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(54) **STENTS FOR PROSTHETIC HEART VALVES**

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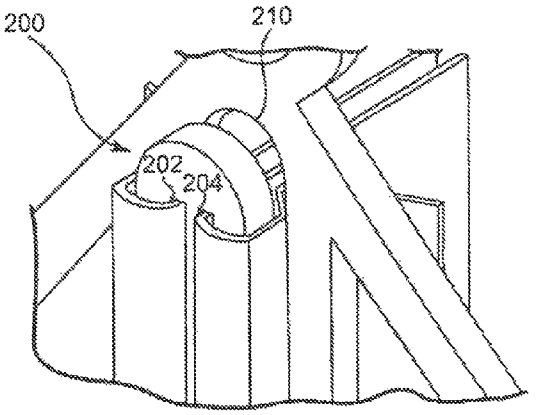
(57) **ABSTRACT**

A stented valve including a stent structure including a generally tubular body portion having a first end, a second end, an interior area, a longitudinal axis, and a plurality of vertical wires extending generally parallel to the longitudinal axis around a periphery of the body portion, wherein the plurality of vertical wires includes multiple commissure wires and at least one structural wire positioned between adjacent commissure wires, and a plurality of V-shaped wire structures having a first end, a second end, and a peak between the first and second ends, wherein a first end of each V-shaped structure extends from a first vertical wire and a second end of each V-shaped structure extends from a second vertical wire that is adjacent to the first vertical wire, wherein each V-shaped structure is oriented so that its peak is facing in the same direction relative to the first and second ends of the body portion, and a valve structure including a plurality of leaflets attached to the stent structure within the tubular body portion.

8 Claims, 9 Drawing Sheets



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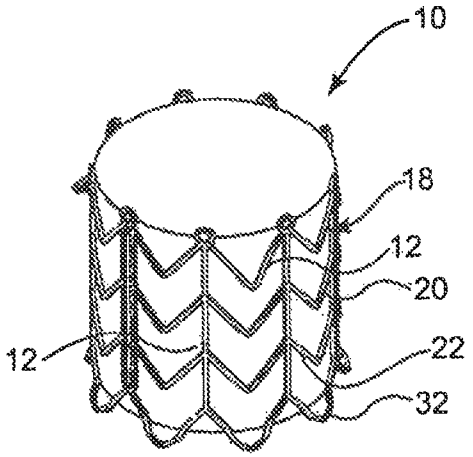

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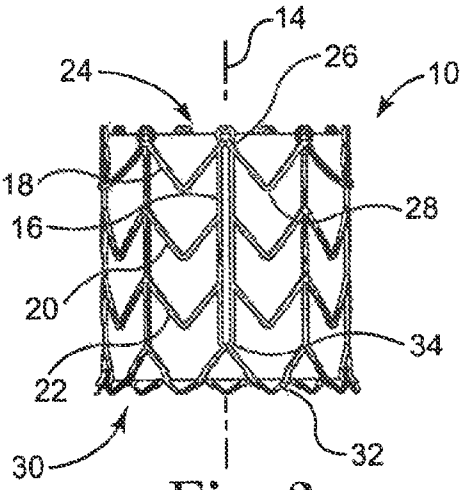

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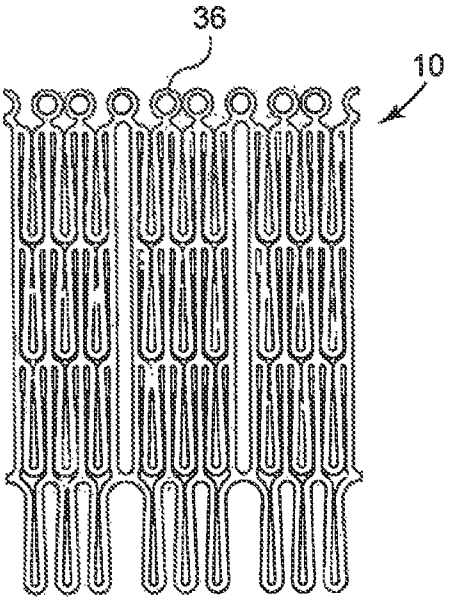

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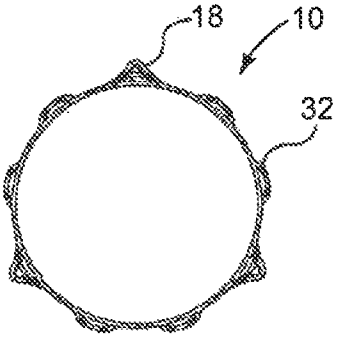

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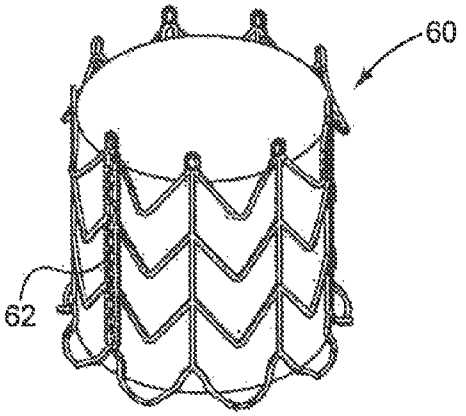

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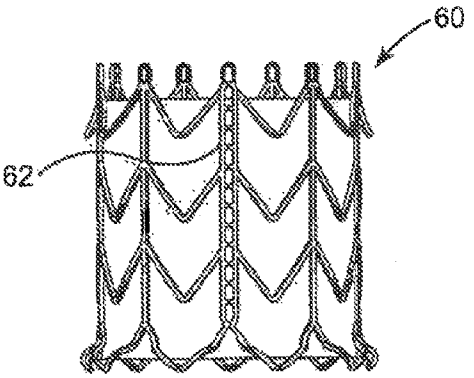

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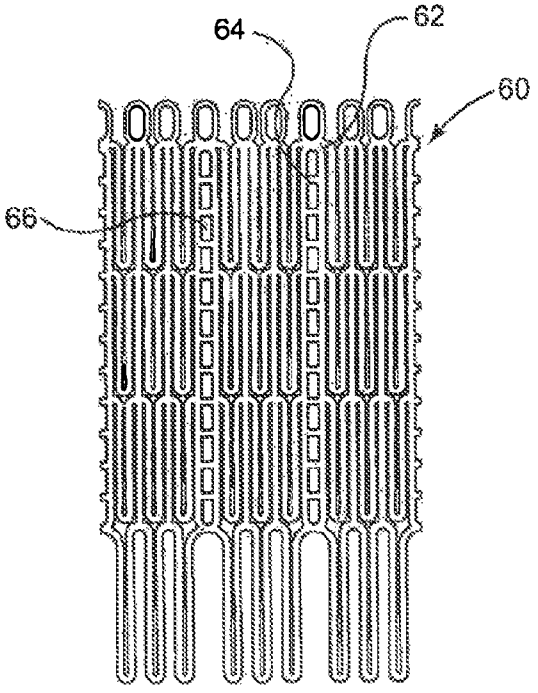

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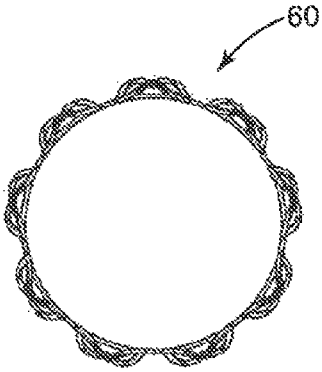

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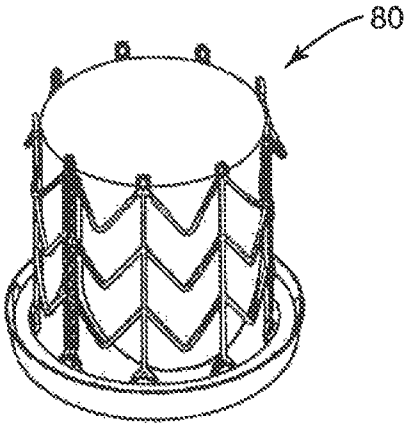

