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(54) **PERCUTANEOUS HEART VALVE DELIVERY SYSTEMS**

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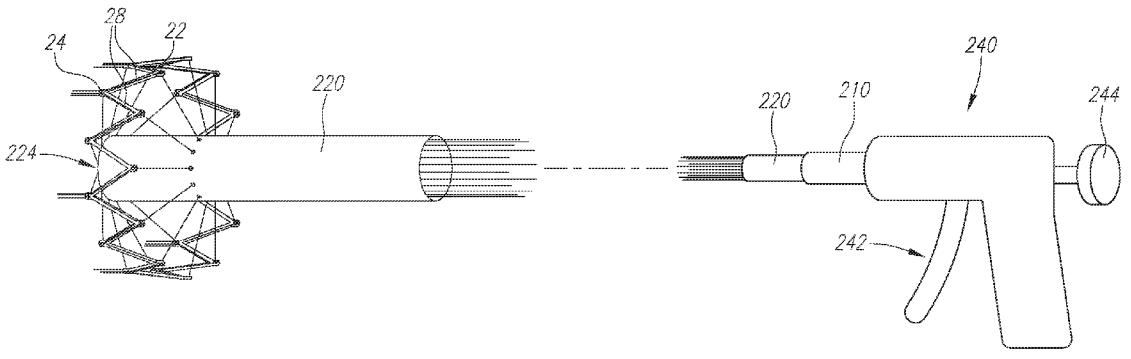
(57) **ABSTRACT**

Embodiments described herein address the need for improved catheter devices for delivery, repositioning and/or percutaneous retrieval of the percutaneously implanted heart valves. One embodiment employs a plurality of spring-loaded arms releasably engaged with a stent frame for controlling expansion for valve deployment. Another embodiment employs a plurality of filaments passing through a distal end of a pusher sleeve and apertures in a self-expandable stent frame to control its state of deployment. With additional features, lateral positioning of the stent frame may also be controlled. Yet another embodiment includes plurality of outwardly biased arms held to complimentary stent frame features by overlying sheath segments. Still another embodiment integrates a visualization system in the subject delivery system. Variations on hardware and methods associated with the use of these embodiments are contemplated in addition to those shown and described.

22 Claims, 14 Drawing Sheets



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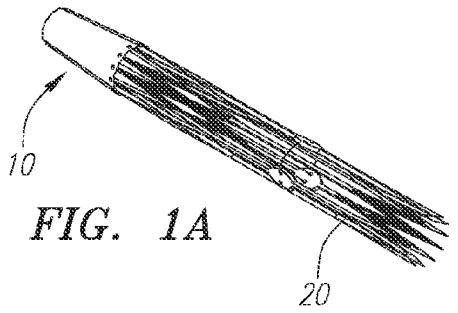
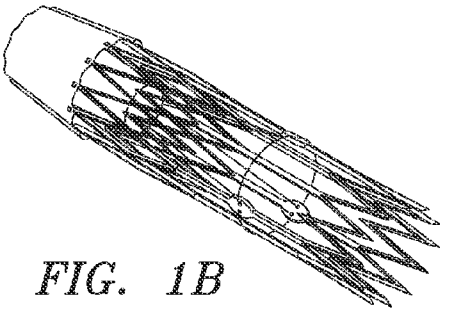


FIG. 1A



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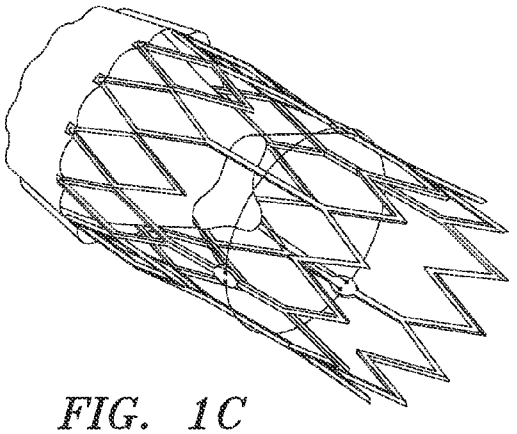

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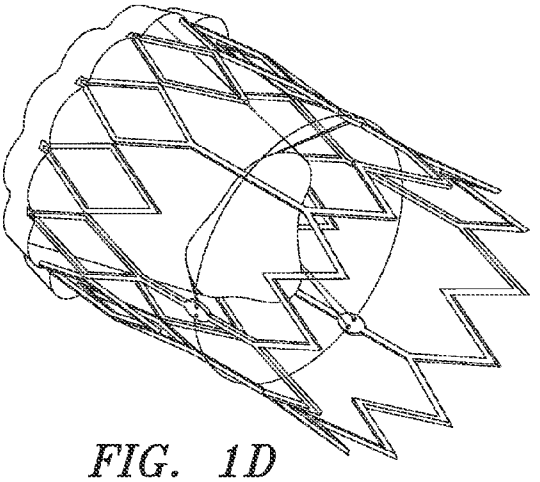

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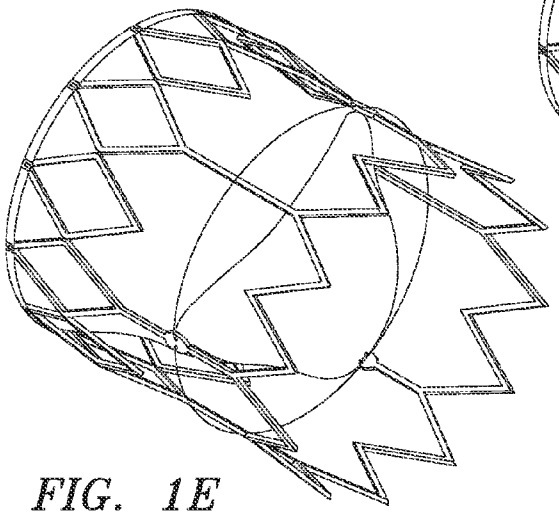

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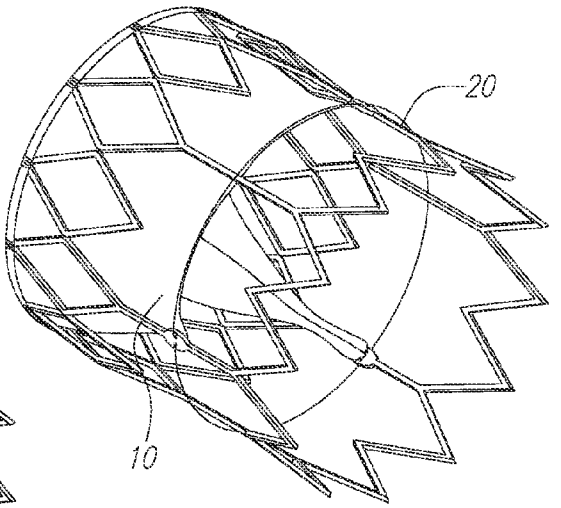

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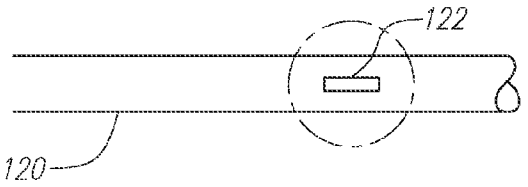

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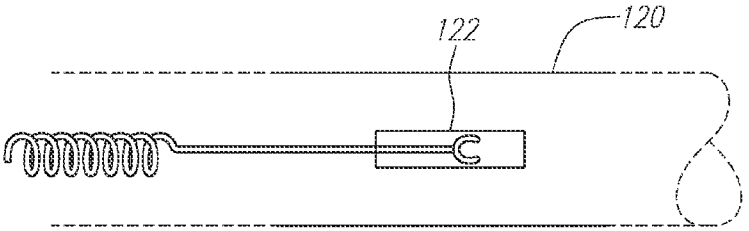

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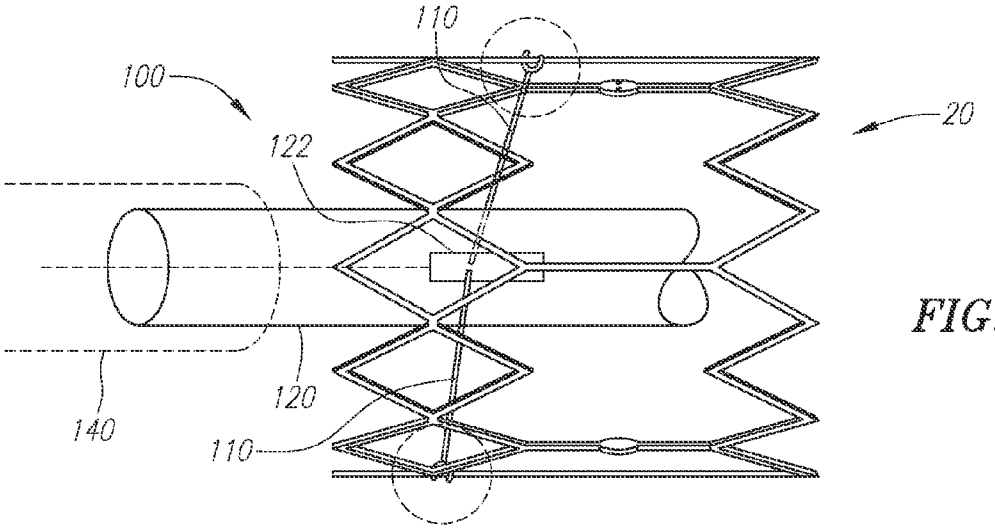

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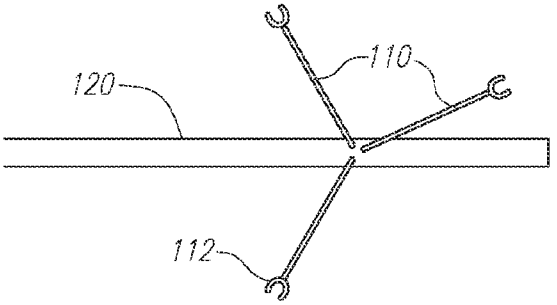

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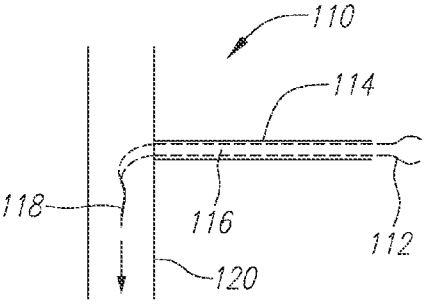
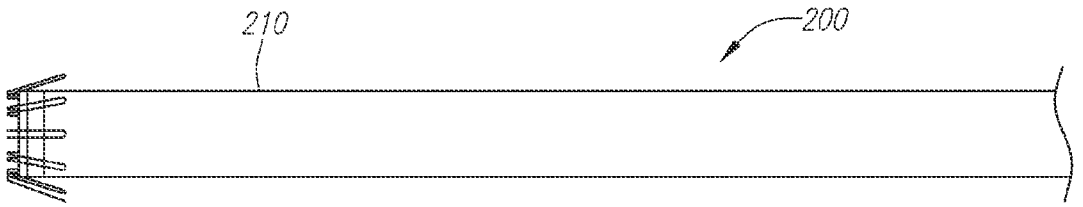


FIG. 4B



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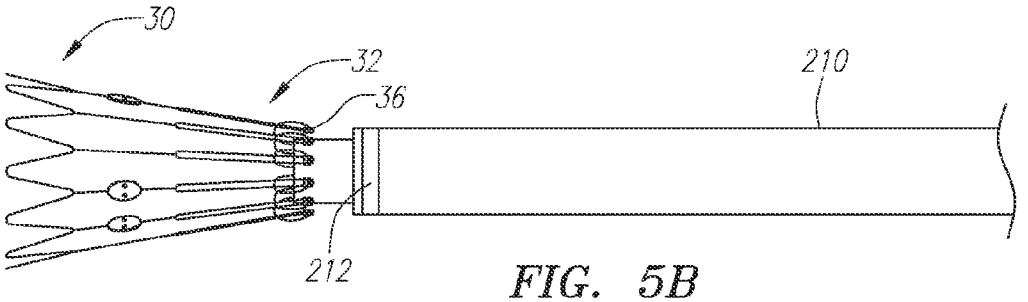


