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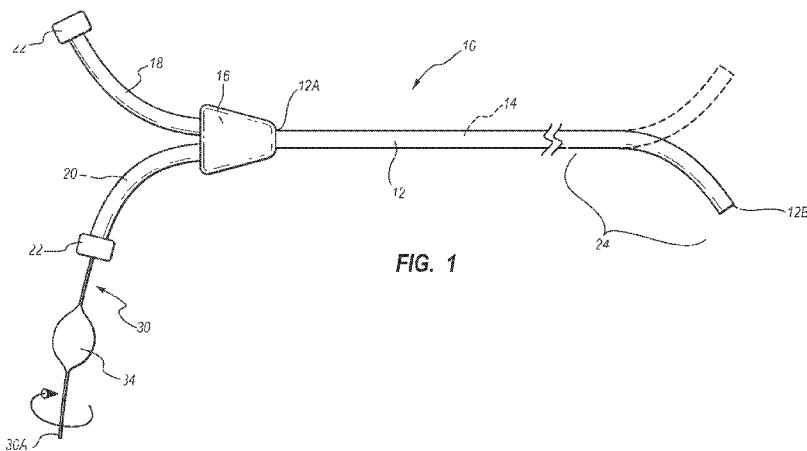
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## (54) Title: CATHETER ASSEMBLY INCLUDING ECG SENSOR AND MAGNETIC ASSEMBLIES

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(57) Abstract: A stylet for use in guiding a distal tip of a catheter to a predetermined location within the body of a patient. In one embodiment the stylet is configured for use within a lumen of the catheter and comprises a core wire, an ECG sensor, and a magnetic assembly. The ECG sensor senses an ECG signal of a patient when the stylet is disposed within the lumen of the catheter and the catheter is disposed within the body of the patient. The magnetic assembly includes at least one element capable of producing a magnetic or electromagnetic field for detection by a sensor external to the patient. In another embodiment, the stylet includes a pre-shaped distal segment that is deflected with respect to a more proximal portion of the stylet, which in turn causes a distal segment of the catheter to be deflected when the stylet is received within the lumen.

## CATHETER ASSEMBLY INCLUDING ECG SENSOR AND MAGNETIC ASSEMBLIES

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims the benefit of U.S. Provisional Patent Application No. 61/091,233, filed August 22, 2008, and entitled "Catheter Including Preloaded Steerable Stylet;" and U.S. Provisional Patent Application No. 61/095,451, filed September 9, 2008, and entitled "Catheter Assembly Including ECG and Magnetic-Based Sensor Stylet," each of which is incorporated herein by reference in its entirety.

### BRIEF SUMMARY

**[0002]** Briefly summarized, embodiments of the present invention are directed to a stylet for use in guiding a distal tip of a catheter to a predetermined location within the body of a patient. In one embodiment the stylet is configured for use within a lumen of the catheter and comprises a core wire, an ECG sensor, and a magnetic assembly. The ECG sensor senses an ECG signal of a patient when the stylet is disposed within the lumen of the catheter and the catheter is disposed within the body of the patient. The magnetic assembly includes at least one element capable of producing a magnetic or electromagnetic field for detection by a sensor external to the patient.

**[0003]** In another embodiment, the stylet includes a pre-shaped distal segment that is deflected with respect to a more proximal portion of the stylet, which in turn causes a distal segment of the catheter to be deflected when the stylet is received within the catheter lumen.

**[0004]** These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

### BRIEF DESCRIPTION OF THE DRAWINGS

**[0005]** A more particular description of embodiments of the invention will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The embodiments will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0006] FIG. 1 is a top view of a catheter assembly including a shaped, torqueable stylet according to one example embodiment of the present invention;

[0007] FIG. 2 is a top view of the stylet of FIG. 1;

[0008] FIG. 3A is a top view of a shaped distal portion of the stylet of FIG. 2, according to one possible configuration;

[0009] FIG. 3B is a top view of the shaped distal portion of the stylet of FIG. 2, according to another possible configuration;

[00010] FIG. 3C is a top view of the shaped distal portion of the stylet of FIG. 2, according to yet another possible configuration;

[00011] FIG. 3D is a top view of the shaped distal portion of the stylet of FIG. 2, according to still another possible configuration;

[00012] FIG. 4A is a top view of a catheter assembly including a stylet loaded therein and configured in accordance with one embodiment of the present invention;

[00013] FIG. 4B is a top view of the stylet of FIG. 4A, according to one embodiment;

[00014] FIG. 5 is a cross sectional view of a distal segment of the stylet of FIG. 4B, according to one embodiment;

[00015] FIGS. 6A-6F are various views of a stylet in accordance with another embodiment;

[00016] FIG. 7 is a cross sectional view of a distal segment of the stylet of FIG. 4B, according to another embodiment;

[00017] FIG. 8 is a partial cross sectional view of a distal segment of a stylet configured in accordance with one example embodiment;

[00018] FIG. 9 is a partial cross sectional view of a distal segment of a stylet configured in accordance with another embodiment;

[00019] FIG. 10 is a partial cross sectional view of a distal segment of a stylet configured in accordance with yet another embodiment;

[00020] FIG. 11 is a partial cross sectional view of a distal segment of a stylet and catheter configured in accordance with one embodiment;

[00021] FIG. 12 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment;

[00022] FIG. 13 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment;

[00023] FIG. 14 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment;

[00024] FIG. 15 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment;

[00025] FIG. 16 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment;

[00026] FIG. 17 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment;

[00027] FIG. 18 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment;

[00028] FIG. 19 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment;

[00029] FIG. 20 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment;

[00030] FIG. 21 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment; and

[00031] FIG. 22 is a cross sectional view of a distal segment of a stylet configured in accordance with one embodiment.

## **DETAILED DESCRIPTION OF SELECTED EMBODIMENTS**

**[00032]** Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the invention, and are not limiting of the present disclosure nor are they necessarily drawn to scale.

**[00033]** FIGS. 1-22 depict various features of embodiments of the present invention, which is generally directed, in one embodiment, to a catheter assembly including a pre-loaded stylet therein. In one embodiment, the catheter assembly includes a distal portion shaped in a bent configuration. The bent configuration of the catheter distal portion is caused by the pre-loaded stylet, which includes a pre-shaped distal segment deflected in a bent configuration. Thus, the pre-shaped distal segment of the stylet urges the distal portion of the catheter into a similar bent configuration.

**[00034]** Further, the pre-loaded stylet is configured to be torqueable, thus enabling the stylet to be rotatable within the catheter lumen. A hydrophilic coating applied to an outer surface of the stylet facilitates such stylet rotation. Rotation of the shaped stylet enables the pre-shaped distal segment to be changed in orientation. This in turn causes a change in orientation of the distal portion of the catheter to occur. Such "steerability" enables the catheter to be more easily guided through the vasculature of a patient during placement of the catheter.

**[00035]** In another embodiment, a stylet for use in guiding a distal tip of a catheter in which the stylet is disposed to a predetermined location within the vasculature of a patient is disclosed. The stylet includes a magnetic assembly proximate its distal tip for use with an external magnetic sensor to provide information relating to general positioning/orientation of the catheter tip during navigation through the patient vasculature. The stylet further includes an ECG sensor proximate its distal tip for use with an external ECG monitoring system to determine proximity of the catheter distal tip relative to an electrical impulse-emitting node of the patient's heart, such as the SA node in one example. Such electrical impulses are also referred to herein as "ECG signals." Inclusion of the magnetic and ECG sensors with the stylet enables the catheter to be guided with a relatively high level of precision to a predetermined location proximate the patient's heart.

[00036] For clarity it is to be understood that the word "proximal" refers to a direction relatively closer to a clinician using the device to be described herein, while the word "distal" refers to a direction relatively further from the clinician. For example, the end of a catheter placed within the body of a patient is considered a distal end of the catheter, while the catheter end remaining outside the body is a proximal end of the catheter. Further, the words "including," "has," and "having," as used herein, including the claims, shall have the same meaning as the word "comprising."

[00037] Reference is first made to FIG. 1, which depicts a catheter assembly, generally designated at 10 and configured in accordance with one example embodiment of the present invention. As shown, the catheter assembly 10 includes a catheter 12 having a proximal end 12A, a distal end 12B, and defining at least one lumen 14 extending therebetween. In the present embodiment, the catheter is a PICC, though in other embodiments other types of catheters, having a variety of size, lumen, and prescribed use configurations can benefit from the principles described herein. Further, though shown here with an open distal end, the catheter in other embodiments can have a closed distal end. As such, the present discussion is presented by way of example and should therefore not be construed as being limiting of the present invention in any way. Note that the catheter 12 can be formed from one or more of a variety of materials, including polyurethane, polyvinyl chloride, and/or silicone.

[00038] A bifurcation, or hub 16, can be included at the catheter proximal end 12A. The hub 16 permits fluid communication between extension tubing 18 and 20 and the lumen(s) 14 of the catheter 12. Each extension tubing component 18 and 20 includes on a proximal end a connector 22 for enabling the catheter assembly 10 to be operably connected to one or more of a variety of medical devices, including syringes, pumps, infusion sets, etc. Again note that the particular design and configuration of the afore-described components are exemplary only.

[00039] The catheter 12 includes a distal portion 24 as part of the catheter that is configured for insertion within the vasculature of a patient. As seen in FIG. 1, the distal portion 24 of the catheter 12 includes a deflected, bent configuration with respect to the more proximal portion of the catheter 12. As will be described further below, this bent configuration is caused by a stylet disposed within the catheter and facilitates relatively easier navigation and placement of the distal tip of the catheter in a preferred location within the patient vasculature.

[00040] Together with FIG. 1, reference is now made to FIG. 2. FIG. 1 further shows a stylet 30 extending from a proximal end of the extension tubing 20 and configured in accordance with one embodiment of the present invention. As shown in FIG. 2 removed from the catheter 12, the stylet 30 includes an elongate core wire that defines a proximal end 30A and a distal end 30B. The stylet 30 is pre-loaded within the lumen 14 of the catheter 12 such that the distal end 30B is substantially flush with the opening at the catheter distal end 12B, and such that the proximal portion of the stylet extends from the proximal end of the catheter or one of the extension tubes 18 and 20. Note that, though considered here as a stylet, in other embodiments a guidewire or other catheter guiding apparatus could include the principles of embodiments of the present disclosure described herein.

[00041] As mentioned, the body of the stylet 30 is configured as an elongate core wire and is composed of a memory material such as, in one embodiment, a nickel and titanium-containing alloy commonly known by the acronym "nitinol." Nitinol possesses characteristics that serve well in the present application, including shape memory and torqueability characteristics, as will be explained. In another embodiment, other suitable materials such as stainless steel could be used for the stylet construction. In yet another embodiment, it is appreciated that the distal segment can be manufactured from a memory material such as nitinol, while the more proximal portion of the stylet core wire is manufactured with stainless steel or other suitable material.

[00042] The stylet 30 further includes a distal segment 32 that is pre-shaped to have a bent configuration with respect to the more proximal portion of the stylet. In particular, the stylet distal segment 32 is bent off-axis with respect to a substantially linear longitudinal axis 36 of the stylet core wire in the view depicted in FIG. 2. Manufacture of the stylet 30 from a shape memory material such as nitinol enables the stylet to be configured such that the core wire retains the curved or other bent distal segment shape shown in FIG. 2 during use with the catheter assembly 10. The distal segment 32 is "pre-shaped" in that it is manufactured to possess a bent or offset configuration before its assembly and retains the configuration after insertion within the catheter 12.

[00043] The bent configuration of the distal segment 32 in the embodiment illustrated in FIG. 2 defines an arc or curve having a radius R. In other embodiments, however, the distal segment can be bent or offset from the more proximal portion of the stylet in other ways, such as in FIG. 3C, for example, where the distal segment is approximately linearly offset to

define an angle  $\theta$  with the longitudinal axis of the proximal portion of the stylet 30. Combinations of linear and curved bend profiles are also possible. These and other possible bent or offset configurations are therefore contemplated as falling within the claims of the present invention.

[00044] Reference is now made to FIG. 3A, which depicts further details of the stylet 30, according to one embodiment. As shown, the pre-shaped distal segment 32 includes a distal portion of the core wire having a diameter D2 that is reduced with respect to the diameter D1 of the more proximal portion of the core wire. The stylet core wire transitions from diameter D1 to D2 at a smooth, linear tapered transition region 40, though in other embodiments a stepped taper, convex or concave taper, or no taper need be present.

