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Gabbay

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(54) **IMPLANTATION SYSTEM FOR DELIVERY OF A HEART VALVE PROSTHESIS**

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Related U.S. Application Data

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A61F 2/24 (2006.01)

(52) **U.S. Cl.** **623/2.11**; 623/1.26

(58) **Field of Classification Search** 623/1.11, 623/1.24, 1.26, 2.11, 2.14, 2.15, 2.16, 2.18; 606/102, 108
See application file for complete search history.

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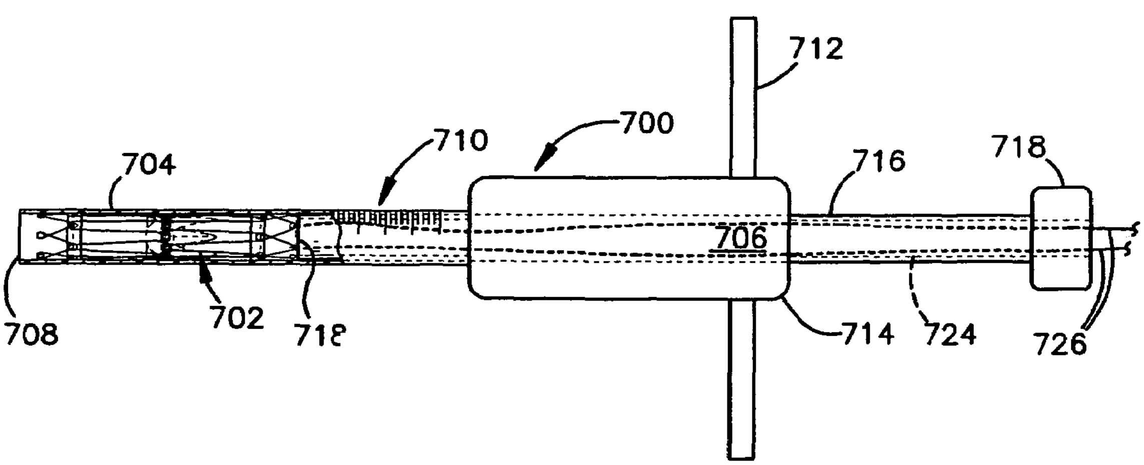
(57) **ABSTRACT**

A heart valve prosthesis and method of implanting the prosthesis are disclosed. A valve is mounted within a support apparatus that is deformable between a first condition and a second condition. The prosthesis has a cross-sectional dimension in the second condition that is less than a cross-sectional dimension of the supported valve when in first condition. The prosthesis can be implanted into a patient's heart, such as during a direct vision procedure through a tubular implantation apparatus that maintains the prosthesis in its second condition until discharged from the tubular apparatus.