FIG. 5B

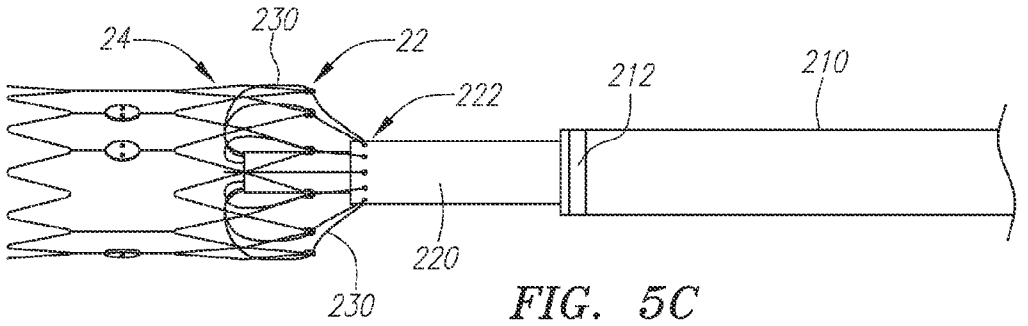
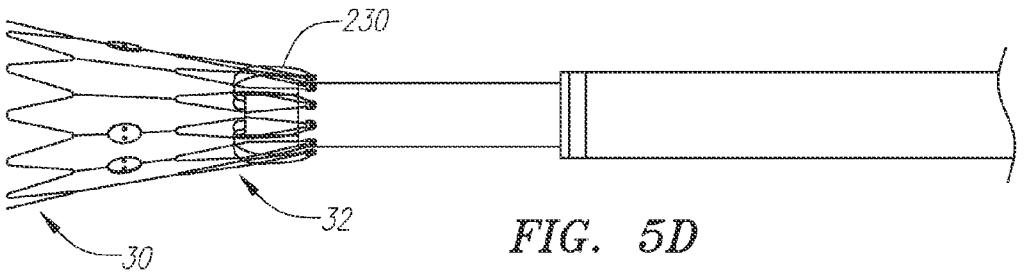


FIG. 5C



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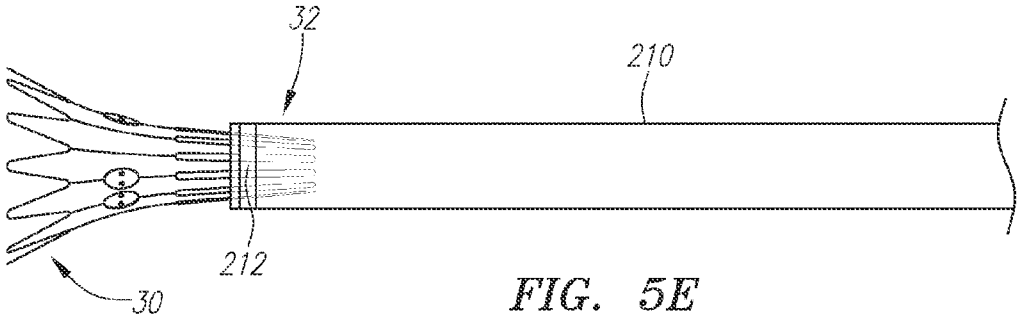


FIG. 5E

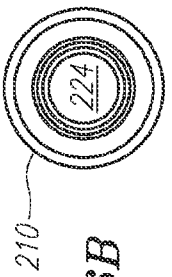
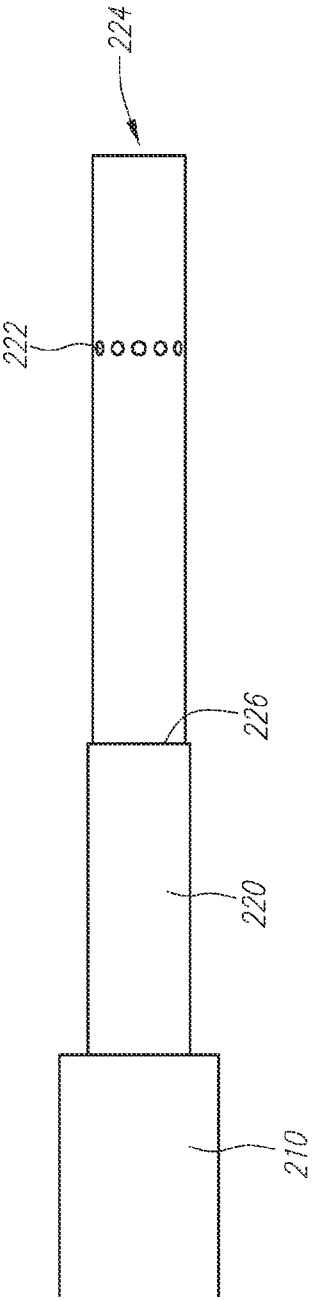


FIG. 6B



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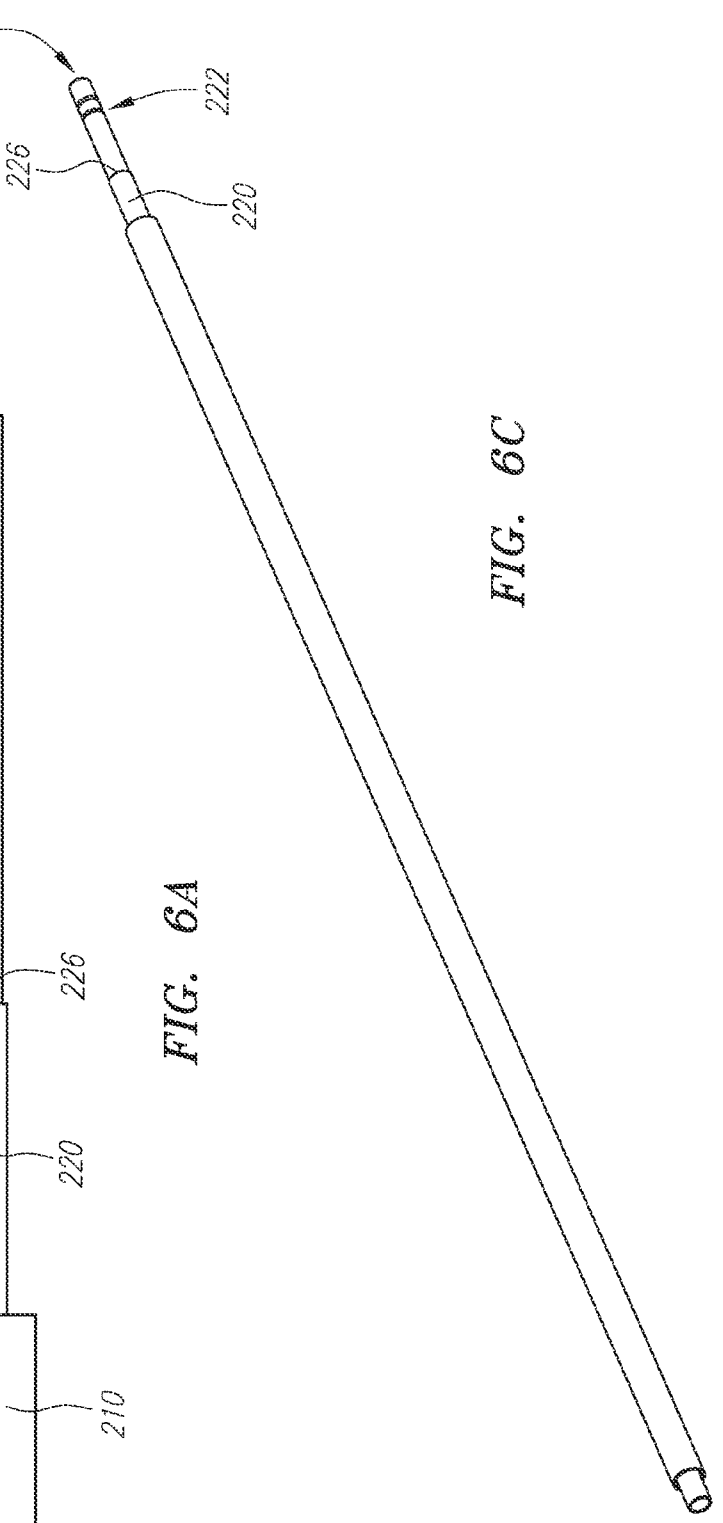

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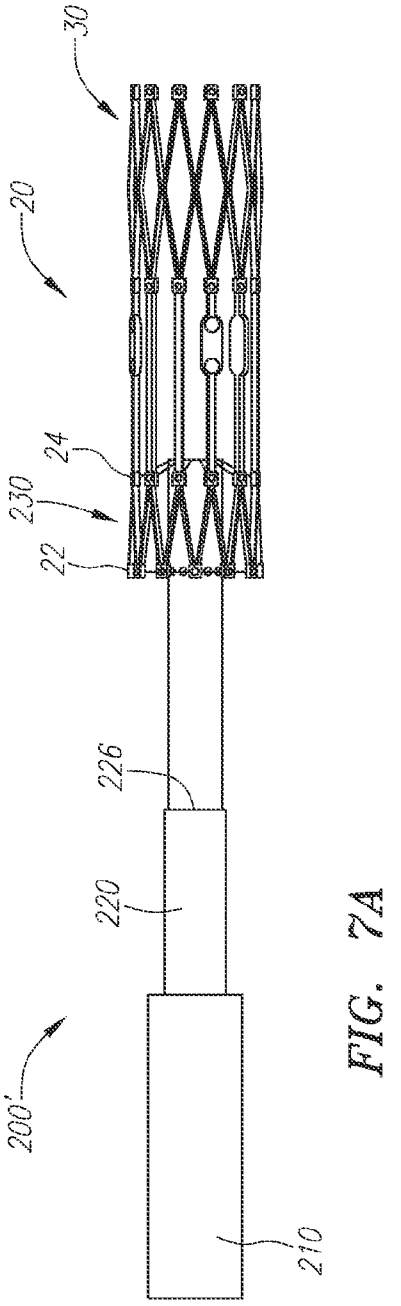
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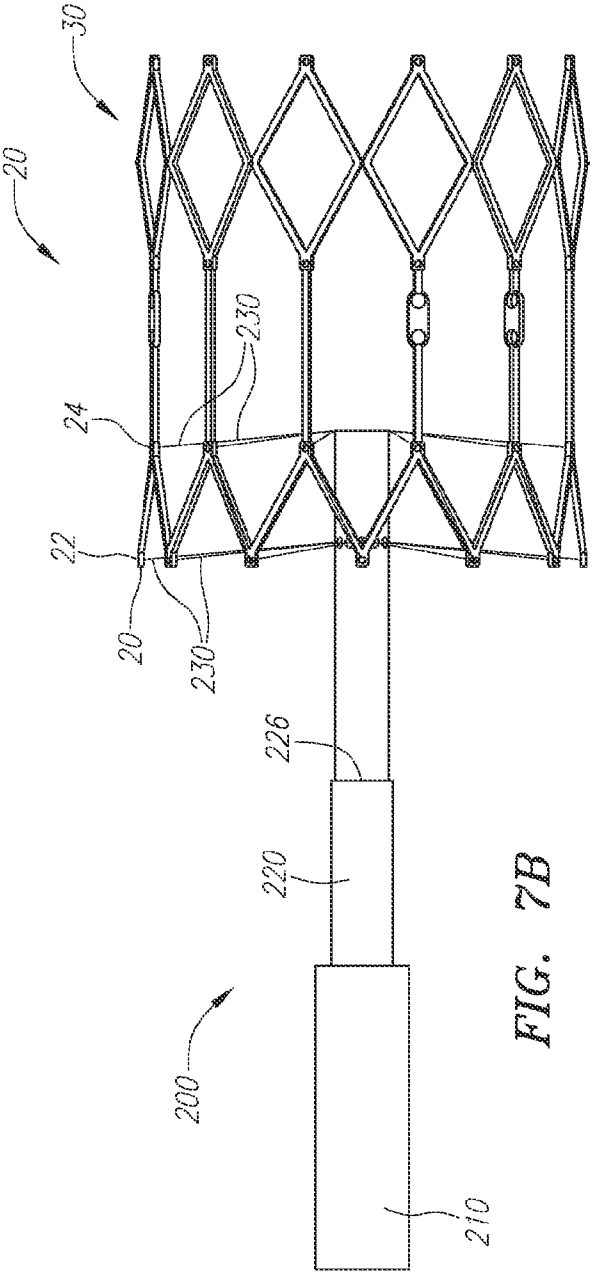
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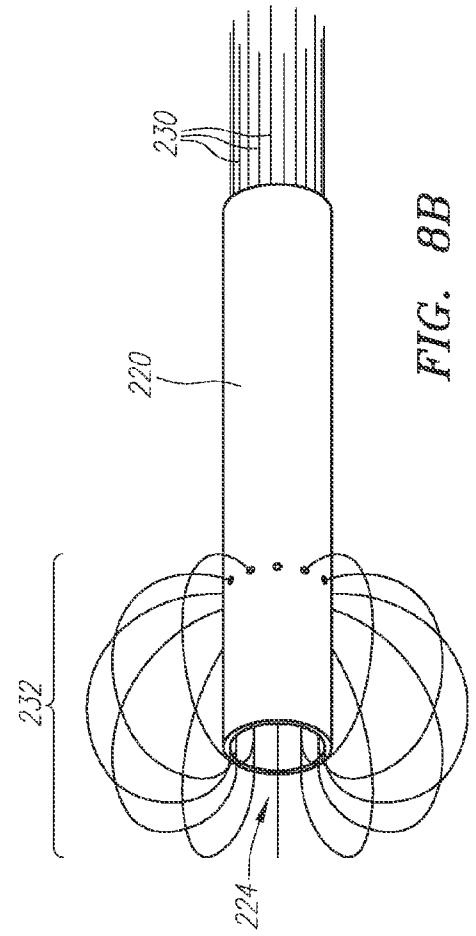
FIG. 7B



