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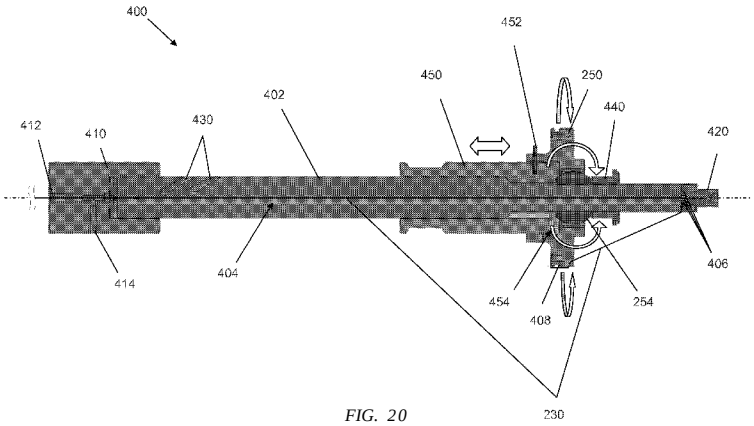


FIG. 20

(57) Abstract: Improved catheter devices for delivery, repositioning and/or percutaneous retrieval of percutaneously implanted heart valves are described, including a medical device handle that provides an array of features helpful in conducting a percutaneous heart valve implantation procedure while variously enabling radial expansion or contraction and/or lateral positioning control over the heart valve during the medical procedure.

WO 2014/144247 A1

HANDLE MECHANISM AND FUNCTIONALITY FOR REPOSITIONING AND RETRIEVAL OF TRANSCATHETER HEART VALVES

FIELD

[0001] The embodiments described herein relate to delivery systems for percutaneously delivered heart valves.

BACKGROUND

[0002] 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.

[0003] 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 a 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.

[0004] Further technical developments with a focus on a positionable, repositionable, and/or percutaneously retrievable valve design would allow optimal placement and may thereby significantly reduce the risk of paravalvular aortic regurgitation, myocardial infarction, **or** ischemia related to improper positioning.

SUMMARY

[0005] Embodiments described herein address the need for improved catheter devices for delivery, repositioning and/or percutaneous retrieval of percutaneously implanted heart valves. Features of a medical device handle are described that provide an array of features helpful in conducting a percutaneous heart valve implantation procedure while variously enabling radial expansion or contraction and/or lateral positioning control over the heart valve during the medical procedure.

[0006] 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.

[0007] 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

[0008] 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.

[0009] Figs. 1A-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.

[0010] Fig. 2A 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. 2B is a detail view illustrating the arm at the location in Fig. 2A connected to a spring system for controlling stent frame deployment.

[001 1] Fig. 3 is a system overview illustrating the arms releasably attached to a stent frame.

[0012] Fig. 4A is a detail view illustrating the arms fully extended from the delivery apparatus and Fig. 4B is a detail view illustrating a hollow deployment arm with strings inside and a pull/push mechanism inside the guide tube or sleeve.

[0013] Figs. 5A-5E illustrate progressive stages of stent frame deployment and recapture for a second embodiment.

[0014] Figs. 6A-6C illustrate side, end, and perspective views, respectively, of the delivery device sleeve of the second embodiment.

[0015] Figs. 7A and 7B are side views illustrating the sent frame associated with the delivery device sleeve in contracted and expanded states, respectively.

[0016] Fig. 8A illustrates a variation of the subject stent frame and Fig. 8B illustrates a variation of the subject delivery sleeve with associated draw line filaments.

[0017] Figs. 9A-9C are side, perspective, and end views, respectively, illustrating the components in Figs. 8A and 8B assembled together.

[0018] Figs. 10A and 10B are side and end views, respectively, illustrating the same assembled components shown in a compressed state.

[0019] Figs. 11A and 11B are partial perspective and detail side views, respectively, illustrating a stent frame for a third embodiment.

[0020] Fig. 12 is a perspective view illustrating a frame retainer with retainer fingers.

[0021] Figs 13A and 13B are perspective and end views, respectively, illustrating a zip tube part or assembly and zip tube fingers.

[0022] Fig. 14A illustrates segments of an expanded heart valve frame, retainer fingers, and zip tube fingers as associated in the subject embodiment and Fig. 14B illustrates a complete assembly of the embodiment including these subcomponents.

[0023] Figs. 15A-15F are detail side views illustrating operation of elements within the Fig. 14A and 14B embodiment.

[0024] Fig. 16 is an enlarged perspective view of a stent frame component as previously illustrated.

[0025] Figs. 17B and 17B are side views illustrating the stent frame embodiment of Fig. 16 associated with a delivery device, with the stent frame in a neutral and a laterally displaced position, respectively.

[0026] Figs. 18A and 18B are photographs illustrating prototype hardware of the delivery system embodiment diagrammatically illustrated in Figs. 17A and 17B.

[0027] Fig. 19 diagrammatically illustrates an alternative user interface for the Fig. 17A and 17B delivery system.

[0028] Fig. 20 is a cross-section view of a full medical device handle incorporating features related to those in Figs. 17A-18B.

DETAILED DESCRIPTION

[0029] 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.

[0030] Figs. 1A-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 USPN 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. 1A-1 F or used in connection with other suitable stent frame and/or other valve architectures.

[0031] 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. 2A-4B. 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. 2B 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. 2B, 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.

[0032] 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.

[0033] As seen in Fig. 4A 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. 4B, 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.

[0034] Figs. 5A-5E 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 6A-6C, 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.

[0035] Regarding interaction between the stent frame and delivery system 200, Figs. 7A and 7B 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.

[0036] Figs. 8A and 8B 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. 9A-9C and Figs. 10A and 10B. Comparing Figs. 9A-9C to Figs. 10A and 10B, the state of the stent frame is changed from open or expanded in the former trio of figures, to compressed in the latter pair.

[0037] Such control is achievable by remote actuation of the loop filaments with a customized handle (e.g., as further described below) 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. 9A for such purposes. Otherwise, mechanism internal to the handle can automate all of the various control procedure(s) by actuating a grip 242, alone.

[0038] Figs. 9A and 9B also offer good illustration of the manner in which filaments 230 pass through apertures 22, 24 and run along interposed strut sections 28. Fig. 9C 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. 10A and 10B.

[0039] As noted above, the transition between the open and compressed states (and states there between) 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.

[0040] Figs. 5A-5E 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. 5A 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. 5B 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. 5D illustrating the same (but in the case of Fig. 5D re-compression after the relaxation of draw lines to allow expansion as in Fig. 5C), the sheath can be advanced to fully recapture the stent frame. With the beginning of such action shown in Fig. 5E, the stent frame can be fully recovered within sheath 210 —whether for the purpose of repositioning or bulk retrieval of the device.

[0041] 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. 11A and 11B. 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.

[0042] Figs. 13A and 13B 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.

[0043] Regardless, Fig. 14A provides a partial assembly drawing illustrating the axial alignment for a plurality of interfacing members. Fig. 14B 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.

[0044] Figs. 15A-15F illustrate the operation of an intended interaction of the subcomponents of system 300. In Fig. 15A, the heart valve frame clasp or link 40 is interfaced with clasp/line 50. In Fig. 15B, 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. 15C. 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. 15D, sheath 60 can cover the entirety of struts 34 up to their junctions 36 with adjacent struts. The net effect is shown in Fig. 15E where the entire proximal side of the stent frame 20 is compressed efficiently by the multiple sheath elements shown.

[0045] As summarized above, the zip tube 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. 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. 15F and allowing delivery system withdrawal from a patient in a successful percutaneous heart valve implantation procedure.

[0046] Fig. 16 is a perspective view of a stent frame 20 component that may be employed herein. Actually, this figure provides an enlarged view of the stent frame shown in Figs. 7A and 7B. So-enlarged, features in addition to those of the stent in USPN 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. 14A and 14B.

[0047] 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 US Patent Application Serial 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. 1A-1F.

[0048] Figs. 17A and 17B are side views of the same stent frame 20 associated with a delivery system 200' related to that in Figs. 5A-10B, 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.

[0049] As shown in Figs. 18A and 18B, loops or end ties 236 around spurs 256 may provide such a connection. As likewise shown, fitment 250 (altertatinvely, a boss, cap or housing) may ride upon or otherwise incorporate one or more spherical bearing surfaces 254/254'.

[0050] However configured, operation of sysem 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. 17A. 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.

[0051] Therefore, as shown in Fig. 17B, tilting the pivot fitment 250 (e.g., by lever 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 and may be integreated into or with with the handle system or its features as further described below.

[0052] Regarding intended system operation, Figs. 18A and 18B are photographs of a functional prototype 200" of the delivery system embodiment diagrammatically shown in Figs. 17A and 17B. Here, blocks 260, 262 simulate the end contraint conditions of a catheter body. Between these, filaments 230 are visable (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. 5A-1 0B, 17A and 17B including its side apertures 222 and an end hole 224.

[0053] In Fig. 18A, stent frame 20 and pivot fitment 250 are shown in a neutral or "home" position. While being tilted/turned, as shown in Fig. 18B, pivot fitment 250 reorents the filaments 230 to move stent 20 laterally in relation to sleeve 264.

[0054] Fig. 19 diagrammatically illustrates an alternative user interface for the Fig. 17A and 17B 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.

[0055] Given all of these options, however, the model will generally at least serve as an interface for lateral valve positionoing. 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 250 to which the filaments are connected (e.g., at spurs 254).

[0056] 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 floroscopy or other medical imaging) to the sight of the model in hand may be particularly benefical to a physican 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. 5A-5C). 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.

17B relative to a zero or neutral position of fitment 252). Naturally, the device can be returned to center and then recompressed and/or re-sheathed for repositioning as well.

[0057] Fig. 20 illustrates another interface option. The figure provides a cross-sectional view of a full medical device handle 400 incorporating features related to those discussed above in connection with Figs. 17A-18B. Notably, handle 400 or features therein may be adapted or otherwise employed in connection with previously-described embodiments or interface features as well.

[0058] In any case, handle 400 is shown with an elongage body 402 for structrual support of handle components and passage of stent lines 230 (variously pictured above, with one line shown in Fig. 20) optionally defining twelve loops 232 capturing a stent frame (again, as pictured above) through a central lumen 404 of the device. Slots 406 through which the lines are passed guide or fix their rotational orientation. The handle may include a catheter hub 410 with a catheter attachment interface 412 and a flushing port 414. A proximal wire port 420 may provide for flushing and/or guidewire access. Additional features include V-ports 430, a stripper ring 440, a side lock 450, and a pivot ring fitment 250 riding on a section of a spherical bearing 254.

[0059] In use, stent lines 230 (and the loops 232 that they define) are positioned through a valve and catheter as previously described, passed through handle body 402 and out of slots 406, where stent lines 230 and are attached to pivot ring 250 (per above, one representiative line 230 is shown in Fig. 20). One end of each loop 232 may pass over a groove 408 in the pivoit ring fitment body or a spur 256, also as described herein.

[0060] Manipulation of an attached stent frame is controlled by pivot ring 250 in two ways as indicated by the action arrows. Rotation of pivot ring 250 along an axis (see centerline indicated in Fig. 20) of the handle body 402 evenly controls the tension in the stent lines, giving control over radial expansion/contraction of the stent frame. Tilting the pivot ring relative to the handle body axis when the valve is in a deployed state shifts the lateral position of the stent relative to its delivery catheter by tensioning some lines and slackening (or letting out) others.

