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(54) **ACTUATION BOLT ASSEMBLY FOR A PROSTHETIC VALVE**

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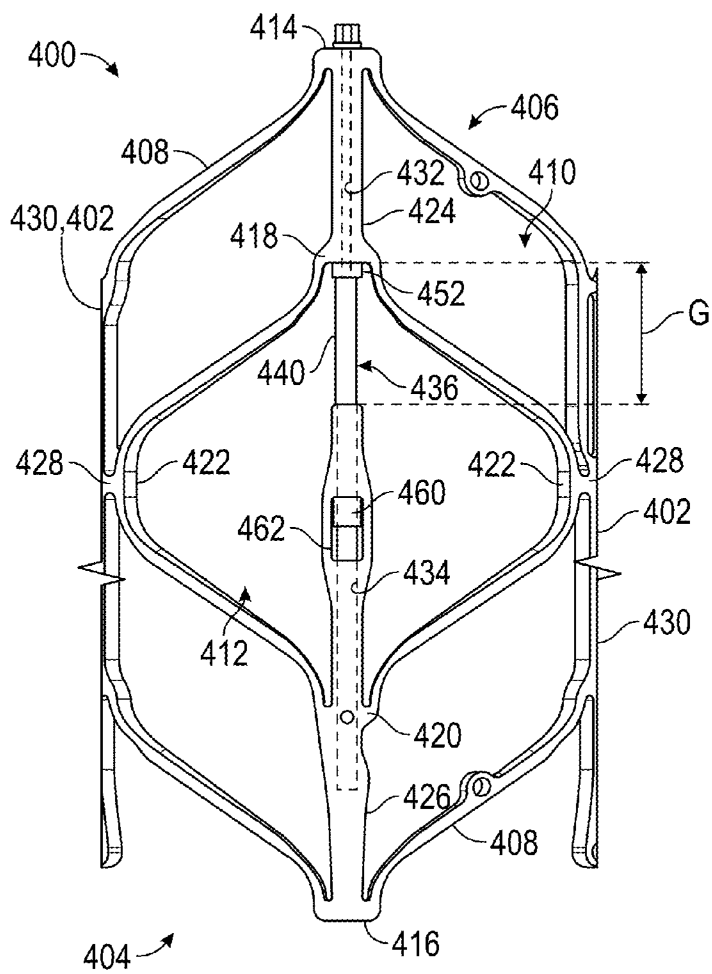
(57) **ABSTRACT**

This disclosure is directed to prosthetic heart valves and frames for prosthetic heart valves having actuation assemblies with at least two bolts coupled to each other. The actuation assembly with at least two bolts allow different portions of the actuation assembly to be designed to meet different needs. In one example, the actuation mechanism can include a first bolt coupled end-to-end with a second bolt. The second bolt can have a greater diameter and correspondingly greater mechanical strength than the first bolt. The first bolt can have a lesser diameter suitable for minimizing the thickness of surrounding and adjacent valve frame components. The actuation assembly can also include one or more of a nut, a washer, and a portion designed to attach to components of a delivery system. Also disclosed herein are actuation assemblies including a washer secured by a pin extending through the bolt of the actuation assembly.



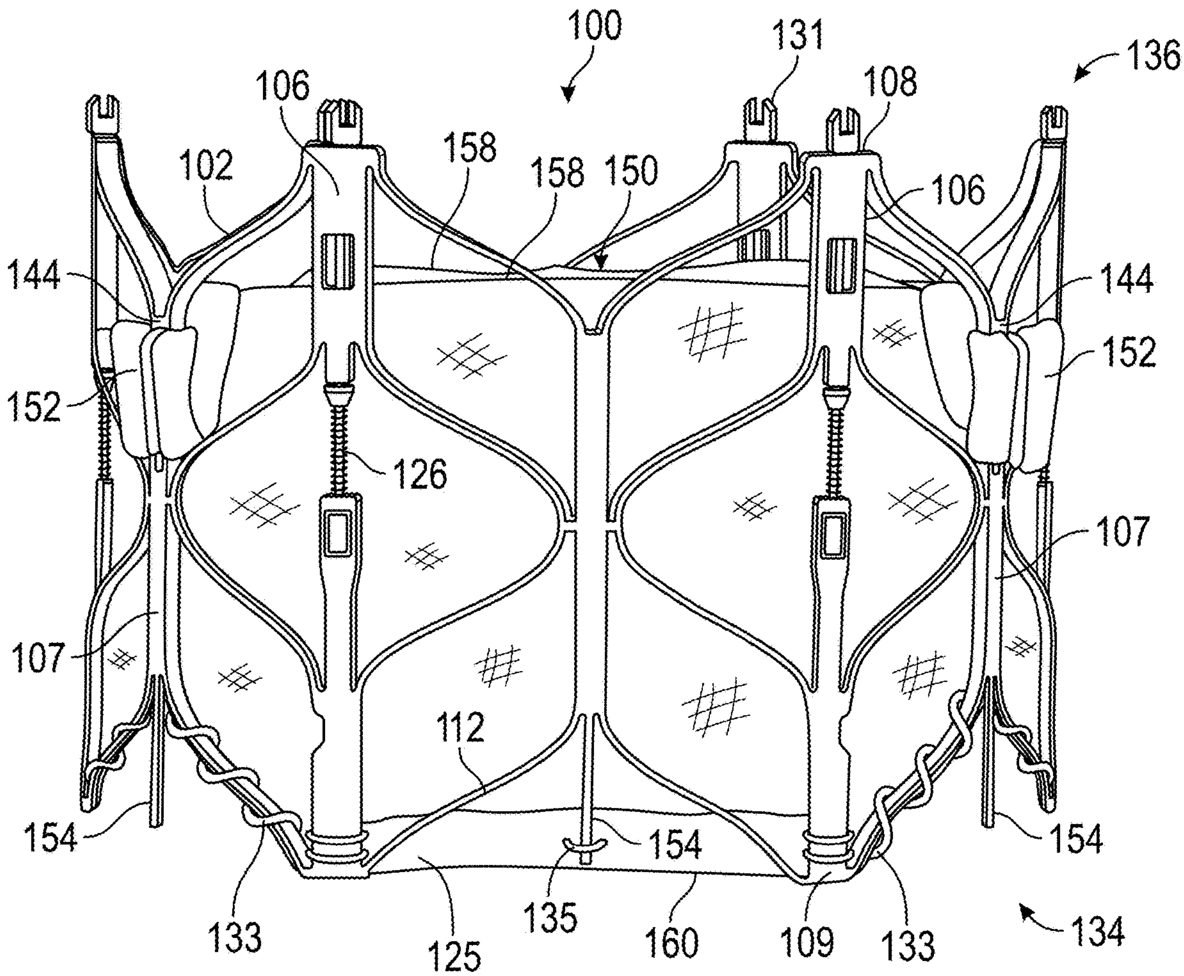

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FIG. 1A

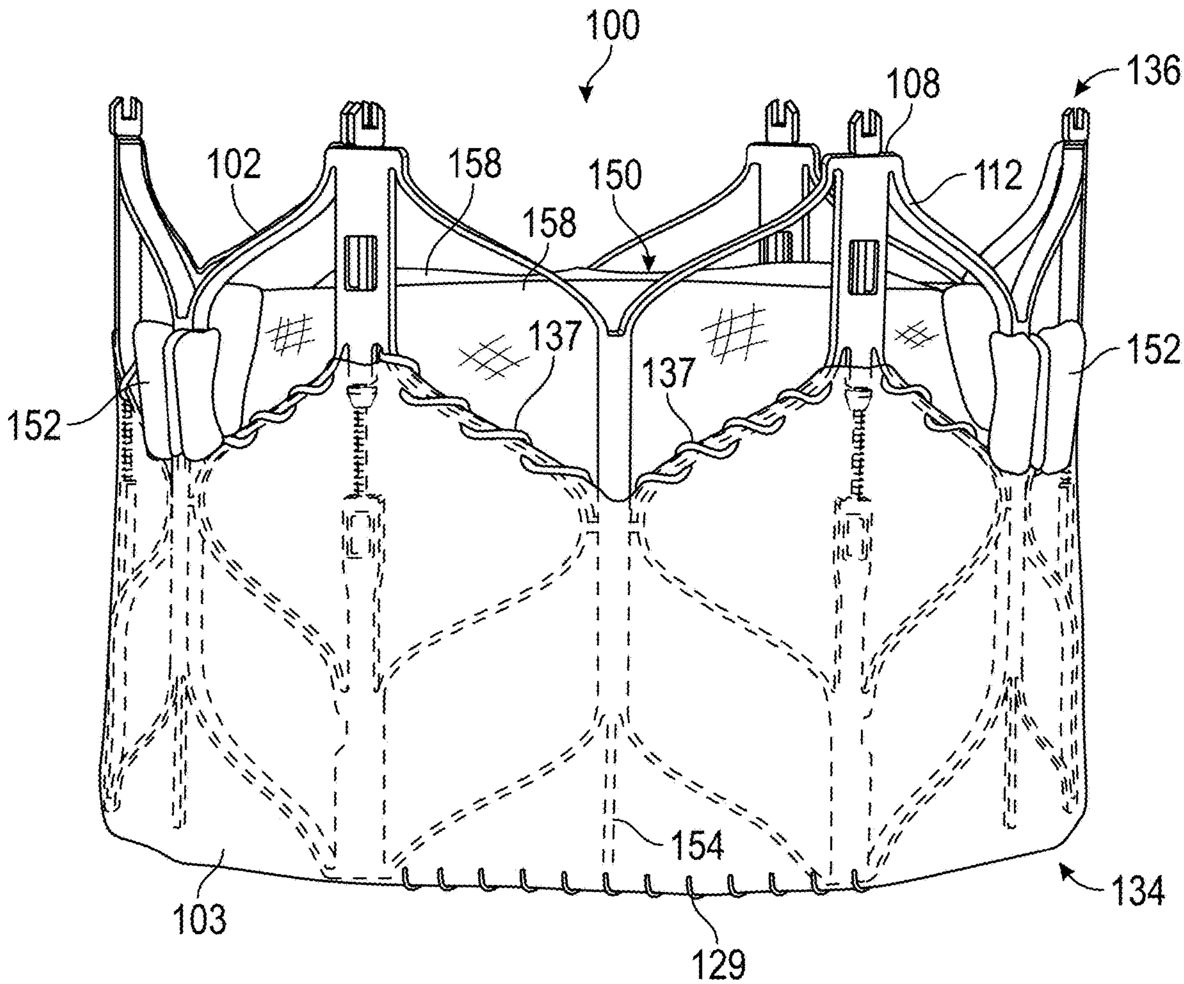

FIG. 1B

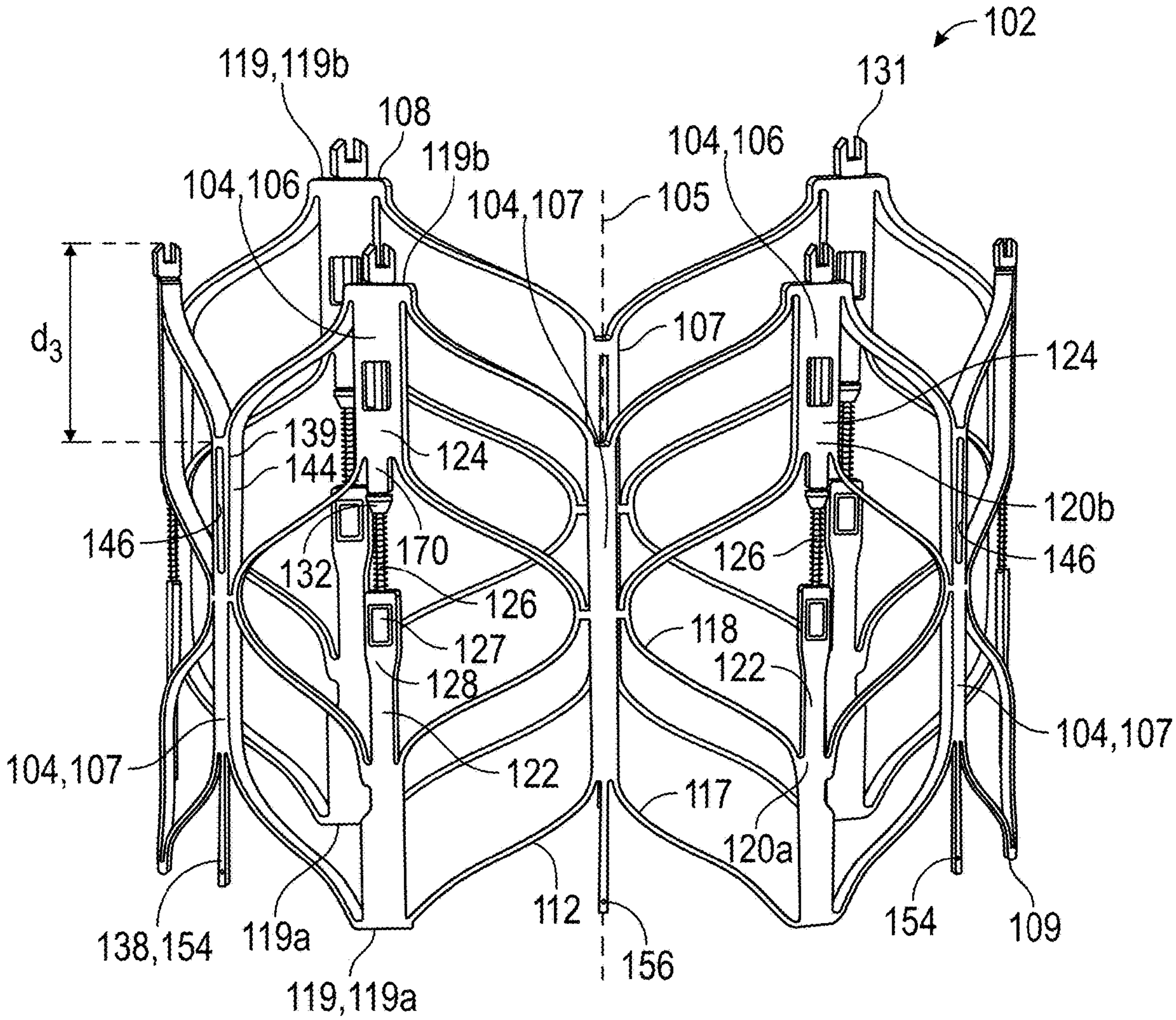
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FIG. 2A

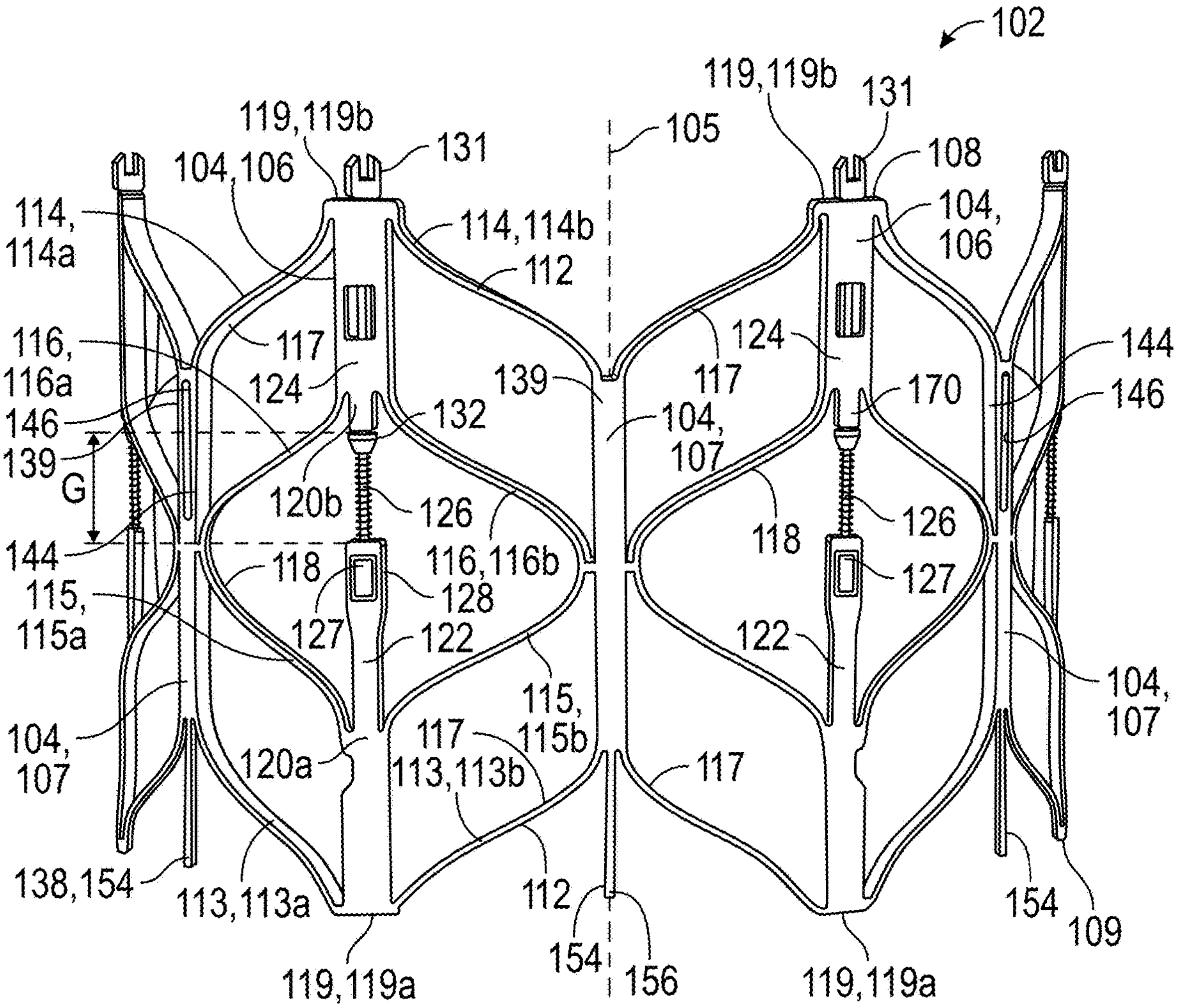
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FIG. 2B

