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(54) **Title:** SUTURE WITH APERTURE FOR USE IN PROSTHETIC DEVICES

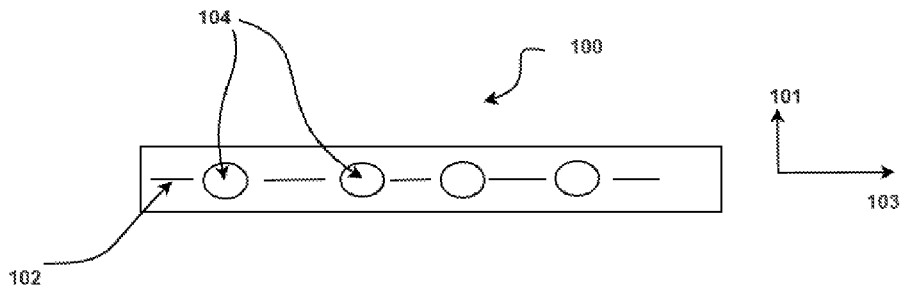

FIG. 1A

(57) **Abstract:** Prosthetic valves can have a reinforcement member designed to protect various components of the valve and the surrounding tissues from damage. The reinforcement member can include a suture with a plurality of apertures. Sutures with apertures can be utilized within or as reinforcement members, which can be attached to a prosthetic valve to reinforce the prosthetic valve.

WO 2021/178216 A1

SUTURE WITH APERTURE FOR USE IN PROSTHETIC DEVICES

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This application claims the benefit of U.S. Provisional Application No. 62/984,959, filed March 4, 2020, the content of which is incorporated herein by reference in its entirety.

FIELD

[002] The present disclosure concerns aspects of prosthetic valves and sutures used to provide enhanced structural integrity and strength thereto.

BACKGROUND

[003] The human heart can suffer from various valvular diseases. These valvular diseases can result in significant malfunctioning of the heart and ultimately require the replacement of the native valve with an artificial valve.

[004] When the native valve is replaced, surgical implantation of a prosthetic valve had required an open-chest surgery during which the heart is stopped, and the patient is placed on cardiopulmonary bypass (a so-called "heart-lung machine"). Because of the drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches are garnering intense attention. In one technique, a prosthetic valve is configured to be implanted in a much less invasive procedure by way of catheterization. For instance, U.S. Pat. Nos. 5,411,522 and 6,730,118, which are incorporated herein by reference, describe collapsible transcatheter heart valves that can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent.

[005] An important design parameter of a transcatheter heart valve is to ensure the integrity of all valve components. Many of the prosthetic valve components are connected with various sutures. Similar sutures are also used to connect the valve's

components with the surrounding tissues as appropriate. One drawback of this structure is that the suture can cut through the tissue causing unnecessary damage to the valve resulting in valve malfunction. Therefore, there are needs for reinforcement members and methods for attaching the same that substantially eliminate these issues and improve the safety of the patient. These needs and other needs are at least partially satisfied by the present disclosure.

SUMMARY

[006] Aspects of the present disclosure relate to prosthetic valves. Some aspects relate to a prosthetic valve that comprises at least one reinforcement member configured to be attached with an attachment member to one or more components of the prosthetic valve. In such aspects, the at least one reinforcement member can comprise a suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures. Furthermore, in certain aspects, each of the plurality of apertures is configured to receive the attachment member for coupling the suture to the prosthetic valve.

[007] One aspect of the prosthetic valve can comprise the attachment member that comprises one or more stitches. In certain aspects, the stitches are used to couple the suture to the prosthetic valve. In such aspects, the stitches pass through the plurality of apertures present in the at least one suture and couple the suture to the device.

[008] Also disclosed herein are aspects that encompass methods of making the disclosed prosthetic valves. In one aspect, the method comprises: providing at least one reinforcement member; attaching the at least one reinforcement member with a first attachment member to one or more components of a prosthetic valve; wherein the at least one reinforcement member comprises a suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures, wherein each of the plurality of apertures is configured to receive the first attachment member for coupling the

suture to the prosthetic valve. In further aspects and similarly to described above, the first attachment member can comprise one or more stitches. It is further understood that the aspects described in the methods of making the disclosed valve can comprise any disclosed above sutures.

[009] Also disclosed herein is a kit comprising: at least one suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures, wherein each of the plurality of apertures is configured to receive an attachment member for coupling the suture to an article. In these aspects, the first attachment member can comprise one or more stitches, flexible connectors, or any combination thereof.

[010] The foregoing and other features and advantages of the disclosure will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[011] **FIGURES 1A-1B** show a top flat-view of exemplary sutures; **FIGURE 1C** shows a photograph of an exemplary suture.

[012] **FIGURE 2** shows a front view of an exemplary aspect of a prosthetic heart valve.

[013] **FIGURE 3** shows a side view of the prosthetic heart valve of **FIG. 2** with the outer skirt removed to show an inner skirt and valvular structure mounted on the frame.

[014] **FIGURE 4** shows a rotated front view of the prosthetic heart valve of **FIG. 3**.

[015] **FIGURES 5A-5B** show an enlarged, partial cross-sectional view of a prosthetic heart valve, according to some aspects.

[016] **FIGURE 6** shows an enlarged, partial cross-sectional view of a prosthetic heart valve, according to one aspect.

[017] **FIGURE 7** shows a top plan view of the prosthetic heart valve of **FIG. 2**.

[018] **FIGURE 8** shows a side view of an exemplary leaflet shown in a flattened configuration.

[019] **FIGURE 9** shows a perspective view of an exemplary frame of the prosthetic heart valve of **FIG. 2**.

[020] **FIGURE 10** shows a perspective view of an exemplary frame of the prosthetic heart valve of **FIG. 2**.

DETAILED DESCRIPTION

[021] The present disclosure can be understood more readily by reference to the following detailed description, examples, drawings, and claims, and their previous and following description. However, before the present articles, systems, and/or methods are disclosed and described, it is to be understood that this disclosure is not limited to the specific or exemplary aspects of articles, systems, and/or methods disclosed unless otherwise specified, as such can, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular aspects only and is not intended to be limiting.

[022] The following description of the disclosure is provided as an enabling teaching of the disclosure in its best, currently known aspect. To this end, those skilled in the relevant art will recognize and appreciate that many changes can be made to the various aspects of the disclosure described herein while still obtaining the beneficial results of the present disclosure. It will also be apparent that some of the desired benefits of the present disclosure can be obtained by selecting some of the features of the present disclosure without utilizing other features. Accordingly, those of ordinary skill in the pertinent art will recognize that many modifications and adaptations to the present disclosure are possible and may even be desirable in certain circumstances and are a part of the present disclosure. Thus, the following description is again provided as illustrative of the principles of the present disclosure and not in limitation thereof.

DEFINITIONS

[023] As used in this application and in the claims, the singular forms "a," "an," and "the" include the plural forms unless the context clearly dictates otherwise. Thus, for example, reference to a "suture" includes aspects having two or more such sutures unless the context clearly indicates otherwise.

[024] It is also to be understood that the terminology used herein is for the purpose of describing particular aspects only and is not intended to be limiting. As used in the specification and in the claims, the term "comprising" can include the aspects "consisting of" and "consisting essentially of." Additionally, the term "includes" means "comprises."

[025] For the terms "for example" and "such as," and grammatical equivalences thereof, the phrase "and without limitation" is understood to follow unless explicitly stated otherwise.

[026] Ranges can be expressed herein as from "about" one particular value and/or to "about" another particular value. When such a range is expressed, another aspect includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another aspect. It should be further understood that the endpoints of each of the ranges are significant both in relation to the other endpoint, and independently of the other endpoint.

[027] Throughout this disclosure, various aspects of the disclosure can be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the disclosure. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from

3 to 6, etc., as well as individual numbers within that range, for example, 1, 2, 2.7, 3, 4, 5, 5.3, 6 and any whole and partial increments therebetween. This applies regardless of the breadth of the range.

[028] Further, the terms "coupled" and "associated" generally means electrically, electromagnetically, and/or physically (*e.g.*, mechanically or chemically) coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items.

[029] As used herein, the term "suture" refers to a multifilament thread, where the filaments are braided together to form a thread having predetermined dimensions. In certain aspects, the suture described herein can comprise two or more threads (cords) that are fused together. It is understood that the sutures of the present disclosure do not comprise woven or nonwoven fabric.

[030] As used herein, the term "stitch" refers to a monofilament or multifilament thread that is used as an attachment member. Some exemplary stitching sutures can have dimensions from 6-0 to 4-0.

[031] As used herein, the term or phrase "effective," "effective amount," or "conditions effective to" refers to such amount or condition that is capable of performing the function or property for which an effective amount or condition is expressed. As will be pointed out below, the exact amount or particular condition required will vary from one aspect to another, depending on recognized variables such as the materials employed and the processing conditions observed. Thus, it is not always possible to specify an exact "effective amount" or "condition effective to." However, it should be understood that an appropriate effective amount will be readily determined by one of ordinary skill in the art using only routine experimentation.

[032] Although the operations of exemplary aspects of the disclosed method may be described in a particular, sequential order for convenient presentation, it should be understood that disclosed aspects can encompass an order of operations other than the particular, sequential order disclosed. For example, operations described

sequentially may, in some cases, be rearranged or performed concurrently. Further, descriptions and disclosures provided in association with one particular aspect are not limited to that aspect and may be applied to any aspect disclosed.

[033] Moreover, for the sake of simplicity, the attached figures may not show the various ways (readily discernable, based on this disclosure, by one of ordinary skill in the art) in which the disclosed system, method, and apparatus can be used in combination with other systems, methods, and apparatuses. Additionally, the description sometimes uses terms such as “produce” and “provide” to describe the disclosed method. These terms are high-level abstractions of the actual operations that can be performed. The actual operations that correspond to these terms can vary depending on the particular implementation and are, based on this disclosure, readily discernible by one of ordinary skill in the art.

[034] In one aspect disclosed herein is a prosthetic valve comprising: at least one reinforcement member configured to be attached with a first attachment member to one or more components of the prosthetic valve; wherein the at least one reinforcement member comprises a suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures, wherein each of the plurality of apertures is configured to receive the first attachment member for coupling the suture to the prosthetic valve. It is understood, however, that the suture, as disclosed herein, does not have to function as a reinforcement member but can be used as a member configured to couple various components of the prosthetic valve or a simple article.

[035] In certain aspects and as described herein, the suture comprises a multifilament thread. In such aspects, the thread comprises two or more filaments wherein the filaments have a thickness from about 0.02 mm to about 0.5 mm, including exemplary values of about 0.03 mm, about 0.04 mm, about 0.05 mm, about 0.06 mm, about 0.07 mm, about 0.1 mm, about 0.12 mm, about 0.15 mm, about 0.17 mm, about 0.2 mm, about 0.22 mm, about 0.25 mm, about 0.27 mm, about 0.3 mm, about 0.32 mm, about 0.35 mm, about 0.37 mm, about 0.4 mm, about 0.42 mm,

about 0.45 mm, and about 0.47 mm. It is further understood that each of the filaments in the thread can have the same thickness or different.

