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(54) **COMMISSURE ASSEMBLY FOR PROSTHETIC HEART VALVE**

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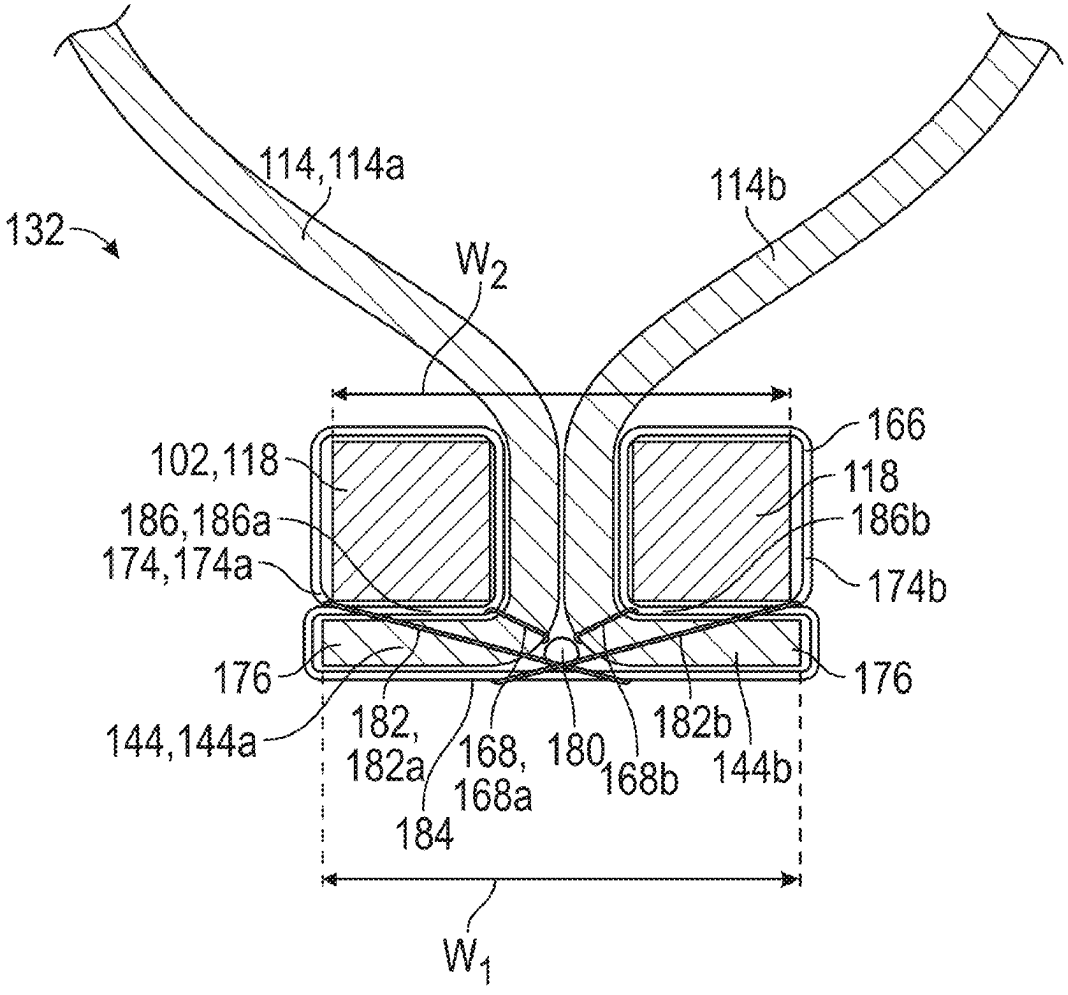
(57) **ABSTRACT**

An implantable prosthetic device can include a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially extending struts that defining one or more commissure windows. The device can further include a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and one or more commissure tabs, and a commissure comprising a flexible connector and the commissure tabs of two adjacent leaflets coupled to the flexible connector via one or more primary sutures. The commissure can be secured to a respective commissure window via one or more secondary sutures, each secondary suture extending through a radially outer layer of the flexible connector, a respective commissure tab, a radially inner layer of the flexible connector, and a free edge portion of the flexible connector.



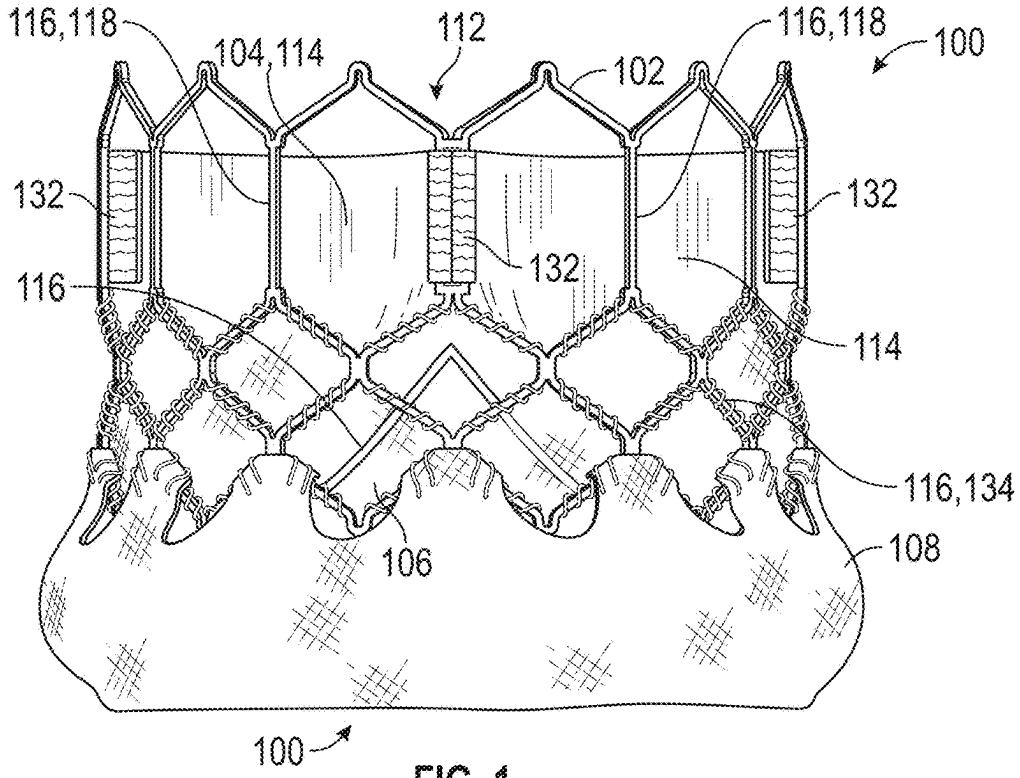

116,118
104,114
112
102
116,118
100
132
132
132
116
114
116,134
106
108
100

FIG. 1

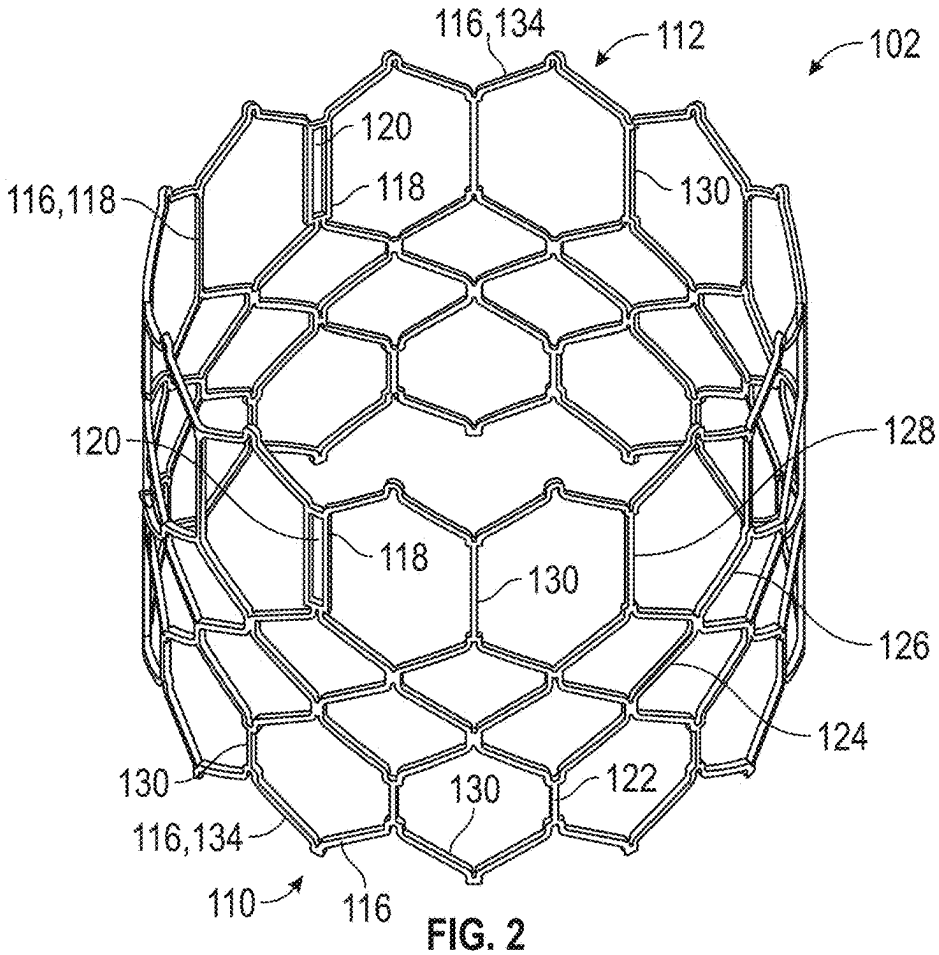

116,134
112
102
120
118
116,118
130
120
128
118
130
126
124
130
130
122
116,134
110
116