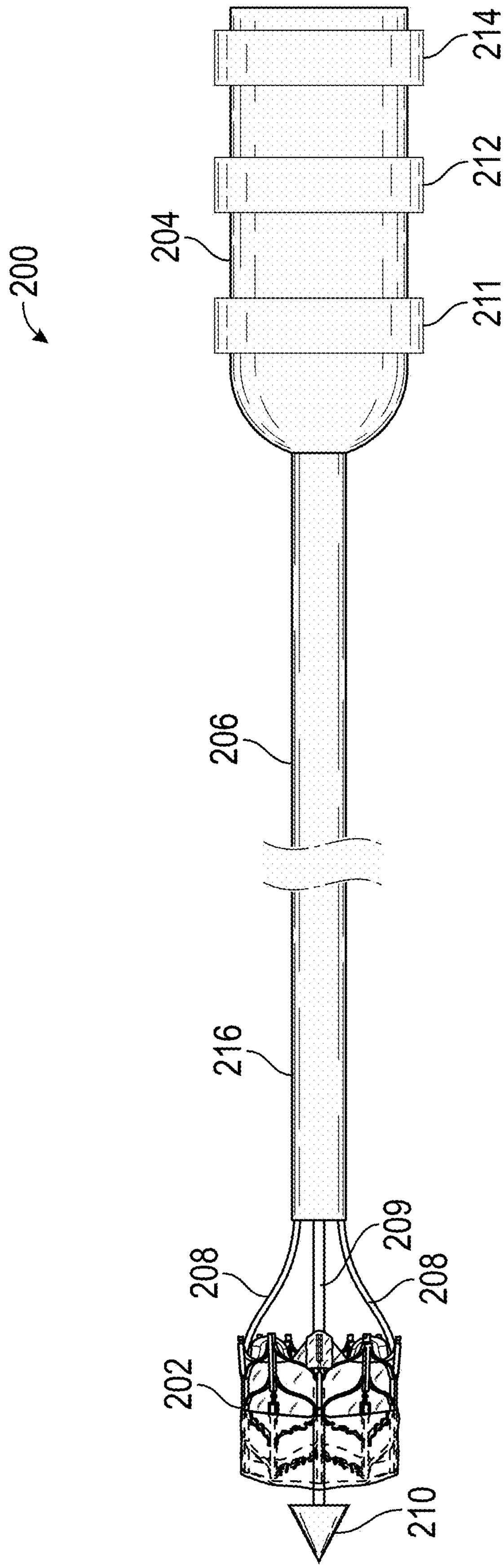

FIG. 3

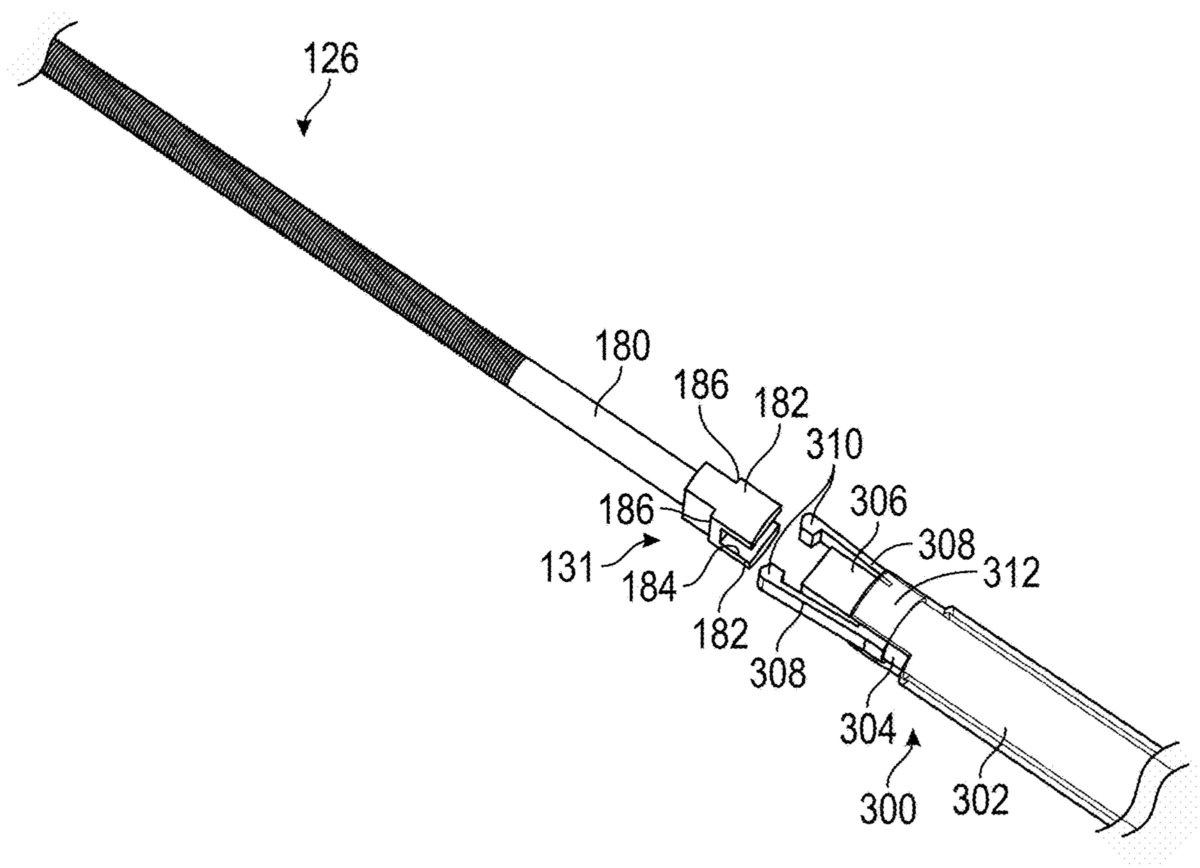

FIG. 4

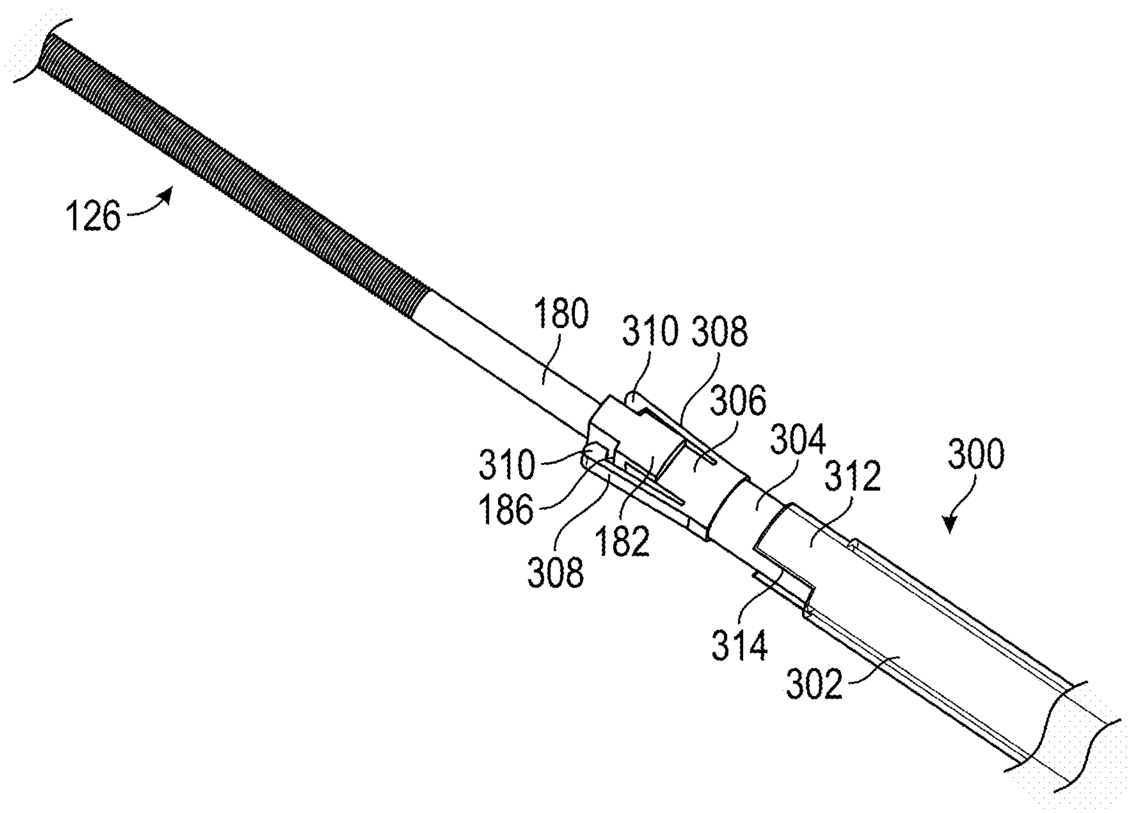

FIG. 5

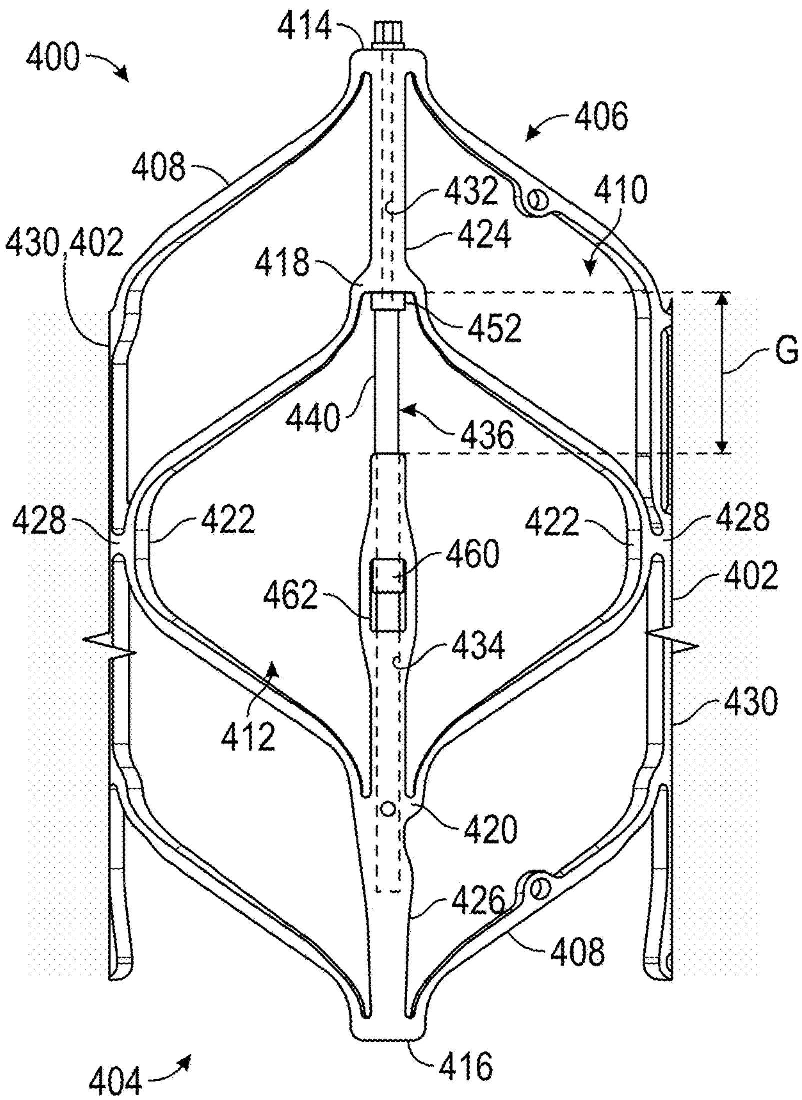
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FIG. 6A

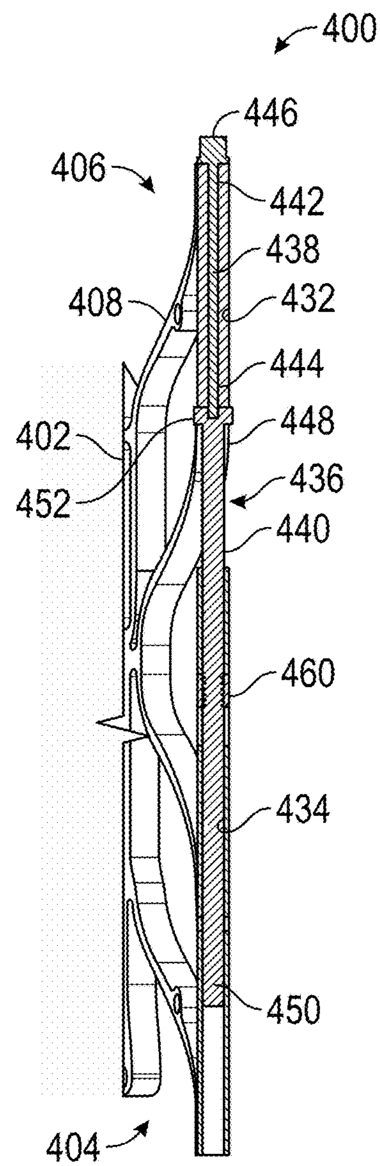
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FIG. 6B