[036] In still further aspects, the suture can comprise two or more threads that are coupled together. In such exemplary aspects, each thread can comprise two or more filaments, as disclosed above. In yet further aspects, the suture can have a width from about 0.1 mm to about 10 mm, including exemplary values about 0.2 mm, about 0.3 mm, about 0.4 mm, about 0.5 mm, about 0.6 mm, about 0.7 mm, about 0.8 mm, about 0.9 mm, about 1.0 mm, about 1.2 mm, about 1.5 mm, about 1.8 mm, about 2 mm, about 2.2 mm, about 2.5 mm, about 2.8 mm, about 3 mm, about 3.2 mm, about 3.5 mm, about 3.8 mm, about 4 mm, about 4.2 mm, about 4.5 mm, about 4.8 mm, about 5 mm, about 5.2 mm, about 5.5 mm, about 5.8 mm, about 6 mm, about 6.2 mm, about 6.5 mm, about 6.8 mm, about 7 mm, about 7.2 mm, about 7.5 mm, about 7.8 mm, about 8 mm, about 8.2 mm, about 8.5 mm, about 8.8 mm, about 9 mm, about 9.2 mm, about 9.5 mm, and about 9.8 mm. It is understood that the width of the suture can have any value between any two foregoing values.

[037] **FIGS 1A-1C** show exemplary aspects of a reinforcement member comprising a suture **100**. **FIG. 1A** and **1B**, for example, show the suture **100**, having a longitudinal axis **103** and transverse axis **101**. The suture **100** also comprises a centerline **102**. Exemplary suture **100** in **FIG. 1A** is a multifilament thread (cord) having a rectangular shape and having a plurality of apertures **104** disposed along at least a portion of the centerline **102**. The plurality of apertures **104**, which forms an opening extending through all or a portion of the suture **100**. **FIG. 1B** shows a braided suture **100** having a plurality of apertures **104** braided within the suture **100**. **FIG. 1C** shows a photograph of the exemplary suture **100** comprising two separate braided threads **105** and **107** fused together to form a plurality of apertures **104**.

[038] Apertures **104**, in certain aspects, can be positioned within at least a portion of the centerline **102**. That is, the opening formed by the apertures **104** is positioned laterally (i.e., along a transverse axis **101** of the suture **100**) along at least a portion of the centerline **102**, along all or a portion of the entire length of the suture **100**. For example, the apertures **104** can be centered along the centerline **102** of the suture

100. That is, the lateral center of the aperture 104 is aligned with the centerline 102. Yet, in other aspects, the plurality of apertures 104 can be located along the centerline 102 such that the center of the aperture 104 is not aligned with the centerline 102. For example, the lateral center of each (or a subset) of the plurality of apertures 104 is not aligned with the centerline 102 of the suture 100, e.g., offset from the centerline 102 along the transverse axis 101 of the suture 100. In further aspects, all or a portion of the plurality of apertures 104 are located along the suture 100 such that the aperture 104 is not aligned with the centerline 102. In such exemplary aspects, some of the plurality of apertures are located along the suture 100 such that the aperture 104 is not aligned with the centerline 102, while others are aligned. In some exemplary aspects, no portion of the opening overlaps/aligns with centerline 102 of the suture 100.

[039] In certain aspects and without any limitations, apertures 104 present in a suture 100 can have any design that would allow the desired outcome. For example, apertures 104 can have any regular or irregular shape, including, for example, a curvilinear (e.g., circular, elliptical, egg-shaped) or rectilinear shape (e.g., square, rectangle, trapezoid, rhombus, triangle, star). Various apertures of a plurality of apertures can have the same or different shapes. In certain aspects, a plurality of apertures 104 can be positioned in one longitudinally-extending row along a length of the suture 100, while in other aspects, a plurality of apertures 104 can be positioned in two or more longitudinally-extending rows along a length of the suture 100. In certain aspects, if a plurality of apertures 104 are positioned in two or more longitudinally-extending rows, the apertures 104 can be positioned on the same line along the transverse axis, or they can be shifted/offset relative to each other. It is understood that the present disclosure does not limit the design and specific positioning of the plurality of apertures 104 in the suture 100.

[040] Various apertures of the plurality of apertures 104 within the suture 100 can have the same size or can have different sizes. The size of each of the plurality of apertures 104 is substantially large enough to allow a needle and a stitch to pass through. In certain aspects and without limitations, the size of each of the plurality of

apertures **104** is from about 0.001 mm to about 1 cm, including exemplary values of about 0.002 mm, about 0.005 mm, about 0.008 mm, about 0.01 mm, about 0.02 mm, about 0.05 mm, about 0.08 mm, about 0.1 mm, about 0.2 mm, about 0.5 mm, about 0.8 mm, about 1.0 mm, about 1.2 mm, about 1.5 mm, about 1.8 mm, about 2.0 mm, about 2.2 mm, about 2.5 mm, about 2.8 mm, about 3.0 mm, about 3.2 mm, about 3.5 mm, about 3.8 mm, about 4.0 mm, about 4.2 mm, about 4.5 mm, about 4.8 mm, about 5.0 mm, about 5.2 mm, about 5.5 mm, about 5.8 mm, about 5.0 mm, about 5.2 mm, about 5.5 mm, about 5.8 mm, about 6.0 mm, about 6.2 mm, about 6.5 mm, about 6.8 mm, about 7.0 mm, about 7.2 mm, about 7.5 mm, about 7.8 mm, about 8.0 mm, about 8.2 mm, about 8.5 mm, about 8.8 mm, about 9.0 mm, about 9.2 mm, about 9.5 mm, and about 9.8 mm. For example, and without limitations, in some aspects, a portion of the plurality of apertures **104** in the suture **100** can have a size different from another portion of the plurality of apertures **104**. Even in further aspects, two adjacent apertures **104** in the plurality of apertures **104** can have the same size or different. It is understood that the size, as defined herein, references to diameter or to the largest dimensional length depending on the specific shape and type of the aperture **104**.

[041] In still further aspects, the apertures of a plurality of apertures **104** are spaced apart by a spacing increment *d* along a length of the suture **100**. The spacing *d* measured between the proximal end of the opening of a first aperture and a distal end of the opening of an adjacent/second aperture. It is understood that in some aspects, the spacing increment *d* between any two adjacent apertures of the plurality of apertures **104** is consistent amongst the plurality. While in other aspects, the spacing increment *d* between any two adjacent apertures of the plurality of apertures **104** varies amongst the plurality. In still further aspects, the spacing increment *d* can have any value that is substantial enough to ensure the structural integrity of the suture **100**. In certain aspects, the spacing increment *d* between any two adjacent apertures is at least about 5% of the largest size aperture of the plurality of apertures present in the suture, at least about 10%, at least about 15%, at least about 20%, at least about 30%, at least about 40%, at least about 50%, about least about 60%, at least about 70%, at least about 80%, at least about 90%, at least about 100%, or at

least about 150% of the largest size aperture of the plurality of apertures present in the suture.

[042] It is understood that the disclosed herein suture **100** is configured to be attached with the first attachment member and/or second attachment member to one or more components of the prosthetic valve. The first attachment member or the second attachment member can be any member configured to permanently, semi-permanently, and/or removably attach the suture **100** to the prosthetic valve. In certain aspects, the first attachment member and the second attachment member are the same, while in other aspects, they are different. In certain aspects, the first attachment member (and/or second attachment member) comprises stitches. In yet other aspects, the first attachment member (and/or second attachment member) comprises any flexible connectors known in the art and applicable to the desired application. The stitches (or any other attachment members as known in the art) pass through one or more apertures to couple the suture to the prosthetic valve. In certain aspects, a needle can be used to pass the stitches (or any other attachment members as known in the art) through the one or more apertures **104**. In certain aspects, the stitches comprise a mono or multifilament thread comprising filaments having a thickness from 6-0 to 4-0. In yet other aspects, the stitches comprise a mono or multifilament thread comprising filaments having a thickness of from about 0.02 mm to about 0.5 mm, including exemplary values of about 0.03 mm, about 0.04 mm, about 0.05 mm, about 0.06 mm, about 0.07 mm, about 0.1 mm, about 0.12 mm, about 0.15 mm, about 0.17 mm, about 0.2 mm, about 0.22 mm, about 0.25 mm, about 0.27 mm, about 0.3 mm, about 0.32 mm, about 0.35 mm, about 0.37 mm, about 0.4 mm, about 0.42 mm, about 0.45 mm, and about 0.47 mm.

[043] In still further aspects, a suture **100** can comprise filaments made of various materials. In certain aspects, a suture **100** can comprise a polyester material, polyethylene, ultrahigh molecular weight polyethylene, silicone, polyurethane, Teflon, polyether ether ketone (PEEK), or natural tissue, or a combination thereof. In yet further aspects, a suture **100** can comprise engineered materials. In such aspects, the engineered materials can comprise, for example, bicomponent filaments. In

some exemplary aspects, bicomponent filaments can be present in core-sheath configuration, side-by-side configuration, or islands-on-sea configurations. It is understood that each component of the bicomponent filaments can be selected depending on the desired application. It is further understood that in certain aspects, a suture **100** comprising a multifilament thread can comprise filaments comprising the same material. While in some alternative aspects, a suture **100** can comprise filaments comprising different materials.

[044] In still further aspects, the one or more components of the prosthetic valve can comprise, for example, and without limitation, leaflets, skirts, support layers, a frame, or any combination thereof.

[045] Some exemplary aspects for the suture's use in the prosthetic valve are shown in the following figures and description.

[046] For example, **FIGS. 2** and **7** show side and top plan views, respectively, of an exemplary prosthetic heart valve **10** having an inflow end **80** and an outflow end **82**, according to one aspect. Example prosthetic heart valves **10** are described in U.S. Patent No. 10,463,484, titled "Prosthetic Heart Valve Having Leaflet Inflow Below Frame," which is incorporated herein by reference. The illustrated prosthetic valve **10** is adapted to be implanted in the native aortic annulus, although in other aspects, it can be adapted to be implanted in the other native annuluses of the heart (the mitral valve, pulmonary valve, and tricuspid valve). The prosthetic valve **10** can have one or more of the following components: a stent or frame, **12**, a valvular structure **14,** and an inner skirt, or sealing member, **16**. The valve **10** can also include an outer skirt, or sealing member, **18**. As can be seen in these figures, and as it is discussed in more detail below, suture **100** can be used to attach various portions of the prosthetic valve together. The position of the suture **100** on these figures is only exemplary and non-limiting. Suture **100** can be utilized in any place or position that is configured to couple two or more components of the valve together.

[047] In certain aspects, a prosthetic valve **10** can comprise one or more leaflets, wherein each of the one or more leaflets **20** has a first surface and an opposite

second surface, a leaflet inflow edge, and a leaflet outflow edge. In some exemplary aspects and as shown in **FIG. 7**, the valvular structure **14** can comprise three leaflets **20**, collectively forming a valvular structure, which can be arranged to collapse in a tricuspid arrangement. The lower edge of valvular structure **14** desirably has an undulating, curved scalloped shape. By forming the leaflets **20** with this scalloped geometry, stresses on the leaflets are reduced, which in turn improves the durability of the valve **10**. Moreover, by virtue of the scalloped shape, folds and ripples at the belly of each leaflet **20** (the central region of each leaflet), which can cause early calcification in those areas, can be eliminated or at least minimized. The scalloped geometry also reduces the amount of tissue material used to form the valvular structure **14**, thereby allowing a smaller, more even crimped profile at the inflow end of the valve. The leaflets **20** can be formed of pericardial tissue (e.g., bovine pericardial tissue), biocompatible synthetic materials, or various other suitable natural or synthetic materials as known in the art and described in U.S. Pat. No. 6,730,118, which is incorporated herein by reference.

