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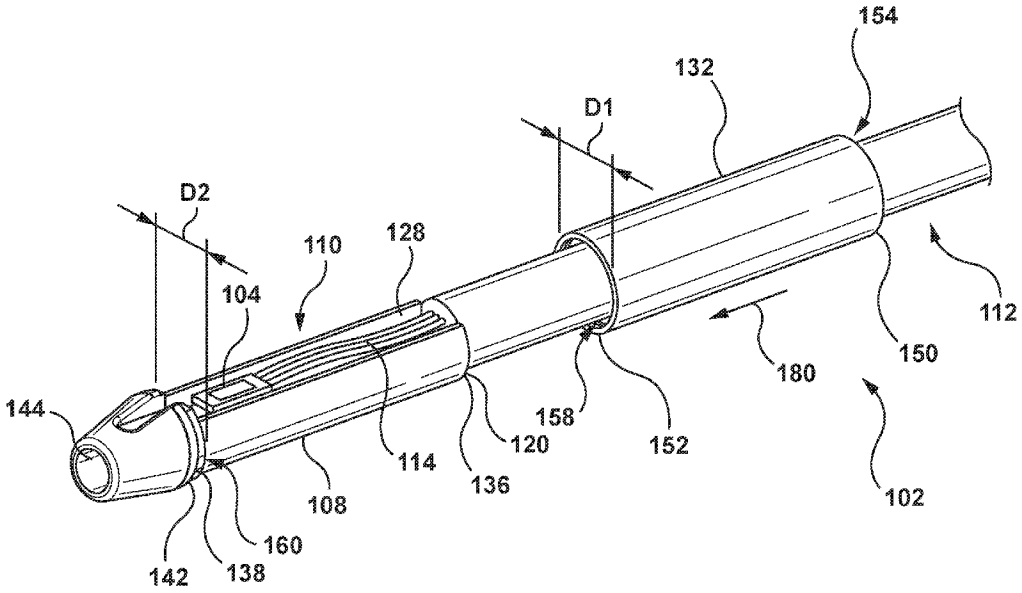

FIG. 3

(57) Abstract: A distal shaft for measuring pressure distal of a stenosis includes a housing, a pressure sensor, a cover, a tip, and an aperture. The pressure sensor is mounted in the housing. The cover is coupled to the housing and covers the pressure sensor. The tip is coupled to a distal end of the housing. The aperture is disposed through the tip and/or cover. The aperture is configured to allow blood flow to the pressure sensor. The cover further includes a coupling mechanism or coupling that couples the cover to the housing. The coupling mechanism may be a snap-fit mechanism, a friction-fit mechanism, and/or an adhesive.

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FFR CATHETER WITH COVERED DISTAL PRESSURE SENSOR AND METHOD OF MANUFACTURE

FIELD OF THE INVENTION

[0001] The present invention relates to systems for calculating a Fractional Flow Reserve, and methods for manufacturing such systems. More particularly, the present invention relates to a distal shaft of an FFR catheter with a cover, and methods of manufacturing the covered distal shaft.

BACKGROUND OF THE INVENTION

[0002] The severity of a stenosis or lesion in a blood vessel may be assessed by obtaining proximal and distal pressure measurements relative to the given stenosis and using those measurements for calculating a value of a Fractional Flow Reserve (FFR). FFR is defined as the ratio of a first or distal pressure P_d measured on the distal side of the stenosis and to a second or proximal pressure P_a measured on the proximal side of the stenosis, usually within the aorta. Conventionally, a sensor is placed on a distal portion of a guidewire or FFR wire to obtain the distal pressure P_d, while an external pressure transducer is fluidly connected via tubing to a guide catheter for obtaining the proximal, or aortic (AO) pressure P_a. Calculation of the FFR value provides a stenosis specific index of the functional severity of the stenosis in order to determine whether the blockage limits blood flow within the vessel to an extent that treatment is needed. An optimal or normal value of FFR in a healthy vessel is 1.00, while values less than about 0.80 are generally deemed significant and in need of an interventional treatment. Common interventional treatment options include balloon angioplasty and/or stent implantation.

[0003] If an interventional treatment is required, the interventional device, such as a balloon catheter, is tracked over a guidewire to the site of the stenosis. Conventional FFR wires generally are not desired by clinicians to be used as guidewires for such

interventional devices. Accordingly, if an interventional treatment is required, the clinician generally removes the FFR wire, inserts a conventional guidewire, and tracks the interventional device to the treatment site over the conventional guidewire.

[0004] To address this concern, efforts have been made to utilize catheters (micro-catheters) to take pressure measurements for calculating FFR. Using a catheter with a pressure sensor mounted within a distal shaft to measure the distal pressure P_d, a clinician may use a preferred guidewire for tracking the FFR catheter to the site of the stenosis. If an interventional treatment is required, the guidewire used with the catheter may remain in situ and the interventional device may be tracked over the existing guidewire to the site of the stenosis.

[0005] However, the pressure sensor mounted to the distal shaft of the catheter is generally exposed to provide access to the surrounding blood flow. The pressure sensor is a sensitive device and may be damaged by contact during handling or contact with tissue during advancement of the FFR catheter through the tortuous vasculature of a patient before positioning at the desired treatment site. Contact damage may result in errors in the measured distal pressure P_d.

[0006] While placing the pressure sensor within the distal shaft may protect the sensor from contact damage, manufacturing of the distal shaft in this configuration is difficult. For example, threading of the sensor wire though the distal shaft, mounting of the pressure sensor, and connection of the sensor wire to the pressure sensor in a confined space inside the distal shaft during manufacturing provides both build and maintenance challenges.

[0007] Additionally, as the distal shaft of the FFR catheter advances through the tortuous vasculature of the patient on its way to the desired treatment site, the distal shaft encounters bending forces as it winds its way to the targeted stenosis. When the distal shaft encounters these bending forces, the distal shaft and the pressure sensor mounted within can bend, damaging the delicate electronic pressure sensor. Bending force damage may result in errors in the measured distal pressure P_d.

[0008] Accordingly, there is a need for systems, and methods for manufacturing such systems, to reduce the occurrence of contact and bending force damage to a pressure sensor of a distal shaft of a FFR catheter.

BRIEF SUMMARY OF THE INVENTION

[0009] Embodiments hereof relate to a distal shaft for measuring a pressure distal of a stenosis including a housing, a pressure sensor, a cover, a tip, and an aperture. The pressure sensor is mounted in the housing. The cover is coupled to the housing and covers the pressure sensor. The tip is coupled to the distal end of the housing. The aperture is disposed though the tip and/or cover. The aperture is configured to allow blood flow to the pressure sensor.

[0010] Embodiments hereof also relate to a system for calculating a Fractional Flow Reserve of a stenosis in a blood vessel including a catheter, a proximal pressure-sensing device, and a processing device. The catheter includes a distal shaft with a housing including a distal pressure sensor mounted therein, a separate cover coupled to the housing, and a tip including an aperture. The aperture is configured to provide blood flow to the pressure sensor. The distal shaft is configured for placement within a blood vessel such that blood distal of the stenosis flows through the aperture into the housing and is in contact with the distal pressure sensor. The distal pressure sensor measures a distal blood pressure distal of the stenosis. The proximal pressure-sensing device is configured to measure a proximal blood pressure proximal of the stenosis. The processing device is in communication with the distal pressure sensor and the proximal pressure-sensing device. The processing device is configured to calculate a Fractional Flow Reserve based on the distal blood pressure relative to the proximal blood pressure.

[0011] Embodiments hereof also relate to a method of manufacturing a distal shaft of an FFR catheter for measuring a distal pressure measurement on a distal side of a stenosis. A cover is positioned at a housing of a distal shaft. The housing includes a pressure sensor mounted therein. The cover is coupled to the housing of the distal shaft to cover the pressure sensor. An aperture is provided through the cover and/or a portion

of the distal shaft. The aperture is configured to enable blood flow into the housing and into contact with the pressure sensor.

BRIEF DESCRIPTION OF DRAWINGS

[0012] FIG. 1 is a partial side and perspective illustration of a catheter for calculating a Fractional Flow Reserve (FFR) in accordance with an embodiment hereof.

[0013] FIG. 2 is a side illustration of a distal shaft of the catheter of FIG. 1.

[0014] FIG. 2A is a side illustrated of a distal shaft with an aperture in a different location.

[0015] FIG. 3 is a perspective illustration of a distal shaft of the catheter of FIG. 1 according to an embodiment hereof, with a cover with a snap-fit coupling mechanism in a first configuration.

[0016] FIG. 4 is a perspective illustration of the distal shaft of FIG. 3, with the cover in a second configuration.

[0017] FIG. 5 is a cross-sectional illustration of the distal shaft of FIG. 3, taken along line 5-5 of FIG. 4.

[0018] FIG. 5A is a longitudinal cross-sectional illustration of the distal shaft of FIG. 3 taken along line 5A-5A of FIG. 3.

[0019] FIG. 6 is a perspective illustration of the distal shaft of the catheter of FIG. 1, with the cover with a friction-fit coupling mechanism in the first configuration.

[0020] FIG. 7 is a perspective illustration of another embodiment of a catheter with another embodiment of a cover with a friction-fit coupling mechanism in a first configuration.

[0021] FIG. 8 is a perspective illustration of the distal shaft of FIG. 7, with the cover in a second configuration.

[0022] FIG. 9 is a cross-sectional illustration of the distal shaft of FIG. 8, taken along line 9-9 of FIG. 8.

[0023] FIG. 10 is a perspective illustration of the distal shaft of FIG. 7, with the cover having a snap-fit coupling mechanism in the first configuration.

[0024] FIG. 11 is a cross-sectional illustration of the distal shaft of FIG. 10, taken along line 11-11 of FIG. 10 and with the cover in the second configuration.

[0025] FIG. 11A is a detail view of area A of FIG. 11.

[0026] FIG. 12 is a perspective illustration of the distal shaft of another embodiment of a catheter with a first aperture disposed through the tip and a second aperture disposed through the cover.

[0027] FIG. 13 is a schematic illustration of the system of FIG. 1 used to calculate a Fractional Flow Reserve.

[0028] FIG. 14 is a block diagram of a method for manufacturing the distal shaft of FIG. 3 according to an embodiment hereof.

[0029] FIG. 15 is a block diagram of a method for manufacturing the distal shaft of FIG. 7 according to an embodiment hereof.

DETAILED DESCRIPTION OF THE INVENTION

[0030] Specific embodiments of the present invention are now described with reference to the figures, wherein like reference numbers indicate identical or functionally similar elements. The terms “distal” and “proximal”, when used in the following description to refer to a catheter or delivery system are with respect to a position or direction relative to the treating clinician. Thus, “distal” and “distally” refer to positions distant from, or in a direction away from the treating clinician, and the terms “proximal” and “proximally” refer to positions near, or in a direction toward the clinician. The terms “distal” and “proximal” used in the following description to refer to a vessel or a stenosis are used with reference to the direction of blood flow. Thus, “distal” and “distally” refer to positions in a

downstream direction with respect to the direction of blood flow, and the terms "proximal" and "proximally" refer to positions in an upstream direction with respect to the direction of blood flow.

[0031] The following detailed description is merely exemplary in nature and is not intended to limit the invention or the application and uses of the invention. Although the description of the invention is in the context of treatment of blood vessels such as the coronary arteries, the invention may also be used in any other body passageways where it is deemed useful such as but not limited to peripheral arteries, carotid arteries, renal arteries, and/or venous applications. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description.

[0032] FIG. 1 is a schematic partial side and partial perspective illustration of a system 100 for calculating a Fractional Flow Reserve (FFR) according to an embodiment hereof. The system 100 includes an FFR catheter or micro-catheter 102, a proximal pressure-sensing device (not shown), and a processing device 106. The catheter 102 is configured to be disposed with a proximal portion thereof extending outside of a patient and a distal portion thereof positioned *in situ* within a lumen 902 of a vessel 904 having a stenosis 900. In an embodiment, the vessel 904 is a blood vessel such as but not limited to a coronary artery. The stenosis 900 is generally representative of any blockage or other structural arrangement that results in a restriction to the flow of fluid through a lumen 902 of the vessel 904. The stenosis 900 may be a result of plaque buildup, including without limitation plaque components such as fibrous, fibro-lipidic (fibro fatty), necrotic core, calcified (dense calcium), blood, fresh thrombus, and mature thrombus. Generally, the composition of stenosis 900 will depend on the type of vessel being evaluated. In that regard, it is understood that embodiments hereof are applicable to various types of blockages or other narrowing of a vessel that results in decreased fluid flow.

[0033] The catheter 102 includes a proximal shaft 112 and a distal shaft 110. A pressure sensor 104, shown in FIG. 1 and in greater detail in FIG. 2, is disposed in a housing 108 of the distal shaft 110. The pressure sensor 104 is coupled to the housing

108 and covered by a cover 132, as described in greater detail below. The cover 132 is configured to protect the pressure sensor 104 during handling and use of the catheter 102. The cover 132 is a separate piece attached to the housing 108 during manufacture to simplify manufacturing of the distal shaft 110 with the pressure sensor 104 disposed therein. As used herein, the term "separate" when used to describe that the cover 132 is a "separate" piece attached to the housing 108 during manufacture, it is meant that the cover 132 is not formed as part of the housing 108. Instead, the two pieces are separate and then are attached as described below during manufacture. Thus, for example, and not by way of limitation, a housing that is formed with a portion covering a pressure sensor would not be a "separate" cover. Similarly, a "cover" that is co-formed with a "housing", such as by molding, is not considered a separate cover attached to the housing.

