;

[0081] **FIGS. 8***a* and **8***b* depict a manufacture process of a composite valve made of flexible PU leaflets, rigid PU construction for mounting and a PET tubular end;

[0082] FIGS. **9** to **9***i* demonstrate different methods of attachment between the valve and stent according to the present invention;

[0083] **FIG. 10** illustrates a dipping mandrel with an extra portion, which improves the sealing ability of the valve, according to the present invention;

[0084] **FIGS. 11***a* to **11***c* illustrate a valve mounted on a stent with an extra support, which improves the force distribution on the valve material and facilitates prolonged durability of the valve, according to the present invention;

[0085] **FIGS. 12***a* to **12***c* depict a valve with rigid supports according to the present invention, located substantially in the center of its leaflets. This design allows the valve leafs to perform without outer support;

[0086] **FIGS. 13***a* to **13***c* illustrate the manufacturing of a reinforced PU tube composed of strong fiber from PU, PET or other and a softer PU coating, for serving as the supporting structure;

[0087] **FIGS. 14***a* to **14***c* demonstrate incorporation of heavy metal markers on the stent, according to the present invention. These markers allow orientation control while positioning the device at the required location;

[0088] **FIGS. 15***a* to **15***c* demonstrate a valve with radio-opaque coating, according to the present invention, which allows imaging of the valve motion under angiogram;

[0089] **FIGS. 16***a* to **16***c* illustrate a procedure, which helps in accurate positioning the valve device with respect to the longitudinal orientation;

[0090] **FIGS. 17***a* and **17***b* describe a valve device according to the present invention, comprising one valve assembly mounted on a stent and an additional portion with a stent only. This allows placing the device in a way that coronaries are not blocked, longitudinal positioning thus becomes less sensitive and the extra stent decreases the risk of device migration within the vasculature;

[0091] **FIGS. 18***a* and **18***b* demonstrate a crimping device according to the present invention, which can crimp a valve device in the operating theater as part of the implantation procedure;

[0092] **FIGS. 19***a* to **19***c* depict a crimping machine according to the present invention, similar to the one described in **FIG. 18** with a different mechanical method;

[0093] **FIGS. 20***a* and **20***b* demonstrate a valve according to the present invention, made of a tube mounted on a stent. During systole the tube is fully open and during diastole the tube collapses according to the mounting geometry providing tight sealing;

[0094] **FIG. 21** depicts a stent structure according to the present invention, with built-in mounting portions of constant length, which allow valve mounting;

[0095] **FIG. 22** depicts yet another preferred embodiment a valve assembly in accordance with the present invention, having dilated supports; and

[0096] **FIGS. 23***a* to **23***e* depict stages in a method of manufacturing an implantable prosthetic valve in accordance with another preferred embodiment of the present invention.

## DETAILED DESCRIPTION OF THE INVENTION

[0097] A main aspect of the present invention is the introduction of several novel designs for an implantable prosthesis valve. Another aspect of the present invention is the disclosure of several manufacture methods for the manufacturing of implantable prosthesis valves in accordance with the present invention. A further aspect of the present invention is the provision of novel deployment and positioning techniques suitable for the valve of the present invention.

[0098] Basically the implantable prosthetic valve of the present invention comprises a leafed-valve assembly, preferably tricuspid but not limited to tricuspid valves only,

consisting of a conduit having an inlet end and an outlet, made of pliant material arranged so as to present collapsible walls at the outlet. The valve assembly is mounted on a support structure such as a stent adapted to be positioned at a target location within the body duct and deploy the valve assembly by the use of deploying means, such as a balloon catheter or similar devices. In embodiments suitable for safe and convenient percutaneous positioning and deployment the annular frame is able to be posed in two positions, a crimped position where the conduit passage cross-section presented is small so as to permit advancing the device towards its target location, and a deployed position where the frame is radial extended by forces exerted from within (by deploying means) so as to provide support against the body duct wall, secure the valve in position and open itself so as to allow flow through the conduit.

[0099] The valve assembly can be made from biological matter, such as a natural tissue, pericardial tissue or other biological tissue. Alternatively, the valve assembly may be made form biocompatible polymers or similar materials. Homograph biological valves need occasional replacement (usually within 5 to 14 years) and this is a consideration the surgeon must take into account, when selecting the proper valve implant according to the patient type. Metal mechanical valves, which have better durability qualities, carry the associated risk of long-term anticoagulation treatment.

[0100] The frame can be made from shape memory alloys such as nickel titanium (nickel titanium shape memory alloys, or NiTi, as marketed, for example, under the brand name Nitinol), or other biocompatible metals. The percutaneously implantable embodiment of the implantable valve of the present invention has to be suitable for crimping into a narrow configuration for positioning and expandable to a wider, deployed configuration so as to anchor in position in the desired target location.

[0101] The support stent is preferably annular, but may be provided in other shapes too, depending on the cross-section shape of the desired target location passage.

[0102] Manufacturing of the implantable prosthetic valve of the present invention can be done in various methods, for example, by dipping, injection, electrospinning, rotation, ironing, or pressing.

[0103] The attachment of the valve assembly to the support stent can be accomplished in several ways, such as by sewing it to several anchoring points on the support stent, or riveting it, pinning it, or adhering it, to provide a valve assembly that is cast or molded over the support stent, or use any other suitable way of attachment.

[0104] To prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to present rolled-up sleeve-like portion at the inlet.

[0105] Furthermore, floating supports may be added to enhance the stability of the device and prevent it from turning inside out.

[0106] An important aspect of certain embodiments of the present invention is the provision of rigid support beams incorporated with the support stent that retains its longitudinal dimension while the entire support stent may be longitudinally or laterally extended.

[0107] The aforementioned embodiments as well as other embodiments, manufacturing methods, different designs and different types of devices are discussed and explained below with reference to the accompanying 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, but this does in no way limit the scope of the present invention as defined in the appended claims.

[0108] Reference is now made to **FIG. 1**, which illustrates a general tricuspid implantable prosthesis valve **20** in accordance with a preferred embodiment of the present invention, suitable for percutaneous deployment using an expandable stent or similar deploying means, shown in its deployed position. A valve assembly **28** comprises a conduit having an inlet **24** and an outlet **26**, the outlet walls consisting of collapsible pliant material **29** that is arranged to collapse in a tricuspid arrangement. The valve assembly **28** is attached to an annular support stent **22**, the one in this figure being a net-like frame designed to be adapted to crimp evenly so as to present a narrow configuration and be radially deployable so as to extend to occupy the passage at the target location for implantation in a body duct. Support beams **23** are provided on annular support stent **22** to provide anchorage to valve assembly **28**. Support beams **23** are optionally provided with bores **25** to allow stitching of valve assembly **28** to support beams **23** by thread, wires, or other attachment means.

[0109] In the embodiment shown in **FIG. 1, a** cuff portion **21** of the valve assembly **28** is wrapped around support stent **22** at inlet **24** to enhance the stability. Preferably cuff portion **21** of valve material **28** is attached to support beams **23**.

[0110] Note that the entire valve structure is adapted to be radially crimped and radially expanded, and this lends to provide ease of navigation through narrow passages in the vasculature during positioning of the device and adequate deployment on the final location. This is made possible by the provision of a collapsible support stent structure. However, the support beams remain at all times constant at their length and thus are suitable for serving as the pliable valve assembly's anchorage. The valve assembly is attached to the support stent at the support beams, and due to their constant length there is no need for slack material as the attachment points **(25)** remain at constant distances regardless of the position of the valve device (crimped or deployed). This is an important feature for this means that the manufacturer of the valve device can make sure the valve assembly is secured and fastened to the support stent at all times. In prior art implantable valve devices the entire support structure changes its dimensions from its initial first crimped position and final deployed position, and this means that in the attachment of the valve assembly to the support structure one must take into consideration these dimension changes and leave slack material so that upon deployment of the device the valve assembly does not tear or deform. In the valve device of the present invention there is no relative movement between the valve assembly and the support beams (along the longitudinal central axis of the device). As a result, the valve device of the present invention acquires greater durability and is capable of withstanding the harsh conditions prevailing within the vasculature and especially the millions of cycles of stress applied by the blood pressure.

[0111] The fixed attachment of the valve assembly to the support stent in the valve device of the present invention results in greater stability, enhanced safety, better sealing and consequently longer lifespan. The novel design of the valve device of the present invention leads to longitudinal strength and rigidity whereas its collapsible support structure results in radial flexibility.

[0112] **FIG. 2** depicts an implantable valve **30** mounted on a deployable stent **32**. The valve assembly **34** is attached to the deployable support stent **32** (dotted lines) along three substantially equidistant and substantially parallel support beams **40** of constant length, which are part of stent **32**. The attachment of valve assembly **34** to stent **32** is facilitated by the support beams **40** to which valve assembly **34** is stitched with thread or fiber **46** (through bores **42** of support beams **40**). Outlet leafs **38**, which are a slack portion of the valve assembly, dangle inwardly, and the whole device is carried by an inflatable balloon **48**, which serves as the deploying device. A portion of the valve assembly **34** at an inlet zone **45** is optionally rolled over support stent **32** at the inlet, making up a rolled sleeve, which enhances the sealing of the device at the valve inlet.

[0113] **FIG. 3** demonstrates an implantable valve mounted to a stent **50** with an inflatable balloon **52**, in a crimped position. The support stent **50** is initially crimped about the balloon **52** so that is presents a narrow cross-section and is thus suitable for percutaneous catheterization and deployment.

[0114] **FIG. 4** depicts an implantable valve deployment in a natural aortic valve position. The implantable valve is advanced while mounted over the balloon **52** until it reaches the desired target location **54** in a body duct, for example, aorta **56**. The balloon is inflated and the support stent **50** expands radially to take up its position.

[0115] **FIG. 5** demonstrates the manufacture of a polyurethane valve in a dipping technique. A dipping mandrel **60** is provided with a tubular portion **62** with surfaces **64** that correspond to the collapsible valve leaflets to be manufactured. Mandrel **60** is dipped into a dissolved polyurethane bath **66** and is coated with a polyurethane coating in the desired form of the valve. Then, after the polyurethane coating has hardened sufficiently, the completed valve is removed from mandrel **60**.

[0116] **FIGS. 6***a* to **6***e* illustrate manufacturing an implantable valve by forging. A suitable tubularly shaped material **74** is placed tightly on a tubular portion **68** of mandrel **67**, covering the cusp portion **69**. Flexible inserts **76** are pressed to mandrel **67**, forging the tubular material to mandrel shape **80**. A tapered ring **70** holds the flexible inserts in place as the whole mold is placed in a hot oven regulated to a desired temperature, which is lower than the material's melting point. **FIG. 6***e* illustrates a sectional side view of the mandrel and a cross cut portion of the mold. The mold is made to press inwardly on the mandrel, which is covered with the valve material. As a result the material takes up the desired shape. The materials used can vary, for example, polyurethane (PU), polyethylene terphthalate (PET), or any other suitable material, which may be formed by heating.

[0117] **FIGS. 7***a* and **7***b* demonstrate a method of manufacturing a composite valve, which has PU leaflets and PET tubular construction with a crown shape. PU is an excellent fatigue resistant material but is sensitive to tear. The PU is reinforced by the PET crown to allow safe attachment to a stent by means of stitching, riveting, or any other suitable attachment method. A PET crown **86** is placed on a mandrel **87**, which is then (turned and) dipped in a container of dissolved PU. The manufactured device is a valve assembly having leaflets **88** composed of pure PU, and thus fatigue resistant, and a main body made of PET with protruding attachment portions **90** suitable for attachment built in the PU.

[0118] **FIGS. 8***a* and **8***b* demonstrate a method of manufacturing a composite valve, which is based on flexible PU **92** for as the main body of the valve, rigid PU support beams **94** serving for the attachment area, and PET sleeve **96** portions for the valve inlet. The need for a rigid portion for attachment (support beams **94**) is explained by the tendency of the flexible, fatigue resistant material to tear as already explained. The advantage of the stiff PU support beams is that they are chemically adhered to the main body, and this improves the overall durability of the valve due to reduction of inner forces and friction in the attachment area specially attachment between two different materials. The valve is dipped in the method mentioned with reference to **FIG. 5**, and the rigid PU support beam **94** is created by way of mold injection, machining or any other suitable way. The rigid PU support beam **94** is placed on the valve and then dipped into the container of dissolved PU. This is done while the valve is positioned on the mandrel (not shown). This method provides the ability to composite several materials into one body and, by that, gain the advantage of the various properties of the materials as they are needed in different areas of the prosthesis.

[0119] FIGS. **9** to **9***i* demonstrate different methods of attachment between a valve assembly and the support stents. A valve assembly **99** shown in **FIG. 9** is incorporated into valve **100** shown in **FIG. 9***a*, where a support stent **102** is attached to valve assembly **99** through support beam **106**. A detail is shown in **FIG. 9***b*, where, in cross-section, it can be seen that layer **108** is an optional inner support made of stainless steel or rigid polymeric material, valve assembly **99** comprises a PET layer **105** coated with a PU layer **104**, with the outer support beam **106**. Connector **107** is a connecting wire made of a strong material, such as stainless steel. **FIG. 9***c* illustrates an alternative arrangement for attachment by a rivet **109**, and in **FIG. 9***d* the attachment is achieved by a suture **110**.

[0120] **FIGS. 9***e* to **9***g* show an attachment method comprising shaped rigid members **116**, preferably made from metal, which tightly hold the PU valve material **118** by fitting in between a PU U-shaped nest **120** and are attached to a stent **122** by extruding portions **124** that are provided on U-shaped rigid member **116**, which fit the bores **126** of the support beam **128** of the stent **122**. **FIGS. 9***h* and **9***i* show another attachment method, where rigid support beams in the form of frame construction **132** are provided, and the valve assembly pliant material **135** made of a tubular material is inserted through a gap **137** in the frame. After insertion, a fastening rod **133** is inserted through the pocket formed between the pliant material and the frame and holds the valve in position.

[0121] **FIG. 10** illustrates a dipping mandrel **139** with an extending portion **141**, which improves the sealing ability of

the valve. Since the valve is attached to a collapsible stent and is itself collapsible, it is difficult to determine the exact shape of the valve after crimping and deploying. It is of major importance that sealing will be achieved. By adding the extension **141** the leaflets are made longer than needed to exactly close the outlet, and therefore when they are in the collapsed state, substantial portions of the leaflets fall on each other creating better sealing.

[**0122**] **FIGS. 11***a* to **11***c* illustrate a valve assembly mounted on a support stent **144** with interlaced strengthening wire **146**, which improves the force distribution on the valve material and facilitates prolonged durability of the valve. The support is in the form of a wire, which has a crown shape as the shape of the three cusp valve base **148**, it also has the ability to be crimped **150** to a small diameter, together with the stent, valve and balloon, as shown in **FIG. 11***b*. The forces applied to the valve edge **148** while working, are applied to the attachment points, by making the attachment line longer we reduce the force on each attachment point. In this support method the valve is attached by suturing **152** the entire line to the extra support wire **146**. This wire can be made of stainless steel, nickel titanium alloy such as nitinol, or polymeric material. The support suture renders the valve assembly default fault lines where the valve material more readily flexes, thus ensuring proper operation of the valve flaps (leaflets). Optionally the valve assembly shown in **FIGS. 11***a* to **11***c* can be mounted on a support stent such as the one described herein or similar supporting structures. The strengthening wire is interlaced in the valve assembly at the outlet of the conduit so as to define a fault line about which the collapsible slack portion **154** of the valve assembly may flap.

[**0123**] **FIGS. 12***a* to **12***c* depict a valve device provided with a stent **159** and substantially equidistant rigid support beams **160**, interlaced or attached to the slack portion of the valve assembly material **161**, arranged longitudinally. This design allows the valve leaflets to perform without outer support. The support in standard valves is by tying the upper edge of the cusp to a rigid embodiment, so that it reacts to the load as a suspension bridge. In this new design the prevention of collapsing is achieved similar to an Indian tent, i.e., the rigid supports lean on each other **162** when the valve is closed but do not interfere in opening **164** when the valve is open.

[**0124**] **FIGS. 13***a* to **13***c* illustrate the manufacturing of a valve assembly in accordance with another preferred embodiment of the present invention. At first a polyurethane thread line **170** is fed from a PU supply **172**, and coiled around a cylindrical drum **174** to form coil **176**. Then, drum **174** with coil **176** is dipped in a PU bath **177**, and a second layer **178** of the PU coats coil **176**, making it a stronger construction capable of withstanding tearing forces both laterally and in other directions. Incorporating two different types of materials—such as PU and PET—may render greater durability and endurance to the valve assembly. This material is an alternative material to be used in the forging method shown in **FIG. 6**.

[**0125**] FIGS. **14** to **14***c* demonstrate the incorporation of heavy metal markers on the stent, which markers allow observation and thereby adjustment of orientation while placing the device in the required location. Heavy metals are radiopaque, that is, they are conspicuous on an angioscopic image, which is a two-dimensional image. Since the coronary arteries ostia **237** and **238** are located near the typical valve deployment location and must stay open, it is extremely important to make sure that the deployed valve assembly is not blocking a coronary ostium. In some cases the stent is lower than the ostium and in those cases it will stay open, but in some cases as shown in these figures it is necessary to make sure that the stent portion **239** that is connecting the valve supports **235** is opposite the coronary ostia, and in that way the blood supply is preserved through the stent struts. Two heavy metal markers **232** are attached at the outlet side, one marker **230** at the inlet side. It is possible to adjust the angiogscopic view to the plane of the left coronary as shown in **FIG. 14***b* and anatomically locate the other accordingly. If the two upper markers **232** are placed in the radiographic two dimensional image, one on top of the other, and the low marker **230** on the opposite side, we make sure that the coronaries are open to blood flow as seen in **FIG. 14***c*. Gold, platinum, iridium or tantalum are all biocompatible materials suitable for the markers described above.

[**0126**] **FIGS. 15***a* to **15***c* illustrate a valve with a portion of radio-opaque material **267** such as a thread of gold at the sealing edge. When a valve is implanted, it is very important to have clear indications of how the valve is functioning in vivo; pressure measurements, flow visualization, and doppler measurements are utilized. It is also possible to examine the valve by ultrasound methods, however, observing the opening and closing of the valve cusps on a monitor. **FIG. 15***b* is an angiographic image **268** of the open valve, while image **169** in **FIG. 15***c* is the closed position as seen on the angiogram.

[**0127**] **FIGS. 16***a* to **16***c* illustrate a procedure, which helps in placing the device in the longitudinal position. It is very important to place the device in the correct longitudinal position, for if it is too deep in the left ventricle it may interfere with the mitral valve function by improper closing or function of the valve. If it is positioned too high it may migrate, it may leak via the sinus cavities, which are located around it, and/or it may block the coronaries. It is a necessary task to position the valve prosthesis in a narrow target location. In **FIG. 14 a** method of lateral orientation placement is shown, and **FIGS. 16***a* to **16***c* illustrate a longitudinal positioning. The valve device (the valve assembly and the support stent) is placed on an inflatable balloon catheter, comprising double independently inflatable chambers **303**, **305**, and is inserted into the left ventricle **302** in the crimped position and guided over a guiding stylet or guide wire **300**. The balloon, which is larger than the annulus diameter when inflated, is inflated in the left ventricle **302**, and then the whole device is pulled slightly backwards. The balloon is supported on the inner part of the annulus **303**, allowing positioning of the device in the exact desired position. In addition, it temporarily blocks the blood flow, and that improves the ability to hold the device in place while inflating it. The next step is inflating the second balloon **305**, which deploys the valve device in the desired location.

[**0128**] The method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient,

as depicted in **FIGS. 16***a*, **16***b* and **16***c*, comprises the steps of:

[**0129**] (a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

[**0130**] (b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

[**0131**] (c) providing a deployable implantable valve prosthesis device adapted to be mounted on the second inflatable portion of the balloon catheter

[**0132**] (d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the second inflatable portion of the balloon catheter until the first inflatable portion of the balloon catheter is inserted into the left ventricle, whereas the second inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

[**0133**] (e) inflating the first inflatable portion of the balloon catheter so as to substantially block blood flow through the natural aortic valve and anchor the distal end of the balloon catheter in position;

[**0134**] (f) inflating the second inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

[**0135**] (g) deflating the first and second inflatable portions of the balloon catheter; and

[**0136**] (h) retracting the balloon catheter and removing it from the patient's body.

[**0137**] **FIG. 17** describes a positioning of a valve device **310** using an additional deployable stent **320**. There are several problems that may be encountered while deploying the stent and valve in the aortic valve location: blockage of coronaries may occur that is dangerous if the diameter of the stent is similar to that of the coronaries aortic root **309**. Secondly, migration of the whole device may also occur, which is a dangerous possibility, and there is the problematic challenge of exact positioning of the valve device that is very difficult to accomplish, as already explained. The newly special designed device with a double diameter inflatable balloon and double stent design allows placement of the device in a way that coronaries will not be blocked because of a safe difference that is kept between the diameters, longitudinal placing is less sensitive because of the small diameter which ensures prevents over expansion of the valved prosthesis. The distal stent **320**, which contains no valve, is expanded into the ascending aorta, while the proximal stent **310** is placed simultaneously in the annular position. This placement method is less challenging due to the smaller diameter of the proximal stent **310** which ensures that the mitral valve is safe too dimensions are preserved, and the additional stent decreases the risk of device migration. It is safer to over dilate in the aorta, which is not true for the annulus.

[**0138**] The method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, as depicted in **FIGS. 17***a* and **17***b*, comprises the steps of:

[**0139**] (a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

[**0140**] (b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

[**0141**] (c) providing a deployable implantable valve prosthesis device adapted to be mounted on the first inflatable portion of the balloon catheter, and a deployable annular stent device adapted to be mounted over the second inflatable portion of the balloon catheter, the deployable implantable valve prosthesis device and the deployable annular stent kept at a predetermined distant apart;

[**0142**] (d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the first inflatable portion of the balloon catheter and the deployable annular stent mounted over the second inflatable portion of the balloon catheter, until the first inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

[**0143**] (e) inflating the second inflatable portion of the balloon catheter so that the deployable stent device is deployed within the aorta thus anchoring the deployable annular stent and the coupled valve device in position;

[**0144**] (f) inflating the first inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

[**0145**] (g) deflating the first and second inflatable portions of the balloon catheter; and

[**0146**] (h) retracting the balloon catheter and removing it from the patient's body.

[**0147**] **FIGS. 118***a* and **18***b* illustrate an accessory crimping device that is adapted to crimp a valve device in the operating theater as part of the implantation procedure. The crimping device **330** comprises several adjustable plates that resemble a typical SLR camera variable restrictor. It is comprised of simultaneously movable plates **332** each provided with a blade **334**, that are equally dispersed in a radial symmetry but each plate moves along a line passing off an opening in the center, all plates equidistant from that center opening **336**. Initially (see **FIG. 18***a*) the plates are drawn apart providing a large enough opening for the implantable valve to be positioned within that opening. When the plates are drawn towards the center (see **FIG. 18***b*), the opening **336** reduces in size but still retains the annular shape, and this facilitates the crimping of the valve frame to a small dimension suitable for percutaneous positioning.

[**0148**] **FIG. 19***a* depicts a crimping method for the support stent of the valve prosthesis device of the present invention, whereby stent **340** is curled. In **FIG. 19***b* a crimping device **343** is shown, comprising a body having an

annular void in which an expanded stent is positioned. Lever **346** is connected to the end **347** of the stent and as the lever is pulled the stent is curled about axle **345** into a curled position **349** (**FIG. 19***c*).

[**0149**] **FIGS. 20***a* and **20***b* depict a valve made of a simple tube mounted to a stent **352**. During systole period the tube is fully open and during diastole period the tube collapses according to the mounting geometry **357** and achieves sealing.

[**0150**] **FIG. 21** describes a newly designed support stent **360** in its open position. Three of the longitudinal struts **362** are full and thick and always stay with their original constant size, serving as anchoring support. Each of these struts **362** is provided with a plurality of bores **364**, which are later used for mounting the valve assembly (not shown) and tying it to stent **360**. Between struts **362** a web-like construction is provided, which is capable of being crimped to a narrow state and capable of being deployed again to a wider state.

[**0151**] **FIG. 22** illustrates another preferred embodiment of an implantable prosthetic valve according to the present invention. It comprises a metal tube **370**, having three portions with a thicker wall **371** than in the rest of the tube **370**, these areas form the longitudinal columns **372** in the construction, after the tube is cut to its final form. The advantage of such a construction is in its superior bending strength, in specific required portions of the construction, with minimal interference to the crimped volume of the whole construction.

[**0152**] **FIGS. 23***a* to **23***c* depict a new method of manufacturing an artificial or biological crimpable valve device. A piece of fabric material **370** (**FIG. 23***a*), is dipped in PU to create a portion which is later formed into valve leaflets **371** (**FIG. 23***b*). This composite material **371** is then attached to an additional piece of fabric such as PET **372** by means of stitching, suturing or other attaching technique **373** (**FIG. 23***c*). The resulting fabric **375** is cut along stitching line **373** leaving enough material to later suture the valve assembly to the support construction. It is then formed to a tubular shape and stitched **374** (**FIG. 23***d*). The tubular valve is then attached to a support construction **380** by suturing the bottom part around the valve **379** tightly to prevent leakage, and around the cut fabric line **376** (**FIG. 23***e*). This open wall structure **378** allows blood flow to the coronary arteries. The valve is later placed with the coronary artery between the support columns **385**. Additional variations of this can be made by replacing the composite material **371**/**370** with a biological patch such as a suitable pericardium patch. In some cases it is possible to make the same valve without cutting the fabric **372** with the shaped cut **376**, and by that create a valve with an outer tubular shape. The embodiment of **FIGS. 23***a* to **23***c* is easy to manufacture as it is generally flat throughout most of the production process and only at the final stage of mounting on the support stent is it given a three-dimensional form.

[**0153**] A typical size of an aortic prosthesis valve is from about 19 to about 25 mm in diameter. A maximal size of a catheter inserted into the femoral artery should be no more than 8 mm in diameter. The present invention introduces a device, which has the ability to change its diameter from about 4 mm to about 25 mm. Artificial valves are not new; however, artificial valves in accordance with the present invention posses the ability to change shape and size for the purpose of delivery and as such are novel. These newly designed valves require new manufacturing methods and technical inventions and improvements, some of which were described herein.

[**0154**] As mentioned earlier, the material of which the valve is made from can be either biological or artificial. In any case new technologies are needed to create such a valve.

[**0155**] To attach the valve to the body, the blood vessels determine the size during delivery, and the requirements for it to work efficiently, there is a need to mount it on a collapsible construction which can be crimped to a small size, be expanded to a larger size, and be strong enough to act as a support for the valve function. This construction, which is in somewhat similar to a large "stent", can be made of different materials such as Nitinol, biocompatible stainless steel, polymeric material or a combination of all. Special requirement for the stent are a subject of some of the embodiments discussed herein.

[**0156**] The mounting of the valve onto a collapsible stent is a new field of problems. New solutions to this problem are described herein.

[**0157**] Another major aspect of the design of the valve of the present invention is the attachment to the body.

[**0158**] In the traditional procedure the valve is sutured in place by a complicated suturing procedure. In the case of the percutaneous procedure there is no direct access to the implantation site therefore different attachment techniques are needed.

[**0159**] Another new problem that is dealt herein is the delivery procedure, which is new and unique. Positioning of the device in the body in an accurate location and orientation requires special marking and measuring methods of the device and surgical site as was disclosed herein.

[**0160**] Artificial polymer valves require special treatment and special conditions when kept on a shelf, as well as a special sterilization procedure. One of the consequences of the shelf treatment is the need to crimp the valve during the implantation procedure. A series of devices and inventions to allow the crimping procedure are disclosed herein.

[**0161**] It should be clear that the description of the embodiments and attached Figures set forth in this specification serves only for a better understanding of the invention, without limiting its scope as covered by the following claims.

[**0162**] It should also be clear that a person skilled in the art, after reading the present specification could make adjustments or amendments to the attached Figures and above described embodiments that would still be covered by the following claims.

**1**. A valve prosthesis device suitable for implantation in body ducts, the device comprising:

a support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the 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 provided with a plurality of longitudinally rigid support beams of fixed length; and

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,

whereby 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, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.

**2**. The valve device of claim 1, wherein the support stent comprises an annular frame.

**3**. The valve device of claim 1, wherein said valve assembly has a tricuspid configuration.

**4**. The valve device of claim 1, wherein said valve assembly is made from biocompatible material.

**5**. The valve device of claim 4, wherein the valve assembly is made from pericardial tissue, or other biological tissue.

**6**. The valve device of claim 1, wherein said valve assembly is made from biocompatible polymers.

**7**. The valve device of claim 6, wherein the valve assembly is made from materials selected from polyurethane and polyethylene terphthalane.

**8**. The valve device of claim 7, wherein said valve assembly comprises a main body made from polyethylene terphthalane and leaflets made from polyurethane.

**9**. The valve device of claim 1, wherein said support stent is made from nickel titanium.

**10**. The valve device of claim 1, wherein the support beams are substantially equidistant and substantially parallel so as to provide anchorage for the valve assembly.

**11**. The valve device of claim 1, wherein the support beams are provided with bores so as to allow stitching or tying of the valve assembly to the beams.

**12**. The valve device of claim 1, wherein the support beams are chemically adhered to the support stent.

**13**. The valve device of claim 1, wherein said valve assembly is riveted to the support beams.

**14**. The valve device of claim 1, wherein said valve assembly is stitched to the support beams.

**15**. The valve device of claim 1, wherein said beams are manufactured by injection using a mold, or by machining.

**16**. The valve device of claim 1, wherein said valve assembly is rolled over the support stent at the inlet.

**17**. The valve device of claim 1, wherein said valve device is manufactured using forging or dipping techniques.

**18**. The valve device of claim 1, wherein said valve assembly leaflets are longer than needed to exactly close the outlet, thus when they are in the collapsed state substantial portions of the leaflets fall on each other creating better sealing.

**19**. The valve device of claim 1, wherein said valve assembly is made from coiled a polymer, coated by a coating layer of same polymer.

**20**. The valve device of claim 19, wherein said polymer is polyurethane.

**21**. The valve device of claim 1, wherein the support stent is provided with heavy metal markers so as to enable tracking and determining the valve device position and orientation.

**22**. The valve device of claim 21, wherein the heavy metal markers are selected from gold, platinum, iridium, or tantalum.

**23**. The valve device of claim 1, wherein the valve assembly leaflets are provided with radio-opaque material at the outlet, so as to help tracking the valve device operation in vivo.

**24**. The valve device of claim 23, wherein said radio-opaque material comprises gold thread.

**25**. The valve device of claim 1, wherein the diameter of said support stent, when fully deployed is in the range of from about 19 to about 25 mm.

**26**. The valve device of claim 1, wherein the diameter of said support stent may be expanded from about 4 to about 25 mm.

**27**. The valve device of claim 1, wherein the support beams are provided with bores and wherein the valve assembly is attached to the support beams by means of u-shaped rigid members that are fastened to the valve assembly and that are provided with extruding portions that fit into matching bores on the support beams.

**28**. The valve device of claim 1, wherein the support beams comprise rigid support beams in the form of frame construction, and the valve assembly pliant material is inserted through a gap in the frame and a fastening rod is inserted through a pocket formed between the pliant material and the frame and holds the valve in position.

**29**. The valve device of claim 1, wherein the main body of the valve assembly is made from coiled wire coated with coating material.

**30**. The valve device of claim **31**, wherein the coiled wire and the coating material is made from polyurethane.

**32**. The valve device of claim 1, wherein a strengthening wire is interlaced in the valve assembly at the outlet of the conduit so as to define a fault line about which the collapsible slack portion of the valve assembly may flap.

**33**. The valve device of claim 32, wherein the strengthening-wire is made from nickel titanium alloy.

**33**. A valve prosthesis device suitable for implantation in body ducts, the device comprising a main conduit body having an inlet and an outlet and pliant leaflets attached at the outlet so that when a flow passes through the conduit from the inlet to the outlet the leaflets are in an open position allowing the flow to exit the outlet, and when the flow is reversed the leaflets collapse so as to block the outlet, wherein the main body is made from polyethylene terphtalate and collapsible leaflets are made form polyurethane.

**34**. The valve device of claim 33, wherein support beams made from polyurethane are provided on the main body and wherein the leaflets are attached to the main body at the support beams.

**35**. The valve device of claim 33, wherein said support beams are chemically adhered to the main body.

**36**. A valve prosthesis device suitable for implantation in body ducts, the device comprising:

support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the 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 provided with a plurality of longitudinally rigid support beams of fixed length;

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;

substantially equidistant rigid support beams interlaced or attached to the slack portion of the valve assembly material, arranged longitudinally.

**37**. A crimping device for crimping the valve device of claim 1, the crimping device comprising a plurality of adjustable plates that resemble a typical SLR camera variable restrictor, each provided with a blade, that are equally dispersed in a radial symmetry but each plate moves along a line passing off an opening in the center, all plates equidistant from that center opening.

**38**. The crimping device of claim 37, wherein the multiple plates are adapted to move simultaneously by means of a lever and transmission.

**39**. A method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, the method comprising the steps of:

(a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

(b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

(c) providing a deployable implantable valve prosthesis device adapted to be mounted on the second inflatable portion of the balloon catheter

(d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the second inflatable portion of the balloon catheter until the first inflatable portion of the balloon catheter is inserted into the left ventricle, whereas the second inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

(e) inflating the first inflatable portion of the balloon catheter so as to substantially block blood flow through the natural aortic valve and anchor the distal end of the balloon catheter in position;

(f) inflating the second inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

(g) deflating the first and second inflatable portions of the balloon catheter; and

(h) retracting the balloon catheter and removing it from the patient's body.

**40**. The method of claim 39, wherein the guiding tool comprises a guide wire.

**41**. A method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, the method comprising the steps of:

(a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

(b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

(c) providing a deployable implantable valve prosthesis device adapted to be mounted on the first inflatable portion of the balloon catheter, and a deployable annular stent device adapted to be mounted over the second inflatable portion of the balloon catheter, the deployable implantable valve prosthesis device and the deployable annular stent kept at a predetermined distant apart;

(d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the first inflatable portion of the balloon catheter and the deployable annular stent mounted over the second inflatable portion of the balloon catheter, until the first inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

(e) inflating the second inflatable portion of the balloon catheter so that the deployable stent device is deployed within the aorta thus anchoring the deployable annular stent and the coupled valve device in position;

(f) inflating the first inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

(g) deflating the first and second inflatable portions of the balloon catheter; and

(h) retracting the balloon catheter and removing it from the patient's body.

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## Ansprüche

1. Synthetisches Gefäßtransplantat in Form einer Doppelvelours-Kettenwirkware aus einem Material, an dem Zellgewebe haften kann, gekennzeichnet durch ein schlauchförmiges Gitterwerk (12), das mit einer Vielzahl gewirkter Fadenschlingen (13, 14) versehen ist, die von den Oberflächen des Gitterwerkes sowohl nach außen als auch nach innen abstehen und an der Außen- und Innenfläche des Gitterwerkes einen Flor aus fadenförmigem Material bilden, der aufnahmefähig für einwachsendes Zellgewebe ist, wobei die Schlingen (13, 14) die Wachstumsgeschwindigkeit von Zellgewebe in das Transplantat hinein wirksam verbessern.

2. Transplantat nach Anspruch 1, dadurch gekennzeichnet, daß das gewirkte schlauchförmige Gitterwerk (12) entlang seiner Länge regelmäßige Umfangsrillen hat.

3. Transplantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß es gegabelt ist. (Fig.3)

4. Transplantat nach einem der vorausgehenden Ansprüche, dadurch gekennzeichnet, daß die nach außen vorstehenden Schlingen (13) drei bis zehnmal so lang sind wie die nach innen stehenden Schlingen (14).

5. Transplantat nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß die nach außen vorstehenden Schlingen (13) vier- bis siebenmal so lang sind wie die nach innen vorstehenden Schlingen (14).

6. Transplantat nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß es von kettengewirkter Charmeuse-Struktur ist, wodurch der Schlauch außerordentlich widerstandsfähig gegen Ausfasern ist.



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7. Transplantat nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß es von kettengewirkter Trikotstruktur ist, wodurch der Schlauch außerordentlich widerstandsfähig gegen Ausfasern ist.

8. Transplantat nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß das Gitterwerk (12) aus einem nichttexturierten einfädigen Garn mit einer Garnnummer von 30 bis 150 Denier ist.

9. Transplantat nach einem der Ansprüche 1-7, dadurch gekennzeichnet, daß das Gitterwerk (12) aus einem nichttexturierten einfädigen Garn mit einer Garnnummer von 30 bis 70 Denier ist.

10. Transplantat nach einem der Ansprüche 1-7, dadurch gekennzeichnet, daß das Gitterwerk (12) aus einem nichttexturierten einfädigen Garn mit einer Garnnummer von etwa 40 Denier ist.

11. Transplantat nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß das Gitterwerk (12) aus einem zwei- oder mehrfädigen nichttexturierten Garn ist, das eine Gesamtgarnnummer zwischen 30 und 150 Denier hat.

12. Transplantat nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß das Gitterwerk (12) aus einem zwei- oder mehrfädigen nichttexturierten Garn ist, das eine Gesamtgarnnummer zwischen 30 und 70 Denier hat.

13. Transplantat nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß das Gitterwerk (12) aus einem zwei- oder mehrfädigen nichttexturierten Garn ist, das eine Gesamtgarnnummer von etwa 40 Denier hat.

14. Transplantat nach Anspruch 8, dadurch gekennzeichnet, daß



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die Schlingen (13, 14) aus einem texturierten einfädigen Garn mit einer Garnnummer von 30 bis 150 Denier sind, wobei die Garnnummer mindestens ebenso groß ist wie diejenige des Gitterwerks (12).

15. Transplantat nach Anspruch 8, dadurch gekennzeichnet, daß die Schlingen (13, 14) aus einem texturierten einfädigen Garn mit einer Garnnummer von 30 bis 70 Denier sind, wobei die Garnnummer mindestens ebenso groß wie diejenige des Gitterwerks (12) ist.

16. Transplantat nach Anspruch 8, dadurch gekennzeichnet, daß die Schlingen (13, 14) aus einem texturierten einfädigen Garn mit einer Garnnummer von etwa 40 Denier sind, wobei die Garnnummer mindestens ebenso groß ist wie diejenige des Gitterwerks (12).

17. Transplantat nach Anspruch 8, dadurch gekennzeichnet, daß die Schlingen (13, 14) aus einem texturierten doppelfädigen Garn sind, dessen Einzelfäden jeweils eine Garnnummer von 30 bis 150 Denier haben, wobei die Garnnummer wenigstens ebenso groß ist wie diejenige des Gitterwerkes (12).

18. Transplantat nach Anspruch 8, dadurch gekennzeichnet, daß die Schlingen (13, 14) aus einem texturierten doppelfädigen Garn sind, dessen Einzelfäden eine Garnnummer von 30 bis 70 Denier haben, wobei die Garnnummer wenigstens ebenso groß ist wie diejenige des Gitterwerkes (12).

19. Transplantat nach Anspruch 8, dadurch gekennzeichnet, daß die Schlingen (13, 14) aus einem texturierten doppelfädigen Garn sind, dessen Einzelfäden jeweils eine Garnnummer von etwa 40 Denier haben, wobei die Garnnummer wenigstens ebenso groß ist wie diejenige des Gitterwerkes (12).

20. Transplantat nach Anspruch 8, dadurch gekennzeichnet, daß



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die Schlingen (13, 14) aus einem texturierten mehrfädigen Garn sind, das eine Gesamtgarnnummer von 60 bis 300 Denier hat, wobei die Gesamtgarnnummer wenigstens ebenso groß ist wie diejenige des Gitterwerks (12).

21. Transplantat nach Anspruch 8, dadurch gekennzeichnet, daß die Schlingen (13, 14) aus einem texturierten mehrfädigen Garn mit einer Gesamtgarnnummer von 60 bis 140 Denier sind, wobei die Gesamtgarnnummer wenigstens ebenso groß ist wie diejenige des Gitterwerks (12).

22. Transplantat nach Anspruch 8, dadurch gekennzeichnet, daß die Schlingen (13, 14) aus einem texturierten mehrfädigen Garn mit einer Gesamtgarnnummer von etwa 80 Denier sind, wobei die Gesamtgarnnummer wenigstens ebenso groß ist wie diejenige des Gitterwerkes (12).

23. Transplantat nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß das Garn ein Polyester ist.

24. Transplantat nach einem der Ansprüche 1 bis 22, dadurch gekennzeichnet, daß das Garn aus Dacron (einer Polyesterfaser aus Terephtalsäure und Äthylenglykol) ist.

25. Transplantat nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß die Schlingen (13, 14) aus einem einfädigen texturierten Garn sind und die Zahl der Maschenreihen pro Zoll (2,54 cm) in dem Transplantat zwischen 60 und 90 liegt, wobei das Transplantat eine verhältnismäßig hohe Porosität hat.

26. Transplantat nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß die Schlingen (13, 14) aus einem zweifädigen texturierten Garn sind und die Zahl der Maschenreihen pro Zoll (2,54 cm) in dem Transplantat zwischen 60



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und 90 liegt, wobei das Transplantat eine verhältnismäßig niedrige Porosität hat.

27. Transplantat nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß die Schlingen (13, 14) aus einem mehrfädigen texturierten Garn sind und die Zahl der Maschenreihen pro Zoll (2,54 cm) in dem Transplantat zwischen 60 und 90 liegt, wobei das Transplantat eine verhältnismäßig niedrige Porosität hat.

28. Transplantat nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß auf ihm mindestens eine Markierungslinie (17) angebracht ist, die eine Verdrehung des Transplantats bei der Implantation verhindern hilft.

29. Transplantat nach einem der Ansprüche 1 bis 7 oder 28, dadurch gekennzeichnet, daß das Gitterwerk (12) aus einem nichttexturierten Garn aus wenigstens einem Faden mit einer Gesamtgarnnummer zwischen 30 und 150 Denier ist und daß die Schlingen (13, 14) aus einem texturierten Garn mit wenigstens einem Faden und mit einer Gesamtgarnnummer von 30 bis 300 Denier sind, wobei die Gesamtgarnnummer des Garns für die Schlingen wenigstens ebenso groß ist wie die Gesamtgarnnummer des Garns für das Gitterwerk.

30. Verfahren zum Herstellen eines synthetischen Transplantats nach einem der Ansprüche 1 bis 29, dadurch gekennzeichnet, daß von einer ersten Gruppe von Bäumen ein nichttexturiertes Garn mit einer ersten Geschwindigkeit zugeführt wird, um das Gitterwerk zu bilden, und daß von einer zweiten Gruppe von Bäumen ein texturiertes Garn mit einer zweiten Geschwindigkeit zugeführt wird, um die nach innen und außen vom Gitterwerk vorstehenden Schlingen zu bilden, wobei das Verhältnis der zweiten Geschwindigkeit zur ersten Geschwindigkeit zwischen 1,75:1 und 4,50:1 liegt.



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31. Verfahren nach Anspruch 30, dadurch gekennzeichnet, daß das nichttexturierte Garn aus wenigstens einem Faden und das texturierte Garn aus wenigstens einem Faden besteht, daß die Gesamtgarnnummer des nichttexturierten Garns zwischen 30 und 150 Denier und die Gesamtgarnnummer des texturierten Garns zwischen 30 und 300 Denier liegt und daß die Gesamtgarnnummer des texturierten Garns mindestens ebenso groß ist wie die Gesamtgarnnummer des nichttexturierten Garns.



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Synthetisches Gefäßtransplantat und Verfahren zu seiner Herstellung

Die Erfindung betrifft ein synthetisches Gefäßtransplantat in Form einer Doppelvelours-Kettenwirkware aus einem Material, an dem Zellgewebe haften kann, sowie ein Herstellungsverfahren für ein solches Gefäßtransplantat.

Gefäßtransplantate aus synthetischen Fasern sind weit verbreitet und es steht eine Vielfalt an Konstruktionen in einer Reihe von Materialien zur Verfügung. Ein wesentlicher Faktor bei der Wahl eines bestimmten Transplantats ist die Porosität des Gewebes, aus dem das Transplantat besteht. Dieser Faktor ist so wichtig, weil die Porosität sowohl die Tendenz zu Blutungen als auch das Einwachsen von Zellgewebe in die Wand des Transplantats beeinflußt.

Im allgemeinen gehört zum Einpflanzen eines Transplantats das vorherige Gerinnenlassen von Blut, ein Schritt, bei dem das Transplantat in das Blut des Patienten eingetaucht wird und man es dann so lange sich überläßt, daß die Gerinnung mit Sicherheit eintritt. Dies hat zur Folge, daß beim chirurgischen Einpflanzen des Transplantats keine Blutung erfolgt; trotzdem kann das Gewebe noch in die Wand des Transplantats hineinwachsen. Dieses Einwachsen ist äußerst wichtig, weil letzten Endes die Wand des Transplantats die Wand des Gefäßes, das



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durch das Transplantat ersetzt wird, simuliert und, wenn alles gut geht, ein Lumen vorsieht, das offen und frei von Klumpen bleibt.

Das Ausmaß der Adhäsion von Zellgewebe an der Wand des Transplantats ändert sich mit dem verwendeten Material. In der US-PS 3 561 441 ist die Verwendung eines nichtklebenden Materials beschrieben, das mit Schlingen versehen ist und zum Abdecken und Behandeln von Wunden dient. Als Material wird in dieser PS ein polyfluoriniertes Polyolefin in Fadenform, gesponnen oder als Kunststoffband vorgeschlagen. Als Vorteil eines solchen Materials wird angeführt, daß es beim Verbandwechsel periodisch von einer Wunde entfernt werden kann, ohne die Wunde selbst aufzureißen.

In der US-PS 3 878 565 ist eine rohrförmige spinnstoffartige synthetische Herzgefäß-Prothese aus Polyester oder anderen Kunststoff-Fasern beschrieben, die aus einem Körper besteht, von dessen Oberfläche viele Faserschlingen nach außen stehen. Der Körper ist außerdem, wie in Fig.2A dieser PS gezeigt, in unregelmäßigen Umfangsrillen gewellt. Diese Rillen sollen einen Schutz gegen ein Knicken oder Zusammenfallen der Röhre und gegen eine Verengung des Lumens der Föhre durch Biegen oder andere Faktoren bieten. Das Ausmaß des von solchen unregelmäßigen Rillen gewährten Schutzes ändert sich jedoch auf der Länge der Röhre und kann unter dem erforderlichen Maß liegen, weil die Rillen in Form und Größe so unregelmäßig sind.

Die Konstruktion gemäß der US-PS 3 878 565 erleichtert zwar das Wachsen von Zellgewebe auf der Außenseite des Körpers oder Gitterwerks des rohrförmigen Transplantats, das Fehlen von Schlingen im Inneren der Röhre kann jedoch dazu führen, daß die synthetischen Fasern, aus denen die Röhre besteht, offen daliegen. Außerdem ist das Transplantat gemäß dieser PS rundgewirkt, so daß die Technik, die die Schlingen an diesem Transplantat vorsieht, nicht auf kettengewirkte Röhren an-



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wendbar ist.

Es besteht demnach der Wunsch nach einem Transplantatschlauch, der auf seiner ganzen Länge eine gleichmäßige Stärke und Steifigkeit hat, der sich für eine Gabelung eignet und der das Wachsen von Zellgewebe sowohl entlang seiner Innenfläche als auch an seiner Außenfläche fördert.

Ziel der Erfindung ist es also, ein synthetisches Gefäßtransplantat in Form eines kettengewirkten Doppelvelours vorzusehen, das aus einem Material ist, an dem Zellgewebe gut haftet, und das die Bildung von Zellgewebe an seiner Außen- und Innenfläche fördert, ohne den Blutstrom durch das Transplantat zu behindern.

Weiter ist die Erfindung auf ein Verfahren zum Herstellen eines solchen synthetischen Gefäßtransplantats aus kettengewirktem Doppelvelours gerichtet. Erfindungsgemäß stehen die Schlingen an der Außenseite des Gewirks weiter nach außen als die Schlingen an der Innenseite des Gewirks nach innen vorstehen. Gemäß dem Verfahren wird das Transplantat kompakt gemacht und gewellt, um dabei durchgehend eine gleichmäßige Festigkeit zu erhalten. Außerdem will das erfindungsgemäße Verfahren ein Transplantat schaffen, das sich gabeln läßt.

Um dies zu erreichen, wird ein synthetisches Gefäßtransplantat aus einer Faser oder einem Faden kettengewirkt, an der bzw. dem Zellgewebe haften kann. Eine bevorzugte Faser ist Polyester und besonders zweckmäßig ist die unter der Handelsbezeichnung Dacron von Dupont hergestellte Faser (eine Polyesterfaser aus Terephtalsäure und Äthylenglykol). Es kann jedoch auch jede vergleichbare Faser verwendet werden und besonders Polyesterfaser oder -garn soll als geeignete Alternative erwähnt werden.

Um das Wachsen von Zellgewebe über die Innenfläche des Schlau-



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ches und auch über dessen Außenfläche zu erleichtern, sind sowohl an der Innenwand als auch an der Außenwand des Transplantatschlauches Fadenschlingen vorgesehen. Damit die Fadenschlingen den Fluß des Blutes durch das Lumen des Schlauches nicht stören, sind die Fadenschlingen an der Innenwand kürzer, d.h. kleiner als diejenigen an der Außenwand des Transplantats. Günstigerweise ragen die äußeren Schlingen um einen Faktor zwischen 3 und 10 mal weiter vor als die inneren Schlingen. Vorzugsweise liegt dieser Faktor zwischen 4 und 7. Die Schlingen bilden einen Flor. Nachstehend wird der Ausdruck "Schlingen" nur für diejenigen verwendet, die von dem Gitterwerk (trellis) nach innen oder außen vorstehen.

Beim Kettenwirken des synthetischen Gefäßtransplantats werden zwei äußere und zwei innere Kettbäume verwendet. Wenn die äusseren Kettbäume das Garn für die Schlingen und die inneren Kettbäume das Garn für das Gitterwerk zuführen, wird das Garn von den äußeren Kettbäumen mit größerer Geschwindigkeit angeliefert als von den inneren Kettbäumen, wobei das Geschwindigkeitsverhältnis zwischen 1,75:1 und 4,50:1 liegt. Der Kunststoffschlauch des Gefäßtransplantats wird nach dem Wirken kompakt gemacht und in einer regelmäßigen, kreisförmigen Wellung gewellt. Die Kettenwirkware hat vorzugsweise, aber nicht unbedingt Charmeuse-Struktur oder Trikotstruktur, wie dies in den Fig. der US-Patentanmeldung Serial Nr. 435 131 gezeigt ist.

Mit dem erfindungsgemäßen Verfahren können gegabelte Doppelvelours-Transplantate kettengewirkt werden.

Weitere Einzelheiten der Erfindung ergeben sich aus der nachfolgenden Beschreibung eines Ausführungsbeispiels anhand der beigefügten Zeichnungen. Darin zeigen:

Fig.1 einen Schnitt quer durch ein erfindungsgemäßes Transplantat;

Fig.2 einen Längsschnitt des Gefäßtransplantats;



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Fig.3 eine perspektivische Ansicht eines gegabelten synthetischen Gefäßtransplantats gemäß der Erfindung.

Ein erfindungsgemäßes synthetisches Gefäßtransplantat aus Doppelvelours ist in Fig.1 quergeschnitten und in Fig.2 längsgeschnitten dargestellt. Das Doppelveloursgewirk ist insgesamt mit 11 bezeichnet, sein Körper oder Gitterwerk (trellis) trägt das Bezugszeichen 12, die nach außen vorstehenden Schlingen sind mit 13 und die nach innen vorstehenden Schlingen mit 14 gekennzeichnet. Wie aus den Fig. ersichtlich, ragen die Schlingen 13 wesentlich weiter nach außen als die Schlingen 14 nach innen stehen. Es hat sich als zweckmäßig erwiesen, daß die Schlingen 13 von der Oberfläche zwischen 3 und 10 mal so weit abstehen wie die Schlingen 14. Vorzugsweise sollen die Schlingen 13 4 bis 7 mal so weit abstehen wie die Schlingen 14. Die Schlingen an der Innenseite ragen eine kleinere Strecke vor als diejenigen an der Außenseite, damit sie den Fluß des Blutes durch das Lumen des Transplantats nicht ernsthaft stören. Nichtsdestoweniger ist eine Erstreckung nach innen zweckmäßig, damit Zellgewebe darin einwachsen kann und dem durch das Transplantat strömenden Blut schließlich in der Hauptsache eine Zellgewebefläche dargeboten wird. Die nach außen vorstehenden Schlingen dienen ebenfalls dem Einwachsen von Zellgewebe.

Wie Fig.2 zeigt, ist es zweckmäßig, daß das Transplantat auf seiner Länge in einer gleichmäßigen kreisförmigen Wellung gerillt wird. Das Resultat ist eine Steifigkeit, die ausreicht, um ein Zusammenfallen des Schlauches zu verhindern, und die eine gleichmäßige Druckfestigkeit auf der ganzen Länge des Schlauches liefert.

Ferner umfaßt die Erfindung auch ein gegabeltes Transplantat, wie es in Fig.3 gezeigt und mit 16 bezeichnet ist.

Bekanntlich muß die Porosität des Transplantats sorgfältig reguliert werden. Allgemein hat sich herausgestellt, daß es



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zweckmäßig ist, das Transplantat nach dem Wirken kompakt zu machen. Dieses Kompaktmachen wird vorzugsweise auf chemischem Weg durchgeführt mit Hilfe von Verfahren, wie das in der US-Patentanmeldung Serial Nr. 448 447, eingereicht am 5.3.1974, beschriebene, oder auch mit anderen geeigneten Mitteln.

In der Beschreibung der Garne für das erfindungsgemäße Transplantat wird, wenn passend, der Ausdruck "Gesamtgarnnummer" für Garne benutzt, die einfädig oder mehr als einfädig sind, ungeachtet der Feinheit der einzelnen Fäden.

Das erfindungsgemäße synthetische Gefäßtransplantat aus Doppelvelours wird auf einer Kettenwirkmaschine mit zwei Nadelbarren hergestellt. Eine geeignete Anzahl von Nadeln pro Zoll (25,4 mm) liegt zwischen etwa 18 und 36. Hinsichtlich der Porosität des Produktes und der bequemen Fertigung sind etwa 28 Nadeln pro Zoll (25,4 mm) besonders zweckmäßig. Das Gitterwerk oder Lattendessin des Transplantats wird aus einem Garn hergestellt, das eine Feinheit oder Garnnummer von 30 bis 150 Denier hat. Ein bevorzugter Bereich der Garnnummer für das Gitterwerk ist 30 bis 70 und besonders günstig ist eine Garnnummer von etwa 40 Denier. Das Garn des Gitterwerks ist vorzugsweise einfädig, kann aber auch doppelfädig sein. Wenn ein doppelfädiges Garn verwendet wird, ist die Gesamtgarnnummer 30 bis 150 Denier, vorzugsweise 30 bis 70 Denier und optimal 40 Denier. Es sei außerdem bemerkt, daß mehrfädiges Garn verwendet werden kann, solange die Gesamtgarnnummer in die oben spezifizierten Bereiche fällt. Unter "mehrfädig" sei hierin mehr als zweifädig verstanden.

In einem Verfahren zum Herstellen des Gitterwerks wird das Garn von zwei inneren Kettbäumen zugeführt und jeder Kettbaum ist eine Spule, die mehrere Enden hält. In Verbindung mit diesen inneren Bäumen werden gemäß dem Verfahren zwei äußere Kettbäume verwendet, die dazu dienen, die Schlingen zu ma-



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chen, und jeder äußere Baum hält ebenfalls mehrere Enden. Es muß jedoch erwähnt werden, daß auch die inneren Bäume zum Bilden der Schlingen und die äußeren Bäume zum Anfertigen des Gitterwerkes dienen können. Unabhängig davon, welche Bäume für das Gitterwerk und welche für die Schlingen verwendet werden, jedenfalls wird nichttexturiertes Garn für das Gitterwerk und texturiertes Garn für die Schlingen benutzt. Allgemein soll die Garnnummer für die Schlingen mindestens ebenso groß sein wie diejenige für das Garn des Gitterwerks. Die kleinste Anzahl von Bäumen zum Herstellen des erfindungsgemäßen Doppelveloursmaterials beträgt vier. Für spezielle Zwecke kann jedoch auch eine größere Zahl von Bäumen nützlich sein.

Die Schlingen werden vorzugsweise aus einfädigem oder doppelfädigem Garn hergestellt, doch kann auch mehrfädiges Garn verwendet werden. Wenn doppelfädiges Garn verwendet wird, ist die Porosität natürlich geringer. Bei doppelfädigem Garn ist die Garnnummer das Doppelte derjenigen für die einzelnen Fäden. Wenn einfädiges Garn für die Schlingen verwendet wird, soll die Garnnummer im allgemeinen zwischen 30 und 150 Denier liegen, mit einem bevorzugten Bereich zwischen 30 und 70 Denier. Eine besonders geeignete Garnnummer für die Schlingen ist 40 Denier. Wenn die Schlingen doppelfädig sein sollen mit dem Ziel, die Porosität herabzusetzen, ist die Garnnummer für die einzelnen Fäden genau die gleiche wie für den einzigen Faden, aber die Gesamtgarnnummer ist natürlich doppelt so groß. Die Garnnummern insgesamt liegen also im allgemeinen zwischen 60 und 300 mit einem bevorzugten Bereich zwischen 60 und 140 und mit 80 als besonders geeigneter Garnnummer. Wenn mehrfädige Garne für die Schlingen verwendet werden, entsprechen die Bereiche der Gesamtgarnnummer denjenigen für doppelfädige Garne.

Die Strecke, um die die Schlingen von dem Gitterwerk abstehen, und das Verhältnis, in dem die Schlingen nach innen und nach außen vorstehen, werden automatisch eingestellt durch die Wahl der relativen Zuführgeschwindigkeiten der Garne für die Schlin-



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gen und für das Gitterwerk.

Damit die Schlingen von beiden Seiten des Gitterwerkes abstehen, wird das Garn von den Bäumen, die das Schlingengarn führen, schneller zugeführt als dasjenige für das Gitterwerk. Das Geschwindigkeitsverhältnis liegt im Bereich von 1,75:1 bis 4,50:1.

Wie schon erwähnt, kann das Garn vorzugsweise entweder in Charmeuse-Struktur oder in Trikot - Struktur gewirkt werden. Nach dem Wirken wird das Gewirk vorzugsweise kompakt gemacht, um die Größe der Öffnungen und damit die Porosität des Fabrikats zu vermindern. Die texturierten Garne besitzen eine andere Schrumpfungsfähigkeit als die nichttexturierten Garne.

Nach dem Kompaktmachen wird das Transplantat gewellt. Ein zweckmäßiges Verfahren zum Wellen ist, in der schwebenden US-Patentanmeldung Serial Nr. 638 580, eingereicht am 8.12.1975, beschrieben. Die Wellung gemäß diesem Verfahren ergibt gleichmäßige, regelmäßige kreisförmige Rillen, die eine gleichmäßige Festigkeit auf der gesamten Fläche des Transplantatschlauches vorsehen und damit gewährleisten, daß in keinem Abschnitt oder Bereich die Gefahr besteht, daß der Schlauch unter Druck knickt oder zusammenfällt.

Wenn ein Material mit geringerer Durchlässigkeit gewünscht wird, werden die Bäume, die das Garn für die Schlingen zuführen, mit zweifädigem texturiertem Garn geladen. Für das weniger poröse Material haben sich 60-90 Maschenreihen pro Zoll (25,4 mm) nach dem Kompaktmachen als befriedigend erwiesen. Für das Transplantat mit Schlingen aus einfädigem Material haben sich 60-90 Maschenreihen pro Zoll (2,54 cm) als hinreichend herausgestellt.

Nach Wunsch können die Transplantate mit Markierungslinien 17 versehen werden, um ein Verdrehen beim Strecken der Transplantate im chirurgischen Gebrauch besser vermeiden zu helfen.



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Wie aus vorstehender Beschreibung deutlich wird, erfüllt die Erfindung die ihr gestellte Aufgabe. Gegenüber dem gezeigten und beschriebenen Ausführungsbeispiel sind im Rahmen der Erfindung Abänderungen möglich.



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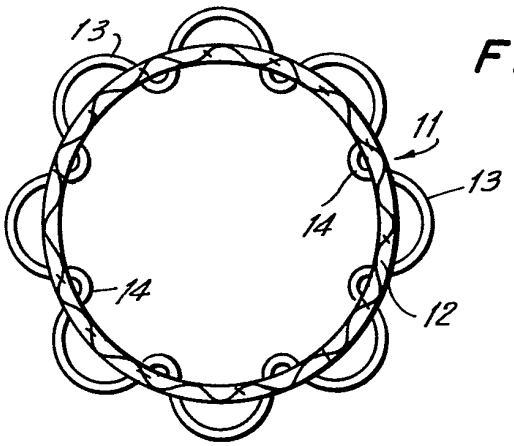
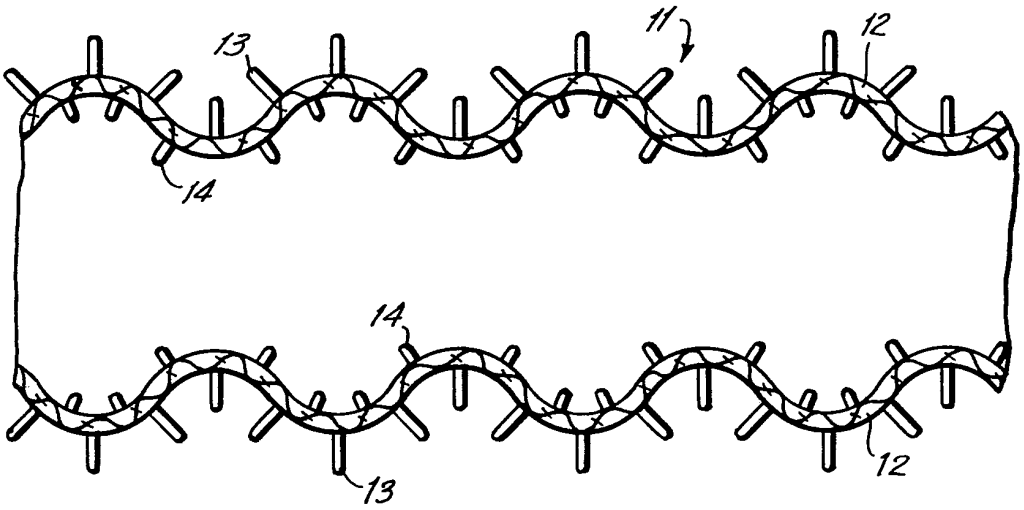



FIG. 1

FIG. 2



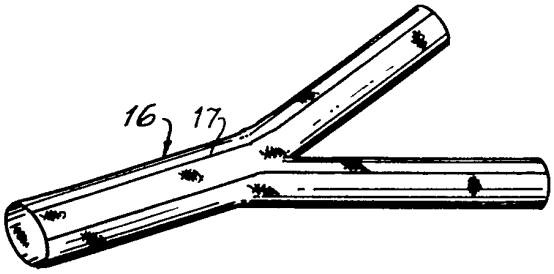




FIG. 3



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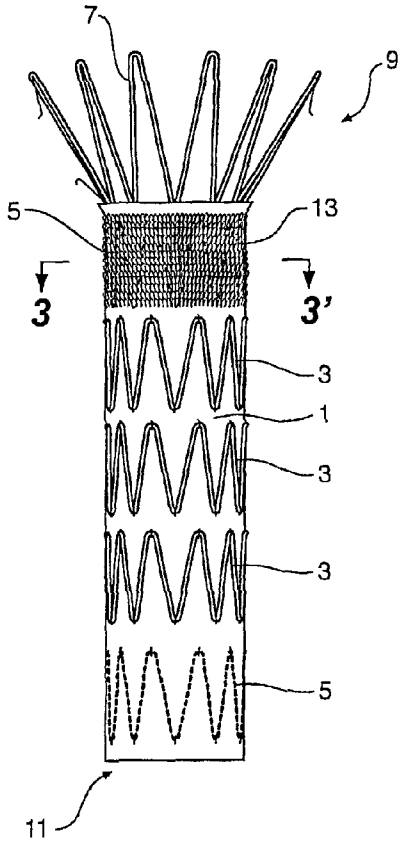
*[Continued on next page]*

(54) Title: STENT GRAFT WITH IMPROVED GRAFT ADHESION




(57) Abstract: A graft (1) having a band of fibrous material (13) on an outer surface thereof adjacent its proximal end (9). The band of fibrous material extends circumferentially around the graft to promote adhesion. The band can be continuous around the proximal end of the graft. The band can be formed from a patch of fibrous material, cut or loop pile velour, by fibres woven or knitted into the material of the graft or by brushing of material of the graft to raise fibres of the material of the graft. The band of fibrous material has a length of from 5 mm to 15 mm along the length of the graft.

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TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— *with international search report*

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# STENT GRAFT WITH IMPROVED GRAFT ADHESION

## Description

### Technical Field

This invention relates to endoluminal stent grafts and in particular to a stent graft for improving the adhesion or incorporation of such grafts into the wall of a lumen.

### Background of the Invention

Throughout this specification when applied to a blood vessel the term distal, with respect to a stent graft or graft, is the end of the stent graft or graft furthest away in the direction of blood flow from the heart within a body lumen. The term proximal means the end of the stent graft or graft nearest to the heart in the direction of blood flow. Where the invention is applied to other lumens of the human or animal body then corresponding terms such as caudal and cranial should be understood.

A surgical stent graft or graft may be placed into a lumen in the body by endoluminal techniques or by surgical techniques. Such a stent graft or graft is constructed from biocompatible materials but it is desirable in the long term for such grafts to be actually incorporated into the wall of the body lumen and this requires that the tissue of the body lumen grows into the material of the graft.

It is known that tufts of fibrous material may be placed on grafts to enhance blood clotting and adhesion but such tufts do not promote complete circumferential adhesion. Particularly when such grafts are deployed endoluminally it is desirable that the amount of fibrous material be kept to a minimum to ensure that the graft can be compressed into small enough volume to enable deployment while at the same time ensuring good adhesion of the graft.

### Summary of the Invention

The object of this invention is to provide a graft with material to ensure good adhesion or incorporation of the graft into a lumen.

In one form therefore the invention is said to reside in a graft or stent graft having a band of fibrous material on an outer surface thereof adjacent a distal or a

proximal end thereof, the band of fibrous material extending circumferentially around the graft to promote adhesion and incorporation. Furthermore, the graft or stent graft can include separate bands of fibrous material extending circumferentially around the graft at both the distal and the proximal ends thereof to promote adhesion and incorporation.

Preferably the band is continuous around the proximal end of the graft.

In one embodiment the band is provided by patches of fibrous material around the proximal end of the graft. Alternatively the band of fibrous material is formed from velour or is provided by fibres woven or knitted into the material of the graft. The velour material may be loop pile material or cut pile material to present either loops of fibres or individual fibres to the wall of the vessel.

The band of fibrous material may alternatively be provided by brushing of the material of the graft to raise fibres of the material to provide the fibrous band.

In an alternative form, the invention may be said to reside in a graft having a continuous band of velour material adjacent a proximal end thereof, the continuous band of velour material extending circumferentially around the graft to promote adhesion.

In a further form, the invention may be said to reside in a continuous band of velour material around one end of a graft to provide adhesion against the wall of a lumen by ingrowth of the tissue of the wall into the velour material, the velour material being a continuous band around the graft.

In a further form, the invention may be said to reside in a stent graft adapted for insertion into an internal lumen of a patient to be incorporated therein, the stent graft comprising a substantially tubular body providing a fluid flow path and having a periphery defined by a biocompatible relatively impervious material wall, the wall having a proximal portion including a continuous external circumferential band of a fibrous biocompatible material.

In a further form, the invention may be said to reside in a stent graft adapted for implantation within a lumen in a human or animal body to reside therein, the stent graft having a proximal end and a distal end and a substantially tubular graft body formed from a relatively impervious biocompatible material, at least one

stent to maintain the patency of the stent graft, and a continuous circumferential band of fibrous material on the outside of the tubular graft body adjacent the proximal end of the stent graft.

It would be seen that by the various forms of the invention there is provided a continuous band of velour material or fibrous material around the outside of the proximal end of a stent graft for good adhesion of that end of the stent graft to the wall of a lumen.

It will be noted that the graft of the present invention is particularly useful in delivery devices when endoluminal deployment is used because the band is of a relatively short length with respect to the length of the graft and hence does not make the device when it is compressed for deployment significantly larger over the entire length of the device.

The band of fibrous material can be a band which is stitched onto the graft at the proximal end, it may be fibres woven or knitted into the material of the graft or where the graft itself is manufactured from a fibrous woven, knitted or non-woven material at which the proximal area of the graft may be brushed to raise the fibres to provide the fibrous band.

To ensure good adhesion the band may be in the region of 5 mm to 15 mm in length along the length of the graft.

In one preferred form of the invention, the invention is particularly related to a stent graft using self-expanding stents such as stainless steel or nitinol stents.

The relatively impervious material may be a knitted or woven biocompatible material such as a dacron or similar material or it may be a non-woven fibrous material or it may be a plastics material sheet formed into a graft tube or extruded into tubular form.

It is desirable that the band be continuous around the proximal end of the graft so that with fibrous ingrowth of the cells of the wall of the lumen into the band of fibrous material on the graft, union of the wall and graft is obtained which provides sealing for blood flow which could occur between the graft and the wall as well as prevention of movement of the graft longitudinally within the lumen. In so doing there is improved incorporation of the graft into the wall of the lumen.

Brief Description of the Drawing

This then generally describes the invention but to assist with understanding reference will now be made to the accompanying drawing which show preferred embodiments of the invention.

In the drawings,

Figure 1 shows a perspective view of a stent graft including the adhesion or incorporation arrangement according to one embodiment of the present invention;

Figure 2 shows a perspective view of a stent graft including the adhesion or incorporation arrangement according to an alternative embodiment of the present invention;

Figure 3A shows a plan view of a stent graft shown in Figure 1 with a first form of velour pile;

Figure 3B shows a plan view of a stent graft shown in Figure 1 with an alternative form of velour pile; and

Figure 4 shows a detailed perspective view of a stent graft including an adhesion or incorporation arrangement of an alternative embodiment.

Detailed Description

Looking more closely at Figure 1 of the drawings it can be seen that in a stent graft comprising a graft material tube 1 which is held into a substantially cylindrical shape by means of external expandable stents 3 in the main body of the graft material 1 and internal stents 5 at each end of the graft. These stents can be self-expanding of, for example, commercially available Gianturco, zigzag or Z stent using a spring like metal such as stainless steel, nitinol, or other alloy metals. These stents can also be balloon or mechanically expandable stents, which are also commercially available.

The graft body has a proximal end 9 and a distal end 11.

In this particular embodiment, a proximally extending stent 7 is provided although this proximally extending stent is not essential to the invention.

Each stent 3, 5 and 7 is a Gianturco zig zag or Z stent manufactured from nitinol or stainless steel and is self expanding from a compressed state, in which the stent graft can be introduced into the lumen, to the expanded state shown.

Extending circumferentially around the graft body 1 at the proximal end 9 is a continuous circumferential region 13 of fibres extending from the graft material. The continuous circumferential region is formed on the material of the graft 1 by portions of the fibrous material woven into the material or extending from the woven graft material. The portions of fibrous material may be in the form of a loop pile or a cut pile to present either loops of fibres or individual fibres to the wall of the vessel when deployed within a body lumen.

The graft may have a diameter in the range of 25 to 50 millimetres and a length of from 100 to 200 millimetres. The band 13 may have a length of from 5 to 15 millimetres and may be adjacent the end of the stent graft or spaced from the proximal end of the graft by a distance of up to 10 millimetres.

Figure 2 shows an alternative embodiment of the invention. In this embodiment the graft 1 is of substantially the same construction as shown in Figure 1 except that it does not have a proximally extending uncovered stent. Around the proximal end 19 of the graft 1 is a continuous band of velour material 20 fastened to the graft 1 by stitching 22 at the proximal end and 21 at the distal end of the velour band 20. The velour provides loops of fibrous material which can be incorporated into the wall of the lumen into which the graft is placed by fibrous ingrowth. This provides adhesion of the graft into the lumen. One again the velour material may be of loop pile or cut pile form.

The provision of the continuous band at the proximal end of the graft provides adhesion and incorporation around the entire circumference of the graft. The adhesion and incorporation around the entire circumference of the graft will prevent blood or other body fluid, depending upon the lumen into which it is introduced, from getting behind the wall of the graft. The adhesion and incorporation will also assist with preventing movement of the graft within the lumen.

Figure 3A and B show cross sectional plan views in the line 3 – 3′ on the stent graft shown in Figure 1 but with different forms of velour pile.

Figure 3A shows loop pile velour as the continuous band 13a of fibrous material around the circumference of the graft 1.

Figure 3B shows cut pile velour as the continuous band 13b of fibrous

material around the circumference of the graft 1.

Figure 4 shows a detailed perspective view of part of a stent graft including an alternative adhesion arrangement for the proximal end of the stent graft. As with Figure 1 the stent graft has a bio-compatible woven material body 1 with a self expanding stent 5 inside the graft body 1 at the proximal end 9 to provide a good contact of the graft material with the wall of a lumen into which it is deployed. In this case the continuous band of fibrous material 25 is provided by brushing or similar means to raise fibres 26 from the material of the graft 1. The brushing can be with a wire brush or a hooking system may be used to raise some of the fibres in a continuous band around the graft.

This brushing or hooking can also be used with non-woven bio-compatible graft materials to raise a fibrous band around the circumference of a graft.

It may be noted that this specification has been particularly directed to the use of a velour band on the proximal end of a graft because that is the end of the graft which it is normally expected to get more blood pressure in the case where the lumen is a blood vessel and the proximal end in the case of an artery being the end nearer the heart. There may be situations, however, where the band of fibrous material may be placed around the distal end of a graft or at both ends and this invention is intended to cover those applications as well.

Throughout this specification various indications have been given as to the scope of this invention but the invention is not limited to any one of these but may reside in two or more of these combined together. The examples are given for illustration only and not for limitation.

Throughout this specification and the claims that follow unless the context requires otherwise, the words 'comprise' and 'include' and variations such as 'comprising' and 'including' will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

Claims

1. A stent graft comprising:

a tubular graft having a distal end, a proximal end, and an outer surface;

at least one expandable stent disposed on said tubular graft; and

a band of fibrous material on said outer surface and adjacent at least one of said distal end and said proximal end of said tubular graft, said band of fibrous material extending circumferentially around said graft.

2. The stent graft as in Claim 1 wherein said band is continuous around said proximal end of said tubular graft.

3. The stent graft as in Claim 1 wherein said band comprises a patch of fibrous material fastened around said proximal end of said tubular graft.

4. The stent graft as in Claim 1 wherein said band of fibrous material includes velour material.

5. The stent graft as in Claim 4 wherein said velour material includes a loop pile velour material.

6. The stent graft as in Claim 4 wherein said velour material includes a cut pile velour material.

7. The stent graft as in Claim 1 wherein said band of fibrous material includes fibres woven or knitted into material of said graft.

8. The stent graft as in Claim 1 wherein said graft includes a graft material and wherein said band of fibrous material comprises brushed raised fibres of said graft material.

9. The stent graft as in Claim 1 wherein said band of fibrous material has a length of from 5 mm to 15 mm along the length of said graft.

10. The stent graft as in Claim 1 wherein said at least one expandable stent extends proximally from said proximal end of said tubular graft.

11. The stent graft as in Claim 1 wherein said stent graft further comprises another band of fibrous material on said outer surface and adjacent a remaining one of said distal end and said proximal end of said tubular graft, said other band of fibrous material extending circumferentially around said graft.

12. A stent graft comprising:

a tubular graft having an outer surface and a proximal end;

at least one expandable stent disposed on said tubular graft; and

a continuous band of velour material adjacent said proximal end of said tubular graft, said continuous band of velour material extending circumferentially around said graft.

13. The stent graft as in Claim 12 wherein said continuous band of velour material is disposed on said outer surface of said tubular graft.

14. A stent graft adapted for insertion into an internal lumen of a patient to be incorporated therein, the stent graft comprising a substantially tubular body providing a fluid flow path and having a periphery defined by a biocompatible relatively impervious material wall, the wall having a proximal portion including a continuous external circumferential band of a fibrous biocompatible material.

15. The stent graft as in Claim 14 wherein the stent graft further comprises at least one stent to maintain the patency of the stent graft, and a continuous circumferential band of fibrous material on the outside of the tubular body adjacent the proximal end of the stent graft.

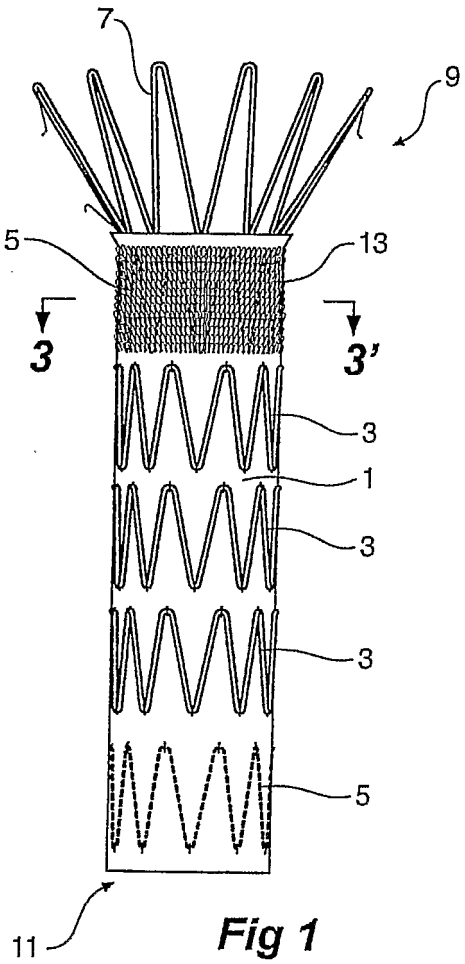


Fig 1

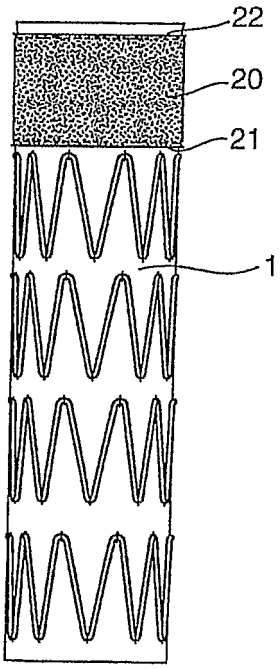


Fig 2

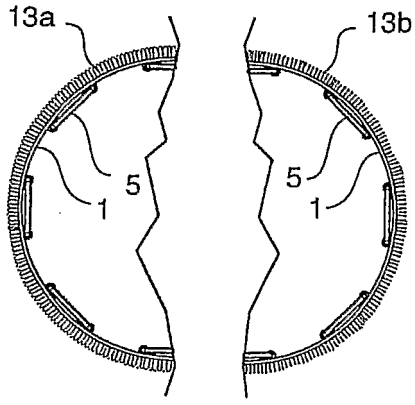


Fig 3A




Fig 3B

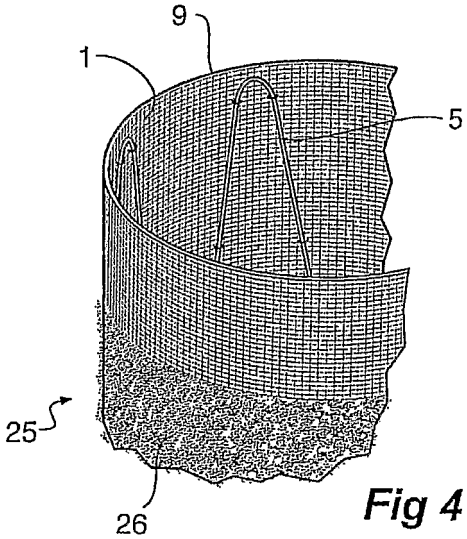


Fig 4

# INTERNATIONAL SEARCH REPORT

Internati Application No
PCT/US 02/40663

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

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)
IPC 7 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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 12 May 2003 | 19/05/2003 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Mary, C |

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US006729356B1

D11

(12) **United States Patent**
**Baker et al.**

(10) **Patent No.: US 6,729,356 B1**
(45) **Date of Patent: May 4, 2004**

(54) **ENDOVASCULAR GRAFT FOR PROVIDING A SEAL WITH VASCULATURE**

(75) Inventors: **Steven G. Baker**, Sunnyvale, CA (US); **Tamara L. Trayer**, Belmont, CA (US); **Arnold M. Escano**, Santa Clara, CA (US); **Mark LeMere**, Mountain View, CA (US); **Elizabeth A. McDermott**, San Carlos, CA (US)

(73) Assignee: **Endovascular Technologies, Inc.**, Santa Clara, CA (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(22) Filed: **Apr. 27, 2000**

(51) **Int. Cl.**[7] ..... **D03D 3/00**

(52) **U.S. Cl.** ..... **139/387 R**; 623/921; 623/1.51; 28/142; 139/383 R; 139/383 AA; 139/DIG. 11

(58) **Field of Search** ..... 28/142; 139/DIG. 11, 139/383 R, 383 AA, 387 R; 623/1, 12, 11, 921, 1.51; 606/198, 195, 194, 192, 191, 108

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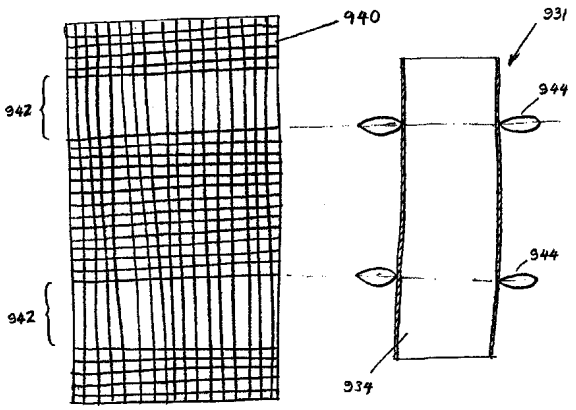
*Primary Examiner*—A Vanatta
*Assistant Examiner*—Robert Muromoto, Jr.
(74) *Attorney, Agent, or Firm*—Fulwider Patton Lee & Utecht, LLP

(57) **ABSTRACT**

A graft provided with a flexible sealing member to substantially prevent blood from leaking between the graft a lumen into which the graft is placed. In one embodiment, the flexible sealing member may be pressed against the vascular wall by an outwardly biased spring means attached to the sealing member. In other embodiments, the sealing member may be self-positioning upon deployment of the graft. The sealing member also may be formed into the shape of a toroid, which may be filled with thrombogenic material causing blood permeating into the toroid-shaped space to coagulate therein and hold the sealing member in place. It is also contemplated that the sealing member be formed from tufts of frayed yarn protruding circumferentially from the outer surface of the graft. A method of manufacturing such tufted yarn sealing members is also disclosed.

**4 Claims, 11 Drawing Sheets**



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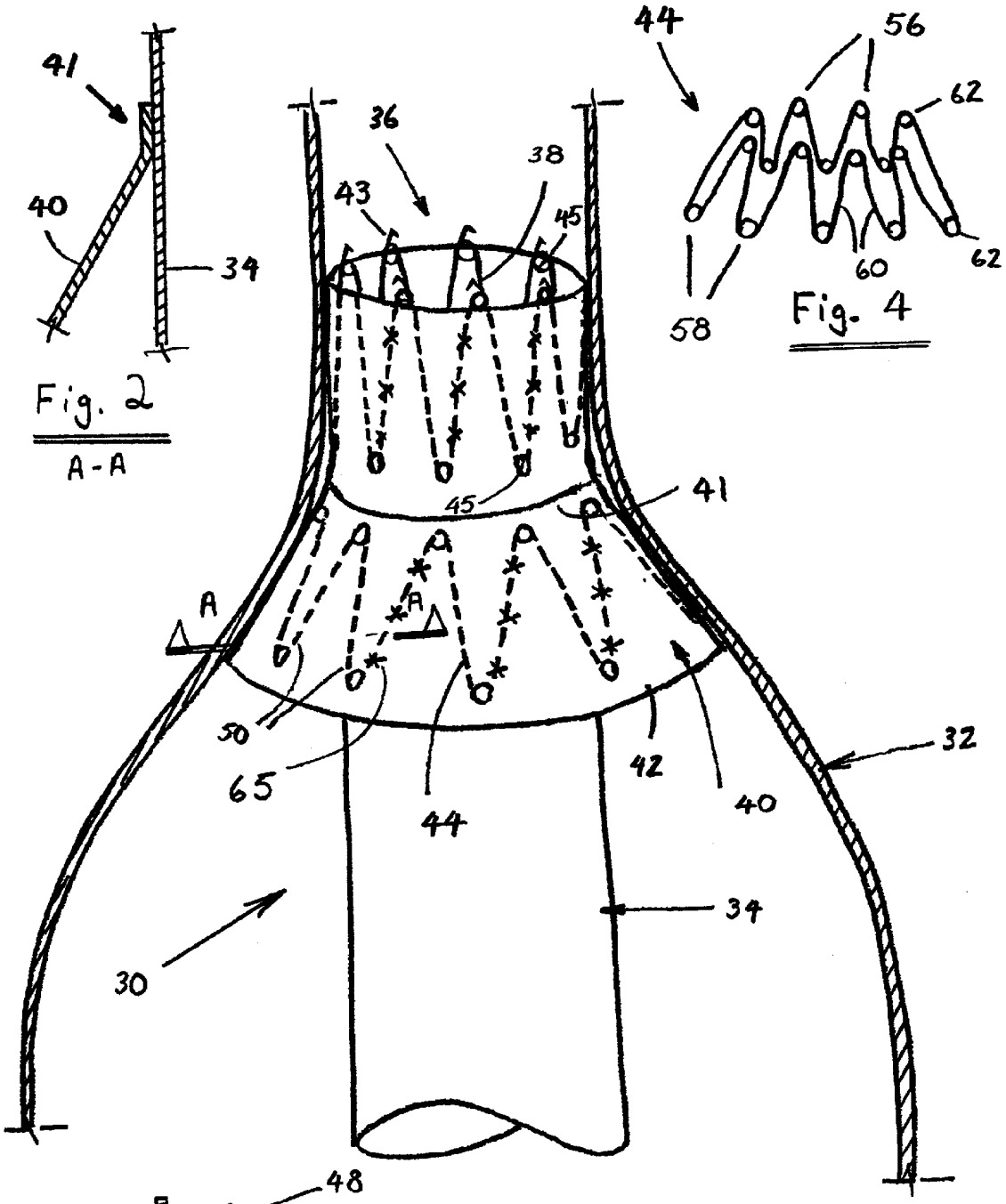



Fig. 1




Fig. 2
A-A




Fig. 4

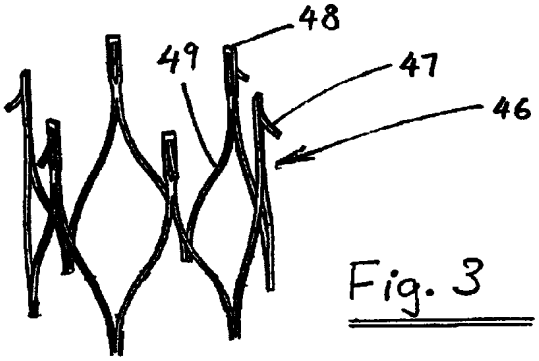



Fig. 3

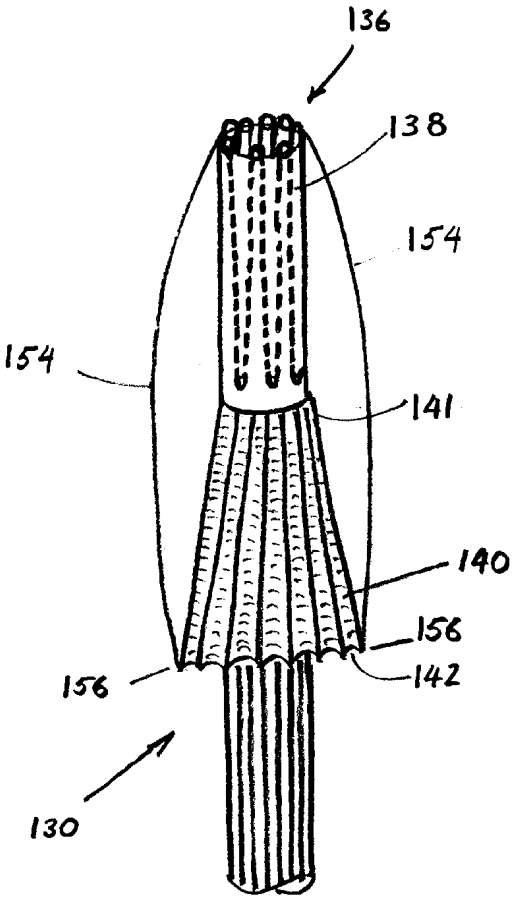



Fig. 5

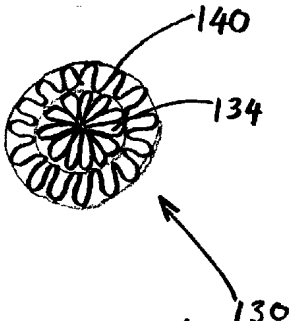



Fig. 6

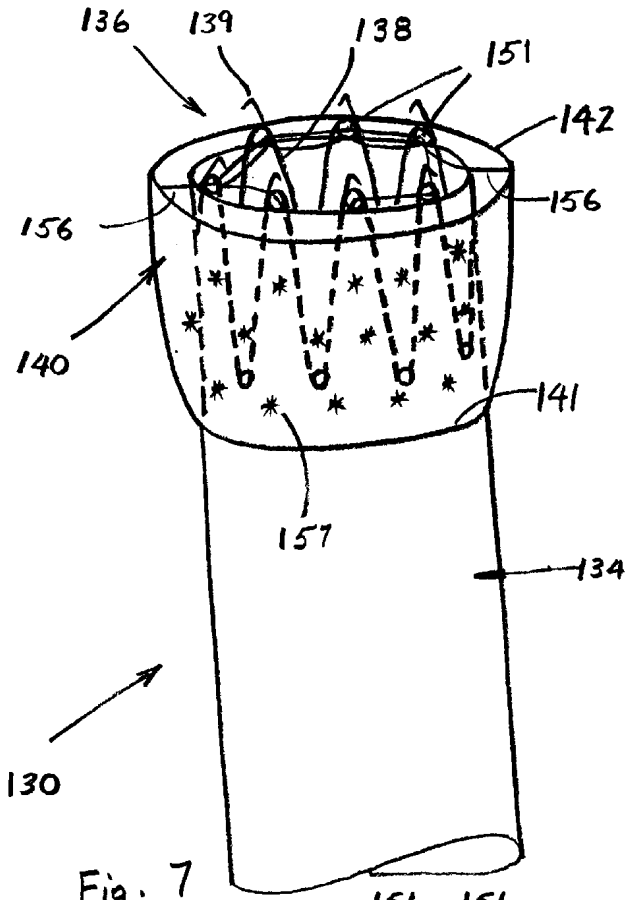



Fig. 7

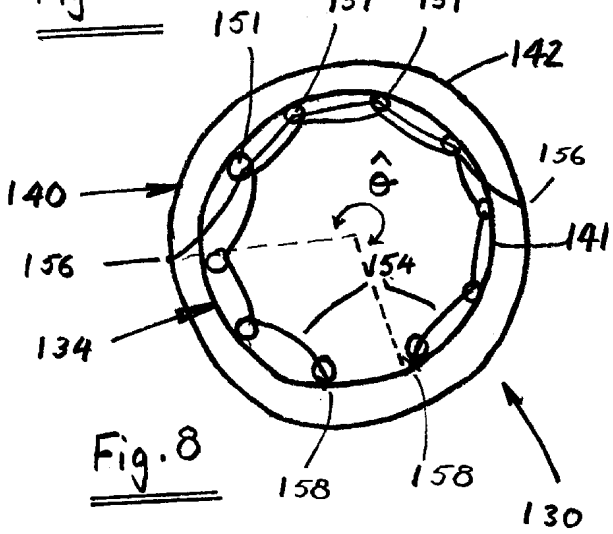



Fig. 8

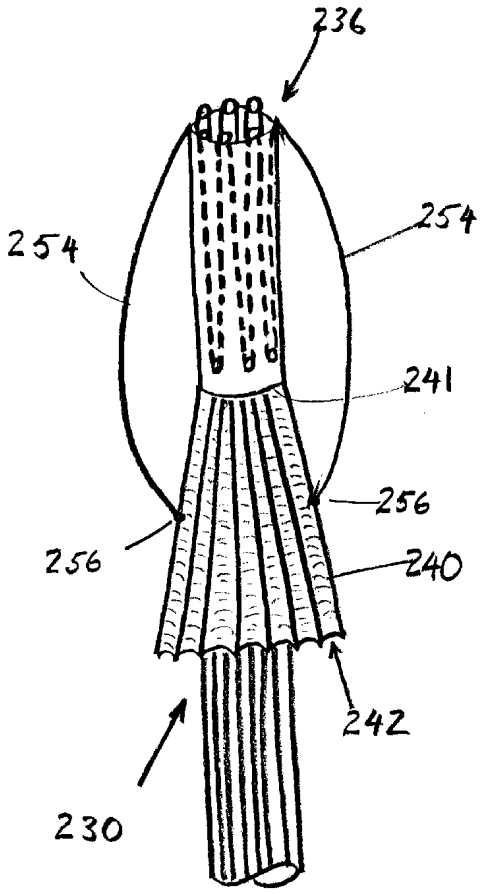

236
254
254
241
256
256
240
242
230

Fig. 9

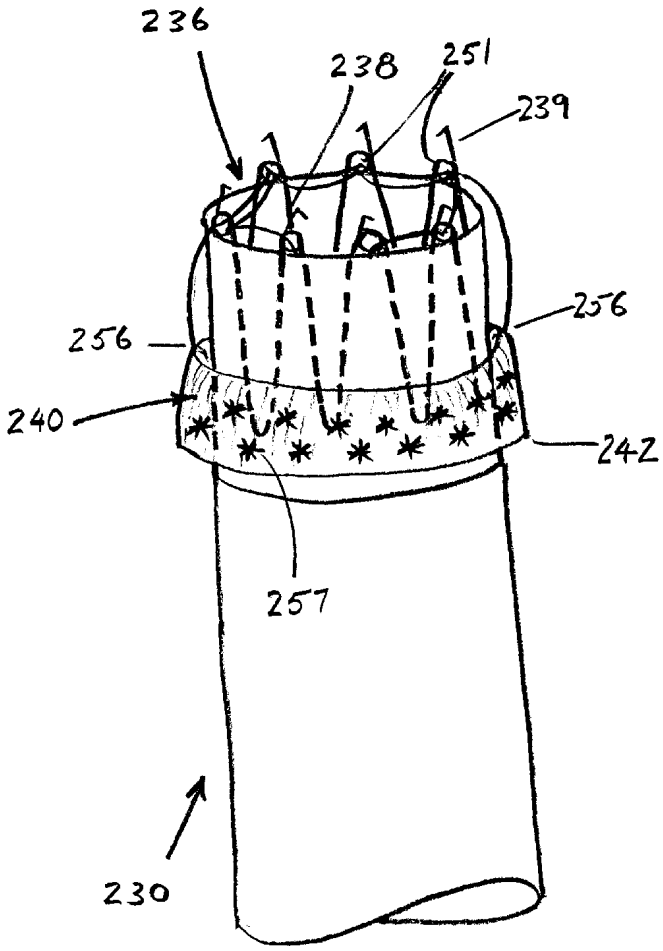

236
238
251
239
256
256
240
242
257
230

Fig. 10

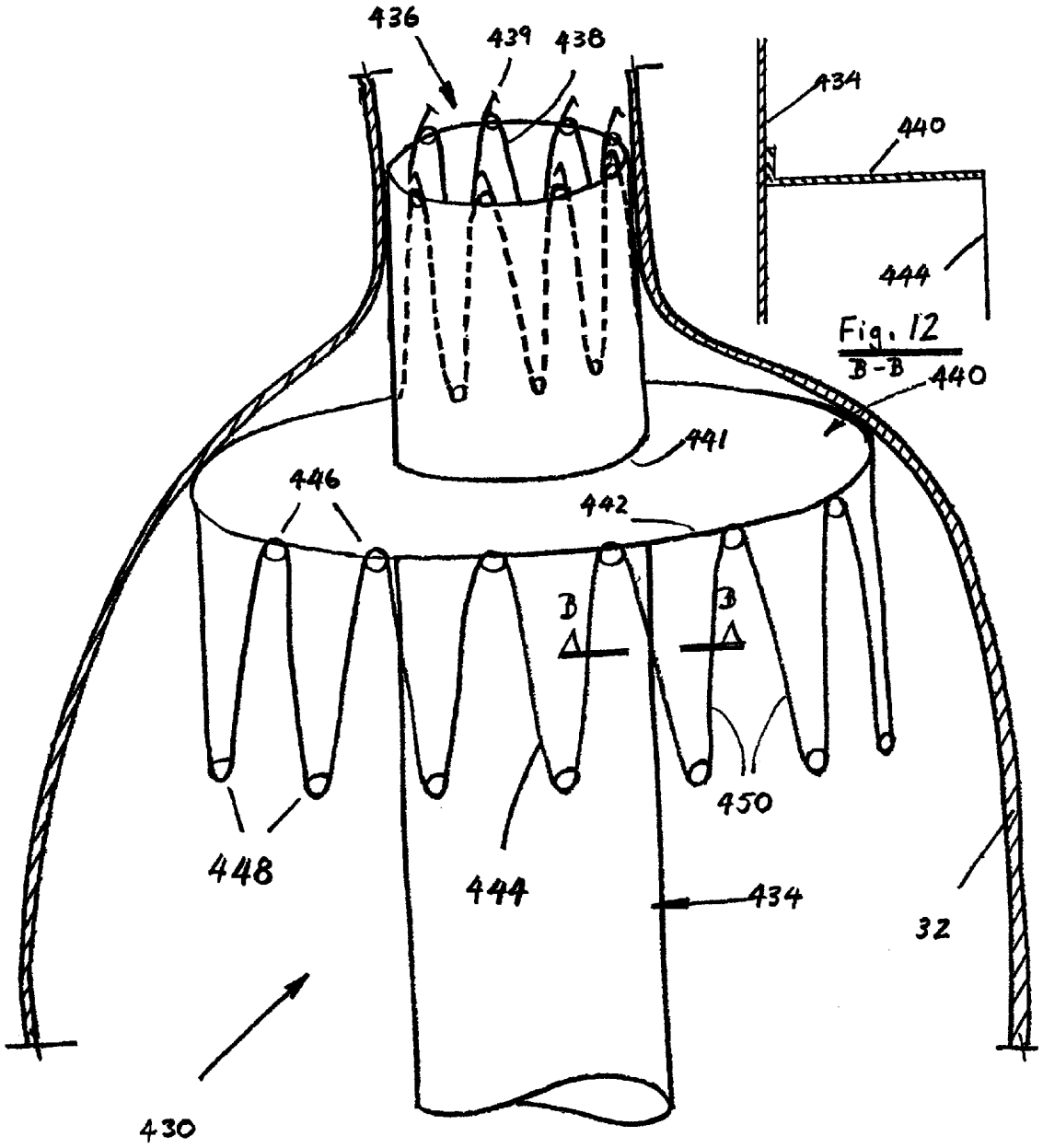

436
439
438
434
440
444
Fig. 12
B-B
440
441
446
442
B
B
450
448
444
434
32
430

Fig. 11

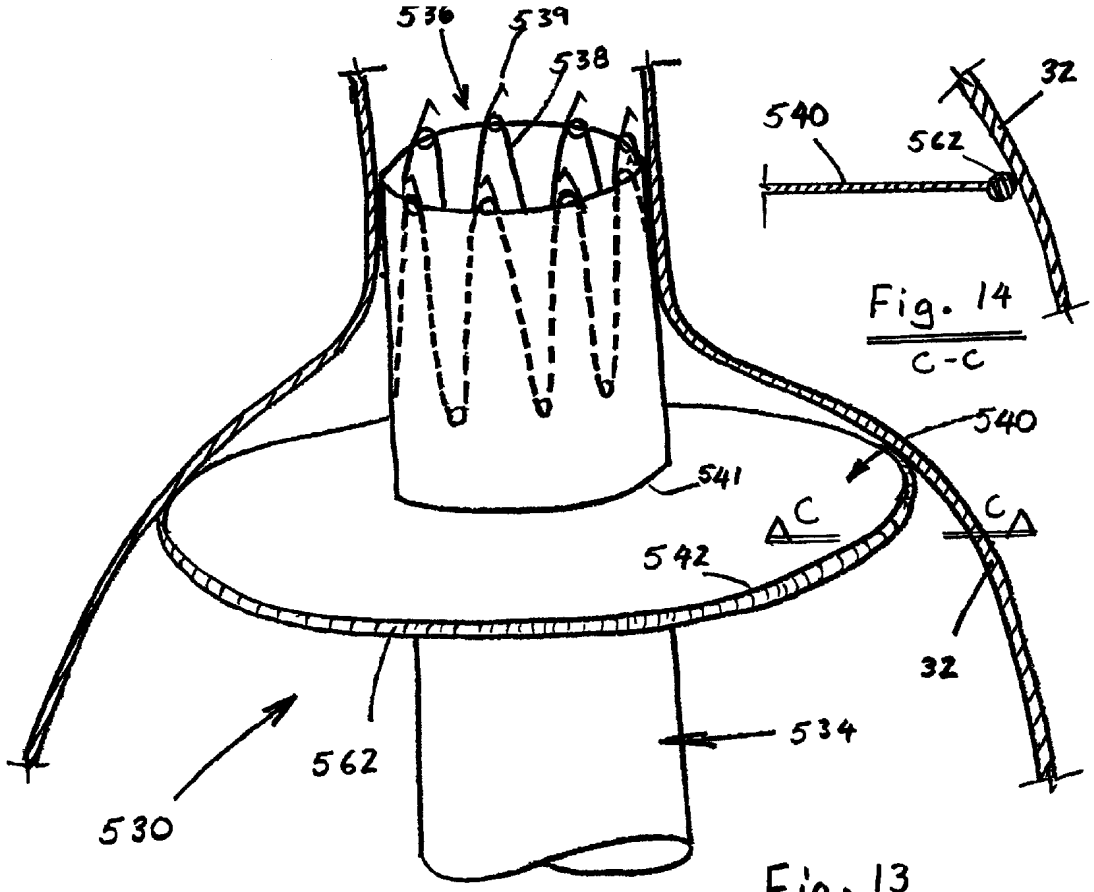



Fig. 13

Fig. 14

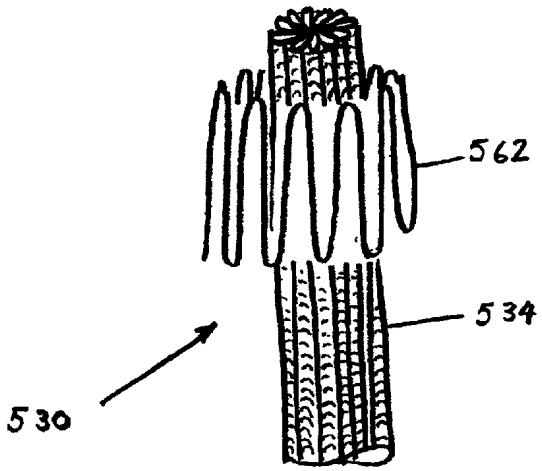



Fig. 15

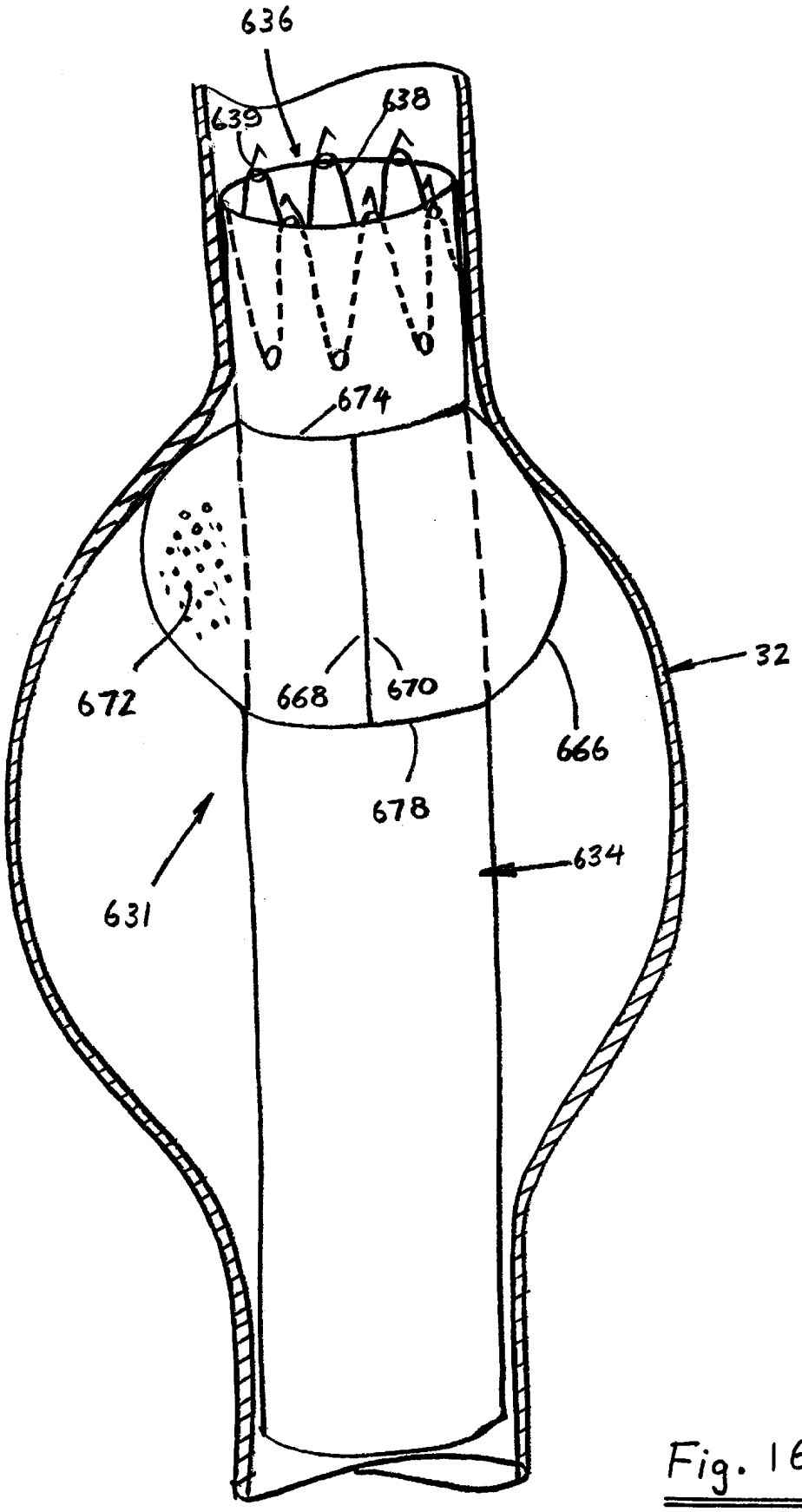



Fig. 16

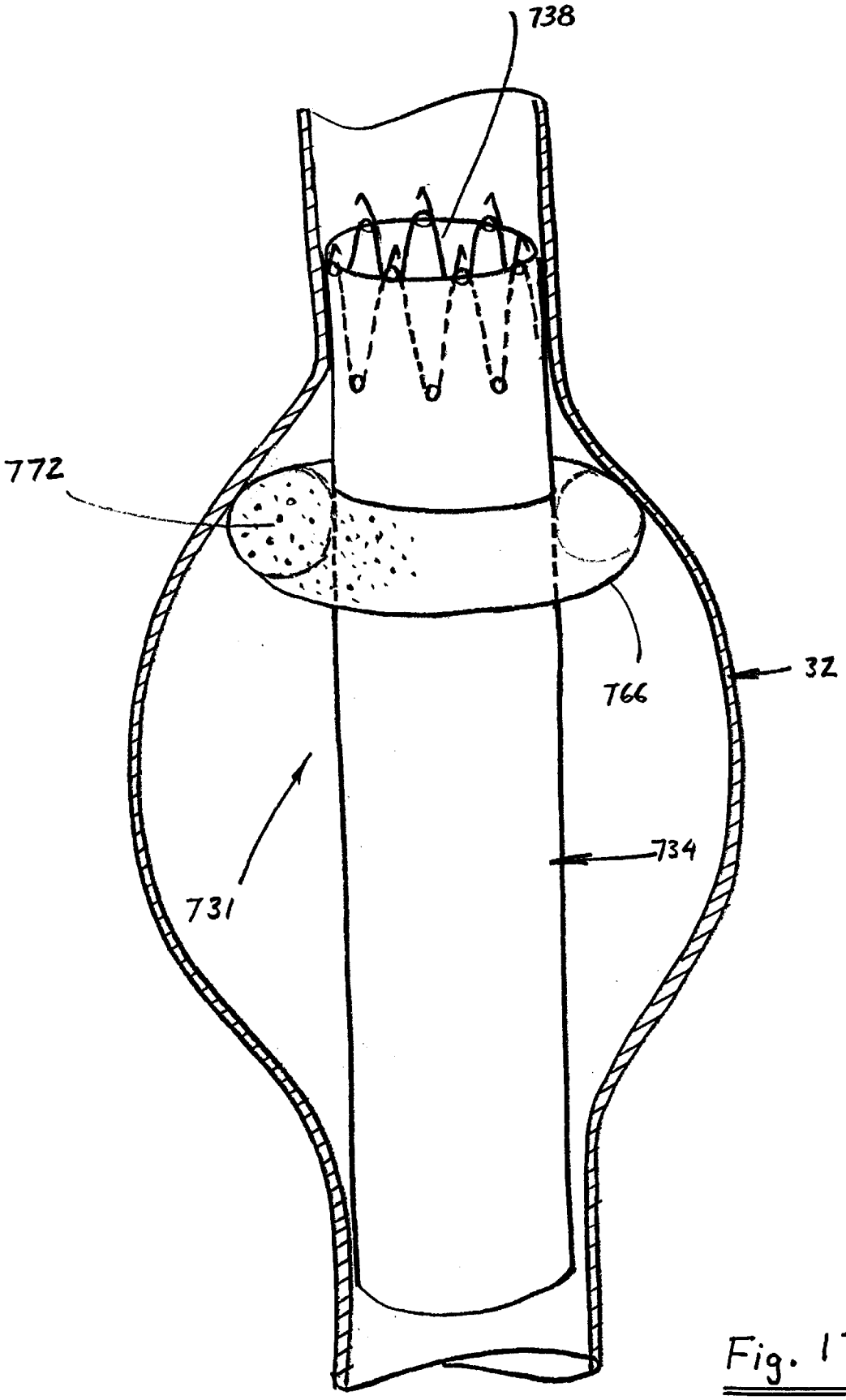



Fig. 17

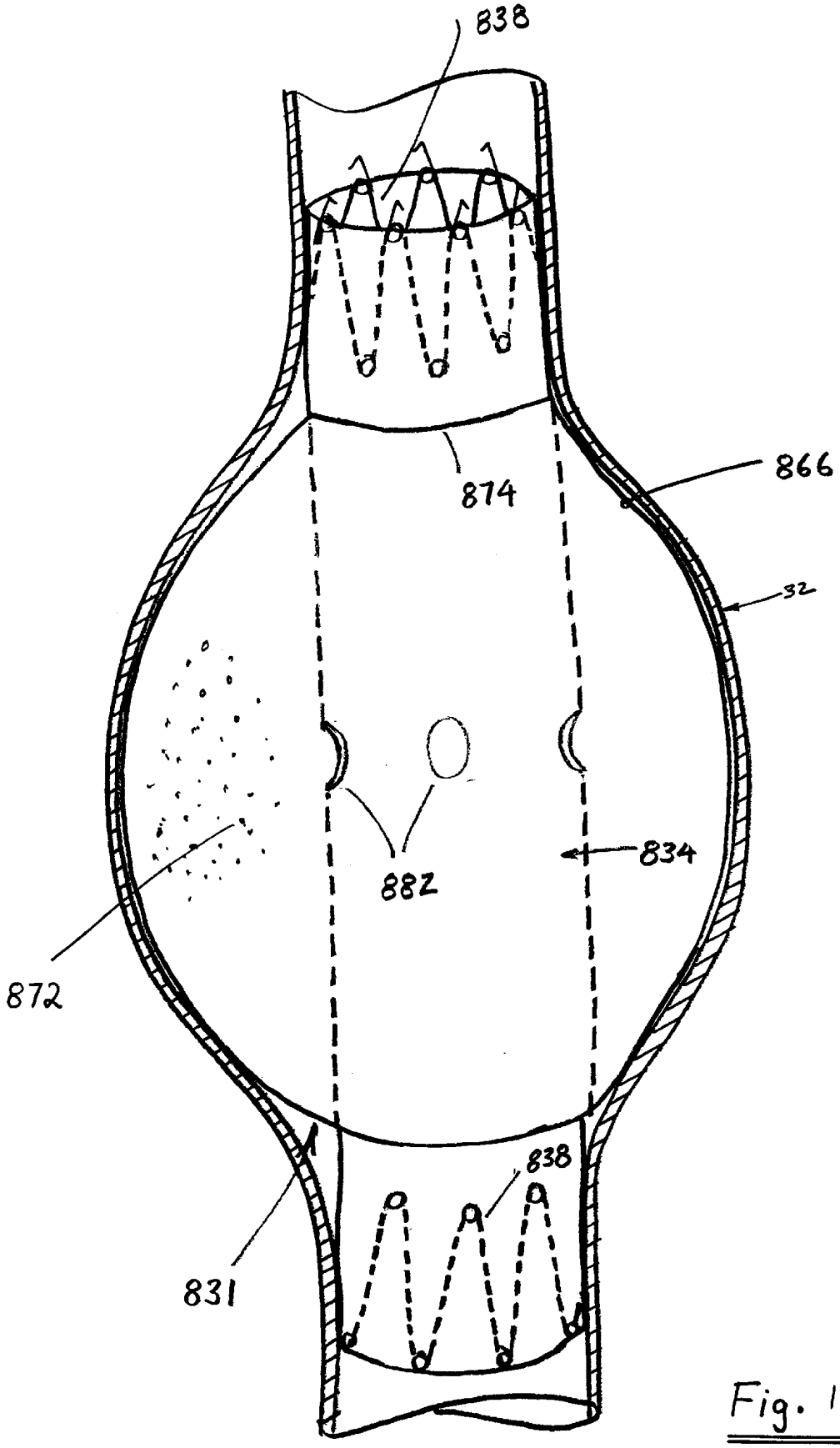



Fig. 18

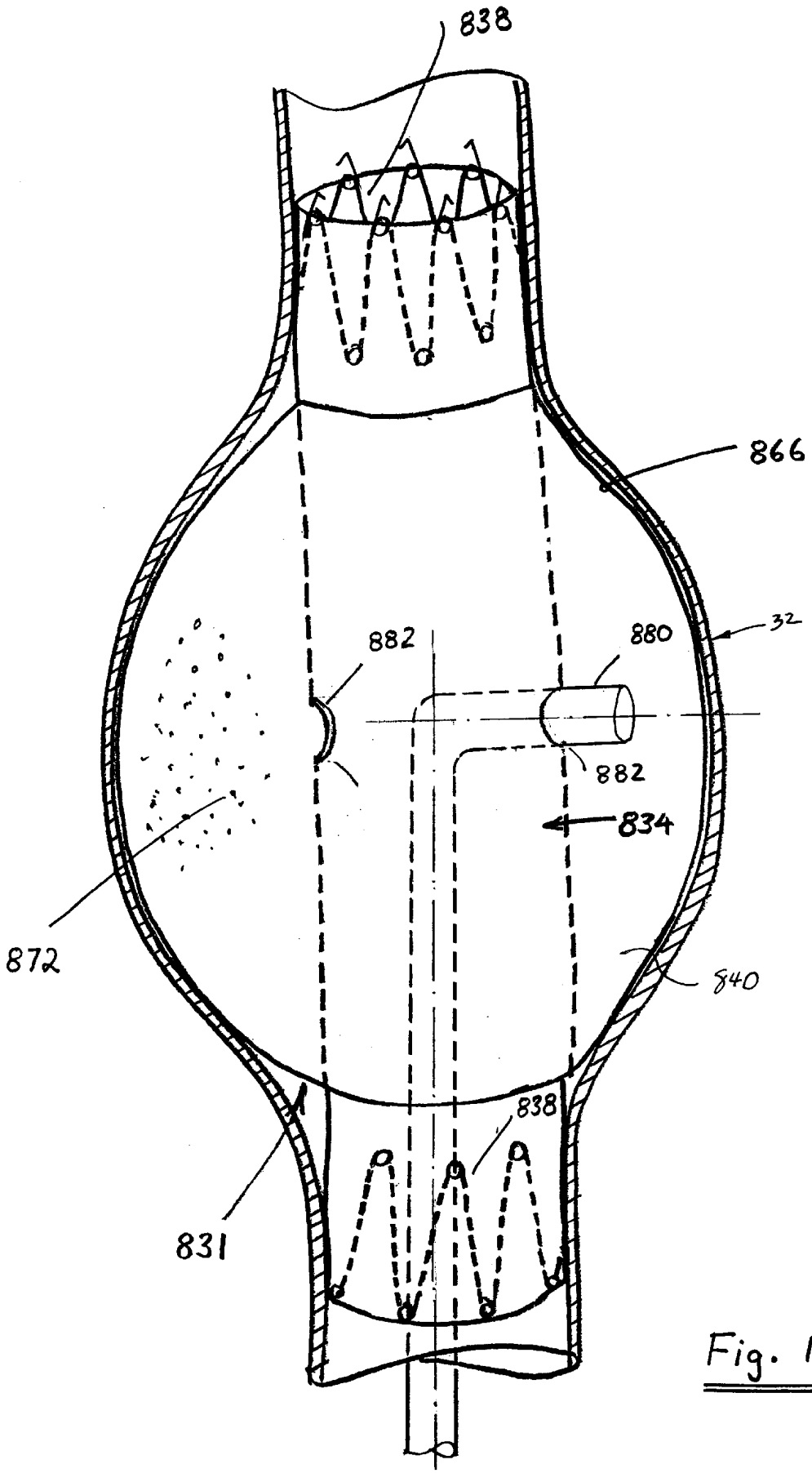



Fig. 19

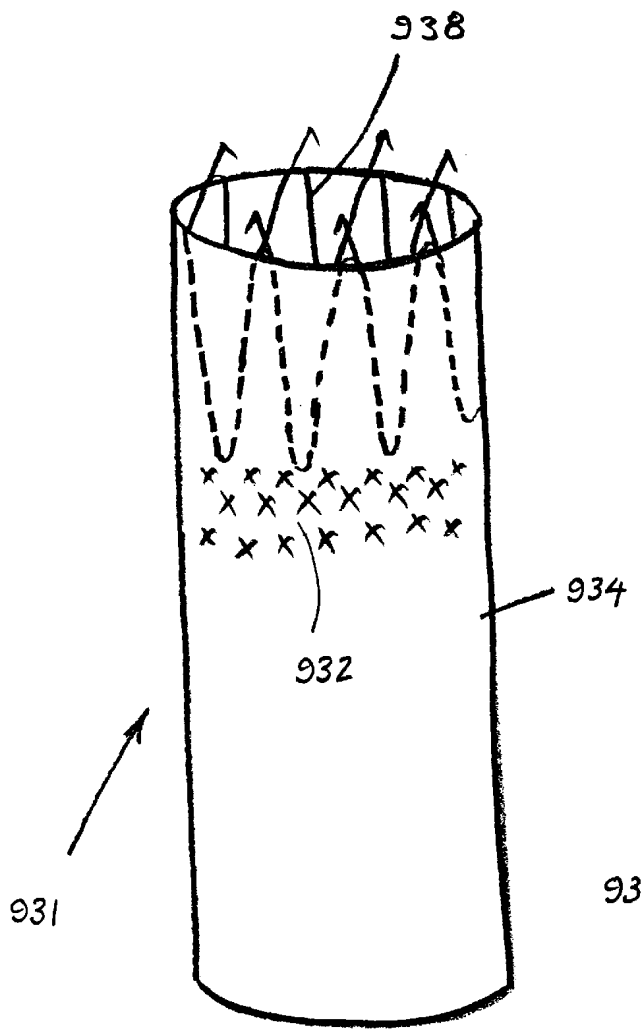



Fig. 20

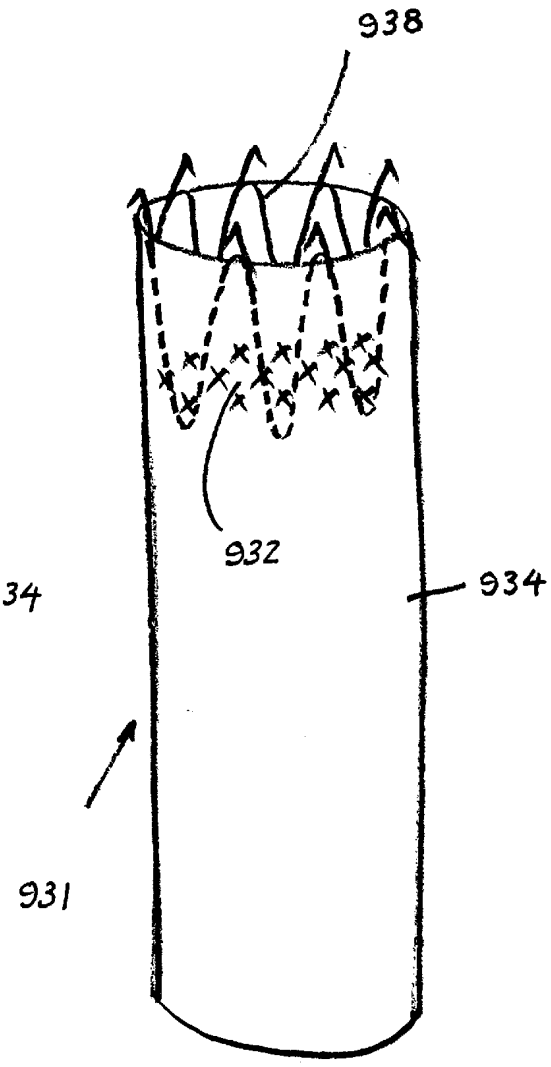



Fig. 21

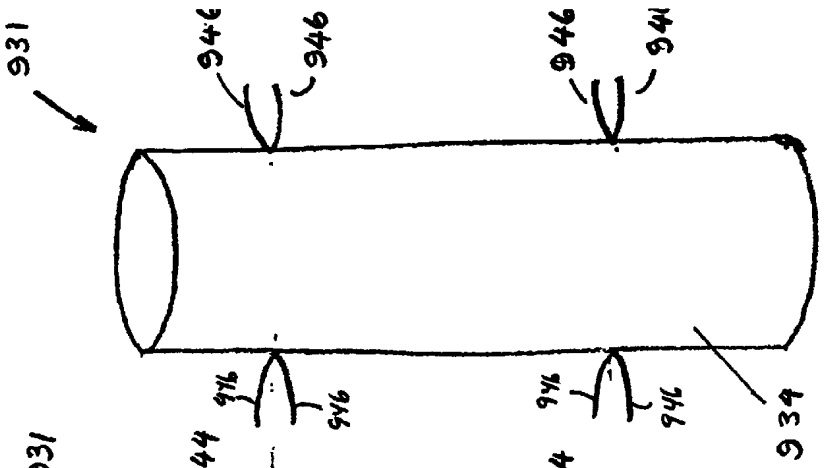



Fig. 24

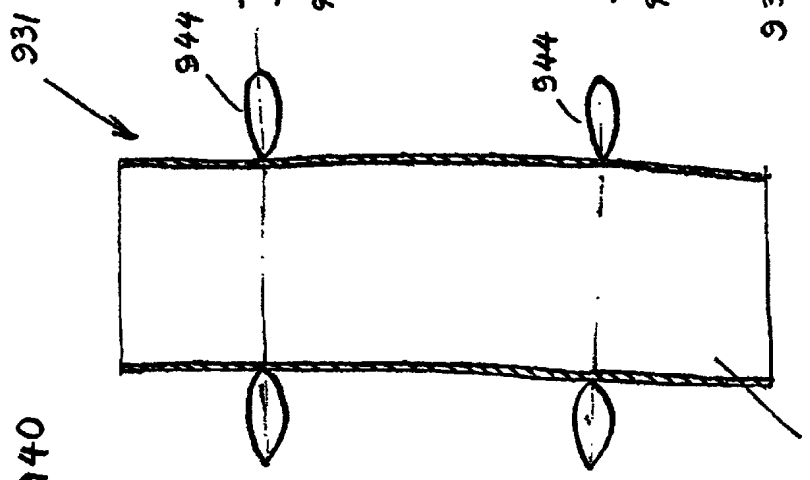



Fig. 23

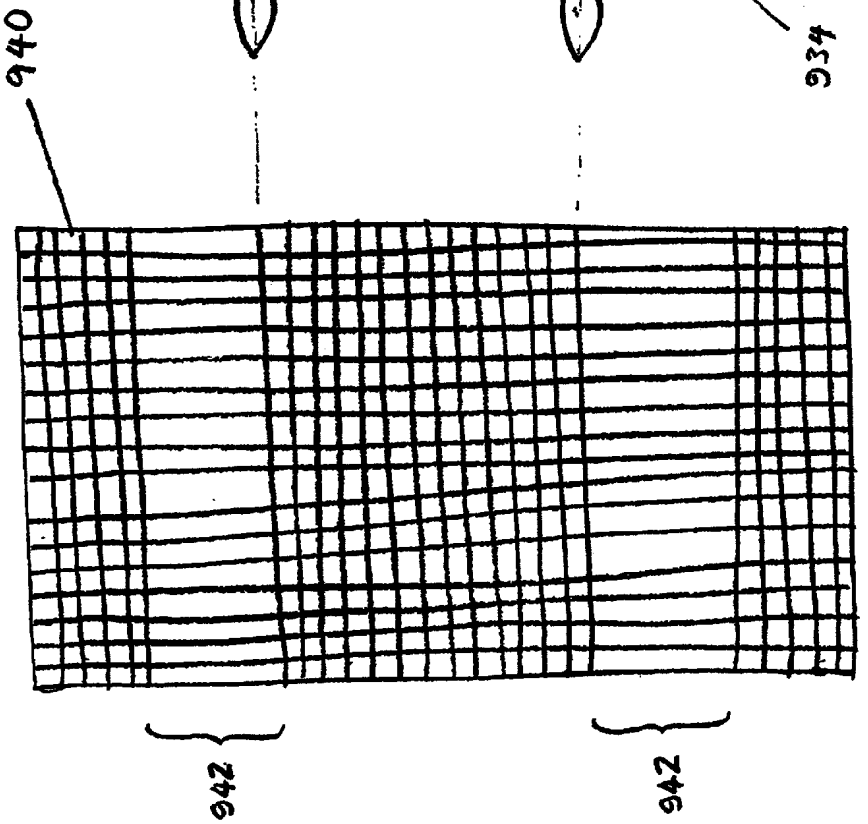



Fig. 22

# ENDOVASCULAR GRAFT FOR PROVIDING A SEAL WITH VASCULATURE

## BACKGROUND OF THE INVENTION

The present invention relates generally to medical devices, and more particularly to methods and apparatus for the endoluminal placement of tubular prostheses, such as grafts, for repairing aneurysms or other vascular defects in humans and animals.