[048] As noted above, valvular structure **14** in the illustrated and unlimited aspect can include three flexible leaflets **20** (although a greater or fewer number of leaflets can be used). An exemplary leaflet **20** is shown in **FIG. 8**. Each leaflet **20** can have the disclosed herein suture **100** secured with the first attachment member **61** through the plurality of apertures **59** to the first surface of the lower edge portion **56**. Each leaflet **20** in the illustrated configuration can have an upper (outflow) free edge **48** extending between opposing upper tabs **50** on opposite sides of the leaflet **20**. Below each upper tab **50,** there can be a notch **52** separating the upper tab **50** from a corresponding lower tab **54**. The lower (inflow) edge portion **56** of the leaflet extending between respective ends of the lower tabs **54** can include vertical, or axial, edge portions **60** on opposites of the leaflets extending downwardly from corresponding lower tabs **54** and a substantially V-shaped, an intermediate edge portion **62** having a smooth, curved apex portion **64** at the lower end of the leaflet and a pair of oblique portions **66** that extend between the axial edge portions **60** and the apex portion **64**. The oblique portions **66** can have a greater radius of curvature than the apex portion **64**. The leaflets can have various other shapes and/or

configurations in other aspects. For example, the leaflets need not have a V-shaped or scalloped inflow edge, and instead, each leaflet can have a square or rectangular shape defining a straight inflow edge. Presence of suture **100** can protect the pericardial tissue of the leaflets **20** from undesirable damages. Certain exemplary aspects of the suture **100** positioning are shown in **FIG. 5A**. In **FIG. 5A** right side, the suture **100** is positioned on the first surface of the lower edge portion of the leaflet, while in **FIG. 5A** left side, the suture **100** is positioned both on the first and the opposite second surface of the lower edge portion of the leaflet such that the leaflet is sandwiched between two sutures. The sutures in this aspect can be the same or different and can comprise any shape, size, or design of the plurality of apertures as disclosed herein.

[049] The exemplary leaflets **20** are coupled with the frame of the prosthetic valve **12** (as shown, for example, in **FIGS. 2-4**). The exemplary bare frame **12** is shown in **FIGS. 9** and **10**. The frame **12** has an inflow end **22**, an outflow end **24**, and a central longitudinal axis **26** extending from the inflow end **22** to the outflow end **24**. The frame **12** can be made of any of various suitable plastically-expandable materials (e.g., stainless steel, etc.) or self-expanding materials (e.g., Nitinol) as known in the art. When constructed of a plastically-expandable material, the frame **12** (and thus the prosthetic valve **10**) can be crimped to a radially compressed state on a delivery catheter and then expanded inside a patient by an inflatable balloon or equivalent expansion mechanism. When constructed of a self-expandable material, the frame **12** (and thus the prosthetic valve **10**) can be crimped to a radially compressed state and restrained in the compressed state by insertion into a sheath or equivalent mechanism of a delivery catheter. Once inside the body, the valve can be advanced from the delivery sheath, which allows the valve to expand to its functional size. Suitable plastically-expandable materials that can be used to form the frame **12** include, without limitation, stainless steel, a nickel-based alloy (e.g., a cobalt-chromium or a nickel-cobalt-chromium alloy), polymers, or combinations thereof. In particular aspects, frame **12** can be made of a nickel-cobalt-chromium-molybdenum alloy, such as MP35N™ (tradename of SPS Technologies), which is equivalent to UNS R30035 (covered by ASTM F562-02). MP35N™/UNS R30035

comprises 35% nickel, 35% cobalt, 20% chromium, and 10% molybdenum, by weight. It has been found that the use of MP35N to form frame **12** provides superior structural results over stainless steel. In particular, when MP35N is used as the frame material, less material is needed to achieve the same or better performance in radial and crush force resistance, fatigue resistance, and corrosion resistance. Moreover, since less material is required, the crimped profile of the frame can be reduced, thereby providing a lower profile valve assembly for percutaneous delivery to the treatment location in the body.

[050] As further shown in **FIGS. 9** and **10**, frame **12** in some exemplary and unlimiting aspects can comprise a first, lower row I of angled struts **28** arranged end-to-end and extending circumferentially at the inflow end of the frame; a second row II of circumferentially extending angled struts **30**; a third row III of circumferentially extending, angled struts **32**; and a fourth row IV of circumferentially extending angled struts **34** at the outflow end of the frame **12**. The fourth row IV of angled struts **34** can be connected to the third row III of angled struts **32** by a plurality of axially extending window frame portions **36** (which define commissure windows **38**) and a plurality of axially extending struts **40**. Each axial strut **40** and each frame portion **36** extends from a location defined by the convergence of the lower ends of two angled struts **34** to another location defined by the convergence of the upper ends of two angled struts **32**.

[051] Each commissure window frame portion **36** mounts a respective commissure **74** of the leaflet structure **14**. As can be seen, each frame portion **36** is secured at its upper and lower ends to the adjacent rows of struts to provide a robust configuration that enhances fatigue resistance under cyclic loading of the valve compared to known cantilevered struts for supporting the commissures of the leaflet structure. This configuration enables a reduction in the frame wall thickness to achieve a smaller crimped diameter of the valve. In particular aspects, the thickness of the frame **12** measured between the inner diameter and outer diameter is about 0.48 mm or less.

[052] The struts and frame portions of the frame collectively define a plurality of open cells of the frame. At the inflow end **22** of the frame **12**, struts **28** and struts **30** define a lower row of cells defining openings **42**. The second and third rows of struts **30** and **32**, respectively, define an intermediate row of cells defining openings **44**. The third and fourth rows of struts **32** and **34**, along with frame portions **36** and struts **40**, define an upper row of cells defining openings **46**. The openings **46** are relatively large and are sized to allow portions of the valvular structure **14** to protrude, or bulge, into and/or through the openings **46** when the frame **12** is crimped in order to minimize the crimping profile.

[053] The frame **12** can have other configurations or shapes in other aspects. For example, the frame **12** can comprise a plurality of circumferential rows of angled struts **28**, **30**, **32**, **34** connected directly to each other without vertical struts **40** or frame portions **36** between adjacent rows of struts, or the rows of struts **28**, **30**, **32**, **34** can be evenly spaced with vertical struts **40** and/or frame portions **36** extending therebetween. In other aspects, the frame can comprise a braided structure braided from one or more metal wires.

[054] The leaflets **20** can be sutured together to form the assembled valvular structure **14**, which can then be secured to the frame **12**. It is understood that when the leaflets **20** are sutured together, each of the leaflets can comprise a disclosed herein suture **100** having a plurality of apertures **104**. The coupling of the two or more sutures together can be done by passing the first attachment member through the plurality of apertures. It is understood that the suture can be positioned on the first and/or second surface of the leaflet. In still further aspects, when two or more leaflets are coupled together, for example, the sutures can be positioned in parallel to each other. Generally, it is understood that the suture can be positioned in any location that requires passing the attachment member through the leaflet or any other tissue. In certain aspects and as described herein, the disclosed sutures are designed to reinforce the tissue and prevent its tear. For example, the leaflets **20** can be secured to one another at their adjacent sides to form commissures **74** of the valvular structure. As can be seen in **FIG. 3**, a suture **100** can

be used to form such commissures. A plurality of flexible connectors (not shown) can be used to interconnect pairs of adjacent sides of the leaflets and to mount the leaflets to the commissure window frame portions **30**, as further discussed below. It is further understood that such a mounting can be done by the use of the sutures when the flexible connectors are passed through the plurality of apertures present in the leaflet. The leaflets **20** can additionally and/or alternatively be secured together via adjacent sub-commissure portions (not shown) of two leaflets that can be sutured directly to each other with the use of one or more sutures described herein.

[055] In still further exemplary aspects, the one or more leaflets **20** can be attached to the inner skirt **16,** as shown, for example, in **FIG. 5B**. In such aspects, to reinforce the leaflets and to prevent any undesirable damages, the disclosed herein suture **100** can be positioned along the lower (inflow) edge portions **56** of the leaflets **20**. The reinforcement suture **100** enables a secure suturing and protects the pericardial tissue of the valvular structure **14** from tears. Valvular structure **14** can be sandwiched between the inner skirt **16** and the suture **100**. The first attachment member **70 (FIG. 3)** secures the suture **100** (**FIG. 3**) to inner skirt **16**. It is understood that the first attachment member can be any member described herein and can comprise stitches such as, for example, an Ethibond suture. The attachment member **70** can track the curvature of the bottom edge of valvular structure **14** and are collectible referred to as scallop line **72**. In other exemplary and unlimiting aspects, in lieu of or in addition to the sutures **100** along the inner surface of the leaflets, sutures **100** can be positioned between the inner skirt **16** and the inflow edge portions (**FIG. 5B**).

[056] The inner skirt **16** can have a plurality of functions, which can include assisting in securing the valvular structure **14** and/or the outer skirt to the frame **12** and to assist in forming a good seal between the valve **10** and the native annulus by blocking the flow of blood below the lower edges of the leaflets. The inner skirt **16** can comprise a tough, tear-resistant material such as polyethylene terephthalate (PET), although various other synthetic or natural materials can be used. The thickness of the skirt desirably is less than 6 mils or 0.15 mm, and

desirably less than 4 mils or 0.10 mm, and even more desirably about 2 mils or 0.05 mm. In particular aspects, the skirt **16** can have a variable thickness, for example, the skirt can be thicker at its edges than at its center. In one implementation, the skirt **16** can comprise a PET skirt having a thickness of about 0.07 mm at its edges and about 0.06 mm at its center. The thinner skirt can provide for better crimping performances while still providing good perivalvular sealing.

[057] **FIGS. 3** and **4** show the frame **12**, the valvular structure **14** and the inner skirt **16** after securing the valvular structure **14** to the inner skirt **16** with the use of suture **100** and then securing these components to the frame **12** also with the use of the sutures **100**. Inner skirt **16** can be secured to the inside of frame **12** via sutures **68**. Suture **100** can be utilized to mitigate damage to the inner skirt **16**. As shown in **FIGS. 3-4**, portions of the inflow edge **56** of the leaflets **20** are positioned between diagonal lines defined by the struts **28**, **30** of the first and second circumferential rows of the struts (as shown in **FIGS. 9** and **10**). In some aspects, the inflow edges **56** of the leaflets **20** can track the diagonal lines defined by the struts **28**, **30**. In such aspects, the portions of the inflow edge **56** above the inflow end of the frame can be coupled to adjacent struts **28**, **30** by use of the disclosed sutures **100**.