[0034] In the embodiment shown in FIG. 1, catheter 102 includes a guidewire lumen 122 extending through the proximal shaft 112 and the distal shaft 110. The guidewire lumen is configured to receive a guidewire 500. However, instead of the over-the-wire configuration shown in FIG. 1, catheter 102 may have a rapid exchange configuration wherein the guidewire lumen 122 extends through the distal shaft 110 and a portion of the proximal shaft 112, and the guidewire 500 exits through a rapid exchange port (not shown) in a distal portion of the proximal shaft 112, as would be understood by those skilled in the art. Catheter 102 also includes a sensor wire lumen 124 extending through the proximal shaft 112 and the distal shaft 110 to the pressure sensor 104. The proximal shaft 112 includes a proximal end 116 coupled to a hub or luer 118 and a distal end 120 coupled to the distal shaft 110.

[0035] In an embodiment, the distal shaft 110 of the catheter 102 includes a proximal end 130 coupled to a distal end 120 of the proximal shaft 112, and a distal end 126, as shown in FIG. 2. A distal portion of the guidewire lumen 122 extends through the distal shaft 110. The distal shaft 110 includes the housing 108, the pressure sensor 104, the cover 132, a distal tip 134, and an aperture 146 through the distal tip 134, as described in more detail below. The distal shaft 110 is configured such that the pressure sensor 104 and the tip 134 are disposed on the distal side 906 of the stenosis 900 such that the

pressure sensor 104 can measure a distal pressure P_d distal of the stenosis 900, as shown in FIG. 1.

[0036] In an embodiment, the housing 108 of the distal shaft 110 is of a generally tubular shape having a proximal end 136 coupled to the distal end 120 of the proximal shaft 112 and a distal end 138 coupled to the distal tip 134, as shown in FIGS. 3 and 5A. The housing 108 defines an open seat 128, extending from an outer surface of the housing 108 inward. In particular, referring to FIG. 5, the open seat 128 may be defined by groove or depression 129 in the housing 108. The open seat 128 is configured to receive the pressure sensor 104 therein. The open seat 128 is further configured to receive a fluid therein from the aperture 146, as described in greater detail below. The housing 108 may be formed of polymeric materials, non-exhaustive examples of which include polyethylene, polyether block amide (PEBA), polycarbonate, acrylonitrile butadiene styrene (ABS), polyether ether ketone (PEEK), polyamide and/or combinations thereof, either blended or co-extruded. The housing 108 may be coupled to the distal end 120 of the proximal shaft 112 and a proximal end 142 of the tip 134 by methods such as, but not limited to adhesives, fusing, welding, or any other method suitable for the purposes described herein. Alternatively, the housing 108 may be formed as an integral component of the proximal shaft 112 and the tip 134. The open seat 128 is shown as a generally rectangular cuboid. However, this is not meant to be limiting and open seat 128 may be of any shape to house the pressure sensor 104 and provide sufficient space for fluid entering therein for the pressure sensor 104 to measure a pressure of the fluid.

[0037] The pressure sensor 104 includes a pressure-sensing surface 140, as shown in FIGS. 2, 5, and 5A. The pressure sensor 104 may be a piezo-resistive pressure sensor, a piezo-electric pressure sensor, a capacitive pressure sensor, an electromagnetic pressure sensor, an optical pressure sensor, and/or combinations thereof suitable for the purpose described herein. While the pressure sensor 104 is shown in FIG. 2 configured with the pressure-sensing surface 140 facing radially outward, the pressure-sensing surface 140 may face in other directions such that pressure-sensing surface 140 measures distal pressure P_d of a fluid outside the distal shaft 110 that has entered the open seat 128 through the aperture 146. The pressure sensor 104 is further configured

to communicate a measured distal pressure P_d with the processing device 106 through the pressure sensor wire(s) 114, as described in U.S. Patent Application Publication No. 2015/0305633 A1 to McCaffrey *et al.*, incorporated by reference herein in its entirety. The pressure sensor 104 is disposed within and coupled to the open seat 128 of the housing 108. The open seat 128 and/or the pressure sensor 104 may include tabs, arms, slots, or other devices suitable to enhance coupling of the pressure sensor 104 in the open seat 128. The pressure sensor 104 may be coupled to the open seat 128, for example, and not by way of limitation, by adhesives, fusing, welding, or any other method suitable for the purposes of the present disclosure. The pressure sensor 104 is further coupled to the pressure sensor wire(s) 114. The pressure sensor 104 may be coupled to pressure sensor wire(s) 114 for example, and not by way of limitation, by soldering, fusing, welding, for any other method suitable for the purposes of the present disclosure.

[0038] In an embodiment, the tip 134 is of a generally frusto-conical shape. The tip 134 includes the proximal end 142 coupled to the distal end 138 of the housing 108, and a distal end 144, as shown in FIGS. 3 and 5A. The tip 134 may be formed of of polymeric materials, non-exhaustive examples of which include polyethylene, polyether block amide (PEBA), polycarbonate, acrylonitrile butadiene styrene (ABS), polyether ether ketone (PEEK), polyamide and/or combinations thereof, or other materials suitable for the purposes described herein. Alternatively, the tip 134 may be formed as an integral component of the housing 108 of the distal shaft 110.

[0039] In an embodiment, the distal shaft 110 further includes the aperture 146 disposed through the tip 134 and in fluid communication with the open seat 128. The aperture 146 is generally aligned with the open seat 128. The aperture 146 is an opening extending from an outer surface 148 of the tip 134, through tip 134, and extends into the open seat 128 of the housing 108. The aperture 146 is configured to receive fluid therethrough such that the fluid outside the distal tip 134 may flow through the aperture 146 and into the open seat 128 of the housing 108. The fluid flows through the aperture 146 and into the open seat 128 such that the fluid is in contact with the pressure-sensing surface 140 of the pressure sensor 104. In an embodiment, the aperture 146 is aligned generally parallel to a central longitudinal axis LA1 of the distal shaft 110 such that the

aperture 146 provides axial fluid flow to the open seat 128 and the pressure sensor 104 disposed therein. FIG. 5A shows an aperture central axis LA2 parallel to the central longitudinal axis LA1 of the distal shaft 110. The aperture 146 is sized such that a sufficient amount of blood flows into the open seat 128 of the housing 108 but tissue is prevented from entering the open seat 128 during advancement of the distal shaft 110 through a vasculature. In an embodiment, the aperture 146 is in the range of 100 to 500 microns. The aperture 146 may be formed as an integral component of the distal tip 134 or may be formed by removing material from the distal tip 134 by any suitable method such as, but not limited to cutting, machining, drilling, laser cutting, laser ablation, or other methods suitable for the purposes described herein. The aperture 146 is shown as generally tubular, but this is not meant to limit the design, and other shapes may be utilized. Moreover, while the aperture 146 is shown as a single aperture disposed through the tip 134, this is not meant to limit the design, and other configurations may be used. For example, and not by way of limitation, there may be multiple apertures 146. In another non-limiting example, the aperture 146 may be disposed through the cover 132, as shown in FIG. 2A.

[0040] In an embodiment, the cover 132 is of a generally tubular shape with a proximal end 150, a distal end 152, and a cover lumen 154 extending through the cover 132 between the proximal and distal ends 150, 152, as shown in FIGS. 3 and 5. The cover 132 may be disposed in a first configuration, as shown in FIG. 3, wherein the cover 132 is not coupled to the housing 108 and is disposed proximal to the housing 108. The first configuration is used during manufacture to simplify installation of the sensor 104 and connection of the sensor 104 to the sensor wire(s) 114. The cover 132 is moved during manufacturing to a second configuration, as shown in FIG. 4, wherein the cover 132 is coupled to the housing 108 such that the housing 108 is disposed within the cover lumen 154. As explained above, the cover 132 is configured to protect the pressure sensor 104 when the cover 132 is in the second configuration. More specifically, the cover 132 prevents contact damage to the pressure sensor 104 during handling, or contact with tissue during advancement of the catheter 102 through a vasculature of a patient. The cover 132 may be formed of a second material different than a first material of the housing 108 such that the cover 132 is more rigid than the housing 108. The increased rigidity of

the cover 132 resists bending of the distal shaft 110, especially in areas adjacent to the cover 132, as the distal shaft 110 advances through the vasculature of the patient. Thus, the more rigid cover 132 protects the pressure sensor 104 from bending damage or bending stresses incurred during handling or advancement through the vasculature of the patient. The cover 132 is coupled to housing 108 by a coupling mechanism such as, but not limited to a friction-fit mechanism, a snap-fit mechanism, adhesives, or any other coupling mechanism suitable for the purposes described herein. The cover 132 may be formed of metals such as, but not limited to, stainless steel, gold, platinum, and/or iridium, and alloys thereof. In some embodiments, such as forming the cover 132 of gold, platinum, platinum-iridium alloys, and other radiopaque materials, the cover 132 may also act as a marker band. In other embodiments, the cover 132 may be formed of metal reinforced polymers, polycarbonate, acrylonitrile butadiene styrene (ABS), polymers (e.g. polyether ether ketone (PEEK)), reinforced polymers (e.g. carbon fiber), or other materials suitable for the purposes described herein.

[0041] FIGS. 3 and 5A show the cover 132 and the housing 108 with a snap-fit coupling mechanism according to an embodiment hereof. The snap-fit coupling mechanism includes a first annular ring 158 extending radially inward from an inside surface of the cover 132 and a corresponding second annular ring 160 extending radially outward from an outer surface of the housing 108. The inner diameter D1 of the first annular ring 158 of the cover 132 in the first configuration is smaller than the outer diameter D2 of the corresponding second annular ring 160 of the housing 108. When the cover 132 is moved distally in the direction of arrow 180 with sufficient force, the distal portion of the cover 132 deforms slightly radially outwardly for the first annular ring 158 of the cover 132 to move over the second annular ring 160 of the housing 108. Upon clearing the second annular ring 160, the cover 132 returns to its initial shape such that the first annular ring 158 is distal of the second annular ring 160, as shown in FIG. 5A. This locks the cover 132 in place. The annular rings 158, 160 may include angled faces such as to minimize the force required to move the cover 132 distally over the second annular ring 160 while preventing movement of the cover 132 in a proximal direction. Thus, the cover 132 has been transitioned from the first configuration to the second configuration. When in the second configuration, the distal end 152 of the cover 132 is adjacent to the proximal end

142 of the tip 134, as shown in FIG. 5A. Moreover, when the cover 132 is in the second configuration, as shown in FIGS. 4 and 5A, the cover 132 encircles an outer surface of the housing 108 and the pressure sensor 104. The annular rings 158, 160 are shown as being disposed at distal portions of the cover 132 and housing 108, respectively. However, this is not meant to be limiting and annular rings may instead be disposed anywhere along the length of the cover 132 and the housing 108. Further, the annular rings 158, 160 do not need to extend around the entire circumference of the cover 132 and the housing 108. Instead, the annular rings may be several protrusions or ring segments extending from the inner surface of the cover 132 and the outer surface of the housing 108, with circumferential gaps between the ring segments. Further, adhesives or other coupled mechanisms may be added to the snap-fit coupling described. Still further, other snap-fit mechanisms suitable for the purposes described herein may be utilized.

[0042] FIG. 6 shows another embodiment of cover 132' that may be used with the catheter 102 of FIG. 1. The cover 132' is similar to the cover 132 described previously, except that the cover 132' utilizes a friction-fit coupling mechanism for coupling the cover 132' to a housing 108'. Other than the cover 132' and the housing 108', the remaining features of the catheter 102 remain as described above, and therefore will not be described here. In the embodiment shown, a distal portion of the cover 132' has a first inner diameter D1 when the cover 132' is in the first configuration. A corresponding distal portion of the housing 108' has a second outer diameter D2, wherein the first diameter D1 is smaller than the second diameter D2. Thus, with cover 132' in the first configuration disposed over the distal portion of the proximal shaft 112, application of a sufficient force distally (in the direction of arrow 180) to the cover 132' will slide or translate the cover 132' distally over the housing 108'. More specifically, with a sufficient force applied thereto, the cover 132' will radially expand to match the larger diameter outer surface of the housing 108'. The cover 132' will attempt to radially collapse to its original shape, thereby coupling the cover 132' to the housing 108' via a friction fit. While the friction fit coupling is described at the corresponding distal ends of the cover 132' and the housing 108', this is not meant to be limiting. Thus, the friction fit may be at the respective proximal ends or over an entire length of the cover 132' and the housing 108' Further, an adhesive

or other coupling mechanism may be added to the friction fit coupling to further secure the cover 132' to the housing 108'.

[0043] Referring to FIGS. 7-11, another embodiment of an FFR catheter or micro-catheter 302 is shown. Catheter 302 includes a proximal shaft 312, a distal shaft 310, and a pressure sensor 304. Further, the distal shaft 310 includes a housing including an open seat 328, a distal tip 334, and an aperture 346. These components are similar to the components described above with respect to catheter 102. Therefore, details and alternatives of these similar components will not be repeated. The embodiment of FIGS. 7-11 differs from the embodiments of FIGS. 1-6 in that the cover 332 is of a generally partial cylindrical shape. Further, the connection between the cover 332 and the housing 308 is different than the connection between the cover 132 and the housing 108.

[0044] In an embodiment, the cover 332 is of a generally partial cylindrical shape. The cover 332 includes a proximal end 350, a distal end 352, a first circumferential edge 351, and a second circumferential edge 353, as shown in FIGS. 7 and 9. An outer surface 354 and an inner surface 356 of the cover 332 are defined between the proximal end 350, the distal end 352, the first circumferential edge 351, and the second circumferential edge 353, as shown in FIG. 7. The outer and inner surfaces 354, 356 define a partial cylinder with an open portion 355 adjacent the inner surface 356, opposite the outer surface 354. The cover 332 includes a first configuration wherein the cover 332 is not coupled to the housing 308, as shown in FIG. 7, and a second configuration wherein the cover 332 is coupled to the housing 308, as shown in FIGS. 8-9. In the second configuration, the open portion 355 of the cover 332 is aligned with and covers the open seat 328 of the housing 308, as shown in FIGS. 8-9. With the cover 332 in the first configuration and positioned over the housing 308 such that the open portion 355 of the cover 332 is aligned with the open space 328 of the housing 308, the cover 332 may transition to the second configuration by moving the cover 332 towards the central longitudinal axis LA1 of the housing 308, as indicated by arrow 380 in FIG. 7. Stated another way, with the cover 332 in the first configuration and disposed over the corresponding open space 328 of the housing 308, the cover 332 may be pressed down onto the housing 308 to transition to the second configuration, as shown in FIGS. 8-9.