[00045] A tubing sleeve 42 is slid over the reduced diameter stylet core wire along the distal segment 32 and is sized to substantially match the diameter D1 of the proximal portion of the stylet core wire, though it can be sized differently, if desired. The sleeve 42 is adhered to the core wire near the transition region 40 and at the distal end 30B of the core wire by an adhesive 46, such as a UV, 2-part epoxy, or other suitable adhesive. So secured, an air gap 48 is created between an outer surface of the core wire and an inner surface of the sleeve 42. in other embodiments, the air gap can be enlarged, reduced, or eliminated.

[00046] In the present embodiment, the sleeve 42 includes reinforcement 44 to maintain the sleeve in a bent configuration similar to the bent configuration of the stylet distal segment core wire. The reinforcement 44 can be a metal coil or braided mesh or substrate that is integrated into the structure of the sleeve 42 and is capable of bending so as to assume and maintain a bent shape similar to that shown in FIG. 3A. Characteristics of the sleeve 42 that can be adjusted so as to modify its performance include its wall thickness, melt index, and composition. In the present embodiment, the sleeve 42 is composed of polyimide and the reinforcement 44 is coiled stainless steel. Of course, other suitable materials can be employed, either in lieu of or in combination with, these constituents. In other embodiments, the reinforcement can be configured so as to merely strengthen the sleeve and not maintain its bent configuration, or the reinforcement can be removed from all or a portion of the sleeve. In the latter case, a sleeve having no reinforcement can nevertheless be formed so as to have a pre-shaped, bent configuration. In any of the above embodiments, however, the sleeve can be configured to assist the distal segment 32 of the stylet core wire in urging the distal portion of

the catheter 12 into a similar bent configuration, as seen in FIG. 1 and as will be explained in further detail below.

[00047] As mentioned, the stylet 30 having a pre-shaped distal segment 32, such as that described in connection with FIG. 3A, is pre-loaded in one embodiment into the catheter 12 before insertion such that the distal segment resides within the lumen 14 at the distal portion 24 of the catheter, placing the distal tips of both the stylet and the catheter in substantial alignment with one another. Note that in other embodiments the distal tips of the stylet and catheter can be in a non-aligning configuration, if desired, and that the catheter can include multiple lumens. So positioned, the distal segment 32 of the stylet 30 imparts an urging force on the distal portion 24 of the catheter 12 such that the catheter distal portion assumes a bent configuration similar to that of the stylet distal segment. As such, it is appreciated that while the stylet 30 is loaded within the catheter 12, the distal portion 24 of the catheter takes on the bent configuration of the distal segment 32 of the stylet. Once the stylet 30 is removed, the catheter 12 is free to return to an unbent configuration commensurate with its original shape when manufactured.

[00048] The stylet 30 in one embodiment further includes on its outer surface a hydrophilic coating 38 to assist in rotating the stylet within the lumen 14 of the catheter 12 during use. The wettable coating 38 can be activated, for instance, by flushing the catheter lumen 14 with saline or other aqueous solution, thereby facilitating rotation of the stylet within the lumen. In other embodiments, no coating is included on the stylet. In yet other embodiments, the coating can be included on an inner surface of the catheter, or the composition of the catheter and stylet can be chosen such that a net low coefficient of friction exists between the two surfaces.

[00049] A handle 34 can be provided near the proximal end 30A of the stylet 30 so as to enable a user to rotate the stylet within the catheter lumen 14. Because the stylet 30 is at least partially composed of nitinol or other suitable material in one embodiment, the stylet is configured to be torqued by user application of a rotational force thereto via the handle 34. The handle 34 may take one of many shapes and configurations, including that shown in FIGS. 1 and 2, for example. Torqueability of the stylet 30, together with its hydrophilic coating 38, makes possible selective rotation of the stylet within the catheter lumen 14, which in turn enables selective rotation and orientation of the bent distal segment 32. As before mentioned, no coating may be necessary in one embodiment. In addition, the handle 34 is

attached to the stylet core wire so as to correspond with the orientation of the bent distal segment 32. Thus one can determine the orientation of the direction of bend of the distal segment 32 when the distal segment is disposed within the vasculature of a patient by observing the orientation of the handle 34. The handle 34 in one embodiment may include a visual guide or key thereon to assist the clinician in ascertaining the orientation of the bent distal segment 32.

[00050] As mentioned, the stylet distal segment 32, having a pre-shaped bent configuration, urges the distal portion 24 of the catheter into a similar bent configuration when the stylet 30 is received in the catheter lumen 14 as shown and described. Rotation of the stylet 30 within the catheter lumen 14 in the manner described above therefore causes a corresponding change in the orientation of the bent configuration of the catheter distal portion 24, shown for example in phantom in FIG. 1. Thus, the catheter distal portion 24 and its corresponding distal tip are "steerable" via torqueable rotation of the stylet 30 by a clinician grasping and turning the handle 34. Such steerability is desirous to enable the catheter distal tip to be navigated through the tortuous vasculature of a patient during placement of the catheter 12. Note that the distal segment 32 is sufficiently resilient to prevent trauma or damage to the vasculature during navigation therein.

[00051] In greater detail, with the handle 34 being oriented in a direction corresponding to the direction of bend in the stylet distal segment 32, the clinician placing the catheter within the patient vasculature can ascertain the orientation of the bent catheter distal portion 24, which is disposed within the vasculature during placement, by observing the orientation of the handle 34. The handle 34 therefore acts as a key in determining orientation of the bent configuration of the distal segment 34 of the stylet 30/distal portion 24 of the catheter 12. This aspect assists the clinician in placing the catheter 12 in the patient vasculature so as to place the distal tip of the catheter 12 in a predetermined position by advancing the catheter 12 with the pre-loaded stylet 30 therein. Once the catheter 12 has been placed as desired, the stylet 30 can be removed from the catheter lumen 14 and corresponding extension tubing 18/20 and the catheter prepared for use.

[00052] Reference is now made to 3B and 3C, which show aspects of other possible stylet distal segment configurations according to embodiments of the present invention. The distal segment 32 shown in FIG. 3B includes a reduced diameter core wire as in FIG. 3A, but includes no sleeve covering the distal core wire segment. The distal segment 32 shown in

FIG. 3C also includes no sleeve, but includes a core wire segment having a non-reduced diameter with respect to the proximal core wire portion. Thus, it is seen that various core wire diameters and omissions of the sleeve or other components may be intended while still residing within the scope of embodiments of the present invention.

[00053] Reference is now made to FIG. 3D, which shows yet another example of a stylet distal segment according to one embodiment. In particular, the stylet distal segment 32 of FIG. 3D includes a reduced diameter core wire , sleeve 42 having reinforcement 44, and air gap 48, as earlier described in connection with FIG. 3A. A plurality of magnets 60 is disposed in a portion of the air gap 48. The magnets 60 are employed in the distal segment to enable the distal segment 32 of the stylet 30 to be observable by an exterior tip location system configured to detect the magnetic field of the magnets as the stylet tip advances, together with the catheter distal tip, through the patient vasculature. In the present embodiment, the magnets 60 are ferromagnetic of a solid cylindrical shape, but in other embodiments they may vary from this design in not only shape, but composition, number, size, magnetic type, and position in the stylet distal segment. For instance, the magnetic assembly may include a single or multiple electromagnets disposed in the distal segment in a uni-polar or bi-polar design, in one embodiment.

[00054] Note that embodiments of the present disclosure may vary from what is explicitly described herein. For instance, differences in sleeve, air gap, and core wire grind may be present in a stylet distal segment so as to alter bend and resiliency characteristics thereof while still falling under the present claims.

[00055] FIGS. 4A-11 depict various features of further embodiments of the present disclosure, directed as before to a stylet for use in guiding a distal tip of a catheter in which the stylet is disposed to a predetermined location within the vasculature of a patient. The stylet includes a magnetic assembly proximate its distal tip for use with an external magnetic sensor to provide information regarding general positioning/orientation of the catheter tip during navigation through the patient vasculature. The stylet further includes an ECG sensor proximate its distal tip for use with an external ECG monitoring system to determine proximity of the catheter distal tip relative to an electrical impulse-emitting node of the patient's heart, such as the SA node in one example. Such electrical impulses are also referred to herein as "ECG signals." Inclusion of the magnetic assembly and ECG sensor

with the stylet enables the catheter to be guided with a relatively high level of precision to a predetermined location proximate the patient's heart.

[00056] Reference is first made to FIG. 4A, which depicts a catheter assembly, generally designated at 110 and configured in accordance with one example embodiment of the present invention. As shown, the catheter assembly 110 includes a catheter 112 having a proximal end 112A, a distal end 112B, and defining at least one lumen 114 extending therebetween. In the present embodiment, the catheter is a peripherally-inserted central catheter ("PICC"), though in other embodiments other types of catheters, having a variety of size, lumen, and prescribed use configurations can benefit from the principles described herein. Further, though shown here with an open distal end, the catheter in other embodiments can have a closed distal end. As such, the present discussion is presented by way of example and should therefore not be construed as being limiting of the present invention in any way.

[00057] A hub 116 is included at the catheter proximal end 112A. The hub 116 permits fluid communication between extension tubing 118 and 120 and the lumen(s) 114 of the catheter 112. Each extension tubing component 118 and 120 includes on a proximal end a connector 122 for enabling the catheter assembly 110 to be operably connected to one or more of a variety of medical devices, including syringes, pumps, infusion sets, etc. Again note that the particular design and configuration of the afore-described components are exemplary only. For instance, in one embodiment, the catheter need not include a hub or extension legs. The composition of the catheter in this and other embodiments described herein includes a suitable material, such as polyurethane, silicone, etc.

[00058] The catheter 112 includes a distal portion 124 configured for insertion within the vasculature of a patient. The catheter 112 is flexible so as to enable it to bend while being advanced through the patient vasculature.

[00059] Together with FIG. 4A, reference is now made to FIG. 4B. FIG. 4A further shows a stylet 130 extending from a proximal end of the extension tubing 120 and configured in accordance with one embodiment of the present invention. As shown in FIG. 4B, the stylet 130 as removed from the catheter 112 defines a proximal end 130A and a distal end 130B and generally includes a core wire 131, a handle 134, and a tether 135. The stylet 130 is pre-loaded within the lumen 114 of the catheter 112 in one embodiment such that the distal end 130B is substantially flush with the opening at the catheter distal end 112B, and such that

the proximal portion of the core wire 131, the handle 134, and the tether 135 are located proximal to the proximal end of the catheter or one of the extension tubes 118 and 120. Note that, though described herein as a stylet, in other embodiments a guidewire or other catheter guiding apparatus could include the principles of the present invention described herein.

[00060] The core wire 131 defines an elongate configuration and is composed of a suitable stylet material including stainless steel or a memory material such as nitinol in one embodiment. Though not shown here, manufacture of the core wire 131 from nitinol in one embodiment enables the portion of the core wire corresponding to a distal segment 132 of the stylet 130 to have a pre-shaped bent configuration, as has already been described.

[00061] Further, the nitinol construction lends torqueability to the core wire 131. Thus, the pre-shaped core wire distal segment 132, together with core wire torqueability, enables the distal segment of the stylet 130 to be manipulated while disposed within the catheter lumen 114 during catheter insertion, which in turn enables the distal portion 124 of the catheter 112 to be navigated through the vasculature during catheter insertion. In the presently illustrated embodiment, no pre-shaping of the stylet distal segment is shown.

[00062] Note also that the present stylet can be employed in a catheter placement system that employs one or more of ultrasound, magnetic-based stylet tip tracking, and ECG-based tip navigation/position confirmation technologies to accurately place a catheter in the vasculature of a patient. Details regarding aspects of an example of such a system are given below, and can also be found in U.S. Patent Application Publication No. 2009/0156926, entitled "Integrated System for Intravascular Placement of a Catheter," filed November 25, 2008; and U.S. Patent Application No. 12/426,175, entitled "Systems and Methods for Breaching a Sterile Field for Intravascular Placement of a Catheter," filed April 17, 2009, each which is incorporated herein by reference in its entirety.

