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(54) **ACCESS DEVICE**

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CPC A61M 25/0097; A61M 25/0612; A61M 25/0631; A61M 25/01; A61M 25/0102; A61B 2017/347
See application file for complete search history.

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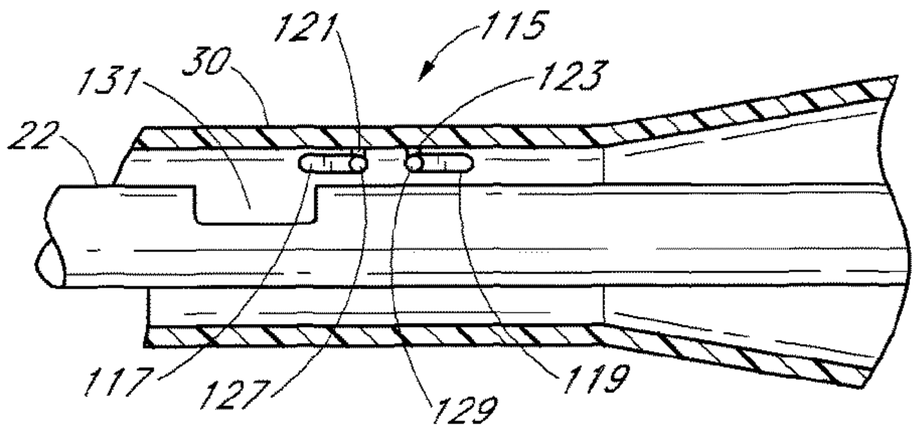
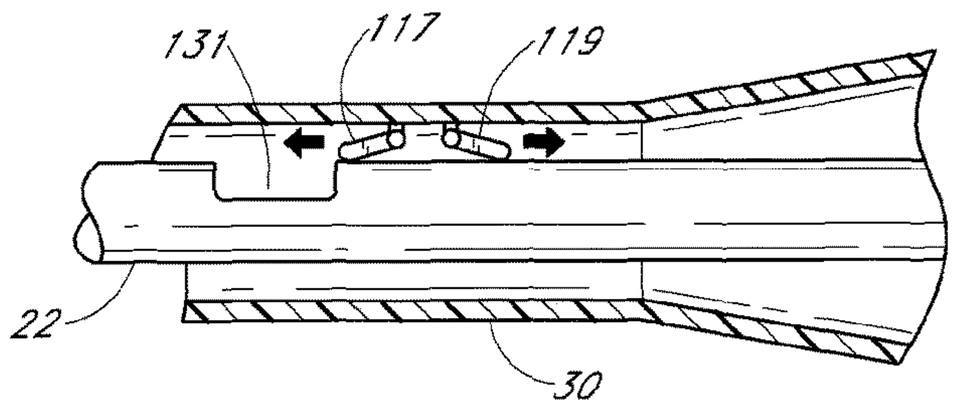
(57) **ABSTRACT**

An access device places a medical article within a body space of a patient. The device has a needle section that includes an elongated body and a needle hub. The device further includes a dilator portion that has a dilator and a dilator hub. The dilator is coaxially disposed and slideable over the elongated body of the needle section. The device further includes a sheath section that has a sheath and a sheath hub. The sheath is coaxially disposed and slideable over the dilator. The device further includes a first locking mechanism operably disposed between the needle hub and the dilator hub to inhibit at least unintentional axial movement between the needle section and the dilator portion and a second locking mechanism operably disposed between the dilator hub and the sheath hub to inhibit at least unintentional axial movement between the dilator portion and the sheath section.

4 Claims, 23 Drawing Sheets





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Photos of a splittable catheter design, Jul. 20, 2011.
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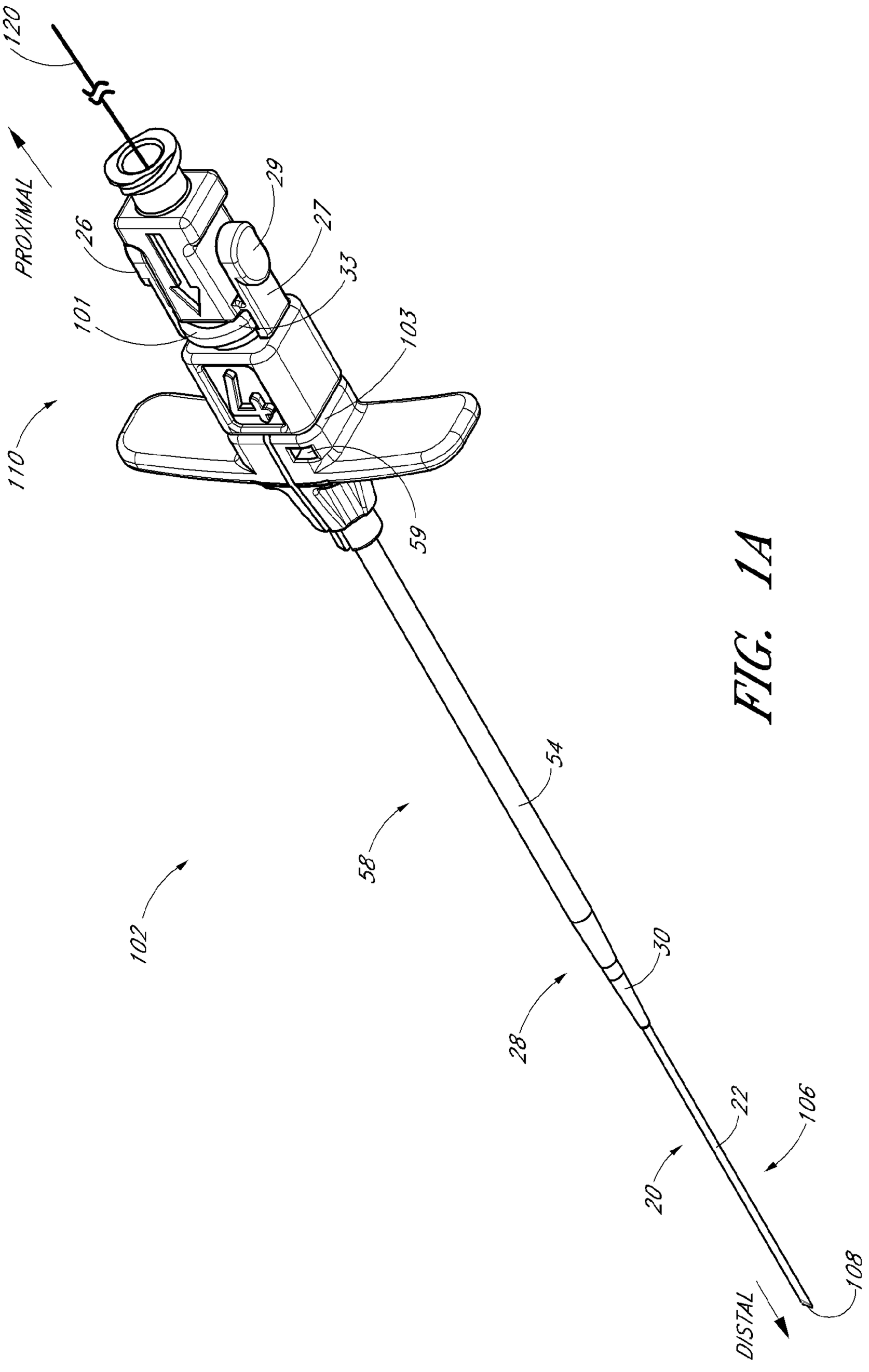
120
PROXIMAL
26
29
27
33
101
103
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59
58
54
102
30
28
22
106
20
108
DISTAL

