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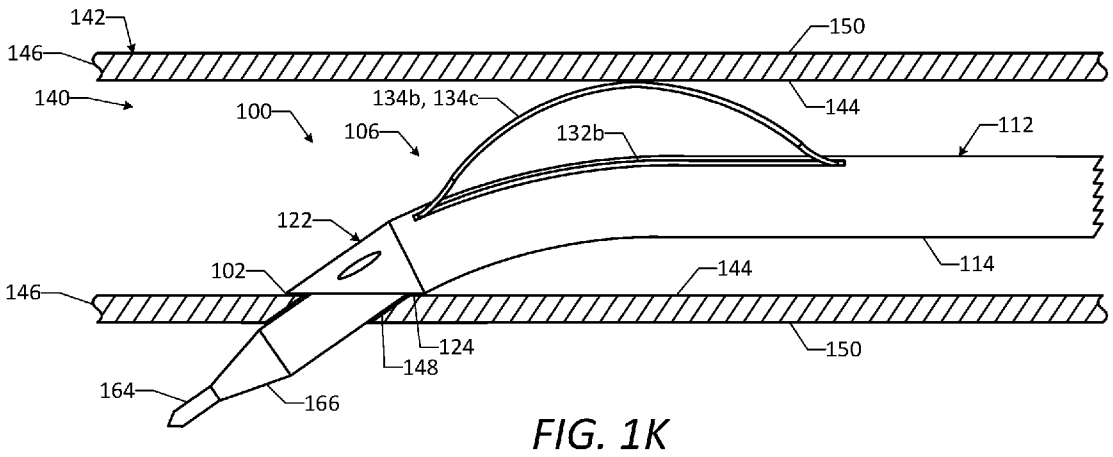

FIG. 1K

(57) Abstract: Vascular access devices and methods of their use are provided. In one embodiment, a vascular access device includes a catheter (112) and at least one deployable wire (134). The catheter includes a primary lumen extending from a proximal end to a distal end of the catheter. The at least one deployable wire is secured to the catheter and configured to move relative to the catheter between a delivery configuration and a deployed configuration.

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VASCULAR ACCESS DEVICES AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/331,254, filed on May 3, 2016, which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present disclosure relates generally to medical devices and methods, and more particularly to endovascular access devices and related methods of using such devices to provide access for performing a medical procedure on a patient in need thereof.

BACKGROUND

[0003] Many types of surgical and interventional procedures have previously been developed for use in organs, tissues, or body cavities of the body. Traditionally, access to such organs, tissues, or body cavities is attained through the formation of one or more open surgical incisions in the body, whereby the affected organs, tissues, or body cavities are surgically exposed. In recent years, "minimally invasive" surgical/interventional techniques have been developed in which endoscopes are utilized to view the affected organ, tissue, or body cavity, and operative instruments or other devices are inserted into the body through relatively small access incisions to accomplish the desired interventional procedure. These minimally invasive techniques have replaced many traditional open surgical techniques in various areas of medicine, such as cardiology.

[0004] In performing certain cardiac interventional procedures, such as a coronary bypass procedure, access to desired vasculature may be achieved by percutaneously inserting an access device through the natural lumen of a vessel, forming a hemostatic connection between the access device and an inner surface of a wall of the vessel, and forming an aperture through the vessel wall to access a thoracic region of the patient. Operative instruments or other devices then may be passed through the access device and the aperture in the vessel wall and into the thoracic region to perform a cardiac procedure on the desired vasculature. Example devices and methods for providing this type of endovascular access for various cardiac procedures, such as a coronary

bypass procedure, are described in U.S. Patent No. 8,663,321 to Crisco, which is incorporated by reference herein.

[0005] There remains a need for improved vascular access devices and methods of using such devices to provide access for performing cardiac interventional procedures on patients in need thereof. In particular, it would be advantageous to provide a vascular access device that easily passes through the natural lumen of a vessel, quickly and effectively forms a hemostatic connection between the access device and an inner surface of a wall of the vessel, and provides a working lumen of sufficient size to allow operative instruments or other devices to be passed therethrough to perform a desired cardiac procedure on the patient. Desirably, the vascular access device should allow a physician to assess the integrity of the hemostatic connection and an aperture formed through the vessel wall. The vascular access device also should allow sufficient blood flow to pass through the natural lumen of the vessel while the access device is positioned therein.

BRIEF SUMMARY

[0006] Vascular access devices and methods of using such devices to provide access for performing cardiac interventional procedures are provided. According to one aspect, a vascular access device is provided. In one embodiment, the vascular access device includes a catheter and at least one deployable wire. The catheter includes a primary lumen extending from a proximal end to a distal end of the catheter. The at least one deployable wire is secured to the catheter and configured to move relative to the catheter between a delivery configuration and a deployed configuration.

[0007] In another aspect, a method of using a vascular access device to provide access for performing a cardiac procedure on a patient is provided. In one embodiment, the method includes the steps of percutaneously inserting a distal end portion of the vascular access device into a natural lumen of a vessel of the patient, deploying at least one deployable wire from a catheter of the vascular access device such that the deployable wire engages an inner surface of a wall of the vessel and biases the catheter to engage the inner surface such that a hemostatic connection is formed between the catheter and the inner surface, and advancing at least one instrument through the catheter and through the wall to form an aperture in the wall, while maintaining the hemostatic connection between the catheter and the inner surface.

[0008] These and other aspects and embodiments of the present disclosure will be apparent or will become apparent to one of ordinary skill in the art upon review of the following detailed description when taken in conjunction with the drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1A is a side view of a vascular access device in accordance with one or more embodiments of the disclosure.

[00010] FIG. 1B is a detailed end view of the vascular access device of FIG. 1A, taken along line 1B-1B in FIG. 1A.

[00011] FIG. 1C is a detailed cross-sectional end view of the vascular access device of FIG. 1A, taken along line 1C-1C in FIG. 1A.

[00012] FIG. 1D is a detailed cross-sectional end view of the vascular access device of FIG. 1A, taken along line 1D-1D in FIG. 1A.

[00013] FIG. 1E is a side view of a distal end portion of the vascular access device of FIG. 1A, showing a number of deployable wires of the vascular access device in a deployed configuration.

[00014] FIG. 1F is a perspective view of the distal end portion of the vascular access device of FIG. 1A, showing the deployable wires of the vascular access device in the deployed configuration.

[00015] FIG. 1G is a detailed end view of the distal end portion of the vascular access device of FIG. 1A, taken along line 1G-1G in FIG. 1E, showing the deployable wires of the vascular access device in the deployed configuration.

[00016] FIG. 1H is a side view of a portion of the vascular access device of FIG. 1A positioned within a natural lumen of a vessel, showing a distal end portion of the vascular access device in a straight configuration and the deployable wires in a delivery configuration.

[00017] FIG. 1I is a side view of a portion of the vascular access device of FIG. 1A positioned within the natural lumen of the vessel, showing the distal end portion in a curved configuration.

[00018] FIG. 1J is a side view of a portion of the vascular access device of FIG. 1A positioned within the natural lumen of the vessel, showing the distal end portion in the curved configuration and the deployable wires in the deployed configuration.

[00019] FIG. 1K is a side view of a portion of the vascular access device of FIG. 1A positioned within the natural lumen of the vessel, showing a guidewire and a dilator passed through the vascular access device and a wall of the vessel to form an aperture in the vessel wall.

[00020] FIG. 1L is a side view of a portion of the vascular access device of FIG. 1A positioned within the natural lumen of the vessel, showing the aperture in the vessel wall and a hemostatic connection formed between the distal end portion and the vessel wall.

[00021] FIG. 1M is a side view of a portion of the vascular access device of FIG. 1A positioned within the natural lumen of the vessel, showing an operative instrument or device passed through the vascular access device and the aperture in the vessel wall.

[00022] FIG. 2A is a side view of a vascular access device in accordance with one or more embodiments of the disclosure.

[00023] FIG. 2B is a top view of the vascular access device of FIG. 2A.

[00024] FIG. 2C is a bottom view of the vascular access device of FIG. 2A.

[00025] FIG. 2D is a cross-sectional side view of the vascular access device of FIG. 2A, taken along line 2D-2D in FIG. 2B.

[00026] FIG. 2E is a detailed end view of the vascular access device of FIG. 2A, taken along line 2E-2E in FIG. 2A.

[00027] FIG. 2F is a detailed cross-sectional end view of the vascular access device of FIG. 2A, taken along line 2F-2F in FIG. 2A.

[00028] FIG. 2G is a detailed cross-sectional end view of the vascular access device of FIG. 2A, taken along line 2G-2G in FIG. 2A.

[00029] FIG. 2H is a side view of a distal end portion of the vascular access device of FIG. 2A, showing a number of deployable wires of the vascular access device in a deployed configuration.

[00030] FIG. 2I is a cross-sectional side view of the distal end portion of the vascular access device of FIG. 2A, showing the deployable wires of the vascular access device in the deployed configuration.

[00031] FIG. 2J is a detailed end view of the distal end portion of the vascular access device of FIG. 2A, taken along line 2J-2J in FIG. 2H, showing the deployable wires of the vascular access device in the deployed configuration.

[00032] FIG. 2K is a side view of a portion of the vascular access device of FIG. 2A positioned within a natural lumen of a vessel, showing the deployable wires of the vascular access device in a delivery configuration.

[00033] FIG. 2L is a side view of a portion of the vascular access device of FIG. 2A positioned within the natural lumen of the vessel, showing the deployable wires in the deployed configuration.

[00034] FIG. 2M is a side view of a portion of the vascular access device of FIG. 2A positioned within the natural lumen of the vessel, showing a guidewire and a dilator passed through the vascular access device and a wall of the vessel to form an aperture in the vessel wall.

[00035] FIG. 2N is a side view of a portion of the vascular access device of FIG. 2A positioned within the natural lumen of the vessel, showing the aperture in the vessel wall and a hemostatic connection formed between the distal end portion and the vessel wall.

[00036] FIG. 2O is a side view of the vascular access device of FIG. 2A and a sheath, showing the sheath in an advanced position.

[00037] FIG. 2P is a side view of the vascular access device of FIG. 2A and the sheath, showing the sheath in a retracted position and the deployable wires in the deployed configuration.

[00038] FIG. 2Q is a detailed cross-sectional end view of the vascular access device of FIG. 2A and the sheath, taken along line 2Q-2Q in FIG. 2O.

[00039] FIG. 2R is a detailed cross-sectional end view of the vascular access device of FIG. 2A and the sheath, taken along line 2R-2R in FIG. 2O.

[00040] FIG. 2S is a side view of a vascular access device in accordance with one or more embodiments of the disclosure.

[00041] FIG. 2T is a top view of the vascular access device of FIG. 2S.

[00042] FIG. 2U is a bottom view of the vascular access device of FIG. 2S.

[00043] FIG. 2V is a cross-sectional side view of the vascular access device of FIG. 2S, taken along line 2V-2V in FIG. 2T.

[00044] FIG. 3A is a top view of a vascular access device in accordance with one or more embodiments of the disclosure.

[00045] FIG. 3B is a cross-sectional side view of the vascular access device of FIG. 3A, taken along line 3B-3B in FIG. 3A.

[00046] FIG. 3C is a side view of a portion of the vascular access device of FIG. 3A positioned within a natural lumen of a vessel, showing a distal end portion of the vascular access device in a straight configuration.

[00047] FIG. 3D is a side view of a portion of the vascular access device of FIG. 3A positioned within the natural lumen of the vessel, showing the distal end portion in a curved configuration and a guidewire of the vascular access device passed through a wall of the vessel to form an aperture in the vessel wall.

[00048] FIG. 3E is a side view of a portion of the vascular access device of FIG. 3A positioned within the natural lumen of the vessel, showing a catheter of the vascular access device passed through the aperture in the vessel wall.

[00049] FIG. 3F is a side view of a portion of the vascular access device of FIG. 3A positioned within the natural lumen of the vessel, showing the catheter passed through the aperture in the vessel wall and a hemostatic connection formed between the catheter and the vessel wall.

[00050] FIG. 4A is a top view of a vascular access device in accordance with one or more embodiments of the disclosure.

[00051] FIG. 4B is a cross-sectional side view of the vascular access device of FIG. 4A, taken along line 4B-4B in FIG. 4A.

[00052] FIG. 4C is a detailed cross-sectional side view of a portion of a catheter of the vascular access device of FIG. 4A.

[00053] FIG. 4D is a side view of a portion of the vascular access device of FIG. 4A positioned within a natural lumen of a vessel, showing a distal end portion of the vascular access device in a straight configuration.

[00054] FIG. 4E is a side view of a portion of the vascular access device of FIG. 4A positioned within the natural lumen of the vessel, showing the distal end portion in a curved configuration and a guidewire of the vascular access device passed through a wall of the vessel to form an aperture in the vessel wall.

[00055] FIG. 4F is a side view of a portion of the vascular access device of FIG. 4A positioned within the natural lumen of the vessel, showing a catheter of the vascular access device passed through the aperture in the vessel wall.

[00056] FIG. 4G is a side view of a portion of the vascular access device of FIG. 4A positioned within the natural lumen of the vessel, showing the catheter passed through the aperture in the vessel wall and a hemostatic connection formed between the catheter and the vessel wall.

[00057] FIG. 5A is a side view of a vascular access device in accordance with one or more embodiments of the disclosure.

[00058] FIG. 5B is a side view of the vascular access device of FIG. 5A and a guidewire, showing the guidewire passed through a vessel wall.

[00059] FIG. 5C is a side view of the vascular access device of FIG. 5A and the guidewire, showing a dilator and a catheter of the vascular access device passed through the vessel wall.

[00060] FIG. 5D is a side view of the vascular access device of FIG. 5A and the guidewire, showing coated regions of the catheter in an expanded state.

[00061] FIG. 5E is a bottom view of the vascular access device of FIG. 2A, showing a coated region of a catheter of the vascular access device.

[00062] FIG. 5F is a side view of the vascular access device of FIG. 2A, showing the coated region of the catheter.

[00063] FIG. 5G is a bottom view of the vascular access device of FIG. 2S, showing showing a coated region of a catheter of the vascular access device.

[00064] FIG. 5H is a side view of the vascular access device of FIG. 2S, showing showing the coated region of the catheter.

[00065] FIG. 6A is a side view of a vascular access device in accordance with one or more embodiments of the disclosure.

[00066] FIG. 6B is a top view of the vascular access device of FIG. 6A.

[00067] FIG. 6C is an end view of the vascular access device of FIG. 6A, taken along line 6C-6C in FIG. 6A.

[00068] FIG. 6D is an end view of the vascular access device of FIG. 6A, taken along line 6D-6D in FIG. 6A.

[00069] FIG. 6E is a cross-sectional side view of the vascular access device of FIG. 6A, taken along line 6E-6E in FIG. 6B.

[00070] FIG. 6F is a cross-sectional side view of the vascular access device of FIG. 6A positioned within a natural lumen of a vessel.

[00071] FIG. 6G is a cross-sectional side view of the vascular access device of FIG. 6A positioned within the natural lumen of the vessel, showing a guidewire and a dilator passed through the vascular access device and a wall of the vessel to form an aperture in the vessel wall.

[00072] FIG. 6H is a cross-sectional side view of the vascular access device of FIG. 6A positioned within the natural lumen of the vessel, showing the aperture in the vessel wall and a hemostatic connection formed between the vascular access device and the vessel wall.

DETAILED DESCRIPTION

[00073] Improved vascular access devices and methods have been developed to provide access for performing cardiac interventional procedures on patients in need thereof. In particular, such access may be achieved by percutaneously inserting the vascular access device through the natural lumen of a vessel, forming a hemostatic connection between the vascular access device and an inner surface of a wall of the vessel, and forming an aperture through the vessel wall to access desired vasculature in a thoracic region of the patient. Operative instruments or other devices then may be passed through the vascular access device and the aperture in the vessel wall and into the thoracic region to perform a cardiac procedure on the desired vasculature. The vascular access devices disclosed herein advantageously may easily pass through the natural lumen of the vessel, may quickly and effectively form the hemostatic connection between the vascular access device and the inner surface of the vessel wall, and may provide a working lumen of sufficient size to allow operative instruments or other devices to be passed therethrough to perform a desired cardiac procedure on the patient. The vascular access devices also may allow a physician to easily assess the integrity of the hemostatic connection and the aperture formed through the vessel wall before, during, or after performing the desired cardiac procedure. Furthermore, the vascular access devices may allow sufficient blood flow to pass through the natural lumen of the vessel while the vascular access device is positioned therein. As a result, the vascular access devices and methods disclosed herein may allow physicians to easily and confidently perform various cardiac interventional procedures in a minimally invasive manner which does not require use of cardiopulmonary bypass.

[00074] As used herein, the term "patient" refers primarily to a human adult or child, but also may include other suitable mammalian animals, for example in a pre-clinical trial or in veterinary care.

[00075] The vascular access devices and methods disclosed herein build upon the devices and methods described in U.S. Patent No. 8,663,321 to Crisco, which is incorporated by reference herein. Additionally, the vascular access devices and methods disclosed herein may be used in conjunction with or as a part of one or more of the devices, systems, and methods described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco, titled "Vascular Access Devices, Systems, and Methods," which is incorporated by reference herein.

[00076] Vascular Access Devices and Methods

[00077] **FIGS. 1A-1M** illustrate a vascular access device **100** (which also may be referred to as an "endovascular access device") configured to provide access for performing cardiac interventional procedures on patients in need thereof, in accordance with one or more embodiments of the disclosure. As described in detail below, the vascular access device **100** is configured to be percutaneously inserted through the natural lumen of a vessel of a patient, to form a hemostatic connection between the device **100** and an inner surface of a wall of the vessel, and to facilitate formation of an aperture through the vessel wall to provide access to desired vasculature in a thoracic region of the patient. The vascular access device **100** also may be configured to allow operative instruments or other devices to be passed through the device **100** to perform a desired cardiac procedure on the patient, to allow a physician to assess the integrity of the hemostatic connection and the aperture formed through the vessel wall before, during, or after performing the desired cardiac procedure, and to allow sufficient blood flow to pass through the natural lumen of the vessel while the device **100** is positioned therein.

[00078] As shown in **FIG. 1A**, the vascular access device **100** has an elongated shape including a distal end **102** (which also may be referred to as a "leading end") and a proximal end **104** (which also may be referred to as a "trailing end") positioned along a longitudinal axis A_L of the device **100**. The vascular access device **100** includes a distal end portion **106** extending from the distal end **102** toward the proximal end **104** along the longitudinal axis A_L, a proximal end portion **108** extending from the proximal end **104** toward the distal end **102** along the longitudinal axis A_L, and an intermediate portion **110** extending axially from the distal end portion **106** to the proximal end portion **108**. It will be appreciated that part of the intermediate portion **110** of the vascular access device **100** is removed from view in **FIG. 1A** for purposes of illustrating the device **100**. When the vascular access device **100** is used to provide access for performing a cardiac procedure on a patient, the distal end portion **106** and at least part of the

intermediate portion **110** may be percutaneously inserted through the natural lumen of a vessel, while the proximal end portion **108** remains at least partially outside of the patient's body. In this manner, the proximal end portion **108** may be manipulated by a physician outside of the patient's body in order to position the distal end portion **106** at a desired location within the vessel lumen and form a hemostatic connection between the distal end portion **106** and the vessel wall, as described below.

[00079] The vascular access device **100** includes a catheter **112**, which may extend axially from the distal end **102** to the proximal end **104** of the device **100**. The catheter **112** may include a flexible shaft **114** (which also may be referred to as a "tube") configured to traverse the vessel lumen in which the vascular access device **100** is inserted. As shown, the shaft **114** may have an elongated tubular shape and a circular axial cross-sectional shape, although other shapes of the shaft **114** may be used. In some embodiments, as shown, a longitudinal axis of the catheter **112** is coaxial with the longitudinal axis A_L of the device **100**. The catheter **112** may include a primary lumen **116** (which also may be referred to as a "working lumen" or an "access lumen") extending therethrough from the distal end **102** to the proximal end **104** of the device **100**. As described below, the primary lumen **116** may be used to facilitate insertion and positioning of the vascular access device **100** within the vessel lumen via a guidewire and/or a dilator, to facilitate formation of an aperture through the vessel wall, and to pass operative instruments or other devices through the device **100** and the aperture to perform a desired cardiac procedure on the patient. As shown, the primary lumen **116** may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the primary lumen **116** may be used. In some embodiments, as shown, a longitudinal axis of the primary lumen **116** is radially offset from the longitudinal axis of the catheter **112** and the longitudinal axis A_L of the device **100**. In this manner, a wall thickness of the catheter **112** may vary along the circumference of the catheter **112**, as shown. In some embodiments, the catheter **112** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the catheter **112** may be formed of a polyether block amide (PEBA), such as PEBAX®, a thermoplastic urethane (TPU), such as PELLETHANE®, or a nylon.

[00080] In some embodiments, as shown, the catheter **112** includes a liner **118** positioned within the lumen of the shaft **114**. The liner **118** may have an elongated tubular shape and a circular axial cross-sectional shape, and the liner **118** may define the primary lumen **116** of the

catheter **112** (i.e., the lumen of the liner **118** may be the primary lumen **116** of the catheter **112**). In other embodiments, the shaft **114** may define the primary lumen **116** of the catheter **112** (i.e., the lumen of the shaft **114** may be the primary lumen **116** of the catheter **112**). In some embodiments, as shown, the catheter **112** also includes a reinforcement structure **120** positioned within the lumen of the shaft **114** and radially between the shaft **114** and the liner **118**. The reinforcement structure **120** may have an elongated tubular shape and a circular axial cross-sectional shape, and the reinforcement structure **120** may include one or more wires arranged in a braided or coiled manner and configured to enhance the integrity of the catheter **112**. In some embodiments, the reinforcement structure **120** extends along the entire length of the catheter **112**. In other embodiments, the reinforcement structure **120** extends along only a portion of the length of the catheter **112**. In some embodiments, the liner **118** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the liner **118** may be formed of a polytetrafluoroethylene (PTFE), a perfluoroalkoxy alkane (PFA), a fluorinated ethylene propylene (FEP), another fluoropolymer, a polyimide (PI), or a polyethylene (PE), such as a high-density polyethylene (HDPE), a low-density polyethylene (LDPE), or a medium-density polyethylene (MDPE). In some embodiments, the reinforcement structure **120** is formed of a biocompatible metal or a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the reinforcement structure **120** may be formed of a stainless steel, a polyether ether ketone (PEEK), a nylon, or KEVLAR®.

[00081] The shaft **114** of the catheter **112** may include a distal tip portion **122** positioned about the distal end **102** of the vascular access device **100**. As shown, the external surface of the distal tip portion **122** may be tapered such that the external surface tapers radially inward in a direction from the proximal end to the distal end of the distal tip portion **122**. The distal tip portion **122** also may be beveled, as shown, such that a distal edge **124** of the distal tip portion **122** is angled at an acute angle relative to the longitudinal axis A_L of the device **100**. In some embodiments, the acute angle between the distal edge **124** and the longitudinal axis A_L of the device **100** is between about 15 degrees and about 45 degrees.

[00082] As shown in **FIGS. 1A-1D**, the catheter **112** may include a number of secondary lumens **126** extending therethrough, in addition to the primary lumen **116**. In particular, the catheter **112** may include a first secondary lumen **126a** (which also may be referred to as a "fixed wire lumen"), a second secondary lumen **126b** (which also may be referred to as a "deployable

wire lumen"), a third secondary lumen **126c** (which also may be referred to as a "deployable wire lumen"), a fourth secondary lumen **126d**, a fifth secondary lumen **126e**, a sixth secondary lumen **126f** (which also may be referred to as an "internal thru lumen"), and a seventh secondary lumen **126g** (which also may be referred to as a "external thru lumen"). The secondary lumens **126** may be defined in the shaft **114** of the catheter **112** and arranged in a circumferential array, as shown in **FIG. 1C**, such that the secondary lumens **126** are circumferentially spaced apart from one another and radially spaced apart from the primary lumen **116** and the external surface of the shaft **114**. As shown, the secondary lumens **126** each may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the secondary lumens **126** may be used. Although the illustrated embodiment includes seven secondary lumens **126**, it will be understood that any number of the secondary lumens **126** may be used in other embodiments. In some embodiments, one or more of the secondary lumens **126** has a liner positioned therein. In some embodiments, the secondary lumen liners are formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the secondary lumen liners may be formed of a polyimide (PI), a polytetrafluoroethylene (PTFE), a perfluoroalkoxy alkane (PFA), a fluorinated ethylene propylene (FEP), another fluoropolymer, or a polyethylene (PE), such as a high-density polyethylene (HDPE), a low-density polyethylene (LDPE), or a medium-density polyethylene (MDPE).

[00083] The secondary lumens **126** each may extend axially through the catheter **112** and parallel to the longitudinal axis A_L of the device **100**, as shown. In some embodiments, the respective distal ends of the first secondary lumen **126a**, the second secondary lumen **126b**, the third secondary lumen **126c**, the fourth secondary lumen **126d**, and the fifth secondary lumen **126e** are closed and positioned within the wall of the shaft **114**. In some such embodiments, the closed distal ends of the first secondary lumen **126a**, the second secondary lumen **126b**, the third secondary lumen **126c**, the fourth secondary lumen **126d**, and the fifth secondary lumen **126e** are positioned at or near the proximal end of the distal tip portion **122** of the shaft **114**, although other positions of the closed distal ends may be used in other embodiments. In some embodiments, the respective proximal ends of the first secondary lumen **126a**, the second secondary lumen **126b**, the third secondary lumen **126c**, the fourth secondary lumen **126d**, and the fifth secondary lumen **126e** are open at respective openings defined in the proximal end of the shaft **114**. In other embodiments, the respective proximal ends of the first secondary lumen

126a, the second secondary lumen **126b**, the third secondary lumen **126c**, the fourth secondary lumen **126d**, and the fifth secondary lumen **126e** may be closed and positioned within the wall of the shaft **114**.

[00084] As shown, the respective distal ends of the sixth secondary lumen **126f** and the seventh secondary lumen **126g** may be open at respective openings defined in the distal tip portion **122** of the shaft **114**. In particular, the sixth secondary lumen **126f** may be in fluid communication with an opening **128** (which also may be referred to as an "exit opening" or an "internal exit opening") that is defined in the internal surface of the distal tip portion **122** and in fluid communication with the primary lumen **116** of the catheter **112**. The seventh secondary lumen **126g** may be in fluid communication with an opening **130** (which also may be referred to as an "exit opening" or an "external exit opening") that is defined in the external surface of the distal tip portion **122**. In some embodiments, the respective proximal ends of the sixth secondary lumen **126f** and the seventh secondary lumen **126g** are open at respective openings (which also may be referred to an "entry openings") that are defined in the proximal end of the shaft **114**. In other embodiments, the respective proximal ends of the sixth secondary lumen **126f** and the seventh secondary lumen **126g** are open at respective openings defined the wall of the shaft **114** near the proximal end of the shaft **114**. As described below, the sixth secondary lumen **126f** and the seventh secondary lumen **126g** may be used to deliver materials through the catheter **112** and out of the respective openings **128**, **130**.

[00085] As shown in **FIGS. 1A and 1D**, the catheter **112** may include a number of deployment openings **132** each defined in the external surface of the shaft **114** and in fluid communication with one of the secondary lumens **126**. In particular, the catheter **112** may include a first deployment opening **132a** defined in the external surface of the shaft **114** and in fluid communication with the second secondary lumen **126b**, and a second deployment opening **132b** defined in the external surface of the shaft **114** and in fluid communication with the third secondary lumen **126c**. The deployment openings **132** may be circumferentially spaced apart from one another and arranged in a circumferential array, as shown in **FIG. 1D**, and may extend inwardly from the external surface of the shaft **114** to the second secondary lumen **126b** and the third secondary lumen **126c**, respectively. As shown, the deployment openings **132** may extend axially along the shaft **114** and parallel to the longitudinal axis A_L of the device **100**, and each deployment opening **132** may have an axial length that is less than the axial length of the shaft

114. The deployment openings **132** each may have an elongated slot shape, as shown, although other shapes of the deployment openings **132** may be used. Although the illustrated embodiment includes two deployment openings **132**, it will be understood that any number of the deployment openings **132** may be used in other embodiments.

[00086] As shown in **FIGS. 1C-1G**, the vascular access device **100** includes a number of wires **134** secured to the catheter **112** and configured to facilitate positioning of the distal end portion **106** of the device **100** relative to the vessel in order to form a hemostatic connection between the device **100** and an inner surface of the vessel wall. In particular, the vascular access device **100** includes a first wire **134a** (which also may be referred to as a "fixed wire" or a "non-deployable wire"), a second wire **134b** (which also may be referred to as a "deployable wire"), and a third wire **134c** (which also may be referred to as a "deployable wire"). As shown in **FIGS. 1C** and **1D**, the first wire **134a** may be positioned within the first secondary lumen **126a**. In particular, the first wire **134a** may be fixedly secured within the first secondary lumen **126a**, such that the first wire **134a** is retained within the wall of the shaft **114** during use of the vascular access device **100**. In some embodiments, the first wire **134a** is formed of a shape memory material, such as a shape memory metal or a shape memory polymer. For example, the first wire **134a** may be formed of nitinol. In this manner, the first wire **134a** may have a natural undeformed shape, but may be deformed to a different shape, after which the first wire **134a** may return to its natural undeformed shape absent opposing forces prohibitively restraining the first wire **134a** from doing so. In some embodiments, the first wire **134a** has a natural undeformed shape that is curved in accordance with the curved shape of the distal end portion **106** of the vascular access device **100** shown in **FIG. 1I**, but may be deformed to have a straight shape in accordance with the straight shape of the distal end portion **106** of the vascular access device **100** shown in **FIG. 1A**. In this manner, the first wire **134a** may be configured to cause the distal end portion **106** of the vascular access device **100** to assume the curved shape shown in **FIG. 1I** absent opposing forces prohibitively restraining the distal end portion **106** from assuming the curved shape.