FIG. 2

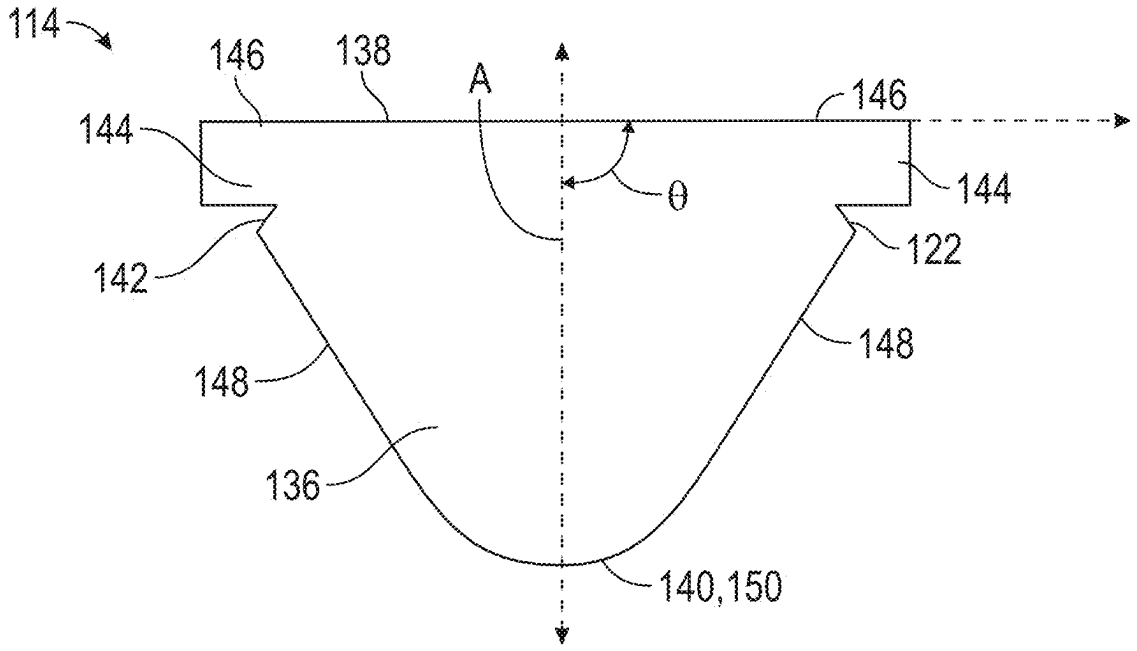

114
146
138
A
146
144
θ
144
142
122
148
148
136
140,150

FIG. 3

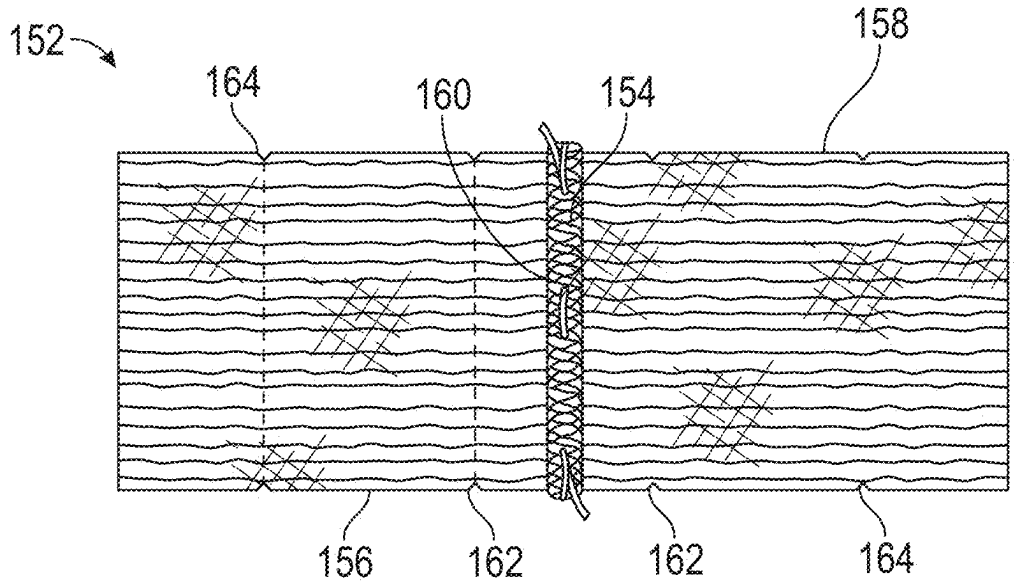

152
158
164
160
154
156
162
162
164

FIG. 4

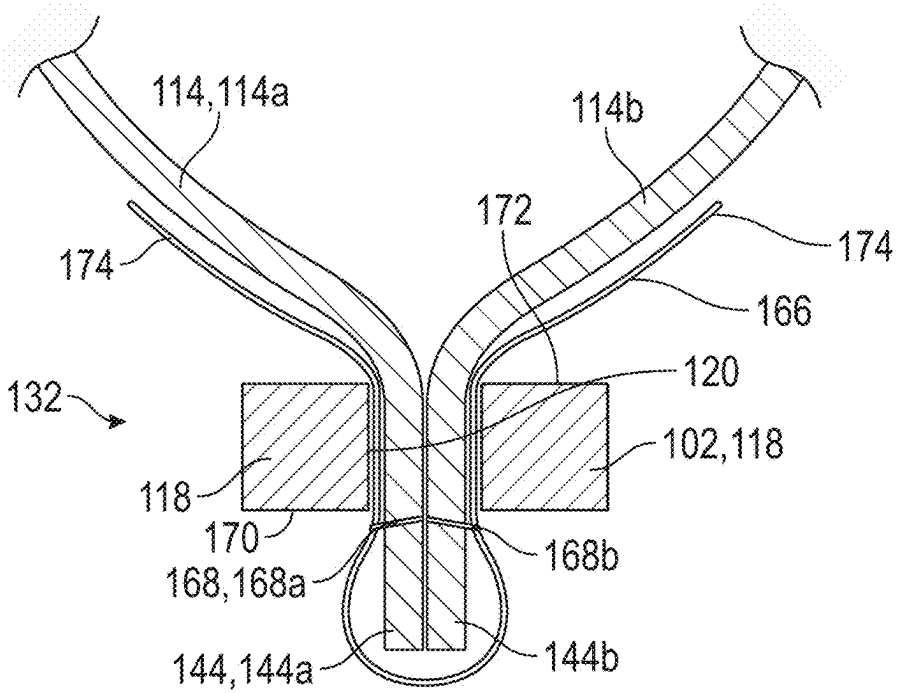

114,114a
114b
172
174
174
166
132
120
102,118
118
170
168b
168,168a
144,144a
144b

FIG. 5

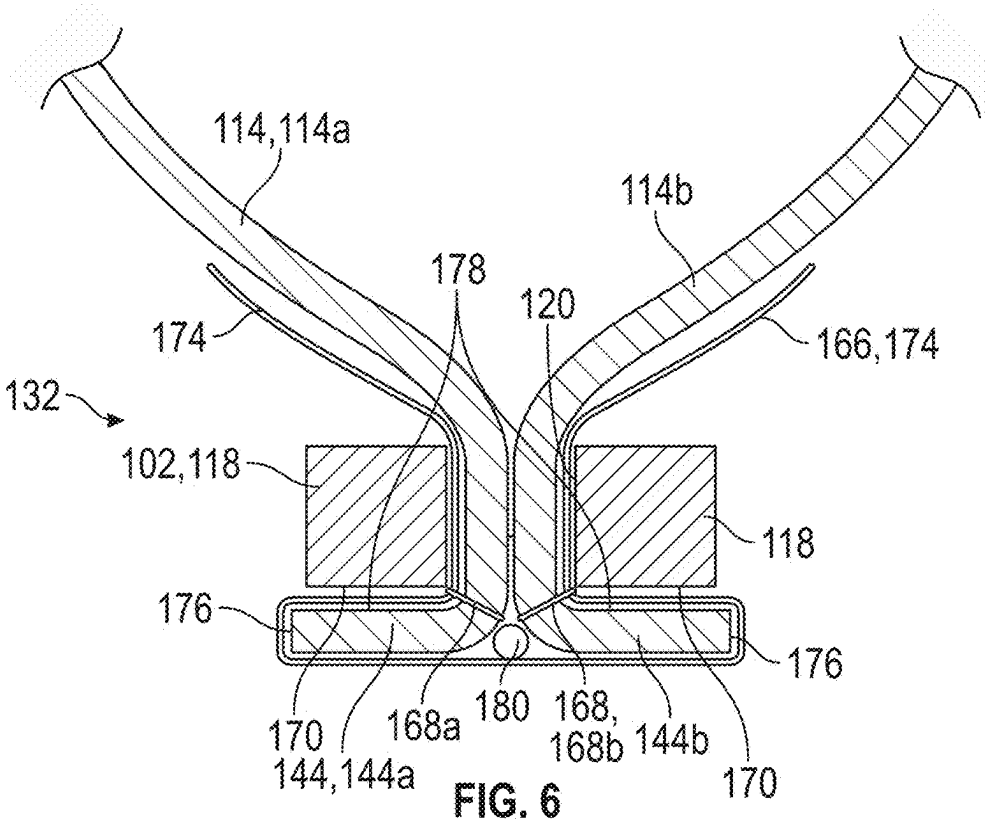

114,114a
114b
178
120
174
166,174
132
102,118
118
176
176
170
144,144a
168a
180
168,
168b
144b
170