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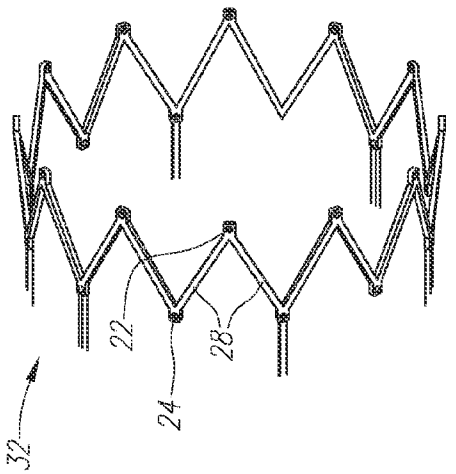

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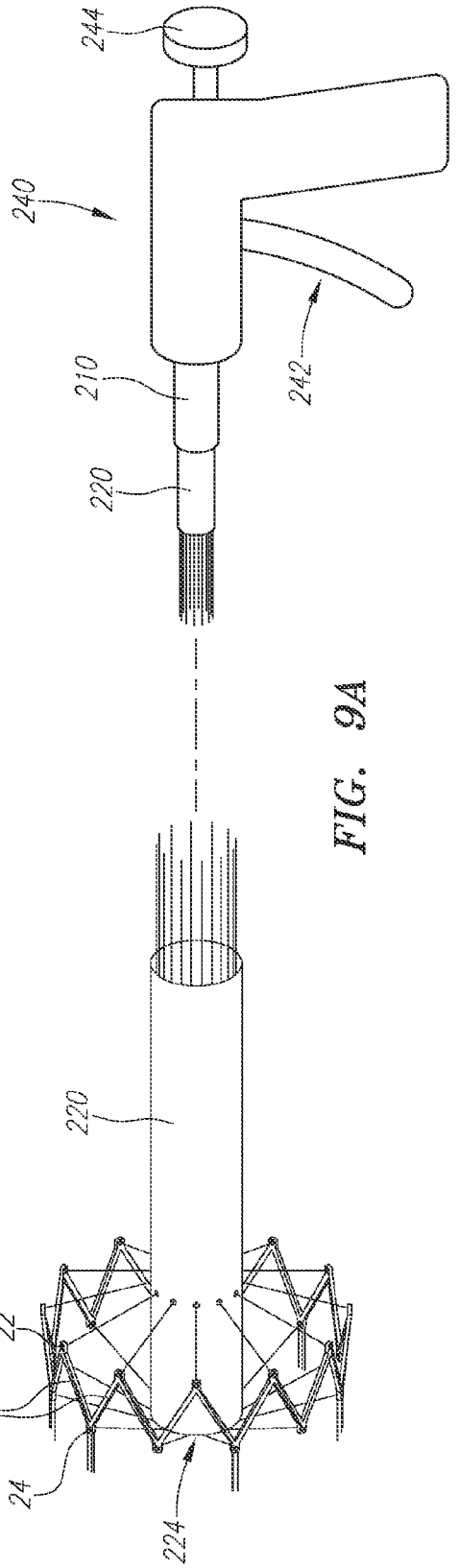
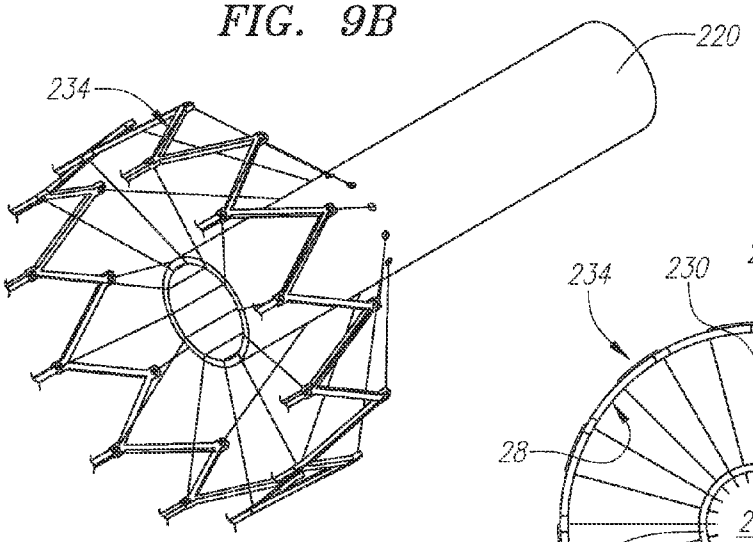
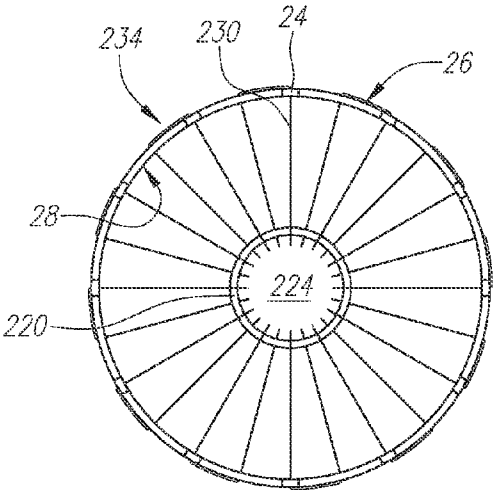


FIG. 9A

FIG. 9B





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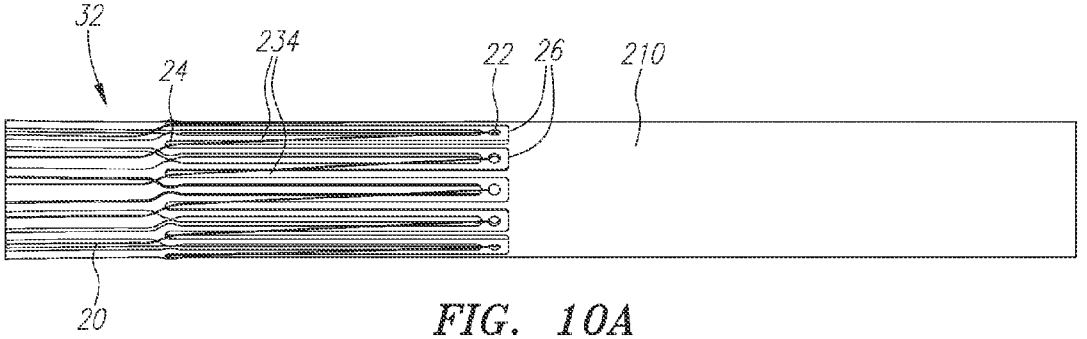

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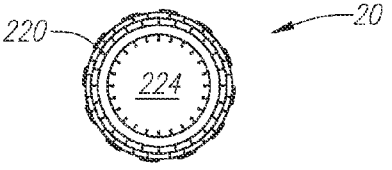

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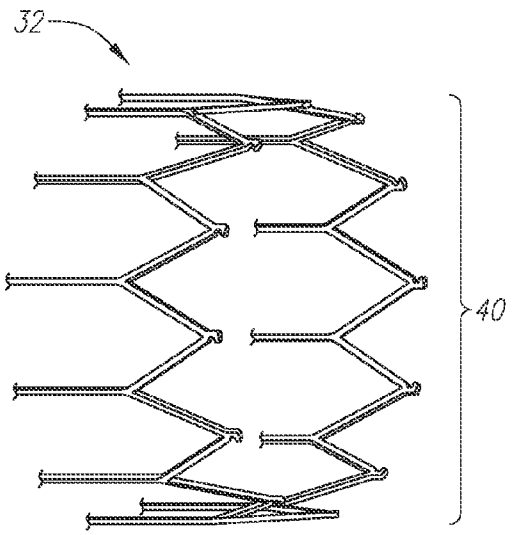

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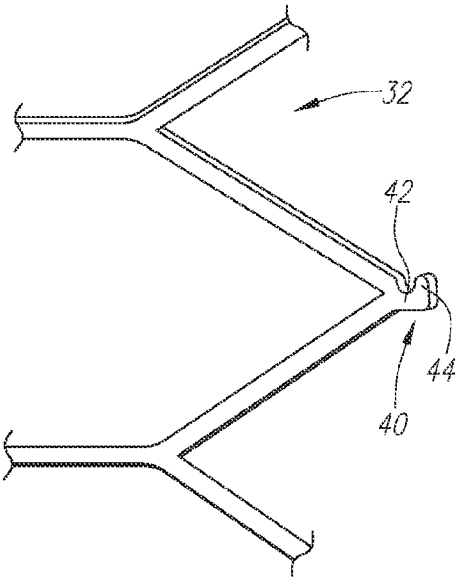
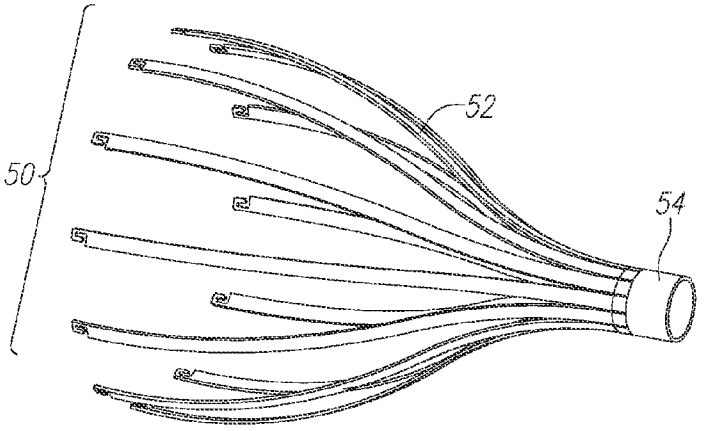
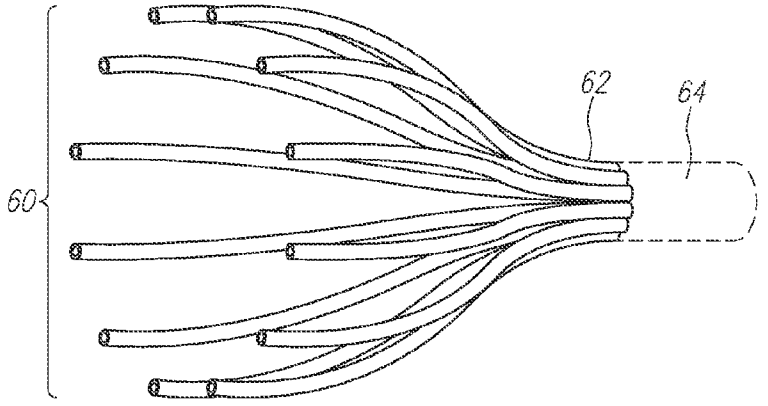


FIG. 11B

FIG. 12





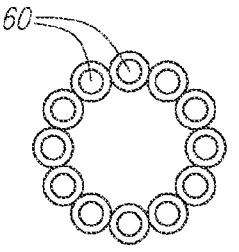
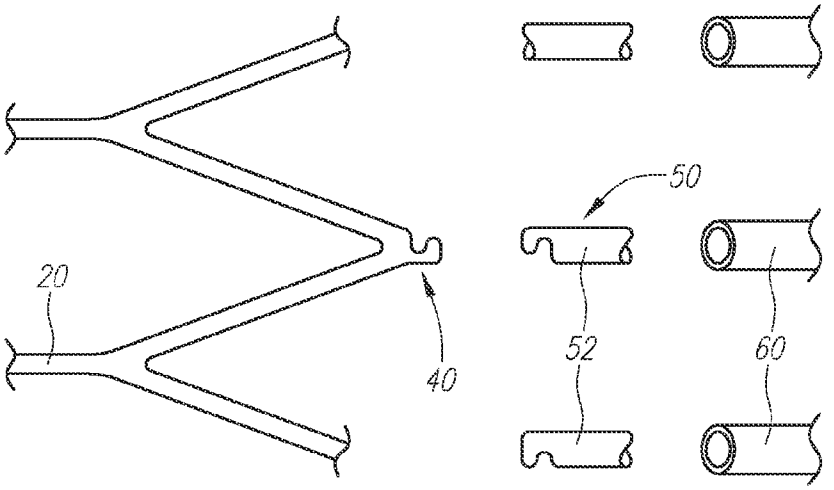


