US006821297B2

(12) **United States Patent**
Snyders

(10) **Patent No.: US 6,821,297 B2**
(45) **Date of Patent: Nov. 23, 2004**

(54) **ARTIFICIAL HEART VALVE, IMPLANTATION INSTRUMENT AND METHOD THEREFOR**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 72 days.

(21) Appl. No.: **10/135,746**

(22) Filed: **Apr. 30, 2002**

(65) **Prior Publication Data**

US 2002/0123802 A1 Sep. 5, 2002

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/775,360, filed on Feb. 1, 2001, now Pat. No. 6,540,782.
(60) Provisional application No. 60/179,853, filed on Feb. 2, 2000.

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/2.18**
(58) **Field of Search** 623/2.1, 2.11, 623/2.13, 2.14, 2.15, 2.16, 2.18, 2.19, 2.12

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(57) **ABSTRACT**

An artificial valve for repairing a damaged heart valve having a plurality of cusps separating upstream and downstream regions. The artificial valve includes a flexibly resilient frame with a plurality of peripheral anchors for anchoring the frame in position between the regions. The frame includes a central portion located between the anchors. The valve includes a flexible valve element attached to the central portion of the frame having an upstream side and a downstream side opposite the upstream side. The valve element moves to an open position when fluid pressure in the upstream region is greater than fluid pressure in the downstream region to permit downstream flow. The valve element moves to a closed position when fluid pressure in the downstream region is greater than fluid pressure in the upstream region to prevent flow reversal. The valve may be used in beating heart procedures, avoiding cardiopulmonary bypass and cardioplegia.

46 Claims, 11 Drawing Sheets

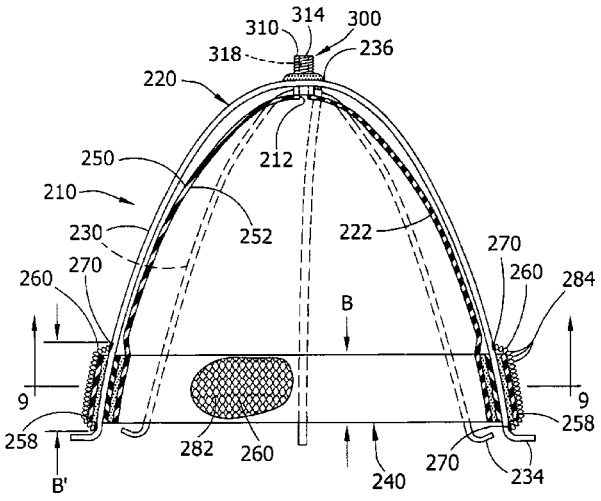

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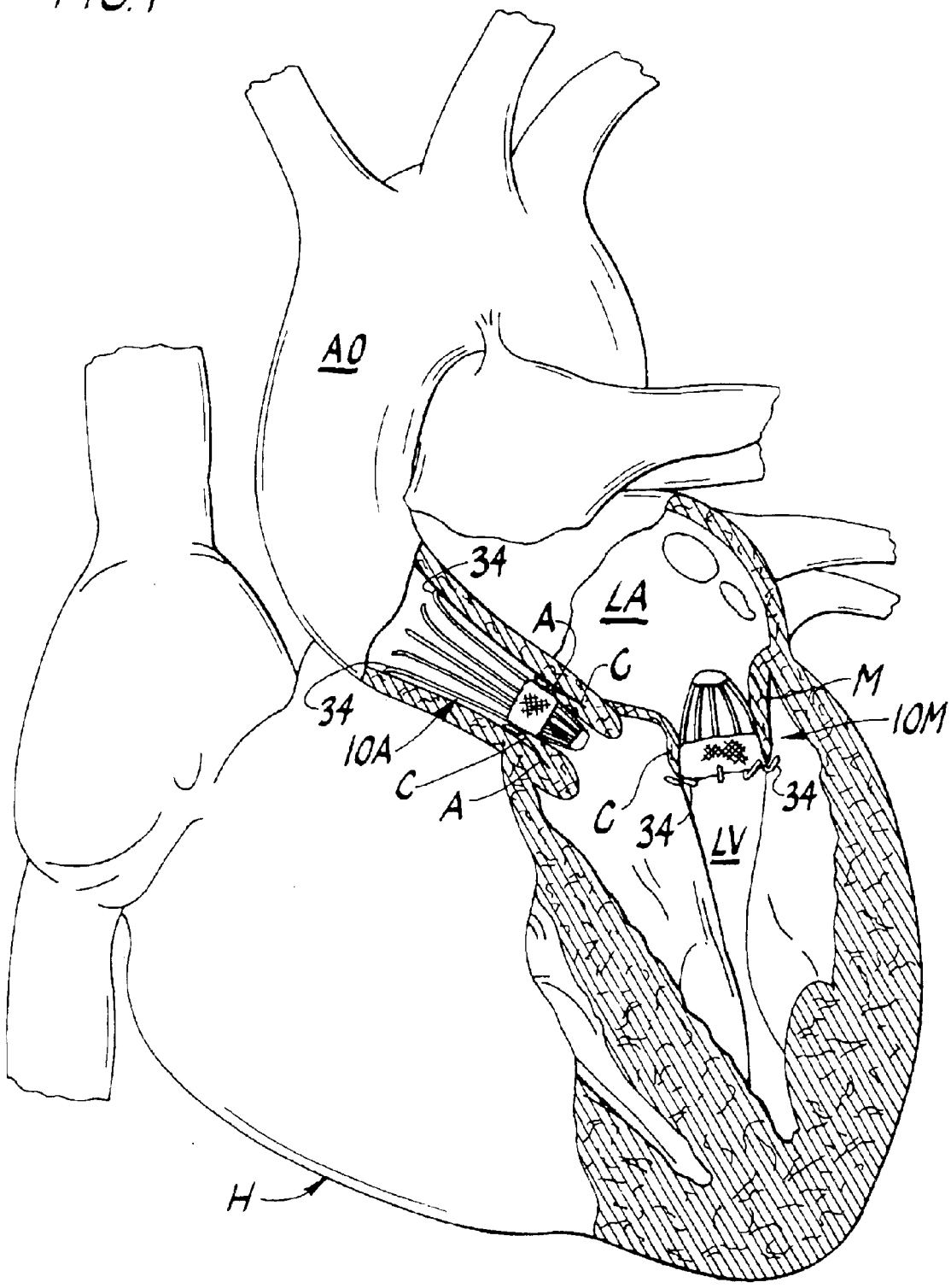
FIG. 1



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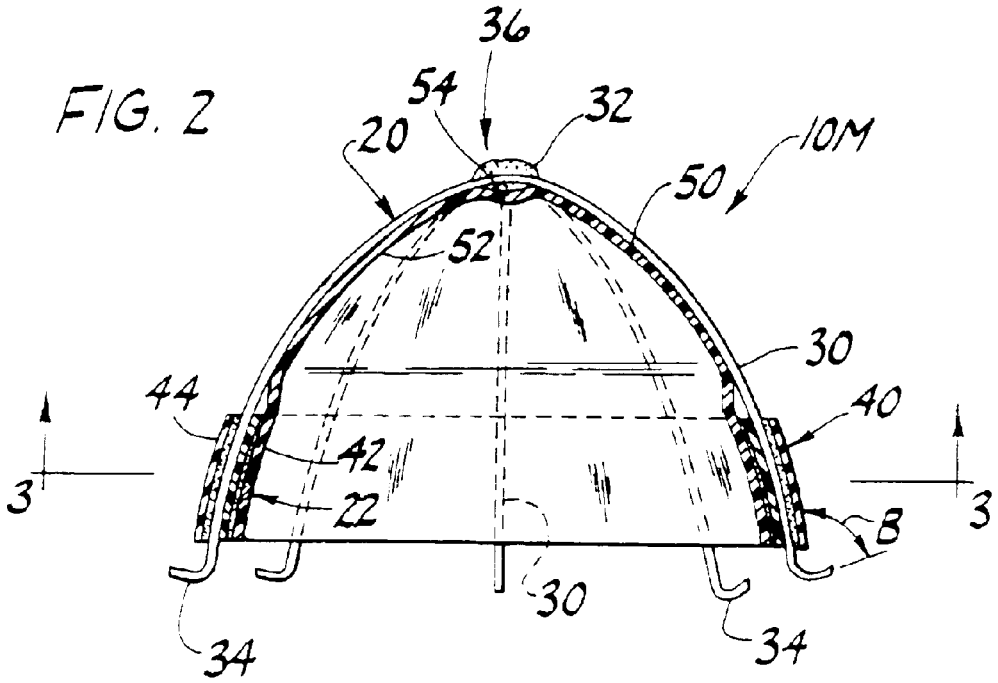
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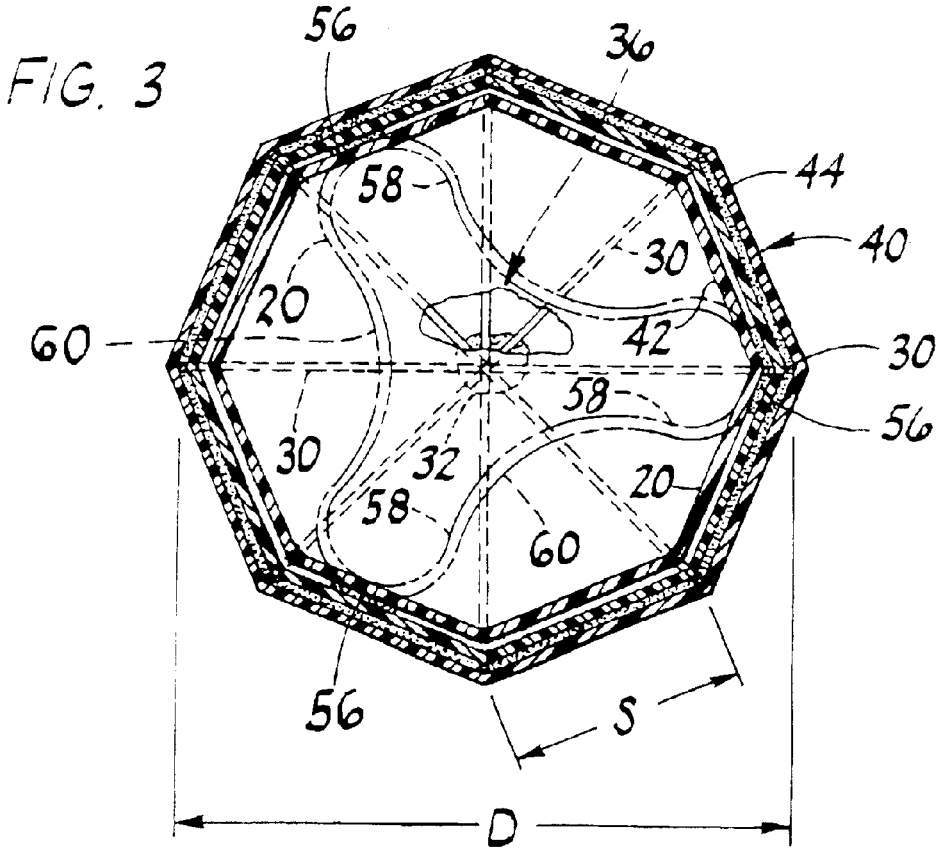
FIG. 3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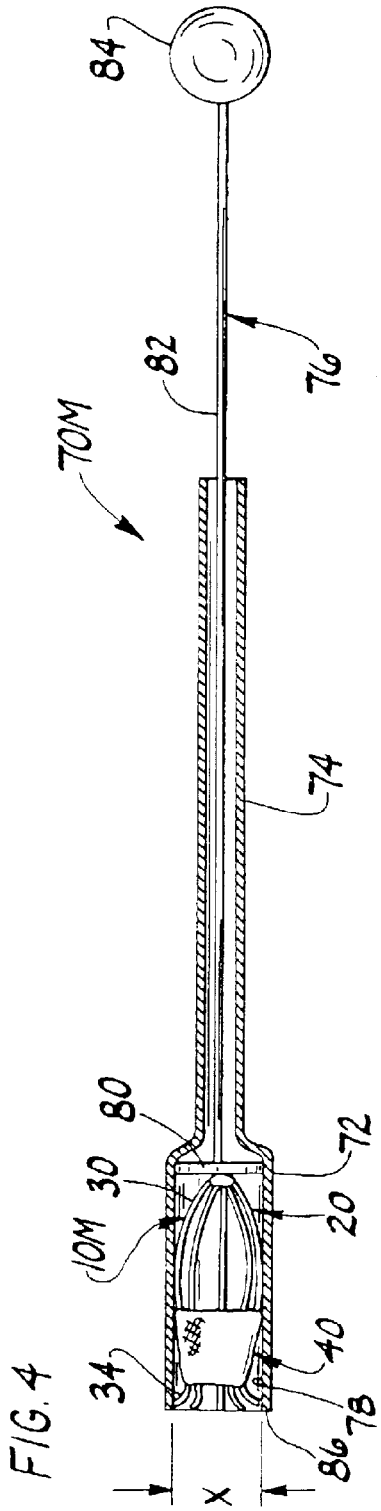
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FIG. 4