Aneurysms are discrete dilations of the arterial wall, caused by weakening of the arterial wall. One of the most common, and among the most life threatening, is an aneurysm of the abdominal aorta between the renal and iliac arteries. If untreated, the aneurysm dilates progressively with an ever increasing risk of rupture and hemorrhagic death.

One method of treatment is provided by direct surgical intervention, in which the defective vessel may be bypassed or replaced using a prosthetic device such as a synthetic graft. The risks involved in direct surgical intervention of this magnitude are great, and include an extensive recovery period.

In recent years a less invasive method of treatment has evolved through a series of inventions. The details vary, but, conventionally, a resilient tubular conduit fashioned from flexible fabric (herein referred to as a "graft") is introduced into the defective vessel by means of catheters introduced into the femoral artery. The graft is attached to the non-dilated or slightly dilated arteries above and below the aneurysm using expandable metallic cylinders (herein referred to as "attachment systems") which may include barbs or hooks to enhance attachment to the vascular wall.

When an attachment system is positioned on the interior of a graft's lumen, it will tend to cause the outer wall of the graft to press against the inner wall of the vessel, thereby providing the additional function of providing a seal, preventing fluid flow to the region between the graft and the vascular wall.

However, the use of generally cylindrical grafts to reinforce vascular walls in a patient is not without problems. Grafts are required to be compressed into a catheter before being delivered and deployed into final position. Furthermore, grafts compressed into a catheter for delivery must be capable of bending around comers and branches of the patient's vascular system. The graft must accordingly be sufficiently flexible to satisfy these requirements.

One of the challenges encountered with the use of a flexible graft is that, because a diseased vessel is often irregularly shaped, the ends of the graft, even when urged outwardly by an attachment system, may not have a continuous circumferential edge pressed firmly against the inner wall of the vessel. As a result, fluid may leak into or out of (through a branch vessel) the region between the graft and the vascular wall, thereby increasing fluid pressure on the weakened walls of the vessel and reducing the protective effect of the graft. The same problem will occur if, as a result of an error in pre-operative sizing of the diseased vessel, a graft is provided that has a diameter slightly smaller than the diameter of the diseased vessel. Moreover, in the event the target vessel changes shape over time (i.e., increase in neck diameter or shrinkage in aneurysm), perigraft flow may occur. It will be appreciated that in these situations, because the fabric from which grafts are conventionally made is not circumferentially expandable, a complete seal around the circumference of the vessel will likely not be achieved.



Accordingly, there is a need for an improved graft that provides an enhanced seal for substantially preventing the flow of blood into the region between the graft and the vascular wall.

## SUMMARY OF THE INVENTION

Briefly, and in general terms, an intraluminal graft in accordance with the present invention is structured to provide an enhanced seal between the graft and the wall of a lumen within which the graft is implanted. The graft of the present invention generally comprises a tubular member, at least one expandable attachment system connected to the tubular member, and at least one expandable sealing member connected to an exterior wall of the tubular member.

In one aspect of the invention, the graft of the present invention is adapted to be radially compressed to a reduced diameter to facilitate insertion into a patient's vasculature and for advancement within the vasculature to a desired location. The graft is further adapted to be radially expandable from its compressed condition to an expanded condition for engagement with the vascular wall, and thus, the graft is contemplated to be made from a biocompatible material. In further embodiments, the graft may be bifurcated to have left and right branches, each with an opening at an inferior end.

The attachment system of the present invention is configured to have a generally cylindrical profile, and is adapted to be radially compressed to a reduced diameter. The attachment system is radially expandable from its compressed condition to an expanded condition, to facilitate implantation of a graft within vasculature. At least one attachment system is connected to the wall of the graft, at a superior end portion thereof. In further embodiments, additional attachment systems may be connected to the graft to provide additional attachment to the vascular wall as desired.

According to one embodiment of the present invention, a sealing member manufactured from a generally flexible fabric and having a frusto-conical shape is connected to an exterior wall of the tubular member of the graft. The sealing member is supported by a biasing member which may be formed from a generally undulating wire frame configured to provide the frusto-conical profile of the sealing member and to impart an outward bias sufficient to compress the sealing member against the vasculature. The sealing member advantageously provides the graft with the ability to expand to assume the shape of the vasculature at the target site, thereby preventing fluid flow into the region between the graft and the vascular wall.

In a second embodiment of the invention, the graft is configured with a sealing member that is adapted to cooperate with the outward expansion of an attachment system of the graft so that, upon deployment of the graft, the sealing member is moved from a first position remote from the attachment system to a second position overlapping the attachment system. In the deployed state, the sealing member of this embodiment cooperates with fluid flow to enhance the seal between tubular member and vascular wall. Additionally, tufted yarn possibly impregnated with thrombogenic material may be attached to the sealing member, thereby further enhancing the sealing effect.

In a third embodiment, the improved graft is adapted with a sealing member that has a flexible disk configuration. In this embodiment, a generally undulating biasing member provides the sealing member with an outward bias. The outward bias of the wire frame causes the sealing member to be pressed against the wall of the vessel, substantially preventing leakage between sealing member and vascular wall.

In a fourth embodiment, there is provided a disk-shaped sealing member, an outer circular edge of which is configured with a wire hoop biasing member. The wire hoop biasing member is packed into a delivery capsule by folding the hoop into a generally zig-zag shape. When deployed from the delivery capsule, the wire hoop unfolds into a circular profile to thereby substantially prevent leakage between sealing member and vascular wall.

In a fifth embodiment, the sealing member has a toroid shape, the outer surface of which is made from a flexible fabric, and the interior of which may be filled with a thrombogenic material such as polyester filaments. It is to be recognized that the seal fabric may be very thin compared to graft since the seal fabric only needs to initiate clotting. The toroid-shaped sealing member is configured to fill with the patient's blood which will subsequently coagulate with the thrombogenic material, thereby creating a rigid obstacle to the flow of blood between sealing member and the vascular wall. In another aspect of the invention, thrombogenic filling material may be introduced into the toroid-shaped interior of the sealing member after the graft has been delivered to a desired position in the patient's vasculature. Additionally, small apertures may be created in a wall between the graft and sealing member so that the sealing member fills with blood flowing from the interior of the graft.

In a sixth embodiment, the sealing member may be formed entirely from tufts of yarn which are fixed to the outer surface of the graft. A method of manufacturing such a graft is also disclosed.

Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross-sectional view, depicting one embodiment of a graft of the present invention, configured with a frusto-conical sealing member;

FIG. **2** is a cross-sectional view, taken along line A—A of FIG. **1**;

FIG. **3** is a perspective view, depicting an alternative embodiment of an attachment system;

FIG. **4** is a perspective view depicting a biasing member;

FIG. **5** is a perspective view, depicting a second embodiment of a graft configured with a frustrum-shaped sealing member;

FIG. **6** is a top view of the graft shown in FIG. **5**;

FIG. **7** is a perspective view of the graft shown in FIG. **5** in a deployed state;

FIG. **8** is a top view of the graft shown in FIG. **7**;

FIG. **9** is a perspective view, depicting a variation of the embodiment of the graft of FIG. **5**;

FIG. **10** is a perspective view of the graft shown in FIG. **9** shown in a deployed state;

FIG. **11** is a cross-sectional view, depicting a third embodiment of the graft of the present invention configured with a disk-shaped sealing member;

FIG. **12** is a sectional view taken along lines B—B of FIG. **11**;

FIG. **13** is a perspective view, depicting a fourth further embodiment of the graft of the present invention, configured with a disk-shaped sealing member;

FIG. **14** is a sectional view taken along lines C—C of FIG. **13**;

FIG. **15** is a perspective view of the graft shown in FIG. **11**, in a compressed condition;

FIG. **16** is a cross-sectional view, depicting a fifth embodiment of the graft of the present invention configured with a toroid-shaped sealing member;

FIG. **17** is a cross-sectional view, depicting the graft of the present invention configured with a variation of a toroid-shaped sealing member;

FIG. **18** is a cross-sectional view, depicting the graft of the present invention configured with another variation of a toroid-shaped sealing member;

FIG. **19** is a cross-sectional view, showing the graft of FIG. **18** with a tube disposed therein;

FIG. **20** is a perspective view, depicting a sixth embodiment of the graft of the present invention configured with tufts;

FIG. **21** is a perspective view, depicting a variation of the graft shown in FIG. **20**;

FIG. **22** is a side view, depicting a graft of the present invention;

FIG. **23** is a cross-sectional view, depicting a manufacturing step involving the graft shown in FIG. **22**; and

FIG. **24** is a perspective view of the graft shown in FIG. **23** after further processing.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In general, the present invention involves configuring a graft with a sealing member that operates to occupy spaces between the graft and a lumen into which the graft is implanted. The preferred embodiments of the improved graft are described below. Although the descriptions set forth below generally relate to configuring a proximal end of a graft with a sealing member, the improvement may be applied to the distal end of a graft as well. Where the graft is bifurcated, the disclosed sealing members may be applied to any or all of the ends of such a graft. The term "proximal" as used herein shall mean upstream, while "distal" shall mean downstream.

FIG. **1** exemplifies a proximal end portion of one embodiment of a graft **30** of the present invention positioned within a vessel **32** of a patient. The vessel **32** is shown to expand from a relatively narrow diameter healthy section to a dilated section where the tissue is diseased. The improved graft **30** comprises a tubular member **34** having a proximal end **36** and distal end (not shown in FIG. **1**), at least one expandable attachment system **38**, and a generally frustrum-shaped sealing member **40** supported by a biasing member **44**. The attachment system **38** is connected to the tubular member **34** adjacent the proximal end **36** of the graft **30**.

As shown in FIGS. **1** and **2**, the sealing member **40** includes an inner circumferential edge **41** and an outer circumferential edge **42**, the inner circumferential edge **41** being connected to an outside surface of the tubular member **34**. In one embodiment, the point of connection between the sealing member **40** and tubular member **34** is longitudinally separated from the attachment system **38**, so as to minimize the outer profile of the graft assembly **30** when it is compressed for insertion into vasculature.

The tubular member **34** and the sealing member **40** are contemplated to be manufactured from any flexible surgical implantable material such as Dacron™ which is known to be sufficiently biologically inert, non-biodegradable, and durable. One material found to be satisfactory is DeBakey soft woven Dacron™ vascular prosthesis (uncrimped) sold

by USCI. In order to prevent the woven material from unraveling at the ends, the ends can be melted with heat to provide a small melted bead of Dacron™.

The attachment system **38** may be either self expanding or balloon-expanded, and may be connected, preferably, but not necessarily, to an inner wall of the tubular member **34**. As shown in FIG. **1**, the attachment system **38** may have a plurality of hooks **43** connected to it to enhance attachment to the vascular wall. The attachment system **38** is made from a wire formed into an undulating configuration defining opposing apices. In a preferred embodiment, the apices include helical springs **45**.

With reference to FIG. **3**, there is shown an alternative embodiment of an attachment system **46**. In this embodiment, the attachment system **46** includes hooks **47** which are integrally formed at proximal apices **48**. The attachment system **46** is further characterized by having a semi or generally flat wire configuration, in that members **49** have a depth that is greater than its width. In a preferred method of manufacture, the flat wire attachment system **46** is contemplated to be laser cut from a tube.

With reference to FIG. **4**, the biasing member **44** may be formed from a wire which follows a generally undulating path, producing a plurality of alternating inner apices **56** and outer apices **58** which are joined by connecting members or legs **60**. The biasing member **44** has a generally frusto-conical profile and is shown connected to the inside surface of the sealing member **40**; however, it can alternatively be attached to an outside surface. The biasing member **44** serves to urge the sealing member **46** from a first compressed position to a second expanded position. When the biasing member **44** is compressed stored energy tends to urge legs **60** and apices **56**, **58** radially outward in a direction generally at a right angle to a longitudinal axis of the device. The biasing member **44** provides a continuous and outwardly directed urging force, pressing the sealing member **40** against the diseased vascular wall **32**, to thereby obstruct the flow of blood into the region between the tubular member **34** and the vascular wall **32**.

The generally undulating shape of the wire frame forming the biasing member **44** also serves to facilitate compression of the biasing member **44** when it is placed within a delivery capsule (not shown). The compression of the biasing member **44** may be accomplished by compressing the biasing member **44** within its elastic limit. Placing selected inner and outer apices **45** in different planes aids in reducing the size to which the biasing member **44** can be compressed. Additionally, incorporating helical springs **62** at the apices **56**, **58** aids in the self-expansion of the biasing member **44**. For tubular members **34** configured with larger diameter sealing members **40**, the biasing member **44** can be provided with additional apices **56**, **58** to enhance the sealing effect.

The biasing member **44** may be formed of a corrosion resistant material that has good spring and fatigue characteristics. One such material found to be particularly satisfactory is Elgiloy™ which is a chromium-cobalt-nickel alloy manufactured and sold by Elgiloy of Elgin, Ill. Another suitable material is Nitinol.

It will be appreciated that the biasing member **44** has the ability to automatically adjust to various shapes of diseased vessel walls **32** or changes in anatomy shape or position over time. This ability is an important design feature, because it may not be possible to accurately predict the shape of the diseased vessel **32** into which the improved graft **30** is delivered, and also because the wall of the diseased vessel **32** may undergo changes in shape due to cardiac pulsation or other movements of the patient. By adjusting to the actual profile of the diseased vessel wall **32**, the biasing member **44** and the sealing member **40** substantially prevent leakage of blood into the region between tubular member **34** and vessel wall **32**.

The biasing member **44** may be secured to the sealing member **40** by suitable connecting means **65**, such as Dacron™ polyester sutures, by which the biasing member **44** may be sewn or stitched onto the sealing member **40**. Connection can be accomplished by sewing suture material into and out of the wall of the sealing member and by forming knots on one or more of the biasing member's legs **50**. The attachment system **38** may be similarly connected to the tubular member **34** using polyester suture connecting means **65**.

Turning now to FIGS. **5–8**, another embodiment of an improved graft **130** of the present invention is described. The graft **130** embodies a tubular member **134**, an attachment system **138**, and a sealing member **140**. The attachment system **138** may embody the undulating wire or flat wire configuration described above, or any other suitable expandable frame arrangement. The attachment system **138** is connected to the tubular member **134**, adjacent a proximal end thereof.

The sealing member **140** has a generally frusto-conical shape with an inner circumferential edge **141** and an outer circumferential edge **142**. The inner circumferential edge **141** is connected at an outside surface of the tubular member **134**. Additionally, pieces of tufted yarn **157**, preferably impregnated with a thrombogenic substance, may be attached to the sealing member **140**. The point of connection between tubular member **134** and sealing member **140** is preferably positioned medical to the attachment system **138** to keep the compressed diameter of the assembly small.

As shown in FIGS. **5** and **6**, to facilitate packing the improved graft **130** into a delivery tube device (not shown), the tubular member **134** and sealing member **140** are positioned in first compressed conditions, wherein the outer circumferential edge **142** of the sealing member **140** is folded away from the proximal end **136** of the tubular member **134**. Folding the sealing member **140** in this manner has the advantage of reducing the overall outside profile of the graft assembly **130** when it is placed in a compressed condition. At least one thread **154** with first end **156** and second end **158** (See FIG. **8**) is provided and are attached to the outer circumferential edge **142** of the sealing member **140**. The second ends **158** of the threads **154** are first passed sequentially through a number of the outer eyelets **151** formed at the proximal apices of the attachment system **138**, and are then connected to the graft **130**. It is contemplated that a monofilament polypropylene thread **154** can be employed, and that the optimal number of threads to use in order to avoid entanglement is three.

It will be appreciated that when the graft **130** is deployed from its compressed condition and the attachment system **138** is activated to expand outward, the first ends **156** of the threads **154**, together with the outer edge **142** of the sealing member, are pulled toward the proximal end **136** of the tubular member. Thus, the sealing member **140** in its deployed state, overlaps the attachment system **138** to thereby benefit from the outward bias of the attachment system **138** and to sealingly engage the vasculature. It will be appreciated that the tufted yarn **157** attached to the sealing member **140** can enhance the seal with the vascular tissue when compressed against the tissue by the attachment system **138**. Additionally, it is also to be recognized that the

tubular yarn **157** may also bunch up at the attachment system **138** and still work as intended.

The number of outer eyelets **151** through which the second ends **158** of the threads **154** are passed will depend on the displacement required to move the outer circumferential edge **142** of the sealing member from its first undeployed position to its final deployed position. The amount of proximal axial displacement that the first end **156** of each thread will experience upon expansion of the attachment system may be expressed as $(D_{expanded}-D_{compressed})*\theta_{wrap}/2$, where $D_{expanded}$ is the diameter of the attachment system **138** in expanded condition, $D_{compressed}$ is the diameter of the attachment system **138** in compressed condition, and $\theta_{wrap}$ (See FIG. **8**) is the angle (in radians) extended to the center of the attachment system by that portion of thread **154** which winds around the circumference of the attachment system passing through the eyelets **151**.

A variation of the graft **130** shown in FIGS. **5–8** is depicted in FIGS. **9** and **10**. In this embodiment, a first end **256** of each thread **254** is connected to a point on the sealing member **240** between an inner edge **241** and an outer edge **242**. It will be appreciated that as so configured, the sealing member **240** will be pulled proximally as the attachment system **238** expands, but that the outer edge **242** will extend distally of the point of connection between thread **254** and sealing member **240**. Thus, in a deployed condition, there are two layers of fabric between a vascular wall and the tubular member **230**. Consequently, a thicker layer of tufted material **257** may be sandwiched between the vascular wall and the tubular member **230** to facilitate forming a seal.

With reference to FIG. **11**, another embodiment of an improved graft **430** of the present invention is shown. In this embodiment, the tubular member **434** and attachment system **438** have a similar configuration as the same of the previously described embodiments. The tubular member **434** is connected to a sealing member **440** supported by a wire frame biasing member **444**. The sealing member **440** may be made from the same flexible material as the sealing members of the previous embodiments, allowing the sealing member to assume both a compressed condition and an expanded condition. The sealing member **440** of this embodiment, however, has a disk shape with an inner circumferential edge **441** and an outer circumferential edge **442**.

As exemplified in FIG. **12**, the inner circumferential edge **441** of the sealing member **440** is continuously connected to an outer surface of the tubular member **434**. The point of connection between tubular member **434** and sealing member **440** is preferably positioned so as not to coincide with the attachment system **438**. The wire frame biasing member **444** may be made of the same wire material as the biasing members of the previous embodiments and accordingly, may have a frusto-conical shape. Alternatively, as shown in FIG. **11**, it is contemplated that the biasing member **440** can define a generally cylindrical expanded profile, with alternating inner apices **446** and outer apices **448** joined by struts **450**. When the wire frame **444** is compressed, stored energy tends to urge the struts **450** and apices **446**, **448** of the wire frame **444** radially outward.

The inner apices **446** of the wire frame biasing member **444** is attached to the outer circumferential edge **442** of the sealing member **440**, the outer apices **448** being allowed to protrude in an inferior direction. The biasing member **444** is adapted to provide an outward bias to the sealing member **440**, thereby causing the outer edge **442** of the sealing member **440** to press against the diseased vascular wall **32**, and substantially prevent leakage of blood between the tubular member **434** and the vascular wall **32**.

As shown in FIGS. **13–15**, another embodiment of a graft **530** of the present invention includes a disk-shaped sealing member **540**. In this aspect of the invention, the sealing member **540** may be supported by a wire hoop **562** with a generally radially outward spring bias. The outer circumferential edges **542** of the sealing member **540** is contemplated to be connected to the wire hoop **562**. Connection may be achieved by any suitable means such as by stitching the two elements together with polyester filaments.

As shown in FIG. **15**, the wire hoop **562** may be compressed for loading into a delivery capsule (not shown), by configuring the hoop **562** into a generally zig-zag shape. The wire hoop **562** may be made of a corrosion resistant material with good spring properties, such as Nitinol™. The wire hoop **562** is fabricated to have a diameter slightly larger than that of the blood vessel **32**, so as to provide a continuous contact therewith and to substantially prevent leakage of blood between tubular member **534** and a vessel wall **32**.

Yet a further embodiment of an improved graft **631** is shown in FIG. **16**. The graft **631** of this embodiment includes a tubular member **634** as well as an attachment system **638** similar to that of the previous embodiments. In this embodiment, a toroid-shaped sealing member **666** which may be made from thrombogenic material, is fixed to an outer wall of the tubular member **634**. The sealing member **666** may be sufficiently porous to permit blood to percolate through it. A compressible thrombogenic material **672** may be introduced into an interior of the toroid-shaped sealing member **666**. When deployed in the patient, it is contemplated that blood will slowly permeate through the porous fabric of the sealing member **666** and coagulate with the thrombogenic material **672** to thereby stiffen the sealing member **666**. This results in forming a seal between the tubular member **634** and the vascular wall **32**.

Further, it is contemplated that the sealing member **666** may be made from planar fabric which is initially generally rectangular, with superior ends **674** and inferior ends **678** and two lateral edges **668**, **670**. The superior **674** and inferior ends **678** are continuously circumferentially connected to the outer wall of the tubular member **634**. The lateral edges **668**, **670** are connected to each other, thereby forming an enclosed toroid-shaped space in which the wall of the tubular member **634** partly encloses the toroid-shaped space. This form has the advantage of minimizing the number of fabric layers the graft **631** will have in its compressed condition.

In another form of the toroid-shaped sealing member **766** (FIG. **17**), the sealing member **766** may be fabricated independently of the graft **731**, as a complete toroid, which is then connected to an outer wall of the tubular member **734**. In yet another form of the toroid-shaped sealing member **866** (FIG. **18**), the sealing member **866** may be formed to occupy the majority of the region between the vascular wall **32** and the tubular member **834**. In each of the embodiments, attachment systems **738**, **838** like those described above can be employed to affixed inferior as well as distal ends of the graft devices **731**, **831** to vasculature. Additionally, in each of the embodiments, holes **882** (See FIG. **18**) may be configured in the material defining the graft so that the sealing member fills with blood flowing through the graft.

Turning now to FIG. **19**, there is shown a feed-tube **880** configured to protrude through an aperture **882** formed in the tubular member **834** of the graft **831** to gain access to an

internal cavity defined by the sealing member **840**. The aperture **882** may be preformed or it can be made by the feed-tube **880** piercing the graft. It is contemplated that such a feed-tube **880** can be used to deliver thrombogenic material to the repair site. The feed-tube **880** may be delivered by a delivery catheter simultaneously with delivery of the improved graft, and may be removed simultaneously with the catheter. Alternatively, the feed-tube **880** can be advanced within the graft **831**, after the graft **831** has been deployed within vasculature.

In another embodiment (See FIGS. **20** and **21**), the graft **931** of the present invention includes a sealing member that is formed from tufted yarn **932**, which may be impregnated with thrombogenic substance to induce coagulating, and which is affixed to an outer wall of the tubular member **934** of the graft **931**. When the graft is deployed in a diseased vessel (not shown), the tufted yarn **932** operates to fill spaces between the vascular wall and the tubular member **934**, thereby substantially forming a seal. In one form of the improved graft **931** having a tufted-yarn sealing member **934**, the yarn **932** may be located on the outer surface of the tubular member **934** distal to the attachment system **938** (FIG. **20**). In another aspect, the tufted-yarn sealing member **931** is located on the outer surface of the graft **931** between members defining the attachment system **938** (See FIG. **21**).

The tufted-yarn sealing member **932**, may simply be attached to an outer wall of the graft **931** by stitching the yarn onto the wall of the tubular member **934**. The tufts of yarn may be made from the fabric making up the tubular member **934** itself. The fabric **940** (See FIG. **22**) from which the graft is manufactured may be woven so that weft threads (running horizontally) are omitted from certain zones **942** thereof. The lengths of warp threads (running vertically) which are not connected to each other by weft threads are pulled radially outward to form a loop **944** (See FIG. **23**). The loops of warp thread **944** are cut at the apex of each loop **944**, leaving single linear strands of yarn **946** (See FIG. **24**) circumferentially protruding from the tubular member **934**. The yarn threads may be frayed to provide maximum surface area and if desired, impregnated with a thrombogenic substance.

It will be apparent from the foregoing that, while particular forms of the invention disclosed herein have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

We claim:

**1**. A method for constructing a graft, comprising the steps of:

weaving a tubular member from fabric having weft threads and warp threads;

omitting weft threads from a portion of the fabric to thereby create warp threads unconnected to weft threads;

pulling radially outward, into loops, the warp threads which are unconnected to weft threads; and

connecting adjacent circumferential edges of fabric containing both weft threads and warp threads.

**2**. The method of claim **1**, further comprising the step of cutting the ends of the loops to create tufts of thread.

**3**. The method of claim **2**, further comprising the step of fraying the tufts of thread.

**4**. The method of claim **3**, further comprising the step of impregnating the tufts of thread with a thrombogenic substance.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

# CERTIFICATE OF CORRECTION

PATENT NO. : 6,729,356 B1
DATED : May 4, 2002
INVENTOR(S) : Steven G. Baker et al.



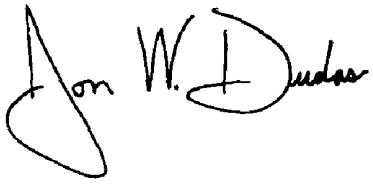
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,
Item [75], Inventors, after the name "**Mark LeMere**", change "Mountain View" to -- San Francisco --

Column 1,
Line 46, change "bending around comers and branches" to -- bending around corners and branches --

Signed and Sealed this

Second Day of November, 2004



JON W. DUDAS
*Director of the United States Patent and Trademark Office*

US 20040082989A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2004/0082989 A1**

**Cook et al.** (43) **Pub. Date: Apr. 29, 2004**

(54) **STENT GRAFT WITH IMPROVED PROXIMAL END**

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(21) Appl. No.: **10/644,129**

(22) Filed: **Aug. 20, 2003**

**Related U.S. Application Data**

(60) Provisional application No. 60/404,662, filed on Aug. 20, 2002.

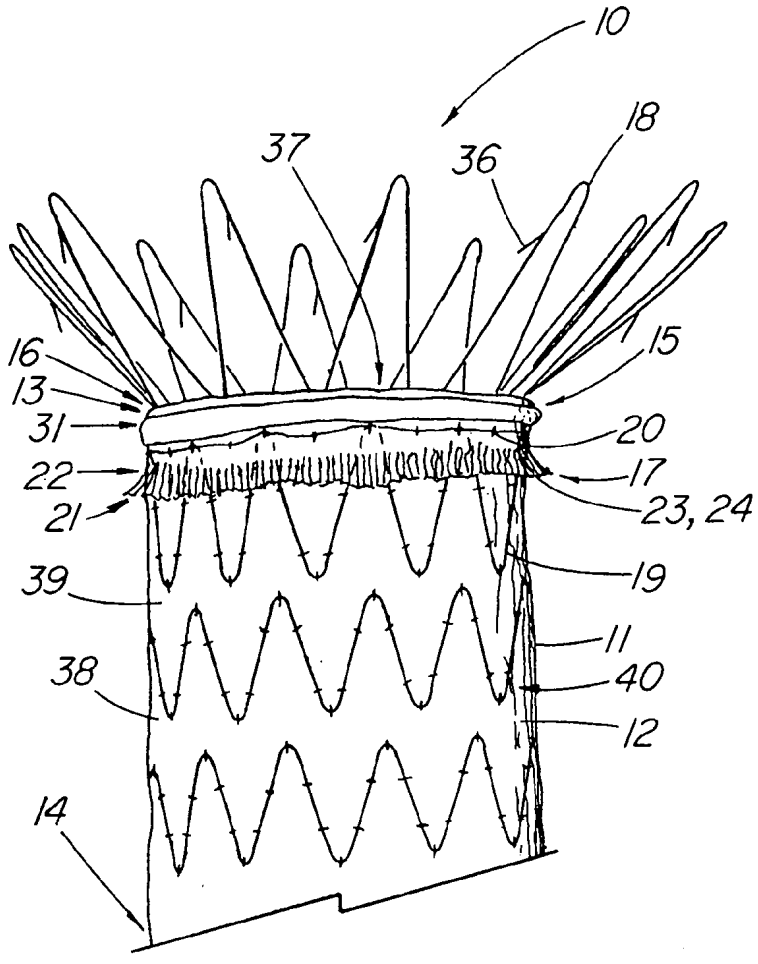
**Publication Classification**

(51) **Int. Cl.**[7] ..... **A61F 2/06**

(52) **U.S. Cl.** ..... **623/1.13**; 623/1.36

(57) **ABSTRACT**

Disclosed is a stent graft prosthesis comprising a graft portion that includes a main body portion and an cuff portion, the cuff portion generally located at or near the proximal end of the main body portion and extending circumferentially therealong. Stents comprising the graft supporting structure are also attached to graft portion about the proximal end. In one embodiment, the cuff portion comprises material that is folded over the outside surface of the main body portion with an anchoring stent being attached over the cuff and main body portions, extending proximally therefrom. In another series of embodiments, the cuff portion comprises an external sealing zone that extends around the outer main body portion to help prevent leakage of fluids. In one example, the material of the second edge of the cuff portion is frayed to better engage the vessel walls and promote thrombus and/or tissue growth.



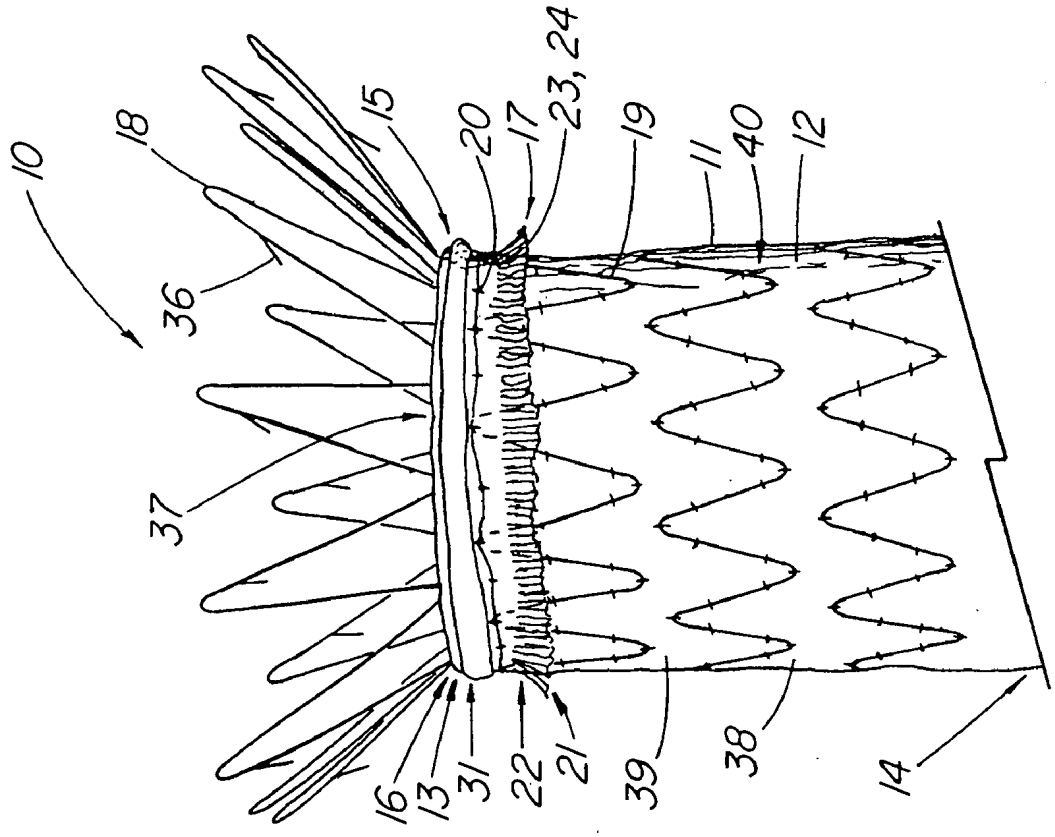

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FIG. 2

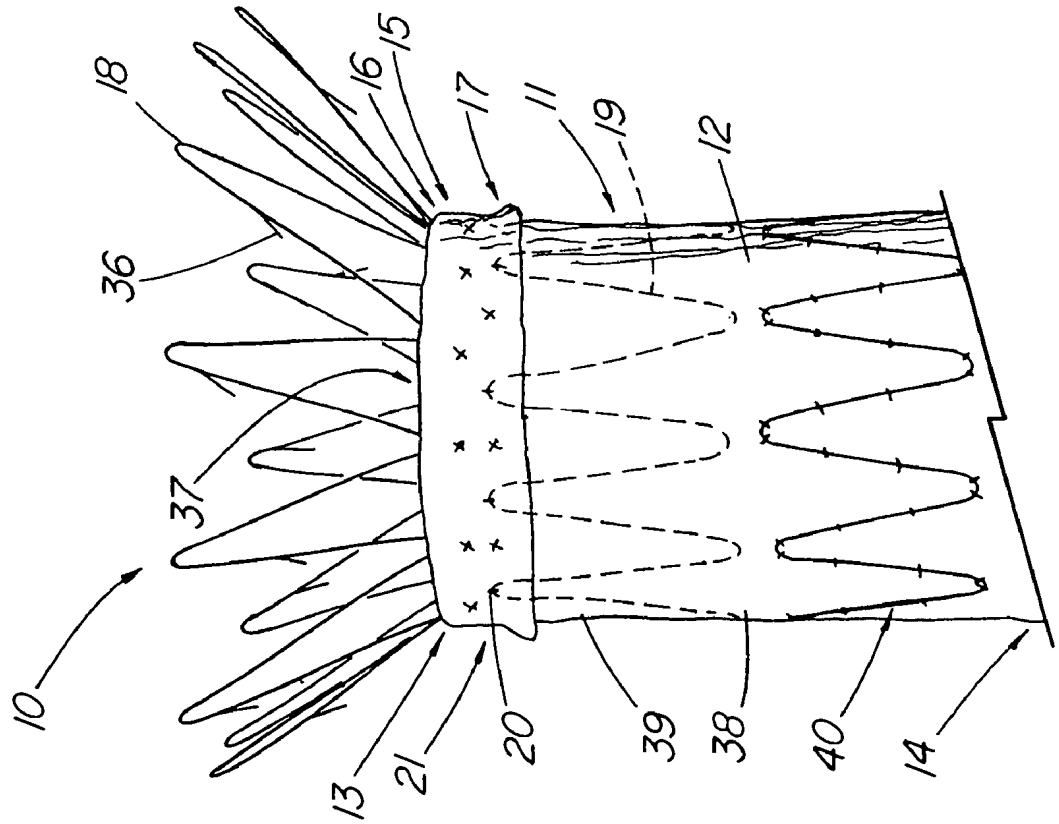
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FIG. 1

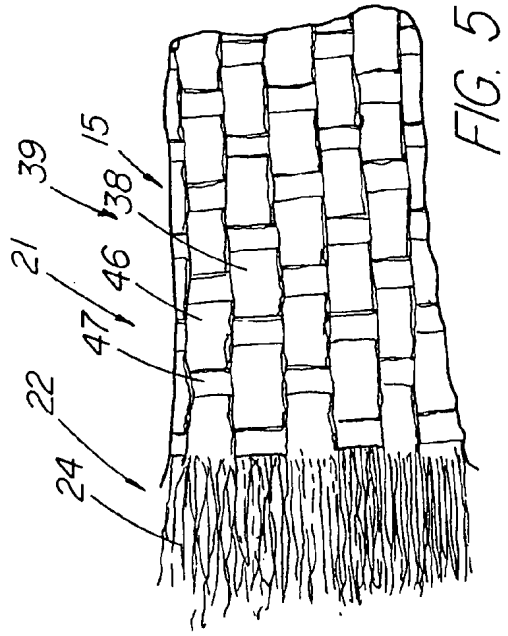



FIG. 5

FIG. 4

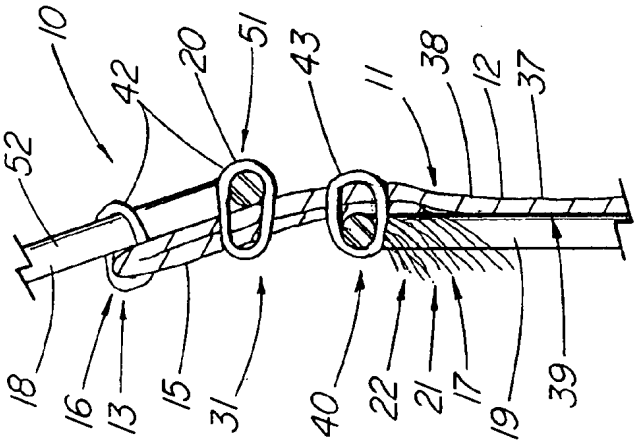
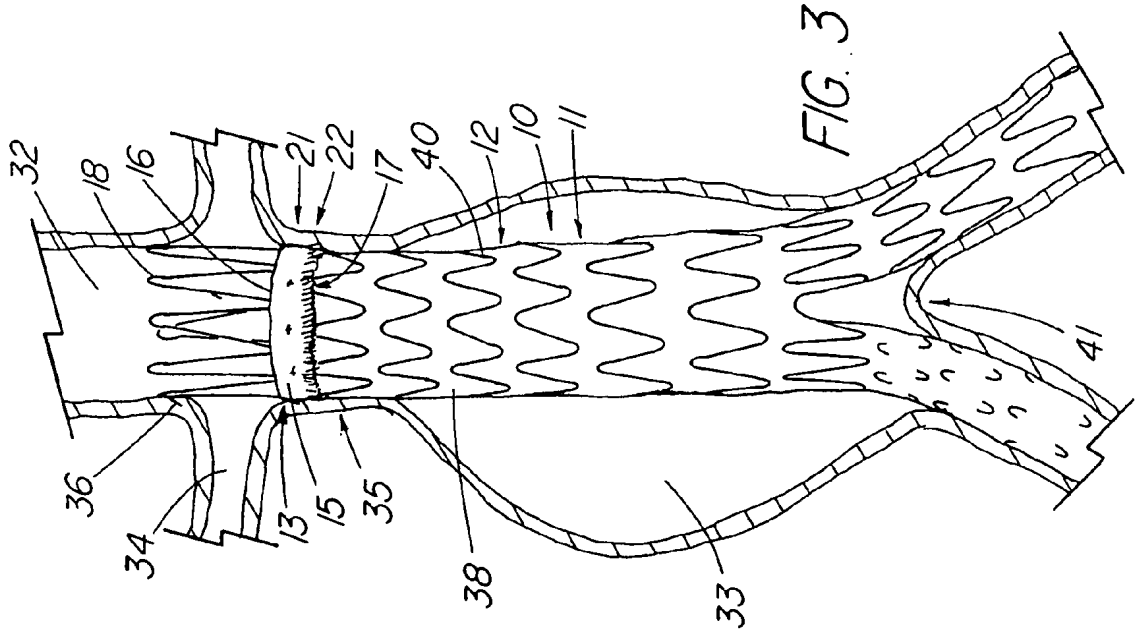



FIG. 3



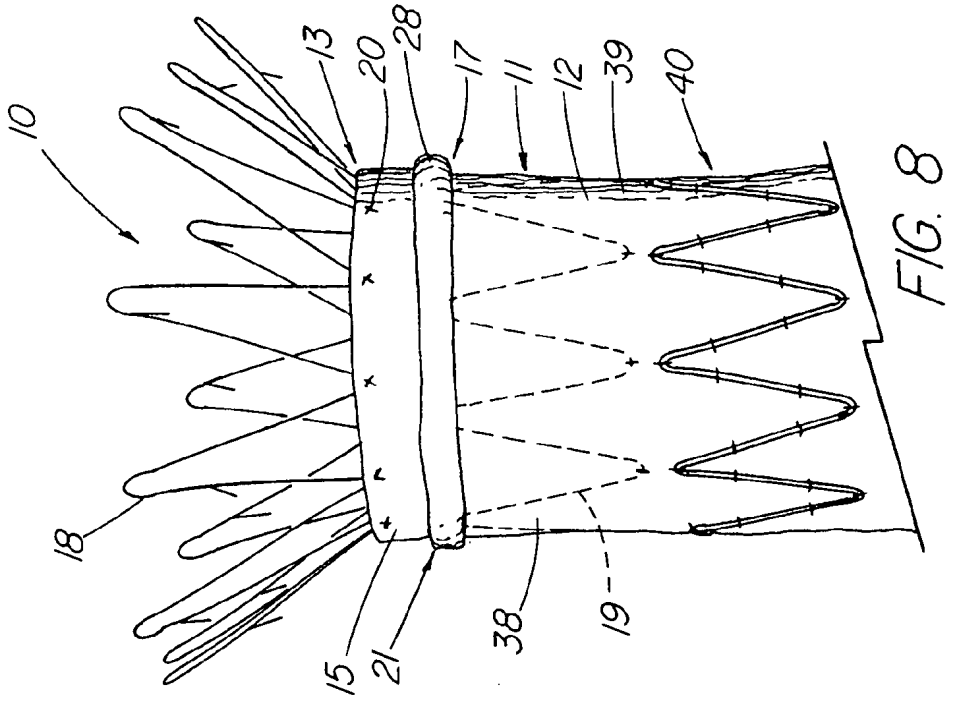



FIG. 8

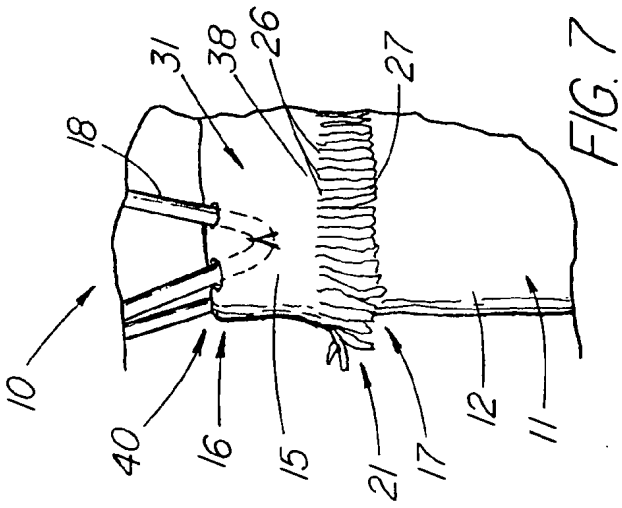



FIG. 7

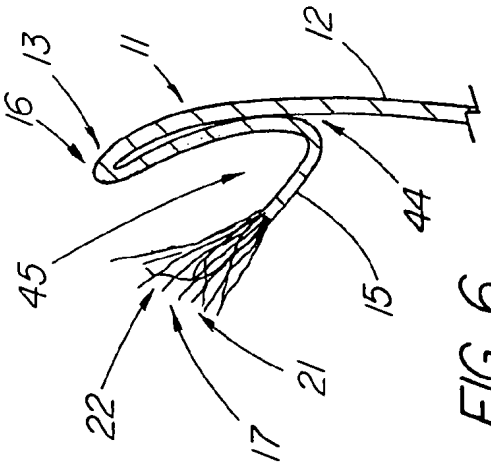



FIG. 6

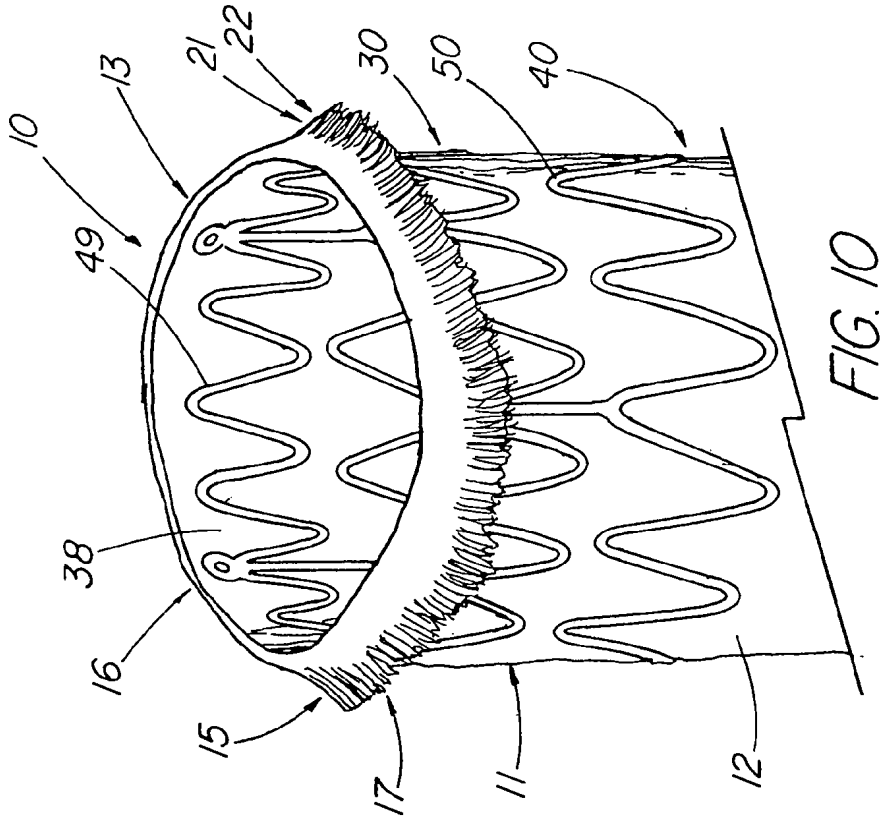



FIG. 10

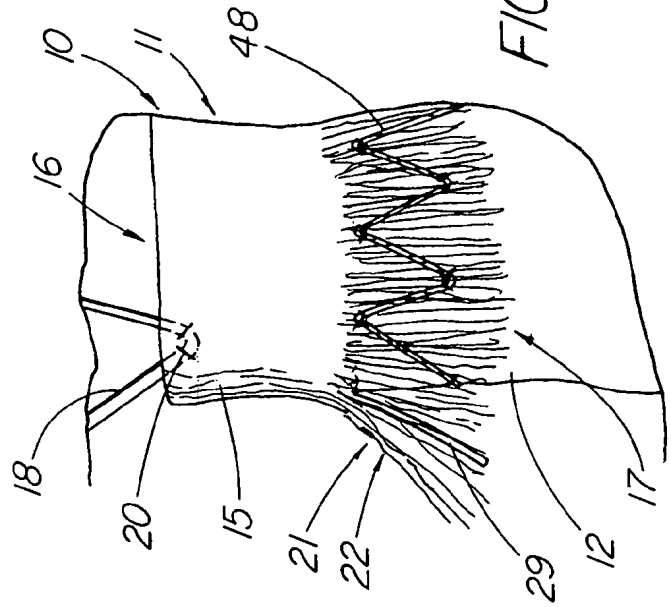



FIG. 9

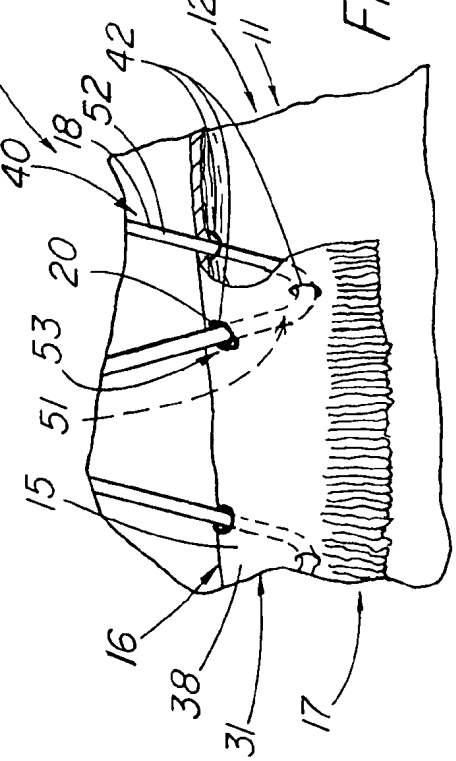



FIG. 11

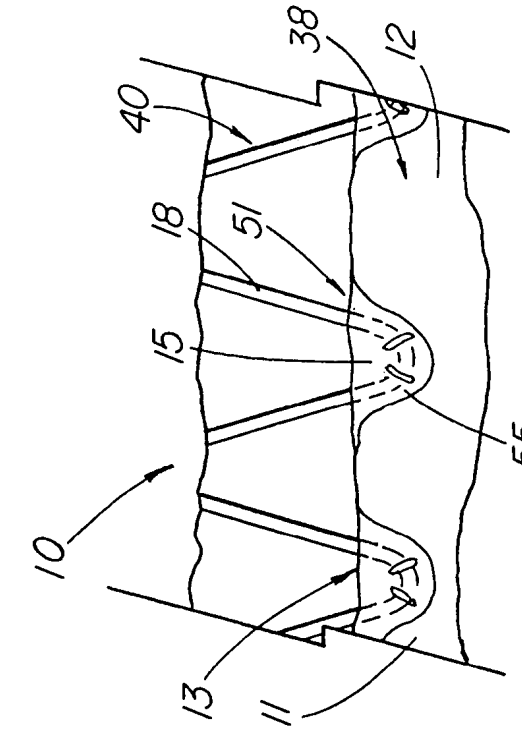



FIG. 14

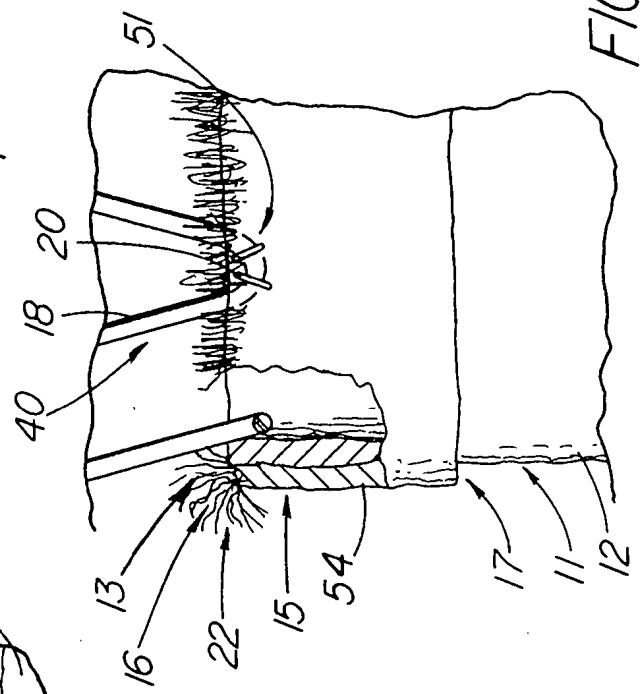



FIG. 13

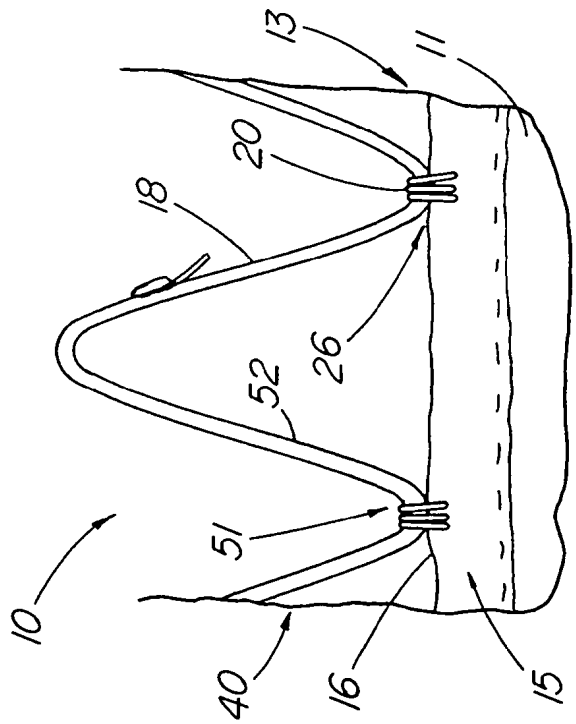



FIG. 12

# STENT GRAFT WITH IMPROVED PROXIMAL END

## CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority of provisional application Serial No. 60/404,662 filed Aug. 20, 2002. This application is related to the U.S. patent application Ser. No. 10/322,862 filed Dec. 18, 2002, entitled Stent Graft With Improved Adhesion.

## TECHNICAL FIELD

[0002] This invention relates to medical devices and more particularly, to intraluminal graft prostheses.

## BACKGROUND OF THE INVENTION

[0003] The top or proximal edge region of a graft prosthesis, particularly one used to exclude an abdominal aortic aneurysm (AAA) or an aneurysm within the thoracic arch, is that portion of the device which is perhaps most critical to clinical success. Typically, it is the portion of the graft that forms the critical seal against the walls of the aorta to prevent leakage of arterial blood directly into the aneurysmal sac (a situation known as a Type I endoleak). In the case of a stent graft that employs a suprarenal stent or other stent that extends beyond the top edge of the tubular graft, (e.g., the ZENITH® AAA Endovascular Graft, Cook Incorporated), the top edge region also represents the portion to which the stent is sewn or otherwise attached or secured to the graft fabric, typically with a series of sutures. For stent grafts placed in the aorta, the pulsatile forces of blood being exerted on the device are sufficiently great such that over time, the sutures may break or pull through the material, which can cause the anchoring stent and graft to separate. If this occurs, the device may migrate or shift, resulting in the aneurysm no longer being excluded and making a subsequent rupture of the aneurysm potentially lethal to the patient.

[0004] While endoleaks can occur anywhere where an aortic stent graft is placed, they can be particularly troublesome when the graft is placed to treat an aneurysm occurring in the region between the renal arteries and the iliac bifurcation. If the neck of the aneurysm (the healthy portion or the vessel between the aneursymal sac and renal arteries) is short or tortuous in shape, it may be difficult to get proper alignment, anchoring, or a good seal between the graft and the vessel wall, possibly resulting in a Type I endoleak in which the sac may continue to be pressurized with blood.

[0005] What is needed is an improved proximal edge region of the graft portion of a stent graft prosthesis or covered stent to help ensure secure anchoring of the supporting structure or stent(s) to the fabric or material, and secondly, to ensure a good seal with the vessel wall such that leakage of blood or fluids does not occur along the proximal edge of the prosthesis.

## SUMMARY OF THE INVENTION

[0006] The foregoing problems are solved and a technical advance is achieved in an illustrative intraluminal prosthesis, such as a stent graft, made of a sleeve of material (e.g., a tight-mesh fabric, extruded polymer, and/or a biomaterial) which includes a leading edge portion having an external structure configured to prevent anchoring stent detachment and/or leakage of blood or fluids around the graft portion. In one aspect of the invention, the stent graft includes a proximal cuff portion to which at least the proximal stent may be attached, thereby providing at least a first and second layer of material that helps provide a more secure substrate for the attached stent(s). The double layer is more likely to hold the sutures and keep them intact, as well as being less likely to have a portion of the stent wear through the fabric over time. A first illustrative embodiment comprises a stent graft adapted for use in treating an aortic aneurysm, such as the ZENITH® AAA Endovascular Graft, in which the most proximal stent extends beyond the proximal or top edge of the graft potion to help anchor the stent graft in the vessel. The prosthesis is placed at or above the iliac bifurcation with the proximal stent acting as a suprarenal stent, attaching to the healthy portion of the aorta about and above the openings to the renal arteries. Because this particular stent typically is only attached about the distal bends and strut portions, there are relatively few sutures to anchor the stent to the material. The cuff of the present invention gives a double-thickness layer of graft material, such as DACRON® polyester fiber (trademark of EI duPont de Nemours & Co., Inc.) for holding the sutures intact and providing better assurance that the distal bends or struts of the zig-zag stent will not wear through the fabric, creating a hole or causing detachment of the suprarenal stent at that point.

[0007] The stent adjacent to the proximal anchoring (suprarenal) stent may also be partially attached to the cuff as well. The proximal stent can be sewn to the cuff from the inside or the outside of the graft, preferably, but not necessarily to both the main body and cuff portions. Additionally, the stent can be sewn to the graft material's folded or leading edge such that the stent and graft material generally abut one another. This reduces thickness by not having the struts of the stent overlapping the material. Furthermore, the cuff can comprise a separate piece of the same or a different material that is sewn, bonded, applied, or otherwise attached to the main body of the graft with the anchoring stent or other supporting structure being attached to both layers to provide added support. While the cuff preferably encircles the entire circumference of the main body of the graft, it is within the scope of the invention (and definition of the term 'cuff') to include a series of discrete cuff 'flaps' or patch-like elements distributed around the circumference of the main body as points to which the bends or struts of the anchoring stent or other supporting structure are attached.

[0008] In one embodiment, at least a portion of the proximal stent is attached to the graft between the layers of the cuff to further strengthen the stent-graft attachment by having the folded edge provide a stop to prevent the stent, which may be inserted through holes about the folded edge, from pulling through if becoming detached from the fabric. Although the folded first edge of the cuff may provide a better substrate for preventing sutures pulling out as compared to a cut edge of material, it is within the scope of the invention to include a cuff in which both the first edge of the cuff and the first end of the main graft body comprise free or cut edges of fabric or other material, rather than a folded edge to unite them.

[0009] In another aspect of the invention, the cuff, which comprises a first edge at the leading or folded edge of the graft extending to second edge that comprises the free or cut

edge of the material, is adapted to extend outward to serve as an external sealing zone to engage the vessel wall and help prevent leakage of blood or fluid around the device. In one illustrative embodiment of a modified ZENITH® AAA Endovascular Graft, approximately 10 mm of the graft material is folded over on itself such that the free edge is on the outside of the graft. Approximately the distal 5 cm of the cuff includes a region in which the threads and fibers of the DACRON® polyester fabric have been at least partially separated from one another to create a frayed region that extends outward from the graft and facilitates sealing by encouraging thrombus formation and tissue ingrowth. Graft material, such as DACRON® polyester fiber, is particularly well-suited to form thrombus. One advantage of the external sealing zone is that the top or first supporting stent, which has the ability to compromise the quality of the graft-vessel seal if placed on the outside of the graft (such as is the case with the ZENITH® AAA Endovascular Graft), can be moved from the inside to the outside of the graft and still allow for adequate sealing. This allows the inner lumen of the graft to remain smooth and stent-free. In a variation of this embodiment, the frayed region is folded or otherwise directed so that it extends proximally, thereby creating a third layer of graft material along the first edge of the cuff. Additionally, the frayed region can be modified to enhance its sealing properties, such as by adding agents to encourage thrombosis or cell proliferation, adding structure capable of stimulating the cell injury response and facilitate tissue ingrowth.

[0010] In yet another aspect of the invention, the external sealing zone can include separate element or series of elements that includes the same material and/or a second material which is affixed to the outer surface of the graft. It can be attached to or below the cuff, or the cuff can be eliminated completely. Some examples of materials for an attached external sealing zone include bands of felt material, foam, lyophilized collagen, such as small intestinal submucosa (SIS) or another extracellular matrix (ECM), or some other suitable material.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings, in which:

[0012] **FIG. 1** depicts a side view of an illustrative embodiment of the present invention in which the graft portion includes a proximal cuff portion;

[0013] **FIG. 2** depicts a side view of an embodiment of the present invention where the cuff portion includes an external sealing zone comprising a frayed portion;

[0014] **FIG. 3** depicts an in situ view of the embodiment of **FIG. 2**;

[0015] **FIG. 4** depicts a cross-sectioned view of the cuff of **FIG. 2**;

[0016] **FIG. 5** depicts a detailed view of the free edge of the cuff portion of **FIG. 2**;

[0017] **FIG. 6** depicts a cross-sectional embodiment of the present invention wherein the free edge of the cuff portion is directed toward the first end of the graft;

[0018] **FIG. 7** depicts a detail view of an alternative cuff embodiment wherein a fringe is cut into the free edge of the graft material;

[0019] **FIG. 8** depicts an alternative embodiment ofthe present invention wherein the external sealing zone comprises a band of material attached to the graft;

[0020] **FIG. 9** depicts an alternative embodiment of the present invention in which the frayed portion includes additional structure to promote thrombus formation and/or tissue ingrowth;

[0021] **FIG. 10** depicts an alternative embodiment of the present invention wherein the cuff portion comprises a portion of the graft material extending over the leading edge of a cannula stent;

[0022] **FIG. 11** depicts a partially sectioned detail view of an alternative embodiment in which the proximal anchoring stent is attached underneath the cuff portion;

[0023] **FIG. 12** depicts an enlarged side view of an alternative embodiment in which the proximal anchoring stent is attached about the edge comprising the first end of the graft material;

[0024] **FIG. 13** depicts a partially sectioned side view of an alternative embodiment in which the cuff portion comprises a layer of material separate to the main body portion of the graft; and

[0025] **FIG. 14** depicts a side of an embodiment in which the cuff portion comprises a plurality of flaps.

## DETAILED DESCRIPTION

[0026] **FIG. 1** depicts a graft prosthesis **10** that includes a graft portion **11** having a first end **13**, which typically forms the proximal or leading edge of the main body **12** of the tubular graft portion, and a second end **14**, which typically is the distal end which is further downstream from the direction of blood or fluid flow. The illustrative graft prosthesis **10** represents a modified ZENITH® AAA Endovascular Graft comprising a tubular graft portion **11** of DACRON® polyester fiber (including a bifurcated distal portion in this embodiment to feed into the right and left iliac arteries), and a supporting structure **40** that comprises a series of zig-zag stents sewn thereto, including a proximal anchoring stent **18**, such as the illustrative suprarenal zig-zag stentwith barbs, extending from the proximal (caudal) end to anchor the stent graft above the aneurysmal sac. The prosthesis **10** further includes a cuff portion **15** comprising material of the main body **12** that is folded over the outside thereof to form a double layer of material. The cuff portion **15** includes a first edge **16** or leading edge, which is typically a folded edge, that also comprises the first end **13** of the graft portion **11**, and extends distally to a second edge **17**, which is the free edge of the cuff. In the illustrative cuff portion **15**, the free edge **17** is unattached to the main body **12** so that it is allowed to extend or flair outward to comprise a lip that serves as an external sealing zone **21** to help provide a better seal graft portion **11** and walls of the vessel in which the device is placed. It should be noted that while it may be preferable to form the cuff portion **15** by folding the excess material over upon itself, it is also within the scope of the invention for the cuff portion **15** to be a separate piece that is secured to the main body **12** of the graft portion, such that

the proximal edges of the main body and cuff portions **13,16** each comprise 'cut' or free edges rather than a single folded edge. The double thickness of the cuff portion typically offers a better foundational substrate through which sutures **20** may be attached, forming knots to secure or anchor stents or other framework of the graft prosthesis **10**. The length of the cuff **15** depends largely on the specific clinical application and size of the prosthesis, but preferably the free edge **17** does not extend more than a few centimeters from the first end **13**, especially in an endovascular stent graft where the seal must be safely proximal of the aneurysm being excluded. The cuff portion **15**, however, may extend any length, including the entire length of the main body portion **12**, particularly if it is not utilized as an external sealing zone **21**. Although it is generally preferred that the cuff be folded or placed over the outer surface of the main body portion **12** so as not to interfere with blood flood and promote formation of thrombus, it may folded inward and attached, particularly if the free edge **17** can be attached or bonded in such a manner that does not interrupt blood flow.

[**0027**] **FIG. 14** depicts an alternative embodiment of the cuff portion **15** in which the cuff is configured as a series of discontinuous flaps **55** distributed around the outer perimeter of the main body portion **12** of the graft. The flaps **55** are spaced to correspond to the attachment points of the bends **51** of the anchoring stent **18**. Although the illustrative embodiments each depict a suprarenal anchoring stent **18**, it is not necessary to the invention that the supporting structure **40** attached to the cuff **15** comprise an anchoring stent extending from the proximal end **13** of the graft **11**.

[**0028**] The illustrative ZENITH® AAA Endovascular Graft represents but one exemplary embodiment of the present invention. As such, the stent graft material **11** and supporting structure **40** may include otherwell-known materials and designs. For example, other biocompatible fabrics and non-woven materials, such as expanded polytetrafluoroethylene (ePTFE) may be used as well as biomaterials, such as cross-linked collagen and remodelable collagen materials, e.g, a tube formed from a single or multiple ply tube of a extracellular collagen matrix material (SIS being an example commercially available from Cook Biotech, Inc., West Lafayette, Ind.).

[**0029**] The suture **20** used to attached supporting structure **40** to the graft material **11** may be made of any biocompatible fiber suitable for the application, including but not limited to, monofilament or braided multi-filament polyester, nylon, polyaramid, polypropylene, and polyethylene. Braided polyester 4-0 suture material is preferred for attaching internal stents to grafts, while monofilament suture material is preferred for attaching top stents to grafts. The polyester 4-0 suture material is nonabsorbable and has limits of 0.150 to 0.199 mm (metric size 1.5). This well-known material is commercially available from a number of companies. The suture material may be attached to a hollow needle used to thread the suture through the graft, thus attaching the stent to the graft using any suitable type of knot. It is not necessary to the invention that fiber suture be used to attach the supporting structure to the graft material. Wire, staples, clips, bonding agents, or other methods also may be used to achieve a secure attachment of the graft material and stents.

[**0030**] To further enhance the sealing properties of the external sealing zone **21**, the free edge may be modified to increase its ability to conform with the vessel, promote thrombus formation, and/or encourage tissue ingrowth into the graft material. **FIG. 2** depicts an embodiment of the present invention in which the cuff **15** includes a frayed portion **22** located about the free end **17** thereof, the frayed portion **22** comprising about 5 mm of threads and fibers (of an approximately 10 mm cuff) that have been at least partially separated from one another or unraveled such that they extend outward from the main graft body **12** and circumferentially therearound. Alternatively, the frayed portion **22** may extend the entire length of the cuff portion **15**. The frayed portion **22** is particularly well adapted to make contact with the vessel and allow thrombocytes to collect and tissue to grow thereinto, thus improving the efficacy of the seal. **FIG. 3** depicts the illustrative embodiment of **FIG. 2** deployed in an abdominal aorta **32** to exclude an aneurysm **33** that has formed below the renal arteries **34**, usually above or at the iliac bifurcation **41**. The external sealing zone **21** comprising the frayed portion **22** is positioned within the neck **35** of the aneurysm **33** where it helps the stent graft **10** seal against the healthy aortic wall tissue so that an endoleak does not occur around the proximal end **16** of the graft. The proximal anchoring stent **18** is placed across the renal arteries where it is anchored to the vessel **32** by a plurality of barbs **36**. In other embodiments, the proximal anchoring stent **18** may include hooks or other structure that extend beyond or through the graft material **38** to engage the vessel and help anchor the prosthesis in place.

[**0031**] **FIG. 4** depicts a cross-sectional view taken about the proximal end **16** of the graft portion **11**, including the cuff portion **15** and proximal anchoring stent **18**. The proximal anchoring stent **18** is attached to the inner surface **37** of the graft material **38** and secured with sutures **20** that are passed through both the main graft body **12** (inner) and the cuff portion **15** (outer) layers of material **38**, preferably through the proximal or anchoring portion **31** of the cuff portion **15**. In particular, a series of interconnecting (running) or separate sutures **42** anchor the proximal anchoring stent **18** to the cuff portion **15** at the bends **51** and struts **52** of the stent **18**, the later being sutured about the proximal or folded edge **16** of the cuff. Additionally, the first adjacent supporting stent **19** is attached to the outer surface **39** of the main graft body **12** with a another series of sutures **43**. The illustrative example depicts the frayed portion **22** extending through and around the struts to minimize direct contact of the stent with the vessel wall, thus resulting in a better seal than would otherwise be possible with an externally placed stent.

[**0032**] **FIG. 11** depicts an alternative embodiment of the present invention in which the proximal anchoring stent **18** is attached to the graft portion **11** between the main body **12** and cuff portion **15**, such that the bends **51** and distal portions of the struts **52** being sandwiched between graft material **38**, providing a more secure anchoring of the stent. One skilled in the medical arts would appreciate thatthere are multiple methods of forming the embodiment of **FIG. 11**. One method is to feed an end of an unassembled proximal anchoring stent through a series of holes **53** formed through the graft material until all of the bends **51** are looped underneath the cuff portion **15**, as shown. The stent **18** is then joined together with cannula and solder, spot or laser welding, etc., and secured with a series of sutures **42**. The illustrative method of attachment provides a backup means

of preventing the proximal anchoring stent **18** from completely detaching from the graft portion **11** in the event of suture **20** failure.

[**0033**] **FIG. 12** depicts an embodiment in which the proximal anchoring stent **18** is attached at the proximal (folded) edge **16** of the cuff portion **15** by a plurality of sutures **20** (either multiple sutures or multiple loops of a single suture) such that no portion of the bends **51** or struts overlaps with the stent graft material **11**. This advantageously reduces the profile of the graft prosthesis **10** during the loading process.

[**0034**] While the cuff portion **15** of the illustrative embodiments is shown as a free edge **17** that is folded over itself (the tubular prosthesis **12**) to create a double thickness of material (new folded leading edge **16**), it is within the scope of the invention for the cuff portion to be a separate element that is attached to the main body **12** of the graft (**FIG. 13**), such as when the sutures **20** penetrated both layers to attach the anchoring stent **18** or other supporting structure **40**. Adhesives, laser/thermal bonding, or other methods may be used supplement or achieve attachment of the two layers of material **12,15**. The separate ring-like outer cuff portion **54** comprising the outer portion of the cuff **15** may be of the same material of the main body **12**, or a different material, particularly one having advantageous properties such as better durability, thinner profile, remodelability/tissue ingrowth facilitation (e.g., an ECM), or superiorability to elute medicaments or agents, etc., without regard to whether the second material is particularly suitable to prevent the leakage of blood therethrough. Furthermore, the separate outer cuff portion **54** can comprise a material, such as a polymer. that is printed, sprayed, painted, dipped, or otherwise applied to the surface of the graft prosthesis to improve the attachment between stent and graft material. The illustrative embodiment of **FIG. 13** further includes a frayed portion **22** located at the leading edge **16** of the cuff portion **15** to facilitate sealing thereat. Alternatively, the optional frayed portion **22** may be located at the second edge **17** of the cuff **15**, similar to the embodiment of **FIG. 2**, or it may be located at the first edge **13** of the main body **12**, or any combination of the three free edges **13,16,17**. By being separate pieces, the outer cuff portion **54** and main body may be used to form a sandwich of material to secure the anchoring stent **18** therebetween (not shown), similar to the embodiment of **FIG. 11**. Although the illustrative separate outer cuff **54** completely encircles the main body **12** to which it is attached, it may be divided into discrete sections that are located at the attachment points of the stent bends **51** to provide a double thickness of material.

[**0035**] **FIG. 5** depicts an enlarged view of the frayed portion **22** and how it is formed from material **38** of the cuff portion **15**. The illustrative TWILLWEAVE™ graft material **38** (Selzer-Vascutek Ltd., Inchinnan, Scotland, UK) comprises a woven DACRON® polyester fabric which is frayed by separating the longitudinal threads **46** from one another and from the cross threads **47** with which they are interwoven. Once the ends **23** of the threads **46** are separated, typically using a tool or machine suitable for creating a frayed portion **22** of the desired length, the fibers **24** that comprise the individual longitudinal threads **46** are preferably, but not necessarily, also unraveled and separated from one another, allowing the frayed portion **22** to assume a 'fuzzier' configuration that enhances the sealing properties of the external sealing zone **21** and provides an improved substrate for tissue ingrowth thereinto. Generally, it is preferred that the portion in which the fibers **24** are separated from one another, comprises at least a substantial portion of the frayed portion **22**. The length of frayed portion **22** of a typical stent graft comprises at least 2 cm of the cuff portion **15** (preferably 5 mm or more).

[**0036**] **FIG. 6** depicts an embodiment in which the external sealing zone **21**, including the illustrative frayed portion **22**, is configured such that the free edge **17** of the cuff portion **15** is directed proximally (toward the first or folded edge **16**), to produce a fold **44** that creates gutter-like pocket **45** that is able to collect any blood passing around the leading edge **16** of the graft **11** to prevent an endoleak and promote thrombus formation. The pocket **45** can be created by any means known to those in the medical arts, including treating and forming the cuff material using a chemical agent, heat, etc. such that it can maintain such a shape; or by adding wires or other supporting structure (not shown) that reshapes the cuff portion **15** into the illustrative pocket **45** configuration.

[**0037**] Although DACRON® polyester fiber and other selected fabrics usable in medical applications are generally able to be unraveled to create a frayed portion **22**, some fabrics and unwoven materials potentially suitable for medical applications, such as polymer sleeves, biomaterials, etc., cannot be frayed in the same manner. **FIG. 7** depicts an external sealing zone **21** created by creating a series of closely adjacent cuts **26** or slices through the material to form fringe elements **27** about the free edge **17** of the material. The length, width, and configuration of the fringe elements **27** (fringed portion) are largely determined by the clinical application and type of material **38** comprising the cuff portion **15**.

[**0038**] In addition to the external sealing zone **21** comprising the free edge **17** of the cuff portion **15**, as with each of the embodiments described above, **FIG. 8** depicts an embodiment wherein the external sealing zone **21** comprises a band **28** of separate material such as open-cell foam or another suitable biocompatible material (e.g., a lyophilized orsponge-form collagen material such as SIS) and configuration which is attached to the outer surface **39** of the graft. Such materials should be effective for creating a seal with vessel wall and/or encouraging cell ingrowth. Such a band of material **28** can be affixed over the cuff portion **15**, such as over the free edge **17**, as shown, attached below the cuff **15** to further take advantage of the free edge **17** for sealing, or the cuff portion **15** may be eliminated entirely if not needed for additional anchoring support. While the illustrative embodiments depicts an external sealing zone **21**/frayed portion **22** that encircles the graft **11** in a ring-like manner, it may assume other configurations, such as a helically or serpentine shaped strips of material, discrete staggered patches of material/fringe, etc.

[**0039**] The external sealing zone **21** may be augmented with additional structure, materials, or agents that further enhance its sealing properties. One example includes tissue-engaging elements **29**, such as the illustrative barbs depicted in **FIG. 9**. The barbs **29** may be configured to help anchor the graft prosthesis **10** in the vessel, or their primary function may be limited to providing irritation or trauma to the vessel wall for stimulating cell proliferation into the external

sealing zone **21**. The tissue engaging elements **29** may comprise any suitable structure, such as a plurality of small diameter wires, which are interwoven into the cuff portion **15**, or attached in any suitable manner, such as the illustrative method in which the barbs **29** originate from a common basal element **48** that encircles the graft portion **11** and is design to be collapsible (e.g., a zig-zag shaped element). The tissue-engaging elements **29** may also configured to bias the cuff portion toward the wall during delivery (e.g., by adding springs or other biasing mechanisms about the common basal element **48**). For example, the prosthesis **10** may be loaded such that the cuff portion could be loaded such it extends proximally from the main body portion **12**. As the graft prosthesis is unsheathed for delivery, the embedded elements **29** spring back and flip the cuff portion distally to engage the walls of the vessel. This has the advantage of eliminating the extra thickness of the cuff portion **15** during loading, yet retaining the advantages it provides following deployment.

[**0040**] Besides tissue-engaging structures **29**, the external sealing zone **21** may be impregnated with a bioactive or pharmacological agent that enhances sealing properties,such as thrombin powder or another agent for stimulating thrombus formation about the external sealing zone **21**. Other possible materials or agents, include, but are not limited to, growth factors or biomaterials for stimulating tissue ingrowth, materials that swell in the presence of blood, or other substances that help form a physical barrier to fluids.

[**0041**] **FIG. 10** depicts an embodiment of the present invention in which the cuff portion **15** extends beyond and over a self-expanding or balloon-expandible outer stent **50** and whose function is primarily to serve as an external sealing zone **21**, rather than also being a substrate for attachment of a proximal anchoring stent or other supporting structure **40**. In the illustrative example, which depicts a cannula-type stent **30**, such as the illustrative ZILVER® Stent (Cook Incorporated), the cuff portion **15** comprising the frayed portion **22**, extends a few millimeters beyond the proximal or first end **13** of the stent and is unattached to the stent **50**, although it optionally might include a series of sutures above the frayed portion **22** to maintain a folded edge **16** and prevent the cuff portion from inverting. In the illustrative example, the prosthesis **10** includes an inner stent **49** to form a sandwich configuration in which the two stents **49**,**50**, one expanding slightly largerthan the other, engage and maintain the graft material **38** therebetween, thereby eliminating the need for suturing the graft portion **11** to the supporting structure **40**. It is certainly within the scope of the invention, however, for either stent to be eliminated and have the graft material sewn or otherwise attached to the stent supporting structure **40** in a manner similar to other depicted embodiments. Additionally, other types of cannula or non-cannula stents can be substituted for the illustrative stents **49**,**50**, which need not be the same as one another.

[**0042**] Any other undisclosed or incidental details of the construction or composition of the various elements of the disclosed embodiment of the present invention are not believed to be critical to the achievement of the advantages of the present invention, so long as the elements possess the attributes needed for them to perform as disclosed. The selection of these and other details of construction are believed to be well within the ability of one of even rudimentary skills in this area, in view of the present disclosure. Illustrative embodiments of the present invention have been described in considerable detail for the purpose of disclosing a practical, operative structure whereby the invention may be practiced advantageously. The designs described herein are intended to be exemplary only. The novel characteristics of the invention may be incorporated in other structural forms without departing from the spirit and scope of the invention. The invention encompasses embodiments both comprising and consisting of the elements described with reference to the illustrative embodiments. Unless otherwise indicated, all ordinary words and terms used herein shall take their customary meaning as defined in The New Shorter Oxford English Dictionary, 1993 edition. All technical terms shall take on their customary meaning as established by the appropriate technical discipline utilized by those normally skilled in that particular art area. All medical terms shall take their meaning as defined by Stedman's Medical Dictionary, 27th edition.

What is claimed is:

**1**. A stent graft prosthesis for placement in a vessel comprising:

a graft portion including a first end, a second end, and a main body portion, generally tubular in shape, that comprises a first layer of material;

a cuff portion, having a first edge and a second edge, located about the first end of the graft portion, the cuff portion comprising a second layer of material closely adjacent the main body portion; and

a supporting structure attached about the first end of the graft portion.

**2**. The stent graft prosthesis of claim 1, wherein the cuff portion is folded over the main body portion such that the proximal, first end of the cuff portion comprises a folded edge and the second end comprises a free edge.

**3**. The stent graft prosthesis of claim 2, wherein the cuff portion is folded over the outside of the main body portion.

**4**. The stent graft prosthesis of claim 3, wherein the cuff portion comprises a plurality of flaps extend over the first edge of the graft portion.

**5**. The stent graft prosthesis of claim 1, wherein the supporting structure includes an anchoring stent attached to the cuff portion and main body portion.

**6**. The stent graft prosthesis of claim 1, wherein the cuff portion comprises one or more elements separate of the main body portion that are attached thereto.

**7**. The stent graft prosthesis of claim 6, wherein the cuff portion comprises an external sealing zone extending laterally from the main body portion, the external sealing zone configured to engage the walls of the vessel to facilitate sealing therebetween and reduce leakage of fluid.

**8**. The stent graft prosthesis of claim 1, wherein the second edge of the cuff portion comprises a frayed portion.

**9**. The stent graft prosthesis of claim 1, wherein the second edge of the cuff portion comprises a fringed portion.

**10**. The stent graft prosthesis of claim 1, wherein the cuff portion comprises a second material different that than of the main body material

**11**. A stent graft prosthesis for placement in a vessel comprising:

a graft portion including a main body portion generally tubular in shape, that includes a first end and a second end;

a cuff portion comprising an external sealing zone generally located at or closely adjacent the first end of the graft portion, the external sealing zone having structure that generally encircles and extends laterally from the main body portion to create a circumferential seal between graft portion and the adjacent walls of the vessel to reduce leakage of bodily fluid thereabout.

**12**. The stent graft prosthesis of claim 11, wherein the cuff portion comprises a frayed portion.

**13**. The stent graft prosthesis of claim 11, wherein the cuff portion comprises a fringed portion.

**14**. The stent graft prosthesis of claim 11, wherein the cuff portion comprises a band of material situated therearound.

**15**. The stent graft prosthesis of claim 14, wherein the band of material comprises a second material, wherein the second material is different than that of the main body of the graft portion.

**16**. A stent graft prosthesis for placement in a vessel comprising:

a graft portion including a main body portion;

an outer cuff portion, having a first edge and a second edge, that is located about the first end of the graft portion and attached thereto; and

an anchoring stent attached to the main body portion and outer cuff portion, the anchoring stent extending proximally therefrom.

**17**. The stent graft prosthesis of claim 16, wherein the outer cuff portion comprises an external sealing zone.

**18**. The stent graft prosthesis of claim 16, wherein the outer cuff portion comprises a frayed portion.

**19**. The stent graft prosthesis of claim 16, wherein the outer cuff portion is folded over the main body portion with the anchoring stent being attached thereover.

**20**. The stent graft prosthesis of claim 16, wherein the outer cuff portion is folded over the main body portion with the anchoring stent being attached between the outer cuff portion and the main body portion.

* * * * *

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# Transluminal Aortic Valve Placement

## A Feasibility Study With a Newly Designed Collapsible Aortic Valve

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**Percutaneous stents are used in vascular applications in conjunction with angioplasty and in combination with graft material for repair of abdominal aneurysms. The authors have designed a collapsible bioprosthetic aortic valve for placement by a transluminal catheter technique. This trileaflet stent valve is composed of stainless steel and bovine pericardium. Stent valves, 23 and 29 mm, were tested in a pulse duplicator system with rigid rings from 21 to 31 mm in 2 mm increments. At a mean flow of 3.1 L/min (±0.7), normal systemic aortic pressure was generated with a transvalvular gradient of 14.9 ± 7 mmHg (mean ± SD). Regurgitation fraction ranged from 10 to 18% (mean 13.8 ± 3%) in the best ring size. Valves with the best hemodynamic profile were used for implantation in three 70 kg pigs in an open chest model. The valve was collapsed in a 24 Fr catheter designed to allow slow, controlled release. After resection of the native leaflets, the new valve was placed in the subcoronary position. No additional sutures were used for securing the valve. Two animals were successfully weaned from cardiopulmonary bypass and maintained systemic pressures of 100/45 (±10) and 116/70 (±15) mmHg, respectively. Intraoperative color echocardiography revealed minimal regurgitation, central flow, full apposition of all leaflets, and no interference with coronary blood flow. Both animals were sacrificed after being off bypass for 2 hr. Postmortem examination revealed the valves to be securely anchored. The third animal was weaned from cardiopulmonary bypass but developed refractory ventricular fibrillation because of valve dislodgment due to structural failure. Although long term survival data are needed, development of a hemodynamically acceptable prosthetic aortic valve for transluminal placement is feasible. *ASAIO Journal* 1996;42:M381–M385.**

Intravascular stents have gradually obtained acceptance for peripheral and coronary vascular occlusive disease.[1–3] Combinations of stents with grafts have allowed for intraluminal bypass of aneurysms and long segment atherosclerotic lesions.[4] Transfemoral percutaneous aortic valve replacement is an extended application of this new technology that offers several new challenges. First, the valve needs to be accurately positioned without the benefit of direct open visualization. Second, the valve must remain firmly in the annulus under physiologic conditions. Finally, in the absence of sutures, the valve must provide a sufficient seal to minimize perivalvular regurgitation.

We have developed a novel sutureless bovine pericardial bioprosthetic aortic valve mounted on a collapsible stent. This prosthetic valve can be collapsed in a 24 Fr catheter for delivery. This report represents our initial characterization of this valve in a pulse duplicator system and in an open chest porcine model.

### Methods

#### *Stent Valve Construction*

Stainless steel wire, size 0.020″, was used to construct all stents, and size 0.022″ was soldered on the ring to serve as the anchoring fixation point in the aortic annulus. For constructing the stent valves at different sizes, because of the collapsible nature of the design, all valves were placed in a ring of predetermined size. Subsequently, bovine pericardium stabilized by a photooxidation process[5] was sewn on the stent from a single sheet to construct trileaflet valves constrained to different sizes.

#### *In Vitro* Measurements

A total of 16 stent valves were constructed. The four that were acceptable in terms of overall symmetry were subjected to further studies. A pulse duplicator similar to a previously described mock circulatory system[6] was constructed

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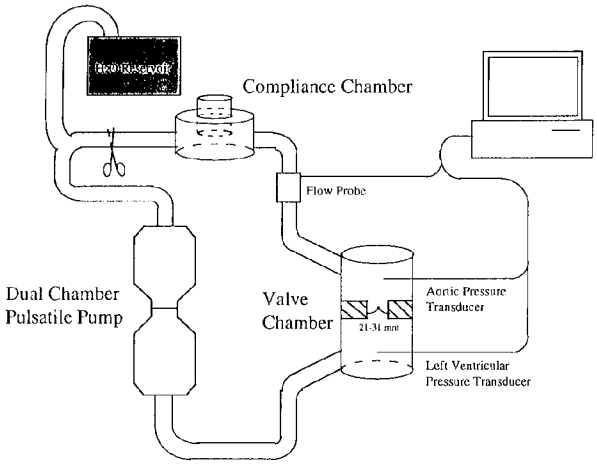


**Figure 1.** Diagram of the mock circulatory loop used for *in vitro* testing of valves. The chamber allows for adjustment of compliance and resistance.

**(Figure 1).** This system uses an Abiomed BVS 5000 dual chamber (Abiomed, Inc., Danvers, MA) to generate pulsatile flow. Each stroke ejects 80–85 ml of saline into the circuit. The system possesses an open reservoir to simulate the venous and atrial systems. In addition, a piston–cylinder–spring arrangement functions as an adjustable compliance chamber. Peripheral vascular resistance could be adjusted by application of a clamp to the circuit partially to impede forward flow. The valve was placed on a ring in a rigid chamber made of Plexiglas. The ring size in the chamber could be changed to a diameter ranging from 21 to 31 mm in 2 mm increments. A 5 Fr Millar catheter (Millar Instruments, Houston, TX) was placed on the ventricular side and the aortic side of the valve to measure transvalvular pressures gradients. An ultrasonic flow probe (Transonics, Ithaca, NY) was placed on the outflow tubing to monitor forward and backward flow. All data were digitized at 200 Hz using a 12 bit A-D board (AD Instruments, Milford, MA) recorded with the MacLab system and stored on the hard drive for subsequent analysis. Regurgitant fraction was calculated by the ratio of the integral of backward flow to the integral of total flow (forward and backward) using customized wave analysis software (IGOR; Wavemetrics, Inc., Lake Oswego, OR).

### *Animal Care*

Animals received humane care in compliance with the *Principles of Laboratory Animal Care* formulated by the Institute of Laboratory Animal Resources and the *Guide for the Care and Use of Laboratory Animals* published by the National Institutes of Health (NIH Publication No. 86-23, revised 1985).

### *Experimental Procedure*

Pigs weighing 60–70 kg were anesthetized with ketamine (20 mg/kg) and thiamylal sodium (4.5 mg/kg). After endotracheal intubation, anesthesia was maintained with isoflurane (1.5–2.5%) mixed with 100% oxygen. Lidocaine 2 mg/kg and bretyllium 5 mg/kg were given as a loading dose, and a continuous drip of 1 mg/kg/hr for each was maintained throughout the experiment. Standard concentrations of phenylephrine (Neo-Synephrine; Winthrop Pharmaceuticals, New York, NY), norepinephrine bitartrate (Levophed; Winthrop Pharmaceuticals), and epinephrine drips were used as needed to maintain a mean blood pressure of 60 while on cardiopulmonary bypass (CPB). Internal paddles charged up to 50 V were used for defibrillation as needed.

### *Surgical Procedure*

Sternotomy was performed, and the pericardium was opened. Heparin (300 μg/kg) was administered and adequate anticoagulation was verified by an activated clotting time of greater than 400 sec. A 14 Fr cannula was inserted in the aorta and a 36 Fr dual stage venous cannula was inserted in the right atrium for CPB. The aorta was dissected proxi-

**Table 1. Hemodynamic Characterization of the Stent Valves in the Mock Circulatory System**

| Valve Size (mm) | Ring Size (mm) | VP (mmHg) | AoP (mmHg) | Regurgitant Fx (%) | Flow (L/min) |
|---|---|---|---|---|---|
| Empty chamber (no valve) | 25 | 177 | 167 | 100 | 3.3 |
| | 27 | 158 | 149 | 100 | 3.3 |
| | 29 | 165 | 156 | 100 | 3.3 |
| | 31 | 157 | 152 | 100 | 3.3 |
| 23 | 21 | 173/20 | 163/70 | 10 | 2.7 |
| | 23 | 188/23 | 178/70 | 14 | 3.2 |
| | 25 | 160/25 | 150/33 | 26 | 2.2 |
| | 27 | 193/35 | 184/36 | 50 | 2.1 |
| 23 | 21 | 130/15 | 120/60 | 14 | 2 |
| | 23 | 174/9 | 169/52 | 18 | 2.1 |
| | 25 | 153/25 | 145/37 | 27 | 2.1 |
| 29 | 27 | 161/10 | 146/63 | 13 | 3.71 |
| | 29 | 163/12 | 149/52 | 15 | 3.67 |
| | 31 | 169/18 | 147/46 | 20 | 4.5 |
| 29 | 27 | 137/9 | 122/60 | 10 | 3.24 |
| | 29 | 145/18 | 120/42 | 17 | 3.46 |
| | 31 | 144/25 | 114/30 | 27 | 3.28 |

VP, ventricular pressure; AoP, aortic pressure; Fx, fraction.

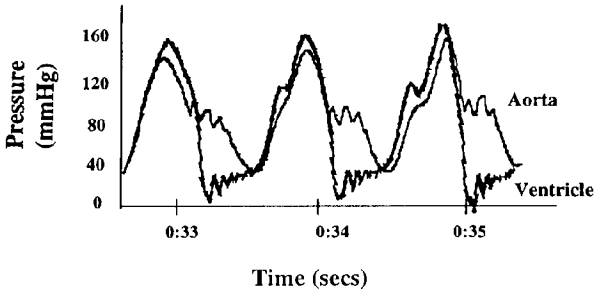


**Figure 2.** Representative *in vitro* aortic and ventricular pressure tracing for a 23 mm stent valve in a 21 mm ring.

mally until the origin of the left main coronary artery could be visualized. Subsequently, the animal was placed on CPB and cooled to 32°C. After placement of a left ventricular vent through the apex of the heart, the proximal aorta was cross-clamped. One liter of 4°C standard crystalloid cardioplegia solution was delivered to the aortic root to arrest the heart. A partial transverse aortotomy was performed as close to the coronary artery as technically feasible. The deep aortic root in this animal model necessitated the use of three traction sutures placed at each commissure to pull the native leaflets into view. After sizing the annulus with standard sizers, the appropriate stent valve, collapsed in a 24 Fr catheter, was delivered under direct vision and secured in placed. No sutures were used for fixation of the stent valve. All traction sutures were removed and the aortotomy was closed with a double layer of running 4-0 polypropylene suture. After removing the cross-clamp, deairing the left ventricle, and rewarming, the animal was slowly weaned from CPB.

*Hemodynamic Measurements*

Pressure was measured with a 5 Fr Millar micromanometer placed in the left ventricle through the apex, and a second catheter guided to the proximal aorta through the left carotid artery. All hemodynamic data were recorded off CPB on the MacLab system. All data are reported as mean ± standard deviation.

*Echocardiography*

Two dimensional and m-mode echocardiograms were obtained using a hand held 5 MHz ultrasound transducer (Vingmed CFM 750; Vingmed Sound, Inc., Salt Lake City, UT). Color flow Doppler was obtained to assess valvular regurgitation.

**Table 2. Size of the Aortic Annulus After Cardiac Arrest Relative to the Size of the Stent Valve Implanted**

| Animal | Annulus Size (mm) | Valve Size (mm) |
|---|---|---|
| 1 | 18 | 23 |
| 2 | 25 | 29 |
| 3 | 20 | 23 |

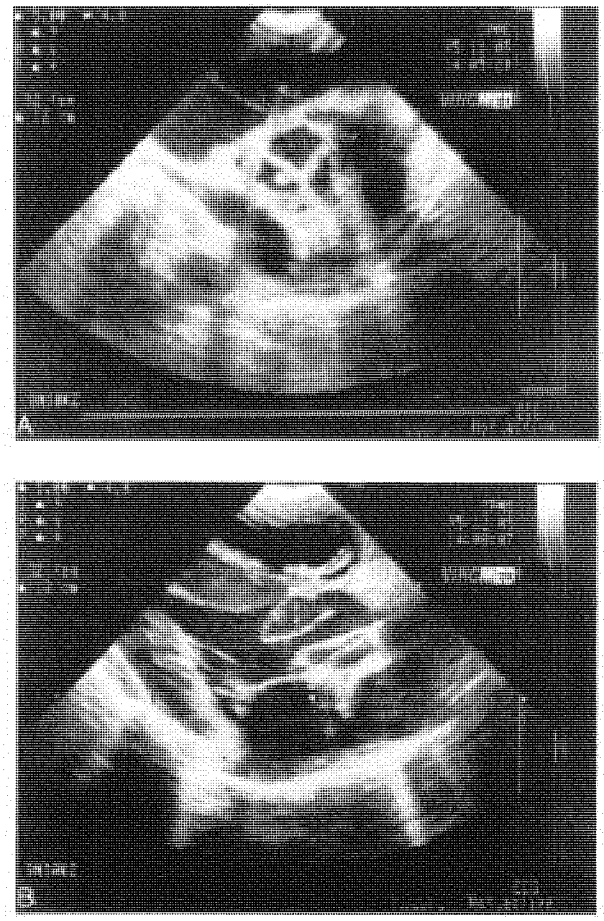

**Figure 3. (A)** Short axis echocardiogram demonstrates the three leaflets to be fully apposed during diastole. One of the leaflets is slightly redundant. **(B)** Long axis view demonstrates opening of the leaflets. The lower, redundant leaflet does not open completely.

## Results

### *In Vitro* Studies

**Table 1** shows the results obtained from studying valves of different sizes in our pulse duplicator system. Flow generated ranged from 2.0 to 4.5 L/min with a mean of 3.1 L/min (±0.7). The lowest regurgitation fractions were obtained by placing the valves in rings 2 mm smaller than the stent valve. Placing the valve in smaller chambers caused too much leaflet redundancy and interference with proper valve opening. The valves were considered adequate for animal implantation if the regurgitant fraction was less than 15% at a given annulus size and a diastolic pressure of 60 mmHg could be maintained. Calibration of the pulse duplicator in absence of any valve shows that the system has a transvalvular gradient of 5–10 mmHg. The stent valves had a mean transvalvular gradient of 14.9 (±7.4) mmHg. In **Figure 2,** representative pressure and flow curves generated in our mock circulatory loop are shown.

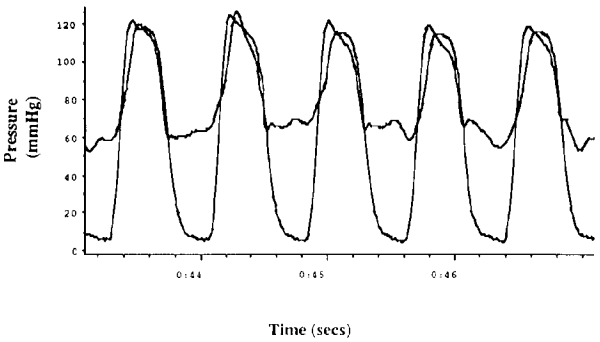


**Figure 4.** Representative *in vivo* aortic and ventricular pressure tracings. Mean aortic root pressure was 116/70 mmHg, with maintenance of a diastolic gradient of 66 mmHg between the aorta and left ventricle.

### *In Vivo* Studies

**Table 2** demonstrates the size of the porcine annulus and the most appropriately sized valve that was available for implantation. Engagement of the valve required approximately 5 min. Cross-clamp time was approximately 20 min in animals 1 and 3 and 40 min in animal 2 because of inadvertent dislodgment of the aortic cannula. All animals were successfully weaned from CPB.

Animal 1 maintained a systemic pressure of 100/45 (±10) mmHg over a period of 2 hr. Intraoperative echocardiography revealed complete opening of two leaflets, with the third leaflet redundant and relatively immobile. All leaflets were fully apposed during diastole **(Figure 3).** The stent valve was in the subcoronary position without any obstruction to coronary blood flow. Color Doppler studies showed mild regurgitation at the level of the non mobile posterior leaflet. Postmortem examination revealed complete fixation of the valve at the annulus without any displacement. Because of the small size of the annulus, one of the leaflets appeared redundant, as had been observed during echocardiography.

Animal 2 was successfully weaned from bypass, but within 5 min refractory ventricular fibrillation developed. Postmortem examination revealed dislodgment of the valve secondary to structural failure.

Animal 3 had an annulus sized at 20 mm and received a 23 mm stent valve. This animal maintained a systemic blood pressure of 116/70 (±15) mmHg. Pressure recordings at the aortic root and left ventricle revealed an asystolic gradient of 2 (±1) mmHg. The mean diastolic gradient was 66 (±3) mmHg with the left ventricular diastolic pressure at 4.9 (±1) mmHg, suggesting absence of significant regurgitation **(Figure 4).** Two dimensional echocardiography revealed no turbulence during systole, with maintenance of central flow. Color Doppler flow showed trace central regurgitation. No perivalvular leak could be identified. m-Mode echocardiography showed full opening of the leaflets with complete apposition during diastole **(Figure 5).**

## Discussion

Development of a percutaneously implantable aortic valve poses many challenging considerations. Two investigators have recently described aortic stent valves for percutaneous aortic valve replacement: a ball-cage and a balloon expandable porcine valve.[7,8] This study presents a new design for a collapsible, sutureless bioprosthetic valve for transluminal application. The acute study was undertaken to evaluate several features of this design.

First, the stability of a sutureless stent in the aortic annulus needed to be determined. In all *in vitro* studies, the valve remained firmly anchored in the ring with no displacement. This was confirmed in the animal studies, with the exception of animal 2. In this animal, valve dislodgment occurred secondary to structural failure of the stent at the weld point. This was probably caused by excessive manipulation and wear of the stent during the multiple *in vitro* studies that were performed. Previous prosthetic valves have also been plagued with this problem, and design changes have included making the strut from a single sheet of metal to eliminate weld sites.[9,10]

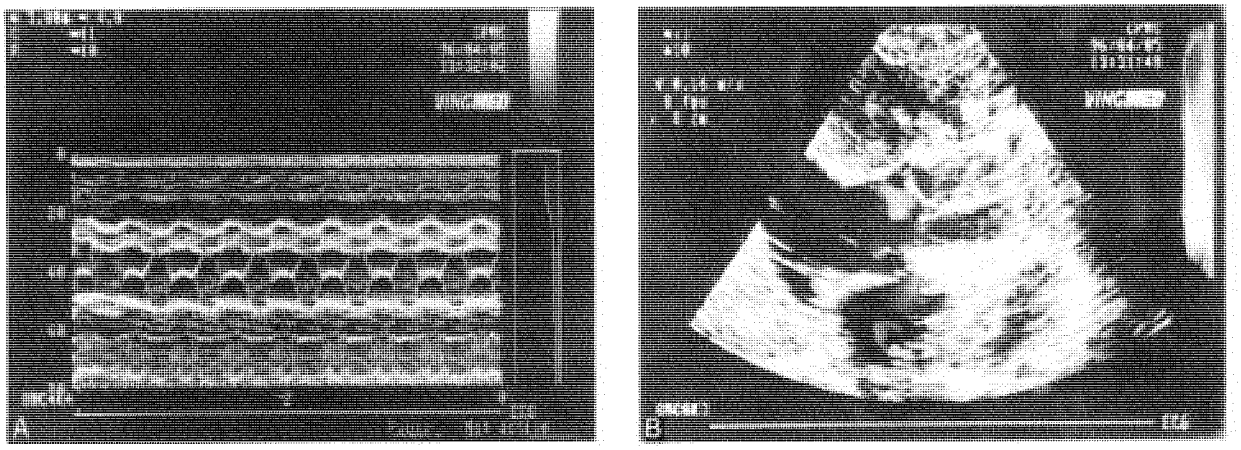


**Figure 5. (A)** m-Mode echocardiogram demonstrates full opening and closing of the leaflets. **(B)** Long axis view with trace regurgitation during diastole represented by the mosaic pattern at the center of the valve. No perivalvular leak is observed.

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Second, an effective watertight seal to prevent perivalvular leakage is of paramount importance. Our studies have demonstrated that the stent valve mechanism effectively prevents regurgitation when the valve is anchored properly. The dynamic nature of the aortic root during the cardiac cycle that causes the aorta to decrease in size[11] is probably another feature in favor of effective sealing. We postulate that this dynamic interaction between the stent valve and aorta is the reason that minimal to trace regurgitation was observed in the animal studies, as opposed to the *in vitro* data, which were collected in a rigid system and resulted in 10–18% regurgitation.

Finally, we have shown that when an appropriately sized valve is implanted in the subcoronary position, flow is unidirectional, with no turbulence and minimal transvalvular gradient and central flow. These factors are important to the design of a prosthetic valve with good hemodynamic performance.[12]

## Conclusion

We have developed a collapsible bioprosthetic aortic valve for implantation in the subcoronary position at the level of the aortic annulus. This report summarizes the preliminary evaluation of this stent valve in terms of secure anchoring, prevention of regurgitation, and adequate flow properties. The study is limited in that long term analyses were not performed, and many questions regarding durability of the stent and leaflets remain open. In addition, chronic studies are needed to assess valve thrombogenicity, thromboembolism, and absence of stent migration. This preliminary study establishes that a sutureless prosthetic stent valve is functional in the aortic position, and is a step toward development of a percutaneous approach in the foreseeable future.

## Acknowledgments

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(54) Title: SYNTHETIC VASCULAR PROSTHESIS

(57) Abstract: The present invention relates to a vascular prosthesis containing an active substance that has the capacity to stimulate the ingrowth of vascular cells, into the prosthesis. The present invention further relates to a method for the treatment of a vascular prosthesis, wherein the prosthesis is provided with an active substance capable of locally inducing the ingrowth of vascular cells, into the prosthesis material. Thus, the connection between vessel and prosthesis can be improved.

Title: SYNTHETIC VASCULAR PROSTHESIS

This invention relates to a vascular prosthesis and to a method to treat a synthetic vascular prosthesis.

Since the beginning of reconstructive vascular surgery at the end of the fifties of the 20th century, synthetic vascular prostheses are successfully used for reconstructive surgery of the heart, aorta and the larger arteries like iliac and femoropopliteal arteries. Synthetic grafts that are being used are made of *e.g.* Dacron® and PTFE (Polytetrafluoroethylene), but other materials are also being used.

In US patent 6,221,099 a synthetic prosthesis material is disclosed that is claimed to have improved properties over the standard prostheses made of Dacron®. The described material consists of metal wires and wires made of a second material. The second material serves as an absorbing part that can contain a drug to prevent the rejection of the graft by the body. This drug can also serve to inhibit intimal hyperplasia and can act as an anti-proliferative drug.

In order to improve prosthesis materials, a lot of attention has been paid to reducing thrombogenicity and inflammatory responses of the implanted material rather than to better healing of the prosthesis.

For example, JP 05 076588 A describes a vessel comprising a tube wall, which tube wall comprises a porous polymer compound. At the inner or outer surface of the tube wall, a substance stimulating and inducing a blood vessel endothelium cell is provided. The vessel is reported to have antithrombotic capability, apparently by the formation of a layer of endothelium at a surface of the vessel. It has been found that although lateral growth of endothelium has antithrombotic capability, such layer does not significantly contribute to the strength of the anastomotic site.

WO 00/30698 relates to a tissue/implant interface comprising an implant and a bioactive polymer layer adjacent to the outer surface of the implant. The implant interface is primarily designed to avoid uncontrolled inflammatory response and tissue fibrosis, at the surface of implanted devices, in particular biosensors. In order to achieve this, polymer layer contains one or more tissue response modifiers, such as anti-inflammatory agents, antifibrotic agents and/or anti-proliferative agents.

US 5,866,113 focuses on enhancing infection resistance of a medical device, such as a device made of biodegradable polyurethane. A biodegradable material is not considered to be particularly suitable for durable vascular prostheses for replacement of or in larger vessels in humans, such as grafts or heart valves for long-term implantation, since such implants would likely deteriorate and potentially put the patient's life at risk. The medical device is provided with a surface graft matrix. Biomolecules are covalently coupled to the matrix, mainly at the outer portion. In the biomolecules, pharmaceutical agents, such as anti-inflammatory and antithrombotic agents, may be located.

US 5,800,541 describes a method to prepare a collagen-hydrophilic synthetic polymer composition. The composition is reported to have a low immunogenicity and is suggested to be suitable for use in a variety of medical applications such as in drug delivery systems or in the manufacture of a formed implant. The material can be provided with a bioactive agent, e.g. an antithrombotic agent.

The colliding document WO 01/82992 relates to an alternative to synthetic implants. According to this publication synthetic DACRON and PTFE vascular prostheses are not ideal in arterial reconstructions, due to high risk of thrombosis and anastomotic hyperplasia. Rather than trying to reduce these risks by modifying the surface of the synthetic prosthesis (as has been proposed before), a different approach is described. As a basic structure for a vessel-prosthesis a decellularised vascular tissue (a biological

material) is used instead of a synthetic material. An anti-thrombogenic compound and a growth factor are linked to the vascular tissue. Potential drawbacks of this approach include availability (if donors of the same species should provide the material) and ethic considerations, in particular if vascular tissue of a different species is used (xenotransplantation).

Besides relevant factors discussed above (such as immunogenicity, and thrombogenicity), it is also of paramount importance that (synthetic) prostheses, especially vascular prostheses, are well incorporated into the human body. This holds in particular for the anastomosis between an artery and a vascular prosthesis. Unfortunately, as a rule, healing is incomplete and the strength of the anastomotic site remains largely dependent on the suture line (even after many years). If the suture breaks, anastomotic dehiscence can occur and a "false" aneurysm can be formed, which may result in a fatal rupture of the anastomosis. The inventors contemplated that, if healing could be induced, the formation of complications like false aneurysm formation could be avoided.

However, several problems are associated with the use of synthetic grafts that replace diseased arteries. First, it is well known that knitted/woven prostheses dilate during the first two years after implantation. Nunn et al demonstrated, among others that the maximum percent dilation for any part of the grafts ranged from 26% to 367% with a mean of 94% (*Nunn DB, Carter MM, Donohue MT, Hudgins PC., Postoperative dilation of knitted Dacron aortic bifurcation graft. J Vasc Surg (1990) 12; 291-297*). Some of their patients had generalized and saccular dilation of the aortic portion of the prostheses and an anastomotic aortic aneurysm.

Secondly, it is well known that "true" and "false" aneurysms may occur during long term follow-up. In previous reports, evaluating long term patient material, it has been found that a high prevalence of false aneurysms is abundant.

False (or anastomotic) aneurysm formation during follow-up is usually associated with considerable morbidity and mortality. False aneurysms may rupture just like normal aneurysms and may cause severe bleeding shock and death of the patient if the aneurysm is located in the abdomen or thorax.

Healing of a vascular prosthesis to the vessel wall of arteries, such as the aorta, is also very important in endovascular aneurysm repair (EVAR), which is an alternative to open conventional repair, in which the aneurysm is replaced by a synthetic vascular prosthesis. With EVAR, a rupture of *e.g.* an aortic or iliac aneurysm can be prevented. In this type of repair, for example an aortic prosthesis- combined with stents loaded in a sheath is introduced via the femoral artery in the aorta guided by fluoroscopy. Subsequently, the prosthesis is deployed at the proper location with the stents at the proximal and distal "landing zones" fixing the graft to the aortic wall. As a result the aneurysm is excluded from the arterial circulation.

A serious problem with EVAR is endoleak. An "endoleak" is defined as flow within the aneurysmal sac between the stent graft and the aortic wall. Endoleakage may be caused by insufficient sealing or by migration which is caused by insufficient attachment of the graft to the aortic wall. Again, healing of the graft to the arterial wall is incomplete and the quality of the connection between the prosthesis and the arterial wall remains primarily dependent on the stent. Insufficient fixation may cause migration of the prosthesis and may result in endoleakage. Endoleakage causes blood pressure in the aneurysmal sac and may ultimately result in rupture of the aneurysm. A serious problem is that the presence of endoleakage may be very difficult to detect with conventional imaging (ultrasound, duplex, computer tomography, MRI or angiography). As a result, aneurysms effectively treated with EVAR, from which the clinician thought that it had

been performed successfully and without endoleakage, have been ruptured causing death of patients.

Another problem is migration of the endoprosthesis, the implanted prosthesis, after EVAR. Again, due to incomplete and insufficient healing the continuous pulsatile blood stream also may cause the endograft to migrate distally with time. This may result in endoleakage and exposes the patient to the risk of rupture, bleeding and death.

It is an object of the present invention to provide an improved synthetic prosthesis, in particular an improved synthetic vascular prosthesis.

Another object is to reduce any of the above mentioned problems. Any additional purposes of the present invention will be elucidated in the description below.

It has been found that an improved synthetic prosthesis, such as a vascular prosthesis, can be provided by applying to a material forming the prosthesis (such as a fabric forming the prosthesis) a substance that can stimulate the ingrowth of cells, such as vascular cells into the prosthesis material.

Therefore, the present invention relates to a prosthesis, such as a vascular prosthesis, containing a substance capable of inducing or stimulating the ingrowth of cells, such as vascular cells, into the prosthesis material.

In particular, the present invention relates to a prosthesis wherein said substance is present in, on or at a material forming the basic structure of the prosthesis, wherein the basic structure contains voids, such as pores, to hold vascular cells. The voids allow ingrowth and/or adhesion of the cells after implantation of the prosthesis into a patient. More in particular the invention relates to a vascular prosthesis wherein said substance is present in, on or at said basic structure forming the tubular wall of a synthetic

vascular graft or in, on or at a material forming a synthetic heart valve or a part thereof, such as a part that is to be contacted with the heart tissue.

Preferably the active substance is at least provided in at least part of the voids of the material.

For a substance capable of inducing or stimulating the ingrowth of cells, in particular for a substance capable of inducing or stimulating the ingrowth of vascular cells, into the prosthesis material, the term "active substance" will be used within this application.

A vascular prosthesis as used herein is a prosthesis that can be used in the heart, in any other blood vessel or in any other vessel, duct or canal in the animal or human body. Examples for vascular prostheses in line of the present invention are vascular grafts, such as cardiovascular grafts, heart valves, stents, drains, bile ducts etc.