[058] The outflow end portion of the valvular structure **14** can be secured to the window frame portions **36** with sutures **100**. In particular, each leaflet **20** can have opposing tab portions, each of which is paired with an adjacent tab portion of another leaflet to form a commissure **74**. It is understood that in such aspect, each of the tab portions of the leaflet is coupled with the adjacent tab portion of another leaflet with the use of suture **100**. It is further understood that in such aspects, one or more sutures **100** can be present. In some aspects, each tab can be sandwiched between at least two sutures **100**, or the suture can be positioned only on one surface of each tab. It is further understood that two adjacent tabs can have sutures positioned on the same or different surfaces of the tab. As shown in **FIG. 2**, the commissures **74** can extend through windows **38** of respective window frame portions **36** and be retained in place with the attachment member passing through

the leaflet and the suture **100**. Further details of the commissures **74** and a method for assembling the commissures and mounting them to the frame are disclosed in U.S. Publication No. 2012/0123529, which is incorporated herein by reference.

[059] Inner skirt **16** can terminate short of the window frame portions **36** and does not extend the entire length of the frame **12**. In alternative aspects, inner skirt **16** can extend the entire length or substantially the entire length of the frame **12** from below the inflow end **22** to the outflow end **24**. In other aspects, inner skirt **16** can extend up to the second row of angled struts **30**.

[060] In particular aspects, and as shown in **FIGS. 2-4**, the valvular structure **14** can extend axially beyond the inflow end **22** of the frame **12** such that at least a portion of the inflow edges **56** of each leaflet is not supported by the frame **12**. For example, the apex portions **64** of the leaflets **20** can extend axially beyond and can be unsupported by the frame **12**. Additionally and/or alternatively, the oblique portions **66** and the apex portions **64** can extend axially beyond and can be unsupported by the frame **12**. Additionally and/or alternatively, the intermediate portions **62**, the oblique portions **66** and the apex portions **64** can extend axially beyond and can be unsupported by the frame **12**. Additionally and/or alternatively, the vertical edge portions **60**, the intermediate portions **62**, the oblique portions **66** and the apex portions **64** can extend axially beyond and can be unsupported by the frame **12**. In some aspects, a portion **76** of each leaflet extends below the inflow end **22** of the frame a length L_1 that is equal to or greater than a length L_2 of each cell opening **42** in the axial direction. In some aspects, L_1 can range between about 2 mm to 8 mm in length, with 4 mm being a specific example. Additionally and/or alternatively, L_1 can be up to 12 mm. In some aspects, L_2 can range between about 3 mm to 5 mm in length, with 4 mm being a specific example. Additionally and/or alternatively, L_2 can range between 2 mm to 7 mm.

[061] Additionally and/or alternatively, as shown in **FIG. 5B**, the inner skirt **16** can include a first portion **84**, also referred to as supported portion, that extends circumferentially around the central longitudinal axis of the prosthetic valve along an inner surface of the frame **12** and a second portion, also referred to as unsupported

portion **78**, at the inflow end **80** of the prosthetic valve **10**. The unsupported portion **78** is unsupported by the frame **12**. The unsupported portion **78** can extend circumferentially around the central longitudinal axis of the prosthetic valve to form an unsupported circumference at the inflow end **80**. As shown in **FIG. 5B**, the portion of each leaflet **20** that is not supported by the frame **12** can be connected to the inner skirt **16**. In some aspects, a length L_3 of the unsupported portion **78** is equal to or greater than the length L_2 of the openings **42**. In some aspects, L_3 can be 2 mm to 3 mm longer than L_1. Additionally and/or alternatively, L_3 can range from the same length as L_1 to 5 mm longer than L_1. In some aspects, L_3 can range between about 2 mm to 11 mm in length, with 6 mm being a specific example. Additionally and/or alternatively, L_3 can be up to 15 mm.

[062] In certain aspects and as described herein, the prosthetic valve can also comprise an outer skirt **18**. The outer skirt **18** can be laser cut or otherwise formed from a strong, durable piece of material, such as woven PET, although other synthetic or natural materials can be used. The outer skirt **18** can be secured to the lower edge of the inner skirt **16** at the inflow end of the prosthetic valve, such as by sutures, welding, and/or an adhesive with or without sutures **100**. In particular aspects, the lower edge of the outer skirt **18** is tightly sutured (with or without sutures **100**) or otherwise secured (e.g., by welding or an adhesive) to the inner skirt **16**. Again, it is further understood that in each coupling location, the disclosed suture **100** can be utilized.

[063] The absence of metal components of the frame or other rigid members along the inflow end portion of the prosthetic valve advantageously reduces mechanical compression of the native valve annulus (e.g., the aortic annulus) and the left ventricular outflow tract (when implanted in the aortic position), thus reducing the risk of trauma to the surrounding tissue.

[064] As shown in **FIG. 6**, some aspects of a prosthetic valve **10** do not include an inner skirt **16** and instead can include a support layer **110** disposed radially between the frame **12** and the outer skirt **18**. In such aspects, the support layer **110** and the outer skirt **18** can form an outer sealing member with the support layer **110**, forming

an inner wall or layer of the sealing member and the outer skirt forming an outer wall or layer of the sealing member. A first portion **112** of the support layer **110** can extend circumferentially around the central longitudinal axis of the prosthetic valve along an outer surface of the frame **12**, and a second portion **114** of the support layer **110** can extend circumferentially around the central longitudinal axis axially beyond the inflow end **22** of the frame. The unsupported portions **76** of the leaflets can be connected to the support layer **110** (e.g., by sutures, an adhesive, and/or welding) similar to the manner that the leaflets are connected to the inner skirt in the aspect **of FIG. 5A-B**. More specifically, in such aspects, the inflow edge portions **56** is sutured to sutures **100** and the support layer **110** with the inflow edge portions **56** sandwiched between the support layer **110** and the suture **100**. Additionally, and/or alternatively, sutures **100** can be positioned between the inflow edge portions **56** and the support layer **110**, with sutures securing these layers together. Additionally and/or alternatively, the outer skirt **18** can be connected to the second portion **114** of the support layer with or without suture **100** (e.g., by sutures, an adhesive, and/or welding).

[065] It is further understood that the attachment members described herein can comprise a first attachment member, a second attachment member, or any other attachment member. It is further understood that the numbering describing the attachment member is used only to demonstrate that the attachment member can be the same or different. For example, in some aspects, the coupling of the suture **100** with any component of the valve can be done with the stitches comprising the same material or the stitches comprising different materials. In yet other aspects, the coupling can be done with the stitches, flexible connectors, wires, or any other known in the art attachment members appropriate for the desired application.

[066] The aspects of the present disclosure also relate to methods of making a prosthetic valve comprising providing at least one reinforcement member; attaching the at least one reinforcement member with a first attachment member to one or more components of a prosthetic valve; wherein the at least one reinforcement member comprises a suture having a longitudinal axis and a transverse axis

perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures, wherein each of the plurality of apertures is configured to receive the first attachment member for coupling the suture to the prosthetic valve.

[067] It is understood that any sutures described herein can be used to produce prosthetic valves. In certain aspects, the plurality of apertures are braided within the suture. In such aspects, the plurality of apertures are formed by braiding. In yet other aspects, the plurality of apertures are formed by combining two or more threads and fusing them together such that the desired apertures are formed. It is further understood that in the methods disclosed herein, the prosthetic valve can comprise any of the components described above. It is further understood that any of the described above attachment members can be used to couple the sutures to any of the prosthetic valve components.

[068] Also disclosed herein is a kit comprising: at least one suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures, wherein each of the plurality of apertures is configured to receive an attachment member for coupling the suture to an article. It is understood that these kits can be used in any known application where the coupling of two or more members is required. In still further aspects, the disclosed herein kit can be used in any known application where the need to protect coupling members from the tears or any other damage exists. For example and without limitation, the articles the suture is configured to be coupled with can comprise a fabric, a tissue, a prosthetic valve, or any combination thereof. In still further aspects, the suture present in the kit is configured to be a reinforcement member. While in other aspects, the suture does not behave as a reinforcement member but is just used as a member configured to couple various components of the article.

[069] Any described herein sutures can be present in the disclosed kits. In certain aspects, the first attachment can also be present in the kit. While in other aspects, the first attachment member is not a part of the kit, and any known in the art

attachment members that are suitable for the desired application can be used. In certain aspects, the first attachment member can comprise one or more stitches, flexible connectors, or any combination thereof. In yet further aspects, the suture present in the kit comprises a centerline positioned along its longitudinal axis. In some exemplary aspects, the plurality of apertures can be positioned within at least a portion of the centerline of the suture. While in other aspects, the plurality of apertures can be positioned along all length of the suture. In alternative aspects, each of the plurality of apertures is spaced apart by a spacing increment *d* along a length of the suture. It is understood that in some aspects, the spacing increment *d* between any two adjacent apertures of the plurality of apertures is the same. While in other aspects, the spacing increment *d* between any two adjacent apertures of the plurality of apertures is different. In yet further aspects, the suture present in the kit can comprise a polyester material, polyethylene, ultrahigh molecular weight polyethylene, silicone, polyurethane, Teflon, polyether ether ketone (PEEK), or natural tissue, or a combination thereof. In still further aspects, the suture comprises a plurality of apertures that can be braided within the suture. While in other aspects, the suture can comprise two or more cords fused together to form the plurality of apertures.

EXEMPLARY ASPECTS

[070] EXAMPLE 1: A prosthetic valve comprising: at least one reinforcement member configured to be attached with a first attachment member to one or more components of the prosthetic valve; wherein the at least one reinforcement member comprises a suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures, and wherein each of the plurality of apertures is configured to receive the first attachment member for coupling the suture to the prosthetic valve.

[071] EXAMPLE 2: The prosthetic valve of any examples herein, particularly example 1, wherein the first attachment member comprises one or more stitches.

[072] EXAMPLE 3: The prosthetic valve of any examples herein, particularly example 1 or 2, wherein the suture comprises a centerline positioned along its longitudinal axis.

[073] EXAMPLE 4: The prosthetic valve of any examples herein, particularly example 3, wherein the plurality of apertures is positioned within at least a portion of the centerline of the suture.

[074] EXAMPLE 5: The prosthetic valve of any examples herein, particularly examples 1-4, wherein each of the plurality of apertures is spaced apart by a spacing increment *d* along a length of the suture.

[075] EXAMPLE 6: The prosthetic valve of any examples herein, particularly example 5, wherein the spacing increment *d* between any two adjacent apertures of the plurality of apertures is the same.

[076] EXAMPLE 7: The prosthetic valve of any examples herein, particularly example 5, wherein the spacing increment *d* between any two adjacent apertures of the plurality of apertures is different.

[077] EXAMPLE 8: The prosthetic valve of any examples herein, particularly examples 1-7, wherein the suture comprises a polyester material, polyethylene, ultrahigh molecular weight polyethylene, silicone, polyurethane, Teflon, polyether ether ketone (PEEK), natural tissue, or a combination thereof.

[078] EXAMPLE 9: The prosthetic valve of any examples herein, particularly examples 1-8, wherein the plurality of apertures is braided within the suture.

[079] EXAMPLE 10: The prosthetic valve of any examples herein, particularly examples 1-8, wherein the suture comprises two or more cords fused together to form the plurality of apertures.

[080] EXAMPLE 11: The prosthetic valve of any examples herein, particularly examples 1-10, wherein the one or more components of the prosthetic valve comprise leaflets, skirts, support layers, a frame, or any combinations thereof.

