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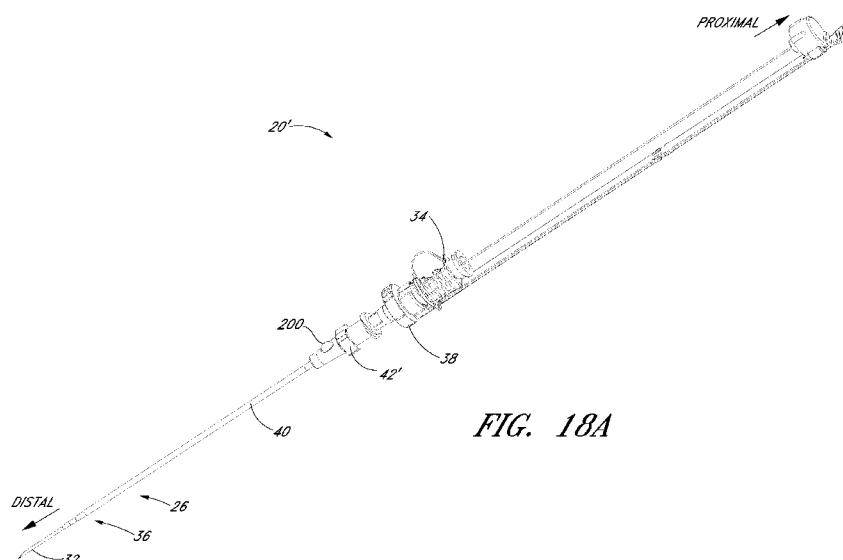


FIG. 18A

(57) Abstract: An access device places a medical article within a body space of a patient. The device has a needle that includes an elongated body and a needle hub. The medical article is disposed over and slideable over the needle. A flash space is provided anywhere between the needle and the outer surface of the medical article. The flash space communicates with a bore of the needle, as well as a variable volume chamber. The variable volume chamber can then draw fluid from the flash space into the chamber.

ACCESS DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is related to and claims the benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Serial Nos. 61/113,989 (filed November 12, 2008) and 61/114,404 (filed November 13, 2008), each of which are hereby expressly incorporated by reference in their entireties.

BACKGROUND

Field of the Invention

[0002] This invention is generally directed to access devices for introducing and/or delivering a medical article (such as, for example, a catheter, cannula, sheath, etc.) into a body space, such as, for example, an artery, vein, vessel, body cavity, or drainage site.

Description of the Related Art

[0003] A preferred non-surgical method for inserting a catheter or vascular sheath into a blood vessel involves the use of the Seldinger or a modified Seldinger technique, which includes an access needle that is inserted into a patient's blood vessel. A guidewire is inserted through the needle and into the vessel. The needle is removed, and a dilator and sheath in combination or separately are then inserted over the guidewire. The dilator and sheath, together or separately, are then inserted a short distance through the tissue into the vessel, after which the dilator and guidewire are removed and discarded. A catheter or other medical article may then be inserted through the sheath into the vessel to a desired location, or the sheath may simply be left in the vessel.

[0004] A number of vascular access devices are known. U.S. Patent Nos. 4,241,019, 4,289,450, 4,756,230, 4,978,334, 5,124,544, 5,424,410, 5,312,355, 5,212,052, 5,558,132, 5,885,217, 6,120,460, 6,179,823, 6,210,332, 6,726,659 and 7,025,746 disclose examples of such devices. None of these devices, however, has the ease and safety of use that physicians and other healthcare providers would prefer. Thus, there exists a need for an easier-to-use and safer vascular access device, especially one that would clearly and promptly indicate when a blood vessel has been punctured and one that would reduce accidental needle sticks and other attendant risks of over-wire vascular access.

SUMMARY

[0005] Embodiments of the present invention involve several features for an access device useful for the delivery of a catheter or sheath into a space within a patient's body, such as, for example, a blood vessel or drainage site. Without limiting the scope of this invention, its more prominent features will be discussed briefly. After considering this discussion, and particularly after reading the Detailed Description of the Preferred Embodiments section below in combination with this section, one will understand how the features and aspects of these embodiments provide several advantages over prior access devices.

[0006] In one embodiment, an access device can be provided for placing a medical article within a body space. The access device can include a needle and a medical article disposed over at least a portion of the needle. The needle can include a bore, and the bore can communicate with a flash space created anywhere between the needle and the outer surface of the medical article. Also communicating with the flash space can be a variable volume chamber. The variable volume chamber can then draw fluid from the flash space into the chamber.

[0007] In another embodiment, another access device can be provided for placing a medical article within a body space. As in the previous embodiment, a needle, medical article, and flash space can be provided. Further, an extended passage can communicate with the flash space at a first end and with a negative pressure element at a second end. A filtering element can be positioned in either the negative pressure element, the tube, or the flash space. The filtering element can thus prevent the egress of a body fluid entering the flash chamber, but allow the egress of air through to the negative pressure element.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] These and other features, aspects, and advantages of the access device disclosed herein are described below with reference to the drawings of preferred embodiments, which are intended to illustrate and not to limit the invention. Additionally, from figure to figure, the same reference numerals have been used to designate the same components of an illustrated embodiment. Like components between the illustrated

embodiments are similarly noted as the same reference numbers with a letter suffix to indicate another embodiment. The following is a brief description of each of the drawings.

[0009] FIGURE 1A is a perspective view of a preferred embodiment of an access device configured in accordance with the present invention and shows a pre-loaded guidewire section coaxially aligned with a needle, a dilator, and a medical article.

[0010] FIGURE 1B is a plan view of the embodiment depicted in FIGURE 1A.

[0011] FIGURE 2A is a plan view of the needle from FIGURE 1A and shows a fenestration near a distal end.

[0012] FIGURE 2B is a side view of the needle from FIGURE 1A and shows a fin near a proximal end.

[0013] FIGURE 2C is a cross-sectional view taken along the lines 2C-2C in FIGURE 2A.

[0014] FIGURE 2D is an enlarged plan view of a portion of the needle of FIGURE 2A and shows the fenestration.

[0015] FIGURE 2E is an enlarged plan view of the needle hub of the needle of FIGURE 2A.

[0016] FIGURE 2F is an enlarged side view of the needle hub of the needle of FIGURE 2A.

[0017] FIGURE 2G is an enlarged proximal end view of the needle hub of the needle of FIGURE 2A.

[0018] FIGURE 3A is a plan view of the dilator from FIGURE 1A and shows a fenestration near a distal end. FIGURE 3A also shows longitudinally arranged grooves in the luer surface for venting air from between the dilator and sheath.

[0019] FIGURE 3B is a cross-sectional view taken along the lines 3B-3B in FIGURE 3A.

[0020] FIGURE 3C is an enlarged plan view of a portion of the dilator from FIGURE 3A and shows the fenestration and longitudinal channel.

[0021] FIGURE 3D is an enlarged end view of the dilator hub from FIGURE 3A.

[0022] FIGURE 3E is a perspective view of another embodiment of the dilator hub that includes a locking spin nut configured to secure to a sheath that has a corresponding screw thread.

[0023] FIGURE 3F is a cross-sectional view taken along the lines 3F-3F in FIGURE 3A and shows the grooves equally spaced about the circumference of the luer surface.

[0024] FIGURE 4A is a plan view of the sheath from FIGURE 1A and shows a sheath hub connected to a proximal end of a sheath.

[0025] FIGURE 4B is a cross-sectional view taken along the lines 4B-4B in FIGURE 4A.

[0026] FIGURE 4C is an enlarged end view of the sheath from FIGURE 4A.

[0027] FIGURE 4D is an enlarged perspective view of a proximal portion of the sheath from FIGURE 4A.

[0028] FIGURE 5A is a perspective view of the guidewire section from FIGURE 1A and shows a guidewire hub connected to a proximal end of a guidewire.

[0029] FIGURE 5B is a plan view of the guidewire section of the embodiment depicted in FIGURE 5A.

[0030] FIGURE 6A is a perspective view of a track from FIGURE 1A.

[0031] FIGURE 6B is a plan view of the track in FIGURE 6A and shows a locking mechanism for locking the needle relative to the dilator.

[0032] FIGURE 6C is a side view of the track in FIGURE 6B.

[0033] FIGURE 6D an enlarged view of the locking mechanism from FIGURE 6B.

[0034] FIGURE 6E is an enlarged view of another locking mechanism that locks the guidewire section in a pre-loaded state.

[0035] FIGURE 7A is a plan view of the access device from FIGURE 1A and shows the locking mechanism from FIGURE 6E with the guidewire section locked to the track in the pre-loaded state.

[0036] FIGURE 7B is a side view of the access device and locking mechanism from FIGURE 7A.

[0037] FIGURE 7C is a cross-sectional view through the access device of FIGURE 7A and shows the guidewire hub disposed between an element and stop of the track.

[0038] FIGURE 7D is an enlarged end view of the access device from FIGURE 7B and shows two arms extending from the track and around at least a portion of the guidewire hub.

[0039] FIGURE 8A is a plan view of the embodiment depicted in FIGURE 1A illustrating the insertion of the distal end of the access device into a patient.

[0040] FIGURE 8B is an enlarged view of the embodiment depicted in FIGURE 8A focusing on the area of the access device adjacent to the patient.

[0041] FIGURE 8C is an enlarged view of a portion of the embodiment depicted in FIGURE 8B and illustrates the needle opening or fenestration aligned with the dilator opening or fenestration in hidden lines.

[0042] FIGURE 8D is an enlarged cross-sectional view of a portion of the embodiment depicted in FIGURE 8C and shows the needle opening or fenestration aligned with the dilator opening or fenestration so as to allow fluid to flow from inside the needle to a channel formed between the sheath and dilator.

[0043] FIGURE 8E is a graph showing the rate fluid is drawn up a channel with a gap height width of 0.002 inches.

[0044] FIGURE 8F is a graph showing the rate fluid is drawn up a channel with a gap height width of 0.001 inches.

[0045] FIGURE 8G is a graph showing the rate fluid is drawn up a channel with a gap height width of 0.0005 inches.

[0046] FIGURE 8H is an enlarged cross-sectional view of a portion of the embodiment depicted in FIGURE 8C taken through a region distal of the channel in the dilator.

[0047] FIGURE 8I is an enlarged view of the embodiment depicted in FIGURE 8A focusing on the area where the needle hub is locked to the dilator hub when the needle hub is in the first position.

[0048] FIGURE 8J is a cross-sectional view of the embodiment depicted in FIGURE 8I.

[0049] FIGURE 9A is a side view of the embodiment depicted in FIGURE 1A illustrating the guidewire advanced from the needle tip in a distal direction.

[0050] FIGURE 9B is an enlarged view of the embodiment depicted in FIGURE 9A focusing on the area where the guidewire hub is locked to the needle hub when the needle hub is in the first position.

[0051] FIGURE 9C is a cross-sectional view of the embodiment depicted in FIGURE 9B.

[0052] FIGURE 10A is a side view of the embodiment depicted in FIGURE 1A illustrating the dilator and sheath being advanced distally relative to the needle body from the position illustrated in FIGURE 9A.

[0053] FIGURE 10B is an enlarged rear view of the embodiment depicted in FIGURE 10A focusing on the area where the needle hub is locked to the track when the needle hub is in the second position.

[0054] FIGURE 11A is a side view of the embodiment depicted in FIGURE 1A illustrating the removal of the guidewire, needle body, and dilator from the sheath.

[0055] FIGURE 11B is an enlarged view of the portion of the embodiment illustrated in FIGURE 11A showing the needle tip covered by the dilator during removal of the guidewire, needle body, and dilator from the sheath.

[0056] FIGURE 12A is an enlarged plan view that illustrates another embodiment of the aligned openings or fenestrations in the needle and dilator.

[0057] FIGURE 12B is an enlarged cross-sectional view along lines 13B-13B in FIGURE 12A and shows the needle opening or fenestration aligned with the dilator opening or fenestration so as to allow fluid to flow from inside the needle to a channel formed between the sheath and dilator.

[0058] FIGURE 13A is an enlarged plan view that illustrates another embodiment of the aligned openings or fenestrations in the needle and dilator.

[0059] FIGURE 13B is an enlarged cross-sectional view along lines 13B-13B in FIGURE 13A and shows the needle opening or fenestration aligned with the dilator opening

or fenestration so as to allow fluid to flow from inside the needle to a channel formed between the sheath and dilator

[0060] FIGURE 14A is an enlarged plan view that illustrates another embodiment of the channel formed between the dilator and the sheath.

[0061] FIGURE 14B is a cross-sectional view along lines 14B-14B in FIGURE 14A and shows the thickness of the channel extending into the sheath.

[0062] FIGURE 15A is an enlarged plan view that illustrates another embodiment of the channel formed between the dilator and the sheath.

[0063] FIGURE 15B is a cross-sectional view along lines 15B-15B in FIGURE 15A and shows the thickness of the channel extending into both the dilator and the sheath.

[0064] FIGURE 16A is an enlarged plan view that illustrates another embodiment of the channel formed between the dilator and the sheath.

[0065] FIGURE 16B is a cross-sectional view along lines 16B-16B in FIGURE 15A and shows a plurality of equally spaced channels in the form of splines extending into the dilator.

[0066] FIGURE 17 is an enlarged cross-sectional view through another embodiment of the access device and shows the channel formed between a sheath and a dilator that have dissimilar shapes.

[0067] FIGURE 18A is a perspective view of another access device configured in accordance with another preferred embodiment of the present invention.

[0068] FIGURE 18B is an enlarged perspective view of a hub of the access device of FIGURE 18A in a contracted configuration.

[0069] FIGURE 18C is an enlarged perspective view of the hub of FIGURE 18B in an expanded configuration.

[0070] FIGURE 19 is a perspective view of an additional access device configured in accordance with a further preferred embodiment of the present invention.

[0071] FIGURE 20 is a perspective view of an additional embodiment of an access device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0072] The present disclosure provides an access device for the delivery of a medical article (e.g., catheter or sheath) to a blood vessel or drainage site. FIGURE 1A illustrates an access device 20 that is configured to be inserted into a blood vessel (e.g., a vein or an artery) in accordance with a preferred embodiment of the present invention. While the access device is described below in this context (i.e., for vascular access), the access device also can be used to access and place a medical article (e.g., catheter or sheath) into other locations within a patient's body (e.g., a drainage site) and for other purposes (e.g., for draining an abscess).

[0073] The present embodiment of the access device is disclosed in the context of placing an exemplary single-piece, tubular medical article into a body space within a patient. Once placed, the tubular article can then be used to receive other medical articles (e.g., catheters, guidewires, etc.) to provide access into the body space and/or be used to provide a passage way for introducing fluids into the body space or removing (e.g., draining) fluids from the body space. In the illustrated embodiment, the tubular medical article is a sheath or catheter that is configured primarily to provide a fluid passage into a vein. The principles of the present invention, however, are not limited to the placement of single piece sheaths or catheters, or to the subsequent insertion of a medical article via the sheath or catheter. Instead, it will be understood by one of skill in this art, in light of the present disclosure, that the access device disclosed herein also can be successfully utilized in connection with placing one or more other types of medical articles, including other types of sheaths, fluid drainage and delivery tubes, and single or multi-lumen catheters directly in the patient or indirectly via another medical article.

[0074] For example, but without limitation, the access device disclosed herein can also be configured to directly or indirectly place central venous catheters, peripherally inserted central catheters, hemodialysis catheters, surgical drainage tubes, tear-away sheaths, multi-piece sheaths, scopes, as well as electrical conduit for wires or cables connected to external or implanted electronic devices or sensors. As explained above, the medical articles listed above may be directly placed in the patient via the dilator, needle, and guidewire of the

access device or subsequently placed within the patient via a medical article that was placed within the patient via the dilator, needle, and guidewire of the access device.

[0075] Further, the embodiments disclosed herein are not limited to co-axial insertion of a single medical article. For example, two catheters may be inserted in the patient via an inserted sheath or a second catheter may be inserted in the patient via an inserted first catheter. Further, in addition to providing a conduit into the vessel or other body space, the medical article inserted via the dilator, needle, and guidewire can form a lumen that is in addition to the lumen(s) of the subsequently inserted medical article. One skilled in the art can also find additional applications for the devices and systems disclosed herein. Thus, the illustration and description of the access device in connection with a sheath (e.g., for micro puncture applications) is merely exemplary of one possible application of the access device.

[0076] FIGURES 1A and 1B illustrated a preferred embodiment of an access device 20. The access device 20 comprises a needle 22, a dilator 24, and a sheath 26. In the illustrated embodiment, the access device also includes a guidewire section 28 and a track 30. As best seen in FIGURE 1B, the dilator 24 is preferably coaxially mounted on the needle 22, and the sheath 26 is coaxially mounted on the dilator 24. The telescoping nature of the access device's components can also be accomplished by arranging the components with their axes arranged substantially parallel rather than coaxially (e.g., a monorail-type design).

[0077] Each of these components includes a luminal fitting at a terminal end or transition (i.e., a hub) and elongated structure that extends from the fitting. Thus, in the illustrated embodiment, the needle 22 includes a needle body 32 that extends distally from the needle hub 34, the dilator 24 includes a dilator shaft 36 that extends distally from a dilator hub 38, and the sheath 26 includes a sheath body 40 that extends distally from a sheath hub 42. The guidewire section 28 comprises a guidewire 44 and preferably a guidewire hub or cap 46. In the illustrated embodiment, the guidewire hub 46 is disposed on the proximal end of the guidewire 44; however, in other applications, the hub 46 can be disposed at a location between the ends of the guidewire 44.

[0078] FIGURES 2A-2G illustrate the needle body 32 and needle hub 34 of the needle 22, which are configured in accordance with a preferred embodiment of the access

device, in isolation from the other components of the access device 20. As best seen in FIGURES 2A and 2B, the needle hub 34 is disposed on a proximal end of the needle body 32. The needle body 32 terminates at a distal end near a distal portion 50 of the needle 22, and the needle hub 34 lies at a proximal portion 52 of the needle 22.

[0079] The needle body 32 preferably has an elongated tubular shape having a circular, constant-diameter inner bore and a circular, constant-diameter exterior surface. In other embodiments, however, the needle body 32 can have other bore and exterior shapes (such as, for example, but without limitation, an oval cross-sectional shape). The interior or exterior of the needle can also include grooves or channels. The grooves or channels may guide fluids within the needle bore either around or to certain structures of the needle 22 or within the needle 22 (e.g., around the guidewire). In some embodiments, the grooves or channels may assist in maintaining a desired orientation of the needle 22 with respect to the dilator.

[0080] The needle body 32 has a sufficiently long length to access a targeted subcutaneous body space and has a sufficient gauge size to withstand the insertion forces when accessing the body space without causing undue trauma. For many applications, the needle body can have a length between 3- 20 cm, and more preferably between 3 and 10 cm. For example, to access a body space (e.g., a vessel) in the thorax of an adult human, the needle body 32 preferably has a length of 7 cm or greater, and more preferably has a length of 9 cm or greater, and most preferably has a length of 9 to 10 cm. The size of the needle preferably is 18 gauge or smaller, and more preferably between 18-28 gauge, and most preferably between 18-26 gauge for micro-puncture applications (peripheral IVs). For applications with a neonate, the length and gauge of the needle body 32 should be significantly shorter and smaller, for example preferably between 3-4 cm and between 26-28 gauge.

[0081] As best seen in FIGURES 2A and 2D, the needle body 32 includes at least one fenestration or opening 56 near a distal end of the needle body 32. The fenestration 56 extends through the wall of the needle body 32 and can have a variety of shapes and orientations on the needle body 32, as described in detail below. In addition, the needle body 32 can have a bevel tip 54 disposed on the distal portion 50.

[0082] As is illustrated in FIGURES 2A, 2B, a fin 58 is preferably disposed at a circumferential location around the needle hub 34 that is aligned with the circumferential locations of the bevel on the needle tip and the opening or fenestration 56 in the needle. That is, the fin 58 is indexed with the bevel and fenestration. During use, the physician or healthcare provider can determine the orientation of the beveled needle tip (and the fenestration 56) by noting the orientation of the exposed fin 58 even though the bevel is inside the vessel and the fenestration is covered by the sheath and/or dilator. For example, in the illustrated embodiment, an orientation of the fin 58 away from the patient coincides with a bevel up orientation of the needle tip within the vessel. The fenestration 56 is also on the same side as the fin 58, as seen in FIGURE 2C.

[0083] The fin 58 also provides a grasping region to manipulate the needle hub 34. For example, a physician or healthcare provider can place an index finger and thumb on the sides of the fin 58 to stabilize the needle hub 34, relative to the dilator 24 and/or sheath 26. In the illustrated embodiment, as the dilator/sheath slides distally over the needle, the needle hub 34 slides relatively along the track 30 between a first position 121 and a second position 123 (example portions illustrated in FIGURE 6A). The fin 58 can be held when performing the insertion step (which will be described below). In addition, the fin 58 can be used to stabilize the needle hub 34 while rotating the dilator hub 38. Furthermore, the fin 58 can be used by a physician or healthcare provider as an aid to grasp the access device 20 when the needle hub 34 is disposed at any position along the track 30.

[0084] FIGURE 2D is an enlarged view of the side opening or fenestration 56 in the needle body 32. The one or more fenestration 56 provides a path through the side of the needle body 32. The fenestration 56 illustrated in FIGURE 2D has an oblong shape. The shape of the side opening 56, however, is not limited to the illustrated embodiment and may be round, oblong, square, or another shape.

[0085] With specific reference now to FIGURES 2E-2G, the needle hub 34 preferably includes locking structures at the proximal portion and distal portion of the needle hub 34. These locking structures may be a luer-thread-type or another type of connections.

[0086] The locking structure on the proximal portion 52 of the needle hub 34 allows the physician or healthcare provider to secure another medical article to the proximal

end of the needle hub 34. For example, the needle hub 34 in the illustrated embodiment includes an annular flange or lip 63. The lip 63 is threaded to allow the needle hub 34 to attach to other medical articles with a corresponding luer-nut locking feature. Additionally, a physician or healthcare provider may attach a syringe or monitoring equipment to the locking structure on the proximal end to perform other procedures as desired. The needle hub 34 can also include a septum at its proximal end and/or a side port if these features are desirably for a particular application.

[0087] The locking structure on the distal portion of the needle hub 34 allows the physician or healthcare provider, for example, to lock the needle hub 34 to the dilator hub 38 when the needle hub 34 is in the first position 121, so as to hinder relative motion between the hubs. In the illustrated embodiment, the locking structure includes a latch element 66 on the needle hub 34. The latch element 66 releasably locks the needle hub 34 to the dilator hub 38. The locking structure allows the healthcare provider to advance the needle into a patient while grasping the needle hub 34, the dilator hub 38 or both. When desired, the locking structure can be released, allowing relative motion between the hubs. In other embodiments, the same or a similar locking structure can lock the needle hub 34 to another piece of the access device, such as the sheath hub 42, or a hub of another medical article. Further, in some embodiments the locking structure can be configured to also engage with other medical fittings, such as screw-thread connections, luer-connections, and the like. The locking structure on the needle hub 34 can be modified to cooperate with the varying locking structure options on the dilator hub 38, sheath hub 42, or other medical article. As another example, in some embodiments the medical article can be a catheter. As would be generally understood in the art, the catheter can have a generally more-flexible structure in comparison to the sheath 26 and the dilator 24. For example, in some embodiments a catheter can safely bend at extreme angles without kinking, so as to maintain a clear channel therethrough when inserted into a body cavity. Further, in some embodiments a catheter might not have sufficient structural strength to dilate a hole created by the needle, or to support itself against the force of gravity when not supported by the needle – causing it to dip.

[0088] As explained below in greater detail, the guidewire 44 is introduced through a hollow portion 62 of the needle hub 34, through the needle body 32, and into a

punctured vessel. The guidewire 44 allows the healthcare provider to guide the dilator 24 and sheath 26 into the vessel.

[0089] The needle hub 34 may also comprise two tangs 68 that allow the needle hub 34 to slide along the track 30 between a first position 121 and a second position 123. While in the preferred embodiment the two tangs 68 of the needle hub 34 are engaged with the track 30 between the first position 121 and the second position 123, in other embodiments the needle hub 34 is only engaged with the track 30 over a portion of the length of the track 30 between the first position 121 and the second position 123. The sliding interconnection between the track 30 and the needle hub 34 also can be accomplished using other cooperating structures (e.g., a corresponding pin and tail of dovetail connection).

[0090] FIGURE 3A is a plan view of the dilator 24 of the embodiment depicted in FIGURE 1A. FIGURE 3B is a cross-sectional view of the dilator 24 of the embodiment depicted in FIGURE 3A, taken along line 3B-3B. As shown in FIGURES 3A and 3B, the illustrated dilator 24 comprises a dilator shaft 36, a dilator hub 38, a distal region 70, and a proximal region 72. In the illustrated embodiment, the dilator shaft 36 includes a side openings or fenestrations 74; however, in other embodiments, the dilator shaft 36 can include fewer or greater numbers of fenestrations 74. For example, the dilator shaft 36 may not include a fenestration 74 where a blood flash chamber(s) or space(s) is disposed within the dilator (as will be described in more detail below).

[0091] The dilator hub 38 may comprise one or more vents. In the illustrated embodiments, the vents in the dilator hub 38 are formed by grooves 75. Additionally, the dilator shaft 36 may comprise one or more longitudinal channels formed in the outer surface of the dilator shaft 36. In the illustrated embodiment, the channel is an open channel. The side walls of the open channel are formed by ridges 76. In the illustrated embodiment, the ridges 76 define generally smooth, arcuate exterior surfaces that interface with the sheath 26; however, in other embodiments, the ridges can have other shapes (e.g., can define more pronounced apexes). Once assembled within a sheath body 40, the open channel in the dilator shaft 36 is closed by the inside diameter of the sheath body 40.

[0092] FIGURE 3C is an enlarged plan view of a portion of the embodiment illustrated in FIGURE 3A. As noted above, the illustrated dilator shaft 36 comprises one or

more side openings 74 and one or more channels formed between ridges 76. The side opening or fenestration 74 provides a fluid path through the side of the dilator shaft 36. The shape of the side opening 74 is not limited to the illustrated embodiment and may be round, oblong, square, or have another shape. The opening or fenestration 74 illustrated in FIGURE 3C has an oblong shape.