The term prosthesis material as used herein is meant to describe the material that forms the basic structure of the prosthesis, *e.g.* a fabric forming the tubular structure of a vascular graft or a material forming the structure of an artificial heart valve.

The basic structure of the prosthesis comprises voids. The term voids should be interpreted broadly and in particular includes any spaces in the basic structure that allow migration of vascular cells into the structure..

The voids should have suitable dimensions to allow migration of the cells of the vessel wall or a precursor thereof into the void. The diameter is typically more than the diameter of the cell and the depth of the voids should be deep enough to allow the formation of a cellular structure of a sufficient thickness to bond with the adjacent tissue. The skilled person will know how to choose suitable dimensions. The voids are preferably such that the ingrowth is possible essentially throughout the basic structure of the prosthesis, e,g. such as is possible with a prosthesis containing a basic structure having open pores. It is possible though to provide a prosthesis wherein the ingrowth is not throughout the thickness of the basic structure,

as long as the ingrowth is deep enough to allow an improved connection between the ingrown cells in the prosthesis and the adjacent tissue.

It is for example possible to provide a basic structure which comprises filaments, e.g. of a biocompatible and biostable material such as a material that is suitable to form the basic structure, at or on one or more surface regions of the basic structure. The spaces between the filaments may serve to hold the vascular cells after implantations. The skilled person will know how to choose suitable materials and design for the filaments, e.g. from those commercially available and/or described in the related literature. Such materials with filaments, also known as "velours" materials are for example commercially available from Meadox/Boston Scientific, Vascutek/Sulzer, Bard or Braun. Very suitable for example for a basic structure in a graft prosthesis is a double-velours type material, i.e. wherein both inner- and outer surface are provided with filaments.

Voids may be formed by slits or indentations at at least one surface of the basic structure.

Preferably the voids have the form of pores. The term pores should be interpreted broadly. For example, the interstitial space in a basic structure constructed of fibres (e.g. a woven or knitted material) may serve as pores, the pores may have the form of holes in the basic structure or the porous basic structure may be a spongy material.

Preferably, at least a substantial part of the pores are open pores, preferably at least the majority of the total pore volume is provided by open pores. Open pores extend from one surface of the prosthesis to another, e.g. from the inner wall to the outer wall of a arterial/venous graft.

Preferably at least part of the voids, such as pores, are filled with one or more active substances, biodegradable compounds and/or components that degrade or are released (e.g. dissolved), under physiological conditions. Thus, at least some time after implantation of the prosthesis, voids become accessible to one or more vascular cells or precursors thereof.

It has been found that after implantation of a prosthesis according to the invention, effective ingrowth and/or adhesion of cells into the basic structure forming the prosthesis is accomplished. As a result, effective healing occurs at the anastomosis of an implanted prosthesis according the invention. This results in a good incorporation of the synthetic prosthesis in the body and the blood vessel in which the anastomosis is made. A prosthesis according the invention can form a firm connection ("biological healing") to the adjacent tissue (in particular the vessel wall) in which the prosthesis is implanted. This results in complete healing of the prosthesis to the tissue (such as the vessel wall), such that the attachment of prosthesis to the tissue is not dependent anymore of a suture line (conventional repair) or stent (endovascular repair). This prevents both rupture of a false aneurysm and endoleakage *e.g.* due to distal migration of the vein graft.

A synthetic heart valve according the present invention, may impart a faster and more complete healing of the valve, resulting a in better attachment to the vessel wall and a reduced risk for leakage and thus reduces the need for re-interventions to correct the problems that occur due to incomplete healing of a synthetic heart valve.

Preferably, the prosthesis contains an active substance that induces and/or stimulates intimal hyperplasia and neointima formation *c.q.* induction and/or stimulation of smooth muscle cell proliferation and migration, preferably in a part of the tissue that is in direct contact with the basic structure containing the active substance. The formed neointima can grow invasively in and through the prosthesis material in such a way that a firm attachment can be obtained of a intravascularly-placed endovascular prosthesis to the vessel wall.

In a preferred embodiment, an active substance in a prosthesis according the present invention induces and/or stimulates the formation of tissue that enhances the fixation. In a particular preferred embodiment an active substance is present that is capable of stimulating fibrosis, i.e. the

accumulation of fibrocellular tissue by the tissue, *e.g.* vessel wall, at and in the prosthesis material. This may result in an extra firm attachment of the prosthesis material and the vessel wall.

It is especially remarkable that a graft prosthesis according the present invention, containing an active substance that induces and/or stimulates intimal hyperplasia and/or smooth muscle cell proliferation, has improved characteristics. After all, the experience in clinical practice would suggest the incorporation of active substances into the graft prosthesis that have opposite effects, *i.e.* the prevention of intimal hyperplasia and neointima formation.

Preferably the active substance is a growth factor. Examples of suitable growth factors are growth factors of the fibroblast growth factor family, *e.g.* bFGF or aFGF, of the platelet-derived growth factor family (PDGFs) and of the transforming growth factor family, *e.g.* TGFβ.

Very good results have been obtained using a prosthesis containing fibroblast growth factor (FGF). Of the fibroblast growth factor family, bFGF is a highly preferred growth factor to be used, *inter alia* because of its good capacity to bind to a coating of prosthesis material. Of course it is possible to apply a combination of active substances to a prosthesis according the present invention.

As a basic structure of the prosthesis (the untreated prosthesis) any kind of synthetic material can be used, as long as it is sufficiently biocompatible and biostable. A material is considered to be biostable, if it does not substantially degrade (chemically, by resorption or otherwise) under physiological conditions, for a prolonged time, typically for the life-time of the patient. More in particular, the material should preferably not substantially degrade under physiological conditions during a period of at least 25 years, more preferably of at least 30 years.

The term synthetic material is used herein to distinguish the material from biological tissues (including modified biological tissues) - such as heart

valves, blood vessels and the like - and biological tissue materials, such as collagen.

For instance a commercially available prosthesis can be used, such as a graft made of Dacron® or another condensation polymer obtainable from ethylene glycol and terephthalic acid, or of polytetrafluoroethylene (PTFE), such as Teflon®. Other suitable materials are *e.g.* polyamide (*e.g.* nylon), polyester, metal (e.g. nitinol, steel, etc.), polyurethane, polycarbonate-urethane, silicon, polyolefin, Orlon, Vinyon-D or any combination of these materials.

Dacron® and Teflon® or any comparable condensation polymer obtainable from ethylene glycol and terephthalic acid respectively PTFE, are particularly preferred. These materials are inexpensive, easy to handle, have good physical characteristics and are in general thought to be suitable for clinical application. Furthermore, no special precautions are required to prevent corrosion as may be the case when metals are used. A prosthesis, in particular a graft, comprising a basic structure of any of these two types of polymers has been found to be particularly advantageous, when it is provided with an impregnation comprising a biopolymer, such as a collagen and/or a heparin, which impregnation further comprises a growth factor, in particular an FGF.

The basic structure of the prosthesis preferably has a certain degree of openness (in the case of a porous basic structure also referred to as porosity), as is the case with a spongy, a woven or a knitted graft material. The desired degree of openness and the mean void diameter (in the case of pores: pore-size) depend on the application. For grafts for instance, the mean void diameter, more in particular the mean pore-size, may be 5-150 μm. Preferably the mean-pore size is in the range of 10 to 150 μm, more preferably in the range of 30 to 100 μm, even more preferably from 55 to 65 μm.

With respect to void-size distribution, it has been found that preferably at least the majority of the voids (such as pores), more in particular 80-100 % of the voids (such as pores), has a diameter in the range of 5-150 μm, more preferably a diameter in the range of 10 to 100 μm, even more preferably a diameter in the range of 30 to 65 μm.

Obviously, at the time of implantation, the voids - e.g. pores - may be filled with active substance and/or an impregnation, which gradually dissolves or degrades after implantation to allow ingrowth of vascular cells

To the vascular prosthesis, a coating, lining or impregnation can be applied. The term coating is used herein to describe a layer that is at least provided at one or more surfaces of the prosthesis. The term lining is used herein to describe a layer that is provided at the inner surface of a prosthesis. The term impregnation is used herein to describe the presence of on or more components inside the basic structure, in particular in the voids - such as pores - of the basic structure. The impregnation may partially or fully fill the voids. Preferably the impregnation is provided as a layer at least partially covering the inner surface of the voids, whilst maintaining a sufficient openness (porosity) to allow migration of endothelial cells or precursors thereof in the voids.

The coating, lining and/or impregnation may be provided to reduce the openness (porosity) of the graft at the time of implantation, e.g. avoid or at least to reduce blood loss through a porous graft. Such a coating/lining/impregnation can also contribute to the biocompatibility of the prosthesis material and/or the realization of a certain release pattern of one or more active substances.

Further, it may serve as a carrier for the active substance(s). The active substance(s) can be blended with the coating/lining/impregnation material or it can be attached to the surfaced thereof. Active substance(s) may be bound physically, by ion-ion interaction or covalently. For practical reasons it is preferred to bind active substance(s) non-covalently. In addition

it has been found that thus a prosthesis with a favourable release-pattern for the active substance(s) is obtained.

Good results have been obtained with at least partially biodegradable coatings, linings or impregnations.

Particularly good results have been achieved with a porous prosthesis provided with an impregnation, present in at least part of the pores. The active substance may form part of the impregnation and/or be provided at the inner surface thereof.

Any suitable compound or composition can be used for the coating, lining or impregnation of the prosthesis material. Very suitable are, amongst others, collagens, heparins, gelatines, fibrin, polyactides, polyglycolides, polygluconates, polydioxanons, elastins, glycosaminoglycans, fibronectins, laminins, proteoglycans, albumin and globulins, or any combination of two or more of the compounds. Of these compounds collagen in combination with heparin are highly preferred. A very suitable collagen is bovine collagen or the like, e.g. collagen derivable from bovine achilles tendon.

Collagen has been found to be very suitable as a carrier material for the active substance(s). For practical reasons the collagen may be cross-linked. By altering the degree of cross-linking, the skilled person will be able to influence the degradation rate of the carrier material and the release pattern of the active substance. The skilled person will know how to cross-link the material in a suitable way to obtain a desired release pattern and degradation rate based upon the information disclosed herein and common general knowledge. Particular good results have been achieved with a prosthesis impregnated with a collagen and with active substance, such as FGF, in particular bFGF.

The present invention provides in a prosthesis from which the active substance may be released in a controlled manner, under physiological

conditions. This can be achieved for instance by using a suitable coating or impregnation that is biodegradable.

Very suitable for obtaining a prosthesis with a constant release of an active substance, such as bFGF, during a certain time period is a prosthesis provided with collagen, heparin and the active substance.

Furthermore, the present invention relates to a method for the production/preparation of a vascular prosthesis, in which the prosthesis contains an active substance capable of inducing and/or stimulating the local ingrowth of vascular cells into the prosthesis.

The active substance can for instance be applied to the prosthesis in a pure form or in any other composition such a (diluted) solution, emulsion or dispersion. The active substance can, for instance, be applied very suitably to the prosthesis by means of impregnating or coating the active substance, or any composition containing the active substance, to the prosthesis material.

Further, it is possible first to apply a coating, lining or impregnation to the prosthesis and then add the active substance to it, or just the other way around, first apply the active substance and then apply the coating, lining or impregnation to the prosthesis material.

In a much preferred embodiment, first a biocompatible material, preferably collagen, is applied to the prosthesis material, to which in a next step heparin or a heparin-like substance is added (which may enable and/or enhance subsequent binding of an active substance), after which an active substance, preferably a growth factor, such as basic fibroblast growth factor, is applied.

The present invention further relates to the use of a fibroblast growth factor, preferably bFGF or FGF2, in the manufacture of a medicament for the stimulation of the ingrowth of vascular cells into an endovascular prosthesis. In a preferred embodiment the fibroblast growth factor, *e.g.* bFGF or FGF2, is used in the manufacture of a medicament for the

stimulation of intimal hyperplasia and smooth muscle cell proliferation and migration into a vascular prosthesis.

In a much preferred form of the medicament the prosthesis acts as an application device, or as an administration unit or dosage unit, (of the active substance of) the medicament.

The present invention relates to a composition for use in endovascular reparation (EVAR), in which said composition comprises one or more stents in a graft according the present invention and wherein the graft is surrounded by a sheath, *e.g.* a tube like cover.

A graft in such a composition comprises a hollow tubular structure (*i.e.* at least in expanded state it is hollow), in which the inner wall forms a circumference of a central passage way in which the passage way extends along the longitudinal direction from one end of the tubular structure towards the other end of the structure; one or more stents are placed in the central passage way of the graft, the stent or stents and the graft are expandable in radial direction; the outer wall of the graft in the preferred composition is enveloped with a cylindrical sheath, wherein the composition has a diameter and length suitable for catheter-based delivery to a vascular segment, *e.g.* an arterial segment, to be treated. Herein the catheter may be positioned via entry in *e.g.* the femoral artery (or any other possible entry, such as *e.g.* the aorta or the illiac artery). Such a composition has been found particularly suitable for treating an aneurysm in the aorta.

Once a said composition is placed at the appropriate site in the blood vessel, the sheath- surrounding the graft can be removed, *e.g.* according the procedures known from the standard EVAR procedure currently in use. The graft containing the stent, or stents, can then expand in radial direction in such a way that the outer wall of the graft is positioned in direct contact with the vessel wall. Subsequently, under influence of the active substance in the graft that can induce and/or stimulate ingrowth of vascular cells, as described herein, the graft may from an firm connection with the vessel

wall. The said sheath and stent(s) may be of any material suitable, preferably, but in no way limited to, those currently in use for the standard EVAR procedure.

The present invention further relates to a novel method for the treatment of a (cardio)vascular disorder, which method comprises the application of an endovascular prosthesis according the present invention to the vascular system of a patient.

In a preferred embodiment of treating a (cardio)vascular prosthesis according to the invention or a composition according to the invention, comprising a graft, a stent and a sheat, is placed into the vacular system by a catheter-delivery based minimal invasive endovascular technique. In particular, the present invention relates to a method to induce and/or stimulate the healing of an endovascular prosthesis to the vessel wall after implantation of the prosthesis.

Very good results have been obtained using a method in which the endovascular graft prosthesis is placed into an artery to repair an aneurysm. In that way it has been found that that rupture of an aneurysm, *e.g.* in the aorta or any other artery, can be prevented. Further, it has been found that after such a treatment only very little or no endoleakage occurred between the graft and the vessel wall. Also the occurrence of distal migration of the implanted graft can be strongly reduced or or even prevented totally.

A prosthesis according the present invention is very suitable for application as an endovascular graft in the treatment of abdominal or thoracic aorta aneurysms (or any other kind of aneurysm), but can be applied to material used for other endovascular grafting procedures, such as percutaneous in situ coronary venous arterialization (PICVA) as described by Oesterle *et al.* (*Oesterle SN, Reifart N, Hauptmann E, Hayase M, Yeung AC: Percutaneous in situ coronary venous arterialization : Report of the first human catheter-based coronary artery bypass. Circulation 2001;103:2539-*

*2543*). In this procedure a catheter based coronary artery bypass is performed based on the construction of a fistula from the proximal coronary artery to the coronary vein using an endovascular graft that requires healing to the vessel wall to prevent endoleakage.

Further, the present invention can be applied on many other devices that are placed in a intra(cardio)vascular setting and suffer from problems that are related to the lack of healing to the vessel wall. This may be a device such as a heart valve.

The present application will now be illustrated while referring to the following examples. It is to be noted that these examples merely serve to illustrate the invention, not to restrict it.

***Example 1***

***Induction of neointima formation/intimal hyperplasia in organ cultures of human and pig aorta***

In contrast to saphenous vein organ cultures *(Slomp J.Gittenberger-deGroot AC.van Munsteren JC.Huysmans HA.van Bockel JH.van Hinsbergh VW.Poelmann RE. Nature and origin of the neointima in whole vessel wall organ culture of the human saphenous vein. Virchows Arch 1995; 428:59-67)*, cultures of aortic wall segments, neither human nor porcine, do not spontaneously develop a neointima in culture medium containing 30% Fetal Calf Serum. However the formation of a neointima can be induced by addition of growth factors to the culture medium, as disclosed in the following described experimental example.

Segments of porcine aorta were collected in sterile RPMI (Roswell Park Memorial Institute) 1640 culture medium supplemented with 20 mmol/l HEPES buffer, 4 IU/ml sodium heparin, 2.5 μg/ml, 100 U/ml penicillin, 100 μg/ml streptomycin, 2 mmol/l L-glutamine and 2.5 μg/ml amphotericin-B, and transported to the laboratory on ice. After removing the adventitia and fat tissue, the aorta segment was opened along its

longitudinal axis. A small piece was cut of for analysis by histochemistry as t=0 reference sample. The remaining part of the aorta was fixed by needles in a petri-dish coated with Sylgard 184 silicone elastomer (Dow Corning), with its endothelial surface upward. The aorta segments were cultured for a period of 4-5 weeks at 37°C in humidified atmosphere of 5% $CO_2$ in culture medium (sterile RPMI 1640 supplemented with 20 mmol/l HEPES buffer, 2.5 μg/ml, 100 U/ml penicillin, 100 μg/ml streptomycin, 2 mmol/l L-glutamine and 2.5 μg/ml amphotericin-B) supplemented with 30% heat-inactivated fetal calf serum. Furthermore, basic Fibroblast Growth Factor (bFGF 10 ng/ml) was added every time the culture medium was replaced. The medium was replaced every 2-3 days.

As can be seen in figure 1, in the pig aorta organ cultures, intimal hyperplasia can be induced by addition of basic fibroblast growth factor, 10 ng/ml, resulting a prominent neointima after 4-5 weeks in culture.

The same experiments were performed with segments of human aorta in organ cultures. Again, in human aortic organ cultures a clear induction of neointima was observed after 4-5 weeks in culture in the presence of 10 ng/ml bFGF.

***Example 2***

***Vascular prosthetic material coating and bFGF release***

Under sterile conditions, the standard woven vascular prosthetic material, Dacron® (Dupont), porosity 60 μm, was impregnated with collagen according the following previously described procedure. Type I insoluble collagen (1 g) derived from Bovine Achilles Tendon (Sigma, St Louis, MO, USA) was swollen overnight in 0.52 M acetic acid solution (50 ml) at 4°C.

The mixture was dispersed with 50 g of crushed ice for 4 minutes in a blender and thereafter homogenized for 30 minutes at 4°C using an Ultra-Turrax T25 (IKA Labortechnik, Staufen, Germany). The resulting slurry

was filtered through a series of filters (Cellector screen, Bellco, Feltham, England), with a pore size decreasing from 140 μm to 10 μm, mounted in 47 mm diameter Swinnex disc filter holders (Millipore, Etten-Leur, The Netherlands).

After de-aeration at a pressure of 0.06 mBar, the resulting suspension was cast as a film on small pieces of Dacron® in sterile petri-dishes and dried at room temperature in a sterile flow cabinet. The Dacron®, pieces impregnated with collagen, were cross-linked using 0.731 g N-(-3-dimethylaminopropyl)-N'-ethylcarbodiimide hydrochloride (EDC) and 0.415 gN-hydroxysuccinimide (NHS). The crosslinking was carried out in 215 ml buffer of 2-morpholinoethane sulfonic acid (MES) buffer, 0.05 M, pH adjusted to 5.4 using 10 M NaOH, to minimize hydrolysis of EDC.

After 4 hours, the crosslinking was completed and stopped by washing the impregnated Dacron® with 0.1 M $Na_2HPO_4$ solution for 2 hours. This treatment resulted in hydrolysis of both activated carboxylic acid groups and remaining EDC. After repeated washing with sterile demineralised water (four times 30 minutes) the Dacron®, impregnated with cross-linked collagen was ready for heparin immobilization.

Heparin sodium salt (Bufa Chemie, Castricum, The Netherlands) was used. The carboxylic acid groups of heparin (Hep-COOH) were activated by adding EDC and NHS to a 2% solution of heparin in 0.05 M MES buffer (pH 5.6), at a molar ratio of EDC: NHS: Hep-COOH of 0.4: 0.24: 1.0. After 2 hours incubation the Dacron®/collagen/heparin was washed with 0.1 M $Na_2HPO_4$ for two hours, 4 M NaCl for four hours and distilled water for three times 24 hours. (*Wissink MJ, Beernink R, Scharenborg NM, Poot AA, Engbers GH, Beugeling T et al. Endothelial cell seeding of (heparinized) collagen matrices: effects of bFGF pre-loading on proliferation (after low density seeding) and pro-coagulant factors. J Control Release 2000; 67(2-3):141-155.;Wissink MJ, Beernink R, Pieper JS, Poot AA, Engbers GH, Beugeling T et al. Immobilization of heparin to EDC/NHS-crosslinked*

*collagen. Characterization and in vitro evaluation. Biomaterials 2001; 22(2):151-163.*).

The binding of bFGF was carried out after incubating the Dacron®/collagen/heparin in phosphate buffered saline (PBS). After blotting dry, the films were incubated with 320-500 ng bFGF in PBS containing 1 mg/ml BSA for 90 minutes at room temperature.

The release of bFGF was tested every 24 h in a sample obtained from the culture media in which the Dacron®/collagen/heparin/bFGF segments (1 cm diameter) were placed. After taken the sample every 24 hours, the medium was replaced. The concentration of bFGF in the release samples was determined using an ELISA for bFGF. The first 3 days a washout effect was detected followed by a stable release of bFGF of approximately 2 ng/ 24 h for 28 days (see figure 2 for the first 10 days). No major differences in long-term release could be observed after incubation with either 300 or 500 ng bFGF (not shown). The release of bFGF from the Dacron®/-collagen/heparin/bFGF segments was also determined in the presence of organ cultures. Incubation of the Dacron® provided with bFGF/collagen/heparin resulted in a similar release of bFGF into the medium (figure 2). Binding of bFGF on the collagen layer without heparin resulted in a quick release of bFGF in 4-5 days, after which no more release of bFGF could be detected.

*Example 3*

*Quantification of ingrowth of neointima in prosthesis*

Experiments for inducing ingrowth of neointima in the vascular prosthetic material were performed as follows. Aortic tissue samples were obtained as previously described and directly attached to samples of one square cm of impregnated Dacron®. Experiments were performed with (a) unimpregnated Dacron® (control experiments), (b) collagen/heparin impregnated Dacron® (control experiments) and (c) collagen/heparin with growth factor impregnated Dacron®. Dacron® samples were attached to the aortic samples by either needles or paperclips. Subsequently, the samples were cultured for up to 35 days.

At different time points, 7, 14, 21, 28 and 35 days, the organ cultures with the prosthetic material were histologically evaluated using formaldehyde (4%) fixated, paraffin embedded tissue sections. After histochemical staining of section of the cultured vessel wall segments, the intimal hyperplasia was evaluated by computer assisted image analysis (Leica Imaging Systems, Cambridge, England). To asses the ingrowth into the Dacron® the number of cell layers was counted as well as the number of cells infiltrating in the Dacron®.

*Ingrowth of neointima in prosthesis*

When organ cultures were grown with an overlay of the bFGF impregnated Dacron®, cells from the neointima start to migrate through the collagen impregnated prosthesis material, eventually resulting in a neointima on top of the prosthesis material (Figure 3A). The cells migrated were shown to be smooth muscle cells that were α-SM actin positive by immunohistochemistry (data not shown). The induction of the neointima formation occurred only in porcine aorta organ cultures covered with prosthesis material provided with bFGF. Neointima formation was absent

in porcine aorta organ cultures with pure Dacron®, Dacron® with collagen/heparin as well as in the control organ cultures without prosthesis material.

The ingrowth of neointima through the Dacron® was measured and quantified. The ingrowth of the neointima progressed in time with a mean neointima area per cross section of the cultured segments of $0.43 \pm 0.11$ mm$^2$ after 5 weeks in culture (figure 3B).

Experiments using human aorta organ cultures showed comparable results. The human aortic organ culture were capable of formation of neointima, induced by the bFGF-collagen impregnated Dacron®. The cells of the neointima in the human aortic wall were capable of growing through the prosthetic material (figure 3 C).

Neointima formation and cellular invasion through the prosthesis material could only be observed when the cultures were overlaid with bFGF impregnated Dacron® prosthesis material.

The neointimal ingrowth into the prosthesis material provided with collagen, heparin and bFGF resulted in a fixation of the prosthesis material to the vessel wall segments, both of porcine and human origin, in this *in vitro* model system.

***Example 4***

The fixation of the Dacron® prosthesis material provided with collagen and bFGF was exemplified using handmade stents prostheses of 2 cm in length that are positioned into the aorta of pigs.

For this, the diameter aorta of the pigs in the study first was measured using angiography. The custom-made stents were made to fit to the size of the aorta and prepared according the required conditions, *i.e.* non-coated, non-impregnated Dacron®; impregnated Dacron® without bFGF and impregnated Dacron® with bFGF. Provision of collagen, heparin

and impregnation with bFGF was done as described above in example 2. The binding of bFGF was carried out after incubating the Dacron®/collagen/heparin in PBS. After blotting dry, the films were incubated with 320 or 500 ng bFGF in PBS containing 1 mg/ml BSA for 90 minutes at room temperature.

The stents were placed through a sheath (20 French pusher, Cook Denmark) under angiographic control and were left in the aorta for 2 months. After two months the pigs were sacrificed and the aortas with the stents were evaluated macroscopically, histologically and by scanning electron microscopy.

Macroscopic analysis revealed that a firm adhesion of the prosthesis material to the aorta wall occurs when bFGF impregnated Dacron® prosthesis material were used, indicating that the graft material had healed to the vessel wall. In none of the other conditions adhesion, and thus healing, occurred. As can be seen in figure 4A, two months after initial placement of the Dacron® prosthesis, it is fixed to the vessel wall of the aorta in such a way that it does not detach, not even after cutting the stent material.

Histological analysis demonstrated that at the moment of sacrifice, two months after initial placement, the bFGF containing impregnated Dacron® graft material was fully incorporated into the vessel wall (figure 4B), whereas the controls were not incorporated.

Figure 5 shows two scanning electron micrographs, illustrating how the graft according to this example was overgrown with neointimal vascular cells.

Claims

1. A vascular prosthesis, containing an active substance that has the capacity to stimulate the ingrowth of vascular cells into the prosthesis, wherein the prosthesis is formed by a synthetic basic structure, which structure comprises voids for holding vascular cells.

2. A vascular prosthesis according claim 1, wherein the active substance is an inducer and/or stimulator for the production and/or deposition of connective tissue, smooth muscle cell proliferation and/or migration, intimal hyperplasia and/or neointima formation.

3. A vascular prosthesis according to claim 1 or 2, wherein the active substance is chosen from the group consisting of basic fibroblast growth factors, acidic fibroblast growth factors, platelet derived growth factors, transform growth factors beta, any other growth factor able to induce and/or stimulate the production and/or deposition of connective tissue, smooth muscle cell proliferation and/or migration, intimal hyperplasia and/or neointima formation and any combination of said growth factors.

4. A vascular prosthesis according to any of the preceding claims, wherein the prosthesis contains an active substance, capable of stimulating fibrosis.

5. A vascular prosthesis according to any of the preceding claims, wherein the prosthesis comprises a coating, lining or impregnation, preferably a coating, lining or impregnation which is at least partially biodegradable.

6. A vascular prosthesis according to claim 5, wherein the coating, lining or impregnation comprises collagen, heparin, gelatin, fibrin, elastin, glycosaminoglycans, fibronectin, laminin, proteoglycans, albumin, globulin, polyactide, polyglycolide, polygluconate, polydioxanon or any combination of two or more of these compounds.

7. A vascular prosthesis according any of the preceding claims, wherein the basic structure of the prosthesis is at least mainly made of a

polycondensate of ethylene glycol and terephtalic acid (*e.g.* Dacron®), polytetrafluorethylene (Teflon®), polyamide (*e.g.* nylon), polyester, metal, metal alloy, polycarbonate-urethane, silicon, polyolefine (*e.g.* polyethene) or any combination thereof.

8. A vascular prosthesis according to any of the preceding claims, wherein the active substance is released under physiological conditions in a controlled manner.

9. A vascular prosthesis according to any of the preceding claims, wherein at least part of the voids in the basic structure are pores.

10. A vascular prosthesis according to any of the preceding claims, wherein the mean void diameter of the voids in the basic structure is in the range of 5-150 μm.

11. A vascular prosthesis according any of the preceding claims in the form of a vascular graft or an artificial heart valve.

12. A composition for use in endovascular repair (EVAR), comprising a graft according to claim 11, a stent and a sheath, wherein the stent is positioned in a central passage way of the graft, wherein the stent and the graft are resiliently compressed to allow expansion in the radial direction and wherein the outer surface of the compressed graft is surrounded by a cylindrical sheath, wherein the composition has a diameter and length suitable for catheter-based delivery to an vascular segment, *e.g.* an arterial segment, to be treated.

13. A method for preparing a vascular prosthesis, wherein a prosthesis is provided with an active substance capable of locally inducing the ingrowth of vascular cells into the prosthesis material.

14. A method according to claim 13, wherein the substance is applied by means of coating, impregnating or lining of a basic structure forming the prosthesis.

15. A method according to claim 12 or 13, wherein the basic structure is first provided with collagen, subsequently with heparin and thereafter with the active substance.

16. A method according to any of the claims 13 -15, wherein the active substance is a growth factor, *e.g.* a fibroblast growth factor.

17. Use of a growth factor, preferably a fibroblast growth factor, in the manufacture of a medicament for stimulating the ingrowth of vascular cells into an endovascular prosthesis, wherein the prosthesis is formed of a synthetic basic structure, which structure comprises voids for holding vascular cells.

18. Use according to claim 17, wherein the administering-unit of the medicament is the vascular prosthesis.

19. A method for the treatment of a vascular disorder, said method comprising the placement of an endovascular prosthesis according to any of the claims 1-11 or a composition according to claim 12 in the vascular system of a patient.

20. A method according to claim 19, wherein the prosthesis or the composition is placed into the vascular system by a catheter-delivery based minimal invasive endovascular technique.

Figure 1

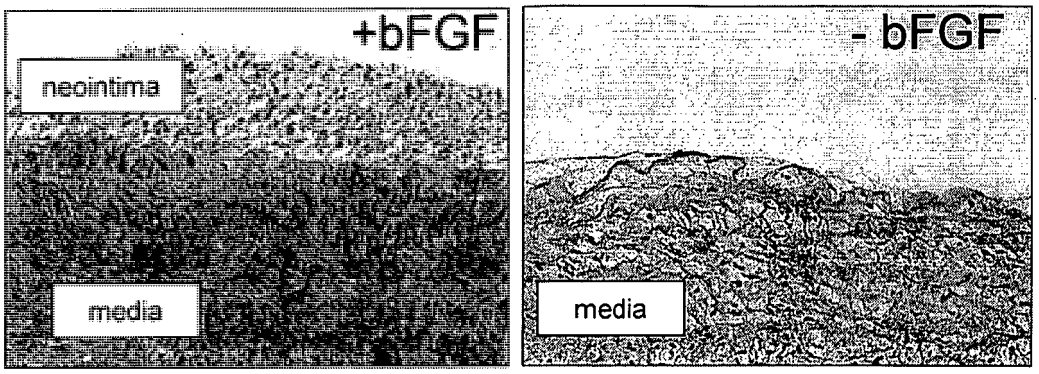


Figure 2

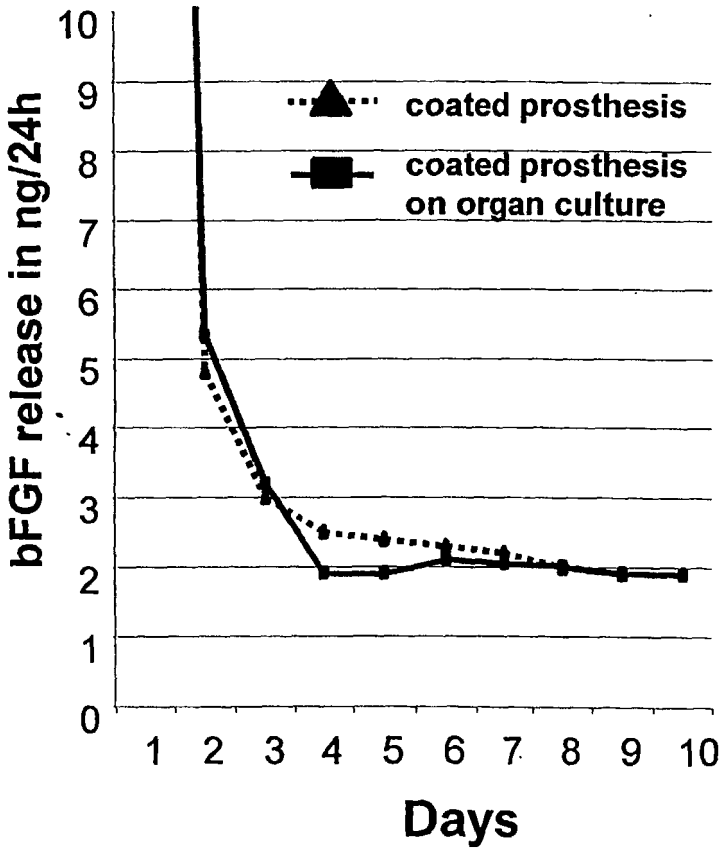

bFGF release in ng/24h
10
9
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10
Days
coated prosthesis
coated prosthesis on organ culture

Figure 3 (pig)

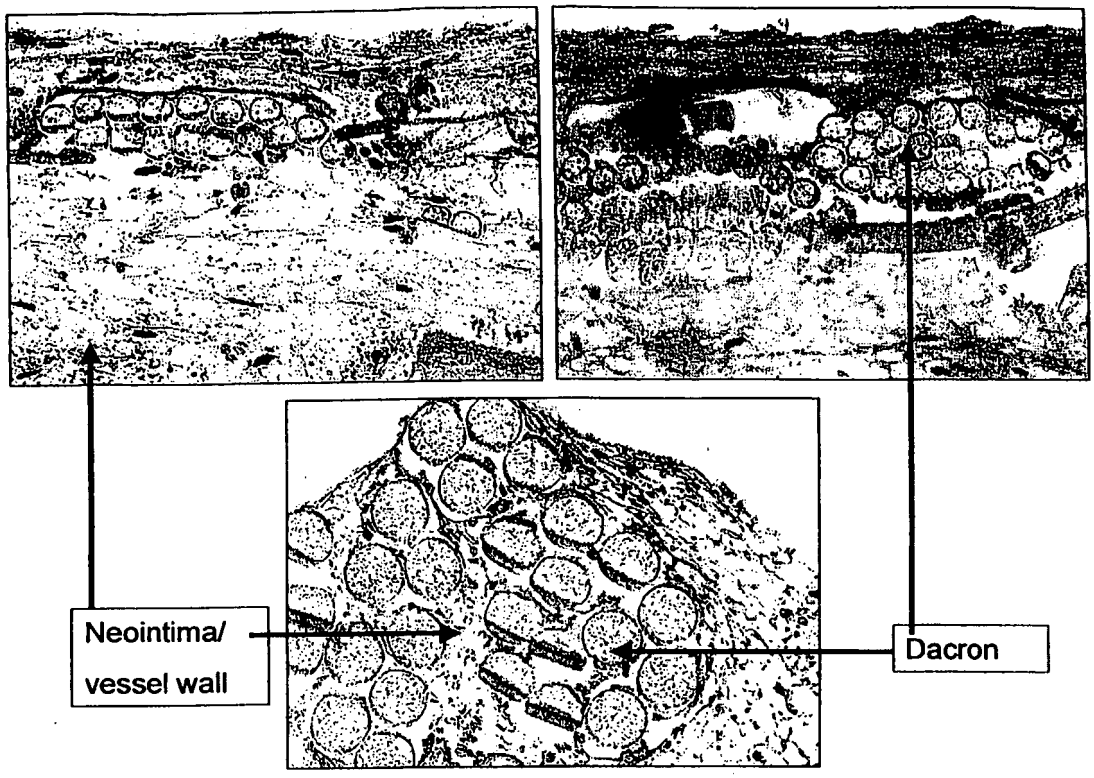


**Figure 3B: neointima mean area ($mm^2$) in pig aorta cultures with Dacron /bFGF overlay**

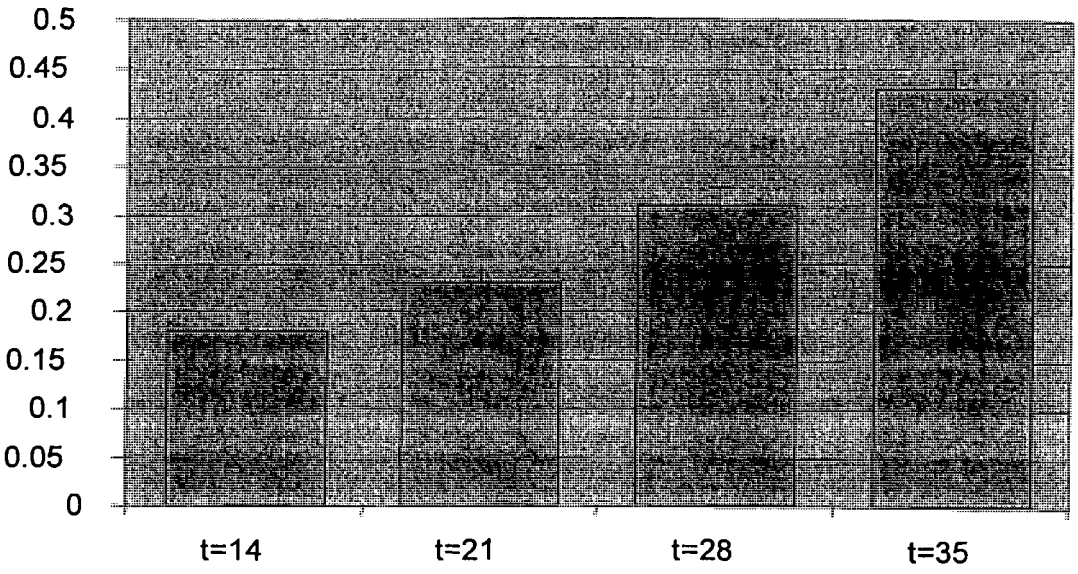



**Figure 3C: neointima mean area ($mm^2$) in human aorta cultures with Dacron /bFGF overlay**

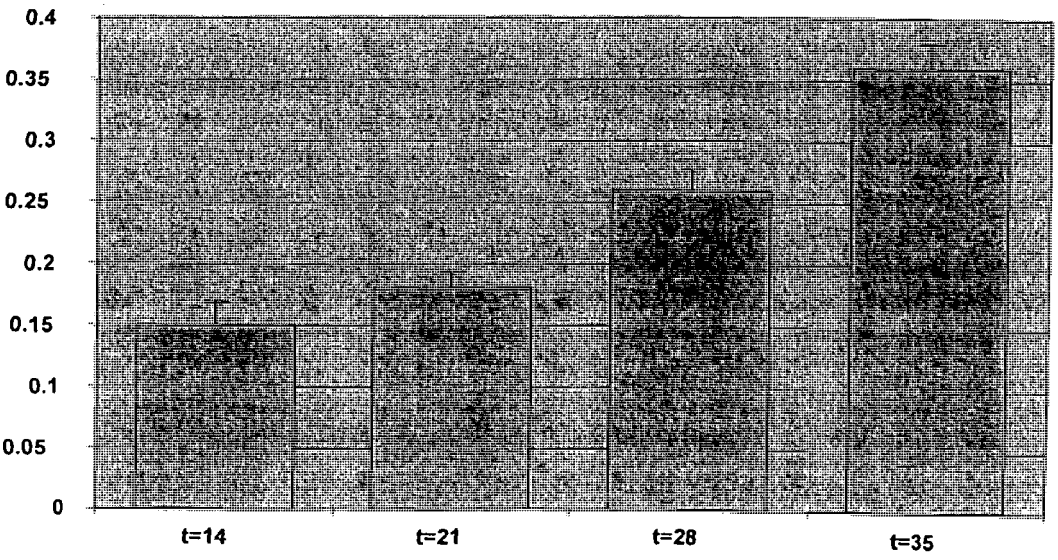


Figure 4
A

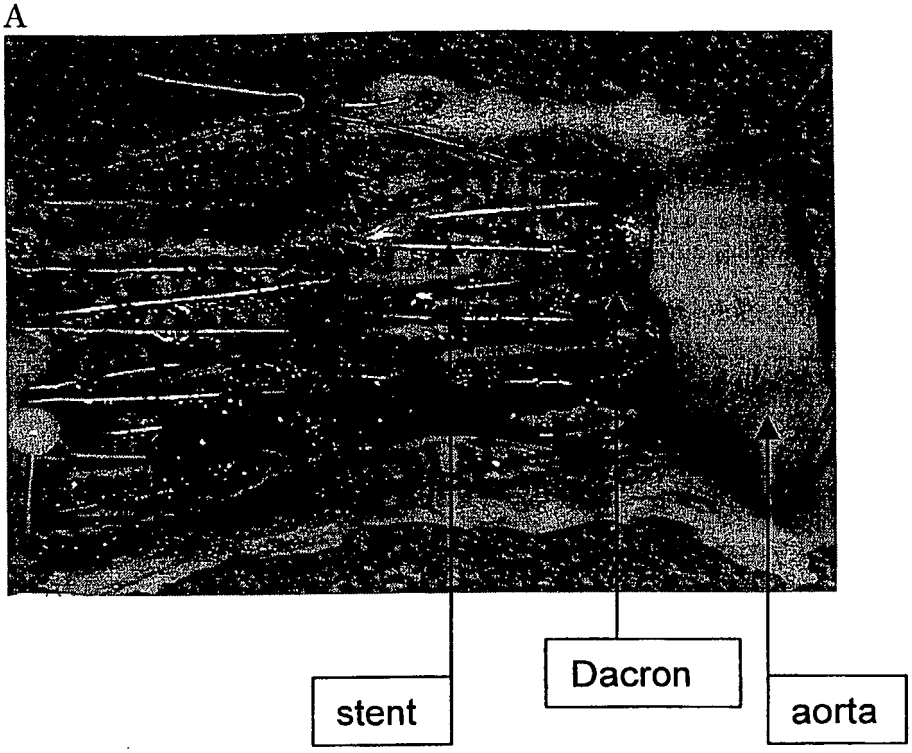
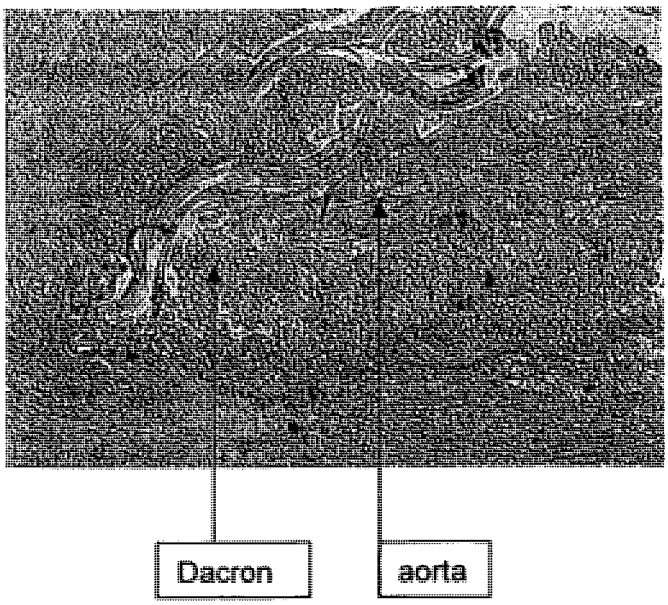


Figure 4B



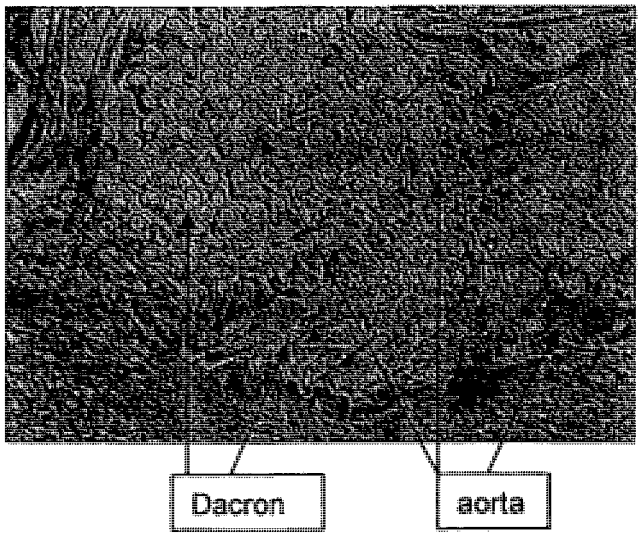
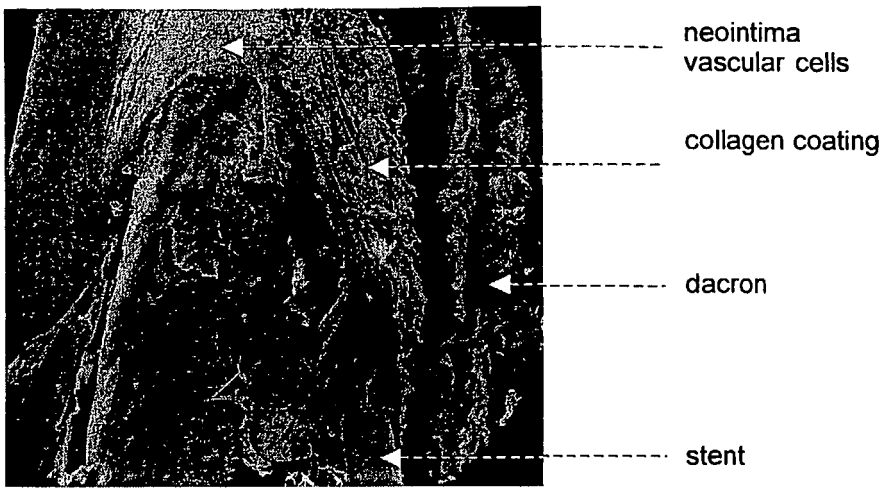
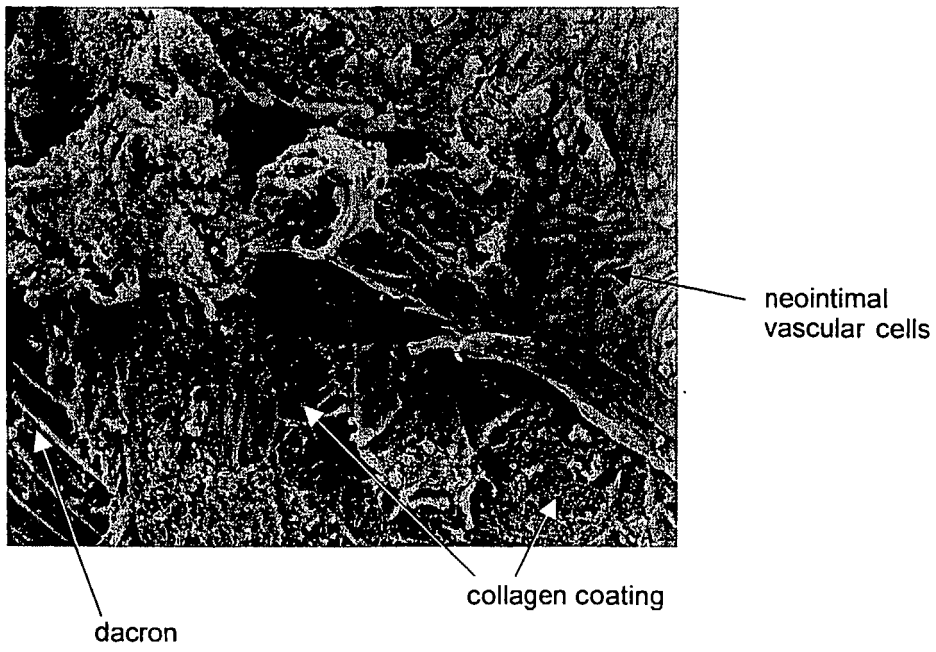



**Figure 5: Illustration of graft being overgrown with vascular cells**



# INTERNATIONAL SEARCH REPORT

PCT/NL 02/00007

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L27/54 A61L31/16

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)
IPC 7 A61L

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 practical, search terms used)
WPI Data, PAJ, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | DATABASE WPI<br>Section Ch, Week 199317<br>Derwent Publications Ltd., London, GB;<br>Class A14, AN 1993-139624<br>XP002204680<br>& JP 05 076588 A (JINKOU KEKKAN GIJYUTSU KENKYU CENT KK),<br>30 March 1993 (1993-03-30)<br>abstract<br>--- | 1-6,9,<br>11,14,<br>16-19 |
| X | WO 00 30698 A (UNIV CONNECTICUT)<br>2 June 2000 (2000-06-02)<br>page 3, line 5 - line 27<br>page 6, line 20 - line 30<br>page 18, line 16 - line 26<br>page 20, line 3 - line 8<br>claims<br>---<br>-/-- | 1-3,5,8,<br>13,16,17 |

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 27 January 2003 | 04/02/2003 |

| Name and mailing address of the ISA | Authorized officer |
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| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Cousins-Van Steen, G |

2

Form PCT/ISA/210 (second sheet) (July 1992)



Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1732
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication,where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
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# INTERNATIONAL SEARCH REPORT

PCT/NL 02/00707

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 19 and 20 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.



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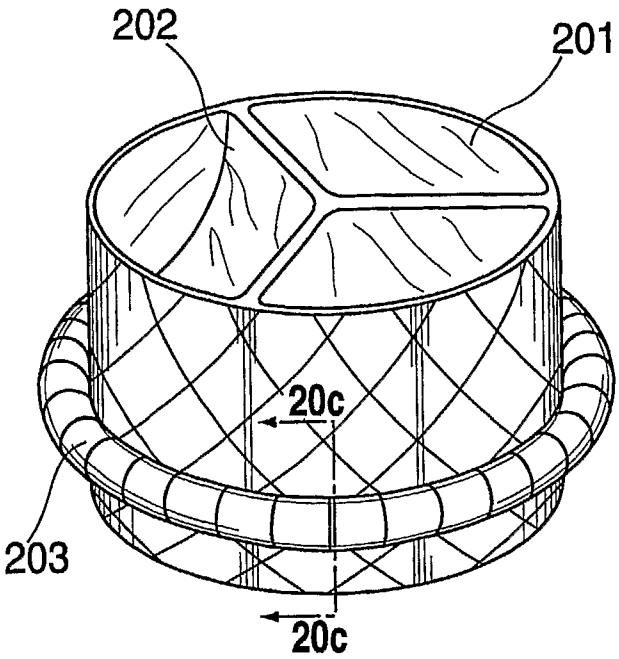
(54) **Title:** PARAVALVULAR LEAK DETECTION, SEALING AND PREVENTION




(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

**[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

**[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.

**[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 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 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 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, 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 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 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, "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 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 transceptal hole and 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 bring comprised of a deployable construction 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 bring provided with a plurality of longitudinally rigid support beams 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, 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 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 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 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 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 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 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.

**[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 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 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 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, 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 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.

**[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, 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.

**[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 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 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 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 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.

**[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, 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 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 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.

**[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 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 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 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 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 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,

**[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 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 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

**[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.

**[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.

**[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.

**[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 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

**[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 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.

## 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 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 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 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.

**[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 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).

**[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 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.

**[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 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..

**[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 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 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 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.

**[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.

**[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

**[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.

**[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 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 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 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 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.

**[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 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.

**[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, 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 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 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 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. 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 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 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 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 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 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 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 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.

**[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 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.

**[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 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.

**[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.

**[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 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 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. 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, 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 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.

**[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, 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 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 guide wire 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 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 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 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 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 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 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 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 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. 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.

**[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 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 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 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 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 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.

**[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 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 (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 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 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. 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 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 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 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 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).

**[00140]** Figures 19a to19d 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 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 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 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 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 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, the hydrogel absorbs fluids from the blood and expands to the 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 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 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 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 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-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 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, 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 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 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 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 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 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 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 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 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.

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.

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.

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. 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 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.

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

a substantially cylindrical stent structure configured for radial expansion;

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 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.

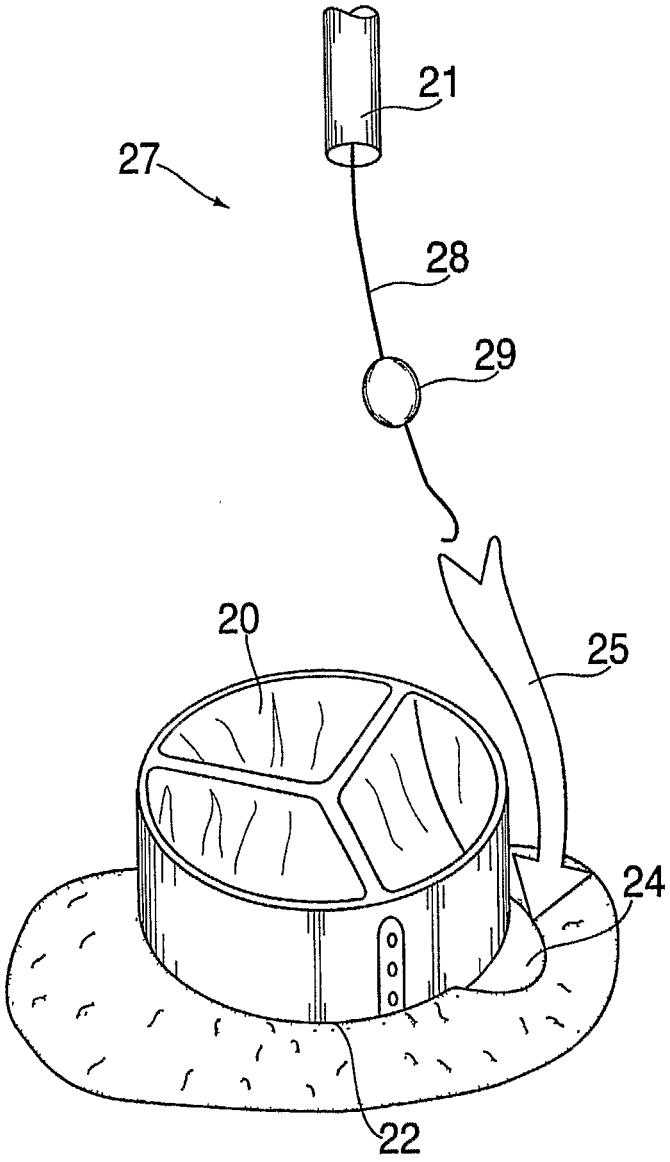


FIG. 1



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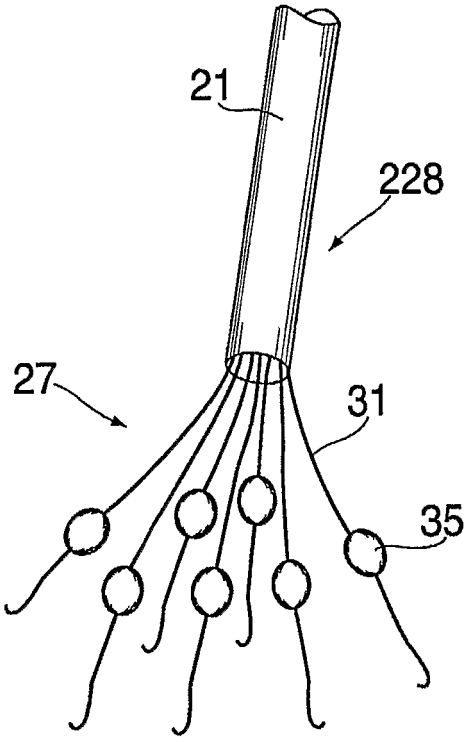


FIG. 2a

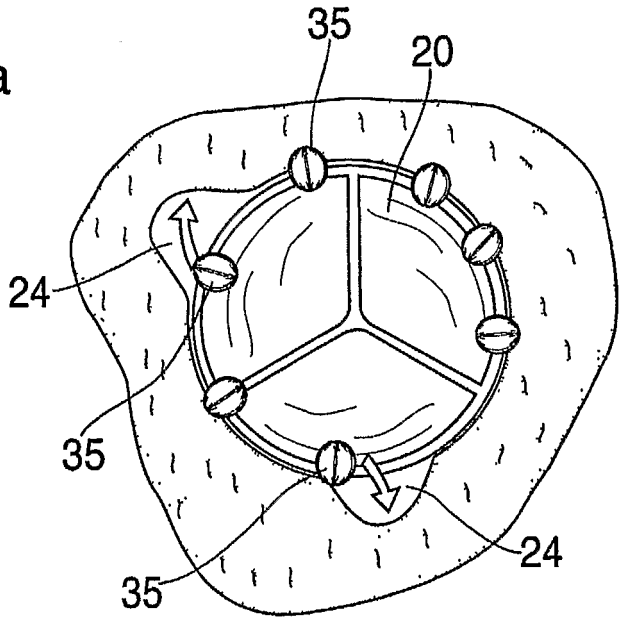


FIG. 2b



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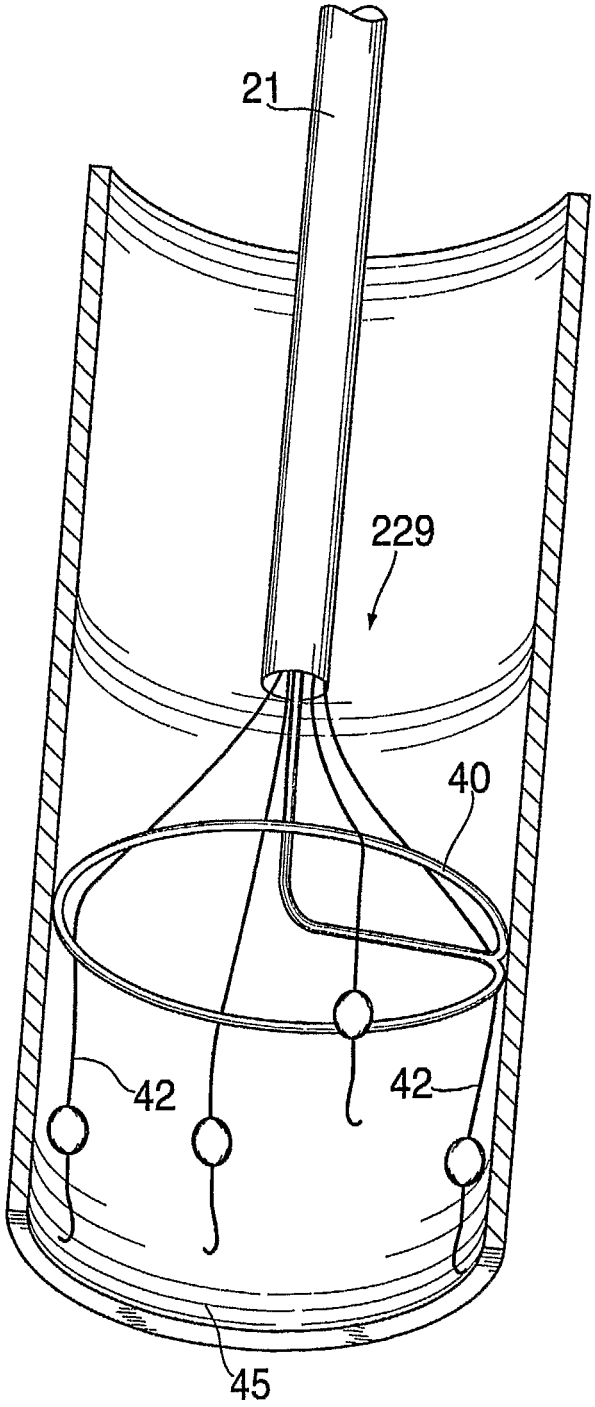


FIG. 3



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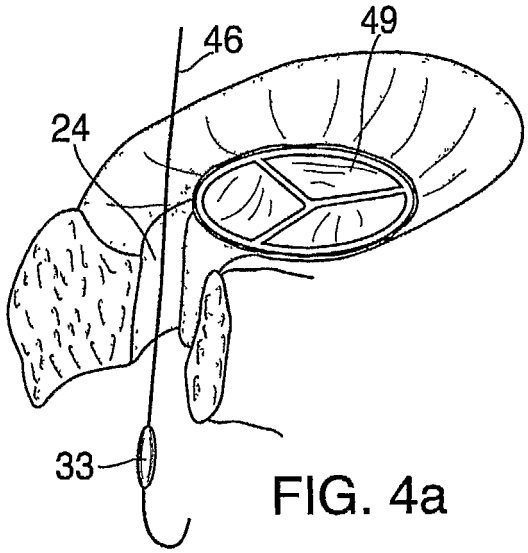


FIG. 4a

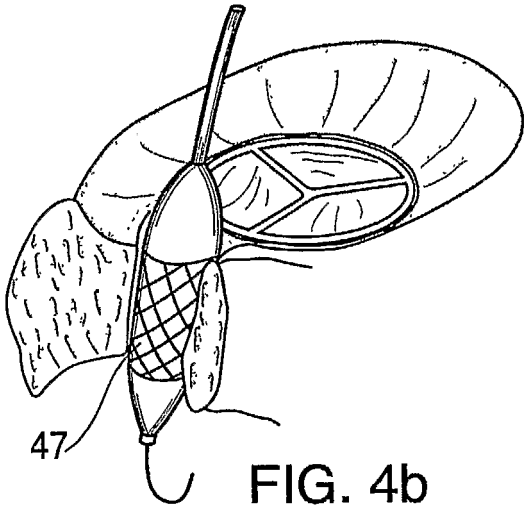


FIG. 4b

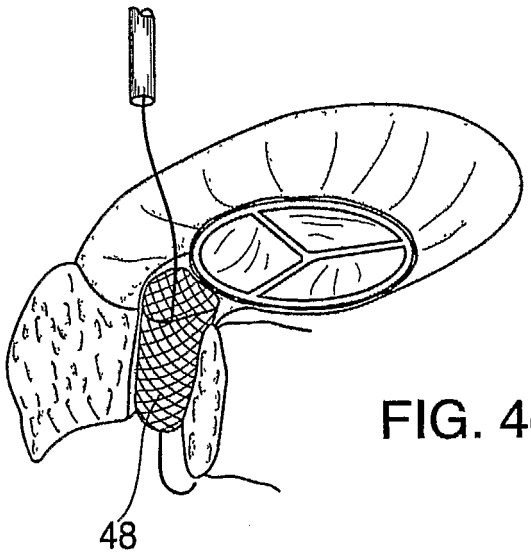


FIG. 4c



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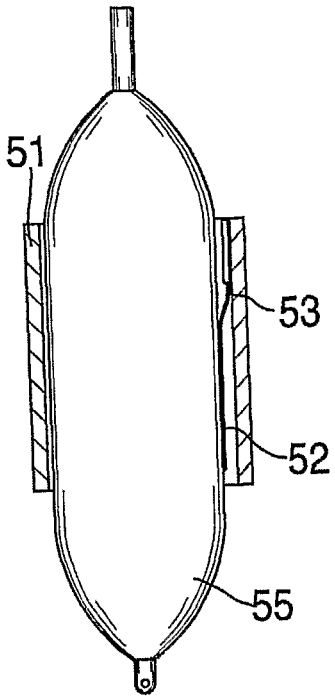


FIG. 5a

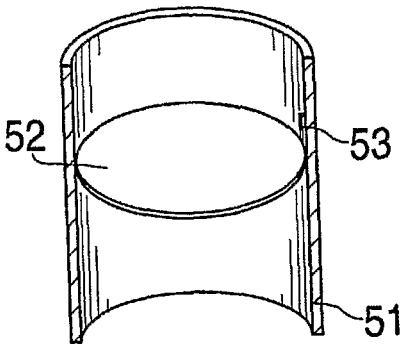


FIG. 5b

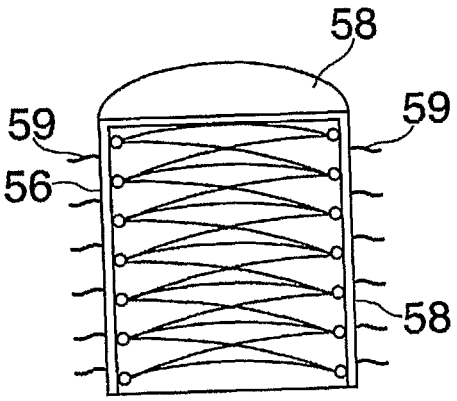


FIG. 5c

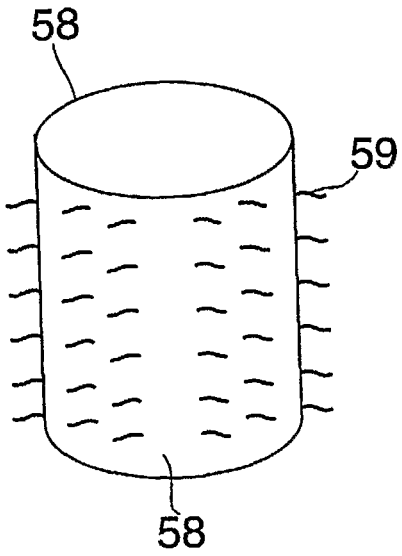


FIG. 5d



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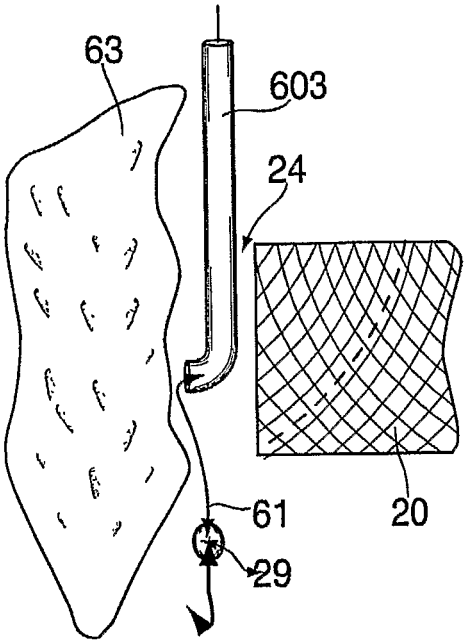


FIG. 6a

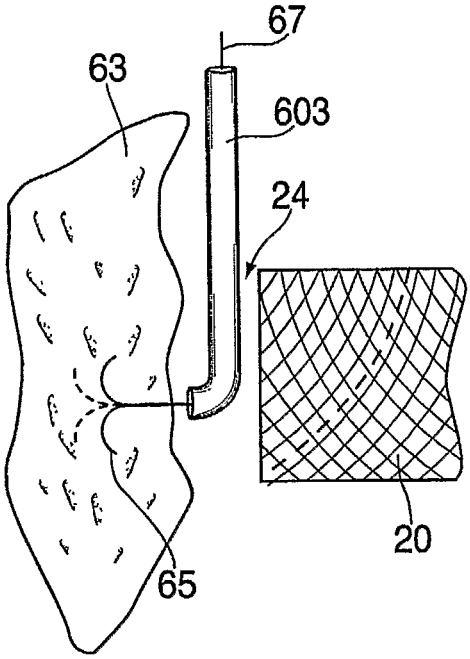


FIG. 6b

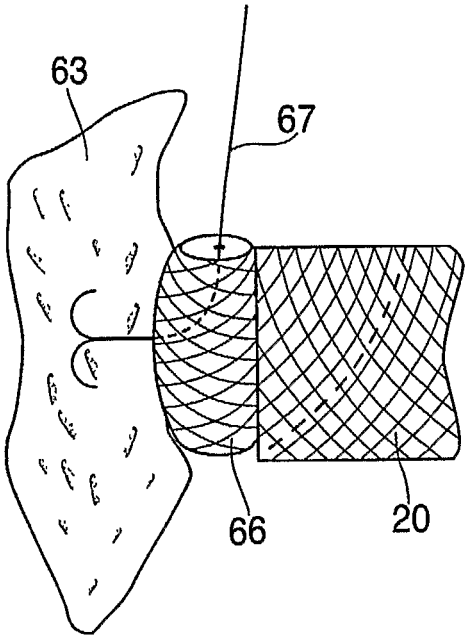


FIG. 6c

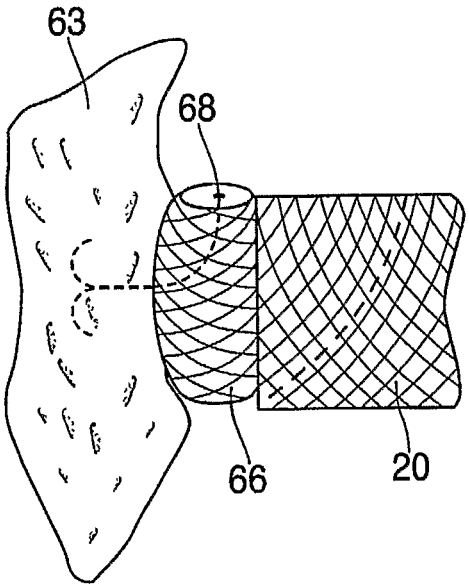


FIG. 6d



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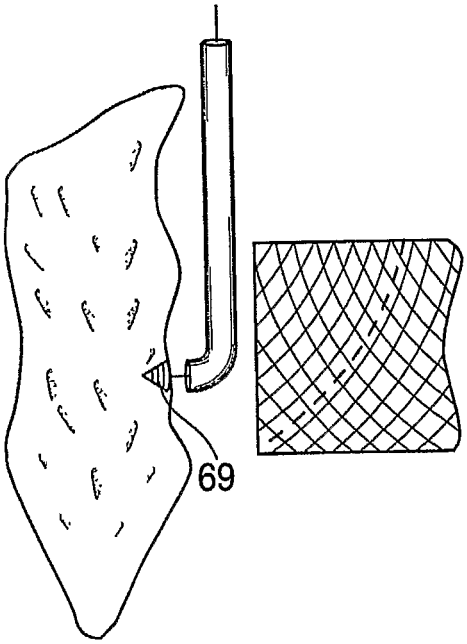


FIG. 7



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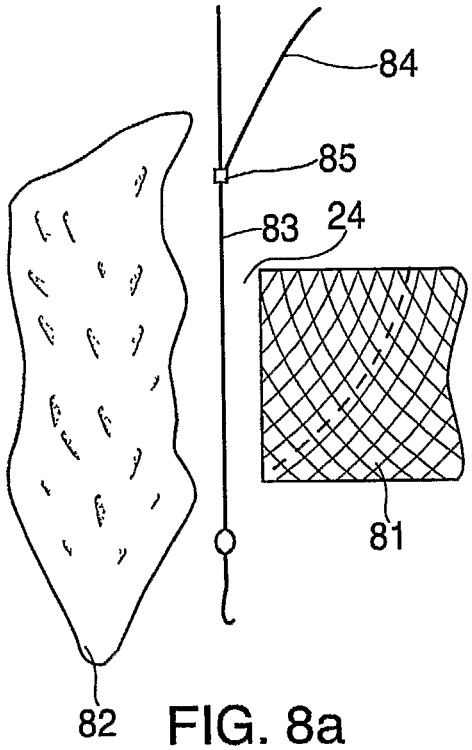


FIG. 8a

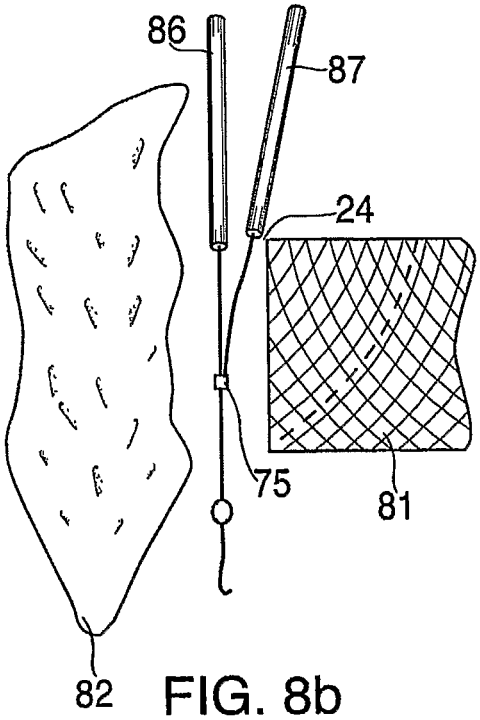


FIG. 8b

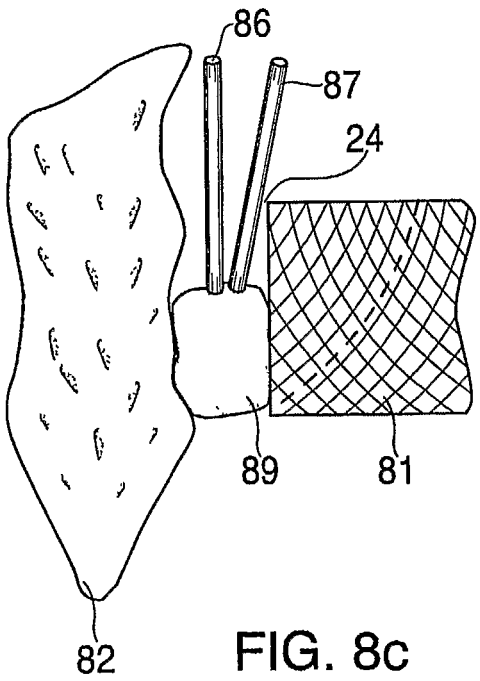


FIG. 8c

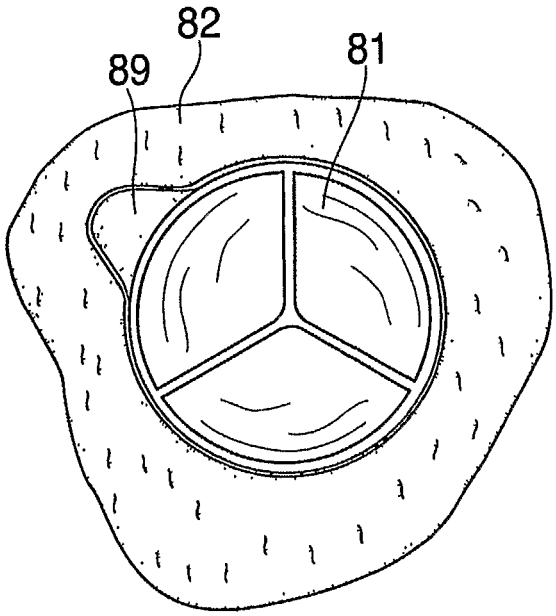


FIG. 8d



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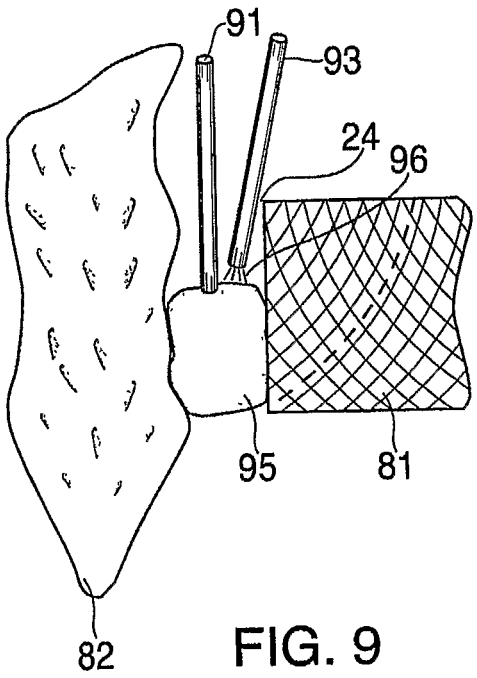


FIG. 9



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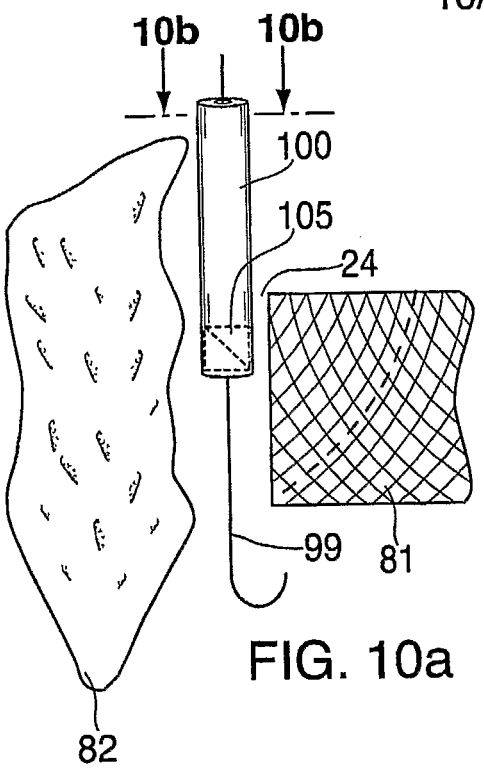


FIG. 10a

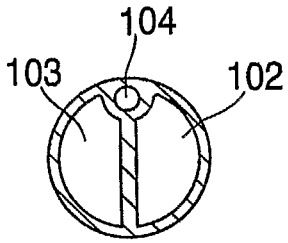


FIG. 10b

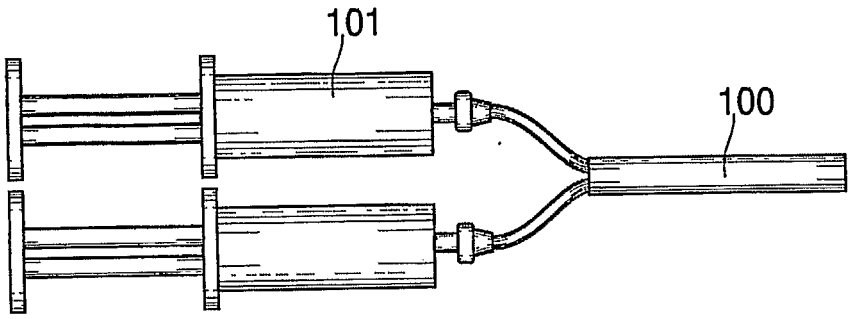


FIG. 10c

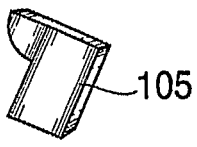


FIG. 10d

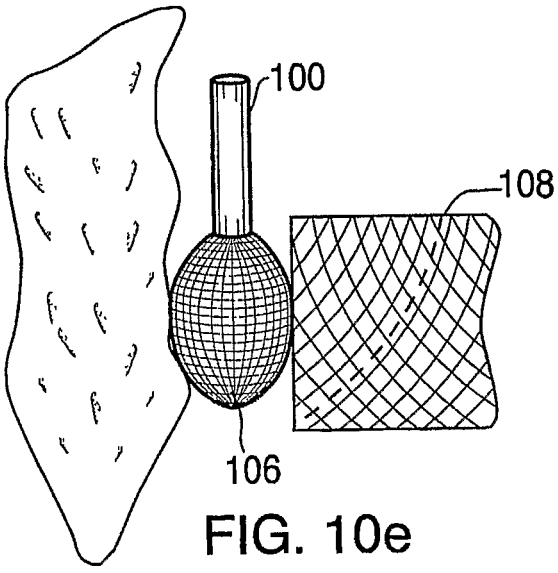


FIG. 10e



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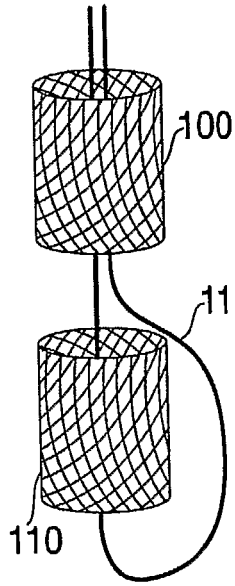


FIG. 11a

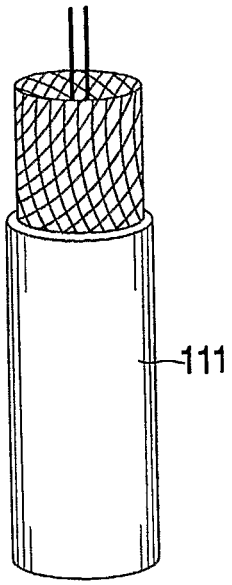


FIG. 11b

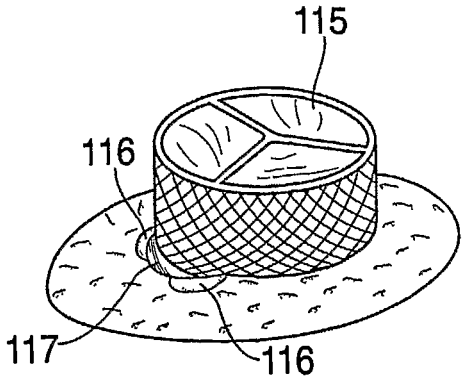


FIG. 11c

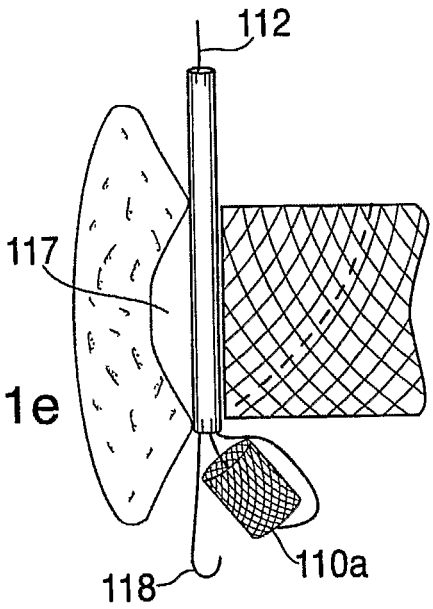


FIG. 11e

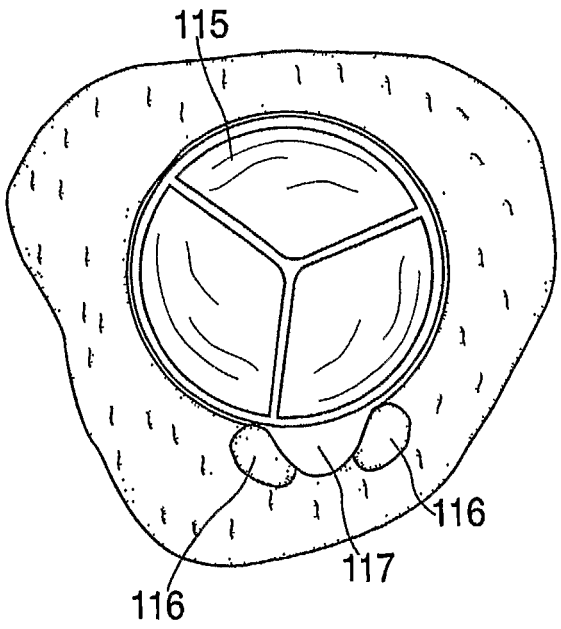


FIG. 11d

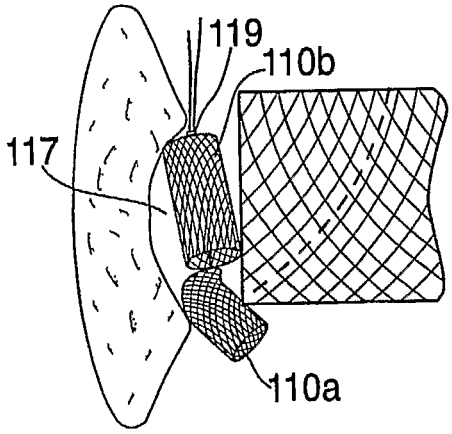


FIG. 11f



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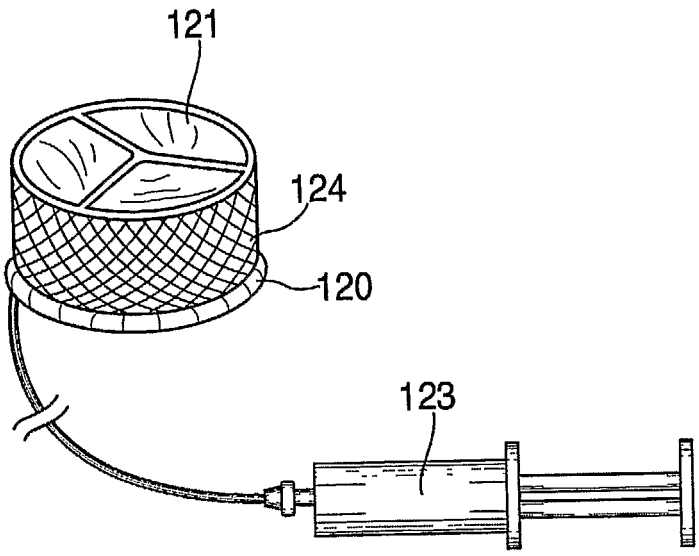


FIG. 12



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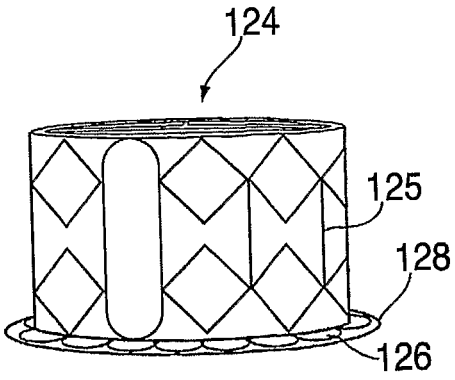


FIG. 13a

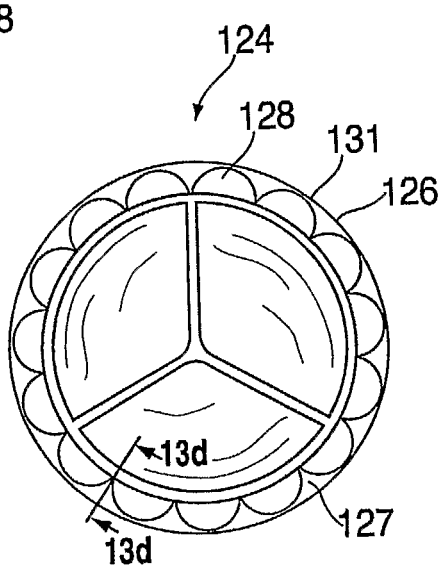


FIG. 13b

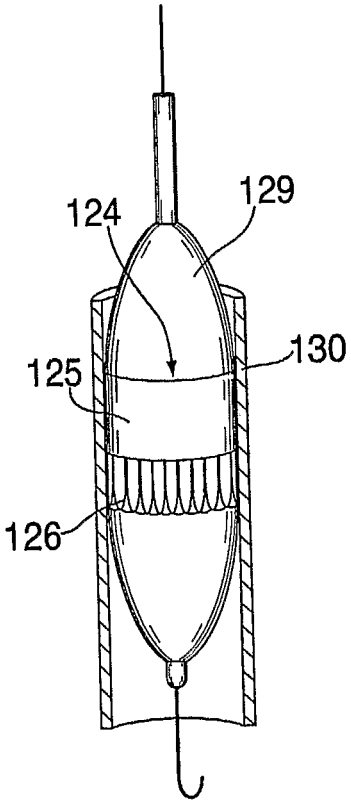


FIG. 13c

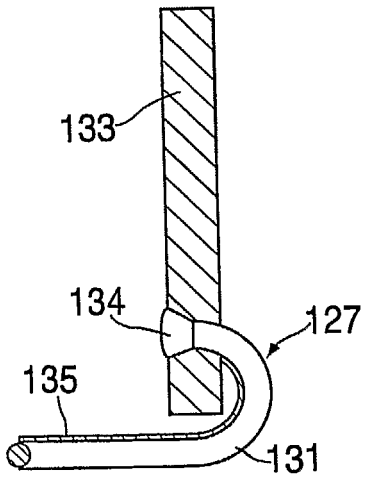


FIG. 13d



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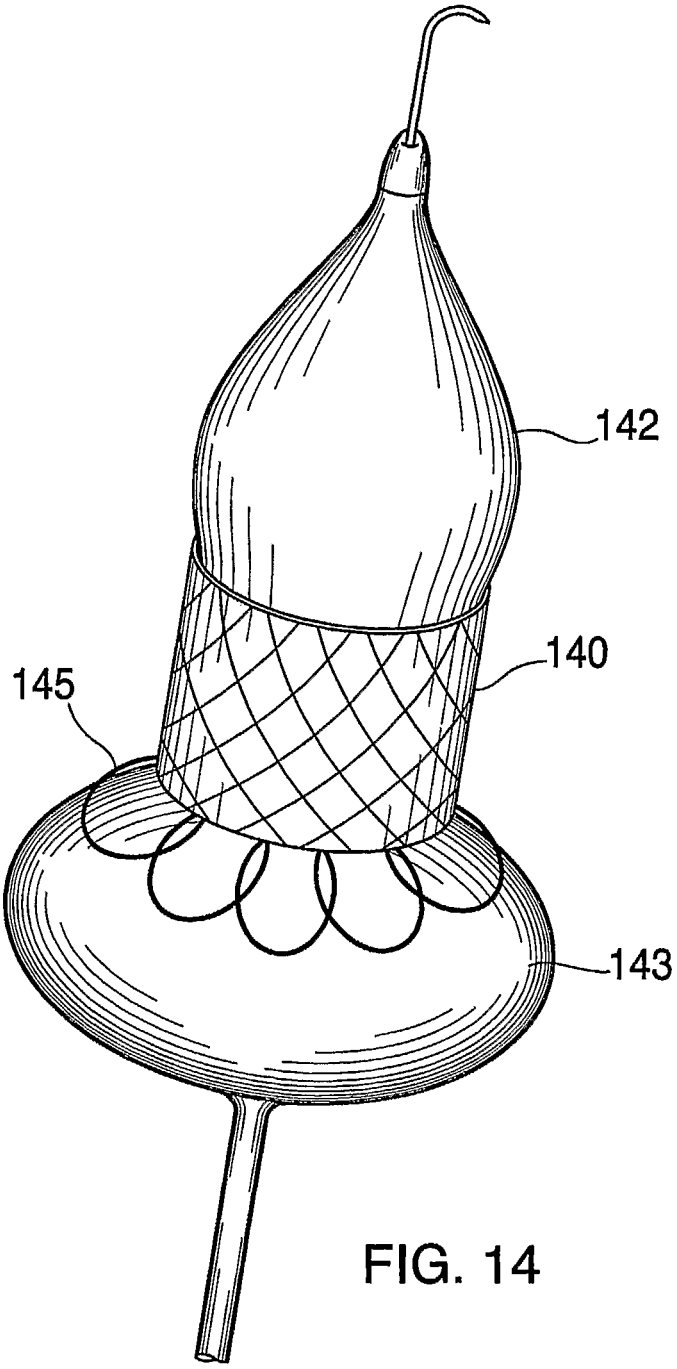


FIG. 14



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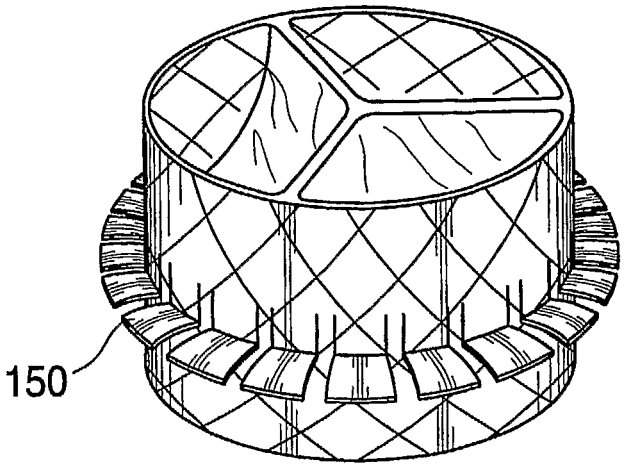


FIG. 15a

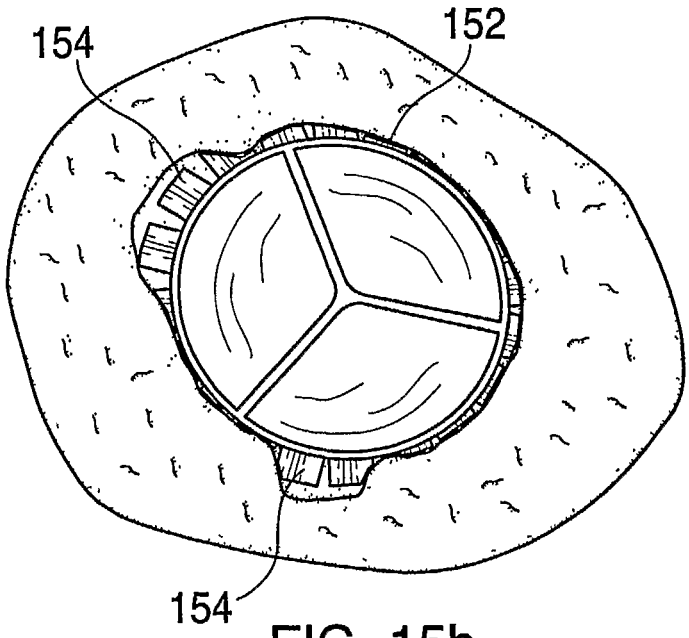


FIG. 15b



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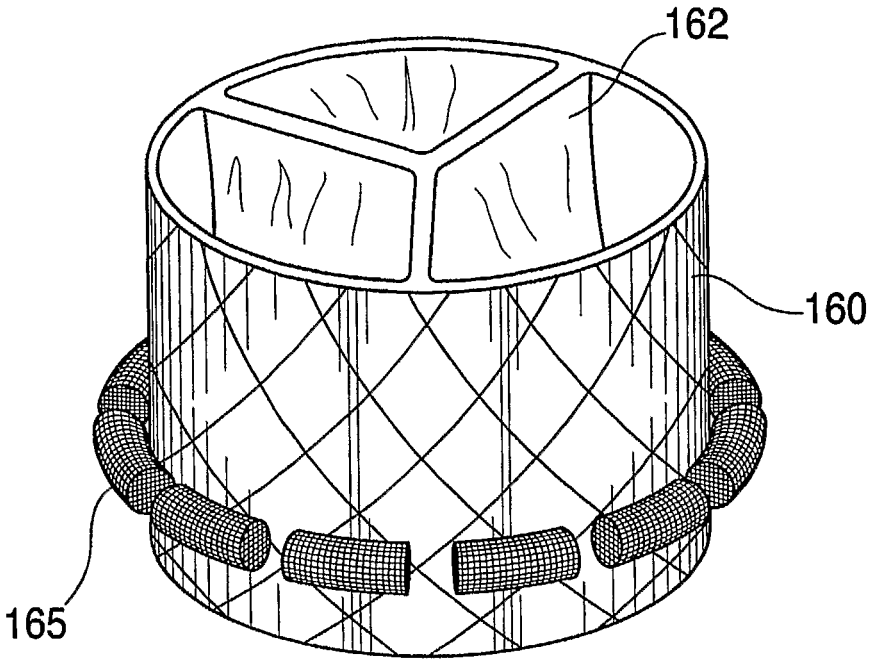


FIG. 16a

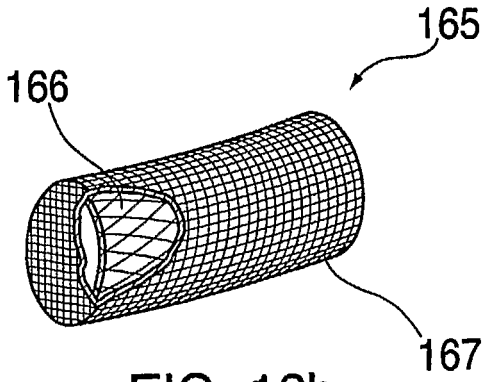


FIG. 16b



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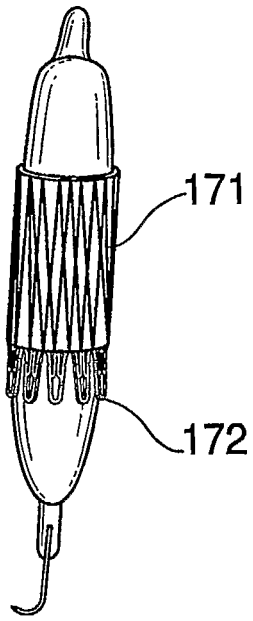


FIG. 17a

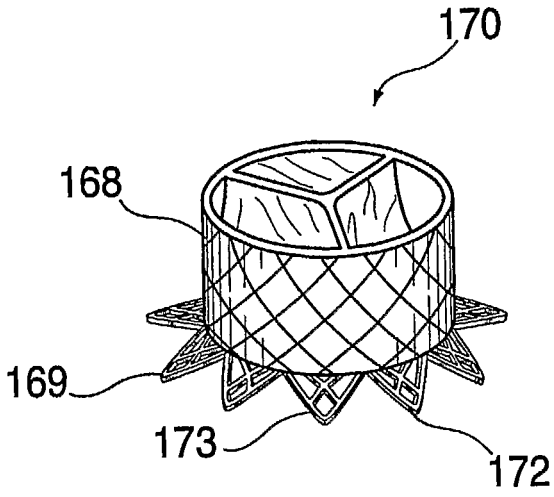


FIG. 17b

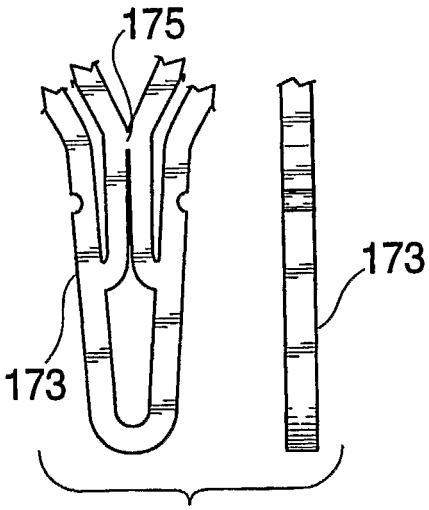


FIG. 17c

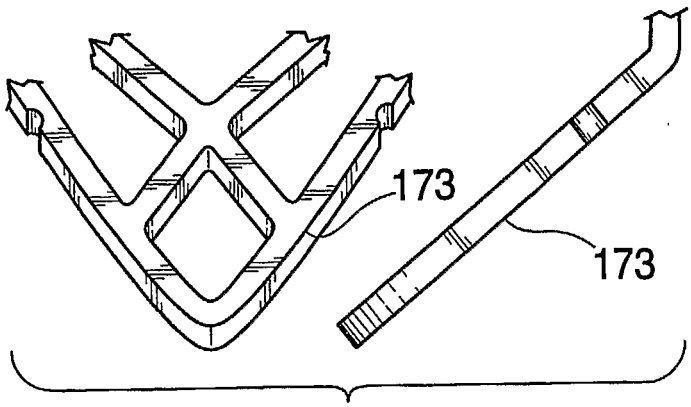


FIG. 17d

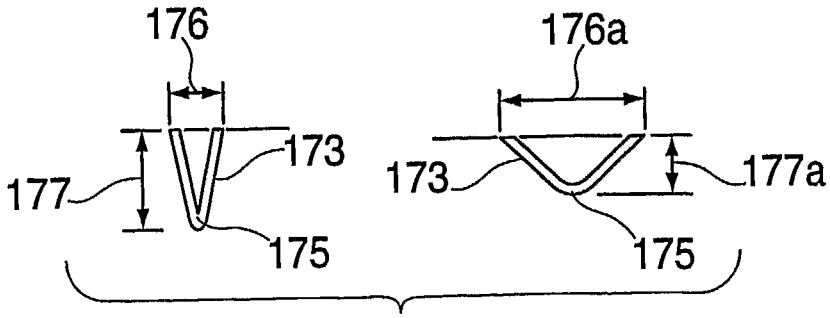


FIG. 17e



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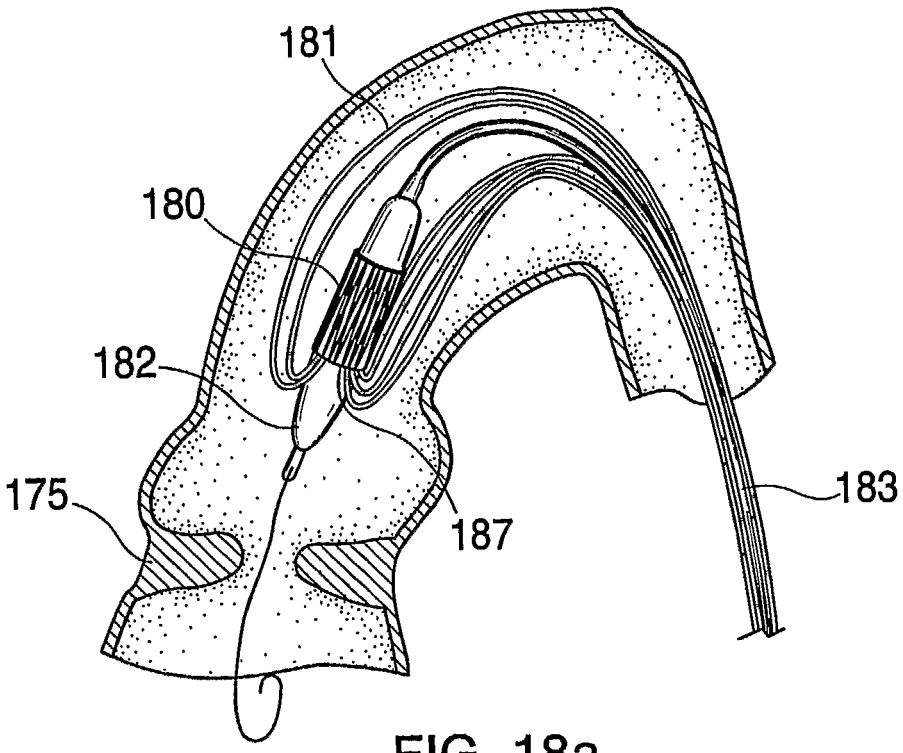


FIG. 18a

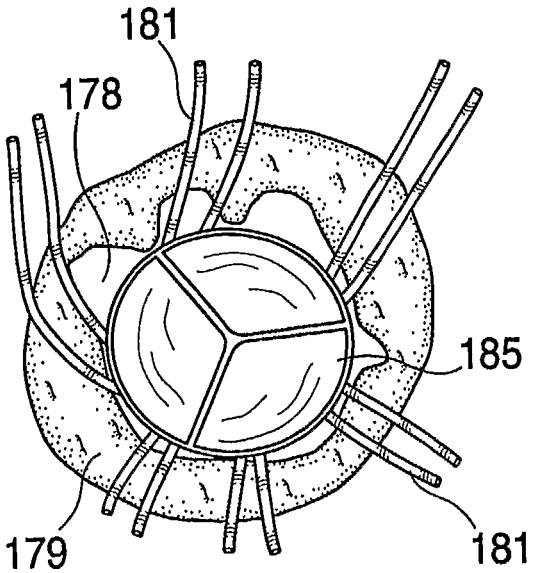


FIG. 18c

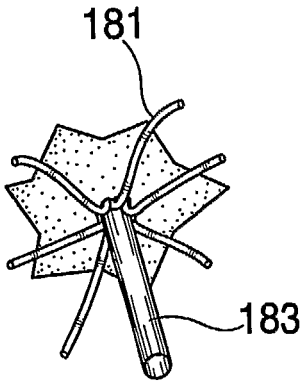


FIG. 18b



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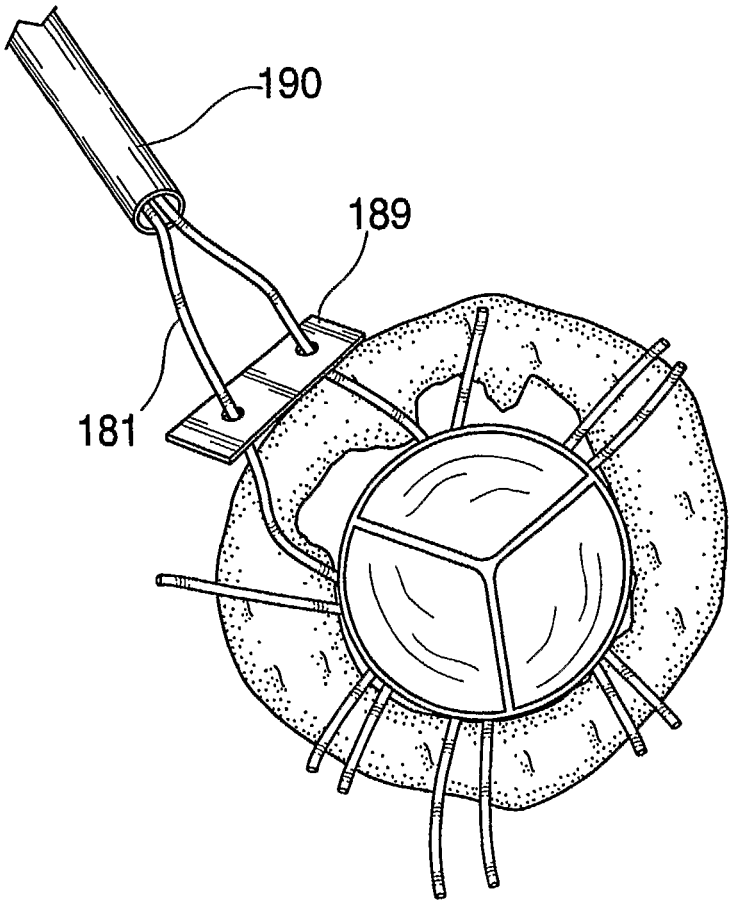


FIG. 18d

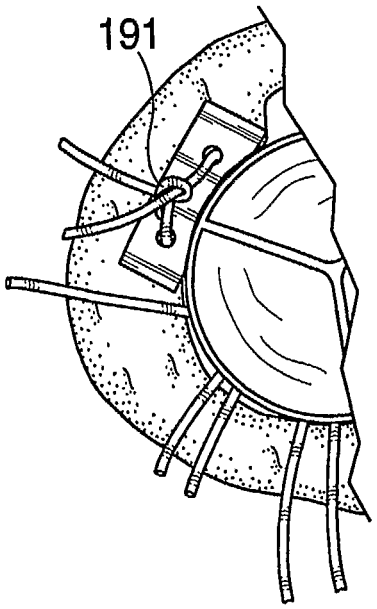


FIG. 18e



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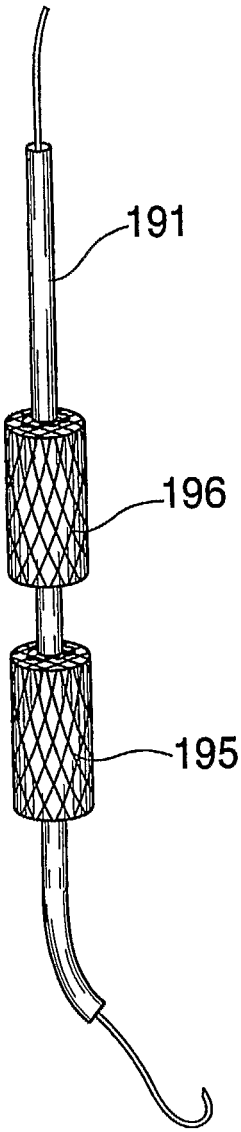


FIG. 19a

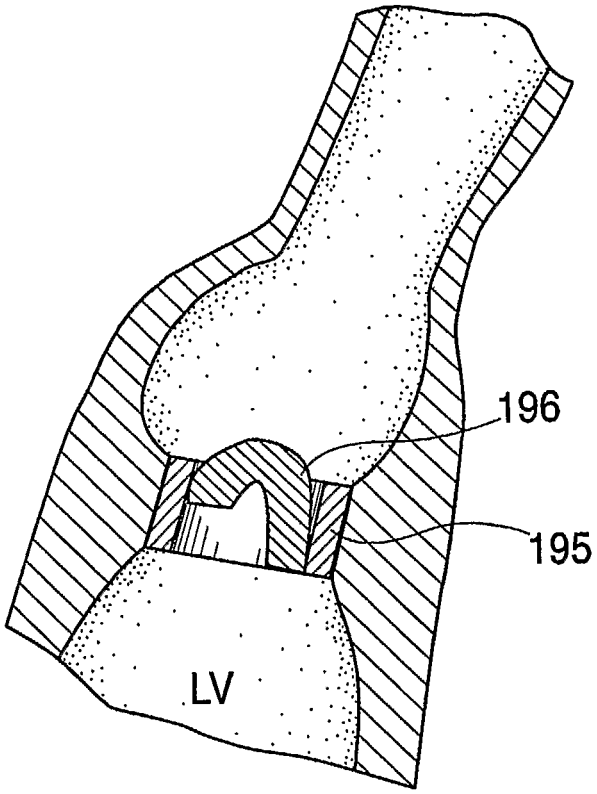


FIG. 19b

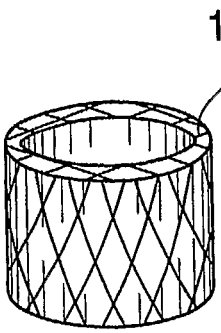


FIG. 19c

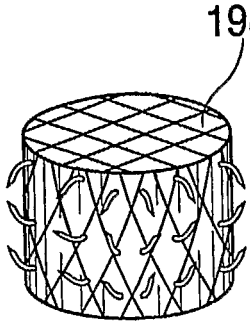


FIG. 19d



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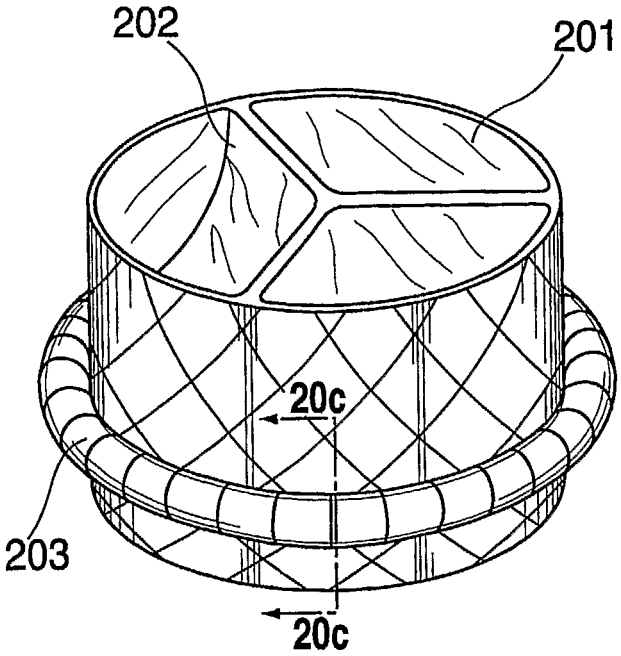


FIG. 20a

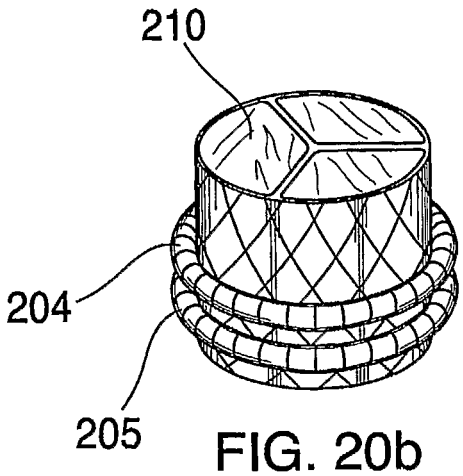


FIG. 20b

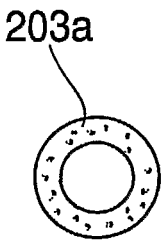


FIG. 20c

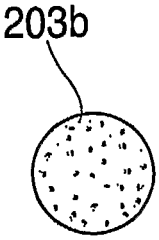


FIG. 20d

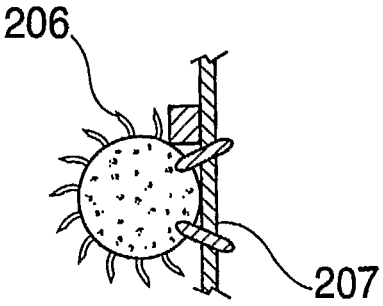


FIG. 20e

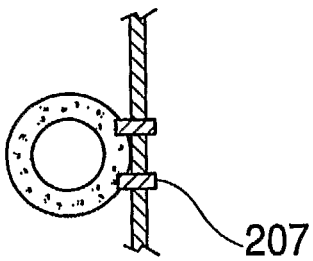


FIG. 20f

FIG. 20g



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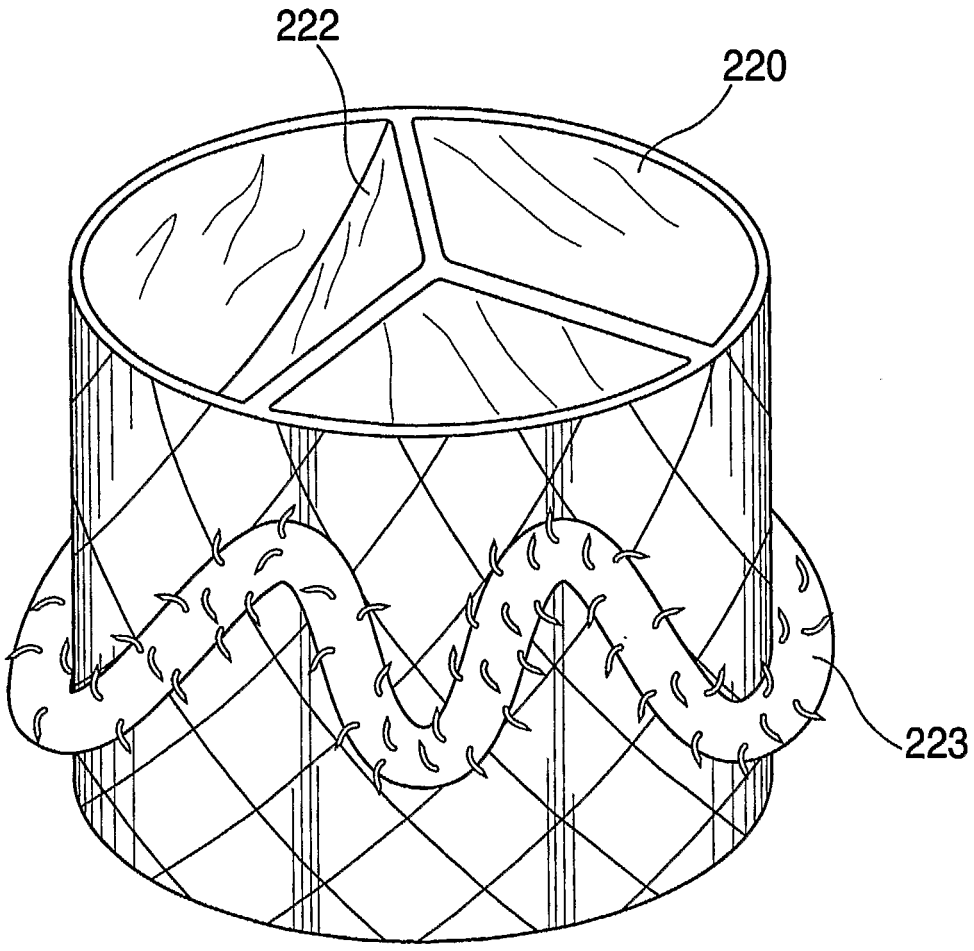


FIG. 21



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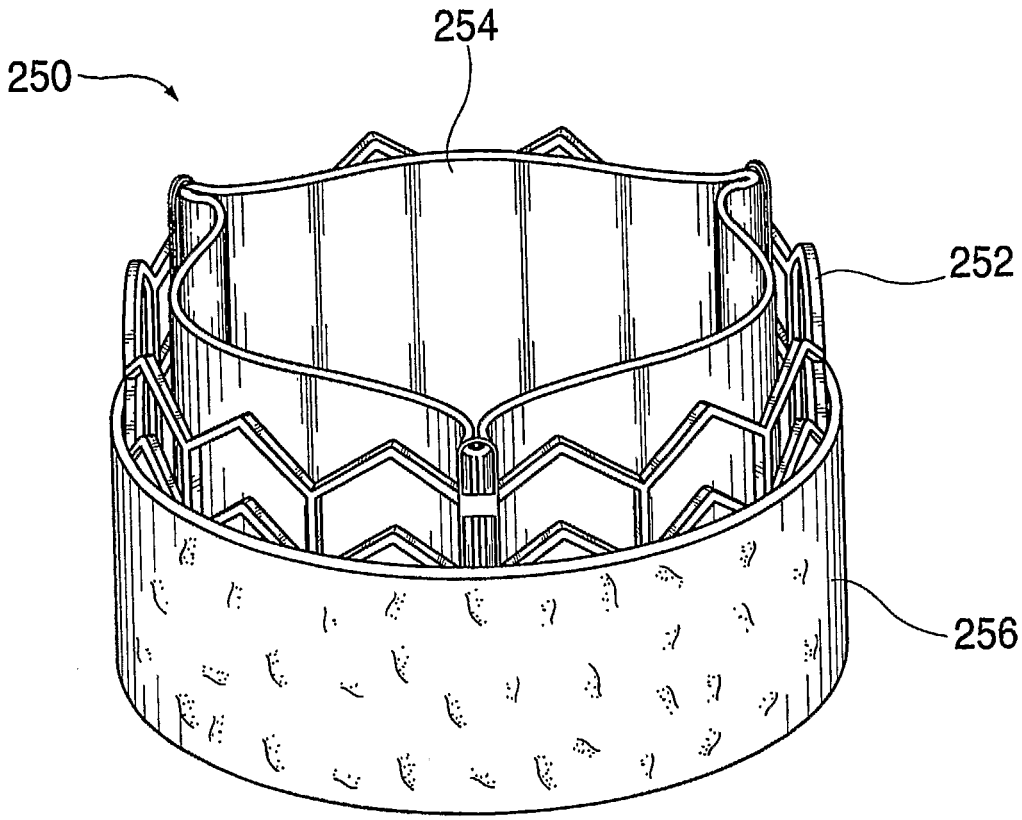


FIG. 22



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LKGLOBAL

Detroit USA
Hamburg Germany
Munich Germany
Phoenix USA
San Diego USA

Lorenz & Kopf PartG mbB Patentanwälte | Brienner Straße 11 | 80333 Munich | Germany | t +49 89 262 09-7170

European Patent Office

80298 Munich

Munich, 25.05.2021

| | |
|---|---|
| Opposition to: | EP 2 982 337 B1 |
| Application No.: | 15180327.7 |
| Proprietor: | Edwards Lifesciences PVT, Inc.<br>Irvine, CA 92614 (US) |
| Title: | Paravalvular leak detection, sealing, and prevention |
| Opponent: | Abbott Cardiovascular Systems, Inc. |
| Our Ref.: | 255.0051G1 |

According to Art. 99(1) EPC, we herewith give

**NOTICE OF OPPOSITION**

to the above indicated patent in the name and on behalf of

Abbott Cardiovascular Systems, Inc.