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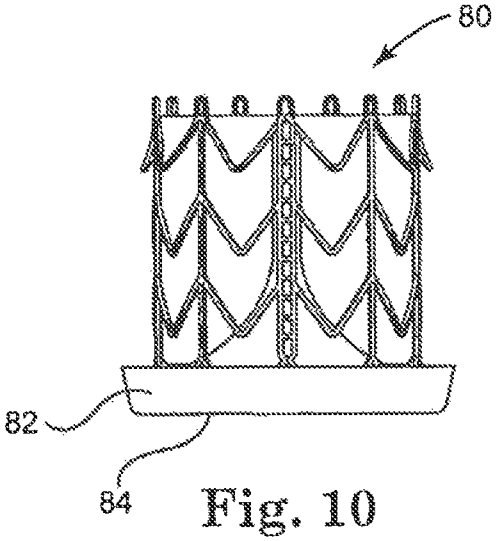

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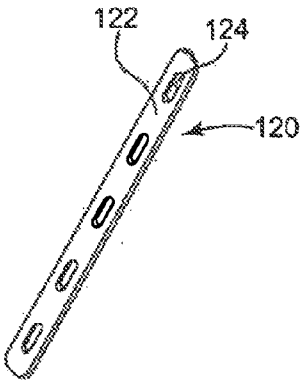

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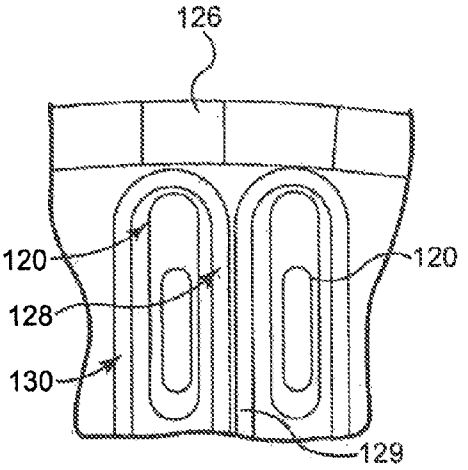

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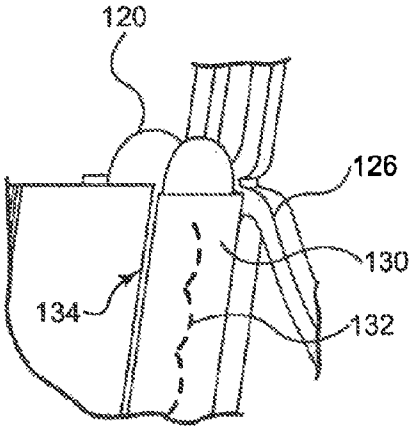

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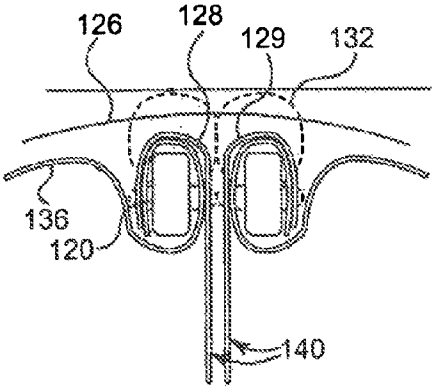

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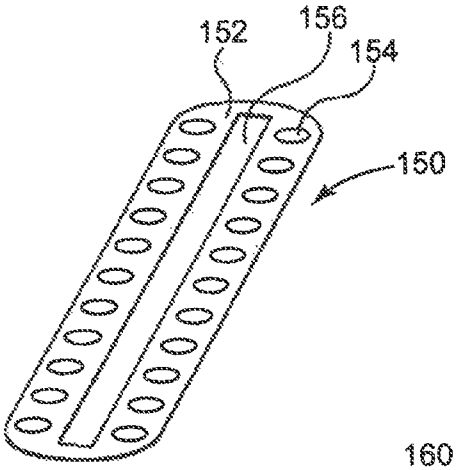

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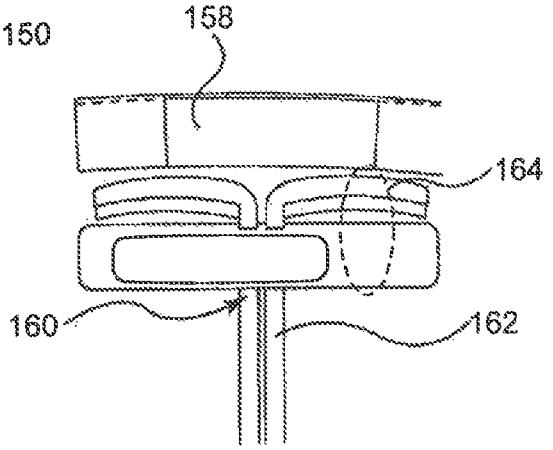

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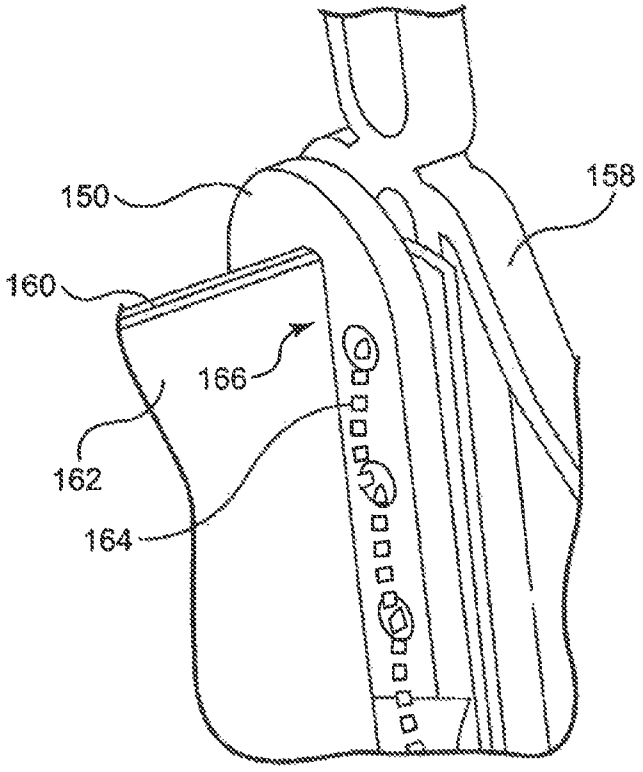