[00063] A handle 134 is provided at a proximal end 131A of the stylet 130 so as to enable insertion/removal of the stylet from the catheter lumen 114. In embodiments where the stylet core wire 131 is torqueable, the handle 134 enables the core wire 131 to be rotated within the catheter lumen 114, such as when rotation of a pre-shaped distal segment 132 of the stylet 130 is desired to assist in navigating the catheter distal portion 124 through the vasculature of the patient. In this case, the handle 134 is attached to the stylet core wire so as to correspond with the orientation of the bent distal segment 132. Thus one can determine the orientation

of the direction of bend of the distal segment 132 when the distal segment is disposed within the vasculature of a patient by observing the orientation of the handle 134. The handle 134 may include a guide or key thereon to assist the clinician in ascertaining the orientation of the bent distal segment 132.

[00064] Rotation, insertion, and/or removal of the stylet 130 via the handle 134 is further facilitated in one embodiment by application of a hydrophilic coating 138 to an outer surface of the core wire 131 and accompanying sleeve to be described further below. The wettable hydrophilic coating 138 can be activated, for instance, by flushing the catheter lumen 114 with saline or other aqueous solution, thereby facilitating rotation of the stylet within the lumen. The handle 134 may take one of many shapes and configurations, including that shown in FIGS. 2, 4A, and 6A, for example. Note also that in an unbent configuration, the core wire 31 of the stylet 130 defines a substantially linear longitudinal axis 136.

[00065] In the present embodiment, the handle 134 attaches to a distal end of the tether 135. In the present embodiment, the tether 135 is a flexible, shielded cable housing a plurality of electrically conductive wires. The wires are electrically connected to components, to be discussed below, disposed in the distal segment 132 of the stylet 130, and as such, they provide a conductive pathway from the distal segment through to the proximal end 130A of the stylet, where an electrical connector 156 is attached. As will be explained, the electrical connector 156 can take one of many forms and is configured for operable connection to an external magnetic and/or ECG sensor device in assisting navigation of the stylet 130 and catheter 112 to a desired location within the patient vasculature. Note that in another embodiment, the stylet can be un-tethered and electrical connectivity with the stylet distal segment components can be achieved by attaching temporary clips at the handle where the electrical wires from such components exit the stylet, for instance.

[00066] Reference is now made to FIG. 5, which depicts further details of the stylet 130, according to one embodiment. As shown, the distal segment 132 includes a distal portion of the core wire 131 defining a diameter D2 that is reduced with respect to the diameter D1 of the more proximal portion of the core wire. The stylet core wire transitions from diameter D1 to D2 at a tapered transition region 140, though in other embodiments no taper need be present. The reduced diameter portion of the core wire lends desired stiffness and tensile properties thereto, though it is appreciated that in other embodiments no reduction in core wire diameter is necessary.

[00067] A sleeve 142 is slid over the reduced diameter stylet core wire along the distal segment 132 and is sized to substantially match the diameter D1 of the proximal portion of the stylet core wire. The sleeve 142 is adhered to the core wire near the transition region 140 and at the distal end 130B of the core wire by an adhesive 146, such as a UV, 2-part epoxy, or other suitable adhesive. So secured, an air gap 148 is created between an outer surface of the core wire and an inner surface of the sleeve 142. In other embodiments, the air gap can be enlarged, reduced, or eliminated.

[00068] In the present embodiment, the sleeve 142 includes reinforcement 144 to assist the core wire 131 in providing proper stylet distal end stiffness and, in cases where the distal segment of the stylet is pre-shaped in a bent configuration, to assist in maintaining the core wire in the bent configuration. The reinforcement 144 can be a metal coil or braided mesh or substrate that is integrated into the structure of the sleeve 142 and is capable of manipulation so as to assume and maintain a bent shape, if desired.

[00069] Characteristics of the sleeve 142 that can be adjusted so as to modify its performance include its wall thickness, melt index, and composition. In the present embodiment, the sleeve 142 is composed of materials including polyimide and the reinforcement 144 is coiled stainless steel. Of course, other suitable materials can be employed, either in lieu of or in combination with, these constituents. As mentioned, in embodiments of the present invention the reinforcement can be configured so as to merely strengthen the sleeve and not maintain a bent configuration as in FIG. 5, to maintain a bent configuration as in FIG. 6A, or the reinforcement can be removed from all or a portion of the sleeve.

[00070] The stylet distal segment 132 further includes an ECG sensor or sensor assembly, generally designated at 150, according to one embodiment. The ECG sensor assembly 150 enables the stylet, preloaded in the lumen 114 of the catheter 112 during patient insertion, to be employed in detecting an intra-atrial ECG signal produced by an SA or other node of the patient's heart, thus assisting in navigating the distal end 112B of the catheter to a predetermined location within the vasculature proximate the patient's heart. Thus, the ECG sensor assembly 150 serves as an aide in confirming proper placement of the catheter distal end 112B.

[00071] In the embodiment illustrated in FIG. 5, the ECG sensor assembly 150 includes a distal portion of the core wire 131, which is electrically conductive, as is the rest of the core wire. A conductive distal coil 152 is disposed about the distal portion of the core wire 131 adjacent the core wire distal tip 131B. The distal coil 152 is composed of a conductive material, such as stainless steel. A tip weld 154 is included on the core wire distal tip 131B to bond the distal coil 152 to the core wire distal tip 131B. The tip weld 154 further provides an atraumatic distal tip configuration for the core wire 131. In another embodiment, the distal coil 152 is configured so as to define a diameter equal to that of the tubing sleeve 142 and to define a constant diameter along the stylet length. In yet another embodiment, no coil is included.

[00072] Before catheter placement, the stylet 130 is preloaded into the lumen 114 of the catheter 112. Note that in one embodiment the stylet 130 is preloaded within the catheter lumen 114 before use such that the distal segment 132 of the stylet resides within the lumen at the distal portion 124 of the catheter, placing the distal tips of both the stylet and the catheter in substantial alignment with one another. Once the catheter has been introduced into the patient vasculature and is advanced toward the patient's heart, the distal portion of the core wire 131, being electrically conductive, begins to detect the electrical impulses produced by the SA node or other suitable node of the patient's heart. The distal coil 152 is included about the core wire distal tip 131B to increase the relative surface area of the core wire distal portion so as to improve reception of the electrical impulses from the SA node. Note that other structures could be provided to provide the same functionality. As such, the ECG sensor assembly 150 serves as a sensor or electrode for detecting the ECG heart signals. The elongate core wire 131 proximal to the core wire distal segment serves as a conductive pathway to convey the electrical impulses produced by the SA node and received by the ECG sensor assembly 150 away from the distal segment 132 of the stylet 130 to the tether 135.

[00073] An electrical wire or other suitable structure in the tether 135 conveys the signals to an ECG sensor module located external to the patient. The tether 135 is operably connected to the ECG sensor module via the electrical connector 156, or other suitable direct or indirect connective configuration. Monitoring of the ECG signal received by the external sensor module enables a clinician to observe and analyze changes in the signal as the catheter advances toward the SA node. When the received ECG signal matches a desired profile, the clinician can determine that the catheter distal end 112B has reached a desired position with

respect to the SA node. In one implementation, for example, this desired position lies within the lower one-third (1/3<sup>rd</sup>) portion of the superior vena cava ("SVC"). Once it has been positioned as desired, the catheter 112 may be secured in place and the stylet 130 removed from the catheter lumen 114.

[00074] In the present embodiment of FIG. 5, the distal segment 132 of the stylet 130 further includes a magnetic assembly, generally designated at 160. The magnetic assembly 160 in the illustrated embodiment includes a plurality of magnets 162 disposed in a portion of the air gap 148, and as such the magnets are interposed between an outer surface of the core wire 131 and an inner surface of the sleeve 142. In the present embodiment, the magnets 162 are ferromagnetic of a solid cylindrical shape stacked end-to-end, but in other embodiments they may vary from this design in not only shape, but also composition, number, size, magnetic type, and position in the stylet distal segment. In one particular embodiment, the magnets 162 include neodymium. In other embodiments, other rare-earth or alternative types of magnets or magnetic elements may be employed. In yet other embodiments, an electromagnet or other element capable of producing an electromagnetic field that can be externally detected and monitored may also be used.

[00075] The magnets 162 are employed in the stylet distal segment 132, preloaded within the lumen 114 of the catheter 112 during catheter placement within the patient's vasculature, to enable the position of the distal segment to be observable relative to a magnetic sensor placed in close proximity to the patient's body as part of an exterior tip location system. The tip location system is configured to detect the magnetic field of the magnets 162 as the stylet distal segment 132 advances, together with the catheter distal portion 124, through the patient vasculature. In this way, a clinician placing the catheter 112 is able to generally determine the location, orientation, and/or advancement of the catheter distal end 112B within the patient vasculature and detect when catheter malposition is occurring, such as advancement of the catheter along an undesired vein, for instance.

[00076] The ECG sensor assembly 150 and magnetic assembly 160 can work in concert in assisting a clinician in placing a catheter within the vasculature. Generally, the magnetic assembly 160 of the stylet 130 assists the clinician in generally navigating the vasculature from initial catheter insertion into the vasculature so as to place the distal end 112B of the catheter 112 in the general region of the patient's heart. The ECG sensor assembly 150 can then be employed to guide the catheter distal end 112B to the desired location within the

SVC by enabling the clinician to observe changes in the ECG signals produced by the heart as the stylet distal segment and its ECG sensor assembly approach the SA node. Again, once a suitable ECG signal profile is observed, the clinician can determine that the distal end of both the stylet 130 and catheter 112 have arrived at the desired location with respect to the patient's heart.

[00077] FIGS. 6A-6F depict the stylet 130 for use in a catheter, such as the catheter 110, according to one embodiment. As shown, the stylet 130 includes the core wire 131 attached to the handle 134, with the tether 135 extending proximally from the handle to the electrical connector 156 to enable interconnection with an external ECG sensor module or other suitable device for receiving ECG signals detected by the ECG sensor assembly of the stylet. Though not shown here, in one embodiment the stylet 130 can include a shaped distal portion as described in connection with FIGS. 1-3D above, such that a distal portion of the catheter is deflected when the stylet is preloaded therein. Note, however, that the discussion to follow applies to stylets including both shaped and non-shaped distal segments.

[00078] The stylet 130 shown in FIG. 6B includes the core wire 131 and the distal segment 132. As shown in FIGS. 6C and 6D, the core wire 131 reduces from a diameter D1 to a diameter D2 over a relatively longer transition region 140 than in the previous embodiment. The portion of the core wire 131 corresponding to the transition region 140 is disposed within the sleeve 142, which attaches to the core wire by the adhesive 146 in the manner shown in FIG. 6C. The air gap 148 is defined between the core wire 131 and the sleeve 142, as before. The reduced diameter portion of the core wire 131 is deflected from an axially central position in the sleeve to an offset position so as to extend adjacent to a portion of the inner surface of the sleeve 142, as shown in FIG. 6D. The core wire 131, in this deflected state, extends to its distal tip 131B, which corresponds to the distal end 130B of the stylet 130.

[00079] The deflected position of the core wire 131 provides space for the placement of a plurality of magnetic elements, in this case permanent magnets 162, along a portion of the length of the distal segment 132. As illustrated in FIGS. 6B, 6D, and 6E, 20 cylindrical permanent ferromagnetic magnets are placed end to end. Of course, the type, number, shape, and arrangement of the magnets or other magnetic elements could vary from what is depicted and described herein. So configured, the magnets 162 define the magnetic assembly 160 that enables the distal end 130B of the stylet 130 to be located via an external magnetic sensor

module during a procedure to place the catheter in the patient vasculature. For example, in one embodiment, the magnets 162 are employed in the stylet distal segment 132 to enable the position/orientation of the stylet distal end 130B to be observable relative to an external sensor placed on the patient's chest. As has been mentioned, the external sensor is configured to detect the magnetic field of the magnets 162 as the stylet advances with the catheter through the patient vasculature. In this way, a clinician placing the catheter is able to generally determine the location/orientation of the catheter distal end within the patient vasculature and detect when catheter malposition is occurring, such as advancement of the catheter along an undesired vein, for instance.