3200 Lakeside Drive, Santa Clara

California 95054, US

The notice of opposition is filed against the following European Patent:

| | |
|---|---|
| European Patent No. | EP 2 982 337 B1 |
| Title: | Paravalvular leak detection, sealing, and prevention |
| Date of filing: | 30.06.2005 |

Paul D. Amrozowicz US-(AZ), PA
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Thomas G. Berry US-(IL, FL, MN), PA
John V. Biernacki US-(OH, MI), PA
Brett A. Carlson US-(AZ), PA
Brian Cromarty US-(NJ, PA), PA
Brandon P. Dailey PA
Daniel P. Dailey US-(MI), PA
James P. Delaney US-(CA), PA
Christopher A. Eusebi US-(PA), PA
F. Drexel Feeling US-(OH), PA
Ralph Fernolend DE, EP
Ryan T. Fortin US-(AZ, MN), PA
Jamie Fraser UK, EP ***
Dr. Mark A. Frentrup US-(MI), PA
Deborah K. Henscheid US-(AZ, CA), PA
Michael Mick Herman PA
Marcus Hock DE
Sean D. Johnson US-(AZ), PA
Lindsay N. Kandow US-(MI), PA
Korbinian Kopf DE, EP
Aditya Krishnan US-(NJ, NY, DC), PA
Jan Ksienzyk DE
Andrew S. Locke US-(IL, MI), PA
Timothy J. Lorenz US-(AZ, DC, MI), PA
Peter Lucas UK, EP ***
Erin P. Madill US-(CA, NC, NY), PA
David A. McClaughry US-(MI), PA
Michael E. McKee US-(MI), PA
David Mixon US-(AL, TX), PA
Dr. Korbinian Mueller-Graff, LL.M. DE, EP
S. Jared Pitts US-(AZ), PA
Christian Rackur DE
Seth E. Rodack US-(MI), PA
Greg Sach UK, EP **
Werner Schaechtele DE
Erica K. Schaefer US-(MI), PA
Knut M. Schwarz DE, EP
Jeffrey A. Sedlar US-(MI), PA
Dr. Rainer Sterthaus DE, EP
Gregory A. Stobbs US-(MI), PA
Philipp Sünder DE, EP
Mark D. Swanson US-(AL), PA
Mark M. Takahashi US-(AZ, CA), PA
Jeffrey P. Thennisch US-(ID, IN, MI)
Charlotte Tilbury EP, UK ***
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James R. Walters US-(CA), PA
Joel C. Watkins US-(AZ, CO), PA
Dr. Daniel Westenberger DE, EP

DE Patentanwalt, Germany *
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PA Registered before the USPTO **
UK UK Patent Attorney
US US Attorney at Law **

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Partnerschaftsregister des
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Offices: Munich, Hamburg.

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registered in Arizona, no. 4004092
Offices: Phoenix, Detroit, San Diego.

*** located in UK and acting for:
LKGLOBAL UK Ltd.



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## I. REQUESTS

1. It is requested to revoke the opposed patent in its entirety for the following reasons:

a) its subject matter is not patentable (Article 100(a) EPC and Articles 52 to 57 EPC);

b) it does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) and Article 83 EPC); and

c) it extends beyond the content of the application as filed (Article 100(c) EPC and Articles 76(1) and 123 (2) EPC).

2. As an auxiliary request, oral proceedings before the Opposition Division are requested.

3. The opposition fee in the amount of 815.00 EURO is to be debited from account number 28003046.

4. Prior art references referred to in this notice of opposition are listed below and filed herewith. The opponent reserves the right to refer to prior art documents referenced in the opposed patent, the search reports or elsewhere in the EPO file history of this patent, or related family members of this patent, and in the references mentioned in foreign equivalent and family member patents and patent applications.


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## II. FILED DOCUMENTS

1. The following documents relate to the opposed patent:

E1a: US 10/883,575 (priority document)
E1b: WO 2006/005015 A2 (original application, i.e., parent application)
E1c: EP 2 982 337 A1 (application as filed)
E1d: EP 2 982 337 B1 (opposed patent)

2. The following prior art documents (together with their respective publication dates or patent dates) are discussed in the "Facts and Evidence" in the present opposition and are enclosed:

D1: US 5,258,023 A (02.11.1993))
D2: FR 2 337 543 (05.08.1977)
D2a: US 4,106,129 (15.08.1978)
D3: WO 00/64380 A1 (02.11.2000)
D4: FR 2 815 844 A1 (03.05.2002)
D5: EP 2 537 487 A1 (26.12.2012)
D5a US 2005/0137688 (23.06.2005)
D5b US 2005/0137698 (23.06.2005)
D6: WO 01/56512 A1 (09.08.2001)
D7: US 6,454,799 B1 (24.09.2002)
D8: US 2003/0153974 A1 (14.08.2003)
D9: DE 26 13 575 A1 (04.08.1977)
D10: WO 03/053287 A1 (03.07.2003)
D11: US 6,729,356 B1 (04.05.2004)
D12: US 2004/0082989 A1 (29.04.2004)
D13: Moazami et al.; Transluminal Aortic Valve Placement (9/10 1996)
D14 : WO 03/039613 A1 (15.03.2003)


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As will be shown in the following, the priority claim of the opposed patent is not valid. The effective date of the opposed patent is therefore the international filing date of the original application E1b, i.e., 30 June 2005. Documents D1, D2, D3, D4 and D5 were cited during the examination proceedings leading to the opposed patent, with D5 cited as prior art under Art. 54(3) EPC. However, documents D5a and D5b include as patent family members the disclosure of D5 and were published before the effective filing date of the opposed patent.

Besides D5, all the above cited prior art documents were published before the effective date of the opposed patent and constitute prior art under Art. 54(2) EPC.


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## III. FACTS AND EVIDENCE

### 1. Feature Analysis of independent claim 1 (also filed as Annex A1)

Independent claim 1 of the opposed patent as granted has been partitioned into the following features:

**F1** A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

**F2** a substantially cylindrical stent structure (252) configured for radial expansion,

**F3** a valvular structure (254) 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,

**F4** characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

**F5** the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

**F6** wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Basically, a stented valve with a layer of material on the outside of the stent is claimed. The material is compressible and includes fibers. Interestingly, these fibers extend from the outer surface of the stent structure outwardly.


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According to paragraph [0064] of the description of the patent, it is intended to encourage coagulation of blood by means of the fibers to fill gaps between the stented valve and surrounding tissue. In consequence, it must be assumed that the fibers extend from the inner side of the layer of material, i.e. from the outer surface of the stent structure into the layer, through the layer and further outwardly. However, there is contradicting disclosure in the patent.

In the following, it will be shown that the claim language is not supported by the description, that neither the original claims nor the original description may form basis for the claims of the opposed patent. The claimed subject-matter cannot be put into practice, and in as far as it can be understood, the subject-matter is known or at least not inventive.

## 2. Inadmissible extension, violation of Art. 100(c) EPC

### 2.1 Potential basis in the originally filed application

With the characterizing feature of "a layer of compressible material", only the embodiment of figure 22 may provide basis for the claimed subject-matter. The embodiment of figure 22 is the only embodiment which is disclosed as having a layer of compressible material.

It will be shown in the following that neither the claims nor the description as originally filed disclose the features of the patent as granted, and in particular not the specific combination of these features. The subject-matter of the granted claims is not directly and unambiguously disclosed in the application E1b as originally filed.


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2.1.1 Claims as originally filed

The originally filed application E1b includes claims 27 to 29 directed to a prosthetic valve comprising, inter alia, a layer of compressible material. These claims read as follows, wherein the reproduced original claims show amendments which would have been necessary to achieve granted claim 1.

> 27. A prosthetic valve for implantation in a body channel, comprising:
> a substantially cylindrical stent structure configured for radial expansion,
> a valvular structure 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 which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel.
>
> 28. The prosthetic valve of claim 27.
>
> 29. The prosthetic valve of claim 28, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

As can be easily recognized, several features are missing in the subject-matter of claim 1 of the opposed patent so that the subject-matter surely extends beyond the content of the claims as originally filed.


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2.1.2 Description as originally filed

Alternatively, there is the embodiment of figure 22 described in the application E1b as originally filed.

In the section of the BRIEF DESCRIPTION OF THE FIGURES in E1b, figure 22 is described as following:

[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.

In the section of the DETAILED DESCRIPTION OF THE INVENTION in E1b, figure 22 is described as follows, wherein the sentences of the related paragraphs [00144] and [00145] are divided and numbered:

> [00144.1] Figure 22 depicts yet another stented valve 250 configured to reduce or prevent paravalvular leaks.
> [00144.2] The stented valve generally comprises an expandable stent structure 252 which supports a valvular structure 254.
> [00144.3] The stent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter.
> [00144.4] The valvular structure 254 forms three leaflets and is illustrated in the open configuration.
>
> [00145.1] To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252.


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[00145.2] 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.

[00145.3] In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm.

[00145.4] In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material.

[00145.5] In various embodiments, the fibers may be straight, curved or hook-shaped.

[00145.6] The compressible material expands after deployment at a treatment site.

[00145.7] As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.

[00145.8] Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage.

[00145.9] 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.

[00145.10] 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.

[00145.11] Any suitable tissue growth factor may be used.

[00145.12] 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.

Based on the description, the subject-matter of claim 1 of the patent cannot be directly and unambiguously achieved. Features are arbitrarily selected


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from sentences, with other features being omitted, and not all features are present in the description at all.

2.2 Inadmissible extension of features **F1**, **F2** and **F3**

Features **F1** to **F3** define a typical stent-valve.

Description paragraph [00144] of E1b mentions a stented valve with an expandable stent structure supporting a valve structure which forms three leaflets. The wording of features **F1**, **F2** and **F3** cannot be found in the description. For example, it is not described that the stent structure is substantially cylindrical and that the valve structure has an inlet and an outlet. Further, it is not described that the valve structure is formed of a pliant material.

Rather, features **F1**, **F2** and **F3** may be taken from claim 27 as indicated above. However, claim 27 defines the valve structure as providing a flexible conduit which has an inlet and an outlet. Feature **F3** of claim 1 of the patent does not include the underlined feature. It is noted that the description does not describe the valve structure in such detail. There is no hint that the flexible conduit may intentionally be omitted.

Consequently, feature **F3** extends beyond the content of the application E1b as originally filed.

2.3 Inadmissible extension of features **F4** and **F5**

Features **F4** and **F5** define a location of compressible material relative to the stent structure as well as a functionality thereof.


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However, original claim 27 of E1b does not include that the compressible material forms a sleeve which extends entirely around the stent structure. The feature combination of feature **F4** may rather be found in sentences [00145.1] and [00145.2] of the description, with the difference that it is disclosed in E1b that the material extends entirely around the stent structure and not a sleeve as in claim feature **F4**.

Further, it is noted that the "sleeve" is present as a distinct structural component in claim 1 of the patent since the claim defines that the compressible material forms a sleeve. However, the original application does not disclose at all a sleeve as a structural component as such. Paragraph sentence [00145.2] reads: *"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"*. This sentence merely describes the geometrical appearance of the material, i.e., that it may have the form of a sleeve (*e.g.*, that it extends entirely around the stent structure), but this sentence does not provide any basis for the presence of a sleeve (as a structural component) as such. In view of the specific language in the original disclosure, the presence of a sleeve in claim 1 as a distinct structural component extends the subject-matter beyond the content of the application as originally filed.

Furthermore, when compared with the wording of claim 27 of E1b, it is missing in feature **F5** of claim 1 of the patent that the compressible material is adapted to expand after deployment to fill gaps between the prosthetic valve and the body channel.

The original disclosure in claim 27 of E1b is in line with the description. Sentence [00145.6] of the description also states that "the compressible material expands after deployment at a treatment site." It is noted that this sentence does not include any wording allowing the expansion to be optional. To the contrary, the next sentence [00145.7] emphasizes that, "as the


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compressible material expands, it fills the gaps between the stented valve and the surrounding tissue." That is, the expansion is disclosed as causing the filling of gaps.

The omission of a feature which is inextricably linked to features already in the claim constitutes an inadmissible extension of the claimed subject-matter.

2.4 Inadmissible extension of feature **F6**

Feature **F6** requires a plurality of fibers extending outwardly.

The wording of feature **F6** may only be found in claim 29 of E1b which depends on claim 28 which in turn depends on claim 27. However, claim 1 of the patent is missing the features "the compressible material is formed of polyethylene terephthalate (PET)" and "the prosthetic valve further comprises a tissue growth factor disposed along the compressible material," at least when trying to find basis for claim 1 of the patent in the originally filed claims in E1b.

When alternatively trying to find support for claim 1 of the patent in paragraph [00145] of the description, three aspects stand in the way.

In sentence [00145.4], it is defined that "the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material." According to that sentence, the fibers are part of a cloth or fabric. This is in contrast to the teaching of the original claims which require the fibers to extend from the stent structure.
Further, claim 1 of the patent allows any other material as compressible material like a foam. According to claim 1, there must be fibers extending from the outer surface. In fact, claim 1 requires that the fibers extend from the outer surface of the stent structure, due to the definite article so that "the

outer surface" refers back to "an outer surface of the stent structure" (in feature F4) along which outer surface a layer of compressible material is disposed.

Moreover, that sentence [00145.4] starts with the language "in certain configurations". In consequence, the fibers are not only isolated from the cloth or fabric but are also arbitrarily selected from features disclosed in a sequence of optional features provided in the sentences of paragraph [00145]. There is no hint in the original disclosure of E1b that, for example, PET as compressible material, i.e., sentence [00145.3] and/or claim 28, may be omitted while the fibers are included.

Summarizing, paragraph [00145] does nowhere disclose fibers that extend **outward from the outer surface** as claimed, such that this paragraph cannot provide a basis for feature **F6**. Original claim 29 is the only basis for this feature, however, in this case at least the above-mentioned features of original claims 28 and 29 are missing.

2.5 No disclosure of feature combination of claim 1

As already discussed above, the feature combination of claim 1 of the patent cannot be based on original claims 27 to 29. The original claims 27 to 29 include four features in addition to those of claim 1 of the patent.

When construing the feature combination of claim 1 of the patent based on the description, the following must be recognized.
Sentence [00145.1] is written as mandatory and is part of feature F4.
Sentence [00145.2] is written as optional but selected as part of feature F4.
Sentence [00145.3] identifies a preferred embodiment but is not present in claim 1.


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Sentence [00145.4] is written as relevant only in certain configuration, wherein a part of that sentence found its way into claim 1.
Sentence [00145.5] is written as optional and is not selected.
Sentence [00145.6] is written as mandatory but is not in claim 1.
Sentence [00145.7] is again written as mandatory but only part of it is in claim 1.
Further optional features are mentioned in sentences [00145.8] to [00145.12] all being not part of claim 1 of the patent.

An arbitrary selection from both mandatory and optional features, without any pointer that the resulting combination was originally intended, does not fulfil the requirements of direct and unambiguous disclosure. Several decisions of the Boards of Appeal made clear that the content of an application must not be considered to be a reservoir from which features could be combined in order to artificially create a particular embodiment. It is established case law that in the absence of any pointer to that particular combination, this combined selection of features does **not**, for the person skilled in the art, emerge clearly and unambiguously from the content of the application as filed (see e.g., **T 686/99**, **T 1853/13** or **T 1252/13**).

The subject-matter of claim 1 of the patent extends beyond the content of the application E1b as originally filed and, thus, violates Art. 76(1) EPC.

2.6 Dependent claims

Since claim 1 of the opposed patent E1d already violates Art. 76(1) EPC, any combination of claim 1 with a dependent claim also leads to an inadmissible extension in violation of Art. 76(1) EPC for the resulting subject-matter. Already for this reason, dependent claims 2 to 9 violate Art. 76(1) EPC.


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As shown in the following, at least some features of the dependent claims have no basis in the original application E1b.

Claim 2:

According to claim 2, the sleeve surrounds an inflow end of the stent structure.

That feature is nowhere disclosed in the application as originally filed. In connection with the embodiment of figure 22, reproduced below, an arrangement of the sleeve is neither mentioned in any of the related claims 27 to 29 of E1b nor discussed in the related description paragraphs [00144] and [00145]. In figure 22, only the front half of the valve is visible. Figure 22 cannot serve as basis for a sleeve much less a sleeve that surrounds an inflow end of the stent structure.

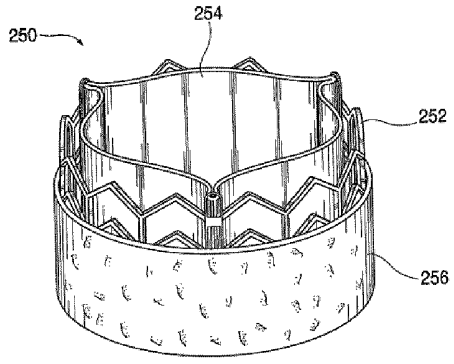


FIG. 22

Claim 2 violates Art. 76(1) EPC.

Claim 3:

According to claim 3, the compressible material has a thickness ranging from 1 to 5mm.


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That feature is only disclosed in sentence [00145.3] of the description. However, that sentence further defines that the compressible material is formed of polyethylene terephthalate (PET). That is, it is only disclosed that a compressible material formed of PET may have a thickness ranging from about 1 to 5 mm.

Claim 3 violates Art. 76(1) EPC.

Claim 4:

According to claim 4, the compressible material comprises a cloth or fabric.

That feature may be taken from sentence [00145.4] of the description, but not in isolation. According to sentence [00145.4], a material which resembles a cloth or fabric is disclosed as having small fibers extending from the surface of the material. In other words, claim 4 confirms that claim 1 is inadmissibly extended, i.e., that it is intended to cover other materials by claim 1.

Claim 4 violates Art. 76(1) EPC.

Claim 5:

According to claim 5, the prosthetic valve further comprises a tissue growth factor disposed along the compressible material.

That feature may be found in claim 29 of E1b. Like claim 4, claim 5 thus proves that claim 1 extends the content of the application E1b as originally filed. Claim 5 introduces the feature omitted in claim 1 as discussed above, thus, illustrates that it is intended to broaden the scope of claim 1.

Claim 5 violates Art. 76(1) EPC.


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Claim 6:

According to claim 6, the growth factor according to claim 5 is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

That language seems to be taken from sentence [00145.12] which however describes a method. Indeed, claim 6 still includes language of a method claim. Without any indication, it is principally not possible to include a method feature that was only disclosed in context with a method into a device claim.

Claim 6 violates Art. 76(1) EPC.

Claim 7:

According to claim 7, the fibers are straight, curved or hook-shaped.

That feature can be found in sentence [00145.5], as aspect of various embodiments. With claim 7 depending from any one of claims 1 to 6, various combinations of features are possible. However, there is no pointer in the description that it was intended at the date of filing of the original application E1b, to combine a specific selection of features while omitting others.

Claim 7 violates Art. 76(1) EPC.

Claim 8:

According to claim 8, the compressible material is configured to expand into the gaps.


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Again, that dependent claim shows that it is intended to broaden the scope of claim 1 by omitting a feature, here the feature of claim 8. As discussed above, the filling of gaps is only disclosed in connection with the expansion of the compressible material (cf. sentence [00145.7]).

Claim 8 violates Art. 76(1) EPC.

Claim 9:

According to claim 9, the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

The original disclosure is completely silent with respect to any behaviour of a sleeve-like compressible material upon stent opening. The features of claim 9 are not disclosed in the application E1b as originally filed.

Consequently, all dependent claims, both when considered alone and in combination with other claims, violate at least Art. 76(1) EPC.

## 3. Insufficient disclosure, violation of Art. 100(b) and Art. 83 EPC

The opposed European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.


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Claim 1 of the patent defines an outer surface of the stent structure in feature F4 as well as fibers extending outward from said outer surface (of the stent) in feature F6. Claim 1 defines only one outer surface, i.e., the outer surface of the stent. It is noted that the second mentioning of the outer surface in feature F6 of claim 1 must be the outer surface of the stent that is first mentioned in feature F4 of claim 1 since the definite article is used (cf. last line in claim 1).

As discussed above, it is only disclosed in paragraph [0064] of the description of the patent that the compressible material is a cloth or fabric from which fibers extend. There is no teaching in the patent as to how fibers can extend outwardly from an outer surface of a stent. This would mean that the fibers must start on the stent and then extend outwardly therefrom. The entire disclosure does not give any hint or indication how fibers should be arranged on the stent such that these fibers might be considered as extending outwardly from the outer surface of the stent. It is noted that the term "outward" is only found in the originally filed claim 29. No description in the specification explains how the fibers of the compressible material extend "outward" particularly outward from the outer surface of the stent.

Even when accepting that the fibers are part of the compressible material, it is not disclosed as to how those fibers might be arranged in the compressible material so as to extend outward from the outer surface of the stent structure.

According to the teaching of the patent, it seems intended to encourage coagulation of blood at the fibers outside of the compressible material. To achieve this, the fibers would have to extend from the stent structure through the compressible material outwardly. There is no disclosure in the patent as to how fibers might be integrated into the compressible material so as to extend through the material and outwardly of it to encourage coagulation of blood. In particular, there is no disclosure in the patent as to how fibers might extend through a compressible material which expands after deployment.


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The skilled person is completely left in the dark when trying to figure out how fibers can extend outward from a stent surface as required in feature F6 of claim 1 of the patent.

The opposed patent therefore does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Consequently, the requirements of Article 83 EPC are not fulfilled.

## 4. Invalid Priority

The priority of the opposed patent is not valid.

As discussed above, the disclosure of the embodiment of figure 22 of the parent application might be a basis for the claimed subject-matter, if at all.

That embodiment, however, is not included in the priority application. In fact, the priority application does not disclose the specific features combination of claim 1 of the opposed patent, in particular not a stent structure covered by a sleeve formed by a compressible material from which fibers extend outwardly.

In consequence, the effective filing date of the opposed patent therefore is the international filing date of the original application E1b, i.e., 30 June 2005.


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## 5. Lack of patentability, Art. 100(a) EPC

In the following, the subject-matter of claim 1 of the patent is discussed in view of prior art, although it is expected that further features must be added to claim 1 due to the above discussed deficiencies of claim 1 in light of the disclosure as originally filed and as present in the patent.

In particular, claim 1 of the patent requires a layer of material on the outside of the stented valve, the material being compressible and includes fibers extending outwardly. The patent is, however, silent as to how such fibers are arranged in the compressible material so as to extend from the outer surface of the stent. The patent is also silent as to how the intended effect of filling gaps is achieved without expansion of the compressible material.

For the assessment of patentability, it is assumed that a skilled person which is, for the sake of argument, assumed to be able to understand what is intended to be covered by the claims and which is able to put the claimed subject-matter into practice, would comparably understand the teaching of prior art documents even without explicit teaching of the one or the other mentioned aspects.

The subject matter of claim 1 is not new and does not establish an inventive step and, therefore, violates the requirements of Art. 100(a) EPC in combination with Art. 52 to 57 EPC. In detail:

### 5.1 Lack of novelty in view of D6 (WO 01/56512 A1)

The subject-matter of claim 1 of the opposed patent lacks novelty in view of D6.


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D6 discloses on page 14, lines 30 to 32 that "the instrument 70A shown in Fig. 5 is intended for use when implanting the valve 10A by a transluminal procedure through a vessel."

Consequently, D6 discloses a prosthetic valve for percutaneous implantation in a body channel, as in feature **F1** of claim 1 of the opposed patent.

In the description of figure 2, D6 discloses on page 8, lines 7 to 10 that, "as illustrated in Fig. 2, the artificial valve 10M comprises a flexibly resilient external frame, generally designated by 20, and a flexible valve element, generally designated by 22", and in lines 18 to 21 that, "Although four frame elements 30 are shown in Figs. 2 and 3, the valve 10M may have fewer or more elements without departing from the scope of the present invention."

That is, D6 discloses features **F2** and **F3** of claim 1 of the opposed patent, i.e., a substantially cylindrical stent structure configured for radial expansion, and a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure. The formation of three valve leaflets is at least implicitly disclosed in D6.

Further, D6 discloses a band 40 which corresponds to the layer of compressible material forming a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure. According to page 9, lines 23 to 25 of D6, the band extends around the frame 20 between each of the frame elements 30. That is, D6 discloses feature **F4**.

Finally, D6 discloses on page 11, lines 6 to 11 that "it is also envisioned that an exterior surface of the band 40 may include a continuous or interrupted sheath of Dacron® velour material, porous PTFE felt or the like to provide sites for vascular connective tissue ingrowth to enhance stability of the device after its implantation."


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First of all, it is noted that "velour" is a fabric characterized by fibers extending from a surface thereof. Also a "felt" can be understood as a basis from which fibers extend outwardly. Further, it is noted that a velour or a felt material can be compressed. Finally, it is noted that gaps will be filled after implantation as soon as even tissue ingrowth occur.

Although not literally, D6 discloses feature **F5** and **F6** of claim 1 of the opposed patent, namely a compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, the compressible material including a plurality of fibers extending outward from the outer surface.

D6 discloses all features of claim 1 of the opposed patent.

The subject matter of claim 1 of the opposed patent is not new in view of D6 and violates Art. 100(a) in combination with Art. 54 EPC.

5.2 Lack of novelty in view of D14 (WO 03/039613 A1)

The subject-matter of claim 1 of the patent lacks novelty in view of D14.

D14 relates to synthetic vascular prosthesis (title of D14) and to a novel method for the treatment of a cardiovascular disorder, inter alia applying an endovascular prosthesis in an intra-cardio-vascular setting, such as a heart valve (page 16, lines 5-8 of D14). The prosthesis can be placed into the vascular system by a catheter-delivery based minimal invasive endovascular technique (page 15, line 8-11 of D14).

Thus, features **F1**, **F2** and **F3** are disclosed, i.e. a prosthetic valve with an expandable stent structure and a valvular structure. It is noted that three-leaflet valve are typically used in the art of replacement heart valve so that


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D14 at least implicitly discloses a valve structure with all aspects as in feature **F3**.

According to page 7, lines 10-25, a graft material with filaments is disclosed, also known as "velours" material, with both inner and outer surfaces are provided with these filaments, as well as with open pores extending from the inner wall to the outer wall of the graft and forming a spongy material.

Thus, a hollow tubular structure formed of compressible material with outwardly extending fibers is disclosed which will, due to the spongy material and the filaments, fill gaps between the valve and the body channel after deployment. Also features **F4**, **F5** and **F6** are disclosed in D14.

When considering the disclosure of D14 strictly literally, one may conclude that e.g. the three leaflets are not mentioned as required in feature **F3**. However, the provision of a three-leaflet valve is notoriously known so that the subject-matter of claim 1 must at least be considered as lacking an inventive step in view of the teaching of D14 together with common knowledge.

5.3 Lack of inventive step in view of D3 in combination with either D9 or D1

Documents D3 have been cited during the examination procedure. The disclosure of D3 has been considered by the examiner in the annex to the summons to attend oral proceedings of 14 January 2019 as follows, (with references to D3 in parentheses):

> "A prosthetic valve (figure 1, feature 100) for percutaneous implantation in a
> body channel, comprising:


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a substantially cylindrical stent structure (feature 110) configured for radial
expansion (page 6, lines 3 - 15);
a valvular structure (feature 120) 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 (figures 1 and 2; page 5, lines 34 - 36);
characterised by a layer of compressible material, which forms a sleeve
disposed along an outer surface of the stent structure and extending entire
around the stent structure, the compressible material being adapted after
deployment to fill gaps between the prosthetic valve and the body channel
(page 6, line 34 - page 7, line 10) wherein the compressible material is polyurethane or polyethylene terephthalate (page 7, line 8)."

In fact, page 7, lines 6 to 10 of D3 discloses that "Gasket 150 may preferably be formed from a soft, deformable biocompatible material, e.g., polyurethane, silicone, Dacron or other suitable material that readily conforms to existing tissue, yet provides a fluid-tight seal around valve 110."

The feature of a plurality of fibers extending from an outer surface of the compressible material, was considered as being not disclosed by D3.

Feature **F6** of claim 1 of the opposed patent may thus be considered as distinguishing feature over D3.


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A technical effect of fibers extending from an outer surface of a material can be seen in a promotion of ingrowth of tissue on the surface.

The objective technical problem, when starting from the teaching of D3, may be to provide a graft material which facilitates formation of tissue on surfaces thereof without impeding the flow of blood therethrough.

When looking for a solution, a person skilled in the art would consider the teaching of document D9 which discloses "Synthetische Gefäßtransplantate" (title of D9). According to claim 1 of D9, a "Synthetisches Gefäßtransplantat in Form einer Doppelvelour-Kettenwirkware aus einem Material, an dem Zellgewebe haften kann" is disclosed. In English, a warp-knit, double velour, synthetic vascular graft" is disclosed in D9. A method of preparing such graft is also disclosed.

In D3, Dacron is already suggested as suitable material for the sleeve on the outside of the stent structure. Dacron is disclosed in claim 24 of D9 as material of the velour material of the graft, solving the above-mentioned problem.

In consequence, a skilled person would have no problems to achieve the claimed subject-matter. The skilled person would have to apply the method of preparing a graft as in D9 when providing the sleeve made of Dacron material as known in D3.

Alternatively, the skilled person knows from D1 that a Dacron velour would be a suitable material for covering a stent structure of a stented heart valve. It is noted that D1 was already cited by the examiner and was considered in the extended European search opinion as including all features of claim 1 as filed. Thus, the skilled person would have no problem to combine the teachings of two documents disclosing almost the same valve prosthesis.


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The subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from D3.

Comparably, the subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from each of D5a, D5b, D7 and D8.

D5 has been considered during examination as disclosing all features of claim 1 (prior to the introduction of feature F6). D5a is a family member of D5 and discloses the embodiments of figures 13, 15A – 16C and 27 – 34 to which the examiner referred to, wherein D5a is published before the effective filing date of the opposed patent. D5b discloses a similar embodiment in figures 8A - 10B, including a stented valve with a sleeve made from compressible material.

D7 also discloses a stent-valve with a covering of the frame. According to column 6, lines 31-33, the fabric section 34, i.e., the covering, is desirably a woven polyester, such as polyethylene terephthalate, i.e., PET like Dacron. Finally, D8 discloses an implantable prosthetic valve with a cuff portion. According to [0104] of D8, to prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to prevent rolled-up sleeve-like portion at the inlet.

D5a, D5b, D7 and D8 may be considered as missing feature F6. Following the problem-solution-approach presented above, a skilled person would achieve the subject-matter of claim 1 of the opposed patent when starting from any one of D5a, D5b, D7 and D8 and combining this document with one of D1 and D9.

5.4 Lack of inventive step in view of D1 in combination with any one of D4, D5a, D5b D7, D8


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As mentioned above, D1 was considered in the extended European search report as disclosing the following claim features (references to D1 in parentheses):

A prosthetic valve for implantation in a body channel (column 7, lines 22 - 24), comprising: a substantially cylindrical stent structure configured
for radial expansion (figures, feature 30, 130, 230); a valvular structure having
an inlet and an outlet, the valvular structure being formed of a pliant material
located within the stent structure and forming three valve leaflets (feature 20);
a layer of compressible material disposed along an outer surface of the stent
structure, the compressible material being adapted after deployment to fill
gaps between the prosthetic valve and the body channel (feature 15; column
8, line 61 - column 9,line14column10,line 37 - column 11, line 3).

During examination, the following marked features have been amended in claim 1:

**F1** A prosthetic valve (250) for <u>percutaneous</u> implantation in a body channel, comprising:

**F3** a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material ~~located within~~ <u>attached to</u> the stent structure and forming three valve leaflets,


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**F4** characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

**F6** wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Document D1 discloses the amendment of feature **F3**, namely that the valvular structure is not just located within but is attached to the stent structure, cf. column 4, lines 12 and 13 of D1. D1 further discloses in column 3, lines 49 to 53, a brim cover comprising a cylinder of material surrounding, folded over, and securely sutured to the two-layered brim to provide a tissue adhering cover above and below the brim, i.e., a sleeve as in amended feature **F4**. With the Dacron velour disclosed in D1, feature **F6** is at least implicitly disclosed. Features **F2** and **F5** remained unamended during examination.

The subject-matter of claim 1 of the opposed patent seems to merely distinguish from the disclosure of document D1 in that the prosthetic valve is suitable for percutaneous implantation, as required by feature **F1**.

However, D1 already discloses in column 8, lines 47 to 49, that the frame may be capable of annular deformity and slight perimetric expansion. Consequently, the subject-matter of claim 1 of the opposed patent actually differs from the disclosure of D1 by a different amount of expansion of the stent structure.

The technical effect of that other amount of expansion can be seen in a suitability of percutaneous implantation.


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When starting from the teaching of D1, a skilled person may thus be confronted with the problem to provide a prosthesis which can be implanted by means of a catheter.

From any one of documents D4 (Title: Support Tubulaire de Mise en Place, par voie Percutanee, d'une valve cardiaque de remplacement), D5 (Abstract: A method for percutaneously replacing a heart valve of a patient.), D7 (Title: Minimally-Invasive Heart Valve and Method of Use), and D8 (Abstract: A valve prosthesis device is disclosed suitable for implantation in body ducts), a skilled person knows how to design a stent structure so as to allow for percutaneous implantation by means of a catheter.

The subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from D1.

5.5 Lack of inventive step in view of D10 in combination with D13

Document D10 is directed to a stent graft with improved graft adhesion. On page 1, lines 13 and 14, it is noted that "a surgical stent graft may be placed into a lumen in the body by endoluminal techniques". In other words, D10 discloses a prosthesis for percutaneous implantation in a body channel with a substantially cylindrical stent structure configured for radial expansion.

Claim 1 of D10 discloses "a stent graft comprising a tubular graft having a distal end, a proximal end, and an outer surface; at least one expandable stent disposed on said tubular graft; and a band of fibrous material on said outer surface and adjacent at least one of said distal end and said proximal end of said tubular graft, said band of fibrous material extending circumferentially around said graft."


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Therefore, D10 discloses features **F1**, **F2** and **F4**.

According to the last paragraph on page 3 of D10, "It is desirable that the band be continuous around the proximal end of the graft so that with fibrous ingrowth of the cells of the wall of the lumen into the band of fibrous material on the graft, union of the wall and graft is obtained which provides sealing for blood flow which could occur between the graft and the wall as well as prevention of movement of the graft longitudinally within the lumen. In so doing there is improved incorporation of the graft into the wall of the lumen."

Providing a sealing for blood flow corresponds to the effect of filling gaps as in feature **F5**.

Feature **F6** is in fact in more detail disclosed in claims 4 to 8 of D10, reading:

"4. The stent graft as in Claim 1 wherein said band of fibrous material includes
velour material.
5. The stent graft as in Claim 4 wherein said velour material includes a loop pile
velour material.
6. The stent graft as in Claim 4 wherein said velour material includes a cut pile
velour material.
7. The stent graft as in Claim 1 wherein said band of fibrous material includes
fibres woven or knitted into material of said graft.
8. The stent graft as in Claim 1 wherein said graft includes a graft material and
wherein said band of fibrous material comprises brushed raised fibres of said graft material."


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In consequence, a three-leaflet valve as in feature **F3** may be seen as distinguishing feature over D10.

When starting from D10, a skilled person may thus be confronted with the objective technical problem to provide a valve functionality for blood flowing through the stented graft.

It is common knowledge, as evidence by the scientific article D13 (cf. paragraph bridging columns 1 and 2 on page 1 of D13), that "intravascular stents have gradually obtained acceptance for peripheral and coronary vascular occlusive disease. Combinations of stents with grafts have allowed for intraluminal bypass of aneurysms and long segment atherosclerotic lesions. Transfemoral percutaneous aortic valve replacement is an extended application of this new technology…". In other words, transfemoral percutaneous aortic valve replacement has been developed based on stented grafts.

The authors of D13 developed a novel sutureless bovine pericardial bioprosthetic aortic valve mounted on a collapsible stent suitable for implantation by means of a catheter (cf. second paragraph of right column on page 1 of D13.

That is, D13 discloses the solution for the above identified problem, namely to provide a stented graft with a valve.

The subject-matter of claim 1 of the opposed patent is thus not inventive when starting from D10.


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Alternatively, a skilled person would be hinted to provide a three-leaflet valve attached to a collapsible and expandable stent from each of, for example, documents D3, D4, D5, D7, and D8.

Comparably, the subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from each of D11 and D12.

Like D10, D11 discloses a stented graft. In particular with reference to figures 20 to 24, D11 discloses in detail how to form a sleeve with fibers protruding therefrom. For example, the following is described in D11, starting in column 9, line 16:

> "When the graft is deployed in a diseased vessel (not shown), the tufted yarn 932 operates to fill spaces between the vascular wall and the tubular member 934, thereby substantially forming a seal…... The tufted-yarn sealing member 932, may simply be attached to an outer wall of the graft 931 by stitching the yarn onto the wall of the tubular member 934. The tufts of yarn may be made from the fabric making up the tubular member 934 itself. The fabric 940 (See FIG. 22) from which the graft is manufactured may be woven so that weft threads (running horizontally) are omitted from certain zones 942 thereof. The lengths of warp threads (running vertically) which are not connected to each other by weft threads are pulled radially outward to form a loop 944 (See FIG. 23). The loops of warp thread 944 are cut at the apex of each loop 944, leaving single linear strands of yarn 946 (See FIG. 24) circumferentially protruding from the tubular member 934.

D12 discloses a stented graft with material folded over on itself such that a

> "distal 5 cm of a cuff includes a region in which the threads and fibers of the DACRON® polyester fabric have been at least partially separated from one another to create a frayed region that extends outward from the graft and facilitates sealing by encouraging


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thrombus formation and tissue ingrowth. Graft material, such as DACRON® polyester fiber, is particularly well-suited to form thrombus." (cf. [0009] of D12).

When starting from either D11 or D12, a skilled person would achieve the claimed subject-matter following the above discussed problem-solution-approach, i.e., simply adding a three-leaflet valve to the stented graft already including a sleeve of compressible material having fibers extending therefrom.

5.6 Dependent claims

The features of the dependent claims are not new, at least constitute straightforward modifications and do not establish an inventive step.

Claim 2:

According to claim 2, the sleeve surrounds an inflow end of the stent structure.

This feature is known, for example, from figures 21, 22 of D1, figure 10 of D2, figure 1 of D3, figure 1 of D8, figure 1 of D10, figure 1 of D11, figure 2 of D12, paragraph bridging pages 5 and 6 of D14.

Claim 3:

According to claim 3, the compressible material has a thickness ranging from 1 to 5mm.

Regarding the feature of claim 3, it is noted that the opposed patent does not provide any indication as to what kind of compressible material is measured in which state (compressed or expanded).


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For example, D2 discloses a resilient foam or sponge rubber 29 in figure 9 and 29' in figure 10. As these sealing elements in D2 are provided to fill gaps like the compressible material, a skilled person will, due to anatomical circumstances at an implantation site, consider the same range of thickness for the compressible material.

Alternatively, when considering a velour material as the compressible material, the skilled person would provide the velour band of D6 with an appropriate thickness, measured from the outermost tips of the outwardly extending fibers in an expanded state. Comparably, the skilled person knows outwardly extending fibers from D10 and would consider an appropriate length. Also the tufted yarns in D11 extend a few millimeters away from the base material.

Claim 4:

According to claim 4, the compressible material comprises a cloth or fabric.

Velour is typically formed as woven or knitted fabric. Thus, that feature is known from D1, D6, D9, D10, D11, D12 and D14 as shown above.

Claim 5:

According to claim 5, the prosthetic valve further comprises a tissue growth factor disposed along the compressible material.

For example, such a tissue growth factor is disclosed as active substance on page 9, lines 11-14 of D14.


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Claim 6:

According to claim 6, the growth factor according to claim 5 is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

It is known from, e.g., paragraph [0040] of D12 that, besides tissue-engaging structures (like fibers), an external sealing zone may be impregnated with a bioactive or pharmacological agent that enhances sealing properties, such as thrombin powder or another agent for stimulating thrombus formation about the external sealing zone 21. Other possible materials or agents, include, but are not limited to, growth factors or biomaterials for stimulating tissue ingrowth, materials that swell in the presence of blood, or other substances that help form a physical barrier to fluids. Also D14 discloses an impregnation of the material by a growth factor on page 12, line 26.

Claim 7:

According to claim 7, the fibers are straight, curved or hook-shaped.

That feature is self-evident. Fibers must be curved in a woven fabric. Outwardly extending fibers will be straight or curved. There is no other possibility.

Claim 8:

According to claim 8, the compressible material is configured to expand into the gaps.


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Assuming a foam as compressible material (as disclosed for example in D2), it is an intrinsic feature of such a material to expand as soon as a compression force is taken away. That is, a foam would surely expand into a gap. The same applies for the spongy material according to D14.

Claim 9:

According to claim 9, the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

This it, what a foam or sponge would do, see e.g. page 8, lines 1-13 of D14.


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## IV. SUMMARY

The subject-matter of the claims is extended beyond the content of the application as originally filed, at least due to an omission of several features. Without any definition regarding specific features of the claims, a skilled person is not able to put the claimed subject-matter into practice, at least not based on the teaching of the patent. Assuming that the skilled person would nevertheless be able to do so, said skilled person would recognize that the subject-matter is known or at least not inventive.

Accordingly, the opposed patent is to be revoked in its entirety.

/electronically signed/
Knut M. Schwarz
Philipp Sünder
Ralph Fernolend
Korbinian Kopf

European Patent Attorneys
Association No. 708

**Enclosures**
Annex A1 - feature analysis
E1a – E1d;
D1 – D14.


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Europäisches Patentamt
European Patent Office
Office européen des brevets

# Notice of opposition to a European patent

## I. Patent opposed

| | |
|---|---|
| Patent No. | EP2982337 |
| Application No. | EP15180327.7 |
| Date of mention of the grant in the European Patent Bulletin (Art. 97(3), Art. 99(1) EPC) | 26 August 2020 |
| Title of the invention | Paravalvular leak detection, sealing, and prevention |

## II. Proprietor of the patent

| | |
|---|---|
| first named in the patent specification | Edwards Lifesciences PVT, Inc. |
| Opponent's or representative's reference | 255.0051G1 |

## III. Opponent

| | |
|---|---|
| Name | Abbott Cardiovascular Systems, Inc. |
| Address: | 3200 Lakeside Drive<br>Santa Clara CA California 95054<br>United States of America |
| State of residence or of principal place of business | United States of America |
| Multiple opponents (see additional sheet) | ☐ |

## IV. Authorisation

1. Representative

| | | |
|---|---|---|
| | LKGLOBAL \| Lorenz & Kopf PartG mbB Patentanwälte | |
| Association No.: | 708 | |
| Address of place of business | Brienner Str. 11<br>80333 München<br>Germany | |
| Telephone/Fax | +49 (89) 262097170 | +49 (89) 550568610 |
| E-mail: | abbott@lkglobal.com | |
| Additional representative(s) on additional sheet/see authorisation | ☐ | |



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Authorisation(s)

is/are enclosed ☐

has/have been registered under No. ☐

## V. Opposition is filed against

the patent as a whole ☒

claim(s) No(s).

## VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not patentable (Art. 100(a) EPC) because:

- it is not new (Art. 52(1); Art. 54 EPC) ☒
- it does not involve an inventive step (Art. 52(1); Art. 56 EPC) ☒
- patentability is excluded on other grounds, namely articles ☐

(b) the patent opposed does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC; see Art. 83 EPC). ☒

(c) the subject-matter of the patent opposed extends beyond the content of the application/of the earlier application as filed (Art. 100(c) EPC, see Art. 123(2) EPC). ☒

## VII. Facts (Rule 76(2)(c) EPC)

presented in support of the opposition are submitted herewith on an attached document ☒

## VIII. Other requests:

- Oral proceedings are hereby requested auxiliarily.



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## IX. Evidence presented

| | | |
|---|---|---|
| **A1** | Other evidence | Annex A1<br>original file name: Annex A1.pdf<br>attached as: Other-evidence-1.pdf |
| **D1** | Patent document | US5,258,023 (A) , 02.11.1993<br>original file name: D1_US000005258023A.pdf<br>attached as: Published-Evidence-1.pdf |
| **D10** | Patent document | WO 03/053287 (A1) , 03.07.2003<br>original file name: D10_WO002003053287A1.pdf<br>attached as: Published-Evidence-13.pdf |
| **D11** | Patent document | US6,729,356 (B1) , 04.05.2004<br>original file name: D11_US000006729356B1.pdf<br>attached as: Published-Evidence-14.pdf |
| **D12** | Patent document | US2004/0082989 (A1) , 29.04.2004<br>original file name: D12_US020040082989A1.pdf<br>attached as: Published-Evidence-15.pdf |
| **D13** | Non-patent literature - article | Moazami, Nader et al., "Transluminal Aortic Valve Placement " Deterioration of bioprosthetic heart valves, 1996<br>original file name: D13_Moazami_Transluminal.pdf<br>attached as: Published-Evidence-17.pdf |
| **D14** | Patent document | WO 03/039613 (A1) , 15.03.2003<br>original file name: D14_WO002003039613A1.pdf<br>attached as: Published-Evidence-16.pdf |
| **D2** | Patent document | FR2337543 (A) , 05.08.1977<br>original file name: D2_FR000002337543A1.pdf<br>attached as: Published-Evidence-2.pdf |
| **D2a** | Patent document | US4,106,129 (A) , 15.08.1978<br>original file name: D2a_US000004106129A.pdf<br>attached as: Published-Evidence-3.pdf |
| **D3** | Patent document | WO 00/64380 (A1) , 02.11.2000<br>original file name: D3_WO002000064380A1.pdf<br>attached as: Published-Evidence-4.pdf |
| **D4** | Patent document | FR2815844 (A1) , 03.05.2002<br>original file name: D4_FR000002815844A1.pdf<br>attached as: Published-Evidence-5.pdf |
| **D5** | Patent document | EP2537487 (A1) , 26.12.2012<br>original file name: D5_EP000002537487A1.pdf<br>attached as: Published-Evidence-6.pdf |
| **D5a** | Patent document | US2005/0137688 (A) , 23.06.2005<br>original file name: D5a_US020050137688A1.pdf<br>attached as: Published-Evidence-7.pdf |
| **D5b** | Patent document | US2005/0137698 (A) , 23.06.2005 |

| | | |
|---|---|---|
| | | original file name: D5b_US020050137698A1.pdf<br>attached as: Published-Evidence-8.pdf |
| **D6** | Patent document | WO 01/56512 (A1) , 09.08.2001<br>original file name: D6_WO002001056512A1.pdf<br>attached as: Published-Evidence-9.pdf |
| **D7** | Patent document | US6,454,799 (B1) , 24.09.2002<br>original file name: D7_US000006454799B1.pdf<br>attached as: Published-Evidence-10.pdf |
| **D8** | Patent document | US2003/0153974 (A1) , 14.08.2003<br>original file name: D8_US020030153974A1.pdf<br>attached as: Published-Evidence-11.pdf |
| **D9** | Patent document | DE26 13 575 (A1) , 04.08.1977<br>original file name: D9_DE000002613575A1.pdf<br>attached as: Published-Evidence-12.pdf |
| **E1a** | Patent document | US10/883,575 (A) , 30.06.2005<br>original file name: E1a_US10883575.pdf<br>attached as: Published-Evidence-18.pdf |
| **E1b** | Patent document | WO 2006/005015 (A2) , 12.01.2006<br>original file name: E1b_WO002006005015A2.pdf<br>attached as: Published-Evidence-19.pdf |
| **E1c** | Patent document | EP2 982 337 (A1) , 10.02.2016<br>original file name: E1c_EP000002982337A1.pdf<br>attached as: Published-Evidence-20.pdf |
| **E1d** | Patent document | EP2 982 337 (B1) , 26.08.2020<br>original file name: E1d_EP000002982337B1.pdf<br>attached as: Published-Evidence-21.pdf |

## X. Payment

Method of payment: Debit from deposit account

The European Patent Office is hereby authorised, to debit from the deposit account with the EPO any fees and costs indicated in the fees section below.

Currency: EUR

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**Refunds**

Any refunds should be made to EPO deposit account: 28003046

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**Fees**

| | Factor applied | Fee schedule | Amount to be paid |
|---|---|---|---|
| 010 Opposition fee | 1 | 815.00 | 815.00 |
| Total: | | EUR | 815.00 |

## A Forms

| | Details: | System file name: |
|---|---|---|
| A-1 | Form for notice of opposition | ep-oppo.pdf |

## B Attached document files

| | Original file name: | System file name: |
|---|---|---|
| B-1 1. Facts and arguments | 20210525_NtcOfOppo.pdf | OPPO.pdf |

## C Attached evidence files

| | Original file name: | System file name: |
|---|---|---|
| C-1 1. Patent document | D1_US000005258023A.pdf | Published-Evidence-1.pdf |
| C-2 2. Patent document | D2_FR000002337543A1.pdf | Published-Evidence-2.pdf |
| C-3 3. Patent document | D2a_US000004106129A.pdf | Published-Evidence-3.pdf |
| C-4 4. Patent document | D3_WO002000064380A1.pdf | Published-Evidence-4.pdf |
| C-5 5. Patent document | D4_FR000002815844A1.pdf | Published-Evidence-5.pdf |
| C-6 6. Patent document | D5_EP000002537487A1.pdf | Published-Evidence-6.pdf |
| C-7 7. Patent document | D5a_US020050137688A1.pdf | Published-Evidence-7.pdf |

| | | | |
|---|---|---|---|
| C-8 | 8. Patent document | D5b_US020050137698A1.pdf | Published-Evidence-8.pdf |
| C-9 | 9. Patent document | D6_WO002001056512A1.pdf | Published-Evidence-9.pdf |
| C-10 | 10. Patent document | D7_US000006454799B1.pdf | Published-Evidence-10.pdf |
| C-11 | 11. Patent document | D8_US020030153974A1.pdf | Published-Evidence-11.pdf |
| C-12 | 12. Patent document | D9_DE000002613575A1.pdf | Published-Evidence-12.pdf |
| C-13 | 13. Patent document | D10_WO002003053287A1.pdf | Published-Evidence-13.pdf |
| C-14 | 14. Patent document | D11_US000006729356B1.pdf | Published-Evidence-14.pdf |
| C-15 | 15. Patent document | D12_US020040082989A1.pdf | Published-Evidence-15.pdf |
| C-16 | 16. Patent document | D14_WO002003039613A1.pdf | Published-Evidence-16.pdf |
| C-17 | 17. Patent document | E1a_US10883575.pdf | Published-Evidence-18.pdf |
| C-18 | 18. Patent document | E1b_WO002006005015A2.pdf | Published-Evidence-19.pdf |
| C-19 | 19. Patent document | E1c_EP000002982337A1.pdf | Published-Evidence-20.pdf |
| C-20 | 20. Patent document | E1d_EP000002982337B1.pdf | Published-Evidence-21.pdf |
| C-21 | 1. Non-patent literature - article | D13_Moazami_Transluminal.pdf | Published-Evidence-17.pdf |
| C-22 | 1. Other evidence | Annex A1.pdf | Other-evidence-1.pdf |

**Signature of opponent or representative**

| | |
|---|---|
| Place | **Munich** |
| Date: | **25 May 2021** |
| Signed by: | **Korbinian Kopf 47644** |
| Association: | **LKGLOBAL \| Lorenz & Kopf PartG mbB Patentanwälte** |
| Representative name: | **Korbinian Kopf** |
| Capacity: | **(Representative)** |

# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US05/023584

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World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

1355325

# THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

*August 10, 2005*

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.**

**APPLICATION NUMBER:** *10/883,575*
**FILING DATE:** *June 30, 2004*
**RELATED PCT APPLICATION NUMBER:** *PCT/US05/23584*

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# UTILITY PATENT APPLICATION TRANSMITTAL

*(Only for new nonprovisional applications under 37 CFR 1.53(b))*

| | |
|---|---|
| *Attorney Docket No.* | 501015.20517 |
| *First Inventor* | Benjamin Spenser |
| *Title* | Paravalvular Leak Detection ... |
| *Express Mail Label No.* | EV 374587856 US |

## APPLICATION ELEMENTS

*See MPEP chapter 600 concerning utility patent application contents.*

1. ☐ Fee Transmittal Form (e.g., PTO/SB/17)
*(Submit an original and a duplicate for fee processing)*
2. ☐ Applicant claims small entity status.
See 37 CFR 1.27.
3. ☑ Specification [*Total Pages* 40 ]
*(preferred arrangement set forth below)*
- Descriptive title of the invention
- Cross Reference to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to sequence listing, a table, or a computer program listing appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

4. ☑ Drawing(s) (*35 U.S.C. 113*) [*Total Sheets* _____ ]
5. Oath or Declaration [*Total Sheets* _____ ]
a. ☑ Newly executed (original or copy) UNExecuted
b. ☐ Copy from a prior application (37 CFR 1.63(d))
*(for continuation/divisional with Box 18 completed)*
i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76
7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission
*(if applicable, all necessary)*
a. ☐ Computer Readable Form (CRF)
b. Specification Sequence Listing on:
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11. ☐ English Translation Document *(if applicable)*
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
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| Applicant: | Benjamin Spenser et al. |
| Serial No: | To Be Assigned |
| Filing Date: | June 30, 2004, herewith |
| For: | Paravalvular Leak Detection, Sealing, & Prevention |
| Enclosures: | (1) Utility Patent Application Transmittal ( page); (2) Specification (40 pages); (3) Drawings (20 sheets); (4) NonPublication Request (1 page); (5) UNExecuted Declaration (3 pages); (6) UNExecuted POA (3 pages); (7) Acknowledgement Postcard. |

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# NONPUBLICATION REQUEST UNDER 35 U.S.C. 122(b)(2)(B)(i)

| | |
|---|---|
| First Named Inventor | Benjamin Spenser |
| Title | Paravalvular Leak Detection, Sealing, And ... |
| Attorney Docket Number | 501015.20517 |

I hereby certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing.

I hereby request that the attached application not be published under 35 U.S.C. 122(b).

June 30, 2004
Date

Signature

949-250-6878
Telephone number

William H. Dippert
Registration No. 26,723
for Christopher James

This request must be signed in compliance with 37 CFR 1.33(b) and submitted with the application **upon filing.**

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. 122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. 122(b)(2)(B)(iii)).**

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# PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

## FIELD OF THE INVENTION

**[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

**[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.

**[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 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 bileaflet valve having appended chordae and tabs.

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





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**[0005]** Schreck in U.S. Patent No. 6,454,799, entitled, "MINIMALLY-INVASIVE HEART VALVES AND METHODS OF 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, 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 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 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, "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 more longitudinal channels or passways therethrough.



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**[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 transceptal hole and 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 bring comprised of a deployable construction 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 bring provided with a plurality of longitudinally rigid support beams 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, 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.



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**[0011]** With regard to the general topic of prosthetic valves, implantation is currently done either through open heart surgery or by use 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 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 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 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 location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself.



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## 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 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.

**[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 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 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 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.





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**[0019]** Furthermore, in accordance with another preferred embodiment of the present invention, the sealing stent is self-expandable, 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 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.

**[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, 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.





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**[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.

**[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 to create the plug in the cavity.





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**[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 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 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 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.

**[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, and, upon egress from the catheter, the tabs spring out to form the sealing ring.





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**[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 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 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.

**[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 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.



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**[0039]** There is thus also provided in accordance with a preferred 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 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 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 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,

**[0043]** 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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**[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 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 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

**[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.





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**[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.

**[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.

**[0055]** There is thus also provided in accordance with a preferred embodiment of the present invention, a method for providing integrated 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:

**[0056]** providing an expandable elastic ring around the outside of the valve; and

**[0057]** expanding the ring,

**[0058]** wherein the ring seals any cavities.

**[0059]** 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 where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

**[0060]** inserting a sealing stent at the distal end of the cavity; and

**[0061]** inserting a second sealing stent attached to the first stent into the cavity.





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## BRIEF DESCRIPTION OF THE FIGURES

**[0062]** 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.

**[0063]** Figure 1 illustrates an implanted valve with a cavity 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.

**[0064]** Figures 2a and 2b depict a plurality of balloons on soft guidewires, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

**[0065]** Figure 3 illustrates a plurality of balloons on soft guidewires and kept along the perimeter of the blood vessel by a ring, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

**[0066]** 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.

**[0067]** Figures 5a to 5d depict several types of sealing stents, in accordance with another preferred embodiment of the present invention.



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**[0068]** 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 aortic wall (or annulus).

**[0069]** 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).

**[0070]** 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.

**[0071]** Figures 9a to 9c depict a leak repair done, in accordance with another preferred embodiment of the present invention, using an ultra-violet light-cured biological glue.

**[0072]** 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.

**[0073]** 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.

**[0074]** Figures 12 depicts a valve, in accordance with another preferred embodiment of the present invention, with a built-in inflatable portion allowing to fill gaps between the valve stent and the aortic wall in order to prevent paravalvular leaks.

**[0075]** 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.





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**[0076]** 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..

**[0077]** 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.

**[0078]** Figures 16a and 16b illustrate a valve device, in accordance with another preferred embodiment of the present invention, comprising an additional portion for blocking possible leaks around the stent.

**[0079]** 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 to protrude radially, thereby blocking possible leaks.

**[0080]** 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 leaks.

**[0081]** 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.



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## DETAILED DESCRIPTION OF THE INVENTION

**[0082]** 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.

**[0083]** 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 are tricuspid valves, it could be another type of valve as well.

**[0084]** A main aspect of the present invention is the introduction of several novel designs and methods for locating paravalvular leaks in prosthetic valves.

**[0085]** Another main aspect of the present invention are several novel designs for sealing paravalvular leaks detected in prosthetic valves.

**[0086]** 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.

**[0087]** Another main aspect of the present invention is a novel design that automatically seals paravalvular leaks when the valve is implanted without requiring valve modification.

**[0088]** 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.





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**[0089]** For locating paravalvular leaks, the present invention 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 and the wall of the blood vessel, thereby providing a means to deliver means for sealing the leak.

**[0090]** For sealing paravalvular leaks, the present invention provides several designs including sealing stents, and multi-component and radiation-cured adhesive compounds.

**[0091]** 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.

**[0092]** 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 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.

**[0093]** Another anchoring means is for the guidewire to be terminated in a screw, which can be threaded into the blood vessel wall.



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**[0094]** 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, 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 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.

**[0095]** The sealing stent is held in place by friction. Additional holding force can be obtained by adding hooks around the perimeter of the stent, such as self-expanding hooks made of shape memory alloy.

**[0096]** 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 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.

**[0097]** 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. 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





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retracted, and the second stent is deployed into the cavity. The catheter is further retracted and the second stent is pulled back, catching it (from the bottom) in the top of the cavity.

**[0098]** An alternative sealing element to the sealing stent is a biological adhesive compound that can be delivered to the cavity via catheter. In such a case, two catheters are brought to the leak 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.

**[0099]** In both sealing element designs there is a need to bring the 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 then slid over their guidewires to meet at the leak location, thereby providing egress for applying the bi-component adhesive or radiation-cured adhesive.

**[00100]** Another delivery design for a bi-component adhesive utilizes a single catheter run over the leak detection guidewire. The 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.

**[00101]** In other embodiments of the present invention, leak sealing means are integrated into the valve as an impermeable ring that, when the valve is implanted, adaptively seals any gaps between the valve and the surrounding lumen.

**[00102]** In one embodiment of such a self-sealing valve, the ring is deflated for delivery and then inflated for sealing.





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**[00103]** In another self-sealing valve embodiment, the ring is a sponge-like material that is compressed for delivery and then expands for sealing.

**[00104]** In another self-sealing valve embodiment, the ring 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.

**[00105]** In another self-sealing valve embodiment, the ring comprises a set of self-expanding tubes.

**[00106]** 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

**[00107]** In another embodiment where sealing means are built into 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.

**[00108]** 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.

**[00109]** The aforementioned embodiments as well as other embodiments, manufacturing methods, different designs and different 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.





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**[00110]** 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.

**[00111]** 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 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 balloon 29 is drawn into the regurgitation flow and lodges in cavity 24 in between valve 20 and annulus 22.

**[00112]** 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. 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.



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**[00113]** Figure 3 illustrates an annular-configured leak detector 229, 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 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.

**[00114]** 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, 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 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.



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**[00115]** 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.

**[00116]** 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.

**[00117]** 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



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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.

**[00118]** 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.

**[00119]** 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 guide wire 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



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midway through cavity 24, catheters 86 and 87 are slid over guidewires 28 and 84, respectively, until the catheters meet at meeting point 75.

**[00120]** 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.

**[00121]** 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 caused by cavity 24.

**[00122]** 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 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



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guidewire 28. Figure 10c shows a bi-component 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 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 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.

**[00123]** 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



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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.

**[00124]** 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 can be saline solution, the patient's blood, or another physiologically acceptable fluid.

**[00125]** 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 blood, causing it to swell and seal the cavity.

**[00126]** 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 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



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connected to the valve stent 125. 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.

**[00127]** 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.

**[00128]** Figure 13d shows a cross-section of a self-expanding sealing flap 127. Stent strut 133 is attached to spring wire ring 131 by 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.

**[00129]** Figure 14 illustrates a valve adapted to seal paravalvular 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 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.



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**[00130]** Figures 15a and 15b depict a valve adapted to seal 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 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.

**[00131]** 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 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 (polyethylene terephthalate) mesh 167 or other impermeable material.

**[00132]** 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 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),



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ring of struts 172 bend to a final diameter 169 substantially larger than the final diameter 168 of the rest of the expanded stent, thereby sealing paravalvular cavities and associate leaks.

**[00133]** 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. 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 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 moves up, pulling the stent to the shape shown in 17d .

**[00134]** 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 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.



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**[00135]** Inflating balloon 183, as shown in Figure 18c, anchors 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).

**[00136]** Figures 19a to19d 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 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.

**[00137]** Figure 19b shows the two stents placed in the native aortic valve. Sealing stent 195 compensates for irregular shapes, while the 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 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).



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**[00138]** The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other 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.





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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 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 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 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-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 comprised of shape memory material.





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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, 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 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 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 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 first catheter to the point, a second component of the two-





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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 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 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 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.





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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 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.

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.





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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.

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. 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 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.

27. A method for locating 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 comprising:

inserting a balloon mounted on a flexible wire next to the valve;

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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28. 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 comprising:

inserting an impermeable stent into the cavity,

whereby the stent seals the cavity.

29. 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 comprising:

inserting a first guidewire into the cavity;

running a loop attached to a second guidewire over the first guide wire to a point inside the cavity;

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

injecting the second component of the two-component adhesive through a catheter over the second guide wire to the cavity,

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

30. The method of Claim 29, wherein 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.

31. The method of Claim 29 where only one guidewire is used and the two components are inserted via separate lumens within a single catheter over the guidewire.





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32. A method for providing integrated 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 comprising:

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

expanding the ring;

whereby the ring seals any cavities.

33. 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 comprising:

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

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





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## ABSTRACT OF THE DISCLOSURE

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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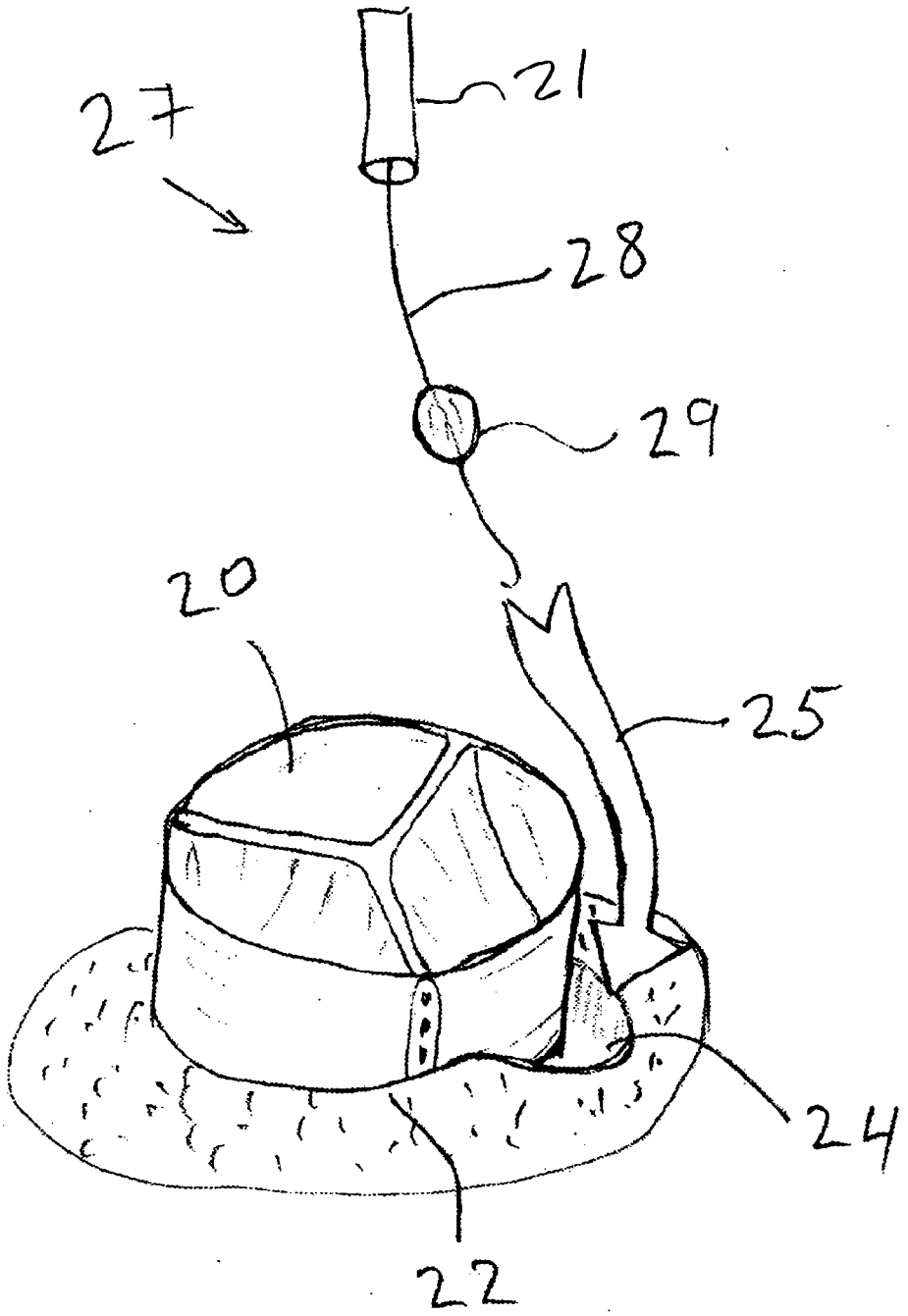



Fig. 1

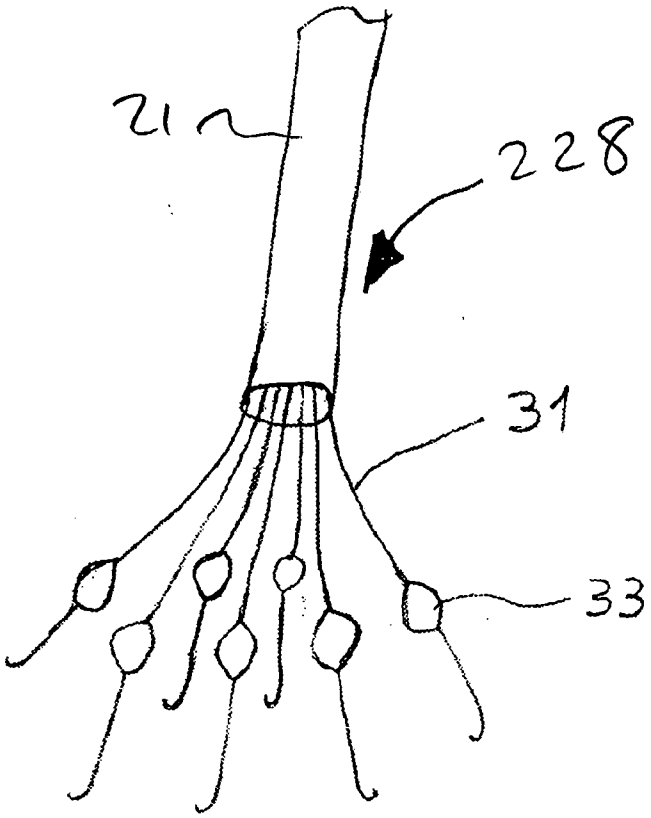



Fig. 2a

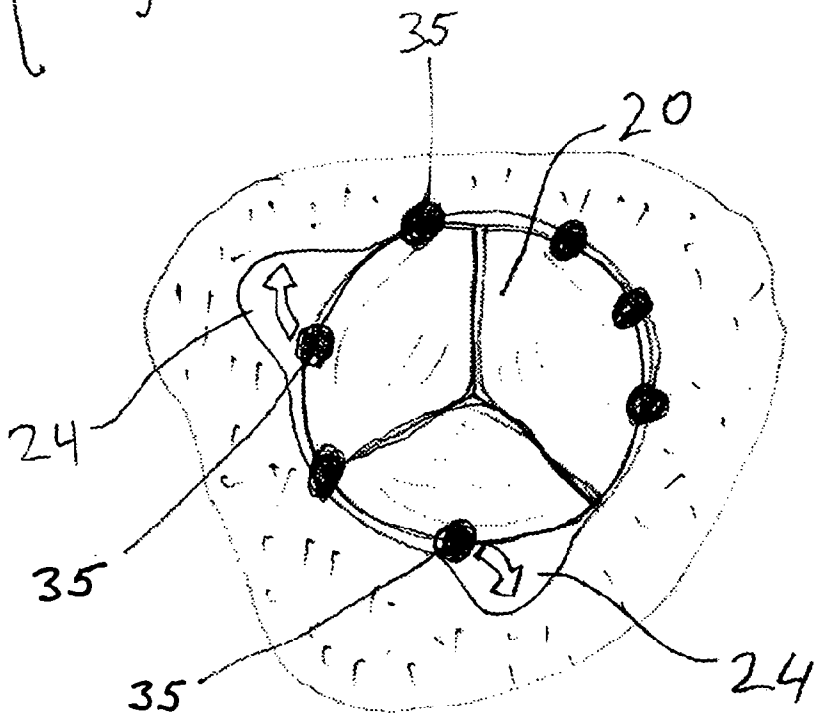



Fig. 2b

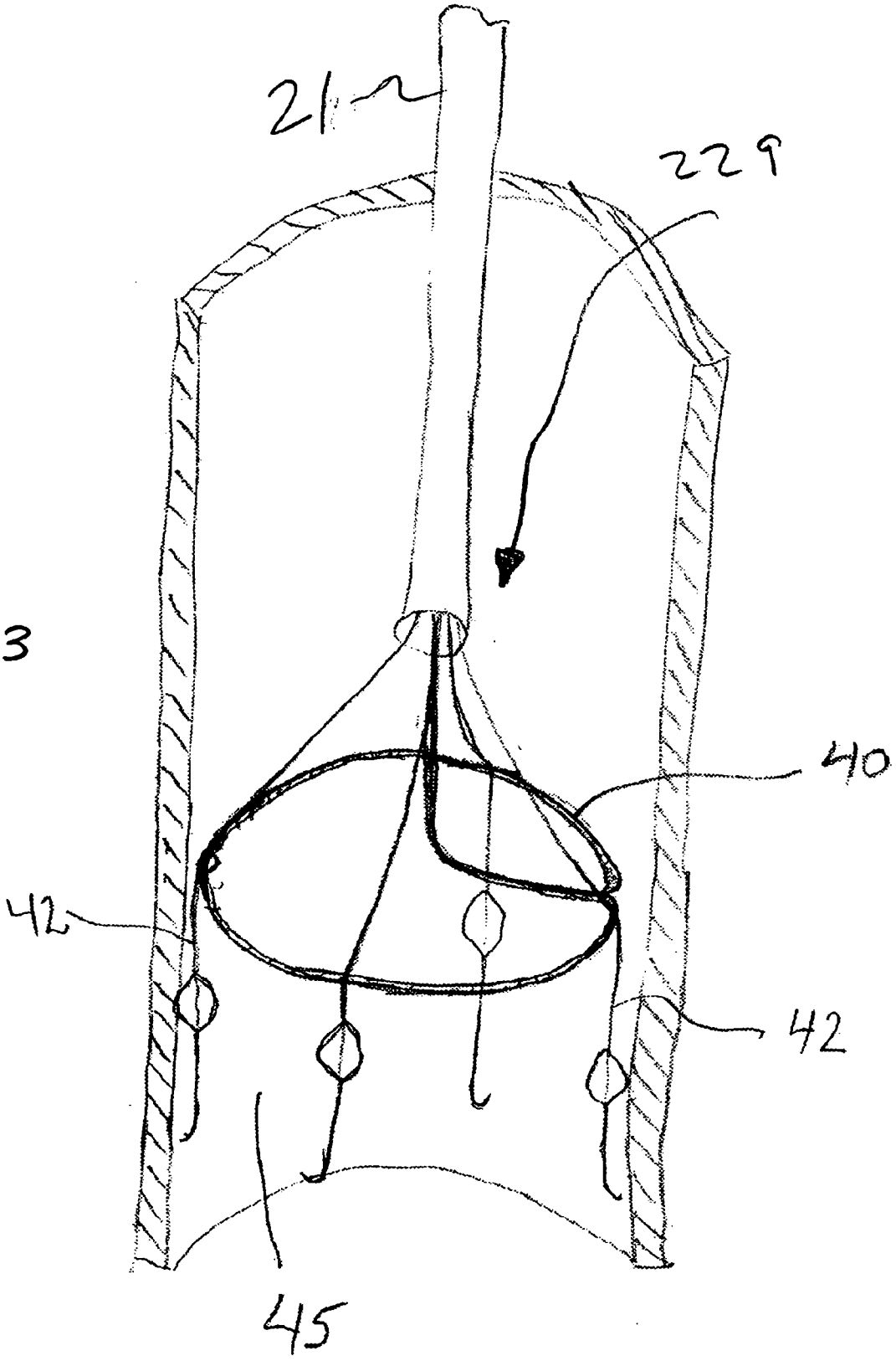



Fig. 3

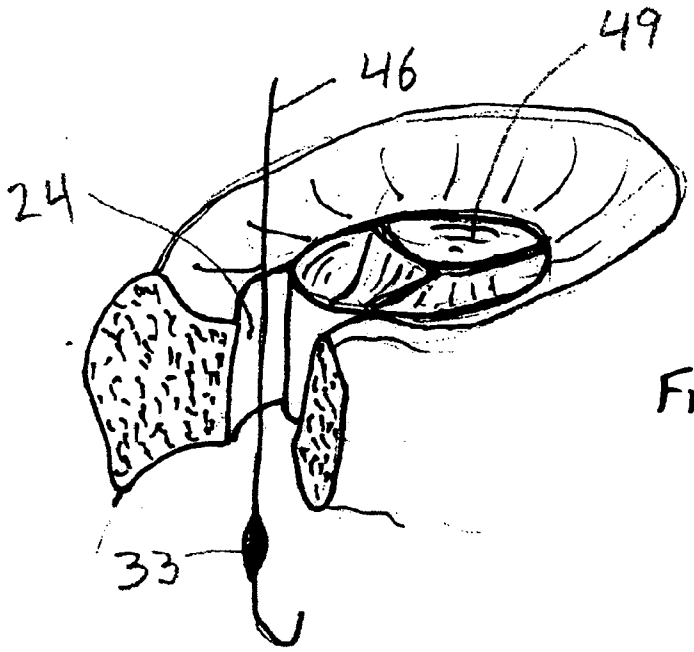
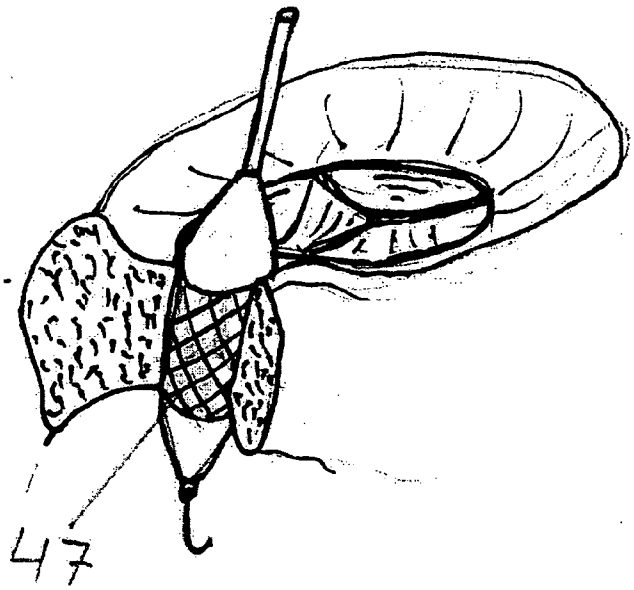



Fig. 4a

Fig. 4b



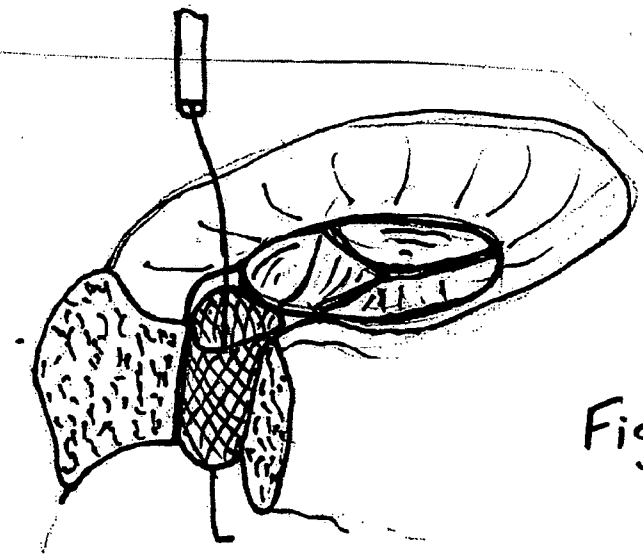



Fig. 4c

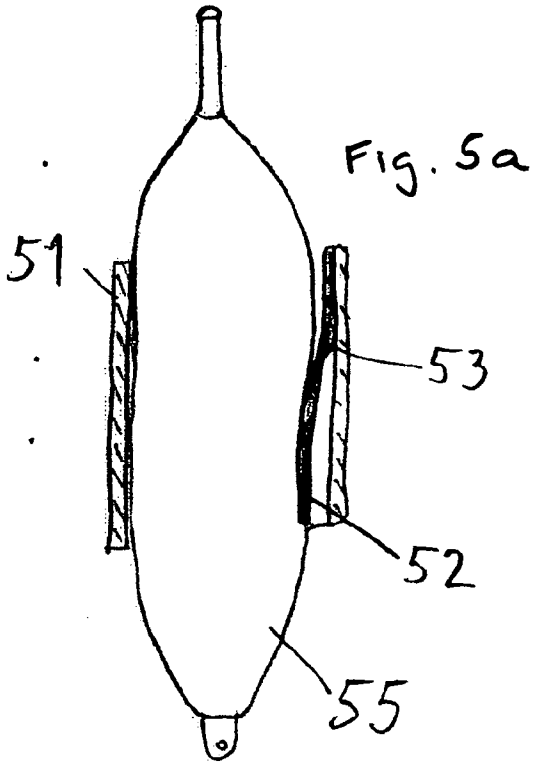



Fig. 5a

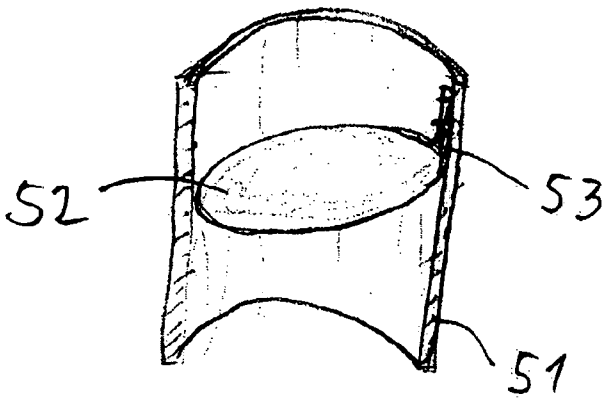



Fig. 5b

Fig. 5c

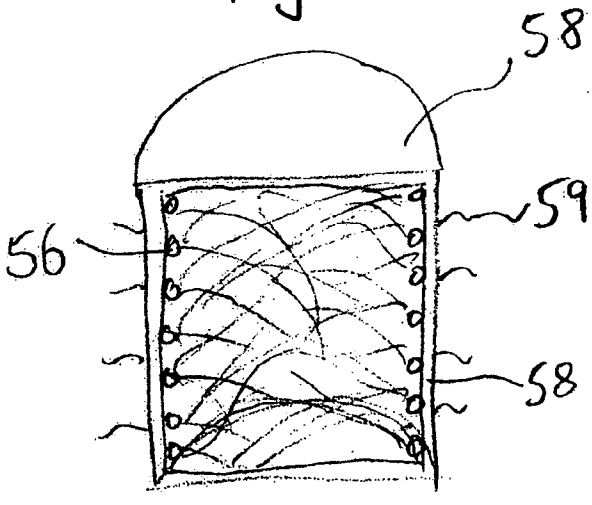
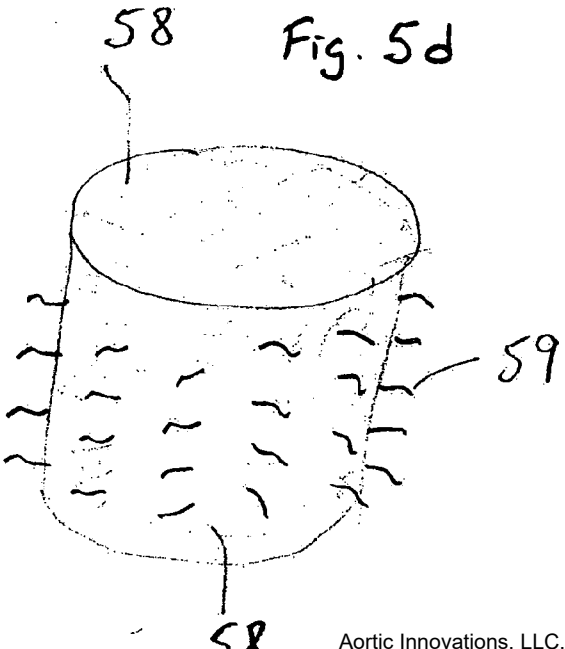



Fig. 5d



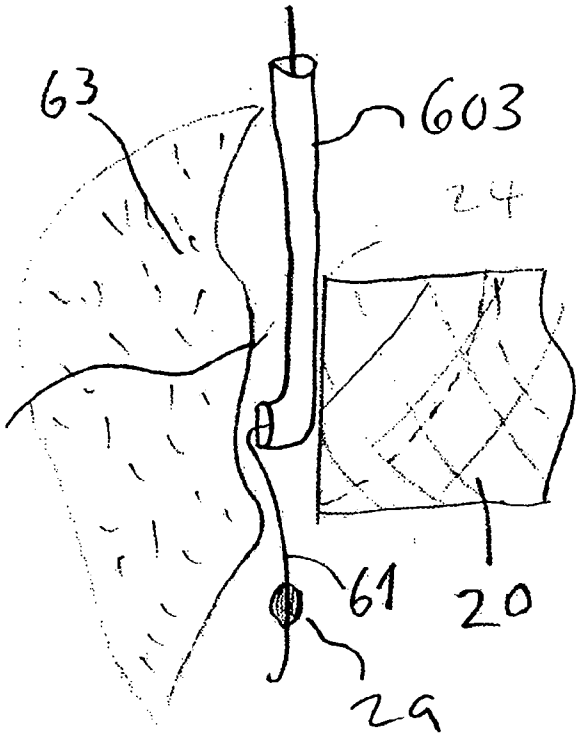



Fig. 6a

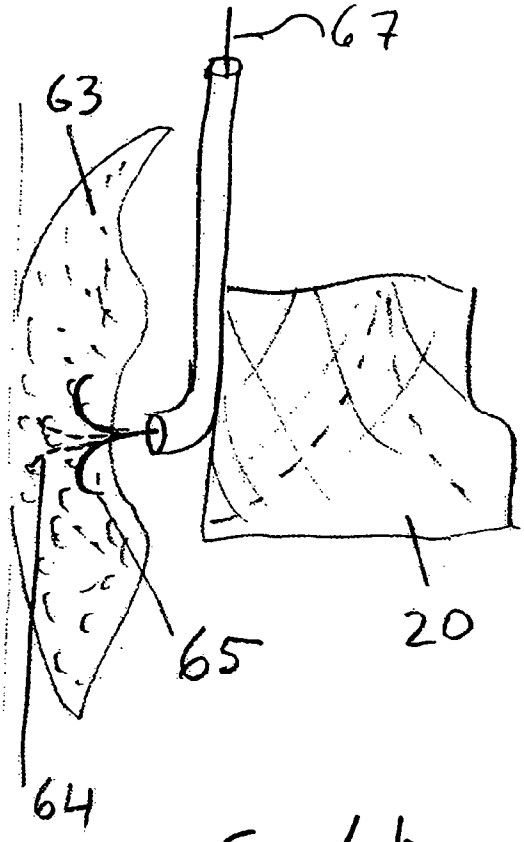



Fig. 6b

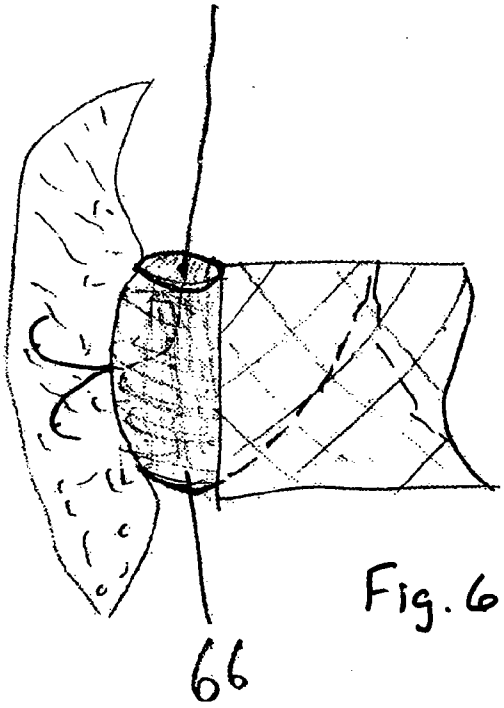



Fig. 6c

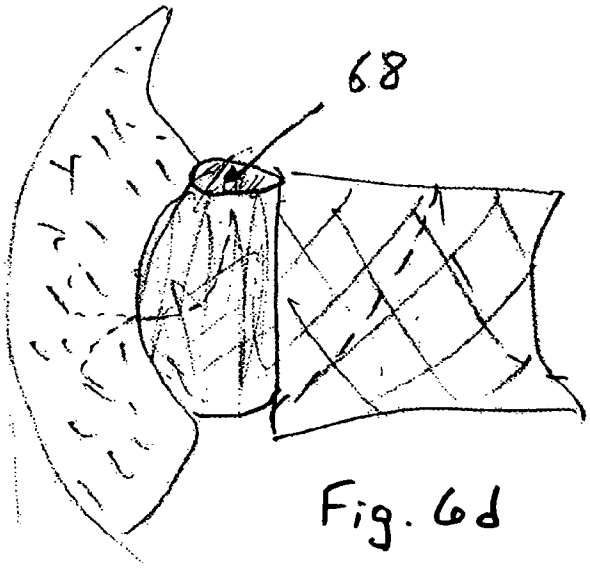



Fig. 6d

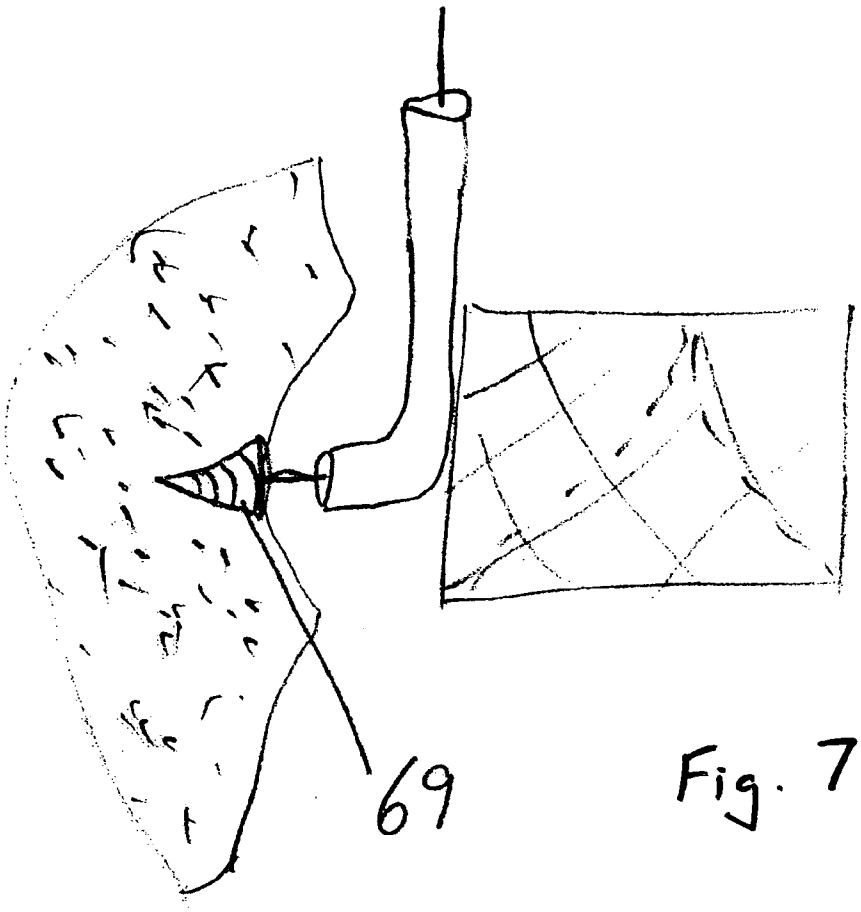



Fig. 7

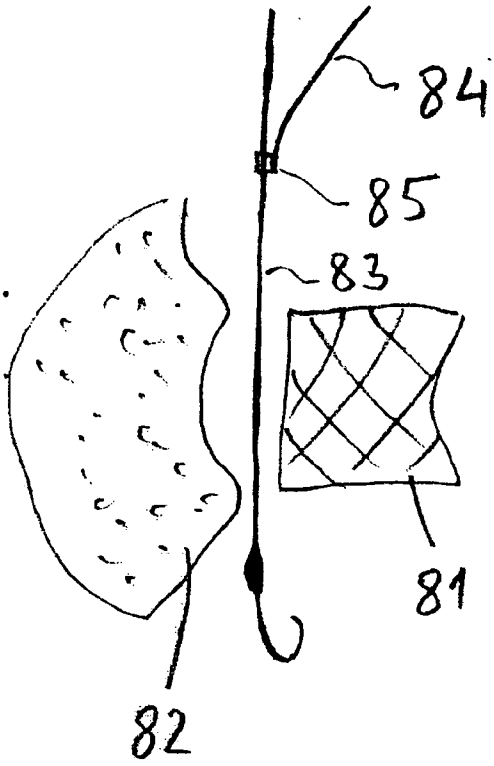



Fig. 8a

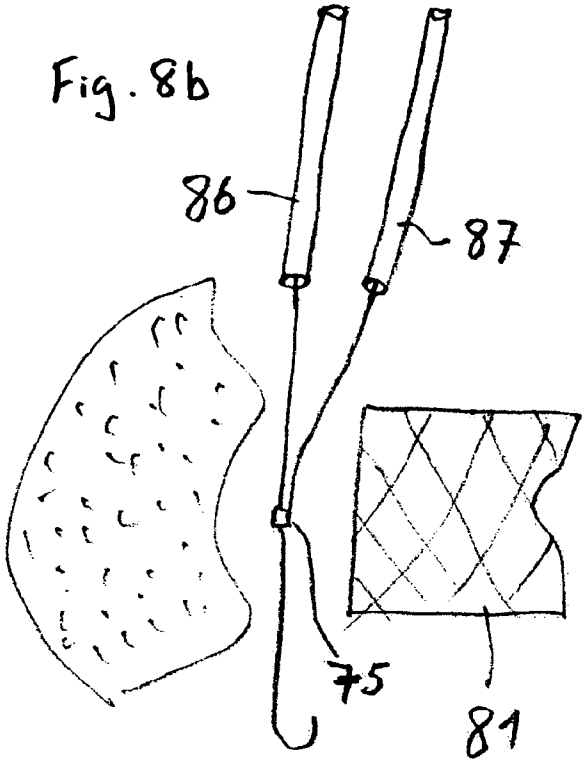



Fig. 8b

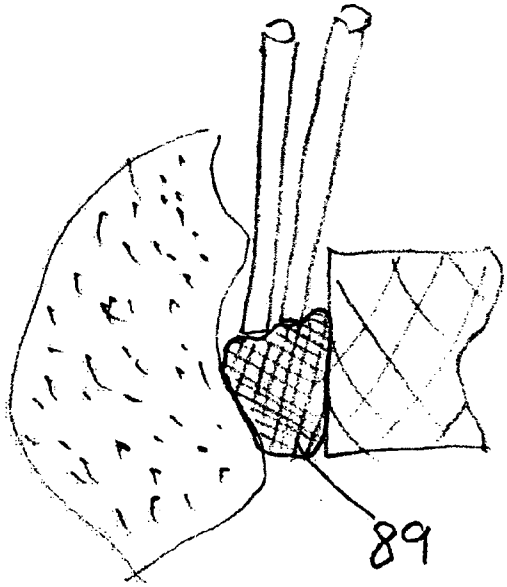



Fig. 8c

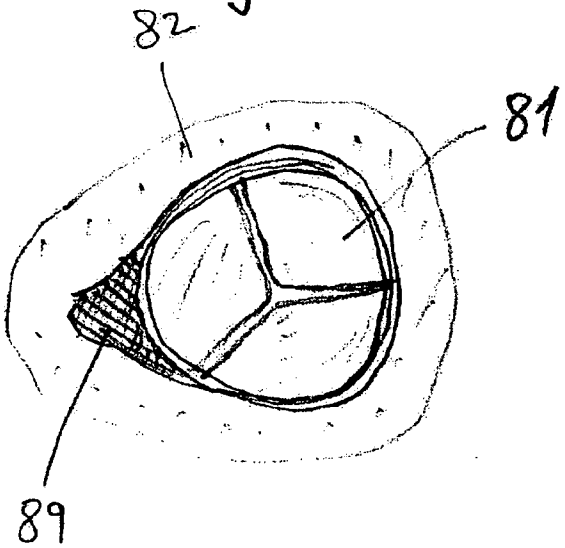



Fig. 8d

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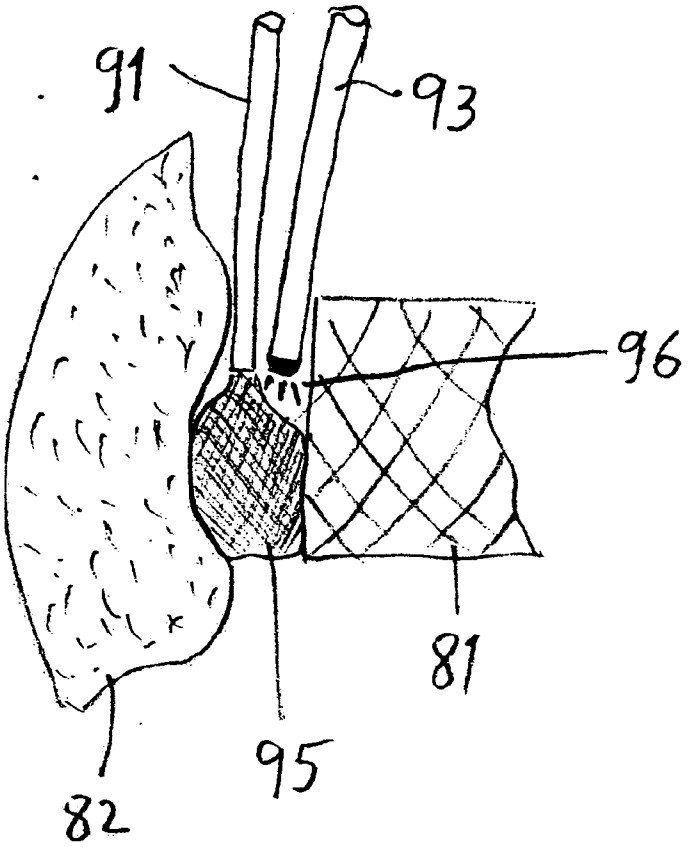


Fig. 9

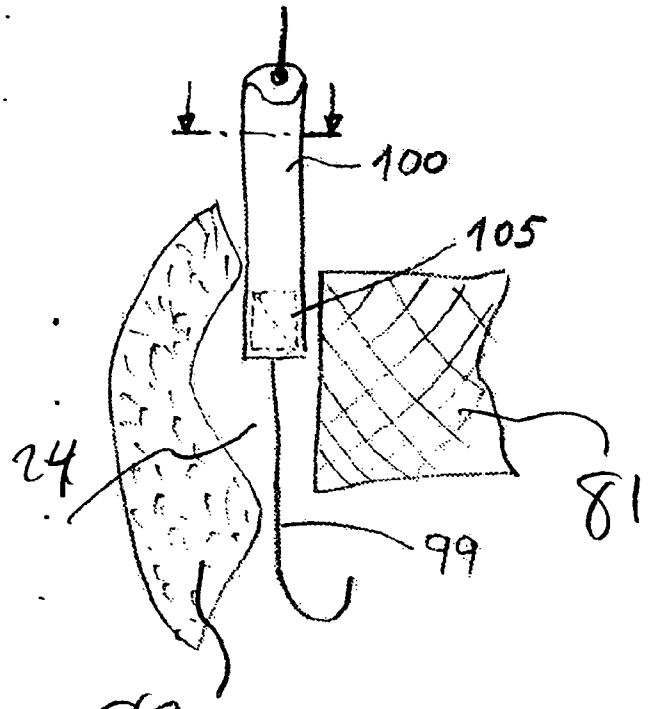


Fig. 10a

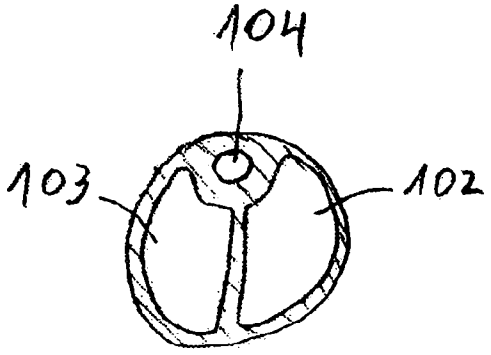


Fig. 10b

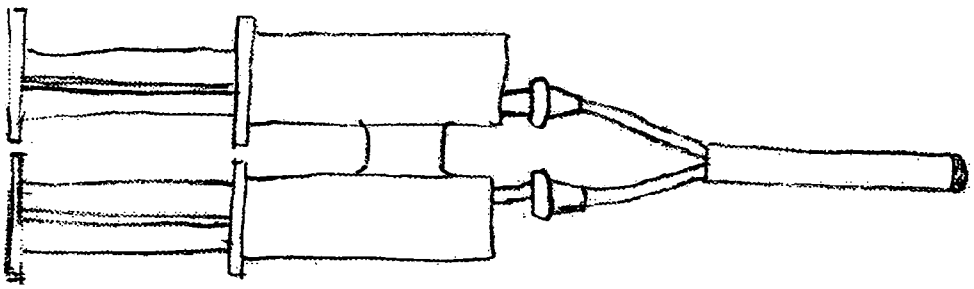

Fig. 10c

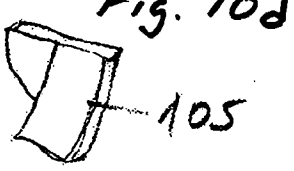


Fig. 10d

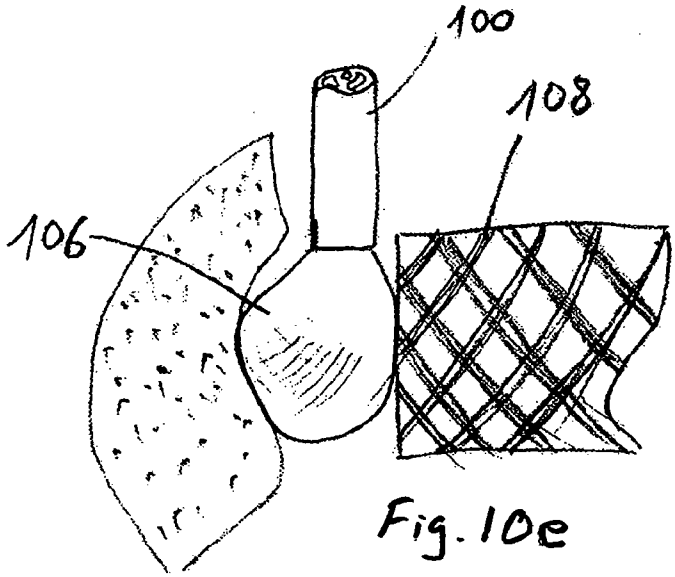


Fig. 10e

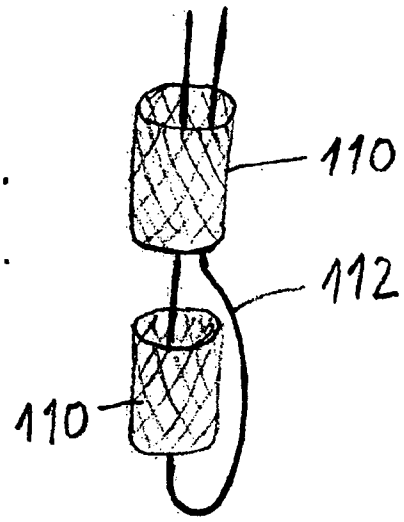


Fig. 11a

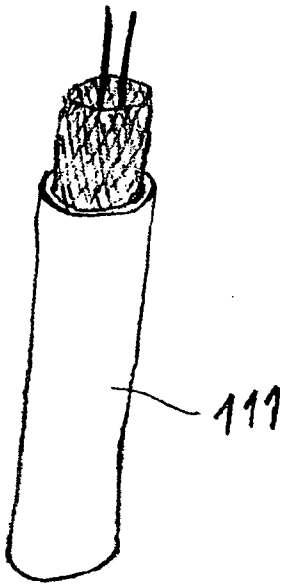


Fig. 11b

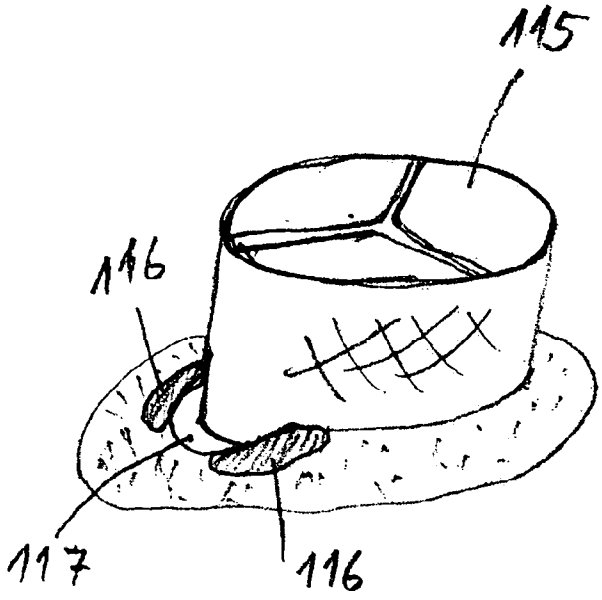


Fig. 11c

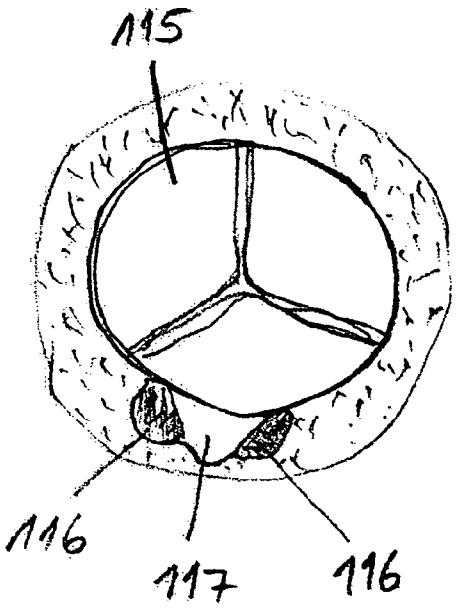


Fig. 11d

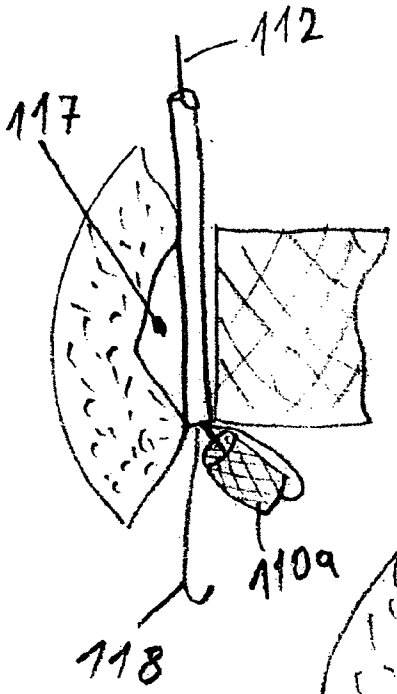


Fig. 11e

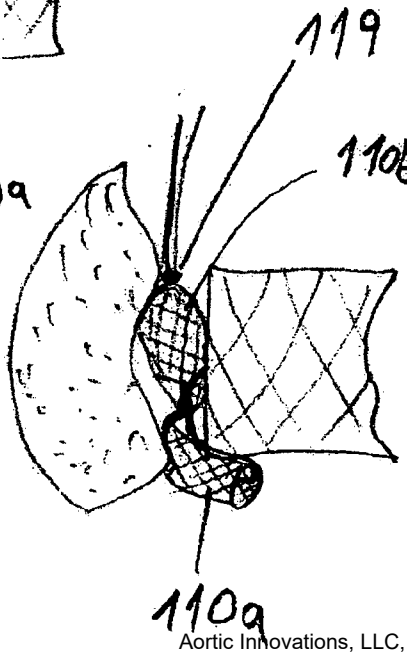


Fig. 11f

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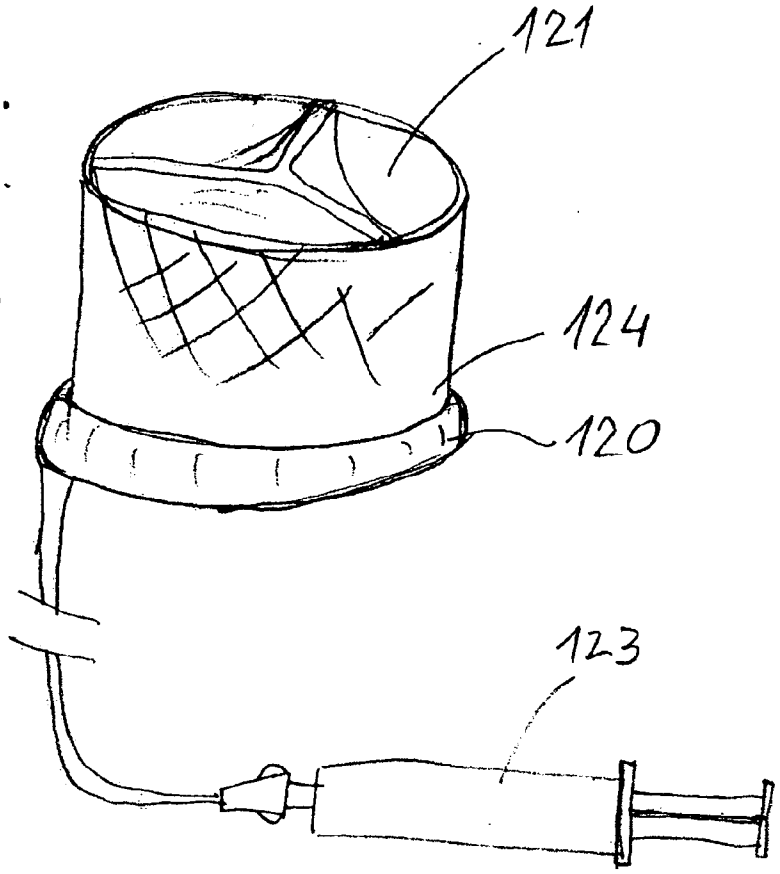