Fig. 17

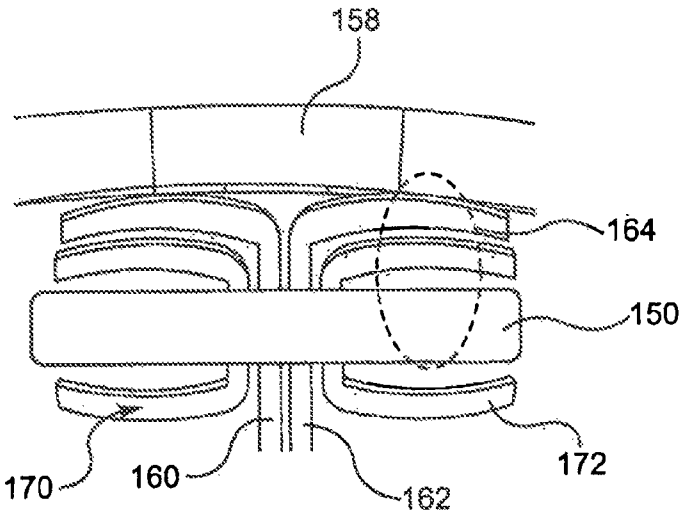

Fig. 18

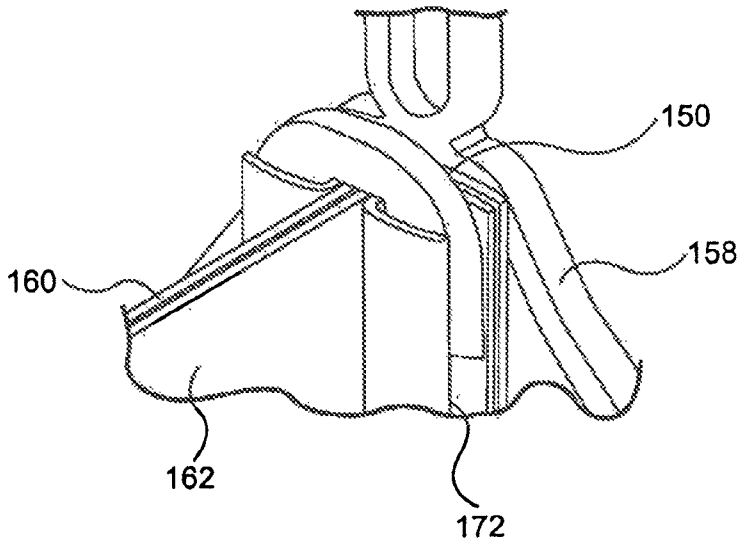

Fig. 19

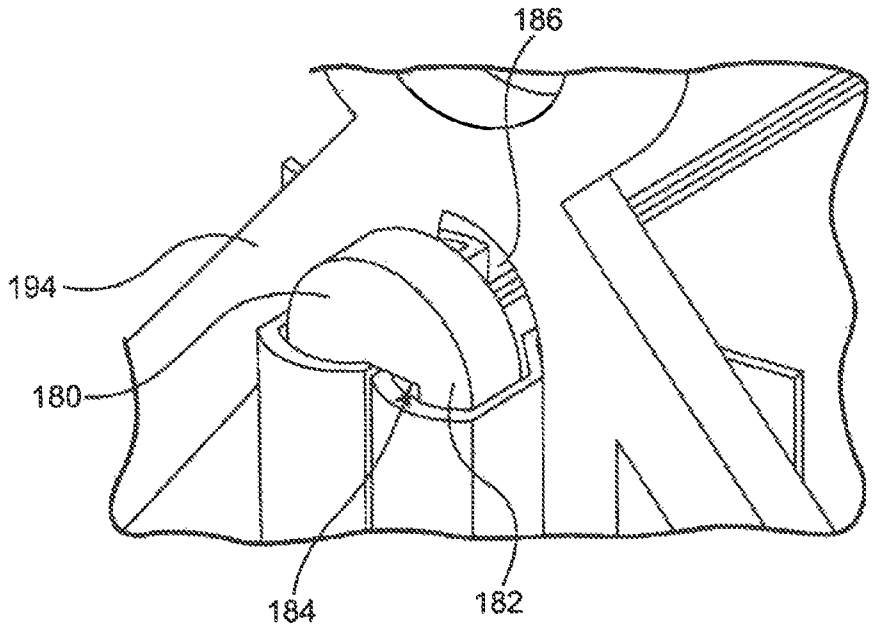

Fig. 20

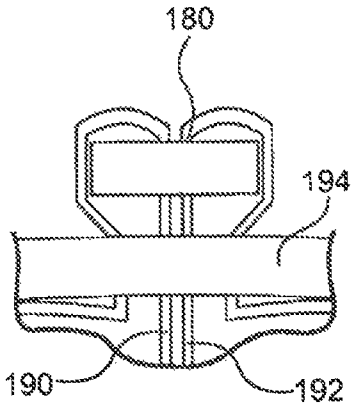

Fig. 21

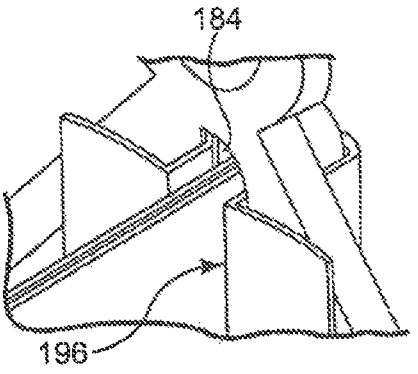

Fig. 22

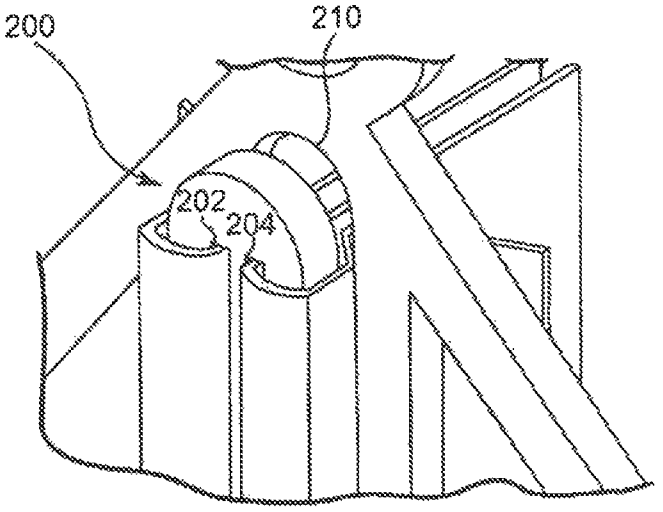

Fig. 23

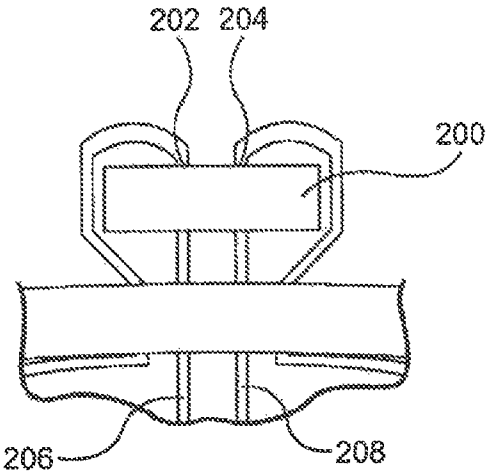

Fig. 24

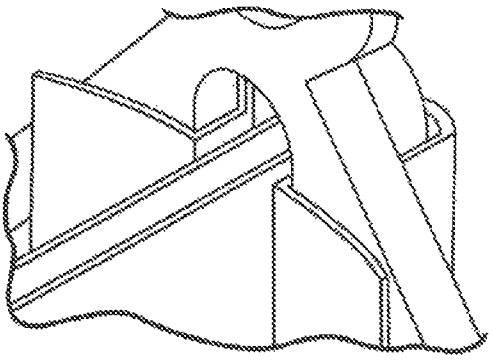

Fig. 25

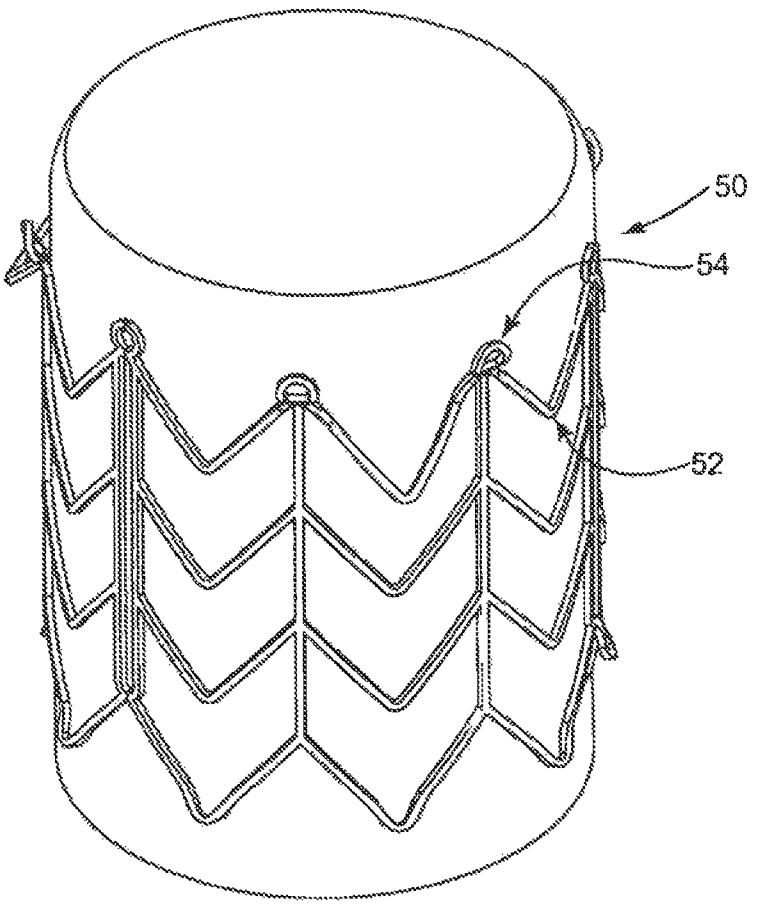

Fig. 26

STENTS FOR PROSTHETIC HEART VALVES

CROSS-REFERENCE TO RELATED APPLICATION

The present application claims priority to U.S. application Ser. No. 12/358,980, filed Jan. 23, 2009, and titled "Stents For Prosthetic Heart Valves", which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Application No. 61/062,207, filed Jan. 24, 2008, and titled "Delivery Systems and Methods of Implantation for Prosthetic Heart Valves", which are incorporated by reference in their entirety.

