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(54) Title: EXPANDABLE VALVE AND METHOD OF USE

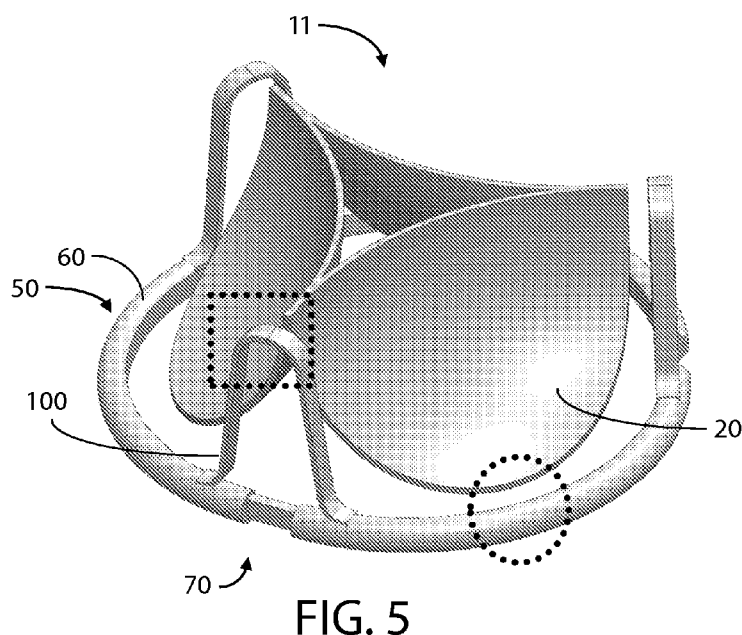


FIG. 5

(57) Abstract: Methods and apparatuses relate to an expandable valve that may be implanted within the body, for example, at a semilunar position of the heart. The valve may include an expandable valve frame disposed about a number of valve leaflets and may be implanted in young patients. The diameter of the expandable valve frame may be suitably increased to accommodate patient growth where the valve is stretched to expand along with the valve frame. In some embodiments, an expandable valve is disposed within a covered stent having expandable cuffs attached at opposite ends of the stent. The expandable cuffs of the device may be surgically attached to separate regions of tissue to provide fluid communication between the tissue regions. In an embodiment, an expandable cuff attached at one end of a stent is sutured to an outer wall of a right ventricle and an expandable cuff attached at the opposite end of the stent is sutured to an outer wall of the main pulmonary artery, providing a passageway for fluid (i.e., blood) to flow between the right ventricle and the main pulmonary artery, through the valve. The implantable device may be expandable to accommodate growth in young patients. For some instances, the shape of the device may be manipulated to suit placement of the expandable valve conduit within the body.

through the valve. The implantable device may be expandable to accommodate growth in young patients. For some instances, the shape of the device may be manipulated to suit placement of the expandable valve conduit within the body.



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EXPANDABLE VALVE AND METHOD OF USE

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BACKGROUND

1. Field

Aspects herein relate to expandable valve frames or conduits for implantation between tissue, such as a wall of the heart and a wall of a blood vessel. Methods for treating heart disease using expandable valve frames or conduits are also described herein.

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2. Discussion of Related Art

Natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. Aortic and pulmonary valves, commonly referred to as semilunar valves, are located at the base of the aorta and the pulmonary artery, respectively. The semilunar valves have three cusps and permit blood to flow into the arteries while preventing backflow of blood from the arteries into the ventricles. The aortic valve lies between the left ventricle and the aorta, and the pulmonary valve lies between the right ventricle and the pulmonary artery.

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Stenosis and regurgitation of aortic and pulmonary valves in the heart can cause chronic ventricular pressure and volume loads leading to short term and long term morbidity, as well as mortality. A therapeutic option for patients that suffer from eventual ventricular failure is aortic or pulmonary valve replacement. However, pulmonary or aortic valve replacement with a bioprosthesis has been associated with progressive valve deterioration despite significant anticoagulation therapy.

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Transcatheter valve replacement is a strategy for mitigating problems associated with multiple surgical procedures and/or palliative medical care. Valve implants are designed to replace the trileaflet structure that extends from a valve circumference to a radial center point of the valve, with each leaflet contacting or slightly overlapping the two adjacent leaflets.

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Surgeries that bypass various anatomical valves have also been contemplated to create an alternative passageway for blood flow.

SUMMARY

Aspects of the present disclosure relate to an expandable valve frame or conduit that may be implanted within the body, for example, at a semilunar position of the heart. An expandable valve may include an expandable valve frame disposed about a number of valve leaflets where the diameter of the expandable valve frame may be suitably increased when a sufficient outward force is applied to the frame. Upon expansion of the valve frame, valve leaflets disposed within the valve frame may also be stretched along with the frame so that the diameter of the entire valve is increased. When a valve with an expandable valve frame is implanted in a young patient, the expandable valve frame may be appropriately expanded to accommodate growth in young patients. In some embodiments, the diameter of an expandable valve frame may be increased through use of a dilation balloon catheter.

In some embodiments, an expandable valve conduit includes an expandable valve disposed within a covered stent having expandable cuffs attached at opposing ends of the stent. The expandable valve conduit may be implanted within the body (e.g., by suturing the expandable cuffs to suitable regions of tissue) so as to provide a passageway for fluid (e.g., blood) to flow through the valve and between cavities. For example, the expandable valve conduit may provide for suitable passage of fluid between the right ventricle and the main pulmonary artery.

In an illustrative embodiment, a valve for implantation at a semilunar position of a heart is provided. The valve includes valve leaflets; and an expandable rigid valve frame cooperating with and disposed about the valve leaflets to support the leaflets, the rigid valve frame adapted for implantation at the semilunar position of the heart, the rigid valve frame having a ring diameter, the rigid valve frame constructed and arranged to be expanded in ring diameter after implantation from a first functioning valve diameter to a second functioning valve diameter, wherein upon application of an outward force to the rigid valve frame, the ring diameter of the rigid valve frame is increased.

In one illustrative embodiment, a medical device for implantation within a body to form a passageway between a first tissue region and a second tissue region is provided. The device includes a conduit having a first end portion, a second end portion, and a lumen; a valve disposed within the lumen; a first expandable cuff disposed at the first end portion of the conduit, the first expandable cuff constructed and arranged to be sutured to the first tissue region; and a second expandable cuff disposed at the second end portion of the conduit, the second expandable cuff constructed and arranged to be sutured to the second tissue region.

In another illustrative embodiment, a method of correcting artificial heart valve function for a patient is provided, the patient having a previously implanted first valve

assembly at a semilunar position of the heart, the first valve assembly having valve leaflets attached to a first valve frame, the first valve frame having a diameter. The method includes applying an outward force to the first valve frame to increase the diameter of the first valve frame; and implanting a second valve assembly in a resulting lumen whereby the second valve assembly replaces the function of the first valve assembly, wherein the first valve frame is constructed and arranged as a docking station for the second valve assembly and at least one of the first valve frame and the second valve assembly is expandable.

In a further illustrative embodiment, a method of improving heart valve function for a patient is provided. The method includes implanting a valve at a semilunar position of the heart having an abnormally small annulus, the valve having leaflets attached to an expandable valve frame, and the valve frame having a diameter; and applying a radially outward force to the valve frame such that the diameter of the valve frame increases such that the small annulus at the semilunar position of the heart increases.

In another illustrative embodiment, a method of improving heart valve function for a growing patient is provided. The method includes implanting a valve at a semilunar position of the heart having an abnormally small annulus, the valve having leaflets attached to an expandable valve frame, and the valve frame having a diameter; and applying a radially outward force to the valve frame upon patient growth such that the diameter of the valve frame can increase as the patient grows.

In another illustrative embodiment, a method of manufacturing a medical device for implantation within a body to form a conduit between a first tissue region and a second tissue region is disclosed. The method includes forming a tube having a first end portion, a second end portion, and a lumen; placing an anatomical valve within the lumen of the tube; attaching a first expandable cuff to the first end portion, the first expandable cuff constructed and arranged to be sutured to the first tissue region; and attaching a second expandable cuff to the second end portion, the second expandable cuff constructed and arranged to be sutured to the second tissue region.

In yet another illustrative embodiment, a method for treating a pulmonary artery is disclosed. The method includes providing a device having a tube defining a lumen, the device having a valve disposed in the lumen, a first expandable cuff disposed at a first end portion of the tube, and a second expandable cuff disposed at a second end portion of the tube; suturing a portion of the first expandable cuff to a first tissue region; and suturing a portion of the second expandable cuff to a second tissue region, thereby forming a conduit to

provide fluid communication between the first tissue region and the second tissue region through the device.

Various embodiments of the present invention provide certain advantages. Not all embodiments of the invention share the same advantages and those that do may not share them under all circumstances.

Further features and advantages of the present invention, as well as the structure of various embodiments of the present invention are described in detail below with reference to the accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

The accompanying drawings are not intended to be drawn to scale. In the drawings, each identical or nearly identical component that is illustrated in various figures is represented by a like numeral. For purposes of clarity, not every component may be labeled in every drawing. Various embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

FIG. 1A depicts a top view of a conventional valve having a frame;

FIG. 1B depicts a side view of a conventional valve having a frame implanted within a vessel;

FIG. 2A depicts a side view of a valve having an expandable valve frame implanted within a vessel;

FIG. 2B depicts a side view of a valve having an expandable valve frame implanted in a vessel, with a catheter and balloon assembly positioned within the valve prior to dilation and expansion of the valve frame;

FIG. 2C depicts a side view of the balloon inflated and increasing the diameter of the expandable valve frame arrangement in the vessel of FIG. 2B;

FIG. 3A depicts a side view of a vessel with a previously implanted valve having an expandable valve frame in a vessel and a transcatheter valve assembly with a catheter and balloon prior to implantation of the transcatheter valve within the expandable valve frame;

FIG. 3B depicts a side view of the catheter, balloon, and valve assembly crossing the expandable valve frame, prior to implantation of the transcatheter valve within the expandable valve frame;

FIG. 3C depicts a side view of the balloon from the transcatheter valve implant system inflated, implanting the transcatheter valve and increasing the diameter of the expandable valve frame;

FIG. 4 depicts a perspective view of one embodiment of a valve having an expandable valve frame in an unexpanded configuration;

FIG. 5 depicts a perspective view of the valve having the expandable valve frame shown in FIG. 4 in a partially expanded configuration;

5 FIG. 6A depicts a close side view of a strut that spans segments of an expandable valve frame prior to expansion;

FIG. 6B depicts a close side view of a strut that spans segments of an expandable valve frame upon expansion;

10 FIG. 7 depicts a perspective view of another embodiment of a valve having an expandable valve frame in an expanded configuration;

FIG. 8A depicts a close side view of a strut that is located at a central region of segments of an expandable valve frame prior to expansion;

FIG. 8B depicts a close side view of a strut that is located at a central region of segments of an expandable valve frame upon expansion;

15 FIG. 9 depicts a close perspective view of a one-way ratchet mechanism for an expandable valve frame;

FIG. 10 depicts a close perspective view of another one-way ratchet mechanism for an expandable valve frame;

20 FIG. 11 depicts a close perspective view of a toothed post of a joint for an expandable valve frame;

FIG. 12 depicts a close perspective view of a ball-in-joint ratchet mechanism with a circular cross-section for an expandable valve frame;

FIG. 13 depicts a close perspective view of a ball-in-joint ratchet mechanism with a rectangular cross-section for an expandable valve frame;

25 FIG. 14 depicts a schematic view of one embodiment of a joint for an expandable valve frame;

FIG. 15 depicts a close schematic view of an embodiment of a joint for an expandable valve frame;

30 FIG. 16 depicts a close schematic view of another embodiment of a joint for an expandable valve frame;

FIG. 17 depicts a close schematic view of a further embodiment of a joint for an expandable valve frame;

FIG. 18 depicts a close schematic view of yet another embodiment of a joint for an expandable valve frame;

FIG. 19A depicts a close schematic view of another embodiment of a joint for an expandable valve frame in an unexpanded configuration;

FIG. 19A depicts a partial perspective view of a further embodiment of an expandable valve frame with concentric rings in an unexpanded configuration;

5 FIG. 19B depicts a partial perspective view of the expandable valve frame shown in FIG. 16A in a partially expanded configuration;

FIG. 20 depicts another schematic view of one embodiment of an expandable valve frame comprising a plurality of overlapping crescent-shaped arcuate segments;

10 FIG. 21 is a perspective representation of another embodiment of a ratcheting arrangement for the expandable valve frame depicting a catch wheel ratcheting arrangement;

FIGS. 22A-22C depict a series of discrete-diameter expansions of the expandable valve frame;

FIGS. 23A-23R are schematic plan representations of various features and configurations for the expandable valve frame;

15 FIG. 24A depicts the expandable valve frame encased in a protective sheath;

FIG. 24B is a representation of FIG. 24A with the protective sheath shown in phantom to reveal the expandable valve frame;

FIG. 25 is a perspective view of the expandable valve frame shown in phantom, with a valve leaflet attachment frame wrapped around the expandable valve frame;

20 FIG. 26 shows an embodiment of an expandable valve conduit with a valve disposed within a stent and expandable cuffs attached at opposite ends of the stent;

FIG. 27 shows an embodiment of a curved mandrel;

FIG. 28 depicts an embodiment of a restrictor engaged with a portion of a stent;

25 FIG. 29 illustrates a schematic of an expandable valve frame in accordance with embodiments described;

FIGS. 30A-30D are schematic plan representations of various examples of the expandable valve frame in accordance with FIGS. 23A, 23B, 23E, and 23M;

FIGS. 31A-31D are more schematic plan representations of various examples of the expandable valve frame in accordance with FIGS. 23A, 23B, 23E, and 23M;

30 FIGS. 32A-32D are further schematic plan representations of various examples of the expandable valve frame in accordance with FIGS. 23A, 23B, 23E, and 23M

FIGS. 33A-33C are schematic plan representations of various examples of the expandable valve frame in accordance with FIGS. 23A, 23B, and 23M;

FIGS. 34A and 34B are schematic plan representations of various examples of the expandable valve frame in accordance with FIGS. 23A and 23B;

FIG. 35 depicts a graph of load versus valve frame deformation for an example in accordance with embodiments herein; and

5 FIG. 36 depicts a graph of load versus valve frame deformation for another example in accordance with embodiments herein.

DETAILED DESCRIPTION

FIGS. 1A and 1B depict a prosthetic valve 10 having valve leaflets 20a, 20b, and 20c
10 attached to a valve frame 30 for implantation at a semilunar position of the heart. FIG. 1B shows the valve 10 implanted in a vessel 12. In one embodiment, the valve frame 30 is attached (not shown) to the surrounding tissue of the vessel 12. When valve leaflets deteriorate to the point where the valve is unable to function properly, or when the patients need a higher output through the valve due to, for example, growth, pregnancy, or athletic
15 training, a further surgery may have been required to replace the valve.

A recently developed alternative to surgical replacement of the deteriorated prosthetic valve is implantation of a transcatheter valve within the existing valve. Deterioration of the transcatheter valve may be treated with concentric implantation of an additional transcatheter valve within the first. However, implantation of subsequent transcatheter valves
20 concentrically within a previously implanted transcatheter valve may give rise to intraluminal bulk that decreases effective orifice area. Such decrease in lumen size may cause obstruction of the subsequently placed valve, and is especially counterproductive if the patient grows, or requires a higher cardiac output, after implantation of the valve.

In addition to the above issues, an important problem in a subset of patients
25 undergoing replacement of the aortic valve is a small aortic annulus. When a prosthetic valve is implanted within an aortic annulus, the valve prosthesis occupies space, and in patients with a relatively small native annulus, insertion of a prosthetic valve may result in residual left ventricular outflow tract obstruction and incomplete relief of symptoms and hemodynamic load. Methods to overcome the problem of the small aortic annulus include
30 technical surgical modifications of the aortic valve replacement to enlarge the annulus (e.g., by incising through the annulus into the ventricular septum, the anterior leaflet of the mitral valve, or otherwise), implantation of the valve in a supraannular position, or insertion of a low-profile valve. Despite these techniques, this remains an important problem that may adversely affect the results of aortic valve replacement surgery.

According to aspects of the invention, a prosthetic expandable valve is disclosed. Expanding the valve can be used to improve heart function, as will be described. For example, in patients with a small aortic annulus, in some cases, the valve may be implanted surgically at a size that the annulus will accommodate. Afterward, the valve and annulus would be enlarged, (e.g., intraoperatively or later in the catheterization lab). The valve may be enlarged, for example, by inflating a balloon within the valve or by using another method of dilation and expanding the valve. In some cases, the valve may be implanted in a younger patient where further growth of the annulus may occur. To accommodate patient growth, the diameter of the expandable valve frame may be increased to maintain functionality of the implanted valve. In some cases, when a previously implanted valve becomes dysfunctional, an expandable valve may be used as a docking station for implantation of a subsequent valve.

In one embodiment, a valve prosthesis that includes an expandable valve frame for implantation at a semilunar position of the heart is described. The expandable valve frame cooperates with and is disposed about valve leaflets. When an outward force is applied to the expandable valve frame, the diameter of the frame is increased in a controlled and predictable fashion. In addition, a method of using an expandable valve frame for correcting artificial heart valve function in a patient is described. The expandable valve frame is useful for restoring function of a previously implanted valve where the valve was implanted at a semilunar position of the heart. An outward force may also be applied to the frame, reducing obstruction in the original valve and reducing obstruction at the original valve. A transcatheter valve assembly may also be implanted in the lumen where the first valve was previously implanted such that the second valve assembly replaces the function of the first valve, for example, supporting the previously implanted valve or replacing the first valve entirely. Because of the expandable frame of the first valve, implantation of the second valve will not cause narrowing of the lumen within the vessel as a result of the combined bulk of the originally implanted and subsequent replacement valves.

FIG. 2A illustrates an embodiment of a valve 11 with an expandable valve frame 50 implanted at a semilunar position of a vessel 12. The valve 11 includes an expandable valve frame 50 and valve leaflets 20 and is attached (e.g., sutured) to the surrounding tissue of the vessel 12. In the embodiment shown, the expandable valve frame 50 also includes expansion joints 52 that serve as expandable connections and provide a method for which the diameter of the expandable valve frame 50 may be increased in a controlled and predictable fashion. Additionally, an appropriate biocompatible material suitable for use in a heart valve may

surround the valve frame, but is not shown for the purposes of clarity. In one embodiment, however, the material is stretchable so as to accommodate expanding valve diameters.

The expandable valve frame addresses problems that arise at the semilunar heart valve position when the outermost valve or prosthesis is fixed in diameter. For example, as current
5 replacement heart valves and associated suture rings have a rigid and fixed diameter, progressive crowding in the lumen and/or leaflet restriction may occur if multiple valves are implanted subsequently and concentrically at the same location. The circumference and diameter of the expandable valve frame may increase in a predictable and precise manner when sufficient outward force (e.g., from inflation of a high-pressure angioplasty balloon or
10 through a different appropriate surgical procedure) is applied to the valve frame. In addition, the expandable valve frame may serve as a docking station in allowing for concentric placement of multiple transcatheter (e.g., stent mounted) valves at the same position over time without substantially incremental narrowing of the lumen. When serving as a docking station for future valves, the expandable valve frame may substantially resist compressive,
15 rotational and torsional forces exerted by the beating heart. In one aspect, the expandable valve frame may remain resistant to compressive loads so as to thereby serve as a docking station. Further, the expandable valve frame may be approximately circularly symmetric so as to be implantable in a semilunar valve position of the heart. As a result, multiple valves may be placed concentrically over time at an aorta or pulmonary valve position providing for
20 appropriate unidirectional flow of fluid away from the ventricle without compromising valve functionality.

The expandable valve frame may be implanted simultaneously along with or as a part of a valve assembly. For example, the expandable valve frame may be a part of a valve (i.e., attached to the valve) prior to implantation so that the valve is implanted together with the
25 expandable valve frame at an aortic or pulmonary valve position. The valve frame may function as an implant site for future valve replacements (e.g., semilunar valve replacements), allowing for multiple valves to be implanted sequentially over time.

The expandable valve frame to be implanted at a semilunar position may include any appropriate material. In some embodiments, the expandable valve frame is made up of a
30 rigid material. For example, the frame may be made from metal (e.g., stainless steel, alloys of suitable metals, etc.), shape memory material (e.g., nitinol), polymer (e.g., synthetic and/or naturally occurring), silicon, rubber, tissue (e.g., allograft and/or xenograft), and/or combinations thereof.

Although embodiments of the expandable valve frame are rigid, the frame may be appropriately attached to the surrounding tissue. In some embodiments, the frame is sutured to the surrounding tissue at the semilunar position. For example, standard suture materials may be wrapped around the body of the expandable valve frame, allowing the frame and the tissue to be sutured together. In other examples, the body of the expandable valve frame may include suture holes where suture material may be threaded so that the valve frame and the tissue may be sutured together. In some embodiments, the expandable frame may be covered with a material that can be sutured to the surrounding tissue. In some embodiments, aspects of the expandable frame promote tissue ingrowth such that the surrounding tissue provides for a biological attachment of the frame at a semilunar position. For example, the expandable frame may include a coating or a copolymer having an appropriate biomolecular arrangement that encourages tissue growth around the expandable frame. In some embodiments, portions of the expandable frame may be attached to surrounding tissue at a semilunar position through a variety of other methods, such as through tissue welding (e.g., using laser and/or heat treatment), surgical staples, surgical adhesives (e.g., glue), and/or combinations thereof.

Portions of a valve for implantation at a semilunar position may also include any appropriate material. For example, the valve leaflets may be made from polymer (e.g., synthetic and/or naturally occurring), tissue (e.g., allograft and/or xenograft), and/or combinations thereof. In some embodiments, valve leaflets may be bioprosthetic valve leaflets and/or completely artificial valve leaflets.

Force may be applied to the expandable valve frame in a suitable fashion. In some embodiments, an appropriate surgical tool may be used to apply outward force to the expandable valve frame. For example, a balloon-mounted stent may be used to position a valve in the expandable valve frame and provide an outward force to the expandable valve frame upon inflation of the balloon. The balloon may be inflated in a controlled manner such that a predictable outward force is applied to the expandable valve frame. In some embodiments, a ratchet mechanism may be provided in the expandable valve frame and may be configured such that known and increasing forces are required for increasing the diameter of the expandable valve frame to successively larger diameters. In some embodiments, the diameter of the expandable valve frame may be manually increased through appropriate tool manipulation.