FIG. 6

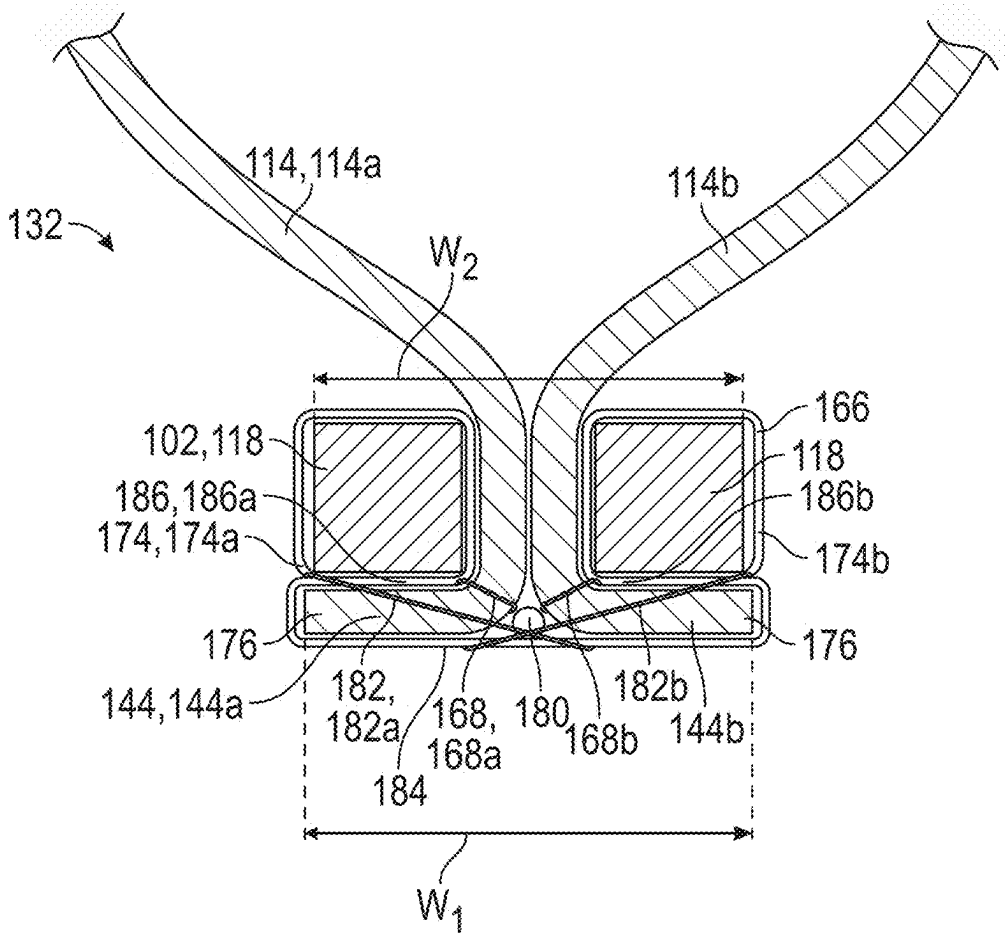

114,114a
114b
132
W_2
166
102,118
118
186,186a
186b
174,174a
174b
176
176
144,144a
182,
182a
168,
168a
180
168b
182b
144b
184
W_1

FIG. 7

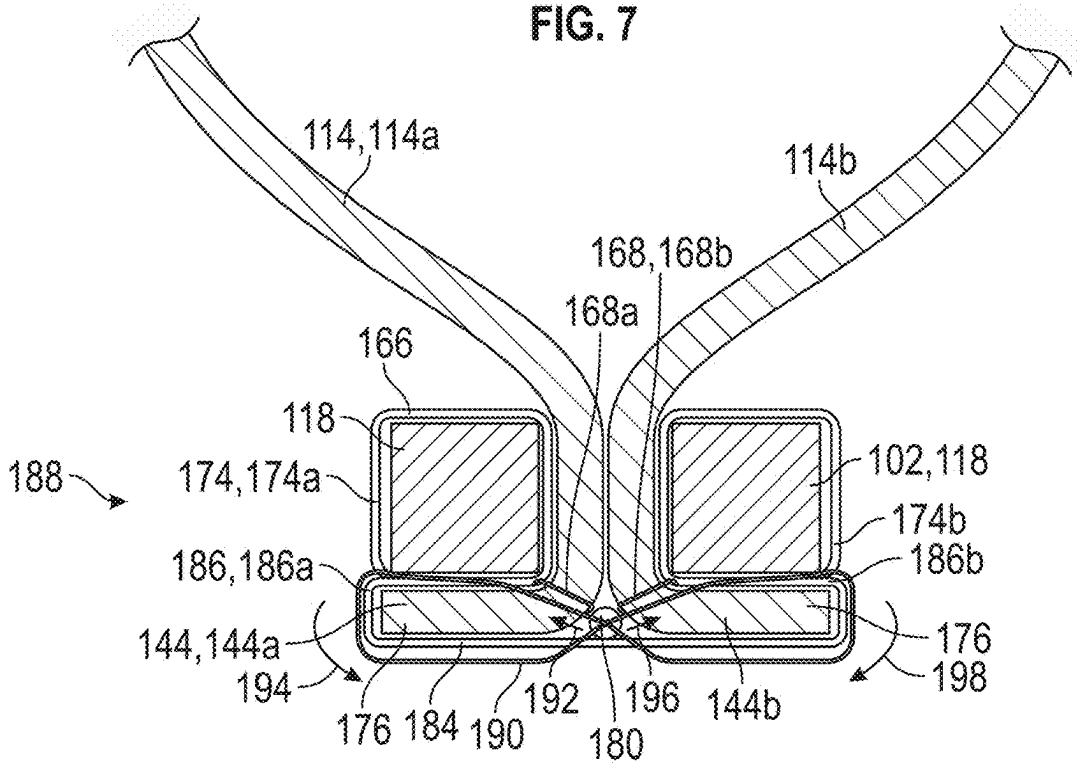

114,114a
114b
168,168b
168a
166
118
188
174,174a
102,118
174b
186,186a
186b
144,144a
176
198
194
176
184
190
192
196
180
144b

FIG. 8

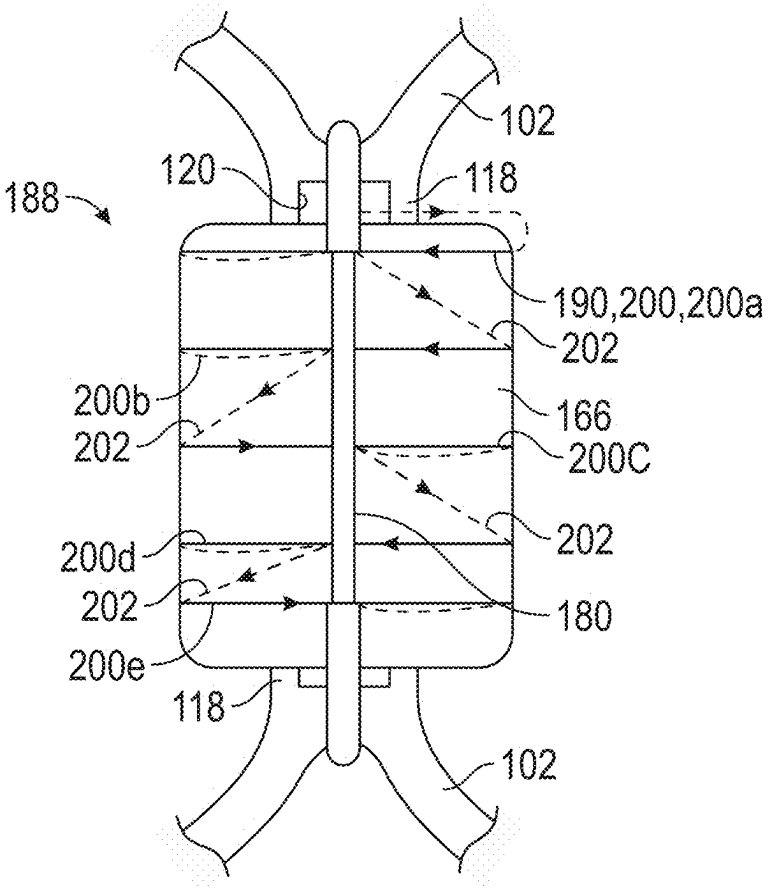

188
120
102
118
190,200,200a
202
200b
202
166
200C
202
200d
202
180
200e
118
102

FIG. 9

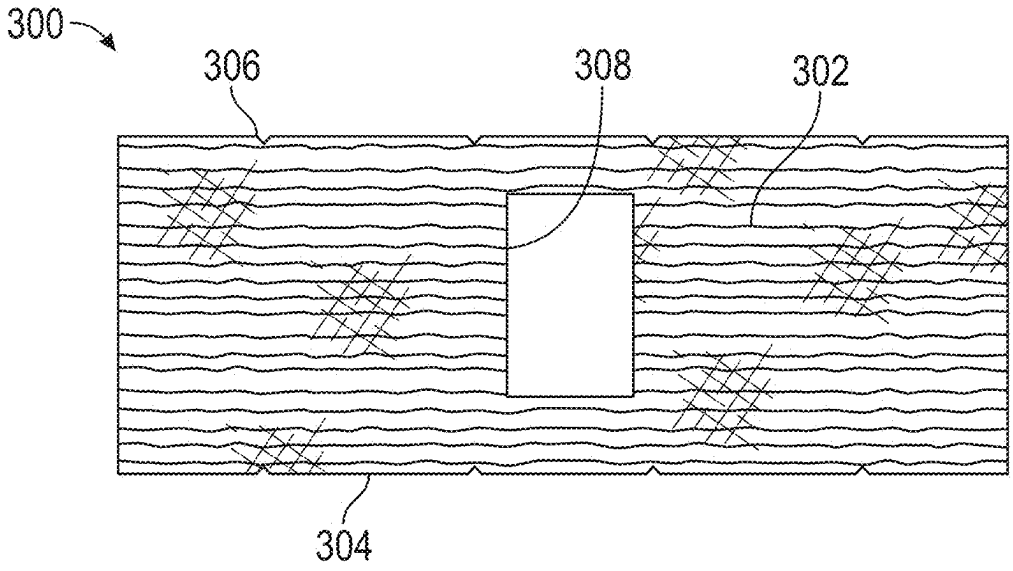

300
306
308
302
304

FIG. 10

COMMISSURE ASSEMBLY FOR PROSTHETIC HEART VALVE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of International Patent Application No. PCT/US2023/079068, filed Nov. 8, 2023, which claims the benefit of U.S. Application No. 63/423,898, filed on Nov. 9, 2022. The prior applications are incorporated herein by reference in their entirety.

FIELD

[0002] The present disclosure relates to prosthetic heart valves, and to methods and assemblies for forming leaflet assemblies and attaching the leaflet assemblies to the frame of such prosthetic heart valves.

BACKGROUND

[0003] The human heart can suffer from various valvular diseases. These valvular diseases can result in significant malfunctioning of the heart and ultimately require repair of the native valve or replacement of the native valve with an artificial valve. There are a number of known repair devices (e.g., stents) and artificial valves, as well as a number of known methods of implanting these devices and valves in humans. Percutaneous and minimally-invasive surgical approaches are used in various procedures to deliver prosthetic medical devices to locations inside the body that are not readily accessible by surgery or where access without surgery is desirable. In one specific example, a prosthetic heart valve can be mounted in a crimped state on the distal end of a delivery apparatus and advanced through the patient's vasculature (e.g., through a femoral artery and the aorta) until the prosthetic heart valve reaches the implantation site in the heart. The prosthetic heart valve is then expanded to its functional size, for example, by inflating a balloon on which the prosthetic valve is mounted, actuating a mechanical actuator that applies an expansion force to the prosthetic heart valve, or by deploying the prosthetic heart valve from a sheath of the delivery apparatus so that the prosthetic heart valve can self-expand to its functional size.

