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(54) **Title**: CATHETER SYSTEM

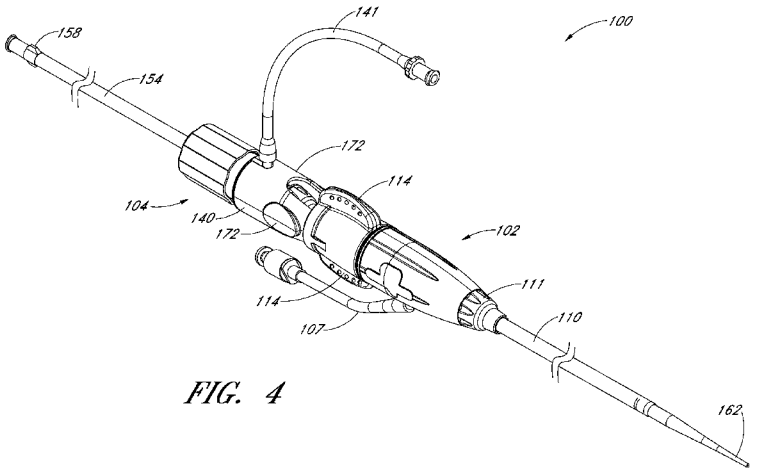

FIG. 4

(57) **Abstract**: Embodiments are directed to a catheter system (100) comprising an introducer (102) having a main body (106), an introducer sheath (110) projecting from the main body, and a first seal supported within the introducer and a catheter (104) having a main body (140), an outer sheath (122) projecting from the main body, a second seal supported within the catheter, and an inner core (154) configured to be advanced axially through the main body, the second seal, and the outer sheath. The introducer can be configured to be selectively engageable with the catheter so that the catheter can be selectively and removably linked with the introducer in the axial direction. The catheter system can also be configured such that, when the introducer and the catheter are linked, the catheter can be rotatable relative to the introducer. The introducer can be configured to radially restrain an endoluminal prosthesis.

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CATHETER SYSTEM

PRIORITY CLAIM AND INCORPORATION BY REFERENCE

[0001] This application claims the benefit under 35 U.S.C. § 119 of U.S. Provisional Patent Application No. 61/077,429, filed July 1, 2008 (entitled "CATHETER SYSTEM AND METHODS OF USING SAME"), and U.S. Provisional Patent Application No. 61/184,742, filed June 5, 2009 (entitled "CATHETER SYSTEM AND METHODS OF USING SAME"), the entirety of each of which is hereby incorporated by reference as if fully set forth herein.

BACKGROUND OF THE INVENTION

Technical Field

[0002] The present invention relates to catheter systems, in particular, catheter systems having an introducer.

Description of the Related Art

[0003] Introducers or introducer sheaths are used for minimal invasive placement of catheters into blood vessels. They typically consist of a tubing that is inserted into the blood vessel and a seal or valve at the proximal end of the tubing which is positioned outside of the body. The seal provides a hemostasis seal against blood loss. Catheters used for diagnostic or therapeutic means are typically passed through the introducer into the blood vessel. The introducer sheath thus provides continuous access for catheters, protects the inner wall of the blood vessel against damage during catheter insertion, and provides a hemostasis seal against blood loss.

[0004] There are situations in which the catheters require substantial maneuvering within the blood vessel. For example, placement of a stent or stent graft may require the delivery catheter to be positioned precisely axially as well as possible rotationally into a specific location within the blood vessel. In addition deployment of the stent may require precise operation of the delivery system within the introducer. In these situations, the operator has to carefully control both the position of the introducer and the delivery system. This sometimes requires assistance by a second operator.

SUMMARY OF THE INVENTION

[0005] Some embodiments disclosed herein pertain to a catheter system for the insertion and positioning of diagnostic or therapeutic devices into blood vessels. In some embodiments, the system comprises an introducer or an introducer sheath and at least one catheter. The catheter can be introduced through the introducer into the blood stream. A docking mechanism can engage the proximal end of the introducer with the proximal end of the catheter and can prevent axial movement between the introducer and the catheter.

[0006] In some embodiments, a catheter system can comprise an introducer and a catheter, wherein the introducer can comprise a sheath (that can be tubular) and a seal that can be an adjustable hemostasis valve connected to the proximal of the sheath. The introducer can define a proximal end and a distal end, and the catheter can be configured to engage with the proximal end of the introducer. The introducer and the catheter can be configured such that the catheter can be slidingly received within the introducer. The introducer and the catheter can be configured such that the catheter can removably engage with the introducer such that, when the catheter is engaged with the introducer, the catheter will be axially fixed to the introducer so as to prevent substantial axial movement between the introducer and the catheter and so that the catheter and introducer can be manipulated in an axial direction as a single unit.

[0007] Additionally, in some embodiments, the catheter and introducer can be configured such that, when the catheter is engaged with the introducer, an inner core of the catheter can be rotatable relative to the introducer and the introducer sheath. Further, in some embodiments, the catheter can be configured such that the inner core of the catheter can be locked or substantially prevented from rotational movement relative to the outer sheath of the catheter and/or relative to the introducer.

[0008] In some embodiments, a method of placement of a catheter into a blood vessel is provided, wherein the catheter is passed through an introducer sheath and the proximal end of the introducer sheath physically engages with, or is removably docked with, the catheter to prevent substantial axial motion between the introducer sheath and the catheter.

[0009] Some stents or stent grafts (collectively referred to herein as a stent or stents) may require precise placement in both axial and circumferential direction. For example, stents or stent grafts with fenestrations require accurate placement of the fenestration at the branch vessel. The embodiments of the catheter systems disclosed herein can be configured to allow for the rotation of the delivery catheter and, hence, the stent, relative to the introducer sheath. In tight and calcified vessels there is often considerable friction between the outer sheath of the catheter and the vessel wall. In some of the embodiments disclosed herein, the delivery catheter and introducer can be configured such that the outer sheath of the delivery catheter will not be in direct contact with the vessel wall during the stent delivery procedure. Rather, in some embodiments, some or all of the length of the outer sheath of the delivery catheter can be contained within the introducer sheath, and the introducer sheath can be in direct contact with the vessel wall. This can considerably reduce the force required to rotate the delivery system relative to the patient's vessel. Accordingly, the delivery catheter and the introducer can be configured such that the delivery catheter can be substantially free to rotate within the introducer sheath.

[0010] In some embodiments, the friction that can otherwise impede the rotational freedom of the delivery catheter can be further reduced by lining the inner surface of the introducer sheath with a low-friction coating such as PTFE or applying hydrophilic coating to the outer surface of the delivery catheter or the inner surface of the introducer sheath.

[0011] Thus, in some embodiments, the introducer sheath can remain rotationally static or still while the deployment catheter is rotated within the introducer sheath. This can protect the delivery catheter and stent from being damaged, torqued, or stressed during the rotational manipulation of the delivery catheter and stent, and also prevent any damage or stress on the vessel wall from the rotation of the delivery catheter or stent.

[0012] Additionally, in some embodiments, delivery catheter can be configured to permit a user or medical practitioner to selectively control or prevent the rotational freedom of the delivery catheter and stent relative to the introducer, or the inner core of the delivery catheter and stent relative to the outer sheath of the delivery catheter. For example, in some embodiments, the delivery catheter can comprise a threaded hub supported at the proximal end portion of the delivery catheter configured to selectively constrict or tighten against an

outer wall of the inner core of the delivery catheter. By constricting the hub against the inner core, the inner core can be prevented or inhibited from rotating relative to the introducer. By loosening the hub relative to the inner core, the rotational freedom of the inner core or delivery catheter relative to the introducer sheath can be restored.

[0013] In some embodiments, the hemostasis valve of the introducer sheath can be opened and closed by rotating the handle of the introducer sheath so as to be adjustable. Active adjustment of the hemostasis valve may be desired to seal against catheters with a wide range of diameters. The docking mechanism can allow the handle of the introducer sheath to be operated (i.e. rotated) while a catheter is inserted in and docked to the introducer sheath. Furthermore, the catheter can be rotationally locked by closing the valve.

[0014] Some embodiments are directed to a catheter system that can comprise an introducer comprising a main body, a introducer sheath projecting from the main body, and a first seal (which can be a rubber seal, an interference or close tolerance fit between adjacent components, an adjustable hemostasis valve, or any other suitable sealing component or feature) supported within the introducer, and a catheter comprising a main body, a outer sheath projecting from the main body, a second seal (which can be a rubber seal, an interference or close tolerance fit between adjacent components, an adjustable hemostasis valve, or any other suitable sealing component or feature) supported within the catheter, and an inner core that is advanceable through the main body, the second seal, and the outer sheath. The first seal can be configured to at least inhibit a flow of blood through the introducer when the catheter is engaged with the introducer. The second seal can be configured to at least inhibit a flow of blood through the catheter. The introducer sheath can be configured to axially receive at least the inner core therethrough. In some embodiments, the introducer can be configured to be selectively engageable with the catheter so that the catheter can be selectively and removably linked with the introducer in the axial direction such that, when the introducer and the catheter are linked, the axial movement of either of the introducer and the catheter will cause the simultaneous and equal axial movement of the other of the introducer and the catheter. In some embodiments, the catheter system can be configured such that, when the introducer and the catheter are linked, the catheter is rotatable relative to the introducer.

[0015] Some embodiments are directed to a catheter system that can comprise an introducer comprising a main body and an introducer sheath projecting from the main body, a catheter comprising a main body, a outer sheath projecting from the main body, and an inner core that is advanceable through the main body and the outer sheath. In some embodiments, the inner core can be configured to axially support a stent such that the stent can be advanced through the outer sheath by advancing the inner core through the outer sheath. The outer sheath can be configured to radially restrain the stent so that no additional radial restraint is required. In some embodiments, the outer sheath can be configured to radially restrain the stent in addition to other forms of restraint. The introducer sheath can be configured to axially receive at least the inner core therein. In some embodiments, the catheter system can be configured such that the outer sheath of the catheter does not advance into the introducer sheath when the catheter is fully axially advanced into the introducer. In some embodiments, the introducer sheath can be configured to directly radially restrain the stent while the stent is positioned within the introducer sheath.

[0016] Therefore, in some embodiments, the outer sheath of the catheter and the introducer sheath can be configured to provide a lumen having a generally uniform cross-sectional size through the catheter system through which the endoluminal prosthesis can be advanced. In some embodiments, the lumen through the catheter system through which the endoluminal prosthesis can be advanced can be substantially continuous, so that the endoluminal prosthesis can be advanced through the catheter system without the prosthesis being obstructed by or snagging on any components or features of the catheter system as it is being advanced. In some embodiments, the lumen can be substantially continuous but have short gaps on the order of approximately 1 mm to approximately 3 mm in the lumen such as, without limitation, adjacent to the distal end of the outer sheath of the catheter and/or adjacent to the proximal end of the introducer sheath. Further, in some embodiments, one or more surfaces of other components comprising the catheter or the introducer in addition to the outer sheath and the introducer sheath, such as without limitation the main body of the introducer, can form portions of the lumen through the catheter system.

[0017] Some embodiments are directed to a method of deploying a stent in a blood vessel, comprising positioning an introducer within a patient's blood vessel so as to

advance an introducer sheath of the introducer into the patient's blood vessel, the introducer having a proximal end portion and a distal end portion, advancing an outer sheath of a catheter into the introducer so that an end portion of the outer sheath of the catheter is positioned approximately adjacent to the proximal end portion of the introducer sheath and such that no portion of the outer sheath overlaps the introducer sheath, the catheter further comprising an inner core that is axially moveable within the outer sheath, axially supporting a stent with the inner core, axially advancing the inner core and the stent through the outer sheath of the catheter, through the introducer sheath, and past the distal end of the introducer sheath, and deploying the stent in the blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] These and other features, aspects and advantages will now be described in connection with certain embodiments, in reference to the accompanying drawings. The illustrated embodiments, however, are merely examples and are not intended to be limiting. The following are brief descriptions of the drawings.

[0019] Figure 1A is a schematic representation of an embodiment of a catheter system comprising a docking arrangement to physically engage a catheter with an introducer sheath.

[0020] Figure 1B is a schematic representation of the embodiment of the catheter system shown in Figure 1A, showing the catheter engaged with the introducer sheath.

[0021] Figure 2A is a schematic representation of another embodiment of a catheter system comprising a docking arrangement to physically engage a catheter with an introducer sheath.

[0022] Figure 2B is a schematic representation of the embodiment of the catheter system shown in Figure 2A, showing the catheter engaged with the introducer sheath.

[0023] Figure 2C is a schematic representation of the embodiment of the catheter system shown in Figure 2A, showing a mechanism for disengaging the catheter from the introducer sheath.

[0024] Figure 3A is a schematic representation of another embodiment of a catheter system comprising a docking arrangement to physically engage a catheter with an

introducer sheath, the catheter system being configured to deliver a stent or stent graft into a blood vessel.

[0025] Figure 3B is a schematic representation of the embodiment of the catheter system shown in Figure 3A, showing the catheter engaged with the introducer sheath.

[0026] Figure 3C is a schematic representation of the embodiment of the catheter system shown in Figure 3A, illustrating the axial insertion of an embodiment of a stent into the tubular sheath of the embodiment of the introducer sheath shown in Figure 3A.

[0027] Figure 3D is a schematic representation of the embodiment of the catheter system shown in Figure 3A, illustrating the embodiment of the stent being deployed after the tubular sheath of the embodiment of the introducer sheath shown in Figure 3A has been retracted from the stent.

[0028] Figure 4 is a perspective view of an embodiment of a catheter system comprising an embodiment of an introducer and an embodiment of a delivery catheter.

[0029] Figure 5 is a perspective view of the embodiment of the introducer shown in Figure 4.

[0030] Figure 6A is a first exploded assembly view of the embodiment of the introducer shown in Figure 5.

[0031] Figure 6B is a second exploded assembly view of the embodiment of the introducer shown in Figure 5.

[0032] Figure 7 is a perspective view of the embodiment of the delivery catheter shown in Figure 4.

[0033] Figure 8A is a first exploded assembly view of the embodiment of the delivery catheter shown in Figure 7.

[0034] Figure 8B is a second exploded assembly view of the embodiment of the delivery catheter shown in Figure 7.

[0035] Figure 9 is a perspective view of the embodiment of the catheter system shown in Figure 4, showing the delivery catheter before the docking mechanism of the delivery catheter has been engaged with the docking mechanism of the introducer.

[0036] Figure 10 is a perspective view of the embodiment of the catheter system shown in Figure 4, showing the delivery catheter after the docking mechanism of the delivery catheter has been engaged with the docking mechanism of the introducer.

[0037] Figure 11 is an end view of the embodiment of the catheter system shown in Figure 4.

[0038] Figure 12 is a section view of the embodiment of the catheter system shown in Figure 4, taken through the line 12-12 of Figure 11.

[0039] Figure 13 is an enlarged section view of the embodiment of the catheter system shown in Figure 4, defined by curve 13-13 of Figure 12.

[0040] Figure 14 is an enlarged section view of the embodiment of the catheter system shown in Figure 4, defined by curve 14-14 of Figure 13.

[0041] Figure 15 is a section view of the embodiment of the catheter system shown in Figure 4, taken through the line 15-15 of Figure 11.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0042] The following detailed description is now directed to certain specific embodiments of the disclosure. In this description, reference is made to the figures wherein like parts are designated with like numerals throughout the description and the drawings. Described below are various embodiments of a catheter system that can comprise an introducer sheath and a docking arrangement. In some embodiments, the catheter systems disclosed herein can be used in diagnostic or therapeutic procedures such as, but not limited to, endoluminal vascular prosthesis deployment procedures.

