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United States Patent	12390330
Kind Code	B2
Date of Patent	August 19, 2025
Inventor(s)	Cohen; Oren et al.

Force limiting mechanism for prosthetic heart valve delivery apparatus

Abstract

A medical assembly can include a radially expandable prosthetic heart valve and a delivery apparatus. The delivery apparatus can include a handle, an actuation member, and a force limiting mechanism within the handle including a pivot arm coupled to a base portion. The actuation member can apply a proximally directed force to the prosthetic valve to cause the valve to expand. The actuation member can be coupled to the pivot arm such that a force applied to the actuation member causes the pivot arm to pivot. The force limiting mechanism can pinch the actuation member between the pivot arm and the base portion when the force applied to the actuation member exceeds a predetermined force to prevent proximal movement of the actuation member and can allow proximal movement of the actuation member to produce radial expansion of the prosthetic valve when the force applied is less than the predetermined force.

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Appl. No.: **17/553688**

Filed: **December 16, 2021**

Prior Publication Data

Document Identifier	Publication Date
US 20220104944 A1	Apr. 07, 2022

Related U.S. Application Data

continuation parent-doc WO PCT/US2020/040323 20200630 PENDING child-doc US 17553688

us-provisional-application US 62870372 20190703

Publication Classification

Int. Cl.: **A61F2/24** (20060101); **A61F2/95** (20130101)

U.S. Cl.:

CPC **A61F2/2439** (20130101); **A61F2/2418** (20130101); **A61F2/243** (20130101); **A61F2/2436** (20130101); A61F2/9517 (20200501)

Field of Classification Search

CPC: A61F (2/2439); A61F (2/2418); A61F (2/243); A61F (2/2436); A61F (2/9517); A61F (2/962)

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION (1) This application is a continuation of PCT Patent Application No. PCT/US2020/040323, filed Jun. 30, 2020, which claims the benefit of U.S. Provisional Patent Application No. 62/870,372, filed Jul. 3, 2019, all of which applications are incorporated herein by reference.

FIELD
(1) The present disclosure relates to mechanisms for limiting the amount of force that can be applied to implantable, expandable prosthetic devices, such as prosthetic heart valves.
BACKGROUND
(2) The human heart can suffer from various valvular diseases. These valvular diseases can result in significant malfunctioning of the heart and ultimately require repair of the native valve or

replacement of the native valve with an artificial valve. There are a number of known repair devices (e.g., stents) and artificial valves, as well as a number of known methods of implanting these devices and valves in humans. Percutaneous and minimally-invasive surgical approaches are used in various procedures to deliver prosthetic medical devices to locations inside the body that are not readily accessible by surgery or where access without surgery is desirable. In one specific example, a prosthetic heart valve can be mounted in a crimped state on the distal end of a delivery device and advanced through the patient's vasculature (e.g., through a femoral artery and the aorta) until the prosthetic valve reaches the implantation site in the heart. The prosthetic 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 valve, or by deploying the prosthetic valve from a sheath of the delivery device so that the prosthetic valve can self-expand to its functional size.

(3) Prosthetic valves that rely on a mechanical actuator for expansion can be referred to as “mechanically expandable” prosthetic heart valves. The actuator typically takes the form of pull cables, sutures, wires and/or shafts that are configured to transmit expansion forces from a handle of the delivery apparatus to the prosthetic valve. When deploying a prosthetic valve, it is important to avoid exerting excessive radial force on the native annulus of the patient, which can rupture the native heart valve annulus.

SUMMARY

(4) Described herein are embodiments of force limiting mechanisms for use with delivery assemblies that implant prosthetic devices. The force limiting mechanisms are primarily intended to limit the amount of force that can be applied to implantable, expandable prosthetic devices, such as prosthetic heart valves.

(5) In a representative embodiment, a medical assembly can comprise a prosthetic heart valve and a delivery apparatus. The prosthetic heart valve can be radially expandable and compressible between a radially compressed configuration and a radially expanded configuration. The delivery apparatus can comprise a handle, at least one actuation member, and a force limiting mechanism. The actuation member can extend from the handle and can be coupled to the prosthetic valve. The actuation member can be configured to apply a proximally directed force to the prosthetic valve to cause the prosthetic valve to foreshorten axially and expand radially. The force limiting mechanism can be positioned within the handle and can comprise a pivot arm and a base portion. The pivot arm can be pivotably coupled to the base portion. The actuation member can be movably coupled to the pivot arm such that a force applied to the actuation member causes the pivot arm to pivot relative to the base portion. The force limiting mechanism can be configured to pinch the actuation member between the pivot arm and the base portion when the force applied to the actuation member exceeds a predetermined force, thereby preventing proximal movement of the actuation member. The force limiting member can permit proximal movement of the actuation member to produce radial expansion of the prosthetic valve when the force applied to the actuation member is less than the predetermined force.

(6) In some embodiments, the pivot arm can be pivotably coupled to the base portion by a pin extending through a first end portion of the pivot arm and the base portion.

(7) In some embodiments, the actuation member can extend around a pulley mounted on the arm. The pulley can pivot with the pivot arm upon application of the force to the actuation member. In some embodiments, the actuation member can extend between the arm and the base portion.

(8) In some embodiments, the pulley can comprise a first pulley and the actuation member can further extend around a second pulley coupled to the handle and spaced from the pivot arm. In some embodiments, the second pulley can be positioned proximal to the pivot arm. In some embodiments, the base portion is connected to a first side of the handle and the second pulley is connected to a second side of the handle, the second side opposite the first side.

(9) In some embodiments, the force limiting mechanism can further comprise a biasing member

configured to exert a biasing force against the pivot arm. The biasing force can be selected such that when the force applied to the actuation member is less than the predetermined force, the pivot arm is prevented from pivoting against the biasing force, and when the force applied to the actuation member exceeds the predetermined force, the pivot arm pivots relative to the base portion.

(10) In some embodiments, the biasing member can comprise a spring that is linearly expandable between a compressed configuration and an expanded configuration. One end portion of the spring can be coupled to the pivot arm and the other end portion of the spring can be coupled to the handle. In some embodiments, the spring can be configured such that a proximally directed force applied to the actuation member causes an expansion force to be applied to the spring.

(11) In some embodiments, the spring can be configured such that, when the spring is in the compressed configuration, when the force applied to the actuation member is less than the predetermined force, the spring remains in the compressed configuration, and when the force applied to the actuation member exceeds the predetermined force, the spring expands to the expanded configuration.

(12) In some embodiments, the spring can be configured such that, when the spring is in the expanded configuration, additional force greater than the predetermined force applied to the actuation member further pinches the actuation member between the pivot arm and the base portion, and when the force is removed from the actuation member, the spring contracts to the compressed configuration, which causes the pivot arm to pivot relative to the base portion such that the actuation member is released from between the pivot arm and the base portion.

(13) In some embodiments, the force limiting mechanism can further comprise an adjustment mechanism configured to adjust the predetermined force.

(14) In some embodiments, the adjustment mechanism can comprise an adjustment screw comprising a threaded portion that extends through the handle and is coupled to the biasing member. The adjustment screw can further comprise a screw head coupled to the threaded portion, the screw head arranged outside of the handle. The handle can include an internally threaded portion secured to an internal surface of the handle, the threaded portion having an internally threaded surface configured to engage with the threaded portion of the adjustment screw. In some embodiments, the adjustment screw is rotatable in a first direction which moves the adjustment screw further outside of the handle, pre-expands the biasing member, and increases the predetermined force. In some embodiments, the adjustment screw is rotatable in a second direction, opposite the first direction, which moves the adjustment screw into the handle and toward the pivot arm, moves the biasing member to a more relaxed state or a fully relaxed state, and decreases the predetermined force.

(15) In some embodiments, the pivot arm is pivotably coupled to the base portion by a pivot element extending through a first end portion of the pivot arm and the base portion and the adjustment mechanism comprises a sliding element arranged within the pivot arm and coupled to the pivot element, the pivot element arranged within an elongate slot extending from the first end portion of the pivot arm, toward a second end portion of the pivot arm, the pivot element configured to slide along the slot in response to movement of the sliding element within the pivot arm. A position of the pivot element can determine a pivot point of the pivot arm and an arc length through which the pivot arm pivots in order to pinch the actuation member. In some embodiments, the sliding element includes an opening arranged around a rail coupled to the pivot arm, the sliding element configured to slide along the rail. Further, in some embodiments, the sliding element includes a threaded opening engaged with threads of a screw coupled to the pivot arm, the screw configured to rotate and cause linear translation of the sliding element along the rail and corresponding linear translation of the pivot element within the slot.

(16) In some embodiments, the actuation member is one of a flexible cable, a suture, a wire, a cord, a flexible rod, and a flexible shaft.