[0093] In the illustrated embodiment, the opening 74 in the dilator shaft 36 has an oblong shape with its major axis being non-parallel relative to the major axis of the oblong opening 56 in the needle 22. For example the needle opening 56 may extend in a longitudinal direction and the dilator opening 74 may extend in a circumferential direction or vice versa. In other words, the long axis of the dilator opening 74 is disposed generally perpendicular to the long axis of the needle opening 56. As explained in connection with additional embodiments below, these openings 56, 76 can have other shapes, sizes and orientations that preferably obtain a significant degree of overlap to account for manufacturing tolerances and rotational misalignments. For this reason, it is preferred that one of the fenestrations has a greater dimension in at least one direction than the other one of the fenestrations in the same direction. Accordingly, in the illustrated embodiment, the needle fenestration 56 has a longer longitudinal dimension than the longitudinal dimension of the dilator fenestration 74.

[0094] The channel formed between the ridges 76 extends in a proximal direction from a point distal to the opening 74. The ridges 76 in the illustrated embodiment are disposed along the dilator shaft 36 and on opposite sides of the dilator shaft 36 so as to balance the dilator shaft 36 within the sheath. In the illustrated embodiment, the ridges 76 form two channels there between. Balancing the dilator within the sheath allows the dilator to apply equal pressure to the inside circumference of the sheath.

[0095] The dilator hub 38 may include locking structures at the proximal region 72 and the distal region of the dilator 24. Each locking structure may be a luer type or other type of connection. In the illustrated embodiment, the dilator hub 38 comprises a first luer connection 78, a second luer connection 80, a lip 77, and a base 79. The first luer connection 78 engages to the needle hub 34 on the needle 22 illustrated in FIGURE 2E. The second luer connection 80 is disposed distal to the first luer connection 78. In some embodiments, the

second luer connection 80 (e.g., a male luer slip connector) can be configured to engage to the sheath hub 42 (e.g., a female luer slip connector) on the sheath 26 illustrated in FIGURE 1A. Additionally, the male-female luer slip connectors on these components can be reversed.

[0096] FIGURE 3D is an enlarged proximal end view of the dilator 24 of FIGURE 3A. As shown most clearly in FIGURE 3D, the dilator hub 38 comprises an opening 82 that releasably engages the latch element 66 on the needle hub 34 illustrated in FIGURE 2E-2F to secure the dilator hub 38 to the needle hub 34 when the needle hub 34 is in the first position 121. Again, the male-female luer slip connectors on the dilator hub and the needle hub 34 can also be reversed in other embodiments. In embodiments where the needle hub locks to another medical article, a similar structure can be provided on that article. For example, in some embodiments the access device 20 can lack a dilator 24, and the needle hub 34 can connect to a sheath hub 42 having an opening similar to the opening 82 on the dilator hub 38 as described above.

[0097] The color of the dilator 24 may be selected to enhance the contrast between the blood or other fluid and the dilator 24. During blood flash, for example, blood is observed flowing between the dilator 24 and the sheath to confirm proper placement of the needle in a blood vessel. To increase the visibility of the fluid as the fluid flows between the sheath and dilator 24, the sheath is preferably manufactured from a clear or transparent material with the dilator 24 having a color that contrasts with the color of the fluid. For example, the dilator 24 may have a white color to enhance its contrast with red blood. Other colors of dilator 24 could be employed depending on the color of the fluid and the degree of contrast desired. Further, only a portion of the dilator in the region of the blood flash can have the contrasting color with the remainder having a different color. For embodiments that have a channel formed between the needle and dilator 24, the dilator 24 may be manufactured of a clear or transparent material similar to the sheath to allow the physician to observe the blood flash through both the sheath and dilator 24.

[0098] FIGURE 3E is an enlarged perspective view of another embodiment of a dilator hub 38A. The dilator hub 38A is similar to the dilator hub 38 illustrated in FIGURE 3A except that the dilator hub 38A further includes a spin nut or collar 84. The proximal end of the spin nut 84 rotates about an annular groove 73 in the dilator hub 38 (see FIGURE 3A).

Once disposed within the annular groove 73, the spin nut 84 is inhibited from moving in the distal direction but is free to rotate about the dilator hub 38A. The spin nut 84 can have an interengaging element that locks to a corresponding interengaging element on the sheath 26. In the illustrated embodiment, the spin nut 84 includes an internal thread which engages with an external thread on the sheath hub 42 on the sheath 26 illustrated in FIGURE 1A.

[0099] The dilator 24 or sheath 26 may separately, or together, form one or more passages to allow air or gas to escape or vent from between the dilator 24 and sheath 26 and/or between the needle and the dilator. The one or more passages may further be sized to inhibit the flow of a liquid, such as blood, while allowing air to pass there through. The one or more passages may be in the wall of the sheath 26, the sheath hub, the dilator hub 38, an exposed section of the dilator shaft, and/or formed between adjacent surfaces of the dilator 24 and sheath 26. For example, FIGURE 3A shows longitudinally arranged grooves 75 that are formed between adjacent surfaces of the dilator 24 and sheath 26. Such venting passages can also be labyrinth. The adjacent surfaces form a luer slip connection between the sheath 26 and dilator 24.

[0100] FIGURE 3F is a cross-sectional view taken along lines 3F-3F in FIGURE 3A and shows the grooves 75 equally spaced, though not required to be equally spaced, about the circumference of the luer slip surface. The grooves 75 are sized to allow air to escape from between the dilator and the medical article, such as a sheath, when the blood flash occurs. As mentioned above, the one or more passages need not be in the form of a surface groove 75 and instead may be in the form of an opening or passageway.

[0101] In the illustrated embodiment, the one or more passages allow air to pass through the luer connection between the sheath and dilator hubs. In the illustrated embodiment, a distal end of the passage 75 is located on the distal side of the luer connection with the proximal end of the passage 75 being located on the proximal side of the luer connection.

[0102] The one or more passages may be sized to filter blood or other liquid or may include a filter or other structure that inhibits the passage of a liquid while allowing the passage of air. For example, the sheath itself may include one or more passages in the form of small openings, pores or porous material. Depending on the size of the one or more

passages and the expected size of the fluid molecules and formed elements (e.g. red blood cells), the one or more small openings, pores or porous material in the sheath can form a porous vent that allows air to pass yet retain blood.

[0103] A method of manufacturing a ridged dilator will now be described. First, an extrusion process is used to create a long tubular body having one or more longitudinal grooves or channels on its outer diameter (OD) or within the substance of the dilator. The long tubular body exceeds the required length of a single dilator and preferably has a length that is many times greater than the length of a single dilator. A manufacturing die is employed in the extrusion process having geometry that reflects the desired geometry for the inside and outside diameters of the dilator and the thickness and circumferential span of the longitudinal grooves or channels or interior channels. In the illustrated embodiment of FIGURES 1-11, the long tubular body includes two longitudinal OD channels on opposite sides of the body to enhance the balance of the dilator within the sheath. However, a single channel can provide a visible indicator for the blood flash, or a flash space. The two channels preferably extend along the length of the extruded tubular body. While the illustrated embodiment includes one or more channel disposed between the dilator and the sheath, one or more channels can in addition or in the alternative be formed between the needle and the dilator, within the dilator, and/or within the sheath. In some embodiments, the dilator 24 thus is made partially or completely from clear, translucent, transparent, or semi-opaque material to visualize the fluid flash within the channel.

[0104] With reference back to the illustrated embodiment, the extruded tubular body is cut to the appropriate length for a single dilator. In the preferred method, the two OD grooves extend for the entire length of the cut dilator.

[0105] A tipping process is then employed on an end of the cut dilator to reform the tip. An end of the cut dilator is forced into a die/mandrel having geometry that matches the desired geometry of the tip of the finished dilator. The desired geometry is selected depending on, for example, the inside diameter of the sheath. It is desirable for the sheath and dilator to form a close fit or seal near the tip to promote blood flow in the proximal direction up the channel formed between the grooved dilator and sheath. Preferably, the OD of the dilator in the tip region tapers in the distal direction.

[0106] When in the die/mandrel, thermal energy is applied to the tip to reform the tip to match the die/mandrel. The thermal energy may be applied by any known technique, including using radiant heating from an infrared or RF heat source. As part of the tipping process, the dilator in the tip region is reformed so that the grooves are essentially removed. With the grooves removed, the dilator is able to form the close fit or seal with the sheath near the tip. The grooves are maintained along the remainder of the dilator on the proximal side of the location where the tip of the sheath 26 sits on the dilator. After removal from the die/mandrel, the tip end of the dilator may be cleaned and cut as necessary to remove any manufacturing remnants.

[0107] The one or more fenestrations in the dilator is cut through the dilator near the tip region and in or near the groove. Each fenestration may be cut by any known means, including a drill or laser. Further, the cutting device may be moved with respect to the dilator or vice versa to achieve an oblong or other shape for the fenestration.

[0108] The end of the dilator opposite from the tip end can be flared to facilitate over molding the dilator hub onto the dilator.

[0109] FIGURE 4A is a plan view of the sheath 26 of the embodiment depicted in FIGURE 1A. FIGURE 4B is a cross-sectional view of the sheath 26 of the embodiment depicted in FIGURE 4A, taken along line 4B-4B. FIGURE 4C is an enlarged proximal end view of the sheath 26 of FIGURE 4A. Figure 4D is an enlarged perspective view of the sheath hub 42 of the sheath 26 of FIGURE 4A. As shown in FIGURES 4A-4D, the sheath 26 may comprise a sheath body 40, a sheath hub 42, a distal portion 90, and a proximal region 92. The sheath body 40 may be made partially or completely from clear, translucent, transparent, or semi-opaque material. The sheath body 40 can also include one or more radiopaque markers, such as, for example, barium sulfate stripes. In a preferred embodiment, the sheath includes two such radiopaque stripes disposed on diametrically opposite sides of the body 40.

[0110] The sheath body 40 may be a single piece sheath through which a catheter or other medical article (e.g., a guidewire) is inserted into the vessel. In such an embodiment, the sheath body 40 forms a conduit for insertion of the catheter or other medical article (e.g., a guidewire). In addition to providing a conduit, the sheath or a portion of the sheath can

form a lumen that is in addition to the lumen(s) of the catheter. For example, an equivalent to a triple lumen catheter can be formed by inserting a dual lumen catheter through the sheath body 40 with the sheath body 40 itself forming a third lumen.

[0111] It may be advantageous to remove a portion or the entire sheath body 40 depending on the type of catheter or medical article that is to be inserted into the vessel after employing the access device 20. For example, after the catheter or other medical article is inserted into the vessel, a portion of the sheath body 40 can be separated or peeled-away and removed. A peel-away sheath can include perforations, serrations, skives, or other structures, or include other materials (e.g., PTFE with bismuth) to allow the physician or healthcare provider to remove easily a portion or the entire sheath body 40.

[0112] The sheath hub 42 may include a luer slip connection and a lock member 94. The locking member 94 may comprise a locking or attaching structure that mates or engages with a corresponding structure. For example, the lock member 94 can be a luer connection 94 which can be configured to engage with the second luer connection 80 of the dilator hub 38.

[0113] The sheath hub 42, as best seen in FIGURE 4C and 4D, preferably is designed so that the locking mechanism or second luer connection 80 of the dilator hub 38 can enter the sheath hub 42 substantially unobstructed. However, in use, once the sheath hub 53 is placed at a desired location over the dilator shaft 36, the physician or healthcare provider can push, pull, or twist the sheath hub 42 and possibly disengage or engage the locking member 94 with a corresponding connector on another medical article. The locking member 94 can be, for example, a luer connection, a protruding bump, dent, etc., that creates a mechanical fit so that the dilator hub 38 and the sheath hub 42 are releasably interlocked. In the illustrated embodiment, the locking member 94 of the sheath hub 42 comprises a luer connection. The sheath hub 42 preferably engages with the corresponding second luer connection 80 on the dilator hub 38. Preferably, the locked position can be disengaged or engaged by pulling, squeezing, pushing or twisting the dilator hub 38 relative to the sheath hub 42.

[0114] In some embodiments, the sheath hub 42 can comprise a lip 95. The lip 95 can be threaded to allow the sheath hub 42 to attach to other medical articles with a corresponding locking feature.

[0115] The sheath hub 42 preferably comprises one or more surface features to allow the physician or healthcare provider to easily grasp or manipulate the sheath 26 and/or access device 20. In the illustrated embodiment, the sheath hub 42 includes a squared grip 96 and ridges 98.

[0116] In additional embodiments, the sheath hub 42 may comprise radially extending wings or handle structures to allow for easy release and removal of the sheath body 40 from other parts of the access device 20. In some applications, the wings are sized to provide the healthcare provider with leverage for breaking apart the sheath hub 42. For example, the sheath hub 42 may comprise a thin membrane connecting the halves of the sheath hub 42. The membrane is sized to keep the halves of the sheath hub 42 together until the healthcare provider decides to remove the sheath hub 42 from the access device. The healthcare provider manipulates the wings to break the membrane and separate the sheath hub 42 into removable halves.

[0117] FIGURE 5A is a perspective view of the guidewire section 28 of the embodiment depicted in FIGURE 1A. FIGURE 5B is a plan view of the guidewire section 28 depicted in FIGURE 5A, which preferably includes the guidewire hub 46. The guidewire hub 46 can comprise one or more surface features to allow the physician or healthcare provider to easily grasp or manipulate the guidewire hub 46 and/or access device 20. In the illustrated embodiment, the guidewire hub 46 comprises one or more ridges 110. In a pre-loaded state, the outer surface of the guidewire hub 46 engages with a locking mechanism 130 on the track 30 when the guidewire hub 46 is in a third position 125 (example third position 125 illustrated in FIGURE 6A).

[0118] In some embodiments, the guidewire 44 may form a close fit with the inside diameter of the needle body so as to provide a self-aspirating function when retracted. For example, an outside diameter of the guidewire 44 may be selected to form a close fit with the needle along the length of the guide wire or along only a portion of the guidewire 44.

[0119] In some embodiments, the distal end portion of the guidewire can have a reduced diameter in comparison to other sections of the guidewire. The size of such reduced diameter section can be selected to permit fluid to pass to the fenestration 56 in the needle body even when the guidewire has been advanced beyond the distal tip of the needle.

[0120] FIGURE 6A is a perspective view of the track 30 of the embodiment depicted in FIGURE 1A. Figure 6B is a plan view of the track 30 illustrated in FIGURE 6A. FIGURE 6C is a side view of the track 30 illustrated in FIGURE 6A. As shown in FIGURES 6A-6C, the track 30 in the illustrated embodiment comprises a distal portion 120, a proximal portion 122, a distal locking member 124 that connects the track to the dilator hub 38, a locking mechanism 128 that inhibits further proximal and distal movement of the needle hub 34 once the needle hub 34 is slid from the first position 121 to the second position 123 along the track 30, and a locking mechanism 130 that allows the guidewire hub 46 to attach to the track 30 when the guidewire hub is in the pre-loaded state or third position 125. Preferably, the track is made of polycarbonate material; however, as explained below, other materials can be used.

[0121] The track 30 may further include a track section 132 of reduced width as shown most clearly in FIGURES 6A and 6B. The reduced width facilitates assembly of the needle hub to the track 30. The illustrated embodiment includes a rib 133 on the distal portion 120 of the track 30. The rib 133 provides additional structural reinforcement between the distal locking member 124 and the remainder of the track 30.

[0122] As illustrated in FIGURE 1A, the distal locking member 124 connects to the dilator 24 and allows the track 30 to extend proximally from the dilator 24. For example, the locking member 124 can comprise two curved arms 124 that connect to the dilator hub 38 between the dilator hub lip 77 and the dilator hub base 79. The locking member 124 limits movement of the track 30 in a distal or proximal direction relative to the dilator hub 38 but allows the track 30 to rotate freely around the dilator hub 38.

[0123] FIGURE 6D is an enlarged view of a portion of the embodiment depicted in FIGURE 6B. As shown, the locking mechanism 128 is formed by varying the width of the track in the region of the second position 123. For example, the illustrated embodiment includes a track section 134 of increasing width in the distal direction, a track section 136 of

reduced width distal to the track section 134 of increasing width, and two finger elements 138. The two finger elements 138 project from the distal end of the track section 136 toward the proximal end of the track 30 and flare away from the longitudinal axis of the track 30.

[0124] FIGURE 6E is an enlarged view of a portion of the embodiment depicted in FIGURE 6B. The locking mechanism 130 is formed by a clip, clasp or other structure that engages with a portion of the guidewire hub or with a portion of the track 30 when the guidewire hub is in the third position. Some or all of the engagement structure may be part of the track 30, be part of the guidewire hub, or be split between the track 30 and guidewire hub. In the illustrated embodiment, the locking mechanism 130 extends from the track 30 and engages with the guidewire hub. The locking mechanism 130 comprises a rectangular element 140 protruding from the track 30, two track arms 142 projecting from the track 30 distal to the rectangular element 140, and a stop 144 protruding from the track 30 distal to the track arms 142.

[0125] In the illustrated embodiment, the locking mechanism between the needle hub and the dilator resides on the proximal side of the dilator hub. In other embodiments, however, the locking mechanism can be disposed at other locations as well. For example, where the locking mechanism includes two pivotal levers which are joined by a locking hinge, the locking mechanism can be disposed radially relative to the needle hub. In such an embodiment, one lever is pivotally coupled to the dilator and the other lever is pivotally coupled to the needle. When the needle hub is moved away from the dilator hub, the levers straighten to a point where the hinge locks. A similar effect can be obtained by a tether limiting proximal movement of the needle hub relative to the dilator beyond a particular point, thereby locking the components together. In a further embodiment, an elongated structure can extend parallel to the needle body from the needle hub within the dilator. Once the needle hub is moved a sufficient distance away from the dilator, additional structure of the locking mechanism (e.g., a detent) engages the elongated structure to inhibit further movement of the needle relative to the dilator. Accordingly, as illustrated by these additional embodiments, the locking mechanism operating between the needle and the dilator can be disposed at a variety of locations relative to the dilator hub.

[0126] FIGURE 7A is an enlarged plan view of the access device of the embodiment depicted in FIGURE 1A pre-loaded with the guidewire. FIGURE 7B is a side view of the embodiment depicted in FIGURE 7A. FIGURE 7C is a cross-sectional view of the embodiment depicted in FIGURE 7A along line 7C-7C. FIGURE 7D is a proximal end view of the access device 20 of FIGURE 7A. In this pre-loaded state, the guidewire hub 46 is locked to the track 30 when the guidewire hub 46 is located in a third position 125. In this position, the guidewire hub 46 can be secured to the track 30 between the rectangular element 140 and the stop 144. For example, the guidewire hub 46 can releasably lock between the rectangular element 140 and the stop 144. In addition, the track arms 142 can further secure the guidewire hub 46 to the track 30. This locking mechanism can arrest unintended rotational and axial movement of the guidewire 44 at least in the distal direction when the guidewire hub 46 is in the third position 125. Of course, the healthcare provider may disengage the guidewire hub 46 from the track 30 to allow distal movement of the guidewire through the access device 20.

[0127] In the preloaded-state illustrated in FIGURES 7A-7C, the needle hub 34 is locked to the dilator hub 38 when the needle hub 34 is in the first position 121. Preferably, in the locked position, the openings or fenestrations in the needle and dilator are in register or in alignment with each other. When locked, the needle 22 and the dilator 24 are inhibited from at least unintentional rotational and axial movement relative to each other. By preventing unintentional rotation of the dilator hub with respect to the needle 34, the fenestrations or openings maintain their general alignment.

[0128] In the pre-loaded state, the dilator hub 38 is secured to the sheath hub 42. This can inhibit at least unintentional rotational and axial movement between the dilator 24 and the sheath 26. In embodiments where the sheath hub 42 and the dilator 24 have only a luer slip connection, the dilator 24 and sheath hub 42 may rotate relative to each other.

[0129] FIGURE 8A is a plan view of the embodiment depicted in FIGURE 1A that illustrates an operational step of one method of using the access device 20. FIGURE 8A depicts the needle body 32 of the access device 20 inserted into a vessel 148, such as a vein. While the described method refers to vascular access, the access device 20 also can be used

to access and place a catheter or sheath into other locations within a patient's body (e.g., for draining an abscess) and for other purposes.

[0130] FIGURE 8B is an enlarged plan view of the portion of the embodiment illustrated in FIGURE 8A which is circled by line 8B-8B. FIGURE 8C is an enlarged plan view of the portion of the embodiment illustrated in FIGURE 8B which is circled by line 8C-8C. FIGURE 8D is an enlarged cross-sectional view of the embodiment depicted in FIGURE 8C along line 8D-8D.

[0131] As noted above, the needle body 32 comprises one or more side openings 56 in its side wall. The dilator shaft 36 comprises one or more side openings 74. The side openings 56, 74 may have the same or different shapes as well as aspect ratios. In the illustrated embodiment, the side opening 56 in the needle body 32 has a different aspect ratio than the side opening 74 in the dilator shaft 36. The side opening 56 in the needle body 32 is elongated in one direction (e.g., substantially parallel to the longitudinal axis of the needle body 32). The side opening 74 in the dilator shaft 36 is elongated in a different direction (e.g., along the circumference of the dilator shaft 36). Having offset elongated openings 56, 74 in the needle body 32 and the dilator shaft 36 increases the likelihood that the openings 56, 74 in the needle body 32 and dilator shaft 36 will be sufficiently aligned so that blood flows through the needle side opening 56 and dilator side opening 74. FIGURES 8A-D illustrate the alignment between only one set of corresponding side openings. Other sets of side openings can also be aligned or be misaligned depending upon the relative orientations of the needle body 32 and the dilator shaft 36.

[0132] In the illustrated embodiment, the dilator shaft 36 is coaxially positioned to minimize an annular space 150 between the needle body 32 and the dilator shaft 36. The inner surface 152 of the dilator shaft 36 need not, though it can, lie directly against the outer-surface 154 of the needle body 32. Preferably, in this embodiment, the annular space 150 between the outer-surface 154 of the needle body 32 and the inner surface 152 of the dilator shaft 36 is minimized to inhibit the flow of blood or its constituents (or other bodily fluids) into the annular space 150 between the dilator shaft 36 and needle body 32. Advantageously, this feature minimizes the blood's exposure to multiple external surfaces and reduces the risk of contamination, infection, and clotting.

[0133] As illustrated in FIGURE 8A, the dilator shaft 36 is coaxially mounted to the needle body 32 such that at least part of one side opening 56 disposed on the needle body 32 is rotationally aligned with at least part of one side opening 74 on the dilator shaft 36. Preferably, the needle body 32 and dilator shaft 36 maintain rotational alignment so that blood flows through the needle side opening 56 and dilator side opening 74.

[0134] The sheath body 40, as noted previously, is preferably made partially or completely from clear, semi-opaque, translucent, or transparent material so that when blood flows into the needle body 32, (1) through the needle side opening 56, (2) through the dilator side opening 74, and (3) into a channel 156, the physician or healthcare provider can see the blood. In some modes, the channel 156 is formed between the dilator shaft 36 and the sheath body 40 and defined by one or more ridges 76 on the dilator shaft 36. In some modes, the channel 156 is formed within a wall of the dilator shaft 36 with the dilator shaft 36 preferably comprising a transparent material. Blood will indicate to the physician or healthcare provider that the bevel tip 54 of the needle body 32 has punctured a vessel 148.

[0135] In some embodiments, the needle body 32 and dilator shaft 36 may (both) have multiple side openings where some or all of these side openings can be rotationally aligned.

[0136] The channel 156 can have an axial length that is almost coextensive with the length of the sheath 26. In other embodiments, the channel 156 can be significantly smaller than the elongated channel 156 just described. For example, but without limitation, the channel 156 can be disposed within a distal, mid and/or proximal portion(s) of the sheath 26. The channel 156 alternatively can have a linear, curved or spiral shape along an axial length of the sheath 26 or can be formed by a plurality of such shapes. The channel 156 may have various thicknesses and span angles. The thickness of the channel 156 can range from almost close to zero to 0.010 inches. Preferably, the channel 156 has a thickness of about 0.0005 to about 0.003 inches. More preferably, the channel 156 can have a thickness of about 0.001 inches to about 0.002 inches. The channel 156 can have a span angle Φ about the axis of the dilator 24 of about 30 degrees to about 210 degrees or more, but preferably less than 360 degrees. More preferably, the channel 156 can have a span angle Φ of about 60 to 150. In the illustrated embodiment, the channel 156 spans 120 degrees. The thickness and

span angle Φ can be chosen so as to optimize the capillary action that occurs within the channel 156 as fluid (e.g., whole blood) enters the channel 156 as may further be selected based on the expected pressure in the body cavity and viscosity of the liquid.

[0137] FIGURES 8E-8G are graphs of test data illustrating how quickly a fluid is drawn up the surfaces of the channel 156 when the span angle is 120 degrees, the contact angle (θ) is 5 degrees, and the circumferential length (H) is 0.64mm at 60 degrees. On each graph, the filling length (mm) is plotted on the y-axis, and time (seconds) is plotted on the x-axis. The tests were performed at hydrodynamic pressures similar to pressures experienced in peripheral vessels. FIGURE 8E illustrates the rate fluid is drawn up a channel 156 with a gap height width of 0.002 inches, FIGURE 8F illustrates the rate fluid is drawn up a channel 156 with a gap height width of 0.001 inches, and FIGURE 8G illustrates the rate fluid is drawn up a channel 156 with a gap height width of 0.0005 inches. As shown in FIGURES 8E-G, fluid is drawn up the fastest in a channel with a gap height width of 0.0005 inches, followed by a channel with a gap height width of 0.001 inches, followed by a channel with a gap height width of 0.002 inches.