A valve may be surgically implanted into a small annulus at a diameter that is appropriate for the annulus size, and the valve may be expanded either during the same surgery or later by transcatheter methods to a larger diameter for improving valve function.

In some embodiments, valve leaflets may be designed to optimize coaptation and load bearing after implant and expansion (e.g., increasing the diameter by 10-20%).

FIGS. 2A-2C show an illustrative embodiment of a valve 11 that is implanted at a vessel 12 of a semilunar position of the heart, the valve having valve leaflets 20 and an expandable valve frame 50. FIG. 2A depicts an implanted valve 11, while FIGS 2B and 2C depict enlargement of the valve 11 having an expandable valve frame 50 through use of a balloon 4. Also not fully shown in the figures, the expandable valve frame 50 and the valve leaflets 20 may be attached to one another by any appropriate method. In some embodiments, an interlocking mechanism serves to attach the expandable valve frame and the valve leaflets to one another. For example, the expandable valve frame 50 and the valve leaflets 20 may include a complementary flanged configuration that allows for the expandable valve frame 50 and the valve leaflets 20 to be appropriately attached. In some embodiments, the expandable valve frame 50 and the valve leaflets 20 are sutured together. In some embodiments, the expandable valve frame 50 and the valve leaflets 20 are formed as a unitary piece. In some embodiments, the expandable valve frame 50 may be surgically implanted at a semilunar position of the heart simultaneously with the valve leaflets.

The expandable valve frame 50 and the valve leaflets 20 may be positioned and attached at a semilunar position of the heart by any appropriate technique. In a preferred embodiment, the expandable valve frame 50 may be surgically implanted at a semilunar position of the heart. In some embodiments, valve leaflets 20 may be implanted simultaneously with the surgically implanted expandable valve frame 50. In some embodiments, valve leaflets 20 may be implanted in a subsequent procedure to implantation of the expandable frame. Shown in FIGS. 2B and 2C, valve leaflets 20 of valve 11 are mounted to a stent 24. That is, portions of valve leaflets 20 are secured to a stent 24 for providing support to the valve.

In some cases, as shown in FIG. 2B a balloon 4 is appropriately placed into a semilunar region through positioning of the balloon using a catheter 2. Subsequently, shown in FIG. 2C, the valve 11 is inflated with a balloon 4. Inflation of the balloon 4 depicted in FIG. 2C is shown by dashed arrows. In this respect, inflation of a balloon 4 applies pressure to the stent 24 and the valve 11 such that the valve 11 is pressed upon against the annular lumen of the vessel 12 at the semilunar position. In some cases, as shown in FIG. 2C, the diameter of both the expandable valve frame 50 and the vessel lumen may increase.

Although it is within the scope of that presented herein for the expandable valve frame 50 to increase in diameter upon first implantation at a semilunar position of the heart, it is not a

required aspect for suitable valve function. Similarly, for the diameter of the vessel lumen at a semilunar position, although the vessel may expand upon implantation of the expandable valve frame and the valve, it is not a requirement for appropriate valve function to result. Indeed, a slight degree of expansion and/or stretching of the vessel may occur when a balloon
5 is properly inflated. It can be appreciated a vessel, as described herein, is not limited to a blood vessel, but can include any suitable bodily conduit, such as a portion of connective tissue in the gastrointestinal system, or other suitable fluid passageways within the body.

In some embodiments, the expandable valve frame 50 may be attached to the annular tissue. For example, the expandable valve frame 50 may be sutured to the surrounding tissue
10 annulus at the point of implantation. In some cases, multiple sutures may be applied along the expandable valve frame 50, forming an attachment fit along the annular lumen so that the valve leaflets may function appropriately. Methods of attachment may assist in reducing the risk of perivalvular leakage through a tight and closely conforming fit between the valve and the annulus. For example, the valve may be implanted in a manner similar to the Hancock
15 Valve developed by Medtronic. It can be appreciated that stent-free valves may also be positioned at the proper site for cooperation with the expandable valve frame 50 as stent mounting is an optional embodiment. For example, valve leaflets 20 and an expandable valve frame 50 may be placed and attached at a semilunar position through a surgical technique without use for an added supporting structure.

Over time and use, the implanted valve may deteriorate to a point of malfunction
20 (e.g., through disease, damage, and/or age). That is, upon malfunction, the implanted valve is unable to properly control flow unidirectionally away from the ventricle through the semilunar position or may become obstructed due to tissue ingrowth. In some cases, portions of the implanted valve are resorbed over time and through exposure to bodily fluids (e.g.,
25 blood). In other cases, portions of the implanted valve are left open or possibly torn. Inability for the implanted valve to properly function may include leakage, obstruction at the level of the valve frame, or through portions of the valve.

As a result of valve malfunction, an additional valve assembly may be required in order to provide appropriate valvular function at the implant position. FIGS. 3A-3C depict an
30 illustrative embodiment of an additional valve assembly 21 that is implanted at the location of the expandable valve frame 50. However, in FIGS. 3A-3C, the additional valve assembly 21 is used to restore function to the previously implanted valve 11. FIG. 3A shows the previously implanted valve 11 in a deteriorated state, yet maintaining expandable valve frame 50. Vessel 12 includes lumen debris 14 that may give rise to obstruction of the vessel. Such

debris 14 that may lead to at least partial occlusion of the vessel may include any material that is commonly associated with blood vessel or valve constriction, for example, biological debris (e.g., tissue), portions of the previously implanted valve, plaque, and/or combinations thereof. FIG. 3A also depicts valve 11 having deteriorated portions 15 (e.g., holes, tears),
5 depicted by dashed regions within valve leaflets 20, that further degrade function of the valve 11. Additional valve assembly 21 includes valve leaflets, a catheter 2 for positioning of the assembly, and balloon 4 for assisting in the subsequent implantation.

FIG. 3B depicts a schematic of the additional valve assembly 21 being placed within the same annular region as the previously implanted valve the expandable valve frame 50. In
10 this embodiment, the expandable valve frame 50 is provided as a docking station for the additional valve assembly 21. Although not required, the additional valve assembly 21 may be attached to the expandable valve frame 50 by any suitable method, for example, through an interlocking attachment mechanism or suturing. In some cases, the additional valve assembly 21 is pushed up against the inner wall of the vessel 12 in a manner that the valve
15 assembly remains stably situated. In some embodiments, the additional valve assembly 21 is appropriately positioned as a stent-mounted valve (stent not shown in the figure). Although a catheter 2 is depicted for positioning the additional valve assembly 21 in a similar location to that of the previously implanted valve, other positioning mechanisms may be used. In some cases, as depicted in FIG. 3C, a balloon 4 may be used for providing an outward force on the
20 additional valve assembly 21 and further anchoring the additional valve assembly 21 to the expandable valve frame 50. In the case of implanting an additional valve assembly 21, due to progressive narrowing of the vessel lumen, it may be beneficial to increase the diameter of the expandable valve frame 50. As shown in FIG. 3C, the diameter of the expandable valve frame 50 increases upon inflation of the balloon 4 (indicated by dashed arrows). In addition,
25 for valvular function to be more closely restored, it may also be beneficial for the overall diameter of the vessel lumen to also increase.

In placing the additional valve assembly in the expandable valve frame to maintain functionality of the semilunar valve system, an outward force may be applied to the expandable valve frame, increasing the diameter of the valve frame. For example, an
30 inflatable balloon may provide the outward force to the expandable valve frame. The additional valve assembly may also be implanted in the lumen where the prior valve was implanted such that the additional valve assembly restores the function of the previously implanted valve assembly. For example, the additional valve assembly may serve to support and/or hold open the previously implanted valve (e.g., valve leaflets). As another example,

the additional valve assembly may replace portions or the entirety of the prior valve. As a result from the increased diameter of the expandable valve frame, multiple transcatheter valves may be implanted at a semilunar position of the heart as the additional valve assembly may include a second valve, third valve, or any subsequent valve.

5 The expandable valve frame can take a variety of forms. In some embodiments, the expandable valve frame may include one or more arcuate segments. For example, the expandable valve frame may have a single continuous, approximately circular segment. In other examples, as will be described further below, the expandable valve frame may have three arcuate segments that span the same arc length over the same angle (e.g., 120 degrees).

10 It should be understood that any number of arcuate segments may be included in the valve frame, each segment having an optionally different own arc length and angle. In some embodiments, the expandable valve frame is formed of a stretchable material that, when stretched beyond an elastic limit, may then exhibit a new larger diameter while maintaining rigidity.

15 As determined herein, the frame diameter is measured as the diameter between inner surfaces of a ring body. In various embodiments, for an unexpanded configuration, the expandable valve frame may have a diameter of between about 5 mm and about 25 mm. For example, in an unexpanded configuration, the expandable valve frame may have a diameter of between about 5 mm and about 15 mm; between about 5 mm and about 20 mm; between
20 about 7 mm and about 25 mm; between about 10 mm and about 20 mm; between about 10 mm and about 25 mm; and/or between about 15 mm and about 25 mm. In some embodiments of an unexpanded configuration, the expandable valve frame may have a circumference of between about 20 mm and about 80 mm. For example, the expandable valve frame may have a circumference of between about 20 mm and about 50 mm; between
25 about 20 mm and about 60 mm; between about 20 mm and about 70 mm; between about 22 mm and about 79 mm; between about 30 mm and about 60 mm; between about 30 mm and about 70 mm; between about 30 mm and about 80 mm; between about 40 mm and about 60 mm; between about 40 mm and about 70 mm; between about 40 mm and about 80 mm; between about 50 mm and about 60 mm; between about 50 mm and about 70 mm; between
30 about 50 mm and about 80 mm; and/or between about 60 mm and about 80 mm.

 In an expanded configuration (partially or fully expanded), in some embodiments, the expandable valve frame may have a diameter of between about 10 mm and about 30 mm. For example, in a partially or fully expanded configuration, the expandable valve frame may have a diameter of between about 15 mm and about 30 mm; between about 20 mm and about

30 mm; between about 25 mm and about 30 mm; between about 10 mm and about 20 mm; and/or between about 10 mm and about 25 mm. In some embodiments, for a partially or fully expanded configuration, the expandable valve frame may have a circumference of between about 30 mm and about 95 mm. For example, in a partially or fully expanded configuration, the expandable valve frame may have a circumference of between about 30 mm and about 60 mm; between about 30 mm and about 70 mm; between about 30 mm and about 80 mm; between about 30 mm and about 95 mm; between about 31 mm and about 95 mm; between about 40 mm and about 60 mm; between about 40 mm and about 70 mm; between about 40 mm and about 80 mm; between about 40 mm and about 95 mm; between about 50 mm and about 60 mm; between about 50 mm and about 70 mm; between about 50 mm and about 80 mm; between about 50 mm and about 95 mm; between about 60 mm and about 70 mm; between about 60 mm and about 80 mm; between about 60 mm and about 95 mm; between about 70 mm and about 80 mm; between about 70 mm and about 95 mm; and/or between about 80 mm and about 95 mm.

In some cases, the diameter of the expandable valve frame may be increased, for example, by placement of a stent-mounted valve within the lumen at a semilunar position and dilation of the stent outwardly (e.g., from inflation of a balloon). Radial strength and maintenance of the enlarged diameter may be provided, at least partially, by the expanded stent. However, an expanded stent may not provide sufficient strength to protect against collapse in environments with high compressive, torsional, and/or cyclic stresses. In some cases, no stent is provided at a semilunar position where an expandable valve frame is implanted.

In providing structural protection against collapse of the annulus at the semilunar position where an expandable valve frame and valve are implanted, in some embodiments, the diameter of the expandable valve frame does not decrease despite the ability for the ring diameter to be increased upon application of a sufficient outward force. For example, a one-way ratcheting mechanism may be used to increase the diameter of the expandable valve frame while substantially preventing the diameter of the expandable valve frame from decreasing. A post-in-hole arrangement may be used as a one-way ratcheting mechanism for the expandable valve frame, which includes a central post that is connected to one of the segments of the body of the valve frame that may fit inside a corresponding hole in an adjacent segment. The valve frame can expand at the joints by sliding of a post within a hole when an outward radial force is applied to the inner surface of the valve frame (e.g., inflation of an angioplasty balloon and/or expansion of a balloon-expandable stent or stent-mounted

valve). In some embodiments, each segment may be connected to one another through such a post-in-hole arrangement. The shape and dimensions of the post may vary, with cross-sectional profiles that are circular, asymmetric, square, rectangular, or any other suitable shape. A post may vary in shape and dimension, for example, in order to optimize function, ratcheting, and/or axial, radial, or torsional strength.

In some embodiments, dimensions of the system that are used for expansion may be pre-measured to better predict the appropriate ring diameter for successive implants. A better prediction of the ring diameter for subsequent implants can lead to a better valve fit for the expandable valve frame, in turn, leading to longer term valve functionality. For example, if a post is straight or has a different radius of curvature than adjacent arcuate segments, each expansion may lead to distortion of the valve frame away from a perfect circle. In some cases, the expandable valve frame may be constructed such that the unexpanded ring is not quite circular (e.g., elliptical, crescent-shaped); the ring in a first expanded state is circular; and the ring in subsequently expanded states are supercircular (e.g., including straight edges from straight posts).

Other embodiments of expandable valve frames having different mechanisms for expansion may also be contemplated. In some embodiments, for expandable valve frames that include one or more segments, a coiled arrangement may be incorporated between ends of segments of an expandable valve frame. For example, ends of segments may be distanced from one another upon application of a tensile force between coil ends. It should be understood that it is not a necessary requirement for the expandable valve frame to be made up of one or more segments. Indeed, as mentioned previously, the expandable valve frame may include a single segment with a diameter that can be increased as a result of an appropriate outward force placed on the ring.

In some embodiments, a compacted structure may be included between segments of an expandable valve frame. For example, zigs or omega shaped elements that can be stretched out upon applying a sufficient tensile force may be included.

Struts may be incorporated in any appropriate manner, for example, along a coil or in between zigs or omega structures. In some embodiments, struts may include breaking points where upon a threshold tensile force applied, struts may break, allowing for segments of the expandable valve frame to be further distanced apart.

In some embodiments, the expandable valve frame may include overlapping segments. Overlapping segments may include arcuate segments with joints that are offset

from one another at locations that provide the valve frame with increased overall radial and torsional stability.

In some embodiments, the expandable valve frame may include one or more crescent-shaped segments. Crescent-shaped segments, for example, may be positioned adjacent to one another such that an outward force applied to the expandable valve frame allows for rotation and sliding of one or more crescent-shaped segments in a manner that increases the overall ring diameter.

Turning again to the figures, FIGS. 4 and 5 illustrate an embodiment of valve 11 having an expandable valve frame 50 that includes a ring body 60 with three arcuate segments that form a continuous circular unit. FIG. 4 illustrates the valve frame 50 in an unexpanded configuration. The arcuate segments of the ring body 60 have the same radius of curvature R. The arcuate segments depicted in this embodiment each span approximately 120 degrees. Alternatively, and as described above, the arcuate segments may span different and unequal arc lengths. In between arcuate segments of the ring body 60 are joints 70 that may function to expand valve frame 50 by distancing arcuate segments from one another. In addition, attached to the ring body 60 of the expandable valve frame 50 are also valve leaflets 20 and struts 100. Though not explicitly shown in FIG. 4, attachment of a valve leaflet 20 and the ring body 60 is located, for example, at the region depicted by the dashed circle. The three struts 100 shown are each attached to at least one of the segments of the ring body 60. In FIG. 4, each strut 100 is attached to two neighboring segments of the ring body. Similarly, attachment of commissures of valve leaflets to a corresponding strut 100 is located, for example, at the region depicted by the dashed square. Valve leaflets and associated commissures between valve leaflets may be attached to the ring body or a strut by any suitable method, such as through a sutured arrangement, an adhesive, a welded attachment, or other appropriate techniques. For the sake of clarity, leaflets are shown to be in a partially open position, but may operate to move to fully open and fully closed positions. It can be appreciated that upon implantation, a biocompatible material often surrounds the valve frame; however, the surrounding material is not shown for the purposes of clarity. For example, attachments of portions of valve leaflets, struts, and the ring body may occur through the material (not shown).

It can be appreciated that the valve that is attached to the expandable valve frame may or may not include struts that support the commissures. When struts are present, they may include a variety of appropriate designs. For example, struts may include a single post, a wire/segment of metal or other material that is arch-shaped, and/or another suitable design.

Struts may include various materials and with various degrees of stiffness and/or flexibility. In some embodiments, struts may generally be based on the design of existing stented and stentless bioprosthetic valve prostheses. For example, struts may include cut or formed metal lengths that are connected to the frame ring and rise in an axial dimension to support the commissures of the bioprosthetic valve. Struts may take various forms. As shown in FIGS. 4 and 5, the three struts that support the three valve commissures may each connect to at least one of the segments of an expandable valve frame. Alternatively, as will be described below, the struts may span the expansion joints that serve as expandable connections and may additionally provide additional radial and torsional strength across the joints. In some embodiments, if a strut includes two or more segments, expansion of the joint and the width of the strut base may not shorten the strut but allow widening of the apex of the strut. In a prosthesis with a competent valve, expansion of the expandable valve frame may alter the geometry of the valve leaflets and commissures, but may still allow adequate coaptation, such that the expanded valve will remain competent and functional without concentric implant of a transcatheter valve.

FIG. 5 depicts the valve 11 with the expandable valve frame 50 in a partially expanded configuration. Arcuate segments of ring body 60 are distanced from one another at joints 70. Similarly to in FIG. 4, one region of attachment of a valve leaflet 20 and the ring body 60 is located at the region depicted by the dashed circle. In addition, attachment of a valve leaflet 20 to a neighboring strut 100 is located at the region depicted by the dashed square. In FIG. 5, although the diameter of the expandable valve frame 50 is increased, the valve leaflets still remain attached to the ring body of the expandable valve frame in a manner that maintains overall functionality of the valve.

FIGS. 6A and 6B depict an illustrative embodiment of a strut 100 that spans a joint 70 between adjacent segments of a ring body 60, similarly to that shown in FIGS. 4 and 5. The two adjacent segments of the ring body 60 with the strut 100 spanning the joint 70 are shown before expansion, in FIG. 6A, and after (or during) expansion, in FIG. 6B. As depicted by the solid arrows and the dotted strut showing the prior strut configuration, the strut 100 may widen and shorten with expansion of the joint 70. In some embodiments, struts that span joints may provide additional radial and torsional strength across the joints. In addition, struts that span the joints will have two base attachment points, one attachment point for each of the adjacent ring segments. Upon expansion of the ring, these adjacent segments separate and the height of the strut shortens. For example, if a strut is composed of a single strand of

wire, then the height of the strut will shorten as adjacent segments are distanced from each other.

FIG. 7 depicts the valve 11 with the expandable valve frame 50 in a partially expanded configuration. Struts 100 are located at a central region of segments of the ring body 60. Arcuate segments of ring body 60 are distanced from one another at joints 70. Valve leaflets and segments of the ring body may be appropriately attached by any suitable method. In some embodiments, when a valve leaflet is attached at a joint region of an expandable valve frame, the valve leaflet may be attached at multiple points to accommodate expansion of the joint. Additionally, commissures of valve leaflets and struts may also be appropriately attached by any suitable method, similarly to that described with respect to FIGS. 4 and 5. When the diameter of the expandable valve frame 50 is increased, the valve leaflets may still remain attached to the ring body of the expandable valve frame in a manner that maintains overall functionality of the valve.

FIGS. 8A and 8B depict an illustrative embodiment of a strut 100 that is located at a central region of segments of the ring body 60, similarly to that shown in FIG. 7. The struts, not spanning the joint 70, are illustrated before expansion, in FIG. 8A, and after (or during) expansion, in FIG. 8B. Instead of the struts being attached to two adjacent segments, each strut is only attached to a single segment of the ring body. As a result, when a joint is expanded, struts do not deform in the manner depicted above for struts that span joints. However, in this arrangement, due to struts being attached to commissures of valve leaflets, it may be possible for struts to slightly deform when the diameter of the expandable valve frame is increased.

FIG. 9 depicts an embodiment of a one-way ratcheting mechanism that includes a post-in-hole arrangement that helps to maintain the valve frame in the expanded diameter (i.e., preventing the ring diameter from decreasing) while allowing for subsequent re-expansions to larger ring diameters. The joint 70 includes toothed regions 72 that are physically located in between segments of the ring body 60. Joint 70 also includes a ratchet mechanism 74 at a hole 76. The ratchet mechanism 74 functions to engage with toothed regions 72 such that segments of the ring body 60 are unable to come closer to one another, but can only be further distanced apart. As a result, in this embodiment, once toothed regions 72 are exposed outside of the ring body 60, the regions 72 will remain in between segments outside of ring body 60. The ratcheting mechanism 74 allows for circumferential and radial rigidity to be maintained, and also reduces the risk of fracture for valves (e.g., stent-mounted) that are deployed within the expandable valve frame 50. On the other hand, to prevent the

ring from being over-expanded inadvertently or pre-maturely, in some embodiments, the diameter of the valve frame 50 may be controlled by increasing the force required to expand to each successive ratchet position.

FIG. 10 depicts another illustrative embodiment of a one-way ratcheting mechanism that includes a toothed post-in-hole arrangement for maintaining the valve frame in an expanded diameter while allowing for subsequent re-expansions to larger ring diameters. The joint 70 is located in between segments of a ring body 60 where a toothed region 72 of the joint is engaged with a ratchet mechanism 74 at a hole 76. The ratchet mechanism 74 is in engagement with toothed regions 72 such that segments of the ring body 60 are unable to come closer to one another, but can only be further distanced apart. The ratcheting mechanism 74 allows for circumferential and radial rigidity to be maintained, and also reduces the risk of fracture for valves (e.g., stent-mounted) that are deployed within the expandable valve frame 50.

FIG. 11 shows an embodiment of a toothed region 72 that includes teeth of graduated tooth size where expansion of the valve frame requires successively greater force for each increasing diameter. As depicted, toothed region 72d is larger than toothed region 72c, which is larger than toothed region 72b, which is larger than toothed region 72a. By way of example, in the ratchet mechanism depicted in FIG. 11, when an associated joint is expanded, an expansion force is required to overcome the barrier provided by toothed region 72a. When the joint is further expanded, a greater expansion force is required to overcome the subsequent barrier provided by toothed region 72b. It can be appreciated that toothed regions having graduated tooth sizes may include any suitable number of toothed regions having any suitable shape and/or dimensions.