[0045] The cover 332 is configured to protect the pressure sensor 304 when the cover 332 is in the second configuration, *i.e.*, when the cover 332 is coupled to the housing 108. More specifically, and as described previously, the cover 332 prevents contact damage to the pressure sensor 304 during handling, or contact with tissue during advancement of the catheter 302 through the vasculature of a patient. The cover 332 may be formed of a second material different than a first material of the housing 308 such that the cover 332 is more rigid than the distal housing 308. The increased rigidity of the cover 332 resists bending of the distal shaft 310 as the distal shaft 310 advances through the vasculature of the patient. Thus, the more rigid cover 332 protects the pressure sensor 304 from bending damage or bending stresses incurred during handling or advancement through the vasculature of the patient. The cover 332 is coupled to the housing 308 by a coupling mechanism such as, but not limited to a friction-fit mechanism, a snap-fit mechanism, adhesives, or any other coupling mechanism suitable for the purposes described herein. The cover 332 may be formed of metals such as, but not limited to, stainless steel, gold, platinum, and/or iridium, and alloys thereof. In some embodiments, such as forming the cover 332 of gold, platinum, platinum-iridium alloys, and other radiopaque materials, the cover 332 may also act as a marker band. . In other embodiments, the cover 332 may be formed of metal reinforced polymers, polycarbonate, acrylonitrile butadiene styrene (ABS), polymers (e.g. polyether ether ketone (PEEK)), reinforced polymers (e.g. carbon fiber), or other materials suitable for the purposes described herein.

[0046] FIGS. 7-9 show the cover 332 with a friction-fit coupling mechanism according to an embodiment hereof. The cover 332 in the first configuration has a first distance D1 between the first circumferential edge 351 and the second circumferential edge 353, as shown in FIG. 7. The housing 308 includes a first shoulder 364 disposed in an outer surface 309 of the housing 308, adjacent to the open seat 328, and a second shoulder 366 disposed in the outer surface 309 of the housing 308, adjacent to the open seat 328, as shown in FIG. 7 and in greater detail in FIG. 9. The first and second shoulders 364, 366 extend inwardly from the outer surface 309 to first and second walls 365, 367, respectively, which extend generally perpendicular to first and second shoulders 364, 366, as shown in FIG. 9. The housing 308 has a second distance D2 between outer

surfaces of the first wall 365 and the second wall 367, as shown in FIG. 9. The second distance D2 is greater than the first distance D1 between the first and second circumferential edges 351, 353 of the cover 332. Thus, when the cover 332 is in the second configuration coupled to the housing 308, the first circumferential edge 351 of the cover 332 is configured to align with and rest on the first shoulder 364 of the housing 308. Similarly, the second circumferential edge 353 of the cover 332 is configured to align with and rest on the second shoulder 366 of the housing 308. Because the first distance D1 between the first and second circumferential edges 351, 353 is smaller than the second distance D2 between the outer surfaces of the walls 365, 367, the cover 332 expands slightly radially outward for the first and second circumferential edges 351, 353 to clear the walls 365, 367 and sit on the first and second shoulders 364, 366. The cover 332 wants to return to its undeformed shape. Thus, the cover 332 squeezes radially inwardly on the respective outer surfaces of first and second walls 365, 367, thereby creating a friction fit between the cover 332 and the housing 308, as shown in FIG. 9. An adhesive or other coupling mechanism may be added to the friction fit to further secure the cover 332 to the housing 308.

[0047] FIGS. 10-11A show a cover 332' coupled to a housing 108' with a snap-fit connection. The cover 332' and the housing 308' are similar to the cover 332 and the housing 308 of FIGS. 7-9 except for the snap-fit connection.

[0048] Thus, the cover 332' includes a first protrusion or lip 360' extending generally radially inward from an inner surface of the cover 332', adjacent to the first circumferential edge 351'. A second protrusion or lip 362' extends generally radially inward from the inner surface of the cover 332', adjacent the second circumferential edge 353'. The first and second protrusions 360', 362' are generally opposite each other and extend towards each other. Further, the first and second protrusions 360', 362' extend longitudinally along the first and second circumferential edges 351, 353. With the cover 332' in the first configuration not coupled to the housing 308', the cover 332' has a first distance D1 between the first protrusion 360' and the second protrusion 362', as shown in FIG. 10.

[0049] The housing 308' of the distal shaft 310' includes a first lip 368 extending radially outwardly from the first wall 365' and a second lip 370 extending radially outwardly from the second wall 367', as shown in FIGS. 11 and 11A. Thus, a first channel 372 is formed between the first shoulder 364' and the first lip 368 and a second channel 374 is formed between the second shoulder 366' and the second lip 370. The first protrusion 360' fits within the first channel 372 of the housing 308' and the second protrusion 362' fits within the second channel 374 of the housing 308'. Further, a second distance D2 between outer surfaces of the first and second lips 368, 370 is larger than the first distance D1 between the first and second protrusions 360', 362' of the cover 332'. Thus, when the cover 332' is pushed towards the housing 308' the cover 332' expands radially outward for the first and second protrusions 360', 362' to clear the first and second lips 368, 370 of the housing 308'. The cover 332' continues to be pushed towards the housing 308' until the first and second protrusions 360', 362' clear the first and second lips 368, 370, respectively. The first and second protrusions 360', 362' then move radially inward into first and second channels 372, 374, respectively, as shown in FIGS. 11 and 11A. The first and second lips 368, 370 prevent the cover 332 from being lifted off of the housing 308'. An adhesive or other coupling mechanism may be added to the snap-fit connection of FIGS. 10-11A to further secure the cover 332' to the housing 308'.

[0050] As previously described, embodiments hereof may include more than one aperture disposed through the tip and/or the cover. Accordingly, another embodiment of a cover 132" useful with the catheter 102 of FIG. 1 is shown in FIG. 12. The catheter 102 includes a first aperture 146 disposed through the tip 134 and a second aperture 146' disposed through the cover 132". With the exception of the second aperture 146' of the cover 132", the remaining features of catheter 102 remain as described above, and therefore will not be repeated. In an embodiment, the second aperture 146' is disposed through the cover 132" and is in fluid communication with the open seat 128 of the housing 108. The second aperture 146' is an opening extending from an outer surface to an inner surface of the cover 132" and extends into the open seat 128 of the housing 108. The second aperture 146' is configured to receive fluid therethrough such that fluid outside the cover 132" may flow through the second aperture 146' and into the open seat 128 of the housing 108. Thus, fluid flows through both the first aperture 146 and the

second aperture 146' into the open seat 128 such that the fluid is in contact with the pressure-sensing surface 140 of the pressure sensor 104. The first aperture 146 and the second aperture 146' are sized such that a sufficient amount of blood flows into the open seat 128 of the housing 108 but tissue is prevented from entering the open seat 128 during advancement of the distal shaft 110 through a vasculature. The second aperture 146' may be formed as an integral component of the cover 132" or may be formed by removing material from the cover 132" by any suitable method, non-limiting examples of which include cutting, machining, drilling, laser cutting; laser ablation, or other methods suitable for the purposes described herein. Although the second aperture 146' is shown as generally tubular with oval opening, this is not meant to be limiting, and other shapes may be utilized. Moreover, while the cover 132" is described herein with one (1) second aperture 146', it will be understood that the cover 132" may include more than one second aperture 146' and that the second aperture(s) 146' may be located at other locations of on the cover 132". Additionally, while described herein as an additional aperture in the generally tubular cover 132, it will be understood that an additional aperture or apertures may be disposed through embodiments of the partial cylindrical shaped cover 332 as well as in other embodiments of covers of the present disclosure.

[0051] With an understanding of the components above, it is now possible to describe their interaction as a system for measuring and calculating a Fractional Flow Reserve (FFR) according to an embodiment of the present disclosure. Referring to FIG. 13, the system 100 is shown disposed through a guide catheter 200, which is utilized as the proximal pressure-sensing device, as explained below. Referring to FIG. 13, the guide catheter 200 and the guidewire 500 are advanced through the vasculature to a desired site. The guidewire 500 may be back-loaded into the FFR catheter 102 (i.e., the proximal end of the guidewire 500 is loaded into the distal end of guidewire lumen 122 at the distal end 126 of the distal shaft 110). The FFR catheter 102 may then be advanced over the guidewire 500 and through a lumen 206 of the guide catheter 200 to the desired treatment site. In particular, with a distal end 204 of the guide catheter 200 disposed at a desired site proximal of the stenosis 900, such as in the sinus 920, the distal shaft 110 of the FFR catheter 102 is advanced through the lumen 206 and distal of the distal end 204 of the guide catheter 200. The FFR catheter 102 is advanced such that the distal shaft 110 is

disposed through the stenosis 900 of the vessel 904. Blood flow from the aortic sinus 920 fills the lumen 206 and tubing 214 via a port 210 of a proximal portion 212 of the guide catheter 200. The blood pressure P_a at the distal end 204 of the guide catheter 200 is measured by an external pressure transducer 250 via the fluid (blood) column extending through the lumen 206 and the tubing 214. Thus, the external pressure transducer 250 is configured to measure proximal, or aortic (AO) pressure P_a at the distal end 204 of the guide catheter 200.

[0052] The external pressure transducer 250 is configured to communicate measured the proximal pressure P_a to the processing device 106 via a pressure transducer wire 252, as shown in FIG. 13. While the pressure transducer 250 is shown in FIG. 13 as communicating the measured proximal pressure P_a with the processing device 106 via the pressure transducer wire 252, this is not meant to limit the design and the pressure transducer 250 may communicate with the processing device 106 by any means suitable for the purposes described, including, but not limited to, electrical cables, optical cables, or wireless devices.

[0053] Simultaneously, blood on the distal side 906 of the stenosis 900 flows through the aperture 146 of the tip 134 and into the open seat 128 (FIG. 2) of the housing 108. The blood within the open seat 128 (FIG. 2) is in contact with the pressure-sensing surface 140 of the pressure sensor 104, coupled therein. The pressure within the open seat 128 is equal to the pressure on the distal side 906 of the stenosis 900. Thus, the distal pressure P_d is sensed by the pressure sensor 104. The sensed distal pressure P_d is communicated with the processing device 106. The processing device 106 calculates the Fractional Flow Reserve (FFR) based on the measured distal pressure P_a divided by the measured proximal/aortic pressure P_a, or $FFR = P_d/P_a$.

[0054] Although the method described above refers to the FFR catheter 102, it applies equally to catheter 302 and to variations described above with respect to the catheters 102, 302.

[0055] Referring to FIG. 14, a method of manufacturing a distal shaft 110 of an FFR catheter for measuring a distal pressure measurement on a distal side of a stenosis

according to an embodiment hereof is described. Steps 1400-1406 of FIG. 14 reference the cover 132 and the distal shaft 110 components shown in FIGS. 3-5. The cover 132 of FIGS. 3-5 includes the cover lumen 154 configured to receive the housing 108 of the distal shaft 110 therein.

[0056] In step 1400, the cover 132 is positioned over the proximal shaft 112 proximal of the housing 108 of the distal shaft 110.

[0057] In step 1402, a sufficient force is applied distally to the cover 132 to distally slide or translate the cover 132 over the housing 108 of the distal shaft 110.

[0058] In step 1404, the force is applied distally to the cover 132 such that the coupling mechanism of the distal shaft 110 is engaged and the cover 132 is coupled to the housing 108 of the distal shaft 110.

[0059] In step 1406, the aperture 146 is created in the tip 134 extending from an outer surface of the tip 134 to the open seat 128 of the housing 108.

[0060] The method of FIG. 14 describes step 1404 as engaging at least one coupling mechanism. The step 1204 may include engaging a snap-fit coupling mechanism, a friction-fit coupling mechanism, an adhesive coupling mechanism, or any other coupling mechanism suitable for the purposes described herein. Moreover, the various coupling mechanisms described may be used in any combination. Further, in embodiments utilizing an adhesive coupling mechanism, the adhesive may be applied to the housing 108 and/or to the cover 132 at any time prior to step 1402.

[0061] Although the method of FIG. 14 describes step 1406 as occurring after steps 1400-1404, step 1406 may occur at any time during the manufacturing process, including being formed as part of the tip 134. Further, while step 1406 describes creating the aperture 146 in the tip 134, this is not meant to limit the method, and step 1406 may alternatively include creating the aperture 146 in a portion of the tip 134, in the cover 132, in a portion of the cover 132, or in any combination thereof. Even further, more than one aperture 146 may be created.

[0062] FIG. 15 shows a method of manufacturing a distal shaft 310 of an FFR catheter for measuring a distal pressure measurement on a distal side of a stenosis according to another embodiment hereof. Steps 1500-1504 of FIG. 15 reference the partial cylinder cover 332 and the distal shaft 310 shown in FIGS. 7-9.

[0063] In step 1500, the cover 332 is positioned with the open portion 355 of the cover 332 over the open seat 328 of the housing 308.

[0064] In step 1502, a sufficient force is applied to the cover 332 and/or the housing 308 towards each other such that the coupling mechanism is engaged and the cover 332 is coupled to the housing 308 of a distal shaft 310.

[0065] In step 1504, the aperture 346 is created in the tip 334 extending from an outer surface of the tip 334 to an open seat 328 of a housing 308.

