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(54) **VESSEL CLOSURE DEVICE WITH IMPROVED SAFETY AND TRACT HEMOSTASIS**

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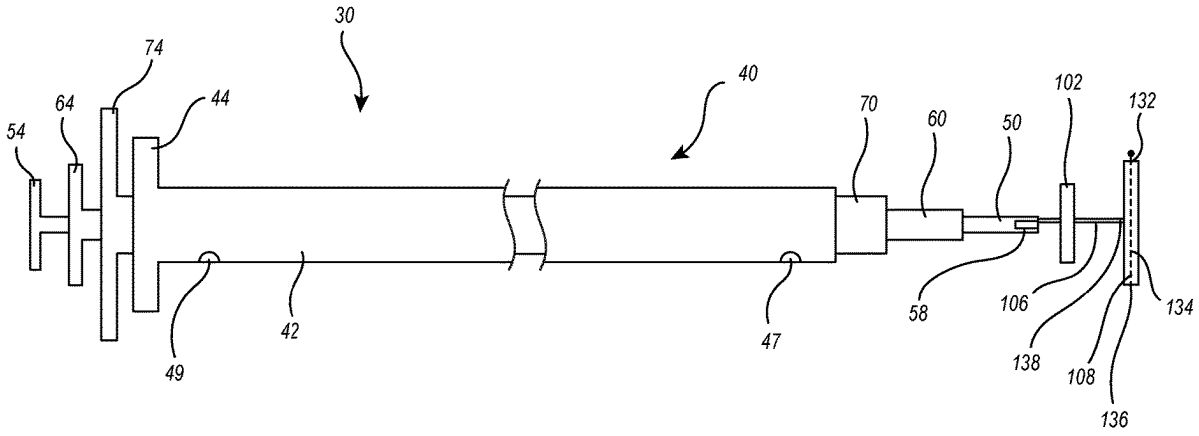
(57) **ABSTRACT**

A vessel closure device for delivering immediate hemostasis at a puncture site in a wall of a blood vessel includes an intravascular anchor having one or more suture attachment points, an extravascular cap having a lumen, a sealant, and a suture connected to at least one of the one or more suture attachment points of the intravascular anchor and threaded through the lumen of the extravascular cap, wherein each of the intravascular anchor, extravascular cap, sealant, and suture are formed of bioabsorbable materials.

13 Claims, 56 Drawing Sheets



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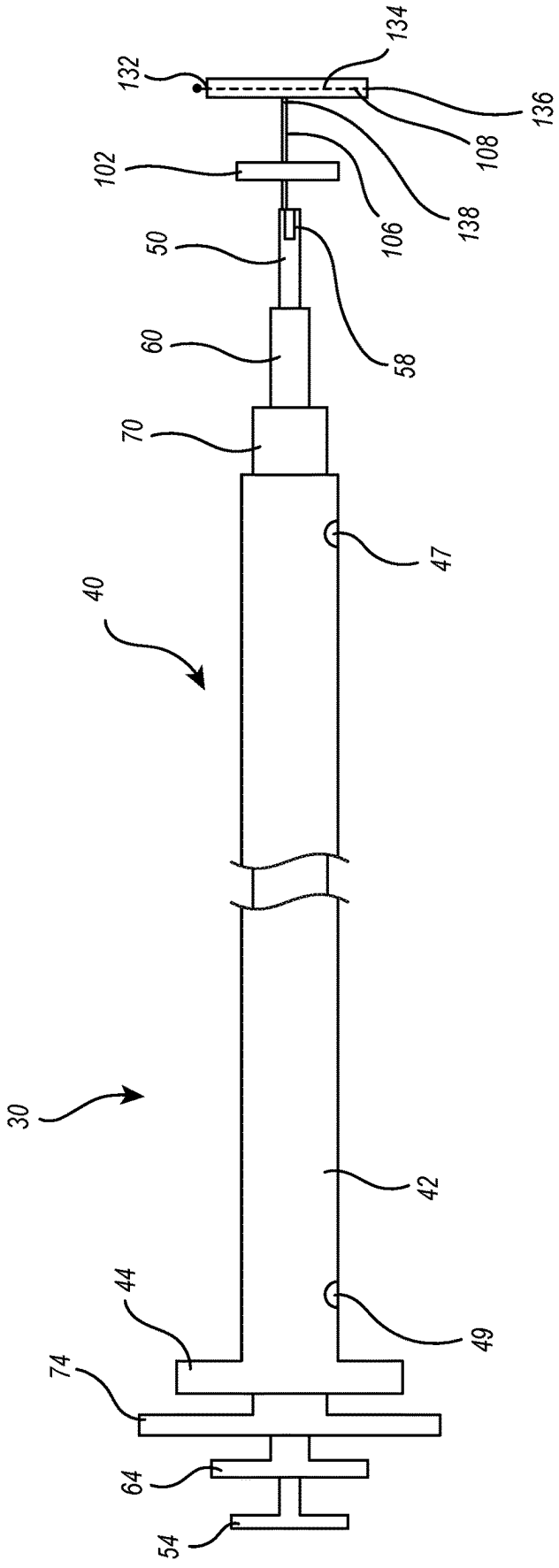
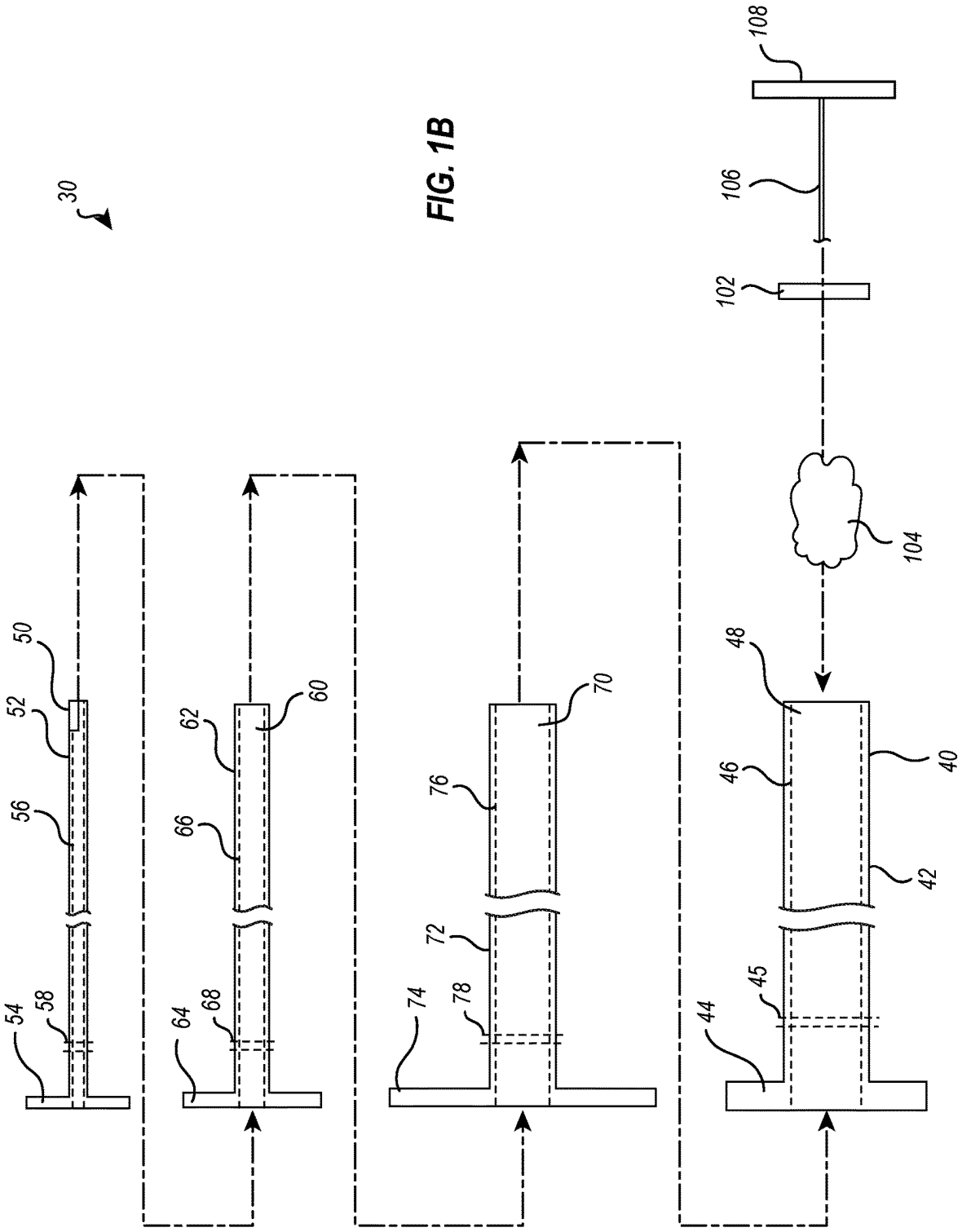


FIG. 1A

FIG. 1B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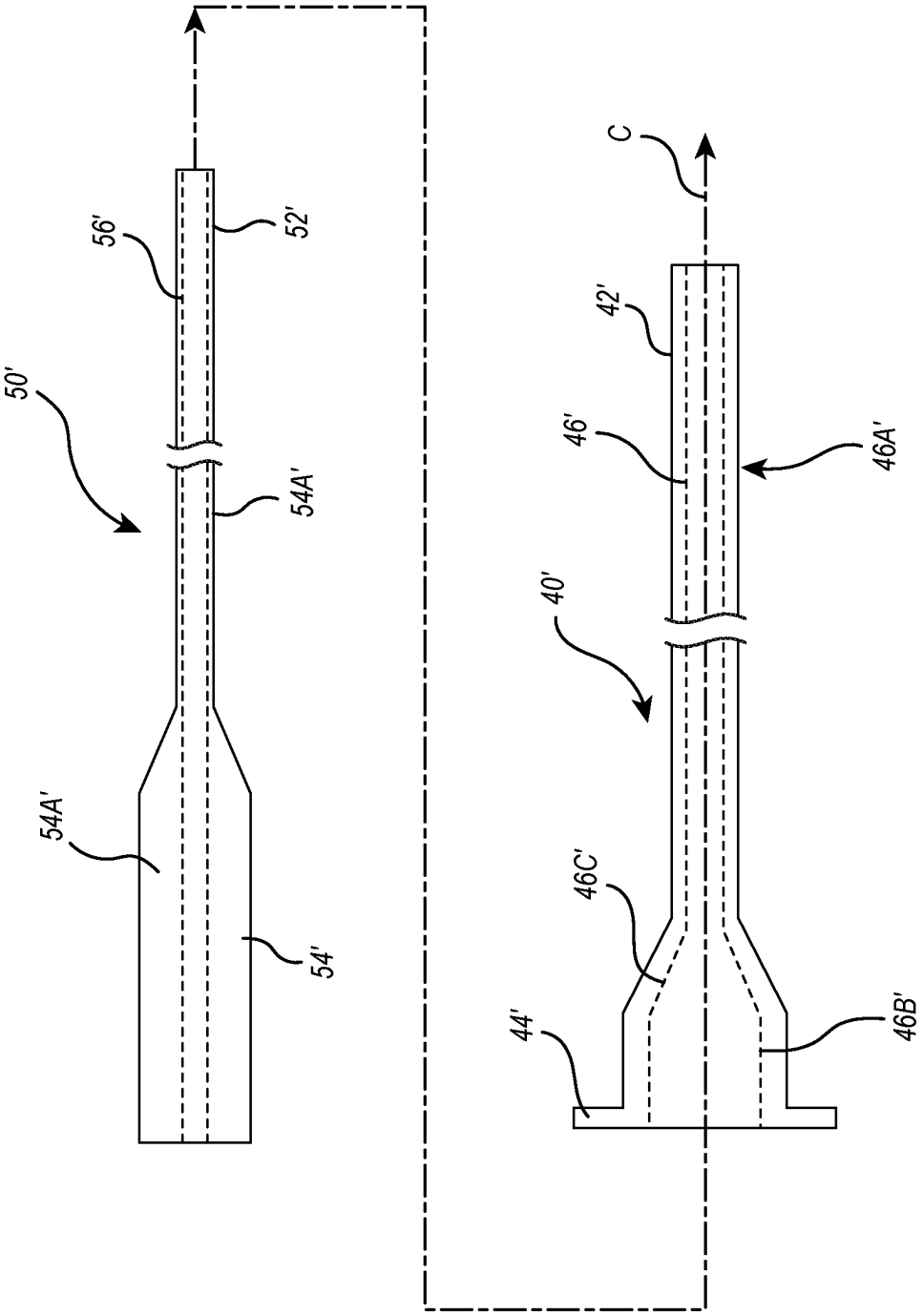