20 Claims, 10 Drawing Sheets



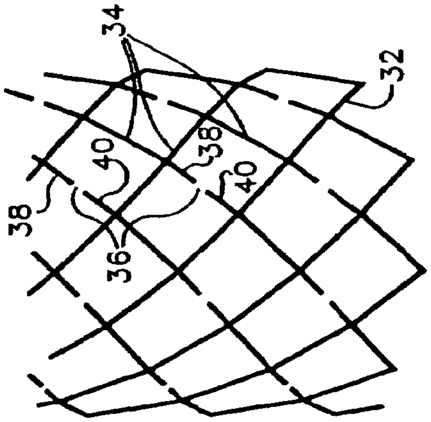


Fig.1A

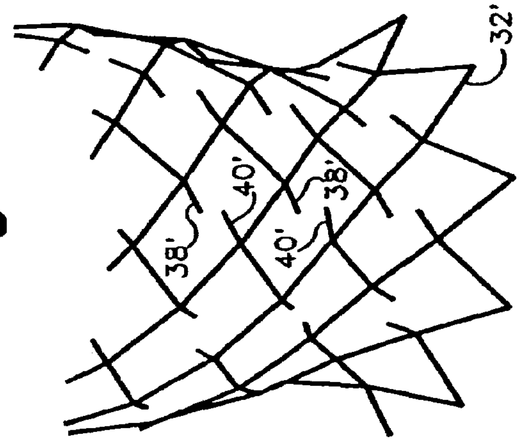


Fig.1B

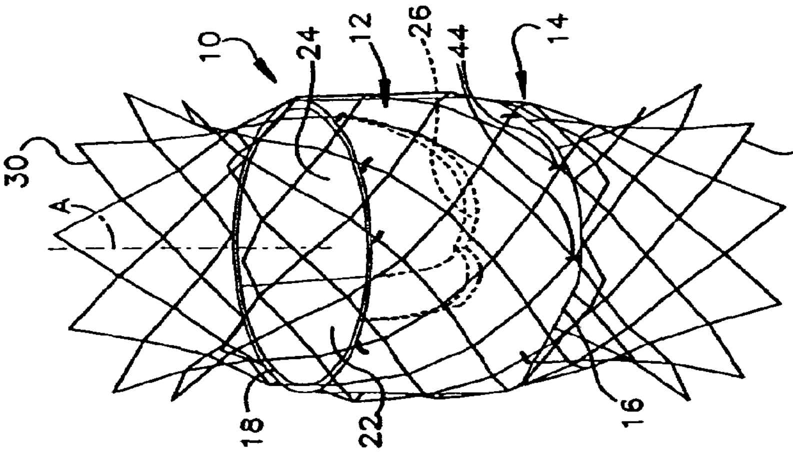


Fig.2

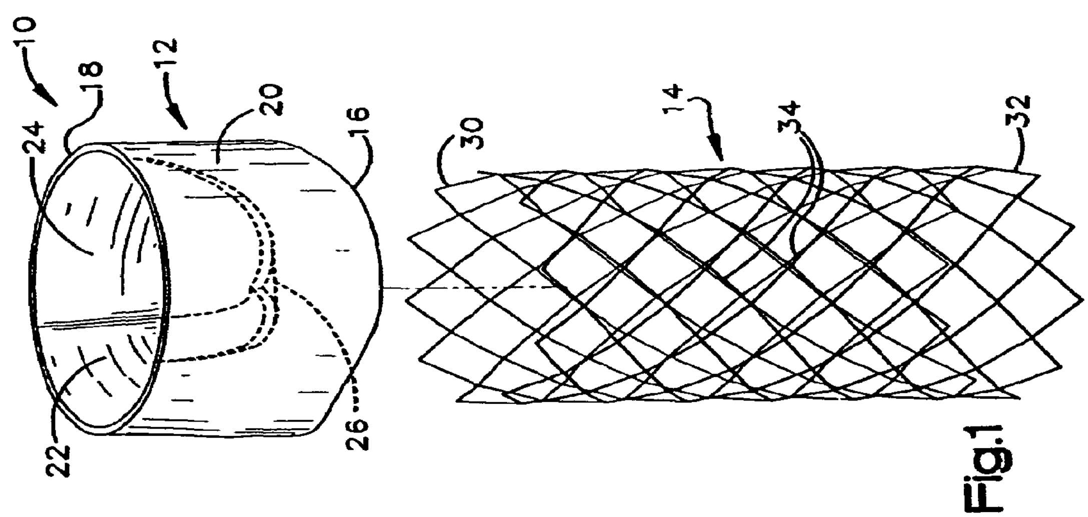


Fig.1

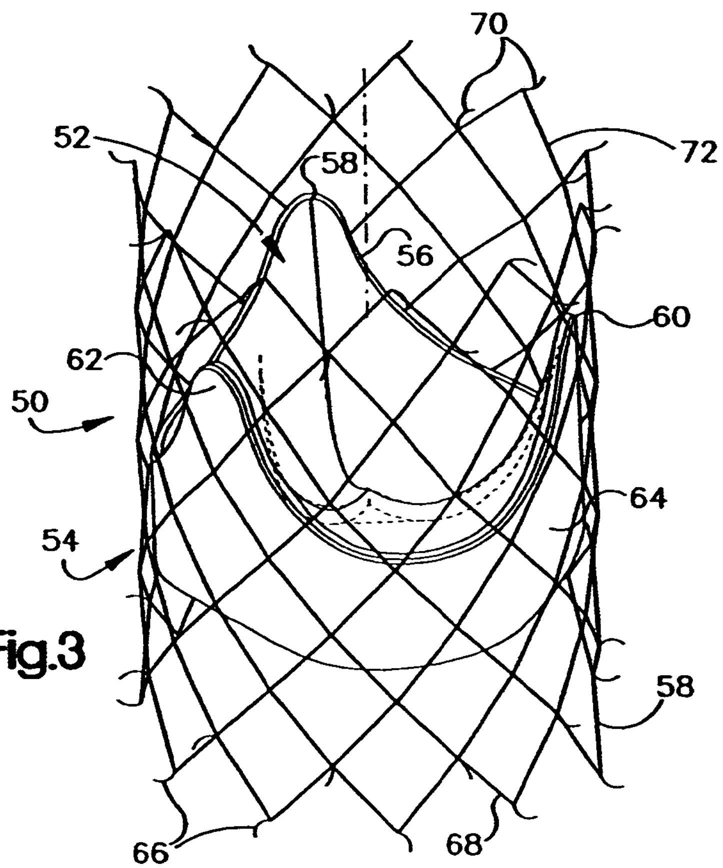


Fig.3

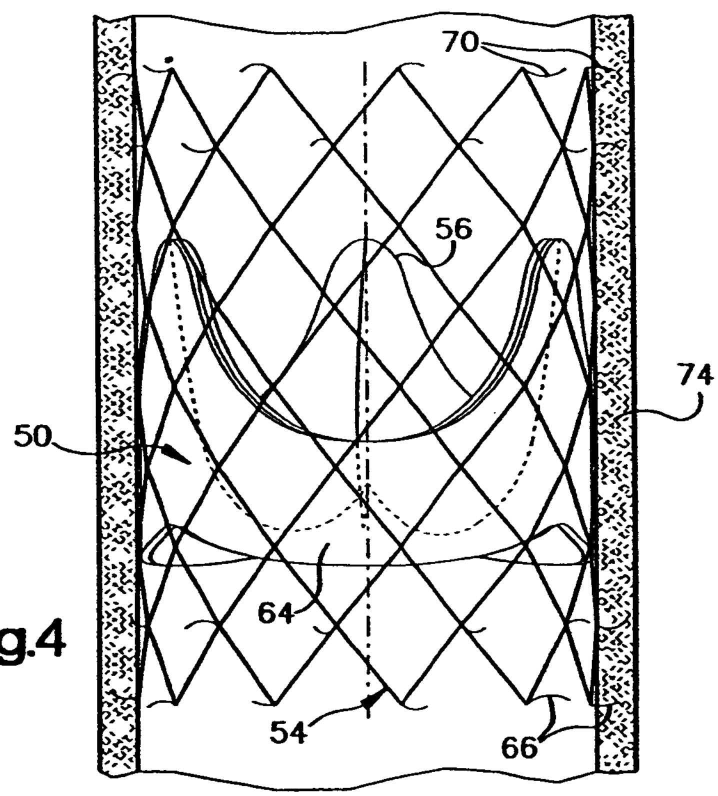


Fig.4

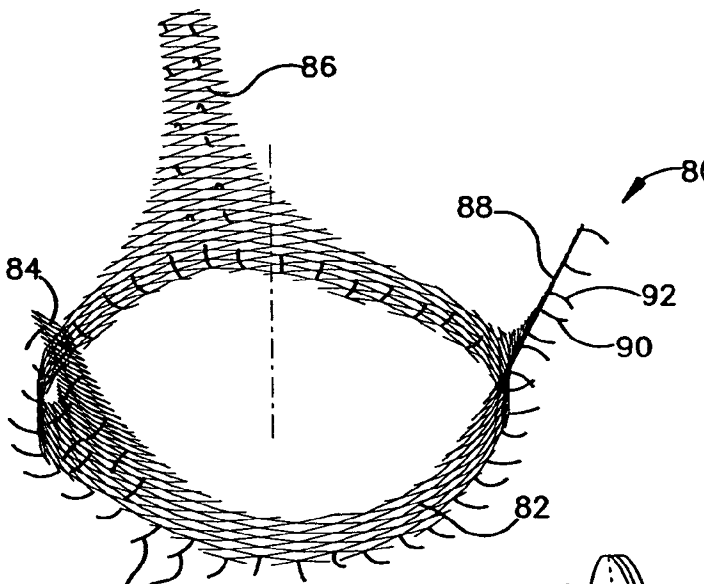


Fig.5

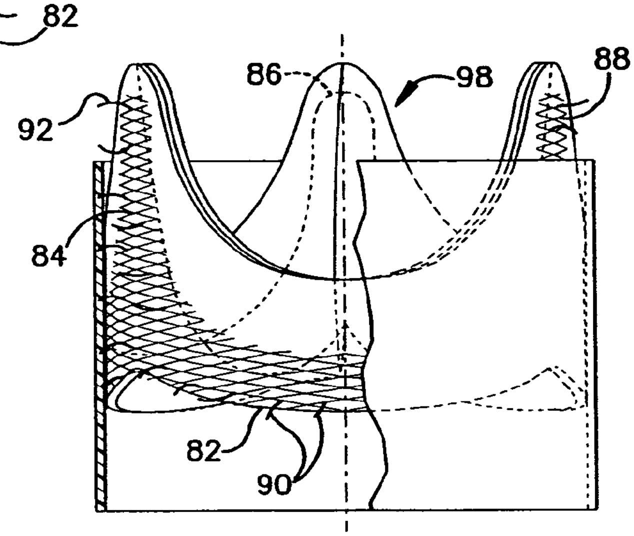


Fig.6A

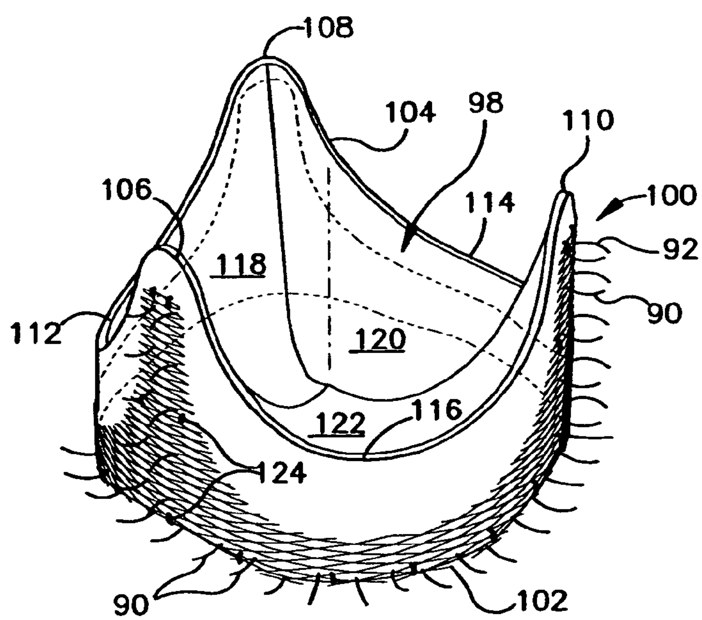


Fig.6B

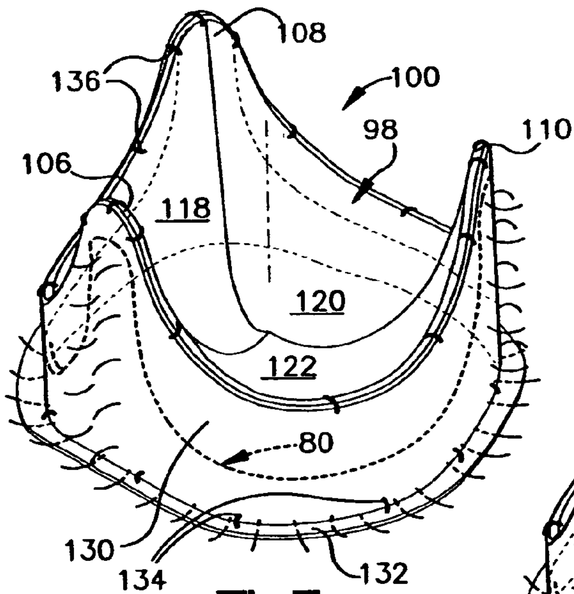


Fig.7

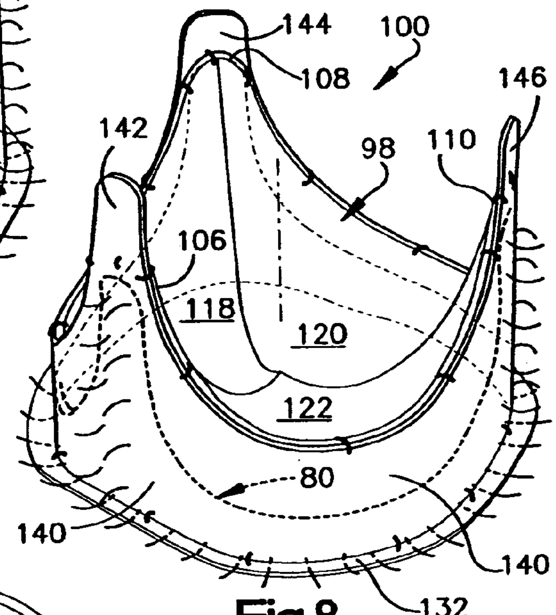


Fig.8

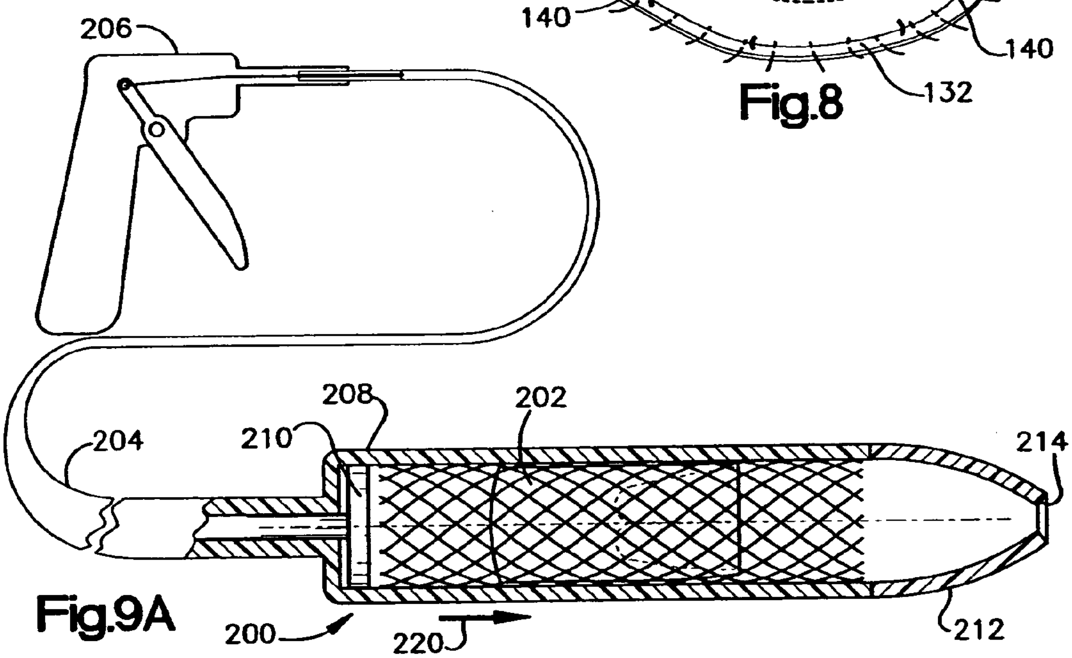


Fig.9A

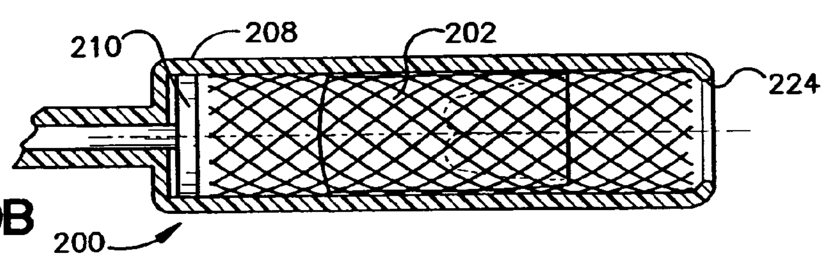


Fig.9B