In some cases, the ratcheting mechanism may provide not only for an increased compressive stability, but may also provide for an increased torsional stability. For example, toothed regions may be shaped so that the expandable valve frame is prevented from collapsing under torsional stresses associated with twisting or shearing forces that may arise during or after implantation at a semilunar valve position. In some embodiments, the expandable valve frame may exhibit stability in torsion through generally stiff materials such as metal or rigid polymers, for example. In some embodiments, the expandable valve frame may exhibit stability in torsion through a layered arrangement, discussed further below.

In another illustrative embodiment shown in FIGS. 12, an expandable valve frame includes a body 60 and a joint 80 having a post 81 with a circular cross-section. FIG. 12 shows a ball 82 that slides out of a hole 86 upon application of sufficient outward force on the

valve frame. As illustrated, an interference fit exists between the ball 82 and the hole 86 such that a threshold force is required to pull the ball 82 out of the hole 86, leading to expansion of the valve frame.

FIG. 13 depicts another illustrative embodiment of an expandable valve frame including a body 60 and a joint 80 having a post 81 with a rectangular cross-section. The joint 80 includes a ball 82 that slides out of a hole 86 upon application of sufficient outward force on the valve frame. An interference fit may exist between the ball 82 and the hole 86 such that a threshold force is required to pull the ball 82 out of the hole 86, leading to expansion of the valve frame. In some embodiments, a post with a rectangular cross-section may provide for added torsional stability of the expandable valve frame. In some cases, a post with a rectangular cross-section may have a greater height (axial dimension) h than a width (radial dimension) w . It can be appreciated that any appropriate type of joint mechanism and number of joints may be constructed in the expandable valve frame.

In some embodiments, arcuate segments of the expandable valve frame may have joints other than the post-in-hole arrangement, as described above. FIGS. 14-18 show other illustrative embodiments of expandable valve frames. FIG. 14 depicts a partial view of an expandable valve frame 50 having a body 60 and a joint 90. FIGS. 15-18 show various embodiments of joints that provide expandable mechanisms for the valve frame. In some embodiments, joints may include thick (or thin) gauged wire, metal, a relatively rigid material that stretches and sets under a threshold tensile force, and/or combinations thereof. Joints made of metal may, for example, be laser cut.

In one embodiment, depicted in FIG. 15, a joint 90 may include coils 92 that stretch out upon application of a tensile force. The tensile force may originate, for example, from the body 60 transmitted from an outward force applied radially to the inner surface of the valve frame. In some embodiments, a joint may include zigs, coils, and/or omega structure(s) that may stretch out in a similar fashion to that of coiled structures.

In another embodiment, shown in FIG. 16, joint 90 may include zigs 94 that are reinforced by supports 96 for holding the diameter of the expandable valve frame. As discussed, a tensile force may arise in the ring body when an outward force is applied to the valve frame. When stretched to a particular tensile threshold, one or more supports 96 will break, and the zig 94 stretches such that the valve frame expands to a new diameter that is larger than the previous diameter. In some embodiments, the tensile threshold for breakage of the one or more supports for the valve frame to expand to a larger diameter ranges between about 12 atm and about 30 atm of balloon inflation pressure.

It can be appreciated that the valve frame may be expanded multiple times by incorporating various configurations, for example, a nested zig/support structure and/or supports with different breaking points.

5 In a different embodiment, shown in FIG. 17, a joint 90 may include longer zigs 94 that are supported by shorter zigs 98 that, similar to supports 96 in FIG. 16, are designed to break under a particular threshold. However, shorter zigs 98 may provide for varying elongation potential between ring body segments. For example, upon application of a tensile force, longer zigs 94 may only slightly stretch out where shorter zigs 98 may completely stretch out to the point of fracture. In this regard, the diameter of the expandable valve frame
10 may slightly increase to a particular threshold (shorter zigs are stretched out) and then once the shorter zigs 98 break, the diameter of the expandable valve frame may further increase based on the length of the longer zigs 94.

In a further embodiment, shown in FIG. 18, a joint 90 may include longer zigs 94 that are supported by shorter zigs 99 or omegas that are located in orthogonal planes (e.g., zigs 94
15 are orthogonally positioned relative to zigs 99). In this case, the embodiment depicted in FIG. 13 functions similarly to the embodiment depicted in FIG. 17 in that shorter zigs 99 may be stretched to a particular threshold limit before breaking. Upon breakage of shorter zigs 99, the diameter of the expandable valve frame is increased as portions of the ring body 60 are distanced further apart from one another.

20 FIGS. 19A and 19B illustrate an embodiment of valve 11 with an expandable valve frame 50 having overlapping segments 62, 64, and 66 in unexpanded and partially expanded configurations. The expandable valve frame 50 is shown to be attached to valve leaflets 20 and struts 100, as described previously. As shown, concentric rings may include arcuate segments, which, in some cases, may be thinner than in previous embodiments. Segments
25 62, 64, and 68 form concentric rings having offsetting joints. For example, joints 102, 104, and 106 are offset from one another. In some embodiments, the offset between concentric rings may be even (e.g., 40 degrees offset). It can be appreciated that the offset between joints may be of any appropriate dimension and is not required to be evenly spaced. In addition, segments within each concentric ring may or may not include a mechanism
30 integrated into the ring for maintaining radial strength and/or diameter after expansion, such as a ratcheting system. In some embodiments, a concentric or layered arrangement may allow for added resistance to compressive loads and/or torsion. For example, a concentric or layered arrangement may include different materials for each layer designed according to varying loads experienced at different locations of the expandable valve frame. It can be

appreciated that a layered arrangement is not required to be concentric, for example, different layers of the expandable valve frame may be side by side with the same diameter. In some embodiments, struts 100 are attached to only one of the concentric ring layers, as shown in FIG. 19A. However, in some embodiments, struts 100 are attached to more than one of the concentric ring layers. FIG. 19B depicts a closer illustration of the expandable valve frame 50 in a partially expanded configuration. As described above, as the diameter of the expandable valve frame 50 is increased, valve leaflets may remain attached to the ring body in a manner that maintains overall functionality of the valve.

In another embodiment, the expandable valve frame may include overlapping crescent-shaped segments. FIG. 20 depicts an expandable valve frame 50 with a body 60 having only four overlapping crescent-shaped segments, with the overlapping denoted by the dashed lines 110. In some embodiments, fewer or more crescent-shaped segments 110 may be fit together to form an expandable valve frame 50. Overlapping crescent-shaped segments 110 may slide relative to one another, allowing for expansion of the ring diameter. As a result, the expandable valve frame 50 may open as an aperture upon application of a sufficient outward radial force (e.g., during balloon dilation). The apices of inner crescents of the overlapping crescent-shaped segments 110 may serve a ratcheting function, for example, with counteracting teeth on the inner surfaces of the outer ellipses.

In another embodiment, depicted in FIG. 21, an expandable valve frame 150 is formed of a strip of material 152 shaped into a cylinder and includes features that allow the cylinder to expand and to hold the cylinder at discrete diameter settings. In this regard, the expandable valve frame 150 incorporates a catch wheel ratcheting arrangement, as will be described below. The strip is formed into a cylinder with overlapping ends 162 and 164. The cylinder is self-biased toward a closed cylinder configuration having an unstressed diameter smaller than that desired. Upon expansion to overcome the spring bias, the cylinder opens to a larger desired diameter. Because the cylinder has a spring bias tending to cause the cylinder to seek a smaller diameter, the ratchet feature maintains the cylinder at the desired diameter.

The strip 152 may be formed of any suitable material such as plastic, metal (e.g., stainless steel), or composite and may have a width of between about 5 mm and 25 mm (e.g., between about 5 mm and about 15 mm), a length between about 40 mm and 100 mm, and a thickness that is approximately less than or equal to 0.1 inches (e.g., between 0.1 mm and about 0.4 mm).

The valve frame 150 may be expanded using any suitable technique. In one embodiment, the valve frame is expandable by balloon dilation, for example. The pressure applied by a balloon during expansion may be between about 2 atm and about 30 atm (in one embodiment, between about 2 atm and about 15 atm or, in another embodiment, between about 8 atm and about 30 atm).

In one configuration, the ratcheting arrangement forms a catch wheel type arrangement that includes a series of evenly spaced protruding tabs 170, 171, and 172 extending radially outward along the outer curved surface of the cylinder, as shown in FIG. 21. Thus, as the cylinder 150 is expanded, the leading edge of the strip 162 engages with a protruding tab 170 and is held at the desired diameter. The protruding tabs may be formed on the strip as a separate component; however, in one embodiment, the protruding tabs are formed by stamping the strip 152 such that the protruding tab 171 extends partially out over a corresponding slot 174. Of course, even if the strip is formed in a process other than a stamping, the strip may still include a slot over which the protruding tabs at least partially extend. Although the protruding tabs 170, 171, 172 are shown protruding radially outward, some embodiments may have tabs that protrude radially inward. Protruding tabs 170, 171, 172 may be separate components that are welded on, attached with adhesive, or attached with a mechanical linkage such as a rivet.

In one embodiment, the leading edge of the strip 162 includes a leading edge tab 180, 182 such as shown in FIGS. 23A, 23B, 23C, 23D, 23G, 23H, 23I, 23 J and 23Q. The leading edge tab 180 may be formed with a slight bend so that it can penetrate through the slot 174. Leading edge tab 180 may be a separate component that is welded on, attached with adhesive, or attached with a mechanical linkage such as a rivet. In this embodiment, the leading edge tab 180 penetrates through slot 174 and engages with the leading edge of slot 174 to hold diameter at an incremental position.

Accordingly, the valve frame may achieve a series of discrete diameter settings to create a suitable fit for specific valve sizes as shown in FIGS. 22A-22C. One advantage to this embodiment is that the thin frame minimizes occlusion at the implantation site. In addition, a planar strip of material with simple protrusions and cutouts is easy to manufacture, thus enabling ease of large-scale fabrication. As discussed, suitable expandable valve frames described herein may have any suitable diameter. In some embodiments, expandable valve frames have diameters between 15 mm and 24 mm. For example, an expandable valve frame may have an initial diameter of between about 10-20 mm (e.g., 16 mm diameter) prior to

implantation of the valve frame, and after expansion within the body, the valve frame may have a diameter of between about 20-30 mm (e.g., 24 mm diameter).

When the cylinder is at a small diameter setting, such as in FIG. 22A, and there is an increased amount of overlap between the two overlapping ends of the strip 162 and 164, one protruding tab 172 catches the leading edge of the strip 162 while the preceding protruding tabs 170 and 171 (protruding tab 171 is not shown in FIG. 22A) sit under the leading edge end of the strip 163. Although not shown in FIG. 22A, it should be understood that the presence of protruding tabs 170 and 171 under strip 163 will create a gap between the overlapping strip ends 162 and 164.

In order to eliminate such a gap, in some embodiments, the strip 163 includes a plurality of evenly spaced slots located behind the leading edge 162. Though this plurality of evenly spaced slots is not shown, one of ordinary skill in the art will appreciate that, when the cylinder is at a small diameter, additional slots behind the leading edge 162 are necessary for the two overlapping ends 162 and 164 to lie flush to one another due to the presence of protruding tabs 170 and 172. In this embodiment, when the cylinder is at a small diameter setting, as shown in FIG. 22A, and there is an increased amount of overlap between the two overlapping ends of the strip 162 and 164, one protruding tab 172 catches the leading edge of the strip while the other protruding tabs 170 and 171 penetrate through the corresponding slots. When the cylinder 150 is expanded (by balloon dilation, for example), protruding tabs 170, 171, and 172 release and the inner surface 166 of the leading edge 162 slips against the outer surface 168 of the opposite end of the strip 164 in the direction of increasing diameter. The cylinder continues to expand until the leading edge 162 catches the next protruding tab 171, subsequently reengaging at a larger diameter, as shown in FIG. 22B.

In some embodiments, the strip includes a plurality of cutouts 190 along the top and bottom edges of the cylinder, as shown in FIGS. 21, 22A-22C, and 23A-23R. These cutouts 190 serve to vary the torsional stiffness and flexibility of the cylinder 150. For example, an increased number of cutouts would decrease the cross-sectional area of the cylinder and thus decrease its torsional stiffness and increase flexibility. Increased flexibility at certain sections of the cylinder 150 may be needed to maintain the circular nature of the cylinder. In addition, these rectangular cutouts 190 are attachment sites for an encasing protective sheath 200, described in more detail later. Although rectangular cutouts 190 are shown, as will be appreciated, the invention is not limited in this respect and differently shaped cutouts may be employed.

Turning now to Figs. 23A-23R, the expandable valve frame 150 may include, but is not limited to, any suitable combination of the arrangements and features. One configuration of the strip, as shown in FIGS. 23B, 23D, 23H, and 23J, includes an increased number of slots 174 and/or protruding tabs 171 (not shown) to permit finer diameter adjustment. In another embodiment, as shown in FIGS. 23C, 23D, 23I, and 23J, the leading edge of the strip includes a tapered tab 182 to guide the tab 182 more easily into each slot 174 and/or beneath a protruding tab 171. In yet another embodiment, an additional tab 184 located just behind the leading edge 162 of the strip, as shown in FIGS. 23B, 23D, 23H and 23J, is included. This additional tab allows for a more secure hold. This embodiment also allows for the engagement of multiple leading edge tabs 180, 184 with slots 174 to serve as a safety measure in the case of failure of one of the tabs. In one embodiment, as in FIGS. 23E and 23K, two square tabs 186 are located on the leading edge, and a corresponding series of paired slots 187 are formed on the opposite end of the strip. Furthermore, this double tab configuration may include tabs with tapered ends 188 such as in FIGS. 23F and 23L. Tapered ends 188 may guide the tabs more easily into each pair of slots 187, as explained previously. In one embodiment, a recess 192, 195 may be provided in leading edge 162 to better engage with protruding tabs 170, 171, 172 and prevent axial slip. This recessed edge is shown in FIGS. 23M, 23N, 23O, 23P, and 23R. To fit this recess 192, a series of protruding tabs 193 may be employed. In this arrangement, the cylinder 150 is held at a discrete diameter when the recess 192 on the leading edge 162 is tucked under one of the protruding tabs 193 located on the opposite end 168 of the strip. The recess may have a square edge, 192 or a tapered edge, 195. The tapered edge recess 195 may be angled so that it may allow the recess to slide more easily under a flap 193. In another embodiment, a series of protruding flaps 194 is formed on sides of the strip corresponding to the top and bottom edges of the cylinder, depicted by FIGS. 23G, 23H, 23I, 23J, 23K, 23L, 23O, and 23P. These flaps may help to lock the frame in a circular shape and prevent the frame from twisting out of alignment. In this regard, these flaps or tabs may be bent over so as to essentially form a track through which the sides of the strip at the leading edge can follow. In yet another embodiment, two additional longitudinal fingers or leaflets 196, as shown in FIGS. 23Q and 23R, may be provided along the trailing side of the of the strip. When the strip is formed into a cylinder configuration, the leading edge 162 of the strip is tucked under the two leaflets 196. During expansion, the leading edge 162 of the strip continues to slip beneath the leaflets 196. The leaflets 196 may aid in guiding the leading edge of the strip during expansion, thereby preventing invagination of the cylindrical frame due to non-uniform dilation.

Accordingly, various embodiments of an expandable valve frame may employ differently shaped catch tabs, catch slots, alignment tabs, stabilization wings, suitable frame thicknesses, any other suitable arrangement, or combination thereof, which allows for the expandable valve frame to maintain discrete diameters upon appropriate expansion. Table 1 provides short descriptions of various embodiments described above and depicted in FIGS. 23A-23R. It can be appreciated that the embodiments illustrated and discussed in FIGS. 23A-23R and Table 1 provide only exemplary descriptions of suitable expandable valve frames contemplated by the inventors, and therefore, the inventions described herein are not limited in this respect.

Table 1 – Descriptions of various embodiments of an expandable valve frame according to different arrangements for expansion.

Embodiment (Figure)	General Description
FIG. 23A	Single catch tab, multiple catch slots, squared catch tab
FIG. 23B	Double longitudinal catch tab, multiple catch slots, squared catch tab
FIG. 23C	Single catch tab, multiple catch slots, tapered catch tab
FIG. 23D	Double longitudinal catch tab, multiple catch slots, tapered catch tab
FIG. 23E	Double lateral catch tab, multiple catch slots, squared catch tab
FIG. 23F	Double lateral catch tab, multiple catch slots, tapered catch tab
FIG. 23G	Single catch tab, multiple catch slots, squared catch tab, with alignment tabs
FIG. 23H	Double longitudinal catch tab, multiple catch slots, squared catch tab, with alignment tabs
FIG. 23I	Single catch tab, multiple catch slots, tapered catch tab, with alignment tabs
FIG. 23J	Double longitudinal catch tab, multiple catch slots, tapered catch tab, with alignment tabs
FIG. 23K	Double lateral catch tab, multiple catch slots, squared catch tab, with alignment tabs
FIG. 23L	Double lateral catch tab, multiple catch slots, tapered catch tab, with alignment tabs
FIG. 23M	Multiple catch tabs, single catch slot, squared catch slot
FIG. 23N	Multiple catch tabs, single catch slot, tapered catch slot
FIG. 23O	Multiple catch tabs, single catch slot, squared catch slot, with alignment tabs
FIG. 23P	Multiple catch tabs, single catch slot, tapered catch slot, with alignment tabs
FIG. 23Q	Single catch tab, multiple catch slots, squared catch tab, longitudinal stabilization wings
FIG. 23R	Multiple catch tabs, single catch slot, tapered catch slot, longitudinal stabilization wings

It may be possible in some situations that the cylindrical frame becomes over-dilated during deployment and so should be constricted to a smaller diameter. Thus, in one embodiment, a non-cylindrical balloon may be employed to constrict the frame. For example, a dilated non-cylindrical balloon that presses outwardly on the frame along one line

of action (e.g. at 90 degrees and 270 degrees) may cause a protruding tab oriented perpendicular to that line of action (in this example, 0 degrees) to release. As the non-cylindrical balloon only exerts force along one line of action, the leading edge located at 0 degrees may release and slip against the cylinder surface, but the non-symmetrical resulting action in the cylinder may cause the leading edge to slip in a direction towards a smaller diameter, thereby constricting the cylinder.

In some embodiments, the cylindrical frame is encased in a thin protective sheath 200 as shown in FIG. 24A to prevent in-growth of tissue into the ratcheting arrangement. In this manner, uninhibited dilation may be permitted. The sheath fully encases the frame 150 between two walls 201 and 202 and, in some cases, the valve frame is permitted to slip relative to the sheath. The seam 203 that joins the two walls 201 and 202 may be completely sealed with a stitch (such as a "baseball" stitch) that permits the sheath 200 to dilate. The sheath 200 may be an elastic material, such as ePTFE (expanded Polytetrafluoroethylene), that can stretch as the frame 150 dilates. As discussed earlier, the sheath 200 may be sewn to the cylindrical frame 150 at the rectangular cutouts 190 located along the top and bottom edge of the cylinder. In FIG. 24B, the sheath is shown semi-transparent for illustrative purposes to reveal the expandable valve frame 150 within the encasing sheath 200. A cylindrical frame 150 enclosed by an outer biocompatible ePTFE sheath may also incorporate sewing cuffs on one or both sides of the device, for implantation within the body. The sheath may include any other suitable biocompatible material besides ePTFE, for example, polymers such as polyester or polyimide. As described in the embodiments of FIGS. 1A and 1B, the valve frame 30 supports a prosthetic valve 10. To attach the valve posts of the valve 10 to the valve frame 150 of the embodiments described with respect to FIGS. 21-25, in some embodiments, a valve attachment frame 210 may be employed. In this embodiment, the attachment frame 210 is located about the expandable valve frame 150 and includes three evenly spaced valve post attachments 212 around the cylinder as shown in FIG. 25. For ease of visualization, the expandable valve frame 150 is shown in phantom. Because the prosthetic valve 10 (not shown in FIG. 25) is attached to the expandable valve frame 150 via these valve post attachments 212 on the valve attachment frame 210, in one embodiment, the valve post attachments 212 are to remain substantially evenly spaced. The valve post attachments 212 loop around the top and bottom edges of the expandable valve frame 150. Pliable diamond-shaped struts 214 connect the valve post attachments 212 to the wire-like external portion 216 of the attachment frame 210. Upon expansion of the internal cylindrical valve frame 150, the diamond shape of the pliable struts 214 straighten, thereby permitting

the wire attachment frame 210 to expand in the circumferential direction and allowing the three valve post attachments 212 to maintain consistent positions around the central axis.

As described herein, when the valve is implanted at a “semilunar” position of the heart, the valve is said to be implanted at an aortic heart valve position or a pulmonary heart valve position. However, though, other locations are contemplated, as aspects are not limited in this regard.

Further, the inventors have recognized and appreciated advantages to constructing an expandable valve conduit, for example, for placement in young patients in treating pulmonary artery disease. An implantable device is contemplated to be expandable in one or more directions and providing an exterior conduit between two separate regions of tissue. A valve, which may or may not be expandable according to aspects described herein, may be appropriately disposed within the lumen of a bodily conduit, providing for fluid communication between the separate tissue regions. The device includes a tube formed as a covered stent arrangement. For example, a stent mounted valve may provide a fluid conduit between a right ventricle and a main pulmonary artery that bypasses the natural anatomical passageway from the heart to the lungs. Expandable cuffs may be positioned at opposite ends of the tube for suitable attachment (e.g., suturing) of ends of the device to the separate regions of tissue. In various embodiments, portions of the device are expandable (e.g., tube, valve, cuffs) so that the device may be surgically placed in smaller patients (e.g., children) with the ability for the device to be expanded at a later time. The tube and/or valve may thus enable fluid flow between the ends of the device subsequent expansion. Accordingly, the prosthesis may include any one of the previously described valve frames. Alternatively, or in addition, an expandable stent supporting the valve may be employed.

Expandable cuffs may be attached to ends of the tube by any suitable method, for example, and without limitation, through suturing, pressure/heat sealing and/or application of an adhesive. During a surgical procedure, an expandable cuff disposed at one end of the tube is sutured to a first tissue region (e.g., an outer wall of a right ventricle having an opening to permit blood flow out of the chamber) and the expandable cuff disposed on the opposite end of the tube is sutured to a second tissue region (e.g., an outer wall of the main pulmonary artery having an opening to permit blood flow into the pulmonary artery). Once the expandable cuffs of the device are appropriately attached to respective tissue regions, creating surgical anastomoses at each end of the device, the device provides a passageway or conduit for fluid flow between the tissue regions, subject to opening and closing of the valve disposed within the tube.