FIG. 1C

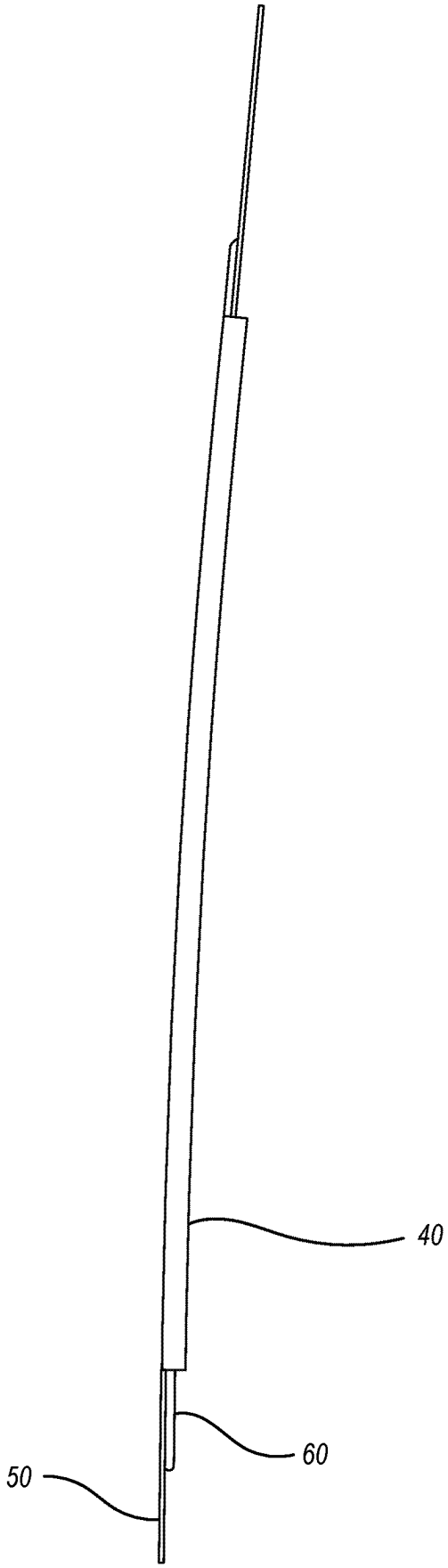

FIG. 1D

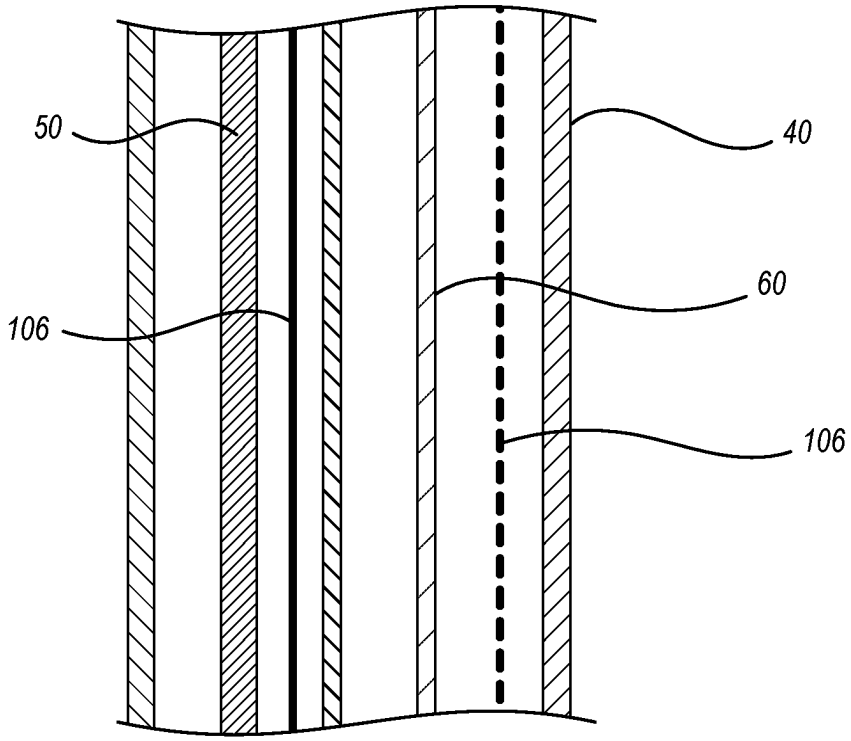

FIG. 1E

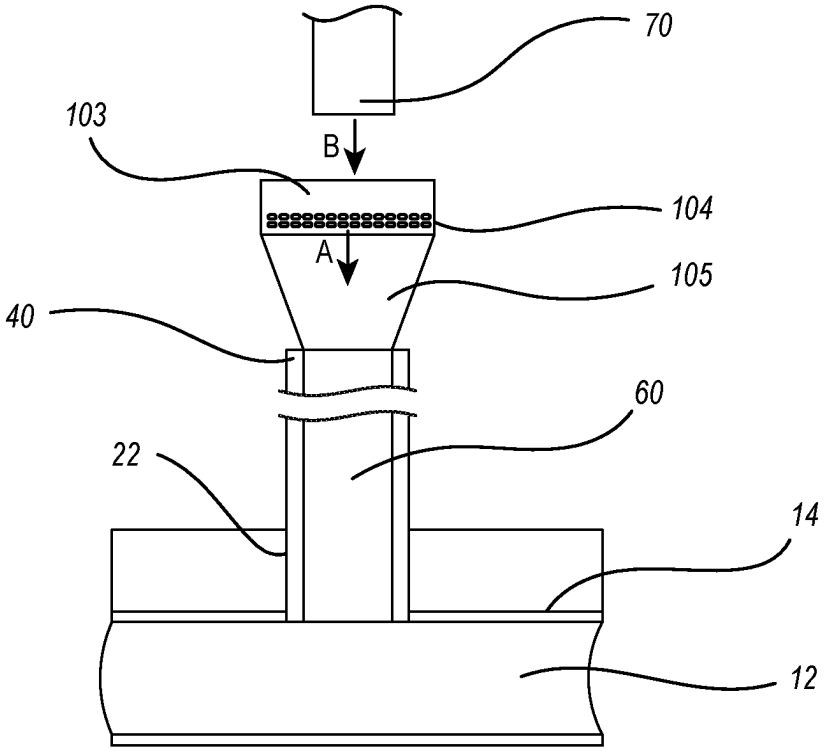

FIG. 1F

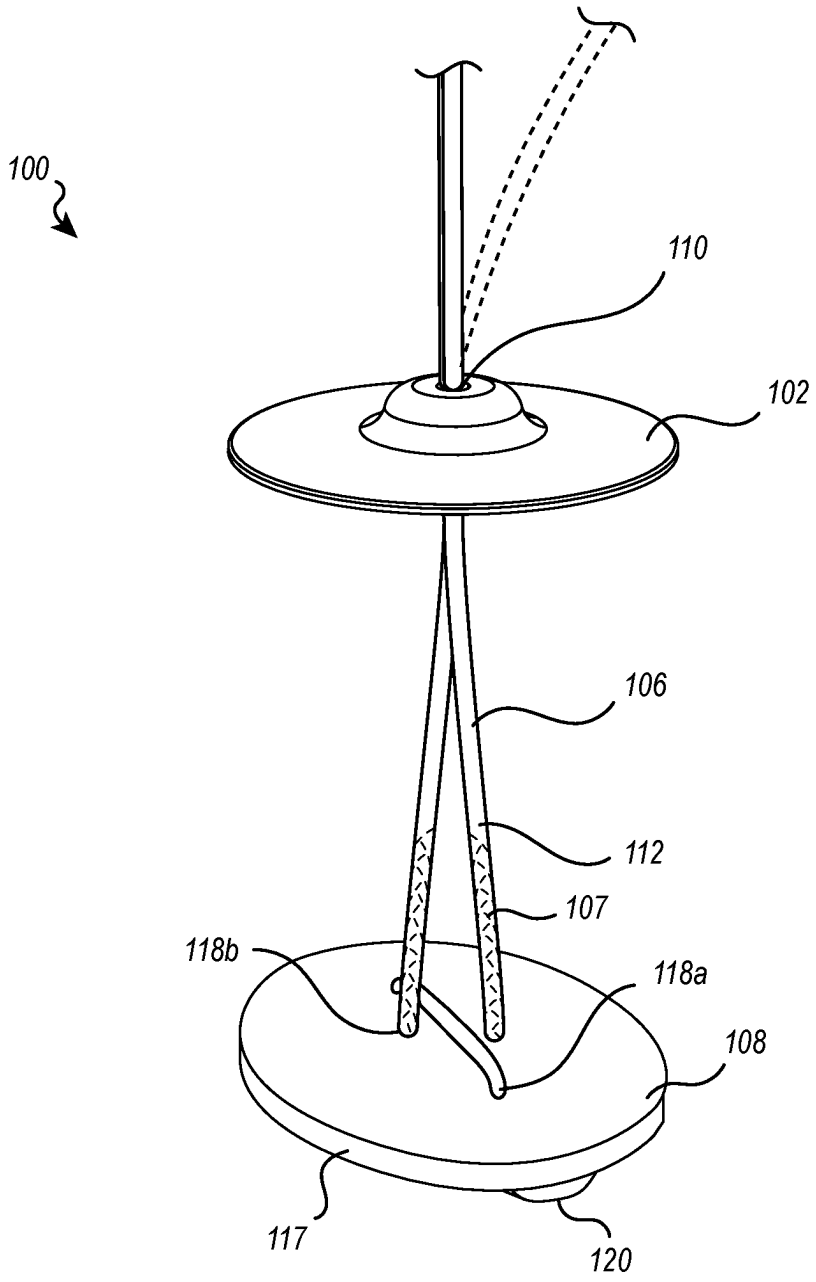

FIG. 2A

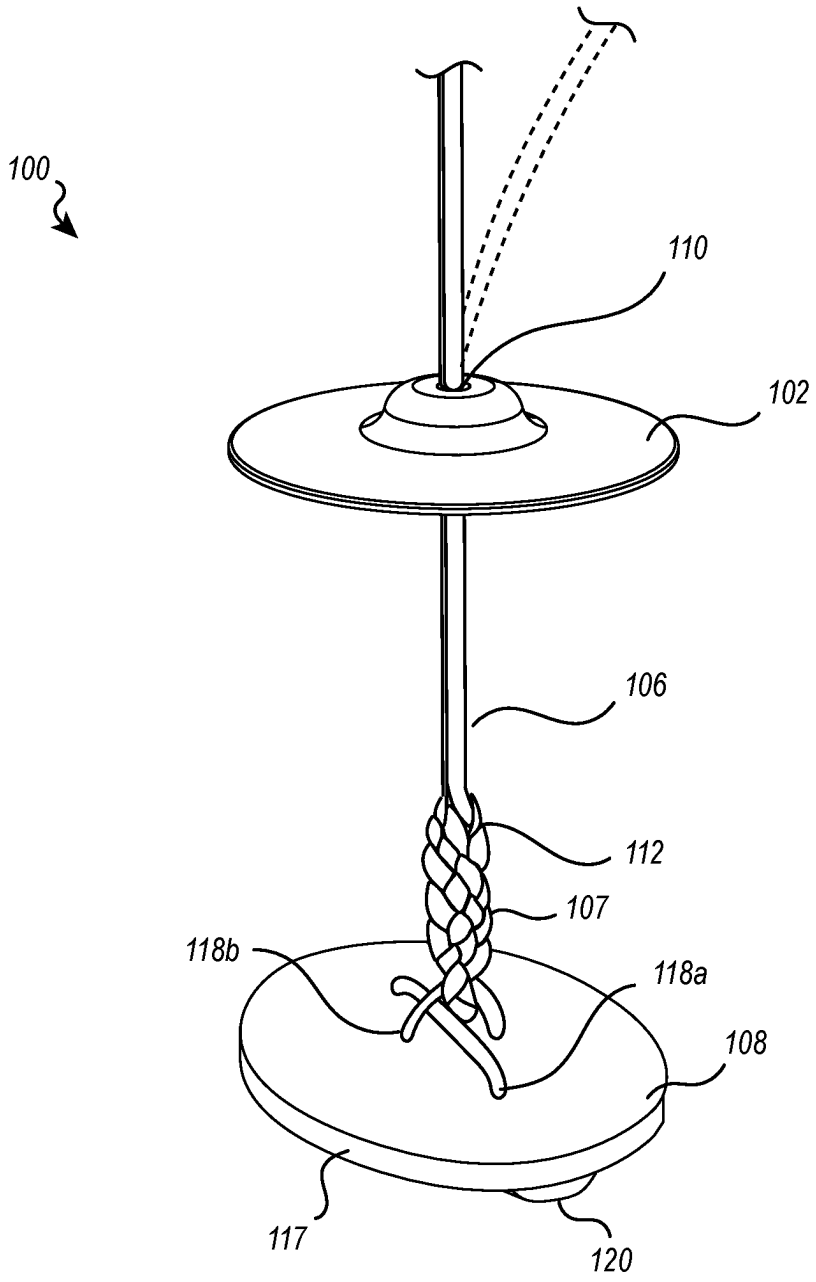

FIG. 2B

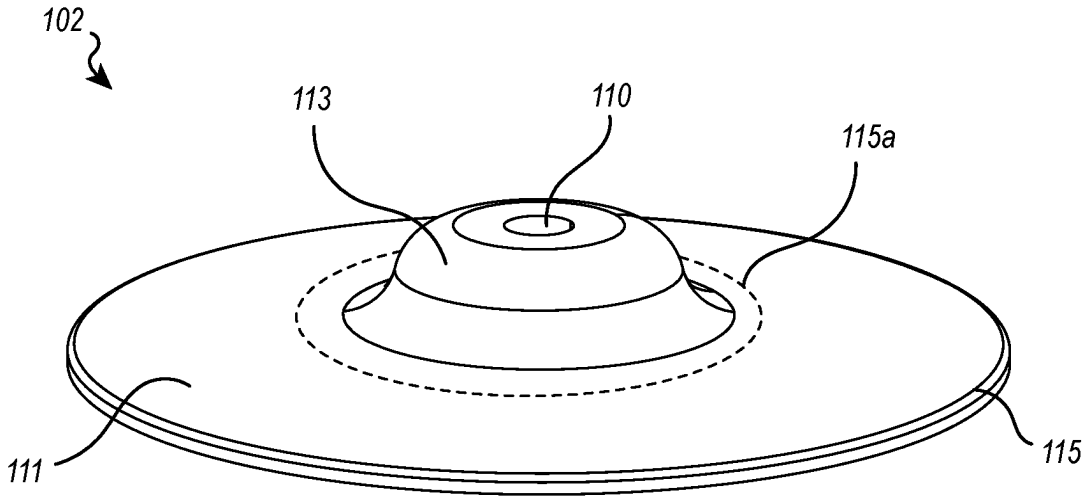

FIG. 3A

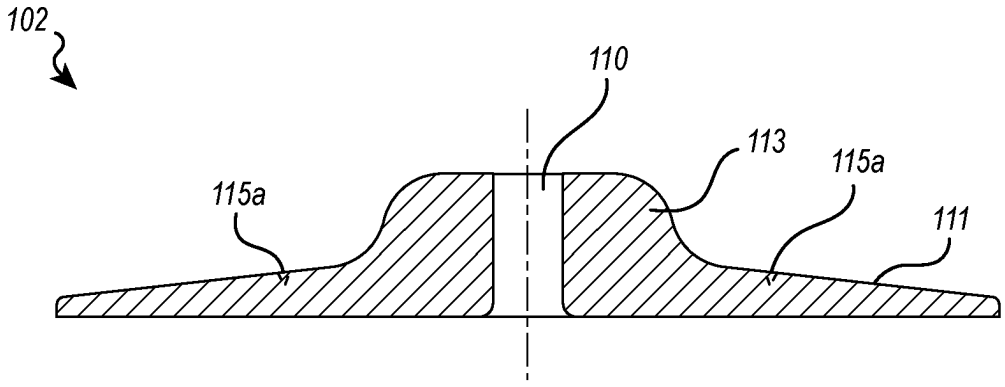

FIG. 3B

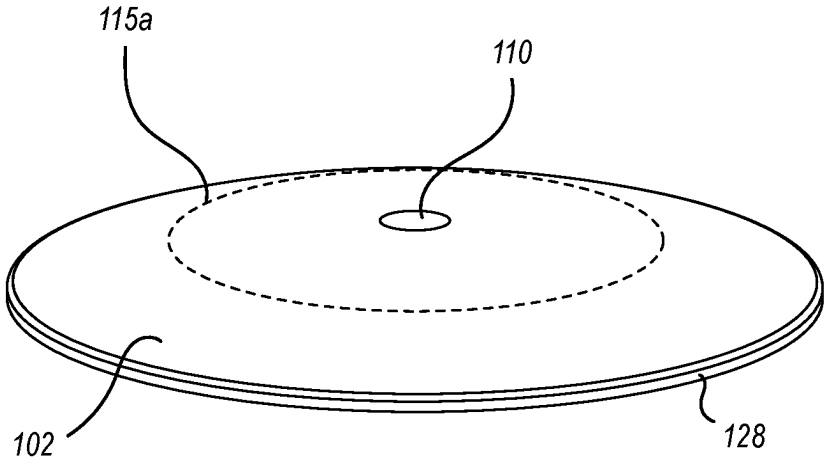

FIG. 3C

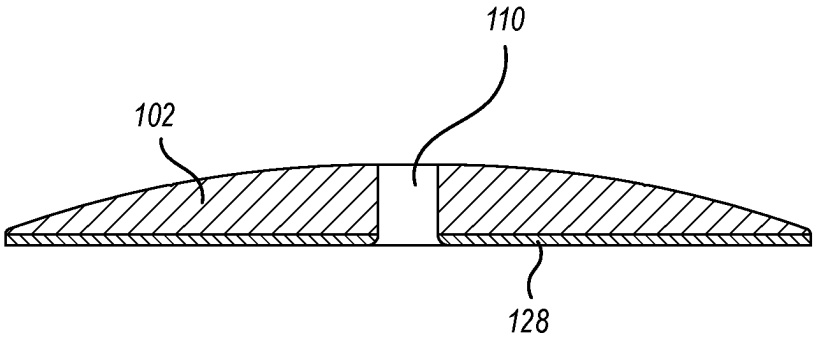

FIG. 3D

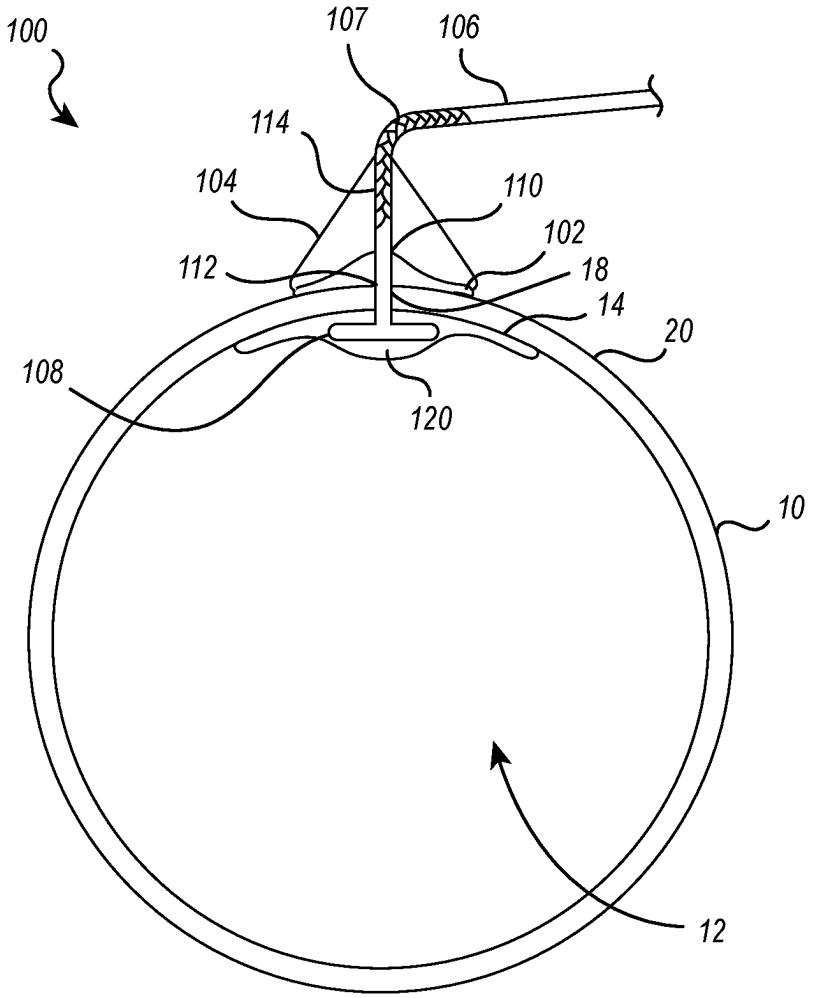

FIG. 4

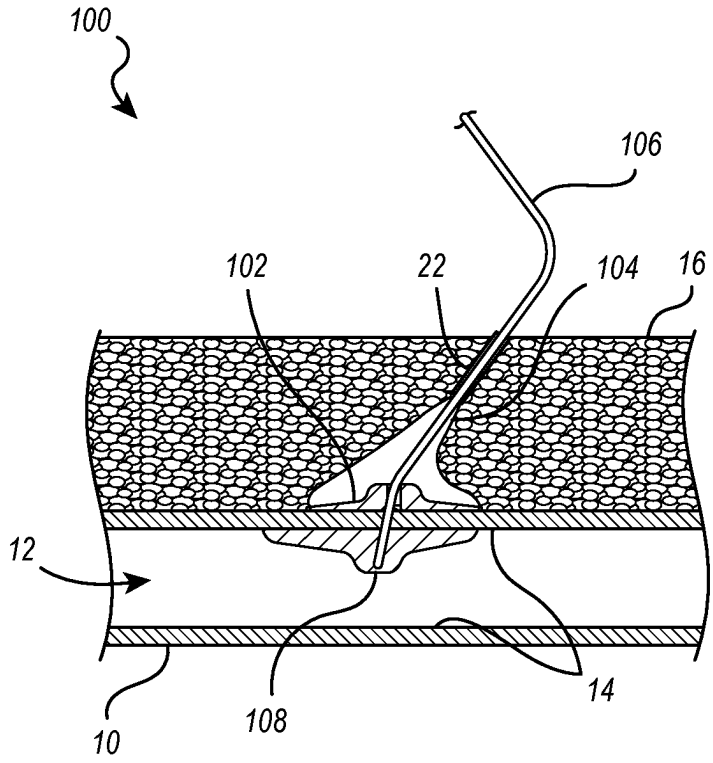

FIG. 5

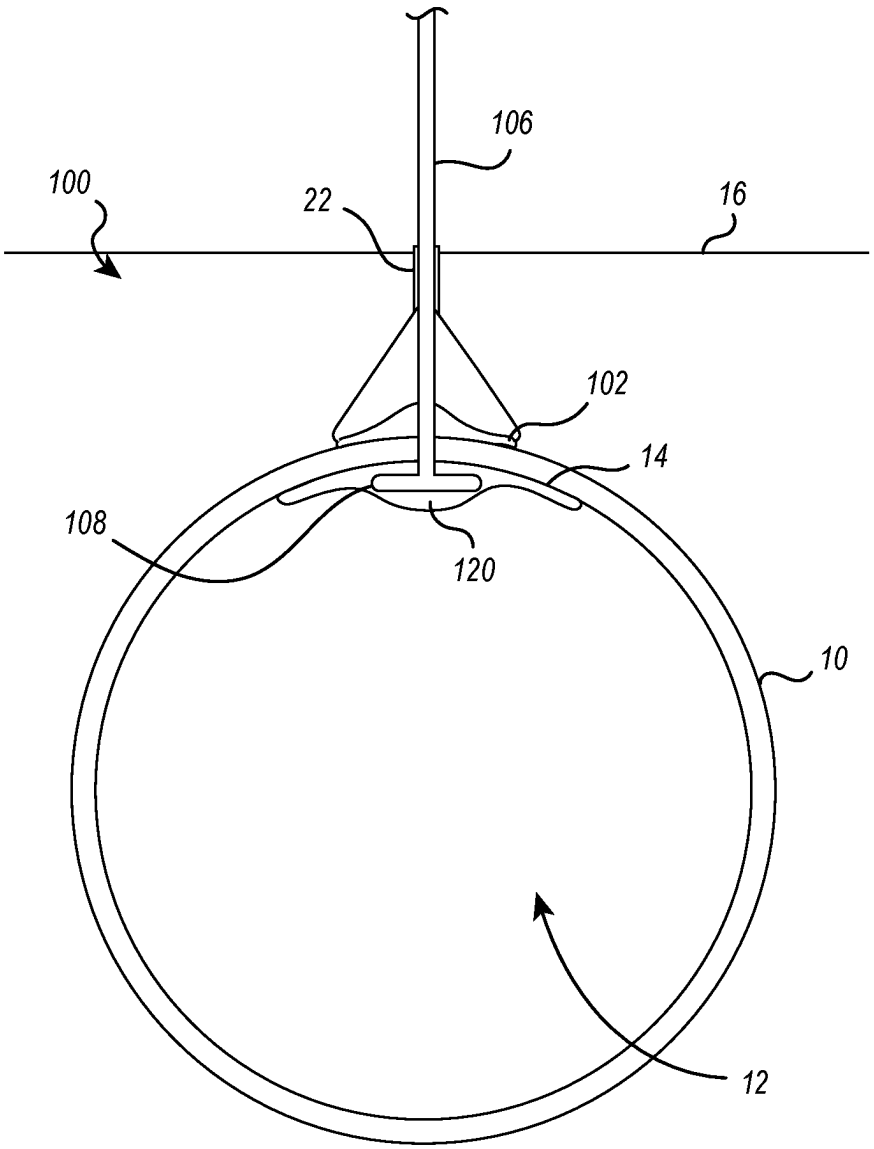

FIG. 6A

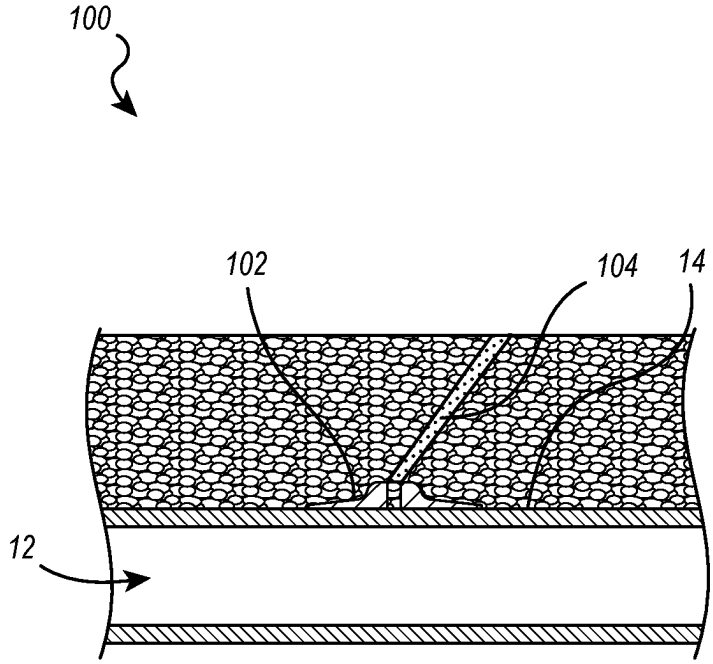

FIG. 6B

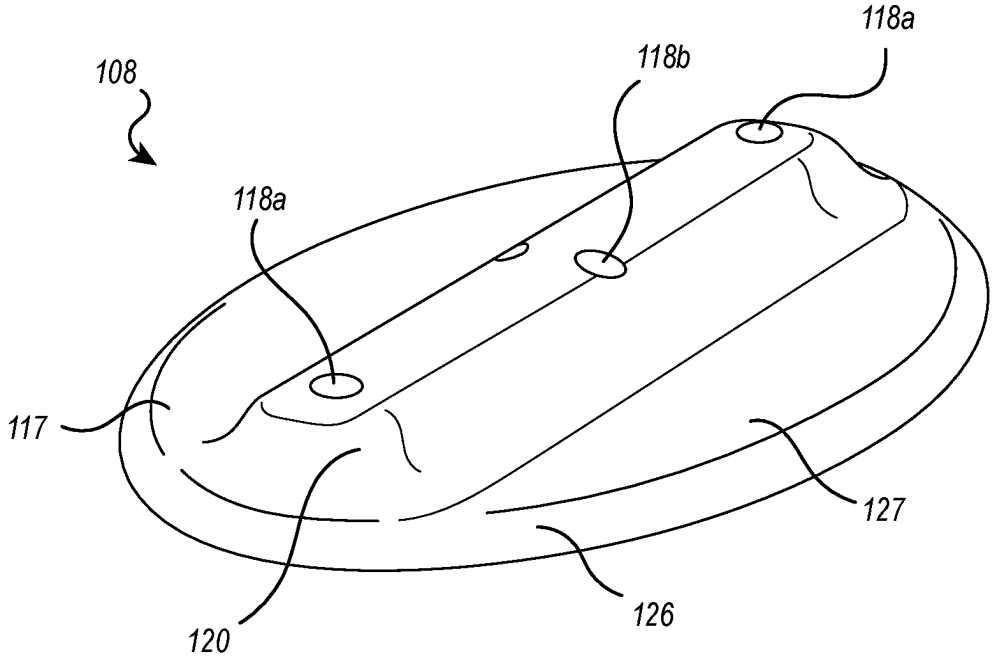
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FIG. 7A

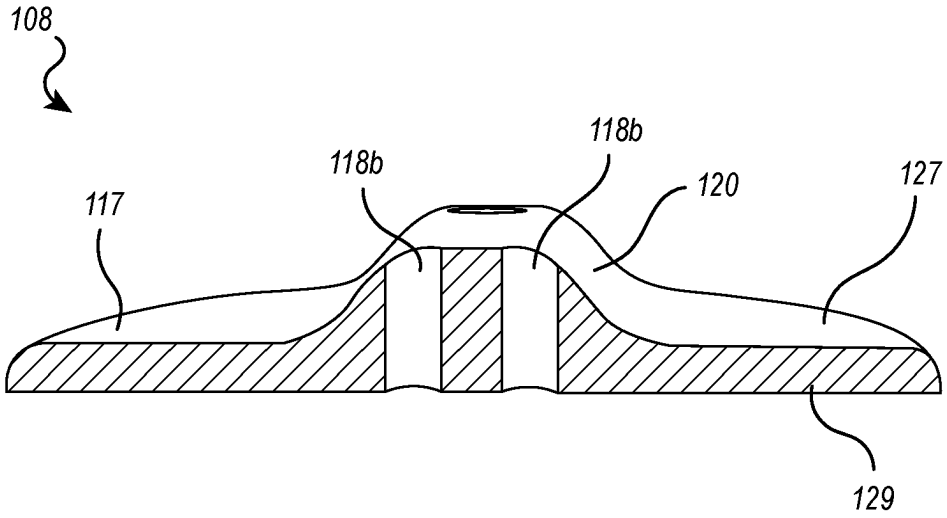
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FIG. 7B

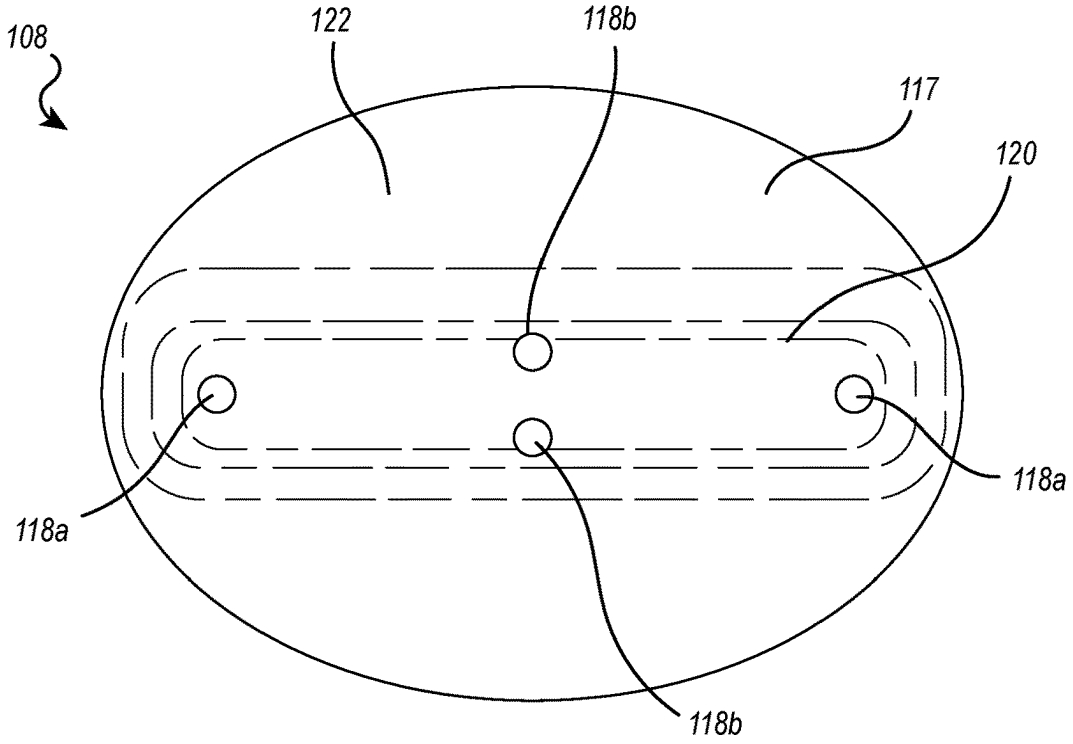
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FIG. 7C

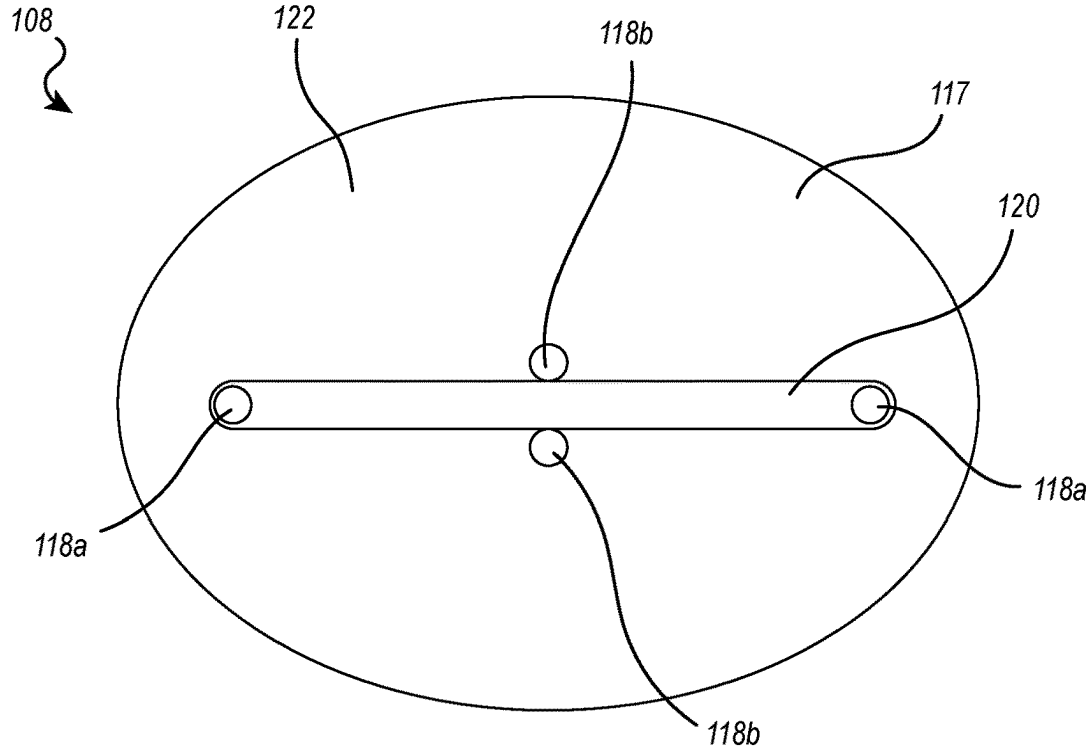
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FIG. 7D

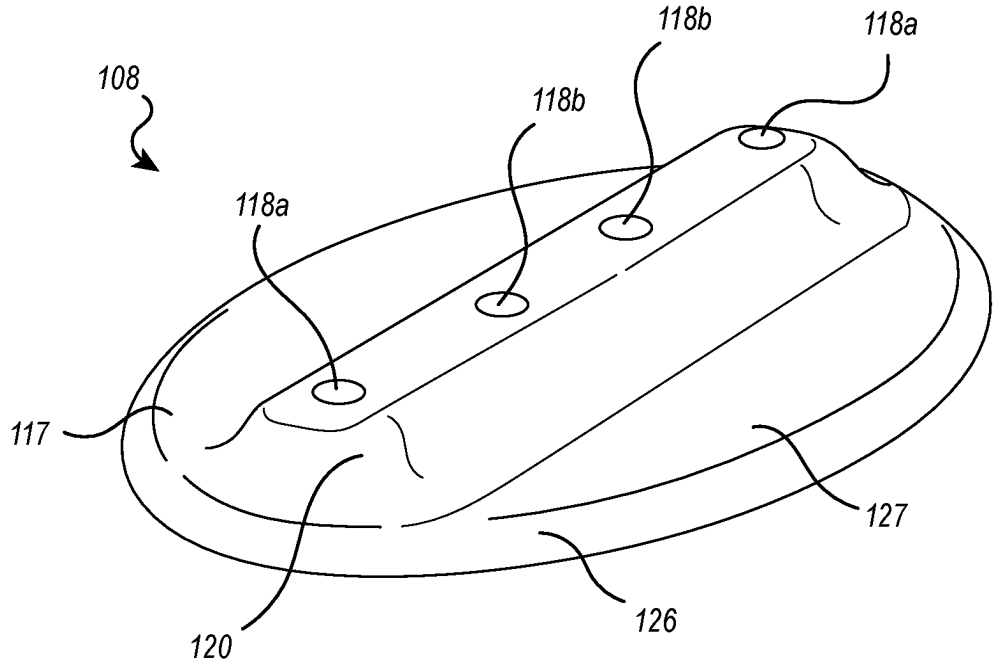
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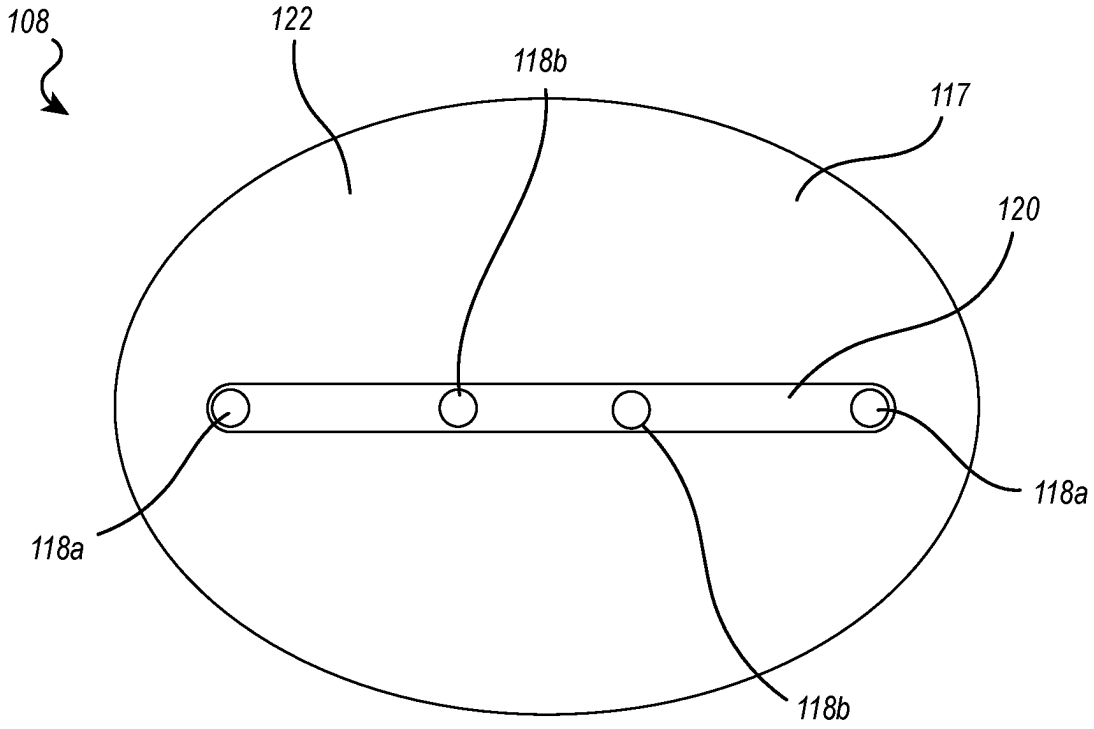
FIG. 7E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122
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118a
118a
118b

FIG. 7F

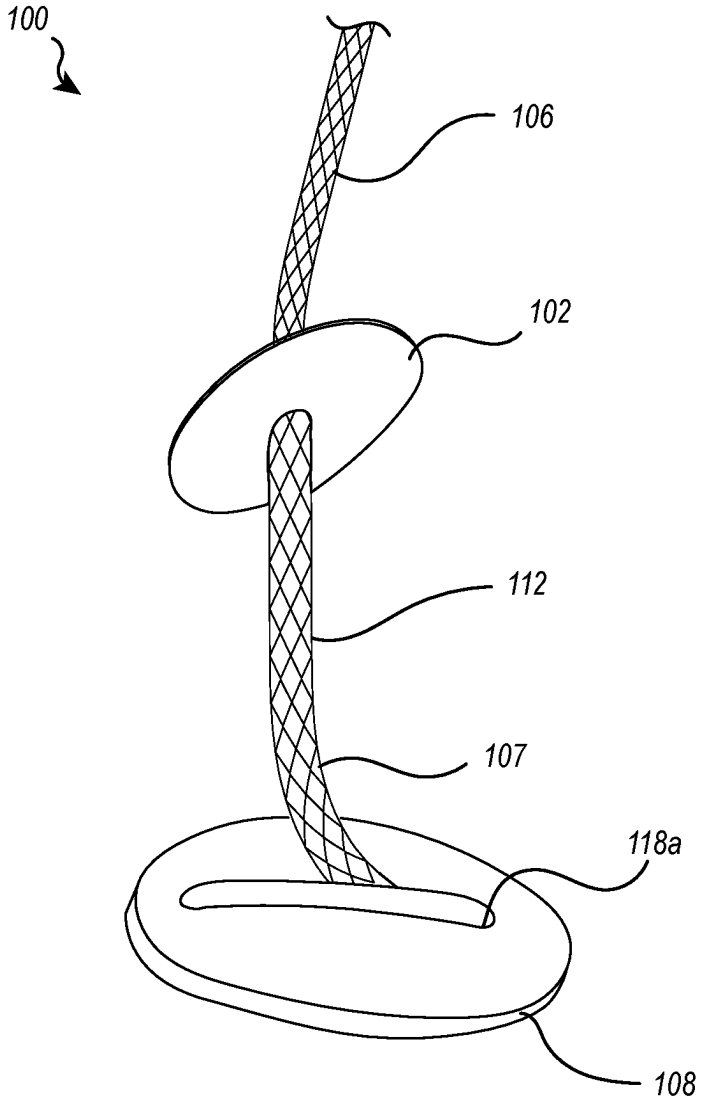

FIG. 7G

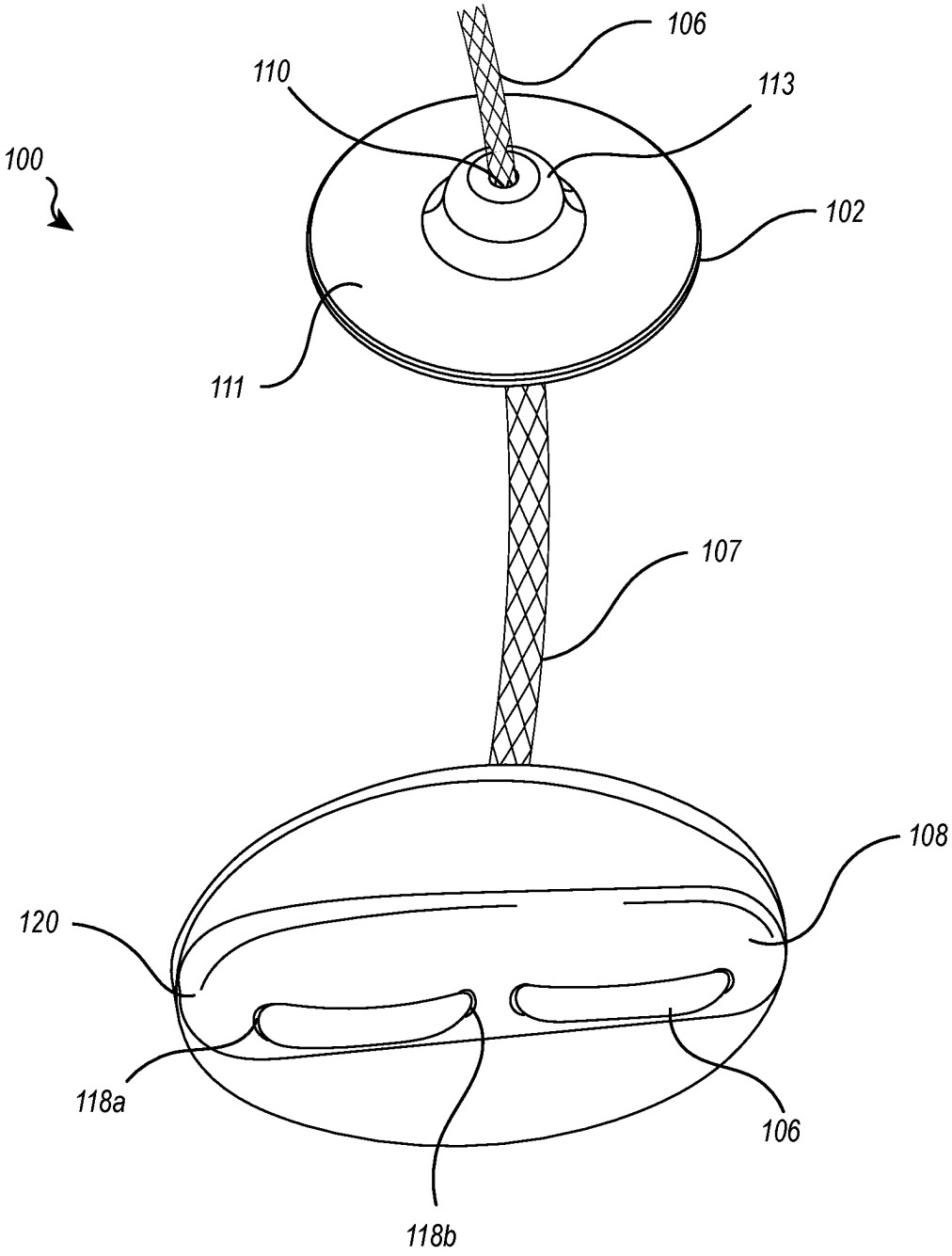

FIG. 7H

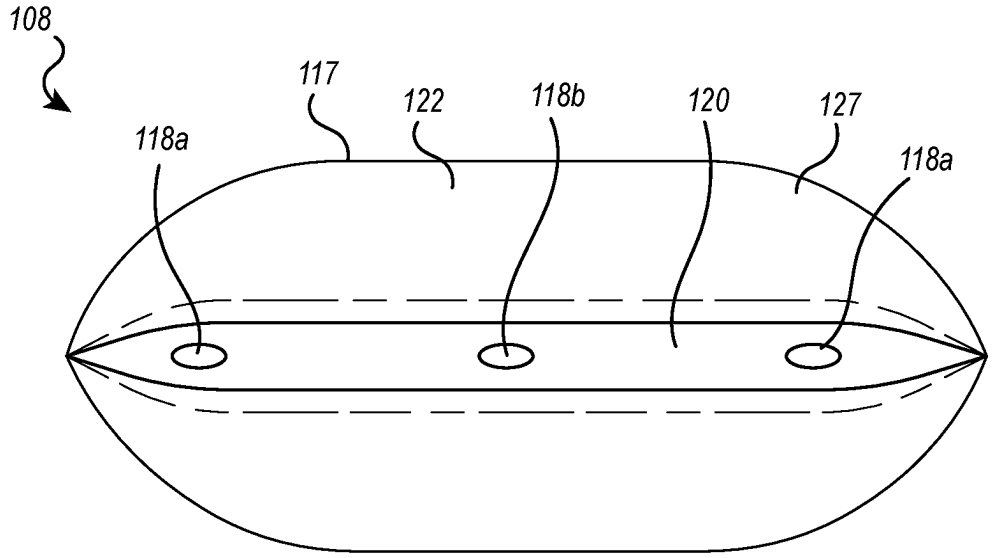
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FIG. 8A

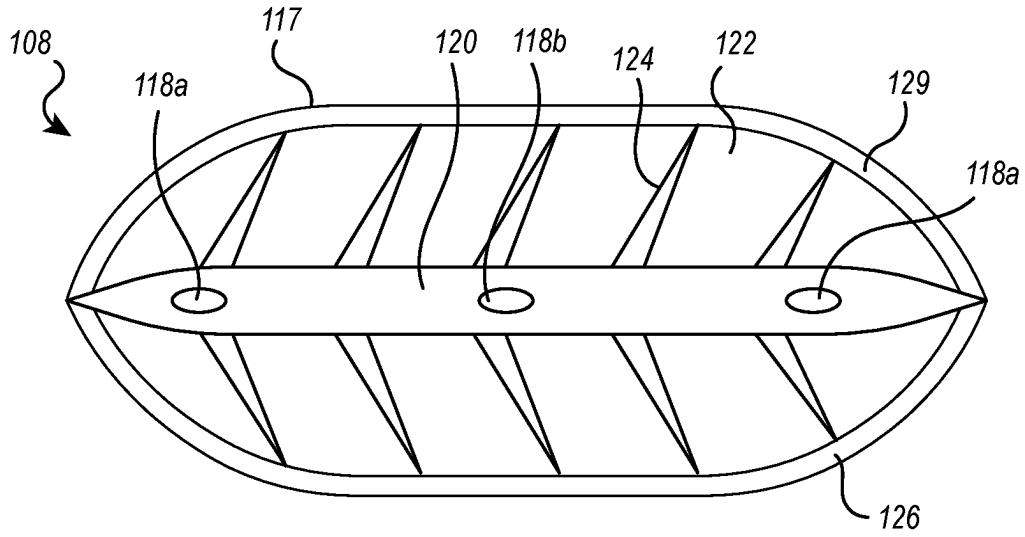
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FIG. 8B

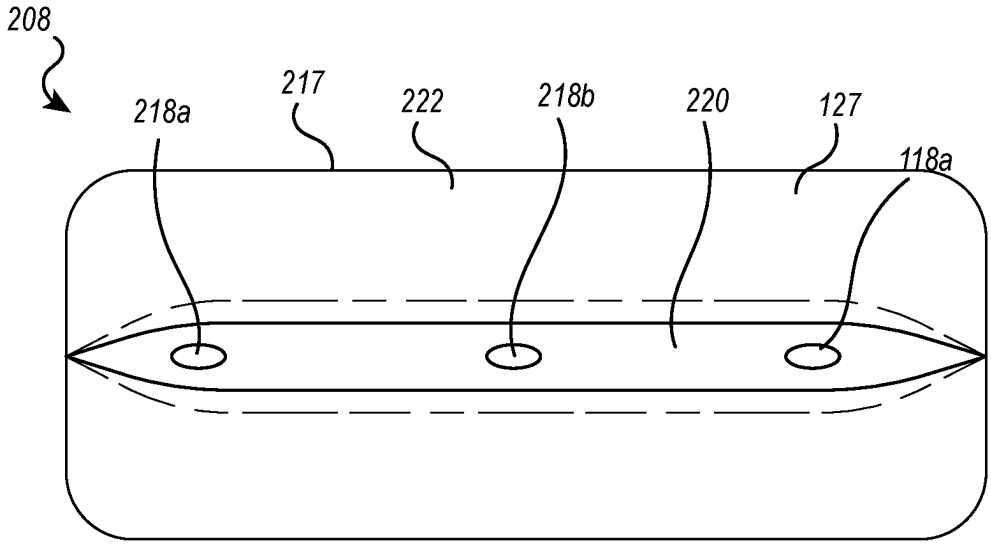
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FIG. 9A

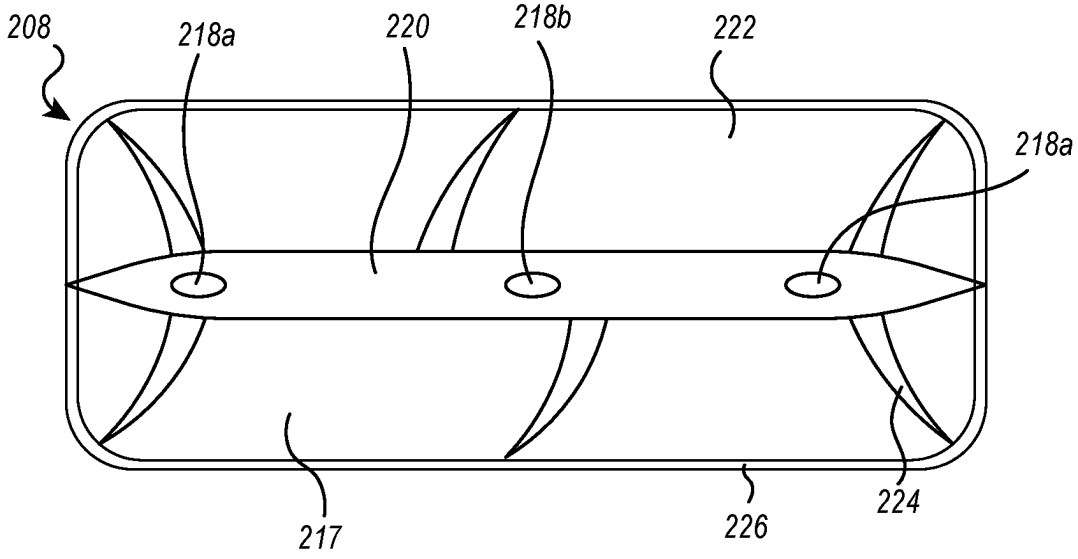
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FIG. 9B