[0066] The method of FIG. 15 describes step 1502 as engaging the coupling mechanism. Step 1502 may including engaging a friction-fit coupling mechanism, a snap-fit coupling mechanism, an adhesive coupling mechanism, or any other suitable coupling mechanism. Further, the various coupling mechanisms described may be used in any combination. If an adhesive coupling mechanism is utilized, the adhesive may be applied to the housing 308 and/or the cover 332 prior to step 1502.

[0067] Although the method of FIG. 15 describes step 1504 as occurring after steps 1500-1502, step 1504 may occur at any suitable time during the manufacturing method, including being formed as part of the tip 334.

[0068] Moreover while step 1504 describes creating the aperture 346 in the tip 334, this is not meant to limit the method, and step 1504 may alternatively include creating the aperture 346 in a portion of the tip 334, in the cover 332, in a portion of the cover 332, or in any combination thereof. Even further, more than one aperture 346 may be created.

[0069] While the methods of FIGS. 14-15 are described with respect to specific embodiments of the invention described herein, this is not meant to limit the methods,

and persons skilled in the art will understand the methods described herein may utilize a cover according to other embodiments.

[0070] While only some embodiments according to the present invention have been described herein, it should be understood that they have been presented by way of illustration and example only, and not limitation. Various changes in form and detail can be made therein without departing from the spirit and scope of the invention. Further, each feature of each embodiment discussed herein, and of each reference cited herein, can be used in combination with the features of any other embodiment. All patents and publications discussed herein are incorporated by reference herein in their entirety.

CLAIMS

What is claimed is:

1. A distal shaft (110) for measuring a pressure distal (P_d) of a stenosis (900), the distal shaft (110) comprising:

a housing (108);

a pressure sensor (104) mounted in the housing (108);

a cover (132) coupled to the housing (108) and covering the pressure sensor (104);

a tip (134) coupled to a distal end (138) of the housing (108); and

an aperture (146) disposed through the tip (134) and/or the cover (132), the aperture (146) configured to allow blood flow to the pressure sensor (104).

2. The distal shaft (110) of claim 1, wherein the cover (132) includes a proximal end (150) and a distal end (152) defining a cover lumen (154) there between, wherein the housing (108) is disposed within the cover lumen (154).

3. The distal shaft (110) of claim 2, wherein the cover (132) includes a coupling mechanism for coupling the cover (132) to the housing (108).

4. The distal shaft (110) of claim 3, wherein the coupling mechanism is a snap-fit mechanism including a first annular ring (158) extending radially inwardly from an inside surface of the cover (132) and a corresponding second annular ring (160) extending radially outwardly from an outer surface of the housing (108).

5. The distal shaft (110) of claim 3, wherein the coupling mechanism is a friction-fit mechanism such that a first portion of the cover (132') includes a first inner diameter (D1) and a corresponding second portion of the housing (108') includes a second outer diameter (D2), wherein the first inner diameter (D1) is smaller than the second outer diameter (D2) with the first portion of the cover (132') not disposed over the second portion of the housing (108'), and wherein with the first portion of the cover (132')

disposed over the second portion of the housing (108'), the second portion expands the first portion such that the cover (132') is frictionally coupled to the housing (108').

6. The distal shaft (110) of claim 3, wherein the coupling mechanism is an adhesive.

7. The distal shaft (310) of claim 1,

wherein the cover (332) includes a proximal end (350), a distal end (352), a first longitudinal edge (351), a second longitudinal edge (353), and a surface (356) between the proximal end (350), the distal end (352), the first circumferential edge (351), and the second circumferential edge (353), the surface (356) defining a partial cylinder with an open portion (355) opposite the surface (356),

wherein the housing (308) has an open seat (328) in which the pressure sensor (304) is disposed, and

wherein the open portion (355) of the cover is aligned with the open seat (328) of the housing (308) such that the surface (356) covers the open seat (328) of the housing (328).

8. The distal shaft (310) of claim 7, wherein the cover (332) includes a coupling mechanism for coupling the cover (332) to the housing (308).

9. The distal shaft (310') of claim 8, wherein the coupling mechanism comprises includes a first protrusion (360') extending inwardly from an inner surface (356) of the cover (332') adjacent the first circumferential edge (351'), a second protrusion (362') extending inwardly from the inner surface (356) of the cover (332') adjacent the second circumferential edge (353'), a first channel (372) corresponding to the first protrusion (360') disposed in an outer surface (309) of the housing (308') adjacent the open seat (328) of the housing (308'), and a second channel (374) corresponding to the second protrusion (362') disposed in the outer surface (309) of the housing (308') adjacent the open seat (328) of the housing (308'), wherein the first protrusion (360') is disposed in

the first channel (372) and the second protrusion (362') is disposed in the second channel (374) to couple the cover (332') to the housing (308').

10. The distal shaft (310') of claim 8, wherein the coupling mechanism comprises a first protrusion (360') extending inwardly from an inner surface (356) of the cover (332') adjacent the first circumferential edge (351'), a second protrusion (362') extending inwardly from the inner surface (356) of the cover (332') adjacent the second circumferential 200edge (353'), a third protrusion (368) corresponding to the first protrusion (360') extending outwardly from an outer surface (365') of the housing (308') adjacent the open seat (328) of the housing (308'), and a fourth protrusion (370) corresponding to the second protrusion (362') extending outwardly from the outer surface (365') of the housing (308') adjacent the open seat (328) of the housing (308), wherein the first (360') and the third (368) protrusions overlap and the second (362') and the fourth protrusions (370) overlap to couple the cover (332') to the housing (308').

11. The distal shaft (310) of claim 8, wherein the coupling mechanism is an adhesive.

12. The distal shaft (110) of claim 1, wherein the housing (108) comprises a first material and the cover comprises a second material, wherein the second material is stiffer than the first material.

13. The distal shaft (110) of claim 1, wherein the aperture (146) is disposed in the tip (134).

14. The distal shaft (110) of claim 13, wherein the aperture (146) is shaped such that the aperture (146) is generally parallel to a longitudinal axis (LA1) of the housing (108).

15. The distal shaft (110) of claim 13, wherein the aperture (146) is configured to provide axial blood flow into a portion of the housing (128) where the pressure sensor (104) is housed.

16. The distal shaft (110) of claim 1, wherein the housing (108) includes a guidewire lumen (122) and an open seat (128), wherein the pressure sensor (104) is disposed in the open seat (128).

17. The distal shaft (110) of claim 1, wherein cover (132) is a separate piece than the housing (108) and is coupled thereto.

18. A system (100) for calculating a Fractional Flow Reserve of a stenosis (900) in a blood vessel (904), the system comprising:

a catheter (102) including a distal shaft (110) with a housing (108) including a distal pressure sensor (104) mounted therein, a separate cover (132) coupled to the housing (108), and a tip (134) including an aperture (146) configured to provide blood flow to the pressure sensor (104);

a proximal pressure-sensing device (250) configured to measure a proximal blood pressure (P_a) proximal of the stenosis (900); and

a processing device (106) in communication the distal pressure sensor (104) and the proximal pressure-sensing device (250),

wherein the distal shaft (110) is configured for placement within a blood vessel (904) such that blood distal of the stenosis (900) flows through the aperture (146) into the housing (108) and in contact with the distal pressure sensor (104) such that the distal pressure sensor (104) measures a distal blood pressure (P_d) distal (906) of the stenosis (900), and

wherein the processing device (106) is configured to calculate a Fractional Flow Reserve based on the distal blood pressure (P_d) relative to the proximal blood pressure (P_a).

19. The system (100) of claim 18, wherein the aperture (146) in the tip (134) of the distal shaft (110) is configured to supply axial blood flow to the pressure sensor (104) disposed in the housing (108).

20. A method of manufacturing a distal shaft (110) of an FFR catheter (102) for measuring a distal pressure (P_d) measurement on a distal side (906) of a stenosis (900), the method comprising the steps of:

positioning a cover (132) at a housing (108) of a distal shaft (110), the housing (108) having a pressure sensor (104) mounted therein;

coupling the cover (132) to the housing (108) of the distal shaft (110) to cover the pressure sensor (104); and

providing an aperture (146) through the cover (132) and/or a portion of the distal shaft (110), wherein the aperture (146) is configured to enable blood flow into the housing (108) and into contact with the pressure sensor (104).

21. The method of claim 20, wherein the cover (132) includes a lumen (154) configured to receive the housing (108) of the distal shaft (110) therein, wherein the step of positioning the cover (132) at the housing (108) of the distal shaft (110) comprises positioning the cover (132) proximal of the housing (108) and sliding the cover (132) distally over the housing (108).

22. The method of claim 20, wherein the cover (332) comprises a partial cylinder, and wherein the step of positioning the cover (332) at the housing (308) of the distal shaft (310) comprises positioning an open portion (355) of the cover over an open seat (328) of the housing (308).

23. The method of claim 20, wherein the step of coupling the cover (132) to the housing (108) comprises engaging at least one snap-fit mechanism.

24. The method of claim 21, wherein the step of coupling the cover (132) to the housing (108) comprises frictionally coupling the cover (132) to the housing (108).

25. The method of claim 20, wherein the step of coupling the cover (132) to the housing (108) comprises adhesively coupling the cover (132) to the housing (108).

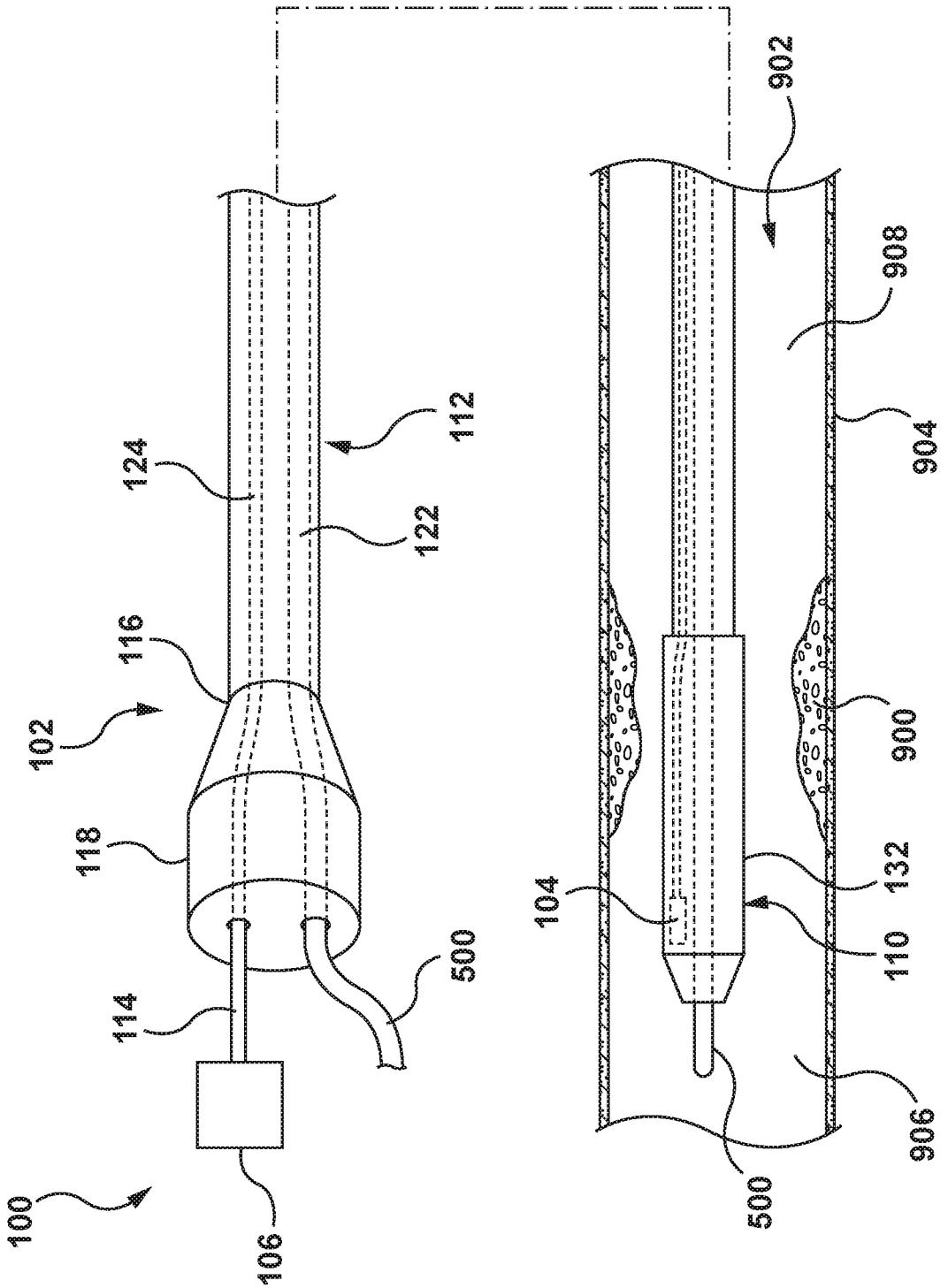
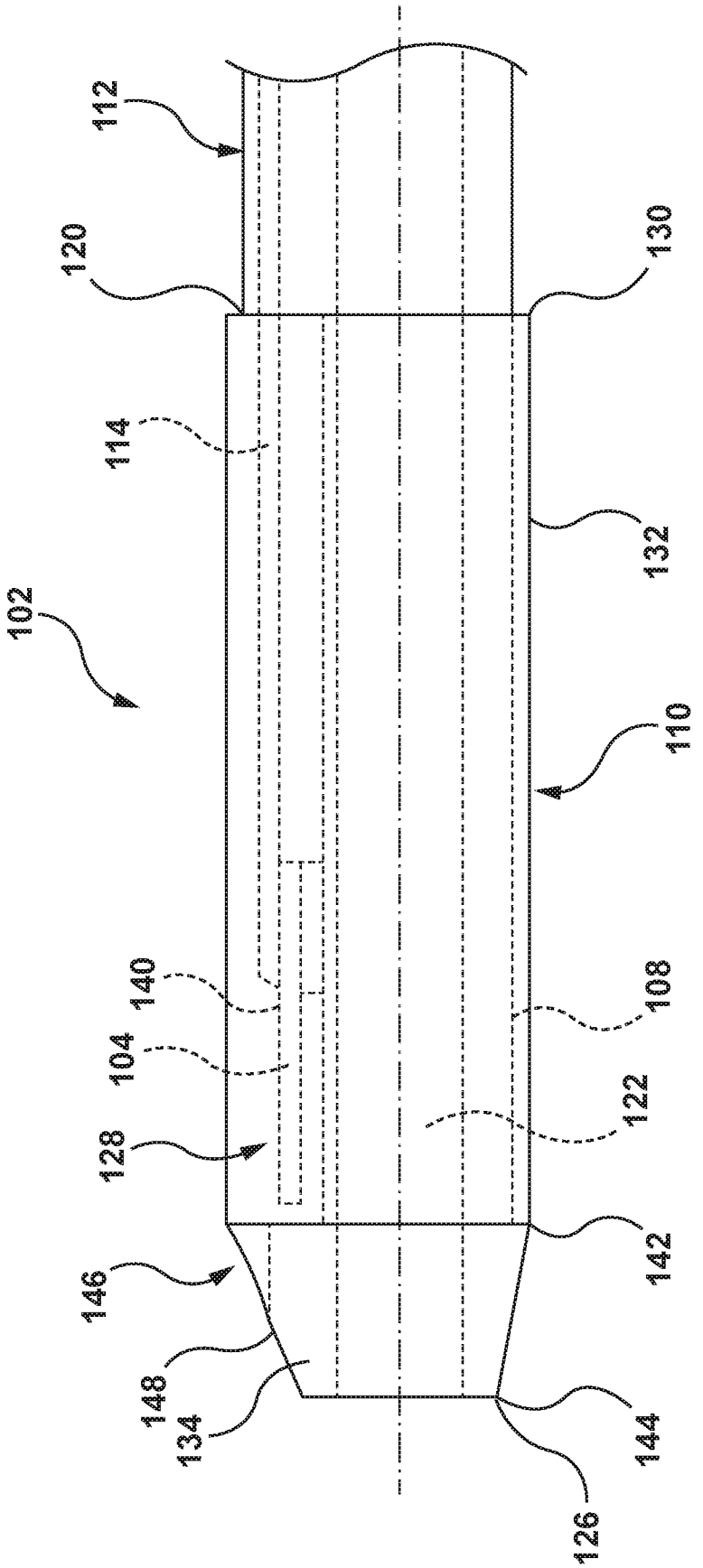