(17) In some embodiments, the delivery apparatus comprises a plurality of actuation members and a plurality of force liming mechanisms, wherein each force limiting mechanism is configured to interface with a corresponding one of the plurality of actuation members.
(18) In some embodiments, the prosthetic heart valve is a mechanically expandable prosthetic heart valve including a plurality of interconnected struts, wherein the struts are pivotably coupled to one another at one or more pivot joints arranged along a length of each strut.
(19) In another representative embodiment, a delivery apparatus for an implantable medical device can comprise a handle, at least one actuation member, and a force limiting mechanism within the handle. The actuation member can extend from the handle and can be coupled to the medical device. The actuation member can be configured to apply a proximally directed force to the medical device. The force limiting mechanism can comprise a pivot arm configured to limit the amount of proximally directed force that can be applied by the actuation member to the medical device.
(20) In some embodiments, the pivot arm can be configured to prevent the actuation member from applying a proximally directed force to the medical device if a proximally directed force greater than a predetermined threshold is applied to the actuation member.
(21) In some embodiments, the force limiting mechanism can further comprise a base portion and the pivot arm can be configured to pivot and retain the actuation member between the pivot arm and the base portion if a proximally directed force greater than the predetermined threshold is applied to the actuation member.
(22) In some embodiments, the force limiting mechanism can further comprise a biasing member. The biasing member can be configured to exert a biasing force against the pivot arm and prevent pivoting of the arm if the proximally directed force applied to the actuation member is less than the predetermined threshold and permit pivoting of the pivot arm if the proximally directed force applied to the actuation member exceeds the predetermined threshold. In some embodiments, the biasing member can comprise a spring.
(23) In some embodiments, the force limiting mechanism further comprises an adjustment screw including a threaded portion in threaded engagement with an internally threaded portion of the handle, where a first end of the threaded portion is coupled to the biasing member and a second end of the threaded portion is configured to be rotated in a first direction that increases the biasing force and an opposite, second direction that decreases the biasing force.
(24) In some embodiments, the pivot arm includes an adjustable pivot element about which the pivot arm pivots relative to the base portion and the pivot element is configured to slide within an elongated slot of the pivot arm extending from a first end portion toward a second end portion of the pivot arm, in response to linear translation of a sliding element coupled to the pivot element and in sliding engagement with a portion of the pivot arm, in order to adjust a position of a pivot point of the pivot arm. In some embodiments, the sliding element is further coupled to a threaded portion of a screw arranged within the pivot arm via a threaded opening of the sliding element and the screw is rotatable to adjust a linear position of the sliding element within the pivot arm, between the first end portion and a location arranged between the first end portion and the second end portion, and correspondingly adjust the linear position of the pivot element within the elongated slot.
(25) In some embodiments, the force limiting mechanism can further comprise a pulley mounted on the pivot arm and the actuation member can be routed at least partially around the pulley. In some embodiments, the actuation member can comprise a cable.
(26) In some embodiments, the actuation member can be configured to produce radial expansion of the medical device upon application of the proximally directed force to the actuation member. In some embodiments, the actuation member can be configured to produce radial compression of the medical device upon application of the proximally directed force to the actuation member.
(27) In some embodiments, the medical device is a mechanically expandable prosthetic heart valve

including a plurality of interconnected struts, wherein the struts are pivotably coupled to one another at one or more pivot joints arranged along a length of each strut

(28) A representative method of implanting a prosthetic heart valve can comprise inserting into the body of a patient a distal end portion of a delivery apparatus and a prosthetic heart valve coupled to the distal end portion of the delivery apparatus in a radially compressed configuration, advancing the delivery apparatus distally until the prosthetic valve is disposed at a selected implantation site, and radially expanding the prosthetic valve. The delivery apparatus can comprise a handle, at least one actuation member, and a force limiting mechanism. The actuation member can extend from the handle and be coupled to the prosthetic valve and can be configured to apply a proximally directed force to the prosthetic valve to cause the valve to foreshorten axially and expand radially. The force limiting mechanism can be configured to limit the amount of proximally directed force that can be applied by the actuation member to the prosthetic valve. The prosthetic valve can be radially expanded by applying a proximally directed force to the actuation member so as to move the actuation member relative to the force limiting mechanism.

(29) In some embodiments, the method can further comprise, when the proximally directed force applied to the at least one actuation member exceeds a predetermined force during the radially expanding the prosthetic valve, arresting movement of the at least one actuation member with the force limiting mechanism. Additionally, the method can further comprise, in response to the proximally directed force applied to the at least one actuation member exceeding the predetermined force, decreasing the amount of proximally directed force applied to the at least one actuation member so that it is less than the predetermined force, and then further moving the at least one actuation member relative to the force limiting mechanism. In some embodiments, arresting movement of the at least one actuation member with the force limiting mechanism includes pivoting a first end portion of a pivot arm of the force limiting mechanism into engagement with the at least one actuation member and pinching the at least one actuation member between the first end portion and a base portion of the force liming mechanism to which the pivot arm is coupled. In some embodiments, further moving the at least one actuation member relative to the force limiting mechanism includes moving the first end portion of the pivot arm out of engagement with the at least one actuation member and allowing the at least one actuation member to slide relative to the pivot arm.

(30) In some embodiments, arresting movement of the at least one actuation member includes stopping radially expanding the prosthetic heart valve.

(31) Another representative method for limiting a force applied to an implantable medical device by an actuation member of a delivery apparatus can comprise applying a proximally directed force to the medical device with the actuation member, the actuation member coupled to the medical device and extending into a handle of the delivery apparatus. The method can further comprise, in response to the proximally directed force being less than a predetermined threshold, spacing a first end portion of a pivot arm of a force limiting mechanism of the delivery apparatus away from the actuation member and allowing the actuation member to continue to apply the proximally directed force to the medical device. The method can further comprise, in response to the proximally directed force being greater than the predetermined threshold, pivoting the first end portion of the pivot arm toward the actuation member and a base portion to which the pivot arm is coupled and configured to pivot around and pinching the actuation member between the first end portion of the pivot arm and the base portion to arrest movement of the actuation member.

(32) In some embodiments, applying the proximally directed force to the medical device includes radially expanding the medical device. In some embodiments, the medical device is a mechanically expandable prosthetic heart valve.

(33) In some embodiments, spacing the first end portion of the pivot arm away from the actuation member and allowing the actuation member to continue to apply the proximally direction force includes maintaining a second end portion of the pivot arm proximate to the base portion with a

biasing element coupled between the second end portion and an internal surface of the handle. In some embodiments, the biasing element is configured to remain in a compressed state when the proximally directed force is less that the predetermined threshold and expand into an expanded state when the proximally directed force is greater than the predetermined threshold, where in the expanded state, the second end portion pivots away from the base portion and the first end portion pivots into engagement with the actuation member to arrest movement of the actuation member.
(34) In some embodiments, pivoting the first end portion of the pivot arm toward the actuation member and pinching the actuation member between the first end portion and the base portion includes pivoting the pivot arm about a pivot element coupling the pivot arm to the base portion.
(35) In some embodiments, the method can further comprise adjusting a location of the pivot element, between the first end portion and the second end portion, to adjust an arc length through which the pivot arm pivots in order to pinch the actuation member and adjust the predetermined threshold. In some embodiments, adjusting the location of the pivot element includes sliding the pivot element within an elongated slot arranged in the pivot arm, the elongated slot extending between the first end portion of the pivot arm and a location between the first end portion and the second end portion.
(36) In some embodiments, the method can further comprise adjusting the predetermined threshold to adjust a maximum amount of force that can be applied to the medical device, during the applying the proximally directed force. In some embodiments, adjusting the predetermined force includes actuating an adjustment mechanism coupled to the biasing element to pre-expand the biasing member to increase a biasing force applied to the second end portion of the pivot arm and increase the predetermined threshold. In some embodiments, adjusting the predetermined threshold includes actuating the adjustment mechanism coupled to the biasing element to move the biasing member into a more relaxed or fully relaxed state to decrease the biasing force and decrease the predetermined threshold. In some embodiments, adjusting the predetermined threshold includes: rotating a screw coupled to an end of the biasing member and in threaded engagement with an inner surface of the handle in a first direction to move the screw away from an end of the biasing element coupled to the pivot arm and increase the predetermined threshold; and rotating the screw in an opposite, second direction to move the screw toward the end of the biasing element coupled to the pivot arm and decrease the predetermined threshold.
(37) The foregoing and other objects, features, and advantages of the invention will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) FIG. **1** is a perspective view of an exemplary embodiment of a prosthetic heart valve.
(2) FIG. **2** is a perspective view of a portion of another exemplary embodiment of a prosthetic heart valve.
(3) FIG. **3** is a side view of the frame of the prosthetic heart valve of FIG. **2** shown in a radially collapsed configuration.
(4) FIG. **4** is a side view of the prosthetic heart valve of FIG. **2** shown in a radially expanded configuration.
(5) FIG. **5** is an exemplary prosthetic valve delivery apparatus shown being used to implant the prosthetic heart valve of FIG. **2**.
(6) FIG. **6** is a side view of an exemplary force limiting mechanism of the delivery apparatus of FIG. **5**.
(7) FIG. **7** is another side view of the exemplary force limiting mechanism of FIG. **6**.

(8) FIG. **8** is another side view of the exemplary force limiting mechanism of FIG. **6**, shown partially in cross-section.
(9) FIG. **9** is another exemplary prosthetic valve delivery apparatus shown being used to implant the prosthetic heart valve of FIG. **2**.
(10) FIG. **10** shows a flow chart of an exemplary method for implanting the prosthetic heart valve of FIG. **2**.
(11) FIG. **11** is a side view of another exemplary force limiting mechanism.