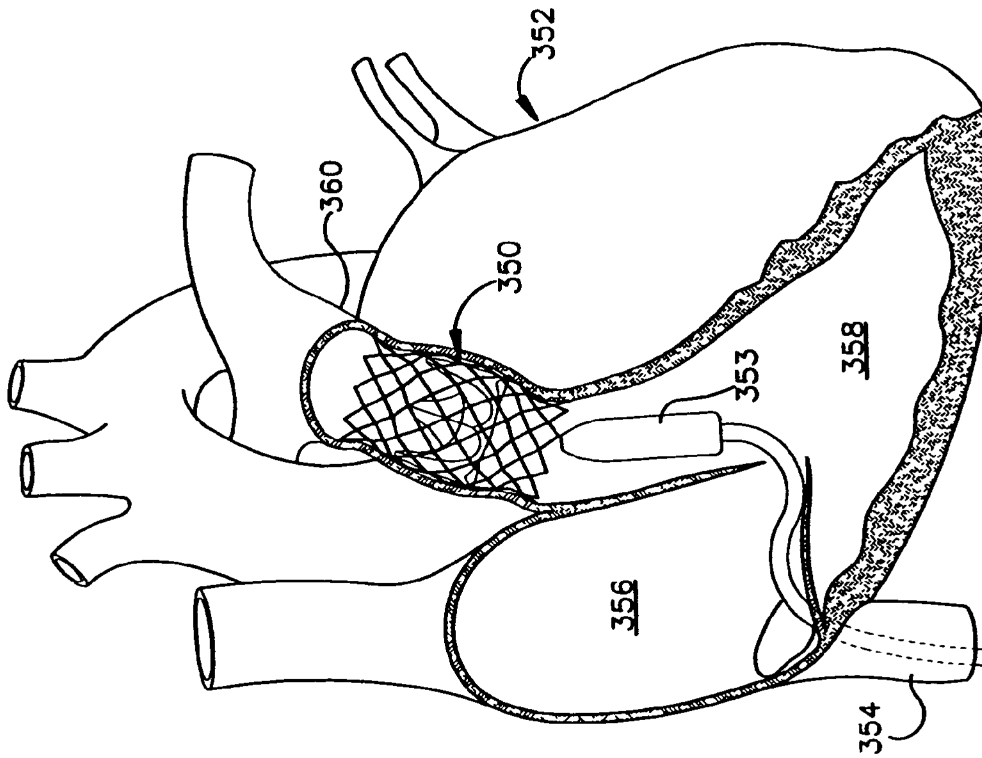


Fig.11

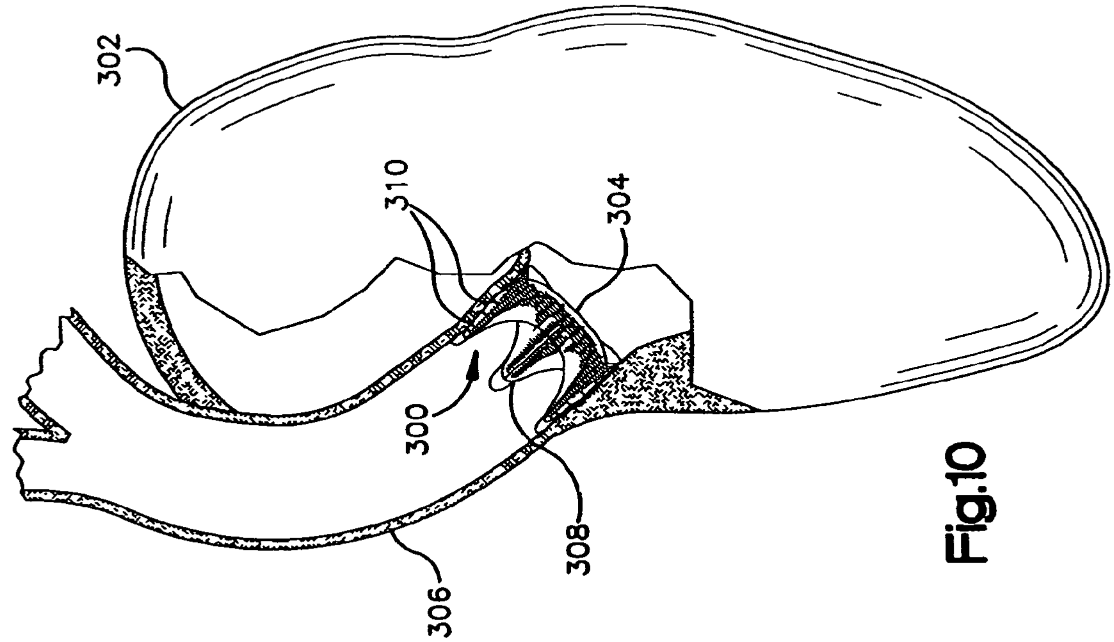


Fig.10

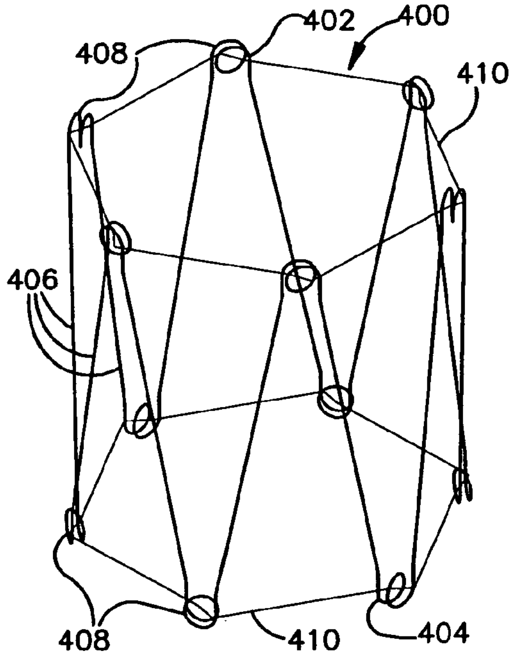


Fig.12

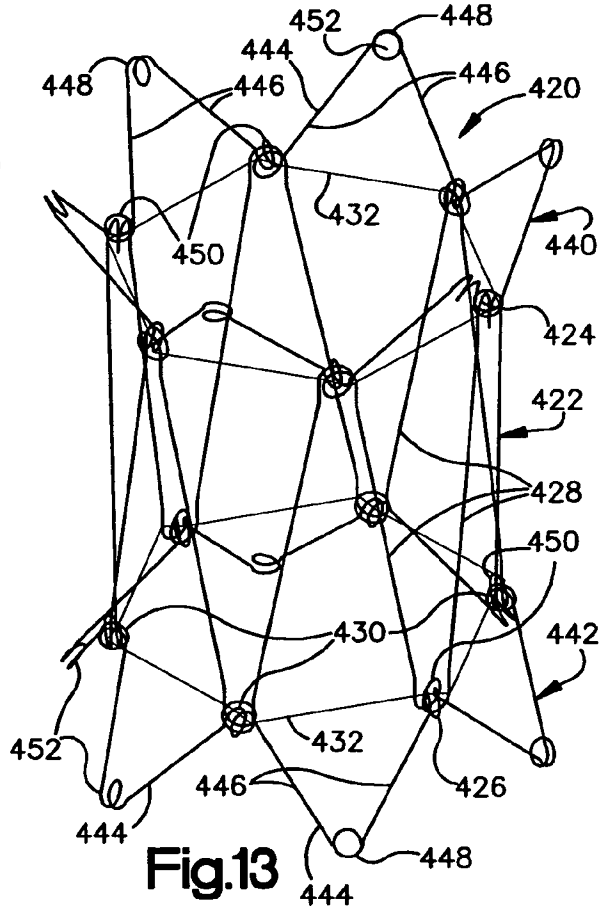


Fig.13

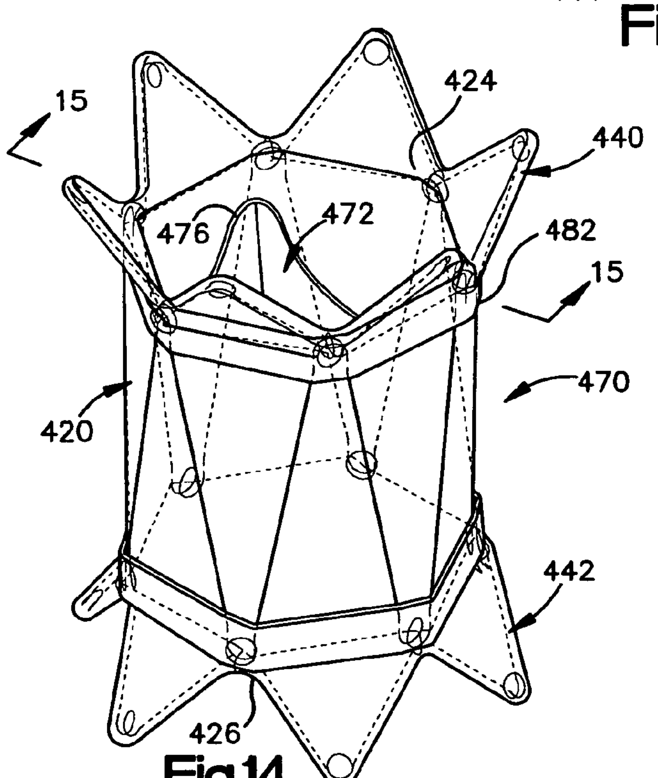


Fig.14

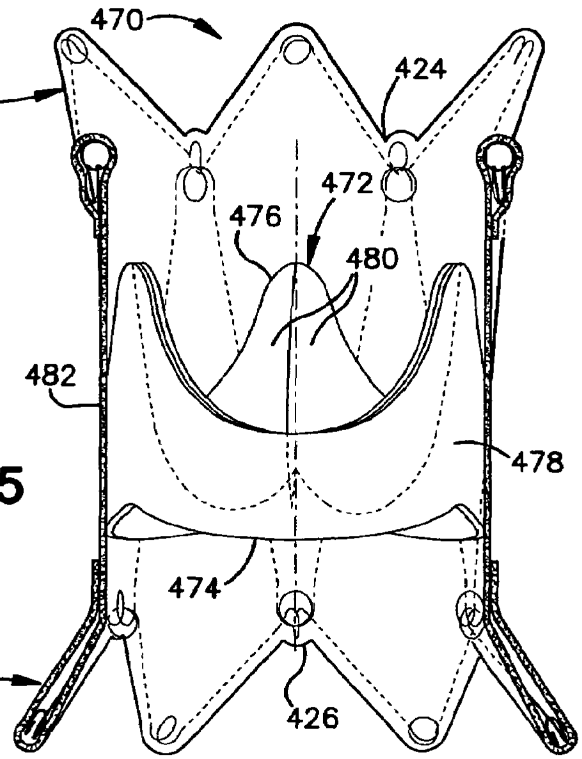


Fig.15

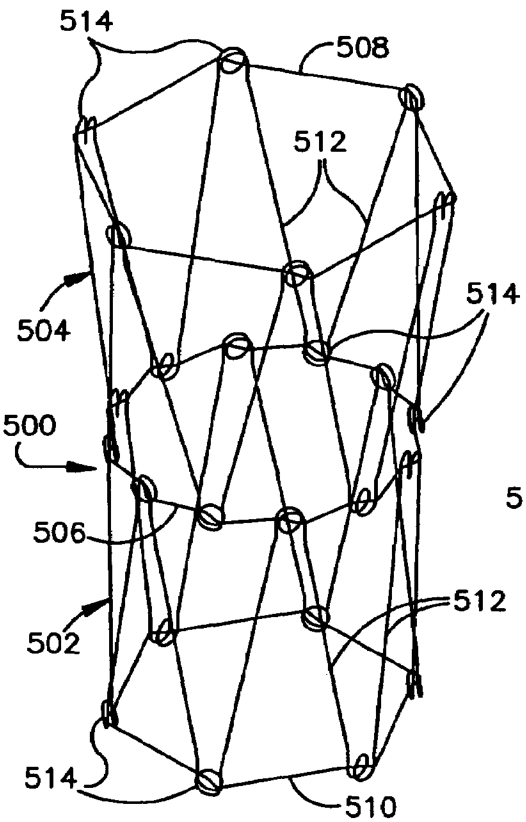


Fig.16

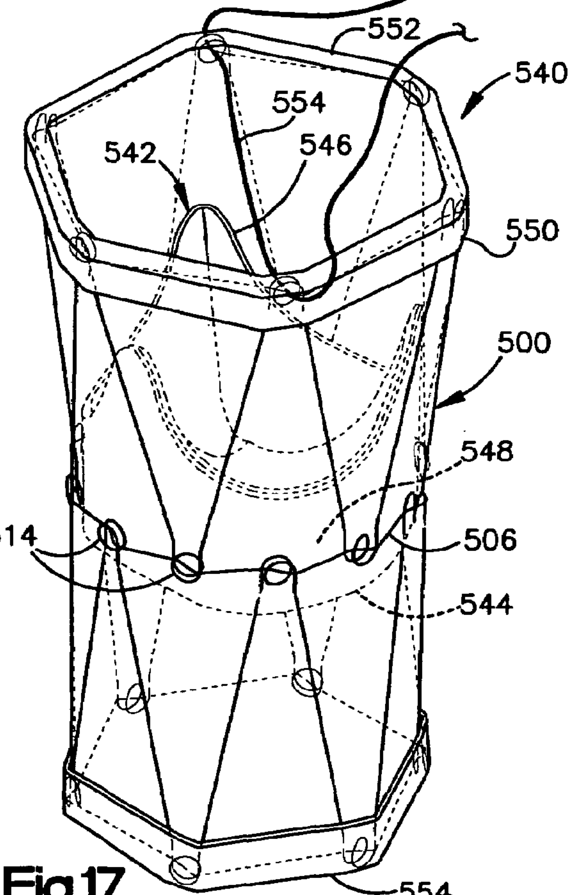


Fig.17

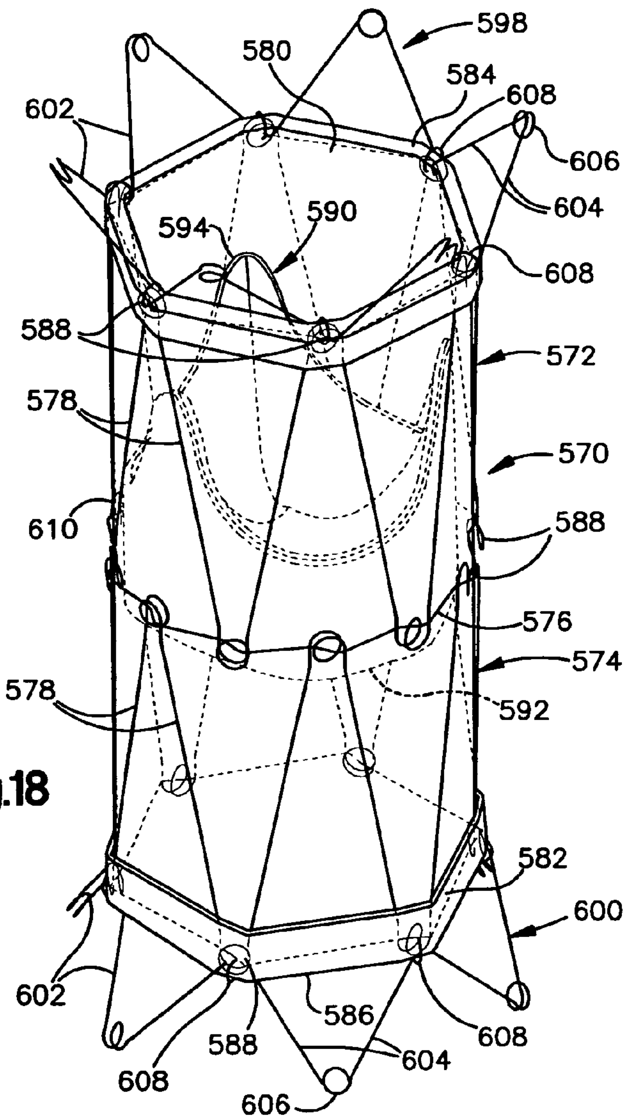

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Fig.18

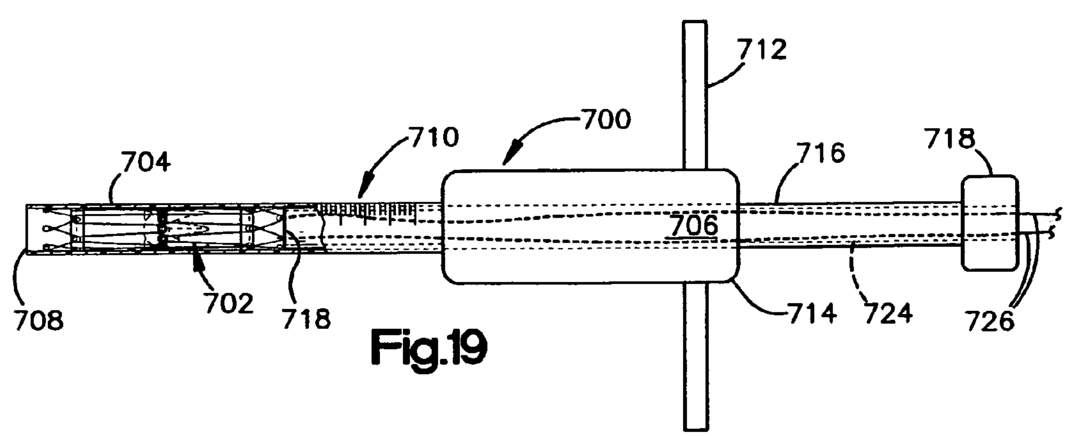
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Fig.19

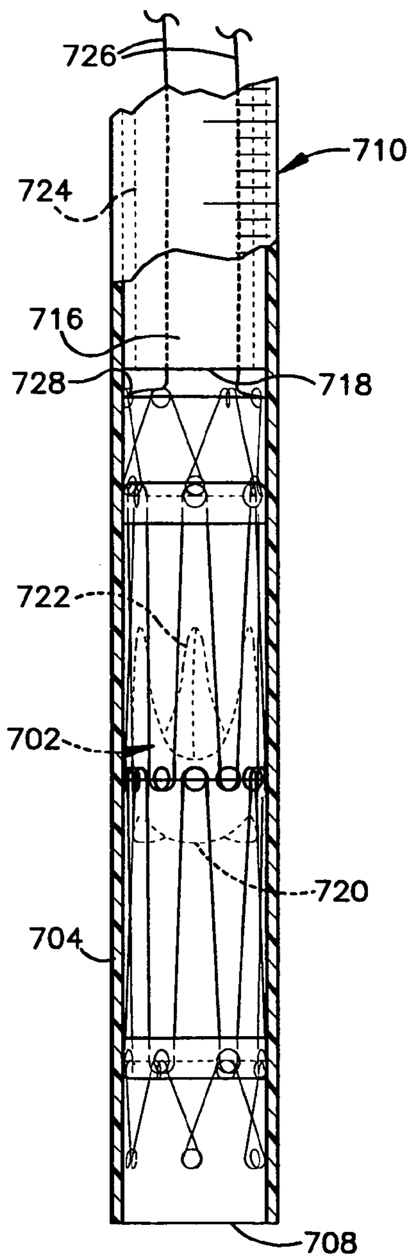
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Fig.20