Fig. 12

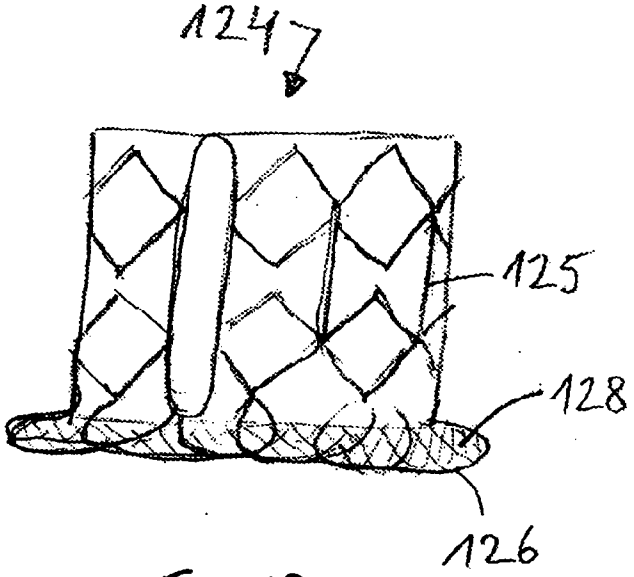


Fig. 13a

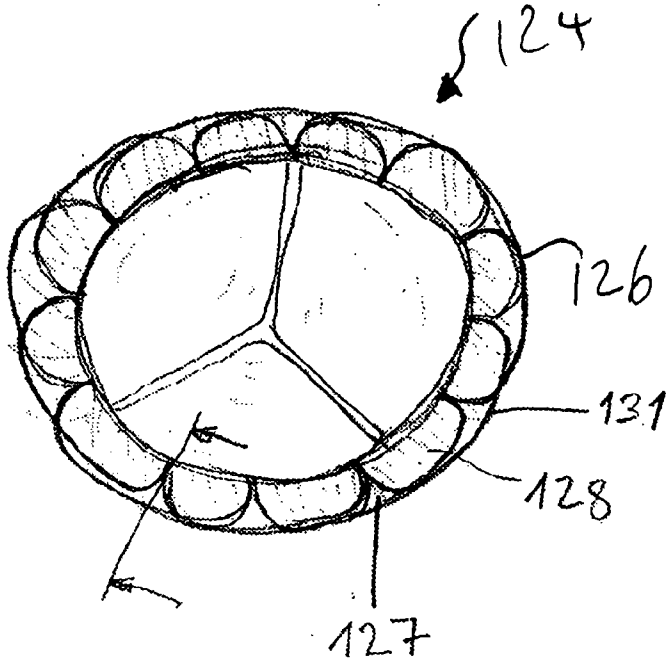


Fig. 13b

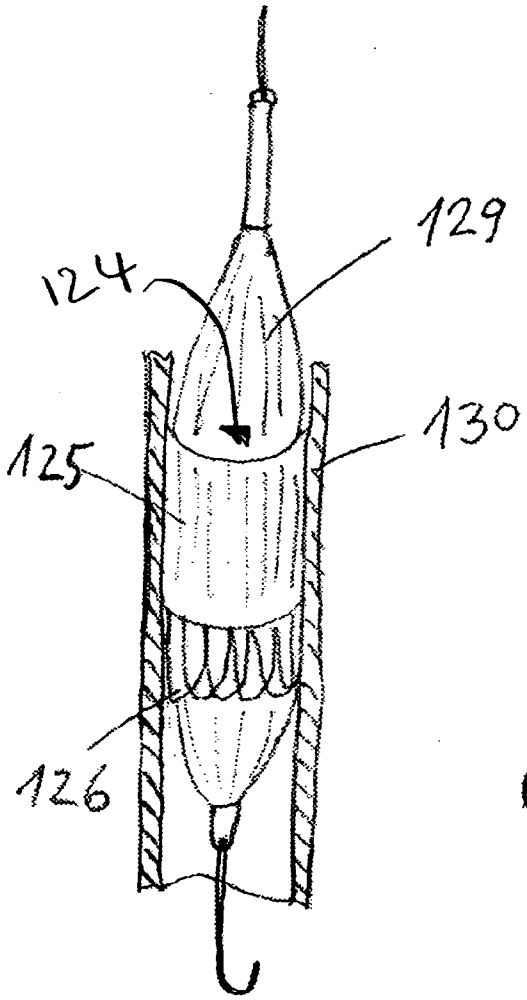


Fig. 13c

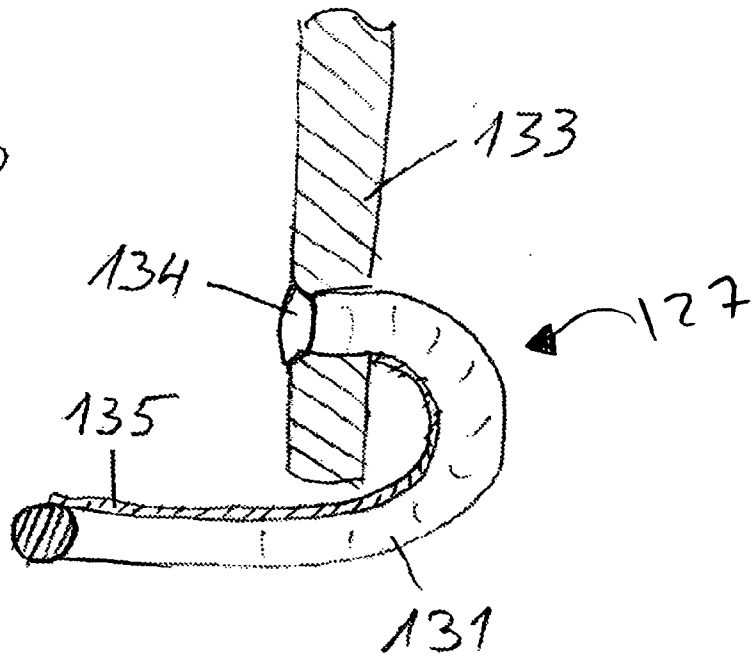


Fig. 13d

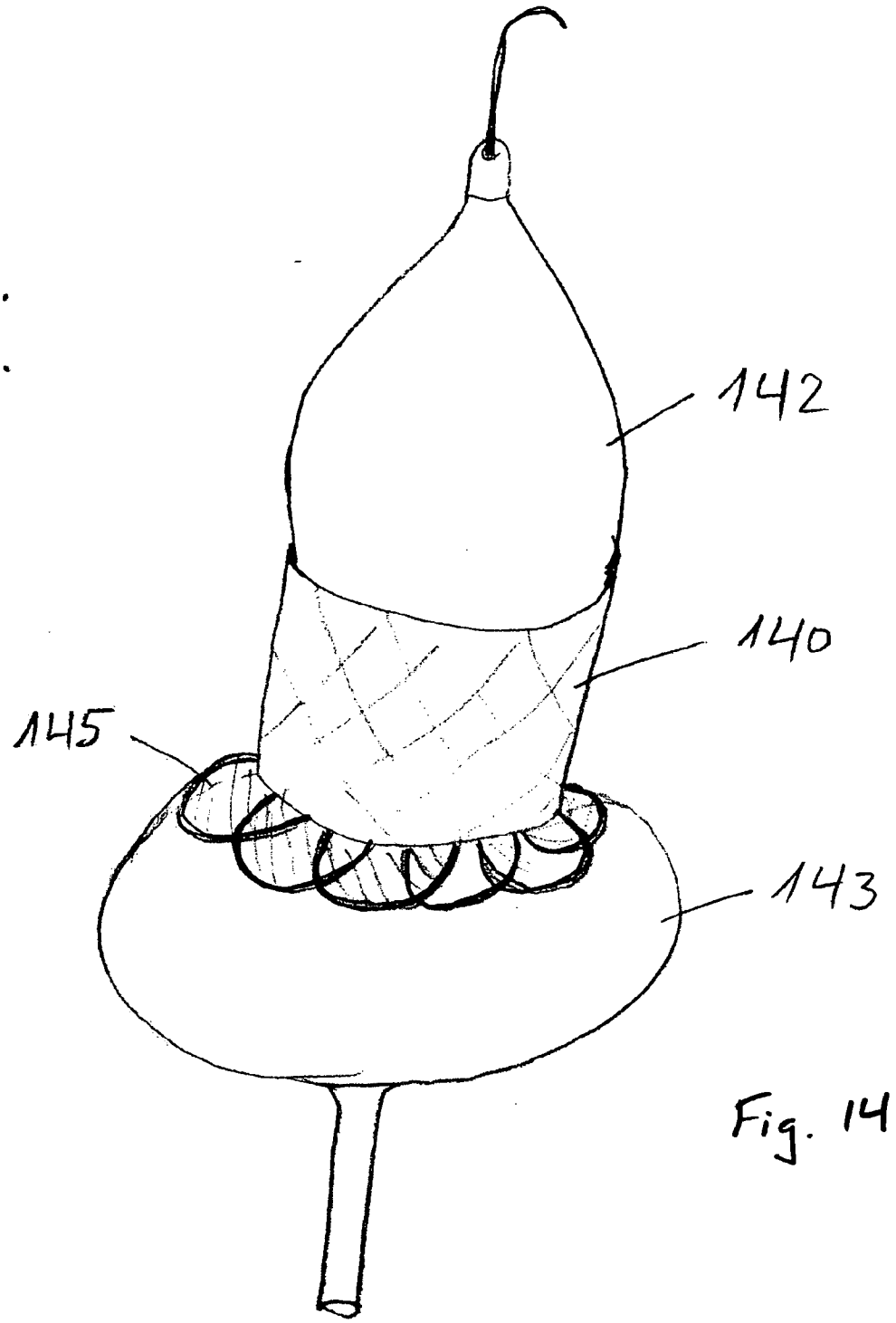


Fig. 14

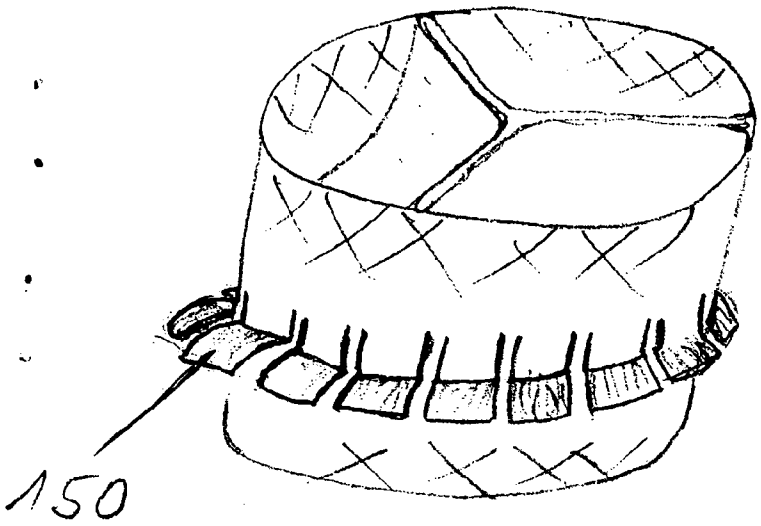


Fig. 15a

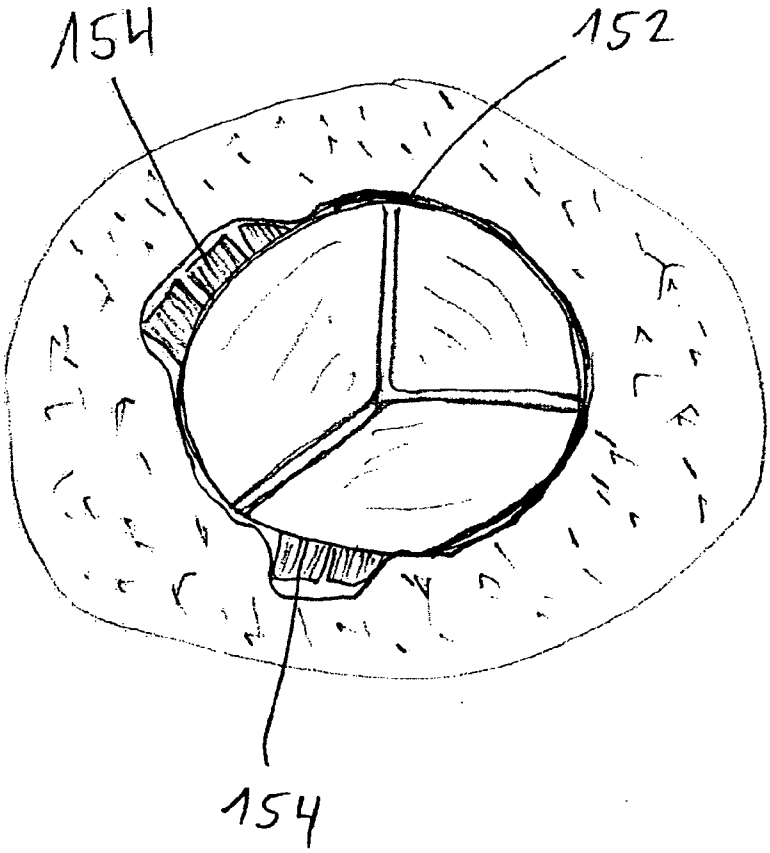


Fig. 15b

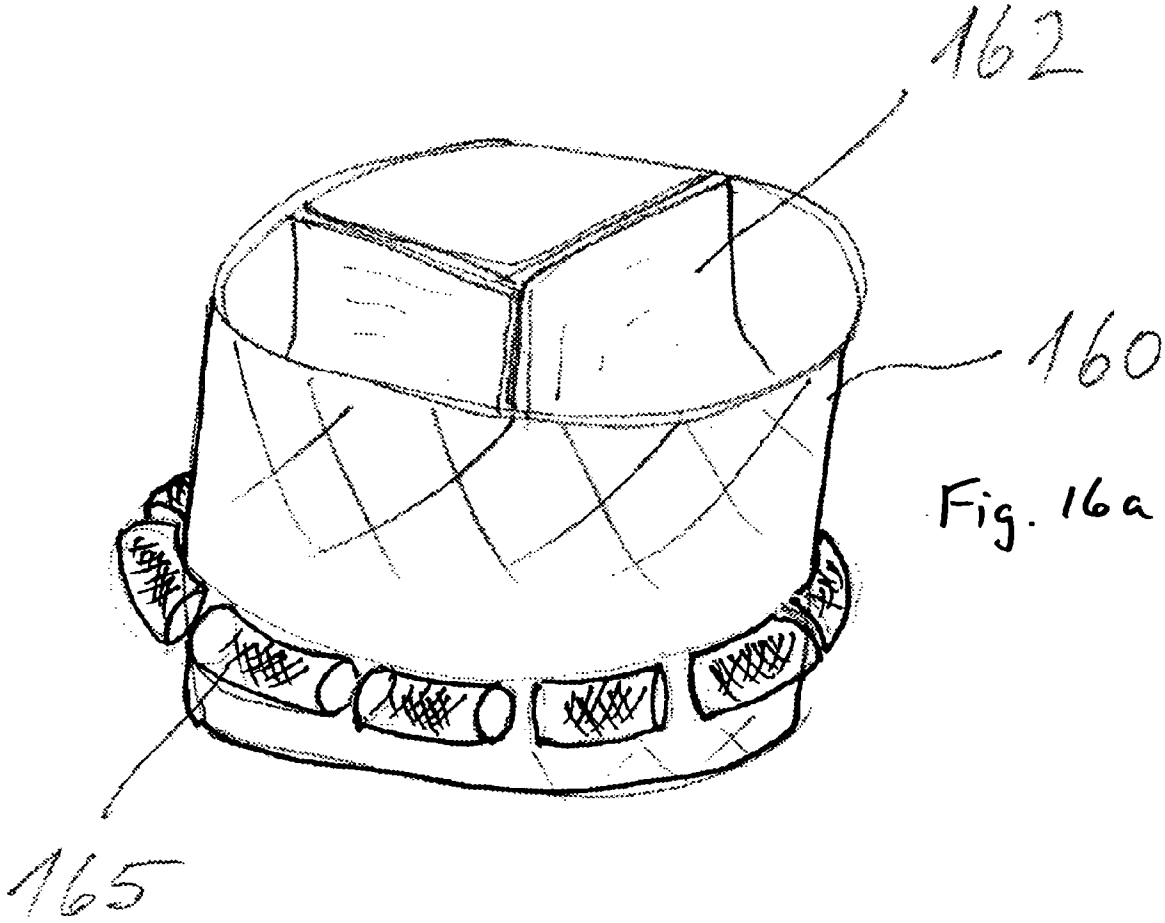


Fig. 16a

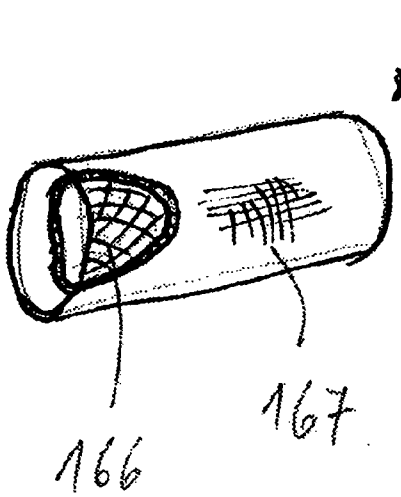


Fig. 16b

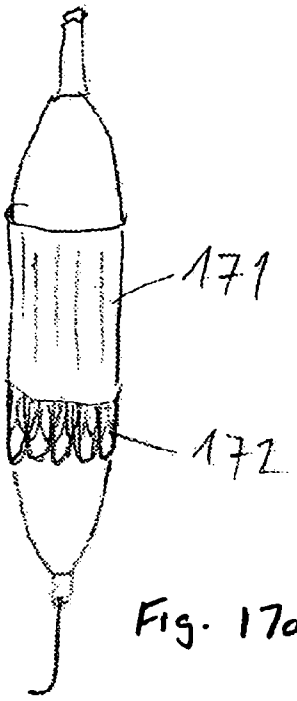


Fig. 17a

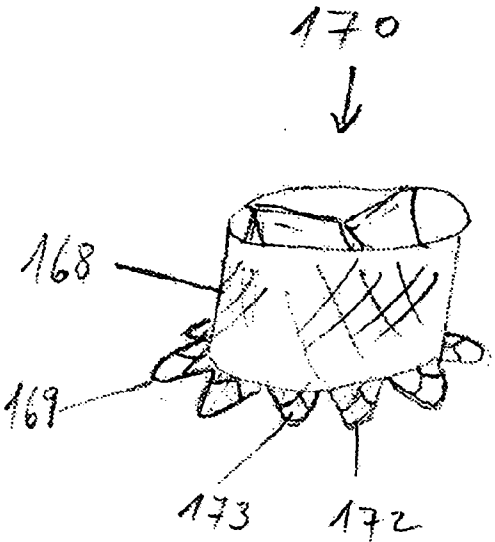


Fig. 17b

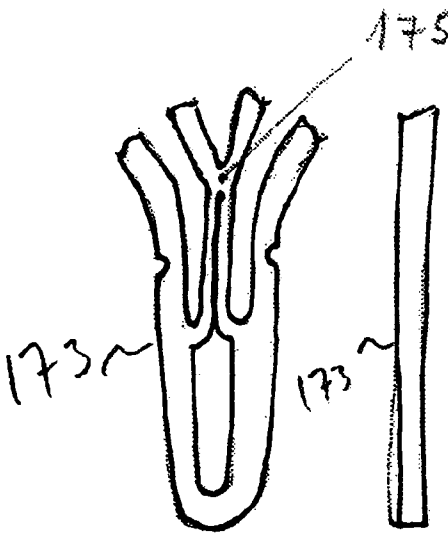


Fig. 17c

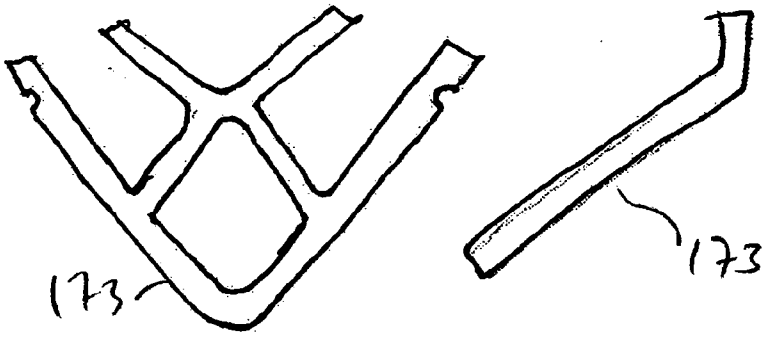


Fig. 17d

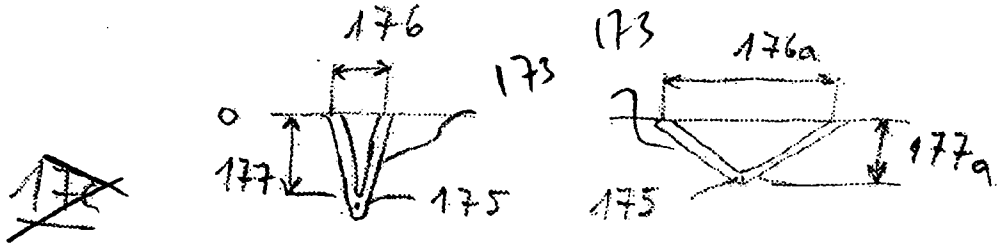


Fig. 17e

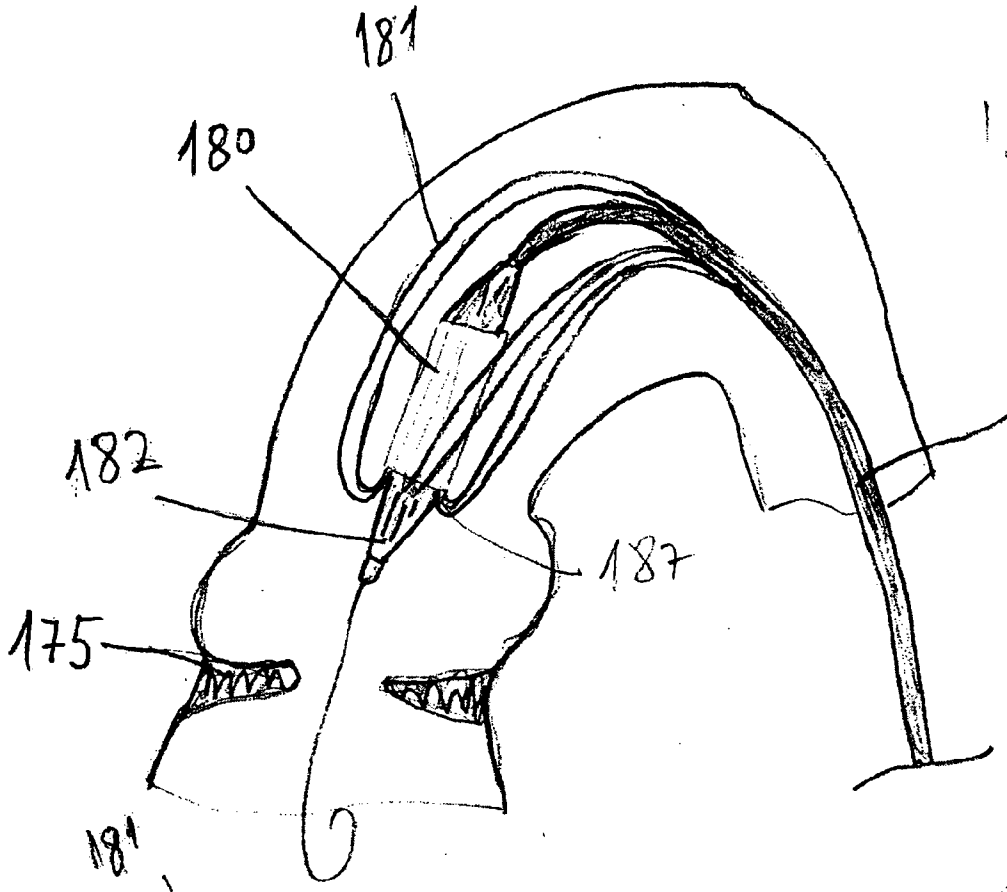


Fig. 18a

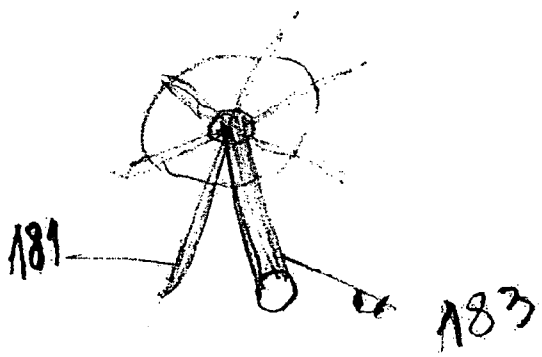


Fig. 18b

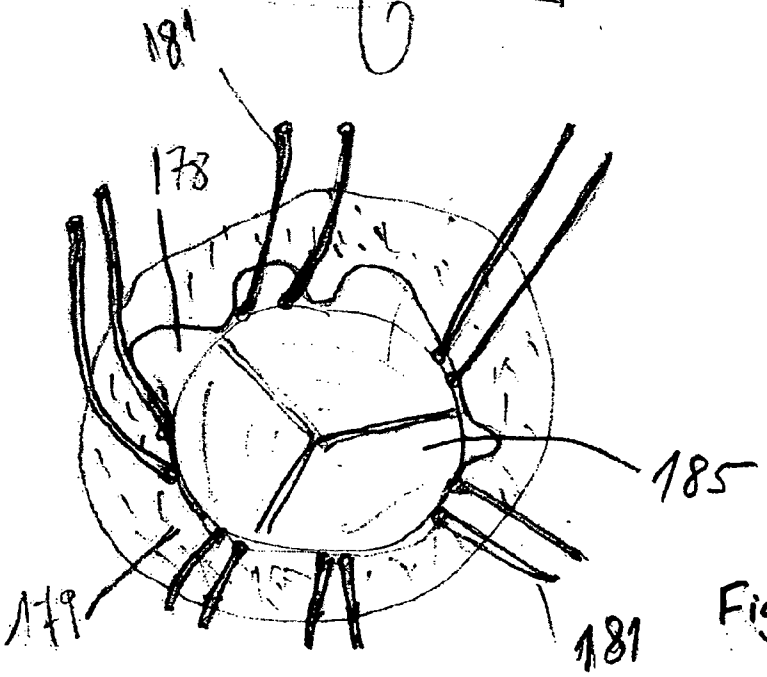


Fig. 18c

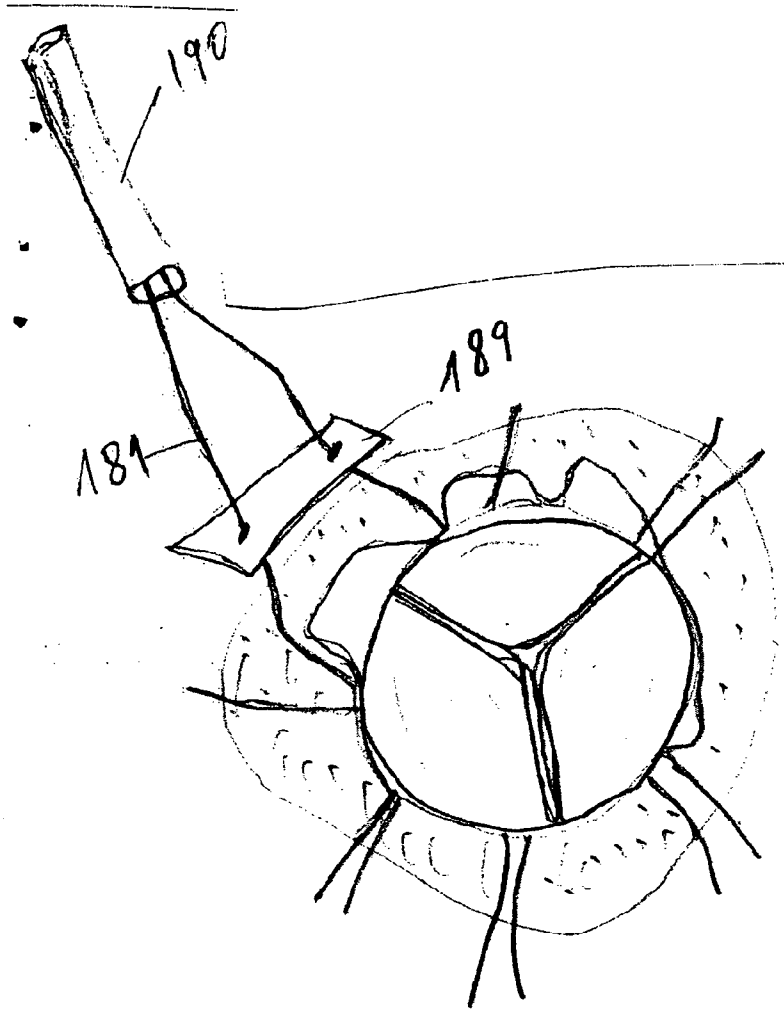


Fig. 18d

Fig. 18e

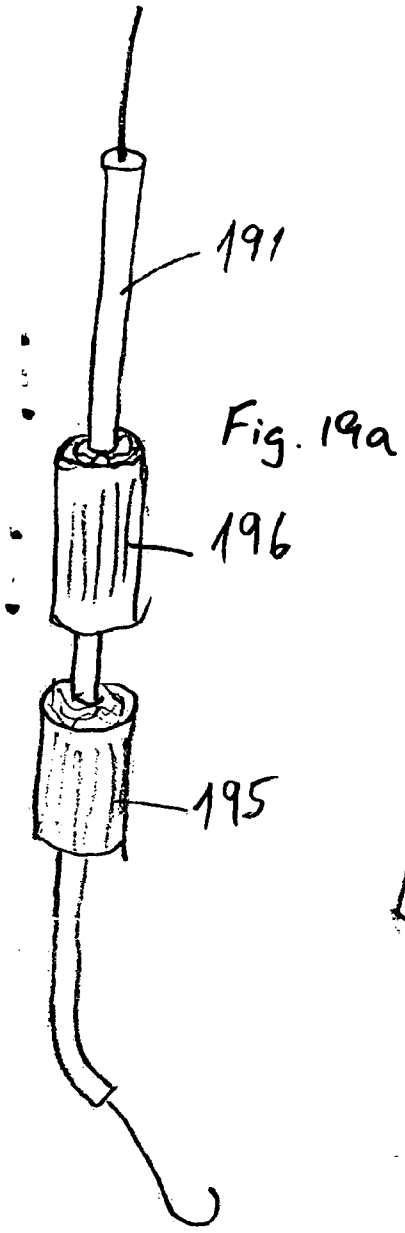


Fig. 19a

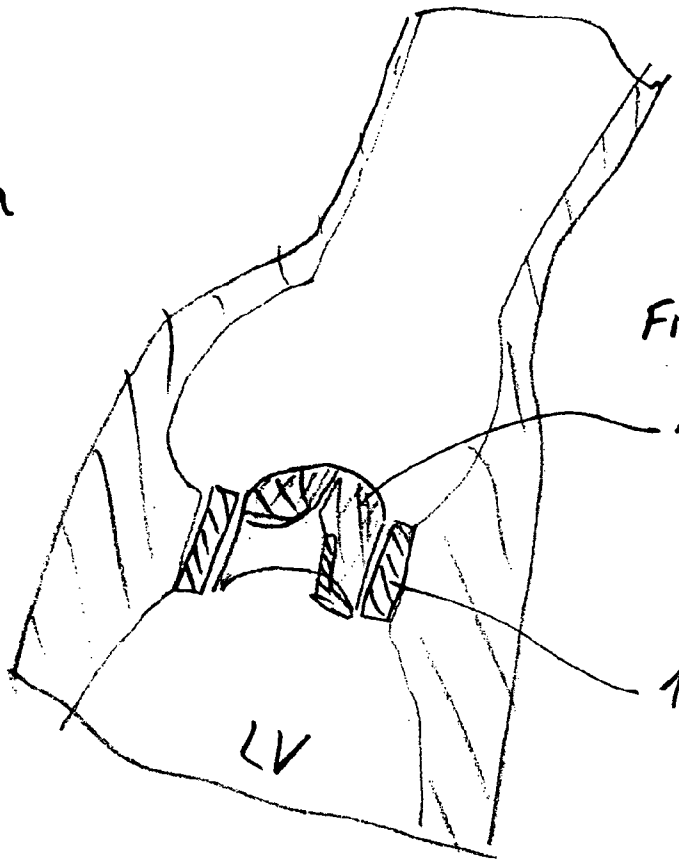


Fig. 19b

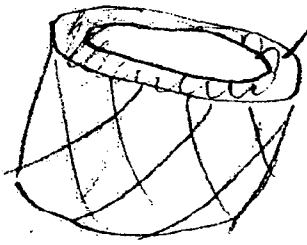


Fig. 19c

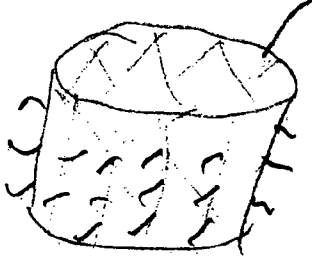


Fig. 19d

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# DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing **OR** ☑ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

| | |
|---|---|
| Attorney Docket Number | 501015.20517 |
| First Named Inventor | Benjamin Spenser |
| *COMPLETE IF KNOWN* | |
| Application Number | To Be Assigned |
| Filing Date | June 30, 2004, herewith |
| Art Unit | |
| Examiner Name | |

**I hereby declare that:**

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

*(Title of the Invention)*

the specification of which

☑ is attached hereto

***OR***

☐ was filed on (MM/DD/YYYY) _____ as United States Application Number or PCT International Application Number _____ and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed | Certified Copy Attached? Yes | No |
|---|---|---|---|---|---|
| | | | ☐ | ☐ | ☐ |
| | | | ☐ | ☐ | ☐ |
| | | | ☐ | ☐ | ☐ |
| | | | ☐ | ☐ | ☐ |

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.



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# DECLARATION — Utility or Design Patent Application

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| Direct all correspondence to: ☑ Customer Number: 30452 | | *OR* ☐ Correspondence address below | |
| Name: Christopher James | | | |
| Address: Edwards Lifesciences LLC<br>One Edwards Way | | | |
| City: Irvine | State: CA | ZIP: 92614 | |
| Country: US | Telephone: 949-250-6878 | Fax: 949-250-6850 | |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**NAME OF SOLE OR FIRST INVENTOR:** ☐ A petition has been filed for this unsigned inventor

| | | | |
|---|---|---|---|
| Given Name (first and middle [if any]): Benjamin | | Family Name or Surname: Spenser | |
| Inventor's Signature | | Date | |
| Residence: City: Caesarea | State: | Country: IL | Citizenship: IL |
| Mailing Address: Havazelet st. 6 | | | |
| City: Caesarea | State: | ZIP: 38900 | Country: IL |

**NAME OF SECOND INVENTOR:** ☐ A petition has been filed for this unsigned inventor

| | | | |
|---|---|---|---|
| Given Name (first and middle [if any]): Netanel | | Family Name or Surname: Benichou | |
| Inventor's Signature | | Date | |
| Residence: City: Hof-Carmel | State: | Country: IL | Citizenship: IL |
| Mailing Address: Nir Etzion D.N. | | | |
| City: Hof-Carmel | State: | ZIP: 30808 | Country: IL |

☑ Additional inventors or a legal representative are being named on the _____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

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# DECLARATION

## ADDITIONAL INVENTOR(S)
**Supplemental Sheet**



| | | | |
|---|---|---|---|
| **Name of Additional Joint Inventor, if any:** | ☐ A petition has been filed for this unsigned inventor | | |
| Given Name (first and middle (if any)) | Family Name or Surname | | |
| Assaf | Bash | | |
| Inventor's Signature | | | Date |
| Residence: City: Givat Ada | State | Country: IL | Citizenship: IL |
| Mailing Address: 1 Haseora St | | | |
| Mailing Address | | | |
| City: Givat Ada | State | Zip: 37808 | Country: IL |

| | | | |
|---|---|---|---|
| **Name of Additional Joint Inventor, if any:** | ☐ A petition has been filed for this unsigned inventor | | |
| Given Name (first and middle (if any)) | Family Name or Surname | | |
| | | | |
| Inventor's Signature | Date | | |
| Residence: City | State | Country | Citizenship |
| Mailing Address | | | |
| Mailing Address | | | |
| City | State | Zip | Country |

| | | | |
|---|---|---|---|
| **Name of Additional Joint Inventor, if any:** | ☐ A petition has been filed for this unsigned inventor | | |
| Given Name (first and middle (if any)) | Family Name or Surname | | |
| | | | |
| Inventor's Signature | Date | | |
| Residence: City | State | Country | Citizenship |
| Mailing Address | | | |
| Mailing Address | | | |
| City | State | Zip | Country |

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| **Application Number** | To Be Assigned |
| **Filing Date** | June 30, 2004, herewith |
| **First Named Inventor** | Benjamin Spenser |
| **Title** | Paravalvular Leak Detection, ... |
| **Art Unit** | |
| **Examiner Name** | |
| **Attorney Docket Number** | 501015.20517 |

I hereby appoint:

☑ Practitioners associated with the Customer Number: 30452

*OR*

☐ Practitioner(s) named below:

| Name | Registration Number |
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as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

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*OR*

| | | | | | |
|---|---|---|---|---|---|
| ☐ Firm or Individual Name | Christopher James | | | | |
| Address | Edwards Lifesciences LLC | | | | |
| Address | One Edwards Way | | | | |
| City | Irvine | State | CA | Zip | 92614 |
| Country | US | | | | |
| Telephone | 949-250-6878 | Fax | 949-250-6850 | | |

I am the:

☑ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
*Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)*

**SIGNATURE of Applicant or Assignee of Record**

| | | | |
|---|---|---|---|
| Name | Benjamin Spenser | | |
| Signature | | | |
| Date | | Telephone | |

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

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| **First Named Inventor** | Benjamin Spenser |
| **Title** | Paravalvular Leak Detection, ... |
| **Art Unit** | |
| **Examiner Name** | |
| **Attorney Docket Number** | 501015.20517 |

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| | | | | | |
|---|---|---|---|---|---|
| ☐ Firm or Individual Name | Christopher James | | | | |
| Address | Edwards Lifesciences LLC | | | | |
| Address | One Edwards Way | | | | |
| City | Irvine | State | CA | Zip | 92614 |
| Country | US | | | | |
| Telephone | 949-250-6878 | Fax | 949-250-6850 | | |

I am the:

☑ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
*Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)*

**SIGNATURE of Applicant or Assignee of Record**

| | | | |
|---|---|---|---|
| Name | Netanel Benichou | | |
| Signature | | | |
| Date | | Telephone | |

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| **Application Number** | To Be Assigned |
| **Filing Date** | June 30, 2004, herewith |
| **First Named Inventor** | Benjamin Spenser |
| **Title** | Paravalvular Leak Detection, ... |
| **Art Unit** | |
| **Examiner Name** | |
| **Attorney Docket Number** | 501015.20517 |

I hereby appoint:

☑ Practitioners associated with the Customer Number: 30452

*OR*

☐ Practitioner(s) named below:

| Name | Registration Number |
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as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

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☐ The address associated with Customer Number: 30452

*OR*

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|---|---|---|---|---|---|
| ☐ Firm or Individual Name | Christopher James | | | | |
| Address | Edwards Lifesciences LLC | | | | |
| Address | One Edwards Way | | | | |
| City | Irvine | State | CA | Zip | 92614 |
| Country | US | | | | |
| Telephone | 949-250-6878 | Fax | 949-250-6850 | | |

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☑ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
*Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)*

**SIGNATURE of Applicant or Assignee of Record**

| | | | |
|---|---|---|---|
| Name | Assaf Bash | | |
| Signature | | | |
| Date | | Telephone | |

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Date
02.03.2021

| Reference | Application No./Patent No. |
|---|---|
| P/14624EPWD1:RK | 15180327.7 - 1122 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Change to bibliographic data after the decision to grant / after the decision to maintain the patent in amended form**

The change you requested has been registered.

☒ It will be published in European Patent Bulletin No. 2021/12 of 24.03.2021 (Section II.12).

☐ A corrigendum of the title page of the European patent specification will be published in due course. The publication will be announced in the European Patent Register and a note concerning the correction will be published in Section III.3 of the European Patent Bulletin.

The corrigendum can be downloaded free of charge from the EPO's publication server https://data.epo.org/publication-server or ordered from the EPO's Vienna sub-office on payment of a fee.

**For the Examining Division / Opposition Division**

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Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1922
NK51373
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Europäisches Patentamt
European Patent Office
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# Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

| | |
|---|---|
| Submission number | 9514211 |
| Application number | EP15180327.7 |
| Date of receipt | 18 February 2021 |
| Receiving Office | European Patent Office, The Hague |
| Your reference | P/14624EPWD1:PE |
| Applicant | All applicants as on file |
| Documents submitted | package-data.xml<br>epf1038.pdf (1 p.)<br>ep-sfd-request.xml<br>CDAPPR-CHOA-1.pdf\21.02.12 - EPO.pdf (1 p.) |
| Submitted by | CN=Philippa Eke 7284 |
| Method of submission | Online |
| Date and time receipt generated | 18 February 2021, 11:33 (CET) |
| Message Digest | 06:88:E6:28:82:A1:A7:E7:AB:4F:97:2F:43:6F:25:DC:07:0F:C3:99 |

/European Patent Office/

Europäisches Patentamt
European Patent Office
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# Letter accompanying subsequently filed items


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The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

| | |
|---|---|
| Application number | 15180327.7 |
| Applicant's or representative's reference | P/14624EPWD1:PE |

| | Description of document | Original file name | Assigned file name |
|---|---|---|---|
| 1 | Request for change of address | 21.02.12 - EPO.pdf | CDAPPR-CHOA-1.pdf |

| | Payment | |
|---|---|---|
| 1 | Method of payment | Not specified |

**Signatures**

| | |
|---|---|
| Place: | **Watford, UK** |
| Date: | **18 February 2021** |
| Signed by: | **Philippa Eke 7284** |
| Representative name: | **Philippa Dianne EKE** |
| Capacity: | **(Representative)** |




Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1924
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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**BY E-MAIL ONLY**

12 February 2021

**Your Ref:**

**Our Ref:**
P/14624.EPWD1:PE::SD

Dear Sirs

**European Patent Application No. 15180327.7**
**Edwards Lifesciences PVT, Inc.**

Please amend the addresses of the following three inventors designated in this patent.

SPENSER, Mr. Benjamin of 22 Zamir Street, Caesarea, 38900, Israel
BENICHOU, Mr. Netanel of Nir-Etzion D.N, Hof-Carmel, 30808, Israel
BASH, Mr. Assaf of Haseora 1, Givat Ada, 37808, Israel

Yours faithfully

EKE, Philippa Dianne
Authorised Representative



Dolleymores is a trading style of Saunders & Dolleymore LLP, which is a limited liability partnership incorporated with partnership no. OC343684 and registered in England & Wales. Regulated by the Intellectual Property Regulation Board.

**Partners:** J Kensett, S Fitchett, P Eke, V Bennett, C Lewis.

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| Date |
| --- |
| 07.09.20 |

| Reference | Application No./Patent No. |
| --- | --- |
| P/14624EPWD1:RK | 15180327.7 - 1122 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Transmission of the certificate for a European patent pursuant to Rule 74 EPC**

The certificate for a European patent is herewith transmitted.

The European patent specification can be downloaded from the EPO publication server **https://data.epo.org/publication-server/** (see OJ EPO 2005, 126).

Note:
A corrected title page of the European patent specification will be published, if the bibliographic data have been changed after completion of the technical preparations.

**For the Examining Division**

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| Date |
|---|
| 30.07.20 |

| Reference | Application No./Patent No. |
|---|---|
| P/14624EPWD1:RK | 15180327.7 - 1122 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Decision to grant a European patent pursuant to Article 97(1) EPC**

Following examination of European patent application No. 15180327.7 a European patent with the title and the supporting documents indicated in the communication pursuant to Rule 71(3) EPC (EPO Form 2004C) or in the information (EPO Form 2004W, cf. Notice from the EPO dated 8 June 2015, OJ EPO 2015, A52) dated 26.03.20 is hereby granted in respect of the designated Contracting States.

Patent No. : 2982337
Date of filing : 30.06.05
Priority claimed : 30.06.04/USA 883575

Designated Contracting States and Proprietor(s) : AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR
Edwards Lifesciences PVT, Inc.
One Edwards Way
Irvine, CA 92614/US

This decision will take effect on the date on which the European Patent Bulletin mentions the grant (Art. 97(3) EPC).

The mention of the grant will be published in European Patent Bulletin 20/35 of 26.08.20.

Examining Division

Steiner, Bronwen Enborg, Andreas Franz, Volker

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**Registered letter**
EPO Form 2006A 07.15 (23/07/20)

to EPO postal service: 24.07.20



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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

ANMERKUNG ZUR ENTSCHEIDUNG ÜBER DIE ERTEILUNG
EINES EUROPÄISCHEN PATENTS (EPA Form 2006)

1. **EPA Informationsbroschüre "Nationales Recht zum EPÜ"**
Diese Broschüre enthält nützliche Informationen zu den formalen Erfordernissen und den Handlungen, die vor den Patentbehörden der Vertragsstaaten vorzunehmen sind, um Rechte in diesen Staaten zu erlangen. Da diese Handlungen einem ständigen Wandel unterworfen sind, sollte immer nur die neueste Ausgabe der Broschüre benutzt werden. Nachträgliche Informationen werden im Amtsblatt veröffentlicht.

2. **Übersetzung der europäischen Patentschrift nach Artikel 65 (1) des Europäischen Patentübereinkommens**
Sie werden erneut darauf hingewiesen, dass bestimmte Vertragsstaaten nach Artikel 65 (1) EPÜ eine Übersetzung der europäischen Patentschrift verlangen; hierauf wird in der Mitteilung gemäß Regel 71 (5) EPÜ verwiesen. Die Nichteinreichung dieser Übersetzung kann zur Folge haben, dass das Patent in dem betreffenden Staat/in den betreffenden Staaten als von Anfang an nicht eingetreten gilt. Weitere Einzelheiten entnehmen Sie bitte der oben genannten Broschüre.

3. **Zahlung von Jahresgebühren für europäische Patente**
Nach Artikel 141 EPÜ können "nationale" Jahresgebühren für das europäische Patent für die Jahre erhoben werden, die an das Jahr anschließen, in dem der Hinweis auf die Erteilung des europäischen Patents im "Europäischen Patentblatt" bekanntgemacht wird. Weitere Einzelheiten entnehmen Sie bitte der oben genannten Broschüre.

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NOTE RELATING TO THE DECISION TO GRANT A
EUROPEAN PATENT (EPO Form 2006)

1. **EPO Information Brochure "National law relating to the EPC"**
This brochure provides useful information regarding formal requirements and the steps to be taken before the patent authorities of the Contracting States in order to acquire rights in those states. Since the necessary steps are subject to change the latest edition of the brochure should always be used. Subsequent information is published in the Official Journal.

2. **Translation of the European patent application under Article 65(1) of the European Patent Convention**
Your attention is again drawn to the requirements regarding translation of the European patent specification laid down by a number of Contracting States under Article 65(1) EPC, to which reference is made in the communication under Rule 71(5) EPC. Failure to supply such translation(s) may result in the patent being deemed to be void "ab initio" in the State(s) in question. For further details you are recommended to consult the above-mentioned brochure.

3. **Payment of renewal fees for European patents**
Under Article 141 EPC "national" renewal fees in respect of a European patent may be imposed for the years which follow that in which the mention of the grant of the European patent is published in the "European Patent Bulletin". For further details you are recommended to consult the above-mentioned brochure.

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REMARQUE RELATIVE A LA DECISION DE DELIVRANCE
D'UN BREVET EUROPEEN (OEB Form 2006)

1. **Brochure d'information de l'OEB "Droit national relatif à la CBE"**
Cette brochure fournit d'utiles renseignements sur les conditions de forme requises et sur les actes à accomplir auprès des offices de brevet des Etats contractants aux fins d'obtenir des droits dans les Etats contractants. Etant donné que les actes indispensables sont susceptibles de modifications, il serait bon de toujours consulter la dernière édition de la brochure. Toute information ultérieure est publiée au Journal Officiel.

2. **Traduction du fascicule du brevet européen en vertu de l'article 65(1) de la Convention sur le brevet européen**
Votre attention est de nouveau attirée sur l'obligation faite par certains États contractants, en vertu de l'article 65(1) CBE, de fournir une traduction du fascicule du brevet européen, à laquelle il est fait référence dans la notification établie conformément à la règle 71(5) CBE. Si la(les) traduction(s) n'est(ne sont) pas fournie(s), le brevet européen peut, dès l'origine, être réputé sans effet dans cet(ces) Etat(s). Pour plus de détails, nous vous renvoyons à la brochure susmentionnée.

3. **Paiement des taxes annuelles pour le brevet européen**
Conformément à l'article 141 CBE des taxes annuelles "nationales" dues au titre du brevet européen peuvent être perçues pour les années suivant celle au cours de laquelle la mention de la délivrance du brevet européen est publiée au "Bulletin européen des brevets. Pour plus de détails, nous vous renvoyons à la brochure susmentionnée.

Europäisches Patentamt
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Office européen des brevets

# Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

| | |
|---|---|
| Submission number | 8844170 |
| Application number | EP15180327.7 |
| Date of receipt | 21 July 2020 |
| Receiving Office | European Patent Office, The Hague |
| Your reference | P/14624.EPWD1:PE |
| Applicant | All applicants as on file |
| Documents submitted | package-data.xml<br>epf1038.pdf (2 p.)<br>CLMSTRAN-FR-1.pdf\French Claims.pdf (2 p.)<br>ep-sfd-request.xml<br>IGRA-1.pdf\20.07.21 - EPO.pdf (1 p.)<br>CLMSTRAN-DE-1.pdf\German Claims.pdf (2 p.) |
| Submitted by | CN=John Kensett 2118 |
| Method of submission | Online |
| Date and time receipt generated | 21 July 2020, 15:17 (CEST) |
| Message Digest | 8E:33:AD:9E:48:FF:92:C4:B1:49:F4:F8:31:7B:48:A2:F3:D6:E6:A7 |

**Correction by the EPO of errors in debit instructions filed by eOLF**
Errors in debit instructions filed by eOLF that are caused by the editing of Form 1038E entries or the continued use of outdated software (all forms) may be corrected automatically by the EPO, leaving the payment date unchanged (see decision T 152/82, OJ EPO 1984, 301 and point 6.3 ff ADA, Supplement to OJ EPO 10/2007).

/European Patent Office/


Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1999
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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**E-FILING ONLY**

21 July 2020

**Our Ref:**
P/14624.EPWD1:PE:MT

Dear Sirs

**European Application No 15180327.7**
**Publication No 2982337**
**In the Name of: Edwards Lifesciences PVT, Inc.**

In response to the Communication pursuant to Rule 71(3) EPC, I confirm that the necessary fees have been paid and now enclose herewith the translation of the claims in the two official languages of the European Patent Office other than the language of the proceedings.

Yours faithfully

[signed electronically]

KENSETT, John Hinton
Authorised Representative

Enc Translation of claims



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**Partners:** J Kensett, S Fitchett, P Eke, V Bennett, R Knights, C Lewis.

peptrans | MT
Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1930
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

**Revendications**

1. Valve prothétique (250) pour implantation percutanée dans un canal corporel, comprenant :

une structure de stent sensiblement cylindrique (252) configurée pour dilatation radiale ;

une structure valvulaire (254) ayant une admission et une sortie, la structure valvulaire formée d'un matériau pliable attaché à la structure de stent et formant trois feuillets de valve ;

caractérisée par une couche de matériau compressible (256), qui forme une douille disposée le long d'une surface extérieure de la structure de stent et s'étendant entièrement autour de la structure de stent, le matériau compressible étant adapté pour remplir, après le déploiement, les espaces entre la valve prothétique et le canal corporel, où le matériau compressible comprend une pluralité de fibres s'étendant vers l'extérieur de la surface extérieure.

2. Valve prothétique selon la revendication 1, dans laquelle la douille entoure une extrémité de flux d'entrée de la structure de stent.

3. Valve prothétique selon la revendication 1 ou 2, dans laquelle le matériau compressible a une épaisseur allant de 1 à 5 mm.

4. Valve prothétique selon l'une quelconque des revendications précédentes, dans laquelle le matériau compressible comprend une étoffe ou un tissu.

5. Valve prothétique selon l'une quelconque des revendications précédentes, comprenant en outre un facteur de croissance tissulaire disposé le long du matériau compressible.



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6. Valve prothétique selon la revendication 5, dans laquelle le facteur de croissance est appliqué le long de la surface extérieure du matériau compressible ou bien le matériau est imbibé de/ou trempé dans le facteur de croissance avant l'emploi.

7. Valve prothétique selon l'une quelconque des revendications précédentes, dans laquelle les fibres sont droites, recourbées ou crochues.

8. Valve prothétique selon l'une quelconque des revendications précédentes, dans laquelle le matériau compressible est configuré pour se dilater dans les espaces.

9. Valve prothétique selon l'une quelconque des revendications précédentes, dans laquelle le matériau compressible est configuré de telle sorte que lors de l'ouverture du stent la forme du matériau compressible s'ajuste à la forme de la cavité existante entre la valve et la paroi du vaisseau corporel, où la valve est implantée, les cavités produisant des fuites paravalvulaires durant la diastole.



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**Patentansprüche**

1. Klappenprothese (250) für die perkutane Implantation in einen Körperkanal, die Folgendes umfasst:

eine im Wesentlichen zylindrische Stent-Struktur (252), die zur radialen Ausdehnung konfiguriert ist;

eine klappenförmige Struktur (254), die einen Einlass und einen Auslass aufweist, wobei die klappenförmige Struktur aus einem biegsamen Material ausgebildet ist, das an der Stent-Struktur angebracht ist und drei Klappensegel ausbildet;

gekennzeichnet durch eine Schicht aus komprimierbarem Material (256), das eine Hülse ausbildet, die entlang einer äußeren Oberfläche der Stent-Struktur angeordnet ist und sich vollständig um die Stent-Struktur erstreckt, wobei das komprimierbare Material geeignet ist, um nach dem Einsatz Lücken zwischen der Klappenprothese und dem Körperkanal auszufüllen, wobei das komprimierbare Material eine Vielzahl von Fasern einschließt, die sich nach außen von der äußeren Oberfläche erstrecken.

2. Klappenprothese nach Anspruch 1, wobei die Hülse ein Eintrittsende der Stent-Struktur umgibt.

3. Klappenprothese nach Anspruch 1 oder 2, wobei das komprimierbare Material eine Dicke im Bereich von 1 bis 5 mm aufweist.

4. Klappenprothese nach einem vorstehenden Anspruch, wobei das komprimierbare Material ein Tuch oder einen Stoff umfasst.

5. Klappenprothese nach einem vorstehenden Anspruch, die weiter einen Gewebewachstumsfaktor umfasst, der entlang des komprimierbaren Materials angeordnet ist.

6. Klappenprothese nach Anspruch 5, wobei der Wachstumsfaktor entlang der äußeren Oberfläche des komprimierbaren Materials aufgetragen ist oder das Material vor der Verwendung in dem Wachstumsfaktor getränkt oder darin getaucht wird.



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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

7. Klappenprothese nach einem vorstehenden Anspruch, wobei die Fasern gerade, gebogen oder hakenförmig sind.

8. Klappenprothese nach einem der vorstehenden Ansprüche, wobei das komprimierbare Material zur Ausdehnung in die Lücken konfiguriert ist.

9. Klappenprothese nach einem der vorstehenden Ansprüche, wobei das komprimierbare Material derart konfiguriert ist, dass bei Öffnung des Stents sich die Form des komprimierbaren Materials an die Form des Hohlraums anpasst, der zwischen der Klappe und der Wand des Körpergefäßes vorliegt, wo die Klappe implantiert wird, wobei die Hohlräume paravalvuläre Lecks während der Diastole erzeugen.



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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Europäisches Patentamt
European Patent Office
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# Letter accompanying subsequently filed items


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The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

| | |
|---|---|
| Application number | 15180327.7 |
| Applicant's or representative's reference | P/14624.EPWD1:PE |

| | Description of document | Original file name | Assigned file name |
|---|---|---|---|
| 1 | Reply to the communication under rule 71(3) EPC | 20.07.21 - EPO.pdf | IGRA-1.pdf |
| 2 | French translations of the claims | French Claims.pdf | CLMSTRAN-FR-1.pdf |
| 3 | German translations of the claims | German Claims.pdf | CLMSTRAN-DE-1.pdf |

| | Fees | Factor applied | Fee schedule | Amount to be paid |
|---|---|---|---|---|
| 15-1 | 007 Fee for grant and printing (not more than 35 pages) or fee for grant including fee for publication | 1 | 960.00 | 960.00 |
| | **Total:** | | **EUR** | **960.00** |

| | Payment | |
|---|---|---|
| 1 | Method of payment | Debit from deposit account |
| | Currency: | EUR |
| | The European Patent Office is hereby authorised, to debit from the deposit account with the EPO any fees and costs indicated on the fees page. | |
| | Deposit account number: | 28050140 |
| | Account holder: | Dolleymores |
| 2 | Refund/Reimburserment | |
| | Reimbursement (if any) to be made to EPO deposit account: | 28050140 |
| | Account holder: | Dolleymores |

**Signatures**

Place: **Watford**

Date: **21 July 2020**

Signed by: **John Kensett 2118**




Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1935
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

| | |
|---|---|
| Association: | **Dolleymores** |
| Representative name: | **John Hinton Kensett** |
| Capacity: | **(Representative)** |



Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1936
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

1 The European search opinion cited the documents

D1 US 5 258 023 A (REGER VINCENT A [US]) 2 November 1993 (1993-11-02)

D2 FR 2 337 543 A1 (AMERICAN HOSPITAL SUPPLY CORP [US]) 5 August 1977 (1977-08-05)

D3 WO 00/64380 A1 (ST JUDE MEDICAL CARDIOVASCULAR [US]) 2 November 2000 (2000-11-02)

D4 FR 2 815 844 A1 (SEGUIN JACQUES [FR]) 3 May 2002 (2002-05-03)

2 In a communication under Article 94(3) EPC issued by the examining division on 21-07-2017, the examiner cited document

D5 EP 2 537 487 A1 (SADRA MEDICAL INC [US]) 26 December 2012 (2012-12-26)

**Main request**

3 The following features of claim 1 are disclosed in document D3 (references to D3 in parentheses):

A prosthetic valve (figure 1, feature 100) for percutaneous implantation in a body channel, comprising:
a substantially cylindrical stent structure (feature 110) configured for radial expansion (page 6, lines 3 - 15);
a valvular structure (feature 120) 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 (figures 1 and 2; page 5, lines 34 - 36);
characterised by a layer of compressible material, which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after



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deployment to fill gaps between the prosthetic valve and the body channel (page 6, line 34 - page 7, line 10) wherein the compressible material is polyurethane or polyethylene terephthalate (page 7, line 8).

3.1 The applicant argues that a tricuspid valve is not disclosed in D3. Although the figures 1 and 2 are not particularly well drawn, three leaflets are still clearly visible.

3.2 The applicant has also provided extensive arguments as to why the gasket of D3 should not be considered equivalent to a sleeve, including a discussion of the difference between a "band", "ring", "sleeve" and "tube". In the examination division's opinion the gasket of D3 is substantially cylindrical, surrounds the outside of the stent of D3 and "protects against leakage through or round the band" (page 7, lines 5 - 6). There is no upper or lower limit to the height possible for a cylinder or for a sleeve and as neither the device of the application, nor that of D3 have any dimensions specified, they are both considered as being cylinders. Claim 1 does not specify that the cylindrical stent structure will extend beyond the native valve annulus in either direction. Furthermore, the wording "gasket" in D3 does not preclude the device from being a sleeve as the term does not imply any limitations on dimensions. The "gasket" of D3 and the "sleeve" of the claims both function in the same manner, fulfil the same purpose and are even made of the same materials.

3.3 As the applicant's arguments are not convincing and the features of the claim are all disclosed in D3 claim 1 does not fulfil the requirements of Article 52(1) EPC as the claim is not novel (Articles 54(1) and (2) EPC).

4 Claims 9 and 10 do not fulfil the requirements of Article 123(2) EPC.

4.1 The original application only discloses the subject-matter of these two claims as part of a different type of sealing stent. The original application describes "dedicated" sealing means i.e. a device which is inserted into a leaking between a previously implanted prosthetic stent and the native tissue and "integrated" means where a prosthetic valve is surrounded by features which prevent leakage between that valve and the native tissue (see paragraph 86 of the application as originally filed). The features of claim 9 "wherein the stent is comprised of shape memory metal, preferably nitinol" and claim 10 "wherein the stent is held in place in the cavity by friction" are disclosed in paragraphs 98 and 99 of the description. These paragraphs are clearly part of the discussion of the first "dedicated" sealing means (paragraphs 95 - 104 and in fact the term



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"sealing stent" used in these paragraphs is only used for this type of device; the second "integrated" sealing means is discussed in paragraphs 105 - 111 and is referred to as a "self-sealing valve".

4.2 The applicant presented further arguments, stating that the device of figure 22 and paragraphs 144 and 145 is an embodiment of claim 1 and that this device is clearly held in place by friction as there are no other means of holding it in place (such as suture rings or barbs). Whilst the division agrees that this embodiment does not specifically disclose any other attachment means for the valve, it does not also clearly and unambiguously disclose that it is held in place by friction only. Paragraphs 145 discusses tissue ingrowth and the use of fibres extending from the surface of the sleeve to encourage blood coagulation which would tend to teach away from friction being the preferred means of holding the valve in place.

**Auxiliary request 1**

5 The features of claim 1 of auxiliary request 1 are a combination of claims 1 and 10 of the main request. For the reasons given above this claim is not considered to conform with the requirements of Article 123(2) EPC as the features of the stent being configured to be held in place in the cavity by friction is not unambiguously disclosed with the other features of claim 1 in the application as originally filed.



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**Annex to EPO Form 2004, Communication pursuant to Rule 71(3) EPC**

Bibliographical data of European patent application No. 15 180 327.7

For the intended grant of the European patent, the bibliographical data are set out below, for information:

**Title of invention:**
- ERKENNUNG, VERSCHLUSS UND PRÄVENTION VON PARAVALVULÄREN LECKS
- PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION
- DÉTECTION DE FUITE PARAVALVULAIRE, ÉTANCHÉITÉ ET PRÉVENTION

**Classification:** INV. A61F2/24

**Date of filing:** 30.06.2005

**Priority** claimed: US / 30.06.2004 / USA883575

**Contracting States*** for which fees have been paid: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR

**Extension States*** for which fees have been paid:

**Validation States*** for which fees have been paid:

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| | |
|---|---|
| *) | If the time limit for the payment of designation fees according to Rule 39(1) EPC has not yet expired and the applicant has not withdrawn any designation, **all Contracting States/Extension States/Validation States** are currently still deemed to be designated. See also Rule 71a(3) EPC and, if applicable, the above Note to users of the automatic debiting procedure. |
| **) | If two or more applicants have designated different Contracting States, this is indicated here. |

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| Application No. | Ref. | Date |
|---|---|---|
| 15 180 327.7 - 1122 | P/14624EPWD1:RK | 26.03.2020 |
| Applicant: Edwards Lifesciences PVT, Inc. | | |

**Communication under Rule 71(3) EPC**

## 1. Intention to grant

You are informed that the examining division intends to grant a European patent on the basis of the above application, with the text and drawings and the related bibliographic data as indicated below.

A copy of the relevant documents is enclosed.

### 1.1 Auxiliary Request 2

**In the text for the Contracting States:**
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR

**Description, Pages**

| | | |
|---|---|---|
| 1-25 | filed in electronic form on | 06-08-2019 |

**Claims, Numbers**

| | | |
|---|---|---|
| 1-9 | filed in electronic form on | 06-08-2019 |

**Drawings, Sheets**

| | |
|---|---|
| 1/23-23/23 | as originally filed |

See also the comments in enclosed EPO Form 2906.

**Registered letter**
EPO Form 2004C 12.17CXP

## 1.2 Bibliographic data

The title of the invention in the three official languages of the European Patent Office, the international patent classification, the designated contracting states, the registered name(s) of the applicant(s) and the other bibliographic data are shown on **EPO Form 2056** (enclosed).

## 2. Invitation

You are invited, **within a non-extendable period of four months** of notification of this communication,

### 2.1 to EITHER approve the text communicated above and verify the bibliographic data (Rule 71(5) EPC)

(1) by filing a translation of the claim(s) in the other two official languages of the EPO

| | | Fee code | EUR |
|---|---|---|---|
| (2a) | by paying the fee for grant including the fee for publication: | **007** | 925.00 |
| | minus any amount already paid (Rule 71a(5) EPC): | | 0.00 |
| | | Total amount: | 925.00 |
| (3) | by paying additional claims fees under Rule 71(4) EPC; number of claims fees payable: 0 | **016** | 0.00 |
| | minus any amount already paid (Rule 71a(5) EPC): | | 0.00 |
| | | Total amount: | 0.00 |

**Important:** If the translations of the claims and fees have already been filed and paid respectively in reply to a previous communication under Rule 71(3) EPC, e.g. in the case of resumption of examination after approval (see Guidelines C-V, 6), **agreement as to the text to be granted** (Rule 71a(1) EPC) must be expressed within the same time limit (e.g. by approving the text and verifying the bibliographic data, by confirming that grant proceedings can go ahead with the documents on file and/or by stating which translations of the claims already on file are to be used).

Note 1: See "Notes concerning fee payments" below.
Note 2: Any overpaid "minus" amounts will be refunded when the decision to grant (EPO Form 2006A) has been issued.
Note 3: For the calculation of the grant fee under Article 2(2), No. 7, RFees (old fee structure), the number of pages is determined on the basis of a clean copy of the application documents, in which text deleted as a result of any amendments by the examining division is not shown. Such clean copy is made available via on-line file inspection only.

### 2.2 OR, in the case of disapproval, to request reasoned amendments or corrections to the text communicated above or keep to the latest text submitted by you (Rule 71(6) EPC).

In this case the translations of the claims and fee payments mentioned under point 2.1 above are NOT due.

The terms "amendment(s)" and "correction(s)" refer only to amendments or corrections of the application documents and not of other documents (e.g. bibliographic data, the designation of the inventor, etc.).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the examining division requesting that you correct this deficiency (Rule 137(4) EPC).



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**2.3 Bibliographic data**

Where you request a change or correction of bibliographic data in response to the Rule 71(3) communication, this will **not** cause the sending of a further communication under Rule 71(3) EPC. You will still have to pay the fees and file translations in reply to the Rule 71(3) communication in the case of 2.1 above, unless you also file a reasoned request for amendments or corrections in response to the Rule 71(3) communication (see case 2.2 above).

**3. Loss of rights**

If neither of the two possible actions above (see points 2.1 or 2.2) is performed in due time, the European patent application will be deemed to be withdrawn (Rule 71(7) EPC).

**4. Further procedure**

**4.1 In the case of point 2.1 above**

**4.1.1** The decision to grant the European patent will be issued, and the **mention of the grant** of the patent will be published in the European Patent Bulletin, if the requirements concerning the translation of the claims and the payment of all fees are fulfilled and there is agreement as to the text to be granted (Rule 71a(1) EPC).

**Note on payment of the renewal fee:**
If a renewal fee becomes due before the next possible date for publication of the mention of the grant of the European patent, publication will be effected only after the renewal fee and any additional fee have been paid (Rule 71a(4) EPC).

Under Article 86(2) EPC, the obligation to pay renewal fees to the European Patent Office terminates with the payment of the renewal fee due in respect of the year in which the mention of the grant of the European patent is published.

**Note on payment of the designation fee(s):**
If the designation fee(s) become(s) due after the communication under Rule 71(3) EPC, the mention of the grant of the European patent will not be published until these fees have been paid (Rule 71a(3) EPC).

**4.1.2** After publication, the **European patent specification** can be downloaded free of charge from the EPO publication server https://data.epo.org/publication-server.

**4.1.3 Filing of translations in the contracting states**

As regards translation requirements prescribed by the contracting states under Article 65(1) EPC, please consult the website of the European Patent Office
www.epo.org ➞Law & practice ➞Legal texts, National law relating to the EPC
www.epo.org ➞Law & practice ➞All Legal texts ➞London Agreement

**In the case of a valid extension or validation**

As regards translation requirements prescribed by the extension or validation states, please consult the website of the European Patent Office
www.epo.org ➞Law & practice ➞Legal texts, National law relating to the EPC

**Failure to supply a prescribed translation in a contracting state, or in an extension or validation state may result in the patent being deemed to be void *ab initio* in the state concerned (Art. 65(3) EPC).**

**4.2 In the case of 2.2 above**

If the present communication under Rule 71(3) EPC is based on an auxiliary request and, within the time limit, you maintain the main request or a higher ranking request which is not allowable, the application will be refused (Art. 97(2) EPC).

If the examining division gives its consent to the requested amendments or corrections, it will issue a new communication under Rule 71(3) EPC; otherwise, it shall resume the examination proceedings (Rule 71(6) EPC).

## 5. Filing of a divisional application

Any divisional application relating to this European patent application must be filed directly with the European Patent Office in Munich, The Hague or Berlin and will be in the language of the proceedings for the present application, or if the latter was not in an official language of the EPO, the divisional application may be filed in the language of the present application as filed (see Article 76(1) and Rule 36(2) EPC). Any such divisional application must be filed while the present application is still pending (Rule 36(1) EPC; Guidelines A-IV, 1.1.1).

## 6. Notes concerning fee payments

### 6.1 Making payments

For payments made via deposit account, please note that as from 1 December 2017 debit orders will only be carried out if filed in an electronically processable format (xml), using an accepted means of filing as laid down in the Arrangements for deposit accounts (ADA), published in the Supplementary publication in the Official Journal.

All relevant information related to the modes of payment of fees to the EPO can be retrieved from the EPO website at "**Making Payments**".

### 6.2 Information concerning fee amounts

Procedural fees are usually adjusted every two years, on even years, with effect from 1 April. Therefore, before making a payment, parties should verify the amounts actually due on the date of payment using the applicable version of the Schedule of fees and expenses, published as a Supplement to the Official Journal of the EPO, available on the EPO website (**www.epo.org**) at **www.epo.org/schedule-of-fees**. The "Schedule of fees" table allows the viewing, downloading and searching of individual fee amounts, both current and previous.

### 6.3 Note to users of the automatic debiting procedure

The fee for grant, including the fee for publication, and any additional claims fees due under Rule 71(4) EPC will be debited automatically on the date of filing of the translations of the claims, or on the last day of the period of this communication. However, if the designation fee(s) become(s) due as set out in Rule 71a(3) EPC and/or a renewal fee becomes due as set out in Rule 71a(4) EPC, these should be paid separately by another permitted way of payment in order not to delay the publication of the mention of the grant. The same applies in these circumstances to the payment of extension and validation fees. The same applies in these circumstances to the payment of extension and validation fees.

Note: If a waiver is expressed in response to a Rule 71(3) communication (see OJ EPO 2015, A52), the fee for grant, including the fee for publication/printing, and any additional claims fees will not be debited automatically. These fees must be paid separately by another means of payment allowed under the Rules relating to Fees.



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**Examining Division:**

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Enclosures: Text intended for grant

EPO Form 2056
EPO Form 2906



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RAK 17/5/19

WO 2006/005015 PCT/US2005/023584

# PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

## FIELD OF THE INVENTION

[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

[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.

[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 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 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 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, 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 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 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, "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 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 transceptal hole and 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 bring comprised of a deployable construction 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 bring provided with a plurality of longitudinally rigid support beams 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, 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 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 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 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 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 location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself.

Further prior art arrangements are known from US 5258023, US 4106129, WO 00/64380 and FR 2815844.

## SUMMARY OF THE INVENTION

[0015] In accordance with a preferred embodiment of the present invention, there is provided a prosthetic valve for percutaneous implantation in a body channel as recited by Claim 1.

The sleeve preferably surrounds an inflow end of the stent structure.

The compressible material may have a thickness ranging from 1 to 5mm.

The compressible material may comprise a cloth or fabric.

A tissue growth factor may be disposed along the compressible material. 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.

The fibers may be straight, curved or hook-shaped.

The compressible material is preferably configured to expand into the gaps.

The compressible material may be configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

## 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 creating a paravalvular leak and a device

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 guidewires

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

designed to identify paravalvular leaks around an implanted valve.

**[0067]** Figures 4a to 4c depict the process

of inserting a sealing stent over a guidewire to close a paravalvular leak.

**[0068]** Figures 5a to 5d depict several types of sealing stents

**[0069]** Figures 6a to 6d illustrate blocking a paravalvular leak with a sealing device

assisted by anchors, which attach the device to the aortic wall (or annulus).

[0070] Figure 7 illustrates an anchoring apparatus 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).

[0071] Figures 8a and 8b depict a leak repair done using a two-component biological glue.

[0072] Figures 9a to 9c depict a leak repair done, using an ultra-violet light-cured biological glue.

[0073] Figure 10 illustrates a catheter that inserts a two-component biological glue into a balloon in order to block a paravalvular leak.

[0074] Figures 11a to 11f illustrate a device and procedure for blocking a paravalvular leak using two connected sealing stents.

[0075] Figures 12 depicts a valve with a built-in inflatable 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 having a flexible and self-expanding portion for blocking possible leaks around the stent.

[0077] Figures 14a to 14c illustrate a valve having a having a flexible and self-expanding portion for blocking possible leaks around the stent..

[0078] Figures 15a to 15c illustrate a valve 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 comprising an additional portion for blocking possible leaks around the stent.

[0080] Figures 17a to 17e illustrate a valve device where the stent is adapted such that when expanded, a portion of the stent is forced to protrude radially, thereby blocking possible leaks.

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

[0082] Figures 19a to 19d depict a 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, having a sealing element made of a flexible and expandable material for blocking leaks around the stent.

**[0084]** Figure 21 illustrates a valve device, wherein the sealing element is attached to the valve in a sealing line for providing an improved crimped profile.

**[0085]** Figure 22 illustrates a valve device, in accordance with an 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

**[0086]** The present invention provides 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.

**[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.

**[0090]** A 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 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.

**[00114]** Figure 1 illustrates a simple leak detector 27 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.

**[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 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 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. 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, 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 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.

**[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, 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 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 a balloon-expandable sealing stent (such as that used in Figure 4b). 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). 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 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.

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 guide wire 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.

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 caused by cavity 24.

**[00126]** Figures 10a to 10e illustrate another apparatus for repairing a paravalvular leak using a bi-component adhesive material. Figure 10a shows a multiple-lumen catheter 100 that can be slid over guidewire 99 to 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 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 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 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.

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).

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.

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 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 blood, causing it to swell and seal the cavity.

**[00130]** Figures 13a to 13d depict a valve adapted to seal paravalvular leaks.

Figure 13a depicts an implantable valve 124. Stent 125 has a sealing component 126 connected to its inlet. Sealing 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. 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.

**[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 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 leaks.

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 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 paravalvular leaks.

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 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.

**[00135]** Figures 16a to 16c depict a valve adapted to seal paravalvular leaks

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 Figure 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 (polyethylene terephthalate) mesh 167 or other impermeable material.

**[00136]** Figures 17a to 17e depict a valve adapted to seal paravalvular leaks

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 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 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. 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 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 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 Figure 18a percutaneous valve 180 crimped on balloon 182 is shown being advanced toward the stenotic 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 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).

**[00140]** Figures 19a to19d depict a valve adapted to include means for sealing paravalvular leaks. 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 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 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 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 structure 202 along an interior region and a mechanism along an exterior region for sealing paravalvular leaks.

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 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. 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 a stented valve 250 in accordance with the invention 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 extends entirely around the stent structure 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. The compressible material 256 resembles 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 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, the hydrogel absorbs fluids from the blood and expands to the 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 expedients known to those skilled in the art or disclosed herein, may be employed without departing from the scope of the appended claims.

## Claims

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) 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;

characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

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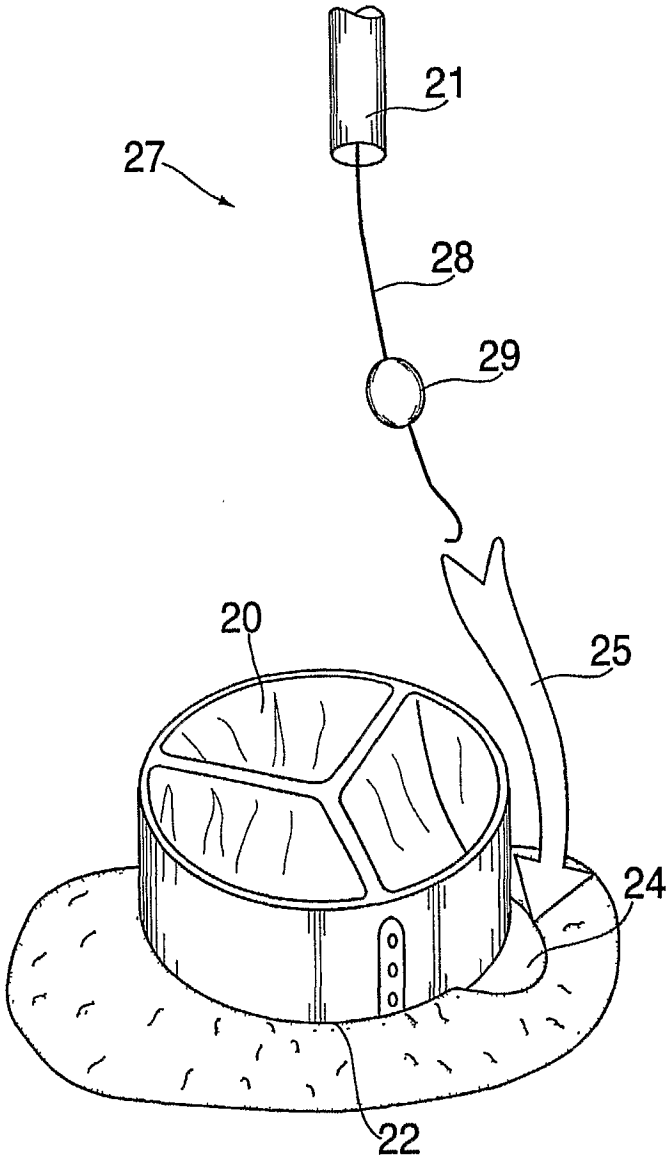


FIG. 1



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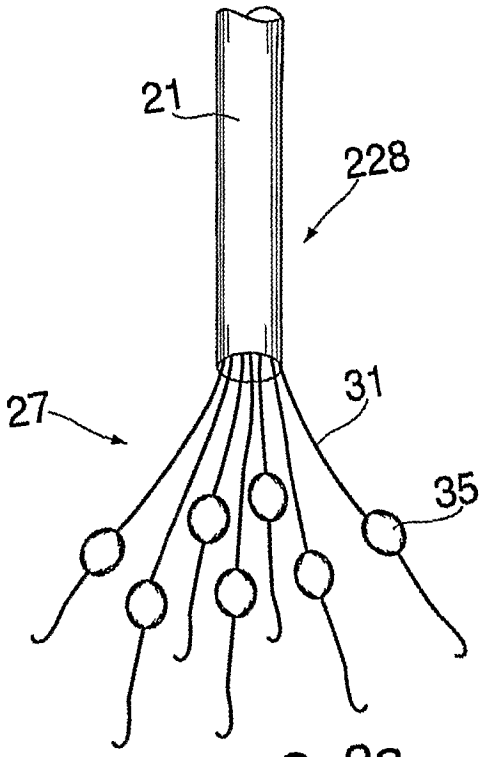


FIG. 2a

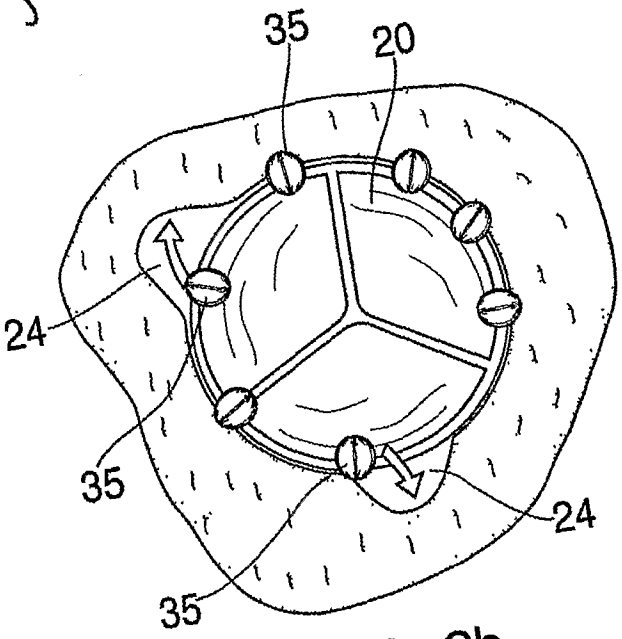


FIG. 2b



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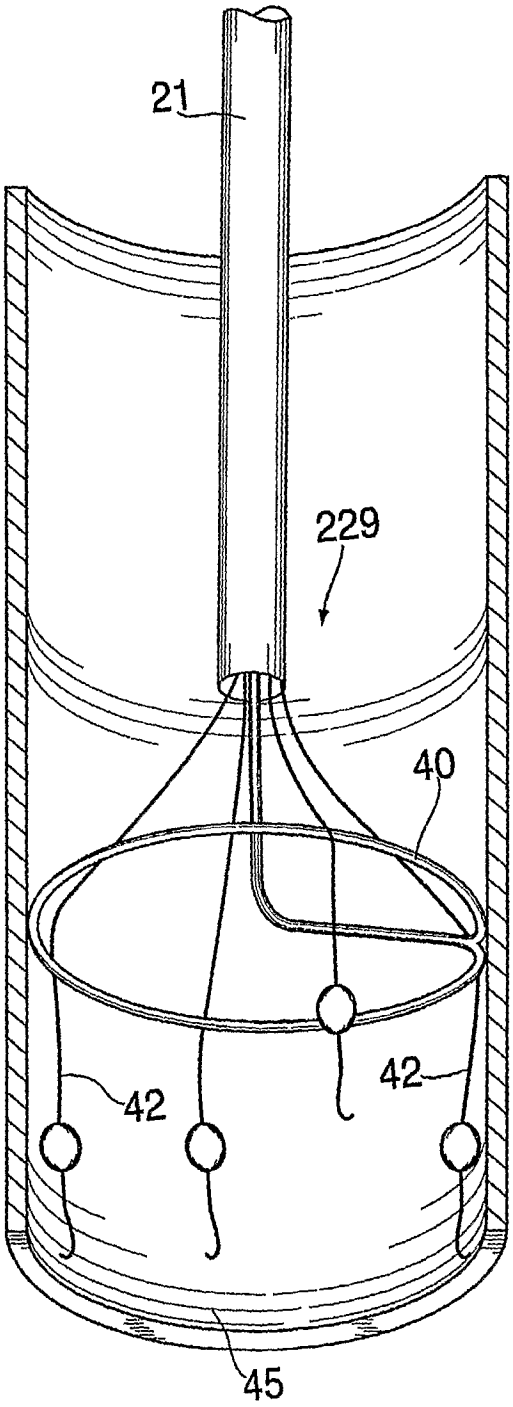


FIG. 3



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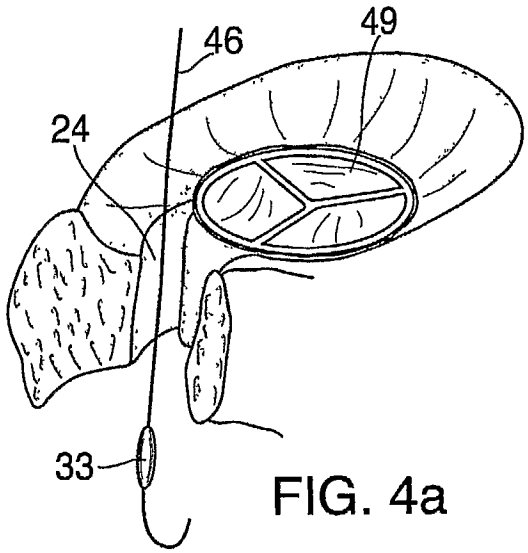


FIG. 4a

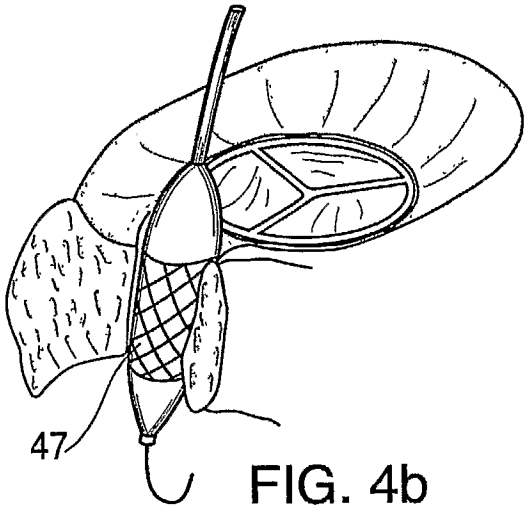


FIG. 4b

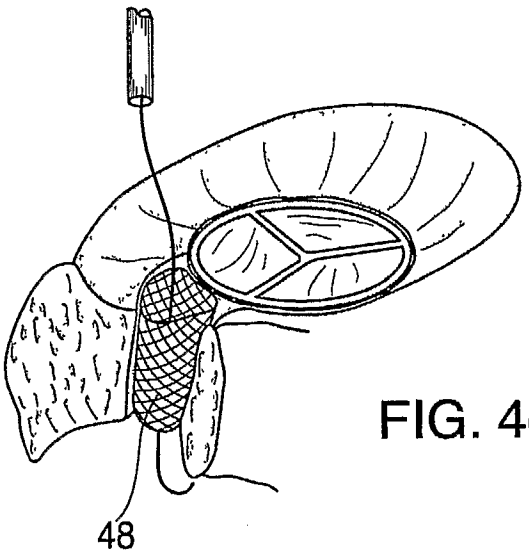


FIG. 4c



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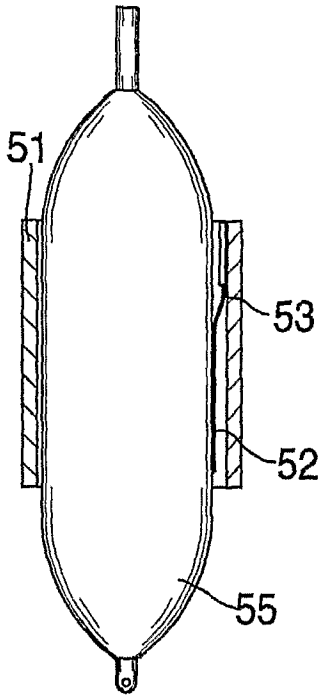


FIG. 5a

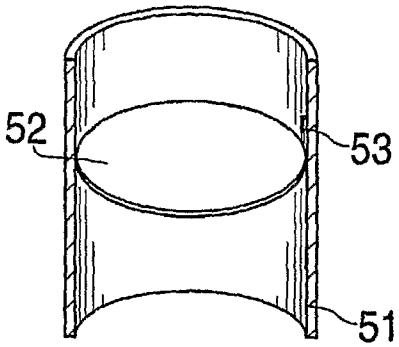


FIG. 5b

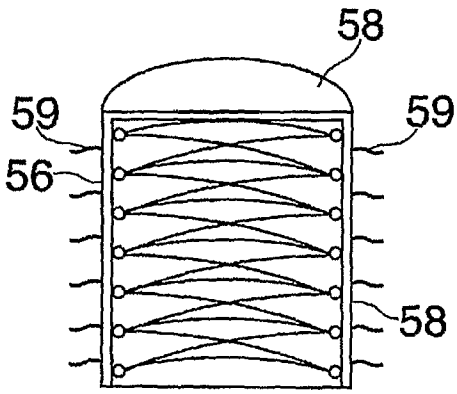


FIG. 5c

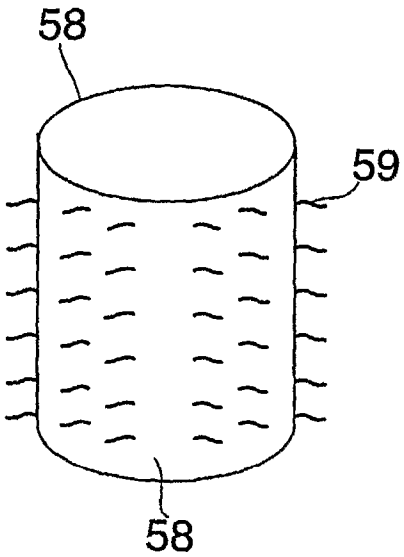


FIG. 5d



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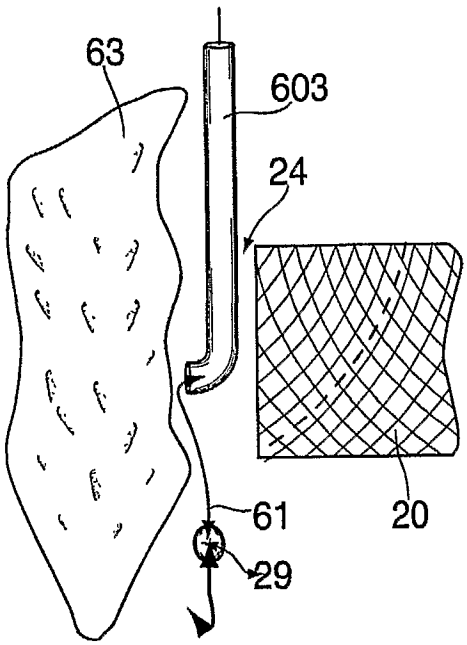


FIG. 6a

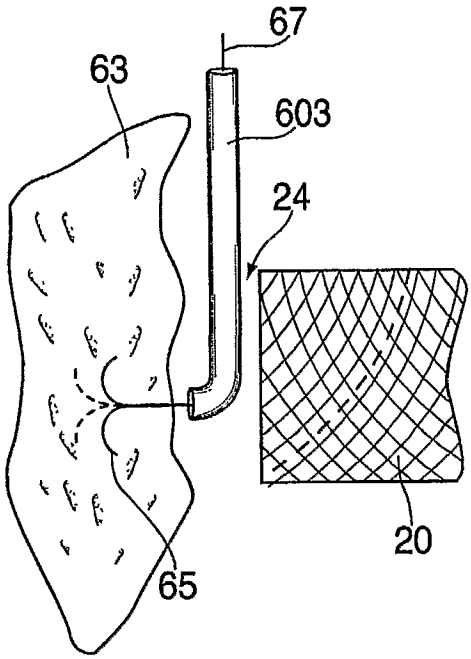


FIG. 6b

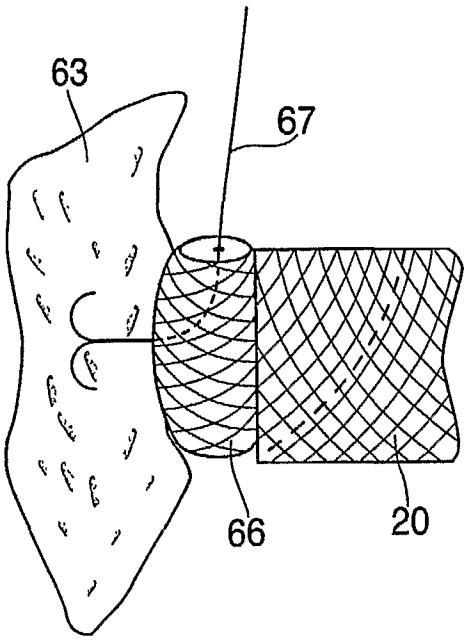


FIG. 6c

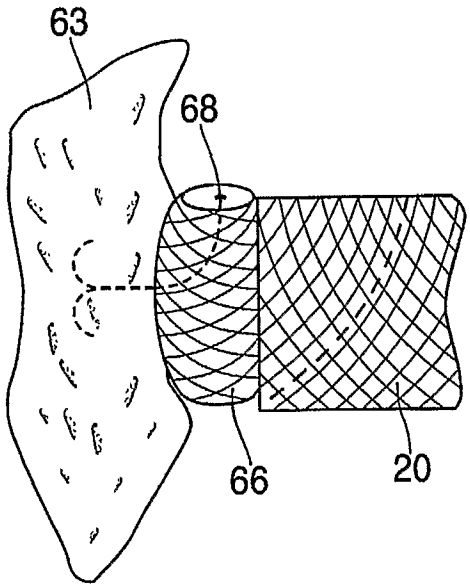


FIG. 6d



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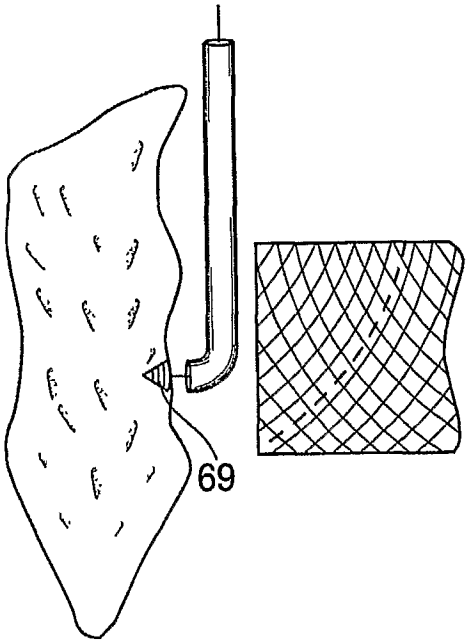


FIG. 7



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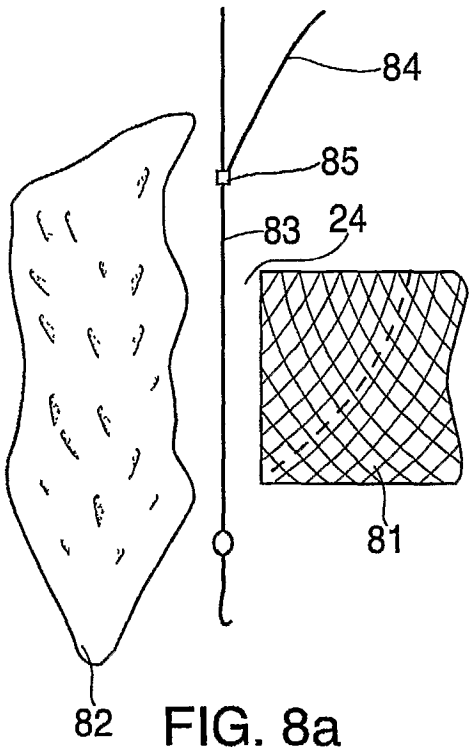


FIG. 8a

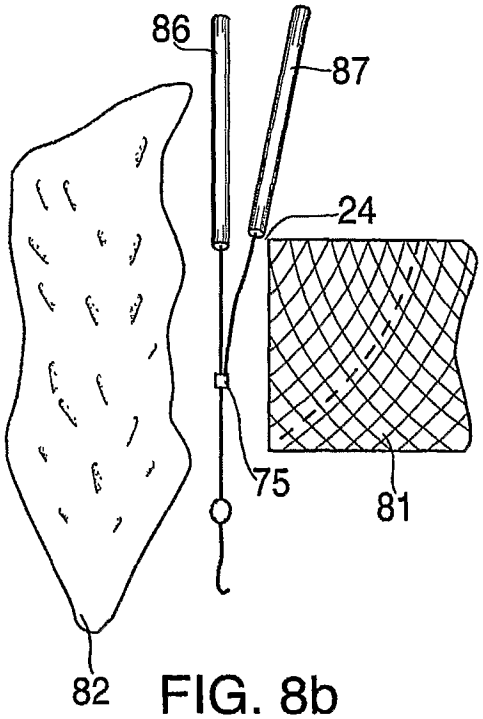


FIG. 8b

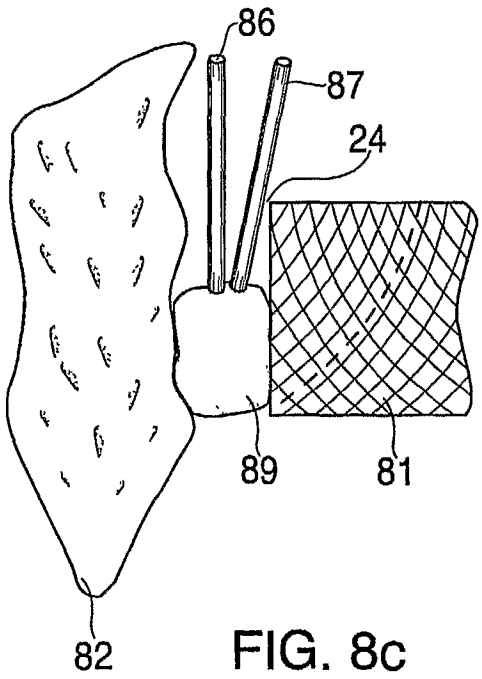


FIG. 8c

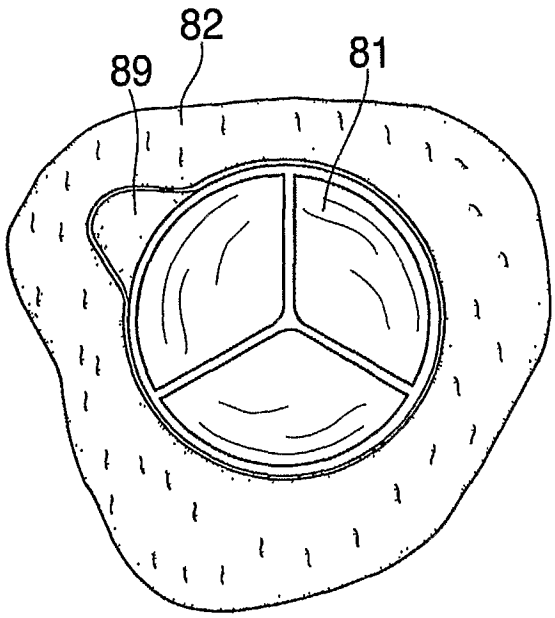


FIG. 8d



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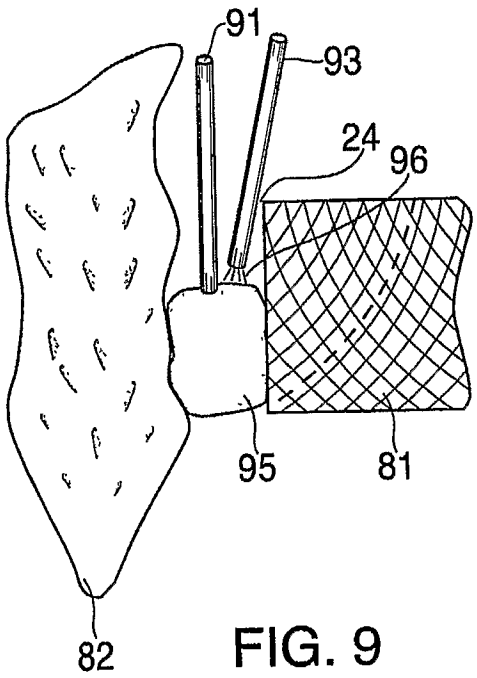


FIG. 9



Aortic Innovations, LLC, Exhibit 2040
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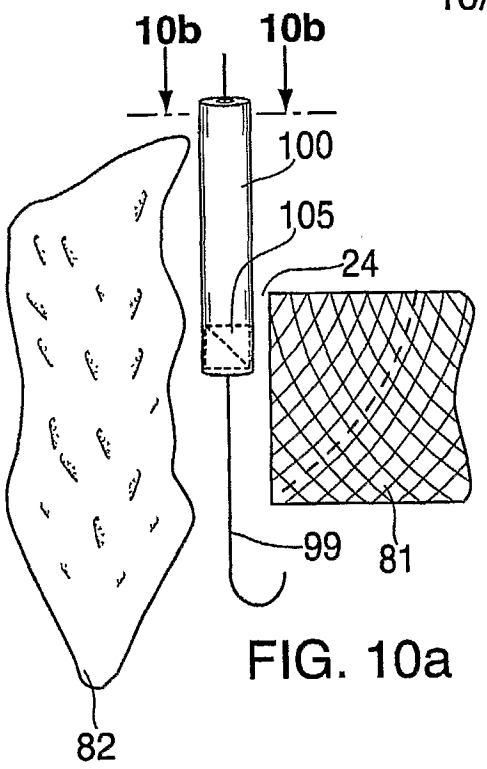


FIG. 10a

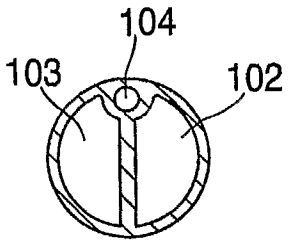


FIG. 10b

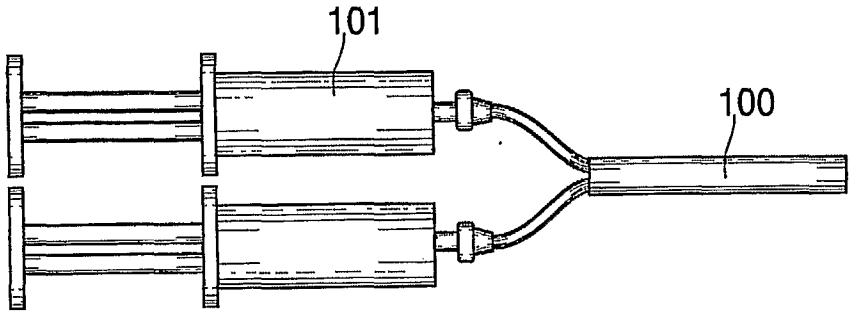


FIG. 10c

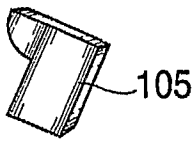


FIG. 10d

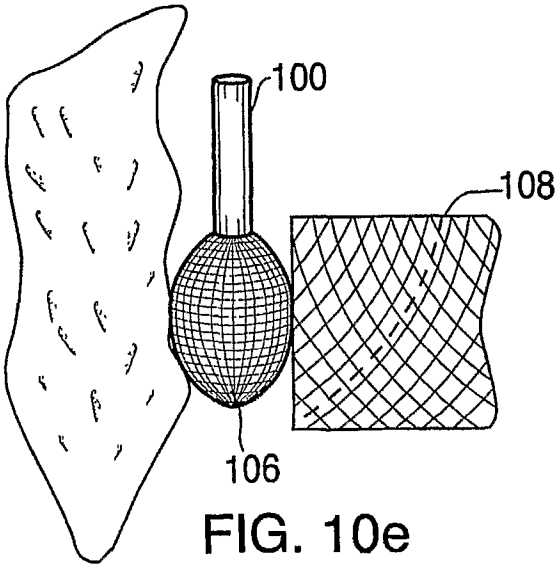


FIG. 10e



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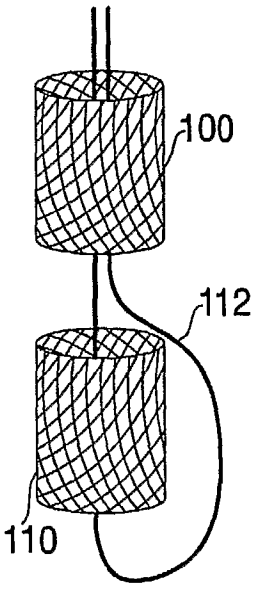


FIG. 11a

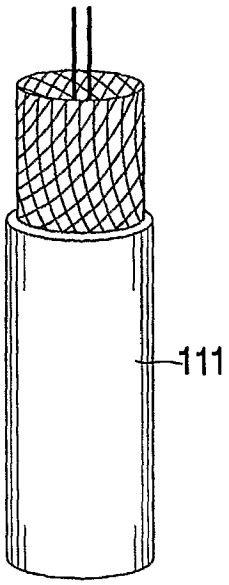


FIG. 11b

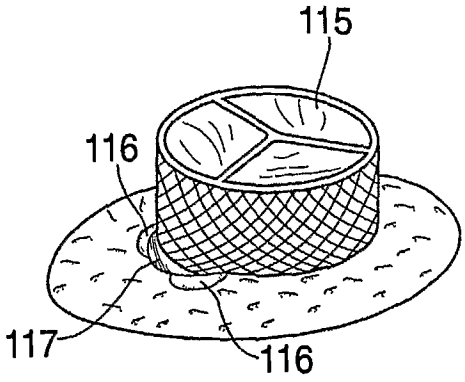


FIG. 11c

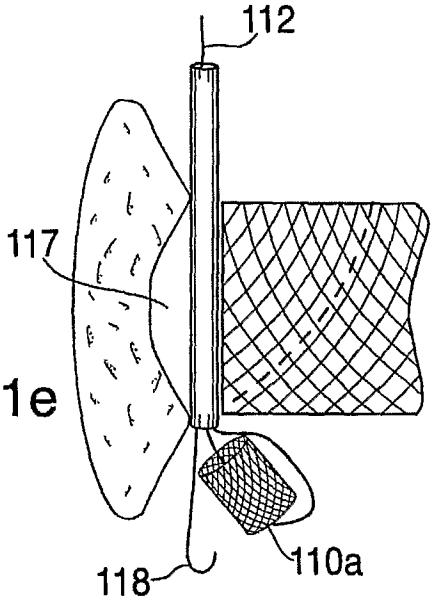


FIG. 11e

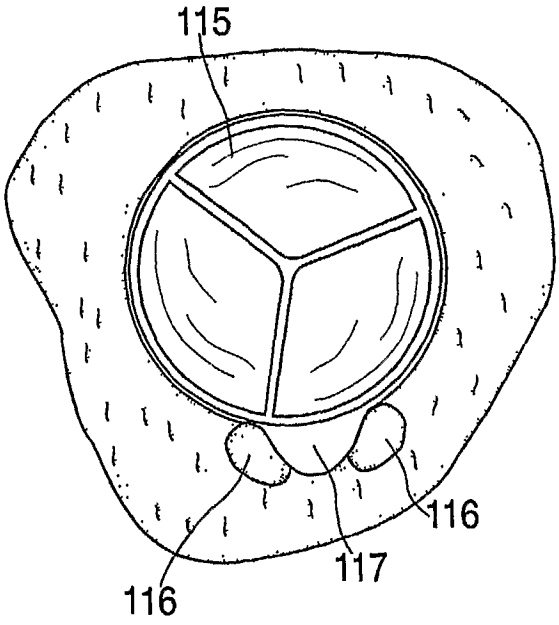


FIG. 11d

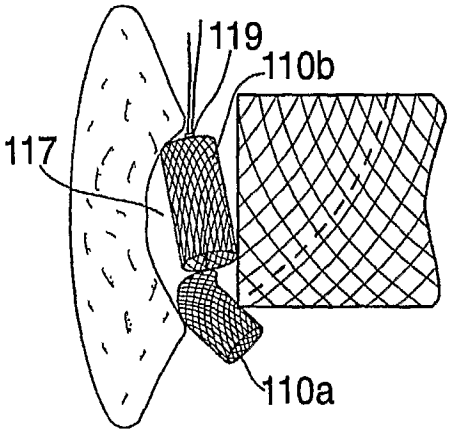


FIG. 11f



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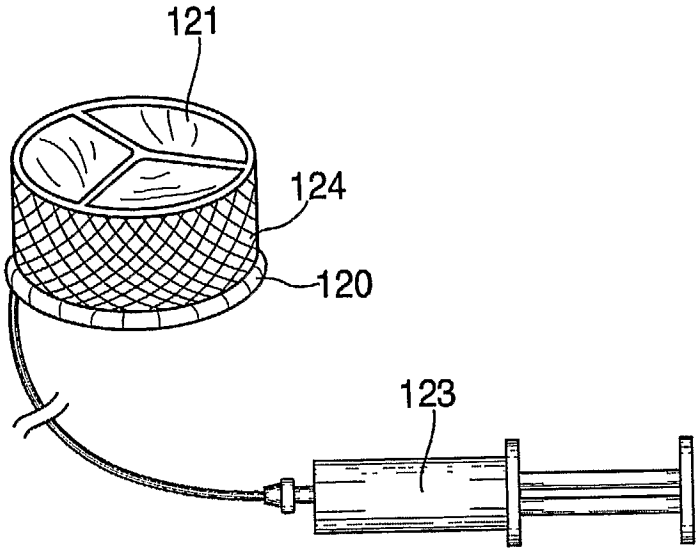


FIG. 12



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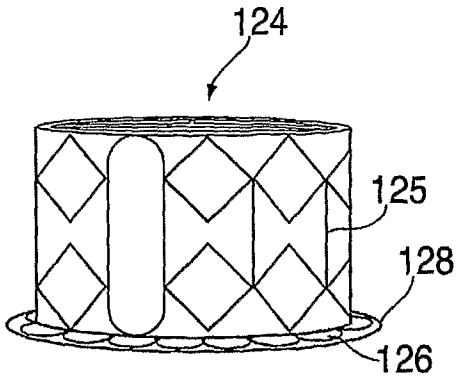


FIG. 13a

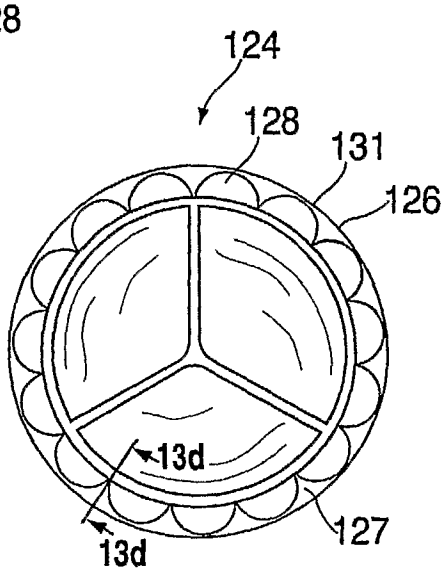


FIG. 13b

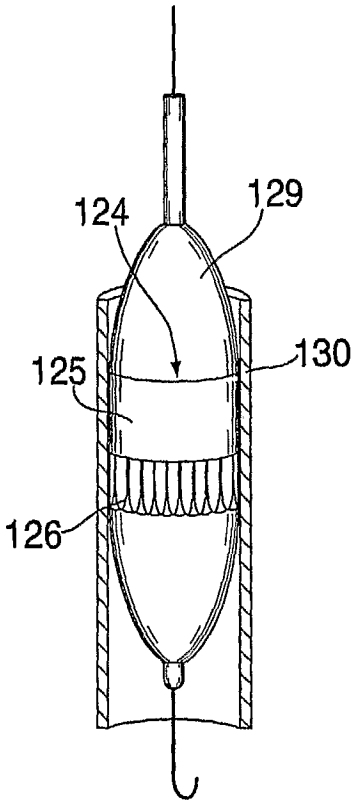


FIG. 13c

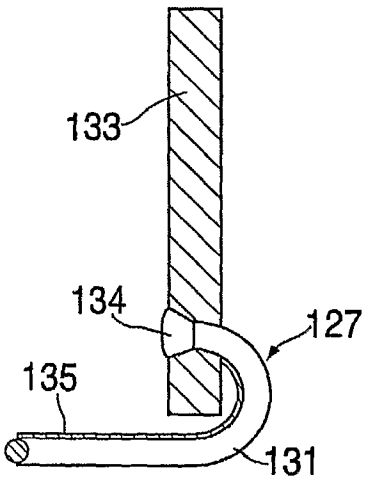


FIG. 13d



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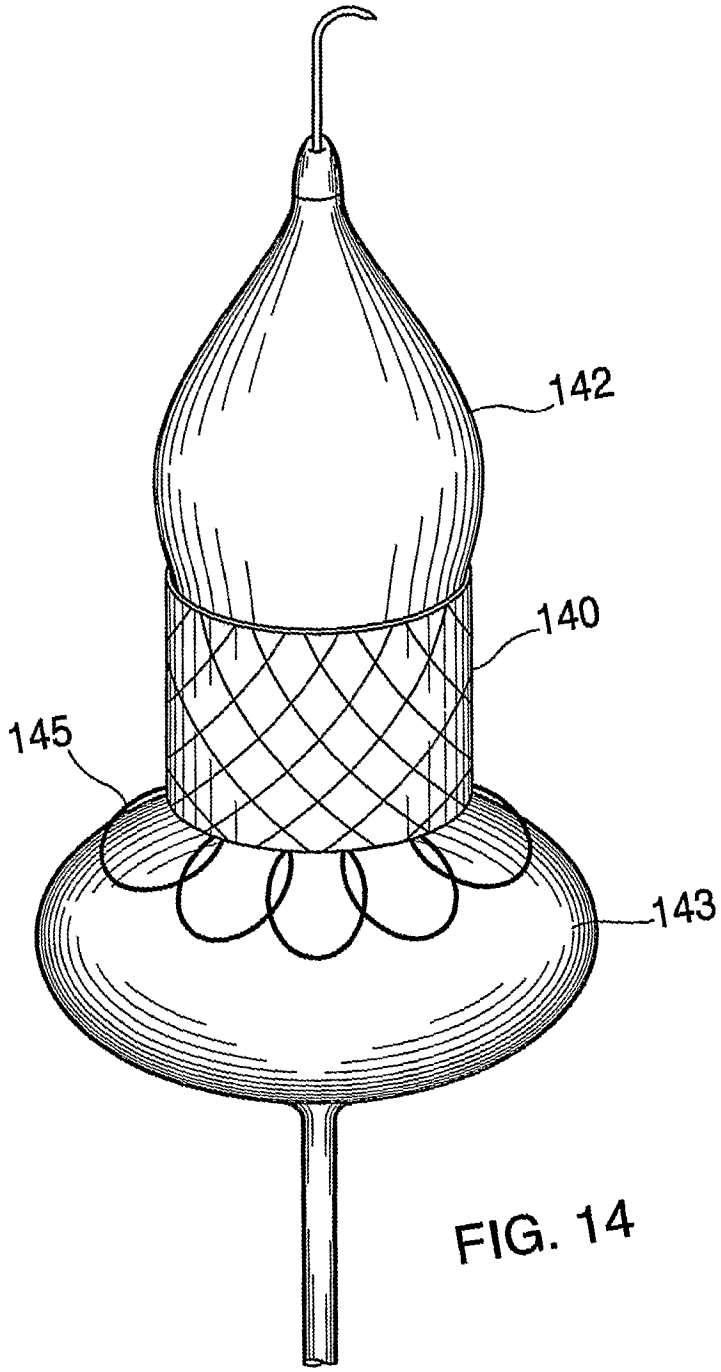


FIG. 14



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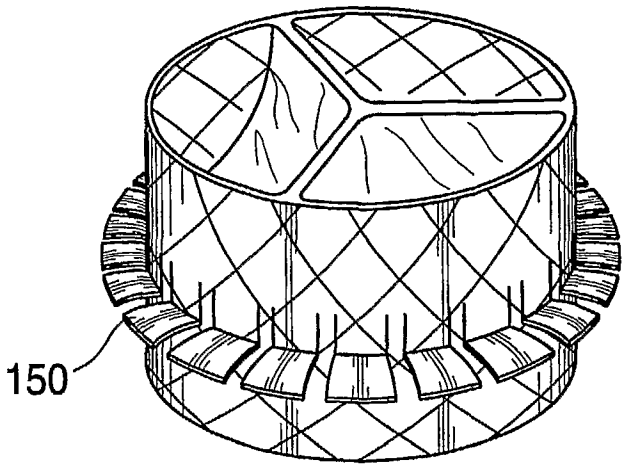


FIG. 15a

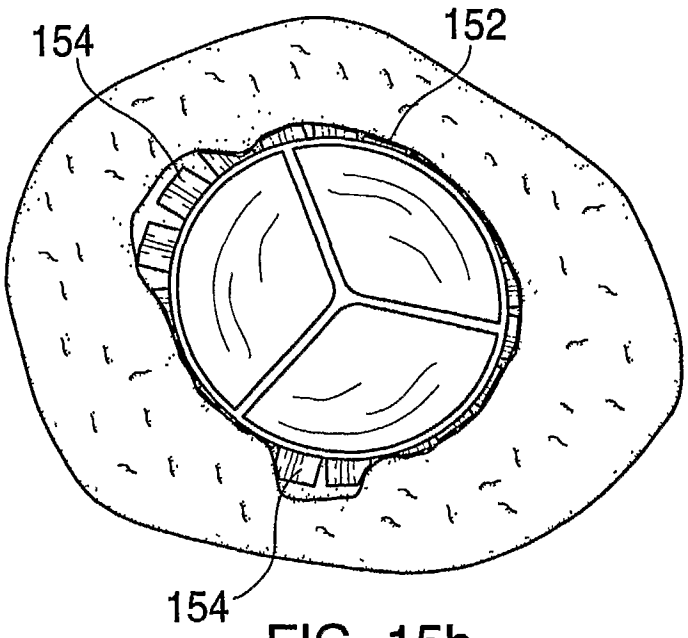


FIG. 15b



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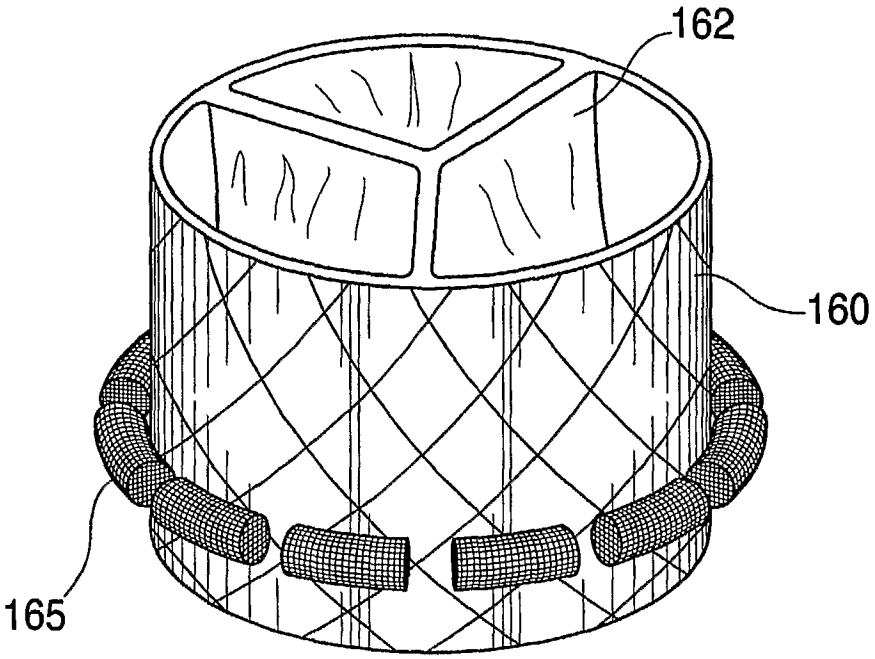


FIG. 16a

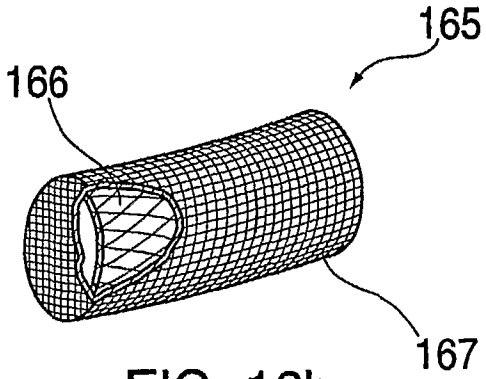


FIG. 16b



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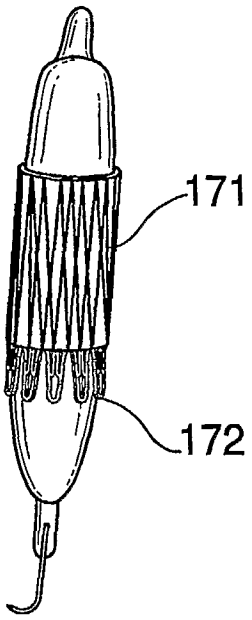


FIG. 17a

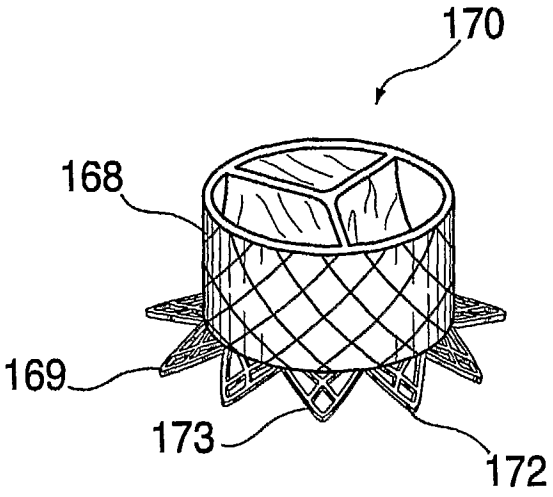


FIG. 17b

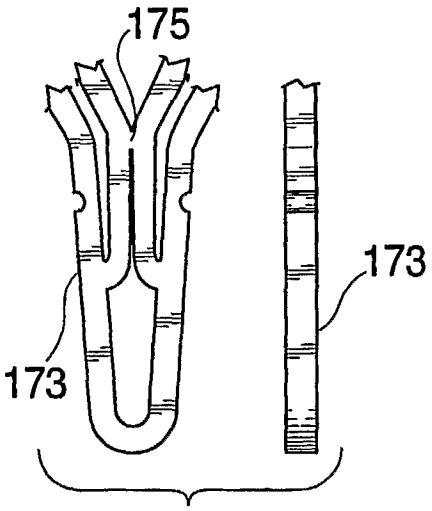


FIG. 17c

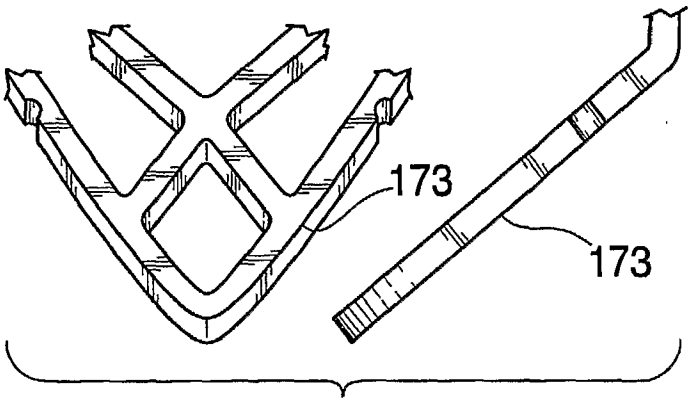


FIG. 17d

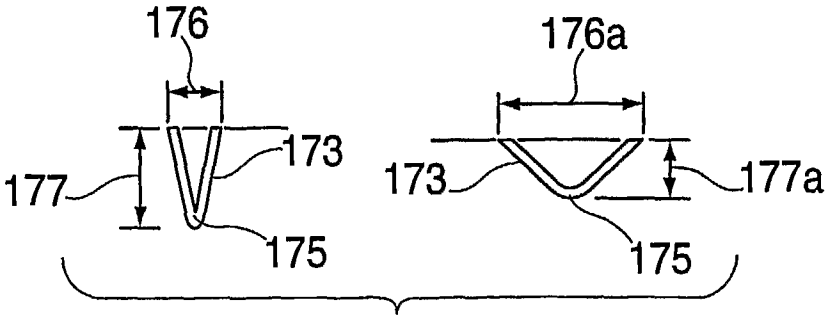


FIG. 17e



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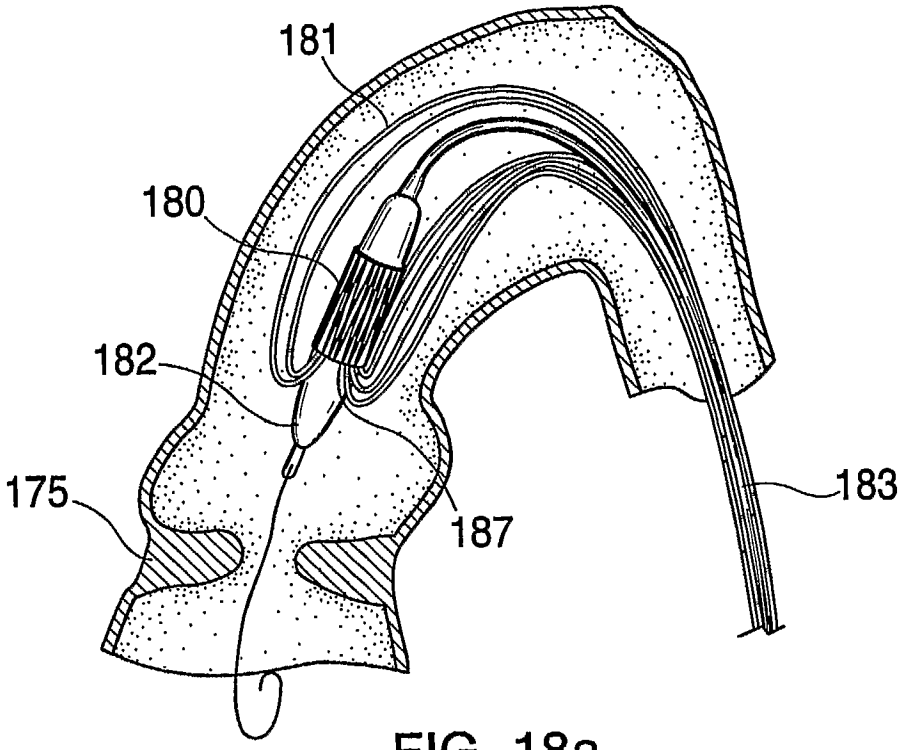


FIG. 18a

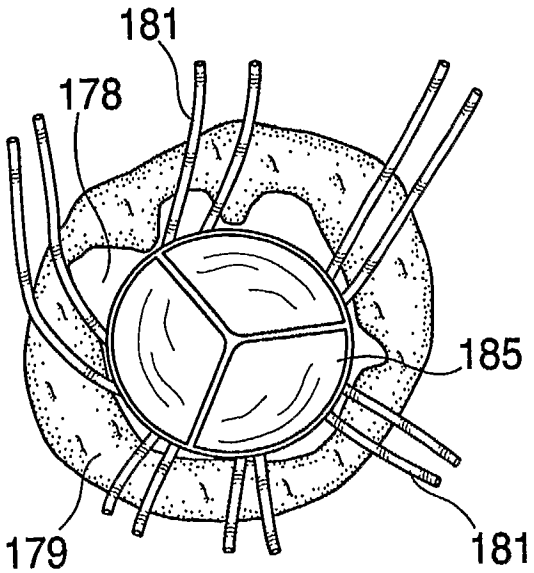


FIG. 18c

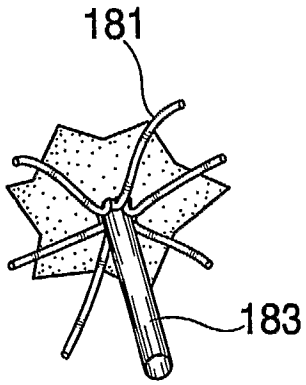


FIG. 18b



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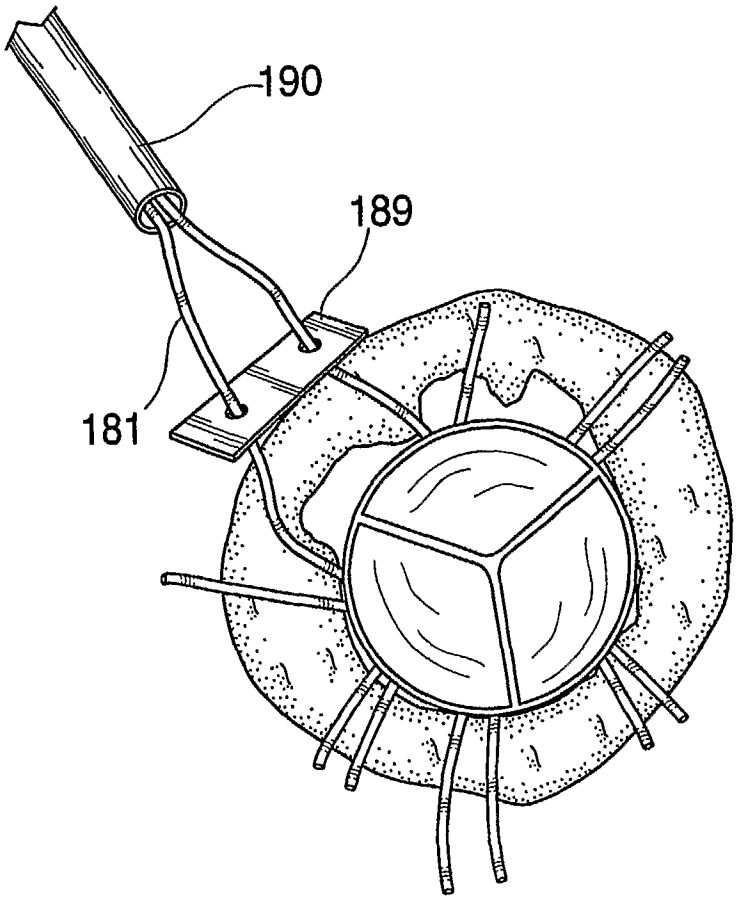


FIG. 18d

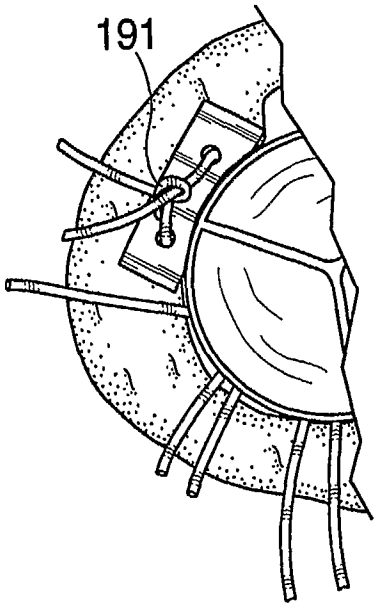


FIG. 18e



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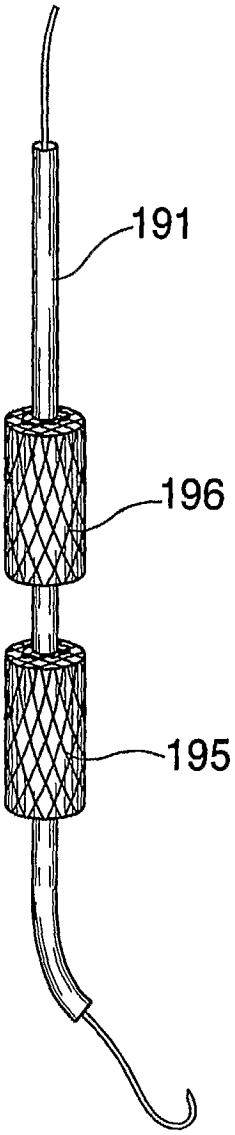


FIG. 19a

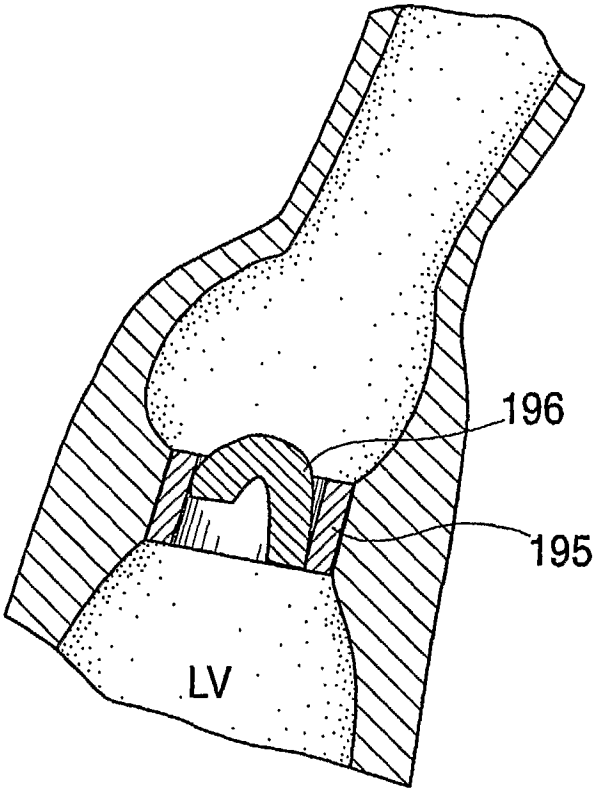


FIG. 19b

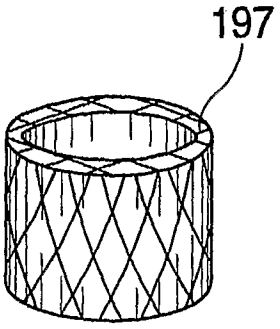


FIG. 19c

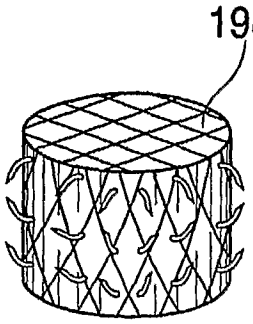


FIG. 19d



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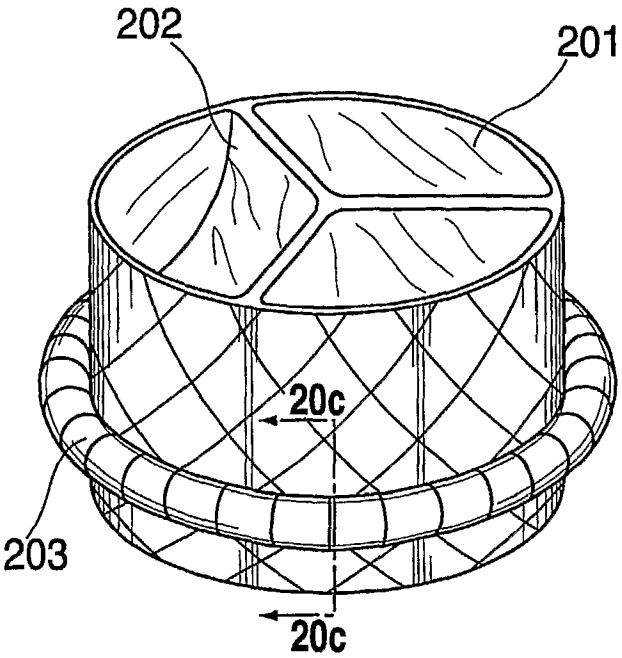


FIG. 20a

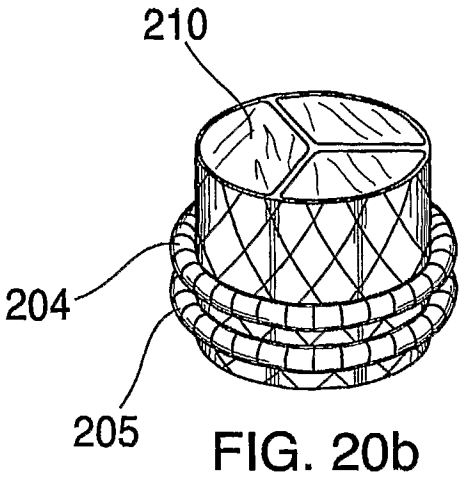


FIG. 20b

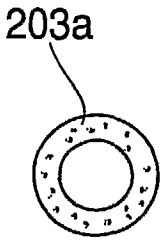


FIG. 20c

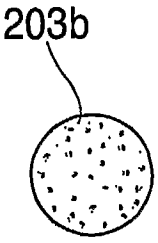


FIG. 20d

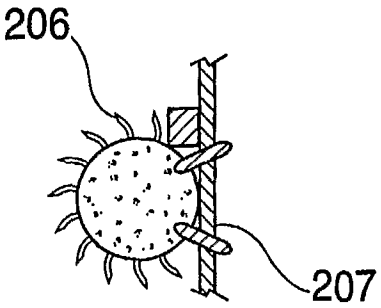


FIG. 20e

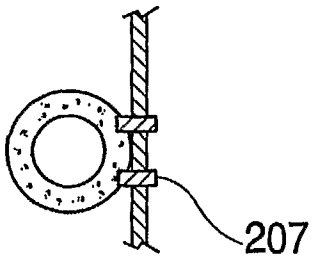


FIG. 20f

FIG. 20g



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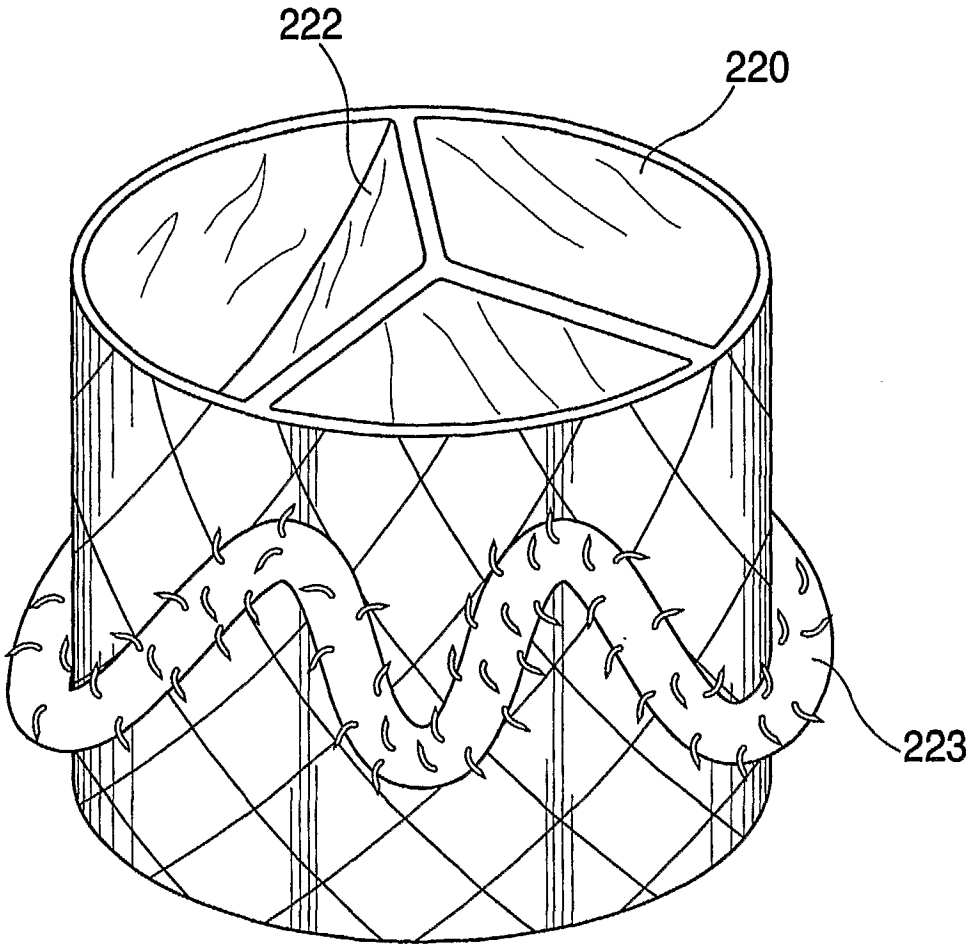


FIG. 21



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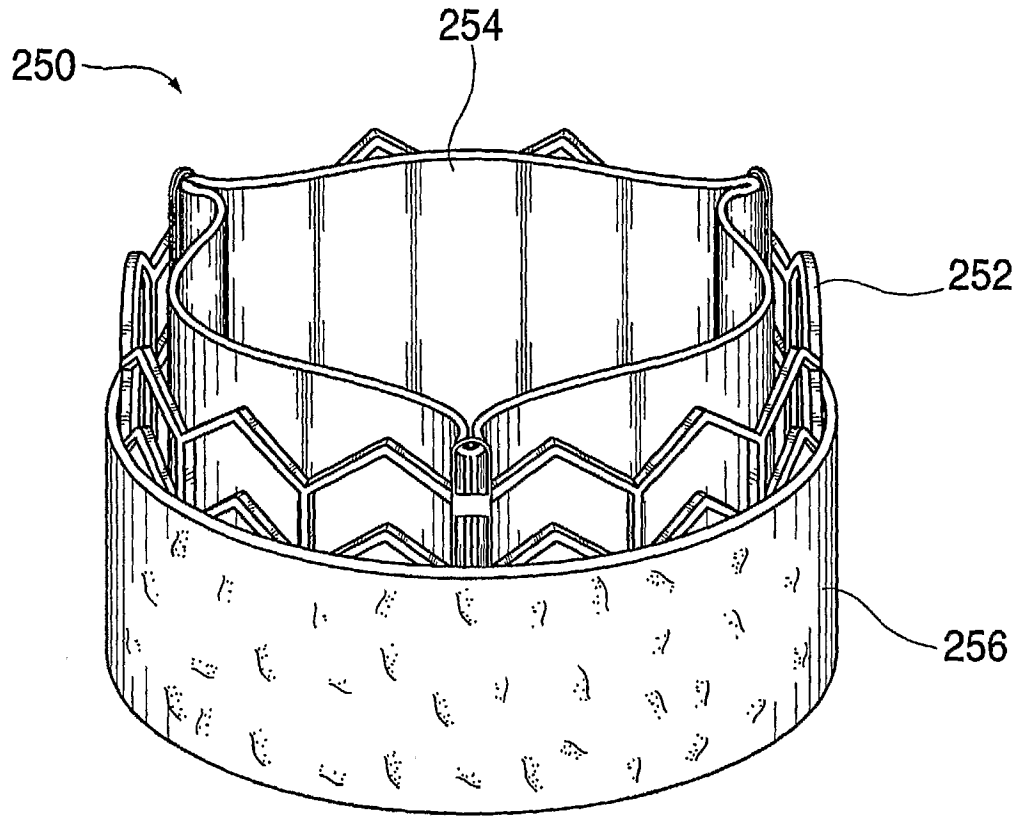


FIG. 22



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RAK 17/5/19

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# PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

## FIELD OF THE INVENTION

[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

[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.