[00080] An electrically conductive epoxy 166 fills the hollow distal end of the sleeve proximate the stylet distal end 130B. The epoxy 166 is in electrical communication with the core wire 131 and serves to increase the relative surface area of the core wire 131 at the distal tip 131B thereof. So configured, the distal portion of the core wire 131 and conductive epoxy 166 define an ECG sensor, with the rest of the core wire defining a conductive pathway with respect to the sensor, thus enabling the location of the stylet distal end 130B and corresponding catheter distal end 112B to be positioned near the SA node of the patient's heart using an external ECG sensor module, in the manner as described above. Thus, the magnetic assembly and ECG sensor assembly both provide assistance in navigating a catheter or other indwelling device: the magnetic assembly by providing position/orientation data for the catheter, and the ECG sensor assembly providing proximity data for the catheter with reference to an ECG-signal emitting component, such as the SA node of the patient's heart. These modalities can be used exclusively of one another, successively, or in concert to aid in catheter advancement. Note that in one embodiment the conductive epoxy 166 can be rounded to provide a rounded stylet distal end 130B. In another embodiment, the conductive epoxy can be replaced by another conductive material such as stainless steel or other suitable metal, etc.

[00081] As a brief example of the use of the stylet magnetic and ECG sensor assemblies in assisting in the placement of a catheter, in one embodiment an external sensor is employed by a catheter placement system to detect a magnetic field produced by the magnetic elements of the stylet, which is removably predisposed within the lumen of the catheter during catheter insertion and advancement. The external sensor can be placed on the chest of the patient during catheter insertion to enable the magnetic field of the stylet magnetic elements,

disposed in the catheter as described above, to be detected during catheter transit through the patient vasculature. As the magnetic elements of the stylet magnetic assembly are co-terminal with the distal end of the catheter, detection by the external sensor of the magnetic field of the magnetic elements provides information to the clinician and enables the clinician to monitor the position/orientation of the catheter distal end during its transit. Such information can be displayed on a display unit of the catheter placement system for instance. In this way, a clinician placing the catheter is able to generally determine the location/orientation of the catheter distal end within the patient vasculature relative to the TLS sensor 50 and detect when catheter malposition, such as advancement of the catheter along an undesired vein, is occurring.

[00082] As described, the stylet further includes an ECG sensor as a sensing component for sensing ECG signals produced by the SA node. In one embodiment the ECG sensor of the stylet works in concert with reference and ground ECG electrodes placed on the skin surface of the patient. ECG signals detected by the stylet ECG sensor can be received by the external sensor referred to above or other suitable component of a catheter placement system, together with signals received by the reference and ground electrodes on the patient's skin. These data can be processed and monitored as the stylet-equipped catheter advances through the patient vasculature. In one embodiment, an electrocardiogram waveform is reproduced on the display using the ECG data. The clinician placing the catheter can monitor the ECG data to determine optimum placement of the distal tip of the catheter, such as proximate the SA node in one embodiment. In one implementation, monitoring of the magnetic assembly data are employed during initial advancement of the catheter through the patient vasculature, while the ECG sensor assembly data are monitored as the catheter approaches a desired final location near the heart, though other combinations of these modalities are also contemplated, including simultaneous use of both modalities in one embodiment.

[00083] Note that, in contrast to what is shown in FIGS. 6B-6E, the distal segment of the stylet can be configured such that it defines a constant outside diameter with respect to the more proximal portion thereof.

[00084] As has been previously mentioned, other types of magnetic elements, alternative to the permanent magnets described in connection with FIGS. 5 and 6A-6E, may be included with the stylet 130 to form a portion of the magnetic assembly 160 for enabling the position/orientation of the catheter distal end 112B to be generally determined during

vasculature navigation. FIG. 7 depicts an example of one such alternative, wherein an electromagnetic ("EM") coil 172 is employed in the magnetic assembly 160 of the stylet distal segment 132. The EM coil 172 is depicted in the present embodiment as a winding of conductive wire, such as insulated copper wire, wound about a portion of the distal core wire 131 in the air gap 148 within the sleeve 142. Note that the covering of the EM coil 172 by the sleeve 142 provides a secondary level of electrical isolation of electrical energy for the EM coil 172. The coil wire is electrically insulated in the present embodiment so as to prevent its interfering with the ECG signals carried by the core wire 131. Lead wires 174 operably connect with the EM coil 172 and extend proximally along the core wire 131, through the handle 134 and tether 135 to terminate at the connector 156. The lead wires 174 are disposed along the core wire 131 and the rest of the stylet 130 in a free floating, strain relief configuration in the present embodiment so as to prevent detachment thereof from the EM coil 172. A suitable power source can be operably coupled to the lead wires 174 to provide electricity to the EM coil 172.

[00085] When energized, the EM coil 172 produces an electromagnetic field that is detectable by an external sensor module in a manner similar to that described in connection with FIG. 5. Note that the relative strength of the field produced by the EM coil 172 is dependent on various factors including the length of the wire from which the coils are made, number of coil windings, and the thickness of the core wire 131 over which the coil is wound. As such, it is appreciated that the electromagnetic field of the EM coil 172 can be varied by altering these and other aspects of the magnetic assembly 160.

[00086] A stylet configured in accordance with yet another embodiment is shown in FIG. 8. The stylet 130 of FIG. 8 includes the ECG sensor assembly 150 and magnetic assembly 160, as before. In contrast to the previous embodiment, the EM coil 172 is not disposed within the sleeve 142. Rather, a distal end of the sleeve 142 terminates at and abuts a proximal end of the EM coil 172. The lead wires 174 for the EM coil 172 are fed through the hollow interior of the sleeve 142 to the handle and tether.

[00087] The ECG sensor assembly 150 is disposed proximally of the magnetic assembly 160 and has a configuration differing from previous embodiments. As shown, the ECG sensor assembly 150 here includes two ECG leads 182. Each ECG lead 182, defining an annular band is disposed about a portion of an outer surface of the sleeve 142 is operably connected to a respective ECG lead wire 174. Each of the ECG lead wires 174 extends

through the hollow interior of the sleeve 142 to the handle and tether, terminating at the electrical connector 156 or other suitable termination. As has been explained, the ECG leads 182 operably connect with an external ECG sensor module, via the lead wires 174 and connector 156, to enable the catheter distal end 112B to be navigated through a patient's vasculature to a predetermined location proximate the heart of the patient. The stylet 130 further includes an atraumatic tip 188 of epoxy, UV adhesive, or other suitable material.

[00088] Note that the annular band structure of the ECG leads of FIG. 8 are merely one example of leads that can be included with the stylet/catheter assembly to enable ECG signals produced by the heart to be detected and forwarded to an external ECG sensor module. As such, the depictions and accompanying descriptions herein should not be considered limiting of embodiments of the present invention in any way. Note also that the number and position of the ECG leads on the stylet or catheter can vary from what is shown and described herein.

[00089] FIGS. 9-11 depict additional possible embodiments of the stylet 130 and catheter assembly 110. In FIG. 9, the stylet distal segment 132 includes the magnetic assembly 160 and ECG sensor assembly 150 as in FIG. 8. In contrast to FIG. 8, however, the ECG lead wires 184 are encapsulated within the wall of the sleeve 142 to provide strain relief for the lead wires and to facilitate ease of manufacturability. Such a configuration also frees up relatively more space in the central portion of the stylet. FIG. 10 shows an embodiment similar to that of FIG. 9, with the sleeve 142 being extended over the EM coil 172 so as to substantially cover the entirety of the stylet distal segment 132.

[00090] In FIG. 11, the stylet 130 is shown disposed in the lumen 114 of the catheter 112 and including the sleeve 142 and magnetic assembly 160 in a configuration similar to that shown in FIG. 8. In the present embodiment, however, the ECG sensor assembly 150 is not included on the stylet 130, but rather includes the ECG leads 182 disposed on the catheter itself. Particularly, the ECG leads 182 are integrated into the wall of the catheter such that an outer surface of each lead is exposed at the outer surface of the catheter. This configuration enables the ECG leads 182 of the ECG sensor assembly 150 to serve as electrodes in the manner previously described, but on a catheter having a closed distal end as shown in FIG. 11. The ECG lead wires 184 are electrically connected to the ECG leads 182 and disposed within the wall of the catheter itself so as to extend proximally to an external ECG sensor module or other suitable device.

[00091] Thus, placement of the ECG leads 182 at an outer catheter surface as shown in FIG. 11 enables the leads to act as electrodes and be in continual contact with the blood present in the vasculature of the patient, which blood serves as a conducting medium for the ECG signal from the heart. Note that in previous embodiments, the ECG leads disposed on the stylet itself are in contact with the blood most often via a catheter having an open proximal end. Again, it should be noted that the embodiments depicted in FIGS. 8-11 are exemplary of the various possible configurations for the stylet and its magnetic and ECG sensor assemblies, and that the type, size, and number of elements of these components may be varied as one skilled in the art will appreciate. For instance, the ECG sensor can be included on a stylet without the magnetic assembly present in one embodiment.

[00092] Attention is now directed generally to FIGS. 12-22, which depict further examples of the distal segment 132 of the stylet 130 including both magnetic and sensor assemblies, according to present embodiments. In FIG. 12, the distal segment 132 includes the tubing 142 inside which is disposed a distal portion of the core wire 131, terminating at the core wire distal end 131B. The magnetic assembly 160, including a plurality of permanent magnets 162 or other suitable magnetic/electromagnetic elements, is disposed distally to the core wire 131, though other positional configurations for the magnetic assembly are possible. A conductive wire 190 proximally extends within the tubing 142 from the stylet distal end 130B to the proximal end of the stylet for connection with a suitable ECG sensor module or other suitable monitoring device. A distal end 190B of the conductive wire 190 is substantially co-terminal with the stylet distal end 130B, though other more proximal terminating configurations are also possible. A conductive epoxy 166 is included at the distal end of the tubing 142 to secure the conductive wire distal end 190B and increase the conductive surface area for ECG signal monitoring by the ECG sensor, implemented here as the distal portion of the conductive wire 190. Of course, other suitable tip configurations can be used, including atraumatic tips, tip welds, non-conductive adhesives, or nothing at all. In another embodiment, the conductive wire can be embedded within the tubing and is exposed only at the distal end of the stylet.

[00093] The embodiment of FIG. 13 is similar to that of FIG. 12, wherein the conductive wire 190 does not extend the length of the stylet 130 but rather is connected at a proximal end 190A thereof to the core wire 131. Thus the conductive pathway from the conductive wire distal end 190B, which serves as the ECG sensor, is established by the lengths of both the

conductive wire 190 and the core wire 131. The conductive wire proximal end 190A can be secured to the core wire via a weld, adhesive, etc. This embodiment may be used, for example, where the tubing 142 does not proximally extend the entire length of the stylet 130, but rather only along the distal segment thereof. Indeed, in the embodiments described herein, the tubing can extend along all or only a portion of the stylet length.

[00094] In FIG. 14, a conductive coil 194 proximally extends within the tubing 142 and about the magnetic assembly 160 from the stylet distal end 130B to a connection point with the core wire 131 at the proximal end 194A of the coil. The conductive coil proximal end 194A can be secured to the core wire 131 via a weld, adhesive, etc. A distal end 194B of the conductive coil 194 is substantially co-terminal with the stylet distal end 130B, though other more proximal terminating configurations are also possible. A conductive epoxy 166 is included at the distal end of the tubing 142 to secure the conductive coil distal end 194B and increase the conductive surface area for ECG signal monitoring by the ECG sensor, implemented here as the distal portion of the conductive coil 194. In other embodiments, the conductive epoxy or other suitable material can extend a greater or lesser distance into the tubing 142 than what is shown in the accompanying drawings. In another embodiment, the conductive coil can proximally extend the length of the stylet 130 for connection with a suitable ECG sensor module or other suitable monitoring device. In yet another embodiment, a distal portion of the core wire can be shaped, such as via grinding, then coiled to form a conductive coil that is integral to the core wire.

[00095] In FIG. 15, the tubing 142 can be made electrically conductive, such as via impregnation therein of a conductive material, or by coating an inner or outer surface thereof with a conductive material. Thus a distal portion of the tubing 142 at the distal end 130B of the stylet 130 serves as an ECG sensor and more proximal portions of the tubing define a conductive pathway for carrying the ECG signals therefrom.