[0043] Figure 1A is a schematic representation of an embodiment of a catheter system 10 comprising a docking arrangement configured to physically engage a catheter 20 with an introducer 12. Figure 1B is a schematic representation of the catheter system 10 shown in Figure 1A, showing the catheter 20 engaged with the introducer 12. In some embodiments, the catheter 20 or any catheter disclosed herein can be a diagnostic or therapeutic catheter, or any other suitable catheter. In some embodiments, the introducer 12 can comprise a tubular sheath 14, a seal 16, and a female docking mechanism 18. The first seal 16 can be a rubber seal, an interference or close tolerance fit between adjacent

components, an adjustable hemostasis valve, or any other suitable sealing component or feature.

[0044] In some embodiments, the catheter 20 catheter can have a shaft 24 and a male docking mechanism 22. In some embodiments, as illustrated in Fig 1B, the catheter 20 can be inserted into the introducer 12 and the female docking mechanism 18 can be engaged with the male docking mechanism 22. In some embodiments, the docking mechanism can prevent the introducer 12 and the catheter 20 from moving axially with respect to each other when the docking mechanism is engaged. Additionally, in some embodiments, the catheter system 10 can be configured so that the catheter 20 can rotate within the introducer 12, even when the catheter 20 is docked with the introducer 12.

[0045] As mentioned, the introducer 12 can comprise a tubular introducer sheath 14 and a seal 16 (which, again, can be a rubber seal, an interference or close tolerance fit, an adjustable hemostasis valve, or any other suitable sealing component or feature)connected to the proximal end of the introducer sheath 14. In some embodiments, the overall design of the sheath 14 and seal 16 may be similar to the design of commercially available introducers, or any other introducers presently known or later developed. The catheter 20 can have an outside dimensional profile that is sized and/or configured to pass through the introducer sheath 14. As discussed above, in some embodiments, the proximal end of the catheter 20 and the proximal end of the introducer sheath 14 can be configured to permanently or removably engage with each other, and to allow for the rotation of the catheter 20 within the introducer sheath 14 while substantially limiting the axial movement of the catheter 20 with respect to the introducer sheath 14.

[0046] In some embodiments, after engagement of the catheter and introducer, the combined system can be operated by a single operator. As mentioned, the catheter system 10 can be configured so that the catheter 20 can substantially freely rotate within the introducer sheath 14, which can allow for precise rotational positioning of the catheter within the introducer. After completion of the procedure, the catheter 20 can be disengaged from the introducer 12 so that the catheter 20 can be removed from the patient's body. Additionally, the introducer 12 can be repositioned for a second intervention and a second catheter can be inserted and engaged with the introducer 12 for additional procedures.

[0047] Figure 2A is a schematic representation of an embodiment of a catheter system 40 comprising a docking arrangement to physically engage a catheter 50 with an introducer 42. Figure 2B is a schematic representation of the embodiment of the catheter system 40, showing the catheter 50 engaged with the introducer 42. Figure 2C is a schematic representation of the embodiment of the catheter system 40 shown in Figure 2A, showing a mechanism for disengaging the catheter 50 from the introducer 42.

[0048] In particular, Figure 2C schematically illustrate that the catheter 50 can be disengaged from the male docking mechanism 52 and the introducer 42 by compressing the levers or tabs 56. Accordingly, in the illustrated embodiment, the male docking mechanism 52 can be elongated and can comprise levers 56.

[0049] Figure 3A is a schematic representation of another embodiment of a catheter system 60 comprising a docking arrangement to physically engage a catheter 70 with an introducer 62, the catheter system 60 being configured to deliver a stent or stent graft 80 into a blood vessel. Figure 3B is a schematic representation of the embodiment of the catheter system 60 shown in Figure 3A, showing the catheter 70 engaged with the introducer 62. Figure 3C is a schematic representation of the embodiment of the catheter system 60 shown in Figure 3A, illustrating the axial insertion of an embodiment of a stent or stent graft 80 into the tubular sheath 64 of the embodiment of the introducer 62 shown in Figure 3A. Figure 3D is a schematic representation of the embodiment of the catheter system 60 shown in Figure 3A, illustrating the embodiment of the stent 80 being deployed after the tubular sheath 64 of the embodiment of the introducer 62 shown in Figure 3A has been retracted from the stent 80.

[0050] Self-expanding stent or stents grafts are typically retained in a deployment sheath within the delivery catheter. The deployment sheath can protect the stent or stent graft and the vessel wall from damage during insertion and can retain the stent or stent graft in a collapsed low-profile configuration during delivery. The stent or stent graft can be deployed in the desired position of the blood vessel by removing the deployment sheath and allowing the stent or stent graft to radially expand against the wall of the blood vessel. In order to pass such a delivery catheter into the desired blood vessel, the catheter system can be configured so that the inner diameter of the introducer sheath is larger than the outer diameter of the

deployment sheath. Clinicians prefer a low profile of the introducer sheath to minimize damage to the blood vessel and allowing for access into small blood vessels. It can be desired to minimize the profile of the delivery catheter.

[0051] Cartridge systems have been developed, in which the stent or stent graft can be transferred from delivery sheath into the introducer sheath and the stent or stent graft can be passed through the introducer sheath to the target location. In such a cartridge system, the introducer sheath effectively acts as a deployment sheath. The transfer eliminates the need of a second sheath and minimizes the profile of the system in the blood vessel. The docking arrangement of the current invention provides a secure engagement of the delivery catheter and the introducer sheath prior to transfer of the stent or stent graft into the introducer sheath. This prevents potential user errors in the transfer and further converts the delivery catheter and introducer sheath into a single-user system.

[0052] As illustrated in Figures 3A-3D, the catheter system 60 can be used to transfer and deploy a stent or stent graft 80 into a blood vessel (blood vessel not shown). As illustrated therein, the introducer 62 can comprise a tubular sheath 64 that can be inserted into the body of the patient. The proximal end 62a of the introducer 62 can be sized and/or configured to accommodate the deployment sheath 74 of the catheter 70. The introducer sheath can also have a seal 66 (referred to herein as a first seal) and a female docking mechanism 68, similar to any of the embodiments of the seal, hemostasis valve, and/or docking mechanisms described above. The seal 66 can be an annular rubber seal (as illustrated), an interference or close tolerance fit between adjacent components, an adjustable hemostasis valve, or any other suitable sealing component or feature. The stent delivery catheter 70 can comprise an inner core 78, a pocket 82 that can house the collapsed stent 80, a deployment sheath 74 that can retain the collapsed stent 80, and a catheter tip 76.

[0053] As illustrated in Figure 3B, in some embodiments, the catheter 70 can be inserted into the introducer 62 when the docking mechanisms 68 and 72 are engaged. In some embodiments (not illustrated), the deployment sheath 74 of the delivery catheter 70 can be sized and configured to be received within the larger diameter proximal end 62a of the introducer sheath and to extend into the distal tubular sheath 64 of the introducer 62. Alternatively, in some embodiments, the deployment sheath 74 of the delivery catheter 70

can be sized and configured to be received within the larger diameter proximal end 62a of the introducer sheath but not the distal tubular sheath 64 of the introducer 62. In some embodiments, as illustrated in Figures 3C and 3D, the deployment sheath 74 and the tubular sheath 64 can be sized and configured such that, when the deployment sheath 74 has advanced through the proximal end 62a of the introducer sheath, the similar size or shape of the distal tubular sheath 64 can prevent the deployment sheath 74 from advancing through the distal tubular sheath 64. In some embodiments, the inner and/or outer diameters of the deployment sheath 74 and the tubular sheath 64 can be substantially the same.

[0054] As illustrated in Figure 3C, in some embodiments, the inner core 78 of the catheter 70 can be pushed distally, thereby transferring the stent 80 from the deployment sheath 74 into the tubular sheath 64 of the introducer 62. The stent 80 can be advanced until the catheter tip 76 reaches the distal end of the tubular sheath 64. In this configuration, the catheter/introducer system effectively becomes a single-unit deployment catheter. Thus, in some embodiments, the tubular sheath 64 can function as a deployment sheath. In some embodiments, the stent 80 can be advanced in a collapsed configuration within the protective introducer 62 to the target location in the blood vessel without increasing the profile of the delivery system. If the delivery catheter were passed through a traditional introducer sheath, the sheath of the introducer would have to be of a larger diameter than the deployment sheath of the delivery catheter in order to accommodate the stent and the deployment sheath.

[0055] Figure 4 is a perspective view of another embodiment of a catheter system 100 comprising an introducer catheter 102 (also referred to as an introducer) and a delivery catheter 104. The delivery catheter 104 can be configured for the delivery of an endoluminal prosthesis, or for any other suitable use. Therefore, the embodiments of the catheters and introducers disclosed herein can be configured for any suitable purpose, and the embodiments of the introducers disclosed herein can be configured to receive any suitable catheter design.

[0056] Figure 5 is a perspective view of the embodiment of the introducer 102 of the embodiment of the catheter system 100 shown in Figure 4. Figures 6A and 6B are a first and a second exploded assembly view of the embodiment of the introducer 102 shown in Figure 5. With reference to Figures 4-6, in some embodiments, the introducer 102 can have a main body 106, a threadably engageable hub portion 108, an introducer sheath 110, and a

threaded cap 111 configured to threadably engage with a threaded end portion of the main body 106.

[0057] In some embodiments, a first tube 107 can be supported by the main body 106 so as to provide an orifice or access port into the main body 106. The first tube 107 can be used to flush the introducer 102 with saline or other suitable substances at any stage, such as but not limited to prior to the advancement of an endoluminal prosthesis through the introducer 102, or prior to other procedures for which an introducer may be used. The first tube 107 can support any suitable medical connector and/or valve on the distal end thereof.

[0058] The introducer sheath 110 can have an elongate portion 110a extending to any predetermined or desired length. As will be discussed in greater detail below, similar to the introducer 12 of the catheter system 10 described above, in some embodiments, the introducer sheath 110 can be configured such that an endoluminal prosthesis that is advanced into the introducer sheath 110 can be constrained or restrained by the introducer sheath 110. In this arrangement, the inside and/or outside diameter of the introducer sheath 110 can be approximately the same as or similar to the inside and/or outside diameter of the outer sheath of a delivery catheter that is engaged with the introducer 102. In some embodiments, the elongate portion 110a can be circular in cross-section (as illustrated), or can define any suitable cross-sectional shape such as without limitation triangular, square, hexagonal, octagonal, or polygonal.

[0059] Further, as shown most clearly in Figure 6A, the introducer sheath 110 can have a flared end portion 110b that can be configured to abut against a fore surface 106a of the main body 106. With reference to Figure 6A, the elongate portion 110a of the introducer sheath 110 can pass through an opening formed in the cap 111 so that the flared portion 110b of the introducer sheath 110 can be engaged with and/or overlap an inside surface of the cap 111. In this configuration, the cap 111 supporting the introducer sheath 110 can be threadedly engaged with the main body 106 so that the introducer sheath 110 can be supported by the main body 106.

[0060] Additionally, with reference to Figures 6A and 6B, a tubular support or spacer 109 can be inserted over the elongate portion 110a of the introducer sheath 110 and positioned approximately adjacent to the flared portion 110b. The tubular spacer 109 can

improve the fit and, hence, the seal between the outside surface of the introducer sheath 110 and the cap 111. The tubular spacer 109 can also provide additional support to the introducer sheath 110.

[0061] Figure 7 is a perspective view of the embodiment of the delivery catheter 104 of the embodiment of the catheter system 100 shown in Figure 4. Figures 8A and 8B are a first and second exploded assembly view of the embodiment of the delivery catheter 104 shown in Figure 7. Figure 9 is a perspective view of the embodiment of the catheter system 100 shown in Figure 4, showing the delivery catheter 104 before the docking mechanism of the delivery catheter 104 has been engaged with the docking mechanism of introducer 102. Figure 10 is a perspective view of the embodiment of the catheter system 100 shown in Figure 4, showing the delivery catheter 104 after the docking mechanism of the delivery catheter 104 has been engaged with the docking mechanism of the introducer 102.

[0062] Figure 11 is an end view of the embodiment of the catheter system shown in Figure 4, with the delivery catheter 104 engaged with the introducer 102. Figure 12 is a section view of the embodiment of the catheter system 100 shown in Figure 4, taken through the line 12-12 of Figure 11. Figure 13 is an enlarged section view of the embodiment of the catheter system 100 shown in Figure 4, defined by curve 13-13 of Figure 12. Figure 14 is an enlarged section view of the embodiment of the catheter system shown in Figure 4, defined by curve 14-14 of Figure 13. Finally, Figure 15 is a section view of the embodiment of the catheter system shown in Figure 4, taken through the line 15-15 of Figure 11.

[0063] As shown most clearly in Figures 12 and 15, the hub portion 108 of the introducer 102 can have a docking mechanism or flange 112 or can be configured to removably receive or engage with the delivery catheter 104. In some embodiments, as in the illustrated embodiment, the docking mechanism 112 of the introducer 102 can be configured to be a female receiver, configured to receive a male docking member of the catheter 104, as will be described below. In some embodiments, the hub portion 108 can comprise one or more tabs 114 configured to improve a user's grip on the hub portion 108, and ability to rotate the hub portion 108 relative to the main body 106.

[0064] With reference to Figures 12, 13, and 15, some embodiments of the seal portion of the introducer 102 will be described. As mentioned above, the hub portion 108

can be configured to be threadably engageable with the main body 106. In some embodiments, the main body 108 can define an inner annular surface 116 that can be angled (so as to not be perpendicular to the axial centerline of the catheter system 100). In some embodiments, the surface 116 can be angled approximately 75 degrees relative to the axial centerline of the catheter system 100, or from approximately 65 degrees or less to approximately 80 degrees or more relative to the axial centerline of the catheter system 100. In some embodiments, the surface 116 can be approximately perpendicular to the axial centerline of the catheter system 100.

[0065] Similarly, in some embodiments, the hub portion 108 can define an inner annular surface 118 that can be angled so as to not be perpendicular to the axial centerline of the catheter system 100. In some embodiments, the surface 118 of the hub portion 108 can be angled approximately 75 degrees relative to the axial centerline of the catheter system 100, or from approximately 65 degrees or less to approximately 80 degrees or more and relative to the axial centerline of the catheter system 100 in a direction that is opposite to the direction of the angle defined by the surface 116 of the main body 106. In some embodiments, as in the illustrated embodiment, the shape and angular orientation of the surface 118 of the hub portion 108 can approximately mirror the shape and angular orientation of the surface 116 of the main body 106. In some embodiments, the surface 118 can be approximately perpendicular to the axial centerline of the catheter system 100.

[0066] An annular seal member 120 can be supported by the introducer 102 and positioned between the surface 116 of the main body 106 and the surface 118 of the hub portion 108. The seal member 120 can be formed from a resilient material, such as silicone, rubber or any other suitable material. The seal member 120 can be configured such that, when the hub portion 108 is threaded onto the main body 106, the surface 118 of the hub portion 108 can be moved axially toward the surface 116 of the main body 106, thereby compressing or squeezing the seal member 120. The relative angles of the surface 116 of the main body 106 and the surface 118 of the hub portion 108 can cause the seal member 120 to be forced against an outer sheath 122 of the delivery catheter 104 or other component of the delivery catheter 104 that is engaged with the introducer 102, thereby creating an adjustable seal between the outer sheath 122 of the delivery catheter 104, which can project distally

from an end portion of the delivery catheter 104, and the introducer 102. In some embodiments, the level of seal can be adjusted by tightening or loosening the hub portion 108 of the introducer 102 relative to the main body 106 of the introducer 102. In some embodiments, the introducer 102 can be configured to provide a seal against devices with a profile ranging from 1 Fr to 20 Fr.