FIG. 1A

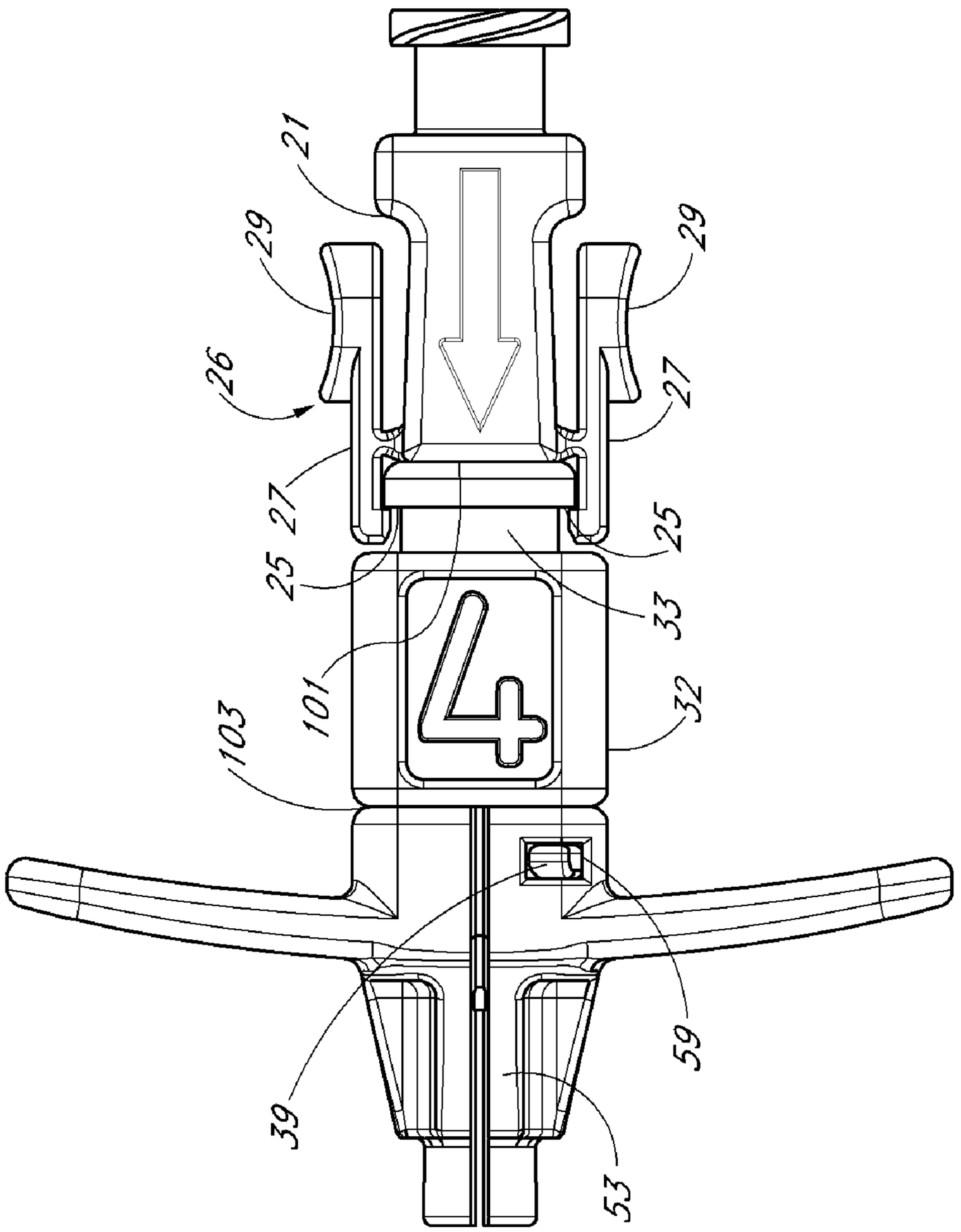

FIG. 1B

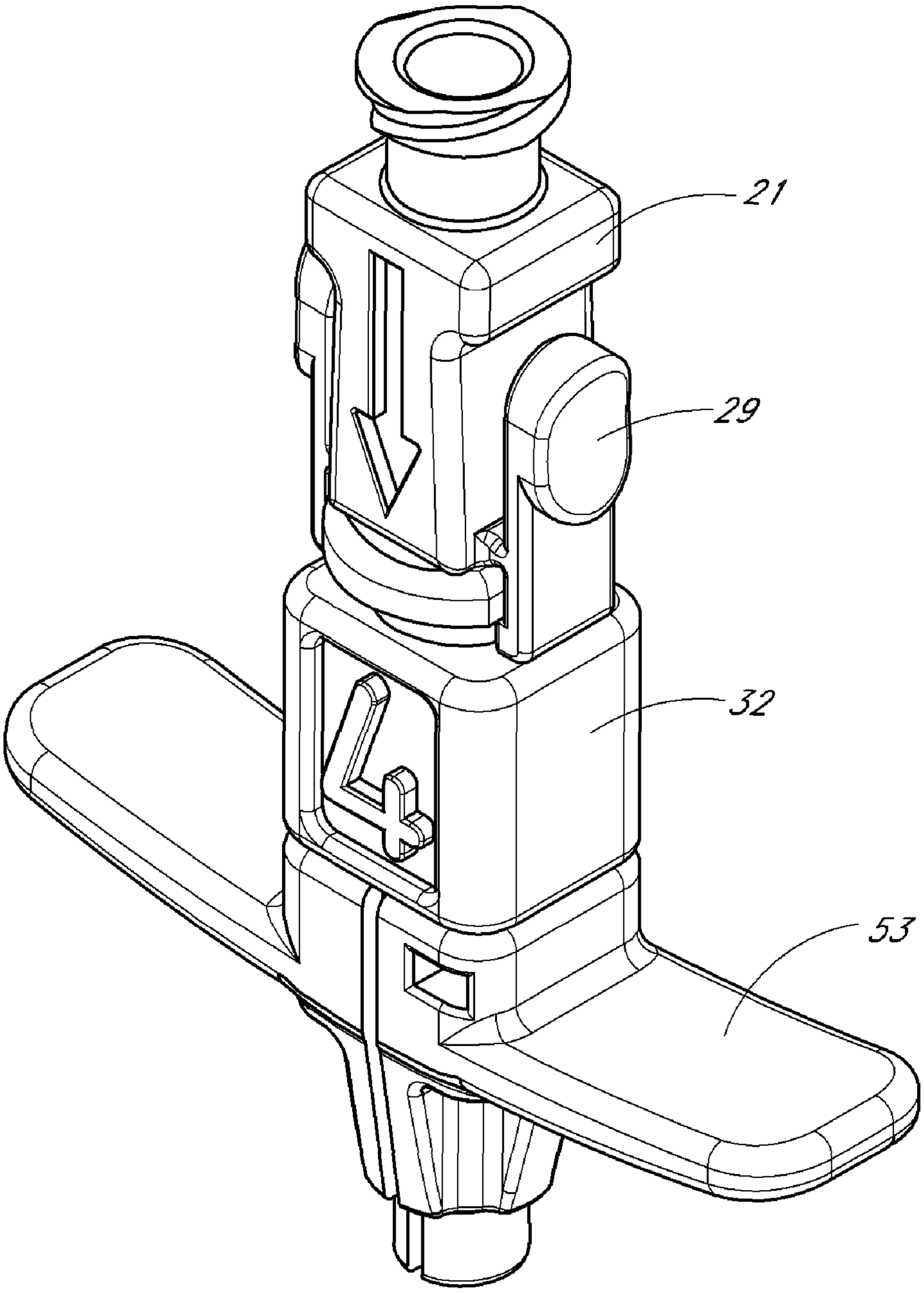

FIG. 1C

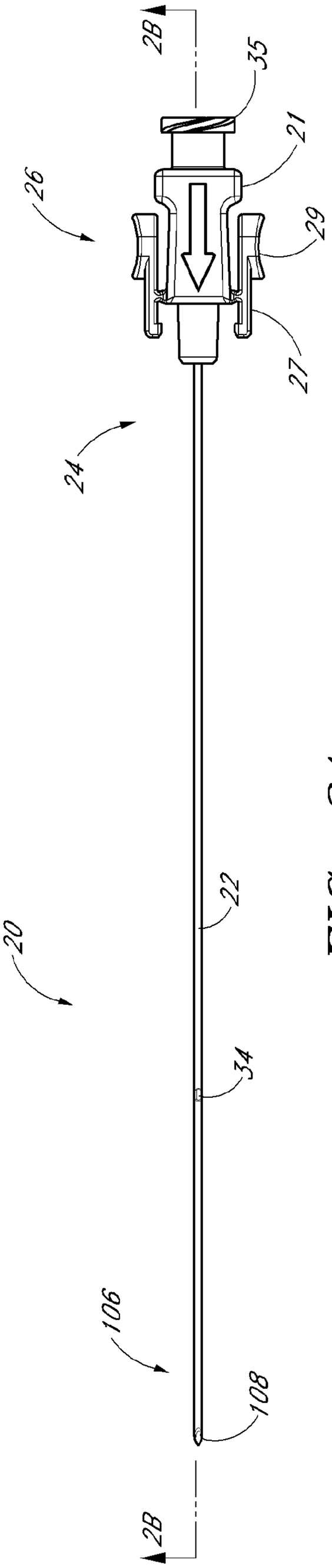

FIG. 2A

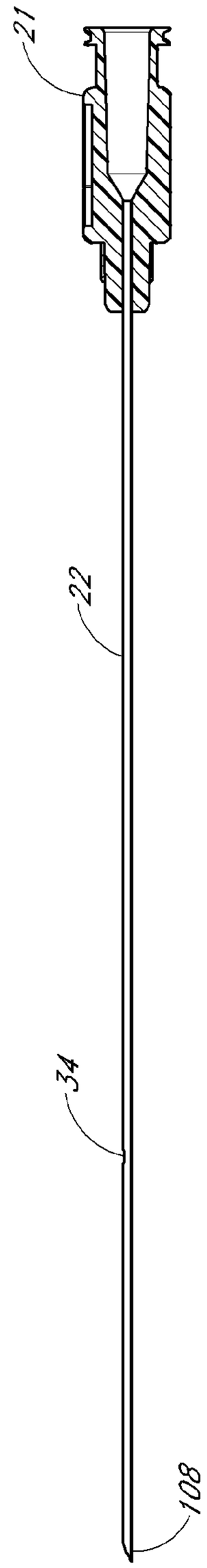

FIG. 2B

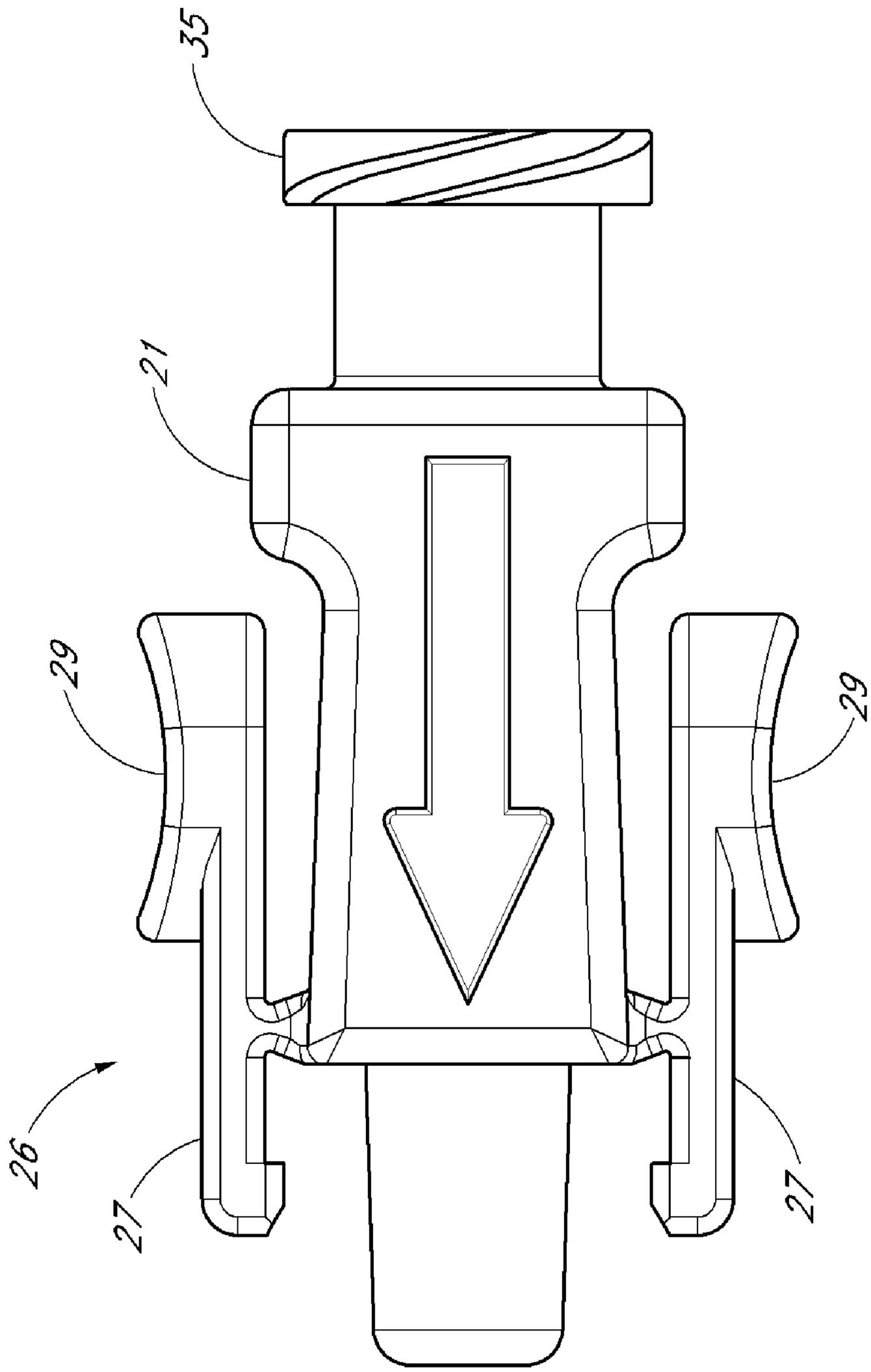

FIG. 2C

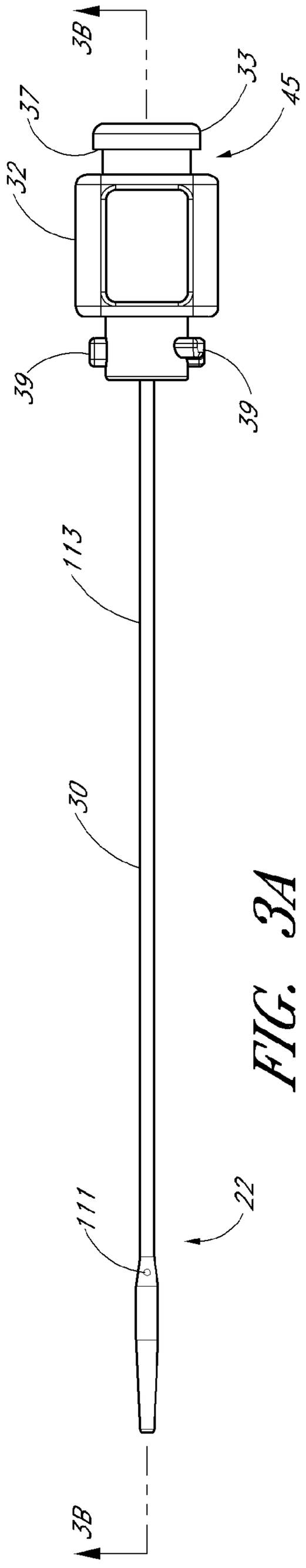

FIG. 3A

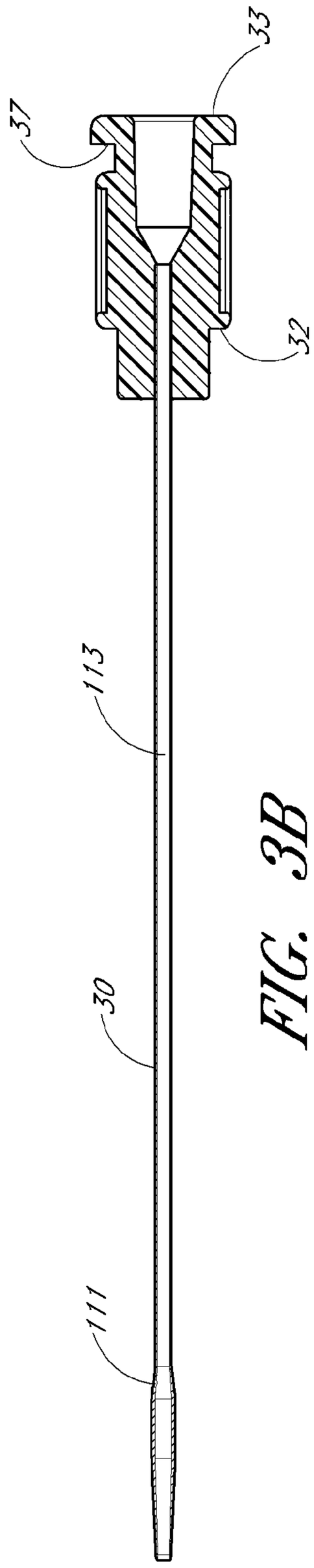

FIG. 3B

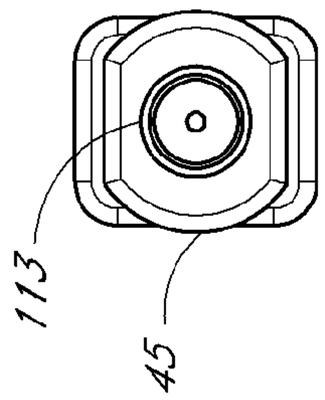

FIG. 3C

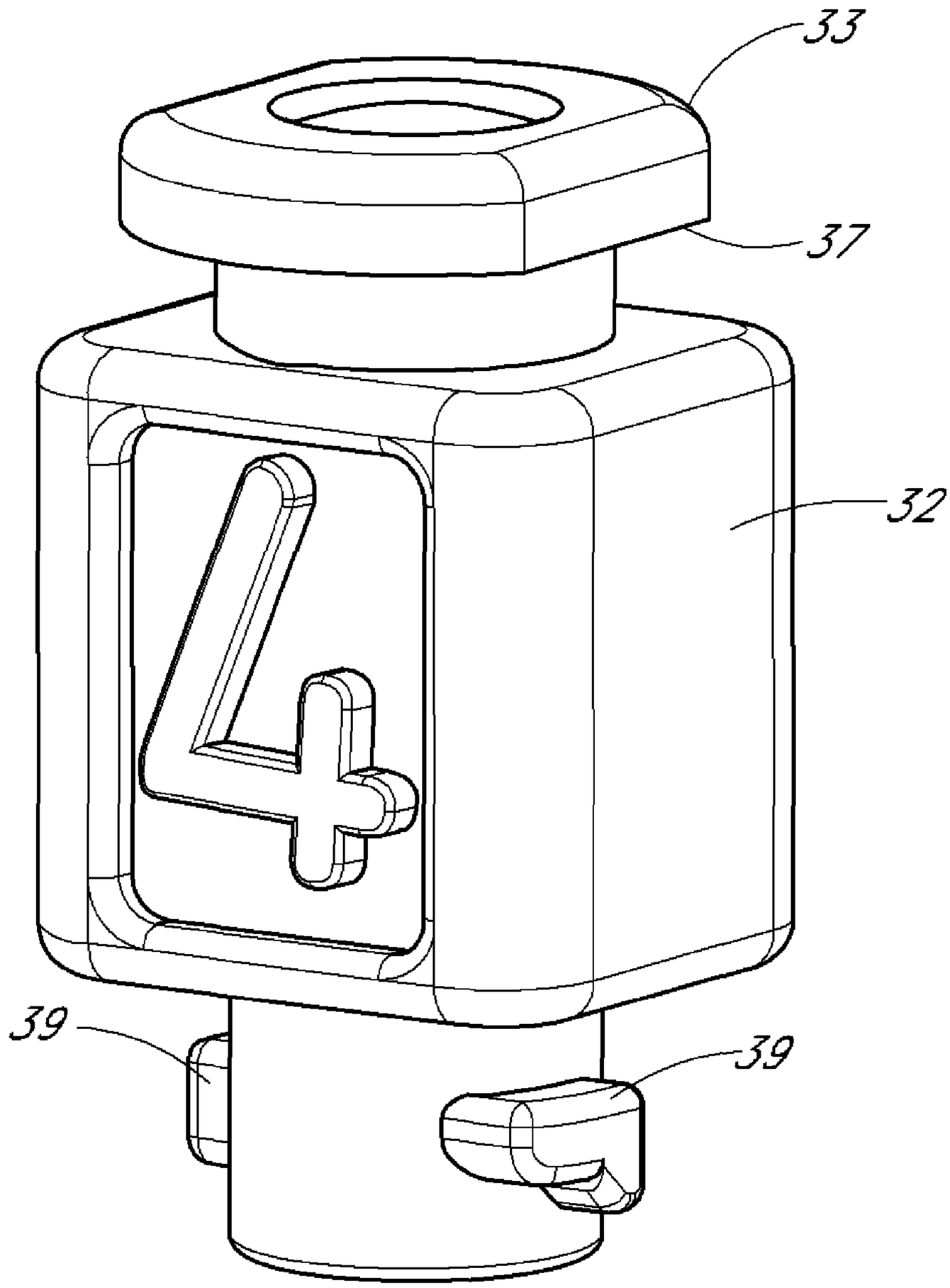

FIG. 3D

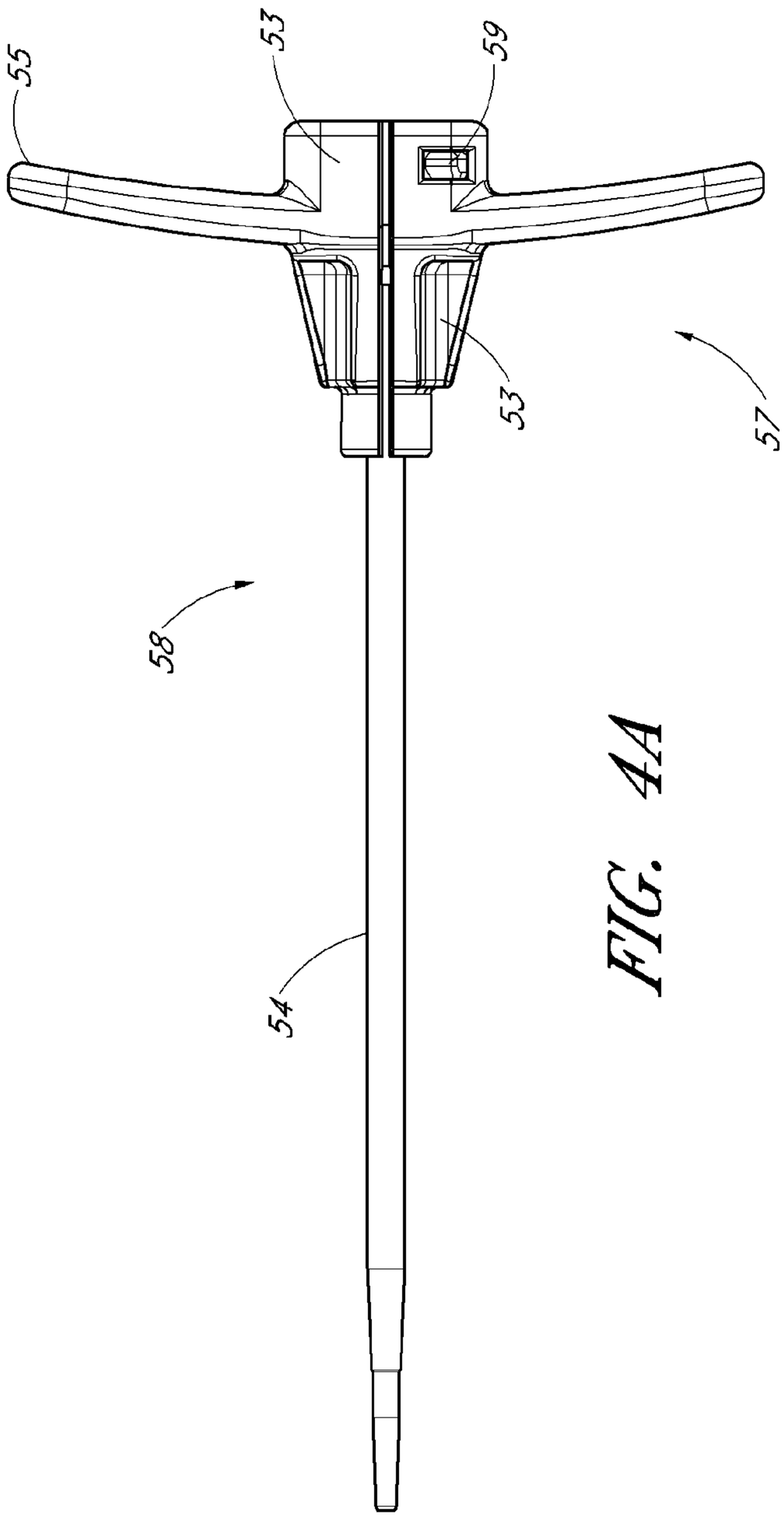