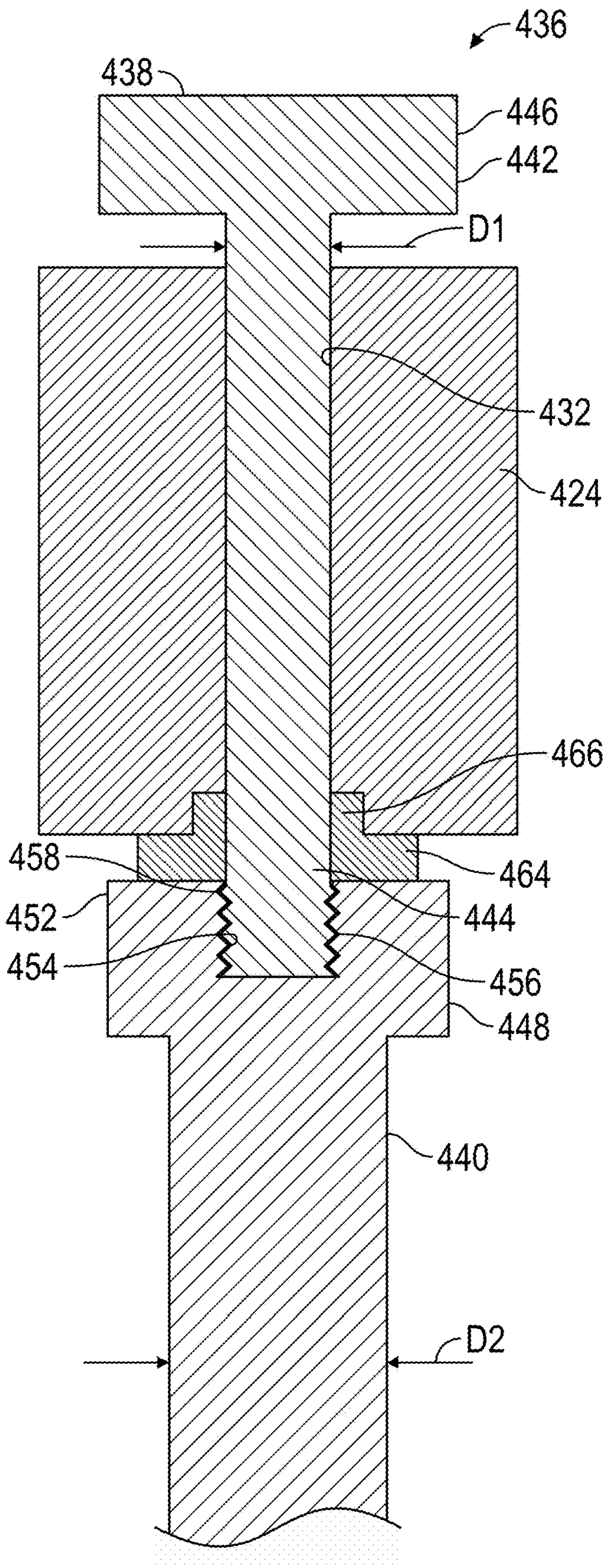

FIG. 7

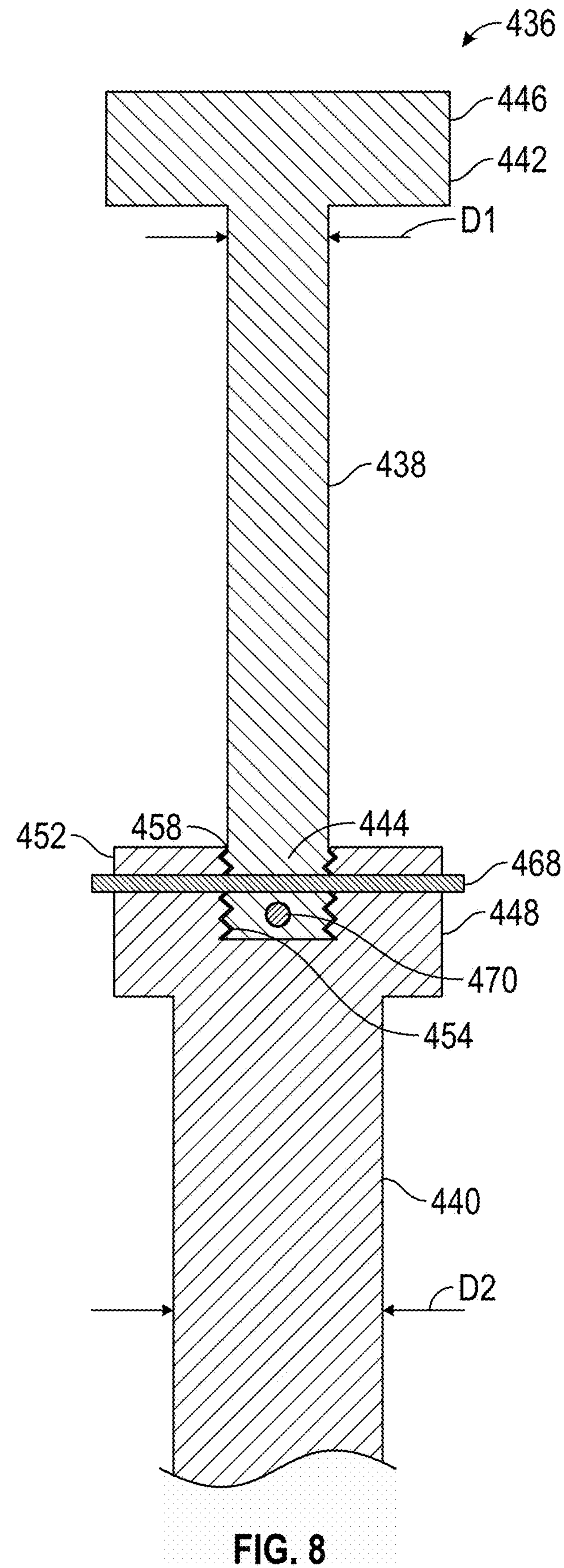

FIG. 8

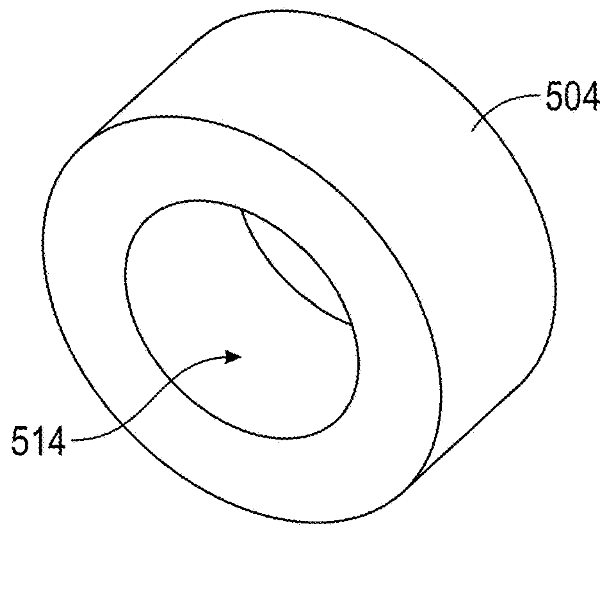

FIG. 9A

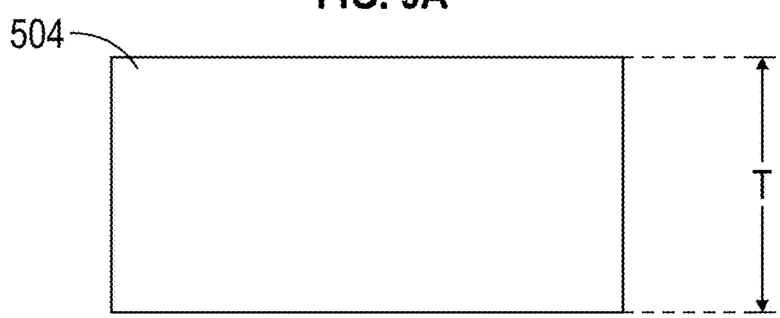

FIG. 9B

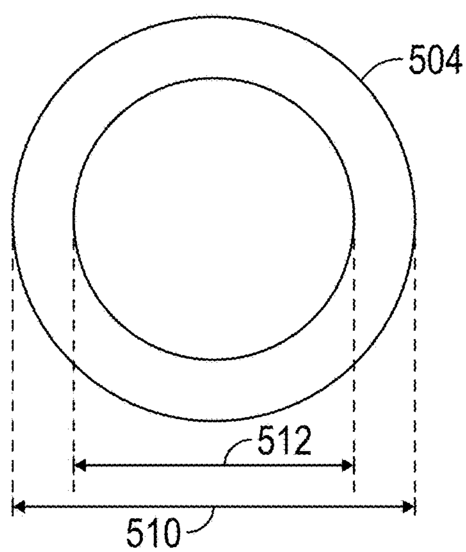

FIG. 9C

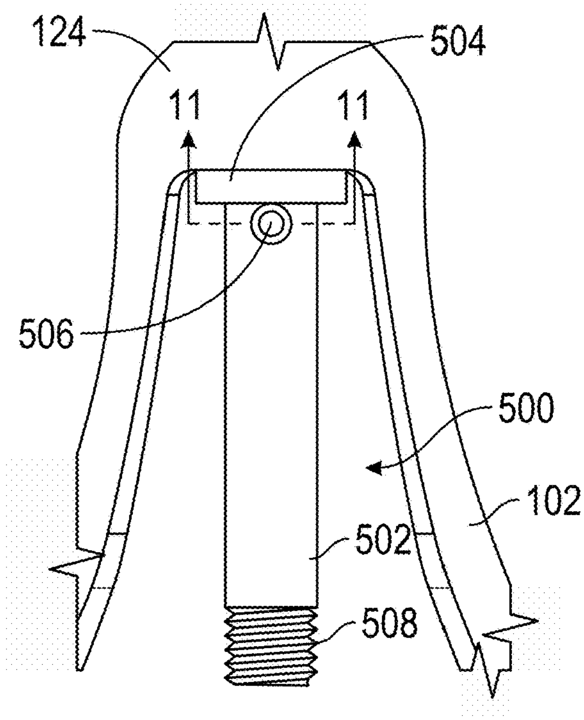

FIG. 10A

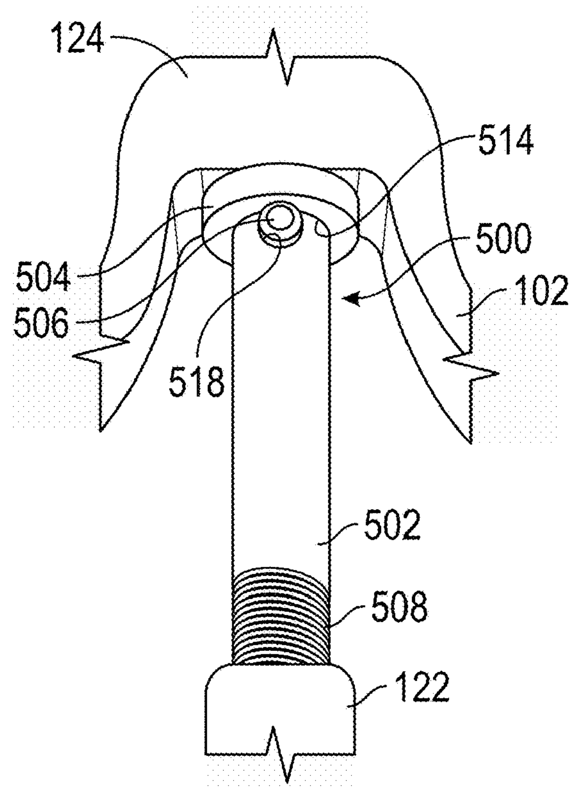

FIG. 10B

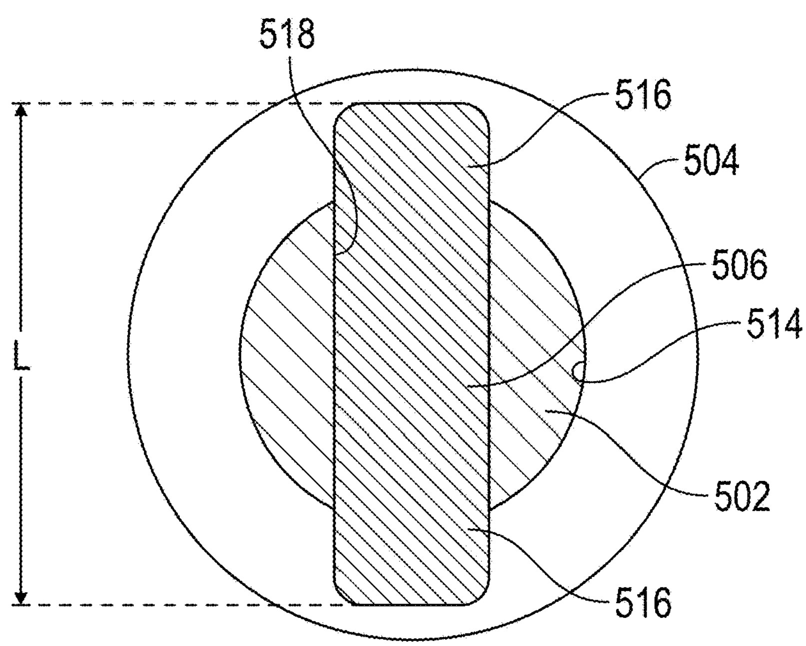

FIG. 11

ACTUATION BOLT ASSEMBLY FOR A PROSTHETIC VALVE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of PCT Application No. PCT/US2023/010867, filed on Jan. 16, 2023, which claims the benefit of U.S. Provisional Patent Application No. 63/301,608, filed on Jan. 21, 2022, and of U.S. Provisional Patent Application No. 63/345,571, filed on May 25, 2022, each of which is incorporated by reference herein in its entirety.

FIELD

[0002] The present disclosure relates to implantable expandable prosthetic heart valves and frame structures for use with expandable 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 (for example, 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 (for example, 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 delivery capsule of the delivery apparatus so that the prosthetic heart valve can self-expand to its functional size.

[0004] Various sorts of mechanical actuators can be used to expand a prosthetic heart valve to its functional size. For example, screw actuators can be rotated relative to various components of the prosthetic heart valve to exert an axial force to cause radial expansion. Screw actuators offer several advantages, including precise control over the radial expansion and/or compression of the prosthetic heart valve, and may not require a separate locking mechanism to prevent the prosthetic heart valve from further expansion or compression after it has been expanded to its functional size. However, prosthetic heart valves with screw actuators are subject to several technical challenges. Particularly, the screw actuators are subject to flexural and compressive stresses when the prosthetic heart valve is retained in a compressed or crimped state. If the actuators do not have sufficient mechanical strength, these stresses can cause bending and buckling of the actuator, among other failure modes that can impair or prevent the prosthetic heart valve from expanding to its functional size. It is also desirable for screw actuators to have a narrow cross section as possible to minimize the overall crimp profile of the prosthetic valve.

[0005] Accordingly, there is a need for frames for prosthetic heart valves having actuation mechanisms that are both strong enough to withstand the stresses of being crimped or compressed for implantation, and which have a minimal cross-sectional profile.

SUMMARY

[0006] Disclosed herein are actuation bolt assemblies for prosthetic heart valve frames having two or more bolts connected end-to-end with each other. The disclosed actuation bolt assemblies can include bolts designed with different geometries and/or materials tailored to the specific mechanical demands at various positions relative to the prosthetic heart valve frame, allowing, for example, stronger bolts to be used in regions with higher mechanical stresses and narrower bolts to be used in regions with lower mechanical stresses in the compressed configuration. Additionally, the actuation bolt assemblies disclosed herein can avoid the need to weld or stamp a separate stopper device onto the actuation assembly, which reduces manufacturing complexity and avoids mechanically weakening the stamped or welded portions of the actuation assembly. As such, the actuation assemblies disclosed herein offer superior mechanical strength for resisting the stresses associated with crimping or compressing the frame for implantation, while minimizing the overall crimp profile of the prosthetic heart valve.

[0007] 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.

[0008] In some examples, a prosthetic heart valve can comprise a sealing member configured to reduce paravalvular leakage.

[0009] In some examples, a prosthetic heart valve can comprise an actuation assembly.

[0010] In some examples, the actuation assembly can comprise a first bolt and a second bolt aligned end to end relative to each other, wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt.

[0011] In some examples, the first bolt has a first diameter and the second bolt has a second diameter.

[0012] In some examples, the second diameter is greater than the first diameter.

[0013] In some examples, the second bolt comprises a threaded bore in the adjacent end portion of the second bolt, wherein a threaded section of the end portion of the first bolt is tightened into the threaded bore of the second bolt.

[0014] In some examples, a head portion of the first bolt is configured to be releasably connected to a component of the delivery apparatus.

[0015] In some examples, the frame of the prosthetic heart valve can comprise a plurality of interconnected struts.

[0016] In some examples, the frame of the prosthetic heart valve can comprise at least one vertically oriented post with a channel extending therethrough.

[0017] In some examples, the first bolt extends through the channel of the at least one vertically oriented post.

[0018] In some examples, the actuation assembly further comprises a washer comprising an aperture, wherein the end portion of the first bolt extends through the aperture.

[0019] In some examples, the washer is disposed between the second bolt and the vertically oriented post.

[0020] In some examples, the at least one vertically oriented post comprises a first vertically oriented post and a second oriented post, the first vertically oriented post comprises a first channel extending therethrough, and the second oriented post comprises a second channel extending therethrough.

[0021] In some examples, the first bolt extends through the first channel and the second bolt extends through the second channel.

[0022] Certain examples concern a prosthetic valve, comprising a radially expandable frame comprising a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state. A valvular structure is disposed within frame and configured to regulate the flow of blood through the frame in one direction. At least one an actuation assembly is operatively coupled to the frame, and the actuation assembly comprises first and second bolts aligned end-to-end relative to each other. An end portion of the first bolt is coupled to an adjacent end portion of the second bolt, and the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state.

[0023] Certain examples concern a medical assembly, comprising a prosthetic heart valve comprising a radially expandable frame comprising a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state. The medical assembly also comprises a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction, at least one an actuation assembly operatively coupled to the frame, and a delivery system configured to be releasably connected to a component of the actuation assembly and to advance the prosthetic heart valve through the vasculature of a patient. The actuation assembly comprises first and second bolts aligned end-to-end relative to each other, wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, and the first and second bolts are rotatably coupled to rotate together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state. The first bolt has a first diameter and the second bolt has a second diameter, and wherein the first diameter is smaller than the second diameter.

[0024] Certain examples concern a prosthetic heart valve, comprising a radially expandable frame having a first end, a second end, and a longitudinal axis extending between the first end and the second end, wherein the frame is radially expandable between a radially compressed state and a radially expanded state. The radially expandable frame also comprises a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction, and at least one actuation assembly operatively coupled to the frame. The frame comprises a plurality of axial posts extending parallel to the longitudinal axis and a plurality of angled struts arranged in circumferentially extending rows of angled struts. The actuation assembly comprises first and second bolts aligned end-to-end relative to each other, wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, wherein the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state, and wherein the first bolt extends through a channel in a first axial post of the plurality of axial posts.

[0025] Certain examples concern a prosthetic heart valve, comprising a radially expandable frame comprising a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state. The prosthetic heart valve also comprises a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction, at least one an actuation assembly operatively coupled to the frame, and at least one nut coupled to the actuation assembly. The actuation assembly comprises first and second bolts aligned end-to-end relative to each other, wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, wherein the second bolt comprises a threaded portion that extends through and engages internal threads of the nut, and the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state.

[0026] Certain examples concern a prosthetic heart valve, comprising a frame having a first end, a second end, and a longitudinal axis extending between the first end and the second end, wherein the frame is radially expandable between a radially compressed state and a radially expanded state, and wherein the frame comprises a plurality of vertical posts extending parallel to the longitudinal axis and a plurality of angled struts arranged in circumferentially extending rows of angled struts. The prosthetic heart valve also comprises a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction, and at least one actuation assembly comprising a first bolt and a second bolt aligned end-to-end. The first bolt extends through a channel in a first vertical post of the plurality of vertical post, an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, and the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state. A washer disposed between the adjacent end portion of the second bolt and the first vertical post.

[0027] Certain examples concern a prosthetic valve, comprising a radially expandable frame comprising a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state. The prosthetic valve also includes a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction and at least one an actuation assembly operatively coupled to the frame. The actuation assembly comprises first and second actuation members aligned end-to-end relative to each other, wherein an end portion of the first actuation member is coupled to an adjacent end portion of the second actuation member, wherein the first and second actuation members are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state.

[0028] Certain examples concern a prosthetic valve comprising a radially expandable frame, a valvular structure disposed within the frame, and an actuation assembly operatively coupled to the frame. The frame comprises a first end portion, a second end portion, and a plurality of interconnected struts, and is radially expandable between a radially compressed state and a radially expanded state. The valvular structure is configured to permit the flow of blood from the first end portion to the second end portion of the frame and to prevent the flow of blood from the second end portion to the first end portion of the frame. The actuation assembly comprises a stopper having an aperture, an actuation member extending through the aperture in the stopper and a securing pin protruding from at least one side of the actuation member. The securing pin limits motion of the stopper relative to the actuation member in a first axial direction, and the actuation member is rotatable in a first direction to produce radial expansion of the frame from a radially compressed state to a radially expanded state and rotatable in a second rotational direction to produce radial compression of the frame from the radially expanded state to the radially compressed state.

[0029] Certain examples concern a prosthetic valve comprising a radially expandable frame, a valvular structure disposed within the frame, and at least one actuation assembly operatively coupled to the frame. The frame comprises a vertically oriented first strut and a vertically oriented second strut, wherein the frame is radially expandable between a radially compressed state and a radially expanded state. The valvular structure is configured to regulate the flow of blood through the frame in one direction. The at least one an actuation assembly comprises an actuation member, a stopper positioned on the actuation member, and a protrusion extending from an outer surface of the actuation member. Bores in the first strut and in the second strut are dimensioned to receive portions of the actuation member. The stopper is positioned between the first strut and the second strut, and the axial movement of the stopper along the actuation member is limited in at least one direction by the protrusion. The actuation member is rotatable in a first direction to move axially with the protrusion contacting the stopper to urge the first strut away from the second strut, thereby radially compressing the frame.

[0030] Certain examples concern a medical assembly, comprising a radially expandable frame having a first frame end portion, a second frame end portion, and a longitudinal axis extending between the first end and the second end. The medical assembly also comprises at least one actuation assembly extending longitudinally from the first frame end portion towards the second frame end portion to interconnect first and second portions of the frame. The actuation assembly comprises an actuation member having a first end portion with a head portion adjacent the first frame end and an externally threaded second end portion, a stopper disposed around the actuation member, and a securing pin extending through the actuation member transverse to the longitudinal axis. The securing pin is configured to limit the movement of the stopper along the longitudinal axis in at least one direction. The stopper is configured to limit the movement of the actuation member along the longitudinal axis in at least one direction. The actuation member is rotatable in a first rotational direction to produce radial expansion of the frame from a radially compressed state to a radially expanded state and rotatable in a second rotational direction to produce radial compression of the frame from the radially expanded state to the radially compressed state.

[0031] In some examples, a prosthetic heart valve comprises one or more of the components recited in Examples 1-113 below.

[0032] 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

[0033] FIG. **1**A is a perspective view of one example of a prosthetic valve including a frame and a plurality of leaflets attached to the frame.

[0034] FIG. **1**B is a perspective view of the prosthetic valve of FIG. **1**A with an outer skirt disposed around the frame.

[0035] FIG. **2**A is a perspective view of a frame for the prosthetic valve of FIG. **1**A.

[0036] FIG. **2**B is a front portion of the frame shown in FIG. **2**A.

[0037] FIG. **3** is a side elevation view of a delivery apparatus for a prosthetic device, such as a prosthetic valve, according to one example.

[0038] FIG. **4** is a perspective view of a portion of an actuator of the prosthetic device of FIGS. **1-2** and an actuator assembly of a delivery apparatus, according to one example.

[0039] FIG. **5** is a perspective view of the actuator and actuator assembly of FIG. **4** with the actuator assembly physically coupled to the actuator.

[0040] FIG. **6**A is a perspective view of a portion of one example of a prosthetic heart valve frame with an actuation mechanism having two bolts.

[0041] FIG. **6**B is a cutaway side view of the frame segment of FIG. **6**A.

[0042] FIG. **7** is a schematic illustration of one example actuation assembly having two actuator elements coupled end to end.

[0043] FIG. **8** is a schematic illustration of the bolts of the actuator assembly of FIG. **7** further including securing bolts.

[0044] FIG. **9**A is a perspective view of one example of an actuation stopper.

[0045] FIG. **9**B is a side elevation view of the actuation stopper of FIG. **9**A.

[0046] FIG. **9**C is a top plan view of the actuation stopper of FIG. **9**A.

[0047] FIG. **10**A is a side elevation view of one example of a frame section and actuation assembly.

[0048] FIG. **10**B is a perspective view of the frame section and actuation assembly of FIG. **10**A.

[0049] FIG. **11** is a cutaway top view of the actuation assembly taken along the line **11-11** of FIG. **10**A, including actuation member, stopper, and securing pin.

DETAILED DESCRIPTION

General Considerations

[0050] For purposes of this description, certain aspects, advantages, and novel features of 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.

[0051] 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.

[0052] 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.

[0053] 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 (for example, 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 (for example, 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.

Introduction to the Disclosed Technology

[0054] Prosthetic valves disclosed herein can be radially compressible and expandable between a radially compressed state and a radially expanded state. Thus, the prosthetic valves can be crimped on or retained by an implant delivery apparatus in the radially compressed state while being advanced through a patient's vasculature on the delivery apparatus. The prosthetic valve can be expanded to the radially expanded state once the prosthetic valve reaches the implantation site. It is understood that the prosthetic valves disclosed herein may be used with a variety of implant delivery apparatuses and can be implanted via various delivery procedures, examples of which will be discussed in more detail later.

[0055] FIGS. **1**A-**2**B illustrate an exemplary prosthetic device (for example, prosthetic heart valve) that can be advanced through a patient's vasculature, such as to a native heart valve, by a delivery apparatus, such as the exemplary delivery apparatus shown in FIG. **3**. The frame of the prosthetic heart valve can include one or more mechanical expansion and locking mechanisms that can be integrated into the frame-specifically, into axially extending posts of the frame. The mechanical expansion and/or locking mechanisms can be removably coupled to, and/or actuated by, the delivery apparatus to radially expand the prosthetic heart valve and lock the prosthetic heart valve in one or more radially expanded states.

The Disclosed Technology and Exemplary Embodiments

[0056] FIGS. **1**A-**2**B show an exemplary prosthetic valve **100**, according to one example. Any of the prosthetic valves disclosed herein are adapted to be implanted in the native aortic annulus, although in other examples they can be adapted to be implanted in the other native annuluses of the heart (the pulmonary, mitral, and tricuspid valves). The disclosed prosthetic valves also can be implanted within vessels communicating with the heart, including a pulmonary artery (for replacing the function of a diseased pulmonary valve, or the superior vena cava or the inferior vena cava (for replacing the function of a diseased tricuspid valve) or various other veins, arteries and vessels of a patient. The disclosed prosthetic valves also can be implanted within a previously implanted prosthetic valve (which can be a prosthetic surgical valve or a prosthetic transcatheter heart valve) in a valve-in-valve procedure.

[0057] In some examples, the disclosed prosthetic valves can be implanted within a docking or anchoring device that is implanted within a native heart valve or a vessel. For example, in one example, the disclosed prosthetic valves can be implanted within a docking device implanted within the pulmonary artery for replacing the function of a diseased pulmonary valve, such as disclosed in U.S. Publication No. 2017/0231756, which is incorporated by reference herein. In another example, the disclosed prosthetic valves can be implanted within a docking device implanted within or at the native mitral valve, such as disclosed in PCT Publication No. WO2020/247907, which is incorporated herein by reference. In another example, the disclosed prosthetic valves can be implanted within a docking device implanted within the superior or inferior vena cava for replacing the function of a diseased tricuspid valve, such as disclosed in U.S. Publication No. 2019/0000615, which is incorporated herein by reference.

[0058] FIGS. **1**A-**2**B illustrate an example of a prosthetic valve **100** (which also may be referred to herein as "prosthetic heart valve **100**") having a frame **102**. FIGS. **2**A-**2**B show the frame **102** by itself, while FIGS. **1**A-**1**B show the frame **102** with a valvular structure **150** (which can comprise leaflets **158**, as described further below) mounted within and to the annular frame **102**. FIG. **1**B additionally shows an optional skirt assembly comprising an outer skirt **103**. While only one side of the frame **102** is depicted in FIG. **2**B, it should be appreciated that the frame **102** forms an annular structure having an opposite side that is substantially identical to the portion shown in FIG. **1**B, as shown in FIGS. **1**A-**2**A.

[0059] As shown in FIGS. **1**A and **1**B, the valvular structure **150** is coupled to and supported inside the frame **102**.

The valvular structure **150** is configured to regulate the flow of blood through the prosthetic valve **100**, from an inflow end portion **134** to an outflow end portion **136**. The valvular structure **150** can include, for example, a leaflet assembly comprising one or more leaflets **158** made of flexible material. The leaflets **158** can be made from in whole or part, biological material, bio-compatible synthetic materials, or other such materials. Suitable biological material can include, for example, bovine pericardium (or pericardium from other sources). The leaflets **158** can be secured to one another at their adjacent sides to form commissures **152**, each of which can be secured to a respective commissure support structure **144** (also referred to herein as "commissure supports") and/or to other portions of the frame **102**, as described in greater detail below.

[0060] In the example depicted in FIGS. **1**A and **1**B, the valvular structure **150** includes three leaflets **158**, which can be arranged to collapse in a tricuspid arrangement. Each leaflet **158** can have an inflow edge portion **160** (which can also be referred to as a cusp edge portion) (FIG. **1**A). The inflow edge portions **160** of the leaflets **158** can define an undulating, curved scallop edge that generally follows or tracks portions of struts **112** of frame **102** in a circumferential direction when the frame **102** is in the radially expanded configuration. The inflow edge portions **160** of the leaflets **158** can be referred to as a "scallop line."