[0004] An important design parameter of a transcatheter heart valve is the diameter of the folded or crimped profile. The diameter of the crimped profile is important because it directly influences the physician's ability to advance the transcatheter heart valve through the femoral artery or vein. More particularly, a smaller profile allows for treatment of a wider population of patients, with enhanced safety.

[0005] Most expandable, transcatheter heart valves comprise a valvular structure disposed within the frame and attached to the frame via a plurality of commissures. Commissures can be formed by connecting adjacent leaflets of the valvular structure to one another and to the frame. However, such assembly techniques can take significant time and effort, thereby increasing production time and costs.

[0006] Accordingly, a need exists for simplifying an assembly process of the prosthetic heart valve, including simplifying the process for attaching the valvular structure to the frame of the prosthetic heart valve.

SUMMARY

[0007] Described herein are prosthetic heart valves, delivery apparatus, and methods for implanting prosthetic heart valves. The disclosed prosthetic heart valves, delivery apparatus, and methods can, for example, provide commissure configurations that minimize the amount of material in the commissure, thus helping reduce the overall bulk and width of the commissure, which can be important for retaining coronary access and for minimizing the crimp profile of the prosthetic valve. As such, the devices and methods disclosed herein can, among other things, overcome one or more of the deficiencies of typical prosthetic heart valves and their delivery apparatus.

[0008] A prosthetic heart valve can comprise a frame and a valve structure coupled to the frame. In addition to these components, a prosthetic heart valve can further comprise one or more of the components disclosed herein.

[0009] In some examples, the prosthetic valve can comprise commissures wherein the overall width of the commissure is equal to or less than the collective width of one or more axially extending struts of the frame and a commissure window of the frame.

[0010] In some examples, the commissure tabs of two adjacent leaflets of the valve structure can be coupled to a flexible connector via one or more primary sutures.

[0011] In some examples, the prosthetic valve can comprise commissures having first and second secondary sutures that couple the commissure to a commissure window of the frame, each secondary suture extending through a radially outer layer of the flexible connector, a respective commissure tab, a radially inner layer of the flexible connector, and a free edge portion of the flexible connector.

[0012] In some examples, the prosthetic valve can comprise commissures having a secondary suture that couples the commissure to a commissure window of the frame, each secondary suture extending in a figure-eight pattern.

[0013] In some examples, the figure-eight pattern extends through a radially outer layer of a flexible connector, a first commissure tab, a first radially inner layer of the flexible connector, a first free edge portion of the flexible connector, a second commissure tab, a second radially inner layer of the flexible connector, and a second free edge portion of the flexible connector.

[0014] In some examples, the figure-eight pattern is a first figure-eight pattern, and the secondary suture is sewn in a plurality of figure-eight patterns extending axially along a length of the commissure.

[0015] In some examples, the prosthetic valve can comprise commissures having a flexible connector, the flexible connector including an opening that extends through a thickness of the flexible connector, the opening sized to allow a wedge member to be inserted through the opening.

[0016] In some examples, each commissure can comprise a wedge member.

[0017] In some examples, the first and second secondary sutures extend through the wedge member.

[0018] In some examples, the one or more primary sutures can be disposed adjacent a radially inner facing surface of the frame.

[0019] In some examples, an implantable prosthetic device, can comprise a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially-extending struts that defining one or more commis-

sure windows. The prosthetic device can further comprise a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and one or more commissure tabs, and a commissure comprising a flexible connector and the commissure tabs of two adjacent leaflets coupled to the flexible connector via one or more primary sutures. The commissure can be secured to a respective commissure window via one or more secondary sutures, each secondary suture extending through a radially outer layer of the flexible connector, a respective commissure tab, a radially inner layer of the flexible connector, and a free edge portion of the flexible connector.

[0020] In some examples, an implantable prosthetic device, can comprise a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially-extending struts that defining one or more commissure windows. The prosthetic device can further comprise a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and opposing commissure tabs, a flexible connector comprising a main body, a first free edge portion, and a second free edge portion, and a commissure comprising the flexible connector, a wedge member disposed on a radially inner surface of the flexible connector, and first and second commissure tabs of two adjacent leaflets coupled to the flexible connector via first and second primary sutures. The commissure can be secured to a respective commissure window via first and second secondary sutures, the first secondary suture extending through a radially outer layer of the flexible connector, the wedge member, the first commissure tab, a first radially inner layer of the flexible connector, and the first free edge portion, the second secondary suture extending through the radially outer layer of the flexible connector, the wedge member, the second commissure tab, a second radially inner layer of the flexible connector, and the second free edge portion.

[0021] In some examples, an implantable prosthetic device can comprise a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially-extending struts that defining one or more commissure windows. The prosthetic device can further comprise a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and opposing commissure tabs, a flexible connector comprising a main body, a first free edge portion, and a second free edge portion, and a commissure comprising the flexible connector and first and second commissure tabs of two adjacent leaflets coupled to the flexible connector via first and second primary sutures. The commissure can be secured to a respective commissure window via a secondary suture sewn in a figure-eight pattern.

[0022] In some examples, an implantable prosthetic device, can comprise a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially extending struts that defining one or more commissure windows. The prosthetic device can further comprise a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and opposing commissure tabs, a flexible connector comprising a main body, a first free edge portion, a second free edge portion, and an opening extending through a thickness of the main body, and a commissure comprising the flexible connector and first and second commissure tabs of two adjacent leaflets coupled to the flexible connector via first and second primary sutures, the commissure further comprising a wedge member disposed on a radially inner surface of the flexible connector such that it is visible through the opening.

[0023] In some examples, a method of assembling a valvular structure can comprise coupling one or more commissure tabs of one or more adjacent leaflets to a flexible connector using one or more primary sutures, and advancing a portion of the flexible connector and the one or more commissure tabs through a commissure window in a radially expandable and compressible annular frame, the commissure window defined by one or more axially extending struts. The method can further comprise folding the one or more commissure tabs such that radially inner facing surfaces of the one or more commissure tabs are adjacent a radially outer facing surface of the frame, wrapping first and second free end portions of the flexible connector around the one or more axially extending struts, and securing the commissure to the frame via one or more secondary sutures, each secondary suture extending through a radially outer layer of the flexible connector, a respective commissure tab, a radially inner layer of the flexible connector, and a free edge portion of the flexible connector.

[0024] In some examples, a method of assembling a valvular structure can comprise coupling a first integral commissure tab of a first leaflet to a first side portion of a flexible connector using a first primary suture, coupling a second integral commissure tab of a second leaflet to a second side portion of the flexible connector using a second primary suture, and advancing a portion of the first and second commissure tabs and the flexible connector through a commissure window in a radially expandable and compressible annular frame, the commissure window defined by one or more axially extending struts. The method can further comprise folding the first and second commissure tabs circumferentially away from one another such that radially inner facing surfaces of the first and second commissure tabs are adjacent a radially outer facing surface of the frame, wrapping first and second free end portions of the flexible connector around the one or more axially extending struts, and securing the commissure to the frame via a first secondary suture extending through a radially outer layer of the flexible connector, the wedge member, the first commissure tab, a first radially inner layer of the flexible connector, and the first free edge portion, and a second secondary suture extending through the radially outer layer of the flexible connector, the wedge member, the second commissure tab, a second radially inner layer of the flexible connector, and the second free edge portion.

[0025] In some examples, a method of assembling a valvular structure can comprise coupling a first integral commissure tab of a first leaflet to a first side portion of a flexible connector using a first primary suture, coupling a second integral commissure tab of a second leaflet to a second side portion of the flexible connector using a second primary suture, and advancing a portion of the first and second commissure tabs and the flexible connector through a commissure window in a radially expandable and compressible annular frame, the commissure window defined by one or more axially extending struts. The method can further comprise folding the first and second commissure tabs circumferentially away from one another such that radially

inner facing surfaces of the first and second commissure tabs are adjacent a radially outer facing surface of the frame, wrapping first and second free end portions of the flexible connector around the one or more axially extending struts, and securing the commissure to the frame via a secondary suture sewn in a figure-eight pattern.

[0026] In some examples, a method comprises sterilizing any of the above described devices.

[0027] In some examples, a prosthetic heart valve comprises one or more of the components recited in Examples 1-71 below.

[0028] The various innovations of this disclosure can be used in combination or separately. This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the detailed description. This summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter. The foregoing and other objects, features, and advantages of the disclosure will become more apparent from the following detailed description, claims, and accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] FIG. **1** is a side elevation view of a prosthetic heart valve, according to one example.

[0030] FIG. **2** is a perspective view of the frame of the prosthetic heart valve of FIG. **1**.

[0031] FIG. **3** is a plan view of a leaflet of the prosthetic heart valve of FIG. **1**, shown in a flattened configuration.

[0032] FIG. **4** is a plan view of an example of a flexible connector, shown in a flattened configuration.

[0033] FIGS. **5-7** are cross-sectional views illustrating steps for assembling a commissure and coupling the commissure to the frame of a prosthetic heart valve.

[0034] FIG. **8** is a cross-sectional view of a commissure coupled to the frame of a prosthetic heart valve, according to one example.

[0035] FIG. **9** is a side elevational view of the commissure of FIG. **8** shown coupled to the frame of a prosthetic heart valve.

[0036] FIG. **10** is a plan view of an example of a flexible connector, shown in a flattened configuration.

DETAILED DESCRIPTION

General Considerations

[0037] For purposes of this description, certain aspects, advantages, and novel features of the examples of this disclosure are described herein. The disclosed methods, apparatus, and systems should not be construed as being limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed examples, alone and in various combinations and sub-combinations with one another. The methods, apparatus, and systems are not limited to any specific aspect or feature or combination thereof, nor do the disclosed examples require that any one or more specific advantages be present or problems be solved.

[0038] Although the operations of some of the disclosed examples are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth below. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be used in conjunction with other methods. Additionally, the description sometimes uses terms like "provide" or "achieve" to describe the disclosed methods. These terms are high-level abstractions of the actual operations that are performed. The actual operations that correspond to these terms may vary depending on the particular implementation and are readily discernible by one of ordinary skill in the art.