902
908
904
112
124
122
116
102
900
118
132
104
110
114
500
906
100
106
500

FIG. 1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132
102
110
140
108
104
122
128
142
146
148
134
144
126

FIG. 2

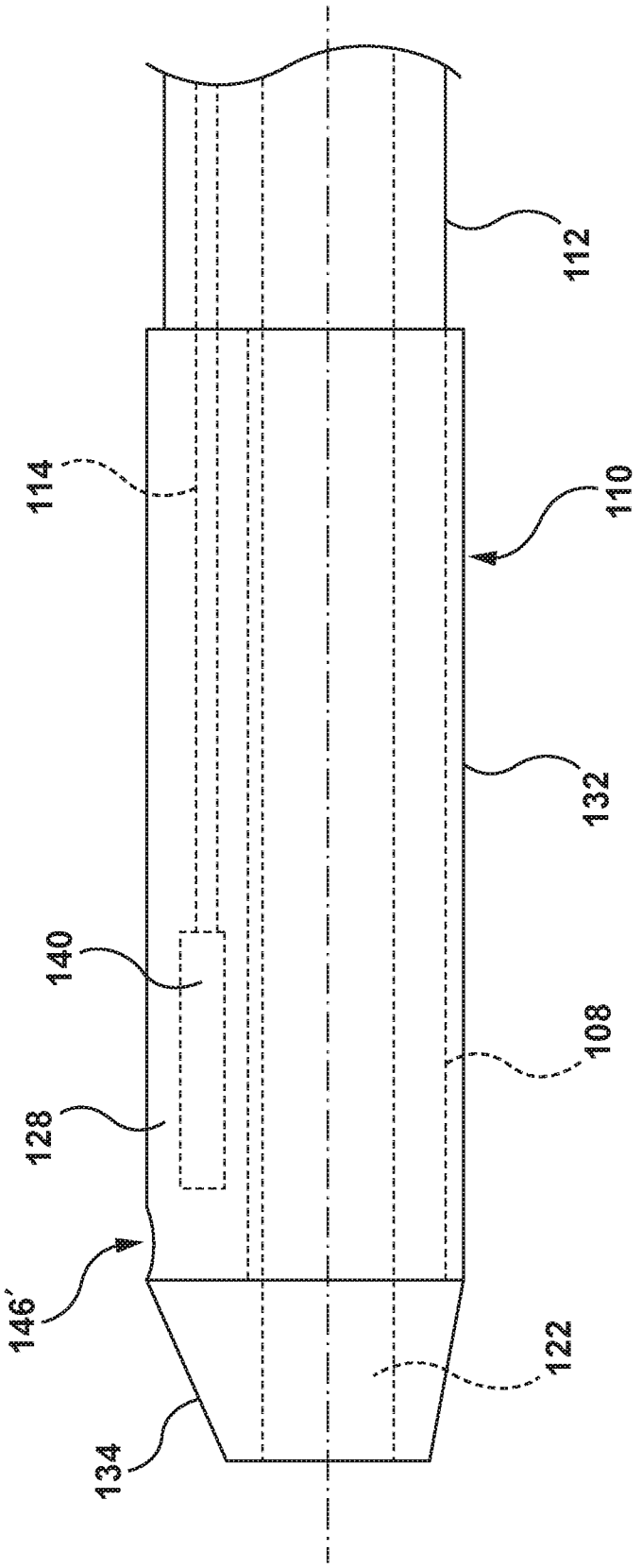

FIG. 2A

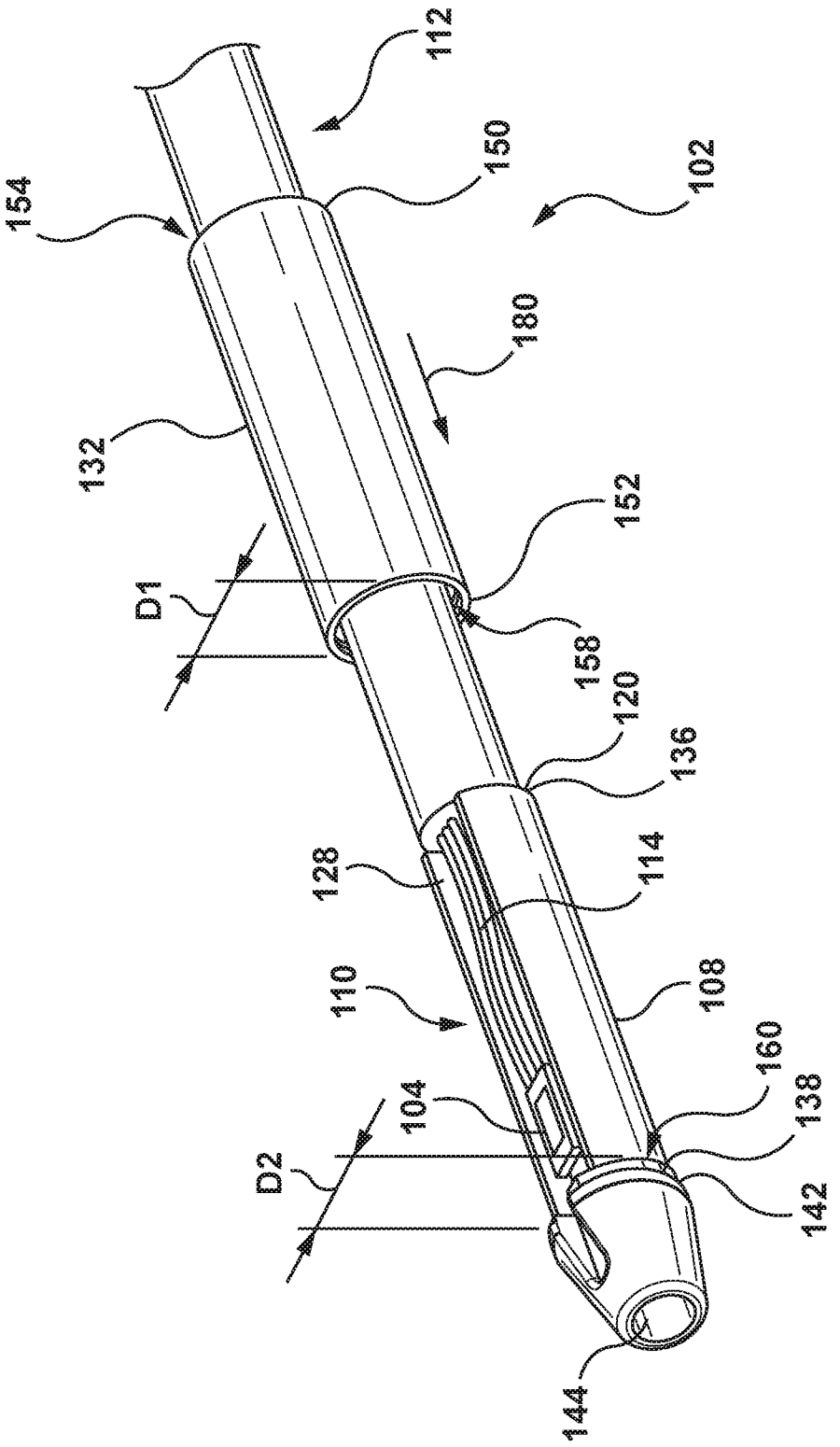
112
150
102
154
180
132
152
D1
158
120
136
128
114
110
108
160
104
138
D2
142
144