[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 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 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 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, 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 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 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, "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 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 transceptal hole and 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 bring comprised of a deployable construction 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 bring provided with a plurality of longitudinally rigid support beams 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, 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 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 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 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 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 location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself.

Further prior art arrangements are known from US 5258023, US 4106129, WO 00/64380 and FR 2815844.

## SUMMARY OF THE INVENTION

[0015] In accordance with a preferred embodiment of the present invention, there is provided a prosthetic valve for percutaneous implantation in a body channel as recited by Claim 1.

The sleeve preferably surrounds an inflow end of the stent structure.

The compressible material may have a thickness ranging from 1 to 5mm.

The compressible material may comprise a cloth or fabric.

A tissue growth factor may be disposed along the compressible material. 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.

The fibers may be straight, curved or hook-shaped.

The compressible material is preferably configured to expand into the gaps.

The compressible material may be configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

## 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 creating a paravalvular leak and a device

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 guidewires

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

designed to identify paravalvular leaks around an implanted valve.

**[0067]** Figures 4a to 4c depict the process

of inserting a sealing stent over a guidewire to close a paravalvular leak.

**[0068]** Figures 5a to 5d depict several types of sealing stents

**[0069]** Figures 6a to 6d illustrate blocking a paravalvular leak with a sealing device

assisted by anchors, which attach the device to the aortic wall (or annulus).

[0070] Figure 7 illustrates an anchoring apparatus 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).

[0071] Figures 8a and 8b depict a leak repair done using a two-component biological glue.

[0072] Figures 9a to 9c depict a leak repair done, using an ultra-violet light-cured biological glue.

[0073] Figure 10 illustrates a catheter that inserts a two-component biological glue into a balloon in order to block a paravalvular leak.

[0074] Figures 11a to 11f illustrate a device and procedure for blocking a paravalvular leak using two connected sealing stents.

[0075] Figures 12 depicts a valve with a built-in inflatable 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 having a flexible and self-expanding portion for blocking possible leaks around the stent.

[0077] Figures 14a to 14c illustrate a valve having a having a flexible and self-expanding portion for blocking possible leaks around the stent..

[0078] Figures 15a to 15c illustrate a valve 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 comprising an additional portion for blocking possible leaks around the stent.

[0080] Figures 17a to 17e illustrate a valve device where the stent is adapted such that when expanded, a portion of the stent is forced to protrude radially, thereby blocking possible leaks.

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

[0082] Figures 19a to 19d depict a 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, having a sealing element made of a flexible and expandable material for blocking leaks around the stent.

**[0084]** Figure 21 illustrates a valve device, wherein the sealing element is attached to the valve in a sealing line for providing an improved crimped profile.

**[0085]** Figure 22 illustrates a valve device, in accordance with an 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

**[0086]** The present invention provides 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.

**[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.

**[0090]** A 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 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.

**[00114]** Figure 1 illustrates a simple leak detector 27 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.

**[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 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 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. 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, 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 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.

**[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, 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 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 a balloon-expandable sealing stent (such as that used in Figure 4b). 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). 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 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.

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 guide wire 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.

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 caused by cavity 24.

**[00126]** Figures 10a to 10e illustrate another apparatus for repairing a paravalvular leak using a bi-component adhesive material. Figure 10a shows a multiple-lumen catheter 100 that can be slid over guidewire 99 to 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 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 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 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.

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).

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.

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 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 blood, causing it to swell and seal the cavity.

**[00130]** Figures 13a to 13d depict a valve adapted to seal paravalvular leaks.

Figure 13a depicts an implantable valve 124. Stent 125 has a sealing component 126 connected to its inlet. Sealing 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. 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.

**[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 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 leaks.

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 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 paravalvular leaks.

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 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.

**[00135]** Figures 16a to 16c depict a valve adapted to seal paravalvular leaks

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 Figure 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 (polyethylene terephthalate) mesh 167 or other impermeable material.

**[00136]** Figures 17a to 17e depict a valve adapted to seal paravalvular leaks

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 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 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. 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 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 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 Figure 18a percutaneous valve 180 crimped on balloon 182 is shown being advanced toward the stenotic 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 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).

**[00140]** Figures 19a to19d depict a valve adapted to include means for sealing paravalvular leaks. 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 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 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 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 structure 202 along an interior region and a mechanism along an exterior region for sealing paravalvular leaks.

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 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. 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 a stented valve 250 in accordance with the invention 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 extends entirely around the stent structure 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. The compressible material 256 resembles 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 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, the hydrogel absorbs fluids from the blood and expands to the 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 expedients known to those skilled in the art or disclosed herein, may be employed without departing from the scope of the appended claims.

## Claims

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) 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;

characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

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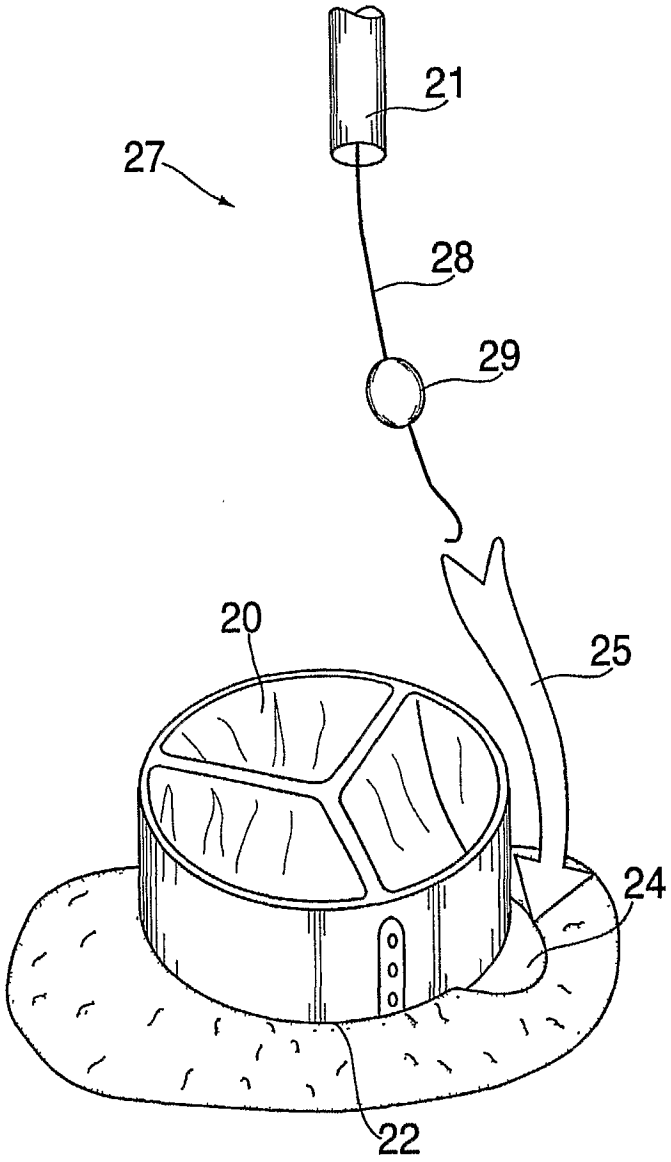


FIG. 1



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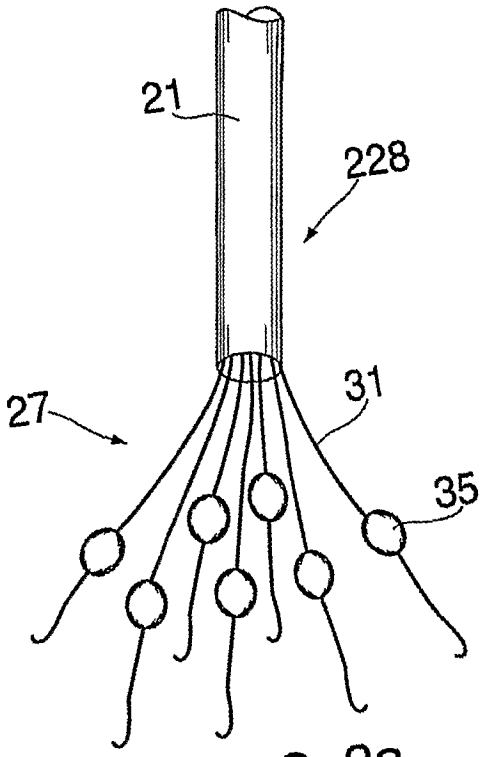


FIG. 2a

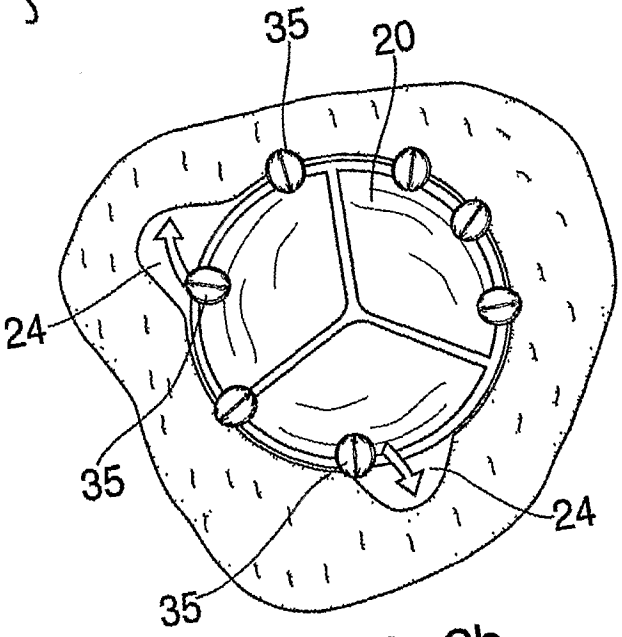


FIG. 2b



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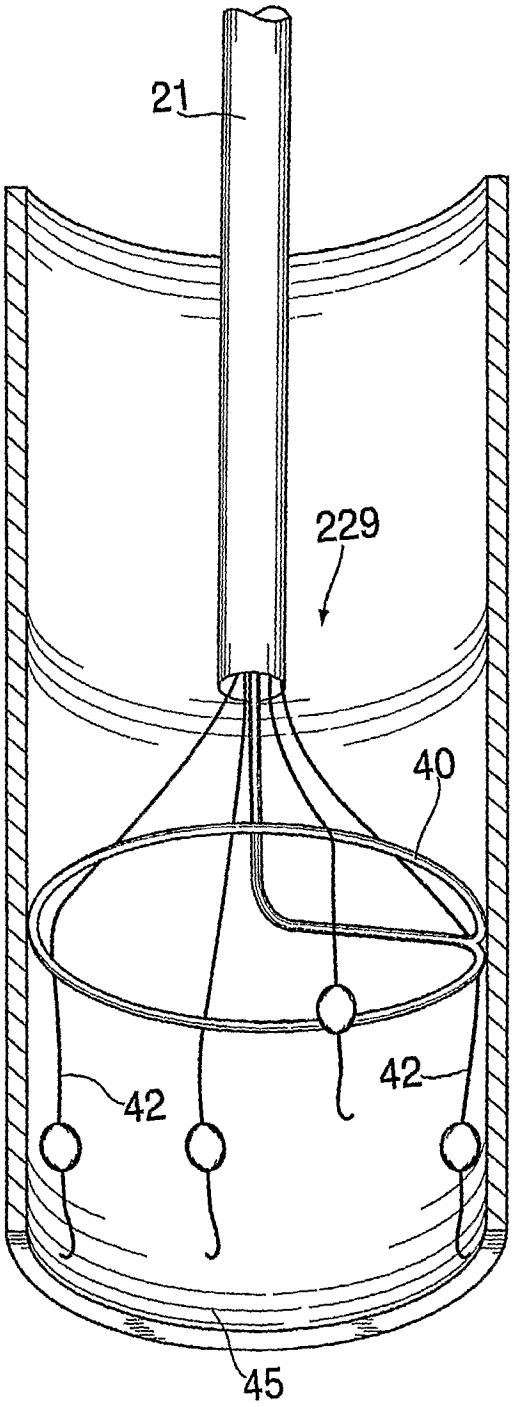


FIG. 3



Aortic Innovations, LLC, Exhibit 2040
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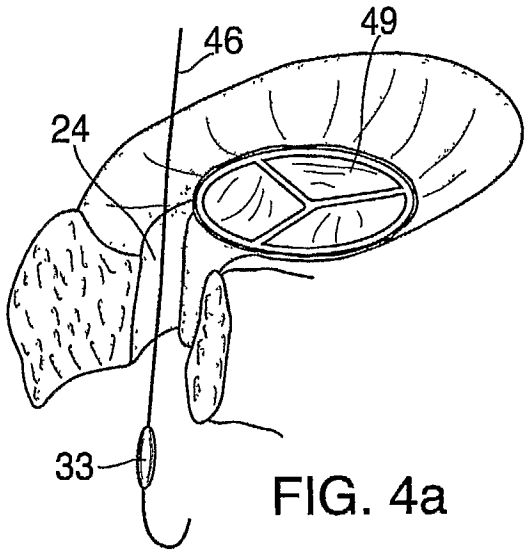


FIG. 4a

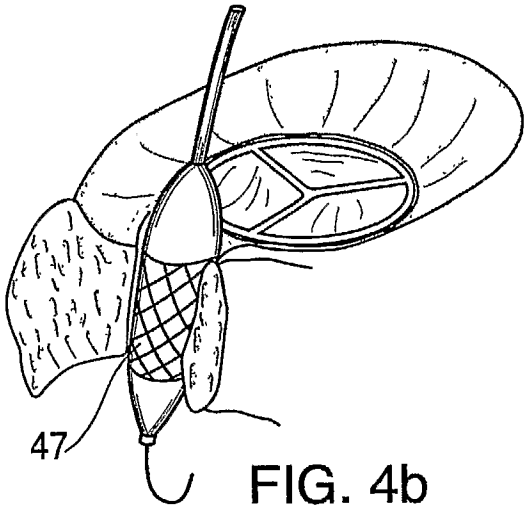


FIG. 4b

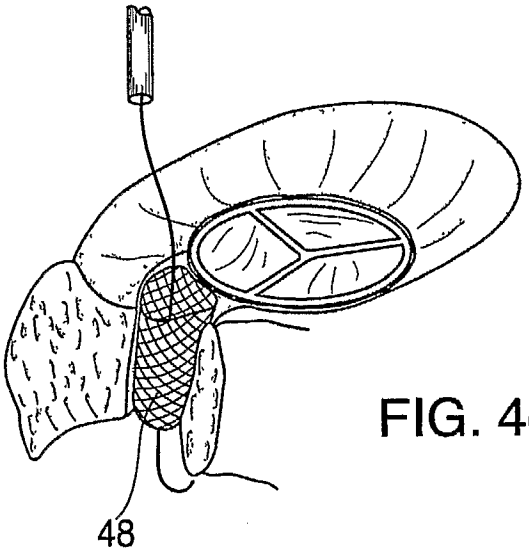


FIG. 4c



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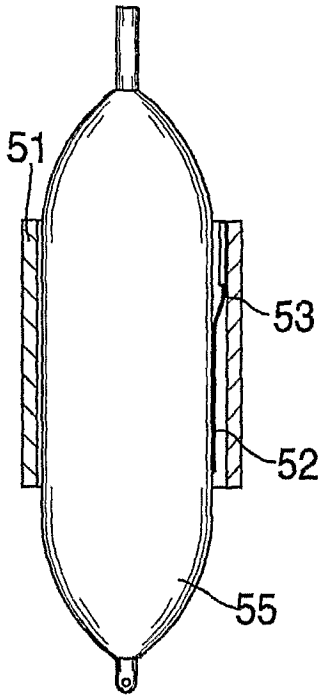


FIG. 5a

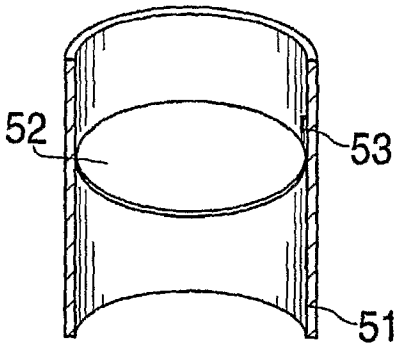


FIG. 5b

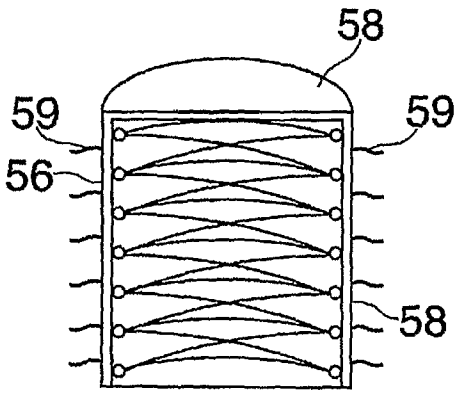


FIG. 5c

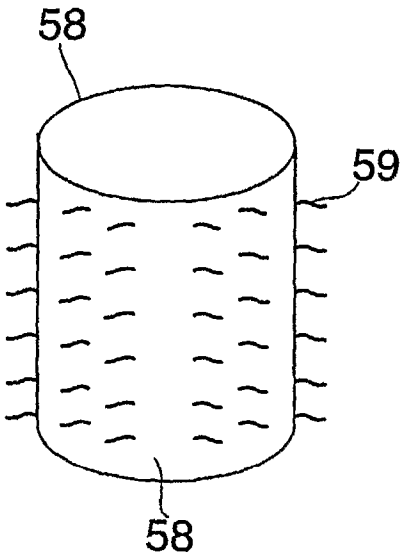


FIG. 5d



Aortic Innovations, LLC, Exhibit 2040
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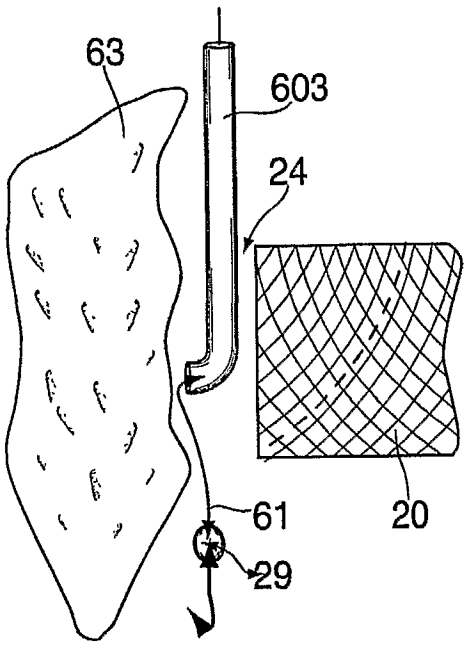


FIG. 6a

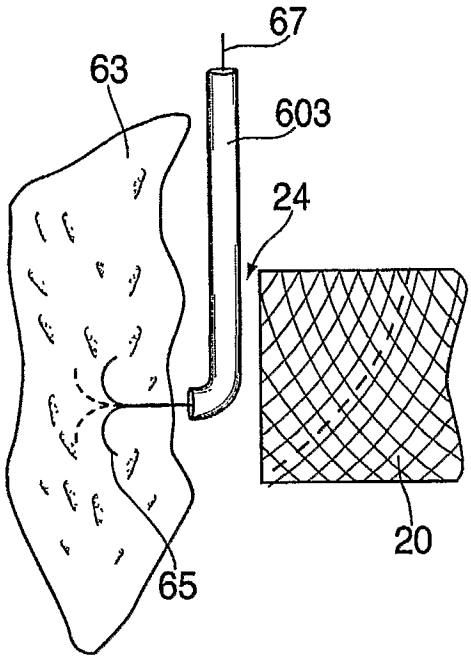


FIG. 6b

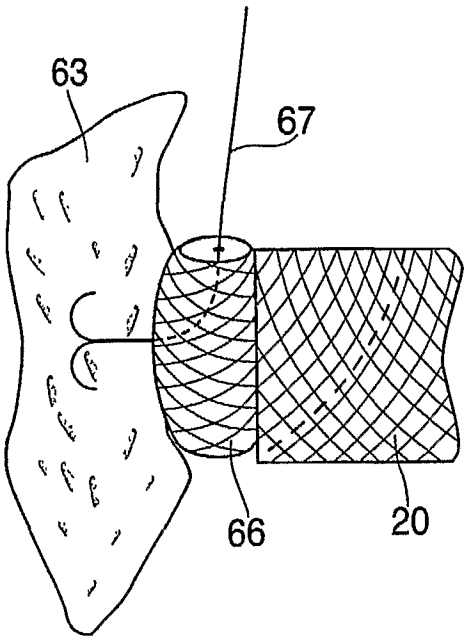


FIG. 6c

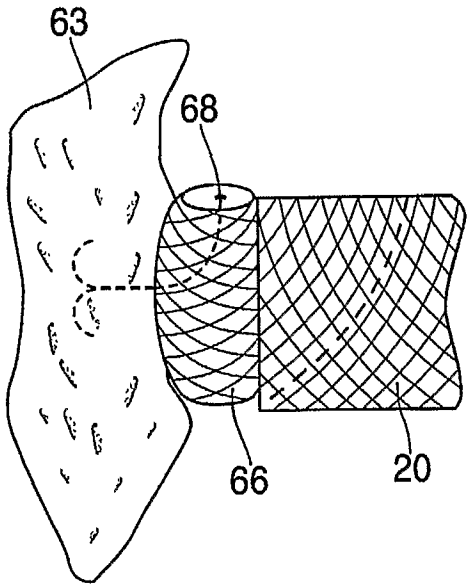


FIG. 6d



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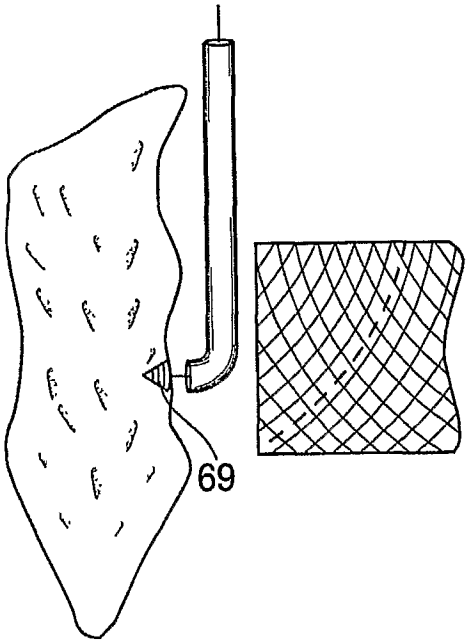


FIG. 7



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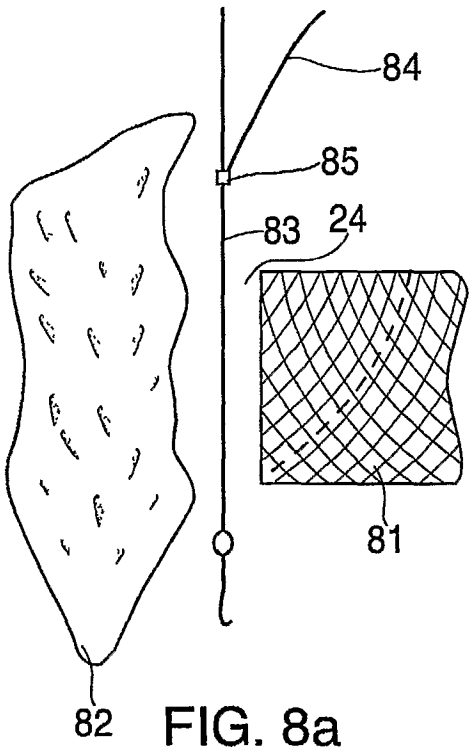


FIG. 8a

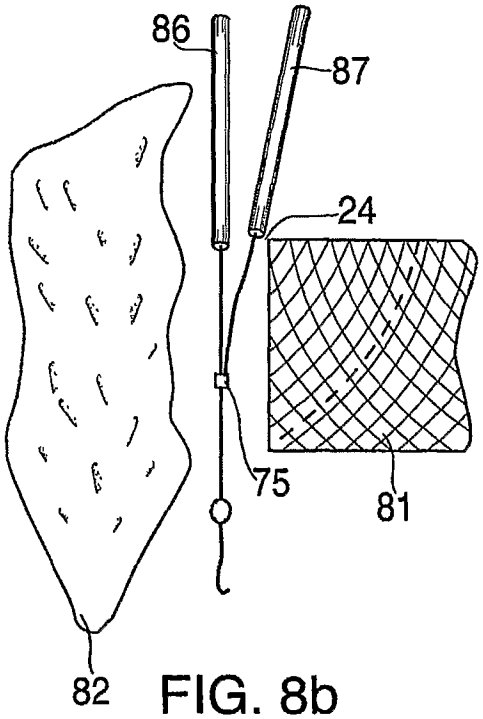


FIG. 8b

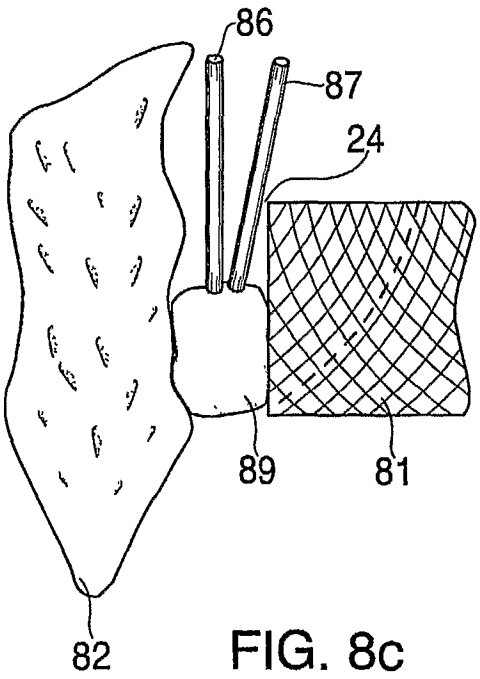


FIG. 8c

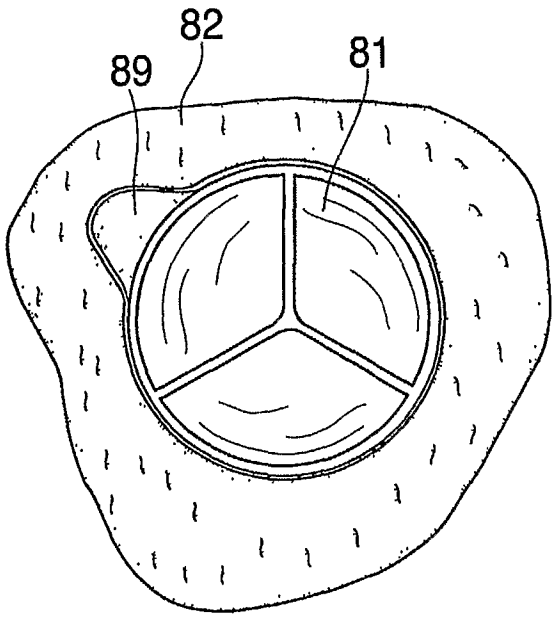


FIG. 8d



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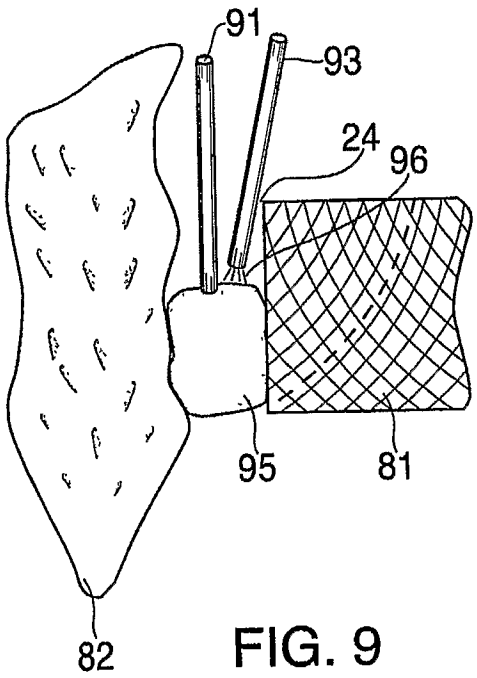


FIG. 9



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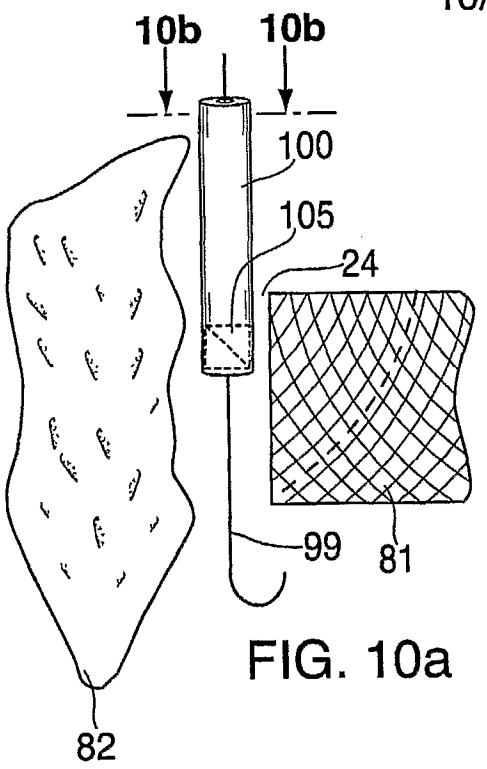


FIG. 10a

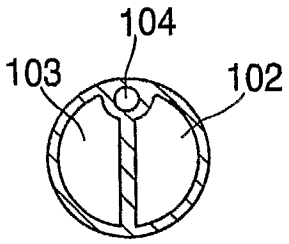


FIG. 10b

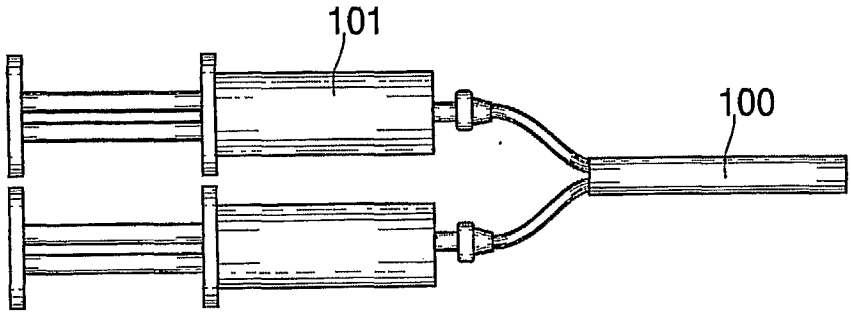


FIG. 10c

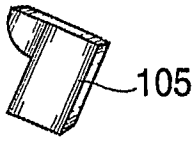


FIG. 10d

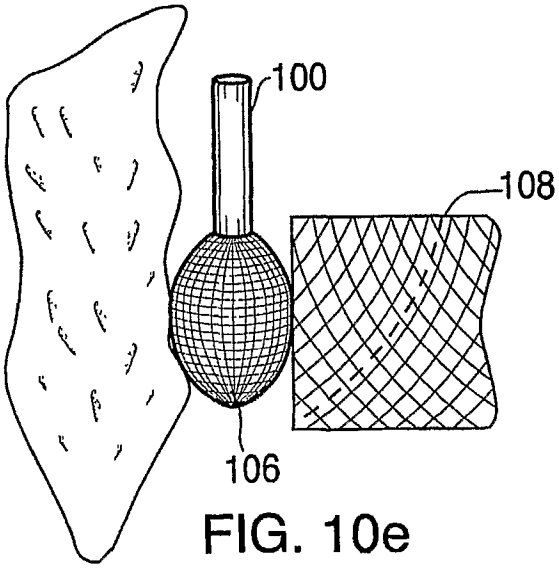


FIG. 10e



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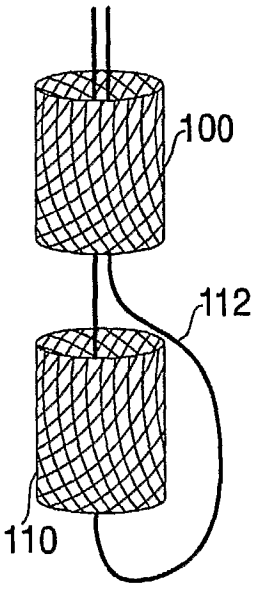


FIG. 11a

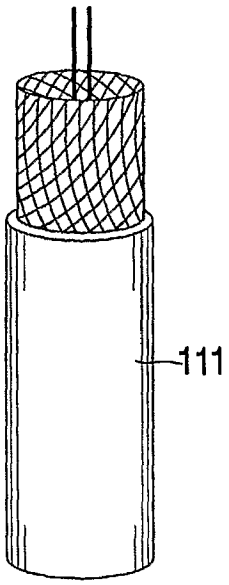


FIG. 11b

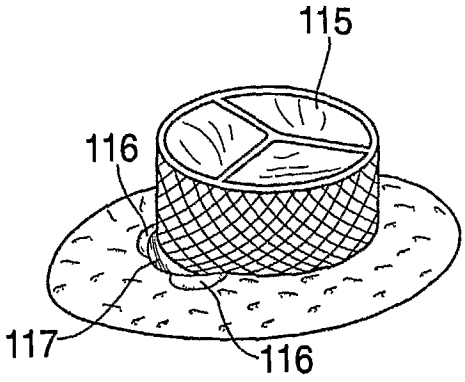


FIG. 11c

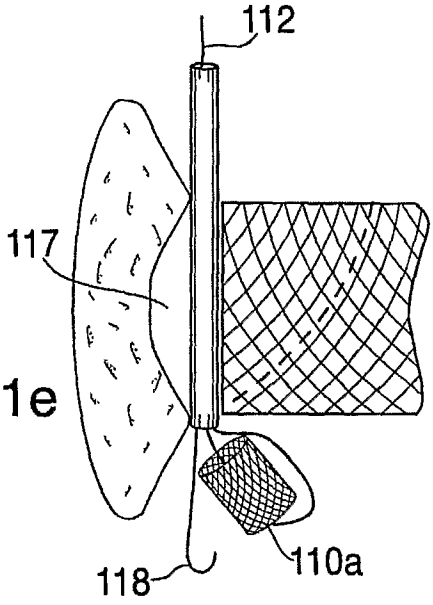


FIG. 11e

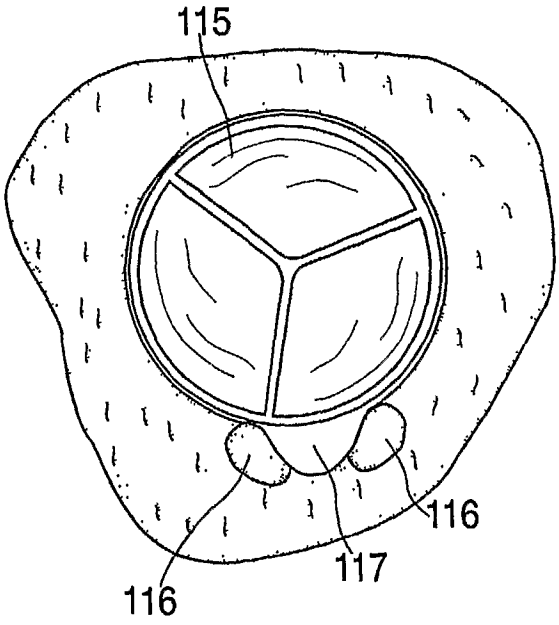


FIG. 11d

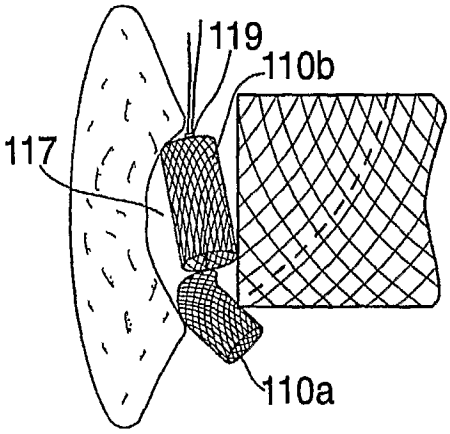


FIG. 11f



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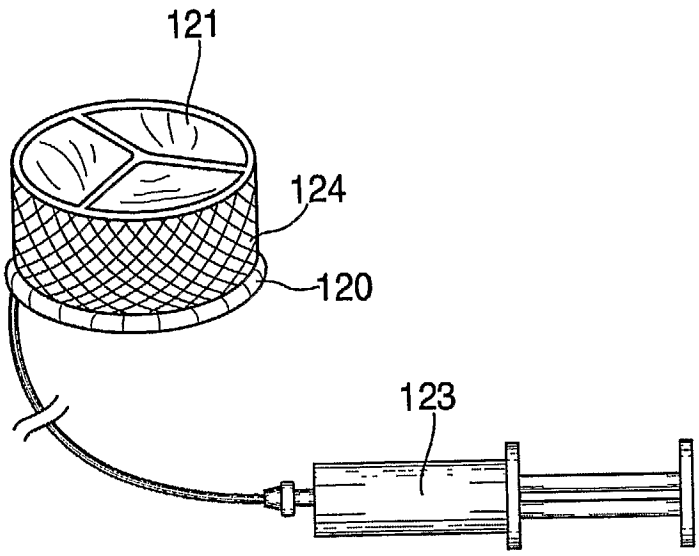


FIG. 12



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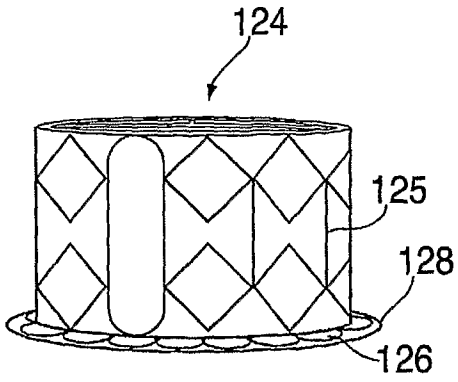


FIG. 13a

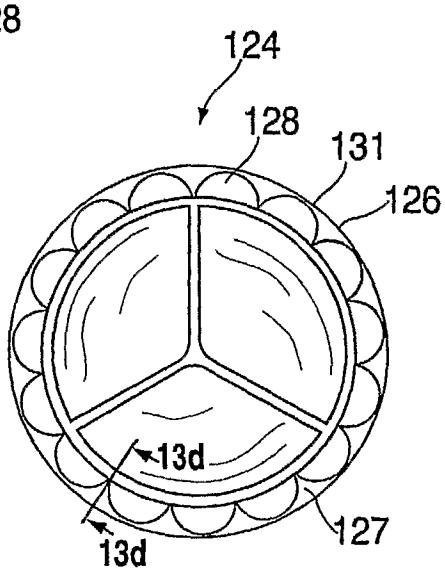


FIG. 13b

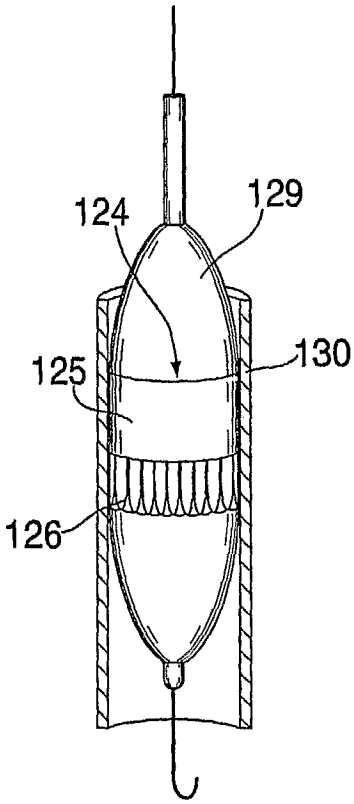


FIG. 13c

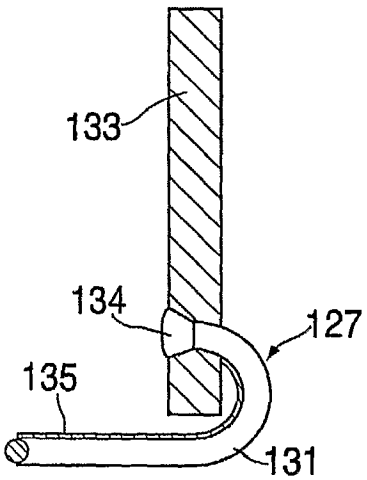


FIG. 13d



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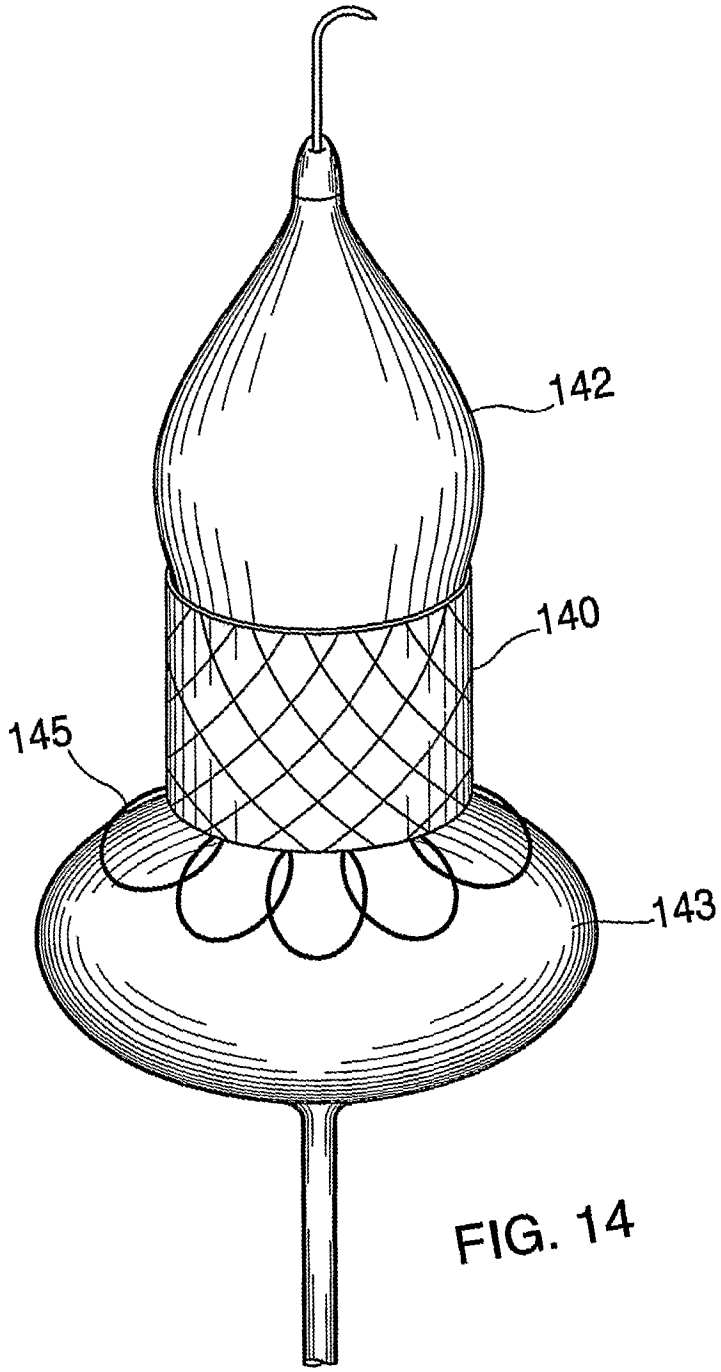


FIG. 14



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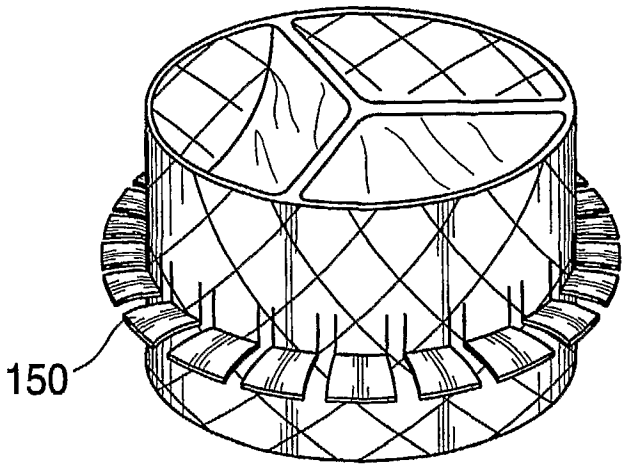


FIG. 15a

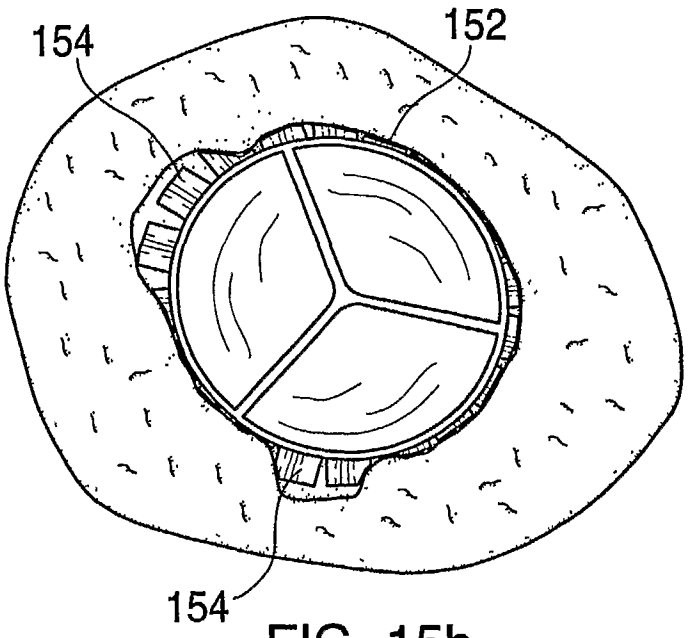


FIG. 15b



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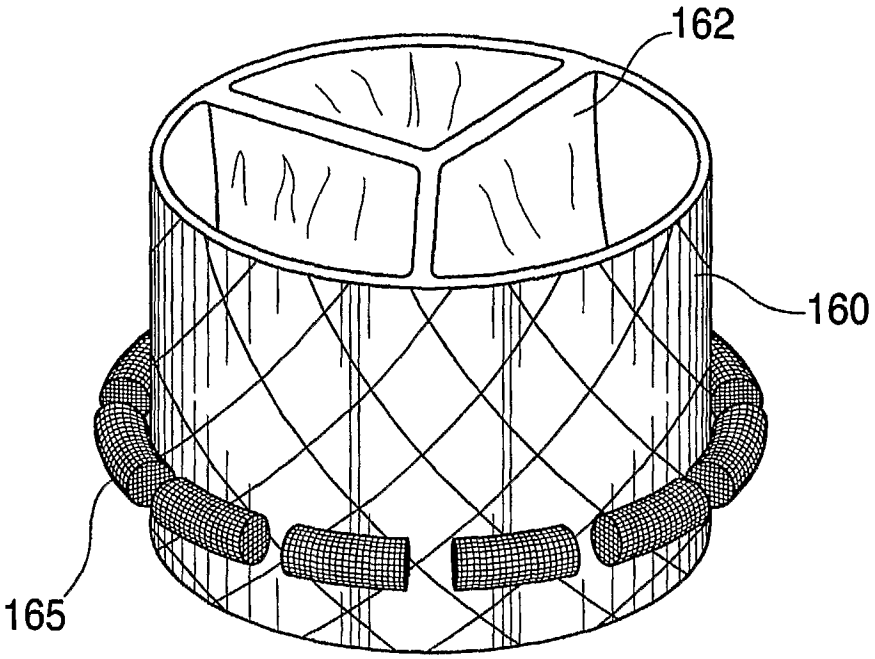


FIG. 16a

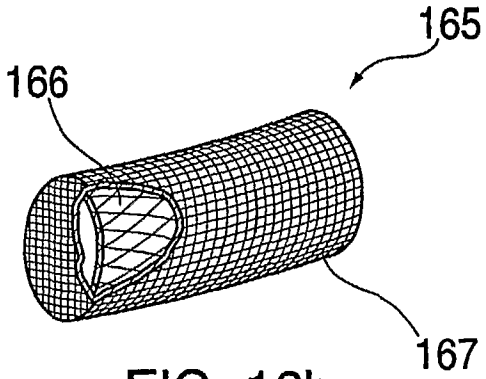


FIG. 16b



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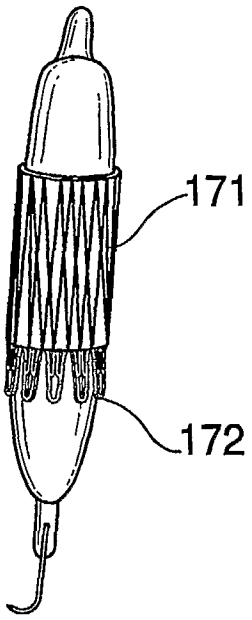


FIG. 17a

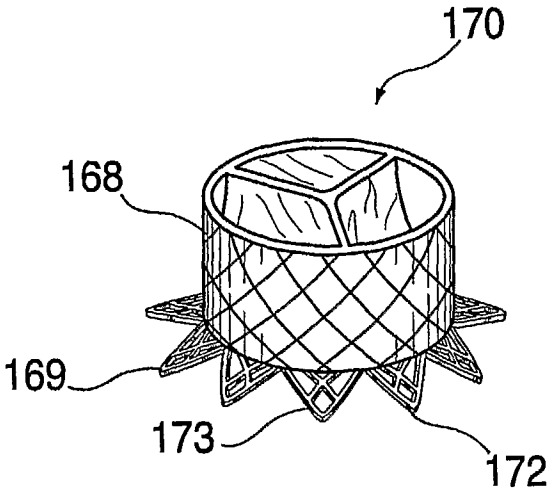


FIG. 17b

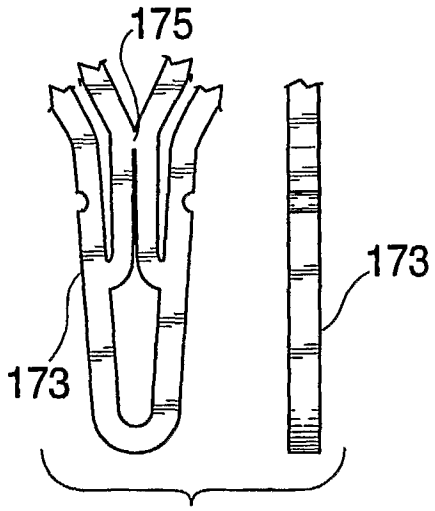


FIG. 17c

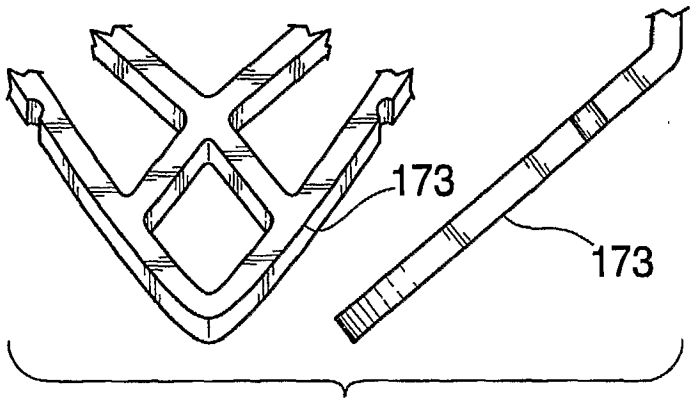


FIG. 17d

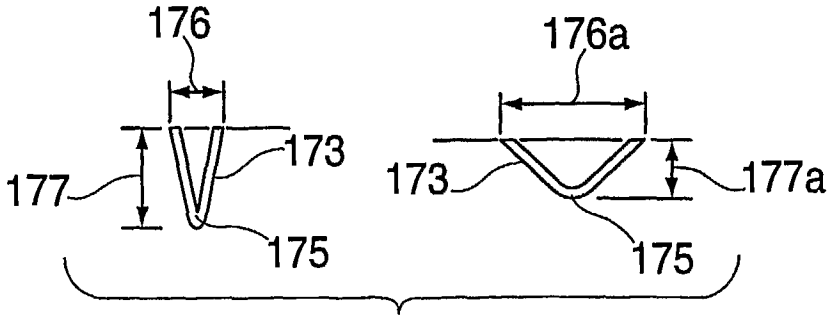


FIG. 17e



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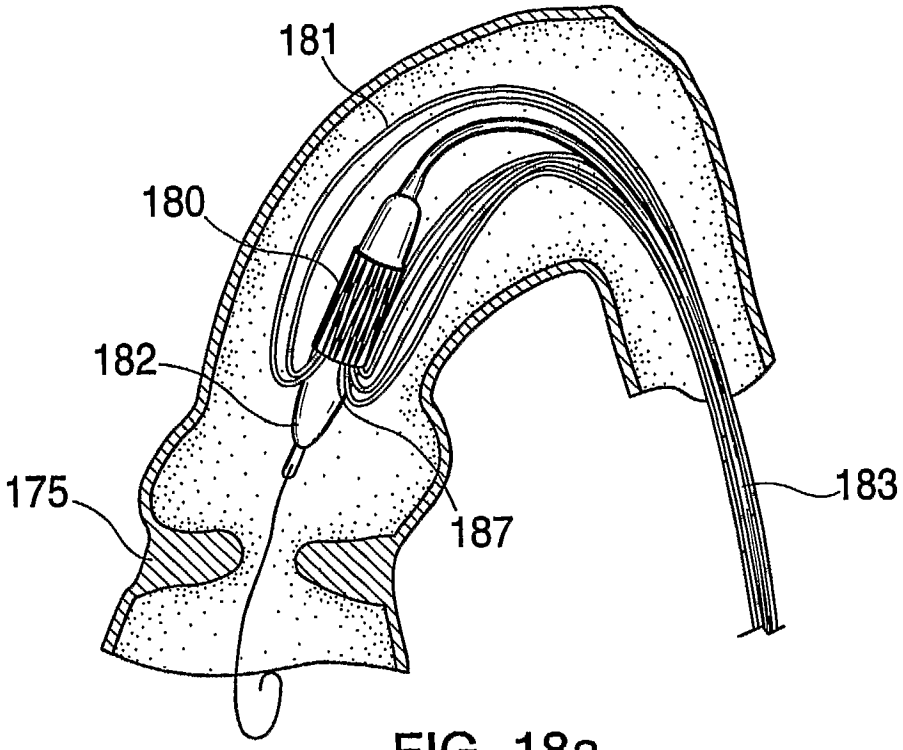


FIG. 18a

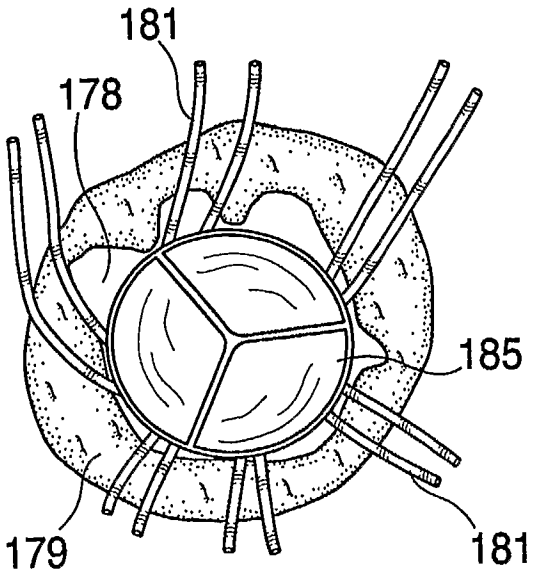


FIG. 18c

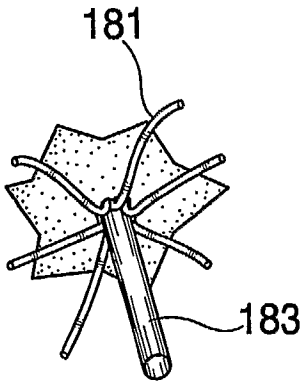


FIG. 18b



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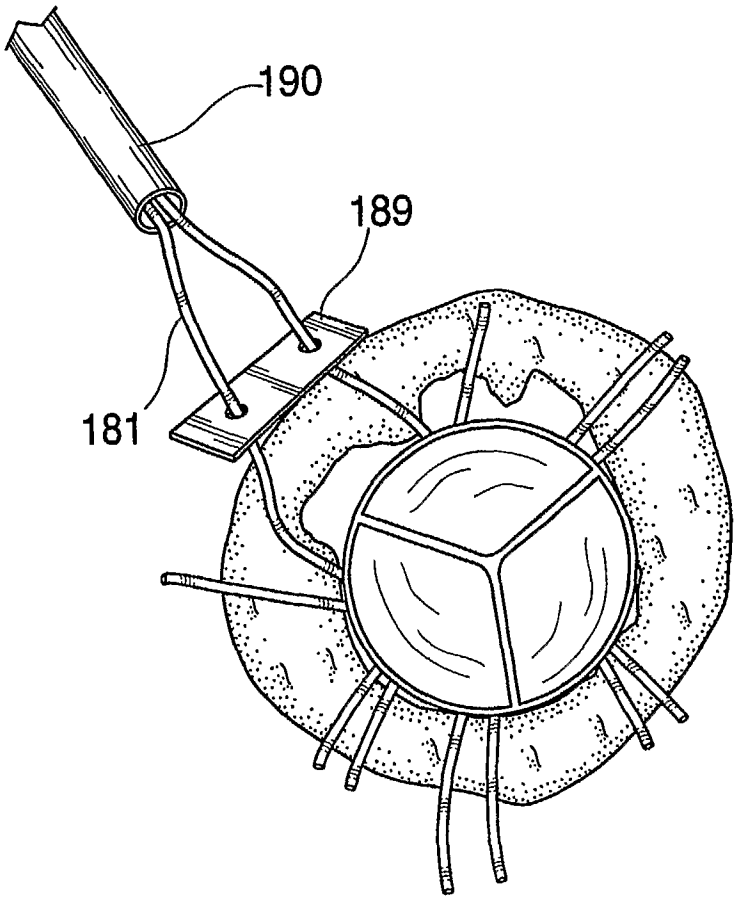


FIG. 18d

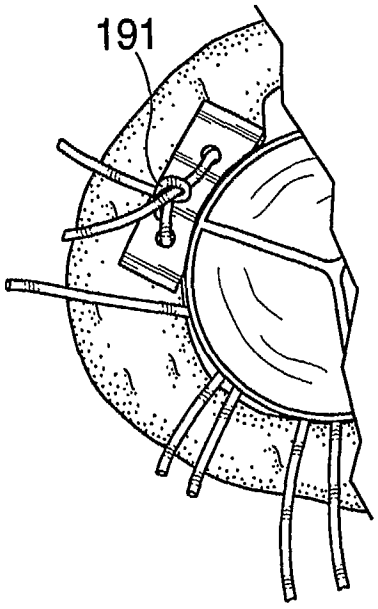


FIG. 18e



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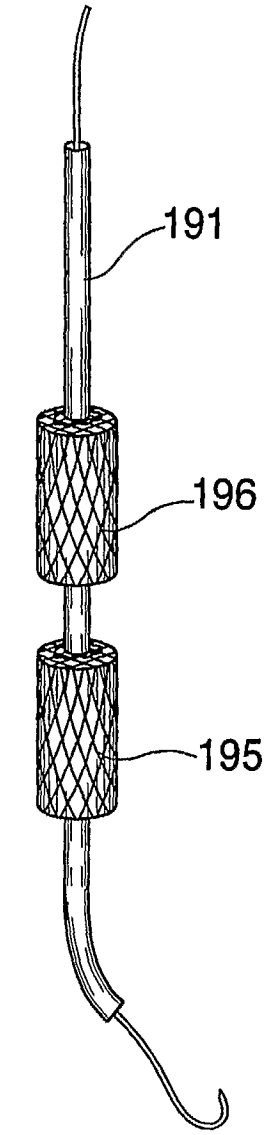


FIG. 19a

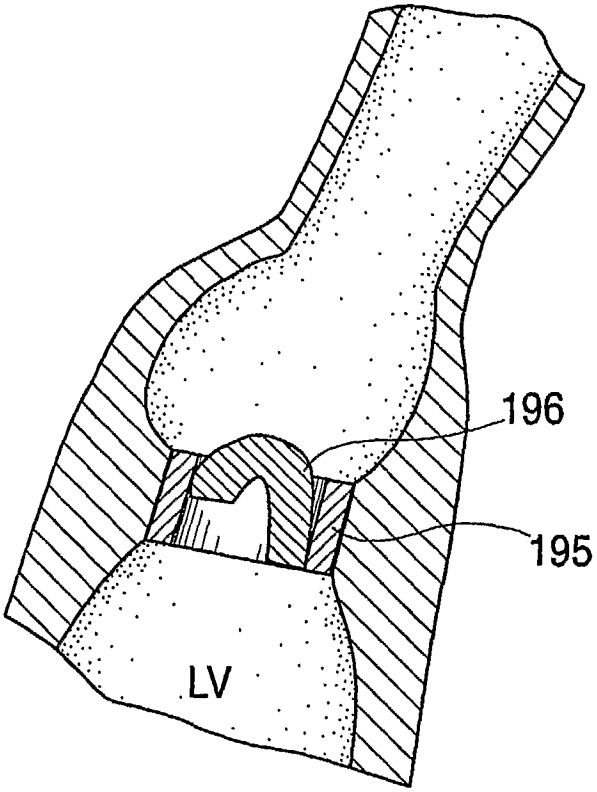


FIG. 19b

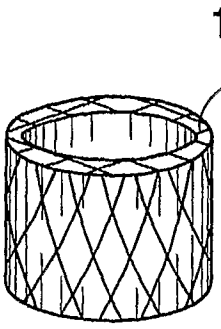


FIG. 19c

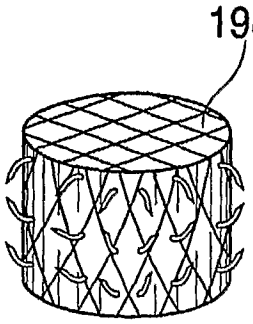


FIG. 19d



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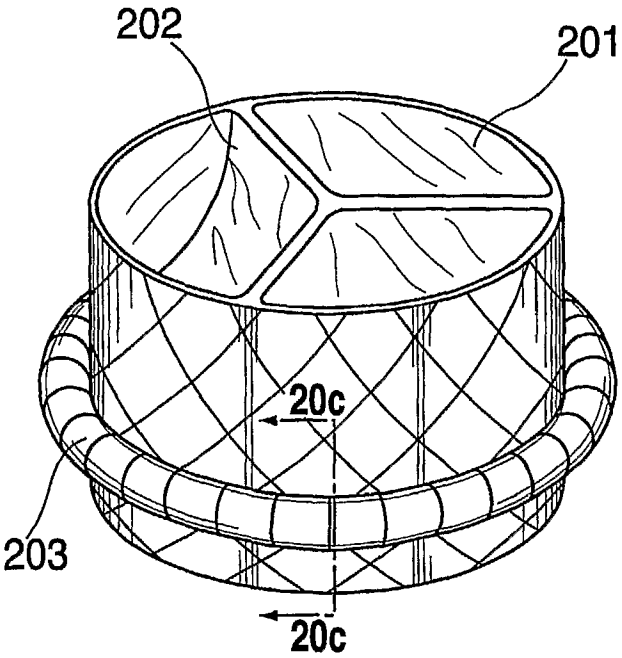


FIG. 20a

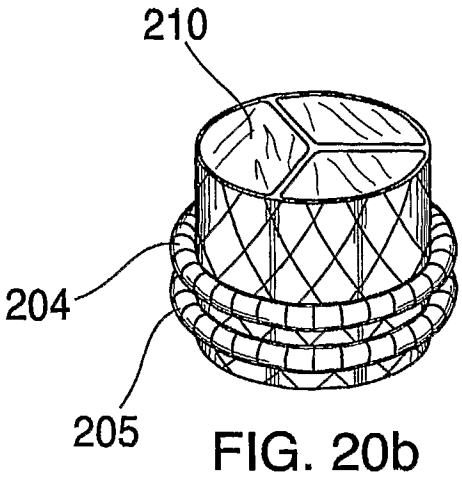


FIG. 20b

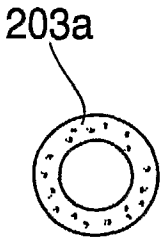


FIG. 20c

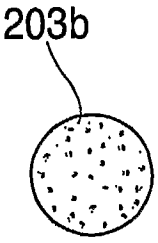


FIG. 20d

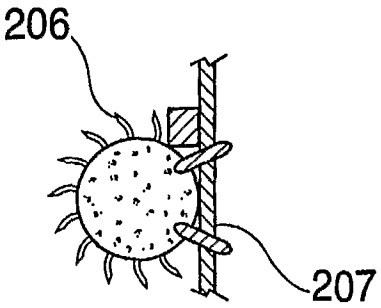


FIG. 20e

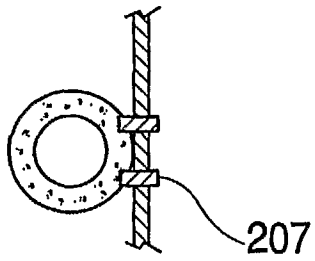


FIG. 20f

FIG. 20g



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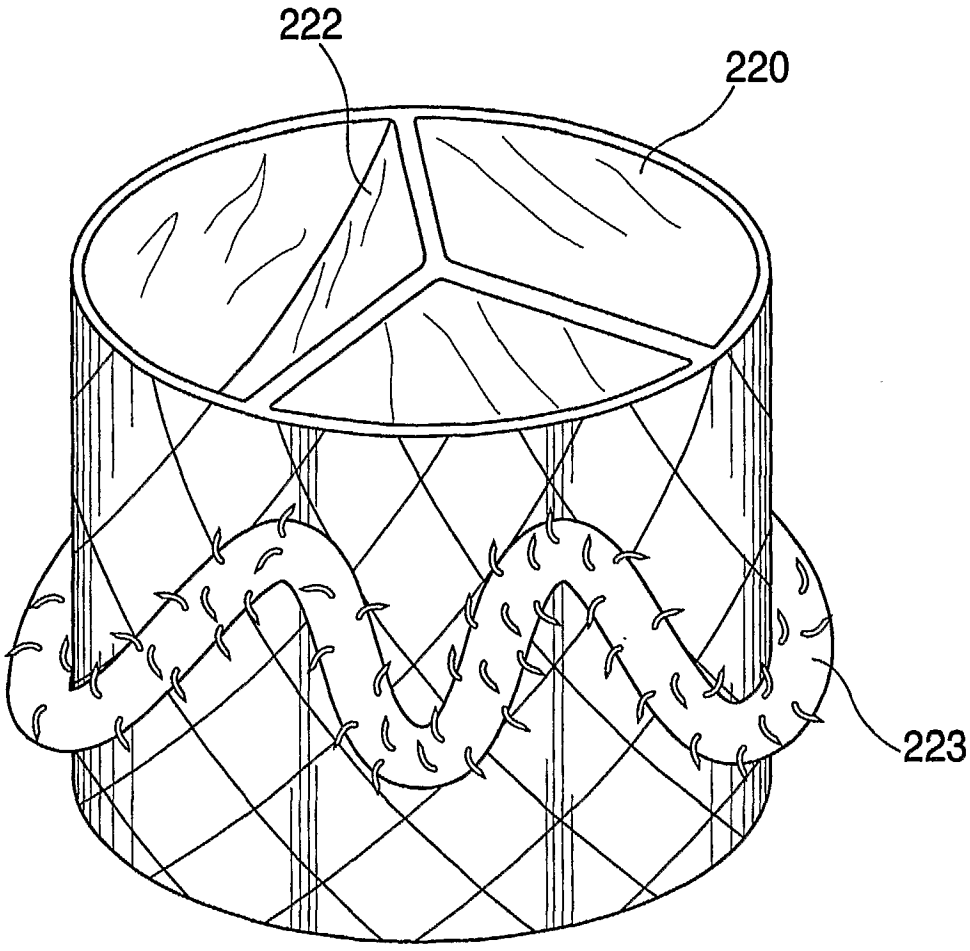


FIG. 21



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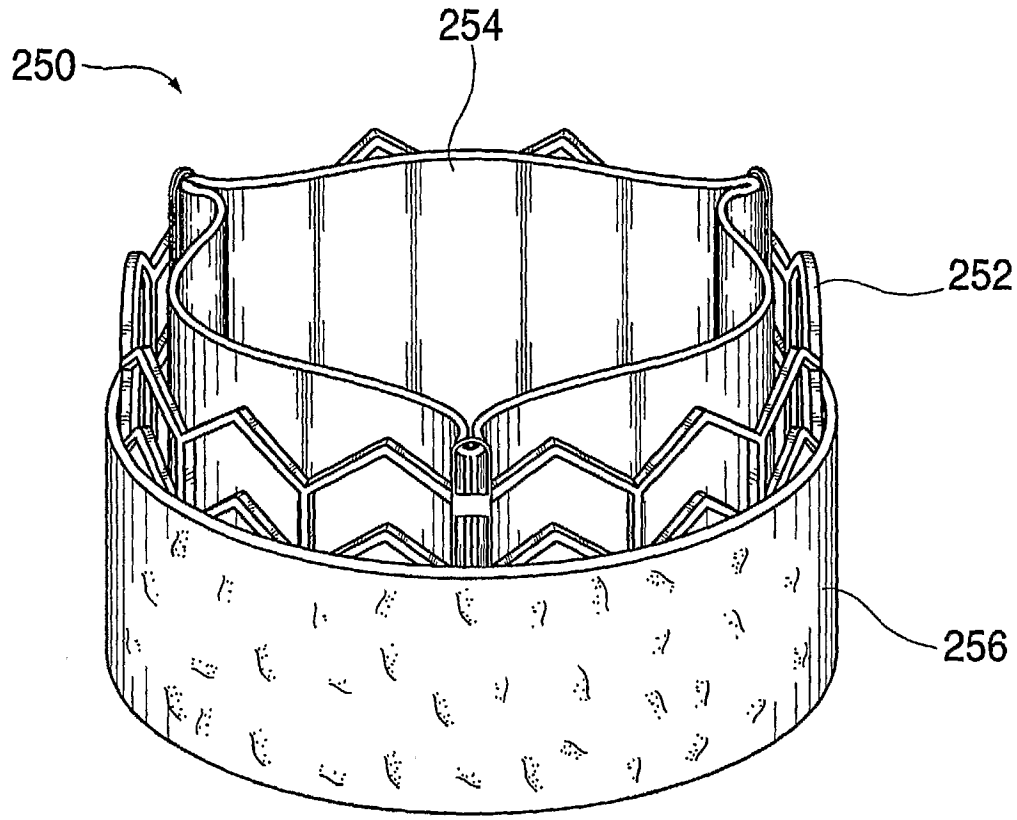


FIG. 22



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# Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

| | |
|---|---|
| Submission number | 7741002 |
| Application number | EP15180327.7 |
| Date of receipt | 06 August 2019 |
| Receiving Office | European Patent Office, The Hague |
| Your reference | P/14624.EPWD1:RK |
| Applicant | All applicants as on file |
| Documents submitted | package-data.xml<br>epf1038.pdf (1 p.)<br>ep-sfd-request.xml<br>DESC-1.pdf\19.08.06 - Amended specification (manuscript changes).pdf (27 p.) |
| Submitted by | CN=Rupert Knights 7287 |
| Method of submission | Online |
| Date and time receipt generated | 06 August 2019, 14:41 (CEST) |
| Message Digest | AF:0B:FD:56:08:B1:22:04:58:F6:C0:54:F0:63:68:B9:D7:A0:F8:80 |

**Correction by the EPO of errors in debit instructions filed by eOLF**
Errors in debit instructions filed by eOLF that are caused by the editing of Form 1038E entries or the continued use of outdated software (all forms) may be corrected automatically by the EPO, leaving the payment date unchanged (see decision T 152/82, OJ EPO 1984, 301 and point 6.3 ff ADA, Supplement to OJ EPO 10/2007).

/European Patent Office/

**Claims**

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) 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;

characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

RMK 17/5/19

# PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

## FIELD OF THE INVENTION

[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

[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.

[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 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 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 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, 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 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 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, "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 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 transceptal hole and 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 bring comprised of a deployable construction 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 bring provided with a plurality of longitudinally rigid support beams 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, 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 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 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 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 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 location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself.

Further prior art arrangements are known from US 5258023, US 4106129, WO 00/64380 and FR 2815844.

## SUMMARY OF THE INVENTION

[0015] In accordance with a preferred embodiment of the present invention, there is provided a prosthetic valve for percutaneous implantation in a body channel as recited by Claim 1.

The sleeve preferably surrounds an inflow end of the stent structure.

The compressible material may have a thickness ranging from 1 to 5mm.

The compressible material may comprise a cloth or fabric.

A tissue growth factor may be disposed along the compressible material. 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.

The fibers may be straight, curved or hook-shaped.

The compressible material is preferably configured to expand into the gaps.

The compressible material may be configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

## 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 creating a paravalvular leak and a device 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 guidewires 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 designed to identify paravalvular leaks around an implanted valve.

[0067] Figures 4a to 4c depict the process of inserting a sealing stent over a guidewire to close a paravalvular leak.

[0068] Figures 5a to 5d depict several types of sealing stents

[0069] Figures 6a to 6d illustrate blocking a paravalvular leak with a sealing device assisted by anchors, which attach the device to the aortic wall (or annulus).

[0070] Figure 7 illustrates an anchoring apparatus 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).

[0071] Figures 8a and 8b depict a leak repair done using a two-component biological glue.

[0072] Figures 9a to 9c depict a leak repair done, using an ultra-violet light-cured biological glue.

[0073] Figure 10 illustrates a catheter that inserts a two-component biological glue into a balloon in order to block a paravalvular leak.

[0074] Figures 11a to 11f illustrate a device and procedure for blocking a paravalvular leak using two connected sealing stents.

[0075] Figures 12 depicts a valve with a built-in inflatable 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 having a flexible and self-expanding portion for blocking possible leaks around the stent.

[0077] Figures 14a to 14c illustrate a valve having a having a flexible and self-expanding portion for blocking possible leaks around the stent..

[0078] Figures 15a to 15c illustrate a valve 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 comprising an additional portion for blocking possible leaks around the stent.

[0080] Figures 17a to 17e illustrate a valve device where the stent is adapted such that when expanded, a portion of the stent is forced to protrude radially, thereby blocking possible leaks.

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

[0082] Figures 19a to 19d depict a 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, having a sealing element made of a flexible and expandable material for blocking leaks around the stent.

**[0084]** Figure 21 illustrates a valve device, wherein the sealing element is attached to the valve in a sealing line for providing an improved crimped profile.

**[0085]** Figure 22 illustrates a valve device, in accordance with an 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

**[0086]** The present invention provides 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.

**[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.

**[0090]** A 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 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.

**[00114]** Figure 1 illustrates a simple leak detector 27 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.

**[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 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 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. 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, 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 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.

**[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, 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 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 a balloon-expandable sealing stent (such as that used in Figure 4b). 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). 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 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.

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 guide wire 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.

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 caused by cavity 24.

**[00126]** Figures 10a to 10e illustrate another apparatus for repairing a paravalvular leak using a bi-component adhesive material. Figure 10a shows a multiple-lumen catheter 100 that can be slid over guidewire 99 to 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 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 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 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.

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).

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.

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 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 blood, causing it to swell and seal the cavity.

**[00130]** Figures 13a to 13d depict a valve adapted to seal paravalvular leaks.

Figure 13a depicts an implantable valve 124. Stent 125 has a sealing component 126 connected to its inlet. Sealing 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. 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.

**[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 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 leaks.

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 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 paravalvular leaks.

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 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.

**[00135]** Figures 16a to 16c depict a valve adapted to seal paravalvular leaks

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 Figure 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 (polyethylene terephthalate) mesh 167 or other impermeable material.

**[00136]** Figures 17a to 17e depict a valve adapted to seal paravalvular leaks

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 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 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. 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 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 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 Figure 18a percutaneous valve 180 crimped on balloon 182 is shown being advanced toward the stenotic 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 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).

**[00140]** Figures 19a to19d depict a valve adapted to include means for sealing paravalvular leaks. 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 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 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 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 structure 202 along an interior region and a mechanism along an exterior region for sealing paravalvular leaks.

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 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. 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 a stented valve 250 in accordance with the invention 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 extends entirely around the stent structure 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. The compressible material 256 resembles 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 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, the hydrogel absorbs fluids from the blood and expands to the 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 expedients known to those skilled in the art or disclosed herein, may be employed without departing from the scope of the appended claims.

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# Letter accompanying subsequently filed items

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The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

| | |
|---|---|
| Application number | 15180327.7 |
| Applicant's or representative's reference | P/14624.EPWD1:RK |

| | Description of document | Original file name | Assigned file name |
|---|---|---|---|
| 1 | Amended description (clean copy) | 19.08.06 - Amended specification (manuscript changes).pdf | DESC-1.pdf |

| | Payment | |
|---|---|---|
| 1 | Method of payment | Not specified |

**Annotations**

Replacement specification(Rupert Knights; 06.08.2019)
1. Remark(Annotate)
In response to the communication dated 6 June 2019, we provide a complete replacement specification, including both description and claims, to replace the amended specification presented at the oral proceedings on 17 May 2019.

**Signatures**

| | |
|---|---|
| Place: | **Watford, UK** |
| Date: | **06 August 2019** |
| Signed by: | **Rupert Knights 7287** |
| Association: | **Dolleymores** |
| Representative name: | **Rupert Knights** |
| Capacity: | **(Representative)** |



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## Opening

The chairman opened the oral proceedings at 9h00. The applicant confirmed the requests filed in the written procedure i.e, a main request and a first auxiliary request.

## Amendments (Art. 123(2) EPC)

The chairman opened the discussion with the topic of amendments in the main request. The first member repeated her arguments from the written procedure against the allowability of claims 9-11 of the main requests for reasons of added subject-matter. The applicant presented his arguments claiming that there is sufficient basis for claims 9-10 in fig. 22 and in the general part of the description.

At 9h31 the chairman interrupted the oral proceedings for deliberation of the examining division.

At 9h45 the oral proceedings were resumed and the chairman announced the opinion of the examining division that claims 9-11 of the main request do not fulfill the requirements of Art. 123(2) EPC since the subject-matter of said claims is not directly and unambiguously disclosed in the application as filed. The chairman pointed out that this also applies to claim 1 of auxiliary request 1 since that claim contains the subject-matter of claim 10 from the main request.

## Novelty (Art. 54 EPC)

Next topic for discussion was novelty of claim 1 of the main request. The applicant handed out excerpts from the Concise Oxford Dictionary of Current English as support for claim 1 being novel over D3. The applicant argued that D3 discloses neither three valve leaflets nor a compressible material forming a sleeve and that claim 1 of the main request therefore should be considered novel over D3. Specifically the applicant argued that the gasket in D3 cannot be interpreted as a sleeve. The first member presented her arguments against novelty of claim 1 over D3.

At 10:05 the chairman interrupted the oral proceedings for deliberation of the examining division.

At 10:23 the oral proceedings were resumed and the chairman announced the opinion of the examining division that claim 1 of the main request is not considered novel over D3.

## Auxiliary request 2



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The applicant then filed an auxiliary request 2 wherein the subject-matter of claim 7 had been incorporated in the new claim 1 and wherein claims 9-11 had been removed and the subsequent claims had been renumbered. The examining division studied the new auxiliary request 2 and concluded that it would be allowable.

## Description

The applicant and the division then discussed what amendments of the description would be necessary for the application to be in order for grant. The applicant amended the description accordingly and filed a hand-written version. The applicant was requested to file a typed clean copy of the amendments within a defined time limit.

## Closing

The applicant confirmed that he maintains all three requests (main, first and second).

The chairman announced the examining division's decision that the main request and auxiliary request 1 are not allowable but that auxiliary request 2 is allowable since it fulfills the requirements of the EPC. At 11h02 the chairman closed the oral proceedings.



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Application No. : 15 180 327.7

**Minutes of the oral proceedings before the EXAMINING DIVISION**

The proceedings were not public.

**Proceedings opened** on 17.05.2019 at 09:00 hours

**Examining Division:**

| | |
|---|---|
| Chairman: | Franz, Volker |
| 1st member: | Steiner, Bronwen |
| 2nd member: | Enborg, Andreas |
| Minute writer: | Enborg, Andreas |

**Present as/for the applicant/s:**

Rupert Knights as authorised representative.

The identity of the person/s present and, where necessary, the authorisation to represent/authority to act were checked.

Essentials of the oral proceedings and relevant statements of the applicant/s:



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The chairman informed the applicant/s as follows:

The applicant/s is/are given a **period of 2 month(s)** to:

The applicant is invited to file a clean copy of the amendments made during the oral proceedings within the given time limit in accordance with Guidelines E-II 8.7.2(b).

After deliberation of the examining division, the chairman announced the following **decision** :

**Main request and first auxiliary request are not allowable.**
**The second auxiliary request is allowable.**

Regarding the reasons for the decision, the chairman referred to:

Main request and first auxiliary request are not allowable since they do not fulfill the requirements of A. 123(2) and A. 54 EPC.

The party/parties was/were informed that the minutes of the oral proceedings and a written decision (including an indication of the possibility of appeal) will be notified to him/them as soon as possible.

The chairman **closed the proceedings** on 17.05.2019 at 11:02 hours.

signed:

Franz, Volker
. . . . . .
Chairman

signed:

Enborg, Andreas
. . . . . .
Minute Writer

Enclosure(s):
Excerpt from the Concise Oxford Dictionary of Current English, Auxiliary request 2, Amended description



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Page 2040 - 2079
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

The chairman informed the applicant/s as follows:

The applicant/s is/are given a period of **2 month(s)** to:

The applicant is invited to file a clean copy of the amendments made during the oral proceedings within the given time limit in accordance with Guidelines E-II 8.7.2(b).

After deliberation of the examining division, the chairman announced the following **decision**:

**Main request and first auxiliary request are not allowable.**
**The second auxiliary request is allowable.**

Regarding the reasons for the decision, the chairman referred to:

Main request and first auxiliary request are not allowable since they do not fulfill the requirements of A. 123(2) and A. 54 EPC.

The applicants were informed that the minutes of the oral proceedings and a written decision (including an indication of the possibility of appeal) will be notified to him/them as soon as possible.

The chairman **closed the proceedings** on 17.05.2019 at 11:02 hours.

Franz, Volker
Chairman

Enborg, Andreas
Minute Writer

Annex(es):
Excerpt from the Concise Oxford Dictionary of Current English, Auxiliary request 2, Amended description



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| Application No. | Ref. | Date |
|---|---|---|
| 15 180 327.7 - 1122 | P/14624EPWD1:RK | 06.06.2019 |
| Applicant: Edwards Lifesciences PVT, Inc. | | |

**Provision of a copy of the minutes in accordance with Rule 124(4) EPC**

The attached copy of the minutes of the oral proceedings is sent to you in accordance with Rule 124(4) EPC.

You are invited to file observations and to correct the deficiencies indicated within a period

**of 2 months**

from the notification of this communication, this period being computed in accordance with Rules 126(2), 131(2) and (4) EPC.

**Failure to comply with this invitation in due time will result in the European patent application being deemed to be withdrawn (Art. 94(4) EPC).**

Sulis, Elisabetta
**For the Examining Division**
Tel. No.: +49 89 2399 - 7922

Enclosure(s): Copy of the minutes (Form 2009)

**Registered Letter**
EPO Form 2042 12.07TRI

The examiner and applicant briefly discussed the applicant's submissions in preparation for the scheduled oral proceedings.

The examiner raised a new objection with respect to Article 123(2) EPC which applies to the claims of the main request and auxiliary request. The features of claims 9 - 11 of the main request appear to have been taken from the first anti-leakage embodiment discussed in the description. The details of this embodiment are found in paragraphs 118 - 127 and figures 4a - 11f. These devices are constructed to seal a leak in a cavity between a previously implanted prosthetic valve and the native heart tissue.

The current claim 1 of the main request finds its support in the rather different device of paragraphs 144 and 145 and figure 22 which is a prosthetic valve with a sealing element surrounding the valve frame and it is not appropriate to combine the features of these two separate embodiments.

As claim 1 of the auxiliary request is based on claims 1 and 10 of the main request, this claim does not fulfil the requirements of Article 123(2) EPC.

The points made in the summons to oral proceedings are still considered valid.

The applicant is welcome to contact the examiner to discuss these points further.



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| Application No. | Ref. | Date |
|---|---|---|
| 15 180 327.7 - 1122 | P/14624EPWD1:RK | 07.05.2019 |
| Applicant<br>Edwards Lifesciences PVT, Inc. | | |

**Result of consultation**

A copy of the result of consultation of 25.04.2019 is enclosed for your information.

Steiner, Bronwen
**For the Examining Division**

Enclosure(s): Copy of result of consultation (Form 2036)

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Application No. : 15 180 327.7

**Consultation by telephone with the applicant / representative**

Despatch for information

**Participants**

Applicant: Edwards Lifesciences PVT, Inc.

Representative: Dolleymores

Member(s) of the Examining Division: Steiner, Bronwen

**Result of consultation**

See Separate Sheet

25.04.2019
. . . . . .
Date

Steiner, Bronwen
. . . . . .
Examiner

Enclosure(s):



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Europäisches Patentamt
European Patent Office
Office européen des brevets

# Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

| | |
|---|---|
| Submission number | 7385434 |
| Application number | EP15180327.7 |
| Date of receipt | 15 April 2019 |
| Receiving Office | European Patent Office, The Hague |
| Your reference | P/14624EPWD1:RK |
| Applicant | All applicants as on file |
| Documents submitted | package-data.xml<br>epf1038.pdf (1 p.)<br>CLMS-1.pdf\19.04.15 - Main request (clean).pdf (2 p.)<br>CLMS-2.pdf\19.04.15 - Auxiliary request 1 (clean).pdf (2 p.)<br>ep-sfd-request.xml<br>ORAL-1.pdf\19.04.15 - EPO.pdf (3 p.)<br>CLMS-HWA-1.pdf\19.04.15 - Main request (marked).pdf (2 p.)<br>CLMS-HWA-2.pdf\19.04.15 - Auxiliary request 1 (marked).pdf (2 p.) |
| Submitted by | CN=Philippa Eke 7284 |
| Method of submission | Online |
| Date and time receipt generated | 15 April 2019, 13:18 (CEST) |
| Message Digest | CE:B1:37:D5:F2:F8:9E:58:91:34:BC:93:2A:97:CE:E7:63:08:02:C1 |

**Correction by the EPO of errors in debit instructions filed by eOLF**

Errors in debit instructions filed by eOLF that are caused by the editing of Form 1038E entries or the continued use of outdated software (all forms) may be corrected automatically by the EPO, leaving the payment date unchanged (see decision T 152/82, OJ EPO 1984, 301 and point 6.3 ff ADA, Supplement to OJ EPO 10/2007).

/European Patent Office/

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

AUXILIARY REQUEST 1

**Claims**

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) 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;

characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material is polyurethane or polyethylene terephthalate, and wherein the stent is configured to be held in place in the cavity by friction.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve as claimed in any preceding claim, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

8. The prosthetic valve of Claim 7, wherein the fibers are straight, curved or hook-shaped.

9. The prosthetic valve of any of the previous claims, wherein the stent is comprised of shape memory material, preferably nitinol.

~~10. The prosthetic valve of any of the previous claims, wherein the stent is held in place in the cavity by friction.~~

~~11~~10. The prosthetic valve of any of the previous claims, wherein the compressible material is a fluid impermeable membrane ~~covering at least one end of the stent~~.

~~12~~11. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

~~13~~12. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

MAIN REQUEST

## Claims

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) 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;

characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material is polyurethane or polyethylene terephthalate.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

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AUXILIARY REQUEST 1

**Claims**

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) 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;

characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material is polyurethane or polyethylene terephthalate, and wherein the stent is configured to be held in place in the cavity by friction.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

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9. The prosthetic valve of any of the previous claims, wherein the stent is comprised of shape memory material, preferably nitinol.

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11. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

12. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

MAIN REQUEST

## Claims

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

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# Letter accompanying subsequently filed items


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The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

| | |
|---|---|
| Application number | 15180327.7 |
| Applicant's or representative's reference | P/14624EPWD1:RK |

| | Description of document | Original file name | Assigned file name |
|---|---|---|---|
| 1 | Letter dealing with Oral proceedings | 19.04.15 - EPO.pdf | ORAL-1.pdf |
| 2 | Amended claims (clean copy) | 19.04.15 - Main request (clean).pdf | CLMS-1.pdf |
| 3 | Amended claims with annotations | 19.04.15 - Main request (marked).pdf | CLMS-HWA-1.pdf |
| 4 | Amended claims (clean copy) | 19.04.15 - Auxiliary request 1 (clean).pdf | CLMS-2.pdf |
| 5 | Amended claims with annotations | 19.04.15 - Auxiliary request 1 (marked).pdf | CLMS-HWA-2.pdf |

| | Payment | |
|---|---|---|
| 1 | Method of payment | Not specified |

**Signatures**

| | |
|---|---|
| Place: | **Watford, UK** |
| Date: | **15 April 2019** |
| Signed by: | **Philippa Eke 7284** |
| Association: | **Dolleymores** |
| Representative name: | **EKE, Philippa Dianne** |
| Capacity: | **(Representative)** |




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**BY E-MAIL ONLY**

15 April 2019

**Your Ref:**

**Our Ref:**
P/14624.EPWD1:RK:
SD

Dear Sirs

**European Patent Application No. 15180327.7**
**Edwards Lifesciences PVT, Inc.**

This letter is in response to the summons to oral proceedings dated 14 January 2019. We enclose a main request and a first auxiliary request as detailed below.

**Request to continue proceedings in writing**

In the event the Examining Division finds merit in the arguments/amendments presented below, it is respectfully requested that the oral proceedings are cancelled and proceedings are continued in writing.

If cancellation of the oral proceedings on this basis is not deemed possible, we shall attend the oral proceedings.

**Main request**

As a main request, we request patent grant on the basis of the claims filed with our response of 31 January 2018 but with amendment to Claim 11 to address the clarity objection (by deletion of the wording "covering at least one end of the stent"). We strongly maintain that Claim 1 is both new and inventive over the cited prior art. We maintain all previous arguments.

To supplement the arguments presented with our response of 31 January 2018, and in consideration of the comments at point 4 of the summons, we note as follows:

In the context of novelty, it is not relevant whether the wording "gasket" in D3 does not preclude the device from being a sleeve. (Although we assert that the term gasket does preclude a sleeve). The fact remains that a sleeve is not disclosed in D3. An analogy can be made to the situation that something is stated only as being coloured. It does not preclude it being red but there is no disclosure of it being red. There must be novelty for this reason alone.

Claim 1 is, moreover, inventive, as detailed in the response of 31 January 2018.

**Auxiliary request 1**

Claim 1 of the main request is amended to include the features of Claim 10 and now specifies "the stent is configured to be held in place in the cavity by friction".

It is noted that no objection is raised against the novelty of Claim 10. Claim 1 as amended is rightly novel over D3, which is focussed on the provision of fingers for securing the band of D3 to a tissue annulus. The band of D3 is not held in place by friction.

The provision of figures is of fundamental importance to the teaching of D3. Fingers are essential in D3. See, for example, Claim 1 and summary of invention on page 3. Note also that fingers (130, 330, 530, 730, 930, 1130, 1230, 1430) are present in every embodiment.

It is notable that with the small axial length of the "band" 110 and the fact that the band 110 is arranged to engage only a thin tissue lip that remains after a native valve has been removed (see, for example, page 1, lines 5 to 8, page 6, lines 13 to 15 and Figures 2, 4, 8 and 10) an arrangement reliant on friction, without the expressly taught fingers, would not be viable. Moreover, it would go directly against the express teaching of D3, which requires fingers as an essential feature.

The features of a frictional fit and a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure have a unique synergistic effect.

There is nothing to obstruct/interrupt the sealing by the sleeve – there is no gap in the sealing by outwardly projecting fingers or other anchoring means - sealing may occur along the axial length of the sleeve, wherein there is thereby more material present to fill gaps created between the stent and the native valve annulus.

The objective technical problem to be solved may therefore be considered to be how to improve sealing reliability in a percutaneously delivered valve.

Starting from D3 and looking to solve the objective technical problem, there is nothing to lead the skilled person to the arrangement of Claim 1, without an inventive step. Any assertion to the contrary must be the result of unallowable ex-post facto analysis.

D3 provides no pointer to the solution of Claim 1, rather it teaches against the solution of the present invention by the expressly required fingers for anchoring the valve to the narrow tissue annulus.

In this regard, it must be borne in mind that the ultimate question with inventive step is not whether the skilled person could arrive at the present invention by modifying the closest prior art, but whether they **would have done** so because the prior art incited them to do so. There is clearly no such incitement in D3, particularly in light of the direct contrary teachings.

For the skilled person to arrive at the invention of Claim 1 starting from D3 they would necessarily have to go against the express teachings of D3, this is something they simply will not do without unallowable ex-post facto analysis.

Claim 1 is new and inventive over D3.



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**Further claim requests**

We respectfully request the opportunity (under the examining division's discretion) to amend the claim requests and/or introduce additional claim requests during the oral proceedings should any objection be maintained against the above claim requests and discussions lead to such amendments or additions appearing likely to lead to a positive conclusion.

Yours faithfully

[signed electronically]

KNIGHTS, Rupert Andrew
European Patent Attorney
Dolleymores

Enc. Main request
Auxiliary request



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102

21 Jan. 2019

| Date |
|---|
| 14-01-2019 |

| Reference | Application No./Patent No. |
|---|---|
| P/14624EPWD1:RK | 15180327.7 - 1122 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

EPA/EPO/OEB Formblatt/Form/Formulaire : 2008, 2906

**Empfangsbescheinigung über den Zugang des vorstehend bezeichneten Schriftstücks**
**Acknowledgement of receipt of the document specified above**
**Récépissé du document spécifié ci-dessus**

Unter Bezugnahme auf die Mitteilung im ABl EPA 7/2010, 377 wird gebeten, die Empfangsbescheinigung mit Empfangsdatum und Unterschrift zu versehen und **umgehend** an das EPA zurückzusenden:

With reference to the Notice in OJ EPO 7/2010, 377, you are requested to date and sign the acknowledgement of receipt and return it to the EPO **immediately**:

Conformément au communiqué paru au JO OEB 7/2010, 377, vous êtes prié d'indiquer sur le récépissé la date de réception du document, de signer le récépissé et de le renvoyer **sans délai** à l' OEB:

- **über die Online-Dienste des EPA** (als Anlage zu EPA Form 1038) / **through EPO Online Services** (as annex to EPO Form 1038) / **par les services en ligne de l'OEB** (en tant que pièce jointe au formulaire OEB 1038),
- **per Fax / by fax / par téléfax (+49 (0) 89 2399-4465 or +31 (0) 70 340-3016)**
- oder per Post / or by post / ou par courrier.

Empfangen am / Received on / Reçu le:
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Unterschrift / Signature:
RECEIVED 18 JAN 2019

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le destinataire ou la personne dûment mandatée

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| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

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- **per Fax / by fax / par téléfax (+49 (0) 89 2399-4465 or +31 (0) 70 340-3016)**
- oder per Post / or by post / ou par courrier.

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DEUTSCHLAND

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EPA/EPO/OEB Form 2936 08.10

The examination is being carried out on the **following application documents**

**Description, Pages**

| | | |
|---|---|---|
| 1-4, 14-36 | as originally filed | |
| 37 | filed in electronic form on | 10-08-2016 |
| 5, 6 | filed in electronic form on | 31-01-2018 |

**Claims, Numbers**

| | | |
|---|---|---|
| 1-13 | filed in electronic form on | 31-01-2018 |

**Drawings, Sheets**

| | |
|---|---|
| 1/23-23/23 | as originally filed |

1 Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

D1 US 5 258 023 A (REGER VINCENT A [US]) 2 November 1993 (1993-11-02)

D2 FR 2 337 543 A1 (AMERICAN HOSPITAL SUPPLY CORP [US]) 5 August 1977 (1977-08-05)

D3 WO 00/64380 A1 (ST JUDE MEDICAL CARDIOVASCULAR [US]) 2 November 2000 (2000-11-02)

D4 FR 2 815 844 A1 (SEGUIN JACQUES [FR]) 3 May 2002 (2002-05-03)

D5 EP 2 537 487 A1 (SADRA MEDICAL INC [US]) 26 December 2012 (2012-12-26)



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2 The examining division intends to refuse the application pursuant to Article 97(2) EPC as it does not meet several requirements of the EPC. Therefore, as requested by the applicant, oral proceedings will be held. The topic of the oral proceedings will be the deficiencies of the application as summarised in the following paragraphs.

3 The following features of claim 1 are disclosed in document D3 (references to D3 in parentheses):

A prosthetic valve (figure 1, feature 100) for percutaneous implantation in a body channel, comprising:
a substantially cylindrical stent structure (feature 110) configured for radial expansion (page 6, lines 3 - 15);
a valvular structure (feature 120) 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 (figures 1 and 2; page 5, lines 34 - 36);
characterised by a layer of compressible material, which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel (page 6, line 34 - page 7, line 10) wherein the compressible material is polyurethane or polyethylene terephthalate (page 7, line 8).

Therefore claim 1 does not fulfil the requirements of Article 52(1) EPC as the claim is not novel (Articles 54(1) and (2) EPC).

4 The applicant's arguments have been considered, but the fact that the valve of D3 is, to use the applicants wording, "squatty" does not change the examination divisions' opinion that it is substantially cylindrical. There is no upper or lower limit to the height possible for a cylinder and as neither the device of the application, nor that of D3 have any dimensions specified, they are both considered as being cylinders. Claim 1 does not specify that the cylindrical stent structure will extend beyond the native valve annulus in either direction. Furthermore, the wording "gasket" in D3 does not preclude the device from being a sleeve as the term does not imply any limitations on dimensions. The "gasket" of D3 and the "sleeve" of the claims both function in the same manner, fulfil the same purpose and are even made of the same materials.



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5 The features of the following dependent claims are disclosed in D3: claim 2 (figures 1 and 2), claim 4 (page 7, line 8), claim 9 (page 6, line 14), claim 11 and 12 (page 6, line 34 - page 7, line 10)

6 Claim 11 is not clear (Article 84 EPC) as it claims that one end of the stent is covered, whereas claim 1 has already claimed that that compressible material is disposed along the outer surface of the stent and extends entirely around the stent structure

7 The applicant's attention is drawn to the fact that oral proceedings can be avoided if an allowable set of claims is filed before the end of the time limit. Claim 7, for example, is not disclosed in D3. Alternatively a decision according to the state of the file can be requested (see the Guidelines, C-VI 4.5).



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Date
14-01-2019

| Reference | Application No./Patent No. |
|---|---|
| P/14624EPWD1:RK | 15180327.7 - 1122 / 2982337 |

Applicant/Proprietor
Edwards Lifesciences PVT, Inc.

**Summons to attend oral proceedings pursuant to Rule 115(1) EPC**

You are hereby summoned to attend oral proceedings arranged in connection with the above-mentioned European patent application.

The matters to be discussed are set out in the communication accompanying this summons (EPO Form 2906).

The oral proceedings, which will not be public, will take place before the Examining Division

on 17.05.19 at 09.00 hrs at the EPO,
PschorrHöfe, Bayerstr. 34, 80335 Munich

No changes to the date of the oral proceedings can be made, except on serious grounds (see OJ EPO 2009, 68). If you do not appear as summoned, the oral proceedings may continue without you (R. 115(2) EPC, see also OJ EPO 2008, 471).

Your attention is drawn to Rule 4 EPC, regarding the language of the oral proceedings, and to Special edition No. 3 OJ EPO 2007, L.1, concerning the filing of authorisations for company employees and lawyers acting as representatives before the EPO.

**The final date for making written submissions and/or amendments (R. 116 EPC) is 17.04.19.**

The actual room number as well as the waiting room numbers will be given to you by the porter in the foyer at the above EPO address.

Parking is available in the underground car park, accessible only via the entrance "Grasserstrasse 2/6". On presentation of the summons to oral proceedings at one of the porters' lodges in the PschorrHöfe, the parking ticket will be revoked.

Please note that the oral proceedings will always take place as scheduled unless you are otherwise informed. The EPO will generally not send a reminder or a further communication prior to the date of oral proceedings.

| 1st Examiner: | 2nd Examiner: | Chairman: |
|---|---|---|
| Steiner, Bronwen | Franz, Volker | Lega, Alessandra Mar |

**Registered letter with advice of delivery** to EPO postal service: 07.01.19



Aortic Innovations, LLC, Exhibit 2040
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**For the Examining Division**

Annexes:
Confirmation of receipt (Form 2936)
Communication (EPO Form 2906)


Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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European Patent Office
80298 MUNICH
GERMANY

**Questions about this communication ?**
Contact Customer Services at www.epo.org/contact

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ROYAUME UNI

| Date |
|---|
| 05.10.18 |

| Reference | Application No./Patent No. |
|---|---|
| P/14624EPWD1:RK | 15180327.7 - 1122 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Communication in response to your enquiry received on 19.09.18**

☑ The EPO will be able to supply a communication within 03 month(s).

☐ Having regard to the current workload, the EPO will not be able to supply a communication within the next 12 months.

☐ Reference is made to the telephone consultation that took place on .

If the proposed time frame does not meet your needs, please contact the responsible examiner or the director:

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Name: Williere G
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General information:
If you wish your application to be examined more quickly than the time frame indicated above, your attention is drawn to the possibility of requesting accelerated examination under the "PACE" programme of the EPO (OJ EPO 2015, A93). However, if a request for accelerated examination has already been filed and the application has been removed from the PACE programme, a second request for accelerated examination can no longer be processed (OJ EPO 2015, A93, point 4).

**For the Examining Division**

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# Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

| | | |
|---|---|---|
| Submission number | 6728063 | |
| Application number | EP15180327.7 | |
| Date of receipt | 19 September 2018 | |
| Filing Office | European Patent Office, The Hague | |
| Procedural phase | Examination | |
| Your reference | P/14624.EPWD1 | |
| Documents submitted | package-data.xml<br><br>ep-cms-sfd-request.pdf (1 p.) | ep-cms-sfd-request.xml<br><br>EPLETT-1.pdf\18.09.19 - Form 1012.pdf (1 p.) |
| Submitted by | CN=secure.epoline.org,OU=PDIS,O=European Patent Office,C=NL | |
| Method of submission | Online | |
| Date and time receipt generated | 19 September 2018, 16:34 (CEST) | |
| Message Digest | 9C:D0:61:76:DA:6E:74:61:54:28:C8:15:BD:B5:81:A8:82:7D:E1:65 | |

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# Anfrage zum Bearbeitungsstand der Akte
# Enquiry as to the processing of the file
# Demande de renseignement concernant l'instruction d'un dossier

Hiermit wird angefragt, wann das EPA den (ergänzenden) europäischen Recherchenbericht/den nächsten Bescheid zusenden wird[1]

I/We hereby enquire when the EPO will deliver the (supplementary) European search report/next communication[1]

Nous vous prions de nous indiquer le délai dans lequel l'OEB enverra le rapport (complémentaire) de recherche européenne / la prochaine notification[1]

für die Anmeldung/das Patent
for application/patent
pour la demande/le brevet

EP 15180327.7 (Dolleymores Ref. P/14624.EPWD1:RK)

Ort / Place / Lieu

Watford, Hertfordshire WD18 0JU

Datum / Date

19 September 2018

Unterschrift(en) des (der) Anmelder(s) oder Vertreter(s):
Signature(s) of applicant(s) or representative(s):
Signature(s) du (des) demandeur(s) ou du (des) mandataire(s) :

John Kensett.

KENSETT, John Hinton
Authorised Representative

*Name des (der) Unterzeichneten bitte in Druckschrift wiederholen. Bei juristischen Personen bitte die Stellung des (der) Unterzeichneten innerhalb der Gesellschaft in Druckschrift angeben. / Please print name(s) under signature(s). In the case of legal persons, the position of the signatory within the company should also be printed. / Le ou les noms des signataires doivent être indiqués en caractères d'imprimerie. S'il s'agit d'une personne morale, la position occupée au sein de celle-ci par le ou les signataires doit également être indiquée en caractères d'imprimerie.*

EPA/EPO/OEB 1012 11.16

[1] ABl. EPA 2016, A66 / OJ EPO 2016, A66 / JO OEB 2016, A66

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# Letter accompanying subsequently filed items


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The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

| | |
|---|---|
| Application number and/or EP publication number | EP15180327.7 |
| Reference | P/14624.EPWD1 |
| Procedural phase | Examination |
| Name of represented party | Edwards Lifesciences PVT, Inc. |

| | Description of document | Original file name | Assigned file name |
|---|---|---|---|
| 1 | Letter relating to the search and examination procedure | 18.09.19 - Form 1012.pdf | EPLETT-1.pdf |

**Signature 1**

| | |
|---|---|
| Place: | **Watford, UK** |
| Date: | **19 September 2018** |
| Signed by: | **/Dolleymores/** |
| Association: | **Dolleymores** |
| Capacity: | **Representative 1** |

**Smart card certificate 1**

| | |
|---|---|
| Common name: | **Marie Tatnall 33843** |
| EPO ID: | **33843** |
| Issued by: | **European Patent Office CA G2** |




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# Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

| | |
|---|---|
| Submission number | 6011835 |
| Application number | EP15180327.7 |
| Date of receipt | 31 January 2018 |
| Receiving Office | European Patent Office, The Hague |
| Your reference | P/14624EPWD1RK |
| Applicant | All applicants as on file |
| Documents submitted | package-data.xml<br>epf1038.pdf (1 p.)<br>DESC-HWA-1.pdf\18.01.31 - Amended pages (marked).pdf (2 p.)<br>CLMS-HWA-1.pdf\18.01.31 - Amended claims (marked).pdf (2 p.)<br>ep-sfd-request.xml<br>EXRE3-1.pdf\18.01.31 - EPO.pdf (4 p.)<br>DESC-1.pdf\18.01.31 - Amended pages (clean).pdf (2 p.)<br>CLMS-1.pdf\18.01.31 - Amended claims (clean).pdf (2 p.) |
| Submitted by | CN=Rupert Knights 7287 |
| Method of submission | Online |
| Date and time receipt generated | 31 January 2018, 18:55 (CET) |
| Message Digest | 17:3F:A3:5C:09:76:5D:D3:ED:57:EB:6C:F5:72:B3:E2:AB:C4:68:3C |


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**Correction by the EPO of errors in debit instructions filed by eOLF**

Errors in debit instructions filed by eOLF that are caused by the editing of Form 1038E entries or the continued use of outdated software (all forms) may be corrected automatically by the EPO, leaving the payment date unchanged (see decision T 152/82, OJ EPO 1984, 301 and point 6.3 ff ADA, Supplement to OJ EPO 10/2007).