[081] EXAMPLE 12: The prosthetic valve of any examples herein, particularly examples 1-11, further comprising an annular frame having an inflow end, an outflow end and a central longitudinal axis extending from the inflow end to the outflow end.

[082] EXAMPLE 13: The prosthetic valve of any examples herein, particularly examples 1-11, comprising one or more leaflets, wherein each of the one or more leaflets has a first surface and an opposite second surface, a leaflet inflow edge, and a leaflet outflow edge.

[083] EXAMPLE 14: The prosthetic valve of any examples herein, particularly example 13, wherein the leaflet inflow edge is positioned at least partially outside of the frame.

[084] EXAMPLE 15: The prosthetic valve of any examples herein, particularly example 13 or 14, wherein the leaflet outflow edge is positioned within the frame.

[085] EXAMPLE 16: The prosthetic valve of any examples herein, particularly examples 13-15, wherein at least a portion of the leaflet inflow edges is unsupported by the frame.

[086] EXAMPLE 17: The prosthetic valve of any examples herein, particularly examples 13-16, wherein the at least one reinforcement member is positioned adjacent to the first surface or the second surface of the one or more leaflets along the leaflet inflow edge.

[087] EXAMPLE 18: The prosthetic valve of any examples herein, particularly examples 13-17, the at least one reinforcement member positioned adjacent to the first surface of the one or more leaflets along the leaflet inflow edge and the at least one reinforcement member positioned adjacent to the second surface of the one or more leaflets along the leaflet inflow edge, such that the one or more leaflets are sandwiched between two reinforcement members.

[088] EXAMPLE 19: The prosthetic valve of any examples herein, particularly examples 13-18, wherein the valve comprises at least two leaflets and wherein each two of the adjacent leaflets are secured to each other.

[089] EXAMPLE 20: The prosthetic valve of any examples herein, particularly example 19, wherein the at least one reinforcement member is positioned adjacent to the first and/or second surface of each of the at least two leaflets such that the adjacent leaflets are secured to each other with the attachment member passing through the plurality of apertures of the suture.

[090] EXAMPLE 21: The prosthetic valve of any examples herein, particularly examples 12-20, further comprising an inner skirt having a first portion that extends circumferentially around the central longitudinal axis along an inner surface of the frame and is supported by the frame and a second portion that extends circumferentially around the central longitudinal axis outside of the frame and is not supported by the frame.

[091] EXAMPLE 22: The prosthetic valve of any examples herein, particularly example 21, wherein the reinforcement member is positioned between the one or more leaflets and at least a portion of the inner skirt such that the one or more leaflets are secured with the at least a portion of the inner skirt with the attachment member passing through the plurality of stitches.

[092] EXAMPLE 23: The prosthetic valve of any examples herein, particularly example 21 or 22, wherein the one or more leaflets are sandwiched between the at least two reinforcement members and at least a portion of the inner skirt.

[093] EXAMPLE 24: The prosthetic valve of any examples herein, particularly examples 13-23, wherein the at least one reinforcement member is positioned adjacent to at least a portion of the inflow edge of the one or more leaflets such that the at least a portion of the inflow edge of the one or more leaflets is secured to the frame with a second attachment member passing through the plurality of apertures.

[094] EXAMPLE 25: The prosthetic valve of any examples herein, particularly example 24, wherein the second attachment member is the same or different as the first attachment member.

[095] EXAMPLE 26: The prosthetic valve of any examples herein, particularly examples 13-15, wherein each of the one or more leaflets is secured to the one or more components of the prosthetic valve with at least one reinforcement member.

[096] EXAMPLE 27: A method comprising: providing at least one reinforcement member; attaching the at least one reinforcement member with a first attachment member to one or more components of a prosthetic valve; wherein the at least one reinforcement member comprises a suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures, and wherein each of the plurality of apertures is configured to receive the first attachment member for coupling the suture to the prosthetic valve.

[097] EXAMPLE 28: The method of any examples herein, particularly example 27, wherein the first attachment member comprises one or more stitches.

[098] EXAMPLE 29: The method of any examples herein, particularly example 27 or 28, wherein the suture comprises a centerline positioned along its longitudinal axis.

[099] EXAMPLE 30: The method of any examples herein, particularly example 29, wherein the plurality of apertures are positioned within at least a portion of the centerline of the suture.

[0100] EXAMPLE 31: The method of any examples herein, particularly examples 27-30, wherein each of the plurality of apertures is spaced apart by a spacing increment *d* along a length of the suture.

[0101] EXAMPLE 32: The method of any examples herein, particularly example 31, wherein the spacing increment *d* between any two adjacent apertures of the plurality of apertures is the same.

[0102] EXAMPLE 33: The method of any examples herein, particularly example 31, wherein the spacing increment *d* between any two adjacent apertures of the plurality of apertures is not the same.

[0103] EXAMPLE 34: The method of any examples herein, particularly examples 27-33, wherein the suture comprises a polyester material, polyethylene, ultrahigh molecular weight polyethylene, silicone, polyurethane, Teflon, polyether ether ketone (PEEK), or natural tissue, or a combination thereof.

[0104] EXAMPLE 35: The method of any examples herein, particularly examples 27-34, wherein the plurality of apertures is braided within the suture.

[0105] EXAMPLE 36: The method of any examples herein, particularly examples 27-35, wherein the suture comprises two or more cords fused together to form the plurality of apertures.

[0106] EXAMPLE 37: The method of any examples herein, particularly examples 27-36, wherein the one or more components of the prosthetic valve comprise leaflets, skirts, support layers, a frame, or any combination thereof.

[0107] EXAMPLE 38: The method of any examples herein, particularly examples 27-37, wherein the prosthetic valve comprises an annular frame having an inflow end, an outflow end and a central longitudinal axis extending from the inflow end to the outflow end.

[0108] EXAMPLE 39: The method of any examples herein, particularly examples 27-38, wherein the prosthetic valve comprises one or more leaflets, wherein each of the one or more leaflets has a first surface and an opposite second surface, a leaflet inflow edge, and a leaflet outflow edge.

[0109] EXAMPLE 40: The method of any examples herein, particularly example 39, wherein the leaflet inflow edge is positioned at least partially outside of the frame.

[0110] EXAMPLE 41: The method of any examples herein, particularly example 39 or 40, wherein the leaflet outflow edge is positioned within the frame.

[0111] EXAMPLE 42: The method of any examples herein, particularly examples 39-41, wherein at least a portion of the leaflet inflow edges is unsupported by the frame.

[0112] EXAMPLE 43: The method of any examples herein, particularly examples 39-42, wherein the at least one reinforcement member is attached to the first surface or the second surface of the one or more leaflets along the leaflet inflow edge.

[0113] EXAMPLE 44: The method of any examples herein, particularly examples 39-43, wherein the at least one reinforcement member is attached to the first surface of the one or more leaflets along the leaflet inflow edge and the at least one reinforcement member is attached to the second surface of the one or more leaflets along the leaflet inflow edge, such that the one or more leaflets are sandwiched between two reinforcement members.

[0114] EXAMPLE 45: The method of any examples herein, particularly examples 39-44, wherein the prosthetic valve comprises at least two leaflets and wherein each two of the adjacent leaflets are secured to each other.

[0115] EXAMPLE 46: The method of any examples herein, particularly example 45, wherein the at least one reinforcement member is positioned adjacent to the first and/or second surface of each of the at least two leaflets such that the adjacent leaflets are secured to each other with the attachment member passing through the plurality of apertures of the suture.

[0116] EXAMPLE 47: The method of any examples herein, particularly examples 38-46, wherein the prosthetic valve further comprises an inner skirt having a first portion that extends circumferentially around the central longitudinal axis along an

inner surface of the frame and is supported by the frame and a second portion that extends circumferentially around the central longitudinal axis outside of the frame and is not supported by the frame.

[0117] EXAMPLE 48: The method of any examples herein, particularly example 47, wherein the reinforcement member is attached such that it is positioned between the one or more leaflets and at least a portion of the inner skirt to secure the one or more leaflets with the at least a portion of the inner skirt, wherein the reinforcement member is attached with the first attachment member passing through the plurality of stitches.

[0118] EXAMPLE 49: The method of any examples herein, particularly example 47 or 48, wherein the one or more leaflets are sandwiched between the at least two reinforcement members and at least a portion of the inner skirt.

[0119] EXAMPLE 50: The method of any examples herein, particularly examples 39-49 wherein the at least one reinforcement member is attached adjacent to at least a portion of the inflow edge of the one or more leaflets to secure the at least a portion of the inflow edge of the one or more leaflets to the frame, wherein the reinforcement member is attached with a second attachment member passing through the plurality of apertures.

[0120] EXAMPLE 51: The method of any examples herein, particularly example 50, wherein the second attachment member is the same or different as the first attachment member.

[0121] EXAMPLE 52: The method of any examples herein, particularly examples 39-51, wherein each of the one or more leaflets is attached to the one or more components of the prosthetic valve with at least one reinforcement member.

[0122] EXAMPLE 53: A kit comprising: at least one suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures, wherein each of the plurality

of apertures is configured to receive an attachment member for coupling the suture to an article.

[0123] EXAMPLE 54: The kit of any examples herein, particularly example 53, wherein the first attachment member comprises one or more stitches, flexible connectors, or any combination thereof.

[0124] EXAMPLE 55: The kit of any examples herein, particularly example 53 or 54, wherein the suture comprises a centerline positioned along its longitudinal axis.

[0125] EXAMPLE 56: The kit of any examples herein, particularly example 55, wherein the plurality of apertures is positioned within at least a portion of the centerline of the suture.

[0126] EXAMPLE 57: The kit of any examples herein, particularly examples 53-56, wherein each of the plurality of apertures is spaced apart by a spacing increment *d* along a length of the suture.

[0127] EXAMPLE 58: The kit of any examples herein, particularly example 57, wherein the spacing increment *d* between any two adjacent apertures of the plurality of apertures is the same.

[0128] EXAMPLE 59: The kit of any examples herein, particularly example 57, wherein the spacing increment *d* between any two adjacent apertures of the plurality of apertures is not the same.

[0129] EXAMPLE 60: The kit of any examples herein, particularly examples 53-59, wherein the suture comprises a polyester material, polyethylene, ultrahigh molecular weight polyethylene, silicone, polyurethane, Teflon, polyether ether ketone (PEEK), or natural tissue, or a combination thereof.

[0130] EXAMPLE 61: The kit of any examples herein, particularly examples 53-60, wherein the plurality of apertures are braided within the suture.

[0131] EXAMPLE 62: The kit of any examples herein, particularly examples 53-61, wherein the suture comprises two or more cords fused together to form the plurality of apertures.

[0132] EXAMPLE 63: The kit of any examples herein, particularly examples 53-62, wherein the article comprises a prosthetic valve.

[0133] EXAMPLE 64: The kit of any examples herein, particularly examples 53-63, wherein the suture is a reinforcement member.

[0134] In view of the many possible aspects to which the principles of the disclosed disclosure can be applied, it should be recognized that the illustrated aspects are only some examples of the disclosure and should not be taken as limiting the scope of the disclosure. Rather, the scope of the disclosure is defined by the following claims. We, therefore, claim as our disclosure all that comes within the scope and spirit of these claims.