FIG. 13B

FIG. 13A



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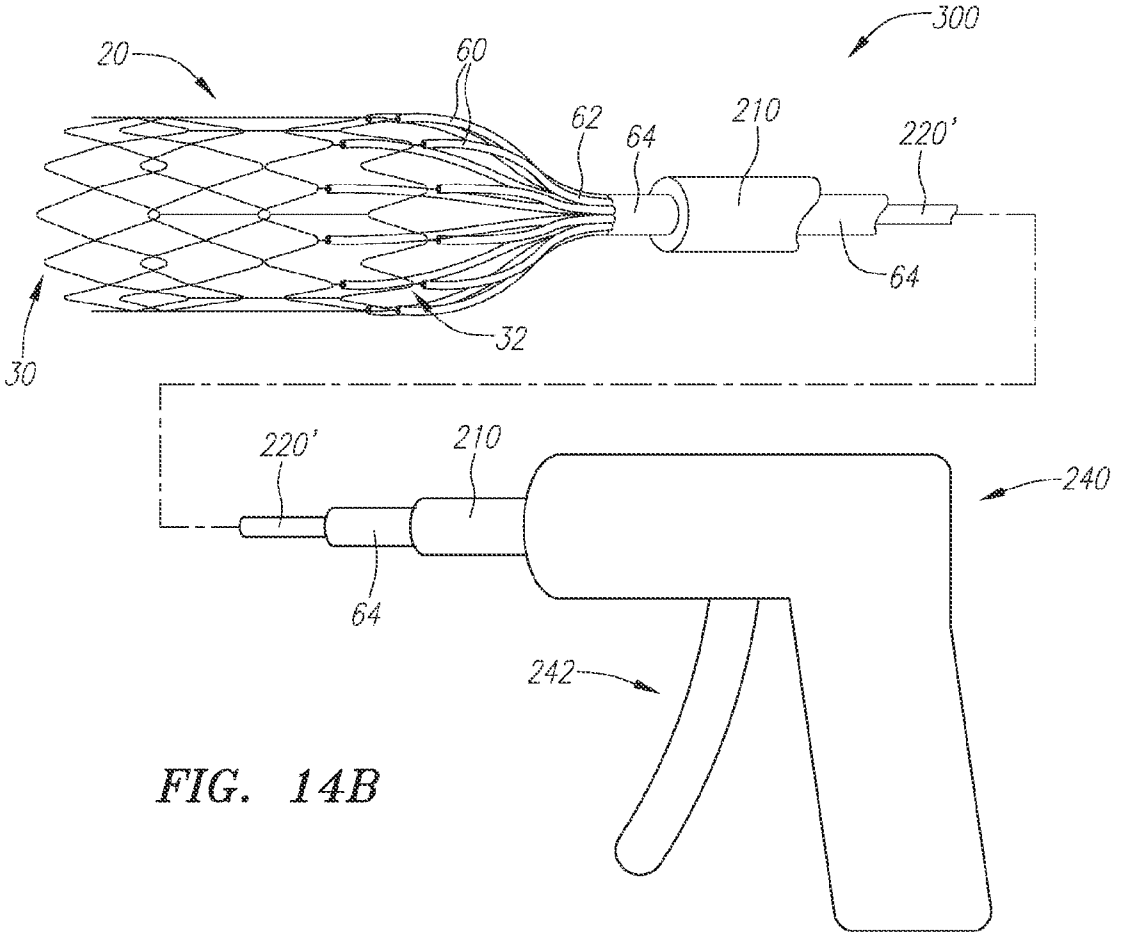

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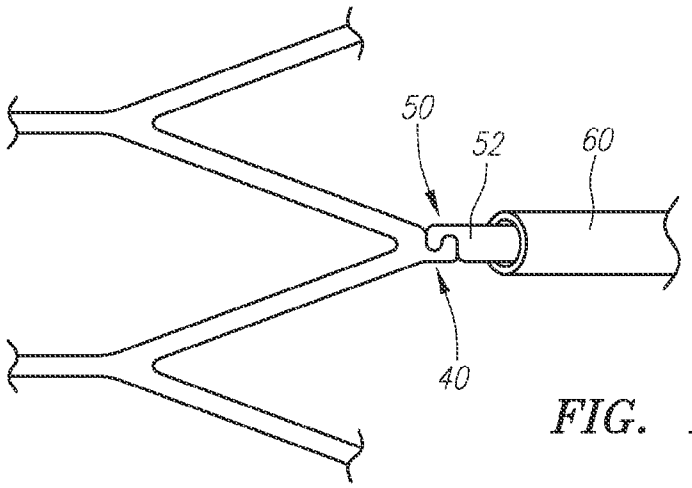

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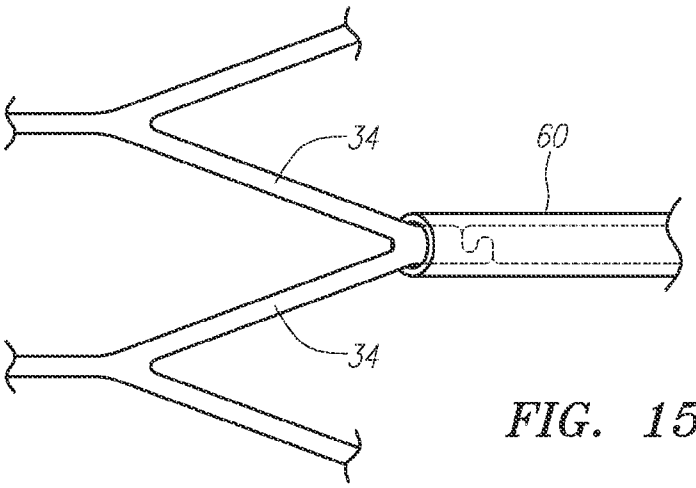

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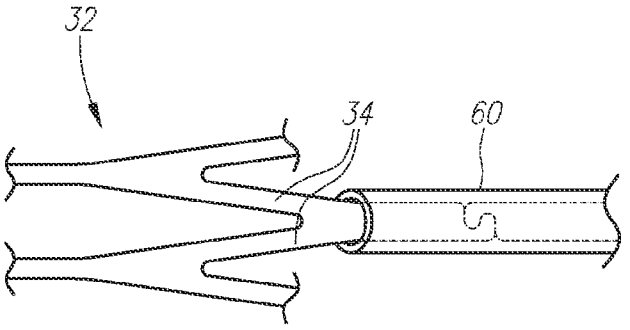
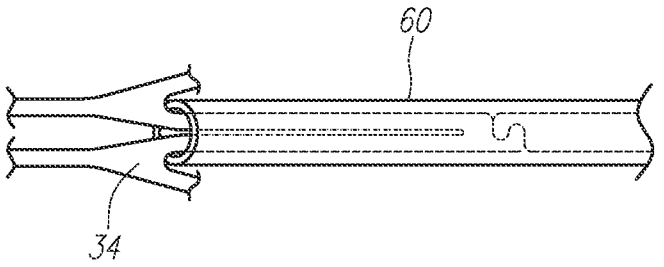


FIG. 15C



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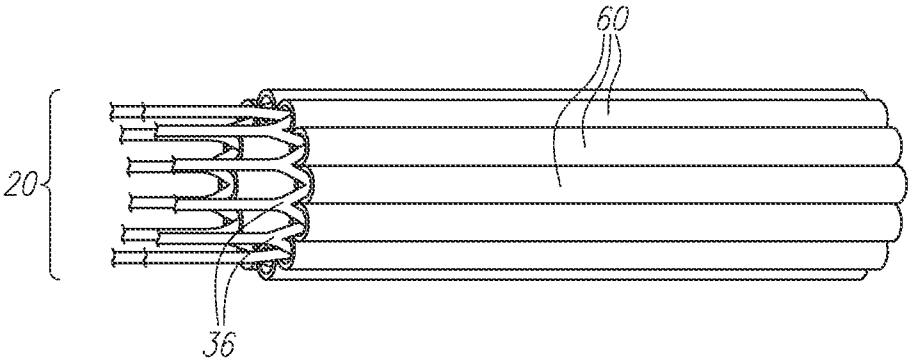

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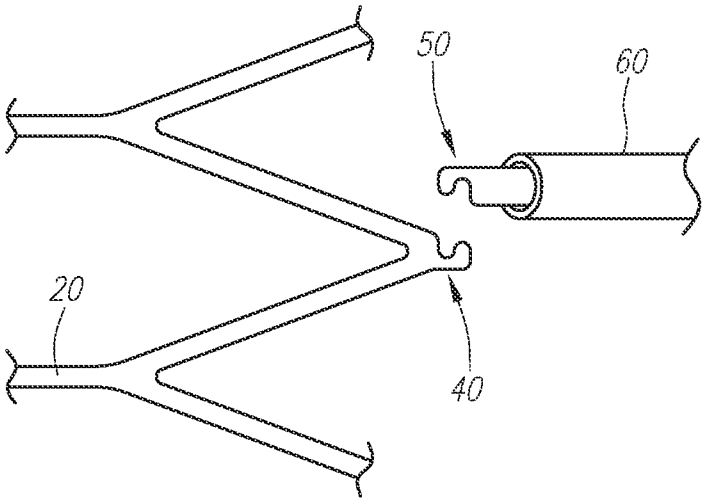

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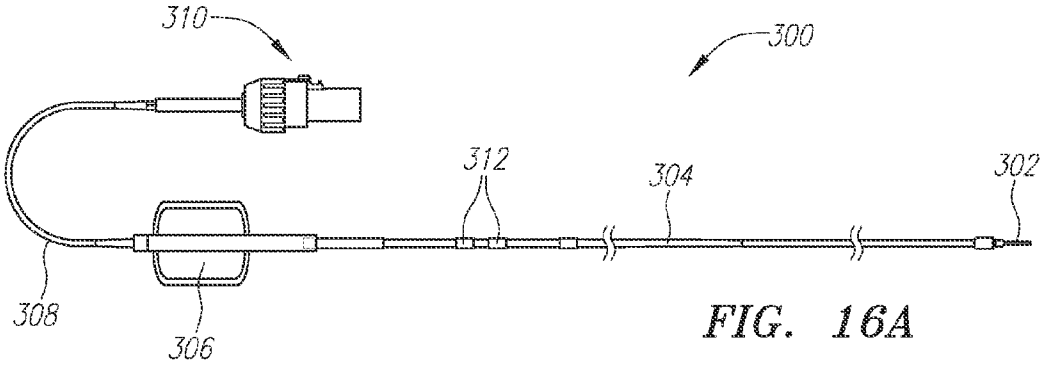

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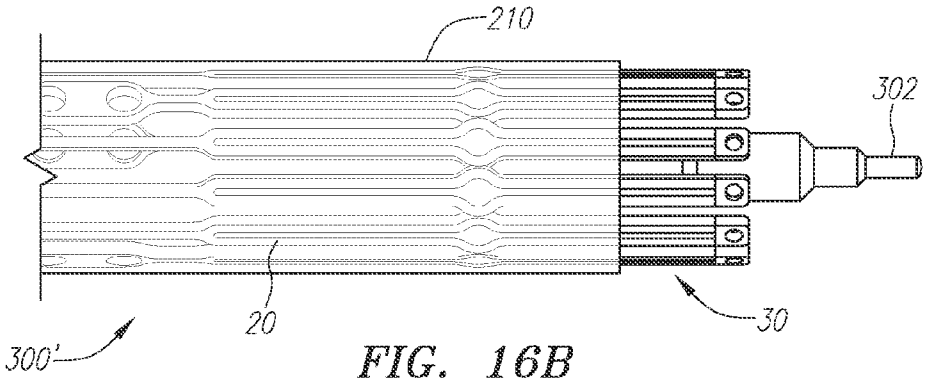