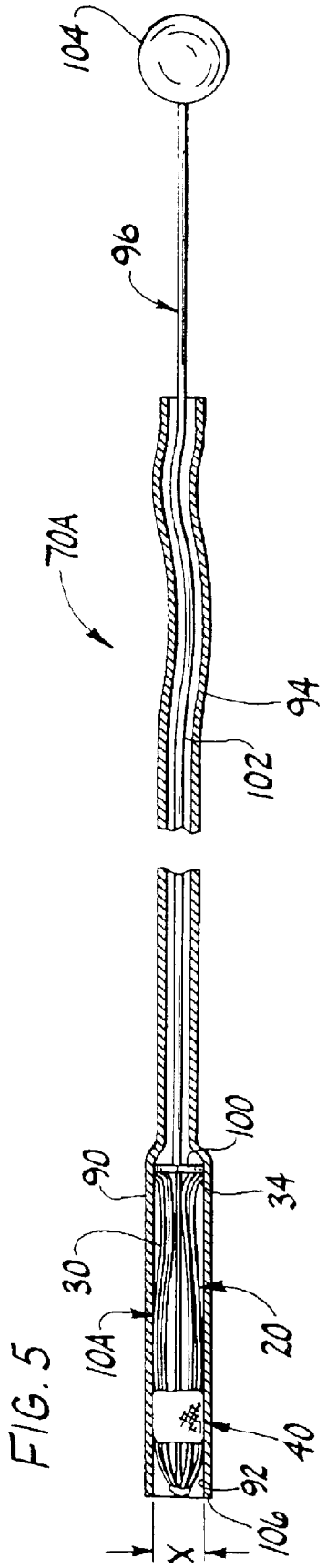
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FIG. 5

FIG. 6

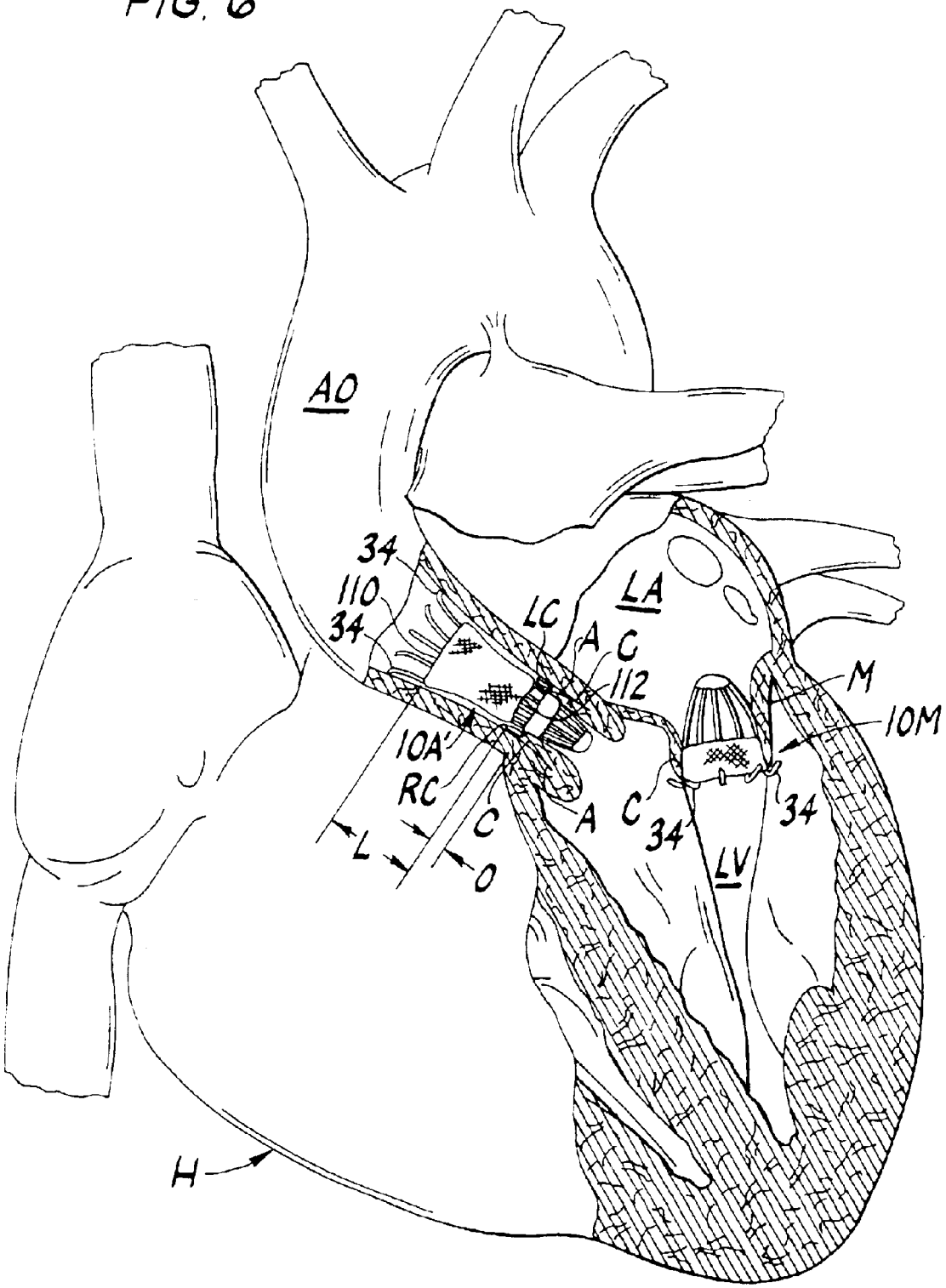


FIG. 7

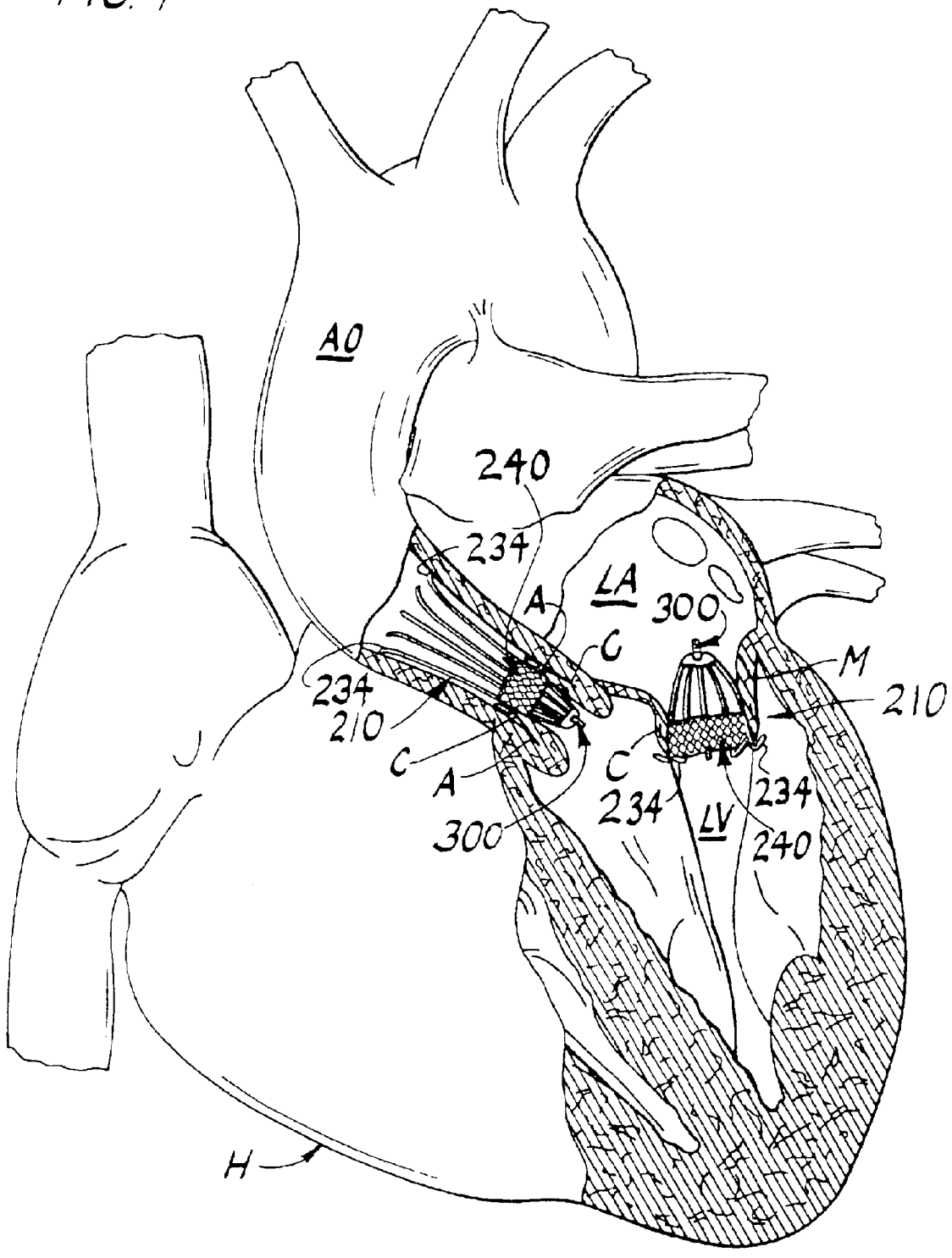


FIG.8

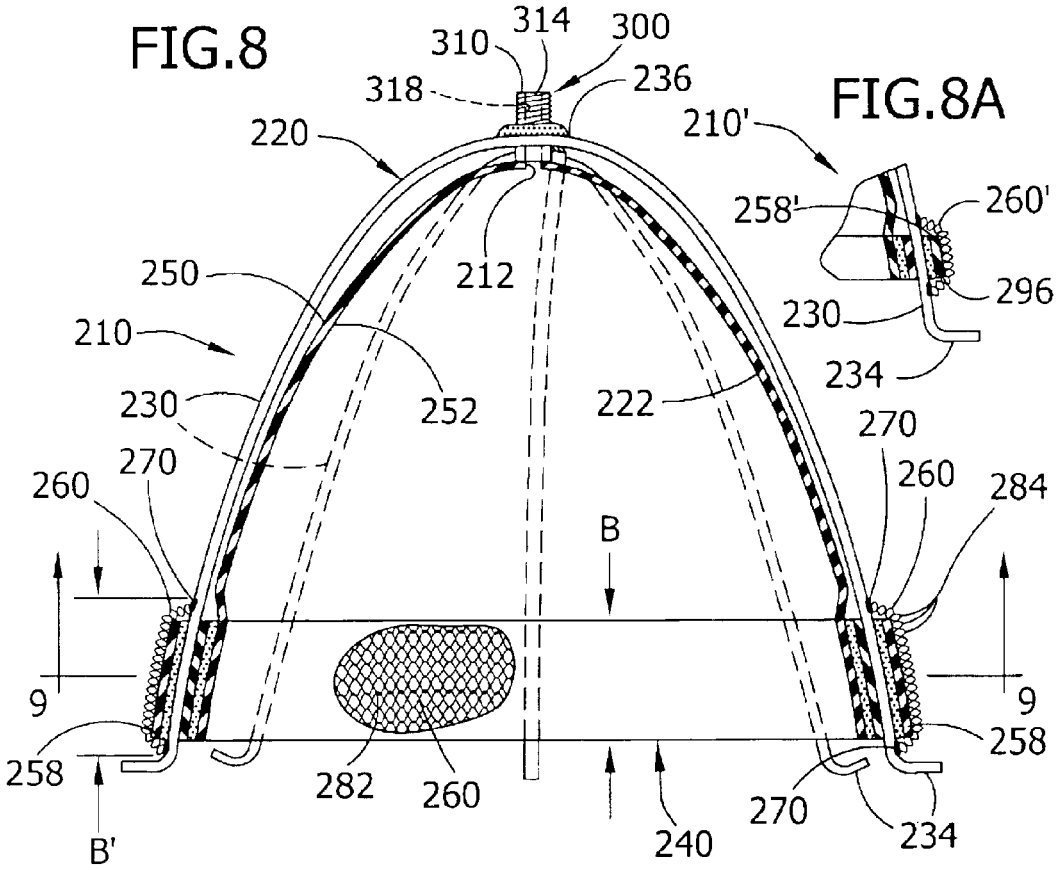
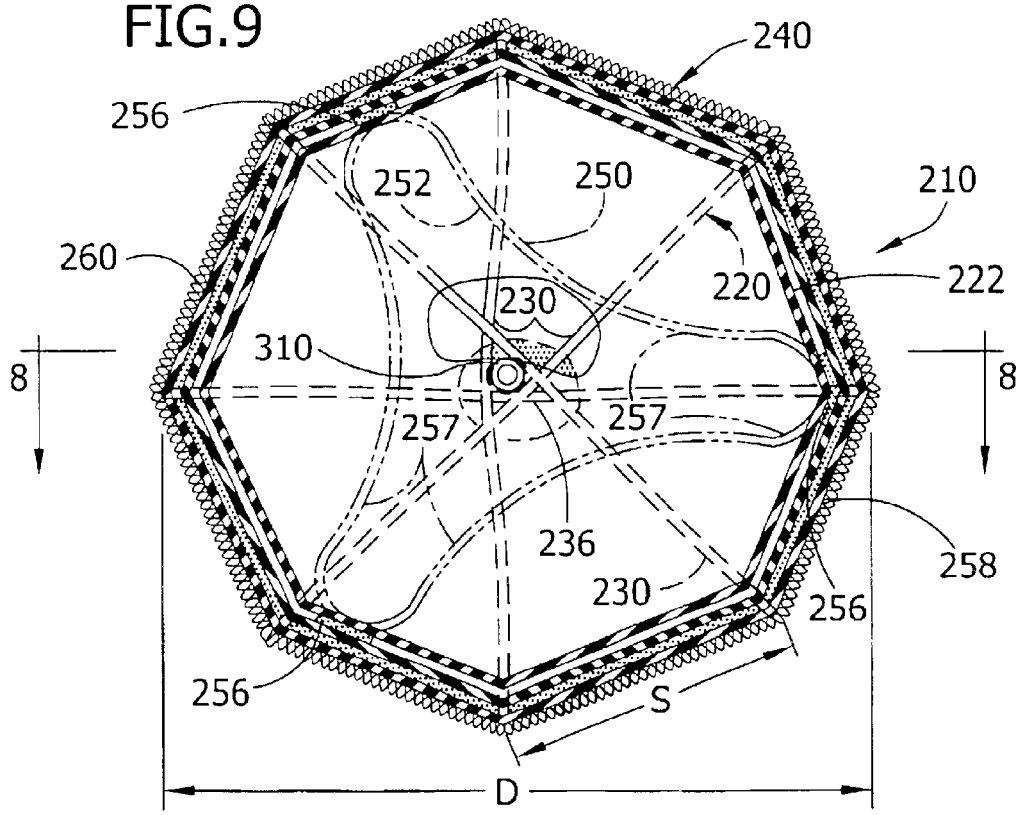