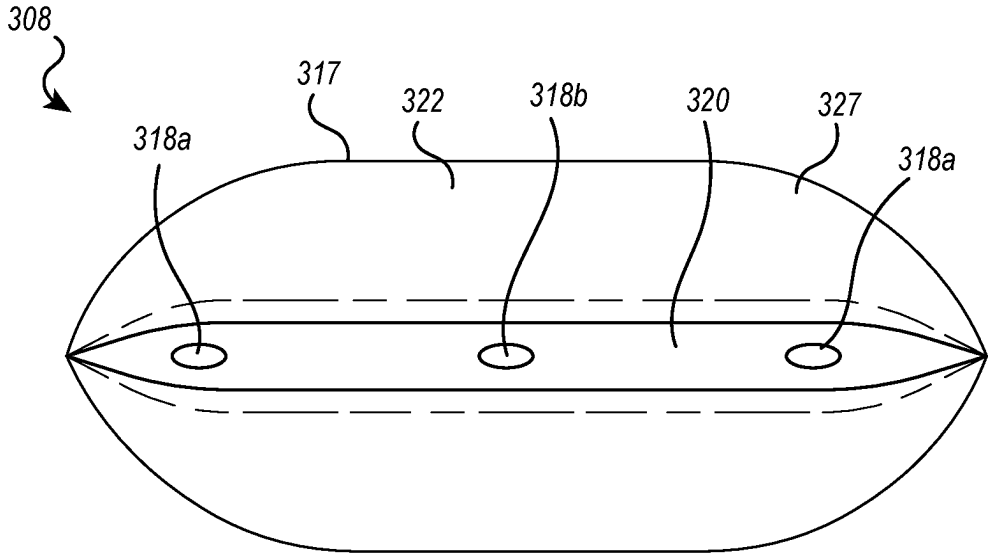

FIG. 10A

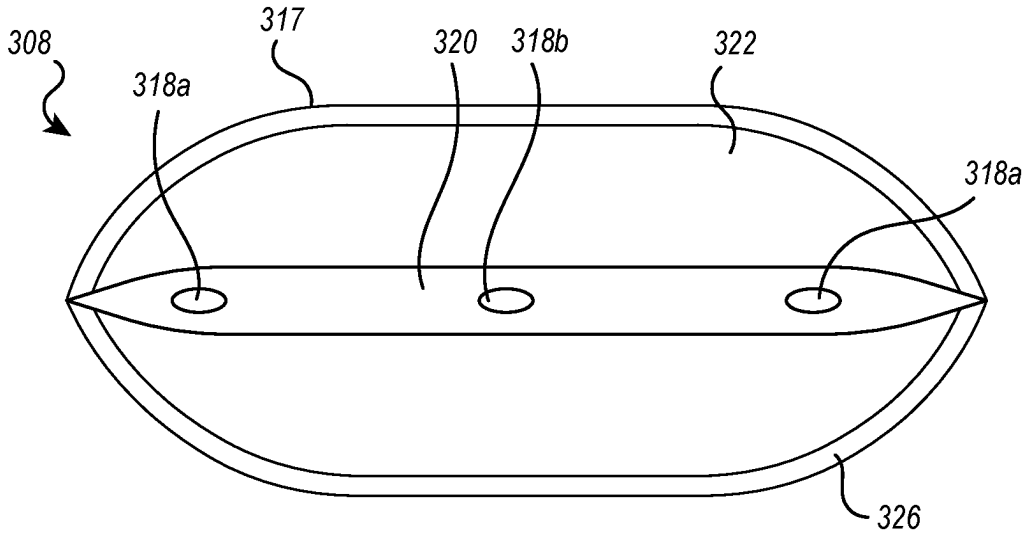

FIG. 10B

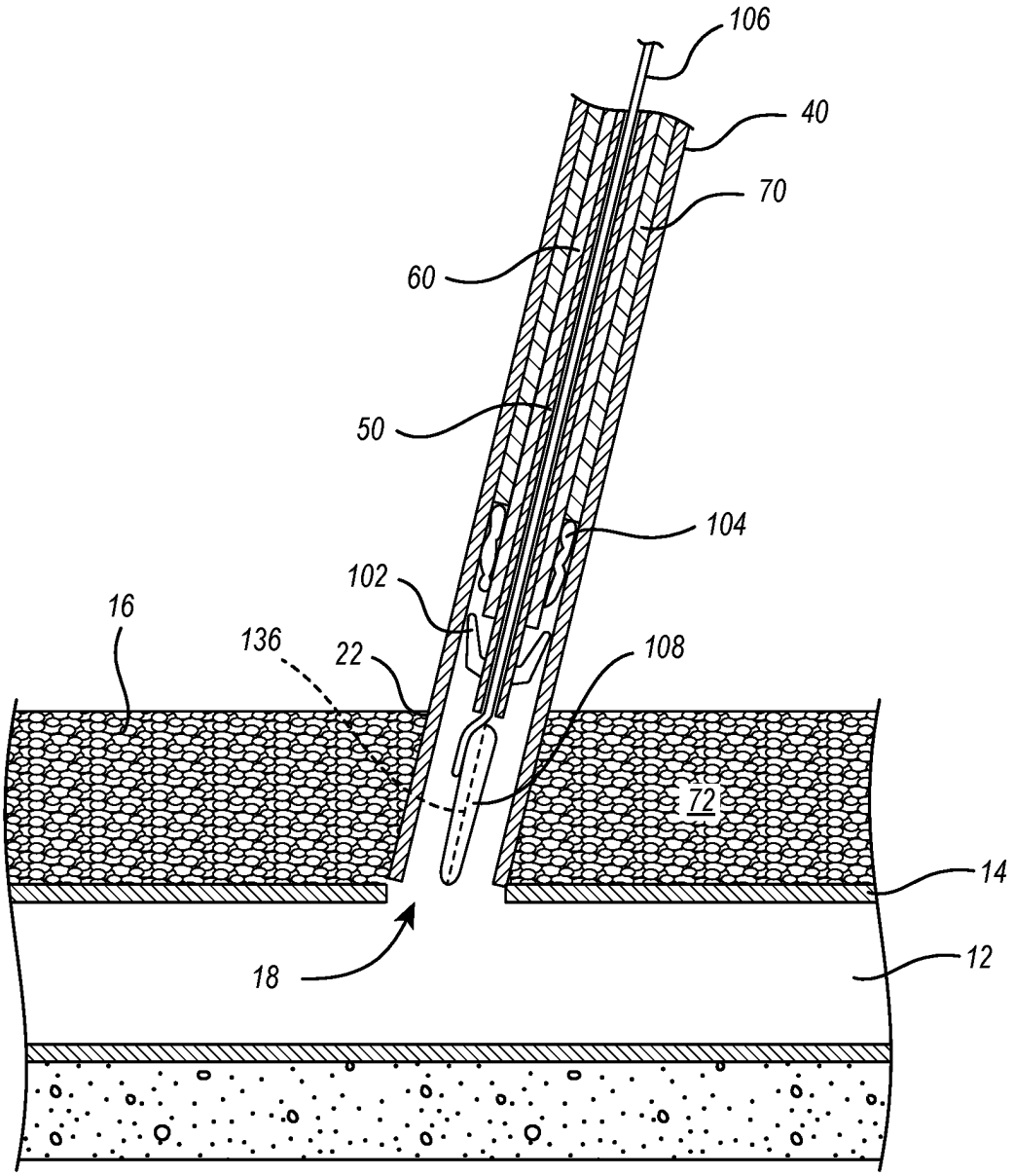

FIG. 11A

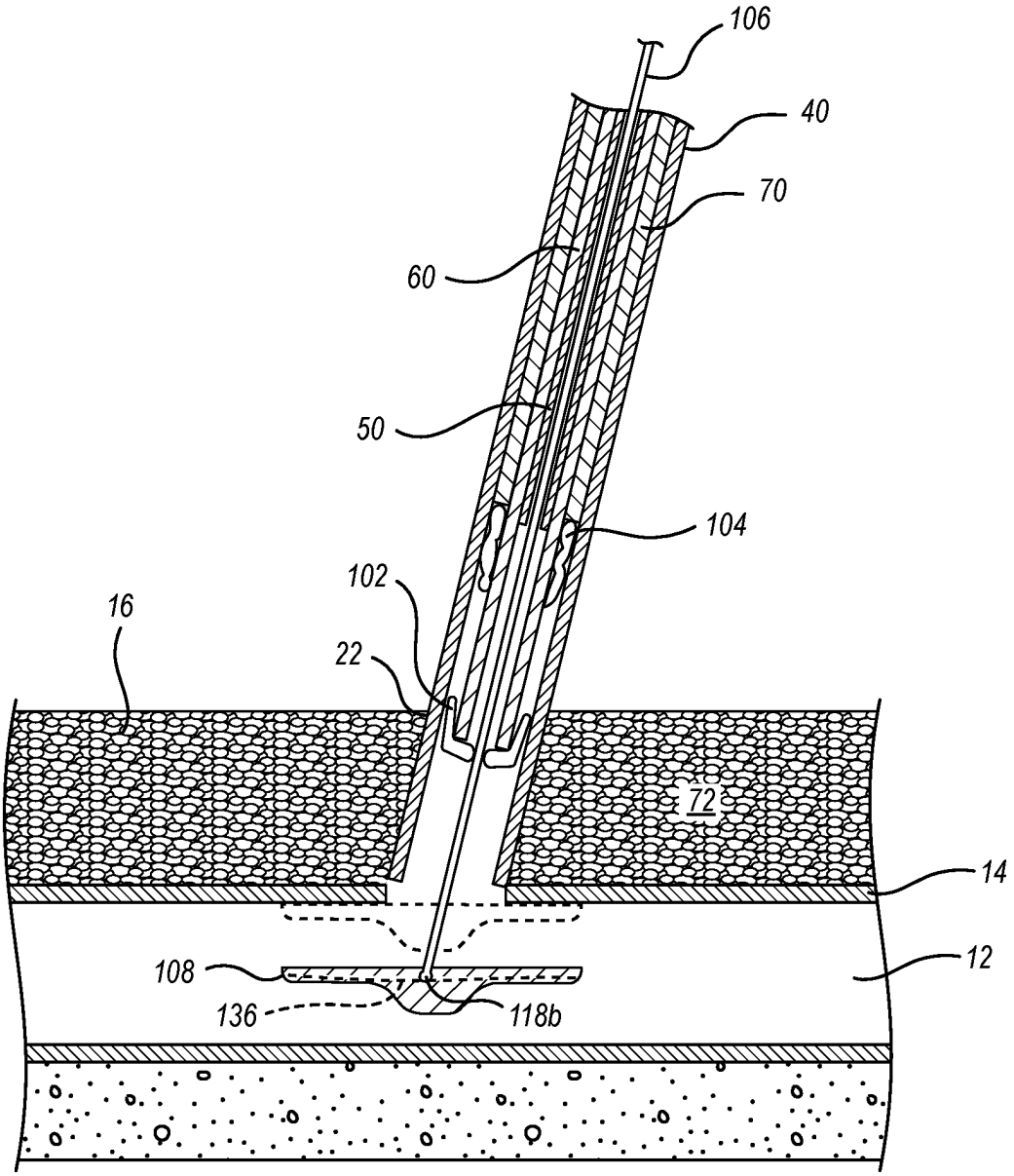

FIG. 11B

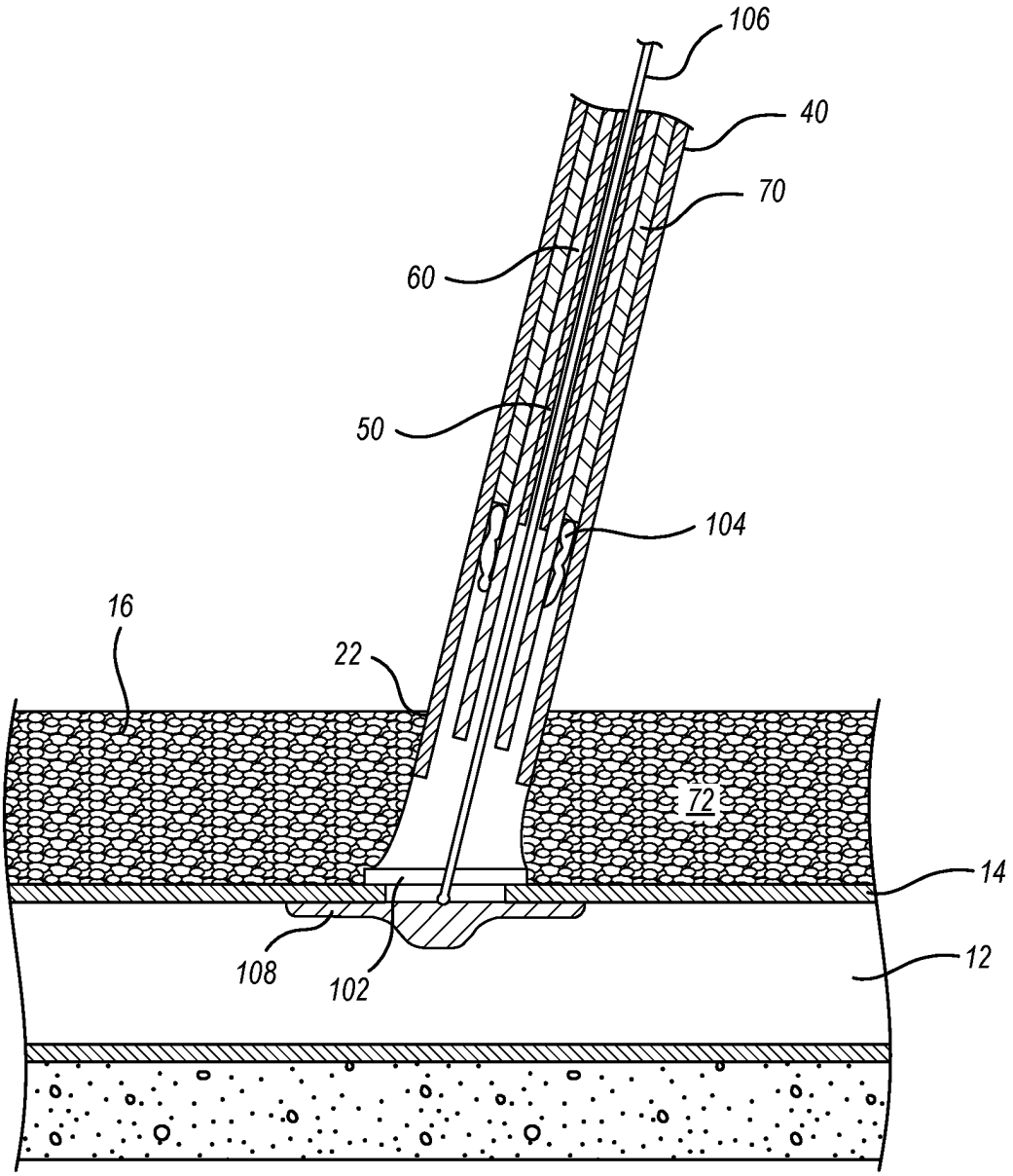

FIG. 11C

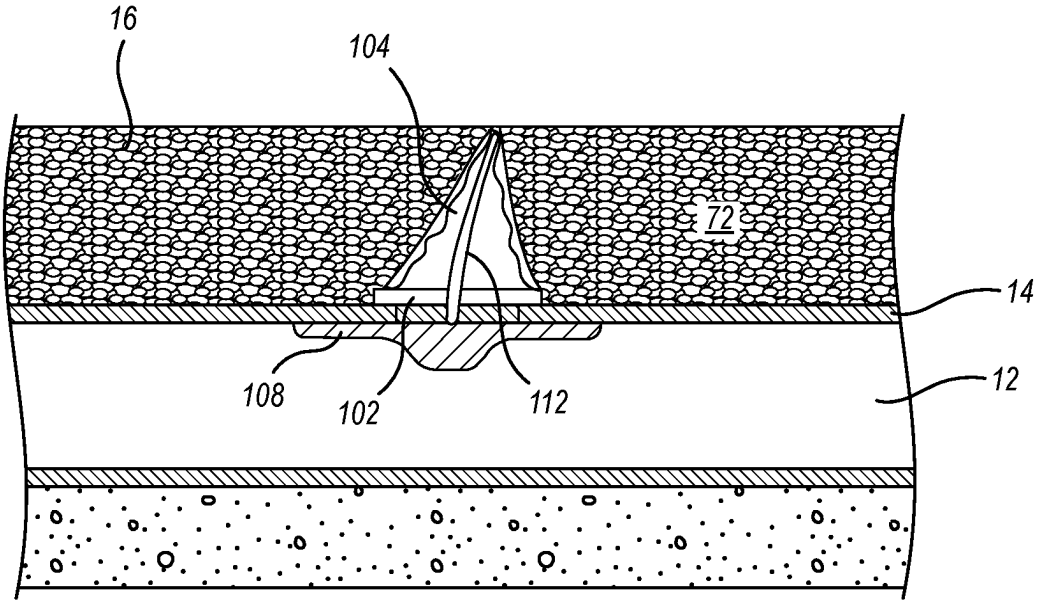

FIG. 11D

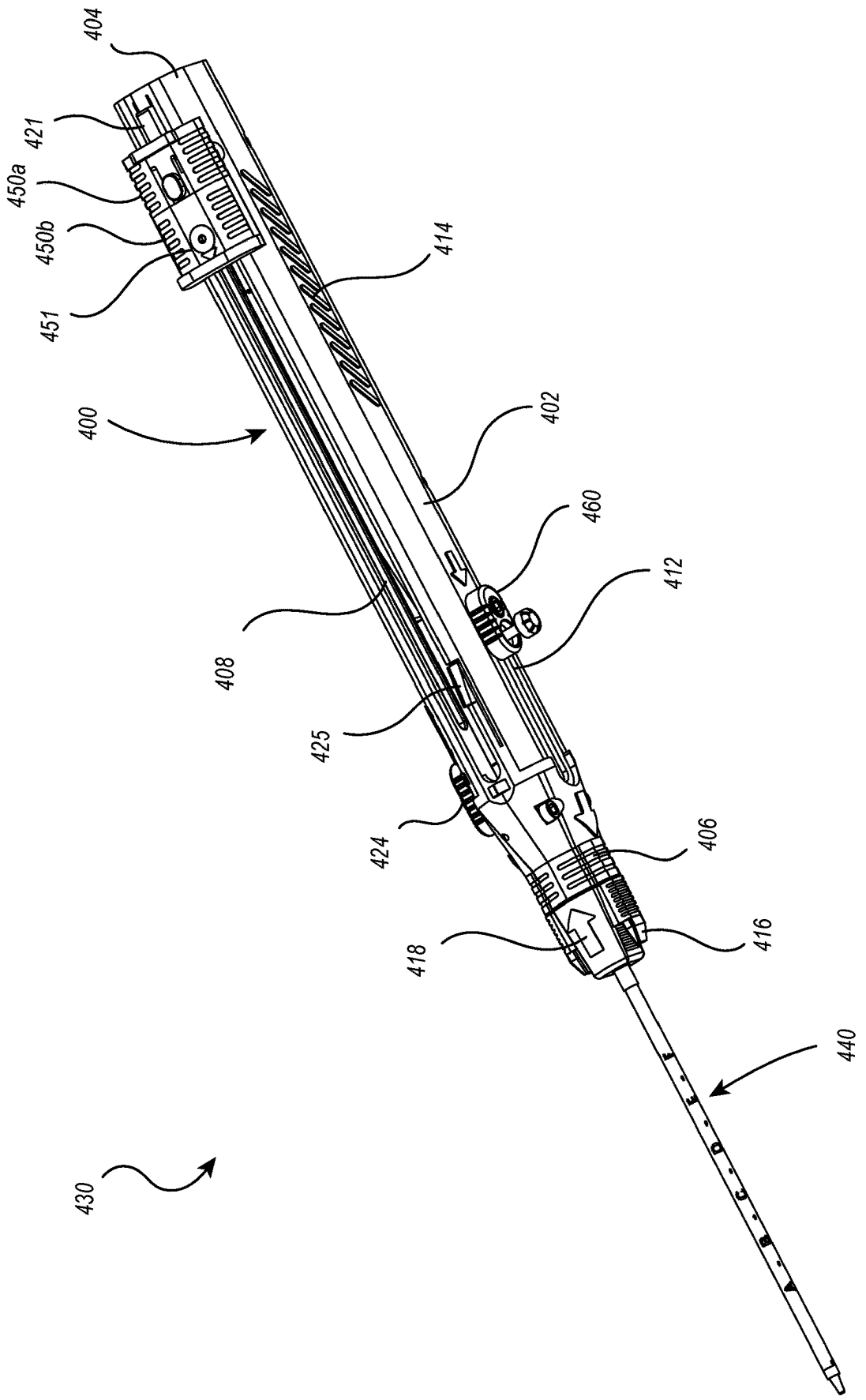
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FIG. 12

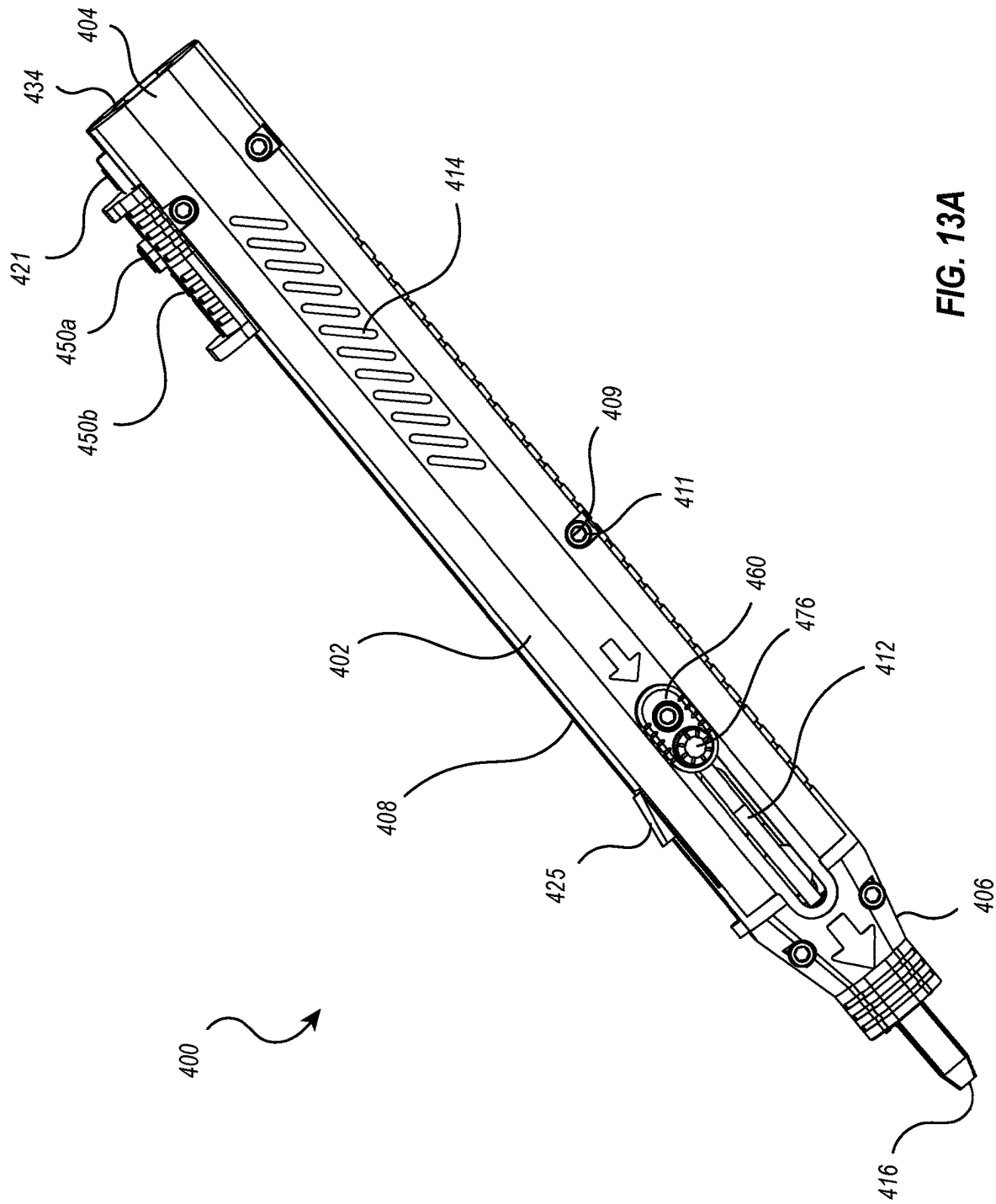
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FIG. 13A

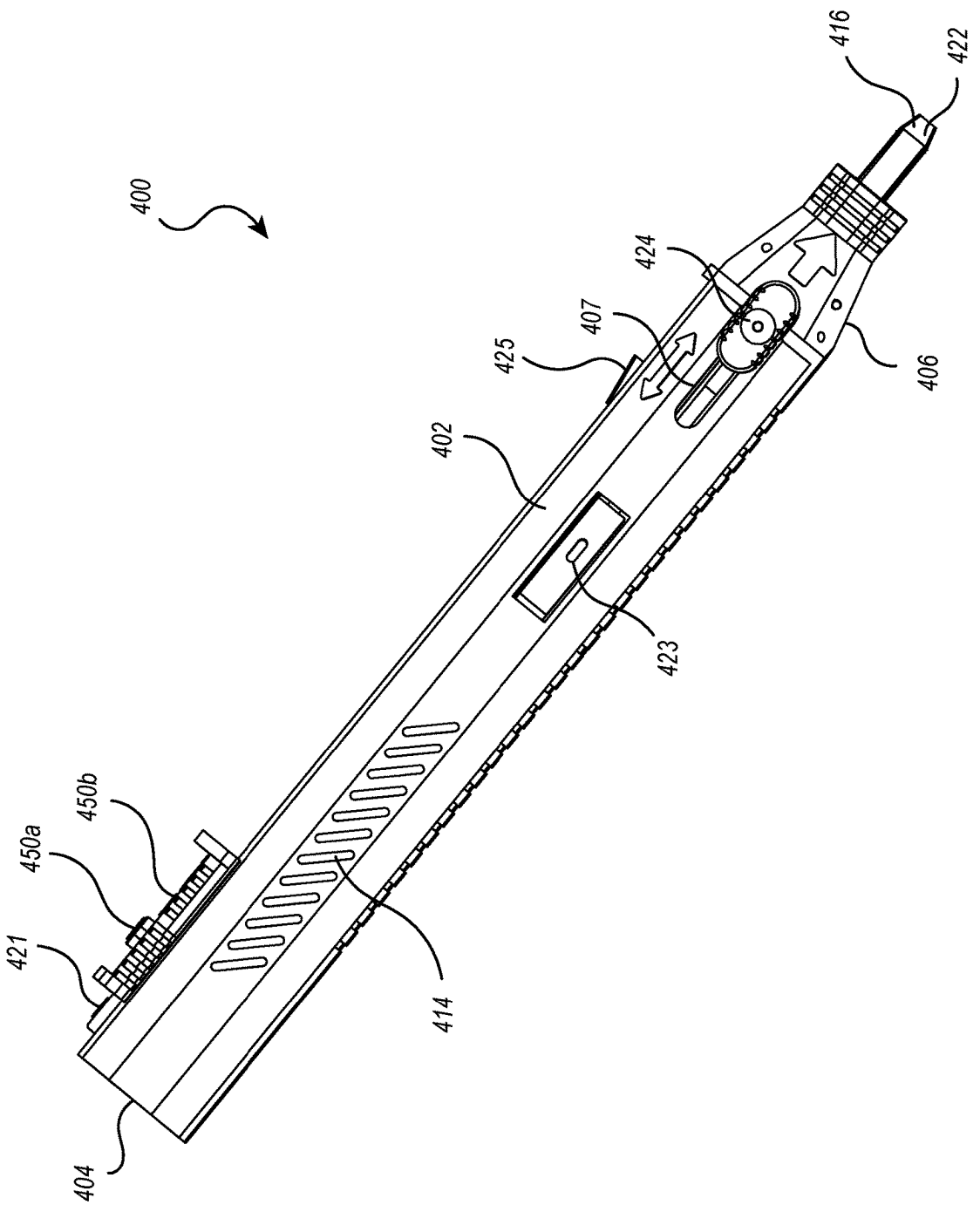

FIG. 13B

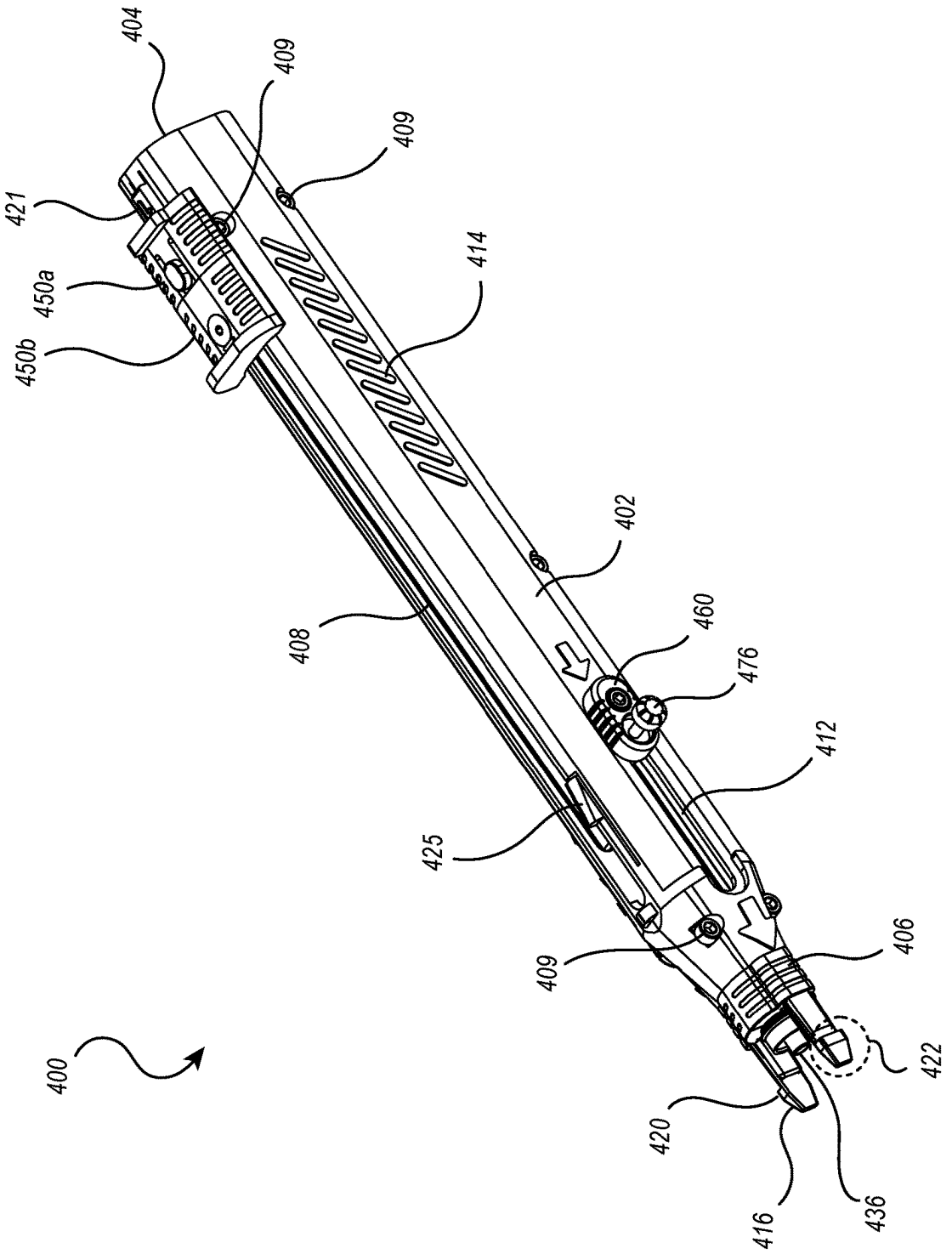
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FIG. 13C

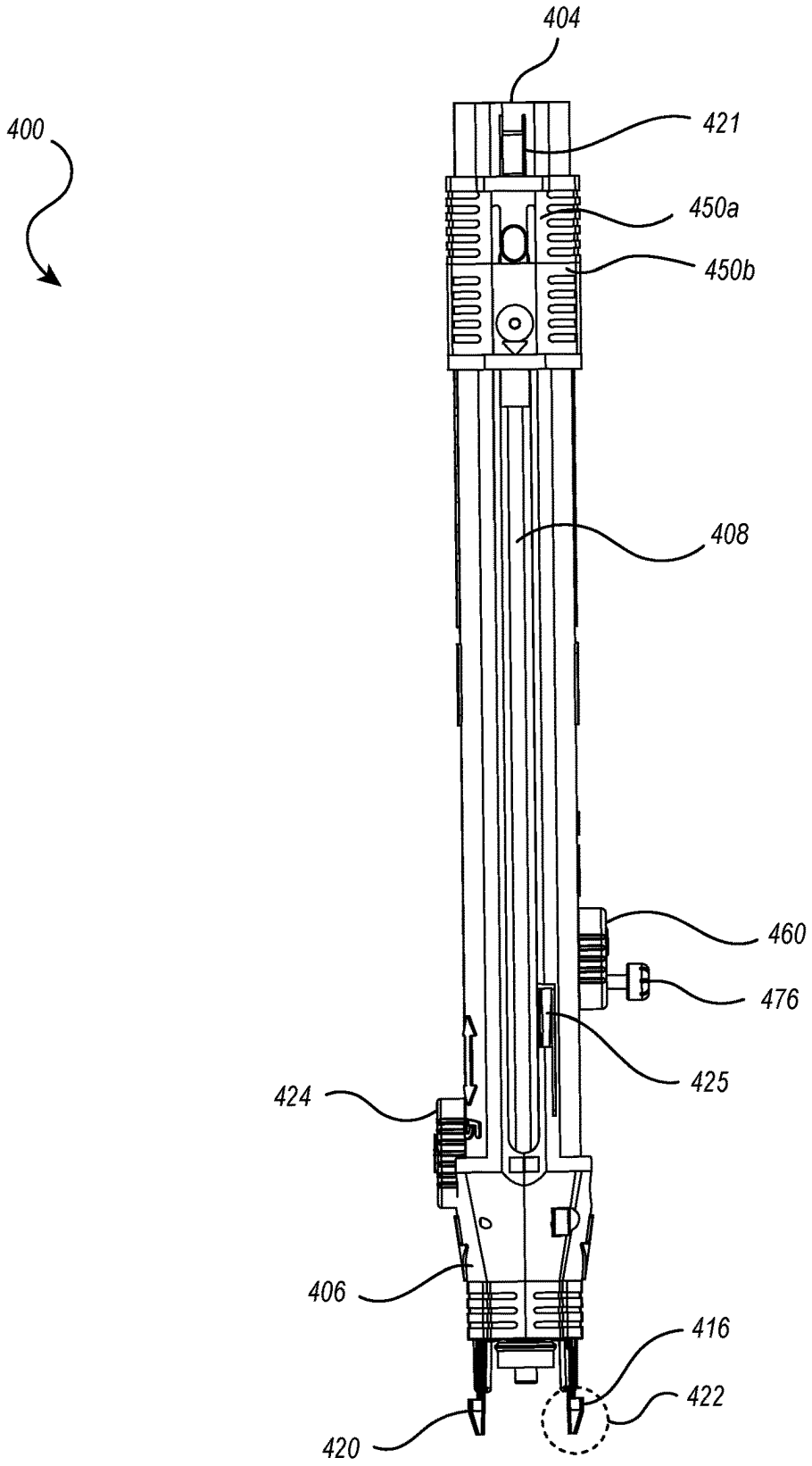

FIG. 13D

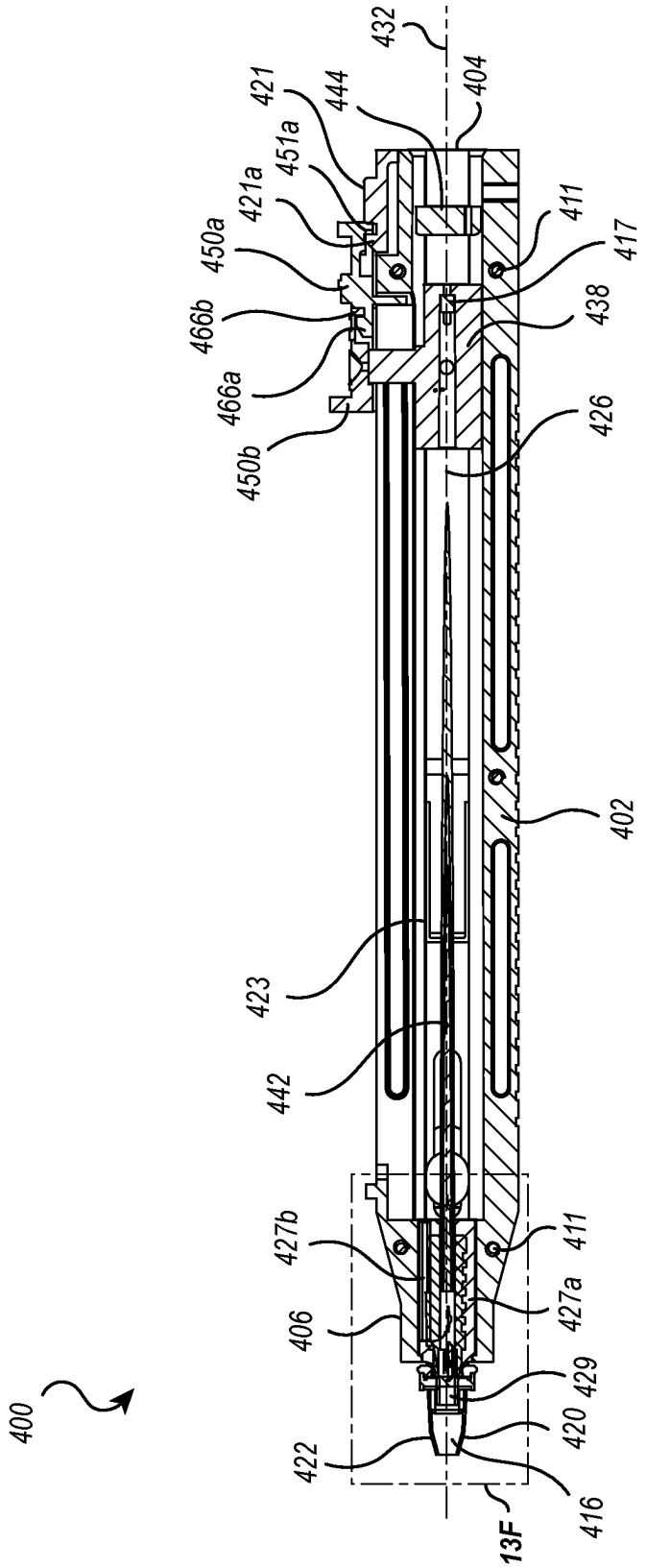
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FIG. 13E