[00096] In FIG. 16, internal tubing 198 can be included within the tubing 142 of the stylet distal segment 132 as part of an ECG sensor assembly. In the present embodiment, a proximal end 198A of the internal tubing 198 is attached to a portion of the core wire 131 via heat-shrinking, adhesive, etc., while a distal end 198B is substantially co-terminal with the stylet distal end 130B or is in intimate contact with the conductive epoxy 166 so as to enable the reception of ECG signals for transmission along the internal tubing 198 and core wire 131 to a suitable ECG sensor module external to the patient, as has been described.

[00097] In FIG. 17, the tubing 142 from earlier embodiments is replaced with a conductive tubing structure, such as a metallic hypotube 202, which attaches to the core wire 131 at a proximal end 202A and extends to the stylet distal end 130B of the stylet 130 where its distal end 202B contacts the conductive epoxy 166. The hypotube 202 can include perforations 204, such as horizontal, vertical, round, or helical notches or through-holes completely or partially defined through the hypotube surface so as to increase flexibility of the hypotube.

[00098] Note that, in this and other embodiments, the conductive epoxy 166 or other tip configuration, such as atraumatic tips, adhesives, tip welds, etc., can be suitable shaped as seen in FIG. 17 so as to ease advancement of the catheter and stylet through patient vasculature. In one embodiment for example, the conductive epoxy tip can be replaced by a tip including stainless steel, either pre-formed before attachment, *e.g.*, via welding, adhesive, etc., to the stylet distal end or shaped after attachment. Such a tip can be attached directly to the stylet core wire, to another conductive wire in the stylet, or to another ECG sensor configuration.

[00099] FIG. 18 shows another tubing embodiment, wherein the tubing is defined by a conductive external coil 208, attached at a proximal end 208A thereof and extending to a distal end 208B, which is in contact with the conductive epoxy 166 at the stylet distal end 130B. A safety wire 210 can be included so as to extend between a distal portion of the core wire 131 and the distal tip epoxy 166 so as to prevent separation of the external coil 208 from the stylet 130. In another embodiment, the safety wire can be replaced with internal tubing that is disposed about the magnetic assembly 160.

[000100] In FIG. 19, the conductive epoxy 166 extends proximally from the distal end 130B of the stylet 130, contained by the tubing 142, so as to be in electrical communication with the core wire 131. Thus, a distal portion of the conductive epoxy 166 serves as an ECG sensor, while more proximal portions thereof provide a conductive pathway, together with the core wire, to enable the transmission of ECG signals through the stylet 130. Note that in another embodiment, the tubing can extend the length of the stylet.

[000101] In FIG. 20, an annular conductive ring 214 is included as an ECG sensor at the stylet distal end 130B and is connected to a lead wire 216 that extends proximally along the length of the stylet 130 for connection with a suitable ECG sensor module or other suitable

device. The ring 214 can be inset into the tubing 142 and can be in electrical communication with the conductive epoxy 166. As before, the conductive epoxy can be omitted from the design. In another embodiment, the lead wire 216 can be electrically connected to the core wire instead of extending the entire length of the stylet.

[000102] In FIG. 21, a conductive coil 218 is positioned distal to and attached to the tubing 142. A tip weld 154 is formed on the stylet distal end 130B so as to electrically connect with the conductive coil 218. The conductive wire 190 extends distally from the core wire 131 to the tip weld 154 as shown in FIG. 21, or to the conductive coil 218. In another embodiment, the conductive wire can extend the length of the stylet. In yet another embodiment, the conductive coil can be replaced by a conductive hypotube, if desired, which can act as filler material for the plasma weld that forms the tip weld 154.

[000103] In FIG. 22, the core wire 130 includes a distal tip 131B that defines an atraumatic tip configuration, with the conductive epoxy 166 included to secure the distal tip to the tubing 142. Such a core wire distal tip can be formed by grinding, plasma welding, etc., and provides an ECG sensor with relatively large surface area for reception of ECG signals.

[000104] It is noted that in example embodiments, distal tips can be formed by a variety of procedures, including grinding or plasma welding as discussed in connection with FIG. 22, insertion and adhesion to the stylet of an already formed tip, insertion of a conductive slug into the stylet tubing that is then melted and formed with a die, etc. It should be further noted that the embodiments shown in the previously described drawings are merely examples of possible configurations for providing a magnetic assembly and an ECG sensor with a stylet for guidance of a catheter or other indwelling device within the body of a patient. As such, the claims of the present disclosure should not be construed as being limited to only those embodiments explicitly described herein.

[000105] Embodiments of the present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the present disclosure is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

CLAIMS

1. A catheter assembly, comprising:
  - a catheter defining at least one longitudinally extending lumen; and
  - a stylet including a pre-shaped distal segment that is deflected with respect to a longitudinal axis of a portion of the stylet proximal to the distal segment, the pre-shaped distal segment of the stylet causing a distal segment of the catheter to be deflected with respect to the longitudinal axis when the stylet is received within the at least one lumen.
2. The catheter assembly as defined in claim 1, wherein the stylet includes a memory shape material, and wherein the pre-shaped distal segment of stylet defines an arc shape.
3. The catheter assembly as defined in claim 2, wherein the stylet includes nitinol, and wherein the stylet further includes a handle to axially rotate the stylet, wherein axial rotation of the stylet causes the pre-shaped distal segment to axially rotate.
4. The catheter assembly as defined in claim 1, wherein the stylet includes a core wire, wherein the pre-shaped distal segment includes the core wire, and wherein the distal segment of the core wire defines a reduced diameter with respect to portions of the stylet proximal thereto.
5. The catheter assembly as defined in claim 1, wherein the longitudinal axis of the stylet is substantially linear.
6. A stylet for use within a longitudinally extending lumen of a catheter, the stylet comprising:
  - an elongate core wire;
  - an ECG sensor for sensing an ECG signal of a patient when the stylet is disposed within the lumen of the catheter and the catheter is disposed within a body of the patient; and
  - a magnetic assembly including at least one element capable of producing a magnetic or electromagnetic field for detection by a sensor external to the patient.

7. The stylet as defined in claim 6, wherein the ECG sensor is in operable communication with a conductive pathway for passing the ECG signal externally with respect to a patient when the catheter is disposed within a patient.

8. The stylet as defined in claim 7, wherein the ECG sensor includes a distal portion of the core wire, and wherein the conductive pathway includes portions of the core wire proximal to the distal portion.

9. The stylet as defined in claim 6, wherein the stylet further includes a tubing portion covering a portion of the core wire.

10. The stylet as defined in claim 9, wherein the ECG sensor includes at least one of the following: an annular ring disposed on the tubing portion of the stylet; and a conductive epoxy, at least a portion of the conductive epoxy being covered by the tubing portion.

11. The stylet as defined in claim 6, wherein the tubing portion defines at least a portion of the ECG sensor.

12. The stylet as defined in claim 9, wherein the tubing portion includes a conductive coil that covers at least a portion of the magnetic assembly.

13. The stylet as defined in claim 6, wherein the ECG sensor includes a conductive wire that is separate from the core wire.

14. A method of guiding a catheter internally within a patient, the catheter defining at least one lumen in which a stylet including a magnetic assembly and an ECG sensor is removably disposed, the method comprising:

introducing the catheter with the stylet disposed therein into the patient body;  
detecting data relating to the magnetic assembly by an external sensor during advancement of the catheter within the patient body; and

monitoring ECG signals sensed by the ECG sensor of the stylet during advancement of the catheter so as to position the catheter in a desired location within the patient.

15. The method of guiding as defined in claim 14, wherein monitoring ECG signals further comprises:

monitoring ECG signals sensed by the ECG sensor of the stylet during advancement of the catheter through a vasculature of the patient so as to position the catheter proximate an SA node of the heart of the patient.

16. The method of guiding as defined in claim 14, further comprising:

withdrawing the stylet from the at least one lumen of the catheter after the catheter has been positioned in a desired location.

17. A catheter assembly, comprising:

a catheter defining a lumen; and

a stylet for removable placement in the lumen, the stylet comprising:

a core wire including a distal segment, the portion of the core wire distal segment defining a reduced diameter with respect to the core wire proximal to the distal segment, the core wire capable of sensing an ECG signal of the patient when the stylet is disposed within the lumen of the catheter and the catheter is disposed within a vasculature of the patient;

a tubing portion covering the distal segment of the core wire, the tubing portion being attached to the core wire; and

at least one magnetic element included adjacent the core wire distal segment and covered by the tubing portion.

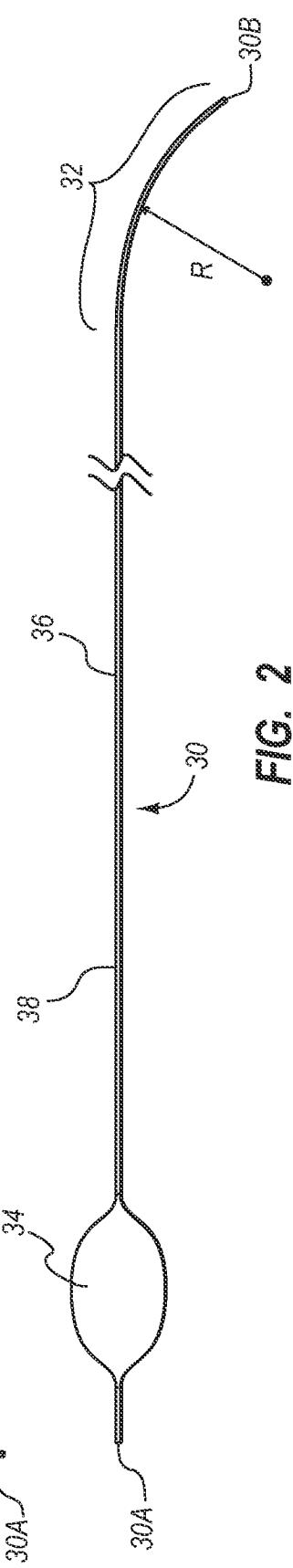
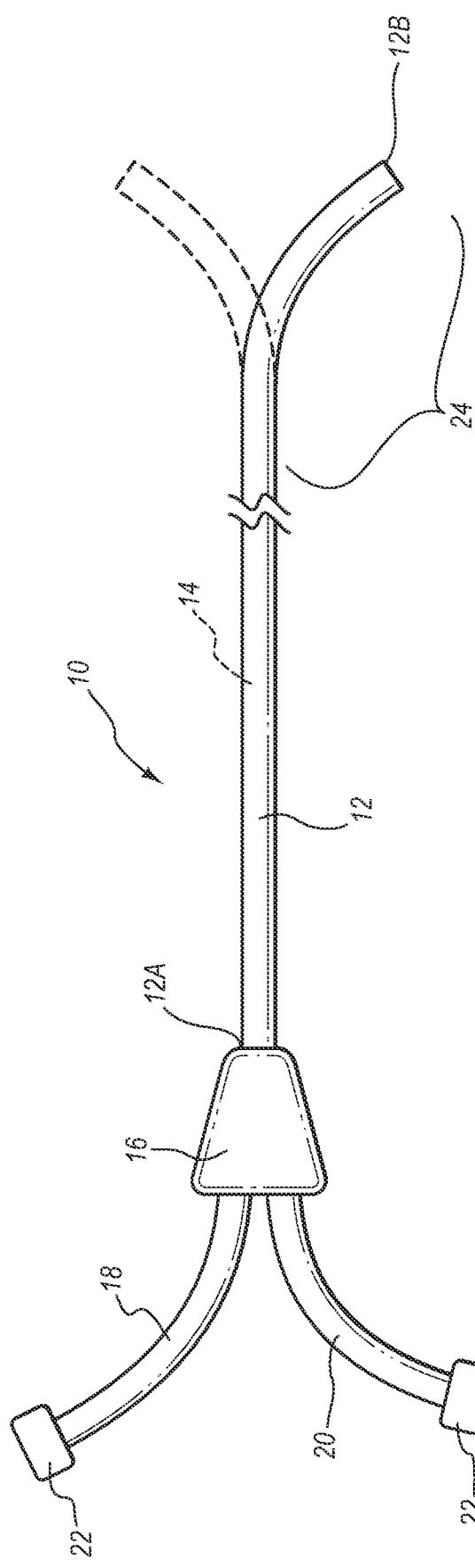
18. The catheter assembly as defined in claim 17, wherein the core wire includes nitinol and a hydrophilic coating, and wherein the catheter assembly further comprises:

an electrically conductive feature included at a distal end of the sleeve, the electrically conductive feature in electrical communication with the core wire to enable the electrically conductive feature to detect an electrical impulse from a heart of a patient when a distal portion of the stylet is disposed within a vasculature of the patient.