FIG.8A

FIG.9



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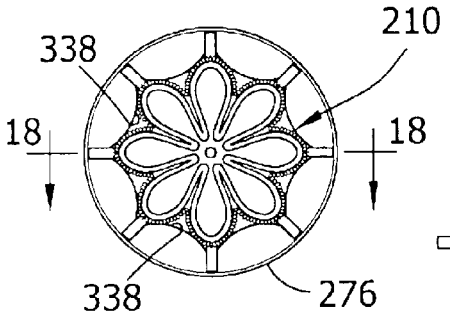

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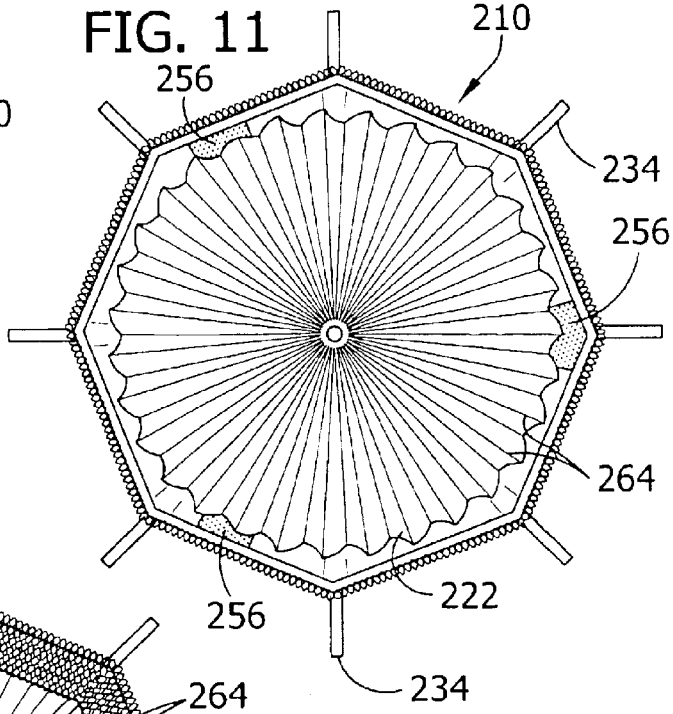


FIG. 12

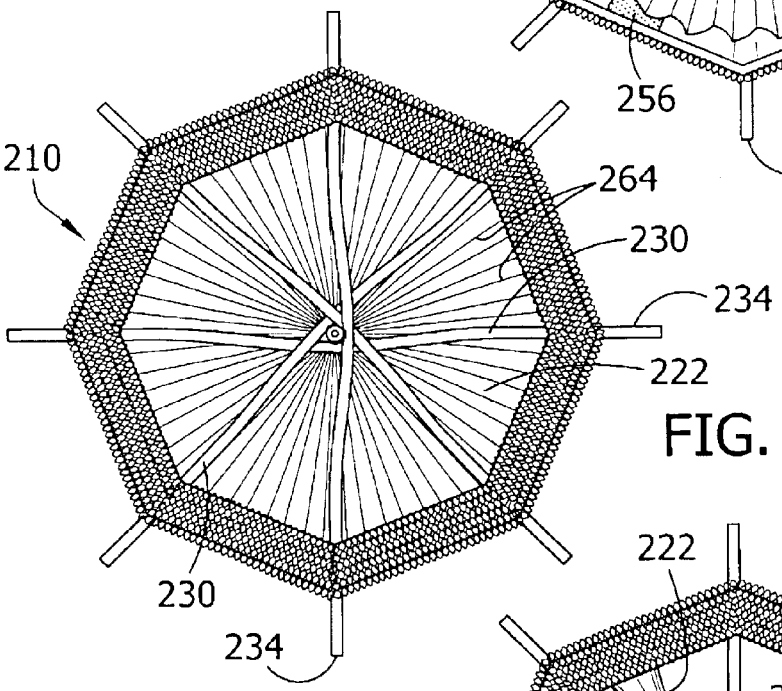


FIG. 13

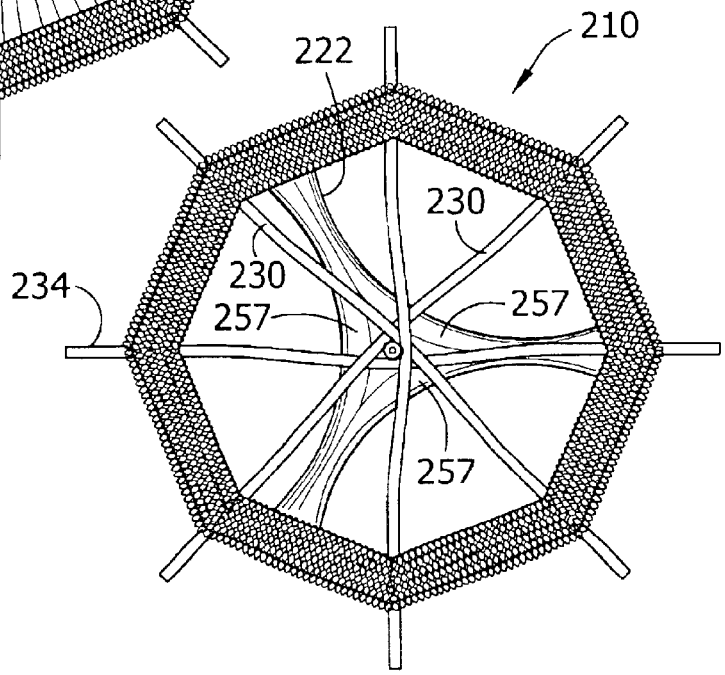
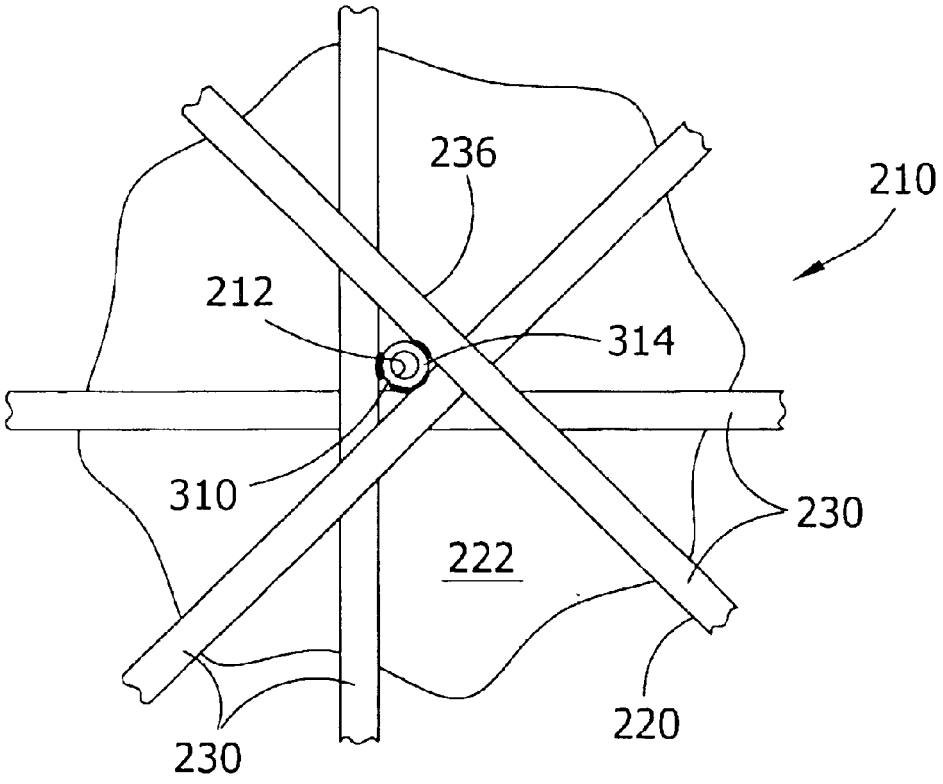


FIG. 14



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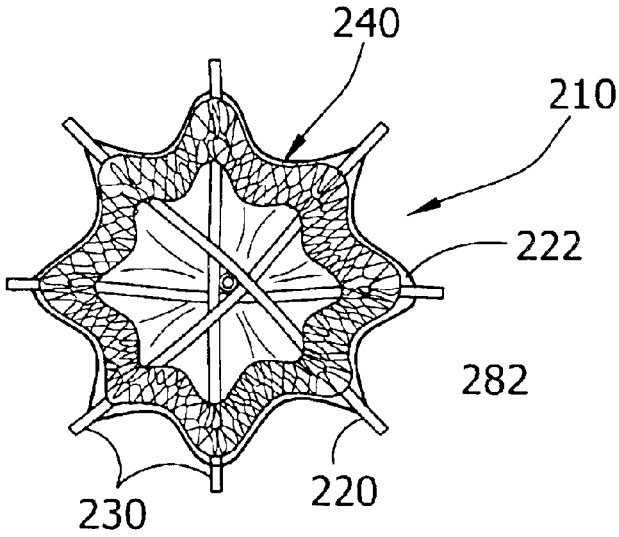

FIG. 16

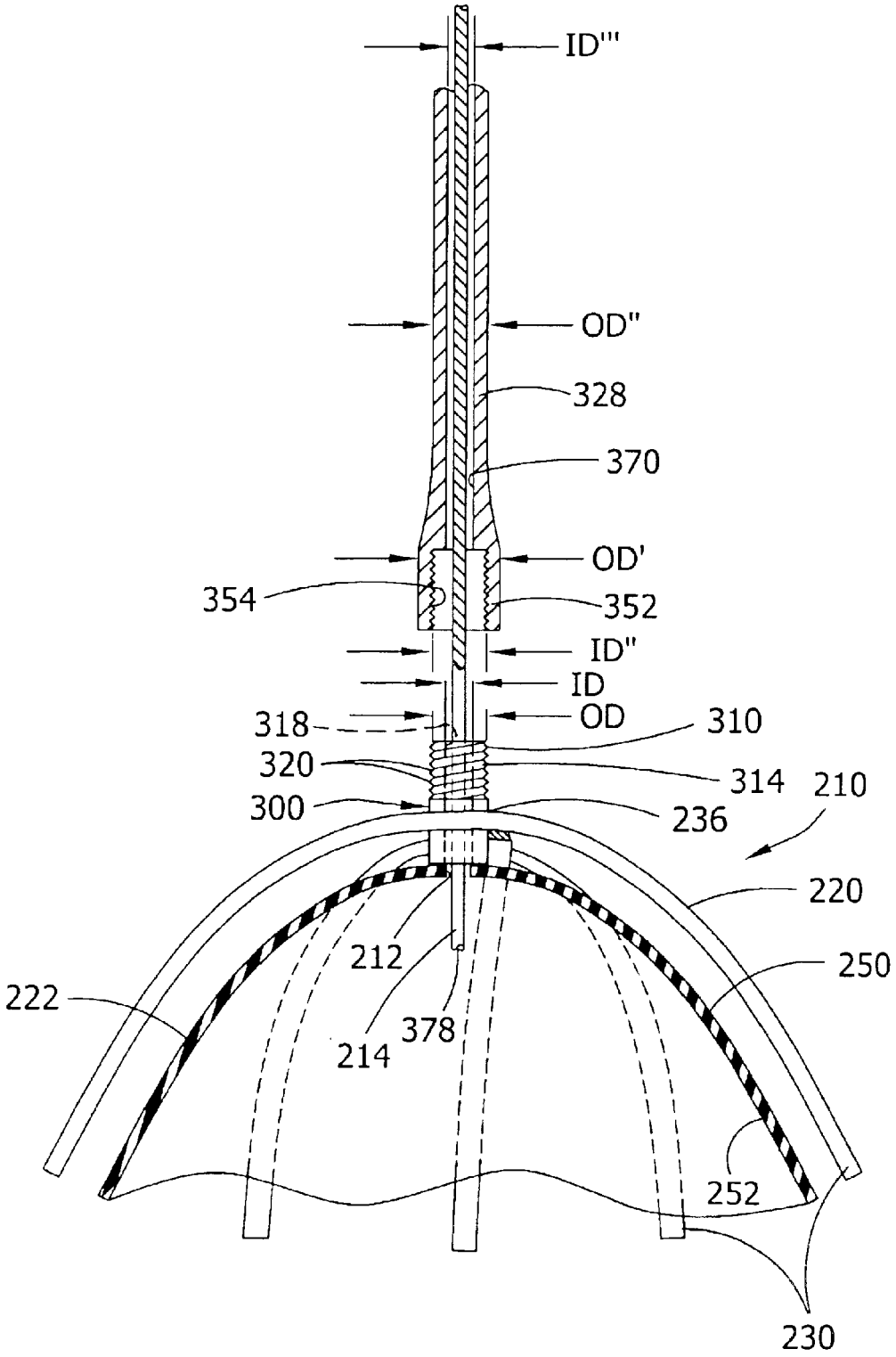
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FIG. 17

