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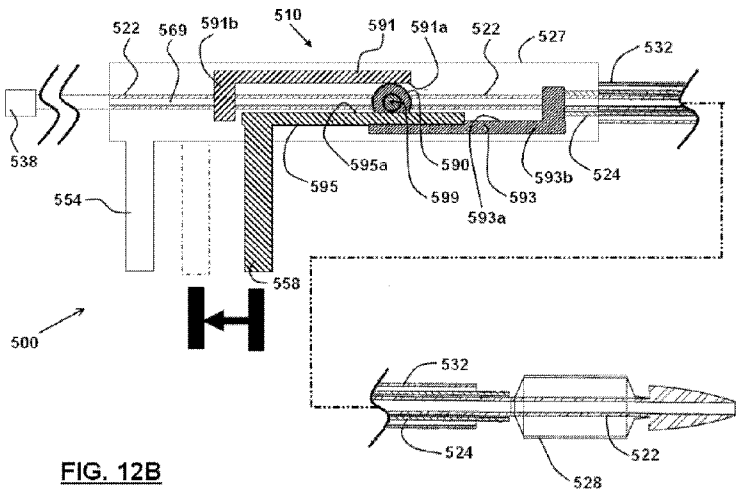

FIG. 12B

(57) Abstract: A stent delivery system and method for implanting a stent are provided. The stent delivery system includes an elongate shaft including a proximal portion, a distal portion, a lumen extending at least partially therethrough, and a stent receiving portion on the distal portion of the shaft. It also includes a stent positioned at the stent receiving portion of the elongate shaft, the stent having a constrained configuration and an expanded configuration. A proximal constraining member and a distal constraining member releasably connected to the stent and having a first position and a second position are also included. The proximal constraining member and the distal constraining member cooperatively apply longitudinal tensile force to at least a portion of the stent with the proximal and distal constraining members each in the first position. A cog and rack mechanism is included to provide mechanical advantage and efficiency during stent deployment.

Short Throw Centered Handle For Stent Delivery System

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a non-provisional application which claims priority to U.S. provisional application Serial No. 61/447,396, filed February 28, 2011, which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] This invention relates to a medical device and, in particular to a device for delivering and deploying a stent and a method of delivering and deploying the stent into a body lumen.

BACKGROUND

[0003] A self-expanding stent is typically introduced into a patient body using a delivery device that includes an outer sheath coaxially disposed and slidable over an inner catheter. The stent is disposed at the distal end of the device between the inner catheter and the outer sheath and held in a compressed position by the outer sheath. The inner catheter and the outer sheath move coaxially with respect to each other. The stent may be deployed by proximally pulling back the outer sheath relative to the inner catheter until the stent is exposed. The self-expanding stent expands from the stent distal end to the stent proximal end as the sheath is proximally withdrawn.

[0004] Several problems may occur with the sheathed delivery device described above. The sheath release delivery devices are difficult to reposition or remove and slow to operate. The stent may only be partially deployed prior to reconstrainment of the stent by the sheath in order to still reposition or remove the stent. After the stent is fully deployed (i.e., radially expanded), the sheath cannot reconstrain the stent. For example, utilizing a conventional outer sheath/inner catheter delivery device may cause the physician to inadvertently use excessive force and pull back the outer sheath too far, thereby prematurely deploying the stent in an incorrect position within a body lumen. At this step in the procedure,

repositioning of the stent becomes difficult, if not impossible, because the stent has already radially self-expanded into the body lumen. Additionally, retraction of the outer sheath may not be achieved with controlled movement because the physician is manually retracting the outer sheath which may lead to uneven or inadvertent jerking back of the outer sheath that can lead to improper positioning of the stent.

[0005] Additionally, in a typical sheath release device where the outer sheath is proximally withdrawn, the first portion of the self-expanding stent to make contact with the body vessel is the most distal portion of the stent. This type of release may cause difficulty in accurately placing the proximal portion of the stent because the distal end of the stent is positioned first while the proximal portion of the stent is still covered by the outer sheath. , Accurate placement of the proximal portion of the stent and/or the stent body may be important in certain applications, for example to prevent stent migration or to properly open a stricture along the entire length of the stricture. An additional drawback occurs with the sheathed stent delivery system where direct visualization of the stent is required. For example, in endoscopically placed stents, the sheath tends to prevent or obscure the location of the stent, making accurate placement of the stent more difficult.

[0006] Further potential drawbacks for the conventional sheathed stent delivery system involve the stent placement within the system prior to use within a patient. Loading and anchoring of a conventional sheathed stent delivery device is an involved process that may require preloading the stent into the device so that the stent remains compressed within the sheath during shipment and storage prior to use in the patient. Extended compression of the stent may lead to an alteration in the stent mechanical properties.

[0007] Conventional sheathed stent delivery devices also require a high force to overcome the friction between the stent and the sheath that may also be a problem for proper stent placement within the patient. The introducer must be mechanically stronger to overcome the frictional forces to avoid undesirable frictional consequences such as stretching of the

introducer catchers and hysterics in the movement of the stent. The sheathed stent delivery device also requires more space within an endoscope compared to a sheathless device and also adds additional expense to the delivery system.

[0008] Accordingly, in view of the drawbacks of current technology, there is a desire for a mechanically expandable delivery system and/or dilation system that can increase the control, accuracy and ease of placement of a stent and/or mechanical dilation device (which those of skill in the art may during deployment of the stent within a patient. A desirable delivery system would reduce the risk of malfunction while providing for a smooth, accurate, and quick deployment of the entire stent. The delivery system also would provide the ability to reconstrain, recapture, reposition, and/ or remove the stent after expansion of the stent.

BRIEF SUMMARY

[0009] A gear-based deployment mechanism may be used to provide a short-throw handle for deploying and recapturing a stent. First and second racks disposed on opposite sides of a common central cog may provide for simultaneous retraction and extension of stent-attached shaft elements that will constrain a stent when operated in a first manner and that will deploy the stent when operated in a second manner opposite the first.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is a side view of a stent delivery system according to one embodiment;

[0011] FIG. 2 is a sectional view of the device shown in FIG. 1 showing the stent in a constrained configuration;

[0012] FIG. 3 is a sectional view of the device shown in FIG. 2 with an outer sheath withdrawn and the stent in a constrained configuration;

[0013] FIG. 4 is a sectional view of the device shown in FIG. 3 with the stent in an expanded configuration;

[0014] FIG. 5A is a partial side view of a proximal portion of the stent and the device shown in FIG. 4 illustrating a proximal constraining member;

[0015] FIG. 5B is a partial side view of a distal portion of the stent and the device shown in FIG. 4 illustrating a distal constraining member;

[0016] FIG. 5C is an enlarged view of a constraining member according to another embodiment;

[0017] FIG. 6A is a partial side view of an alternative embodiment of a proximal constraining member;

[0018] FIG. 6B is a partial side view of an alternative embodiment of a distal constraining member;

[0019] FIG. 6C is an enlarged view of an alternative embodiment of a constraining member;

[0020] FIG. 6D is a partial sectional view of a constraining member;

[0021] FIGS. 7A and 7B are sectional views of a delivery system illustrating a stiffening member;

[0022] FIG. 8 is a partial view of a distal portion of a delivery system according to certain embodiments;

[0023] FIGS. 9A-9D are cross sectional views of the delivery system shown in FIG. 8;

[0024] FIGS. 10A and 10B are side views of a delivery system having alternative constraining members;

[0025] FIG. 11A is a longitudinal section view of a stent deployment system, which shows a handle in a state where the stent will be constrained;

[0026] FIG. 11B is a longitudinal section view of the system of FIG. 11A, which shows a handle in a state where the stent will be deployed/expanded;

[0027] FIG. 11C shows a detail view of a cog component of the system of FIGS. 11A-11B; and

[0028] FIG. 11D shows a transverse section view of the handle of the system depicted in FIGS. 11A-11B.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0029] Various embodiments are described with reference to the drawings in which like elements are generally referred to by like numerals. The relationship and functioning of the various elements of the embodiments may better be understood by the following detailed description. However, the embodiments of the claimed invention are not limited to the embodiments illustrated in the drawings. It should be understood that the drawings are not necessarily to scale, and in certain instances details have been omitted which are not necessary for an understanding of the presently disclosed embodiments, such as conventional fabrication and assembly, and features described with reference to other embodiments.

[0030] As used in the specification, the terms proximal and distal should be understood as being from the perspective of a physician delivering the stent to a patient. Hence the term “distal” means the portion of the delivery system that is farthest from the physician and the term “proximal” means the portion of the delivery system that is nearest to the physician.

[0031] FIG. 1 illustrates a stent delivery system 10. The stent delivery system 10 includes an inner shaft 22, an outer shaft 24 and a handle 26 at a proximal portion 27 of the system 10. A stent 28 (shown in FIG. 2) is positionable on a stent region 30 of the inner shaft 22 at a distal portion 31 of the delivery system 10. The stent delivery system 10 may include an outer sheath 32 slidably positionable over a portion of the outer shaft 24 and the inner shaft 22 to cover the stent region 30 and the stent 28. One or more radio-opaque markers may be included on the delivery system 10 to indicate the position of the stent 28. The stent delivery system 10 may also include a stiffening member or wire guide 36 extendable through a port 38 of the inner shaft 22 through a distal tip 41 at the distal portion 31 of the delivery system 10.

[0032] FIG. 2 illustrates a sectional view of the stent delivery system 10 shown in FIG. 1. As shown in FIG. 2, the stent 28 is in a constrained configuration 40 collapsed against the inner shaft 22. In some

embodiments, the stent 28 may be a self-expanding stent and may be configured – for example – as an esophageal stent. The stent 28 may be any kind of stent that has a tendency to radially collapse when a longitudinal force is applied to the ends of the stent proximally and distally outward along its central longitudinal axis (centerline). By way of non-limiting example, the stent 28 may be formed as a woven mesh formed from a metal or polymer or a laser cut pattern formed in a metal stent. The stent may also be formed from a bioabsorbable material. One example of a woven stent is the EVOLUTION® stent (Wilson-Cook Medical, Inc.)

[0033] An outer sheath 32 that may be included is shown extended distally over the stent 28 and abutting the distal tip 41 of the inner shaft 22 forming a smooth outer surface 42 of the delivery system 10. The outer sheath 32 is operably connected to the handle 26. The outer sheath 32 may be provided to facilitate a smoother delivery of the system 10 through a body lumen of the patient. The stent 28 is held in the constrained configuration 40 by a different mechanism that may be provided with or without the outer sheath 32, one embodiment of which is described in detail below with reference to FIGS. 5A-5C. That embodiment includes a proximal stent constraining member 44 and a distal stent constraining member 46 configured to longitudinally constrain the stent 28 and hold the stent 28 collapsed against the inner shaft 22. The proximal and distal stent constraining members 44, 46 are operably connected to the handle 26 by connection of the proximal constraining member 44 to the outer catheter 24 and the distal constraining member 46 to the inner catheter 22. When present, the outer sheath 32 may provide some compressive force to the stent in addition to the proximal and distal constraining members 44, 46. The handle 26 is shown FIG. 2 in a closed position 52. The handle 26 may include a lock 53 to releasably lock the handle 26 in the closed position 52.

[0034] As shown in FIG. 3, the outer sheath 32 has been proximally pulled back, completely exposing the stent 28 in the constrained configuration 40 on the inner shaft 22. The outer sheath 32 may be releasably locked against the handle 26 to keep the sheath 32 stationary

relative to the handle 26. The stent 28 is held compressed against the inner shaft 22 by the proximal and distal stent constraining members 44, 46 in a first position 47 applying longitudinal force to the stent 28 in opposite directions (which may be described as "central constraint" as the function is not accomplished by any external encompassing structure). The handle 26 is in the closed position 52 and the outer sheath 32 has manually been pulled proximally away from the stent region 30 of the inner shaft 22 and anchored to the sheath controlling portion 54 of the handle 26 to expose the stent 28.

[0035] The handle 26 further includes a proximal handle portion 58 that is operably connected to the inner shaft 22 and the outer shaft 24 to move the inner and outer shafts 22, 24 relative to each other as discussed below. The proximal handle portion 58 is movable between the closed position 52 (shown in FIG. 3) and an open position 64 (shown in FIG. 4). A midpoint 56 for attachment of the proximal handle portion 58 is shown for the handle 26. A second attachment midpoint 60 is shown for the sheath controlling portion 54. A distance 62 between the attachment midpoints 56, 60 remains constant when the proximal handle portion 58 is moved from the closed position 52 shown in FIG. 3 to the open position 64 shown in FIG. 4.

[0036] The stent 28 is shown in an expanded configuration 66 in FIG. 4 where the stent 28 is expanded away from the inner shaft 22. The proximal and distal constraining members 44, 46 are in a second position 49 and remain connected to the stent 28 but the longitudinal force on the stent 28 has been removed to allow the stent 28 to expand. The proximal portion 58 of the handle 26 has been moved to the open position 64 by expanding arms 58a, 58b of the proximal handle portion 58 in equal and opposite directions. The inner shaft 22 and the outer shaft 24 are moved in equal and opposite directions relative to each other by the proximal handle portion 58 and the proximal and distal constraining members 44, 46 are moved closer together. The stent 28 is released from the constrained configuration 40 to the expanded configuration 66 in response to the equal

and opposite motion of the opening of the proximal handle portion 58 so that the release of the tension on the stent 28 is uniform within the patient's lumen.

[0037] The proximal handle portion 58 may be spring loaded to facilitate the expansion of the arms 58a, 58b to the open position 64. The proximal handle portion 58 moves the inner shaft 22 relative to the outer shaft 24 so that the longitudinal tension exerted on the stent 28 by the proximal and distal constraining members 44, 46 is relaxed when the members 44, 46 are closer together and the stent 28 expands uniformly due to the uniform release of the tension on the stent 28 by the proximal and distal constraining members 44, 46.

[0038] As shown in FIG.4, the proximal and distal constraining members 44, 46 remain connected to the stent 28 in the expanded configuration 66. The connection allows the stent 28 to be moved from the expanded configuration 66 with the outer sheath 32 completely removed from the stent 28 to the constrained configuration 40 so that the stent 28 is recollapsed onto the inner shaft 22 by moving the proximal handle portion 58 to the closed position 52. The proximal handle portion 58 moves the inner shaft 22 and the outer shaft 24 relative to each other so that the proximal and distal constraining members 44, 46 are spaced further apart and the longitudinal tension is returned to the stent 28 to collapse the stent onto the inner shaft 22. The stent 28 may be repeatedly moved between the constrained configuration 40 and the expanded configuration 66 by moving the proximal handle portion 58 between the closed position 52 and the open position 64 until the stent is properly positioned. With the stent repositioned in the constrained configuration 40, the outer sheath 32 may be repositioned over the stent 28 as shown in FIG. 2 and the stent 28 may even be withdrawn from the patient, for example if an incorrect size of stent was originally selected. The stent configurations may be changed multiple times within the patient for repositioning or removal until the proximal and distal constraining members 44, 46 are released from connection with the stent 28 as described below.

[0039] FIGS. 5A-5C illustrate an exemplary embodiment of a proximal constraining member 44 (FIG. 5A) and a distal constraining member (FIG. 5B). An exploded view of the components of the proximal constraining member 44 is shown in FIG. 5C and the components of the distal constraining member 46 may be a mirror image of the components of the proximal constraining member 44 (not shown). As shown in FIG. 5A, a proximal end portion 70 of the stent 28 remains connected to the inner shaft 22 even in the expanded configuration 66 using the proximal constraining member 44 in combination with the distal constraining member 46. The proximal constraining member 44 may include a first loop 72 that may be interwoven through one or more peaks 74 of the stent 28 so that the first loop 72 when pulled taught will collapse the peaks 74 of the stent 28 onto the inner shaft 22. The proximal constraining member 44 may further include a second retaining loop 76 that may be attached to the outer shaft 24.

[0040] The proximal constraining member 44 may also include a proximal retaining wire 78 that is configured to cooperate with the first loop 72 and the second retaining loop 76 to releasably lock the first loop 72 to the second retaining loop 76 to allow selective expansion and contraction of the stent 28 when the proximal handle portion 58 is moved between the open position 64 and the closed position 52 in cooperation with the distal constraining member 46. The first loop 72, the second loop 76 or both may be anchored at one or more points to better secure the stent 28 on the inner catheter 22, for example in a system 10 that is provided without a sheath. In some embodiments, the first loop 72 may be wound around the inner catheter 22 or the outer shaft 24 to facilitate holding the stent to the inner catheter 22 as the delivery system 10 is advanced to the treatment site through a curve, for example through an elevator of a duodenal endoscope. In some embodiments, the second loop 76 may be at least partially covered by a tubular member 79 as shown in dashed lines in FIG. 5A. The tubular member may be clear and may be made from any

material known to one skilled in the art having suitable flexibility. By way of non-limiting example, the tubular member 79 may be made from PTFE.

