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(54) **VALVE RETENTION FEATURES**

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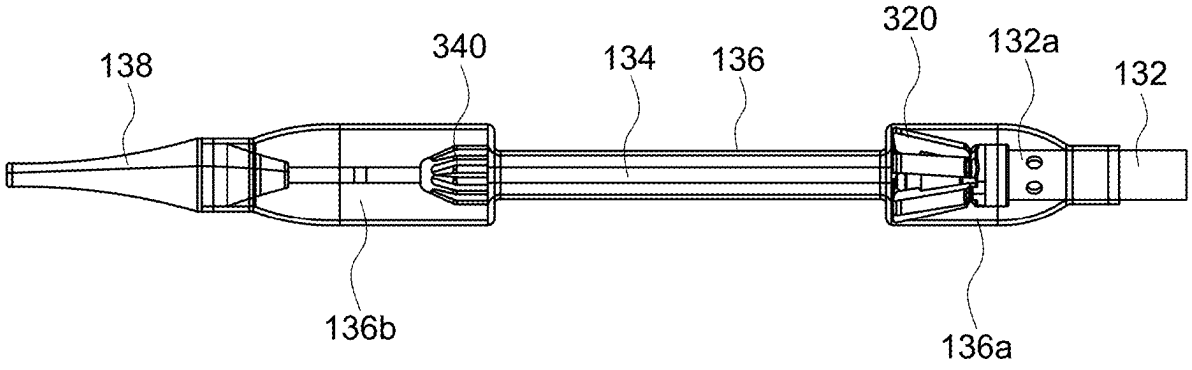
A61F 2/24 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 2/2433*** (2013.01)

(57) **ABSTRACT**

A system for delivering a prosthetic heart valve may include, a handle, an outer catheter, an inner catheter, a nose cone coupled to the inner catheter, and an inflatable balloon having a proximal leg coupled to the outer catheter and a distal leg coupled to the nose cone or the inner catheter. A first valve retainer may be coupled to the inner catheter and positioned within the balloon. In an assembled state of the first valve retainer, an inner stop is directly fixed to the inner catheter and an outer stop is positioned around and coupled to the inner stop. The inner stop has a maximum outer diameter that is smaller than a maximum inner diameter of the distal leg. In the assembled condition of the first valve retainer, the outer stop has a maximum outer diameter that is larger than the maximum inner diameter of the distal leg.



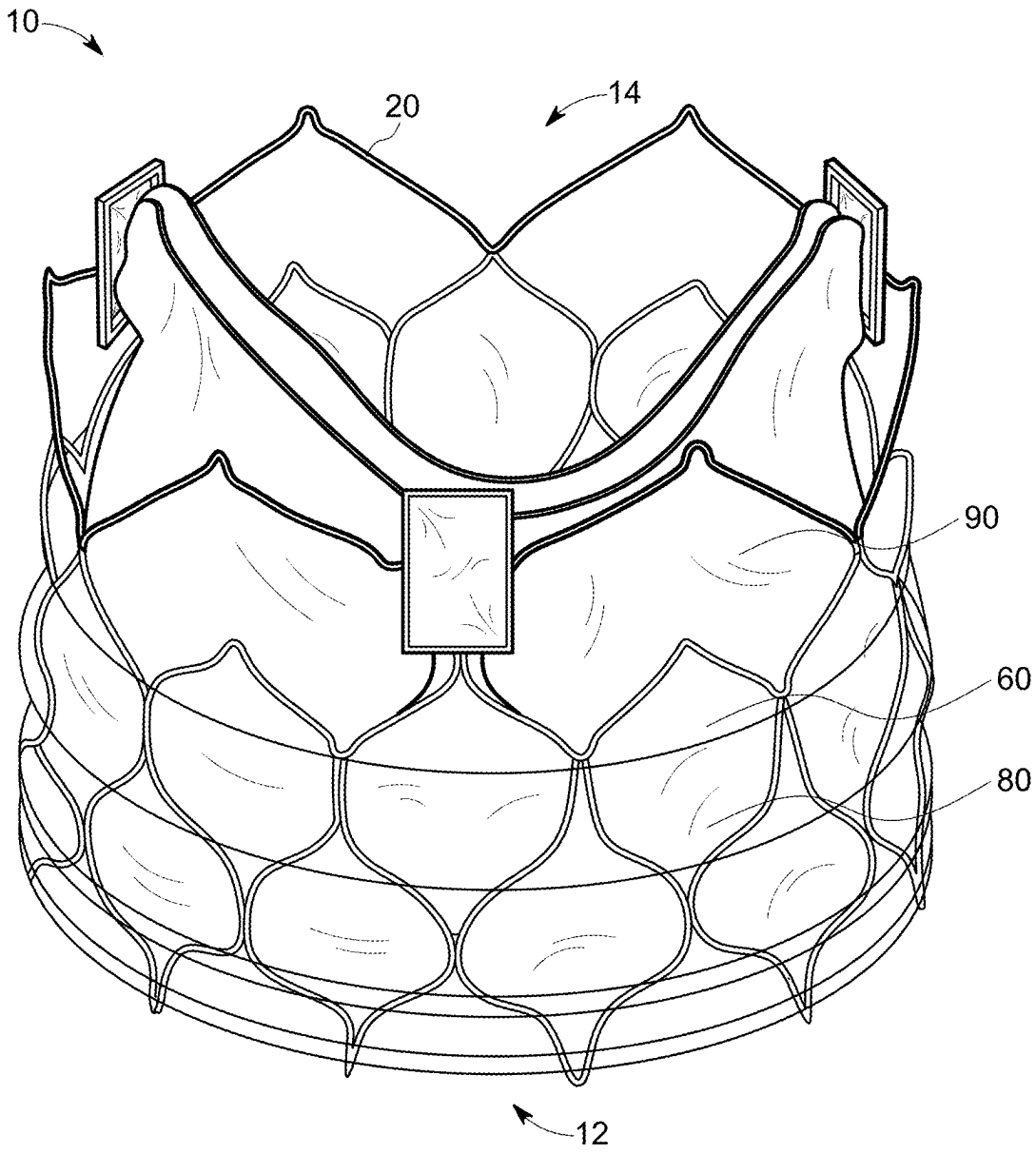


FIG. 1

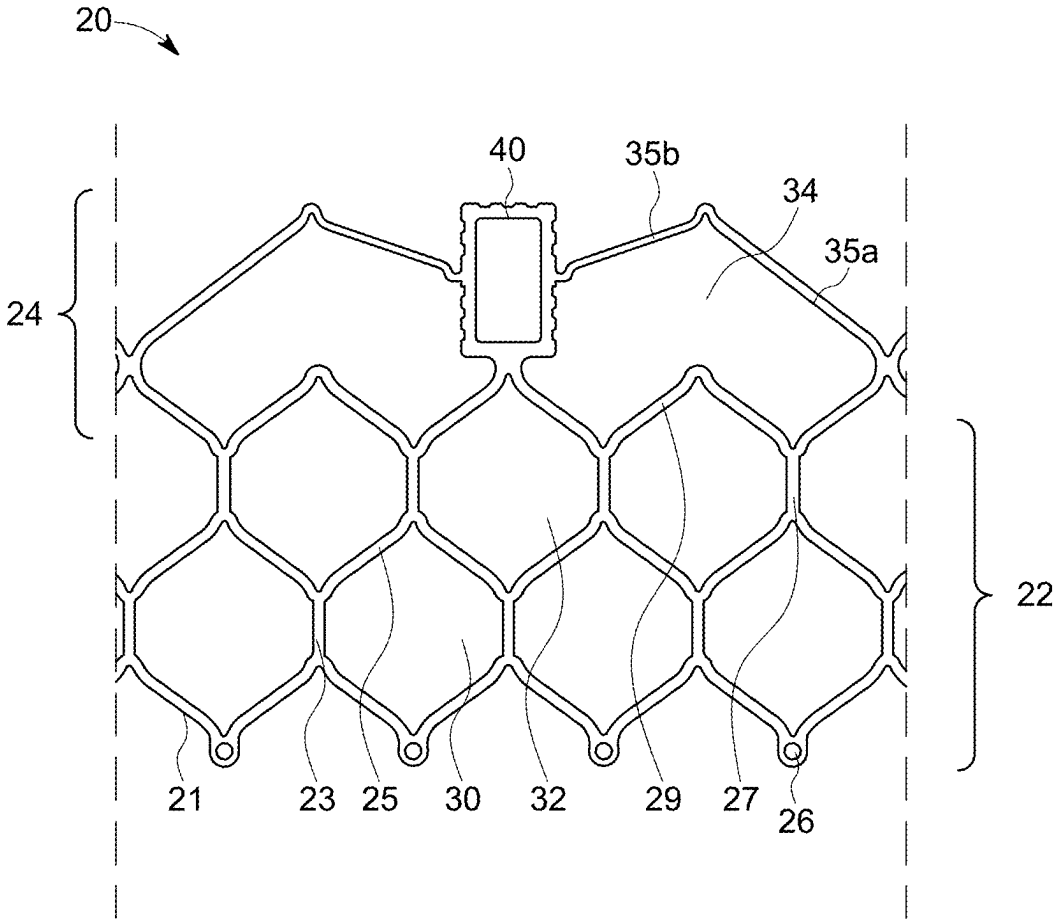


FIG. 2

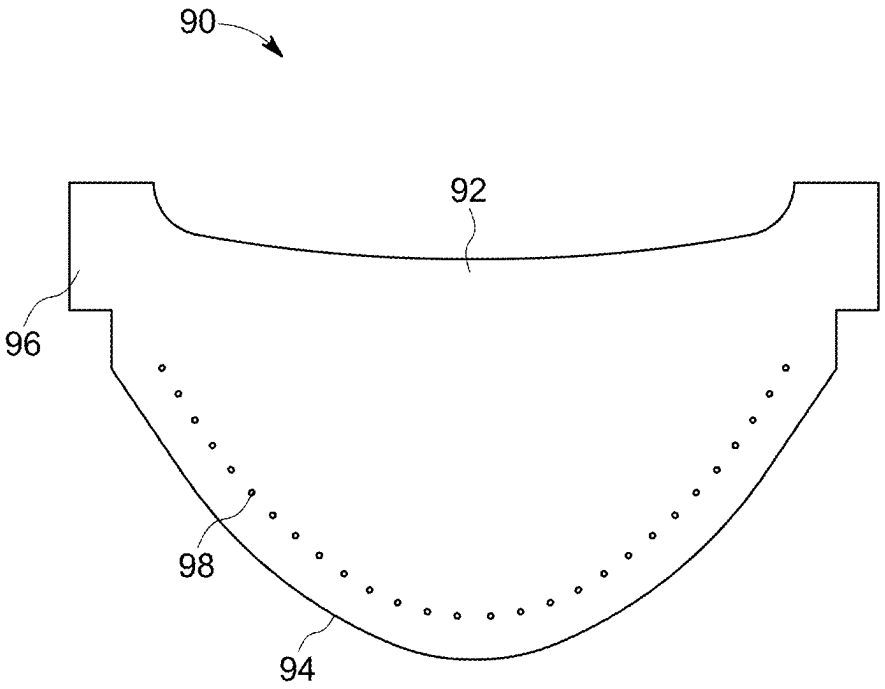


FIG. 3

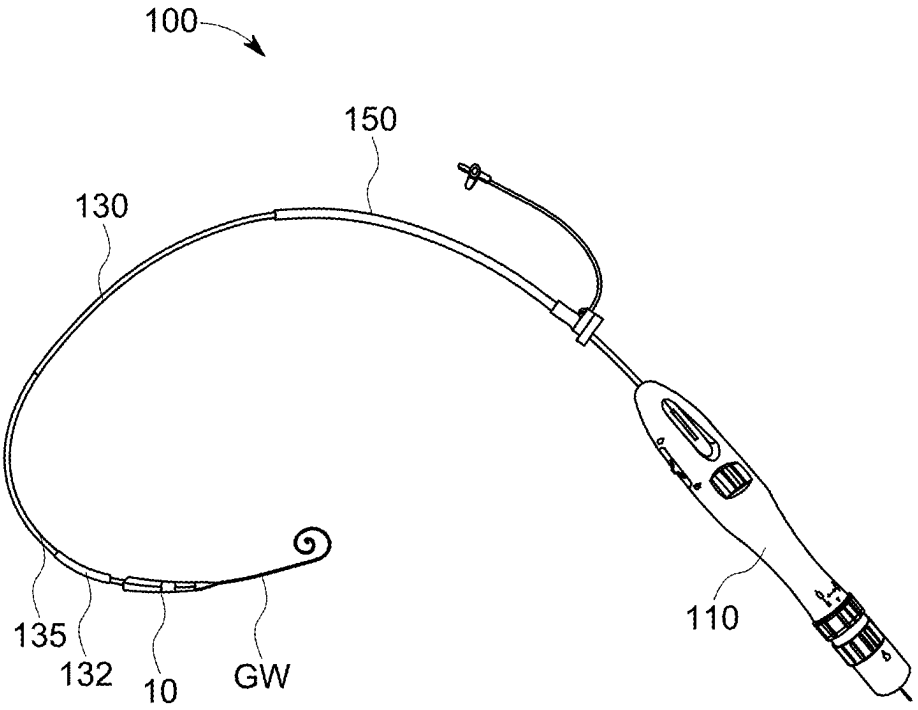


FIG. 4

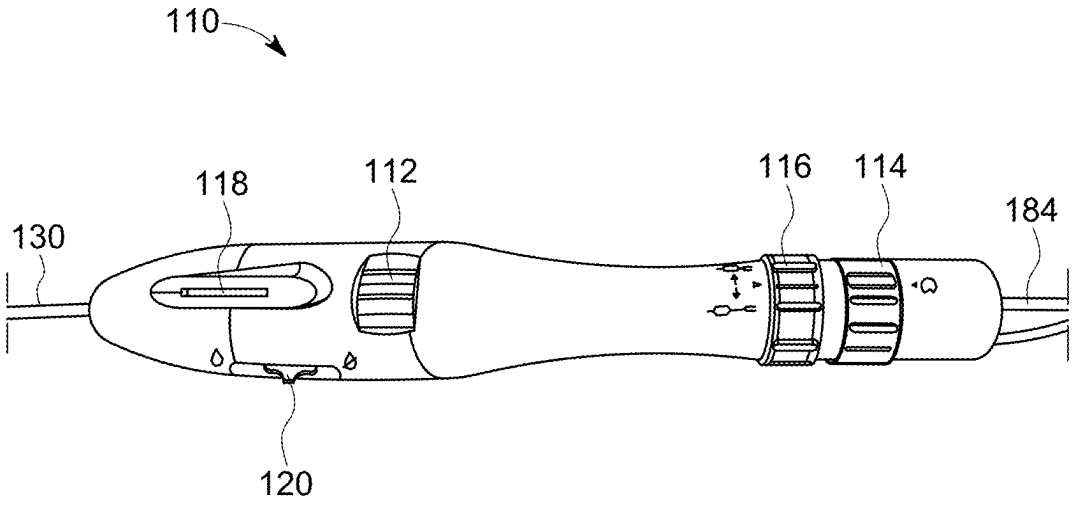


FIG. 5

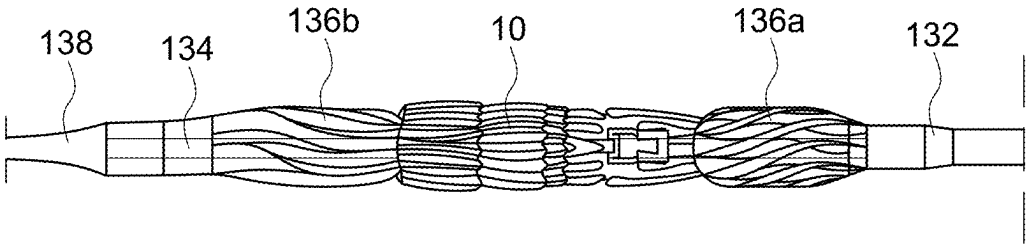


FIG. 6

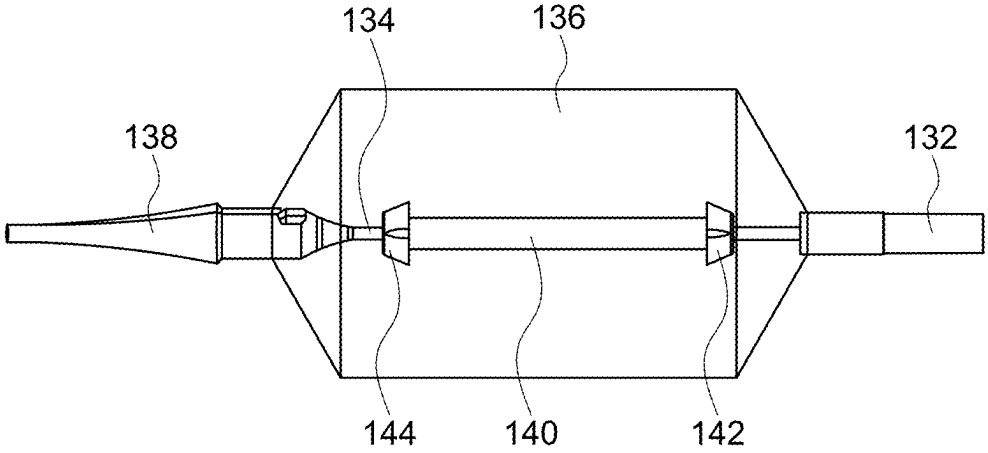


FIG. 7

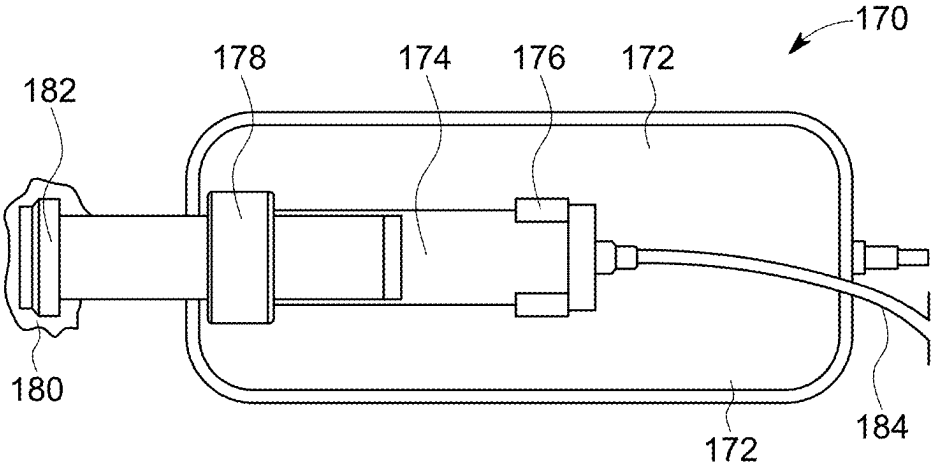


FIG. 8

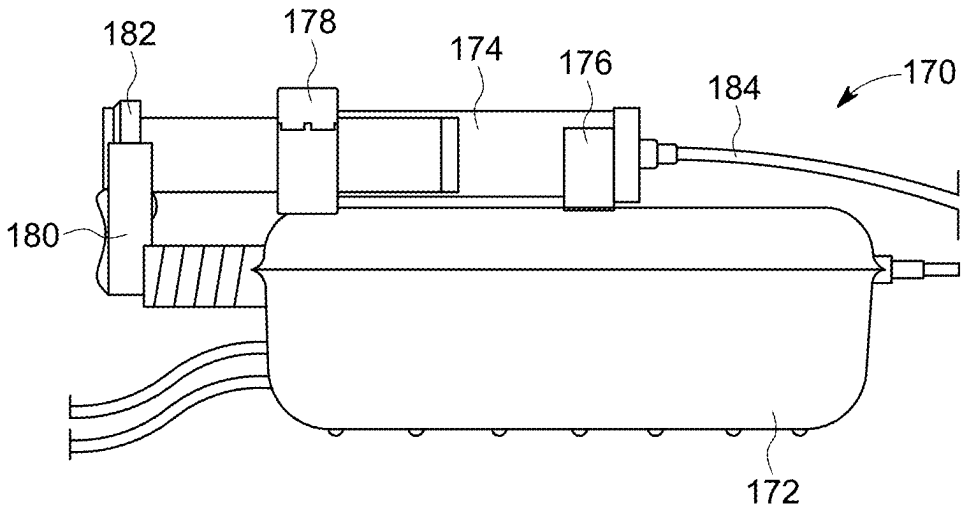

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FIG. 9

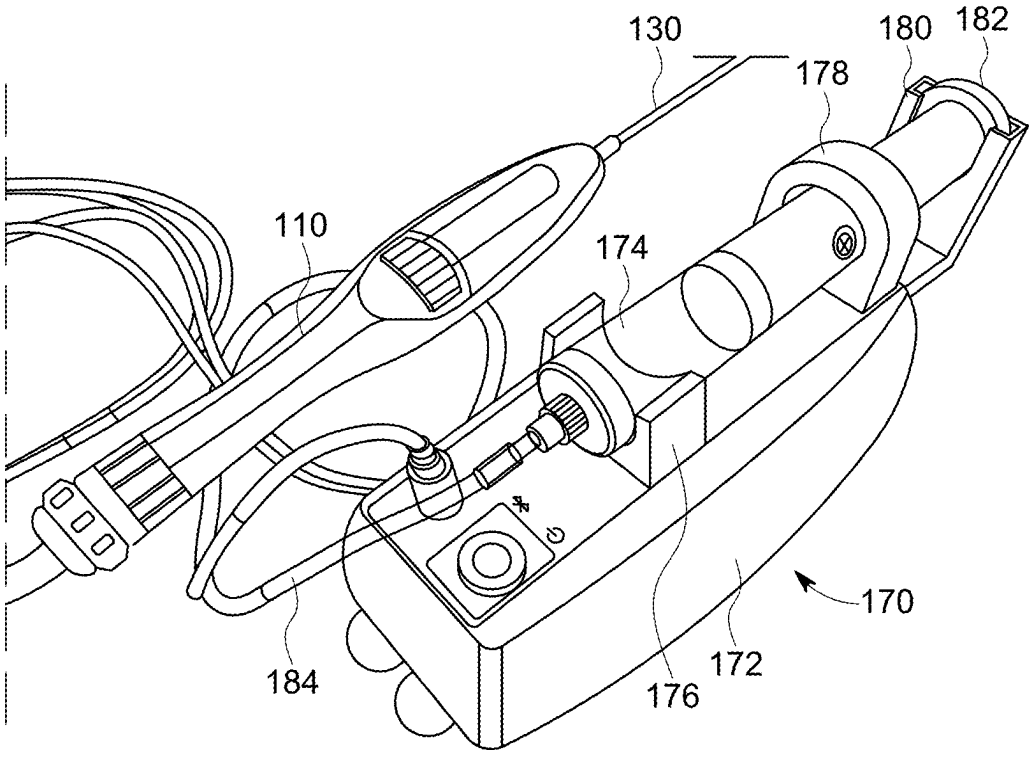
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FIG. 10

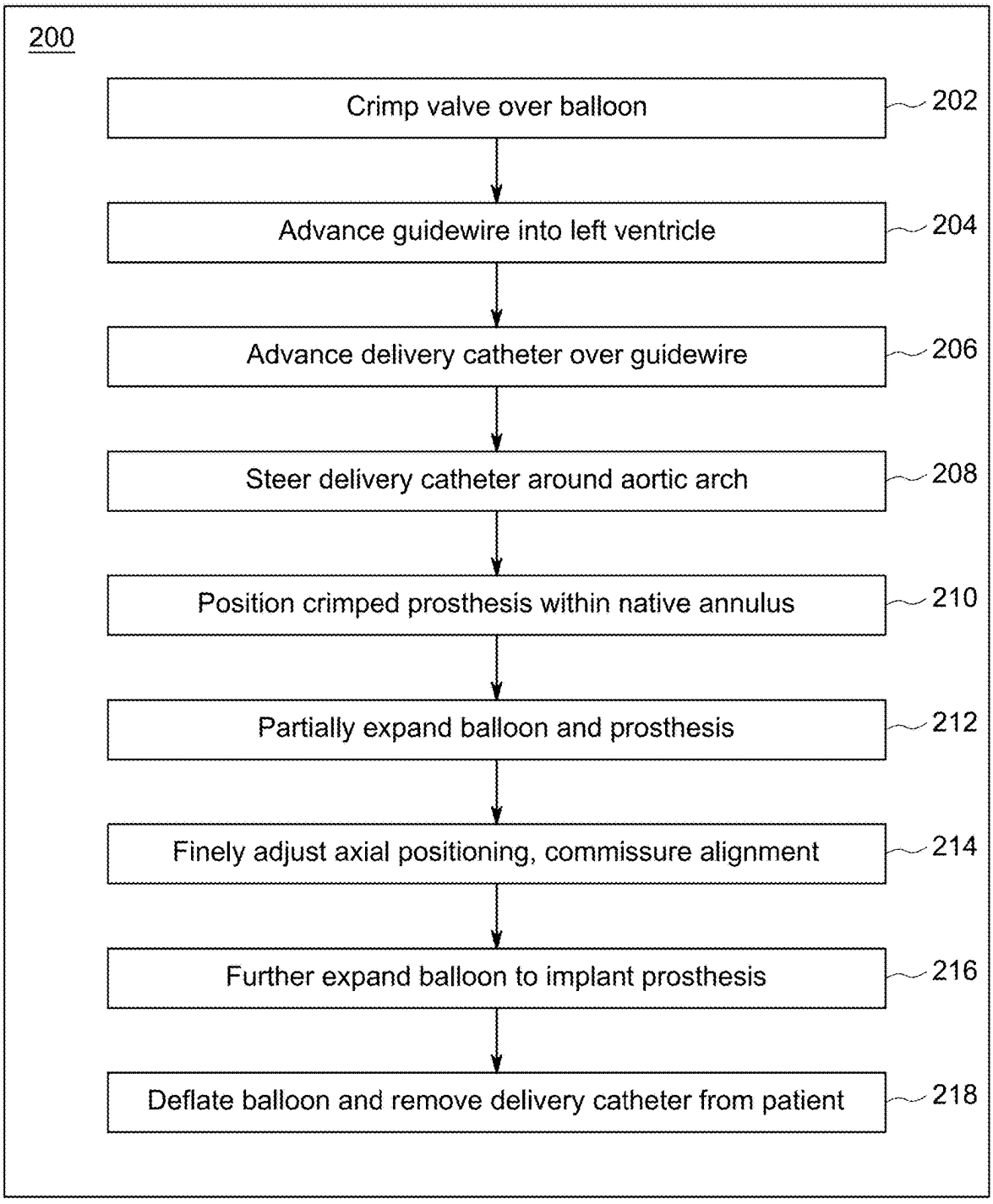
200
Crimp valve over balloon
202
Advance guidewire into left ventricle
204
Advance delivery catheter over guidewire
206
Steer delivery catheter around aortic arch
208
Position crimped prosthesis within native annulus
210
Partially expand balloon and prosthesis
212
Finely adjust axial positioning, commissure alignment
214
Further expand balloon to implant prosthesis
216
Deflate balloon and remove delivery catheter from patient
218