[0061] Slide lock 450 is adapted to releasably engage pivot ring 250 to allow or prevent its rotation (prevented with lock 450 in the proximal position and allowed with lock 450 in the central position) and to allow or prevent tilt of pivot ring 250 (allowed with lock 450 in a distal position). Slide lock 450 may be spring loaded toward the proximal position and/or manual detent features may be provided to assist in position control or inadvertent state change.

[0062] Using handle 400 in an prosthetic valve implantation procedure, various maneuvers may be desired. In one example, the valve stent frame is in a deployed state and the intent is to compress it. To do so, slide lock 450 is moved distally (to the left in the drawing to its central position) to disengage a slot (not shown) interfacing with a locking pin 452 (or splines or another anti-rotation feature). Pivot ring 250 is rotated until the stent is compressed by (in effect) winding-up the lines, and slide lock 450 is then returned to its proximal position to maintain stent compression.

[0063] In another example, the stent is in a compressed state and the intent is to release it. Here, slide lock 450 is, again, moved distally to its central position out of rotationally-locked engagement with pivot ring 250. Ring 250 is then rotated until the stent is released and slide lock 450 is moved back into pivot ring engagement to maintain the released state.

[0064] In yet another example, the stent is in a deployed state and the intent is to shift the lateral position of the stent relative to its catheter. To do so, slide lock 450 is moved to its distal-most position out of lateral engagment with socket 454 and pivot ring 250 is tilted in the desired direction to shift the stent laterally in the desired direction.

[0065] V-Ports 430 provide access for valve inversion and locking loops (i.e., with lines - not shown —defining three or more loops that may be connected to valve membrane leaflets for their inversion from a delivery configuration and then locking them in place, e.g., as with locking-pin type hardware described in US Patent Application Serial No. 13/773,389 (incorporated by reference above). After such valve manipulation, the locking loops are cut and pulled through the port(s) out from one end.

[0066] To facilitate external access of the lines through ports and to lower the frictional interaction between the lines and the handle body, the ports may be angled by between about 30 and about 60 degrees with respect to an axis of body 402. While pivot ring 250 provides rotational control for the state of deployment and tilt control for the lateral position (relative to catheter) of stent, it may also include a groove 408 therein providing clearance for cutting stent lines 230 to release a deployed valve. Last, stripper ring 440 provides a means to simultaneously pull all the stent lines 230 out of the stent, and catheter/handle combination after they have been cut for release.

[0067] VARIATIONS

[0068] 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.

[0069] 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.

[0070] 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.

[0071] 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.

[0072] 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.

[0073] 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.

CLAIMS

1. A medical device handle, the handle comprising:

an elongate body, the body adapted to receive a plurality of filaments for connection to a stent frame in a radial orientation;

a slide lock adapted to slide along the body;

a pivot fitment, the fitment adapted for connection of the filaments spaced in a radial orientation matching the radial orientation of the filaments at the stent frame; and

a spherical bearing surface,

wherein the pivot fitment rides on the spherical bearing surface,

wherein in a first axial position the slide lock permits no rotation of the fitment around and no tilting of the fitment relative to an axis of the body,

wherein in a second axial position the slide lock permits rotation of the fitment around but no tilting relative to the body axis, and

wherein in a third axial position the slide lock permits tilting of the fitment relative to the axis of the body.

2. The handle of claim 1, wherein in the third axial position the slide lock permits no rotation of the fitment around the axis of the body.

3. The handle of claim 1, wherein the body includes a lumen for receiving the filaments.

4. The handle of claim 1, further comprising a catheter hub including a flushing port.

5. The handle of claim 1, wherein the body includes at least one side port.

6. The handle of claim 5, wherein a plurality of side ports are provided.

7. The handle of claim 1, further comprising a plurality of slots for the filaments.

8. The handle of claim 1, further comprising a ring proximal to the fitment for simultaneously removing the filaments upon being cut.

9. The handle of claim 9, further comprising a guidewire axis port.

10. The handle of claim 1, wherein the fitment includes a socket receiving the slide lock in the first and second axial positions.

11. A method of valve stent frame control in an prosthetic valve implantation procedure, wherein the stent frame is connected to a handle body at a pivot fitment by a plurality of filaments loops received through the handle body and also through a catheter body connected to the handle body, where a slide lock is movable on the body, the method comprising:

moving the slide lock to a position that rotationally releases the pivot fitment; and

rotating the pivot fitment.

12. The method of claim 11, wherein the rotation expands the stent frame.

13. The method of claim 12, wherein the rotation contracts the stent frame.

14. The method of claim 11, further comprising moving the slide lock on the handle body to a position that locks the pivot fitment from rotating relative to an axis of the handle body.

15. The method of claim 14, wherein the locked position also locks the pivot fitment from tilting relative to the body axis.

16. The method of claim 11, further comprising moving the slide lock on the handle body to a position that releases the pivot fitment for tilting relative to an axis of the handle body.

17. The method of claim 16, further comprising tilting the pivot fitment to move the stent frame laterally with respect to the catheter body.

18. The method of claim 17, further comprising moving the slide lock on the handle body to a position that locks the pivot fitment from tilting relative to an axis of the handle body.

19. The method of claim 17, wherein the locked position also locks the pivot fitment from rotating relative to the body axis.

20. The method of claim 11 further comprising:

cutting the filaments loops; and

simultaneously pulling the filaments through the handle with a stripper ring at least initially positioned around the handle body.