TECHNICAL FIELD

The present invention relates to prosthetic heart valves. More particularly, it relates to devices, methods, and delivery systems for percutaneously implanting prosthetic heart valves.

BACKGROUND

Diseased or otherwise deficient heart valves can be repaired or replaced using a variety of different types of heart valve surgeries. Typical heart valve surgeries involve an open-heart surgical procedure that is conducted under general anesthesia, during which the heart is stopped while blood flow is controlled by a heart-lung bypass machine. This type of valve surgery is highly invasive and exposes the patient to a number of potentially serious risks, such as infection, stroke, renal failure, and adverse effects associated with use of the heart-lung machine, for example.

Recently, there has been increasing interest in minimally invasive and percutaneous replacement of cardiac valves. Such surgical techniques involve making a very small opening in the skin of the patient into which a valve assembly is inserted in the body and delivered to the heart via a delivery device similar to a catheter. This technique is often preferable to more invasive forms of surgery, such as the open-heart surgical procedure described above. In the context of pulmonary valve replacement, U.S. Patent Application Publication Nos. 2003/0199971 A1 and 2003/0199963 A1, both filed by Tower, et al., describe a valved segment of bovine jugular vein, mounted within an expandable stent, for use as a replacement pulmonary valve. The replacement valve is mounted on a balloon catheter and delivered percutaneously via the vascular system to the location of the failed pulmonary valve and expanded by the balloon to compress the valve leaflets against the right ventricular outflow tract, anchoring and sealing the replacement valve. As described in the articles: "Percutaneous Insertion of the Pulmonary Valve", Bonhoeffer, et al., Journal of the American College of Cardiology 2002; 39: 1664-1669 and "Transcatheter Replacement of a Bovine Valve in Pulmonary Position", Bonhoeffer, et al., Circulation 2000; 102: 813-816, the replacement pulmonary valve may be implanted to replace native pulmonary valves or prosthetic pulmonary valves located in valved conduits.

Various types and configurations of prosthetic heart valves are used in percutaneous valve procedures to replace diseased natural human heart valves. The actual shape and configuration of any particular prosthetic heart valve is dependent to some extent upon the valve being replaced (i.e., mitral valve, tricuspid valve, aortic valve, or pulmonary valve). In general, the prosthetic heart valve designs attempt to replicate the function of the valve being replaced and thus will include valve leaflet-like structures used with either bioprostheses or mechanical heart valve prostheses. In other words, the

replacement valves may include a valved vein segment that is mounted in some manner within an expandable stent to make a stented valve. In order to prepare such a valve for percutaneous implantation, the stented valve can be initially provided in an expanded or uncrimped condition, then crimped or compressed around the balloon portion of a catheter until it is as close to the diameter of the catheter as possible.

Other percutaneously-delivered prosthetic heart valves have been suggested having a generally similar configuration, such as by Bonhoeffer, P. et al., "Transcatheter Implantation of a Bovine Valve in Pulmonary Position." Circulation, 2002; 102:813-816, and by Cribier, A. et al. "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis." Circulation, 2002; 106:3006-3008, the disclosures of which are incorporated herein by reference. These techniques rely at least partially upon a frictional type of engagement between the expanded support structure and the native tissue to maintain a position of the delivered prosthesis, although the stents can also become at least partially embedded in the surrounding tissue in response to the radial force provided by the stent and balloons that are sometimes used to expand the stent. Thus, with these transcatheter techniques, conventional sewing of the prosthetic heart valve to the patient's native tissue is not necessary. Similarly, in an article by Bonhoeffer, P. et al. titled "Percutaneous Insertion of the Pulmonary Valve." J Am Coll Cardiol, 2002; 39:1664-1669, the disclosure of which is incorporated herein by reference, percutaneous delivery of a biological valve is described. The valve is sutured to an expandable stent within a previously implanted valved or non-valved conduit, or a previously implanted valve. Again, radial expansion of the secondary valve stent is used for placing and maintaining the replacement valve.

Although there have been advances in percutaneous valve replacement techniques and devices, there is a continued desire to provide different designs of cardiac valves that can be implanted in a minimally invasive and percutaneous manner.

SUMMARY

The replacement heart valves of the invention each include a stent to which a valve structure is attached. The stents of the invention include a wide variety of structures and features that can be used alone or in combination with features of other stents of the invention. In particular, these stents provide a number of different docking and/or anchoring structures that are conducive to percutaneous delivery thereof. Many of the structures are thus compressible to a relatively small diameter for percutaneous delivery to the heart of the patient, and then are expandable either via removal of external compressive forces (e.g., self-expanding stents), or through application of an outward radial force (e.g., balloon expandable stents). The devices delivered by the delivery systems described herein can be used to deliver stents, valved stents, or other interventional devices such as ASD (atrial septal defect) closure devices, VSD (ventricular septal defect) closure devices, or PFO (patent foramen ovale) occluders.

Methods for insertion of the replacement heart valves of the invention include delivery systems that can maintain the stent structures in their compressed state during their insertion and allow or cause the stent structures to expand once they are in their desired location. In addition, delivery methods of the invention can include features that allow the stents to be retrieved for removal or relocation thereof after they have been deployed or partially deployed from the stent delivery systems. The methods may include implantation of the

stent structures using either an antegrade or retrograde approach. Further, in many of the delivery approaches of the invention, the stent structure is rotatable in vivo to allow the stent structure to be positioned in a desired orientation.

One embodiment of a stent of the invention comprises a tubular wire structure including multiple longitudinal wires that extend generally parallel to the longitudinal axis of the stent. The wires are spaced from each other around the periphery of the stent. The stent further includes tissue attachment features, such as commissure attachment posts. In one embodiment, the stent includes three commissure attachment posts, where each of the posts is used as a connection location for one of the commissures of a tri-leaflet valve that will be attached thereto. Alternatively, more or less than three posts can be provided for a valve having more or less than three leaflets, respectively. The stent further includes multiple V-shaped wire structures between a pair of wires and/or between a wire and an adjacent attachment post. In one embodiment, the stent includes three V-shaped wires that are longitudinally spaced from each other along the height of the stent between each adjacent pair of wires or between a wire and an adjacent post. There may alternatively be more or less than three V-shaped wires spaced longitudinally from each other.

A first end of each V-shaped wire extends from a first end of an attachment post or wire, and a second end of wire extends from the first end of an adjacent wire or attachment post. In this way, a peak of each V-shaped wire will be positioned generally in the center of the space between adjacent longitudinal wires, and will be directed toward a second or inlet end of the stent. All or some of the wires can be flared at least slightly outward relative to the outer tubular shape of the stent, thereby creating integrated flange structures that can be used to capture the native leaflets when the stent is implanted in a patient. Each wire is spaced longitudinally from a corresponding wire, and each wire is spaced longitudinally from a corresponding wire.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be further explained with reference to the appended Figures, wherein like structure is referred to by like numerals throughout the several views, and wherein:

FIG. **1** is a perspective view of an embodiment of a stent in accordance with the invention;

FIG. **2** is a front view of the stent of FIG. **1**;

FIG. **3** is a top view of the stent of FIG. **1**;

FIG. **4** is a top view of a cutting pattern for the stent of FIG. **1**;

FIG. **5** is a perspective view of an embodiment of a stent in accordance with the invention;

FIG. **6** is a front view of the stent of FIG. **5**;

FIG. **7** is a top view of the stent of FIG. **5**;

FIG. **8** is a top view a cutting pattern for the stent of FIG. **5**;

FIG. **9** is a perspective view of an embodiment of a stent in accordance with the invention;

FIG. **10** is a front view of the stent of FIG. **9**;