[0067] Alternatively, in some embodiments, any of the seals or seal portions described herein can be an interference or close tolerance fit between adjacent components such as, without limitation, the outer sheath 122 and one or more inside surfaces of the main body 106 or the hub portion 108 of the introducer 102. In some embodiments, any of the seals or seal portions described herein can be an interference or close tolerance fit between the inner core 154 and one or more inside surfaces of the main body 140 or the hub portion 142 of the catheter 104.

[0068] As shown in Figures 7, 8A, and 8B, some embodiments of the delivery catheter 104 can comprise a main body 140 and a hub portion 142 threadably engageable with the main body 140. Some embodiments of the delivery catheter 104 can also have an outer sheath 122 supported by the main body 140. In particular, the outer sheath 122 can be removably supported by the main body 140 using a cap 123 threadably supported by the main body 140. Further, in some embodiments, the outer sheath 122 can have an elongate portion 122a extending to any predetermined or desired length.

[0069] As mentioned above, in some embodiments, the inside and/or outside diameter of the outer sheath 122 of a delivery catheter 104 can be approximately the same as or similar to the inside and/or outside diameter of the introducer sheath 110. In some embodiments, the elongate portion 122a can be circular in cross-section (as illustrated), or can define any suitable cross-sectional shape such as without limitation triangular, square, hexagonal, octagonal, or polygonal.

[0070] The outer sheath 122 can have a flared end portion 122b that can be configured to abut against a fore surface 140a of the main body 140. With reference to Figure 8A, the elongate portion 122a of the outer sheath 122 can pass through an opening formed in the cap 123 so that the flared portion 122b of the outer sheath 122 can be engaged with and/or overlap an inside surface of the cap 123. In this configuration, the cap 123

supporting the outer sheath 122 can be threadedly engaged with the main body 140 as mentioned above so that the outer sheath 122 is supported by the main body 140.

[0071] Additionally, with reference to Figures 8A and 8B, a tubular support or spacer 125 can be inserted over the elongate portion 122a of the outer sheath 122 and positioned approximately adjacent to the flared portion 122b of the outer sheath 122. The tubular spacer 125 can improve the fit and, hence, the seal between the outside surface of the outer sheath 122 and the cap 123. The tubular spacer 125 can also provide additional support to the outer sheath 122.

[0072] Similar to the hub portion 108 of the introducer 102, the hub portion 142 of the delivery catheter 104 can be configured to be threadably engageable with the main body 140 of the delivery catheter 104. In some embodiments, the main body 140 can define an inner annular surface 146 that can be angled so as to not be perpendicular to the axial centerline of the catheter system 100. In some embodiments, the surface 146 can be angled approximately 75 degrees relative to the axial centerline of the catheter system 100, or from approximately 80 degrees or more to approximately 65 degrees or less relative to the axial centerline of the catheter system 100. In some embodiments, the surface 146 can be approximately perpendicular to the axial centerline of the catheter system 100.

[0073] In some embodiments, a second tube 141 can be supported by the main body 140 so as to provide an orifice or access port into the main body 140. The second tube 141 can be used to flush the delivery catheter 104 with saline or other suitable substances at any stage, such as but not limited to prior to the advancement of an endoluminal prosthesis through the delivery catheter 104 and/or introducer 102, or prior to other procedures for which an delivery catheter may be used. The second tube 141 can support any suitable medical connector and/or valve on the distal end thereof.

[0074] Similarly, in some embodiments, the hub portion 142 can define an inner annular surface 148 that can be angled so as to not be perpendicular to the axial centerline of the catheter system 100. In some embodiments, the surface 148 of the hub portion 142 can be angled approximately 75 degrees relative to the axial centerline of the catheter system 100, or from approximately 65 degrees or less to approximately 80 degrees or more relative to the axial centerline of the catheter system 100 in a direction that is opposite to the direction of

the angle defined by the surface 146 of the main body 140. In some embodiments, the surface 148 can be approximately perpendicular to the axial centerline of the catheter system 100.

[0075] Similar to that of the introducer, in some embodiments, a seal or seal portion comprising an annular seal member 150 can be supported by the delivery catheter 104 and positioned between the surface 146 of the main body 140 and the surface 148 of the hub portion 142. The seal member 150 can be formed from a resilient material, such as silicone, rubber or any other suitable material. The seal member 150 can be configured such that, when the hub portion 142 is threaded onto the main body 140, the surface 148 of the hub portion 142 can be moved axially toward the surface 146 of the main body 140, thereby compressing or squeezing the seal member 150. The relative angles of the surface 146 of the main body 140 and the surface 148 of the hub portion 142 can cause the seal member 150 to be forced against the inner core 154 of the delivery catheter 104, thereby creating an adjustable seal between the inner core 154 the outer sheath 122 of the delivery catheter 104.

[0076] In some embodiments, the level of seal can be adjusted by tightening or loosening the hub portion 142 of the delivery catheter 104 relative to the main body 140 of the delivery catheter 104. Additionally, in some embodiments, the rotational freedom of inner core 154 of the delivery catheter 104 can be inhibited or prevented by tightening the seal member 150 as described above. Thus, the force exerted by the seal member 150 on the inner core 154 can be adjusted to permit the inner core 154 and/or other components to rotate relative to the main body 140 and hub portion 142 of the delivery catheter 104. As illustrated in Figure 4, an end portion or cap 158 can be supported at the proximal end of the inner core 154 to facilitate a user's ability to axially slide and/or rotate that inner core 154 relative to the main body 140 and hub portion 142 of the delivery catheter 104. In some embodiments, the cap 158 can have wings or tabs formed thereon to increase the torque or rotational force that can be exerted on the inner core 154. Alternatively, in some embodiments, the seal or seal portion within the catheter 104 can be formed from an interference or close tolerance fit between adjacent components such as, without limitation, the inner core 154 and one or more inside surfaces of the main body 140 or the hub portion 142 of the catheter 104.

[0077] In some embodiments, the inner core 154 can have a band or other marking 155 near a distal end thereof. The marking 155 can be sized, positioned, and configured to provide a visual indication to the medical practitioner as to the location of the end portion 154a of the inner core 154 and/or the location of a catheter tip 162 as the inner core 154 is being advanced into or withdrawn from the introducer 102.

[0078] In some embodiments, as illustrated most clearly in Figures 12 and 13, an additional seal member 160 can be supported by the main body 106 of the introducer 102 to provide an additional seal between the outer sheath 122 of the delivery catheter 104 and the introducer 102. In some embodiments, the seal 160 can be a flap type seal formed from a conically shaped piece of resilient material such as, but not limited to, rubber having one or more slits therein to allow the distal tip 162 and the outer sheath 122 to pass therethrough. In some embodiments, a supported flange 161 can be supported within the main body 106 and positioned behind the seal 160 to support the seal 160 and maintain the position of the seal 160 so that the seal 160 does not become inverted when the delivery catheter 104 is removed from the introducer 102. In some embodiments, the distal tip 162 can be formed from a soft material such as rubber and can be configured to be atraumatic so as to prevent any damage to a patient's vasculature as the catheter 104 is being advanced through the patient's vasculature.

[0079] As mentioned above, in some embodiments, as in the illustrated embodiment, the docking mechanism 112 of the introducer 102 can be configured to receive a male docking member or portion of the catheter 104. In particular, with reference to Figures 7, 8A and 8B, one or more deflectable tabs 170 can be supported by the main body 140 of the catheter 104. In some embodiments, the tabs 170 can be deflected by pressing or exerting a radial inward force against pads 172, causing the ends of the tabs 170 to move radially inward toward the axial centerline of the main body 104. By deflecting the tabs 170 inwardly, the main body 140 of the catheter 104 can be moved axially into engagement with the hub portion 108 of the introducer 102. In some embodiments, the tabs 170 can be automatically deflected inwardly when the main body 140 of the catheter 104 is moved axially into engagement with the hub portion 108 of the introducer 102. Once the main body 140 of the catheter 104 is moved axially into engagement with the hub portion 108 of the

introducer 102 so as to abut against the hub portion 108 of the introducer, the tabs 170 can be released, thereby removably locking the main body 140 of the catheter 104 to the hub portion 108 of the introducer 102.

[0080] In this configuration, the catheter 104 can be axially engaged with or locked to the introducer 102 so that a user can axially manipulate the introducer 102 and the catheter 104 simultaneously. Additionally, in some embodiments, in this configuration, as discussed above, the catheter system 100 can be configured such that at least the inner core 122 of the catheter 104 can be rotated relative to the main body 140 of the catheter 104 and the introducer 102.

[0081] In some embodiments, as shown in Figures 7, 8A, and 8B, the inner core 122 can have a central tube or wire 176 configured to support a stent, such as stent 157 illustrated in Figures 7 and 12-14. Additionally, one or more beads or tabs 174 can be formed on or supported by the central tube or wire 176. The tabs 174 can be configured to increase the axial support or connection between the inner core 122 and an endoluminal prosthesis supported by the central tube 176 when the prosthesis is supported in a collapsed configuration by the central tube 176. In some embodiments, the catheter 104 can be configured such that an opening passes through the distal tip 162, the central tube 176, and the inner core 124. The opening can be configured so that at least the distal tip 162, the central tube 176, and the inner core 124 can be advanced over a guidewire positioned within a patient's vasculature, such as is described in U.S. Patent Application No. 12/101,863 filed on April 11, 2008 (titled: BIFURCATED GRAFT DEPLOYMENT SYSTEMS AND METHODS), which application is hereby incorporated by reference in its entirety as if fully set forth herein.

[0082] Additionally, in some embodiments (not illustrated), the tabs 174 can be sized, spaced, and otherwise configured to provide axially support to multiple individual stent segments. For example, without limitation, multiple independent or tethered stent segments can be positioned within a tubular or bifurcated graft, and the stent graft can be positioned relative to the tabs 174 such that the tabs 174 are positioned between the stent segments. This arrangement can reduce the overall diameter of the outer sheath 122, the introducer sheath 110, and other components comprising the catheter system, can enhance the axial

support provided by the tabs 174 to the endoluminal prosthesis, and can allow for a more uniform distribution of support forces between the tabs 174 and the endoluminal prosthesis. In some embodiments, the tabs 174 can be sized, spaced, and otherwise configured so as to be positioned adjacent to the links, bends, loops, and/or other connectors formed in a tubular or bifurcated stent, such as the links, bends, loops, and/or other connectors comprising the embodiments of the stents disclosed in U.S. Patent No. 6,077,296 titled ENDOLUMINAL VASCULAR PROSTHESIS, which patent is hereby incorporated by reference as if fully set forth herein.

[0083] With reference to Figures 13-15, the outer sheath 122 of the deployment catheter 104 can be advanced into an axial opening within the introducer 102 when the deployment catheter 104 is engaged with the introducer 102. In some embodiments, the outer sheath 122 can be sized and configured such that the distal end portion 122c of the outer sheath 122 can terminate within the introducer 102 prior or proximal to the proximal end or flared portion 110b of the introducer sheath 110. Although not required, the introducer 102 can have a constricted portion 113 formed in the main body 106 of the introducer. In some embodiments, as shown most clearly in Figure 14, the catheter system 100 can be configured such that the distal end 122c of the outer sheath 122 terminates prior to or approximately adjacent to a constricted portion 113 of the main body 106 of the introducer 102.

[0084] In some embodiments (not illustrated), the distal end portion 122c of the outer sheath 122 can be positioned near to or approximately adjacent to the proximal end portion or the flared portion 110b of the introducer sheath 110, regardless of whether the catheter 104 has a constricted portion 113. The inner diameter of the constricted portion 113 can be approximately the same as the inner diameter of the outer sheath 122 and/or the inner diameter of the introducer sheath 110.

[0085] Therefore, in some embodiments, the outer sheath 122 of the catheter 104 and the introducer sheath 110 can be configured to provide a lumen having a generally uniform cross-sectional size through the catheter system through which the endoluminal prosthesis can be advanced. In some embodiments, the lumen through the catheter system 100 through which the endoluminal prosthesis can be advanced can be substantially continuous, so that the endoluminal prosthesis can be advanced through the catheter system

100 without the prosthesis being obstructed by or snagging on any components or features of the catheter system 100 as it is being advanced. In some embodiments, the lumen can be substantially continuous but have short gaps on the order of approximately 1 mm to approximately 3 mm in the lumen such as, without limitation, adjacent to the distal end of the outer sheath 122 of the catheter 104 and/or adjacent to the proximal or flared end 110b of the introducer sheath 110. For example, in some embodiments, short gaps can be formed adjacent to the distal end of the outer sheath 122 of the catheter 104 and/or adjacent to the proximal or flared end 110b of the introducer sheath 110 as some components comprising the catheter system 100 are threadedly engaged with other components comprising the catheter system 100. Further, in some embodiments, one or more surfaces of other components comprising the catheter 104 or the introducer 102 in addition to the outer sheath 122 and the introducer sheath 110, such as without limitation the constricted portion 113 of the main body 106 of the introducer 102 as discussed above, can form portions of the lumen through the catheter system 100.

[0086] In some embodiments, the outer sheath 122 can constrain or restrain an endoluminal prosthesis supported by the central tube 176 as described above. In this configuration, as the catheter tip 162, central core 154, and an endoluminal prosthesis (such as, but not limited to, stent 157 illustrated in Figures 7 and 12-14) are advanced through the outer sheath 122, the outer sheath 122 can restrain the endoluminal prosthesis and prevent the endoluminal prosthesis from expanding before reaching the target position within the patient's vasculature. Additionally, the catheter system 100 can be configured such that, as the catheter tip 162, central core 154, and endoluminal prosthesis are advanced past the distal end 122c of the outer sheath 122, the constricted portion 113 and, subsequently, the introducer sheath 110 can radially restrain the endoluminal prosthesis as the endoluminal prosthesis is advanced through the introducer sheath 110.

[0087] In some embodiments, the endoluminal prosthesis or the stent 157 can be a tubular stent, a bifurcated stent, or any other desirable stent, graft, stent graft, or endoluminal prosthesis (collectively referred to herein as stent or stents), including without limitation any of the stents or grafts disclosed in U.S. Patent Application No. 12/101,863 referenced above and incorporated herein by reference as if fully set forth herein. Accordingly, in some

embodiments, the catheter system 100 or catheter 104 can be configured to deploy any suitable or desirable stent or stents.

[0088] Thus, in this configuration, the endoluminal prosthesis can be transferred from the outer sheath 122 to the introducer sheath 110. In this arrangement, using the introducer sheath 110 as the restraint can allow the outside diameter of the introducer sheath 110 to be reduced, which can minimize trauma to the patient's vasculature and assist in the deployment of the endoluminal prosthesis.

[0089] Many embodiments of the docking mechanism and catheter system have been described in connection with Figures 1-15. It will apparent to one of ordinary skill in the art that there are many potential embodiments of a permanent or removable docking mechanism that may be suitable for medical use and which are contemplated herein. For example, in some embodiments, a nut-screw combination could be used to connect the introducer sheath and the catheter. As another example, a bayonet style locking mechanism, such as is used for camera lenses, can also be used. In some embodiments, any of the components or features of some embodiments of the catheters disclosed herein or other catheters available in the field can be combined to form additional embodiments, all of which are contemplated herein.

[0090] While the above description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the device or process illustrated may be made without departing from the spirit of the disclosure. Additionally, the various features and processes described above may be used independently of one another, or may be combined in various ways. All possible combinations and subcombinations are intended to fall within the scope of this disclosure.