19. The catheter assembly as defined in claim 18, wherein the at least one magnetic element includes a plurality of permanent magnets interposed between the core wire and the tubing portion, and wherein the electrically conductive feature includes a conductive metal, an epoxy, and a tip weld material.

20. The catheter assembly as defined in claim 19, wherein a distal end of the core wire extends substantially to a distal end of the stylet, wherein the electrically conductive feature includes a conductive epoxy that is electrically connects proximate the distal end of the core wire, and wherein the core wire defines a conductive pathway for the passage of the ECG signal to a point exterior to the catheter.

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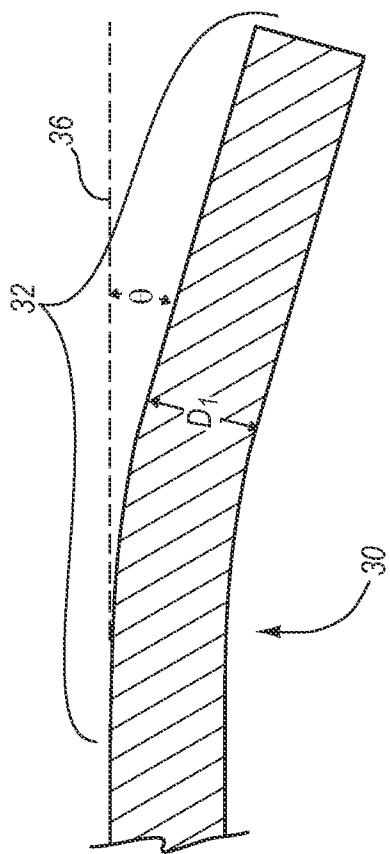


FIG. 3C

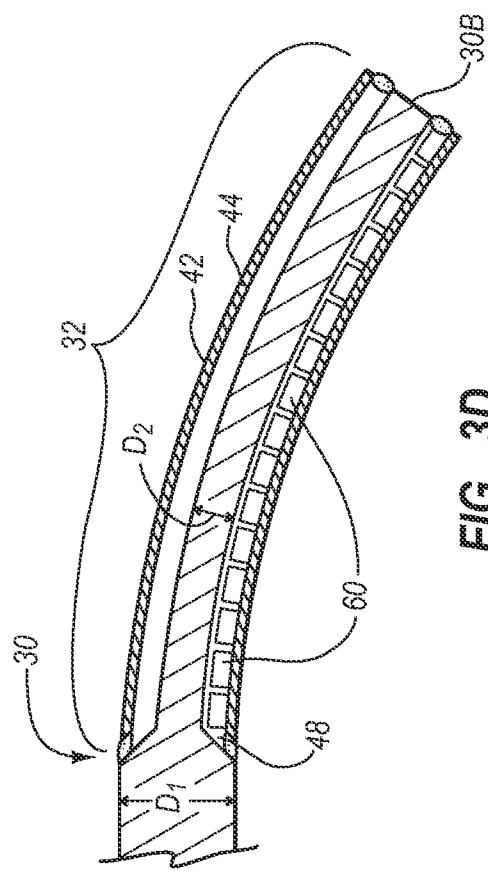


FIG. 3D

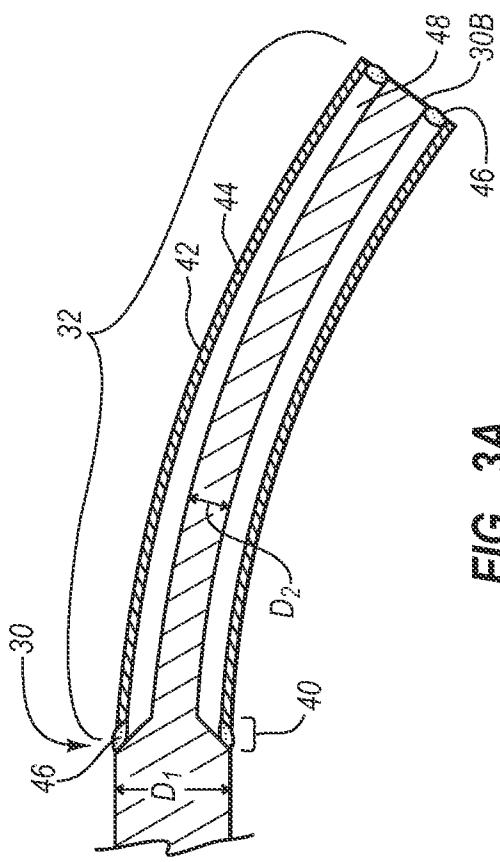


FIG. 3A

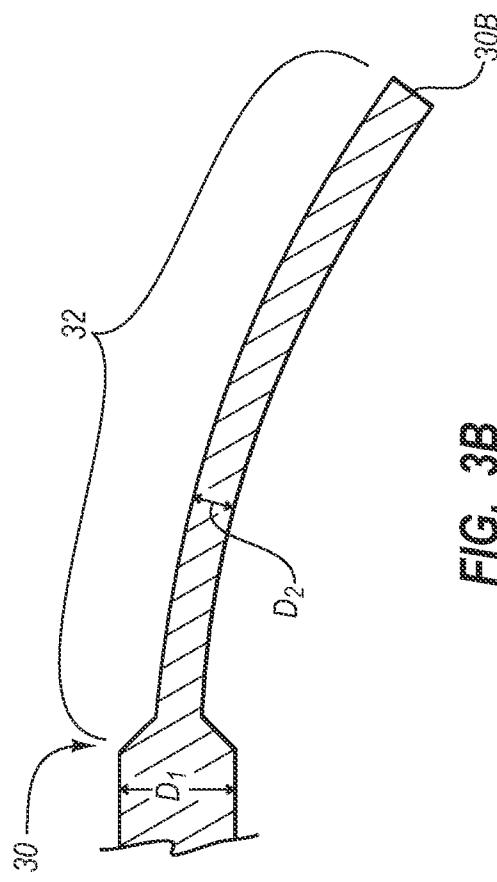


FIG. 3B

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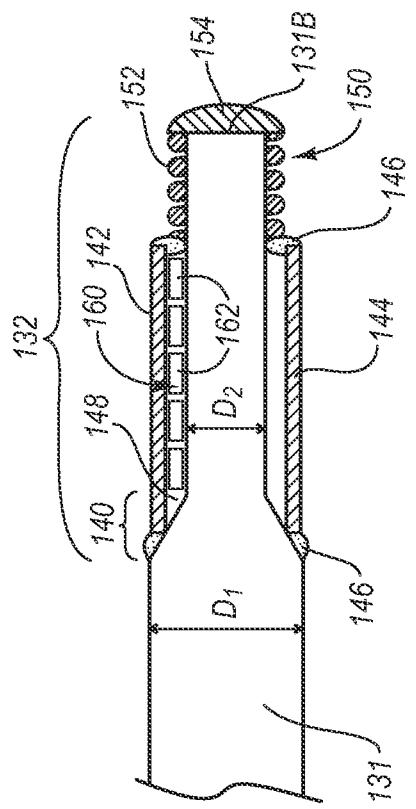