CLAIMS

We claim:

1. A prosthetic valve comprising:

at least one reinforcement member configured to be attached with a first attachment member to one or more components of the prosthetic valve;

wherein the at least one reinforcement member comprises a suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis,

wherein at least a portion of the suture comprises a plurality of apertures, and

wherein each of the plurality of apertures is configured to receive the first attachment member for coupling the suture to the prosthetic valve.

2. The prosthetic valve of claim 1, wherein the first attachment member comprises one or more stitches.

3. The prosthetic valve of claim 1 or 2, wherein the suture comprises a centerline positioned along its longitudinal axis.

4. The prosthetic valve of claim 3, wherein the plurality of apertures are positioned within at least a portion of the centerline of the suture.

5. The prosthetic valve of any one of claims 1-4, wherein each of the plurality of apertures is spaced apart by a spacing increment *d* along a length of the suture.

6. The prosthetic valve of claim 5, wherein the spacing increment *d* between any two adjacent apertures of the plurality of apertures is the same.

7. The prosthetic valve of claim 5, wherein the spacing increment *d* between any two adjacent apertures of the plurality of apertures is different.

8. The prosthetic valve of any one of claims 1-7, wherein the suture comprises a polyester material, polyethylene, ultrahigh molecular weight polyethylene, silicone, polyurethane, Teflon, polyether ether ketone (PEEK), natural tissue, or a combination thereof.

9. The prosthetic valve of any one of claims 1-8, wherein the plurality of apertures is braided within the suture.

10. The prosthetic valve of any one of claims 1-8, wherein the suture comprises two or more cords fused together to form the plurality of apertures.

11. The prosthetic valve of any one of claims 1-10, wherein the one or more components of the prosthetic valve comprise leaflets, skirts, support layers, a frame, or any combinations thereof.

12. The prosthetic valve of any one of claims 1-11, further comprising an annular frame having an inflow end, an outflow end and a central longitudinal axis extending from the inflow end to the outflow end.

13. The prosthetic valve of any one of claims 11-12, comprising one or more leaflets, wherein each of the one or more leaflets has a first surface and an opposite second surface, a leaflet inflow edge, and a leaflet outflow edge.

14. The prosthetic valve of claim 13, wherein the leaflet inflow edge is positioned at least partially outside of the frame.

15. The prosthetic valve of claim 13 or 14, wherein the leaflet outflow edge is positioned within the frame.

16. The prosthetic valve of any one of claims 13-15, wherein at least a portion of the leaflet inflow edges is unsupported by the frame.

17. The prosthetic valve of any one of claims 13-16, wherein the at least one reinforcement member is positioned adjacent to the first surface or the second surface of the one or more leaflets along the leaflet inflow edge.

18. The prosthetic valve of any one of claims 13-17, the at least one reinforcement member positioned adjacent to the first surface of the one or more leaflets along the leaflet inflow edge and the at least one reinforcement member positioned adjacent to the second surface of the one or more leaflets along the leaflet inflow edge, such that the one or more leaflets are sandwiched between two reinforcement members.

19. The prosthetic valve of any one of claims 13-18, wherein the valve comprises at least two leaflets, and wherein each two of adjacent leaflets are secured to each other.

20. The prosthetic valve of claim 19, wherein the at least one reinforcement member is positioned adjacent to the first and/or second surface of each of the at least two leaflets such that the adjacent leaflets are secured to each other with the attachment member passing through the plurality of apertures of the suture.

21. The prosthetic valve of any one of claims 12-20, further comprising an inner skirt having a first portion that extends circumferentially around the central longitudinal axis along an inner surface of the frame and is supported by the frame and a second portion that extends circumferentially around the central longitudinal axis outside of the frame and is not supported by the frame.

22. The prosthetic valve of claim 21, wherein the reinforcement member is positioned between the one or more leaflets and at least a portion of the inner skirt such that the one or more leaflets are secured with the at least a portion of the inner skirt with the attachment member passing through the plurality of stitches.

23. The prosthetic valve of claim 21 or 22, wherein the one or more leaflets are sandwiched between the at least two reinforcement members and at least a portion of the inner skirt.

24. The prosthetic valve of any one of claims 13-23, wherein the at least one reinforcement member is positioned adjacent to at least a portion of the inflow edge of the one or more leaflets such that the at least a portion of the inflow edge of the one or more leaflets is secured to the frame with a second attachment member passing through the plurality of apertures.

25. The prosthetic valve of claim 24, wherein the second attachment member is the same or different as the first attachment member.

26. The prosthetic valve of any one of claims 13-15, wherein each of the one or more leaflets is secured to the one or more components of the prosthetic valve with at least one reinforcement member.

27. A method comprising:

providing at least one reinforcement member;

attaching the at least one reinforcement member with a first attachment member to one or more components of a prosthetic valve;

wherein the at least one reinforcement member comprises a suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures, and

wherein each of the plurality of apertures is configured to receive the first attachment member for coupling the suture to the prosthetic valve.

28. A kit comprising:

at least one suture having a longitudinal axis and a transverse axis perpendicular to the longitudinal axis, and wherein at least a portion of the suture comprises a plurality of apertures, wherein each of the plurality of apertures is configured to receive an attachment member for coupling the suture to an article.

29. The kit of claim 28, wherein the first attachment member comprises one or more stitches, flexible connectors, or any combination thereof.