FIG. 4A

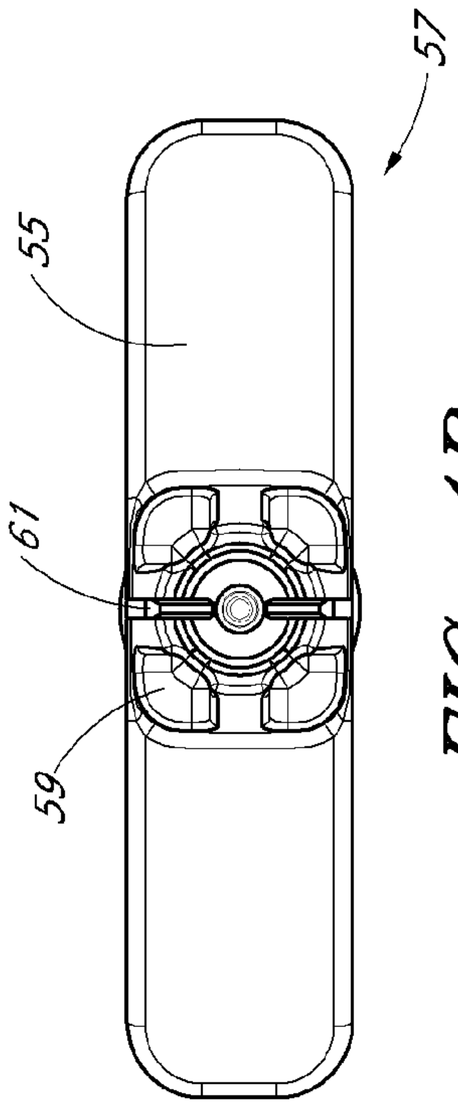

FIG. 4B

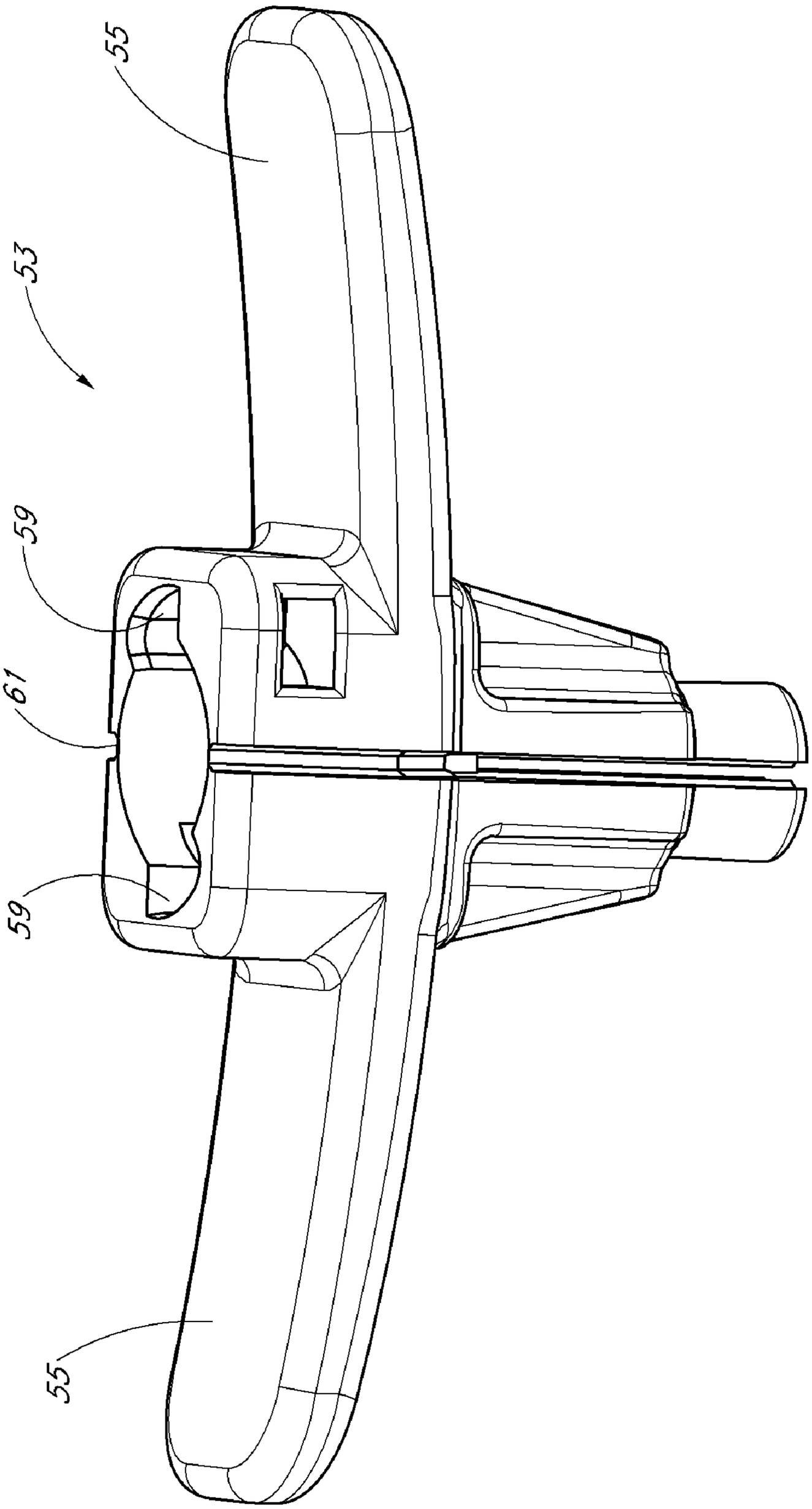

FIG. 4C

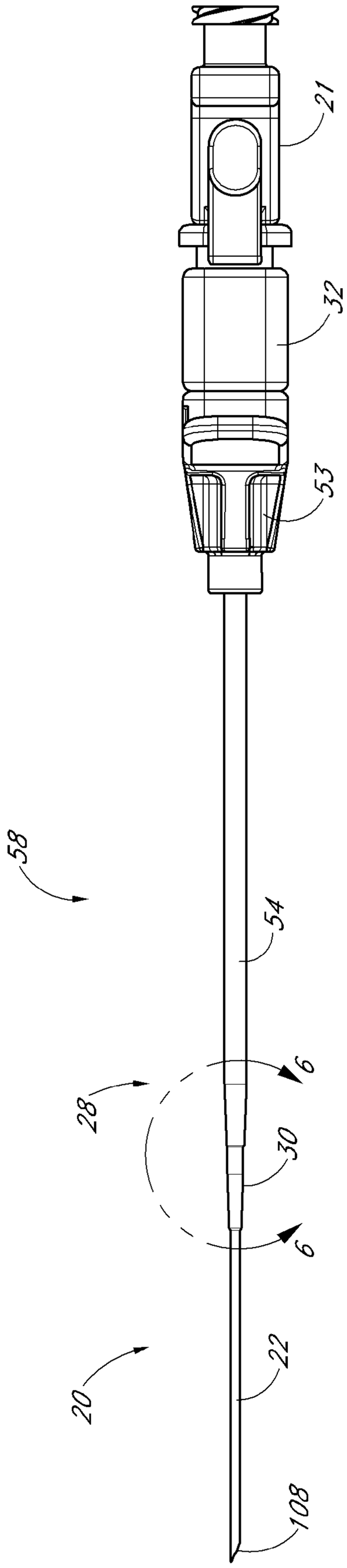

FIG. 5

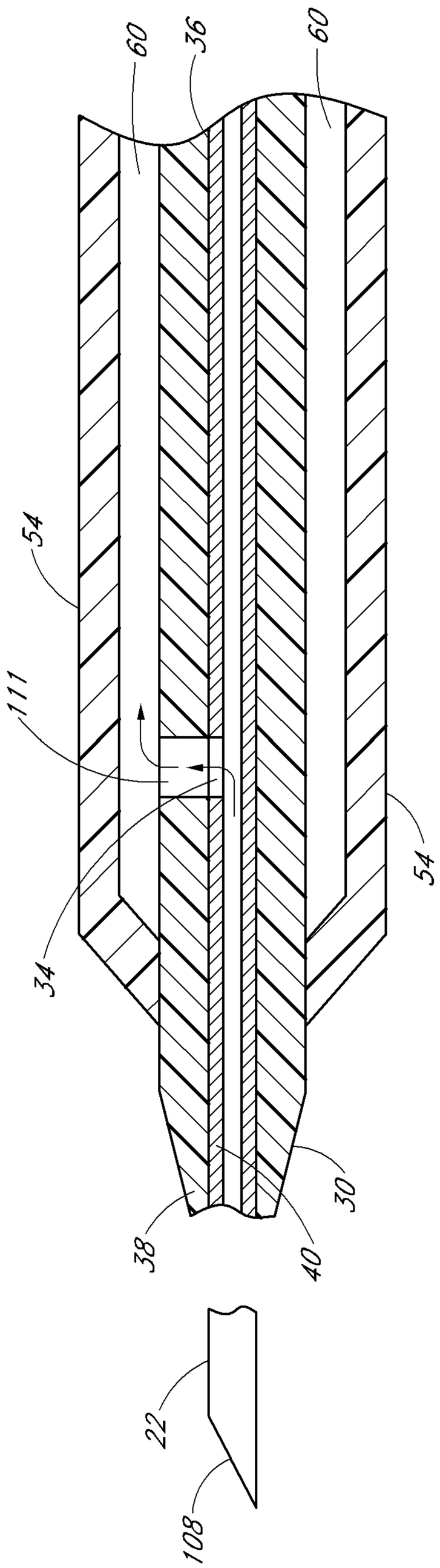

FIG. 6

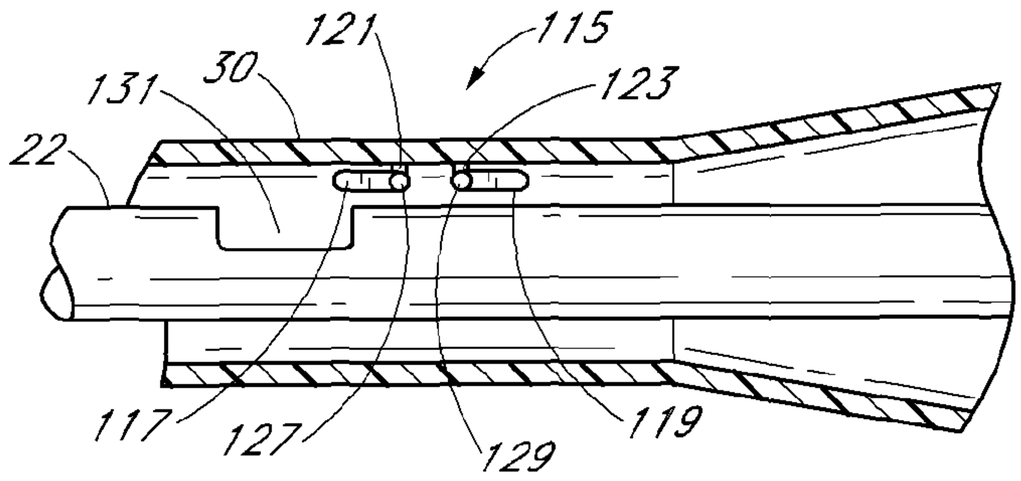

FIG. 7A

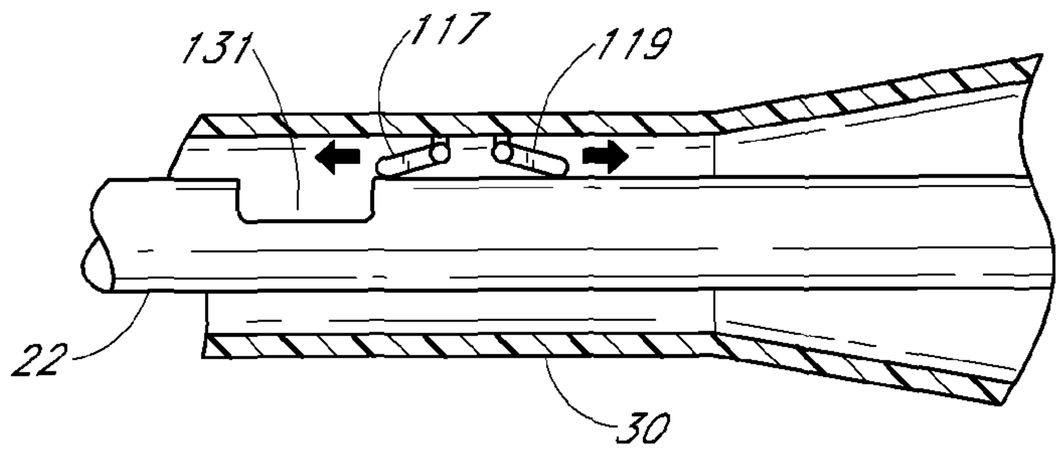

FIG. 7B

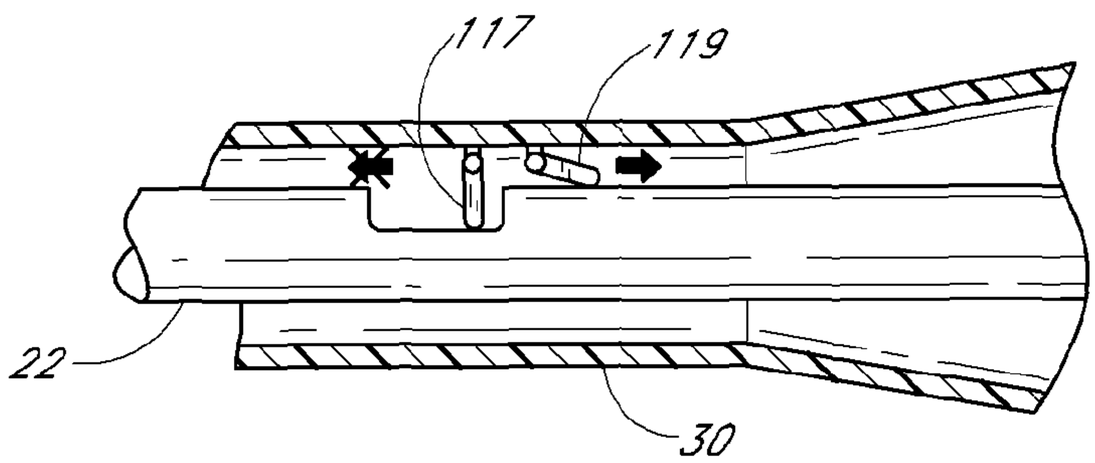

FIG. 7C

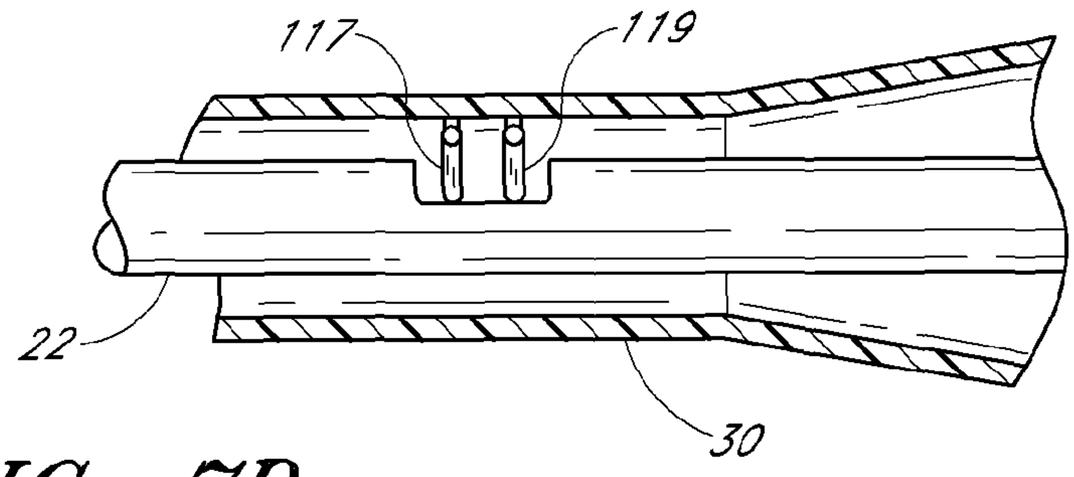

FIG. 7D

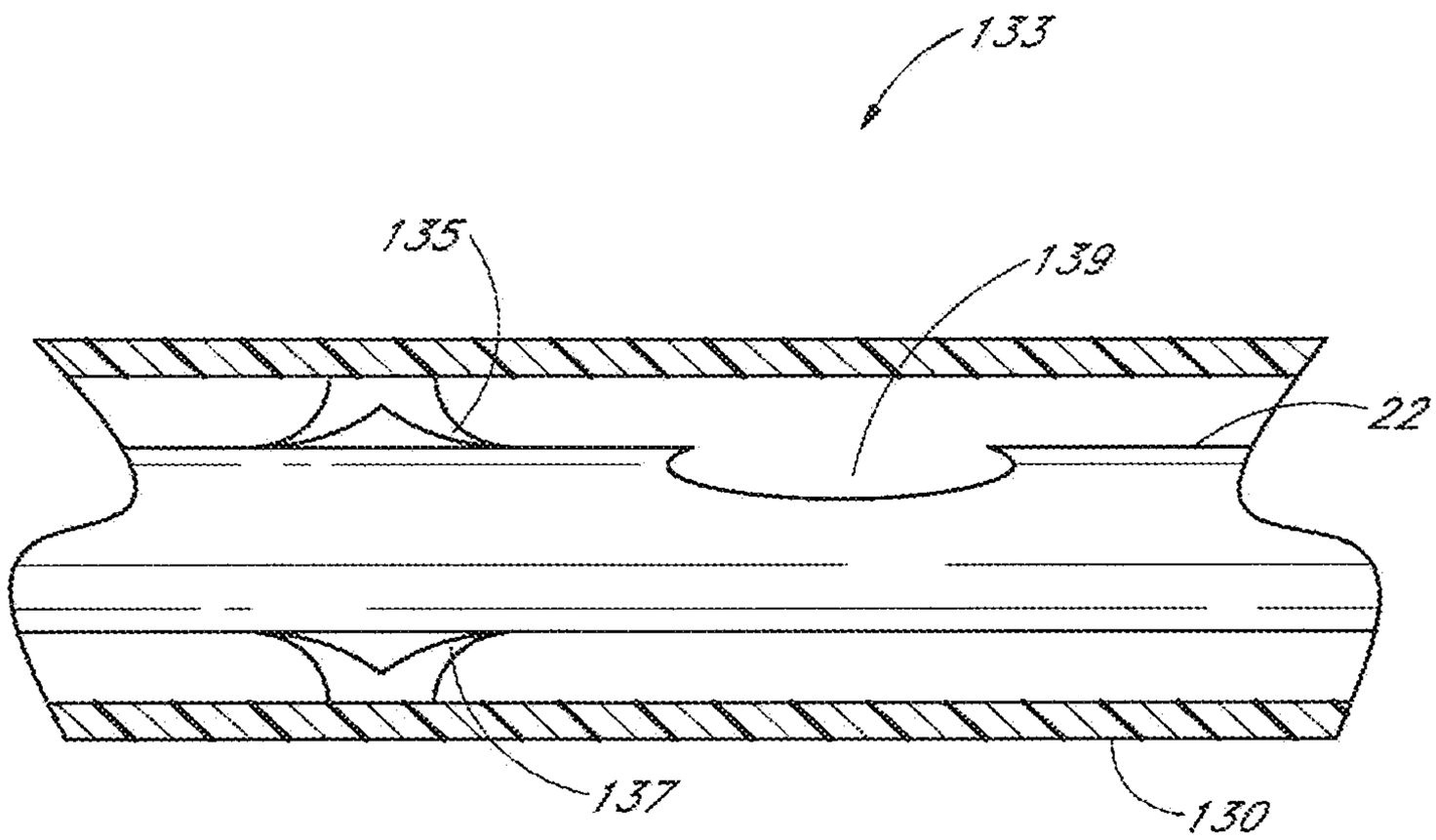

FIG. 8A

"Amended"