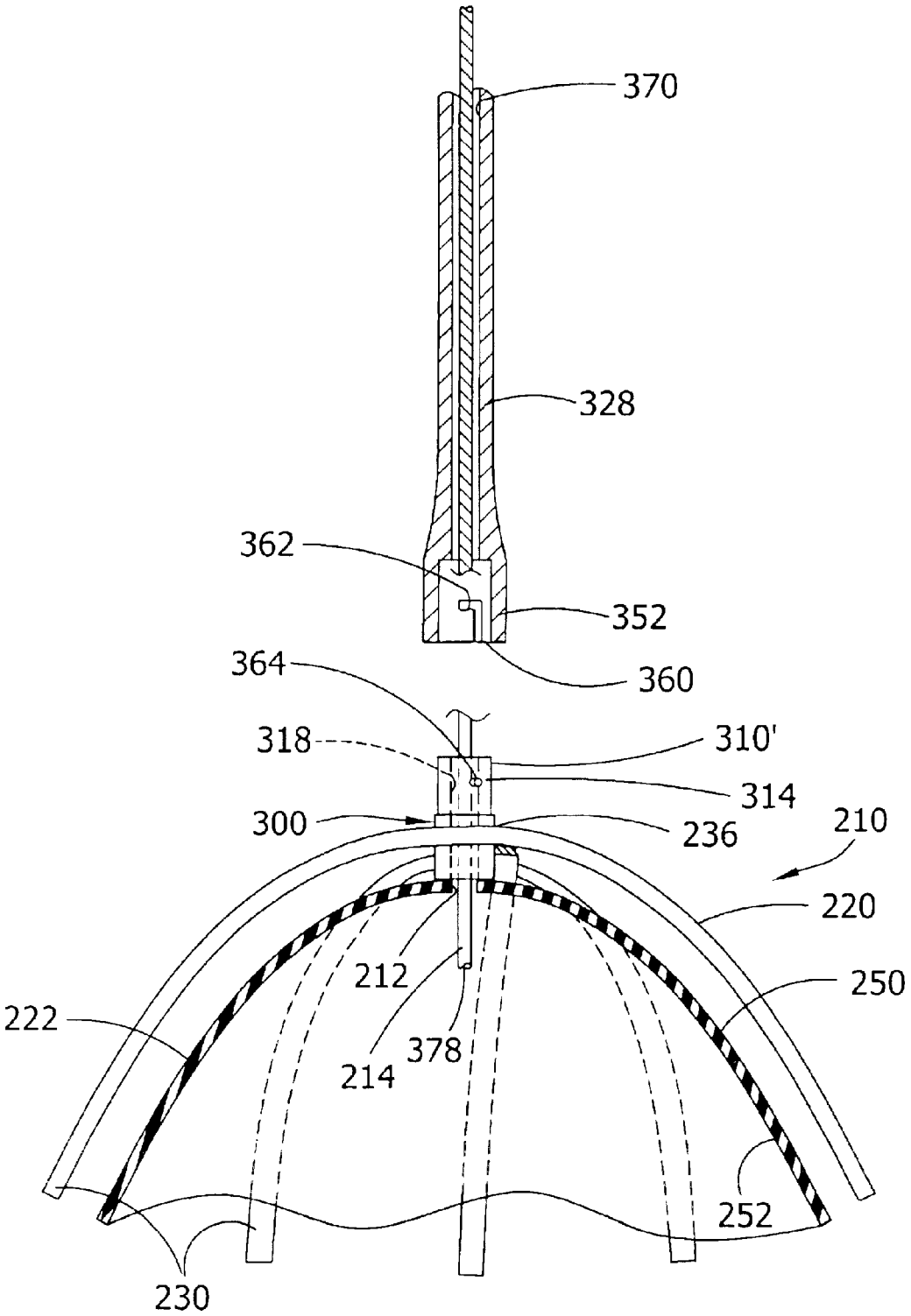
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FIG. 18

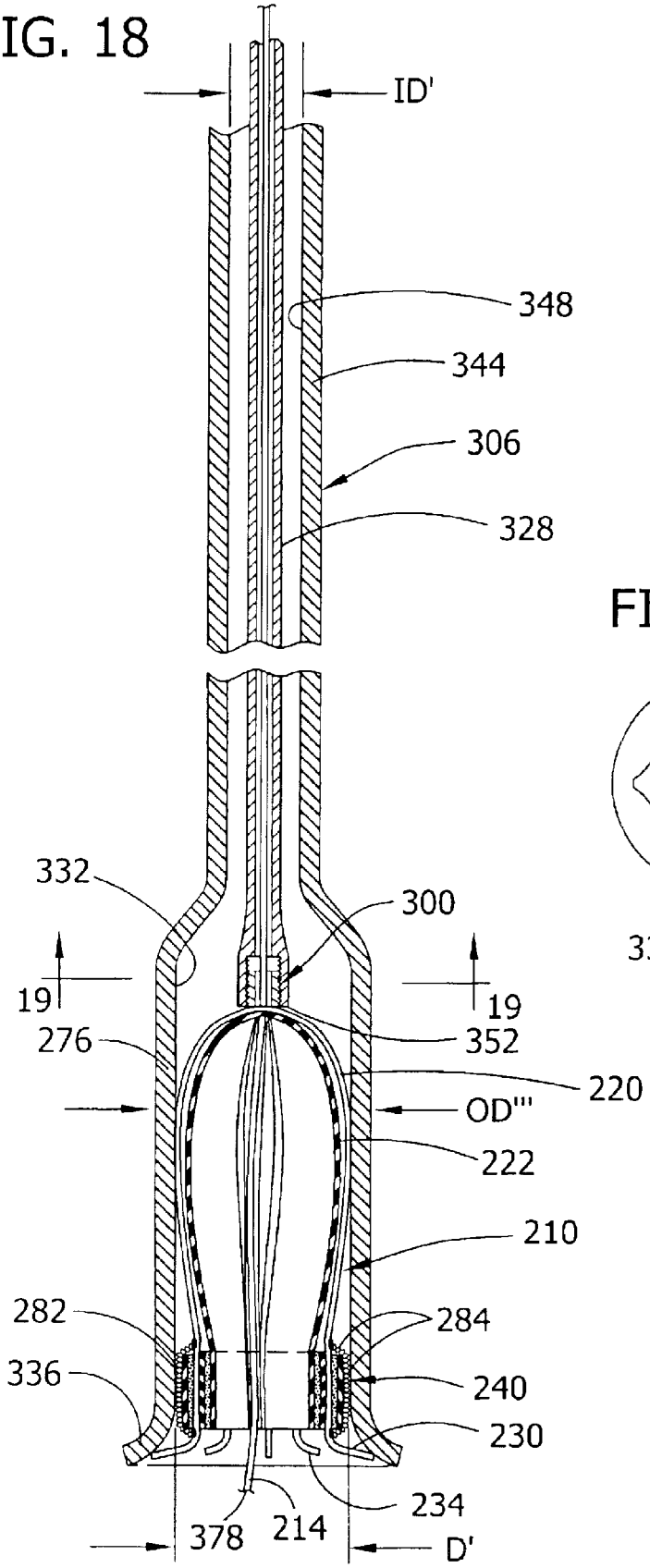
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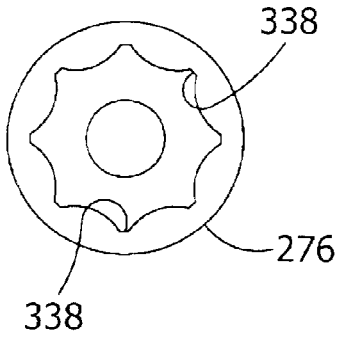
FIG. 19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ARTIFICIAL HEART VALVE, IMPLANTATION INSTRUMENT AND METHOD THEREFOR

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of Utility Patent application Ser. No. 09/775,360 filed Feb. 1, 2001, now U.S. Pat. No. 6,540,782, which claims benefit of Provisional Patent Application No. 60/179,853 filed Feb. 2, 2000, both of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention relates generally to valve implants, and more particularly to artificial heart valves for repairing damaged heart valves.

A human heart has four chambers which alternately expand and contract to pump blood through the vessels of the body. The heart also includes a check valve at the upstream end of each chamber to ensure that blood flows in the correct direction through the body as the heart chambers expand and contract. These valves sometimes become damaged resulting in their inability to close when the downstream chamber contracts. When the valves do not close, blood flows backward through the valve resulting in diminished blood flow and lower blood pressure. The valves can also become damaged so they do not open sufficiently thereby resulting in diminished downstream blood flow.

Although replacement valves and surgical procedures have been developed to alleviate these conditions, they have significant drawbacks. Many earlier valves require invasive implantation techniques in which the chest is opened, the ribs are spread, the heart is paralyzed, and following cardiopulmonary bypass, the heart is cut open to implant the valve. These invasive techniques are stressful on the patient, increase the opportunity for infection and slow recovery. As a result, valves which may be implanted with non-invasive techniques have been developed. These valves are implanted by transluminal or endothoracoscopic techniques which reduce many of the drawbacks associated with invasive surgery. However, many of these valves also require the damaged native heart valve be removed prior to implanting the artificial valve. Removing the native valve increases the risk that a portion of the valve will migrate through the body and block vessels downstream from the heart.

Many mechanical and bioprosthetic valves have been developed to replace native heart valves. See C. A. Hufnagel, *Basic Concepts in the Development of Cardiovascular Prostheses,* 137 Am. J. of Surg. at 285–300 (1972). See also D. E. Harken et al., *Partial and Complete Prosthesis in Aortic Insufficiency*, 40 J. Thorac & Cdvsc Surg., no. 6., at 744–62 (1960). These valves include ball-valve prostheses, flap-valve prostheses, polymeric trileaflet synthetic valves, and bioprosthetic valves made from animal allograft tissues such as pig valves and preserved heterologous bovine and porcine pericardial tissue valves. See H. B. Lo et al., *A Tricuspid Polyurethane Heart Valve as an Alternative to Mechanical Prostheses or Bioprostheses,* 34 Trans. Am. Soc. of Art. Int. Organs at 839–44 (1988); and S. L. Hilbert et al., *Evaluation of Explanted Polyurethane Trileaflet Cardiac Valve Prostheses*, 94 J. Thorac & Cdvsc Surg. at 419–29 (1987). Most of the aforementioned valves require open chest surgery and cardiopulmonary bypass for implantation.

More recently percutaneous and transluminal implantation have been suggested. See Steven R. Bailey, *Percutaneous Expandable Prosthetic Valves* Textbook of Interventional Cardiology, chap. 75 (1995)(referencing work of Andersen et al.) See also Knudsen et al., *Catheter-implanted Prosthetic Heart Valves*, 6 Int'l J. of Art. Organs, no. 5, at 253–62 (1993); Knudsen et al. *Transluminal Implantation of Artificial Heart Valves. Description of New Expandable Aortic Valve and Initial Results With Implantation by Catheter Technique in Closed Chest Pigs*, 13 European Heart J. at 704–08 (1992); and U.S. Pat. No. 5,411,552 (Andersen). The Andersen device includes a heterologous pig valve mounted in an annular ring. Due to the size of this device, it must be implanted by direct abdominal aortic incision and entry. Further, the Andersen device requires a separate inflating balloon for its deployment. U.S. Pat. No. 5,397,351 (Pavcnik) describes an expandable caged poppet for percutaneous implantation in an aortic valve site. However, the size of the Pavcnik device makes percutaneous implantation difficult. U.S. Pat. No. 5,885,601 (Bessler) describes a transluminal valve implantation but does not describe the specific valve construction. The Bessler procedure includes excision, vacuum removal of the native valve, cardiopulmonary bypass and backflushing of the coronary arterial tree.

SUMMARY OF THE INVENTION

Among the several objects and features of the present invention may be noted the provision of an artificial heart valve which accommodates implantation without removing the damaged native heart valve; the provision of a valve which may be implanted using non-invasive surgery; the provision of a valve which permits implantation without the need for cardio-pulmonary bypass; the provision of a valve which permits implantation by conventional open chest surgery and cardio-pulmonary bypass; provision of a valve which allows for repositioning the valve during implantation; and the provision of a valve which allows for guiding the valve to the point of implantation along a guide.

Generally, an artificial valve of the present invention repairs a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region. The artificial valve comprises a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region. The frame has a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors. A flexible valve element attaches to the central portion of the frame having an upstream side facing the upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing the downstream region when the frame is anchored in the position between the upstream region and the downstream region. The valve element moves in response to a difference between fluid pressure in the upstream region and fluid pressure in the downstream region between an open position, in which the element permits downstream flow between the upstream region and the downstream region, and a closed position, in which the element blocks flow reversal from the downstream region to the upstream region. The valve element moves to the open position when fluid pressure in the upstream region is greater than fluid pressure in the downstream region, permitting downstream flow from the upstream region to the downstream region. The valve element moves to the closed position when fluid pressure in the downstream region is greater than fluid pressure in the upstream region, preventing flow reversal from the down-

stream region to the upstream region. An opening extends through at least one of the frame and the valve element for receiving an implement.

In a second embodiment of the present invention, an artificial valve includes a flexibly resilient frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream and the downstream region. A flexible valve element attaches to the frame having a convex upstream side and a concave downstream side. An opening extends through at least one of the frame and the valve element.

The present invention is also directed to a combination of an artificial valve, including a frame, a valve element, an opening and a flexible, elongate guide sized for receipt within the opening to guide the valve into position.

Another aspect of the present invention is directed to a combination of an artificial valve, including a frame and valve element, and an instrument including a holder, an elongate manipulator and an installer. The holder has a hollow interior sized for holding the artificial valve when the frame is in a collapsed configuration. The elongate manipulator attaches to the holder for manipulating the holder into position between the upstream region and the downstream region. The installer is received within the hollow interior of the holder and is releasably attachable to the frame of the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

The present invention is also directed to an endothoracoscopic method of inserting an artificial valve between a plurality of cusps of a damaged heart valve. The method comprises the steps of making an opening in a chest wall of a patient and making an incision in a heart of the patient. An end of an elongate instrument is inserted through the opening made in the chest wall and the incision made in the heart. The inserted end of the instrument is positioned adjacent the plurality of cusps of the damaged heart valve. An artificial valve is ejected from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between the plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart. The artificial valve is then retrieved into the end of the instrument and the inserted end of the instrument is repositioned adjacent the plurality of cusps of the damaged heart valve. The repositioned artificial valve is ejected from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into position between the plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

Another aspect of the present invention is directed to a transluminal method of inserting an artificial valve between a plurality of cusps of a damaged heart valve, including the steps of ejecting, retrieving, repositioning and a second ejecting step. The method further comprises making an incision in a vessel leading to the heart and inserting an end of an elongate flexible instrument through the incision made in the vessel. The method further comprises pushing the end of the instrument through the vessel and positioning the end adjacent the plurality of cusps of the damaged heart valve.