[0041] An exemplary cooperative configuration of the proximal constraining member 44 is shown in FIG. 5C where a portion of the first loop 72 and the second retaining loop 76 are overlapping and the proximal retaining wire 78 extends through the overlapping loops 72, 76 to releasably hold the two loops 72, 76 together. The proximal retaining wire 78 shown in FIG. 5A may be frictionally engaged with a portion of the outer shaft 24 to hold the proximal retaining wire 78 in position until the stent 28 is in the proper position for release as discussed above. The proximal retaining wire 78 may be proximally withdrawn to release the proximal constraining member 44 and to completely release the stent 28 from connection to the inner shaft 22.

[0042] As shown in FIG. 5B, a distal end portion 80 of the stent 28 may remain connected the inner shaft 22 even in the expanded configuration 66 using the distal constraining member 46. The distal constraining member 46 may include a first loop 82 that may be interwoven through one or more peaks 74 of the stent 28 so that the first loop 82 when pulled taught will collapse the peaks 74 of the stent 28 onto the outer shaft 24. The distal constraining member 46 may further include a second retaining loop 86 that may be attached to the inner shaft 22. The first loop 82, the second loop 86 or both may be anchored at one or more points to better secure the stent 28 on the inner catheter 22, for example in a system 10 that is provided without a sheath. In some embodiments, the first loop 82 may be wound around the inner catheter 22 or the outer shaft 24 to facilitate holding the stent to the inner catheter 22 as the delivery system 10 is advanced to the treatment site through a curve similar to the loop 72 described above.

[0043] The distal constraining member 46 may also include a distal retaining wire 88 that is configured to cooperate with the first loop 82 and the second retaining loop 86 to releasably hold the loops 82, 86 together to allow selective expansion and contraction of the stent 28 when the

proximal handle portion 58 is moved between the open position 64 and the closed position 52. The distal retaining wire 88 may be frictionally engaged with the inner shaft 22 or the distal tip 41 to hold the distal retaining wire 88 in position until the stent 28 is properly positioned for release. The distal constraining member 46 may be configured similarly to the proximal constraining member 44 shown in FIG. 5C with the distal retaining wire 88 releasably locking the first loop 82 and the second retaining loop 86 together. The distal retaining wire 88 may be proximally withdrawn to release the distal constraining member 46 and to completely release the stent 28 from connection to the inner shaft 22.

[0044] The proximal and distal retaining wires 78, 88 may be connected to the handle 26 for proximal withdrawal from the loops 72, 76, 82, 86. The withdrawal of the proximal and distal retaining wires 78, 88 may be simultaneous or sequential. Because the stent 28 has been positioned in the proper position within the lumen of the patient by equal and opposite movement of the handle 26 to the open position 64 allowing the stent 28 to move to the expanded configuration 66, the timing of the release of the retaining wires 78, 88 is not critical for the positioning of the stent 28. As will be understood by one skilled in the art, the proximal constraining member 44 may be connected to the inner catheter 22 and the distal constraining member 46 may be connected to the outer catheter 24. In embodiments provided without the outer sheath 32, the peaks 74 of the stent 28 are collapsed closely against the inner catheter 22 at both ends of the stent 28 for delivery to the patient site.

[0045] While the proximal and distal restraining members 44, 46 have been described with reference to connection to the proximal and distal end portions 70, 80 of the stent 28, it is also possible to provide proximal and distal constraining members 44, 46 that are connected to other portions of the stent 28 and still provide a constrained configuration 40 for the stent 28. For example, the proximal constraining member may be connected to a mid proximal portion or mid-point of the stent and the distal constraining member may be connected to the distal end portion of the stent. Similarly,

the proximal constraining member may be connected to the proximal end portion of the stent and the distal constraining member may be connected to the midpoint of mid distal portion of the stent or both the proximal and distal constraining members may be connected to other than the proximal and distal end portions of the stent. In some embodiments, the proximal or the distal constraining members or both proximal and distal constraining members may be connected to the stent at a plurality of positions on the stent.

[0046] In some embodiments, the stent delivery system 10 may be provided with a proximal constraining member 144 and a distal constraining member 146 as shown in FIGS. 6A and 6B. Similar to the proximal and distal constraining members 44, 46 described above the proximal and distal constringing members 144, 146 cooperatively apply and release tensioning force on the stent 28 in connection with the handle 26. The proximal constraining member 144 is shown in FIG. 6A with stent 28 in the constrained configuration 40. The proximal constraining member 144 includes a first loop 172 and a proximal retaining wire 178. The first loop 172 may be connected to the outer catheter 24. By way of non-limiting example, one portion 173 of the first loop 172 may be connected to the outer catheter 24 through an opening 180 in the outer catheter 24 so that the portion 173 of the loop 172 is constrained under the proximal retaining wire 178 as shown in FIG. 6C. The first loop 172 may also be connected to the outer catheter 24 by welding, gluing, bonding or other fastening method known to one skilled in the art. Another portion 175 of the first loop 172 may be woven through one or more peaks 74 of the stent 28 so that the first loop 172 when pulled taught will collapse the peaks 74 of the stent 28 onto the inner shaft 22 as described above. The proximal constraining member 144 may also include a proximal retaining wire 178 that cooperatively engages a portion of the first loop 172 to releasably hold the first loop 172 on the stent 28 to allow the stent 28 to be expanded and collapsed repeatedly for proper positioning within the patient's lumen. The proximal retaining wire 178 may be proximally withdrawn from the first loop

172 to release the stent 28 from connection with the proximal constraining member 144. The first loop 172 may be withdrawn with the device 10 from the patient and released from the stent 28.

[0047] The distal constraining member 146 is shown in FIG. 6B with stent 28 in the expanded configuration 66. The distal constraining member 146 includes a first loop 182 and a distal retaining wire 188. A portion 183 of the first loop 182 may be connected to the inner catheter 22 in a similar manner to the first loop 172 of the proximal constraining member 144 described above. Another portion 185 of the first loop 182 may be woven through one or more peaks 74 at the distal end 80 of the stent 28 so that when the first loop 182 of the distal constraining member 146 is pulled taught will collapse the peaks 74 of the stent 28 onto the inner shaft 22 as described above. The distal constraining member 146 may also include the distal retaining wire 188 that cooperatively engages a portion of the first loop 182 to releasably hold the first loop 182 on the stent 28 to allow the stent 28 to be expanded and collapsed repeatedly in cooperation with the proximal constraining member 144 for proper positioning within the patient's lumen. The distal retaining wire 188 may be proximally withdrawn from the first loop 182 to release the stent 28 from connection with the distal constraining member 146. The first loop 182 may be withdrawn with the device 10 from the patient and released from the stent 28. As will be understood by one skilled in the art, the proximal constraining member 144 may be connected to the inner shaft 22 and the distal constraining member 146 may be connected to the outer shaft 24 and be movable in equal and opposite directions by operation of the proximal portion 58 of the handle 26.

[0048] In some embodiments, a stiffening member 67 may be removably provided in a lumen 69 of the inner shaft 22 as shown in FIGS. 7A and 7B. The stiffening member may be provided as a mandrel, catheter, rod and the like that is removably insertable into the lumen 69. The stiffening member 67 may be provided to help increase the rigidity of the inner catheters 22 against the inward tensioning force of the stent 28

when the stent 28 is in the constrained configuration 40. In some embodiments, the inner shaft 22 may be provided in a soft material to facilitate passage through the body lumen. In the event that the materials are sufficiently soft, the inner catheter 22 may collapse or deform in response to the tensioning force of the stent 28 provided by the first and second constraining members 44, 46 longitudinally constraining the stent 28 against the inner shaft 22. The stiffening member 67 may be made from any material having suitable stiffness to provide support for the inner shaft 22 with the stent 28 longitudinally tensioned on the inner shaft 22. Exemplary materials for forming the shaft include, but are not limited to, metal alloys such as stainless steel, tantalum or its alloys, tungsten, platinum, gold, copper, palladium, rhodium, or a superelastic alloys, such as nitinol or polymers that can be provided with sufficient shore hardness, such as Pebax, Peek, polyimide, liquid crystal polymers (LCP) such as Vectran, polyethylene, polyethylene terephthalate and Nylon.

[0049] As shown in FIG. 7A, the outer sheath 32 may be provided for delivery of the stent to the area of the treatment site. The outer sheath 32 compresses the stent against the inner shaft 22 for delivery of the device 10 to the treatment site with the stiffening member 67 removed and the stent 28 in the constrained configuration 40. (See FIG. 1.) The stiffening member 67 may be inserted into the lumen 69 when the stent 28 is near the proper position for implantation into the patient and the outer sheath is over the stent 28 as shown in FIG. 7A. The outer sheath 32 may be withdrawn and the stent 28 remains constrained on the inner shaft 22 by the proximal and distal constraining members 44, 46. The stiffening member 67 supports the inner shaft 22 against the compressive tensioning force exerted by the proximal and distal constraining members 44, 46.

[0050] FIG. 8 illustrates a sectional view of the distal portion 31 of the stent delivery device 10 provided in a rapid exchange configuration. FIGS. 9A-9D show cross sectional views of an exemplary lumen configuration through the device 10 along different portions indicated in FIG. 8 in relation to a working channel of an endoscope. Many other

lumen configurations are possible with the stent delivery device 10 and the following discussion is provided by way of non-limiting example. A working channel 100 of an endoscope is represented by the dashed line in FIGS. 9A-9D. FIG. 9A shows the cross sectional view along line A—A of FIG. 8 that is distal to the stent 28. The cross section view in FIG. 9A illustrates an inner catheter 110 having a first lumen 112 and a second lumen 114. A guide wire 118 is shown in the first lumen 112 and a first retaining wire 120 is shown in the second lumen 114. The first retaining wire 120 is a component of the distal constraining member 46. FIG. 9B shows the cross sectional view along line B—B of FIG. 8 taken proximal to the stent 28 and shows the inner shaft 110 within a first lumen 132 of an outer shaft 130 in relation to the working channel 100. A second retaining wire 134 is shown within a second lumen 136 of the outer shaft 130. The second retaining wire 134 is a component of the proximal constraining member 44 shown in FIG. 8.

[0051] FIG. 9C illustrates the cross sectional view taken along line C—C of FIG. 8. FIG. 9C illustrates a rapid exchange port 140 within a distal portion 31 of the device 10. The rapid exchange port 140 provides access to the first lumen 132 of the outer shaft 130 and to the first lumen 112 of the inner shaft 110. As shown in FIG. 9C, the guide wire 118 is being exchanged in the rapid exchange port 140. Any other type of device suitable for insertion into a rapid exchange port may also be inserted into the rapid exchange port 140. By way of non-limiting example, the stiffening member 67 described above may be inserted into the rapid exchange port 140 to provide additional stiffness to support the stent 28 on the inner shaft 22 in the longitudinally tensioned constrained configuration 40 as discussed above with reference to FIG. 7B.

[0052] FIG.9D illustrates the cross sectional view taken along line D—D in FIG. 8 proximal to the rapid exchange port 140. FIG. 8D illustrates the wire guide 118, or other device suitable for insertion into the rapid exchange port 140, external to the outer shaft 130 and within the working

channel 100 of the endoscope. The inner shaft 110 is enclosed within the first lumen 132 of the outer shaft 130.

[0053] The stent delivery system 10 may also be provided in an over-the wire configuration, for example, as shown in FIG. 1. In the over-the-wire configuration, the first lumen 112 of the inner shaft 110 is accessible from the proximal end portion of the inner shaft 110. In the over-the-wire configuration, the cross sectional views taken along the lines C—C and D—D would be the same as the cross-sectional view taken along line B—B as shown in FIG. 9B.

[0054] As shown in FIGS. 10A and 10B, a stent delivery system 200 may be provided with two wires 212, 214 to control the expansion and contraction of a stent 228. The stent delivery system 200 includes an inner shaft 222 and a handle 226 at a proximal portion 227 of the system 200. The stent 228 is positionable on the inner shaft 222 at a distal portion 231 of the stent delivery system 200. The stent delivery system 200 may include an outer sheath 232 slidably positionable over a portion of the inner shaft 222 to cover the stent 228. The stent delivery system 200 may also include a stiffening member 267 similar to the stiffening member 67 described above with reference to FIGS. 7A and 7B. The stent 228 is shown in FIG. 10A in a constrained configuration 240. Similar to the stent 28 described above, the stent 228 is movable between the constrained configuration 240 and an expanded configuration 266 shown in FIG. 10B. The stent 228 is moved between the constrained and expanded configuration with a proximal constraining member 244 and a distal constraining member 246.

[0055] The proximal and distal constraining members 244, 246 cooperatively apply and release longitudinal tension on the stent 228 to move the stent between the constrained configuration 240 and the expanded configuration 266. In the embodiment shown in FIGS. 10A and 10B, the wires 212 and 214 of the proximal and distal constraining members 244, 246, respectively move in equal and opposite directions in connection with arms 258a, 258b of the handle portion 258 moving in

equal and opposite directions. By way of non-limiting example, the handle 226 is shown in an open position 264 that holds the proximal and distal constraining members 244, 246 apart in a first position 147 to apply longitudinal force to the stent 228 to hold the stent 228 against the inner shaft 222 in the constrained configuration 240 as shown in FIG. 10A. In FIG. 10B, the arms 258a, 258b are moved to a closed position 252 and the proximal and distal constraining members 244, 246 are moved closer together in a second position 149 and release the tension on the stent 228 so the stent 228 moves to an expanded configuration 226 with the proximal and distal constraining members 244, 246 still connected to the stent 228. Similar to the embodiments described above, the stent 228 may be moved between the expanded and constrained configurations 266, 240 multiple times until the correct position within the patent's lumen is obtained.

[0056] The proximal constraining member 244 may include the wire 212, a loop 272 and a proximal retaining wire 278. The wire 212 may be provided with a loop to overlap with the loop 272 so that the proximal retaining wire 278 may releasably lock the wire 212 and the loop 272 together until the proximal retaining wire 278 is withdrawn. The distal constraining member 246 may be provided with the wire 214, a loop 282 and a distal retaining wire 288 in a similar arrangement to the proximal constraining member 244. The proximal and distal retaining wires 278, 288 may be proximally withdrawn to completely release the stent 228 when the stent 228 is properly positioned.

[0057] The materials used to manufacture the components of the stent delivery systems and mechanical dilator systems described herein may be any materials known to one skilled in the art that are suitable for use in patients. By way of non-limiting example, the shafts and sheaths may be formed from polytetrafluoroethylene (PTFE) particularly when a low friction outer sheath is desirable. Nylon and HDPE may also be used for clarity. Additional possible materials include, but are not limited to the following, polyethylene ether ketone (PEEK), fluorinated ethylene propylene (FEP),

perfluoroalkoxy polymer resin (PFA), polyamide, polyurethane, high density or low density polyethylene, and nylon including multi-layer or single layer structures and the like and may also include reinforcement wires, braid wires, coils, coil springs and or filaments. The stent may be formed from but is not limited to the following materials: Nickel titanium alloys, for example, nitinol, stainless steel, cobalt alloys and titanium alloys. The loops of the constraining members may be made from common suture material as known in the art, for example polyester suture such as 4-0 Tevdek®, nylon, silk, polypropylene, ultra high molecular weight polyethylene (UHMPE) and the like. The sutures may be monofilament, braided, twisted or multifilament. The loops and the retaining wires may also be made from a metallic alloy such as stainless steel or nickel titanium. In some embodiments, the stent, the loops and/or the retaining wires may be made from biodegradable materials. A number of bioabsorbable homopolymers, copolymers, or blends of bioabsorbable polymers are known in the medical arts. These include, but are not necessarily limited to, polyesters including poly-alpha hydroxy and poly-beta hydroxy polyesters, polycaprolactone, polyglycolic acid, polyether-esters, poly(p-dioxanone), polyoxaesters; polyphosphazenes; polyanhydrides; polycarbonates including polytrimethylene carbonate and poly(iminocarbonate); polyesteramides; polyurethanes; polyisocyanates; polyphosphazines; polyethers including polyglycols, polyorthoesters; epoxy polymers including polyethylene oxide; polysaccharides including cellulose, chitin, dextran, starch, hydroxyethyl starch, polygluconate, hyaluronic acid; polyamides including polyamino acids, polyester-amides, polyglutamic acid, poly-lysine, gelatin, fibrin, fibrinogen, casein, collagen.

[0058] Other suitable biocompatible materials may also be used for any of the components described herein. In some embodiments, reinforcements such as, for example, helically braided wires made from metal, polymer (e.g., nylon) or other materials, stainless steel hypotube, or other reinforcing materials configured to provide and/or assist in maintaining structural integrity and functionality.