[0138] The shape of the channel 156 described above and the resulting capillary action was optimized for use with whole blood as opposed to other fluids having a different viscosity than whole blood (e.g. leukocytes, pus, urine, plasma). However, the shape of the channel 156 is not limited to the disclosed shape and may be optimized for draining other liquids, such as pus. Further, the shape of the channel 156 described above was optimized for peripherally located vessels where the pressure in the vessel enhances the capillary action and resulting blood flash as well as for vessels located in the regions where the pressure may be low. For example, in the thorax region of the body, the expected pressure in the veins may be lower than in a peripherally located vein when the patient breathes. A different size of the channel for use of the access device 20 in other regions of the body may be employed taking into account the expected pressure within the vessel or body cavity.

[0139] Additionally, an outer-surface 160 of the dilator shaft 36 and/or an inner surface 158 of the sheath body 40 can be coated with a substance to promote or enhance the capillary action within the channel 156. For example a hydrophilic substance can be used to coat outer-surface 160 of the dilator shaft 36 and/or the inner surface 158 of the sheath body

40 to enhance capillary action. Similarly, one or both of these components can be made of a hydrophilic material. A hydrophilic substance additionally can be applied to the outer surface of the sheath 26 to act as a lubricant to ease insertion of the sheath 26 into a patient. Other lubricants or lubricous coatings can be used on the exterior of the sheath 26 or at least the outer surface of the sheath can be formed of a lubricous material. Additionally, the sheath 26 can be coated or formed with agents (e.g., heparin), which elute from the sheath, to facilitate the clinical application of the access device 20.

[0140] FIGURE 8H is a cross sectional view of the embodiment depicted in FIGURE 8C along line 8H-8H. In this region of the illustrated access device 20, the sheath body 40 is coaxially positioned to minimize the annular space 157 between the sheath body 40 and the dilator shaft 36 while still allowing relative movement of the sheath body 40 and the dilator shaft 36. The inner surface 158 of the sheath body 40 need not, though it can, lie directly against the outer-surface 160 of the dilator shaft 36. The annular interface 157 between the outer-surface 160 of the dilator shaft 36 and the inner surface 158 of the sheath body 40 may be reduced in this region to inhibit the distal flow of blood or its constituents (or other bodily fluids) from the opening 74 in the dilator shaft 36.

[0141] FIGURE 8I is an enlarged plan view of the portion of the embodiment illustrated in FIGURE 8A which is circled by line 8I-8I. FIGURE 8J is a cross-sectional view of the embodiment depicted in FIGURE 8I. FIGURES 8I and 8J illustrate the needle hub 34 locked to the dilator hub 38 when the needle hub is in the first position 121. The dilator shaft 36 may be coaxially mounted to the needle body 32 by slipping a hollow section 84 of the dilator shaft 36 over the needle body 32 and releasably securing the dilator hub 38 to the needle hub 34. The proximal end 86 of the dilator hub 38 is configured to mechanically fit and interlock with the needle hub 34.

[0142] The dilator shaft 36 may be releasably mounted to the needle body 32 so that the dilator shaft 36 can be mounted and released, or vice versa, from a coaxial position relative to the needle body 32. This locking mechanism can inhibit at least some unintentional rotational and axial movement between the needle 22 and the dilator 24 when the needle hub 34 is in the first position. As shown, the needle hub 34 may have a luer connection 64 that locks to the luer connection 78 of the dilator hub 38. Furthermore, the

needle hub 34 may also have latch element 66 that locks to the opening 82 in the dilator hub 38.

[0143] In addition, FIGURES 8I and 8J illustrate the dilator hub 38 engaged with the sheath hub 42 when the access device 20 is inserted into a vessel 148. Preferably, the proximal end 86 of the sheath hub 42 is configured to mechanically fit and releasably engaged with the dilator hub 38. As shown, the luer connection 80 in the dilator hub 38 can engage with the lock member 94 of the sheath hub. The resulting friction fit can inhibit at least some unintentional rotational and axial movement between the dilator 24 and the sheath 26 when the access device 20 is inserted into a vessel 148.

[0144] FIGURE 9A is a side view of the embodiment depicted in FIGURE 1A that illustrates a further operational step of the access device 20. FIGURE 9A depicts the guidewire 44 of the access device 20 advanced in a distal direction into a vessel 148. This can be achieved by advancing guidewire hub 46 from the third position 125 in a distal direction. The guidewire hub 46 is then locked to the needle hub 34 when the needle hub 34 is in the first position 121.

[0145] FIGURE 9B is an enlarged side view of the portion of the embodiment illustrated in FIGURE 9A which is circled by line 9B-9B. FIGURE 9C is a cross-sectional view of the embodiment depicted in FIGURE 9B. FIGURE 9C illustrates the locking mechanism between the guidewire hub 46 and the needle hub 34. Preferably, the guidewire hub 46 is configured to mechanically fit and releasably or irreversibly interlock with the needle hub 34. As shown, the guidewire hub 46 includes a nub 162 on the inner surface of the guidewire hub 46. The nub 162 of the guidewire hub can lock onto the needle hub 34 by advancing the guidewire hub 46 in a distal direction until the nub 162 is secured within the threaded groove on the lip of the needle hub 46. In other embodiments, the guidewire hub 46 can lock to the needle hub 34 via corresponding threaded elements.

[0146] FIGURE 10A is a side view of the embodiment depicted in FIGURE 1A that illustrates another operational step of the access device 20. FIGURE 10A depicts the dilator shaft 36 and the sheath body 40 advanced in a distal direction into a vessel 148. This can be achieved by releasing the dilator hub 38 from the needle hub 34 and advancing the dilator 24 and sheath 26 in a distal direction relative to the needle hub 34 along the guidewire

and needle. FIGURE 10A further illustrates the proximal movement of the needle 22 and guidewire section 28 relative to the dilator 24 and the sheath 26. The needle hub 34 will lock to the track 30 when the needle hub 36 reaches the second position 123.

[0147] FIGURE 10B is an enlarged rear view of the portion of the embodiment illustrated in FIGURE 10A which is circled by line 10B-10B. As depicted in FIGURE 10B, the needle hub 34 locks onto the track 30 via the locking mechanism 128 in the second position 123. The needle hub tangs 68 slide in a proximal direction over the track fingers 138 and the tangs 68 can lock into place between the track fingers 138 and the track section of increasing width 134. This arrests and, more preferably, substantially irreversibly prevents axial movement of the needle body 32 at least in the distal direction when the needle hub 34 is in the second position 123. In the illustrated embodiment, the locking mechanism 128 irreversibly prevents the needle hub 34 from moving in either the proximal or distal directions once engaged. Furthermore, the distal tip 54 of the needle 22 is drawn into the dilator 24 to sheath the distal tip 54 when the needle hub 34 is in the second position 123. Thus, this locking mechanism 128 inhibits the bevel tip 54 disposed on the distal portion 50 of the needle body 32 from being advanced beyond the distal end of the dilator shaft 36 once the dilator shaft 36 has been advanced over the needle body 32 during use. The dilator shaft 36 thus sheaths the sharp bevel tip 54 of the needle body 32 to inhibit accidental needle sticks from occurring.

[0148] FIGURE 11A is a side view of the embodiment depicted in FIGURE 1A that illustrates the final operational step of the access device 20. FIGURE 11A illustrates the removal of the guidewire 44 and the dilator shaft 36 from the vessel leaving the sheath body 40 properly inserted within the vessel 148. FIGURE 11B is an enlarged plan view of the portion of the embodiment illustrated in FIGURE 11A which is circled by line 11B-11B. As clearly shown in FIGURE 11B, the distal end of the dilator shaft 36 and the guidewire 44 extend beyond the sharp bevel tip 54 of the needle body 32 to inhibit accidental needle sticks from occurring.

[0149] As noted above, having openings 56, 74 in the needle body 32 and dilator shaft 36 with different aspect ratios will increase the likelihood that the openings 56, 74 in

the needle body 32 and dilator shaft 36 will be aligned so that blood flows substantially unobstructed through the needle side opening 56 and dilator side opening 74.

[0150] In the following embodiments, structure from one embodiment that is similar to structure from another embodiment share the same root reference number with each embodiment including a unique suffix letter (32, 32A, 32B, etc.). FIGURE 12A is a plan view of another embodiment of the openings 56, 74 in the needle body 32 and dilator shaft 36 illustrated in FIGURES 8B and 8C. FIGURE 12B is an enlarged cross-sectional view of the embodiment depicted in FIGURE 12A along line 12B-12B. FIGURES 12A and 12B depict a needle body 32A with an oblong opening 56A and a dilator shaft 36A with a circular opening 74A. In other embodiments, the needle can have a circular opening and the dilator can have an oblong opening. These embodiments can increase the likelihood that the openings 56A, 74A will be at least substantially aligned so that blood flows through the needle side opening 56A and dilator side opening 74A.

[0151] FIGURE 13A is a plan view of another embodiment of the openings 56, 74 in the needle body 32 and dilator shaft 36 illustrated in FIGURES 8B and 8C. FIGURE 13B is an enlarged cross-sectional view of the embodiment depicted in FIGURE 13A along line 13B-13B. FIGURES 13A and 13B depict a needle body 32B with a circular opening 56B and a dilator shaft 36B with a circular opening 74B that is larger than the circular opening 56B in the needle body 32B. In other embodiments, the opening in the dilator can be smaller than the opening in the needle. These embodiments can also increase the likelihood that the openings 56B, 74B will be at least substantially aligned so that blood flows through the needle side opening 56B and dilator side opening 74B.

[0152] As noted above, the dilator shaft 36 may have one or more channels 156 formed between ridges 76 to form a conduit or flow path between the sheath body 40 and the dilator shaft 36 to enable the physician or health care provider to view the blood after the bevel tip 54 of the needle body 32 has properly punctured a vessel or the channels may be formed without ridges but by extruding axial indentations of various possible configurations or by forming fully enclosed channels within the dilator shaft or body.

[0153] FIGURE 14A is a plan view of another embodiment of the ridges 76 depicted in FIGURE 8C. FIGURE 14B is an enlarged cross-sectional view of another

embodiment of the ridges 76 depicted in FIGURE 8D. FIGURES 14A and 14B depict two ridges 76C on the inner surface 158C of the sheath body 40C that form at least one channel 156C between the sheath body 40C and the dilator shaft 36C.

[0154] FIGURE 15A is a plan view of another embodiment of the ridges 76 depicted in FIGURE 8C. FIGURE 15B is an enlarged cross-sectional view of another embodiment of the ridges 76 depicted in FIGURE 8D. FIGURES 15A and 15B depict two ridges 76D on the inner surface 158D of the sheath body 40D and two ridges 76E on the outer surface 160D of the dilator shaft 36D that combine to form a channel 156D between the sheath body 40D and the dilator shaft 36D. For example, if the desired channel thickness is about 0.001 inches, the two ridges 76D on the inner surface 158D of the sheath body 40D can each be about 0.0005 inches thick and the two ridges 76E on the outer surface 160D of the dilator shaft 36D can each be about 0.0005 inches thick.

[0155] FIGURE 16A is a plan view of another embodiment of the ridges 76 depicted in FIGURE 8C. FIGURE 16B is an enlarged cross-sectional view of another embodiment of the ridges 76 depicted in FIGURE 8D. FIGURES 16A and 16B depict many ridges on the outer surface 160E of the dilator shaft 36E. Between adjacent ridges are splines 76F. The splines 76F form a plurality of channels 156E between the sheath body 40E and the dilator shaft 36E. One or more of the channels 156E can have the same span angle Φ or different span angles Φ . In the illustrated embodiment the channels 156E have span angles of 120 degrees and 23 degrees. In another embodiment, a single ridge 76 can spiral around the exterior of the dilator along its length.

[0156] FIGURE 17 is an enlarged cross-sectional view through another embodiment of the access device and shows the channel 156F formed between a medical article or sheath body 40F and a dilator shaft 36F that have dissimilar shapes. In the illustrated embodiment, the outer surface of the dilator shaft 36F has an oval shape while the inner surface of the sheath body 40F has a round shape. The oval dilator shaft 36F and the adjacent round sheath body 40F form one or more channels or gaps 156F between the sheath body 40F and the dilator shaft 36F. Of course the shapes of the sheath body 40F and dilator shaft 36F are not limited to round and oval and may include any other combination of dissimilar shapes in adjacent regions of the sheath body 40F and dilator shaft 36F. In some

modes, the outer surface of the dilator shaft 36F is oblong and the inner surface of the sheath body or medical article 40F is round. In some modes, the outer surface of the dilator shaft 36F is round and the inner surface of the medical article 40F is square. The gap or channel 156F can follow a longitudinal axis, a spiral path along the longitudinal axis, a linear path along the longitudinal axis or other path along the access device. In some modes, the linear path is parallel to the longitudinal axis. The gap or channel 156F thickness can vary along at least a portion of a length of the gap or channel 156F.

[0157] In other embodiments, the channel 156 can be formed by having one complete ridge on the inner surface of the sheath and one complete ridge on the outer surface of the dilator. In other embodiments, the inner surface of the sheath can have two ridges that run 50% of the length of the channel 156 and the outer surface of the dilator can have two ridges that run the remaining 50% of the channel 156.

[0158] FIGURE 18A is a perspective view of another preferred embodiment of an access device 20'. As depicted, the sheath hub 42' includes a variable volume space such as a flexible cavity 200. In other embodiments, the variable volume space, such as a flexible cavity, can be placed on another hub such as a dilator hub 38 or a needle hub 34. For example, in some embodiments a flash chamber or space can be provided between a dilator shaft and a needle body in manners similar to those used to create a space between the dilator shaft and sheath body, as described herein. Some examples of spaces between a needle body and a dilator shaft are included in International Publication No. WO 2009/114837 (published September 17, 2009 and incorporated herein by reference in its entirety) at Figures 18A-18C and the associated text. Similarly, in some embodiments the flash chamber or space can be provided between a needle body and a sheath body, such as when there is no dilator or the sheath also functions as its own dilator. More generally, the flash chamber or space can be provided at any portion between the exterior of the needle body and the interior of a medical article mounted directly or indirectly to the needle body. While the flexible cavity 200 has at least one flexible wall so as to vary the volume within the space, the variable volume space can be defined between two or more components that move relative to each other (e.g., a piston-cylinder arrangement).

[0159] As depicted in FIGURES 18B, 18C the flexible cavity 200 can have the shape of a bubble, but in other embodiments it can have different shapes such as being generally rectangular, pyramid-shaped, or otherwise. The depicted flexible cavity 200 extends laterally from the sheath hub 42' and communicates with a hub aperture 205 in the sheath hub. The hub aperture 205 can put the flexible cavity 200 in communication with a fluid flash space, such as the channel(s) or a generally annular space, as described herein, between the sheath body 40 and the dilator shaft 36. In other embodiments, a similar flexible cavity can be positioned for example on the dilator hub 38 or the needle hub and communicate with an annular space or channel between the dilator shaft 36 and the needle body 32. For example, in some embodiments a flash space can be disposed between the needle body 32 and the dilator shaft 36, and a flexible cavity such as those described herein can be in communication therewith. In such embodiments, a side fenestration in the dilator shaft 36 can be omitted while maintaining substantially similar functionality. In further embodiments, the flexible cavity 200 can communicate with any of the other spaces described herein, or similar spaces directly or indirectly in communication with the needle tip. The variable volume chamber can also be disposed between the hubs or forward of the hubs.

[0160] As depicted in FIGURE 18B, the flexible cavity 200 can initially be contracted. Typically, a human hand can hold the flexible cavity 200 in the contracted state by depressing the cavity, holding it in a pinching position, or by some other means. However, in other embodiments it can be held contracted by a mechanical contracting mechanism integrated with other grip portions of the access device 20'. In some preferred embodiments, the flexible cavity 200 can be positioned and configured such that a hand holding the access device 20' by the sheath hub 42' could also contract the flexible cavity. Similarly, in embodiments where the flexible cavity 200 is on a dilator hub or needle hub, the flexible cavity can be configured such that a hand holding the device by said hub could also contract the flexible cavity.

[0161] Upon entry into a patient, the flexible cavity 200 can be released and allowed to expand freely (as depicted in FIGURE 18C). To this end, the flexible cavity 200 can naturally tend or be biased to tend toward this expanded position upon release. Outside a

patient, this would cause the flexible cavity 200 of the depicted embodiment to fill with air passing through the needle body 32. However, if the flexible cavity 200 is released in a contracted state while inside a patient, the negative pressure produced by the released cavity can facilitate the uptake of a body fluid once the needle 32 enters a fluid filled body space such as a vein, as further described below.

[0162] The uptake of body fluids such as blood flash can be hastened or hindered by frictional resistance related to the access device 20' and the pressure inside the access device 20'. Further, uptake can increase with the pressure of the relevant fluid. In some embodiments the resistance and negative pressure from a contracted flexible cavity 200 can be chosen such that the flexible cavity fills upon entry into a blood vessel, but not when in the general surrounding body tissue. The application of negative pressure can facilitate the uptake of body fluids even from lower pressure environments such as central veins. In alternative embodiments the negative pressure provided can be chosen to indicate uptake from other vessels, such as arteries which have a higher blood pressure and thus could utilize a smaller negative pressure. As described further below, in some embodiments an operator can inter-operatively choose the magnitude of the negative pressure provided.

[0163] To maintain the negative pressure, the variable volume chamber and the spaces with which it communicates can be sealed from the ambient atmosphere. For example, the sheath hub 42' can include or engage with a sealing member such as an O-ring, Bodok seal, gasket, or other flexible non-porous materials. The sealing member can thus inhibit the transmission of gases between the sheath hub 42' and another part of the access device 20' such as the dilator hub. In other embodiments sealing members can be provided between other parts described herein. Further, in some embodiments sealing members can be provided between the sheath body 40, dilator shaft 36, and/or the needle body 32. For example, the sheath body 40 and the dilator shaft 36 can be sized in at least one portion to create a seal when the sheath body mounts on the dilator shaft. Similarly, the dilator shaft 36 and needle body 32 can be sized in at least one portion to create a seal when the dilator shaft mounts the needle body.

[0164] Thus, in operation the flexible cavity 200 can initially be contracted outside the patient. Upon the access device 20' entering the patient, the flexible cavity 200

can be released, producing a negative pressure tending to pull fluids into the access device 20'. Upon entry into a blood vessel, the flexible cavity 200 can expand as blood is pulled into the access device 20' and air displaced by that blood into the flexible cavity 200. The added negative pressure from the flexible cavity 200 can accelerate the uptake of blood into the access device 20'. Where the access device 20' includes for example a transparent sheath, an operator of the access device 20' can receive a more immediate indication of venous entry.

[0165] FIGURE 19 is a perspective view of another preferred embodiment of an access device configured in accordance with the present invention. As depicted, instead of a flexible cavity 200 directly connected to the sheath hub 42', a sheath hub 42'' can attach to a tube 210 leading to a pump 215. The tube 210 can connect to the sheath hub 42' via a one-way valve 220 (for example preventing an injection of air into the patient). Similarly, the pump 215 can communicate with ambient air through a one-way valve 225. The pump 215 can thus provide a similar negative pressure as described with regard to the flexible cavity 200. Additionally, the tube 210 can connect to other portions of the access device 20'', as discussed with regard to the flexible cavity 200, such as to a dilator hub or a needle hub. In some embodiments, a negative pressure can be provided by a syringe, in place of or in addition to the pump 215. As discussed above, a variety of sealing members can be included with the access device 20'', such as at the valves 220, 225.

[0166] It will be clear from the description herein, that the embodiments in FIGURE 18 and 19 can be combined. For example, in some embodiments a flexible cavity 200 and a pump 215 can combine to produce increased negative pressure. Other embodiments can include multiple variable volume chambers of the same or different types. Advantageously, in those embodiments with multiple chambers, an operator can choose an amount of negative pressure to apply by contracting a specific set of chambers. For example, in one embodiment two chambers can be provided with different associated negative pressures. The larger chamber can be contracted when an operator desires indication of entry into a lower pressure vessel such as a vein; and the smaller chamber can be intended for higher pressure vessels such as an artery. Additionally or alternatively, chambers can be configured for negative pressure necessary for neonate arteries or veins, or other vessels of

further varying pressures. In further embodiments, multiple chambers can be activated at once, providing a combined negative pressure. Notably, in some embodiments no negative pressure will be necessary for uptake of body fluids from the higher pressure vessels, motivating the additional option of activating none of the chambers.

[0167] In some preferred embodiments, the total maximum volume of the variable volume chambers employed can be no less than the volume of the space(s) with which they communicate. For example, in embodiments with only a single variable volume chamber, the chamber's maximum volume can be greater than or equal to the volume of a flash space with which it communicates. If two variable volume chambers are used, the sum of their maximum volumes can be greater than or equal to the volume of the flash space. Similar adjustments can be provided for multiple flash spaces. Further, although the description herein generally characterizes the chambers as filling with air, they might also fill with body fluid; an example embodiment having a volume of the chamber greater than a volume of the flash space.

[0168] FIGURE 20 is a perspective view of another embodiment of an access device. As depicted, the access device comprises a needle 22 and a guidewire 44 similar to those described above in other embodiments. Further, the access device can include a catheter 300, with structure generally similar to the dilator 24. Further, the catheter 300 can have an elongated body that is partially translucent or transparent, as discussed above in relation to a sheath. Further, the catheter can include a hub with a locking structure configured to releasably lock with corresponding locking structure on the needle. The locking structures can be similar to those described above connecting the needle to the dilator, such as depicted in FIGURES 2E, 2F, 2G, 3B, and 3D. The locking structure between the catheter and needle can prevent unintentional gross relative movement between them, and release the needle to allow the needle to slide relative to the catheter when desired.

[0169] A flash space can be disposed between the needle 22 and the exterior surface of the catheter 300 body, and can communicate with an interior of the needle body so that a body fluid within the needle can flow into the space and be visible through the translucent or transparent portion of the catheter body.

[0170] In some embodiments, the locking structure can be a luer-lock connector, a threaded locking structure, a releasable locking structure, or some combination thereof. Advantageously, in some embodiments a plurality of locking structures can be provided on the catheter 300 hub such that one locking structure can lock with a medical device fitting and another can lock with the needle locking structure.

[0171] Further, it should be clear from the description herein that the embodiment of FIGURE 20 can be combined with other embodiments described herein (as can said other embodiments be combined with each other). For example, the embodiment of FIGURE 20 can also include a negative pressure element or a variable volume chamber.

[0172] In further embodiments, a surfactant can be provided to further accelerate the uptake of a body fluid by an access device. The surfactant can be applied to any surface contacting the body fluid. Thus, for example, in the embodiment of FIGURE 18A the surfactant can be applied to any one of the needle body, dilator shaft, sheath body, and/or the sheath hub.

[0173] In additional embodiments, it may be desirable to allow the egress of air to the ambient atmosphere while hindering the egress of fluids. In such embodiments, a filtering member such as a porous membrane, sufficiently small pores, or other elements can be provided to the access device 20'. For example, a porous membrane can be provided over the hub aperture 205, allowing air to pass into a flexible cavity 200 or a pump 215, but hindering the passage of a body fluid such as blood. In other embodiments such filtering members can locate within a tube 215, at valves 220, 225, or within the flash space where the fluid may be visible.

[0174] The embodiments herein described are comprised of conventional, biocompatible materials. For example, the needle preferably consists of ceramic, a rigid polymer, or a metal such as stainless steel, nitinol, or the like. The other elements can be formed of suitable polymeric materials, such as polycarbonate, nylon, polyethylene, high-density polyethylene, polypropylene, fluoropolymers and copolymers such as perfluoro (ethylene-propylene) copolymer, polyurethane polymers or co-polymers.

[0175] As noted above, the present access device can be used to place a catheter at other locations within a patient's body. Thus, for example, but without limitation, the

access device can be used as or with a variety of catheters to drain fluids from abscesses, to drain air from a pneumotorax, and to access the peritoneal cavity. In such applications, body fluids flow into the viewing space to indicate when the needle has been properly placed.

[0176] Although this invention has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In addition, while a number of variations of the invention have been shown and described in detail, other modifications, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the invention. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed invention. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the disclosure and the claims that follow.

WHAT IS CLAIMED IS:

1. An access device for placing a medical article within a body space, comprising:
 - a needle comprising a bore;
 - a medical article disposed over at least a portion of the needle and comprising an outer surface;
 - a flash space disposed between the needle and the outer surface of the medical article, the flash space communicating with the bore of the needle; and
 - a variable volume chamber communicating with the flash space so as to draw fluid from the flash space into the chamber.
2. The access device of Claim 1, further comprising a hub on which the medical article is mounted.
3. The access device of Claim 2, wherein the variable volume chamber communicates with the flash space through a fenestration in the hub, the fenestration being sealed by the variable volume chamber.
4. The access device of Claim 1, wherein the medical article is a dilator.
5. The access device of Claim 1, wherein the medical article is a sheath.
6. The access device of Claim 5, further comprising a sheath hub mounted on the sheath and wherein the variable volume chamber communicates with the flash space through the dilator hub.
7. The access device of Claim 5, further comprising a dilator.
8. The access device of either of Claims 4 and 7, further comprising a dilator hub mounted on the dilator and wherein the variable volume chamber communicates with the flash space through the dilator hub.
9. The access device of either of Claims 4 and 7, wherein the flash space is located between the needle and the dilator.
10. The access device of Claim 7, wherein the flash space is located between the dilator and the sheath.
11. The access device of Claim of any of the preceding claims, wherein the variable volume chamber communicates directly with the flash space.

12. The access device of Claim of any of the preceding claims, wherein the variable volume chamber comprises a deformable wall.

13. The access device of Claim of any of the preceding claims, wherein the variable volume chamber comprises a piston-cylinder assembly.

14. The access device of Claim of any of the preceding claims, wherein the needle comprises a side fenestration, the flash space communicating with the bore of the needle through the side fenestration.

15. The access device of Claim of any of the preceding claims, wherein the variable volume chamber is biased toward an expanded position wherein the chamber has a larger volume in the expanded position.

16. The access device of Claim of any of the preceding claims, wherein the variable volume chamber provides a negative pressure sufficient to draw a body fluid from a body cavity selected from the group consisting of a vein, artery, and body cavity.