[0061] The prosthetic valve **100** may include one or more skirts mounted around the frame **102**. For example, as shown in FIG. **1**B, the prosthetic valve **100** may include an outer skirt **103** mounted around an outer surface of the frame **102**. The outer skirt **103** can function as a sealing member for the prosthetic valve **100** by sealing against the tissue of the native valve annulus and helping to reduce paravalvular leakage past the prosthetic valve **100**. In some cases, an inner skirt (not shown) may be mounted around an inner surface of the frame **102**. The inner skirt can function as a sealing member to prevent or decrease perivalvular leakage, to anchor the leaflets **158** to the frame **102**, and/or to protect the leaflets **158** against damage caused by contact with the frame **102** during crimping and during working cycles of the prosthetic valve **100**. In some examples, the inflow edge portions **160** of the leaflets **158** can be sutured to the inner skirt generally along the scallop line. The inner skirt can in turn be sutured to adjacent struts **112** of the frame **102**. In other examples, as shown in FIG. **1**A, the leaflets **158** can be sutured directly to the frame **102** or to a reinforcing member **125** (also referred to as a reinforcing skirt or connecting skirt) in the form of a strip of material (for example, a fabric strip) which is then sutured to the frame **102**, along the scallop line via stitches (for example, whip stitches) **133**.

[0062] The inner and outer skirts and the connecting skirt **125** can be wholly or partly formed of any suitable biological material, synthetic material (for example, any of various polymers), or combinations thereof. In some examples, the skirt can comprise a fabric having interlaced yarns or fibers, such as in the form of a woven, braided, or knitted fabric. In some examples, the fabric can have a plush nap or pile. Exemplary fabrics having a plus nap or pile include velour, velvet, velveteen, corduroy, terrycloth, fleece, etc. In some examples, the skirt can comprise a fabric without interlaced yarns or fibers, such as felt or an electrospun fabric. Exemplary materials that can be used for forming such fabrics (with or without interlaced yarns or fibers) include, without limitation, polyethylene (PET), ultra-high molecular weight polyethylene (UHMWPE), polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (ePTFE), polyamide etc. In some examples, the skirt can comprise a non-textile or non-fabric material, such as a film including any of a variety of polymeric materials, such as PTFE, PET, polypropylene, polyamide, polyetheretherketone (PEEK), polyurethane (such as thermoplastic polyurethane (TPU)), etc. In some examples, the skirt can comprise a sponge material or foam, such as polyurethane foam. In some examples, the skirt can comprise natural tissue, such as pericardium (for example, bovine pericardium, porcine pericardium, equine pericardium, or pericardium from other sources). Further details regarding the use of skirts or sealing members in prosthetic valve can be found, for example, in U.S. Patent Publication No. 2020/0352711, which is incorporated herein by reference.

[0063] Further details regarding the assembly of the leaflet assembly and the assembly of the leaflets and the skirts to the frame can be found, for example, in U.S. Provisional Application Nos. 63/209,904, filed Jun. 11, 2021, and 63/224,534, filed Jul. 22, 2021, which are incorporated herein by reference. Further details of the construction and function of the frame **102** can be found in International Patent Application No. PCT/US2021/052745, filed Sep. 30, 2021, which is incorporated herein by reference.

[0064] The frame **102**, which is shown alone and in greater detail in FIGS. **2**A and **2**B, comprises and inflow end **109**, an outflow end **108**, and a plurality of axially extending posts **104**. The axial direction of the frame **102** is indicated by a longitudinal axis **105**, which extends from the inflow end **109** to the outflow end **108** (FIGS. **2**A and **2**B). Some of the posts **104** can be arranged in pairs of axially aligned first and second struts or posts **122**, **124**. An actuator **126** (such as the illustrated threaded rod or bolt) can extend through one or more pairs of posts **122**, **124** to form an integral expansion and locking mechanism or actuator mechanism **106** configured to radially expand and compress the frame **102**, as further described below. One or more of posts **104** can be configured as support posts **107**.

[0065] The actuator mechanisms **106** (which can be used to radially expand and/or radially compress the prosthetic valve **100**) can be integrated into the frame **102** of the prosthetic valve **100**, thereby reducing the crimp profile and/or bulk of the prosthetic valve **100**. Integrating the actuator mechanisms **106** (which can also be referred to herein as "expansion and locking mechanisms") into the frame **102** can also simplify the design of the prosthetic valve **100**, making the prosthetic valve **100** less costly and/or easier to manufacture. In the illustrated example, an actuator **126** extends through each pair of axially aligned posts **122**, **124**. In other examples, one or more of the pairs of posts **122**, **124** can be without a corresponding actuator.

[0066] The posts **104** can be coupled together by a plurality of circumferentially extending link members or struts **112**. Each strut **112** extends circumferentially between adjacent posts **104** to connect all of the axially extending posts **104**. As one example, the prosthetic valve **100** can include equal numbers of support posts **107** and pairs of actuator posts **122**, **124** and the pairs of posts **122**, **124** and the support posts **107** can be arranged in an alternating order such that each strut **112** is positioned between one of the pairs of posts **122**, **124** and one of the support posts **107** (that is, each strut **112** can be coupled on one end to one of the posts **122**, **124** and can be coupled on the other end to one of the support posts **107**). However, the prosthetic valve **100** can include different numbers of support posts **107** and pairs of posts **122**, **124** and/or the pairs of posts **122**, **124** and the support posts **107** can be arranged in a non-alternating order, in other examples.

[0067] As illustrated in FIG. **2**B, the struts **112** can include a first row of struts **113** at or near the inflow end **109** of the prosthetic valve **100**, a second row of struts **114** at or near the outflow end **108** of the prosthetic valve **100**, and third and fourth rows of struts **115**, **116**, respectively, positioned axially between the first and second rows of struts **113**, **114**. The struts **112** can form and/or define a plurality of cells (that is, openings) in the frame **102**. For example, the struts **113**, **114**, **115**, and **116** can at least partially form and/or define a plurality of first cells **117** and a plurality of second cells **118** that extend circumferentially around the frame **102**. Specifically, each first cell **117** can be formed by two struts **113***a*, **113***b* of the first row of struts **113**, two struts **114***a*, **114***b* of the second row of struts **114**, and two of the support posts **107**. Each second cell **118** can be formed by two struts **115***a*, **115***b* of the third row of struts **115** and two struts **116***a*, **116***b* of the fourth row of struts **116**. As illustrated in FIGS. **2**A and **2**B, each second cell **118** can be disposed within one of the first cells **117** (that is, the struts **115***a*-**116***b* forming the second cells **118** are disposed between the struts forming the first cells **117** (that is, the struts **113***a*, **113***b* and the struts **114***a*, **114***b*), closer to an axial midline of the frame **102** than the struts **113***a*-**114***b*).

[0068] As illustrated in FIGS. **2**A and **2**B, the struts **112** of frame **102** can comprise a curved shape. Each first cell **117** can have an axially-extending hexagonal shape including first and second apices **119** (for example, an inflow apex **119***a* and an outflow apex **119***b*). In examples where the delivery apparatus is releasably connected to the outflow apices **119***b* (as described below), each inflow apex **119***a* can be referred to as a "distal apex" and each outflow apex **119***b* can be referred to as a "proximal apex". Each second cell **118** can have a diamond shape including first and second apices **120** (for example, distal apex **120***a* and proximal apex **120***b*). In some examples, the frame **102** comprises six first cells **117** extending circumferentially in a row, six second cells **118** extending circumferentially in a row within the six first cells **117**, and twelve posts **104**. However, in other embodiments, the frame **102** can comprise a greater or fewer number of first cells **117** and a correspondingly greater or fewer number of second cells **118** and posts **104**.

[0069] As noted above, some of the posts **104** can be arranged in pairs of first and second posts **122**, **124**. The posts **122**, **124** are aligned with each other along the length of the frame **102** and are axially separated from one another by a gap G (FIG. **2**B) (those with actuators **126** can be referred to as actuator posts or actuator struts). Each first post **122** (that is, the lower post shown in FIGS. **2**A and **2**B) can extend axially from the inflow end **109** of the prosthetic valve **100** toward the second post **124**, and the second post **124** (that is, the upper post shown in FIGS. **2**A and **2**B) can extend axially from the outflow end **108** of the prosthetic valve **100** toward the first post **122**. For example, each first post **122** can be connected to and extend from an inflow apex **119***a* and each second post **124** can be connected to and extend from an outflow apex **119***b*. Each first post **122** and the second post **124** can include an inner bore (sometimes referred to as a channel) configured to receive a portion of an actuator member, such as in the form of a substantially straight threaded rod **126** (or bolt) as shown in the illustrated example. The threaded rod **126** also may be referred to herein as actuator **126**, actuator member **126**, and/or screw actuator **126**. In examples where the delivery apparatus can be releasably connected to the outflow end **108** of the frame **102**, the first posts **122** can be referred to as distal posts or distal axial struts and the second posts **124** can be referred to as proximal posts or proximal axial struts.

[0070] Each threaded rod **126** extends axially through a corresponding first post **122** and second post **124**. Each threaded rod **126** also extends through a bore of a nut **127** captured within a slot or window formed in an end portion **128** of the first post **122**. The threaded rod **126** has external threads that engage internal threads of the bore of the nut **127**. The inner bore of the second post **124** (through which the threaded rod **126** extends) can have a smooth and/or non-threaded inner surface to allow the threaded rod **126** to slide freely within the bore. Rotation of the threaded rod **126** relative to the nut **127** produces radial expansion and compression of the frame **102**, as further described below.

[0071] In some examples, the threaded rod **126** can extend past the nut **127** toward the inflow end **109** of the frame **102** into the inner bore of the first post **122**. The nut **127** can be held in a fixed position relative to the first post **122** such that the nut **127** does not rotate relative to the first post **122**. In this way, whenever the threaded rod **126** is rotated (for example, by a physician) the threaded rod **126** can rotate relative to both the nut **127** and the first post **122**. The engagement of the external threads of the threaded rod **126** and the internal threads of the nut **127** prevent the rod **126** from moving axially relative to the nut **127** and the first post **122** unless the threaded rod **126** is rotated relative to the nut **127**. Thus, the threaded rod **126** can be retained or held by the nut **127** and can only be moved relative to the nut **127** and/or the first post **122** by rotating the threaded rod **126** relative to the nut **127** and/or the first post **122**. In other examples, in lieu of using the nut **127**, at least a portion of the inner bore of the first post **122** can be threaded. For example, the bore along the end portion **128** of the first post **122** can comprise inner threads that engage the external threaded rod **126** such that rotation of the threaded rod causes the threaded rod **126** to move axially relative to the first post **122**.

[0072] When a threaded rod **126** extends through and/or is otherwise coupled to a pair of axially aligned posts **122**, **124**, the pair of axially aligned posts **122**, **124** and the threaded rod **126** can serve as one of the expansion and locking mechanisms **106**. In some examples, a threaded rod **126** can extend through each pair of axially aligned posts **122**, **124** so that all of the posts **122**, **124** (with their corresponding rods **126**) serve as expansion and locking mechanisms **106**. As just one example, the prosthetic valve **100** can include six pairs of posts **122**, **124**, and each of the six pairs of posts **122**, **124** with their corresponding rods **126** can be configured as one of the expansion and locking mechanisms **106** for a total of six expansion and locking mechanisms **106**. In other examples, not all pairs of posts **122**, **124** need be expansion and locking mechanisms (that is, actuators). If a pair of posts **122**, **124** is not used as an expansion and locking mechanism, a threaded rod **126** need not extend through the posts **122**, **124** of that pair.

[0073] The threaded rod **126** can be rotated relative to the nut **127**, the first post **122**, and the second post **124** to axially foreshorten and/or axially elongate the frame **102**, thereby radially expanding and/or radially compressing, respectively, the frame **102** (and therefore the prosthetic valve **100**). Specifically, when the threaded rod **126** is rotated relative to the nut **127**, the first post **122**, and the second post **124**, the first and second posts **122**, **124** can move axially relative to one another, thereby widening or narrowing the gap G (FIG. **2**B) separating the posts **122**, **124**, and thereby radially compressing or radially expanding the prosthetic valve **100**, respectively. Thus, the gap G (FIG. **2**B) between the first and second posts **122**, **124** narrows as the frame **102** is radially expanded and widens as the frame **102** is radially compressed.

[0074] The threaded rod **126** can extend proximally past the proximal end of the second post **124** and can include a head portion **131** at its proximal end that can serve at least two functions. First, the head portion **131** can removably or releasably couple the threaded rod **126** to a respective actuator assembly of a delivery apparatus that can be used to radially expand and/or radially compress the prosthetic valve **100** (for example, the delivery apparatus **200** of FIG. **3**, as described below). Second, the head portion **131** can prevent the second post **124** from moving proximally relative to the threaded rod **126** and can apply a distally directed force to the second post **124**, such as when radially expanding the prosthetic valve **100**. Specifically, the head portion **131** can have a width greater than a diameter of the inner bore of the second post **124** such that the head portion **131** is prevented from moving into the inner bore of the second post **124**. Thus, as the threaded rod **126** is threaded farther into the nut **127**, the head portion **131** of the threaded rod **126** draws closer to the nut **127** and the first post **122**, thereby drawing the second post **124** towards the first post **122**, and thereby axially foreshortening and radially expanding the prosthetic valve **100**.

[0075] The threaded rod **126** also can include a stopper **132** (for example, in the form of a nut, washer or flange) disposed thereon. The stopper **132** can be disposed on the threaded rod **126** such that it sits within the gap G. Further, the stopper **132** can be integrally formed on or fixedly coupled to the threaded rod **126** such that it does not move relative to the threaded rod **126**. Thus, the stopper **132** can remain in a fixed axial position on the threaded rod **126** such that it moves in lockstep with the threaded rod **126**.

[0076] Rotation of the threaded rod **126** in a first direction (for example, clockwise) can cause corresponding axial movement of the first and second posts **122**, **124** toward one another, thereby decreasing the gap G and radially expanding the frame **102**, while rotation of the threaded rod **126** in an opposite second direction causes corresponding axial movement of the first and second posts **122**, **124** away from one another, thereby increasing the gap G and radially compressing the frame. When the threaded rod **126** is rotated in the first direction, the head portion **131** of the rod **126** bears against an adjacent surface of the frame (for example, an outflow apex **119***b*), while the nut **127** and the first post **122** travel proximally along the threaded rod **126** toward the second post **124**, thereby radially expanding the frame. As the frame **102** moves from a compressed configuration to an expanded configuration, the gap G between the first and second posts **122**, **124** can narrow.

[0077] When the threaded rod **126** is rotated in the second direction, the threaded rod **126** and the stopper **132** move toward the outflow end **108** of the frame until the stopper **132** abuts the inflow end **170** of the second post **124** (as shown in FIGS. **2**A and **2**B). Upon further rotation of the rod **126** in the second direction, the stopper **132** can apply a proximally directed force to the second post **124** to radially compress the frame **102**. Specifically, during crimping/radial compression of the prosthetic valve **100**, the threaded rod **126** can be rotated in the second direction (for example, counterclockwise) causing the stopper **132** to push against (that is, provide a proximally directed force to) the inflow end **170** of the second post **124**, thereby causing the second post **124** to move away from the first post **122**, and thereby axially elongating and radially compressing the prosthetic valve **100**.

[0078] Thus, each of the second posts **124** can slide axially relative to a corresponding one of the first posts **122** but can be axially retained and/or restrained between the head portion **131** of a threaded rod **126** and a stopper **132**. That is, each second post **124** can be restrained at its proximal end by the head portion **131** of the threaded rod **126** and at its distal end by the stopper **132**. In this way, the head portion **131** can apply a distally directed force to the second post **124** to radially expand the prosthetic valve **100** while the stopper **132** can apply a proximally directed force to the second post **124** to radially compress the prosthetic valve **100**. As explained above, radially expanding the prosthetic valve **100** axially foreshortens the prosthetic valve **100**, causing an inflow end portion **134** and outflow end portion **136** of the prosthetic valve **100** (FIGS. **1**A and **1**B) to move towards one another axially, while radially compressing the prosthetic valve **100** axially elongates the prosthetic valve **100**, causing the inflow and outflow end portions **134**, **136** to move away from one another axially.

[0079] In other examples, the threaded rod **126** can be fixed against axial movement relative to the second post **124** (and the stopper **132** can be omitted) such that rotation of the threaded rod **126** in the first direction produces proximal movement of the nut **127** and radial expansion of the frame **102** and rotation of the threaded rod **126** in the second direction produces distal movement of the nut **127** and radial compression of the frame **102**.

[0080] As also introduced above, some of the posts **104** can be configured as support posts **107**. As shown in FIGS. **2**A and **2**B, the support posts **107** can extend axially between the inflow and outflow ends **109**, **108** of the frame **102** and each can have an inflow end portion **138** and an outflow end portion **139**. The outflow end portion **139** of one or more support posts **107** can include a commissure support structure or member **144**. The commissure support structure **144** can comprise strut portions defining a commissure opening **146** therein.

[0081] The commissure opening **146** (which can also be referred to herein as a "commissure window **146**") can extend radially through a thickness of the support post **107** and can be configured to accept a portion of a valvular structure **150** (for example, a commissure **152**) to couple the valvular structure **150** to the frame **102**. For example, each commissure **152** can be mounted to a respective commissure support structure **144**, such as by inserting a pair of commissure tabs of adjacent leaflets **158** through the commissure opening **146** and suturing the commissure tabs to each other and/or the commissure support structure **144**. In some embodiments, the commissure opening **146** can be fully enclosed by the support post **107** such that a portion of the valvular structure **150** can be slid radially through the commissure opening **146**, from an interior to an exterior of the frame **102**, during assembly. In the illustrated embodiment, the commissure opening **146** has a substantially rectangular shape that is shaped and sized to receive commissure tabs of two adjacent leaflets therethrough. However, in other embodiments, the commissure opening can have any of various shapes (for example, square, oval, square-oval, triangular, L-shaped, T-shaped, C-shaped, etc.).

[0082] The commissure openings **146** are spaced apart about the circumference of frame **102** (or angularly spaced apart about frame **102**). The spacing may or may not be even. In one example, the commissure openings **146** are axially offset from the outflow end **108** of the frame **102** by an offset distance d**3** (indicated in FIG. **2**A). As an example, the offset distance d**3** may be in a range from 2 mm to 6 mm. In general, the offset distance d**3** should be selected such that when the leaflets are attached to the frame **102** via the commissure openings **146**, the free edge portions (for example, outflow edge portions) of the leaflets **158** will not protrude from or past the outflow end **108** of the frame **102**.

[0083] The frame **102** can comprise any number of support posts **107**, any number of which can be configured as commissure support structures **144**. For example, the frame **102** can comprise six support posts **107**, three of which are configured as commissure support structures **144**. However, in other embodiments, the frame **102** can comprise more or less than six support posts **107** and/or more or less than three commissure support structures **144**.

[0084] The inflow end portion **138** of each support post **107** can comprise an extension **154** (show as a cantilevered strut in FIGS. **2**A and **2**B) that extends toward the inflow end **109** of the frame **102**. Each extension **154** can comprise an aperture **156** extending radially through a thickness of the extension **154**. In some examples, the extension **154** can extend such that an inflow edge of the extension **154** aligns with or substantially aligns with the inflow end **109** of the frame **102**. In use, the extension **154** can prevent or mitigate portions of an outer skirt from extending radially inwardly and thereby prevent or mitigate any obstruction of flow through the frame **102** caused by the outer skirt. The extensions **154** can further serve as supports to which portions of the inner and/or outer skirts and/or the leaflets and/or the connecting skirt **125** can be coupled. For example, sutures used to connect the inner and/or outer skirts and/or the leaflets and/or the connecting skirt **125** can be wrapped around the extensions **154** and/or can extend through apertures **156**.

[0085] As an example, each extension **154** can have an aperture **156** (FIG. **2**A) or other features to receive a suture or other attachment material for connecting an adjacent inflow edge portion **160** of a leaflet **158** (FIG. **1**A), the outer skirt **103** (in FIG. **1**B), the connecting skirt **125**, and/or an inner skirt. In some examples, the inflow edge portion **160** of each leaflet **158** can be connected to a corresponding extension via a suture **135** (FIG. **1**A).