DETAILED DESCRIPTION

(12) Described herein are embodiments of a method and apparatus to limit a force that can be applied to a radially expandable prosthetic device, such as a prosthetic heart valve. Disclosed embodiments include a method and apparatus that can limit an expansion force that can be applied to a prosthetic heart valve, such as during deployment of the prosthetic valve in the body. Prosthetic valves disclosed herein can be radially compressible and expandable between a radially compressed configuration and a radially expanded configuration. Thus, the prosthetic valves can be crimped on an implant delivery apparatus in the radially compressed configuration during delivery, and then expanded to the radially expanded configuration once the prosthetic valve reaches the implantation site.
(13) FIG. **1** shows an exemplary prosthetic valve **10**, according to one embodiment. The prosthetic valve **10** can be radially compressible and expandable between a radially compressed configuration for delivery into a patient (see e.g., FIG. **3**) and a radially expanded configuration (see e.g., FIGS. **1** and **4**). In particular embodiments, the prosthetic valve **10** can be implanted within the native aortic annulus, although it also can be implanted at other locations in the heart, including within the native mitral valve, the native pulmonary valve, and the native tricuspid valve. The prosthetic valve **10** can include an annular stent or frame **12** having a first end **14** and a second end **16**.
(14) In the depicted embodiments, the first end **14** is an inflow end and the second end **16** is an outflow end. The outflow end **16** can be coupled to a delivery apparatus for delivering and implanting the prosthetic valve within the native aortic valve in a transfemoral, retrograde delivery approach. In other embodiments, the inflow end **14** can be coupled to the delivery apparatus, depending on the particular native valve being replaced and the delivery technique that is used (e.g., transfemoral, transapical, etc.).
(15) The prosthetic valve **10** can also include a valvular structure **18** which is coupled to the frame **12** and configured to regulate the flow of blood through the prosthetic valve **10** from the inflow end to the outflow end. The prosthetic valve **10** can further include a plurality of actuators **20** mounted to and equally spaced around the inner surface of the frame **12**. Each of the actuators **20** can be configured to form a releasable connection with one or more respective actuators of a delivery apparatus, as further described below.
(16) The valvular structure **18** can include, for example, a leaflet assembly comprising one or more leaflets **22** (there are three leaflets **22** in the illustrated embodiment) made of a flexible material. The leaflets **22** of the leaflet assembly 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 **22** can be arranged to form commissures **24**, which can be, for example, mounted to respective actuators **20**. Further details regarding transcatheter prosthetic heart valves, including the manner in which the valvular structure can be coupled to the frame **12** of the prosthetic valve **10**, can be found, for example, in U.S. Pat. Nos. 6,730,118, 7,393,360, 7,510,575, 7,993,394, 8,652,202, and U.S. Patent Publication 2018/0325665, all of which are incorporated herein by reference in their entireties.
(17) In some embodiments, the prosthetic valve **10** can include a plurality of commissure support elements configured as commissure clasps or clamps **26**. In the illustrated configuration, the prosthetic valve **10** includes a commissure clamp **26** positioned at each commissure **24** and configured to grip adjacent portions of two leaflets **22** at each commissure **24** at a location spaced

radially inwardly of the frame **12**. Each clamp **26** can be mounted on an actuator **20** as shown. In alternative embodiments, the commissure support elements (such as clamps **26**) can be mounted to the struts **28** of the frame, or alternatively, the commissures **24** can be mounted (e.g., sutured) directly to the struts of the frame. Further details of the commissure clamps **26** and other techniques for mounting the commissures of a valve assembly to a frame can be found in U.S. Patent Publication No. 2018/0325665.

(18) Although not shown, the prosthetic valve **10** can also include one or more skirts or sealing members. For example, the prosthetic valve **10** can include an inner skirt mounted on the inner surface of the frame. The inner skirt can function as a sealing member to prevent or decrease perivalvular leakage, to anchor the leaflets **22** to the frame, and/or to protect the leaflets against damage caused by contact with the frame during crimping and during working cycles of the prosthetic valve. The prosthetic valve **10** can also include an outer skirt mounted on the outer surface of the frame **12**. The outer skirt can function as a sealing member for the prosthetic valve by sealing against the tissue of the native valve annulus and helping to reduce perivalvular leakage past the prosthetic valve. The inner and outer skirts can be formed from any of various suitable biocompatible materials, including any of various synthetic materials (e.g., polyethylene terephthalate (PET)) or natural tissue (e.g., pericardial tissue). The inner and outer skirts can be mounted to the frame using sutures, an adhesive, welding, and/or other means for attaching the skirts to the frame.

(19) The frame **12** can be made of any of various suitable materials, such as stainless steel, a cobalt chromium alloy, or a nickel titanium alloy ("NiTi"), for example Nitinol. Referring again to FIG. **1**, as shown, the frame **12** can include a plurality of interconnected struts **28** arranged in a lattice-type pattern. The struts **28** are shown as positioned diagonally, or offset at an angle relative to, and radially offset from, a longitudinal axis of the prosthetic valve **10** when the prosthetic valve is in the expanded configuration. In other implementations, the struts **28** can be offset by a different amount than depicted in FIG. **1**, or some or all of the struts **28** can be positioned parallel to the longitudinal axis of the prosthetic valve **10**.

(20) In the illustrated embodiment, the struts **28** are pivotably coupled to one another at one or more pivot joints along the length of each strut. For example, in the illustrated configuration, each of the struts **28** can be formed with apertures (see e.g., apertures **114** in FIG. **4**) at opposing ends of the strut and with apertures spaced along the length of the strut. Respective hinges can be formed at the locations where struts **28** overlap each other via fasteners or pivot members, such as rivets or pins **30** that extend through the apertures. The hinges can allow the struts **28** to pivot relative to one another as the frame **12** is radially expanded or compressed, such as during assembly, preparation, or implantation of the prosthetic valve **10**.

(21) In some embodiments, the frame **12** can be constructed by forming individual components (e.g., the struts and fasteners of the frame) and then mechanically assembling and connecting the individual components together. In other embodiments, the struts **28** are not coupled to each other with respective hinges but are otherwise pivotable or bendable relative to each other to permit radial expansion and contraction of the frame **12**. For example, the frame **12** can be formed (e.g., via laser cutting, electroforming or physical vapor deposition) from a single piece of material (e.g., a metal tube). Further details regarding the construction of the frame and the prosthetic valve are described in U.S. Patent Publication Nos. 2018/0153689, 2018/0344456, and 2019/0060057, all of which are incorporated herein by reference. Additional examples of expandable prosthetic valves that can be used with the delivery apparatuses disclosed herein are described in U.S. Pat. Nos. 9,700,442 and 9,827,093, which are incorporated herein by reference.

(22) Referring still to FIG. **1**, in some embodiments, the prosthetic valve **10** can comprise one or more actuators **20** configured to produce radial expansion and compression of the frame **12**. The one or more actuators in the illustrated embodiment comprise one or more push-pull mechanisms **32** coupled to the frame **12**. In the illustrated embodiment, the prosthetic valve **10** has three push-

pull mechanisms **32**, however, in other embodiments a greater or fewer number of push-pull mechanisms **32** can be used.

(23) Each push-pull mechanism **32** can generally comprise an inner member **34**, such as an inner tubular member, and an outer member **36** disposed about the inner member **34**. The inner members **34** and the outer members **36** can be movable longitudinally relative to each other in a telescoping manner to radially expand and contract the frame **12**, as further described in U.S. Patent Publications Nos. 2018/0153689 and 2018/0325665, which are incorporated herein by reference. The inner members **34** can be, for example, rods, cables, wires, or tubes. The outer members **36** can be, for example, tubes or sheaths having sufficient rigidity such that they can apply a distally directed force to the frame without bending or buckling.

(24) The inner members **34** can have distal end portions **34***a* coupled to the inflow end **14** of the frame **12** (e.g., with a coupling element such as a pin member **30**). In the illustrated embodiment, each of the inner members **34** are coupled to the frame at respective apices **38** at the inflow end **14** of the frame **12**. For example, the distal end portion **34***a* of each inner member **34** can be pivotably connected to the rivet or pin **30** that connects the two struts at the adjacent apex **38**. The outer members **36** can be coupled to apices **38** at the outflow end **16** of the frame **12** at, for example, a mid-portion of the outer member **36**, as shown in FIG. **1**, or at a proximal end portion of the outer member, as desired. The outer members **36** can be pivotably connected to the rivet or pin **30** that connects the two struts at the adjacent apex **38**.

(25) The inner member **34** and the outer member **36** can telescope relative to each other between a fully contracted state (corresponding to a fully radially expanded state of the prosthetic valve) and a fully extended state (corresponding to a fully radially compressed state of the prosthetic valve). In the fully extended state, the inner member **34** is fully extended from the outer member **36**. In this manner, the push-pull mechanisms **32** allow the prosthetic valve **10** to be fully expanded or partially expanded to different diameters and retain the prosthetic valve in the partially or fully expanded state.

(26) In use, a delivery apparatus can be releasably coupled to the push-pull mechanisms **32** of prosthetic valve **10**. For example, the delivery apparatus can have one or more actuator assemblies that are releasably coupled to respective push-pull mechanisms **32** of the prosthetic valve. The actuators of the delivery apparatus can be configured to transfer pushing and/or pulling forces from a handle of the delivery apparatus to the push-pull mechanisms **32** of the prosthetic valve. Each of the actuator assemblies of the delivery apparatus can include an inner member **42** that is releasably coupled to a respective inner member **34** of a push-pull mechanism **32**. Each actuator assembly of the delivery apparatus can also include an outer member (not shown) that is releasably coupled to a respective outer member **36** of a push-pull mechanism **32**.

(27) Once coupled to the delivery apparatus, the prosthetic valve **10** can then be radially collapsed (see e.g., FIG. **3**) and the distal end portion of the delivery apparatus, along with the radially collapsed valve, can be inserted into a patient. Once the prosthetic valve **10** is at the desired implantation site, the prosthetic valve can be radially expanded (see e.g., FIG. **4**). In some embodiments, as shown in FIG. **1**, the push-pull mechanisms **32** can comprise one or more locking mechanisms **40**, allowing the frame **12** to maintain an expanded diameter after the prosthetic valve is released from the delivery apparatus. Additional details of the locking mechanism can be found in U.S. Patent Publication No. 2018/0153689.