17. The access device of any of the preceding claims, further comprising a sealing member that inhibits the passage of gases between the variable volume chamber and the ambient atmosphere.

18. The access device of Claim 17, wherein a sheath hub comprises the sealing member and the sealing member inhibits the passage of gases between a sheath hub and a dilator hub.

19. The access device of Claim 18, wherein the sealing member is chosen from the group consisting of an O-ring, a Bodok seal, and a gasket.

20. The access device of any of the preceding claims, comprising a plurality of variable volume chambers in communication with the flash space.

21. The access device of any of the preceding claims, wherein the total maximum volume of the variable volume chamber or chambers employed is no less than the volume of the flash space.

22. An access device for placing a medical article within a body space, comprising:

a needle comprising a bore;

a medical article disposed over at least a portion of the needle and comprising an outer surface;

a flash space disposed between the needle and the outer surface of the medical article, the flash space communication with the bore of the needle;

an extended passage in communication with the flash space at a first end and further comprising a second end;

a negative pressure element in communication with the second end of the tube; and

a filtering member in at least one of the negative pressure element, passage, or flash space allowing the transit of air but inhibiting the transit of a body fluid.

23. The access device of Claim 22, further comprising a hub on which the medical article is mounted, the extended passage being in communication with the flash space through the hub.

24. The access device of any of Claims 22 and 23, wherein the medical article is a dilator.

25. The access device of any of Claims 22 and 23, wherein the medical article is a sheath.

26. The access device of any of Claims 22-25, wherein the negative pressure element comprises a syringe.

27. The access device of any of Claims 22-26, wherein the negative pressure element comprises a pump.

28. The access device of any of Claims 22-27, wherein the filtering element comprises a porous membrane.

29. The access device of any of Claims 22-28, wherein the extended passage is a tube.

30. The access device of any of Claims 22-29, further comprising a one-way valve disposed between the negative pressure element and the flash space.

31. The access device of any of Claims 22-30, further comprising a one-way valve disposed between the negative pressure element and the ambient atmosphere.

32. The access device of Claim 31, wherein the one-way valve allows direct communication between the negative pressure element and the ambient atmosphere.

33. The access device of any of the preceding claims, comprising a plurality of negative pressure elements.

34. The access device of any of the preceding claims, further comprising a locking structure between the needle and the medical article.

35. A method for accessing a body cavity comprising:

inserting an access device into a body cavity, the access device comprising a needle, a medical article, a flash space disposed between the needle and an outer surface of the medical article, and a variable volume chamber in communication with the flash space, wherein the variable volume chamber is in a contracted, lower volume position;

expanding the volume of the variable volume chamber to produce a negative pressure in the variable volume chamber sufficient to draw a body fluid from the body cavity into the flash space; and

observing the body fluid in the flash space from outside the access device.

36. The method of Claim 35, wherein the step of expanding the volume of the variable volume chamber comprises releasing the variable volume chamber.

37. The method of Claim 36, wherein the step of expanding further comprises allowing the variable volume chamber to expand automatically upon release of the variable volume chamber.

38. The method of any of Claims 35-37, further comprising the steps of:

locking the needle to the medical article so as to hinder relative movement between the needle and the medical article; and

unlocking the needle from the medical article.

39. An access device for placing a catheter within a body space, comprising:

a needle comprising an elongated body with a distal end, a hub from which the needle body extends, and a locking structure disposed on the hub; and

a catheter disposed on the needle body and movable relative to the needle body, the catheter comprising a flexible catheter body and a locking structure

configured to interengage with the needle locking structure to hinder relative movement between the needle and the catheter, the catheter locking structure also being configured to interengage with a medical fitting,

wherein the access device lacks a dilator between the needle and the catheter.

40. The access device of Claim 39, wherein the locking structure prevents relative movement between the catheter and needle when the catheter and needle are adjacent.

41. The access device of either of Claims Claim 39 and 40, wherein the catheter is configured to safely bend at extreme angles without kinking, so as to maintain a clear channel there through when inserted in a body cavity.

42. The access device of any of Claims 39-41, wherein the catheter does not have sufficient structural strength to dilate a hole created by the needle.

43. The access device of Claims 39-42, wherein the catheter is not self-supporting, and substantially dips downward under the force of gravity when not supported by the needle.

44. An access device for placing a catheter within a body space, comprising:

a needle comprising an elongated body with a distal end, a hub from which the needle body extends, and a locking structure disposed on the hub;

a catheter at least partially disposed on the needle body and comprising an elongated catheter body being at least partially translucent or transparent, and a hub from which the catheter body extends, the hub including locking structure configured to releasably lock with the needle locking structure to prevent unintentional gross relative movement between the needle and the catheter and configured to release from the needle locking structure to allow the needle to be slide relative to the catheter;

a flash space disposed between the needle and an exterior surface of the catheter body, the flash space communicating with an interior of the needle body so that body fluid within the needle body flows into the space and is visible through the translucent or transparent portion of the catheter body; and

a guidewire preloaded into the needle, the guidewire having a length greater than the length of the needle body and being slideable through the needle body.

45. The access device of Claim 44, wherein the catheter hub locking structure is configured to engage a luer-lock connector fitting on a medical article.

46. The access device of any of Claims 44 and 45, wherein the catheter hub locking structure includes threads.

47. The access device of any of Claims 44-46, wherein the hub locking structure is further configured to releasably lock with a medical fitting.

48. The access device of any of Claims 44-47, wherein the catheter hub locking structure comprises a first locking structure element and a second locking structure element, the first locking structure element configured to releasably lock with medical device fitting and the second locking structure element configured to releasably lock with the needle locking structure.

49. The access device of any of Claims 44-48, wherein the locking structures of the catheter hub and the needle hub interlock when catheter hub is disposed adjacent to the needle hub.

50. The access device of any of Claims 44-49, wherein the catheter is configured to bend at acute angles without kinking.

51. The access device of any of Claims 44-50, wherein the catheter does not have sufficient axial and structural strength to dilate a hole created by the needle.

52. The access device of any of Claims 44-51, wherein the catheter is not self-supporting, and substantially dips downward under the force of gravity when not supported by the needle.

53. The access device of any of Claims 44-52 additionally comprising a negative pressure element communicating with the flash space.

54. The access device of any of Claims 44-53, wherein the guidewire includes a proximal end and a distal end, the distal end being disposed within the needle body and the proximal end being disposable apart from the needle hub in a manner permitting a proximal portion of the guidewire, which is disposed outside the needle, to be bent away from an axis of the needle.

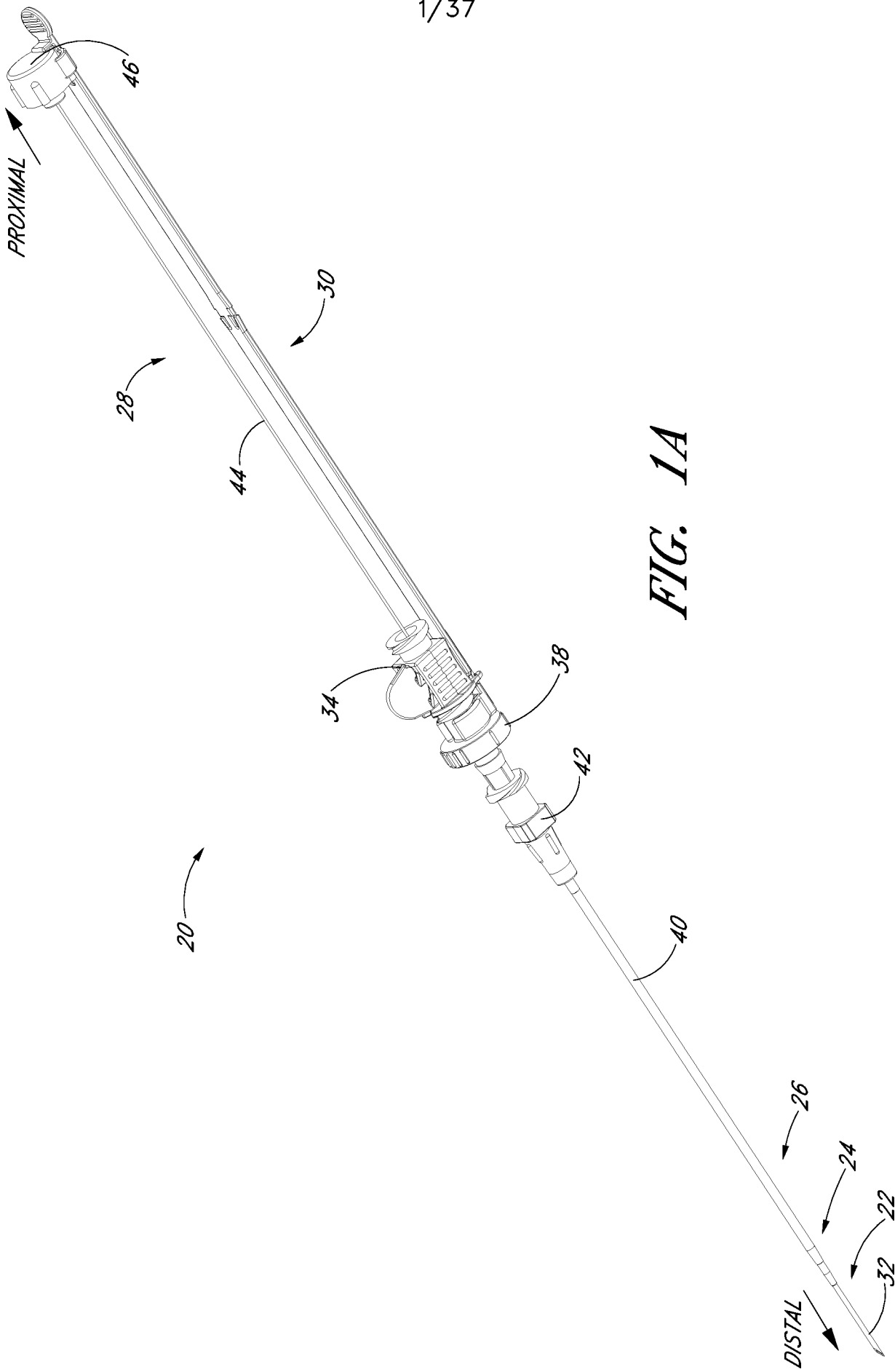


FIG. 1A

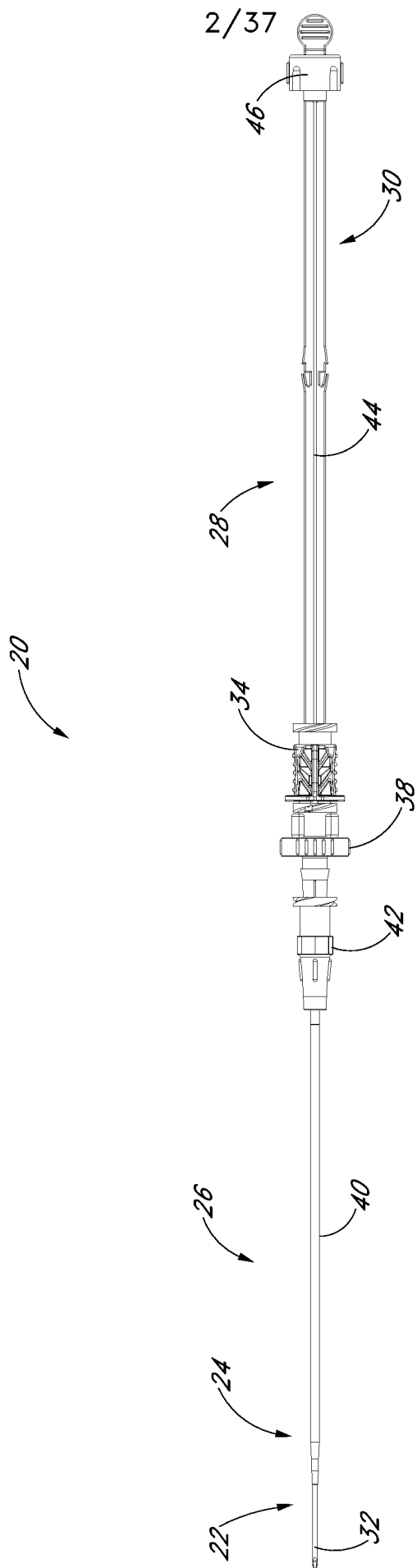
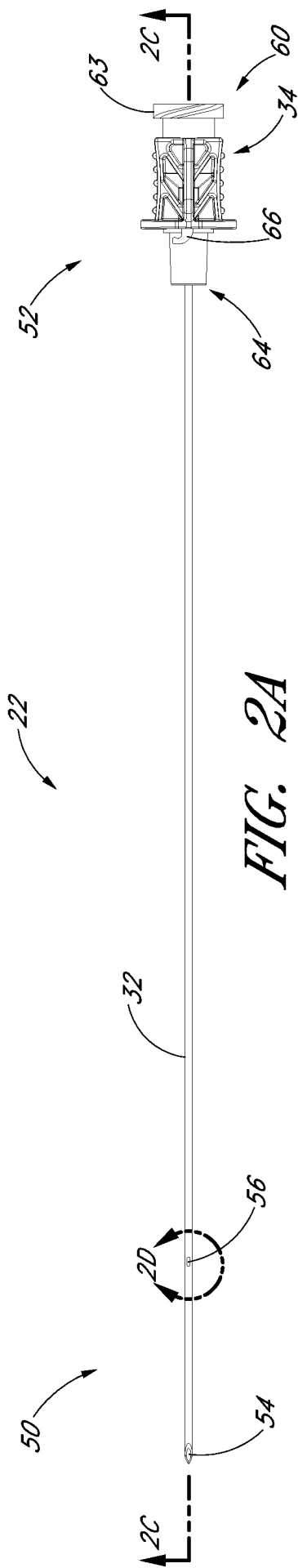
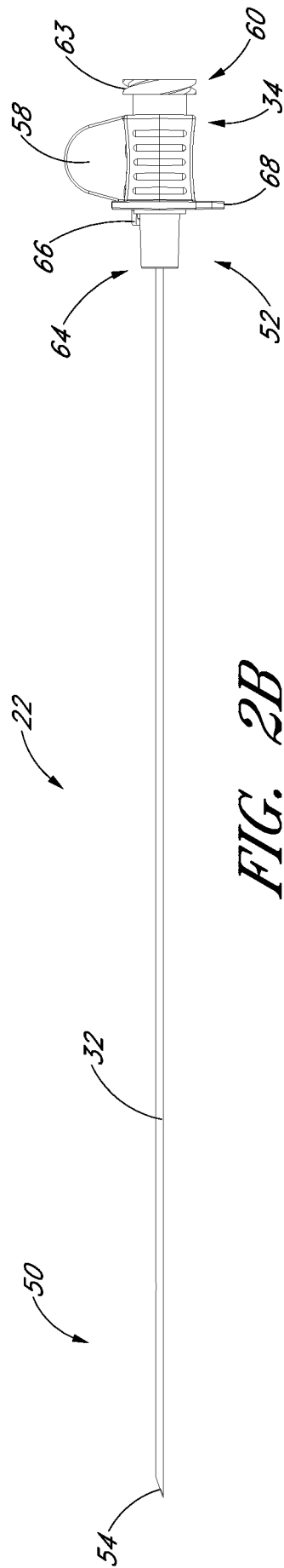


FIG. 1B



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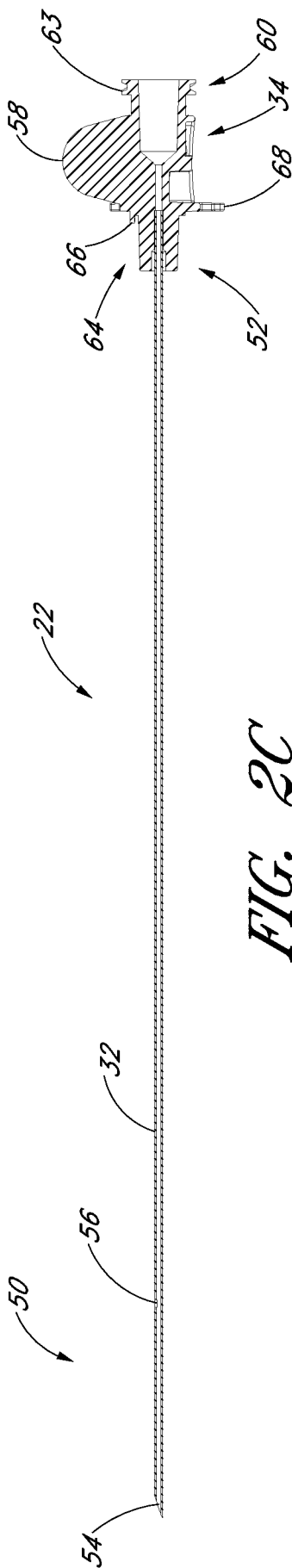


FIG. 2C

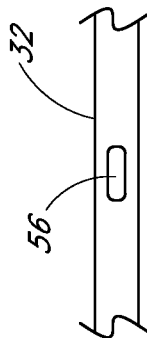


FIG. 2D

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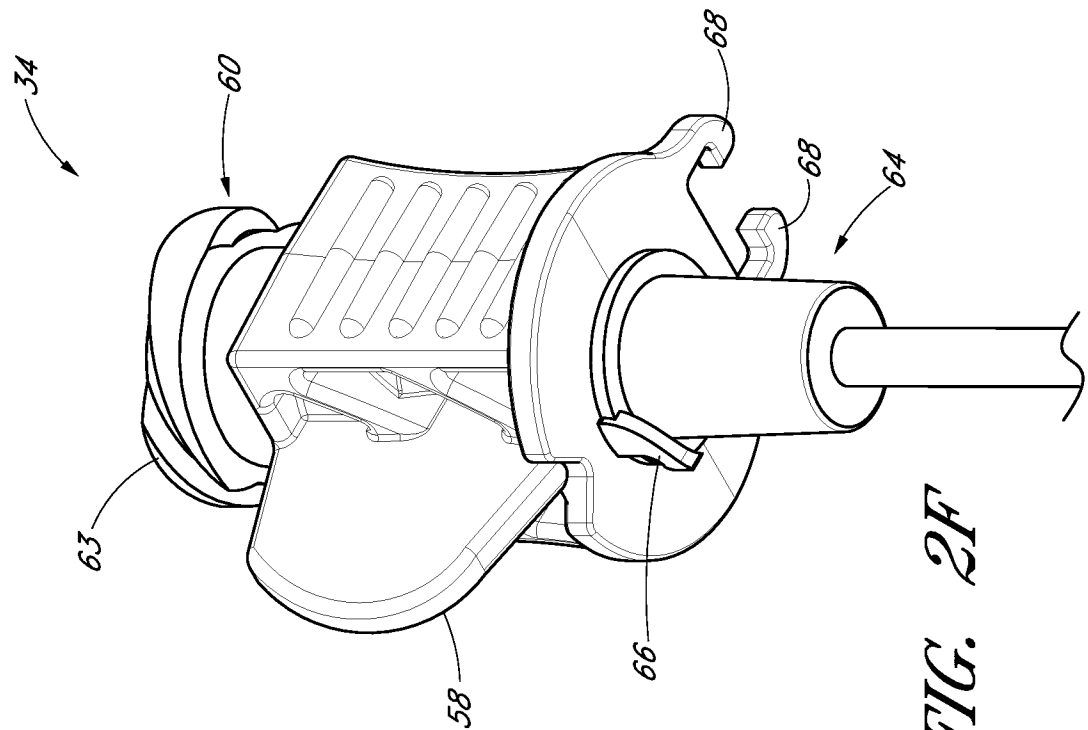


FIG. 2F

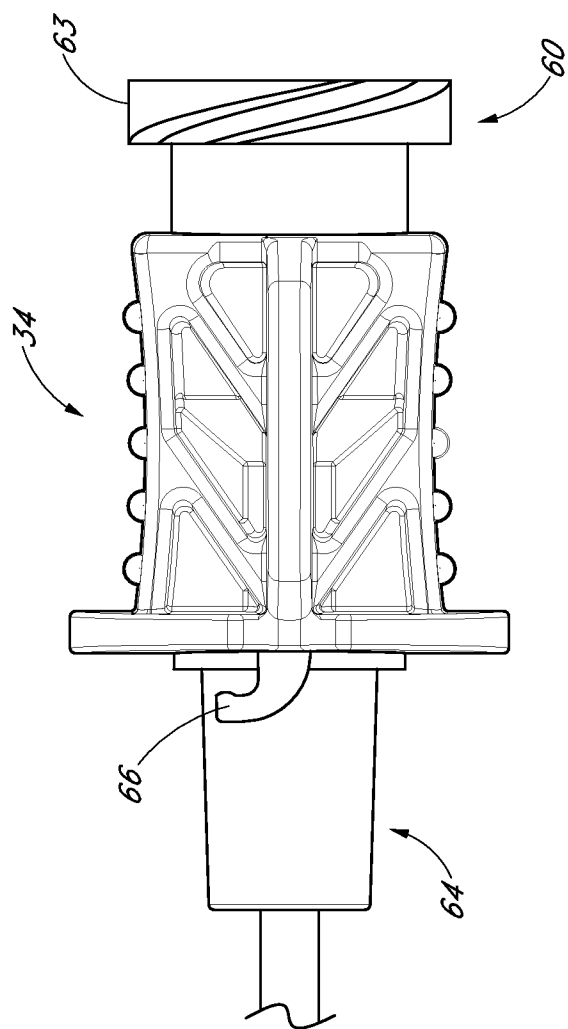


FIG. 2E

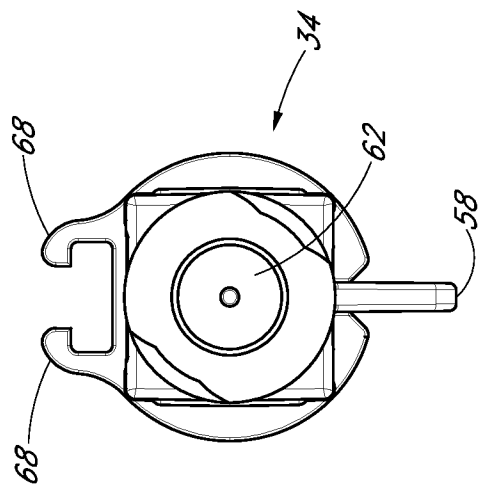
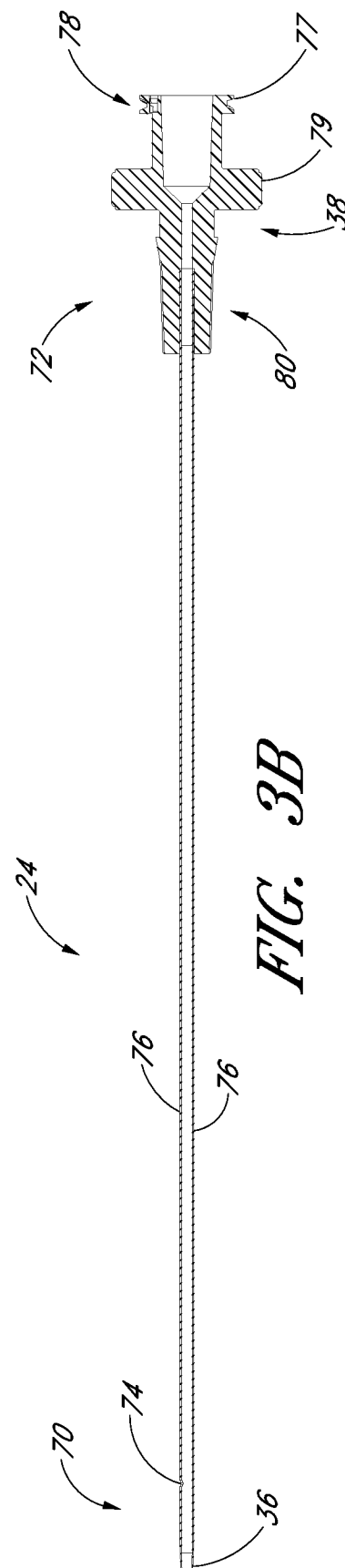
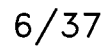
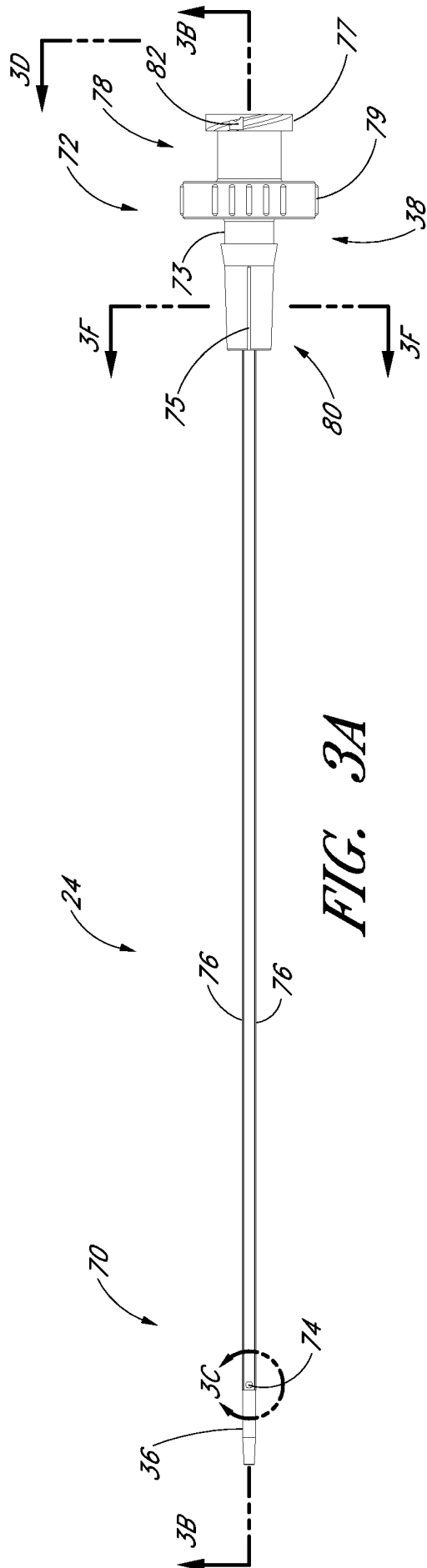