[0059] Operation of the stent delivery systems in keeping with illustrated embodiments is described with reference to the stent delivery system 10 by way of non-limiting example. Alternative methods of operating the system may also be used. The stent delivery system 10 may be provided in a sterile packaging. The stent 28 may be provided in the expanded configuration 66 or constrained configuration 40 within the packaging. For example, some stent materials may weaken or otherwise deform when stored in a constrained configuration 40 with the longitudinal tension exerting force on the stent during shipping and storage. In some embodiments provided with an outer sheath 32, the outer sheath 32 may be provided to hold the stent 28 in position on the stent region 30 without having the proximal and distal constraining members 44, 46 tensioning the stent. For example, the system 10 may be provided with the handle 26 in the open position 64 and the outer sheath 32 over the stent 28 on the inner shaft 22. Prior to insertion of the distal portion 31 of the system 10 into the patient, the operator may move the handle 26 to the closed position 52 and place longitudinal tension on the stent 28 using the proximal and distal constraining members 44, 46 to constrain the stent 28 against the inner shaft 22. The stent 28 may be provided in the expanded configuration 66 in the absence of a sheath as well and be moved to the constrained configuration 40 by operation of the handle 26 to the closed position 52 prior to delivery to the patient.

[0060] Minimal fluoroscopy may be used for placement of the stent 28 within the patient's lumen because of the simultaneous release of the stent. The simultaneous release of the stent 28 means that the midpoint of the stent 28 in the constrained configuration 40 on the inner shaft 22 is also the midpoint when the stent 28 is released, so that the stent 28 may precisely be positioned based on the known midpoint of the stent 28. Fluoroscopy is not required during placement of the stent 28 once the placement position has been determined. The stricture length within the patient's lumen at the treatment site is measured using fluoroscopy. Then

the stent 28 may be placed at the proper position within the lumen using an endoscope alone.

[0061] The outer sheath 32 may include two different sets of distance measurement markings 37, 39, one to be used when the outer sheath 32 is covering the stent 28 and one set to be used when the outer sheath 32 has been withdrawn and locked to the handle 26 (See FIGS. 2 and 3). The markings 37, 39 may be of different colors, for example, to easily identify the two measurements. The operator measures the distance from the incisor teeth to the midpoint of the stricture. The stent delivery system 10 is inserted into the patient's alimentary canal via the mouth using the first set of sheath markings 37 to place the constrained stent 28 in the stricture by measuring the distance relative to the incisor teeth. The sheath 32 is withdrawn proximally and locked to the handle 26 to expose the stent 28. The second set of markings 39 may be used once the sheath 32 is withdrawn to measure the distance between the stricture and the incisor teeth to ensure that the stent 28 is still in the correct position relative to the stricture. Because the outer sheath 32 is not used to deploy the stent 28, the markings 37, 39 can be placed clearly on the outside of the sheath and the outer sheath can be locked to the handle 26 and held steady relative to the patient's incisor teeth to increase the accuracy of the stent placement.

[0062] An endoscope may be positioned within the patient's lumen so the operator can view the proximal side of the stricture. The guidewire 36 is inserted through the stricture and the endoscope is removed. The proper length stent 28 is selected based on the stricture measurement. The operator inserts the distal portion 31 of the stent delivery system into the patient's lumen with the stent 28 in the constrained configuration 40 on the inner shaft 22. The guidewire 36 may be inserted first to navigate a tortuous pathway to the treatment site and the system 10 is delivered over the guidewire 36 to the treatment site. The endoscope may then be placed into the patient's lumen adjacent and parallel to the system 10. Alternatively, the stent delivery system 10 may be inserted into the

patient's lumen through the working channel of an endoscope, depending on the size and location of the lumen.

[0063] A viewing port of the endoscope is used to identify the proximal end of the stricture at the treatment site. The stent region 30 is positioned within the lumen at the treatment point. For embodiments having a softer inner shaft 22, the stiffening member 67 is inserted through the lumen 69 of the inner shaft 22 to provide support for the longitudinally tensioned stent. The outer sheath 32, if present, is proximally withdrawn and the stent 28 in the constrained configuration 40 is exposed within the patient's lumen. The constrained stent 28 may be moved within the lumen to correctly position the stent 28 at the implant/treatment site. The stent 28 is moved to the expanded configuration 66 by movement of the handle portion 58 to the open position 64 that moves the proximal and distal constraining members 44, 46 to the second position 49 releasing the longitudinal tension on the stent 28. The position of the expanded stent 28 is monitored using the endoscope. The stent 28 may be returned to the constrained configuration 40 by the operator moving the proximal portion 58 of the handle 26 to the closed position 52 and returning the proximal and distal constraining members 44, 46 to the first position 47 to longitudinally tension the stent 28 against the inner shaft 22, for example if the stent 28 is incorrectly positioned. The stent 28 may be moved from the constrained configuration 40 to the expanded configuration 66 as many times as needed.

[0064] Once the proper position for the stent 28 is achieved within the patient's lumen, the proximal and distal retaining wires 78, 88 may be proximally withdrawn from the stent 28 to completely release the stent 28 from the proximal and distal constraining members 44, 46. The delivery system 10 is withdrawn proximally from the patient and the endoscope removed.

[0065] Another embodiment of a stent deployment system 400, including a short-throw centered handle 410 is illustrated with reference to FIGS. 11A-11D. FIGS. 11A-11B each show a longitudinal section view of

the system 400, in different actuation states. FIG. 11A shows the handle 410 in a state where the stent 428 is constrained, and FIG. 11B shows the handle in a state where the stent 428 is expanded circumferentially and foreshortened. FIG. 11C shows a detail view of a cog component 490, and FIG. 11D shows a transverse section view of the handle 410 illustrating the interaction of the cog 490 and rack components 491, 493, which are configured for actuation of the inner and outer shafts 422, 424 and, thereby, the stent 428. The general principle of operation for stent deployment of this embodiment 400 is substantially the same as described with reference to other embodiments above. The mechanisms for stent attachment and release to the inner and outer shafts may be any of those addressed in this and/or other disclosures including U.S. provisional application Serial No. 61/299,605, filed January 29, 2010, which is incorporated by reference herein in its entirety.

[0066] The handle 410 includes a housing 427 (shown only diagrammatically) that encloses its inner components. A pistol-style grip 454 is fixed near the proximal end of the handle housing 427. A trigger-style actuating grip 458 is disposed longitudinally slidably with reference to the housing 427. The device may also include an outer sheath 432, which may be present during introduction into a patient's lumen then withdrawn to expose the constrained stent at an implant site in that lumen. The structure of the device 400 is generally similar to embodiments described above, including that the constraint of a stent 428 and its attachment to the inner and outer shafts may be accomplished in any of the manners described herein or elsewhere with reference to centrally-constrained configurations where the stent is stretched longitudinally to constrain/reduce its outer diameter (e.g., to provide a lower profile for introduction into a patient's lumen). The distance moved by one handle relative to the other is the "throw," and it will be appreciated that the throw of this embodiment will be shorter than that afforded by other embodiments described herein when otherwise operating the same with respect to stent size.

[0067] FIG. 11A shows the device 400 with the stent 428 in a constrained configuration. The distal end of the stent 428 is attached to the elongate inner shaft 422, which is longitudinally slidable relative to the handle 410. The proximal end of the stent 428 is attached to the elongate tubular outer shaft 424, which is disposed coaxially around and longitudinally slidable relative to the inner shaft 422. The actuating grip 458 is relatively close to the proximal pistol grip 454. The centered short-throw mechanism elements are also disposed within the handle housing 427. The inner shaft 422 may include a longitudinal lumen 469 extending therethrough. A proximal port 438 may be provided for introducing a wire guide, stiffening element or other structure or material into the lumen 469.

[0068] In contrast with the lever action associated with the embodiments of FIGS. 1-4, this embodiment uses a geared stent deployment mechanism in the housing 427 including a toothed cog 490 that is mounted on a housing-attached axle 499, which is oriented transverse to the long axis of the housing 427 (as shown in FIG. 11D). The toothed cog 490, which is shown in more detail in FIG. 11C, has a first toothed portion 490x with a larger outer diameter than a second, parallel toothed portion 490y. The ratio between the diameters and/or teeth-counts of cog portions 490x, 490y may be configured to optimize rack advancement/retraction relative to a particular stent construction in a manner that will readily be understood by one of skill in the art with reference to the present disclosure and drawings. In an embodiment configured to provide a 1:1 gear ratio between the cog/first-rack and cog/second rack interfaces, 490x and 490y will have the same outer diameter and tooth count (or the first and second racks will just engage opposite sides of a single-diameter cog). In the embodiment shown, the distal movement distance of the inner shaft 422 upon actuation will be a gear ratio multiple of the proximal movement distance of the outer shaft 424 upon actuation.

[0069] The cog 490 confers mechanical advantage by simultaneously imparting proximal and dual movement to deploy/release or recapture a

stent with less handle movement than the same deployment/recapture operation would require with a lever mechanism as described above. This design may therefore be particularly useful for stents that are very long and/or that have high foreshortening percentages. One preferred design includes a 1:4 ratio (where the cog is geared such that total proximal and distal linear movement is four times the relative linear movement of the grips 454, 458), but other designs may provide a 1:2 ratio or another predetermined ratio. This configuration may be modified within the state of the art in view of, and within the scope of, this invention to provide a desirable ergonomic, motion-efficient design with which treating personnel may deploy and recapture/retract a stent with a shorter handle throw than available with other handle designs.

[0070] The linear movement is imparted to the stent 428 through racks attached to the inner and outer shafts, and disposed in mechanical communication with the cog 490. The first rack 491 includes a proximal portion 491b that is attached to the inner shaft 422 and thereby to the distal end of the stent 428, which is releasably attached to a distal portion of the inner shaft 422. The first rack 491 also includes a distal toothed portion 491a that is engaged in mechanical communication with the first cog portion 490x. The second rack 493 includes a distal portion 493b that is attached to the outer shaft 424 and thereby to the proximal end of the stent 428, which is removably attached to the outer shaft 424 (in a manner similar to other embodiments described herein). The second rack also includes a central toothed portion 493a that is in mechanical communication with the second cog portion 490y, and a proximal end that is fixed to the trigger grip 458.

[0071] Accordingly, the second rack 493 will slide longitudinally when the trigger grip 458 is actuated longitudinally. This motion is transferred to the cog 490 by its interface with the second rack toothed portion 493a, such that the cog 490 rotates about its axis 499. This cog rotation transfers the longitudinal motion of the second rack 493 by continued mechanical communication to the toothed surface 491a of the first

rack 491. Rotation of the cog 490 in contact with the first rack 491 moves it opposite the direction of the motion of the second rack 493. As each rack 491, 493 moves, the corresponding attached shaft 422, 424 is moved longitudinally as well – also in the opposite direction.

[0072] Those of skill in the art will appreciate the simple elegance of this design with regard to efficiently transferring movement to the stent 428 via its distal and proximal attachments, respectively, to the inner and outer shafts 422, 424. As is illustrated with reference to the difference in handle positions between FIGS. 11A and 11B, operation of the handle 410 will open/deploy the stent 428 by allowing it to expand radially as it foreshortens. The motion may be reversed, moving the first and second racks toward the first position (of FIG. 11A) to recapture/constrain the stent 428.

[0073] The transition from FIG. 11A to FIG. 11B shows a deployment step. As the fixed grip 454 and trigger grip 458 are moved apart relative to each other (e.g., by movement of one or both, but preferably of the trigger grip relative to the other grip), the second rack 493 is moved longitudinally distally. This action simultaneously advances the outer shaft 424 and proximal stent end distally while rotating the cog 490 counterclockwise (viewed from the perspective of FIGS. 11A-11B) as the toothed surface 493a engages and mechanically communicates the longitudinal movement of the trigger grip 458 and its rack 493 to the cog 490. The rotation of the cog 490 is mechanically communicated to the first rack 491 via the interface of the first cog portion 490x with its toothed surface 491a. The first rack 491 is thus moved proximally, thereby pulling the inner shaft 422 proximally (with its attachment to the distal stent end).

[0074] As shown in FIG. 11B, when the trigger grip 458 is distally advanced, the stent 428 will be disposed in a deployed/expanded configuration. If the stent 428 needs recaptured and/or otherwise reduced in outer diameter to be repositioned, the trigger grip 458 may be moved to the position shown in FIG. 11A. The orientation and interaction of the cog 490, first rack 491, and second rack 493 may better be understood

with reference to FIG. 11D, which is a transverse section view taken along line 11D-11D of FIG. 11A.

[0075] FIG. 11D shows the first rack 491 at its interface with the cog 490, as well as the interface of the cog 490 with the second rack 493. The axle 499 about which the cog 490 is configured to reciprocatingly pivot is also shown as extending from the housing 427. The axle 499 is generally transverse/ perpendicular to the longitudinal axes of the racks 491, 493. With the stent deployment mechanism shown and described, it should be appreciated that, in a different embodiment, the fixed handle 454 may be disposed on the housing 427 in a location that is distal of the movable handle 458.

[0076] In addition, although not shown, it should be appreciated that one may easily provide one or more springs or other biasing means configured to bias the handles 454, 458 into a position that corresponds to a stent-constrained state or to a stent-expanded state to provide such as a default handle position. It should also be appreciated that one may actuate the stent deployment mechanism of the handle, racks, and cog by manually advancing or retracting the inner shaft 422 (e.g., by grasping its proximal exposed portion). In addition, one more keeper pawls may be provided to engage the cog and/or one or both of the racks, where the keeper pawl(s) is/are configured to prevent retrograde motion in the system that may be introduced by a tension in the stent that could oppose a desired direction of movement, or that could introduce undesired movement. Preferred keeper pawl(s) or other keeper mechanisms preferably will be manipulable into and out of a keeper position, and may be biased into a default keeper or free-motion position.

[0077] Another embodiment of a stent deployment system 500, including a short-throw centered handle 510 is illustrated with reference to FIGS. 12A-12D, which is similar to the embodiment shown in FIGS. 11A-11D. FIGS. 12A-12B each show a longitudinal section view of the system 500, in different actuation states. FIG. 12A shows the handle 510 in a state where the stent 528 is constrained, and FIG. 12B shows the

handle in a state where the stent 528 is expanded circumferentially and foreshortened. FIG. 12C shows a detail view of a cog component 590, and FIG. 12D shows a transverse section view of the handle 510 illustrating the interaction of the cog 590 and three rack components 591, 593, 595, which are configured for actuation of the inner and outer shafts 522, 524 and, thereby, the stent 528. The general principle of operation for stent deployment of this embodiment 500 is substantially the same as described with reference to other embodiments above. The mechanisms for stent attachment and release to the inner and outer shafts may be any of those addressed in this and/or other disclosures including U.S. provisional application Serial No. 61/299,605, filed January 29, 2010, which is incorporated by reference herein in its entirety.

[0078] The handle 510 includes a housing 527 (shown only diagrammatically) that encloses its inner components. A pistol-style grip 554 is fixed near the proximal end of the handle housing 527. A trigger-style actuating grip 558 is disposed longitudinally slidably with reference to the housing 527. The device may also include an outer sheath 532, which may be present during introduction into a patient's lumen then withdrawn to expose the constrained stent at an implant site in that lumen. The structure of the device 500 is generally similar to embodiments described above, including that the constraint of a stent 528 and its attachment to the inner and outer shafts may be accomplished in any of the manners described herein or elsewhere with reference to centrally-constrained configurations where the stent is stretched longitudinally to constrain/reduce its outer diameter (e.g., to provide a lower profile for introduction into a patient's lumen). The distance moved by one handle relative to the other is the "throw," and it will be appreciated that the throw of this embodiment will be shorter than that afforded by other embodiments described herein when otherwise operating the same with respect to stent size.

[0079] FIG. 12A shows the device 500 with the stent 528 in a constrained configuration. The distal end of the stent 528 is attached to

the elongate inner shaft 522, which is longitudinally slidable relative to the handle 510. The proximal end of the stent 528 is attached to the elongate tubular outer shaft 524, which is disposed coaxially around and longitudinally slidable relative to the inner shaft 522. The actuating grip 558 is relatively close to the proximal pistol grip 554. The centered short-throw mechanism elements are also disposed within the handle housing 527. The inner shaft 522 may include a longitudinal lumen 569 extending therethrough. A proximal port 538 may be provided for introducing a wire guide, stiffening element or other structure or material into the lumen 569.

[0080] In contrast with the lever action associated with the embodiments of FIGS. 1-4, this embodiment uses a geared stent deployment mechanism in the housing 527 including a toothed cog 590 that is mounted on a housing-attached axle 599, which is oriented transverse to the long axis of the housing 527 (as shown in FIG. 12D). The toothed cog 590, which is shown in more detail in FIG. 12C, has a first toothed portion 590x with a larger outer diameter than a second, parallel toothed portion 590y. The ratio between the diameters and/or teeth-counts of cog portions 590x, 590y may be configured to optimize rack advancement/retraction relative to a particular stent construction in a manner that will readily be understood by one of skill in the art with reference to the present disclosure and drawings. In an embodiment configured to provide a 1:1 gear ratio between the cog/first-rack and cog/second rack interfaces, 590x and 590y will have the same outer diameter and tooth count (or the first and second racks will just engage opposite sides of a single-diameter cog). In the embodiment shown, the distal movement distance of the inner shaft 522 upon actuation will be a gear ratio multiple of the proximal movement distance of the outer shaft 524 upon actuation.