FIG. 11

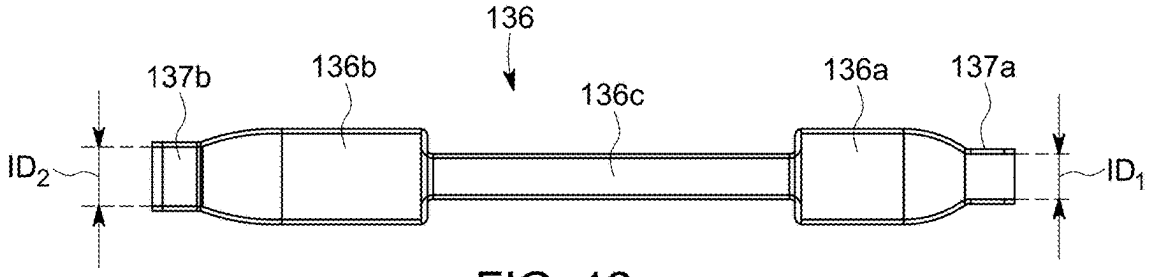

FIG. 12

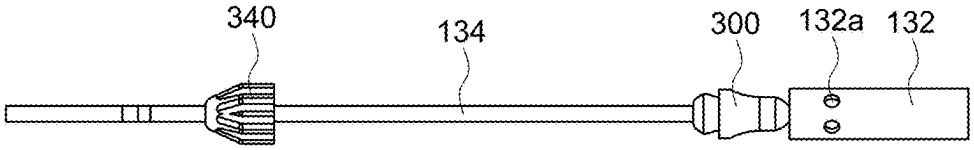

FIG. 13A

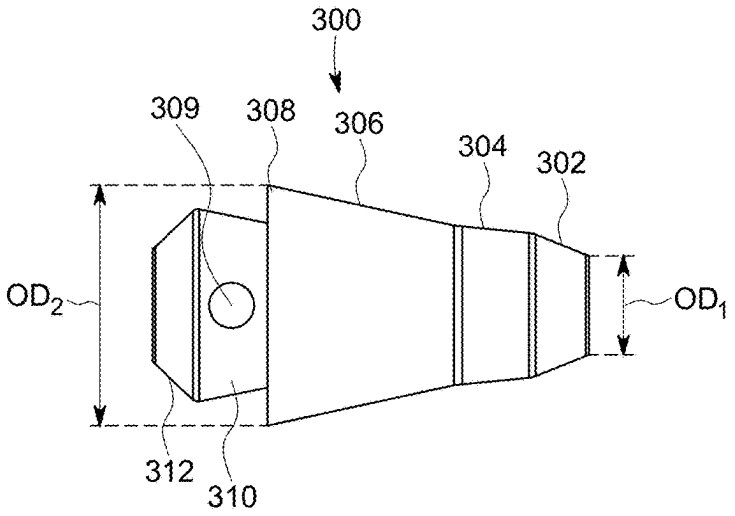

FIG. 13B

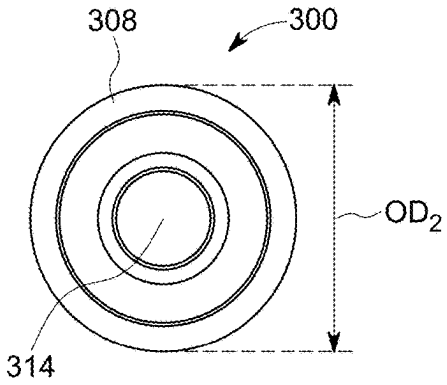

FIG. 13C

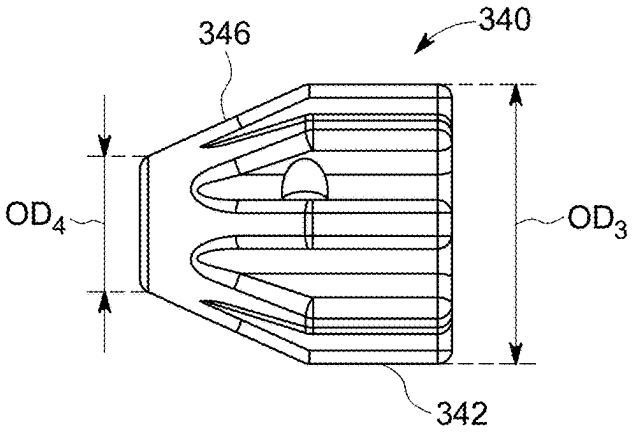

FIG. 13D

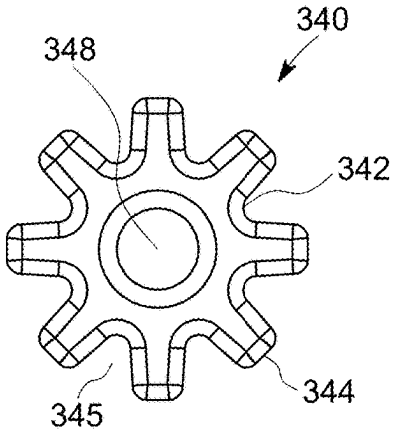

FIG. 13E

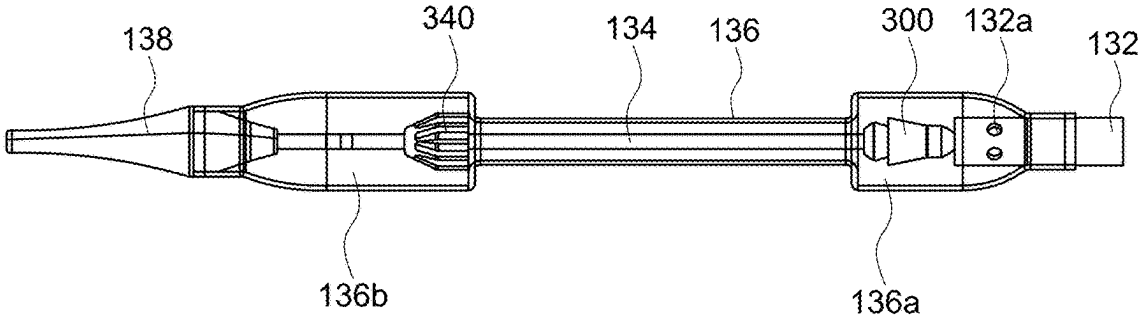

FIG. 13F

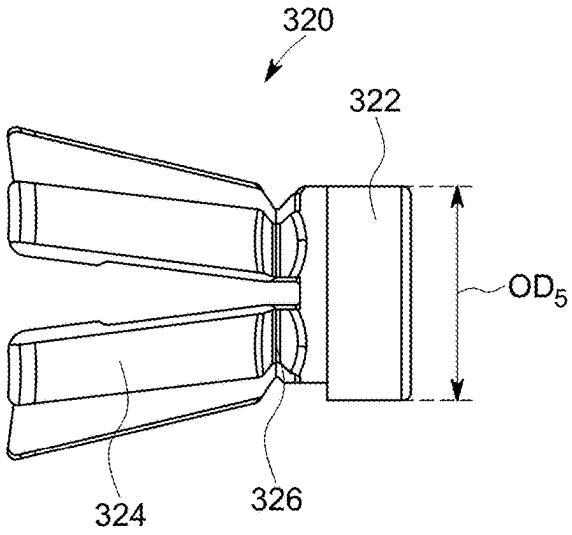

FIG. 13G

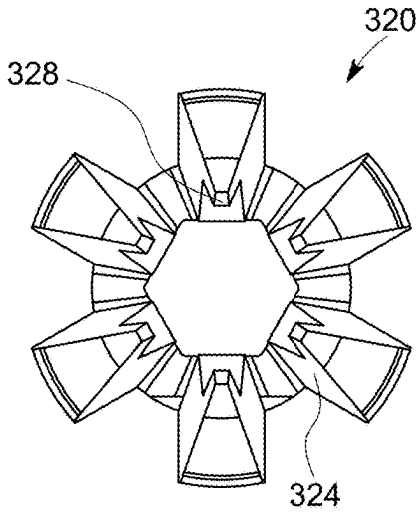

FIG. 13H

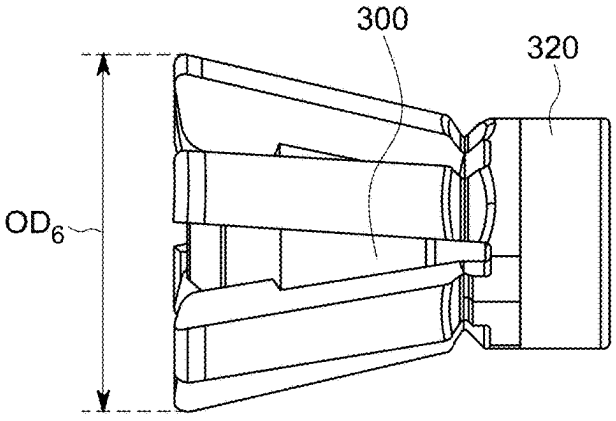

FIG. 13I

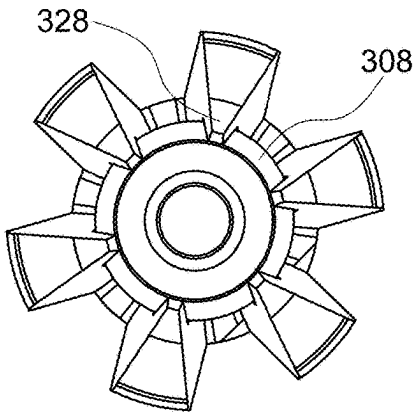

FIG. 13J

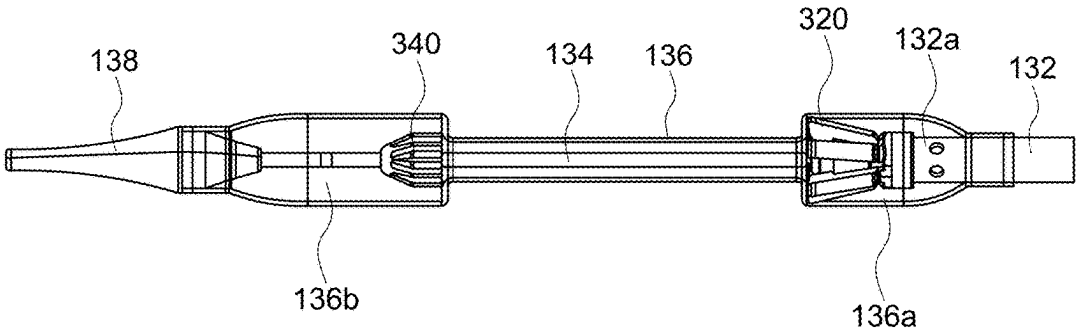

FIG. 13K

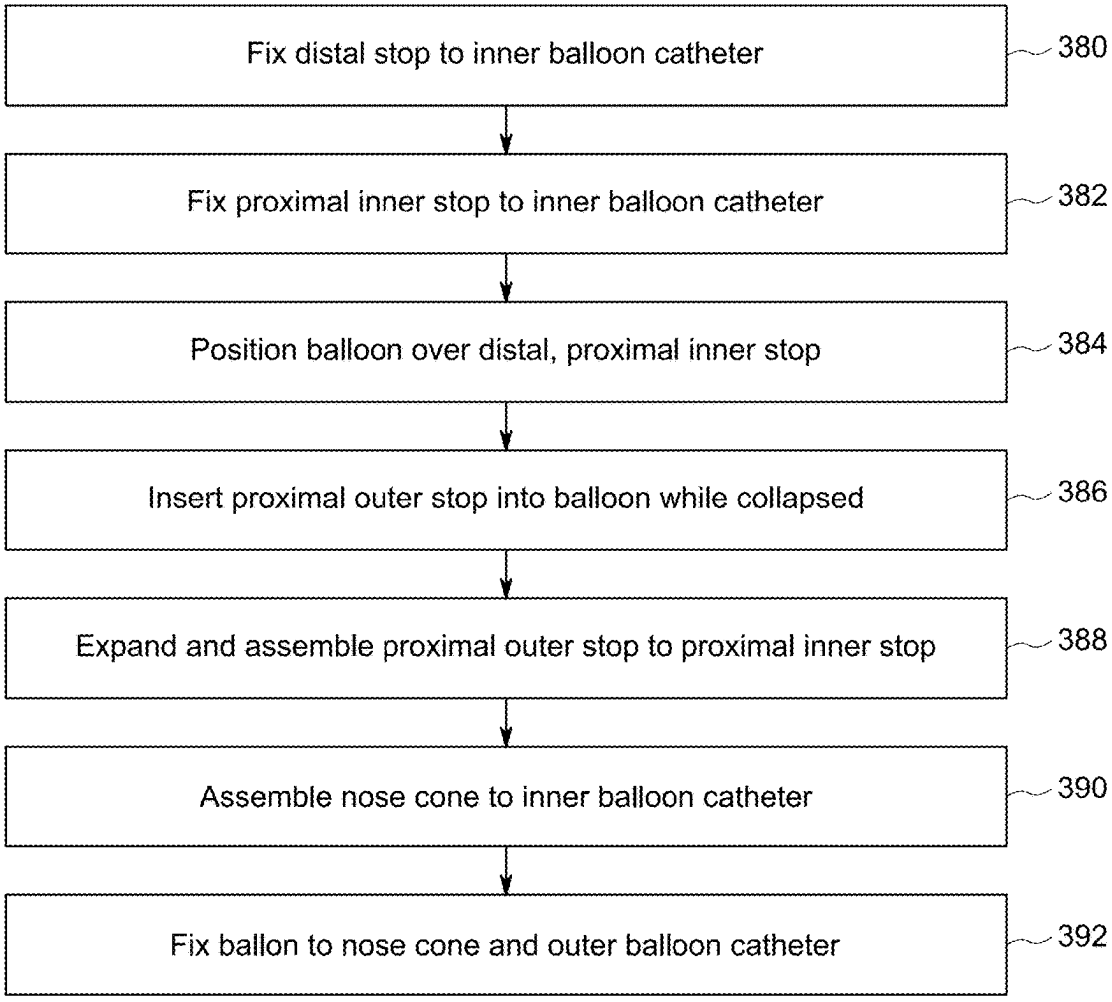

FIG. 13L

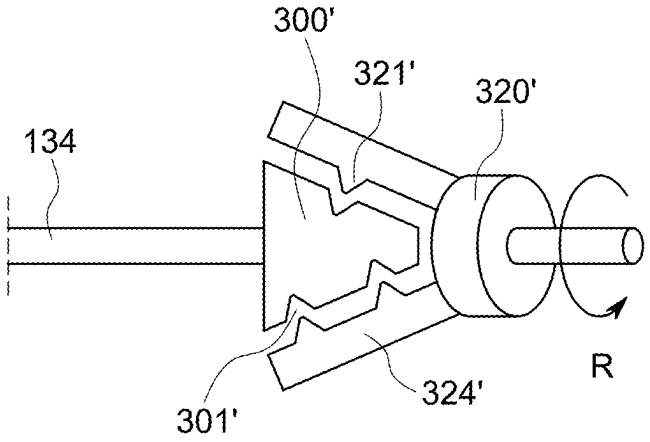

FIG. 14

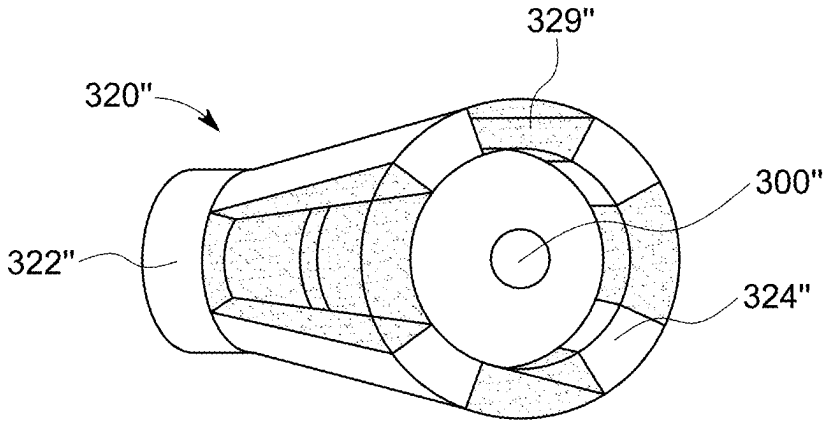

FIG. 15A

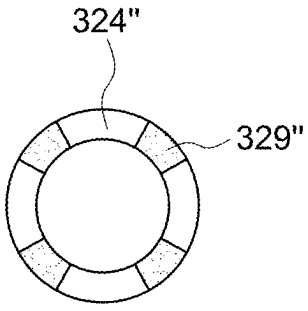

FIG. 15B

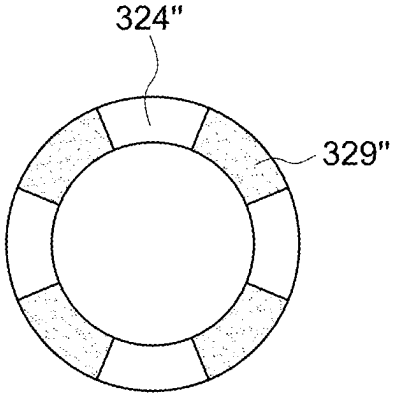

FIG. 15C

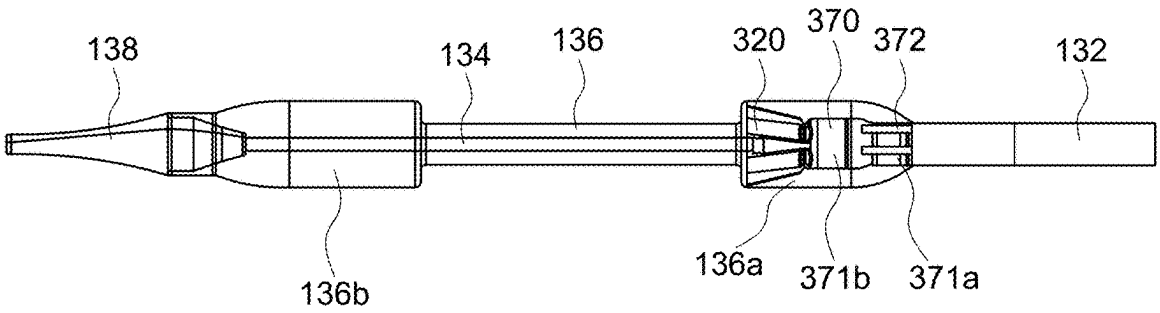
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FIG. 16

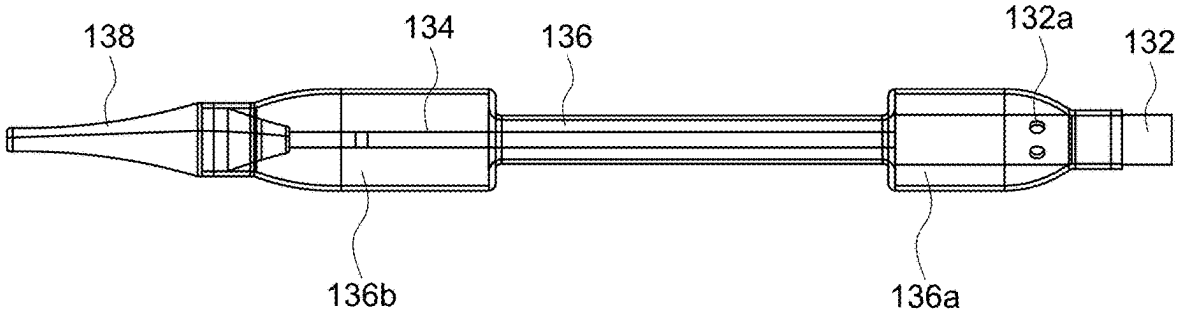
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FIG. 17