FIG. 2G



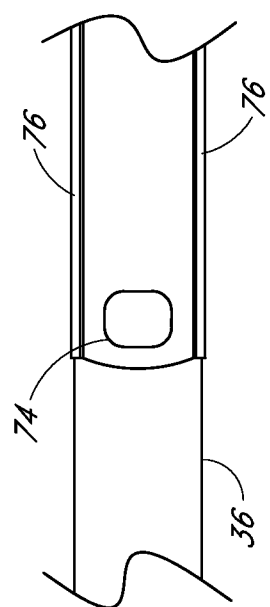


FIG. 3C

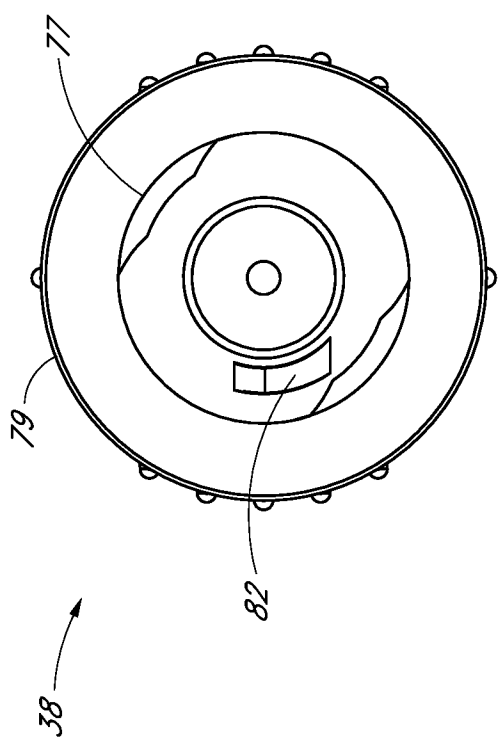


FIG. 3D

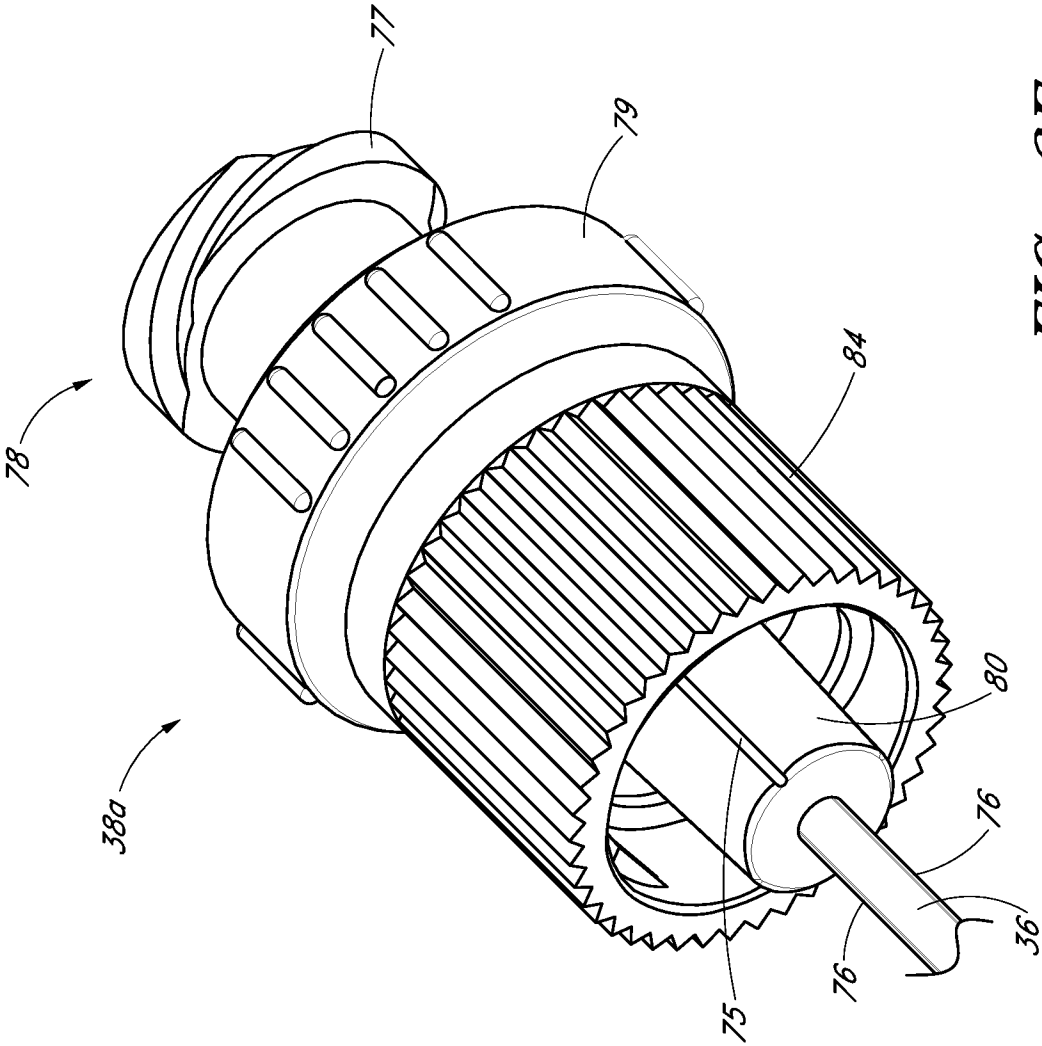


FIG. 3E

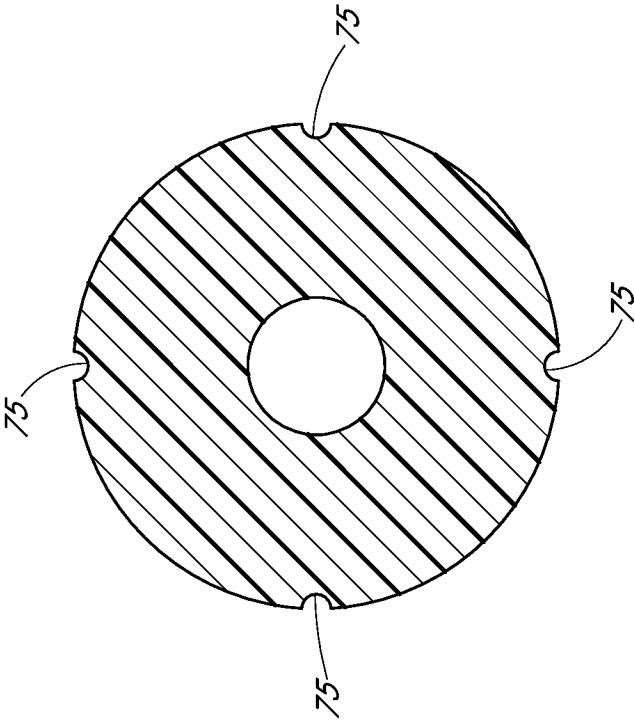
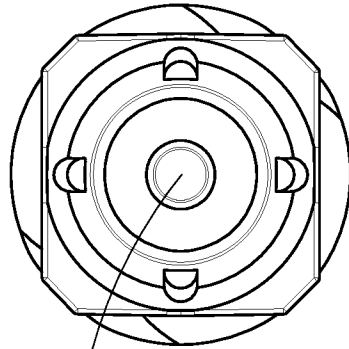
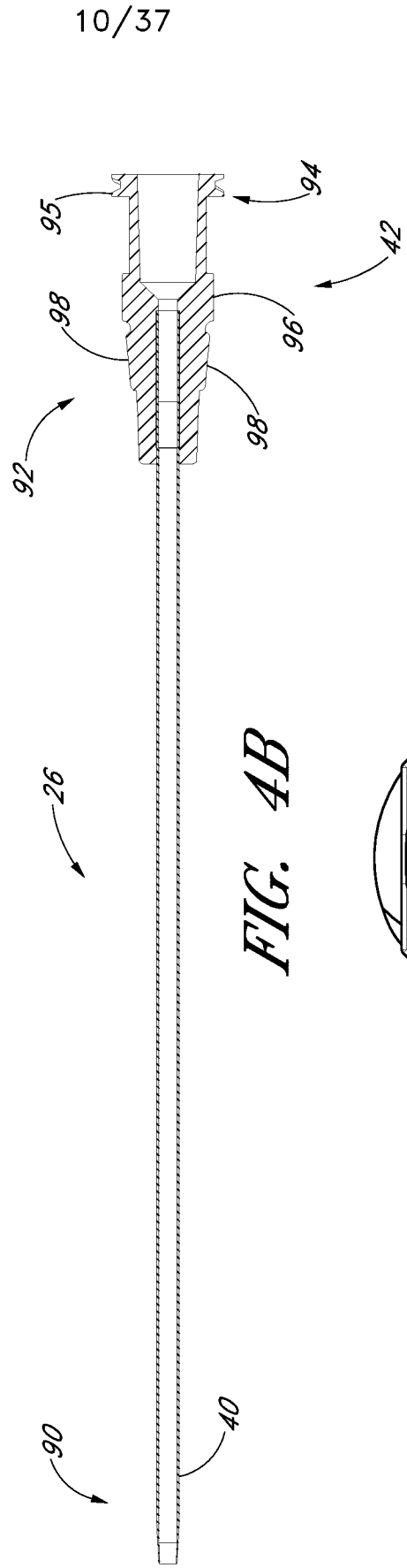
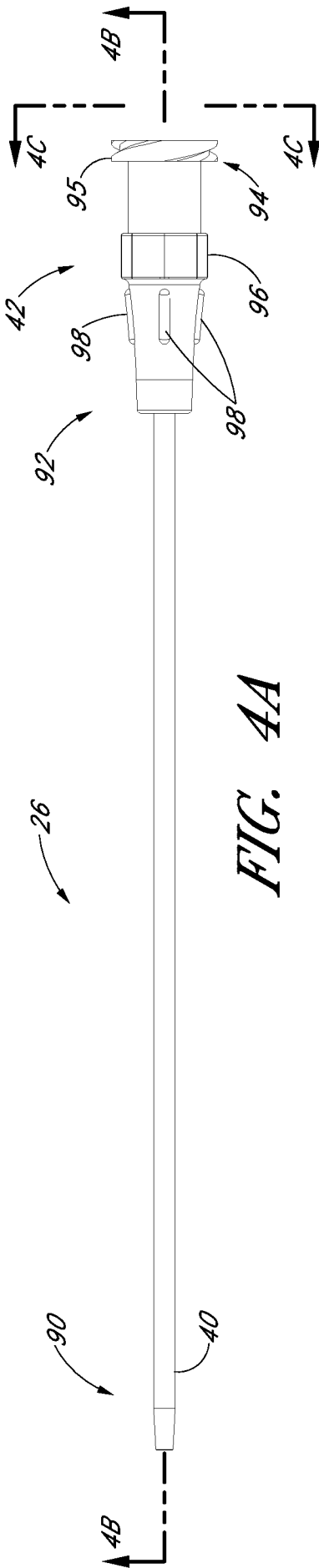


FIG. 3F



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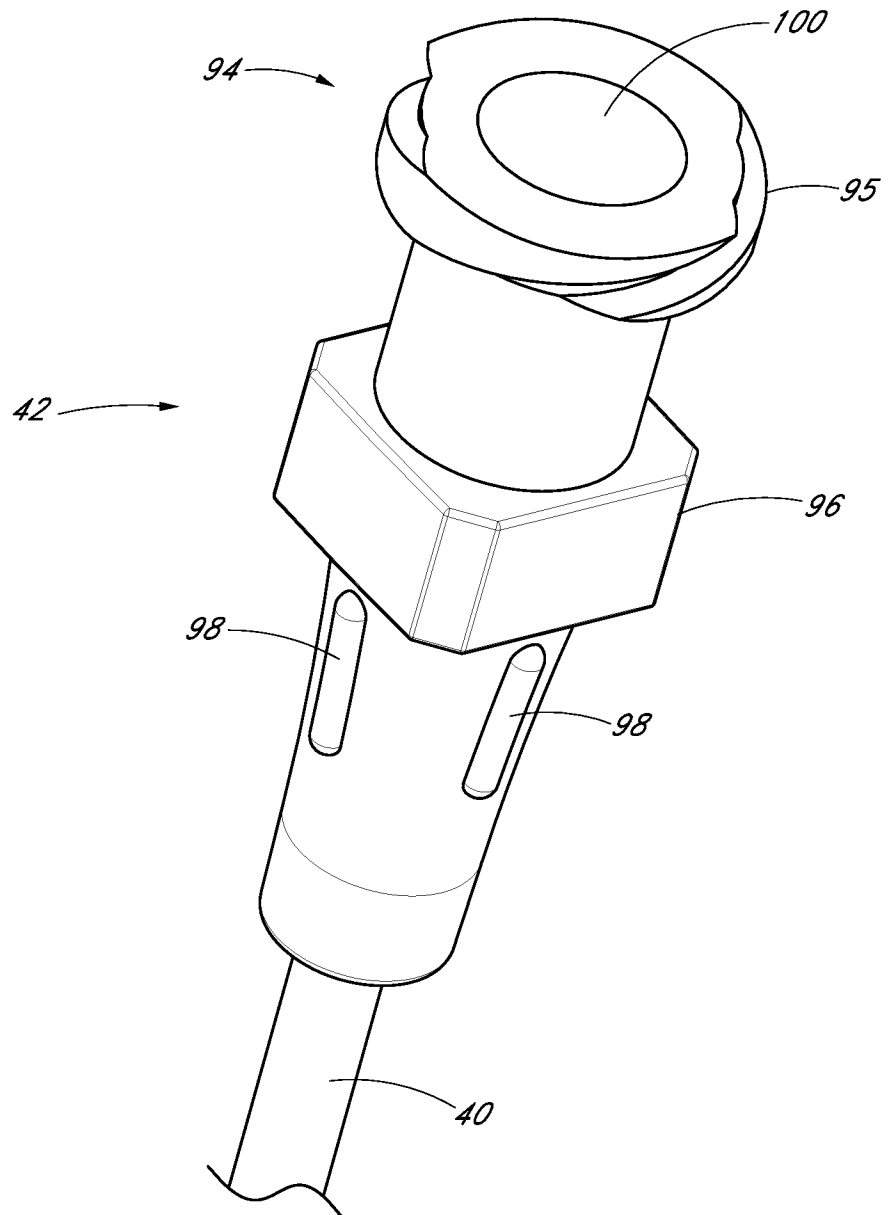
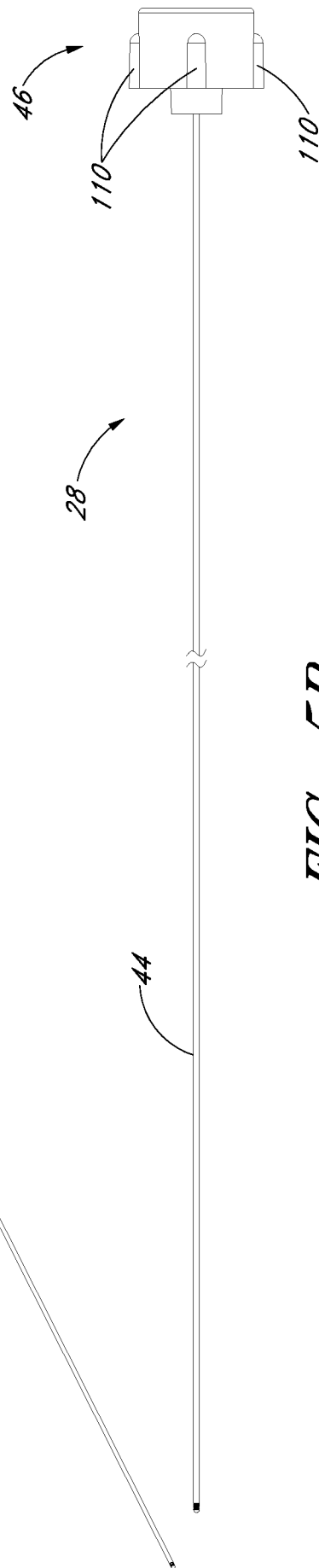
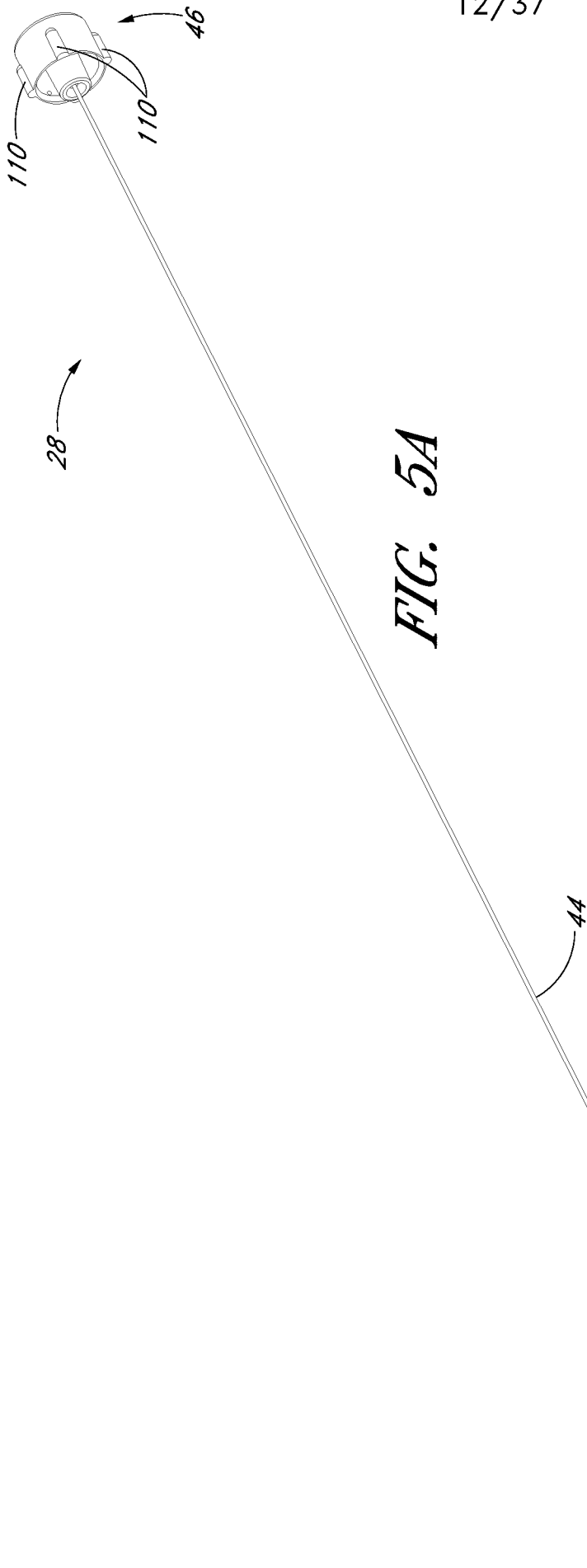


FIG. 4D



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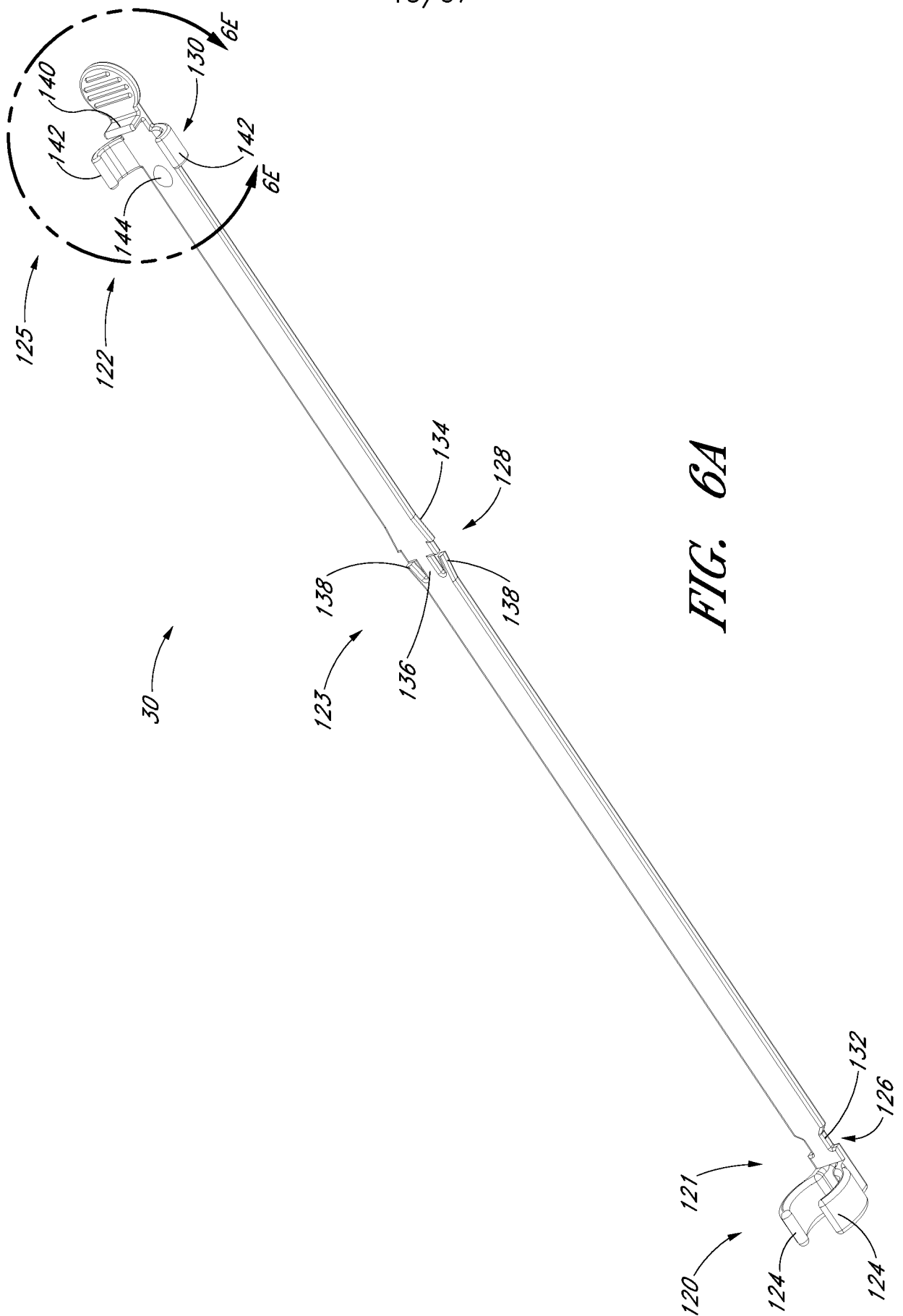
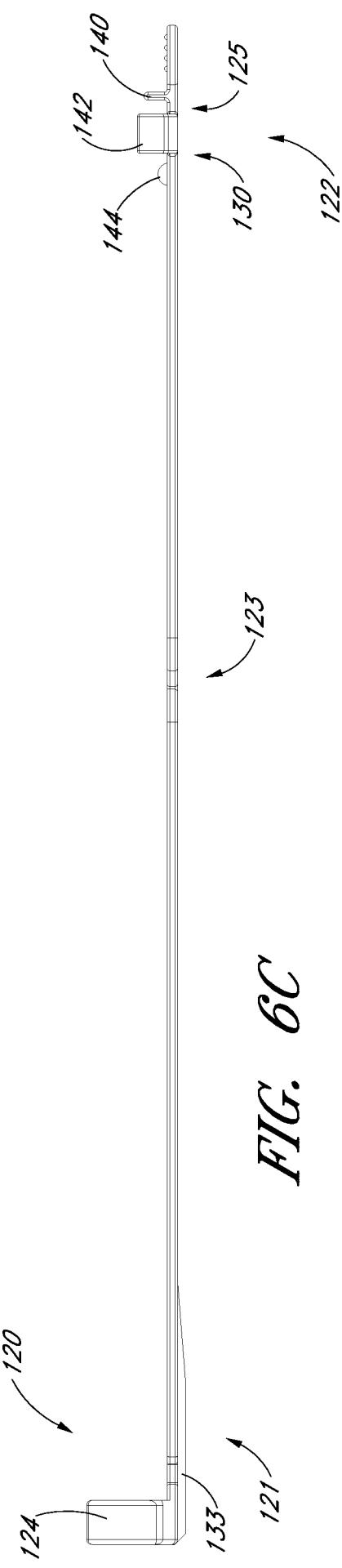
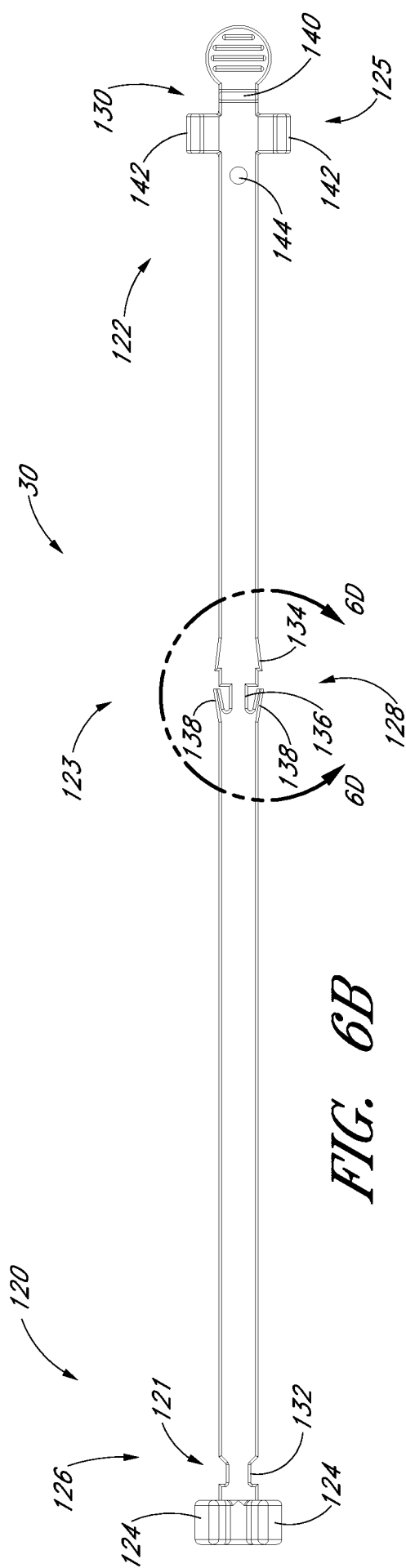