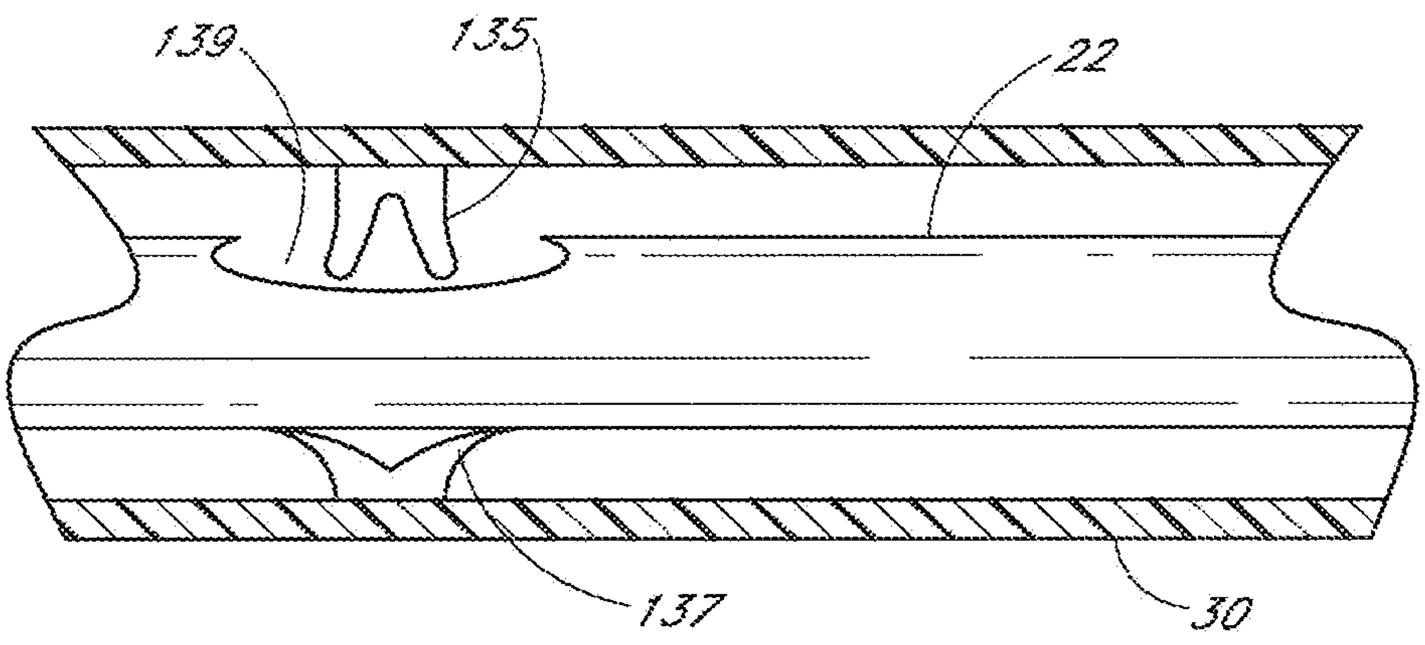

FIG. 8B

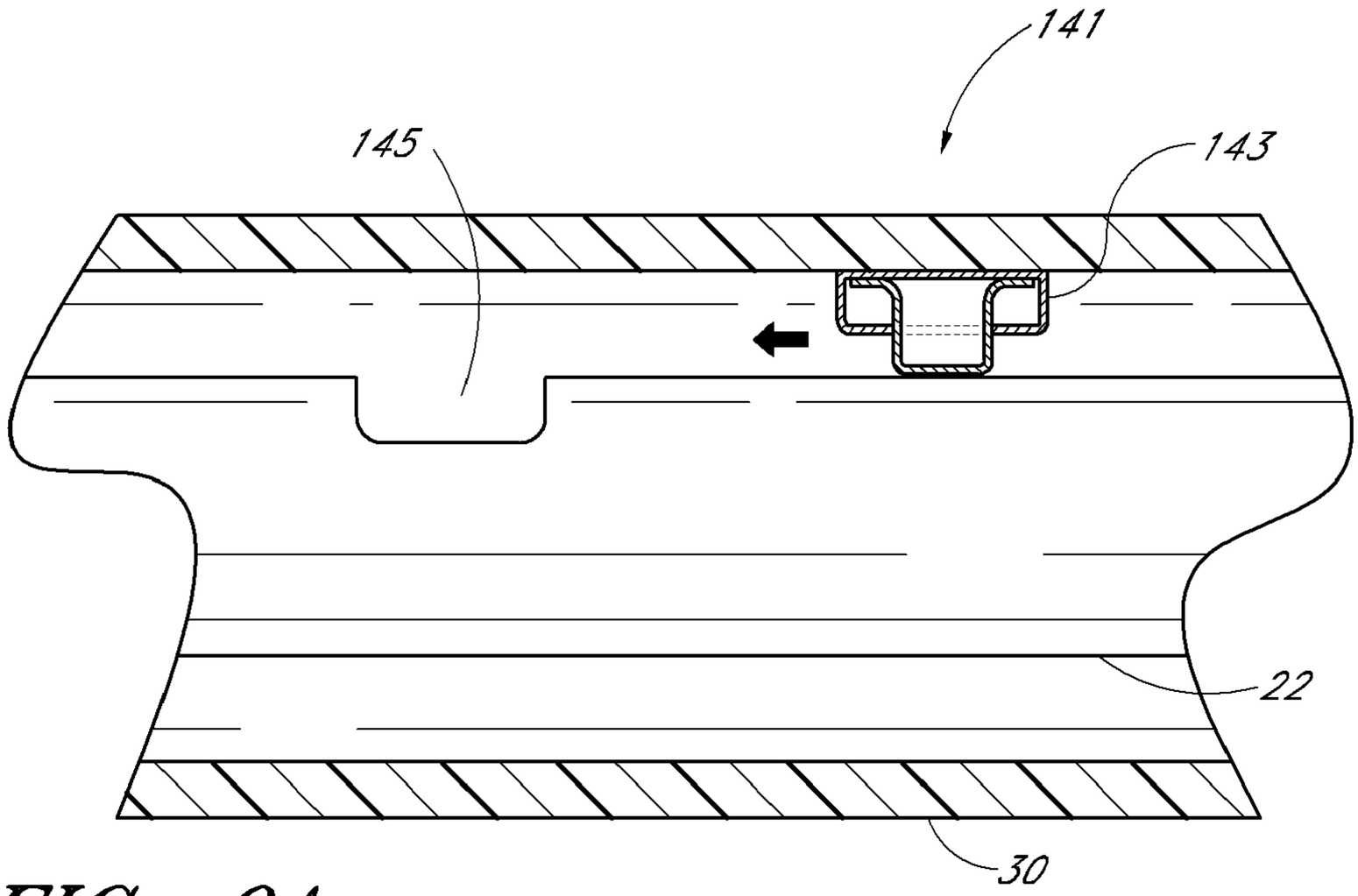

FIG. 9A

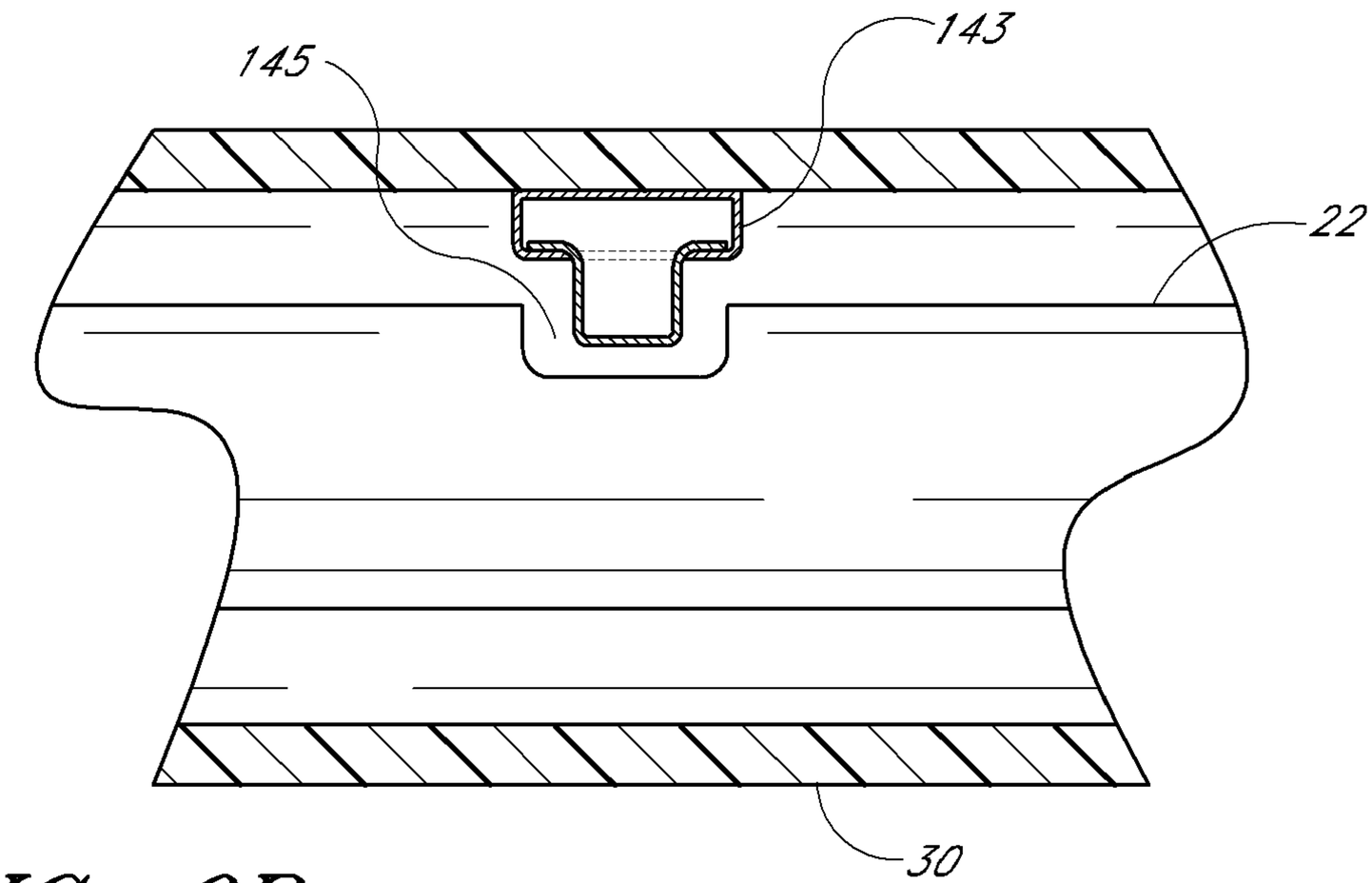

FIG. 9B

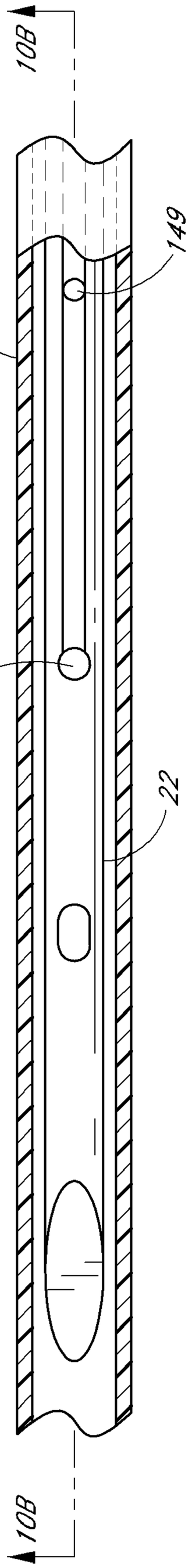

FIG. 10A

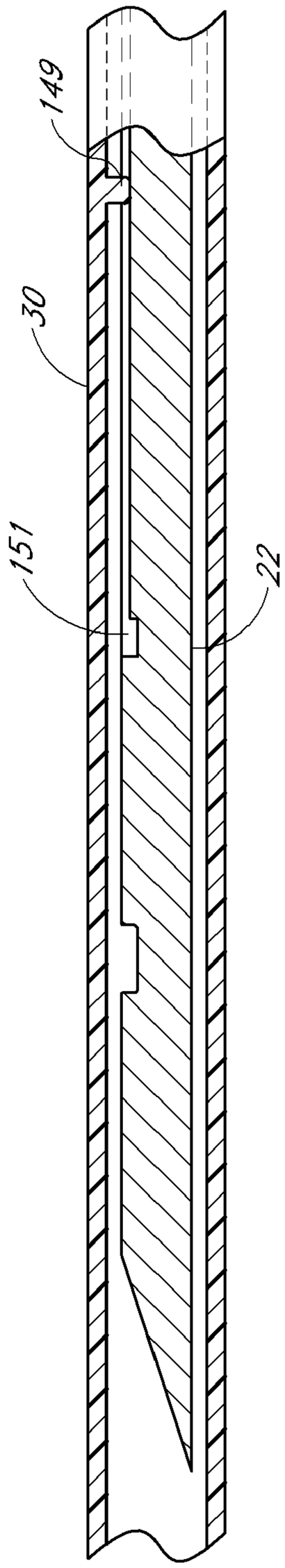

FIG. 10B

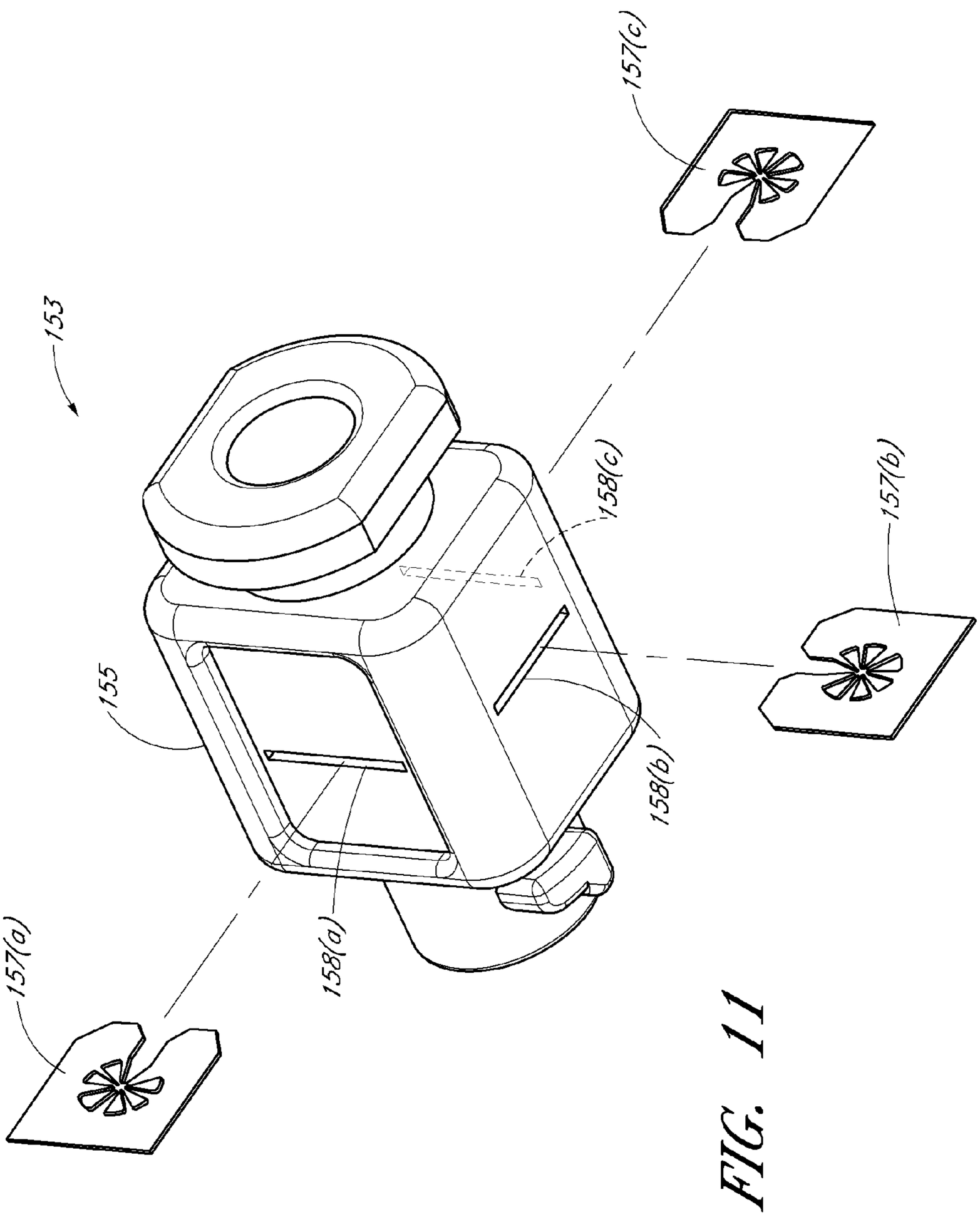

FIG. 11

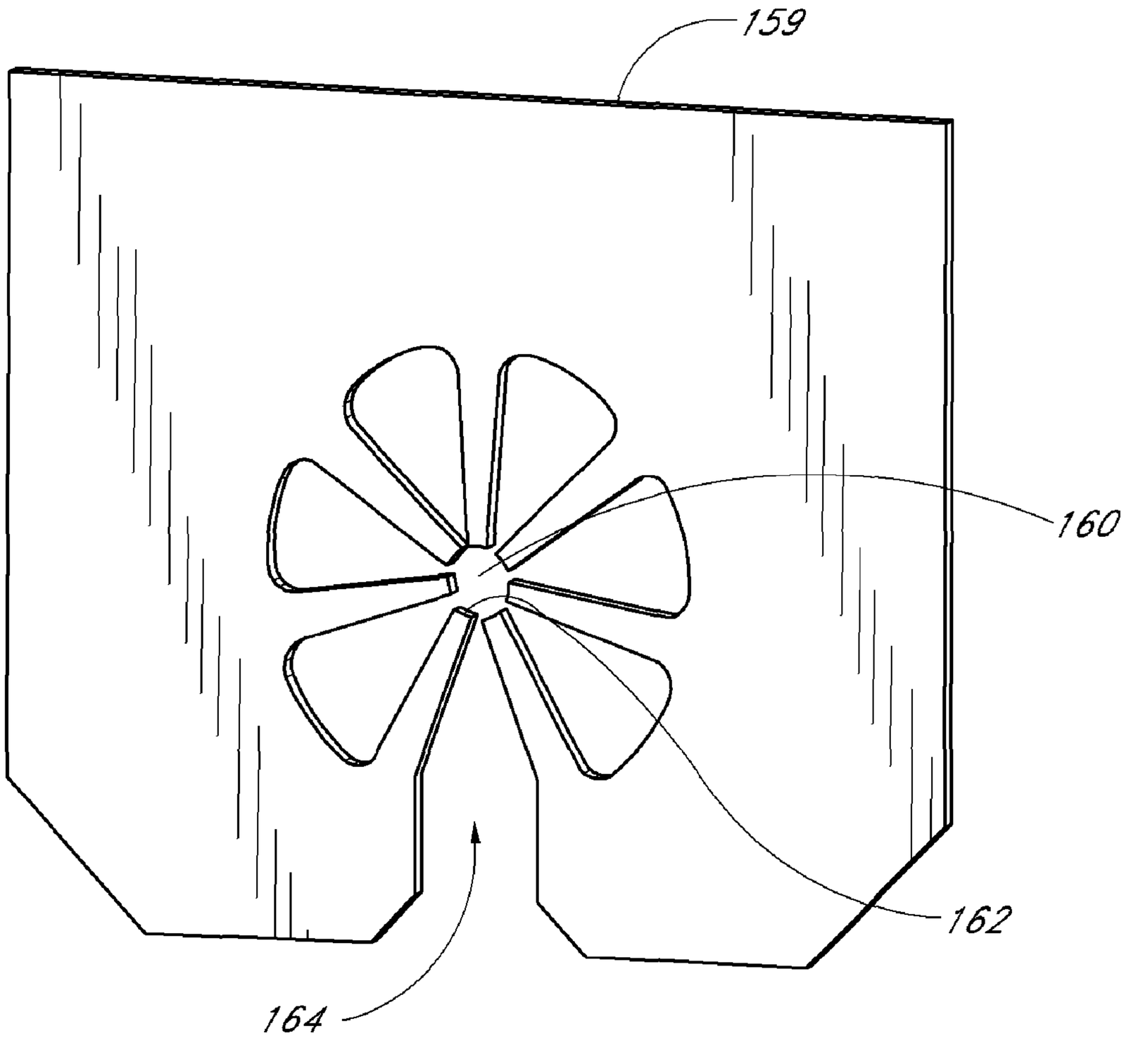

FIG. 12A

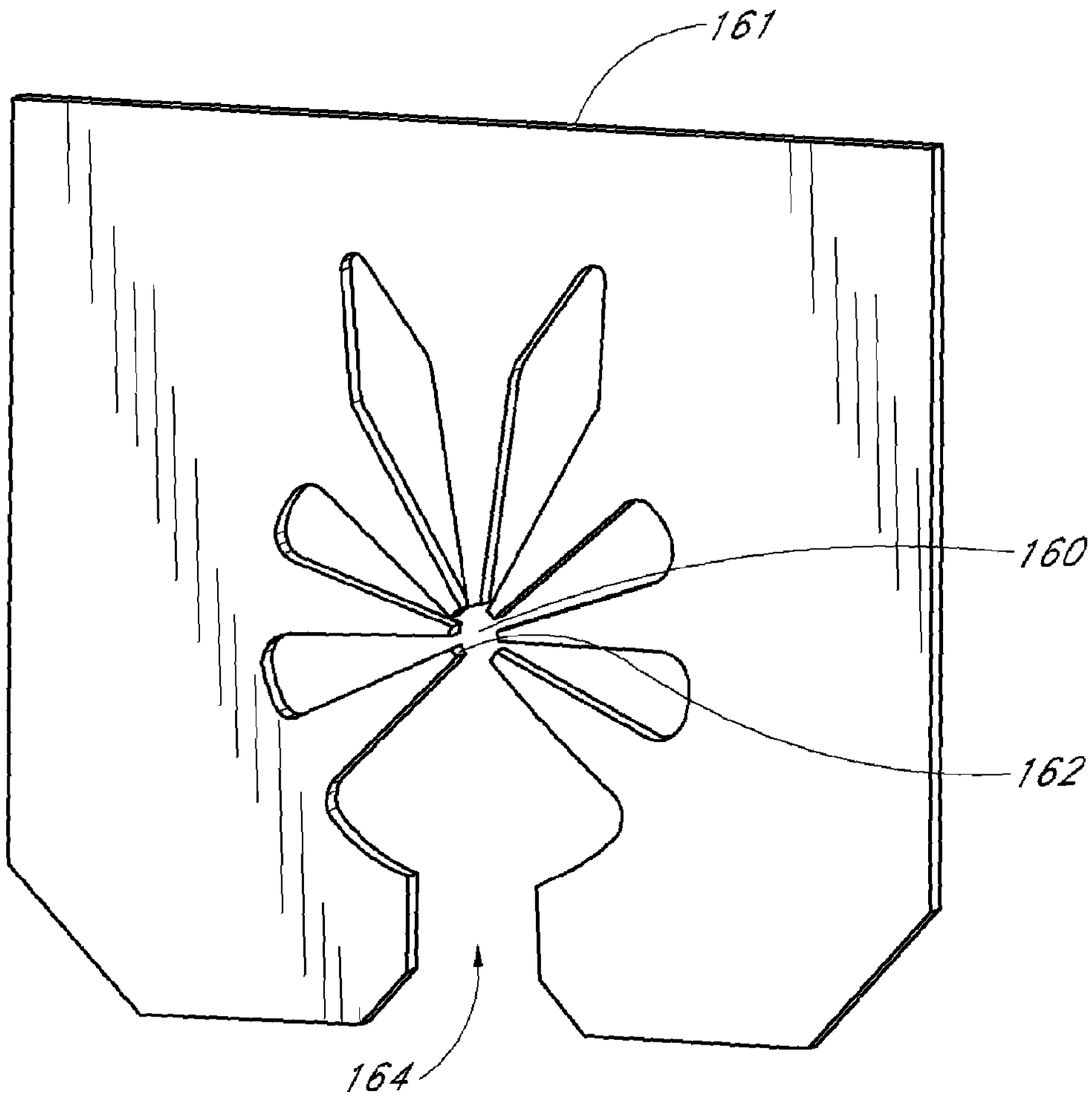

FIG. 12B

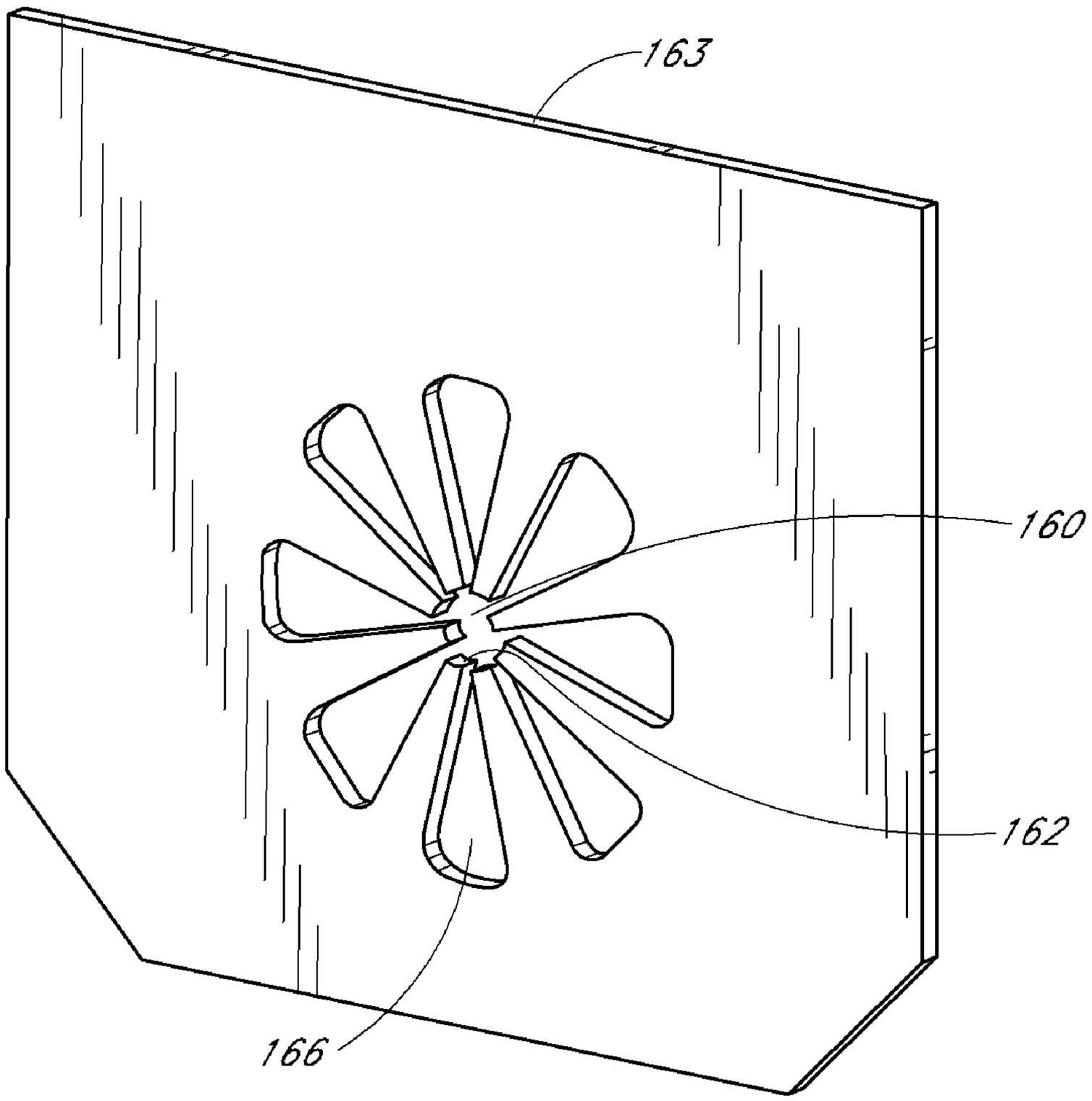

FIG. 12C

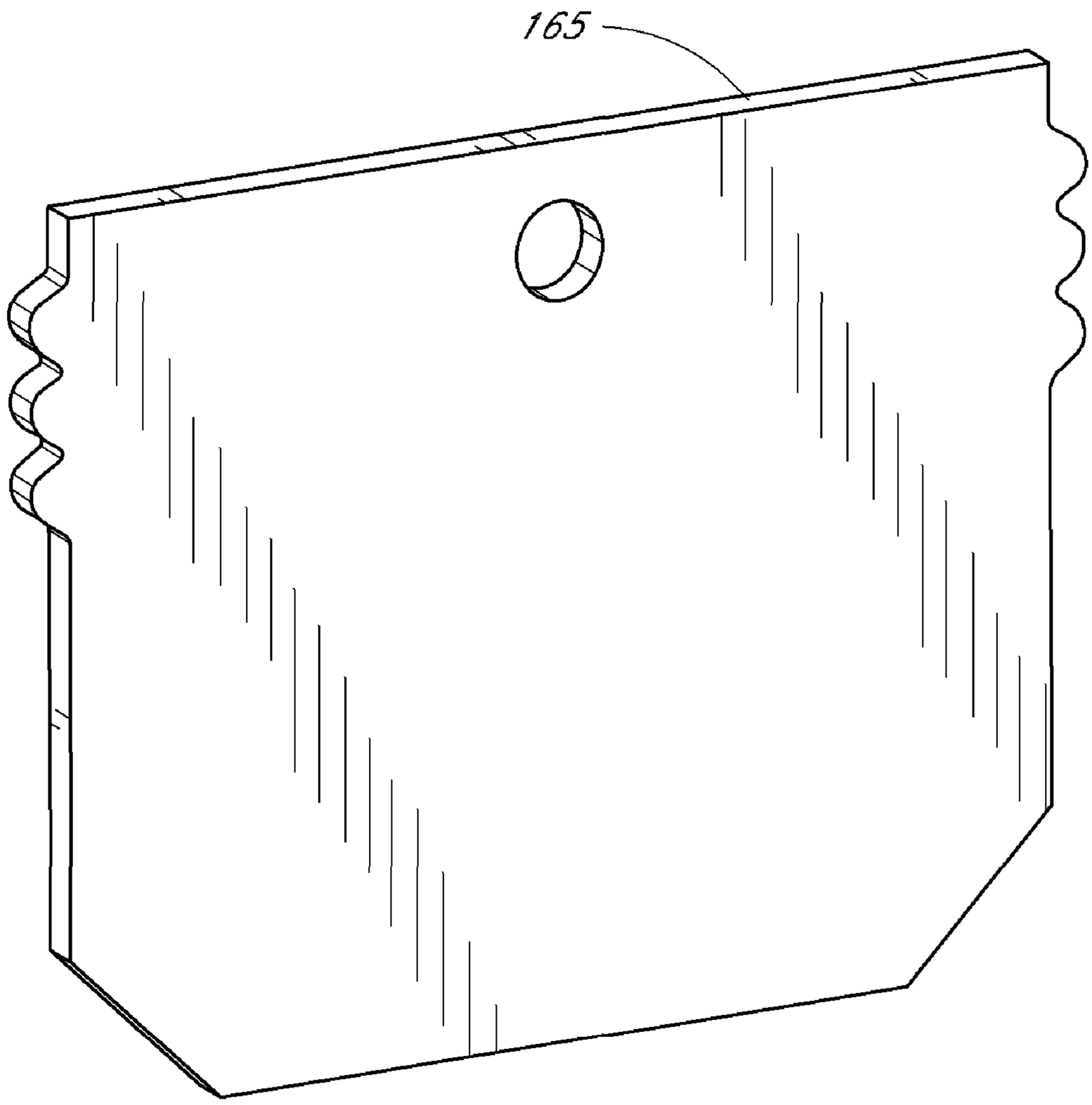

FIG. 13A

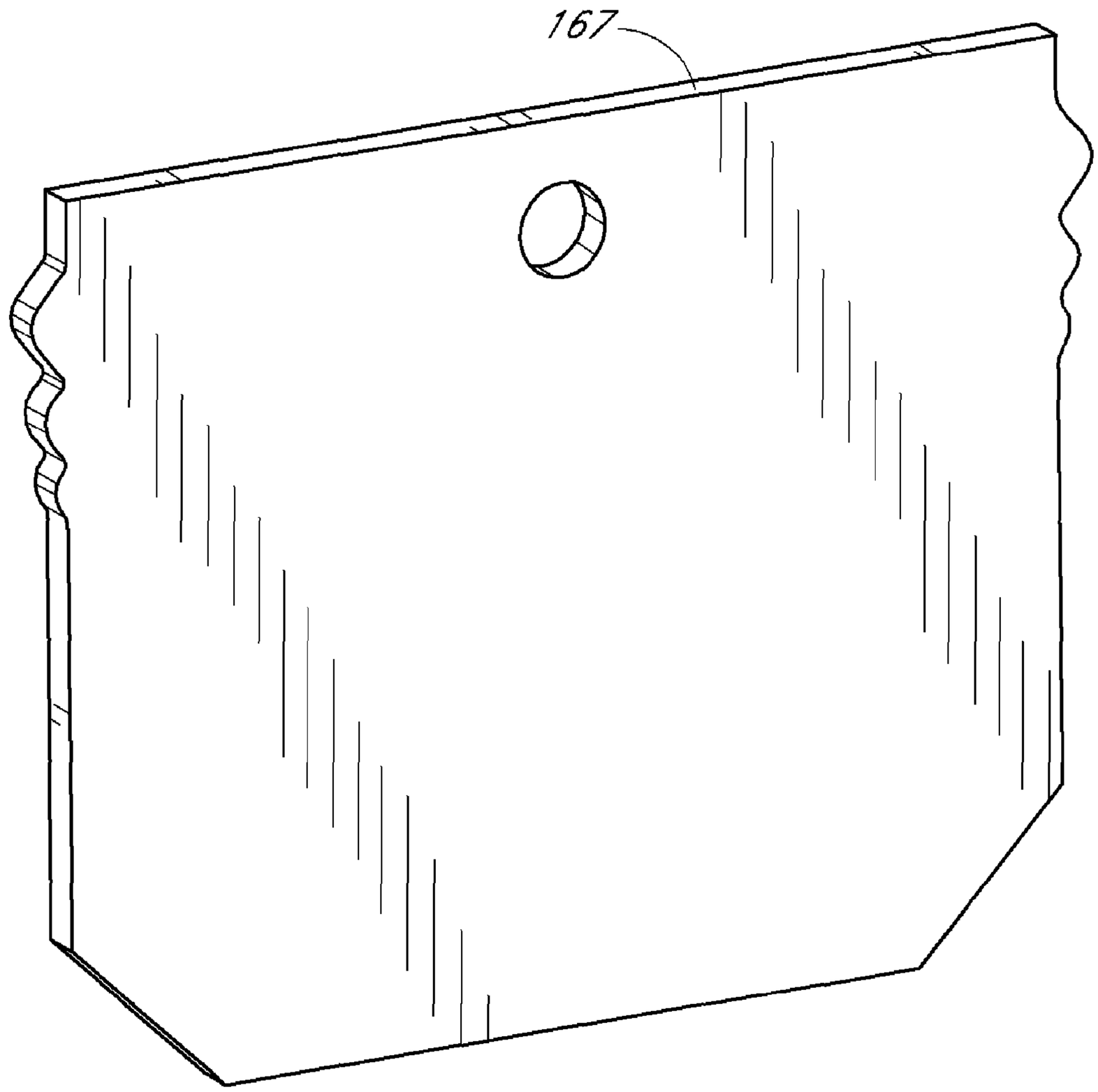

FIG. 13B

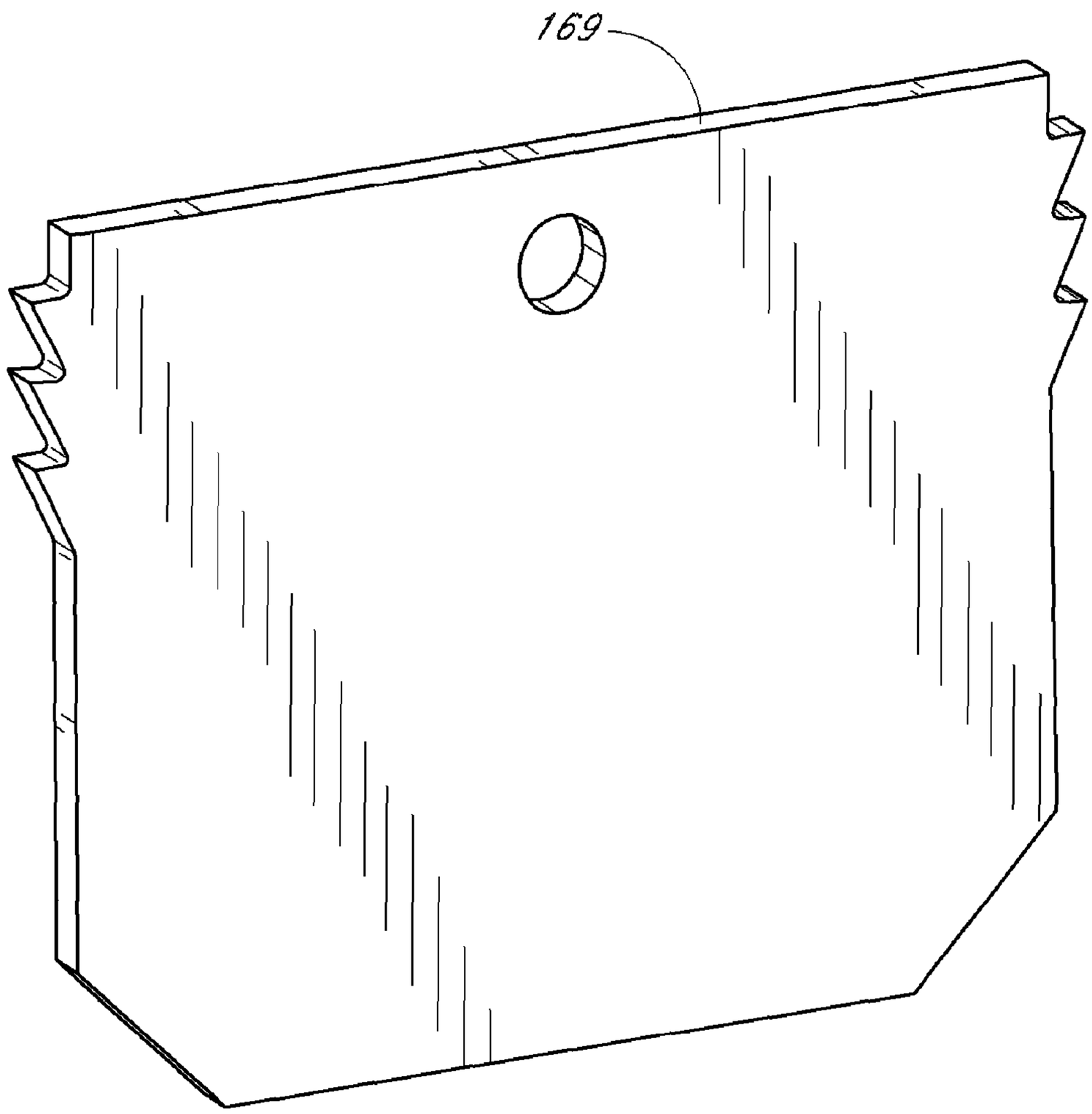

FIG. 13C

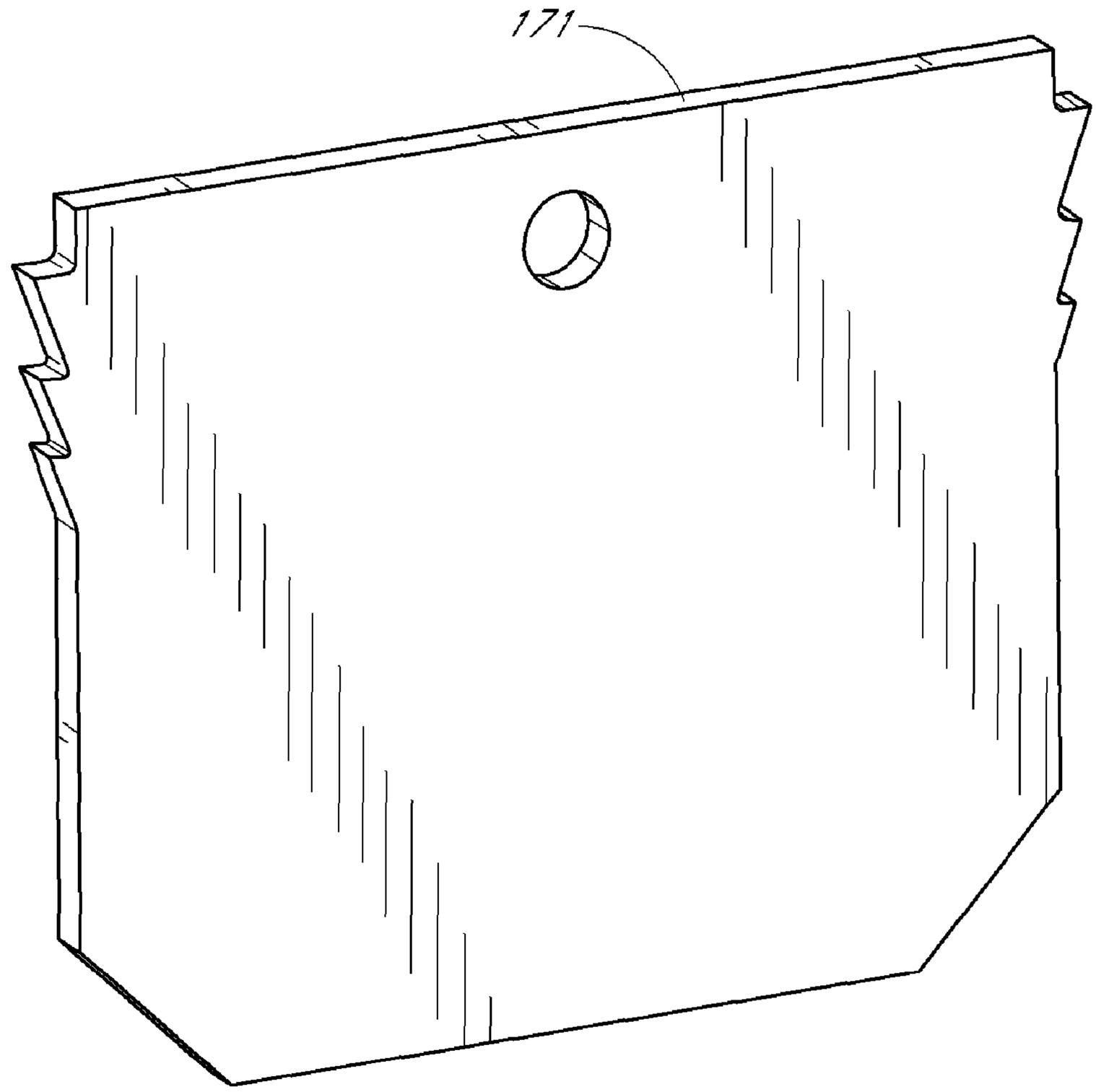

FIG. 13D

ACCESS DEVICE

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 12/019,598, filed on Jan. 24, 2008 and entitled "ACCESS DEVICE," issued as U.S. Pat. No. 7,922,696 on Apr. 12, 2011, which claims the benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 60/886,443, filed Jan. 24, 2007, the entire contents of each hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention is generally directed to access devices for introducing and delivering a catheter cannula or sheath into an artery, vein, vessel, body cavity, or drainage site.

2. Description of the Related Art

A preferred non-surgical method for inserting a catheter or vascular sheath into a blood vessel involves the use of the 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 combination are then inserted over the guidewire. The dilator and sheath combination is then inserted a short distance through the tissue into the vessel, after which the dilator and guidewire are removed and discarded. The catheter may then be inserted through the sheath into the vessel to a desired location.

A number of vascular access devices are known. U.S. Pat. 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, and 6,210,332 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 and, thus, there is a need for an easier-to-use and safer vascular access device, especially one that would clearly indicate when a blood vessel has been punctured.

SUMMARY OF THE INVENTION

The present invention involves 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 this invention provide several advantages over prior access devices.

One aspect of the present invention is an access device for placing a medical article within a body space. The device has a needle section that includes an elongated body and a needle hub. The elongated body has distal and proximal ends. The distal end is configured for insertion into a patient's body. The proximal end is coupled with the needle hub. The device further includes a dilator portion including a dilator and a dilator hub. The dilator is coaxially disposed and slideable over the elongated body of the needle section with the dilator hub being disposed distal of the needle hub. The device further includes a sheath section that has a sheath and a sheath hub. The sheath is coaxially disposed and slideable over the dilator with the sheath hub being disposed distal of the dilator hub. The device further includes a first locking mechanism operably disposed between the needle hub and the dilator hub to inhibit at least unintentional axial movement between the needle section and the dilator portion when the first locking mechanism is engaged and a second locking mechanism operably disposed between the dilator hub and the sheath hub to inhibit at least unintentional axial movement between the dilator portion and the sheath section when the second locking mechanism is engaged. Each of said first and second locking mechanisms is configured to be engaged by moving the respective hubs in a non-axial manner relative to each other. The first locking mechanism is configured to move in a manner different from the manner in which the second locking mechanism is engaged.

Another aspect of the invention is an access device for placing a medical article within a body space. The device includes a needle section including an elongated needle body with a sharp distal tip and a needle hub from which the needle body extends. The device further includes a dilator portion that includes a dilator and a dilator hub. The dilator is coaxially disposed and slideable over the needle body with the dilator hub being disposed distal of the needle hub. The device further includes a sheath section that includes a sheath and a sheath hub. The sheath is coaxially disposed and slideable over the dilator with the sheath hub being disposed distal of the dilator hub. The device further includes a locking mechanism disposed within the dilator and selectively operating between the needle body and the dilator. The locking mechanism is configured to arrest axial movement of the needle body at least in the distal direction once the distal tip of the needle body is drawn into the dilator portion to sheath the distal tip.

Yet another aspect of the invention is an access device for placing a medical article within a body space. The device includes a dilator hub that has a passageway configured to receive an elongated needle. The needle has at least one side receptacle. The device further includes one or more fingers or tangs disposed in the dilator hub and configured to engage with the at least one side receptacle at least when the needle is retracted through the passageway.

Additionally, a releasable interlock can be provided in some embodiments to inhibit relative rotational movement between the needle section and the dilator section, at least when the needle is inserted into a patient. By inhibiting such relative rotational movement, communicating side openings in the needle and the dilator can be held in alignment to provide a simplified passageway through which the blood or fluid may flow. Thus, when the needle enters a blood vessel or drainage site in the patient, blood or other body fluid quickly flows into the passageway. The resulting blood or fluid flash is visible through the sheath section (or catheter) to indicate that the needle tip has entered the vessel or drainage site.

For example, but without limitation, the dilator portion or section can comprise, in some embodiments, a dilator hub and dilator having one or more side openings. The dilator hub may have a luer connection and a releasable locking mechanism. The releasable locking mechanism can be configured to releasably engage and secure the dilator section to