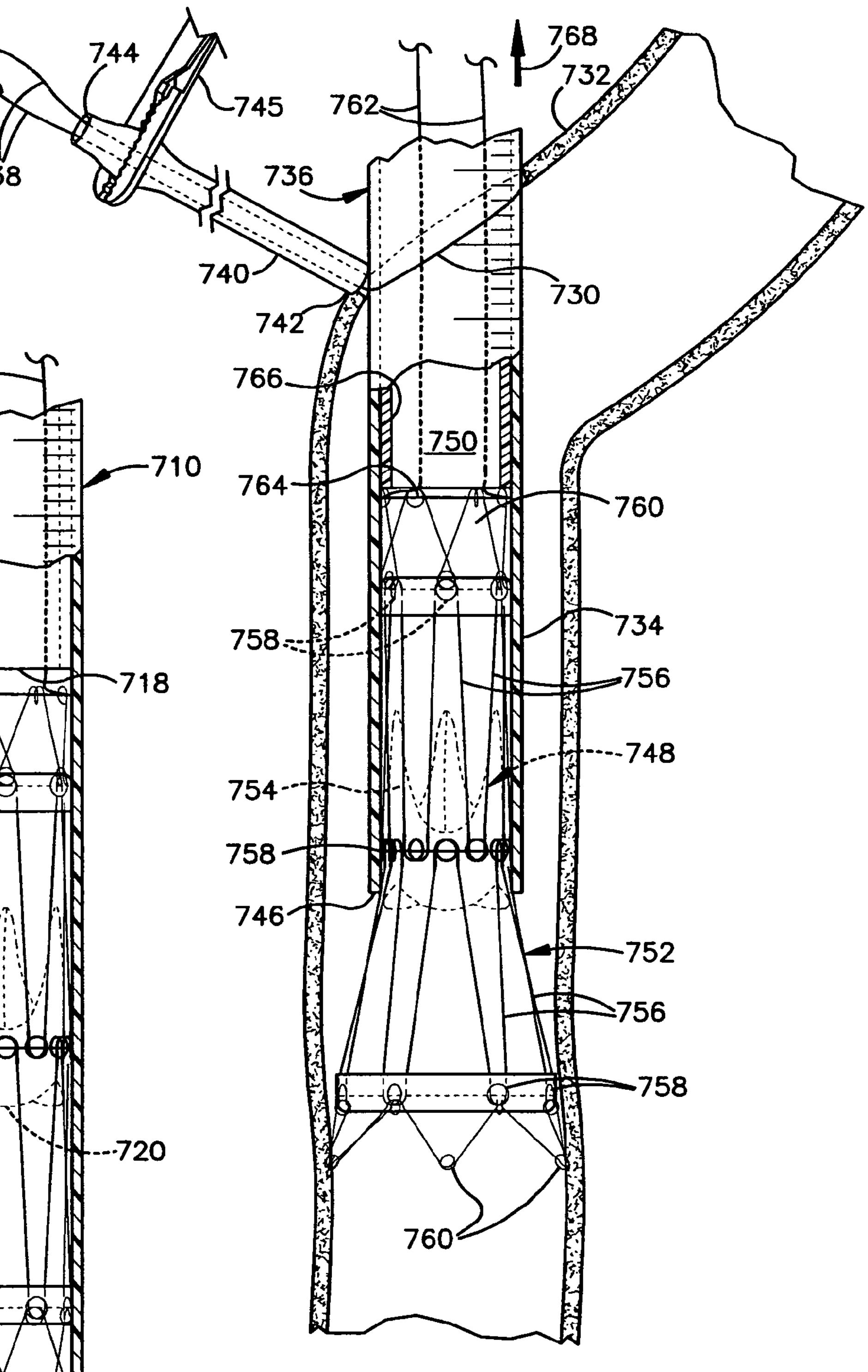
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Fig.21

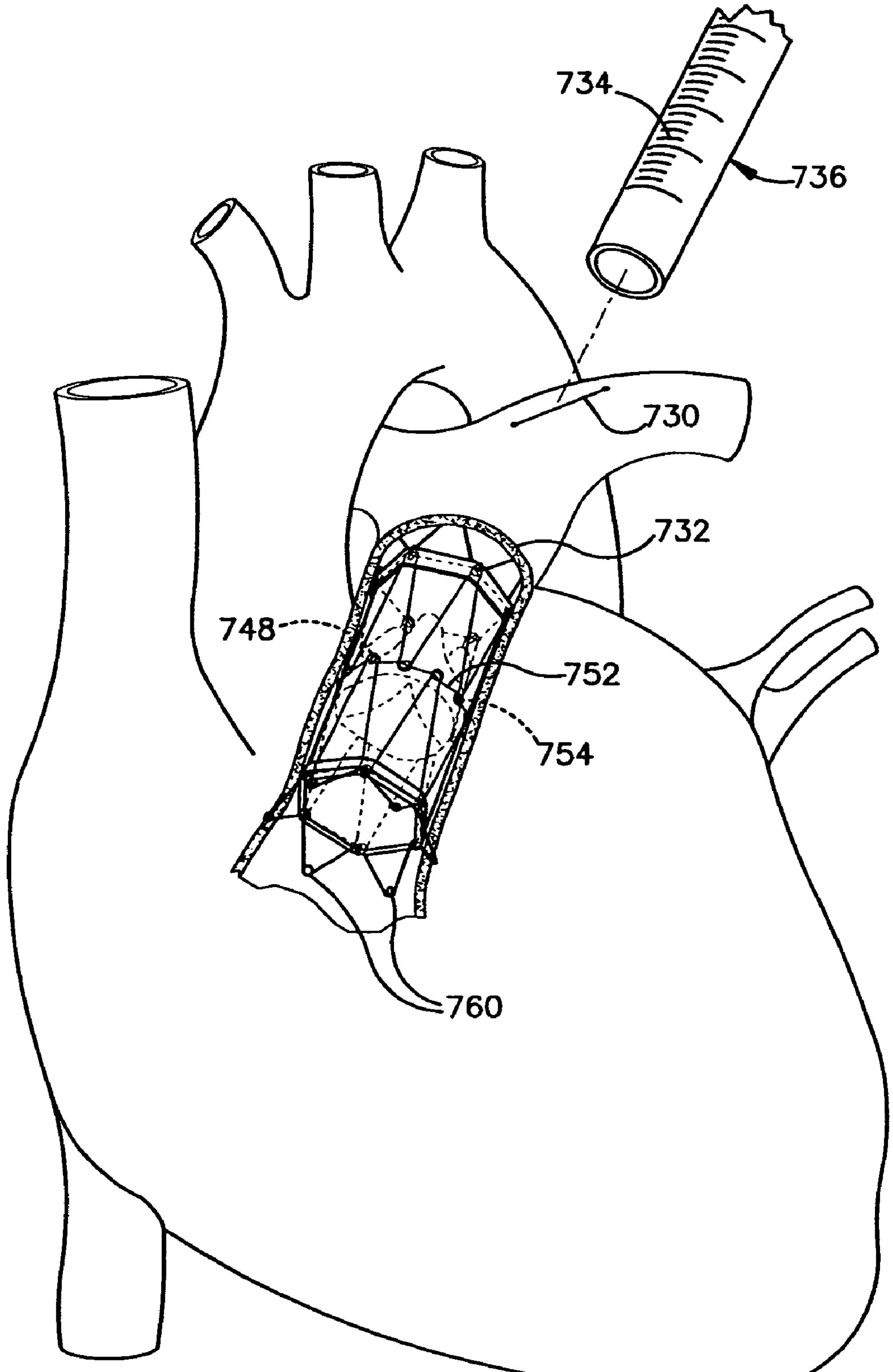

Fig.22

IMPLANTATION SYSTEM FOR DELIVERY OF A HEART VALVE PROSTHESIS

REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. patent application Ser. No. 09/659,882, which was filed on Sep. 12, 2000 now abandoned and entitled VALVULAR PROSTHESIS AND METHOD OF USING SAME, which is incorporated herein by reference.

TECHNICAL FIELD

The present invention relates to an implantable prosthetic device and, more particularly, to a heart valve prosthesis and to a method of implanting the prosthesis.

BACKGROUND

It is well known to utilize mechanical heart valves, such as the ball check valve, and natural tissue cardiac valves to replace defective aortic and mitral valves in human patients. One type of natural tissue heart valve typically employs a porcine valve for implantation in a human, as they are very similar to human valves of appropriate size and generally are easy to procure. Typically, the porcine valve is fixed by chemically treating it, such as with an appropriate glutaraldehyde solution. The treated porcine valve further may be mounted into a stent to support the valve at a fixed position.

A stent typically is formed of a resilient material, such as a plastic (e.g., DELRIN). Examples of various stent structures are disclosed in U.S. Pat. No. 3,983,581, U.S. Pat. No. 4,035,849. The stent usually is covered with a fabric material, such as DACRON or a suitable textile material. The fabric material provides structure for securing the valve relative to the stent. The stented heart valve prosthesis may be implanted into a patient for a heart valve replacement.

In order to surgically implant a heart valve into a patient, the patient typically is placed on cardiopulmonary bypass during a complicated, but common, open chest procedure. In certain situations, an individual requiring a heart valve replacement may be sufficiently ill, such that placing the individual on cardiopulmonary bypass may pose too great of risk. Such individuals may correspond to a class of patients who may have a non-functioning pulmonary valve or severe aortic valve insufficiency. In particular, many older patients having a deficient aortic or pulmonic valve may be too ill to survive conventional open-heart surgery.

Patients exhibiting these and other conditions would benefit from an improved heart valve prosthesis that may be implanted by a less invasive and/or more efficient implantation procedure.

SUMMARY

The following presents a simplified summary of the invention in order to provide a basic understanding of some aspects of the invention. This summary is not an extensive overview of the invention. It is intended to neither identify key or critical elements of the invention nor delineate the scope of the invention. Its sole purpose is to present some concepts of the invention in a simplified form as a prelude to the more detailed description that is presented later.

One aspect of the present invention provides a heart valve prosthesis. The prosthesis includes a generally cylindrical support having a plurality of support features that extend generally axially between opposed ends of the support. For

example, the support features can be formed of elongated, thin resilient wire or rods. Adjacent support features further can be connected together by biasing elements (e.g., springs) that urge interconnected support features apart from each other so as to bias the support radially outwardly. The biasing elements can be arranged in a circular array at each of the opposed ends of the support, such as to provide a cage-like cylindrical support. A valve, such as a treated natural tissue valve, is mounted within the support to define a supported valve. The supported valve can be deformed between reduced and expanded cross-sectional conditions to facilitate implantation of the prosthesis, while also providing desired functionality and coaptation of the valve when it is implanted.

Another aspect of the present invention provides a method for implanting a heart valve prosthesis. The heart valve prosthesis can be of the type described in the preceding paragraph, although other types of valves also could be implanted according to such method. The heart valve prosthesis is inserted into a generally cylindrical and elongated enclosure, such that the prosthesis has a reduced cross-sectional dimension generally corresponding to an internal dimension of the cylindrical enclosure. An opening is formed in a blood vessel and the portion of the enclosure holding the prosthesis is inserted through the opening. The cylindrical enclosure is positioned at a desired position and the prosthesis is discharged from the enclosure. As a result, the discharged heart valve prosthesis expands from the reduced cross-sectional dimension to an expanded cross-sectional dimension, such that an exterior portion of the heart valve prosthesis engages adjacent tissue to mitigate axial movement of the prosthesis relative to the adjacent tissue. The method can be performed without cardiopulmonary bypass as well as without opening the patient's heart.

BRIEF DESCRIPTION OF THE DRAWINGS

To the accomplishment of the foregoing and related ends, certain illustrative aspects of the invention are described herein in connection with the following description and the annexed drawings. These aspects are indicative, however, of but a few of the various ways in which the principles of the invention may be employed and the present invention is intended to include all such aspects and their equivalents. Other advantages and novel features of the invention will become apparent from the following detailed description of the invention when considered in conjunction with the drawings, in which:

FIG. **1** is an exploded isometric view of a valve and stent apparatus that may be utilized to form a prosthesis in accordance with the present invention.

FIG. **1**A is an enlarged view of part of the stent of FIG. **1** in a first condition.

FIG. **1**B is an enlarged view of part of the stent of FIG. **1**, similar to FIG. **1**A, illustrating the part of the stent in a second condition.

FIG. **2** is an example of a valvular prosthesis in accordance with the present invention.

FIG. **3** is another example of valvular prostheses in accordance with the present invention.

FIG. **4** is an example of the valvular prostheses of FIG. **3** implanted within a tubular member in accordance with the present invention.

FIG. **5** is another example of a stent apparatus in accordance with the present invention.

FIG. **6**A is an example of the stent of FIG. **5** mounted within an enclosure in accordance with the present invention.

FIG. **6**B is an example of valvular prostheses having the stent of FIG. **5** mounted therein in accordance with the present invention.

FIG. **7** is an example of a valvular prosthesis, illustrating an outer sheath over the prosthesis of FIG. **6**B in accordance with the present invention.

FIG. **8** is another example of a valvular prosthesis, illustrating an outer sheath over the prosthesis of FIG. **6**B in accordance with the present invention.

FIG. **9**A is an example of enclosure that may be utilized for implanting a valvular prosthesis in accordance with the present invention.

FIG. **9**B is an example of another enclosure catheter mechanism that may be utilized for implanting a valvular prosthesis in accordance with the present invention.

FIG. **10** is an example of a valvular prostheses implanted in an aortic position of a heart in accordance with the present invention.

FIG. **11** is an example of a valvular prostheses implanted in a pulmonic position of a heart in accordance with the present invention.

FIG. **12** is an example of a support structure in accordance with an aspect of the present invention.

FIG. **13** is an example of another support structure in accordance with an aspect of the present invention.

FIG. **14** is an example of a heart valve prosthesis employing the support structure in accordance with an aspect of the present invention.

FIG. **15** is a cross-sectional view of a heart valve prosthesis taken along line **15-15** in FIG. **14**.

FIG. **16** is an example of another type of support structure in accordance with an aspect of the present invention.

FIG. **17** is another example of a heart valve prosthesis employing the support structure of FIG. **16** in accordance with an aspect of the present invention.

FIG. **18** is an example of a heart valve prosthesis employing a support structure in accordance with an aspect of the present invention.

FIG. **19** is an example of an implanter apparatus for implanting a prosthesis in accordance with an aspect of the present invention.

FIG. **20** is an enlarged view of part of the implanter apparatus of FIG. **19**.

FIG. **21** is an example of a prosthesis being implanted at a desired location in accordance with an aspect of the present invention.

FIG. **22** is an example of a prosthesis mounted at a pulmonary position of a patient's heart in accordance with an aspect of the present invention.

DESCRIPTION OF THE INVENTION

FIG. **1** is an exploded view of a valvular prosthesis **10** in accordance with an aspect of the present invention. The prosthesis **10** includes a valve portion **12** and a stent portion **14** that may be assembled to form the valvular prosthesis **10**, such as shown in FIG. **2**.