In some embodiments, prior to or during implantation, the shape (e.g., curvature) of portions of the device are adjusted to circumvent certain anatomical features, such as for example, a sternum of a patient.

After implantation, the device may be expanded, for example, to accommodate for patient growth in cases where the device was initially implanted into a child. In some embodiments, the device, including the tube, the expandable cuffs and the valve, are expanded radially from an initial diameter to a larger diameter. For example, an initial diameter of the device may be about 10-20 mm (e.g., 15 mm) and a final diameter of the device may be about 21-31 mm (e.g., 26 mm). The device may be expanded to any suitable diameter between the initial and final diameters (e.g., between about 15 mm and about 26 mm) depending on patient growth and/or other factors. Additionally, portions of the device, such as the tube and/or expandable cuffs may be lengthened from an initial length to a final length. For example, an initial length of the device may be about 1-10 mm (e.g., 5 mm) and a final length of the device may be about 10-20 mm (e.g., 15 mm). The implantable device may be suitably dimensioned according to the size of the patient. Accordingly, a device may be longer and have a larger diameter for implantation in older children as compared to a device for implantation in infants, where a shorter and narrower device may be appropriate.

FIG. 26 illustrates a non-limiting example of an implantable device 300 that may be used to form a conduit between tissue regions in the body. The device 300 includes an expandable valve 310 disposed within a stent 320 and expandable cuffs 330, 340 which are attached to the stent 320 at opposite ends. The expandable cuffs 330, 340 may be formed of any suitable material, such as ePTFE (e.g., GORE-TEX®). Oppositely positioned expandable cuffs 330, 340 permit the device to be attached (e.g., anastomotically sutured) to respective tissue regions to create a fluid conduit between the tissue regions. Other biocompatible materials, such as biological materials, may be employed in the cuffs.

While not explicitly shown in the figures, the device 300 may also include a covering disposed over the stent 320 to prevent leakage of fluid from the device. Such a covering may include any appropriate material, such as for example, ePTFE, biological materials, synthetic materials (e.g., polyester, polyimide, etc.) or other biocompatible materials, similar to the expandable cuffs.

In some embodiments, a device covering and/or expandable cuffs include an anisotropic material having an orientation that provides for the device to be expanded in a desired manner (e.g., direction and degree of expansion). Indeed, for example, an expandable cuff and/or covering that includes an anisotropic material prone to expansion in one direction

may be constructed so that the anisotropic material expands more readily, for example, in a radial direction as compared to a longitudinal direction, or vice versa. As such, the direction and degree of expansion of the device may be controlled through appropriate use and orientation of suitable materials. In addition to expandable PTFE, the covering and/or expandable cuffs may include any biocompatible, generally compliant and thin material. Further, the covering and/or expandable cuffs may include engineered biomaterials, such as for example a collagen scaffold.

The device 300 may be expanded by any appropriate method. In some embodiments, an expandable balloon is used to enlarge portions of the device, such as the valve 310, the stent 320 and/or the expandable cuffs 330, 340. While the valve 310, the stent 320 and/or the expandable cuffs 330, 340 depicted in FIG. 26 can be suitably enlarged, it should be appreciated that not all portions of implantable devices described herein are required to be expandable. However, in certain embodiments, every portion of the implantable device is expandable.

Expandable cuffs 330, 340 are appropriately attached to the stent 320, for example, by application of an adhesive (e.g., glue), pressure/heat sealing and/or by suturing directly to the stent itself. In one embodiment, the expandable cuffs are attached on each end upon manufacture of the device, though the cuffs may be attached during implantation. Also, a covering that extends beyond the stent to provide cuff ends may be employed.

In some embodiments, upon implantation, the properties of tissue regions corresponding to ends of the device where expandable cuffs are attached (e.g., sutured) may differ. For example, the properties of the tissue at a right ventricle wall to which one cuff may be attached may differ substantially from the properties of the tissue at a wall of a pulmonary artery to which an opposing cuff may be attached. In some cases, it may be desirable for the properties of a cuff to be similar to the region of tissue to which the cuff is attached. Accordingly, expandable cuffs may be selected to have different thicknesses and/or materials based on the properties of the tissue region where the respective cuffs will be attached. For example, an expandable cuff attached at an arterial outlet may be thicker than an expandable cuff attached at a venous outlet. In such a case, the expandable cuff having a larger thickness may be able to provide added support for accommodating increased fluid pressure at an arterial location in comparison to a venous location. In some embodiments, the device includes longer cuffs in certain anatomical regions for navigating the device around existing bodily structures, for example, a native outflow tract or a protruding atrium.

It may be desirable for an implantable device to form a curved conduit from one tissue region to the other tissue region. In instances where the device forms a conduit between the right ventricle and the pulmonary artery, it may be appropriate for the device to curve around the sternum which can obstruct a path between the right ventricle and the pulmonary artery. Thus, it may be advantageous for the implantable device to be adjustably bendable. That is, during implantation, it may be determined that the device should incorporate a substantial curvature to avoid the sternum, or alternatively, for other cases, the device might not require any curvature at all.

FIG. 27 depicts a curved mandrel 400 that an implantable device may be crimped around prior to implantation. The mandrel 400 includes a central region 410, a first end portion 420 and a second end portion 430. The central region 410 may have a diameter that is smaller than the first and second end portions 420, 430, to accommodate placement of the valve of the device during crimping. During an implantation operation, a surgeon may have access to a plurality of curved mandrels having different curvatures, shapes and sizes from which to select. For example, the radius of curvature for one mandrel may be significantly larger than the radius of curvature for another mandrel. Or, in some cases, a mandrel may include an irregularly or an elliptically-shaped arc. Hence, a surgeon may inspect the anatomy of the patient and adjust the device (e.g., crimping about a suitably shaped mandrel) to incorporate the type of curvature that is most appropriate, upon implantation.

During an implantation procedure, despite usage of an appropriately curved mandrel, it may also be desirable for the device to be adjusted even further. Or, in some cases, a surgeon may be required or prefer to shape the device without the benefit of having an appropriately curved/sized mandrel available. FIG. 28 is a schematic representation illustrating an arrangement 500 where portions of cells of a stent 510 are urged together by a restrictor 520. Upon dilation of the device during implantation, the presence of a restrictor 520 may induce curvature in the stent, hence, the device as a whole. As such, a surgeon may tailor the curvature of the device upon implantation of the device by deploying one or more restrictors at appropriate locations. In some embodiments, a restrictor applicator (not shown) is used to deploy and/or actuate restrictors between cells of a stent. For example, such an applicator may function similarly to a medical stapler where the user positions the applicator in an appropriate position and the restrictor is suitably placed into position. Alternatively, the restrictor may be included on the device and the applicator may be used to actuate the restrictor imparting a desired curvature.

In some cases, the implantable device may be suitably protected from external loading, such as, from contact with the sternum. In an embodiment, one or more ratcheting rings (not shown) and/or other suitable protection device(s) are positioned in spaced apart relation and placed external to the tube. Such an arrangement may support the device to maintain its structure upon experiencing contact with surrounding anatomical features.

EXAMPLES

Aspects of the following description are intended to illustrate certain embodiments of the present disclosure as exemplified through a design process for an expandable valve frame, and is not to be construed as limiting and does not encompass the full scope of the invention.

A number of examples were designed and fabricated in accordance with various aspects described herein. In producing these examples, it was generally desirable to design a device that: has an adjustable diameter over a prescribed range of suitable diameters; can be expanded using suitable dilation devices (e.g., using catheter balloon dilation); may be implemented in conjunction with existing implantable valves (e.g., Melody Valve produced by Medtronic); is biocompatible; can be implanted within the body (i.e., human and animal); and exhibits a suitable degree of manufacturability.

The examples described below incorporate a number of concepts included in the embodiment shown in FIGS. 24A and 24B, which illustrate two main subcomponents – an outer biocompatible barrier made of ePTFE, and an inner cylindrical valve frame that can be expanded and has a ratcheting structure. The valve frame is encased inside of the outer biocompatible ePTFE barrier.

FIG. 29 illustrates a schematic of an expandable valve frame, having various dimensions, such as inner diameter A, width B and thickness C. In contemplating the manufacture of examples of expandable valve frames, a number of design parameters were considered. Respective values for each of the design parameters are listed in Table 2, such as dimensions A, B, C, the number of ratchet settings, the maximum allowable strain of the wall of the bodily conduit per ratchet setting, and the expansion pressure of the expanding device (e.g., balloon). It can be appreciated that suitable expandable valve frames in accordance with aspects of the invention may include parameters having values different than those listed below. Other parameters than those listed in Table 2 having appropriate ranges of values may also be considered and employed for suitable expandable valve frames.

Table 2: Design parameters for example expandable valve frames

Design Parameters	Values
Inner Diameter (Dimension A of Fig. 29)	15-24 mm
Width (Dimension B of Fig. 29)	5-15 mm
Thickness (Dimension C in Fig. 29)	Less than 0.4 mm
Max. Allowable Strain of Bodily Conduit per Ratchet Setting	15%
Number of Ratchet Settings	4 or more
Pressure within Expanding Device	8-30 atm

Expandable valve frames were formed through laser cutting (by Ameristar Laser Cutting, Inc.) from sheets of stainless steel 316L having thicknesses of 0.127 mm, 0.179 mm, 0.254 mm, and 0.381 mm. The valve frames were expanded using a dilation catheter balloon from the smallest ratchet setting, having a diameter of 16 mm, to the next setting, having a diameter of 18 mm. The valve frames were further expanded from a diameter of 18 mm to a diameter of 20 mm, and subsequently to a diameter of 22 mm. In several cases where the ratchet arrangement provided for suitable expansion of the valve frame, the diameter of the dilation catheter balloon substantially matched the ratchet setting diameter of the valve frame. For example, an 18 mm dilation catheter balloon was used in expanding a valve frame from a 16 mm diameter to a 18 mm diameter.

Variations of the expandable valve frame were formed in accordance with the examples as depicted in FIGS. 30A-30D, 31A-31D, 32A-32D, 33A-33C, and 34A-34B. The valve frames of FIGS. 30A-30D, 31A-31D, and 32A-32D are generally of a similar design to those embodiments illustrated in FIGS. 23A, 23B, 23E, and 23M, respectively, yet have different values for width dimension B. The valve frames of FIGS. 30A-30D have a width dimension B of 15 mm, the valve frames of FIGS. 31A-31D have a width dimension B of 10 mm, and the width dimension B of the valve frames of FIGS. 32A-32D is 12 mm. The valve frames of FIGS. 33A-33C have a similar design as the embodiments depicted in FIGS. 23A, 23B, and 23M, respectively, and have a width dimension B of 7 mm. And, the valve frames of FIGS. 34A and 34B are similar in design to the embodiments shown in FIGS. 23A and 23B, respectively, and have a width dimension B of 5 mm.

In contrast to the plurality of cutouts 190 of FIGS. 23A-23R, which are substantially aligned with one another, the valve frames of FIGS. 30A-34B have a plurality of cutouts 191 where cutouts along one edge of the valve frame are offset with respect to cutouts on an opposite edge of the valve frame. Similar to the cutouts 190 described previously, cutouts 191 may be used as attachment sites for the valve frame to be sutured to the protective sheath

encasing and may also be suitable for varying the torsional stiffness and flexibility of the valve frame. In some instances, though not all, the offset alignment of the cutouts 191 may provide for a stronger attachment of the valve frame to the protective sheath encasing than that for the substantially aligned cutouts 190. In addition, the examples shown in FIGS. 30A-30C, 31A-31C, 32A-32C, 33A-33B, and 34A-34B include a slotted tab 169 which, in some cases, may allow for further flexibility of the valve frame to be engaged with a corresponding tab on the opposite side. Similarly for the examples illustrated in FIGS. 30D, 31D, 32D, and 33C, a slotted tab 183 may provide additional flexibility for the valve frame when placed into a functional arrangement prior to and/or after implantation.

Certain features of the valve frames were machined using wire-electrical discharge machining, so as to account for small clearances and tight tolerances. Axially rigid ePTFE tubing having a diameter of 16 mm and a wall thickness of 0.127 mm was used as a sheath for each of the above valve frames. Once formed, each valve frame was inserted over the ePTFE tubing and the ePTFE tubing was then folded back over the valve frame. The edges of the ePTFE tubing were then folded multiple times to form 2 mm wide cuffs. The cuffs were then sutured with a 6-0 polypropylene baseball stitch, ensuring that enough suture length was included and allowing for full expansion of the respective valve frame. Samples of ePTFE were obtained from Philips Scientific, Inc., Zeus Inc., and Applied Tubing Inc.

To evaluate functionality and strength, a number of tests were performed on assembled expandable valve frames created in accordance with FIGS. 30A and 30C, where the width dimension B is 15 mm. In an expansion test, the influence of various features such as the pressure required for expansion to occur and the material thickness as related to expansion was observed. A 18 mm x 2 Bard Balloon Dilation Catheter was used to apply outward force so as to ratchet the diameters of valve frames from 16 mm to 18 mm. Further, a 20 mm x 4 Bard Balloon Dilation Catheter was used to apply outward force for ratcheting the diameters of valve frames from 18 mm to 20 mm. In addition, a 22 mm x 2 B. Braun Impact Balloon Dilation Catheter was used to ratchet the diameters of valve frames from 20 mm to 22 mm. It is worth noting that for these examples, no attempt was made to ratchet diameters from 22 mm to 24 mm because no 24 mm dilation balloon catheter was available at the time of testing. Table 3 summarizes results of the balloon pressure used for each of six valve frames having certain thickness values to be expanded from one diameter to another.

Table 3. Balloon pressure required for expansion of expandable valve frames having different thickness values.

Example	Embodiment (Figure)	Thickness (mm)	Dilation Pressure Used for Diameter Expansion from 16 mm to 18 mm (atm)	Dilation Pressure Used for Diameter Expansion from 18 mm to 20 mm (atm)	Dilation Pressure Used for Diameter Expansion from 20 mm to 22 mm (atm)
1	FIG. 30A	0.127	2	15	4
2	FIG. 30A	0.179	6	9	4
3	FIG. 30A	0.254	6	8	4
4	FIG. 30C	0.127	10	9.5	3.5
5	FIG. 30C	0.179	6	10.5	4.5
6	FIG. 30C	0.254	6	15	4.5

Crush test evaluations were performed on the expandable valve frames. A DALSA vision system was used to record position and deformation of the valve frame by calculating the diameter on the crush axis. A force sensor was used to record the force exerted on the crush axis. Valve frames were crushed at a 16 mm diameter and at a 22 mm diameter, so as to provide upper and lower bounds for the load characteristics.

Fig. 35 shows the load plotted as a function of percent deformation for valve frames having a 16 mm diameter under crush testing. Dotted curve 600 represents a range of load vs. percent deformation behavior of valve frames having a thickness of 0.254 mm. Solid curve 602 represents a range of load vs. percent deformation behavior of valve frames having a thickness of 0.179 mm. Dashed curve 604 represents a range of load vs. percent deformation behavior of valve frames having a thickness of 0.127 mm.

Fig. 36 shows the load plotted as a function of percent deformation for valve frames tested having a 22 mm diameter subject to crush testing. Dotted curve 700 represents a range of load vs. percent deformation behavior of valve frames having a thickness of 0.254 mm. Solid curve 702 represents a range of load vs. percent deformation behavior of valve frames having a thickness of 0.179 mm. Dashed curve 704 represents a range of load vs. percent deformation behavior of valve frames having a thickness of 0.127 mm.

Embodiments described may be for use as an improvement of the Melody Transcatheter Pulmonary Valve, manufactured by Medtronic, Inc. However, it should be appreciated that aspects of the invention may be used in any suitable arrangement where a

valve conduit is incorporated. Also, valve conduits described may be used to provide a fluid passageway between any appropriate regions, such as for example, between ends of a resected bodily vessel, cavities and/or channels within the body.

5 The above aspects may be employed in any suitable combination as the present invention is not limited in this respect. Also, any or all of the above aspects may be employed in a valve arrangement; however, the present invention is not limited in this respect, as aspects of the may be employed with other medical devices.

10 Having thus described several aspects of at least one embodiment of this invention, it is to be appreciated various alterations, modifications, and improvements will readily occur to those skilled in the art. For example, the prosthesis described herein may be adapted for placement in other locations. In some embodiments, prosthesis described herein may include material that is radioopaque so that suitable imaging may occur. Such alterations, modification, and improvements are intended to be part of this disclosure, and are intended to be within the spirit and scope of the invention. Accordingly, the foregoing description and
15 drawings are by way of example only.

What is claimed is:

CLAIMS

1. A valve for implantation at a semilunar position of a heart, the valve comprising:
valve leaflets; and
5 an expandable rigid valve frame cooperating with and disposed about the valve leaflets to support the leaflets, the rigid valve frame adapted for implantation at the semilunar position of the heart, the rigid valve frame having a ring diameter, the rigid valve frame constructed and arranged to be expanded in ring diameter after implantation from a first functioning valve diameter to a second functioning valve diameter, wherein upon application
10 of an outward force to the rigid valve frame, the ring diameter of the rigid valve frame is increased.
2. The valve of claim 1, further comprising struts attached to a ring body of the expandable rigid valve frame, the struts supporting commissures of the valve leaflets.
15
3. The valve of claim 1, wherein the ring diameter of the rigid valve frame can only be increased.
4. The valve of claim 1, wherein the rigid valve frame is circular.
20
5. The valve of claim 1, wherein the rigid valve frame is continuous.
6. The valve of claim 1, wherein the outward force is radial.
- 25 7. The valve of claim 1, wherein the ring diameter ranges between about 7 mm and about 30 mm.
8. The valve of claim 1, wherein the ring circumference ranges between about 22 mm and about 95 mm.
30
9. The valve of claim 1, wherein the rigid valve frame comprises a plurality of arcuate segments joined to each other via an expandable connection.

10. The valve of claim 9, wherein the expandable connection comprises a post-in-hole interface.

5 11. The valve of claim 10, wherein the post-in-hole interface comprises a rectangular cross-section.

12. The valve of claim 9, wherein the expandable connection comprises a one-way ratcheting mechanism.

10 13. The valve of claim 9, wherein the expandable connection comprises a plurality of supports, each support having a tensile threshold, wherein upon application of a tensile force reaching the tensile threshold, the support breaks and the ring diameter is increased.

14. The valve of claim 13, wherein the tensile threshold ranges between about 12 atm and
15 about 30 atm of balloon inflation pressure.

15. The valve of claim 1, wherein the rigid valve frame comprises a plurality of concentric rings.

20 16. The valve of claim 15, wherein each of the plurality of concentric rings comprises an expandable connection, wherein a first expandable connection of one ring is offset from a second expandable connection of an adjacent ring.

25 17. The valve of claim 1, wherein the rigid valve frame is constructed and arranged to expand in in a controlled fashion while maintaining resistance to compressive, torsional and rotational forces.

18. The valve of claim 2, wherein the struts span expandable connections of the expandable rigid valve frame.

30

19. The valve of claim 18, wherein upon the ring diameter of the rigid valve frame being increased, the struts decrease in height.

20. The valve of claim 1, wherein upon the ring diameter of the rigid valve frame being increased, function of the valve remains competent.

21. The valve of claim 1, wherein the rigid valve frame constructed and arranged to be expanded in ring diameter from an implantation diameter to the first functioning valve diameter.

22. The valve of claim 1, wherein the expandable rigid valve frame comprises a thin strip of material formed into a cylinder configured with an expansion mechanism.

23. The valve of claim 22, wherein the expansion mechanism comprises a catch wheel ratcheting mechanism.

24. The valve of claim 23, wherein the catch wheel ratcheting mechanism comprises a tab located on the leading edge of the thin strip and a series of spaced prongs and slots located on a trailing side of the strip.

25. The valve of claim 22, wherein the expandable rigid valve frame is encased in a protective sheath.

26. The valve of claim 22, further comprising a valve attachment frame cooperating with the expandable frame, the valve attachment frame configured to attach the valve to the expandable frame.

27. A medical device for implantation within a body to form a passageway between a first tissue region and a second tissue region, the device comprising:

a conduit having a first end portion, a second end portion, and a lumen;

a valve disposed within the lumen;

a first expandable cuff disposed at the first end portion of the conduit, the first expandable cuff constructed and arranged to be sutured to the first tissue region; and

a second expandable cuff disposed at the second end portion of the conduit, the second expandable cuff constructed and arranged to be sutured to the second tissue region.

28. The device of claim 27, wherein the valve is an expandable valve.

29. The device of claim 28, wherein the expandable valve is radially expandable.

30. The device of claim 27, wherein the conduit comprises a stent.

5

31. The device of claim 27, wherein the conduit comprises a covering.

32. The device of claim 27, wherein the first expandable cuff and the second expandable cuff comprise ePTFE.

10

33. The device of claim 27, wherein the first expandable cuff and the second expandable cuff are radially expandable.

34. The device of claim 27, wherein a property of the first expandable cuff is different than a property of the second expandable cuff.

15

35. The device of claim 27, wherein the conduit is constructed and arranged to exhibit curvature between the first end portion and the second end portion.

36. The device of claim 27, further comprising a restrictor adapted to induce curvature in the conduit.

20

37. A method of correcting artificial heart valve function for a patient, the patient having a previously implanted first valve assembly at a semilunar position of the heart, the first valve assembly having valve leaflets attached to a first valve frame, the first valve frame having a diameter, the method comprising:

25

applying an outward force to the first valve frame to increase the diameter of the first valve frame; and

implanting a second valve assembly in a resulting lumen whereby the second valve assembly replaces the function of the first valve assembly, wherein the first valve frame is constructed and arranged as a docking station for the second valve assembly and at least one of the first valve frame and the second valve assembly is expandable.

30

38. The method of claim 37, wherein implanting the second valve assembly comprises the second valve assembly holding open the valve leaflets of the previously implanted first valve.

39. The method of claim 37, wherein applying the outward force to the first valve frame
5 comprises applying an outward radial force to the first valve frame.

40. The method of claim 39, wherein applying the outward radial force to the first valve frame comprises inflating a balloon.

10 41. The method of claim 37, wherein implanting the second valve assembly at the semilunar position of the heart comprises positioning a catheter at the semilunar position of the heart.