(28) FIG. **2** illustrates another embodiment of a prosthetic valve **100** comprising a frame **102**. The prosthetic valve **100** can include leaflets **18** and inner and/or outer skirts as previously described, although these components are omitted for purposes of illustration. The frame **102** comprises a plurality of struts **116** formed with apertures **114** (see FIG. **4**) and pivot members **118** (e.g., pins or rivets) connecting the struts to each other to form a plurality of pivot joints. The frame **102** can have the same construction as the frame **12**, except that the frame **102** includes struts **116** that are longer than struts **28** of frame **12**. The longer struts **116** form more pivot joints along the length of

each strut and more openings or cells of the frame compared to the struts **28**.
(29) The prosthetic valve **100** is configured to be releasably coupled to one or more actuator assemblies **205** of a delivery apparatus **200** (further described below) to produce radial expansion and compression of the frame **102**. To such ends, the prosthetic valve **100** can include one or more nuts or threaded sleeves **110** affixed to the frame **102**, such as at an inflow portion **104** of the frame **102**. The prosthetic valve **100** can further comprise one or more stoppers **112** affixed to the frame **102**, such as at an outflow portion **106** of the frame. In the illustrated embodiment, the sleeve **110** is circumferentially aligned with the stopper **112**. However, in other embodiments, the sleeve **110** can be circumferentially offset from the stopper **112**.
(30) The actuator assemblies **205** can be used to radially expand the prosthetic valve **100** from a radially compressed state to a radially expanded state at an implantation site within a patient's body, as further described below. In some embodiments, the prosthetic valve **100** can further include one or more locking mechanisms (not shown), for example, a locking screw and a nut, that maintain the prosthetic valve in an expanded configuration. After the frame **102** is expanded to a desired radially expanded size, the locking mechanism can be actuated or can self-actuate to lock the frame **102** in the desired radially expanded size. The actuator assemblies **205** can then be released from the prosthetic valve **100** and removed from the body. Further details of the actuator assemblies and the locking mechanism can be found in U.S. Patent Publication 2018/0153689.
(31) FIGS. **3-4** illustrate the bare frame **102** (without the leaflets and other components) of the prosthetic valve **100** for purposes of illustrating expansion of the prosthetic valve from the radially compressed configuration to the radially expanded configuration. FIG. **3** shows the frame **102** in the radially compressed configuration, and FIG. **4** shows the frame **102** in the fully radially expanded configuration. The prosthetic valve **100** in the illustrated configuration can be radially expanded by maintaining the first end **104** of the frame **102** at a fixed position while applying a force in the axial direction against the second end **106** toward the first end **104**. Alternatively, the prosthetic valve **100** can be expanded by applying an axial force against the first end **104** while maintaining the second end **106** at a fixed position, or by applying opposing axial forces to the first and second ends **104**, **106**, respectively.
(32) FIG. **5** illustrates a delivery apparatus **200**, according to one embodiment, adapted to deliver a prosthetic heart valve, such as the illustrated prosthetic heart valve **100**, described above. The prosthetic valve **100** can be releasably coupled to the delivery apparatus **200**, as further described below. 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.
(33) The delivery apparatus **200** in the illustrated embodiment generally includes a handle **202**, a first elongated shaft **204** (which comprises an outer shaft in the illustrated embodiment) extending distally from the handle **202**, at least one actuator assembly **205** extending distally through the outer shaft **204**, and a force limiting mechanism **210** within the handle **202**. The handle **202** and the force limiting mechanism **210** inside the handle is enlarged in FIG. **5** for purposes of illustration. The handle **202** typically has a diameter suitable to allow a user to grasp the handle with the user's hand. The at least one actuator assembly **205** can comprise an inner shaft **206** and an actuation member **208** extending through the inner shaft **206**. The inner shaft **206** can have a distal end portion **206***a* that extends distally beyond the distal end of the outer shaft **204**.
(34) In the illustrated embodiment, only one actuator assembly **205** is shown. However, the delivery apparatus **200** can include a plurality of actuator assemblies **205**, which can be circumferentially spaced apart from each other and can extend axially through the outer shaft **204** from the handle **202** to the prosthetic valve **100**. The prosthetic valve **100** can include a pair of a sleeve **110** and a stopper **112** for each actuator assembly **205**. Similarly, only one force limiting mechanism **210** is shown in the illustrated embodiment. However, in alternative embodiments, a force limiting mechanism **210** can be provided for each actuator assembly **205** where multiple

actuator assemblies are provided.
(35) In the following description, reference is made to a single actuator assembly **205**. However, it should be understood that the description also applies to each actuator assembly where multiple actuator assemblies are present. The actuation member **208** can extend through the handle **202**, and through the inner shaft **206** and can be coupled to a screw **212** at a distal end portion of the actuation member **208**. The screw **212** can be configured to be received in and threadably engage internal threads of the nut **110** so as to releasably couple the delivery apparatus **200** to the prosthetic valve **100**, as shown in FIG. **5**. As such, a proximally directed force applied to the actuation member **208** applies a proximally directed force to the distal end portion **104** of the prosthetic valve **100**.
(36) In some embodiments, as shown in FIG. **2**, the actuator assembly **205** can further comprise a cover tube **213** disposed around the actuation member **208** and extending through the inner shaft **206** from the prosthetic valve to the handle. The actuation member **208** can comprise any member configured to transfer a proximally directed pulling force from the handle **202** to the prosthetic valve **100** to produce radial expansion of the prosthetic valve **100**, as described above. The actuation member **208** desirably is sufficiently flexible so that it can be reeved around one or more pulleys of a force limiting mechanism **210**, as described in detail below. The actuation member **208** can comprise, for example, a flexible cable, a suture (e.g. a single filament suture or a multi-filament suture), a wire, a cord, a flexible rod, or a flexible shaft. In particular embodiments, actuation member **208** comprises a flexible cable formed from a plurality of helically twisted filaments or wires (e.g., metal wires or filaments).
(37) As further shown in FIG. **2**, the actuation member **208** and the cover tube **213** can extend through the stopper **112**. The inner shaft **206** can annularly surround the cover tube **213**. The stopper **112** can have an annular inner surface with an inner diameter larger than the outer diameter of the cover tube **213** and the screw **212** such that the cover tube **213** and the screw **212** can be retracted through the stopper **112** after the frame **102** is expanded and the delivery apparatus **200** is disconnected from the frame. The stopper **112** is sized to abut or engage the distal end **206***a* of the inner shaft **206** such that the inner shaft is prevented from moving distally beyond the stopper. The cover tube **213** facilitates passage of the screw **212** through the stopper **112**.
(38) Although the prosthetic valve **100** in the illustrated embodiment is shown as having only one pair of a nut **110** and a corresponding stopper **112** for coupling with a respective actuator assembly **205** of the delivery apparatus **200**, it should be understood that a pair of a nut **110** and a stopper **112** can be provided for each actuator assembly. Each pair of a nut **110** and a stopper **112** can be mounted to the frame **102** at circumferentially spaced apart locations.
(39) In some embodiments, the outer shaft **204** of the delivery apparatus **200** can be configured as a steerable guide catheter having an adjustable curvature for use in steering the delivery apparatus through a patient's vasculature. A steering or pull wire (not shown) can extend through the outer shaft **204** and can have a distal end fixed at a location along the distal section and a proximal end operatively connected to an adjustment mechanism, for example, a knob on the handle **202**. Further details of steering mechanisms that can be incorporated in the delivery apparatus can be found in U.S. Pat. Nos. 9,061,119 and 10,076,638, which are incorporated herein by reference.
(40) In some embodiments, the outer shaft **204** and the actuator assembly **205** can be moved relative to one another (axially and/or rotationally) to facilitate delivery and positioning of the prosthetic valve **100** at an implantation site in the patient's body. The handle **202** can include an adjustment mechanism configured to produce relative movement between the outer shaft **204** and the actuator assembly **205**. For example, the handle **202** can include a slidable or rotatable adjustment knob that is operatively connected to the actuator assembly **205** and configured to produce axial movement of the actuator assembly **205** in the proximal and distal directions relative to the outer shaft **204**.
(41) In some embodiments, the distal end portion of the outer shaft **204** can form a sheath that is

sized and shaped to receive and house the prosthetic valve **100** in a radially compressed state for delivery into and through a patient's vasculature. Once the prosthetic valve **100** is advanced to the implantation site or adjacent the implantation site, the prosthetic valve can be advanced from the outer shaft **204** by advancing the actuator assembly **205** relative to the outer shaft **204**, after which the prosthetic valve can be radially expanded. In alternative embodiments, the outer shaft **204** can be configured to move axially relative to the inner shaft **206** such as by operating a knob on the handle **202**. The knob can be operatively connected to the proximal end portion of the outer shaft **204** and can be configured to retract the outer shaft **204** proximally relative to the inner shaft **206** to deploy a prosthetic valve from the distal end of the sheath.

(42) As shown in FIG. **5**, a medical assembly can comprise the delivery apparatus **200** and the prosthetic valve **100** coupled to the distal end of the delivery apparatus. When the prosthetic valve **100** is coupled to the delivery apparatus **200**, the distal end portion **206***a* of the inner shaft **206** can abut a corresponding stopper **112** of the frame **102**. The stopper **112** is sized to prevent the inner shaft **206** from moving distally beyond the stopper **112**. When the distal end portion **206***a* of the inner shaft **206** abuts the stopper **112** of the frame **102** and a proximally directed force is applied to the actuation member **208**, the stopper **112** prevents the proximal end portion **106** of the frame **102** from moving while the distal end portion **104** of the frame **102** is moved proximally by the actuation member **208**, thereby causing the frame **102** to foreshorten axially and expand radially.

(43) As noted above, the screw **212** can be screwed into a corresponding nut **110** on the frame **102** to effectively couple the prosthetic valve **100** to the delivery apparatus **200**. Once the prosthetic valve **100** has been radially expanded at the desired implantation location, the screw **212** can be removed from the nut **110** by rotating the actuation member **208** to unscrew the screw **212** from the nut **110** so as to release the prosthetic valve from the delivery apparatus **200**. The stopper **112** can have an annular inner surface with an inner diameter larger than the outer diameter of the cover tube **213** and the screw **212** such that the actuation member **208**, the cover tube **213** and the screw **212** can be retracted through the stopper **112** after the frame **102** is expanded and the actuation member **208** is disconnected from the frame by unscrewing the screw **212** from the nut **110**.