30. The kit of any one of claims 28-29, wherein the article comprises a prosthetic valve.

31. The kit of any one of claims 28-30, wherein the suture is a reinforcement member.

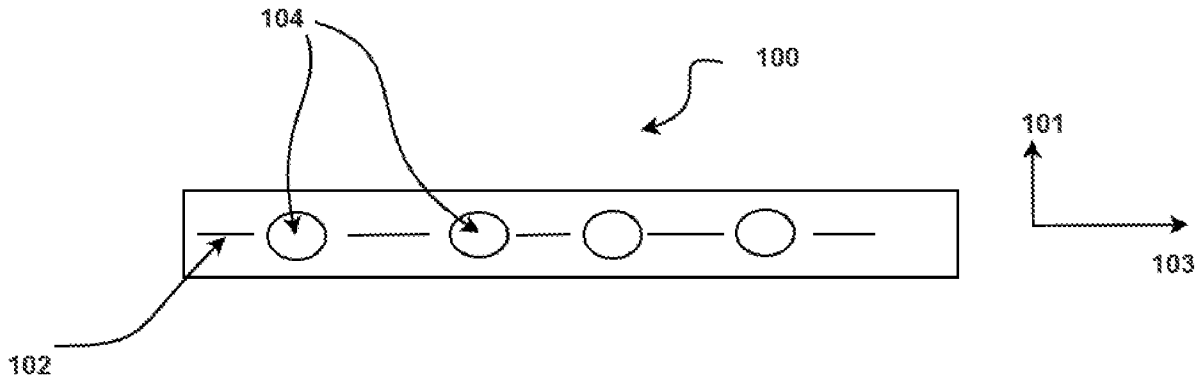

FIG. 1A

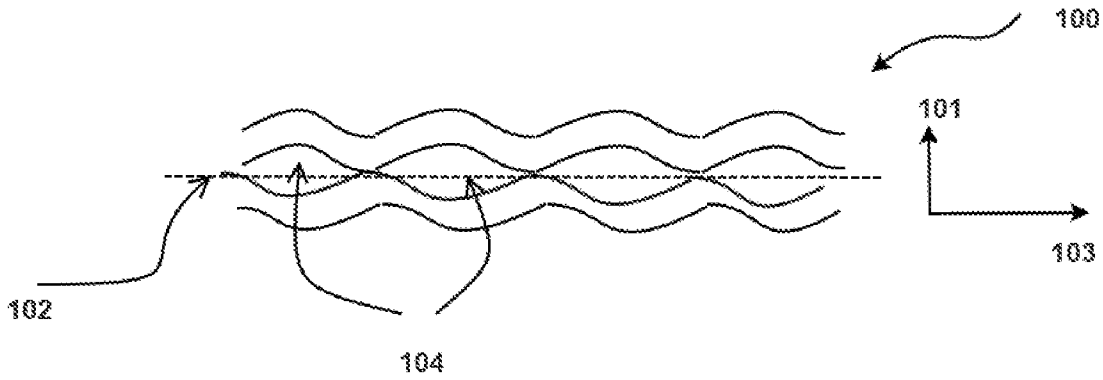

FIG. 1B

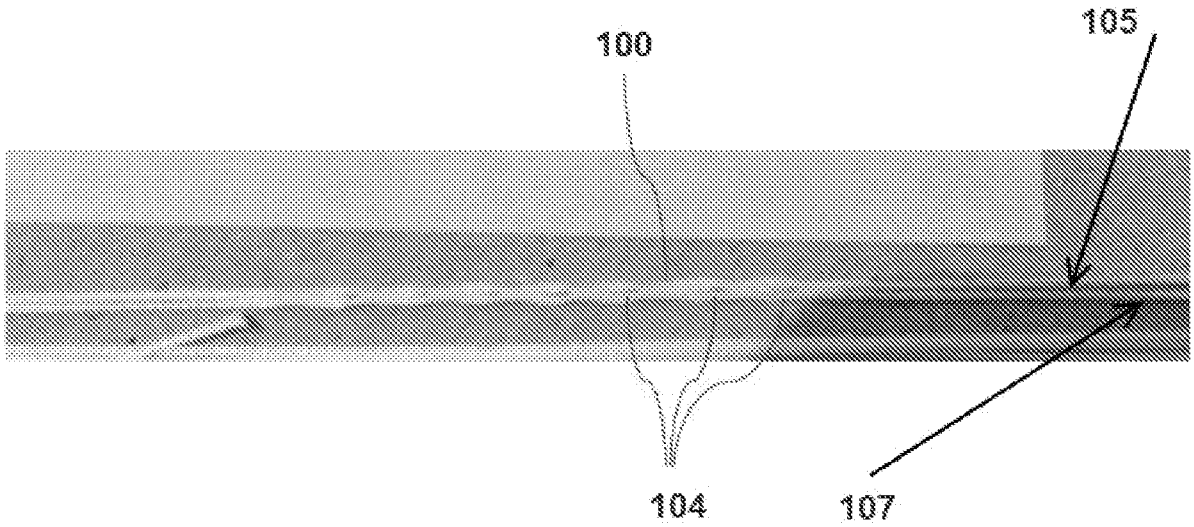

FIG. 1C

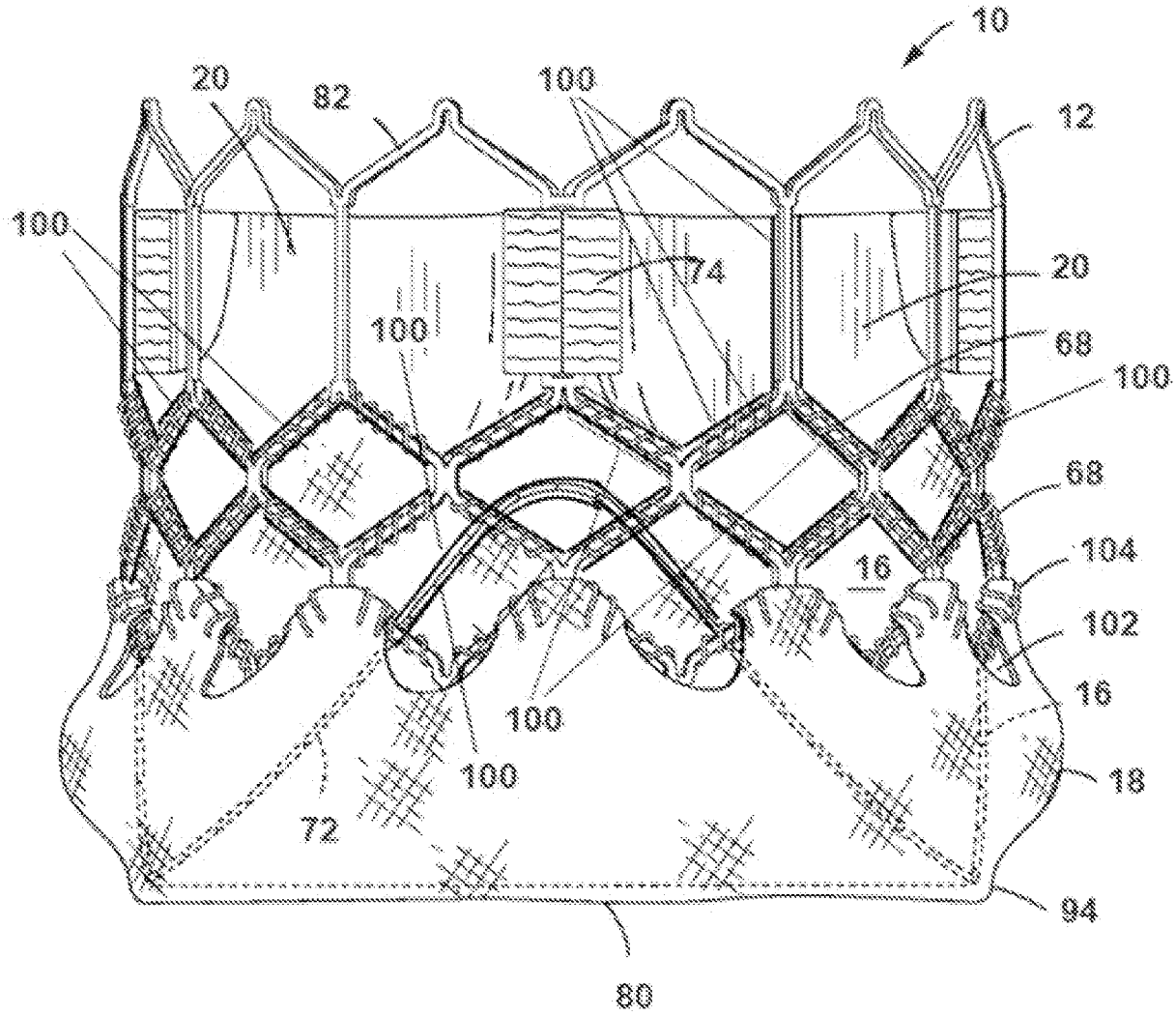
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FIG. 2

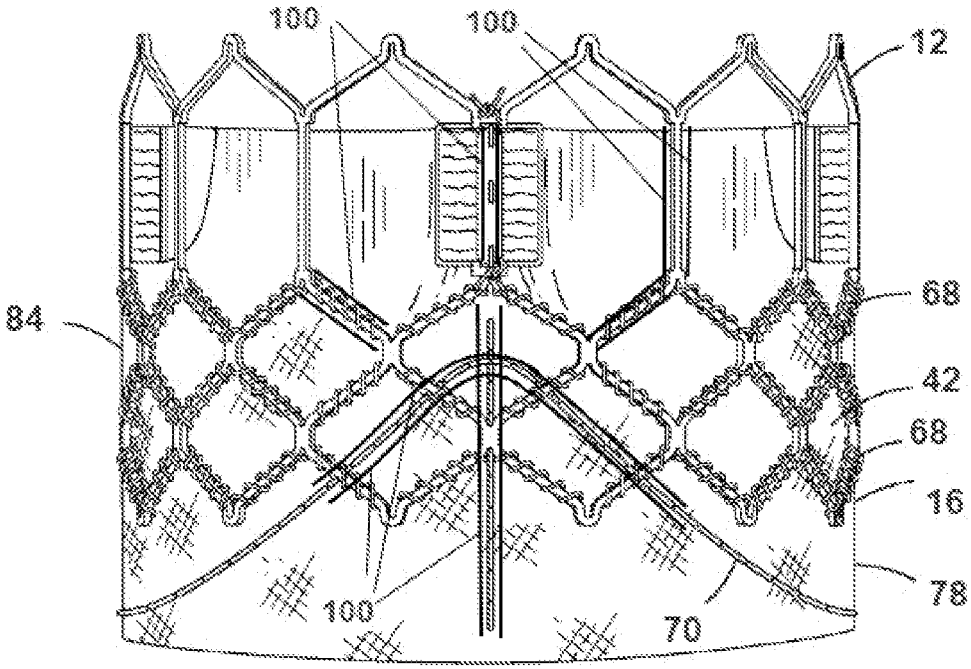
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FIG. 3

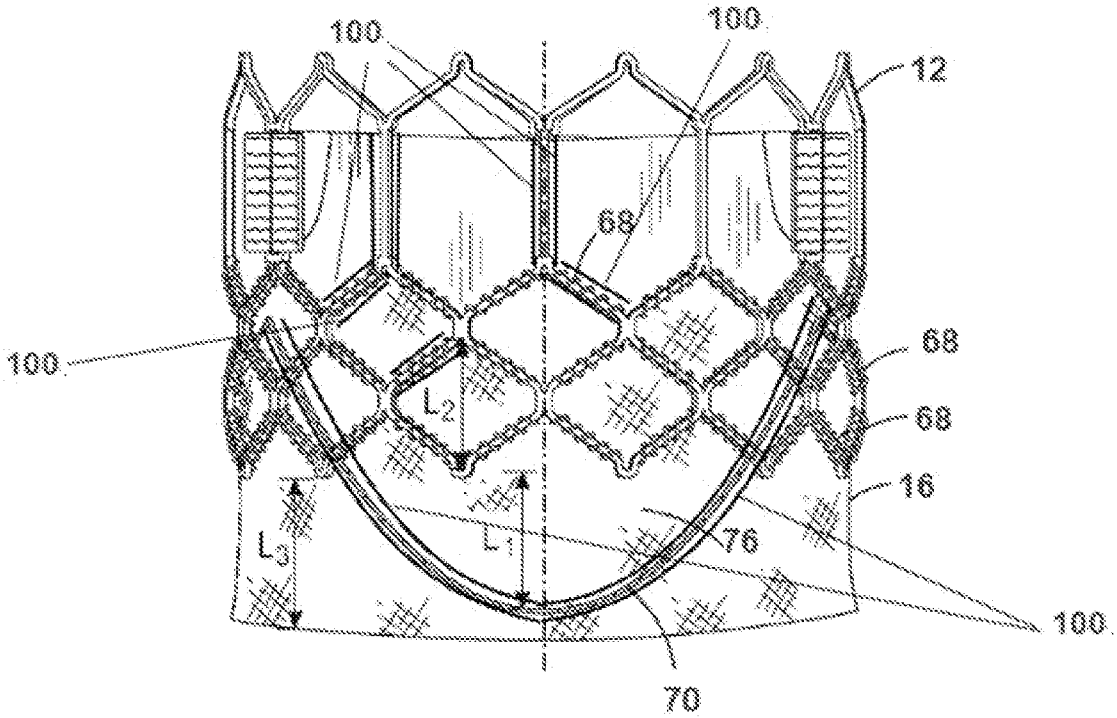
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FIG. 4