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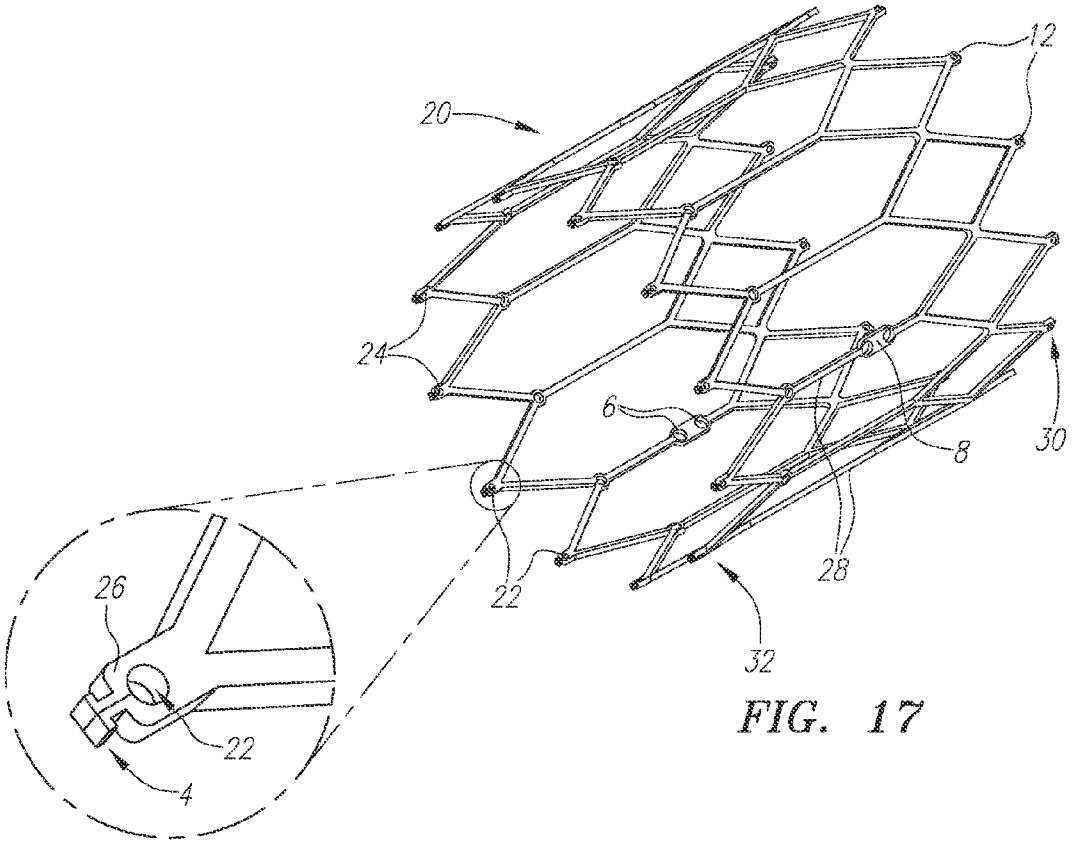

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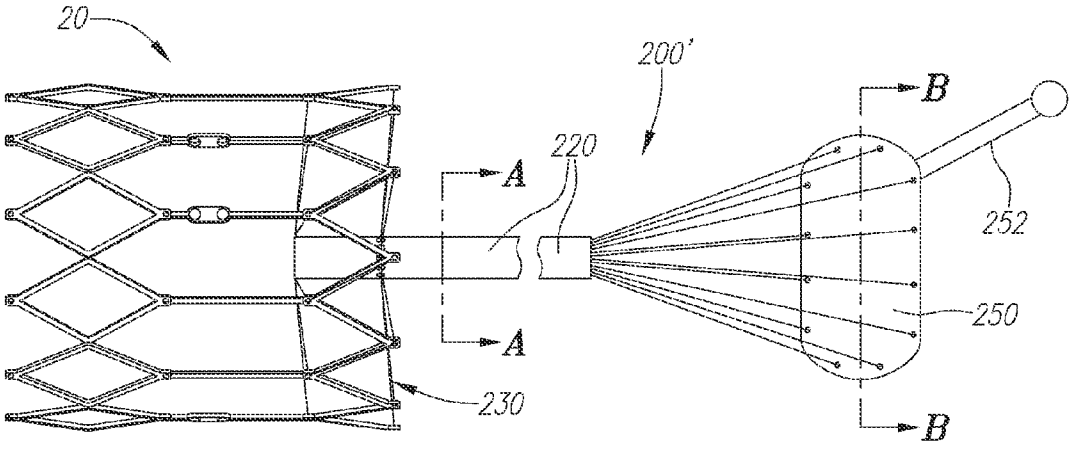

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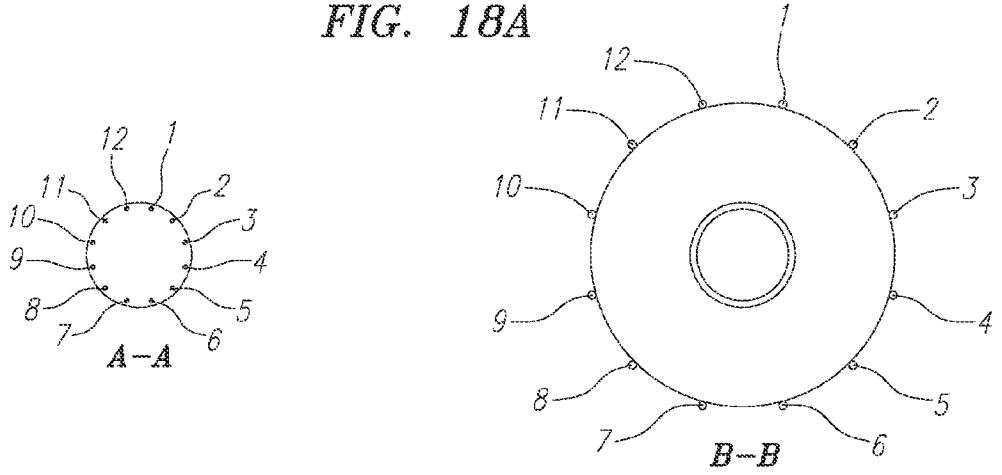

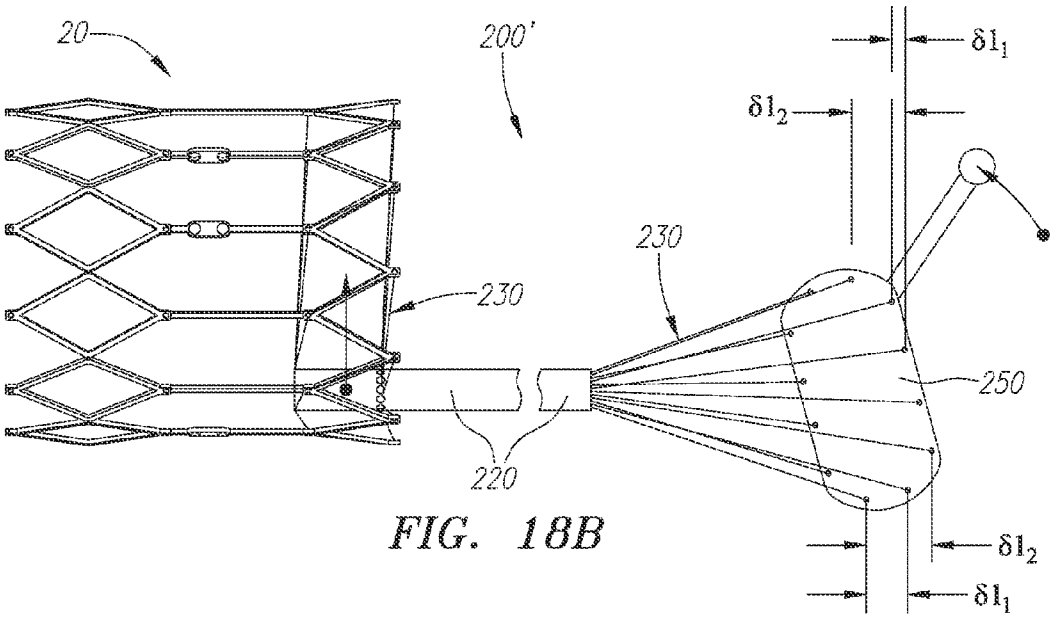

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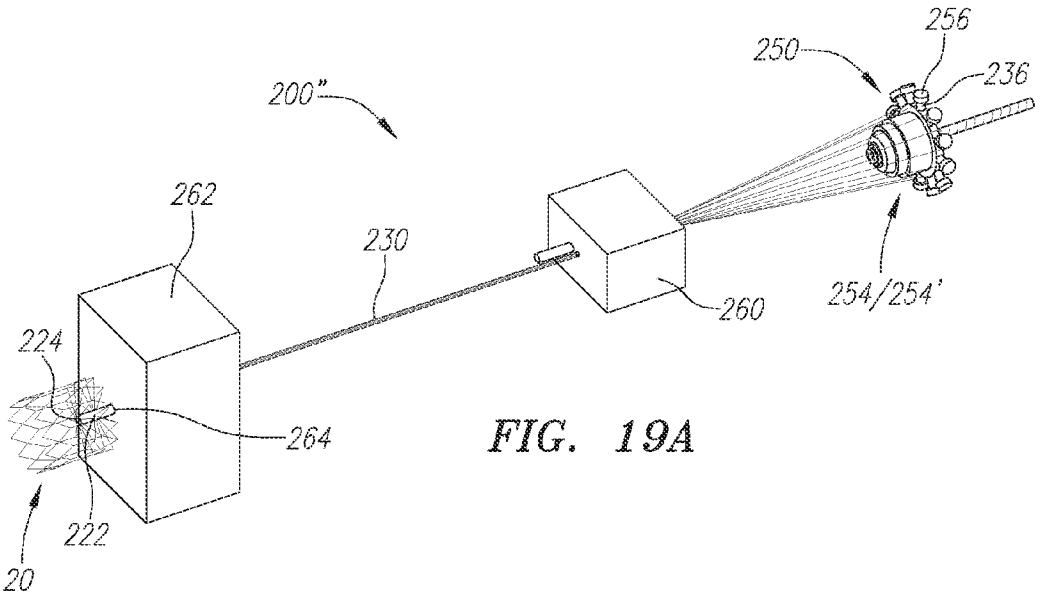

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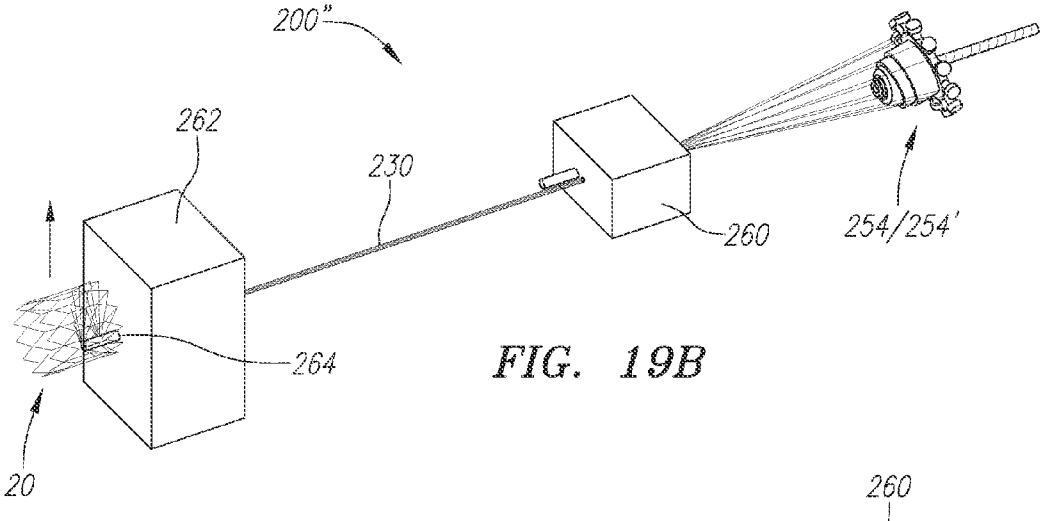

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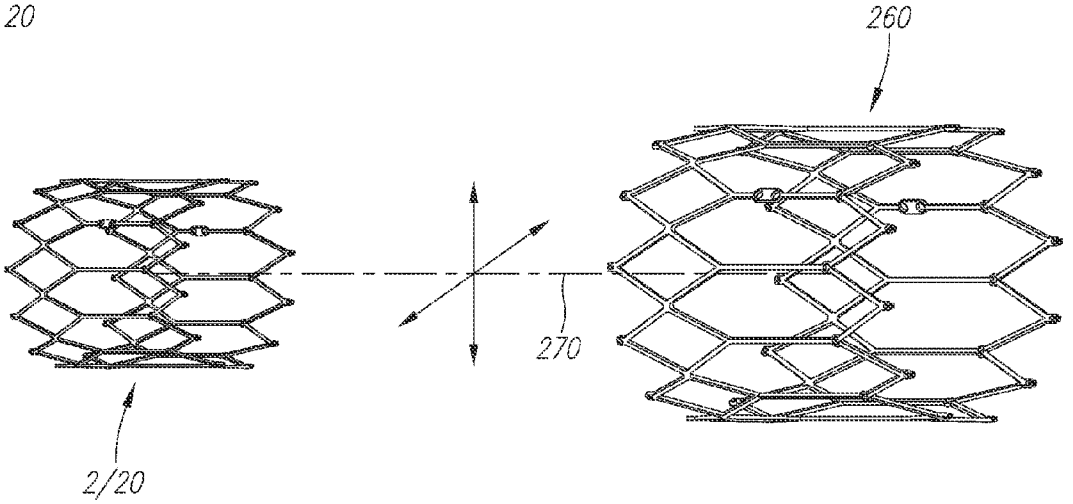

FIG. 20

PERCUTANEOUS HEART VALVE DELIVERY SYSTEMS

RELATED APPLICATIONS

This filing claims the benefit of and priority to U.S. Provisional Patent Application No. 61/732,117 filed Nov. 30, 2012, U.S. Provisional Patent Application No. 61/682,663 filed Aug. 13, 2012, and U.S. Provisional Patent Application No. 61/623,410 filed Apr. 12, 2012. This filing is also a Continuation-in-Part of PCT/US12/49645 filed Aug. 3, 2012, which claims the benefit of U.S. Provisional Patent Application No. 61/515,679 filed Aug. 5, 2011 and U.S. Provisional Patent Application No. 61/666,657 filed Jun. 29, 2012. All preceding applications are incorporated by reference herein in their entireties for all purposes.