FIG. 6A



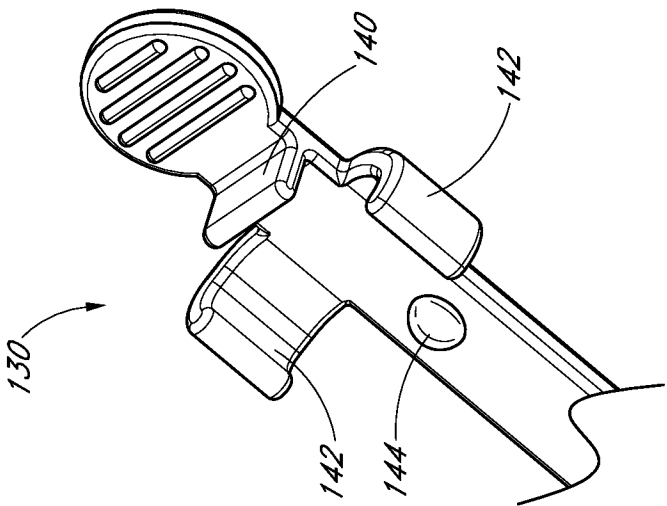


FIG. 6E

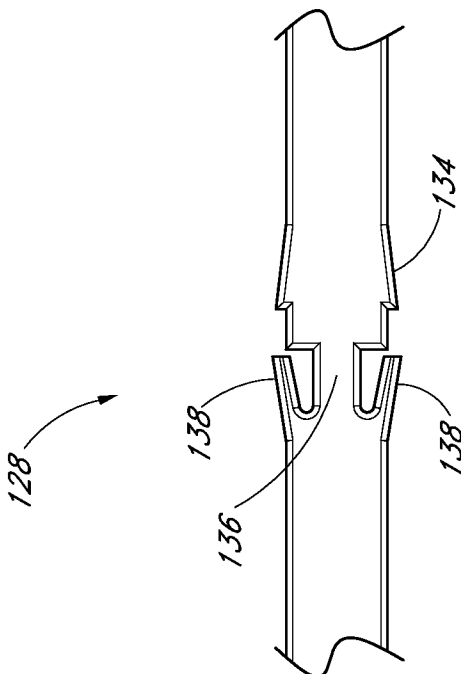


FIG. 6D

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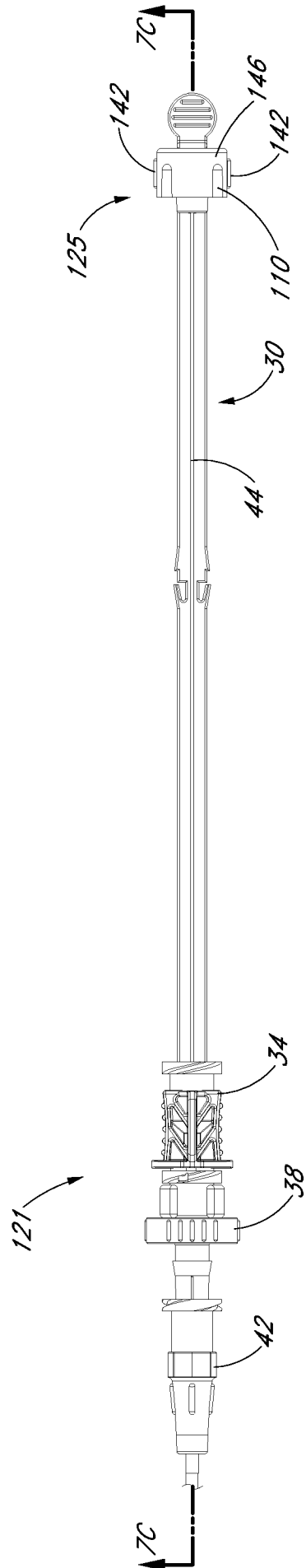


FIG. 7A

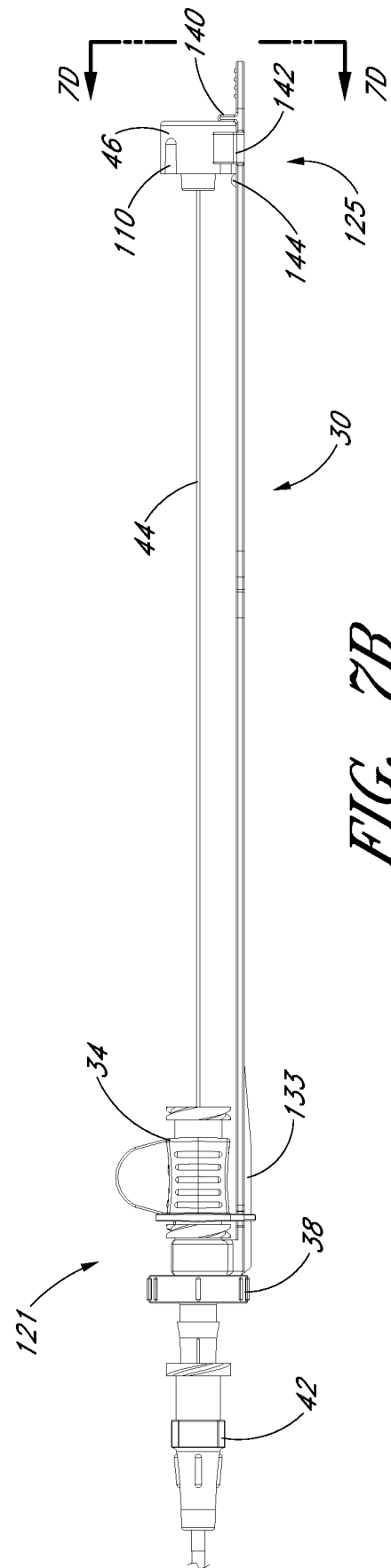


FIG. 7B

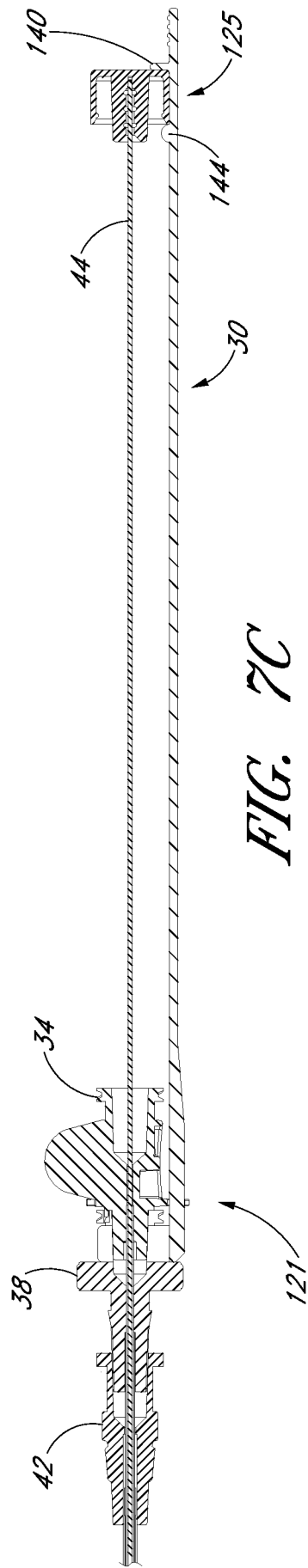


FIG. 7C

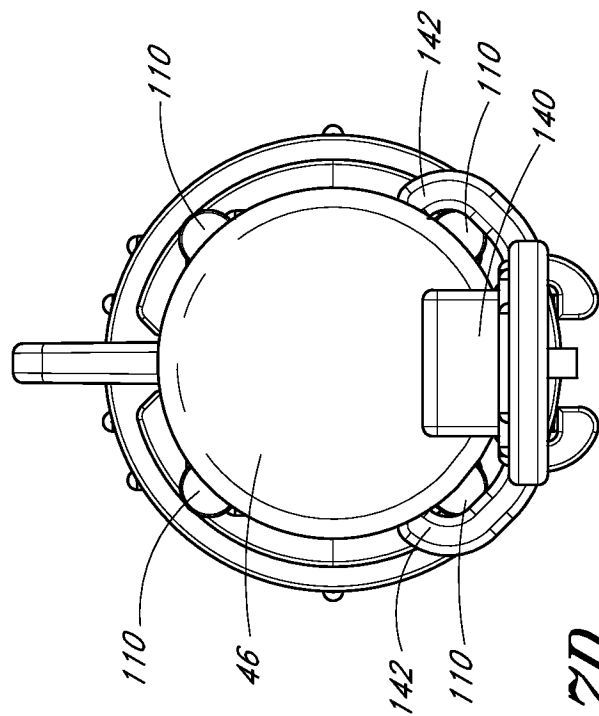
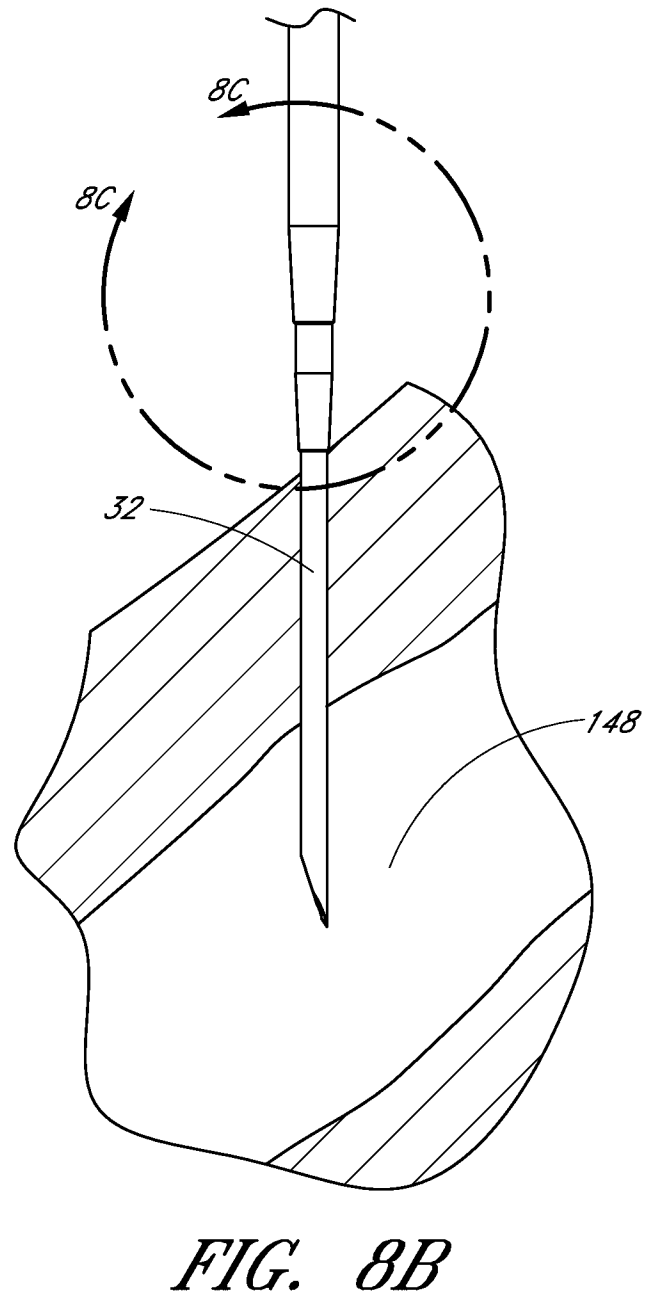
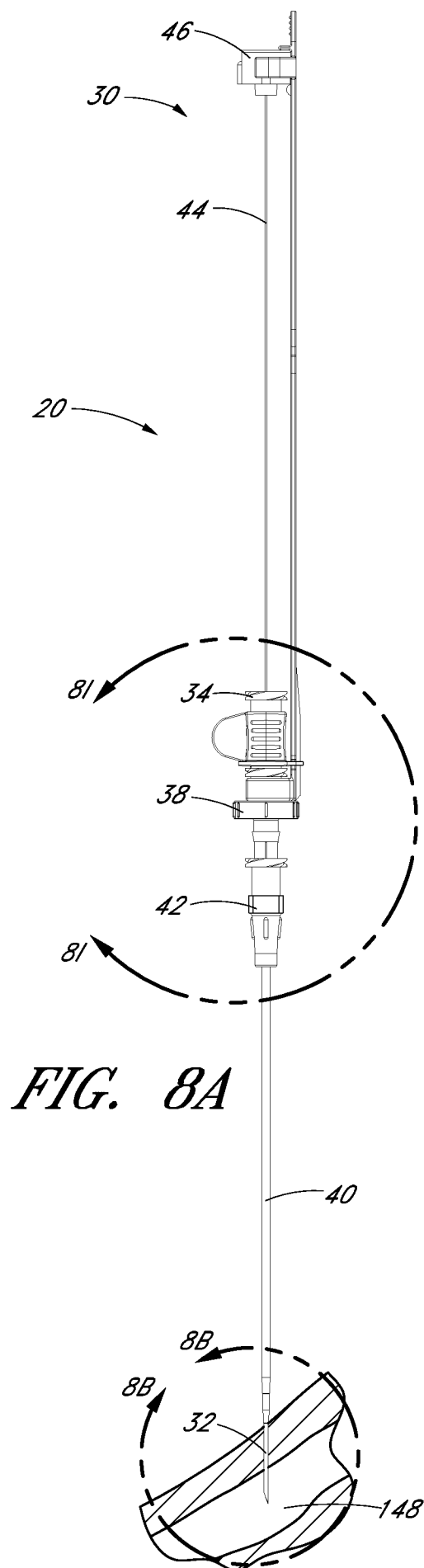


FIG. 7D

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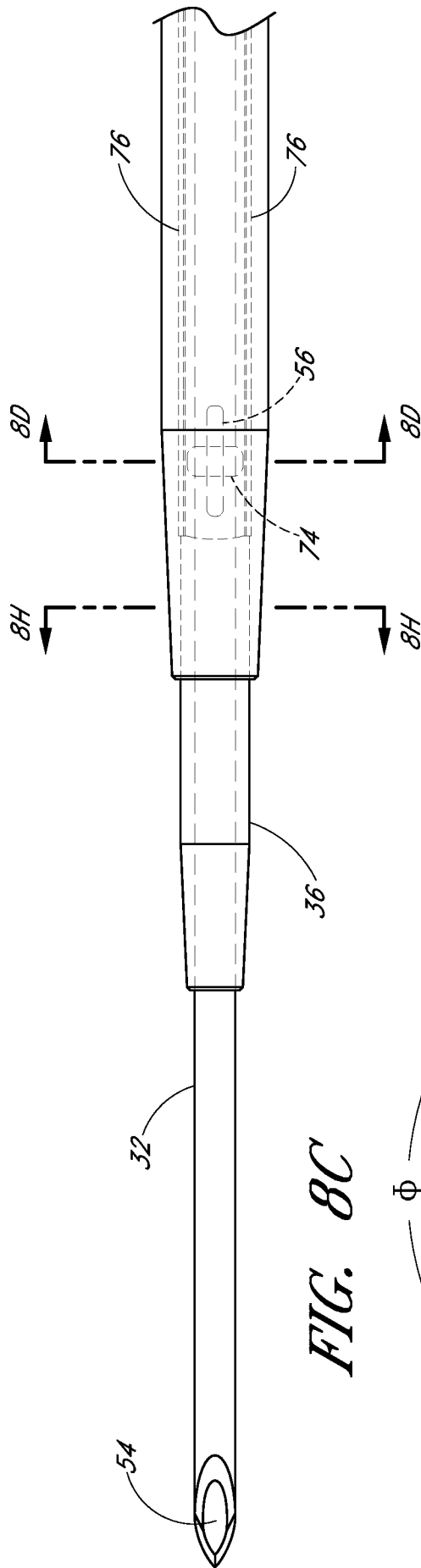