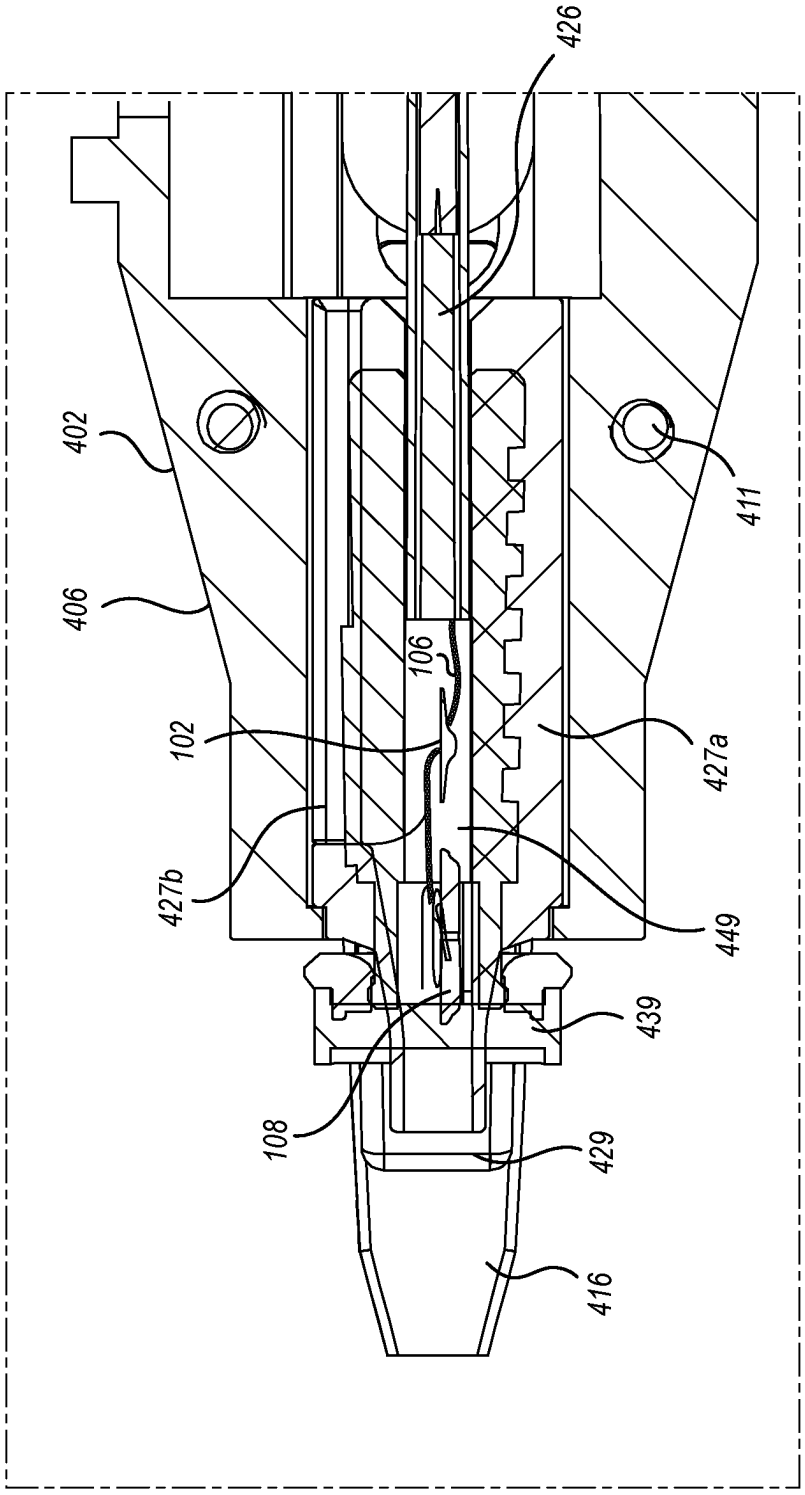

FIG. 13F

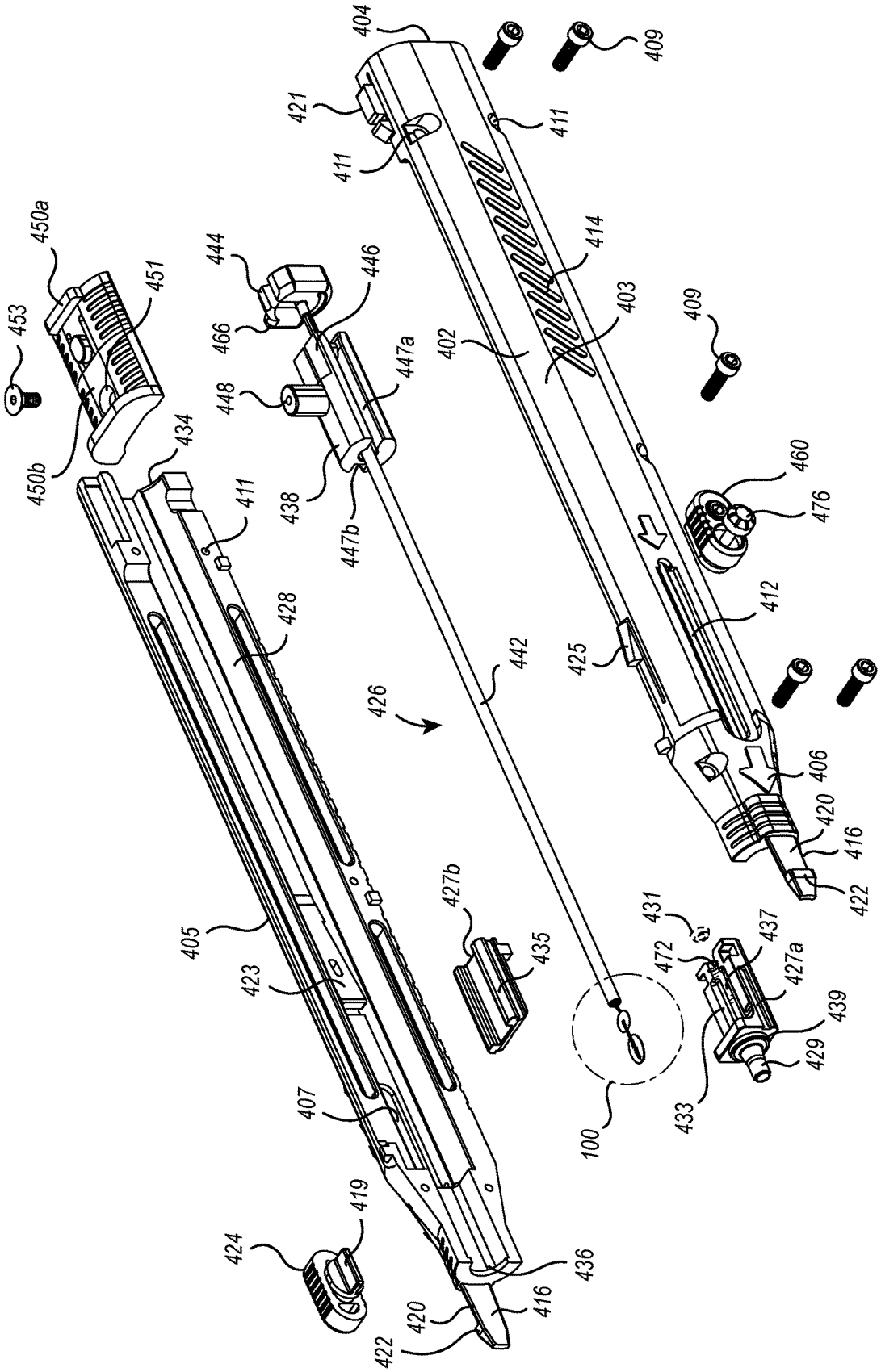
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FIG. 14A

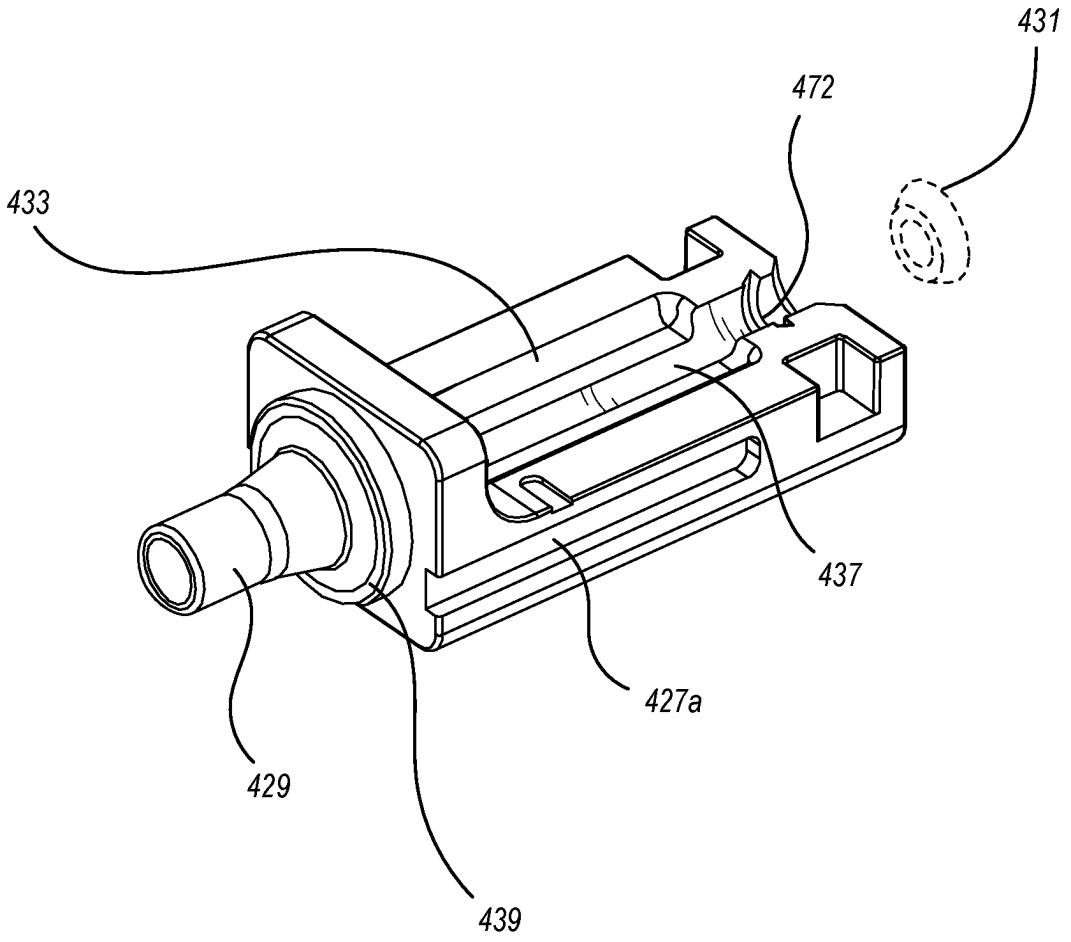

FIG. 14B

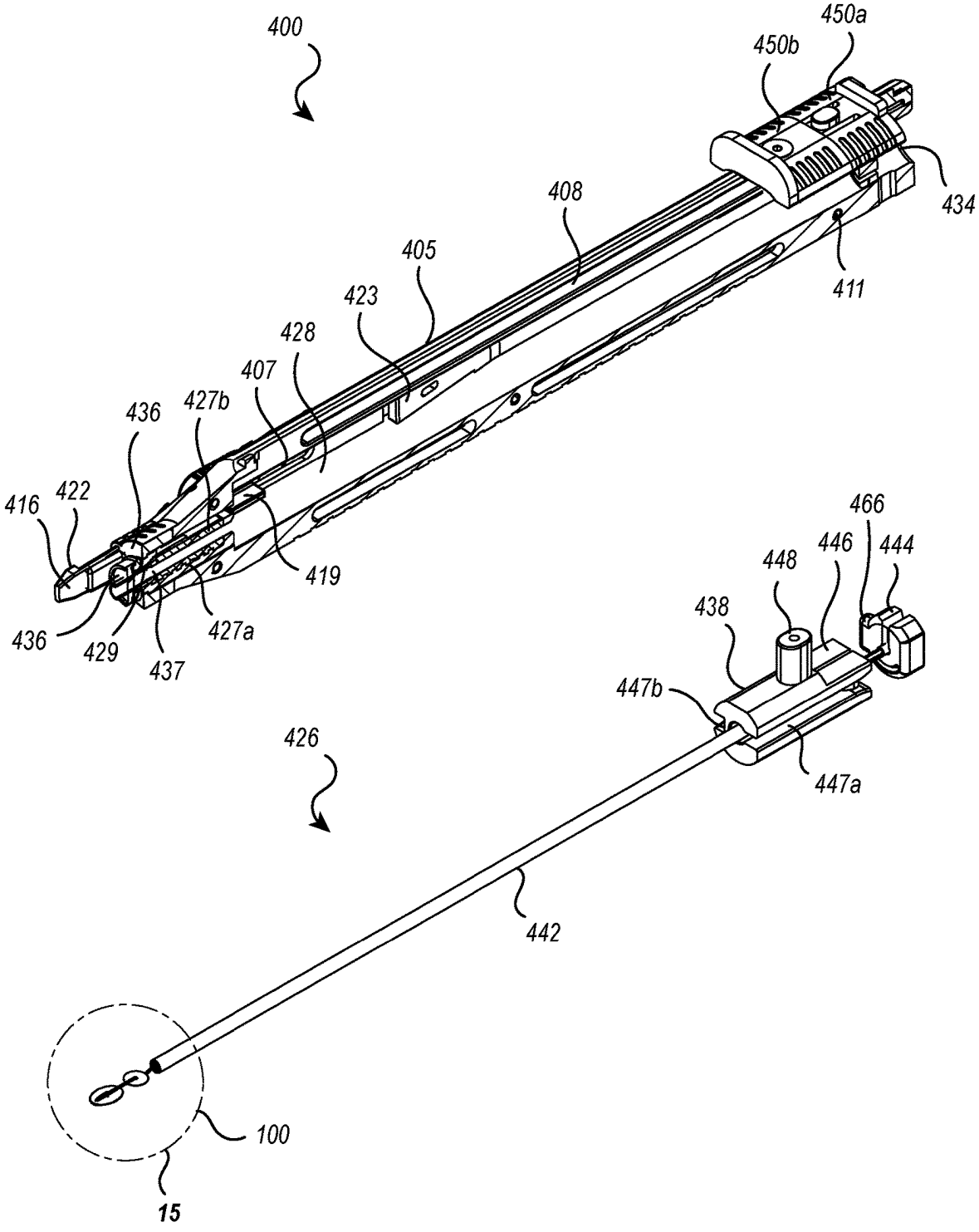
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FIG. 14C

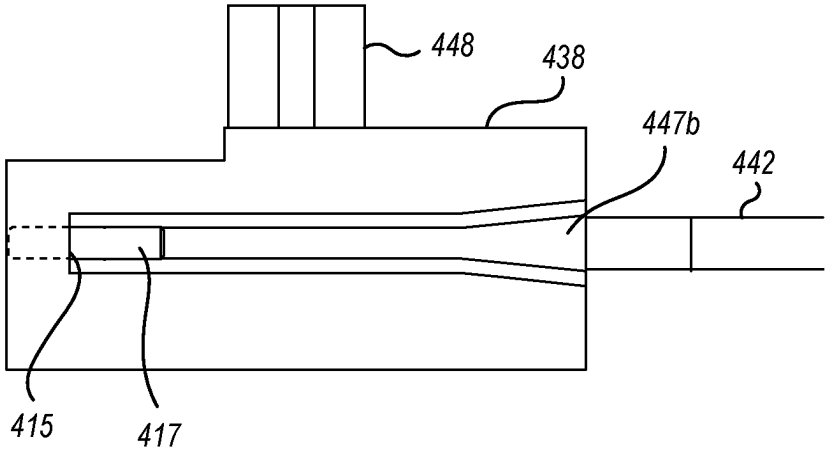

FIG. 14D

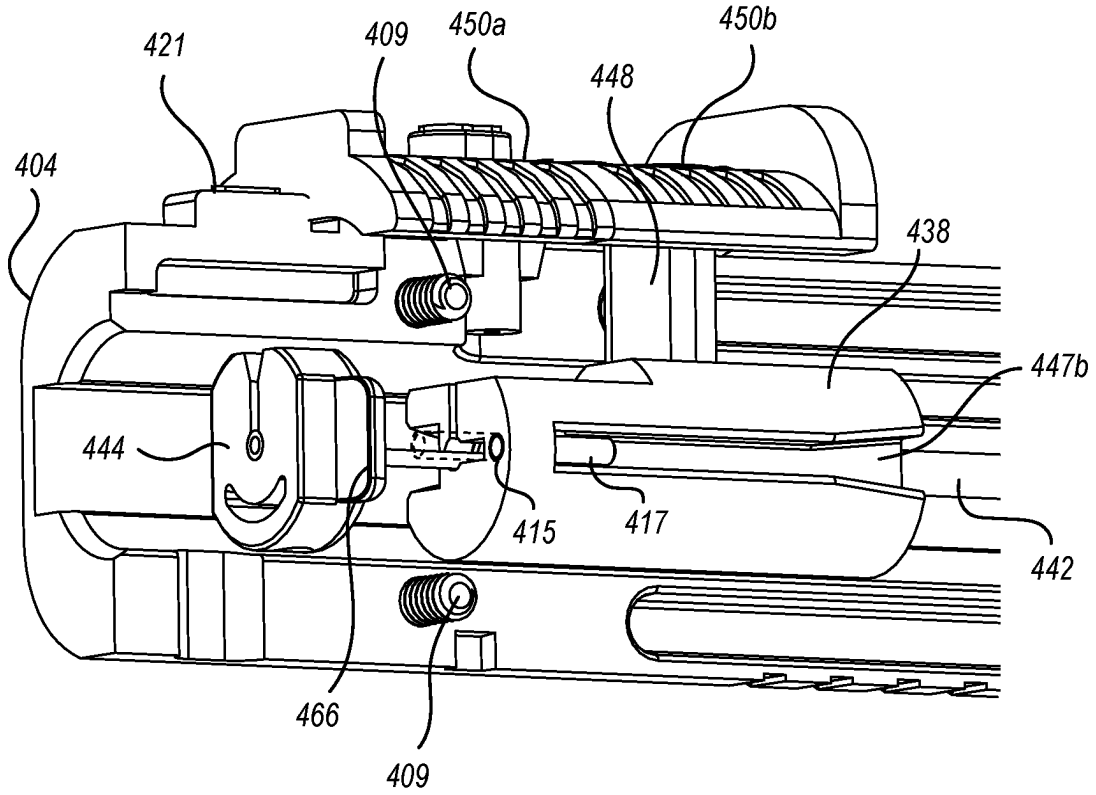

FIG. 14E

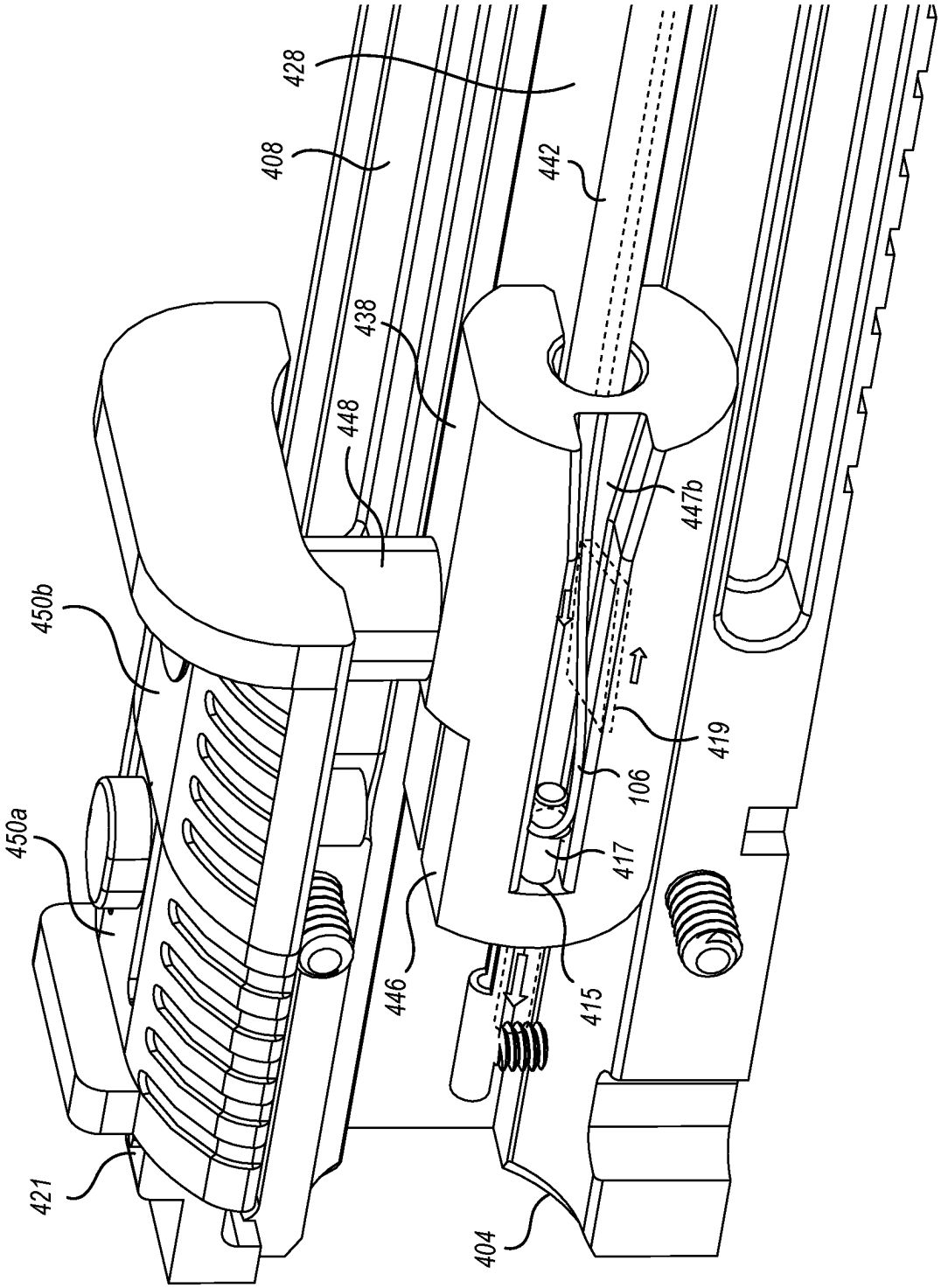

FIG. 14F

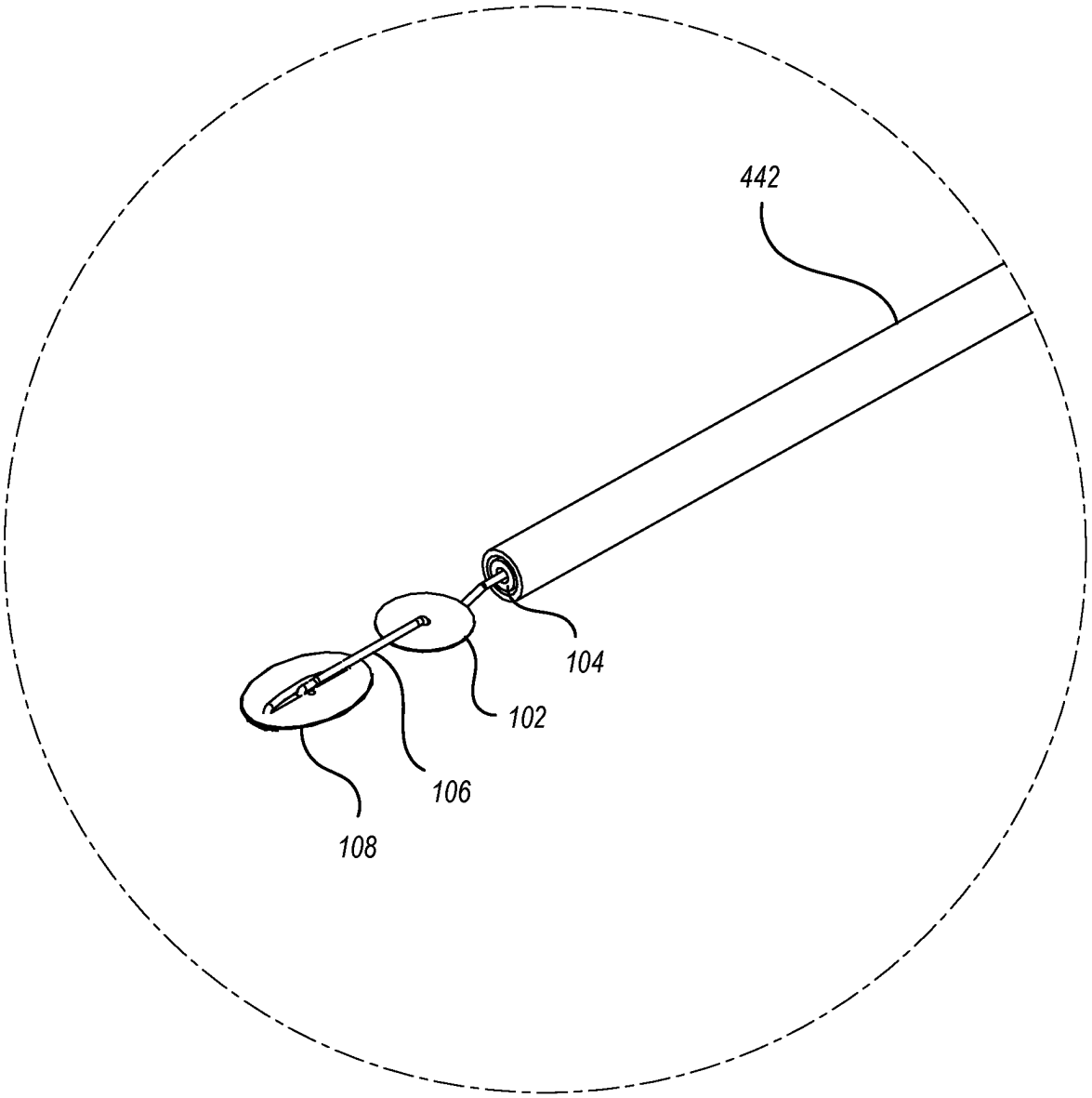

FIG. 15

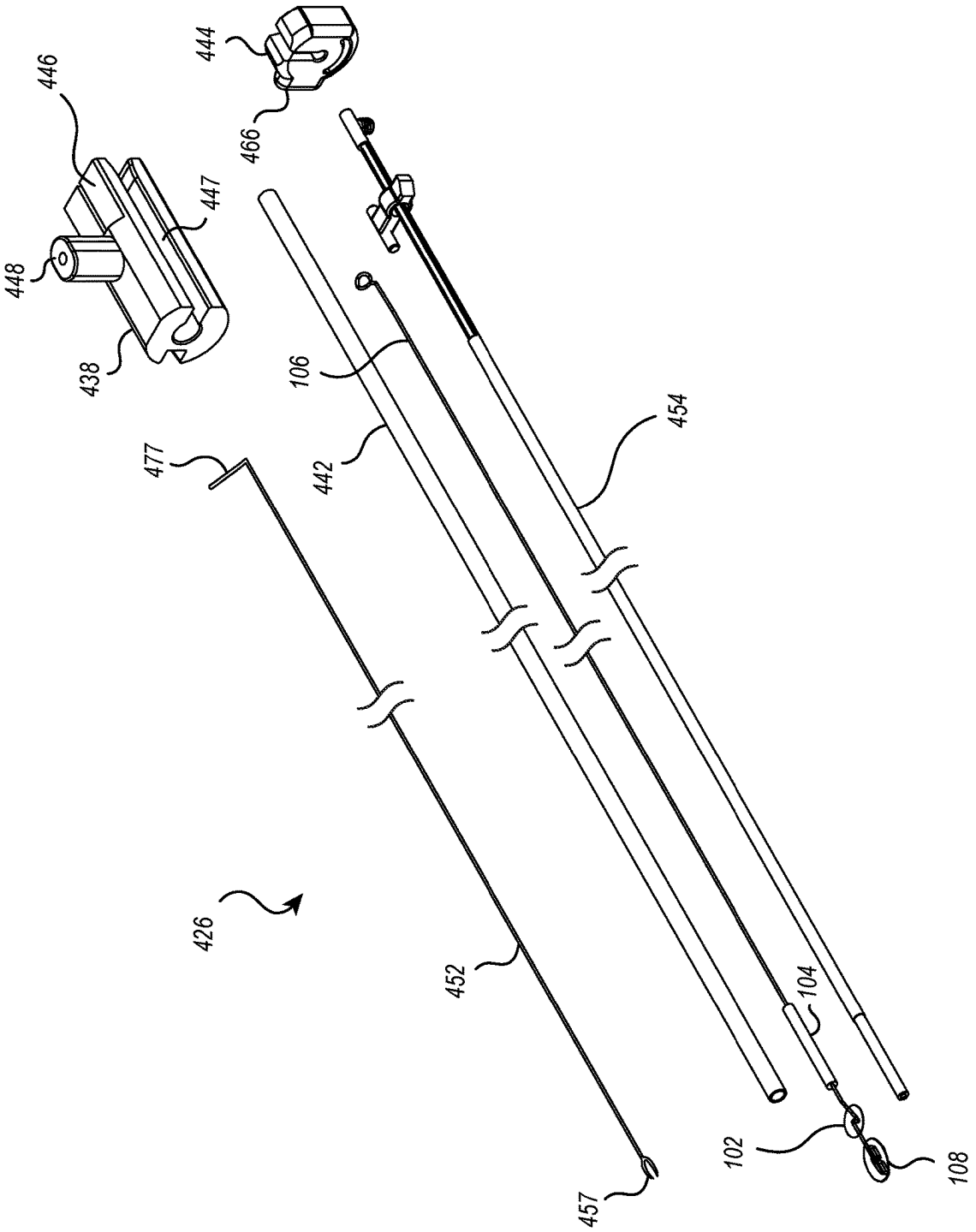

FIG. 16

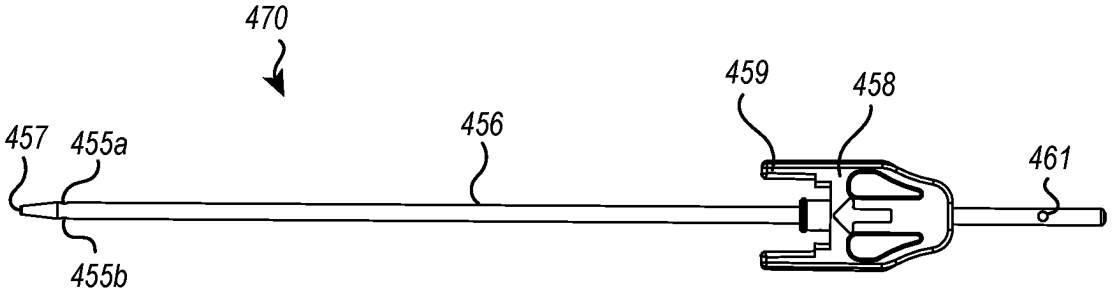

FIG. 17A

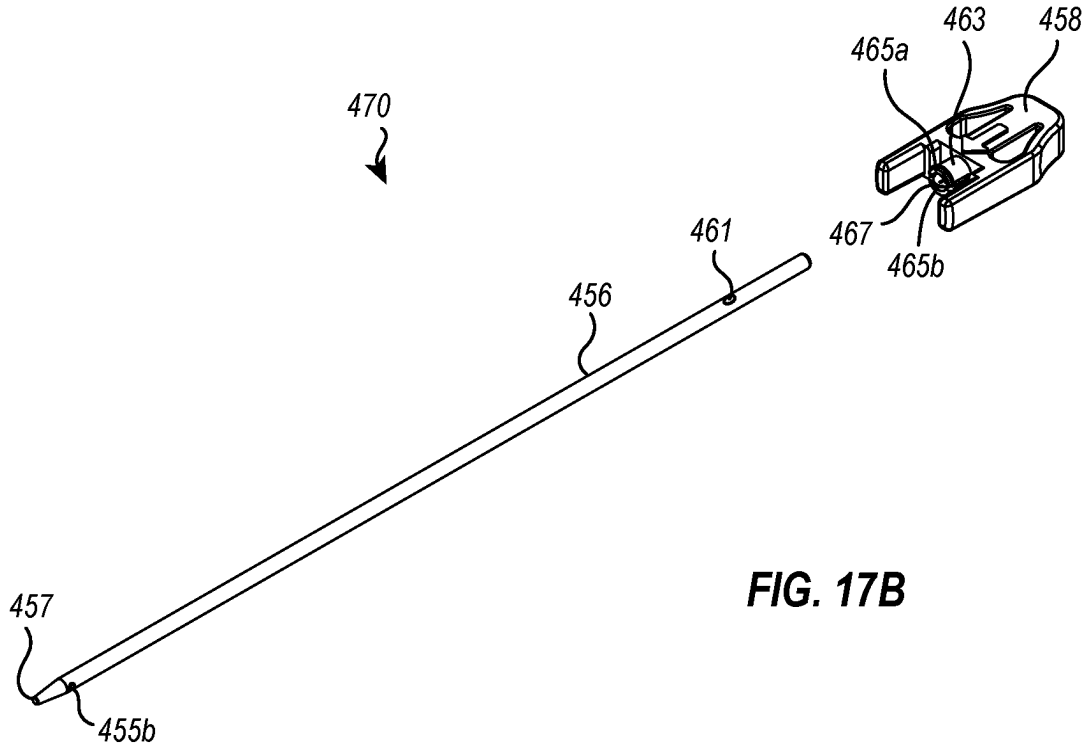

FIG. 17B

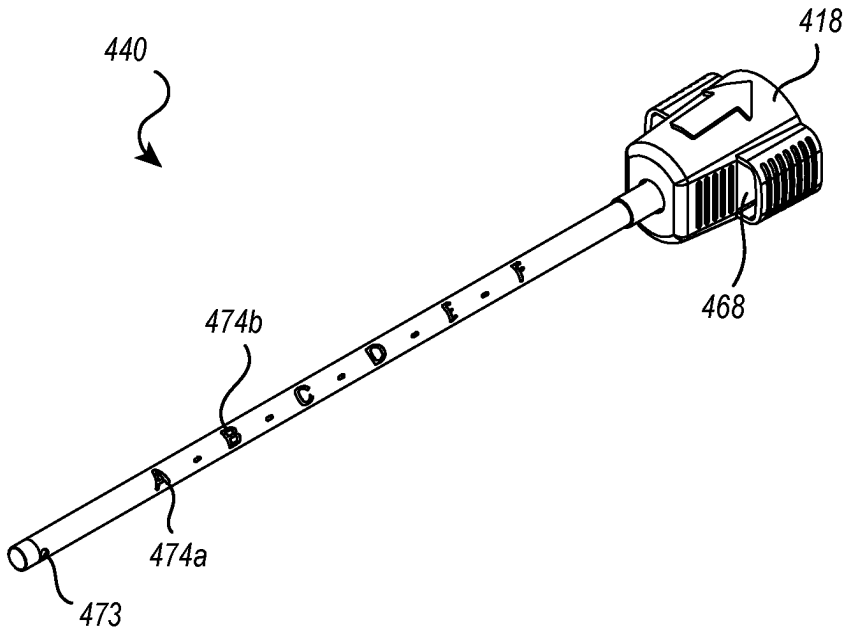

FIG. 18A

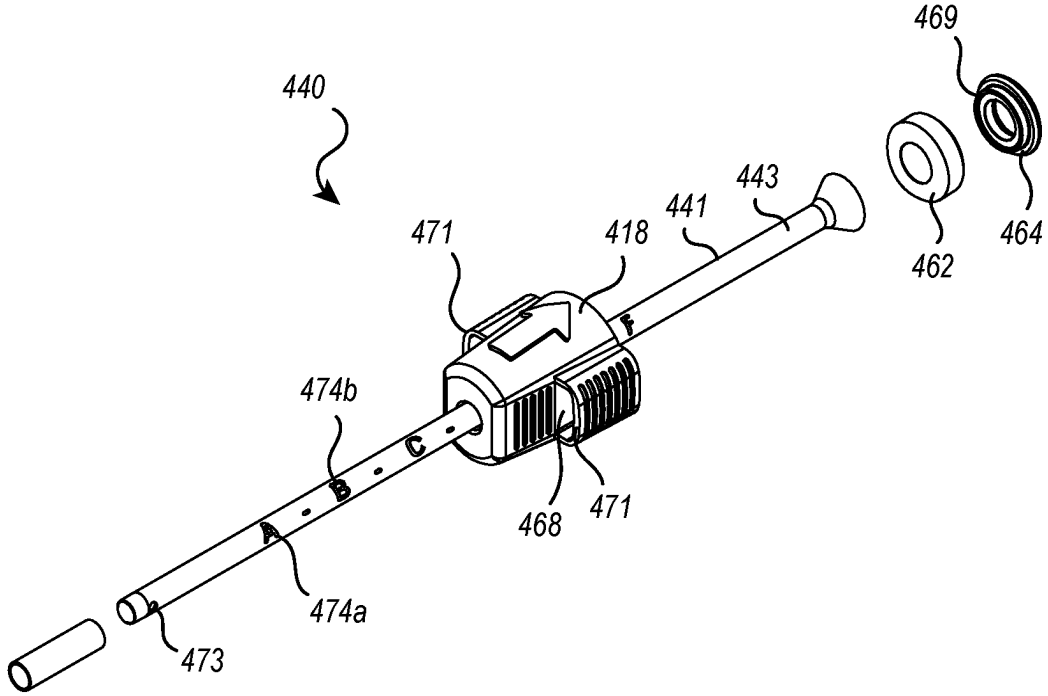

FIG. 18B

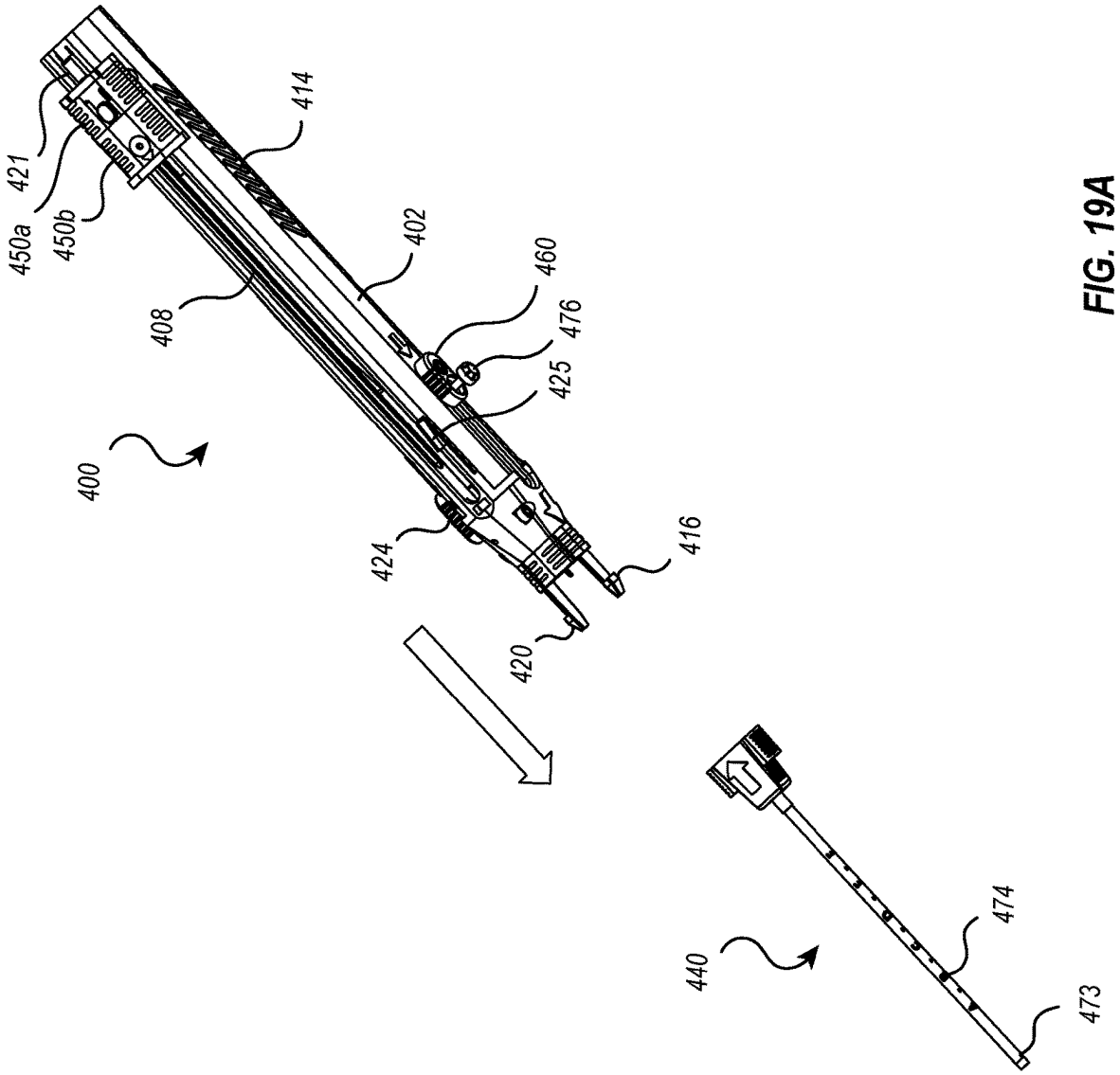
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FIG. 19A