The valve portion **12** includes inflow and outflow ends **16** and **18** spaced apart from each other by a length of a generally cylindrical sidewall portion **20**. While the inflow and outflow ends **16** and **18** are illustrated as being annular in FIGS. **1** and **2**, those skilled in the art will understand and appreciate that other configurations (e.g., generally sinusoidal ends) also could be used in accordance with the present invention.

The valve portion **12** also includes one or more leaflets **22**, **24**, and **26** that are attached to and extend from an interior of the sidewall portion **20**. In the example illustrated in FIG. **1** and **2**, the valve portion **12** includes three leaflets **22**, **24** and **26**, although other numbers of leaflets, such as a single leaflet or two leaflets, also could be used.

The valve portion **12** may be formed of any substantially biocompatible valve apparatus. By way of example, the valve portion **12** may include an animal heart valve (e.g., pulmonic or aortic), a manufactured valve device (e.g., a valve as shown and described in U.S. Pat. No. 4,759,758 or U.S. Pat. No. 5,935,163) a venous valve (e.g., a bovine or equine jugular venous valve). Those skilled in the art will understand and appreciate that the foregoing list is not intended to be exhaustive but, instead, is intended illustrate a few examples of the types of valves that may be utilized in a valvular prosthesis **10** in accordance with an aspect of the present invention.

If the valve portion **12** is formed of a natural tissue material, such as an animal heart valve, a venous valve, or a composite valve manufactured of natural tissue, the valve should be chemically fixed, such as in a suitable solution of glutaraldehyde in a closed condition (as is known in the art). The fixation process facilitates closure of the valve **12** under application of back flow pressure, while remaining open during normal forward blood flow through the valve **12**. By way of example, the natural tissue valve may be cross-linked with glutaraldehyde and undergo a detoxification process with heparin bonding, such as according to a NO-REACT® treatment process from Shelhigh, Inc. of Millburn, N.J. The NO-REACT® treatment improves biocompatibility of the valve apparatus **12** and mitigates calcification and thrombus formation.

In accordance with an aspect of the present invention, the valve portion **12** exhibits structural memory. That is, if the valve apparatus **12** is compressed, such as to a reduced diameter at the time of being implanted, it will return substantially to its original shape and configuration upon removal of radially inward forces. As a result, the valve apparatus **12** is able to maintain coaptation of the leaflets **22**, **24**, and **26** even after being deformed. The memory feature of the valve is further improved by mounting it within the stent portion **14**.

Turning now to the stent portion **14**, such as shown in FIGS. **1** and **2**, the stent includes an inflow end **30** and an outflow end **32**. In this example, the inflow and outflow ends **30** and **32** are spaced apart from each other a distance that is greater than the distance between the corresponding ends **18** and **16** of the valve **12**. In this way, the ends of the stent **30** and **32** may extend beyond the respective ends **18** and **16** of the valve **12** (e.g., by about a few millimeters), such as shown in FIG. **2**. The stent portion **14** also may include outwardly turned portions at the inflow and outflow ends **30** and **32** of the stent, which, when implanted, may engage and/or be urged into the surrounding tissue to mitigate movement thereof.

According to an aspect of the present invention, the stent **14** may deformable between first and second conditions, in which the first condition has a reduced cross-sectional dimension relative to the second condition. FIGS. **1** and **2** illustrate the stent portion **14** as being formed of a mesh or weave **34** extending between the ends **30** and **32**. The mesh **34** may be a metal, an alloy, or other suitable material that may help support a valve mounted therein and/or help anchor the valve at a desired position when implanted.

By way of example, the mesh may be formed of a shape memory alloy material, such as may be formed of a nitinol (nickel-titanium alloy) wire. Shape memory (or thermal memory) is a characteristic in which a deformed part remembers and recovers to a pre-deformed shape upon heating. By forming the stent **14** of a shape memory alloy, the stent is inelastically deformable to new shape, such as a reduced cross-sectional dimension, when in its low-temperature (martensitic) form. For example, the stented valve (FIG. **2**) may be cooled, such as by being introduced to a cooling solution (e.g., water), and then compressed.

When the stent **14** is heated to its transformation temperature, which may vary according to the alloy composition, it quickly reverts to its high-temperature (austenitic) form. The stented valve may retain the compressed condition by keeping it cooled. Alternatively, the stent and valve may be retained in the compressed position, such as with sutures circumscribing the structure, a cylindrical enclosure around the structure, etc. The prosthesis **10** will then return toward its high-temperature (or original) position upon removal of the retaining element.

It is to be appreciated that, alternatively, the stent **14**, in accordance with an aspect of the present invention, could be inelastically deformable so as to require an intervening force to return the deformed stent substantially to a desired configuration. For example, a balloon catheter or spring mechanism could be employed to urge the stent and the valve located therein generally radially outward so that, after being implanted to a desired position, the stent will engage the surrounding tissue in a manner to inhibit movement relative to the surrounding tissue.

FIGS. **1**A and **1**B illustrate an enlarged view of part of the stent **14** in accordance with an aspect of the present invention. In this example, some strands of the mesh **34** are broken to define spaces **36** between adjacent lateral extensions or spike portions **38** and **40**. As the stent **14** is deformed, such as shown in FIG. **1** B, the spike portions **38'** and **40'** may extend radially outwardly from the stent in different directions. In addition, the inflow end **32'** also may flare outwardly for engagement with surrounding tissue when implanted. For example, some spikes **40**, **40'** may extend generally outwardly and toward an outflow end of the stent **14**, while others **38**, **38'** may extend generally outwardly and toward an inflow end **32**, **32'**. The spikes thus are operable to engage tissue, when implanted, so as to inhibit axial movement of the stent **14** relative to the surrounding tissue.

Referring back to FIG. **2**, the valve portion **12** is disposed generally coaxially within the cylindrical stent portion **14** relative to the central axis A. The valve **12** may be affixed relative to the stent portion **14**, such as by one or more sutures **44**. The sutures **44** may be located at the inflow and outflow ends **16** and **18** of the valve **12** to connect the valve to the stent **14** to inhibit axial movement of the valve relative to the stent. Alternatively or additionally, axial movement between the stent **14** and valve **12** may be mitigated due to friction fitting between the stent and valve portion. For example, as illustrated in FIG. **2**, the valve portion **12** has a cross-sectional diameter that is slightly larger than that of the stent **14**, such that the prosthesis **10** bulges somewhat in the middle and is narrower near the inflow and outflows ends **16** and **18** of the valve portion **12**.

As mentioned above, the stent portion **14** may be formed of a shape memory alloy. In this way, the valvular prosthesis **10** may be compressed to a reduced cross-sectional dimension about the axis A and maintained at the reduced dimension while being implanted. Once the valvular prosthesis **10** is at a desired implantation position, the prosthesis may be permitted to return toward its original cross-sectional dimension so as to engage a valve wall or other surrounding tissue at the desired position. The engagement between the stented valvular prosthesis **10** and the surrounding tissue inhibits axial movement of the prosthesis relative to the tissue. In accordance with an aspect of the present invention, lateral extensions or spikes (see, e.g., FIGS. **1**A and **1**B) may extend outwardly from the stent to further inhibit axial movement.

Those skilled in the art will understand and appreciate that a valvular prosthesis **10**, in accordance with the present invention, may be utilized to replace a heart valve or utilized as an intravascular implant to provide an operable venous valve.

FIG. **3** illustrates another example of a stented valvular prosthesis **50** in accordance with an aspect of the present invention. The prosthesis **50** in this example includes a valve portion **52** mounted within a stent portion **54**. The valve portion **52** in this example, has a generally sinusoidal outflow end **56** having a plurality of commissure posts **58**, **60**, and **62** extending from an annular base portion **64**, with corresponding sinuses located between each adjacent pair of posts. It is to be appreciated that, alternatively, a valve having a sidewall portion according to generally cylindrical configuration of FIGS. **1** and **2** also could be used in conjunction with the stent portion **54**.

The stent portion **54** in this example is formed of a deformable mesh, which may be substantially identical to that described above with respect to FIGS. **1**-**2**. The stent portion **54** also includes a plurality of spikes extending generally radially outwardly from the stent portion. In particular, one set of spikes **66** extend from an inflow end **68** of the stent portion **54** and another set of spikes **70** extend from an outflow end **72** of the stent.

FIG. **4** illustrates the prosthesis **50** of FIG. **3** mounted in an expanded condition within a generally cylindrical sidewall **74**. The sidewall **74**, for example, may be a venous valve wall, a pulmonary artery, an aorta, etc. In this example, the spikes **66** and **70** engage and/or extend into the valvular wall **74** to inhibit axial movement of the prosthesis **50** relative to the valve wall **74**.

FIG. **5** illustrates another example of a stent apparatus **80** which may be utilized as part of a valvular prosthesis in accordance with an aspect of the present invention. The stent **80** includes a generally annular base portion **82** and a plurality of axially extending portions (or stent posts) **84**, **86** and **88** extending generally axially from the base portion. The post portions **84**, **86** and **88** are circumferentially spaced apart for generally radial alignment with corresponding commissure posts of an associated valve wall. While the example of the stent **80** in FIG. **5** has three stent posts **84**, **86** and **88**, those skilled in the art will understand and appreciate that other numbers of posts also could be utilized in accordance with an aspect of the present invention. Typically, however, the number of posts and their relative circumferential position correspond to the number of leaflets of a valve to be mounted within the stent **80**.

In accordance with an aspect of the present invention, each of the stent posts **84**, **86**, **88** may extend radially outwardly an angle T relative to the axis A. By way of example, the angle T may range from about 10 to about 60 degrees relative to a line drawn through the juncture of each post and the base **82** parallel to the central axis A. The outwardly extending posts **84**, **86**, and **88** facilitate engagement between each respective post and surrounding tissue when implanted, as the posts (being resilient) tend to urge radially outwardly and into engagement with such tissue.

The stent **80** also includes a plurality of spikes **90** and **92** that extend radially outwardly from the stent. In particular, some outwardly extending spikes **90** are curved generally toward an outflow end of the stent and others **92** are curved generally toward an inflow end of the stent. In addition, a row of spikes **90** may extend outwardly relative to the stent **80** at the inflow end thereof, which spikes also are curved generally toward the outflow end. The varying contour of the spikes **90** and **92** mitigates axial movement of the stent **80** (in both axial directions) relative to tissue engaged thereby, such as after being implanted. It is to be understood and appreciated that, while a single row of spikes is illustrated near the inflow end of the stent in FIG. **5**, two or more axially spaced apart rows of spikes extending generally radially outwardly from the stent **80** could also be utilized in accordance with an aspect of the present invention. The rows of spikes may be curved toward each other to provide a clamping function on surrounding tissue when implanted.

FIG. **6**A illustrates the stent of FIG. **5** mounted within a tubular structure **94** that has an inner diameter that is substantially commensurate with the outer diameter of the base portion **82** of the stent **80**. The tubular structure **94** may be formed of a plastic or other material effective to hold the stent posts **84**, **86**, and **88** at a radial inward position. In this way, the tubular structure **94** urges the stent posts **84**, **86**, and **88** radially inward to a position that facilitates mounting a valve **98** therein. For example, the valve **98** may be positioned within and connected to the stent **80**, such as by sutures applied along the base portion **82** and the stent posts **84**, **86**, and **88**; without having to manually hold each of the posts against corresponding parts of the valve.

FIG. **6**B illustrates an example in which a valve **98** has been mounted within the stent **80** of FIG. **5** to form a valvular prosthesis **100**. The valve **98** includes an inflow end **102** and an outflow end **104**. The inflow end **102** of the valve **98** is positioned adjacent relative to the inflow end of the stent **80**. The outflow end **104** of the valve **98** is contoured to include axially extending commissure posts **106**, **108** and **110** with sinuses **112**, **114** and **116** located between each adjacent pair of posts. Valve leaflets **118**, **120** and **122** extend between adjacent posts commensurate with the location of each of the sinuses **112**, **114** and **116**. The stent **80** may be connected to the valve **98** via sutures **124**.

In accordance with an aspect of the present invention, the prosthesis **100** of FIG. **6**B is a stented valve, which may be covered with an outer sheath of a substantially biocompatible material.

FIG. **7** illustrates an example of a valvular prosthesis in which an outer sheath **130** has been applied over the stent **80** and at least part of the exposed exterior portion of the valve **98** in accordance with an aspect of the present invention. As illustrated, the outer sheath **130** may have inflow and outflow ends having generally the same contour as the sidewall of the valve **98** and the stent **80**. The outer sheath **130** may be a sheath of natural tissue pericardium (e.g., bovine, equine, porcine, etc.), another biological tissue material (e.g., collagen), or a synthetic material (e.g., Dacron). When a biological tissue is utilized, for example, it may be cross-linked with glutaraldehyde and detoxified with heparin bonding, such as one of the NOREACT® natural tissue products that are commercially available from Shelhigh, Inc. of Millburn, N.J.

An implantation flange (or sewing ring) **132** may be formed at the inflow end of the prosthesis **100**. The implantation flange **132** may be formed of substantially the same material as the outer sheath **140**, such as formed from the outer sheath **130** or by attaching a separate flange by other methods. The outer sheath **130** may be attached to the valve **98** and/or to the stent **80** by applying sutures **134** and **136** at the respective inflow and outflow ends of the prosthesis **100**. Some of the spikes **90**, **92** may extend through the outer sheath **130** so as to mitigate axial movement of the prosthesis **100** relative to surrounding tissue when the prosthesis is implanted. Sutures **134** and **136** may be applied respectively at the inflow and outflow ends to secure the outer sheath relative to the stent **80** and the valve **100**. The outer sheath **130** may include an outflow end that conforms to the contour of the outflow end **104** of the valve **100**.