FIG. 3

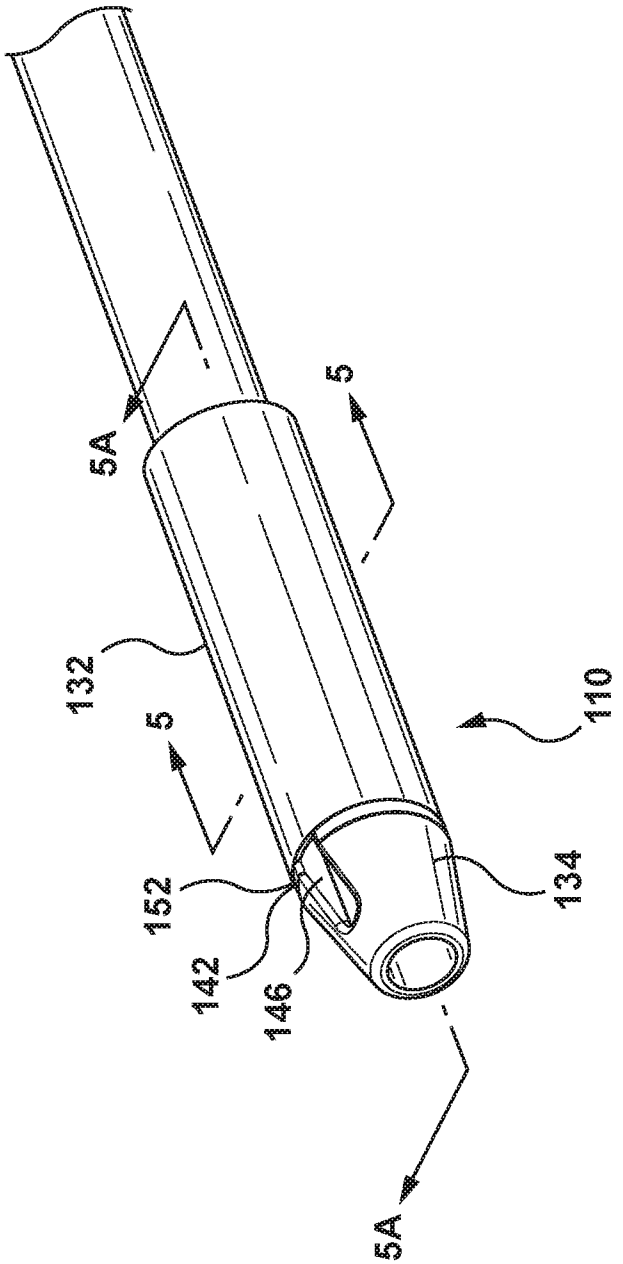

FIG. 4

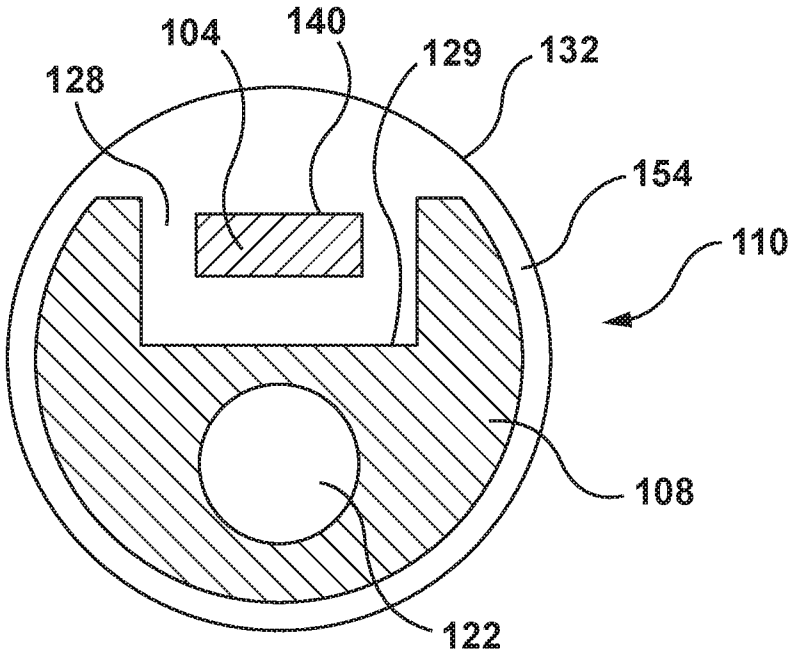

FIG. 5

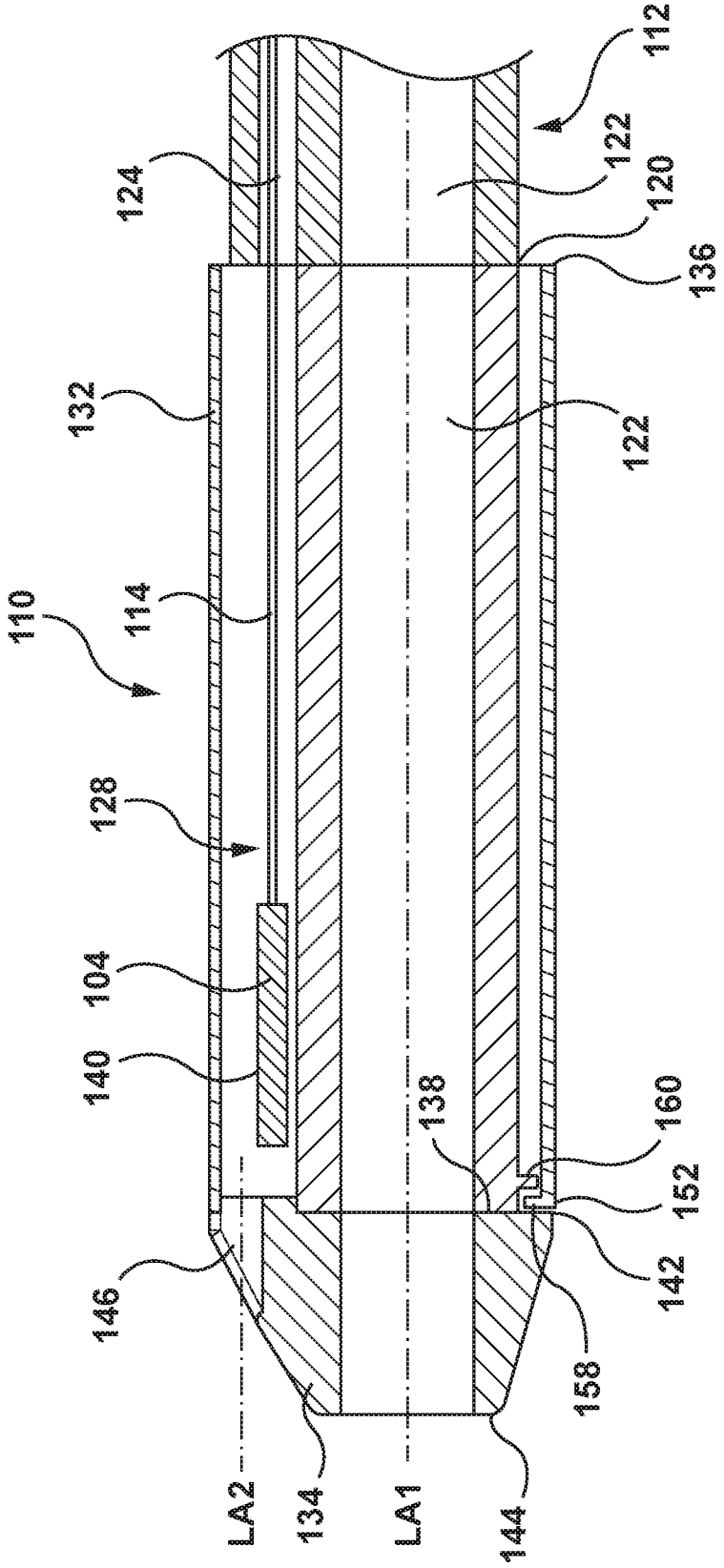
112
122
124
120
136
132
122
110
114
128
104
140
138
160
152
142
146
158
LA2
134
LA1
144

FIG. 5A

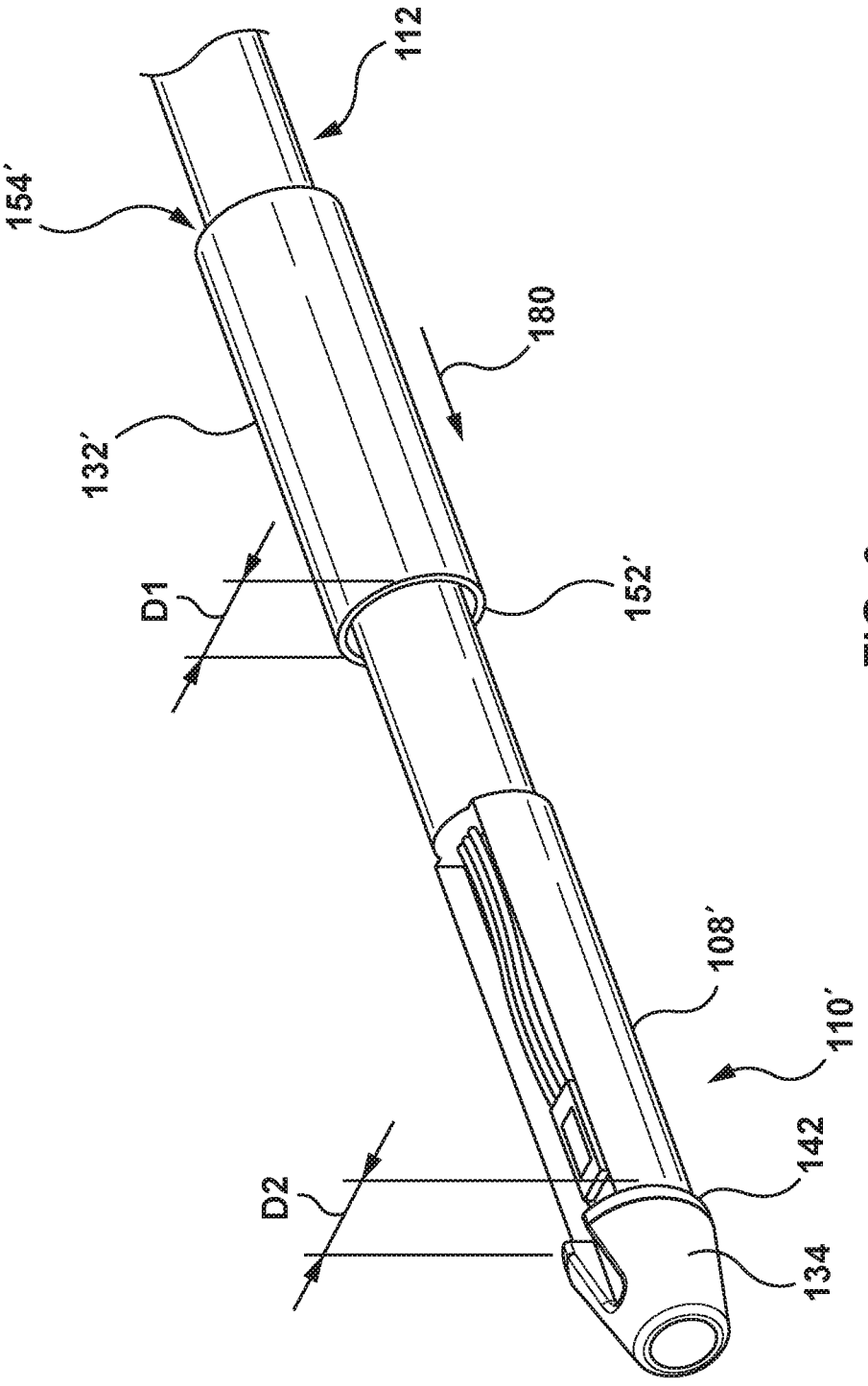

FIG. 6

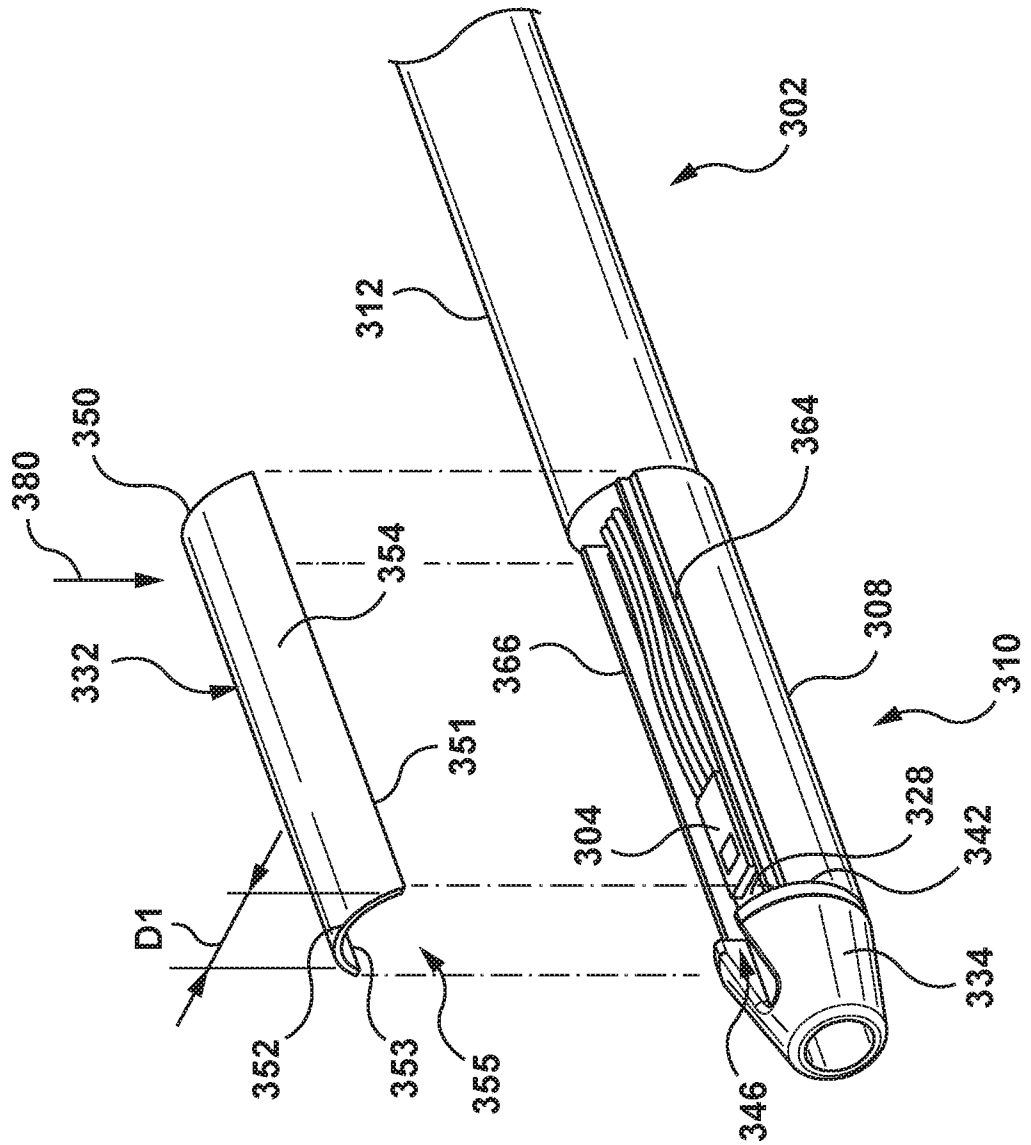
302
312
350
380
354
364
332
366
308
310
351
328
304
342
D1
334
352
353
355
346