another part, such as the needle hub. When the needle hub and the dilator hub are releasably locked to prevent rotation therebetween, one or more of the side openings in the dilator are aligned with one or more side openings in the needle. The locking mechanism can also be configured to inhibit unintentional relative axial movement between the needle and the dilator.

The sheath section preferably, but not necessarily, includes a sheath and sheath hub. The sheath may be made partially or completely from a clear, translucent, semi-opaque, or transparent material. Such transparent, translucent, semi-opaque and clear materials allow a clinician the ability to see when blood or other body fluids flows into the needle, through the needle side opening(s), through the side dilator opening(s), and into the viewing space between the dilator and sheath.

These and other aspects of the present invention will become readily apparent to those skilled in the art from the following detailed description of the preferred embodiments, which refers to the attached figures. The invention is not limited, however, to the particular embodiments that are disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects, and advantages of the invention disclosed herein are described below with reference to the drawings of preferred embodiments, which are intended to illustrate and not to limit the invention.

FIG. **1**A is a perspective view of a preferred embodiment of an access device configured in accordance with the present invention.

FIG. **1**B is an enlarged plan view of a needle hub, a dilator hub, and a sheath hub of the access device illustrated in FIG. **1**A, shown in an assembled state.

FIG. **1**C is a perspective view of the assembly of the needle hub, dilator hub and sheath hub illustrated in FIG. **1**B.

FIG. **2**A is side view of a needle section of the embodiment depicted in FIG. **1**A.

FIG. **2**B is a cross-sectional view of the needle section of the embodiment depicted in FIG. **2**A taken along line A-A.

FIG. **2**C is an enlarged plan view of the needle hub of the needle section of FIG. **2**B.

FIG. **3**A is a side view of the dilator portion of the embodiment depicted in FIG. **1**A.

FIG. **3**B is a proximal end view of the dilator portion of FIG. **3**A.

FIG. **3**C is a cross-sectional view of the dilator portion of the embodiment depicted in FIG. **3**A, taken along line B-B.

FIG. **3**D is an enlarged perspective view of the dilator hub of the dilator portion of FIG. **3**A.

FIG. **4**A is a side view of a sheath section of the embodiment from FIG. **1**A.

FIG. **4**B is a proximal end view of the sheath section of FIG. **4**A.

FIG. **4**C is an enlarged perspective view of the sheath hub of the sheath section of FIG. **4**A.

FIG. **5** is a side view of the access device of FIG. **1**A.

FIG. **6** is an enlarged cross-sectional view of a portion of the embodiment illustrated in FIG. **5** which is circled by line C-C.

FIG. **7**A is a schematic, enlarged cross-sectional view of a portion of the needle within the dilator and illustrates an embodiment of a locking mechanism configured in accordance with one aspect of the present invention.

FIGS. **7**B-**7**D illustrate the operational steps of the locking mechanism of FIG. **7**A when arresting relative axial movement between the needle and the dilator.

FIG. **8**A is a similar cross-sectional view of a portion of a locking mechanism which is configured in accordance with another preferred embodiment of present invention. FIG. **8**A illustrates the locking mechanism in an unlocked state.

FIG. **8**B illustrates the locking mechanism of FIG. **8**A in a locked state.

FIG. **9**A is a schematic, enlarged cross-sectional view of a locking mechanism configured in accordance with an additional embodiment of the present invention. FIG. **9**A illustrates the locking mechanism in an unlocked state.

FIG. **9**B illustrates the locking mechanism of FIG. **9**A in a locked state.

FIG. **10**A is a schematic, enlarged cross-sectional view of a locking mechanism configured in accordance with a further embodiment of the present invention. FIG. **10**A illustrates the locking mechanism in an unlocked state.

FIG. **10**B is a cross-sectional view of the locking mechanism of FIG. **10**A taken along lines **10**B-**10**B.

FIG. **11** is an enlarged exploded view of a dilator hub and locking plate assembly configured in accordance with an additional preferred embodiment of the present invention.

FIG. **12**A is an enlarged view of an embodiment of the locking plate that can be used with the dilator hub shown in FIG. **11**.

FIG. **12**B is an enlarged view of another embodiment of the locking plate that can be used with the dilator hub shown in FIG. **11**.

FIG. **12**C is an enlarged view of an additional embodiment of the locking plate that can be used with the dilator hub shown in FIG. **11**.

FIGS. **13**A-**13**D are enlarged views of perimeter shapes that the locking plate can have in accordance with additional embodiments of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present disclosure provides an access device for the delivery of a catheter or sheath to a blood vessel or drainage site. FIG. **1** illustrates an access device **102** that is configured to be inserted into a blood vessel 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 catheter or sheath into other locations within a patient's body (e.g., for draining an abscess) and for other purposes.

FIG. **1**A is a perspective view of a preferred embodiment of an access device **102**. The access device **102** comprises a needle section **20**, a dilator portion **28**, a sheath section (e.g., catheter or cannula) **58**, and a guidewire **120**. In preferred embodiments, the dilator portion **28** is coaxially mounted on the needle section **20**, and the sheath section **58** is coaxially mounted on the dilator portion **28**. The needle section **20** comprises a needle **22** and a needle hub **21**. The needle hub **21** is disposed on a proximal end of the needle **22**. The dilator portion **28** comprises a dilator **30** and a dilator hub **32**. The dilator hub **32** is disposed on the proximal end of the dilator **30**. The sheath section **58** comprises a sheath **54** and a sheath hub **53**. The sheath hub **53** is disposed on the proximal end of the sheath **54**.