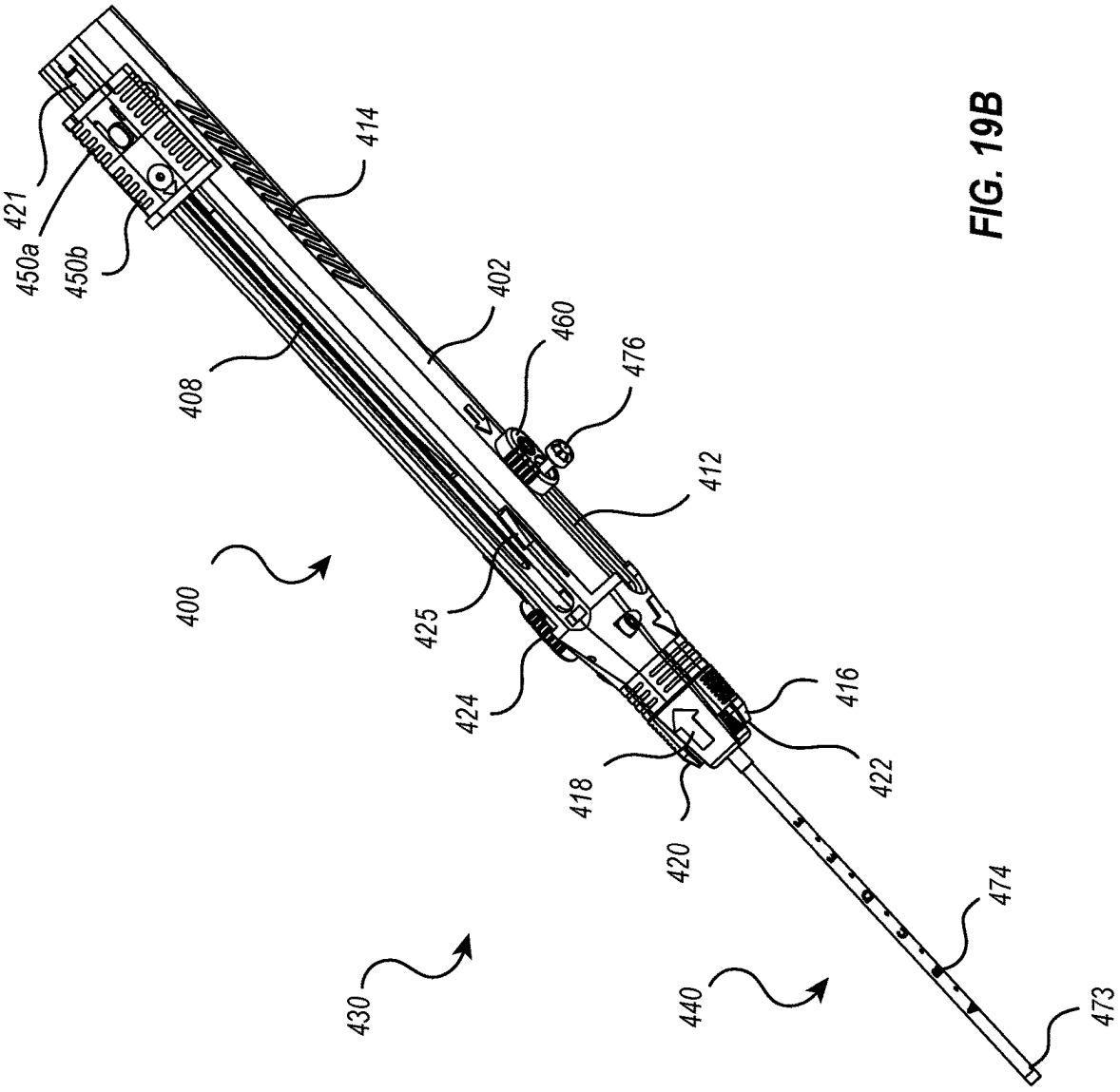
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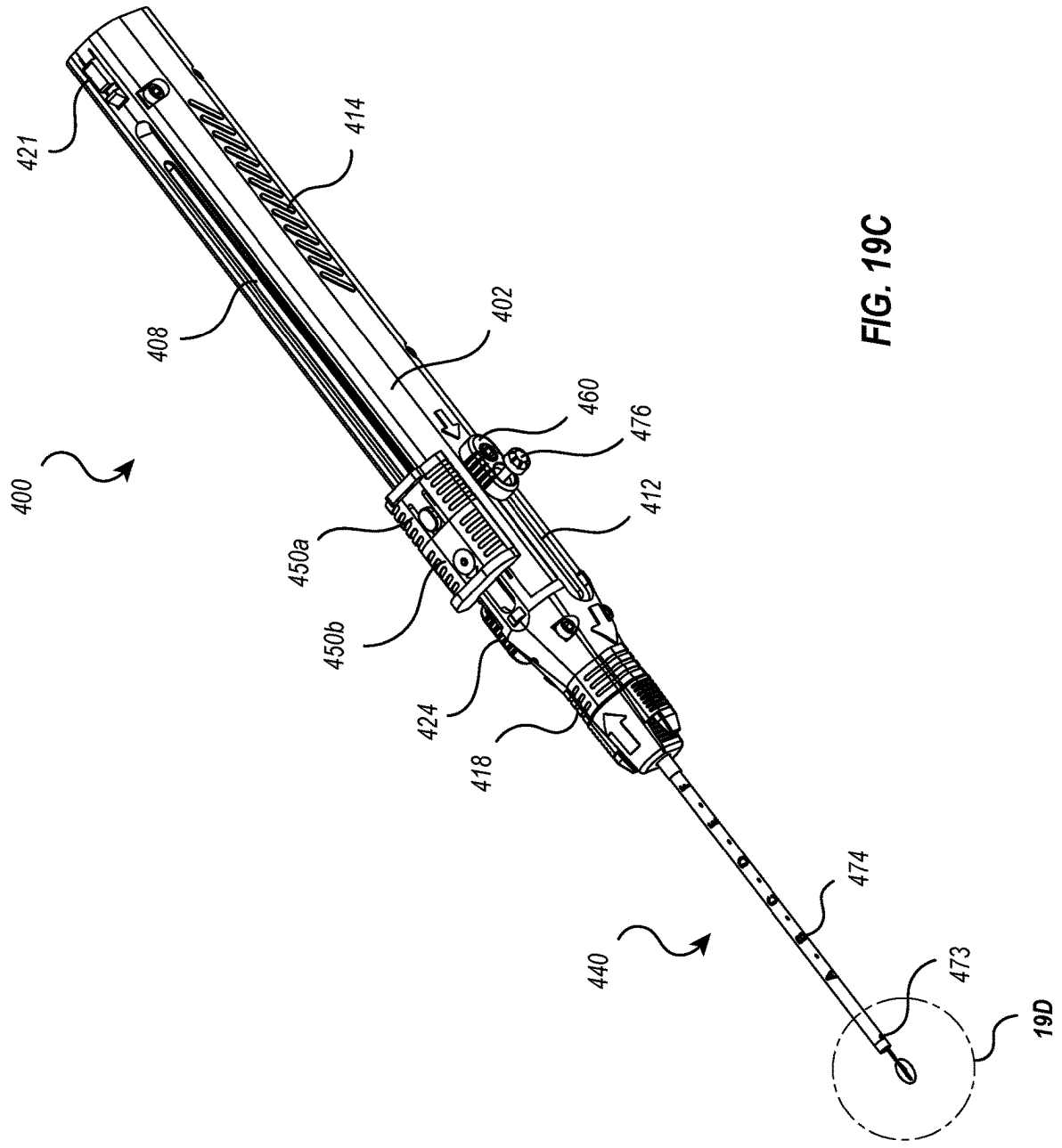
FIG. 19B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19D

FIG. 19C

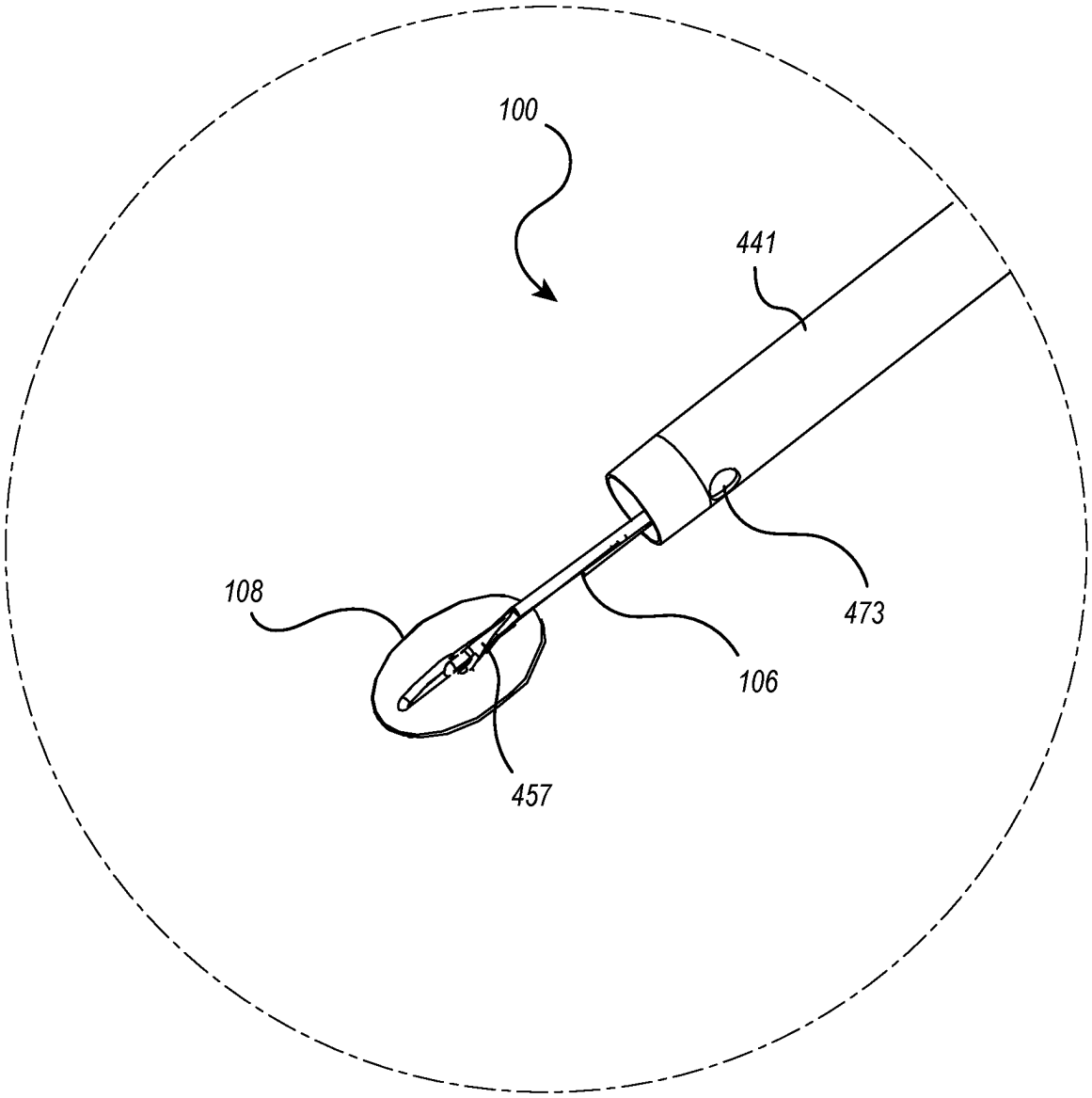

FIG. 19D

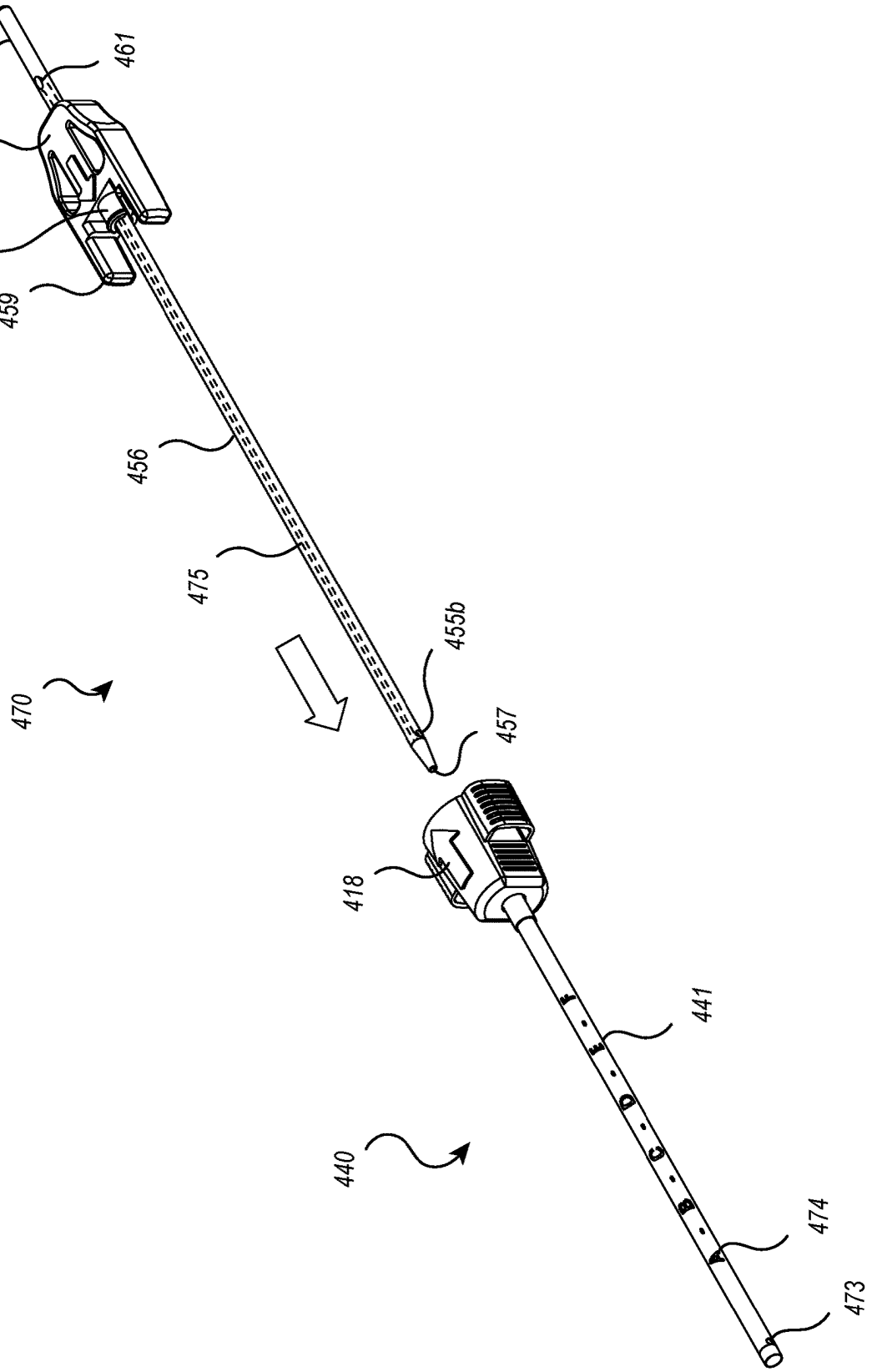

FIG. 20A

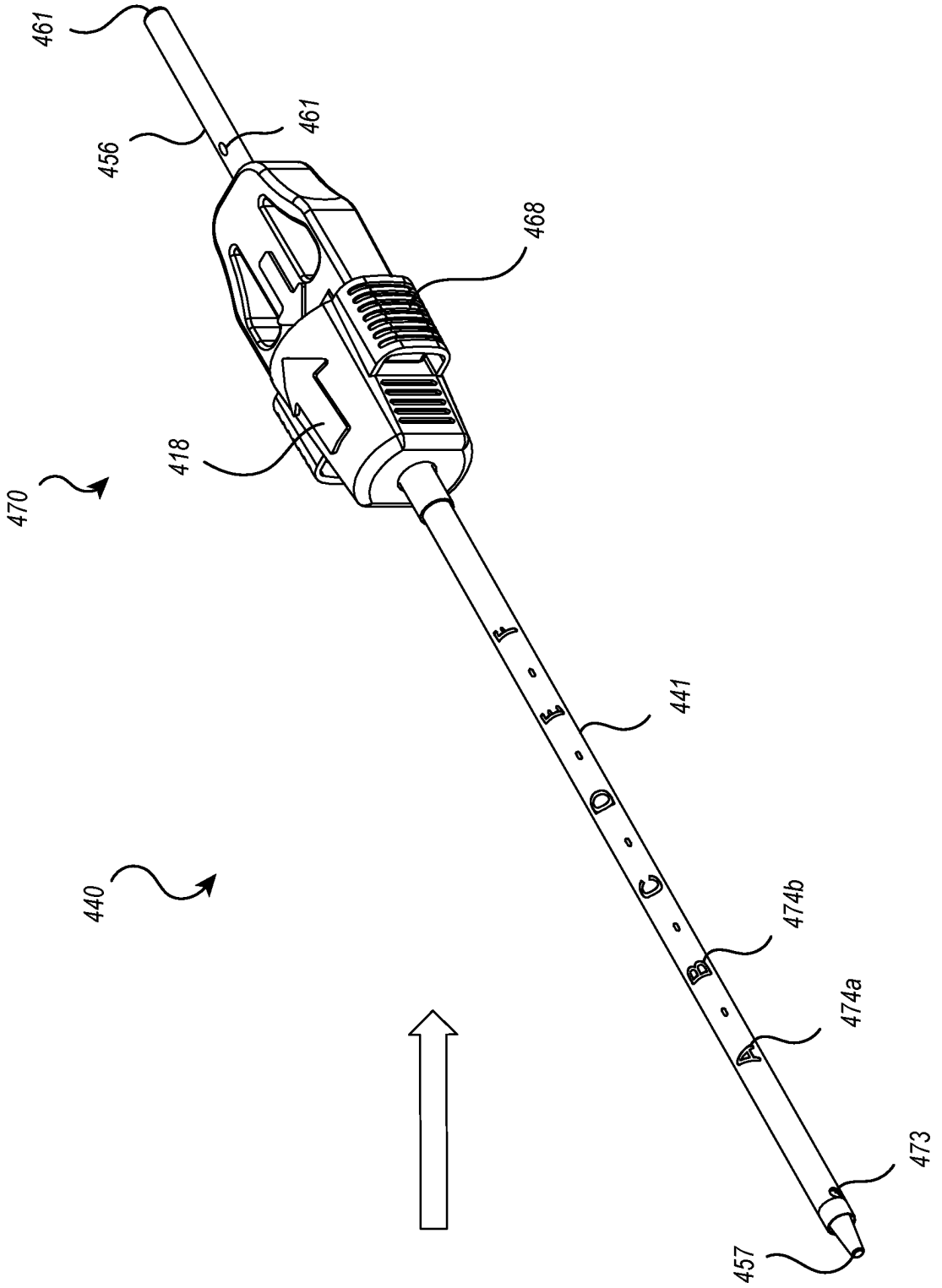

FIG. 20B

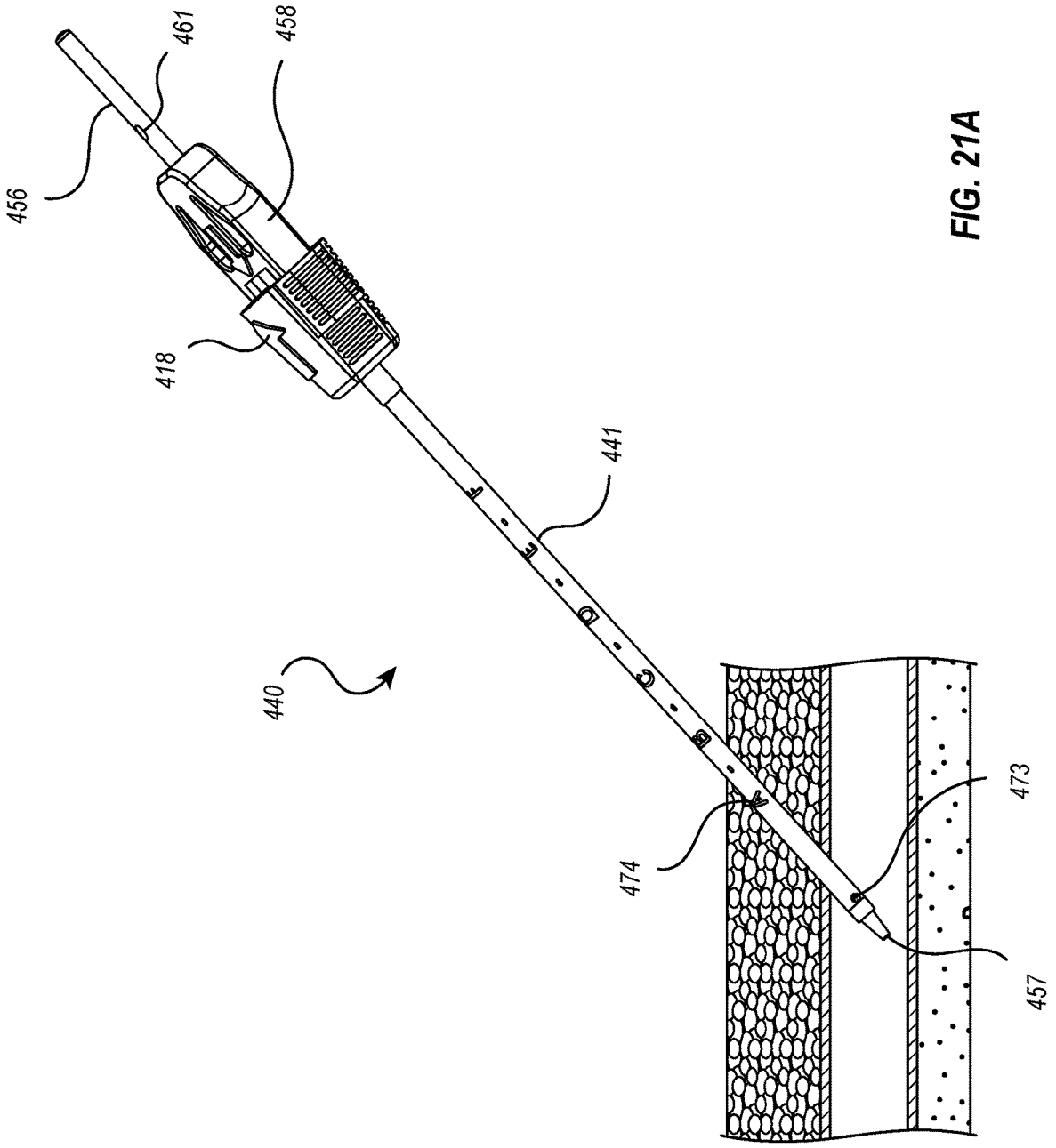

FIG. 21A

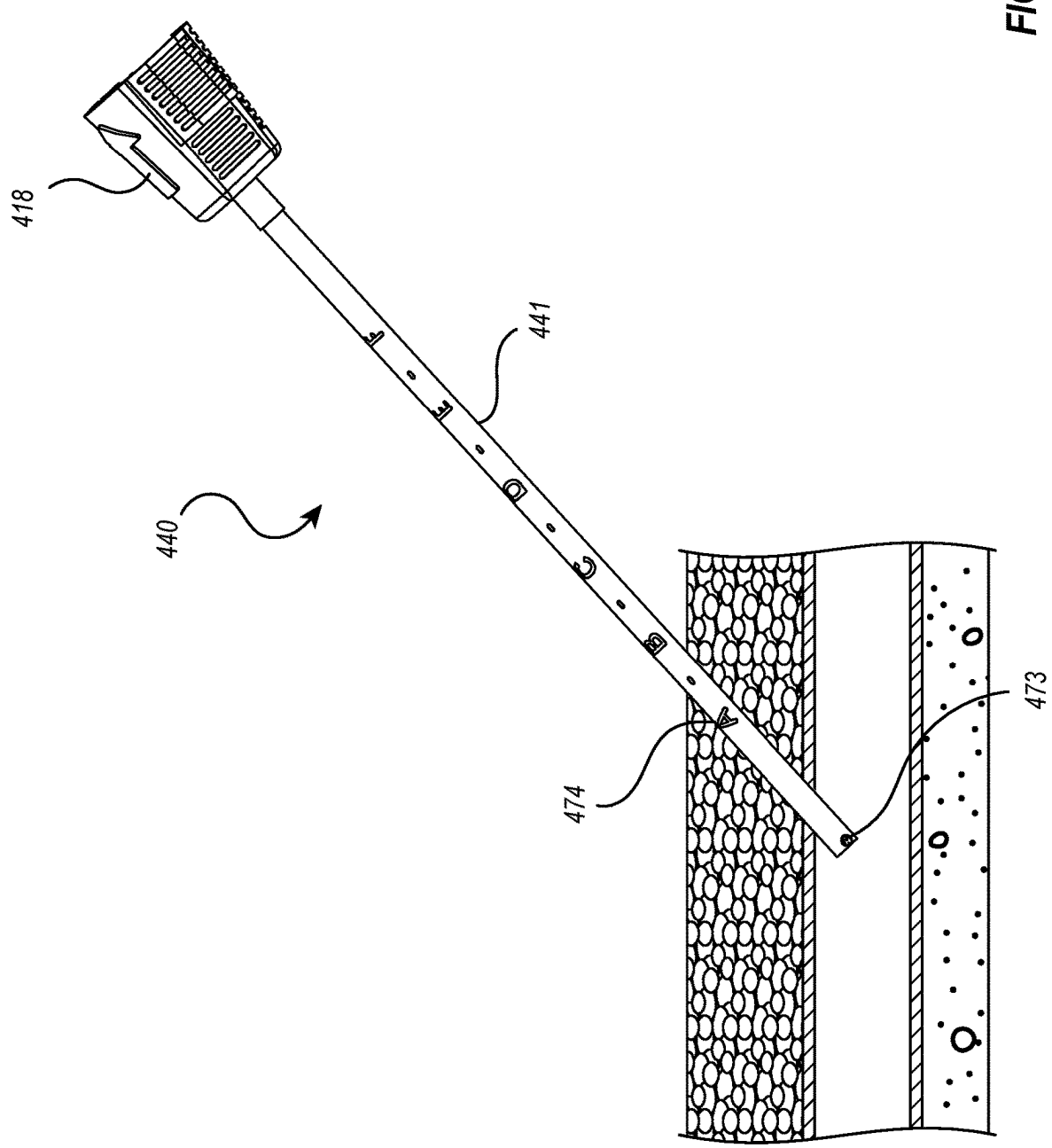

FIG. 21B

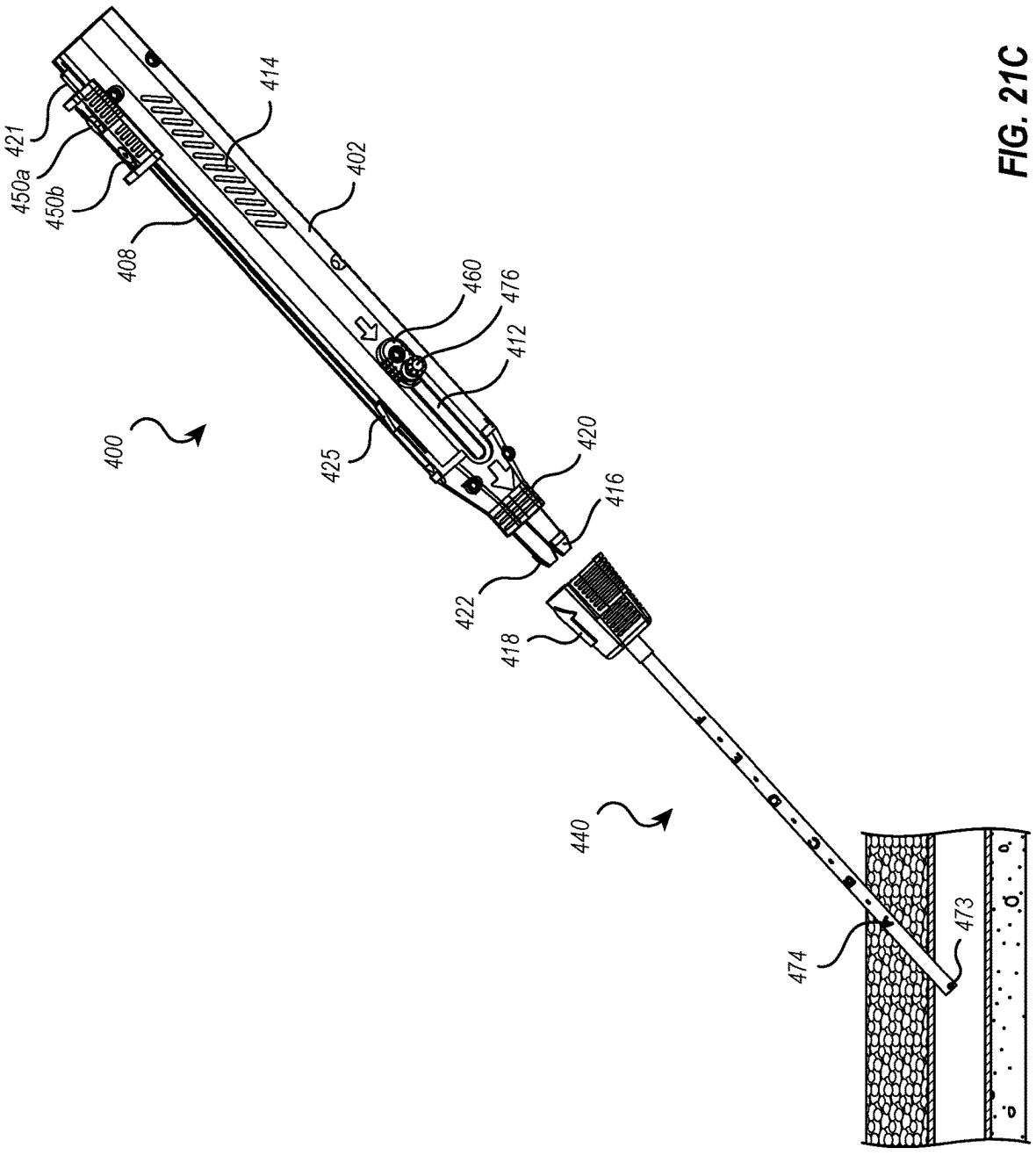
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FIG. 21C