[00087] As shown in **FIGS. 1C** and **1D**, the second wire **134b** may be positioned at least partially within the second secondary lumen **126b**, and the third wire **134c** may be positioned at least partially within the third secondary lumen **126c**. The second wire **134b** and the third wire **134c** each may be configured to move between a first configuration (which also may be referred

to as a "delivery configuration"), as shown in **FIGS. 1A-1D**, and a second configuration (which also may be referred to as a "deployed configuration"), as shown in **FIGS. 1E-1G**. When the second wire **134b** and the third wire **134c** are in the first configuration, the second wire **134b** may be received within the second secondary lumen **126b** and/or the first deployment opening **132a** without extending outward beyond the external surface of the shaft **114**, and the third wire **134c** may be received within the third secondary lumen **126c** and/or the second deployment opening **132b** without extending outward beyond the external surface of the shaft **114**, as shown. When the second wire **134b** and the third wire **134c** are in the second configuration, the second wire **134b** may be received partially within the second secondary lumen **126b** and/or the first deployment opening **132a** and may extend partially outward beyond the external surface of the shaft **114**, and the third wire **134c** may be received partially within the third secondary lumen **126c** and/or the second deployment opening **132b** and may extend partially outward beyond the external surface of the shaft **114**. In this manner, the extended portions of the second wire **134b** and the third wire **134c** may be configured to engage the inner surface of the vessel wall when the second wire **134b** and the third wire **134c** are in the second configuration. In some embodiments, the second wire **134b** and the third wire **134c** each are formed of a shape memory material, such as a shape memory metal or a shape memory polymer. For example, the second wire **134b** and the third wire **134c** each may be formed of nitinol. In this manner, the second wire **134b** and the third wire **134c** each may have a natural undeformed shape, but may be deformed to a different shape, after which the wires **134b**, **134c** may return to their respective natural undeformed shapes absent opposing forces prohibitively restraining the wires **134b**, **134c** from doing so. In some embodiments, the second wire **134b** and the third wire **134c** each have a natural undeformed shape that is curved, as shown in **FIGS. 1E-1G**, but may be deformed to have a straight shape in accordance with the straight shape of the distal end portion **106** of the vascular access device **100** shown in **FIG. 1A**. In this manner, the second wire **134b** and the third wire **134c** each may be configured to assume the curved second configuration absent opposing forces prohibitively restraining the wires **134b**, **134c** from doing so.

[00088] **FIGS. 1H-1M** illustrate an example method of using the vascular access device **100** to provide access for performing a cardiac interventional procedure on a patient. Initially, the vascular access device **100** may be percutaneously inserted into the patient through a vascular access site formed in an artery, such as a femoral artery. With the proximal end portion **108** of

the device **100** outside of the patient, the physician may manipulate the proximal end portion **108** in order to advance the distal end portion **106** of the device **100** through the vasculature and position the distal end portion **106** at a desired location within a natural lumen **140** of a desired vessel **142**, as shown in **FIG. 1H**. In some embodiments, as shown, the vascular access device **100** is advanced over a guidewire **160** to facilitate guiding the distal end portion **106** of the device **100** through the vasculature and positioning the distal end portion **106** at the desired location within vessel **142**. Additionally, in some embodiments, as shown, a dilator **162** is positioned within the primary lumen **116** of the catheter **112** and advanced along with the distal end portion **106** of the device **100** through the vasculature. When the dilator **162** is positioned within the primary lumen **116** of the catheter **112**, the dilator **162** may maintain the first wire **134a** in its deformed, straight shape (i.e., the dilator **162** may restrain the first wire **134a** from assuming its natural undeformed, curved shape), such that the distal end portion **106** of the device **100** is maintained in its straight configuration, as shown in **FIG. 1H**.

[00089] After the distal end portion **106** of the device **100** is positioned at the desired location within the natural lumen **140** of the vessel **142**, the guidewire **160** and the dilator **162** may be removed from the primary lumen **116** of the catheter **112** or at least partially retracted (i.e., moved proximally with respect to the catheter **112**) within the primary lumen **116** such that the guidewire **160** and the dilator **162** are not positioned within the distal end portion **106**. Upon such removal or retraction of the guidewire **160** and the dilator **162**, the first wire **134a** may assume its natural undeformed, curved shape, thereby causing the distal end portion **106** to assume its curved configuration, as shown in **FIG. 1I**. When the distal end portion **106** assumes its curved configuration, a first part of the distal end portion **106** may engage a first part of an inner surface **144** of a wall **146** of the vessel **140**, and a second part of the distal end portion **106** may engage a circumferentially opposite second part of the inner surface **144** of the wall **146** of the vessel **140**. In particular, the distal edge **124** of the distal tip portion **122** may at least partially engage the first part of the inner surface **144** of the vessel wall **146**, and the external surface of the shaft **114** may at least partially engage the second part of the inner surface **144** of the vessel wall **146**, as shown in **FIG. 1I**.

[00090] After the distal end portion **106** assumes its curved configuration, the second wire **134b** and the third wire **134c** may be deployed from the catheter **112**, as shown in **FIG. 1J**. In other words, the second wire **134b** and the third wire **134c** may be moved or allowed to move

from their straight first configuration to their curved second configuration, as shown. In some embodiments, the second wire **134b** and the third wire **134c** are moved from their straight first configuration to their curved second configuration by manipulating respective proximal ends of the wires **134b**, **134c**, or intermediate components attached to the wires **134b**, **134c**, positioned about the proximal end **104** of the vascular access device **100**. In other embodiments, the second wire **134b** and the third wire **134c** are allowed to move from their straight first configuration to their curved second configuration by removing or retracting a sheath positioned over the deployment openings **132** of the catheter **112**. Still other components or mechanisms may be used to move the second wire **134b** and the third wire **134c** or allow the wires **134b**, **134c** to move from their straight first configuration to their curved second configuration in other embodiments. When the second wire **134b** and the third wire **134c** are in their curved second configuration, the wires **134b**, **134c** may at least partially engage the first part of the inner surface **144** of the vessel wall **146** and may bias the distal end portion **106** of the device **100** toward the second part of the inner surface **144** of the vessel wall **146**. As shown in **FIG. 1J**, the biasing force provided by the second wire **134b** and the third wire **134c** may cause the external surface of the shaft **114** to disengage the first part of the inner surface **144** of the vessel wall **146** and the curvature of the distal end portion **106** to decrease. Additionally, the biasing force provided by the second wire **134b** and the third wire **134c** may cause the entire distal edge **124** of the distal tip portion **122** to fully engage the first part of the inner surface **144** of the vessel wall **146**, such that a hemostatic connection is formed between the distal edge **124** and the inner surface **144** of the vessel wall **146**, as shown. Furthermore, the biasing force provided by the second wire **134b** and the third wire **134c** and the resulting engagement between the wires **134b**, **134c** and the first part of the inner surface **144** of the vessel wall **146** and between the distal edge **124** and the second part of the inner surface **144** of the vessel wall **146** may secure the position of the distal end portion **106** of the device **100** within the vessel lumen **140**.

[00091] After the hemostatic connection is formed between the distal edge **124** of the distal tip portion **122** and the inner surface **144** of the vessel wall **146**, a guidewire **164** and/or a dilator **166** may be advanced through the primary lumen **116** of the catheter **112** and through the vessel wall **146**, as shown in **FIG. 1K**. The guidewire **164** and/or the dilator **166** may form an aperture **148** in the vessel wall **146** extending from the inner surface **144** to an outer surface **150** of the vessel wall **146**, while the hemostatic connection is maintained between the distal edge **124** of

the distal tip portion **122** and the inner surface **144** of the vessel wall **146**. In this manner, the hemostatic connection may surround the aperture **148**, thereby preventing or at least inhibiting blood from flowing out of the vessel lumen **140** through the aperture **148** and preventing or at least inhibiting body fluids or other materials from entering the vessel lumen **140** through the aperture **148**. In some embodiments, the guidewire **164** is different than the guidewire **160**. For example, the guidewire **164** may have a sharp distal tip, and the guidewire **160** may have a blunt or rounded distal tip. In other embodiments, the guidewire **164** may be the same as the guidewire **160** (i.e., the guidewire **160** may be used to guide the distal end portion **106** of the device **100** to the desired location in the vessel lumen **140** and to puncture the vessel wall **146** to form the aperture **148**). In some embodiments, the dilator **166** is different than the dilator **160**. For example, the distal end portion of the dilator **166** may have a different taper angle or length as compared to the taper angle or length of the distal end portion of the dilator **162**. In other embodiments, the dilator **166** may be the same as the dilator **162** (i.e., the dilator **162** may be used to guide the distal end portion **106** of the device **100** to the desired location in the vessel lumen **140** and to dilate the vessel wall **146** to form the aperture **148**).

[00092] After the aperture **148** is formed in the vessel wall **146**, the guidewire **164** and the dilator **166** may be retracted and removed from the primary lumen **116** of the catheter **112**, while the hemostatic connection is maintained between the distal edge **124** of the distal tip portion **122** and the inner surface **144** of the vessel wall **146**, as shown in **FIG. 1L**. After removal of the guidewire **164** and the dilator **166** from the primary lumen **116**, the physician may assess the integrity of the hemostatic connection and the aperture **148** in the vessel wall **146**. In particular, a first fluid may be injected through the sixth secondary lumen **126f** of the catheter **112** and out of the opening **128**. The first fluid may include a first contrast medium that is visible under medical imaging, and thus the physician may observe the flow of the first fluid to assess the integrity of the hemostatic connection and/or the aperture **148**. In a similar manner, a second fluid may be injected through the seventh secondary lumen **126g** of the catheter **112** and out of the opening **130**. The second fluid may include a second contrast medium that is visible under medical imaging, and thus the physician may observe the flow of the second fluid to assess the integrity of the hemostatic connection and/or the aperture **148**. It will be appreciated that this technique of assessing the integrity of the hemostatic connection and/or the aperture **148** may be carried out at any point during the method of using the vascular access device **100** to provide

access. For example, this technique may be carried out before, during, or after the aperture **148** is formed in the vessel wall **146**.

[00093] After the aperture **148** is formed in the vessel wall **146**, a cardiac interventional procedure may be performed through the vascular access device **100** and through the aperture **148**, while the hemostatic connection is maintained between the distal edge **124** of the distal tip portion **122** and the inner surface **144** of the vessel wall **146**. In particular, as shown in **FIG. 1M**, one or more operative instruments or devices **168** may be passed through the primary lumen **116** of the catheter **112** and the aperture **148** in the vessel wall **146** and into the thoracic cavity of the patient to perform a desired cardiac procedure on the desired vasculature. Upon completion of the cardiac procedure, the aperture **148** in the vessel wall **146** may be closed, and the vascular access device **100** may be removed from the patient.

[00094] In some embodiments, the vascular access device **100** may be used in combination with other devices to perform a desired cardiac procedure. For example, the vascular access device **100** may be used in combination with one of the puncturable balloon catheter devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform a desired cardiac procedure, such as a coronary bypass procedure, as described therein. In such uses, the vascular access device **100** may be used inside of the vessel **142** in the manner described above, and the puncturable balloon catheter device may be used outside of the vessel **142** in the extravascular space, in the soft tissue of a limb of other anatomical locations including the chest and the pericardium, for the purpose of creating space for delivery of catheters, wires, delivery systems, and bypass conduits for the purposes of revascularization. Moreover, the vascular access device **100** may be used instead of the vascular access devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform any of the cardiac procedures described therein.

[00095] **FIGS. 2A-2V** illustrate a vascular access device **200** (which also may be referred to as an "endovascular access device") configured to provide access for performing cardiac interventional procedures on patients in need thereof, in accordance with one or more embodiments of the disclosure. As described in detail below, the vascular access device **200** is configured to be percutaneously inserted through the natural lumen of a vessel of a patient, to form a hemostatic connection between the device **200** and an inner surface of a wall of the vessel, and to facilitate formation of an aperture through the vessel wall to provide access to

desired vasculature in a thoracic region of the patient. The vascular access device **200** also may be configured to allow operative instruments or other devices to be passed through the device **200** to perform a desired cardiac procedure on the patient, to allow a physician to assess the integrity of the hemostatic connection and the aperture formed through the vessel wall before, during, or after performing the desired cardiac procedure, and to allow sufficient blood flow to pass through the natural lumen of the vessel while the device **200** is positioned therein.

[00096] As shown in **FIGS. 2A-2C**, the vascular access device 200 has an elongated shape including a distal end **202** (which also may be referred to as a "leading end") and a proximal end **204** (which also may be referred to as a "trailing end") positioned along a longitudinal axis A_L of the device **200**. The vascular access device **200** includes a distal end portion **206** extending from the distal end **202** toward the proximal end **204** along the longitudinal axis A_L, a proximal end portion **208** extending from the proximal end **204** toward the distal end **202** along the longitudinal axis A_L, and an intermediate portion **210** extending axially from the distal end portion **206** to the proximal end portion **208**. It will be appreciated that part of the intermediate portion **210** of the vascular access device **200** is removed from view in **FIGS. 2A-2C** for purposes of illustrating the device **200**. When the vascular access device **200** is used to provide access for performing a cardiac procedure on a patient, the distal end portion **206** and at least part of the intermediate portion **210** may be percutaneously inserted through the natural lumen of a vessel, while the proximal end portion **208** remains at least partially outside of the patient's body. In this manner, the proximal end portion **208** may be manipulated by a physician outside of the patient's body in order to position the distal end portion **206** at a desired location within the vessel lumen and form a hemostatic connection between the distal end portion **206** and the vessel wall, as described below.

[00097] The vascular access device **200** includes a catheter **212**, which may extend axially from the distal end **202** to the proximal end **204** of the device **200**. The catheter **212** may include a flexible shaft **214** (which also may be referred to as a "tube") configured to traverse the vessel lumen in which the vascular access device **200** is inserted. As shown, the shaft **214** may have an elongated tubular shape and a circular axial cross-sectional shape, although other shapes of the shaft **214** may be used. In some embodiments, as shown, a longitudinal axis of the catheter **212** is coaxial with the longitudinal axis A_L of the device **200**. The catheter **212** may include a primary lumen **216** (which also may be referred to as a "working lumen" or an "access lumen")

extending therethrough from the proximal end **204** of the device **200** to an access opening **218** defined in a side wall of the shaft **214**, as shown. As described below, the primary lumen **216** may be used to facilitate insertion and positioning of the vascular access device **200** within the vessel lumen via a guidewire and/or a dilator, to facilitate formation of an aperture through the vessel wall, and to pass operative instruments or other devices through the device **200** and the aperture to perform a desired cardiac procedure on the patient. As shown, the primary lumen **216** may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the primary lumen **216** may be used. In some embodiments, as shown, a longitudinal axis of the primary lumen **216** is radially offset from the longitudinal axis of the catheter **212** and the longitudinal axis A_L of the device **200**. In this manner, a wall thickness of the catheter **212** may vary along the circumference of the catheter **212**, as shown. The catheter **212** also may include a guidewire lumen **220** (which also may be referred to as a "guiding lumen" or a "distal lumen") extending therethrough from the distal end **202** of the device **200** to a lumen transition portion **222** positioned axially between the guidewire lumen **220** and the primary lumen **216**, as shown in **FIG. 2D**. The lumen transition portion **222** may be contoured to provide a smooth transition from the larger-diameter primary lumen **216** to the smaller-diameter guidewire lumen **220**, as shown. The guidewire lumen **220** may include a first portion **220a** and a second portion **220b**, and a seal **224** (which also may be referred to as a "guidewire seal") may be positioned axially between the first portion **220a** and the second portion **220b**. As shown, the longitudinal axis of the first portion **220a** of the guidewire lumen **220** may be coaxial with the longitudinal axis of the catheter **212** and the longitudinal axis A_L of the device **200** and radially offset from the longitudinal axis of the primary lumen **216**, and the longitudinal axis of the second portion **220b** of the guidewire lumen **220** may be angled at an acute angle relative to the longitudinal axis A_L of the device **200**. As shown, the first portion **220a** and the second portion **220b** of the guidewire lumen **220** each may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the portions **220a**, **220b** may be used. The seal **224** may be configured to form a hemostatic seal around a guidewire when the guidewire is positioned within the guidewire lumen **220**, and to close to form a hemostatic seal itself when no guidewire is positioned within the guidewire lumen **220**. In some embodiments, the catheter **212** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the catheter **212** may be formed of a polyether block amide (PEBA), such as

PEBAX®, a thermoplastic urethane (TPU), such as PELLETHANE®, or a nylon. In some embodiments, the seal **224** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the seal **224** may be formed of a polyether block amide (PEBA), such as PEBAX®, a thermoplastic urethane (TPU), such as PELLETHANE®, or a nylon.

[00098] In some embodiments, as shown, the catheter **212** includes a liner **228** positioned within the lumen of the shaft **214**. The liner **228** may have an elongated tubular shape and a circular axial cross-sectional shape, and the liner **228** may define the primary lumen **216** of the catheter **212** (i.e., the lumen of the liner **228** may be the primary lumen **216** of the catheter **212**) along at least a portion of the axial length of the primary lumen **216**. In some embodiments, the shaft **214** may define the primary lumen **216** of the catheter **212** (i.e., the lumen of the shaft **214** may be the primary lumen **216** of the catheter **212**) along at least a portion of the axial length of the primary lumen **216**. In some embodiments, as shown, the catheter **212** also includes a reinforcement structure **230** positioned within the lumen of the shaft **214** and radially between the shaft **214** and the liner **228**. The reinforcement structure **230** may have an elongated tubular shape and a circular axial cross-sectional shape, and the reinforcement structure **230** may include one or more wires arranged in a braided or coiled manner and configured to enhance the integrity of the catheter **212**. In some embodiments, as shown, the reinforcement structure **230** extends along only a portion of the axial length of the primary lumen **216**. In other embodiments, the reinforcement structure **230** extends along the entire length of the primary lumen **216**. In some embodiments, the liner **228** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the liner **228** may be formed of a polytetrafluoroethylene (PTFE), a perfluoroalkoxy alkane (PFA), a fluorinated ethylene propylene (FEP), another fluoropolymer, a polyimide (PI), or a polyethylene (PE), such as a high-density polyethylene (HDPE), a low-density polyethylene (LDPE), or a medium-density polyethylene (MDPE). In some embodiments, the reinforcement structure **230** is formed of a biocompatible metal or a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the reinforcement structure **230** may be formed of a stainless steel, a polyether ether ketone (PEEK), a nylon, or KEVLAR®.

[00099] The shaft **214** of the catheter **212** may include a distal tip portion **232** (which also may be referred to as a "dilator tip portion") positioned about the distal end **202** of the vascular

access device **200**. As shown, the external surface of the distal tip portion **232** may be tapered such that the external surface tapers radially inward in a direction from the proximal end to the distal end of the distal tip portion **232**. In this manner, the distal tip portion **232** may facilitate guiding of the distal end portion **206** of the vascular access device **200** through the natural lumen of a vessel in which the device **200** is inserted. As shown in **FIG. 2D**, the first portion **220a** of the guidewire lumen **220** and the seal **224** each may be positioned at least partially within the distal tip portion **232** of the shaft **214**.

[000100] As shown in **FIGS. 2D** and **2F**, the catheter **212** may include a number of secondary lumens **236** extending therethrough, in addition to the primary lumen **216** and the guidewire lumen **220**. In particular, the catheter **212** may include a first secondary lumen **236a** (which also may be referred to as a "deployable wire lumen"), a second secondary lumen **236b** (which also may be referred to as a "deployable wire lumen"), and a third secondary lumen **236c** (which also may be referred to as a "deployable wire lumen"). The secondary lumens **236** may be defined in the shaft **214** of the catheter **212** and arranged in a circumferential array, as shown in **FIG. 2F**, such that the secondary lumens **236** are circumferentially spaced apart from one another and radially spaced apart from the primary lumen **216**, the guidewire lumen **220**, and the external surface of the shaft **214**. As shown, the secondary lumens **236** each may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the secondary lumens **236** may be used. Although the illustrated embodiment includes three secondary lumens **236**, it will be understood that any number of the secondary lumens **236** may be used in other embodiments.

[000101] The secondary lumens **236** each may extend axially through the catheter **212** and parallel to the longitudinal axis A_L of the device **200**, as shown. In some embodiments, the respective distal ends of the first secondary lumen **236a**, the second secondary lumen **236b**, and the third secondary lumen **236c** are closed and positioned within the wall of the shaft **214**. In some such embodiments, the closed distal ends of the first secondary lumen **236a**, the second secondary lumen **236b**, and the third secondary lumen **236c** are positioned at or near the proximal end of the distal tip portion **232** of the shaft **214**, although other positions of the closed distal ends may be used in other embodiments. In some embodiments, the respective proximal ends of the first secondary lumen **236a**, the second secondary lumen **236b**, and the third secondary lumen **236c** are open at respective openings defined in the proximal end of the shaft **214**. In other embodiments, the respective proximal ends of the first secondary lumen **236a**, the

second secondary lumen **236b**, and the third secondary lumen **236c** are closed and positioned within the wall of the shaft **214**. In some embodiments, one or more of the secondary lumens **236** has a liner positioned therein. In some embodiments, the secondary lumen liners are formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the secondary lumen liners may be formed of a polyimide (PI), a polytetrafluoroethylene (PTFE), a perfluoroalkoxy alkane (PFA), a fluorinated ethylene propylene (FEP), another fluoropolymer, or a polyethylene (PE), such as a high-density polyethylene (HDPE), a low-density polyethylene (LDPE), or a medium-density polyethylene (MDPE).

[000102] As shown in **FIGS. 2A**, **2B**, **2D**, and **2G**, the catheter **212** may include a number of deployment openings **242** each defined in the external surface of the shaft **214** and in fluid communication with one of the secondary lumens **236**. In particular, the catheter **212** may include a first deployment opening **242a** defined in the external surface of the shaft **214** and in fluid communication with the first secondary lumen **236a**, a second deployment opening **242b** defined in the external surface of the shaft **214** and in fluid communication with the second secondary lumen **236b**, and a third deployment opening **242c** defined in the external surface of the shaft **214** and in fluid communication with the third secondary lumen **236c**. The deployment openings **242** may be circumferentially spaced apart from one another and arranged in a circumferential array, as shown in **FIGS. 2B** and **2G**, and may extend inwardly from the external surface of the shaft **214** to the respective secondary lumens **236**. As shown, the deployment openings **242** may extend axially along the shaft **214** and parallel to the longitudinal axis A_L of the device **200**, and each deployment opening **242** may have an axial length that is less than the axial length of the shaft **214**. The deployment openings **242** each may have an elongated slot shape, as shown, although other shapes of the deployment openings **242** may be used. Although the illustrated embodiment includes three deployment openings **242**, it will be understood that any number of the deployment openings **242** may be used in other embodiments.

[000103] As shown in **FIGS. 2D** and **2F-2J**, the vascular access device **200** includes a number of wires **244** secured to the catheter **212** and configured to facilitate positioning of the distal end portion **206** of the device **200** relative to the vessel in order to form a hemostatic connection between the device **200** and an inner surface of the vessel wall. In particular, the vascular access device **200** includes a first wire **244a** (which also may be referred to as a "deployable wire"), a

second wire **244b** (which also may be referred to as a "deployable wire"), and a third wire **244c** (which also may be referred to as a "deployable wire"). As shown in **FIGS. 2D**, **2F**, and **2G**, the first wire **244a** may be positioned at least partially within the first secondary lumen **236a** and at least partially within the first deployment opening **242a**, the second wire **244b** may be positioned at least partially within the second secondary lumen **236b** and at least partially within the second deployment opening **242b**, and the third wire **244c** may be positioned at least partially within the third secondary lumen **236c** at least partially within the third deployment opening **242c**. The wires **244** each may be configured to move between a first configuration (which also may be referred to as a "delivery configuration"), as shown in **FIGS. 2D**, **2F**, and **2G**, and a second configuration (which also may be referred to as a "deployed configuration"), as shown in **FIGS. 2H-2J**. When the wires **244** are in the first configuration, the first wire **244a** may be received partially within the first secondary lumen **236a** and partially within the first deployment opening **242a** without extending outward beyond the external surface of the shaft **214**, the second wire **244b** may be received partially within the second secondary lumen **236b** and partially within the second deployment opening **242b** without extending outward beyond the external surface of the shaft **214**, and the third wire **244c** may be received partially within the third secondary lumen **236c** and partially within the third deployment opening **242c** without extending outward beyond the external surface of the shaft **214**. When the wires **244** are in the second configuration, the first wire **244a** may be received partially within the first secondary lumen **236a** and partially within the first deployment opening **242a** and may extend partially outward beyond the external surface of the shaft **214**, the second wire **244b** may be received partially within the second secondary lumen **236b** and partially within the second deployment opening **242b** and may extend partially outward beyond the external surface of the shaft **214**, and the third wire **244c** may be received partially within the third secondary lumen **236c** and partially within the third deployment opening **242c** and may extend partially outward beyond the external surface of the shaft **214**. In this manner, the extended portions of the wires **244** may be configured to engage the inner surface of the vessel wall when the wires **244** are in the second configuration. In some embodiments, the wires **244** each are formed of a shape memory material, such as a shape memory metal or a shape memory polymer. For example, the wires **244** each may be formed of nitinol. In this manner, the wires **244** each may have a natural undeformed shape, but may be deformed to a different shape, after which the wires **244** may return to their respective natural

undeformed shapes absent opposing forces prohibitively restraining the wires **244** from doing so. In some embodiments, the wires **244** each have a natural undeformed shape that is curved, as shown in **FIGS. 2H-2J**, but may be deformed to have a substantially straight shape, as shown in **FIG. 2D**. In this manner, the wires **244** each may be configured to assume the curved second configuration absent opposing forces prohibitively restraining the wires **244** from doing so.

[000104] **FIGS. 2K-2N** illustrate an example method of using the vascular access device **200** to provide access for performing a cardiac interventional procedure on a patient. Initially, the vascular access device **200** may be percutaneously inserted into the patient through a vascular access site formed in an artery, such as a femoral artery. With the proximal end portion **208** of the device **200** outside of the patient, the physician may manipulate the proximal end portion **208** in order to advance the distal end portion **206** of the device **200** through the vasculature and position the distal end portion **206** at a desired location within a natural lumen **250** of a desired vessel **252**, as shown in **FIG. 2K**. In some embodiments, as shown, the vascular access device **200** is advanced over a guidewire **270** to facilitate guiding the distal end portion **206** of the device **200** through the vasculature and positioning the distal end portion **206** at the desired location within vessel **252**.

[000105] After the distal end portion **206** of the device **200** is positioned at the desired location within the natural lumen **250** of the vessel **252**, the wires **244** may be deployed from the catheter **212**, as shown in **FIG. 2L**. In other words, the wires **244** may be moved or allowed to move from their straight first configuration to their curved second configuration, as shown. In some embodiments, the wires **244** are moved from their straight first configuration to their curved second configuration by manipulating respective proximal ends of the wires **244** or intermediate components attached to the wires **244**, positioned about the proximal end **204** of the vascular access device **200**. In other embodiments, the wires **244** are allowed to move from their straight first configuration to their curved second configuration by removing or retracting a sheath positioned over the deployment openings **242** of the catheter **212**. Still other components or mechanisms may be used to move the wires **244** or allow the wires **244** to move from their straight first configuration to their curved second configuration in other embodiments. When the wires **244** are in their curved second configuration, the wires **244** may at least partially engage a first part of an inner surface **254** of a wall **256** of the vessel **252** and may bias the catheter **212** toward a circumferentially opposite second part of the inner surface **254** of the vessel wall **256**.

As shown in **FIG. 2L**, the biasing force provided by the wires **244** may cause the external surface of the shaft **214** to engage the second part of the inner surface **254** of the vessel wall **256**, such that a hemostatic connection is formed between a portion of the external surface of the shaft **214** which surrounds the access opening **218** and the inner surface **254** of the vessel wall **256**. Furthermore, the biasing force provided by the wires **244** and the resulting engagement between the wires **244** and the first part of the inner surface **254** of the vessel wall **256** and between the external surface of the shaft **214** and the second part of the inner surface **254** of the vessel wall **256** may secure the position of the distal end portion **206** of the device **200** within the vessel lumen **250**. After the hemostatic connection is formed between the external surface of the shaft **214** and the second part of the inner surface **254** of the vessel wall **256**, the guidewire **270** may be retracted and removed from the guidewire lumen **220** and the primary lumen **216** of the catheter **212**, as shown in **FIG. 2L**.