FIG. **11** is a perspective view of a "ladder" mechanism used for attachment of tissue to a stent;

FIG. **12** is a top view of two ladder mechanisms of FIG. **11** positioned relative to leaflets and a stent;

FIG. **13** is a perspective view of the ladder mechanisms, tissue, and portion of a stent illustrated in FIG. **12**;

FIG. **14** is a top schematic view of the stent arrangement of FIGS. **12** and **13**;

FIG. **15** is a perspective view of a "slot bar" mechanism used for attachment of tissue to a stent;

FIG. **16** is a top view of a slot bar mechanism of FIG. **15** positioned relative to leaflets and a stent;

FIG. **17** is perspective view of the slot bar mechanism, tissue, and portion of a stent illustrated in FIG. **16**;

FIG. **18** is a top view of a "padded slot bar" mechanism positioned relative to leaflets and a stent;

FIG. **19** is a perspective view of the padded slot bar mechanism, tissue, and portion of a stent illustrated in FIG. **18**;

FIG. **20** is a perspective view of a "buckle" mechanism positioned relative to leaflets and a stent;

FIG. **21** is a top view of the portion of a stent, leaflets, and buckle mechanism illustrated in FIG. **20**;

FIG. **22** is another perspective view of the portion of a stent illustrated in FIG. **20**;

FIG. **23** is a perspective view of a "padded buckle" mechanism positioned relative to leaflets and a stent;

FIG. **24** is a top view of the portion of a stent, leaflets, and padded buckle mechanism illustrated in FIG. **23**;

FIG. **25** is another perspective view of the portion of a stent illustrated in FIG. **23**; and

FIG. **26** is a perspective view of another stent embodiment of the invention.

DETAILED DESCRIPTION

As referred to herein, the prosthetic heart valves used in accordance with the various devices and methods of heart valve delivery may include a wide variety of different configurations, such as a prosthetic heart valve having tissue leaflets or a synthetic heart valve having polymeric, metallic, or tissue-engineered leaflets, and can be specifically configured for replacing any heart valve. That is, while much of the description herein refers to replacement of aortic valves, the prosthetic heart valves of the invention can also generally be used for replacement of native mitral, pulmonic, or tricuspid valves, for use as a venous valve, or to replace a failed bioprosthesis, such as in the area of an aortic valve or mitral Valve, for example.

Although each of the valves used with the delivery devices and methods described herein would typically include leaflets attached within an interior area of a stent, the leaflets are not shown in many of the illustrated embodiments for clarity purposes. In general, the stents described herein include a support structure comprising a number of strut or wire portions arranged relative to each other to provide a desired compressibility, strength, and leaflet attachment zone(s) to the heart valve. Other details on particular configurations of the stents of the invention are also described below; however, in general terms, stents of the invention are generally tubular support structures, and leaflets will be secured within the inner portion of the support structure to provide a valved stent. The leaflets can be formed from a variety of materials, such as autologous tissue, xenograph material, or synthetics as are known in the art. The leaflets may be provided as a homogenous, biological valve structure, such as a porcine, bovine, or equine valve. Alternatively, the leaflets can be provided independent of one another (e.g., bovine or equine pericardial leaflets) and subsequently assembled to the support structure of the stent. In another alternative, the stent and leaflets can be fabricated at the same time, such as May be accomplished using high strength nano-manufactured NiTi films of the type produced at Advanced Bio Prosthetic Surfaces Ltd. (ABPS) of San Antonio, Tex., for example. The support structures are generally configured to accommodate

three leaflets; however, the replacement prosthetic heart valves of the invention can be configured to incorporate more or less than three leaflets.

In more general terms, the combination of a support structure with one or more leaflets can assume a variety of other configurations that differ from those shown and described, including any known prosthetic heart valve design. In certain embodiments of the invention, the support structure with leaflets utilize certain features of known expandable prosthetic heart valve configuration, whether balloon expandable, self-expanding, or unfurling (as described, for example, in U.S. Pat. Nos. 3,671,979; 4,056,854; 4,994,077; 5,332,402; 5,370,685; 5,397,351; 5,554,185; 5,855,601; and 6,168,614; U.S. Patent Application Publication No. 2004/0034411; Bonhoeffer P., et al., "Percutaneous Insertion of the Pulmonary Valve", Pediatric Cardiology, 2002; 39:1664-1669; Anderson H R, et al., "Transluminal Implantation of Artificial Heart Valves", EUR. Heart J., 1992; 13:704-708; Anderson, J. R., et al., "Transluminal Catheter Implantation of New Expandable Artificial Cardiac Valve", BUR Heart J., 1990, 11: (Suppl) 224a; Hilbert S. L., "Evaluation of Explanted Polyurethane Trileaflet Cardiac Valve Prosthesis", J Thorac Cardiovascular Surgery, 1989; 94:419-29; Block P C, "Clinical and Hemodynamic Follow-Up After Percutaneous Aortic Valvuloplasty in the Elderly", The American Journal of Cardiology, Vol. 62, Oct. 1, 1998; Boudjemline, Y., "Steps Toward Percutaneous Aortic Valve Replacement", Circulation, 2002; 105:775-558; Bonhoeffer, P., "Transcatheter Implantation of a Bovine Valve in Pulmonary Position, a Lamb Study", Circulation, 2000: 102:813-816; Boudjemline, Y., "Percutaneous Implantation of a Valve in the Descending Aorta In Lambs", EUR Heart J, 2002; 23:1045-1049; Kulkinski, D., "Future Horizons in Surgical Aortic Valve Replacement: Lessons Learned During the Early Stages of Developing a Transluminal Implantation Technique", ASAIO J, 2004; 50:364-68; the teachings of which are all incorporated herein by reference).

Orientation and positioning of the stents of the invention may be accomplished either by self-orientation of the stents (such as by interference between features of the stent and a previously implanted stent or valve structure) or by manual orientation of the stent to align its features with anatomical or previous bioprosthetic features, such as can be accomplished using fluoroscopic visualization techniques, for example. For example, when aligning the stents of the invention with native anatomical structures, they should be aligned so as to not block the coronary arteries, and native mitral or tricuspid valves should be aligned relative to the anterior leaflet and/or the trigones/commissures.

Some embodiments of the support structures of the stents described herein can be a series of wires or wire segments arranged so that they are capable of transitioning from a collapsed state to an expanded state. In some embodiments, a number of individual wires comprising the support structure can be formed of a metal or other material. These wires are arranged in such a way that a support structure allows for folding or compressing to a contracted state in which its internal diameter is greatly reduced from its internal diameter when it is in an expanded state. In its collapsed state, such a support structure with attached valves or leaflets can be mounted over a delivery device, such as a balloon catheter, for example. The support structure is configured so that it can be changed to its expanded state when desired, such as by the expansion of a balloon catheter. The delivery systems used for such a stent should be provided with degrees of rotational and axial orientation capabilities in order to properly position the stent at its desired location within the patient.

The wires of the support structure of the stents in other embodiments can alternatively be formed from a shape memory material such as a nickel titanium alloy (e.g., Nitinol). With this material, the support structure is self-expandable from a contracted state to an expanded state, such as by the application of heat, energy, and the like, or by the removal of external forces (e.g., compressive forces). This support structure can also be repeatedly compressed and re-expanded without damaging the structure of the stent. In addition, the support structure of such an embodiment may be laser cut from a single piece of material or may be assembled from a number of different components. For these types of stent structures, one example of a delivery system that can be used includes a catheter with a retractable sheath that covers the stent until it is to be deployed, at which point the sheath can be retracted to allow the stent to expand.

Referring now to the Figures, wherein the components are labeled with like numerals throughout the several Figures, and initially to FIGS. **1-4**, an exemplary embodiment of a stent **10** is illustrated. Stent **10** may be referred to as a subcoronary stent for use in replacement of the aortic valve in that it is preferably relatively short to enable stent placement below the coronaries. Stent **10** may be made of a self-expanding material, such as Nitinol, for example. In one embodiment, the stent **10** is generally tubular in shape and can be approximately 25 mm long, for example, although it can be longer or shorter than 25 mm, depending on the anatomy of the patient, the preferences of the surgeon, and other factors. The stent **10** includes multiple longitudinal or vertical wires **12** that extend generally parallel to a longitudinal axis **14** of the stent. The wires **12** are spaced from each other around the periphery of the generally tubular shape of the stent **10**. Stent **10** further includes features to which tissue can be attached to make the stent into a valve, such as commissure attachment posts **16** that can be approximately 18 mm long, for example. The commissure attachment posts **16** each include two longitudinal wires that are spaced closer to each other than the spacing of the wires **12** from each other.