[0081] The cog 590 confers mechanical advantage by simultaneously imparting proximal and dual movement to deploy/release or recapture a stent with less handle movement than the same deployment/recapture

operation would require with a lever mechanism as described above. This design may therefore be particularly useful for stents that are very long and/or that have high foreshortening percentages. One preferred design includes a 1:4 ratio (where the cog is geared such that total proximal and distal linear movement is four times the relative linear movement of the grips 554, 558, where those of skill in the art will appreciate that the relative motion of the first and second racks 591, 593 may be more symmetrical than in the embodiment of FIGS. 11A-11D), but other designs may provide a 1:2 ratio or another predetermined ratio. This configuration may be modified within the state of the art in view of, and within the scope of, this invention to provide a desirable ergonomic, motion-efficient design with which treating personnel may deploy and recapture/retract a stent with a shorter handle throw than available with other handle designs.

[0082] The linear movement is imparted to the stent 528 through three racks attached in mechanical communication with the inner and outer shafts, and disposed in mechanical communication with the cog 590. The first rack 591 includes a proximal portion 591b that is attached to the inner shaft 522 and thereby to the distal end of the stent 528, which is releasably attached to a distal portion of the inner shaft 522. The first rack 591 also includes a distal toothed portion 591a that is engaged in mechanical communication with the first cog portion 590x. The second rack 593 includes a distal portion 593b that is attached to the outer shaft 524 and thereby to the proximal end of the stent 528, which is removably attached to the outer shaft 524 (in a manner similar to other embodiments described herein). The second rack also includes a proximal toothed portion 593a that is in mechanical communication with the first cog portion 590y on the opposite side of its engagement with the first rack 591. A third rack 595 includes a proximal end that is fixed to the trigger grip 558 and a distal toothed portion 595a that engages the second cog portion 490y.

[0083] Accordingly, the first and second racks 591, 593 will slide longitudinally in opposite directions from each other when the trigger grip 558 is actuated longitudinally. This motion is transferred to the first

and second racks 591, 593 via the cog 590 by its interface with the third rack's toothed portion 595a, which – when the trigger 558 is moved longitudinally – rotates the cog 590 about its axis 599. This cog rotation transfers the longitudinal motion of the third rack 595 to the toothed surfaces 591a, 593a of the first and second racks 591, 593. Rotation of the cog 590 in contact with the first rack 591 moves it opposite the direction of the motion of the second rack 593. As each rack 591, 593 moves, the corresponding attached shafts 522, 524 are moved longitudinally opposite directions relative to each other.

[0084] Those of skill in the art will appreciate the efficiently transfer of movement to the stent 528 via its distal and proximal attachments, respectively, to the inner and outer shafts 522, 524. As is illustrated with reference to the difference in handle positions between FIGS. 12A and 12B, operation of the handle 510 will open/deploy the stent 528 by allowing it to expand radially as it foreshortens. The motion may be reversed, moving the first and second racks toward the first position (of FIG. 12A) to recapture/constrain the stent 528. This resheathing feature may be highly useful to physicians for optimizing placement of a stent. Often, deployment and carefully targeted placement may be rendered difficult by the foreshortening that occurs when the stent is deployed. However, as will be appreciated with reference to the controlled stent release features of the present device embodiments, a physician may partially or wholly recapture/collapse/resheath the stent one or more times during a procedure until the stent is directed into exactly the desired location and finally completely released from the deployment device.

[0085] The transition from FIG. 12A to FIG. 12B shows a deployment step. As the fixed grip 554 and trigger grip 558 are moved apart relative to each other (e.g., by movement of one or both, but preferably of the trigger grip relative to the other grip), the second rack 593 is moved longitudinally distally. This action simultaneously advances the outer shaft 524 and proximal stent end distally while rotating the cog 590 counterclockwise (viewed from the perspective of FIGS. 12A-12B) as the toothed

surface 593a engages and mechanically communicates the longitudinal movement of the trigger grip 558 and its third rack 595 to the cog 590. This rotation of the cog 590 is simultaneously mechanically communicated to the first and second racks 591, 593 via the interface of the first cog portion 590x with their toothed surfaces 591a, 593a. The first rack 591 is thus moved proximally, thereby pulling the inner shaft 522 proximally (with its attachment to the distal stent end), while the second rack 593 (and its attached shaft 424) moves distally.

[0086] As shown in FIG. 12B, when the trigger grip 558 is distally advanced, the stent 528 will be moved toward a deployed/expanded configuration. If the stent 528 needs recaptured and/or otherwise reduced in outer diameter to be repositioned, the trigger grip 558 may be moved to the position shown in FIG. 12A. The orientation and interaction of the cog 590, first and second racks 591, 593, and third rack 595 may better be understood with reference to FIG. 12D, which is a transverse section view taken along line 12D-12D of FIG. 12A.

[0087] FIG. 12D shows the first and second racks 591, 593 at their interface with the cog 590, as well as the interface of the cog 590 with the third rack 595. The axle 599 about which the cog 590 is configured to reciprocatingly pivot is also shown as extending from the housing 527. The axle 599 is generally transverse/ perpendicular to the longitudinal axes of the racks 591, 593, 595. With the stent deployment mechanism shown and described, it should be appreciated that, in a different embodiment, the fixed handle 554 may be disposed on the housing 527 in a location that is distal of the movable handle 558.

[0088] The above figures and disclosure are intended to be illustrative and not exhaustive. This description may suggest many variations and alternatives to one of ordinary skill in the art, including that variants and elements of each embodiment may be applied in other embodiments unless clearly excluded. Such variations and alternatives may be practiced within the scope of the claims that are part of this specification. Those familiar with the art may recognize other equivalents to the specific

embodiments described herein, which equivalents are intended to be encompassed by the claims, as are the various possible combinations of different elements of embodiments described in the present application.

CLAIMS

1. A stent delivery system comprising:

an elongate outer tubular shaft including a proximal portion, a distal portion, and a stent attachment portion on the distal portion of the outer shaft, said stent attachment portion configured for attachment to a proximal stent end;

an elongate inner shaft extending longitudinally, coaxially, slidably through the outer elongate tubular shaft including a proximal portion, a distal portion, and a stent receiving portion on the distal portion of the shaft, said stent receiving portion configured for attachment to a distal stent end;

a fixed handle that is fixedly attached to a housing, which housing is configured to house a stent-deployment mechanism; and

a stent deployment mechanism disposed in the housing, the mechanism comprising:

a movable handle configured to be longitudinally slidable relative to the housing;

a first rack member attached to a proximal portion of the inner shaft and comprising a first cog-engaging surface;

a second rack member attached to the movable handle, attached to a proximal portion of the outer shaft, and comprising a second cog-engaging surface; and

a cog rotatably attached to the housing in a manner configured to provide mechanical communication between the first and second cog-engaging surfaces of the first and second rack members;

wherein the inner shaft and the outer shaft are configured to cooperatively apply opposing longitudinal tensile forces to at least a portion of a stent in the constrained configuration with the proximal and distal constraining members each in a first position corresponding to a first

relative position of the movable handle, first rack member, and second rack member.

2. The stent delivery system of claim 1, further comprising a third rack attached to the movable handle and comprising a third cog-engaging surface.

3. The stent delivery system of claim 2, wherein the cog comprises a first outer diameter contacting the first and second cog-engaging surfaces and a second outer diameter contacting the third cog-engaging surface.

4. The stent delivery device of claim 3, wherein the first outer diameter is greater than the second outer diameter.

5. The stent delivery system of claim 4, configured wherein mechanical communication between the first and second racks via the cog will move the first rack a greater linear distance than a corresponding longitudinal movement of the second rack.

6. The stent delivery system of claim 2, wherein the cog comprises a first outer diameter contacting the first and second cog-engaging surfaces and a second outer diameter contacting the third cog-engaging surface, and wherein the first and second outer diameters are configured to provide a predetermined ratio of movement between the first and second cog-engaging surfaces and the third cog-engaging surface.

7. The stent delivery system of claim 1, further comprising a stent attached to the inner and outer shafts, the stent having a constrained configuration and an expanded configuration.

8. The stent delivery system of claim 7, wherein the stent is repeatedly movable between the constrained configuration and the expanded configuration.

9. The stent delivery system of claim 7, wherein the stent is configured as an esophageal stent.

10. The stent delivery system of claim 7, further comprising a sheath removably positionable over the stent and a portion of the elongate shaft.

11. The stent delivery system of claim 7, further comprising a distal sheath positionable over a distal portion of the stent.

12. The stent delivery system of claim 7, wherein the outer shaft and the inner shaft are configured to mechanically communicate through the first and second racks and across the cog to move in opposite directions in relation to each other, thereby to move the proximal and distal stent ends in opposite directions in relation to each other to expand or constrain the stent depending upon the movement direction.

13. The stent delivery system of claim 1, configured wherein mechanical communication between the first and second racks via the cog will move the first rack distally when the second rack is moved proximally.

14. The stent delivery system of claim 1, wherein the fixed and movable handles are configured to be movable in equal and opposite directions in relation to each other to uniformly release the stent to the expanded configuration.

15. The stent delivery system of claim 1, further comprising a stiffening member removably positionable in the lumen to support the elongate shaft against the longitudinal force applied to the stent.

16. A method of implanting a stent in a patient's lumen, the method comprising:

inserting a distal portion of a stent delivery system according to claim 1 into a lumen of a patient, the stent delivery system further

comprising a stent attached to the inner and outer shafts, the stent having a constrained configuration and an expanded configuration:

holding the stent in the constrained configuration with longitudinal tensile force applied to the stent by the first and second rack members each located in the first position;

directing the stent to an implant site;

deploying the stent to the expanded configuration by moving the first and second rack members to a second position by actuation of the handles in a manner moving the inner shaft proximally, the outer shaft distally, and thereby releasing longitudinal force on the stent.

17. The method of claim 16, further comprising reapplying longitudinal force to the stent to move the stent from the expanded configuration to the constrained configuration by moving the first and second rack members toward the first position.

18. The method of claim 16, wherein the stent is configured as an esophageal stent.

19. The method of claim 16, further comprising providing a removable sheath over the stent and a portion of the inner shaft and withdrawing the sheath from the stent in the patient's lumen such that the stent is exposed.

20. The method of claim 14, further comprising providing a stiffening member extending into the lumen when the delivery device is in the patient's lumen.

21. A handle for a stent delivery system, the handle comprising:

a housing configured to house components of a stent deployment mechanism;

a handle member movably attached to the housing;

a first rack member fixed to the handle member and disposed longitudinally slidably in the housing, where the first rack member is configured for attachment to a proximal stent end;

a rotatable cog attached to the housing, the cog comprising a first cog surface and a second cog surface, wherein the first cog surface is configured in engagement with the first rack member such that a first longitudinal movement of the first rack member will rotate the cog; and

a second rack member disposed longitudinally slidably within the housing and configured for attachment to a distal stent end, wherein the second rack member is configured in engagement with the second cog surface such that rotation of the cog will generate a second longitudinal movement of the second rack member in a direction opposite the first longitudinal direction.