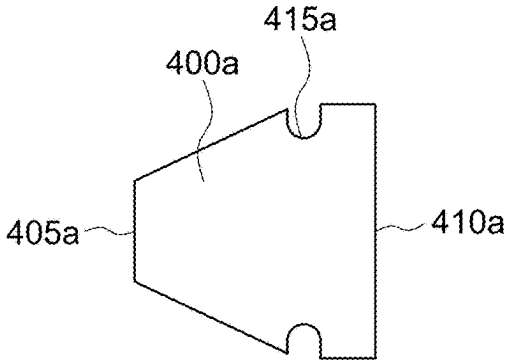

FIG. 18A

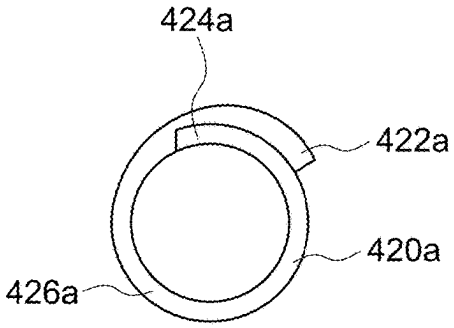

FIG. 18B

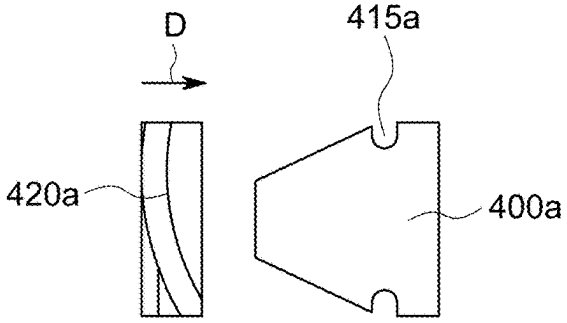

FIG. 18C

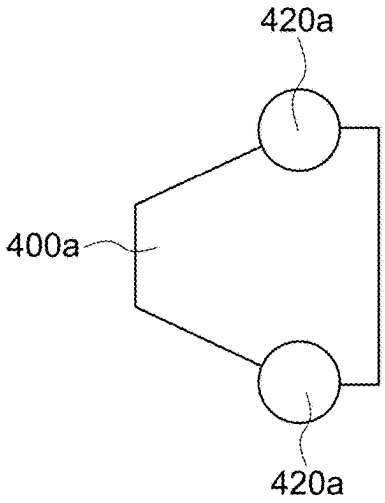

FIG. 18D

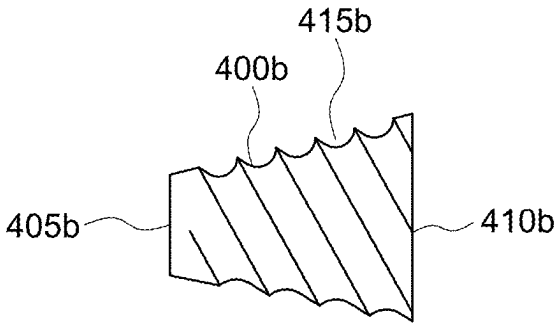

FIG. 19A

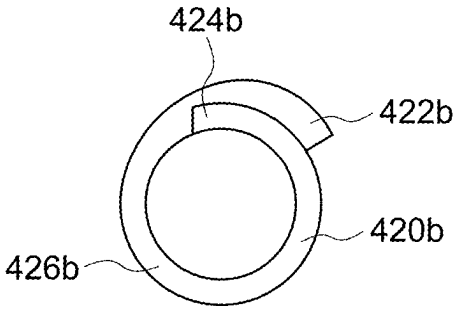

FIG. 19B

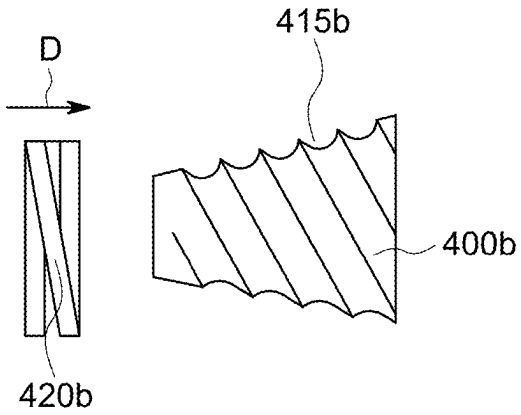

FIG. 19C

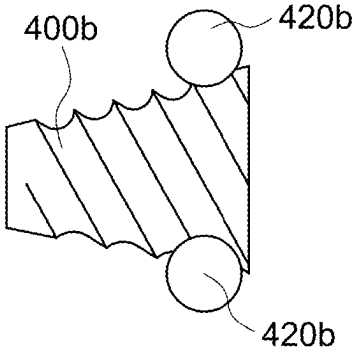

FIG. 19D

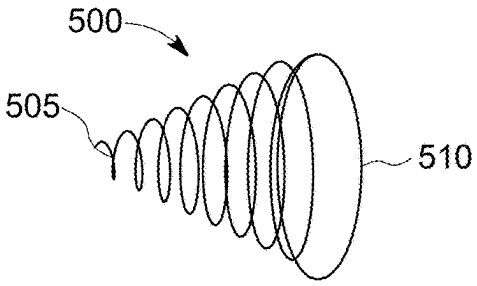

FIG. 20A

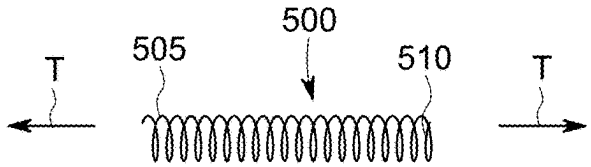

FIG. 20B

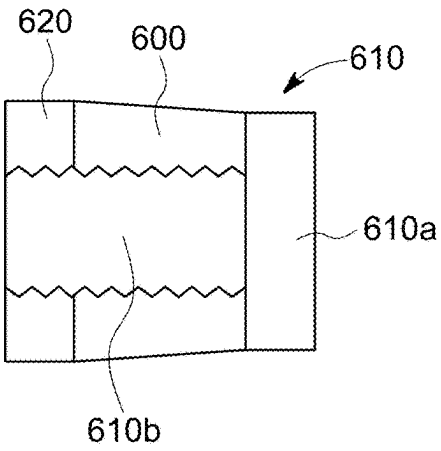

FIG. 21A

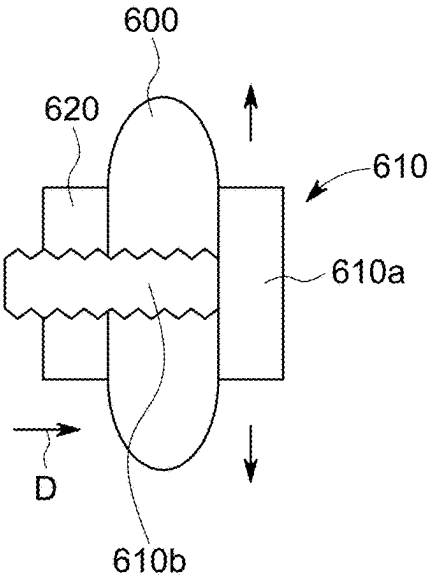

FIG. 21B

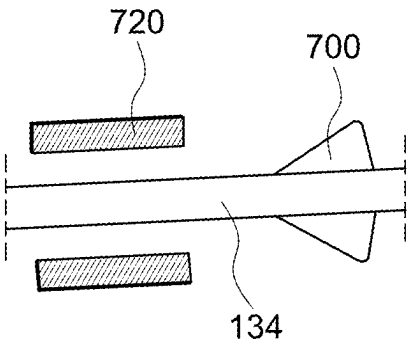

FIG. 22A

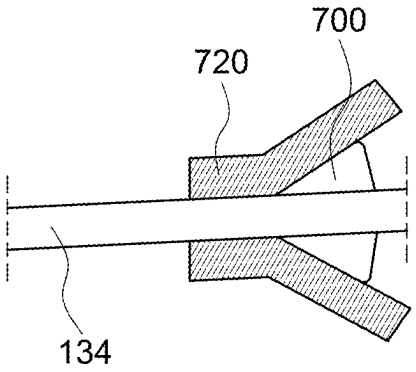

FIG. 22B

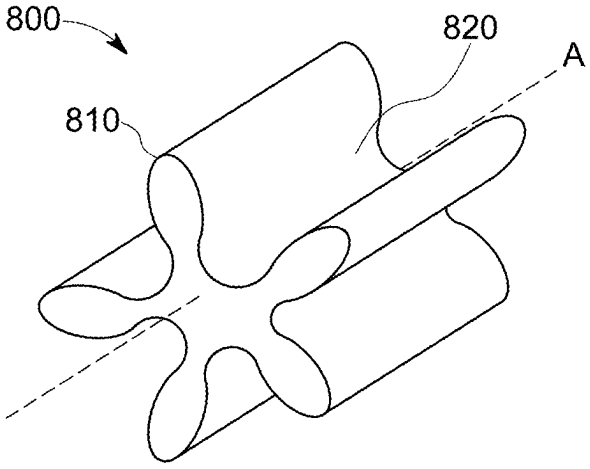

FIG. 23A

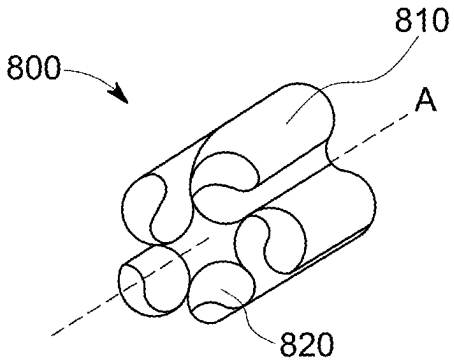

FIG. 23B

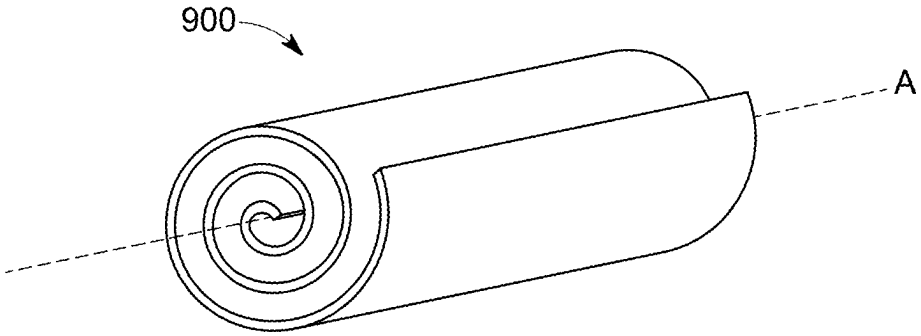

FIG. 24

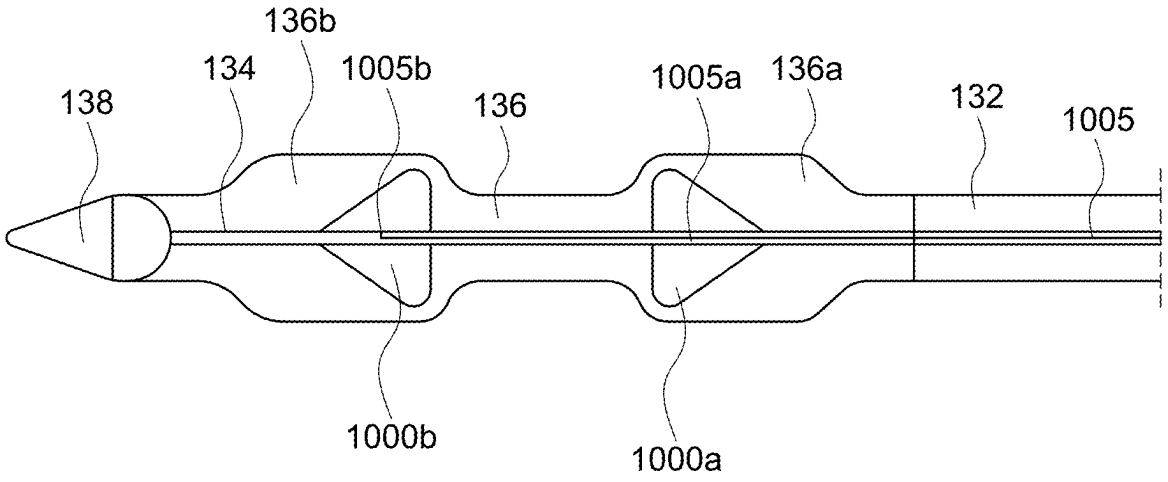

FIG. 25

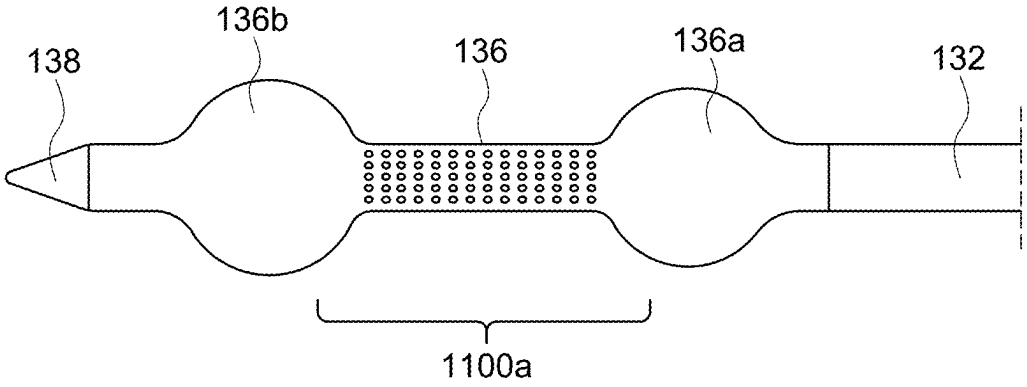

FIG. 26A

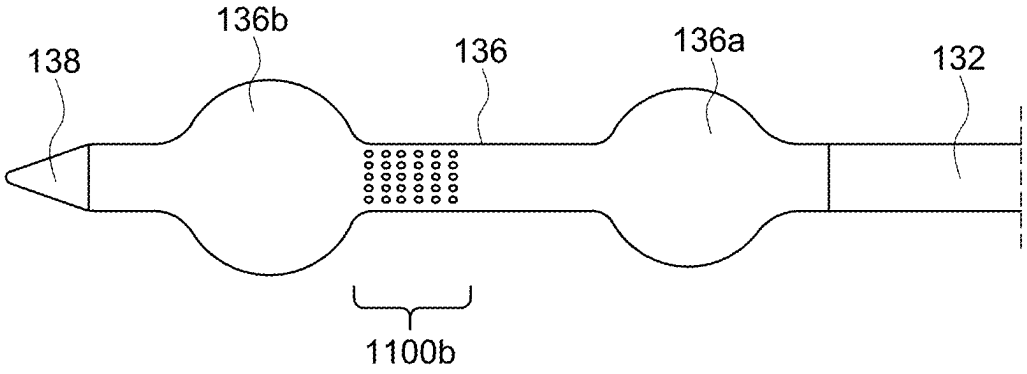

FIG. 26B

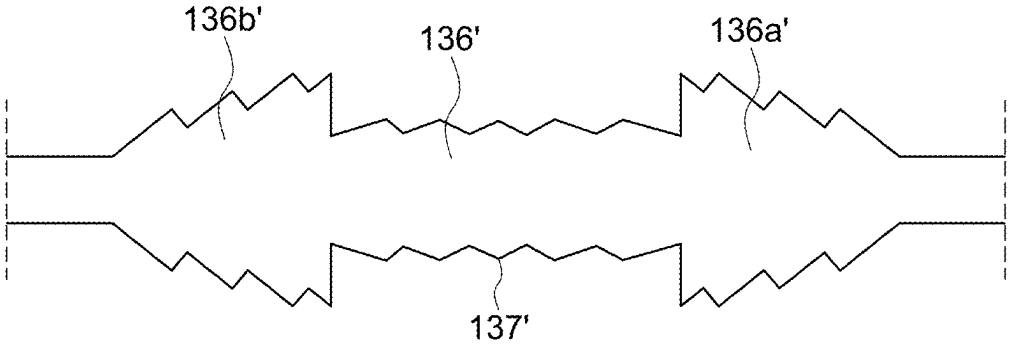

FIG. 27

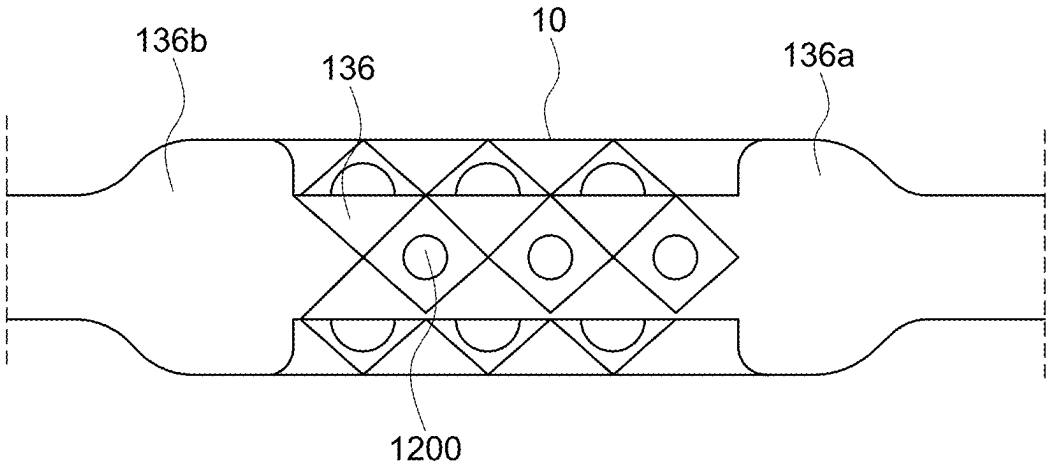

FIG. 28

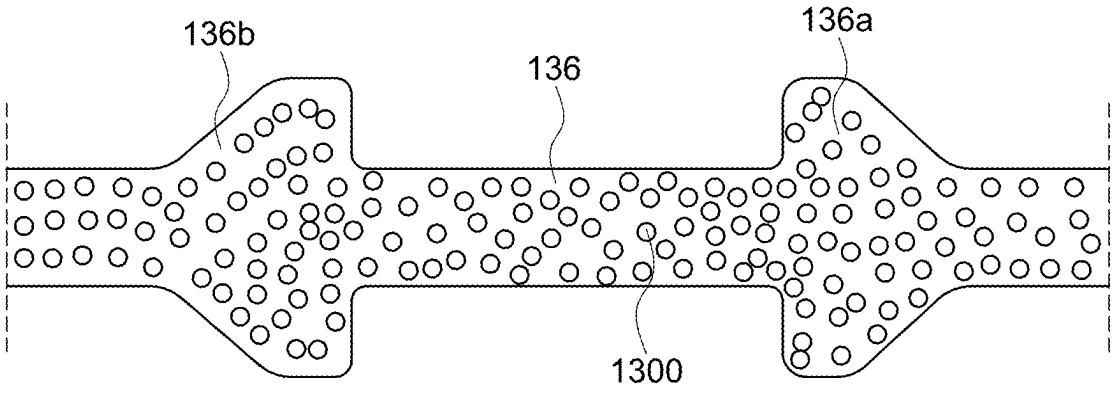

FIG. 29

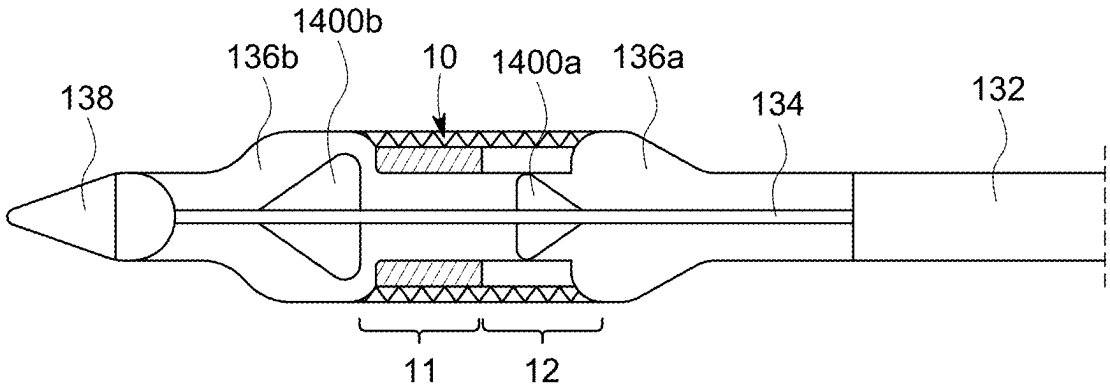

FIG. 30

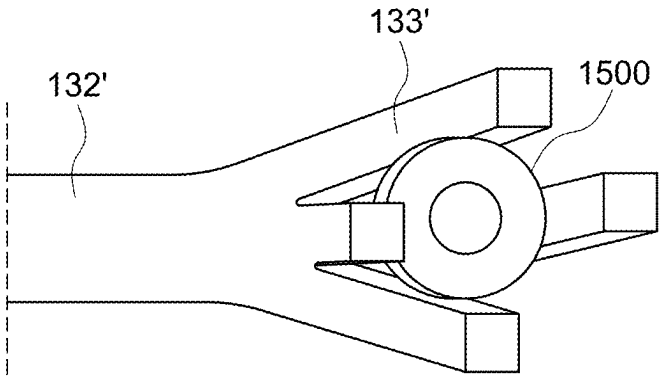

FIG. 31A

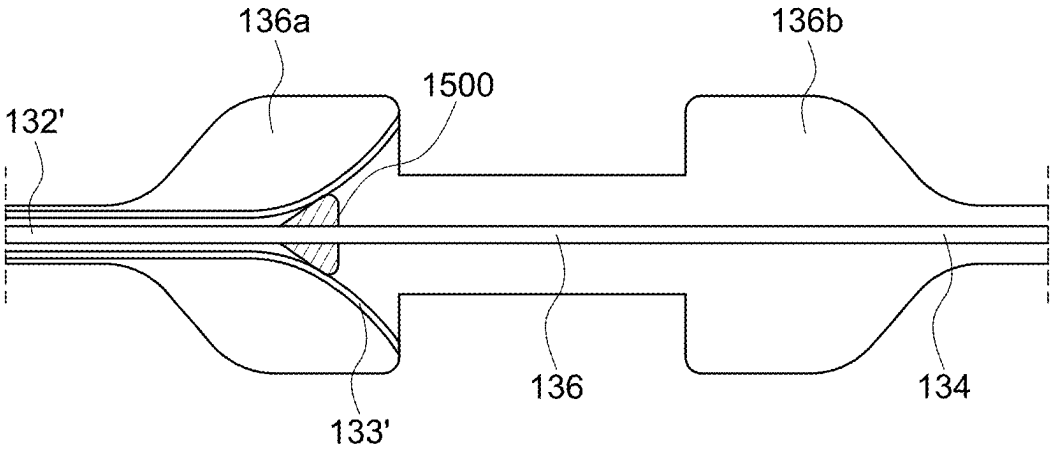

FIG. 31B

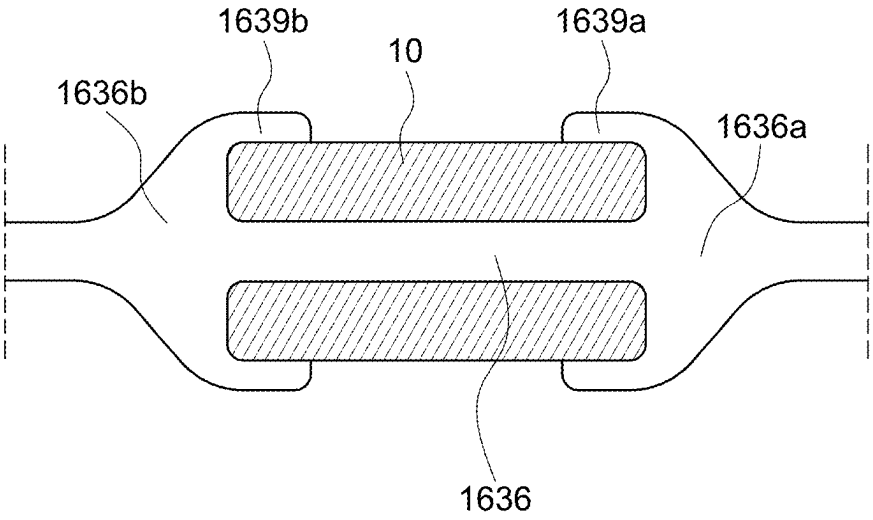

FIG. 32

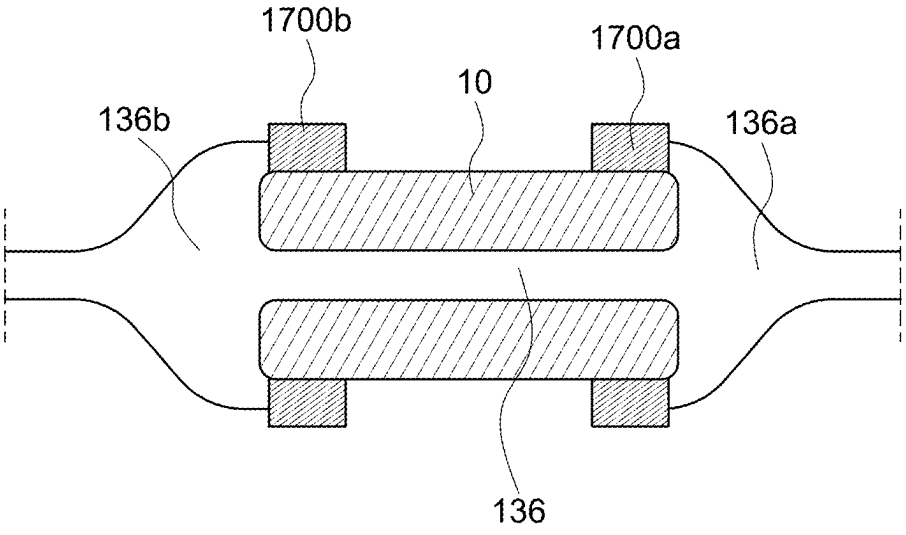

FIG. 33

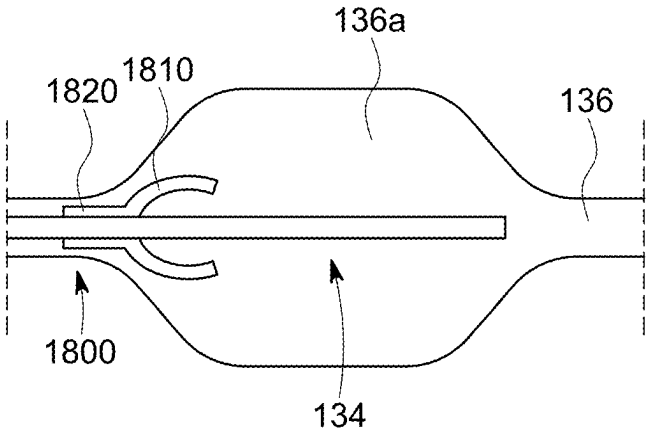

FIG. 34A

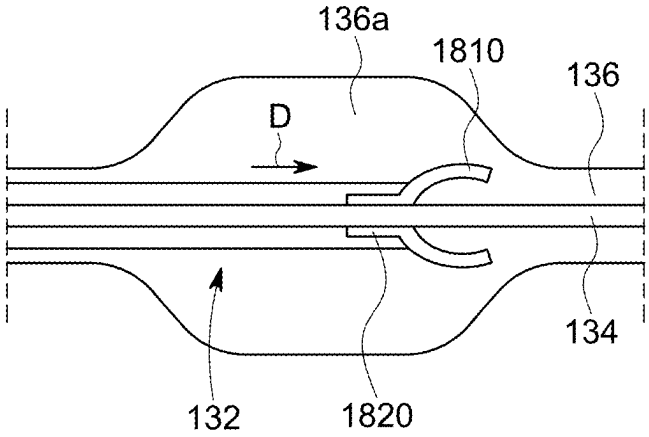

FIG. 34B

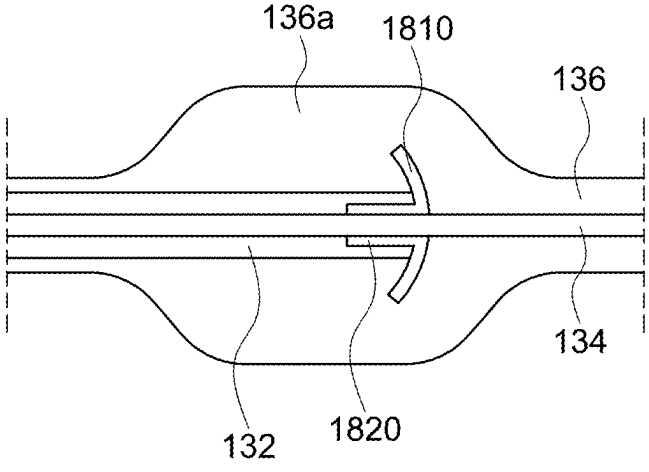

FIG. 34C

VALVE RETENTION FEATURES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to the filing date of U.S. Provisional Patent Application No. 63/554,326, filed Feb. 16, 2024, the disclosure of which is hereby incorporated by reference herein.

BACKGROUND OF THE DISCLOSURE

[0002] Valvular heart disease, and specifically aortic and mitral valve disease, is a significant health issue in the United States. Valve replacement is one option for treating heart valve diseases. Prosthetic heart valves include surgical heart valves, as well as collapsible and expandable heart valves intended for transcatheter aortic valve replacement or implantation ("TAVR" or "TAVI") or transcatheter mitral valve replacement ("TMVR"). Surgical or mechanical heart valves may be sutured into a native annulus of a patient during an open-heart surgical procedure, for example. Collapsible and expandable heart valves may be delivered into a patient via a delivery apparatus such as a catheter to avoid a more invasive procedure such as full open-chest, open-heart surgery. As used herein, reference to a "collapsible and expandable" heart valve includes heart valves that are formed with a small cross-section that enables them to be delivered into a patient through a catheter in a minimally invasive procedure, and then expanded to an operable state once in place, as well as heart valves that, after construction, are first collapsed to a small cross-section for delivery into a patient and then expanded to an operable size once in place in the valve annulus.

[0003] The present disclosure addresses problems and limitations associated with the related art.

SUMMARY OF THE DISCLOSURE

[0004] Generally, this disclosure relates to features for use in balloon catheters for use in delivering and/or deploying balloon-expandable prosthetic heart valves. In some examples, a balloon-expandable prosthetic heart valve is crimped over a balloon of a balloon catheter prior to being inserted into the patient's vasculature where it is advanced through the vasculature to the native heart valve being treated. At various points during the procedure, including while passing the prosthetic heart valve through an introducer leading to the patient's vasculature, as well as advancement through tortuous vasculature such as an approximately 180-degree bend of the aortic arch, there is an increased chance that the prosthetic heart valve is shifted or otherwise dislocated from its position relative to the balloon of the balloon catheter. In some examples, to help reduce the likelihood of such shifting or dislocation, components may be provided internal to the balloon or on the balloon to help maintain the position of the prosthetic heart valve relative to the balloon during the delivery. In some examples in which components are provided internal to the balloon, sizing of the balloon and limits on the ability to stretch the balloon result in difficulties in inserting valve retainer features into the balloon while allowing the valve retainer features to have a large enough size to assist with maintaining the prosthetic heart valve in the desired position. Various example provided herein allow for valve retainer(s) to be inserted into the balloon while having a relatively small profile, and then expanding or otherwise changing configuration to a larger profile to better function to retain the prosthetic heart valve in the desired positioning on the balloon during delivery.

[0005] According to one example of the disclosure, a system for delivering a prosthetic heart valve includes a handle, an outer catheter extending from the handle, an inner catheter extending from the handle and through an interior of the outer catheter, a nose cone coupled to a distal end of the inner catheter, and an inflatable balloon having a proximal leg coupled to the outer catheter and a distal leg coupled to (i) the nose cone or (ii) the inner catheter. A first valve retainer may be coupled to the inner catheter and positioned within the balloon. The first valve retainer may have an assembled state in which an inner stop is directly fixed to the inner catheter and an outer stop is positioned around and coupled to the inner stop. The inner stop may have a maximum outer diameter that is smaller than a maximum inner diameter of the distal leg, and in the assembled condition of the first valve retainer, the outer stop may have a maximum outer diameter that is larger than the maximum inner diameter of the distal leg. The inner stop may include a ramped outer surface portion that increases in diameter in a proximal-to-distal direction of the inner stop. The outer stop may include a rim and a plurality of extensions extending from the rim. The outer catheter may be directly coupled to the rim. When the first valve retainer is in an unassembled condition, and in the absence of applied forces, the outer stop may have a maximum outer diameter that is smaller than the maximum inner diameter of the distal leg. The inner stop may include a shoulder at a distal end of the ramped outer surface portion. At least one of the plurality of extensions may include an interiorly extending prong at a distal end thereof, the interiorly extending prong configured to engage the shoulder in the assembled condition of the first valve retainer. In the assembled condition of the first valve retainer, each of the plurality of extensions may flare radially outwardly relative to the rim. Each of the plurality of extensions may be coupled to the rim via a living hinge. The balloon may include a proximal pillow, a distal pillow, and a central portion between the proximal pillow and the distal pillow. The proximal pillow and the distal pillow may each have a diameter that is greater than a diameter of the central portion, the central portion being configured to receive the prosthetic heart valve in a crimped condition. The first valve retainer may be positioned inside the proximal pillow. A distal end of the outer catheter may extend into the proximal pillow. The outer catheter may include a catheter wall, and a plurality of apertures may be formed within the catheter wall, the plurality of apertures being positioned within the proximal pillow.