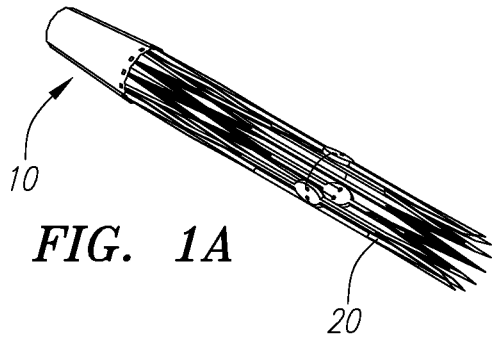


FIG. 1A

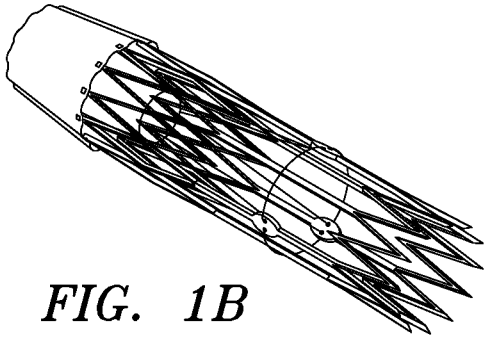


FIG. 1B

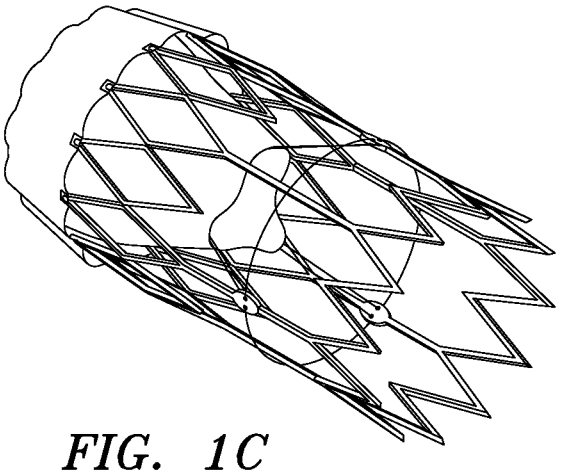


FIG. 1C

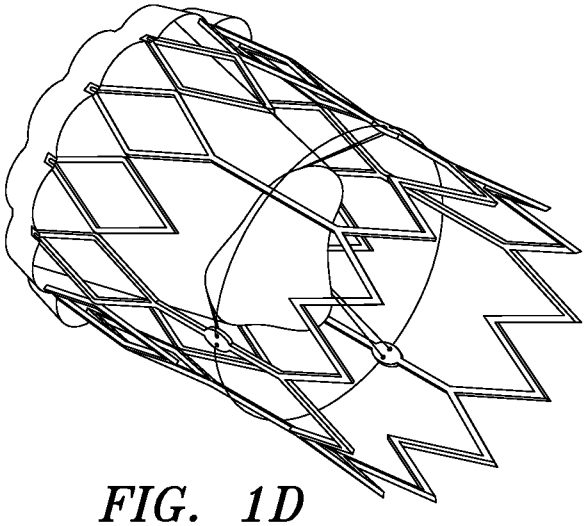


FIG. 1D

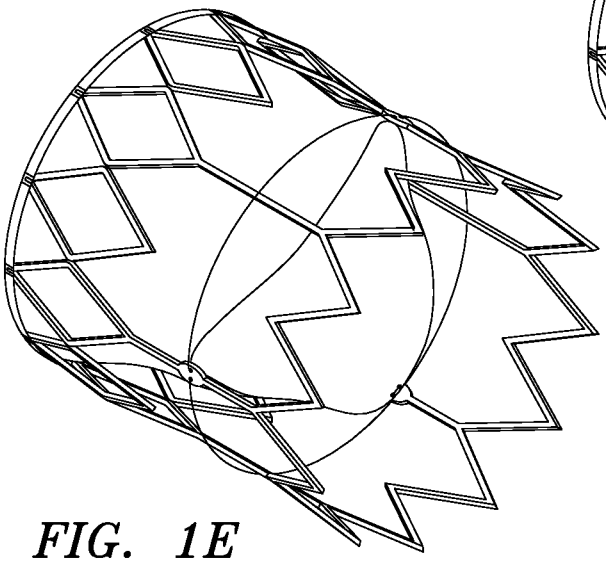


FIG. 1E

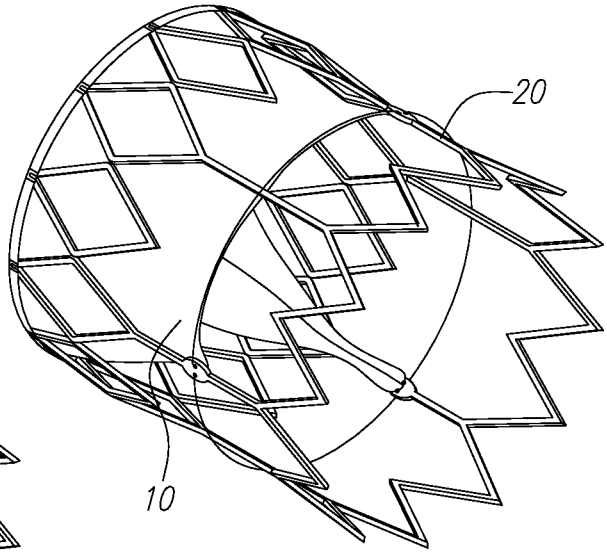


FIG. 1F

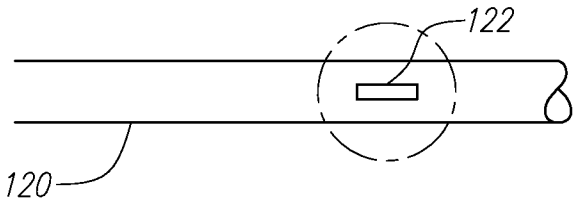


FIG. 2A

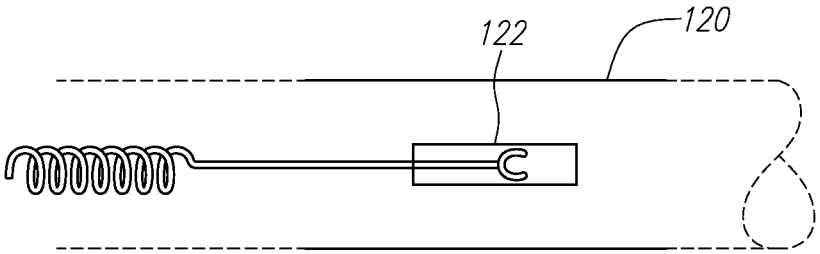


FIG. 2B

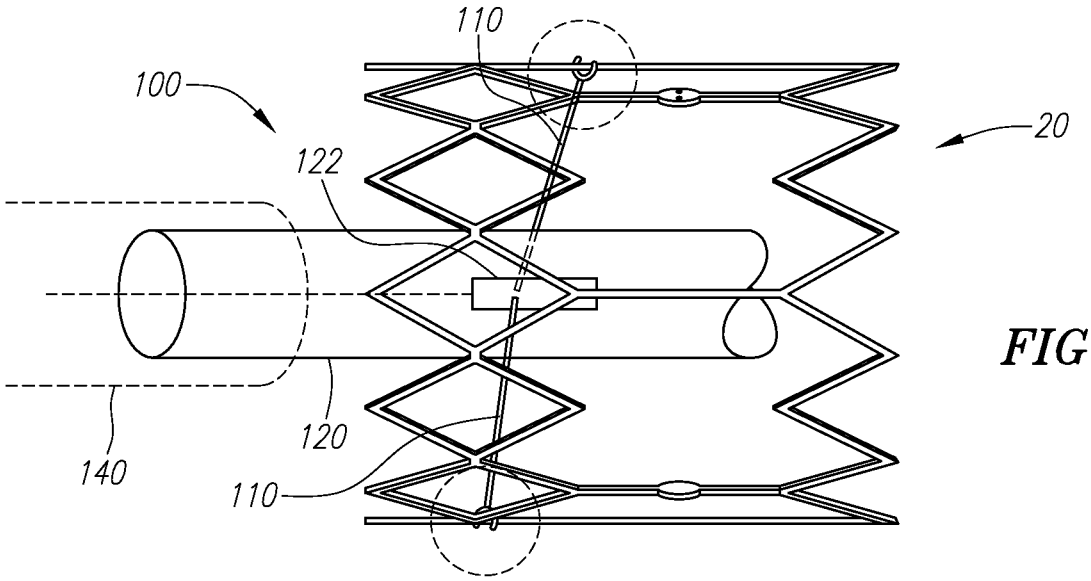


FIG. 3

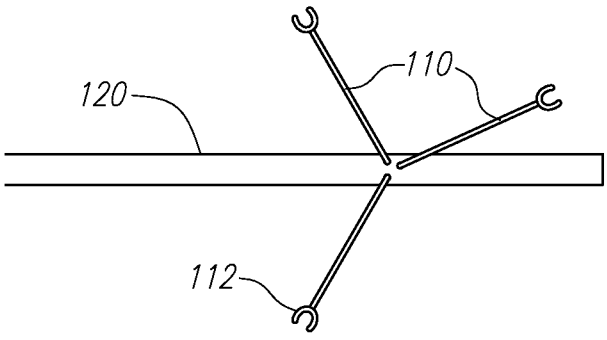


FIG. 4A

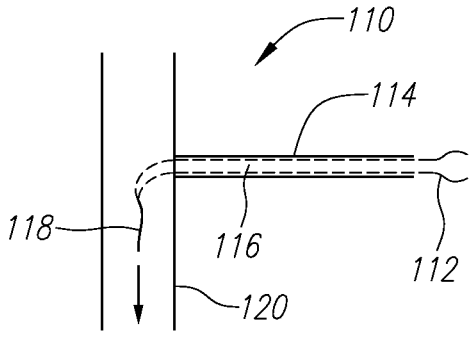


FIG. 4B

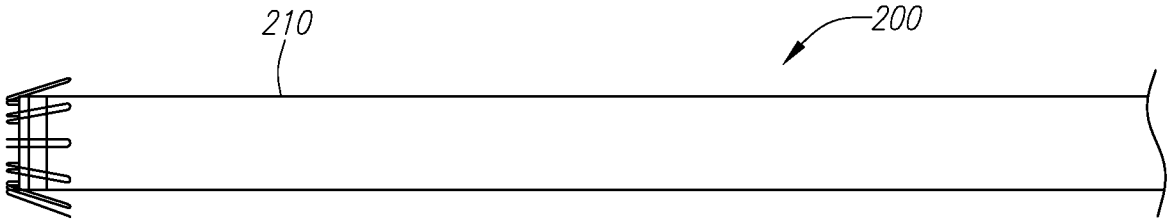


FIG. 5A

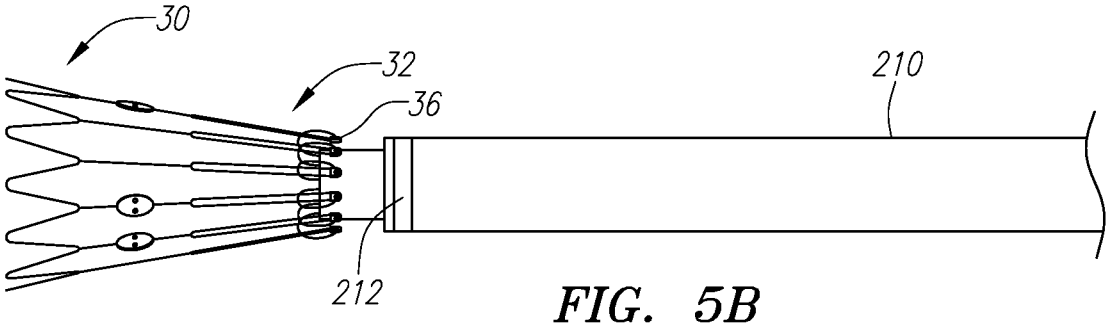


FIG. 5B