[0086] In some examples, the outer skirt **103** can be mounted around the outer surface of frame **102** as shown in FIG. **1**B and the inflow edge of the outer skirt **103** (lower edge in FIG. **1**B) can be attached to the connecting skirt **125** and/or the inflow edge portions **160** of the leaflets **158** that have already been secured to frame **102** as well as to the extensions **154** of the frame by sutures **129**. The outflow edge of the outer skirt **103** (the upper edge in FIG. **1**B) can be attached to selected struts with stitches **137**. In implementations where the prosthetic valve includes an inner skirt, the inflow edge of the inner skirt can be secured to the inflow edge portions **160** before securing the cusp edge portions to the frame so that the inner skirt will be between the leaflets and the inner surface of the frame. After the inner skirt and leaflets are secured in place, then the outer skirt can be mounted around the frame as described above.

[0087] The frame **102** can be a unitary and/or fastener-free frame that can be constructed from a single piece of material (for example, Nitinol, stainless steel or a cobalt-chromium alloy), such as in the form of a tube. The plurality of cells can be formed by removing portions (for example, via laser cutting) of the single piece of material. The threaded rods **126** can be separately formed and then be inserted through the bores in the second (proximal) posts **124** and threaded into the threaded nuts **127**.

[0088] In some examples, the frame **102** can be formed from a plastically-expandable material, such as stainless steel or a cobalt-chromium alloy. When the frame is formed from a plastically-expandable material, the prosthetic valve **100** can be placed in a radially compressed state along the distal end portion of a delivery apparatus for insertion into a patient's body. When at the desired implantation site, the frame **102** (and therefore the prosthetic valve **100**) can be radially expanded from the radially compressed state to a radially expanded state via actuation of actuation assemblies of the delivery apparatus (as further described below), which rotate the rods **126** to produce expansion of the frame **102**. During delivery to the implantation site, the prosthetic valve **100** can be placed inside of a delivery capsule (sheath) to protect against the prosthetic valve contacting the patient's vasculature, such as when the prosthetic valve is advanced through a femoral artery. The capsule can also retain the prosthetic valve in a compressed state having a slightly smaller diameter and crimp profile than may be otherwise possible without a capsule by preventing any recoil (expansion) of the frame once it is crimped onto the delivery apparatus.

[0089] In other examples, the frame **102** can be formed from a self-expandable material (for example, Nitinol). When the frame **102** is formed from a self-expandable material, the prosthetic valve can be radially compressed and placed inside the capsule of the delivery apparatus to maintain the prosthetic valve in the radially compressed state while it is being delivered to the implantation site. When at the desired implantation site, the prosthetic valve is deployed or released from the capsule. In some examples, the frame (and therefore the prosthetic valve) can partially self-expand from the radially compressed state to a partially radially expanded state. The frame **102** (and therefore the prosthetic valve **100**) can be further radially expanded from the partially expanded state to a further radially expanded state via actuation of actuation assemblies of the delivery apparatus (as further described below), which rotate the rods **126** to produce expansion of the frame.

[0090] 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.

[0091] As introduced above, the threaded rods **126** can removably couple the prosthetic valve **100** to actuator assemblies of a delivery apparatus. Referring to FIG. **3**, it illustrates an exemplary delivery apparatus **200** for delivering a prosthetic device or valve **202** (for example, prosthetic valve **100**) to a desired implantation location. The prosthetic valve **202** can be releasably coupled to the delivery apparatus **200**. It should be understood that the delivery apparatus **200** and other delivery apparatuses disclosed herein can be used to implant prosthetic devices other than prosthetic valves, such as stents or grafts.

[0092] The delivery apparatus **200** in the illustrated embodiment generally includes a handle **204**, a first elongated shaft **206** (which comprises an outer shaft in the illustrated example) extending distally from the handle **204**, at least one actuator assembly **208** extending distally through the first shaft **206**, a second elongated shaft **209** (which comprises an inner shaft in the illustrated example) extending through the first shaft **206**, and a nosecone **210** coupled to a distal end portion of the second shaft **209**. The second shaft **209** and the nosecone **210** can define a guidewire lumen for advancing the delivery apparatus through a patient's vasculature over a guidewire. The at least one actuator assembly **208** can be configured to radially expand and/or radially collapse the prosthetic valve **202** when actuated, such as by one or more knobs **211**, **212**, **214** included on the handle **204** of the delivery apparatus **200**.

[0093] Though the illustrated embodiment shows two actuator assemblies **208** for purposes of illustration, it should be understood that one actuator assembly **208** can be provided for each actuator (for example, actuator or threaded rod **126**) on the prosthetic valve. For example, three actuator assemblies **208** can be provided for a prosthetic valve having three actuators. In other embodiments, a greater or fewer number of actuator assemblies can be present.

[0094] In some embodiments, a distal end portion **216** of the shaft **206** can be sized to house the prosthetic valve in its radially compressed, delivery state during delivery of the prosthetic valve through the patient's vasculature. In this manner, the distal end portion **216** functions as a delivery sheath or capsule for the prosthetic valve during delivery,

[0095] The actuator assemblies **208** can be releasably coupled to the prosthetic valve **202**. For example, in the illustrated embodiment, each actuator assembly **208** can be coupled to a respective actuator (for example, threaded rod **126**) of the prosthetic valve **202**. Each actuator assembly **208** can comprise a support tube and an actuator member. When actuated, the actuator assembly can transmit pushing and/or pulling forces to portions of the prosthetic valve to radially expand and collapse the prosthetic valve as previously described. The actuator assemblies **208** can be at least partially disposed radially within, and extend axially through, one or more lumens of the first shaft **206**. For example, the actuator assemblies **208** can extend through a central lumen of the shaft **206** or through separate respective lumens formed in the shaft **206**.

[0096] The handle **204** of the delivery apparatus **200** can include one or more control mechanisms (for example, knobs or other actuating mechanisms) for controlling different components of the delivery apparatus **200** in order to expand and/or deploy the prosthetic valve **202**. For example, in the illustrated embodiment the handle **204** comprises first, second, and third knobs **211**, **212**, and **214**, respectively.

[0097] The first knob **211** can be a rotatable knob configured to produce axial movement of the first shaft **206** relative to the prosthetic valve **202** in the distal and/or proximal directions in order to deploy the prosthetic valve from the delivery sheath **216** once the prosthetic valve has been advanced to a location at or adjacent the desired implantation location with the patient's body. For example, rotation of the first knob **211** in a first direction (for example, clockwise) can retract the sheath **216** proximally relative to the prosthetic valve **202** and rotation of the first knob **211** in a second direction (for example, counter-clockwise) can advance the sheath **216** distally. In other embodiments, the first knob **211** can be actuated by sliding or moving the first knob **211** axially, such as pulling and/or pushing the knob. In other embodiments, actuation of the first knob **211** (rotation or sliding movement of the first knob **211**) can produce axial movement of the actuator assemblies **208** (and therefore the prosthetic valve **202**) relative to the delivery sheath **216** to advance the prosthetic valve distally from the sheath **216**.

[0098] The second knob **212** can be a rotatable knob configured to produce radial expansion and/or compression of the prosthetic valve **202**. For example, rotation of the second knob **212** can rotate the threaded rods of the prosthetic valve **202** via the actuator assemblies **208**. Rotation of the second knob **212** in a first direction (for example, clockwise) can radially expand the prosthetic valve **202** and rotation of the second knob **212** in a second direction (for example, counter-clockwise) can radially collapse the prosthetic valve **202**. In other embodiments, the second knob **212** can be actuated by sliding or moving the second knob **212** axially, such as pulling and/or pushing the knob.

[0099] The third knob **214** can be a rotatable knob operatively connected to a proximal end portion of each actuator assembly **208**. The third knob **214** can be configured to retract an outer sleeve or support tube of each actuator assembly **208** to disconnect the actuator assemblies **208** from the proximal portions of the actuators of the prosthetic valve (for example, threaded rod). Once the actuator assemblies **208** are uncoupled from the prosthetic valve **202**, the delivery apparatus **200** can be removed from the patient, leaving just the prosthetic valve **202** in the patient.

[0100] Referring to FIGS. **4-5**, they illustrate how each of the threaded rods **126** of the prosthetic device **100** can be removably coupled to an exemplary actuator assembly **300** (for example, actuator assemblies **208**) of a delivery apparatus (for example, delivery apparatus **200**). Specifically, FIG. **5** illustrates how one of the threaded rods **126** can be coupled to an actuator assembly **300**, while FIG. **4** illustrates how the threaded rod **126** can be detached from the actuator assembly **300**.

[0101] As introduced above, an actuator assembly **300** can be coupled to the head portion **131** of each threaded rod **126**. The head portion **131** can be included at a proximal end portion **180** of the threaded rod **126** and can extend proximally past a proximal end of the second post **124** (FIG. **2**A). The head portion **131** can comprise first and second protrusions **182** defining a channel or slot **184** between them, and one or more shoulders **186**. As discussed above, the head portion **131** can have a width greater than a diameter of the inner bore of the second post **124** such that the head portion **131** is prevented from moving into the inner bore of the second post **124** and such that the head portion **131** abuts the outflow end **108** of the frame **102**. In particular, the head portion **131** can abut an outflow apex **119***b* of the frame **102**. The head portion **131** can be used to apply a distally-directed force to the second post **124**, for example, during radial expansion of the frame **102**.

[0102] Each actuator assembly **300** can comprise a first actuation member configured as a support tube or outer sleeve **302** and a second actuation member configured as a driver **304**. The driver **304** can extend through the outer sleeve **302**. The outer sleeve **302** is shown transparently in FIGS. **4-5** for purposes of illustration. The distal end portions of the outer sleeve **302** and driver **304** can be configured to engage or abut the proximal end of the threaded rod **126** (for example, the head portion **131**) and/or the frame **102** (for example, the apex **119***b*). The proximal portions of the outer sleeve **302** and driver **304** can be operatively coupled to the handle of a delivery apparatus (for example, handle **204**). The delivery apparatus in this embodiment can include the same features described previously for delivery apparatus **200**. In particular embodiments, the proximal end portions of each driver **304** can be operatively connected to the knob **212** such that rotation of the knob **212** (clockwise or counterclockwise) causes corresponding rotation of the drivers **304**. The proximal end portions of each outer sleeve **302** can be operatively connected to the knob **214** such that rotation of the knob **214** (clockwise or counterclockwise) causes corresponding axial movement of the sleeves **302** (proximally or distally) relative to the drivers **304**. In other embodiments, the handle can include electric motors for actuating these components.

[0103] The distal end portion of the driver **304** can comprise a central protrusion **306** configured to extend into the slot **184** of the threaded rod **126**, and one or more flexible elongated elements or arms **308** including protrusions or teeth **310** configured to be releasably coupled to the shoulders **186** of the threaded rod **126**. The protrusions **310** can extend radially inwardly toward a longitudinal axis of the second actuation member **304**. As shown in FIGS. **4-5**, the elongated elements **308** can be configured to be biased radially outward to an expanded state, for example, by shape setting the elements **308**.

[0104] As shown in FIG. **5**, to couple the actuator assembly **300** to the threaded rod **126**, the driver **304** can be positioned such that the central protrusion **306** is disposed within the slot **184** (FIG. **4**) and such that the protrusions **310** of the elongated elements **308** are positioned distally to the shoulders **186**. As the outer sleeve **302** is advanced (for example, distally) over the driver **304**, the sleeve **302** compresses the elongated elements **308** they abut and/or snap over the shoulders **186**, thereby coupling the actuator assembly **300** to the threaded rod **126**. Thus, the outer sleeve **302** effectively squeezes and locks the elongated elements **308** and the protrusions **310** of the driver **304** into engagement with (that is, over) the shoulders **186** of the threaded rod **126**, thereby coupling the driver **304** to the threaded rod **126**.

[0105] Because the central protrusion **306** of the driver **304** extends into the slot **184** of the threaded rod **126** when the driver **304** and the threaded rod **126** are coupled, the driver **304** and the threaded rod **126** can be rotational locked such that they co-rotate. So coupled, the driver **304** can be rotated (for example, using knob **212** the handle of the delivery apparatus **200**) to cause corresponding rotation of the threaded rod **126** to radially expand or radially compress the prosthetic device. The central protrusion **306** can be configured (for example, sized and shaped) such that it is advantageously spaced apart from the inner walls of the outer sleeve **302**, such that the central protrusion **306** does not frictionally contact the outer sleeve **302** during rotation. Though in the illustrated embodiment the central protrusion **306** has a substantially rectangular shape in cross-section, in other embodiments, the protrusion **306** can have any of various shapes, for example, square, triangular, oval, etc. The slot **184** can be correspondingly shaped to receive the protrusion **306**.

[0106] The outer sleeve **302** can be advanced distally relative to the driver **304** past the elongated elements **308**, until the outer sleeve **302** engages the frame **102** (for example, a second post **124** of the frame **102**). The distal end portion of the outer sleeve **302** also can comprise first and second support extensions **312** defining gaps or notches **314** between the extensions **312**. The support extensions **312** can be oriented such that, when the actuator assembly **300** is coupled to a respective threaded rod **126**, the support extensions **312** extend partially over an adjacent end portion (for example, the upper end portion) of one of the second posts **124** on opposite sides of the post **124**. The engagement of the support extensions **312** with the frame **102** in this manner can counter-act rotational forces applied to the frame **102** by the rods **126** during expansion of the frame **102**. In the absence of a counter-force acting against these rotational forces, the frame can tend to “jerk” or rock in the direction of rotation of the rods when they are actuated to expand the frame. The illustrated configuration is advantageous in that outer sleeves, when engaging the proximal posts **124** of the frame **102**, can prevent or mitigate such jerking or rocking motion of the frame **102** when the frame **102** is radially expanded.

[0107] To decouple the actuator assembly **300** from the prosthetic device **100**, the sleeve **302** can be withdrawn proximally relative to the driver **304** until the sleeve **302** no longer covers the elongated elements **308** of the driver **304**. As described above, the sleeve **302** can be used to hold the elongated elements **308** against the shoulders **186** of the threaded rod **126** since the elongated elements **308** can be naturally biased to a radial outward position where the elongated elements **308** do not engage the shoulders **186** of the threaded rod **126**. Thus, when the sleeve **302** is withdrawn such that it no longer covers/constrains the elongated elements **308**, the elongated elements **308** can naturally and/or passively deflect away from, and thereby release from, the shoulders **186** of the threaded rod **126**, thereby decoupling the driver **304** from the threaded rod **126**.

[0108] The sleeve **302** can be advanced (moved distally) and/or retracted (moved proximally) relative to the driver **304** via a control mechanism (for example, knob **214**) on the handle **204** of the delivery apparatus **200**, by an electric motor, and/or by another suitable actuation mechanism. For example, the physician can turn the knob **214** in a first direction to apply a distally directed force to the sleeve **302** and can turn the knob **214** in an opposite second direction to apply a proximally directed force to the sleeve **302**. Thus, when the sleeve **302** does not abut the prosthetic device and the physician rotates the knob **214** in the first direction, the sleeve **302** can move distally relative to the driver **304**, thereby advancing the sleeve **302** over the driver **304**. When the sleeve **302** does abut the prosthetic device, the physician can rotate the knob **214** in the first direction to push the entire prosthetic device distally via the sleeve **302**. Further, when the physician rotates the knob **214** in the second direction the sleeve **302** can move proximally relative to the driver **304**, thereby withdrawing/retracting the sleeve **302** from the driver **304**.

[0109] Also disclosed herein are examples of actuation assemblies having two bolts or rods coupled end-to-end. In some prosthetic heart valves, the portions of the actuation assembly closer to the distal and/or proximal ends of the frame may experience less compressive and/or flexural stress than portions of the actuation assembly closer to the axial midpoint of the prosthetic heart valve frame. If the actuation assembly does not have sufficient strength to withstand these compressive and/or flexural stresses, parts of the actuation assembly could buckle, particularly when the prosthetic heart valves are retained in the compressed configuration. Accordingly, those parts of the actuation assembly nearer to the axial midpoint of the frame require greater thickness (and thus greater strength) than the parts of the actuation assembly nearer the ends of the frame. However, in actuation assemblies comprising only one bolt or otherwise comprising only a single, unitary actuator body, the entire length of the actuator must be of sufficient thickness to withstand the compressive and/or flexural forces at the highest point of stress along the axial length of the actuation assembly. At the same time, thinner actuation assemblies are desirable because the thickness of the actuation assembly controls the minimum thickness of any components of the frame through which those assemblies extend. A frame with thinner components can be radially compressed to a smaller diameter in the fully compressed state, allowing for greater ease of delivery and implantation. Accordingly, the design of actuation assemblies for prosthetic heart valves faces two competing demands: the desire for minimal component thickness, and the need to withstand compressive and/or flexural stresses on the actuation assembly components.

[0110] This may be addressed through the use of actuation assemblies comprising two connected members, such as in the form of bolts, arranged end to end, such as those discussed in greater detail below, allowing for a bolt positioned nearer to the axial midpoint of the frame to be designed with a greater thickness than a bolt positioned towards one end of the frame. Additionally, this allows the use of thinner bolts in the portions of actuation assemblies positioned nearer to one end of the frame, as these bolts need only be strong enough to withstand the lesser compressive and/or flexural stresses experienced near the ends of the frame, and to rotate the bolts positioned nearer to the axial midpoint of the frame. The use of thinner bolts in the portions of the actuation assemblies positioned nearer to a frame end in turn allows for a thinner overall frame profile, while the use of thicker, stronger bolts in portions of the actuation assemblies positioned nearer to the axial midpoint of the frame allows for actuator assembly designs capable of withstanding greater compressive and/or flexural stresses when the frame (and thus the prosthetic heart valve) is in the compressed configuration.

[0111] FIGS. **6**A and **6**B show a section of an exemplary prosthetic heart valve frame **400** having an actuator comprising two separate members in the form of bolts. The frame **400** can comprise a plurality of vertically oriented posts **402** extending from an inflow end **404** towards an outflow end **406** of the frame **400**, and connected by a plurality of circumferentially extending link members or struts **408**. Each strut **408** extends between adjacent posts **402** to connect all of the vertically oriented posts **402**. A plurality of frame sections such as that shown in FIG. **6**A can be arranged side by side, such that each frame section is adjacent to two neighboring frame sections, and adjacent frame sections share a vertically oriented post **402**, in an annular pattern to form the frame **400**.

[0112] As illustrated in FIG. **6**A, the axially extending posts **402** and circumferentially extending struts **408** can form and/or define a plurality of cells (that is, openings) of the frame **400**. For example, the posts **402** and the struts **408** can form or define a plurality of first cells (sometimes called outer cells) **410** and a plurality of second cells (sometimes called inner cells) **412** that extend circumferentially around the frame **400**. Specifically, each first cell **410** can be formed by two axially extending posts **402** and four circumferentially extending struts **408**, and each second cell **412** can be formed by four circumferentially extending struts **408**.

[0113] Each first cell **410** can have a hexagonal shape, including a first apex (sometimes called an outflow apex) **414** positioned at the outflow end **404** of the frame **400** and a second apex (sometimes called an inflow apex) **416** positioned at the inflow end **404** of the frame **400**. In examples where the delivery apparatus is releasably connected to the outflow apices **414**, as previously described, each inflow apex **416** can be referred to as a "distal apex" and each outflow apex **412** can be referred to as a "proximal apex". In other examples where the delivery apparatus is releasably connected to the inflow apices, each inflow apex **416** may be referred to as a "proximal apex" and each outflow apex **412** may be referred to as a "distal apex" While FIG. **6**A shows the first cell **410** having a hexagonal shape, formed by two posts **402** and four struts **408**, it is to be understood that that in other examples, the first cell **410** can be formed from a differing number of struts and/or posts and have a different geometry.

[0114] Each second cell **412** can be formed by four circumferentially extending struts **408** and can be disposed within a corresponding first cell **410** as shown in FIG. **6**A. Each second cell **412** can have a diamond shape including a first apex (sometimes called an outflow apex) **418** and a second apex (sometimes called an inflow apex) **420** and two lateral vertices **422**. As shown in FIG. **6**A, the second cell **412** may be connected to a corresponding first cell **410** by a first post **424** extending from the first apex **414** of the first cell **410** to the first apex **418** of the second cell **412**, and by a second post **426** extending from the second apex **420** of the second cell **412** to the second apex **416** of the first cell **410**. The second cell **412** may also be connected to the corresponding first cell **410** by lateral members **428** extending from the lateral vertices **422** to the nearest adjacent axially oriented post **402** of the corresponding first cell **410**, as shown in FIG. **6**A. It is to be understood that while FIG. **6**A shows a second cell **412** formed by four circumferentially extending struts **408** and having a diamond shape, in other examples, the second cell **412** can be formed from a different combination of struts **408** and/or posts **402**, and may have a different geometry.