[0006] According to another example of the disclosure, a method of manufacturing a delivery catheter may include providing a balloon having a distal leg and a proximal leg, and inserting an inner catheter into an interior of the balloon so that an inner stop fixed to the inner catheter passes through the distal leg, the inner stop having a maximum outer diameter that is smaller than a maximum inner diameter of the distal leg. The method may also include inserting an outer stop into the interior of the balloon so that the outer stop passes through the distal leg while the inner catheter is received through the outer stop. During inserting the outer stop, the outer stop may have a maximum outer diameter that is smaller than the maximum inner diameter of the distal

leg. While the inner stop and the outer stop are both within the interior of the balloon, the outer stop may be advanced over the inner stop to increase the maximum outer diameter of the outer stop, the increased maximum outer diameter of the stop being larger than the maximum inner diameter of the distal leg. The inner stop may have a ramped outer surface portion and the outer stop may have a rim and a plurality of extensions extending from the rim, and advancing the outer stop over the inner stop may include advancing the outer stop over the ramped outer surface portion to force the plurality of extensions to flare outwardly relative to the rim. The inner stop may include a shoulder, and at least one of the plurality of extensions may include an interiorly extending prong. In the absence of applied forces, the outer stop may have the maximum outer diameter that is smaller than the maximum inner diameter of the distal leg. The method may also include continuing to advance the outer stop over the inner stop until the at least one interiorly extending prong advances past the shoulder. When the at least one interiorly extending prong advances past the shoulder, the corresponding extension may snap inwardly toward the inner catheter such that the at least one interiorly extending prong engages the shoulder to prevent the outer stop from retracting relative to the inner stop. The method may also include advancing an outer catheter through the proximal leg into the interior of the balloon. The rim may be fixed to a distal end of the outer catheter, and inserting the outer stop into the interior of the balloon may be performed by advancing the outer catheter toward the balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. **1** is a perspective view of an example of a prosthetic heart valve.

[0008] FIG. **2** is a front view of an example of a section of the frame of the prosthetic heart valve of FIG. **1**, as if cut longitudinally and laid flat on a table.

[0009] FIG. **3** is a front view of an example of a prosthetic leaflet of the prosthetic heart valve of FIG. **1**, as if laid flat on a table.

[0010] FIG. **4** is a top view of the prosthetic heart valve of FIG. **1** mounted on an example of a portion of a delivery system.

[0011] FIG. **5** is an enlarged view of a handle of the delivery system shown in FIG. **4**.

[0012] FIG. **6** is an enlarged view of a distal end of the delivery system shown in FIG. **4**.

[0013] FIG. **7** is a top view of an example of a balloon catheter when the balloon is inflated.

[0014] FIG. **8** is a top view of an example of an inflation system for use with a delivery system similar to that shown in FIG. **4**.

[0015] FIG. **9** is a side view of the inflation system of FIG. **8**.

[0016] FIG. **10** is a perspective view of a connection between the inflation system of FIGS. **8-9** and the handle of the delivery system of FIG. **4**.

[0017] FIG. **11** is a flowchart showing exemplary steps in a procedure to implant the prosthetic heart valve of FIG. **1** into a patient using the delivery system of FIG. **4**.

[0018] FIG. **12** is a side view of an example of the balloon of FIG. **6** isolated from other components of the delivery system.

[0019] FIG. **13**A is a side view of an example of a distal end of the delivery catheter of FIG. **4** in a state of assembly.

[0020] FIGS. **13**B-**13**C are side and front views, respectively, of an example of a proximal inner stop of FIG. **13**A.

[0021] FIGS. **13**D-**13**E are side and rear views, respectively, of an example of a distal stop of FIG. **13**A.

[0022] FIG. **13**F is a side view of an example of a distal end of the delivery catheter of FIG. **4** in a state of assembly with the balloon of FIG. **12**, the proximal inner stop of FIGS. **13**B-**13**C, and the distal stop of FIGS. **13**D-**13**E.

[0023] FIGS. **13**G-**13**H are side and front views, respectively, of an example of a proximal outer stop.

[0024] FIGS. **13**I-**13**J are side and front views, respectively, of the proximal outer stop of FIGS. **13**G-**13**H assembled to the proximal inner stop of FIGS. **13**B-**13**C.

[0025] FIG. **13**K is a side view of an example of a distal end of the delivery catheter of FIG. **4** in a state of assembly with the proximal outer stop of FIGS. **13**G-**13**H assembled to the proximal inner stop of FIGS. **13**B-**13**C.

[0026] FIG. **13**L is a flow chart showing an example of a method of assembling a distal end of a delivery catheter.

[0027] FIG. **14** is a highly schematic view of another example of an assembled proximal stop.

[0028] FIG. **15**A is a highly schematic perspective view of another example of an assembled proximal stop.

[0029] FIGS. **15**B-**15**C are highly schematic cross-sections of a proximal outer stop of the assembled proximal stop of FIG. **15**A in collapsed and expanded configurations, respectively.

[0030] FIG. **16** is a side view of an example of a distal end of the delivery catheter of FIG. **4** with a pusher feature engaged with a proximal stop.

[0031] FIG. **17** is a side view of an example of a distal end of the delivery catheter of FIG. **4**.

[0032] FIG. **18**A is a side view of an example of an inner stop.

[0033] FIG. **18**B is a front view of an example of an outer stop for use with the inner stop of FIG. **18**A.

[0034] FIG. **18**C is a schematic view of an example step of assembling the outer stop of FIG. **18**B to the inner stop of FIG. **18**A.

[0035] FIG. **18**D is a cross-section of the outer stop of FIG. **18**B assembled to the inner stop of FIG. **18**A.

[0036] FIG. **19**A is a side view of an example of an inner stop.

[0037] FIG. **19**B is a front view of an example of an outer stop for use with the inner stop of FIG. **19**A.

[0038] FIG. **19**C is a schematic view of an example step of assembling the outer stop of FIG. **19**B to the inner stop of FIG. **19**A.

[0039] FIG. **19**D is a cross-section of the outer stop of FIG. **19**B assembled to the inner stop of FIG. **19**A.

[0040] FIG. **20**A is a highly schematic illustration of an example of a stop in a relaxed condition.

[0041] FIG. **20**B is a highly schematic illustration of the stop of FIG. **20**A in a tensioned configuration.

[0042] FIG. **21**A is a highly schematic cross-section of an example of a stop in an uncompressed condition.

[0043] FIG. **21**B is a highly schematic cross-section of the stop of FIG. **21**B in a compressed condition.

[0044] FIG. **22**A is a highly schematic cross-section of an example of an inner stop and outer stop in a state of assembly.

[0045] FIG. **22**B is a highly schematic cross-section of the outer stop and inner stop of FIG. **22**A assembled together with the outer stop in an expanded condition.

[0046] FIG. **23**A is a highly schematic view of an example of a stop in an uncompressed condition.

[0047] FIG. **23**B is a highly schematic view of the stop of FIG. **23**B in a compressed condition.

[0048] FIG. **24** is a highly schematic view of an example of a stop in an uncompressed condition.

[0049] FIG. **25** is a highly schematic cross-section of an example of a distal end of the delivery catheter of FIG. **4**.

[0050] FIG. **26**A is a highly schematic side view of an example of the distal end of the delivery catheter of FIG. **4** with a first friction-enhancing surface.

[0051] FIG. **26**B is a highly schematic side view of an example of the distal end of the delivery catheter of FIG. **4** with a second friction-enhancing surface.

[0052] FIG. **27** is a highly schematic side view of an example of a balloon of the delivery catheter of FIG. **4** with a friction-enhancing features.

[0053] FIG. **28** is a highly schematic side view of an example of a balloon of the delivery catheter of FIG. **4** with studs or nodules in contact with a prosthetic heart valve crimped on the balloon.

[0054] FIG. **29** is a highly schematic side view of an example of a balloon of the delivery catheter of FIG. **4** with microbeads received therein.

[0055] FIG. **30** is a highly schematic cut-away view of an example of a distal end of the delivery catheter of FIG. **4** with non-expandable stops within the balloon.

[0056] FIG. **31**A is a highly schematic perspective view of a distal end of an example of a spreadable outer balloon catheter.

[0057] FIG. **31**B is a highly schematic cross-section of an example of the distal end of the delivery catheter of FIG. **4** incorporating the spreadable outer balloon catheter of FIG. **31**A.

[0058] FIG. **32** is a highly schematic cross-section of an example of a balloon with overhangs.

[0059] FIG. **33** is a highly schematic cross-section of an example of a balloon with retainer features mounted on the balloon.

[0060] FIGS. **34**A-**34**C are highly schematic cross-sections of an example method of forming an example of a valve retainer within a balloon.

DETAILED DESCRIPTION OF THE DISCLOSURE

[0061] As used herein, the term "inflow end" when used in connection with a prosthetic heart valve refers to the end of the prosthetic valve into which blood first enters when the prosthetic valve is implanted in an intended position and orientation, while the term "outflow end" refers to the end of the prosthetic valve where blood exits when the prosthetic valve is implanted in the intended position and orientation. Thus, for a prosthetic aortic valve, the inflow end is the end nearer the left ventricle while the outflow end is the end nearer the aorta. The intended position and orientation are used for the convenience of describing valves disclosed herein. However, it should be noted that the use of the valve is not limited to the intended position and orientation but may be deployed in any type of lumen or passageway. For example, although prosthetic heart valves are described herein as prosthetic aortic valves, those same or similar structures and features can be employed in other heart valves, such as the pulmonary valve, the mitral valve, or the tricuspid valve. Further, the term "proximal," when used in connection with a delivery device or system, refers to a position relatively close to the user of that device or system when it is being used as intended, while the term "distal" refers to a position relatively far from the user of the device. In other words, the leading end of a delivery device or system is positioned distal to the trailing end of the delivery device or system, when the delivery device is being used as intended. As used herein, the terms "substantially," "generally," "approximately," and "about" are intended to mean that slight deviations from absolute are included within the scope of the term so modified. As used herein, the prosthetic heart valves may assume an "expanded state" and a "collapsed state," which refer to the relative radial size of the stent.

[0062] Collapsible and expandable prosthetic heart valves typically take the form of a one-way valve structure (often referred to as a valve assembly) mounted within an expandable frame (the terms "stent" and "frame" may be used interchangeably herein). In general, these collapsible and expandable heart valves include a self-expanding, mechanically-expandable, or balloon-expandable frame, often made of nitinol or another shape-memory metal or metal alloy (for self-expanding frames) or steel or cobalt chromium (for balloon-expandable frames). The one-way valve assembly mounted to/within the stent includes one or more leaflets and may also include a cuff or skirt. The cuff may be disposed on the stent's interior or luminal surface, its exterior or abluminal surface, and/or on both surfaces. A cuff helps to ensure that blood does not just flow around the valve leaflets if the valve or valve assembly is not optimally seated in a valve annulus. A cuff, or a portion of a cuff disposed on the exterior of the stent, can help prevent leakage around the outside of the valve (the latter known as paravalvular or "PV" leakage).

[0063] Balloon expandable valves are typically delivered to the native annulus while collapsed (or "crimped") onto a deflated balloon of a balloon catheter, with the collapsed valve being either covered or uncovered by an overlying sheath. Once the crimped prosthetic heart valve is positioned within the annulus of the native heart valve that is being replaced, the balloon is inflated to force the balloon-expandable valve to transition from the collapsed or crimped condition into an expanded or deployed condition, with the prosthetic heart valve tending to remain in the shape into which it is expanded by the balloon. Typically, when the position of the collapsed prosthetic heart valve is determined to be in the desired position relative to the native annulus (e.g. via visualization under fluoroscopy), a fluid (typically a liquid although gas could be used as well) such as saline is pushed via a syringe (manually, automatically, or semi-automatically) through the balloon catheter to cause the balloon to begin to fill and expand, and thus cause the overlying prosthetic heart valve to expand into the native annulus.

[0064] FIG. **1** is a perspective view of one example of a prosthetic heart valve **10**. Prosthetic heart valve **10** may be a balloon-expandable prosthetic aortic valve, although in other examples it may be a self-expandable or mechanically-expandable prosthetic heart valve, intended for replacing a native aortic valve or another native heart valve. Prosthetic heart valve **10** is shown in an expanded condition in FIG. **1**. Prosthetic heart valve **10** may extend between an inflow end **12** and an outflow end **14**. Prosthetic heart valve **10** may include a collapsible and expandable frame **20**, an inner cuff

or skirt **60**, an outer cuff or skirt **80**, and a plurality of prosthetic leaflets **90**. As should be clear below, prosthetic heart valve **10** is merely one example of a prosthetic heart valve, and other examples of prosthetic heart valves may be suitable for use with the concepts described below.

[0065] FIG. **2** is a front view of an example of a section of the frame **20** of prosthetic heart valve **10**, as if cut longitudinally and laid flat on a table. The section of frame **20** in FIG. **2** may represent approximately one-third of a complete frame, particularly if frame **20** is used in conjunction with a three-leaflet prosthetic heart valve. In the illustrated example, frame **20** is a balloon-expandable stent and may be formed of stainless steel or cobalt-chromium, and which may include additional materials such as nickel and/or molybdenum. However, in some embodiments the stent may be formed of a shape memory material such as nitinol or the like. The frame **20**, when provided as a balloon-expandable frame, is configured to collapse upon being crimped to a smaller diameter and/or expand upon being forced open, for example via a balloon within the frame expanding, and the frame will substantially maintain the shape to which it is modified when at rest.

[0066] Frame **20** may include an inflow section **22** and an outflow section **24**. The inflow section **22** may also be referred to as the annulus section. In one example, the inflow section **22** includes a plurality of rows of generally hexagon-shaped cells. For example, the inflow section **22** may include an inflow-most row of hexagon-shaped cells **30** and an outflow-most row of hexagon-shaped cells **32**. The inflow-most row of hexagonal cells **30** may be formed of a first circumferential row of angled or zig-zag struts **21**, a second circumferential row of angled or zig-zag struts **25**, and a plurality of axial struts **23** that connect the two rows. In other words, each inflow-most hexagonal cell **30** may be formed by two angled struts **21** that form an apex pointing in the inflow direction, two angled struts **25** that form an apex pointing in the outflow direction, and two axial struts that connect the two angled struts **21** to two corresponding angled struts **25**. The outflow-most row of hexagonal cells **32** may be formed of the second circumferential row of angled or zig-zag struts **25**, a third circumferential row of angled or zig-zag struts **29**, and a plurality of axial struts **27** that connect the two rows. In other words, each outflow-most hexagonal cell **32** may be formed by two angled struts **25** that form an apex pointing in the inflow direction, two angled struts **29** that form an apex pointing in the outflow direction, and two axial struts that connect the two angled struts **27** to two corresponding angled struts **29**. It should be understood that although the term "outflow-most" is used in connection with hexagonal cells **32**, additional frame structure, described in more detail below, is still provided in the outflow direction relative to the outflow-most row of hexagonal cells **32**.

[0067] In the illustrated embodiment, assuming that frame **20** is for use with a three-leaflet valve and thus the section shown in FIG. **2** represents about one-third of the frame **20**, each row of cells **30**, **32** includes twelve individual cells. However, it should be understood that more or fewer than twelve cells may be provided per row of cells. Further, the inflow or annulus section **22** may include more or fewer than two rows of cells. Still further, although cells **30**, **32** are shown as being hexagonal, the some or all of the cells of the inflow section **22** may have other shapes, such as diamond-shaped, chevron-shaped, or other suitable shapes. In the illustrated embodiment, every cell **30** in the first row is structurally similar or identical to every other cell **30** in the first row, every cell **32** in the second row is structurally similar or identical to every other cell **32** in the second row, and every cell **30** in the first row is structurally similar or identical (excluding the aperture **26**) to every cell **32** in the second row. However, in other examples, the cells in each row are not identical to every other cell in the same row or in other rows.

[0068] An inflow apex of each hexagonal cell **30** may include an aperture **26** formed therein, which may accept sutures or similar features which may help couple other elements, such as an inner cuff **60**, outer cuff **80**, and/or prosthetic leaflets **90**, to the frame **20**. However, in some examples, one or more or all of the apertures **26** may be omitted.

[0069] Still referring to FIG. **2**, the outflow section **24** of the frame **20** may include larger cells **34** that have generally asymmetric shapes. For example, the lower or inflow part of the larger cells **34** may be defined by the two upper struts **29** of a cell **32**, and one upper strut **29** of each of the two adjacent cells **32**. In other words, the lower end of each larger cell **34** may be formed by a group of four consecutive upper struts **29** of three circumferentially adjacent cells **32**. The tops of the larger cells **34** may each be defined by two linking struts **35***a*, **35***b*. The first linking strut **35***a* may couple to a top or outflow apex of a cell **32** and extend upwards at an angle toward a commissure attachment feature ("CAF") **40**. The second linking strut **35***b* may extend from an end of the first linking strut **35***a* back downwardly at an angle and connect directly to the CAF **40**. To the extent that the larger cells **34** include sides, a first side is defined by a portion of the CAF **40**, and a second side is defined by the connection between first linking strut **35***a* and the corresponding upper strut **29** of the cell **32** attached to the first linking strut **35***a*.

[0070] The CAF **40** may generally serve as an attachment site for leaflet commissures (e.g. where two prosthetic leaflets **90** join each other) to be coupled to the frame **20**. In the illustrated example, the CAF **40** is generally rectangular and has a longer axial length than circumferential width. The CAF **40** may define an interior open rectangular space. The struts that form CAF **40** may be generally smooth on the surface defining the open rectangular space, but some or all of the struts may have one or more suture notches on the opposite surfaces. For example, in the illustrated example, CAF **40** includes two side struts (on the longer side of the rectangle) and one top (or outflow) strut that all include alternating projections and notches on their exterior facing surfaces. These projections and notches may help maintain the position of one or more sutures that wrap around these struts. These sutures may directly couple the prosthetic leaflets **90** to the frame **20**, and/or may directly couple an intermediate sheet of material (e.g., fabric or tissue) to the CAF **40**, with the prosthetic leaflets **90** being directly coupled to that intermediate sheet of material. In some embodiments, tabs or ends of the prosthetic leaflets **90** may be pulled through the opening of the CAF **40**, but in other embodiments the prosthetic leaflets **90** may remain mostly or entirely within the inner diameter of the frame **20**. It should be understood that balloon-expandable frames are typically formed of metal or metal alloys that are very stiff, particularly in comparison to self-expanding frames. At least in part because of this stiffness, although the prosthetic

leaflets **90** may be sutured or otherwise directly coupled to the frame at the CAFs **40**, it may be preferable that most or all of the remaining portions of the prosthetic leaflets **90** are not attached directly to the frame **20**, but are rather attached directly to an inner skirt **60**, which in turn is directly connected to the frame **20**. Further, it should be understood that other shapes and configurations of CAFs **40** may be appropriate. For example, various other suitable configurations of frames and CAFs are described in greater detail in U.S. Provisional Patent Application No. 63/579,378, filed Aug. 29, 2023 and titled "TAVI Deployment Accuracy-Stent Frame Improvements," the disclosure of which is hereby incorporated by reference herein.

[0071] With the example described above, frame **20** includes two rows of hexagon-shaped cells **30**, **32**, and a single row of larger cells **34**. In a three-leaflet embodiment of a prosthetic heart valve that incorporates frame **20**, each row of hexagon-shaped cells **30**, **32** includes twelve cells, while the row of larger cells includes six larger cells **34**. As should be understood, the area defined by each individual cell **30**, **32** is significantly smaller than the area defined by each larger cell **34** when the frame **20** is expanded. There is also significantly more structure (e.g., struts) that create each row of individual cells **30**, **32** than structure that creates the row of larger cells **34**.

[0072] One consequence of the above-described configuration is that the inflow section **22** has a higher cell density than the outflow section **24**. In other words, the total numbers of cells, as well as the number of cells per row of cells, is greater in the inflow section **22** compared to the outflow section **24**. The configuration of frame **20** described above may also result in the inflow section **22** being generally stiffer than the outflow section **24** and/or more radial force being required to expand the inflow section **22** compared to the outflow section **24**, despite the fact that the frame **20** may be formed of the same metal or metal alloy throughout. This increased rigidity or stiffness of the inflow section **22** may assist with anchoring the frame **20**, for example after balloon expansion, into the native heart valve annulus. The larger cells **34** in the outflow section **24** may assist in providing clearance to the coronary arteries after implantation of the prosthetic heart valve **10**. For example, after implantation, one or more coronary ostia may be positioned above the frame **20**, for example above the valley where two adjacent larger cells **34** meet (about halfway between a pair of circumferentially adjacent CAFs **40**). Otherwise, one or more coronary ostia may be positioned in alignment with part of the large interior area of a larger cell **34** after implantation. Either way, blood flow to the coronary arteries is not obstructed, and a further procedure that utilizes the coronary arteries (e.g. coronary artery stenting) will not be obstructed by material of the frame **20**. Still further, the lower rigidity of the frame **20** in the outflow section **24** may cause the outflow section **24** to preferentially foreshorten during expansion, with the inflow section **22** undergoing a relatively smaller amount of axial foreshortening. This may be desirable because, as the prosthetic heart valve **10** expands, the position of the inflow end of the frame **20** may remain substantially constant relative to the native valve annulus, which may make the deployment of the prosthetic heart valve **10** more precise. This may be, for example, because the inflow end of the frame **20** is typically used to gauge proper alignment with the native valve annulus prior to deployment, so axial movement of the inflow end of the frame **20** relative to the native valve annulus during deployment may make precise placement more difficult.

[0073] Referring back to FIG. **1**, the prosthetic heart valve **10** may include an inner skirt **60** mounted to the interior surface of frame **20**. The inner skirt **60** may be formed of tissue, such as pericardium, although other types of tissue may be suitable. In the illustrated example, the inner skirt **60** is formed of a woven synthetic fabric, such as polyethylene terephthalate ("PET") or polytetrafluoroethylene ("PTFE"), although other fabrics may be suitable, including fabrics other than woven fabrics. In some examples, the inner skirt **60** has straight or zig-zag shaped inflow and outflow ends that generally follow the contours of the cells **30**, **32** of the inflow section **22** of frame **20**. Preferably, inner skirt **60** is sutured to the frame **20** along the struts that form cells **30**, **32**. If apertures **26** are included, inner skirt **60** may also be coupled to frame **20** via sutures passing through apertures **26**. Preferably, the inner skirt **60** does not cover (or does not cover significant portions of) the larger cells **34**. The inner skirt **60** may be coupled to the frame **20** via mechanisms other than sutures, including for example ultrasonic welding or adhesives. Further, the inner skirt **60** may have shapes other than that shown, and need not have a zig-zag inflow or outflow end, and need not cover every cell in the inflow section **22**. In fact, in some examples, the inner skirt **60** may be omitted entirely, with the outer skirt **80** (described in greater detail below) being the only skirt used with prosthetic heart valve **10**. If the inner skirt **60** is provided, it may assist with sealing the prosthetic heart valve **10** within the heart, as well as serving as a mounting structure for the prosthetic leaflets **90** (described in greater detail below) within the frame **20**.

[0074] Still referring to FIG. **1**, the prosthetic heart valve **10** may include an outer skirt **60** mounted to the exterior surface of frame **20**. The outer skirt **80** may be formed of tissue, such as pericardium, although other types of tissue may be suitable. In the illustrated example, the outer skirt **80** is formed of a woven synthetic fabric, such as PET or PTFE, although other fabrics may be suitable, including fabrics other than woven fabrics. In some examples, the outer skirt **80** has straight or zig-zag inflow end. Preferably, outer skirt **80** is sutured to the frame **20** and/or inner skirt **60** along the inflow edge of the outer skirt **80**. If apertures **26** are included, outer skirt **80** may also be coupled to frame **20** via sutures passing through apertures **26**. The outer skirt **80** may include a plurality of folds or pleats, such a circumferentially extending folds or pleats. The folds or pleats may be formed in the outer skirt **80** via heat setting, for example by placing the outer skirt **80** within a mold that forces the outer skirt **80** to form folds of pleats, and the outer skirt **80** may be treated with heat so that the outer skirt **80** tends to maintain folds or pleats in the absence of applied forces. The outflow edge of outer skirt **80** may be coupled to the frame **20** at selected, spaced apart locations around the circumference of the frame **20**. In some embodiments, the outflow edge of outer skirt **80** may be connected to the inner skirt **60** along a substantially continuous suture line. Some or all of the outer skirt **80** between its inflow and outflow edges may remain not directly couples to the frame **20** or inner skirt **60**. Preferably, the outer skirt **80** does not cover (or does not cover significant portions of) the larger cells **34**. In use, the outer skirt **80** may directly contact the interior surface of the native heart valve annulus to assist with scaling, including

sealing against PV leak. If folds or pleats are included with the outer skirt **80**, the additional material of the folds or pleats may help further mitigate PV leak. However, it should be understood that the folds or pleats may be omitted from outer skirt **80**, and the outer skirt **80** may have shapes other than that shown. In fact, in some examples, the outer skirt **80** may be omitted entirely, with the inner skirt **60** being the only skirt used with prosthetic heart valve **10**. If the inner skirt **60** is omitted, the prosthetic leaflets **90** may be attached directly to the frame **20** and/or directly to the outer skirt **80**.

[0075] FIG. **3** is a front view of a prosthetic leaflet **90**, as if laid flat on a table. In the illustrated example of prosthetic heart valve **10**, a total of three prosthetic leaflets **90** are provided, although it should be understood that more or fewer than three prosthetic leaflets may be provided in other example of prosthetic heart valves. The prosthetic leaflet **90** may be formed of a synthetic material, such a polymer sheet or woven fabric, or a biological material, such a bovine or porcine pericardial tissue. However, other materials may be suitable. In on example, the prosthetic leaflet **90** is formed to have a concave free edge **92** configured to coapt with the free edges of the other leaflets to help provide the one-way valve functionality. The prosthetic leaflet **90** may include an attached edge **94** which is attached (e.g., via suturing) to other structures of the prosthetic heart valve **10**. For example, the attached edge **94** may be coupled directly to the inner skirt **60**, directly to the frame **20**, and/or directly to the outer skirt **80**. It may be preferable that the attached edge **94** is coupled directly only to the inner skirt **60**, which may help reduce stresses on the prosthetic leaflet **90** compared to if the attached edge **94** were coupled directly to the frame **20**. In some embodiments, a plurality of holes **98** may be formed along the attached edge **94** (or a spaced distance therefrom), for example via lasers. If included, the holes **98** may be used to receive sutures therethrough, which may make it easier to couple the prosthetic leaflet **90** to the inner skirt **60** during manufacturing. For example, the holes **98** may serve as guides if suturing is performed manually, and if the positions of the holes **98** are controlled via the use of layers, the holes **98** may be consistently placed among different prosthetic leaflets **90** to reduce variability between different prosthetic leaflets **90**. Leaflet tabs **96** may be provided at the junctions between the free edge **92** and the attached edge **94**. Each leaflet tab **96** may be joined to a leaflet tab of an adjacent prosthetic leaflet to form prosthetic leaflet commissures, which may be coupled to the frame **20** via CAFs **40**.