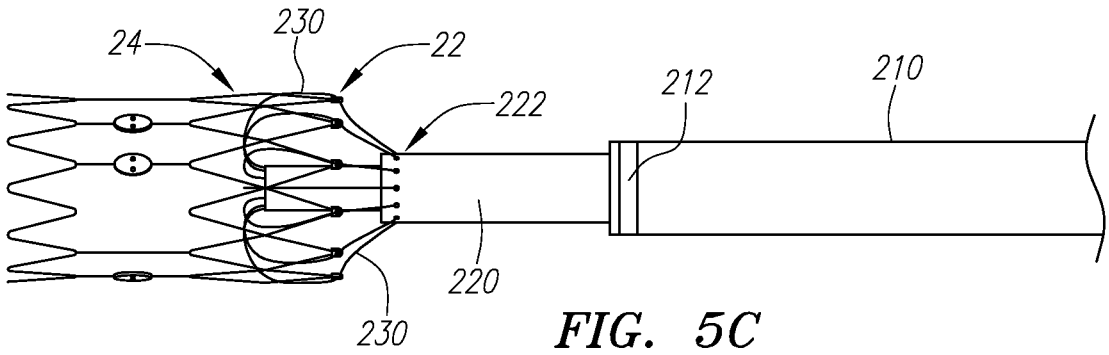


FIG. 5C

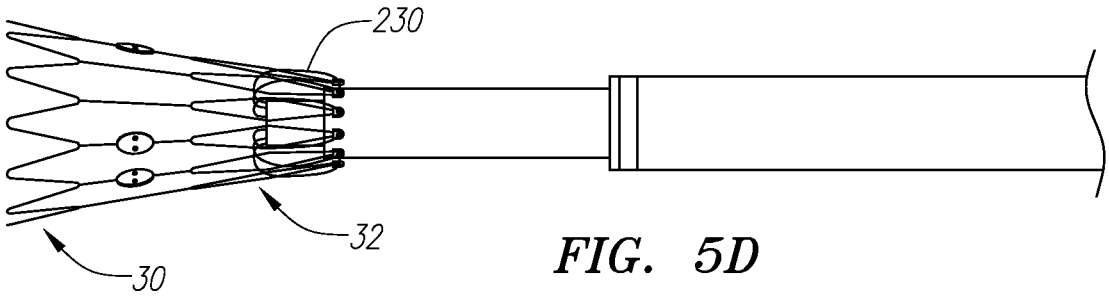


FIG. 5D

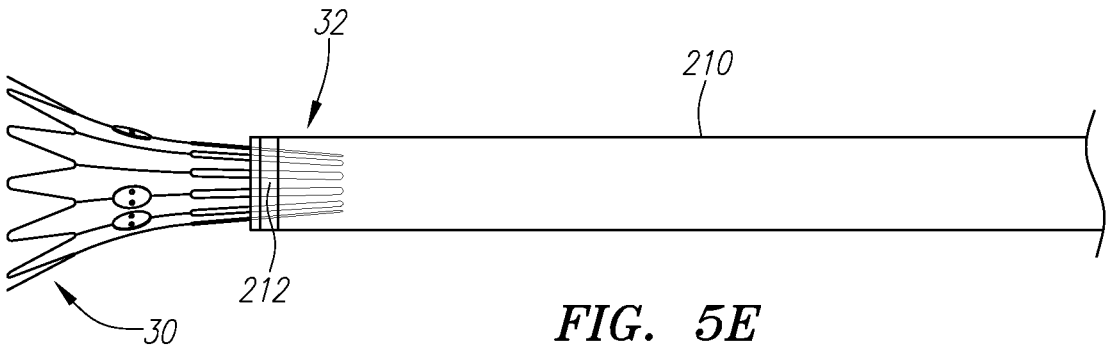


FIG. 5E

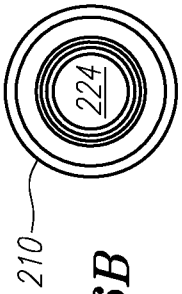


FIG. 6B

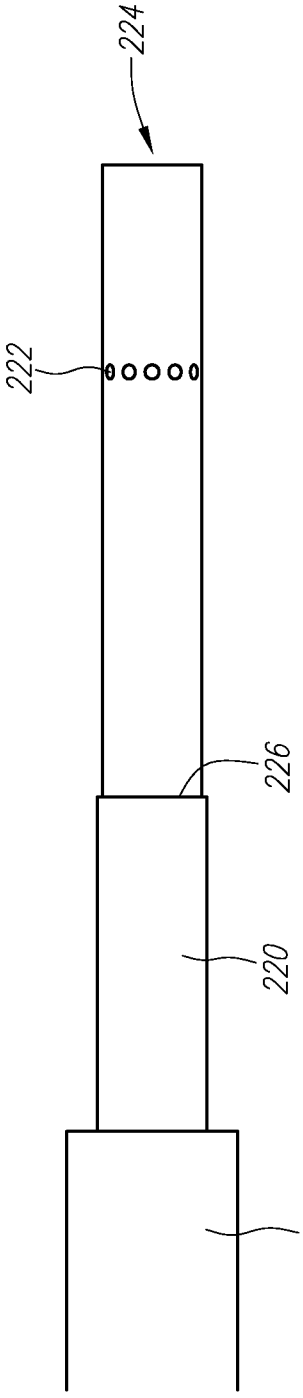


FIG. 6A

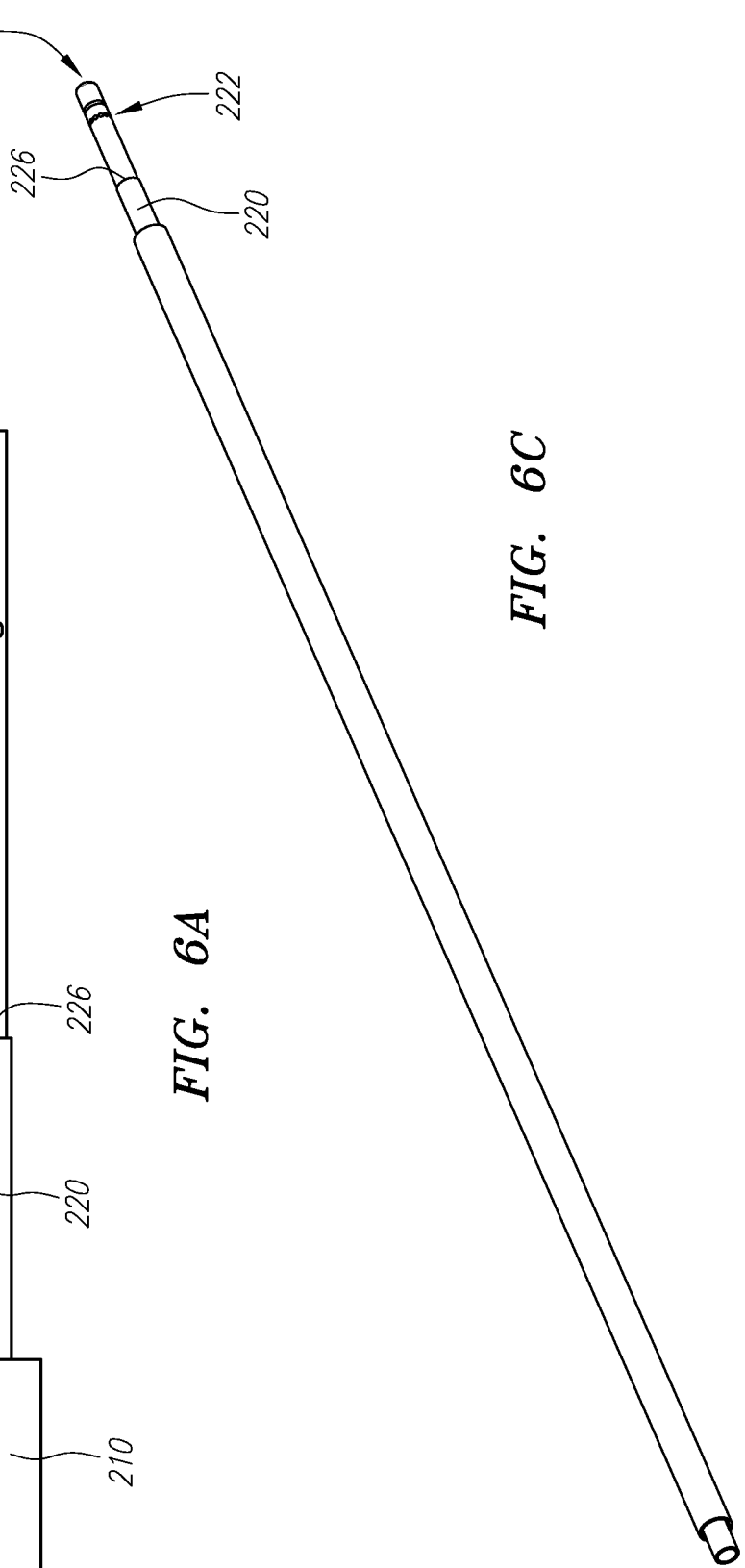
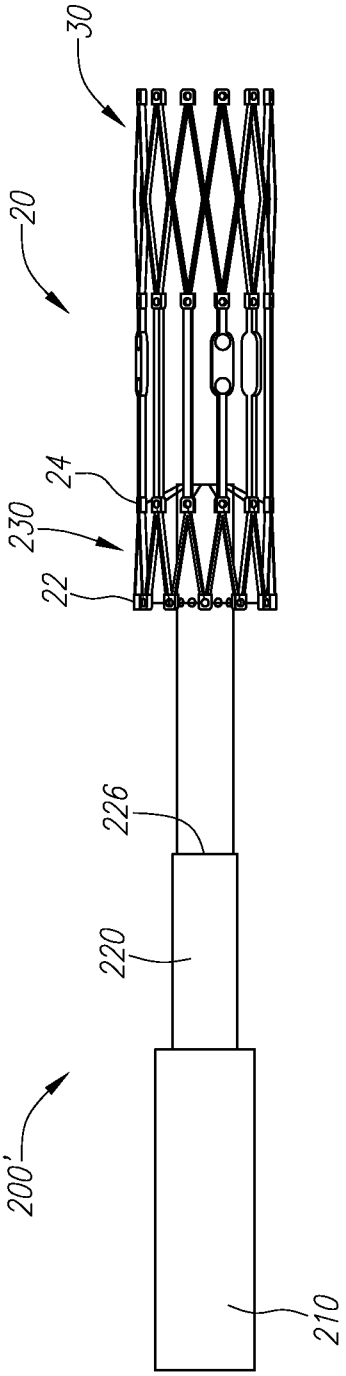


FIG. 6C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226
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210

FIG. 7A

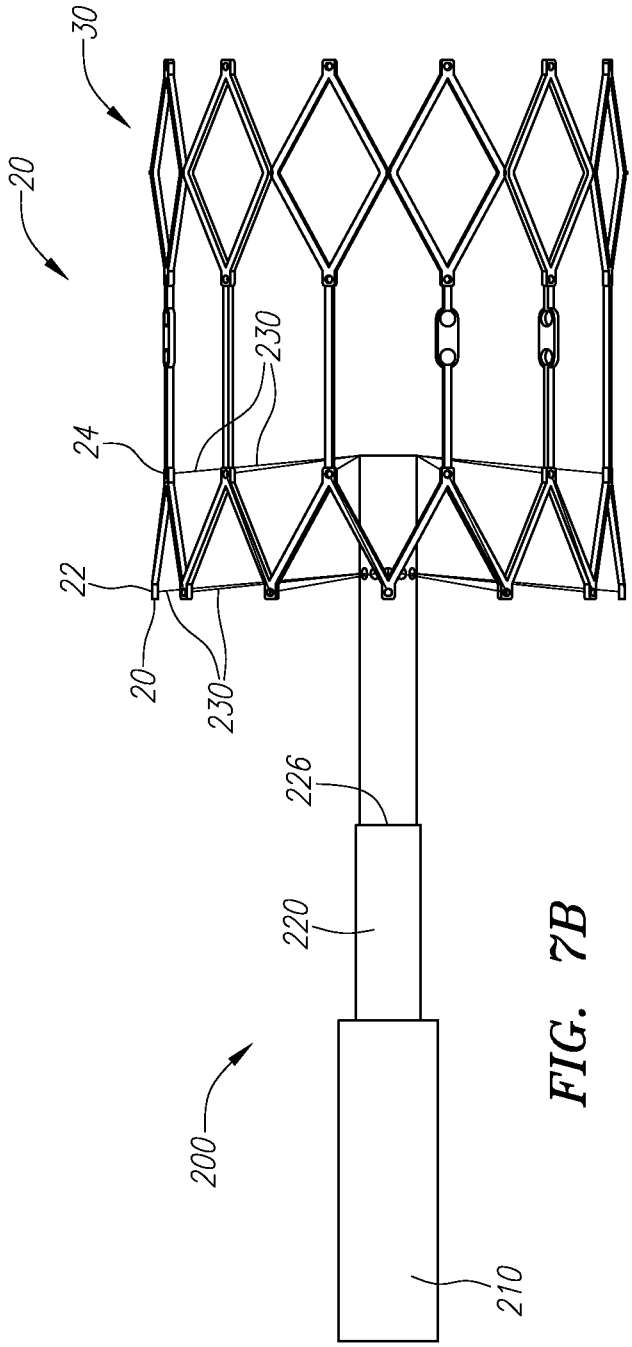
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FIG. 7B

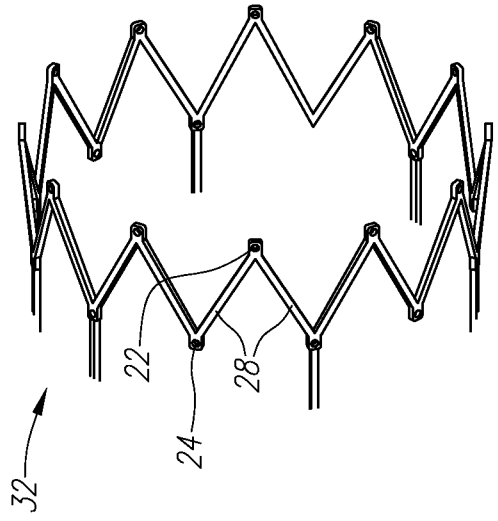


FIG. 8A

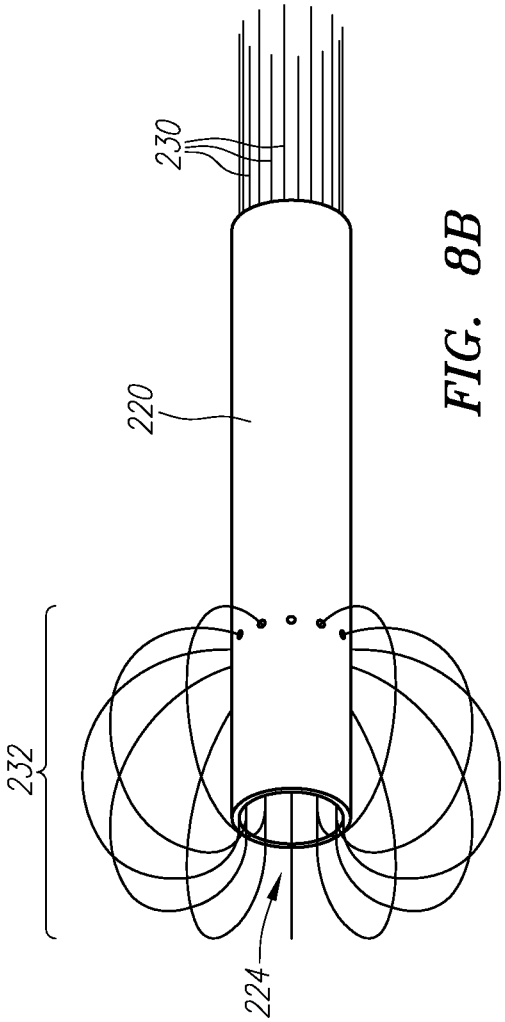
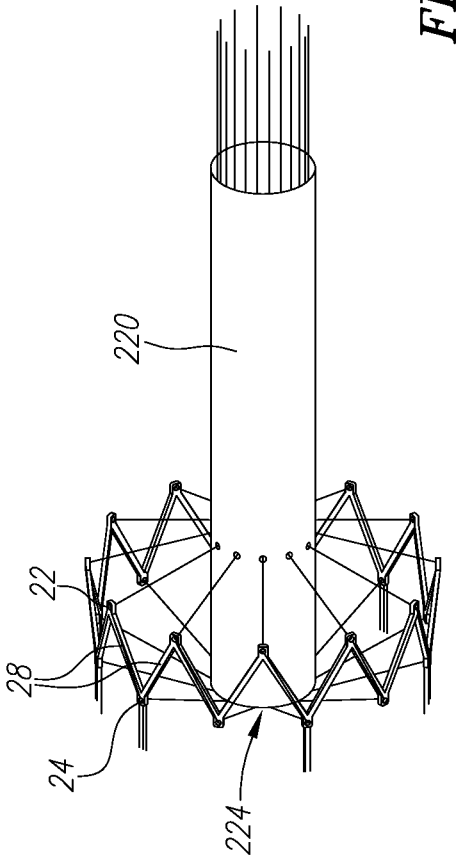