FIG. 5

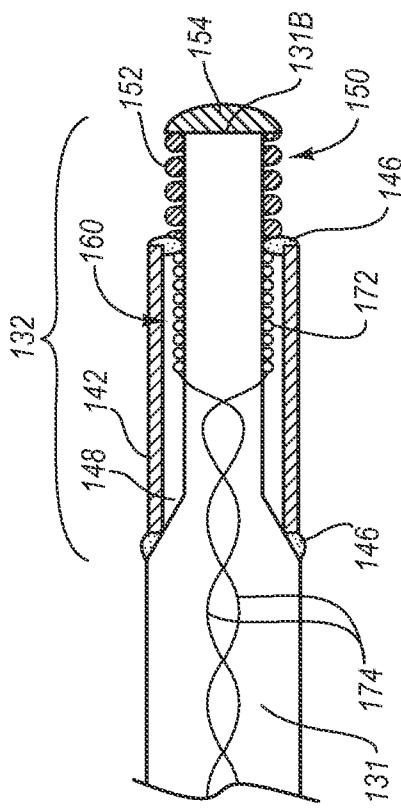


FIG. 7

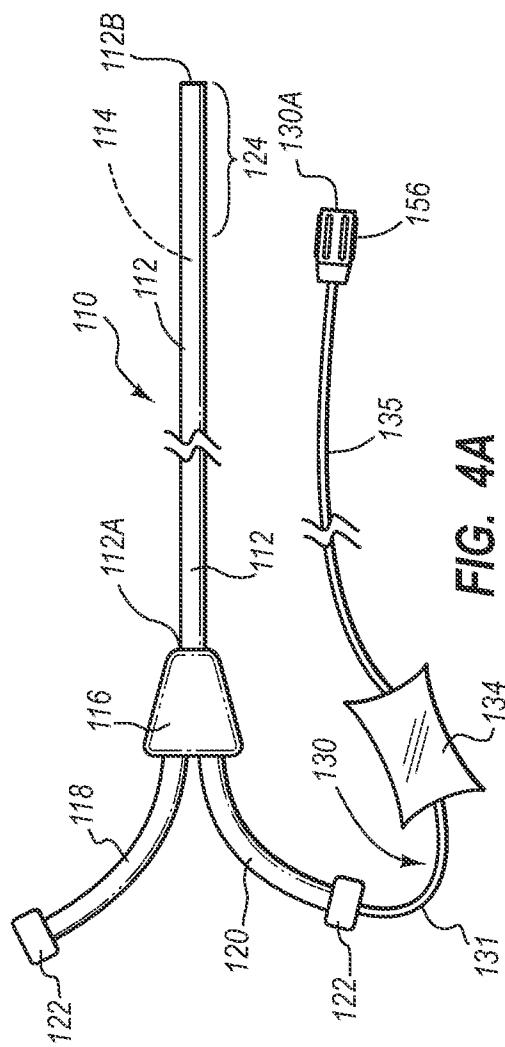


FIG. 4A

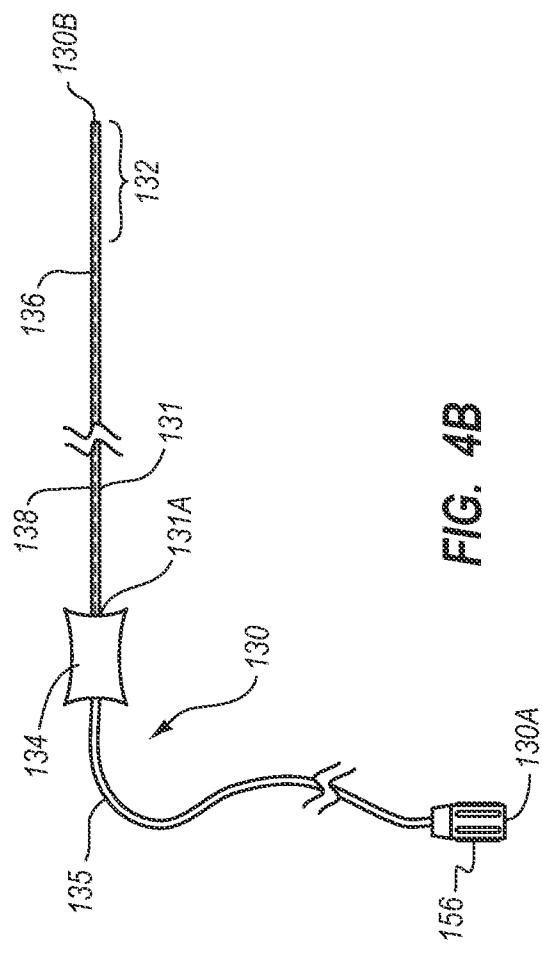
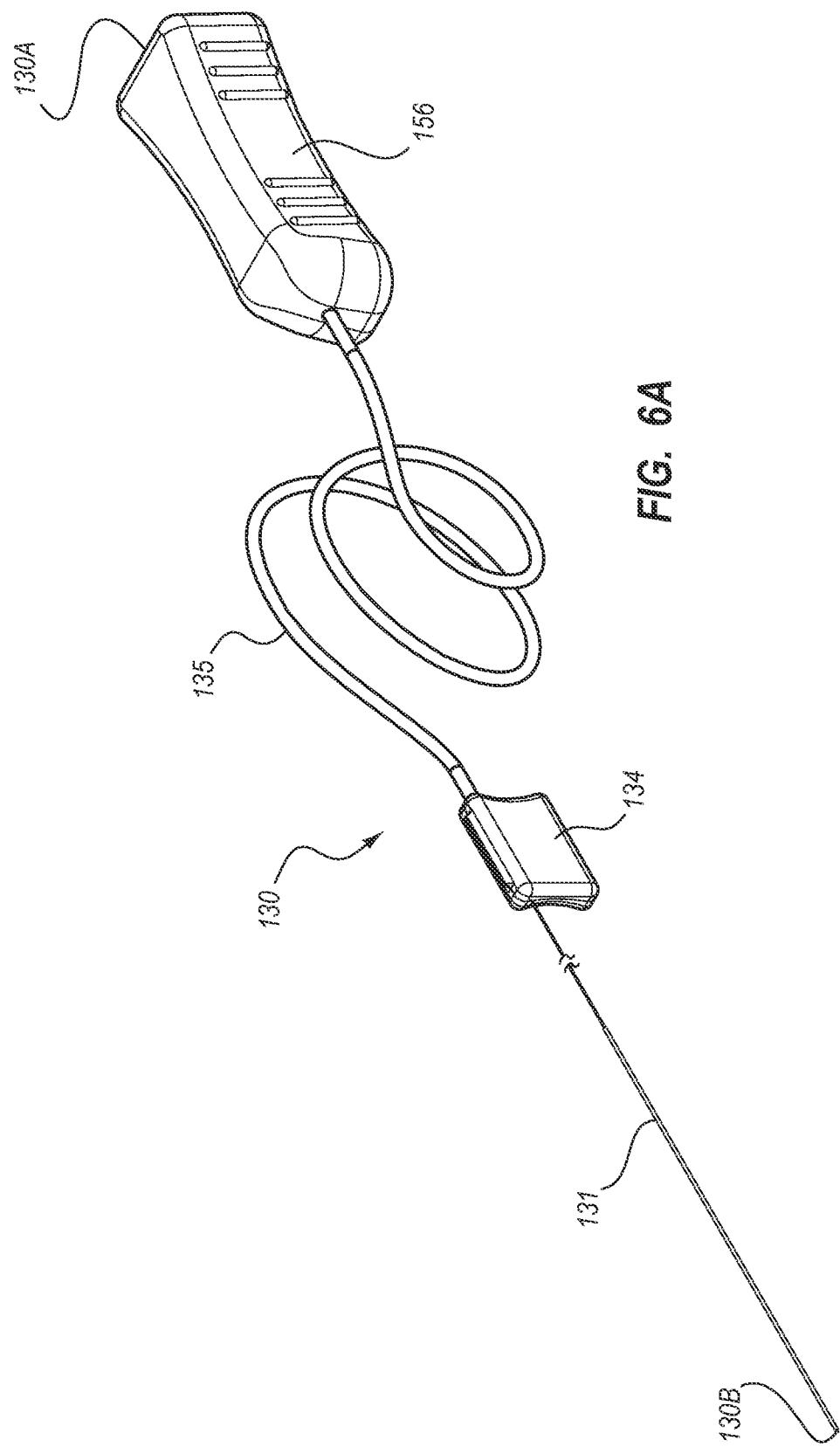


FIG. 4B



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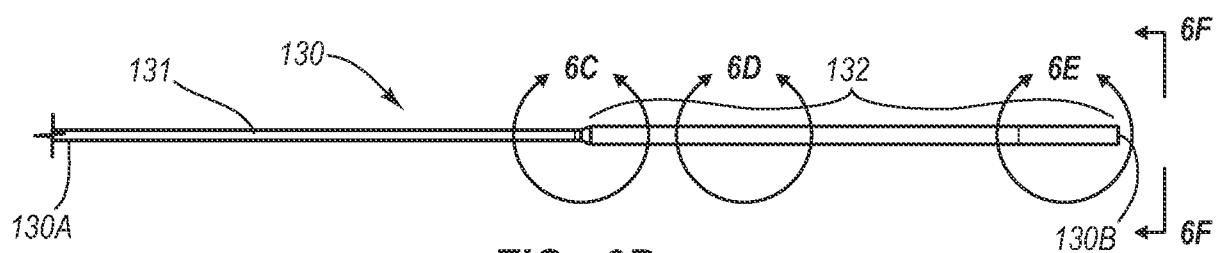


FIG. 6B

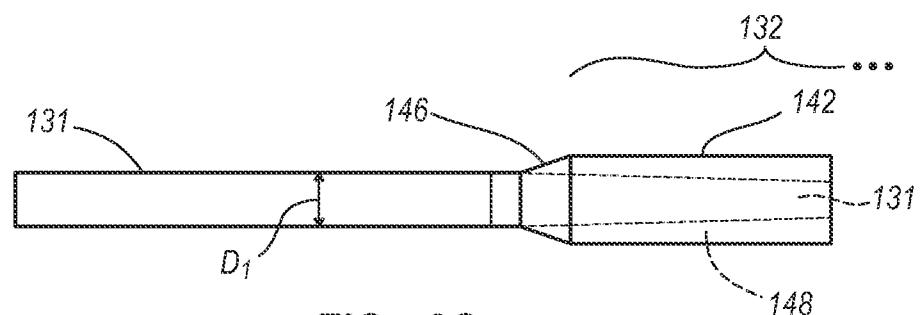


FIG. 6C

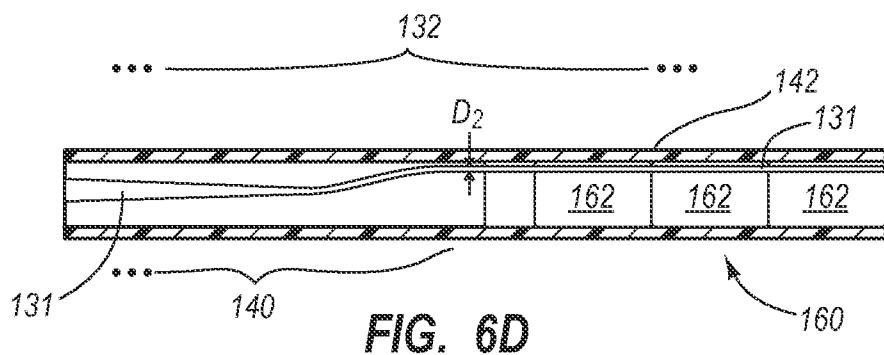


FIG. 6D

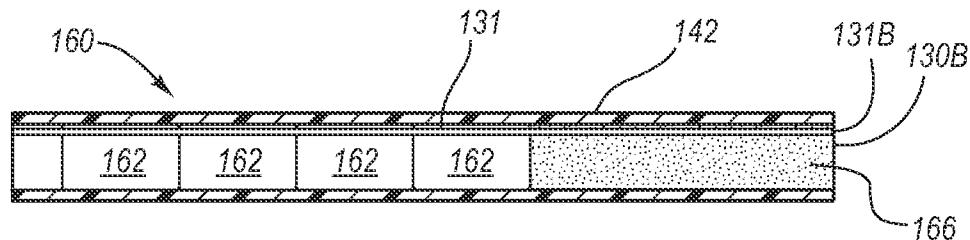


FIG. 6E

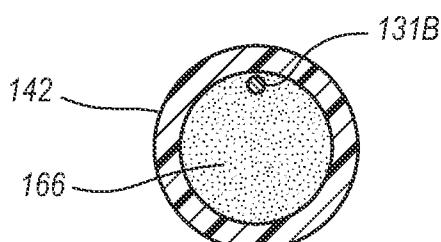
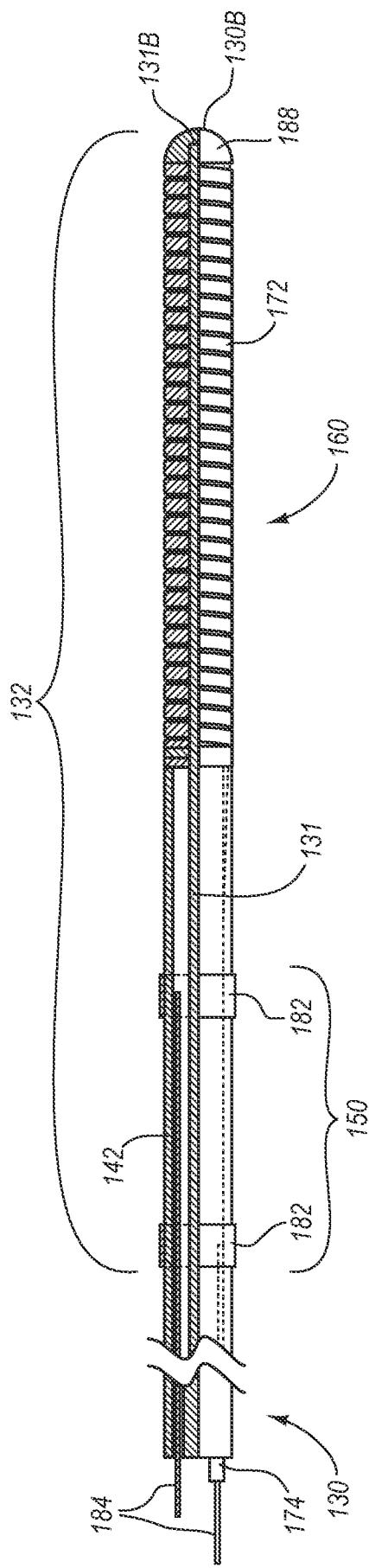
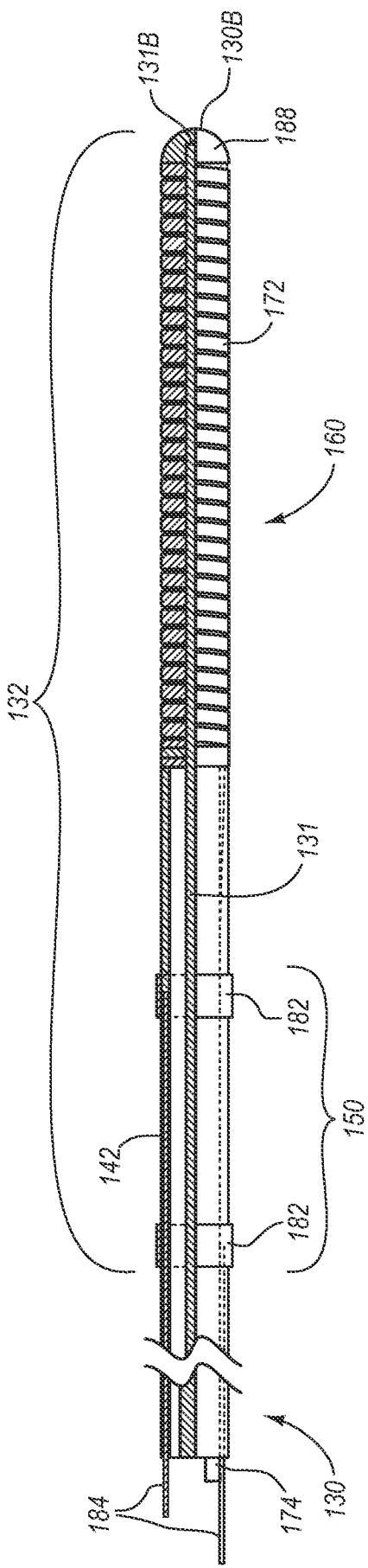