[000106] After the guidewire **270** is retracted and removed from the guidewire lumen **220** and the primary lumen **216** of the catheter **212**, a guidewire **274** and/or a dilator **276** may be advanced through the primary lumen **216** and the access opening **218** of the catheter **112** and through the vessel wall **256**, as shown in **FIG. 2M**. The guidewire **274** and/or the dilator **276** may form an aperture **258** in the vessel wall **256** extending from the inner surface **254** to an outer surface **260** of the vessel wall **256**, while the hemostatic connection is maintained between the external surface of the shaft **214** and the second part of the inner surface **254** of the vessel wall **256**. In this manner, the hemostatic connection may surround the aperture **258**, thereby preventing or at least inhibiting blood from flowing out of the vessel lumen **250** through the aperture **258** and preventing or at least inhibiting body fluids or other materials from entering the vessel lumen **250** through the aperture **258**. In some embodiments, the guidewire **274** is different than the guidewire **270**. For example, the guidewire **274** may have a sharp distal tip, and the guidewire **270** may have a blunt or rounded distal tip. In other embodiments, the guidewire **274** may be the same as the guidewire **270** (i.e., the guidewire **270** may be used to guide the distal end portion **206** of the device **200** to the desired location in the vessel lumen **250** and to puncture the vessel wall **256** to form the aperture **258**).

[000107] After the aperture **258** is formed in the vessel wall **256**, the guidewire **274** and/or the dilator **276** may be retracted and removed from the primary lumen **216** of the catheter **212**, while the hemostatic connection is maintained between the external surface of the shaft **214** and the

second part of the inner surface **254** of the vessel wall **256**, as shown in **FIG. 1N**. After removal of the guidewire **274** and/or the dilator **276** from the primary lumen **216**, a cardiac interventional procedure may be performed through the vascular access device **200** and through the aperture **258**, while the hemostatic connection is maintained between the external surface of the shaft **214** and the second part of the inner surface **254** of the vessel wall **256**. In particular, one or more operative instruments or devices may be passed through the primary lumen **216** and the access opening **218** of the catheter **212** and the aperture **258** in the vessel wall **256** and into the thoracic cavity of the patient to perform a desired cardiac procedure on the desired vasculature. Upon completion of the cardiac procedure, the aperture **258** in the vessel wall **256** may be closed, and the vascular access device **200** may be removed from the patient.

[000108] In some embodiments, the vascular access device **200** may be used in combination with other devices to perform a desired cardiac procedure. For example, the vascular access device **200** may be used in combination with one of the puncturable balloon catheter devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform a desired cardiac procedure, such as a coronary bypass procedure, as described therein. In such uses, the vascular access device **200** may be used inside of the vessel **252** in the manner described above, and the puncturable balloon catheter device may be used outside of the vessel **252** in the extravascular space, in the soft tissue of a limb of other anatomical locations including the chest and the pericardium, for the purpose of creating space for delivery of catheters, wires, delivery systems, and bypass conduits for the purposes of revascularization. Moreover, the vascular access device **200** may be used instead of the vascular access devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform any of the cardiac procedures described therein.

[000109] **FIGS. 2O-2R** illustrate the vascular access device **200** and a sheath **246** that may be used with the device **200** or as a part of the device **200**. The sheath **246** may have an elongated tubular shape and a circular axial cross-sectional shape, as shown, although other shapes of the sheath **246** may be used. As shown, the sheath **246** may be movably positioned over the catheter **212**. In particular, the sheath **246** may be configured to translate axially relative to the catheter **212** between a first position (which also may be referred to as an "advanced position"), as shown in **FIG. 2O**, and a second position (which also may be referred to as a "retracted position"), as shown in **FIG. 2P**. When the sheath **246** is in the first position, the sheath **246** may be

positioned over and cover the deployment openings **242** and the access opening **218** of the catheter **212**. In this manner, the sheath **246** may prevent the wires **244** from assuming their curved second configuration and extending outward beyond the external surface of the shaft **214** when the sheath **246** is in the first position. When the sheath **246** is in the second position, the sheath **246** may be spaced apart from and not cover the deployment openings **242** and the access opening **218** of the catheter **212**. In this manner, the wires **244** may be allowed to assume their curved second configuration and extend outward beyond the external surface of the shaft **214** when the sheath **246** is in the second position.

[000110] **FIGS. 2S-2V** illustrate the vascular access device **200** having a different configuration of the access opening **218**, the guidewire lumen **220**, and the lumen transition portion **222** as compared to the embodiment illustrated in **FIGS. 2A-2J**. In particular, as shown in **FIGS. 2U** and **2V**, the acute angle between the longitudinal axis of the second portion **220b** of the guidewire lumen **220** and the longitudinal axis A_L of the device **200** may be greater such that the second portion **220b** extends proximally to an opening **248** (which also may be referred to as a "guidewire opening" or a "guidewire entry opening"). As shown, the opening **248** may be defined at least partially in the side wall of the shaft **214** and at least partially in the lumen transition portion **222**, and the opening **248** may partially overlap the access opening **218** of the catheter **212**. As shown in **FIGS. 2U** and **2V**, the access opening **218** may include a first portion **218a** and a second portion **218b** positioned proximally relative to the first portion **218a**. The opening **248** and the first portion **218a** of the access opening **218** may partially overlap one another, as shown. The second portion **218b** of the access opening **218** may be shaped as a contoured notch or cutout that is in communication with the first portion **218a** of the access opening **218**, as shown. During use of the illustrated embodiment of the vascular access device **200**, the guidewire **270** may pass through the opening **248**, through the guidewire lumen **220**, and out of the distal end **202** of the device **200**, and the second portion **218b** of the access opening **218** may accommodate the portion of the guidewire **270** that extends proximally out of and alongside the catheter **212**. In this manner, according to the illustrated embodiment, the guidewire **270** is not passed through the primary lumen **216** of the catheter **212**.

[000111] **FIGS. 3A-3F** illustrate a vascular access device **300** (which also may be referred to as an "endovascular access device") configured to provide access for performing cardiac interventional procedures on patients in need thereof, in accordance with one or more

embodiments of the disclosure. As described in detail below, the vascular access device **300** is configured to be percutaneously inserted through the natural lumen of a vessel of a patient, to form a hemostatic connection between the device **300** and a surface of a wall of the vessel, and to facilitate formation of an aperture through the vessel wall to provide access to desired vasculature in a thoracic region of the patient. The vascular access device **300** also may be configured to allow operative instruments or other devices to be passed through the device **300** to perform a desired cardiac procedure on the patient, to allow a physician to assess the integrity of the hemostatic connection and the aperture formed through the vessel wall before, during, or after performing the desired cardiac procedure, and to allow sufficient blood flow to pass through the natural lumen of the vessel while the device **300** is positioned therein.

[000112] As shown in **FIGS. 3A** and **3B**, the vascular access device **300** has an elongated shape including a distal end **302** (which also may be referred to as a "leading end") and a proximal end **304** (which also may be referred to as a "trailing end") positioned along a longitudinal axis A_L of the device **300**. The vascular access device **300** includes a distal end portion **306** extending from the distal end **302** toward the proximal end **304** along the longitudinal axis A_L, a proximal end portion **308** extending from the proximal end **304** toward the distal end **302** along the longitudinal axis A_L, and an intermediate portion **310** extending axially from the distal end portion **306** to the proximal end portion **308**. It will be appreciated that part of the intermediate portion **310** of the vascular access device **300** is removed from view in **FIGS. 3A** and **3B** for purposes of illustrating the device **300**. When the vascular access device **300** is used to provide access for performing a cardiac procedure on a patient, the distal end portion **306** and at least part of the intermediate portion **310** may be percutaneously inserted through the natural lumen of a vessel, while the proximal end portion **308** remains at least partially outside of the patient's body. In this manner, the proximal end portion **308** may be manipulated by a physician outside of the patient's body in order to position the distal end portion **306** at a desired location within the vessel lumen and form a hemostatic connection between the distal end portion **306** and the vessel wall, as described below.

[000113] The vascular access device **300** includes a catheter **312**, which may extend axially along the longitudinal axis A_L of the device **300**. The catheter **312** may include a flexible shaft **314** (which also may be referred to as a "tube") configured to traverse the vessel lumen in which the vascular access device **300** is inserted. As shown, the shaft **314** may have an elongated

tubular shape and a circular axial cross-sectional shape, although other shapes of the shaft **314** may be used. In some embodiments, as shown, a longitudinal axis of the catheter **312** is coaxial with the longitudinal axis A_L of the device **300**. The catheter **312** may include a primary lumen **316** (which also may be referred to as a "working lumen" or an "access lumen") extending therethrough from the proximal end to the distal end of the catheter **312**, as shown. As described below, the primary lumen **316** may be used to facilitate insertion and positioning of the vascular access device **300** within the vessel lumen via a guidewire, to facilitate formation of an aperture through the vessel wall, and to pass operative instruments or other devices through the device **300** and the aperture to perform a desired cardiac procedure on the patient. As shown, the primary lumen **316** may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the primary lumen **316** may be used. In some embodiments, as shown, the longitudinal axis of the primary lumen **316** is coaxial with the longitudinal axis of the catheter **312** and the longitudinal axis A_L of the device **300**. In this manner, a wall thickness of the catheter **312** may be constant along the circumference of the catheter **312**, as shown. In some embodiments, the catheter **312** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the catheter **312** may be formed of a polyether block amide (PEBA), such as PEBAX®, a thermoplastic urethane (TPU), such as PELLETHANE®, or a nylon. In some embodiments, the catheter **312** includes a liner and/or a reinforcement structure arranged in a manner similar to the corresponding features of the catheters described above.

[000114] The shaft **314** of the catheter **312** may include a distal tip portion **322** (which also may be referred to as a "dilator tip portion") positioned about the distal end of the catheter **312**. As shown, the external surface of the distal tip portion **322** may be curved or tapered such that the external surface curves or tapers radially inward in a direction from the proximal end to the distal end of the distal tip portion **322**. In this manner, the distal tip portion **322** may facilitate guiding of the distal end portion **306** of the vascular access device **300** through the natural lumen of a vessel in which the device **300** is inserted. As shown in **FIG. 3B**, the catheter **312** may include one or more marker bands **324** positioned within the side wall of the shaft **314** and radially spaced apart from the primary lumen **316** and the external surface of the shaft **314**. The marker bands **324** may have a ring shape and a circular axial cross-sectional shape, although other shapes of the marker bands **324** may be used. The marker bands **324** may be positioned

near but axially spaced apart from the distal end of the catheter **312**. In some embodiments, as shown, one marker band **324** is positioned at or near the proximal end of the distal tip portion **322**. According to the illustrated embodiment, the catheter **312** includes only one marker band **324**. However, it will be appreciated that the catheter **312** may include any number of marker bands **324** in other embodiments. The marker bands **324** may be formed of a radiopaque material that is visible under medical imaging. In this manner, a physician may observe the marker bands **324** via medical imaging as the catheter **312** is advanced through the vasculature and positioned within the vessel lumen. In some embodiments, the marker bands **324** are formed of platinum, tungsten, gold, or tantalum, although other suitable radiopaque materials may be used in other embodiments. In some embodiments, as an alternative to marker bands, one or more radiopaque additives may be compounded with a polymer to form the catheter **312**, such that one or more portions of the catheter **312** is visible under medical imaging.

[000115] As shown, the vascular access device **300** also includes a dilator **332** (which also may be referred to as a "steerable dilator"), which may extend axially along the longitudinal axis A_L of the device **300**. The dilator **332** may include a flexible shaft **334** (which also may be referred to as a "tube") configured to traverse the vessel lumen in which the vascular access device **300** is inserted. As shown, the shaft **334** may have an elongated tubular shape and a circular axial cross-sectional shape, although other shapes of the shaft **334** may be used. In some embodiments, as shown, a longitudinal axis of the dilator **332** is coaxial with the longitudinal axis of the catheter **312** and the longitudinal axis A_L of the device **300**. The dilator **332** may include a primary lumen **336** (which also may be referred to as a "guidewire lumen" or a "guiding lumen") extending therethrough from the proximal end to the distal end of the dilator **332**, as shown. As described below, the primary lumen **336** may be used to facilitate insertion and positioning of the vascular access device **300** within the vessel lumen via a guidewire, and to facilitate formation of an aperture through the vessel wall. As shown, the primary lumen **336** may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the primary lumen **336** may be used. In some embodiments, as shown, the longitudinal axis of the primary lumen **336** is coaxial with the longitudinal axis of the dilator **332**, the longitudinal axis of the catheter **312**, and the longitudinal axis A_L of the device **300**. In this manner, a wall thickness of the dilator **332** may be constant along the circumference of the dilator **332**, as shown. In some embodiments, the dilator **332** is formed of a biocompatible polymer, although

other suitable materials may be used in other embodiments. For example, the dilator **332** may be formed of a polyimide (PI), a polytetrafluoroethylene (PTFE), a perfluoroalkoxy alkane (PFA), a fluorinated ethylene propylene (FEP), another fluoropolymer, or a polyethylene (PE), such as a high-density polyethylene (HDPE), a low-density polyethylene (LDPE), or a medium-density polyethylene (MDPE). In some embodiments, the dilator **332** includes a liner and/or a reinforcement structure arranged in a manner similar to the corresponding features of the catheters described above.

[000116] The shaft **334** of the dilator **332** may include a distal tip portion **342** (which also may be referred to as a "dilator tip portion") positioned about the distal end of the dilator **332**. As shown, the external surface of the distal tip portion **342** may be curved or tapered such that the external surface curves or tapers radially inward in a direction from the proximal end to the distal end of the distal tip portion **342**. In this manner, the distal tip portion **342** may facilitate guiding of the distal end portion **306** of the vascular access device **300** through the natural lumen of a vessel in which the device **300** is inserted. As shown in **FIG. 3B**, the dilator **332** may include one or more marker bands **344** positioned within the side wall of the shaft **334** and radially spaced apart from the primary lumen **336** and the external surface of the shaft **334**. The marker bands **344** may have a ring shape and a circular axial cross-sectional shape, although other shapes of the marker bands **344** may be used. The marker bands **344** may be positioned near but axially spaced apart from the distal end of the dilator **332**. In some embodiments, as shown, one marker band **344** is positioned within the distal tip portion **342** and spaced apart from the proximal end and the distal end of the distal tip portion **342**. According to the illustrated embodiment, the dilator **332** includes only one marker band **344**. However, it will be appreciated that the dilator **332** may include any number of marker bands **344** in other embodiments. The marker bands **344** may be formed of a radiopaque material that is visible under medical imaging. In this manner, a physician may observe the marker bands **344** via medical imaging as the dilator **332** is advanced through the vasculature and positioned within the vessel lumen. In some embodiments, the marker bands **344** are formed of platinum, tungsten, gold, or tantalum, although other suitable radiopaque materials may be used in other embodiments. In some embodiments, as an alternative to marker bands, one or more radiopaque additives may be compounded with a polymer to form the dilator **332**, such that one or more portions of the dilator **332** is visible under medical imaging.

[000117] As shown, the dilator **332** may include a wire **346** (which also may be referred to as a "pull wire" or a "steering wire") positioned at least partially within the side wall of the shaft **334**. In particular, the wire **346** may be fixedly secured within a wire lumen **348** defined in the side wall of the shaft **334**. As shown, the wire lumen **348** may be radially spaced apart from the primary lumen **336** and the external surface of the shaft **334**. The wire lumen **348** may extend axially along the shaft **334** and parallel to the longitudinal axis of the dilator **332**, and may have an open proximal end and a closed distal end. As shown in **FIG. 3B**, the open proximal end of the wire lumen **348** may be positioned at the proximal end of the dilator **332**, and the closed distal end of the wire lumen **348** may be axially spaced apart from the distal end of the dilator **332**. In some embodiments, as shown, the closed distal end of the wire lumen **348** is positioned at or near the proximal end of the distal tip portion **342**, although other positions, such as within the distal tip portion **342** may be used in other embodiments. The wire **346** may have an elongated shape, with the distal end of the wire **346** positioned at the closed distal end of the wire lumen **348** and the proximal end of the wire **346** positioned proximally from the open proximal end of the wire lumen **348**. In this manner, a proximal end portion of the wire **346** may extend proximally away from the proximal end of the dilator **332**, such that the physician may grasp and manipulate the wire **346**, for example by pulling the wire **346**, in order to steer the dilator **332** and the overall vascular access device **300** from outside of the patient.

[000118] **FIGS. 3C-3F** illustrate an example method of using the vascular access device **300** to provide access for performing a cardiac interventional procedure on a patient. Initially, the vascular access device **300** may be percutaneously inserted into the patient through a vascular access site formed in an artery, such as a femoral artery. With the proximal end portion **308** of the device **300** outside of the patient, the physician may manipulate the proximal end portion **308** in order to advance the distal end portion **306** of the device **300** through the vasculature and position the distal end portion **306** at a desired location within a natural lumen **350** of a desired vessel **352**, as shown in **FIG. 3C**. In some embodiments, as shown, the vascular access device **300** is advanced over a guidewire **370** to facilitate guiding the distal end portion **306** of the device **300** through the vasculature and positioning the distal end portion **306** at the desired location within vessel **352**.

[000119] After the distal end portion **306** of the device **300** is positioned at the desired location within the natural lumen **350** of the vessel **352**, the wire **346** may be manipulated by the

physician, such as by pulling the wire **346** proximally relative to the proximal end portion **308** of the device **300** in order to steer the distal end portion **306**. Such pulling of the wire **346** may cause the distal end portion **306** of the device **300** and a distal end portion of the guidewire **370** to curve or bend, as shown in **FIG. 3D**. With the guidewire **370** and the distal end portion **306** of the device **300** in the curved or bent configuration and in a desired orientation, the guidewire **370** may be advanced through a wall **356** of the vessel **352**. In this manner, the guidewire **370** may form an aperture **358** in the vessel wall **356** extending from an inner surface **354** to an outer surface **360** of the vessel wall **356**, as shown in **FIG. 3D**. The distal tip portion **342** of the dilator **332** and the distal tip portion **322** of the catheter **312** then may be advanced through the aperture **358** in the vessel wall **356**, as shown in **FIG. 3E**. In this manner, the dilator **332** and the catheter **312** may dilate the aperture **358**, and a hemostatic connection may be formed between the external surface of the catheter **312** and the circumferential inner surface of the aperture **358**.

[000120] After the hemostatic connection is formed between the catheter **312** and the vessel wall **356**, the guidewire **370** may be retracted and removed from the device **300**, as shown in **FIG. 3F**. The dilator **332** also may be retracted and removed from the catheter **312** or may be left in place. After removal of the guidewire **373**, a cardiac interventional procedure may be performed through the vascular access device **300** and through the aperture **358**, while the hemostatic connection is maintained between the external surface of the catheter **312** and the inner surface of the aperture **358** in the vessel wall **356**. In particular, one or more operative instruments or devices may be passed through the primary lumen **316** of the catheter **312** and/or the primary lumen **336** of the dilator **332**, through the aperture **358** in the vessel wall **356**, and into the thoracic cavity of the patient to perform a desired cardiac procedure on the desired vasculature. Upon completion of the cardiac procedure, the aperture **358** in the vessel wall **356** may be closed, and the vascular access device **300** may be removed from the patient.

[000121] In some embodiments, the vascular access device **300** may be used in combination with other devices to perform a desired cardiac procedure. For example, the vascular access device **300** may be used in combination with one of the puncturable balloon catheter devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform a desired cardiac procedure, such as a coronary bypass procedure, as described therein. In such uses, the vascular access device **300** may be used inside of the vessel **352** in the manner described above, and the puncturable balloon catheter device may be used outside of the vessel

352 in the extravascular space, in the soft tissue of a limb of other anatomical locations including the chest and the pericardium, for the purpose of creating space for delivery of catheters, wires, delivery systems, and bypass conduits for the purposes of revascularization. Moreover, the vascular access device **300** may be used instead of the vascular access devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform any of the cardiac procedures described therein.

[000122] **FIGS. 4A-4G** illustrate a vascular access device **400** (which also may be referred to as an "endovascular access device") configured to provide access for performing cardiac interventional procedures on patients in need thereof, in accordance with one or more embodiments of the disclosure. As described in detail below, the vascular access device **400** is configured to be percutaneously inserted through the natural lumen of a vessel of a patient, to form a hemostatic connection between the device **400** and a surface of a wall of the vessel, and to facilitate formation of an aperture through the vessel wall to provide access to desired vasculature in a thoracic region of the patient. The vascular access device **400** also may be configured to allow operative instruments or other devices to be passed through the device **400** to perform a desired cardiac procedure on the patient, to allow a physician to assess the integrity of the hemostatic connection and the aperture formed through the vessel wall before, during, or after performing the desired cardiac procedure, and to allow sufficient blood flow to pass through the natural lumen of the vessel while the device **400** is positioned therein.

[000123] As shown in **FIGS. 4A** and **4B**, the vascular access device **400** has an elongated shape including a distal end **402** (which also may be referred to as a "leading end") and a proximal end **404** (which also may be referred to as a "trailing end") positioned along a longitudinal axis A_L of the device **400**. The vascular access device **400** includes a distal end portion **406** extending from the distal end **402** toward the proximal end **404** along the longitudinal axis A_L, a proximal end portion **408** extending from the proximal end **404** toward the distal end **402** along the longitudinal axis A_L, and an intermediate portion **410** extending axially from the distal end portion **406** to the proximal end portion **408**. It will be appreciated that part of the intermediate portion **410** of the vascular access device **400** is removed from view in **FIGS. 4A** and **4B** for purposes of illustrating the device **400**. When the vascular access device **400** is used to provide access for performing a cardiac procedure on a patient, the distal end portion **406** and at least part of the intermediate portion **410** may be percutaneously inserted

through the natural lumen of a vessel, while the proximal end portion **408** remains at least partially outside of the patient's body. In this manner, the proximal end portion **408** may be manipulated by a physician outside of the patient's body in order to position the distal end portion **406** at a desired location within the vessel lumen and form a hemostatic connection between the distal end portion **406** and the vessel wall, as described below.

[000124] The vascular access device **400** includes a catheter **412** (which also may be referred to as a "steerable catheter"), which may extend axially along the longitudinal axis A_L of the device **400**. The catheter **412** may include a flexible shaft **414** (which also may be referred to as a "tube") configured to traverse the vessel lumen in which the vascular access device **400** is inserted. As shown, the shaft **414** may have an elongated tubular shape and a circular axial cross-sectional shape, although other shapes of the shaft **414** may be used. In some embodiments, as shown, a longitudinal axis of the catheter **412** is coaxial with the longitudinal axis A_L of the device **400**. The catheter **412** may include a primary lumen **416** (which also may be referred to as a "working lumen" or an "access lumen") extending therethrough from the proximal end to the distal end of the catheter **412**, as shown. As described below, the primary lumen **416** may be used to facilitate insertion and positioning of the vascular access device **400** within the vessel lumen via a guidewire, to facilitate formation of an aperture through the vessel wall, and to pass operative instruments or other devices through the device **400** and the aperture to perform a desired cardiac procedure on the patient. As shown, the primary lumen **416** may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the primary lumen **416** may be used. In some embodiments, as shown, the longitudinal axis of the primary lumen **416** is coaxial with the longitudinal axis of the catheter **412** and the longitudinal axis A_L of the device **400**. In this manner, a wall thickness of the catheter **412** may be constant along the circumference of the catheter **412**, as shown. In some embodiments, the catheter **412** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the catheter **412** may be formed of a polyether block amide (PEBA), such as PEBAX®, a thermoplastic urethane (TPU), such as PELLETHANE®, or a nylon. In some embodiments, the catheter **412** includes a liner and/or a reinforcement structure arranged in a manner similar to the corresponding features of the catheters described above.

[000125] The shaft **414** of the catheter **412** may include a distal tip portion **422** (which also may be referred to as a "dilator tip portion") positioned about the distal end of the catheter **412**.

As shown, the external surface of the distal tip portion **422** may be curved or tapered such that the external surface curves or tapers radially inward in a direction from the proximal end to the distal end of the distal tip portion **422**. In this manner, the distal tip portion **422** may facilitate guiding of the distal end portion **406** of the vascular access device **400** through the natural lumen of a vessel in which the device **400** is inserted. As shown in **FIGS. 4B** and **4C**, the catheter **412** may include one or more marker bands **424** positioned within the side wall of the shaft **414** and radially spaced apart from the primary lumen **416** and the external surface of the shaft **414**. The marker bands **424** may have a ring shape and a circular axial cross-sectional shape, although other shapes of the marker bands **424** may be used. The marker bands **424** may be positioned near but axially spaced apart from the distal end of the catheter **412**. In some embodiments, as shown, one marker band **424** is positioned at or near the proximal end of the distal tip portion **422**. According to the illustrated embodiment, the catheter **412** includes only one marker band **424**. However, it will be appreciated that the catheter **412** may include any number of marker bands **424** in other embodiments. The marker bands **424** may be formed of a radiopaque material that is visible under medical imaging. In this manner, a physician may observe the marker bands **424** via medical imaging as the catheter **412** is advanced through the vasculature and positioned within the vessel lumen. In some embodiments, the marker bands **424** are formed of platinum, tungsten, gold, or tantalum, although other suitable radiopaque materials may be used in other embodiments. In some embodiments, as an alternative to marker bands, one or more radiopaque additives may be compounded with a polymer to form the catheter **412**, such that one or more portions of the catheter **412** is visible under medical imaging.

[000126] As shown, the catheter **412** may include a wire **426** (which also may be referred to as a "pull wire" or a "steering wire") positioned at least partially within the side wall of the shaft **414**. In particular, the wire **426** may be fixedly secured within a wire lumen **428** defined in the side wall of the shaft **414**. As shown, the wire lumen **428** may be radially spaced apart from the primary lumen **416** and the external surface of the shaft **414**. The wire lumen **428** may extend axially along the shaft **414** and parallel to the longitudinal axis of the catheter **412**, and may have an open proximal end and a closed distal end. As shown in **FIG. 4B**, the open proximal end of the wire lumen **428** may be positioned at the proximal end of the catheter **412**, and the closed distal end of the wire lumen **428** may be axially spaced apart from the distal end of the catheter **412**. In some embodiments, as shown, the closed distal end of the wire lumen **428** is positioned

at or near the proximal end of the distal tip portion **422**, although other positions, such as within the distal tip portion **422** may be used in other embodiments. The wire **426** may have an elongated shape, with the distal end of the wire **426** positioned at the closed distal end of the wire lumen **428** and the proximal end of the wire **426** positioned proximally from the open proximal end of the wire lumen **428**. In this manner, a proximal end portion of the wire **426** may extend proximally away from the proximal end of the catheter **412**, such that the physician may grasp and manipulate the wire **426**, for example by pulling the wire **426**, in order to steer the catheter **412** and the overall vascular access device **400** from outside of the patient.

[000127] As shown, the vascular access device **400** also includes a dilator **432**, which may extend axially along the longitudinal axis A_L of the device **400**. The dilator **432** may include a flexible shaft **434** (which also may be referred to as a "tube") configured to traverse the vessel lumen in which the vascular access device **400** is inserted. As shown, the shaft **434** may have an elongated tubular shape and a circular axial cross-sectional shape, although other shapes of the shaft **434** may be used. In some embodiments, as shown, a longitudinal axis of the dilator **432** is coaxial with the longitudinal axis of the catheter **412** and the longitudinal axis A_L of the device **400**. The dilator **432** may include a primary lumen **436** (which also may be referred to as a "guidewire lumen" or a "guiding lumen") extending therethrough from the proximal end to the distal end of the dilator **432**, as shown. As described below, the primary lumen **436** may be used to facilitate insertion and positioning of the vascular access device **400** within the vessel lumen via a guidewire, and to facilitate formation of an aperture through the vessel wall. As shown, the primary lumen **436** may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the primary lumen **436** may be used. In some embodiments, as shown, the longitudinal axis of the primary lumen **436** is coaxial with the longitudinal axis of the dilator **432**, the longitudinal axis of the catheter **412**, and the longitudinal axis A_L of the device **400**. In this manner, a wall thickness of the dilator **432** may be constant along the circumference of the dilator **432**, as shown. In some embodiments, the dilator **432** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the dilator **432** may be formed of a polyimide (PI), a polytetrafluoroethylene (PTFE), a perfluoroalkoxy alkane (PFA), a fluorinated ethylene propylene (FEP), another fluoropolymer, or a polyethylene (PE), such as a high-density polyethylene (HDPE), a low-density polyethylene (LDPE), or a medium-density polyethylene (MDPE). In some embodiments, the dilator **432**

includes a liner and/or a reinforcement structure arranged in a manner similar to the corresponding features of the catheters described above.

[000128] The shaft **434** of the dilator **432** may include a distal tip portion **442** (which also may be referred to as a "dilator tip portion") positioned about the distal end of the dilator **432**. As shown, the external surface of the distal tip portion **442** may be curved or tapered such that the external surface curves or tapers radially inward in a direction from the proximal end to the distal end of the distal tip portion **442**. In this manner, the distal tip portion **442** may facilitate guiding of the distal end portion **406** of the vascular access device **400** through the natural lumen of a vessel in which the device **400** is inserted. As shown in **FIG. 4B**, the dilator **432** may include one or more marker bands **444** positioned within the side wall of the shaft **434** and radially spaced apart from the primary lumen **436** and the external surface of the shaft **434**. The marker bands **444** may have a ring shape and a circular axial cross-sectional shape, although other shapes of the marker bands **444** may be used. The marker bands **444** may be positioned near but axially spaced apart from the distal end of the dilator **432**. In some embodiments, as shown, one marker band **444** is positioned within the distal tip portion **442** and spaced apart from the proximal end and the distal end of the distal tip portion **442**. According to the illustrated embodiment, the dilator **432** includes only one marker band **444**. However, it will be appreciated that the dilator **432** may include any number of marker bands **444** in other embodiments. The marker bands **444** may be formed of a radiopaque material that is visible under medical imaging. In this manner, a physician may observe the marker bands **444** via medical imaging as the dilator **432** is advanced through the vasculature and positioned within the vessel lumen. In some embodiments, the marker bands **444** are formed of platinum, tungsten, gold, or tantalum, although other suitable radiopaque materials may be used in other embodiments. In some embodiments, as an alternative to marker bands, one or more radiopaque additives may be compounded with a polymer to form the dilator **432**, such that one or more portions of the dilator **432** is visible under medical imaging.