In this embodiment, stent **10** includes three commissure attachment posts **16**, where each of the posts **16** is used as a connection location for one of the commissures of a tri-leaflet valve that will be attached thereto. Alternatively, more or less than three posts **16** can be provided for a valve having more or less than three leaflets, respectively. In addition to providing the structure for attachment of commissures, the posts **16** also provide additional stability to the stent **10**. The wires **12** and posts **16** are preferably spaced at generally the same distance from each other around the periphery of the stent **10**, although it is contemplated that some of the wires **12** and/or posts **16** can be spaced at different distances from each other around the periphery of the stent **10**. Further, the specific illustrated embodiment of stent **10** includes two wires **12** positioned between two commissure attachment posts **16**, although an alternate embodiment may include more or less wires **12** between adjacent commissure posts **16**. However, the specific embodiment of stent **10** illustrated in FIGS. **1-4** comprises nine longitudinal structures around its periphery, including six longitudinal wires **12** and three commissure attachment posts **16**.

Stent **10** further includes multiple V-shaped wire structures between a pair of wires **12** and/or between a wire **12** and an adjacent attachment post **16**. As shown, the stent **10** includes three wires **18**, **20**, **22** that are longitudinally spaced from each other along the height of the stent **10** between each adjacent pair of wires **12** or between a wire **12** and an adjacent post **16**. The size and shape of the wires **18**, **20**, **22** determines the spacing between adjacent longitudinal structures of the stent

10, which is generally uniform around the periphery of the stent, as discussed above. Although the stent **10** includes three of these V-shaped wires **18**, **20**, **22** that are spaced longitudinally from each other between adjacent vertical wire structures, there may be more or less than three V-shaped wires spaced longitudinally from each other.

Wires **18** are positioned at a first or outlet end **24** of the stent **10**. A first end of each wire **18** extends from a first end **26** of an attachment post **16** or wire **12**, and a second end of wire **18** extends from the first end **26** of an adjacent wire **12** or attachment post **16**. In this way, a peak **28** of each wire **18** will be positioned generally in the center of the space between adjacent longitudinal wires, and will be directed toward a second or inlet end **30** of the stent **10**. All or some of the wires **18** can be flared at least slightly outward relative to the outer tubular shape of the stent **10**, thereby creating integrated flange structures that can be used to capture the native leaflets when the stent is implanted in a patient. Each wire **20** is spaced longitudinally from a corresponding wire **18**, and each wire **22** is spaced longitudinally from a corresponding wire **20**.

Additional wire structures **32** are positioned at the second end **30** of the stent **10** to correspond with each set of wires **18**, **20**, **22**. In particular, each wire structure **32** is generally V-shaped, where the peak of each of the "V" structures is oriented in generally the same direction as the peaks of the wires **18**, **20**, **22**. A first end of each wire structure **32** extends from a second end **34** of an attachment post **16** or wire **12**, and a second end of wire structure **32** extends from the second end **34** of an adjacent wire **12** or attachment post **16**. All or some of the wire structures **32** are flared at least slightly outward relative to the outer tubular shape of the stent **10**. The amount and angle at which the wire structures extend relative to the tubular outer shape of the stent can be selected for capturing native patient anatomical features. In addition, this flare of the wire structures **32** can help to prevent or minimize leakage between the implant and the native annulus and/or to provide a physical and/or visual docking feature to secure the stent **10** against a wall of an opening in the heart to prevent migration of the stent, for example.

The stent **10** has a relatively high-density strut pattern to contain leaflets within the inner stent area during crimping of the stent. That is, while the exact number of longitudinal wires and V-shaped wires can vary somewhat from that illustrated in the Figures, it is preferable that the number of wires provided is sufficient to keep the leaflet material from becoming compressed and potentially damaged between the stent struts during the crimping process or from protruding beyond the periphery of the stent when it is in a crimped condition.

The first end **26** of all or some of the wires **12** and posts **16** can further include a loop or eyelet **36** that can be used for attachment to a delivery system and/or tissue valve, for example. The eyelets **36** can be in the same general plane as the outer tubular shape of the stent **10**, or they can be directed at least slightly inward toward the central area of the stent or at least slightly outward relative to the outer tubular surface of the stent. The single-sided eyelet attachment end can be used in a resheathable delivery system for both antegrade and retrograde procedures, for example. Attachment end crown reducers can optionally be added to the stent to reduce the attachment crown number, although the stout would be lengthened at least slightly by such a modification.

FIG. **4** illustrates an exemplary laser cutting pattern that can be used to form the stent **10** out of a tube or single sheet of material. The stout **10** can alternatively be made from multiple components that are attached to each other and formed into a tubular shape. However, if the stout will be cut from a tube or single sheet of material as shown, the various structures will be designed so that they do not interfere with each other in the pattern.

FIG. **26** illustrates another exemplary embodiment of a stent **50** positioned for clarity on a mandrel, which also may be referred to as a sub-coronary stent in that it is preferably relatively short (e.g., 25 mm long) to enable stent placement below the coronary arteries in the aorta. This stent includes a number of the same features as the stent of FIGS. **1-4**, although this stent **50** does not include the integrated petals shown and described above relative to stent **10**. Rather, the shaped structures **52** at the outlet end of the stent **50** are generally in the same plane as the tubular outer shape of the stent **50** (i.e., the structures **52** are not flared outwardly). The strut **50** also includes eyelets **54** at the outlet end of the stent, which can be in the same general plane as the outer tubular shape of the stent **50**, or they can be directed at least slightly inward or at least slightly outward relative to the outer tubular shape of the stent **50**.

FIGS. **5-8** illustrate another exemplary embodiment of a stent **60**, which is similar in structure to the strut **10** described above, including a wire structure with multiple commissure attachment posts **62**. These posts **62** include two vertical struts that are spaced at least slightly from each other. These posts **62** further include multiple horizontal members **64** that are spaced from each other along the length or height of each post **62**. The spaces or openings **66** that are created between the horizontal members **64** provide locations through which suture material, needles, and/or other fastening materials can be inserted for attachment of leaflet or valve material to the stent at the commissure posts. In addition, the horizontal members **64** can be used as defined anchoring points for the fastening materials. For example, a suture material can be inserted through a first opening **66** and then through another opening **66** in a predetermined pattern to stitch valve material to the commissure attachment posts **62**. The horizontal members **64** can further be used as anchoring structures that keep sutures or other attachment mechanisms from moving vertically past a certain position along the attachment posts **62**.

Another embodiment of a stent **80** is illustrated in FIGS. **9** and **10**, which has a similar structure to stent structures described above relative to tubular stent constructions. Stent **80** further includes a sealing skirt **82** at its inlet end **84**. The sealing skirt **82** can provide for improved sealing between the stent **80** and the anatomy in which the stent **80** is placed, such as the annulus of a valve, for example. The sealing skirt **82** can be configured to unfurl away from the inlet end **84** of the valve and into the delivery system that was used to deliver the stent **80**, if desired. In this way, the material used to make the sealing skirt **82** does not increase the overall size of the stent **80** when it is crimped or compressed. The sealing skirt **82** can further be provided with radiopaque, echogenic properties or other visually detectable properties so that an operator can assess the proper positioning of the stent **80** in the patient's anatomy prior to releasing it from the delivery system.

A number of systems, components, and devices are described below for attachment of valve material (e.g., tissue leaflets) within the interior area of a stent structure. It is understood that the systems that are shown and described herein for this purpose can be used with stent configurations described above and/or other stent constructions.

In one exemplary embodiment, a tubular stent structure includes at least one commissure post, along with a first leaflet and a second leaflet. Leaflets are attached or sewn to the post using suture material. In this embodiment, a tissue "cushion" is provided on both sides of the commissure attachment post to help absorb and distribute stress away from the

stitch points and to minimize tissue abrasion that can be caused without such protection. In this configuration, the leaflets **104**, **106** can flex along the tissue and the leaflet/tissue seam like and the tissue cushion distributes stress from flexing during opening and closing of leaflets away from the suture points where leaflets are attached into the attachment post.