[0039] All features described herein are independent of one another and, except where structurally impossible, can be used in combination with any other feature described herein. For example, a flexible connector **300** as shown in FIG. **10** or a flexible connector **152** as shown in FIG. **4** can be used in combination with any of the commissures **132**, **188** described herein. In some examples, secondary figure-eight sutures **190** as shown in FIGS. **8-9** can be used in combination with secondary sutures **182** shown in FIG. **7**.

[0040] 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. Additionally, the term "includes" means "comprises." Further, the term "coupled" generally means physically, mechanically, chemically, magnetically, and/or electrically coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items absent specific contrary language.

[0041] In some examples, values, procedures, or apparatus may be referred to as "lowest," "best," "minimum," or the like. It will be appreciated that such descriptions are intended to indicate that a selection among many alternatives can be made, and such selections need not be better, smaller, or otherwise preferable to other selections.

[0042] In the description, certain terms may be used such as "up," "down," "upper," "lower," "horizontal," "vertical," "left," "right," and the like. These terms are used, where applicable, to provide some clarity of description when dealing with relative relationships. But, these terms are not intended to imply absolute relationships, positions, and/or orientations. For example, with respect to an object, an "upper" surface can become a "lower" surface simply by turning the object over. Nevertheless, it is still the same object.

[0043] As used herein, the term "proximal" refers to a position, direction, or portion of a device that is closer to the user and further away from the implantation site. As used herein, the term "distal" refers to a position, direction, or portion of a device that is further away from the user and closer to the implantation site. Thus, for example, proximal motion of a device is motion of the device away from the implantation site and toward the user (e.g., out of the patient's body), while distal motion of the device is motion of the device away from the user and toward the implantation site (e.g., into the patient's body). The terms "longitudinal" and "axial" refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined.

Examples of the Disclosed Technology

[0044] FIG. **1** shows a prosthetic heart valve **100**, according to one example. The illustrated valve is adapted to be implanted in the native aortic annulus, although in other

examples it can be adapted to be implanted in the other native annuluses of the heart. The valve **100** can generally comprise a stent or frame **102**, a valvular or leaflet structure **104**, an inner skirt **106**, and an outer skirt **108**. The prosthetic heart valve can have an inflow end portion **110** and an outflow end portion **112**.

[0045] The valvular structure **104** can comprise three leaflets **114** which can be arranged to collapse in a tricuspid arrangement. The lower edge of leaflet structure **104** desirably has an undulating, curved scalloped shape (suture line **116** shown in FIG. **1** tracks the scalloped shape of the leaflet structure). By forming the leaflets with this scalloped geometry, stresses on the leaflets are reduced, which in turn improves durability of the valve. Moreover, by virtue of the scalloped shape, folds and ripples at the belly of each leaflet (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 leaflet structure, thereby allowing a smaller, more even crimped profile at the inflow end of the valve. The leaflets **114** 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 at least in U.S. Pat. No. 6,730,118, which is incorporated by reference herein in its entirety.

[0046] FIG. **2** illustrates the frame **102** with the other components removed for purposes of illustration. The frame **102** can comprise a plurality of struts **116**, including a plurality of axially-extending struts **118**, one or more of which can define commissure windows **120** (for example, three in the illustrated example). The commissure windows **120** are adapted to mount the commissures of the valvular structure **104** to the frame, as described in greater detail below. The frame **102** 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 **102** (and thus the valve **100**) 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 **102** (and thus the valve **100**) 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 **100** can be advanced from the delivery sheath, which allows the valve to expand to its functional size.

[0047] Suitable plastically-expandable materials that can be used to form the frames disclosed herein (for example, the frame **102**) include, metal alloys, polymers, or combinations thereof. Example metal alloys can comprise one or more of the following: nickel, cobalt, chromium, molybdenum, titanium, or other biocompatible metal. In some examples, the frame **102** can comprise stainless steel. In some examples, the frame **102** can comprise cobalt-chromium. In some examples, the frame **102** can comprise nickel-cobalt-chromium. In some examples, the frame **102** comprises 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. In some examples, 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 resistances, 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.

[0048] The frame **102** can comprise a plurality of struts **116** arranged to define one or more circumferentially extending rows of cells. In the illustrated example, the frame **102** can comprise four circumferentially extending rows of cells **130**, namely, first row **122**, second row **124**, third row **126**, and fourth row **128**. However, in other examples, the frame **102** can have a greater or fewer number of rows. In some examples, the cells **130** in one or more rows of cells can have a different shape relative to the remaining cells. For example, in the illustrated example, the fourth row of cells **128** (disposed adjacent the outflow end portion **112** of the frame **102**) can have a relatively larger open cell area compared to the cells of rows **126**, **124**, and/or **122**. Accordingly, the cells **130** in the fourth row **128** can be referred to as "larger" or "elongated" cells. The elongated cells are relatively large and are sized to allow portions of the valvular structure **104** to protrude, or bulge, into and/or through the cells **130** when the frame **120** is crimped in order to minimize the crimping profile. In some examples, the cells **130** in the first row of cells **122** can also have a relatively larger open cell area compared to the cells of rows **124** and/or **126**.

[0049] As mentioned previously and shown in FIG. **1**, the prosthetic valve **100** can also include a valvular structure **104**, which is coupled to and supported by the frame **102**. The valvular structure **104** can include, for example, one or more leaflets **114**. The leaflets **114** can be secured to one another at their adjacent sides to form commissures **132**, each of which can be secured to a respective commissure window **120** of the frame **102**. The axially-extending struts **118** which define the commissure windows **120** can be secured at their upper and lower ends to angled struts **134** to provide a robust configuration that enhances fatigue resistance under cyclic loading of the valve. In the illustrated example, the commissure windows **120** can have an elongated rectangular shape. However, in other examples, the commissure windows can have any of various shapes, including but not limited to, square, oval, square oval, triangular, trapezoidal, etc.

[0050] Further details of the frame and leaflet structure can be found, at least, in U.S. Pat. No. 9,393,110, which is incorporated by reference herein in its entirety.

[0051] FIG. **3** illustrates a leaflet **114** of the valvular structure **104** according to one example. The leaflet **114** can comprise a main body **136**, an upper edge portion **138** (also referred to as the coaptation edge or free edge), a lower edge portion **140** (also referred to as the cusp edge or scallop edge) which terminates at openings/recesses/gaps **142** that extend laterally into the main body **136** of the leaflet, and laterally projecting integral tabs **144** (also referred to as commissure tabs), which are spaced apart from the lower edge portion **140** by the gaps **142**. In some examples, such as the illustrated example, the tabs **144** are formed integrally with the main body **136** of the leaflet. The tabs **144** can extend from the main body such that an upper or outflow edge **146** of each tab is positioned at an angle θ relative to a longitudinal axis A of the leaflet **114**. In the illustrated example, the tabs **144** can extend from the main body **136**

such that the angle θ is a 90 degree angle. In other examples, the angle θ can be any of various angles, for example, corresponding to (for example, being substantially parallel to) the draft angle of the frame of the prosthetic valve.

[0052] The leaflet **114** can have an overall V-shape. The sub-commissure portion of the leaflet **114** (that is, the portion below the tabs **144**) includes two substantially straight edges **148** that extend from respective locations below the tabs **144** to a curved lower edge **150**. The tapered profile of the sub-commissure portion of the leaflet reduces the amount of leaflet material in the lower half of the crimped valve to minimize the crimp diameter of that portion of the valve. Thus, if additional components are mounted to that portion of the valve, such as an outer skirt **108**, the reduced profile of that portion of the valve can help offset or minimize the increase in diameter caused by the additional component. Additionally, the commissure tabs **144** are relatively short and require fewer sutures for forming the commissures of the leaflet structure than other known commissure designs, which better distributes and reduces the bulkiness of the leaflet material when the valve is crimped.

[0053] As mentioned, the leaflets **114** can be secured to one another at their adjacent sides to form commissures **132** of the valvular structure. A plurality of flexible connectors **152**, also referred to as "commissure attachment members" or "posts" (one of which is shown in FIG. **4**) can be used to interconnect pairs of adjacent tabs **144** and to mount the leaflets to the commissure window frame portions **120**. In some examples, the flexible connectors **152** can be made from a piece of woven PET fabric, although other synthetic and/or natural materials can be used. In some examples, the flexible connector **152** can include a reinforcing member/wedge member **154** extending from the lower or inflow edge **156** to the upper or outflow edge **158** at the center of the connector **152**. The wedge member **154** can comprise a non-metallic material, such as a rope, a piece of fabric (such as PET), and/or a piece of Ethibond 2-0 suture material, secured to the connector (for example, with a temporary suture **160**). The wedge member **154** can help prevent rotational and radial movement of the leaflet tabs once they are secured to the commissure window frame portions **120**. In some examples, the connector **152** can have one or more inner notches **162** and/or outer notches **164** formed along its upper and lower edges. The notches **162**, **164** can be used to help align the flexible connector to the leaflets **114** and for folding during the commissure assembly process.

[0054] FIGS. **5-7** illustrate the formation of an exemplary commissure **132** for coupling a portion of the valvular structure **104** to the frame **102**. To form each commissure **132**, the tab portions **144***a*, **144***b* of two adjacent leaflets **114***a*, **114***b* can be coupled to a respective flexible connector **166**, as shown in FIG. **5**. The flexible connector **166** can be the same or similar to flexible connector **152** described previously. A first stitch/suture/suture line **168***a* can extend through the first tab portion **144***a* and the flexible connector **166**, and a second stitch/suture/suture line **168***b* can extend through the second tab portion **144***b* and the flexible connector **166**. The first and second suture lines **168***a*, **168***b* can collectively be referred to as the "primary suture lines" **168**.

[0055] Thus coupled, the tabs **144***a*, **144***b* and flexible connector **166** can be inserted through the commissure opening **120** of the frame **120**, as shown in FIG. **5**. The free end portions **174** of the flexible connector **166** can remain radially inside of the frame **102**. The tabs **144***a*, **144***b* can be advanced until the primary sutures **168** are positioned adjacent the radially outer surface **170** of the frame **102**. In other examples, the primary sutures **168** can be positioned such that they are adjacent the radially inner surface **172** of the frame **102**. Coupling the tabs **144***a*, **144***b* to the flexible connector **166** prior to insertion through the commissure window **120** can advantageously allow the tabs **144***a*, **144***b* to be pulled rather than pushed through the commissure window **120**, which can prevent or mitigate damage to the tabs during this step of assembly.