[0091] As will be recognized, certain embodiments described herein may be embodied within a form that does not provide all of the features and benefits set forth herein, as some features may be used or practiced separately from others. The scope of the inventions is indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A catheter system comprising:

an introducer comprising a main body, a tubular introducer sheath projecting from the main body, and a first seal supported within the introducer;

a catheter comprising a main body, a outer sheath projecting from the main body, a second seal supported within the catheter, and an inner core that is advanceable through the main body, the second seal, and the outer sheath;

wherein:

the first seal is configured to at least inhibit a flow of blood through the introducer when the catheter is engaged with the introducer;

the second seal is configured to at least inhibit a flow of blood through the catheter;

the introducer sheath is configured to axially receive at least the inner core therethrough and to be selectively engageable with the catheter so that the catheter can be selectively and removably linked with the introducer in the axial direction such that, when the introducer and the catheter are linked, the axial movement of either of the introducer and the catheter will cause the simultaneous and equal axial movement of the other of the introducer and the catheter; and

the catheter system is configured such that, when the introducer and the catheter are linked, the catheter is rotatable relative to the introducer.

2. The catheter system of Claim 1, wherein the catheter is configured to deploy a stent.

3. The catheter system of Claim 1, wherein the catheter system is configured such that the outer sheath of the catheter does not overlap any portion of the introducer sheath when the catheter is axially engaged with the introducer.

4. The catheter system of Claim 1, wherein the outer sheath defines a proximal end portion supported by the main body of the catheter and a distal end portion, and the introducer sheath defines a proximal end portion supported by the main body of the introducer and a distal end portion, and the introducer sheath is configured to directly radially

restrain a stent that is axially supported by the catheter after the stent has been axially advanced past the distal end portion of the outer sheath and the proximal end portion of the introducer sheath.

5. The catheter system of Claim 1, wherein the outer sheath defines a proximal end portion supported by the catheter and a distal end portion, and the introducer sheath defines a proximal end portion supported by the introducer and a distal end portion, and the distal end portion of the outer sheath is positioned approximately adjacent to the proximal end portion of the introducer sheath when the catheter is axially engaged with the introducer.

6. The catheter system of Claim 5, wherein the introducer sheath is configured to directly radially restrain a stent that is axially supported by the catheter after the stent has been axially advanced past the distal end portion of the outer sheath.

7. The catheter system of Claim 1, wherein an inner diameter of the outer sheath is approximately the same as an inner diameter of the introducer sheath.

8. The catheter system of Claim 1, wherein the catheter further comprises a central tube axially supported by and projecting from the inner core, the central tube being configured to support a stent thereon, the catheter being configured such that the central tube and the stent are axially advanceable through at least the main body of the catheter and the outer sheath of the catheter by axially advancing the inner core.

9. The catheter system of Claim 8, further comprising one or more tabs supported by the central tube, the one or more tabs being configured to provide axial support to the stent that is supported by the catheter when the stent is in a collapsed configuration.

10. The catheter system of Claim 8, wherein the catheter further comprises a distal tip supported by an end portion of the central tube, and both the distal tip and the central tube have an opening therethrough configured to receive a guidewire.

11. The catheter system of Claim 1, wherein the catheter system is configured such that a stent can be transferred from the outer sheath into the introducer sheath as the stent is advanced into the introducer.

12. The catheter system of Claim 1, wherein the outer sheath and the introducer sheath form a lumen having a substantially uniform cross-sectional size through the catheter system through which a stent can be advanced.

13. The catheter system of Claim 12, wherein the lumen is substantially continuous along a length thereof.

14. The catheter system of Claim 1, wherein the catheter comprises at least one deflectable tab and the introducer comprises at least one flange, and the at least one deflectable tab is configured to selectively engage with the at least one flange so as to axially engage the catheter with the introducer.

15. The catheter system of Claim 14, wherein the catheter can be disengaged from the introducer by deflecting the at least one deflectable tab radially inwardly and axially retracting the catheter away from the introducer.

16. The catheter system of Claim 1, wherein the first seal is an adjustable hemostasis valve.

17. The catheter system of Claim 1, wherein the first seal is created by a close tolerance fit between the outer sheath and an inside surface of the main body of the introducer.

18. The catheter system of Claim 1, wherein the second seal is created by a close tolerance fit between the inner core and an inside surface of the main body of the catheter.

19. A catheter system comprising:

an introducer comprising a main body and an introducer sheath projecting from the main body;

a catheter comprising a main body, a outer sheath projecting from the main body, and an inner core that is advanceable through the main body and the outer sheath;

wherein:

the inner core is configured to axially support a stent such that the stent can be advanced through the outer sheath by advancing the inner core through the outer sheath;

the outer sheath is configured to radially restrain the stent;

the introducer sheath is configured to axially receive at least the inner core therein;

the catheter system is configured such that the outer sheath of the catheter does not advance into the introducer sheath when the catheter is fully axially advanced into the introducer; and

the introducer sheath is configured to directly radially restrain the stent while the stent is positioned within the introducer sheath.

20. The catheter system of Claim 19, wherein the introducer is configured to be selectively engageable with the catheter so that the catheter can be selectively and removably linked with the introducer in the axial direction such that, when the introducer and the catheter are linked, the axial movement of either of the introducer and the catheter will cause the simultaneous and equal axial movement of the other of the introducer and the catheter.

21. The catheter system of Claim 19, wherein the catheter system is configured such that, when the introducer and the catheter are linked, the catheter is rotatable relative to the introducer.

22. The catheter system of Claim 19, wherein an inner diameter of the outer sheath is approximately the same as an inner diameter of the introducer sheath.

23. The catheter system of Claim 19, wherein the introducer comprises an adjustable hemostasis valve.

24. A method of deploying a stent in a blood vessel, comprising:

positioning an introducer within a patient's blood vessel so as to advance an introducer sheath of the introducer into the patient's blood vessel, the introducer having a proximal end portion and a distal end portion;

advancing an outer sheath of a catheter into the introducer so that an end portion of the outer sheath of the catheter is positioned approximately adjacent to the proximal end portion of the introducer sheath and such that no portion of the outer sheath overlaps the introducer sheath, the catheter further comprising an inner core that is axially moveable within the outer sheath;

axially supporting a stent with the inner core;

axially advancing the inner core and the stent through the outer sheath of the catheter, through the introducer sheath, and past the distal end of the introducer sheath; and

deploying the stent in the blood vessel.

25. The method of deploying a stent of Claim 24, further comprising selectively axially engaging the catheter with the introducer such so as to removably link the catheter to the introducer in the axial direction.

26. The method of deploying a stent of Claim 25, further comprising rotating the catheter relative to the introducer so as to change the rotational orientation of the catheter relative to the introducer without disengaging the catheter from the introducer.

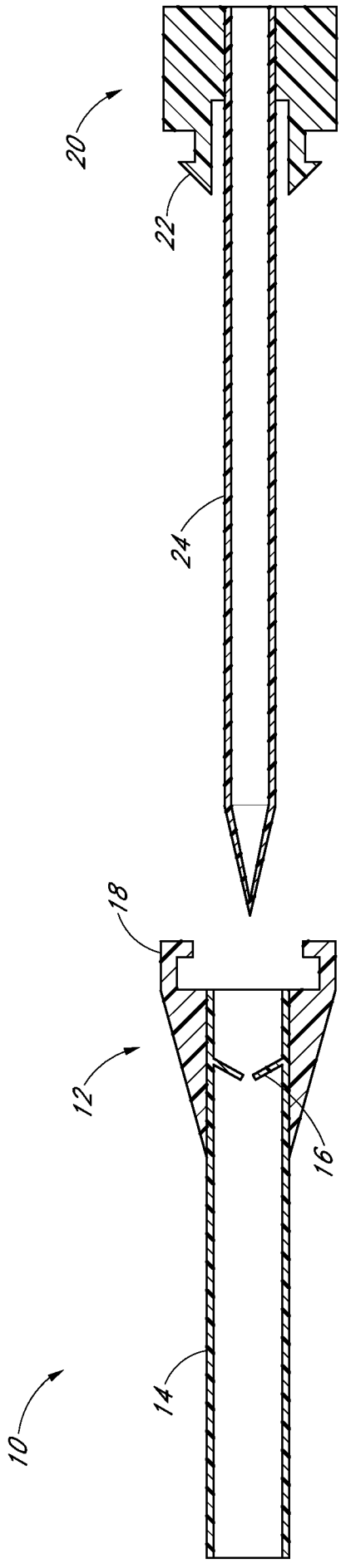

FIG. 1A

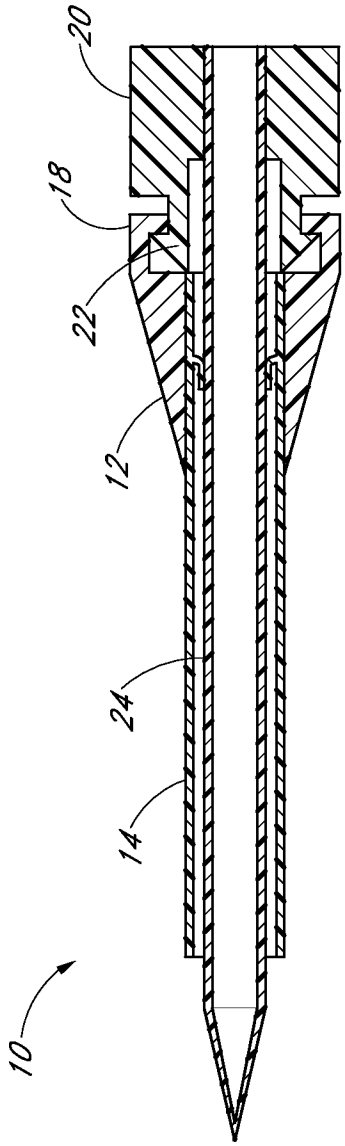

FIG. 1B

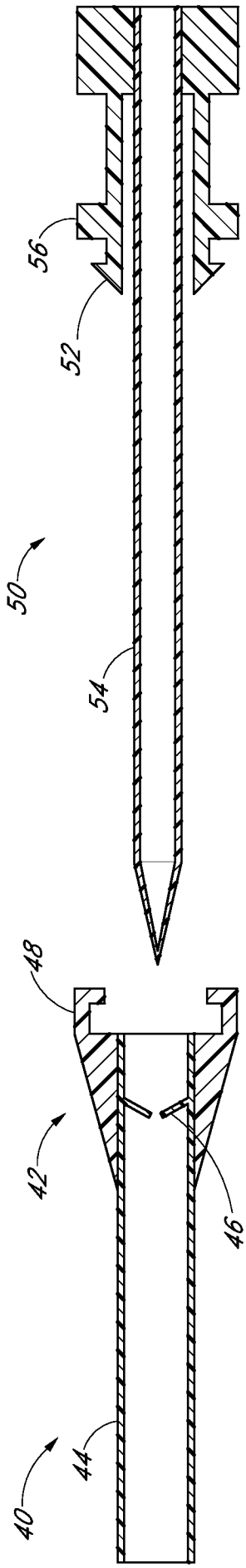

FIG. 2A

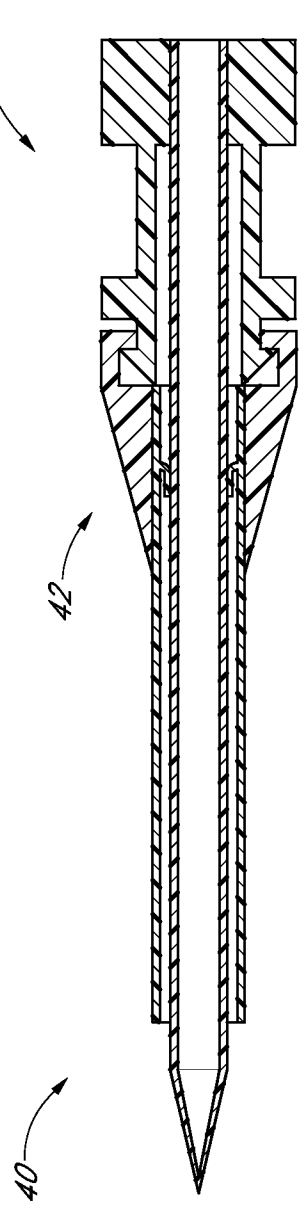

FIG. 2B

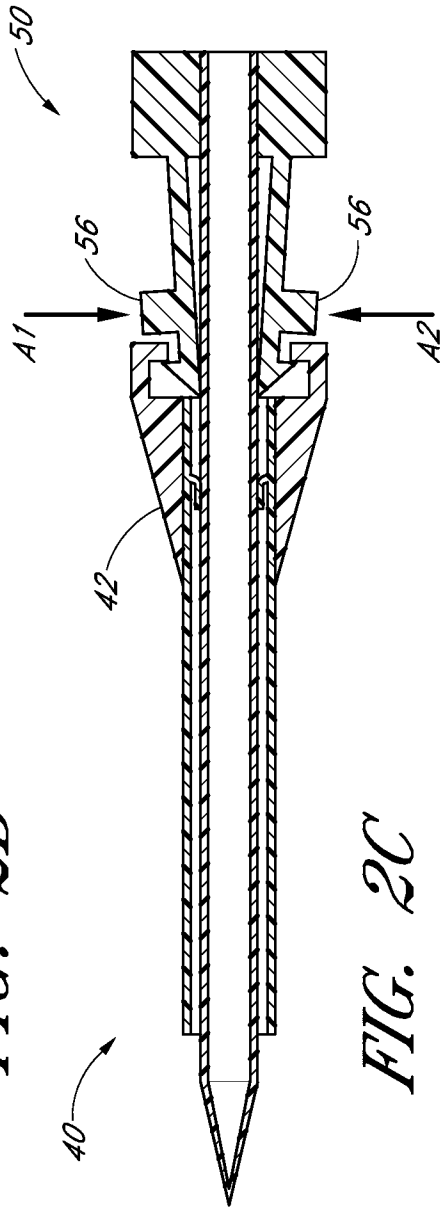

FIG. 2C

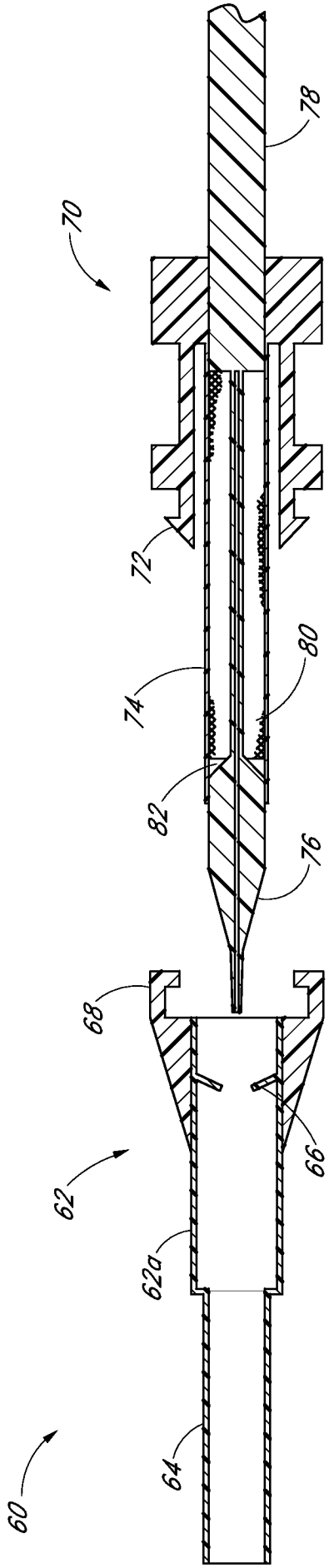
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FIG. 3A