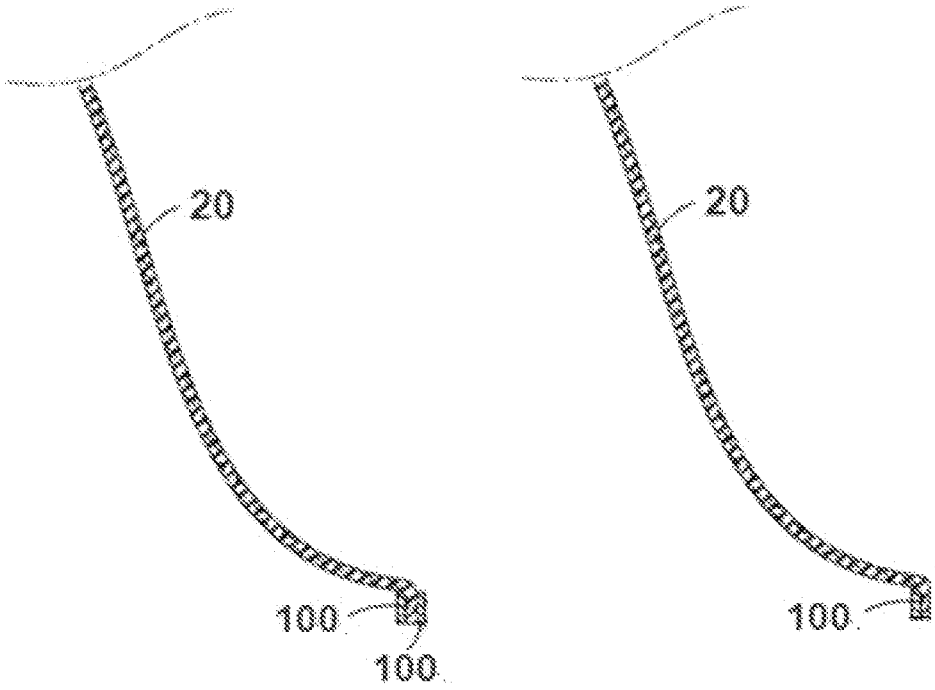

FIG. 5A

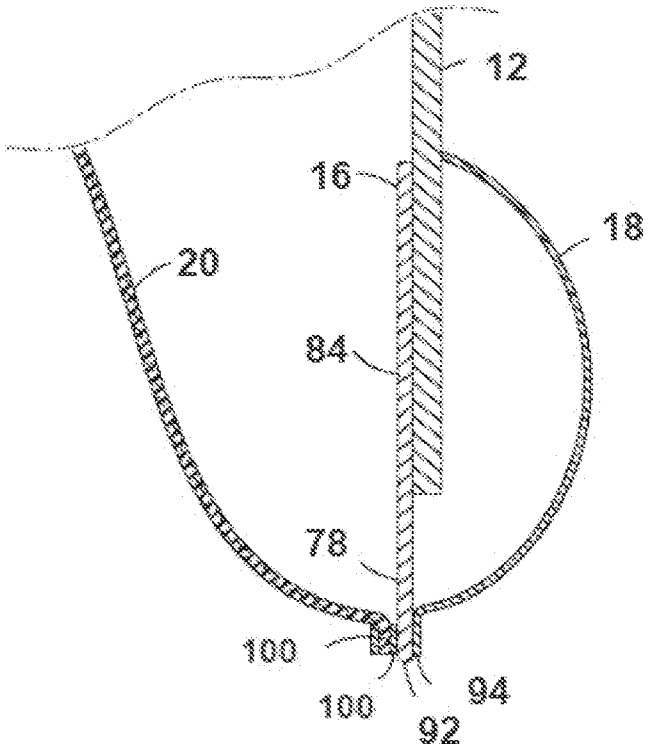

FIG. 5B

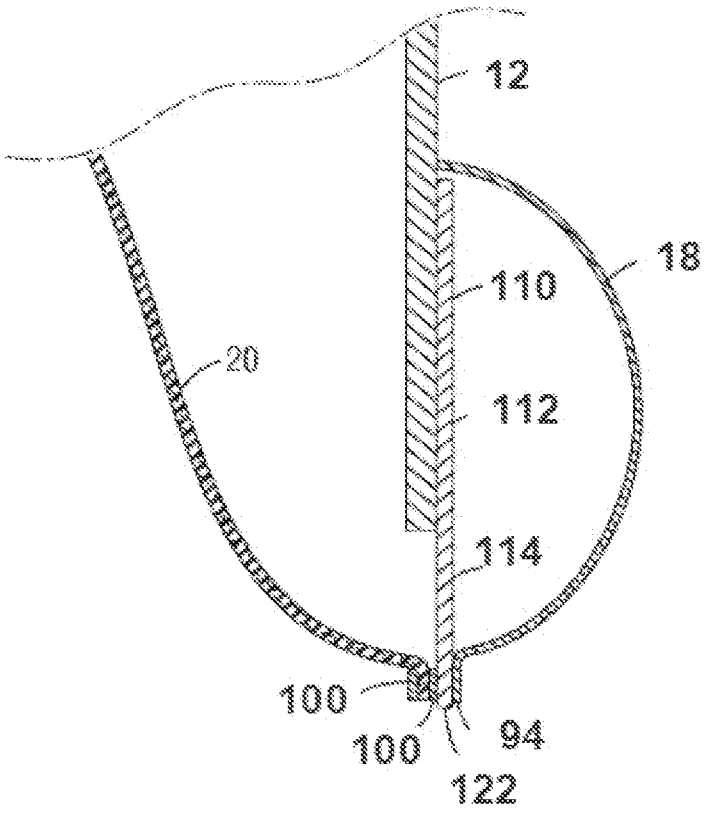

FIG. 6

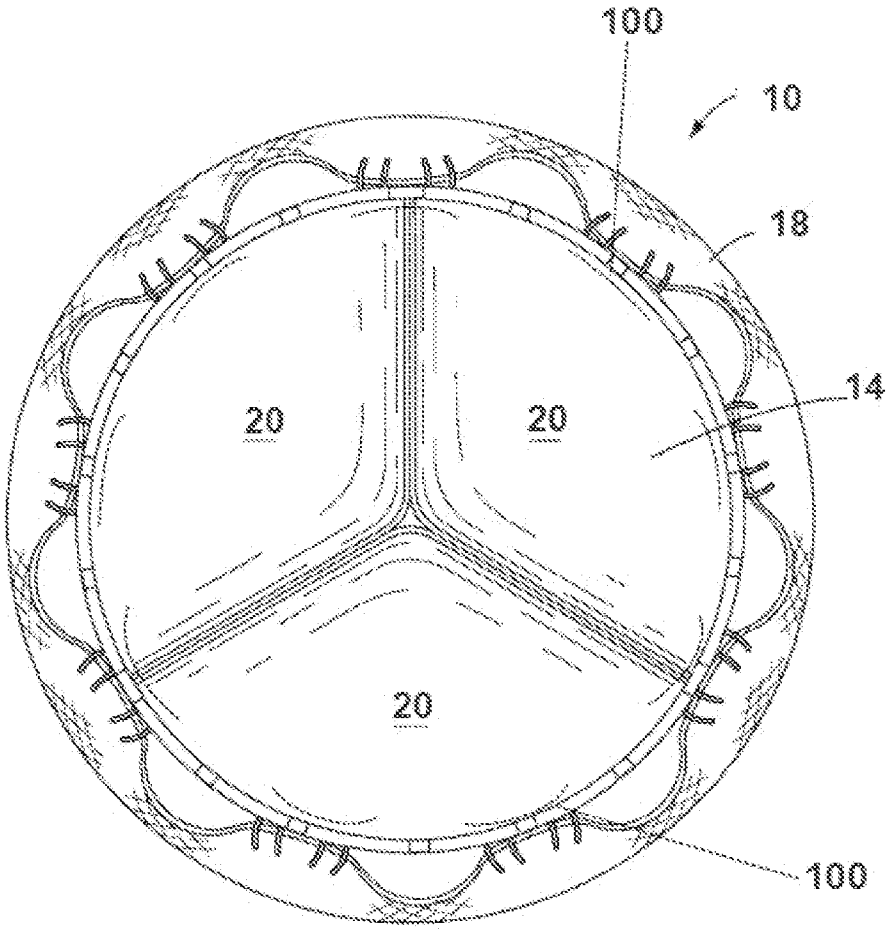
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FIG. 7

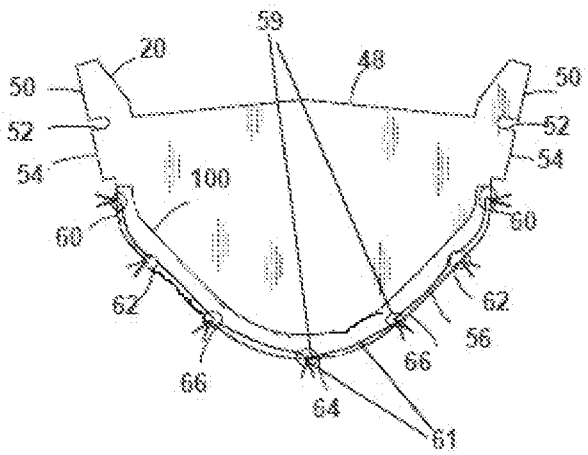
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FIG. 8

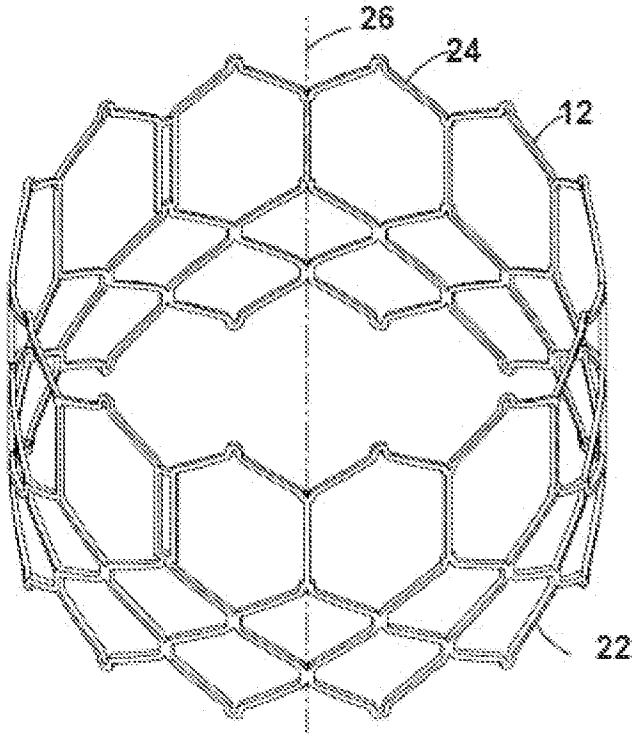

FIG. 9

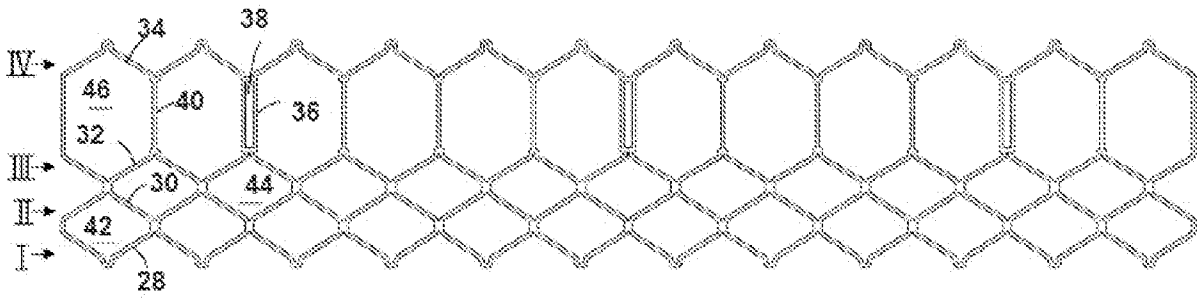

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2021/019681

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F B31D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/325665 A1 (GUROVICH NIKOLAY [IL] ET AL) 15 November 2018 (2018-11-15)	1-8, 11-13, 15,16, 19-23, 26-31
Y	paragraphs [0092], [0112], [0118], [0119], [0124]; figures 1,13A,14-18 paragraphs [0118], [0124]	9,10,14, 18
X	US 2018/028310 A1 (GUROVICH NIKOLAY [IL] ET AL) 1 February 2018 (2018-02-01)	1-8, 11-13, 15-17, 19,24-31
A	figures 13A,15D,24-25,32 paragraphs [0127], [0135], [0137]	9,10

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier application or patent but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 June 2021	02/07/2021

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Aubry, Yann

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/019681

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-31

   Prosthetic valve with reinforcing member comprising a suture with apertures

1.1. claims: 28-31

   Kit comprising a suture with apertures

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2021/019681

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2015/109027 A2 (UNIV CALIFORNIA [US]; KHERADVAR ARASH [US]; KELLEY GREGORY S [US]) 23 July 2015 (2015-07-23) figure 2F paragraph [0056] -----	9
Y	US 2 451 355 A (PECKER JOSEPH S) 12 October 1948 (1948-10-12) figure 3 -----	10
Y	US 2018/133003 A1 (LEVI TAMIR S [IL]) 17 May 2018 (2018-05-17) claim 1 figures 4,5A -----	14,18

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2021/019681

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2018325665 A1	15-11-2018	CA 3063388 A1	22-11-2018
		CN 110868962 A	06-03-2020
		CR 20190510 A	31-03-2020
		EP 3624733 A1	25-03-2020
		US 2018325665 A1	15-11-2018
		WO 2018213284 A1	22-11-2018
US 2018028310 A1	01-02-2018	AU 2017305328 A1	14-02-2019
		CA 3032308 A1	08-02-2018
		CN 109561964 A	02-04-2019
		CN 209059539 U	05-07-2019
		CN 211934426 U	17-11-2020
		CR 20190054 A	20-08-2019
		EP 3490501 A1	05-06-2019
		JP 2019523090 A	22-08-2019
		KR 20190026051 A	12-03-2019
		SG 11201900855T A	27-02-2019
		US 2018028310 A1	01-02-2018
		WO 2018026865 A1	08-02-2018
		ZA 201900642 B	30-10-2019
WO 2015109027 A2	23-07-2015	US 2016331566 A1	17-11-2016
		WO 2015109027 A2	23-07-2015
US 2451355 A	12-10-1948	NONE	
US 2018133003 A1	17-05-2018	CA 3043631 A1	24-05-2018
		CN 110167488 A	23-08-2019
		CR 20190234 A	19-09-2019
		EP 3541327 A2	25-09-2019
		US 2018133003 A1	17-05-2018
		US 2020078168 A1	12-03-2020
		WO 2018093711 A2	24-05-2018