[0056] Referring to FIG. **6**, the edge portions **176** of the tabs **144***a*, **144***b* can be folded circumferentially outwardly such that a radially inner facing surface of the tabs **178** is positioned adjacent to the radially outer facing surface **170** of the frame **102**. A wedge member **180** can be positioned on a radially inner surface of the flexible connector **166** between the first and second tabs **144***a*, **144***b* as shown in FIG. **6**. In some examples, the wedge **180** can be inserted after the tabs **144** are folded circumferentially, however, in other examples, the wedge member **180** can be coupled to the flexible member **166** prior to coupling the flexible member to the tabs **144**.

[0057] Referring now to FIG. **7**, the first and second free end portions **174***a*, **174***b* of the flexible connector **166** can be folded radially outwardly such that they wrap around the struts **118** of the frame **102** that define the commissure window **120**. A third stitch/suture/suture line **182***a* can extend through the first free end portion **174***a*, through the leaflet tab **144***a*, through the wedge member **180**, and through one or more layers of the flexible connector **166**. For example, in the illustrated example, the third suture **182** can extend through an outer layer **184** of the flexible connector **166**, the wedge member **180**, the first tab **144***a*, a first inner layer **186***a* of the flexible connector, and the first free end portion **174***a* of the flexible connector **166**. A fourth stitch/suture/suture line **182***b* can extend through the second free end portion **174***b*, through the second leaflet tab **144***b*, through the wedge member **180**, and through one or more layers of the flexible connector **166**. For example, in the illustrated example, the fourth suture **182***b* can extend through the outer layer **184** of the flexible connector **166**, the wedge member **180**, the second tab **144***b*, a second inner layer **186***b* of the flexible connector **166**, and the second free end portion **174***b*. The third and fourth suture lines can collectively be referred to as the "secondary suture lines" **182**.

[0058] As shown in FIG. **7**, the secondary suture lines **182** can cross over one another to form a X-shape. Such a configuration includes fewer assembly steps, facilitates a simplified commissure assembly process, and reduces the overall number of suture lines extending through the commissure **132** thus helping reduce the overall bulk and width of the commissure, which can be important for retaining coronary access and for minimizing the crimp profile of the prosthetic valve. The leaflet tabs **144** can be sized such that when folded they have a width W_1 that is substantially equal to or less than the collective width W_2 of the struts **118** that define the commissure window **120** and the commissure window **120** itself, and the commissure configuration **132** can use fewer sutures than previous configurations, thereby reducing the overall material present in the commissure. These features additionally help reduce the overall width of the commissure, which can advantageously minimize the

overall profile of the valve, particularly when in the crimped configuration. In some examples, the commissures described herein can have an overall width of less than about 4 mm. For example, between about 1.5 mm and about 2.5 mm, between about 1.8 mm and about 2.3 mm, between about 2 mm and about 2.1 mm.

[0059] FIG. **8** illustrates an alternative suture configuration to the configuration illustrated in FIG. **7**, resulting in an alternative commissure **188**. The steps leading up to FIG. **8** are the same as those shown and described with respect to FIGS. **5-6**. As shown in FIG. **8**, in some examples, in lieu of third and fourth sutures **182***a,* **182***b* (the "secondary suture lines"), the commissure **188** can comprise a secondary suture line formed by suture **190**. In some examples, the secondary suture line can comprise only a single suture.

[0060] The suture **190** can extend through the various components of the commissure in a 'figure-eight' pattern, such as shown in FIG. **8**. That is, as illustrated by arrow **192**, the suture **190** can extend through the outer layer **184** of the flexible connector **166**, the wedge member **180**, the first tab **144***a,* the first inner layer **186***a* of the flexible connector, and the first free end portion **174***a.* As illustrated by arrow **194**, the suture **190** can then wrap around the edge portion **176** of the first tab **144***a* and then, as shown by arrow **196**, extend through the outer layer **184** of the flexible connector and through the wedge member **180** (crossing over itself in an X-shape), then through the second tab **144***b,* the second inner layer **186***b* of the flexible connector **166**, and the second free end portion **174***b.* The suture **190** can then wrap around the edge portion **176** of the second tab **144***b,* as shown by arrow **198**.

[0061] Such a configuration advantageously secures the edge portions **176** of the tabs **144** while also simplifying the commissure assembly, and minimizing the amount of material in the commissure (one secondary suture line rather than two). Additionally, this configuration allows the commissure **188** to be tightened into its final configuration by pulling/tightening a single suture **190**, rather than having to tighten various sutures.

[0062] As mentioned previously, the leaflet tabs **144** can be sized such that when folded against the radially outer facing surface of the frame they have a width that is substantially the same as the collective width of the struts **118** that define the commissure window **120** and the commissure window **120** itself, and the commissure configuration **188** can use fewer sutures than previous configurations, thereby reducing the overall material present in the commissure. These features additionally help reduce the overall width of the commissure which can advantageously minimize the overall profile of the valve, particularly when in the crimped configuration. In some examples, the commissures described herein can have an overall width of less than about 4 mm. For example, between about 1.5 mm and about 2.5 mm, between about 1.8 mm and about 2.3 mm, between about 2 mm and about 2.1 mm.

[0063] Referring to FIG. **9**, in some examples, the "figure-eight" pattern of the secondary suture line **190** can continue in an axial direction along the length of the commissure **188** to form a plurality of figure-eight sutures **200**. For example, once a first figure-eight **200***a* has been completed, the suture **190** can be sewn in an axial direction (e.g., toward the inflow end) before beginning a second figure-eight **200***b.* In some examples, such as shown in FIG. **9**, the axially-extending portions **202** of the suture **190** can be disposed on alternating sides of the wedge member **180**. In the illustrated example, the commissure **188** comprises a first figure-eight **200***a,* a second figure-eight **200***b,* a third figure-eight **200***c,* a fourth figure-eight **200***d,* and a fifth figure-eight **200***e.* In other examples, the commissure **188** can comprise one, two, three, four, five, six, seven, eight, nine, or ten figure-eight sutures.

[0064] FIG. **10** illustrates another example of a flexible connector **300**, which can be used in lieu of or in addition to flexible connectors **152** or **166** described previously. Flexible connector **300** can be similar to flexible connectors **152** and **166** (e.g., having a main body **302** made from a piece of woven PET fabric, although other synthetic and/or natural materials can be used, an inflow edge **304**, and an outflow edge **306**), except that flexible connector **300** includes an optional aperture/window/opening **308** extending through a thickness of the flexible connector **300**. The opening **308** can be configured to allow insertion of a wedge member, e.g., wedge member **180** described previously, through the opening **308**. This can further simplify assembly of the commissure and can help ensure that the secondary suture lines **182/190** pass through the wedge member **180** during the assembly process.

[0065] Any of the systems, devices, apparatuses, etc. herein can be sterilized (for example, with heat/thermal, pressure, steam, radiation, and/or chemicals, etc.) to ensure they are safe for use with patients, and any of the methods herein can include sterilization of the associated system, device, apparatus, etc. as one of the steps of the method. Examples of heat/thermal sterilization include steam sterilization and autoclaving. Examples of radiation for use in sterilization include, without limitation, gamma radiation, ultra-violet radiation, and electron beam. Examples of chemicals for use in sterilization include, without limitation, ethylene oxide, hydrogen peroxide, peracetic acid, formaldehyde, and glutaraldehyde. Sterilization with hydrogen peroxide may be accomplished using hydrogen peroxide plasma, for example.

Additional Examples of the Disclosed Technology

[0066] In view of the above-described implementations of the disclosed subject matter, this application discloses the additional examples enumerated below. It should be noted that one feature of an example in isolation or more than one feature of the example taken in combination and, optionally, in combination with one or more features of one or more further examples are further examples also falling within the disclosure of this application.

[0067] Example 1. An implantable prosthetic device, comprising:

[0068] a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially-extending struts that defining one or more commissure windows;

[0069] a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and one or more commissure tabs;

[0070] a commissure comprising a flexible connector and the commissure tabs of two adjacent leaflets coupled to the flexible connector via one or more primary sutures;

[0071] wherein the commissure is secured to a respective commissure window via one or more secondary sutures, each secondary suture extending through a radially outer

layer of the flexible connector, a respective commissure tab, a radially inner layer of the flexible connector, and a free edge portion of the flexible connector.

[0072] Example 2. The prosthetic device of any example herein, particularly example 1, wherein the flexible connector comprises a main body and first and second free edge portions, and wherein the first and second free edge portions are folded around respective axially-extending struts of the frame.

[0073] Example 3. The prosthetic device of any example herein, particularly any one of examples 1-2, further comprising a wedge member disposed on a radially inner facing surface of the flexible connector between the adjacent leaflet tabs.

[0074] Example 4. The prosthetic device of any example herein, particularly example 3, wherein the wedge member comprises an ethibond suture.

[0075] Example 5. The prosthetic device of any example herein, particularly example 3, wherein the wedge member comprises a strip of PET fabric.

[0076] Example 6. The prosthetic device of any example herein, particularly any one of examples 1-5, wherein the one or more primary sutures are disposed adjacent a radially outer facing surface of the frame.

[0077] Example 7. The prosthetic device of any example herein, particularly any one of examples 1-5, wherein the one or more primary sutures are disposed adjacent a radially inner facing surface of the frame.

[0078] Example 8. The prosthetic device of any example herein, particularly any one of examples 1-7, wherein the commissure windows have an elongated rectangular shape.

[0079] Example 9. The prosthetic device of any example herein, particularly any one of examples 1-8, wherein the flexible connector has a rectangular shape.

[0080] Example 10. The prosthetic device of any example herein, particularly example 9, wherein the flexible connector comprises an opening extending through a thickness of a main body of the flexible connector.

[0081] Example 11. The prosthetic device of any example herein, particularly example 10, wherein the opening is sized such that a wedge member can be disposed through the opening.