(44) The proximal end portion of the actuation member **208** can be operatively connected to a control mechanism, such as a control knob on the handle **202**, that allows a doctor or operator of the delivery apparatus **200** to rotate the actuation member **208** (e.g., to unscrew the screw **212** from the nut **110**) and/or to pull the actuation member **208** axially relative to the inner shaft **206** to apply a proximally directed force to distal end portion **104** of the frame **102** during valve expansion. For example, the control knob can be a manually rotatable knob that is effective to pull the actuation member **208** proximally when rotated by a user. In another embodiment, the actuation member **208** can be operatively connected to a motor (which can be housed inside the handle **202**) that is operable to pull the actuation member **208** proximally when actuated by a user, such as by pressing a button or switch on the handle. The delivery apparatus can include another motor (which can be housed inside the handle **202** and actuated by a respective button or switch) to produce rotation of the actuation member **208** for disconnecting the screw **212** from the nut **110**.

(45) When expanding the prosthetic valve **100** by applying a proximally directed force to the distal end portion **104** of the frame **102** as described above, if too great a force is applied, it is possible to overload the patient's annulus, which risks annular rupture. It is also possible that applying too great of a force to the frame **102** can damage the components of the delivery apparatus **200**, which risks delivery system failure during an implantation procedure. Accordingly, it can be desirable to limit the amount of force that can be applied to the frame **102** while expanding the prosthetic valve **100**. The force limiting mechanism **210** can limit the amount of force that can be applied to expand the prosthetic valve **100**, as explained in further detail below, to limit these potential risks.

(46) Referring to FIG. **5**, the force limiting mechanism **210** can be located inside the handle **202** and can comprise a pivot arm **214** pivotably coupled to a base portion **216** for pivoting movement relative to the base portion. The base portion **216** can have an upper portion **218** and a lower

portion **224**. The lower portion **224** of the base portion **216** can be connected to a first side **226** of the handle **202** such that the position of the base portion **216** is fixed with respect to the handle **202**. The upper portion **218** of the base portion **216** can have two ears **215** that extend away from the lower portion **224** (FIGS. **6** and **7** show one ear of the upper portion **218**) such that the arm **214** can be positioned between the ears **215** of the upper portion **218**.

(47) The ears **215** of the upper portion **218** can each have an opening **219** through which a pin or pivot element **220** can be extended. A first end portion **222** of the arm **214** can have an opening extending therethrough that can be aligned with the openings **219** in the ears **215** of the upper portion **218** such that the pin **220** can extend through the ears **215** of the upper portion **218** and through the first end portion **222** of the arm **214**, thereby coupling the arm **214** to the base portion **216**. The pin **220** can create an axis about which the arm **214** can pivot. This axis can be orthogonal to a longitudinal axis of the prosthetic valve **100**.

(48) The force limiting mechanism **210** can further comprise a first pulley **228**, as best shown in FIG. **5**, coupled to a second end portion **232** of the arm **214** via a first pulley pin or shaft **230** that can extend through the second end portion **232** of the arm **214**. In the illustrated embodiment, the first pulley **228** is positioned within the interior of the arm **214** and is free to rotate around the pin **230** within the arm.

(49) In the illustrated embodiment, a second pulley **234** can be positioned within the handle **202** and can be laterally and axially offset from the arm **214** as shown in FIG. **5** (e.g., the second pulley **234** can be positioned proximal to the arm **214** and axially further from the base portion **216** than the arm **214**). A pulley support member **236** can be connected to a second side **240** of the handle **202**, opposite the first side **226**. A second pulley pin or shaft **238** can be connected to the support member **236** and can extend through the second pulley **234** such that the second pulley **234** is free to rotate around the second pulley pin **238**.

(50) In the illustrated embodiment, within the handle **202**, the actuation member **208** is routed underneath the arm **214** between the arm and the base portion **216**, partially around the first pulley **228** and partially around the second pulley **234**. The proximal end portion **208***p* of the actuation member **208**, proximal to the force limiting mechanism **210**, can then be routed and operatively connected to a control mechanism (e.g., a knob or motor) that can allow an operator of the delivery apparatus **200** to apply a proximally directed force to the actuation member **208** to expand the prosthetic valve **100**, as described above. Because of the routing of the actuation member **208** around the first and second pulleys **228**, **234**, when a proximally directed force is applied to the actuation member **208**, a pivoting force is applied to the arm **214** (that is, a force applied in a direction to cause the arm to pivot). This pivoting force can cause the arm **214** to pivot about the pin **220** in a first direction (in a counterclockwise direction in the orientation of FIGS. **5-8**) in the absence of countervailing forces.

(51) In some embodiments, the force limiting mechanism **210** can comprise one or more additional pulleys around which the actuation member **208** is routed within the handle **202**. In other embodiments, the force limiting mechanism **210** can comprise a single pulley around which the actuation member **208** is routed. For example, in a specific implementation, the second pulley **234** can be eliminated and the proximal end portion **208***p* of the actuation member can extend toward a control mechanism on or adjacent to the second side **240** of the handle.

(52) In alternative embodiments, the actuation member **208** can be routed around and slide relative to adjacent surfaces of the arm **214** and/or the handle **202** rather than one or both pulleys **228**, **234**. For example, in a specific implementation, in place of pulleys **228**, **234**, the actuation member **208** can be routed around curved surfaces on the arm **214** and the inside of the handle **202**.

(53) In the illustrated embodiment, the force limiting mechanism **210** can further comprise a biasing member, such as a coil spring **242**, configured to bias the pivoting arm **214** to a release position (the downward position shown in FIG. **6**; discussed further below). A first end portion of the spring **242** can be coupled to a spring base **244**, which is connected to the first side **226** of the

handle **202**. In particular embodiments, the first end portion of the spring **242** can comprise a first spring hook **245** that can be hooked onto a bar or pin (not shown) of the spring base **244** to connect the spring **242** to the spring base **244**. A second end portion of the spring **242** can be coupled to the second end portion **232** of the arm **214**. In particular embodiments, the second end portion of the spring **242** can comprise a hook **246**, as shown in FIG. **6**. The arm **214** can comprise a projection **248** that can extend from the second end portion **232** of the arm. The projection **248** can be connected to the arm **214** by a pin **250**. In particular embodiments, the hook **246** can extend around the projection **248**, thereby coupling the hook to the arm.

(54) The spring **242** can be an extension spring such that it remains in a contracted state, as shown in FIG. **6**, when no force is applied to it, and linearly expands to an expanded state, as shown in FIG. **7**, when a linear expansion force greater than a threshold amount is applied to it. Thus, the spring **242** can exert a biasing force on the second end portion **232** of the arm **214**. This biasing force can be selected to limit the amount of force that can be applied by the actuation member **208** to the prosthetic valve **100**, as explained below. In alternative embodiments, other types of springs and other types of biasing members can be used in lieu of the coil spring **242**, including, without limitation, a torsion spring, an elastic band, or other biasing means. When a torsion spring is utilized, it can be situated adjacent the pivot element **220** of the arm **214** and can have opposing end portions that bear against the arm **214** and the base portion **216**.

(55) When the actuation member **208** is pulled in a proximal direction with a force less than a predetermined threshold, a pivoting force is applied to the second end portion **232** of the arm **214**, as explained above. This, in turn, causes a linear expansion force to be applied to the spring **242**. However, the biasing force of the spring **242** can be selected such that when the force applied to the actuation member **208** is less than the threshold, the spring **242** remains in its contracted state, thereby preventing the arm **214** from pivoting and keeping the arm **214** in a first, release position as shown in FIG. **6**. In the release position, the actuation member **208** can move axially between the arm **214** and the base portion **216**, thereby applying a proximally directed force to the distal end portion **104** of the frame **102** and causing the frame to radially expand.

(56) When the actuation member **208** is pulled in a proximal direction with a force greater than the predetermined threshold, a greater upwardly directed force is applied to the second end portion **232** of the arm **214**, thereby causing a greater linear expansion force to be applied to the spring **242**. The biasing force of the spring **242** can be selected such that when the force applied to the actuation member **208** is greater than the predetermined threshold, the spring **242** expands to its expanded state. This allows the arm **214** to pivot to a second, engaged position, in which the actuation member **208** is pinched between the first end portion **222** of the arm **214** and an adjacent surface of the base portion **216**, as shown in FIGS. **7-8**. The force applied to the actuation member **208** by the first end portion **222** of the arm **214** prevents the actuation member from moving axially between the arm **214** and the base portion **216**, and thus prevents the frame **102** from further expansion.

(57) Once the spring **242** expands and the actuation member **208** is pinched between the arm **214** and the base portion **216**, additional proximally directed force applied to the actuation member **208** will create additional tension in the actuation member and will cause the arm **214** to pinch the actuation member tighter. This will increase the force preventing the actuation member **208** from axial movement between the arm **214** and the base portion **216**. When the tension in the actuation member **208** is released, the spring **242** can return to its compressed state. This causes the spring **242** to pull downwards on the second end portion **232** of the arm **214**, which causes the arm to pivot clockwise (in the orientation of FIGS. **5-8**) and return to the first, release position, as shown in FIG. **6**. In this position, the actuation member **208** is once again free to move in a proximal direction between the arm **214** and the base portion **216** to expand the prosthetic valve **100**. Thus, the force limiting mechanism **210** prevents excessive forces from being transferred along the length of the delivery apparatus **200** and to the prosthetic valve **100**, which can otherwise damage the

delivery apparatus and/or cause trauma to the patient. Additionally, by limiting the amount of force that can be applied to the actuation member **208**, the force limiting mechanism **210** assists the user in applying a constant force at a desired rate to the actuation member **208** so as to expand the prosthetic valve **100** at a desired expansion rate.

(58) In alternative embodiments, a biasing member can be coupled between the second end portion **232** of the arm **214** and the second side **240** of the handle **202**. For example, the biasing member can be a coil compression spring having one end that bears against an adjacent inner surface of the second side **240** of the handle **202** and another end that bears against an adjacent surface of the second end portion **232** of the arm **214**. The compression spring can apply a biasing force against the arm **214** that biases the arm toward the release position (FIG. **6**) and can become axially compressed when pivoted to the engaged position (FIG. **5**) by exerting a pulling force on the actuation member **208** that exceeds the predetermined threshold.