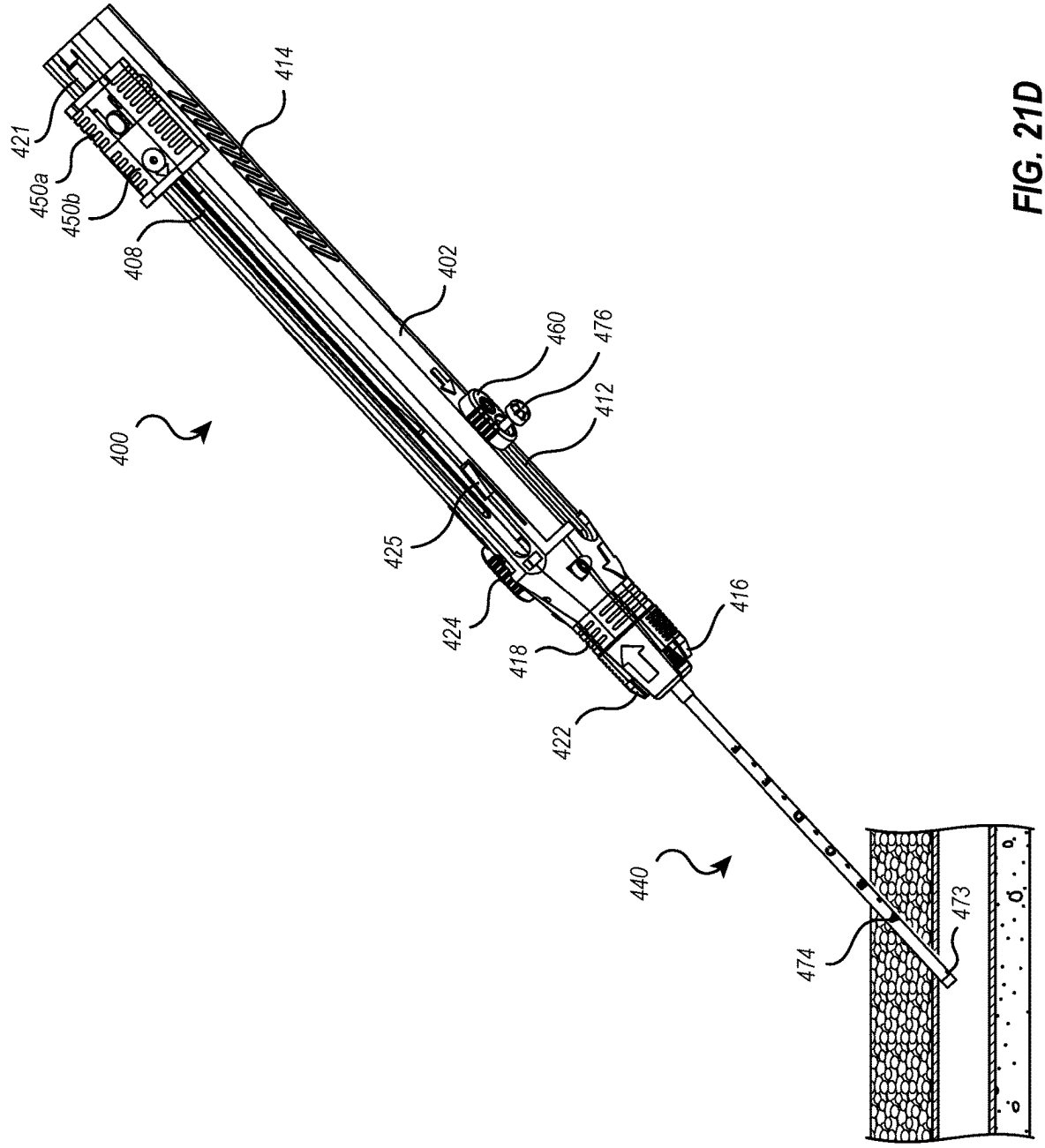
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FIG. 21D

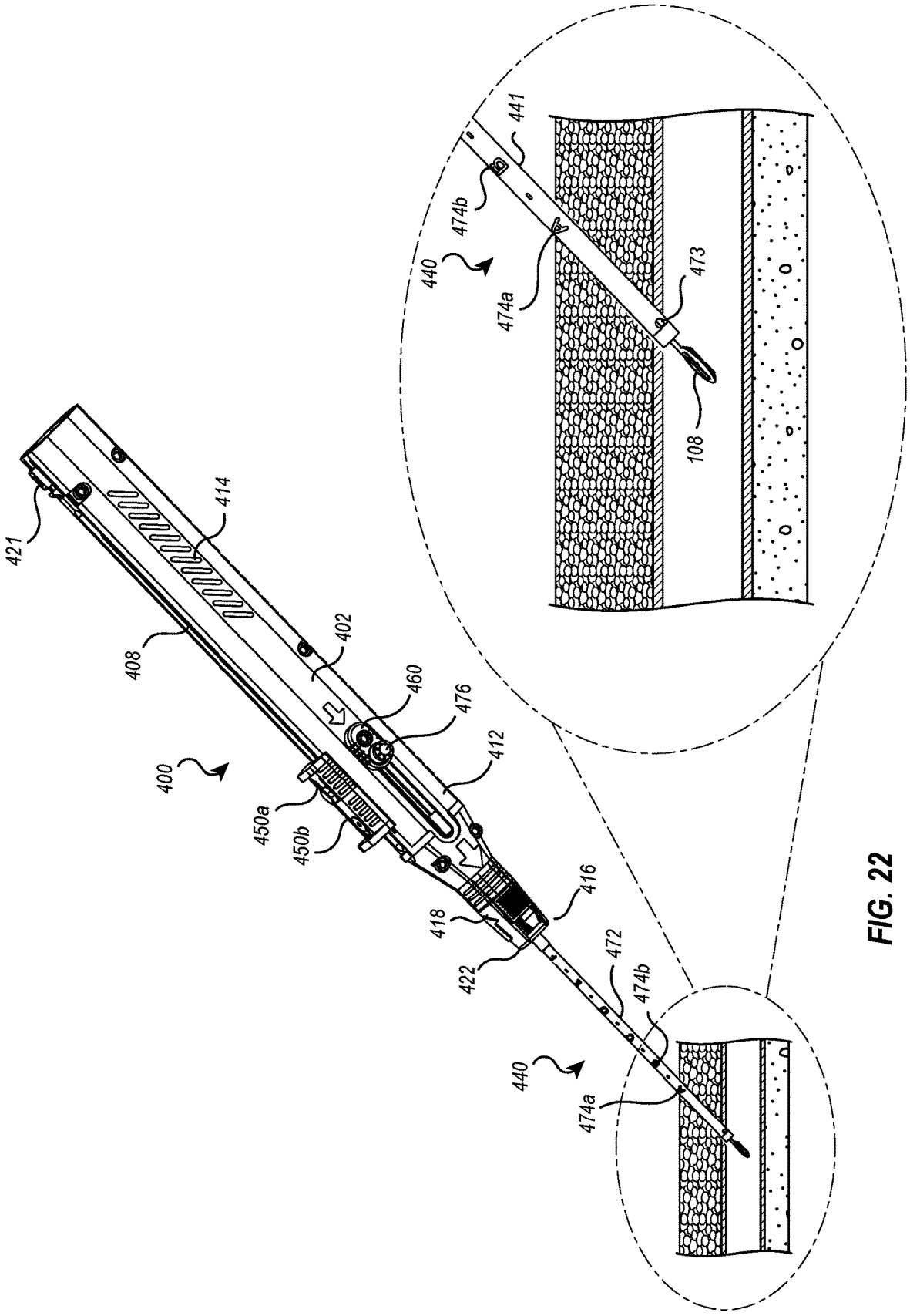
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FIG. 22

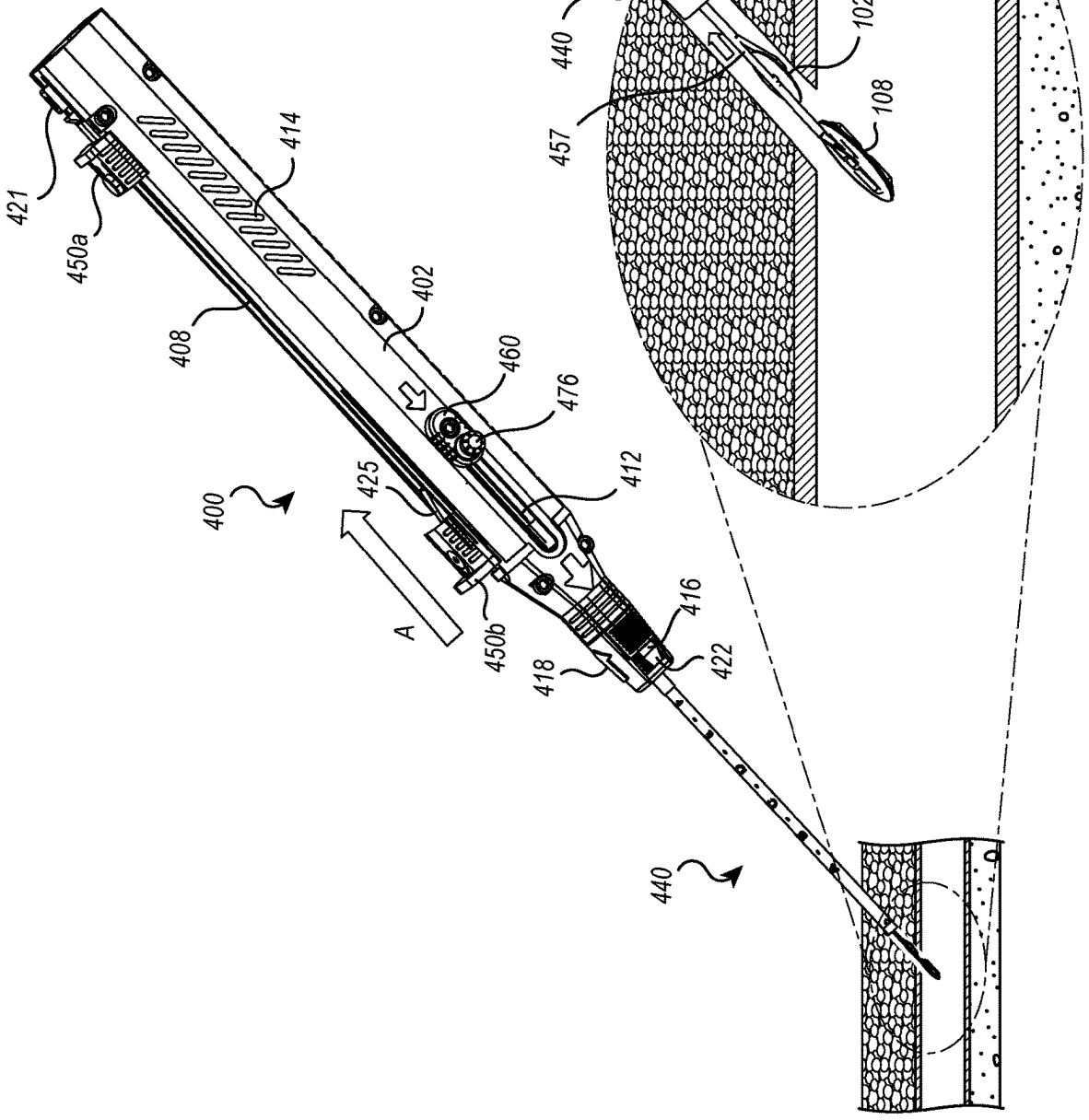
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FIG. 23A

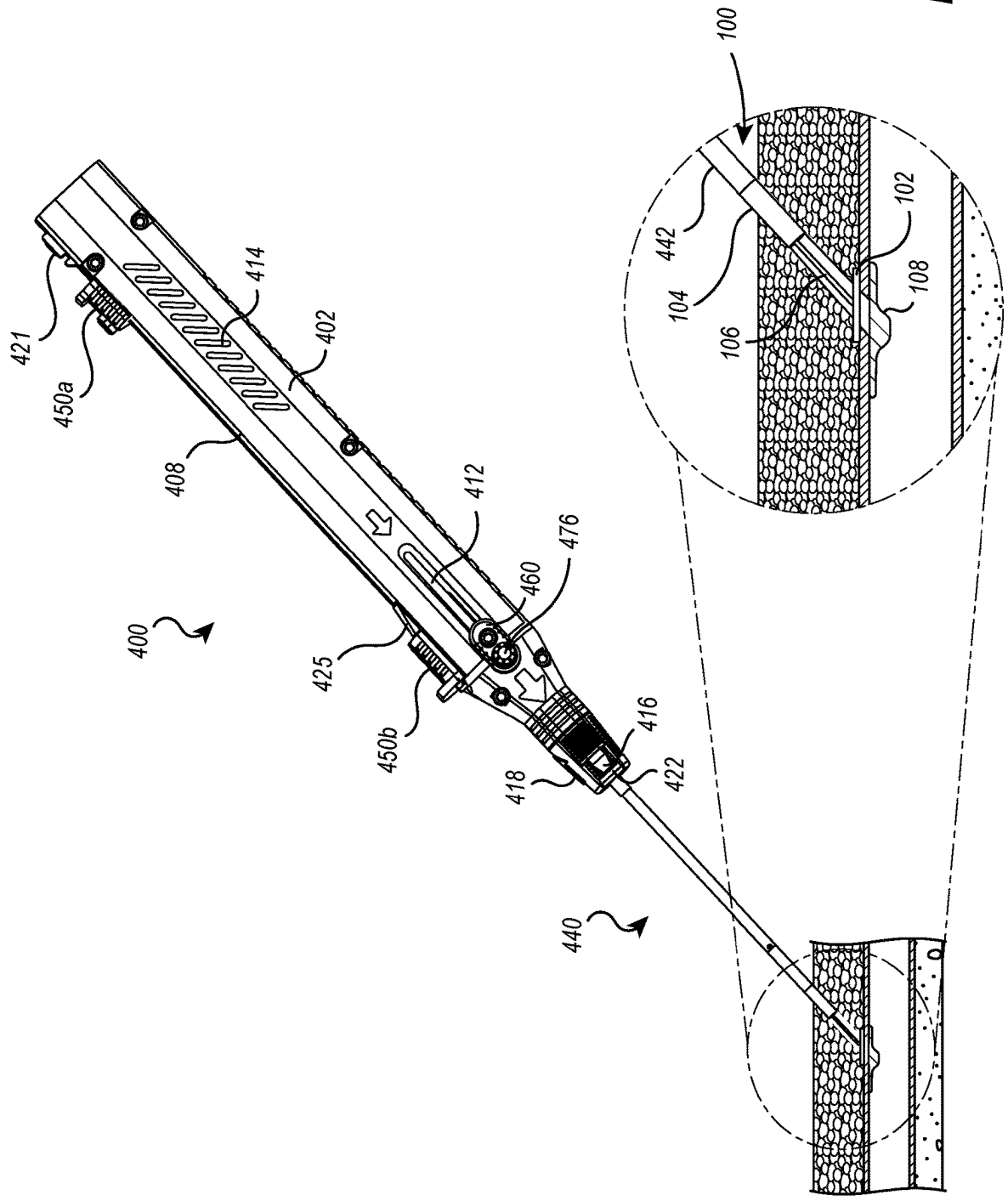
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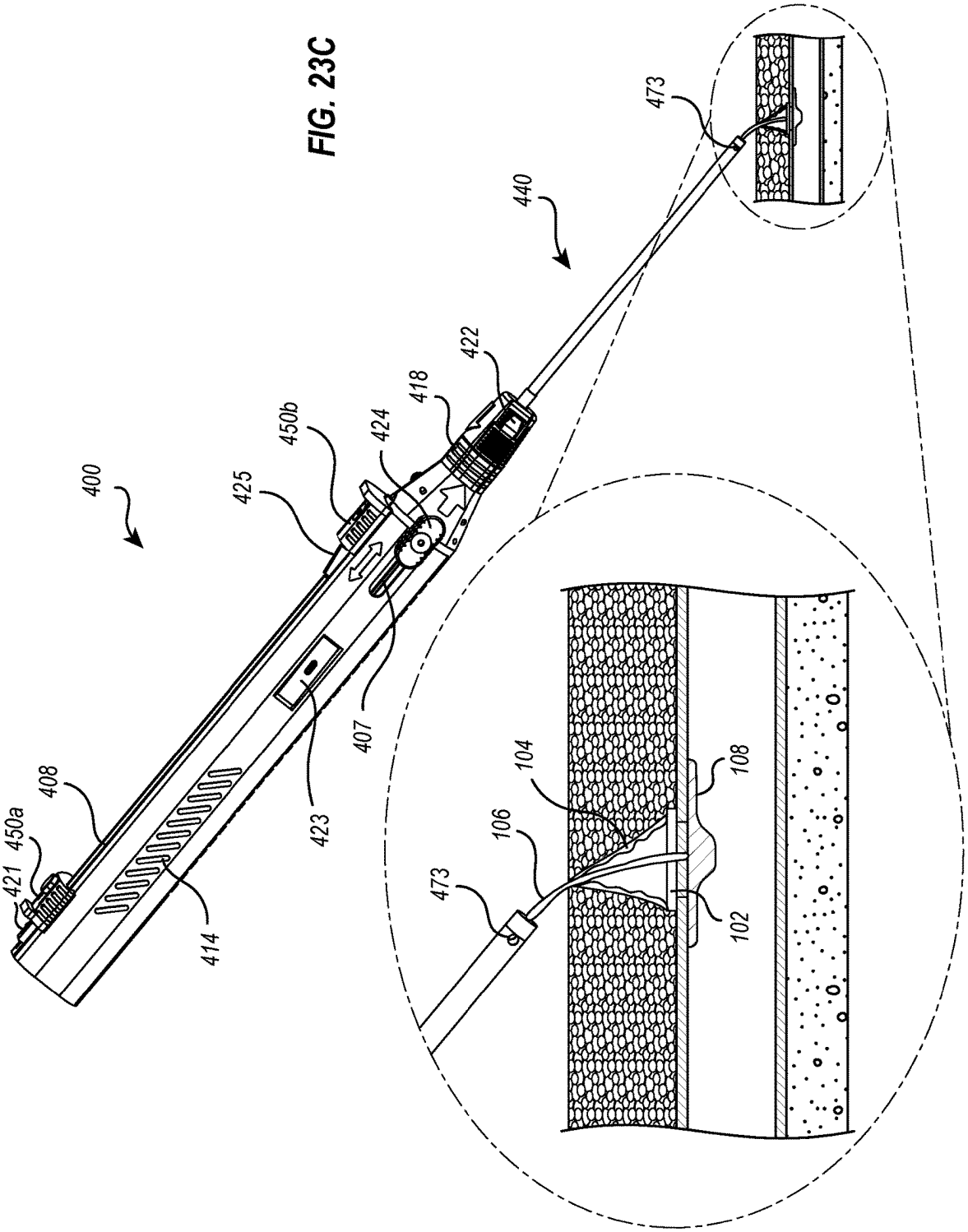
FIG. 23B

FIG. 23C


400
440
473
422
418
424
450b
425
407
423
414
408
450a
421
104
106
108
102

VESSEL CLOSURE DEVICE WITH IMPROVED SAFETY AND TRACT HEMOSTASIS

CROSS REFERENCE

This application claims the benefit of priority to U.S. Provisional Patent Application Ser. No. 63/090,556, filed Oct. 12, 2020, and to U.S. Provisional Patent Application Ser. No. 63/114,202, filed Nov. 16, 2020, the disclosures of which are incorporated herein in their entireties.

BACKGROUND

1. The Field of the Invention

The present disclosure relates generally to systems, devices, and methods for blocking an opening in body lumens. More particularly, the present disclosure relates to techniques for percutaneous closure of arterial and venous puncture sites, which are usually accessed through a tissue tract.

2. The Relevant Technology

A number of diagnostic and interventional vascular procedures are now performed translumenally. A catheter is introduced to the vascular system at a convenient access location and guided through the vascular system to a target location using established techniques. Such procedures require vascular access, which is usually established during the well-known Seldinger technique. Vascular access is generally provided through an introducer sheath, which is positioned to extend from outside the patient body into the vascular lumen. When vascular access is no longer required, the introducer sheath is removed and bleeding at the puncture site stopped.

One common approach for providing hemostasis (the cessation of bleeding) is to apply external force near and upstream from the puncture site, typically by manual compression. This approach suffers from a number of disadvantages. For example, the manual compression procedure is time consuming, frequently requiring one-half hour or more of compression before hemostasis is achieved. Additionally, such compression techniques rely on clot formation, which can be delayed until anticoagulants used in vascular therapy procedures (such as for heart attacks, stent deployment, non-optical PTCA results, and the like) wear off. The anticoagulants may take two to four hours to wear off, thereby increasing the time required before completion of the manual compression procedure.

The manual compression procedure is uncomfortable for the patient and frequently requires analgesics to be tolerable. Moreover, the application of excessive pressure can at times totally occlude the underlying blood vessel, resulting in ischemia and/or thrombosis. Following manual compression, the patient typically remains recumbent from four to as much as twelve hours or more under close observation to assure continued hemostasis. During this time, renewed bleeding may occur, resulting in blood loss through the tract, hematoma and/or pseudo-aneurysm formation, as well as arteriovenous fistula formation. These complications may require blood transfusion and/or surgical intervention.

The incidence of complications from the manual compression procedure increases when the size of the introducer sheath grows larger, and/or when the patient is anticoagulated. The compression technique for arterial closure can be

risky, and is expensive and onerous to the patient. Although the risk of complications can be reduced by using highly trained individuals, dedicating such personnel to this task is both expensive and inefficient. Nonetheless, as the number and efficacy of translumenally performed diagnostic and interventional vascular procedures increases, the number of patients requiring effective hemostasis for a vascular puncture continues to increase.

Vascular closure devices were introduced to reduce the time to hemostasis, enable early ambulation and improve patient comfort. Initially, devices focused on technologies involving a suture or collagen plug. These technologies close the hole or puncture site, however, they often leave an intravascular component in the vessel which can cause complications and result in residual bleeding or tract ooze. Some amount of slow and steady tract bleeding is a common occurrence. This bleeding usually requires direct management by a trained health care professional until it is completely stopped. Anticoagulant medications typically given to catheterized patients can exacerbate bleeding and may require management with manual compression until the medication wears off.

BRIEF SUMMARY OF THE INVENTION

This application is directed to a vessel closure device for delivering rapid hemostasis at a puncture site in a wall of a blood vessel. The vessel closure device can include an intravascular anchor having one or more suture attachment points, an extravascular cap having a lumen, a sealant, and a suture connected to at least one of the one or more suture attachment points of the intravascular anchor and threaded through the lumen of the extravascular cap. Each of the intravascular anchor, extravascular cap, sealant, and suture can be formed of bioabsorbable materials.

The present invention relates to a vessel closure device for delivering immediate hemostasis at a puncture site in a wall of a blood vessel, the closure device includes an intravascular anchor comprising one or more suture attachment points, an extravascular cap having a lumen, a sealant, and a suture connected to at least one of the one or more suture attachment points of the intravascular anchor and threaded through the lumen of the extravascular cap and through the sealant to connect the intravascular anchor to the extravascular cap and to the sealant. Each of the intravascular anchor, extravascular cap, sealant, and suture are formed of bioabsorbable materials.

The present also relates to a vessel closure device having one or more of an elongate body having a flexible member and a keel (optionally with a plurality of ribs radiating from the keel to a raised edge of the elongate body), an extravascular cap being formed of an elastomeric material, the sealant being formed of polyethylene glycol (PEG), the suture having a distal suture portion and a proximal suture portion, the diameter of the lumen of the extravascular cap being smaller than the diameter of the distal suture portion, the intravascular anchor being formed or having a material selected from Polyglycolic acid (PGA), Poly-L-Latic acid (PLLA), Polycaprolactone (PCL), Poly-DL-lactic acid (PDLLA), Poly trimethylene carbonate (PTMC), and Poly para-dioxanone (PPDO), and the sealant can expand up to 4 times its original size when introduced to fluids.

A vessel closure device for delivering immediate hemostasis at a puncture site in a wall of a blood vessel, the closure device including an intravascular anchor having one or more suture attachment points, an extravascular cap having a lumen, a sealant having a lumen, and a suture

connected to at least one of the one or more suture attachment points of the intravascular anchor and threaded through the lumen of the extravascular cap and through the lumen of the sealant to connect the intravascular anchor to the extravascular cap and to the sealant. The suture can include a proximal suture portion and a distal suture portion, wherein the distal suture portion has a diameter greater than a diameter of the lumen of the extravascular cap. The distal suture portion can create an interference fit to lock the extravascular cap over the puncture site, and each of the intravascular anchor, extravascular cap, sealant, and suture are formed of bioabsorbable materials.

The present also relates to a vessel closure device having one or more of the extravascular cap is formed of flexible material, the suture being a braided suture, the sealant is threaded onto the suture at a location proximal to the extravascular cap, the sealant when activated locks the extravascular cap in place and coagulates an access tract of the puncture site providing immediate hemostasis, the intravascular anchor having an elongate body, a raised keel located on a central axis of the elongate body and spanning the length of the elongate body (optionally including one or more suture attachment points), and the sealant being formed of polyethylene glycol (PEG).

The present invention also relates to an intravascular anchor for a vessel closure device for delivering immediate hemostasis at a puncture site in a wall of a blood vessel, the intravascular anchor including an elongate body comprising a flexible membrane for conforming to the wall of the blood vessel, a keel having one or more suture attachment points, wherein the keel is an elongate member centrally located along a central axis of the elongate body, and wherein the intravascular anchor comprises a bioabsorbable material selected from Polyglycolic acid (PGA), Poly-L-Latic acid (PLLA), Polycaprolactone (PCL), Poly-DL-lactic acid (PDLLA), Poly trimethylene carbonate (PTMC), and Poly para-dioxanone (PPDO).

These and other objects and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set form hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

A description of various aspects and features of the invention will be rendered by reference to various representative embodiments thereof illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope.

FIGS. **1**A-**1**C illustrate a delivery system in which a closure device can be implemented according to one example.

FIG. **1**D illustrates an alternate delivery system for deploying the closure device according to the present invention.

FIG. **1**E illustrates a partial cross-sectional view of the alternate delivery system of FIG. **1**D.

FIG. **1**F illustrates a schematic representation of another alternate delivery system according to the present invention.

FIGS. **2**A and **2**B illustrate example embodiments of a closure device.

FIG. **3**A illustrates an embodiment of a cap of a closure device.

FIG. **3**B illustrates a cross-sectional view of the cap of FIG. **3**A.

FIG. **3**C illustrates the cap of FIG. **3**A with an adhesive layer.

FIG. **3**D illustrates a cross-sectional view of the cap of FIG. **3**C.

FIG. **4** illustrates a cross-sectional view of a closure device as applied to a vessel.

FIG. **5** illustrates a cross-sectional view of a closure device as applied to a vessel through an access tract.

FIGS. **6**A and **6**B illustrate cross-sectional views of a closure device as applied to a vessel through an access tract.

FIGS. **7**A-**7**D illustrate an embodiment of an intravascular anchor of a closure device.

FIGS. **7**E and **7**F illustrate an alternate embodiment of an intravascular anchor of a closure device.

FIGS. **7**G and **7**H illustrate an alternate embodiment of a closure device.

FIG. **8**A illustrates a lumen facing side of an alternate embodiment of an intravascular anchor.

FIG. **8**B illustrates an intima facing side of the embodiment of the intravascular anchor of FIG. **8**A.

FIG. **9**A illustrates a lumen facing side of another embodiment of an intravascular anchor.

FIG. **9**B illustrates an intima facing side of the embodiment of the intravascular anchor of FIG. **9**A.

FIG. **10**A illustrates a lumen facing side of another embodiment of an intravascular anchor.

FIG. **10**B illustrates an intima facing side of the embodiment of the intravascular anchor of FIG. **10**A.

FIGS. **11**A-**11**D illustrate a method of delivering a closure device to an access site on a vessel.

FIG. **12** illustrates an alternate embodiment of a delivery system in which a closure device can be implemented.

FIGS. **13**A and **13**B illustrate side views of a handle assembly of the delivery system of FIG. **12**.

FIG. **13**C illustrates a perspective view of the handle assembly of FIGS. **13**A and **13**B.

FIG. **13**D illustrates a top plan view of the handle assembly of FIGS. **13**A-**13**C.

FIG. **13**E illustrates a cross-sectional view of the handle assembly of FIGS. **13**A-**13**D.

FIG. **13**F illustrates an enlarged view of **13**F of the handle assembly as shown in FIG. **13**E.

FIG. **14**A illustrates an exploded view of the handle assembly of the delivery system.

FIG. **14**B illustrates an enlarged view of a chamber of the handle assembly of FIGS. **12**-**14**A.

FIG. **14**C illustrates a cross-sectional view of the handle assembly of FIGS. **13**A-**13**E with an implant assembly removed from the handle assembly.

FIG. **14**D illustrates a cross-sectional view of a slider of the implant assembly of FIG. **14**C.

FIGS. **14**E and **14**F illustrates a perspective views of the slider of FIG. **14**D as positioned within a handle body.

FIG. **15** illustrates the implant assembly of FIGS. **14**A and **14**C.

FIG. **16** illustrates an exploded view of the implant assembly of FIG. **15**.

FIGS. **17**A and **17**B illustrate a dilator tube for implantation of a closure device.

FIGS. **18**A and **18**B illustrate a delivery sheath of a delivery system.

FIGS. **19**A and **19**B illustrate the insertion and attachment of a handle assembly to a delivery sheath.

FIG. **19**C illustrates the delivery system of FIG. **19**A in a partially-deployed state.

FIG. **19**D illustrates a close up view of the implant assembly partially deployed from the delivery sheath as shown in FIG. **19**B.

FIGS. **20**A-**20**B illustrate a dilator tube being inserted into a deliver sheath according to a method of delivering a closure device to an access site on a vessel.

FIG. **21**A illustrates the combination dilator tube and delivery sheath being inserted through a tissue tract according to according to a method of delivering a closure device to an access site on a vessel.

FIG. **21**B illustrates the delivery sheath in the tissue tract according to a method of delivering a closure device to an access site on a vessel.

FIGS. **21**C-**21**D illustrates the handle assembly being connected to the delivery sheath according to a method of delivering a closure device to an access site on a vessel.

FIG. **22** illustrates partial deployment of the closure device according to a method of delivering a closure device to an access site on a vessel.

FIGS. **23**A-**23**C illustrate deployment of the closure device and removal of the handle assembly and delivery sheath according to a method of delivering a closure device to an access site on a vessel.

DETAILED DESCRIPTION

One or more specific embodiments of the present disclosure will be described below. In an effort to provide a concise description of these embodiments, some features of an actual embodiment may be described in the specification. It should be appreciated that in the development of any such actual embodiment, as in any engineering or design project, numerous embodiment-specific decisions will be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one embodiment to another. It should further be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

One or more embodiments of the present disclosure may generally relate to apparatuses, systems, and methods to provide a closure device or closure implant configured to close an opening formed in tissue. The closure devices or closure implants can be configured to provide immediate or substantially immediate hemostasis at the vessel puncture and delivery of a hemostatic agent in the access tract to eliminate track ooze. The configuration of the disclosed closure devices or closure implants can prevent extravascular components from passing through the puncture site, as well as improved resistance to fracture and possible embolization.

One or more embodiments of the present disclosure may also generally related to apparatuses, systems, and methods used to close an opening, with a portion of the closure device or closure implants temporary remaining within the patient to close the opening and being subsequently degraded, absorbed, or resorbed over a period of time.

While the present disclosure will describe a particular implementation of apparatuses and systems, with associated methods, for removing closing an opening in tissue, it should be understood that any of systems, apparatuses, and methods described herein may be applicable to other uses, including and not limited to closing existing or formed openings in tissue or body lumens in other locations with a patient's anatomy. Additionally, elements described in relation to any embodiment depicted and/or described herein may be combinable with elements described in relation to any other embodiment depicted and/or described herein.

Vessel Closure Delivery System

The present disclosure relates to devices, systems, and methods for closing an opening in a blood vessel. For example, the present disclosure includes an anchor, such as an intravascular anchor formed from, in one configuration, a bioabsorbable, bioresorbable, and/or biodegradable material. The anchor may be passed through an opening defined in a wall of a blood vessel and deployed. The anchor can then be drawn proximally to draw the anchor into contact with a distal side of the blood vessel lumen wall. A closure element, such as an extravascular cap, can then be deployed to close the puncture.

In at least one example, once deployed within a blood vessel, the anchor (and optionally the cap) may degrade, absorb, or resorb in a predetermined amount of time, such as between about 36-72 hours, in less than 48 hours, less than about 36 hours, in a day, less than an hour, or some other amount of time as desired. The rapid degradation, absorption, or resorption of one or more components of the device can allow the anchor, for example, to be left in place after the closure device or closure implant has been deployed by obviating the need for removal of the anchor. By leaving the anchor in place until it degrades, absorbs, or resorbs, damage that may occur by drawing the anchor through the closed puncture and/or the deployed closure element can be reduced or eliminated.

In addition, the degradation, absorption, or resorption time of the anchor may fall within the time frame of the action of an anti-thrombotic medication being used in conjunction with the treatment of a patient. Accordingly, the closure device or closure implant of the present disclosure may reduce the risk of formation of intra-arterial clots associated with the closure of the blood vessel puncture site.

While reference has been made to the anchor remaining in the blood vessel and degraded, absorbed, or resorbed by the patient's body, it will be understood that in other configurations the anchor may be deployed and subsequently removed once sufficient closure of the puncture has occurred.

Reference is now made to FIGS. **1**A-**1**B, which illustrates a closure device delivery system or closure implant delivery system **30** according to one example. As shown in FIGS. **1**A-**1**B, the delivery system **30** may include a delivery sheath **40** with a nested set of actuators **50**, **60**, and **70** that are configured to cooperate to deploy a closure device or closure implant **100** including an anchor **108**, such as an intravascular "foot" or anchor, a closure element, such as a cap **102** (see FIGS. **2**-**4**), a fluid-blocking component **104**, such as a sealant (see FIGS. **2**-**4**) (the term fluid-blocking component and sealant will be used interchangeably herein), and a suture element **106**. For instance, the actuator **50** can be used to deploy the anchor **108**, the actuator **60** can be used to deploy the cap **102**, and the actuator **70** can be used to deploy the fluid-blocking component **104**. In at least one example, the delivery sheath **40** is configured to house the anchor **108**, the cap **102**, and the fluid-blocking component **104** while the actuators **50**, **60**, and **70** are configured to deploy the anchor **108**, the cap **102**, and the fluid-blocking component **104**, respectively from the delivery sheath **40**. The exemplary delivery sheath **40**, actuators **50**, **60**, and **70**, anchor **108**, and closure device **100** of FIG. **1**A will be discussed in more detail with reference to FIG. **1**B.

While the set of actuators **50**, **60**, and **70** are illustrated as being coaxially disposed within the delivery sheath **40**, the actuators **50**, **60**, and **70** can be non-coaxially disposed in the delivery sheath **40**, such as illustrated in FIGS. **1**D and **1**E where the actuator **50** is disposed to a side of the actuator **60**. Additionally, returning to FIGS. **1**A-**1**B, while the following discussion provides one manner by which specific actuators can be used to deploy the anchor **108**, the cap **102**, and the fluid-blocking component **104**, it will be understood by those skilled in the art that one of the actuators **50**, **60**, and **70** can deploy any combination of the anchor **108**, the cap **102**, and the fluid-blocking component **104** in any order or sequence. For instance, while the actuator **60** can deploy the cap **102** and the actuator **70** can deploy the fluid-blocking component **104**, in other configurations one of the actuators can be eliminated, such as for example the actuator **70**, and the actuator **60** can deploy the cap **102**, advance the fluid-blocking component **104** toward the cap **102**, and deploy the fluid-blocking component **104** through a combination of distal and/or proximal movement in relation to the anchor **108**. In other configurations, the delivery system **30** can include two or more actuators, such as two or more of the actuators **50**, **60**, or **70**, to delivery/deploy the anchor **108**, the cap **102**, and the fluid-blocking component **104**. It is also possible for other combinations of deployment functions to be performed by other individual or combination of actuators. The one or more lumens of the one or more actuators **50**, **60**, or **70** can include one or more valves or seals **58**, **68**, and **78**, and the delivery sheath **40** can also include one or more valves or seals **45**, to prevent blood flowing from the ends of the delivery sheath **40** and the actuators **50**, **60**, and **70**.

FIG. **1**B illustrates an exploded view of the delivery system **30**. As shown in FIG. **1**B, the delivery sheath **40** includes an outer housing **42** and a handle or grip portion **44**. Each of the actuators **50**, **60**, and **70** include, respectively, a shaft or housing portion **52**, **62**, **72**, a handle or grip portion **54**, **64**, and **74**, and distal ends that can cooperate with, respectively, the anchor **108**, the cap **102**, and the fluid-blocking component **104**. For instance, the actuator **50** can include a notch **58** (FIG. **1**A) to receive the suture **106** and optionally a portion of the anchor **108**. An interior lumen **46** is defined in the outer housing **42** that is configured to receive the actuators **50**, **60**, and **70** in such a manner as to allow the actuators **50**, **60** and **70** to be extended from and retracted within a distal end **48** of the outer housing **42**. Each actuator **50**, **60** and **70** also includes, respectively interior lumens **56**, **66**, and **76** to allow for translation of the actuators **50**, **60**, and **70**, either independently or in combinations of 2 or more of the actuators, and the delivery sheath **40**. Translation distance of the actuators **50**, **60**, and **70** can be controlled through contact between adjacent handle or grip portions **44**, **54**, **64**, and **74**. For instance, the grip portion **44** can limit distal movement of each of the grip portions **54**, **64**, and **74** associated with the actuators **50**, **60**, and **70**, while grip portion **74** can limit distal movement of each of the grip portions **54**, and **64** and the grip portion **64** can limit movement of the grip portion **54**. In this way, over translation of individual actuators is limited and the anchor **108**, cap **102**, and fluid-blocking component **104** can be effectively deployed to access and close a tissue opening.