FIG. 8B



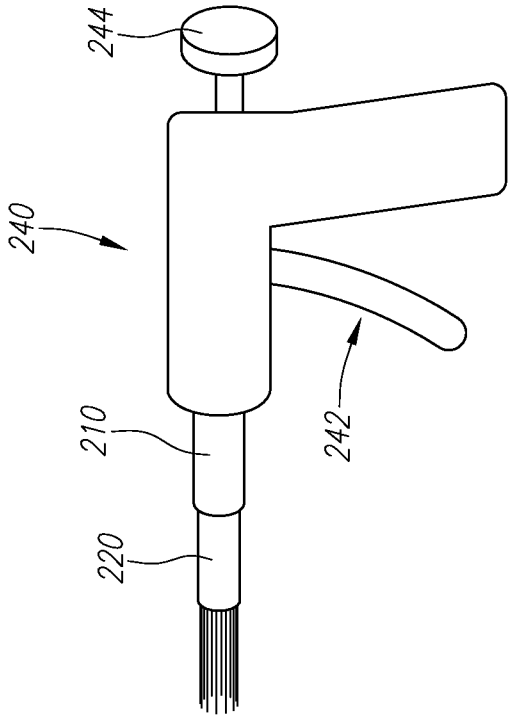
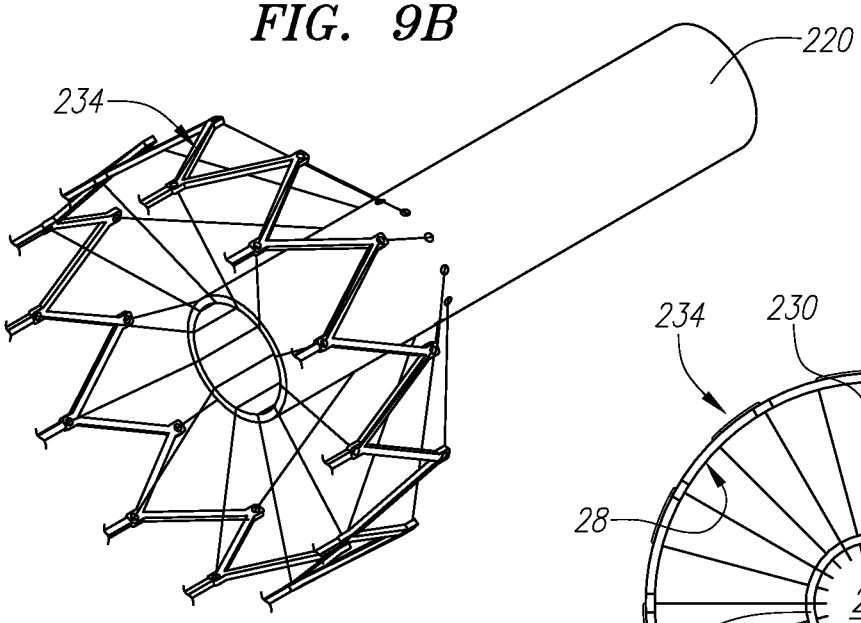


FIG. 9A

FIG. 9B



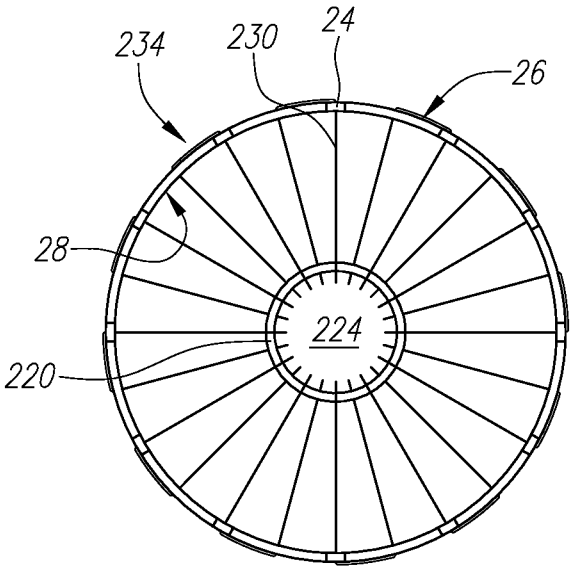


FIG. 9C

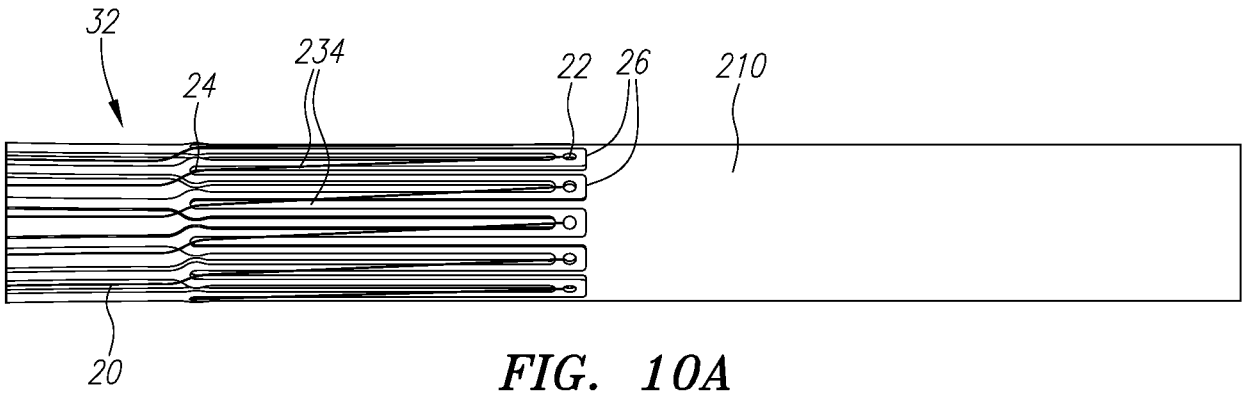


FIG. 10A

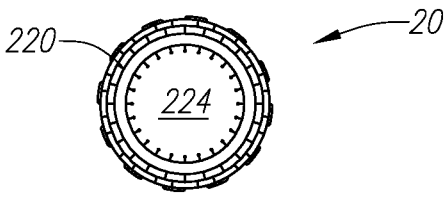


FIG. 10B

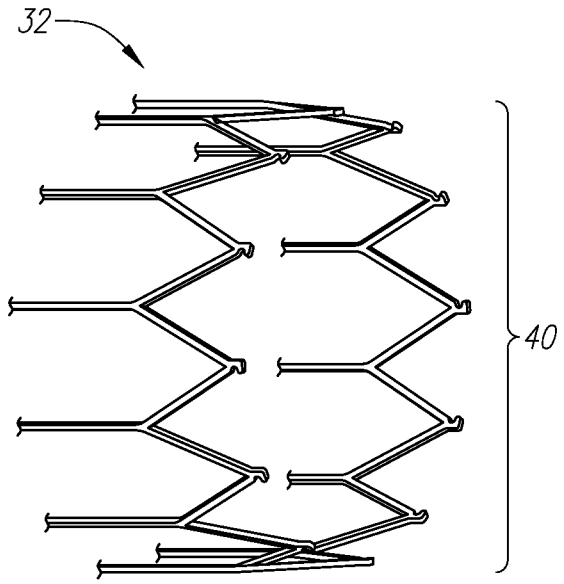


FIG. 11A

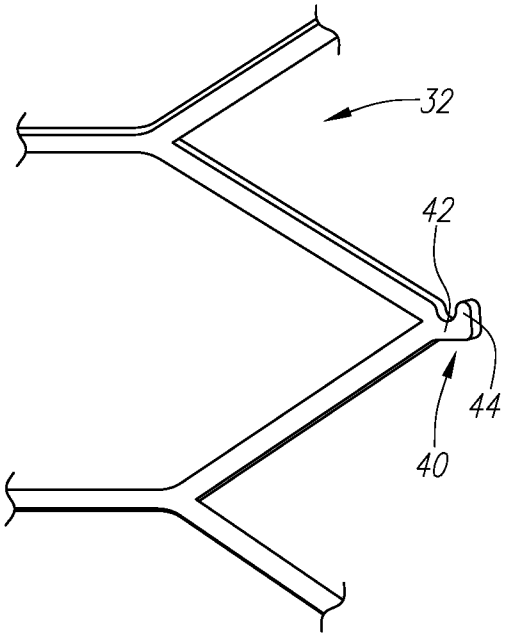


FIG. 11B

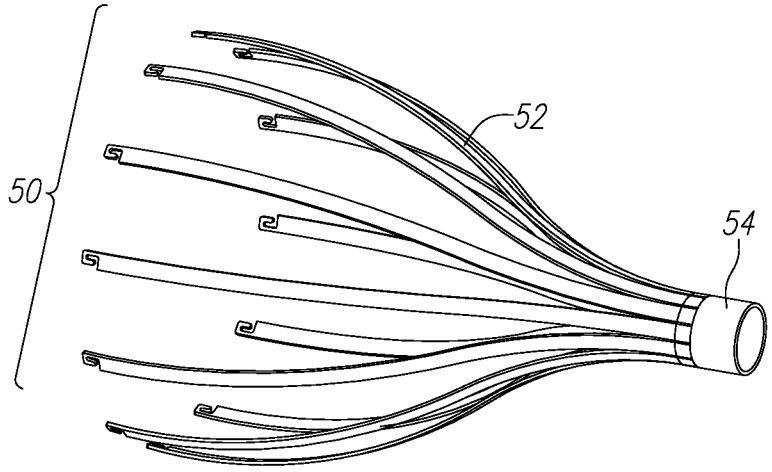
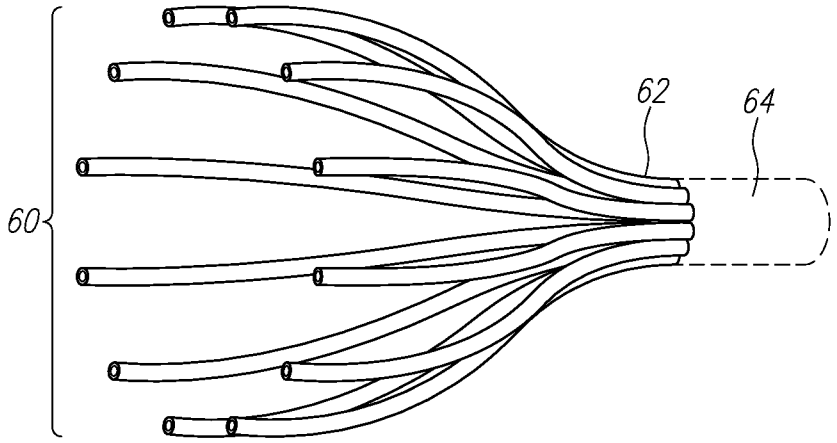