[000129] **FIGS. 4D-4G** illustrate an example method of using the vascular access device **400** to provide access for performing a cardiac interventional procedure on a patient. Initially, the vascular access device **400** may be percutaneously inserted into the patient through a vascular access site formed in an artery, such as a femoral artery. With the proximal end portion **408** of the device **400** outside of the patient, the physician may manipulate the proximal end portion **408**

in order to advance the distal end portion **406** of the device **400** through the vasculature and position the distal end portion **406** at a desired location within a natural lumen **450** of a desired vessel **452**, as shown in **FIG. 4D**. In some embodiments, as shown, the vascular access device **400** is advanced over a guidewire **470** to facilitate guiding the distal end portion **406** of the device **400** through the vasculature and positioning the distal end portion **406** at the desired location within vessel **452**.

[000130] After the distal end portion **406** of the device **400** is positioned at the desired location within the natural lumen **450** of the vessel **452**, the wire **426** may be manipulated by the physician, such as by pulling the wire **426** proximally relative to the proximal end portion **408** of the device **400** in order to steer the distal end portion **406**. Such pulling of the wire **426** may cause the distal end portion **406** of the device **400** and a distal end portion of the guidewire **470** to curve or bend, as shown in **FIG. 4E**. With the guidewire **470** and the distal end portion **406** of the device **400** in the curved or bent configuration and in a desired orientation, the guidewire **470** may be advanced through a wall **456** of the vessel **452**. In this manner, the guidewire **470** may form an aperture **458** in the vessel wall **456** extending from an inner surface **454** to an outer surface **460** of the vessel wall **456**, as shown in **FIG. 4E**. The distal tip portion **442** of the dilator **432** and the distal tip portion **422** of the catheter **412** then may be advanced through the aperture **458** in the vessel wall **456**, as shown in **FIG. 4F**. In this manner, the dilator **432** and the catheter **412** may dilate the aperture **458**, and a hemostatic connection may be formed between the external surface of the catheter **412** and the circumferential inner surface of the aperture **458**.

[000131] After the hemostatic connection is formed between the catheter **412** and the vessel wall **456**, the guidewire **470** may be retracted and removed from the device **400**, as shown in **FIG. 4G**. The dilator **432** also may be retracted and removed from the catheter **412** or may be left in place. After removal of the guidewire **470**, a cardiac interventional procedure may be performed through the vascular access device **400** and through the aperture **458**, while the hemostatic connection is maintained between the external surface of the catheter **412** and the inner surface of the aperture **458** in the vessel wall **456**. In particular, one or more operative instruments or devices may be passed through the primary lumen **416** of the catheter **412** and/or the primary lumen **436** of the dilator **432**, through the aperture **458** in the vessel wall **456**, and into the thoracic cavity of the patient to perform a desired cardiac procedure on the desired

vasculature. Upon completion of the cardiac procedure, the aperture **458** in the vessel wall **456** may be closed, and the vascular access device **400** may be removed from the patient.

[000132] In some embodiments, the vascular access device **400** may be used in combination with other devices to perform a desired cardiac procedure. For example, the vascular access device **400** may be used in combination with one of the puncturable balloon catheter devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform a desired cardiac procedure, such as a coronary bypass procedure, as described therein. In such uses, the vascular access device **400** may be used inside of the vessel **452** in the manner described above, and the puncturable balloon catheter device may be used outside of the vessel **452** in the extravascular space, in the soft tissue of a limb of other anatomical locations including the chest and the pericardium, for the purpose of creating space for delivery of catheters, wires, delivery systems, and bypass conduits for the purposes of revascularization. Moreover, the vascular access device **400** may be used instead of the vascular access devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform any of the cardiac procedures described therein.

[000133] **FIGS. 5A-5D** illustrate a vascular access device **500** (which also may be referred to as an "endovascular access device") configured to provide access for performing cardiac interventional procedures on patients in need thereof, in accordance with one or more embodiments of the disclosure. As described in detail below, the vascular access device **500** is configured to be percutaneously inserted through the natural lumen of a vessel of a patient, to form a hemostatic connection between the device **500** and a surface of a wall of the vessel, and to facilitate formation of an aperture through the vessel wall to provide access to desired vasculature in a thoracic region of the patient. The vascular access device **500** also may be configured to allow operative instruments or other devices to be passed through the device **500** to perform a desired cardiac procedure on the patient, to allow a physician to assess the integrity of the hemostatic connection and the aperture formed through the vessel wall before, during, or after performing the desired cardiac procedure, and to allow sufficient blood flow to pass through the natural lumen of the vessel while the device **500** is positioned therein.

[000134] As shown in **FIG. 5A**, the vascular access device **500** has an elongated shape including a distal end **502** (which also may be referred to as a "leading end") and a proximal end **504** (which also may be referred to as a "trailing end") positioned along a longitudinal axis A_L of

the device **500**. The vascular access device **500** includes a distal end portion **506** extending from the distal end **502** toward the proximal end **504** along the longitudinal axis A_L, a proximal end portion **508** extending from the proximal end **504** toward the distal end **502** along the longitudinal axis A_L, and an intermediate portion **510** extending axially from the distal end portion **506** to the proximal end portion **508**. It will be appreciated that part of the intermediate portion **510** of the vascular access device **500** is removed from view in **FIG. 5A** for purposes of illustrating the device **500**. When the vascular access device **500** is used to provide access for performing a cardiac procedure on a patient, the distal end portion **506** and at least part of the intermediate portion **510** may be percutaneously inserted through the natural lumen of a vessel, while the proximal end portion **508** remains at least partially outside of the patient's body. In this manner, the proximal end portion **508** may be manipulated by a physician outside of the patient's body in order to position the distal end portion **506** at a desired location within the vessel lumen and form a hemostatic connection between the distal end portion **506** and the vessel wall, as described below.

[000135] The vascular access device **500** includes a catheter **512** (which also may be referred to as a "steerable catheter"), which may extend axially along the longitudinal axis A_L of the device **500**. The catheter **512** may include a flexible shaft **514** (which also may be referred to as a "tube") configured to traverse the vessel lumen in which the vascular access device **500** is inserted. As shown, the shaft **514** may have an elongated tubular shape and a circular axial cross-sectional shape, although other shapes of the shaft **514** may be used. In some embodiments, as shown, a longitudinal axis of the catheter **512** is coaxial with the longitudinal axis A_L of the device **500**. The catheter **512** may include a primary lumen (which also may be referred to as a "working lumen" or an "access lumen") extending therethrough from the proximal end to the distal end of the catheter **512**. As described below, the primary lumen may be used to facilitate insertion and positioning of the vascular access device **500** within the vessel lumen via a guidewire, to facilitate formation of an aperture through the vessel wall, and to pass operative instruments or other devices through the device **500** and the aperture to perform a desired cardiac procedure on the patient. The primary lumen may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the primary lumen may be used. In some embodiments, as shown, the longitudinal axis of the primary lumen is coaxial with the longitudinal axis of the catheter **512** and the longitudinal axis A_L of the device **500**. In this

manner, a wall thickness of the catheter **512** may be constant along the circumference of the catheter **512**, as shown. In some embodiments, the catheter **512** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the catheter **512** may be formed of a polyether block amide (PEBA), such as PEBAX®, a thermoplastic urethane (TPU), such as PELLETHANE®, or a nylon. In some embodiments, the catheter **512** includes a liner and/or a reinforcement structure arranged in a manner similar to the corresponding features of the catheters described above.

[000136] The shaft **514** of the catheter **512** may include a distal tip portion **522** (which also may be referred to as a "dilator tip portion") positioned about the distal end of the catheter **512**. As shown, the external surface of the distal tip portion **522** may be tapered such that the external surface tapers radially inward in a direction from the proximal end to the distal end of the distal tip portion **522**. In this manner, the distal tip portion **522** may facilitate guiding of the distal end portion **506** of the vascular access device **500** through the natural lumen of a vessel in which the device **500** is inserted. As shown, the catheter **512** may include a number of coated regions **524** positioned on the external surface of the shaft **514**. In particular, the catheter **512** may include a first coated region **524a** positioned at or near the proximal end of the distal tip portion **522**, and a second coated region **524b** that is axially spaced apart from the first coated region **524a**, as shown. The coated regions **524** may include a hydrophilic coating having absorption characteristics that allow the coating to expand beyond its original state. For example, the hydrophilic coating may be configured to expand up to 180% of its original state. As described below, the coated regions **524** may assist in securing the catheter **512** with respect to the vessel wall and forming a hemostatic connection between the catheter **512** and the vessel wall. When the coating is expanded, the coating may still be sufficiently compliant such that the catheter **512** may be removed from the vessel wall when desired. In some embodiments, the coating of the coated regions **524** is formed of one or more hydrophilic materials, although other suitable materials may be used in other embodiments.

[000137] As shown, the vascular access device **500** also includes a dilator **532**, which may extend axially along the longitudinal axis A_L of the device **500**. The dilator **532** may include a flexible shaft **534** (which also may be referred to as a "tube") configured to traverse the vessel lumen in which the vascular access device **500** is inserted. As shown, the shaft **534** may have an elongated tubular shape and a circular axial cross-sectional shape, although other shapes of the

shaft **534** may be used. In some embodiments, as shown, a longitudinal axis of the dilator **532** is coaxial with the longitudinal axis of the catheter **512** and the longitudinal axis A_L of the device **500**. The dilator **532** may include a primary lumen (which also may be referred to as a "guidewire lumen" or a "guiding lumen") extending therethrough from the proximal end to the distal end of the dilator **532**. As described below, the primary lumen may be used to facilitate insertion and positioning of the vascular access device **500** within the vessel lumen via a guidewire, and to facilitate formation of an aperture through the vessel wall. The primary lumen may have a cylindrical shape and a circular axial cross-sectional shape, although other shapes of the primary lumen may be used. In some embodiments, the longitudinal axis of the primary lumen is coaxial with the longitudinal axis of the dilator **532**, the longitudinal axis of the catheter **512**, and the longitudinal axis A_L of the device **500**. In this manner, a wall thickness of the dilator **532** may be constant along the circumference of the dilator **532**, as shown. In some embodiments, the dilator **532** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the dilator **532** may be formed of a polyimide (PI), a polytetrafluoroethylene (PTFE), a perfluoroalkoxy alkane (PFA), a fluorinated ethylene propylene (FEP), another fluoropolymer, or a polyethylene (PE), such as a high-density polyethylene (HDPE), a low-density polyethylene (LDPE), or a medium-density polyethylene (MDPE). In some embodiments, the dilator **532** includes a liner and/or a reinforcement structure arranged in a manner similar to the corresponding features of the catheters described above.

[000138] The shaft **534** of the dilator **532** may include a distal tip portion **542** (which also may be referred to as a "dilator tip portion") positioned about the distal end of the dilator **532**. As shown, the external surface of the distal tip portion **542** may be tapered such that the external surface tapers radially inward in a direction from the proximal end to the distal end of the distal tip portion **542**. In this manner, the distal tip portion **542** may facilitate guiding of the distal end portion **506** of the vascular access device **500** through the natural lumen of a vessel in which the device **500** is inserted.

[000139] **FIGS. 5B-5B** illustrate an example method of using the vascular access device **500** to provide access for performing a cardiac interventional procedure on a patient. Initially, the vascular access device **500** may be percutaneously inserted into the patient through a vascular access site formed in an artery, such as a femoral artery. With the proximal end portion **508** of the device **500** outside of the patient, the physician may manipulate the proximal end portion **508**

in order to advance the distal end portion **506** of the device **500** through the vasculature and position the distal end portion **506** at a desired location within a natural lumen of a desired vessel **552**. In some embodiments, as shown, the vascular access device **500** is advanced over a guidewire **570** to facilitate guiding the distal end portion **506** of the device **500** through the vasculature and positioning the distal end portion **506** at the desired location within vessel **552**.

[000140] After the distal end portion **506** of the device **500** is positioned at the desired location within the natural lumen of the vessel **552**, the guidewire **570** may be advanced through a wall **556** of the vessel **552**, as shown in **FIG. 5B**. In this manner, the guidewire **570** may form an aperture **558** in the vessel wall **556** extending from an inner surface **554** to an outer surface **560** of the vessel wall **556**, as shown. The distal tip portion **542** of the dilator **532** and the distal tip portion **522** of the catheter **512** then may be advanced through the aperture **558** in the vessel wall **556**, as shown in **FIG. 5C**. In this manner, the dilator **532** and the catheter **512** may dilate the aperture **558**, and a hemostatic connection may be formed between the external surface of the catheter **512** and the circumferential inner surface of the aperture **558**. The catheter **512** may be positioned with respect to the vessel wall **556** such that the vessel wall **556** is positioned between the first coated region **524a** and the second coated region **524b**, as shown in **FIG. 5C**. While the catheter **512** is maintained in this position relative to the vessel wall **556**, the coating of the coated regions **524** may expand, as shown in **FIG. 5D**, such the coated regions **524** form a pair of rings that respectively engage the inner surface **554** and the outer surface **560** of the vessel wall **556**. In this manner, the coated regions **524** may maintain the secure positioning of the catheter **512** relative to the vessel wall **556** and also may assist in forming and maintaining the hemostatic connection between the catheter **512** and the vessel wall **556**.

[000141] After the hemostatic connection is formed between the catheter **512** and the vessel wall **556**, the guidewire **570** may be retracted and removed from the device **500**. The dilator **532** also may be retracted and removed from the catheter **512** or may be left in place. After removal of the guidewire **570**, a cardiac interventional procedure may be performed through the vascular access device **500** and through the aperture **558**, while the hemostatic connection is maintained between the external surface of the catheter **512** and the inner surface of the aperture **558** in the vessel wall **556**. In particular, one or more operative instruments or devices may be passed through the primary lumen of the catheter **512** and/or the primary lumen of the dilator **532**, through the aperture **558** in the vessel wall **556**, and into the thoracic cavity of the patient to

perform a desired cardiac procedure on the desired vasculature. Upon completion of the cardiac procedure, the aperture **558** in the vessel wall **556** may be closed, and the vascular access device **500** may be removed from the patient.

[000142] In some embodiments, the vascular access device **500** may be used in combination with other devices to perform a desired cardiac procedure. For example, the vascular access device **500** may be used in combination with one of the puncturable balloon catheter devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform a desired cardiac procedure, such as a coronary bypass procedure, as described therein. In such uses, the vascular access device **500** may be used inside of the vessel **552** in the manner described above, and the puncturable balloon catheter device may be used outside of the vessel **552** in the extravascular space, in the soft tissue of a limb of other anatomical locations including the chest and the pericardium, for the purpose of creating space for delivery of catheters, wires, delivery systems, and bypass conduits for the purposes of revascularization. Moreover, the vascular access device **500** may be used instead of the vascular access devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform any of the cardiac procedures described therein.

[000143] **FIGS. 5E** and **5F** illustrate an embodiment of the vessel access device **200** described above with a coated region **280** positioned on the external surface of the shaft **214** of the catheter **212**. In particular, the coated region **280** may be positioned about the access opening **218** of the catheter **212** along a bottom half of the external surface of the shaft **214** and may surround the access opening **218**. **FIGS. 5G** and **5H** illustrate another embodiment of the vessel access device **200** described above with a coated region **280** positioned on the external surface of the shaft **214** of the catheter **212**. In particular, the coated region **280** may be positioned about the access opening **218** of the catheter **212** along a bottom half of the external surface of the shaft **214** and may surround the access opening **218**. The coated region **280** may include a hydrophilic coating having absorption characteristics that allow the coating to expand beyond its original state. For example, the hydrophilic coating may be configured to expand up to 180% of its original state. In this manner, the coated region **280** may assist in securing the catheter **212** with respect to the vessel wall and forming a hemostatic connection between the catheter **212** and the vessel wall. In some embodiments, the coating of the coated region **280** is formed of one or more hydrophilic materials, although other suitable materials may be used in other embodiments.

[000144] **FIGS. 6A-6H** illustrate a vascular access device **600** (which also may be referred to as an "endovascular access device") configured to provide access for performing cardiac interventional procedures on patients in need thereof, in accordance with one or more embodiments of the disclosure. As described in detail below, the vascular access device **600** is configured to be percutaneously inserted through the natural lumen of a vessel of a patient, to form a hemostatic connection between the device **600** and an inner surface of a wall of the vessel, and to facilitate formation of an aperture through the vessel wall to provide access to desired vasculature in a thoracic region of the patient. The vascular access device **600** also may be configured to allow operative instruments or other devices to be passed through the device **600** to perform a desired cardiac procedure on the patient, to allow a physician to assess the integrity of the hemostatic connection and the aperture formed through the vessel wall before, during, or after performing the desired cardiac procedure, and to allow sufficient blood flow to pass through the natural lumen of the vessel while the device **600** is positioned therein.

[000145] As shown in **FIGS. 6A-6E**, the vascular access device **600** has an elongated shape including a distal end **602** (which also may be referred to as a "leading end") and a proximal end **604** (which also may be referred to as a "trailing end") positioned along a longitudinal axis A_L of the device **600**. The vascular access device **600** includes an outer tube **606** and an inner guide member **608**, as shown. The outer tube **606** may extend axially along the longitudinal axis A_L of the device **600** and may have an elongated tubular shape and a circular axial cross-sectional shape, although other shapes of the outer tube **606** may be used. The outer tube **606** may include a primary lumen **616** (which also may be referred to as a "blood flow lumen") extending therethrough from the proximal end to the distal end of the device **606**. As described below, the primary lumen **616** may allow blood to flow therethrough when the vascular access device **600** is positioned within the natural lumen of a vessel. The outer tube **606** also may include an access opening **618** defined in the external surface of the outer tube **606**, as shown. The outer tube **606** may be formed a resiliently flexible material, such that the outer tube **606** may conform to the shape of the vessel. In some embodiments, the outer tube **606** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the outer tube **606** may be formed of a polyether block amide (PEBA), such as PEBAX®, a thermoplastic urethane (TPU), such as PELLETHANE®, or a nylon. In some embodiments, the

outer tube **606** includes a liner and/or a reinforcement structure arranged in a manner similar to the corresponding features of the catheters described above.

[000146] The inner guide member **608** may be positioned within the outer tube **606** and fixedly secured to the internal surface of the outer tube **606**. In some embodiments, as shown, the outer tube **606** and the inner guide member **608** may be intergrally formed with one another. The inner guide member **608** may be curved and contoured as shown in **FIGS. 6C-6E**, such that a guide lumen **620** is defined between the inner guide member **608** and the outer tube **606**. As shown, the guide lumen **620** may be in fluid communication with the access opening **618** and an entry opening **622** defined in the proximal end **604** of the device **600**. In this manner, operative instruments or other devices may be passed through the device **600** via the entry opening **622**, the guide lumen **620**, and the access opening **618**. In some embodiments, the inner guide member **608** is formed of a biocompatible polymer, although other suitable materials may be used in other embodiments. For example, the inner guide member **608** may be formed of a polyether block amide (PEBA), such as PEBAX®, a thermoplastic urethane (TPU), such as PELLETHANE®, or a nylon. In some embodiments, the inner guide member **608** includes a liner and/or a reinforcement structure arranged in a manner similar to the corresponding features of the catheters described above.

[000147] **FIGS. 6F-6H** illustrate an example method of using the vascular access device **600** to provide access for performing a cardiac interventional procedure on a patient. Initially, the vascular access device **600** may be percutaneously inserted into the patient through a vascular access site formed in an artery, such as a femoral artery. A catheter or other delivery device may be used to advance the device **600** through the vasculature and position the device **600** at a desired location within a natural lumen **650** of a desired vessel **652**. In some embodiments the vascular access device **600** is advanced over a guidewire to facilitate guiding the device **600** through the vasculature and positioning the device **600** at the desired location within vessel **652**. When the device **600** is positioned at the desired location within the natural lumen **650** of the vessel **652**, a hemostatic connection may be formed between the external surface of the outer tube **606** and an inner surface **654** of a wall **656** of the vessel **652**, as shown in **FIG. 6F**. In particular, the hemostatic connection may be formed between the portion of the external surface of the outer tube **606** that surrounds the access opening **618**.

[000148] After the hemostatic connection is formed between the external surface of the outer tube **606** and the inner surface **654** of the vessel wall **656**, a guidewire **670** and/or a dilator **672** may be advanced through the entry opening **622**, the guide lumen **620**, and the access opening **618** of the device **600** and through the vessel wall **656**, as shown in **FIG. 6G**. In this manner, the guidewire **670** may form an aperture **658** in the vessel wall **656** extending from the inner surface **654** to an outer surface **660** of the vessel wall **656**, as shown. After the aperture **658** is formed in the vessel wall **656**, the guidewire **670** and/or the dilator **672** may be retracted and removed from the guide lumen **620** of the device **600**, while the hemostatic connection is maintained between the external surface of the outer tube **606** and the inner surface **654** of the vessel wall **656**, as shown in **FIG. 6H**. Before or after removal of the guidewire **670** and/or the dilator **672** from the guide lumen **620**, a cardiac interventional procedure may be performed through the vascular access device **600** and through the aperture **658**, while the hemostatic connection is maintained between the external surface of the outer tube **606** and the inner surface **654** of the vessel wall **656**. In particular, one or more operative instruments or devices may be passed through the guide lumen **620** and the access opening **618** of the device **600** and the aperture **658** in the vessel wall **656** and into the thoracic cavity of the patient to perform a desired cardiac procedure on the desired vasculature. Upon completion of the cardiac procedure, the aperture **658** in the vessel wall **656** may be closed, and the vascular access device **600** may be removed from the patient.

[000149] In some embodiments, the vascular access device **600** may be used in combination with other devices to perform a desired cardiac procedure. For example, the vascular access device **600** may be used in combination with one of the puncturable balloon catheter devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform a desired cardiac procedure, such as a coronary bypass procedure, as described therein. In such uses, the vascular access device **600** may be used inside of the vessel **652** in the manner described above, and the puncturable balloon catheter device may be used outside of the vessel **652** in the extravascular space, in the soft tissue of a limb of other anatomical locations including the chest and the pericardium, for the purpose of creating space for delivery of catheters, wires, delivery systems, and bypass conduits for the purposes of revascularization. Moreover, the vascular access device **600** may be used instead of the vascular access devices described in U.S. Provisional Patent Application Serial No. 62/331,229 to Crisco to perform any of the cardiac procedures described therein.

[000150] Publications cited herein and the materials for which they are cited are specifically incorporated by reference. Modifications and variations of the devices, systems, and methods described herein will be obvious to those skilled in the art from the foregoing detailed description. Such modifications and variations are intended to come within the scope of the appended claims.

CLAIMS

We claim:

1. A vascular access device comprising:

a catheter comprising a primary lumen extending from a proximal end to a distal end of the catheter; and

at least one deployable wire secured to the catheter and configured to move relative to the catheter between a delivery configuration and a deployed configuration.

2. The vascular access device of claim 1, wherein the deployable wire is positioned inward from an external surface of the catheter when the deployable wire is in the delivery configuration, and wherein the deployable wire extends at least partially outward from the external surface of the catheter when the deployable wire is in the deployed configuration.

3. The vascular access device of claim 1 or claim 2, wherein the deployable wire is formed of a shape-memory material, such that the deployable wire has a natural undeformed shape but may be deformed to a different deformed shape.

4. The vascular access device of claim 3, wherein the deployable wire is formed of nitinol.

5. The vascular access device of claim 3 or claim 4, wherein the deployable wire has the deformed shape when the deployable wire is in the delivery configuration, and wherein the deployable wire has the natural undeformed shape when the deployable wire is in the deployed configuration.

6. The vascular access device of any one of claims 3 to 5, wherein the natural undeformed shape of the deployable wire is curved, and wherein the deformed shape of the deployable wire is substantially straight.

7. The vascular access device of any one of claims 1 to 6, wherein the at least one deployable wire comprises a plurality of deployable wires each secured to the catheter and

configured to move relative to the catheter between the delivery configuration and the deployed configuration.

8. The vascular access device of any one of claims 1 to 7, wherein the catheter further comprises at least one deployable wire lumen that is spaced apart from the primary lumen, and wherein the deployable wire is positioned at least partially within the deployable wire lumen.

9. The vascular access device of claim 8, wherein the catheter further comprises a deployment opening defined in an external surface of the catheter and in communication with the deployable wire lumen.

10. The vascular access device of claim 9, wherein the deployable wire extends at least partially through the deployment opening and outward from the external surface of the catheter when the deployable wire is in the deployed configuration.

11. The vascular access device of any one of claims 1 to 10, further comprising at least one non-deployable wire secured to the catheter and positioned within a wall of the catheter.

12. The vascular access device of claim 11, wherein the non-deployable wire is formed of a shape-memory material, such that the non-deployable wire has a natural undeformed shape but may be deformed to a different deformed shape.

13. The vascular access device of claim 12, wherein the non-deployable wire is formed of nitinol.

14. The vascular access device of claim 12 or claim 13, wherein the non-deployable wire has the deformed shape when a distal end portion of the device is in a straight configuration, and wherein the non-deployable wire has the natural undeformed shape when the distal end portion of the device is in a curved configuration.

15. The vascular access device of claim 14, wherein the non-deployable wire is configured to bias the distal end portion of the device toward the curved configuration.

16. The vascular access device of any one of claims 12 to 15, wherein the natural undeformed shape of the non-deployable wire is curved, and wherein the deformed shape of the non-deployable wire is substantially straight.

17. The vascular access device of any one of claims 11 to 16, wherein the catheter further comprises at least one non-deployable wire lumen that is spaced apart from the primary lumen, and wherein the non-deployable wire is positioned within the non-deployable wire lumen.

18. The vascular access device of any one of claims 1 to 17, wherein the catheter comprises a distal tip portion positioned about a distal end of the device, wherein an external surface of the distal tip portion is tapered such that the external surface tapers radially inward in a direction from a proximal end to a distal end of the distal tip portion.

19. The vascular access device of claim 18, wherein the distal tip portion is beveled such that a distal edge of the distal tip portion is angled at an acute angle relative to a longitudinal axis of the device.

20. The vascular access device of claim 18 or claim 19, wherein the catheter further comprises an internal thru lumen and an external thru lumen each spaced apart from the primary lumen, wherein the internal thru lumen extends from the proximal end of the catheter to an internal surface of the distal tip portion, and wherein the external thru lumen extends from the proximal end of the catheter to the external surface of the distal tip portion.

21. A method of using a vascular access device to provide access for performing a cardiac procedure on a patient, the method comprising:

percutaneously inserting a distal end portion of the vascular access device into a natural lumen of a vessel of the patient;

deploying at least one deployable wire from a catheter of the vascular access device such that the deployable wire engages an inner surface of a wall of the vessel and biases the catheter to engage the inner surface such that a hemostatic connection is formed between the catheter and the inner surface; and

advancing at least one instrument through the catheter and through the wall to form an aperture in the wall, while maintaining the hemostatic connection between the catheter and the inner surface.

22. The method of claim 21, wherein percutaneously inserting the distal end portion of the vascular access device into the natural lumen of the vessel comprises maintaining a proximal end portion of the vascular access device outside of the patient.

23. The method of claim 21 or claim 22, wherein percutaneously inserting the distal end portion of the vascular access device into the natural lumen of the vessel comprises inserting the distal end portion through an access site formed in an artery of the patient.

24. The method of any one of claims 21 to 23, wherein percutaneously inserting the distal end portion of the vascular access device into the natural lumen of the vessel comprises passing the vascular access device over a guidewire.

25. The method of any one of claims 21 to 24, wherein the distal end portion is configured to move between a straight configuration and a curved configuration, and wherein percutaneously inserting the distal end portion of the vascular access device into the natural lumen of the vessel comprises inserting the distal end portion into the natural lumen while the distal end portion is in the straight configuration.

26. The method of claim 25, further comprising, prior to deploying the at least one deployable wire from the catheter, moving the distal end portion or allowing the distal end portion to move from the straight configuration to the curved configuration.

27. The method of claim 26, wherein moving the distal end portion or allowing the distal end portion to move from the straight configuration to the curved configuration comprises engaging the inner surface of the wall with the catheter.

28. The method of claim 26 or claim 27, wherein moving the distal end portion or allowing the distal end portion to move from the straight configuration to the curved configuration comprises allowing at least one non-deployable wire of the device to bias the distal end portion toward the curved configuration.

30. The method of any of claims 21 to 28, wherein the catheter comprises a distal tip portion positioned about a distal end of the vascular access device, and wherein the hemostatic connection is formed between the distal tip portion and the inner surface.

30. The method of claim 29, wherein the distal tip portion is beveled such that a distal edge of the distal tip portion is angled at an acute angle relative to a longitudinal axis of the vascular access device, and wherein the hemostatic connection is formed between the distal edge and the inner surface.

31. The method of claim 30, wherein the distal edge surrounds the aperture in the wall of the vessel.

32. The method of any one of claims 21 to 31, wherein the hemostatic connection surrounds the aperture in the wall of the vessel.