42. The method of claim 37, wherein the expandable valve frame is resistant to
15 compressive loads.

43. The method of claim 37, wherein the first valve frame is expandable.

44. The method of claim 37, wherein the second valve assembly includes a second valve
20 frame that is expandable.

45. A method of improving heart valve function for a patient, the method comprising:
implanting a valve at a semilunar position of the heart having an abnormally small
annulus, the valve having leaflets attached to an expandable valve frame, and the valve frame
25 having a diameter; and

applying a radially outward force to the valve frame such that the diameter of the
valve frame increases such that the small annulus at the semilunar position of the heart
increases.

30 46. A method of improving heart valve function for a growing patient, the method comprising:

implanting a valve at a semilunar position of the heart having an abnormally small
annulus, the valve having leaflets attached to an expandable valve frame, and the valve frame
having a diameter; and

applying a radially outward force to the valve frame upon patient growth such that the diameter of the valve frame can increase as the patient grows.

47. A method of manufacturing a medical device for implantation within a body to form a conduit between a first tissue region and a second tissue region, the method comprising:
forming a tube having a first end portion, a second end portion, and a lumen;
placing an anatomical valve within the lumen of the tube;
attaching a first expandable cuff to the first end portion, the first expandable cuff constructed and arranged to be sutured to the first tissue region; and
attaching a second expandable cuff to the second end portion, the second expandable cuff constructed and arranged to be sutured to the second tissue region.

48. The method of claim 47, further comprising inducing a curvature between the first end portion and the second end portion.

49. The method of claim 48, wherein inducing the curvature comprises crimping the tube around a curved mandrel.

50. The method of claim 47, wherein inducing the curvature comprises placing a restrictor at a region of the tube.

51. A method for treating a pulmonary artery, the method comprising:
providing a device having a tube defining a lumen, the device having a valve disposed in the lumen, a first expandable cuff disposed at a first end portion of the tube, and a second expandable cuff disposed at a second end portion of the tube;
suturing a portion of the first expandable cuff to a first tissue region; and
suturing a portion of the second expandable cuff to a second tissue region, thereby forming a conduit to provide fluid communication between the first tissue region and the second tissue region through the device.

52. The method of claim 51, further comprising radially expanding the device upon growth of the patient.

53. The method of claim 51, further comprising inducing curvature between the first end portion and the second end portion of the device to accommodate an anatomical feature of the patient.

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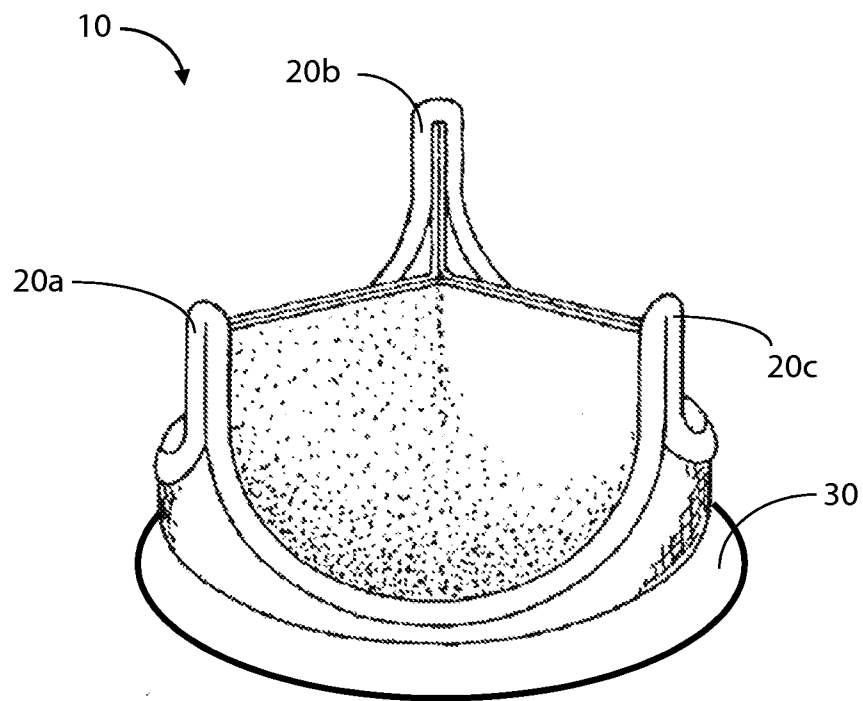


FIG. 1A
(Prior Art)

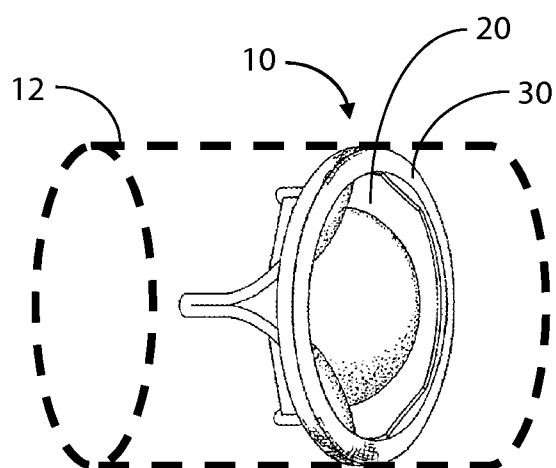


FIG. 1B
(Prior Art)

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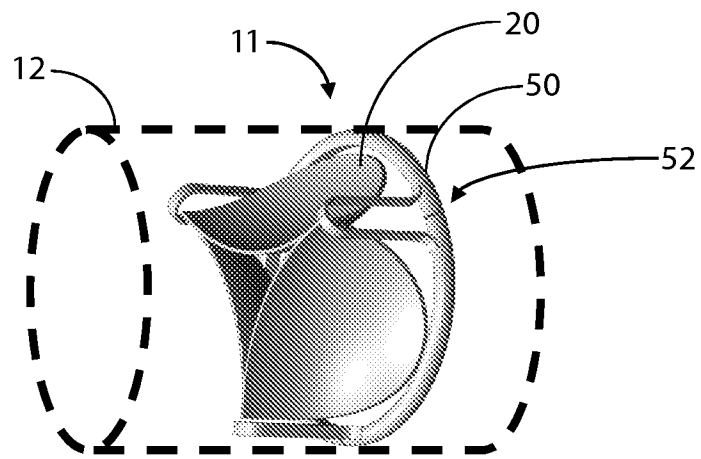


FIG. 2A

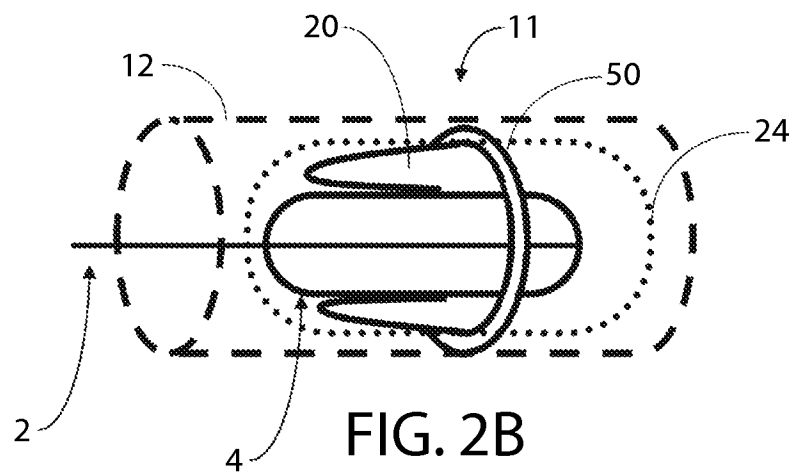


FIG. 2B

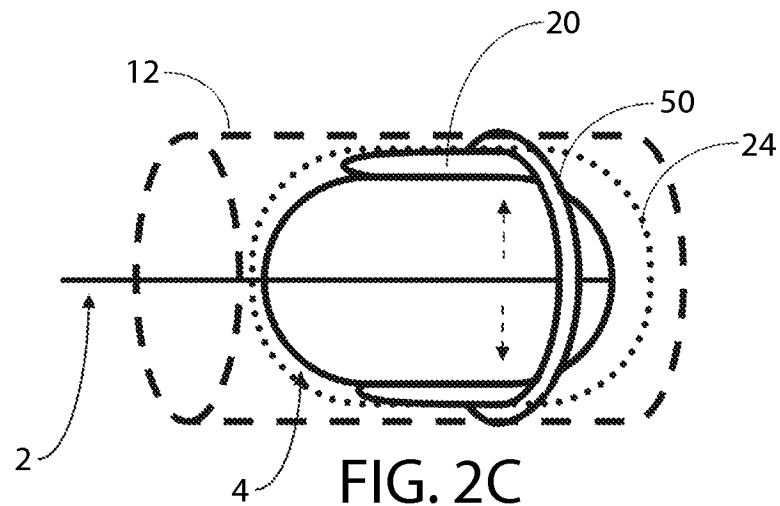


FIG. 2C

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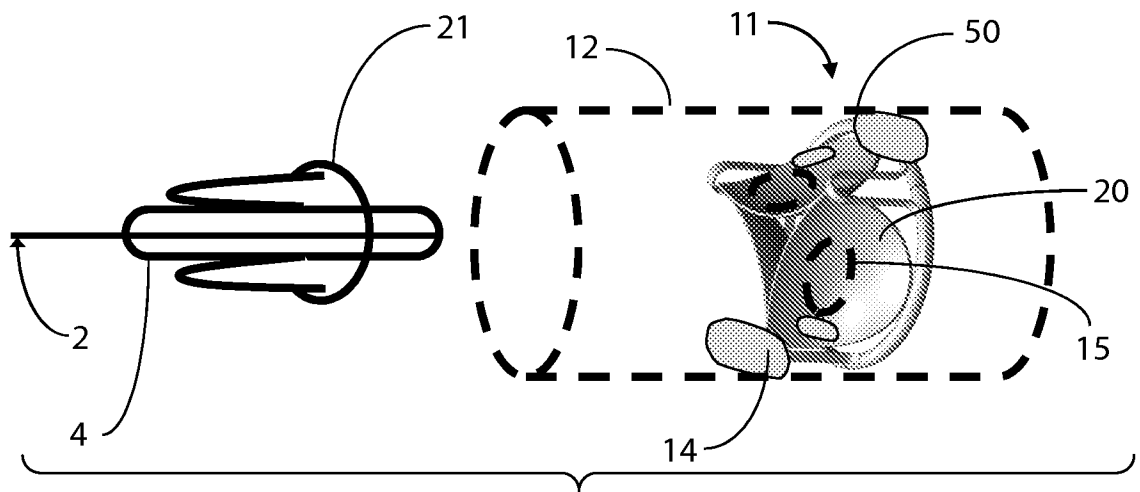


FIG. 3A

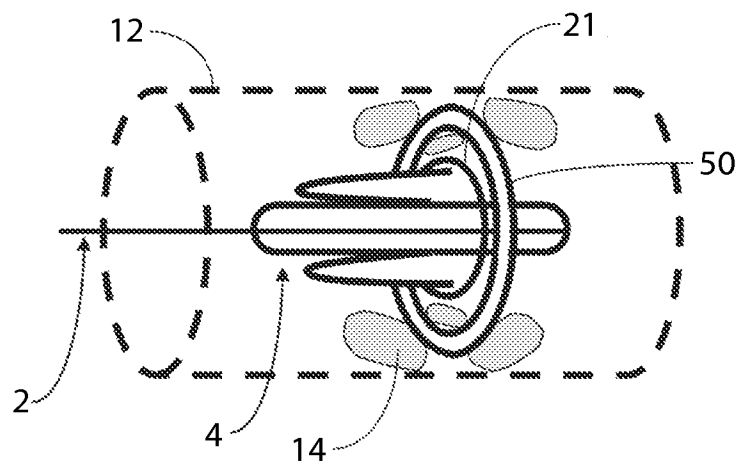


FIG. 3B

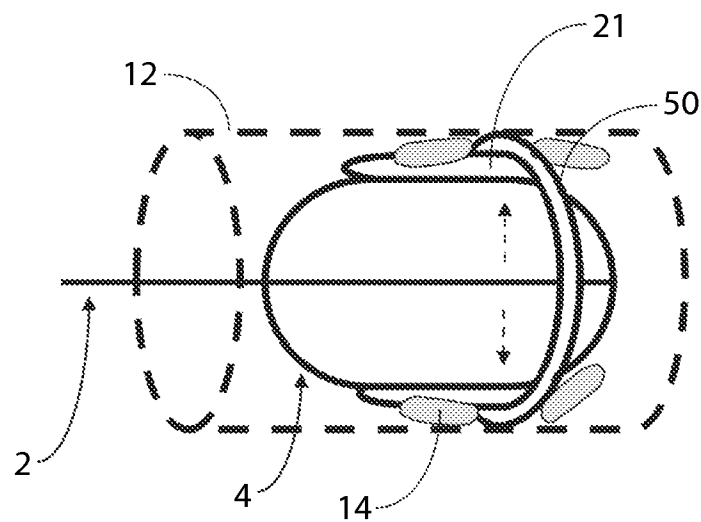


FIG. 3C

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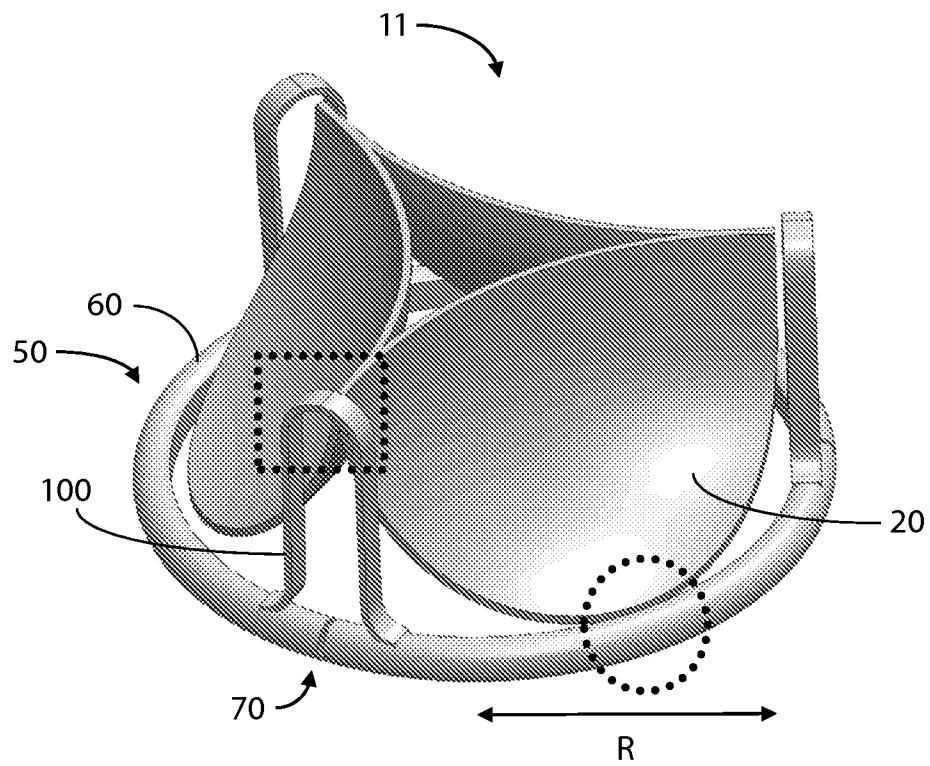


FIG. 4

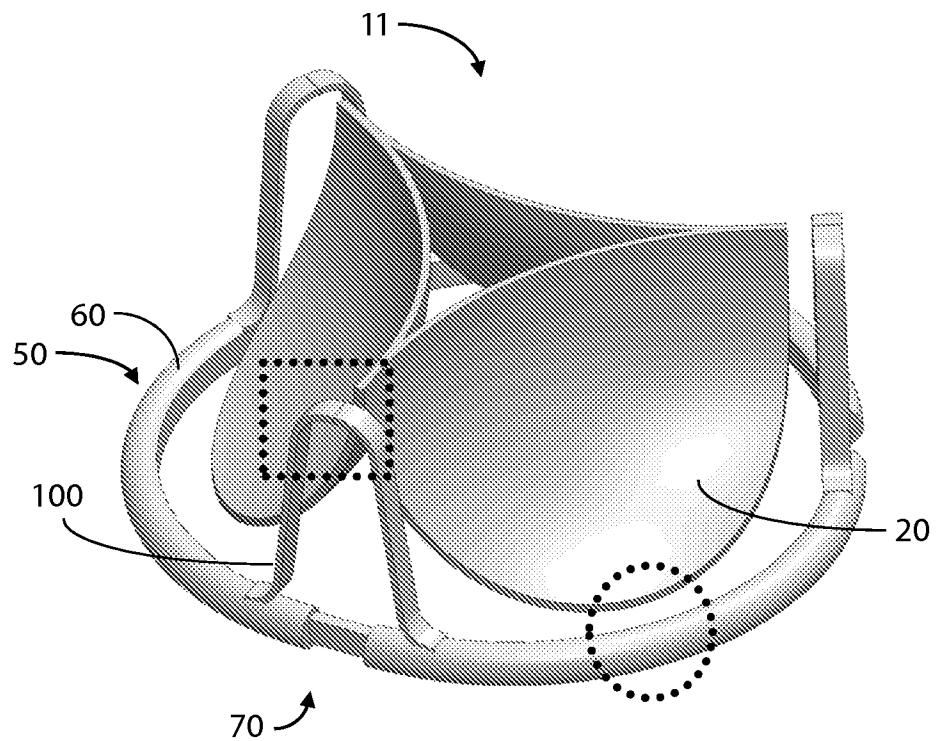


FIG. 5

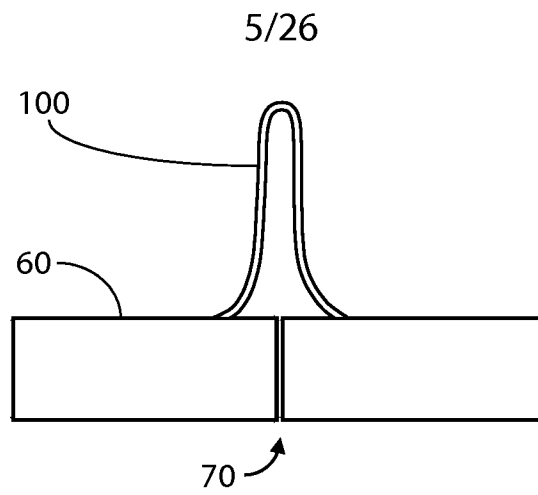


FIG. 6A

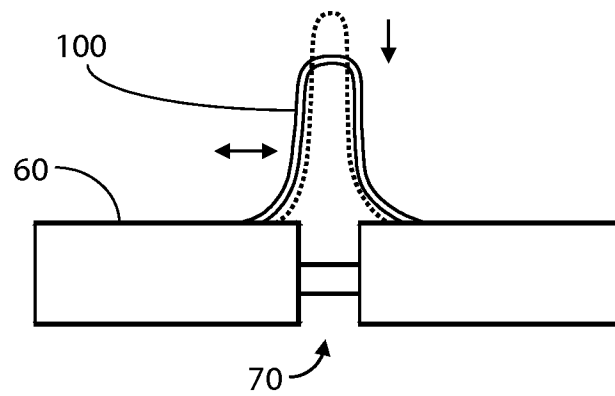


FIG. 6B

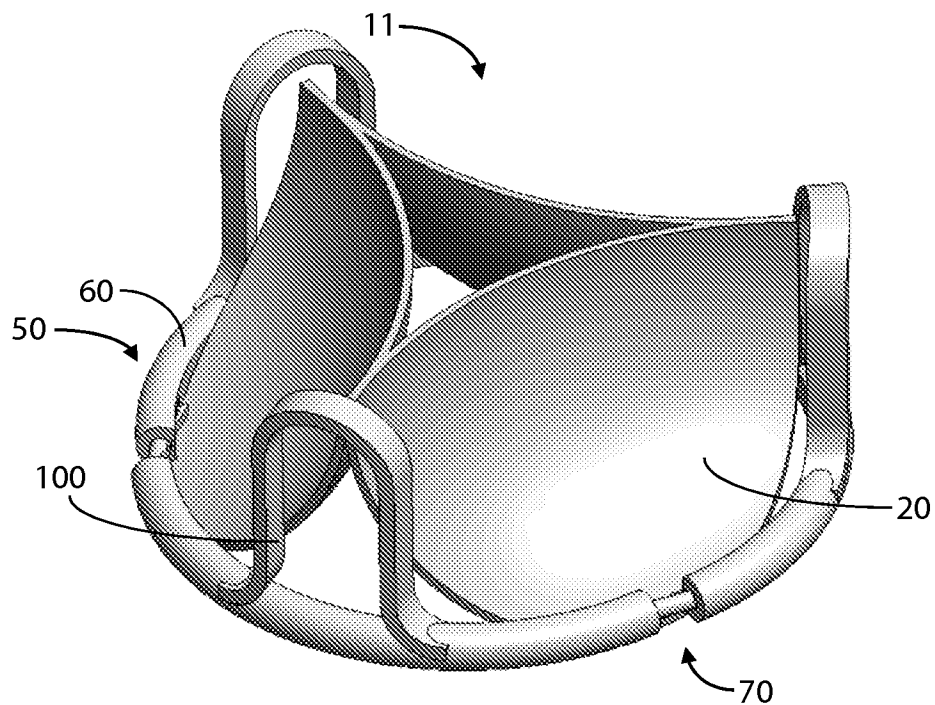


FIG. 7

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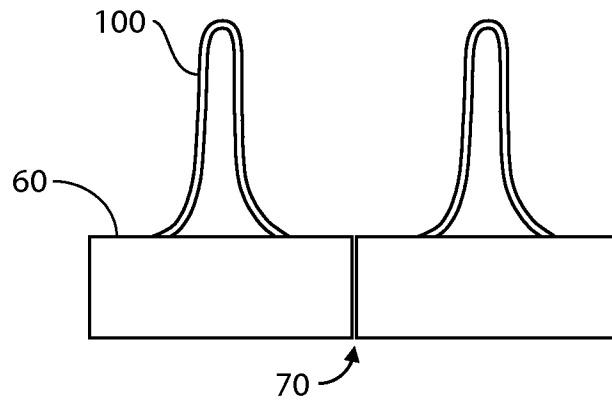