/European Patent Office/

## Claims

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) 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;

characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material is polyurethane or polyethylene terephthalate.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

~~3. The prosthetic valve of any preceding claim, wherein the compressible material is formed of polyethylene terephthalate.~~

4~~3~~. The prosthetic valve of Claim ~~3~~1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

5~~4~~. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

6~~5~~. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

7~~6~~. The prosthetic valve as claimed in Claim 6~~5~~, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

8~~7~~. The prosthetic valve as claimed in any preceding claim, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

~~9~~8. The prosthetic valve of Claim ~~8~~7, wherein the fibers are straight, curved or hook-shaped.

~~10~~9. The prosthetic valve of any of the previous claims, wherein the stent is comprised of shape memory material, preferably nitinol.

~~11~~10. The prosthetic valve of any of the previous claims, wherein the stent is held in place in the cavity by friction.

~~12~~11. The prosthetic valve of any of the previous claims, wherein the compressible material is a fluid impermeable membrane covering at least one end of the stent.

~~13~~12. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

~~14. The prosthetic valve of any of the previous claims, wherein the compressible material is polyurethane.~~

~~15. The prosthetic valve of any of the previous claims, wherein the compressible material is a sealing ring that comprises a set of flaps.~~

~~16~~13. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Further prior art arrangements are known from US 5258023, US 4106129, WO 00/64380 and FR 2815844.

## SUMMARY OF THE INVENTION

[0015] In accordance with a preferred embodiment of the present invention, there is provided a prosthetic valve for percutaneous implantation in a body channel, comprising: a substantially cylindrical stent structure (252) configured for radial expansion; a valvular structure (254) 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; characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material is polyurethane or polyethylene terephthalate.

The sleeve preferably surrounds an inflow end of the stent structure.

The compressible material may have a thickness ranging from 1 to 5mm.

The compressible material may comprise a cloth or fabric.

A tissue growth factor may be disposed along the compressible material. 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.

The compressible material may include a plurality of fibers extending outward from the outer surface. The fibers may be straight, curved or hook-shaped.

The stent may be comprised of shape memory material, preferably nitinol.

The stent may be held in place in the cavity by friction.

The compressible material may be a fluid impermeable membrane covering at least one end of the stent.

The compressible material is preferably configured to expand into the gaps.

The compressible material may be configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

~~as recited by Claim 1.~~

~~Further, preferred features are presented in the dependent claims.~~

## 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

**page 14 follows**

## Claims

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) 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;

characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material is polyurethane or polyethylene terephthalate.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve as claimed in any preceding claim, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

8. The prosthetic valve of Claim 7, wherein the fibers are straight, curved or hook-shaped.

9. The prosthetic valve of any of the previous claims, wherein the stent is comprised of shape memory material, preferably nitinol.

10. The prosthetic valve of any of the previous claims, wherein the stent is held in place in the cavity by friction.

11. The prosthetic valve of any of the previous claims, wherein the compressible material is a fluid impermeable membrane covering at least one end of the stent.

12. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

13. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Further prior art arrangements are known from US 5258023, US 4106129, WO 00/64380 and FR 2815844.

## SUMMARY OF THE INVENTION

[0015] In accordance with a preferred embodiment of the present invention, there is provided a prosthetic valve for percutaneous implantation in a body channel, comprising: a substantially cylindrical stent structure (252) configured for radial expansion; a valvular structure (254) 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; characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material is polyurethane or polyethylene terephthalate.

The sleeve preferably surrounds an inflow end of the stent structure.

The compressible material may have a thickness ranging from 1 to 5mm.

The compressible material may comprise a cloth or fabric.

A tissue growth factor may be disposed along the compressible material. 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.

The compressible material may include a plurality of fibers extending outward from the outer surface. The fibers may be straight, curved or hook-shaped.

The stent may be comprised of shape memory material, preferably nitinol.

The stent may be held in place in the cavity by friction.

The compressible material may be a fluid impermeable membrane covering at least one end of the stent.

The compressible material is preferably configured to expand into the gaps.

The compressible material may be configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

## 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

**page 14 follows**

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# Letter accompanying subsequently filed items


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The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

| | |
|---|---|
| Application number | 15180327.7 |
| Applicant's or representative's reference | P/14624EPWD1RK |

| | Description of document | Original file name | Assigned file name |
|---|---|---|---|
| 1 | Reply to examination report | 18.01.31 - EPO.pdf | EXRE3-1.pdf |
| 2 | Amended description with annotations | 18.01.31 - Amended pages (marked).pdf | DESC-HWA-1.pdf |
| 3 | Amended description (clean copy) | 18.01.31 - Amended pages (clean).pdf | DESC-1.pdf |
| 4 | Amended claims with annotations | 18.01.31 - Amended claims (marked).pdf | CLMS-HWA-1.pdf |
| 5 | Amended claims (clean copy) | 18.01.31 - Amended claims (clean).pdf | CLMS-1.pdf |

| | Payment | |
|---|---|---|
| 1 | Method of payment | Not specified |

**Signatures**

| | |
|---|---|
| Place: | **Watford, UK** |
| Date: | **31 January 2018** |
| Signed by: | **Rupert Knights 7287** |
| Representative name: | **Rupert Andrew KNIGHTS** |
| Capacity: | **(Representative)** |




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**BY E-FILING**

31 January 2018

**Your Ref:**

**Our Ref:**
P/14624.EPWD1:RK:
SD

Dear Sirs

**European Patent Application No. 15180327.7**
**Edwards Lifesciences PVT, Inc.**

This letter is in response to the Examination Report of 21 July 2017. We enclose new pages 5 and 6 to replace page 5 of the description presently on file as well as a replacement set of claims. Also enclosed, to aid the Examiner, is a copy of the previous pages on which all amendments are marked.

Amendments

Claim 15, which clearly conflicts with Claim 1, has been deleted.

The features of Claims 3 and 14 have been introduced into Claim 1.

The introductory portion of the description has been brought into conformity with the amended claims by the inclusion of statements of invention corresponding to all of the claims.

Clarity

With the introduction of the statement of invention corresponding to Claim 1, there is now explicit support in the description for the feature "the valvular structure being formed of a pliant material attached to the stent structure". The Examiner's objection at point 4 is deemed to be met.

It is important to note that the wording of Claim 1, in this regard, conforms directly to the wording of original Claim 27 of the parent application as filed, upon which original Claim 1 of the present application was based. Claim 27 of the parent application was included as Clause 27 of the present application as originally filed (see column 25 of the published application).



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Novelty and inventive step

Claim 1 is novel over D3 for at least the reason that D3 fails to disclose a layer of compressible material, which forms **a sleeve** disposed along an outer surface of the stent structure and extending entirely around the stent structure.

A sleeve is a tubular element. Note the dictionary definition of sleeve:

noun

1. the part of a garment that covers the arm, varying in form and length but commonly **tubular**.
3. *Machinery.* a **tubular** piece, as of metal, fitting over a rod or the like.

A ring is not equivalent to a sleeve. A ring is not a tubular element. Note the dictionary definition of ring:

noun

1. a small circular band, typically of precious metal and often set with one or more gemstones, worn on a finger as an ornament or a token of marriage, engagement, or authority.
   "a diamond ring"
2. a ring-shaped or circular object.
   "an inflatable rubber ring"

Any possible interpretation that a ring falls within the scope of a sleeve is removed by the deletion of Claim 15.

Considering D3, it is merely disclosed that the outer walls of the band 110 may comprise a gasket-like material (which term has no clear meaning) or that a separate gasket 150 may be provided. The only depicted arrangement is of gasket 150, which clearly takes the form of a sealing ring.

A sleeve (i.e. tubular element) of compressible material disposed along an outer surface of the stent structure is not disclosed in D3.

Claim 1 must be held to be novel over D3.

D5, which is citable under Article 54(3) EPC, is relevant to novelty only. There is no disclosure in D5 of a layer of compressible material that comprises polyurethane or polyethylene terephthalate.

Claim 1 is novel over D5 for at least this reason. D5 is not relevant to the patentability of Claim 1.

Considering inventive step, and applying the problem solution approach:

D3 is the only cited document relevant to inventive step.

As compared to the sealing ring of D3, the sleeve of the present invention, being tubular in form, provides a far larger sealing zone. In other words, there is a larger “landing zone” created, which provides for more “forgiving” valve placement where exact placement of the seal is less critical. With a single ring that provides sealing, as in D3, the placement of that ring within the native valve annulus becomes more critical and less than ideal placement results in less than ideal sealing.

Further, by the provision of a sleeve in place of a sealing ring there is more material present to fill gaps created between the stent and the native valve annulus.



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The objective technical problem to be solved may therefore be considered to be how to improve sealing reliability in a percutaneously delivered valve.

Starting from D3 and looking to solve the objective technical problem, there is nothing to lead the skilled person to the arrangement of Claim 1, without an inventive step. Any assertion to the contrary must be the result of unallowable ex-post facto analysis.

D3 provides no pointer to the solution of Claim 1.

In this regard, it must be borne in mind that the ultimate question with inventive step is not whether the skilled person could arrive at the present invention by modifying the closest prior art, but whether they **would have done** so because the prior art incited them to do so. There is clearly no such incitement in D3.

More than this, it is notable that there is no hint or suggestion whatsoever of the use of a sleeve in any of the remaining prior art cited by the Examiner and relevant to consideration of inventive step.

Claim 1 has a clear inventive step over the cited prior art.

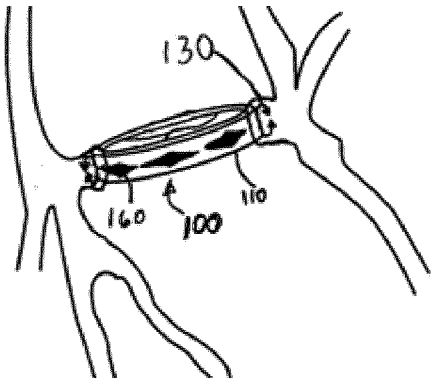
Moreover, Claim 1 is inventive over the D3 for the following additional reasons:

D3 mainly concerns valves being implanted by surgery (introduction on page 1). Furthermore, all valves disclosed in D3 are designed to be implanted in a site after the native valve leaflets have been removed (see in particular also D3, page 1, ll. 3-11).

The removal process is vital for the invention in D3 because the valve prosthesis disclosed in D3 comprises fingers 130 with barbed heads that need to "grab" the tissue annulus where the native valve used to be. This is clear from figures 1 and 2 and from page 5, ll. 13-15 and ll. 28-32:

> *"The invention operates as follows: first, valve 100 is positioned for securing to the tissue annulus that **surrounded** the old valve."*
> *"The shortening in length causes the barbed heads on each corresponding pair of retention fingers 130 to converge and engage the surrounding tissue annulus, thereby securing valve 100 to the tissue annulus."*

As shown in figures 1 and 2 the opposing fingers 130 are spaced so that they can effectively engage the relatively thin tissue lip. As further shown in figures 1 and 2 this design of the apparatus in D3 limits the axial length of the valve prosthesis to a Frisbee-like shape as shown in in fact all figures of D3. One embodiment is shown in figure 2:




Because of its "squatty" design, the valve prosthesis in D3 is not enabled for a tricuspid valve design as claimed in claim 1 of the present patent application. Without sufficient axial length of the stent the three commissures fixing the three valve leaflets to the stent



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are too short (see also present patent application, page 2, ll. 8-21). As a consequence, a tricuspid valve in a stent as disclosed in D3 would not seal properly and further rupture when expanded with the cylindrical balloon shown in figure 1 of D3. The suggestion in D3 in the sentence bridging pages 5 and 6 in connection with figure 2 that the valve tissue would "naturally" return to a functioning valve following balloon expansion is technically not credible if the valve is a tricuspid valve.

Accordingly, in the description of D3 no pointer towards the use of a tricuspid valve is found.

What is required is shown in figure 22 of the present patent application, namely a sufficiently large stent (in the axial direction) that can operate three valve leaflets:

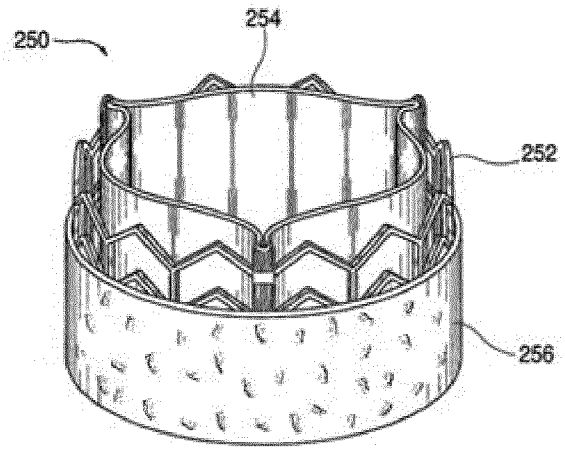


FIG. 22

Such three valve leaflets are expressly specified in claim 1 of the present patent application.

For the reasons outlined above the average skilled person when starting from D3 would not have selected such valve comprising three leaflets. Furthermore, due to its squatty design, in D3 also no layer of sealing material is disclosed that forms a sleeve that extends entirely around the stent structure as specified in present claim 1 and discussed in detail above.

Favourable reconsideration of the Examiner's objections is respectfully requested.

The present application is strongly believed to be in order for allowance. Purely as a precaution, however, in the event the Examiner is minded to refuse the application at any stage, we herewith request oral proceedings.

Yours faithfully

[signed electronically]

KNIGHTS, Rupert Andrew
European Patent Attorney
Dolleymores

Enc. Replacement pages as above
Claims with amendments marked



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GERMANY

**Questions about this communication ?**
Contact Customer Services at www.epo.org/contact

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| Date |
| --- |
| 01.12.17 |

| Reference | Application No./Patent No. |
| --- | --- |
| P/14624EPWD1:RK | 15180327.7 - 1664 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Extension of time limit pursuant to Rule 132(2) EPC**

Examination procedure

With reference to your request, the time limit for replying to the communication pursuant to Article 94(3) EPC dated 21.07.17 has been extended

by 2 months

to a total of 6 months

from the date of notification of the above-mentioned communication.

Please note: To the extent that your request exceeded the above extension, your request has been refused.

**Note**
The granting of extensions to time limits is governed by the Implementing Regulations to the EPC and the Guidelines for Examination in the EPO, E-VII, 1.6. A request for extension, which would result in the total period set exceeding six months, must be reasoned and supported by evidence.

**If no reply to the communication is received in due time, the European patent application will be deemed to be withdrawn (Art. 94(4) EPC).**


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**Important information in case of a PACE request**
If a PACE request has been validly filed for the application, the applicant is herewith informed that with the grant of the request for extension of time limit the application is removed from the PACE programme. A second PACE request for that application during the same stage of the procedure will not be processed (see OJ EPO 2015, A93, point 4).

**For the Examining Division**

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# Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

| | |
|---|---|
| Submission number | 5826622 |
| Application number | EP15180327.7 |
| Date of receipt | 28 November 2017 |
| Receiving Office | European Patent Office, The Hague |
| Your reference | P/14624.EPWD1 |
| Applicant | All applicants as on file |
| Documents submitted | package-data.xml<br>epf1038.pdf (1 p.)<br>ep-sfd-request.xml |
| Submitted by | CN=Rupert Knights 7287 |
| Method of submission | Online |
| Date and time receipt generated | 28 November 2017, 14:31 (CET) |
| Message Digest | 9A:A6:49:C9:EB:0B:F8:F6:9A:43:40:10:A7:04:26:61:FE:73:63:64 |

**Correction by the EPO of errors in debit instructions filed by eOLF**
Errors in debit instructions filed by eOLF that are caused by the editing of Form 1038E entries or the continued use of outdated software (all forms) may be corrected automatically by the EPO, leaving the payment date unchanged (see decision T 152/82, OJ EPO 1984, 301 and point 6.3 ff ADA, Supplement to OJ EPO 10/2007).

/European Patent Office/


Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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Office européen des brevets

# Letter accompanying subsequently filed items


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Tel. +49(0)30 25901-0 | Fax -840


The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

| | |
|---|---|
| Application number | 15180327.7 |
| Applicant's or representative's reference | P/14624.EPWD1 |

| | Description of document | Original file name | Assigned file name |
|---|---|---|---|

| | Payment | |
|---|---|---|
| 1 | Mode of payment | Not specified |

**Annotations**

Extension of Time(Rupert Knights; 28.11.2017)

1. Remark(Annotate)

We hereby request a two month extension of time to respond to the Communication pursuant to Article 94(3) EPC dated 21 July 2017.

**Signatures**

| | |
|---|---|
| Place: | **Watford, UK** |
| Date: | **28 November 2017** |
| Signed by: | **Rupert Knights 7287** |
| Association: | **Dolleymores** |
| Representative name: | **Rupert Knights** |
| Capacity: | **(Representative)** |




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The examination is being carried out on the **following application documents**

**Description, Pages**

| | | |
|---|---|---|
| 1-4, 14-36 | as originally filed | |
| 5, 37 | filed in electronic form on | 10-08-2016 |

**Claims, Numbers**

| | | |
|---|---|---|
| 1-16 | filed in electronic form on | 10-08-2016 |

**Drawings, Sheets**

| | |
|---|---|
| 1/23-23/23 | as originally filed |

1 Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

D3 WO 00/64380 A1 (ST JUDE MEDICAL CARDIOVASCULAR [US]) 2 November 2000 (2000-11-02)

2 The following document is cited by the Examiner. A copy of the document is annexed to the communication and the numbering will be adhered to in the rest of the procedure.

D5 EP 2 537 487 A1 (SADRA MEDICAL INC [US]) 26 December 2012 (2012-12-26)

3 The current claim set appears to conform to the requirements of Article 123(2) EPC, but some defects remain:

4 The wording "the valvular structure being formed of a pliant material attached to the stent structure" is broader than the originally filed claim 1 as it would allow for the possibility of the stent leaflets being outside the stent. There is no support in the description apart from the one deleted passage (formerly a claim of the parent application) for a configuration where the valvular



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structure is not located within the stent structure. As the scope of claim 1 is broader than justified by the description and drawings it does not conform to the requirements of Article 84 EPC.

5 Claim 15 is not clear (Article 84 EPC). If one is to follow the applicant's reasoning in his communication of 10.8.2016, a **ring** is not the same as a **sleeve**. Therefore it is not apparent how a "layer of compressible material, which forms a sleeve" (claim 1) can also be "a sealing ring that comprises a set of flaps" (claim 15).

6 If one uses the interpretation that the applicant clearly has used, that a **ring** is equivalent to a **sleeve**, bearing in mind that the sleeve of claim 1 does not have a defined length and is not necessarily disposed along the entire outer surface of the stent structure, then the features of claim 1 are still disclosed in D3, see particularly page 6, line 34 - page 7, line 10. A soft deformable biocompatible material is clearly disclosed in this passage. The other features of claim 1 are disclosed in page 5, lines 34 - 36, page 12, lines 3 - 6 and figures 1 and 2.

7 The features of dependent claims 2, 5, 10, 13, 14 and 16 are also disclosed in D3.

8 Feature of the other dependent claims, whilst possibly novel are not inventive over a combination of D3 and general knowledge of the skilled practitioner.

9 The applicant's attention is also brought to document D5 with the filing date of 22.12.2004 and multiple priorities, the earliest of which is 23.12.2003. The features of claim 1 are disclosed in this document, in particular in figures 13, 15A - 16C and 37 - 34, and paragraphs 114 - 117, 122 and 123.

10 The applicant is invited to file new claims taking account of the above comments.

10.1 Independent claims should be placed in the two-part form in accordance with Rule 43(1) EPC with those features known from the prior art (document D1) being placed in the preamble (Rule 43(1)(a) EPC) and with the remaining features being included in the characterising part (Rule 43(1)(b) EPC).



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10.2 The features of the claims should be provided with reference signs placed in parentheses to increase the intelligibility of the claim Rule 43(7) EPC). This applies to both the preamble and characterising portion (see the Guidelines, C-III, 4.19).

10.3 In order to facilitate the examination of the conformity of the amended application with the requirement of Article 123(2) EPC, the applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and the indicate the passages of the application as filed in which these amendments are based.



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**Substantive Examiner**
Name: Steiner, Bronwen
Tel: +49 89 2399 - 6035

| Application No. | Ref. | Date |
|---|---|---|
| 15 180 327.7 - 1664 | P/14624EPWD1:RK | 21.07.2017 |
| Applicant<br>Edwards Lifesciences PVT, Inc. | | |

**Communication pursuant to Article 94(3) EPC**

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

**of 4 months**

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the Examining Division requesting that you correct this deficiency (R. 137(4) EPC).

In case you withdraw the application within the above-mentioned period, the examination fee will be refunded at a rate of 50% (Art. 11 (b) RFees).

**Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).**

**Registered letter**



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Steiner, Bronwen
Primary Examiner
**For the Examining Division**

Enclosure(s): 3 page/s reasons (Form 2906)
EP-2537487-A1



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European Patent Office
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Application No.: 15180327.7

Substantive examination has started on 13.07.17 (see Notice from the European Patent Office dated 29.01.2013, OJ EPO 2013, 153).

**For the Examining Division**



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European Patent Office
80298 MUNICH
GERMANY

**Questions about this communication ?**
Contact Customer Services at www.epo.org/contact

Dolleymores
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| Date |
|---|
| 21.06.17 |

| Reference | Application No./Patent No. |
|---|---|
| P/14624EPWD1:RK | 15180327.7 - 1664 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Communication in response to your enquiry received on 07.06.17**

☑ The EPO will be able to supply a communication within 01 month(s).

☐ Having regard to the current workload, the EPO will not be able to supply a communication within the next 12 months.

☐ Reference is made to the telephone consultation that took place on .

If the proposed time frame does not meet your needs, please contact the responsible examiner or the director:

**Primary Examiner (substantive examination)**
Name: Steiner B
Tel.: +49 (0)89 2399 - 6035

**Director**
Name: Williere G
Tel.: +49 (0)89 2399 - 2201

General information:
If you wish your application to be examined more quickly than the time frame indicated above, your attention is drawn to the possibility of requesting accelerated examination under the "PACE" programme of the EPO (OJ EPO 2015, A93). However, if a request for accelerated examination has already been filed and the application has been removed from the PACE programme, a second request for accelerated examination can no longer be processed (OJ EPO 2015, A93, point 4).

**For the Examining Division**

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# Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

| | | |
|---|---|---|
| Submission number | 5343813 | |
| Application number | EP15180327.7 | |
| Date of receipt | 07 June 2017 | |
| Filing Office | European Patent Office, The Hague | |
| Procedural phase | Examination | |
| Your reference | P/14624.EPWD1 | |
| Documents submitted | package-data.xml<br><br>ep-cms-sfd-request.pdf (1 p.) | ep-cms-sfd-request.xml<br><br>EPLETT-1.pdf\17.06.07 - EPO Form 1012.pdf (1 p.) |
| Submitted by | CN=secure.epoline.org,OU=PDIS,O=European Patent Office,C=NL | |
| Method of submission | Online | |
| Date and time receipt generated | 07 June 2017, 16:11 (CEST) | |
| Message Digest | 73:0D:08:64:68:35:70:67:47:90:EE:BA:A9:B7:2B:67:E7:B3:9B:D4 | |

/European Patent Office/



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# Anfrage zum Bearbeitungsstand der Akte
# Enquiry as to the processing of the file
# Demande de renseignement concernant l'instruction d'un dossier

Hiermit wird angefragt, wann das EPA den (ergänzenden) europäischen Recherchenbericht/den nächsten Bescheid zusenden wird[1]

I/We hereby enquire when the EPO will deliver the (supplementary) European search report/next communication[1]

Nous vous prions de nous indiquer le délai dans lequel l'OEB enverra le rapport (complémentaire) de recherche européenne / la prochaine notification[1]

für die Anmeldung/das Patent
for application/patent
pour la demande/le brevet

EP 15180327.7 (Dolleymores Ref. P/14624.EPWD1:RK)

Ort / Place / Lieu

Watford, Hertfordshire WD18 0JU

Datum / Date

7 June 2017

Unterschrift(en) des (der) Anmelder(s) oder Vertreter(s):
Signature(s) of applicant(s) or representative(s):
Signature(s) du (des) demandeur(s) ou du (des) mandataire(s) :

John Kensett.

KENSETT, John Hinton
Authorised Representative

*Name des (der) Unterzeichneten bitte in Druckschrift wiederholen. Bei juristischen Personen bitte die Stellung des (der) Unterzeichneten innerhalb der Gesellschaft in Druckschrift angeben. / Please print name(s) under signature(s). In the case of legal persons, the position of the signatory within the company should also be printed. / Le ou les noms des signataires doivent être indiqués en caractères d'imprimerie. S'il s'agit d'une personne morale, la position occupée au sein de celle-ci par le ou les signataires doit également être indiquée en caractères d'imprimerie.*

EPA/EPO/OEB 1012 11.16

[1] ABl. EPA 2016, A66 / OJ EPO 2016, A66 / JO OEB 2016, A66

Europäisches Patentamt
European Patent Office
Office européen des brevets

# Letter accompanying subsequently filed items


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The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

| | |
|---|---|
| Application number and/or EP publication number | EP15180327.7 |
| Reference | P/14624.EPWD1 |
| Procedural phase | Examination |
| Name of represented party | Edwards Lifesciences PVT, Inc. |

| | Description of document | Original file name | Assigned file name |
|---|---|---|---|
| 1 | Letter relating to the search and examination procedure | 17.06.07 - EPO Form 1012.pdf | EPLETT-1.pdf |

**Signature 1**

| | |
|---|---|
| Place: | **Watford, UK** |
| Date: | **07 June 2017** |
| Signed by: | **/Dolleymores/** |
| Association: | **Dolleymores** |
| Capacity: | **Representative 1** |

**Smart card certificate 1**

| | |
|---|---|
| Common name: | **Marie Tatnall 33843** |
| EPO ID: | **33843** |
| Issued by: | **European Patent Office CA G2** |




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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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# Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

| | |
|---|---|
| Submission number | 4558450 |
| Application number | EP15180327.7 |
| Date of receipt | 10 August 2016 |
| Receiving Office | European Patent Office, The Hague |
| Your reference | P/14624.EPWD1RK |
| Applicant | All applicants as on file |
| Documents submitted | package-data.xml<br><br>epf1038.pdf (2 p.)<br><br>DESC-1.pdf\16.08.10 - Amended description (clean).pdf (2 p.)<br><br>CLMS-HWA-1.pdf\16.08.10 - Amended claims (tracked).pdf (2 p.)<br><br>ep-sfd-request.xml<br><br>WOREPLY-1.pdf\16.08.10 - EPO.pdf (4 p.)<br><br>CLMS-1.pdf\16.08.10 - Amended claims (clean).pdf (2 p.) |
| Submitted by | CN=Rupert Knights 7287 |
| Method of submission | Online |
| Date and time receipt generated | 10 August 2016, 12:04 (CEST) |
| Message Digest | 34:B8:28:76:A8:77:25:BF:1B:22:56:07:AA:76:DA:DC:84:E3:22:A3 |


Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 2138
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

**Correction by the EPO of errors in debit instructions filed by eOLF**

Errors in debit instructions filed by eOLF that are caused by the editing of Form 1038E entries or the continued use of outdated software (all forms) may be corrected automatically by the EPO, leaving the payment date unchanged (see decision T 152/82, OJ EPO 1984, 301 and point 6.3 ff ADA, Supplement to OJ EPO 10/2007).

/European Patent Office/

## Claims

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) 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;

characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of any preceding claim, wherein the compressible material is formed of polyethylene terephthalate.

4. The prosthetic valve of Claim 3, wherein the compressible material has a thickness ranging from 1 to 5mm.

5. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

6. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

7. The prosthetic valve as claimed in Claim 6, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

8. The prosthetic valve as claimed in any preceding claim, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

9. The prosthetic valve of Claim 8, wherein the fibers are straight, curved or hook-shaped.

10. The prosthetic valve of any of the previous claims, wherein the stent is comprised of shape memory material, preferably nitinol.

11. The prosthetic valve of any of the previous claims, wherein the stent is held in place in the cavity by friction.

12. The prosthetic valve of any of the previous claims, wherein the compressible material is a fluid impermeable membrane covering at least one end of the stent.

13. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

14. The prosthetic valve of any of the previous claims, wherein the compressible material is polyurethane.

15. The prosthetic valve of any of the previous claims, wherein the compressible material is a sealing ring that comprises a set of flaps.

16. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

## Claims

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material ~~located within~~attached to the stent structure and forming three valve leaflets;

characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel.

~~2. The prosthetic valve of Claim 1, wherein the compressible material extends entirely around the stent structure.~~

~~3. The prosthetic valve of Claim 2, wherein the compressible material forms a sleeve.~~

~~4~~2. The prosthetic valve of Claim ~~3~~1, wherein the sleeve surrounds an inflow end of the stent structure.

~~5~~3. The prosthetic valve of any preceding claim, wherein the compressible material is formed of polyethylene terephthalate.

~~6~~4. The prosthetic valve of Claim ~~5~~3, wherein the compressible material has a thickness ranging from 1 to 5mm.

~~7~~5. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

~~8~~6. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

~~9~~7. The prosthetic valve as claimed in Claim ~~8~~6, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

~~10~~8. The prosthetic valve as claimed in any preceding claim, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

~~11~~9. The prosthetic valve of Claim ~~10~~8, wherein the fibers are straight, curved or hook-shaped.

10. The prosthetic valve of any of the previous claims, wherein the stent is comprised of shape memory material, preferably nitinol.

11. The prosthetic valve of any of the previous claims, wherein the stent is held in place in the cavity by friction.

12. The prosthetic valve of any of the previous claims, wherein the compressible material is a fluid impermeable membrane covering at least one end of the stent.

13. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

14. The prosthetic valve of any of the previous claims, wherein the compressible material is polyurethane.

15. The prosthetic valve of any of the previous claims, wherein the compressible material is a sealing ring that comprises a set of flaps.

16. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Further prior art arrangements are known from US 5258023, US 4106129, WO 00/64380 and FR 2815844.

## SUMMARY OF THE INVENTION

[0015] In accordance with a preferred embodiment of the present invention, there is provided a prosthetic valve for percutaneous implantation in a body channel, as recited by Claim 1.

Further, preferred features are presented in the dependent claims.

## 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

**page 14 follows**

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 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, the hydrogel absorbs fluids from the blood and expands to the 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 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.

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**BY E-FILING**

10 August 2016

**Your Ref:**

**Our Ref:**
P/14624.EPWD1:RK

Dear Sirs

**European Patent Application No. 15180327.7**
**Edwards Lifesciences PVT, Inc.**

This letter is in response to the extended European search report of 8 January 2016. For the avoidance of doubt, the applicant wishes to proceed further with the application. We are concurrently attending to payment of the examination and designation fees and enclose herewith new pages 5 and 37 to 39 to replace pages 5 to 13 and 37 to 43 presently on file. Also enclosed, to aid the Examiner is a copy of the previous claims on which the amendments have been marked.

The claims have been amended to more clearly distinguish the present invention from the cited prior art, in order to expedite patent grant. Some additional dependent claims have been introduced, as discussed below.

Claim 1 has been limited by the inclusion of the features of Claims 2 and 3. Claim 1 now recites "a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure". Claim 1 has further been limited to specify "A prosthetic valve (250) for percutaneous implantation in a body channel". Basis for this latter amendment may be found throughout the specification, including for example in paragraph 0014. Finally, Claim 1 has been amended to specify "a pliant material attached to the stent structure", which returns the wording to the form of Claim 27 of the parent application, upon which Claim 1 is based.

Contrary to the Examiner's assertions, it is respectfully submitted that the prosthetic valve as defined by amended Claim 1 is both new and inventive over the cited prior art.

Claim 1 is novel over D1 and D2 for at least the reason that neither document discloses "A prosthetic valve (250) for percutaneous implantation in a body channel, comprising a substantially cylindrical stent structure configured for radial expansion".



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**Partners:** J Kensett, J Trebble, S Fitchett, P Eke, V Bennett, R Knights.

The valves of D1 and D2 may not radially expand. Whilst they have some flexibility and may deform slightly during the operation of the heart following implantation, this does not constitute radial expansion in the context of Claim 1. The valves of D1 and D2 are not suitable for percutaneous implantation.

As is well understood by those in the art, radially expandable valves for percutaneous delivery, are inserted into the body in a contracted state via a catheter, or similar, and are then radially expanded in situ for the fixing of their position in the body and to allow for their operation.

As is equally well understood by those in the art, valves of the form shown in D1 and D2 cannot be introduced percutaneously and radially expanded. They must rather be directly implanted (in their final form) into the heart by a surgeon by opening the patient's chest, stopping the heart, putting the patient on a heart-lung machine, cutting open the heart/aorta, and sewing the valve in place.

The valves of D1 and D2 are of an entirely different form to the valve of Claim 1. Claim 1 is novel over D1 and D2.

Moreover, the stent structures of D1 and D2 are plainly not substantially cylindrical. Note that the dictionary definition of cylindrical is "Of, relating to, or having the shape of a cylinder, especially of a circular cylinder". Neither frame 110 of D1 nor wire frame 16 of D2 can reasonably be considered to have the shape of a cylinder. The frame 110 of D1 is rather of undulating ring-like form and the wire frame 16 is rather, as the name suggests, a wire frame (again of undulating form).

Claim 1 is novel over D3 and D4 for at least the reason that neither document discloses a layer of compressible material, which forms **a sleeve** disposed along an outer surface of the stent structure and extending entirely around the stent structure.

A sleeve is a tubular element. Note the dictionary definition of sleeve:

noun
1. the part of a garment that covers the arm, varying in form and length but commonly **tubular**.
3. *Machinery.* a **tubular** piece, as of metal, fitting over a rod or the like.

In D3, it is merely disclosed that the outer walls of the band 110 may comprise a gasket-like material (which term has no clear meaning) or that a separate gasket 150 may be provided. A sleeve of compressible material disposed along an outer surface of the stent structure is not disclosed. The only depicted arrangement is of gasket 150, which clearly takes the form of a sealing ring.

In D4, there is only disclosed the provision of a compressible band 8, which again is shown to take the form of a sealing ring.

It follows that there is no disclosure in D3 or D4 of the provision of a sleeve of compressible material disposed along an outer surface of the stent.

Claim 1 is clearly novel over D3 and D4.

Considering inventive step, and applying the problem solution approach:

Of the cited prior art, only D3 and D4 are suitable for percutaneous delivery. It is submitted therefore that one of these documents must form the only appropriate starting point for an inventive step consideration.



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It is to be noted that the unique arrangement of Claim 1 brings about clear technical advantages over D3 and D4.

As compared to the sealing rings of D3 and D4, the sleeve of the present invention forms a far larger sealing zone. In other words, there is a larger "landing zone" created, which provides for more "forgiving" valve placement where exact placement of the seal is less critical. With a single ring that provides sealing, as in D3 and D4, the placement of that ring within the native valve annulus becomes more critical and less than ideal placement results in less than ideal sealing.

Further, by the provision of a sleeve in place of a sealing ring there is more material present to fill gaps created between the stent and the native valve annulus.

The objective technical problem to be solved may therefore be considered to be how to improve sealing reliability in a percutaneously delivered valve.

Starting from either D3 or D4, and looking to solve the objective technical problem, there is nothing in the cited prior art to lead the skilled person to the arrangement of Claim 1, without an inventive step. Any assertion to the contrary must be the result of unallowable ex-post facto analysis.

D3 and D4 provide no pointer to the solution of Claim 1. Looking beyond D3 and D4, there is no reasonable combination of documents that could lead the skilled person to the invention of Claim 1.

D1 and D2, as discussed, disclose stents/support frames that by virtue of their expressly required forms are not percutaneously implantable.

D3 and D4, in contrast to D1 and D2, are arranged for percutaneous implantation and thereby take entirely different forms to D1 and D2.

For the skilled person to modify the disclosed arrangement of either D3 or D4 in light of D1 or D2 would necessarily require the skilled person to go directly against the express teaching of a document, this is not something the skilled person will do without unallowable ex-post facto analysis. In any event it would not lead to the arrangement of Claim 1.

In this regard, it must be borne in mind that the ultimate question with inventive step is not whether the skilled person could arrive at the present invention by modifying the closest prior art, but whether they **would have done** so because the prior art incited them to do so. There is clearly no such incitement in any of the cited documents.

Claim 1 has a clear inventive step over the cited prior art.

Favourable reconsideration of the Examiner's objections is respectfully requested.

New dependent Claims 10 to 16 have been introduced. Basis for these new claims may be found in the application as filed as follows:

Claim 10 – paragraphs [0020] and [0021]; Claim 11 – paragraphs [0017] and [0099]; Claim 12 – paragraphs [0017] and [0019]; Claim 13 – paragraphs [0055] and [00145]; Claim 14 – paragraph [00128]; Claim 15 – paragraph [00108]; and Claim 16 – paragraphs [0044] and [00145].

The introductory portion of the description has been brought into conformity with the amended claims; the statements on pages 37 to 41 have been deleted; D1 to D4 have been mentioned; and Claim 1 has been placed into two-part form over D3.



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The present application is strongly believed to be in order for allowance. Purely as a precaution, however, in the event the Examiner is minded to refuse the application at any stage during the forthcoming examination phase, we herewith request oral proceedings.

Yours faithfully

[signed electronically]

KNIGHTS, Rupert Andrew
European Patent Attorney
Dolleymores

Enc. Replacement pages as above
Claims with amendments marked



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# Letter accompanying subsequently filed items


Representative:

**Mr Rupert Andrew KNIGHTS**
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10958 Berlin
Germany
Tel. +49(0)30 25901-0 | Fax -840


The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

| | |
|---|---|
| Application number | 15180327.7 |
| Applicant's or representative's reference | P/14624.EPWD1RK |

| | Description of document | Original file name | Assigned file name |
|---|---|---|---|
| 1 | Reply to search opinion/written opinion/IPER | 16.08.10 - EPO.pdf | WOREPLY-1.pdf |
| 2 | Amended description (clean copy) | 16.08.10 - Amended description (clean).pdf | DESC-1.pdf |
| 3 | Amended claims (clean copy) | 16.08.10 - Amended claims (clean).pdf | CLMS-1.pdf |
| 4 | Amended claims with annotations | 16.08.10 - Amended claims (tracked).pdf | CLMS-HWA-1.pdf |

| | Fees | Factor applied | Fee schedule | Amount to be paid |
|---|---|---|---|---|
| 15-1 | 005e Designation fee - For all contracting States designated for applications filed on/after 01.04.2009 | 1 | 585.00 | 585.00 |
| 15-2 | 006 Examination fee - For applications filed on/after 01.07.2005 | 1 | 1 635.00 | 1 635.00 |
| | **Total:** | | **EUR** | **2 220.00** |

| | Payment | |
|---|---|---|
| 1 | Mode of payment | Debit from deposit account |
| | Currency: | EUR |
| | The European Patent Office is hereby authorised, to debit from the deposit account with the EPO any fees and costs indicated on the fees page. | |
| | Deposit account number: | 28050140 |
| | Account holder: | Dolleymores |
| 2 | Refund/Reimburserment | |
| | Reimbursement (if any) to be made to EPO deposit account: | 28050140 |
| | Account holder: | Dolleymores |




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**Signatures**

| | |
|---|---|
| Place: | **Watford, UK** |
| Date: | **10 August 2016** |
| Signed by: | **Rupert Knights 7287** |
| Representative name: | **Rupert Andrew KNIGHTS** |
| Capacity: | **(Representative)** |



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ROYAUME UNI

| Date |
|---|
| 15.02.16 |

| Reference | Application No./Patent No. |
|---|---|
| P/14624EPWD1:RK | 15180327.7 - 1662 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Communication pursuant to Rule 69 EPC - reminder concerning payment of the designation fee (Art. 79(2) EPC) and of the examination fee (Art. 94(1) EPC) - and invitation pursuant to Rule 70a(1) EPC**

The date on which the European Patent Bulletin mentions the publication of the European search report for the above-mentioned European patent application is: 10.02.16.

Your attention is drawn to Article 79(2) and Rule 39(1) EPC as well as Article 94(1), Rule 70(1) and Rule 70a(1) EPC, according to which within **six months** of the above-mentioned publication date of the search report

- the designation fee must be paid,
- the request for examination must be filed and the examination fee must be paid,
- comments on the objections raised in the opinion accompanying the European search report and/or any amendments to the description, claims and drawings correcting any deficiencies noted in the opinion must be filed (R. 70a(1), 137(2) EPC; Guidelines for Examination in the EPO, B-XI, 8).

**1. Payment of the designation fee and of the examination fee**

The current designation fee for one or more Contracting States designated is: EUR 580,00

The current examination fee is: EUR 1620,00

If the written request for examination is filed in an admissible non-EPO language in accordance with Article 14(4) EPC, a reduction of the examination fee according to Rule 6(3) EPC applies.

For European patent applications filed on or after 01.04.2014, the reduction applies only if the applicant(s) has (have) declared to be an entity or a natural person within the meaning of Rule 6(4) EPC (Decision of the Administrative Council of 13 December 2013, OJ EPO 2014, A4).

If the designation fee and the examination fee are not paid within the period laid down in Rule 39(1) and Rule 70(1) EPC, the application **will be deemed to be withdrawn** (R. 39(2) and Art. 94(2) EPC).

Any extension or validation fees are also payable within the above-mentioned period.


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## 2. Comments on the opinion accompanying the European search report and filing of amendments

Should the reply to the invitation pursuant to Rule 70a(1) EPC be filed in an admissible non-EPO language, a translation is to be submitted within one month of its filing (R. 6(2) EPC).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the Examining Division requesting that you correct this deficiency (R. 137(4) EPC).

Should you not comply with this invitation within the time limit, the application **will be deemed to be withdrawn** in accordance with Rule 70a(3) EPC.

**Note to users of the automatic debiting procedure**
**Unless** the EPO receives prior instructions to the contrary, the examination fee and the designation fee will be debited on the last day of the period for payment. For further details see the Arrangements for the automatic debiting procedure, supplementary publication 3 - OJ EPO 2015.

**Important information concerning fee amounts**
Following any amendment to the Rules relating to Fees, the amount(s) mentioned in this communication may be different from the amount(s) **actually due on the date of payment.** The latest version of the Schedule of fees and expenses, published as a Supplement to the Official Journal of the EPO, is also available on the EPO website (**www.epo.org**) and can be found under **www.epo.org/schedule-of-fees**, which allows the viewing, downloading and searching for individual fee amounts, both current and previous.
Please note that procedural fees are usually adjusted every two years, on even years, with effect from 1 April.

Payments by cheque delivered or sent direct to the EPO are no longer accepted as from 1 April 2008 (see OJ EPO 2007, 626).

**Note concerning renewal fees**
Under Article 86 EPC renewal fees shall be paid to the EPO for the European patent application. These fees shall be due in respect of the third and each subsequent year, calculated from the date of filing. Due account should be taken that the EPO will not send invoices or reminders to pay any fees in due time.

**Receiving Section**

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| Date |
| --- |
| 04.02.16 |

| Reference | Application No./Patent No. |
| --- | --- |
| P/14624EPWD1:RK | 15180327.7 - 1662 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Communication of amended entries concerning the representative (R. 143(1)(h) EPC)**

As requested, for the above-mentioned European patent application / European patent the entries concerning the representative have been amended as follows:

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GB

The amendment will be recorded in the Register of European Patents.

**Receiving Section**



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EB21171

# Saunders & Dolleymore LLP

European Patent Office
80298 Munich
Germany

Attn: Claudia Reva

**By Fax Only**

Our Ref: M/3838:JK:SD

27 January 2016

Dear Sirs

**Association of Representatives Amendment**

Further to the telephone conversation you had with Philippa Eke a few days ago, I write to ask if you could firstly amend the name of our Association (number 573) from Saunders & Dolleymore LLP to Dolleymores. This is the trading name that we will be using from 1 February 2016. Please therefore change it from 1 February 2016. If there is a form I should fill in then please let me know by return.

Secondly, many of our applications currently name individual European Patent Attorneys in the firm rather than the Association as such. Is it possible to transfer the Authorised Representative on each of these cases from the individual to the association? The Patent Attorneys are:

John Hinton Kensett
Philippa Dianne Eke
Stuart Paul Fitchett
Rupert Knights

We also believe there is one application which is currently pending which is due in the name of Ken Griffin and this is Application Number 04737617.3. If possible, could you also change the representation for this application to the Association Number 573.

We shall be trading in the name of Dolleymores from 1 February 2016.

Yours faithfully

KENSETT, John Hinton
Authorised Representative

Patent & Trade Mark Attorneys

Saunders & Dolleymore LLP is a limited liability partnership incorporated with partnership no. OC343684 and registered in England & Wales

Partners: J Kensett, J Trebble, S Fitchett, P Eke, V Bennett, R Knights

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Received at the EPO on Jan 27, 2016 16:49:04. Page 1 of 1
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| Date |
|---|
| 19.01.16 |

| Reference | Application No./Patent No. |
|---|---|
| P/14624EPWD1:RK | 15180327.7 - 1662 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Refund of fees**

The following fee(s) was (were) paid in respect of the application 15180327.7:

| Fee | Reference | Voucher No | Date | Currency | Amount |
|---|---|---|---|---|---|
| Search fee | 002 | 01065769 | 10.08.15 | EUR | 1 285,00 |

The fee(s) was (were) paid by Saunders & Dolleymore LLP.

According to the present state of the file the refund will be made by:

CREDITING THE DEPOSIT ACCOUNT 28050140 Saunders & Dolleymore LLP Chartered Pa.

| Amount refundable: | Reference | Currency | Amount | Voucher No |
|---|---|---|---|---|
| | 002 | EUR | 269,85 | 01432679 |

Reason for refund: Partial use of earlier search report with written opinion drawn up by the EPO (21 % of fee paid for current search refunded).

The Authorising Officer
Jagodic
(49)(89)23992312

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| Date |
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| Reference | Application No./Patent No. |
|---|---|
| P/14624EPWD1:RK | 15180327.7 - 1662 / 2982337 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Notification of European publication number and information on the application of Article 67(3) EPC**

You are hereby informed that the technical preparations for the publication of the above-mentioned European patent application have been completed.

The application will be published on 10.02.16 with the European search report.
The publication number is: 2982337.
The publication will be mentioned in European Patent Bulletin number 2016/06.
(**http://bulletin.european-patent-office.org**).

The provisional protection under Article 67(1) and (2) EPC in the individual contracting states becomes effective only when the conditions referred to in Article 67(3) EPC have been fulfilled. For further information, also with respect to extension states, please refer to the EPO brochure "National Law relating to the EPC" (**http://www.epo.org/patents/law/legal-texts/national-law-epc.html**).

The title of the invention in the three official languages of the European Patent Office is worded as follows:

ERKENNUNG, VERSCHLUSS UND PRÄVENTION VON PARAVALVULÄREN LECKS
PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION
DÉTECTION DE FUITE PARAVALVULAIRE, ÉTANCHÉITÉ ET PRÉVENTION

In all future communications to the EPO, please quote the application number as indicated above, i.e. including the final four figures (which identify the Directorate responsible for the subsequent procedure).

**Remark**
The publication can be downloaded, free of charge, from the EPO publication server **https://data.epo.org/publication-server/** or can be ordered from the Vienna sub-office upon payment of a fee (see Decision of the President of the EPO dated 12 July 2007 concerning the form of publication of European patent applications, European search reports and European patent specifications, Special edition No. 3, OJ EPO 2007, 97).



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**Note concerning renewal fees**
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**Accelerated prosecution of European patent applications**
Applicants wishing to accelerate proceedings before the EPO may file a request according to the programme for accelerated prosecution of European patent applications - "PACE" (OJ EPO 2010, 352). EPO Form 1005 is available on the EPO website (www.epo.org) for this purpose.

**Receiving Section**

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# Saunders & Dolleymore LLP

European Patent Office
80298 Munich
Germany

**By Fax & Post**

Our Ref: M/3838:PE:EB

11 January 2016

Dear Sirs

**Adoption of the trading name "Dolleymores" by Saunders & Dolleymore LLP**

We are pleased to announce that with effect from 1 February 2016 our company will commence trading under the name **Dolleymores**.

There will be no changes to the legal status of Saunders & Dolleymore LLP which will simply be trading as **Dolleymores** and our contact details will remain the same.

Please would you reflect this change of trading style in your records so that from 1 February 2016 our name appears as Dolleymores instead of Saunders & Dolleymore LLP in any correspondence and also in your record of us as Representatives in relation to any patents.

If you have any questions, please let us know.

Yours faithfully

EKE, Philippa Dianne
Authorised Representative

Patent & Trade Mark Attorneys

Saunders & Dolleymore LLP is a limited liability partnership incorporated with partnership no. OC343684 and registered in England & Wales

Partners: J Kensett, J Trebble, S Fitchett, P Eke, V Bennett, R Knights

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Received at the EPO on Jan 11, 2016 17:06:52. Page 1 of 1
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| Date |
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| 08.01.16 |

| Reference | Application No./Patent No. |
| --- | --- |
| P/14624EPWD1:RK | 15180327.7 - 1662 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

## Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the European search report (R. 61 EPC) or the partial European search report/ declaration of no search (R. 63 EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☑ 0 additional set(s) of copies of such documents is (are) enclosed as well.

The following have been approved:

☐ Abstract ☑ Title

☑ The Abstract was modified and the definitive text is attached to this communication.

The following figure(s) will be published together with the abstract: 22

**Refund of search fee**
If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued once the date of publication of the European search report has been mentioned in the European Patent Bulletin (R. 69(1), R. 70(2) EPC).

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The examination is being carried out on the **following application documents**

**Description, Pages**

1-41 as originally filed

**Claims, Numbers**

1-11 as originally filed

**Drawings, Sheets**

1/23-23/23 as originally filed

1 Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

D1 US 5 258 023 A (REGER VINCENT A [US]) 2 November 1993 (1993-11-02)

D2 FR 2 337 543 A1 (AMERICAN HOSPITAL SUPPLY CORP [US]) 5 August 1977 (1977-08-05)

D3 WO 00/64380 A1 (ST JUDE MEDICAL CARDIOVASCULAR [US]) 2 November 2000 (2000-11-02)

D4 FR 2 815 844 A1 (SEGUIN JACQUES [FR]) 3 May 2002 (2002-05-03)

2 D1 discloses the following features of claim 1 (references to D1 in parentheses): a prosthetic valve for implantation in a body channel (column 7, lines 22 - 24), comprising: a substantially cylindrical stent structure configured for radial expansion (figures, feature 30, 130, 230); a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material located within the stent structure and forming three valve leaflets (feature 20); a layer of compressible material disposed along an outer surface of the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel (feature 15; column 8, line 61 - column 9, line 14column 10, line 37 - column 11, line 3).



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The subject-matter of claim 1 is therefore not novel (Article 54(1) and (2) EPC).

2.1 The features of claim 1 are also disclosed in each of documents D2, D3 and D4.

3 The features of dependent claims 2 - 5, 7, 8, 10 and 11 are also disclosed in documents D1 - D4 and these claims are also not novel.

4 The additional features of claim 6 and 9, whilst not specifically discussed in any of the cited documents are nonetheless considered to be implicitly disclosed.

4.1 The thickness specified in claim 6 would be obvious to the person skilled in the art and familiar with the average dimensions of native heart valves.

4.2 The method of applying growth factor of claim 9 is considered to be merely one option which would be known to the person skilled in the art when faced with the problem of applying a growth factor to fabric for a stent.

4.3 Therefore claims 6 and 9 do not contain an inventive step (Articles 52(1) and 56 EPC).

5 The statements on the description pages 37 - 41 are misleading and could render the application unclear (Article 84 EPC) as they imply that protection is sought for material differing from that in the claims. These statements should be removed from the description.

6 The applicant is invited to file new claims taking account of the above comments.

6.1 Independent claims should be placed in the two-part form in accordance with Rule 43(1) EPC with those features known from the prior art (document D1) being placed in the preamble (Rule 43(1)(a) EPC) and with the remaining features being included in the characterising part (Rule 43(1)(b) EPC).

6.2 The features of the claims should be provided with reference signs placed in parentheses to increase the intelligibility of the claim Rule 43(7) EPC). This applies to both the preamble and characterising portion (see the Guidelines, C-III, 4.19).



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Page 2040 - 2162
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

6.3 In order to facilitate the examination of the conformity of the amended application with the requirement of Article 123(2) EPC, the applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and the indicate the passages of the application as filed in which these amendments are based.

7



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# EUROPEAN SEARCH REPORT

Application Number
EP 15 18 0327

## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (IPC) |
|---|---|---|---|
| X | US 5 258 023 A (REGER VINCENT A [US])<br>2 November 1993 (1993-11-02)<br>* the whole document *<br>----- | 1-11 | INV.<br>A61F2/24 |
| X | FR 2 337 543 A1 (AMERICAN HOSPITAL SUPPLY CORP [US]) 5 August 1977 (1977-08-05)<br>* the whole document *<br>----- | 1-7 | |
| X | WO 00/64380 A1 (ST JUDE MEDICAL CARDIOVASCULAR [US])<br>2 November 2000 (2000-11-02)<br>* page 3, line 1 - line 21; figures 1,2 *<br>* page 6, line 34 - page 7, line 10 *<br>----- | 1-4,7 | |
| X | FR 2 815 844 A1 (SEGUIN JACQUES [FR])<br>3 May 2002 (2002-05-03)<br>* page 6, line 24 - page 7, line 5; figures 2,6,9,17-21 *<br>* page 11, line 30 - page 12, line 21 *<br>----- | 1-3 | |
| | | | TECHNICAL FIELDS SEARCHED (IPC)<br>A61F |

The present search report has been drawn up for all claims

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| Munich | 16 December 2015 | Steiner, Bronwen |

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)



Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 2164
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

## ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 15 18 0327

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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16-12-2015

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 5258023 A | 02-11-1993 | US 5258023 A | 02-11-1993 |
| | | US 5469868 A | 28-11-1995 |
| FR 2337543 A1 | 05-08-1977 | AU 503001 B2 | 16-08-1979 |
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| WO 0064380 A1 | 02-11-2000 | AT 308288 T | 15-11-2005 |
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| | | DE 60023676 T2 | 01-06-2006 |
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| | | JP 2004516870 A | 10-06-2004 |
| | | WO 0236048 A1 | 10-05-2002 |

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

**Information on Search Strategy** - **Pilot phase (see OJ 2015, A86)**
The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

EP 15 18 0327

TITLE: PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

APPLICANT: Edwards Lifesciences PVT, Inc.

IPC CLASSIFICATION: A61F2/24

EXAMINER: Steiner, Bronwen

CONSULTED DATABASES: DOSYS, EPODOC, WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61F2/2409, A61F2/2412, A61F2/2418, A61F2259/0069

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:
heart valve, sealing, leak, compressible material

EPO FORM P04A42

ABSTRACT / ZUSAMMENFASSUNG / ABRÉGÉ

15180327.7

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 (250) 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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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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Application No.: 15180327.7

The search has started on 15.12.15 (see Notice from the European Patent Office dated 03/2013, OJ EPO 2013, 153).

**Receiving Section**



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Page 2040 - 2168
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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# Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

| | | |
|---|---|---|
| Submission number | 3946755 | |
| Application number | EP15180327.7 | |
| Date of receipt | 30 November 2015 | |
| Receiving Office | European Patent Office, The Hague | |
| Your reference | P/14624.EPWD1:RK | |
| Applicant | All applicants as on file | |
| Documents submitted | package-data.xml<br>epf1038.pdf (2 p.) | ep-sfd-request.xml |
| Submitted by | CN=Rupert Knights 7287 | |
| Method of submission | Online | |
| Date and time receipt generated | 30 November 2015, 12:28 (CET) | |
| Message Digest | 28:A6:1E:B7:AF:07:00:F9:B3:8D:6B:A4:94:07:65:5C:D5:E8:13:6E | |

**Correction by the EPO of errors in debit instructions filed by eOLF**
Errors in debit instructions filed by eOLF that are caused by the editing of Form 1038E entries or the continued use of outdated software (all forms) may be corrected automatically by the EPO, leaving the payment date unchanged (see decision T 152/82, OJ EPO 1984, 301 and point 6.3 ff ADA, Supplement to OJ EPO 10/2007).

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Aortic Innovations, LLC, Exhibit 2040
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# Letter accompanying subsequently filed items


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Germany
Tel. +49(0)30 25901-0 | Fax -840


The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

| | |
|---|---|
| Application number | 15180327.7 |
| Applicant's or representative's reference | P/14624.EPWD1:RK |

| | Description of document | Original file name | Assigned file name |
|---|---|---|---|

| | Fees | Factor applied | Fee schedule | Amount to be paid |
|---|---|---|---|---|
| 15-1 | 033 Renewal fee for the 3rd year | 1 | 465.00 | 465.00 |
| 15-2 | 034 Renewal fee for the 4th year | 1 | 580.00 | 580.00 |
| 15-3 | 035 Renewal fee for the 5th year | 1 | 810.00 | 810.00 |
| 15-4 | 036 Renewal fee for the 6th year | 1 | 1 040.00 | 1 040.00 |
| 15-5 | 037 Renewal fee for the 7th year | 1 | 1 155.00 | 1 155.00 |
| 15-6 | 038 Renewal fee for the 8th year | 1 | 1 265.00 | 1 265.00 |
| 15-7 | 039 Renewal fee for the 9th year | 1 | 1 380.00 | 1 380.00 |
| 15-8 | 040 Renewal fee for the 10th year | 1 | 1 560.00 | 1 560.00 |
| 15-9 | 041 Renewal fee for the 11th year | 1 | 1 560.00 | 1 560.00 |
| | **Total:** | | **EUR** | **9 815.00** |

| | Payment | |
|---|---|---|
| 1 | Mode of payment | Debit from deposit account |
| | Currency: | EUR |
| | The European Patent Office is hereby authorised, to debit from the deposit account with the EPO any fees and costs indicated on the fees page. | |
| | Deposit account number: | 28050140 |
| | Account holder: | Saunders & Dolleymore LLP |
| 2 | Refund/Reimburserment | |
| | Reimbursement (if any) to be made to EPO deposit account: | 28050140 |
| | Account holder: | Saunders & Dolleymore LLP |

**Signatures**

| | |
|---|---|
| Place: | **Watford, UK** |
| Date: | **30 November 2015** |
| Signed by: | **Rupert Knights 7287** |
| Representative name: | **Rupert Andrew KNIGHTS** |
| Capacity: | **(Representative)** |



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**Questions about this communication ?**
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ROYAUME UNI

| Date |
| --- |
| 26.11.15 |

| Reference | Application No./Patent No. |
| --- | --- |
| P/14624EPWD1:RK | 15180327.7 - 1662 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Communication pursuant to Rule 19(1) EPC**

The communication issued pursuant to Rule 19(3) EPC, sent to the inventor designated below, has been returned by the postal services.
You are requested to indicate the correct address of the inventor (R. 19(1) EPC).

**Inventor :** Spenser, Benjamin
22 Zamir Street
US / Caesarea, IL Illinois 38900

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Page 2040 - 2172
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Spenser, Benjamin
22 Zamir Street
Caesarea, IL Illinois 38900
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| Date |
|---|
| 02.10.15 |

| Reference | Application No./Patent No. |
|---|---|
| | 15180327.7 - 1662 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Designation as inventor - communication under Rule 19(3) EPC**

You have been designated as inventor in the above-mentioned European patent application. Below you will find the data contained in the designation of inventor and further data mentioned in Rule 143(1) EPC:

DATE OF FILING : 30.06.05

PRIORITY : US/30.06.04/ USA 883575

TITLE : PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

DESIGNATED STATES : AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR

INVENTOR (PUBLISHED = 1, NOT PUBLISHED = 0):

1/Spenser, Benjamin/22 Zamir Street/Caesarea, IL Illinois 38900/US
1/Benichou, Netanel/Nir-Etzion D.N/Hof-Carmel, IL Illinois 30808/US
1/Bash, Assaf/Haseora 1/Givat Ada, IL Illinois 37808/US
1/Dehdashtian, Mark/5672 Highgate Terrace/Irvine, CA California 92603/US

DECLARATION UNDER ARTICLE 81 EPC:
The applicant(s) has (have) acquired the right to the European patent as employer(s).

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Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 2174

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| Date |
| --- |
| 03.11.15 |

| Reference | Application No./Patent No. |
| --- | --- |
| P/14624EPWD1:RK | 15180327.7 - 1662 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Communication pursuant to Rule 19(1) EPC**

The communication issued pursuant to Rule 19(3) EPC, sent to the inventor designated below, has been returned by the postal services.
You are requested to indicate the correct address of the inventor (R. 19(1) EPC).

**Inventor :** Benichou, Netanel
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Benichou, Netanel
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ETATS-UNIS D'AMERIQUE

| Date |
|---|
| 02.10.15 |

| Reference | Application No./Patent No. |
|---|---|
| | 15180327.7 - 1662 |
| Applicant/Proprietor | |
| Edwards Lifesciences PVT, Inc. | |

**Designation as inventor - communication under Rule 19(3) EPC**

You have been designated as inventor in the above-mentioned European patent application. Below you will find the data contained in the designation of inventor and further data mentioned in Rule 143(1) EPC:

DATE OF FILING : 30.06.05

PRIORITY : US/30.06.04/ USA 883575

TITLE : PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

DESIGNATED STATES : AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR

INVENTOR (PUBLISHED = 1, NOT PUBLISHED = 0):

1/Spenser, Benjamin/22 Zamir Street/Caesarea, IL Illinois 38900/US
1/Benichou, Netanel/Nir-Etzion D.N/Hof-Carmel, IL Illinois 30808/US
1/Bash, Assaf/Haseora 1/Givat Ada, IL Illinois 37808/US
1/Dehdashtian, Mark/5672 Highgate Terrace/Irvine, CA California 92603/US

DECLARATION UNDER ARTICLE 81 EPC:
The applicant(s) has (have) acquired the right to the European patent as employer(s).

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27 -10- 2015

IPR2023-01232, Edwards Lifesciences Corp. et alv. Aortic Innovations, LLC
Aortic Innovations, LLC, Exhibit 2040
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## Abstract

Paravalvular Leak Detection, Sealing and Prevention

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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# Acknowledgement of receipt

We hereby acknowledge receipt of your request for grant of a European patent as follows:

| | |
|---|---|
| Submission number | 3689115 |
| Application number | EP15180327.7 |
| File No. to be used for priority declarations | EP15180327 |
| Date of receipt | 10 August 2015 |
| Your reference | P/14624EPWD1:RK |
| Applicant | Edwards Lifesciences PVT, Inc |
| Country | US |
| Title | Paravalvular Leak Detection, Sealing, and Prevention |
| Documents submitted | package-data.xml<br>application-body.xml<br>SPECEPO-1.pdf\14624EPWD1 (Description).pdf (41 p.)<br>SPECEPO-3.pdf\14624EPWD1 (Abstract).pdf (1 p.)<br>f1002-1.pdf (1 p.)<br>ep-request.xml<br>ep-request.pdf (5 p.)<br>SPECEPO-2.pdf\14624 EPWD1 (Claims).pdf (2 p.)<br>SPECEPO-4.pdf\14624 EPWD1 (Figures).pdf (23 p.) |
| Submitted by | CN=Rupert Knights 7287 |
| Method of submission | Online |
| Date and time receipt generated | 10 August 2015, 09:18 (CEST) |
| Message Digest | 98:87:71:1A:65:10:36:FE:38:A8:2E:95:32:78:E0:6A:77:C7:E2:85 |


Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 2179
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

**Correction by the EPO of errors in debit instructions filed by eOLF**

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## Claims

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

a substantially cylindrical stent structure configured for radial expansion;

a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material located within 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 after deployment to fill gaps between the prosthetic valve and the body channel.

2. The prosthetic valve of Claim 1, wherein the compressible material extends entirely around the stent structure.

3. The prosthetic valve of Claim 2, wherein the compressible material forms a sleeve.

4. The prosthetic valve of Claim 3, wherein the sleeve surrounds an inflow end of the stent structure.

5. The prosthetic valve of any preceding claim, wherein the compressible material is formed of polyethylene terephthalate.

6. The prosthetic valve of Claim 5, wherein the compressible material has a thickness ranging from 1 to 5mm.

7. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

8. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

9. The prosthetic valve as claimed in Claim 8, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

10. The prosthetic valve as claimed in any preceding claim, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

11. The prosthetic valve of Claim 10, wherein the fibers are straight, curved or hook-shaped.

# PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

## FIELD OF THE INVENTION

**[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

**[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.

**[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 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 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 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, 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 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 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, "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 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 transceptal hole and 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 bring comprised of a deployable construction 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 bring provided with a plurality of longitudinally rigid support beams 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, 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 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 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 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 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 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 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.

**[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 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 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 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, 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 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.

**[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, 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.

**[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 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 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 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 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.

**[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, 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 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 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.

**[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 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 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 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 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 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,

**[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 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 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

**[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.

**[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.

**[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.

**[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 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

**[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 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.

## 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 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 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 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.

**[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 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).

**[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 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.

**[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 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..

**[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 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 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 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.

**[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.

**[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

**[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.

**[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 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 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 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 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.

**[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 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.

**[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, 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 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 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 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. 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 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 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 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 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 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 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 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.

**[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 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.

**[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 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.

**[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.

**[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 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 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. 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, 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 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.

**[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, 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 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 guide wire 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 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 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 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 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 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 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 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 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. 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.

**[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 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 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 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 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 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.

**[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 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 (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 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 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. 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 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 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 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 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).

**[00140]** Figures 19a to19d 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 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 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 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 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 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, the hydrogel absorbs fluids from the blood and expands to the 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 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.

**[00139]** The present invention may be defined in accordance with the following clauses:

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 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 Clause 1 further comprising a spacing 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 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 Clause 3, wherein the sealing stent is balloon-expandable type and the membrane comprises a tab spring-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 Clause 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 Clause 5, wherein the stent is comprised of shape memory material.

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

8. The device of Clause 5 further 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.

9. The device of Clause 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 vessel wall, anchoring itself in the vessel wall and providing greater anchorage for the stent.

10. The device of Clause 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 extends out, anchoring the guide wire into the vessel wall.

11. The device-of Clause 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 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 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 Clause 12 adapted to apply an adhesive with more than two components.

14. The device of Clause 12, wherein, 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, the catheter terminating in a mixer that forces the components to mix when the exit the catheter in the cavity, thereby creating the plug that seals the cavity.

15. The device of clause 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 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 Clause 17, wherein the ring comprises a balloon.

19. The device of Clause 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 Clause 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 Clause17, wherein 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 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.

22. The device of Clause 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.

23. The device of Clause 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.

24. The device of Clause 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. 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 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.

27. A prosthetic valve for implantation in a body channel, comprising: a substantially cylindrical stent structure configured for radial expansion; 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 the body channel.

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

29. The prosthetic valve of clause 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.

# Form 1002 - 1: Public inventor(s)

## Designation of inventor

User reference: P/14624EPWD1:RK
Application No:

Public

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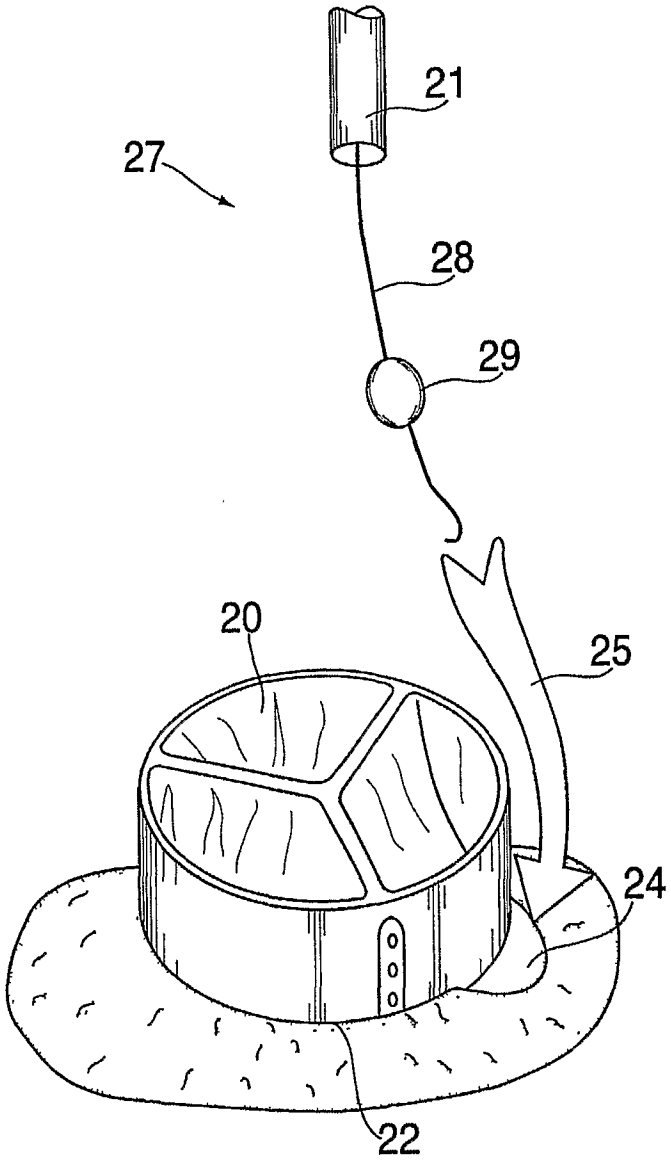


FIG. 1



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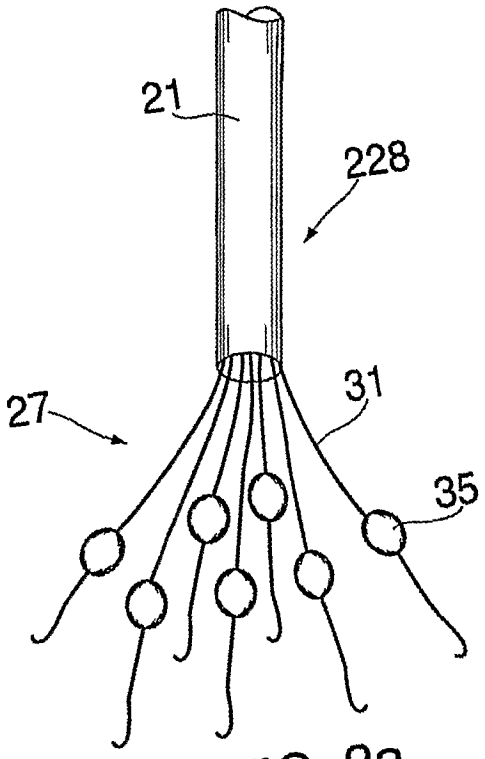


FIG. 2a

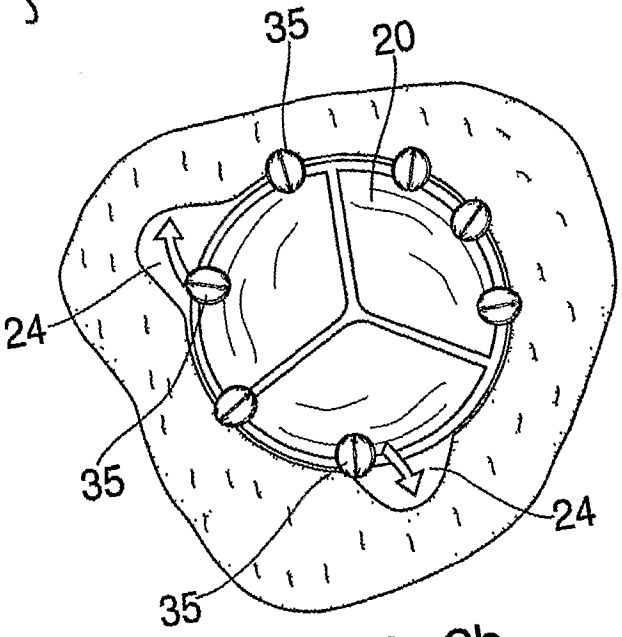


FIG. 2b



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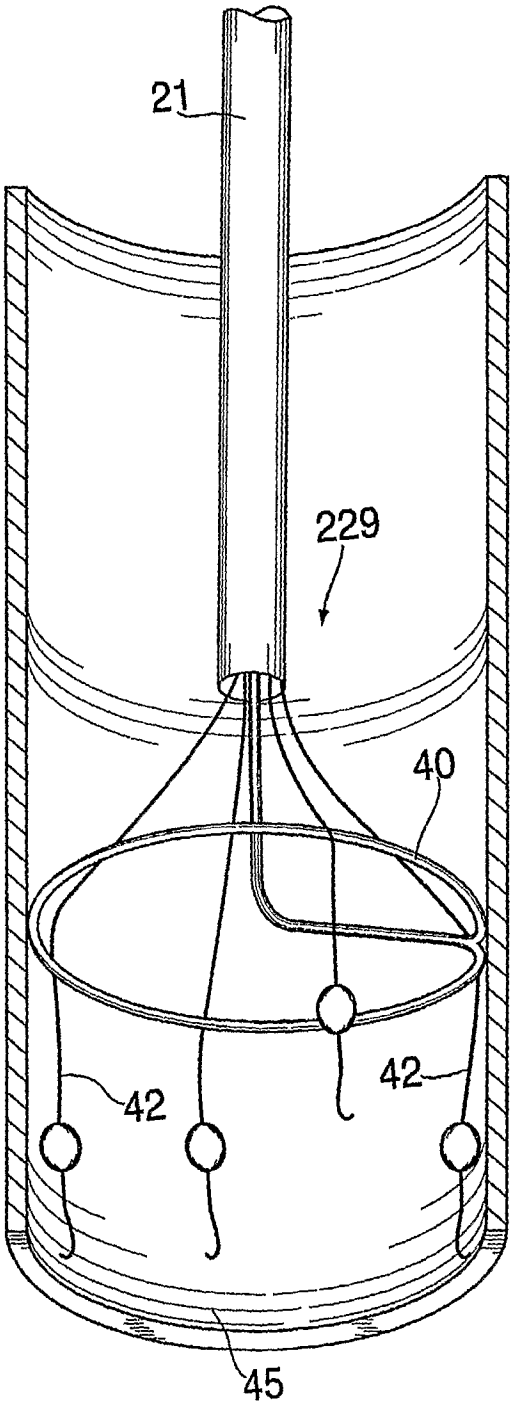


FIG. 3



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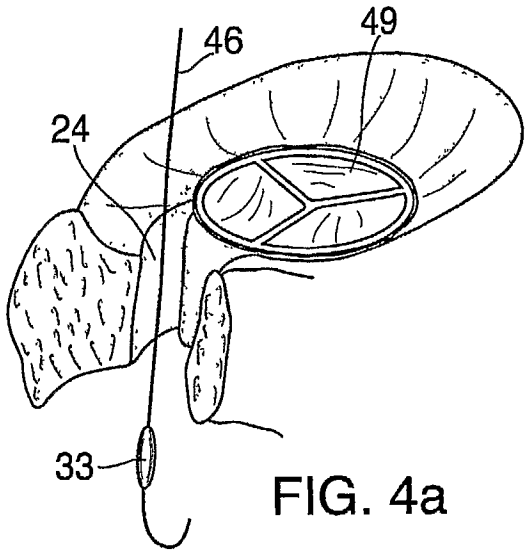


FIG. 4a

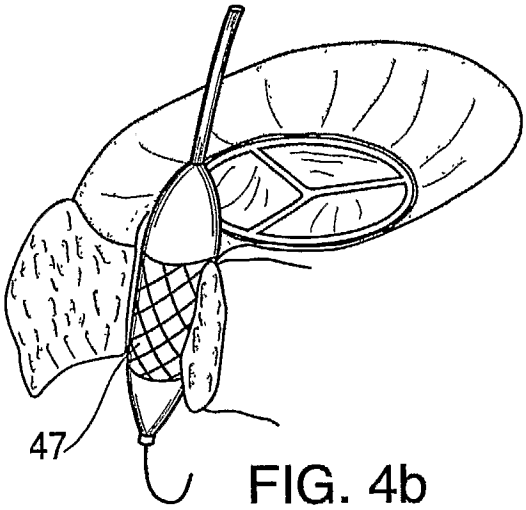


FIG. 4b

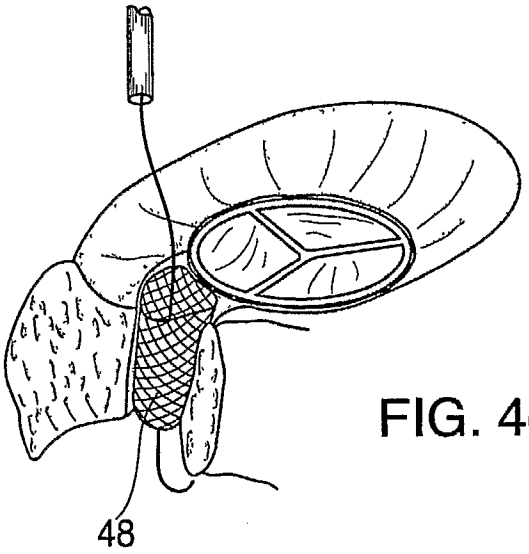


FIG. 4c



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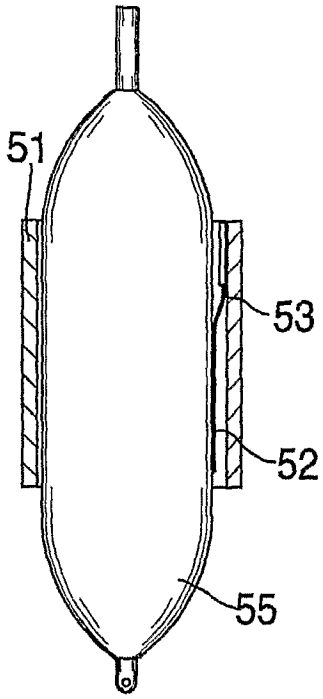


FIG. 5a

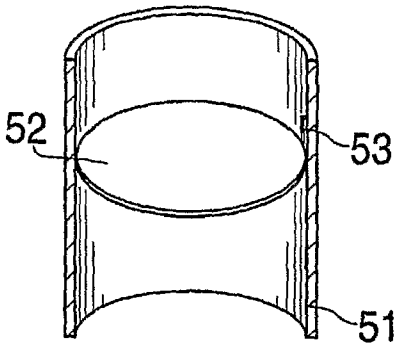


FIG. 5b

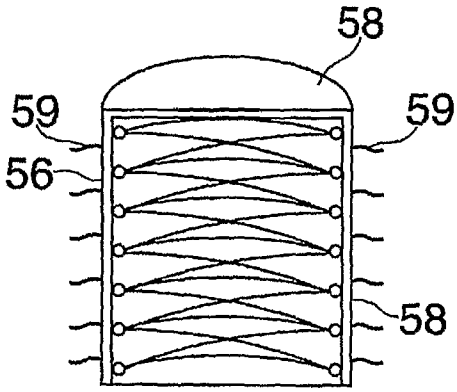


FIG. 5c

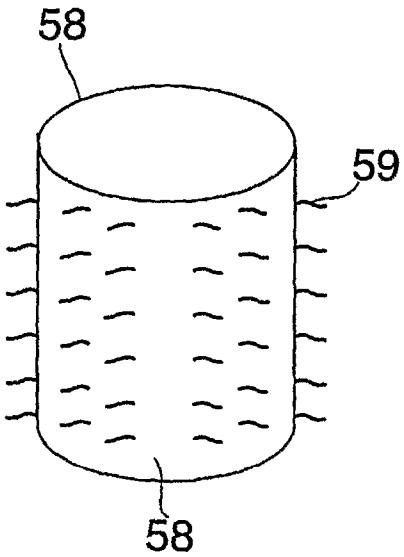


FIG. 5d



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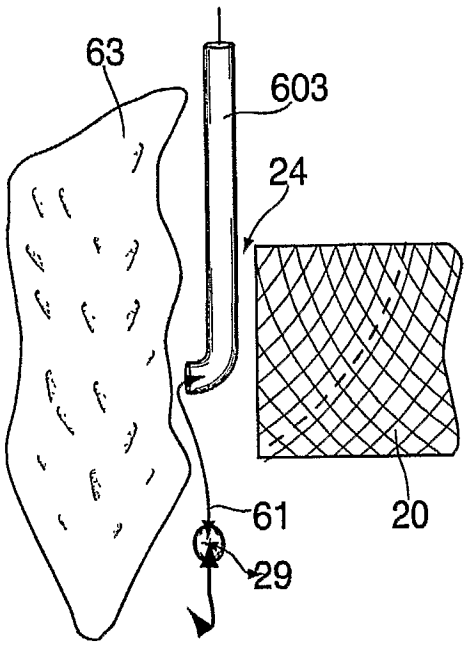


FIG. 6a

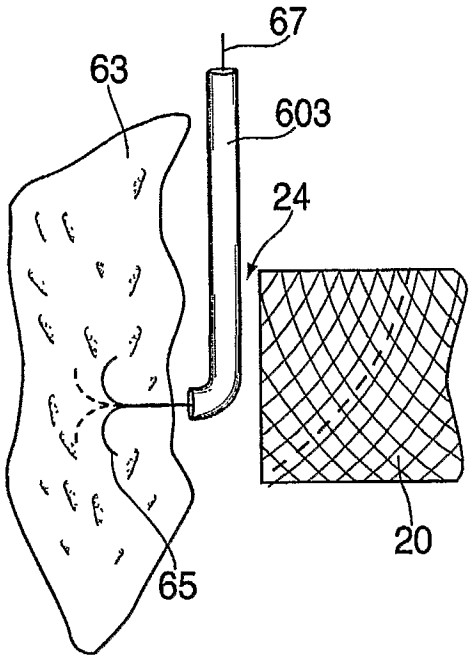


FIG. 6b

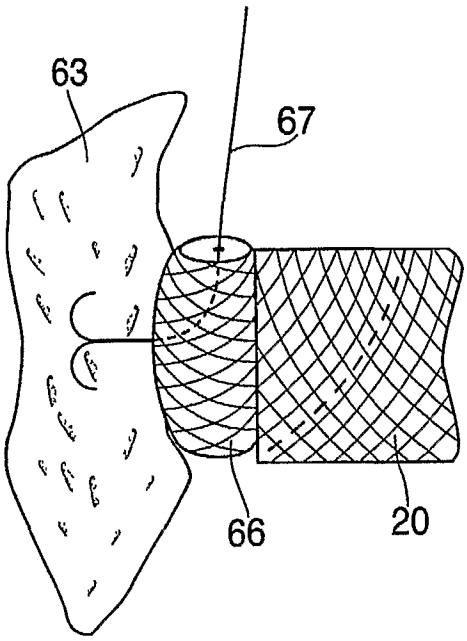


FIG. 6c

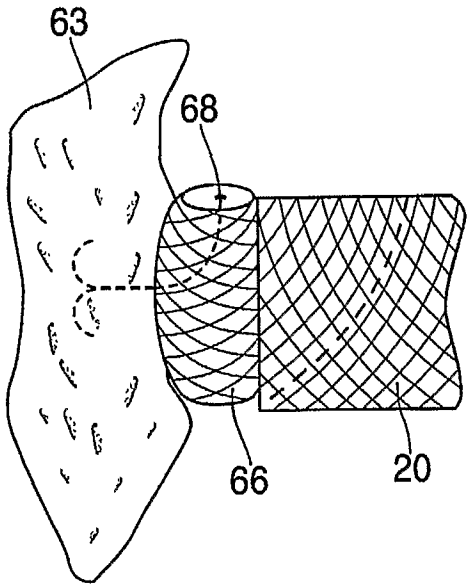


FIG. 6d



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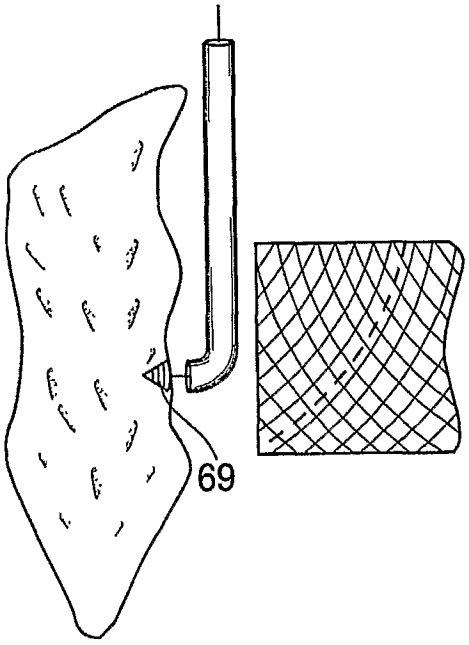


FIG. 7



Aortic Innovations, LLC, Exhibit 2040
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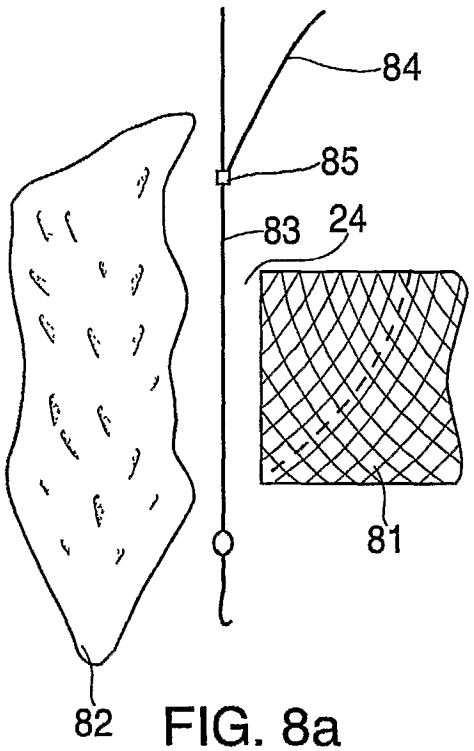


FIG. 8a

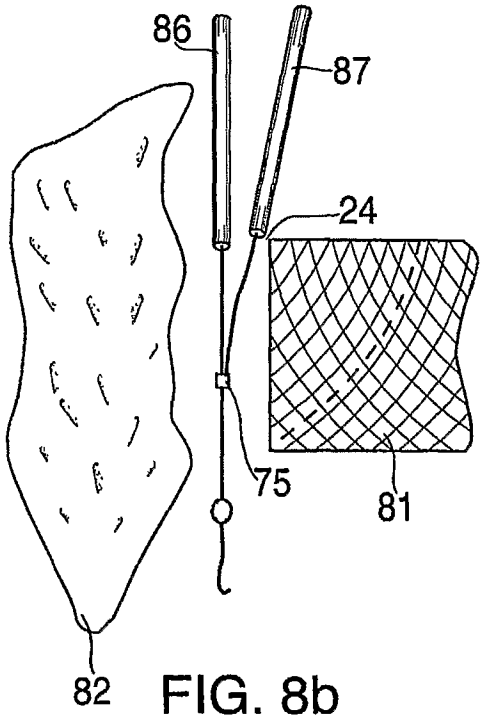


FIG. 8b

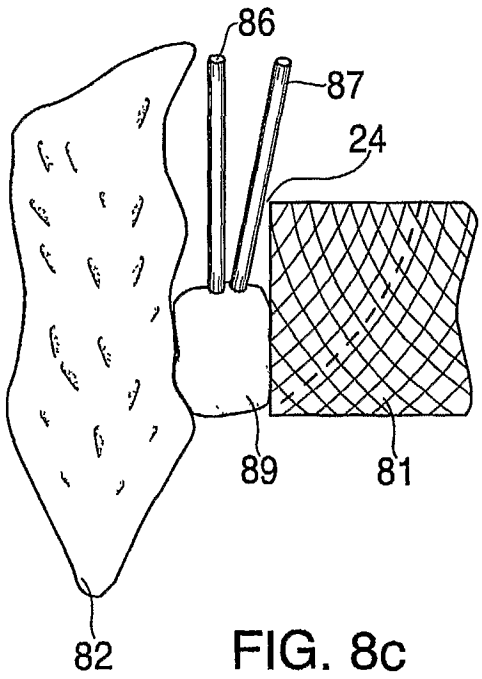


FIG. 8c

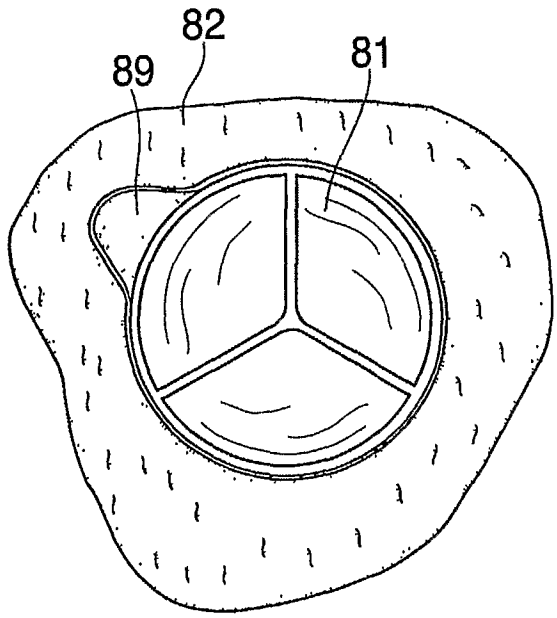


FIG. 8d



Aortic Innovations, LLC, Exhibit 2040
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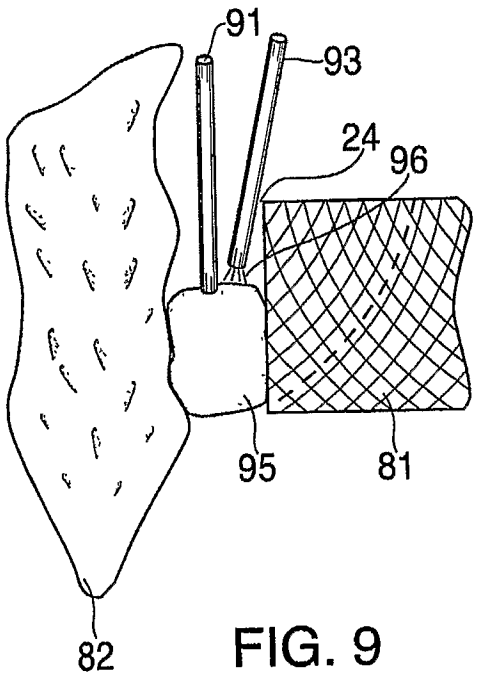


FIG. 9



Aortic Innovations, LLC, Exhibit 2040
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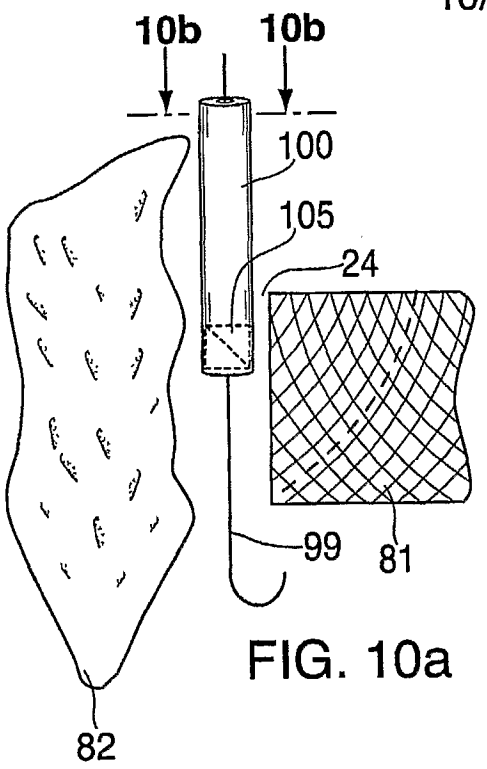


FIG. 10a

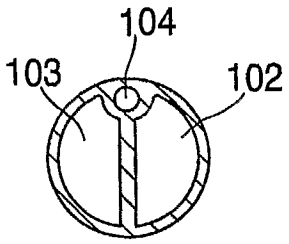


FIG. 10b

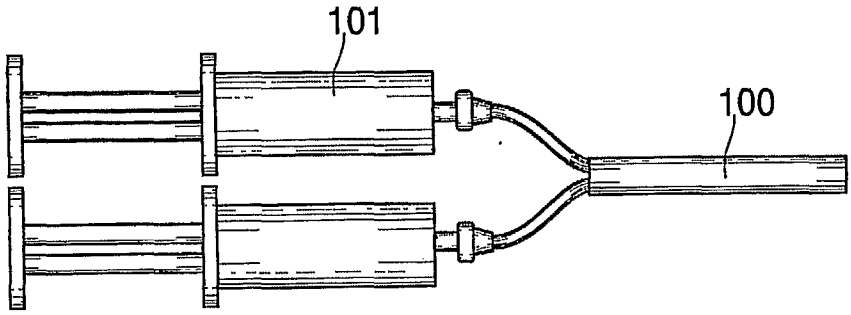


FIG. 10c

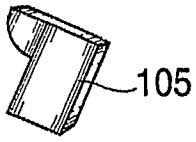


FIG. 10d

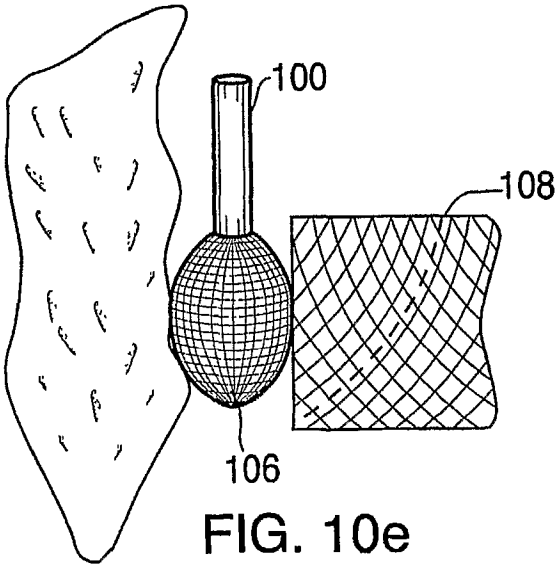


FIG. 10e



Aortic Innovations, LLC, Exhibit 2040
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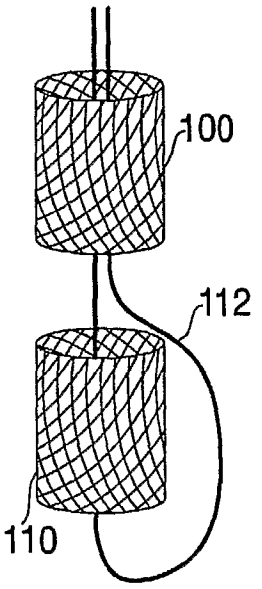


FIG. 11a

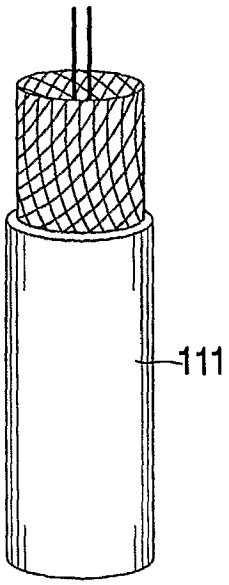


FIG. 11b

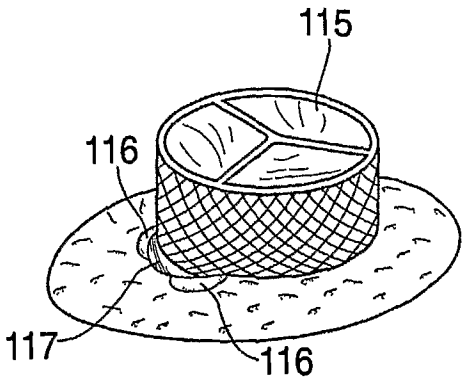


FIG. 11c

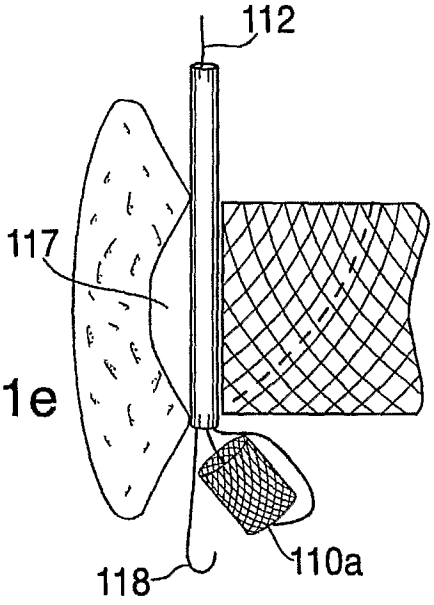


FIG. 11e

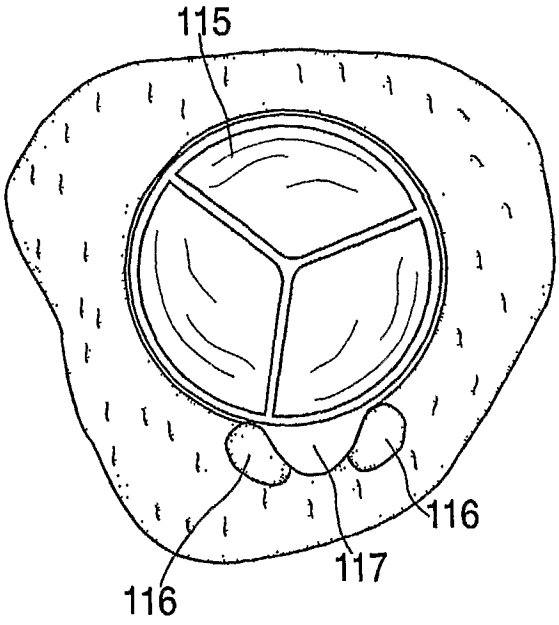


FIG. 11d

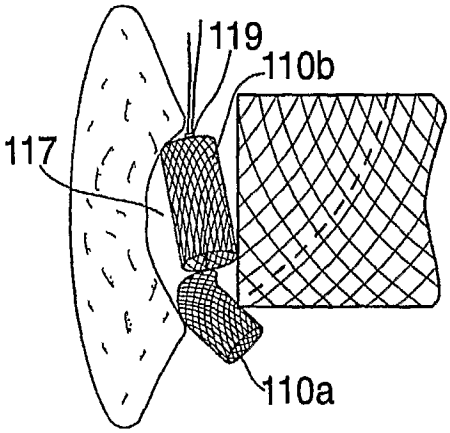


FIG. 11f



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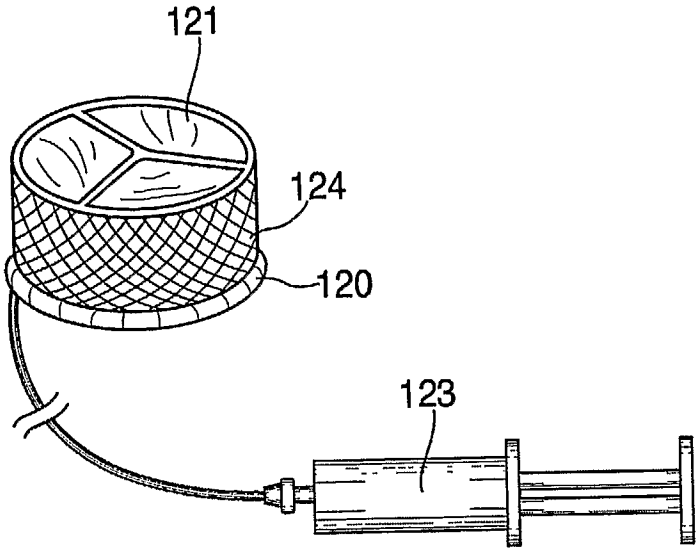


FIG. 12



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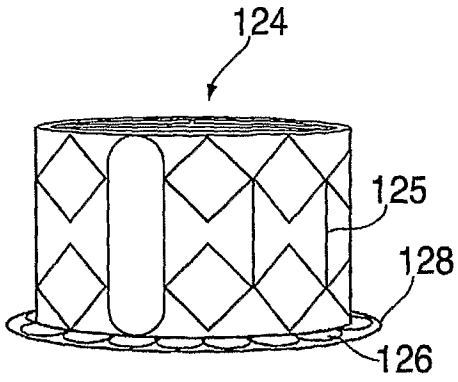


FIG. 13a

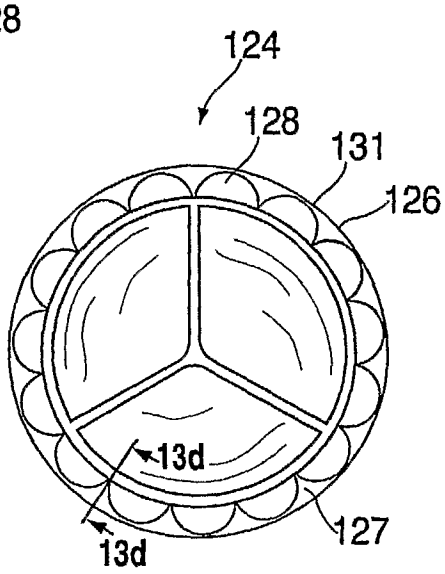


FIG. 13b

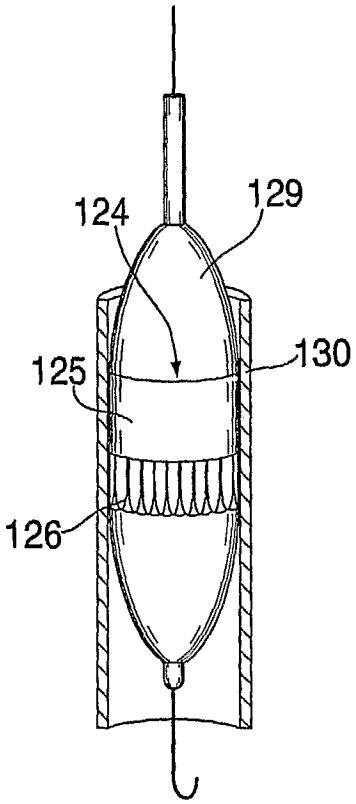


FIG. 13c

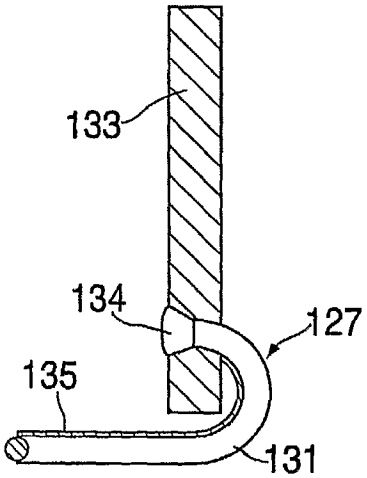


FIG. 13d



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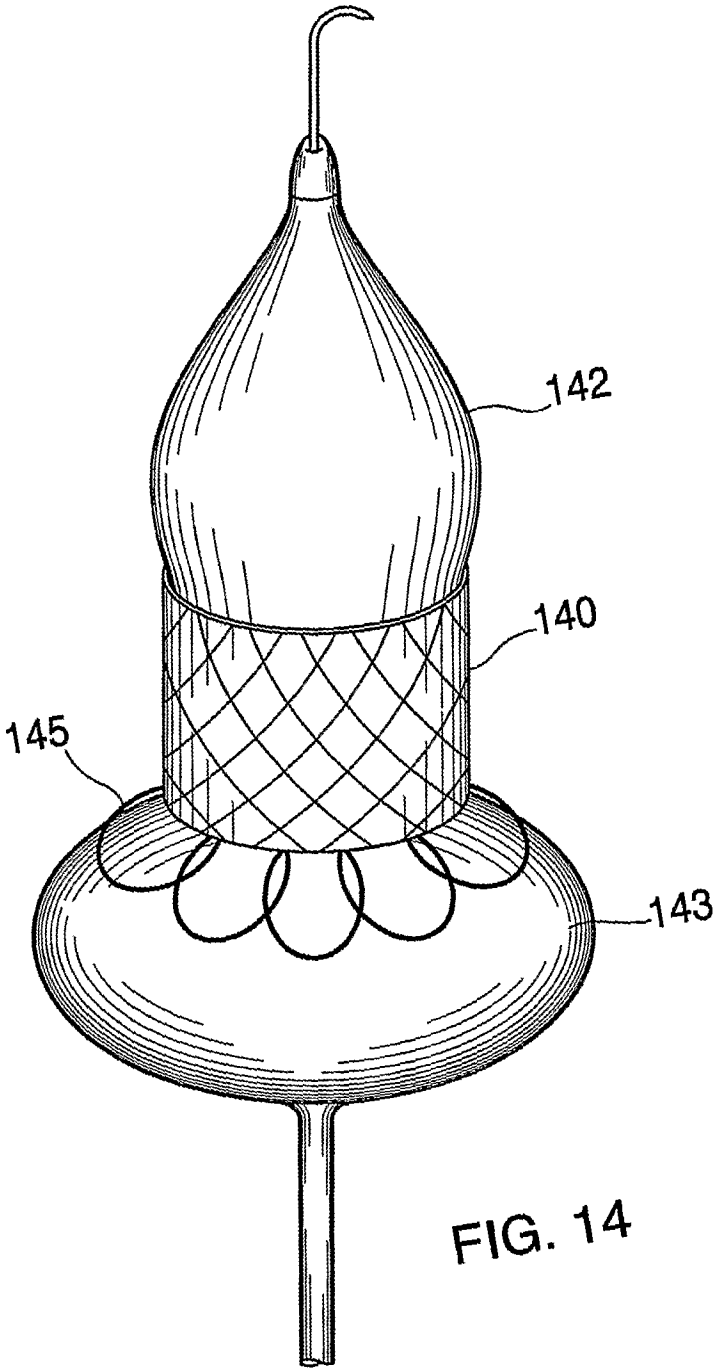


FIG. 14



Aortic Innovations, LLC, Exhibit 2040
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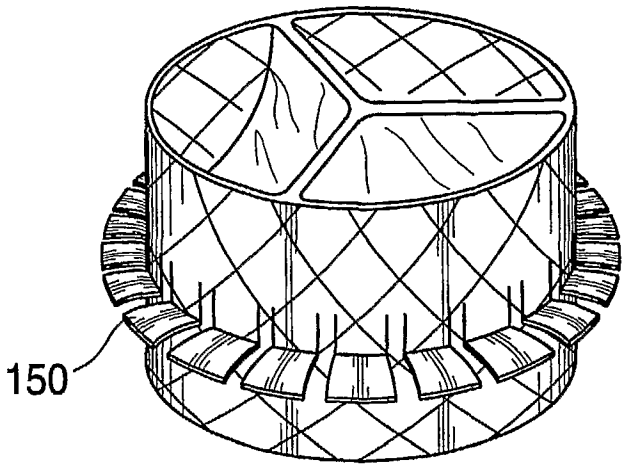


FIG. 15a

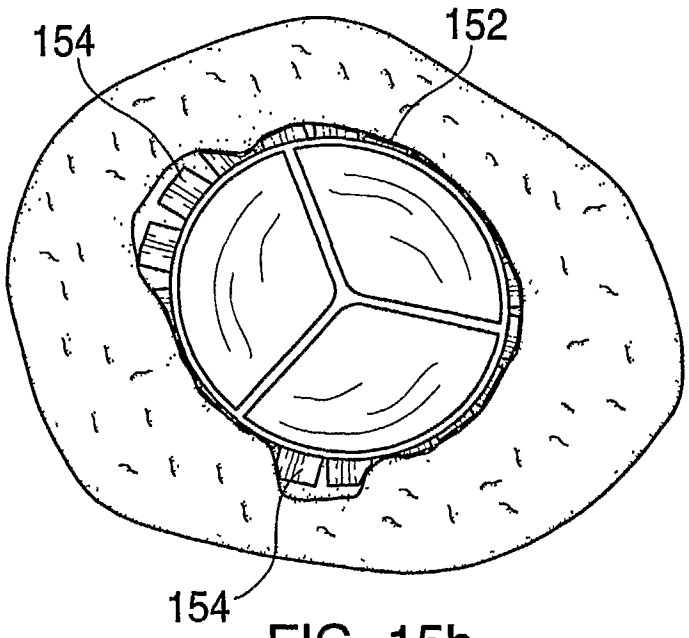


FIG. 15b



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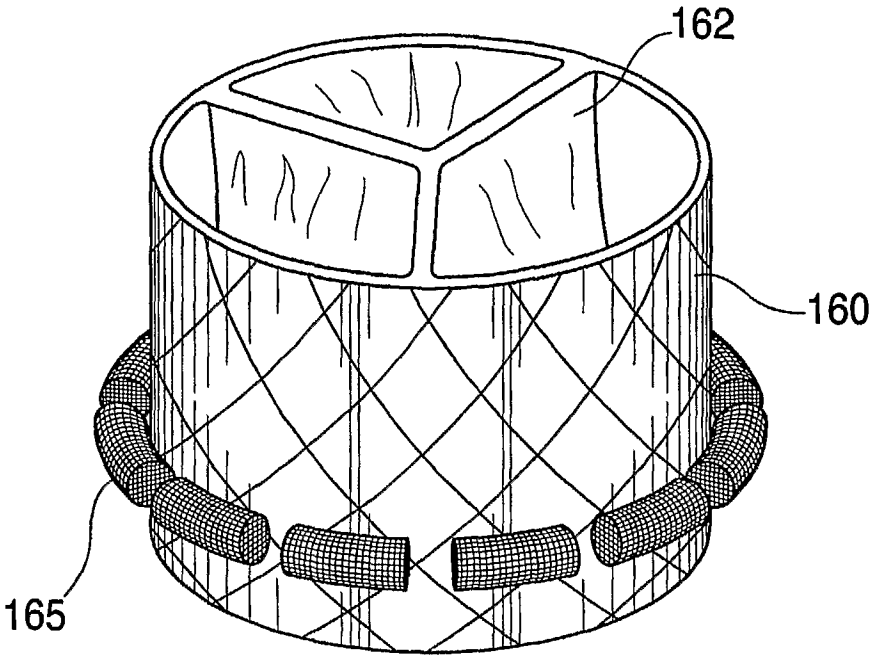


FIG. 16a

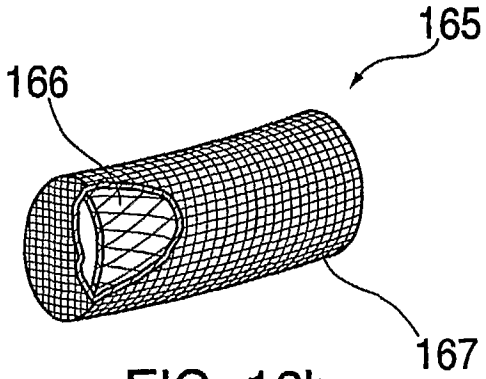


FIG. 16b



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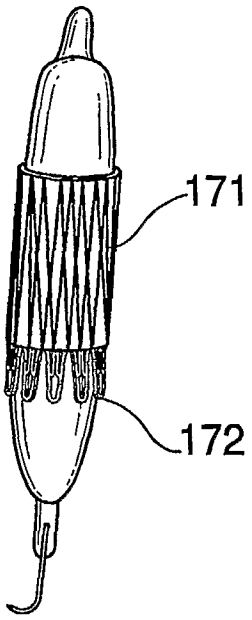


FIG. 17a

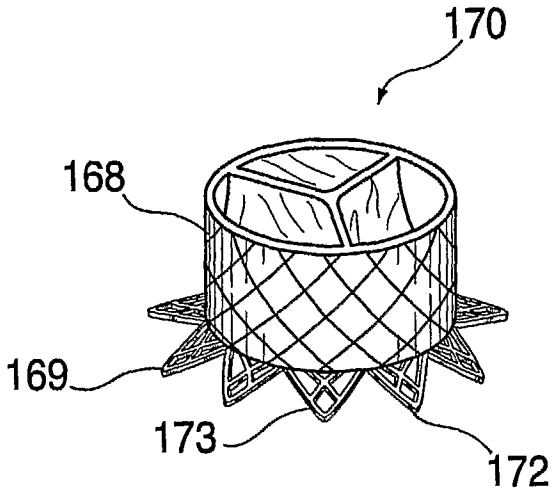


FIG. 17b

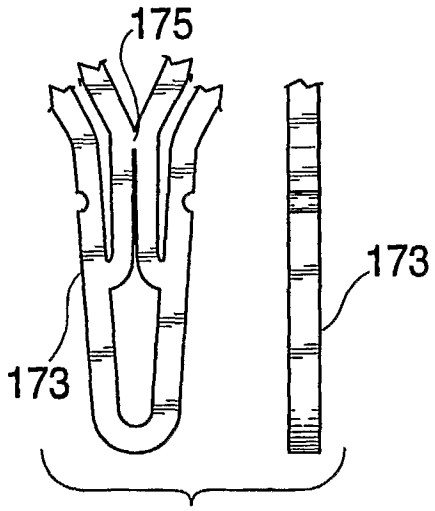


FIG. 17c

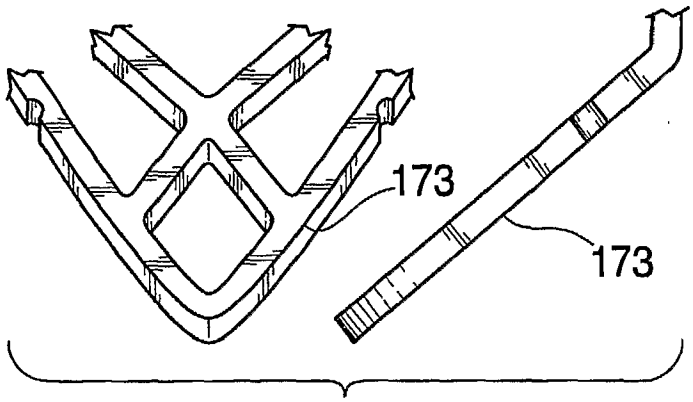


FIG. 17d

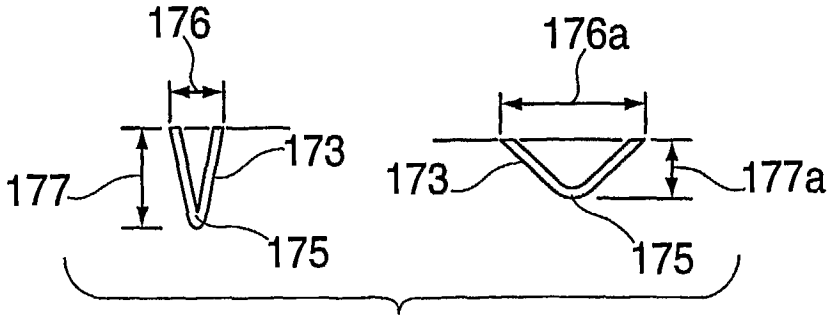


FIG. 17e



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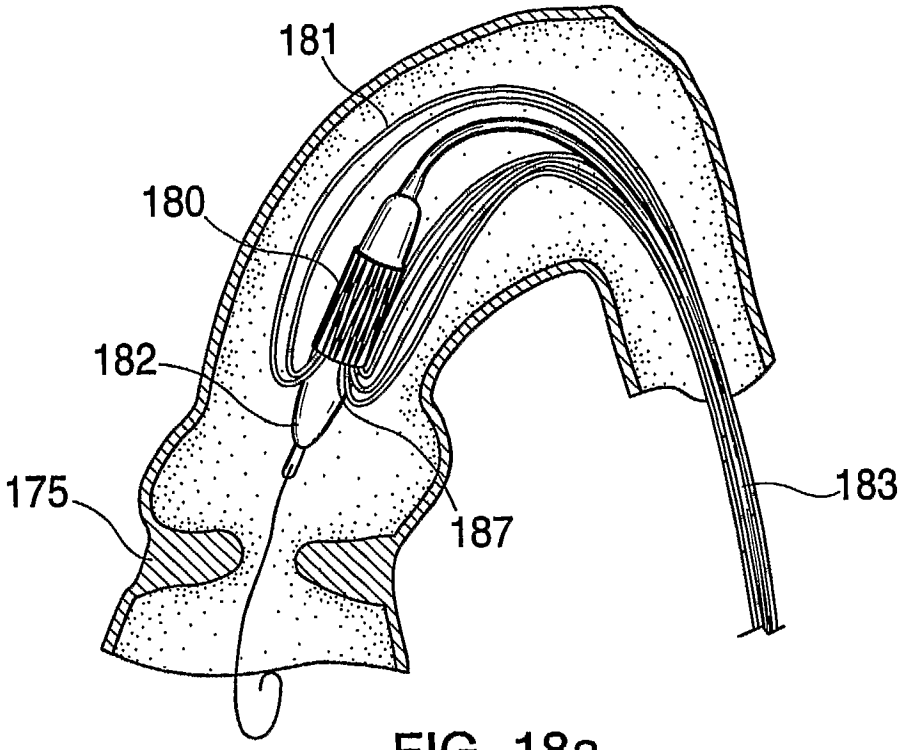


FIG. 18a

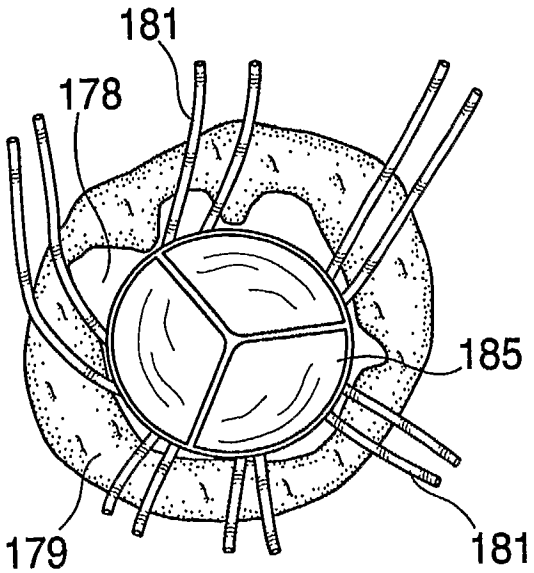


FIG. 18c

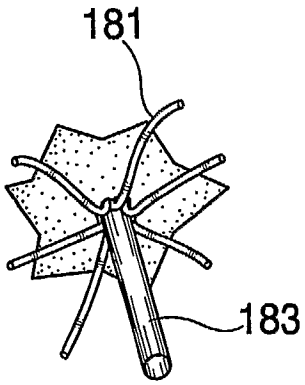


FIG. 18b



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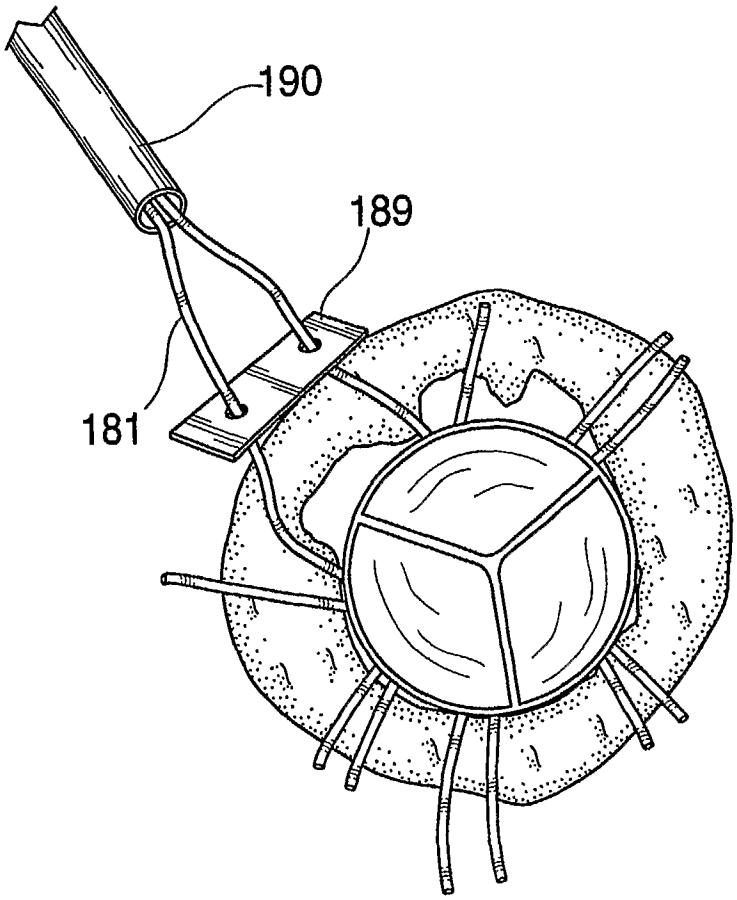


FIG. 18d

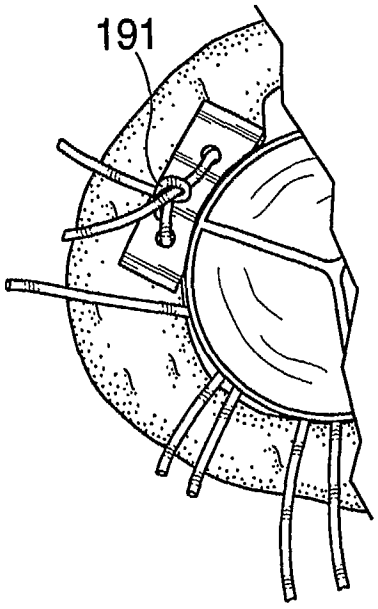


FIG. 18e



Aortic Innovations, LLC, Exhibit 2040
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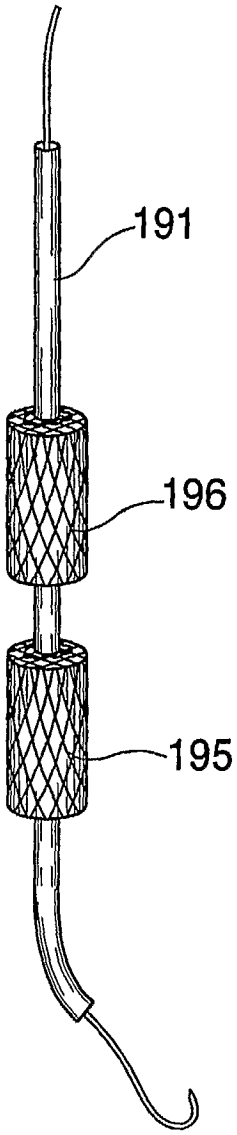


FIG. 19a

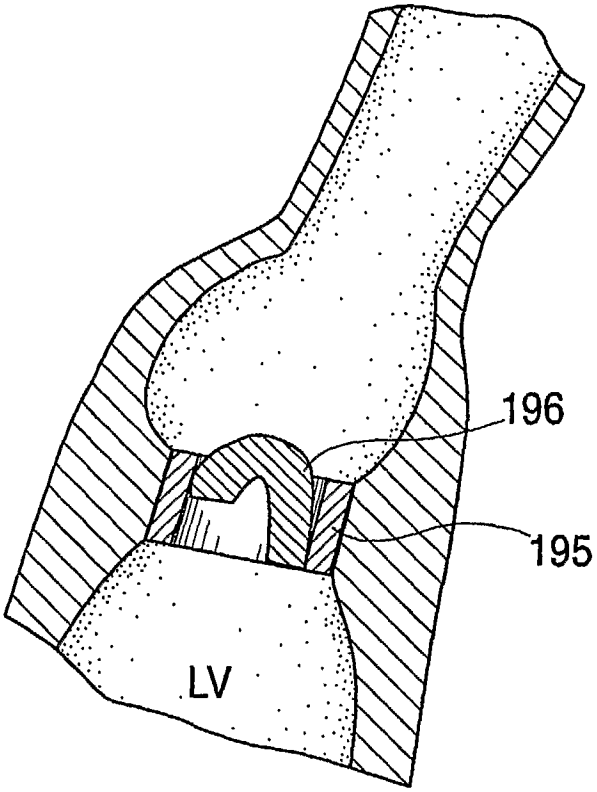


FIG. 19b

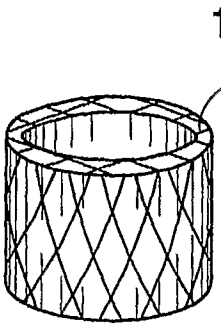


FIG. 19c

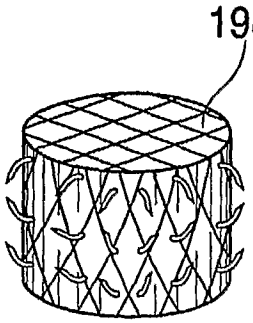


FIG. 19d



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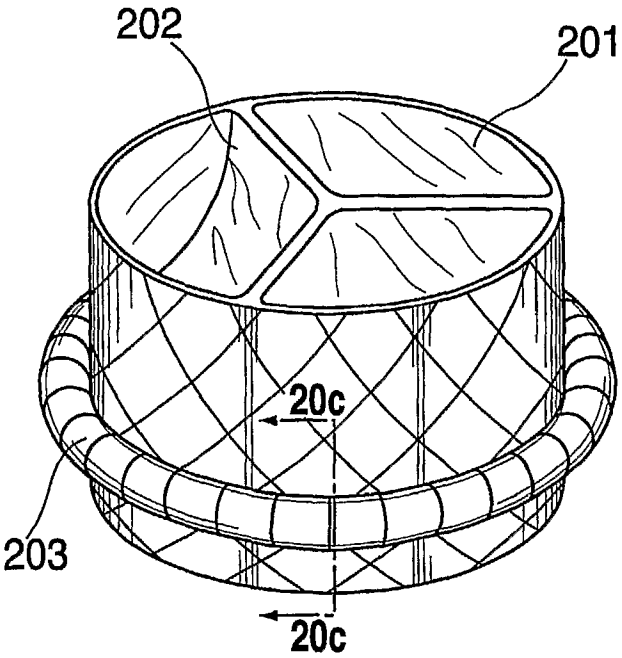


FIG. 20a

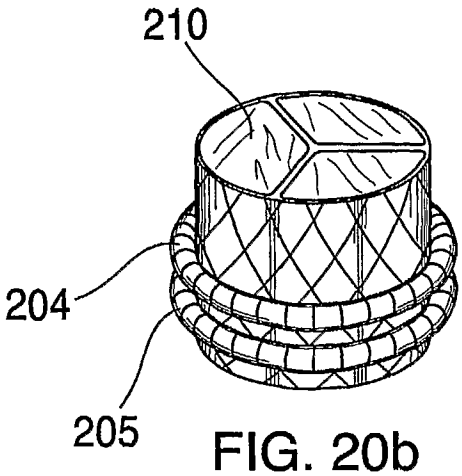


FIG. 20b

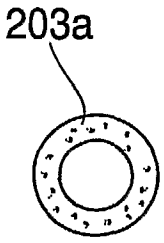


FIG. 20c

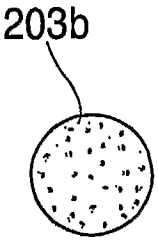


FIG. 20d

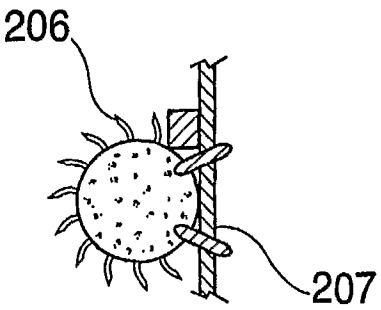


FIG. 20e

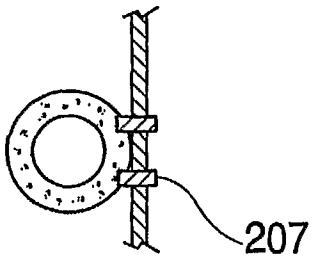


FIG. 20f

FIG. 20g



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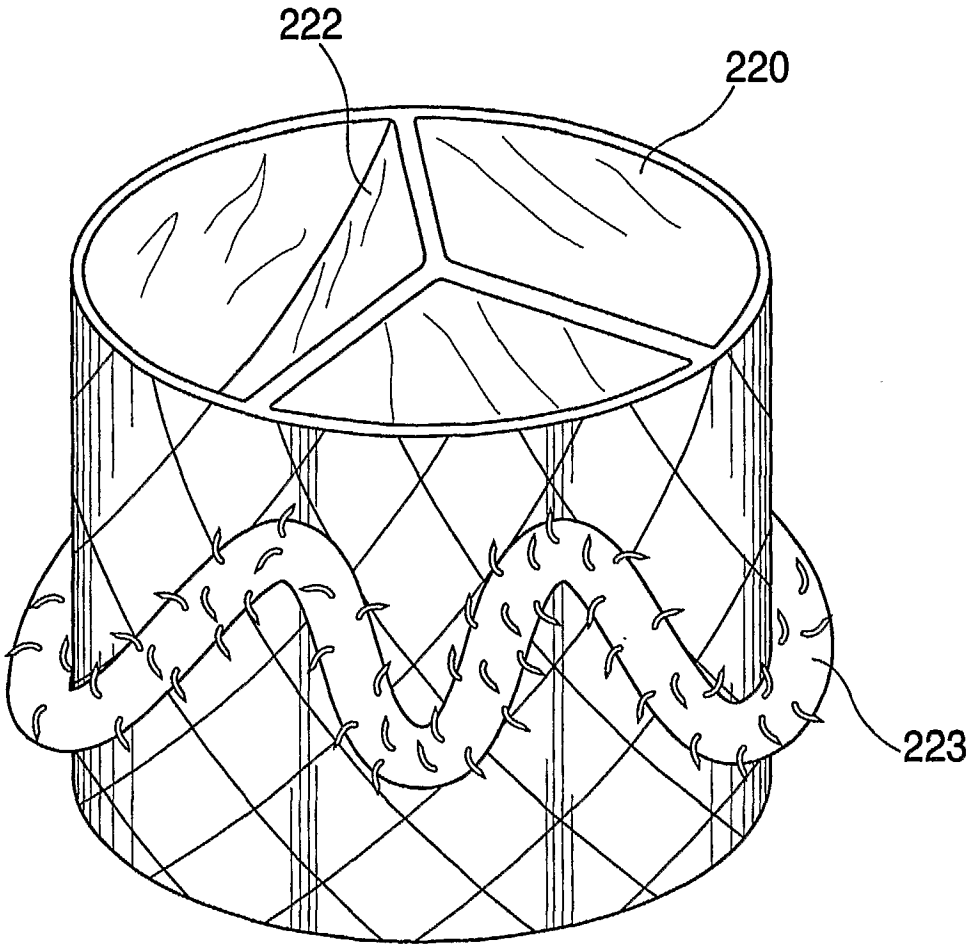


FIG. 21



Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

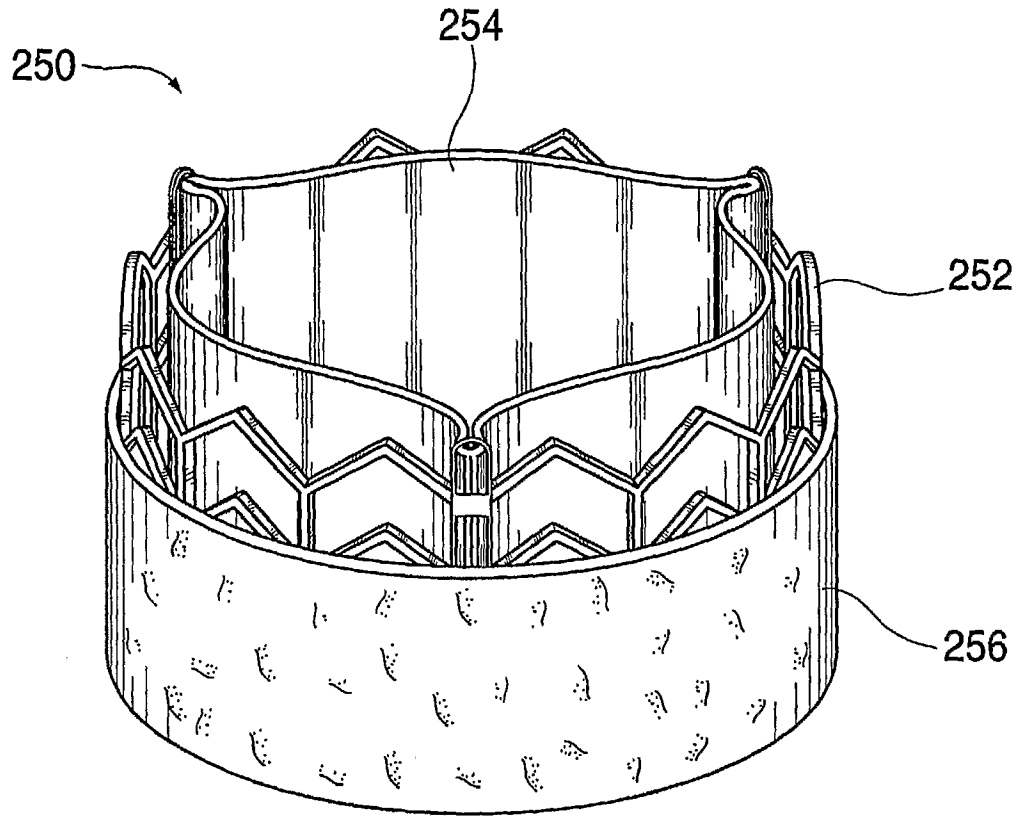


FIG. 22



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Europäisches Patentamt
European Patent Office
Office européen des brevets

# Request for grant of a European patent

| *For official use only* | | |
|---|---|---|
| **1** Application number: | MKEY | **MKEY - EP15180327.7** |
| **2** Date of receipt (Rule 35(2) EPC): | DREC | **DREC - 10 Aug 2015** |
| **3** Date of receipt at EPO (Rule 35(4) EPC): | RENA | |
| **4** Date of filing: | | |

**5** Grant of European patent, and examination of the application under Article 94, are hereby requested. ☒

**5.1** The applicant waives his right to be asked whether he wishes to proceed further with the application (Rule 70(2)) ☐

Procedural language: en

Description and/or claims filed in: en

**6** Applicant's or representative's reference: P/14624EPWD1:RK

**Applicant 1**

**7-1** Name: Edwards Lifesciences PVT, Inc

**8-1** Address:
One Edwards Way
Irvine CA California 92614
United States of America

**10-1** State of residence or of principal place of business: United States of America

**14.1** The/Each applicant hereby declares that he is an entity or a natural person under Rule 6(4) EPC. ☐

**Representative 1**

**15-1** Name: KNIGHTS, Mr Rupert Andrew

Company: Saunders & Dolleymore LLP

**16-1** Address of place of business:
9 Rickmansworth Road
Watford Hertfordshire WD18 0JU
United Kingdom

**17-1** Telephone: +44 1923 238311

**17-1** Fax: +44 1923 246491



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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

17-1 E-mail: info@dolleymores.com

**Inventor(s)**

23 Inventor details filed separately ☒

24 **Title of invention**

Title of invention: Paravalvular Leak Detection, Sealing, and Prevention

25 **Declaration of priority (Rule 52)**

A declaration of priority is hereby made for the following applications

| | State | Filing date | Kind | Application number: | Search results under Rule 141(1) are attached |
|---|---|---|---|---|---|
| Priority 01 | US | 30.06.2004 | ap | 10/883,575 | ☐ |

25.2 This application is a complete translation of the previous application ☐

25.3 It is not intended to file a (further) declaration of priority ☐

26 **Reference to a previously filed application**

27 **Divisional application** ☒

Application number of earlier application: EP05769359.0

Date of Filing (Art. 80/Rule 40 EPC): 30 June 2005

27.1 This divisional application is of the following generation: ☒ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 or subsequent

28 **Article 61(1)(b) application** ☐

29 **Claims**

Number of claims: 11

29.1 ☒ as attached

29.2 ☐ as in the previously filed application (see Section 26.2)

29.3 ☐ The claims will be filed later

30 **Figures**

It is proposed that the abstract be published together with figure No. 22



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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

**31 Designation of contracting states**

All the contracting states party to the EPC and valid for the parent application at the time of filing of this divisional application are deemed to be designated (see Article 76(2)).