33. The method of any one of claims 21 to 32, further comprising injecting at least one fluid comprising a contrast medium through at least one thru lumen of the catheter, and assessing the integrity of the hemostatic connection or the aperture in the wall of the vessel by observing the flow of the fluid.

34. The method of claim 33, wherein the at least one thru lumen comprises an internal thru lumen extending from the proximal end of the catheter to an internal surface of a distal tip portion of the catheter.

35. The method of claim 33, wherein the at least one thru lumen comprises an external thru lumen extending from the proximal end of the catheter to an external surface of a distal tip portion of the catheter.

36. The method of any one of claims 21 to 35, wherein the at least one instrument comprises a guidewire, and wherein advancing the at least one instrument through the catheter and through the wall to form the aperture comprises puncturing the wall with the guidewire.

37. The method of any one of claims 21 to 36, wherein the at least one instrument comprises a dilator, and wherein advancing the at least one instrument through the catheter and through the wall to form the aperture comprises dilating the aperture with the dilator.

38. The method of claim 21, wherein the catheter comprises an access opening defined in a side wall of the catheter, and wherein the hemostatic connection is formed between a portion of an external surface of the catheter surrounding the access opening and the inner surface.

39. The method of claim 38, wherein an edge of the access opening surrounds the aperture in the wall of the vessel.

40. The method of any one of claims 21 to 39, wherein the at least one deployable wire comprises a plurality of deployable wires.

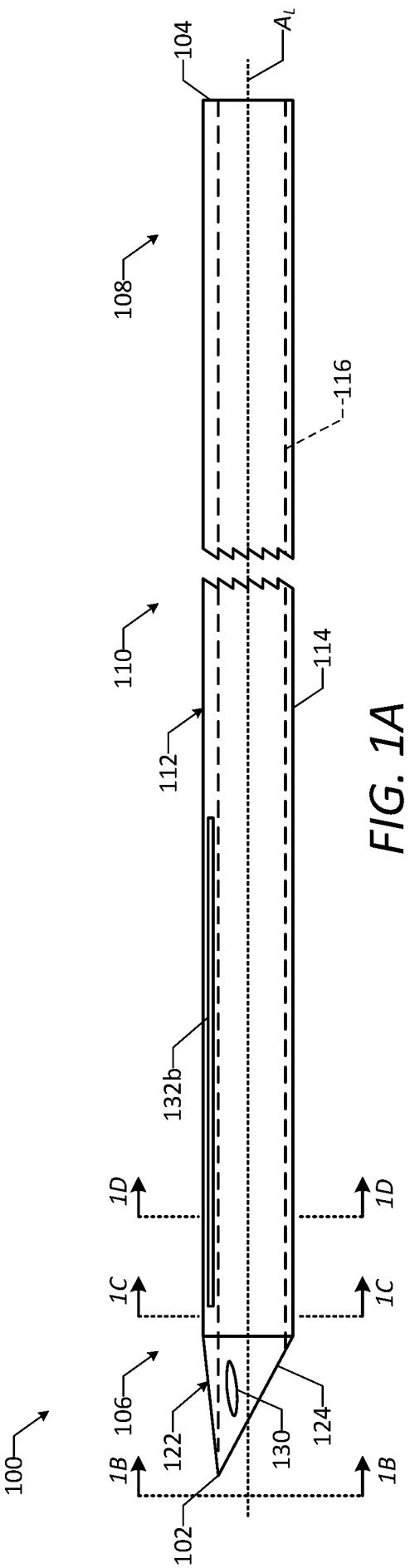

FIG. 1A

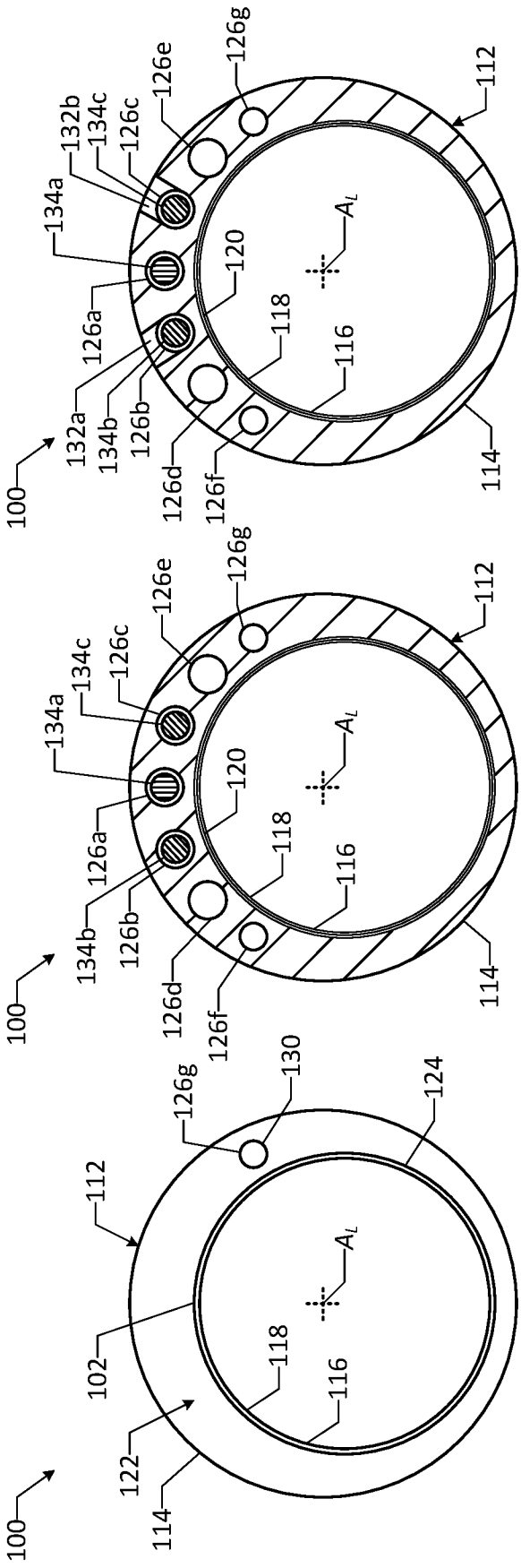

FIG. 1B

FIG. 1C

FIG. 1D

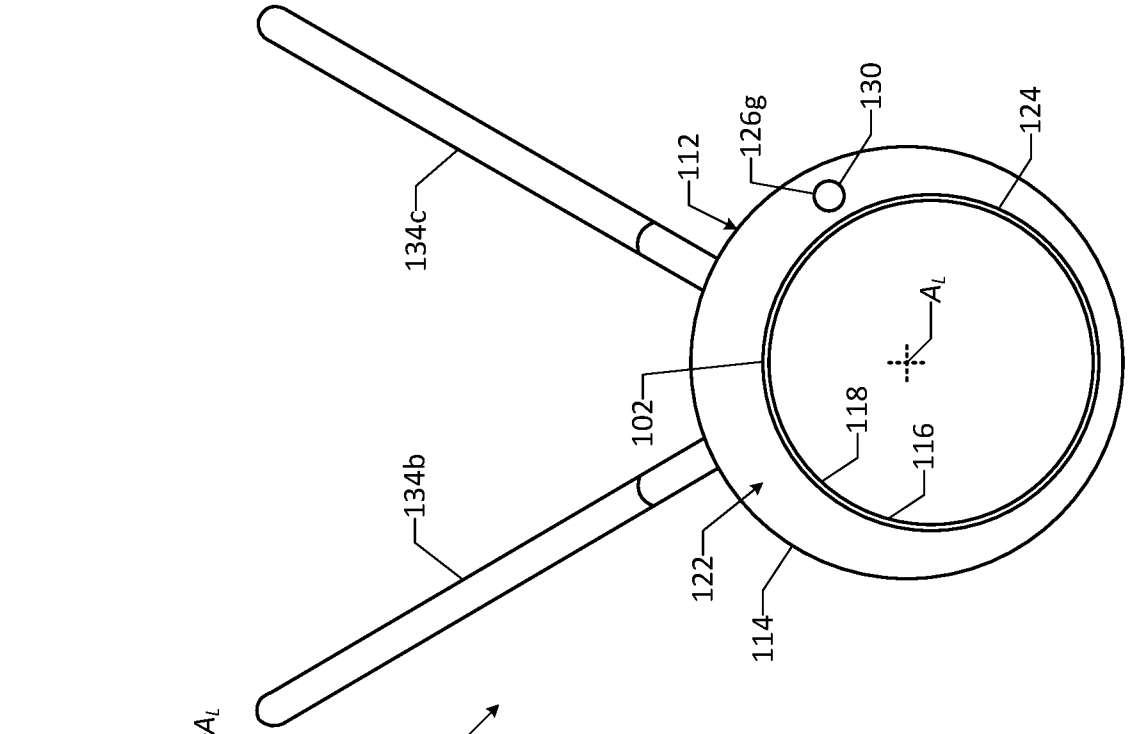

FIG. 1G

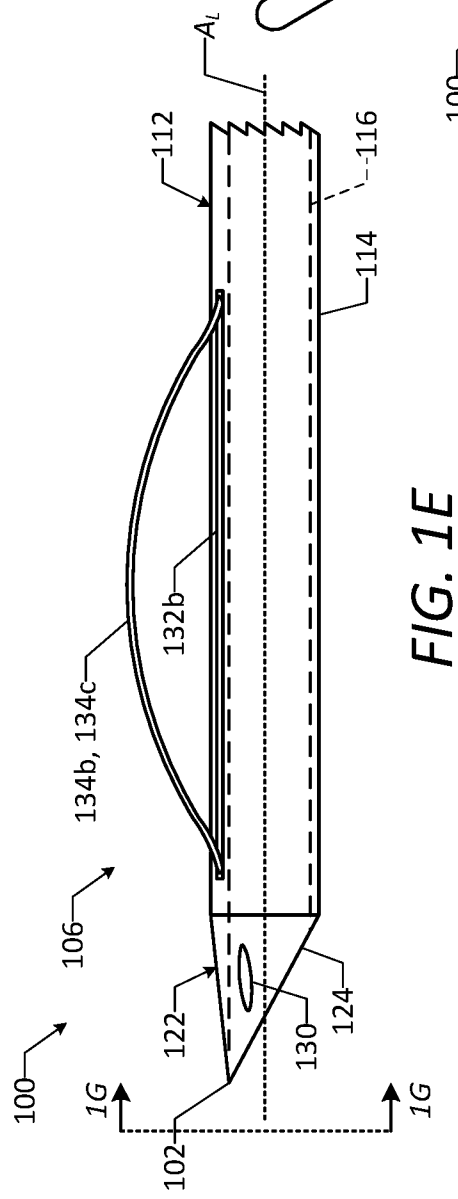

FIG. 1E

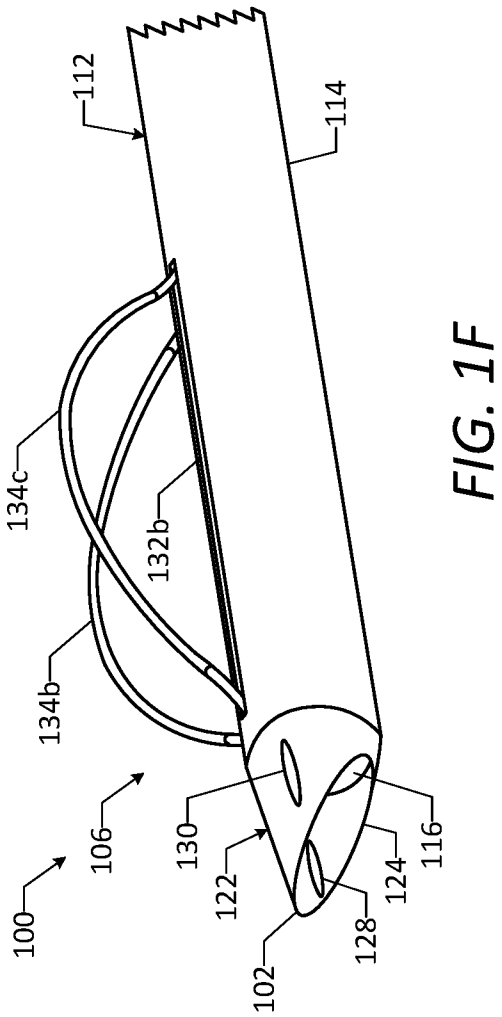

FIG. 1F

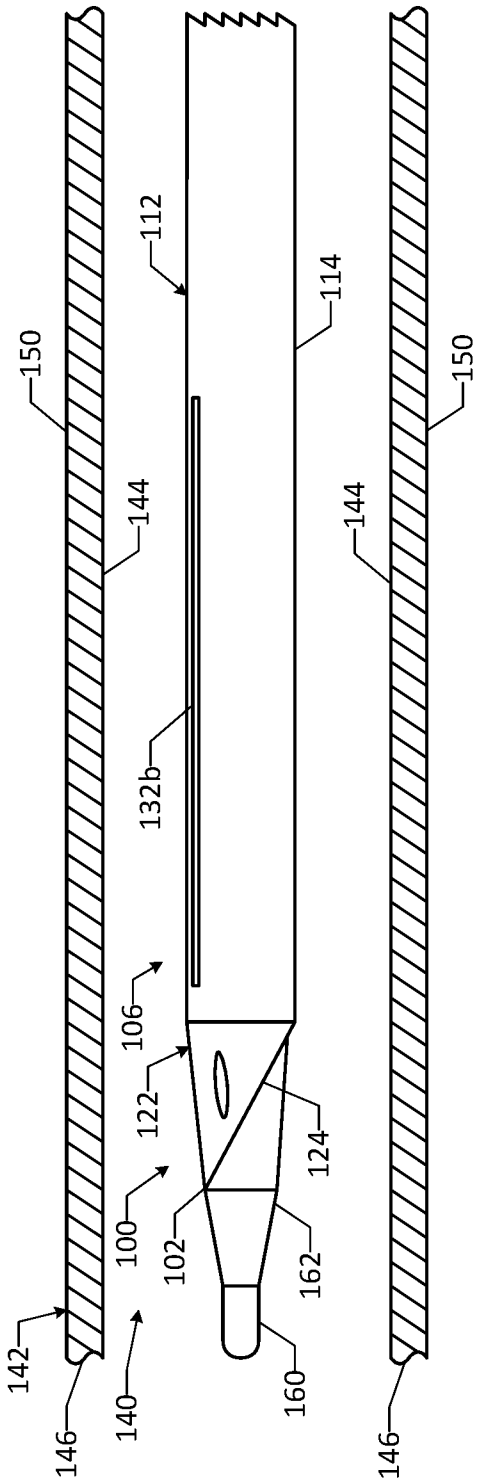
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FIG. 1H

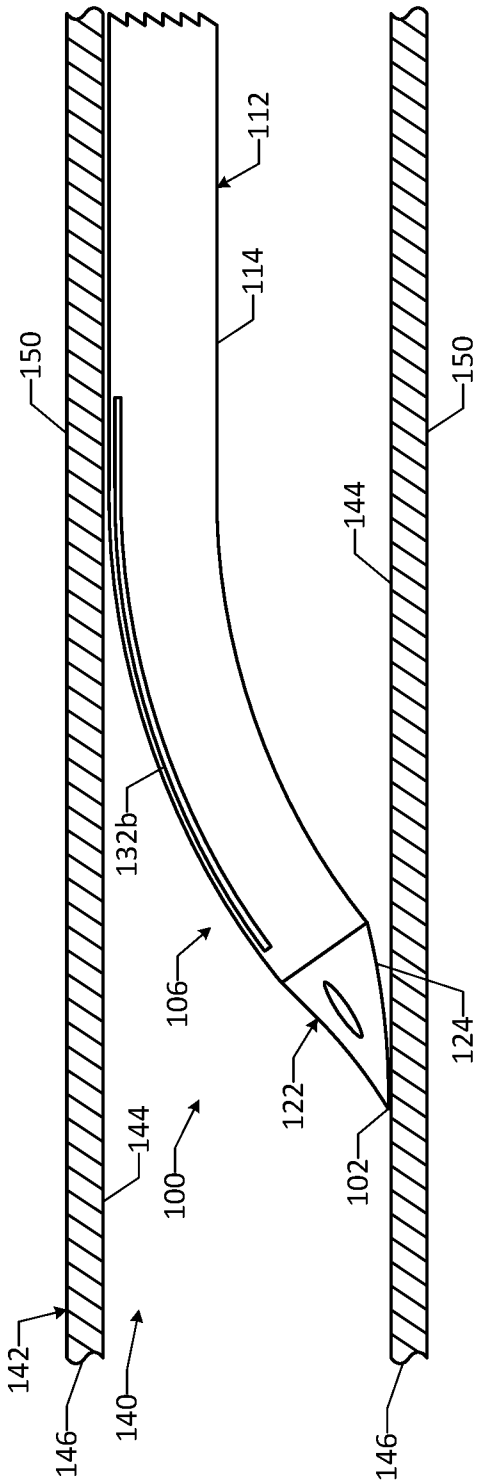
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FIG. 1I

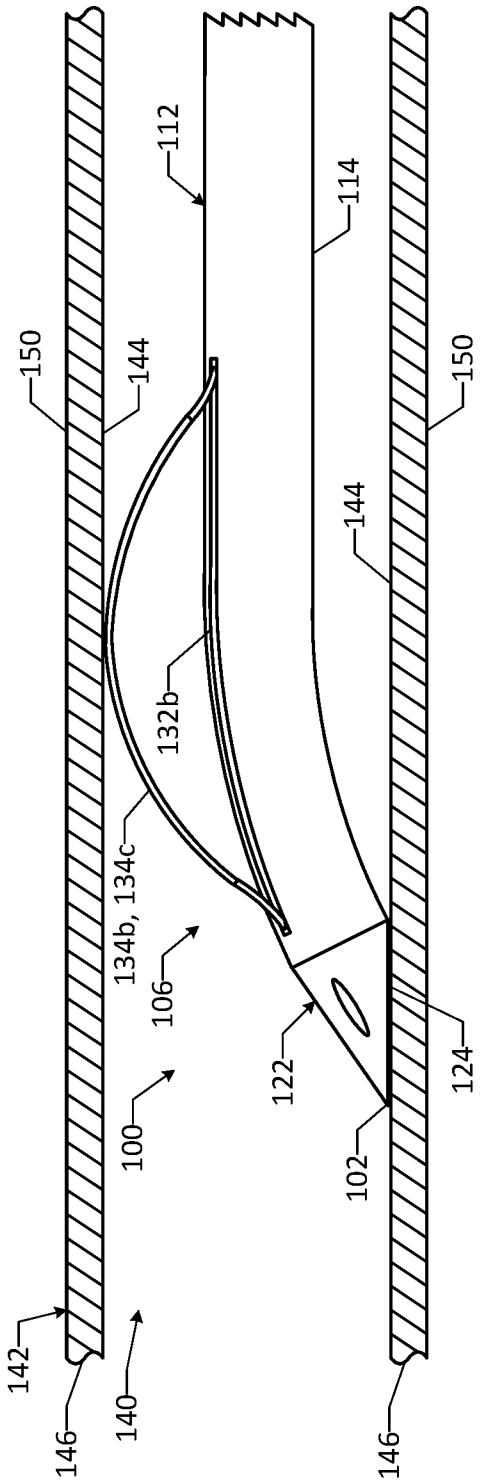
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FIG. 1J

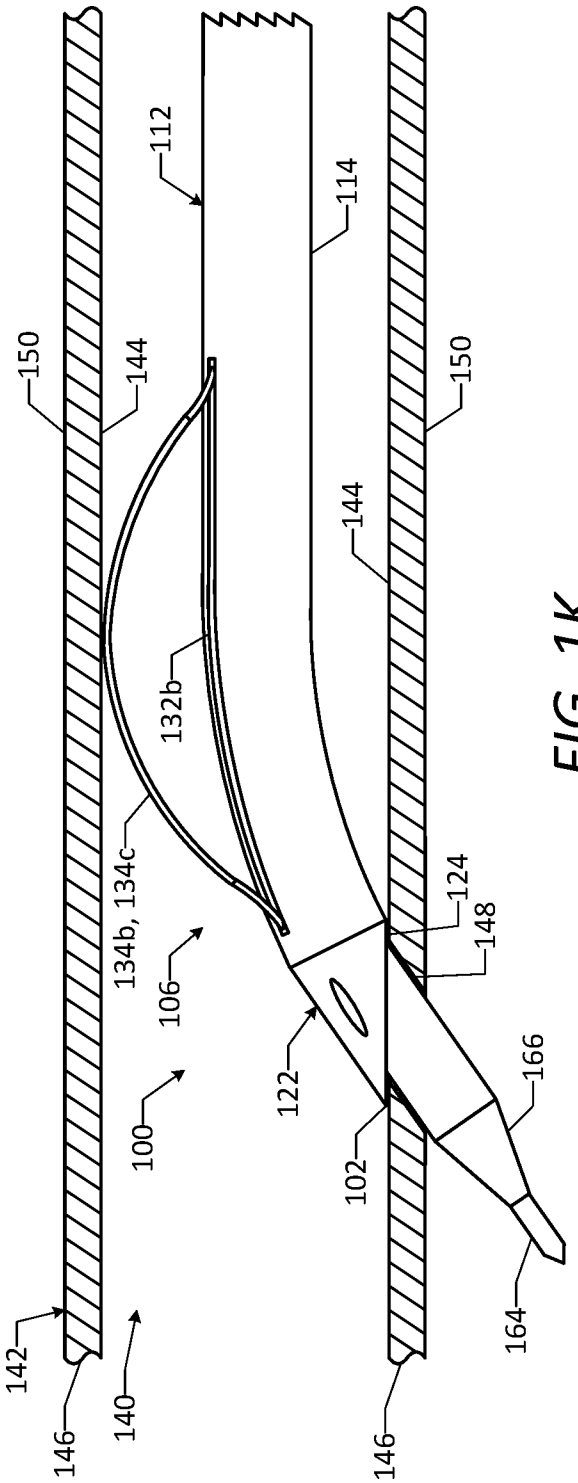
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FIG. 1K

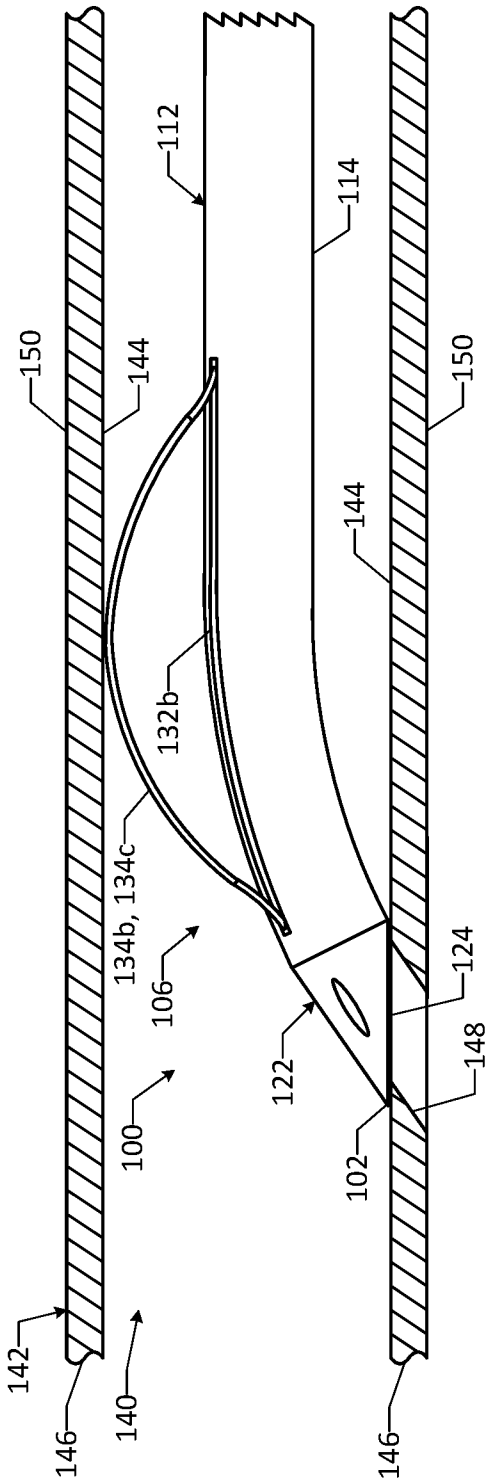
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FIG. 1L

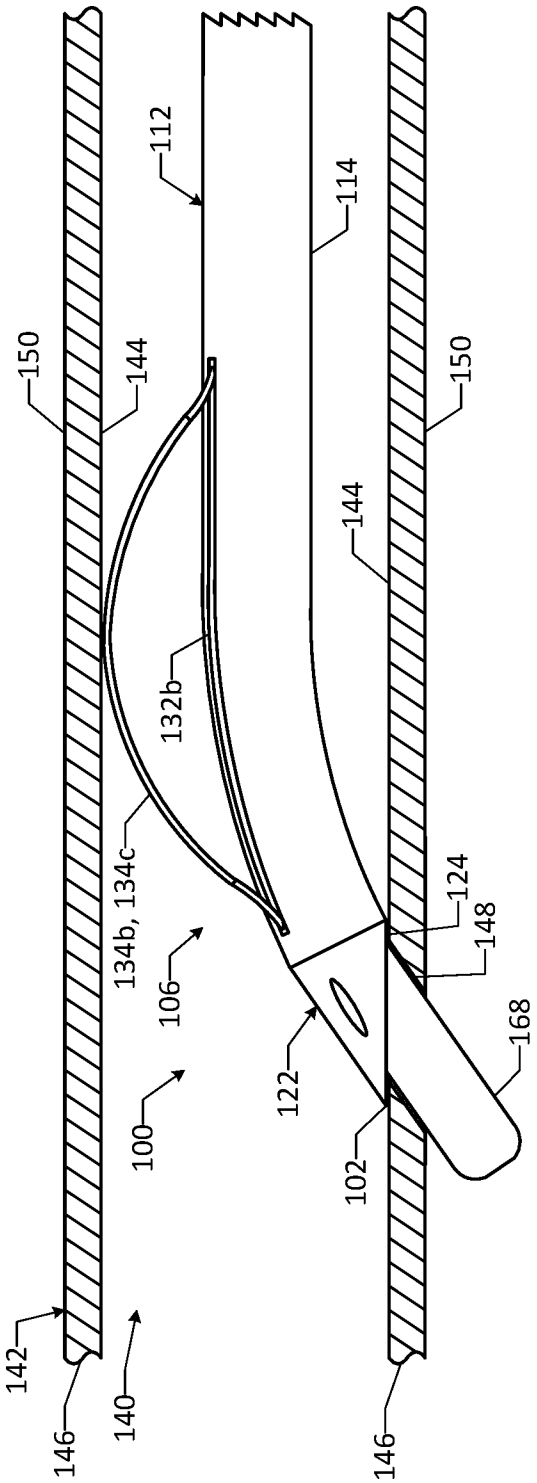
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FIG. 1M