FIG. **8** illustrates another example of valvular prosthesis **100** that is similar to that shown and described in FIG. **7**, in which identical reference numbers refer to corresponding parts previously identified herein. The prosthesis **100** includes having an outer sheath **140** that is disposed about the stent **80** and the valve **98** and having an outflow end that follows the contour of the prosthesis **100** (e.g., generally sinusoidal. In addition, the outer sheath **140** includes a plurality of axially extending lobes **142**, **144** and **146** extending axially beyond the outflow attachment of the valve leaflets **118**, **120**, and **122**. In this example, the lobes **142**, **144** and **146** extend axially a length beyond the commissure posts **106**,**108** and **110** of the valve **98**. The axially extending lobes **142**, **144** and **146** provide additional structure that may be utilized to help secure the prosthesis **100** relative to surrounding tissue when being implanted. When the prosthesis **100** of FIG. **8** is implanted, for example, sutures may be applied through the lobes **142**, **144** and **146** to help secure the commissure posts of the prosthesis relative to the surrounding tissue. Additional sutures also could be applied at the inflow end to the implantation flange **132** located thereat.

FIGS. **9**A and **9**B illustrate variations of an implantation apparatus **200** that may be utilized to implant a valvular prosthesis **202** in accordance with an aspect of the present invention. It is to be understood and appreciated that any of the prosthesis shown and/or described herein may be implanted with such an implantation apparatus.

With reference to FIG. **9**A, by way of example, the implantation apparatus **200** may be in the form of a catheter system. The implantation apparatus includes an elongated connecting element **204** extending between a trigger mechanism **206** and an enclosure **208**, in which the prosthesis **202** is located. At least a portion of the prosthesis **202** is located within the enclosure **208**. A plunger mechanism **210** is located at a proximal end of the enclosure **208** for urging the prosthesis **202** generally axially from the enclosure **208**. An opposite end **212** of the enclosure **208** may be formed of a pliable material or a plurality of moveable members that may open as the prosthesis **202** is urged through an opening **214** located at a distal end. It is to be appreciated that the length of the connecting element **204** may vary according to where the valvular prosthesis **202** is to be implanted and the method of implantation.

The valvular prosthesis **202** is illustrated within the enclosure **208** in a compressed condition, such as described above. That is, the valvular prosthesis **202** within the enclosure **208** has a cross-sectional dimension that is less than its normal cross-sectional dimension, being maintained in such position by the enclosure. Those skilled in the art will appreciate that the orientation of the valvular prosthesis **202** will vary depending upon the direction in which blood is to flow through the valve when implanted.

By way of example, the external stent of the valvular prosthesis **202** may be formed of a deformable material, such as a shape memory alloy material (e.g., nitinol), which maintains its shape when cooled. Accordingly, the prosthesis **202** may be cooled (e.g., within a suitable fluid), compressed to a desired reduced cross-sectional dimension so as to fit within the enclosure **208**, and then inserted within the enclosure. The prosthesis **202**, after the stent being heated (e.g. to an ambient temperature), may desire to expand to its original dimension and configuration. However, the enclosure **208** or another retaining mechanism, such as a suture or other tubular member around the prosthesis, may be used to restrict its expansion. The compression of the valvular prosthesis **202** may be performed just prior to surgery to mitigate undesired permanent deformation of the valvular prosthesis **202**. The plunger mechanism may be urged in the direction of arrow **220**, such as by activating the trigger **206**. Movement of the plunger **210**, in turn, causes the prosthesis **202** to also be moved in the direction of the arrow **220**. As the prosthesis **202** is urged through the opening **214** and discharged therefrom, the prosthesis may expand. Accordingly, the opening **214** should be positioned at the location where the prosthesis **202** is to be implanted prior to discharge. When the prosthesis **202** expands toward its original condition, the sidewall of the stent and/or spikes associated with the stent may engage and/or be urged into surrounding tissue so as to mitigate axial movement of the prosthesis relative to the surrounding tissue. As a result, the prosthesis may be implanted without sutures to provide an operable valve, such as a heart valve or a venous valve. When a valvular prosthesis is being employed as a heart valve, in accordance with present invention, it will be appreciated that the prosthesis may be implanted either as part of an open chest procedure or the patient's chest may be closed. Additionally, other expandable stent structures also could be utilized in accordance with an aspect of the present invention.

FIG. **9**B illustrates another example of an enclosure **208** which may be utilized, in accordance with an aspect of the present invention, to implant a prosthesis **202**. The enclosure **208** has an opening **224** at its distal end through which the prosthesis **202** may be discharged. In this example, the opening **224** is about the same diameter as the enclosure itself, although it may be curved slightly inwardly at the distal end thereof. This facilitates discharge of the prosthesis **202** without having an expandable distal end portion, such as shown and described with respect to FIG. **9**A.

FIG. **10** illustrates an example of a valvular prosthesis **300** implanted in a heart **302** in an aortic position. When being implanted at an aortic position, an aortic valve (e.g., equine, porcine, bovine, etc.) may be utilized for the valve portion of the prosthesis, although other types of valve portion also could be used. Prior to implanting the prosthesis **300**, the aortic valve or at least calcified portions thereof should be removed. An inflow end **304** of the prosthesis **300** is annularized with respect to the annulus of the aorta **306**. An outflow portion **308** of the prosthesis **300** extends axially into the aorta **306**, with the stent posts engaging the interior of the aortic wall. As mentioned above, a plurality of spikes **310** may extend laterally from the stent portion of the valvular prosthesis **300** to engage the aorta **306** to help maintain a desired axial orientation of the valvular prosthesis relative to the aorta **306**.

The valvular prosthesis **300** may be implanted in a compressed condition. It is to be appreciated that the valvular prosthesis **300** may be implanted in the aortic position during a conventional open chest procedure or during a closed chest procedure. The valvular prosthesis **300** may be implanted by using a catheter (or other structure) to retain the prosthesis in a compressed condition. The catheter may then be used to position the valve at a desired position, such as by utilizing a suitable imaging technology (e.g., x-ray, ultrasound, or other tomography device) or a direct line of sight. Once at the desired position, the prosthesis **300** may be discharged from its retaining mechanism (e.g., an enclosure) so that it expands toward its original expanded configuration at the desired position within the aorta **306**.

It is to be understood and appreciated, though, if the patient has a calcified aortic valve, the patient typically must be put on cardiopulmonary bypass to remove the calcium and implant the valve. Advantageously, a valvular prosthesis **300** in accordance with the present invention may be implanted more efficiently so as to mitigate morbidity and mortality of the patient. In addition, the prosthesis may be implanted without sutures or, alternatively, some sutures may be utilized. For example, sutures may be applied at the inflow end **304** (e.g., at a sewing ring) and/or at the outflow end **308**, such as when the prosthesis is configured to have axially extending lobes (see FIG. **8**).

FIG. **11** illustrates an example of a valvular prosthesis **350** implanted in a pulmonary position of a heart **352**. The particular example illustrated in FIG. **11** shows an enclosure **353**, such as may be part of a catheter, which has been inserted into the heart **352** to place the prosthesis at a desired position. Specifically, the catheter has traveled through the inferior vena cava **354**, into the right atrium **356** and into the right ventricle **358** to position the valvular prosthesis **350** at a desired position relative to the pulmonary artery **360**.

As mentioned above, the prosthesis **350** is mounted within the enclosure **353** in a compressed condition prior to implantation. The enclosure **353** and the prosthesis **350**, for example, may be introduced into the inferior vena cava through the patient's right femoral vein. The prosthesis **350** and enclosure **353** may traverse the vascular system to the inferior vena cava **354** with the assistance of suitable imaging equipment such as x-ray, ultrasound, or other imaging devices. The imaging equipment is utilized to navigate the enclosure **353** and the prosthesis **350** to the desired position. Once at the desired position, such as at the opening to the pulmonary artery **360**, the prosthesis **350** may be discharged through a distal opening of the enclosure **353**. The valvular prosthesis **350** then expands from its compressed condition to an expanded condition, as illustrated in FIG. **11**. Advantageously, when the valvular prosthesis **350**, which is formed of an elastic material (e.g., nitinol in its heated form), is urged through the opening of the enclosure **353**, it will automatically expand and dilate, thereby also expanding the valve that is attached to the stent. Therefore, the valvular prosthesis **350** becomes functional almost immediately. The enclosure **353** may then removed out of the heart **352**, through the inferior vena cava **354** and removed from the patient.

Advantageously, the valvular prosthesis **350** may be implanted in the patient without cardiopulmonary bypass. As a result, a significant amount of time may be saved with less stress on the patient, thereby mitigating the risks of morbidity and mortality associated with conventional open-heart surgery typically employed to implant a heart valve prosthesis. Those skilled in the art will understand and appreciate that this process also may be utilized to implant a valvular prosthesis for a venous valve, such as in a patient's lower limb.

FIG. **12** illustrates another support structure **400** that can be employed as part of a heart valve prosthesis in accordance with an aspect of the present invention. The support **400** has a generally cylindrical configuration that extends between spaced apart ends **402** and **404**. A plurality of interconnected support features **406** extend generally axially between the ends **402** and **404**. The support features **406**, for example, are formed of a length of a resilient rod or wire. Biasing elements **408**, such as coil springs, interconnect at least some of the support features **406** at the respective ends **402** and **404**. The biasing elements **408**, for example, are arranged in a circular array spaced circumferentially apart from each other at the respective ends **402** and **404**. The biasing elements **408** urge each pair features **406** interconnected by the respective biasing elements apart from each other in a circumferential direction. As a result of the circumferential expansion between features **406** imposed by the biasing elements **408**, the cylindrical support **400** tends to expand radially outwardly.

The support **400** also includes one or more retaining elements **410** that inhibit radial expansion of the support beyond a certain desired amount. For example, the retaining element **410** can be in the form of one or more flexible cords (e.g., sutures) that limit circumferential expansion of the features **406** caused by the biasing elements **408**. In the example in FIG. **12**, cords are in the form of flexible loop of material attached to the biasing elements **408** located at each end **402**, **404** of the support **400**. The cords further are threaded through apertures of each of the biasing elements, although the cords could be connected at the ends **402** and **404** by other attachment arrangements. For example, one or more cords could be threaded between adjacent support features an axial location between the ends **402** and **404**. Alternatively, other types of flexible retaining mechanisms (e.g., a strip of treated animal tissue, fabric, etc.) could be attached to the support **400** to limit its circumferential expansion, although still permit a desired reduction in its cross-sectional dimension.

FIG. **13** illustrates another example of a generally cylindrical support structure **420** that could be used to form a heart valve prosthesis in accordance with an aspect of the present invention. The support **420** is similar to the support shown and described with respect to FIG. **12**. Briefly stated, the support includes a cylindrical intermediate portion **422** having spaced apart ends **424** and **426**. The intermediate portion **422** includes a plurality of interconnected support features **428** that extend generally axially between the ends **424** and **426**. At least some of the features **428** are interconnected with adjacent features by biasing elements **430** located at the juncture between adjacent interconnected features. While the biasing elements **430** are illustrated as being located at the ends **424** and **426**, it is to be understood and appreciated that they alternatively could be located between adjacent features at a different axial position (e.g., intermediate) somewhere between an adjacent pair of features in accordance with an aspect of the present invention.

The support **420** also includes retaining features **432** that limit the circumferential expansion of the support to a desired amount. The retaining feature **432** is in the form of a pair of cords (e.g., sutures) having ends connected together to form a loop that is connected at each end **424** and **426** of the support. Each loop **432** is flexible to permit the support to be deformed into a reduced cross-sectional dimension. The loops **432** also inhibit expansion at each of the ends **424** and **426** according to the dimensions of the respective loops. For example, one end **426** (e.g., the inflow end) can have a larger maximum diameter than the other end **424** (e.g., the outflow end) of the intermediate portion **422**.

The support **420** further includes members **440** and **442** that extend axially and radially outwardly from the respective ends **424** and **426** of the support. In this example, each of the members **440** and **442** includes a plurality of triangular projections **444**. Each projection **444** includes a pair of legs **446** that are connected to the respective ends **440** and **442**. The legs **446** extend radially axially and radially outwardly from the respective ends **440** and **442** and terminate in an apex **448** spaced apart from the intermediate portion **422**.

In the example in FIG. **13**, each triangular projection **444** has a width that approximates the width of an elongated triangle formed of a pair of adjacent elongated features **428** of the intermediate portion **422**. Each projection can have an axial length that is quite less than intermediate portion. Adjacent triangular projections **444** are coupled together at the ends **424** and **426** by additional biasing elements **450**. The apex **448** also includes a similar biasing element **452**, which further tends to urge respective legs **446** apart from each other. Thus, the biasing elements **450** and **452** of the triangular projections cooperate with the biasing elements **430** of the intermediate portion to increase the associated radially expansive force of the support **420**. As mentioned, however, the dimensions of the retaining feature **432** can limit the radial expansion of the support **420**. The projections **444** also provide a mechanism that can engage adjacent tissue, such as when implanted in a patient's heart, so as to inhibit axial movement of the prosthesis relative to the heart. Each of the members **440**, **442** and the intermediate portion **422** can be formed from a separate length of a generally resilient wire that connected together at the ends by the associated connecting elements **432**, as shown in FIG. **13**. While six symmetrical triangular projections are illustrated in FIG. **13**, it is to be appreciated that other numbers and shapes of projections could be used in accordance with an aspect of the present invention.

FIGS. **14** and **15** illustrate an example of a heart valve prosthesis **470** in accordance with an aspect of the present invention. The prosthesis **470** is particularly useful during a direct vision implantation, which can be sutureless, in accordance with an aspect of the present invention. The prosthesis **470** includes a heart valve **472** mounted within a support, such as the support **420** of FIG. **13**, which can expand from a reduced cross-sectional dimension to an expanded condition as shown. Identical reference numbers refer to parts of the support **420** previously identified with respect to FIG. **13**. It is to be understood and appreciated that other deformable, self-expanding supports also can be utilized in accordance with an aspect of the present invention.