(59) FIG. **9** shows an exemplary embodiment of a delivery apparatus **400** comprising a force limiting mechanism **410**. The force limiting mechanism **410** allows a physician to adjust the maximum amount of force that can be applied to a radially expandable prosthetic device, as described below. Many of the elements of delivery apparatus **400** are the same as the elements of the delivery apparatus **200** and many of the elements of the force limiting mechanism **410** are the same as the elements of force limiting mechanism **210**. Accordingly, the same reference numbers used to describe the elements of the delivery apparatus **200** and the force limiting mechanism **210** are used to describe elements that are also present in the delivery apparatus **400** and the force limiting mechanism **410**.

(60) The force limiting mechanism **410** comprises the same elements as the force limiting mechanism **210** except that the force limiting mechanism **410** does not comprise a spring base **244** and instead comprises an adjustment member or mechanism, such as an adjustment screw **420**, configured to adjust the bias of the spring **242** as explained below. Adjusting the bias of the spring **242** can increase or decrease the maximum amount of force (also referred to herein as a predetermined threshold force) that can be applied to the prosthetic valve as described below. This can allow a physician to adjust the maximum radial force that can be applied by the prosthetic valve against the native annulus for each patient individually, which can be beneficial for patients that have a higher risk of annular rupture than others (e.g., based on calcification level, calcification distribution, calcification geometry, whether a bicuspid valve is present, and/or other factors).

(61) In particular embodiments, the adjustment screw **420** can comprise a screw head **422** and a threaded portion **424**. The screw head **422** can be positioned outside of the handle **202** and the threaded portion **424** can extend through an opening in the first side **226** of the handle and an internally threaded portion **426** adjacent the first side **226** of the handle. The threaded portion **426** can have an internally threaded surface that can engage the threaded portion **424** of the screw **420**. This can allow the adjustment screw **420** to be screwed into or out of the first side **226** of the handle **202**. The screw head **422** can have a textured outer surface, such as ridges, to aid a user in grasping and rotating it. The internally threaded portion **426** can be a nut that can be secured to an inner surface of the first side **226** of the handle.

(62) A first end portion of the threaded portion **424** of the screw **420** can be coupled to the first spring hook **245** at the first end portion of the spring **242**. In particular embodiments, the end portion of the threaded portion **424** adjacent the screw can have an opening through which the first spring hook **245** can extend. In other embodiments, the first spring hook **245** can be welded or otherwise coupled or connected to the threaded portion **424** of the adjustment screw **420** using other techniques and/or mechanisms.

(63) The second end portion of the spring **242** can be coupled to the pivot arm **214** by a swivel joint **428** configured to permit rotation of the spring relative to the pivot arm **214**. The swivel joint **428** comprises a female component configured as a socket **430** and a male component configured as a pin or shaft **432** having an enlarged end portion that is captured within the socket **430**. The second

end portion of the spring **242** (which can be in the shape of a hook, as shown) can be connected to the socket **430** (for example, the hook of the spring can extend through one or more openings in the socket). An upper portion of the shaft **432** can be connected to the second end portion **232** of the pivot arm **214** (e.g., the shaft **432** can be connected to the pin **250**). The interior of the socket **430** is sized to permit relative rotation between the socket **430** and the shaft **432**. This allows the screw **420** and the spring **242** to freely rotate relative to the pivot arm **214** upon adjustment of the screw, as described further below. In other embodiments, the lower end portion of the spring **242** can be coupled to the screw **420** via a respective swivel joint, or the upper and lower ends of the spring can be coupled to the pivot arm and the screw via respective swivel joints.

(64) In particular embodiments, the screw head **422** can be rotated to screw the adjustment screw **420** further into or out of the handle **202**. This can cause the first hook **245** and the first end portion of the spring **242** to move closer to or further away from the arm **214**, thereby pre-compressing or pre-expanding the spring, which in turn adjusts the amount of force required to actuate the pivot arm **214** and arrest further expansion of the prosthetic valve.

(65) Rotating the screw **420** in a first direction to move the screw further out of the handle pre-expands the spring **242** (e.g., from the relaxed state shown in FIG. **6**), which will then require the user to apply a greater force to the actuation member **208** to actuate the pivot arm **214**. The degree to which the adjustment screw is rotated influences the required pull force on the actuation member **208** to actuate the pivot arm. Specifically, a higher degree of rotation applied to the screw in the first direction produces a greater amount of pre-extension of the spring **242**, which in turn will require the user to apply a higher pull force on the actuation member **208** relative to a non-extended state of the spring. This, in turn, will enable the actuation member **208** to be pulled to a greater extent prior to being pinched to a full stop, thereby expanding the prosthetic valve to a larger outer diameter. In other words, adjusting the screw in this manner increases the maximum force that can be applied to the prosthetic valve via the actuation member **208**.

(66) Conversely, when the adjustment screw **420** is rotated in a second direction, opposite the first direction, the screw moves into the handle **202** toward the pivot arm **214**. If starting from a pre-expanded state of the spring, rotating the screw **420** in the second direction allows the spring to move toward a more relaxed state or the fully relaxed state shown in FIG. **6**, which in turn decreases the amount of force required to expand the spring **242** and move the pivot arm **214** to the engaged position. In other words, adjusting the screw in this manner decreases the maximum force that can be applied to the prosthetic valve via the actuation member **208**. Accordingly, the adjustment screw **420** can be used to adjust the threshold force needed to cause the spring **242** to expand and consequently, the maximum amount of force that can be applied to the prosthetic valve **100** by the actuation member **208**.

(67) In certain embodiments, further rotation of the adjustment screw **422** in the second direction when spring **242** is fully relaxed can cause the pivot arm **214** to pivot toward the engaged position (counterclockwise in the drawings) (the second end portion **232** of the pivot arm **214** moves closer to the first side **226** of the handle **202** and the first end portion **222** of the pivot arm moves closer to the base portion **216**). Thus, adjustment of the screw **422** in this manner positions the pivot arm at an intermediate position between the position shown in FIG. **6** and the position shown in FIG. **7**. The decreases the arc length through which the pivot arm pivots before pinching the actuation member **208**. As a result, this decreases the amount of spring expansion that occurs due to pivoting motion of the pivot arm, thereby decreasing the amount of force applied by the user to arrest further motion of the actuation member **208**.

(68) In this way, adjusting the adjustment screw **422**, or a similar adjustment mechanism, as described above, can adjust a predetermined threshold force exerted by the actuation member, thereby adjusting a maximum amount of force that can be applied to the prosthetic heart valve (or alternative implantable medical device). As explained herein, this adjusting can occur during an implantation procedure, during applying the proximally directed force to the prosthetic heart valve

via the actuation member. In some embodiments, adjusting the predetermined force can include actuating the adjustment screw **420** to pre-expand the biasing member (e.g., spring **242**) to increase a biasing force applied to the second end portion **232** of the pivot arm **214** and increase the predetermined threshold. In some embodiments, adjusting the predetermined threshold includes actuating the adjustment screw **420** to move the biasing member into a more relaxed or fully relaxed state to decrease the biasing force and decrease the predetermined threshold.

(69) In some embodiments, the adjustment screw **420** can be rotated continuously. In other embodiments, the screw **420** can be configured to be rotated in discreet steps. For example, in some embodiments, stop members can be provided for regulating the rotation of the screw **420**. Stop members can be, for example, moveable or removable pins or equivalent structures positioned to the handle to block rotation of the screw head **422** after a pre-determined amount of rotation. After the screw head comes into contact with a pin, the user can remove the pin or move it out of engagement with the screw head to permit further rotation of the screw.

(70) In some embodiments, the screw head **422** and/or a portion of the handle can include markings indicating pre-determined positions of the screw head that correspond to different force limits for the force limiting mechanism **410**, such as “low” (indicating a relatively low force is required to actuate the pivot arm), “medium” (indicating a medium or intermediate force is required to actuate the pivot arm), and “high” (indicating a relatively high force is required to actuate the pivot arm).

(71) In certain embodiments, the adjustment screw **420** can be adjusted manually by a doctor or other operator of the delivery apparatus **400**. In other embodiments, the adjustment screw **420** can be adjusted automatically by a motor (e.g., an electric motor) or other mechanism that is configured to adjust the position of the adjustment screw. For example, the delivery apparatus **400** can include a controller having a user interface. The controller can be integrated into the handle **202** or it can be a separate component from the handle that is in communication with the motor (which can be in the handle) via a wired or wireless connection. The user interface can have one or more buttons (physical buttons or icons on a touch screen) that allow the user to select the force limit of the force limiting mechanism **410**. Depending on the user input, the controller controls the motor to adjust the position of the adjustment screw **420** to either decrease or increase the bias of the spring **242** until the desired maximum force that can be applied to the prosthetic valve is achieved. In embodiments that include a motor to adjust the adjustment screw, the screw head **422** optionally can be eliminated or it can be disposed inside of the handle.

(72) In alternative embodiments, the force limiting mechanism **410** can comprise other mechanical and/or electrical mechanisms configured to pre-expand or pre-compress the spring **242**, thereby adjusting the maximum amount of force that can be applied to the prosthetic valve **100**. Such other mechanisms can comprise, for example, ratcheting mechanisms, rack-and-pinion mechanisms, a slidable piston, electrically operable displacement mechanisms, and the like, which can be operatively connected to the spring **242** in such a manner to adjust the tension in the spring **242**.