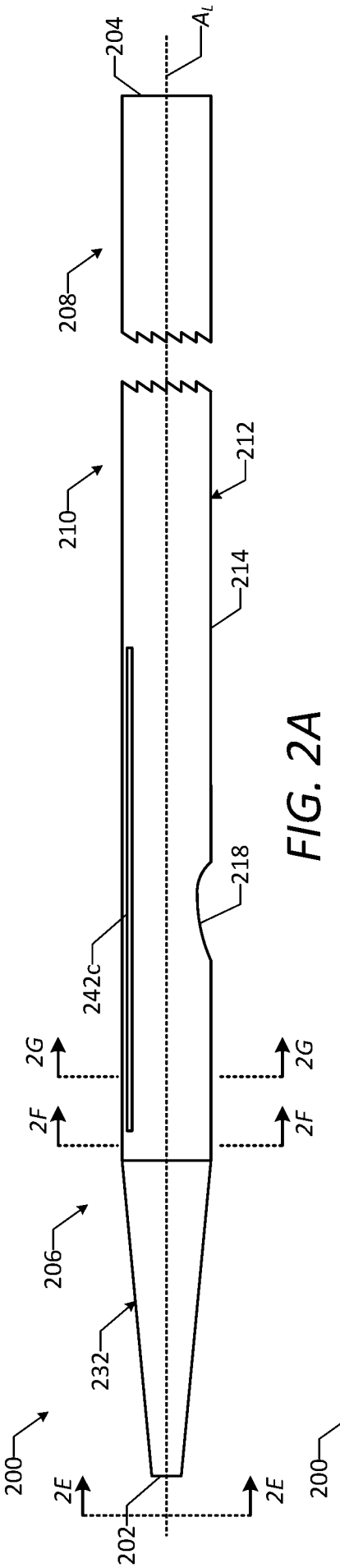


FIG. 2A

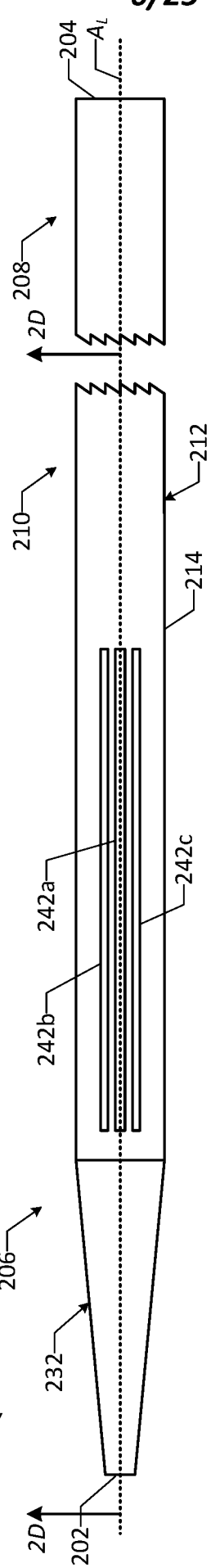


FIG. 2B

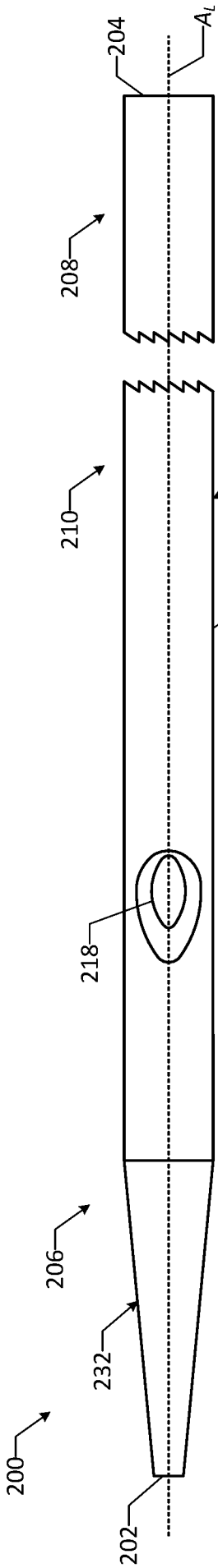


FIG. 2C

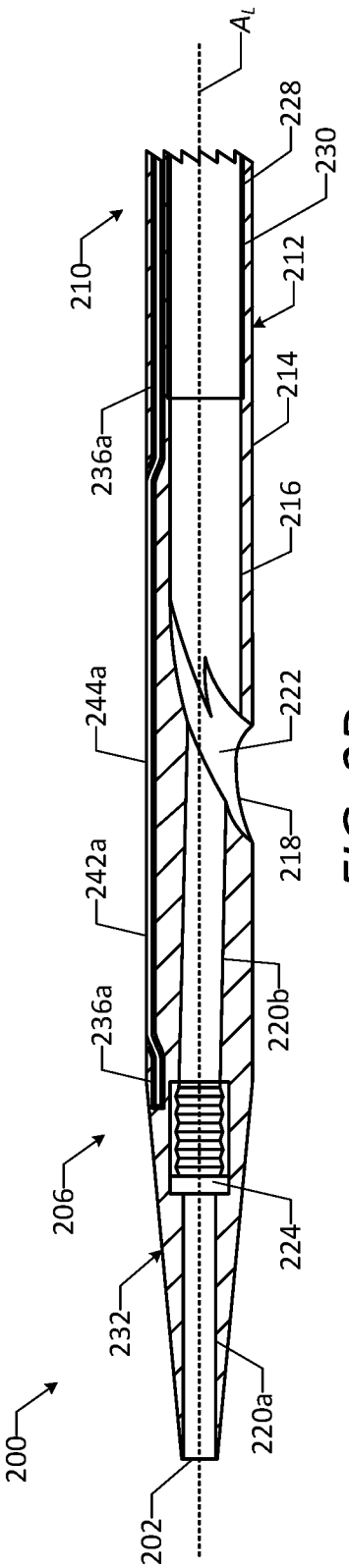


FIG. 2D

FIG. 2E

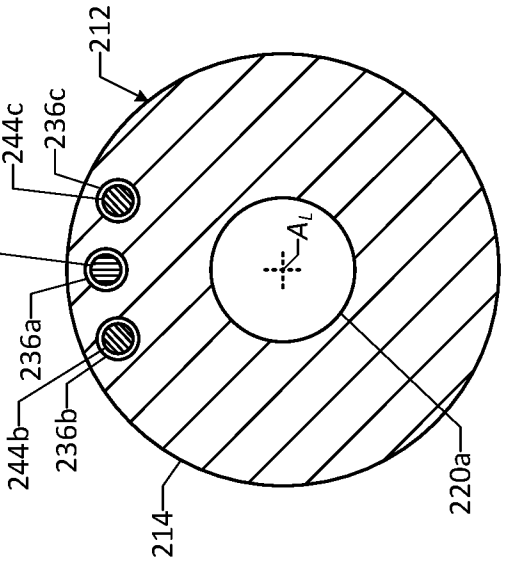


FIG. 2F

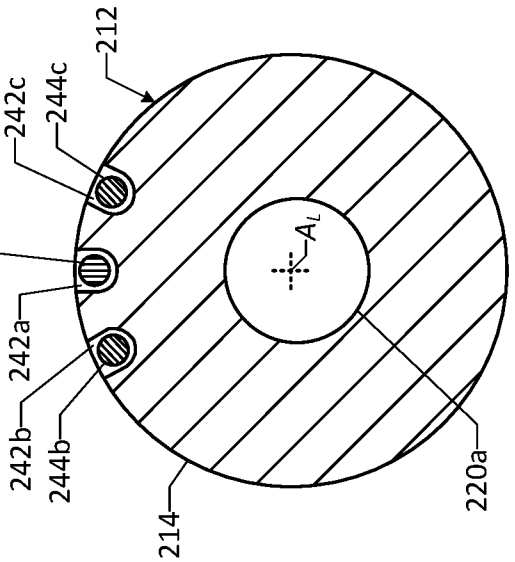


FIG. 2G

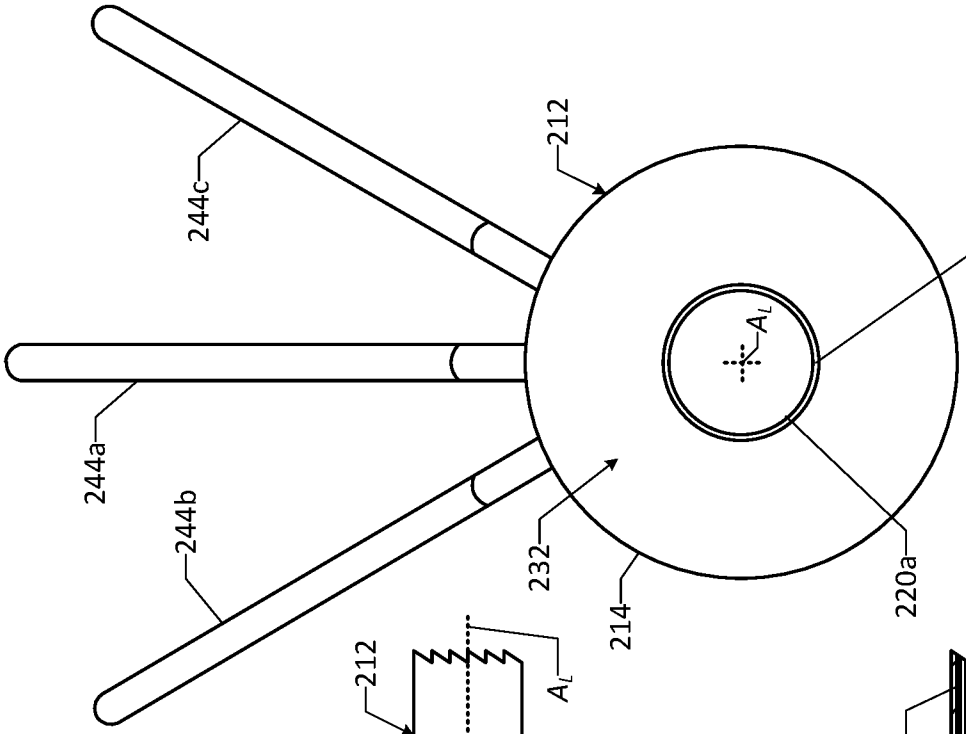
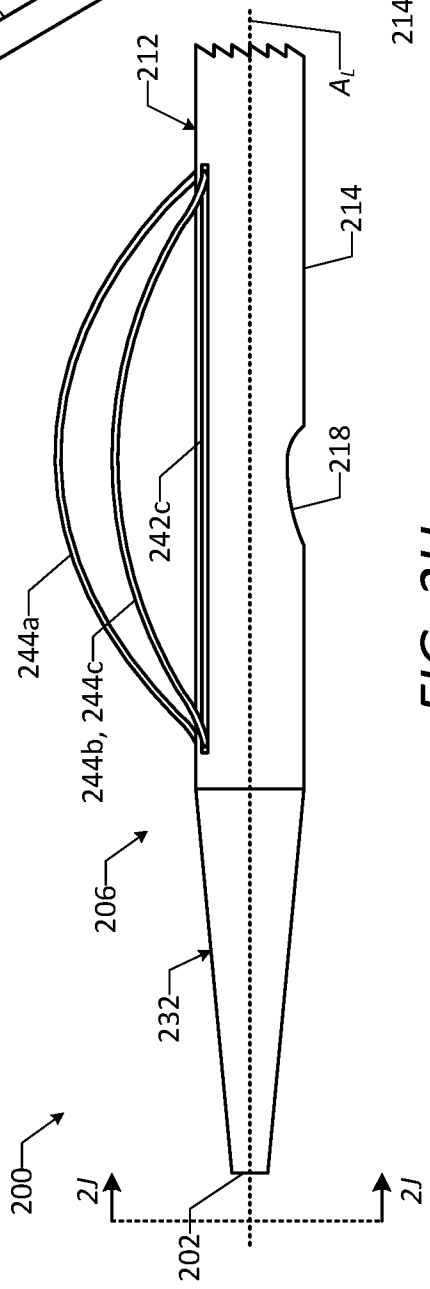


FIG. 2J



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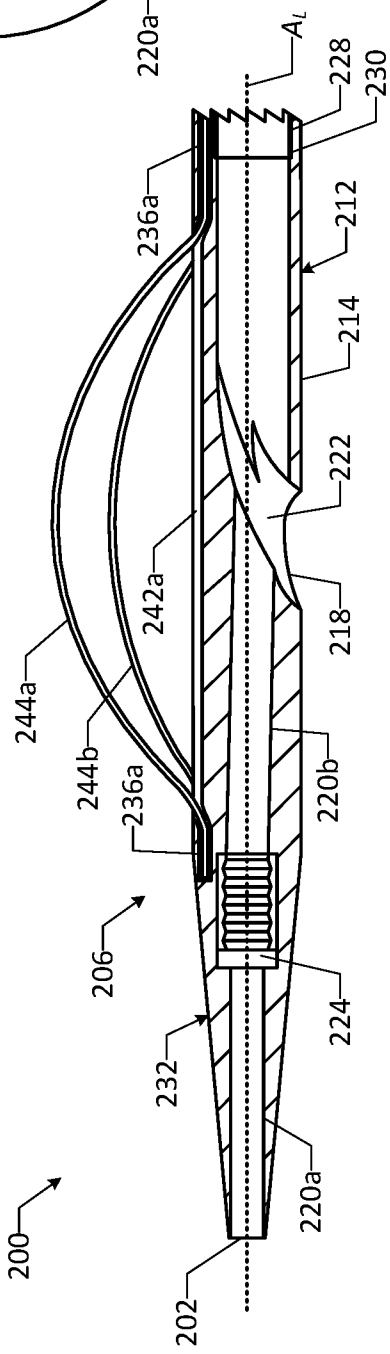
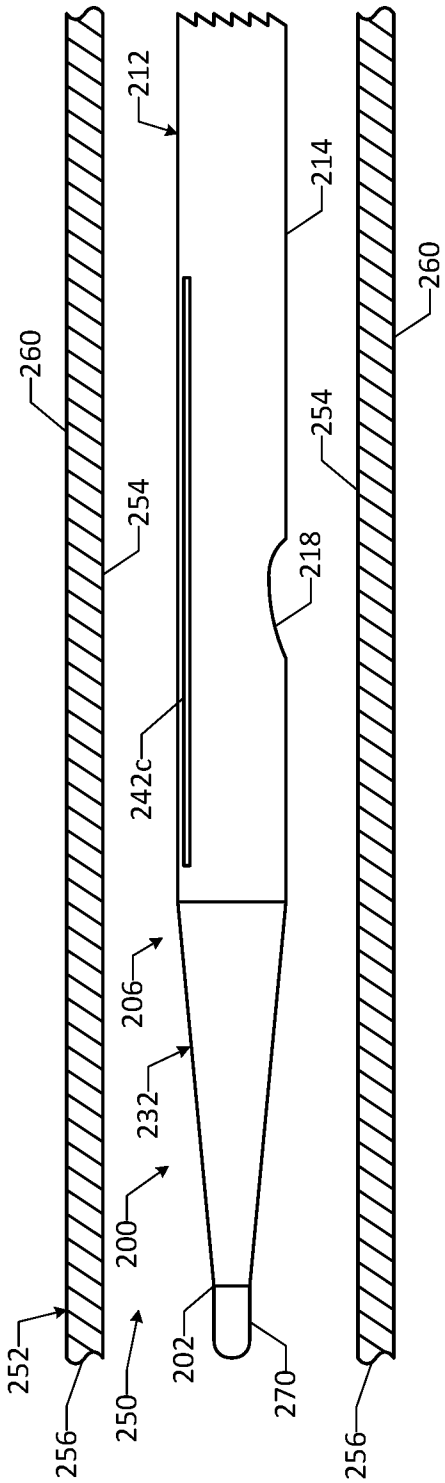


FIG. 2I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242c
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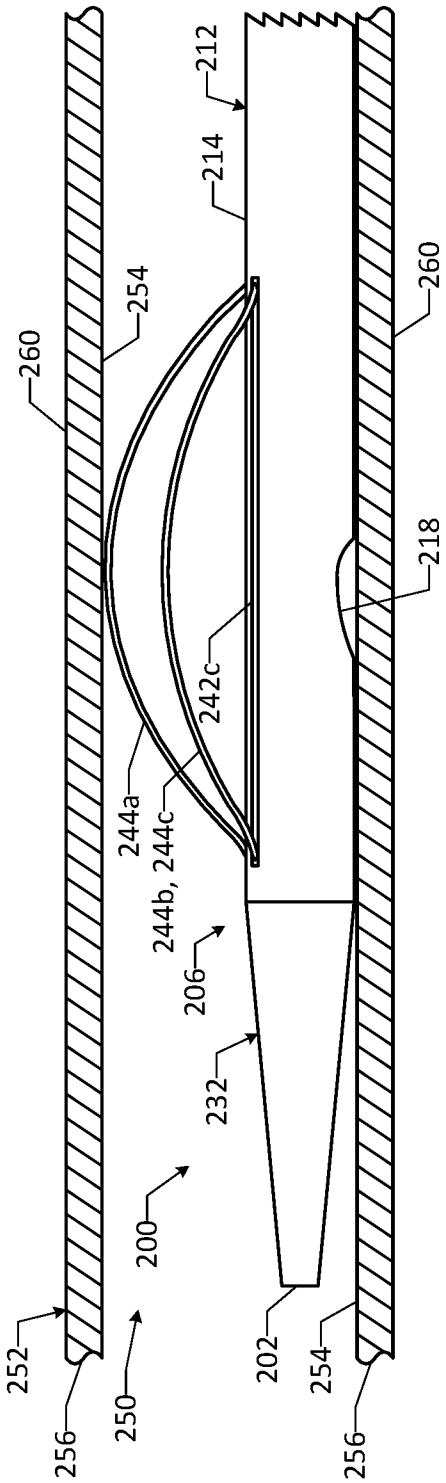
256

FIG. 2K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242c
244a
244b, 244c
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232
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252
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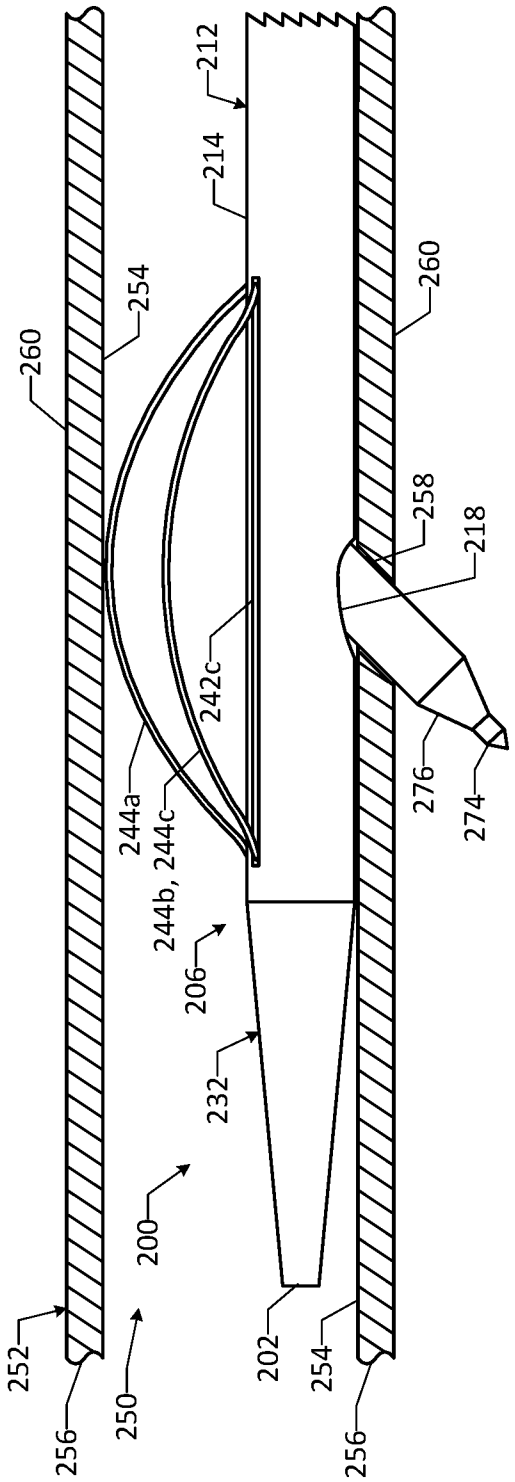
254
256

FIG. 2L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254
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242c
244a
244b, 244c
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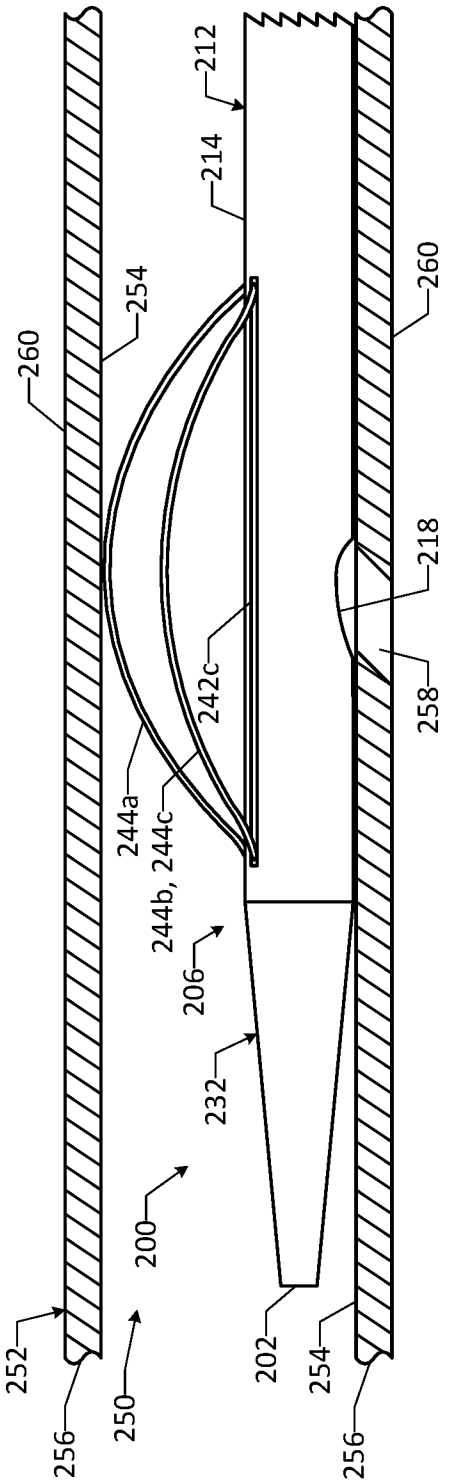
FIG. 2M


260
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242c
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244a
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FIG. 2N

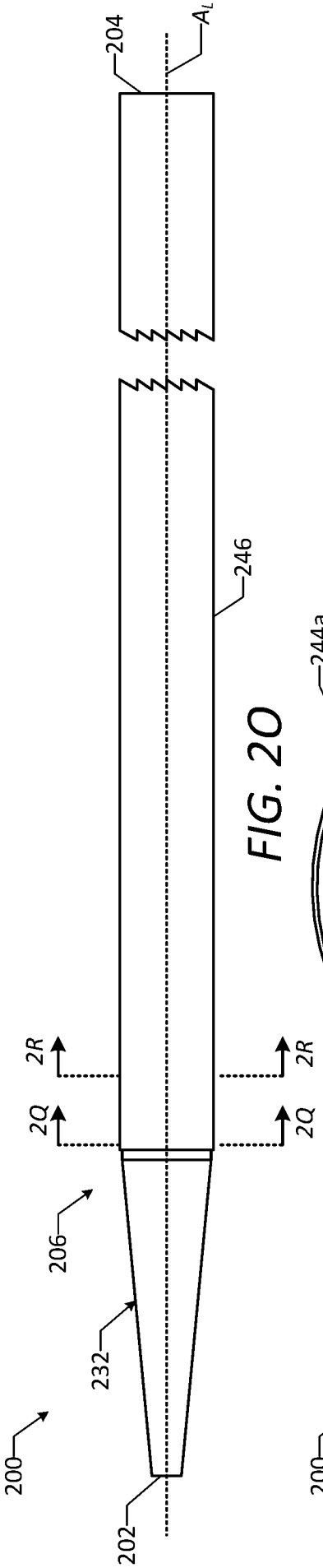

FIG. 2O

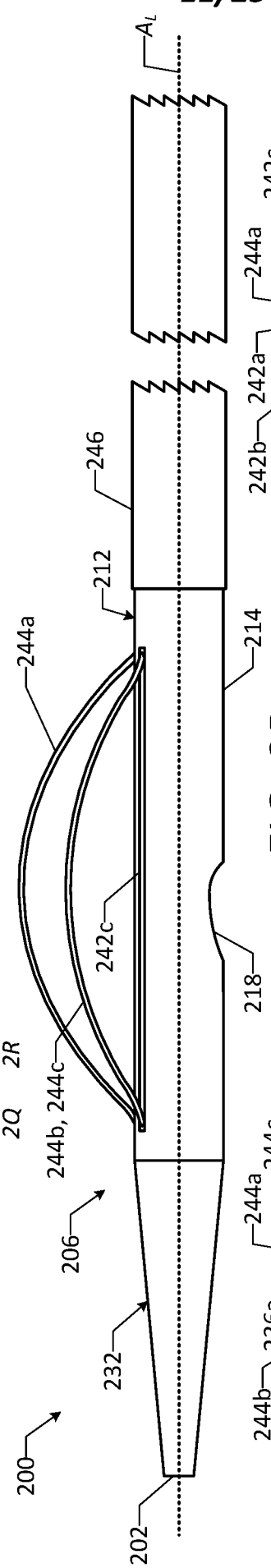

FIG. 2P

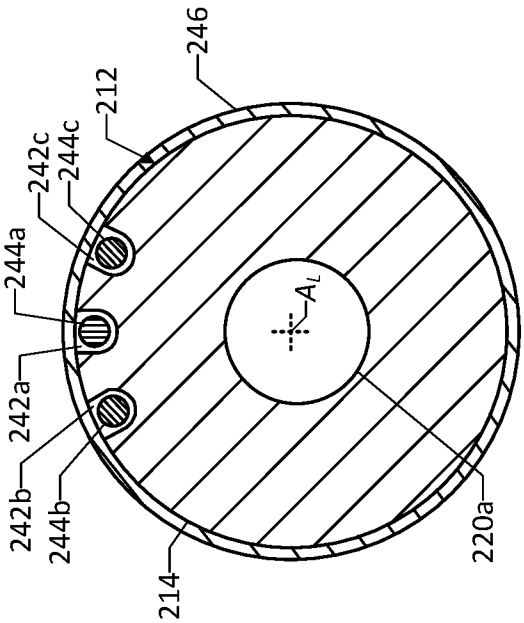

FIG. 2R

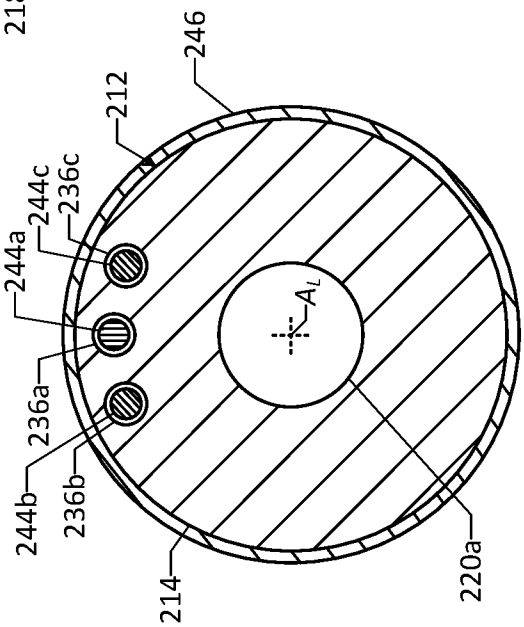

FIG. 2Q

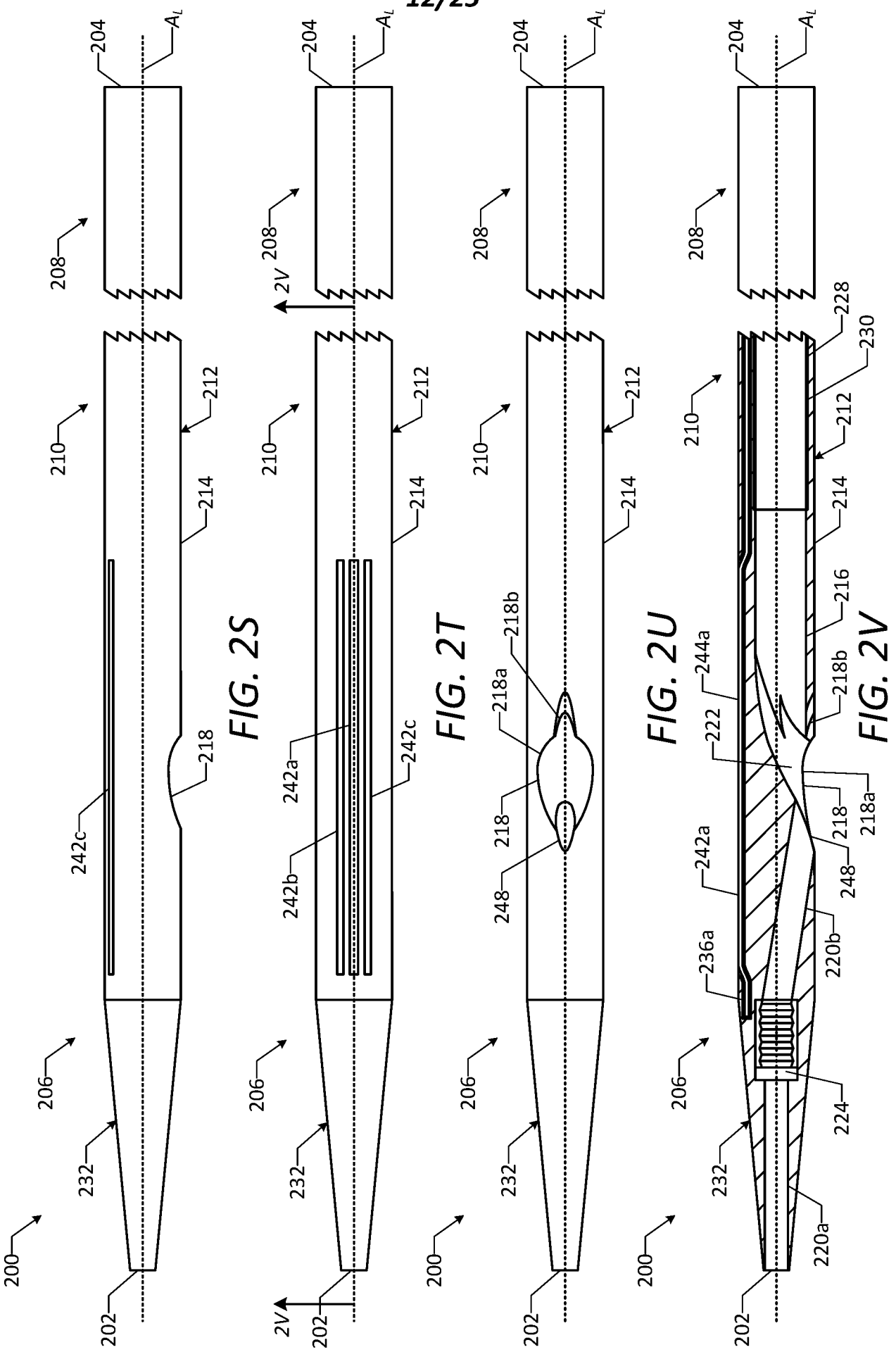

FIG. 2S FIG. 2T FIG. 2U FIG. 2V

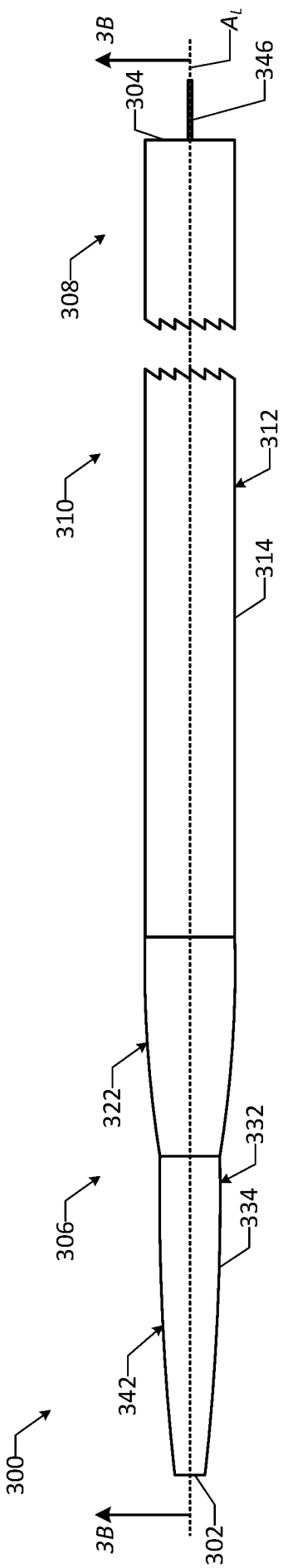
3B
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FIG. 3A