FIG. 12



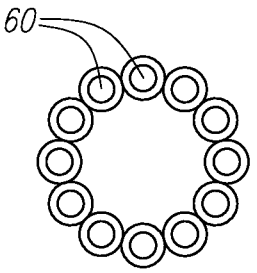


FIG. 13B

FIG. 13A

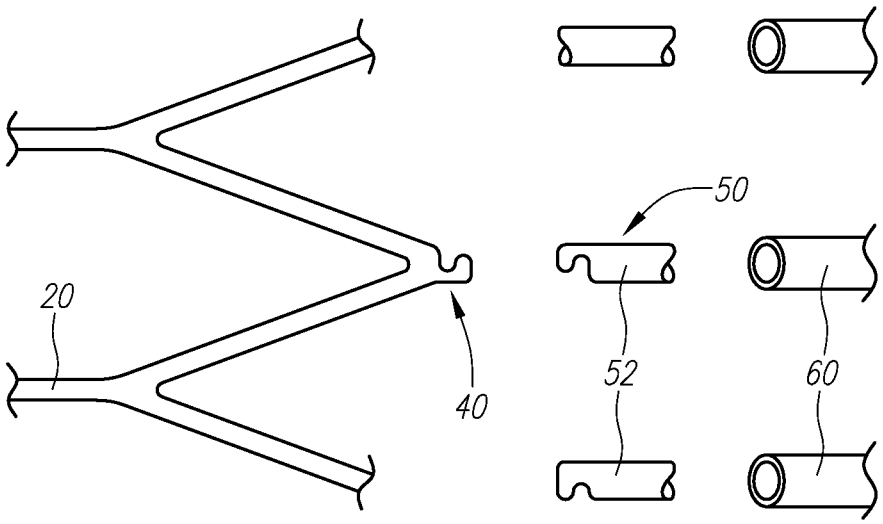


FIG. 14A

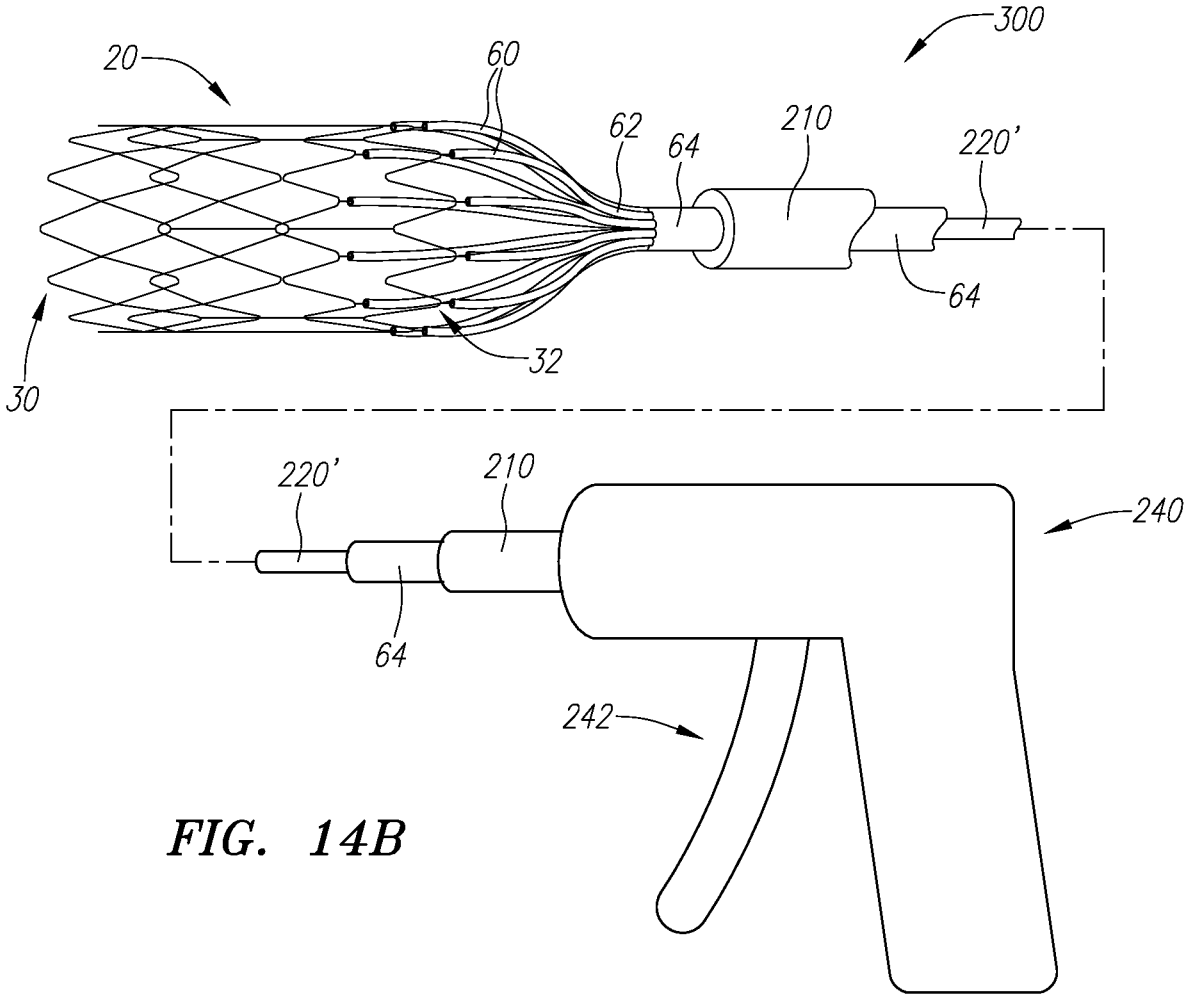


FIG. 14B

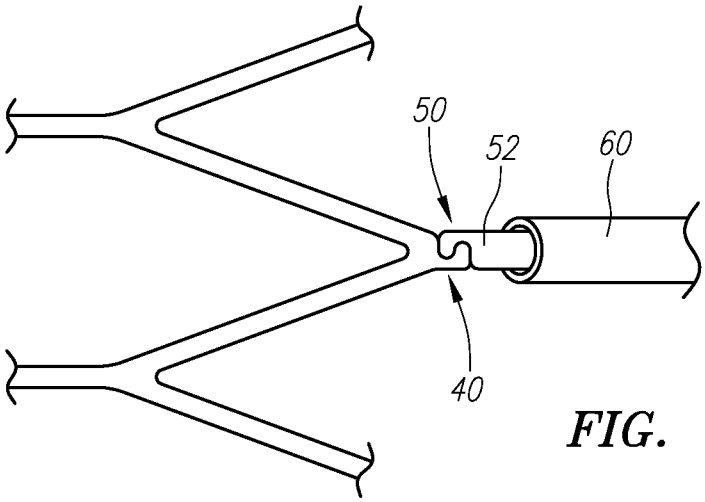


FIG. 15A

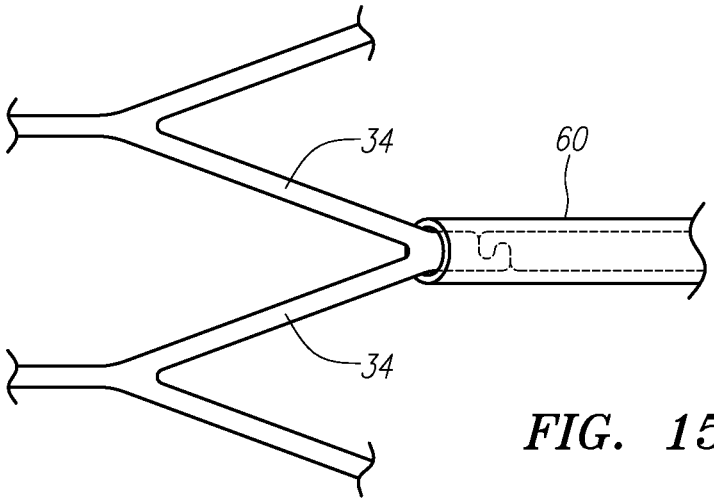


FIG. 15B

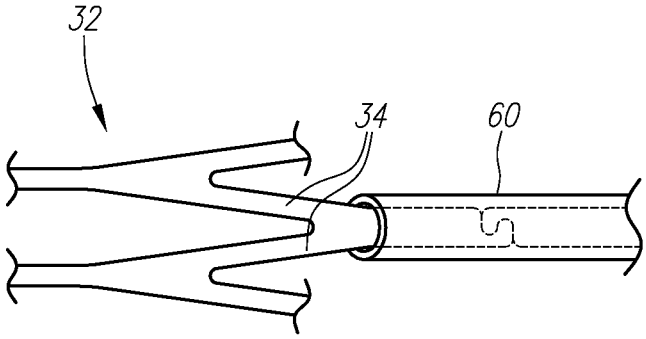