FIELD

The embodiments described herein relate to percutaneously-delivered heart valves and associated delivery systems.

BACKGROUND

Transcatheter aortic valve replacement (TAVR) procedures require image-guidance during implantation to successfully deploy the heart valve into the correct position within the patient's aortic annulus. Current image technology uses X-Ray, CT, MRI, or ultrasound to visualize the surrounding anatomy. However, only X-Ray can be used during the procedure for image guidance. X-Ray is not sufficient for visualization because it is a 2D projection of 3D anatomy that depends on the orientation angle of visualization. Currently, other imaging modalities can be used prior to the procedure and during follow-up, with the hopes that anatomical visualization can be directly correlated to the X-Ray images seen during the procedure. However, differences in contrast, resolution, and artifacts can produce differing results.

Correct valve positioning is crucial for treatment success and optimal outcomes after transcatheter valve implantation. For example, to maintain a stable and correct lengthwise position with respect to the aortic annulus, a stepwise deployment that allows the valve to be repositioned both circumferentially and in the axial direction (i.e., towards the left ventricle (LV) or the ascending aorta) is important.

However, most of the current technologies are limited by instant deployment, and once the valve is deployed, repositioning and/or percutaneous retrieval is not possible—or at least difficult or potentially problematic. Placement of the stented valve in a position that is too high (or proximal) can totally or partially obstruct the coronary ostia in a case of aortic implantation, which may result in myocardial infarction or ischemia. Additionally, if the valve is placed too high in the aorta, it may embolize into the aorta causing significant paravalvular regurgitation. On the other hand, implantation in a position that is too low (or distal) is accompanied by compression of the atrioventricular (AV) node in the membranous septum, which leads to conduction abnormalities.

Further technical developments with a focus on a positionable, repositionable, and/or percutaneously retrievable valve design allow optimal placement and may thereby significantly reduce the risk of paravalvular aortic regurgitation, myocardial infarction, or ischemia related to improper positioning. Likewise, advances in imaging to facilitate optimal heart valve placement are needed.

SUMMARY

The embodiments described herein address the need for improved catheter devices for coordinated delivery, positioning, repositioning and/or percutaneous retrieval of the percutaneously implanted heart valves. The delivery system apparatus is a tool that may incorporate a guide wire lumen. As such, a given device may be suitable for so-called "over-the-wire" use and include a delivery sheath covering that restrains the stent frame of the valve. Alternatively, the delivery device may be tracked trough a catheter serving such function, as in a so-called "guide" or "delivery" catheter.

In one embodiment, the delivery apparatus includes a number of arms (such as, but not limited to three) embedded within its body that hold the valve's stent during the delivery procedure when it is in the collapsed state. The arms are equipped with adjustable springs that are remotely controllable by the operator, and allow for robust radial expansion or deployment of the collapsed stent in increments.

In use, the arms remain attached to the valve stent frame until the stent frame is fully deployed. If the stent/stent frame is not properly deployed, the arms, which are still releasably attached to the stent until intended release, can be used for partial contraction of the stent for repositioning purposes. When the stented valve is properly positioned as desired within the heart, the arms will be released from the stent, and return to their embedded/retracted positions within the apparatus. Then the entire apparatus is retracted. It may be retracted from the heart or vasculature over any guide wire used and/or through any delivery catheter employed for site access.

In another system embodiment allowing for stented valve delivery, repositioning, and/or percutaneous retrieval, draw line filaments are positioned through the distal end of a pusher sleeve (or draw tube), along a lumen of the sleeve (or tube), out through holes in the sleeve (or tube), out through proximal frame holes, along the surface of a heart valve frame, in through distal frame holes, in through the distal end of the sleeve (or tube), along the lumen of the sleeve (or tube), and out the proximal end of the sleeve (or tube). Variations on this approach are possible as are various optional features of the stent frame facilitating such use.

The draw lines may comprise polyester (PE), PTFE, suture material, or another high strength (and preferably biocompatible fiber) braid or bundle of fibers such as ultra-high-molecular-weight polyethylene (UHMWPE, sometimes shortened to UHMW). In this embodiment and others described herein, the heart valve frame may comprise superelastic NiTi alloy heatset in a desired shape, it may be constructed of a so-called "engineering plastic" such as polyetheretherketone (PEEK) or may be constructed otherwise. Various surface treatments or finishes may be desirable. In the case of a NiTi (Nitinol) or another metallic material implant, an electro-polished surface may be preferred.

Collapsed and expanded states of a heart valve can be controlled by varying the position and/or tension applied to the draw lines. A customized handle may be provided for user interface. Draw line tension can be increased until the heart valve frame is fully collapsed and fully releasing the draw line tension allows the self-expanding heart valve frame to fully expand. The heart valve frame may be put in an intermediate state by varying the tension applied to the

draw lines. Moreover, the system can be setup to allow a range of lateral control of the stent position during delivery. In one variation, a "joystick" control interface is provided; in another a model of the implant (or at least the stent frame portion of the valve to be delivered) is used.

In yet another delivery system embodiment allowing for delivery, repositioning, and/or percutaneous retrieval, different means or entities are provided to control the state of device deployment (variably, from fully collapsed to fully expanded) of the proximal end of a self-expanding heart valve device. Such means or entities pertain to the use of multiple sleeve or sheath features (herein optimally referred to as "zip tube" parts or an assembly with "zip tube" sheaths or fingers) provided to mechanically change an angle between adjacent strut elements and thereby the proximity of the struts. In use, the zip tube sheaths (or fingers) collapse the heart valve frame by "zipping" the struts into closer proximity.

In this embodiment, the ends of a self-expanding heart valve frame are configured with a link feature. A self-expanding retainer is constructed and configured with diametrically collapsible retainer arms or fingers. A zip tube part or assembly with diametrically expandable/collapsible sheath fingers is configured in such a manner to allow the zip tube fingers to slide over the retainer fingers. The ends of the retainer fingers are configured with a clasp or link feature so as to mate to the heart valve frame clasp or link features.

The zip tube assembly may be partially advanced (distally) to trap the heart valve frame and retainer such that they will not unlink because the inner diameter (or inner dimension(s)) of the zip tube fingers are constructed so as to constrain the linked heart valve frame and retainer from unlinking when positioned around the linked frame or retainer. With the retainer serving as a means to secure the valve in position, the zip tube assembly may be variably advanced (relative to the linked heart valve frame or retainer) to variably (e.g., partially) collapse the proximal end of the heart valve device or fully advanced to fully collapse the proximal end of the heart valve device.

The zip tube part assembly may be variably retracted to allow the proximal end of the self-expanding heart valve device to variably (partially) expand or retracted sufficient to allow the self-expanding heart valve device to fully expand. Alternatively, the zip part or assembly may be secured in position and the retainer may be variably retracted to variably collapse the proximal end of the heart valve device up to fully collapsed or variably advanced to allow the self-expanding heart valve device to variably expand up to fully expanded. The zip tube part or assembly can be fully retracted allowing the heart valve frame and retainer to unlink thereby releasing the heart valve device from the delivery system so that the heart valve device may be left in position and the delivery system may be removed.

In addition, any of the subject delivery system architectures may incorporate a visualization system for image-directed heart valve delivery. Alternatively, other features for restraining and/or manipulating a self-expanding stent frame or a ballooned stent frame approach may be employed in an image-guided system. All of these embodiments involve a catheter or catheter-like device that utilizes an integrated imaging modality with a deployment mechanism. As such, these embodiments may be used to accurately deploy a heart valve into a patient with greater accuracy and precision than with current procedural imaging modalities where direct visual confirmation is not possible.

In these embodiments, the delivery system incorporates a catheter-based imaging modality within the device, such as, but not limited to, intravascular ultrasound (IVUS), intravascular photoacoustic (IVPA) imaging, optical coherence tomography (OCT), raman spectroscopy, or an optical method, capable of detecting features of a vessel in which the catheter is inserted. The selected imaging systems allow clinicians to image both the surrounding anatomy and the advancing catheter in real-time during the procedure.

In one example, since IVUS is a tomographic imaging modality, a 3D image of the aortic root can be produced through pull-back imaging. High-resolution IVUS is well-known for interrogating the lumen wall of vessels and has also been used to visualize metal stents in vivo. In the example of IVUS hardware, a physician can accurately image and position the implantable valve device without the use of ionizing radiation or nephrotoxic contrast agents. Furthermore, IVUS advantageously provides for a real-time imaging modality.

A catheter system can be based upon an imaging catheter or a valve delivery catheter. In an embodiment where the catheter system is based upon the valve delivery catheter, the imaging modality device can be inserted through the center of the valve delivery catheter, where the active imaging element is aligned with a feature of the valve delivery catheter, such as, but not limited to the catheter tip, the distal or proximal end of the valve stent, or some other predetermined landmark of the valve delivery catheter. Positioning of the imaging device on the circumference of the valve delivery catheter is also possible in another embodiment to prevent visual hindrance from the implanted stent.

In yet another embodiment, the valve delivery system is based upon the imaging catheter, and the deployment mechanism is inserted through the lumen of the imaging catheter, such as, but not limited to, through a guidewire port of the imaging catheter. Furthermore, the delivery system referred herein is not limited to the delivery of a heart valve device, but could be used to deliver therapy to a localized region through the use of a catheter. Such examples of delivery could include, but are not limited to, delivery of drugs or other therapeutic agents, delivery of RF irradiation, or delivery of another device.

Operation of the delivery system allows visualization of the surrounding anatomy during insertion of the imaging catheter in the context of the location of the delivery catheter. As such, the location of the delivery catheter relative to the surrounding environment may always be known. In one embodiment, the delivery system is fixed relative to the imaging transducer within the catheter. In another embodiment, the two components can be moved relative to one another. However, in embodiments where relative motion is allowed, the relative motion is advantageously tracked or known in order to maintain accuracy in the advancing catheter.

The subject delivery devices, kits in which they are included (with and without valve installation or assembly), methods of use and manufacture (such as assembly of the delivery system and frame alone and/or with included valve) are all included within the scope of the present disclosure. Some aspects of the same are described above; more detailed discussion is presented in connection with the figures below.

Other systems, devices, methods, features, and/or advantages of the subject matter described herein will be or will become apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, devices, methods, features, and/or advantages be included within this description and be within the scope of the subject matter described

herein, regardless of whether recited in this summary section. In no way should the features of the example embodiments in this or any other section be construed as limiting the appended claims, absent express recitation of those features in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The details of the subject matter set forth herein, both as to its structure and operation, may be apparent by study of the accompanying figures, in which like reference numerals refer to like parts. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the subject matter. Moreover, all illustrations are intended to convey concepts, where relative sizes, shapes and other detailed attributes may be illustrated schematically rather than literally or precisely. Variations other than those shown in the figures are contemplated as described in a broader sense in the above summary section, as generically claimed, or otherwise.

FIGS. **1**A-**1**F are perspective views illustrating an example embodiment of a stent frame and valve in various stages of deployment as may be employed in connection with the embodiments herein.

FIG. **2**A is a detail view illustrating the delivery device sleeve of a first embodiment showing the location of one of a plurality of embedded arms.

FIG. **2**B is a detail view illustrating the arm at the location in FIG. **2**A connected to a spring system for controlling stent frame deployment.

FIG. **3** is a system overview illustrating the arms releasably attached to a stent frame.

FIG. **4**A is a detail view illustrating the arms fully extended from the delivery apparatus and FIG. **4**B is a detail view illustrating a hollow deployment arm with strings inside and a pull/push mechanism inside the guide tube or sleeve.