The valve **472** includes an inflow end **474** and an outflow end **476** at axially opposed ends of the valve, with a sidewall portion **478** extending between the ends thereof. The inflow end **474** of the valve **472** is positioned near an inflow end **426** of the support **420**. The sidewall portion **478** can be a tubular valve wall. A plurality of leaflets **480** extend radially inward from the valve wall **478** and coapt along their side edges to provide for substantially unidirectional flow of blood through the valve **472**. The outflow end **476** of the valve **472**, which is located near the outflow end **424**, has a generally sinusoidal contour. The peaks are aligned with commissures between adjacent leaflets **480**, with sinuses located between the commissures. The valve **472** can be connected within the support **420** via sutures **124** or other connecting means.

By way of illustration, when the prosthesis is to be implanted at the pulmonary position, the valve **472** can be a treated porcine pulmonic valve. When it is to be implanted at an aortic position, the valve **472** can be a porcine aortic valve. For example, the valve can be of the type shown and described in U.S. Pat. Nos. 5,935,163, 5861,028 or 5,855,602. It is to be understood and appreciated that other valve configurations of could be used in accordance with an aspect of the present invention. For example, one or more leaflets of the valve **472** could be mounted within a length of tubular valve wall or other generally cylindrical biocompatible material and operate in a known manner to provide for the unidirectional flow of fluid through the valve from the inflow to outflow ends.

In accordance with an aspect of the present invention, the prosthesis **470** also includes an outer sheath **482** of a substantially biocompatible material. The outer sheath **474** covers at least a substantial amount of exposed portions of the support **420** (including the ends **424** and **426**) so as to mitigate contact between the blood and the support when the prosthesis is implanted. In the example of FIGS. **14** and **15**, the outer sheath **482** covers the entire support, including the end portions **440** and **442** as well as the intermediate portion **422**. The outer sheath **482**, for example, is formed of one or more NO-REACT® natural tissue sheets (e.g., animal pericardium), although other nature or synthetic biocompatible materials also could be used to provide an outer sheath in accordance with an aspect of the present invention.

FIG. **16** illustrates another example of an elongated generally cylindrical support **500** that can be employed to support a heart valve in accordance with an aspect of the present invention. The support **500** generally consists of two cylindrical support portions **502** and **504**, similar to the support of FIG. **12**. The support portions **502** and **504** are connected together end-to-end in a substantially coaxial arrangement. For example, a length of a flexible cord **506** or other flexible retaining element connects adjacent ends of the respective support portions **502** and **504**. The cord **506** has ends that are connected together to form a loop that determines a maximum diameter of the support **500** at the juncture between the two support portions **502** and **504**. Other similar loops of flexible cords **508** and **510** are connected at opposite ends of the support **500** to inhibit expansion of the ends beyond a desired maximum diameter. The length of the cords **508** and **510** at the respective ends can be different so that one end (e.g., the inflow end) has a greater diameter than the other end (e.g., the outflow end).

The support **500** includes a plurality of generally axially extending features **512** (e.g., resilient rods or wires) that are biased to urge adjacent interconnected features circumferentially apart from each other. Because a plurality of such features are interconnected in a cylindrical arrangement, the biasing of the features apart from each other results in radially outward expansion of the cylindrical support **500** according to the dimensions of the retaining cords **506**, **508**, and **510**. In one aspect, biasing elements **514**, which can be springs, connect each adjacent pairs of features **512** together at each end of each respective support portion **502** and **504**. Each of the cords **506**, **508**, **510** further interconnect a respective set of biasing elements at a corresponding axial location, with the cord **506** interconnecting biasing elements of both support portions at the intermediate axial location. While substantially identical biasing elements **514** are illustrating throughout the support **500**, it is to be understood and appreciated that different types of biasing elements could be used at different locations of the support. Additionally, a separate length of a flexible cord can be used to interconnect adjacent support features, instead of the single loop inserted through an aperture of the respective biasing elements shown and described herein.

In view of the arrangement described above, it is to be appreciated that a length of the cord **506**, **508** or **510** that extends between adjacent biasing elements **514** of each support portion **502**, **504** and the pair of interconnected adjacent features **512** define a generally triangular structure. A plurality of such triangular structures are interconnected in a circumferential arrangement to define the generally cylindrical sidewalls of the respective support portions **502** and **504**. The features **512** of each such triangular structure are urged apart from each other by the interconnecting biasing element **514**. The juncture of the support portions **502** and **504** are connected by the connecting element **506** so as to provide radial expansion combined from both of the support portions. As a result, about twice the amount of radial expansive force is provided along the length of the cord **506**.

The resulting support **500** thus provides a cage-like structure in which a valve can be mounted in accordance with an aspect of the present invention. The support **500** can be deformed to a reduced cross-sectional dimension, such as by applying a radially inward force to the sidewall portion thereof. Upon removal of the radially inward force, the support will expand to its expanded cross-sectional configuration due to the radial expansion provided by the arrangement of biasing elements **514** and interconnected axially extending features **512**.

In accordance with an aspect of the present invention, FIG. **17** illustrates an example of a heart valve prosthesis **540** that includes a valve **542** mounted within a support **500**, such as shown and described with respect to FIG. **16**. Identical reference numbers refer to parts previously identified with respect to the support **500** of FIG. **16**. The valve **542** has an inflow end **544** and an outflow end **546**, which are positioned on axially opposed sides of the intermediate cord **506**. In particular, the cord **506** and associated biasing elements **514** substantially circumscribe an annular base portion **548** of the valve **542** and help maintain it in a desired annular shape when the prosthesis **540** is in its expanded condition, as shown in FIG. **17**.

The valve **542** illustrated in FIG. **17** includes three leaflets that extend radially inwardly from a length of trimmed valve wall so as to coapt and provide for the unidirectional flow of blood through the prosthesis from the inflow end **544** to the outflow end **546**. The outflow end **546** has a generally sinusoidal contour, with peaks at the commissures between adjacent leaflets and sinuses between commissures extending an arc length commensurate with the arc length of the associated leaflet.

By way of illustration, when the prosthesis **540** is to be implanted at the pulmonary position, the valve **542** could be a treated porcine pulmonic valve and a porcine aortic valve when it is to be implanted at an aortic position. For example, the valve can be of the type shown and described in U.S. Pat. Nos. 5,935,163, 5861,028 or 5,855,602. Of course, other types and valve configurations also could be used in combination with the support **500** to form the prosthesis **540** in accordance with an aspect of the present invention.

The prosthesis **540** further includes an outer sheath **550** of a flexible biocompatible material, such as treated and detoxified animal pericardium, as described herein. The outer sheath **550** covers at least some of the exposed support **500**, such as the interior of the prosthesis and the ends **552** and **554**. The outer sheath **550** can be formed of one or more sheets of the biocompatible material, which are attached to the prosthesis **540** to reduce exposure of the support to blood when implanted in its expanded condition. The outer sheath **550** is sufficiently flexible and resilient so as to facilitate deforming the prosthesis **540** to a reduced cross-sectional dimension and its subsequent expansion to its expanded cross-sectional dimension, as shown in FIG. **17**.

The sidewall portion of the valve **542** is attached (e.g., by sutures) to the support **500**, such as to features and/or biasing elements, so that when the support expands, the valve also expands to its desired expanded configuration. Also, because the valve **542** has been fixed (e.g., in a suitable glutaraldehyde solution) to a desired shape and configuration, the valve maintains its desired shape and coaptation between leaflets when the prosthesis **540** is in its expanded condition.

Prior to implanting the **540**, such as by a direct implantation procedure through a blood vessel that provides a generally linear path to the desired implantation site, one or more sutures **554** can be attached to the proximal end **552** of the prosthesis. For example, the suture **554** is applied through loops that form generally diametrically opposed biasing elements **514** at the proximal end **552**. The sutures **554** can be used to adjust the relative position of the prosthesis **540** after positioned in the heart in its expanded condition. Additionally or alternatively, the prosthesis **540** could be adjusted to a desired position manually by a surgeon by applying external force to the prosthesis through the heart. Advantageously, the prosthesis **540** can be directly implanted without cardiopulmonary bypass, such as in the pulmonary position or with minimal bypass to the aortic position in accordance with an aspect of the present invention.

FIG. **18** illustrates another example of a heart valve prosthesis **570** in accordance with an aspect of the present invention. The prosthesis **570** is similar to that show and described with respect to FIG. **17**. Briefly stated, the prosthesis **570** includes first and second generally cylindrical portions **572** and **574** that are connected together end to end by an intermediate flexible connecting element **576** having a desired diameter, such as a loop of a cord (e.g., suture). The connecting element **576** limits the radial expansion of an intermediate portion of the prosthesis to predetermined diameter.

Each of the cylindrical portions **572** and **574** includes a plurality of generally axially extending support features **578**, such as thin rods, bands, or wire of a substantially resilient material. The features **578**, for example, are arranged as a plurality of interconnected triangles in which the features define elongated legs that extend between the intermediate connecting element **576** and additional connecting elements **580** and **582** located at the opposite ends **584** and **586** of the associated cylindrical portions **572** and **574**. The connecting element **582** at the inflow end of the valve also can have a greater diameter than the connecting element **580** at the outflow end. The features **578** in each cylindrical portion **572** and **574** are connected by biasing elements **588** that urge each adjacent pair of interconnected features circumferentially apart from each other. Because the features **578** are connected in a circumferential array, the collective forces of the biasing elements result in radially outward expansion of the prosthesis **570** up to a maximum dimension defined by the respective connecting elements **576**, **580** and **582**.

The prosthesis **570** further includes a heart valve **590** mounted within the support. The valve **590** has an inflow end **592** and an outflow end **594**, which are positioned on axially opposed sides of the intermediate cord **576**. In particular, the intermediate connecting element **576** and associated biasing elements **588** substantially circumscribe an annular base portion near the inflow end **592** of the valve **590**. Because the valve **590** is attached (e.g., by sutures) to the support formed of the cylindrical portions **572** and **574**, the radial outward forces provided by the support help maintain the base of valve in a desired annular shape when the prosthesis **570** is in its expanded condition shown in FIG. **18**. When the inflow end of the valve **590** is in its desired annular shape, the leaflets of the valve also are in desired orientation to provide desired coaptation between the leaflets, which facilitates the unidirectional flow of blood through the valve.

By way of example, when the prosthesis **570** is to be implanted at the pulmonary position, the valve **590** could be a treated porcine pulmonic valve. A porcine aortic valve can be used for the aortic position. Those skilled in the art will understand and appreciate other types and valve configurations also could be used in the prosthesis **570** in accordance with an aspect of the present invention.

The prosthesis **570** further includes an arrangement of members **598** and **600** that extend axially and radially outwardly from the respective ends **584** and **586** of the prosthesis **570**. The members **598** and **600** are operative to help secure the prosthesis **570** to surrounding tissue when it is implanted. The members **598** and **600** include a plurality of triangular projections **602** that extend axially and radially outwardly from the ends. While six substantially symmetrical projections are shown at each end, those skilled in the art will understand and appreciate that any number could be used (e.g., 4, 6, 9, 12, 18, etc.).

Each triangular projection **602** includes a pair of legs **604** that are connected together by an interconnecting biasing element **606**. The biasing elements form apices of the triangular projection **602** spaced from the respective ends **584**, **586**. Adjacent triangular projections **602** also are coupled together and to respective ends **584** and **586** by additional biasing elements **608** located at the ends of the prosthesis **570**. The biasing elements **588**, **606**, and **608** bias the support portion of the prosthesis **570** and valve **590** attached thereto in a radially outward direction toward its fully expanded condition. Additionally, the triangular projections **602** can further engage surrounding tissue when the prosthesis is implanted to help hold the prosthesis at a desired position relative to the surrounding tissue.

The prosthesis **570** also can include an outer sheath **610** of biocompatible material (e.g., animal pericardium) that covers most (or all) of the support structure that would be exposed to blood when implanted. The covering further could be an expansion of the valve wall the contains the leaflets of the heart valve **590**. In this example, the outer sheath **610** covers the support between the ends **584** and **586** of the cylindrical portions **572** and **574** and the support features **578** in the interior of the prosthesis **570**. The triangular projections **602** are left uncovered, which may facilitate their insertion and integration into surrounding tissue. It is to be understood and appreciated, however, that the projections **602** also could be covered with biocompatible material, similar to the example of FIGS. **14** and **15**.

The prosthesis **570** is well suited for direct implantation without cardiopulmonary bypass, such as in the pulmonary position, or direct implantation with minimal bypass to the aortic position in accordance with an aspect of the present invention. Direct implantation with the prosthesis also can be sutureless, although one or more sutures can be applied to further fix the prosthesis at a desired position.

In view of the various arrangements of heart valve prostheses described herein, a simplified and efficient method of using such prosthesis is described below with respect to FIGS. **19-22**. The prosthesis can be directly implanted into the patient's heart in an efficient and low-invasive procedure, which also can be sutureless. While the particular example utilizes a heart valve prosthesis similar to that shown and described in FIG. **18**, it is to be understood and appreciated that any of the prosthesis (see, e.g., FIGS. **1-18**) described herein, could be implanted in a similar manner.

FIGS. **19** and **20** illustrates an implanter apparatus **700** for implanting a heart valve prosthesis **702** in accordance with an aspect of the present invention, such as to facilitate sutureless implantation under direct vision of the surgeon. The implanter **700** includes an elongated cylindrical barrel **704** that extends from a body portion **706** and terminates in an open end **708**. The barrel **704** has an inner diameter that is less than the outer diameter of the heart valve prosthesis **702** in its expanded condition. Thus, in order to insert the prosthesis **702** into the barrel **704**, the prosthesis must be deformed to a reduced cross-sectional dimension, such as at about one-half or less of its fully expanded condition, as shown in the enlarged view of FIG. **20**.