(73) In alternative embodiments, in lieu of or in addition to the screw **422**, another adjustment member can be connected to the second end portion **232** of the pivot arm **214** and can be configured to adjust the position of the pivot arm prior to expansion of the prosthetic valve. The adjustment member can be, for example, a string, tether, cable, rod, or a second spring, connected at one end to the second end portion **232** of the pivot arm **214** and extending toward the second side **240** of the handle **202**. The end of the another adjustment member opposite the pivot arm **214** can be connected to a knob or equivalent mechanism on the handle that is configured to tension or pull the adjustment member toward the second side **240** of the handle. In use, prior to expanding the prosthetic valve, the adjustment member can be adjusted (e.g., by tensioning or pulling it toward the second side **240** of the handle) which causes the second end portion **232** of the pivot arm to pivot towards the second side **240** of the handle, thereby bringing the pivot arm closer to the engaged position (e.g., the pivot arm is between the position shown in FIG. **6** and the position shown in FIG. **7**). As a result, when a force is applied to the actuation member **208** to expand the

prosthetic valve, the pivot arm **214** can pivot to the engaged position and arrest further expansion more quickly than if the pivot arm is closer to the position shown in FIG. **6**.

(74) In still alternative embodiments, the gap between the first end portion **222** of the pivot arm **214** and the upper surface of the base portion **216**, through which the actuation member **208** can pass, can be adjustable. Adjusting this gap can adjust the path of travel of the pivot arm between the release position and the engaged position. Reducing the gap can decrease the path of travel of the pivot arm **214**, thereby allowing the pivot arm to reach the engaged position under lower force. Conversely, increasing the gap can increase the path of travel of the pivot arm, and the force required for the pivot arm to reach the engaged position.

(75) FIG. **11** shows an exemplary embodiment of a force limiting mechanism **500** that has an adjustable hinge pin. Many of the elements of the force limiting mechanism **500** are the same as the elements of the force limiting mechanism **210**. Accordingly, the same reference numbers used to describe the elements of the force limiting mechanism **210** are used to describe elements that are also present in the force limiting mechanism **500**.

(76) The force limiting mechanism **500** can comprise a pivot arm **502**. The pivot arm **502** is similar to the pivot arm **214** except for the differences described herein. The pivot arm **500** can have a slot **504** in which the pivot element **220** can slide. The ends of the pivot element **220** can be supported in respective elongated slots (not shown) in the ears **215** of the base portion **216**. By moving the pivot element **220** along the length of the slot **504**, the pivot point of the arm **500** can be adjusted, thereby adjusting the arc length through which the arm pivots in order to pinch the actuation member **208**. This can change the amount of spring expansion that occurs before the pivot arm pinches the actuation member **208**.

(77) The arm **500** can further comprise a sliding element **506** that can slide along a length of the pivot arm relative to the slot **504**. The sliding element **506** can comprise a nut or threaded opening **508**. A screw **510** can extend through the nut **508** along an upper portion of the arm **502**. The screw **510** can have external threads that engage internal threads of the threaded opening **508**.

(78) A first end of the screw **510** can comprise a knob **512** that extends out of the first end portion **222** of the arm **502**. A second end of the screw **510** can comprise an enlarged screw head **514** captured within an opening **518** in the pivot arm that axially retains the screw **510** relative to the arm **502**. The arm **502** can also comprise a rail **516** that can extend along a lower portion of the arm **502** and through a respective opening **520** in the sliding element **208** such that the sliding element **506** can slide along the rail **516**. The pivot element **220** can be coupled to the sliding element **506** such that they move together relative to the slot **504** and the rail **516**. Thus, rotation of the knob **512** causes the sliding element **506** to move axially along the screw **510** and the pivot element **220** within the slot **504**.

(79) Rotation of the knob **512** in a first direction causes the pivot element **220** to move closer to the second end portion **232** of the pivot arm, which decreases the arc length through which the pivot arm pivots before pinching the actuation member **208**. This decreases the amount of spring expansion that occurs due to pivoting motion of the pivot arm, thereby decreasing the amount of force applied by the user to arrest further motion of the actuation member **208**. Conversely, rotation of the knob in a second direction, opposite the first direction, causes the pivot element to move closer to the first end portion **222** of the pivot arm, which increases the arc length through which the pivot arm pivots before pinching the actuation member **208**. This increases the amount of spring expansion that occurs due to pivoting motion of the pivot arm, thereby increasing the amount of force applied by the user to arrest further motion of the actuation member **208**.

(80) A representative method of implanting the prosthetic heart valve **100** using the delivery apparatus **200** can proceed in the following manner. The prosthetic valve **100** can be connected to delivery apparatus **200** as described above and compressed to a radially compressed state, and optionally placed in a sheath of the delivery apparatus (e.g., the distal end portion of the shaft **204**). The distal end portion of the delivery apparatus **200** (along with the prosthetic valve **100**) can be

advanced through a femoral artery and the aorta toward the native aortic valve **300**, as shown in FIG. **5**.

(81) Once the prosthetic valve **100** is at the desired implantation location, the prosthetic valve can be deployed by, for example, rotating a knob of the handle **202** to advance the prosthetic valve **100** from the sheath. To expand the prosthetic valve **100**, the inner shaft **206** can, for example, be advanced distally relative to the handle **202** or can be held against the stopper **112** while the actuation member **208** is pulled in a proximal direction. If too great a force is applied to the actuation member **208**, the force limiting mechanism **210** will prevent the actuation member from being pulled further, as described above. If this occurs, the user can release or decrease the pulling force applied to the actuation member **208**, allowing the force limiting mechanism **210** to release the actuation member. Additional expansion of the prosthetic valve **100** can then be achieved by again pulling the actuation member **208** in a proximal direction.

(82) FIG. **10** shows a flow chart **1000** of another representative method for expanding the prosthetic heart valve using the delivery apparatus **400**. The delivery apparatus **400** can be used to expand the prosthetic valve **100** until the diameter of the native anatomy is reached (block **1002**). Prior to valve expansion, the adjustment screw **420** can be pre-set to a value whereby the force limiting mechanism **410** prevents further expansion of the prosthetic valve **100** once the prosthetic valve comes into contact with the native annulus. For example, prior to valve expansion, the adjustment screw **420** can be used to set the force limiting mechanism **410** based on the patient's anatomy (e.g., calcification level, bi-cuspid valve, etc.). For patients with a high risk of annular rupture, the screw **420** can be used to set the force limitation mechanism **410** to a low force level. For patients with a relatively lower risk of annular rupture, the screw **420** can be used to set the force limitation mechanism **410** to a higher force level.

(83) In some cases, the physician can use the delivery apparatus to rapidly expand the prosthetic valve **100** until the force limiting mechanism **410** prevents further expansion. In other cases, the physician can expand the prosthetic valve at a relatively slower pace and monitor the hemodynamics of the prosthetic valve (e.g., paravalvular leakage and pressure gradient) and if the physician determines that the hemodynamics are satisfactory, the physician can cease further expansion before the force limiting mechanism **410** is ever actuated. Thus, in such cases, the physician may be able to complete the implantation process without the force limiting mechanism being actuated.

(84) If the force limiting mechanism is actuated, a paravalvular leak evaluation can then be performed (block **1004**), such as using echocardiography (e.g., transesophageal echocardiography or transaortic echocardiography). If there is any paravalvular leakage, the adjustment screw **420** can be adjusted to increase the maximum force that can be applied and the prosthetic valve **100** can be further expanded slowly until expansion is arrested by the force limiting mechanism (block **1008**). The user can then re-assess for paravalvular leaks (block **1004**) and if necessary, further adjust the adjustment screw and further expand the prosthetic valve. The process of checking for paravalvular leaks and further expanding the prosthetic valve can be repeated incrementally as desired until the proper sealing of the prosthetic valve with the native anatomy is achieved.

(85) If there is no paravalvular leakage, a pressure gradient evaluation can be performed (for example, by using echocardiography) (block **1010**). If the pressure gradient is acceptable (e.g., 2-3 mmHG or less), then expansion of the prosthetic valve **100** can be stopped (block **1014**) and the delivery apparatus can be released from the prosthetic valve and removed from the patient. If the pressure gradient needs to be decreased (e.g., it is 3 mmHg or higher), the adjustment screw **420** can be adjusted to increase the maximum force that can be applied and the prosthetic valve **100** can continue to be expanded slowly (block **1016**). Expansion of the prosthetic valve **100** can continue until either the pre-set maximum force limit is met. The user can then re-assess the pressure gradient and if necessary, further adjust the adjustment screw and further expand the prosthetic valve. The process of assessing the pressure gradient and further expanding the prosthetic valve can

be repeated incrementally as desired until the desired pressure gradient is achieved.
(86) Although the disclosed embodiments pertain generally to delivery apparatuses and methods for implantation of prosthetic heart valves in the native aortic valve, it should be understood that the disclosed embodiments can be used to implant prosthetic devices at any location of the heart or elsewhere in the body. Additionally, although the disclosed embodiments pertain generally to transfemoral delivery of prosthetic devices, it should be understood that the disclosed embodiments can be adapted for use with, for example, transapical procedures, transaortic procedures, trans-subclavian procedures, transradial procedures, or trans-septal procedures.
(87) Additionally, the force limiting mechanism **210** can be incorporated in various other types of delivery apparatuses to control the amount of force that can be applied to an actuation member. For example, known delivery apparatuses for self-expandable prosthetic valves typically have one or more actuation members in the form of sutures that extend around or through portions the prosthetic valve. The sutures (also referred to as tension members) are coupled to the prosthetic valve such that decreasing tension applied to the sutures allows the prosthetic valve or a portion thereof to self-expand to an expanded state, while increasing tension applied to the sutures radially compresses the prosthetic valve or a portion thereof to a compressed state. The sutures therefore can be used to control expansion of the prosthetic valve. One such example of a self-expandable prosthetic valve and a delivery apparatus that uses sutures to control expansion of the prosthetic valve is disclosed in U.S. Pat. No. 7,837,727, which is incorporated herein by reference. In particular embodiments, a delivery apparatus for a self-expandable prosthetic valve can include at least one actuation member (e.g., a suture) that controls expansion of the prosthetic valve and a force limiting mechanism **210** configured to limit the amount of force that can be applied to the actuation member when radially compressing the prosthetic valve.
(88) The force limiting mechanism **210** also can be incorporated into various other types of medical devices to control the amount of force that can be applied to an actuation member.
(89) General Considerations
(90) For purposes of this description, certain aspects, advantages, and novel features of the embodiments 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 embodiments, 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 embodiments require that any one or more specific advantages be present or problems be solved.
(91) Although the operations of some of the disclosed embodiments 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.
(92) All features described herein are independent of one another and, except where structurally impossible, can be used in combination with any other feature described herein. For example, a delivery apparatus **200** as shown in FIG. **5** can be used in combination with prosthetic valve **10**. In another embodiment, a locking mechanism as shown in FIG. **1** can be used in combination with the prosthetic valve **100** shown in FIG. **2**.
(93) 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.
(94) As used herein, the term “proximal” refers to a position, direction, or portion of a device that is closer to the user and further away from the implantation site. As used herein, the term “distal” refers to a position, direction, or portion of a device that is further away from the user and closer to the implantation site. Thus, for example, proximal motion of a device is motion of the device away from the implantation site and toward the user (e.g., out of the patient's body), while distal motion of the device is motion of the device away from the user and toward the implantation site (e.g., into the patient's body). The terms “longitudinal” and “axial” refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined.
(95) In view of the many possible embodiments to which the principles of the disclosed invention may be applied, it should be recognized that the illustrated embodiments are only preferred examples of the invention and should not be taken as limiting the scope of the invention. Rather, the scope of the invention is defined by the following claims. We therefore claim as our invention all that comes within the scope of these claims.