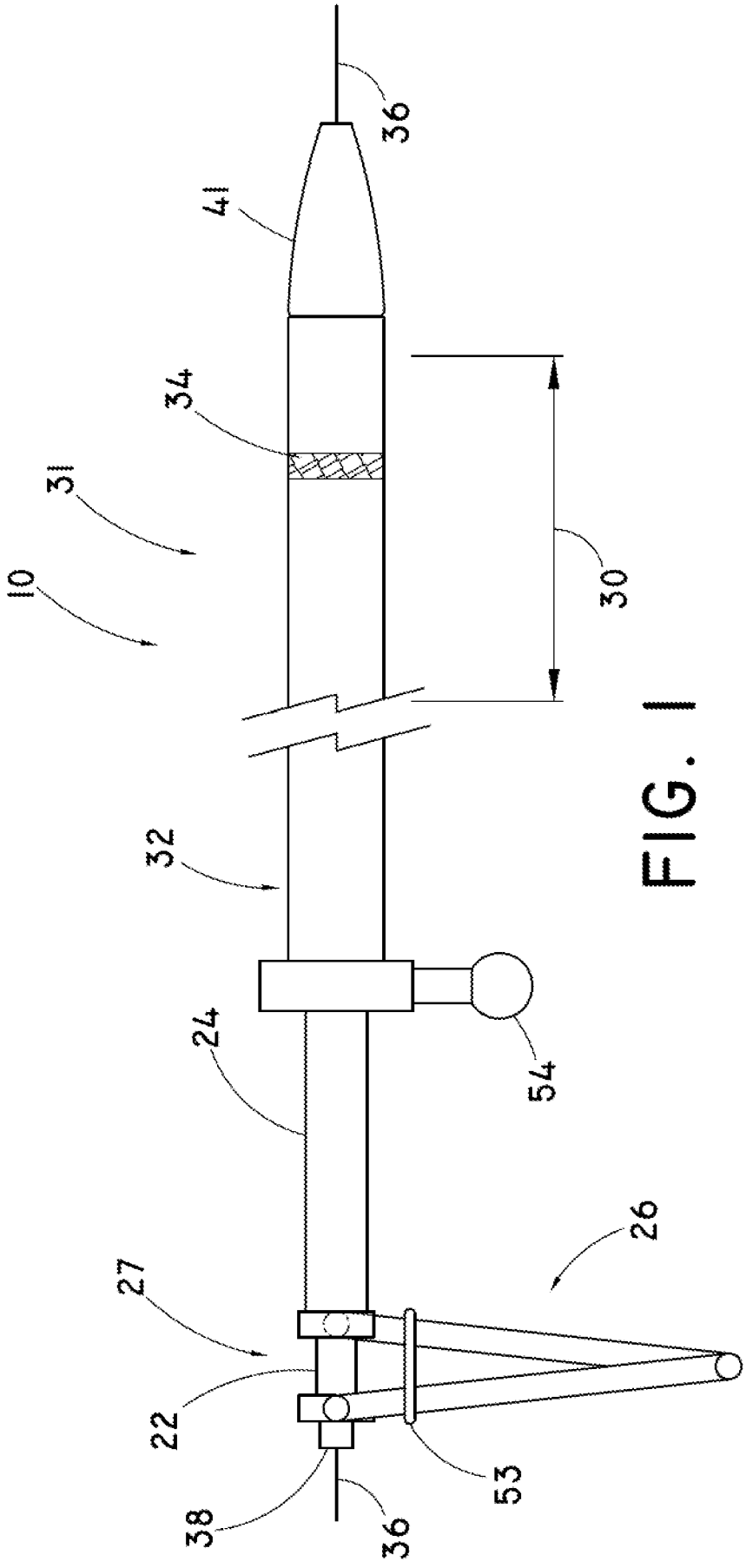

FIG. 1

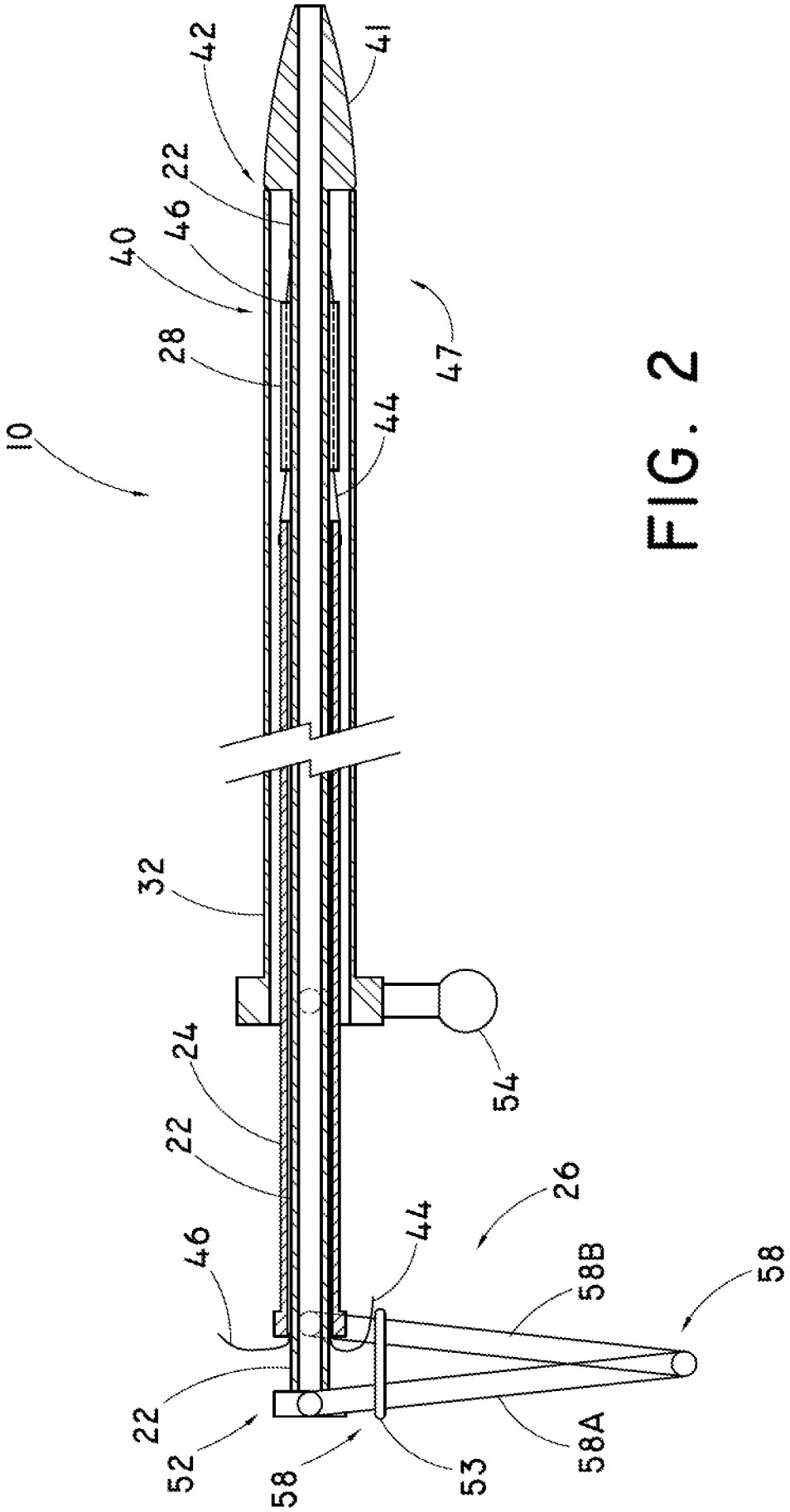

FIG. 2

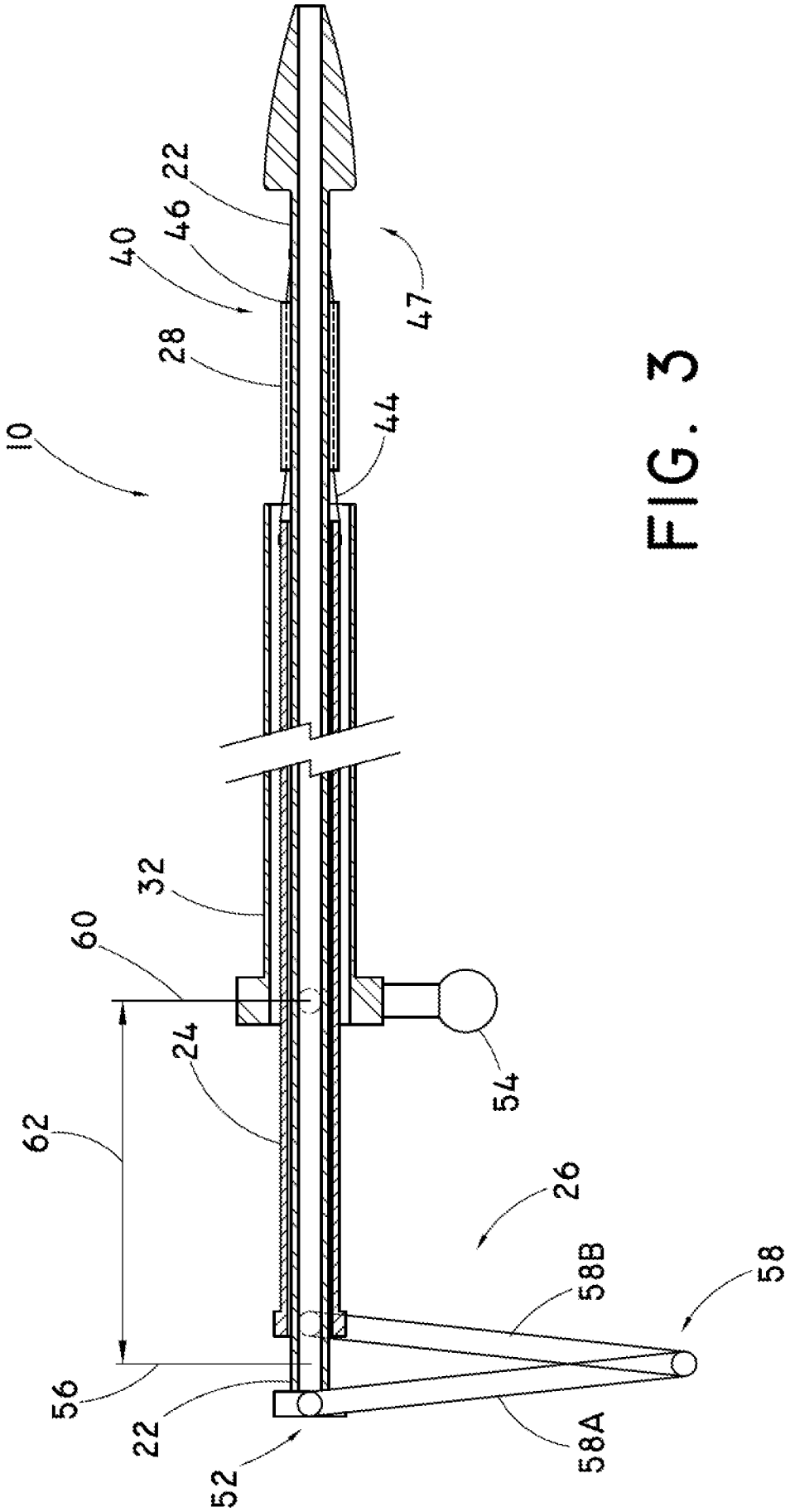

FIG. 3

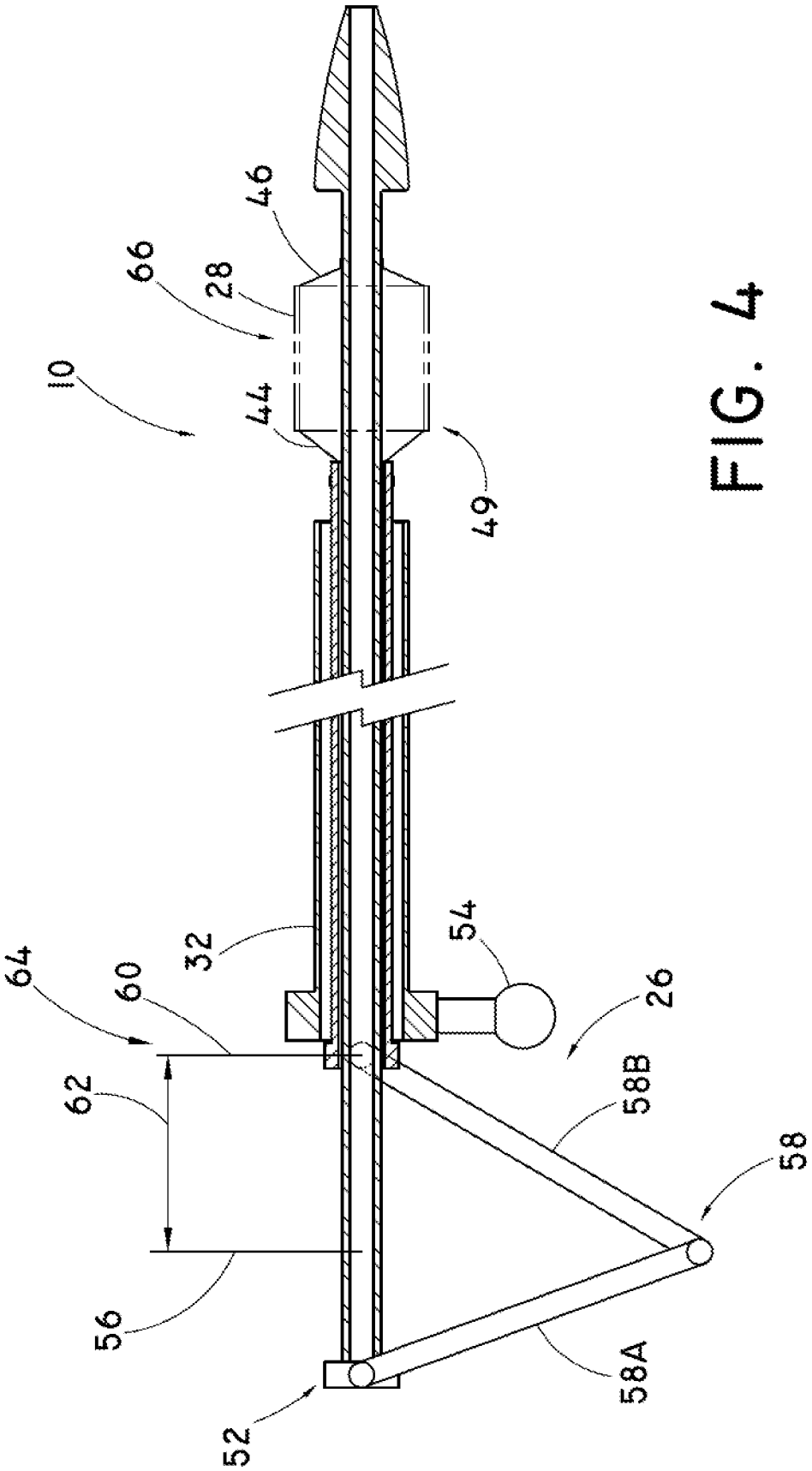

FIG. 4

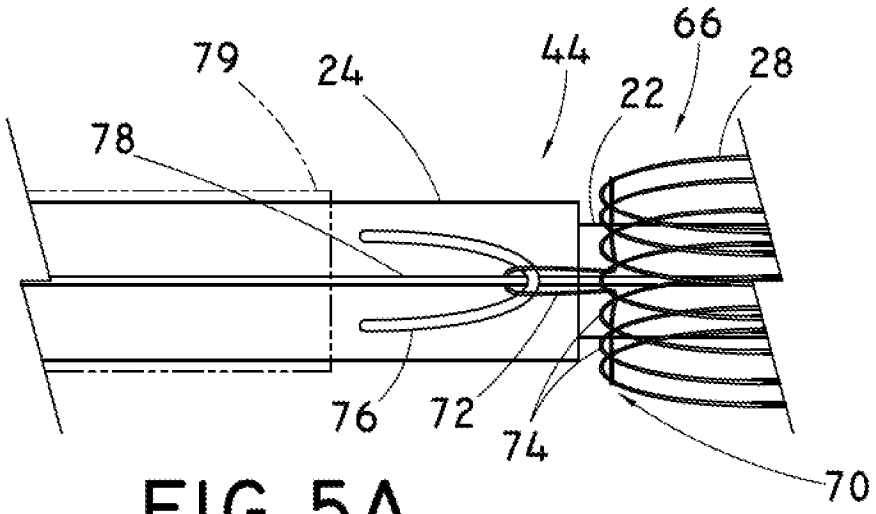

FIG.5A

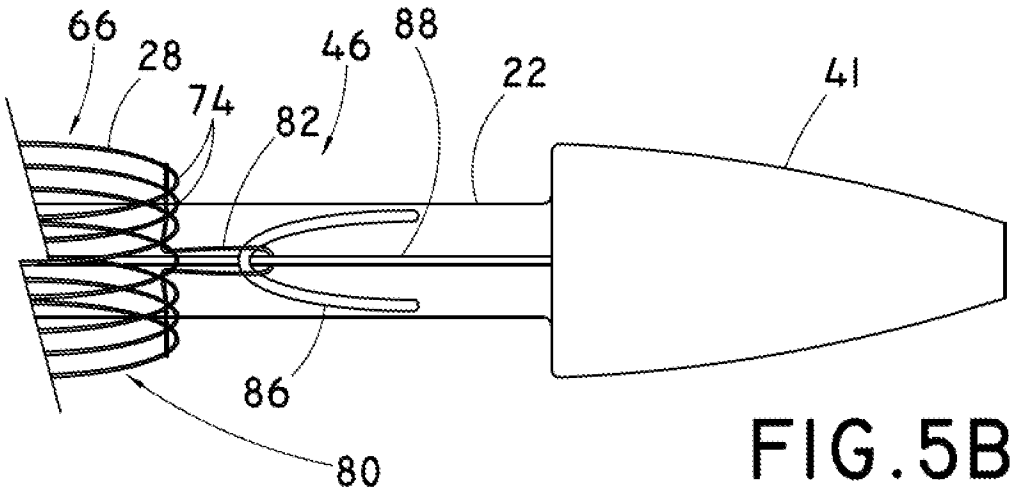

FIG.5B

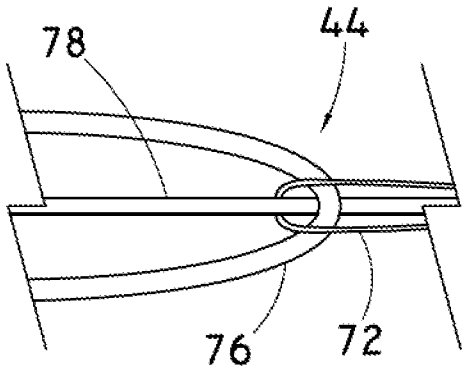

FIG.5C

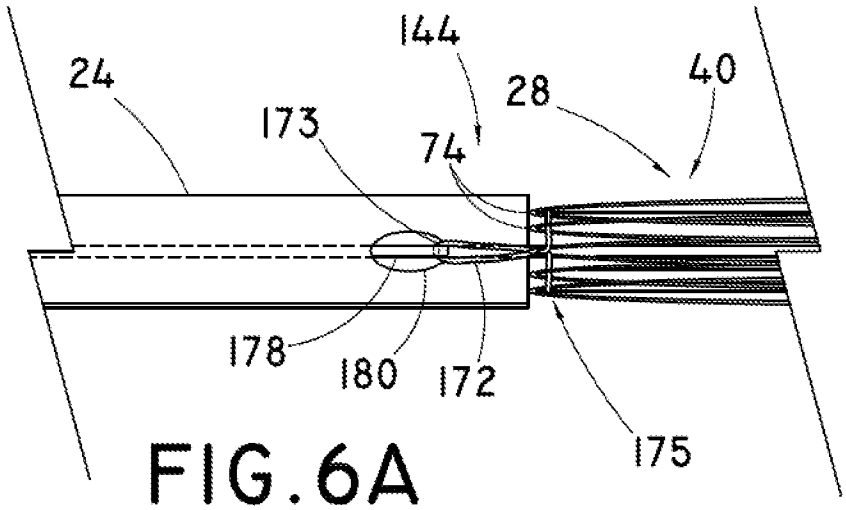

FIG.6A

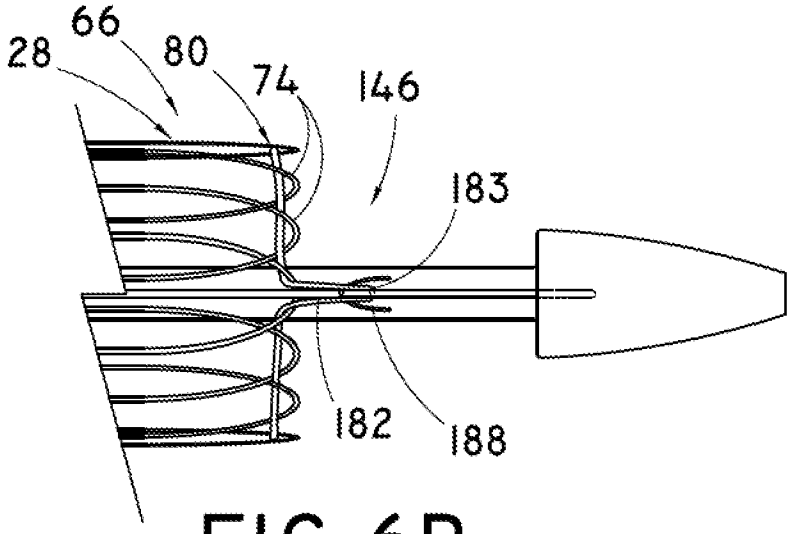

FIG.6B