While reference is made to the handle or grip portions limiting actuator translation, it is understood that other approaches can be used for controlling translation. For instance, complementary structures can be formed in the housings and the interior lumens to limit translation. In another configuration, the handle or grip portions are combined into a single handle assembly having different actuation controls, such as switches, knobs, sliders, etc. to allow independent or combined movement of one or more of the actuators **50**, **60**, and **70**.

In another configuration, as illustrated in FIG. **1**C, an interior lumen **46'** can include a first portion **46**A' configured to receive the shaft portion **54'** of the actuator **50'** while a second portion **46**B' of the interior lumen **46'** can be configured to receive a distal end **54**A' of the shaft portion **54'** having the interior lumen **56'**. More specifically, the second portion **46**B' of the interior lumen **46'** may have a larger width aspect than the width aspect of the first portion **46**A'. The width aspects of the first portion **46**A' and the second portion **46**B' can be the diameters thereof or other cross-sectional profiles that are generally transverse to a center axis C of the delivery sheath **40'**. For ease of reference, the center axis C of the delivery sheath **40'** will be referenced in describing the position and movement of the other components described herein. In the illustrated example, the interior lumen **46'** may transition from the smaller diameter of the first portion **46**A' to a second larger diameter of the second portion **46**B' at a shoulder **46**C'.

Such a configuration can allow the actuator **50'** to translate axially relative to the delivery sheath **40'** within a desired range of motion. In particular, the handle portion **52'** can translate within the second portion **46**B' of the interior lumen **46'** to advance the shaft portion **54'** within the outer housing **42'** and in relation to the handle or grip port **44'** to thereby move the distal end **54**A of the shaft portion **54'** relative to the distal end **42**A of the outer housing **42'**. Interaction between the handle portion **52'** and the shoulder **46**C' can help ensure the distal end **54**A' does not extend beyond a desired position within the outer housing **42**.

In the illustrated example, the first portion **46**A' may also be configured to receive the anchor **108** and the cap **102** proximally of the distal end **54**A' of the shaft portion **54'**. Accordingly, as the distal end **54**A' of the shaft portion **54'** is advanced toward the distal end **42**A' of the outer housing **42'**, the distal end **54**A' of the shaft portion **54'** can engage the anchor **108** and/or the cap **102** to move the anchor **108** and/or the cap **102** distally from the outer housing **42**.

Returning to FIG. **1**A, the anchor **108** can be configured to move from a pre-deployed state having a pre-deployed width aspect to a deployed state having a deployed width aspect. The deployed width aspect may be greater than the pre-deployed width aspect. The anchor **108** can have any configuration that allows for this. In the illustrated example, anchor **108** is configured to rotate or be rotated between the pre-deployed state and the deployed state. In other examples, portions or all of the anchor **108** may be configured to unfold from a configuration have a pre-deployed width aspect to a deployed state having a greater width aspect. For example, one or more arms or wings may be configured to unfold and fold about a plurality of pivot points, hinges, living hinges, bending locations, preferential bending location, combinations or modifications thereof.

As shown in FIG. **1**A, the anchor **108** includes wing members **132**, **134** that define a major axis **136** of the anchor **108**. The anchor **108** can further include one or more holes or eyelets **138** disposed along a length of the anchor **108**. The holes or eyelets **138** can be located at a position that causes the anchor **108** to rotate when a force acting initially parallel to the major axis **136** is exerted on the eyelets **138**. Such a configuration can allow the anchor **108** to move from a state in which the major axis **136** is aligned with the central

axis C to a state in which the major axis **136** is oriented more obliquely to the central axis C, such as generally perpendicular to the central axis C.

This rotation can be accomplished by applying a distally acting force on the anchor **108** to move the anchor **108** out of the outer housing **42** and then a proximally directed force to the anchor **108** by way of the interaction between the suture **106** and the eyelets **138**. In at least one example, the distally acting force applied to the anchor **108** can be provided from the actuator **50** while the proximally directed force can be applied by way of the suture element **106**. The anchor **108** can thus be used to position the delivery system **30** for deployment of the closure element **102**.

In one embodiment, the closure element **102** may be configured to close an opening in a lumen of a blood vessel as well as at least partially obstruct a tissue tract leading from an external surface of the tissue to the lumen. The shape of the closure element **102** may be configured to be housed within the interior lumen **46** (or one of the other lumens of the actuators **50**, **60**, **70**). For example, the closure element **102** may conform to the shape of the interior lumen **46**. In one embodiment, the closure element **102** may be generally cylindrical in shape prior to being deployed from the delivery sheath **40** in which portions of the closure element **102** are at least partially wrapped around or curved towards a central portion of the closure element **102**, whether or not those peripheral portions curve proximally, distally, or transverse to a direction of deployment of the closure element **102** toward the previously deployed anchor **108**. Once deployed from the delivery sheath **40**, at least a portion of the closure element **102** may be at least partially deformable to conform to any desired shape of the vessel wall to close an opening in a blood vessel and/or the tissue tract leading to the lumen opening.

As shown, the suture element **106** can loop through the anchor **108** such that the suture element **106** passes through or near the closure element **102**, and extends proximally into or beyond the handle portion **52** of the actuator **50'**. In at least one example, the free end of the suture element **106** passes through separate portions or channels of the closure element **102**. The suture element **106** can be extended from the closure element **102** and into the actuator **50** by way of the interior lumen **56**.

Generally, the structures and components of the delivery system **30** can be formed of polymers, metals, alloys, combinations or modifications thereof. For instance, by way illustration only, the delivery sheath and the actuators can be formed from metal hypotubes, polymer tubes, composite tubes have a multilayer configuration, or other tubular structures optionally including reinforcing members or braids. The delivery sheath and the actuators can range in outside diameter from about 6 F to about 10 F, from about 2 mm to about 4 mm, from about 2 mm to about 3.33 mm, or other sizes as known to those skilled in the art.

Vessel Closure Device

FIGS. **2A-2B** illustrates an example of the closure device **100**. In this particular configuration, the closure device **100** can be a fully bioabsorbable vessel closure implant including intravascular and extravascular components. The extravascular components can include an extravascular cover or cap **102** (hereinafter "extravascular cap" or "cap") and a second extravascular component or fluid-blocking component **104**, such as a bioabsorbable sealant (see FIGS. **4-6B**), which can also be collectively referred to as a closure element. The intravascular components can include an intravascular foot or anchor **108** and a suture **106**, both of which can be bioabsorbable. As mentioned above, in other configurations, the intravascular foot or anchor **108** can be temporarily deployed, with the extravascular components being fully bioabsorbable (such as through degradation, absorption, and/or resorption).

The extravascular cap **102** can be made from bioabsorbable materials and be of sufficient size and geometry to prevent it from passing through the punctured access site **18** at the surface of the blood vessel **10**. The size and geometry of the extravascular cap **102** can significantly increase patient safety by preventing extravascular components from passing through the access site **18** during or after deployment. The cap **102** can have a diameter from about 1 mm to about 10 mm, from about 3 mm to about 8 mm, from about 4 mm to about 5 mm, or other size based upon the specific dimensions of the access site **18** so that the cap **102** does not pass through the access site **18**.

The cap **102** can be of low profile and made from a biodegradable material having desired flexibility to conform to the patient's access site anatomy (especially in vessels with significant calcification present) and provide more effective sealing than would rigid materials. The cap can be deployed through a small catheter access tissue tract **22** and placed on top of the vessel **10** as the primary extravascular seal.

Turning to FIGS. **2A-3B**, illustrated is one configuration of the cap **102**. As illustrated, the cap **102** can have a generally circular disk shape, though in other embodiments, the shape of the cap **102** can be interrupted (e.g. star-shape) which can impart the cap **102** with increased flexibility to allow it to conform to the access tract **22** which is typically narrow. The cap **102** can include a medial portion **113** which may be raised relative to the surrounding surface **111** of the cap **102**. The medial portion **113** can have a thickness of about 0.050 mm to about 5 mm, from about 0.10 mm to about 2 mm, from about 0.10 mm to about 0.5 mm, or various other thicknesses. The cap surface **111** can include relief cuts **115** which may provide for increased cap flexibility and conformance to the access tract **22** above the vessel **10**. The relief cuts **115** can extend to a longitudinal axis of the cap **102**, inclined, curved, non-linear, combinations or modifications thereof. Alternatively, or in addition to the relief cuts **115**, a relief cut **115*a*** can have a generally circular form disposed around the medial portion **113**, such as to circumscribe, surround, or encircle all or a portion of the medial portion **113**. The relief cut **115*a*** can modify the flexibility of surface **111** to improve conformance to the tract and resist entry to the vessel. The cap **102** can have a mass ranging from about 4.0 mg to about 10.0 mg (for 4 mm to about 6 mm diameter cap). With a lower overall mass, less force is used to hold the cap **102** in place between the frictional engagement between the cap **102** and the suture **106**. This results in smaller overall system, thereby making positioning within the patient simpler with reduced overall impact on the patient's recovery.

The access tract **22** (see FIGS. **4-6B**) is typically size restricted, circular, and formed at an angle in relation to the vessel wall. The cap **102** can be configured to slide down a delivery system **30** through the access tract **22** and be deposited on top of the artery or vessel **10**. The suture **106** can then be pulled to tension the cap **102** and intravascular anchor **108** towards each other to seal the access site **18**. The cap **102** can include a lumen **110** in the medial portion **113** through which the suture **106** can be threaded to attach the suture **106** to the intravascular anchor **108**. The lumen **110** can have a diameter ranging from about 0.010" (0.254 mm) to about 0.020" (0.508 mm), from about 0.012" (0.3048 mm)

to about 0.017" (0.4318 mm), or from about 0.014" (0.3556 mm) to about 0.015" (0.381 mm).

The lumen **110** can be sized to accommodate the suture **106** of a certain diameter. For instance, as illustrated FIGS. **2**A-**2**B, with the suture **106** looped around the anchor **108**, two rails or portions of the suture **106** can pass through the lumen **110** and proximally along the delivery device **30**. Optionally, portions of the two sutures **106** can be braided together with two suture tails extending proximally from the cap **102**. Alternatively, as illustrated in FIG. **4**, the suture **106** is looped back on itself and braided into itself to increase a portion of the suture that interference fits or otherwise engages with the lumen wall of the lumen **110**, with a single rail extending proximally along the delivery device **30**. In still another case, the two sutures **106** can pass through or cooperate with an elongate member **107** (such as another suture portion or braided tubular member), shown in phantom in FIG. **2**A-**2**B, and be braided to and with the elongate member **107**, to increase a size of the portion(s) of the suture **106** disposed within the cap **102**. One or more elongated member **107** can optionally be inserted into the one or more sutures **106** to increase their dimensions. In each case, i.e., the two adjacent non-braided sutures rails, two adjacent braided suture rails, braided suture and tubular member, or a suture end braided into another portion of the suture after being interwoven through 2 or more holes of the anchor **108**, a thick suture portion **112** is formed which can interference fit with the lumen **110**, which is narrow relative to the thick suture portion **112**, to secure the cap **102** in the desired position. The thick suture portion **112** can have a diameter ranging from about 0.020" (0.508 mm) to about 0.040" (1.016 mm), from about 0.024" (0.6096 mm) to about 0.034" (0.8636 mm), from about 0.028" (0.7112 mm) to about 0.030" (0.762 mm).

The suture **106** can be made of a bioabsorbable material. For example, the suture **106** can be a multifilament or braided absorbable suture, such as those available from VITREX®. In one configuration, the suture is a braided 3-0 suture. It may be advantageous for the suture to have a high tensile strength which can maintain its integrity under the application of from about 3 lbf. to about 6 lbf., although other sutures can accommodate application of forces ranging from about 1 lbf. to about 16 lbf., from about 1 lbf. to about 8 lbf., from about 2 lbf. to about 6 lbf., from about 2.5 lbf. to about 5 lbf., or about 2 lbf.

The cap **102** can be initially positioned on the proximal suture end **116**, or the end of the suture **106** which does not have a diameter larger than the diameter of the lumen **110** of the cap **102**. When the cap **102** is advanced along the suture **106** to the external vessel surface **20** at the arteriotomy location, the thick suture portion **112** causes an interference that can lock the cap **102** in place, resulting in an immediate dry close.

The interference fit can eliminate the need for the use of a knot to maintain the dry close. Use of a knot can pose serious risk to a patient if the set tension on the suture becomes overtightened. The suture can become stressed by a patient walking or coughing causing the suture to over tension and break. The interference fit may be advantageous because it is knotless and the flexibility of the cap can adapt to force applied to the suture.

In addition to, or instead of the interference fit between the cap **102** and the thick suture portion **112**, the cap can optionally include an adhesive applied to a side of the cap contacting the extravascular tissue, as illustrated in the embodiment of FIGS. **3**C-**3**D. For instance, the cap **102** can include an adhesive layer **128** that bonds to the extravascular tissue when the cap **102** is advanced towards the anchor **108**. The adhesive for the adhesive layer **128** can be a non-migrating adhesive in that it will not flow through the puncture as the extravascular tissue is sandwiched between the cap **102** and the anchor **108**. Such adhesive can include a non-expanding glue, such as a non-expanding polyethylene glycol (PEG), a glue protein, such as a barnacle glue, cross-linked gelatins (non-biologic) cyanoacrylates, polyurethane adhesives, or glues or adhesives, combinations and modifications thereof. More generally, the adhesives can use cross-linking mechanisms that rely on chemical conjugation between reactive groups, free radical polymerization, oxidation reduction reaction, biological or biochemical coupling.

FIGS. **4**-**6**B illustrate an example of a second extravascular component or fluid-blocking component **104**, which can be a sealant. The fluid-blocking component **104** can be an active biologic material, such as polyethylene glycol (PEG), fibrin sealants, copolymer of glucosamine and N-acetyl glucosamine, dextran (complex branched glucan(a polysaccharide. polypeptide adhesive structures, adhesive protein containing L-3,4-dihydroxyphenylalanine (L-DOPA), adhesive protein containing DOPA and phosphoserine, collagen, polyacrylic acid, cross-linked with allyl sucrose or allyl pentaerythritol, polyacrylic acid, cross-linked with divinyl glycol, Acrylic resinous polymer composed of methyl-2-cynoacrylate units, or another fully bioabsorbable sealant-type material that could be optionally incorporated into a shaped, flexible substrate. The sealant material could be activated by fluids present in the patient's tissue tract, such as blood or other fluids, and can be protectively stored inside the sheath/actuators or a chamber of the delivery device until positioned directly on top of the cap **102**.

Once advanced into the desired location, the sealant **104** can be exposed to the blood or fluid, such as through unsheathing the fluid-blocking component **104** and positioning the fluid-blocking component **104** into direct contact with the tissue where it can react by coming into contact with blood and other fluids. This reaction can cause the fluid-blocking component **104** to expand and absorb blood and other fluids and bond to surrounding tissue and the cap **102**. The sealant can act as a glue and aid with "locking" the cap **102** in place on the blood vessel **10**, and actively coagulates the entire access tract **22**. The chemical formulation, quantity, carrier matrix, and dimensions of the fluid-blocking component **104** can be selected specifically to provide one or more of the functions of locking in place of the sealing component (e.g. cap **102**), to provide a fast acting and leak-free dry close, and reduce tissue tract oozing.

For instance, the sealant can form a plug having a length of about 1 mm to about 10 mm and can optionally be trimmed to length in the patient along with the suture after deployment, or the adhesive component can extend the full length of the tissue tract and trimmed to fit the patient. When the fluid-blocking component **104** is formed of a matrix, the matrix can have an area of about 0.012 square inches to about 0.12 square inches, about 0.12 square inches to 0.6 square inches, about 0.6 to 1.0 square inches. The matrix material can be thin and flexible such that it can be wrapped around the suture in the delivery system to fit inside a tube for delivery to the implant location. This results in a volume of fluid-blocking component, optionally including a matrix containing a sealant such as PEG or other biocompatible material, of between about 0.004 to about 0.040 cubic inches in volume, about 0.0.040 to about 0.100 cubic inches, about 0.100 to about 0.400 cubic inches.

The fluid-blocking component **104** can be deployed so that is disposed on the suture **106**. The fluid-blocking component **104**, therefore, can be deployed in a flowable composition without a carrier matrix or can be formed as part or with a carrier matrix. For instance, the fluid-blocking component **104** can be disposed around the suture in a generally cylindrical component, can be bonded to the suture itself, can be bonded to the cap, and combinations or modifications thereof. Because the sealant **104** is positioned proximal relative to the cap **102**, the sealant **104** can actively coagulate the access tract **22** and optionally actively coagulate all of access tract **22** to the surface of the skin **16**.

Sealant **104**, as shown in FIGS. **4-6**B, can have a conical configuration when deployed, though in other embodiments the sealant **104** can have a continuous or uniform thickness along its length. The extravascular cap **102** can displace tissue at the access site **18** because the cap **102** can be larger than the arteriotomy. The sealant **104** can also fill the space created by the displaced tissue. The sealant **104** can be formed of material with properties which can cause it to swell from its original size when it comes into contact with bodily fluids, causing it to effectively cover and reinforce the seal formed by the cap **102**. The sealant **104** can swell from its original size about 1 time to about 6 times, from about 2 times to about 4 times, or from about 2.5 times to about 3.5 times. It can be advantageous to optionally have the sealant expand up the access tract **22** as close as possible to the skin **16** to mitigate any bleeding.

When the sealant has a predetermined conical or tapered shape, the sealant **104** can be formed as a separate sealant component with a hole through the center, or other locations, to allow the sealant **104** to be threaded on to the suture **106**. More generally, the suture may be threaded through one or more points through or around the sealant. The sealant component could be foam matrix or other formed substrate that a biocompatible material can be infused into and then formed into the desired shape, such as PEG. The sealant **104** can be a combination of two or more components which can be loaded into one of the actuators **50**, **60**, or **70**, and then simultaneously activated by pressing down the handle or grip portions to expose the sealant **104** to bodily fluid. The two or more components can include one or more flowable component, with or without a matrix having a preformed shape or being biased to a particular shape.

In other embodiments, the sealant **104** and cap **102** can be deployed together as if they are one component. The cap **102** can cover the access site **18** and the sealant **104** can be activated on top of and above the cap **102** to seal the access tract **22**.

In other embodiments, as illustrated schematically in FIG. **1**F (in which the actuator **50**, the anchor **108**, and the cap **102** are omitted for ease of explanation), the fluid-blocking component or sealant **104** can be stored in a chamber **103** at a proximal end of the delivery system. The fluid-blocking component or sealant **104** can be stored in a generally planar or flat-sheet form, optionally biased to that generally planar or flat-sheet form, and advanced to the cap **102** through a funnel **105** or other proximal deployment port that curls, folds, or otherwise changes the planar or flat-sheet form to a formed capable of being advanced toward the cap **102**. In one configuration, the actuator **70** can be used to advance the fluid-blocking component or sealant **104** from the chamber (arrow A) along the actuator **60** to deploy the sealant **104** from within the actuator **60**, such as when the actuator **70** is distally advanced (arrow B), when the actuator **60** is partially withdrawn proximally from engagement with the cap **102** following sandwiching the tissue between the cap **102** and the anchor, through movement of another actuator or structure, or combinations or modifications thereof. The movement exposes the fluid-blocking component or sealant **104** to the blood or other fluids causing the fluid-blocking component or sealant **104** to expand.

When introducing a coagulant or sealant, there is a risk of introducing embolizing material into the vessel **10** which can cause a clot and threaten a limb. Emergency surgery may be required to remove the foreign body. This risk can be mitigated by the configuration of closure device **100** due to the use of the cap **102** to first cover the access site **18** so that the extravascular fluid-blocking component or sealant **104** **104** cannot pass into the vessel **10**.

The combination of a low profile cap component, including degradable, absorbable, or resorbable material that is stable (material does not expand or aggressively bond to tissue), plus the active sealant material on top, combined as an extravascular implant is unique and distinguishes this design from other closure devices.

Turning now to FIGS. **7**A-**7**H, the closure device **100** can include an intravascular anchor **108**, for example, a graft-type anchor. The intravascular anchor **108** can include one or more of the following elements: 1) a large surface area in an elongate shape otherwise referred to as elongate member **117**, 2) a central keel **120** which can provide suture attachment and overall rigidity, 3) a flexible portion or membrane **122** which can conform to a vessel wall, 5) holes, eyelets, or other structure **118** which can provide for suture attachment to an extravascular component (e.g., cap **102**) of a closure device **100**, and 6) flexible edges **126** of the flexible portion or membrane which can allow for storage in a cylindrical state to permit delivery of the closure device **100** to the vessel **10**. The anchor **108** can be formed of multiple sub-components that are joined together or be formed as a monolithic component where the identified one or more elements are formed as a single component, such as through casting or through machining of a starting workpiece.

The intravascular anchor **108** (also referred to as "anchor") can be formed of a bioabsorbable material, while having flexibility properties that allow the anchor **108** to be curled up into a smaller profile inside of a delivery sheath, such as the delivery sheath **40**. This allows a larger sealing surface that can unfurl once free of the delivery tube. The intravascular anchor **108** is attached to the suture **106** using a pattern that can distribute the tensile load more widely across the breadth of the anchor **108** to prevent fracture from a high concentration of force during device deployment.

The intravascular anchor **108** can have a curved profile in order to better conform to the curvature of the vessel wall. The anchor **108** can also have an enlarged central portion or a keel **120**. The keel **120** can help to reinforce the seal formed over the access site **18** by the closure device **100** and provide a suture attachment point. The rigidity of the keel **120** can provide mechanical leverage and a robust location to advance and eject the anchor **108** out from the delivery sheath **40**. The keel **120** can have a thickness of about 0.5 mm to about 0.8 mm, of about 0.6 mm to about 0.9 mm, of about 0.7 mm to about 1.0 mm, or other thickness to provide the desired suture attachment location.

Surrounding the keel **120** is the elongate member **117**. The materials forming the elongate member **117** can be the same as the keel **120**, such a bioabsorbable material, with the material a have a durometer ranging from about 50 Shore A to about 100 Shore A, from about 80 Shore A to about 90 Shore A, or durometers as chosen based upon the closure location. The elongate member **117** can have thinner, flexible sections relative to the keel **120**, which can conform to

the curved vessel wall **14**. The flexibility can also allow the anchor **108** to conform to the unique calcification buildup in the vessel **10**. The elongate member **117** can have an ellipse or oval shape having a minor axis dimension from about 2.0 mm to about 10.0 mm, from about 3.0 mm to about 5.0 mm, or about 4 mm, while a major axis can range from about 4.0 mm to about 12.0 mm, from about 6.0 mm to about 8.0 mm, or about 6.0 mm. It is understood that the configuration of the anchor, and more generally, the closure device or implant can be varied based upon the particular opening to close so that the dimensions can be adjusted to accommodate, generally, 5-8 F openings or openings larger than 8 F and smaller than 5 F.

The ridge or keel **120** can run the length of the central axis of the elongate member **117** and can impart rigidity where suture **106** can be attached. The suture **106** can be attached through suture attachment points or holes **118** in the keel **120**. One or more holes **118** can provide points through which the suture **106** can be threaded to attach the anchor **108** to the cap **102** and sealant **104**. The holes **118** can be evenly or non-evenly spaced along the length of the keel **120**. The spacing of the holes **118** can help to spread the tensile load across a desired length of the anchor **108**, such as all or some portion of the length of the anchor **108**, and can prevent fracture of the anchor **108** under load. In the embodiment shown in FIGS. **7**A-**7**H, free distal ends of the suture **106** can each be threaded through each of the outermost holes **118***a* and then both can be threaded through the middle holes **118***b* and up through the access site **18** and braided back onto the suture **106** to form the thick suture portion **112**.

The anchor **108** can be injection molded, cast, stamped, machined, combinations or modifications thereof, and include one or more bioabsorbable materials, bioabsorbable polymers, or bioabsorbable elastomers depending on the degree of strength, stiffness and absorption rate desired. The anchor **108** structure can be formed of a homogenous material mixture where flexibility is adjusted through a combination of geometry and material formulation. A secondary adhesive material may be attached or bonded to the bottom surface of anchor **108** to increase attachment strength and improve sealing performance against the blood vessel. The anchor provides a safe manner for the sealant to interact directly with the blood vessel tissue without risk of embolizing into the blood vessel lumen because it is attached to anchor **108**. The bioabsorbable materials can include, for example, and not by way of limitation, Polyglycolic acid (PGA), Polylactide (PLA), Poly-L-Latic acid (PLLA), Polycaprolactone (PCL), Poly-DL-lactic acid (PDLLA), Poly trimethylene carbonate (PTMC), Poly paradioxanone (PPDO), combinations and/or modifications thereof. More generally, the materials forming the anchor **108** can have a durometer ranging from about 80 Shore A to about 90 Shore A. Alternatively, when the anchor **108** is temporarily deployed, the anchor can be formed of a non-bioabsorbable material, such as polyvinyl chloride (PVC), Polyether ether ketone (PEEK), Polytetrafluorethylene (PTFE), nylon, silicone, urethane, thermoplastic elastomers like Polyether block amide (PEBAX), polyethylene terephthalate (PET), Fluoropolymers, or biocompatible materials, combinations and/or modifications thereof.

The anchor **108** can have a mass ranging from about 4 mg to 8 mg (for 4 mm×6 mm ellipse), from about 8 mg to about 16 mg (for 5 mm×7 mm ellipse), or from about 15 mg to 30 mg (for 8×10 mm ellipse). With a lower overall mass, less force is used to hold the anchor **108** in place between the frictional engagement between the cap **102** and the suture **106**. This results in smaller overall system, thereby making positioning within the patient simpler with reduced overall impact on the patient's recovery.

FIGS. **8**A and **8**B illustrate another example embodiment of the intravascular anchor **108**. In FIGS. **8**A-**8**B, the anchor **108** includes a lumen facing side **127** (FIG. **8**A) and an intima facing side **129** (FIG. **8**B). The anchor **108** can include an elongate body **117** having a flexible member or membrane **122**, a keel **120** positioned at the central axis of the elongate body **117** and spanning the length of the elongate body **117** which can provide adequate stiffness for attachment of the intravascular anchor **108** to the extravascular element of the closure device **100** by suture **106** (e.g., cap **102**).

The keel **120** can be raised relative to the lumen facing side surface of the anchor **108**, which can help to maintain the position of the anchor **108** on the vessel wall **114**. The intima side of the anchor **108** can include a plurality of ribs **124** radiating outward from the keel **120** to the raised edge **126** forming the perimeter of the elongate body **117**. The raised elements of the ribs **124** and raised edge **126** provide for encapsulation of localized plaque on the vessel wall **114**. The stiffness of the raised edge **126** of the anchor **108** may be correlated to the stiffness and/or pattern, number, and/or thickness of the ribs **124** ribs radiating from the keel **120**. The width and taper of the ribs **124** may be varied to influence the compliance or the stiffness of the edge **126** of the anchor **108**.

FIGS. **9**A-**9**B illustrate another embodiment of an anchor **208**. The anchor **208** can include an elongate body **217** having a flexible member or membrane **222** and a centrally-located raised keel **220** spanning the length of the elongate body **217**. The elongate shape of the anchor **208** is modified to maximize the surface area of the anchor **208**. In this depiction the number of ribs **224** is reduced which may increase compliance to the vessel lumen wall **14**. The anchor **208** can also have a raised edge **226** running the perimeter of the elongate body **117**. One or more holes **218** in the keel **220** provide points through which a suture **106** can be threaded to attach the anchor **208** to extravascular components of the closure device **100**.

FIGS. **10**A-**10**B, illustrate another embodiment of an anchor **308**. The anchor **308** can include an elongate body **317** having a flexible membrane and a raised keel **320** located on and spanning the length of the central axis of the elongate body **317**. The keel **320** can include one or more holes **318** through which suture **106** can be threaded. In this embodiment the ribs (**124**, **224**) are omitted to permit maximum flexibility of the anchor **308**. The raised edge **326** running the perimeter of the intima side of the anchor **308** can impart the anchor **308** with requisite structural integrity to maintain the shape of the anchor **308** when positioned on the lumen wall **14**.

Method of Closure Device Insertion

Reference is now made to FIG. **11**A, which illustrates a step in the process of deploying the anchor **108**. As shown in FIG. **11**A, the delivery sheath **40** can be positioned to move the distal end of the outer housing **42** through an access tract **22** defined in tissue **72** and into proximity with a lumen **12** and a puncture or access site **18** defined in a lumen wall **14** in particular. The distal end of the delivery sheath **40** is advanced into the lumen **12** until pulsating blood is visually observed from a proximally positioned blood outlet port **49** (FIG. **1**A) of a bleed back or blood marker lumen formed in a wall of the delivery sheath **40** or formed by a separated bleed back tube formed either interior or externally of the delivery sheath **40**. The blood inlet port

47 (FIG. 1A) in fluid communication with the blood outlet port 49 is disposed toward the distal end of the delivery sheath.

Once blood flow is observed, the actuator 50 can be manipulated as described above (and as shown in FIG. 11B) to cause the anchor 108 to be pushed out of the distal end 42A of the outer housing 42. Alternatively, the actuator 60 may push the closure element or cap 102 which may, in turn, push the anchor 108 distally relative to the outer housing 42, thereby deploying the anchor 108 from the distal end 42A of the outer housing 42. In such a case the actuator 50 can optionally be omitted.

In one embodiment, once deployed, the anchor 108 may rotate or be rotated from a first orientation, in which the major axis 136 of the anchor 108 is at a small angle or generally parallel with the outer housing 42 and generally perpendicular to the lumen wall 14 as shown in FIG. 11A, to a second orientation in which the major axis 136 of the anchor 108 is generally parallel with the lumen 12 and at a greater angle or generally perpendicular to the delivery sheath 40 as shown in FIG. 11B.

In particular, as shown in FIG. 11B, once the anchor 108 is pushed from the distal end 42A of the outer housing 42, the anchor 108 may rotate or be rotated to the second orientation, such as by tension applied to by the suture element 106 to the anchor 108 by way of the central or middle hole 118*b*. The anchor 108 can then be drawn in the proximal direction to secure the anchor 108 against a distal surface 14A of the lumen wall 14, as illustrated in phantom in FIG. 11B. While the suture 106 is illustrated extending proximally within the lumen of the actuator 50 in FIG. 11A and FIG. 11B, when the actuators are non-coaxial, such as illustrated in FIGS. 15 and 16, the suture 106 need not extend within a lumen of the actuator 50 and actuator 50 need not include a lumen. The suture 106 can extend within any lumen of the delivery system 30, such as illustrated in solid and dashed schematic representations of the suture 106 in FIG. 16

With the anchor 108 deployed and positioned against the lumen wall 14 and the delivery sheath 40 partially retracted into the access tract 22 so that the distal, the actuator 60 may then deploy the cap 102 proximal the puncture 18 between the lumen wall 14 and the tissue 72 through which the tract 22 is formed. In particular, as shown in FIG. 11C the actuator 60 can be advanced distally, the delivery sheath 40 can be drawn proximally, and/or some combination of such movements can be used to move the cap 102 distally out of the outer housing 42 and into contact with the proximal side or extravascular side 14B of the lumen wall 14 adjacent the puncture 18. The lumen wall 14 is positioned between the anchor 108 and the cap 102 with the cap 102 positioned on the extravascular side of the access site 18 and "locked" in place as a result of an interference fit created by the thick suture portion 112. Thus, the cap 102 can be positioned to reduce or stop the flow of fluid out of the tract 22 by covering the puncture 18 and/or obstructing the tract 22.

To verify that flow is reduced or stopped, the practitioner can view blood flow from the blood outlet port 49 (FIG. 1A) and determine a degree of hemostasis. A continued degree of blood flow from the blood outlet port 49 (FIG. 1A) may indicate that hemostasis has not been adequately achieved and indicate to the practitioner to continue positioning the cap 102 against the tissue to provide improved hemostasis. Alternatively, blood flow can be observed by maintaining one or more of the valves or seals 58, 68, 78 of the actuators 50, 60, or 70 or the one or more valves or seals 45 of the delivery sheath 40 open to allow blood to flow from an end of one or more of the actuators 50, 60, or 70 or the delivery sheath 40. For instance, by way of example of one particular configuration, the actuator 60 can include an enlarged portion that maintains the valve or seal 45 of the delivery sheath 40 open so that blood exits from the end of the lumen when hemostasis has not been achieved. As with the blood flow from the blood outlet port 49 (FIG. 1A), a continued degree of blood flow from the end of one or more of the actuators 50, 60, or 70 or delivery sheath 40 may indicate that hemostasis has not been adequately achieved and indicate to the practitioner to continue positioning the cap 102 against the tissue to provide improved hemostasis. Retracting the enlarged portion away from or advancing the enlarged portion through the one or more valves or seals allows the valves or seals to close following advancing the cap 102 towards the anchor 108 to improve hemostasis and reduce blood flow.

Returning to FIG. 11C, advancing the cap 102 towards the anchor 108 aids with stabilizing the tissue around the puncture 18 in order to facilitate closure of the puncture 18. In particular, once the anchor 108 and the cap 102 are deployed, tension can be applied to the suture 106 to secure the anchor 108 against a distal side 14A of the lumen wall 14 while the actuator 60 advances the cap 102 distally. In one example, a suture lock (not shown) can be utilized to help maintain the tension in the suture element 106. The combination of the forces exerted by the anchor 108 and the cap 102 on the lumen wall 14 provides a compressive force on the tissue near the puncture 18, i.e., sandwiching the tissue between the anchor 108 and the cap 102. The tension applied to the suture can range 1 lbf. to about 16 lbf., from about 1 lbf. to about 8 lbf., from about 2 lbf. to about 6 lbf., or about 2.5 lbf. Because the anchor 108 is formed of a resilient compliably material and the cap 102 can be formed of elastomeric materials (such as bioabsorbable polymers, bioabsorbable elastomers, etc.), the properties allow the anchor 108 and the cap 102 to accommodate the applied forces without fracturing. The suture 106 can also include a visual indicator to show the user when the cap 102 has reached the proper depth, i.e. the cap 102 has reached the artery. If too much force is applied, this may cause the suture to break, however, due to the lack of a knot or other static element maintaining the cap 102 in a fixed position, the cap 102 and the anchor 108 will not over-tension. Because of this feature, the user does not have to worry about the degree of force applied.

Placement of the cap 102 also pushes the tissue 72 in a transverse direction in relation to an axis of the tract 22. This increases a space for subsequent delivery of the sealant 104 and so increases a surface area of the lumen wall 14 and the cap 102 that can receive the sealant 104. By so doing, the efficacy of access site closure is enhanced.

Optionally, in a configuration when the actuator 60 can deploy both the anchor 108 and the cap 102, the actuator 60 can remain in continuous contact with the cap 102 throughout the deployment process. Such a configuration can allow the anchor 108 and/or cap 102 to be deployed by advancing the actuator 60 in a single direction. By facilitating deployment of the anchor 108 and cap 102 using one-way movement of the actuator 60, and by utilizing a single actuator, the delivery system can be used quickly and easily deploy the anchor 108 and/or cap 102 and sealant 104.

Optionally, in one configuration when the actuator 60 can both deploy the cap 102 and advance the sealant 104 towards the cap 102, the distal movement of the actuator 60 advances the sealant 104 towards the cap 102, with subsequent

proximal movement releasing the sealant **104** from within the actuator **60**. In this configuration, the actuator **70** is optionally omitted.