FIG. 15C

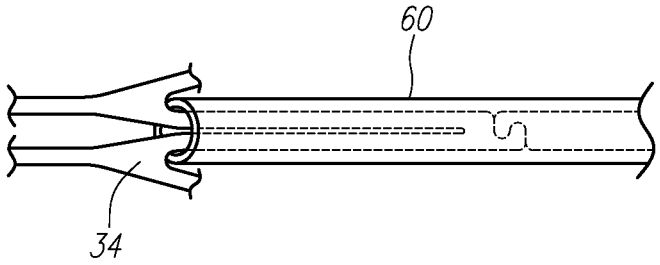


FIG. 15D

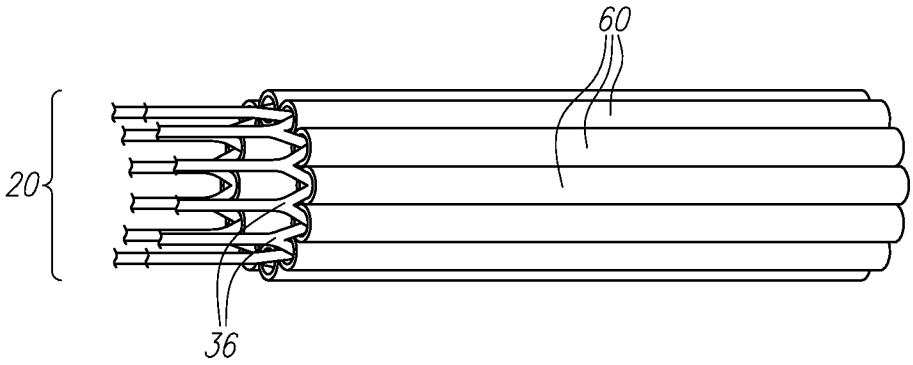


FIG. 15E

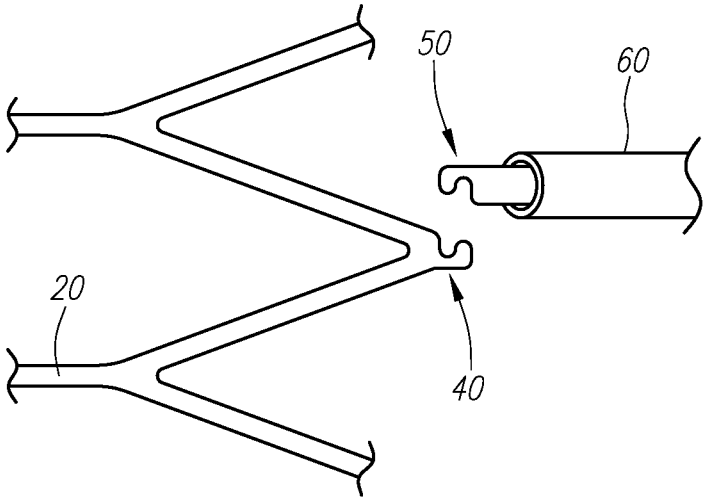


FIG. 15F

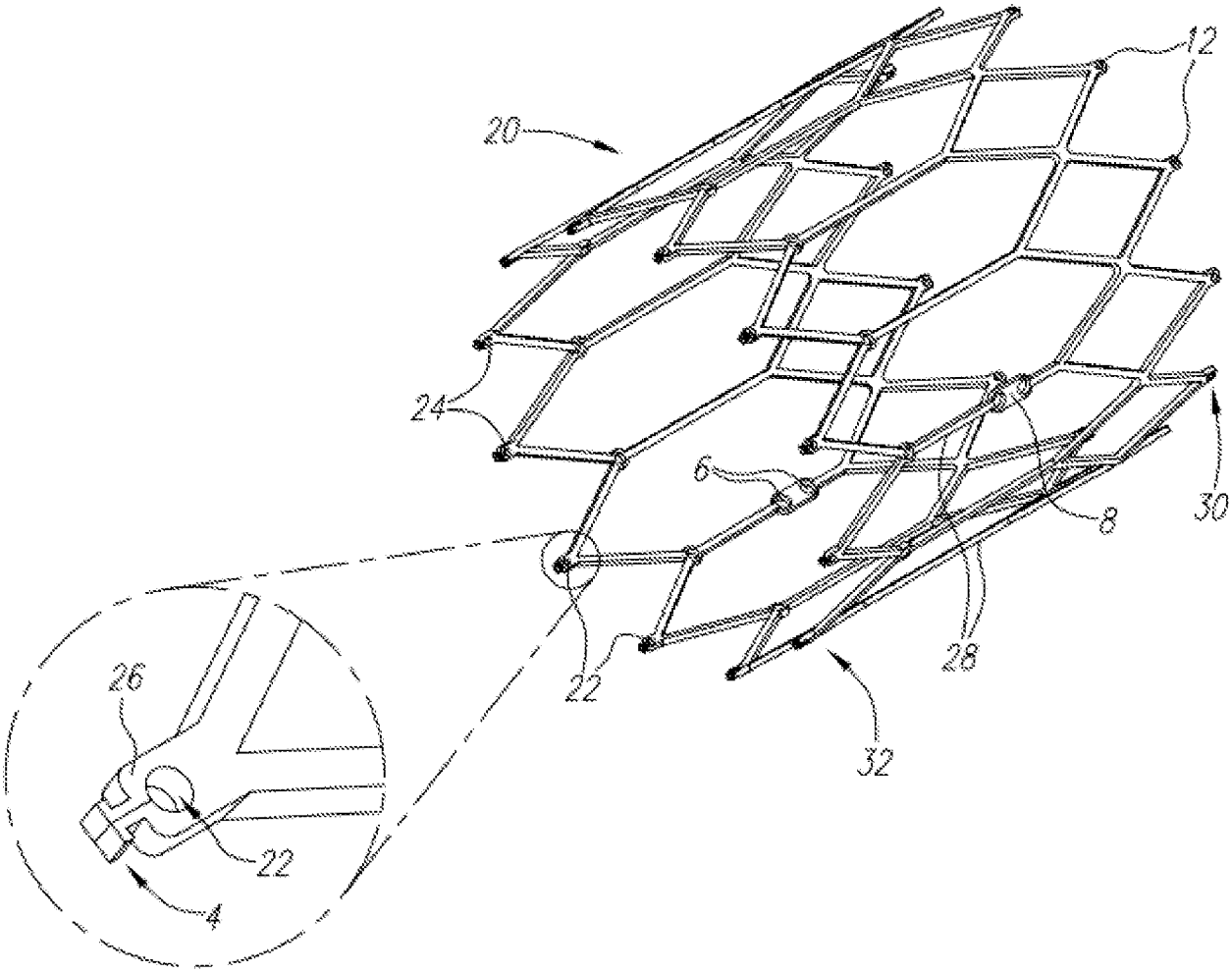


FIG. 16

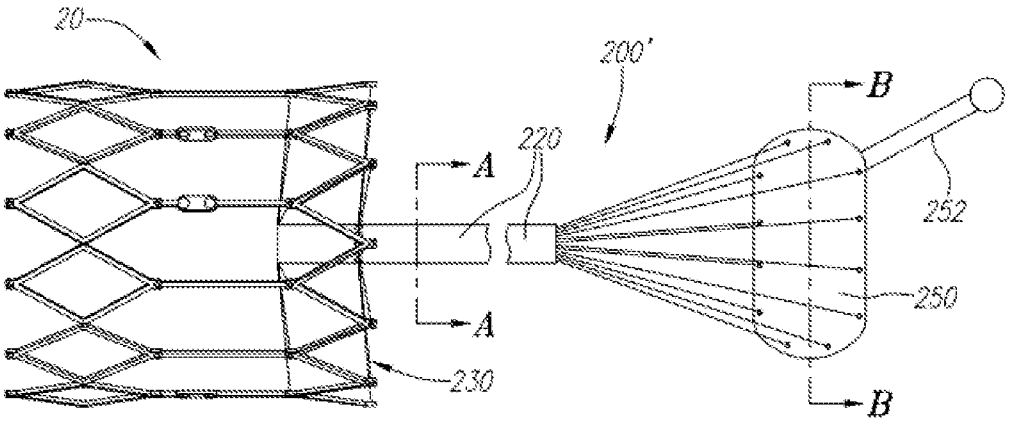
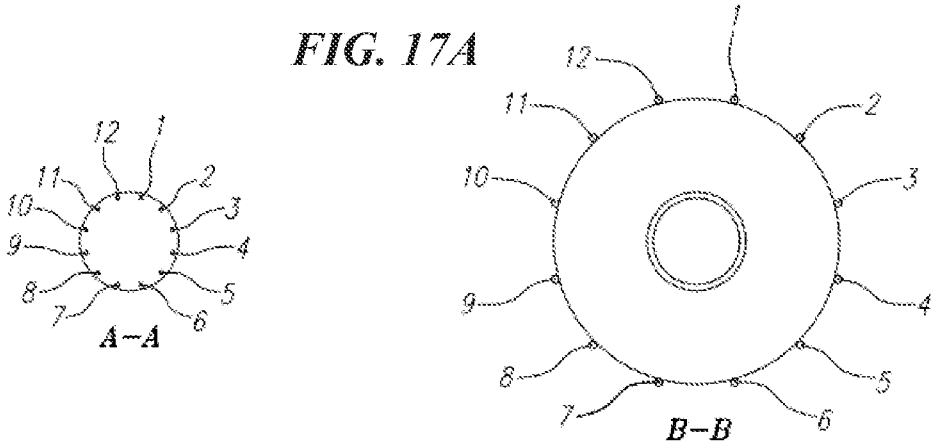