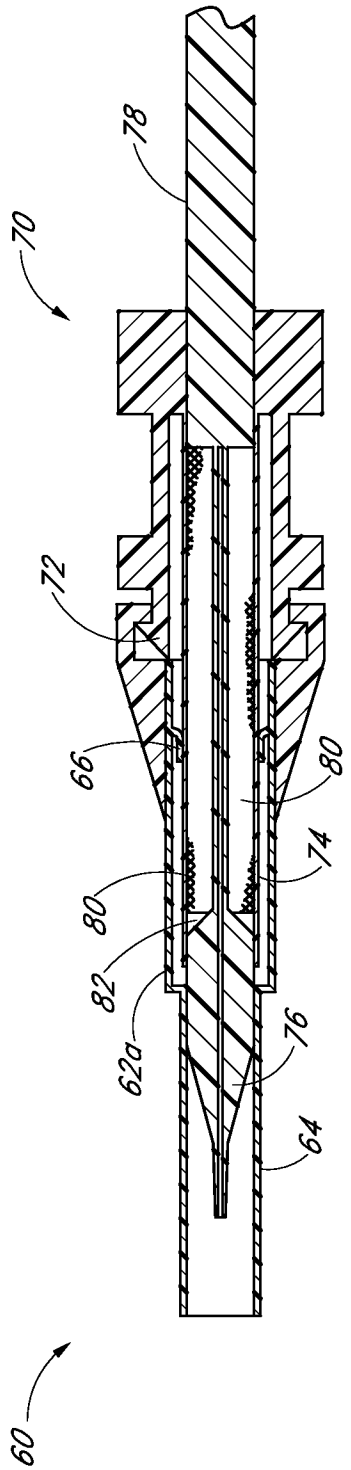
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FIG. 3B