Another configuration and device that can be used in the attachment of valve material to a stent structure is shown and described relative to FIGS. **11-14**. In particular, a relatively rigid "ladder" member **120** is provided to support the leaflet commissure area and transfer the line or point about which the leaflets **140** flex or bend to a location that is spaced from the suture line. In this way, the stresses can be more evenly distributed and durability of the valve improved. Ladder member **120** includes a relatively flat elongated plate **122** having multiple holes or openings **124** along its length. In order to minimize or prevent damage to the tissue of the valve, the corners and edges of the ladder member **120** are preferably rounded or smoothed. The holes **124** are preferably spaced from each other by a distance that corresponds with a desired stitching pattern that will be used to both secure the member **120** to the stent structure and attach the leaflets. It is further contemplated that the ladder member **120** is configured to match specific commissure features of the stent.

FIGS. **12** and **13** illustrate two ladder members **120** positioned relative to a portion of a stent **126** and portions of two leaflets. In particular, portions **128**, **129** of adjacent leaflet commissures are secured in the space between two ladder members **120**. The ladder members **120** are spaced from each other by a distance that allows the components to be securely fastened to each other, but that accommodates the thickness of the leaflets that are positioned between them. Additional material from the leaflets extends around the ends of the ladder members **120** between the edge of the ladder members **120** and the stent **126**, then along the outwardly facing sides of the ladder members **120**, such as is indicated by the reference number **130**. This additional material provides for improved security in tissue attachment and also provides additional attachment locations.

Sutures **132** can be inserted through the tissue material to secure it to the ladder members **120**, where one exemplary stitching pattern is illustrated in FIG. **15**. An appropriate number of stitches should be made through the tissue material and ladder member **120** to securely attach the ladder members **120** to the leaflets. The same or a different suture material can be used to attach or position adjacent ladder members **120** relative to each other. Additional sutures or an extension of the sewing pattern can also be used to connect the ladder members **120** to the stent **126**. The suture pattern can follow the holes in the ladder member **120** such that the ladder member **120** provides a template for sewing the leaflet tissue to the ladder members **120**, or an alternate stitching pattern can be used. The leaflets can then flex against a long vertical edge **134** of each of the ladder members **120**, thereby transferring the stress away from the attachment suture line.

FIG. **14** illustrates another tissue attachment arrangement that includes the use of two ladder members **120**, as described above, along with additional protective layers **136**. Each protective layer **136** can provide supplemental padding between a ladder and the adjacent leaflet material, and can also provide additional strength at the attachment sites. The protective layers **136** can be made of a material such as cloth, tissue, polymeric sheets, or the like. As shown, one protective layer **136** is used for each of the ladder members **120**, with the protective layer **136** being positioned between each ladder member **120** and its corresponding leaflet **128**, **129**. Each protective layer **136** can wrap around at least a portion of the periphery of its corresponding ladder member **120**, and in one embodiment will wrap around almost the entire periphery of the ladder members **120**, as shown. Further, each protective layer **136** can extend along the entire length or height of its corresponding ladder **120**, or it may extend along only a portion of the length of the ladder member **120**. An exemplary pattern of stitching the components to each other and to the stent **126** is illustrated with the sutures **132** (shown as broken lines), although a different stitching pattern can instead be used.

Another configuration and device that can be used in the attachment of valve material to a stent structure is shown and described relative to FIGS. **15-17**. In particular, a relatively rigid "slot bar" member **150** is provided to support the leaflet commissure area and transfer the line or point about which the leaflets flex or bend to a location that is spaced from the suture line. In this way, the stresses can be more evenly distributed. Slot bar member **150** includes a relatively flat elongated plate **152** having a longitudinal slot **156** extending along a portion of its length, and multiple holes or openings **154** along the length of the member **150** on both sides of the slot **156**. Alternatively, one or both ends could be open and/or two separate portions can make up the slot bar member. In order to minimize or prevent damage to the tissue of the valve, the corners and edges of the slot bar member **150** are preferably rounded or smoothed. The holes **154** are preferably spaced from each other by a distance that corresponds with a desired stitching pattern that will be used to both secure the member **150** to the stent structure and the tissue to the slot bar. It is further contemplated that the slot bar member **150** is configured to match specific commissure features of the stent to which it will be attached. In addition, the width of the slot **156** is preferably selected based on the thickness of the leaflets that will be inserted through the slot **156**. Thus, the slot **156** should be wide enough to accommodate two thicknesses of leaflet material; however, the slot **156** may be designed for more layers of material or for an optimized compression fit, if desired. In order to provide secure positioning of the tissue layers within the slot **156** and to minimize the potential for the tissue to be pulled from the slot **156**, the slot should not be substantially wider than the thickness of the materials that will be positioned within it.

FIGS. **16-17** illustrate slot bar member **150** positioned relative to a portion of a stent **158** and portions of two leaflets **160**, **162**. In particular, the end portions of adjacent leaflet commissures **160**, **162** are pulled through the slot **156** by a sufficient distance that the free edge of each of the leaflets extends at least slightly past the holes **154** on the flat side of the plate **152**. This end portion of the leaflets **160**, **162** will thereby be positioned between the slot bar member **150** and the stent to which they will be attached. In this way, the leaflets **160**, **162** can be securely fastened to the slot bar member **150** and the stent **158**. Sutures **164** can then be inserted through the tissue material to secure it to the slot bar member **150**, where one exemplary stitching pattern is illustrated in FIGS. **16** and **17**. The stitching pattern can follow the holes **154** in the slot bar member **150** such that the slot bar member **150** provides the template for sewing the leaflet tissue to the slot bar member **150**, or an alternate stitching pattern can be used. The sutures **164** can thereby connect the slot bar member **150** to the leaflets **160**, **162**. Additional sutures or the same sutures can also be used to connect the slot bar member **150** to the stent **158**. The leaflets **160**, **162** can then flex over a long vertical edge **166** on each side of the slot bar member **150** during valve leaflet opening and closing,

thereby transferring the stress away from the attachment suture line and increasing the durability of the valve.

FIGS. **18** and **19** illustrate another tissue attachment arrangement that includes the use of a slot bar member **150** of the type described above, along with additional protective members **170**, **172**. Protective members **170**, **172** are positioned on opposite sides of the slot **156** of the slot bar member **150** so that each of the members **170**, **172** can protect one of the leaflets **160**, **162**. Each protective member **170**, **172** can provide additional padding or cushioning between one of the leaflets **160**, **162** and the slot bar member **150** during opening and closing of the leaflets. The protective members **170**, **172** can be made of a material such as cloth, tissue, polymeric sheets, or the like. Further, each protective member **170**, **172** can extend along the entire length of its corresponding slot bar member **150**, or it may extend along only a portion of the length of the slot bar member **150**. An exemplary pattern of stitching the components to each other and to the stent **158** is illustrated with the schematic representation of a suture **164**, although a different stitching pattern can instead be used. The suture material can be used to attach the excess tissue material to only the slot bar member **150**, if desired. Alternatively, the protective members on the leaflet side of the slot bar member could be extended circumferentially beyond the slot bar member and attached to the stent (not shown). In this way, the leaflet would be prevented from contacting the suture material during opening of the valve reducing the potential for leaflet abrasion and tearing. In order to accommodate the thickness of the extra layers provided by the protective members **170**, **172**, the slot **156** should have an appropriate width.

Another configuration and device that can be used in the attachment of valve material to a stent structure is shown and described relative to FIGS. **20-22**. In particular, a relatively rigid "buckle" member **180** is provided to support the leaflet commissure area and transfer the line or point about which the leaflets flex or bend to a location that is spaced away from the suture line. In this way, the stresses can be more evenly distributed increasing the durability of the valve. Buckle member **180** includes a relatively flat elongated plate **182** having a longitudinal slot **184** extending along a portion of its length. The slot could alternatively be open at either one or both ends of the plate. In order to minimize or prevent damage to the tissue of the valve, the corners and edges of the buckle member **180** are preferably rounded or smoothed. The width of the slot **184** is preferably selected based on the thickness of the layers of material that will be inserted through the slot **184**. Thus, the slot **184** should be wide enough to accommodate the two thicknesses of leaflet material that will extend through it, as described below; however, the slot **184** may be designed for more layers of material or for an optimized compression fit, if desired. In order to provide secure positioning of the tissue layers within the slot **184** and to minimize the potential for the tissue to be pulled from the slot **184**, the slot should not be substantially wider than the width of the material that will be positioned within it.