FIG. 8A

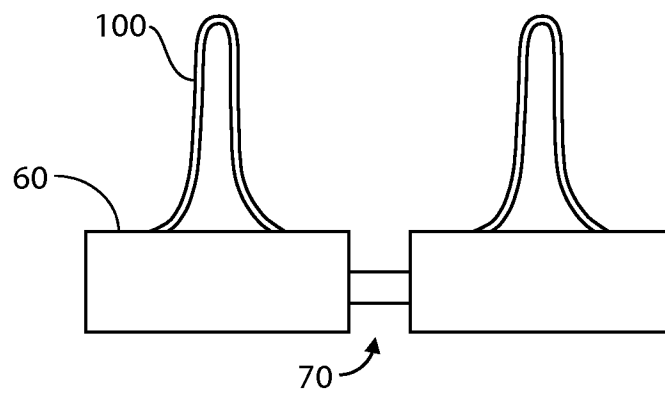


FIG. 8B

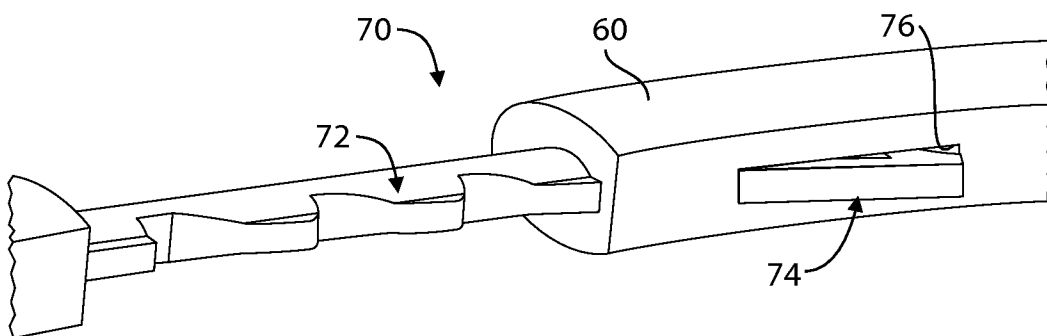


FIG. 9

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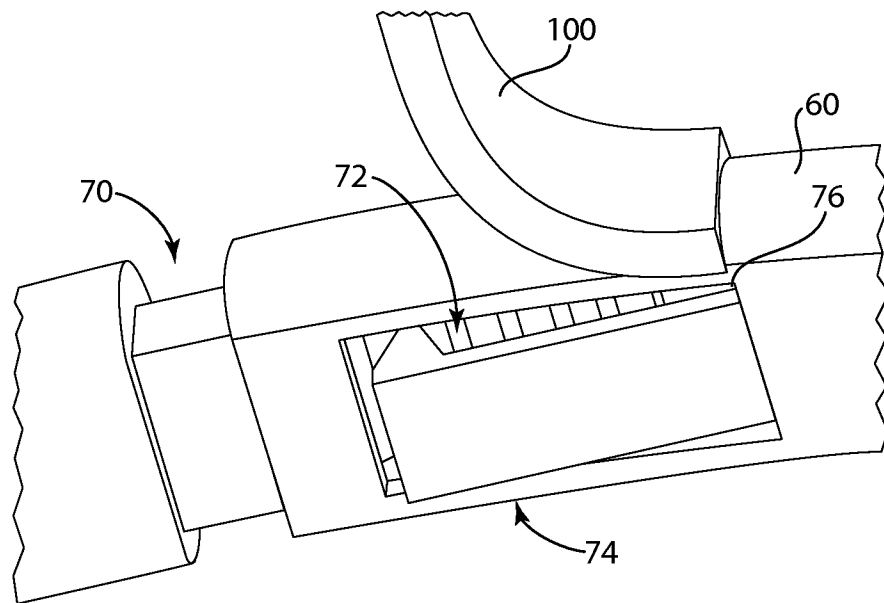


Fig. 10

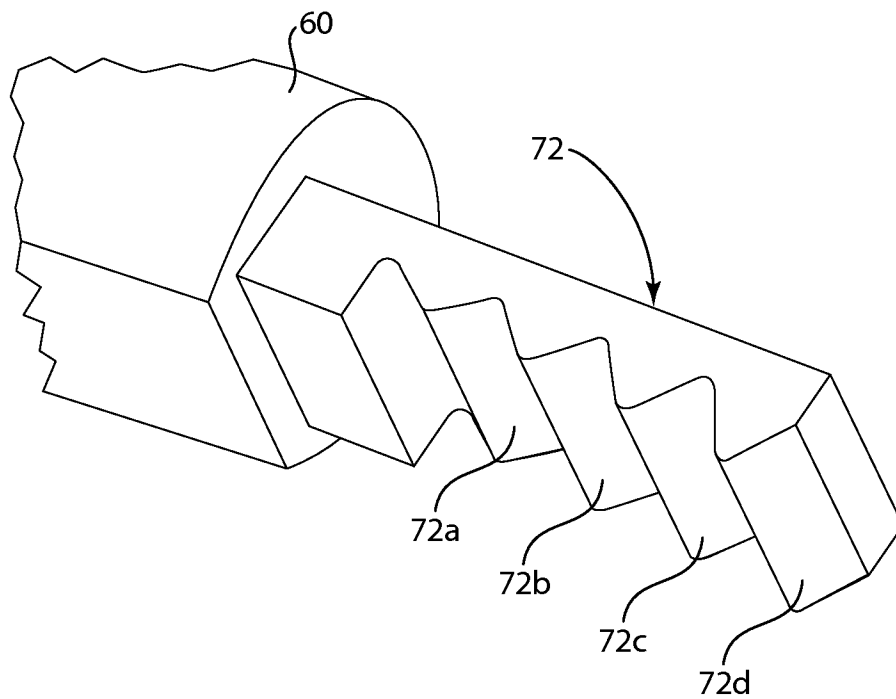


Fig. 11

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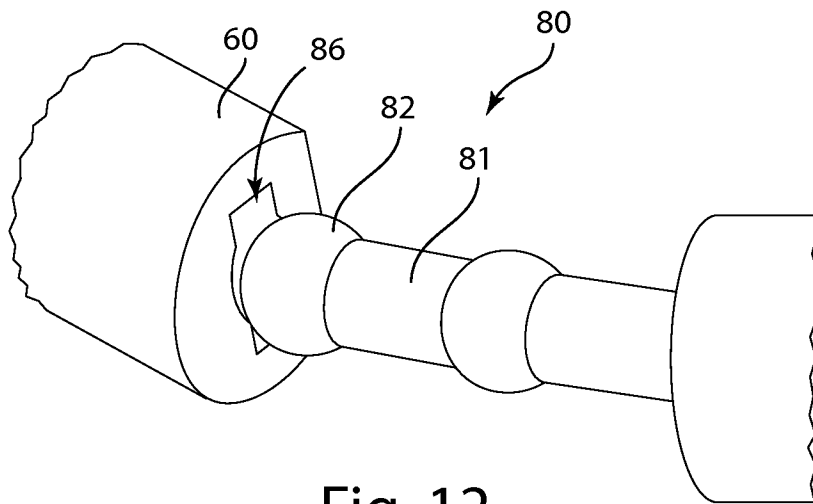


Fig. 12

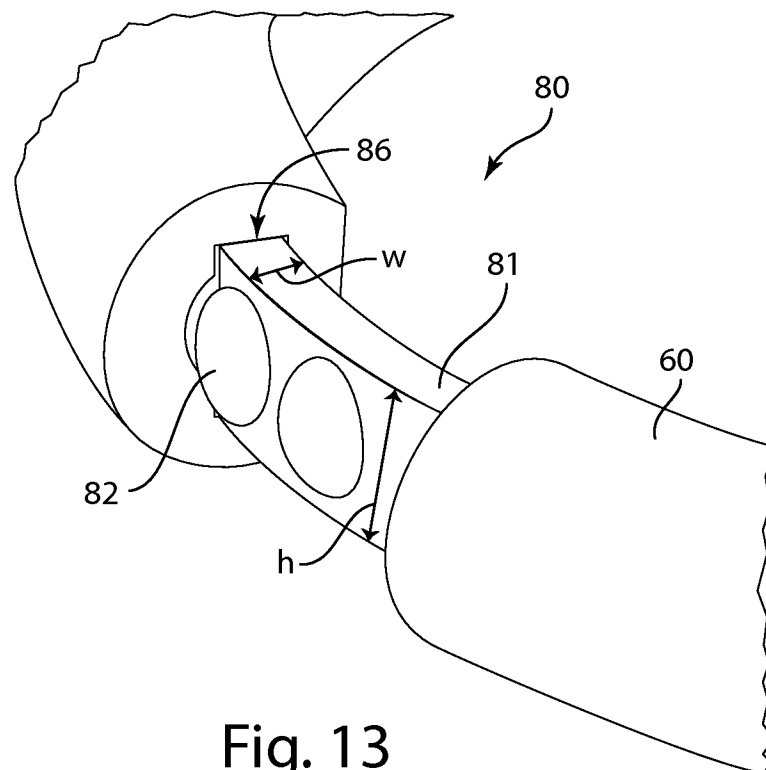


Fig. 13

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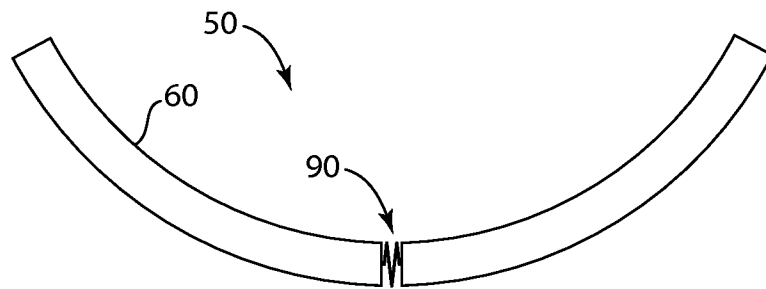


Fig. 14

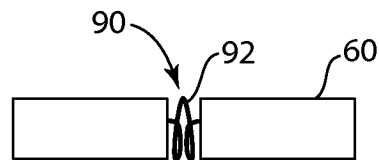


Fig. 15

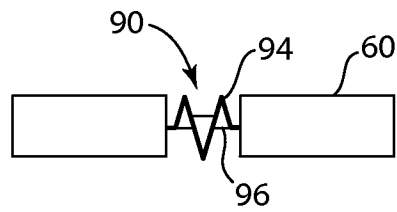


Fig. 16

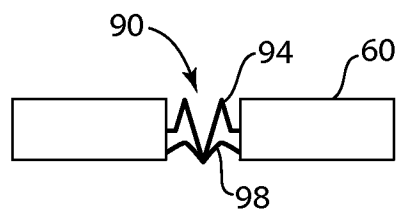


Fig. 17

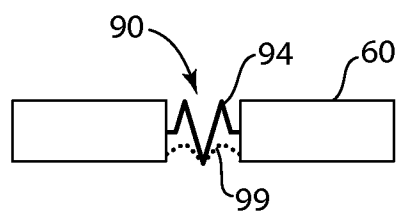
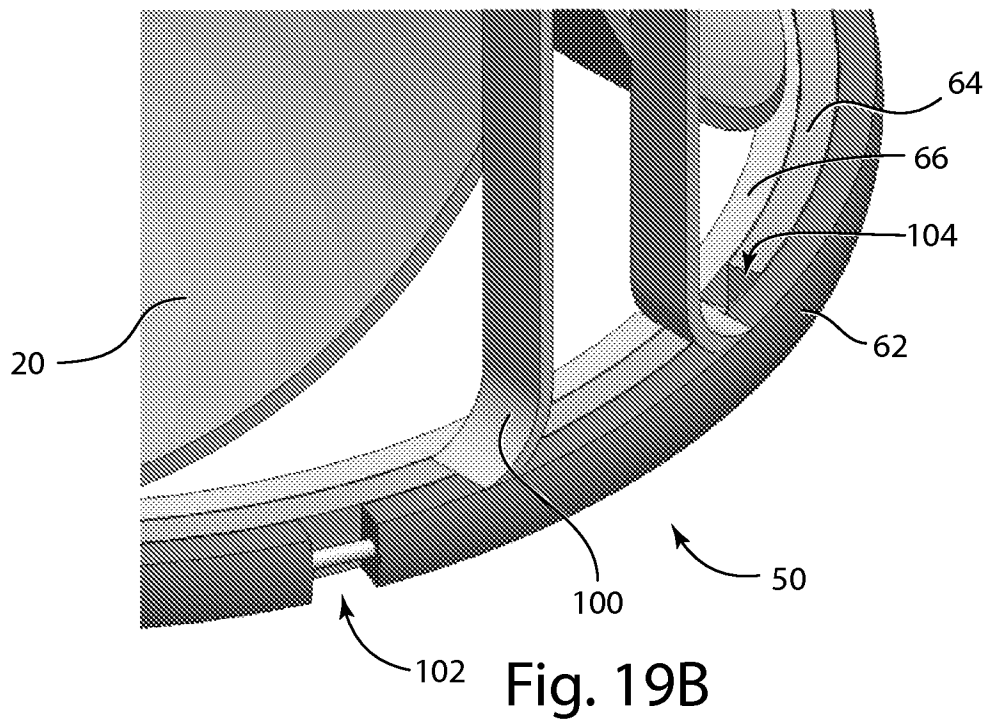
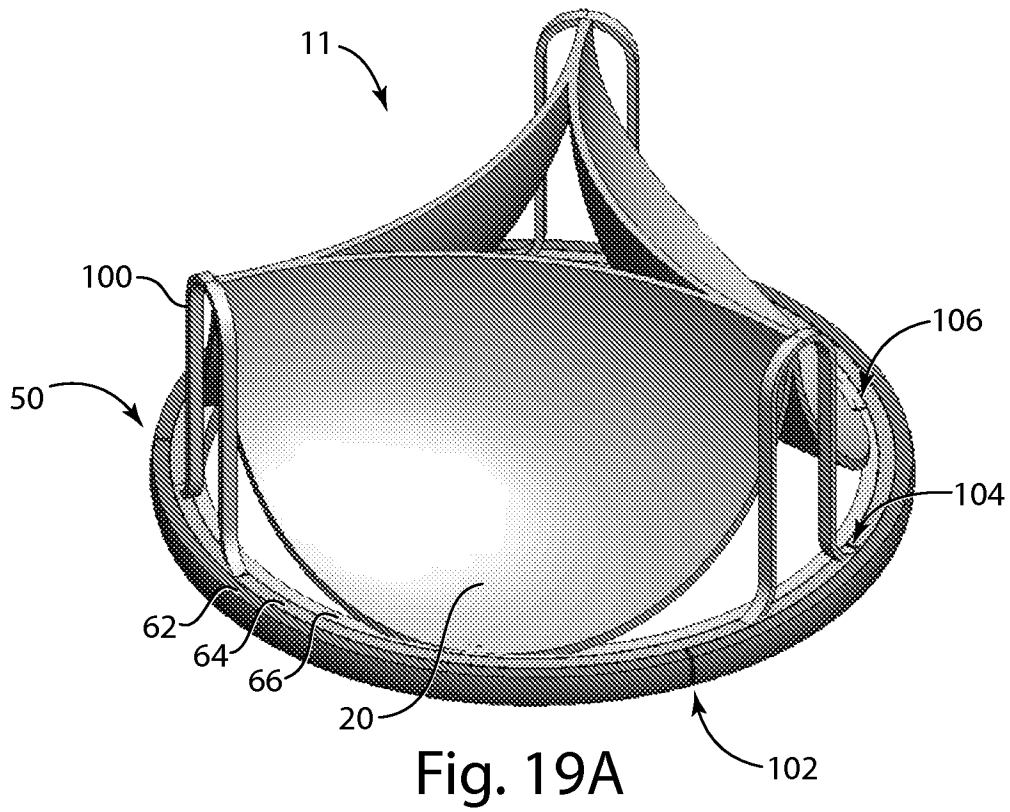


Fig. 18

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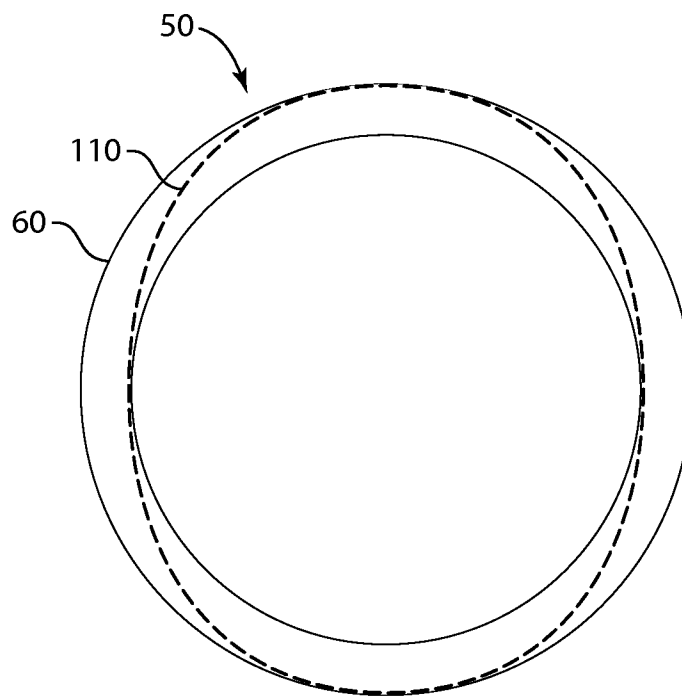


Fig. 20

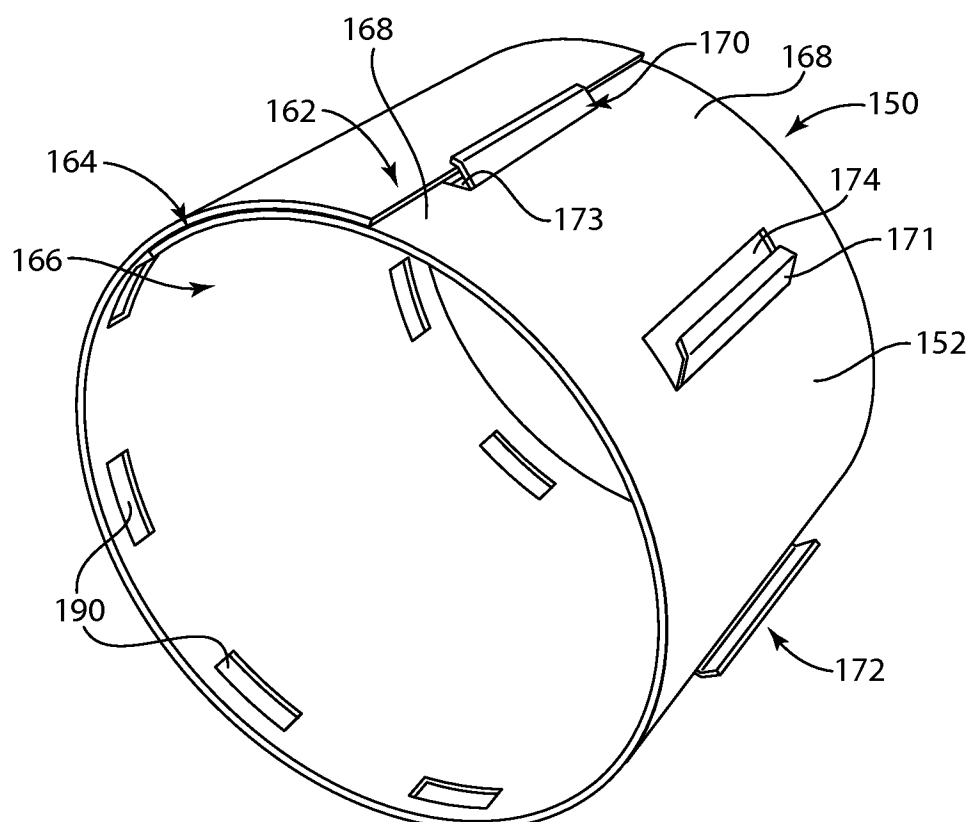


Fig. 21

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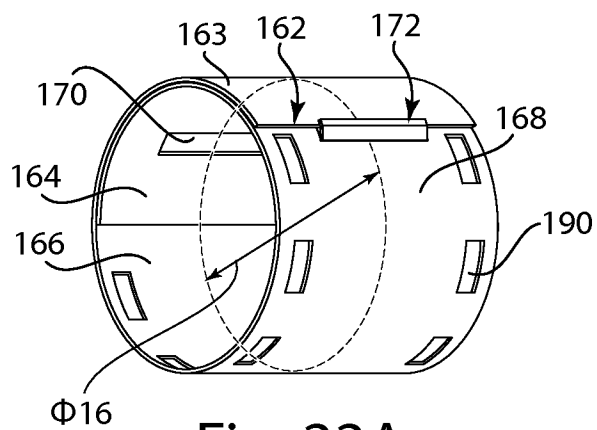


Fig. 22A

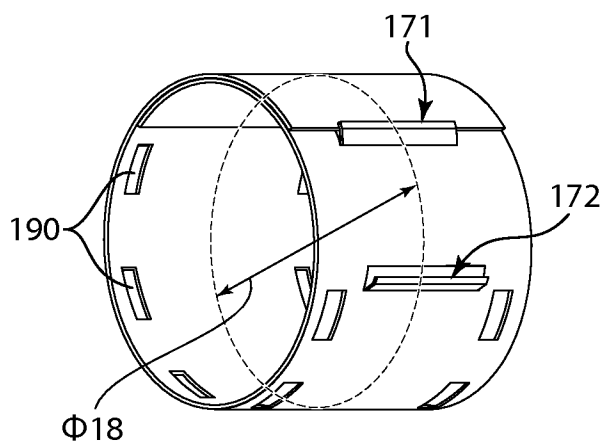


Fig. 22B

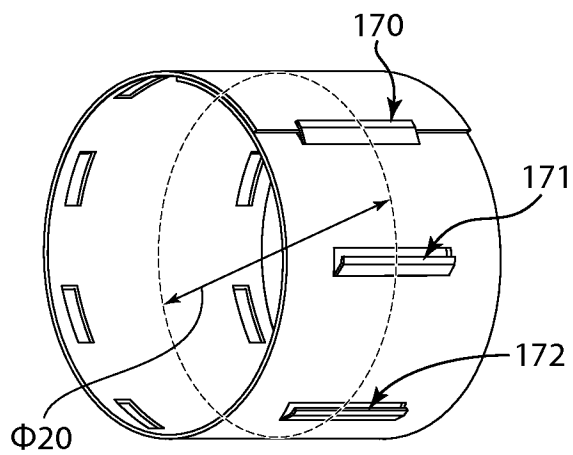


Fig. 22C

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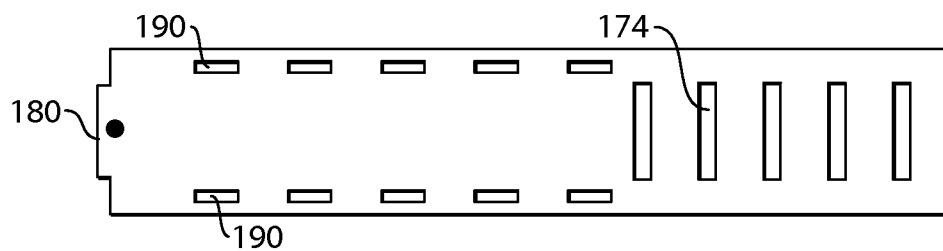