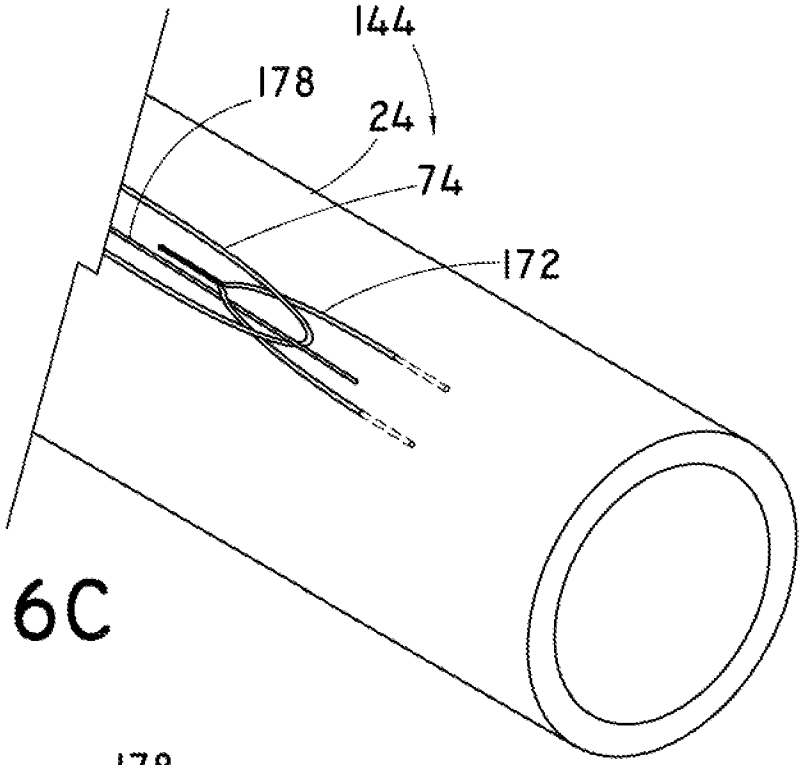

FIG.6C

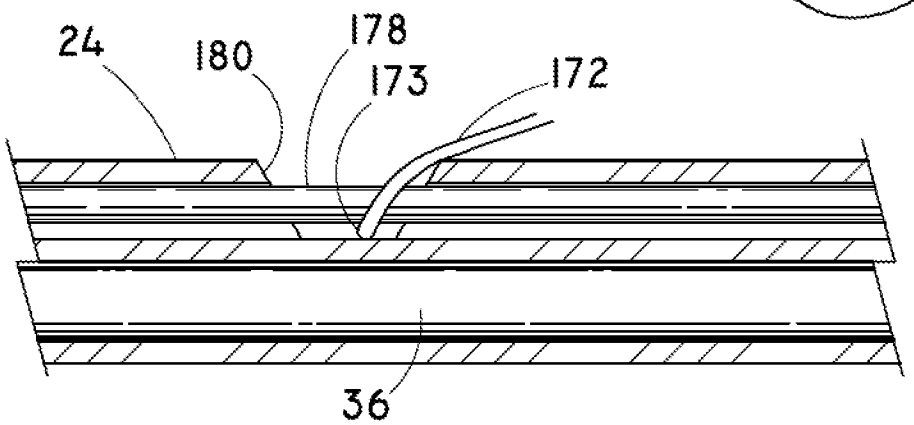

FIG.6D

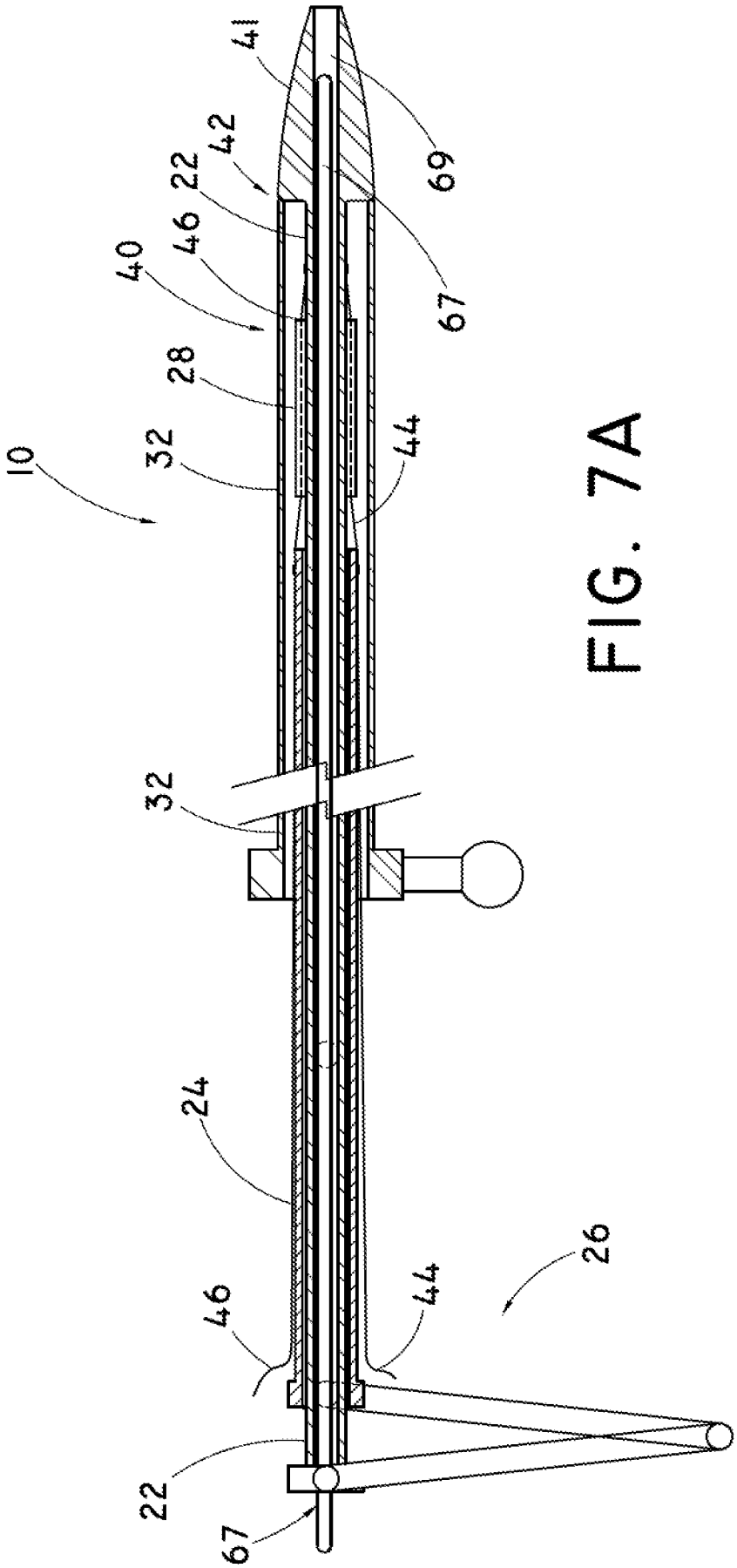

FIG. 7A

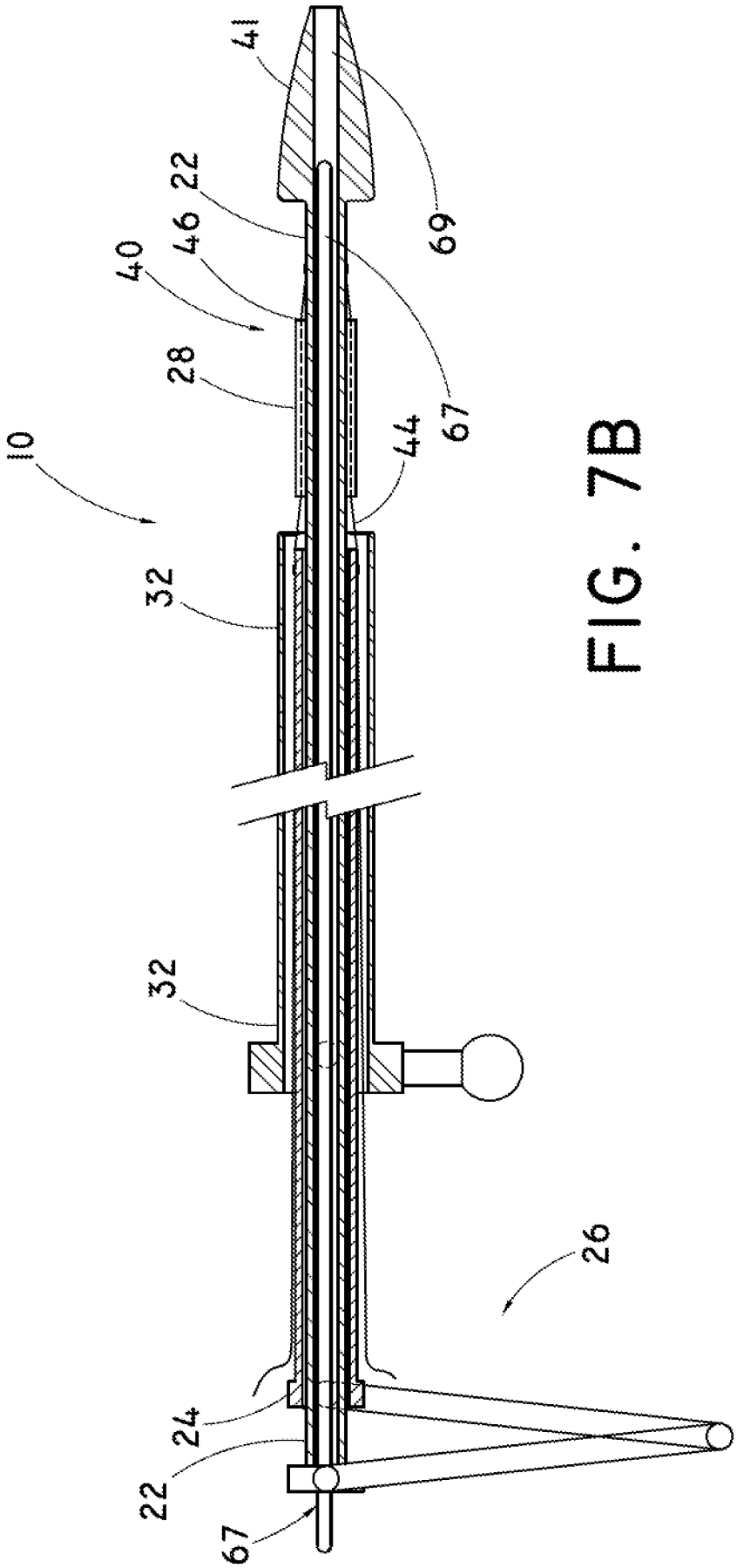

FIG. 7B

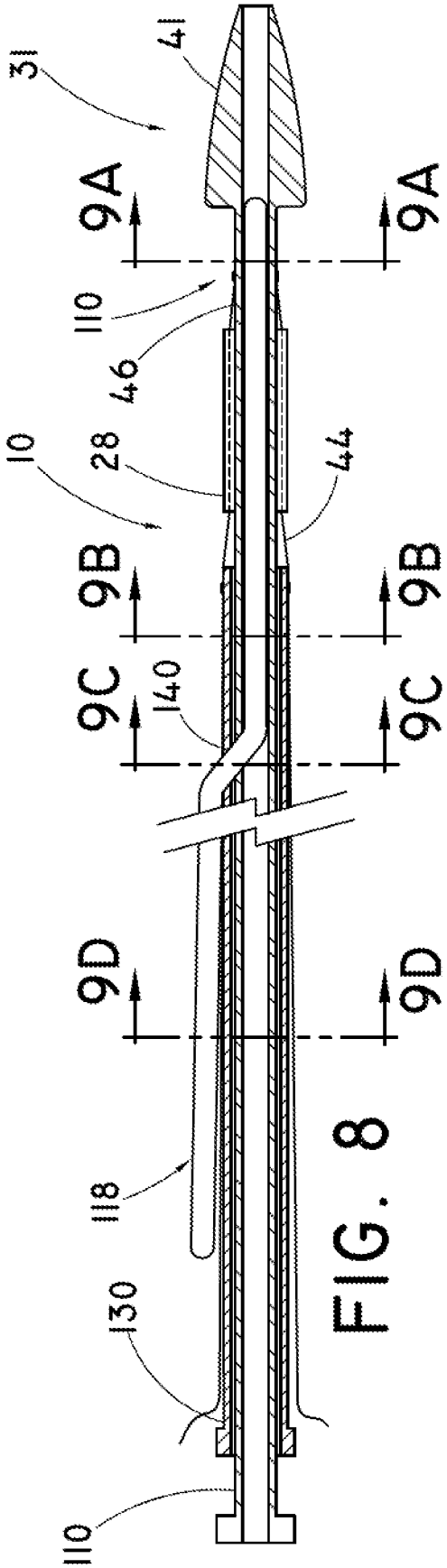

FIG. 8

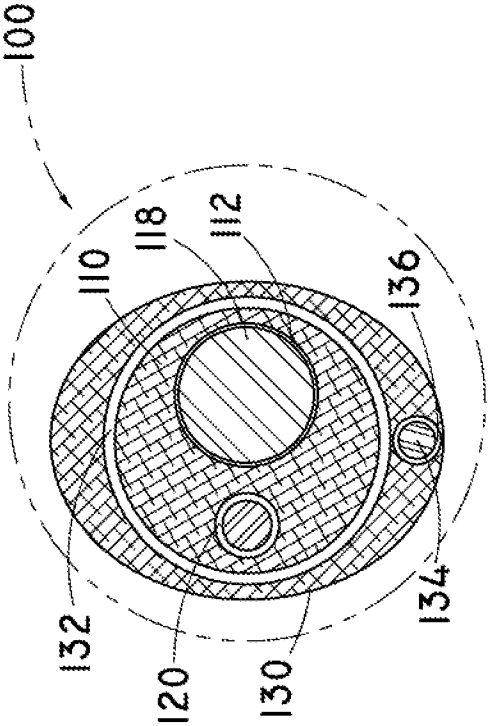

FIG. 9B

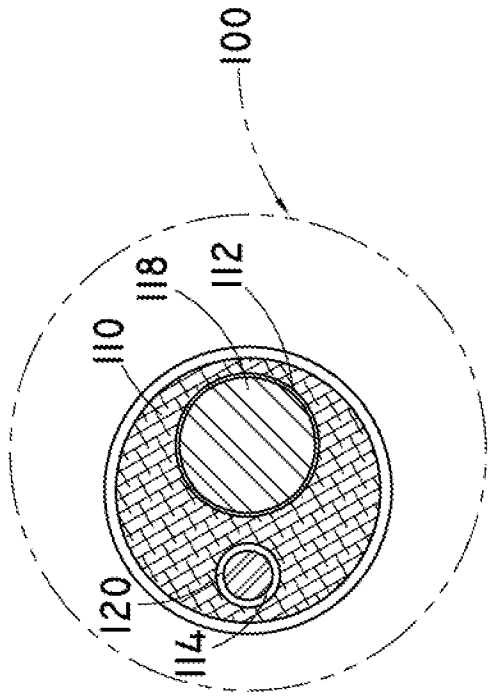

FIG. 9A

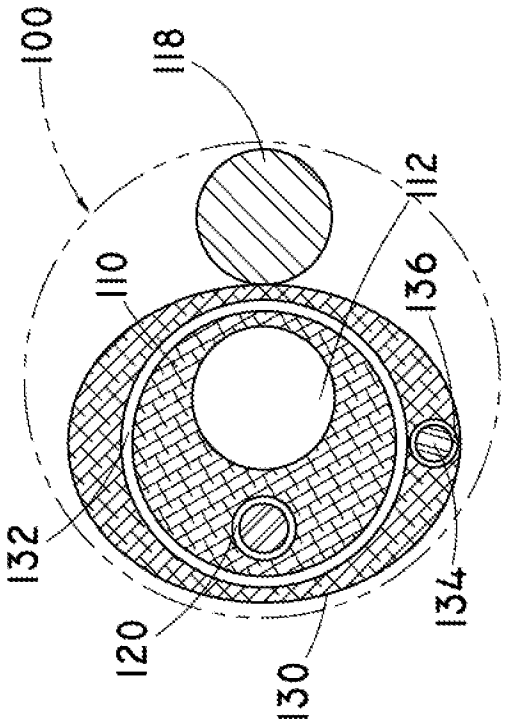
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FIG. 9D