Claims

1. A medical assembly comprising: a prosthetic heart valve that is radially expandable and compressible between a radially compressed configuration and a radially expanded configuration; and a delivery apparatus comprising: a handle; at least one actuation member extending from the handle and coupled to the prosthetic heart valve, wherein the at least one actuation member is configured to apply a proximally directed force to the prosthetic heart valve to cause the prosthetic heart valve to foreshorten axially and expand radially; and a force limiting mechanism positioned within the handle and comprising a pivot arm and a base portion, wherein the pivot arm is pivotably coupled to the base portion, wherein the actuation member is movably coupled to the pivot arm such that a force applied to the actuation member causes the pivot arm to pivot relative to the base portion; wherein the force limiting mechanism is configured to pinch the at least one actuation member between the pivot arm and the base portion when the force applied to the at least one actuation member exceeds a predetermined force, thereby preventing proximal movement of the at least one actuation member, and wherein the force limiting mechanism permits proximal movement of the at least one actuation member to produce radial expansion of the prosthetic heart valve when the force applied to the at least one actuation member is less than the predetermined force.
2. The medical assembly of claim 1, wherein the at least one actuation member extends around a pulley mounted on the pivot arm, wherein the pulley can pivot with the pivot arm upon application of the force to the at least one actuation member, and wherein the at least one actuation member extends between the pivot arm and the base portion.
3. The medical assembly of claim 2, wherein the pulley comprises a first pulley and the at least one actuation member further extends around a second pulley coupled to the handle and spaced from the pivot arm, the second pulley positioned proximal to the pivot arm, and wherein the base portion is connected to a first side of the handle and the second pulley is connected to a second side of the handle, the second side opposite the first side.
4. The medical assembly of claim 1, wherein the force limiting mechanism further comprises a biasing member configured to exert a biasing force against the pivot arm, wherein the biasing force is selected such that: when the force applied to the at least one actuation member is less than the predetermined force, the pivot arm is prevented from pivoting relative to the base portion, against the biasing force; and when the force applied to the at least one actuation member exceeds the

predetermined force, the pivot arm pivots relative to the base portion.
5. The medical assembly of claim 4, wherein the biasing member comprises a spring that is linearly expandable between a compressed configuration and an expanded configuration, wherein one end portion of the spring is coupled to the pivot arm, wherein another end portion of the spring is coupled to the handle, and wherein the spring is configured such that a proximally directed force applied to the at least one actuation member causes an expansion force to be applied to the spring.
6. The medical assembly of claim 4, further comprising an adjustment mechanism configured to adjust the predetermined force, and wherein the adjustment mechanism comprises an adjustment screw comprising a threaded portion that extends through the handle and is coupled to the biasing member.
7. The medical assembly of claim 6, wherein the adjustment screw further comprises a screw head coupled to the threaded portion, the screw head arranged outside of the handle, wherein the handle includes an internally threaded portion secured to an internal surface of the handle, the internally threaded portion having an internally threaded surface configured to engage with the threaded portion of the adjustment screw, wherein the adjustment screw is rotatable in a first direction which moves the adjustment screw further outside of the handle, pre-expands the biasing member, and increases the predetermined force, and wherein the adjustment screw is rotatable in a second direction, opposite the first direction, which moves the adjustment screw into the handle and toward the pivot arm, moves the biasing member to a more relaxed state or a fully relaxed state, and decreases the predetermined force.
8. The medical assembly of claim 4, wherein the pivot arm is pivotably coupled to the base portion by a pivot element extending through a first end portion of the pivot arm and the base portion, further comprising an adjustment mechanism configured to adjust the predetermined force, and wherein the adjustment mechanism comprises a sliding element arranged within the pivot arm and coupled to the pivot element, the pivot element arranged within an elongate slot extending from the first end portion of the pivot arm, toward a second end portion of the pivot arm, the pivot element configured to slide along the slot in response to movement of the sliding element within the pivot arm, where a position of the pivot element determines a pivot point of the pivot arm and an arc length through which the pivot arm pivots in order to pinch the actuation member.
9. The medical assembly of claim 1, wherein the actuation member is one of a flexible cable, a suture, a wire, a cord, a flexible rod, and a flexible shaft.
10. A delivery apparatus for an implantable medical device comprising a handle; at least one actuation member extending from the handle and coupled to the medical device, wherein the at least one actuation member is configured to apply a proximally directed force to the medical device; and a force limiting mechanism arranged within the handle, the force liming mechanism comprising a pivot arm configured to limit an amount of the proximally directed force that can be applied by the at least one actuation member to the medical device.
11. The delivery apparatus of claim 10, wherein the pivot arm is configured to prevent the at least one actuation member from applying a proximally directed force to the medical device if a proximally directed force greater than a predetermined threshold is applied to the at least one actuation member, wherein the force limiting mechanism further comprises a base portion, and wherein the pivot arm is configured to pivot and retain the at least one actuation member between the pivot arm and the base portion if a proximally directed force greater than the predetermined threshold is applied to the at least one actuation member.
12. The delivery apparatus of claim 11, wherein the force limiting mechanism further comprises a biasing member configured to exert a biasing force against the pivot arm and prevent pivoting of the pivot arm if the proximally directed force applied to the at least one actuation member is less than the predetermined threshold and permit pivoting of the pivot arm if the proximally directed force applied to the at least one actuation member exceeds the predetermined threshold.
13. The delivery apparatus of claim 12, wherein the biasing member comprises a spring.

14. The delivery apparatus of claim 12, wherein the force limiting mechanism further comprises an adjustment screw including a threaded portion in threaded engagement with an internally threaded portion of the handle, where a first end of the threaded portion is coupled to the biasing member and a second end of the threaded portion is configured to be rotated in a first direction that increases the biasing force and an opposite, second direction that decreases the biasing force.
15. The delivery apparatus of claim 12, wherein the pivot arm includes an adjustable pivot element about which the pivot arm pivots relative to the base portion, and wherein the pivot element is configured to slide within an elongated slot of the pivot arm extending from a first end portion toward a second end portion of the pivot arm, in response to linear translation of a sliding element coupled to the pivot element and in sliding engagement with a portion of the pivot arm, in order to adjust a position of a pivot point of the pivot arm.
16. The delivery apparatus of claim 10, wherein the force limiting mechanism further comprises a pulley mounted on the pivot arm and the at least one actuation member is routed at least partially around the pulley.
17. The delivery apparatus of claim 10, wherein the at least one actuation member is configured to produce radial expansion of the medical device upon application of the proximally directed force to the at least one actuation member, wherein the medical device is a mechanically expandable prosthetic heart valve including a plurality of interconnected struts, and wherein the struts are pivotably coupled to one another at one or more pivot joints arranged along a length of each strut.
18. A method of implanting a prosthetic heart valve, comprising: inserting into a body of a patient a distal end portion of a delivery apparatus and a prosthetic heart valve coupled to the distal end portion of the delivery apparatus in a radially compressed configuration, the delivery apparatus comprising: a handle; at least one actuation member extending from the handle and coupled to the prosthetic heart valve and configured to apply a proximally directed force to the prosthetic heart valve to cause the prosthetic heart valve to foreshorten axially and expand radially; and a force limiting mechanism configured to limit an amount of the proximally directed force that can be applied by the at least one actuation member to the prosthetic heart valve; advancing the delivery apparatus distally until the prosthetic heart valve is disposed at a selected implantation site; and radially expanding the prosthetic heart valve by applying a proximally directed force to the at least one actuation member so as to move the at least one actuation member relative to the force limiting mechanism.
19. The method of claim 18, further comprising, when the proximally directed force applied to the at least one actuation member exceeds a predetermined force during the radially expanding the prosthetic heart valve, arresting movement of the at least one actuation member with the force limiting mechanism and stopping radially expanding the prosthetic heart valve, and wherein arresting movement of the at least one actuation member with the force limiting mechanism includes pivoting a first end portion of a pivot arm of the force limiting mechanism into engagement with the at least one actuation member and pinching the at least one actuation member between the first end portion and a base portion of the force liming mechanism to which the pivot arm is coupled.
20. The method of claim 19, further comprising, in response to the proximally directed force applied to the at least one actuation member exceeding the predetermined force, decreasing an amount of the proximally directed force applied to the at least one actuation member so that it is less than the predetermined force, and then further moving the at least one actuation member relative to the force limiting mechanism, and wherein further moving the at least one actuation member relative to the force limiting mechanism includes moving the first end portion of the pivot arm out of engagement with the at least one actuation member and allowing the at least one actuation member to slide relative to the pivot arm.