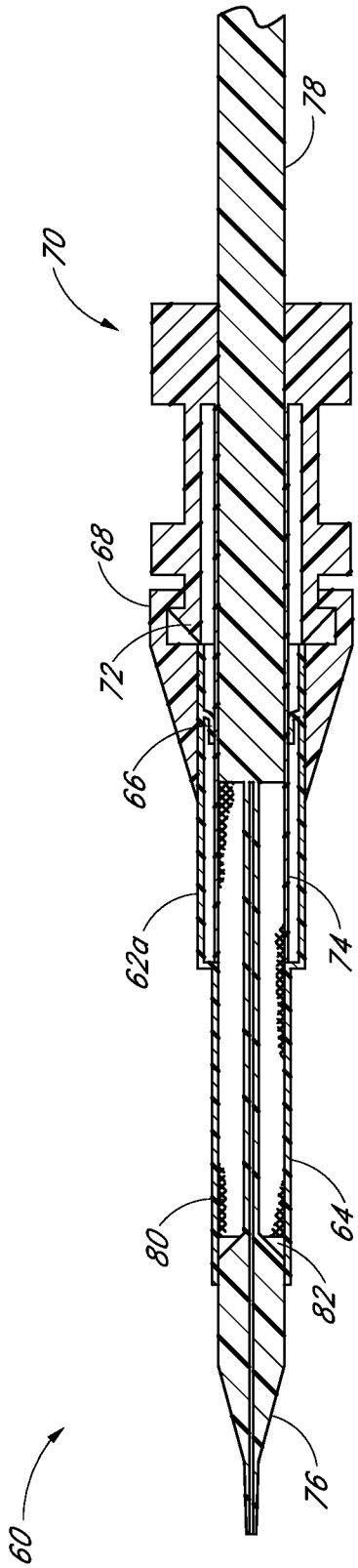

FIG. 3C

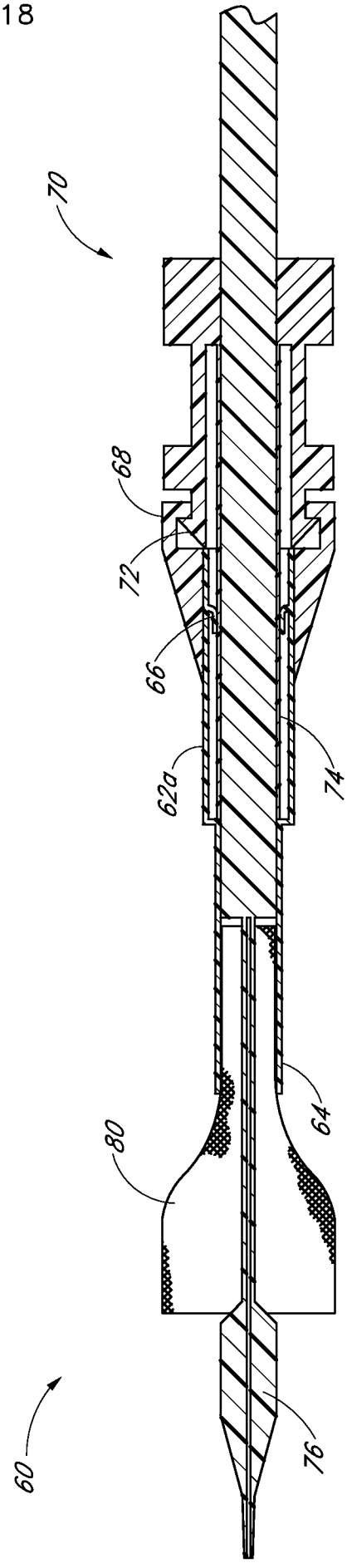

FIG. 3D

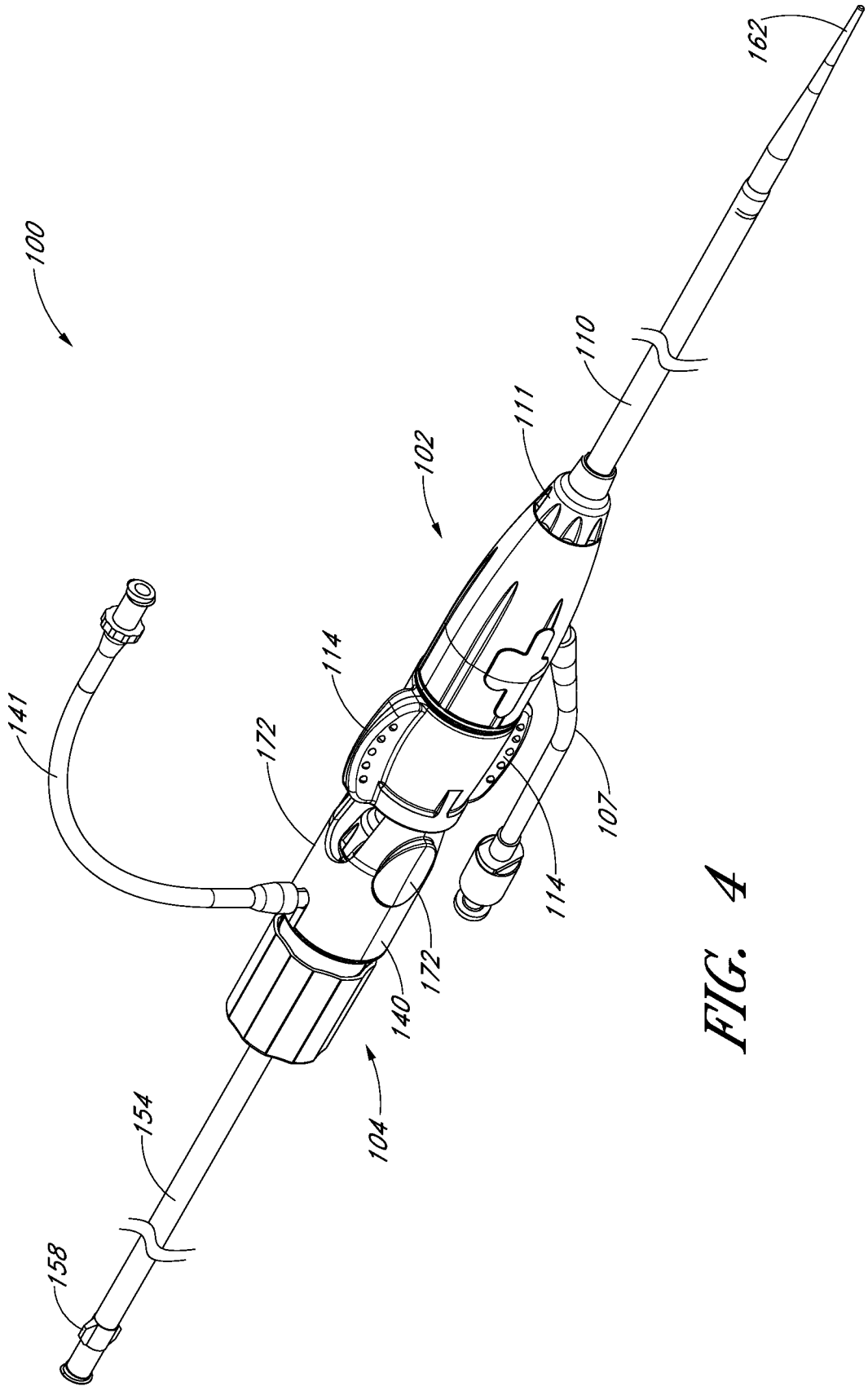

FIG. 4

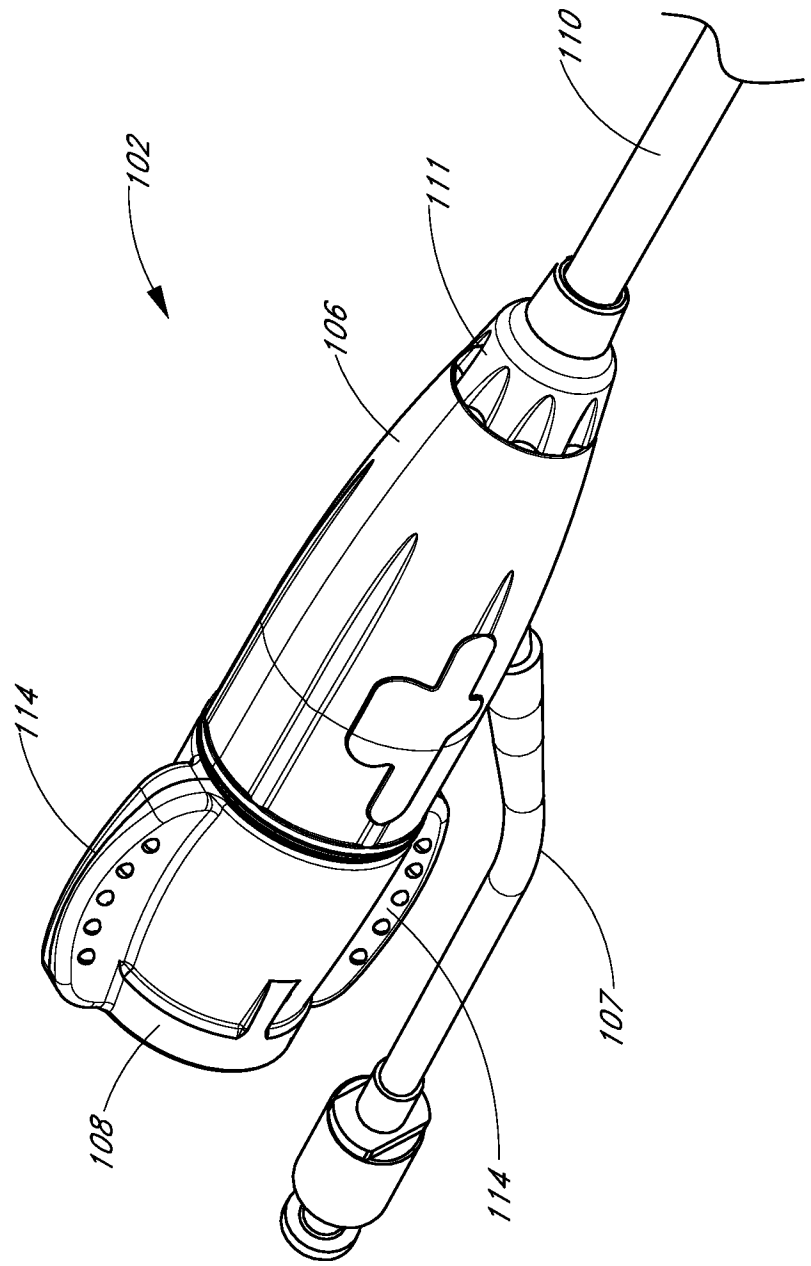

FIG. 5

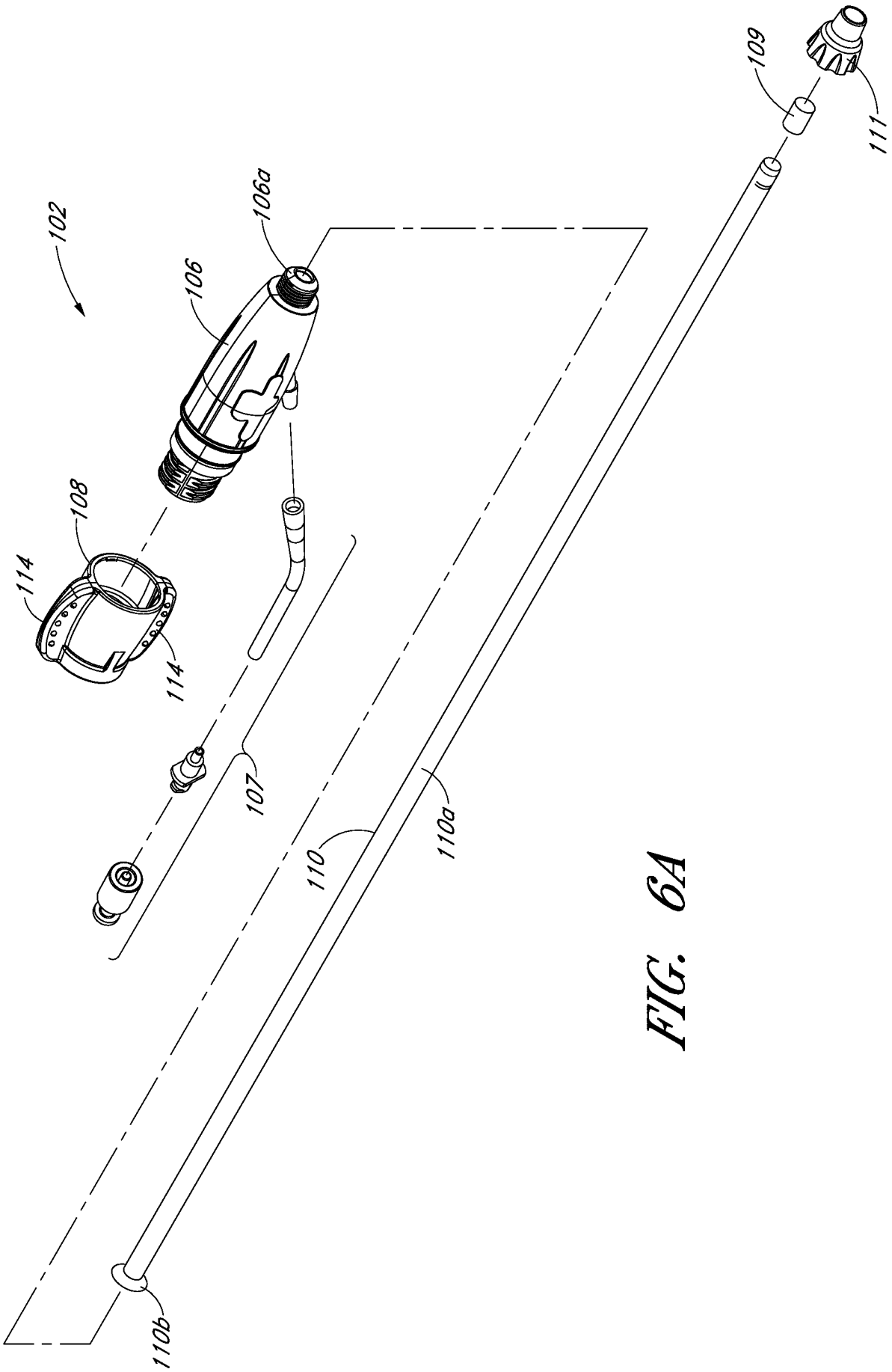

FIG. 6A

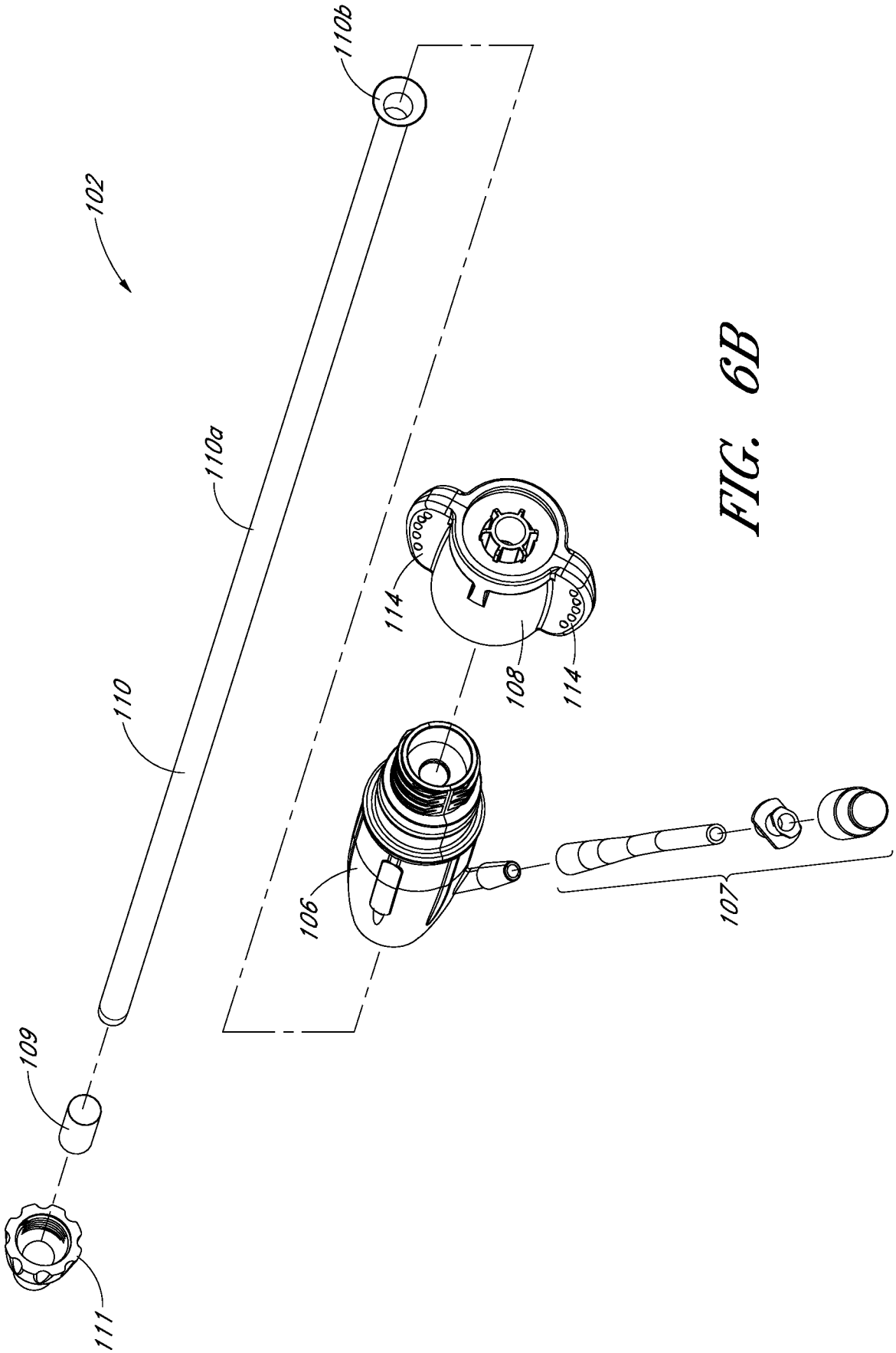

FIG. 6B

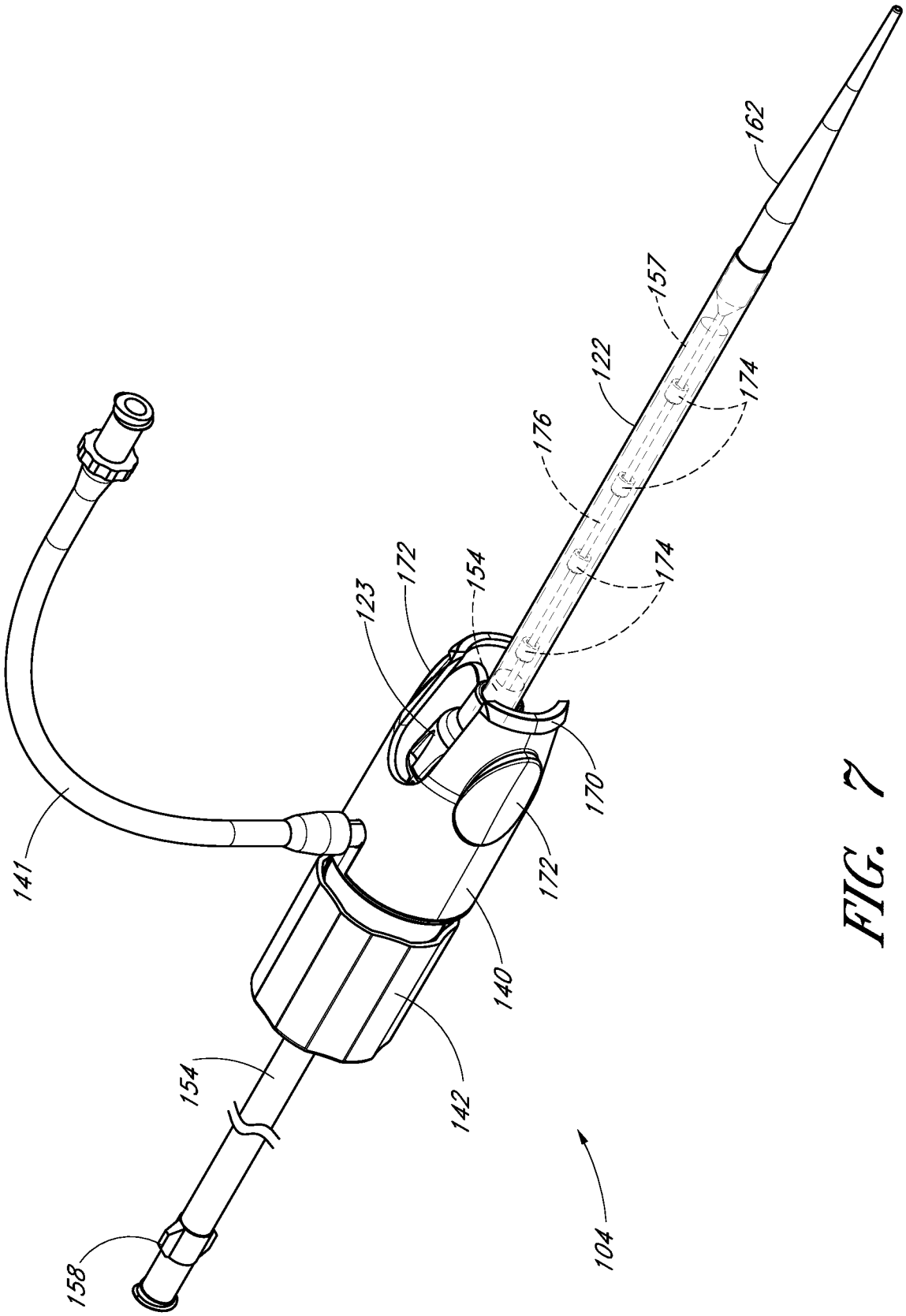
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FIG. 7

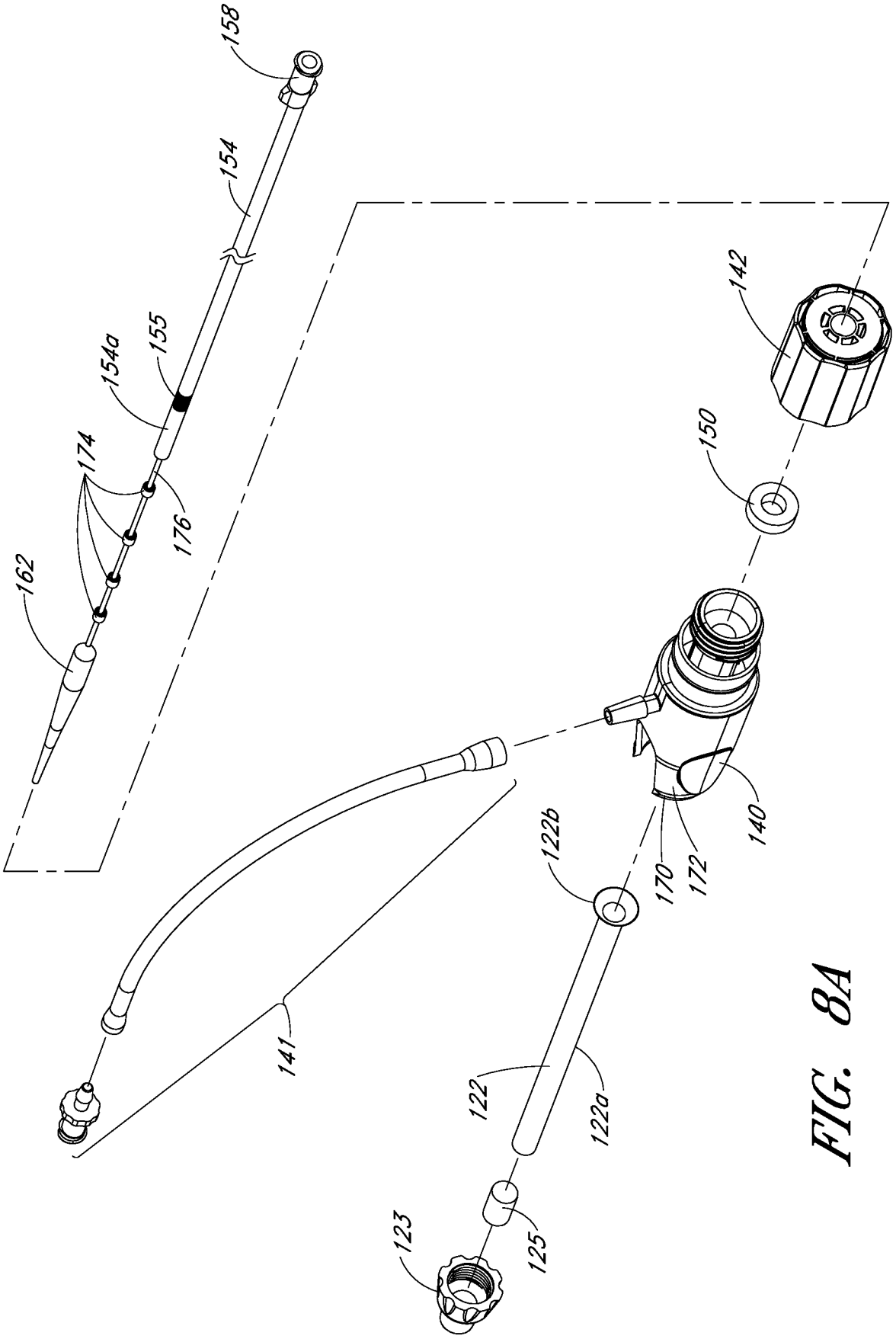
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FIG. 8A