Returning to the illustrated configuration, once the cap **102** is placed, the sealant **104** can be deployed from the delivery sheath **40** by proximally withdrawing the delivery sheath **40**, and optionally the actuator **60**, and distally advancing the actuator **70**, or some combination of one or more of such movements, to advance or release the sealant **104** from the outer housing **42** and into contact with the proximal side **14**B of the lumen wall **14** and the cap **102**. As the delivery sheath **40** is proximally moved or removed, and/or the actuator **60** is proximally moved or withdrawn, the sealant **104** is exposed to bodily fluids to activate the sealant **104**, as illustrated in FIG. **11**D. The activated sealant **104** can act as an adhesive to secure the cap **102** in place as well as reinforce the hemostatic effect of the cap **102** by preventing leakage and coagulating the access tract **22**. It can be advantageous to have the sealant as close to the surface of the skin as possible to mitigate any potential bleeding.

While the sealant is activated, such as can occur in from about 0.25 minutes to about 5 minutes, from about 0.5 minutes to about 4 minutes, from about 1 minute to about 3 minutes, from about 0.25 minutes to about 1 minute, from about 0.25 minutes to about 0.75 minutes, the practitioner can view blood flow, if any, from the blood outlet port **49** (FIG. **1**A) and determine a degree of hemo stasis. Based upon the force applied to the cap **102** to seal the access site **18**, the cap **102** can seal or substantially seal the access site **18** resulting in the sealant **104** being used to limit tissue oozing around the cap **102** and from the tissue tract **22** and provide secondary securing of the cap **102** in relation to the suture **106** and the access site **18**. Stated another way, primary closure of the access site **18** can be achieved through the sealing provided by the anchor and cap, while the sealant **104** provides secondary sealing and/or stopping of tract ooze. If there is, however, a continued degree of blood flow from the blood outlet port **49** (FIG. **1**A), the physician can manipulate the actuators and anchor to tighten the cap **102** on the suture **106** or optionally wait for the sealant **104** to sufficiently activate to reduce or eliminate blood flow to the physician's preferences. More generally, with the cap **102** and sealant **108** combination, dry close may be achieved within seconds of activating the sealant. Users can also compress the area with a gauze to express out any blood and then check for hemostasis. While illustrative times to hemostasis are provided, time to hemostasis can be impacted by anticoagulant medications given to patient. With the combination of cap and proximal sealant, hemostasis may be achieved faster than sealant alone.

Whether complete or substantial complete hemostasis occurs from the cap **102**, or a combination of the cap **102** and the sealant **104**, after hemostasis is achieved, the suture **106** can be trimmed by pushing down on the skin **16** while tensioning the suture **106** and using a suture trimming device (not shown), such as scalpel or other suture trimming device, to trim the suture as close to the skin as possible. Once the skin is released, the suture will sit well below the surface of the skin as shown in FIG. **11**D.

While reference has been made to the anchor **108** (**208**, **308**) remaining in the blood vessel and degraded, absorbed, or resorbed by the patient's body, it will be understood that in other configurations, the anchor **108** may be deployed and subsequently removed once sufficient closure of the puncture has occurred. In such a case, the anchor **108** is "temporarily" deployed and the other portions of the closure element, such as the cap **102** with the adhesive layer **128** (see FIGS. **3**C and **3**D) and the fluid-blocking component **104** described herein can be used to close the access site following removal of the anchor **108**. The cap **102** with the adhesive layer **128** may or may not cooperate with a suture **106** and lock onto a suture **106** that is optionally attached to the anchor **108**. The cap **102** is maintained in place against the vessel wall **14** by the adhesive layer **128** and optionally the fluid-blocking component **104**, with the fluid-blocking component **104** reducing or eliminating any tissue tract oozing. Delivery of the temporary anchor, the cap, and the sealant in this alternate configuration can be performed using the delivery systems and devices described herein, while accommodating removal of the anchor **108** by proximally drawing on the suture **106**, or another anchor actuator, to remove the anchor **108**. The anchor **108** may optionally pass through the lumen **110** of the cap **102**, with the body of the cap being sufficiently resilient to return to a closed state to close the access site. Alternatively, the anchor **108** can be withdrawn past a side of the cap **102**, with the cap **102** having sufficient resiliency to temporary deformation to return to a state to seal against the extravascular side of the vessel wall.

Handle Assembly Vessel Closure Delivery System

FIGS. **12**-**23**B illustrate a delivery system and method of inserting a closure device of the type disclosed above. Delivery system **430** can comprise a handle assembly **400** and a delivery sheath **440**. The handle assembly **400** can be configured to be selectively attached to a delivery sheath **440** (similar to delivery sheath **40**). Once attached to the delivery sheath **440**, the handle assembly **400** can be used to insert a closure device, such as, for example, closure device **100**.

As shown in FIGS. **12**-**13**E, the handle assembly **400** can include a handle body **402** having a proximal end **404** and a distal end **406**, an actuator, such as slider **450**, and an elongate opening **408** configured to provide a track for the slider **450**. The slider **450** can be configured to slide along the elongate opening **408** when engaged by a user and be selectively locked in place by the locking assembly **425**. This engagement can deploy the closure device **100**. The handle assembly **400** can also include a second slider **460** (see FIG. **13**A) configured in a second elongate opening **412** on the handle body **402**. Engagement of the slider **450** can deploy the anchor **108**, and then engagement of the second slider **460** can deploy the cap **102**.

In other embodiments, the handle assembly **400** may only have one actuator element, such as slider **450**, which when engaged can subsequently deploy the anchor **108** and cap **102** without the need for a second slider.

In some embodiments, such as the embodiment shown in the drawing, the handle body **402** can include one or more textured portions **414** to improve a user's grip on the handle assembly **400**. The handle assembly **400** can further include a connecting member **416** located at the distal end **406** of the handle body **402** and configured to be selectively attached to and removeable from a delivery sheath **440**. The connecting member **416** can be configured to attach to a sheath hub **418** of a delivery sheath **440**. The connecting member **416**, as shown in FIGS. **13**A-**13**F, comprises a set of locking members **420** having hooked ends **422**. The locking members **420** can be configured to selectively attach to the sheath hub **418** of a delivery sheath **440**, which attaches the handle assembly **400** to the delivery sheath **440** to form the delivery system **430**.

The handle assembly **400** can also include a release button **424** which can release the suture **106** once the closure device **100** is placed at a desired location. Engagement of the

release button **424** can release the delivery system **430** from the implanted closure device **100**. The release button **424** can include an engagement element such as release button fin **419**. The release button fin **419** can fit within release groove **407** and can be configured to slide within the length of groove **407** to release the suture **106** of the closure device **100** from the handle assembly **400**. In other embodiments, the functions of the release button **424** may be incorporated into one or more actuator elements such as slider **450** and/or secondary slider **460**.

FIG. **13**E illustrates a cross-sectional view of the handle assembly **400**. As shown in the Figures, slider **450** can include a first slider portion **450***a* and a second slider portion **450***b*. Slider portions **450***a*,**450***b* can be selectively connected together by interlocking ends **466***a*,**466***b*. A proximal locking assembly **421** can engage slider **450** to "lock" slider **450** at the proximal end **404** of the handle assembly **400**. For instance, complementary structures **421***a* and **451***a* on the proximal locking assembly **421** and the slide portion **450***a* of the slider **450** can engage to limit movement of the slider **450**, while depressing the proximal locking assembly **421** detaches or separates the complementary structure **421***a* from the complementary structure **451***a* to allow the slider **450** to move distally. The slider portions **450***a*,**450***b*, interlocking ends **466***s*,**466***b* and proximal locking assembly **421** can be made of a resilient material, such as flexible plastic, to allow the components to flex when depressed by a user. For example, a user can depress proximal locking assembly **421** to release slider **450** and allow the slider **450** to slide along elongate groove **408**. The proximal locking assembly **421** can be formed with the handle body **402**, such as having a living hinge connection with the handle body **402** or can be a separated mechanism connected or mounted to the handle body **402**.

FIGS. **14**A and **14**C illustrate an exploded view of the handle assembly **400**. The handle body **402** can comprise a first side **403** and a second side **405**, which when assembled together form the lumen **428** of the handle body **402**. The first side **403** and second side **405** can be assembled together to form the handle body **402** by using fasteners, such as screws **409** inserted into corresponding bores **411**.

The handle body **402** can also house a chamber assembly **427** having a chamber body **427***a* and a chamber cap **427***b* as shown in FIGS. **13**F and **14**B, which can be disposed at the distal end **406** of the handle body **402**. While the chamber assembly **427** is illustrated as two pieces, it will be understood that the chamber assembly **427** can utilize less or more pieces to form an assembly that can provide the functions described herein. The chamber assembly **427** can also be formed separately from the handle body **402**, as shown, though in other embodiments, the chamber assembly **427** may be integrally formed within the handle body **402**. The chamber assembly **427**, and in particular the chamber body **427** can align with the lumen **428** and the distal opening **436** to form a channel **437** through which the implant assembly **426** can deploy the closure device **100**.

The chamber assembly **427** can include a chamber body **427***a* with a nozzle **429** and a nozzle ring **439**. The nozzle **429** and ring **439** can be shaped to interface with the delivery sheath **440** and form a fluid-tight seal. The implant assembly **426** can be deployed from the lumen **428** through the channel **437** and then out of the nozzle **429** of the chamber assembly **427**, such as from the chamber body **427***a*, into the delivery sheath **440**. In some embodiments, the chamber assembly **427** can include a valve **431**. The valve **431** can be a one-way valve, preventing fluids from entering the lumen **428** of the handle body **402**. The valve **431** can be seated within a valve notch **472** at the proximal end of the chamber body **427***a*. The chamber body **427***a* can also include a plateau **433**. The chamber assembly **427** as shown includes a chamber cap **427***b*. The chamber cap **427***b* can be situated on top of the chamber **427** in the distal end **406** of the handle body **402**. The chamber cap **427***b* can help form the channel **437** and can include one or more positioning elements **435** which can retain the chamber cap **427***b* in the correct orientation and location in the handle body **402**. The chamber body **427***a* and the chamber cap **427***b*, when connected or coupled together, form a cavity **449** to receive the closure device, as illustrated in FIG. **13**F. The cavity **449** communicates with, and forms part of the lumen **428**.

An implant assembly **426** is contained within the handle body **402**. The implant assembly **426** houses the closure device **100** and other elements required to place the closure device **100**. The implant assembly **426** can be configured to be positioned within the lumen **428** of the handle body **402**. The lumen **428** can extend from a proximal opening **434** of the proximal end **404** along a longitudinal axis **432** and terminate at a distal opening **436** on the distal end **406** of the handle body **402**. The implant assembly **426** can be situated within the lumen **428** so that it can be in mechanical communication with elements of the handle body (i.e., slider **450** and secondary slider **460**).

The implant assembly **426**, shown in detail in FIGS. **14**A, **14**C-**14**F, **15** and **16**, includes a closure device such as closure device **100**, a support tube **442**, a slider **438**, and a stopper **444**. The slider **438** can comprise a slider body **446** having a protrusion **448** providing for mechanical interface between slider **450** on the external side of the handle body **402** and slider body **446** situated on the implant assembly **426** within the lumen **428** of the handle body **402**. The slider **438** can also include a groove **447***a* configured to receive the nested elements (support tube **442**, closure device **100**, tamper tube **454**, and push wire **452**) of the implant assembly **426**. Slider **438** can also include suture groove **447***b*, which can allow mechanical communication between the implant assembly and the handle body **402** to facilitate release of suture **106** from the implant assembly **426**.

The stopper **444** can include a stopper elbow **466** configured to engage with interior locking mechanism **423**. When the stopper **444** is moved in a distal direction towards the distal end **406** of the handle body **402** the stopper **444** will pass the interior locking assembly **423**. Once past the interior locking assembly **423**, the stopper elbow **466** can engage the interior locking assembly **423**, preventing the stopper **444** from moving in a proximal direction. The stopper **444** can prevent closure device elements, such as the fluid blocking component **104**, from flowing back into the handle assembly **400**. The interior locking mechanism **423** can be formed with the handle body **402**, such as having a living hinge connection with the handle body **402** or can be a separated mechanism connected or mounted to the handle body **402**.

FIGS. **14**D and **14**E illustrate detailed views of slider **438** of the implant assembly **426**. As discussed above, the slider **438** can include one or more structures configured to engage with exterior elements of the handle body **402** to control insertion and placement of the closure device **100** and disengagement of the closure device **100** from the delivery system **430**. The suture groove **447***b* of slider **438** can house a pin **417** positioned within a bore **415**.

As shown in FIG. **14**F, the suture **106** can be looped around the pin **417** during assembly and a friction fit of the suture **106** between the pin and the suture groove **447***b* can retain the suture **106** within the slider **438** during insertion

of the closure device **100**. After the closure device **100** is deployed to the blood vessel, the delivery system **430** is decoupled from the closure device **100** by releasing the suture **106** from the slider **438**. The release button **424** is slid in a proximal direction towards the pin **417**, causing the release button fin **419** to push the pin **417** into bore **415**. When the pin **417** is pushed into the bore **415**, the suture **106** is released from the pin **417**, effectively releasing the suture **106** and closure device **100** from the delivery system **430**.

The support tube **442** can contain the suture **106** which can be threaded therethrough. The support tube **442** can also contain a push wire **452** and a tamper tube **454**. The distal tip **456** of the push wire **452** can have a forked or pronged shape to help push the closure device **100** out of the delivery system **430**, while a proximal end includes a push wire bend **477** that mounts to the slider portion **450***a* so that the push wire **452** can be moved through movement of the slider portion **450***a*. The tamper tube **454** can be used to tamp the cap **102** of the closure device **100** after the anchor **108** is positioned. The stopper **444** can prevent the implant assembly **426** from sliding out of the distal opening **436** of the handle body **402**. The closure device **100**, as discussed above, can comprise an anchor **108**, a cap **102**, and a fluid-blocking component **104** all configured on a suture **106**. The fluid-blocking component **104** can be an active biologic material, such as polyethylene glycol (PEG), fibrin sealants, copolymer of glucosamine and N-acetyl glucosamine, dextran (complex branched glucan(a polysaccharide. polypeptide adhesive structures, adhesive protein containing L-3,4-dihydroxyphenylalanine (L-DOPA), adhesive protein containing DOPA and phosphoserine, collagen, polyacrylic acid, cross-linked with allyl sucrose or allyl pentaerythritol, polyacrylic acid, cross-linked with divinyl glycol, Acrylic resinous polymer composed of methyl-2-cynoacrylate units, or another fully bioabsorbable sealant-type material that could be optionally incorporated into a shaped, flexible substrate. The sealant material could be activated by fluids present in the patient's tissue tract, such as blood or other fluids, and can be protectively stored inside the sheath/actuators or a chamber of the delivery device until positioned directly on top of the cap **102**.

Once advanced into the desired location, the sealant **104** can be exposed to the blood or fluid, such as through unsheathing the fluid-blocking component **104** and positioning the fluid-blocking component **104** into direct contact with the tissue where it can react by coming into contact with blood and other fluids. This reaction can cause the fluid-blocking component **104** to expand and absorb blood and other fluids and bond to surrounding tissue and the cap **102**. The sealant can act as a glue and aid with "locking" the cap **102** in place on the blood vessel **10**, and actively coagulates the entire access tract **22**. The chemical formulation, quantity, carrier matrix, and dimensions of the fluid-blocking component **104** can be selected specifically to provide one or more of the functions of locking in place of the sealing component (e.g. cap **102**), to provide a fast acting and leak-free dry close, and reduce tissue tract oozing.

For instance, the sealant can form a plug having a length of about 1 mm to about 10 mm and can optionally be trimmed to length in the patient along with the suture after deployment, or the adhesive component can extend the full length of the tissue tract and trimmed to fit the patient. When the fluid-blocking component **104** is formed of a matrix, the matrix can have an area of about 0.012 square inches to about 0.12 square inches, about 0.12 square inches to 0.6 square inches, about 0.6 to 1.0 square inches. The matrix material can be thin and flexible such that it can be wrapped around the suture in the delivery system to fit inside a tube for delivery to the implant location. This results in a volume of fluid-blocking component, optionally including a matrix containing a sealant such as PEG or other biocompatible material, of between about 0.004 to about 0.040 cubic inches in volume, about 0.0.040 to about 0.100 cubic inches, about 0.100 to about 0.400 cubic inches.

The fluid-blocking component **104** can be deployed so that is disposed on the suture **106**. The fluid-blocking component **104**, therefore, can be deployed in a flowable composition without a carrier matrix or can be formed as part or with a carrier matrix. For instance, the fluid-blocking component **104** can be disposed around the suture **106** in a generally cylindrical component, can be bonded to the suture **106** itself, can be bonded to the cap **102**, and combinations or modifications thereof. Because the sealant **104** is positioned proximal relative to the cap **102**, the sealant **104** can actively coagulate the access tract **22** and optionally actively coagulate all of access tract **22** to the surface of the skin **16**.

FIGS. **17**A and **17**B illustrate a dilator assembly **470** having a dilator tube **456** with a dilator hub **458** which can be assembled on the dilator tube **456**. The dilator tube **456** can be inserted into the delivery sheath **440** in order to stretch the opening in the skin **16** and access tract **22** to allow for insertion of the delivery sheath **440**. The dilator hub **458** can be configured to be selectively attached to and removed from the delivery sheath **440** via the sheath hub **418**. The dilator hub **458** can include locking arms **459** which can selectively engage the receiving members **468** of the sheath hub **418**, such as through an interference or friction fit. The dilator tube **456** and/or the dilator hub **458** can be formed of biocompatible materials, such as but not limited to nylon, Polyethylene, High Density Polyethylene (HDPE), or other polymeric materials.

The dilator tube **456** includes distal openings **455***a*,**455***b* toward a distal end and a proximal opening **461** towards a proximal end. The distal openings **455***a*,**455***b* communicate with a passageway **475** to form a fluid marker (e.g., blood marker) to aid with positioning the dilator tube **456** within a body lumen. For instance, a fluid from inside a body lumen, such as blood, is permitted to flow through one or both of the distal openings **455***a*, **455***b* and through the passage **475** and out of the proximal opening **461** to indicate a particular depth. While the distal openings **455***a*, **455***b* are illustrated as being positioned on opposite sides of the dilator tube **456**, it will be understood that the location and number of openings can vary.

Disposed between the locking arms **459** is a mounting member **463** that aids with mounting the dilator hub **458** to the delivery sheath **440**. The mounting member **463** can be bifurcated with a first leg **465***a* and a second leg **465***b* each having a protruding portion **467**. The bifurcated structure allows for flexing of the mounting member **463** as it engages with the delivery sheath **440**, while the protruding portion **467** friction or interference fits within the sheath hub **418**.

The delivery sheath **440** shown in FIGS. **18**A and **18**B comprises a sheath **441** for delivering the dilator tube **456** and the implant assembly **426** through the access tract **22**. A sheath hub **418** can be assembled on the sheath **441** in order to allow for the selective attachment of other surgical instruments to the delivery sheath **440** such as dilator tube **456**. The sheath hub **418** can include receiving members **468** configured to receive surgical instruments and selectively retain the surgical instruments on the delivery sheath **440**, such as but not limited to the locking member **420** and the locking arms **459** of the dilator hub **458**. The receiving

member **468** can be channels or passages formed by a wall **471**. The proximal end **443** of the sheath **441** can cooperate with a valve **462** to prevent the backflow of fluid into a surgical instrument attached to the delivery sheath **440**. The valve **462** is retained within the sheath hub **418** by a valve cap **464**, with a strain relief member **469** extending distally from the sheath hub **418**. One or more of the sheath hub **418**, the sheath **441**, the valve **462**, the valve cap **464**, the strain relief member **469** can be bonded together through an overmold bond technique or otherwise mounted together using a combination of friction or interference fit and adhesives, thermal, chemical, or other bonding techniques.

When the dilator assembly **470** is mounted to the delivery sheath **440**, the mounting member **463** passes through the valve cap **464** and the valve **462**. With one or more ports **473** aligned with the distal openings **455** a fluid pathway is formed to allow for depth determination and location of the delivery sheath **440**. Additionally, indicia **474** are provided on the sheath **441** to provide a depth indication for the delivery sheath **440**. For instance, letters, numbers, or other symbols can be used to identify insertion depth. In one configuration, first indica **474***a*, can be separated by about 1 cm, with a second indica **474***b* being about 0.5 cm from the adjacent first indicia **474***a*. It will be understood that one or more second indica **474***b* can be disposed between adjacent first indica **474***a*, thereby changing the depth granularity. Additionally, the separation of the first indica **474***a* can range from about 0.1 cm to about 5 cm, from about 0.25 cm to about 2.5 cm, about 0.5 cm to about 1 cm, less than about 5 cm, less than about 4 cm, less than about 3 cm, less than about 2 cm, less than about 1 cm, less than about 0.5 cm.

As shown in FIGS. **19**A and **19**B, the handle assembly **400** can be selectively attached to the delivery sheath **440** by inserting locking members **420** of the handle assembly **400** into the receiving members **418** of the delivery sheath to form the delivery system **430**. The locking members **420** can be made of a resilient material, such as flexible plastic, to allow the locking members **420** to flex when inserted into the receiving member **418**. The locking members **420** can be flexed to disengage the hooked ends **422** to decouple the handle assembly **400** from the delivery sheath **440**. As the locking members **420** cooperate with the receiving members **468**, the chamber nozzle **429** penetrates the valve **462** to provide access to the sheath **441** for delivery and deployment of the closure device **100**. When the delivery system **430** is engaged to deploy the closure device **100**, as in FIG. **19**C, the slider **450** can be moved in a distal direction towards the delivery sheath **440**, which can cause the anchor **108** of the closure device **100** to be deployed.

FIG. **19**D illustrates a close-up view of the partially-deployed closure device of FIG. **19**C. The forked end **457** of the push wire **454** deploys the anchor **108** of the closure device **100** out from the delivery sheath **441**.

Method of Closure Device Insertion with Handle Assembly

FIGS. **20**A through **23**C illustrate an example of a method of inserting a closure device using deployment system **430**. First the dilator tube **456** can be inserted into the delivery sheath **440**. The dilator tube **456** can be selectively attached to the sheath **441** by connecting the dilator hub **458** to the sheath hub **418** in order to maintain the position of the dilator tube **456** in the delivery sheath **440** (FIGS. **20**A-**20**B). The dilator tube **456** can be used to stretch the opening of the skin **16** and access tract **22** to allow for placement of a closure device **100**.

Next, the dilator hub **458** can be disengaged from the sheath hub **418** and the dilator tube **456** can be removed, as shown in FIG. **21**B. The delivery sheath **440** can remain in the access tract **22**. FIGS. **21**C and **21**D illustrate a method of connecting the handle assembly **400** to the delivery sheath **440**. The handle assembly **400** can be selectively connected to the delivery sheath **440** by engaging the connecting members of the handle assembly **400** with the receiving member or sheath hub **418** of the delivery sheath **440**.

Once the handle assembly **400** is connected to the delivery sheath **440**, the user can depress the proximal locking assembly **421** to unlock the slider **450** and push the slider in a distal direction towards the distal end **406** of the handle body **400**, as illustrated in FIG. **22**. This causes the delivery system **430** to eject the anchor **108** into the blood vessel lumen **12** so that the anchor **108** can contact the lumen wall **14** and be positioned on the puncture or access site **18**. Once the slider **450** reaches the distal end **406**, the anchor **108** should be ejected from the delivery system **430**, with the cap **102** and fluid-blocking component **104** remaining in the support tube **442** of the implant assembly **426** within the delivery sheath **440**.

Turning to FIG. **23**A, the slider **450** can be configured to slide along the elongate opening **408** until slider portion **450***b* slides past locking assembly **425**, at which point locking assembly **425** can lock slider portion **450***b* at the distal end of elongate opening **408** (the locking assembly **425** can be formed with the handle body **402**, such as having a living hinge connection with the handle body **402** or can be a separated mechanism connected or mounted to the handle body **402**). Once slider portion **450***b* is locked by the locking assembly **425**, the user can depress slider portion **450***a* to release interlocking end **466***a* from interlocking end **466***b*, effectively releasing slider portion **450***a* from slider portion **450***b*. Slider portion **450***a*, to which the push wire bend **477** of the push wire **452** is mounted, can be moved proximally to retract the push wire **452** in a proximal direction from the tissue and into the handle assembly **400**.

After the anchor **108** is deployed, a user can engage the secondary slider **460** by depressing plunger **476** and pushing the slider **460** in a distal direction toward the distal end **406** of the handle assembly **400**. FIG. **23**B illustrates the secondary slider **460** engaging the tamper tube **454** (or a portion of the slider **438**) and tamping the cap **102** to eject the cap **102** from the delivery system **430**. The delivery system **430** can then be pulled in a proximal direction to tension the suture **106** and secure the position of the anchor **108** and cap **102**. After the anchor **108** and cap **102** are placed, the release button **424** can be engaged to release the suture **106** and closure device **100** from the delivery system **430** with the fluid-blocking component **104** remaining in the access tract **22**, as illustrated in FIG. **23**C. Thereafter the suture can be trimmed at or below the level of the skin or tissue.

The articles "a," "an," and "the" are intended to mean that there are one or more of the elements in the preceding descriptions. The terms "comprising," "including," and "having" are intended to be inclusive and mean that there may be additional elements other than the listed elements. Additionally, it should be understood that references to "one embodiment" or "an embodiment" of the present disclosure are not intended to be interpreted as excluding the existence of additional embodiments that also incorporate the recited features. Numbers, percentages, ratios, or other values stated herein are intended to include that value, and also other values that are "about" or "approximately" the stated value, as would be appreciated by one of ordinary skill in the art encompassed by embodiments of the present disclosure. A stated value should therefore be interpreted broadly enough to encompass values that are at least close enough to the stated value to perform a desired function or achieve a

desired result. The stated values include at least the variation to be expected in a suitable manufacturing or production process, and may include values that are within 5%, within 1%, within 0.1%, or within 0.01% of a stated value.

A person having ordinary skill in the art should realize in view of the present disclosure that equivalent constructions do not depart from the spirit and scope of the present disclosure, and that various changes, substitutions, and alterations may be made to embodiments disclosed herein without departing from the spirit and scope of the present disclosure. Equivalent constructions, including functional "means-plus-function" clauses are intended to cover the structures described herein as performing the recited function, including both structural equivalents that operate in the same manner, and equivalent structures that provide the same function. It is the express intention of the applicant not to invoke means-plus-function or other functional claiming for any claim except for those in which the words 'means for' appear together with an associated function. Each addition, deletion, and modification to the embodiments that falls within the meaning and scope of the claims is to be embraced by the claims.

The terms "approximately," "about," and "substantially" as used herein represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately," "about," and "substantially" may refer to an amount that is within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of a stated amount. Further, it should be understood that any directions or reference frames in the preceding description are merely relative directions or movements. For example, any references to "up" and "down" or "above" or "below" are merely descriptive of the relative position or movement of the related elements.

Following are some further example embodiments of the invention. These are presented only by way of example and are not intended to limit the scope of the invention in any way. Further, any example embodiment can be combined with one or more of the example embodiments.

Embodiment 1. A vessel closure device including a bioabsorbable vessel closure device for delivering immediate hemostasis at a puncture site in a wall of a blood vessel, the closure device including an intravascular anchor comprising one or more suture attachment points, an extravascular cap comprising a lumen, a sealant, and a suture connected to at least one of the one or more suture attachment points of the intravascular anchor and threaded through the lumen of the extravascular cap and through the sealant to connect the intravascular anchor to the extravascular cap and to the sealant, wherein each of the intravascular anchor, extravascular cap, sealant, and suture are formed of bioabsorbable materials.

Embodiment 2. The vessel closure device of embodiment 1, wherein the intravascular anchor includes an elongate body comprising a flexible member and a keel.

Embodiment 3. The vessel closure device of any of embodiment 1-2, wherein the extravascular cap is formed of a flexible material.

Embodiment 4. The vessel closure device of any of embodiment 1-3, wherein the sealant comprises polyethylene glycol (PEG).

Embodiment 5. The vessel closure device of any of embodiment 1-4, wherein the suture comprises a distal suture portion and a proximal suture portion.

Embodiment 6. The vessel closure device of any of embodiment 1-5, wherein the diameter of the lumen of the extravascular cap is smaller than the diameter of the distal suture portion.

Embodiment 7. The vessel closure device of any of embodiment 1-6, wherein the intravascular anchor comprises a material selected from Polyglycolic acid (PGA), Poly-L-Latic acid (PLLA), Polycaprolactone (PCL), Poly-DL-lactic acid (PDLLA), Poly trimethylene carbonate (PTMC), and Poly para-dioxanone (PPDO).

Embodiment 8. The vessel closure device of any of embodiment 1-7, wherein the intervascular anchor comprises a plurality of ribs radiating from the keel to a raised edge of the elongate body.

Embodiment 9. The vessel closure device of any of embodiment 1-8, wherein the sealant can expand up to 4 times its original size when introduced to fluids.

Embodiment 10. A vessel closure device for delivering immediate hemostasis at a puncture site in a wall of a blood vessel, the closure device including an intravascular anchor comprising one or more suture attachment points, an extravascular cap comprising a lumen, a sealant comprising a lumen, and a suture connected to at least one of the one or more suture attachment points of the intravascular anchor and threaded through the lumen of the extravascular cap and through the lumen of the sealant to connect the intravascular anchor to the extravascular cap and to the sealant, wherein the suture comprises a proximal suture portion and a distal suture portion, wherein the distal suture portion has a diameter greater than a diameter of the lumen of the extravascular cap, wherein the distal suture portion creates an interference fit to lock the extravascular cap over the puncture site, wherein each of the intravascular anchor, extravascular cap, sealant, and suture are formed of bioabsorbable materials.

Embodiment 11. The vessel closure device of any of embodiment 10, wherein the extravascular cap is formed of a flexible material.

Embodiment 12. The vessel closure device of any of embodiment 10-11, wherein the suture is a braided suture.

Embodiment 13. The vessel closure device of any of embodiment 10-12, wherein the sealant is threaded onto the suture at a location proximal to the extravascular cap.

Embodiment 14. The vessel closure device of any of embodiment 10-13, wherein the sealant when activated locks the extravascular cap in place and coagulates an access tract of the puncture site providing immediate hemostasis.

Embodiment 15. The vessel closure device of any of embodiment 10-14, wherein the intravascular anchor comprises an elongate body comprising a flexible member.

Embodiment 16. The vessel closure device of any of embodiment 10-15, wherein the intravascular anchor comprises a raised keel located on a central axis of the elongate body and spanning the length of the elongate body.

Embodiment 17. The vessel closure device of any of embodiment 10-16, wherein the raised keel comprises one or more suture attachment points.

Embodiment 18. The vessel closure device of any of embodiment 10-17, wherein the sealant comprises polyethylene glycol (PEG).

Embodiment 19. An intravascular anchor for a vessel closure device for delivering immediate hemostasis at a puncture site in a wall of a blood vessel, the intravascular anchor includes an elongate body including a flexible member for conforming to the wall of the blood vessel, a keel having one or more suture attachment points, wherein the keel is an elongate member centrally located along a central

axis of the elongate body, wherein the intravascular anchor comprises a bioabsorbable material selected from Polyglycolic acid (PGA), Poly-L-Latic acid (PLLA), Polycaprolactone (PCL), Poly-DL-lactic acid (PDLLA), Poly trimethylene carbonate (PTMC), and Poly para-dioxanone (PPDO).

Embodiment 20. The intravascular anchor of claim 19, wherein the elongate body includes a plurality of ribs radiating from the keel to a raised edge forming the perimeter of the elongate body.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope. It shall be further understood that although the present invention has been described in relation to vessel closure, it is contemplated that the closure component of the present invention may be utilized to close other openings in the body such as PFO openings, or openings formed in organs such as the stomach for certain surgical procedures.

What is claimed is:

1. A vessel closure device for delivering hemostasis at a puncture site in a wall of a blood vessel, the vessel closure device is configured to be disposed within a handle that is configured to attach to a delivery sheath before delivery of the vessel closure device to the wall of the blood vessel through the delivery sheath, the vessel closure device comprising:

an intravascular anchor comprising one or more suture attachment points;

an extravascular cap comprising a lumen;

a sealant comprising polyethylene glycol (PEG), the sealant being configured to expand from about 2 times to about 4 times its original size when introduced to fluids, the sealant being configured to lock the extravascular cap in a spaced relationship with the intravascular anchor when the sealant is disposed on the extravascular cap; and

a suture connected to at least one of the one or more suture attachment points of the intravascular anchor and threaded through the lumen of the extravascular cap and through the sealant to connect the intravascular anchor to the extravascular cap and to the sealant, a first portion of the suture configured to extend between the intravascular anchor and the extravascular cap and a second portion of the suture configured to extend between the intravascular anchor and the extravascular cap, the first portion of the suture and the second portion of the suture being braided together to form an engagement portion configured to extend between the intravascular anchor and the extravascular cap and having a diameter greater than a remainder of the suture, the engagement portion being configured to cooperate with the extravascular cap,

wherein each of the intravascular anchor, extravascular cap, sealant, and suture are formed of bioabsorbable materials.

2. The vessel closure device of claim **1**, wherein the intravascular anchor comprises an elongate body comprising a flexible member and a keel.

3. The vessel closure device of claim **1**, wherein the extravascular cap is formed of an elastomeric material.

4. The vessel closure device of claim **1**, wherein the suture comprises a distal suture portion and a proximal suture portion.

5. The vessel closure device of claim **4**, wherein the diameter of the lumen of the extravascular cap is smaller than the diameter of the distal suture portion.

6. A vessel closure device for delivering hemostasis at a puncture site in a wall of a blood vessel, the vessel closure device is configured to be disposed within a handle that is configured to attach to a delivery sheath before delivery of the vessel closure device to the wall of the blood vessel through the delivery sheath, the closure device comprising:

an intravascular anchor comprising one or more suture attachment points;

an extravascular cap comprising a lumen;

a sealant comprising a preformed lumen comprising polyethylene glycol (PEG), the sealant being configured to expand about 2 times to about 4 times its original size, including expanding longitudinally, when introduced to fluids to provide secondary sealing of the puncture site and stop oozing of a tissue tract extending to the puncture site; and

a suture connected to at least one of the one or more suture attachment points of the intravascular anchor and threaded through the lumen of the extravascular cap and through the lumen of the sealant to connect the intravascular anchor to the extravascular cap and to the sealant,

wherein the suture comprises a proximal suture portion and a distal suture portion, wherein the distal suture portion has a diameter greater than a diameter of the lumen of the extravascular cap, the distal suture portion being formed of a first portion of the suture configured to extend between the intravascular anchor and the extravascular cap and a second portion of the suture configured to extend between the intravascular anchor and the extravascular cap, the first portion of the suture and the second portion of the suture being braided together to form an engagement portion configured to extend between the intravascular anchor and the extravascular cap and having a diameter greater than a remainder of the suture, the engagement portion having the diameter greater than the diameter of the lumen of the extravascular cap and being configured to cooperate with the extravascular cap;

wherein the distal suture portion creates an interference fit to lock the extravascular cap over the puncture site;

wherein each of the intravascular anchor, extravascular cap, sealant, and suture are formed of bioabsorbable materials.

7. The vessel closure device of claim **6**, wherein the extravascular cap is formed of flexible material.

8. The vessel closure device of claim **7**, wherein the sealant when activated locks the extravascular cap in place and coagulates an access tract of the puncture site providing hemostasis.

9. The vessel closure device of claim **6**, wherein the suture is a braided suture.

10. The vessel closure device of claim **6**, wherein the sealant is threaded onto the suture at a location proximal to the extravascular cap.

11. The vessel closure device of claim **6**, wherein the intravascular anchor comprises an elongate body comprising a flexible member.

12. The vessel closure device of claim 11, wherein the intravascular anchor comprises a raised keel located on a central axis of the elongate body and spanning a length of the elongate body.

13. The vessel closure device of claim 12, wherein the raised keel comprises one or more suture attachment points.

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