**32 Different applicants for different contracting states**

**33 Extension/Validation**

This application is deemed to be a request to extend the effects of the European patent application and the European patent granted in respect of it to all non-contracting states to the EPC with which extension or validation agreements are in force on the date on which the application is filed. However, the request is deemed withdrawn if the extension fee or the validation fee, whichever is applicable, is not paid within the prescribed time limit.

**33.1** It is intended to pay the extension fee(s) for the following state(s):

**33.2** It is intended to pay the validation fee(s) for the following state(s):

**34 Biological material**

**38 Nucleotide and amino acid sequences**

The European patent application contains a sequence listing as part of the description ☐

The sequence listing is attached in computer-readable format in accordance with WIPO Standard ST.25 ☐

The sequence listing is attached in PDF format ☐

**Further indications**

**39** Additional copies of the documents cited in the European search report are requested

Number of additional sets of copies:

**40** Refund of the search fee under to Article 9 of the Rules relating to Fees is requested ☒

Application or publication number of earlier search report: 05769359.0

**42 Payment**

Mode of payment: Debit from deposit account

The European Patent Office is hereby authorised, to debit from the deposit account with the EPO any fees and costs indicated on the fees section below.

Currency: EUR

Deposit account number: 28050140

Account holder: Saunders & Dolleymore LLP

**43 Refunds**



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Page 2040 - 2250
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

| Fees | Factor applied | Fee schedule | Amount to be paid |
|---|---|---|---|
| 001 Filing fee - EP direct - online | 1 | 120.00 | 120.00 |
| 002 Fee for a European search - Applications filed on/after 01.07.2005 | 1 | 1 285.00 | 1 285.00 |
| 015 Claims fee - For the 16th to the 50th claim | 0 | 235.00 | 0.00 |
| 015e Claims fee - For the 51st and each subsequent claim | 0 | 580.00 | 0.00 |
| 501 Additional filing fee for the 36th and each subsequent page | 32 | 15.00 | 480.00 |
| Total: | | EUR | 1 885.00 |

| 44-A Forms | | Details: | System file name: |
|---|---|---|---|
| A-1 | Request | | as ep-request.pdf |
| A-2 | 1. Designation of inventor | 1. Inventor | as f1002-1.pdf |

| 44-B Technical documents | | Original file name: | System file name: |
|---|---|---|---|
| B-1 | Specification | 14624EPWD1 (Description).pdf<br>Description | SPECEPO-1.pdf |
| B-2 | Specification | 14624 EPWD1 (Claims).pdf<br>11 claims | SPECEPO-2.pdf |
| B-3 | Specification | 14624EPWD1 (Abstract).pdf<br>abstract | SPECEPO-3.pdf |
| B-4 | Specification | 14624 EPWD1 (Figures).pdf<br>65 figure(s) | SPECEPO-4.pdf |

| 44-C Other documents | Original file name: | System file name: |
|---|---|---|

45 General authorisation:

46 Signature(s)

Place: **Watford, UK**

Date: **07 August 2015**

Signed by: **Rupert Knights 7287**



Aortic Innovations, LLC, Exhibit 2040
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Representative name: **Rupert Andrew KNIGHTS**

Capacity: **(Representative)**



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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US05/023584

International filing date: 30 June 2005 (30.06.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 10/883,575
Filing date: 30 June 2004 (30.06.2004)

Date of receipt at the International Bureau: 17 August 2005 (17.08.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

1355325

# THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

*August 10, 2005*

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.**

**APPLICATION NUMBER:** *10/883,575*
**FILING DATE:** *June 30, 2004*
**RELATED PCT APPLICATION NUMBER:** *PCT/US05/23584*

Certified by

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

21861 U.S.PTO
063004

22386 U.S.PTO
10/883575
063004

PTO/SB/05 (08-03)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE
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# UTILITY PATENT APPLICATION TRANSMITTAL

*(Only for new nonprovisional applications under 37 CFR 1.53(b))*

| | |
|---|---|
| *Attorney Docket No.* | 501015.20517 |
| *First Inventor* | Benjamin Spenser |
| *Title* | Paravalvular Leak Detection ... |
| *Express Mail Label No.* | EV 374587856 US |

## APPLICATION ELEMENTS

*See MPEP chapter 600 concerning utility patent application contents.*

*ADDRESS TO:* **Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450**

1. ☐ Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. ☐ Applicant claims small entity status. See 37 CFR 1.27.
3. ☑ Specification [*Total Pages* 40 ] *(preferred arrangement set forth below)*
   - Descriptive title of the invention
   - Cross Reference to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to sequence listing, a table, or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. ☑ Drawing(s) (*35 U.S.C. 113*) [*Total Sheets* _____ ]
5. Oath or Declaration [*Total Sheets* _____ ]
   a. ☑ Newly executed (original or copy) UNExecuted
   b. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional with Box 18 completed)*
      i. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76
7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

## ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement *(when there is an assignee)* ☑ Power of Attorney UNExecuted
11. ☐ English Translation Document *(if applicable)*
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☑ Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. ☑ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other: .....

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

*Prior application information:* *Examiner* _____ *Art Unit:* _____

**For CONTINUATION OF DIVISIONAL APPS only; The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.**

## 19. CORRESPONDENCE ADDRESS

☑ Customer Number: 30452 *OR* ☐ Correspondence address below

| | | | | | |
|---|---|---|---|---|---|
| *Name* | Christopher James | | | | |
| *Address* | Edwards Lifesciences LLC | | | | |
| | One Edwards Way | | | | |
| *City* | Irvine | *State* | CA | *Zip Code* | 92614 |
| *Country* | US | *Telephone* | 949-250-6878 | *Fax* | 949-250-6850 |

| | | | |
|---|---|---|---|
| *Name (Print/Type)* | William H. Dippert | *Registration No. (Attorney/Agent)* | 26,723 |
| *Signature* | William H. Dippert | *Date* | June 30,2004 |

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

PTO/SB92 (08-00)
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U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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## Certificate of Express Mail Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service Express Mail under 37 CFR 1.10 on the date indicated below and is addressed to:

Mail Stop: NEW APPLICATION
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on June 30, 2004 (Date) — EV374587856US (Express Mail Label)

William H. Dippert

William H. Dippert, Registration No. 26,723

Reed Smith LLP
599 Lexington Avenue
29th Floor
New York, New York 10022-7650
Telephone: 212-521-5400; Facsimile: 212-521-5450

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

| | |
|---|---|
| Applicant: | Benjamin Spenser et al. |
| Serial No: | To Be Assigned |
| Filing Date: | June 30, 2004, herewith |
| For: | Paravalvular Leak Detection, Sealing, & Prevention |
| Enclosures: | (1) Utility Patent Application Transmittal ( page); (2) Specification (40 pages); (3) Drawings (20 sheets); (4) NonPublication Request (1 page); (5) UNExecuted Declaration (3 pages); (6) UNExecuted POA (3 pages); (7) Acknowledgement Postcard. |

Burden Hour Statement: This form is estimated to take 0.03 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/35 (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# NONPUBLICATION REQUEST UNDER 35 U.S.C. 122(b)(2)(B)(i)

| | |
|---|---|
| First Named Inventor | Benjamin Spenser |
| Title | Paravalvular Leak Detection, Sealing, And ... |
| Attorney Docket Number | 501015.20517 |

I hereby certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing.

I hereby request that the attached application not be published under 35 U.S.C. 122(b).

June 30, 2004
Date

Signature

949-250-6878
Telephone number

William H. Dippert
Registration No. 26,723
for Christopher James

This request must be signed in compliance with 37 CFR 1.33(b) and submitted with the application **upon filing.**

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. 122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. 122(b)(2)(B)(iii)).**

This collection of information is required by 37 CFR 1.213(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, **P.O. Box 1450, Alexandria, VA 22313-1450.** DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

# PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

## FIELD OF THE INVENTION

**[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

**[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.

**[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 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 bileaflet valve having appended chordae and tabs.

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



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June 30, 2004 2:59 PM

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**[0005]** Schreck in U.S. Patent No. 6,454,799, entitled, "MINIMALLY-INVASIVE HEART VALVES AND METHODS OF 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, 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 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 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, "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 more longitudinal channels or passways therethrough.





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**[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 transceptal hole and 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 bring comprised of a deployable construction 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 bring provided with a plurality of longitudinally rigid support beams 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, 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.



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**[0011]** With regard to the general topic of prosthetic valves, implantation is currently done either through open heart surgery or by use 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 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 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 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 location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself.



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## 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 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.

**[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 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 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 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.





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**[0019]** Furthermore, in accordance with another preferred embodiment of the present invention, the sealing stent is self-expandable, 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 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.

**[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, 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.





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**[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.

**[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 to create the plug in the cavity.





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**[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 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 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 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.

**[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, and, upon egress from the catheter, the tabs spring out to form the sealing ring.



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**[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 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 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.

**[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 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.





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**[0039]** There is thus also provided in accordance with a preferred 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 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 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 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,

**[0043]** 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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**[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 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 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

**[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.





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**[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.

**[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.

**[0055]** There is thus also provided in accordance with a preferred embodiment of the present invention, a method for providing integrated 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:

**[0056]** providing an expandable elastic ring around the outside of the valve; and

**[0057]** expanding the ring,

**[0058]** wherein the ring seals any cavities.

**[0059]** 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 where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

**[0060]** inserting a sealing stent at the distal end of the cavity; and

**[0061]** inserting a second sealing stent attached to the first stent into the cavity.





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## BRIEF DESCRIPTION OF THE FIGURES

**[0062]** 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.

**[0063]** Figure 1 illustrates an implanted valve with a cavity 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.

**[0064]** Figures 2a and 2b depict a plurality of balloons on soft guidewires, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

**[0065]** Figure 3 illustrates a plurality of balloons on soft guidewires and kept along the perimeter of the blood vessel by a ring, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

**[0066]** 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.

**[0067]** Figures 5a to 5d depict several types of sealing stents, in accordance with another preferred embodiment of the present invention.



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**[0068]** 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 aortic wall (or annulus).

**[0069]** 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).

**[0070]** 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.

**[0071]** Figures 9a to 9c depict a leak repair done, in accordance with another preferred embodiment of the present invention, using an ultra-violet light-cured biological glue.

**[0072]** 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.

**[0073]** 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.

**[0074]** Figures 12 depicts a valve, in accordance with another preferred embodiment of the present invention, with a built-in inflatable portion allowing to fill gaps between the valve stent and the aortic wall in order to prevent paravalvular leaks.

**[0075]** 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.





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**[0076]** 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..

**[0077]** 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.

**[0078]** Figures 16a and 16b illustrate a valve device, in accordance with another preferred embodiment of the present invention, comprising an additional portion for blocking possible leaks around the stent.

**[0079]** 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 to protrude radially, thereby blocking possible leaks.

**[0080]** 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 leaks.

**[0081]** 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.



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## DETAILED DESCRIPTION OF THE INVENTION

**[0082]** 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.

**[0083]** 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 are tricuspid valves, it could be another type of valve as well.

**[0084]** A main aspect of the present invention is the introduction of several novel designs and methods for locating paravalvular leaks in prosthetic valves.

**[0085]** Another main aspect of the present invention are several novel designs for sealing paravalvular leaks detected in prosthetic valves.

**[0086]** 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.

**[0087]** Another main aspect of the present invention is a novel design that automatically seals paravalvular leaks when the valve is implanted without requiring valve modification.

**[0088]** 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.





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**[0089]** For locating paravalvular leaks, the present invention 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 and the wall of the blood vessel, thereby providing a means to deliver means for sealing the leak.

**[0090]** For sealing paravalvular leaks, the present invention provides several designs including sealing stents, and multi-component and radiation-cured adhesive compounds.

**[0091]** 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.

**[0092]** 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 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.

**[0093]** Another anchoring means is for the guidewire to be terminated in a screw, which can be threaded into the blood vessel wall.



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**[0094]** 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, 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 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.

**[0095]** The sealing stent is held in place by friction. Additional holding force can be obtained by adding hooks around the perimeter of the stent, such as self-expanding hooks made of shape memory alloy.

**[0096]** 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 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.

**[0097]** 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. 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





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retracted, and the second stent is deployed into the cavity. The catheter is further retracted and the second stent is pulled back, catching it (from the bottom) in the top of the cavity.

**[0098]** An alternative sealing element to the sealing stent is a biological adhesive compound that can be delivered to the cavity via catheter. In such a case, two catheters are brought to the leak 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.

**[0099]** In both sealing element designs there is a need to bring the 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 then slid over their guidewires to meet at the leak location, thereby providing egress for applying the bi-component adhesive or radiation-cured adhesive.

**[00100]** Another delivery design for a bi-component adhesive utilizes a single catheter run over the leak detection guidewire. The 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.

**[00101]** In other embodiments of the present invention, leak sealing means are integrated into the valve as an impermeable ring that, when the valve is implanted, adaptively seals any gaps between the valve and the surrounding lumen.

**[00102]** In one embodiment of such a self-sealing valve, the ring is deflated for delivery and then inflated for sealing.



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**[00103]** In another self-sealing valve embodiment, the ring is a sponge-like material that is compressed for delivery and then expands for sealing.

**[00104]** In another self-sealing valve embodiment, the ring 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.

**[00105]** In another self-sealing valve embodiment, the ring comprises a set of self-expanding tubes.

**[00106]** 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

**[00107]** In another embodiment where sealing means are built into 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.

**[00108]** 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.

**[00109]** The aforementioned embodiments as well as other embodiments, manufacturing methods, different designs and different 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.





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**[00110]** 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.

**[00111]** 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 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 balloon 29 is drawn into the regurgitation flow and lodges in cavity 24 in between valve 20 and annulus 22.

**[00112]** 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. 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.



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**[00113]** Figure 3 illustrates an annular-configured leak detector 229, 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 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.

**[00114]** 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, 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 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.



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**[00115]** 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.

**[00116]** 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.

**[00117]** 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



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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.

**[00118]** 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.

**[00119]** 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 guide wire 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



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midway through cavity 24, catheters 86 and 87 are slid over guidewires 28 and 84, respectively, until the catheters meet at meeting point 75.

**[00120]** 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.

**[00121]** 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 caused by cavity 24.

**[00122]** 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 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



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guidewire 28. Figure 10c shows a bi-component 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 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 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.

**[00123]** 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



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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.

**[00124]** 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 can be saline solution, the patient's blood, or another physiologically acceptable fluid.

**[00125]** 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 blood, causing it to swell and seal the cavity.

**[00126]** 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 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



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connected to the valve stent 125. 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.

**[00127]** 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.

**[00128]** Figure 13d shows a cross-section of a self-expanding sealing flap 127. Stent strut 133 is attached to spring wire ring 131 by 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.

**[00129]** Figure 14 illustrates a valve adapted to seal paravalvular 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 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.



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**[00130]** Figures 15a and 15b depict a valve adapted to seal 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 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.

**[00131]** 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 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 (polyethylene terephthalate) mesh 167 or other impermeable material.

**[00132]** 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 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),



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ring of struts 172 bend to a final diameter 169 substantially larger than the final diameter 168 of the rest of the expanded stent, thereby sealing paravalvular cavities and associate leaks.

**[00133]** 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. 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 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 moves up, pulling the stent to the shape shown in 17d .

**[00134]** 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 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.



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**[00135]** Inflating balloon 183, as shown in Figure 18c, anchors 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).

**[00136]** Figures 19a to19d 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 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.

**[00137]** Figure 19b shows the two stents placed in the native aortic valve. Sealing stent 195 compensates for irregular shapes, while the 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 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).



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**[00138]** The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other 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.

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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 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 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 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-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 comprised of shape memory material.





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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, 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 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 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 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 first catheter to the point, a second component of the two-





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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 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 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 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.



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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 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.

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.





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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.

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. 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 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.

27. A method for locating 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 comprising:

inserting a balloon mounted on a flexible wire next to the valve;

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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28. 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 comprising:

inserting an impermeable stent into the cavity,

whereby the stent seals the cavity.

29. 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 comprising:

inserting a first guidewire into the cavity;

running a loop attached to a second guidewire over the first guide wire to a point inside the cavity;

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

injecting the second component of the two-component adhesive through a catheter over the second guide wire to the cavity,

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

30. The method of Claim 29, wherein 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.

31. The method of Claim 29 where only one guidewire is used and the two components are inserted via separate lumens within a single catheter over the guidewire.





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32. A method for providing integrated 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 comprising:

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

expanding the ring;

whereby the ring seals any cavities.

33. 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 comprising:

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

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



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## ABSTRACT OF THE DISCLOSURE

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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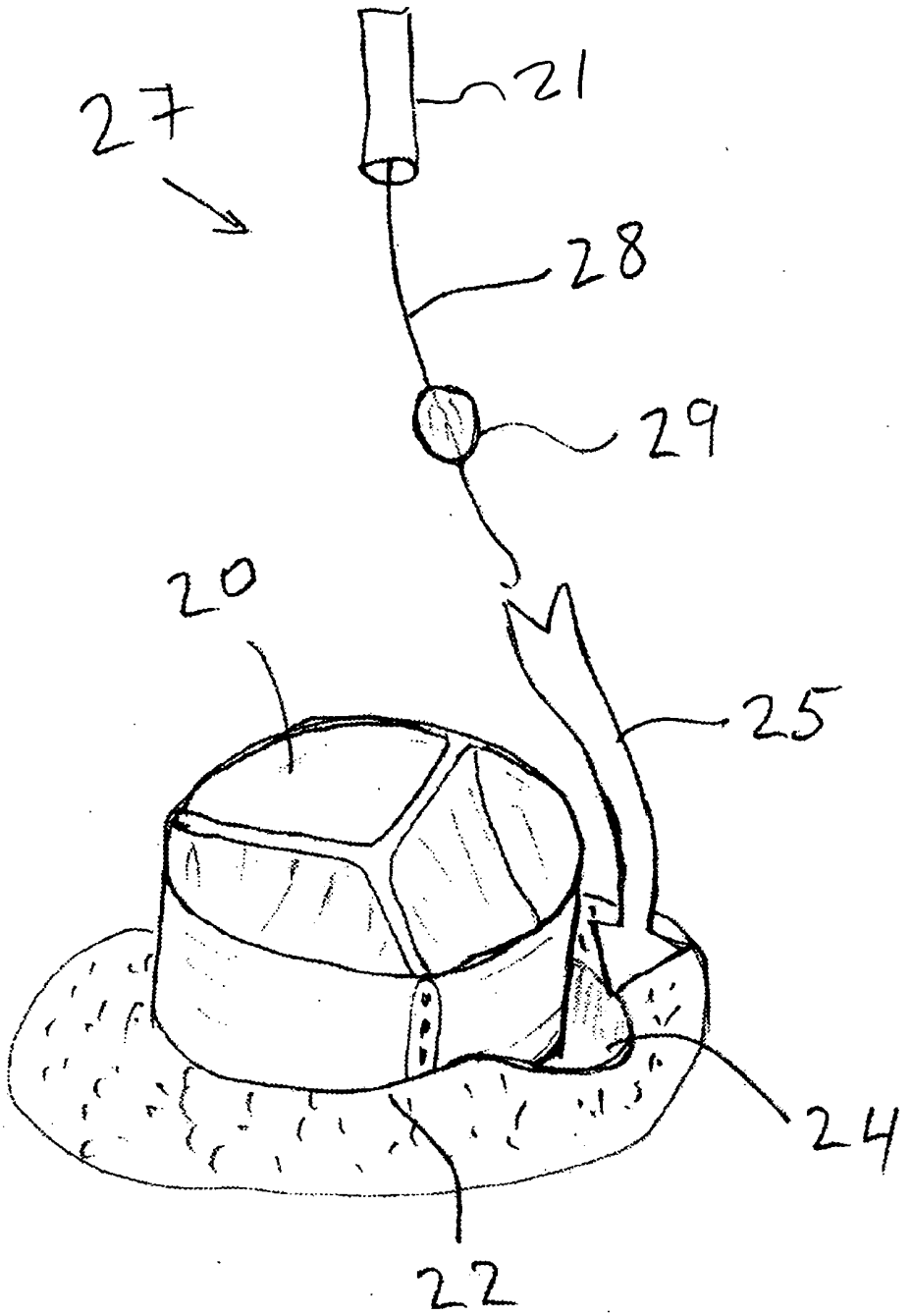


Fig. 1

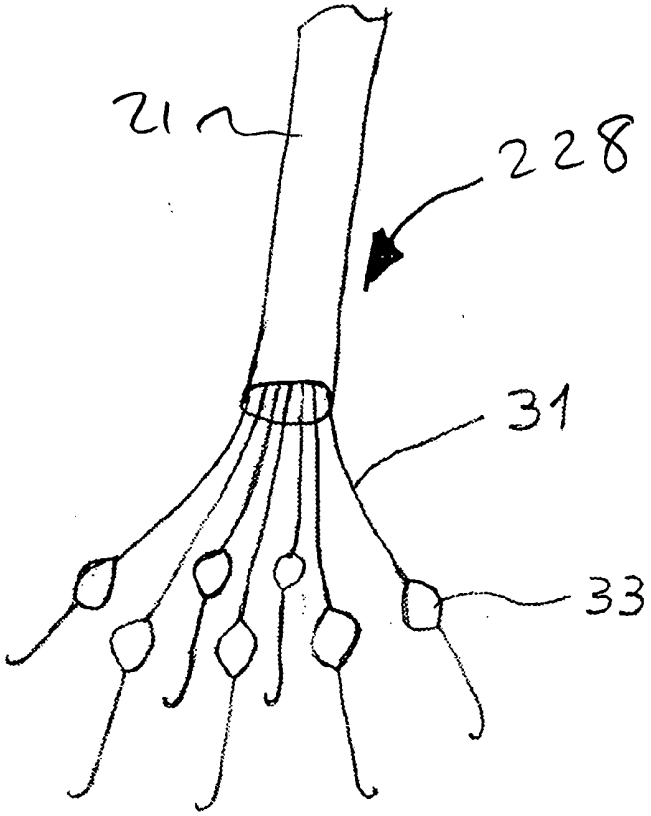


Fig. 2a

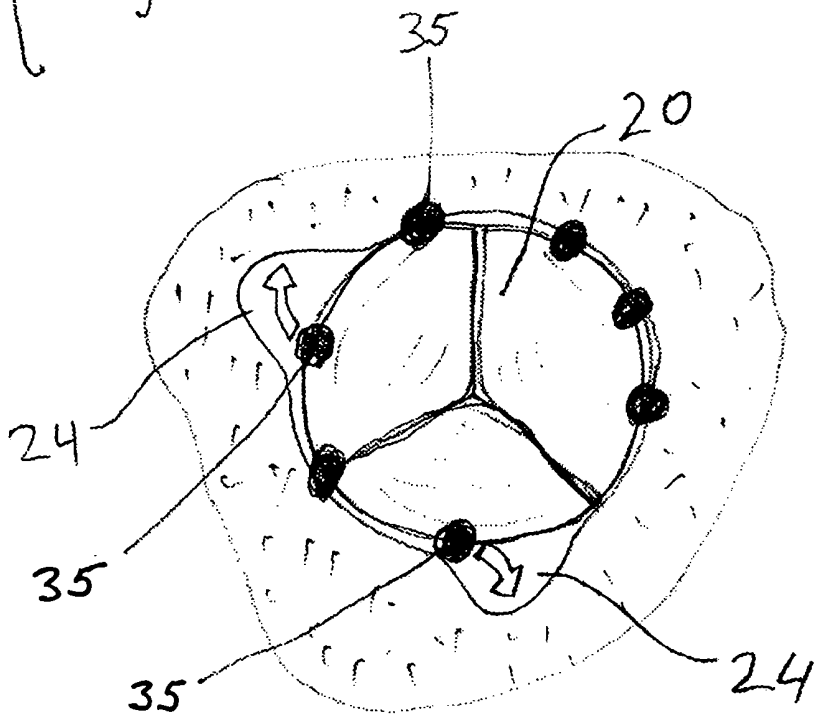


Fig. 2b

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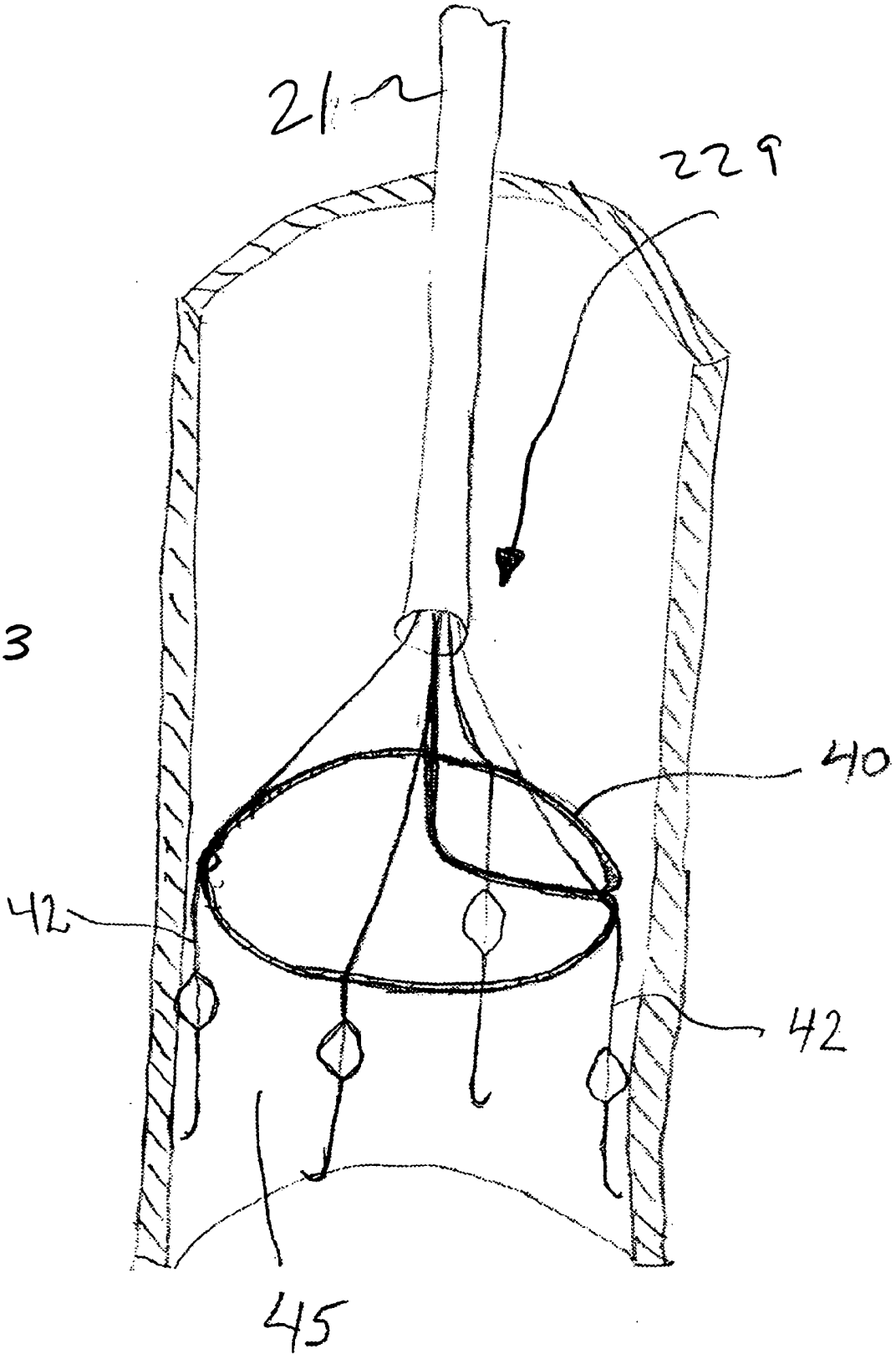


Fig. 3

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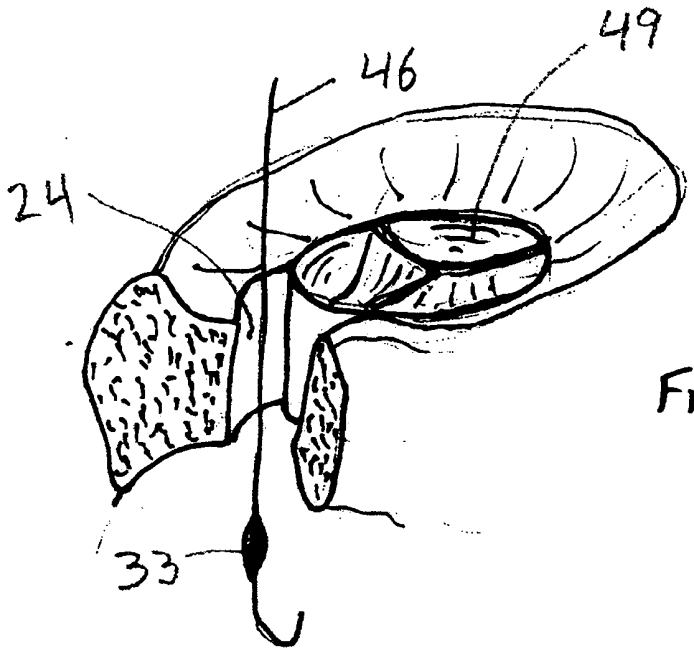
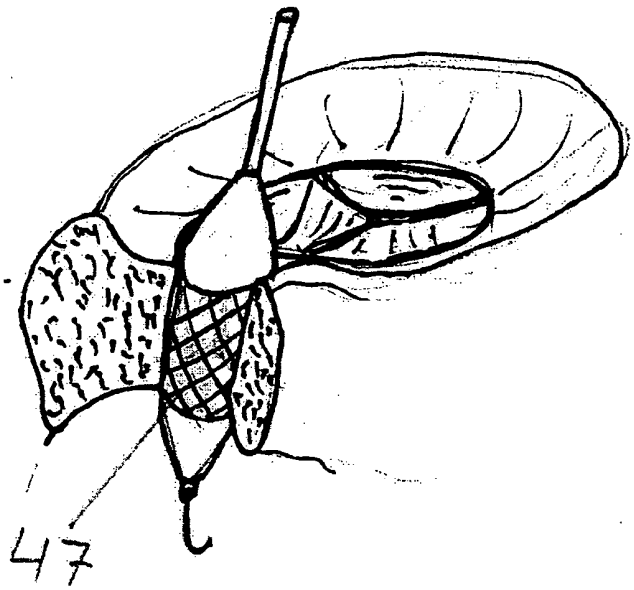



Fig. 4a

Fig. 4b



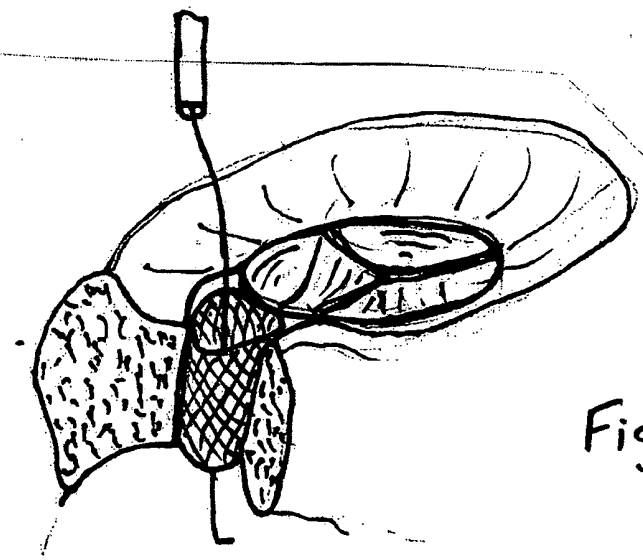



Fig. 4c

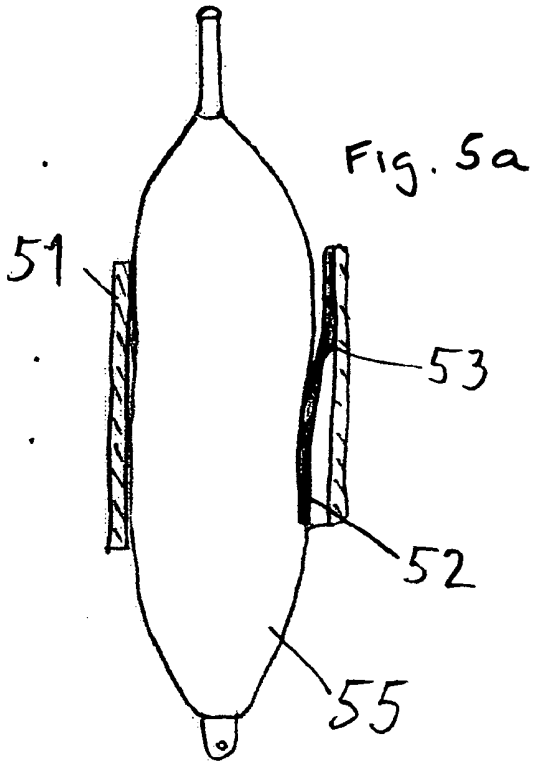



Fig. 5a

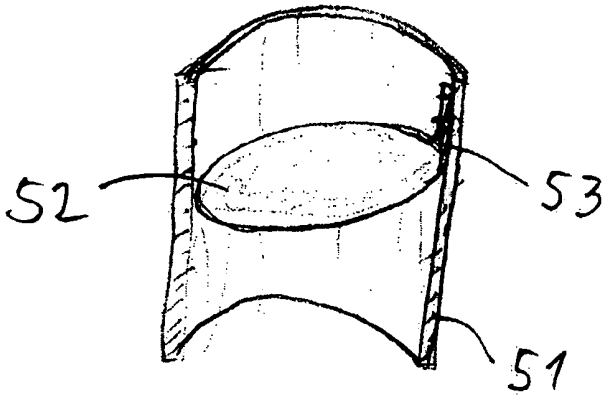



Fig. 5b

Fig. 5c

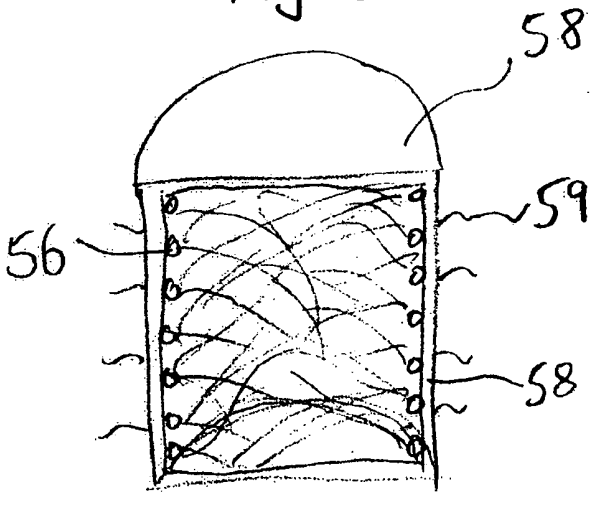
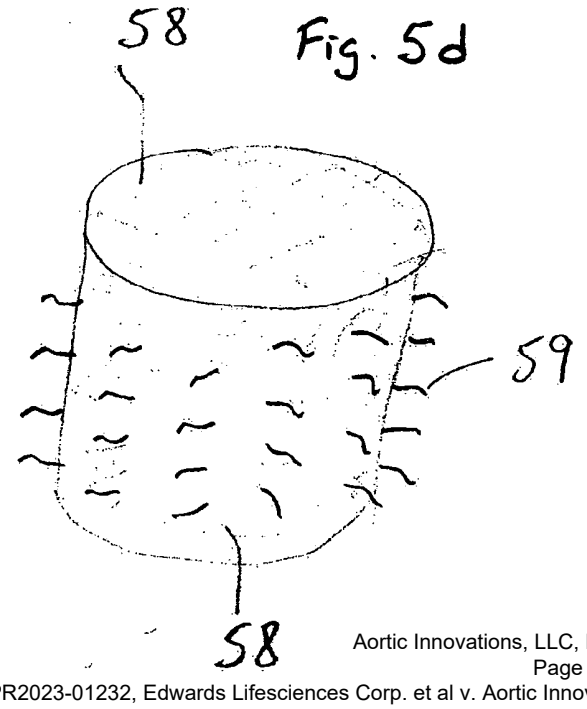



Fig. 5d



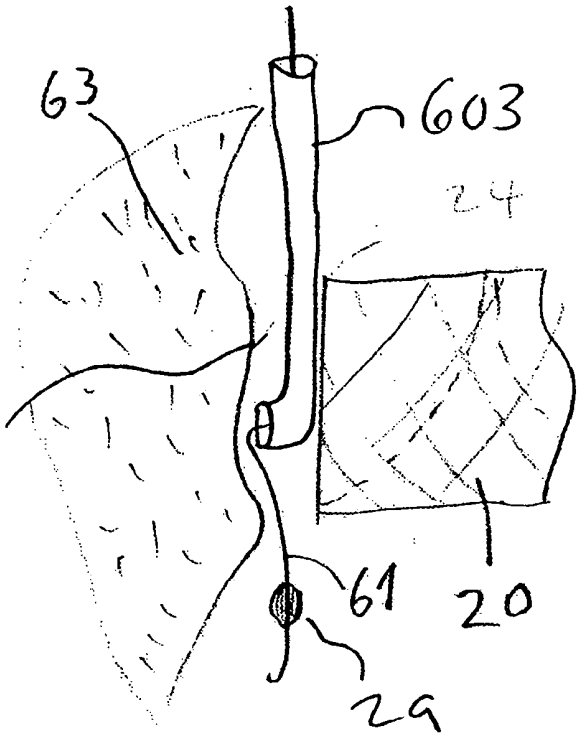



Fig. 6a

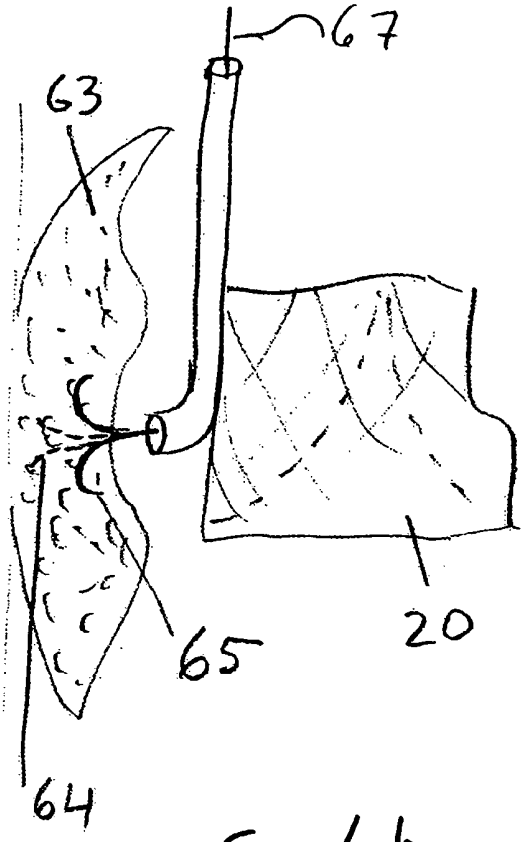



Fig. 6b

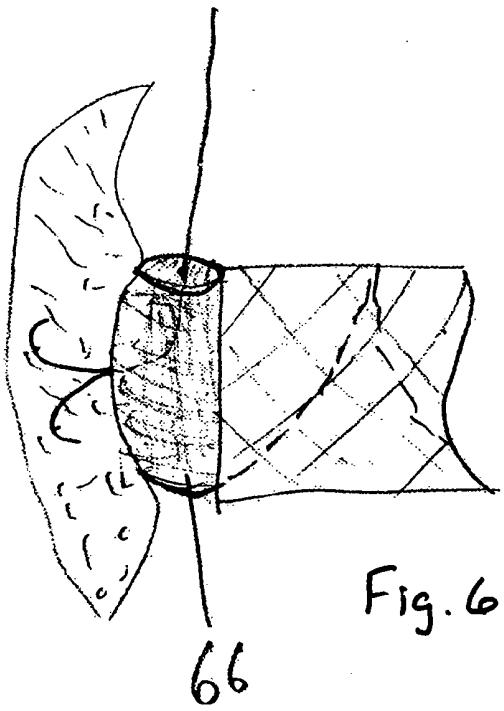



Fig. 6c

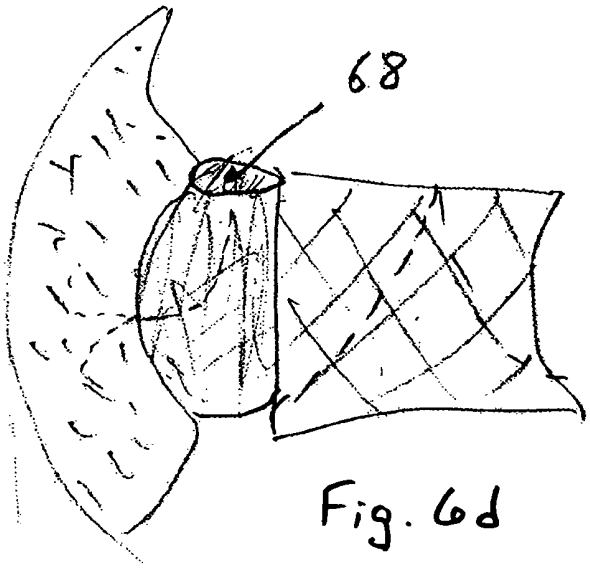



Fig. 6d

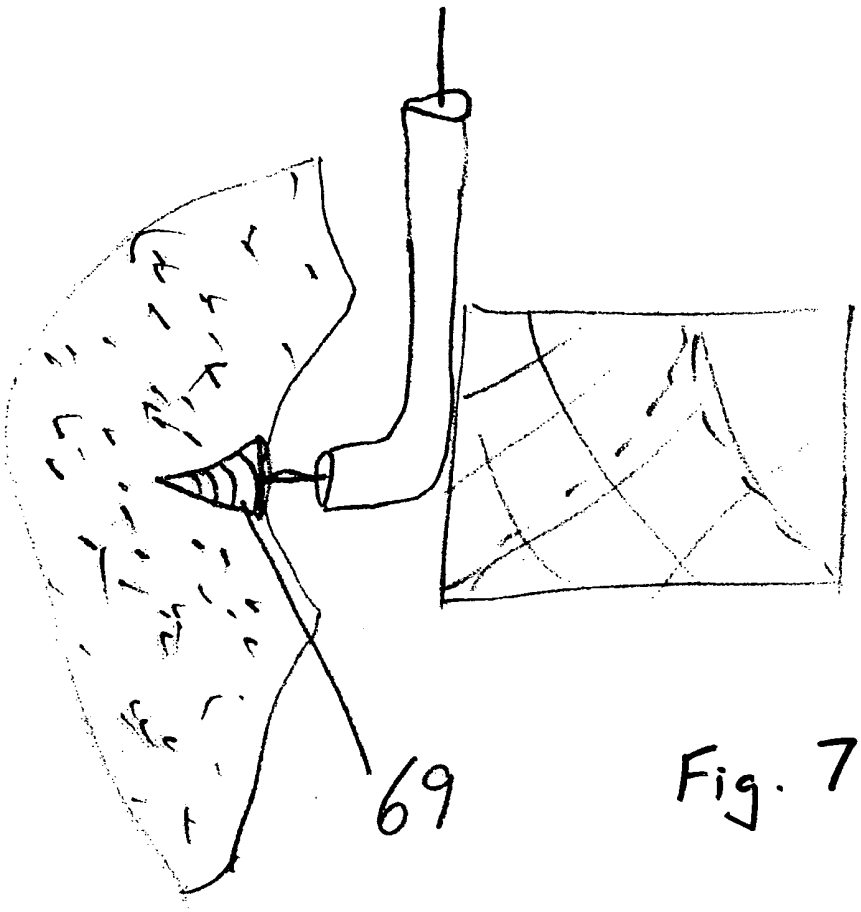



Fig. 7

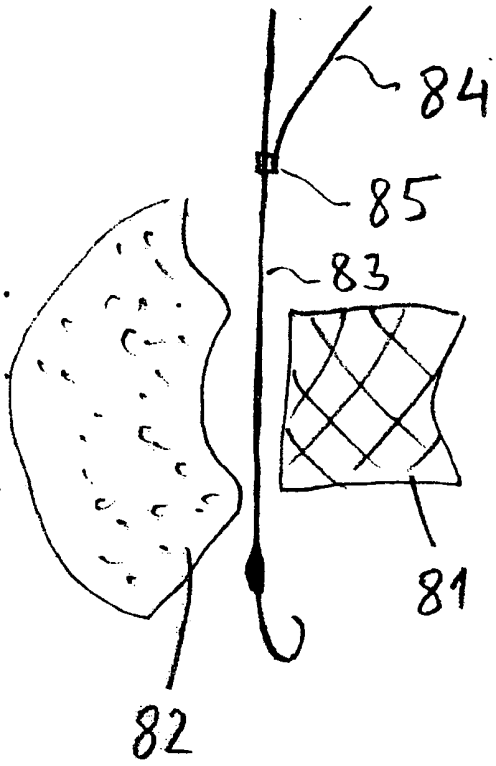



Fig. 8a

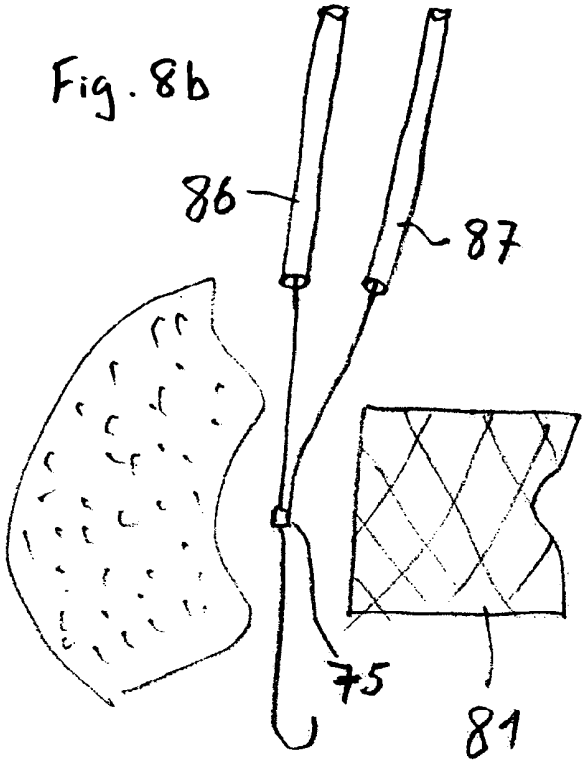



Fig. 8b

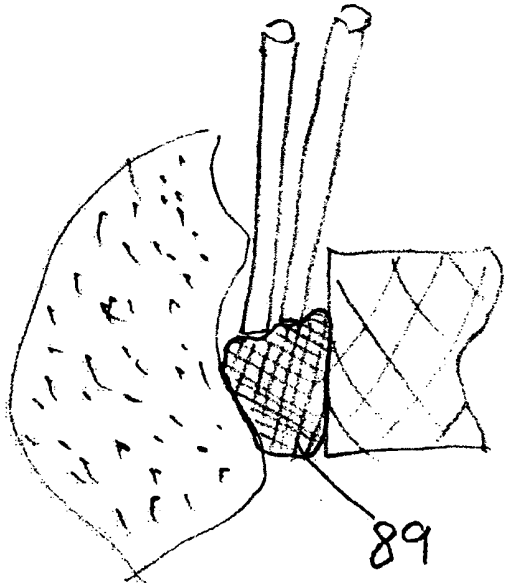



Fig. 8c

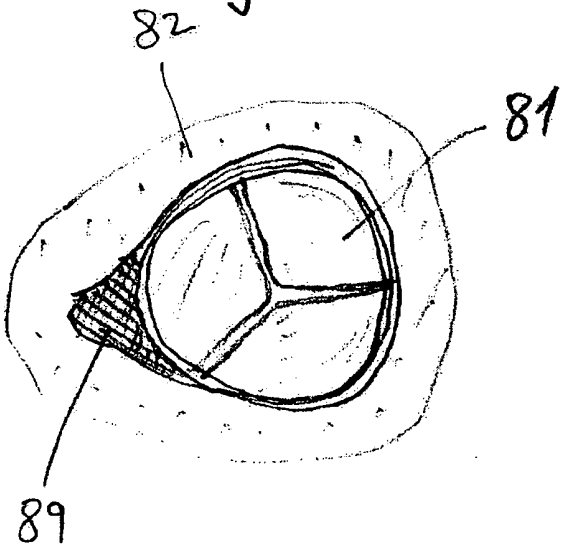



Fig. 8d

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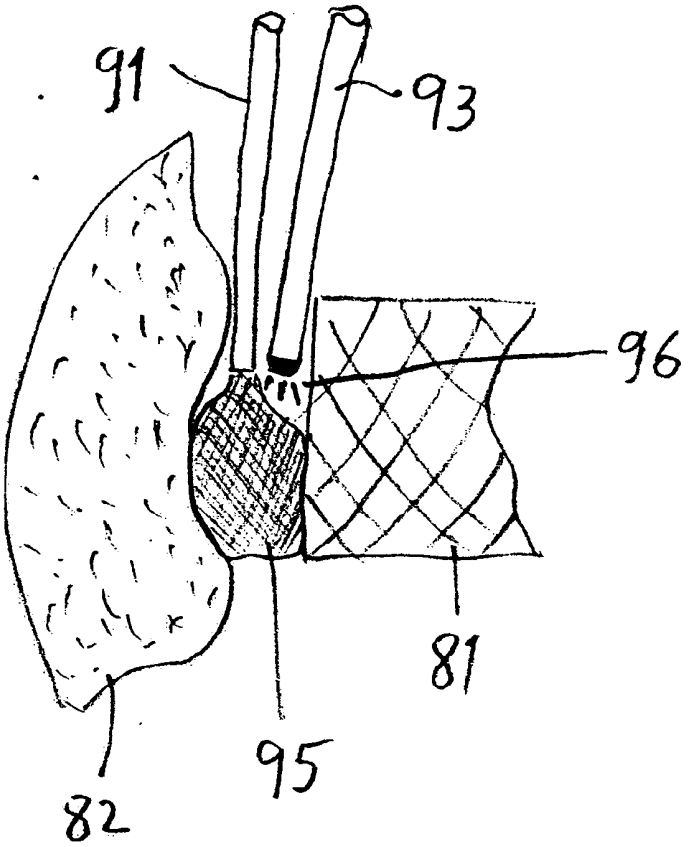


Fig. 9

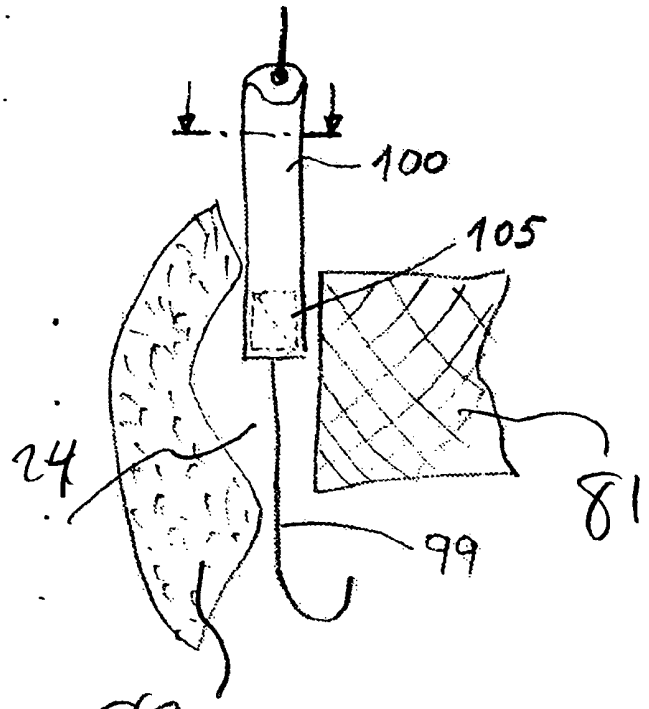


Fig. 10a

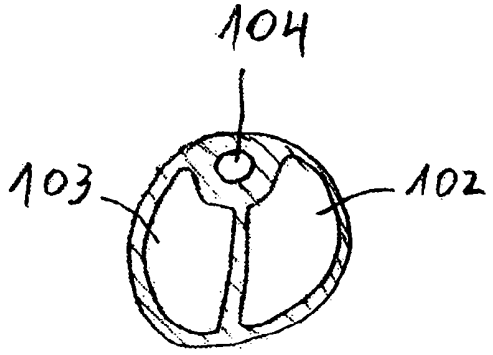


Fig. 10b

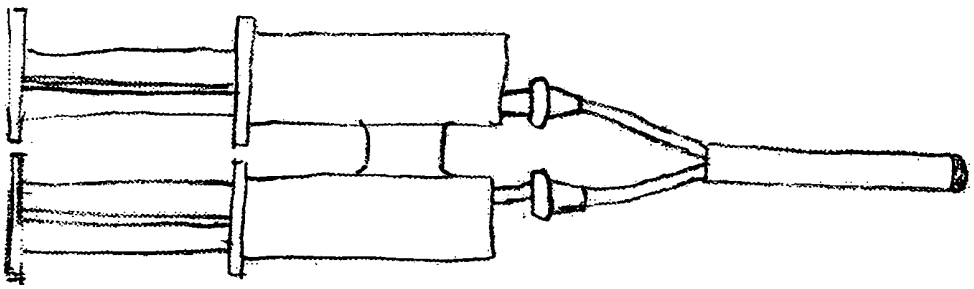

Fig. 10c

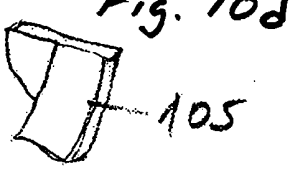


Fig. 10d

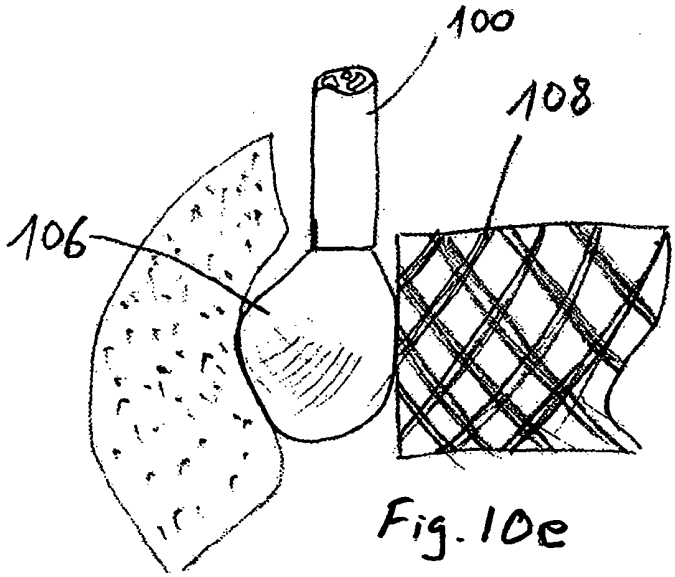


Fig. 10e

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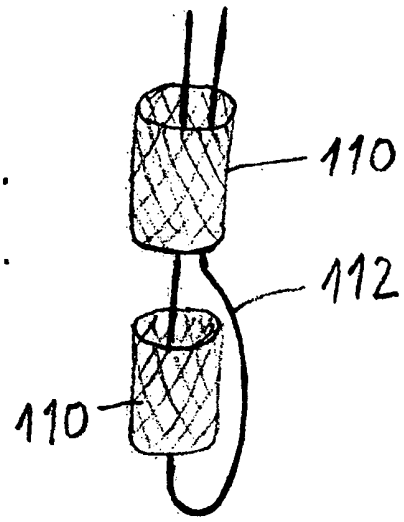


Fig. 11a

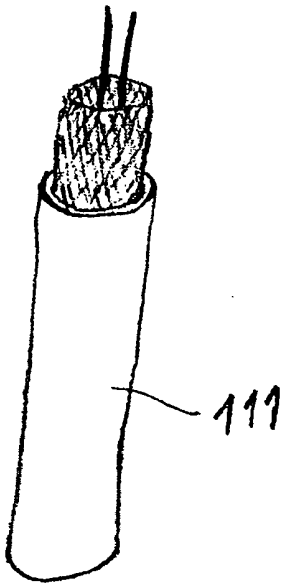


Fig. 11b

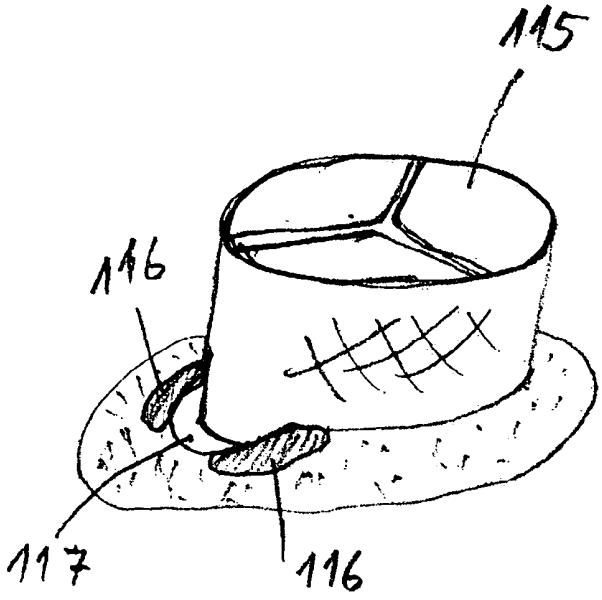


Fig. 11c

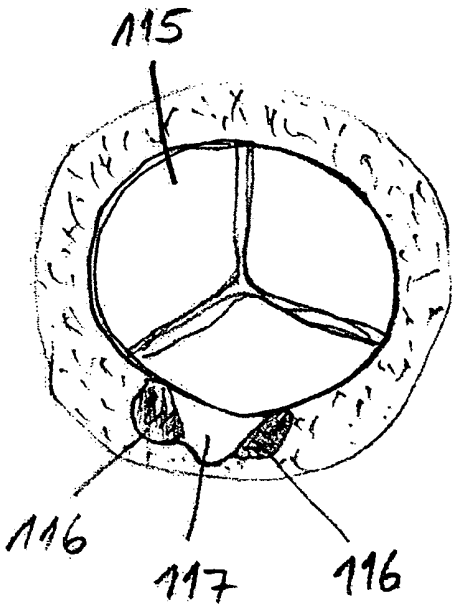


Fig. 11d

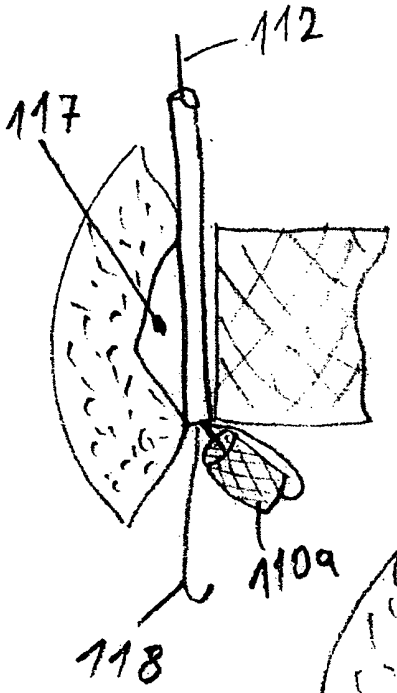


Fig. 11e

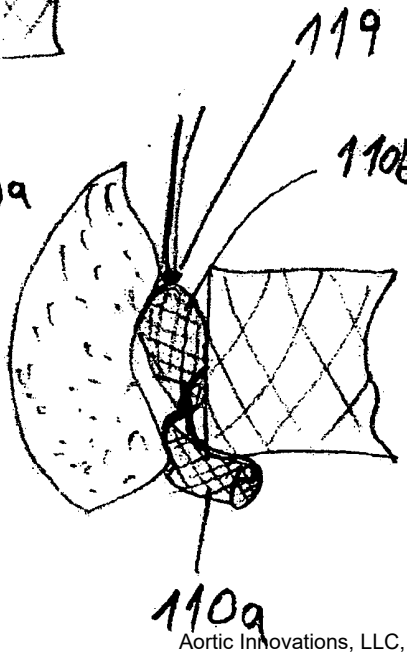


Fig. 11f

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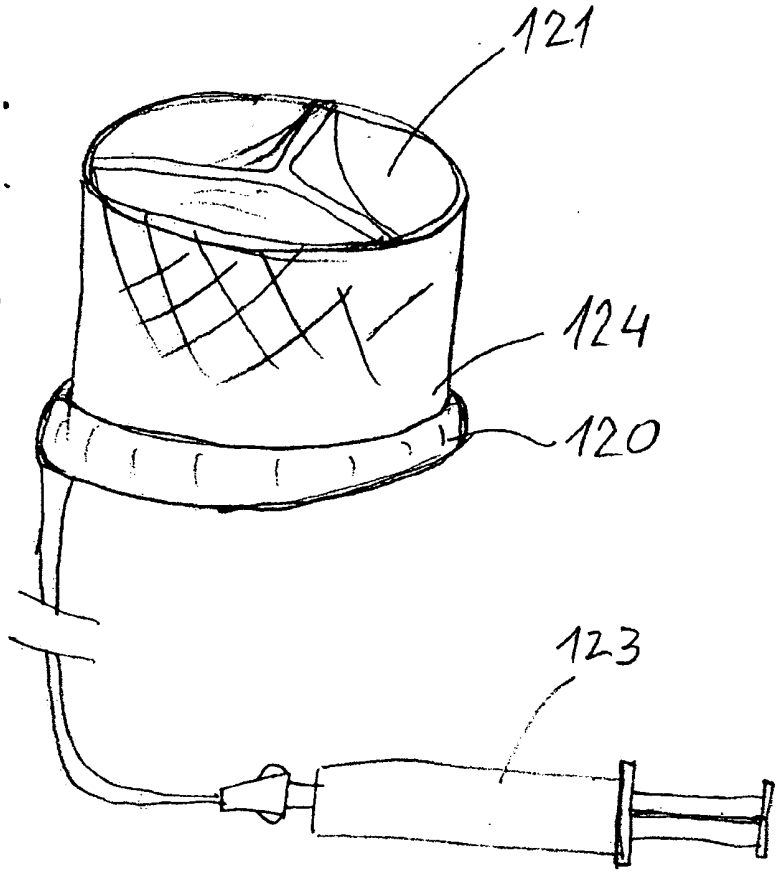


Fig. 12

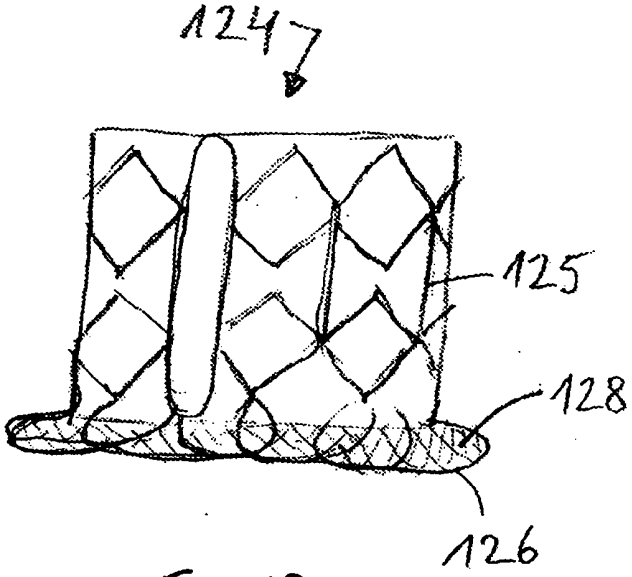


Fig. 13a

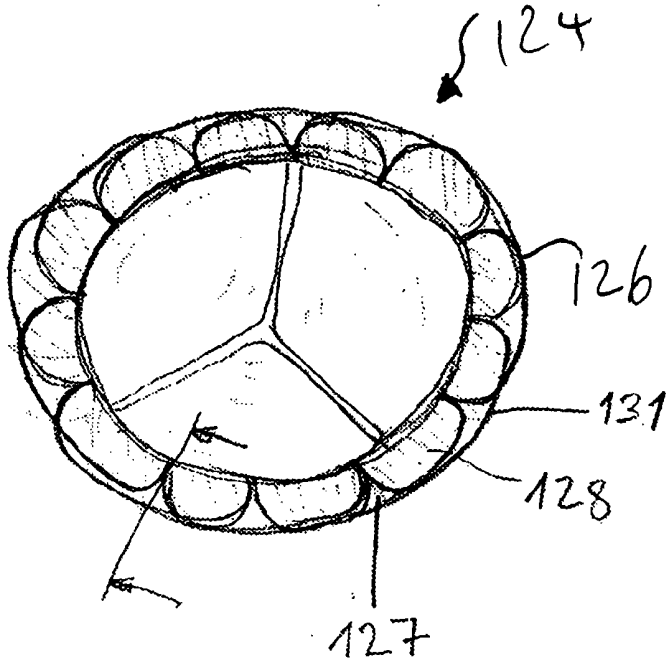


Fig. 13b

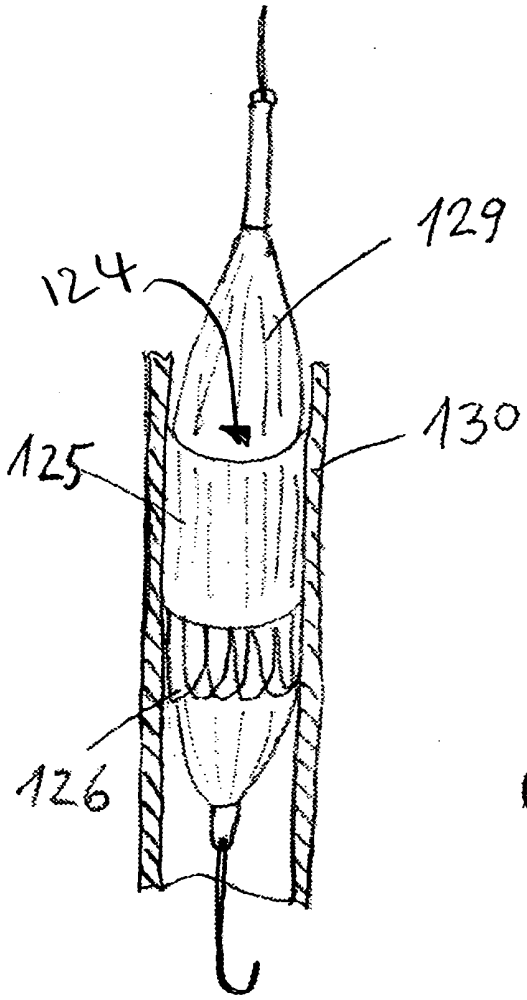


Fig. 13c

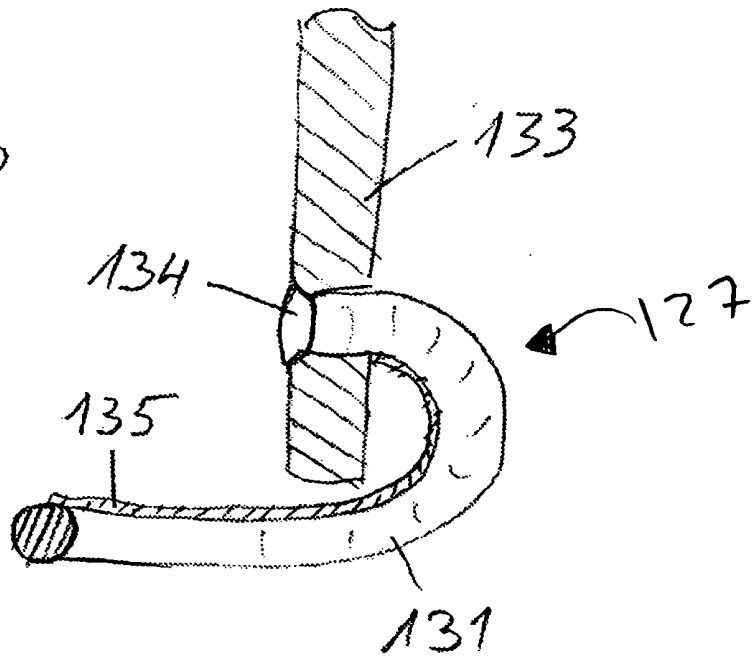


Fig. 13d

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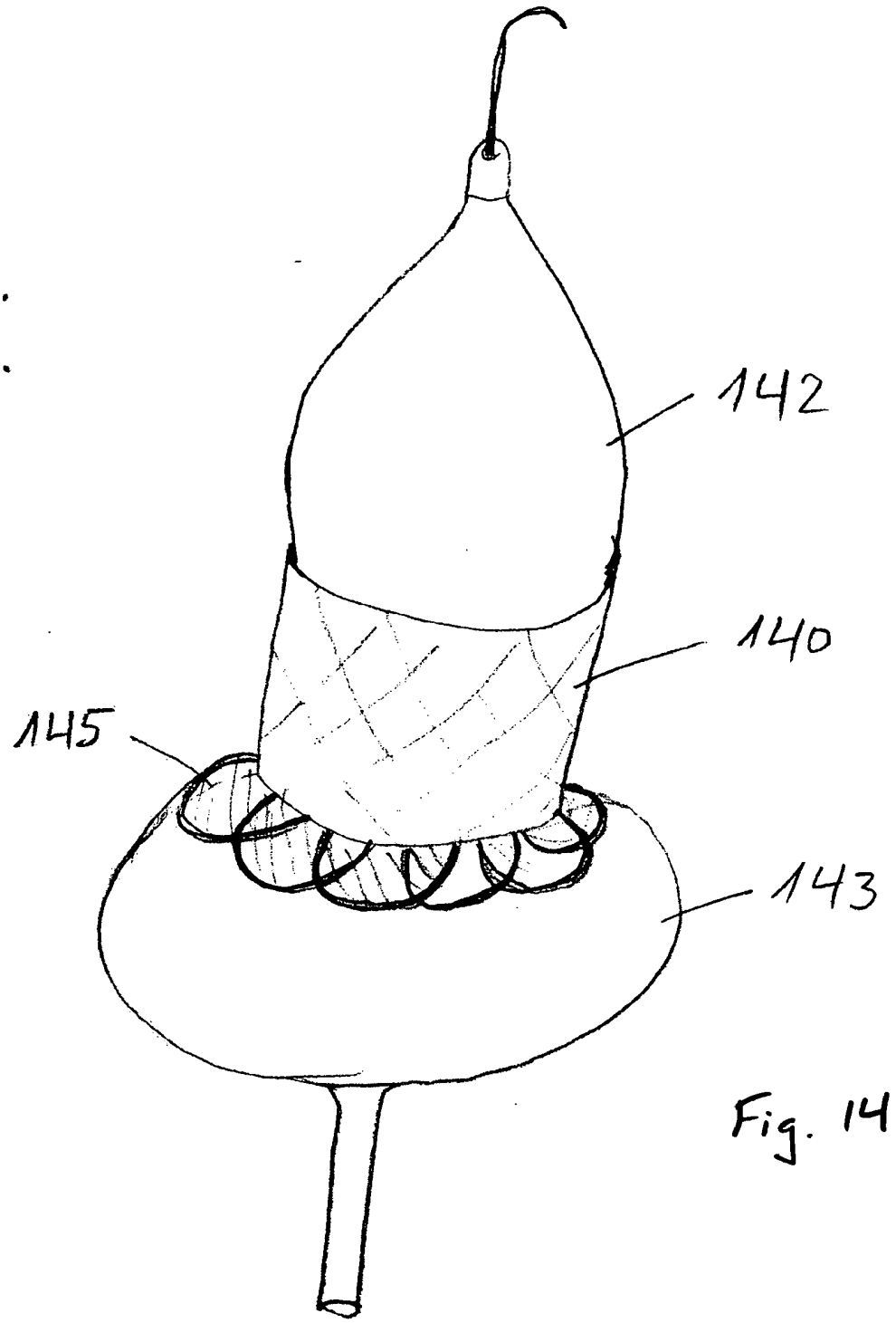


Fig. 14

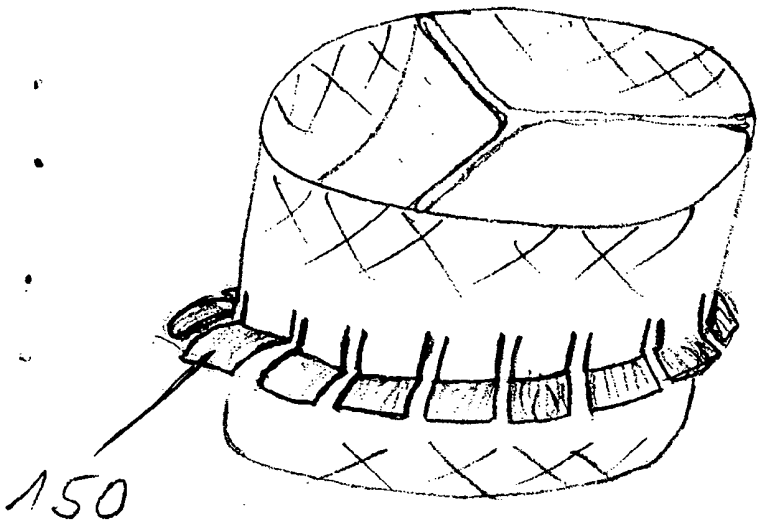


Fig. 15a

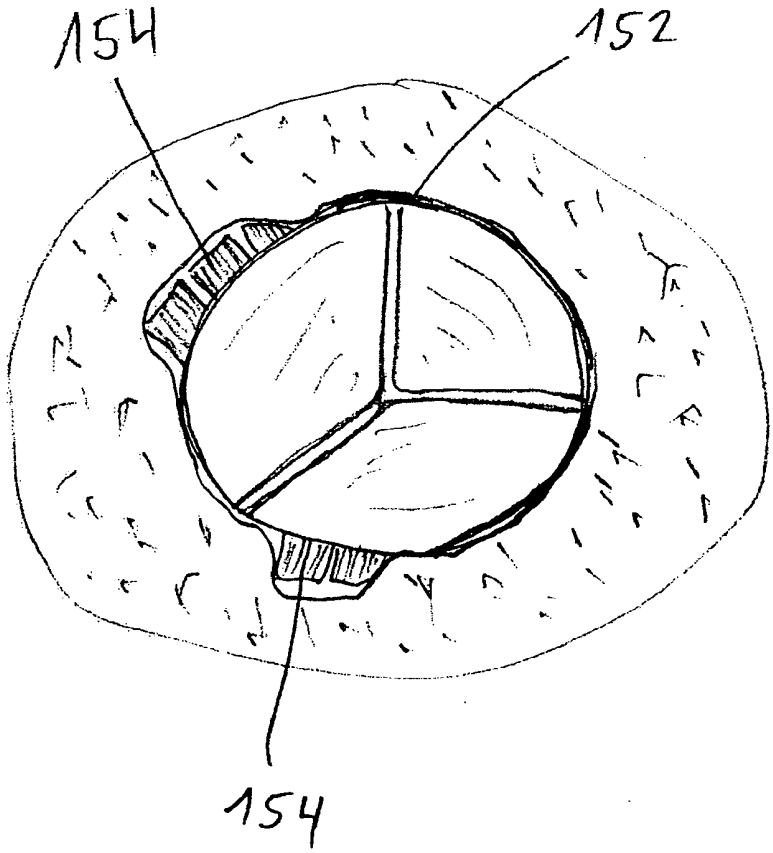


Fig. 15b

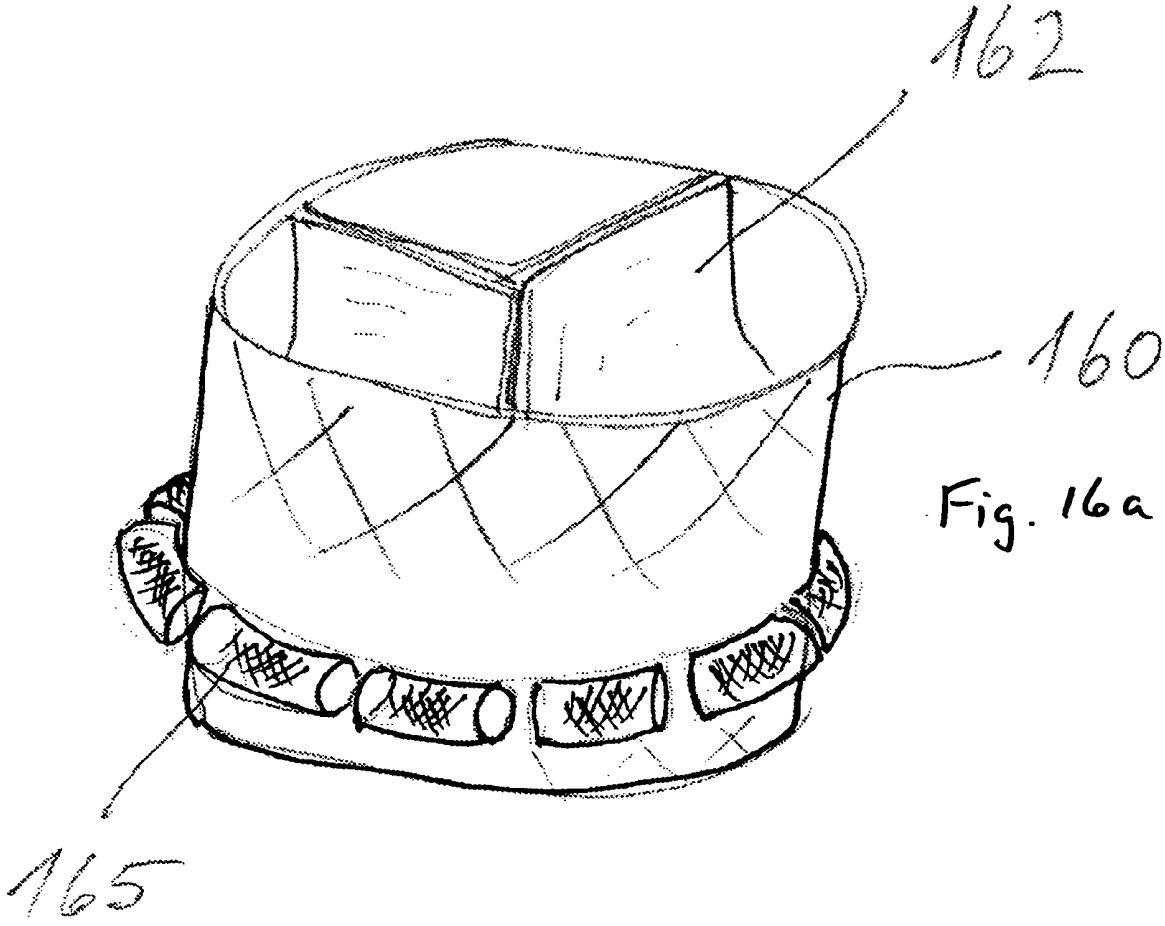


Fig. 16a

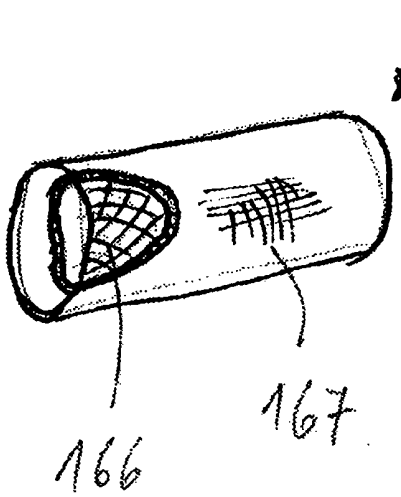


Fig. 16b

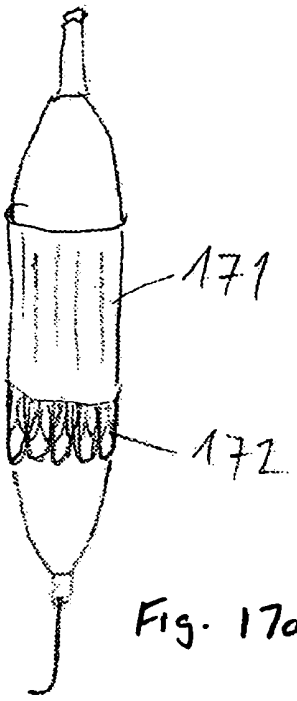


Fig. 17a

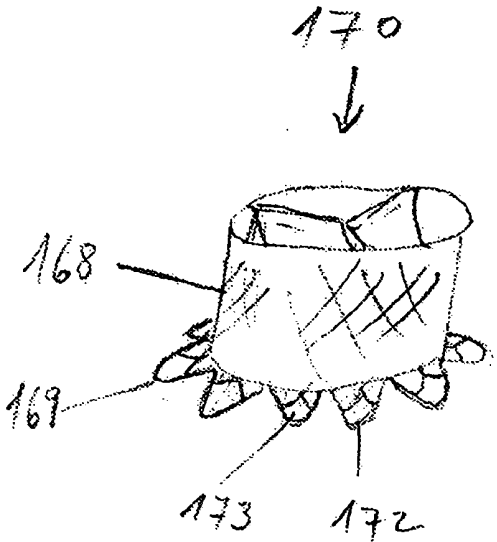


Fig. 17b

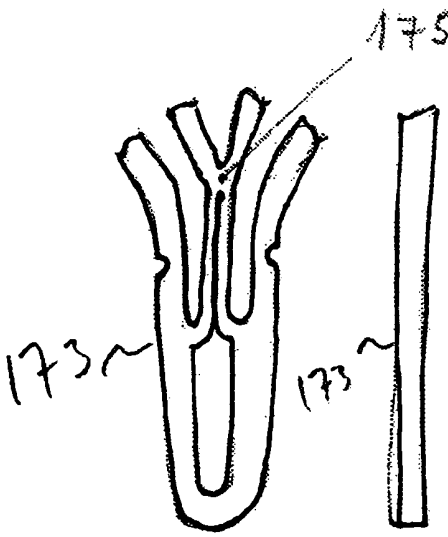


Fig. 17c

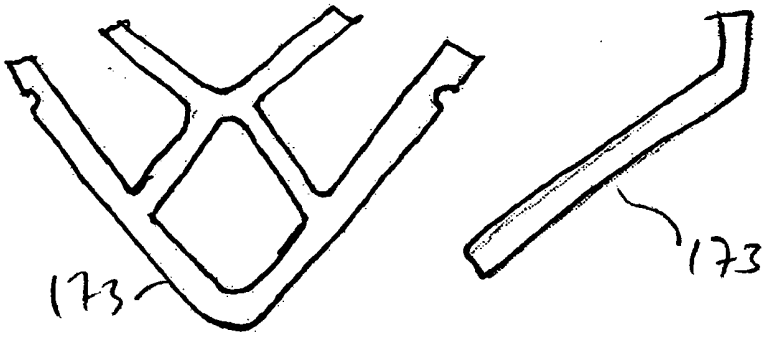


Fig. 17d

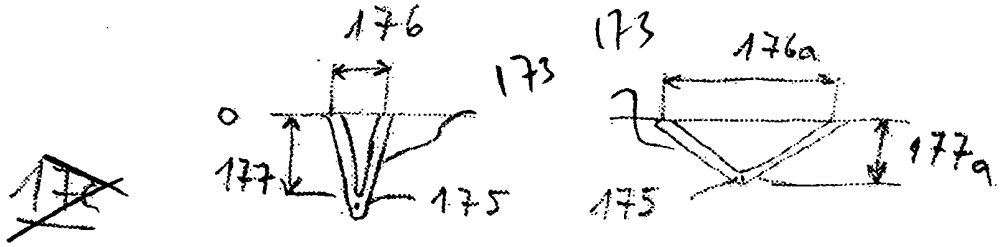


Fig. 17e

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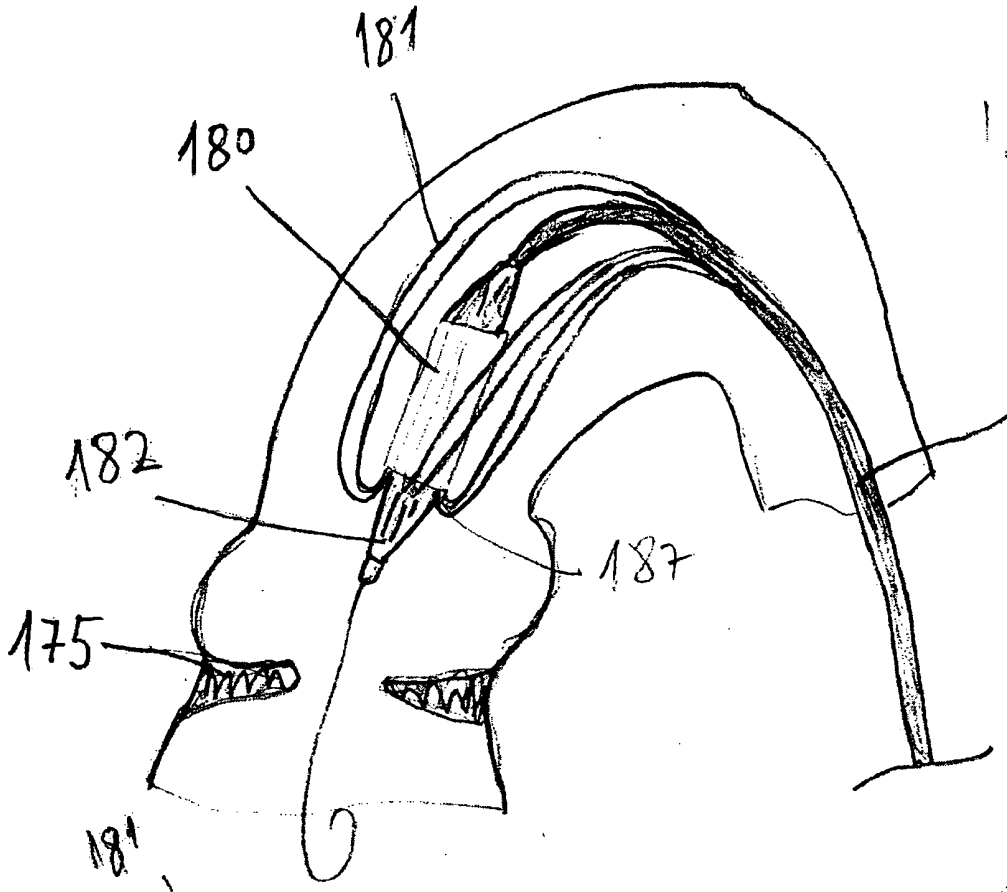


Fig. 18a

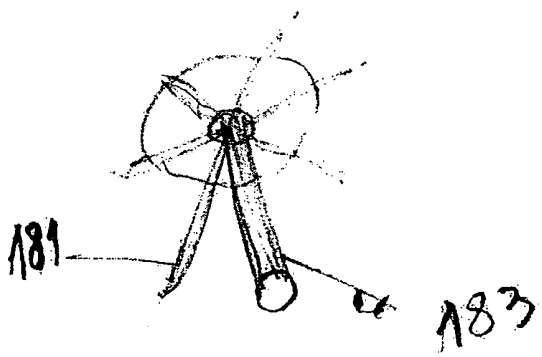


Fig. 18b

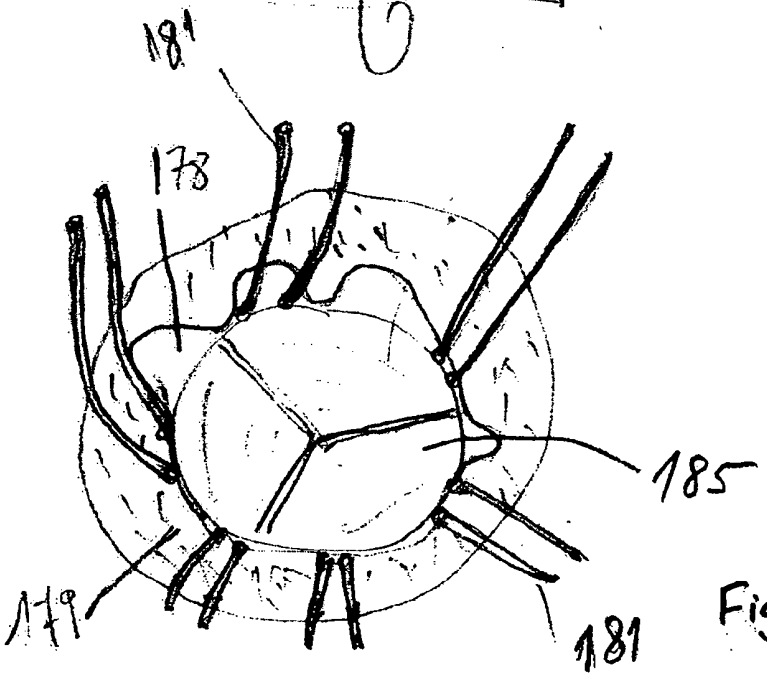


Fig. 18c

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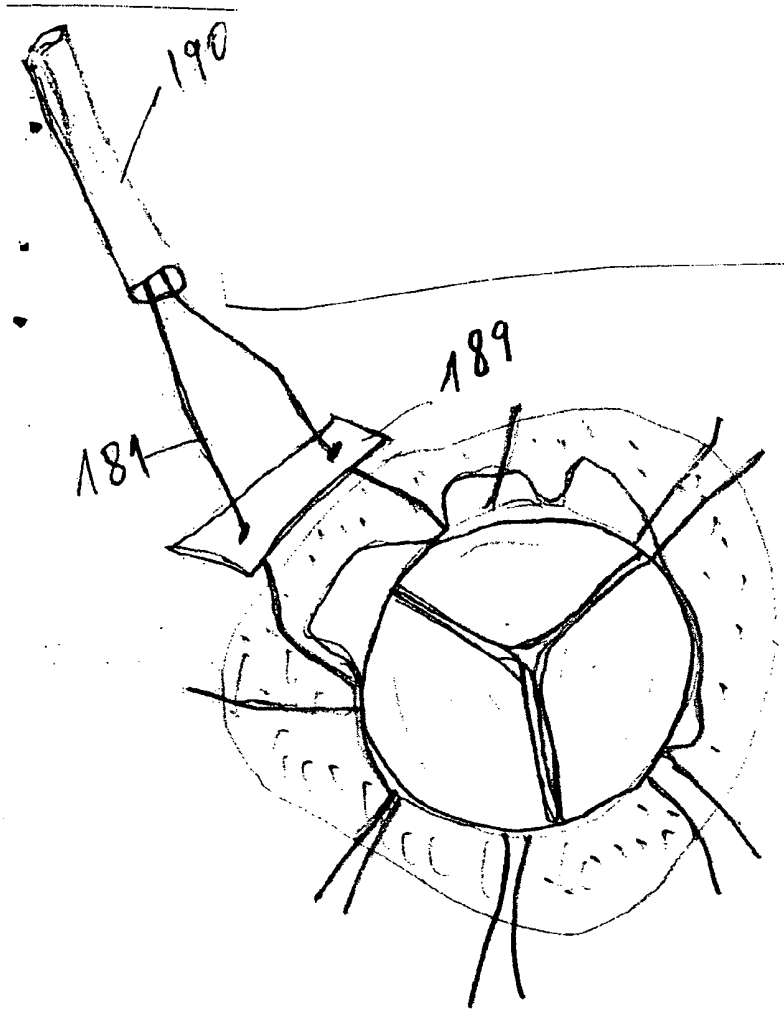


Fig. 18d

Fig. 18e

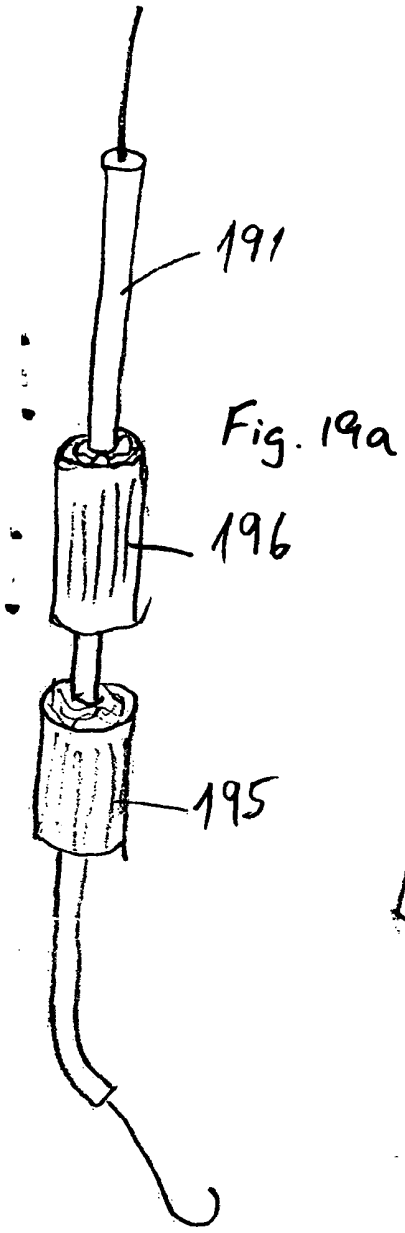


Fig. 19a

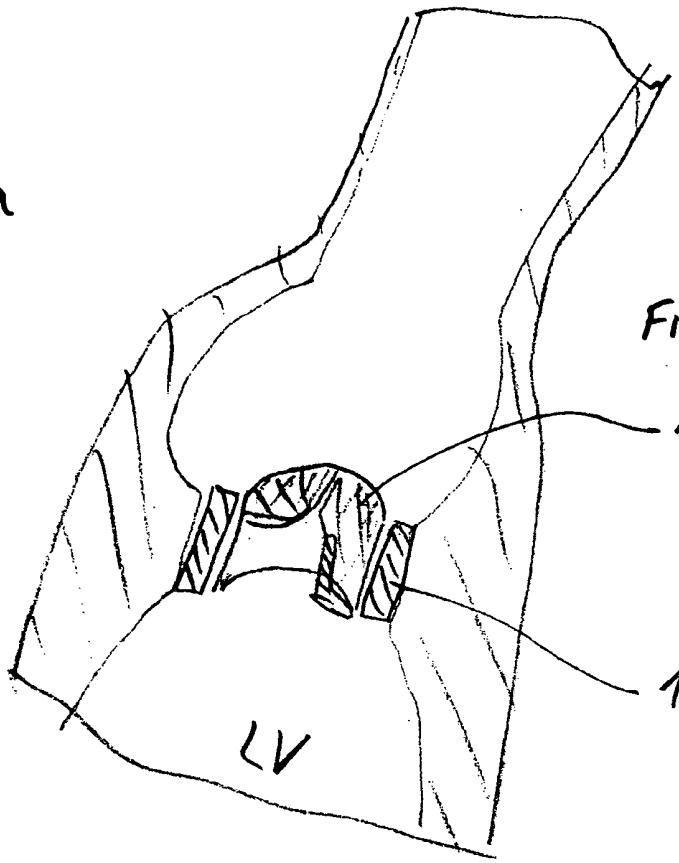


Fig. 19b

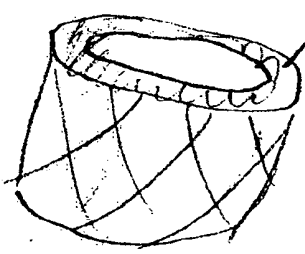


Fig. 19c

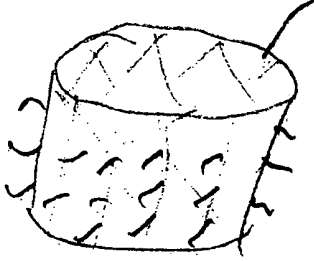


Fig. 19d

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# DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing **OR** ☑ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

| | |
|---|---|
| Attorney Docket Number | 501015.20517 |
| First Named Inventor | Benjamin Spenser |
| *COMPLETE IF KNOWN* | |
| Application Number | To Be Assigned |
| Filing Date | June 30, 2004, herewith |
| Art Unit | |
| Examiner Name | |

**I hereby declare that:**

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

*(Title of the Invention)*

the specification of which

☑ is attached hereto

***OR***

☐ was filed on (MM/DD/YYYY) _____ as United States Application Number or PCT International Application Number _____ and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed | Certified Copy Attached? Yes | No |
|---|---|---|---|---|---|
| | | | ☐ | ☐ | ☐ |
| | | | ☐ | ☐ | ☐ |
| | | | ☐ | ☐ | ☐ |
| | | | ☐ | ☐ | ☐ |

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.



This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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# DECLARATION — Utility or Design Patent Application

| | | | |
|---|---|---|---|
| Direct all correspondence to: ☑ Customer Number: 30452 | | *OR* ☐ Correspondence address below | |
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| Address: Edwards Lifesciences LLC<br>One Edwards Way | | | |
| City: Irvine | State: CA | ZIP: 92614 | |
| Country: US | Telephone: 949-250-6878 | Fax: 949-250-6850 | |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**NAME OF SOLE OR FIRST INVENTOR:** ☐ A petition has been filed for this unsigned inventor

| | | | |
|---|---|---|---|
| Given Name (first and middle [if any]): Benjamin | | Family Name or Surname: Spenser | |
| Inventor's Signature | | Date | |
| Residence: City: Caesarea | State: | Country: IL | Citizenship: IL |
| Mailing Address: Havazelet st. 6 | | | |
| City: Caesarea | State: | ZIP: 38900 | Country: IL |

**NAME OF SECOND INVENTOR:** ☐ A petition has been filed for this unsigned inventor

| | | | |
|---|---|---|---|
| Given Name (first and middle [if any]): Netanel | | Family Name or Surname: Benichou | |
| Inventor's Signature | | Date | |
| Residence: City: Hof-Carmel | State: | Country: IL | Citizenship: IL |
| Mailing Address: Nir Etzion D.N. | | | |
| City: Hof-Carmel | State: | ZIP: 30808 | Country: IL |

☑ Additional inventors or a legal representative are being named on the _____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

PTO/SB/02A (08-03)
Approved for use through 08/31/2003. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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# DECLARATION

## ADDITIONAL INVENTOR(S)
**Supplemental Sheet**



| | | | |
|---|---|---|---|
| **Name of Additional Joint Inventor, if any:** | ☐ A petition has been filed for this unsigned inventor | | |
| Given Name (first and middle (if any)) | Family Name or Surname | | |
| Assaf | Bash | | |
| Inventor's Signature | | | Date |
| Residence: City: Givat Ada | State | Country: IL | Citizenship: IL |
| Mailing Address: 1 Haseora St | | | |
| Mailing Address | | | |
| City: Givat Ada | State | Zip: 37808 | Country: IL |

| | | | |
|---|---|---|---|
| **Name of Additional Joint Inventor, if any:** | ☐ A petition has been filed for this unsigned inventor | | |
| Given Name (first and middle (if any)) | Family Name or Surname | | |
| | | | |
| Inventor's Signature | Date | | |
| Residence: City | State | Country | Citizenship |
| Mailing Address | | | |
| Mailing Address | | | |
| City | State | Zip | Country |

| | | | |
|---|---|---|---|
| **Name of Additional Joint Inventor, if any:** | ☐ A petition has been filed for this unsigned inventor | | |
| Given Name (first and middle (if any)) | Family Name or Surname | | |
| | | | |
| Inventor's Signature | Date | | |
| Residence: City | State | Country | Citizenship |
| Mailing Address | | | |
| Mailing Address | | | |
| City | State | Zip | Country |

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/81 (09-03)
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# POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM

| | |
|---|---|
| **Application Number** | To Be Assigned |
| **Filing Date** | June 30, 2004, herewith |
| **First Named Inventor** | Benjamin Spenser |
| **Title** | Paravalvular Leak Detection, ... |
| **Art Unit** | |
| **Examiner Name** | |
| **Attorney Docket Number** | 501015.20517 |

I hereby appoint:

☑ Practitioners associated with the Customer Number: 30452

*OR*

☐ Practitioner(s) named below:

| Name | Registration Number |
|---|---|
| | |
| | |
| | |
| | |

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:

☑ The address associated with the above-mentioned Customer Number:

*OR*

☐ The address associated with Customer Number: 30452

*OR*

| | | | | | |
|---|---|---|---|---|---|
| ☐ Firm or Individual Name | Christopher James | | | | |
| Address | Edwards Lifesciences LLC | | | | |
| Address | One Edwards Way | | | | |
| City | Irvine | State | CA | Zip | 92614 |
| Country | US | | | | |
| Telephone | 949-250-6878 | Fax | 949-250-6850 | | |

I am the:

☑ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
*Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)*

**SIGNATURE of Applicant or Assignee of Record**

| | | | |
|---|---|---|---|
| Name | Benjamin Spenser | | |
| Signature | | | |
| Date | | Telephone | |

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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# POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM

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|---|---|
| **Application Number** | To Be Assigned |
| **Filing Date** | June 30, 2004, herewith |
| **First Named Inventor** | Benjamin Spenser |
| **Title** | Paravalvular Leak Detection, ... |
| **Art Unit** | |
| **Examiner Name** | |
| **Attorney Docket Number** | 501015.20517 |

I hereby appoint:

☑ Practitioners associated with the Customer Number: 30452

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| Name | Registration Number |
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☐ The address associated with Customer Number: 30452

*OR*

| | | | | | |
|---|---|---|---|---|---|
| ☐ Firm or Individual Name | Christopher James | | | | |
| Address | Edwards Lifesciences LLC | | | | |
| Address | One Edwards Way | | | | |
| City | Irvine | State | CA | Zip | 92614 |
| Country | US | | | | |
| Telephone | 949-250-6878 | Fax | 949-250-6850 | | |

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☐ Assignee of record of the entire interest. See 37 CFR 3.71.
*Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)*

**SIGNATURE of Applicant or Assignee of Record**

| | | | |
|---|---|---|---|
| Name | Netanel Benichou | | |
| Signature | | | |
| Date | | Telephone | |

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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| **Application Number** | To Be Assigned |
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| **First Named Inventor** | Benjamin Spenser |
| **Title** | Paravalvular Leak Detection, ... |
| **Art Unit** | |
| **Examiner Name** | |
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*OR*

☐ The address associated with Customer Number: 30452

*OR*

| | | | | | |
|---|---|---|---|---|---|
| ☐ Firm or Individual Name | Christopher James | | | | |
| Address | Edwards Lifesciences LLC | | | | |
| Address | One Edwards Way | | | | |
| City | Irvine | State | CA | Zip | 92614 |
| Country | US | | | | |
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**SIGNATURE of Applicant or Assignee of Record**

| | | | |
|---|---|---|---|
| Name | Assaf Bash | | |
| Signature | | | |
| Date | | Telephone | |

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