As shown in the Figures, the buckle member **180** is positioned on the opposite side of a stent **194** than the other embodiments discussed above (i.e., on the outer side of the stent structure rather than on the inner side of the stent structure). In this embodiment, the stent **194** has a vertical slot **186** in its commissure post that generally corresponds to the slot **184** in the buckle member **180**. The end portions of two leaflets **190**, **192** are pulled through the slot **186** in the stent commissure post, then through the slot **184** in the buckle member **180**. The ends of the leaflets are then wrapped around the back side of the buckle member **180** and pulled back through the slot **186** in the commissure post in the opposite direction than the first insertion of the leaflets through this slot **186**. The leaflets **190**, **192** should continue to be pulled through the slot **186** by a sufficient distance that the free edge of each of the leaflets **190**, **192** extends at least slightly past the structure of the stent in the internal area of the stent. With this arrangement, the leaflets **190**, **192** will flex generally along a vertical line **196**, which is the tissue that covers a vertical edge of the stent. In this embodiment, no sutures are required for attachment of the leaflets **190**, **192** to the stent and/or the buckle member **180**. Rather, the force on the commissure caused by the closing of the leaflets **190**, **192** will cause the buckle member **180** to be pressed toward the stent, thereby compressing and locking the excess tissue material between the buckle member and the stent. This secures the commissure and prevents the tissue material of the leaflets from pulling out of the assembly.

FIGS. **23-25** illustrate another configuration and device for the attachment of valve material to a stent structure that includes the use of a buckle member **200** that is similar in design and operation to the buckle member **180** discussed above. In this embodiment, however, the buckle member **200** includes two longitudinal slots **202**, **204** that are spaced from each other across the width of the buckle member **200**, rather than a single, central slot. In this way, a first leaflet **206** can be pulled through a longitudinal slot **210** in the stent and through longitudinal slot **202** of the buckle member **200**, and a second leaflet **208** can be pulled through a longitudinal slot **210** in the stent and through longitudinal slot **204** of the buckle member **200**. The leaflets **206**, **208** can then be wrapped around the back side of the buckle member **200**, pulled back through the longitudinal slot **210** in the commissure post, and pulled through the slot by a sufficient distance that the leaflets can be secured to the stent without stitching, similar to the arrangement that uses the buckle member **180**.

It is noted that in many of the stent embodiments shown and described herein, the aspect ratio of certain portions of the stent can be somewhat different from that shown. Further, stent embodiments described herein may be modified to include additional structure for attachment of tissue for the valve, such as the vertical stent posts described in many of the embodiments.

Delivering any balloon-expandable stents of the invention to the implantation location can be performed percutaneously. In general terms, this includes providing a transcatheter assembly, including a delivery catheter, a balloon catheter, and a guide wire. Some delivery catheters of this type are known it the art, and define a lumen within which the balloon catheter is received. The balloon catheter, in turn, defines a lumen within which the guide wire is slideably disposed. Further, the balloon catheter includes a balloon that is fluidly connected to an inflation source. It is noted that if the stent being implanted is the self-expanding type of stent, the balloon would not be needed and a sheath or other restraining means would be used for maintaining the stent in its compressed state until deployment of the stent, as described herein. In any case, for a balloon-expandable stent, the transcatheter assembly is appropriately sized for a desired percutaneous approach to the implantation location. For example, the transcatheter assembly can be sized for delivery to the heart valve via an opening at a carotid artery, a jugular vein, a sub-clavian vein, femoral artery or vein, or the like. Essentially, any percutaneous intercostals penetration can be made to facilitate use of the transcatheter assembly.

Prior to delivery, the stent is mounted over the balloon in a contracted state to be as small as possible without causing permanent deformation of the stent structure. As compared to the expanded state, the support structure is compressed onto

itself and the balloon, thus defining a decreased inner diameter as compared to an inner diameter in the expanded state. While this description is related to the delivery of a balloon-expandable stent, the same basic procedures can also be applicable to a self-expanding stent, where the delivery system would not include a balloon, but would preferably include a sheath or some other type of configuration for maintaining the stent in a compressed condition until its deployment.

With the stent mounted to the balloon, the transcatheter assembly is delivered through a percutaneous opening (not shown) in the patient via the delivery catheter. The implantation location is located by inserting the guide wire into the patient, which guide wire extends from a distal end of the delivery catheter, with the balloon catheter otherwise retracted within the delivery catheter. The balloon catheter is then advanced distally from the delivery catheter along the guide wire, with the balloon and stent positioned relative to the implantation location. In an alternative embodiment, the stent is delivered to an implantation location via a minimally invasive surgical incision non-percutaneously). In another alternative embodiment, the stent is delivered via open heart/chest surgery. In one embodiment of the stents of the invention, the stent includes a radiopaque, echogenic, or MRI visible material to facilitate visual confirmation of proper placement of the stent. Alternatively, other known surgical visual aids can be incorporated into the stent. The techniques described relative to placement of the stent within the heart can be used both to monitor and correct the placement of the stent in a longitudinal direction relative to the length of the anatomical structure in which it is positioned.

Once the stent is properly positioned, the balloon catheter is operated to inflate the balloon, thus transitioning the stent to an expanded state. Alternatively, where the support structure is formed of a shape memory material, the stent can self-expand to its expanded state.

The present invention has now been described with reference to several embodiments thereof. The foregoing detailed description and examples have been given for clarity of understanding only. No unnecessary limitations are to be understood therefrom. It will be apparent to those skilled in the art that many changes can be made in the embodiments described without departing from the scope of the invention. Thus, the scope of the present invention should not be limited to the structures described herein.

What is claimed is:

1. A stented valve comprising:

a stent structure comprising a plurality of wires and multiple commissure attachment structures;

a valve structure comprising a plurality of leaflets; and

at least one slot bar for securing the plurality of leaflets to the commissure attachment structures, the slot bar disposed exterior to the stent structure and secured to the stent structure, the at least one slot bar comprising a longitudinal slot extending along a portion of its length;

wherein a first leaflet and a second leaflet of the plurality of leaflets extend though a slot in the stent structure, through the longitudinal slot of the slot bar, and are secured to the slot bar.

2. The stented valve of claim **1**, wherein the longitudinal slot of the slot bar comprises a first longitudinal slot and a second longitudinal slot extending along a portion of its length,

wherein the first leaflet extends through the first longitudinal slot and the second leaflet extends through the second longitudinal slot.

3. The stented valve of claim **2**, further comprising a first protective member extending through the first longitudinal slot and positioned between the first leaflet and the slot bar and a second protective member extending through the second longitudinal slot and positioned between the second leaflet and the slot bar.

4. The stented valve of claim **3**, wherein the slot bar further comprises a plurality of holes along the length of the slot bar on outer sides of the first and second longitudinal slots, and wherein the first and second leaflets and the first and second protective members are secured to the slot bar by one or more sutures passing through at least one of the plurality of holes.

5. The stented valve of claim **1**, further comprising at least one protective member extending through the longitudinal slot of the slot bar and disposed between the slot bar and at least one of the first and second leaflets.

6. The stented valve of claim **5**, wherein the slot bar further comprises a plurality of holes along the length of the slot bar on both sides of the longitudinal slot, and wherein the first and second leaflets and the at least one protective member are secured to the slot bar by one or more sutures passing through at least one of the plurality of holes.

7. The stented valve of claim **6**, wherein the one or more sutures securing the at least one protective member to the slot bar also secure the slot bar to the stent structure.

8. The stented valve of claim **5**, wherein the at least one protective member comprises a first protective member extending through the longitudinal slot and disposed between the slot bar and the first leaflet, and a second protective member extending through the longitudinal slot and disposed between the slot member and the second leaflet.

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