[0076] The prosthetic heart valve **10** may be delivered via any suitable transvascular route, for example transapically or transfemorally. Generally, transapical delivery utilizes a relatively stiff catheter that pierces the apex of the left ventricle through the chest of the patient, inflicting a relatively higher degree of trauma compared to transfemoral delivery. In a transfemoral delivery, a delivery device housing or supporting the valve is inserted through the femoral artery and advanced against the flow of blood to the left ventricle. In either method of delivery, the valve may first be collapsed over an expandable balloon while the expandable balloon is deflated. The balloon may be coupled to or disposed within a delivery system, which may transport the valve through the body and heart to reach the aortic valve, with the valve being disposed over the balloon (and, in some circumstances, under an overlying sheath). Upon arrival at or adjacent to the aortic valve, a surgeon or operator of the delivery system may align the prosthetic valve as desired within the native valve annulus while the prosthetic valve is collapsed over the balloon. When the desired alignment is achieved, the overlying sheath, if included, may be withdrawn (or advanced) to uncover the prosthetic valve, and the balloon may then be expanded causing the prosthetic valve to expand in the radial direction, with at least a portion of the prosthetic valve foreshortening in the axial direction.

[0077] FIG. **4** illustrates one example of a delivery system **100**, with the prosthetic heart valve **10** crimped over a balloon on a distal end of the delivery system **100**. Although delivery system **100** and various components thereof are described below, it should be understood that delivery system **100** is merely one example of a balloon catheter that may be appropriate for use in delivering and deploying prosthetic heart valve **10**.

[0078] In some examples, delivery system **100** includes a handle **110** and a delivery catheter **130** extending distally from the handle **110**. An introducer **150** may be provided with the delivery system **100**. Introducer **150** may be an integrated or captive introducer, although in other embodiments introducer **150** may be a non-integrated or non-captive introducer. In some examples, the introducer **150** may be an expandable introducer, including for example an introducer that expands locally as a large diameter components passes through the introducer, with the introducer returning to a smaller diameter once the large diameter components passes through the introducer. In other examples, the introducer **150** is a non-expandable introducer.

[0079] A guidewire GW may be provided that extends through the interior of all components of the delivery system **100**, from the proximal end of the handle **110** through the atraumatic distal tip **138** (which may also be referred to as a "nose cone") of the delivery catheter **130**. The guidewire GW may be introduced into the patient to the desired location, and the delivery system **100** may be introduced over the guidewire GW to help guide the delivery catheter **130** through the patient's vasculature over the guidewire GW.

[0080] In some examples, the delivery catheter **130** is steerable. For example, one or more steering wires may extend through a wall of the delivery catheter **130**, with one end of the steering wire coupled to a steering ring coupled to the delivery catheter **130**, and another end of the steering wire operable coupled to a steering actuator on the handle **110**. In such examples, as the steering actuator is actuated, the steering wire is tensioned or relaxed to cause deflection or straightening of the delivery catheter **130** to assist with steering the delivery catheter **130** to the desired position within the patient. For example, FIG. **5** is an enlarged view of the handle **110**. Handle **110** may include a steering knob **112** that, upon rotation, tensions or relaxes the steering wires to deflect the distal end of the delivery catheter **130**. Handle **110** may include a slot **118** with an indicator extending therethrough, the indicator moving along the slot **118** as the delivery catheter **130** deflects (e.g., the indicator moves proximally as deflection increases). If included, the indicator and slot **118** may provide the user an easy reference of how much the delivery catheter **130** is deflected at any given point. However, it should be understood that the steering functionality may be omitted in some examples, and in other examples steering actuators other than knobs may be utilized. Further, in some examples, including those shown in FIGS. **6-7**, the delivery catheter **130** includes an outer

catheter **132**, and an inner catheter **134**. The inner catheter **134** may also be referred to as a guidewire catheter. The steering functionality may be provided in either the outer catheter **132**, or the inner catheter **134**, or in both catheters. However, in some examples, a separate steering catheter **135** may be provided. For example, as shown in FIG. **4**, the steering catheter **135** may be positioned outside of the outer catheter **132** and may terminate just proximal to the balloon **136**. With this configuration, deflection of the steering catheter **135** will also cause deflection of the outer catheter **132** and the inner catheter **134** which are both nested within the steering catheter **135**.

[0081] Still referring to FIGS. **4-5**, the delivery system **100** may include additional functionality to assist with positioning the prosthetic heart valve **10**. For example, in the illustrated example, handle **110** includes a commissure alignment actuator **114**, which may be positioned near a proximal end of the handle or at any other desired location. In the illustrated example, the commissure alignment actuator **114** is in the form of a rotatable knob, although other forms may be suitable. The commissure alignment knob **114** may be rotationally coupled to a portion of the delivery catheter **130** supporting the prosthetic heart valve **10**. For example, the commissure alignment actuator **114** may be rotationally coupled to an inner catheter **134** which supports the prosthetic heart valve **10** in the crimped condition. With this configuration, rotating the commissure alignment knob **114** may cause the inner catheter **134** to rotate about its longitudinal axis, and thus cause the prosthetic heart valve **10** to rotate about its longitudinal axis. If a commissure alignment actuator **114** is included, it may be used to help ensure that, upon deployment of the prosthetic heart valve **10** into the native valve annulus, the commissures of the prosthetic heart valve are in rotational alignment with respective ones of the native valve commissures (e.g. within +/−2.5 degrees of rotational alignment, within +/−5 degrees of rotational alignment, within +/−10 degrees of rotational alignment, within +/−15 degrees of rotational alignment, etc.). Although commissure alignment actuator **114** is shown in this example as a knob positioned at or near a proximal end of the handle **110**, it should be understood that the actuator **114** may take forms other than a knob, may be positioned at other suitable locations, and may be omitted entirely if desired.

[0082] Still referring to FIGS. **4-5**, the delivery system **100** may include even further functionality to assist with positioning the prosthetic heart valve **10**. For example, in the illustrated example, handle **110** includes an axial alignment actuator **116**, which may be positioned near a proximal end of the handle, including distal to the commissure alignment actuator **114**, or at any other desired location. In the illustrated example, the axial alignment actuator **116** is in the form of a rotatable knob, although other forms may be suitable. The axial alignment knob **116** may be operably coupled to a portion of the delivery catheter **130** supporting the prosthetic heart valve **10**. For example, the axial alignment actuator **116** may include internal threads that engage external threads of a carriage that is coupled to the inner catheter **134** which supports the prosthetic heart valve **10** in the crimped condition. In such an example, the carriage may be rotatably fixed to the handle **110**. With this configuration, rotating the axial alignment knob **116** may cause the carriage to advance distally or retract proximally as the inner threads of the axial alignment knob **116** mesh with the external threads of the carriage, but the carriage is prevented from rotating. As the carriage advances distally or retracts proximally, the inner catheter **134** may correspondingly advance distally or retract proximally, and thus cause the prosthetic heart valve **10** to advanced distally or retract proximally. It should be understood that, if axial alignment actuator **116** is included, it may have a small total range of motion. In other words, the rough or coarse axial alignment between the prosthetic heart valve **10** and native valve annulus may be achieved by physically advancing the entire delivery catheter **130** by pushing it through the vasculature while holding the handle **110**. However, for fine and more controlled adjustment of the axial position of the prosthetic heart valve **10** relative to the native valve annulus, which may be performed just prior to or during deployment of the prosthetic heart valve **10**, the axial alignment knob **116** may be used. If an axial alignment actuator **116** is included, it may be used to help ensure that, upon deployment of the prosthetic heart valve **10** into the native valve annulus, the inflow end of the of the prosthetic heart valve is in axial alignment with the inflow aspect of the native valve annulus (e.g. within +/−0.5 mm of axial alignment, within +/−1.0 mm of axial alignment, within +/−1.5 mm of axial alignment, within +/−2.0 mm of axial alignment, etc.). Although axial alignment actuator **116** is shown in this example as a knob positioned at or near a proximal end of the handle **110**, it should be understood that the actuator **116** may take forms other than a knob, may be positioned at other suitable locations, and may be omitted entirely if desired.

[0083] In addition to steering and positioning actuators, delivery system **100** may include a balloon actuator **120**. In the illustrated example, balloon actuator **120** is positioned on the handle **110** near a distal end thereof, and is provided in the form of a switch. Balloon actuator **120** may be actuated to cause inflation or deflation of a balloon **136** that is part of the delivery system **100**. For example, referring briefly to FIGS. **6-7**, the delivery system **100** may include a balloon **136** that overlies a distal end of inner catheter **134** and which receives the prosthetic heart valve **10** in a crimped condition thereon. In the example illustrated in FIG. **6**, the balloon **136** includes a proximal pillowed portion **136***a*, a distal pillowed portion **136***b*, and a central portion over which the prosthetic heart valve **10** is crimped. The proximal pillow **136***a* and the distal pillow **136***b* may form shoulders on each side of the prosthetic heart valve **10**, which may help ensure the prosthetic heart valve **10** does not move axially relative to the balloon **136** and/or inner catheter **134** during delivery. The shoulder formed by the distal pillow **136** may also help protect the inflow edge of the prosthetic heart valve **10** from contact with the anatomy during delivery. For example, during a transfemoral delivery, as the distal end of the delivery catheter **130** traverse the sharp bends of the aortic arch (or during initial introduction into the patient), there is a relatively high likelihood the inflow end of the prosthetic heart valve **10** (which is the leading edge during transfemoral delivery) will contact a vessel wall (or a components of an introduction system) causing dislodgment of the prosthetic heart valve **10** relative to the balloon **136**. The distal pillow **136** may tend to have an equal or larger outer diameter than the inflow end of the prosthetic heart valve **10** (when the prosthetic heart valve **10** is crimped and the balloon **136** is deflated), which may help ensure the inflow edge of the prosthetic heart valve **10** does not inadvertently contact another structure during delivery. In

some examples, the pillowed portions **136***a*, **136***b* may be formed via heat setting. Additional related features for use in similar balloon catheter delivery systems are described in greater detail in U.S. Provisional Patent Application No. 63/382,812, filed Nov. 8, 2022 and titled "Prosthetic Heart Valve Delivery and Trackability," the disclosure of which is hereby incorporated by reference herein.

[0084] In order to deploy the prosthetic heart valve **10**, the balloon **136** is inflated, for example by actuating the balloon actuator **120** to force fluid (such as saline, although other fluids, including liquids or gases, could be used) into the balloon **136** to cause it to expand, causing the prosthetic heart valve **10** to expand in the process. For example, the balloon actuator **120** may be pressed forward or distally to cause fluid to travel through an inflation lumen within delivery catheter **130** to inflate the balloon **136**. FIG. **7** illustrates an example of the balloon **136** after being inflated, with the prosthetic heart valve **10** omitted from the figure for clarity. In the illustrated example, the balloon **136** may be formed to have a distal end that is fixed to a portion of an atraumatic distal tip **138**. The distal tip **138** may be tapered to help the delivery catheter **130** move through the patient's vasculature more smoothly. A proximal end of the balloon **136** may be fixed to a distal end of outer catheter **132**. The inflation lumen may be the space between the outer catheter **132** and the inner catheter **134**, or in other embodiments may be provided in a wall of the inner catheter **134**, or in any other location that fluidly connects the interior of the balloon **136** to a fluid source outside of the patient that is operable coupled to the delivery system **100**.

[0085] Referring to FIG. **7**, in some examples, a mounting shaft **140** may be provided on the inner catheter **134**. A proximal stop **142** and/or a distal stop **144** may be provided, for example at opposite ends of the mounting shaft **140**. If the mounting shaft **140** is included, it may provide a location on which the prosthetic heart valve **10** may be crimped. If the proximal stop **142** and/or distal stop **144** is provided, they may provide physical barriers to the prosthetic heart valve **10** moving axially relative to the balloon **136**. In one example, the proximal stop **142** may taper from a larger distal diameter to a smaller proximal diameter, and the distal stop may taper from a larger proximal diameter to a smaller distal diameter. The spacing between the proximal stop **142** and the distal stop **144**, if both are included, may be slightly larger than the length of the prosthetic heart valve **10** when it is crimped over mounting shaft **140**. However, it should be understood that one or both of the stops **142**, **144** may be omitted, and the mounting shaft **140** may also be omitted. If the mounting shaft **140** is included, it is preferably axially and rotationally fixed to the inner catheter **134** so that movement of the inner catheter **134** causes corresponding movement of the mounting member **140**, and thus the prosthetic heart valve **10** when mounted thereon.

[0086] Before describing the use of balloon actuator **120** in more detail, it should be understood that in some embodiments, the balloon actuator **120** may be omitted and instead a manual device, such as a manual syringe, may be provided along with delivery system **100** in order to manually push fluid into balloon **136** during deployment of the prosthetic heart valve **10**. As used herein, the phrase "fluid reservoir" and "syringe" may be used interchangeably. However, in the illustrated example of delivery system **100**, the balloon actuator **120** provides for a motorized and/or automated (or semi-automated) balloon inflation functionality. For example, FIG. **8** and FIG. **9** illustrate an example of a balloon inflation system **170**. Balloon inflation system **170** may include a housing **172** that houses one or more components, which may include a motor, one or more batteries, electronics for control and/or communication with other components, etc. Housing **172** may include one or more fixed cradles to receive a syringe **174**. In the illustrated embodiment, a distal cradle **176** is provide with an open "C"- or "U"-shaped configuration so that the distal end of the syringe **174** may be snapped into or out of the distal cradle **176**. A proximal cradle **178** may also be provided, which may have a "C"- or "U"-shaped bottom portion hingedly connected to a "C"- or "U"-shaped top portion. This configuration may allow for the proximal end of the outer body of the syringe **174** to be snapped into the bottom portion of proximal cradle **178**, and the top portion of proximal cradle **178** may be closed and connected to the bottom portion to fully circumscribe the outer body of the syringe **174** to lock the syringe **174** to the housing **172**. It should be understood that more or fewer cradles, of similar or different designs, may be included with housing **172** to help secure the syringe **174** to the housing **172** in any suitable fashion.

[0087] The balloon inflation system **170** may include a moving member **180**. In the illustrated embodiment, moving member **180** includes a "C"- or "U"-shaped cradle to receive a plunger handle **182** of the syringe **174** therein, the cradle being attached to a carriage that extends at least partially into the housing **172**. The carriage of the moving member **180** may be generally cylindrical, and may include internal threading that mates with external threading of a screw mechanism (not shown) within the housing **172** that is operably coupled to a motor. In some embodiments, the carriage may have the general shape of a "U"-beam with the flat face oriented toward the top. The moving member **180** may be rotationally fixed to the housing **172** via any desirable mechanism, so that upon rotation of the screw mechanism by the motor, the moving member **180** advances farther into the housing **172**, or retracts farther away from the housing **172**, depending on the direction of rotation of the screw mechanism. While the plunger handle **182** is coupled to the moving member **180**, advancement of the moving member **180** forces fluid from the syringe **174** toward the balloon **136**, while retraction of the moving member **180** withdraws fluid from the balloon **136** toward the syringe **174**. It should be understood that the motor, or other driving mechanism, may be located in or outside the housing **172**, and any other suitable mechanism may be used to operably couple the motor or other driving mechanism to the moving member **180** to allow for axial driving of the plunger handle **182**.

[0088] As shown in each of FIG. **8**, FIG. **9**, and FIG. **10**, the distal end of syringe **174** may be coupled to tubing **184** that is in fluid communication with an inflation lumen of delivery catheter **130** that leads to the balloon **136** at or near the distal end of the delivery system **100**. Tubing **184** may allow for the passage of the fluid (e.g., saline) from the syringe **174** toward the balloon **136**, or for withdrawal of fluid from the balloon **136** toward the syringe **174**, for example based on whether the balloon actuator **120** is pressed forward or backward.

[0089] Although not separately numbered in FIG. **8**, FIG. **9**, and FIG. **10**, the housing **172** may include one or more cables extending from the housing, for example to allow for

transmission of power (e.g., from AC mains or another component with which the cable is coupled) and/or transmission of data, information, control commands, etc. For example, one cable may couple the housing **172** to handle **110** so that controls on the handle **110** (e.g., balloon actuator **120**) may be used to activate the balloon inflation system **170** in the desired fashion. Another cable may couple to a computer display or similar device to provide information regarding the inflation of the balloon **136**. However, it should be understood that any transmission of data or information may be provided wirelessly instead of via a wired connection, for example via a Bluetooth or other suitable connection. Additional and related features of balloon inflation system **170**, related systems, and the uses thereof are described in U.S. patent application Ser. No. 18/311,458, the disclosure of which is hereby incorporated by reference herein.

[0090] FIG. **11** is a flowchart showing exemplary steps in an implantation procedure **200** to implant the prosthetic heart valve **10** of FIG. **1** into a patient using the delivery system **100** of FIG. **4**. However, it should be understood that not all of the steps shown in connection with implantation procedure **200** need to be performed, and various steps not explicitly shown and described in connection with procedure **200** may be performed as part of the implantation procedure. At the beginning of the procedure **200** in step **202**, the prosthetic heart valve **10** may be collapsed over or crimped onto balloon **136**, with the balloon **136** being mostly or entirely deflated after the crimping procedure. It should be understood that crimping step **202** may be performed at any time prior to the procedure, including at the beginning of the procedure, or at an earlier stage before the delivery system **100** is provided to the end user. In other words, the crimping step **202** may be performed during a manufacturing stage of the delivery system **100** and/or prosthetic heart valve **10**. During an early stage of the implantation procedure **200**, a guidewire GW may be advanced into the patient in step **204**, for example via the femoral artery, around the aortic arch, through the native aortic valve, and into the left ventricle. The guidewire GW may be used as a rail for other devices that need to access this pathway. For example, in step **206**, the atraumatic distal tip **138** may be advanced over the proximal end of the guidewire GW, and the delivery catheter **130** may be advanced over guidewire GW toward the native aortic valve. During this initial advancement of the delivery catheter **130** into the patient, the introducer **150** (if included) may be positioned distally, for example so that it covers the prosthetic heart valve **10** or so that it is positioned just proximal to the prosthetic heart valve **10**. Advancement of the delivery catheter **130** and introducer **150** may continue until a proximal hub of the introducer is in contact with the patient's skin (or in contact with another device that enters the patient's femoral artery. At this point, the introducer **150** may stop moving axially relative to the patient, with the delivery catheter **130** continuing to advance relative to the introducer **150**. If steering capability is provided, the delivery catheter **130** may be steered or deflected at any point to assist with achieving the desired pathway of the delivery catheter **130**. As on example, in step **208**, the steering knob **112** may be actuated to deflect the distal end of the delivery catheter **130** as it traverses the sharp bends of the aortic arch. Advancement of the delivery catheter **130** may continue in step **210** until the prosthetic heart valve **10**, while still crimped or collapsed, is positioned within the native aortic valve annulus. With the desired position achieved, the balloon **136** may be partially inflated, for example by pressing balloon actuator **120** forward, to partially expand the prosthetic heart valve **10** in step **212**. In some examples, it is desirable to expand the prosthetic heart valve **10** only partially in step **212**, because the position of the prosthetic heart valve **10** (including rotational and/or axial positioning) relative to the native aortic valve annulus may shift during this partial expansion. After the partial expansion of step **212**, the user may examine the positioning of the prosthetic heart valve **10** relative to the native aortic valve annulus. If desired, in step **214**, the axial positioning of the partially-expanded prosthetic heart valve **10** relative to the native aortic valve annulus may be finely adjusted (e.g., by actuating axial alignment actuator **116**) and/or the rotational orientation of the prosthetic heart valve **10** relative to the native aortic valve may be finely adjust (e.g., by actuating commissure alignment actuator **114**). When the desired axial alignment is achieve and the desired rotational alignment (e.g., rotational alignment between the prosthetic commissure and the native commissures) is achieved, the balloon **136** may be fully expanded in step **216** to fully expand the prosthetic heart valve **10** and to anchor the prosthetic heart valve **10** in the native aortic valve annulus in the desired position and orientation. After deployment is complete, the balloon **136** may be deflated in step **218**, for example by pressing actuating balloon **120** backward, and the delivery catheter **130** and guidewire GW may be removed from the patient to complete the procedure. It should be understood that the nine steps shown in FIG. **11** as part of procedure **200** are merely exemplary of a single example of an implantation procedure, and steps shown may be omitted, steps not shown may be included, and steps may be provided in any order deemed appropriate by the physician and/or medical personnel. In one example, the delivery catheter **130** may be guided to the right atrium and/or right ventricle for a tricuspid valve or pulmonary valve procedure. In another example, the delivery catheter **130** may be guided to the left atrium and/or left ventricle for a mitral valve procedure.

[0091] Although various components of a prosthetic heart valve **10** and delivery system **100** are described above, it should be understood that these components are merely intended to provide better context to the systems, features, and/or methods described below. Thus, various components of the systems described above may be modified or omitted as appropriate without affecting the systems, features, and/or methods described below. For example, prosthetic heart valves other than the specific configuration shown and described in connection with FIGS. **1-3** may be used with delivery systems other than the specific configuration shown and described in connection with FIGS. **4-10** as part of an implantation procedure that uses steps other than the specific configuration shown and described in connection with FIG. **11**, without affecting the inventive systems, features, and/or methods described below.

[0092] As noted above, for example in connection with FIG. **7**, in some examples it may be desirable to include one or more features within the balloon **136**, including on the inner catheter **134**, to contact opposite ends of the prosthetic heart valve **10** when the prosthetic heart valve **10** is crimped over the balloon **136**. Such features, including for examples stops **142**, **144**, may help maintain the prosthetic heart valve **10** retain its axial position on the balloon **136** as the prosthetic heart valve **10** is passed through the introducer

150 and/or through the patient's vasculature. In some examples, stops **142**, **144** that have relatively large radial extents (or diameters) may provide better valve retention than stops **142**, **144** that have relatively small radial extents (or diameters). However, one potential limitation on providing a stop with a relatively large radial extent is that, during manufacturing, the balloon **136** is typically pulled over the inner catheter **134** so that the ends of the balloon **136** may be fixed to the delivery device (e.g., a proximal end of the balloon **136** may be fixed to outer catheter **132** and a distal end of the balloon **136** may be fixed to nose cone **138**). In some examples, this limitation exists because the balloon **136** is formed separately from other components of the delivery system **100**.

[0093] Referring now in addition to FIG. **12**, FIG. **12** illustrates an example of a balloon **136**. Balloon **136** is shown in this example in a formed state but prior to coupling the balloon **136** to another component of delivery system **100**. As noted in connection with FIG. **6**, in some examples balloon **136** may be formed and processed to include a proximal pillow **136***a* and a distal pillow **136***b* that may abut the opposite axial ends of the prosthetic heart valve **10** when the prosthetic heart valve **10** is crimped over the crimp zone **136***c* of the balloon **136**. An example of possible contact between the opposite ends of the prosthetic heart valve **10** and the proximal pillow **136***a* and distal pillow **136***b* is shown in FIG. **6**. Although the proximal pillow **136***a* and distal pillow **136***b* may in some examples help the prosthetic heart valve **10** retain its axial position on the balloon **136** during delivery (including while passing the prosthetic heart valve through introducer **150**), it may be desirable in some examples to provide one or more additional valve retention features. However, if such one or more additional valve retention features is to be located within the interior of the balloon **136**, it may in some examples be helpful for the outer diameter of such features to be smaller than the inner diameter ID_1 of the proximal balloon leg **137***a* and/or smaller than the inner diameter ID_2 of the distal balloon leg **137***b*. For example, the proximal balloon leg **137***a* and the distal balloon leg **137***b* may be unable to stretch to any meaningful degree to allow them to slide over a component that has an outer diameter that is larger than the inner diameter of the respective balloon leg.

[0094] In some examples, the above restriction may be overcome by providing a stop (the term "stop" may be used interchangeably herein with the phrase "valve retainer") that is sized for insertion through the opening defined by proximal leg **137***a* (or distal leg **137***b*), but which can expand in diameter once positioned within the balloon **136**.

[0095] Referring now to FIG. **13**A, FIG. **13**A is an example of a distal end portion of delivery catheter **130**, prior to the delivery catheter **130** being fully assembled. In particular, in the example of FIG. **13**A, the valve retainers (described in further detail below) have not been fully assembled, the nose cone **138** has not yet been coupled to the inner balloon catheter **134**, and the balloon **136** has not been coupled to any portion of the delivery catheter **130**. In the illustrated example, the outer balloon catheter **132** may have one or more apertures **132***a* formed in a wall thereof near a distalmost end of the outer balloon catheter **132**, the one or more apertures **132***a* configured to be positioned at or near a proximal end of proximal pillow **136***a* when the device is assembled. As is described in greater detail below, such apertures **132***a* in some examples may assist with enhanced de-airing of the balloon **136**.

[0096] In the illustration of the example of the stage of assembly shown in FIG. **13**A, an inner proximal stop **300** and a distal stop **340** are already coupled to inner balloon catheter **134**. In some examples, inner proximal stop **300** and distal stop **340** may be formed integrally with the inner balloon catheter **134**, such as by injection molding inner balloon catheter **134** together with inner proximal stop **300** and distal stop **340**. In some examples, inner proximal stop **300** and distal stop **340** may be formed in a second step after forming the inner balloon catheter **134**, such as by overmolding the inner proximal stop **300** and the distal stop **340** onto the inner balloon catheter **134**. In some examples, inner proximal stop **300** and distal stop **340** may be fixed to the inner balloon catheter **134**, for example via adhesives.