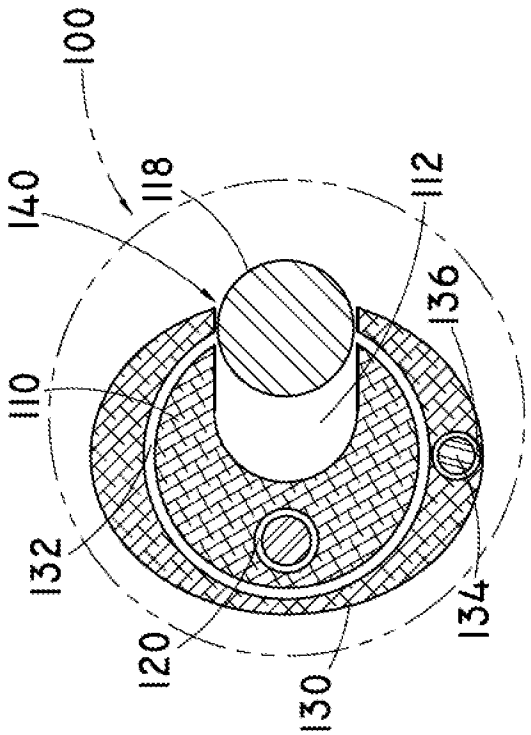
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FIG. 9C

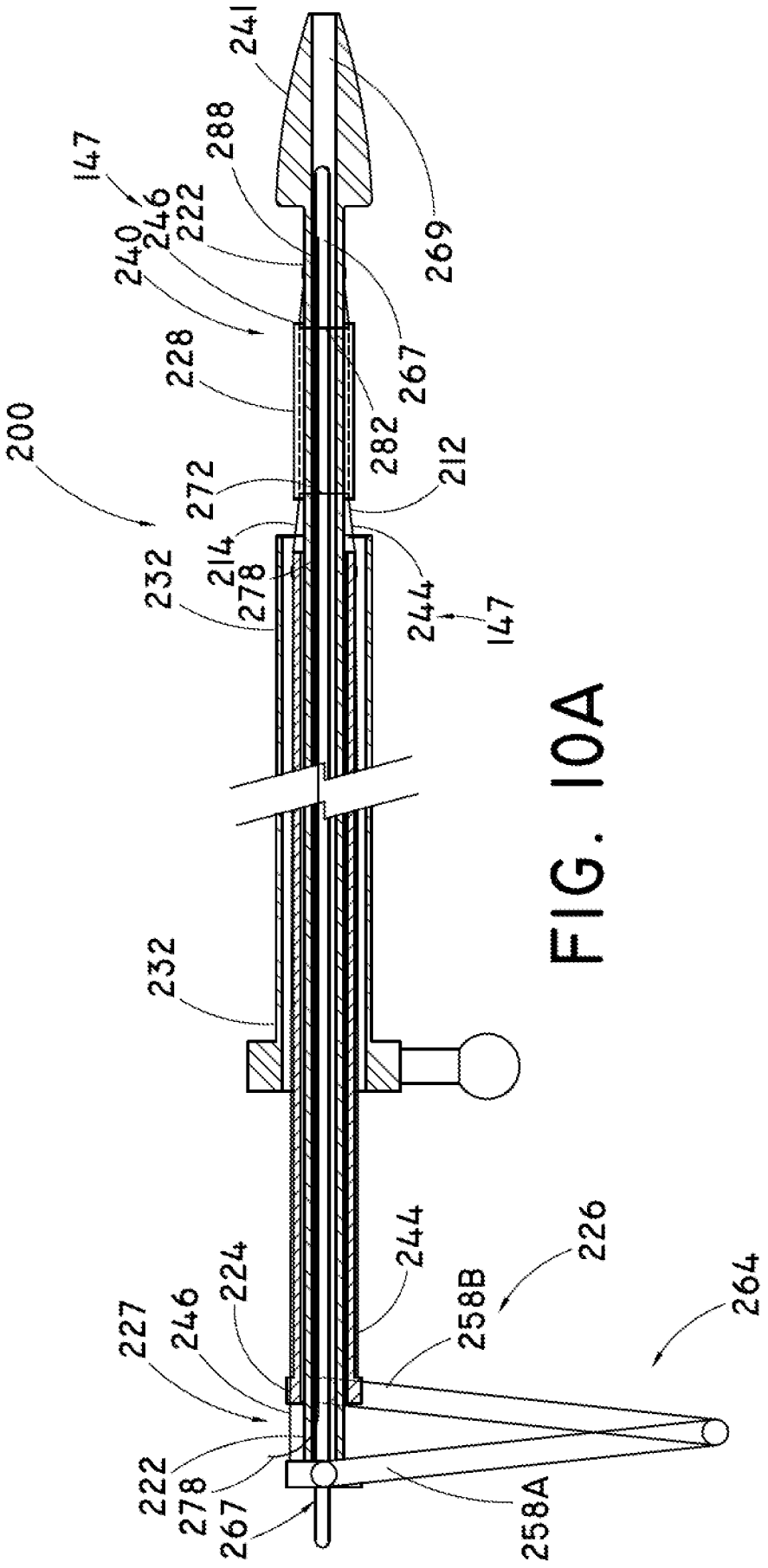
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FIG. 10A

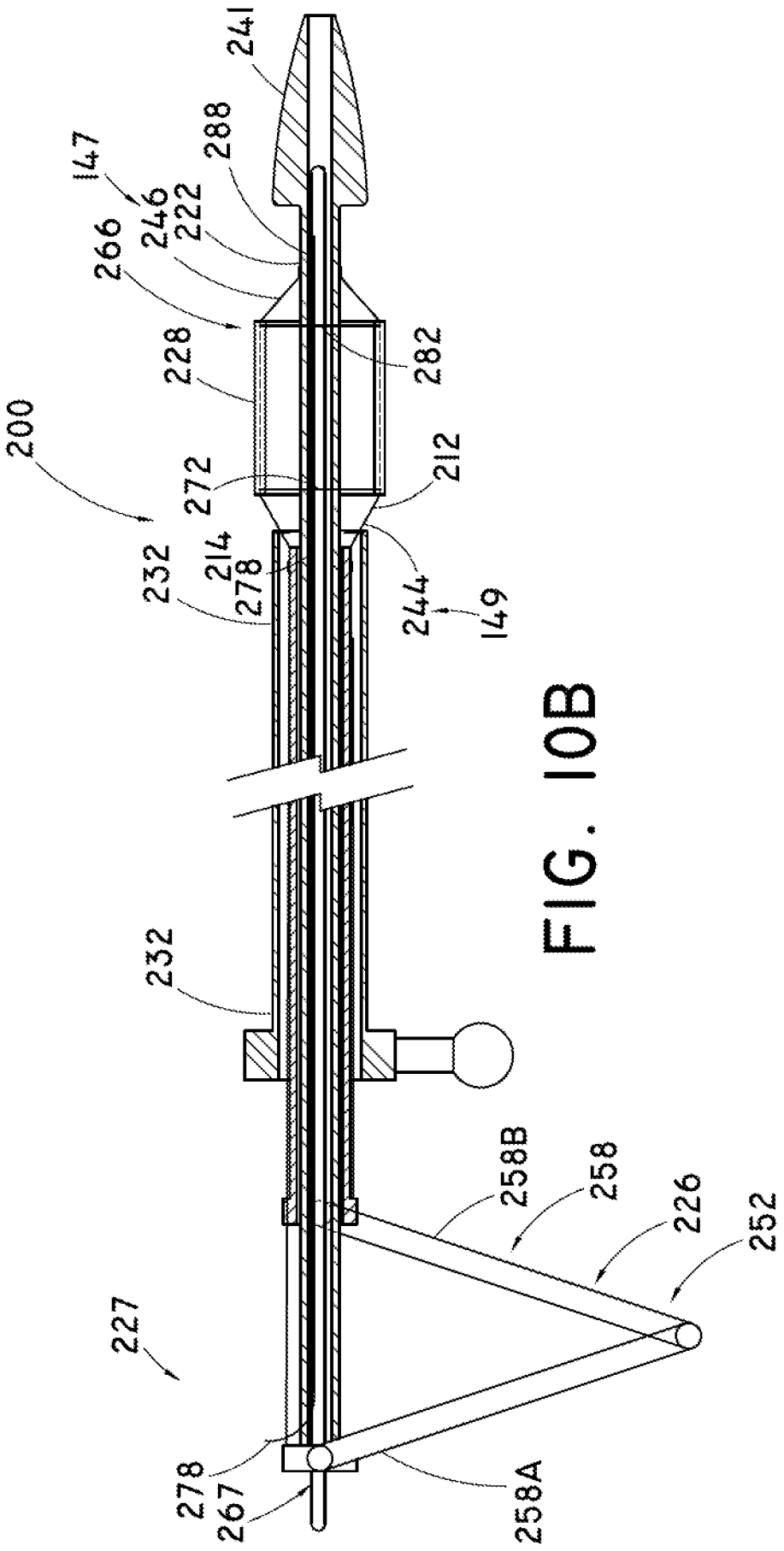
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FIG. 10B

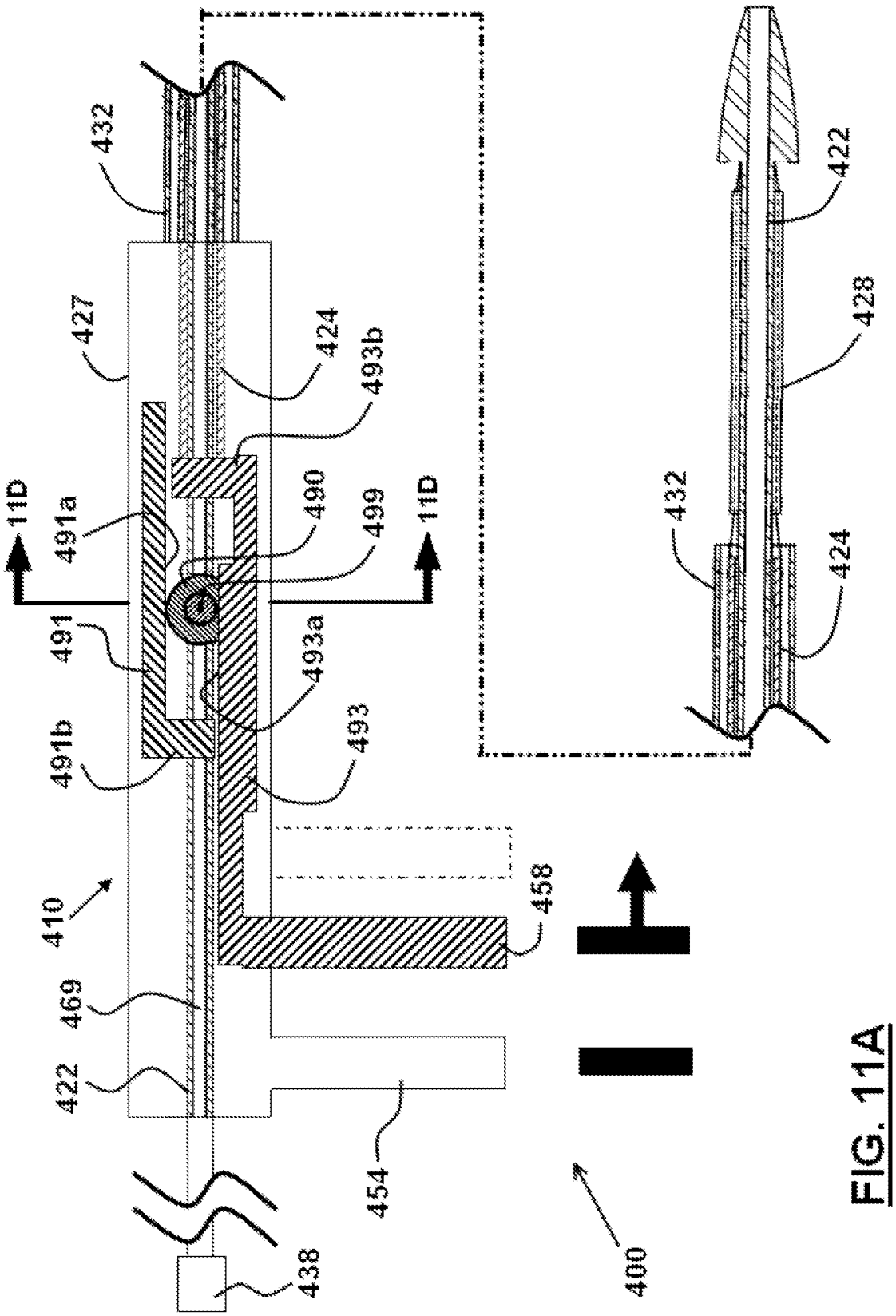
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FIG. 11A

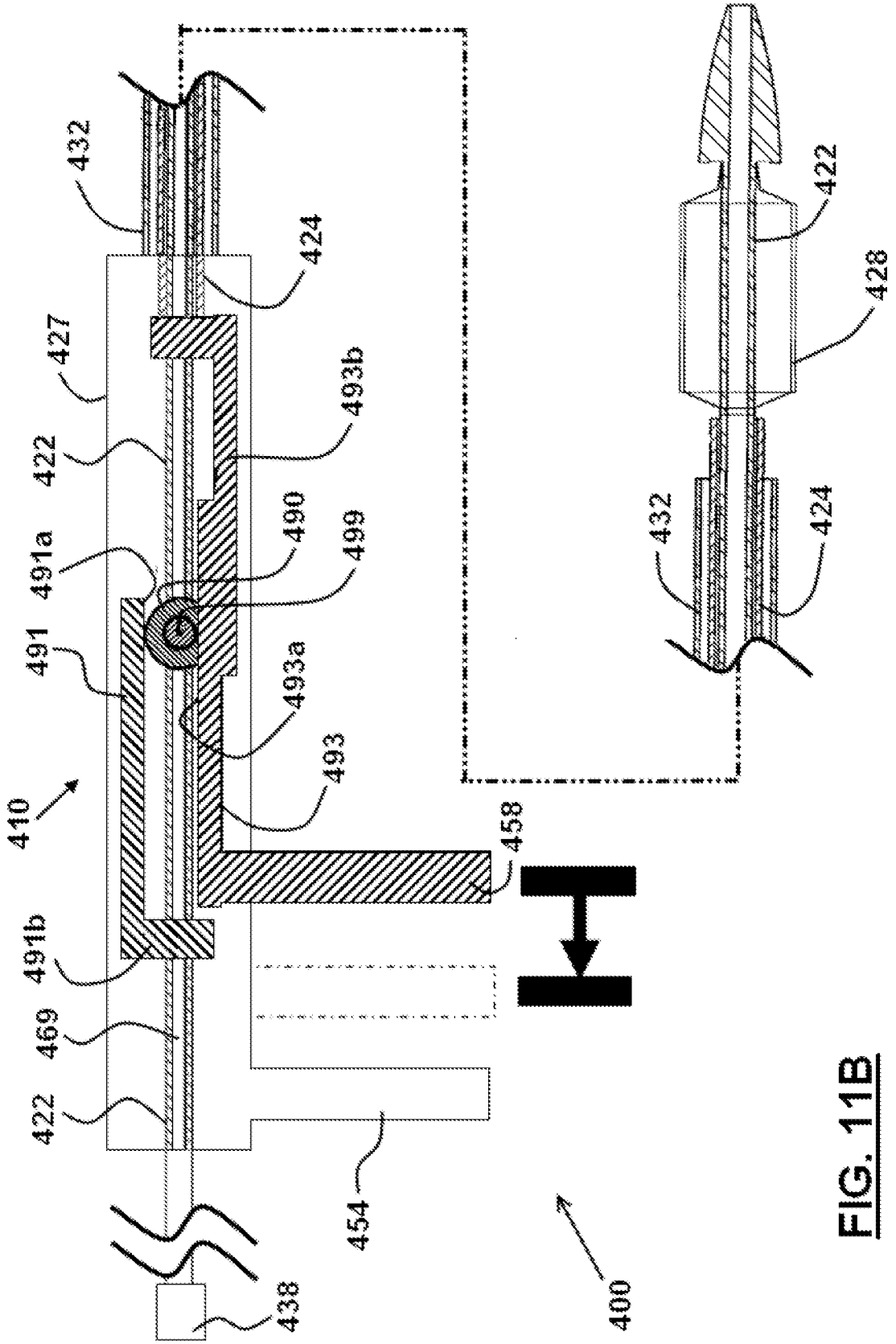
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FIG. 11B