FIG. **1**B is an enlarged plan view of the needle hub **21**, the dilator hub **32**, and the sheath hub **53** of the access device

illustrated in FIG. **1**A, shown in an assembled state. The needle hub **21**, the dilator hub **32**, and the sheath hub **53** include structures that releasably interlock the hubs so as to provide a structural and fluid connection between the needle section **20**, the dilator portion **28**, and the sheath section **58**.

FIG. **1**C is a perspective view of the assembly of the needle hub **21**, dilator hub **32** and sheath hub **53** illustrated in FIG. **1**B. With reference to FIGS. **1**A and **1**B, the needle section **20**, dilator portion **28**, and sheath section **58** are interlocked at the proximal end **110** of the access device **102**. In some embodiments, the releasable interlock between the needle section **20**, dilator portion **28**, and sheath section **58** is a tandem interlock where the dilator portion **28** is locked to the needle section **20** at interface **101** and the sheath section **58** is locked to the dilator portion **28** at interface **103**. In additional to a structural connection, the interlocks provide a fluidic connection through the access device **102**.

Preferably, the needle section **20** locks to the dilator portion **28** via a lock mechanism **26**. The lock mechanism **26** may comprise an engaging mechanism such as hinged clips **27** with actuator sides **29**. The hinged clips **27** may releasably engage and secure to corresponding catches **25** on the dilator portion **28**. In some embodiments, the clip sides **29** engage and secure the dilator portion **28** by clipping to the outer lip of a luer connection **33** on the dilator portion **28**. Although hinged clips **27** are shown, the lock member **26** may comprise any suitable engaging mechanism known in the art. In the illustrated embodiment, as best seen in FIG. **3**B, the portions of the outer lip onto which the hinge clips **27** engage are flats to inhibit rotation of the needle hub **21** relative to the dilator hub **32** after a certain degree of relative rotation (e.g., 180 degrees) between the needle hub **21** and the dilator hub **32**.

Similarly, the sheath section **58** is secured to the dilator portion **28** through a lock member **59**. The sheath section **58** may, preferably, comprise a twist lock member **59** so that the user may releasably engage and secure the dilator portion **28** to the sheath section **58**. In some preferred embodiments, the dilator portion **28** comprises teeth or prongs that are configured to mate or attach to corresponding areas on the sheath section **58**. Preferably, the needle **20**, dilator **28** and sheath **58** are releasably locked so that a physician or user may remove sections or portions of the access device as needed for treatment.

FIG. **2**A is side view of the needle section **20** of the embodiment depicted in FIG. **1**A. FIG. **2**B is a cross-sectional view of the needle section **20** depicted in FIG. **2**A taken along line A-A. As shown in both FIGS. **2**A and **2**B, the needle section **20** has a needle **22**, distal portion **106**, and proximal portion **24**. Preferably, the proximal portion **24** has the needle hub **21** and the lock member **26**. In addition, the needle **22** may have a bevel tip **108** disposed on the distal portion **106**. The needle **22** may further comprise one or more side openings **34**.

FIG. **2**C is an enlarged plan view of the needle hub **21** of the needle section **20** of FIG. **2**B. As most clearly shown in FIG. **2**C, the needle hub **21** may also have a luer connection **35** at the proximal portion **24** of the needle **20**. This allows the physician or healthcare provider, for example, to introduce a guidewire **120** through the hollow portion of the luer connection **35**, through the needle **22**, and into a punctured vessel. Additionally, a physician or healthcare provider may also attach a syringe to the luer connection **35** to perform other procedures as desired.

As discussed above, in preferred embodiments, the needle hub **21** comprises the lock member **26**. The lock member **26** may be configured to lock or secure another part such as, for example, the dilator portion **28** or the sheath section **58**, to the needle section **20**. As shown most clearly in FIG. **2**C, the lock member **26** can comprise an engaging mechanism such as a pair of hinged clips **27**, although other types of locking mechanisms comprising tabs and/or slots can also be used. Preferably, the clip sides **29** of the hinged clips **27** can engage a lipped surface such as the outer lip of a luer connection **33**, shown in FIG. **1**A. Once engaged, the clip sides **29** prevent the locked part from undesired slipping or releasing. In certain embodiments, the clips **27** are hinged to provide a bias towards the center of the needle hub **21**. Preferably, the bias prevents the secured part from slipping or disengaging from the hinged clips **27**. More preferably, the bias of the hinged clips **27** can be overcome by simultaneously applying pressure on the sides **29** of the clips **27** to release, for example, the luer connection **33** from the needle hub **21**. To apply the appropriate releasing pressure, a physician or healthcare provider may, for example, place an index finger and thumb on the sides **29** of the hinged clips **27** and apply squeezing pressure to overcome the hinge bias. The hinged clips **27** will, preferably, release only when sufficient releasing pressure is applied to both clip sides **29**.

As shown most clearly in FIG. **2**A, the needle proximal portion **24** may have color coding, words, or other indicia, such as a pivot or notch, to indicate to the operator the position of the bevel tip **108** relative to the dilator **28** or the sheath section **58**. For example, the arrow embedded into the needle hub **21** indicates the bevel up position of the needle **22** and may further indicate to the healthcare provider the proper way to use the device. Also, there may be a mechanical fit between the dilator **28** and the needle **22** so that the physician or healthcare provider would sense by feel or sound (e.g., by a click) when the needle **22** has been rotated to change the position of the bevel tip **108**.