[0115] In some examples, the frame **400** comprises six first cells **410** extending circumferentially in a row, six second cells **412** extending circumferentially in a row within the six first cells **410**, and twelve posts **402**. However, in other embodiments, the frame **400** can comprise a greater or fewer number of first cells **410** and a correspondingly greater or fewer number of second cells **412** and posts **402**.

[0116] Although only one first cell **410** and one second cell **412** is shown in FIG. **6**A, it should be understood that a complete frame **400** include multiple pairs of such cells **410**, **412** connected side-by-side, in the same manner as the frame **102** of FIGS. **2**A-**2**B. Moreover, a prosthetic valve can comprise the frame **400** and the other components of the prosthetic valve **100** of FIGS. **1**A-**1**B, including leaflets **158** and a skirt **103**.

[0117] In some examples, the first posts **424** and the second posts **426** can be arranged in pairs of axially aligned vertical posts along the length of the frame **400**. The first and second posts **424**, **426** axially separated from one another by a gap G. Each first post **424** (that is, the upper post shown in FIG. **6**A) can extend axially from the outflow end **406** of the frame **400** toward the second post **426**, and the second post **426** (that is, the lower post shown in FIG. **6**A) can extend axially from the inflow end **404** of the frame **400** toward the first post **424**. In other words, each first post **424** can be connected to and extend from an outflow apex **414** and each second post **426** can be connected to and extend from an inflow apex **416**.

[0118] Other posts **402** can be support posts **430**, extending from the inflow end **404** and the outflow end **406** of the frame **400**. In one example, the frame **400** can comprise an equal number of support pots **430** and pairs of axially aligned posts **424**, **426** arranged in an alternating order such that each circumferentially extending strut **408** extends from one of the pairs of axially aligned posts **424**, **426** to one of the support posts **430** (that is, each strut **408** can be coupled on one end to one of the posts **424**, **426** and can be coupled on the other end to one of the support posts **430**). However, it is to be appreciated that in other examples, the frame **400** can have differing numbers of support posts **430** and pairs of axially aligned posts **424**, **426**, or that the support posts **430** and pairs of axially aligned posts **424**, **426** may be arranged in a non-alternating order.

[0119] In some examples, as illustrated in FIGS. **6**A and **6**B, the first post **424** of each pair of axially aligned vertical posts can include a first internal axially extending bore **432** (sometimes referred to as a channel **432**) and the second post **426** can include a second internal axially extending bore **434**. The first and second internal bores **432**, **434** can be configured to receive portions of an actuation assembly, such as the threaded rods (or bolts) of actuation assembly **436** as shown in FIGS. **6**A and **6**B, and illustrated in greater detail in FIG. **7**. In some examples, an actuation assembly **436** can extend through each pair of axially aligned posts **424**, **426** so that all of the posts **424**, **426** (with their corresponding actuation mechanism **436**) serve as expansion and locking mechanisms for the frame **400**. As just one example, the frame **400** can include six pairs of posts **424**, **426**, and each of the six pairs of posts **424**, **426** with their corresponding actuation assemblies for a total of six expansion and locking mechanisms. In other examples, not all pairs of posts **424**, **426** need be expansion and locking mechanisms (that is, actuators). If a pair of posts **424**, **426** is not used as an expansion and locking mechanism, an actuation assembly **436** need not extend through the posts **424**, **426** of that pair.

[0120] Turning now to FIG. **6**B, the actuation assembly **436** can include a first actuation member in the form of a first bolt **438** and a second actuation member in the form of a second bolt **440**. The first bolt **438** can have a first end portion **442** and a second end portion **444** and can extend through the first internal bore **432**. In examples where the frame **400** is configured to releasably attach to a delivery apparatus at the outflow end **406**, the first end portion **442** of the first bolt **438** can be referred to as the proximal end portion of the first bolt **438** and the second end portion **444** of the first bolt **438** can be referred to as the distal end portion of the first bolt **438**. The first bolt **438** can extend proximally past the proximal end of the first post **424** and the first end portion **442** can include an enlarged head portion **446** at its proximal end that can serve at least two functions. First, the head portion **446** can removably or releasably couple the first bolt **438** to a respective actuator assembly of a delivery apparatus that can be used to radially expand and/or radially compress the frame **400**, as previously discussed. Second, the head portion **446** can prevent the first post **424** from moving proximally relative to the first bolt **438** and can apply a distally directed force to the first post **424**, such as when radially expanding the frame **400**, as previously discussed.

[0121] The second bolt **440** can have a first end portion **448** and a second end portion **450**, and can extend through the second internal bore **434**. As illustrated in FIGS. **6**A and **6**B, the first end portion **448** of the second bolt **440** can include an enlarged head portion **452**. In some examples, the head portion **452** of the second bolt **440** serves the same function as the stopper **132** in the example of FIGS. **1**-**2**. Thus, when the actuation assembly **436** is rotated to radially compress the frame **400**, the enlarged head portion **452** can apply a proximally directed force to the first post **424** to move the first post **424** away from the second post **426**, thereby increasing gap G and radially compressing the frame. Use of a separate stopper that is welded to an actuator member can weaken the actuation assembly and increase the complexity of the manufacturing process. Advantageously, the enlarged head portion **452** is integrally formed as part of the second bolt **440** and does not need to be separately formed and welded to the second bolt. Thus, use of the integral head portion **452** as the stopper can overcome the deficiencies of a separately formed stopper.

[0122] The first bolt and the second bolt may be coupled to each other end-to-end, as best shown in FIG. **7**. For example, the second end portion (for example, the distal end portion) **444** of the first bolt **438** can be directly attached to the first end portion (for example, the proximal end portion) **448**, particularly the head portion **452**, of the second bolt **440**. In some examples, the head portion **452** of the second bolt **440** can include a bore **454** that receives a portion of the second end portion **444** of the first bolt **438**. In some examples, as illustrated in FIG. **7**, the bore **454** can include internal threads **456**, which may threadably engage corresponding external threads **458** on the second end portion **444** of the first bolt **438**.

[0123] It is to be appreciated, however, that in other examples, other methods and/or techniques may be used to attach the first bolt **438** to the second bolt **440**. For example, in lieu of or in addition to the threaded connected between the first and second bolts, the actuation assembly **436** can include one or more pins extending through both the second end portion **444** of the first bolt **438** and the first end portion

446 of the second bolt **440**, or any other device or method suitable for coupling the first bolt **438** and the second bolt **440**.

[0124] For example, as illustrated in FIG. **8**, the first bolt **438** and the second bolt **440** can be coupled by a first pin **468** extending through both the first bolt **438** and the second bolt **440**. In some examples, the actuation assembly **436** can also include a second pin **470** extending through both the first bolt **438** and the second bolt **440**. As shown, the pins **468**, **470** can extend through the head portion **452** of the second bolt **440** and the end portion **444** of the first bolt **438**. It should be understood that the threaded connection between the bolts shown in FIG. **8** is optional and can be removed. While FIG. **8** shows that the first pin **468** and the second pin **470** can be perpendicular or substantially perpendicular to each other, it is to be appreciated that in some examples, the first pin **468** and the second pin **470** can have a different orientation relative to each other.

[0125] In another example, the position of the external and internal threads can be reversed. Specially, the end portion **448** of the second bolt **440** can be formed with external threads and the end portion **444** of the first bolt **438** can be formed with a bore having internal threads, such that the end portion **448** can be tightened into the bore of the end portion **444**.

[0126] In these examples, the first bolt **438** and the second bolt **440** are rotationally fixed to each other, such that rotating the first bolt **438** in a first rotational direction (for example, when the first bolt is rotated in a first rotational direction by a component of a delivery system such as actuator **300**), also rotates the second bolt **440** in the first rotational direction.

[0127] In other examples, the first and second bolts **438**, **440** can be indirectly coupled to each other by one or more intermediate components. For example, a coupling member can be disposed between and couple the adjacent end portions of the first and second bolts **438**, **440** to each other. For example, the coupling member can comprise a sleeve coupling having internal threads that engage external threads of the first and second bolts. Thus, the second end portion **444** of the first bolt **438** having external threads **458** can be tightened into the sleeve coupling. Likewise, the first end portion **448** of the second bolt **440** can have external threads such that the first end portion **448** can be tightened into the sleeve coupling.

[0128] In further examples, the actuation assembly **436** can include more than two actuation members (for example, bolts), such as three or more actuation members (for example, bolts), coupled end-to-end to each other using any of the coupling techniques and/or mechanisms described above for the first and second bolts **438**, **440**.

[0129] In some examples, best shown in FIGS. **6**A and **6**B, the second bolt **440** can also extend through a bore of a nut **460** captured within a window (sometimes called a slot) **462** formed in the second post **426**. In such examples, the nut **460** may have internal threads that engage with corresponding external threads of the second bolt **440**. Rotation of the second bolt **440** relative to the nut **460** produces radial expansion and compression of the frame **400**, as further described below. In such examples, interior of the second bore **434** (through which the second bolt **440** extends) can have a smooth and/or non-threaded inner surface to allow the second bolt **440** to slide freely within the bore. It is to be appreciated, however, that in other examples, the actuation assembly **436** can omit the nut **460**, and in such examples the interior of the second bore **434** may include an internal thread that engages with corresponding external threads on the second bolt **440**.

[0130] In some examples, the second bolt **440** can extend past the nut **460** toward the inflow end **404** of the frame **400** and into the second bore **434**. The nut **460** can be held in a fixed position relative to the second post **426** such that the nut **460** does not rotate relative to the second post **426**. In this way, whenever the second bolt **440** is rotated (for example, when the first bolt **438** is rotated) the threaded the second bolt **440** can rotate relative to both the nut **460** and the second post **426**. The engagement of the external threads of the second bolt **440** and the internal threads of the nut **460** prevent the second bolt **440** from moving axially relative to the nut **460** and the second post **426** unless the second bolt **440** is rotated relative to the nut **460**. Thus, the second bolt **440** can be retained or held by the nut **460** and can only be moved relative to the nut **460** and/or the second post **426** by rotating the second bolt **440** relative to the nut **460** and/or the second bolt **440**. In other examples, in which a portion of the second bore **434** is threaded in lieu of using the nut **460**, the rotation of the second bolt **440** causes the second bolt **440** to move axially relative to the second post **426**.

[0131] The actuation assembly **436** can be rotated relative to the nut **460**, the first post **424**, and the second post **424** to axially foreshorten and/or axially elongate the frame **400**, thereby radially expanding and/or radially compressing, respectively, the frame **400** (and therefore any prosthetic heart valve including the frame **400**). Specifically, when the first bolt **438** is rotated relative to the first post **424**, the second bolt **440** rotates along with the first bolt **438** relative to the nut **460** and the second post **426**. The first post **424** and the second post **426** can move axially relative to one another, by deflecting or bending struts **408** under the axial force applied by the actuation assembly **436**, thereby widening or narrowing the gap G (FIG. **6**A) separating the posts **424**, **426**. This thereby radially compresses or radially expands the frame **400** respectively. Thus, the gap G (FIG. **2**B) between the first and second posts **424**, **426** narrows as the frame **400** is radially expanded and widens as the frame **400** is radially compressed.

[0132] Rotation of the first bolt **438** and the second bolt **440** of the actuation assembly **436** in a first rotational direction (for example, clockwise) can cause corresponding axial movement of the first and second posts **424**, **426** toward one another, thereby decreasing the gap G and radially expanding the frame **400**, while rotation of the bolts **438** and **440** in an opposite second rotational direction causes corresponding axial movement of the first and second posts **424**, **426** away from one another, thereby increasing the gap G and radially compressing the frame. When first bolt **438** is rotated in the first direction, the head portion **446** of the first bolt **438** bears against an adjacent surface of the frame (for example, an outflow apex **414**), while the nut **127** and the second post **426** travel proximally along the second bolt **440** toward the first post **424**, thereby radially expanding the frame. As the frame **400** moves from a compressed configuration to an expanded configuration, the gap G between the first and second posts **424**, **426** can narrow.

[0133] When the first bolt **438** is rotated in the second direction, the second bolt **440** moves toward the outflow end **406** of the frame **400** until the head portion **452** abuts the distal end of the first post **424** or an optional washer **464**

coupled to the distal end of the first post (as shown in FIG. **7**). Upon further rotation of the first bolt **438** in the second direction, the head portion **452** can apply a proximally directed force to the first post **424** to radially compress the frame **400**. Specifically, during crimping/radial compression of the prosthetic valve frame **400**, the first bolt **438** can be rotated in the second direction (for example, counterclockwise) causing the head portion **452** to push against (that is, provide a proximally directed force to) the distal end of the first post **424** (or against the washer **464** coupled to the first post **424**), thereby causing the first post **424** to move away from the second post **426**, and thereby axially elongating and radially compressing the frame **400**.

[0134] Thus, each of the first posts **424** can slide axially relative to a corresponding one of the second posts **426** but can be axially retained and/or restrained between the head portion **446** of the first bolt **438** and the head portion **442** of the second bolt **440**. That is, each first post **424** can be restrained at its proximal end by the head portion **446** of the first bolt **438** and at its distal end by the head portion **452** of the second bolt. In this way, the head portion **446** of the first bolt **438** can apply a distally directed force to the first post **424** to radially expand the frame **400** while the head portion **452** can apply a proximally directed force to the first post **424** to radially compress the frame **400**. As explained above, radially expanding the frame **400** axially foreshortens the frame **400**, causing the inflow end **404** and the outflow end **406** (FIGS. **6**A and **6**B) to move towards one another axially, while radially compressing the frame **400** axially elongates the frame **400**, causing the inflow end **404** and outflow end **406** of the frame **400** to move away from one another axially.

[0135] In other examples, the first bolt **438** can be fixed against axial movement relative to the first post **424** such that rotation of the first bolt **438** in the first direction produces rotation of the second bolt **440** in the first direction, proximal movement of the nut **460**, and radial expansion of the frame **400** and rotation of the first bolt **438** in the second direction produces rotation of the second bolt **440** in the second direction, distal movement of the nut **460** and radial compression of the frame **400**.

[0136] In some examples, as shown in FIG. **7**, the actuation assembly **436** also can include an optional washer **464**. The washer **464** can be coupled to the distal end of the first post **424** and can have a central aperture aligned with the bore **432** such that the distal end portion **444** of the first bolt **438** can extend through the washer. In some examples, such as that illustrated in FIG. **7**, the washer **464** is positioned between the head portion **452** of the second bolt **440** and the distal end of the first post **424** to reduce wear between these two components. The washer **464** can also include a sleeve portion **466** that extends axially into the first internal bore **432** in the first post **424**, as illustrated in FIG. **7**. The washer **464** can be fixed to the first post **424**, such as with an adhesive, welding, and/or via a press fit between the sleeve portion **466** and the inner surface of the bore **432**, and/or other techniques or mechanisms. Advantageously, the sleeve portion **466** may seal the first internal bore **432**, preventing the formation of thromboses or the occurrence of crevice corrosion after a prosthetic heart valve including frame **400** has been implanted in the vasculature of a patient. Although not shown, another washer **464** can be positioned between the head portion **446** of the first bolt **438** and the proximal end of the first post **424**. The additional washer **464** can include a sleeve portion **466** that extends into the bore **432** at the proximal end of the first post **424** to seal that end of the first post.

[0137] Because the actuation assembly **436** includes two separate bolts, each bolt **438**, **440** can be easily manufactured to have different dimensions and/or shapes, and/or can be manufactured from different materials to optimize the performance of the frame. For example, as noted above, when radially compressed, the frame experiences the greatest compressive and/or flexural stresses at the along the middle of the frame. Thus, as shown in FIG. **7**, the first bolt **438** can have a first diameter D**1**, and the second bolt **440** can have a second diameter D**2**. The first diameter D**1** can, as illustrated in FIG. **7**, be less than the second diameter D**2**. In one particular example, the first diameter D**1** can be 0.55 mm, and the second diameter can be 0.78 mm. In other examples, the first diameter D**1** can be greater or less than 0.55 mm, such as between 0.35 and 0.75 mm, or 0.35 mm, 0.40 mm, 0.45 mm, 0.50 mm, 0.55 mm, 0.60 mm, 0.65 mm, 0.75 mm, or any diameter in between. In other examples, the second diameter D**2** can be greater or less than 0.78 mm, such as 0.55 mm to 0.95 mm, or 0.55 mm, 0.60 mm, 0.65 mm, 0.70 mm, 0.75 mm, 0.80 mm, 0.85 mm, 0.90 mm, 0.95 mm, or any diameter in between.

[0138] By forming the second bolt **440** with a greater diameter, it can better resist buckling when the frame is radially compressed. Further, due to the increased strength provided by the relatively wider second bolt **440**, the overall length of the second post **426** (compared to bolt **126** in the example of FIGS. **2**A-**2**B) can be reduced, which reduces the amount of metal along the middle portion of the frame and therefore reduces the crimp profile along this portion of the frame. Because the compressive and/or flexural stresses along the outflow end portion of the frame are relatively smaller than the middle portion of the frame, the diameter of the first bolt **438** can be relatively smaller than the second bolt **440**. This allows the first post **424** to have a relatively smaller thickness and/or width compared to the second post **426**, which reduces the overall frame thickness and crimp profile the frame along the outflow end portion when in the radially compressed configuration.

[0139] In lieu or in addition to utilizing bolts with different diameters, the first and second bolts can be formed from different materials. For example, the second bolt **440** can be formed a relatively stiffer or stronger material than the material used to form the first bolt **438** to better resist the compressive and/or flexural forces along the middle portion of the frame when the frame is radially compressed.

[0140] Also disclosed herein are examples of actuation assemblies having a stopper (sometimes in the form of a washer) secured by a pin extending laterally through the actuation member. As discussed above, actuation assemblies for prosthetic heart valves may include a stopper to facilitate the radial expansion and/or compression of the frame. To enable the radial expansion and compression of the frame, the stopper is fixed relative to the actuation member, such that as the actuation member moves axially relative to the frame, the stopper may apply axial forces to the components of the frame. These stoppers may, in some examples, be welded to the actuation member or secured by mechanical deformation such as crimping or stamping. When the stopper is attached to the actuation member in these ways, however, the actuator and/or the stopper may be mechanically weakened. When the stopper is attached by welding, the localized melting and re-solidification of the material of the actuation member can cause localized embrittlement or loss of strength, and portions of the actuation member adjacent to the weld site may be weakened from residual heat from the welding process. Additionally, welded sections of material may be particularly susceptible to corrosion after re-solidification. When the stopper is attached by mechanical deformation such as stamping or crimping, the actuator and/or stopper may become deformed or damaged, may lose mechanical strength, and/or may experience reduced fatigue tolerance.

[0141] This may be addressed through the use of actuation assemblies having a securing pin to fix the stopper relative to the actuation member. The securing pin can extend laterally through the actuation member and can be sized such that the stopper cannot travel axially along the actuation member past the position of the securing pin. In this way, the need to physically attach the stopper to the actuation member by welding or mechanical deformation can be avoided. Additionally, because the stopper does not need to be welded or mechanically deformed onto the actuation member, the stopper can be formed of a wider range of materials, such as polymer materials or metals which do not readily weld to the materials used for the actuation member. Advantageously, the use of polymer materials may also reduce the friction between the frame, the actuator, and the stopper, which can reduce resistance to the rotation of the actuators during the radial expansion and/or radial compression of the frame.

[0142] FIGS. **10**A and **10**B show a portion of an actuation assembly **500** comprising a securing pin **506** to restrain a stopper **504**. The actuation assembly **500** can be operatively attached to a frame similar to the frame **102**, described in greater detail above, having first posts **122** and second posts **124** axially aligned with each other to form pairs of posts. The actuation assembly **500** generally comprises an actuation member **502**, the stopper **504**, and the securing pin **506**. As illustrated, the actuation member **502** extends axially between one of the first posts **122** and an aligned one of the second posts **124**, and through one or more axially aligned bores (see, for example, FIGS. **6**A and **6**B). In some examples, the actuation member **502** can have an externally threaded end portion **508** to engage with other components of the frame and/or the actuation assembly, such as the nut **127** (see, for example, FIG. **2**A), as discussed in greater detail above.