Fig. 23A

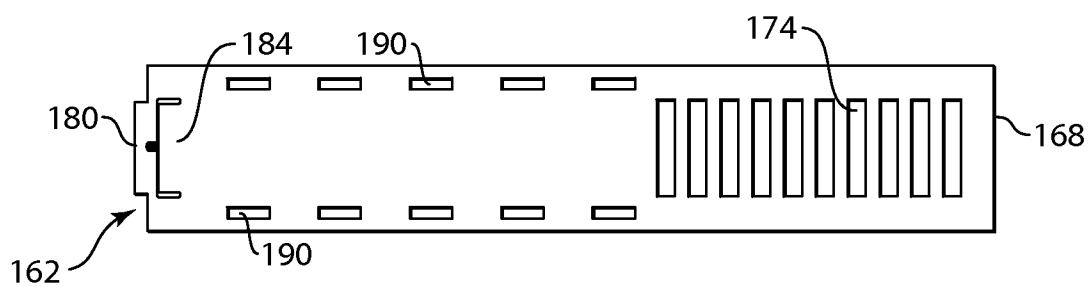


Fig. 23B

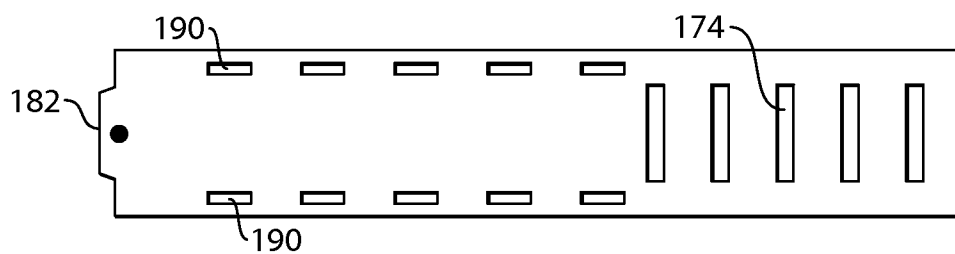


Fig. 23C

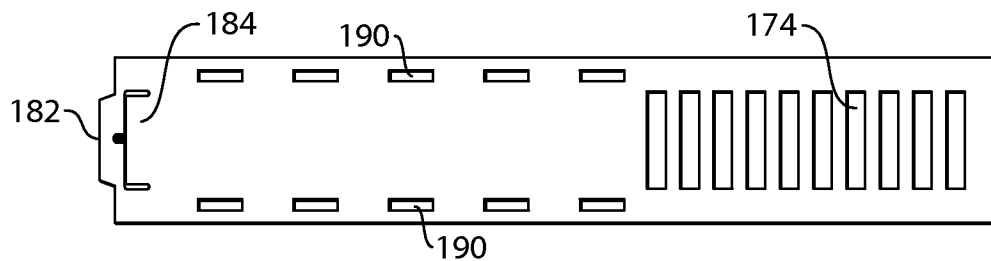


Fig. 23D

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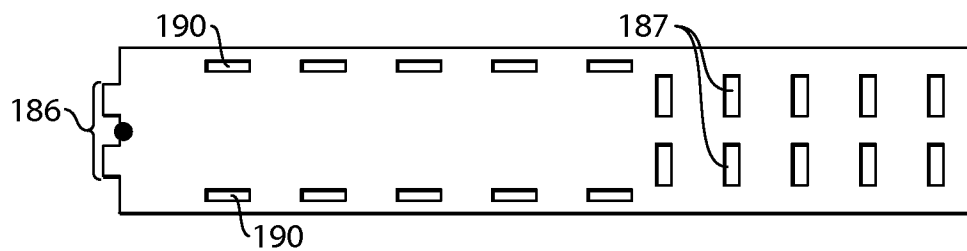


Fig. 23E

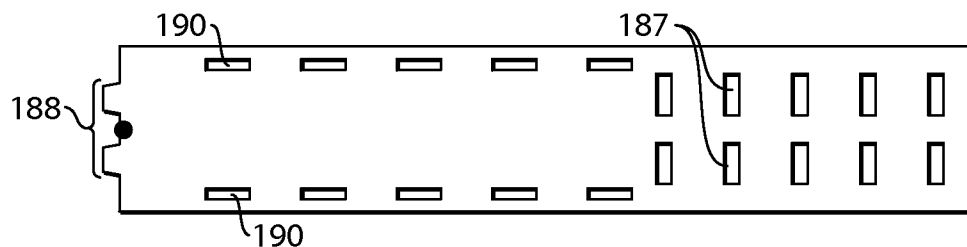


Fig. 23F

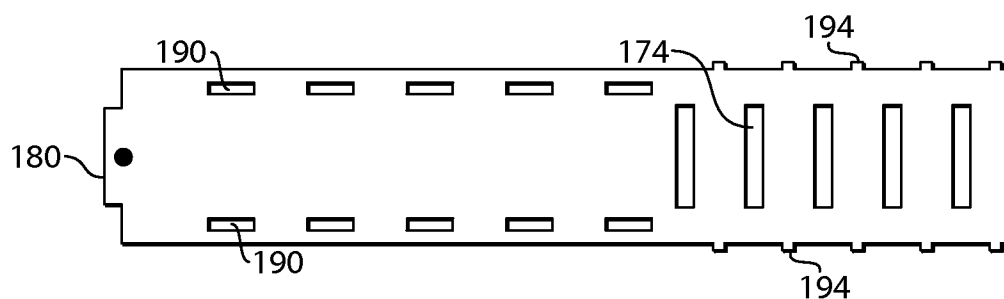


Fig. 23G

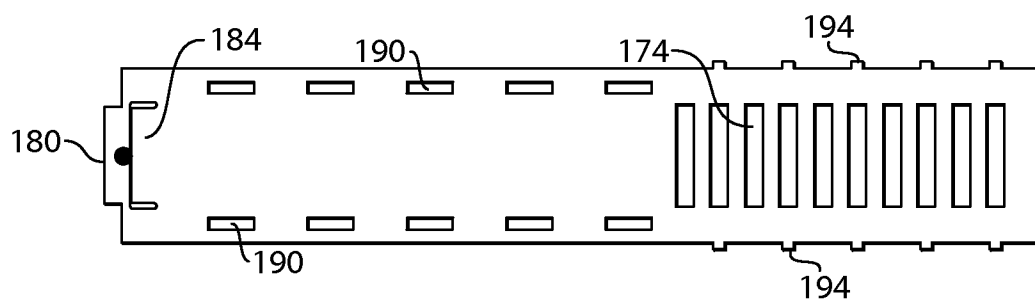


Fig. 23H

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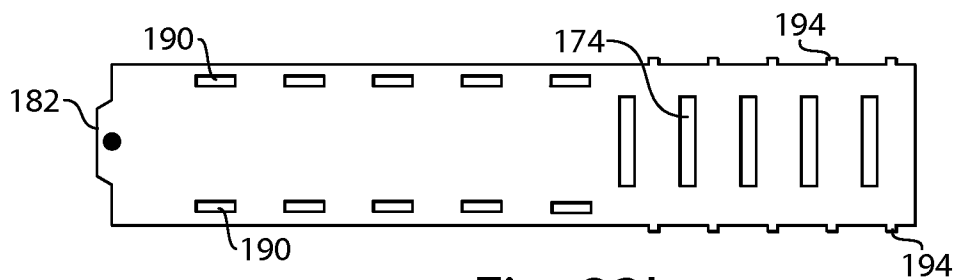


Fig. 23I

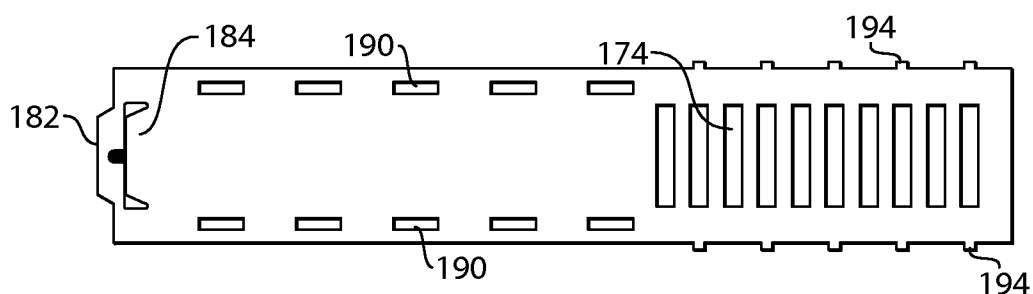


Fig. 23J

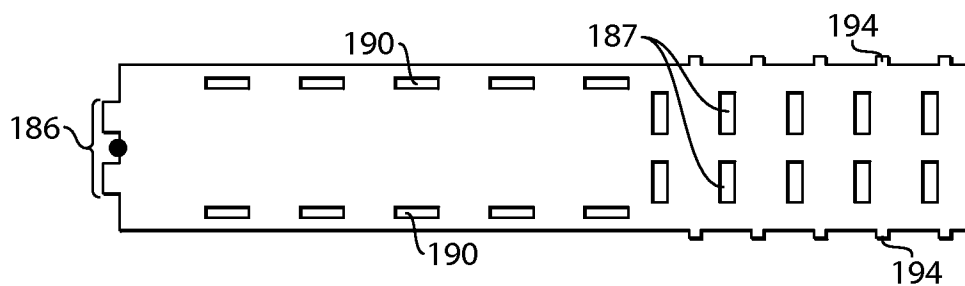


Fig. 23K

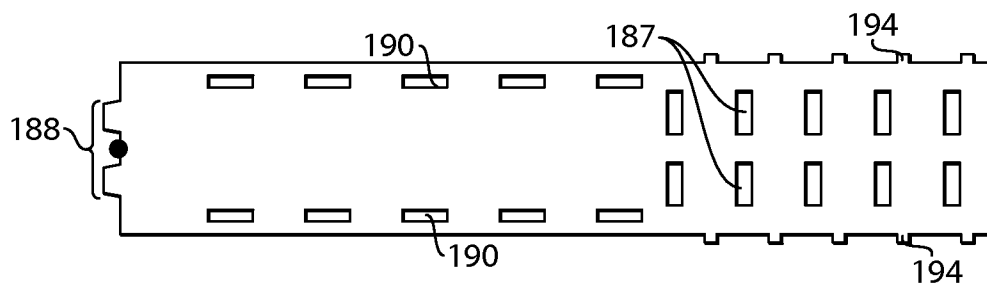


Fig. 23L

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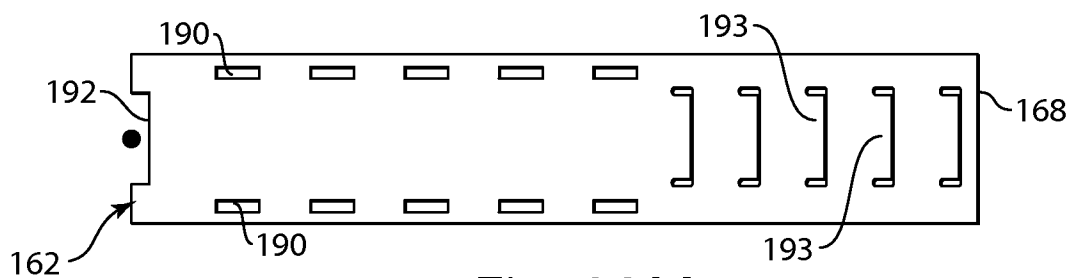


Fig. 23M

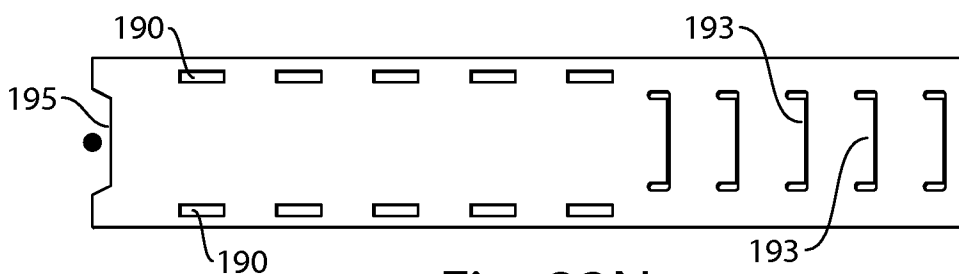


Fig. 23N

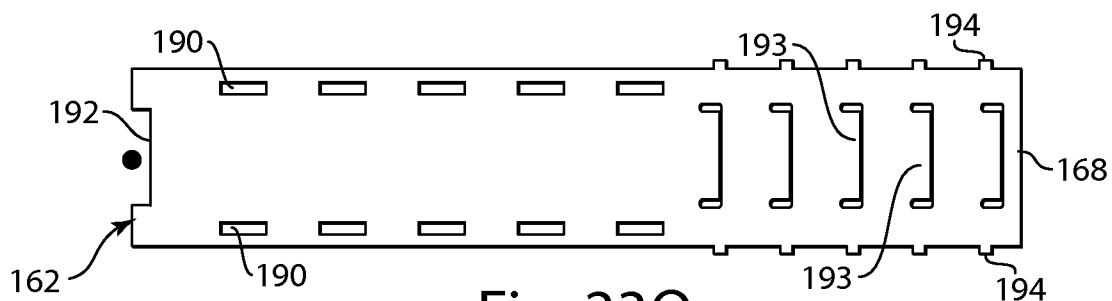


Fig. 23O

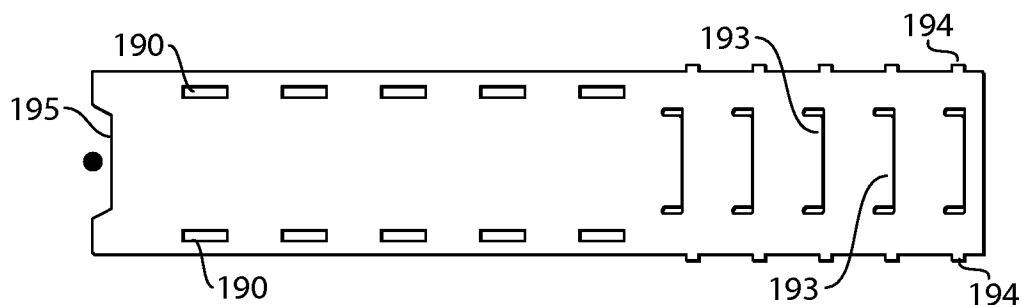


Fig. 23P

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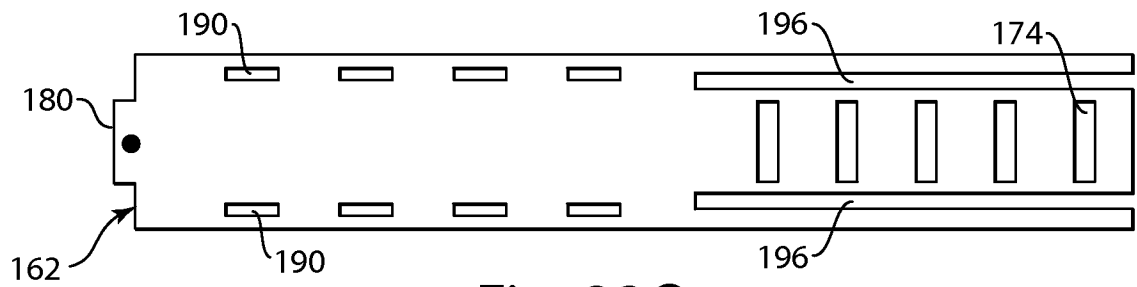


Fig. 23Q

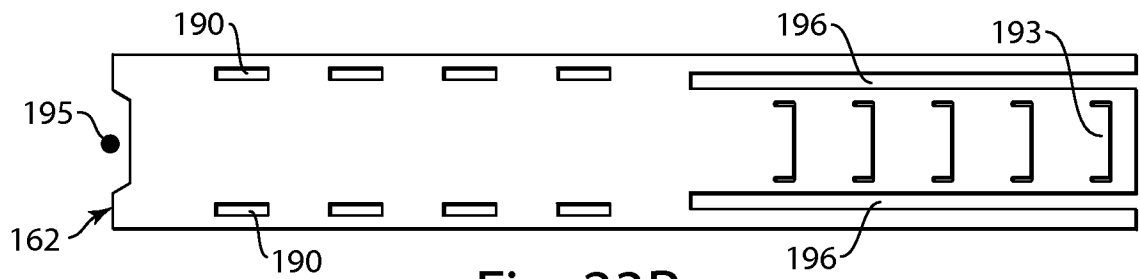


Fig. 23R

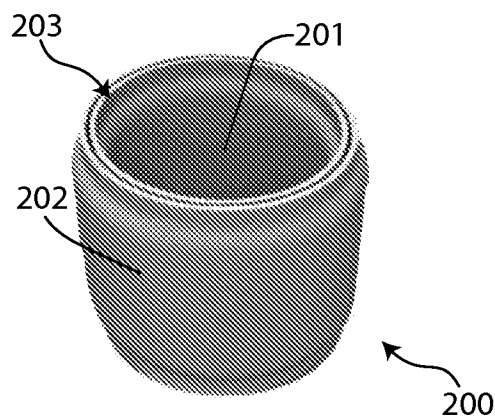


Fig. 24A

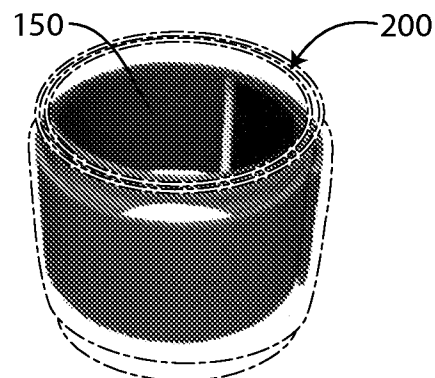


Fig. 24B

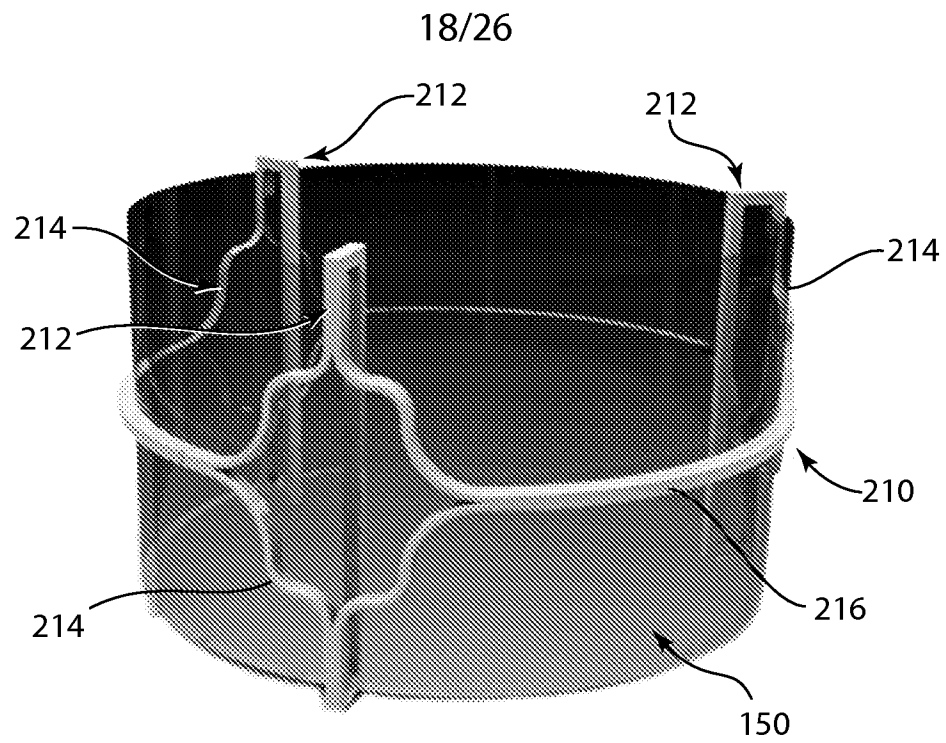


Fig. 25

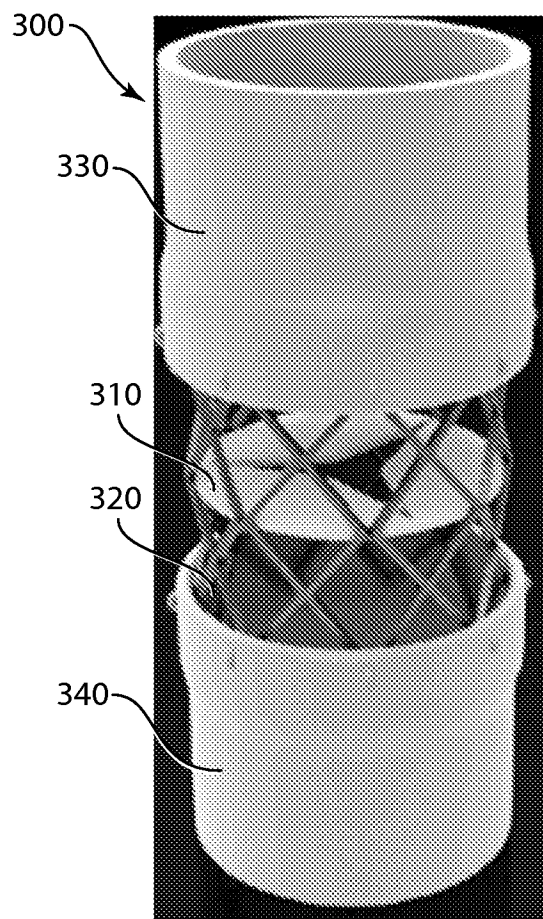


Fig. 26

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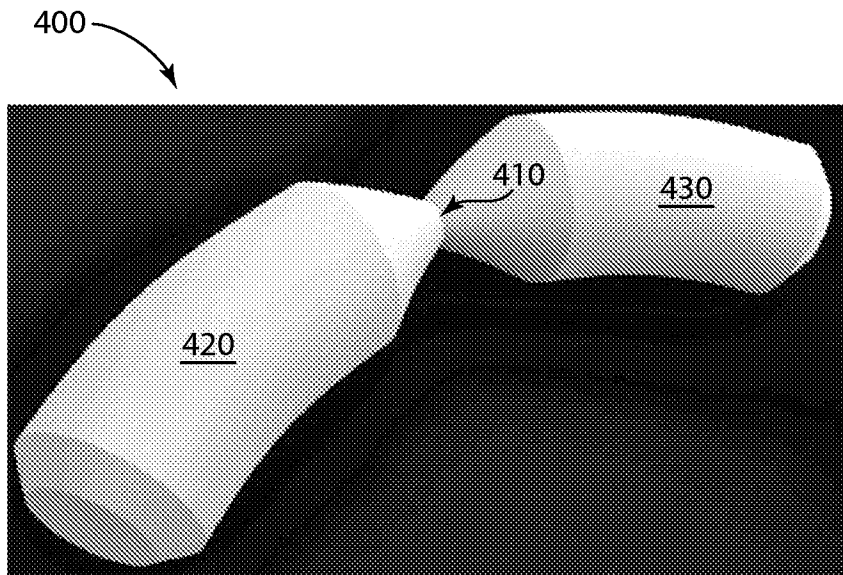