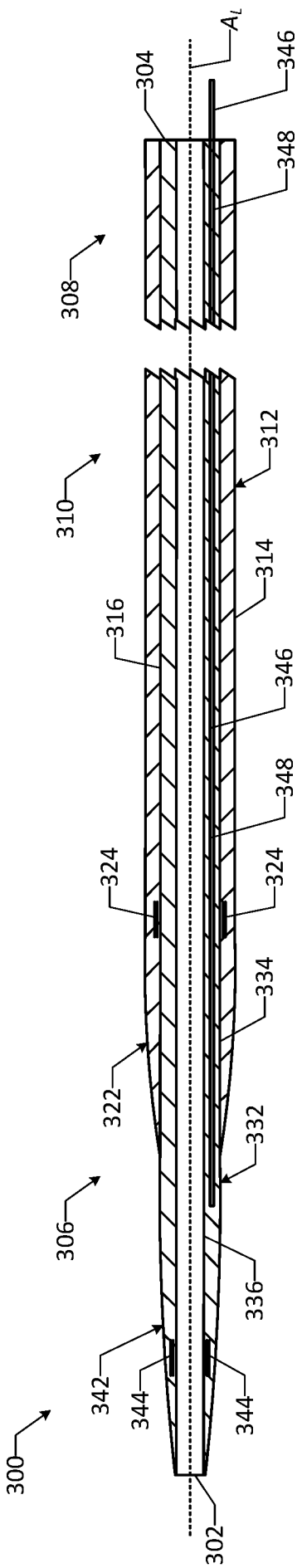
A_L
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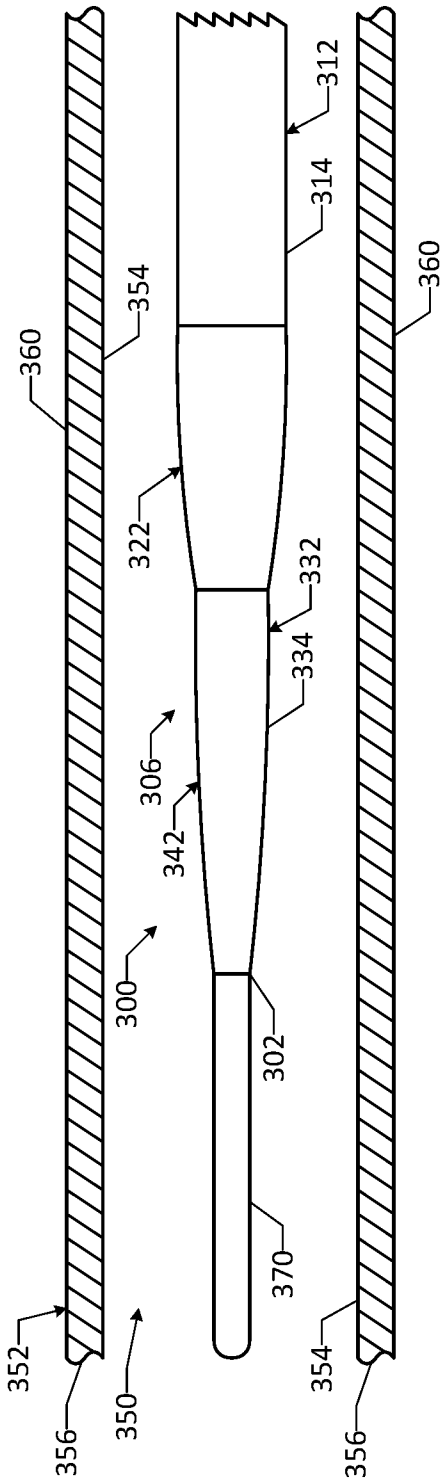
FIG. 3B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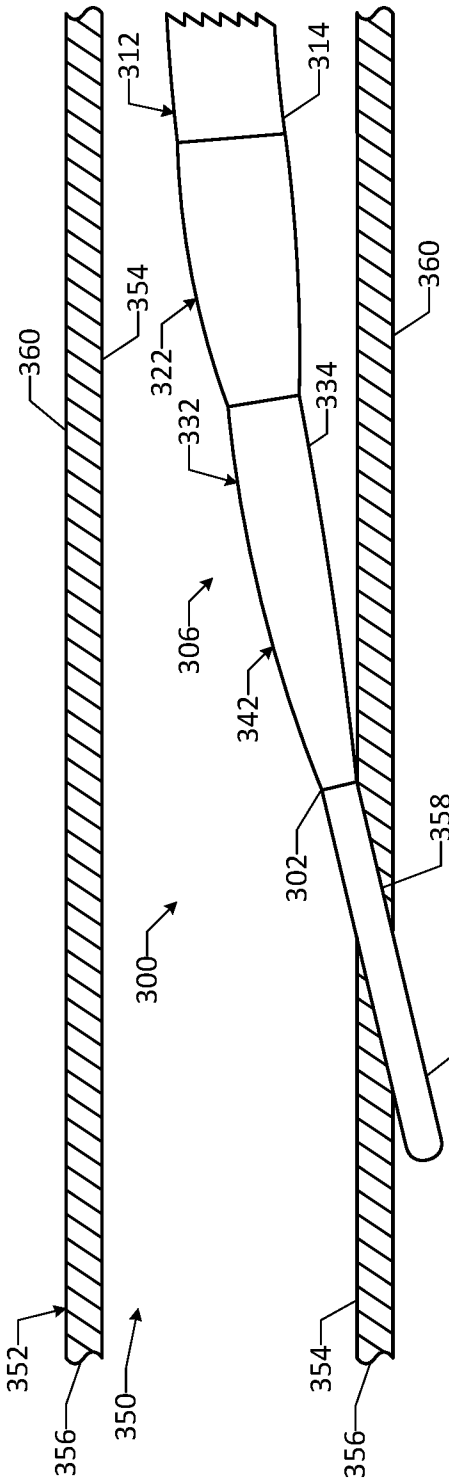
360

FIG. 3C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360

FIG. 3D

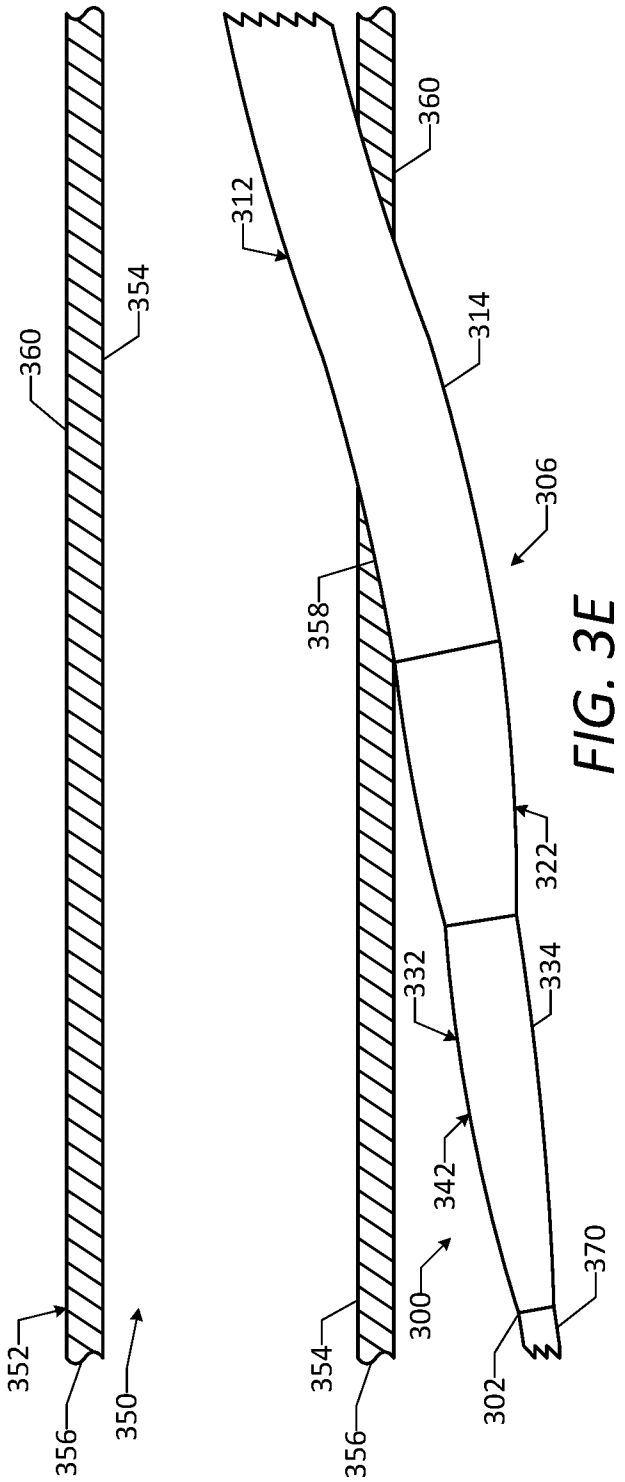
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FIG. 3E

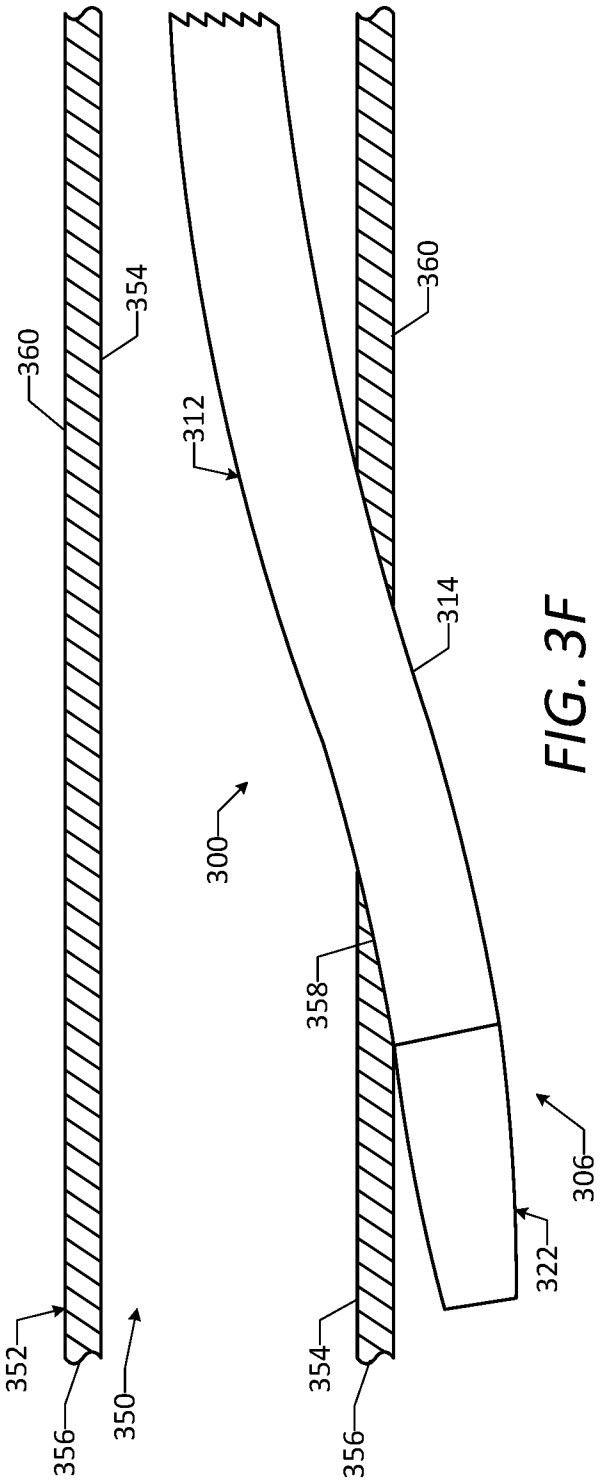
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FIG. 3F

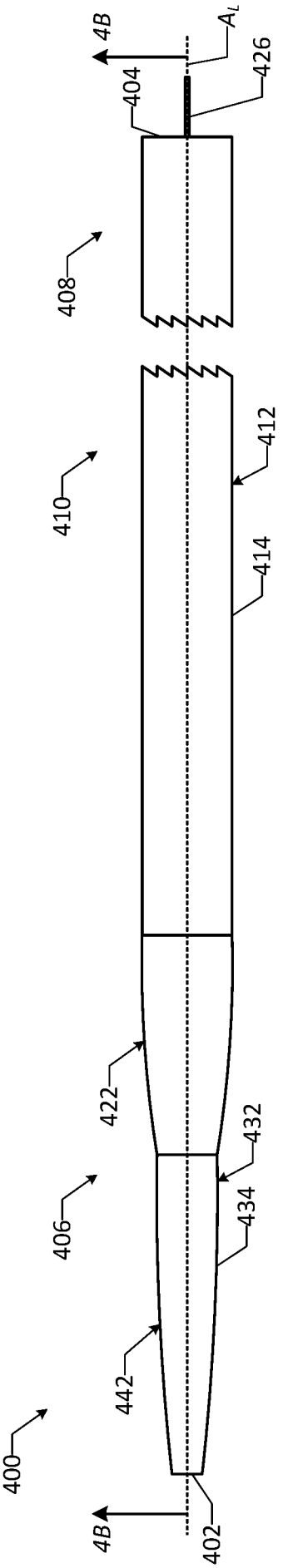


FIG. 4A

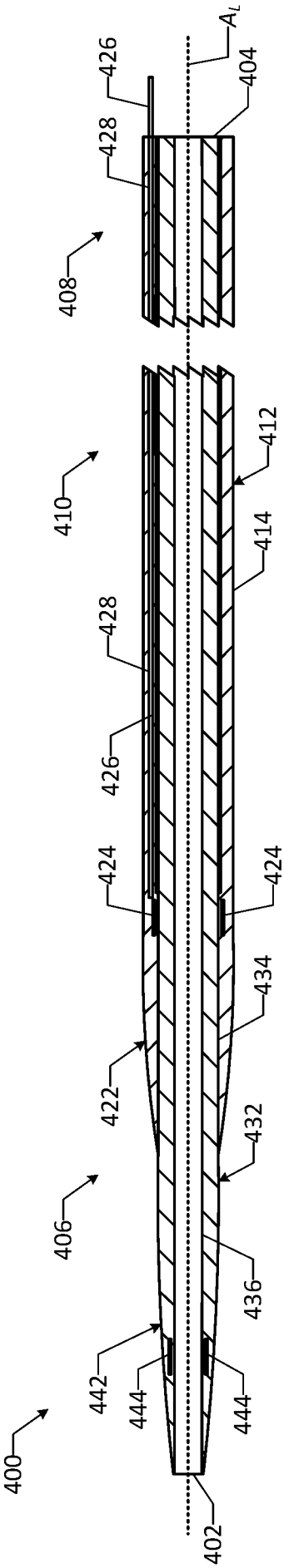


FIG. 4B

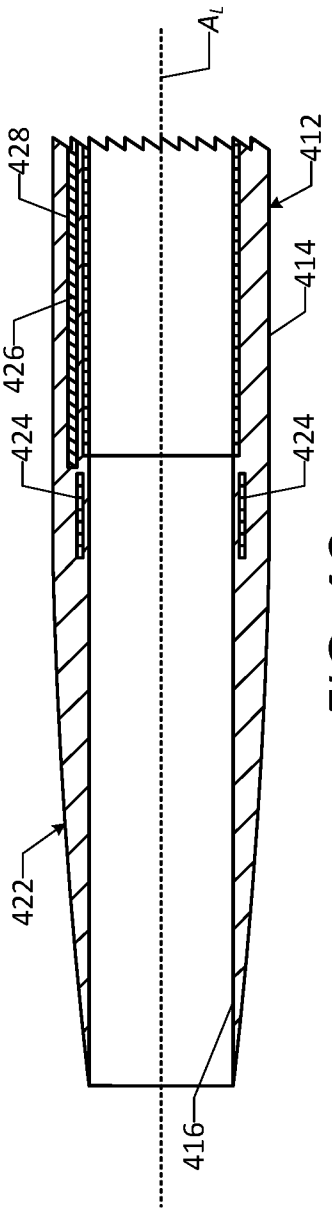
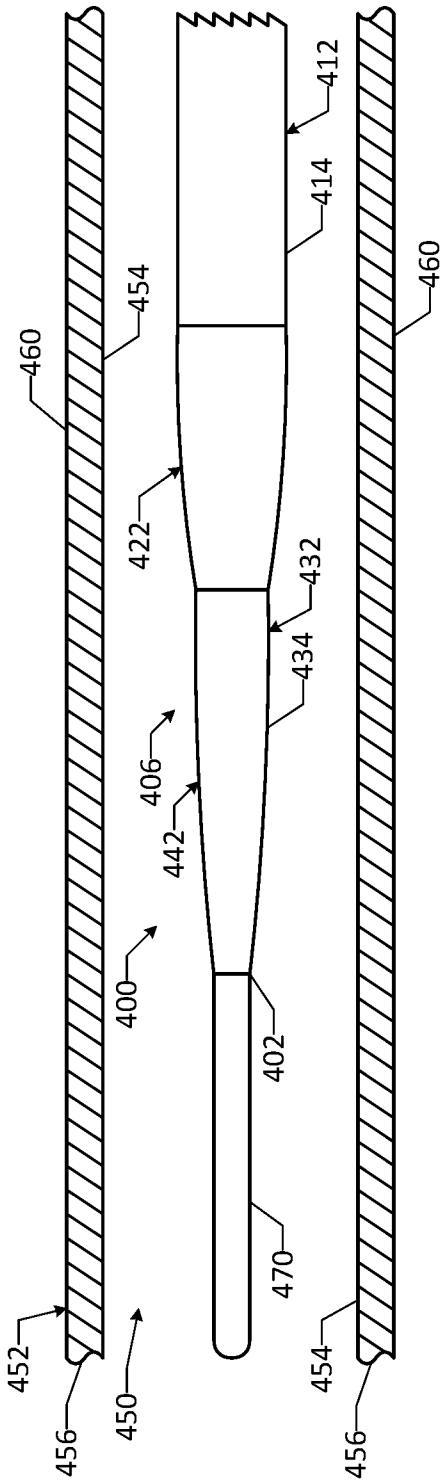


FIG. 4C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422
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456

FIG. 4D

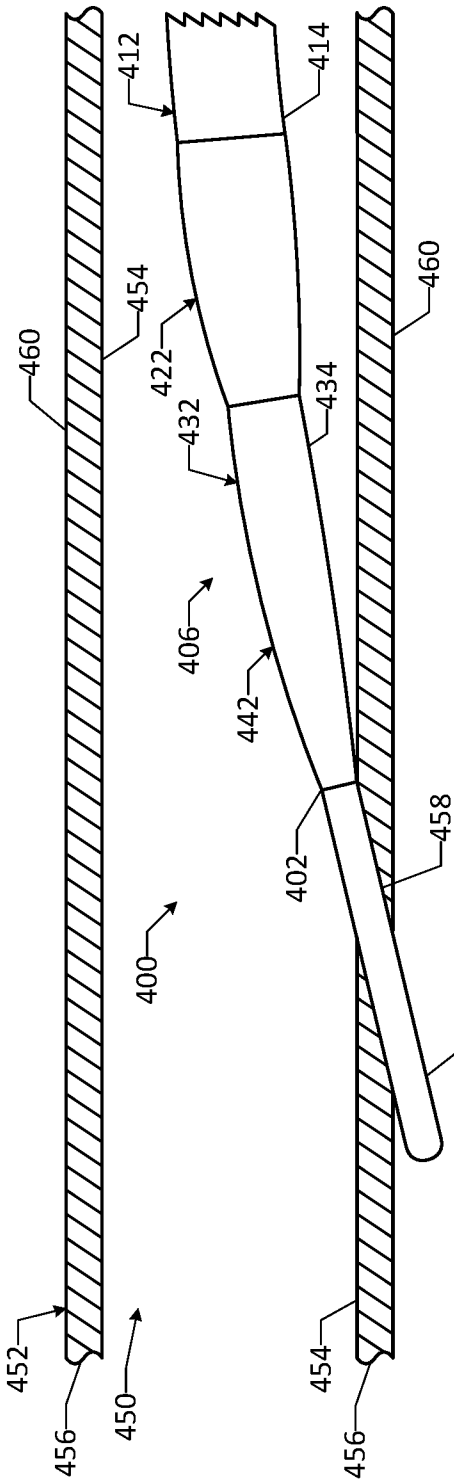
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FIG. 4E

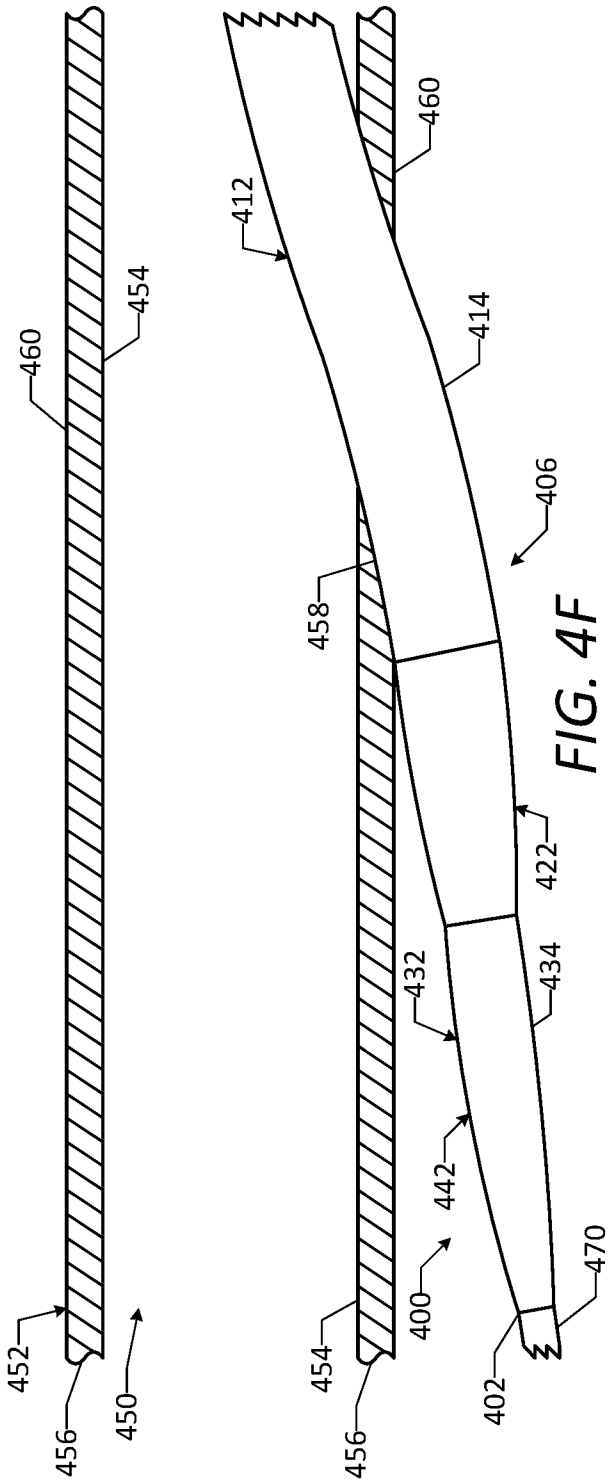
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FIG. 4F

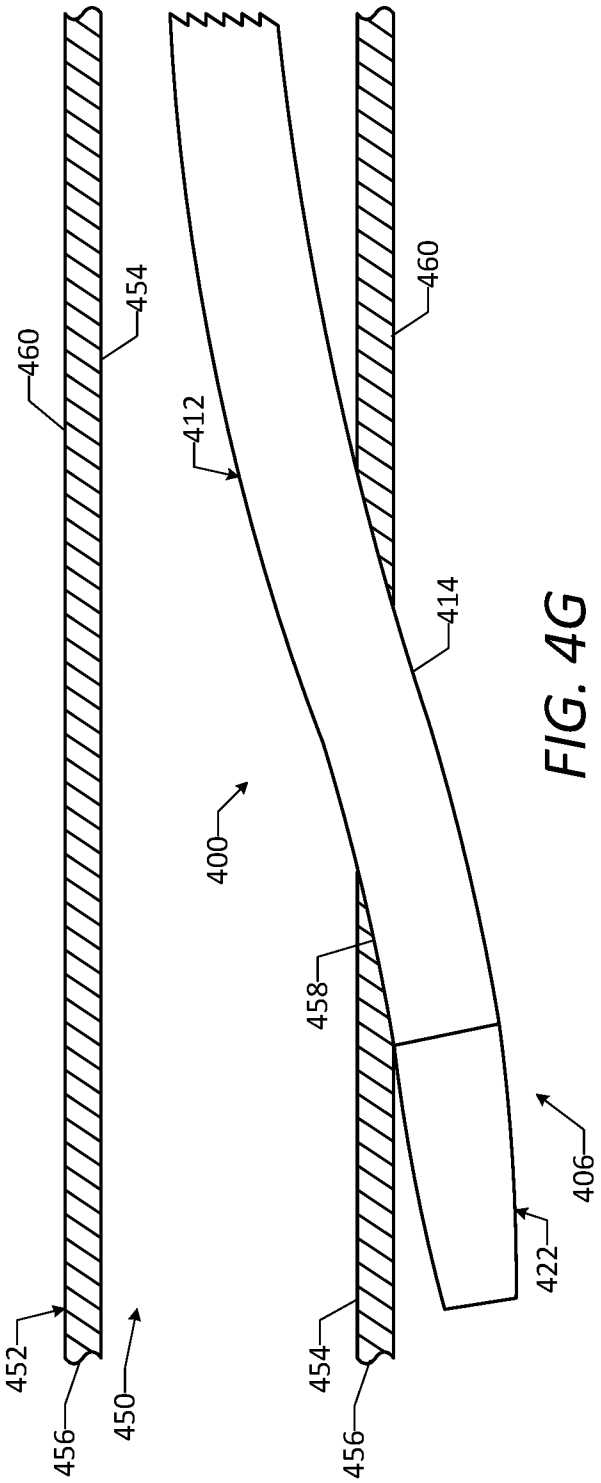
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FIG. 4G

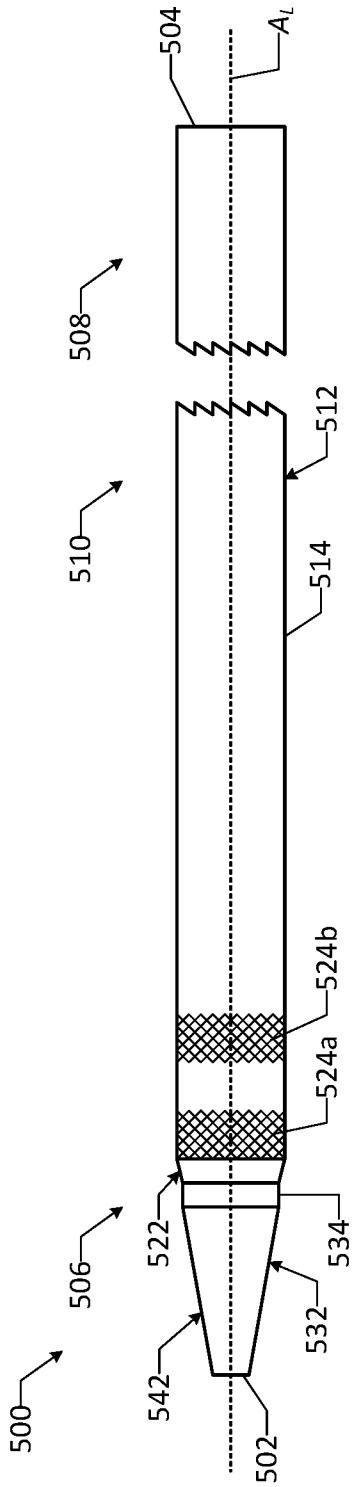
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FIG. 5A