[0097] Now referring in addition to FIGS. **13**B-**13**C, FIGS. **13**B-**13**C show side and front views, respectively, of an example of inner proximal stop **300** in isolation. In the illustrated example, proximal inner stop **300** may include a plurality of sections, such as five sections. A proximalmost first section **302** in some examples has a proximal end defining an outer diameter OD_1, which tapers outwardly in a distal direction to a second section **304**, which tapers outwardly in the distal direction to a third section **306**, which ends in a distalmost section having an outer diameter OD_2, which is larger than outer diameter OD_1. In the illustrated example, the first section **302** and third section **306** may have tapers that slope at larger angles compared to second section **304**, although in other examples other relative levels of slope may be provided. In some examples, one or more of the first section **302**, second section **304**, and third section **306** may be combined to provide fewer than three distinct sections. The third section **306** in some examples terminates in a shoulder **308** that abruptly decreases in outer diameter into a fourth section **310**, which may taper outwardly in the distal direction to a fifth section **312**, which may taper back inwardly to a distalmost end of the inner proximal stop. In some examples, a hole, such as port hole **309**, may be provided on the inner proximal stop **300**, for example in the fourth section **310**, to allow for glue or other adhesives to fill the space between inner balloon catheter **134** and inner proximal stop **300**. Although various individual sections of inner proximal stop **300** are shown and described, it should be understood that various other specific examples of sections may be provided, but in many or all examples, a generally ramped surface (or conical or frustoconical geometry) may be provided that increases from outer diameter OD_1 to outer diameter OD_2, with the ramped surface terminating in a shoulder (such as shoulder **308**). In some examples, the inner proximal stop **300** may define a central lumen or through bore **314** therethrough, the through bore **314** sized and shaped to snugly fit over the inner balloon catheter **134** during assembly. In embodiments described herein in which ramped (or conical or frustoconical) surfaces are provided, it should be understood that the ramp may be the entire, or only a portion of, the corresponding outer surface.

[0098] Now referring in addition to FIGS. **13**D-**13**E, FIGS. **13**D-**13**E show side and rear views, respectively, of an example of distal stop **340** in isolation. In the illustrated example, distal stop **340** may include a plurality of sections, such as two sections. In some examples, a proximal first

section **342** may be generally cylindrical, and a plurality of fins **344** may extend radially outward from the first section **342**. In some examples, the fins **344** may each extend a distance radially outwardly to define an outer diameter OD_3 of the first section **342**. The distal stop **340** in some examples includes a second section **346** distal to the first section **342**, the second section **346** tapering to an outer diameter OD_4 that is smaller than outer diameter OD_3. In some examples, the fins **344** extend at least partially along the second section **346**, with the fins **344** terminating prior to the distalmost end of the second section **346**. In some examples, the distal stop **340** may define a central lumen or through bore **348** therethrough, the through bore **348** sized and shaped to snugly fit over the inner balloon catheter **134** during assembly. In some examples, channels, recesses, or grooves **345** are formed between adjacent ones of the fins **344**. In such examples, the grooves **345** may extend along at least part of the length of the first section **342** and at least a part of the length of the second section **346**. In some examples, the grooves **345** may enhance the ability of fluid (e.g., inflation media such as saline) to flow around the outside of the distal stop **340**.

[0099] Referring now in addition to FIG. **13**F, in some examples, the balloon **136** may be pulled over the inner balloon catheter **134** after the inner proximal stop **300** and the distal stop **340** have been fixed to the inner balloon catheter **134**, and the nose cone **138** may be fixed to the distal end of the inner balloon catheter **134** after the balloon **136** is positioned around the inner balloon catheter **134**. However, in other examples, after the inner proximal stop **300** and distal stop **340** are coupled (e.g., fixed, bonded, adhered, etc.) to the inner balloon catheter **134**, the proximal end of the inner balloon catheter **134** (not shown in FIG. **13**F) is pulled proximally through the distal balloon leg **137***b*. In these examples, the maximum inner diameter ID_2 of the distal balloon leg **137***b* may be larger than the maximum outer diameters of the inner proximal stop **300** and distal stop **340**, although the maximum inner diameter ID_1 of the proximal balloon leg in these embodiments need not be larger than the maximum outer diameters of the inner proximal stop **300** and distal stop **340**. Also, in these examples, the nosecone **138** may be attached to the inner balloon catheter **134** before positioning the balloon **136** over the inner proximal stop **300** and distal stop **340**. In the example of FIG. **13**F, the inner proximal stop **300** is positioned within proximal pillow **136***a*, the distal stop **340** is positioned with distal pillow **136***b*. It should be understood that, in some examples, the balloon **136** is capable of being positioned in FIG. **13**F because the inner diameter ID_1 of proximal balloon leg **137***a* and the inner diameter ID_2 of distal balloon leg **137***b* are each about equal to or larger than the outer diameter OD_2 of the inner proximal stop **300** and the outer diameter OD_3 of the distal stop **340**. It should also be understood that, in the example of the stage of assembly shown in FIG. **13**F, the balloon **136** may not yet be fixed to any other components of the delivery system **100**.

[0100] Referring now in addition to FIGS. **13**G-**13**H, FIGS. **13**G-**13**H are side and front views, respectively, of an example proximal outer stop **320** isolated from other components of the delivery system **100**. In some examples, proximal outer stop **320** may include a generally cylindrical proximal rim **322** which may have an annular shape. In some examples, a plurality (e.g., 2, 3, 4, 5, 6 or more) of fingers or extensions **324** may extend distally from the rim **322**, the extensions **324** being positioned at spaced distances from each other around a perimeter of the rim **322**. In the example shown in FIGS. **13**G-**13**H, the extensions **324** are shown in an expanded condition, although it should be understood that the extensions **324** may be formed so that, in the absence of applied forces, no portions of the extensions **324** extend radially outwardly of an outer diameter OD_5 of the rim **322**. In some examples, the extensions **324** may be hingedly coupled to the rim **322**, for example via living hinges **326**. In some examples, as best shown in the example of FIG. **13**H, one or more (including all) of the extensions **324** may include a radially-inwardly extending prong **328** near a distal end thereof.

[0101] Referring now in addition to FIGS. **13**I-**13**J, FIGS. **13**I-**13**J are side and front views, respectively, of the proximal outer stop **320** of FIGS. **13**G-**13**H having been assembled to the proximal inner stop **300** of FIGS. **13**B-**13**C, with the assembly isolated from other components of the delivery system **100**. As noted above, in some examples, the extensions **324** of the proximal outer stop **320** do not flex outwardly in the absence of applied forces. In some examples, as the extensions **324** of the proximal outer stop **320** are advanced distally over the proximal end of proximal inner stop **300**, as the extensions **324** ride along the outer ramped surface of the proximal inner stop **300**, the extension **324** flex outwardly via bending at hinge **326**. Thus, in this example, as the proximal outer stop **320** continues being advanced over the proximal inner stop **300**, the extensions **324** flex farther and farther outwardly until the prongs **328** move past the shoulder **308**, at which point the extensions **324** may "snap" back since the extensions **324** are biased to a non-expanded (or collapsed) configuration. As best shown in the example of FIG. **13**J, once the prongs **328** engage the shoulder **308**, the proximal outer stop **320** is prevented from being pulled proximally relative to the proximal inner stop **300**. Further, in some examples, the rim **322** is unable to change size or shape, so that it can only be advanced a given distance distally along the outer ramped surface of the inner proximal stop **300**. Thus, in the example shown in FIGS. **13**I-**13**J, once the proximal outer stop **320** has been assembled to the proximal inner stop **300** with the prongs **328** "snapped" over the shoulder **308**, the proximal outer stop **320** is substantially axially fixed with respect to the proximal inner stop **300**. When in this assembled condition, in some examples, the distal ends of the extensions **324** are positioned along a generally circular profile having an outer diameter OD_6 that is larger than outer diameters OD_5 and OD_2 and also larger than the inner diameter ID_1 of the proximal balloon leg **137***a* and the inner diameter ID_2 of the distal balloon leg **137***b*.

[0102] Referring now in addition to FIG. **13**K, FIG. **13**K illustrates the view of FIG. **13**F after the proximal outer stop **320** has been slid distally through the interior of the proximal balloon leg **137***a* and expanded after it slides over and is assembled to the proximal inner stop **300**. However, in some examples, including those in which the inner balloon catheter **134** is pulled proximally through the distal balloon leg **137***b* during assembly, the proximal outer stop **320** may be slid over the proximal end of the inner balloon catheter **134** and positioned just proximal to the proximal inner stop **300**, with that assembly being passed proximally through the distal balloon leg **137***b*. The inner balloon catheter **134** may continue to slide proximally through the proximal outer stop **320** until the nosecone **138** bottoms out on the distal balloon leg **137***b*. In some examples, the proximal outer stop **320**

requires a force applied on its proximal face to force it to advance over the proximal inner stop **300** until the extensions **324** of the proximal outer stop **320** snap over the proximal inner stop **300** (e.g., the shoulder **308** thereof) into place. Referring back to FIG. **13**F, prior to passing the proximal outer stop **320** into the interior of the balloon **136**, the proximal leg **137***a* of the balloon **136** remains unfixed to the outer balloon catheter **132**. It should be understood that, although the outer balloon catheter **132** is illustrated in FIGS. **13**A, **13**F, and **13**K, the outer balloon catheter **132** may be positioned over the inner balloon catheter **134** in some examples only after the proximal outer stop **320** has been assembled to the proximal inner stop **300** within the balloon **136**.

[0103] In some examples, after the balloon **136** is positioned around the distal stop **340** and the assembled proximal inner stop **300** and outer stop **320**, the outer balloon catheter **132** may be advanced through the interior of the proximal balloon leg **137***a* until the distal end of the outer balloon catheter **132** is snugly received within the interior of rim **322**. In some examples, the distal end of the outer balloon catheter **132** may be fixed to the rim **322**, for example via adhesives. In some examples, the distal end of the outer balloon catheter **132** may be fixed to the rim **322** prior the positioning the proximal outer stop **320** within the balloon **136**, and in such examples the proximal outer stop **320** may be advanced into the balloon **136** by advancing the outer balloon catheter **132** toward and/or into the balloon **136**. In some examples, after the outer balloon catheter **132** is fixed to the proximal outer stop **320**, the proximal leg **137***a* of the balloon **136** may be fixed to the balloon outer catheter **132**, for example via adhesive, at a spaced distance proximal to the apertures **132***a*. In some examples, the distal leg **137***b* of the balloon **136** may be fixed to the nosecone **138**, for example via adhesive. As should be understood, in some examples, by inserting the proximal outer stop **320** into the balloon **136** while it is in a collapsed or unexpanded state, the proximal outer stop **320** is able to fit within the balloon **136**. Further, in some examples, by allowing the proximal outer stop **320** to expand only after it has entered the balloon **136**, the proximal outer stop **320** may be able to achieve an outer diameter OD_6 that is larger than (e.g., between 1.5 and 2.5 times larger, including about twice as large) the inner diameter ID_1 of the proximal balloon leg **137***a* and larger than (e.g., between 1.5 and 2.5 times larger, including about twice as large) the inner diameter ID_2 of the distal balloon leg **137***b*. It should be understood that, in this example, the proximal stop generally (and the proximal outer stop **320** in particular) is able to achieve an outer diameter OD_6 within the balloon **136** that may not be possible if the outer stop **320** had a fixed outer diameter. In some examples, this larger outer diameter may be useful by providing a larger surface against which the prosthetic heart valve **10** may abut, which may provide for additional stability compared to if the prosthetic heart valve **10** abutted a stop having a relatively small outer diameter.

[0104] In the examples described in connection with FIGS. **13**A-**13**K, the distal stop **340** is different than the proximal stop and has an outer diameter OD_3 that is smaller than the outer diameter OD_6 of proximal outer stop **320** when it is assembled to proximal inner stop **300**. In some examples, it is more important to stabilize the outflow edge of the prosthetic heart valve **10** (which abuts proximal outer stop **320**) compared to the inflow edge of the prosthetic heart valve **10** (which abuts distal stop **340**), for example because the forward pushing of the delivery assembly **100** (including prosthetic heart valve **10**) tends to create proximally-directed forces on the prosthetic heart valve **10** that may need to be counteracted. However, it should be understood that in some examples, the positioning of the proximal stop (i.e., assembled proximal inner stop **300** and proximal outer stop **320**) and distal stop **340** may be reversed, while in other examples two versions of distal stop **340** (albeit with orientations that are opposite to each other) may be used, or two versions of the proximal stop (again with orientation that are opposite to each other) may be used. Further, although the examples of FIG. **13**K shows the outer balloon catheter **132** extending a distance into the interior of the balloon **136**, in other examples little or no length of the outer balloon catheter **132** may extend into the interior of the balloon **136**.

[0105] Now referring in addition to FIG. **13**L, FIG. **13**L is a flowchart of example methods of assembling a distal end of a delivery catheter (e.g., delivery catheter **130**) that may include one or more of the following steps. In the example method shown, in step **380** a distal stop (e.g., distal stop **340**) is affixed to an inner balloon catheter (e.g., inner balloon catheter **134**), and in step **382** a proximal inner stop (e.g., proximal inner stop **300**) is affixed to the inner balloon catheter. In some examples, steps **380** and **382** may be performed simultaneously, for example if the distal stop and proximal inner stop are formed integrally with the inner balloon catheter via injection molding. In example step **384**, a formed balloon (e.g., balloon **136**) is positioned over the inner balloon catheter, the distal stop, and the proximal inner stop. In example step **386**, a proximal outer stop (e.g., proximal outer stop **320**) slides over the inner balloon catheter through the interior of the balloon while the proximal outer stop is in a collapsed condition in the absence of applied forces. In some examples, steps **384** and step **386** are performed by positioning the proximal outer stop over the inner balloon catheter just proximal to the proximal inner stop, and then pulling that entire assembly proximally through a distal leg (e.g., distal balloon leg **137***b*) of the balloon until a proximal balloon pillow (e.g., proximal pillow **136***a*) is positioned over the proximal inner stop and proximal outer stop, while a distal balloon pillow (e.g., distal pillow **136***b*) is positioned over the distal stop. In example step **388**, once the proximal outer stop is within the balloon, it is advanced over the proximal inner stop causing the proximal outer stop to expand in diameter, and the proximal outer stop is engaged with the proximal inner stop. In example step **390**, an atraumatic distal tip or nose cone (e.g., nose cone **138**) is fixed to the distal end of the inner balloon catheter. However, it should be understood that in some embodiments the nosecone may be fixed to the distal end of the inner balloon catheter at, or prior to, the beginning of the assembly process. In an example final step **392**, the proximal end of the balloon is fixed to a balloon outer catheter (e.g., balloon outer catheter **132**) which at least partially surrounds the balloon inner catheter, and the distal end of the balloon is fixed to the nose cone. It should be understood that the method steps described in connection with FIG. **13**L are only exemplary, and more or fewer steps than shown may be performed, and steps may be performed in different orders than shown in FIG. **13**L.

[0106] Now referring in addition to FIG. **14**, FIG. **14** is a highly schematic side view of an example of a proximal inner stop **300'** assembled to a proximal outer stop **320'** over

inner balloon catheter **134**. Proximal inner stop **300'** and proximal outer stop **320'** may be similar or identical to counterpart proximal inner stop **300** and proximal outer stop **320**, and may in some examples be used in the same way as described in connection with proximal inner stop **300** and proximal outer stop **320**, except for the differences explicitly described below. In the example illustrated in FIG. **14**, the proximal inner stop **300'** includes helical threads and/or a helically-extending recess **301'** and the extensions **324'** include interiorly-extending protrusions **321'** that have helical positioning corresponding to helically-extending recess **301'**. As with proximal outer stop **320**, proximal outer stop **300** in some examples may be formed so that the extensions **324'** are biased to a collapsed, non-extended, or small-diameter configuration. However, while in some examples proximal outer stop **320** is pushed and/or translated distally over proximal inner stop **300** during assembly, proximal outer stop **320'** in some examples may be rotated (e.g., in rotational direction R) relative to proximal inner stop **300'**. In these examples, the protrusions **321'** are received within the recess **301'**, and as the proximal outer stop **320'** is rotated relative to proximal inner stop **300'**, the proximal outer stop **320'** is pulled distally as the threading/rotating continues, forcing the extensions **324'** to expand as they drive forward over the outer ramped surface of the proximal inner stop **300'**. Other than the threading feature described herein, the structure and use of the example of FIG. **14** may be similar or identical to the features and methods described in connection with FIGS. **13**A-**13**L. It should be understood that, due to threading function and structure, in some examples, the shoulder **308** described in connection with inner proximal stop **300**, and the prongs **328** described in connection with outer proximal stop **320**, may be omitted from the example shown in FIG. **14**.

[0107] Now referring in addition to FIG. **15**A, FIG. **15**A is a highly schematic side view of an example of a proximal inner stop **300"** assembled to a proximal outer stop **320"**. Proximal outer stop **320"** may be similar or identical to either proximal outer stop **320** or proximal outer stop **320'**, with the exception of material **329"** described in greater detail below. Proximal inner stop **300"** may be similar or identical to proximal inner stop **300** or proximal inner stop **300'**. Thus, the similar features are not described in detail again here. In the example shown in FIG. **15**A, a material **329"** is connected circumferentially between each adjacent pair of extensions **324"** and to the rim **322"**. In some examples, the material **329"** is provided between all of the pairs of extensions **324"** so that the extensions **324"** and material **329"**, in combination, form a substantially continuous surface. In some examples, the material **329"** may be soft and may be formed of an elastic material capable of stretching. In some examples, the material **329"** effectively connects each extension **324"** to each other extension **324"**, even if such connection is indirect. Now referring in addition to FIG. **15**B, FIG. **15**B is a highly schematic cross-section of the proximal outer stop **320"** in an initial or collapsed condition, for example prior to being advanced over (and/or assembled to) the proximal inner stop **300"**. As the proximal outer stop **320"** is advanced over the proximal inner stop **300"** (e.g., via pushing as shown and described in connection with FIGS. **13**A-**13**L or by rotating as shown and described in connection with FIG. **14**), the extensions **324"** may begin to flare outwardly. However, in some examples, because the material **329"** connects adjacent pairs of extensions **324"** along some, most, or all of the length of the extensions **324"**, the material **329"** (which as noted above may be elastic) may cause the extensions **324"** to flare outwardly in a more radially symmetric fashion than might occur in the absence of the material **329"**. Now referring in addition to FIG. **15**C, FIG. **15**C is a highly schematic cross-section of the proximal outer stop **320"** in an assembled or expanded condition, for example after being advanced over (and/or assembled to) the proximal inner stop **300"** (which is omitted from the view of FIG. **15**C for clarity of illustration). As can be seen in the example of FIG. **15**C, the material **329"** may help the extensions **324"** in maintaining a circular and/or radially symmetric profile during and after expansion. In some examples, because the material **329"** may eliminate any spacing between adjacent pairs of extensions **324"**, a softer and/or more consistent interface may be provided against which the balloon **136** may contact, which may reduce potential damage (e.g., pinching between adjacent extensions **324"**) to the balloon **136**. Other than the material **329"** described herein, the structure and use of the example of FIGS. **15**A-**15**C may be similar or identical to the features and methods described in connection with FIGS. **13**A-**13**L and/or FIG. **14**.

[0108] In the examples described in connection with FIGS. **13**A-**13**L, including in particular the view of FIG. **13**K, the outer balloon catheter **132** extends into the proximal pillow **136** and contacts and/or is fixed to the proximal outer stop **320**. In these types of examples, the outer balloon catheter **132** may provide additional column strength to the proximal outer stop **320**, which may be desirable. However, as noted above, in some examples the outer balloon catheter **132** does not extend into (or does not extend a significant distance into) the interior of the proximal pillow **136***a*. Now referring in addition to FIG. **16**, FIG. **16** shows an example that is similar to the assembly of FIG. **13**K but in which the outer balloon catheter **132** does not extend into the interior of the proximal pillow **136***a*. In this particular example, in order to provide enhanced column strength to the assembly, a pusher **370** is included between the distal end of the outer balloon catheter **132** and the rim **322** of the outer proximal stop **320**. In some examples, the proximal end of the pusher **370** may be in abutting contact with and/or fixed to the distal end of the outer balloon catheter **132**, and the distal end of the pusher **370** may be in abutting contact with and/or fixed to the proximal end of the outer proximal stop **320** (e.g., the rim **322**). In the absence of the pusher **370**, in examples in which the outer balloon catheter **132** does not extend into the proximal pillow **136***a*, a potential problem could arise. In such an example, as the delivery catheter **130** is advanced through the patient's vasculature, the force from the outer balloon catheter **132** being pushed distally could cause the proximal pillow **136***a* to collapse and/or buckle. However, in the example of FIG. **16**, the pusher **370**, which may be a substantially rigid structure, may provide column strength between the outer balloon catheter **132** and the proximal outer stop **320**, preventing or reducing the likelihood of buckling of the proximal pillow **136***a* during use. In some examples, the pusher **370** may include a generally cylindrical a proximal section **371***a* that had an outer diameter about equal to or slightly larger or smaller than the outer diameter of the outer balloon catheter **132**. In some examples, the pusher **370** may include a generally cylindrical distal section **371***b* that has an outer diameter that is larger than that of the proximal section **371***a*, and which is configured to abut the

rim **322**, be received within the rim **322**, or be received over the rim **322**. In some examples, the proximal section **371***a* includes one or more axially extending slots **372** which may create channels that are in fluid communication with the interior of the outer balloon catheter **132**. In such examples, during de-airing, deflation, and/or inflation of the balloon **136**, fluid may pass from the interior of the outer balloon catheter **132**, through the channels of the slots **372**, and into the proximal pillow **136***a*. In some examples, if slots **372** are provided, they may be provided at substantially equal intervals around the circumference of the proximal section **371***a*. In some examples, if slots **372** are included, they may extend any desired length along the pusher **370** that provides for fluid communication between the interior of the outer balloon catheter **132** and the interior of the proximal pillow **136***a*.

[0109] Now referring in addition to FIG. **17**, FIG. **17** is a side view of an example of the distal end of delivery catheter **130** in which the outer balloon catheter extends into the interior of proximal pillow **136***a*, but additional stop features or valve retainers are not provided. In the example of FIG. **17**, the outer balloon catheter **132** extends most or all (e.g., at least 80%, at least 90%, or about 100%) of the axial distance of the proximal pillow **136***a*. In the illustrated example, the distalmost end of the outer balloon catheter **132** terminates at about the same location, in the axial direction, that the proximal pillow **136***a* terminates. In this example, although a separate valve retainer or stop is not provided, the distal end of the outer balloon catheter **132** may functionally serve as a proximal stop, although the outer balloon catheter **132** does not have as large an outer diameter as certain other examples described herein, for example including outer diameter OD_6 of proximal inner stop **320** which may be a larger diameter than outer balloon catheter **132**. However, even with the outer balloon catheter **132** having a relatively small outer diameter in this example, it may still provide a suitable level of axial force against the outflow end of the prosthetic heart valve **10** (some of which force may be transmitted through the distal end of the proximal pillow **136***a*) when the prosthetic heart valve **10** is crimped over the balloon **136** with the terminal ends of the prosthetic heart valve **10** abutting the proximal pillow **136***a* and the distal pillow **136***b*. As noted in connection with FIGS. **13**A-L, one or more apertures **132***a* may be provided in the wall of the outer balloon catheter **132**, with the apertures **132***a* being located at or near a proximal end of the proximal pillow **136***a* and in fluid communication with the interior of the proximal pillow **136***a*. In some examples, the apertures **132***a* are provided at substantially equal intervals around the circumference of the outer balloon catheter **132**, for example four apertures **132***a* provided every 90 degrees (+/−10 degrees), five apertures **132***a* provided every 72 degrees (+/−10 degrees), etc. In use, at any point at which fluid is being introduced into the interior of the balloon **136** or removed from the interior of the balloon **136**, the fluid flows through a pathway between the inner balloon catheter **134** and the outer balloon catheter **132**. However, in examples in which the outer balloon catheter **132** extends a distance into the interior of the balloon **136**, the point at which fluid enters or exits the balloon may be a spaced distance from the proximal end of the balloon **136**. For example, in the example of FIG. **17**, if apertures **132***a* were omitted, fluid flowing into or out of the balloon **136** would enter/exit near the distal end of the proximal pillow **136***a*. This may not be desirable in all circumstances. For example, it may be desirable during inflation of the balloon **136** for fluid to easily enter the proximal pillow **136***a*. Further, during de-airing of the balloon **136** when the delivery system **100** is being prepared for use, in the absence of apertures **132***a*, air bubbles may tend to get trapped within proximal pillow **136***a*, including near the point at which the proximal pillow **136***a* (or proximal leg **137***a*) is fixed to the outer balloon catheter **132**. However, by providing one or more apertures **132***a* that provide an additional inlet/outlet for fluid flowing between the outer balloon catheter **132** and balloon **136**, inflation media may tend to more easily enter the proximal pillow **136***a* during inflation and exit the proximal pillow **136***a* during deflation, while air bubbles that might otherwise get trapped within the proximal pillow **136***a* may more easily be removed through the system via apertures **132***a* during de-airing. It should be understood that the description of the structure and function of apertures **132***a* described in connection with FIG. **17** may be applied to all other embodiments herein in which the outer balloon catheter **132** extends a distance into the interior of the balloon **136** (including for example the examples of FIGS. **13**A-**13**L). Further, in some examples, the entire outer balloon catheter **132**, or only the portion extending into the proximal pillow **136***a*, may be formed of Pebax 6333, or another polyether block amide, having a Shore durometer of about 63 D. However, in other examples, the entire outer balloon catheter **132**, or only the portion extending into the proximal pillow **136***a*, may be formed of a polyether block amide or nylon having a Shore durometer of between about 55 D and about 90 D, which may provide the desired column strength without being too stiff in axial bending.

[0110] Now referring in addition to FIG. **18**A, FIG. **18**A is a schematic side view of an example of an inner stop **400***a* that may be used as part of an expanding proximal and/or distal stop or valve retainer in a similar fashion as the proximal stop(s) described in connection with FIGS. **13**A-**15**C. Inner stop **400***a* in some examples may have a generally conical or frustoconical shape extending between a first end **405***a* having a relatively small outer diameter and a second end **410***a* having a relatively large outer diameter. If inner stop **400***a* is being used as a proximal stop, first end **405***a* in some examples may be the proximal end and second end **410***a* may be the distal end. If inner stop **400***a* is being used as a distal stop, first end **405***a* in some examples may be the distal end and second end **410***a* may be the proximal end. In some examples inner stop **400***a* may include a circumferential recess **415***a* sized and shaped to receive an outer stop **420***a* therein. If recess **415***a* is included, in some examples it is positioned nearer the second end **410***a* than the first end **405***a* where the outer diameter of the inner stop is relatively large. Although not shown in FIG. **18**A, inner stop **400***a* may include a through bore (such as through bore **348**) so that the inner stop **400***a* may be slid over and fixed (e.g., via adhesives) to inner balloon catheter **134**. However, in other embodiments, inner stop **400***a* may be formed integrally with and/or overmolded onto inner balloon catheter **134**.

[0111] Now referring in addition to FIG. **18**B, FIG. **18**B is a schematic front view of an example of an outer stop **420***a* that may be used with inner stop **400***a*. Outer stop **420***a* in the illustrated example is a coil having a first end **422***a*, a second end **424***a*, and an intermediate portion **426***a* extending between the first end **422***a* and the second **424***a*. The

intermediate portion **426** in some examples includes one or more loops forming a generally circular shape, and in the absence of applied forces, the outer stop **420***a* may have an inner diameter that is larger than the outer diameter of the first end **405***a* but smaller than the outer diameter of the second end **410***a* of the inner stop **400***a*.