The present invention is also directed to a transluminal method of inserting an artificial valve between a plurality of cusps of a damaged heart valve, including the steps of making, inserting and ejecting. The method further comprises inserting an end of a guide through the incision made in the vessel, pushing the guide through the vessel, threading an elongate flexible instrument having a hollow interior onto the guide and pushing the end of the instrument through the vessel along the guide until the end is adjacent the plurality of cusps of the damaged heart valve.

Other objects and features of the present invention will be in part apparent and in part pointed out hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a front elevation of a heart in partial section showing two artificial valves of the present invention;

FIG. **2** is a vertical cross section of an artificial valve;

FIG. **3** is a cross section of the valve taken in the plane of line **3-3** of FIG. **2**;

FIG. **4** is a vertical cross section of an instrument for implanting a valve using an endothoracoscopic procedure of the present invention;

FIG. **5** is a vertical cross section of an instrument for implanting a valve using a transluminal procedure of the present invention;

FIG. **6** is a front elevation of a heart in partial section showing artificial valves of the present invention;

FIG. **7** is a front elevation of a heart in partial section showing two artificial valves of further embodiments of the present invention;

FIG. **8** is a front elevation of the artificial valve of FIG. **7** in partial section;

FIG. **8A** is an enlarged partial section of an alternative embodiment of the artificial valve illustrated in FIG. **8**;

FIG. **9** is a cross section of the valve of FIG. **8** taken in the plane of line **9—9** of FIG. **8**;

FIG. **10** is an enlarged end view of an instrument with an artificial valve;

FIG. **11** is a bottom plan of an artificial valve having a pleated valve member in its expanded configuration;

FIG. **12** is a top plan of the valve of FIG. **11**;

FIG. **13** is a top plan of the valve of FIG. **12** with the valve member collapsed inward to allow flow through the valve;

FIG. **14** is an enlarged partial top plan of the artificial valve of FIG. **8**;

FIG. **15** is a top plan of the artificial valve of FIG. **8** partially collapsed;

FIG. **16** is an enlarged partial section of an artificial valve and installer,

FIG. **17** is an enlarged partial section of an artificial valve and an installer of an alternative embodiment to that shown in FIG. **16**;

FIG. **18** is an enlarged section of an instrument with the artificial valve and installer taken in the plane of line **18-18** of FIG. **10**; and

FIG. **19** is a cross section of the instrument of FIG. **18** with the artificial valve and installer removed.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings and in particular to FIG. **1**, artificial heart valves of the present invention are designated in their entireties by the reference numbers **10**A and **10**M. The artificial valve **10**A is specifically configured for repairing a damaged aortic valve A of a heart, generally designated by H. The artificial valve **10**M is specifically configured for repairing a damaged mitral valve M. In addition, an artificial

valve having a configuration similar to valve **10**A may be used to repair a damaged pulmonary heart valve (not shown), and a valve having a configuration similar to valve **10**M may be used to repair a damaged tricuspid heart valve (not shown). Each native heart valve (e.g., mitral valve M) normally has two cusps C (or three cusps in the case of the tricuspid valve) separating an upstream region (e.g., the left atrium LA) of the heart H from a downstream region (e.g., the left ventricle LV) of the heart positioned downstream from the upstream region. In use, the artificial heart valves (e.g., the artificial heart valve **10**M) are positioned between the upstream region and the downstream region, preferably between the cusps C of the respective native valve (e.g., the mitral valve M), to ensure blood flows through the heart H in the appropriate direction as will be explained in greater detail below.

As illustrated in FIG. **2**, the artificial valve **10**M comprises a flexibly resilient external frame, generally designated by **20**, and a flexible valve element, generally designated by **22**. The frame **20** includes a plurality of U-shaped stenting elements **30**. Each of the U-shaped elements **30** has a length extending between opposite ends. Although the elements **30** may have other lengths without departing from the scope of the present invention, the elements of the preferred embodiment have approximately equal lengths. Further, the elements **30** are joined generally midway between their respective ends at a junction **32** of the elements. Although four frame elements **30** are shown in FIGS. **2** and **3**, the valve **10**M may have fewer or more elements without departing from the scope of the present invention. Preferably, the stenting elements **30** are sufficiently compressible to permit the valve **10**M to be compressed to a configuration such as shown in FIG. **4** during implantation in the respective heart valve as will be explained below. Still further, the stenting elements **30** preferably are sufficiently resilient to hold the artificial valve **10**M in position between the cusps C of the native valve M after implantation and to hold the cusps of the native valve open. As used herein, the term "stenting" is intended to convey that the element **30** holds the cusps C of the native valve at least partially open.

Although the elements **30** of the preferred embodiment are made of nickel alloy wire, such as Nitinol superelastic alloy wire, available from Unitek Corp. of Monrovia, Calif., other materials may be used without departing from the scope of the present invention. The Nitinol may additionally include a PTFE (polytetrafluoroethylene) coating. Further, although the wire of the preferred embodiment has a rectangular cross section with dimensions of about 0.50 mm by about 0.762 mm, wires having other shapes and sizes may be used without departing from the scope of the present invention. In addition, the frame **20** may be of unitary construction. For instance, a small diameter tube of Nitinol or other appropriate material may have longitudinal slits extending from one end of the tube nearly to the opposite end, thereby forming multiple portions cantilevered from one end. Such cantilevered portions may be bent outward to form the frame of the artificial valve.

A peripheral anchor **34** is formed at each end of the frame elements **30**. As illustrated in FIG. **1**, these anchors **34** are used to attach the frame **20** between the plurality of cusps C of the damaged valve (e.g., the mitral valve M) in a position between an upstream region and a downstream region. Although other conventional anchor formations may be used without departing from the scope of the present invention, the anchors **34** of the preferred embodiment are hooks. It is envisioned the anchors **34** may also include conventional barbs (not shown) for preventing the hooks from being dislodged from the heart H after implantation. Further, as illustrated in FIG. **2**, in the most preferred embodiment the hooks form an angle B of between about 55 degrees and about 80 degrees with the ends of the frame elements **30**. In addition, the frame **20** includes a central portion, generally designated by **36**, located between the plurality of peripheral anchors **34**.

As further shown in FIG. **2**, a band, generally designated by **40**, extends around the frame **20** between each of the frame elements **30**. The band **40** extends between each frame element **30** and an adjacent frame element to limit maximum spacing S between the frame elements and to shape and cooperate with the elements to create a structurally sound frame construction. The band **40** permits the frame elements **30** to be pushed together so the flexibly resilient frame **20** can be collapsed to a collapsed configuration as shown in FIGS. **4** and **5**. Depending upon the procedure which is intended to be used when implanting the valve, the frame **20** collapses to configurations having different maximum widths X. For instance, if the artificial valve (e.g., **10**M) is implanted using endothoracoscopic methods, the maximum width X is less than about 18 mm and more preferably between about 12 mm and about 18 mm. However, if the valve (e.g., the artificial valve **10**A) is implanted through a smaller blood vessel, such as transvenously or transluminally, the maximum width X must be smaller. For instance, the maximum width X must be between about 4 mm and about 8 mm, more preferably between about 6 mm and about 8 mm and still more preferably about 6 mm. Thus, the frame **20** is sized and shaped for insertion between the plurality of cusps C of the damaged heart valve in a position between an upstream region and a downstream region. Further, because the frame **20** is flexible, it expands to an expanded configuration as shown In FIG. **2** when not collapsed. When in the expanded configuration, the frame **20** has different sizes depending upon which native valve it is intended to replace. For instance, if the artificial valve is intended to repair a damaged mitral valve M or a tricuspid valve, the opposite ends of the frame elements **30** are spaced by a distance D of between about 2 cm and about 5 cm. If the artificial valve is intended to repair a damaged aortic valve A or a pulmonary valve, preferably the opposite ends of the frame elements **30** are spaced by a distance D of between about 2 cm and about 3 cm.

Although the band **40** may be made of other materials, such as heterologous animal pericardium (e.g., bovine or porcine pericardium) or autologous tissue engineered substrates, without departing from the scope of the present invention, the band of the preferred embodiment is made of a biocompatible, radiopaque, elastic material such as silicone rubber or polyurethane or polytetrafluoroethylene. Further, although the band **40** may have other constructions without departing from the scope of the present invention, the band of the preferred embodiment comprises an internal strip **42** and an external strip **44** joined in face-to-face relation. Although the band **40** may be attached to the frame elements **30** by other means, in the most preferred embodiment, the internal and external strips **42**, **44**, respectively, are adhesively bonded to the frame elements and to each other. Further, although the band **40** illustrated in FIG. **2** is substantially cylindrical, it is envisioned the band may have other shapes without departing from the scope of the present invention. For example, it is envisioned the band **40** may include a rim or flange (not shown) surrounding the valve adjacent the hooks for engaging the cusps C. It is also envisioned that an exterior surface of the band **40** may include a continuous or interrupted sheath of

Dacron® velour material, porous PTFE (polytetrafluoroethylene) felt or the like to provide sites for vascular connective tissue ingrowth to enhance stability of the device after its implantation. (Dacron is a U.S. federally registered trademark of E.I. duPont de Nemours and Company of Wilmington, Del.)

The flexible valve element **22** is disposed within the frame **20** and attached to the central portion **36** of the frame. The valve element **22** has a convex upstream side **50** facing an upstream region (e.g., the left atrium LA) when the frame **20** is anchored between the cusps C of the damaged heart valve (e.g., mitral valve M) in a position between the upstream region and a downstream region; and a concave downstream side **52** opposite the upstream side facing the downstream region (e.g., the left ventricle LV) when the frame **20** is anchored between the cusps of the damaged heart valve in a position between the upstream region and the downstream region. The valve element **22** moves in response to differences between fluid pressure in the upstream region and the downstream region between an open position (as shown in phantom lines in FIG. **3**) and a closed position (as shown in solid lines in FIG. **3**). When the valve element **22** is in the open position, with the valve element **22** collapsed inward, it permits flow between the upstream region and the downstream region. When in the closed position, with the valve element **22** extended outward, the element **22** blocks flow between the upstream and downstream regions. The valve element **22** moves to the open position, with the element collapsed inward, when fluid pressure in the upstream region is greater than fluid pressure in the downstream region to permit downstream flow from the upstream region to the downstream region. The valve element **22** moves to the closed position, with the element extended outward, when fluid pressure in the downstream region is greater than fluid pressure in the upstream region to prevent flow reversal from the downstream region to the upstream region. Although the valve element **22** may be made of other materials without departing from the scope of the present invention, the valve element of the preferred embodiment is made of a biocompatible elastic material such as silicone rubber, polyurethane, PTFE, heterologous animal pericardium (e.g., bovine or porcine pericardium), or autologous tissue engineered substrates. Further, although the valve element **22** may have other thicknesses without departing from the scope of the present invention, the valve element of the preferred embodiment has a thickness of between about 0.127 mm and about 0.381 mm. In addition, it is envisioned the valve element **22** may be longitudinally pleated, as discussed in more detail below, without departing from the scope of the present invention (FIGS. **11–13**). Without wishing to be bound by any particular theory, it is envisioned that longitudinal pleats may encourage laminar flow through the valve when in the open position, with the valve element collapsed inward.

The upstream side **50** of the flexible valve element **22** has an apex **54** which is attached to the frame **20** at the junction **32** of the elements **30**. As illustrated in FIG. **3**, the flexible valve element **22** is attached to the central portion **36** of the frame **20** at a position substantially centered between the anchors **34**. Although the valve element **22** may be attached to the frame **20** by other means without departing from the scope of the present invention, the valve element of the preferred embodiment is attached to the frame by adhesive bonding. Further, the flexible valve element **22** is attached to the frame **20**, and more particularly to the band **40**, at several attachment points **56** around the frame. Thus, the valve element **22** forms flaps **58** extending between adjacent attachment points **56**. Each of the flaps **58** and a corresponding portion of the band **40** extending between adjacent attachment points **56** defines an opening **60** through the valve when the valve element **22** moves to the open position, with the flaps of the valve element collapsed inward. The artificial valve depicted in FIG. **3** depicts the preferred flap configuration, having three attachments points **56** and three flaps **58** spaced around the frame **20**. It is contemplated that other numbers of attachment points **56** (e.g., 2, 4, 5, 6, etc.) may be used without departing from the scope of the present invention. Although the valve element **22** may be attached to the band **40** using other means, the valve element of the preferred embodiment is attached to the band by adhesive bonding.

As illustrated in FIGS. **4** and **5**, the artificial valves **10**M, **10**A, respectively, are used in combination with instruments, generally designated by **70**M, **70**A, for inserting the artificial valve between the cusps C of damaged heart valves M, A. The instrument **70**M shown in FIG. **4** is intended for use when implanting the valve **10**M using an endothoracoscopic or transluminal procedure. It is envisioned this instrument would be used primarily when implanting an artificial valve in the mitral valve M, however similar instruments could be used to implant artificial valves in other native valves of the heart H such as the tricuspid or pulmonary valves. When used to implant an artificial valve in a mitral, tricuspid or pulmonary valve, the instrument could be introduced through a jugular or femoral vein. The endothoracoscopic instrument **70**M comprises a tubular holder **72**, and an elongate tubular manipulator **74** attached to the holder for manipulating the holder into position. Further, the instrument **70**M includes an ejector, generally designated by **76**, positioned in a hollow interior **78** of the holder **72** for ejecting the artificial heart valve **10**M from the holder. The hollow interior **78** of the holder **72** is sized for holding the artificial valve **10**M when the frame **20** is in the collapsed configuration (e.g., less than about 18 mm). Further, the hollow interior **78** may have axial grooves for receiving the anchors **34** of the valve to prevent the anchors from being tangled during valve implantation. Such grooves are described in greater detail below with respect to another embodiment. The manipulator **74** is a flexible tube attached to the holder **72** for manipulating the holder through an incision made in the heart H or selected vessel and into position adjacent the plurality of cusps C of the damaged heart valve. The ejector **76** includes a flat plunger tip **80** which engages the valve **10**M, a push rod **82** attached to the tip for moving the tip forward in the holder **72** for ejecting the valve from the holder, and a handle **84** attached to the push rod opposite the plunger tip for gripping the ejector when ejecting the valve from the holder.