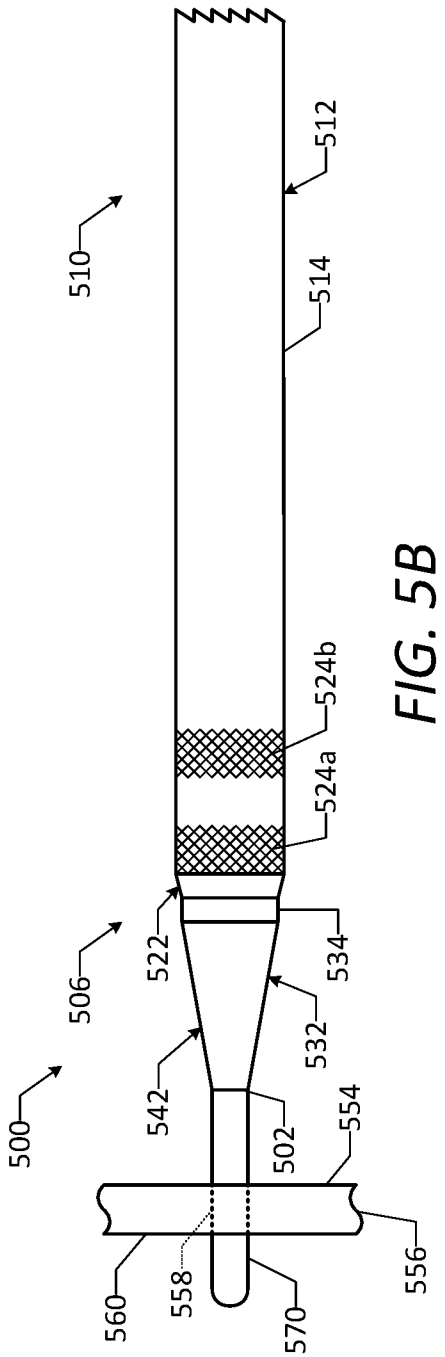
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FIG. 5B

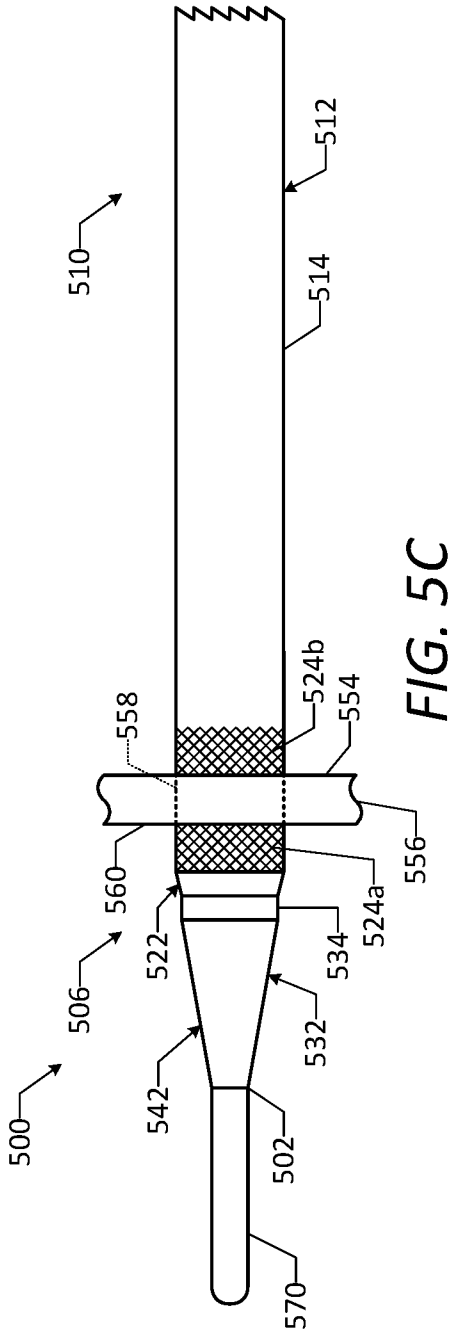
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FIG. 5C

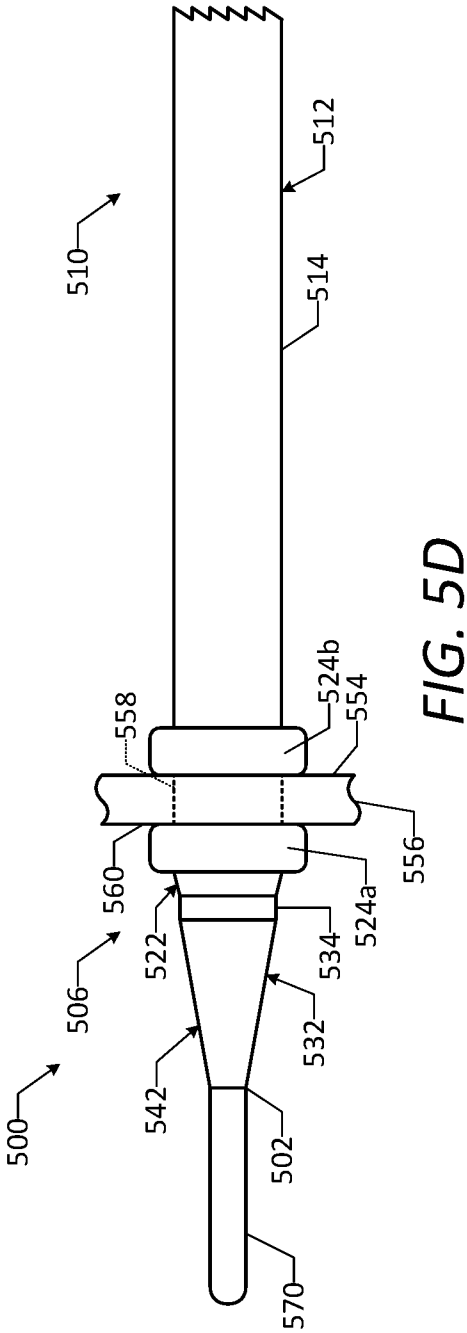
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FIG. 5D

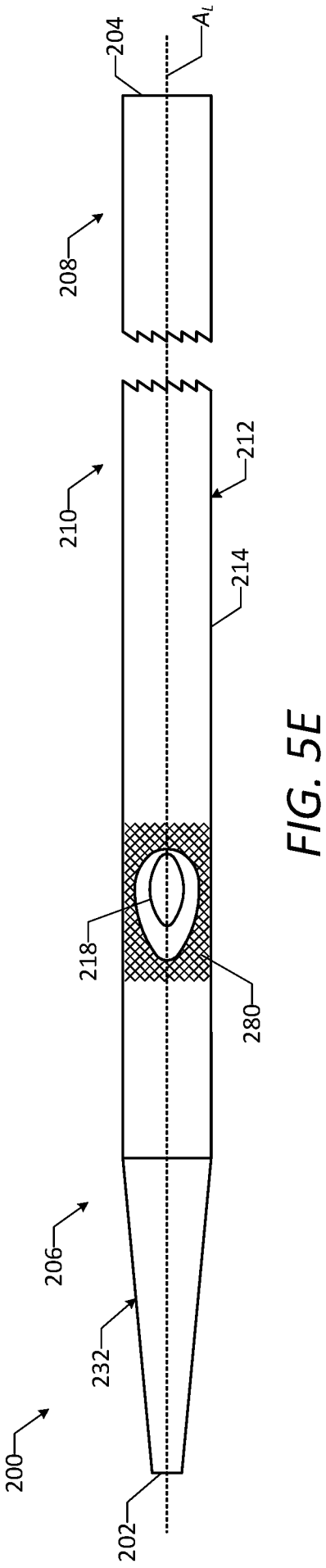
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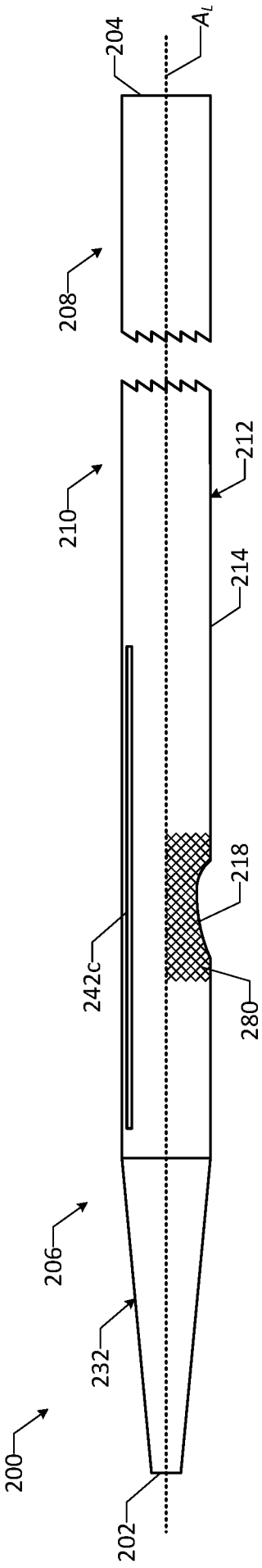
FIG. 5E


204
A_L
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242c
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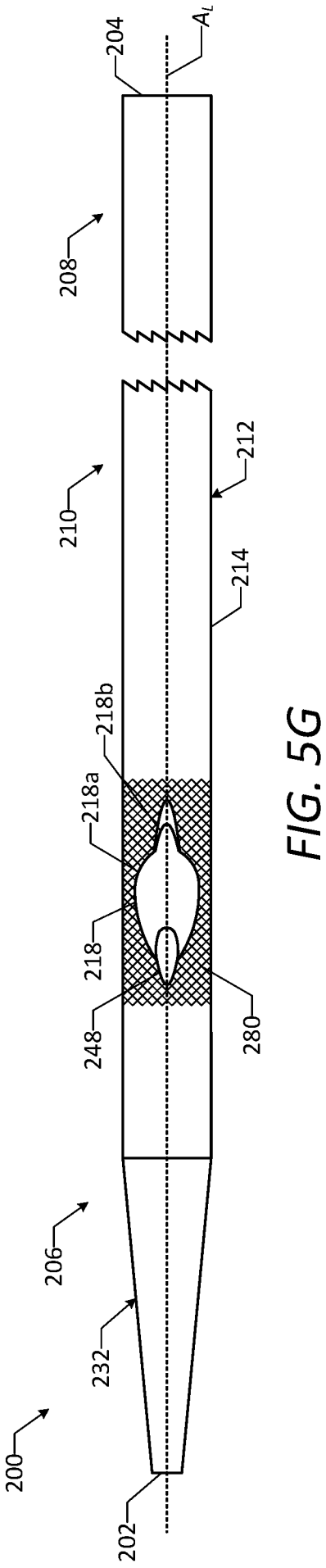
FIG. 5F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A_L

FIG. 5G

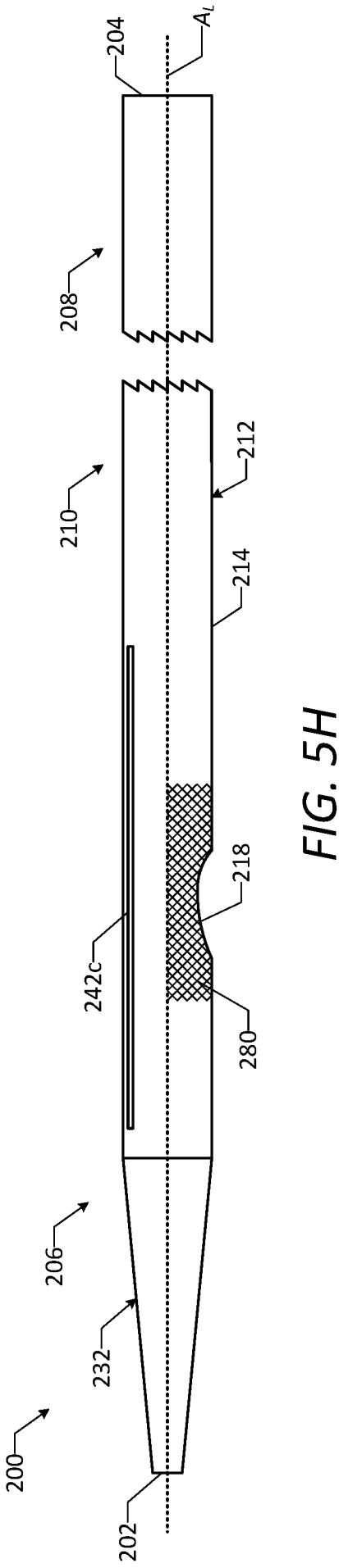
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FIG. 5H

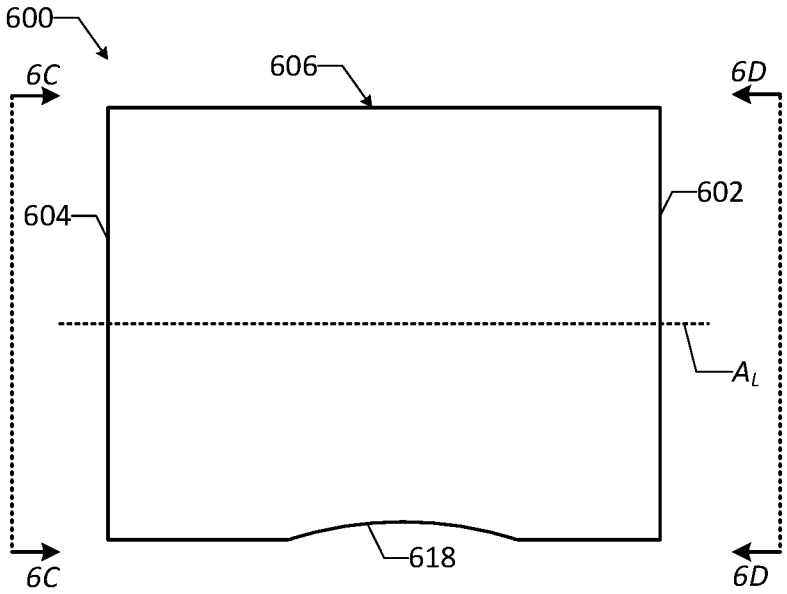

FIG. 6A

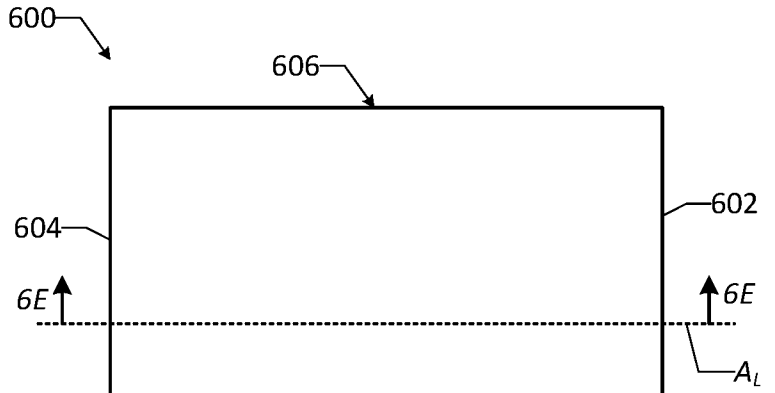

FIG. 6B

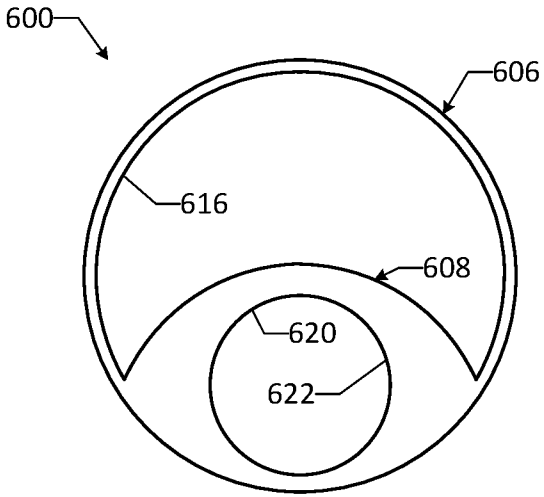

FIG. 6C

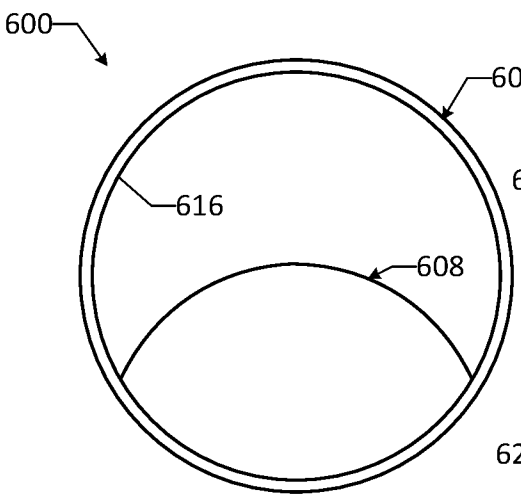

FIG. 6D

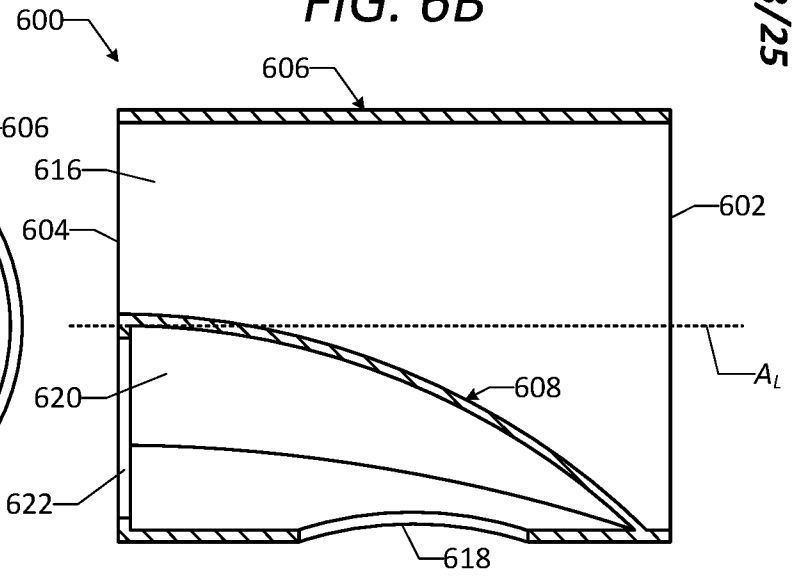

FIG. 6E

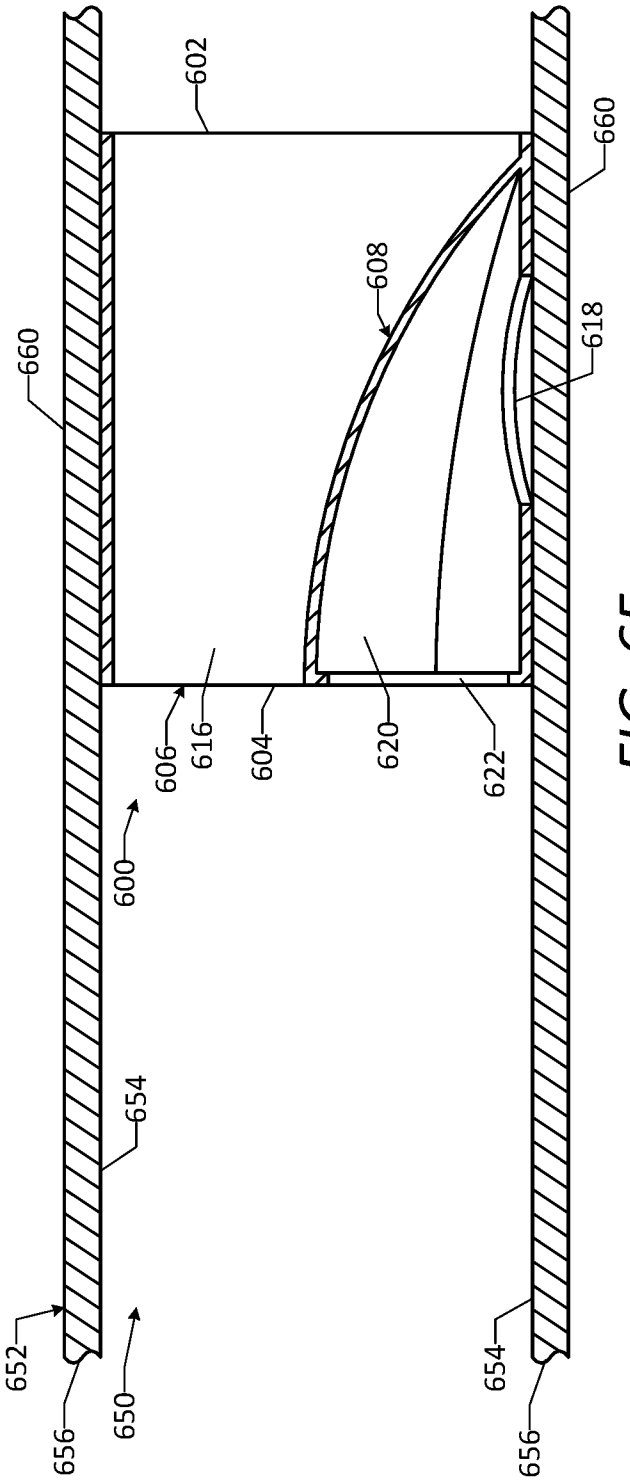
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FIG. 6F

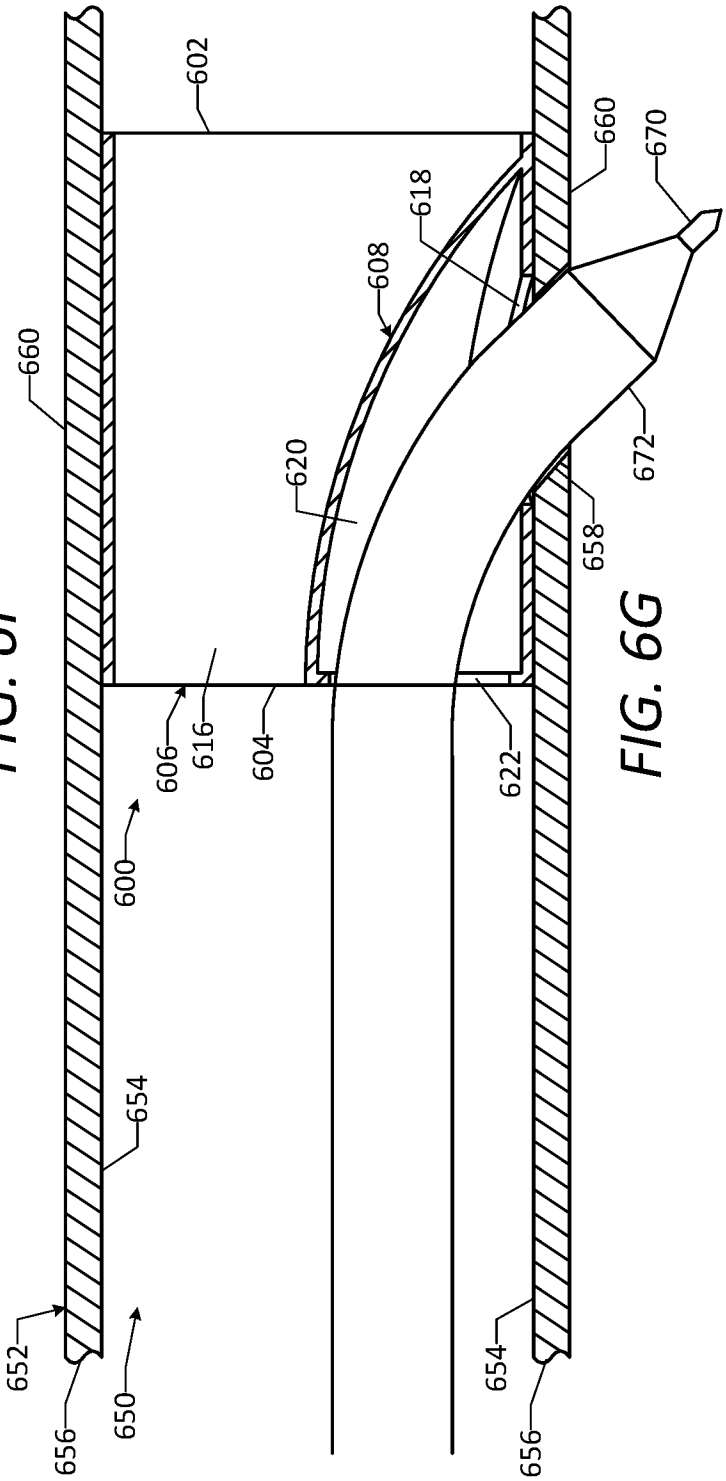
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FIG. 6G

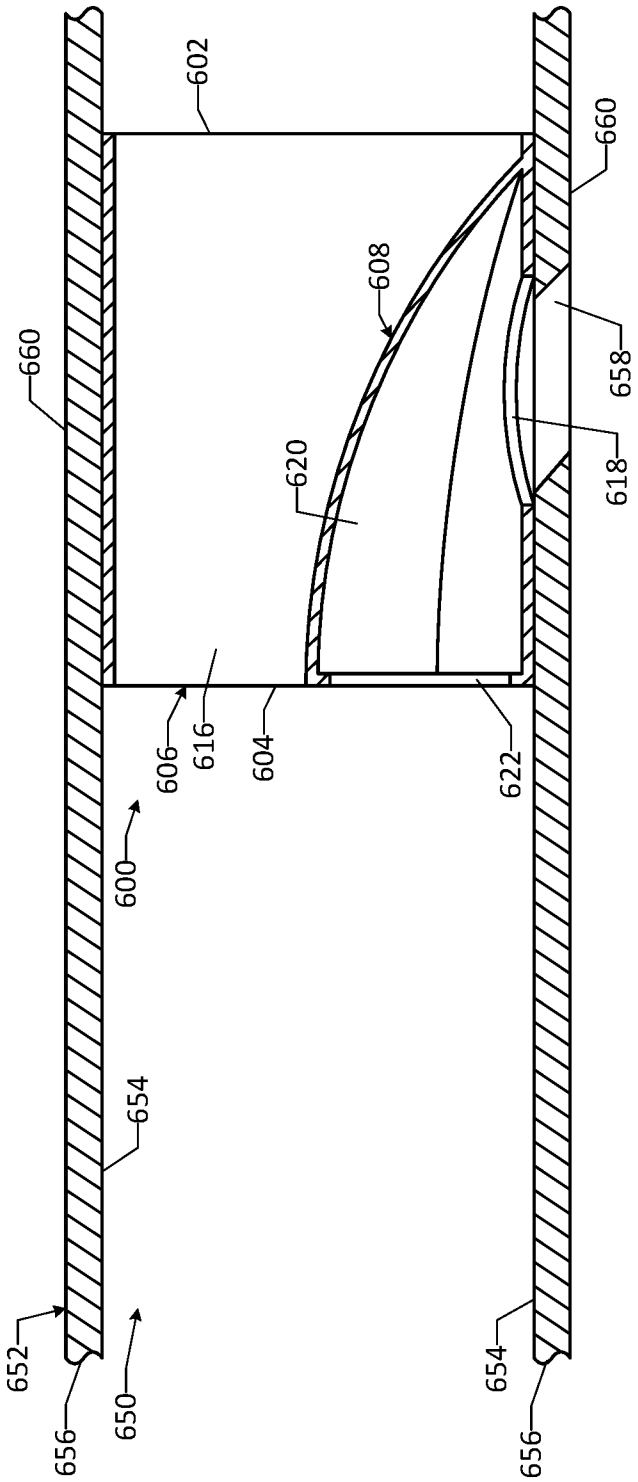
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FIG. 6H

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/030819

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 21-40
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/030819

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/34 A61M25/01
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/006282 A1 (WILKINSON MATTHEW [US]) 3 January 2013 (2013-01-03) paragraph [0044] - paragraph [0051]; figures 1-14	1-20
X	US 6 645 160 B1 (HEESCH CHRISTIAN M [US]) 11 November 2003 (2003-11-11) column 3, line 52 - column 5, line 63; figures 3-9b	1-10
X	US 2009/230167 A1 (XIAO JIA-HUA [US] ET AL) 17 September 2009 (2009-09-17) abstract; figures 1-6	1
X	US 4 813 930 A (ELLIOTT CLYDE D [US]) 21 March 1989 (1989-03-21) abstract; figures 1-6	1-10

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 July 2017	12/07/2017

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

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/030819

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/182360 A1 (MAKOWER JOSHUA [US]) 16 July 2009 (2009-07-16) abstract; figures 1, 13-20 paragraph [0066] -----	1,11-17
A	US 2003/171714 A1 (KATOH OSAMU [JP] ET AL) 11 September 2003 (2003-09-11) paragraph [0064] - paragraph [0066]; figures 3-7 -----	1
A	US 2009/198153 A1 (SHRIVER EDGAR L [US]) 6 August 2009 (2009-08-06) abstract; figures 1-3c -----	11-17

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/030819

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2013006282 A1	03-01-2013	AU 2012275757 A1	16-01-2014
		AU 2017202442 A1	04-05-2017
		CA 2840200 A1	03-01-2013
		CN 103796705 A	14-05-2014
		EP 2726137 A1	07-05-2014
		JP 2014520597 A	25-08-2014
		US 2013006282 A1	03-01-2013
		US 2015112374 A1	23-04-2015
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