FIG. 7

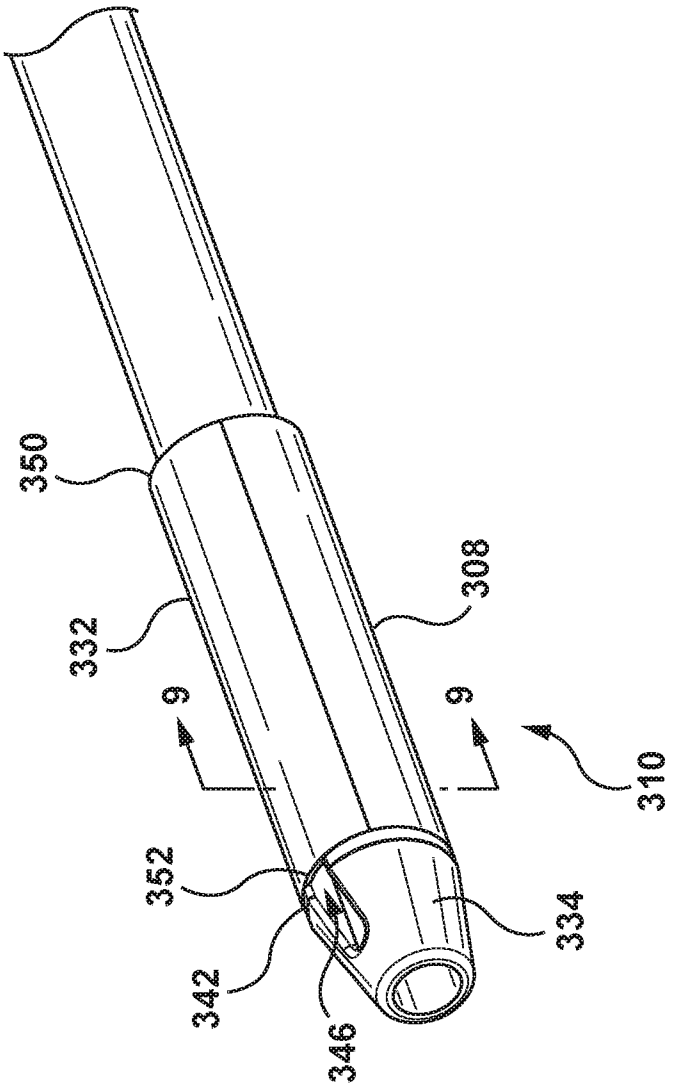

FIG. 8

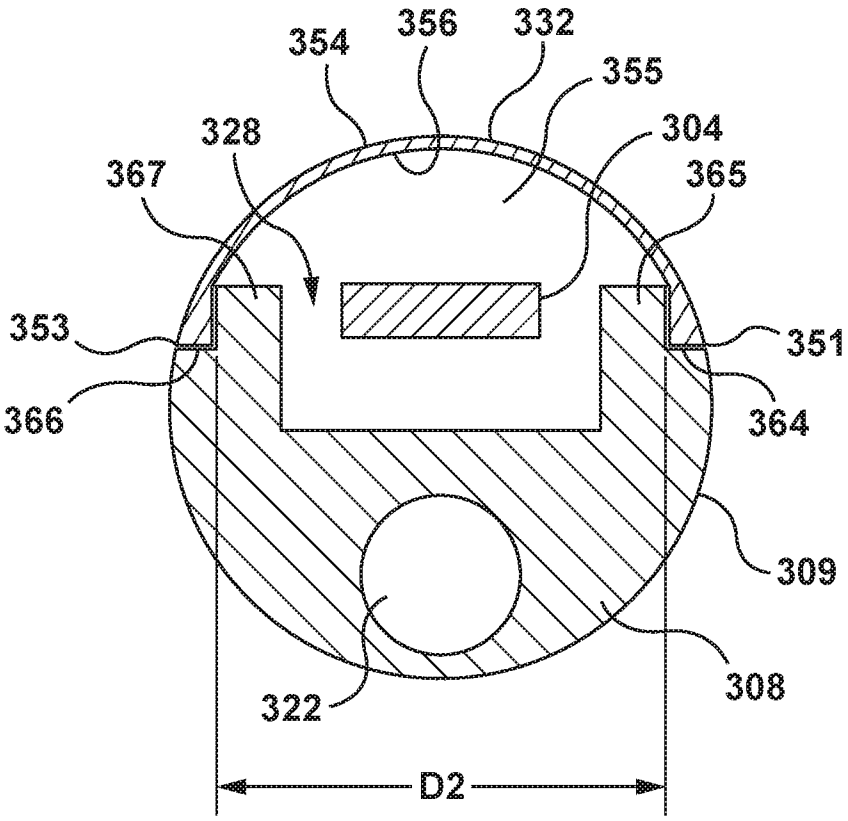

FIG. 9

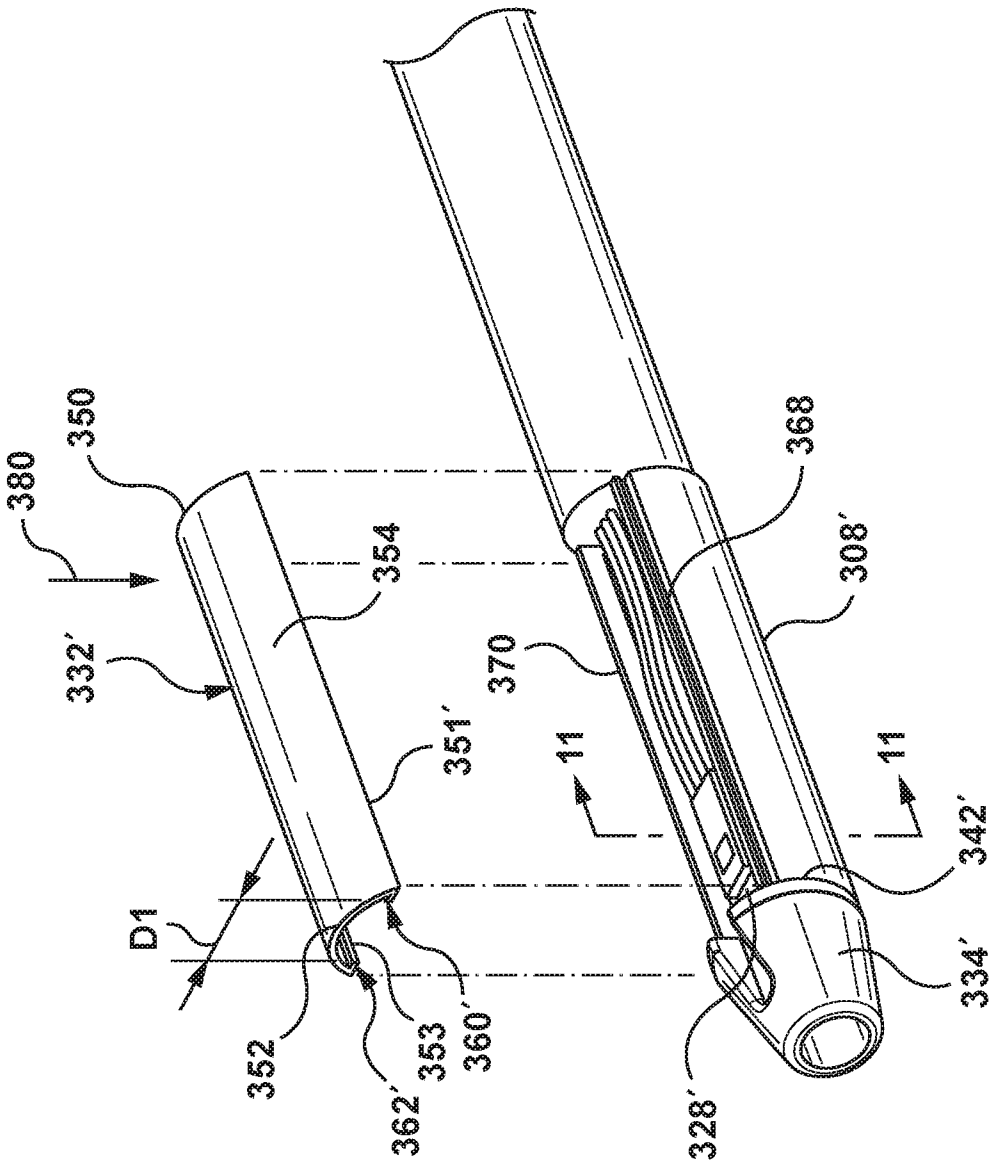
380
350
354
332'
351'
370
368
308'
11
11
342'
D1
352
353
360'
362'
328'
334'