FIG. 8C

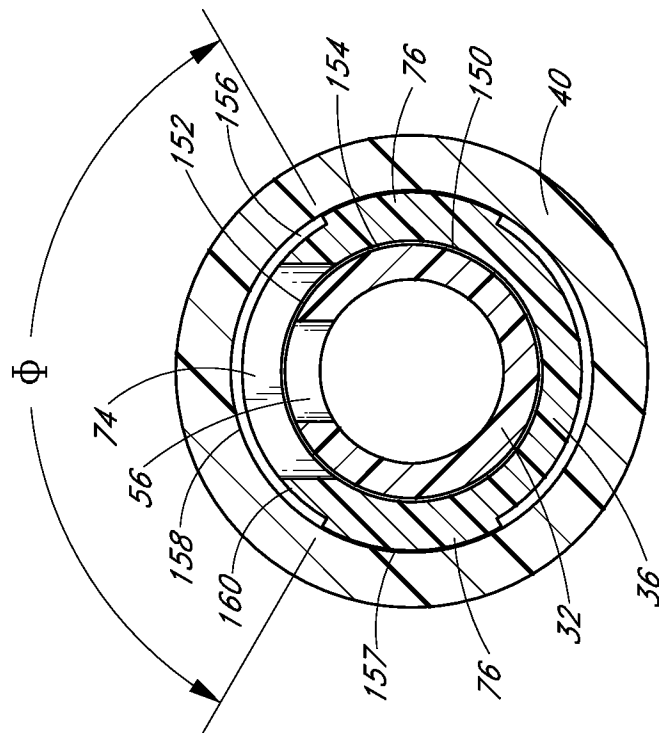


FIG. 8D

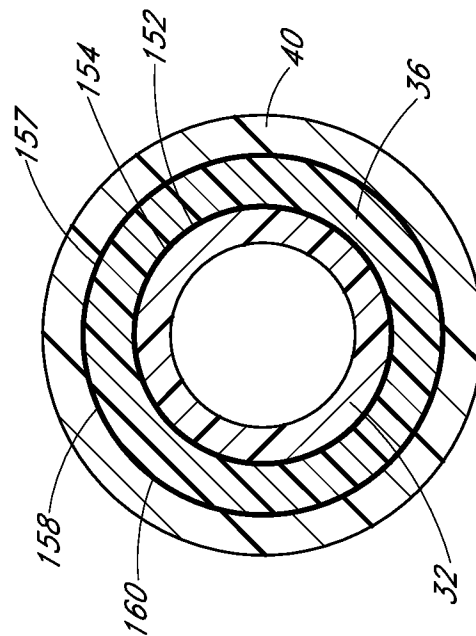


FIG. 8H

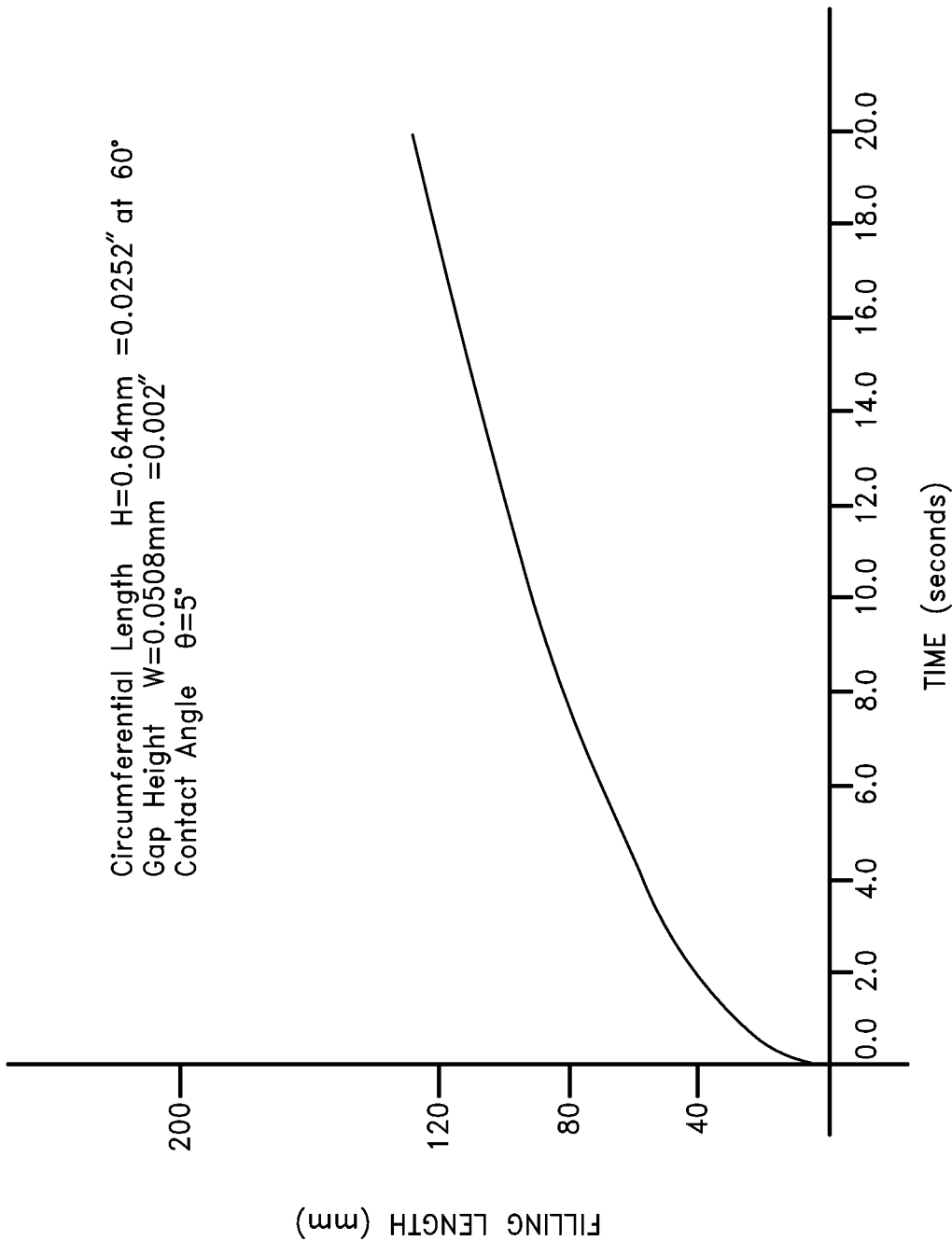


FIG. 8E

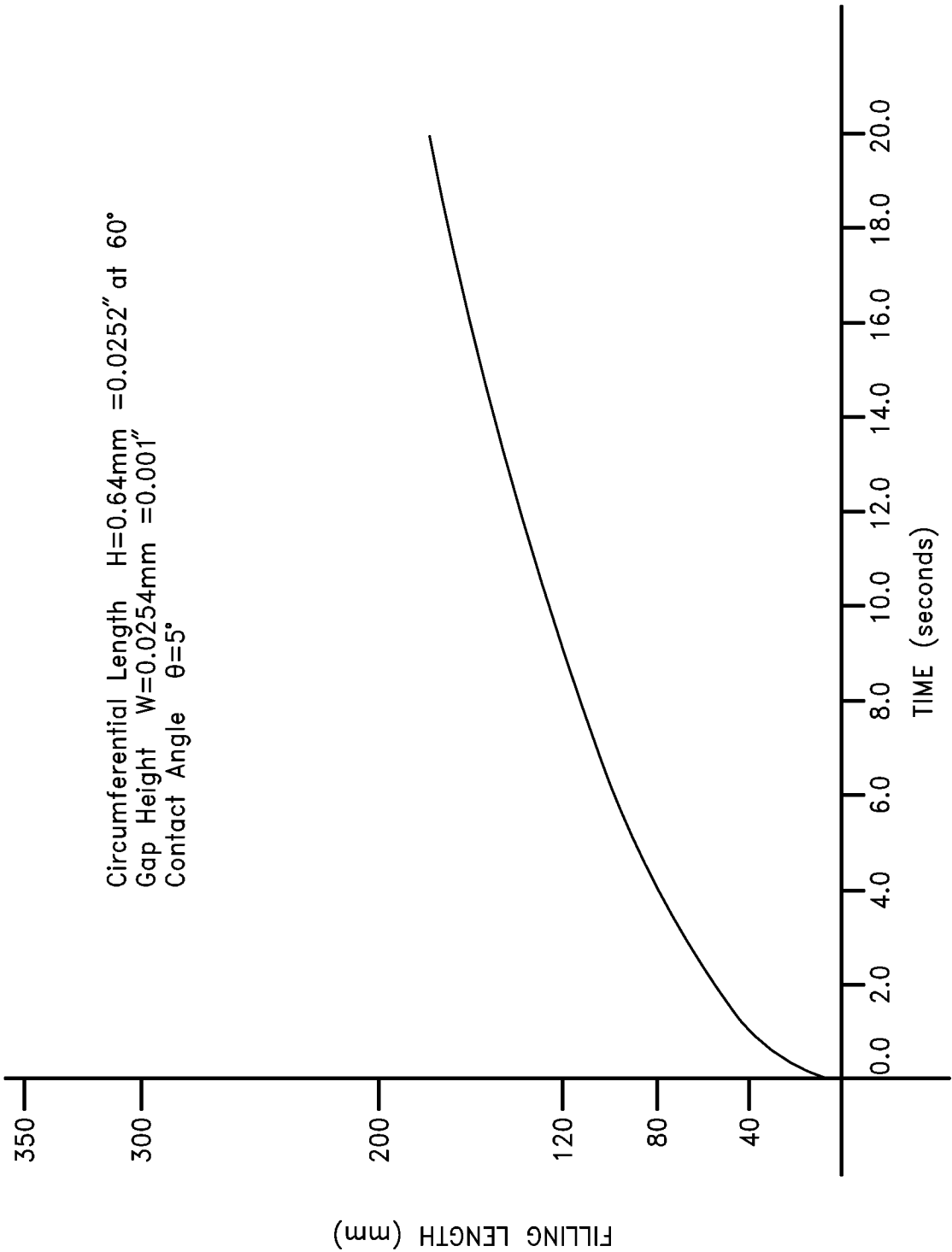


FIG. 8F

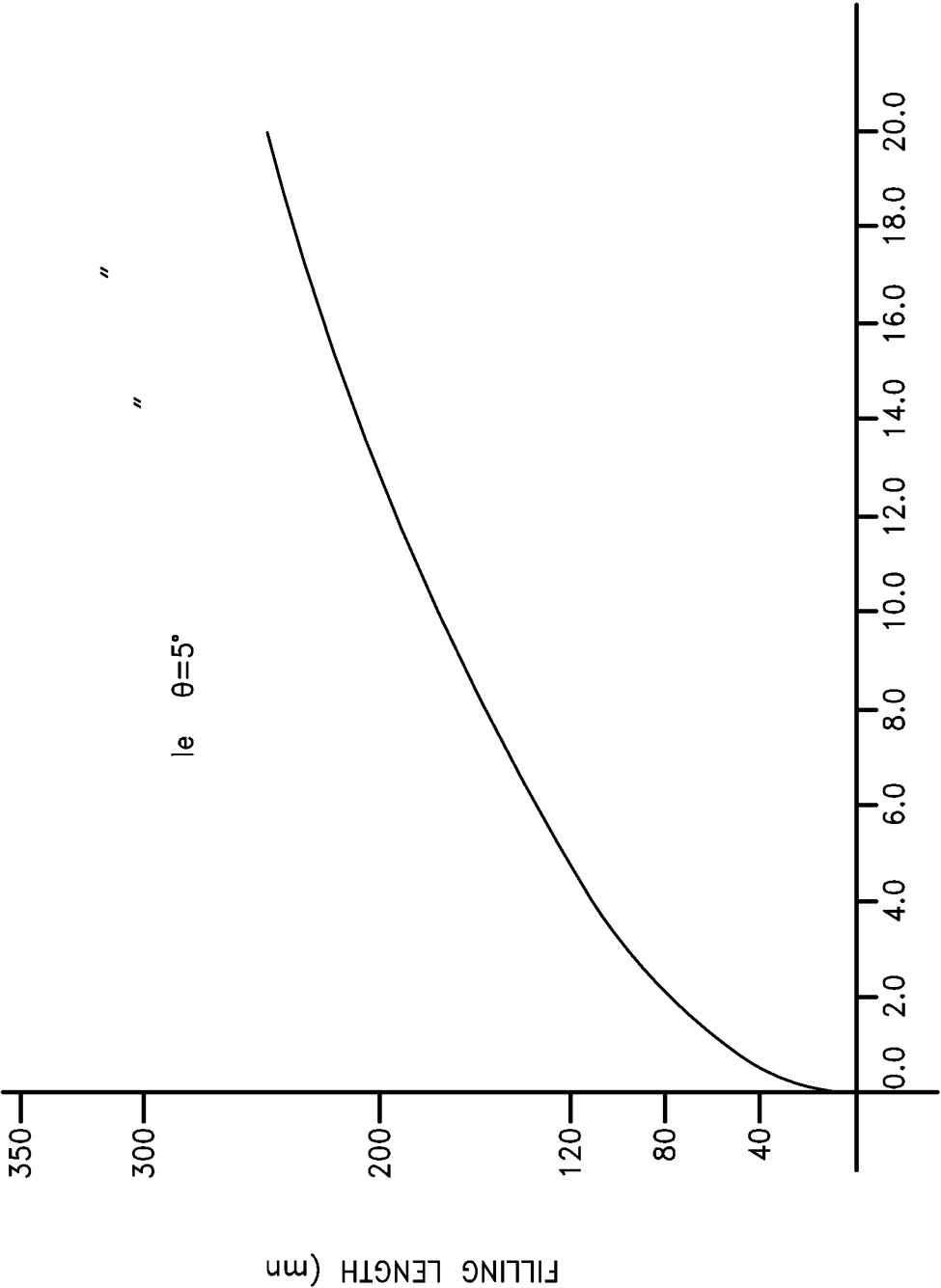


FIG. 8G

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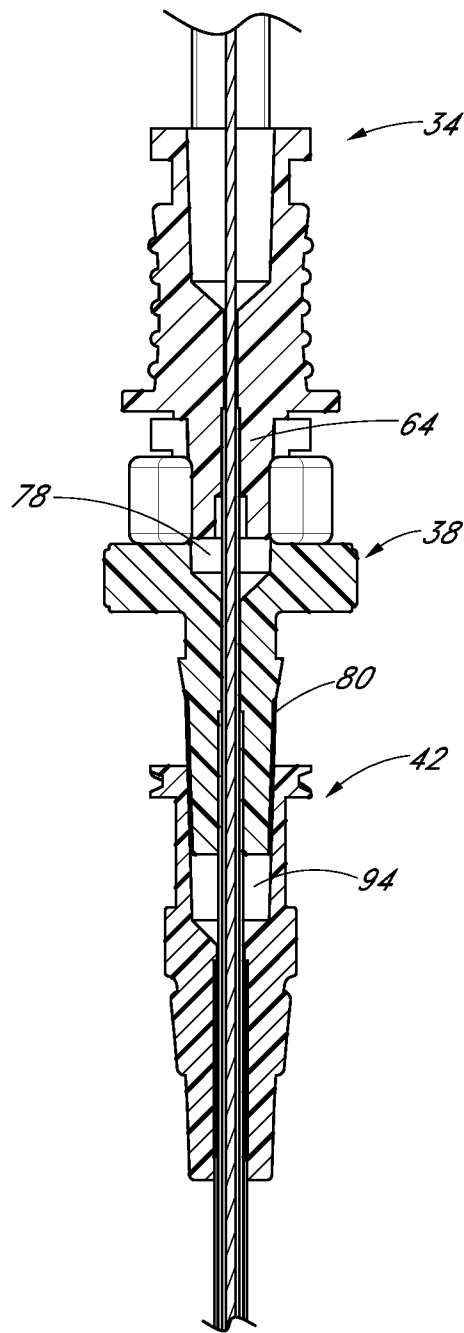


FIG. 8J

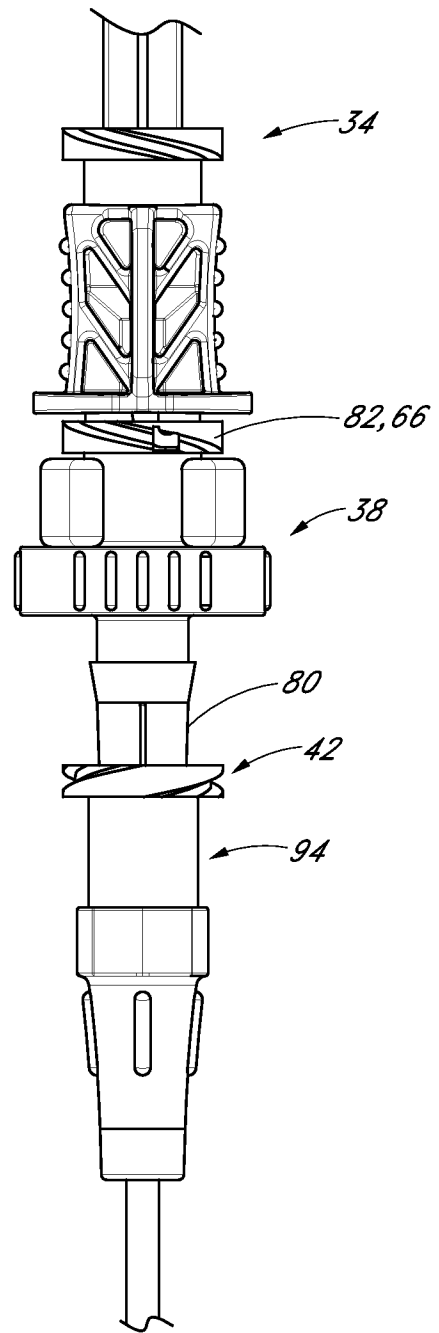


FIG. 8I

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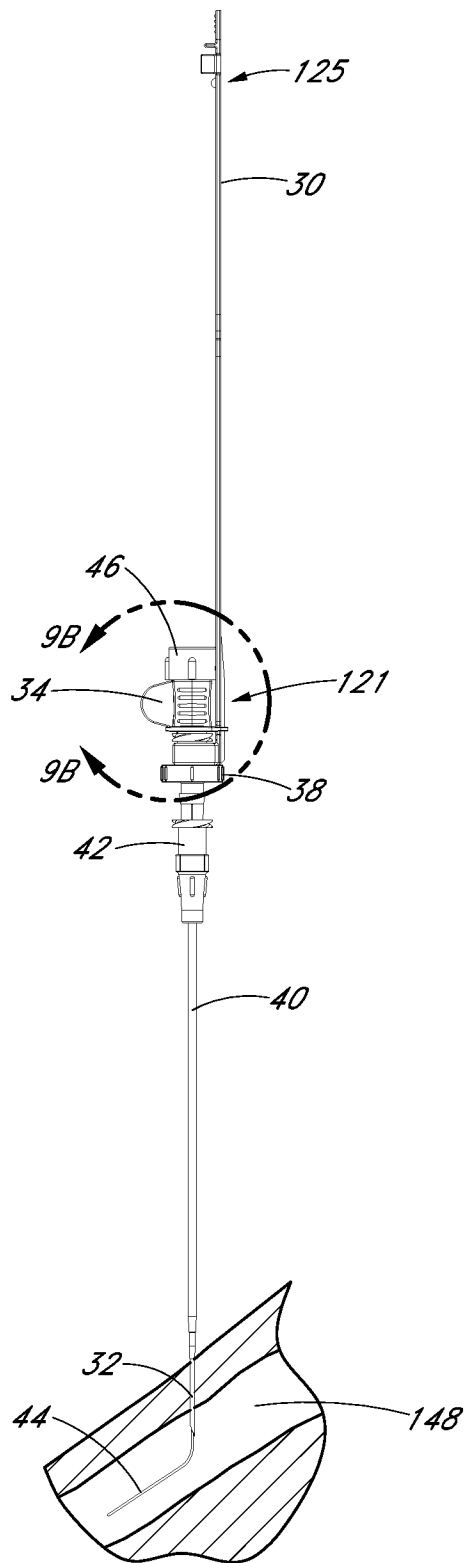


FIG. 9A

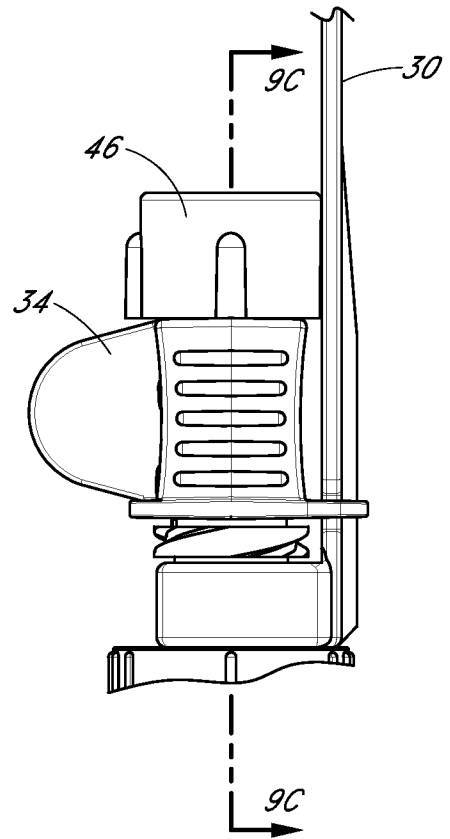


FIG. 9B

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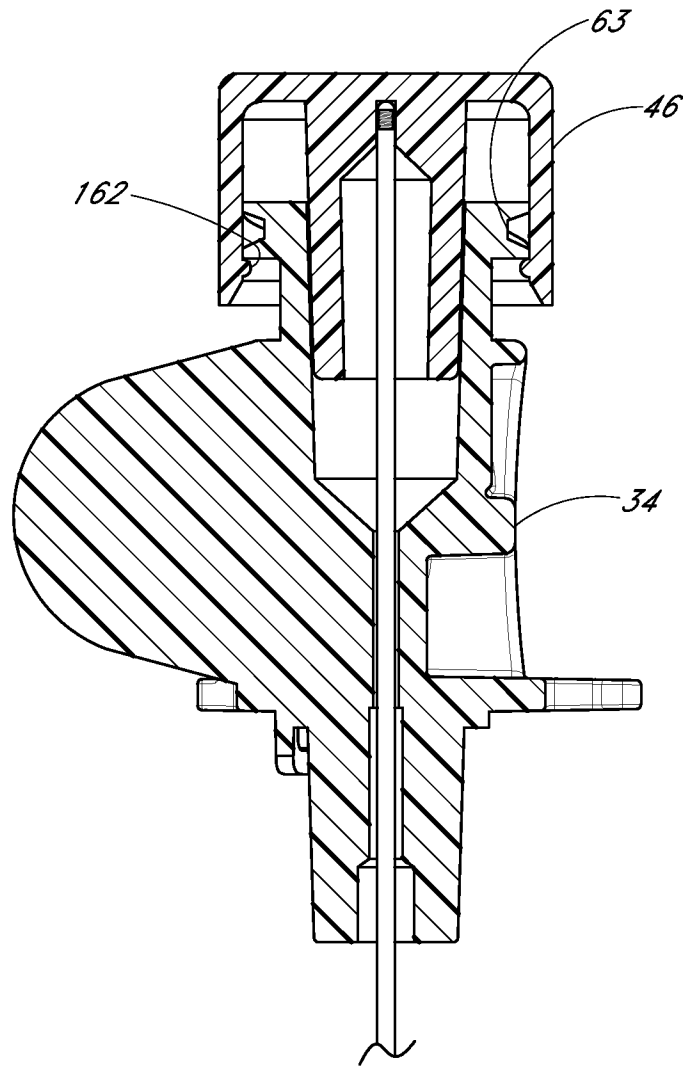


FIG. 9C

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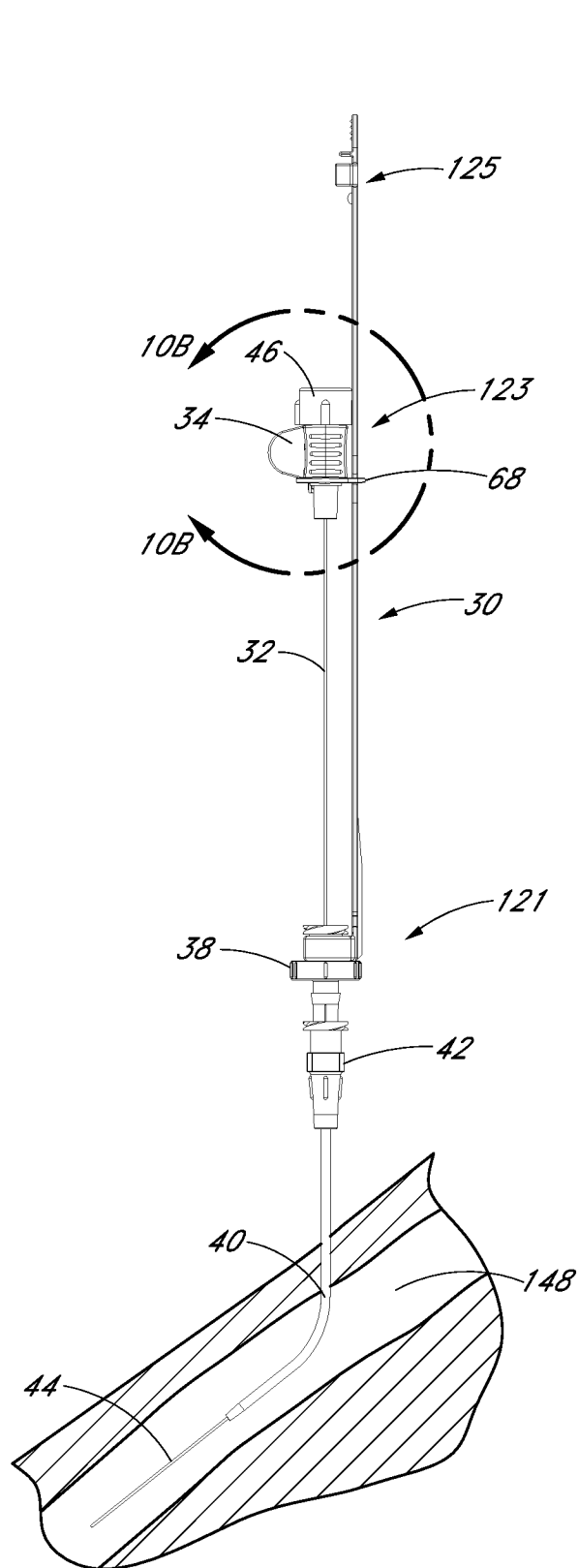


FIG. 10A

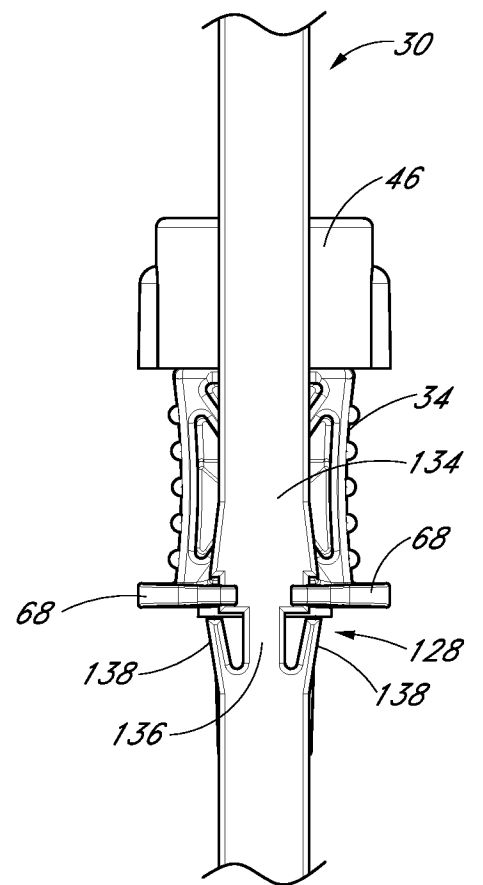


FIG. 10B

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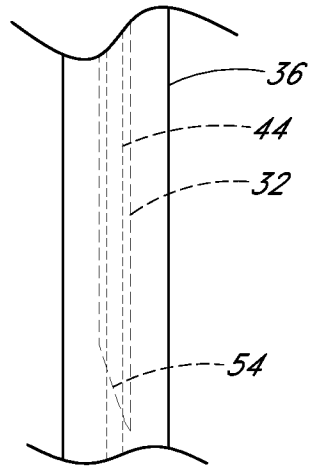


FIG. 11B

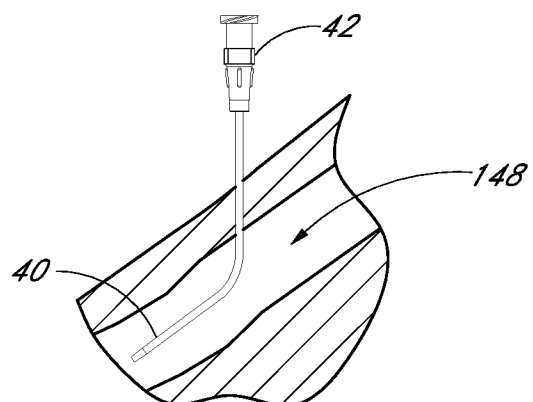
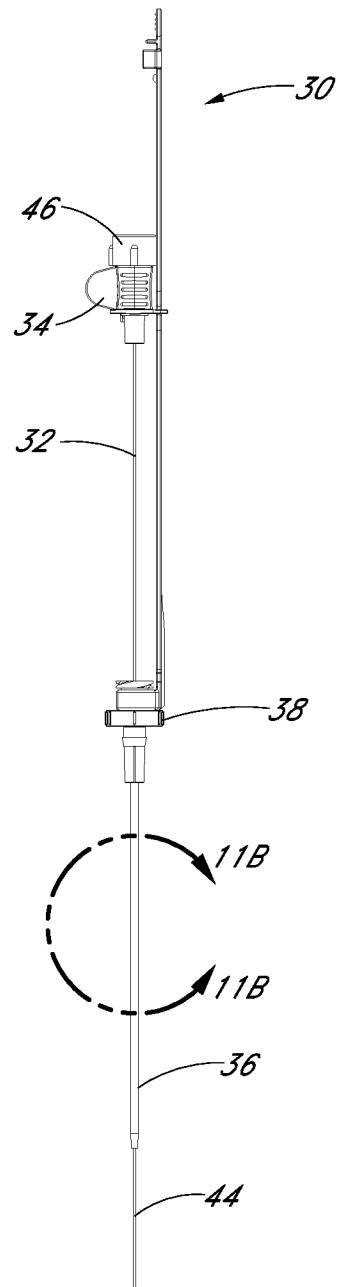


FIG. 11A

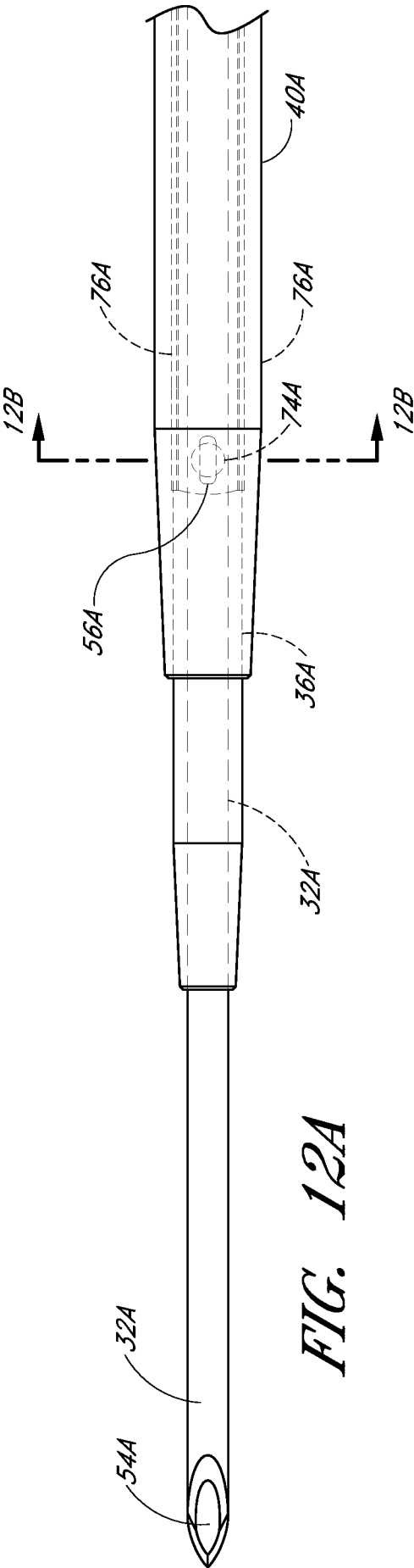


FIG. 12A

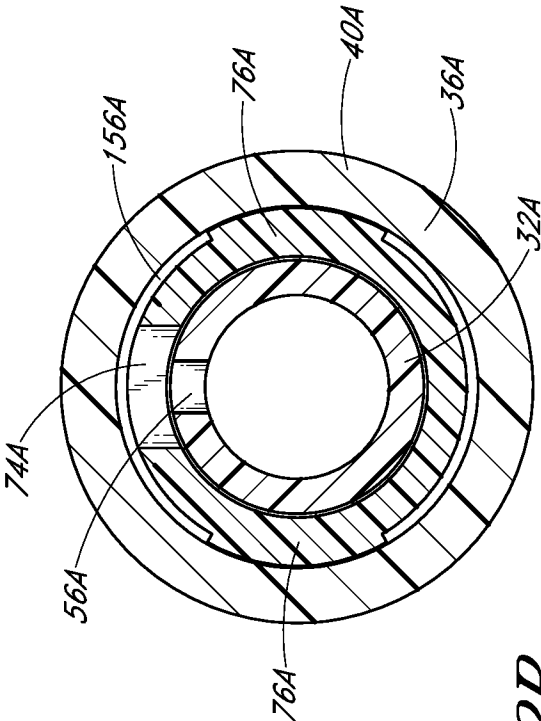
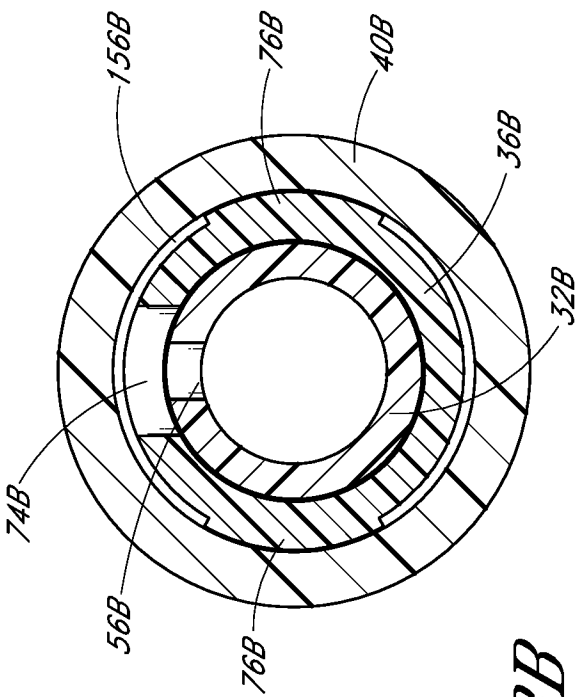
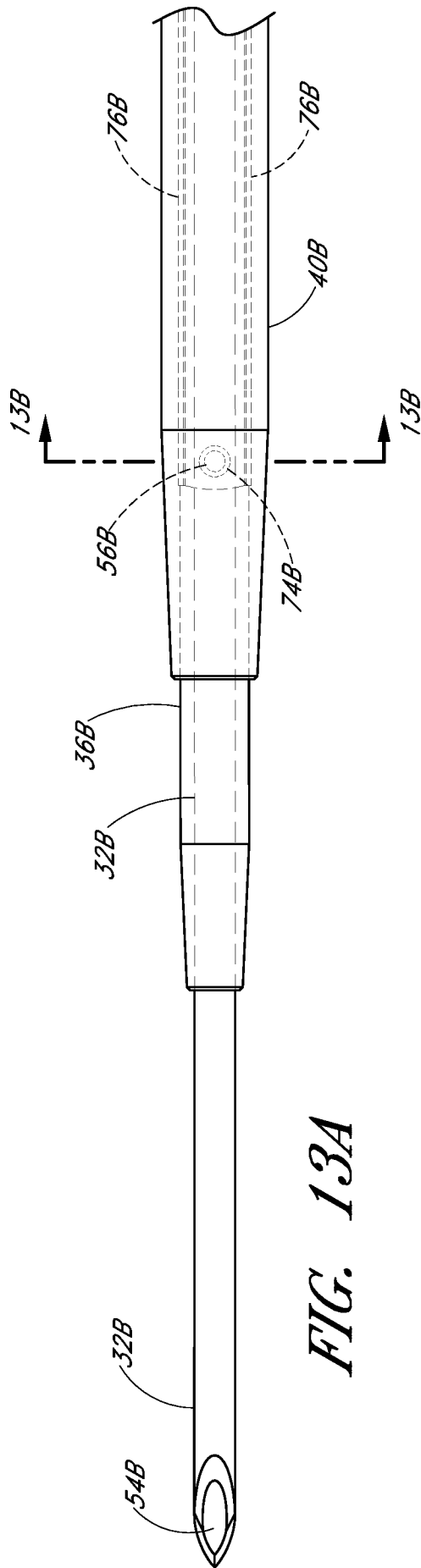