[0082] Example 12. The prosthetic device of any example herein, particularly any one of examples 1-11, wherein the one or more secondary sutures comprise a first secondary suture and a second secondary suture, wherein the first secondary suture extends through the radially outer layer of the flexible connector, a first commissure tab of the one or more commissure tabs, a first radially inner layer of the flexible connector, and a first free edge portion of the flexible connector, and wherein the second secondary suture extends through the radially outer layer of the flexible connector, a second commissure tab of the one or more commissure tabs, a second radially inner layer of the flexible connector, and a second free edge portion of the flexible connector.

[0083] Example 13. The prosthetic device of any example herein, particularly example 12, further comprising a wedge member disposed on a radially inner facing surface of the flexible connector between the first and second commissure tabs, wherein the first and second secondary sutures each extend through the wedge member.

[0084] Example 14. The prosthetic device of any example herein, particularly any one of examples 1-11, wherein the one or more secondary sutures comprise a secondary suture that extends in a figure-eight pattern.

[0085] Example 15. The prosthetic device of any example herein, particularly example 14, wherein the figure-eight pattern extends through a radially outer layer of the flexible connector, a first commissure tab, a first radially inner layer of the flexible connector, a first free edge portion of the flexible connector, a second commissure tab, a second radially inner layer of the flexible connector, and a second free edge portion of the flexible connector.

[0086] Example 16. The prosthetic device of any example herein, particularly example 15, wherein the commissure further comprises a wedge member disposed on a radially inner surface of the flexible connector, and wherein the figure-eight pattern passes through the wedge member twice.

[0087] Example 17. The prosthetic device of any example herein, particularly any one of examples 14-16, wherein the figure-eight pattern is a first figure-eight pattern, and wherein the secondary suture is sewn in a plurality of figure-eight patterns extending axially along a length of the commissure.

[0088] Example 18. The prosthetic device of any example herein, particularly example 17, wherein each figure-eight pattern is connected to one or more adjacent figure-eight patterns via one or more axially-extending portions of the secondary suture.

[0089] Example 19. The prosthetic device of any example herein, particularly example 18, wherein the axially-extending portions of the secondary suture are disposed on alternating sides of the wedge member.

[0090] Example 20. The prosthetic device of any example herein, particularly any one of examples 1-19, wherein an outflow edge of each of the one or more commissure tabs is disposed at an angle relative to a longitudinal axis of the leaflet.

[0091] Example 21. The prosthetic device of any example herein, particularly example 20, wherein the angle is a 90 degree angle.

[0092] Example 22. The prosthetic device of any example herein, particularly any one of examples 1-21, wherein the overall width of the commissure is equal to or less than to the collective width of the one or more axially extending struts and the commissure window. Example 23. An implantable prosthetic device, comprising:

[0093] a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially-extending struts that defining one or more commissure windows;

[0094] a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and opposing commissure tabs;

[0095] a flexible connector comprising a main body, a first free edge portion, and a second free edge portion;

[0096] a commissure comprising the flexible connector, a wedge member disposed on a radially inner surface of the flexible connector, and first and second commissure tabs of two adjacent leaflets coupled to the flexible connector via first and second primary sutures; and

[0097] wherein the commissure is secured to a respective commissure window via first and second secondary sutures, the first secondary suture extending through a radially outer layer of the flexible connector, the wedge

member, the first commissure tab, a first radially inner layer of the flexible connector, and the first free edge portion, the second secondary suture extending through the radially outer layer of the flexible connector, the wedge member, the second commissure tab, a second radially inner layer of the flexible connector, and the second free edge portion.

[0098] Example 24. The prosthetic device of any example herein, particularly example 23, wherein the flexible connector comprises a main body and first and second free edge portions, and wherein the first and second free edge portions are folded around respective axially-extending struts of the frame.

[0099] Example 25. The prosthetic device of any example herein, particularly any one of examples 23-24, wherein the wedge member comprises an ethibond suture.

[0100] Example 26. The prosthetic device of any example herein, particularly any one of examples 23-24, wherein the wedge member comprises a strip of PET fabric.

[0101] Example 27. The prosthetic device of any example herein, particularly any one of examples 23-26, wherein the one or more primary sutures are disposed adjacent a radially outer facing surface of the frame.

[0102] Example 28. The prosthetic device of any example herein, particularly any one of examples 23-26, wherein the one or more primary sutures are disposed adjacent a radially inner facing surface of the frame.

[0103] Example 29. The prosthetic device of any example herein, particularly any one of examples 23-28, wherein the commissure windows have an elongated rectangular shape.

[0104] Example 30. The prosthetic device of any one of claims 23-29, wherein the flexible connector has a rectangular shape.

[0105] Example 31. The prosthetic device of any example herein, particularly example 30, wherein the flexible connector comprises an opening extending through a thickness of a main body of the flexible connector.

[0106] Example 32. The prosthetic device of any example herein, particularly example 31, wherein the opening is sized such that a wedge member can be disposed through the opening.

[0107] Example 33. The prosthetic device of any example herein, particularly any one of examples 23-32,wherein an outflow edge of each of the one or more commissure tabs is disposed at an angle relative to a longitudinal axis of the leaflet.

[0108] Example 34. The prosthetic device of any example herein, particularly example 33, wherein the angle is a 90 degree angle.

[0109] Example 35. The prosthetic device of any example herein, particularly any one of examples 23-34, wherein the overall width of the commissure is equal to or less than to the collective width of the one or more axially extending struts and the commissure window.

[0110] Example 36. An implantable prosthetic device, comprising:

[0111] a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially-extending struts that defining one or more commissure windows;

[0112] a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and opposing commissure tabs;

[0113] a flexible connector comprising a main body, a first free edge portion, and a second free edge portion;

[0114] a commissure comprising the flexible connector and first and second commissure tabs of two adjacent leaflets coupled to the flexible connector via first and second primary sutures; and

[0115] wherein the commissure is secured to a respective commissure window via a secondary suture sewn in a figure-eight pattern.

[0116] Example 37. The prosthetic device of any example herein, particularly example 36, wherein the figure-eight pattern extends through a radially outer layer of the flexible connector, the first commissure tab, a first radially inner layer of the flexible connector, a first free edge portion of the flexible connector, the second commissure tab, a second radially inner layer of the flexible connector, and a second free edge portion of the flexible connector.

[0117] Example 38. The prosthetic device of any example herein, particularly any one of examples 36-37, wherein the commissure further comprises a wedge member disposed on a radially inner surface of the flexible connector, and wherein the figure-eight pattern passes through the wedge member twice.

[0118] Example 39. The prosthetic device of any example herein, particularly example 38, wherein the wedge member comprises an ethibond suture.

[0119] Example 40. The prosthetic device of any example herein, particularly example 38, wherein the wedge member comprises a strip of PET fabric.

[0120] Example 41. The prosthetic device of any example herein, particularly any one of examples 36-40, wherein the figure-eight pattern is a first figure-eight pattern, and wherein the secondary suture is sewn in a plurality of figure-eight patterns extending axially along a length of the commissure.

[0121] Example 42. The prosthetic device of any example herein, particularly example 41, wherein each figure-eight pattern is connected to one or more adjacent figure-eight patterns via one or more axially-extending portions of the secondary suture.

[0122] Example 43. The prosthetic device of any example herein, particularly example 42, wherein the axially-extending portions of the secondary suture are disposed on alternating sides of the wedge member.

[0123] Example 44. The prosthetic device of any example herein, particularly any one of examples 36-43, wherein the first and second free edge portions of the flexible connector are folded around respective axially-extending struts of the frame.

[0124] Example 45. The prosthetic device of any example herein, particularly any one of examples 36-44, wherein the one or more primary sutures are disposed adjacent a radially outer facing surface of the frame.

[0125] Example 46. The prosthetic device of any example herein, particularly any one of examples 36-44, wherein the one or more primary sutures are disposed adjacent a radially inner facing surface of the frame.

[0126] Example 47. The prosthetic device of any example herein, particularly any one of examples 36-46, wherein the commissure windows have an elongated rectangular shape.

[0127] Example 48. The prosthetic device of any example herein, particularly any one of examples 36-47, wherein the flexible connector has a rectangular shape.

[0128] Example 49. The prosthetic device of any example herein, particularly example 48, wherein the flexible connector comprises an opening extending through a thickness of a main body of the flexible connector.

[0129] Example 50. The prosthetic device of any example herein, particularly example 49, wherein the opening is sized such that a wedge member can be disposed through the opening.

[0130] Example 51. The prosthetic device of any example herein, particularly any one of examples 36-50, wherein an outflow edge of each of the one or more commissure tabs is disposed at an angle relative to a longitudinal axis of the leaflet.

[0131] Example 52. The prosthetic device of any example herein, particularly example 51, wherein the angle is a 90 degree angle.

[0132] Example 53. The prosthetic device of any example herein, particularly any one of examples 36-52, wherein the overall width of the commissure is equal to or less than to the collective width of the one or more axially extending struts and the commissure window.

[0133] Example 54. An implantable prosthetic device, comprising:

[0134] a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially extending struts that defining one or more commissure windows;

[0135] a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and opposing commissure tabs;

[0136] a flexible connector comprising a main body, a first free edge portion, a second free edge portion, and an opening extending through a thickness of the main body;

[0137] a commissure comprising the flexible connector and first and second commissure tabs of two adjacent leaflets coupled to the flexible connector via first and second primary sutures, the commissure further comprising a wedge member disposed on a radially inner surface of the flexible connector such that it is visible through the opening.

[0138] Example 55. The prosthetic device of any example herein, particularly example 54, wherein the opening is sized such that the wedge member can be inserted through the opening.

[0139] Example 56. The prosthetic device of any example herein, particularly any one of examples 54-55, wherein the commissure is secured to a respective commissure window via a secondary suture sewn in a figure-eight pattern.

[0140] Example 57. The prosthetic device of any example herein, particularly example 56, wherein the figure-eight pattern extends through a radially outer layer of the flexible connector, the wedge member, the first commissure tab, a first radially inner layer of the flexible connector, a first free edge portion of the flexible connector, the second commissure tab, a second radially inner layer of the flexible connector, and a second free edge portion of the flexible connector.

[0141] Example 58. The prosthetic device of any example herein, particularly any one of examples 56-57, wherein the figure-eight pattern is a first figure-eight pattern, and wherein the secondary suture is sewn in a plurality of figure-eight patterns extending axially along a length of the commissure.