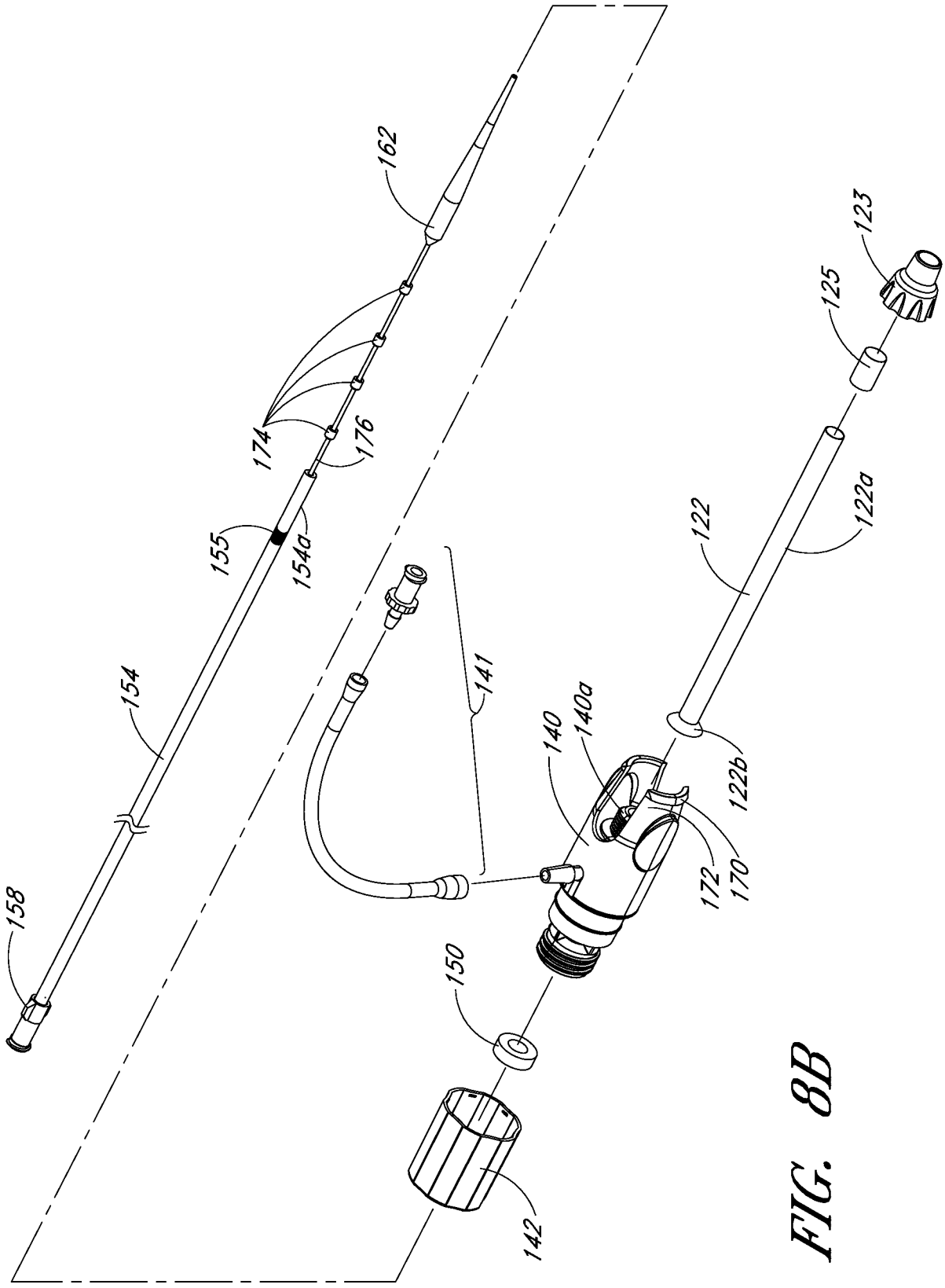
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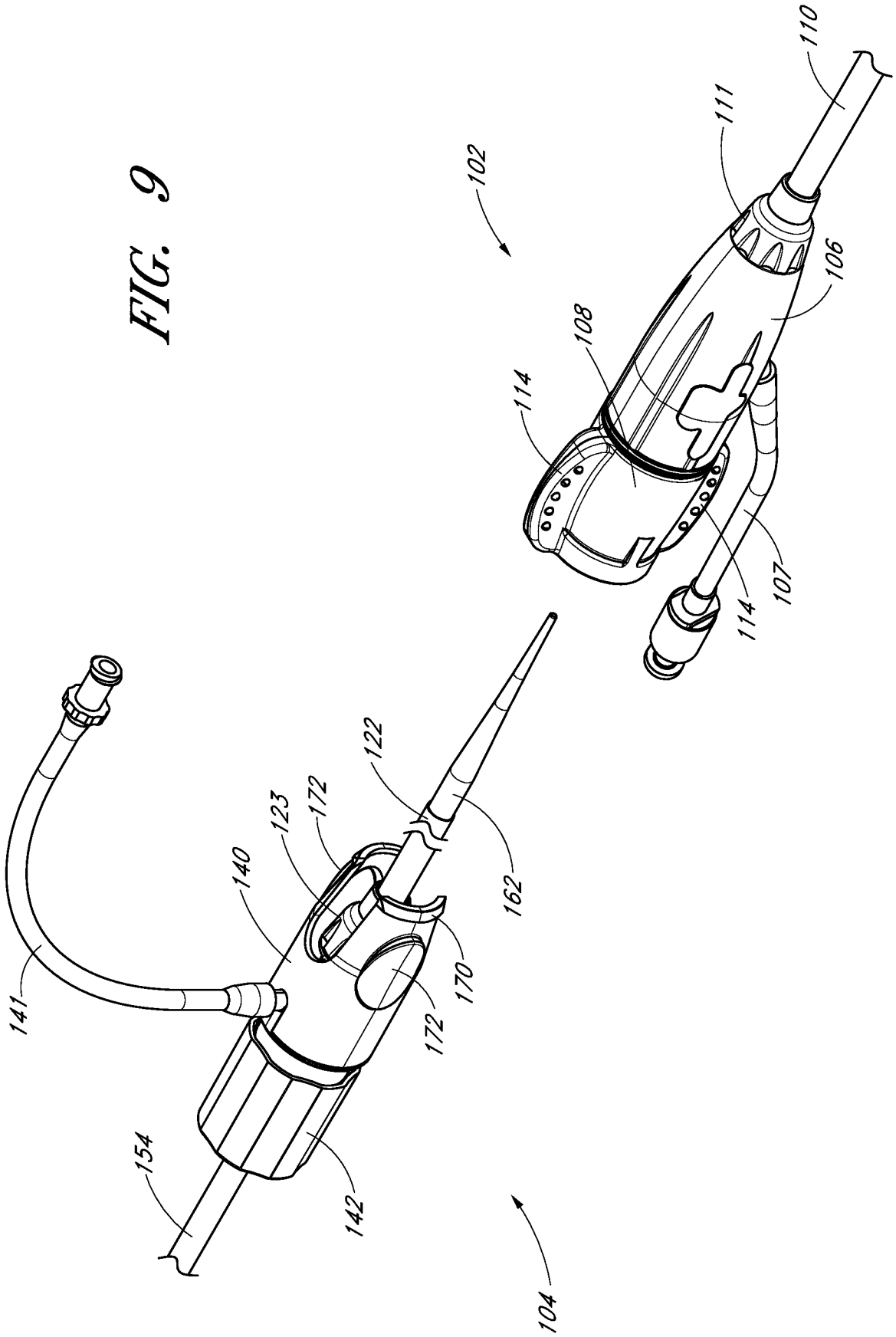
FIG. 8B

FIG. 9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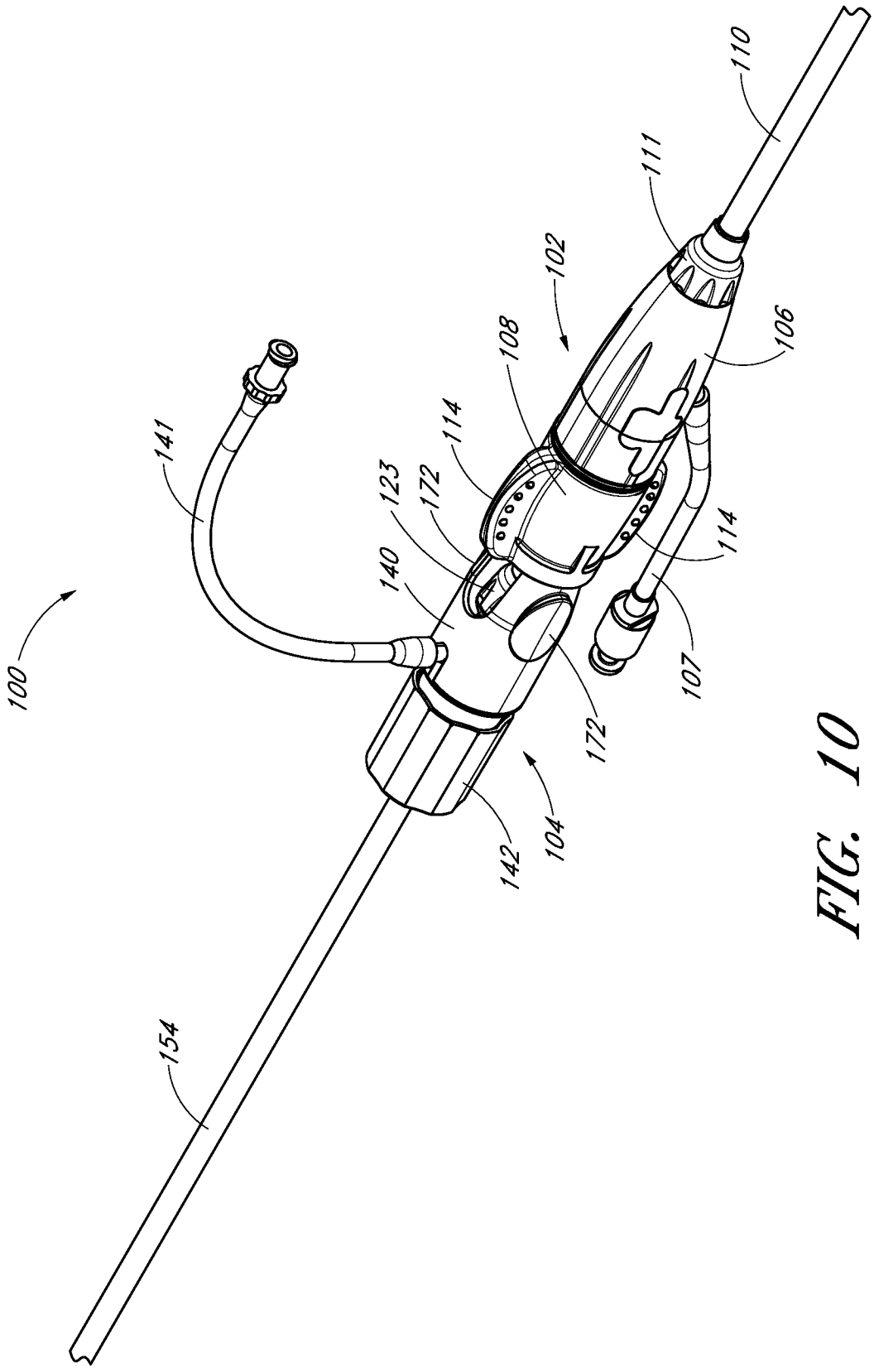
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FIG. 10

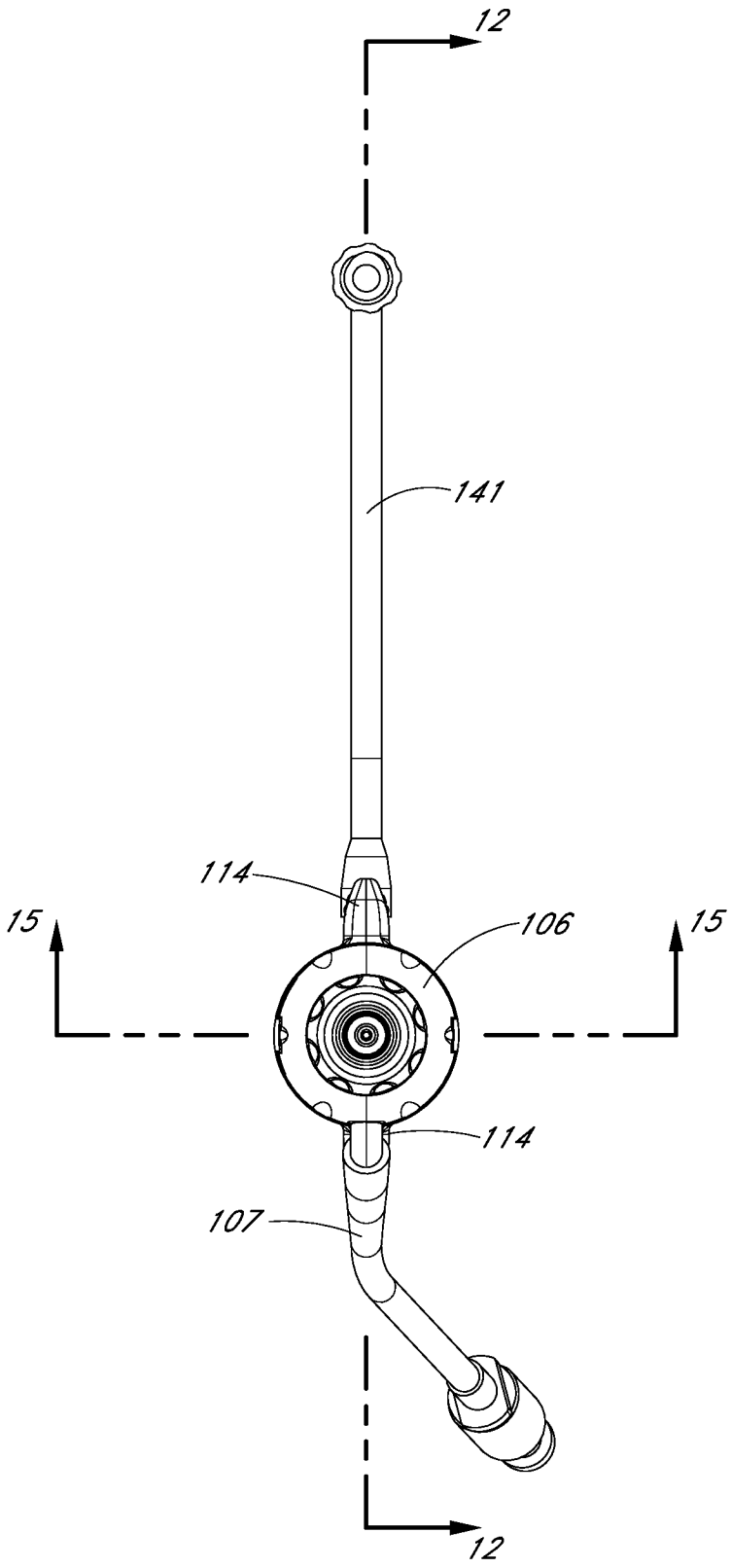

FIG. 11

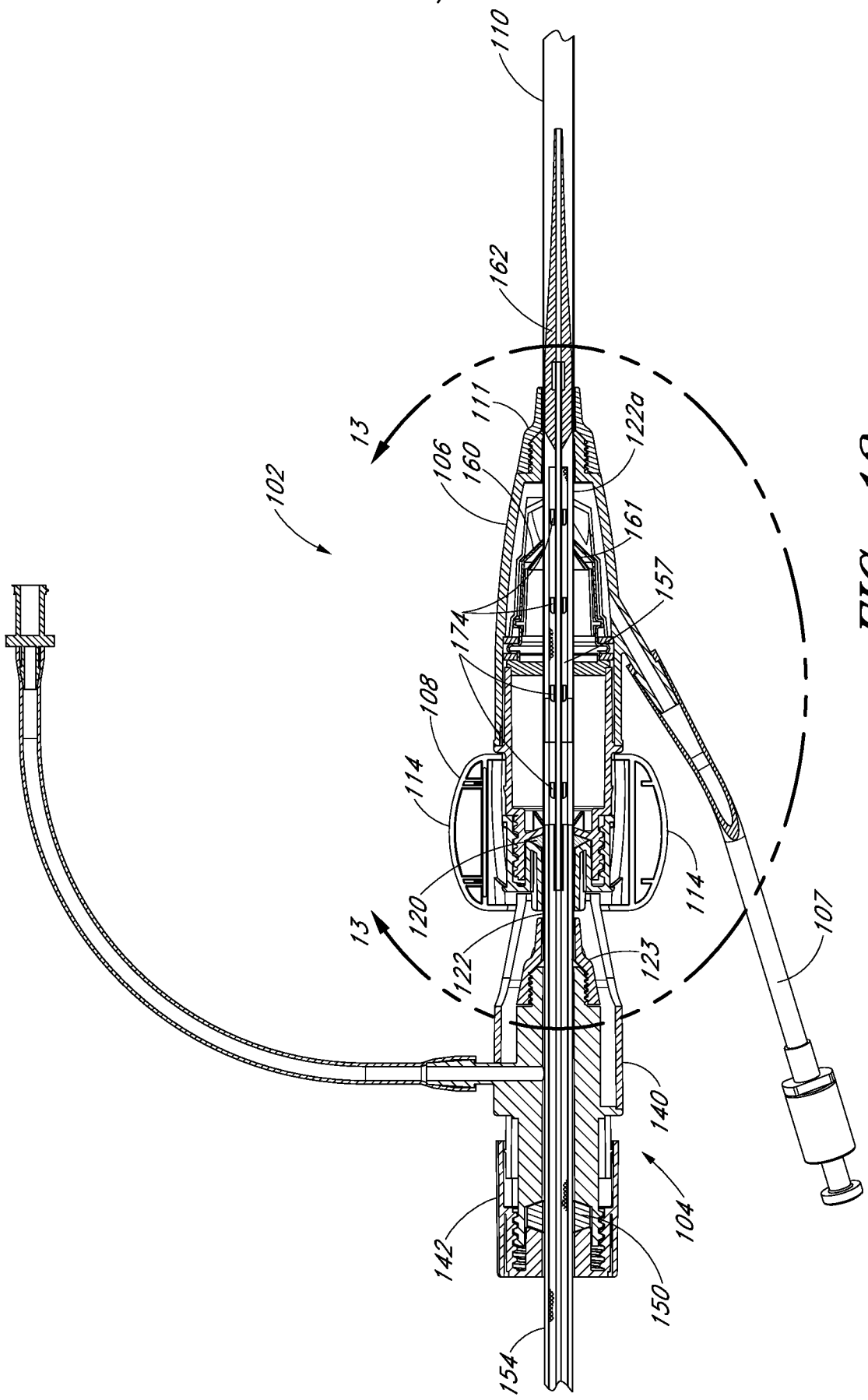
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FIG. 12