FIG. **3**A is a side view of the dilator portion **28** of the embodiment depicted in FIG. **1**A. FIG. **3**B is a proximal end view of the dilator portion **28** of FIG. **3**A. FIG. **3**C is a cross-sectional view of the dilator portion **28** of the embodiment depicted in FIG. **3**A, taken along line B-B. As shown, the dilator portion **28** may comprise the dilator **30** and the dilator hub **32**. The dilator **30** may further comprise one or more side openings **111**. The dilator hub **32** preferably comprises a luer connection **33** with an outer lip **37**. In some embodiments, the outer lip **37** can be configured to engage to the lock member **26** on the needle section **20** illustrated in FIG. **2**C.

Additionally, the dilator **30** may be coaxially mounted to the needle **22** by slipping a hollow section **113** of the dilator **30** over the needle **22** and releasably securing the dilator hub **32** to the needle hub **21**. Preferably, the proximal end **45** of the dilator hub **32** is configured to mechanically fit and interlock with the needle lock member **26** to inhibit at least some rotational and axial motion. More preferably, the dilator **30** is releasably mounted to the needle **22** so that the dilator **30** can be mounted and released, or vice versa, from a coaxial position relative to the needle **22**.

FIG. **3**D is an enlarged perspective view of the dilator hub **32** of the dilator portion **28** of FIG. **3**A. As is most clearly illustrated in FIG. **3**D, the dilator hub **32** may further comprise a locking mechanism **39**. The locking mechanism **39** comprises one or more posts, teeth, or prongs projecting from the dilator hub **32**. The locking mechanism **39**, which may be in the form of teeth, can be configured to mate or attach to corresponding receiving areas disposed on another part such as the sheath section **58** or the needle hub **21**. This locking mechanism **39** will be explained in greater detail in the following section.

FIG. **4**A is a side view of the sheath section **58** of the embodiment from FIG. **1**A. FIG. **4**B is a proximal end view of the sheath section **58** of FIG. **4**A. In preferred embodiments, the sheath section **58** comprises a sheath **54** and a sheath hub **53**. The sheath **54** may also be made partially or completely from clear, translucent, transparent, or semi-opaque material. The sheath hub **53** may further comprise winged ends **55** and a lock member **59**.

FIG. **4**C is an enlarged perspective view of the sheath hub **53** of the sheath section **58** of FIG. **4**A. Preferably, the locking member **59** may comprise a locking or attaching structure that mates or engages with a corresponding structure. As most clearly shown in FIGS. **4**B and **4**C, the locking member **59** may comprise indentations, bumps, or grooves designed to engage and secure the locking mechanism or teeth **39** on the dilator hub **32** described above with reference to FIG. **3**D.

The sheath hub **53**, as best seen in FIGS. **4**B and **4**C, preferably is designed so that the locking mechanism or teeth **39** of the dilator hub **32** can enter the sheath hub **53** substantially unobstructed. However, in use, once the sheath hub **53** is placed at a desired location over the dilator **30**, the physician or healthcare provider can twist the sheath hub **53** and disengage or engage the locking member **59**. The locking member **59** can be, for example, a protruding bump, dent, etc., that creates a mechanical fit so that the dilator hub **32** and the sheath hub **53** are releasably interlocked. In the illustrated embodiment, the locking member **59** of the sheath hub **53** comprises a pair of axial arranged grooves which extend from a distal side of the sheath hub **53** and terminate at a protruding bump, dent, etc. Preferably, the locked position can be disengaged by twisting the dilator hub **32** relative to the sheath hub **53**. Additionally, the sheath hub may comprise wings **55** or handle structures to allow for easy release and removal of the sheath **54** from other parts of the access device **102**.

In some applications, the wings **55** are sized to provide the healthcare provider with leverage for breaking apart the sheath hub **53**. For example, the sheath hub **53** may comprise a thin membrane **61** connecting the halves of the sheath hub **53**. The membrane **61** is sized to keep the halves of the sheath hub **53** together until the healthcare provider decides to remove the sheath hub **53** from the access device. The healthcare provider manipulates the wings **55** to break the membrane **61** and separate the sheath hub **53** into removable halves.

FIG. **5** is a side view of the access device of FIG. **1**A in which the needle section **20**, dilator portion **28**, and sheath section **58** are interlocked together. In the assembly, as noted above the needle section **20**, dilator portion **28** and sheath section **58** are coaxially disposed about a common longitudinal axis and form a central fluid connection.

FIG. **6** is an enlarged cross-sectional view of a portion of the embodiment illustrated in FIG. **5** which is circled by line C-C. As noted above, the needle **22**, preferably, comprises one or more side openings **34** in its side wall. Additionally, the dilator may comprise one or more side openings **111**. FIG. **6**, however, illustrates 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 and the dilator.

Preferably the dilator **30** may be coaxially positioned to minimize the annular space **36** between the needle **22** and the dilator **30**. The inner surface **38** of the dilator **30** need not, though it can, lie directly against the outer-surface **40** of the needle **22**. Preferably, the annular interface **36** between the outer-surface **40** of the needle **22** and the inner surface **38** of the dilator **30** is minimized to inhibit the flow of blood or its constituents (or other bodily fluids) into the annular interface **36** between the dilator **30** and needle **22**. Advantageously, this feature minimizes the blood's exposure to multiple external surfaces and reduces the risk of contamination, infection, and clotting.

The sheath **54** is made partially or completely from clear, semi-opaque, translucent, or transparent material so that when blood flows into the needle **22**, (1) through the needle side opening **34**, (2) through the dilator side opening **111**, and (3) into an annular space **60** between the dilator **30** and the sheath **54**, the physician or healthcare provider can see the blood. This will indicate to the physician or healthcare provider that the bevel tip **108** of the needle **22** has punctured a blood vessel.

More preferably, the dilator **30** can be coaxially mounted to the needle **22** such that at least one side opening **34** disposed on the needle **22** is rotationally aligned with at least one side opening **111** on the dilator **30**. In some embodiments, the needle **22** and dilator **30** may (both) have multiple side openings **34**, **111** where some or all of these side openings **34**, **111** can be rotationally aligned. Preferably, the needle **22** and dilator **30** maintain rotational alignment so that blood flows substantially unobstructed through the needle side opening **34** and dilator side opening **111**.

While the side openings **34**, **111** in the needle **22** and the dilator **30** are aligned in the embodiment illustrated in FIG. **6**, the side openings alternatively can overlap with each other or can be connected via a conduit. The conduit can be formed between the side openings **111**, **34** in the dilator and the needle.

In accordance with another aspect of the present invention, there is provided an interlock or interconnection between the needle **22** and at least one of the dilator **30** or dilator hub **32**. The interlock or interconnection inhibits the bevel tip **108** disposed on the distal portion **106** of the needle **22** from being advanced beyond the distal end of the dilator **30** once the dilator **30** has been advanced over the needle **22** during use. The dilator **30** thus sheaths the sharp bevel tip **108** of the needle **22** to inhibit accidental needle sticks from occurring.

FIG. **7**A is a schematic, enlarged cross-sectional view of a portion of the needle **22** within the dilator **30** and illustrates an embodiment of a locking mechanism **115** configured in accordance with one aspect of the present invention. When engaged, the locking mechanism **115** inhibits movement of the needle **22** with respect to the dilator **30** in at least one direction. For example, the locking mechanism **115** can inhibit movement of the needle **22** at least in the distal direction once the distal tip of the needle body is drawn into the dilator portion to sheath the distal tip. The embodiment of the locking mechanism **115** illustrated in FIG. **7**A comprises one or more arms or tangs **117**, **119**, one or more bases **121**, **123**, and one or more pivot couplings or hinges **127**, **129**.

The arm **117** may be axially aligned with the arm **119**. Alternatively, the arms **117**, **119** may be offset from each other in a radial direction. The arms **117**, **119** may be slightly rotated relative to each other or disposed at different radial locations on the inside surface of the dilator **30**. The tang or arm **117**, **119** may move in a direction generally transverse to a longitudinal axis of the needle body when engaging the receptacle or hole **131**.

The locking mechanism **115** is illustrated on the dilator **30**. However, the needle **22** may instead comprise the locking mechanism **115**. In the illustrated embodiment, the needle **22** comprises a receptacle, recess, opening, or hole

131 which interacts with the locking mechanism 115 of the dilator 30 when the needle 22 is sufficiently retracted into the dilator 30. The receptacle, recess, opening, or hole 131 may extend entirely around the needle 22 forming an annular groove or around only a portion of the needle 22.

For embodiments that have arms 117, 119 disposed at different radial locations on the inside surface of the dilator 30, the needle 22 may comprise more than one recess, opening, or hole 131. The multiple recesses, openings, or holes 131 are disposed at radial locations around the outer surface of the needle 22 that correspond to the radial spacing of the arms 117, 119 around the inside surface of the dilator 30.

The arm 117 is coupled to the base 121 via hinge 127 and rotates from an unlocked position to a locked position in a counter-clockwise direction. The arm 119 is coupled to the base 123 via hinge 129 and rotates from an unlocked position to a locked position in a clockwise direction. In the illustrated embodiment, each arm 117, 119 rotates approximately 90 degrees between the unlocked position and the locked position. However, the locked position may be more or less than 90 degrees from the unlocked position. The arms 117, 119 need only rotate a sufficient amount to allow their distal ends to abut against a portion of the perimeter of the recess, opening, or hole 131.

The recess, opening, or hole 131 in the needle 22 locally increases a gap located between an outside surface of the needle 22 and an inside surface of the dilator 30 a sufficient amount to allow the arms 117, 119 to rotate about their respective hinges 121, 123 and towards the locked position. When the arm 117 is in the locked position, the needle 22 is inhibited from relative axial movement with respect to the dilator 30 in a proximal direction. When the arm 119 is in the locked position, the needle 22 is inhibited from relative axial movement with respect to the dilator 30 in a distal direction.

The one or more bases 121, 123 are attached to or integral with the dilator 30 and extend generally towards the coaxially aligned needle 22. The bases 121, 123 are sized so as to not interfere with movement of the needle 22 through the dilator 30 while providing hinge points for attachment of the arms 117, 119. The arms 117, 119 are sized to allow movement of the needle 22 through the dilator 30 when the arms 117, 119 are in the unlocked position. The hinges 127, 129 permit the arms 117, 119 to move from the unlocked position illustrated in FIG. 7A to a locked position illustrated in FIG. 7D.

Each arm 117, 119 can separately move to the locked position when the arm 117, 119 is axially aligned with the recess, opening, or hole 131 in the needle 22. Once in the locked position, the hinge 127, 129 does not permit the arm 117, 119 to move back to the unlocked position. In some embodiments, the hinges 127, 129 slightly bias the arms 117, 119 to move towards the locked position. For example, the tang or arm 117, 119 can be biased toward the receptacle, recess, opening, or hole 131.

FIGS. 7B-7D illustrate the operational steps of the locking mechanism 115 of FIG. 7A when arresting relative axial movement between the needle 22 and the dilator 30. FIG. 7B illustrates the arms 117, 119 in the unlocked position. In the unlocked position, the recess, opening, or hole 131 in the needle 22 is not axial aligned with the arms 117, 119 of the locking mechanism 115. A healthcare provider can move the needle 22 with respect to the dilator 30 in both proximal and distal directions as long as the recess, opening, or hole 131 in the needle 22 stays on the proximal side of the locking mechanism 115 as is illustrated in FIG. 7B.

FIG. 7C illustrates the arm 117 in the locked position. In the locked position, the distal end of the arm 117 is disposed within the recess, opening, or hole 131 in the needle 22. Once in the locked position, the hinge 127 does not permit the arm 117 to rotate back to the unlocked position. When the arm 117 is in the locked position, the needle 22 may still move in a distal direction with respect to the dilator 32 until the recess, opening, or hole 131 is aligned with the arm 119.

FIG. 7D illustrates both arms 117, 119 in the locked position. In the dual locked position, the distal ends of the arms 117, 119 are disposed within the recess, opening, or hole 131 in the needle 22. Once in the dual locked position, the hinges 127, 129 do not permit the arms 117, 119 to rotate back to the unlocked position. When the arm 119 is in the locked position, the needle 22 is inhibited from moving in the distal direction with respect to the dilator 32.

FIG. 8A is a similar cross-sectional view of a portion of a locking mechanism 137 which is configured in accordance with another preferred embodiment of present invention. When engaged, the locking mechanism 137 inhibits movement of the needle 22 with respect to the dilator 30 in both directions. The embodiment of the locking mechanism 137 illustrated in FIG. 8A comprises one or more pairs of v-shaped arms 135, 137. The pairs of arms 135, 137 are disposed on diametrically opposite sides of the needle 22. Alternatively, the arms 135, 137 may be offset from each other in a radial direction more or less than 180 degrees apart.

The locking mechanism 133 is illustrated on the dilator 30. However, the needle 22 may instead comprise the locking mechanism 133. In the illustrated embodiment, the needle 22 comprises a recess, opening, or hole 139 which interacts with the locking mechanism 133 of the dilator 30 when the needle 22 is sufficiently retracted into the dilator 30. The receptacle, recess, opening, or hole 139 may extend entirely around the needle 22 forming an annular groove or around only a portion of the needle 22. The needle 22 may comprise more than one recess, opening, or hole 139. The multiple recesses, openings, or holes 139 are disposed at radial locations around the outer surface of the needle 22 that correspond to the radial spacing of the arms 135, 137 around the inner surface of the dilator 30.

The pairs of arms 135, 137 extend from the dilator 30 towards the needle 22. Each pair of arms 135, 137 is biased towards the needle 22 and is illustrated in a compressed or unlocked state in FIG. 8A. In the unlocked state or position, the recess, opening, or hole 139 in the needle 22 is not axial aligned with the arms 135, 137 of the locking mechanism 133. A healthcare provider can move the needle 22 with respect to the dilator 30 in both proximal and distal directions as long as the recess, opening, or hole 139 in the needle 22 stays on the proximal side of the locking mechanism 133 as is illustrated in FIG. 8B. Each pair of arms 135, 137 gently presses against the outer surface of the needle 22 as the needle 22 slides within the dilator 30 when the arms are in the unlocked state. Each pair of arms 135, 137 can rotate or bend to reach a locked state when the arms 135, 137 are axially aligned with the recess, opening, or hole 139.

In the illustrated embodiment, each arm of each pair of arms 135, 137 rotates towards the other arm between the unlocked position and the locked position. The arms 135, 137 need only be sufficiently biased so that when the arms 135, 137 align with the hole 139 their distal ends abut against a portion of the perimeter of the recess, opening, or hole 139. In the locked position, the distal ends of the arms 135, 137 are disposed within the recess, opening, or hole 139 in the needle 22.

The recess, opening, or hole **139** in the needle **22** locally increases a gap located between an outside surface of the needle **22** and an inside surface of the dilator **30** a sufficient amount to allow the arms **135**, **137** to flex from their biased or unlocked state towards the locked position. FIG. **8**B illustrates the pair of arms **135** of the locking mechanism **133** of FIG. **8**A in a locked state. When one or both of the pair of arms **135**, **137** is in the locked position the needle **22** is inhibited from relative axial movement with respect to the dilator **30** in both proximal and distal directions.

In the unlocked state Illustrated in FIG. **8**A, the arms **135**, **137** are biased to contact the needle **22** but not substantially interfere with movement of the needle **22** through the dilator **30**. The arms **135**, **137** are sized in their unbiased or locked state to inhibit movement of the needle **22** through the dilator **30**. The biasing of the arms **135**, **137** moves the arms **135**, **137** from the unlocked position illustrated in FIG. **8**A to the locked position illustrated in FIG. **8**B.

Each pair of arms **135**, **137** can separately move to the locked position when the pair of arms **135**, **137** is axially aligned with the recess, opening, or hole **139** in the needle **22**. Once in the locked position, the size and shape of the pair of arms **135**, **137** inhibit movement back to the unlocked position.

FIG. **9**A is a schematic, enlarged cross-sectional view of a locking mechanism **141** configured in accordance with an additional embodiment of the present invention. When engaged, the locking mechanism **141** inhibits movement of the needle **22** with respect to the dilator **30** in both directions. The embodiment of the locking mechanism **141** illustrated in FIG. **9**A comprises a protrusion **143**.

The locking mechanism **141** is illustrated on the dilator **30**. However, the needle **22** may instead comprise the locking mechanism **141**. In the illustrated embodiment, the needle **22** comprises a recess, opening, or hole **145** which interacts with the locking mechanism **141** of the dilator **30** when the needle **22** is sufficiently retracted into the dilator **30**. The receptacle, recess, opening, or hole **145** may extend entirely around the needle **22** forming an annular groove or around only a portion of the needle **22**. The needle **22** may comprise more than one recess, opening, or hole **145**.

The protrusion **143** extends from the dilator **30** towards the needle **22** and is biased towards the needle **22**. FIG. **9**A illustrates the protrusion **143** in a compressed or unlocked state. In the unlocked state or position, the recess, opening, or hole **145** in the needle **22** is not axial aligned with the protrusion **143** of the locking mechanism **141**. A healthcare provider can move the needle **22** with respect to the dilator **30** in both proximal and distal directions as long as the recess, opening, or hole **145** in the needle **22** stays on the proximal side of the locking mechanism **141** as is illustrated in FIG. **9**A. The protrusion **143** gently presses against the outer surface of the needle **22** as the needle **22** slides within the dilator **30** when the locking mechanism **141** is in the unlocked state. At least a portion of the protrusion **143** can extend to reach a locked state when the protrusion **143** is axially aligned with the recess, opening, or hole **145**.

The protrusion **143** need only be sufficiently biased so that when the protrusion **143** aligns with the hole **145** its distal end abuts against a portion of the perimeter of the recess, opening, or hole **145**. In the locked position, the distal end of the protrusion **143** is disposed within the recess, opening, or hole **145** in the needle **22**.

The recess, opening, or hole **145** in the needle **22** locally increases a gap located between an outside surface of the needle **22** and an inside surface of the dilator **30** a sufficient amount to allow the protrusion **143** to flex or extend from its biased or unlocked state towards the locked position. FIG. **9**B illustrates the protrusion **143** of the locking mechanism **141** of FIG. **9**A in a locked state. When the protrusion **143** is in the locked position the needle **22** is inhibited from relative axial movement with respect to the dilator **30** in both proximal and distal directions.

In the unlocked state Illustrated in FIG. **9**A, the protrusion **143** is biased to contact the needle **22** but not substantially interfere with movement of the needle **22** through the dilator **30**. The protrusion **143** is sized in its unbiased or locked state to inhibit movement of the needle **22** through the dilator **30**. The biasing of the protrusion **143** moves the distal end of the protrusion from the unlocked position illustrated in FIG. **9**A to the locked position illustrated in FIG. **9**B.