[0142] Example 59. The prosthetic device of any example herein, particularly any one of examples 54-55, wherein the commissure is secured to a respective commissure window via first and second secondary sutures, the first secondary suture extending through a radially outer layer of the flexible connector, the wedge member, the first commissure tab, a first radially inner layer of the flexible connector, and the first free edge portion, the second secondary suture extending through the radially outer layer of the flexible connector, the wedge member, the second commissure tab, a second radially inner layer of the flexible connector, and the second free edge portion.

[0143] Example 60. The prosthetic device of any example herein, particularly any one of examples 54-59, wherein the overall width of the commissure is equal to or less than to the collective width of the one or more axially extending struts and the commissure window.

[0144] Example 61. A method of assembling a valvular structure, comprising:

[0145] coupling one or more commissure tabs of one or more adjacent leaflets to a flexible connector using one or more primary sutures;

[0146] advancing a portion of the flexible connector and the one or more commissure tabs through a commissure window in a radially expandable and compressible annular frame, the commissure window defined by one or more axially extending struts;

[0147] folding the one or more commissure tabs such that radially inner facing surfaces of the one or more commissure tabs are adjacent a radially outer facing surface of the frame;

[0148] wrapping first and second free end portions of the flexible connector around the one or more axially extending struts;

[0149] securing the commissure to the frame via one or more secondary sutures, each secondary suture extending through a radially outer layer of the flexible connector, a respective commissure tab, a radially inner layer of the flexible connector, and a free edge portion of the flexible connector.

[0150] Example 62. The method of any example herein, particularly example 61, wherein the one or more secondary sutures comprise a first secondary suture and a second secondary suture, wherein the first secondary suture extends through the radially outer layer of the flexible connector, a first commissure tab of the one or more commissure tabs, a first radially inner layer of the flexible connector, and a first free edge portion of the flexible connector, and wherein the second secondary suture extends through the radially outer layer of the flexible connector, a second commissure tab of the one or more commissure tabs, a second radially inner layer of the flexible connector, and a second free edge portion of the flexible connector.

[0151] Example 63. The method of any example herein, particularly example 61, wherein the one or more secondary sutures comprise a secondary suture that extends in a figure-eight pattern.

[0152] Example 64. The method of any example herein, particularly example 63, wherein the figure-eight pattern extends through a radially outer layer of the flexible connector, a first commissure tab, a first radially inner layer of

the flexible connector, a first free edge portion of the flexible connector, a second commissure tab, a second radially inner layer of the flexible connector, and a second free edge portion of the flexible connector.

[0153] Example 65. A method of assembling a valvular structure, comprising:

[0154] coupling a first integral commissure tab of a first leaflet to a first side portion of a flexible connector using a first primary suture;

[0155] coupling a second integral commissure tab of a second leaflet to a second side portion of the flexible connector using a second primary suture;

[0156] advancing a portion of the first and second commissure tabs and the flexible connector through a commissure window in a radially expandable and compressible annular frame, the commissure window defined by one or more axially extending struts;

[0157] folding the first and second commissure tabs circumferentially away from one another such that radially inner facing surfaces of the first and second commissure tabs are adjacent a radially outer facing surface of the frame;

[0158] wrapping first and second free end portions of the flexible connector around the one or more axially extending struts; and

[0159] securing the commissure to the frame via a first secondary suture extending through a radially outer layer of the flexible connector, the wedge member, the first commissure tab, a first radially inner layer of the flexible connector, and the first free edge portion, and a second secondary suture extending through the radially outer layer of the flexible connector, the wedge member, the second commissure tab, a second radially inner layer of the flexible connector, and the second free edge portion.

[0160] Example 66. A method of assembling a valvular structure, comprising:

[0161] coupling a first integral commissure tab of a first leaflet to a first side portion of a flexible connector using a first primary suture;

[0162] coupling a second integral commissure tab of a second leaflet to a second side portion of the flexible connector using a second primary suture;

[0163] advancing a portion of the first and second commissure tabs and the flexible connector through a commissure window in a radially expandable and compressible annular frame, the commissure window defined by one or more axially extending struts;

[0164] folding the first and second commissure tabs circumferentially away from one another such that radially inner facing surfaces of the first and second commissure tabs are adjacent a radially outer facing surface of the frame;

[0165] wrapping first and second free end portions of the flexible connector around the one or more axially extending struts; and

[0166] securing the commissure to the frame via a secondary suture sewn in a figure-eight pattern.

[0167] Example 67. The method of any example herein, particularly example 66, wherein the figure-eight pattern extends through a radially outer layer of the flexible connector, the first commissure tab, a first radially inner layer of the flexible connector, a first free edge portion of the flexible connector, the second commissure tab, a second radially inner layer of the flexible connector, and a second free edge portion of the flexible connector.

[0168] Example 68. The method of any example herein, particularly any one of examples 66-67, wherein the figure-eight pattern is a first figure-eight pattern, and wherein the secondary suture is sewn in a plurality of figure-eight patterns extending axially along a length of the commissure.

[0169] Example 69. The method of any example herein, particularly example 64, wherein each figure-eight pattern is connected to one or more adjacent figure-eight patterns via one or more axially-extending portions of the secondary suture.

[0170] Example 70. An implantable prosthetic device according to any example herein, particularly any one of examples 1-69, wherein the device is sterilized.

[0171] Example 71. A method, comprising:

[0172] sterilizing an implantable prosthetic device as described in any example herein, particularly any one of examples 1-69.

[0173] In view of the many possible ways in which the principles of the disclosure may be applied, it should be recognized that the illustrated configurations depict examples of the disclosed technology and should not be taken as limiting the scope of the disclosure nor the claims. Rather, the scope of the claimed subject matter is defined by the following claims and their equivalents.

We claim:

1. An implantable prosthetic device, comprising:

a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially-extending struts that defining one or more commissure windows;

a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and one or more commissure tabs;

a commissure comprising a flexible connector and the commissure tabs of two adjacent leaflets coupled to the flexible connector via one or more primary sutures; and

wherein the commissure is secured to a respective commissure window via one or more secondary sutures, each secondary suture extending through a radially outer layer of the flexible connector, a respective commissure tab, a radially inner layer of the flexible connector, and a free edge portion of the flexible connector.

2. The prosthetic device of claim **1**, wherein the flexible connector comprises a main body and first and second free edge portions, and wherein the first and second free edge portions are folded around respective axially-extending struts of the frame.

3. The prosthetic device of claim **1**, further comprising a wedge member disposed on a radially inner facing surface of the flexible connector between the adjacent leaflet tabs.

4. The prosthetic device of claim **1**, wherein the one or more primary sutures are disposed adjacent a radially outer facing surface of the frame.

5. The prosthetic device of claim **1**, wherein the one or more primary sutures are disposed adjacent a radially inner facing surface of the frame.

6. The prosthetic device of claim **1**, wherein the commissure windows have an elongated rectangular shape.

7. The prosthetic device of claim **1**, wherein the flexible connector comprises an opening extending through a thickness of a main body of the flexible connector.

8. The prosthetic device of claim **7**, wherein the opening is sized such that a wedge member can be disposed through the opening.

9. The prosthetic device of claim **1**, wherein the one or more secondary sutures comprise a first secondary suture and a second secondary suture, wherein the first secondary suture extends through the radially outer layer of the flexible connector, a first commissure tab of the one or more commissure tabs, a first radially inner layer of the flexible connector, and a first free edge portion of the flexible connector, and wherein the second secondary suture extends through the radially outer layer of the flexible connector, a second commissure tab of the one or more commissure tabs, a second radially inner layer of the flexible connector, and a second free edge portion of the flexible connector.

10. The prosthetic device of claim **9**, further comprising a wedge member disposed on a radially inner facing surface of the flexible connector between the first and second commissure tabs, wherein the first and second secondary sutures each extend through the wedge member.

11. The prosthetic device of claim **1**, wherein the one or more secondary sutures comprise a secondary suture that extends in a figure-eight pattern.

12. The prosthetic device of claim **11**, wherein the figure-eight pattern extends through a radially outer layer of the flexible connector, a first commissure tab, a first radially inner layer of the flexible connector, a first free edge portion of the flexible connector, a second commissure tab, a second radially inner layer of the flexible connector, and a second free edge portion of the flexible connector.

13. The prosthetic device of claim **12**, wherein the commissure further comprises a wedge member disposed on a radially inner surface of the flexible connector, and wherein the figure-eight pattern passes through the wedge member twice.

14. The prosthetic device of claim **11**, wherein the figure-eight pattern is a first figure-eight pattern, and wherein the secondary suture is sewn in a plurality of figure-eight patterns extending axially along a length of the commissure.

15. The prosthetic device of claim **14**, wherein each figure-eight pattern is connected to one or more adjacent figure-eight patterns via one or more axially-extending portions of the secondary suture.

16. The prosthetic device of claim **15**, wherein the axially-extending portions of the secondary suture are disposed on alternating sides of a wedge member disposed on a radially inner facing surface of the flexible connector between the adjacent leaflet tabs.

17. The prosthetic device of claim **1**, wherein an outflow edge of each of the one or more commissure tabs is disposed at an angle relative to a longitudinal axis of the leaflet.

18. The prosthetic device of claim **17**, wherein the angle is a 90 degree angle.

19. The prosthetic device of claim **1**, wherein an overall width of the commissure is equal to or less than to a collective width of the one or more axially extending struts and the commissure window.

20. An implantable prosthetic device, comprising:

a radially expandable and compressible annular frame comprising an inflow end portion and an outflow end portion, the frame comprising one or more axially-extending struts that defining one or more commissure windows;

a valvular structure comprising a plurality of leaflets arranged within the frame, each leaflet comprising a main body and opposing commissure tabs;

a flexible connector comprising a main body, a first free edge portion, and a second free edge portion;

a commissure comprising the flexible connector, a wedge member disposed on a radially inner surface of the flexible connector, and first and second commissure tabs of two adjacent leaflets coupled to the flexible connector via first and second primary sutures; and

wherein the commissure is secured to a respective commissure window via first and second secondary sutures, the first secondary suture extending through a radially outer layer of the flexible connector, the wedge member, the first commissure tab, a first radially inner layer of the flexible connector, and the first free edge portion, the second secondary suture extending through the radially outer layer of the flexible connector, the wedge member, the second commissure tab, a second radially inner layer of the flexible connector, and the second free edge portion.

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