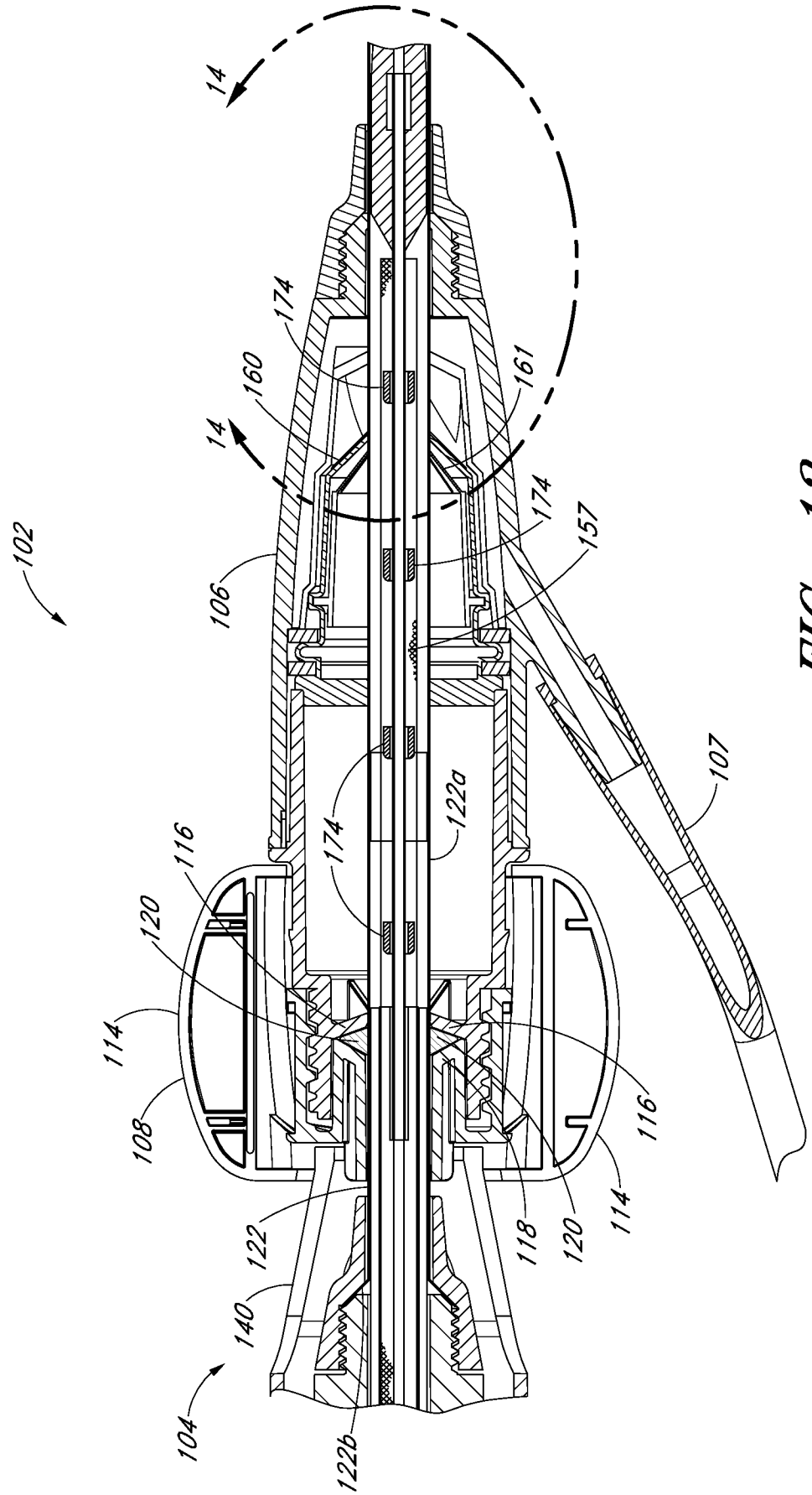
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FIG. 13

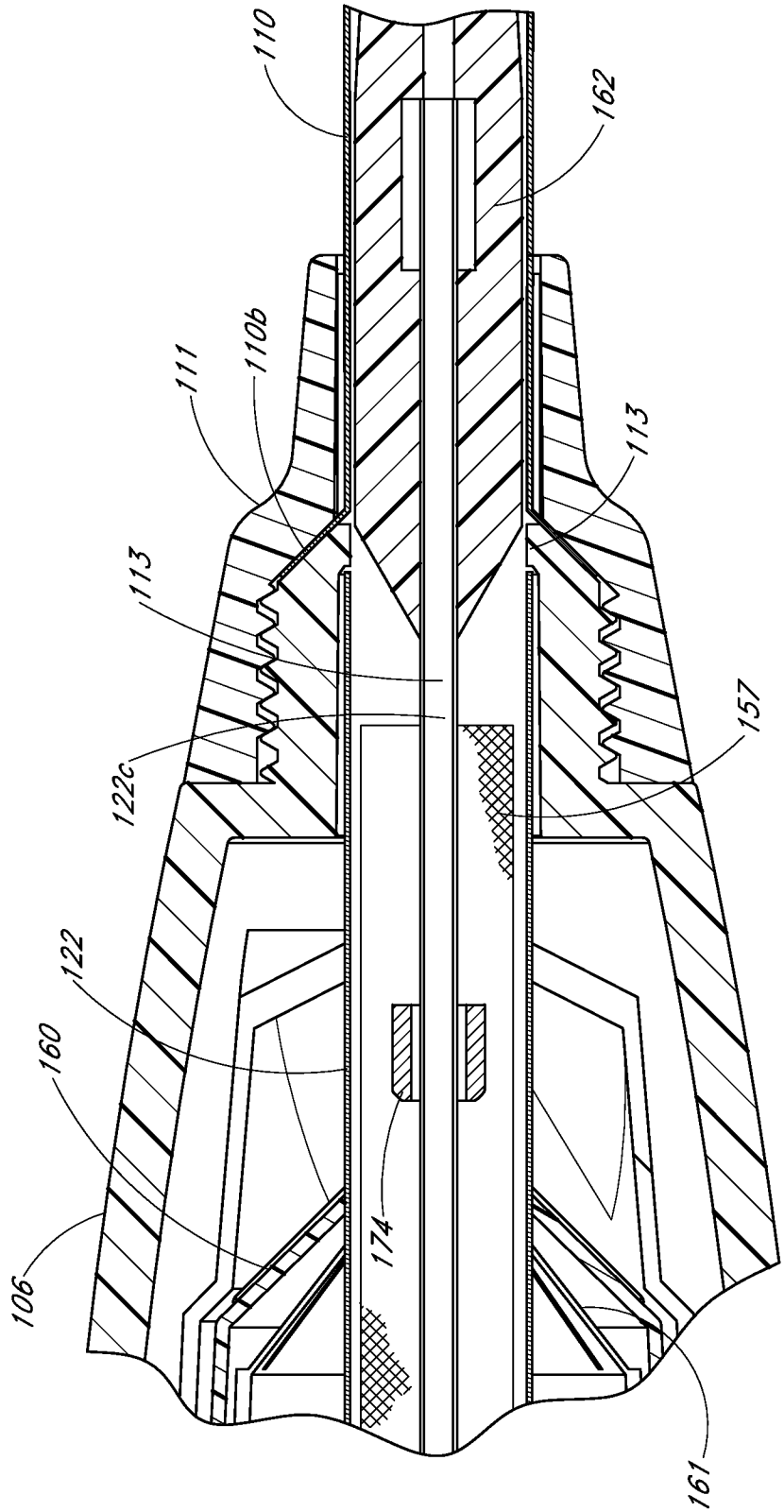

FIG. 14

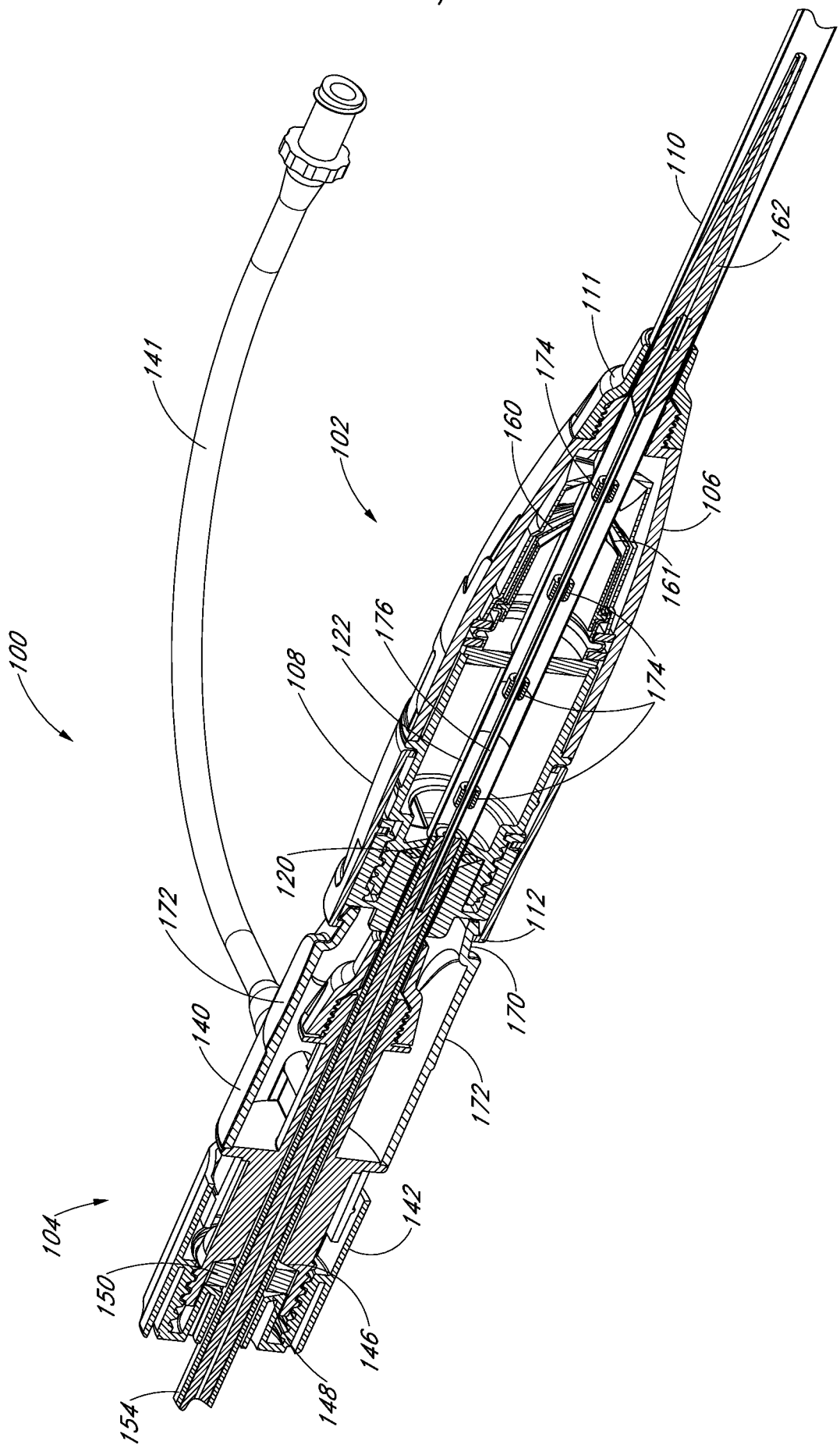
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FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/049316

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/06 A61F2/82

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 A61M

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 practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/052750 A1 (LENKER JAY [US] ET AL) 9 March 2006 (2006-03-09) paragraphs [0058] - [0061]; figure 3a paragraphs [0102] - [0166]; figures 13a-14 paragraph [0015]	1,2,14, 16-18
X	US 2007/191775 A1 (DIEP NHUT M [US] ET AL) 16 August 2007 (2007-08-16) paragraphs [0021] - [0026]; figure 4	1,14,15, 17,18
X	WO 02/36179 A (MEDAMICUS INC [US]; KRAUS MARK C [US]) 10 May 2002 (2002-05-10) page 7, lines 5-29; figures 1,2	1,15-18

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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 document 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
3 December 2009	11/12/2009

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	Jameson, Patricia

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/049316

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 875 262 A (SCHNEIDER NAMIC [US] SCHNEIDER NAMIC) 4 November 1998 (1998-11-04) column 10, line 51 - column 12, line 52; figures 6,7	1,16-18
A	US 5 505 710 A (DORSEY III JAMES H [US]) 9 April 1996 (1996-04-09) column 3, line 22 - column 5, line 49; figures 1-6	1,14,15, 17
A	GB 1 193 759 A (SARNS INC [US]) 3 June 1970 (1970-06-03) the whole document	1,14,15
A	US 2007/005001 A1 (ROWE DOUGLAS [US] ET AL) 4 January 2007 (2007-01-04) paragraph [0031]; figures 1,2 paragraphs [0066] - [0068]; figures 4,6-8	1
A	US 5 064 414 A (REVANE JAMES E [US]) 12 November 1991 (1991-11-12) the whole document	1
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A	US 2005/240255 A1 (SCHAEFFER DARIN G [US]) 27 October 2005 (2005-10-27) paragraphs [0026] - [0028]; figures 1,2	19
A	EP 1 508 313 A (MEDTRONIC VASCULAR INC [US]) 23 February 2005 (2005-02-23) paragraphs [0026] - [0035]; figures 1-8,10-15	19
A	US 5 662 703 A (YUREK MATTHEW T [US] ET AL) 2 September 1997 (1997-09-02) abstract; figures 1,2	19

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/049316

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2006/071915 A (COOK INC [US]) 6 July 2006 (2006-07-06) abstract; figures 1,2	19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/049316

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.: 24-26
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal 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:

see additional sheet

1. [X] 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.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-18

A catheter system comprising: an introducer comprising a main body, a tubular introducer sheath projecting from the main body, and a first seal supported within the introducer; a catheter comprising a main body, a outer sheath projecting from the main body, a second seal supported within the catheter, an an inner core that is advanceable through the main body, the second seal, and the outer sheath; wherein: the first seal is configured to at least inhibit a flow of blood through the introducer when the catheter is engaged with the introducer; the second seal is configured to at least inhibit a flow of blood through the catheter; the introducer sheath is configured to axially receive at least the inner core therethrough and to be selectively engageable with the catheter so that the catheter can be selectively and removably linked with the introducer in the axial direction such that, when the introducer and the catheter are linked, the axial movement of either of the introducer and the catheter will cause the simultaneous and equal axial movement of the other of the introducer and the catheter, and the catheter system is configured such that, when the introducer and catheter are linked, the catheter is rotatable relative to the introducer.

---

2. claims: 19-23

A catheter system comprising: an introducer comprising a main body and an introducer sheath projecting from the main body; a catheter comprising a main body, a outer sheath projecting from the main body and an inner core that is advanceable through the main body and the outer sheath; wherein: the inner core is configured to axially support a stent such that the stent can be advanced through the outer sheath by advancing the inner core through the outer sheath; the outer sheath is configured to restrain the stent; the introducer sheath is configured to axially receive at least the inner core therein; the catheter system is configured such that the outer sheath of the catheter does not advance into the introducer sheath when the catheter is fully axially advanced into the introducer; and the introducer sheath is configured to directly radially restrain the stent while the stent is positioned within the introducer sheath.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/049316

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