FIGS. **5**A-**5**E illustrate progressive stages of stent frame deployment and recapture for a second embodiment.

FIGS. **6**A-**6**C illustrate side, end, and perspective views, respectively, of the delivery device sleeve of the second embodiment.

FIGS. **7**A and **7**B are side views illustrating the sent frame associated with the delivery device sleeve in contracted and expanded states, respectively.

FIG. **8**A illustrates a variation of the subject stent frame and FIG. **8**B illustrates a variation of the subject delivery sleeve with associated draw line filaments.

FIGS. **9**A-**9**C are side, perspective, and end views, respectively, illustrating the components in FIGS. **8**A and **8**B assembled together.

FIGS. **10**A and **10**B are side and end views, respectively, illustrating the same assembled components shown in a compressed state.

FIGS. **11**A and **11**B are partial perspective and detail side views, respectively, illustrating a stent frame for a third embodiment.

FIG. **12** is a perspective view illustrating a frame retainer with retainer fingers.

FIGS. **13**A and **13**B are perspective and end views, respectively, illustrating a zip tube part or assembly and zip tube fingers.

FIG. **14**A illustrates segments of an expanded heart valve frame, retainer fingers, and zip tube fingers as associated in the subject embodiment and FIG. **14**B illustrates a complete assembly of the embodiment including these subcomponents.

FIGS. **15**A-**15**F are detail side views illustrating operation of elements within the embodiment.

FIGS. **16**A and **16**B are side views illustrating an example embodiment of imaging catheter and stent frame components of an imaged-guided delivery system.

FIG. **17** is an enlarged perspective view of a stent frame component as previously illustrated.

FIGS. **18**A and **18**B are side views illustrating the stent frame embodiment of FIG. **17** associated with a delivery device, with the stent frame in a neutral and a laterally displaced position, respectively.

FIGS. **19**A and **19**B are photographs illustrating prototype hardware of the delivery system embodiment diagrammatically illustrated in FIGS. **18**A and **18**B.

FIG. **20** diagrammatically illustrates an alternative user interface for the FIGS. **18**A and **18**B delivery system.

DETAILED DESCRIPTION

Various example embodiments are described below. Reference is made to these examples in a non-limiting sense, as it should be noted that they are provided to illustrate more broadly applicable aspects of the devices, systems and methods. Various changes may be made to these embodiments and equivalents may be substituted without departing from the true spirit and scope of the various embodiments. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process act, or step to the objective(s), spirit, or scope of the present inventive subject matter. All such modifications are intended to be within the scope of the claims made herein.

FIGS. **1**A-**1**F illustrate an implant **2** and a suitable approach to valve **10** attachment and its manipulation for delivery in coordinated use with an expandable stent frame **20**. Further details as to valve construction and/or its manipulation for delivery may be appreciated in review of U.S. Pat. No. 8,133,270 to Kheradvar, et al., incorporated by reference herein in its entirety for all purposes. Features of the stent frame elaborated upon below in the various embodiments may be added to those shown in FIGS. **1**A-**1**F or used in connection with other suitable stent frame and/or other valve architectures.

In any case, implant **2** (e.g., valve **10** and stent frame **20**) is directly applicable for coordinated use with a delivery system as shown in FIGS. **2**A-**4**B. More specifically, a delivery system apparatus for controlled deployment of a stented heart valve system in increments is shown. The system provides for repositioning a stented heart valve system during and after deployment. As variously illustrated, device **100** includes a plurality of deployable arms **110**. These are adjustably deployable. The arms are first embedded inside the apparatus. FIG. **2**B illustrates the location of one of the embedded arms **110** within a delivery device sleeve **120**. For tracking to the target site, the arms are hidden. The arms exit the sleeve through ports or slots **122** in the wall of the sleeve. The arm lengths are adjustable and the arms are releasably attached to the stent of the stented valve. As shown in FIG. **2**B, each arm may be equipped with an in-line adjustable spring that is controllable by the operator remotely. As illustrated in FIG. **3**, such actuation allows for robust radial expansion or deployment of the collapsed stent frame in increments.

The arms remain attached to the stent until the stent is fully deployed. During tracking to a site for deployment, the stented valve may be covered by a sheath incorporated in the delivery system or pass within a delivery catheter (either

case illustrated by an optional sleeve **140**). If the stent is not properly deployed, the arms, which are still releasably attached to the stent, can be used for partial contraction of the stent for repositioning purposes. When the stented valve is properly positioned within the heart, the arms will be released from the stent, and return to their embedded positions within the apparatus. Then the apparatus will be retracted into the sheath or through the delivery catheter from the heart or vasculature.

As seen in FIG. **4**A in which the stent frame is detached, each arm may terminate in a releasable hook, jaw, clevis **112** or the like for such purpose(s). The connection and release may be provided by a simple snap fit. Otherwise it may be provided by a more active means for stent frame interface as illustrated in FIG. **4**B, that shows an arm comprising a hollow micro tube or sheath **114** with spring loaded strings or filaments **116** inside where a string or filament **118** inside the guide tube or sleeve **120** can be used to control the closing and opening of the hooks **112**.

FIGS. **5**A-**5**E illustrate progressive stages of implant deployment and recapture for a second embodiment. Here, in a system pictured for over-the-wire tracking to its deployment site, a delivery system **200** includes a sheath **210** (with distal radiopaque marker **212**) coaxial with a pusher sleeve **220**. A distal portion of sleeve **220** includes apertures **222** through which filaments **230** pass into and proximally within the length of the sleeve. The filaments loop from these apertures through proximal stent frame apertures **22** and more distal stent frame apertures **24** (or alternatively past strut junctions in a different stent configuration) and into a distal end **224** of the sleeve (or a second set of distal apertures (not shown) in the sleeve if so-desired). Such details of the sleeve are shown unobscured in FIGS. **6**A-**6**C, as is an optional shoulder **226** for abutting proximal end or crown sections **26** of the stent frame and guide sheath **210** of the proximal end or crowns of the stent frame.

Regarding interaction between the stent frame and delivery system **200**, FIGS. **7**A and **7**B provide side views of the stent frame associated with the delivery device sleeve in contracted and expanded states, respectively. Here, the manner of stent frame expansion and contraction as related to extended filament **230** length is clearly visible.

FIGS. **8**A and **8**B further illustrate such details as described above. When assembled in a delivery system **200**, stent frame **20** will be captured within loops **232**. The assembled relation of elements is shown in each of FIGS. **9**A-**9**C and FIGS. **10**A and **10**B. Comparing FIGS. **9**A-**9**C to FIGS. **10**A and **10**B, the state of the stent frame is changed from open or expanded in the former trio of figures, to compressed in the latter pair.

Such control is achievable by remote actuation of the loop filaments with a customized handle or other user interface means. Any handle may include means for group control of the filaments and independent control of sheath position. Such a handle **240** may include separate "grip" **242** and "plunger" or "slide" **244** interfaces as illustrated by example in FIG. **9**A for such purposes. Otherwise, mechanism internal to the handle can automate all of the various control procedure(s) by actuating a grip **242**, alone.

FIGS. **9**A and **9**B also offer good illustration of the manner in which filaments **230** pass through apertures **22**, **24** and run along interposed strut sections **28**. FIG. **9**C illustrates the radial relationship of the apertures and filament **230** portions. Here, a crossing segment **234** of the filament between the apertures **22** and **24** is positioned outside of and opposing strut section **28**. The crossing segments are angled with the struts when the stent frame is in an expanded state and more close to axially aligned when the stent is compressed as shown in FIGS. **10**A and **10**B.

As noted above, the transition between the open and compressed states (and states therebetween) is managed by letting-out or reeling-in the draw line filament determining the size of the control loop. Ultimately, one end of the line is pulled all of the way through the stent aperture to finally release the implant.

FIGS. **5**A-**5**E illustrate a range of activity that is possible in terms of device manipulation before such release. In succession, these views show progressive stent frame deployment and steps toward complete recapture. FIG. **5**A pictures (literally, given that the figures are based on photographs) the beginning of stent frame deployment as sheath **210** is withdrawn and a distal end **30** of the stent self-expands. FIG. **5**B shows the sheath fully withdrawn and full tension on the draw lines or filaments, maintaining a proximal side **32** of the stent **20** in a compressed state. As in FIG. **5**D illustrating the same (but in the case of FIG. **5**D re-compression after the relaxation of draw lines to allow expansion as in FIG. **5**C), the sheath can be advanced to fully recapture the stent frame. With the beginning of such action shown in FIG. **5**E, the stent frame can be fully recovered within sheath **210**—whether for the purpose of repositioning or bulk retrieval of the device.

A third delivery device embodiment is able to offer similar advantages in terms of delivery, repositioning, and/or percutaneous retrieval. Stent frame components of such a system are shown in FIGS. **11**A and **11**B. In each view, a proximal end **32** of a stent frame **20** includes clasp features **40**. Each clasp feature **40** may comprise a bridge section **42** and an overhang section **44**. Complementary clasp features **50** are provided at the end of resilient retainer "arms" or "fingers" **52** associated with a delivery system pusher. Arms **52** may comprise Nitinol or another elastic or superelastic material. Arms **52** are biased outward such that they spring out to a position as shown in FIG. **12** when released from restraint (e.g., upon exiting a delivery system sheath element or delivery/guide catheter body). Arms **52** are joined or meet at a hub **54**. These components may be cut from a single hypotube or polymer sleeve that extends to the proximal end of the delivery system (not shown) as one piece or be assembled using conventional techniques such as laser welding, etc. In any case, pairs of complementary clasp elements **40**/**50** are releasably engaged in sheaths **60**.

FIGS. **13**A and **13**B illustrate a construct in which multiple sheaths **60** extend to and join at a hub **62** optionally extending proximally as a single sleeve **64**. Such a structure can be produced by bundling and reconfiguring (e.g., by fusing) a plurality of thermoplastic sheaths, bundling and bonding a plurality of sheaths, and splitting an end of a multi-lumen extrusion into a plurality of separate sheaths. Other means of construction will be appreciated by those of skill in the art as well.

Regardless, FIG. **14**A provides a partial assembly drawing illustrating the axial alignment for a plurality of interfacing members. FIG. **14**B shows the same components of the third device embodiment brought together in a completed apparatus assembly **300**. As in the embodiments above, such a system may optionally include a cover sheath **210** and a handle **240**. In addition, system **300** may include an innermost elongate sleeve **220'** optionally providing a lubricious PTFE liner for a guidewire lumen and/or column or "push" strength to the system.

FIGS. **15**A-**15**F illustrate the operation of an intended interaction of the subcomponents of system **300**. In FIG. **15**A, the heart valve frame clasp or link **40** is interfaced with

clasp/line **50**. In FIG. **15**B, clasps features **40**/**50** are trapped within sheath **60**. At this point, further withdrawal of stent frame **20** into sheath element **60** or (stated otherwise) advancement of sheath **60** over adjacent proximal stent struts **34** results in a condition as shown in FIG. **15**C. Here, struts **34** are brought together collapsing the entirety of the proximal end **32** of stent frame **20** (given that the same condition is achieved around the entire periphery of the stent by paired device features). As shown in FIG. **15**D, sheath **60** can cover the entirety of struts **34** up to their junctions **36** with adjacent struts. The net effect is shown in FIG. **15**E where the entire proximal side of the stent frame **20** is compressed efficiently by the multiple sheath elements shown.

As summarized above, the zip tub part assembly (sheaths **60** and associated components) may be variably retracted to allow the proximal end **32** of the stent frame to partially expand or retracted sufficiently to allow the stent frame to fully expand. Alternatively, the zip part/assembly may be secured in position and the arm retainer **54** retracted to variably collapse the proximal end of the heart valve device (up to fully collapsed) or variably advanced to allow the self-expanding heart valve device to variably expand (up to fully expanded). Further action associated with collapse/compression and expansion of the stent frame is achieved by covering and uncovering the stent frame with optional sheath **210** or by a guide catheter.

In any case, upon achieving desired implant placement, clasp elements **40**/**50** can be freed from confinement within the sheath member(s) **60** thereby unlinking the elements allowing stent frame **20** release as shown in FIG. **15**F and allowing delivery system withdrawal from a patient in a successful percutaneous heart valve implantation procedure.

FIG. **16**A illustrates a suitable IVUS catheter **300** for use in an image-guided valve delivery system according to another embodiment. The figure shows an EAGLE-EYE IVUS imaging catheter (Volcano Corp). Imaging catheter **300** includes a distal transducer tip **302**, an intermediate catheter shaft or body **304**, handle/grip **306**, lead **308**, and a proximal connector **310**. Radiopaque shaft markers **312** are provided that may be relocated or additional markers added for coordination with a valve delivery catheter to (together) provide an overall valve delivery catheter system (e.g., by inserting catheter **300** within delivery system **100** or **200** as previously illustrated).