To implant an artificial valve **10**M using the instrument **70**M via an endothoracoscopic procedure, a small opening is made in a chest wall (or another vascular access site) of a patient and a small incision is made in a heart H of the patient. The holder end **86** of the instrument **70**M is inserted through the opening made in the chest wall and the incision made in the heart H. The inserted end **86** of the instrument **70**M is positioned adjacent the cusps C of the damaged heart valve M and the artificial valve **10**M is ejected from the end of the instrument into a position between the cusps of the damaged valve as shown in FIG. **1**. When ejecting the valve **10**M from the end **86** of the instrument **70**M, it is envisioned that the handle **84** of the ejector **76** will be held in place while the manipulator **74** and holder **72** are withdrawn to push the valve out of the holder. Once the valve **10**M is in position, the instrument **70**M is withdrawn from the chest (or

another vascular access site) before the opening and incision are closed using conventional procedures. As will be appreciated by those skilled in the art, the valve **10**M may be implanted using this procedure with minimal trauma to the heart H and without removing the damaged heart valve from the heart.

The instrument **70**A shown in FIG. **5** is intended for use when implanting the valve **10**A by a transluminal procedure through a vessel. It is envisioned this instrument **70**A would be used when implanting an artificial valve in the aortic valve A. When used to implant an artificial valve **10**A in an aortic valve A, the instrument **70**A could be introduced through a femoral artery. The instrument **70**A comprises a holder **90** having a hollow interior **92** sized for holding the artificial valve **10**A when the frame **20** is in the collapsed configuration (e.g., less than about 6 mm) and an elongate flexible manipulator **94** attached to the holder for manipulating the holder through a vessel and into position adjacent the plurality of cusps C of the damaged heart valve A. Further, the instrument **70**A has a flexible ejector, generally designated by **96**, mounted in the hollow interior **92** of the holder **90** for ejecting the artificial heart valve **10**A from the hollow interior of the holder into position between the cusps C of the damaged heart valve A. The manipulator **94** is used to manipulate the instrument **70**A through the vessel. The ejector **96** includes a flat plunger tip **100** which engages the valve **10**A, a push rod **102** attached to the tip for moving the tip forward in the holder **90** for ejecting the valve from the holder, and a handle **104** attached to the push rod opposite the plunger tip for gripping the ejector when ejecting the valve from the holder. Both manipulators **74**,**94** may be configured to be long and flexible enough to be pushed or pulled through a vessel and/or over a conventional guidewire as discussed in greater detail below.

To implant an artificial valve **10**A using a transluminal procedure with instrument **70**A, a small incision is made in a vessel (e.g., the femoral artery) leading to a heart H. An end **106** of the instrument **70**A having the holder **90** is inserted through the incision made in the vessel and the end is pushed through the vessel and over a guidewire until the end is adjacent the cusps C of the damaged heart valve A. Once in position, the artificial valve **10**A is ejected from the end **106** of the instrument **70**A between the cusps C of the damaged heart valve A. As with the endothoracscopic procedure described above, the transluminal procedure may be performed with minimal trauma to the heart H and without removing the damaged heart valve from the heart and without cardiopulmonary bypass or heart arrest.

A second embodiment of the aortic valve is generally designated by **10**A' in FIG. **6**. This second embodiment is identical to the aortic valve of the first embodiment except that it includes a second band **110** surrounding the frame **20** downstream from the first band **40**. The second band **110** permits the frame elements **30** to be pushed together so the frame **20** can be collapsed to the collapsed configuration, but limits the maximum spacing between adjacent frame elements. It is envisioned that the second band **110** may be constructed similarly to the first band **40** and may be made from similar materials to the first band. As will be appreciated by those skilled in the art, the second band **100** of the aortic valve **10**A' supports the tissue surrounding the downstream region (i.e., the ascending aorta) and prevents the tissue from distending. An opening **112** provided between the first and second bands **40**, **110**, respectively, corresponds to openings of the right and left coronary arteries (designated by RC, LC, respectively) which enter the aorta immediately above the cusps C of the native valve so the replacement valve does not obstruct blood flow through these openings. Although the opening **112** may have other widths O without departing from the scope of the present invention, in one embodiment the opening has a width of between about 5 mm and about 10 mm. Although the second band **110** may have other lengths L without departing from the scope of the present invention, in one embodiment the second band **110** has a length of between about 6 cm and about 12 cm. It is further envisioned that hooks (not shown) may be provided along the frame elements **30** adjacent the second band **110** to engage the tissue to further prevent distention of the tissue.

In yet another embodiment of the present invention illustrated in FIGS. **8** and **9**, an artificial heart valve of another embodiment of the present invention, generally indicated by **210**, includes a flexibly resilient frame, generally indicated by **220**, having a plurality of peripheral anchors **234** for anchoring the frame in an expanded configuration, generally as set forth above. The flexibly resilient frame **220** includes frame elements **230** biased outward as set forth above. A central portion **236** of the frame **220** is centrally located between the plurality of peripheral anchors **234** of the frame. In addition, the artificial heart valve **210** includes a flexible valve element **222** attached to the central portion **236** of the frame having a convex upstream side **250** and a concave downstream side **252** opposite the upstream side. The valve element **222** moves in response to fluid pressure between an open position, with the valve element collapsed inward, and a closed position, with the element extended outward.

In addition, the artificial valve **210** may include a band, generally indicated by **240**, extending around the frame elements **230** to limit outward movement of the frame elements to the expanded configuration and to sealingly engage adjacent heart H tissue (FIGS. **7** and **8**). In one embodiment, the band **240** includes an inner portion **258** and an outer portion **260**. The inner portion **258** is formed to limit outward movement of the frame elements **230** and to act as a sealing surface for the valve element **222** in its closed position, where the element extends outward to seal against the inner portion. The outer portion **260** at least partially surrounds the inner portion **258** and has a memory, such that when the frame elements **230** are forced inward to a collapsed configuration, the outer portion urges the inner portion inward to a position inside the frame elements. Preferably, the frame elements **230** are biased outward by a spring force sufficient to overcome the inward force of the outer portion **260**, so that the frame elements maintain the frame **220** in the expanded configuration. The flexible valve element **222** is attached to the frame **220**, and more particularly to the band **240**, at several attachment points **256** around the frame. Thus, the valve element **222** forms flaps **257** extending between adjacent attachment points **256**. The preferred embodiment of the valve, shown in FIG. **13**, has three attachment points **256** and three flaps **257**. It is contemplated that other numbers of attachment points **256** (e.g., 2, 4, 5, 6, etc.) may also be used without departing from the scope of the present invention. FIG. **13**, however, shows a preferred embodiment having three equally spaced attachment points **256**, forming three flaps **257**. This configuration is thought to provide the maximum flow of blood through the valve **210** while maintaining flaps **257** that will close quickly when required. Flaps **257** of the three-flap preferred embodiment are also configured to be an optimal length circumferentially. The length of such flap **257** in the closed position, with the element extended outward, is approximately equal to 2.09r, where r is the radius of the valve. In the open position, with the valve element **222**

collapsed inward, the ideal length for the valve flap **257** is 2r, which is approximately equal to 2.09r. The substantial congruence of these two lengths (2r and 2.09r) facilitates proper support of the valve element **222** without undue stress due to incongruence of optimal flap length between the open and closed positions.

In addition, it is envisioned the valve element **222** may be longitudinally pleated as depicted in FIGS. **11–13**. Pleats **264** encourage proper folding of the valve element **222** when the valve **210** collapses (FIG. **10**). The pleats **264** may be of a wide range of numbers and spacing. For example, the valve **210** of FIGS. **10** and **11** includes a valve element **222** having many pleats of uniform size and shape. The number of pleats **264** may be reduced or increased from what is shown in FIGS. **11** and **12**, without departing from the scope of the present invention. Moreover, the spacing between the pleats **264** may be altered. For example, for an element **222** having pleats **264**, half of the pleats may have wide spacing while the other half may have narrow spacing. These pleats may be alternated, for example, wide-narrow-wide-narrow etc. Other combinations of pleats **264** having relatively different spacing are also contemplated as within the scope of the present invention. Without wishing to be bound by any particular theory, it is envisioned that longitudinal pleats **264** may encourage laminar flow through the valve when in the open position, with the valve element **222** collapsed inward, as shown in FIG. **13**.

The inner portion **258** preferably has a width B between about 4.0 mm and about 6.0 mm. The opposite sides of the band **240** are preferably spaced by a distance D of between about 21 mm and about 33 mm, depending upon the intended application of the artificial valve **210**. This yields an artificial valve **210** with a perimeter in the expanded configuration of between about 60 mm and about 100 mm. In the collapsed configuration, the opposite sides of the band **240** are preferably spaced by a distance of no more than between about 6.0 mm and about 8.0 mm.

The inner portion **258** may comprise a material selected from the group consisting of PTFE, Dacron® velour material, Dacron® porous cloth, a synthetic polymer and biological source tissue. Alternately, non-synthetic materials may be used for the inner portion **258**. Heterologous preserved tissues from bovine or porcine pericardium may be used as disclosed above. In addition, autologous tissues (i.e., those derived from a patient's own tissue) may be used as a substitute for synthetic or heterologous tissues. It is envisioned that the previously described band **240** and flexible valve element **222**, described below, could be made from autologous tissues, thereby eliminating the possibility of immune system or foreign body rejection complications sometimes caused by synthetic material or heterologous tissue.

The outer portion **260** has a width B' that is substantially similar, yet slightly wider than the inner portion. This larger width B' allows the outer portion **260** to attach to the frame elements **230** at several contact points **270** outside the opposite edges of the inner portion **258**. The outer portion **260** preferably attaches to the frame elements **230** by laser welding, epoxy bonding or other means as would be readily understood by one skilled in the art, such that the outer portion **260** can move independent from the inner portion **258**. Therefore, when the artificial valve **210** collapses or expands, the outer portion **260** and inner portion **258** are free to move independently, without binding upon one another. The outer portion **260** urges the inner portion **258** inward between the frame elements as shown in FIG. **15**. This ensures that the inner portion **258** of the band **240** folds into the proper shape upon collapse of the artificial valve **210**. The purpose of the outer portion **260** of the band **240** is to prevent the inner portion **258** from protruding outward beyond the frame elements **230** when the artificial valve **210** is collapsed. Without the outer portion **260**, segments of the inner portion **258** located between the frame elements **230** would be free to flex either inward or outward as the frame elements **230** move inward. With the outer portion **260**, the inner portion folds inward between the frame elements **230**. The outer portion **260** essentially prevents the inner portion **258** from prolapsing outwardly as the valve collapses, which could impede loading of the artificial valve **210** into a holder **276**, as will be described below. Folding the inner portion **258** inward also provides a smaller distance D between opposite sides of the band **240** when the artificial valve **210** is in the collapsed configuration. Moreover, the outer portion **260**, due to its inherent material properties, provides a lower friction surface for the artificial valve **210** as it moves to and from the holder **276**.

The outer portion **260** preferably comprises a braided mesh **282**, in which thin filaments **284** are braided into a woven fabric (FIGS. **8** and **9**). Such filaments **284** each preferably have a thickness of between about 0.05 mm and about 0.13 mm. The filaments **284** may comprise Nitinol superelastic alloy, stainless steel alloy, Elgiloy® alloy (available from Elgin National Watch Company of Elgin, Ill.), fiberglass, PTFE, polyester or Lycra® (available from E.I. duPont de Nemours and Company of Wilmington, Del.). The thin filaments **284** of the mesh **282** preferably move freely with respect to one another, such that the mesh may change its shape and size as the artificial valve **210** moves between its expanded and collapsed configurations. Where the material of the braided mesh **282** is a metal with shape memory, the outer portion **260** may be heat treated to set the unrestricted perimeter of the braided mesh to be smaller than the size of the desired collapsed configuration. Treating the braided mesh **282** to constrict to smaller than the collapsed configuration ensures that the braided mesh continues to exert a compressive force upon the artificial valve **210** irrespective of valve configuration. Therefore, for an artificial valve **210** having a collapsed dimension of between about 6.0 mm and about 8.0 mm, the braided mesh **282** preferably is heat treated to a dimension less than the collapsed valve dimension. Thus, by heat treating the braided mesh **282** of the outer portion **260** as described above, it biases the inner portion **258** and frame elements **230** inward in all configurations. Such inward forces caused by the outer portion **260** oppose the outward spring forces of the frame elements **230**. As such, the outwardly directed force of the frame elements **230** are preferably greater than the inwardly directed force of the band **240** to ensure the artificial valve **210** will expand to its expanded configuration when released from its holder **276**.

In an alternative embodiment depicted in FIG. **8A**, the valve **210'** comprises a thin strand **296**, instead of a band **240**, extending around the frame elements **230** to limit outward movement of the frame elements to their expanded configuration. The thin strand **296** functions in primarily the same way as the band **240**. The strand **296** includes an inner portion **258'** and an outer portion **260'** substantially as disclosed above with respect to the band **240**. The valve **210'** of the alternative embodiment is identical to the valve **210** of the previously described embodiment in all other respects.