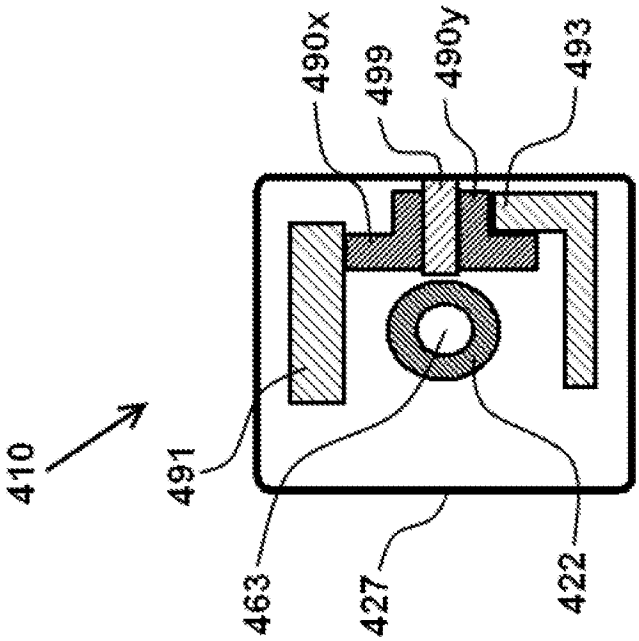

FIG. 11D

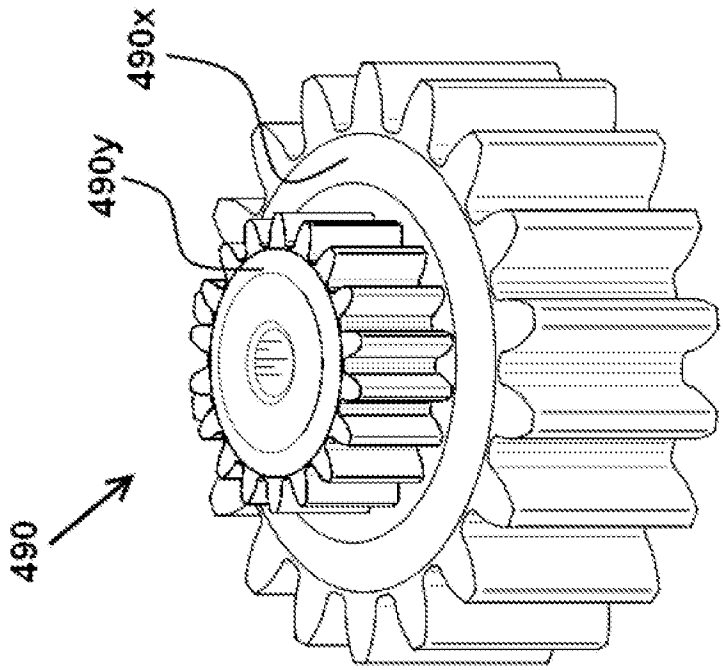

FIG. 11C

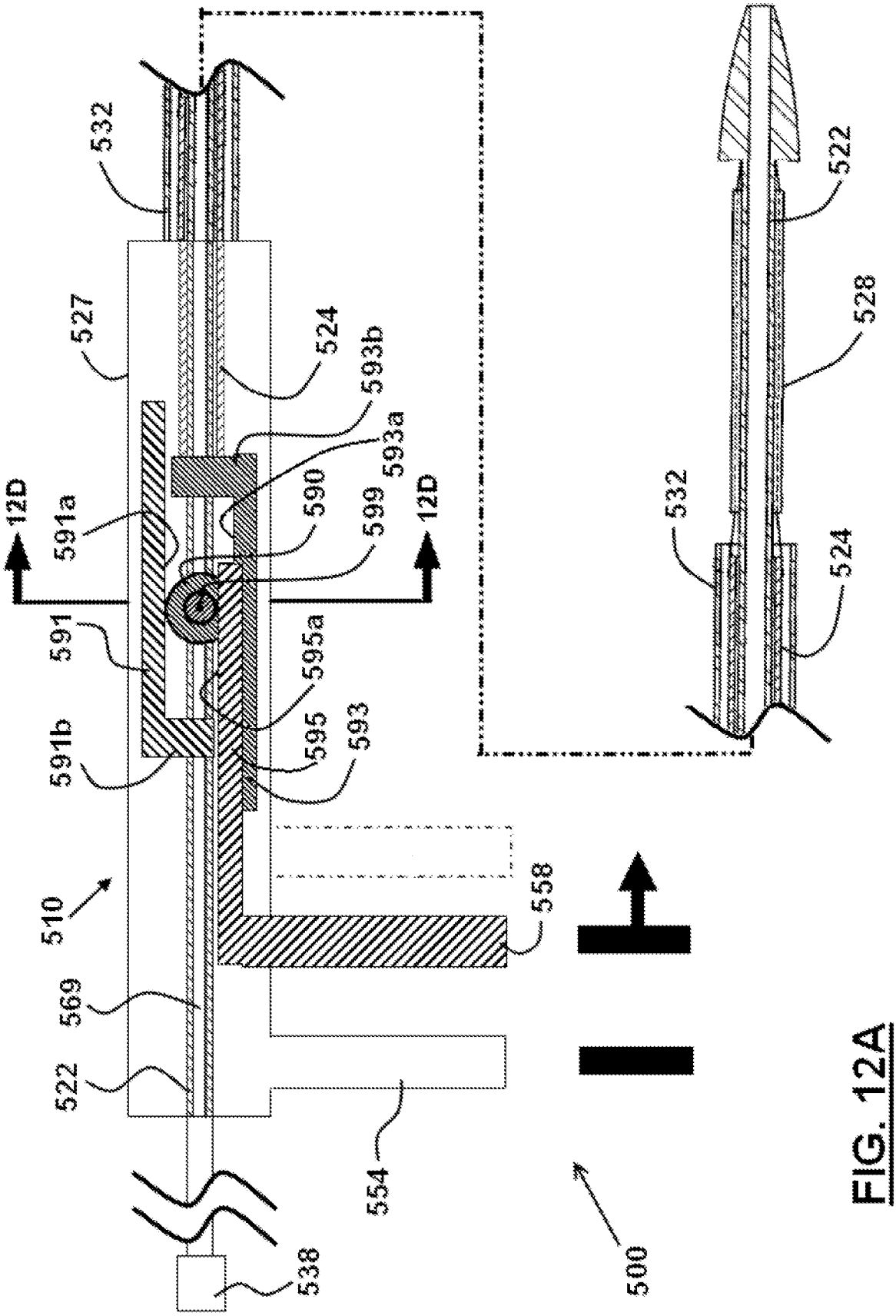
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FIG. 12A

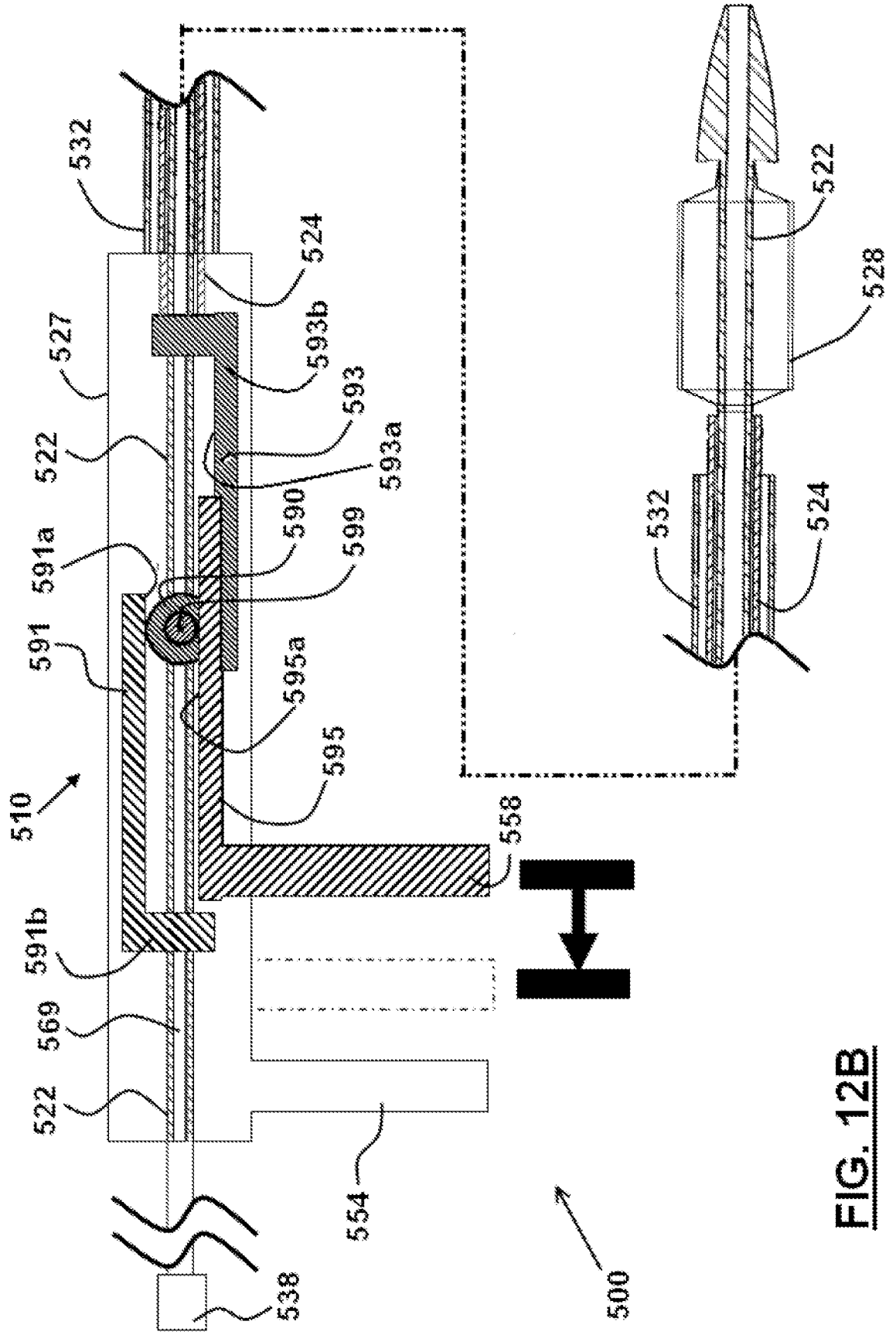
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FIG. 12B

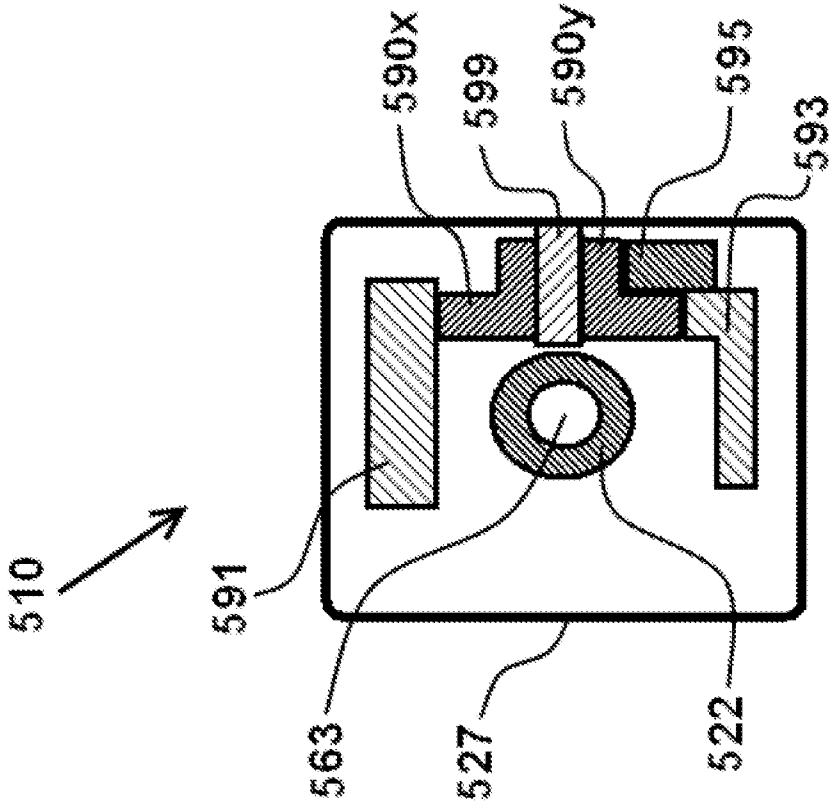

FIG. 12D

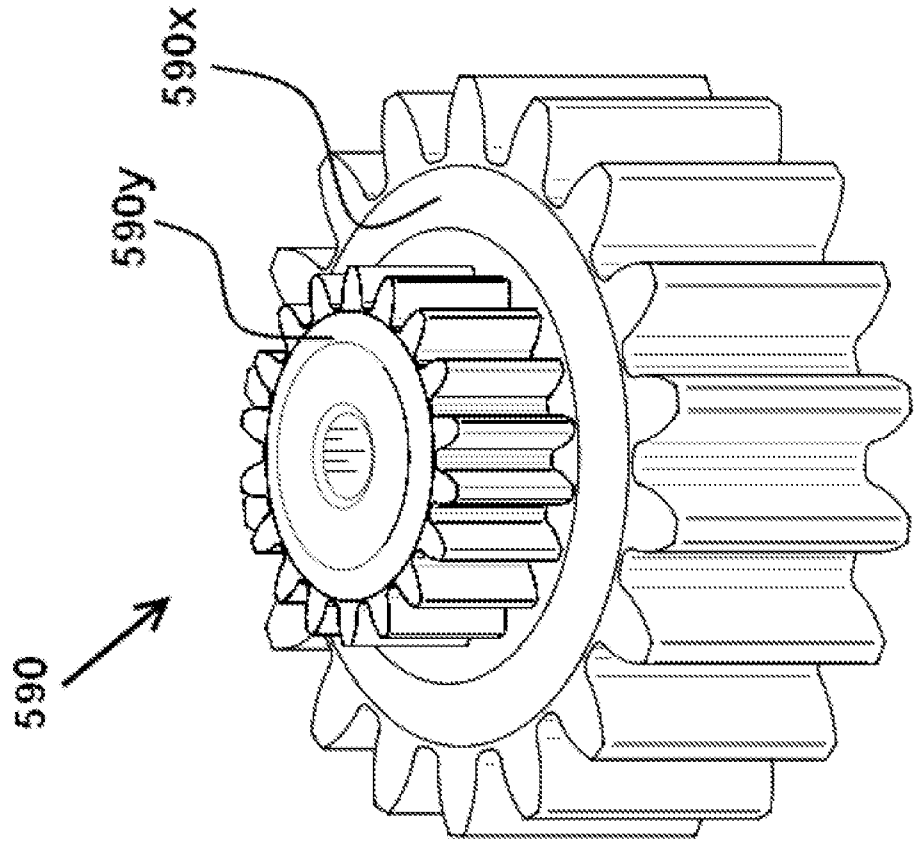

FIG. 12C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/025895

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/962 A61F2/95
ADD.

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

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/262157 A1 (SILVER MICHELE [US] ET AL) 14 October 2010 (2010-10-14) paragraphs [0027] - [0041]; figures 1-7C	1-15,21
X	EP 0 566 807 A1 (SGRO JEAN-CLAUDE [FR] COGENT [FR]) 27 October 1993 (1993-10-27) column 4, lines 23-53; figures 6-8	1-15,21
A	WO 2008/042266 A2 (COOK INC [US]; YI TSENG DAVID [US]; LLORT FRANCISCO M [US]) 10 April 2008 (2008-04-10) page 31, line 6 - page 34, line 2; figures 12-18 page 54, line 21 - page 56, line 2; figures 67,68	1-15,21
A	US 2003/191516 A1 (WELDON JAMES [US] ET AL) 9 October 2003 (2003-10-09) paragraphs [0034] - [0039]; figures 2A-2c	1-15,21

☐ 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
31 May 2012	06/06/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Chevalot, Nicolas

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/025895

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. [X] Claims Nos.: 16-20
because they relate to subject matter not required to be searched by this Authority, namely:

The subject-matter of claims 16-20 has not been searched (Rule 39.1(iv) PCT) and no examination of said subject-matter will be carried out (Rule 67.1(iv) PCT): said-subject-matter is related to a method for treatment of the human body by surgery.

2. [ ] Claims Nos.:
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:

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 additional 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 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/US2012/025895

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010262157 A1	14-10-2010	EP 2419062 A2	22-02-2012
		US 2010262157 A1	14-10-2010
		WO 2010120415 A2	21-10-2010
EP 0566807 A1	27-10-1993	DE 69220355 D1	17-07-1997
		DE 69220355 T2	25-09-1997
		EP 0566807 A1	27-10-1993
		ES 2104880 T3	16-10-1997
		FR 2671280 A1	10-07-1992
WO 2008042266 A2	10-04-2008	AT 544428 T	15-02-2012
		AU 2007305383 A1	10-04-2008
		EP 2066269 A2	10-06-2009
		ES 2382364 T3	07-06-2012
		JP 2010504820 A	18-02-2010
		US 2008082154 A1	03-04-2008
		US 2008082158 A1	03-04-2008
		US 2008082159 A1	03-04-2008
		WO 2008042266 A2	10-04-2008
US 2003191516 A1	09-10-2003	AT 347867 T	15-01-2007
		AU 2003225873 A1	20-10-2003
		CA 2478474 A1	16-10-2003
		DE 60310392 T2	31-10-2007
		EP 1494620 A1	12-01-2005
		JP 4448697 B2	14-04-2010
		JP 2005521514 A	21-07-2005
		US 2003191516 A1	09-10-2003
		WO 03084439 A1	16-10-2003