A distal portion of such a combined system **300'** in shown in FIG. **16**B. This photograph shows a distal end **30** of a TAVR stent **20** compressed to 4.3 mm diameter (13Fr). It is held in a sheath **210** that may form part of an overall delivery system **300'**. Otherwise, it may be regarded as a loading sheath or surrogate (or stand-in) for a delivery catheter through which the stent **20** will track in a medical procedure. As shown, an ATLANTIS SR PRO IVUS transducer (Boston Scientific Corp.) **302** is placed through the center of the valve stent frame **20** for sizing purposes.

The image does not show the valve leaflets (e.g., as in FIGS. **1**A-**1**F) for the overall implant that contribute to the inner diameter space constraints or the specific delivery system features that may be employed. Yet, the image illustrates the general hardware (stent frame, delivery system/sheath components and IVUS device) that may be employed in the subject systems and methods.

FIG. **17** is a perspective view of a stent frame **20** component that may be employed therein. Actually, this figure provides an enlarged view of the stent frame shown in FIGS. **7**A and **7**B. So-enlarged, features in addition to those of the stent in U.S. Pat. No. 8,133,270 upon which the overall architecture may be based are easily highlighted. Specifically, two sets of holes **22** and **24** (proximal and more distal) are provided at the proximal side **32** of the stent frame **20** (i.e., on the "top" of the stent that would be positioned in the aortic root). These holes allow for passage of a network of pull-strings or filaments used for step-wise deployment, repositioning of the stent, and retrievability back to the guide-wire catheter (as discussed above) and also lateral positioning (as discussed below). Further, T-shaped structures **4** at the proximal side **32** are added to proximal crown features **26** to accommodate repositioning and retrievability of the valve during implantation procedure by way of attachment to complimentary delivery system features **40** like the example shown in FIGS. **14**A and **14**B.

In addition, connector holes **6** in tabs **8** of material at the middle of a number of struts **28** are provided to accommodate locking with pin-shape structures that permanently affix/connect the valve **10** material to the stent frame structure as further described in U.S. patent application Ser. No. 13/773,389 filed Feb. 21, 2013, which application is incorporated by reference herein in its entirety. A set of distal holes **12** at distal end **30** or "bottom" ventricular side of the stent advantageously provide attachment points (e.g., by suturing) of the valve leaflets to the stent frame as illustrated in FIGS. **1**A-**1**F.

FIGS. **18**A and **18**B are side views of the same stent frame **20** associated with a delivery system **200'** related to that in FIGS. **5**A-**10**B, but including additional manipulation features. Specifically, delivery system **200'** is adapted for controlling the lateral position of a heart valve device, for positioning or repositioning during deployment. Draw lines (or filaments) **230** (configured as in the referenced embodiments) are further connected to a pivot fitment **250** and a joystick-type handle **252**.

As shown in FIGS. **19**A and **19**B loops or end ties **236** around spurs **256** may provide such a connection. As likewise shown, fitment **250** (alternatively, a boss, cap or housing) may ride upon or otherwise incorporate one or more spherical bearing surfaces **254**/**254'**.

However configured, operation of system **200'** is such that the angular ordering of the draw lines **230** in the overall heart valve (stent frame **20** shown) will correspond to the angular ordering of the draw lines on pivot fitment **250**. Such activity is assured by the corresponding relationship of draw lines (or filaments) as shown in cross-sections A-A and B-B in FIG. **18**A. The radial orientation of filaments **230** at the stent frame **20** and leading to the stent frame are matched with the radial orientation of the filaments at fitment **250** is indicated by the matching numeral position in the two cross-sectional views.

Therefore, as shown in FIG. **18**B, tilting the pivot fitment **250** (e.g., by leaver arm/joystick **252**) causes coordinated pull and release (or relaxation) of the draw lines proportional to the angular ordering and the direction of tilt to drive a corresponding change in the lateral position of the heart valve device (denoted by the directional arrows). Thus, the lateral position of the heart valve device can be controlled and manipulated by tilting the pivot fitment. While a joystick or similar interface can be incorporated into or connected to the pivot fitment to facilitate control of the tilt mechanism, other approaches including remote/robotic control are contemplated as well.

In any case, FIGS. **19**A and **19**B are photographs of a functional prototype **200"** of the delivery system embodiment diagrammatically shown in FIGS. **18**A and **18**B. Here, blocks **260**, **262** simulate the end constraint conditions of a catheter body. Between these, filaments **230** are visible

(whereas they would generally be housed within a catheter body/sleeve). A short sleeve **264** extends from block **262** to simulate the distal portion of the catheter body **220** shown in FIGS. **5**A-**10**B, **18**A and **18**B including its side apertures **222** and an end hole **224**.

In FIG. **19**A, stent frame **20** and pivot fitment **250** are shown in a neutral or "home" position. While being tilted/turned, as shown in FIG. **19**B, pivot fitment **250** reorients the filaments **230** to move stent **20** laterally in relation to sleeve **264**.

Finally, FIG. **20** diagrammatically illustrates an alternative user interface for the FIGS. **18**A and **18**B delivery system. Here, instead of using a handle, a model **260** of the implant **2** (or at least the stent frame **20**) to be delivered is employed. The model may be a scale replica of the stent frame **20** and/or the entire implant **2**. Generally, it will be configured in an expanded shape. However, it may be controlled so that its state of expansion matches that of implant **2**. Alternatively, manipulation of the model expansion may alter the expansion state of the implant. Given all of these options, however, the model will generally at least serve as an interface for lateral valve positioning.

In which case, the model may be connected to the filaments in the same manner/fashion as the stent frame **20** to be manipulated along a catheter centerline **270** by movement of the model in any combination of lateral directions indicated by the axis arrows shown. Alternatively, model **260** may overlay and be connected to fitment **252** to which the filaments are connected (e.g., at spurs **254**).

Use of the model **260** in manipulating the stent frame **20** and being able to visualize the direct correspondence of movement between the implant (via fluoroscopy or other medical imaging) to the sight of the model in hand may be particularly beneficial to a physician in attempting ideal implant positioning and placement. In a method of use, the method may comprise at least partially deploying stent frame **20** by withdrawing a sheath **210** covering the stent frame and relaxing the filaments **230** passing through a catheter sleeve **220** and attached to the stent frame to expand the stent frame (e.g., as in such activity shown in FIGS. **5**A-**5**C). Then, a proximal interface such as a joystick or model is manipulated to move the stent frame laterally relative to the catheter sleeve by selectively tightening and relaxing the filaments (e.g., as in such activity shown in FIG. **18**B relative to a zero or neutral position of fitment **252**). Naturally, the device can be returned to center and then recompressed and/or resheathed for repositioning as well.

In the various delivery system architectures, the catheter/pusher shaft or sleeve may comprise a simple extrusion (e.g., PTFE, FEP, PEEK, PI etc.) or may be constructed using conventional catheter construction techniques and include a liner, braid support and outer jacket (not shown). Likewise, the various tubular members may comprise extrusion (per above), metal hypotube, etc. Further, the stent frame may be constructed using conventional laser cutting and electropolishing techniques and/or be otherwise constructed. In embodiments intended for tracking through a guide/delivery catheter without an incorporated sheath, a loading sheath (optionally peel-away or splittable) may be provided over the implant. Other typical percutaneous access instruments (such as wires, etc.), valves, and other hardware may also be employed in connection with the subject matter described herein.

The subject methods may include each of the physician activities associated with implant positioning, re-positioning, retrieval and/or release. Regarding these methods, including methods of manufacture and use, these may be carried out in any order of events which is logically possible, as well as any recited order of events.

Furthermore, where a range of values is provided, it is understood that every intervening value, between the upper and lower limit of that range and any other stated or intervening value in the stated range is encompassed within the invention. Also, it is contemplated that any optional feature of the described variations may be set forth and claimed independently, or in combination with any one or more of the features described herein.

Reference to a singular item includes the possibility that there are a plurality of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "an," "said," and "the" include plural referents unless specifically stated otherwise. In other words, use of the singular forms allow for "at least one" of the subject item in the description above as well as the claims below. It is further noted that the claims may exclude any optional element and may explicitly limit each element to a "single" instance or "only one" such instance of that element. As such, this paragraph is intended to serve as antecedent basis for the use of such exclusive terminology as "solely," "only," "a single" and the like in connection with the recitation of claim elements, or the use of a negative limitation.

Without the use of such exclusive terminology, the terms "comprising," "including," and "having" in the claims shall allow for the inclusion of any additional element—irrespective of whether a given number of elements are enumerated in the claim, or the addition of a feature could be regarded as transforming the nature of an element set forth in the claims. Except as specifically defined herein, all technical and scientific terms used herein are to be given as broad a commonly understood meaning as possible while maintaining claim validity.

The breadth of the different embodiments or aspects described herein is not to be limited to the examples provided and/or the subject specification, but rather only by the scope of the issued claim language.

The invention claimed is:

1. A medical device comprising:

an elongate sleeve having a distal end and a proximal end;

a plurality of apertures in the sleeve adjacent the distal end;

an elastic stent frame comprising a plurality of struts, each strut including a proximal aperture,

wherein the proximal aperture in each strut together form a plurality of proximal apertures of the stent frame, wherein the stent frame further comprises a plurality of distal apertures, each distal aperture being in one of the plurality of struts of the stent frame; and

a plurality of filaments, each filament received within the sleeve from the proximal end, passing out of and looping over the sleeve, passing through one of the strut distal apertures, running directly along a length of one of the struts, passing through one of the strut proximal apertures, and passing through one of the sleeve apertures and into the sleeve.

2. The device of claim **1**, further comprising a valve connected to the stent frame.

3. The device of claim **1**, wherein the sleeve comprises a distal proximal shoulder for abutting the stent frame during advancement.

4. The device of claim **1**, further comprising a sheath to cover the stent frame.

5. The device of claim 4, where the sheath is connected to a handle adapted to advance the sheath to cover the stent frame or retract the sheath to uncover the stent frame.

6. The device of claim 5, wherein the handle is adapted to select and actuate the sheath to intermediate states between full advancement and full retraction.

7. The device of claim 6, wherein retraction of the sheath allows a distal end of the stent frame to expand, and advancement of the sheath compresses the distal portion of the stent frame.

8. The device of claim 1, wherein two ends of each filament pass through the proximal end of the sleeve.

9. The device of claim 8, wherein the two ends of each filament are connected to a handle adapted to actuate the filaments.

10. The device of claim 9, wherein the handle is adapted to select and actuate a proximal portion of the stent frame between states of full expansion for deployment and full compression for retrieval.

11. The device of claim 10, wherein the handle is adapted to select and actuate the proximal end of the stent frame to intermediate states between full compression and full expansion.

12. The delivery system of claim 1, further comprising a handle at the proximal end, the handle including a pivot fitment, the filaments connected to the pivot fitment spaced in a radial orientation matching a radial orientation of the filaments at the stent frame.

13. The delivery system of claim 12, wherein the pivot fitment rides on a spherical bearing surface.

14. The delivery system of claim 12, further comprising a joystick to actuate the fitment.

15. The delivery system of claim 12, further comprising an implant model to actuate the fitment, the model at least substantially resembling the stent frame in appearance.

16. The delivery system of claim 15, wherein the model is a scale replica of the stent frame in an expanded state.

17. A medical device delivery system comprising:

an elongate sleeve having a distal end and a proximal end, a plurality of apertures in the sleeve adjacent the distal end;

an elastic stent frame comprising a plurality of struts, each strut including an aperture, wherein the aperture in each strut together form a plurality of proximal apertures of the stent frame, wherein the stent frame further comprises a plurality of distal apertures, each distal aperture being in one of the plurality of struts of the stent frame;

a plurality of filaments, each filament received within the sleeve from the proximal end, passing out and looping over the sleeve, passing through one of the proximal strut apertures, directly running along the length of one of the struts to, and passing through one of the distal apertures, and passing through one of the sleeve apertures and into the sleeve; and

a handle at the proximal end, the handle including a pivot fitment, the filaments connected to the pivot fitment spaced in a radial orientation matching a radial orientation of the filaments at the stent frame.

18. The delivery system of claim 17, wherein the filaments pass out of the distal end of the sleeve.

19. The delivery system of claim 17, wherein the pivot fitment rides on a spherical bearing surface.

20. The delivery system of claim 17, further comprising a joystick to actuate the fitment.

21. The delivery system of claim 17, further comprising an implant model to actuate the fitment, the model at least substantially resembling the stent frame in appearance.

22. The delivery system of claim 21, wherein the model is a scale replica of the stent frame in an expanded state.

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