The frame **220** preferably includes a post **310**, or more generally a mount, generally indicated by **300**, for selectively connecting the artificial valve **210** to an instrument,

generally indicated by **306** (FIG. **18**). In one embodiment, the post **310** mounts on the frame **220** (FIGS. **8**, **14**, **16** and **17**) and includes an opening **212** (FIG. **14**) to allow an implement **214**, such as a guide, or guidewire, as depicted in FIG. **16** and described in detail below, to pass through the valve **210**. The opening **212** extends through at least one of the frame **220** and the valve element **222** for receiving the implement **214** (FIGS. **8** and **16**). Although the opening **212** of the illustrated embodiment extends through the central portion **236** of the frame **220** and the valve element **222**, it is envisioned that the opening **212** could extend through other portions of the artificial valve **210** without departing from the scope of the present invention. After removal of the implement **214**, it is envisioned the opening **212** may provide surface washing to reduce a potential for blood to coagulate adjacent the downstream side (i.e., the concave side **252**) of the valve element **222**. It is further envisioned the opening **212** may be used even where an implement **214** is not needed to reduce potential for blood to coagulate adjacent the valve element **222**. Although this opening **212** may have other dimensions without departing from the scope of the present invention, in one embodiment the opening has a width of between about 0.5 mm and about 1 mm, and more preferably a width of about 1 mm.

The post **318** may additionally include a releasable fastener **314**. For example, the post **318** may include threads **320** (FIG. **16**) for attaching the valve **210** to the instrument **306**. Either the inside or outside of the post **318** may be threaded, but is preferably externally threaded, as shown in FIGS. **8** and **16**. Preferably, the post **318** has an inner diameter ID of about 1.0 mm (FIG. **16**) and an outer diameter OD of about 2.0 mm. The post **318** is also preferably right-hand threaded, although left-hand threads are contemplated as being within the scope of the present invention.

As illustrated in FIG. **18**, the instrument **306** of the present invention further includes the holder **276**, having a hollow interior **332** sized for holding the artificial valve **210** when the frame **220** of the valve is in the collapsed configuration. The holder **276** includes an outwardly flared end **336** for receiving the peripheral anchors **234** while the artificial valve **210** is within the holder. This shields the anchors **234** from engaging valvular or endocardial structures as the artificial valve **210** is retrieved into the holder **276** for repositioning, as will be discussed in greater detail below. In addition, the flared end **336** facilitates receiving the artificial valve **210** within the holder **276** by creating a smooth and gradual entry for the valve, such that the frame elements **230** may collapse more easily as the artificial valve is pulled into the holder by the instrument **306**. The holder **276** additionally includes internal, longitudinal grooves **338** extending the length of the holder (FIGS. **10** and **19**). This grooving **338** helps guide the frame elements **230** and anchors **234** into individual grooves as the valve **210** is ejected from or retrieved into the holder **276**. By providing a groove **338** for each frame element **230**, the valve **210** will collapse uniformly within the holder **276**, thereby ensuring that the valve element **222** collapses properly, as shown in FIG. **10**. The holder **276** is formed from a material sufficiently strong to limit outward movement of the frame elements **230** when the valve **210** is in the holder. An artificial valve **210** of the present invention is preferably collapsible to its collapsed configuration such that the dimension D' of the artificial valve is about 5 mm to about 8 mm. Thus, the holder **276** requires an inner dimension D' of at least about 5 mm to about 8 mm to receive the artificial valve **210** in its collapsed configuration. It is contemplated that the holder **276** will have an outer dimension OD'" of about 6 mm to about 9 mm along most of its length. The outwardly flared end **336** is formed to have a slightly larger dimension than the holder **276** (e.g., about 7 mm to about 10 mm) to accommodate the anchors **234**. Although the holder **276** must be sufficiently strong to limit outward movement of the frame elements **230**, once the valve **210** is removed, the holder may collapse slightly as it is removed from the body to ease its removal.

The instrument **306** further comprises an elongate manipulator **344** extending from the holder **276** for manipulating the holder into position between the upstream region and the downstream region. As shown in FIG. **18**, the holder **276** and elongate manipulator **344** are of unitary construction, although it is contemplated that they may be formed separately and then joined. Depending upon the size of the patient and the entry point of the elongate manipulator **344** (e.g., femoral artery, femoral vein, jugular vein, endoscopic trans-thoracic), manipulators of different length are needed. The manipulator **344** must be long enough to allow the artificial valve **210** to reach the damaged heart valve, without having additional unnecessary length which may hinder remote movement of the manipulator. The elongate manipulator **344** preferably has a minimum inner dimension ID' of about 2.5 mm to about 3.0 mm to accommodate an installer **328**, as described in detail below.

The elongate manipulator **344** is preferably formed of a material sufficiently flexible to allow bending as it passes through the body of the patient. In addition, the material is preferably sufficiently rigid such that the holder **276** at the end of the manipulator **344** moves in response to manual movements of the elongate manipulator. The elongate manipulator **344** is preferably both flexible for threading through the vessel of the patient, while still possessing the column strength required to push the elongate manipulator through the vessel. Materials capable of meeting such requirements include PTFE, polyurethane, polyvinyl or polyethylene combined with a radiopaque treatment. In addition, magnetically directed catheter guidance technology may also be applied to the elongate manipulator **344** to aid in guiding the manipulator through the vessel. One skilled in the art would readily understand how to apply such technology to the present invention. An example of magnetically directed catheter guidance technology is available from Stereotaxis, Inc. of St. Louis, Mo.

The elongate manipulator **344** further includes a hollow interior **348** shaped and sized to receive the installer **328**. The installer is releasably attachable to the artificial heart valve **210** for maneuvering the artificial heart valve from the hollow interior **332** of the holder **276** into position between the upstream region and the downstream region of the damaged heart H. In one embodiment, an end **352** of the installer **328** includes an internally threaded portion **354** for threadably receiving the externally threaded post **310** of the valve **210**. This allows the user to push the valve **210** from the holder **276** and selectively release the installer **328** from the post **310** of the valve by rotating the installer, thereby unscrewing the installer from the post. The installer **328** and elongate manipulator **344** may then be removed from the surgical field. Preferably, the internally threaded portion **354** would have an inner dimension ID" of about 2.0 mm to match the outer dimension OD of the externally threaded post **310**. In one embodiment, the end **352** of the installer **328** preferably has an outer dimension OD' of about 2.5 mm while the remaining portion of the installer has an outer dimension OD" of about 2.0 mm.

In a different installer and post embodiment, the post **310'** includes a bayonet fastener **360** as depicted in FIG. **17**.

Rather than threading onto the installer **328**, the bayonet fastener **360** includes a keyway **362** for receiving a key **364** extending from the post **310'**. The key **364** and keyway **362** cooperate to maintain the installer **328** connected to the post **310'**. To disengage the bayonet fastener **360**, the user simply rotates the installer **328** and pulls, thereby allowing the key **364** to pass through and escape from the keyway **362**. The positions of the keyway **362** and key **364** may switch, such that the post **310'** includes the keyway and the installer includes the key, without departing from the scope of the present invention.

Returning to the previous embodiment, illustrated in FIG. **16**, the installer **328** further includes an open central channel **370** passing through the length of the installer. This channel **370** permits passage of implements **214** (e.g., guides, catheters, etc.) to aid in installing the artificial valve **210**. Preferably, the channel **370** has an inner dimension ID'" of about 1.0 mm for accommodating implements **214** of up to that dimension. The ID'" and OD" may vary somewhat, however, depending upon the particular valvular implant procedure. The sizes indicated here are for illustrative purposes only, and one skilled in the art would readily understand that such dimensions may vary without departing from the scope of the present invention. The installer **328** is preferably fabricated from any type of biocompatible metallic or elastomeric material. Preferably, the installer **328** is also of a flexible construction and is radiopaque.

The guide **214** of the present invention aids in guiding the artificial valve **210** through a body of a patient and into position between the upstream region and the downstream region of the damaged heart H. The guide **214** is elongate, flexible and sized for receipt within the opening **212** to guide the valve **210** into position. As discussed above, the guide **214** is much smaller than the elongate manipulator **344**, preferably formed with a dimension no greater than about 1.0 mm. Because the guide **214** is much smaller than the manipulator **344**, it can be more easily maneuvered through the vessels of the patient to the heart H. Once the guide **214** is placed within the patient and guided to the area of interest, the manipulator **344** and installer **328** may be threaded onto the guide for passage to the area of surgical interest as explained below.

The present invention may further comprise an implement **214** functioning as a vascular catheter **214**. The vascular catheter **214** may include a sensor for registering and sending a signal through the vascular catheter for vascular monitoring. Such a sensor may preferably comprise a pressure sensor or an oximetry sensor. In addition, the vascular catheter **214** may comprise a dye injector for injecting dye into the heart H. Each of these vascular catheters **214** performs a specific function, readily understood by one skilled in the art.

The artificial valve **210** of the present invention is preferably installed in an antegrade orientation, meaning that the valve is ejected from the holder **276** in the direction of blood flow. Such antegrade applications include implantation to the mitral M, pulmonary or tricuspid valves via transvenous routes, typically via the femoral vein. For the mitral valve M implantation, the artificial valve **210** typically passes through the femoral vein and into the right atrium. From there, the surgeon performs a septostomy to create a small atrial septal perforation (i.e., atrial septal defect (ASD)) between the right atrium and left atrium LA to gain access to the left atrium. Such an ASD may require closure if unacceptable levels of shunting across the ASD are shown by testing (e.g., Doppler color flow imaging, blood oximetry, excessive pressure gradients). Such an antegrade orientation will apply to both endoscopic and open thoracotomy implants into the mitral valve M through a left closed atriotomy beating heart procedure without cardio pulmonary bypass and cardioplegia or a left open atriotomy with cardio pulmonary bypass and cardioplegia.

It is envisioned that the previously described instrument **306** would permit implantation of an artificial valve **210** by a transseptal procedure or a retrograde non-transseptal procedure. Transseptal access is conventionally used for balloon valvuloplasty of the mitral valve M with an Inoue single balloon catheter or another type of balloon catheter (e.g., Mansfield balloon catheter, available from Mansfield Scientific, Inc., of Mansfield, Mass.). Each of these procedures requires the intentional, controlled creation of an ASD between the right and left atria. Such a septostomy is required for the transseptal procedures noted above. The initial penetration of the atrial septum is typically performed using a Brockenbrough® catheter/needle (available from C.R. Bard, Inc. of Murray Hill, N.J.), which provides an atrial septal penetration of about 8.5 French (Fr.) (2.8 mm). Further dilation may then be provided using a 24 Fr. (8.0 mm) dilation catheter balloon about 30 mm in length. For the Inoue balloon, a 14 Fr. (4.7 mm) or 16 Fr. (5.3 mm) dialator sheath may be advanced through the septum after the initial penetration. Such procedures provide a relatively low incidence rate of a significant residual ASD. Such rates tend to fall in a range of about ten to about fifteen percent. Identifying such residual ASDs is readily accomplished by measuring transluminal pressure gradients or blood oximetry within the heart H. For example, an excessive left atrium to right atrium transmural pressure gradient may indicate a shunt between atria. Similarly, blood oximetry indicators, such as an oxygen saturation in the right atrium more than about seven percent by volume greater than blood in the superior vena cava, may also indicate a shunt. However, what may in fact be an insignificant residual ASD can present as a false positive on a color-flow Doppler study, but this can be further analyzed by a Valsalva maneuver bubble test, as one skilled in the art would appreciate. Finally, although the projected size of ASDs are quite large when considering the balloon dimensions noted above, the atrial septum in the area of penetration (i.e., fossa ovalis) is elastic, thereby contracting and closing the septostomy after removal of a balloon or other surgical tool. These surgically created defects typically close and heal spontaneously, but may also be closed with some type of closure device if required. One skilled in the art would readily understand how to make such determinations concerning possible shunts.

Aortic valve A access with an antegrade valve implant procedure is also possible by the method disclosed above (i.e., femoral vein to right atrium to left atrium LA) with the additional passage of the artificial valve through the mitral valve M and into the left ventricle LV. Alternately, access to the aortic valve A is possible in a retrograde configuration (e.g., from the femoral artery), as described above with respect to FIG. **5**. Such an installation would not include the use of a releasable fastener, but would incorporate a plunger tip **80** and push rod **82** as set forth above. The push rod **82** could be configured with a central channel, however, such that the advantages of the presently disclosed guide **214** may be adapted to retrograde applications. The artificial valve **210**, push rod **82** and manipulator **74** may be threaded onto the guide **214** to facilitate positioning the artificial valve adjacent the damaged aortic valve A. Such an arrangement also provides access for a vascular catheter **214** as described herein, such that pressure readings and dye injections may be made near the aortic valve A implant site.

In addition, the present invention is directed to an endothoracoscopic method of inserting the artificial valve **210** described above between a plurality of cusps C of a damaged heart valve. The method comprises multiple steps, some of which are not depicted in the figures because one skilled in the art would readily understand how to perform such steps by referencing the claims and specification only. First, an opening is made in a chest wall of a patient. Then, an incision is made in the heart H of the patient. Determining the location, orientation and size of such an opening and incision are well within the skill and understanding of one skilled in the art. The end **336** of the elongate instrument **306** is then inserted through the opening made in the chest wall and the incision made in the heart H. The surgeon may then position the inserted end **336** of the instrument adjacent the plurality of cusps C of the damaged heart valve. This procedure is particularly applicable to the mitral valve or the tricuspid valve. The artificial valve **210** within the instrument **306** may then be ejected from the end **336** of the instrument and positioned adjacent the plurality of cusps C of the damaged heart valve. If placed properly, this ejection will place the artificial valve **210** into a position between the plurality of cusps C of the damaged heart valve without removing the damaged heart valve from the heart H and without cardiopulmonary bypass or cardioplegia. With the artificial valve **210** properly placed within the heart H, the surgeon may then remove the instrument **306** from the patient and complete the surgery.

In some instances, however, the position of the artificial valve **210** in the heart H may not be optimal after the first ejection from the instrument **306**. In those cases, the surgeon may then retrieve the artificial valve **210** into the end **336** of the instrument **306**. Retrieving the artificial valve **210** into the instrument **306** is accomplished by advancing the elongate manipulator **344** over the installer **328**. Such relative movement between the installer **328** and the elongate manipulator **344** retrieves the artificial valve **210** to within the holder **276**, thereby forcing the valve from its expanded configuration to its collapsed configuration. The surgeon may then reposition the inserted end **336** of the instrument **306** adjacent the plurality of cusps C of the damaged heart valve and eject the repositioned artificial valve **210** from the end of the instrument again. This provides the surgeon with the flexibility to reposition the artificial valve **210** between the plurality of cusps C of the damaged heart valve multiple times until the positioning is optimal.