FIG. **10**A is a schematic, enlarged cross-sectional view of a locking mechanism **147** configured in accordance with a further embodiment of the present invention. When engaged, the locking mechanism **141** inhibits movement of the needle **22** with respect to the dilator **30** in both directions. The embodiment of the locking mechanism **141** illustrated in FIG. **10**A comprises a detent **149**.

The locking mechanism **147** is illustrated on the dilator **30**. However, the needle **22** may instead comprise the locking mechanism **147**. In the illustrated embodiment, the needle **22** comprises a recess, opening, or hole **151** which interacts with the locking mechanism **149** of the dilator **30** when the needle **22** is sufficiently retracted into the dilator **30**. The receptacle, recess, opening, or hole **151** may extend entirely around the needle **22** forming an annular groove or around only a portion of the needle **22**. The needle **22** may comprise more than one recess, opening, or hole **151**.

The detent **149** extends from the dilator **30** towards the needle **22** and rides in an axial groove in the needle **22**. The proximal end of the groove connects with the hole **151**. FIG. **10**A illustrates the detent **149** in an unlocked state. In the unlocked state or position, the recess, opening, or hole **151** in the needle **22** is not axial aligned with the detent **149** of the locking mechanism **147**. A healthcare provider can move the needle **22** with respect to the dilator **30** in both proximal and distal directions as long as the recess, opening, or hole **151** in the needle **22** stays on the proximal side of the locking mechanism **147** as is illustrated in FIG. **10**A. The detent **149** rides in the groove in the outer surface of the needle **22** as the needle **22** slides within the dilator **30** when the locking mechanism **147** is in the unlocked state. The detent **149** and groove further inhibit relative rotation of the needle **22** with respect to the dilator **30**. The detent **149** reaches a locked state when the detent **149** is axially aligned with the recess, opening, or hole **151**.

The recess, opening, or hole **151** in the needle **22** locally increases a gap located between a bottom surface of the groove in the needle **22** and an inside surface of the dilator **30** a sufficient amount to allow the detent **149** to flex or extend from a biased or unlocked state towards the locked position. FIG. **10**B illustrates the detent **149** of the locking mechanism **147** in the unlocked state. While not illustrated, when the detent **149** is in the locked position the needle **22** is inhibited from relative axial movement with respect to the dilator **30** in both proximal and distal directions.

In the unlocked state illustrated in FIGS. **10**A and **10**B, the detent **149** is slightly biased to contact the bottom of the groove in the needle **22** but not to substantially interfere with movement of the needle **22** through the dilator **30**. The detent **149** is sized in its unbiased or locked state to inhibit movement of the needle **22** through the dilator **30**.

FIG. **11** is an enlarged exploded view of a dilator hub and locking plate assembly **153** configured in accordance with

an additional preferred embodiment of the present invention. The assembly **153** includes a dilator hub **155** and one or more fingers or tangs **162**. The one or more fingers or tangs **162** are spaced and sized such that they enter or snap into the side hole or holes in the needle **22** when the needle **22** is retracted. In some applications, a single finger or tang **162** is employed.

The one or more fingers or tangs **162** inhibit the bevel tip **108** disposed on the distal portion **106** of the needle **22** from being advanced beyond the distal end of the dilator **30** once the dilator **30** has been advanced over the needle **22** during use. The dilator **30** thus sheaths the sharp bevel tip **108** of the needle **22** to inhibit accidental needle sticks from occurring.

The one or more fingers or tangs **162** may be integrated into the dilator hub **155** or part of a separate structure that is combined with the dilator hub **155**. In the embodiment illustrated in FIG. **11**, the one or more fingers or tangs **162** are formed on a separate structure in the form of a locking plate **157**(a)-(c). In this way, the locking plate **157**(a)-(c) comprises the one or more fingers or tangs **162**. Exemplary locking plates **157**(a)-(c) are illustrated in FIGS. **12**A-**12**C. Of course the structure of the locking plates **157**(a)-(c) is not limited to the illustrated embodiments. For example, the locking plate **157** could be configured to include one or more of the locking mechanisms illustrated in FIGS. **7**A, **8**A, **9**A, and **10**A. For embodiments that have the one or more fingers or tangs **162** integrated into the dilator **155**, the assembly **153** need not include a separate locking plate **157**.

The dilator hub **155** and locking plate **157**(a)-(c) may be separately manufactured and assembled as is illustrated in FIG. **11** or manufactured as a unitary assembly. The dilator hub **155** and locking plate **157**(a)-(c) may be manufactured from the same or different materials, including, for example, plastics, metals, combinations thereof, and other materials. The locking plate **157** can be co-molded within the dilator hub **155** to form a unitary assembly. For example, a metal locking plate **157** can be molded into a plastic dilator hub **155**. As explained above, a separate structure in the form of the locking plate **157** is for the In some applications, the locking plates **157**(a)-(c) are movable with respect to the dilator hub **155** between unlocked and locked positions.

The dilator hub **155** is similar to the dilator hub **32** illustrated in FIG. **3**A except that the dilator hub **155** is configured to slideingly receive the one or more locking plates **157**(a)-(c) through one or more slots **158**(a)-(c). While multiple locking plates **157**(a)-(c) and slots **158**(a)-(c) are illustrated in FIG. **11**, only a single locking plate **157**(a)-(c) and slot **158**(a)-(c) can inhibit movement of the needle **22**. In some applications, multiple locking plates **157**(a)-(c) are inserted from different sides of the dilator hub **155** so that the fingers or tangs **162** from the locking plates **157**(a)-(c) combine to completely surround the needle **22** even though separately the tangs or fingers **162** of each locking plate **157** would not surround the needle **22**. The slot **158**(a)-(c) need not be arranged perpendicular to the axis of the needle **22** or located in a specific side or surface of the dilator hub **155** as is illustrated in FIG. **11**. Multiple locking plates **157**(a)-(c) may be inserted into a single slot **158**.

A healthcare provider slides the locking plate **157**(a)-(c) from an unlocked position to a locked position relative to the dilator hub **155**. The locking plate **157**(a)-(c) may be completely removed from the slot **158**(a)-(c) or partially inserted into the slot **158**(a)-(c) when in the unlocked position. When the locking plate **157**(a)-(c) is in the locked position, the needle **22** is disposed in a hole or center region **160** of the locking plate **157**(a)-(c). The small size of the guide wire **120** inside the needle **22** does not affect the locking feature of the assembly.

FIG. **12**A is an enlarged view of an embodiment of a locking plate **159** that can be used with the dilator hub **155** shown in FIG. **11**. The locking plate **159** comprises a hole **160** surrounded by one or more fingers or tangs **162**. An opening **164** extends from an outer perimeter of the locking plate **159** to the hole **160**. The opening **164** permits the locking plate **159** to be inserted into the dilator hub **155** after the needle **22** is inserted through the dilator hub **155**. The needle **22** passes through the opening **164** as the locking plate **159** is slid into the slot **158** and eventually enters the hole **160** when the locking plate **159** is in the locked position or state. Since the one or more fingers or tangs **162** do not extend entirely around the needle **22** when the needle **22** is inserted through the dilator hub **155**, preferably the one or more side holes, receptacles, or annular groove in the needle **22** extend or are spaced radially about the needle **22** so that one of the fingers or tangs **162** will catch the one or more side holes, receptacles, or annular groove when the one or more side holes, receptacles, or annular groove passes through the locking plate **159**.

When in the locked position, at least one of the distal ends of the fingers or tangs **162** extends a sufficient distance toward the needle **22** to enter a hole or slot in the needle **22** and inhibit further axial movement of the needle **22**. In some applications, the hole or slot in the needle **22** falls onto the finger or tang **162**. The hole may be the one or more side openings **34** in the side wall of the needle **22** or the receptacle, recess, opening, or hole **131**, **139**, **145**, and **151** illustrated in, for example, FIGS. **7**A, **8**A, **9**A, and **10**A, respectively. In some applications, the receptacle, recess, opening, or hole **131**, **139**, **145**, and **151** is the same structure as the one or more side openings **34**.

FIG. **12**B is an enlarged view of another embodiment of a locking plate **161** that can be used with the dilator hub **155** shown in FIG. **11**. The locking plate **161** comprises a hole **160** surrounded by one or more fingers or tangs **162**. An opening **164** extends from an outer perimeter of the locking plate **161** to the hole **160**. The opening **164** permits the locking plate **161** to be inserted into the dilator hub **155** after the needle **22** is inserted through the dilator hub **155**. The needle **22** passes through the opening **164** as the locking plate **161** is slid into the slot **158** and eventually enters the hole **160** when the locking plate **161** is in the locked position or state.

Since the one or more fingers or tangs **162** do not extend entirely around the needle **22** when the needle **22** is inserted through the dilator hub **155**, preferably the one or more side holes, receptacles, or annular groove in the needle **22** extend or are spaced radially about the needle **22** so that one of the fingers or tangs **162** will catch the one or more side holes, receptacles, or annular groove when the one or more side holes, receptacles, or annular groove passes through the locking plate **161**.

FIG. **12**C is an enlarged view of an additional embodiment of a locking plate **163** that can be used with the dilator hub **155** shown in FIG. **11**. The locking plate **163** comprises a hole **160** surrounded by one or more fingers or tangs **162**. Unlike the embodiments illustrated in FIGS. **12**A and **12**B, the locking plate **163** has a closed pedal **166** instead of an opening. Further, the fingers or tangs **162** extend all the way around the needle **22**. When the needle **22** passes through the dilator hub **155**, the side hole in the needle **22** will be caught by the fingers or tangs **162** irrespective of whether the needle **22** is rotated relative to the dilator hub **155**.

In this embodiment, the locking plate **163** is inserted in the dilator hub **155** before the needle **22** is axially inserted into the dilator hub **155**. Since the fingers or tangs **155** extend entirely around the needle **22**, a sheath or mandrel temporarily covers the side hole in the needle **22** to allow the needle **22** to be assembled through the dilator hub **155**. Once assembled, the sheath or mandrel is removed from the needle **22**.

FIGS. **13**A-**13**D are enlarged views of perimeter shapes that the locking plate **157**(a)-(c) can have in accordance with additional embodiments of the present invention. Any of the perimeter shapes illustrated in FIGS. **13**A-D can be added to any of the locking plates **159**, **161**, **163**. Of course the perimeter shapes are not limited to the illustrated embodiments. In some applications, the perimeter shape is selected to prevent the locking plate **157** from being removed from the dilator hub **155** or merely inhibit the locking plate **157** from falling out of the dilator hub **155**.

The slot **158**(a)-(c) in the dilator hub **155** would include corresponding shaped surfaces which engage with the perimeter shape **165**, **167**, **169**, *171* of the locking plate to inhibit the healthcare provider from removing the locking plate from the dilator hub **155** once the locking plate **157** has been slid to the locked position. In this way, the healthcare provider is prevented from accidently removing the locking plate and releasing the needle **22**.

The embodiments herein described are comprised of conventional, biocompatible materials. For example, the needle preferably consists of 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 nylon, polyethylene, high-density polyethylene, polypropylene, fluoropolymers and copolymers such as perfluoro (ethylene-propylene) copolymer, polyurethane polymers or co-polymers.

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 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.

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 subcombinations 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.

What is claimed is:

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

a needle section including an elongated needle body with a sharp distal tip and a needle hub from which the needle body extends;

a medical article section comprising a tubular portion and a tube hub fixed to the tubular portion, the tubular portion being coaxially disposed and slideable over the needle body with the tube hub being disposed distal of the needle hub; and

a locking mechanism disposed within the medical article section and selectively operating between the needle section and the medical article section, the locking mechanism being configured to move into a locked position from an unlocked position to arrest axial movement of the needle body at least in the distal direction once the distal tip of the needle body is drawn into the medical article section to protect the distal tip, wherein once in the locked position the locking mechanism is prevented from moving back to the unlocked position.**]**

[2. The access device of claim **1**, wherein the locking mechanism comprises a receptacle and a tang biased toward the receptacle, the receptacle being formed on either the outer surface of the needle body or an inner surface of the tube hub, and the tang extending from the other one of the needle body outer surface and the tube hub inner surface.**]**

[3. The access device of claim **2**, wherein the receptacle comprises a hole in the needle body.**]**

[4. The access device of claim **2**, wherein the receptacle comprises an annular groove about the needle body.**]**

[5. The access device of claim **2** additionally comprising a second tang oriented to arrest axial movement of the needle body in a proximal direction.**]**

[6. The access device of claim **5**, wherein the first and second tangs engage said receptacle when the distal tip of the needle body is sufficiently withdrawn into the medical article section.**]**

[7. The access device of claim **5**, wherein the locking mechanism includes another receptacle disposed so as to receive the second tang when the distal tip of the needle body is withdrawn into the medical article section.**]**

[8. The access device of claim **2**, wherein the tang is attached to the tube hub by a pivot coupling.**]**

[9. The access device of claim **2**, wherein the tang is configured to move in a direction generally transverse to a longitudinal axis of the needle body when engaging the receptacle.**]**

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

a dilator portion comprising a dilator and a dilator hub having a passageway configured to receive an elongated needle, the needle having at least one side hole;

one or more fingers or tangs disposed in the dilator hub and configured to engage with the at least one side hole at least when the needle is retracted through the passageway, wherein the one or more fingers or tangs is prevented from moving back out of engagement with the at least one side hole.**]**

[11. The access device of claim **10**, wherein the side hole provides a passageway through which a fluid may flow.**]**

[12. The access device of claim **10**, further comprising a dilator attached to the dilator hub, the dilator comprising a side hole that can be held in alignment with the needle side hole.**]**

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

a needle section including an elongated needle body with a sharp distal tip and a needle hub from which the needle body extends;

a medical article section comprising a tubular portion and a tube hub fixed to the tubular portion, the tubular portion being coaxially disposed and slideable over the needle body with the tube hub being disposed distal of the needle hub; and

a locking mechanism disposed entirely within the medical article section and selectively operating between the needle section and the medical article section, the locking mechanism being configured to arrest axial movement of the needle body at least in the distal direction once the distal tip of the needle body is drawn into the medical article to protect the distal tip.]

[14. The access device of claim 13, wherein the locking mechanism comprises a receptacle and a tang biased toward the receptacle, the receptacle being formed on either the outer surface of the needle body or an inner surface of the tube hub, and the tang extending from the other one of the needle body outer surface and the tube hub inner surface.]

[15. The access device of claim 14, wherein the receptacle comprises a hole in the needle body.]

[16. The access device of claim 14, wherein the receptacle comprises an annular groove about the needle body.]

[17. The access device of claim 14 additionally comprising a second tang oriented to arrest axial movement of the needle body in a proximal direction.]

[18. The access device of claim 17, wherein the first and second tangs engage said receptacle when the distal tip of the needle body is sufficiently withdrawn into the medical article section.]

[19. The access device of claim 17, wherein the locking mechanism includes another receptacle disposed so as to receive the second tang when the distal tip of the needle body is withdrawn into the medical article section.]

[20. The access device of claim 14, wherein the tang is attached to the tube hub by a pivot coupling.]

[21. The access device of claim 14, wherein the tang is configured to move in a direction generally transverse to a longitudinal axis of the needle body when engaging the receptacle.]

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

a needle section including an elongated needle body with a sharp distal tip and a needle hub from which the needle body extends, the sharp distal tip forming an opening and the needle body comprising a side wall defining at least one side opening therein;

a medical article section comprising a tubular portion and a tube hub fixed to the tubular portion, the tubular portion being coaxially disposed and slideable over the needle body with the tube hub being disposed distal of the needle hub; and

a locking mechanism disposed within the medical article section and selectively operating between the needle section and the medical article section, the locking mechanism being configured to move into a locked position from an unlocked position to arrest axial movement of the needle body at least in the distal direction once the distal tip of the needle body is drawn into the medical article section to protect the distal tip, wherein once in the locked position the locking mechanism is prevented from moving back to the unlocked position, wherein the locking mechanism is configured to rotate into the locked position from the unlocked position once the distal tip of the needle body is drawn into the medical article section.

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

a needle section including an elongated needle body with a sharp distal tip and a needle hub from which the needle body extends, the sharp distal tip forming an opening and the needle body comprising a side wall defining at least one side opening therein;

a medical article section comprising a tubular portion and a tube hub fixed to the tubular portion, the tubular portion being coaxially disposed and slideable over the needle body with the tube hub being disposed distal of the needle hub; and

a locking mechanism disposed within the medical article section and selectively operating between the needle section and the medical article section, the locking mechanism being configured to move into a locked position from an unlocked position to arrest axial movement of the needle body at least in the distal direction once the distal tip of the needle body is drawn into the medical article section to protect the distal tip, wherein once in the locked position the locking mechanism is prevented from moving back to the unlocked position, wherein the locking mechanism is configured to move into the locked position from the unlocked position to arrest axial movement of the needle body, relative to the medical article section, in both a proximal direction and the distal direction once the distal tip of the needle body is drawn into the medical article section.

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

a needle section including an elongated needle body with a sharp distal tip and a needle hub from which the needle body extends, the sharp distal tip forming an opening and the needle body comprising a side wall defining at least one side opening therein;

a medical article section comprising a tubular portion and a tube hub fixed to the tubular portion, the tubular portion being coaxially disposed and slideable over the needle body with the tube hub being disposed distal of the needle hub; and

a locking mechanism disposed entirely within the medical article section and selectively operating between the needle section and the medical article section, the locking mechanism being configured to arrest axial movement of the needle body at least in the distal direction once the distal tip of the needle body is drawn into the medical article section to protect the distal tip, wherein the locking mechanism is configured to rotate into a locked position from an unlocked position once the distal tip of the needle body is drawn into the medical article section.

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

a needle section including an elongated needle body with a sharp distal tip and a needle hub from which the needle body extends, the sharp distal tip forming an opening and the needle body comprising a side wall defining at least one side opening therein;

a medical article section comprising a tubular portion and a tube hub fixed to the tubular portion, the tubular portion being coaxially disposed and slideable over the needle body with the tube hub being disposed distal of the needle hub; and

a locking mechanism disposed entirely within the medical article section and selectively operating between the needle section and the medical article section, the locking mechanism being configured to arrest axial movement of the needle body at least in the distal direction once the distal tip of the needle body is drawn into the medical article section to protect the distal tip, wherein the locking mechanism is configured to arrest axial movement of the needle body, relative to the medical article section, in both a proximal direction and the distal direction once the distal tip of the needle body is drawn into the medical article section.

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