[0143] As also illustrated in FIGS. **9**A through **9**C, the stopper **504** can comprise an annular body with an outer diameter **510** and an aperture **514** having an inner diameter **512**. The aperture **514** receives the actuation member **502** (that is, the stopper **504** is disposed radially around the actuation member **502**). The dimensions of the outer diameter **510** and the inner diameter **512** may be defined by the dimensions of the other components of the frame **102**. For instance, in some examples, the outer diameter **510** may be sized such that the stopper **504** does not exceed the thickness of the first post **122** and/or the second post **124**, so as not to increase the crimp profile of the frame **102** in a radially compressed configuration. In some specific examples, the outer diameter **510** may be less than or equal to 1 mm, such as 0.9 mm or less, 0.8 mm or less, 0.7 mm or less, or 0.6 mm or less. In other examples, the outer diameter **510** may be greater than 1.0 mm. The inner diameter **512** may similarly be defined by the outer diameter of the actuation member **502**, such that the inner diameter **512** exceeds the outer diameter of the actuation member **502** only by a small margin so that the stopper **504** can slidingly translate relative to the actuation member **502**.

[0144] The stopper **504** also has a thickness T, as best illustrated in FIG. **9**B. The thickness T of the stopper **504** is generally sufficiently large that the stopper **504** has adequate mechanical strength to withstand the forces associated with radially expanding and compressing the frame, but also not so great that the stopper **504** prevents the first post **122** and the second post **124** from achieving the spacing required to radially expand the frame to its maximum desired diameter. For some example frames, the thickness T of the stopper **504** is 0.5 mm or less. For other example frames, the thickness T of the stopper can be greater than 0.5 mm.

[0145] The stopper **504** can be formed of any suitable biocompatible material with sufficient mechanical strength to withstand the compressive and other forces that the stopper **504** experiences during the radial compression and radial expansion of the frame **102**. Such materials include biocompatible alloys including cobalt-chromium alloys, and biocompatible polymers such as polyether ether ketone, teflon, polyethylenimine, or a combination thereof.

[0146] The dimensions (such as the outer diameter **510**, the inner diameter **512**, and the thickness T) of the stopper **504** can be varied for frames with a variety of configurations and dimensions and selected such that the stopper **504** is configured to withstand a given compressive force. In some examples, the given compressive force can be at least 20 N, such as 20 N, 30 N, 40 N, 50 N, 60 N, 70 N, or 80 N. In one specific working example, the stopper **504** can be formed from a cobalt-chromium alloy, with a thickness T of about 0.4 mm, an outer diameter **510** of about 0.8 mm, and an inner diameter **512** of about 0.56 mm, and can be configured to withstand a compressive force of at least 40 N.

[0147] Turning now to FIG. **11**, the securing pin **506** can extend laterally through the cross section of the actuation member **502**, such that at least one end portion **516** protrudes beyond an outer surface of the actuation member **502** (see for example, FIG. **10**B). A length L of the securing pin **506** may be varied depending on the geometries of the actuation member **502** and the stopper **504**. In the illustrated example, the length L is greater than the outer diameter of the actuation member **502**, such that both of the end portions **516** can extend radially outwards from the actuation member **502**. Similarly, the length L is generally less than the outer diameter **510** of the stopper **504**, so that the securing pin **506** does not increase the crimp profile of the frame **102**.

[0148] In some examples, the securing pin **506** can be integrally formed with the actuation member **502**. In other examples, the actuation member **502** can comprise a slot or aperture **518** configured to accommodate the securing pin **506**. In such examples, the securing pin **506** can be press fit into the slot or aperture **518**, or thermally fitted into the slot or aperture **518**. While FIGS. **10**A and **10**B show a securing pin **506** having a circular cross section, the securing pin **506** may have other cross-sectional geometries, such as a rectangular cross section, an irregularly-shaped cross section, or any other cross section that allows the securing pin **506** to be fixed relative to the actuation member **502**, and to secure the stopper **504**.

[0149] The cross-sectional area of the securing pin **506** may be determined by the mechanical demands on both the stopper **504** and the actuation member **502**. The cross-sectional area of the securing pin **506** should be great enough to withstand the axial forces applied to the stopper **504** during the radial compression (that is, the axial expansion) of the frame **102**. If the cross-sectional area of the securing pin **506** is too small, it may shear or buckle during the radial compression of the frame **102**. However, if the cross-sectional area of the securing pin **506** is increased, then the size of any slot or aperture in the frame to accommodate the securing pin **506** is also increased, which in turn may reduce the mechanical strength of the actuation member **502**, which should remain sufficient to withstand tensile and/or rotational stresses associated with the radial expansion and/or compression of the frame **102**.

[0150] The maximum and minimum diameter of the securing pin **506** can be varied for frames with a variety of configurations and dimensions and selected such that the pin **506** can withstand a given compressive force, and such that the actuation member **502** with the aperture **518** extending therethrough can withstand a given tensile stress. In some examples, the given compressive force can be at least 20 N, such as 20 N, 30 N, 40 N, 50 N, 60 N, 70 N, or 80 N, and the given tensile stress can be at least 200 MPa, such as 200 MPa, 300 MPa, 400 MPa, 500 MPa, 600 MPa, 700 MPa, or 800 MPa. In one specific working example, the actuation member **502** with a diameter of approximately 0.55 mm and the securing pin **506** extending through the actuation member has a diameter of 0.25 mm. The securing pin **506** is configured to withstand an axial force of at least 40 N, and the actuation member **502** is configured to withstand tensile stresses of at least 400 MPa.

[0151] Returning now to FIGS. **10**A and **10**B, the securing pin **506** can be positioned axially between the first post **122** and the second post **124**. As also shown in FIGS. **10**A and **10**B, the stopper **504** in some examples can be positioned between the securing pin **506** and the second post **124**, and the securing pin **506** can be positioned between the stopper **504** and the first post **122**. In such examples, the stopper **504** can be bounded on one side by an end portion of the second post **124** and on the other side by the securing pin **506**.

[0152] The actuation assembly **500** can operate similar to the threaded rod **126** and the stopper **132** described in greater detail above, except that the stopper **504** is not integrally formed with or fixedly attached to the actuation member **502**, and thus does not necessarily move in lockstep or rotate with the actuation member **502**. Rather, the securing pin **506** is integrally formed with or fixedly attached to the actuation member **502** and provides a limit on the axial movement of the stopper **504** relative to the actuation member **502** in one direction. The axial movement of the stopper **504** relative to the actuation member **502** in an opposite direction can be limited by the second post **124**.

[0153] Because the stopper **504** is not integrally formed with or fixedly attached to the actuation member **502**, the movement of the stopper relative to the frame **102** can be reduced or eliminated. In some examples, when the actuation member **502** is rotated, the actuation member **502** can rotate relative to the stopper **504** such that an outer surface of the actuation member **502** rotates along the inner diameter **512** of the aperture **514**, and the securing pin **506** can rotate along with the actuation member **502** and travel along an axial surface of the stopper **504**. In some examples, the stopper **504** may remain stationary relative to the frame **102** as the frame is radially expanded and/or radially compressed. In other examples, the stopper **504** may rotate relative to the frame **102** to a lesser degree than the rotation of the actuation member **502** and the securing pin **506** relative to the frame **102**. This in turn can reduce the resistance to the rotation of the actuation member **502** imparted by the stopper **504** and can also reduce the wear occurring from friction between components of the actuation assembly **500** and the frame **102**.

[0154] In the illustrated example, for example, when the actuation member **502** is rotated to radially compress the frame, the actuation member **502** and securing pin **506** translate towards the second post **124**. As the securing pin **506** travels towards the second post **124**, it urges the stopper **504** along with it until the stopper **504** abuts an end portion of the second post **124**. Further rotation of the actuation member **502** in the same direction causes the stopper **504** to bear on the end portion of the second post **124**, applying a proximally directed force to the second post **124** and pulling the second post **124** axially away from the first post **122** and thereby axially compressing the frame **102**. In the illustrated example, the actuation member **502** is threadedly engaged such that its rotation causes axial movement. The stopper **504** is slidingly engaged with the actuation member **502**, and thus it may or may not rotate as the actuation member **502** is threaded or unthreaded.

[0155] Radially expanding and radially compressing the frame can be accomplished as previously described for the examples of FIGS. **1**-**8**. Thus, the actuation member **502** can include an enlarged head portion (not shown, but similar to head portion **131** or head portion **446**) that bears against an adjacent surface of the post **124** when the actuation member **502** is rotated. The threaded engagement of the threaded portion **508** of the actuation member **502** with a threaded portion of the frame (for example, a corresponding nut **127**), brings the first post **122** closer to the second post, thereby radially expanding the frame.

Delivery Techniques

[0156] For implanting a prosthetic valve within the native aortic valve via a transfemoral delivery approach, the prosthetic valve is mounted in a radially compressed state along the distal end portion of a delivery apparatus. The prosthetic valve and the distal end portion of the delivery apparatus are inserted into a femoral artery and are advanced into and through the descending aorta, around the aortic arch, and through the ascending aorta. The prosthetic valve is positioned within the native aortic valve and radially expanded (for example, by inflating a balloon, actuating one or more actuators of the delivery apparatus, or deploying the prosthetic valve from a delivery capsule to allow the prosthetic valve to self-expand). Alternatively, a prosthetic valve can be implanted within the native aortic valve in a transapical procedure, whereby the prosthetic valve (on the distal end portion of the delivery apparatus) is introduced into the left ventricle through a surgical opening in the chest and the apex of the heart and the prosthetic valve is positioned within the native aortic valve. Alternatively, in a transaortic procedure, a prosthetic valve (on the distal end portion of the delivery apparatus) is introduced into the aorta through a surgical incision in the ascending aorta, such as through a partial J-sternotomy or right parasternal mini-thoracotomy, and then advanced through the ascending aorta toward the native aortic valve.

[0157] For implanting a prosthetic valve within the native mitral valve via a transseptal delivery approach, the prosthetic valve is mounted in a radially compressed state along the distal end portion of a delivery apparatus. The prosthetic valve and the distal end portion of the delivery apparatus are inserted into a femoral vein and are advanced into and through the inferior vena cava, into the right atrium, across the atrial septum (through a puncture made in the atrial septum), into the left atrium, and toward the native mitral valve. Alternatively, a prosthetic valve can be implanted within the native mitral valve in a transapical procedure, whereby the prosthetic valve (on the distal end portion of the delivery apparatus) is introduced into the left ventricle through a surgical opening in the chest and the apex of the heart and the prosthetic valve is positioned within the native mitral valve.

[0158] For implanting a prosthetic valve within the native tricuspid valve, the prosthetic valve is mounted in a radially compressed state along the distal end portion of a delivery apparatus. The prosthetic valve and the distal end portion of the delivery apparatus are inserted into a femoral vein and are advanced into and through the inferior vena cava, and into the right atrium, and the prosthetic valve is positioned within the native tricuspid valve. A similar approach can be used for implanting the prosthetic valve within the native pulmonary valve or the pulmonary artery, except that the prosthetic valve is advanced through the native tricuspid valve into the right ventricle and toward the pulmonary valve/pulmonary artery.

[0159] Another delivery approach is a transatrial approach whereby a prosthetic valve (on the distal end portion of the delivery apparatus) is inserted through an incision in the chest and an incision made through an atrial wall (of the right or left atrium) for accessing any of the native heart valves. Atrial delivery can also be made intravascularly, such as from a pulmonary vein. Still another delivery approach is a transventricular approach whereby a prosthetic valve (on the distal end portion of the delivery apparatus) is inserted through an incision in the chest and an incision made through the wall of the right ventricle (typically at or near the base of the heart) for implanting the prosthetic valve within the native tricuspid valve, the native pulmonary valve, or the pulmonary artery.

[0160] In all delivery approaches, the delivery apparatus can be advanced over a guidewire and/or an introducer sheath previously inserted into a patient's vasculature. Moreover, the disclosed delivery approaches are not intended to be limited. Any of the prosthetic valves disclosed herein can be implanted using any of various delivery procedures and delivery devices known in the art.

[0161] Advantageously, prosthetic heart valves according to the examples previously discussed can reduce the bending stresses on the attached actuators by reducing the radial displacement between the end portions and the center portions of the actuators. In turn, this may mitigate the tendency of the actuators to bend or buckle during the implantation procedure, and reduce resulting impairment to the ability of the prosthetic heart valve to be radially expanded or contracted at the desired implantation site.

[0162] 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

[0163] 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.

[0164] Example 1. A prosthetic valve, comprising a radially expandable frame comprising a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state, a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction, and at least one an actuation assembly operatively coupled to the frame, wherein the actuation assembly comprises first and second bolts aligned end-to-end relative to each other, wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, wherein the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state.

[0165] Example 2. The prosthetic valve of any example herein, particularly example 1, wherein the second bolt comprises a threaded bore in the adjacent end portion of the second bolt, wherein a threaded section of the end portion of the first bolt is tightened into the threaded bore of the second bolt.

[0166] Example 3. The prosthetic valve of any example herein, particularly example 1, wherein a pin extends through the end portion of the first bolt and the adjacent end portion of the second bolt.

[0167] Example 4. The prosthetic valve of any example herein, particularly example 3, further comprising a second pin extending through the end portion of the first bolt and the adjacent end portion of the second bolt.

[0168] Example 5. The prosthetic valve of any example herein, particularly any of examples 1-4, wherein the frame comprises at least one vertically oriented post with a channel extending therethrough, and wherein the first bolt extends through the channel.

[0169] Example 6. The prosthetic valve of any example herein, particularly example 5, further comprising a washer disposed between the second bolt and the vertically oriented post, wherein the washer has an aperture and the end portion of the first bolt extends through the aperture.

[0170] Example 7. The prosthetic valve of any example herein, particularly example 6, wherein the washer further comprises an annular sleeve disposed around the aperture and extending axially into the channel.

[0171] Example 8. The prosthetic valve of any example herein, particularly any of examples 5-7, wherein the frame comprises at least a second vertically oriented post with a second channel extending therethrough, and wherein the second bolt extends through the second channel.

[0172] Example 9. The prosthetic valve of any example herein, particularly any of example 8, further comprising a threaded nut disposed within the second channel through which the second bolt extends.

[0173] Example 10. The prosthetic valve of any of any example herein, particularly any of examples 1-9, wherein the first bolt has a first diameter and the second bolt has a second diameter, wherein the second diameter is greater than the first diameter.

[0174] Example 11. The prosthetic valve of any example herein, particularly any of examples 1-10, wherein the diameter of the first bolt is less than or equal to 0.55 mm.

[0175] Example 12. The prosthetic valve of any example herein, particularly any of examples 1-11, wherein the diameter of the second bolt is greater than or equal to 0.6 mm.

[0176] Example 13. The prosthetic valve of any example herein, particularly any of examples 1-12, wherein the frame may be radially compressed to a diameter of less than 12 mm without either the first bolt or the second bolt buckling.

[0177] Example 14. The prosthetic valve of any example herein, particularly any of examples 1-13, wherein a head portion of the first bolt is configured to be releasably connected to a component of a delivery apparatus actuator.

[0178] Example 15. A medical assembly, comprising a prosthetic heart valve comprising a radially expandable frame comprising a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state, a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction, and at least one an actuation assembly operatively coupled to the frame, and a delivery system configured to be releasably connected to a component of the actuation assembly and to advance the prosthetic heart valve through the vasculature of a patient, wherein the actuation assembly comprises first and second bolts aligned end-to-end relative to each other, wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, wherein the first and second bolts are rotatably coupled to rotate together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state, and wherein the first bolt has a first diameter and the second bolt has a second diameter, and wherein the first diameter is smaller than the second diameter.

[0179] Example 16. The medical assembly of any example herein, particularly example 15, wherein the second bolt comprises a threaded bore in the adjacent end portion of the second bolt, wherein a threaded section of the end portion of the first bolt is tightened into the threaded bore of the second bolt.

[0180] Example 17. The medical assembly of any example herein, particularly example 15, wherein a pin extends through an end portion of the first bolt and the adjacent end portion of the second bolt.

[0181] Example 18. The medical assembly of any example herein, particularly example 17, further comprising a second pin extending through the end portion of the first bolt and the adjacent end portion of the second bolt.

[0182] Example 19. The medical assembly of any example herein, particularly any of examples 15-18, wherein the first bolt extends through a bore in at least one vertically oriented post.

[0183] Example 20. The medical assembly of any example herein, particularly example 19, further comprising a washer disposed between a head portion of the second bolt and a distal end of the vertically oriented post, wherein the first bolt extends through an aperture of the washer.

[0184] Example 21. The actuation assembly of any example herein, particularly example 20, wherein the washer further comprises an annular sleeve portion extending axially into the bore of the vertically oriented post.

[0185] Example 22. The actuation assembly of any example herein, particularly any of examples 15-21, wherein the second bolt extends through a bore in a second vertically oriented post.

[0186] Example 23. The medical assembly of any example herein, particularly example 22, further comprising a threaded nut coupled to the second vertically oriented post through which the second bolt extends.

[0187] Example 24. The actuation assembly of any example herein, particularly any of examples 15-23, wherein the diameter of the first bolt is less than or equal to 0.55 mm.

[0188] Example 25. The actuation assembly of any example herein, particularly any of examples 15-23, wherein the diameter of the second bolt is greater than or equal to 0.6 mm.

[0189] Example 26. A prosthetic heart valve, comprising a radially expandable frame having a first end, a second end, and a longitudinal axis extending between the first end and the second end, wherein the frame is radially expandable between a radially compressed state and a radially expanded state, a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction, and at least one actuation assembly operatively coupled to the frame, wherein the frame comprises a plurality of axial posts extending parallel to the longitudinal axis and a plurality of angled struts arranged in circumferentially extending rows of angled struts, and wherein the actuation assembly comprises first and second bolts aligned end-to-end relative to each other, wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, wherein the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state, and wherein the first bolt extends through a channel in a first axial post of the plurality of axial posts.

[0190] Example 27. The prosthetic heart valve of any example herein, particularly example 26, wherein the second bolt extends through a channel in a second axial post of the plurality of axial posts.

[0191] Example 28. The prosthetic heart valve of any example herein, particularly any of examples 26-27, wherein the actuation assembly further comprises a threaded nut disposed within a window in the second axial post, wherein the second bolt extends through the nut.

[0192] Example 29. The prosthetic heart valve of any example herein, particularly any of examples 25-28, wherein the adjacent end portion of the second bolt comprises a threaded bore, wherein a threaded section of a distal end portion of the first bolt is tightened into the threaded bore of the second bolt.

[0193] Example 30. The prosthetic heart valve of any example herein, particularly any of examples 25-29, wherein the actuation assembly further comprises a first pin extending through the end portion of the first bolt and the adjacent end portion of the second bolt.

[0194] Example 31. The prosthetic heart valve of any example herein, particularly example 30, wherein the actuation assembly further comprises a second pin extending through the end portion of the first bolt and the adjacent end portion of the second bolt.

[0195] Example 32. The prosthetic heart valve of any example herein, particularly any of examples 26-31, further comprising a washer disposed between the adjacent end portion of the second bolt and the first axial post, wherein the washer comprises an aperture through which the first bolt extends.

[0196] Example 33. The prosthetic heart valve of any example herein, particularly example 32, wherein the washer further comprises an annular sleeve portion extending axially into the channel in the first axial post.

[0197] Example 34. The prosthetic heart valve of any example herein, particularly any of examples 26-33, wherein the first bolt has a first diameter and the second bolt has a second diameter larger than the first diameter.

[0198] Example 35. The prosthetic heart valve of any of any example herein, particularly any of examples 26-34, wherein the first bolt and the second bolt are rotatable together in a second rotational direction opposite to the first rotational direction to produce radial compression of the frame from the radially expanded state to a radially compressed state or to a partially radially expanded state.

[0199] Example 36. The prosthetic heart valve of any example herein, particularly any of examples 25-35, wherein the diameter of the first bolt is less than or equal to 0.55 mm.

[0200] Example The prosthetic heart valve of any example herein, particularly any of examples 25-36, wherein the diameter of the second bolt is greater than or equal to 0.6 mm.

[0201] Example 38. The prosthetic heart valve of any example herein, particularly example 25-37, wherein a proximal end portion of the first bolt is configured to be releasably attached to a component of a delivery apparatus.

[0202] Example 39. The prosthetic heart valve of any example herein, particularly example 25-37, further comprising a skirt disposed around and attached to the exterior of the frame.

[0203] Example 40. A prosthetic heart valve, comprising a radially expandable frame comprising a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state, a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction, at least one an actuation assembly operatively coupled to the frame, at least one nut coupled to the actuation assembly, and wherein the actuation assembly comprises first and second bolts aligned end-to-end relative to each other, wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, wherein the second bolt comprises a threaded portion that extends through and engages internal threads of the nut, wherein the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state.

[0204] Example 41. The prosthetic heart valve of any example herein, particularly example 40, further comprising a bore in one strut of the plurality of interconnected struts, which receives a component of the actuation assembly.