[0112] To assemble the distal end of the delivery catheter **130**, the maximum outer diameter of the inner stop **400***a* (e.g., at the second end **410***a*) may in some examples be small enough to fit through either proximal balloon leg **137***a* or distal balloon leg **137***b*. Similarly, in the absence of applied forces, the outer diameter of the outer stop **420***a* may in some examples be small enough to fit through either proximal balloon leg **137***a* or distal balloon leg **137***b*. Once the balloon **136** is positioned over both the inner stop **400***a* and the outer stop **420***a*, in the example shown in FIG. **18**C, the outer stop **420***a* may be advanced in direction D toward the first end **405***a* of the inner stop **400***a*. If the stop is being used as a proximal stop, the direction D may be the distal direction, and if the stop is being used as a distal stop, the direction D may be the proximal direction. In some examples, as the outer stop **420***a* is advanced along the inner stop **400***a*, the ramped outer surface of the inner stop **400***a* forces the outer stop **420***a* to expand in diameter as the outer stop **420***a* begins to uncoil (e.g., the first end **422***a* and second end **424***a* may begin to move closer to each other as the amount of overlap between the first end **422***a* and the second end **424***a* decreases). In some examples the outer stop **420***a* may continue to translate along the ramped surface of the inner stop **400***a* toward the second end **410***a* until the outer stop **420***a* reaches the recess **415***a*. Now referring in addition to FIG. **18**D, FIG. **18**D is a highly schematic cross-section of the configuration in which the outer stop **420***a* has been advanced along the inner stop **400***a* until the outer stop **420***a* has reached the recess **415***a* and "snapped" back into the recess **415***a* at least in part due to the outer stop **420***a* being biased to a small diameter configuration. In the resulting configuration of the example of FIG. **18**D, the outer stop **420***a* is effectively locked to the inner stop **400***a* due to the engagement with the recess **415***a*, and the outer stop **420***a* has an outer diameter that is larger than the largest outer diameter of the inner stop **400***a*. In other words, in some examples, similar to the examples described in connection with FIGS. **13**A-**13**L, the assembled stop (including inner stop **400***a* and outer stop **420***a*) can have a larger outer diameter than the maximum size that can readily be inserted through either proximal balloon leg **137***a* or distal balloon leg **137***b*, providing for a relatively large diameter stop surface for assisting with retaining the axial position of the prosthetic heart valve **10**. It should be understood that, in terms of positioning with respect to the remainder of the delivery system **100**, inner stop **400***a* and outer stop **420***b*, when assembled, may have the same or similar position as the proximal inner stop **300** and proximal outer stop **320** (if being used as a proximal stop) or the same or similar position as the distal stop **340** (if being used as a distal stop) as shown in the example of FIG. **13**K.

[0113] Now referring in addition to FIGS. **19**A-**19**D, FIGS. **19**A-**19**D illustrate an example of an inner stop **400***b* and an outer stop **420***b* which are similar (in both configuration and use) to the example inner stop **400***a* and outer stop **420***b* of FIGS. **18**A-**18**D. For example, inner stop **400***b* may be ramped from first end **405***b* to second end **410***b* in substantially the same fashion as inner stop **400***a*. However, in this example, the main difference between inner stop **400***a* and inner stop **400***b* is that, instead of including a circumferential recess **415***a* like stop **400***a*, inner stop **400***b* includes a helical recess or thread **415***b* extending along most or all of the length of the inner stop **400***b*. As shown in FIG. **19**B, the outer stop **420***b* may be identical to outer stop **420***a*, and is thus not described in detail again here, other than that the outer stop **420***b* may include a first end **422***b*, a second end **424***b*, an intermediate section **426***b* extending between the ends, and that the outer stop **420***b* may be biased to a relatively small diameter in the absence of applied forces.

[0114] Now referring in addition to FIG. **19**C, FIG. **19**C shows that in some examples the outer stop **420***b* may be assembled to the inner stop **400***b* (e.g., after the balloon **136** has been positioned over both stops) in a generally similar fashion as shown and described in connection with FIG. **18**C. However, whereas in the example of FIG. **18**C, the outer stop **420***a* is pushed over the inner stop **400***a* in direction D, in the example of FIG. **19**C, the outer stop **420***b* is advanced in direction D over the inner stop **400***b* by rotating the outer stop **420***b* relative to the inner stop **400***b* so that the outer stop **420***b* effectively threads over the helical recess or thread **415***b*. Similar to as described in connection with the example of FIG. **18**C, as the outer stop **420***b* advances toward the second end **410***b*, it will increase in diameter as the outer stop **420***b* unwinds or uncoils. Referring now in addition to FIG. **19**D, similar as described in connection with FIG. **18**D, when the outer stop **420***b* is assembled to the inner stop **420***a*, the outer stop **420***b* may have an outer diameter that is larger than the largest outer diameter of the inner stop **400***b*. Otherwise, the functionality described in connection with inner stop **400***a* and outer stop **420***a* may be similar or identical to the functionality of inner stop **400***b* and outer stop **420***b*, and is thus not described in further detail again here.

[0115] Now referring in addition to FIG. **20**A, FIG. **20**A is a highly schematic illustration of an example of a stop **500** in a relaxed state (e.g., in the absence of applied forces). In the illustrated example, the stop **500** is formed of a coiled wire (which may in some examples be a single wire and in other examples by formed by two or more wire strands braided together) that extends from a first end **505** to a second end **510**. In the illustrated example, the coiled wire that forms stop **500** is biased so that, when the stop **500** is relaxed, the second end **510** has a larger outer diameter than the first end **505**. For example, the second end **510** may have an outer diameter when relaxed that is larger than the inner diameters of the proximal balloon leg **137***a* and the distal balloon leg **137***b*. In some examples, to assemble the distal end of the delivery catheter **130**, after the balloon **136** is positioned over the inner balloon catheter **134**, the first end **505** of stop **500** may be pulled away from the second end **510** of stop **500** in opposite directions of tension T to temporarily force the stop **500** to have a reduced diameter in which the maximum outer diameter of the stop **500** is small enough to readily fit through either the proximal balloon leg **137***a* and/or the distal balloon leg **137***b*. An example of this temporarily tensioned and reduced-diameter state is shown in FIG. **20**B. While the stop **500** has a temporary configuration similar to the example shown in FIG. **20**B, it may be passed over the inner balloon catheter **134** and through either the proximal balloon leg **137***a* or distal balloon leg **137***b* into the proximal pillow **136***a* or the distal pillow **136***b*.

In this example, once the stop **500** is within the proximal pillow **136***a* or the distal pillow **136***b*, the tension on the stop **500** may be released, which may allow the stop **500** to return mostly or entirely to the example shape shown in FIG. **20**A.

[0116] Similar to the examples of the stops shown and described in connection with FIGS. **18**A-**19**D, stop **500** may be used as a proximal stop, a distal stop, or both. However, dissimilar to the examples shown and described in connection with FIGS. **18**A-**19**D, stop **500** may be used without a separate inner and outer component, at least in part because the stop **500** is set to the larger diameter when unbiased, whereas the outer stops **420***a*, **420***b* in the examples of FIGS. **18**A-**19**D are set to a smaller diameter when unbiased. In some examples, it may be useful to provide additional stiffness to stop **500** because it may lack a separate inner component to which it may be fixed. For example, in some examples the stop **500** may be formed of a nickel-titanium alloy (e.g., nitinol), and shape-set to a relatively stiff austenite phase at or around typical body temperature. In such examples, when the stop **500** is used within a patient, it may increase in temperature to or close to the patient's body temperature, and become stiffer within the body than when it is outside of the body, which may provide for enhanced valve retention.

[0117] Now referring in addition to FIG. **21**A, FIG. **21**A is a schematic cross-section of another example of a stop **600**. In the illustrated example, stop **600** may be formed of a compressible material and have a generally cylindrical shape with an interior through bore configured to be received over a shaft **610***b* of a bolt **610**. Bolt **610** in the illustrated example may also include a head **610***a* coupled to the shaft **610***b*. In some examples, bolt **610** may be provided as a unit that can be slid over and coupled to the inner balloon catheter **134**, for example at a position over which the proximal pillow **136***a* or distal pillow **136***b* will eventually surround. In some examples, the bolt **610** may be fixed (e.g., via adhesives) or be formed integrally with (e.g., by injection molding or overmolding) the inner balloon catheter **134**. In some examples, the shaft **610***b* may include exterior threads. In the illustrated example, a nut **620** may be positioned over the shaft **610***b*, and the nut **620** may include internal threading so that the nut **620** may be threaded over the shaft **610***b* to translate the nut **620** toward or away from the head **610***a*. The stop **600** may in some examples be positioned with the opposite terminal ends of the stop **600** abutting the head **610***a* of the bolt **610** and the nut **620**. The configuration shown in the example of FIG. **21**A may represent an initial state prior to the balloon **136** being pulled over the components shown in FIG. **21**A. In this example initial state, the outer diameters of the head **610***a*, stop **600**, and nut **620** may be small enough to readily pass through the proximal leg **137***a* and/or distal leg **137***b* of the balloon **136**. It should be understood that the example assembly shown in FIG. **21**A may be used as a proximal stop within proximal pillow **136***a*, as a distal stop within distal pillow **136***b*, or both.

[0118] Now referring in addition to FIG. **21**B, after the balloon **136** has been positioned over the stop **600** while the stop **600** is in an uncompressed (or substantially uncompressed) condition, the nut **620** may be rotated to drive the nut **620** in a direction D toward the head **610***a*. In this example, because the stop **600** is formed of a compressible and/or elastic material, as the nut **620** advances along shaft **610***b*, the nut **620** and head **610***a* together compress the stop **600** in an axial direction, forcing the stop **600** to expand radially. In one example, the nut **620** may be advanced toward head **610***a* until the stop **600** has been expanded radially outwardly to a desired diameter. In some examples, the outer diameter of the stop **600** after it has been expanded radially, for example similar to the configuration shown in FIG. **21**B, is larger than the inner diameter of the proximal leg **137***a* and/or distal leg **137***b* of the balloon. The overall functionality of the example stop **600** shown and described in connection with FIGS. **21**A-**21**B may be generally similar or identical to the other examples of expandable stops described herein, and is thus not described in greater detail here. In some examples, because stop **600** does not rely on any ramped surface to expand, the orientation of the bolt head **610***a* compared to the nut **620** (e.g., which is positioned proximally of the other) may not be important.

[0119] Now referring in addition to FIG. **22**A, FIG. **22**A is highly schematic cross-section of an example of an inner stop **700** in an initial state of assembly with an outer stop **720**. Inner stop **700** may be fixed (e.g., by adhesives) and/or integrally formed (e.g., via injection molding or overmolding) to the inner balloon catheter **134**. As with other inner stops described herein (e.g., inner proximal stop **300** or inner stops **400***a*, **400***b*), inner stop **700** may be substantially conical or frustoconical with the larger diameter end configured to abut an end of the prosthetic heart valve **10** when the prosthetic heart valve **10** is crimped over balloon **136** between proximal pillow **136***a* and distal pillow **136***b*. The example of outer stop **720** in FIG. **22**A may be an elastic sleeve, which may for example have a generally cylindrical shape. In some examples, the outer diameter of the outer stop **720** may be about equal to or smaller than the largest outer diameter of the inner stop **700** when no forces are applied to the outer stop **720**. As with other examples described herein, the largest outer diameters of the outer stop **720** (in the absence of applied forces) and of the inner stop **700** may in some examples be about equal or slightly smaller than the inner diameter of the proximal balloon leg **137***a* and/or the distal balloon leg **137***b*. In such examples, as shown in FIG. **22**A, the balloon **136** may readily be slid over the inner stop **700** and outer stop **720** (when the outer stop **720** is in the unbiased configuration). Once the inner stop **700** and the outer stop **720** are both positioned in the proximal pillow **136***a* or the distal balloon **136***b*, in some examples the outer stop **720** may be manually advanced over the stop **700**. In this example, as shown in FIG. **22**B, as the outer stop **720** advances over the ramped outer surface of the inner stop **700**, the outer stop **720** expands in diameter, at least in part due to its elasticity. In some examples, the outer stop **720** can be advanced beyond the large-diameter end of the inner stop. In various examples, once the outer stop **720** is assembled to the inner stop **700**, for example similar to the configuration shown in FIG. **22**B, the largest outer diameter of the outer stop **720** may be larger than the inner diameter of the proximal balloon leg **137***a* and/or the distal balloon leg **137***b*. In some examples, the outer stop **720** and/or inner stop **700** may include features to assist with locking of the outer stop **720** to the inner stop **700** in the desired position. For example, in some examples the outer stop **720** may include inwardly facing prongs similar or identical to prongs **328**, and the inner stop **700** may include a shoulder similar or identical to shoulder **308**. The overall functionality of the example inner stop **700** and outer stop **720** shown and described in connection with FIGS. **22**A-**22**B may be gen-

erally similar or identical to the other examples of expandable stops described herein, and is thus not described in greater detail here.

[0120] Referring now in addition to FIG. **23**A, FIG. **23**A shows another example of a stop **800**. FIG. **23**A illustrates an example of stop **800** in an uncompressed or unbiased condition. In some examples, stop **800** may be formed as an ultra-thin foldable extrusion. In some examples, the ultra-thin foldable extrusion may have a thickness of less than about 0.01 inches (0.254 mm), including between about 0.001 inches (0.0254 mm) and about 0.005 inches (0.127 mm). In some examples, the stop **800** maybe formed of nylon or a high durometer polyether block amide (e.g., the product offered under the tradename Pebax®). In some examples, the material forming the stop **800** may have a durometer of between about 63 D and about 90 D Shore durometer. In the example of FIG. **23**A, the stop **800** is formed to extend along a central longitudinal axis A with a hollow interior. The stop **800** in some examples has a star- or flower-shape, for example with a plurality of fins or petals **810**. In some examples, each petal **810** may be formed of two wall portions of the stop **800** extending radially outward from near the central longitudinal axis, and circumferentially adjacent petals **810** may form a groove or channel **820** therebetween. The groove or channel **820** may in some examples be formed by a wall portion of the stop that extends radially inwardly toward central longitudinal axis A from the two adjacent petals **810**. In some examples, the stop **800** is formed as an extrusion and includes a continuous structure around the central longitudinal axis A. In other examples, the stop **800** is formed as a flat sheet with edges of the flat sheet coupled together and the flat sheet being shaped to have a shape similar to the example of FIG. **23**A. In some examples, in the absence of applied forces, the stop **800** has a shape similar to that shown in FIG. **23**A. In some examples, the radially-outer-most points on the plurality of petals **810** may be inscribed by a circle having a diameter that is larger than the inner diameter of the proximal leg **137***a* and/or the inner diameter of the distal leg **137***b*.

[0121] Now referring in addition to FIG. **23**B, in order to reduce the size of stop **800** to fit for insertion into the proximal leg **137***a* or the distal leg **137***b*, in some examples the petals **810** may be temporarily wrapped or twisted around the central longitudinal axis A. As shown in the example of FIG. **23**B, in this wrapped or twisted state, the petals **810** in some examples curl around the central longitudinal axis A instead of extending mostly or exclusively radially outwardly from the central longitudinal axis A. In this example, the outer perimeter of the stop **800** may be inscribed by a circle having a diameter that is smaller than the inner diameter of the proximal leg **137***a* and/or the inner diameter of the distal leg **137***b* so that, while in this temporarily reduced-diameter state, the stop **800** may be inserted into the balloon **136** through the proximal leg **137***a* or the distal leg **137***b*. It should be understood that, in both states of the examples of FIGS. **23**A and **23**B, the inner balloon catheter **134** may extend through the interior of the stop **800**, for example generally along the central longitudinal axis A of the stop **800**. In some examples, after the stop **800** is inserted into the proximal pillow **136***a* or the distal pillow **136***b* while in the curled or wrapped condition, the grip on the stop **800** may be released allowing the stop **800** to unwrap or unfurl back toward an undeformed state similar to that shown in FIG. **23**A. In some examples, after partly or entirely returning to a shape similar to that shown in FIG. **23**A, the large outer diameter of the stop **800** may act to provide a stop surface against which the inflow or outflow end of the prosthetic heart valve **10** may contact.

[0122] In some examples, stop **800** may be used in isolation without a separate inner stop as described in connection with other embodiments herein. In such examples, the large surface area of stop **800** may tend to create enough friction so that the stop **800** is not able to move significantly during use, even if forces are applied in the axial direction (e.g., by the prosthetic heart valve **10** pressing on an end of the stop **800**) onto the stop **800** during use. The example of stop **800** shown in FIGS. **23**A-**23**B may allow for fluid (e.g., air during de-airing, or saline during balloon deflation or inflation) to easily move through the hollow central section of stop **800** without obstruction. The overall functionality of the example stop **800** shown and described in connection with FIGS. **23**A-**23**B may be generally similar or identical to the other examples of expandable stops described herein, and is thus not described in greater detail here.

[0123] Referring now in addition to FIG. **24**, FIG. **24** shows another example of a stop **900**. FIG. **24** illustrates an example of stop **900** in an uncompressed or unbiased condition. In some examples, stop **900** may be formed as an extrusion and/or flat sheet that is rolled into a spiral configuration, with stop spiraling around a central longitudinal axis A. Stop **900** in some examples may be formed of a material similar to that described in connection with stop **800** and may be used substantially the same manner. Briefly, when the stop **900** is in an unbiased or unwrapped or uncompressed configuration, the outer diameter of the stop **900** (in a direction orthogonal to the central longitudinal axis A) may in some examples be larger than the inner diameter of the proximal balloon leg **137***a* and/or the inner diameter of the distal balloon leg **137***b*. Similar to as described in connection with FIG. **23**B, in some examples stop **900** may be temporarily transitioned into a reduced diameter configuration in which the space between adjacent layers of the spiral shape are reduced. In other words, in some examples the stop **900** may be more tightly wound to temporarily reduce the outer diameter of the stop **900**, at which point it may be inserted into the interior of the balloon **136** (e.g., through proximal balloon leg **137***a* or distal balloon leg **137***b*). In this example, after the stop **900** is inserted into the proximal pillow **136***a* or the distal pillow **137***b*, it will begin to unfurl or unroll partly or completely back to the initial configuration, similar to that shown in FIG. **24**. Otherwise, in some examples, the functionality of stop **900** may be similar or identical to that described in connection with stop **800**, including the ability of fluid to readily flow through the interior of the stop **900** during inflation, deflation, and/or de-airing of the balloon **136**.

[0124] Now referring in addition to FIG. **25**, FIG. **25** illustrates an example of a distal end of delivery catheter **130** which includes inflatable stops **1000***a*, **1000***b*. In the illustrated example, a proximal stop **1000***a* is provided within the proximal pillow **136***a* and a distal stop **1000***b* is provided within the distal pillow **136***b*. However, it should be understood that proximal stop **1000***a* may be provided in some examples without a corresponding distal stop **1000***b*, and in other examples the distal stop **1000***b* may be provided without a corresponding proximal stop **1000***a*. In the illustrated example, each stop **1000***a*, **1000***b* is formed of an inflatable member, such as a secondary balloon positioned

within balloon **136**. In the illustrated example, proximal stop **1000***a* may have an inflated or expanded condition in which the proximal stop **1000***a* has a generally conical or frustoconical shape, with the smaller diameter end of the proximal stop **1000***a* positioned proximally and the larger diameter end of the proximal stop **1000***a* positioned distally, in substantial alignment with or proximally adjacent to the distal end of the proximal pillow **136***a*. Similarly, in the illustrated example, distal stop **1000***b* may have an inflated or expanded condition in which the distal stop **1000***b* has a generally conical or frustoconical shape, with the smaller diameter end of the distal stop **1000***b* positioned distally and the larger diameter end of the distal stop **1000***b* positioned proximally, in substantial alignment with or distally adjacent to the proximal end of the distal pillow **136***b*.

[0125] Still referring to FIG. **25**, in some examples during manufacturing the proximal stop **1000***a* and/or distal stop **1000***b* may be coupled to the inner balloon catheter **134** and in a deflated condition before positioning the balloon **136** over the proximal stop **1000***a* and/or distal stop **1000***b*. In some examples, after the balloon **136** is positioned over the proximal stop **1000***a* and/or distal stop **1000***b*, the proximal stop **1000***a* and/or distal stop **1000***b* may be expanded by filling with a settable material, such as filling with epoxy that hardens, for example taking the shape shown in FIG. **25**. In the example of FIG. **25**, when the proximal stop **1000***a* and the distal stop **1000***b* are inflated or expanded, the outer diameter of the larger diameter end of each stop **1000***a*, **1000***b* may be larger than the inner diameter of the proximal leg **137***a* and/or the inner diameter of the distal leg **137***b*. With this type of embodiment, the proximal stop **1000***a* and distal stop **1000***b* may be permanently inflated after manufacturing and not need to be inflated again. If the proximal stop **1000***a* and distal stop **1000***b* are inflated with epoxy or a similar hard-setting fluid during the manufacturing stage, the filling may be performed while the balloon **136** surrounds the proximal stop **1000***a* and/or distal stop **1000***b*, but before the balloon **136** is fixed to the nose cone **138** and/or to the outer balloon catheter **132**. This example of manufacturing may provide for additional filling options as the proximal stop **1000***a* and distal stop **1000***b* may be directly accessible through the proximal balloon leg **137***a* and/or the distal balloon leg **137***b* prior to the balloon **136** being fixed to other components of the delivery catheter **130**.

[0126] In some embodiments, the proximal stop **1000***a* and distal stop **1000***b* may be configured to be inflated, filled, and/or expanded by the user during preparation for implantation of prosthetic heart valve **10**. In such examples, one or more separate inflation lumens (e.g., inflation lumen **1005**) may be provided to couple a fluid reservoir (e.g., a syringe similar to syringe **174**) to the interior of the proximal stop **1000***a* and distal stop **1000***b*. In some examples, these separate inflation lumen(s) **1005** may run through the wall of the inner balloon catheter **134** with openings (e.g., openings **1005***a*, **1005***b*) to the interior of the proximal stop **1000***a* and/or the distal stop **1000***b*. In this type of example, the proximal stop **1000***a* and distal stop **1000***b* may be inflated or expanded just prior to crimping the prosthetic heart valve **10** onto the balloon **136**. Similarly, in this type of example, the proximal stop **1000***a* and/or distal stop **1000***b* may be deflated at any desired point in the procedure, for example immediately after the prosthetic heart valve **10** is deployed. Whether the proximal stop **1000***a* and/or distal stop **1000***b* are expanded during manufacturing with a fluid that sets into a solid or is filled with saline (or another non-setting fluid) just prior to use, the inflated/expanded proximal stop **1000***a* and/or distal stop **1000***b* may be substantially rigid valve retention structures upon inflation.

[0127] Now referring in addition to FIG. **26**A, FIG. **26**A shows an example of a distal end of delivery catheter **130** prior to the prosthetic heart valve **10** being crimped onto the balloon **136**. Instead of including interior stops or valve retainers, the example of balloon **136** of FIG. **26**A may include a high-friction surface **1100***a* to help maintain the axial position of the prosthetic heart valve **10** during delivery. In the illustrated example, as with other embodiments described herein, the balloon **136** may include a reduced diameter area between the proximal pillow **136***a* and the distal pillow **136***b* which is configured to receive the prosthetic heart valve **10** crimped thereon with opposite ends of the prosthetic heart valve abutting the proximal pillow **136***a* and the distal pillow **136***b*. In the illustrated example, in order to better help maintain the axial position of the prosthetic heart valve **10** on the balloon **136** during delivery, the high-friction surface **1100***a* may be positioned on the balloon **136** along substantially the entire length of the balloon **136** between the proximal pillow **136***a* and the distal pillow **136***b*. As used herein, the phrase "high-friction surface," when used in relation to balloon **136**, refers to the surface having a higher coefficient of friction compared to other areas of the balloon **136** that are not treated to have the high-friction surface. In one example, the high-friction surface **1100***a* may be created by coating the desired section of the balloon **136** with a higher friction material, such as coating the area of the balloon **136** between the proximal pillow **136***a* and the distal pillow **136***b* with polyurethane. As an alternative to or in addition to using a coating to increase the coefficient of friction, in another example, texturization (e.g., micro-texture including ridges, small bumps, cylindrical features, etc.) may be added to the desired section of the balloon **136**. In some examples, this texturization may be created via 5-axis micro precision computer numerical control ("CNC") milling, electrical discharge machining ("EDM"), lasers, electroforming, and/or other suitable techniques. Although the example of FIG. **26**A includes the high-friction surface **1100***a* only along the entire length of the portion of the balloon **136** between the proximal pillow **136***a* and the distal pillow **136***b*, it should be understood that other options may be suitable. For example, in some alternatives, the entire length of the balloon **136** may be provided with the high-friction surface. In other examples, including the example shown in FIG. **26**B, the high-friction surface **1100***b* may be provided on only a distal length of the balloon **136** between the proximal pillow **136***a* and the distal pillow **136***b*. For example, in some examples the high-friction surface **1100** may be provided on the distal half, distal third, distal quarter, etc. of the length of balloon **136** between the proximal pillow **136***a* and the distal pillow **136***b*. The example of FIG. **26**B may provide inflow edge stability for the prosthetic heart valve **10** during delivery but also during deployment, which may be desirable. Although the examples described in connection with FIGS. **26**A-B focus on exterior treatments to enhance axial stability of the prosthetic heart valve **10** relative to the balloon **136**, it should be understood that any of the interior valve retainers or stops described herein may be combined with any of the exterior valve retainer embodiments described herein.

[0128] Now referring in addition to FIG. **27**, whereas the examples described in connection with FIGS. **26**A-**26**B may achieve high-friction surfaces via coatings, micro texturing, or the like, in other embodiments, including the example shown in FIG. **27**, pleating may be used to create increased friction to assist with valve retention. For example, FIG. **27** shows an example of balloon **136'** that may be identical to balloon **136** (as well as have an identical use with delivery system **100**), with one exception being that the balloon **136'** includes perpendicular pleats. In the illustrated example, balloon **136'** may include a proximal pillow **136***a'* and a distal pillow **136***b'* having similar or identical purposes and structures as proximal pillow **136***a* and distal pillow **136***b*. However, during manufacturing of the balloon **136'**, pleats **137'** may be formed in balloon **136'** by creating folds (e.g., double or overlapping folds) with the pleats **137'** extending in a direction generally perpendicular or orthogonal to the central longitudinal axis of the balloon **136'**. In other words, the pleats **137'** in some examples extend in a direction that encircles the central longitudinal axis of the balloon **136'**. In some examples, the pleats **137'** may be formed prior to forming the balloon by blow-molding or after forming the balloon by blow-molding. In some examples, the pleats **137'** may be manually created and heat set so that, when the balloon **137'** is collapsed, the pleats **137'** are maintained. In some examples, the pleats **137'** are set so that, upon expansion of the balloon **137'**, the pleats effectively disappear as the balloon **137'** reaches full expansion for deploying the prosthetic heart valve **10**. In some examples, the pleats **137'** may serve as frictional ribs that increase the axial stability of the prosthetic heart valve **10** during delivery (e.g., reduce the likelihood of axial movement of the prosthetic heart valve **10** during delivery). In some examples, the pleats **137'** may be formed using a pillowing mold with a series of crevices for the pleats to form along with applying axial compression to push material into those crevices.