FIG. 17A



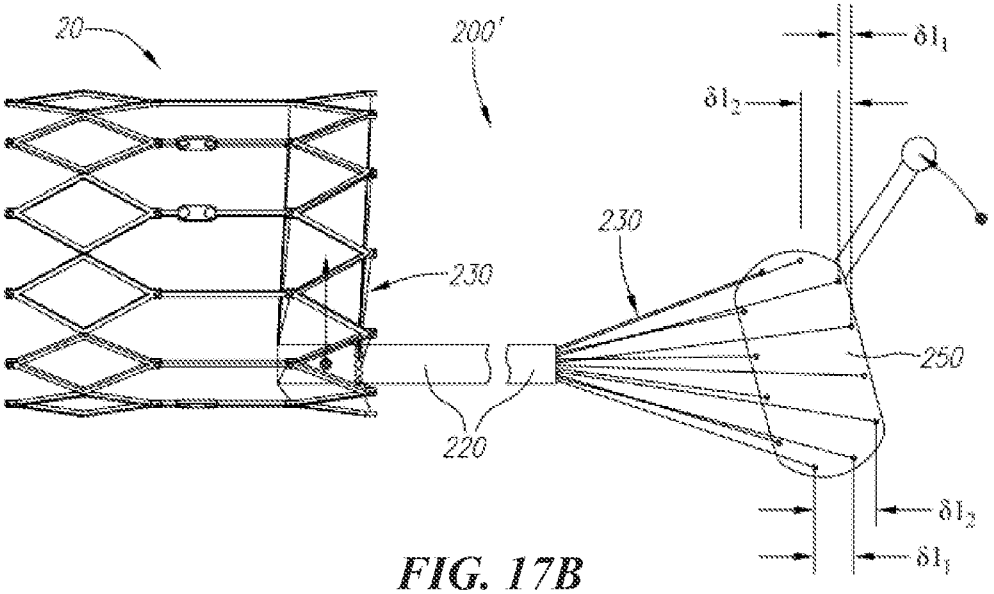


FIG. 17B

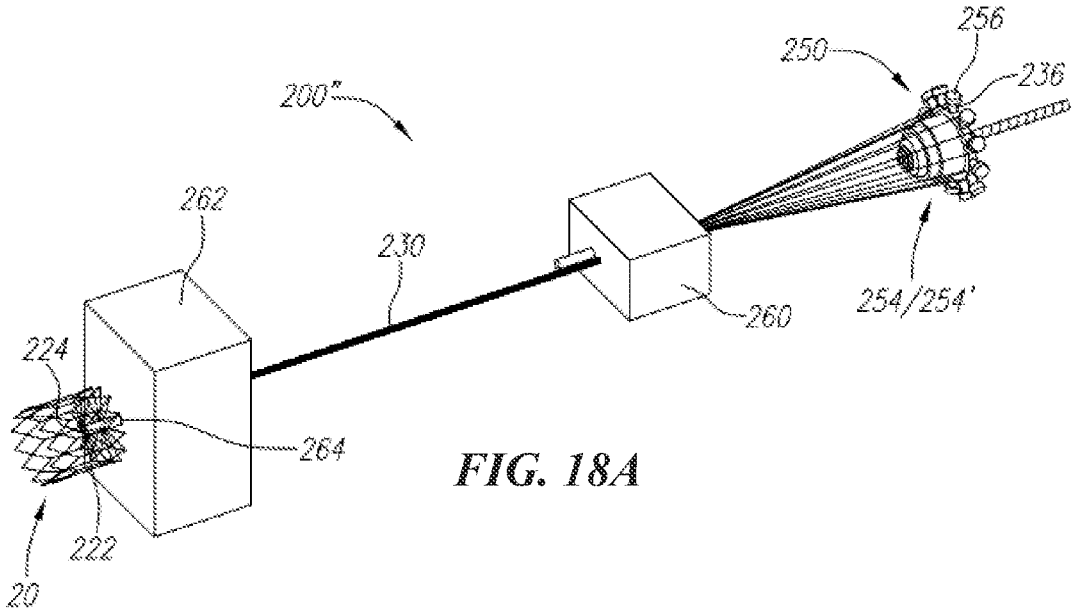


FIG. 18A

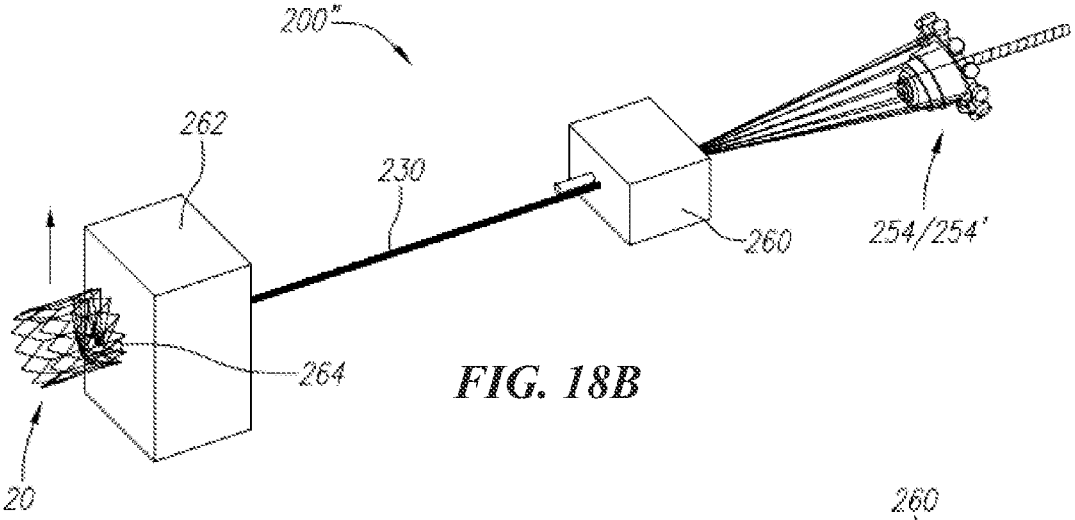


FIG. 18B

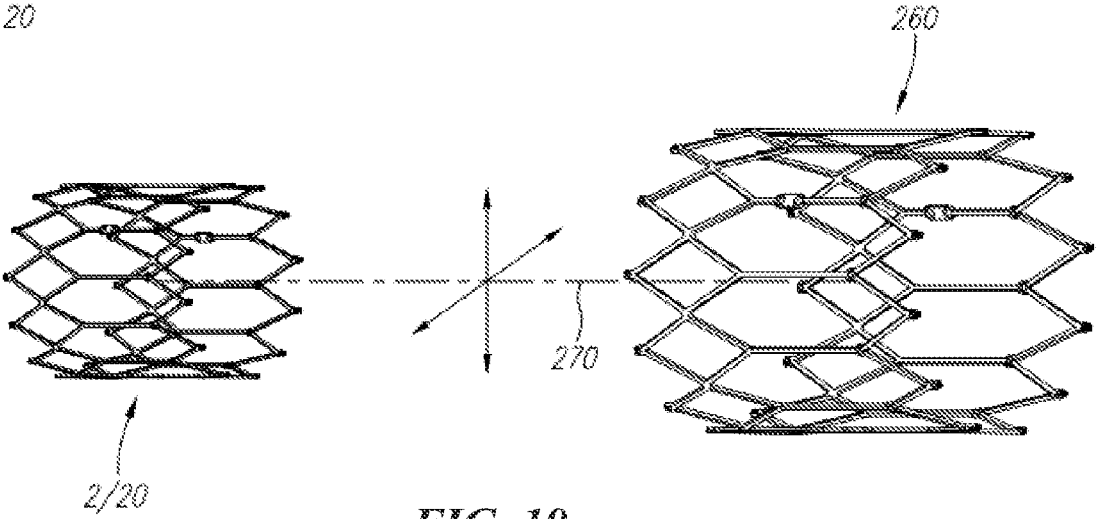


FIG. 19

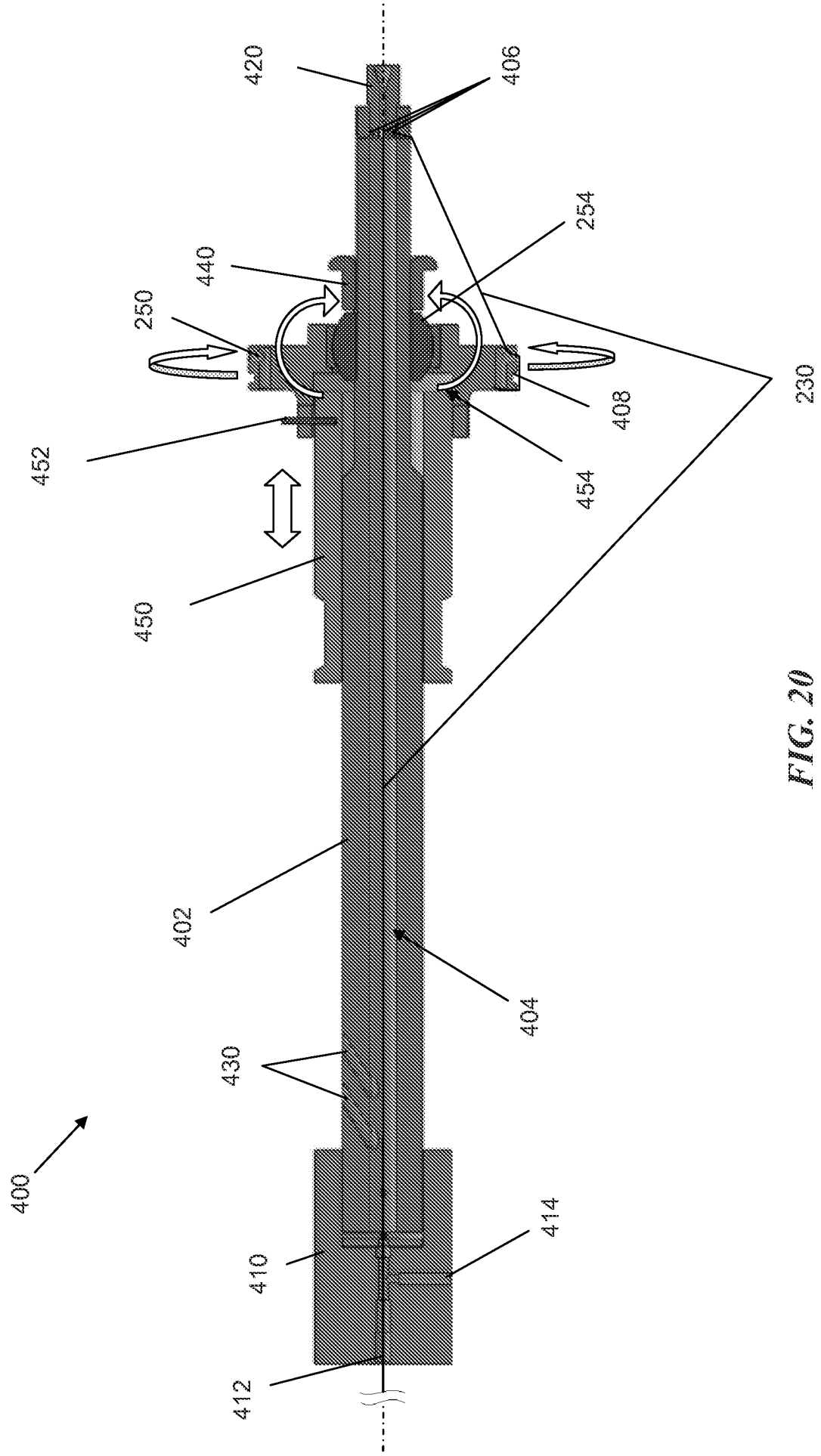

420
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FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/028576

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/95(2013.01)i, A61F 2/82(2006.01)i, A61M 25/09(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F 2/95; A61F 2/06; A61F 2/82; A61B 17/94; A61B 17/24; A61F 2/84; A61M 25/09

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: stent, frame, crimping, clasp, rotation, percutaneous, slide, tilt, pivot fitment, bearing, deployment, lock

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	¥0 2013-022798 Al (CALIFORNIA INSTITUTE OF TECHNOLOGY et al.) 14 February 2013 See claims 1-28; paragraphs [0041]-[0049]; figures 8A-15F	1-8,10
A	US 8318078 B2 (JAGGER, K. A. et al.) 27 November 2012 See column 4, line 43 - column 7, line 52; figures 1-12.	1-8,10
A	US 2013-0046373 Al (CARTLEDGE, R. et al.) 21 February 2013 See claims 1-2; paragraphs [0186]-[0211]; figures 1-35.	1-8,10
A	US 2011-0112622 Al (PHAN, H. et al.) 12 May 2011 See the whole document.	1-8,10
A	US 2010-0175693 Al (WONDKA, A. et al.) 15 July 2010 See the whole document.	1-8,10

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 June 2014 (25.06.2014)	**01 July 2014 (01.07.2014)**

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/028576

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 11-20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 11-20 pertain to a method for treatment of the human body by surgery and thus relate to a subject matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and Rule 39.1(iv) of the Regulations under the PCT, to search.

2. ☒ Claims Nos.: 9
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claim 9 is referring to itself, thereby rendering the definition of the subject matter of said claim unclear (PCT Article 6).

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US20 14/028576

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2013-022798 Al	14/02/2013	US 2014-0001830 Al	02/01/2014
		WO 2014-005017 Al	03/01/2014
US 8318078 B2	27/11/2012	EP 1635901 A2	22/03/2006
		US 2004-0260379 Al	23/12/2004
		WO 2005-004971 A2	20/01/2005
		WO 2005-004971 A3	24/03/2005
US 2013-0046373 Al	21/02/2013	US 2013-0123909 Al	16/05/2013
		US 2013-0166017 Al	27/06/2013
		WO 2013-059776 Al	25/04/2013
		WO 2013-126529 A2	29/08/2013
US 2011-0112622 Al	12/05/2011	EP 2434961 Al	04/04/2012
		EP 2434961 A4	19/12/2012
		JP 2012-527955 A	12/11/2012
		JP 2014-014722 A	30/01/2014
		US 2012-0136426 Al	31/05/2012
		US 8357193 B2	22/01/2013
		WO 2010-138277 Al	02/12/2010
US 2010-0175693 Al	15/07/2010	EP 1812098 A2	01/08/2007
		JP 2008-520360 A	19/06/2008
		US 2006-0162731 Al	27/07/2006
		US 2014-0081308 Al	20/03/2014
		US 8409168 B2	02/04/2013
		WO 2006-055692 A2	26/05/2006
		WO 2006-055692 A3	16/04/2009