For example, the inner diameter of the barrel **704** can range from about 5 mm to about 15 mm, whereas the outer diameter of the heart valve prosthesis **702** (in its expanded condition) typically ranges from about 15 mm to about 35 mm. Thus, the barrel can accommodate a prosthesis **702**, which has been deformed to reduced cross-sectional dimension, without compromising the durability and operation of the valve. The exterior of the barrel further can include indicia (e.g., ruler markings) **710** that can help indicate the distance the barrel is inserted into a patient.

The implanter **700** also includes a handle **712** that extends outwardly from a proximal end **714** of the body portion **706**. The handle **712**, which may be gripped by a surgeon, facilitates manipulating the barrel **704** along a desired path. A plunger **716** has a distal end **718** that can be urged into engagement with the prosthesis **702** to push the prosthesis from the opening **708** of the barrel **704**. The plunger **716** includes an elongated portion that extends from its distal end **718** and terminates in a proximal end portion **718**. The proximal end portion **718** operates as a trigger that can be grasped by a surgeon to move the plunger through the barrel **704**. Other means to discharge the heart valve also could be utilized in accordance with an aspect of the present invention. Fluid, such as saline, also can be introduced into the barrel **704**, such as through an opening (not shown) in the plunger **716**, to facilitate the discharge of the prosthesis **702** from the barrel.

In the examples of FIGS. **19** and **20**, the heart valve prosthesis **702** is positioned within the barrel **704** with its inflow end **720** adjacent to the outflow end, such as for implanting the valve in a pulmonary position. Those skilled in the art will understand and appreciate that the outflow end **722** of the valve **702** alternatively could be positioned adjacent the opening **708** of the barrel. The particular orientation of the valve **702** within the barrel **704** will depend on where the valve is being implanted and the direction from which the implanter **700** is being inserted relative to the implant site. In accordance with a particular aspect of the present invention, the implanter **700** and heart valve prosthesis **702** is particularly useful for an open chest procedure in which the prosthesis is introduced into the heart under substantially direct vision of the surgeon.

For example, the implanter **700** could be introduced into a blood vessel (e.g., the pulmonary artery) that provides a substantially direct and linear path to the desired implantation position. Further, the procedure can be implemented without cardiopulmonary bypass, such as when the prosthesis is implanted through the pulmonary artery. Alternatively, cardiopulmonary bypass can be used, but for a generally short period of time, such as when the prosthesis is implanted at the aortic position. Bypass generally is required when implanting at the aortic position due to the relatively high blood pressure as well as to facilitate decalcification of the patient's existing heart valve, as needed.

The implanter **700** further can include an aperture **724** (or interconnected apertures) that extend longitudinally through the plunger **716** and the end **718**. The aperture **724** provides a passage through which one or more sutures **726** connected to a proximal end **728** of the prosthesis **702** can extend. For example, prior to loading the prosthesis **702** into the barrel **704**, the suture **726** can be applied to the end **728** of the prosthesis, such as through generally diametrically opposed biasing elements (e.g., coil springs) at the respective end. Part of the suture **726** extends between the opposed sides of the prosthesis **702**. The remaining lengths of the suture **726**, which extends from one or both sides of the prosthesis, can be fed through the barrel and aperture **724** to a location external to the implanter **700**, such as shown in FIG. **19**. The suture **726** should have a sufficient length to extend through the implanter **700**, as shown. After the prosthesis **702** has been discharged from the implanter, the suture **726** then can be grasped by a surgeon to adjust the position of the prosthesis.

FIG. **21** illustrates an intermediate part of an implantation procedure in accordance with an aspect of the present invention. In this example, cardiopulmonary bypass is not required, as blood loss is mitigated through application of a purse string suture. For example, after the patient's chest is opened, a purse string suture **730** is applied to the pulmonary artery or other vessel **732** through which a barrel **734** of an implanter **736** is to be inserted. A small incision or puncture is made at the center of the purse string **730**, which should approximate or be slightly smaller than the outer diameter of the barrel. Alternatively, the incision could be made prior to application of the purse string to the vessel wall.

The surgeon can then insert the barrel **734** through the opening in the vessel wall **732**. Two lengths **738** of the purse string **730** suture extend from the vessel **732** through an elongated cylindrical guide **740** of a generally rigid material, such as rubber, plastic, or metal material. One end **742** of the cylinder **740** engages the vessel wall **732** and/or the barrel **734**, and the two lengths **738** of suture extend through the other end **744**. By fixing the length of suture relative to the cylinder **740**, such as by clamping the sutures to the cylinder by a clamp **745**, the vessel wall surrounding the barrel **734** can be kept relatively tight around the barrel so as to mitigate blood loss through the incision. As a result, cardiopulmonary bypass is not required. However, it is to be understood that in certain situations, such as when implanting the prosthesis at the aortic position, some bypass may be necessary, although usually for a much shorter period of time than with conventional procedures.

After the distal end **746** of the barrel **734** has been inserted a desired length into the vessel **732**, such as indicated by indicia printed on the barrel, the heart valve prosthesis **748** located in the barrel can be discharged. For example, a plunger **750** positioned for axial movement relative to the barrel **734** can be moved toward the distal end **746** of the barrel and into engagement with the prosthesis **748**. The heart valve prosthesis **748** is configured to expand toward its fully expanded condition when it is discharged from the barrel **734** because radial inward forces that maintain the prosthesis at a reduced cross-sectional dimension are removed. In particular, the prosthesis **748** includes a self-expanding support **752** in which an associated heart valve **754** is mounted. In the example of FIG. **21**, the support **752** and valve **754** are configured as shown and described in FIG. **18**. That is, the support **752** includes a cage-like frame of axially extending resilient support features **756** interconnected by biasing elements **758** that urge the support in a radially outward direction. Generally triangular projections **760**, which also are biased radially outwardly, further extend from the ends of the support **752**. The triangular projections **760** operate to engage the surrounding valve wall (or other surrounding tissue) when the support expands so as to anchor the prosthesis **748** relative to the valve wall. As the prosthesis **748** is being discharged, the implanter barrel **734** can be concurrently withdrawn from the vessel to help ensure that the prosthesis is positioned at the desired position.

One or more sutures **762** can be attached to a proximal end **764** of the prosthesis **748** so as to pass through an aperture **766** that extends through at least a substantial portion of the implanter **736**. For example, the suture **762** can be applied through the centers of generally opposed circular biasing elements located at the proximal end **764**. After the prosthesis **748** is discharged into the patient's heart, a surgeon can grasp the sutures to adjust the position of the prosthesis, such as by urging both ends of the suture in the direction **768**, shown in FIG. **21**. Additionally or alternatively, the relative position of the discharged prosthesis **748** can be adjusted through the heart or blood vessel manually or by employing other tools. Once the prosthesis **748** is at a desired position, one end of the suture can be pulled so as to remove the suture from the prosthesis. The adjustments can be performed with part of the implanter **736** still within the blood vessel **732** or after the implanter has been removed from the vessel.

FIG. **22** illustrates the heart valve prosthesis **748** mounted at a pulmonary position after the implanter **736** has been removed from the pulmonary artery **732** through which the prosthesis **748** was implanted in accordance with an aspect of the present invention. After the barrel **734** of the implanter **736** has been withdrawn from the pulmonary artery **732**, the purse string **730** facilitates closure of the incision. For example, the guide **740** (FIG. **21**) can be held against the pulmonary artery **732** while concurrently pulling additional length of the suture **738** through the cylinder **740** and then tying off the purse string at the pulmonary artery. Additional sutures can be applied to the incision site to ensure proper closure. With the projections **760** engaging surrounding tissue and the outward force of the support **752**, the prosthesis **748** should be adequately anchored at the desired position. Although, to help ensure that the prosthesis remains at the desired position, one or more sutures also can be applied to the prosthesis, such as directly through the heart muscle itself. The support **752** further helps maintain desired coaptation between the leaflets by urging the inflow end of the valve toward a desired annular shape.

In view of the foregoing example, those skilled in the art will understand and appreciated that the prosthesis **748** can be implanted without opening the heart and without cardiopulmonary bypass. When the patient's existing valve needs to be removed and or calcium deposits cleaned, such cleaning can be performed through the pulmonary artery or other connecting vessels prior to implanting the prosthesis **748**, such as through a trocar and/or by endoscopic means.

What has been described above includes examples of the present invention. It is, of course, not possible to describe every conceivable combination of components or methodologies for purposes of describing the present invention, but one of ordinary skill in the art will recognize that many further combinations and permutations of the present invention are possible. Accordingly, the present invention is intended to embrace all such alterations, modifications and variations that fall within the spirit and scope of the appended claims. Furthermore, to the extent that the term "includes" and variants thereof or the term "having" and variants thereof are used in either the detailed description or the claims, each such term is intended to be inclusive in a manner similar to the term "comprising."

What is claimed is:

1. An implantation system, comprising:

an elongated cylindrical member having spaced apart ends, at least one of the ends providing an opening;

a body portion from which the cylindrical member extends to terminate in the opening that is spaced longitudinally apart from the body portion, the body portion having a greater outer diameter than the cylindrical member, the cylindrical member having an inner diameter in a range from about 5 mm to about 15 mm, the cylindrical member and body portion being substantially coaxial along a linear axis extending through the cylindrical member and the body portion;

a heart valve prosthesis including a generally cylindrical support having axially spaced apart ends, a valve mounted within the support at a fixed axial position between the spaced apart ends of the support, the prosthesis being deformable to a first condition in which the prosthesis has a reduced cross-sectional dimension, the support being biased to expand the prosthesis radially outwardly from the first condition to a second condition in which the prosthesis has a cross-sectional dimension that is greater than the reduced cross-sectional dimension, the prosthesis being mounted within the cylindrical member in the first condition; and

a plunger operative to traverse at least part of the cylindrical member and urge the prosthesis from the cylindrical member through the opening.

2. The system of claim **1**, the support being formed of a shape memory alloy operative to urge the prosthesis to the second condition.

3. The system of claim **1**, the support further comprising a plurality of elongated support features that extend generally axially between ends of the support, biasing elements interconnecting adjacent support features in a circumscribing relationship around the valve, the biasing elements urging the interconnected adjacent support features apart from each other, so as to urge the prosthesis toward the second condition.

4. The system of claim **3**, further comprising at least one connecting element operative to hold the biasing elements in a generally circular array and to limit the radial outward expansion of the prosthesis at the location of the circular array.

5. The system of claim **3**, further comprising a plurality of resilient projections that extend radially outwardly from the axially opposed ends of the support.

6. The system of claim **5**, the projections further comprising a set of triangular projections attached to each of the opposed ends of the support by biasing elements that bias the triangular projections to extend axially and radially outwardly from each of the respective opposed ends of the support.

7. The system of claim **3**, the support features and the biasing elements being formed of a continuous length of a substantially resilient and elastic material that facilitates expansion of the prosthesis from the first condition to the second condition.

8. The system of claim **1**, further comprising an outer sheath of a substantially biocompatible material that covers exposed parts of the support.

9. The system of claim **1** wherein the valve further comprises a pulmonic animal heart valve having leaflets located within a valve wall to permit substantially unidirectional flow of blood through the valve, the support engaging an outer surface of the valve wall.

10. The system of claim **1**, further comprising indicia along an exterior portion of the cylindrical member to facilitate implantation of the heart valve prosthesis.

11. The system of claim **1**, wherein the valve comprises a natural tissue heart valve mounted within the support.

12. An implantation system, comprising:

an implanter comprising:

an elongated cylindrical member having spaced apart ends and a lumen extending through the cylindrical member, at least one of the ends providing an opening into the lumen;

a body portion having a greater outer diameter than the cylindrical member, the cylindrical member extending from the body portion to terminate in the opening spaced longitudinally apart from the body portion, the cylindrical member and body portion being substantially coaxial along a linear axis that extends through the implanter;

a plunger operative to traverse at least part of the lumen along the linear axis; and a heart valve prosthesis comprising:

a generally cylindrical support having axially spaced apart ends, and

a valve mounted within the support, the prosthesis being deformable to a first condition in which the prosthesis has a reduced cross-sectional dimension and being expandable from the first condition to a second condition in which the prosthesis has a cross-sectional dimension that is greater than the reduced cross-sectional dimension, the prosthesis being mounted within the cylindrical member in the first condition, such that the plunger is operative to traverse at least part of the cylindrical member and urge the prosthesis from the cylindrical member through the opening.

13. The implantation system of claim **12**, the cylindrical member of the implanter having an inner diameter in a range from about 5 mm to about 15 mm, and the body portion having a diameter that is greater than tat of the cylindrical enclosure.

14. The implantation system of claim **13**, wherein the support of the prosthesis further comprises axially extending support features interconnected by biasing elements that bias the support to expand radially outwardly from the first condition to the second condition.

15. The implantation system of claim **14**, the biasing elements further comprising springs arranged in a generally

circular array at the opposed ends of the support, the springs interconnecting adjacent support features to bias the support radially outwardly.

16. The implantation system of claim **13**, the prosthesis further comprising projections biased to extend radially outwardly from the support.

17. The implantation system of claim **12**, the implanter further comprising a handle portion attached to and extending radially outwardly from the body portion at a position that is spaced axially from an end of the body portion from which the cylindrical member enclosure extends.

18. The implantation system of claim **12**, wherein the valve comprises a natural tissue heart valve mounted within the support.

19. The implantation system of claim **12**, the prosthesis further comprising a flexible connecting element attached to the support to inhibit radial outward expansion of at least part of the support beyond a predetermined amount.

20. The implantation system of claim **19**, the prosthesis further comprising a loop of a flexible material connected to the support at each of the axially spaced apart ends to inhibit radial outward expansion of the support at the opposed ends beyond a predetermined amount.

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