[0129] Now referring in addition to FIG. **28**, FIG. **28** shows is an example of the distal end of balloon catheter **130** with the prosthetic heart valve **10** crimped thereon between the proximal pillow **136***a* and the distal pillow **136***b*. Rather than including a high-friction coating on the portion of the balloon **136** between the proximal pillow **136***a* and the distal pillow **136***b*, in the example of FIG. **28**, a plurality of studs or nodules **1200** are provided on the central portion of the balloon **136** between the proximal pillow **136***a* and the distal pillow **136***b*. The studs or nodules **1200** are shown in FIG. **28** as being distributed in four columns oriented along the axial direction of the balloon **136**, with each column being spaced about 90 degrees (+/−10 degrees) around the circumference of the balloon **136**. However, it should be understood that the studs or nodules **1200** may be provided in other numbers and patterns. In some examples, the studs or nodules **1200** are formed separately from the balloon **136** and later fixed to the balloon **136**. In other examples, the studs or nodules **1200** are formed integrally with the balloon **136**, for example prior to or after forming the balloon **136** by blow-molding. In some examples, the studs or nodules **1200** may be molded individually and placed into nests surrounding the blow mold cavity prior to blowing the balloon. In such examples, the temperature of the chamber may chemically bond the studs or nodules **1200** onto the outer diameter of the balloon **136** when the balloon **136** is blown. When the prosthetic heart valve **10** is crimped over the balloon **136** between the proximal pillow **136***a* and the distal pillow **136***b*, the studs or nodules **1200** may contact the interior surface of the prosthetic heart valve **10**, including for example the prosthetic leaflets **90**, the inner skirt **60**, and/or the frame **20**, to increase friction on the prosthetic heart valve **10**, making it more difficult for the prosthetic heart valve **10** to shift axially relative to the balloon **136** during delivery of the prosthetic heart valve **10**. In some examples, the studs or nodules **1200** may be considered as macro-texturing, compared to the example of FIGS. **26**A-**26**B that rely on micro-texturing.

[0130] Now referring in addition to FIG. **29**, FIG. **29** is a highly schematic view of balloon **136** after having been filled with microbeads **1300**. As shown in the example of FIG. **29**, balloon **136** may be formed to have the same shape as many of the other balloons described herein, including a proximal pillow **136***a* and a distal pillow **136***b*. Prior to fixing the balloon **136** to other components of the delivery system **100** (such as to the nose cone **138** and the outer balloon catheter **132**), the balloon **136** may be filled with a large quantity of microbeads **1300**, which may be formed of silicone or another biocompatible material. In some examples, one end of the balloon **136** may be fixed to another component of the delivery device prior to filling the balloon **136** with microbeads **1300**. In some examples, the microbeads **1300** may pack into the balloon **136** so that the balloon **136** becomes stiff prior to inflation. In these examples, the stiffness provided to the balloon **136** by the microbeads **1300** may further help prevent axial movement of the prosthetic heart valve **10** when the prosthetic heart valve **10** is mounted (e.g., crimped) on the balloon **136** with the axial ends of the prosthetic heart valve **10** in contact with the proximal pillow **136***a* and the distal pillow **136***b*. When the balloon **136** is inflated (e.g., via pressurized saline), the microbeads **1300** do not inhibit normal expansion of the balloon **136** and deployment of the prosthetic heart valve **10**.

[0131] Now referring in addition to FIG. **30**, FIG. **30** is a highly schematic cut-away view of a distal end of delivery catheter **130** in which prosthetic heart valve **10** has been crimped over balloon with axial ends of the prosthetic heart valve **10** in contact with proximal pillow **136***a* and distal pillow **136***b*. An expandable or non-expandable distal stop **1400***b* may be positioned within distal pillow **136***b*, which may in some examples be the same or similar (in both configuration and use) to distal stop **340**. In some examples, distal stop **1400***b* may be omitted entirely. In the example of FIG. **30**, a proximal stop **1400***a* is provided on the inner balloon catheter **134**. However, unlike other examples of proximal stops described herein, proximal stop **1400***a* in some examples is not positioned within proximal pillow **136***a*, but is rather positioned between the proximal pillow **136***a* and the distal pillow **136***b*. In some examples, proximal stop **1400***a* is non-expandable, has a conical or frusto-conical shape with the large-diameter end facing distally. In some examples, the largest outer diameter of the proximal stop **1400***a* is smaller than the inner diameter of proximal balloon leg **137***a*.

[0132] As shown in the example of FIG. **30**, when prosthetic heart valve **10** is crimped over balloon **136**, the mass of structure of the prosthetic heart valve **10** is not necessarily evenly distributed in the axial direction. In the example of FIG. **30**, the outflow end of the prosthetic heart valve **10** may have less total bulk when considering the radial stack-up of frame **20**, inner cuff **60**, outer cuff **80**, and prosthetic leaflets **90**. For example, when the prosthetic heart valve **10** is

crimped over balloon **136**, a relatively low bulk zone **12** may be defined proximally while a relatively high bulk zone **11** may be defined distally. In some examples, the low bulk zone **12** may be positioned along the proximal half, proximal third, or proximal quarter of the length between the proximal pillow **136***a* and the distal pillow **136***b*. In some examples, the high bulk zone **11** may be positioned along the distal half, distal third, or distal quarter of the length between the proximal pillow **136***a* and the distal pillow **136***b*.

[0133] In the example of FIG. **30**, the proximal stop **1400***a* is positioned along the inner balloon catheter **134** so that, when the prosthetic heart valve **10** is crimped over the balloon **136** between the proximal pillow **136***a* and the distal pillow **136***b*, the large-diameter distal end or distal face of the proximal stop **1400***a* is positioned at or proximally adjacent to the transition point between the low bulk zone **12** and the high bulk zone **11**. With this example configuration, contact between the high bulk zone **11** of the prosthetic heart valve and the proximal stop **1400***a* (which contact may occur across the wall of the balloon **136**) may provide axial stability against the prosthetic heart valve **10** sliding proximally relative to the balloon **136** during delivery of the prosthetic heart valve.

[0134] Now referring in addition to FIG. **31**A, FIG. **31**A is a highly schematic view of an example of a distal end of a spreadable outer balloon catheter **132'** being advanced over a spreader **1500**. In some examples, outer balloon catheter **132'** may be similar or identical to outer balloon catheter **132**, and may be used with delivery system **100** (or similar delivery systems) in place of outer balloon catheter **132**, with at least one difference. For examples, whereas the distal end of outer balloon catheter **132** is a continuous cylinder like other portions of the catheter, the distal end of balloon catheter **132'** may include a plurality of axially-extending slits along the wall thickness of the balloon catheter **132'** that allow the distal end of the balloon catheter **132'** to have spreadable fingers **133'**. In the example of FIG. **31**A, the distal end of outer balloon catheter **132'** is being advanced distally over a ramped spreader feature **1500** causing the fingers **133'** to splay radially outwardly, as described in greater detail below in connection with FIG. **31**B. It should be understood that, in some examples, it may be useful to make other modifications to outer balloon catheter **132'** to assist with allowing the fingers **133'** to splay. For example, outer balloon catheter **132** may include a plurality of layers when being formed, including at least one braided layer. In the example of FIGS. **31**A-**31**B, it may be preferable to form the outer balloon catheter **132'** without any braided layers, or at least without a braided layer in the vicinity of the fingers **133'**. As with other examples of outer balloon catheter **132** herein, outer balloon catheter **132'** may include one or more apertures similar to apertures **132***a* to assist with fluid flow.

[0135] Referring now in addition to FIG. **31**B, FIG. **31**B shows an example of the distal end of delivery catheter **130** that incorporates outer balloon catheter **132'** instead of outer balloon catheter **132**. In the illustrated example, spreader **1500** may be coupled to inner balloon catheter **134** and be positioned within proximal pillow **136***a*. Spreader **1500** may be generally conical or frustoconical with the larger diameter end of the spreader **1500** positioned distally to the smaller diameter end of the spread **1500** to form a surface that is ramped in the distal direction. Prior to fixing the proximal leg **137***a* of balloon **136** to the balloon outer catheter **132'**, the balloon outer catheter **132'** may be advanced through the proximal leg **137***a*. It should be understood that, in some examples, in the absences of applied forces that fingers **133'** form a generally cylindrical shape in combination that is similar to the shape of the remainder of the outer balloon catheter **132'**. However, in the illustrated example, as the balloon outer catheter **132'** is advanced distally into the proximal pillow **136***a* and over spreader **1500**, the ramped surface of the spreader **1500** forces the fingers **133'** to flare or splay radially outwardly. In some examples, the outer balloon catheter **132'** may be advanced distally relative to the inner balloon catheter **134** and the spreader **1500** until the fingers **133'** splay radially outwardly and are in contact with, or are proximally adjacent, the distal end of the proximal pillow **136***a*, for example similar to the configuration shown in FIG. **31**B. During use, when the prosthetic heart valve **10** is crimped over the balloon **136** and positioned between the proximal pillow **136***a* and the distal pillow **136***b*, in some examples as the prosthetic heart valve **10** is delivered, the fingers **133'** provide axial support to the outflow end of the prosthetic heart valve **10**, helping to ensure that the prosthetic heart valve **10** remains axially stable relative to the balloon **136** during delivery.

[0136] Now referring in addition to FIG. **32**, FIG. **32** is a highly schematic cross-section of an example of a balloon **1636** that may be similar or identical to balloon **136**, and used in place of balloon **136** in delivery system **100** (or similar delivery systems), with certain differences noted below. In some examples, the balloon **1636** includes a proximal pillow **1636***a* and a distal pillow **1636***b* that are similar in structure and purpose to counterpart proximal pillow **136***a* and distal pillow **136***b*. However, in some examples, whereas proximal pillow **136***a* and distal pillow **136***b* may only contact the crimped prosthetic heart valve **10** at its axial ends, proximal pillow **1636***a* and/or distal pillow **1363***b* may cover a portion of an outer or abluminal surface of the crimped prosthetic heart valve **10** for additional support. In the example of FIG. **32**, proximal pillow **1636***a* includes a distally-extending overhang **1639***a* which may be generally cylindrical in shape. Similarly, in the example of FIG. **32**, distal pillow **1636***b* includes a proximally-extending overhang **1639***b* which may be generally cylindrical in shape. It should be understood that in some embodiments, only one of the overhangs **1639***a*, **1639***b* may be included. If either overhang **1639***a*, **1639***b* is omitted from one of the pillows, the pillow may in some examples take the same or similar shape as its counterpart proximal pillow **136***a* or distal pillow **136***b*. In some examples the overhangs **1639***a*, **1639***b* may be formed into the corresponding pillow **1636***a*, **1636***b* during a process in which the pillow is being heat set. In other words, in some examples, the overhangs **1639***a*, **1639***b* may tend to take the shape shown in FIG. **32** in the absence of applied forces. In such examples, when crimping the prosthetic heart valve **10** over the balloon **1636**, it may be helpful or necessary to temporarily pull the overhangs **1639***a*, **1639***b* in opposite directions to allow for clearance of the prosthetic heart valve **10** to be crimped onto the balloon **1636**. In these examples, after the prosthetic heart valve **10** is crimped over the balloon **1636**, the temporary force on the overhangs **1639***a*, **1639***b* may be removed so that they tend to move back to their set shape, including for example that shown in FIG. **32**. In the illustrated example, in addition to providing axial stability to the prosthetic heart valve **10** via the axial ends of the prosthetic heart valve **10** contacting the

corresponding pillows **1636***a*, **1636***b*, the overhangs **1639***a*, **1639***b* may provide additional protection via at least partial covering, and may also provide enhanced axial stability. Although various lengths of overhangs **1639***a*, **1639***b* may be suitable, in some examples, each overhang **1639***a*, **1639***b* that is incorporated into the balloon **1636** may extend an axial distance of between about 5% and about 15%, including about 10%, of the axial length of the crimped prosthetic heart valve **10**. However, these numbers are merely exemplary, and lengths of less than 5% and greater than 0%, or above 15%, may in some examples be suitable. It should be understood that, in the example shown in FIG. **32** (and similarly configured examples), when the balloon **1636** is inflated to deploy the prosthetic heart valve **10**, the overhangs **1639***a*, **1639***b* may effectively disappear as the balloon **1636** inflates, helping to ensure that the overhangs **1639***a*, **1639***b* do not interfere with deployment of the prosthetic heart valve **10**.

[0137] Now referring in addition to FIG. **33**, FIG. **33** is a highly schematic cross-section of an example of balloon **136** (e.g., as shown and described in connection with delivery system **100**) that has been modified to include retainers **1700***a*, **1700***b* that may provide similar functionality to the overhangs **1639***a*, **1639***b* of FIG. **32**. In some examples, the balloon **136** includes proximal pillow **136***a* and distal pillow **136***b* as described previously. In the example of FIG. **33**, proximal pillow **136***a* includes a distally-extending retainer **1700***a* which may be generally cylindrical in shape. Similarly, in the example of FIG. **33**, distal pillow **136***b* includes a proximally-extending retainer **1700***b* which may be generally cylindrical in shape. It should be understood that in some embodiments, only one of the retainers **1700***a*, **1700***b* may be included. Although retainers **1700***a*, **1700***b* may have a cylindrical shape, in some examples the retainers **1700***a*, **1700***b* may formed as a plurality of individual retainers **1700***a*, **1700***b* extending around the circumference of the corresponding pillow **136***a*, **136***b*. In some examples, if retainers **1700***a*, **1700***b* are provided as continuous cylindrical structures, they may inhibit the ability of the balloon **136** to expand. Thus, in some examples, each retainer **1700***a*, **1700***b* may be formed of two, three, four, or more individual retainers **1700***a*, **1700***b* that are not directly coupled to each other, with the plurality of individual retainers **1700***a*, **1700***b* spaced from each other around the circumference of the corresponding pillow **136***a*, **136***b*. In some examples, the retainers **1700***a*, **1700***b* may be formed of a rigid material, such as a polymer, that can be fixed to the corresponding pillow **136***a*, **136***b* by adhesives, overmolding, or any other suitable method. In some examples, the retainers **1700***a*, **1700***b* may be formed of an amide polymer such as Pebax or Nylon, which may be bonded to the balloon **136** when overmolded. The retainers **1700***a*, **1700***b* may in some examples function similarly to the overhangs **1639***a*, **1639***b* described above. For example, when crimping the prosthetic heart valve **10** over the balloon **136**, it may be helpful or necessary to temporarily move the retainers **1700***a*, **1700***b* in opposite directions to allow for clearance of the prosthetic heart valve **10** to be crimped onto the balloon **136**. In the illustrated example, in addition to providing axial stability to the prosthetic heart valve **10** via the axial ends of the prosthetic heart valve **10** contacting the corresponding pillows **136***a*, **136***b*, the retainers **1700***a*, **1700***b* may provide additional protection via at least partial covering, and may also provide enhanced axial stability. Although various lengths of retainers **1700***a*, **1700***b* may be suitable, in some examples, each retainer **1700***a*, **1700***b* that is incorporated into the balloon **136** may extend an axial distance of between about 5% and about 15%, including about 10%, of the axial length of the crimped prosthetic heart valve **10**. However, these numbers are merely exemplary, and lengths of less than 5% and greater than 0%, or above 15%, may in some examples be suitable. It should be understood that, in the example shown in FIG. **33** (and similarly configured examples), when the balloon **136** is inflated to deploy the prosthetic heart valve **10**, the prosthetic heart valve **10** will tend to axially foreshorten as it expands radially, and the axial foreshortening may help ensure that the retainers **1700***a*, **1700***b* do not interfere with deployment of the prosthetic heart valve **10**.

[0138] Now referring in addition to FIGS. **34**A-**34**C, FIGS. **34**A-**34**C are highly schematic cross-sections of example methods of forming an example of a stop **1800** within a balloon **136** that may include or more of the following steps. In the example view of FIG. **34**A, the proximal pillow **136***a* is shown with the inner balloon catheter **134** being inserted through the interior of the balloon **136**, in a distal direction, during assembly. The stop **1800** in this example is fixed to the inner balloon catheter **134**, and may include a distal retaining surface **1810** and a proximal shaft **1820**. In some examples, the proximal shaft **1820** is fixed to the inner balloon catheter **134**, for example via adhesives, while the retaining surface **1810** is not directly fixed to the inner balloon catheter **134**. During an initial state of assembly, including the example shown in FIG. **34**A, the retaining surface **1810** may be temporarily configured to have a cup-shape or leading concave surface in which the retaining surface **1810** has a generally "C"- or "U"-shaped profile, with the open end of the "C"- or "U"-shaped profile facing distally. In the illustrated example, when the retaining surface **1810** of stop **1800** has this temporary cup-shape, the maximum outer diameter of the stop **1800** may be smaller than the inner diameter of the proximal balloon leg **137***a*, allowing the stop **1800** to readily pass through the proximal balloon leg **137***a* and into the interior of the balloon **136** during manufacturing.

[0139] Now referring in addition to FIG. **34**B, FIG. **34**B illustrates an example of a second stage of assembly occurring after that shown in FIG. **34**A, in which the inner balloon catheter **134** has been advanced in the distal direction D to its final desired position, which may correspond to the configuration in which the stop **1800** is positioned at or adjacent to the distal end of the proximal pillow **136***a*. In the example configuration of FIG. **34**B, the retaining surface **1810** of stop **1800** is still in the temporary distally-facing cup shape, and the outer balloon catheter **132** has been advanced in the distal direction D until it is overlying the proximal shaft **1820** of the stop **1800** but just prior to contacting the retaining surface **1810**.

[0140] Now referring in addition to FIG. **34**C, FIG. **34**C illustrates an example of a third stage of assembly occurring after that shown in FIG. **34**B. In particular, in this example, between the stages shown in FIG. **34**B and FIG. **34**C, the outer balloon catheter **132** was slightly advanced in the distal direction D until the distalmost end of the outer balloon catheter **132** applied pressure to the proximal surface of the retainer surface **1810**, causing the retainer surface **1810** to revert to a mushroom cap shape om which the leading or distal end of the retainer surface **1810** has a slight

convexity. In some examples, the entire stop **1800** or at least the retainer surface **1810** is formed of a semi-compliant material (for example such as a Pebax material or a thermoplastic polyurethane "TPU") that is set (e.g., via heat treatment) to have the mushroom-shape shown in FIG. **34**C in the absence of applied forces (i.e. "mushroom shape" including a rectangular stem portion interconnected to a domed, cup shape portion that has a width that is greater than a width of both the outer balloon catheter **132** and the stem portion). It should be understood that, in some examples, although the retainer surface **1810** is set to have the mushroom shape of FIG. **34**C in the absence of applied forces, it may be effectively inverted manually prior to the first assembly step shown in the example of FIG. **34**A, and the inverted cup shape may be stable enough to retainer that cup shape until additional forces are applied. In this example, as the outer balloon catheter **132** is driven distally into the proximal side of the retainer surface **1810**, similar to the configuration shown in FIG. **34**B, the applied forces from the outer balloon catheter **132** disrupts the semi-stable cup shape shown in FIG. **34**B, allowing the retainer surface **1810** to "snap" back or revert to the set mushroom shape shown in FIG. **34**C. In some examples, when the retainer surface **1810** has the mushroom shape of FIG. **34**C, it has a maximum outer diameter that is larger than the inner diameter of the proximal balloon leg **137***a*, allowing the stop **1800** to have a relatively large outer diameter to provide axial stability to a prosthetic heart valve **10** mounted to the balloon **136** in axial contact with the proximal pillow **136***a*.

[0141] Although many examples of valve retainers and/or stops are described herein, they my all provide a substantially similar functionality in the overall process of delivering and deploying a prosthetic heart valve such as prosthetic heart valve **10**. For example, referring briefly to the example method **200** of FIG. **11**, during some examples of step **206** of advancing the delivery catheter (e.g., delivery catheter **130**) over a guidewire, the delivery catheter is advanced through an introducer with a hemostasis valve. In such examples, any of the valve retainers or stops described herein (including examples in which a high-friction feature is provided on the balloon (e.g., the examples of FIGS. **26**A-**28**) and examples in which the outer balloon catheter itself provides valve-retaining functionality (e.g., the example of FIG. **17**)) may help prevent the prosthetic heart valve from axial movement relative to the balloon (e.g., balloon **136**), including helping to prevent proximal movement as the delivery catheter is advanced distally. This example functionality may also be provided at other stages of delivery, including for example when tracking around the aortic arch in step **208** if the procedure is a transfemoral aortic valve replacement. Further, as noted above, although protection against proximal movement of the prosthetic heart valve during distal advancement may in some examples be more important than protection against distal movement of the prosthetic heart valve, the inclusion of any of the distal stops (including high-friction surfaces described here) may be helpful in preventing such axial movement. Still further, it should be understood that different classes of examples may be combined. For example, features are described herein that involve (i) modification of the outer surface of a balloon (e.g., high-friction examples of FIGS. **26**A-**28**), (ii) placing physical stops or valve retainers within a proximal pillow, (iii) placing physical stops or valve retainers within a distal pillow, (iv) placing physical stops or valve retainers within a crimp zone between proximal and distal pillows (e.g., the example of FIG. **30**), and (v) adding features to the balloon that will at least partially cover an outer surface of the prosthetic heart valve (e.g., the examples of FIGS. **32**-**33**) may be combined. It should be understood that any of the examples of classes (i), (ii), (iii), (iv), and (v) may be combined with any examples of the other classes in a single device. As one illustrative example, the overhangs **1639***a*, **1639***b* of FIG. **32** may be used in a system having a high-friction surface **1100***a* of FIG. **26**A, along with a stop **800** of FIGS. **23**A-**23**B used within a distal pillow **136***b* and a proximal stop **400***a* of FIGS. **18**A-**18**B used within a proximal pillow **136***a* in addition to the stop **1400***a* of FIG. **30** positioned inside of the crimped prosthetic heart valve **10**. This is just one example to show how different classes of retaining features described herein may be combined into a single device, and other suitable combinations would be readily apparent to the skilled artisan.

[0142] Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

1. A system for delivering a prosthetic heart valve, the system comprising:

a handle;

an outer catheter extending from the handle;

an inner catheter extending from the handle and through an interior of the outer catheter;

a nose cone coupled to a distal end of the inner catheter;

an inflatable balloon having a proximal leg coupled to the outer catheter, and a distal leg coupled to (i) the nose cone or (ii) the inner catheter; and

a first valve retainer coupled to the inner catheter and positioned within the balloon, the first valve retainer having an assembled state in which an inner stop is directly fixed to the inner catheter and an outer stop is positioned around and coupled to the inner stop,

wherein the inner stop has a maximum outer diameter that is smaller than a maximum inner diameter of the distal leg, and in the assembled condition of the first valve retainer, the outer stop has a maximum outer diameter that is larger than the maximum inner diameter of the distal leg.

2. The system of claim **1**, wherein the inner stop includes a ramped outer surface portion that increases in diameter in a proximal-to-distal direction of the inner stop.

3. The system of claim **2**, wherein the outer stop includes a rim and a plurality of extensions extending from the rim.

4. The system of claim **3**, wherein the outer catheter is directly coupled to the rim.

5. The system of claim **3**, wherein when the first valve retainer is in an unassembled condition, and in the absence of applied forces, the outer stop has a maximum outer diameter that is smaller than the maximum inner diameter of the distal leg.

6. The system of claim **5**, wherein the inner stop includes a shoulder at a distal end of the ramped outer surface portion.

7. The system of claim **6**, wherein at least one of the plurality of extensions includes an interiorly extending

prong at a distal end thereof, the interiorly extending prong configured to engage the shoulder in the assembled condition of the first valve retainer.

8. The system of claim **3**, wherein in the assembled condition of the first valve retainer, each of the plurality of extensions flares radially outwardly relative to the rim.

9. The system of claim **8**, wherein each of the plurality of extensions is coupled to the rim via a living hinge.

10. The system of claim **1**, wherein the balloon includes a proximal pillow, a distal pillow, and a central portion between the proximal pillow and the distal pillow, the proximal pillow and the distal pillow each having a diameter that is greater than a diameter of the central portion, the central portion being configured to receive the prosthetic heart valve in a crimped condition.

11. The system of claim **10**, wherein the first valve retainer is positioned inside the proximal pillow.

12. The system of claim **10**, wherein a distal end of the outer catheter extends into the proximal pillow.

13. The system of claim **12**, wherein the outer catheter includes a catheter wall, and a plurality of apertures are formed within the catheter wall, the plurality of apertures being positioned within the proximal pillow.

14. A method of manufacturing a delivery catheter, the method comprising:

providing a balloon having a distal leg and a proximal leg;

inserting an inner catheter into an interior of the balloon so that an inner stop fixed to the inner catheter passes through the distal leg, the inner stop having a maximum outer diameter that is smaller than a maximum inner diameter of the distal leg;

inserting an outer stop into the interior of the balloon so that the outer stop passes through the distal leg while the inner catheter is received through the outer stop, wherein during inserting the outer stop, the outer stop has a maximum outer diameter that is smaller than the maximum inner diameter of the distal leg; and

while the inner stop and the outer stop are both within the interior of the balloon, advancing the outer stop over the inner stop to increase the maximum outer diameter of the outer stop, the increased maximum outer diameter of the stop being larger than the maximum inner diameter of the distal leg.

15. The method of claim **14**, wherein the inner stop has a ramped outer surface portion and the outer stop has a rim and a plurality of extensions extending from the rim, and advancing the outer stop over the inner stop includes advancing the outer stop over the ramped outer surface portion to force the plurality of extensions to flare outwardly relative to the rim.

16. The method of claim **15**, wherein the inner stop includes a shoulder, and at least one of the plurality of extensions includes an interiorly extending prong.

17. The method of claim **16**, wherein in the absence of applied forces, the outer stop has the maximum outer diameter that is smaller than the maximum inner diameter of the distal leg.

18. The method of claim **17**, further comprising continuing to advance the outer stop over the inner stop until the at least one interiorly extending prong advances past the shoulder.

19. The method of claim **18**, wherein when the at least one interiorly extending prong advances past the shoulder, the corresponding extension snaps inwardly toward the inner catheter such that the at least one interiorly extending prong engages the shoulder to prevent the outer stop from retracting relative to the inner stop.

20. The method of claim **19**, further comprising advancing an outer catheter through the proximal leg into the interior of the balloon.

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