[0205] Example 42. The prosthetic heart valve of any example herein, particularly example 41, wherein the bore further comprises a window configured to receive the nut.

[0206] Example 43. The prosthetic heart valve of any example herein, particularly example 40-42, wherein the second bolt comprises a threaded bore in the adjacent end portion of the second bolt, wherein a threaded section of the end portion of the first bolt is tightened into the threaded bore of the second bolt.

[0207] Example 44. The prosthetic heart valve of any example herein, particularly example 40-42, wherein a pin extends through an end portion of the first bolt and the adjacent end portion of the second bolt.

[0208] Example 45. The prosthetic heart valve of any example herein, particularly example 44, further comprising a second pin extending through the end portion of the first bolt and the adjacent end portion of the second bolt.

[0209] Example 46. The prosthetic heart valve of any example herein, particularly any of examples 40-45, wherein the frame comprises a first axially oriented post and a second axially oriented post, wherein the first axially oriented post and the second axially oriented post are axially aligned with each other, wherein a bore extends axially through both the first axially oriented post and the second axially oriented post and receives the first and second bolts.

[0210] Example 47. The prosthetic heart valve any example herein, particularly example 46, further comprising a washer disposed between the adjacent end portion of the second bolt and a distal end portion of the first axially oriented post.

[0211] Example The prosthetic heart valve of any example herein, particularly example 47, wherein the washer comprises an aperture and the first bolt extends through the aperture.

[0212] Example 49. The prosthetic heart valve of any example herein, particularly any of examples 47-48, wherein the washer comprises an annular sleeve portion extending axially into the bore in the first axially oriented post.

[0213] Example 50. The prosthetic heart valve of any example herein, particularly any of examples 40-49, wherein the first bolt has a first diameter, the second bolt has a second diameter, and the second diameter is greater than the first diameter.

[0214] Example 51. The prosthetic heart valve of any example herein, particularly any of examples 40-50, wherein the diameter of the first bolt is less than or equal to 0.55 mm.

[0215] Example 52. The prosthetic heart valve of any example herein, particularly any of examples 40-51, wherein the diameter of the second bolt is greater than or equal to 0.6 mm.

[0216] Example 53. The prosthetic heart valve of any example herein, particularly any of examples 40-52, wherein the first bolt comprises a head portion and the head portion is configured to be releasably connected to a component of a delivery apparatus actuator.

[0217] Example 54. A prosthetic heart valve, comprising a frame having a first end, a second end, and a longitudinal axis extending between the first end and the second end, wherein the frame is radially expandable between a radially compressed state and a radially expanded state, and wherein the frame comprises a plurality of vertical posts extending parallel to the longitudinal axis and a plurality of angled struts arranged in circumferentially extending rows of angled struts, a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction, at least one actuation assembly comprising a first bolt and a second bolt aligned end-to-end, wherein the first bolt extends through a channel in a first vertical post of the plurality of vertical post wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, and wherein the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state, and a washer disposed between the adjacent end portion of the second bolt and the first vertical post.

[0218] Example 55. The prosthetic heart valve of any example herein, particularly example 54, wherein the washer comprises an aperture and the first bolt extends through the aperture.

[0219] Example 56. The prosthetic heart valve of any example herein, particularly any of examples 54-55, wherein the washer comprises an annular sleeve portion extending axially into the channel in the first vertical post.

[0220] Example 57. The prosthetic heart valve of any example herein, particularly any of examples 54-56, wherein the second bolt extends through a second channel in a second vertical post of the plurality of vertical posts.

[0221] Example The prosthetic heart valve of any example herein, particularly any of examples 54-57, wherein the second channel further comprises an opening that receives a nut through which the second bolt extends.

[0222] Example 59. The prosthetic heart valve of any example herein, particularly any of examples 54-58, wherein the second bolt comprises a threaded bore in the adjacent end portion of the second bolt, wherein a threaded section of the end portion of the first bolt is tightened into the threaded bore of the second bolt.

[0223] Example 60. The prosthetic heart valve of any example herein, particularly any of examples 54-59, wherein a pin extends through an end portion of the first bolt and the adjacent end portion of the second bolt.

[0224] Example 61. The prosthetic heart valve of any example herein, particularly example 60, further comprising a second pin extending through the end portion of the first bolt and the adjacent end portion of the second bolt.

[0225] Example 62. The prosthetic heart valve of a any example herein, particularly any of examples 54-61, wherein the first bolt has a first diameter and the second bolt has a second diameter larger than the first diameter.

[0226] Example 63. The prosthetic heart valve of any example herein, particularly any of examples 54-62, wherein the first bolt comprises a head portion and the head portion is configured to be releasably connected to a component of a delivery apparatus actuator.

[0227] Example 64. A prosthetic valve, comprising a radially expandable frame comprising a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state, a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction, and at least one an actuation assembly operatively coupled to the frame, wherein the actuation assembly comprises first and second actuation members aligned end-to-end relative to each other, wherein an end portion of the first actuation member is coupled to an adjacent end portion of the second actuation member, wherein the first and second actuation members are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state.

[0228] Example 65. The prosthetic valve of any example herein, particularly example 64, wherein the second actuation member comprises a threaded bore in the adjacent end portion of the second actuation member, wherein a threaded section of the end portion of the first actuation member is tightened into the threaded bore of the second actuation member.

[0229] Example 66. The prosthetic valve of any example herein, particularly example 64, wherein a pin extends through the end portion of the first actuation member and the adjacent end portion of the second actuation member.

[0230] Example 67. The prosthetic valve of any example herein, particularly example 66, further comprising a second pin extending through the end portion of the first actuation member and the adjacent end portion of the second actuation member.

[0231] Example 68. The prosthetic valve of any example herein, particularly any of examples 64-67, wherein the frame comprises at least one vertically oriented post with a channel extending therethrough, and wherein the first actuation member extends through the channel.

[0232] Example 69. The prosthetic valve of any example herein, particularly example 68, further comprising a washer disposed between the second actuation member and the vertically oriented post, wherein the washer has an aperture and the end portion of the first actuation extends through the aperture.

[0233] Example 70. The prosthetic valve of any example herein, particularly example 69, wherein the washer further comprises an annular sleeve disposed around the aperture and extending axially into the channel.

[0234] Example 71. The prosthetic valve of any example herein, particularly any of examples 68-70, wherein the frame comprises at least a second vertically oriented post with a second channel extending therethrough, and wherein the second actuation member extends through the second channel.

[0235] Example 72. The prosthetic valve of any example herein, particularly example 71, further comprising a threaded nut disposed within the second channel through which the second actuation member extends.

[0236] Example 73. The prosthetic valve of any example herein, particularly any of examples 64-72, wherein the first actuation member has a first diameter and the second actuation member has a second diameter, wherein the second diameter is greater than the first diameter.

[0237] Example 74. The prosthetic valve of any example herein, particularly any of examples 64-73, wherein the diameter of the first actuation member is less than or equal to 0.55 mm.

[0238] Example 75. The prosthetic valve of any example herein, particularly any of examples 64-74, wherein the diameter of the second actuation member is greater than or equal to 0.6 mm.

[0239] Example 76. The prosthetic valve of any example herein, particularly any of examples 64-75, wherein the frame may be radially compressed to a diameter of less than

12 mm without either the first actuation member or the second actuation member buckling.

[0240] Example 77. The prosthetic valve of any example herein, particularly any of examples 64-76, wherein a head portion of the first actuation member is configured to be releasably connected to a component of a delivery apparatus actuator.

[0241] Example 78. A prosthetic valve, comprising a radially expandable frame comprising a first end portion, a second end portion, and a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state; a valvular structure disposed within frame and configured to permit the flow of blood from the first end portion to the second end portion of the frame and to prevent the flow of blood from the second end portion to the first end portion of the frame; and an actuation assembly operatively coupled to the frame, the actuation assembly comprising a stopper having an aperture, an actuation member extending through the aperture in the stopper and a securing pin protruding from at least one side of the actuation member; wherein the securing pin limits motion of the stopper relative to the actuation member in a first axial direction, and wherein the actuation member is rotatable in a first direction to produce radial expansion of the frame from a radially compressed state to a radially expanded state and rotatable in a second rotational direction to produce radial compression of the frame from the radially expanded state to the radially compressed state.

[0242] Example 79. The prosthetic valve of any example herein, particularly example 78, wherein the securing pin is positioned further towards the first end portion of the frame than the stopper.

[0243] Example 80. The prosthetic valve of any example herein, particularly example 78, wherein the securing pin is positioned further towards the second end portion of the frame than the stopper.

[0244] Example 81. The prosthetic valve of any example herein, particularly any of examples 78-80, wherein the frame comprises at least one axially extending first post and at least one axially extending second post arranged as a pair of axially aligned vertical posts, and wherein the actuation assembly extends between and interconnects the first post and the second post.

[0245] Example 82. The prosthetic valve of any example herein, particularly example 81, wherein the first post comprises a first axial bore and the second post comprises a second axial bore, wherein the first axial bore and the second axial bore are dimensioned to receive portions of the at least one actuation assembly.

[0246] Example 83. The prosthetic valve of any example herein, particularly any of examples 81-82, wherein the stopper is positioned between the first post and the second post.

[0247] Example 84. The prosthetic valve of any example herein, particularly any of examples 78-83, wherein the securing pin has a length, the stopper has an outer diameter, and the length of the pin is less than the outer diameter of the stopper.

[0248] Example 85. The prosthetic valve of any example herein, particularly example 84, wherein the outer diameter of the stopper is 0.8 mm or less.

[0249] Example 86. The prosthetic valve of any example herein, particularly any of examples 78-85, wherein the stopper has a height that is 0.5 mm or less.

[0250] Example 87. The prosthetic valve of any example herein, particularly any of examples 78-86, wherein the stopper comprises a biocompatible material.

[0251] Example 88. The prosthetic valve of any example herein, particularly example 87, wherein the biocompatible material is a cobalt-chromium alloy.

[0252] Example 89. The prosthetic valve of any example herein, particularly example 87, wherein the biocompatible material comprises polyether ether ketone, teflon, polyethylenimine, or a combination thereof.

[0253] Example 90. The prosthetic valve of any example herein, particularly any of examples 78-89, wherein the securing pin has a diameter ranging from 0.2 mm to 0.4 mm.

[0254] Example 91. The prosthetic valve of any example herein, particularly any of examples 78-90, wherein rotation of the actuation member in one direction produces translation in a second axial direction opposite the first axial direction with the securing pin bearing against the stopper and urging the stopper to translate relative to the actuation member.

[0255] Example 92. The prosthetic valve of any example herein, particularly any of examples 78-91, wherein the actuation member comprises a head portion that is configured to be releasably connected to a component of a delivery apparatus actuator.

[0256] Example 93. The prosthetic valve of any example herein, particularly example 92, wherein the head portion is driveable in rotation to extend and retract threadedly engaged components of the actuation assembly to radially expand and radially compress the frame.

[0257] Example 94. The prosthetic valve of any example herein, particularly any of examples 78-93, wherein the prosthetic heart valve comprises two or more actuation assemblies, each operatively coupled to the frame and rotatable in a first rotational direction to produce radial expansion of the frame from a radially compressed state to a radially expanded state and rotatable in a second rotational direction to produce radial compression of the frame from the radially expanded state to the radially compressed state.

[0258] Example 95. A prosthetic valve, comprising a radially expandable frame comprising a vertically oriented first strut and a vertically oriented second strut, wherein the frame is radially expandable between a radially compressed state and a radially expanded state; a valvular structure disposed within the frame and configured to regulate the flow of blood through the frame in one direction; and at least one an actuation assembly operatively coupled to the frame, comprising an actuation member, a stopper positioned on the actuation member, and a protrusion extending from an outer surface of the actuation member; wherein bores in the first strut and in the second strut are dimensioned to receive portions of the actuation member; wherein the stopper is positioned between the first strut and the second strut, and the axial movement of the stopper along the actuation member is limited in at least one direction by the protrusion; and wherein the actuation member is rotatable in a first direction to move axially with the protrusion contacting the stopper to urge the first strut away from the second strut, thereby radially compressing the frame.

[0259] Example 96. The prosthetic valve of any example herein, particularly example 95, wherein the first strut comprises a window, the actuation assembly further comprises a nut positioned in the window and the actuation member comprises an externally threaded end portion that engages with the nut.

[0260] Example 97. The prosthetic valve of any example herein, particularly any of examples 95-96, wherein the actuation member comprises a lateral bore to receive the securing pin.

[0261] Example 98. The prosthetic valve of any example herein, particularly any of examples 95-97, wherein the protrusion is configured to withstand an axially oriented force of at least 40 N.

[0262] Example 99. The prosthetic valve of any example herein, particularly any of examples 95-98, wherein the actuation member is configured to withstand a tensile stress of at least 400 MPa.

[0263] Example 100. The prosthetic valve of any example herein, particularly any of examples 95-99, wherein the protrusion comprises a biocompatible material.

[0264] Example 101. The prosthetic valve of any example herein, particularly example 100, wherein the biocompatible material is biocompatible metal alloy or biocompatible polymer.

[0265] Example 102. The prosthetic valve of any example herein, particularly any of examples 95-101, wherein the protrusion is positioned between the stopper and the first post.

[0266] Example 103. The prosthetic valve of any example herein, particularly any of examples 95-102, wherein the actuation member comprises a head portion that is configured to be releasably connected to a component of a delivery apparatus actuator.

[0267] Example 104. The prosthetic valve of any example herein, particularly any of examples 95-103, wherein the prosthetic valve comprises two or more actuation assemblies, each operatively coupled to the frame and rotatable in a first rotational direction to produce radial expansion of the frame from a radially compressed state to a radially expanded state and rotatable in a second rotational direction to produce radial compression of the frame from the radially expanded state to the radially compressed state.

[0268] Example 105. A medical assembly, comprising a radially expandable frame having a first frame end portion, a second frame end portion, and a longitudinal axis extending between the first end and the second end; and at least one actuation assembly extending longitudinally from the first frame end portion towards the second frame end portion to interconnect first and second portions of the frame, the actuation assembly comprising an actuation member having a first end portion with a head portion adjacent the first frame end and an externally threaded second end portion, a stopper disposed around the actuation member, and a securing pin extending through the actuation member transverse to the longitudinal axis; wherein the securing pin is configured to limit the movement of the stopper along the longitudinal axis in at least one direction; wherein the stopper is configured to limit the movement of the actuation member along the longitudinal axis in at least one direction; and wherein the actuation member is rotatable in a first rotational direction to produce radial expansion of the frame from a radially compressed state to a radially expanded state and rotatable in a second rotational direction to produce radial compression of the frame from the radially expanded state to the radially compressed state.

[0269] Example 106. The medical assembly of any example herein, particularly example 105, wherein the first end portion of the frame comprises a first post extending along the longitudinal axis from the first end portion towards the second end portion and the second end portion of the frame comprises a second post extending from the second end portion towards the first end portion of the frame, and wherein the actuation member has an exposed segment extending between the first post and the second post.

[0270] Example 107. The medical assembly of any example herein, particularly example 106, wherein the stopper is positioned between the first post and the second post and configured to contact an end portion of the second post as the frame is radially compressed from the radially expanded state to the radially compressed state.

[0271] Example 108. The medical assembly of any example herein, particularly example 107, wherein the securing pin is positioned between the stopper and the first post.

[0272] Example 109. The medical assembly of any example herein, particularly any of examples 105-108, wherein the securing pin extends through a bore in the actuation member.

[0273] Example 110. The medical assembly of any example herein, particularly any of examples 105-108, wherein the securing pin is integrally formed with the actuation member.

[0274] Example 111. The medical assembly of any example herein, particularly any of examples 105-110, wherein the head portion is releasably connectable to a component of a delivery apparatus actuator.

[0275] Example 112. The medical assembly of any example herein, particularly any of examples 105-111, further comprising a valvular structure disposed within frame and configured to permit the flow of blood along the longitudinal axis in a first axial direction and to restrict the flow of blood along the longitudinal axis in a second axial direction opposite to the first axial direction.

[0276] Example 113. The medical assembly, frame, prosthetic heart valve, valvular structure, or delivery device of any example herein, particularly any of examples 1-112, wherein the medical assembly, frame, prosthetic heart valve, valvular structure, or delivery device is sterilized.

[0277] In view of the many possible embodiments to 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 or the claims. Rather, the scope of the claimed subject matter is defined by the following claims and their equivalents.

1. A prosthetic valve, comprising:

a radially expandable frame comprising a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state;

a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction; and

at least one an actuation assembly operatively coupled to the frame, wherein the actuation assembly comprises first and second bolts aligned end-to-end relative to each other, wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, wherein the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state.

2. The prosthetic valve of claim **1**, wherein the second bolt comprises a threaded bore in the adjacent end portion of the second bolt, wherein a threaded section of the end portion of the first bolt is tightened into the threaded bore of the second bolt.

3. The prosthetic valve of claim **1**, wherein a pin extends through the end portion of the first bolt and the adjacent end portion of the second bolt.

4. The prosthetic valve of claim **1**, wherein the frame comprises at least one vertically oriented post with a channel extending therethrough, and wherein the first bolt extends through the channel.

5. The prosthetic valve of claim **4**, further comprising a washer disposed between the second bolt and the vertically oriented post, wherein the washer has an aperture and the end portion of the first bolt extends through the aperture.

6. The prosthetic valve of claim **5**, wherein the washer further comprises an annular sleeve disposed around the aperture and extending axially into the channel.

7. The prosthetic valve of claim **1**, wherein the first bolt has a first diameter and the second bolt has a second diameter, wherein the second diameter is greater than the first diameter.

8. The prosthetic valve of claim **1**, wherein the diameter of the first bolt is less than or equal to 0.55 mm.

9. The prosthetic valve of claim **1**, wherein the diameter of the second bolt is greater than or equal to 0.6 mm.

10. The prosthetic valve of claim **1**, wherein a head portion of the first bolt is configured to be releasably connected to a component of a delivery apparatus actuator.

11. A prosthetic heart valve, comprising

a radially expandable frame comprising a plurality of interconnected struts, wherein the frame is radially expandable between a radially compressed state and a radially expanded state;

a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction;

at least one an actuation assembly operatively coupled to the frame; and

at least one nut coupled to the actuation assembly; and

wherein the actuation assembly comprises first and second bolts aligned end-to-end relative to each other, wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, wherein the second bolt comprises a threaded portion that extends through and engages internal threads of the nut, wherein the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state.

12. The prosthetic heart valve of claim **11**, further comprising a bore in one strut of the plurality of interconnected struts, which receives a component of the actuation assembly.

13. The prosthetic heart valve of claim **12**, wherein the bore further comprises a window configured to receive the nut.

14. The prosthetic heart valve of claim **11**, wherein a pin extends through an end portion of the first bolt and the adjacent end portion of the second bolt.

15. The prosthetic heart valve of claim **11**, wherein the frame comprises a first axially oriented post and a second axially oriented post, wherein the first axially oriented post and the second axially oriented post are axially aligned with each other, wherein a bore extends axially through both the first axially oriented post and the second axially oriented post and receives the first and second bolts.

16. The prosthetic heart valve of claim **11**, wherein the first bolt has a first diameter, the second bolt has a second diameter, and the second diameter is greater than the first diameter.

17. A prosthetic heart valve, comprising:

a frame having a first end, a second end, and a longitudinal axis extending between the first end and the second end, wherein the frame is radially expandable between a radially compressed state and a radially expanded state, and wherein the frame comprises a plurality of vertical posts extending parallel to the longitudinal axis and a plurality of angled struts arranged in circumferentially extending rows of angled struts;

a valvular structure disposed within frame and configured to regulate the flow of blood through the frame in one direction;

at least one actuation assembly comprising a first bolt and a second bolt aligned end-to-end, wherein the first bolt extends through a channel in a first vertical post of the plurality of vertical post wherein an end portion of the first bolt is coupled to an adjacent end portion of the second bolt, and wherein the first and second bolts are rotatable together in a first rotational direction to produce radial expansion of the frame from the radially compressed state to the radially expanded state; and

a washer disposed between the adjacent end portion of the second bolt and the first vertical post.

18. The prosthetic heart valve of claim **17**, wherein the washer comprises an annular sleeve portion extending axially into the channel in the first vertical post.

19. The prosthetic heart valve of claim **17**, wherein the second bolt comprises a threaded bore in the adjacent end portion of the second bolt, wherein a threaded section of the end portion of the first bolt is tightened into the threaded bore of the second bolt.

20. The prosthetic heart valve of claim **17**, wherein the first bolt has a first diameter and the second bolt has a second diameter larger than the first diameter.

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