FIG. 10

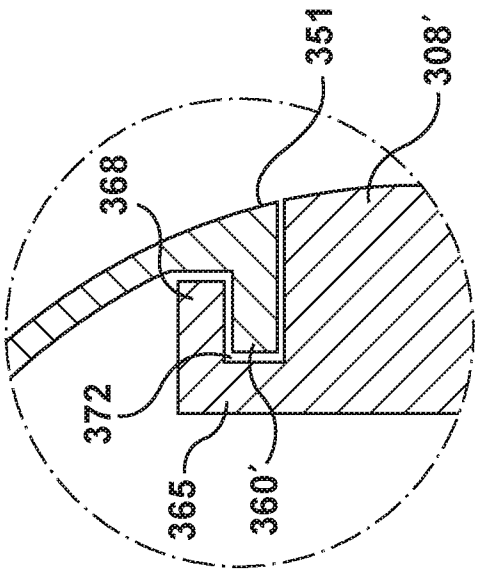

FIG. 11A

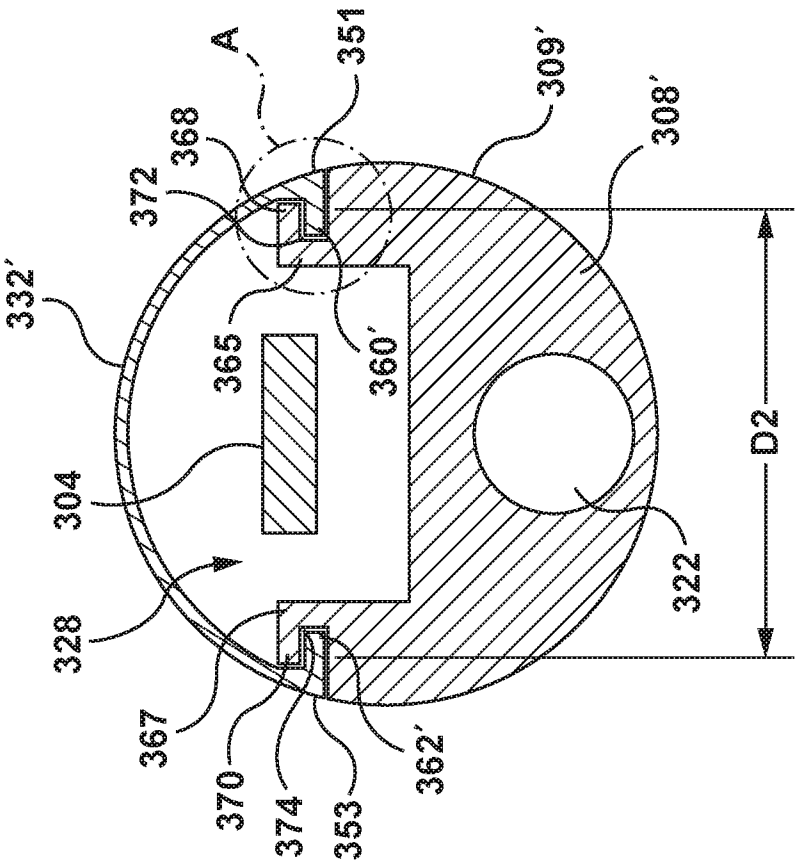

FIG. 11

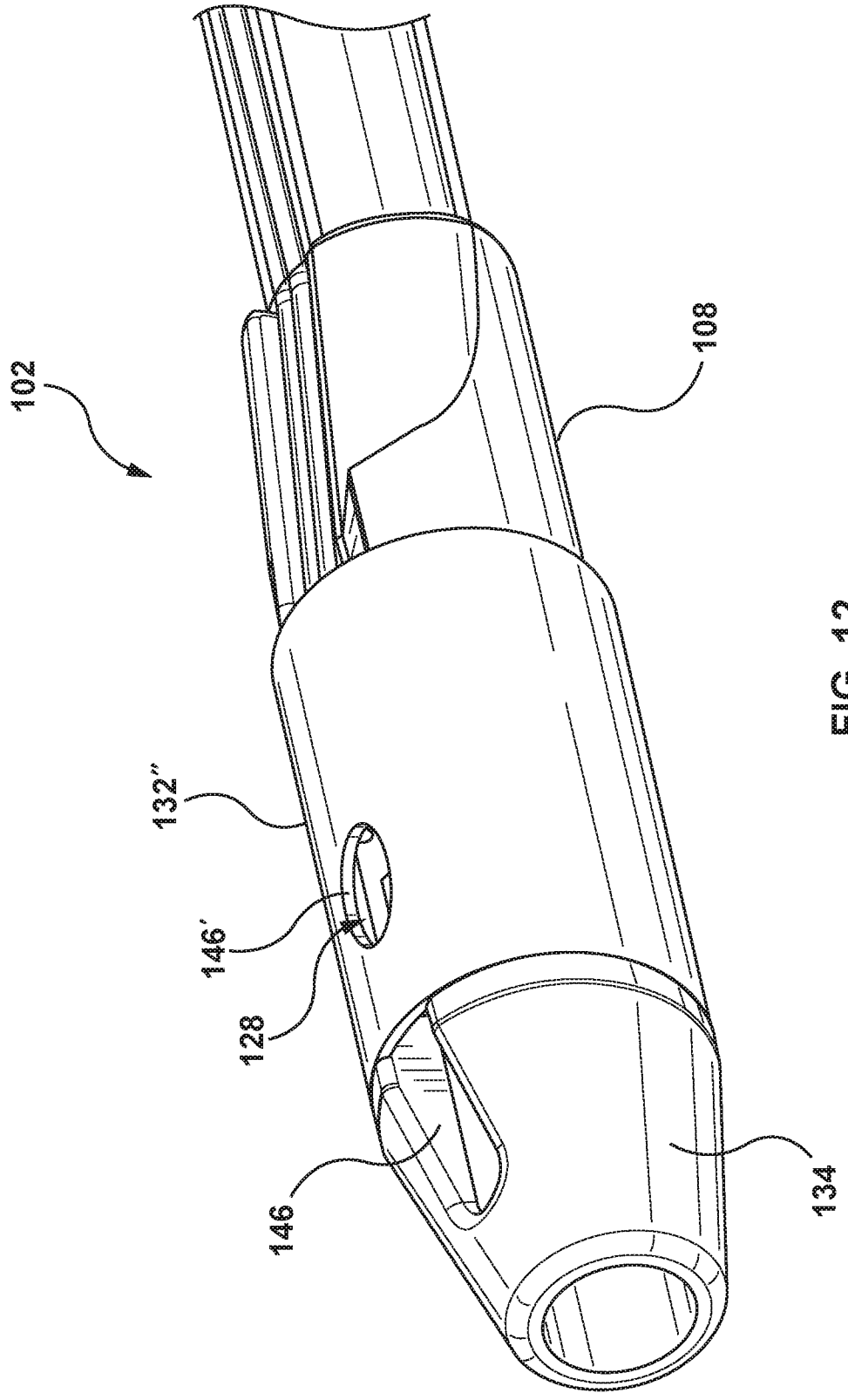

FIG. 12

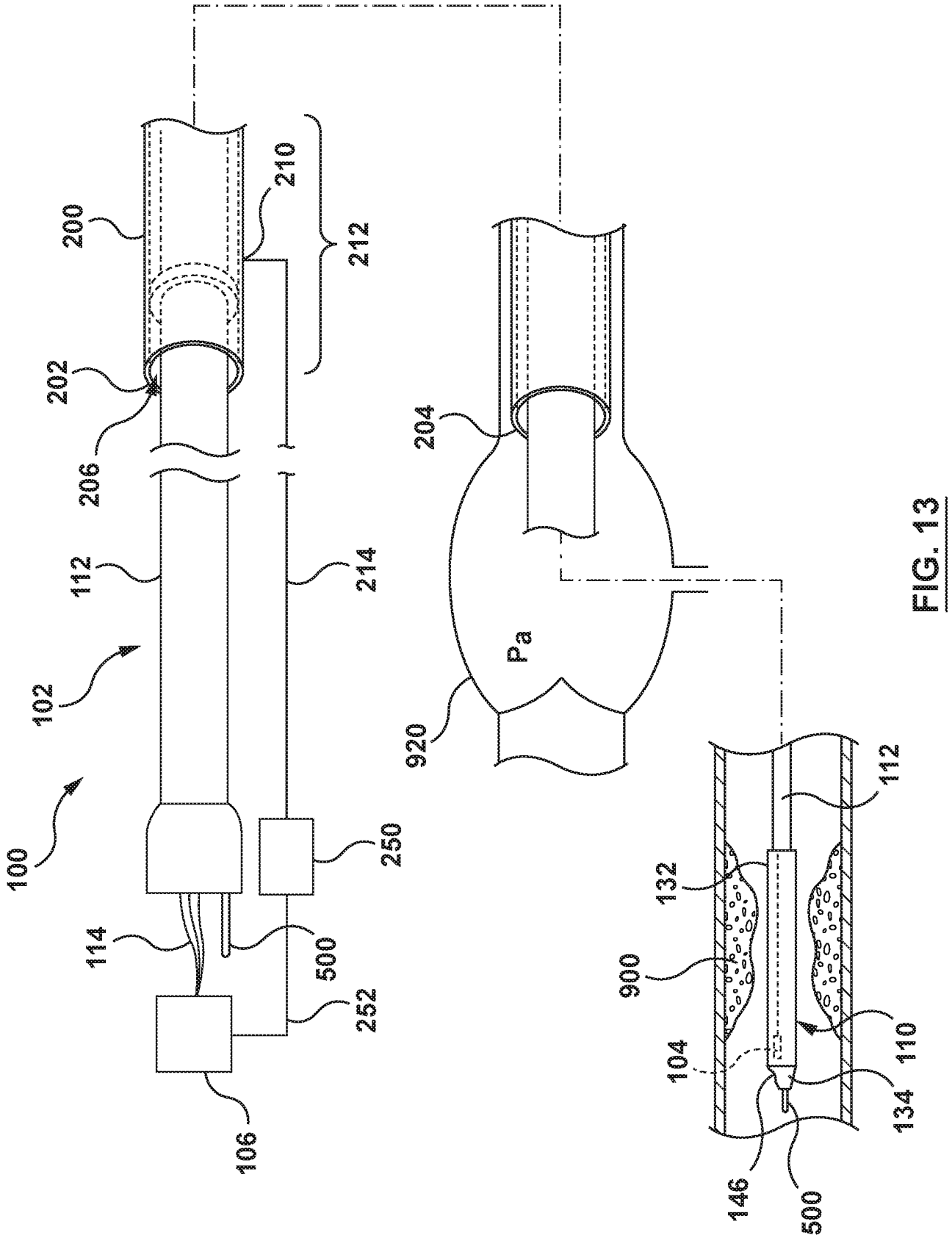
100
102
106
112
114
132
134
146
200
202
204
206
210
212
214
250
252
500
900
920
Pa
104
110

FIG. 13

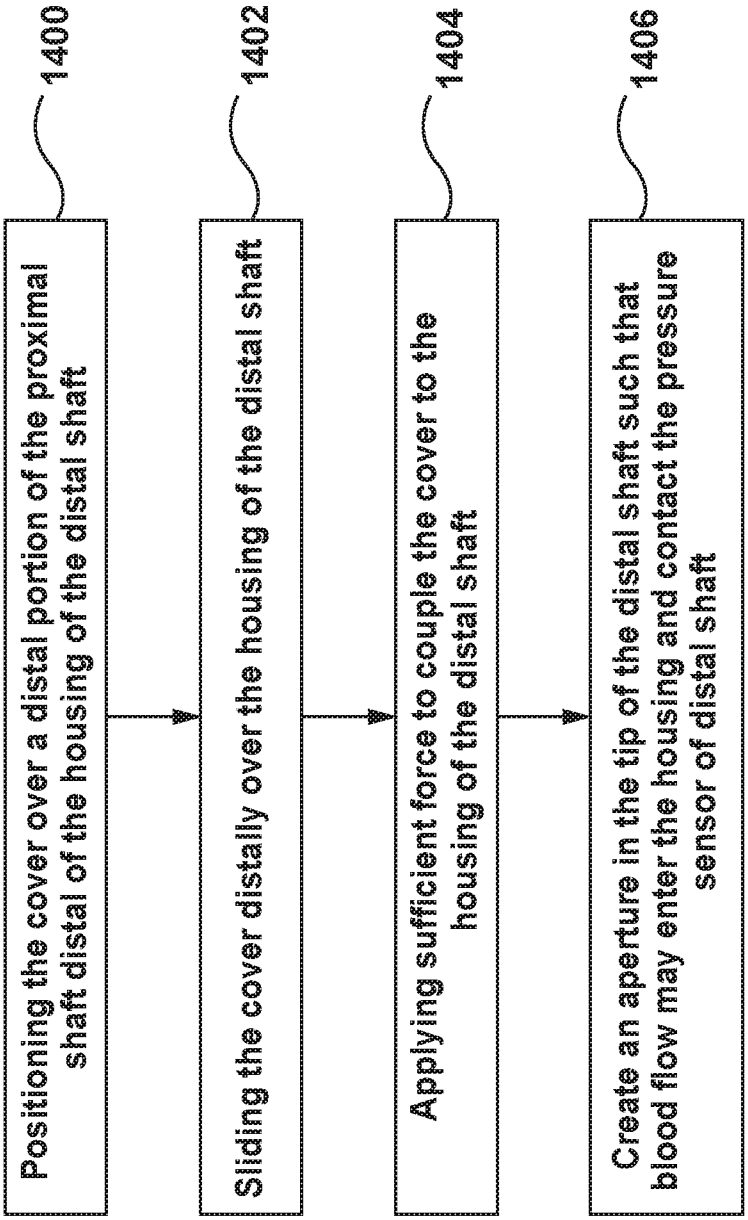
1400
Positioning the cover over a distal portion of the proximal shaft distal of the housing of the distal shaft
1402
Sliding the cover distally over the housing of the distal shaft
1404
Applying sufficient force to couple the cover to the housing of the distal shaft
1406
Create an aperture in the tip of the distal shaft such that blood flow may enter the housing and contact the pressure sensor of distal shaft

FIG. 14

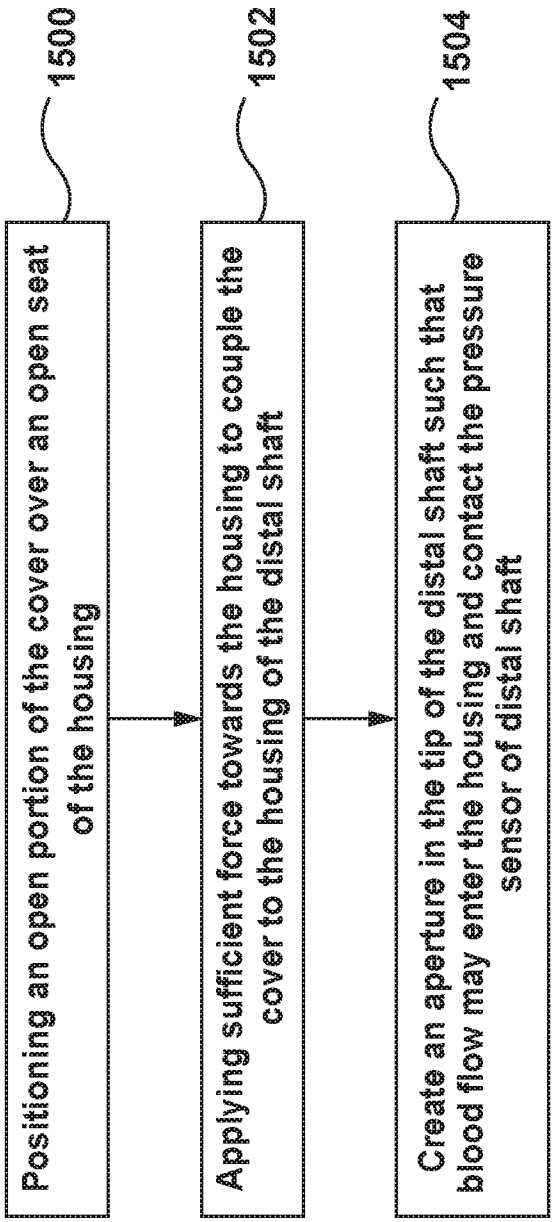
1500
Positioning an open portion of the cover over an open seat of the housing
1502
Applying sufficient force towards the housing to couple the cover to the housing of the distal shaft
1504
Create an aperture in the tip of the distal shaft such that blood flow may enter the housing and contact the pressure sensor of distal shaft

FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/029650

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/0215 A61B5/02
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

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 2016/249821 A1 (BOYE SHAWN [US] ET AL) 1 September 2016 (2016-09-01) paragraphs [0077], [0093] - [0097]; figure 7 -----	1-6, 12-19, 21,23-25
X	US 8 127 618 B1 (ZHAO YONG D [US] ET AL) 6 March 2012 (2012-03-06) column 6, lines 12-42; figure 1A column 7, line 60 - column 8, line 52; figure 3 column 12, line 6 - column 13; figure 10 ----- -/--	1,7-20, 22,23,25

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

[X] See patent family annex.

* Special categories of cited documents :

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"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

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"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
25 June 2018	03/07/2018

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	Sarcia, Regis

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/029650

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 106 476 A (CORL PAUL D [US] ET AL) 22 August 2000 (2000-08-22) column 9, lines 28-56; figures 14-15 column 7, line 39 - column 8, line 17 figure 4 the whole document	1,7-20, 22
A	US 2002/120200 A1 (BROCKWAY BRIAN [US] ET AL) 29 August 2002 (2002-08-29) paragraph [0078]; figure 4D	4,23
A	US 2015/196210 A1 (MCCAFFREY GERRY [IE] ET AL) 16 July 2015 (2015-07-16) paragraphs [00S2], [0021], [0026], [0030]; figures 1, 1D, 4	18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/029650

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016249821 A1	01-09-2016	EP 3261521 A1	03-01-2018
		JP 2018509207 A	05-04-2018
		US 2016249821 A1	01-09-2016
		WO 2016138226 A1	01-09-2016
US 8127618 B1	06-03-2012	US 8127618 B1	06-03-2012
		US 2012130219 A1	24-05-2012
US 6106476 A	22-08-2000	AU 3212895 A	27-03-1996
		CA 2198909 A1	14-03-1996
		DE 69534748 T2	02-11-2006
		EP 0778746 A1	18-06-1997
		EP 1658808 A1	24-05-2006
		JP 3619845 B2	16-02-2005
		JP H10505269 A	26-05-1998
		US 5715827 A	10-02-1998
		US 6106476 A	22-08-2000
		US 6767327 B1	27-07-2004
		US 2003018273 A1	23-01-2003
		US 2003040674 A1	27-02-2003
		US 2006094982 A1	04-05-2006
		US 2007135718 A1	14-06-2007
		US 2007149885 A1	28-06-2007
		US 2011251497 A1	13-10-2011
		WO 9607351 A1	14-03-1996
US 2002120200 A1	29-08-2002	AU 2002251973 A1	04-09-2002
		CA 2438394 A1	29-08-2002
		EP 1367934 A2	10-12-2003
		JP 4184795 B2	19-11-2008
		JP 2004532052 A	21-10-2004
		US 2002120200 A1	29-08-2002
		US 2005182330 A1	18-08-2005
		US 2008064966 A1	13-03-2008
		WO 02065894 A2	29-08-2002
US 2015196210 A1	16-07-2015	CN 106132294 A	16-11-2016
		EP 3094240 A1	23-11-2016
		US 2015196210 A1	16-07-2015
		WO 2015108733 A1	23-07-2015

专利名称(译)	具有覆盖的远端压力传感器的导管及其制造方法		
公开(公告)号	EP3614907A1	公开(公告)日	2020-03-04
申请号	EP2018725976	申请日	2018-04-26
[标]申请(专利权)人(译)	美敦力瓦斯科尔勒公司		
申请(专利权)人(译)	美敦力公司血管INC.		
当前申请(专利权)人(译)	美敦力公司血管INC.		
[标]发明人	MCCAFFREY GERRY WARD SEAN		
发明人	MCCAFFREY, GERRY WARD, SEAN		
IPC分类号	A61B5/00 A61B5/0215 A61B5/02		
CPC分类号	A61B5/02007 A61B5/0215 A61B5/02152 A61B5/02158 A61B5/6852 A61B2560/0406 A61B2560/0418 A61B2562/0247 A61B2562/12 A61B2562/16 A61B2562/168 A61B2562/187 A61B5/02028		
优先权	15/581309 2017-04-28 US		
外部链接	Espacenet		

摘要(译)

用于测量狭窄远侧压力的远侧轴包括壳体，压力传感器，盖，尖端和孔。 压力传感器安装在外壳中。 盖联接到壳体并且覆盖压力传感器。 尖端联接到壳体的远端。 孔穿过尖端和/或盖布置。 孔被配置为允许血液流到压力传感器。 盖还包括将盖联接至壳体的联接机构或联接器。 联接机构可以是卡扣配合机构，摩擦配合机构和/或粘合剂。