In yet another method of the present invention, an artificial valve **210** as described above may be inserted transluminally and placed between a plurality of cusps C of a damaged heart valve. Such a method is similar to the method disclosed immediately above, except that an incision is made in a vessel leading to the heart H, an end **336** of an elongate flexible instrument **306** is inserted through the incision made in the vessel and the end of the instrument is pushed through the vessel to be positioned adjacent the plurality of cusps C of the damaged heart valve. Once in position, the method is essentially the same. The method provides a surgeon with the flexibility to position and reposition the artificial valve **210** within the heart H.

In another method of the present invention, the artificial valve **210** is again inserted transluminally after making an incision in a vessel leading to the heart H. Here, however, an end **378** of the guide **214** is first inserted through the incision made in the vessel. The guide **214** is preferably smaller in its width dimension than the instrument **306** that will be inserted later. The smaller dimension of the guide **214** simplifies the task of pushing the guide through the vessel to the heart H of the patient, especially where the vein is of a smaller inner dimension. Once the guide **214** is in the proper position near the heart valve of the patient, the elongate flexible instrument **306** with hollow interior **348** is threaded onto the guide. The end **336** of the elongate flexible instrument **306** may then be threaded through the incision made in the vessel and pushed through the vessel along the guide **214** until the end is adjacent the plurality of cusps C of the damaged heart valve. Because the guide **214** has delineated a path for the instrument **306** to the heart H, the instrument may more easily pass through the vessel. Once in position, the artificial valve **210** may be ejected from the end **336** of the instrument **306** positioned adjacent the plurality of cusps C of the damaged heart valve into a position between the plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart H.

As will be appreciated by those skilled in the art, the valves and instruments described above permit "beating heart" procedures (i.e., without cardiopulmonary bypass or cardioplegic arrest) in part due to the relatively small size of the valves and instruments. Further, the valves described above permit implantation without removal of the native valves. The valves also permit some correction of valvular stenosis along with correction of regurgitant valvular disease. It is further envisioned that the valves described above may be coated with heparin or other protective coatings and immune suppressant coatings (e.g., rapamycin coating) to reduce coagulation or immune inflammatory response initiation.

It is envisioned that the valves of the present invention may be suitable for implant in pediatric patients due to their small size and substantially unrestricted flow characteristics. Further, because the valves adaptively expand, they are capable of expanding to fit a growing child.

It is further envisioned that rapidly implanting the valves of the present invention using an endothoracoscopic technique may provide a suitable remedy of acute papillary muscle dysfunction due to major chordal rupture or frank papillary muscle infarction.

In heavily calcified native valves, implantation of the valve described above could remedy regurgitant disease without disturbing the calcific deposits.

When used in the mitral M site, the valve described above avoids problems associated with valve cusp stents and fabric arms present in prior art bioprosthetic valves. Also use of the valve described above at the mitral M site eliminates removal of or damage to papillary muscles and all of the chordae tendinae thereby preserving systolic apical movement. Still further, the valve described above is compliant and capable of regurgitant control in cases of ischemic mitral regurgitation.

When used in the aortic valve A site, placement of the valve may be controlled using fluoroscopic guidance or echocardiographic guidance to ensure the native cusps C are positioned in the valve sinuses and the coronary openings above the valve site are not obstructed. It is envisioned that a conventional dye injection technique may be used to identify the coronary openings.

When used to implant the valve in either the Mitral or Atrial site, fluoroscopy and/or echocardiographic studies may be used to verify proper device positioning prior to release of the artificial valve.

In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results attained.

When introducing elements of the present invention or the preferred embodiment(s) thereof, the articles "a", "an",

"the" and "said" are intended to mean that there are one or more of the elements. The terms "comprising", "including" and "having" are intended to be inclusive and mean that there may be additional elements other than the listed elements.

As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

What is claimed is:

1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:

a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located along a centerline extending between the plurality of peripheral anchors and between the upstream region and the downstream region when said frame is inserted in the position between the upstream region and the downstream region;

a flexible valve element attached to the central portion of the frame having an upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region, said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region; and

an opening extending through at least one of said frame and said flexible valve element for receiving an implement.

2. An artificial valve as set forth in claim **1** wherein said opening extends through the central portion of the frame and the flexible valve element.

3. An artificial valve as set forth in claim **2** further comprising a releasable fastener mounted on the frame for selectively connecting the valve to an instrument.

4. An artificial valve as set forth in claim **3** wherein the fastener comprises a hollow post mounted on the central portion of the frame coaxial with the opening.

5. An artificial valve as set forth in claim **4** wherein said fastener comprises a threaded fastener.

6. An artificial valve as set forth in claim **5** wherein said post is externally threaded.

7. An artificial valve as set forth in claim **4** wherein said fastener comprises a bayonet fastener.

8. An artificial valve as set forth in claim **1** wherein said flexibly resilient frame includes frame elements extending outward from the central portion, said frame elements being biased outward to engage the heart tissue and hold the frame in an expanded configuration in the position between the upstream region and the downstream region.

9. An artificial valve as set forth in claim **8** further comprising a band extending around the frame elements to limit outward movement of the frame elements to the expanded configuration and to sealingly engage adjacent heart tissue.

10. An artificial valve as set forth in claim **9** wherein said band includes an inner portion formed to limit outward movement of the frame elements, and an outer portion at least partially surrounding said inner portion and being biased inward, such that when the frame elements are forced inward to a collapsed configuration, the outer portion urges the inner portion inward to a position inside the frame elements.

11. An artificial valve as set forth in claim **10** wherein the frame elements are biased outward by a spring force sufficient to overcome the inward bias of the outer portion, so that the outward spring force maintains the frame in the expanded configuration.

12. An artificial valve as set forth in claim **11** wherein said outer portion comprises a braided mesh.

13. An artificial valve as set forth in claim **12** wherein said braided mesh comprises a woven fabric of filaments, each having a width of between about 0.05 mm and about 0.13 mm.

14. An artificial valve as set forth in claim **12** wherein said braided mesh comprises a material selected from the group consisting of Nitinol superelastic alloy, stainless steel alloy, Elgiloy® alloy, fiberglass, PTFE, polyester and Lycra®.

15. An artificial valve as set forth in claim **10** wherein said inner portion comprises a material selected from the group consisting of PTFE, Dacron® velour, Dacron® porous cloth, a synthetic polymer and biological source tissue.

16. A artificial valve as set forth in claim **8** further comprising a thin strand extending around the frame elements to limit outward movement of the frame elements to the expanded configuration.

17. An endothoracoscopic method of inserting an artificial valve as set forth in claim **1** between a plurality of cusps of a damaged heart valve, said method comprising the steps of:

making an opening in a chest wall of a patient;

making an incision in a heart of the patient;

inserting an end of an elongate instrument through the opening made in the chest wall and the incision made in the heart;

positioning the inserted end of the instrument adjacent the plurality of cusps of the damaged heart valve;

ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart;

retrieving the artificial valve into the end of the instrument;

repositioning the inserted end of the instrument adjacent the plurality of cusps of the damaged heart valve; and

ejecting the repositioned artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

18. A transluminal method of inserting an artificial valve as set forth in claim 1 between a plurality of cusps of a damaged heart valve, said method comprising the steps of:

making an incision in a vessel leading to the heart;

inserting an end of an elongate flexible instrument through the incision made in the vessel;

pushing the end of the instrument through the vessel;

positioning the end adjacent the plurality of cusps of the damaged heart valve;

ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart;

retrieving the artificial valve into the end of the instrument;

repositioning the inserted end of the instrument adjacent the plurality of cusps of the damaged heart valve; and

ejecting the repositioned artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

19. A transluminal method as set forth in claim 18 further comprising performing a septostomy between the atria of the heart and pushing the instrument through an atrial septal perforation created by the septostomy.

20. A transluminal method of inserting an artificial valve as set forth in claim 1 between a plurality of cusps of a damaged heart valve, said method comprising the steps of:

making an incision in a vessel leading to the heart;

inserting an end of a guide through the incision made in the vessel;

pushing the guide through the vessel;

threading an elongate flexible instrument having a hollow interior onto the guide;

inserting an end of the elongate flexible instrument through the incision made in the vessel;

pushing the end of the instrument through the vessel along the guide until the end is adjacent the plurality of cusps of the damaged heart valve; and

ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

21. A transluminal method as set forth in claim 20 further comprising performing a septostomy between the atria of the heart and pushing the instrument through an atrial septal perforation created by the septostomy.

22. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:

a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region;

a flexible valve element fixedly attached to the frame so that at least a portion of the element is substantially immobile with respect to at least a portion of the frame, said element having a convex upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region, said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region; and

an opening extending through at least one of said frame and the flexible valve element.

23. An artificial valve as set forth in claim 22 further comprising a releasable fastener mounted on the frame for selectively connecting the valve to an instrument.

24. An artificial valve as set forth in claim 23 wherein the fastener comprises a hollow post mounted on the frame coaxial with the opening.

25. An artificial valve as set forth in claim 24 wherein said fastener comprises a threaded fastener.

26. An artificial valve as set forth in claim 25 wherein said post is externally threaded.

27. An artificial valve as set forth in claim 24 wherein said fastener comprises a bayonet fastener.

28. An artificial valve as set forth in claim 27 wherein said flexibly resilient frame includes frame elements extending outward from the central portion, said frame elements being biased outward to engage the heart tissue and hold the frame in an expanded configuration in the position between the upstream region and the downstream region.

29. An artificial valve as set forth in claim 28 further comprising a band extending around the frame elements to limit outward movement of the frame elements to the expanded configuration and to sealingly engage adjacent heart tissue and form a seal with the heart.

30. An artificial valve as set forth in claim 29 wherein said band includes a inner portion formed to limit outward movement of the frame elements, and an outer portion at least partially surrounding said inner portion and being biased inward, such that when the frame elements are forced inward to a collapsed configuration, the outer portion urges the inner portion inward to a position inside the frame elements.

31. In combination, an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, and a guide for guiding the artificial valve between the upstream region and the downstream region, said combination comprising:

said artificial valve including

a flexibly resilient frame sized and shaped for insertion between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region and a central portion

located along a centerline extending between the plurality of peripheral anchors,

a flexible valve element fixedly attached to the central portion of the frame so that at least a portion of the element is substantially immobile with respect to the central portion of the frame, said element having an upstream side fading said upstream region when the frame is anchored between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored between the upstream region and the downstream region, said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region, and

an opening extending through at least one of said frame and the flexible valve element; and

said flexible, elongate guide sized for receipt within the opening to guide the valve into position.

32. A combination as set forth in claim **31** further comprising a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration.

33. A combination as set forth in claim **32** further comprising an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region.

34. A combination as set forth in claim **33** further comprising an installer received within the hollow interior of the holder and releasably attachable to the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

35. A combination as set forth in claim **32** wherein the holder comprises an outwardly flared end for receiving the artificial valve within the holder.

36. A combination as set forth in claim **32** wherein the holder comprises internal, longitudinal grooving for guiding the flexibly resilient frame.

37. A combination as set forth in claim **31** further comprising a vascular catheter.

38. In combination, an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, and an instrument for inserting the artificial valve between the upstream region and the downstream region, said combination comprising:

said artificial valve including

a flexibly resilient frame sized and shaped for insertion between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors, and

a flexible valve element fixedly attached to the frame so that at least a portion of the element is substantially immobile with respect to the central portion of the frame, said element having an upstream side facing said upstream region when the frame is anchored between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored between the upstream region and the downstream region, said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region, and

an opening extending through at least one of said frame and the flexible valve element; and

an instrument including

a holder having a hollow interior sized for holding the artificial valve when the frame is in a collapsed configuration,

an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region, and

an installer received within the hollow interior of the holder and releasably attachable to the frame of the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

39. A combination as set forth in claim **38** wherein the frame includes a mount for selectively connecting the valve to the instrument.

40. A combination as set forth in claim **39** wherein the mount comprises a post mounted on the frame.

41. A combination as set forth in claim **40** wherein said post comprises a threaded fastener.

42. A combination as set forth in claim **41** wherein said post is externally threaded.

43. A combination as set forth in claim **42** wherein said installer includes an internally threaded portion for threadably receiving said externally threaded post.

44. A combination as set forth in claim **40** wherein said post comprises a bayonet fastener.

45. A combination as set forth in claim **38** wherein said holder has an outwardly flared end for receiving the peripheral anchors when the artificial valve is within the holder.

46. A combination as set forth in claim **38** wherein the holder comprises internal, longitudinal grooving for guiding the flexibly resilient frame.

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(12) **INTER PARTES REVIEW CERTIFICATE** (1966th)
United States Patent
Snyders

(10) **Number: US 6,821,297 K1**
(45) **Certificate Issued: Mar. 19, 2021**

(54) **ARTIFICIAL HEART VALVE, IMPLANTATION INSTRUMENT AND METHOD THEREFOR**

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Trial Number:

IPR2018-00109 filed Oct. 23, 2017

Inter Partes Review Certificate for:

Patent No.: **6,821,297**
Issued: **Nov. 23, 2004**
Appl. No.: **10/135,746**
Filed: **Apr. 30, 2002**

The results of IPR2018-00109 are reflected in this inter partes review certificate under 35 U.S.C. 318(b).

INTER PARTES REVIEW CERTIFICATE
U.S. Patent 6,821,297 K1
Trial No. IPR2018-00109
Certificate Issued Mar. 19, 2021

AS A RESULT OF THE INTER PARTES REVIEW PROCEEDING, IT HAS BEEN DETERMINED THAT:

Claims **18** and **20** are found patentable.

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