Fig. 27

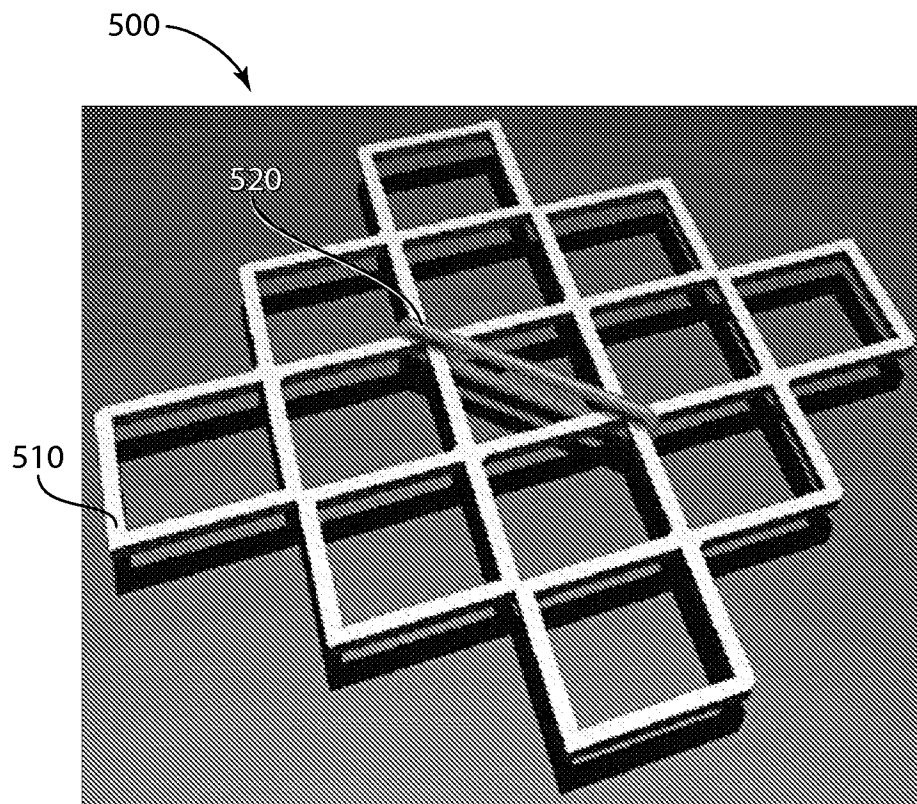


Fig. 28

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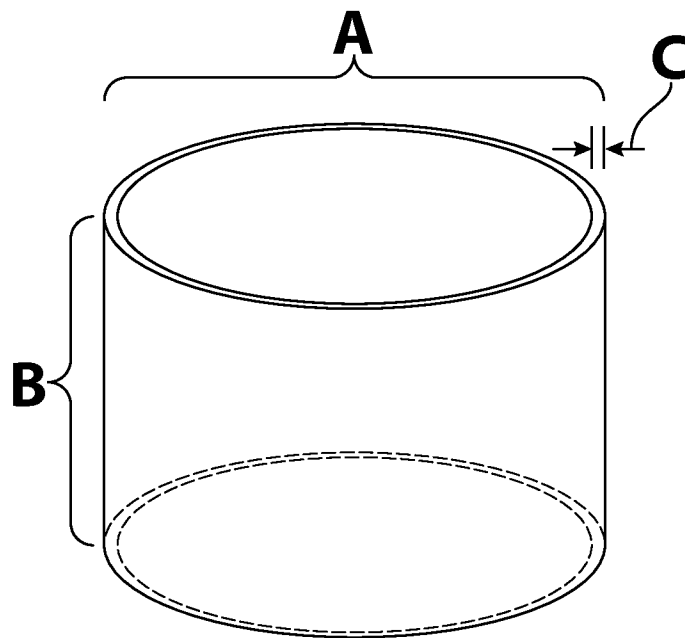


Fig. 29

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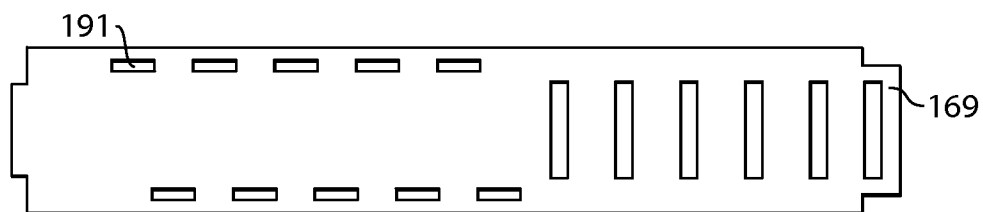


Fig. 30A

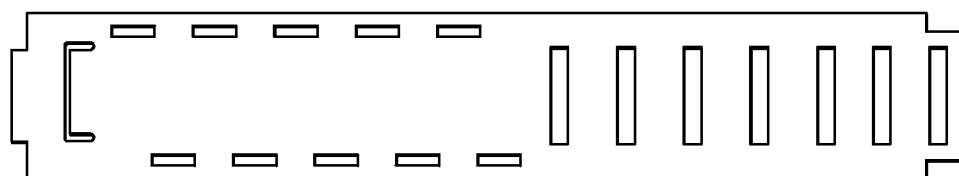


Fig. 30B

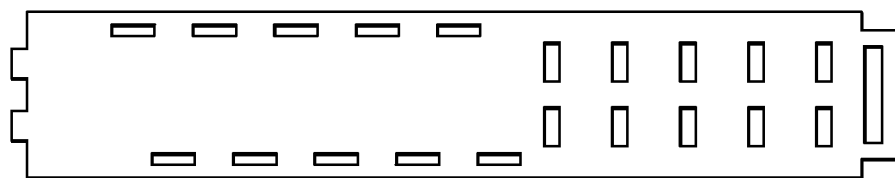


Fig. 30C

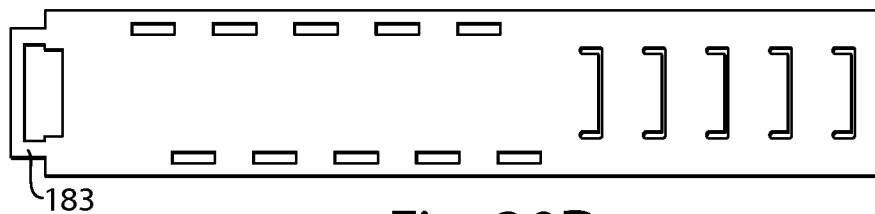
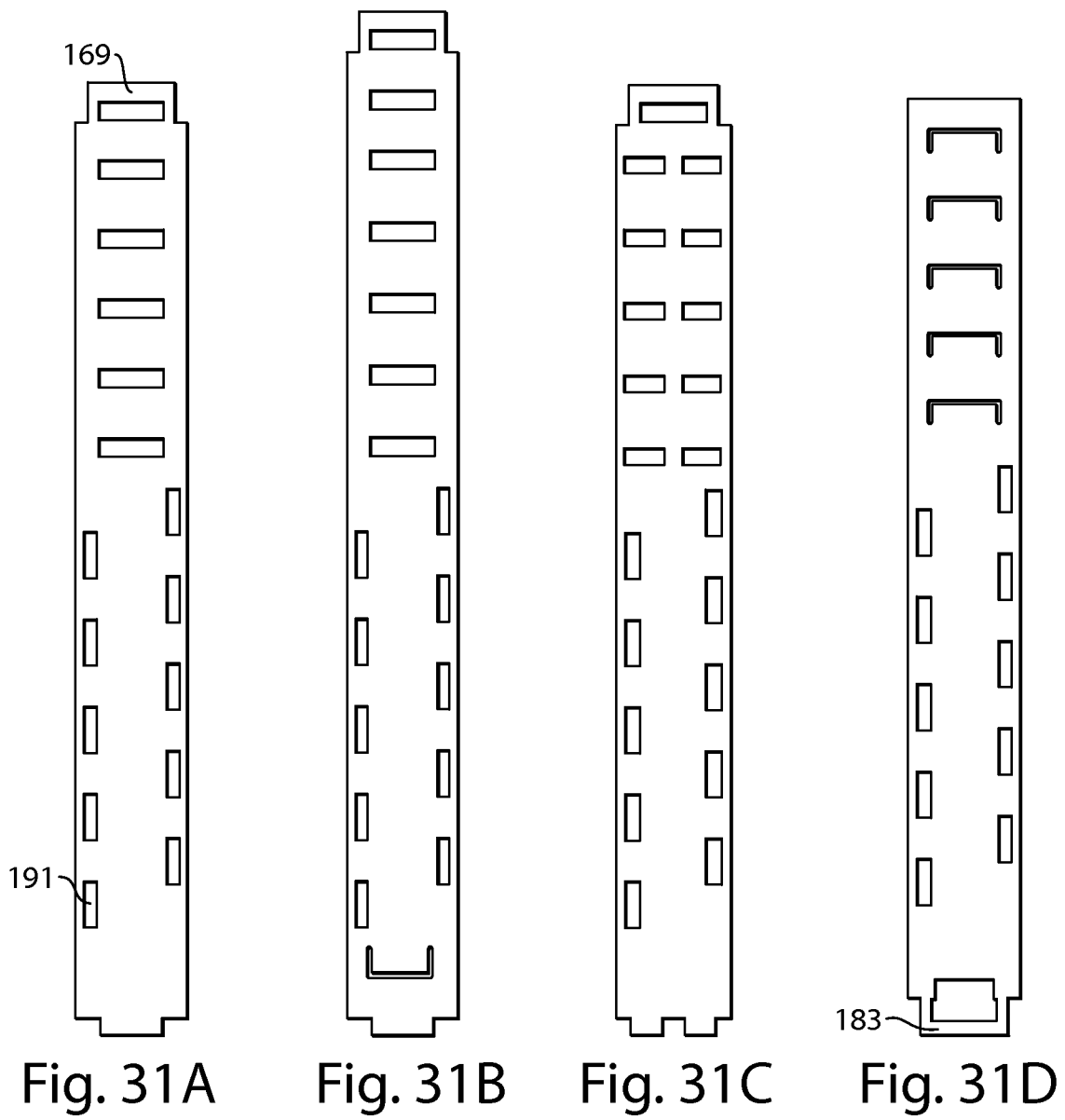


Fig. 30D



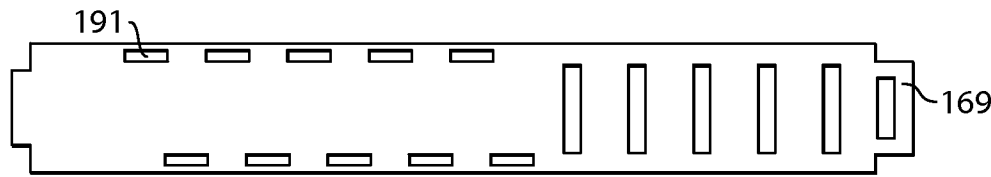


Fig. 32A

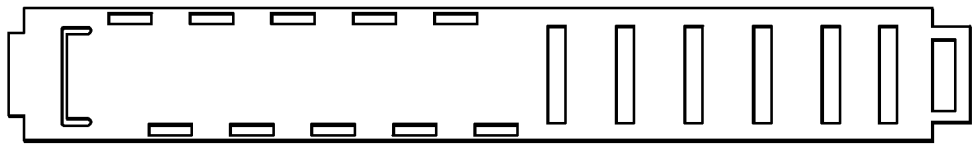


Fig. 32B

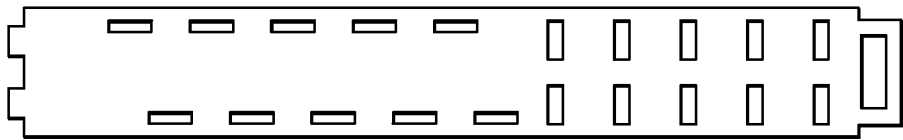


Fig. 32C

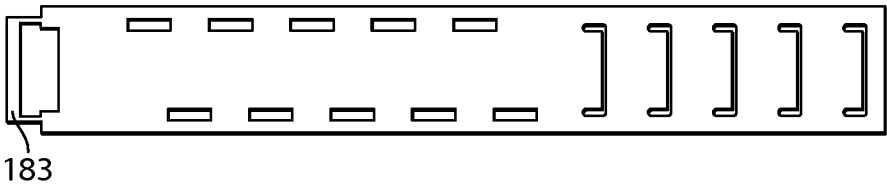


Fig. 32D

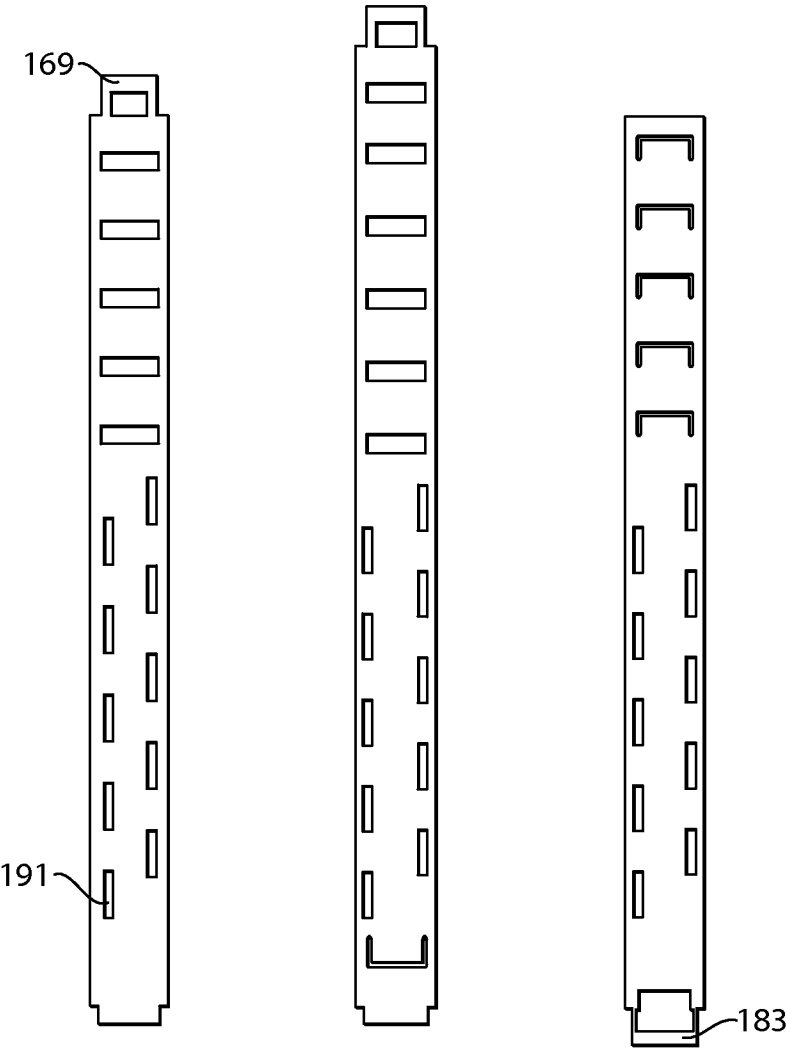


Fig. 33A Fig. 33B Fig. 33C

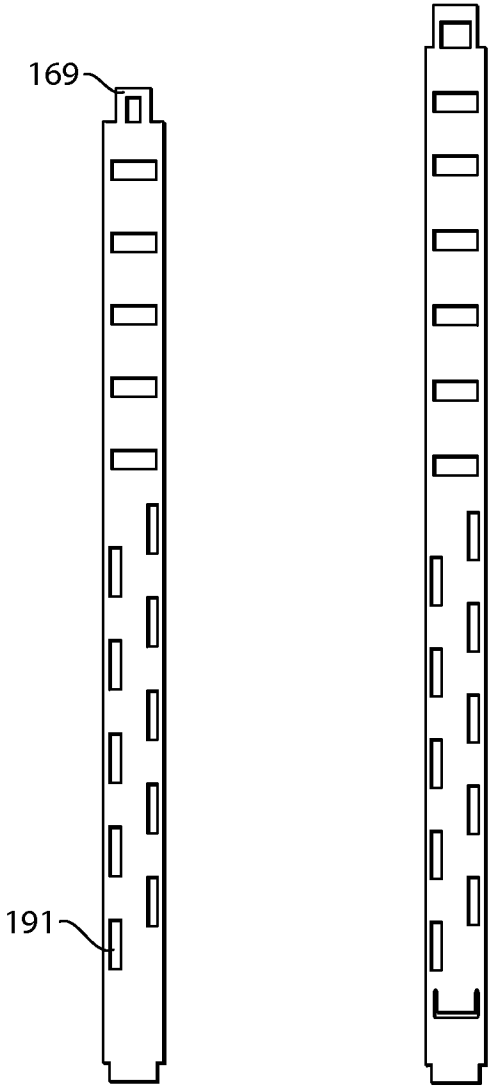


Fig. 34A Fig. 34B

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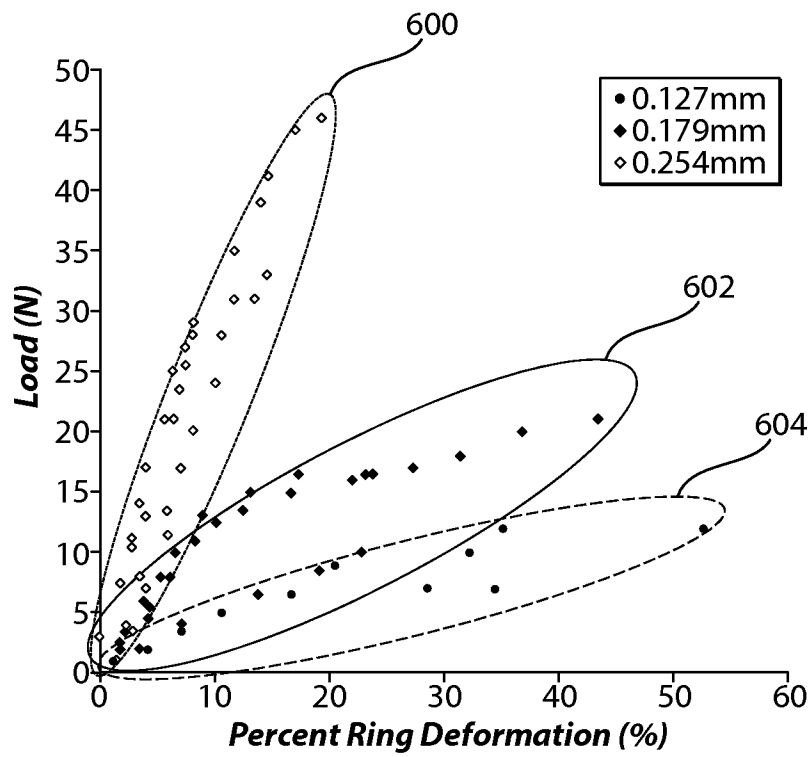


Fig. 35

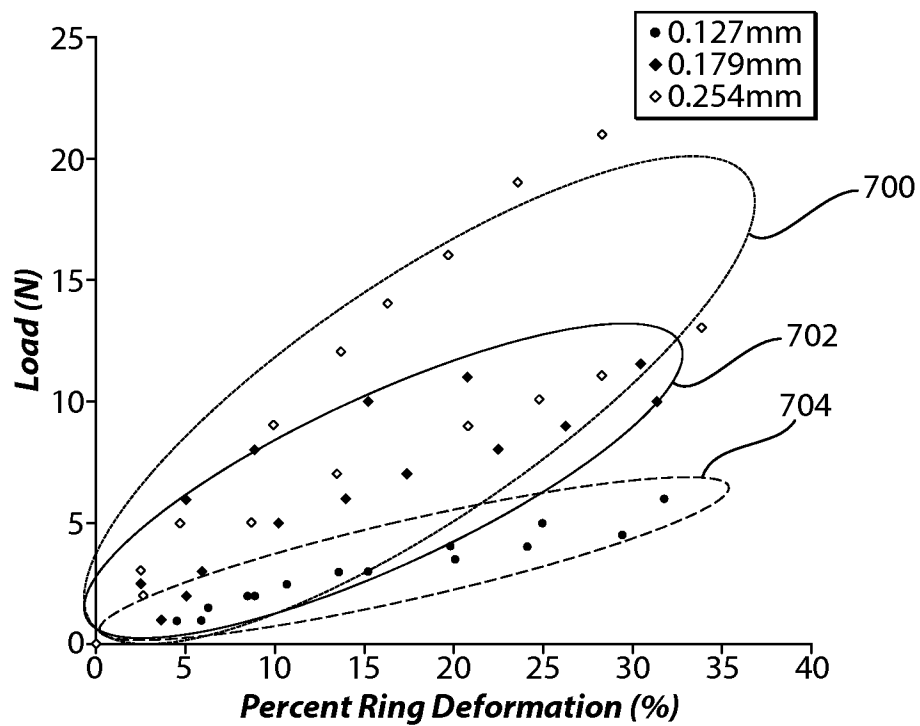


Fig. 36