FIG. 12B



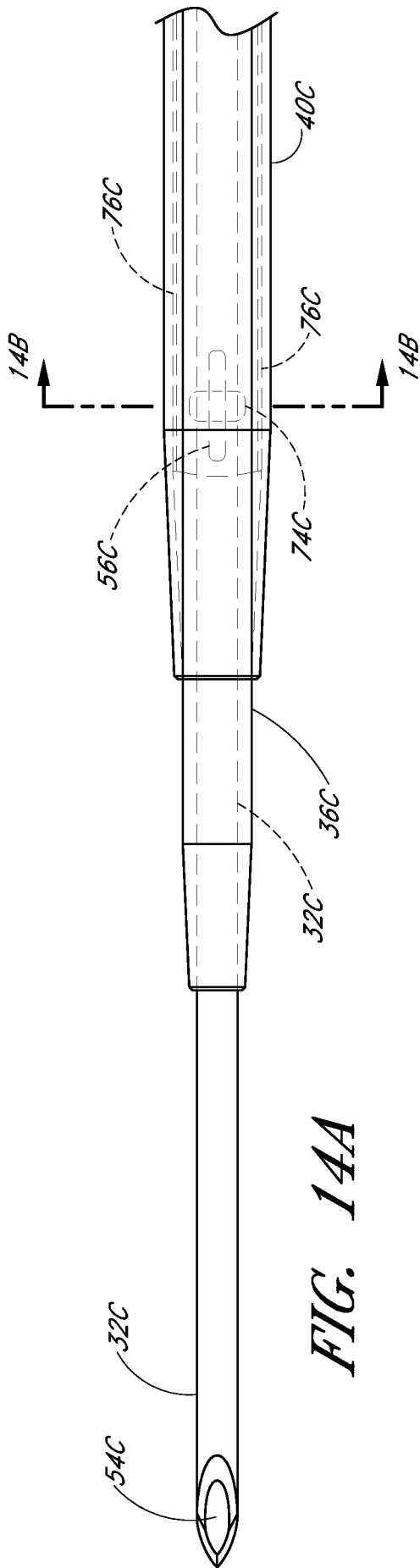


FIG. 14A

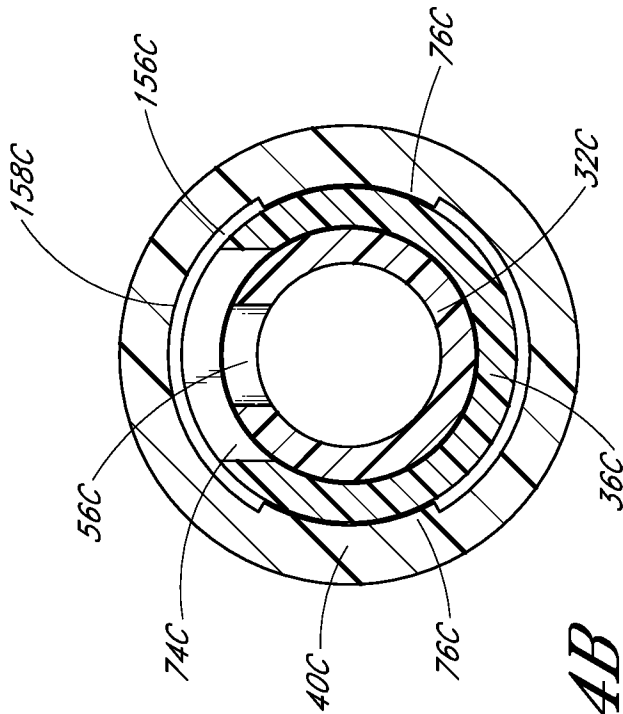


FIG. 14B

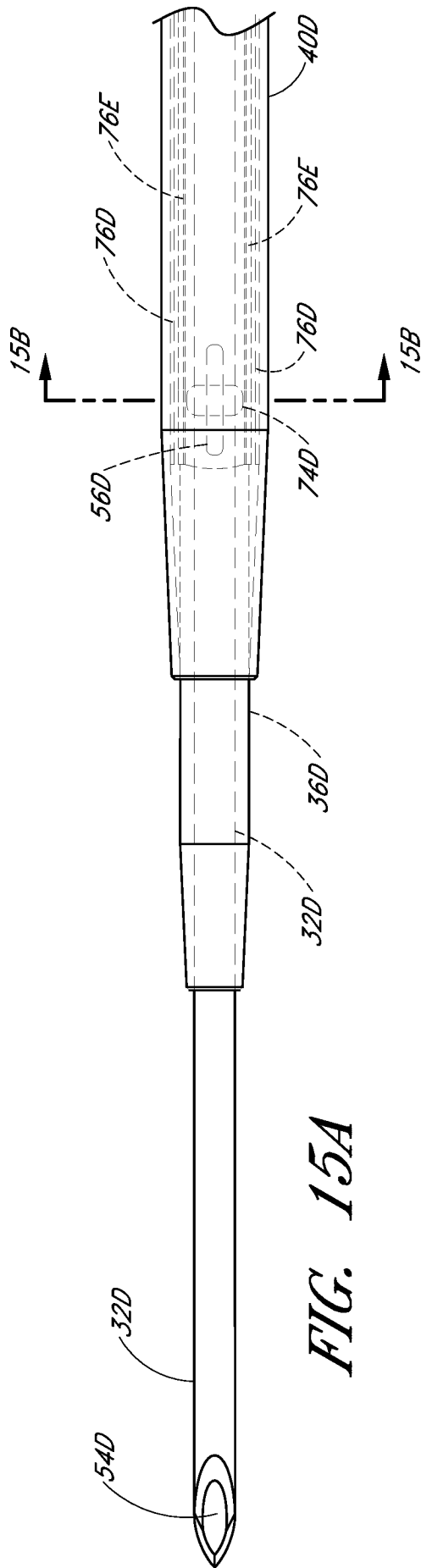


FIG. 15A

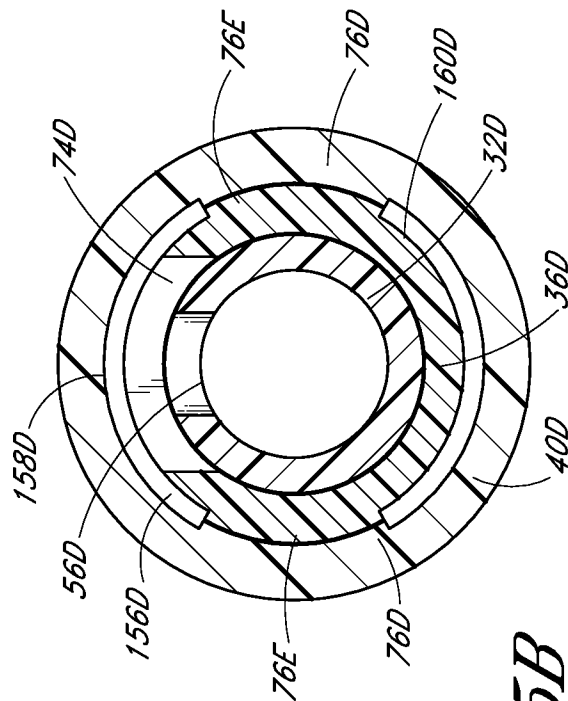


FIG. 15B

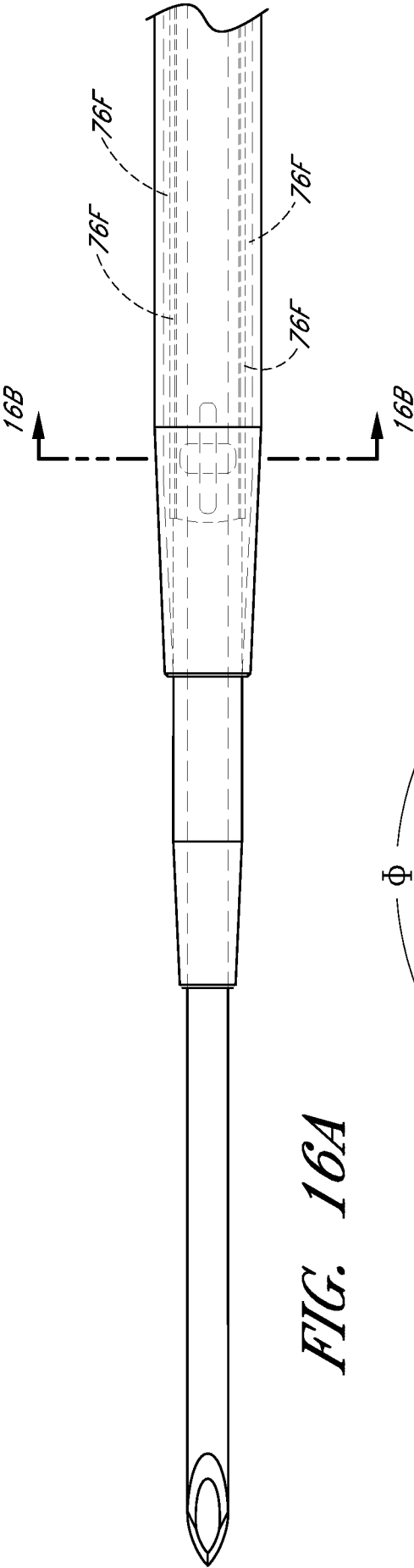


FIG. 16A

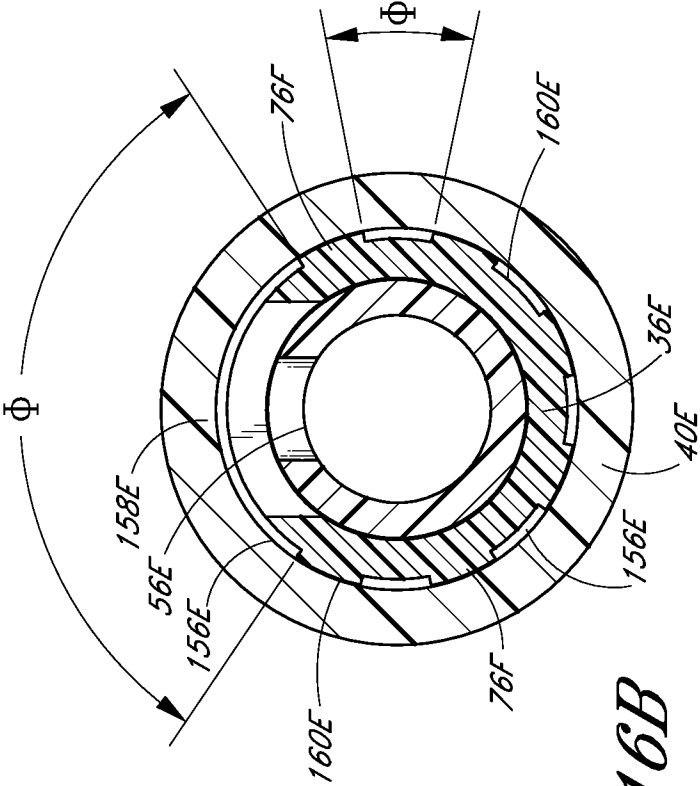


FIG. 16B

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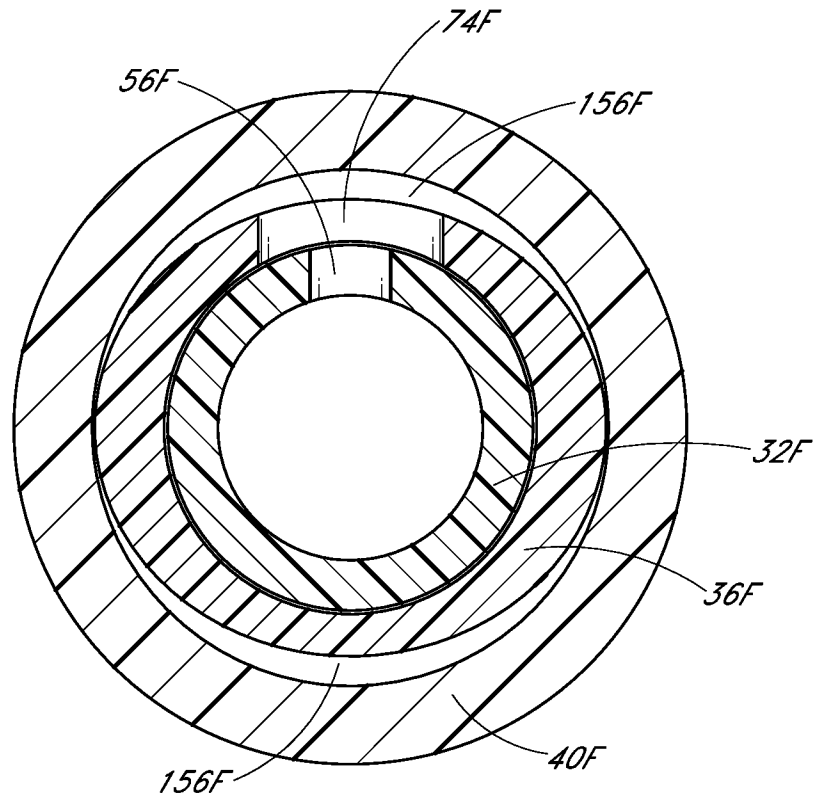


FIG. 17

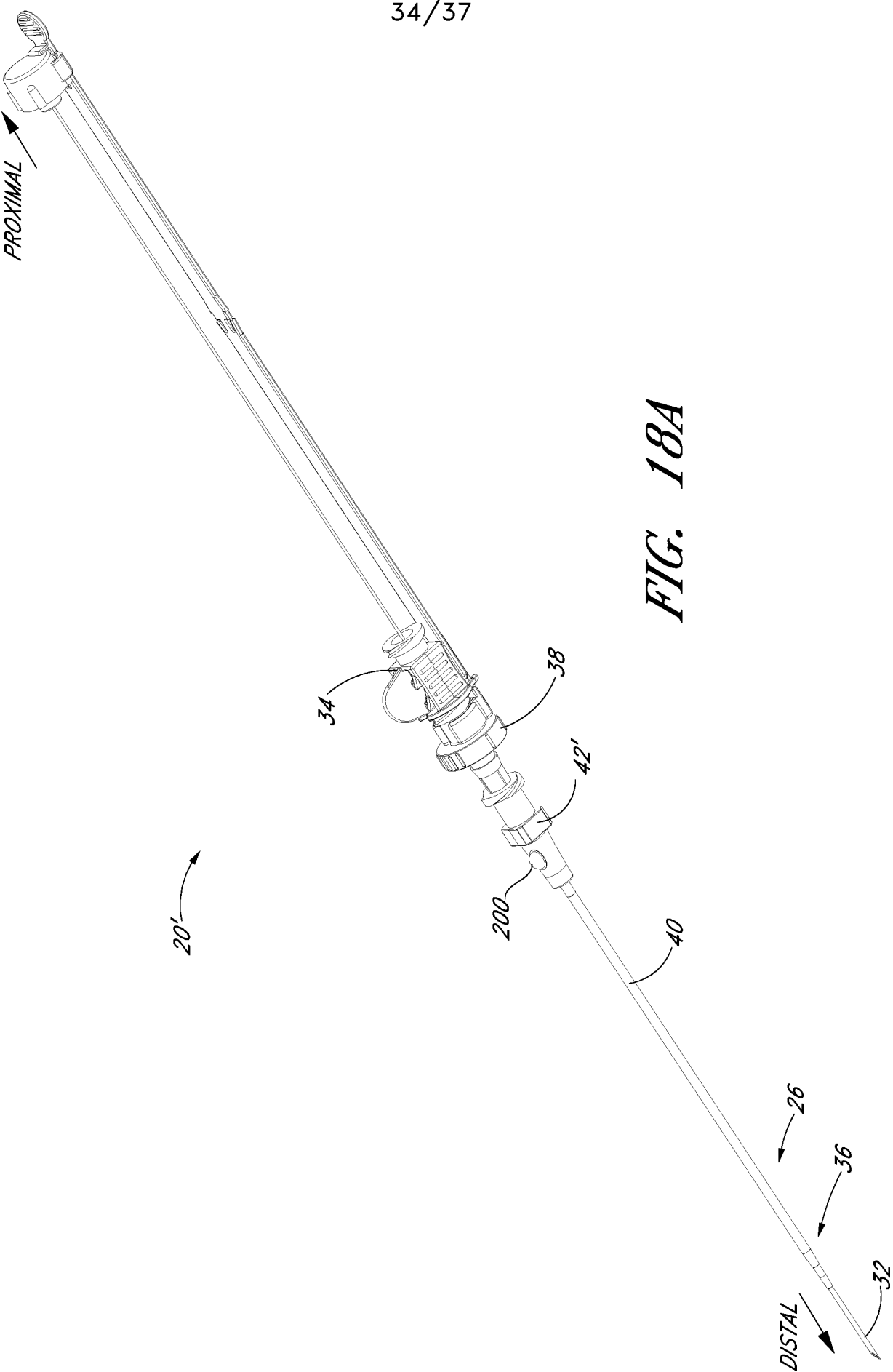
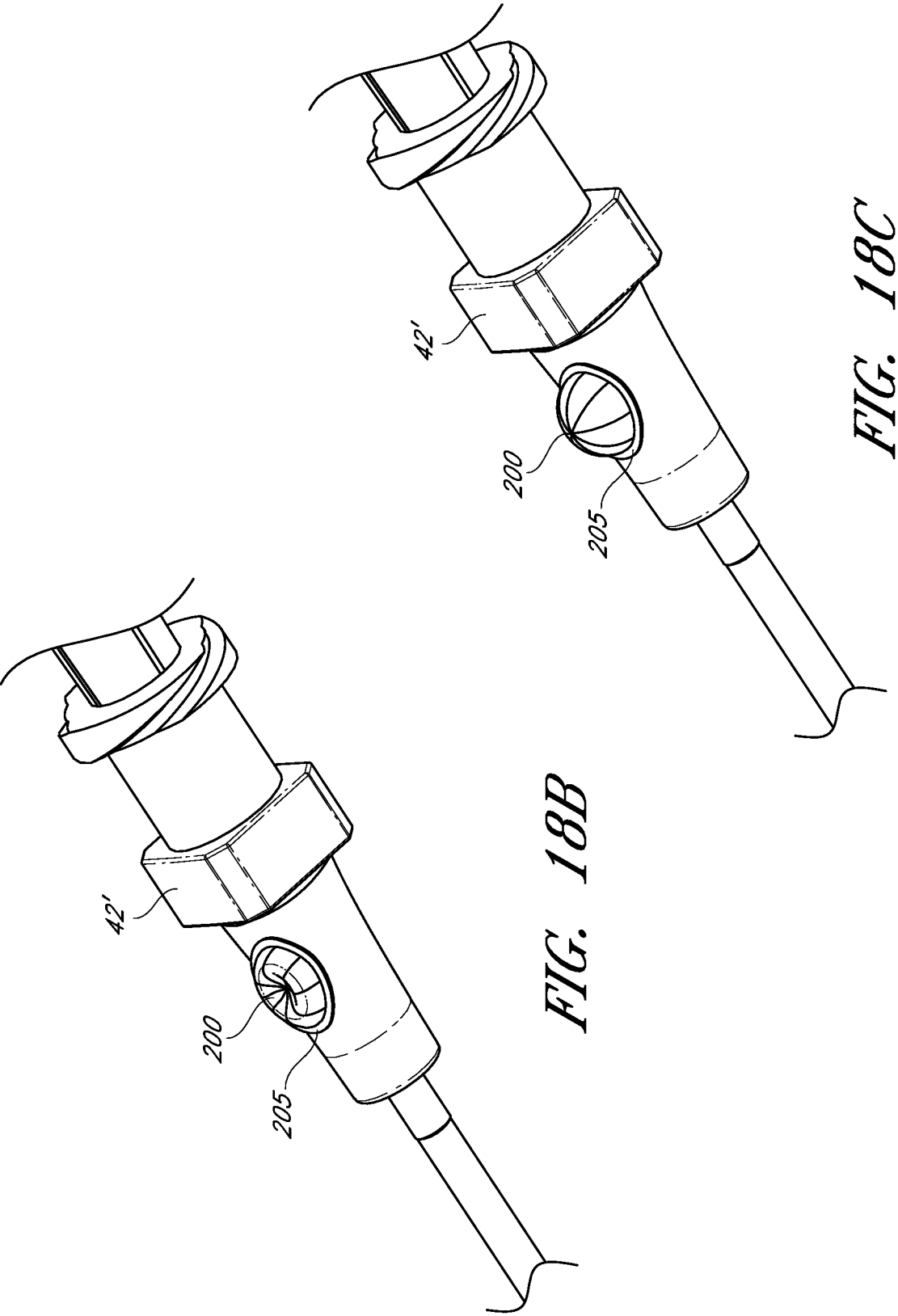


FIG. 18A



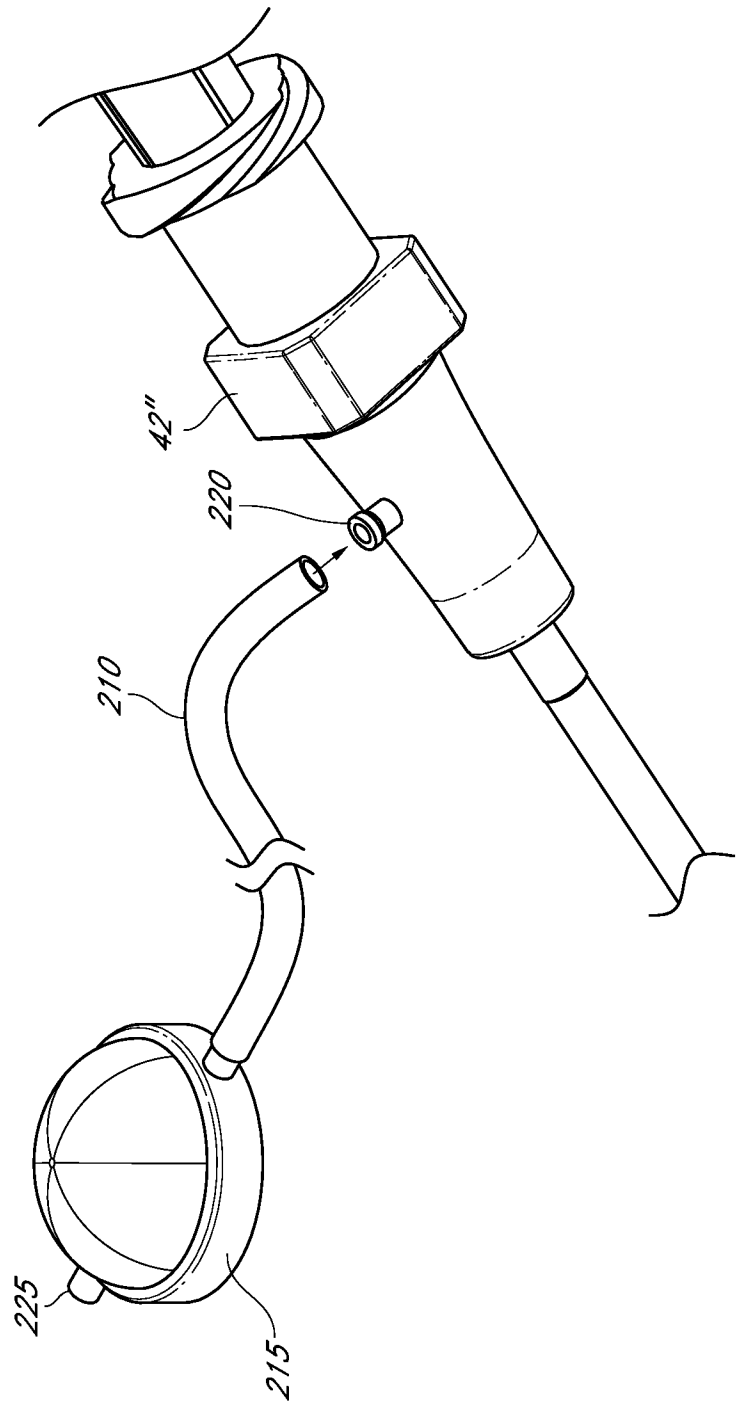


FIG. 19