FIG. 6F

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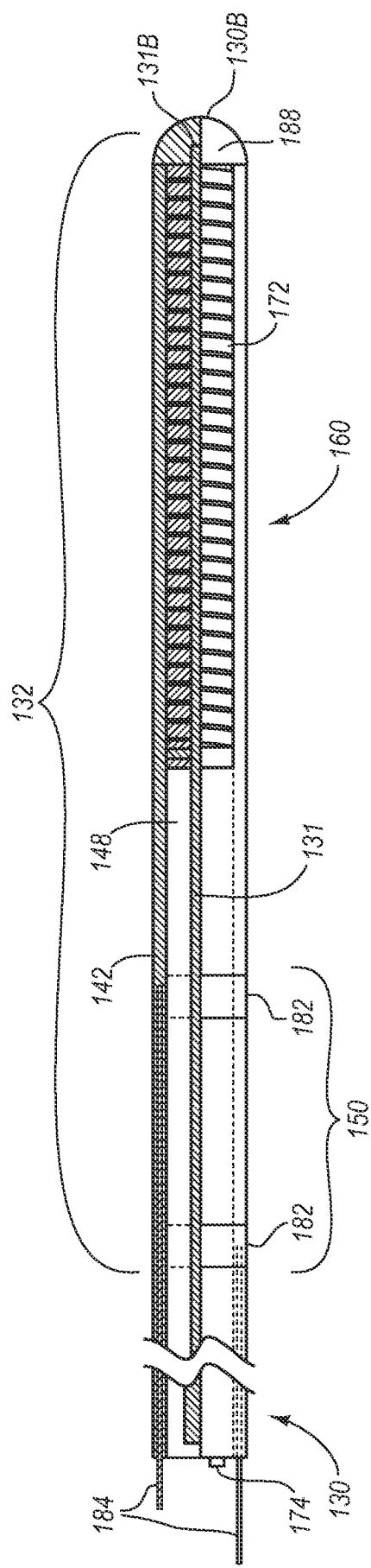


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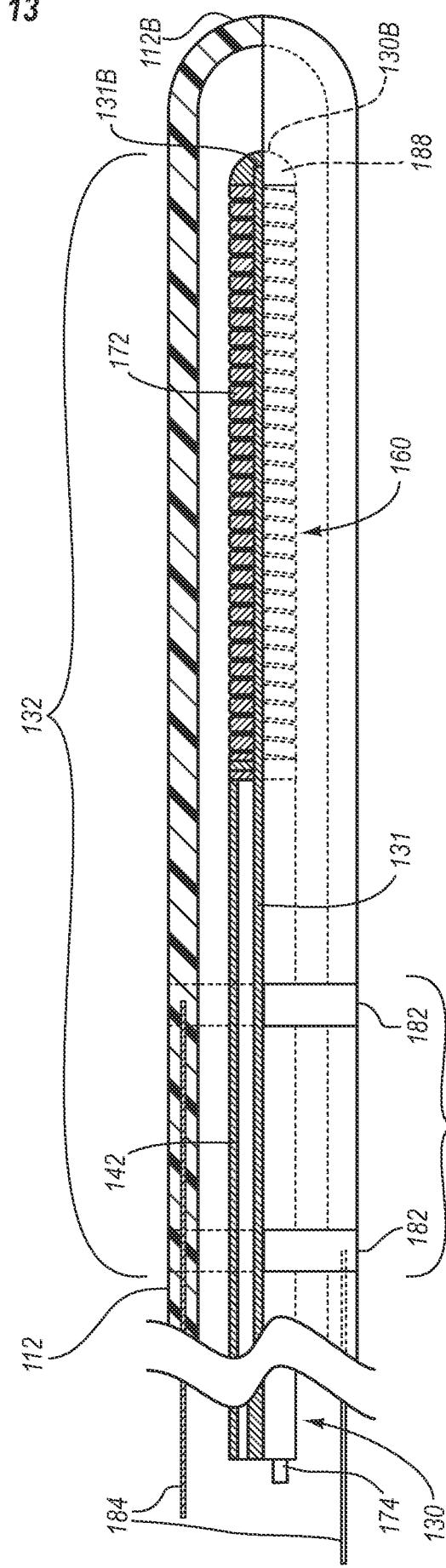


6  
FIG.

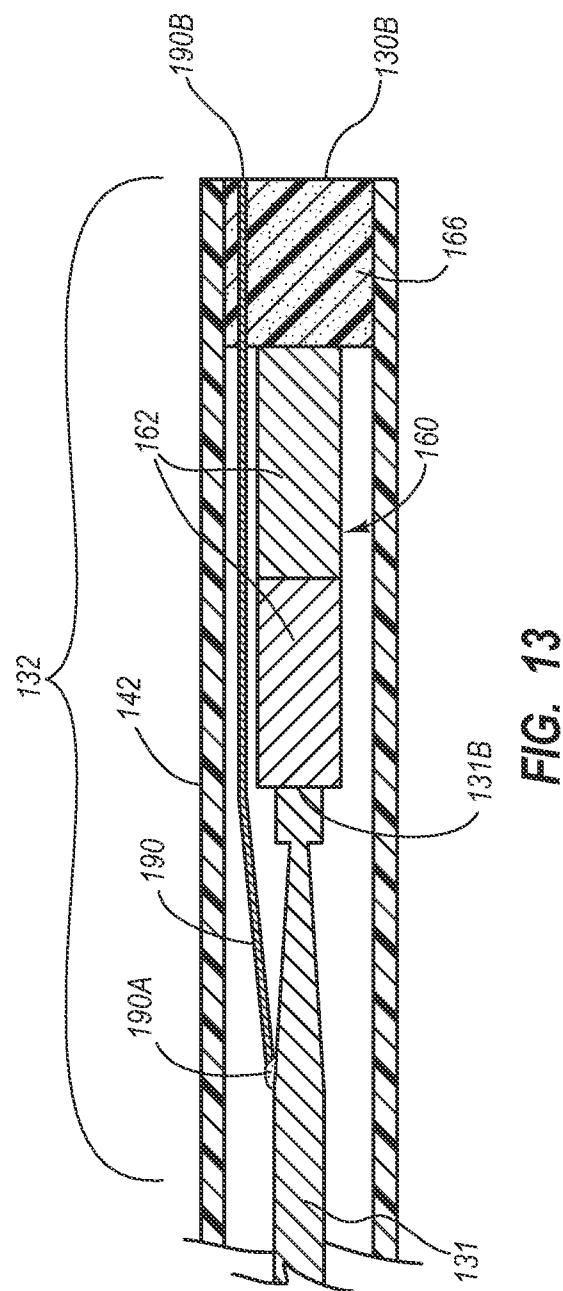
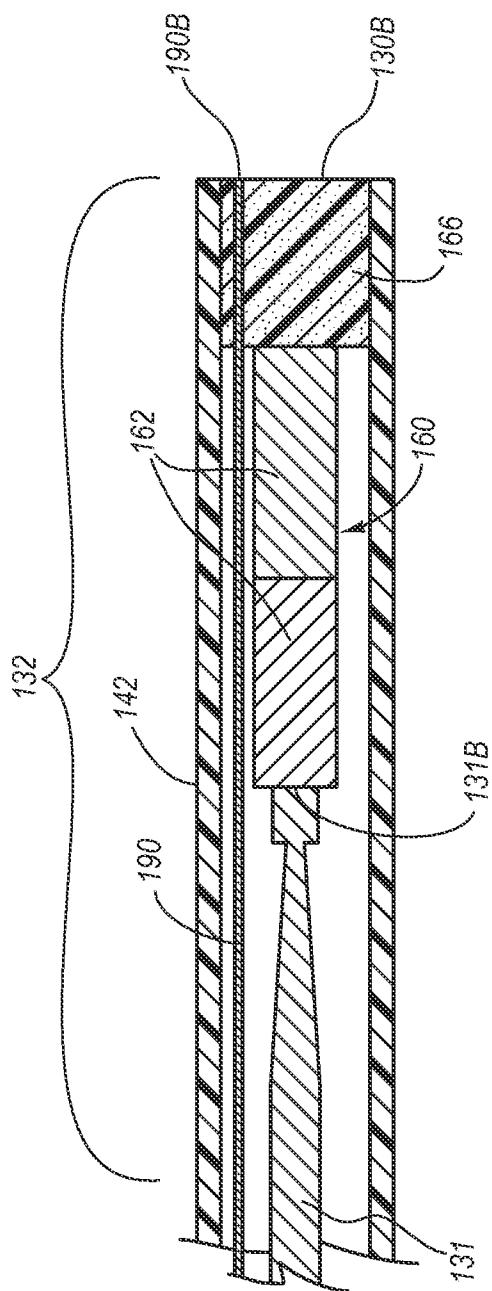
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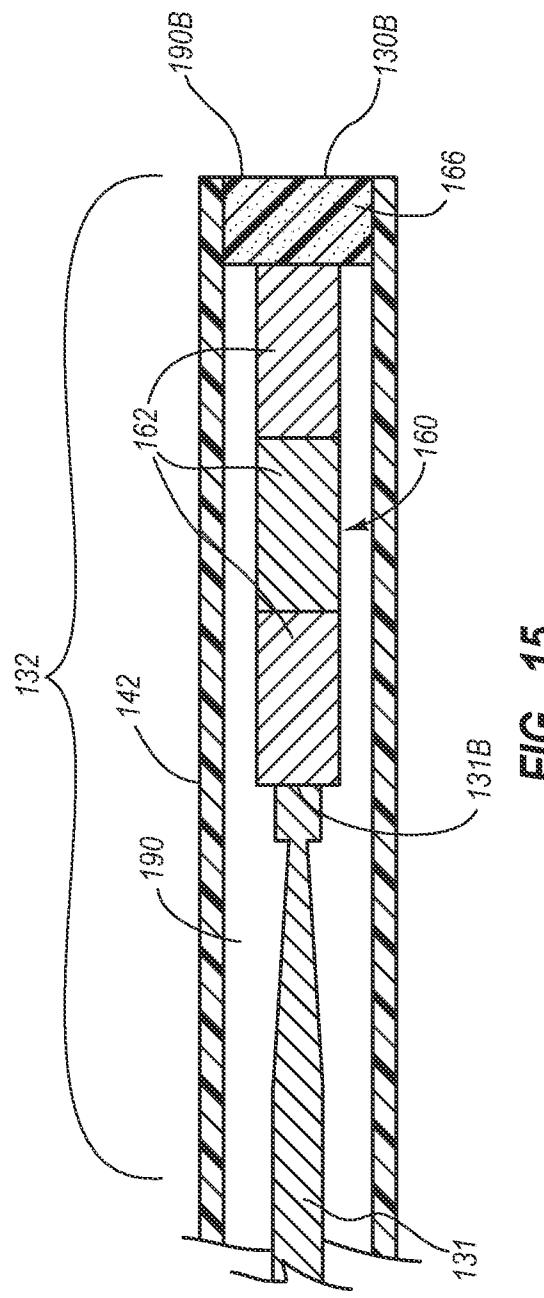
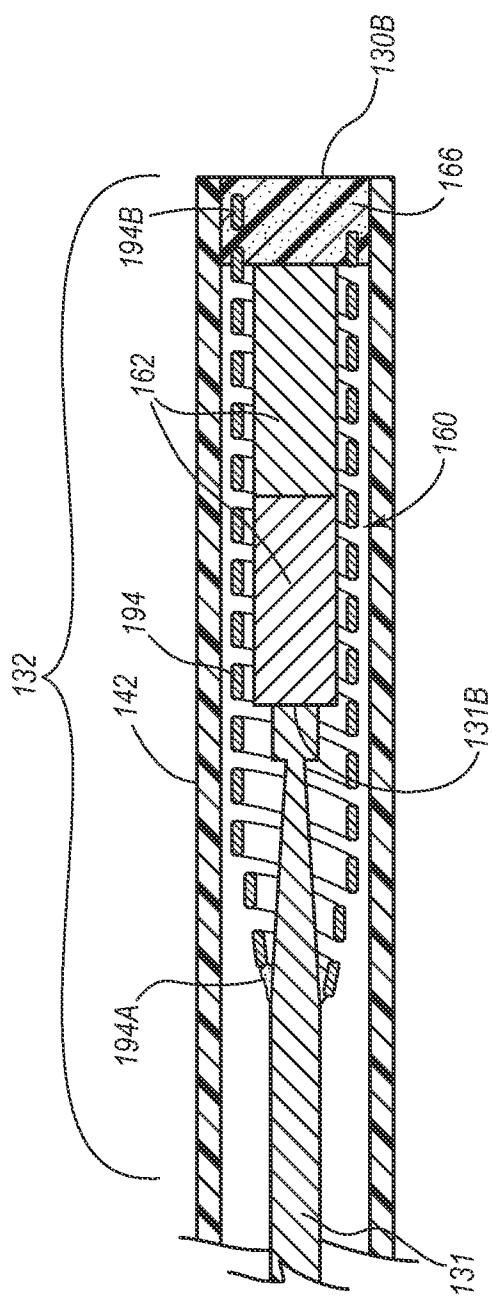


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FIG.

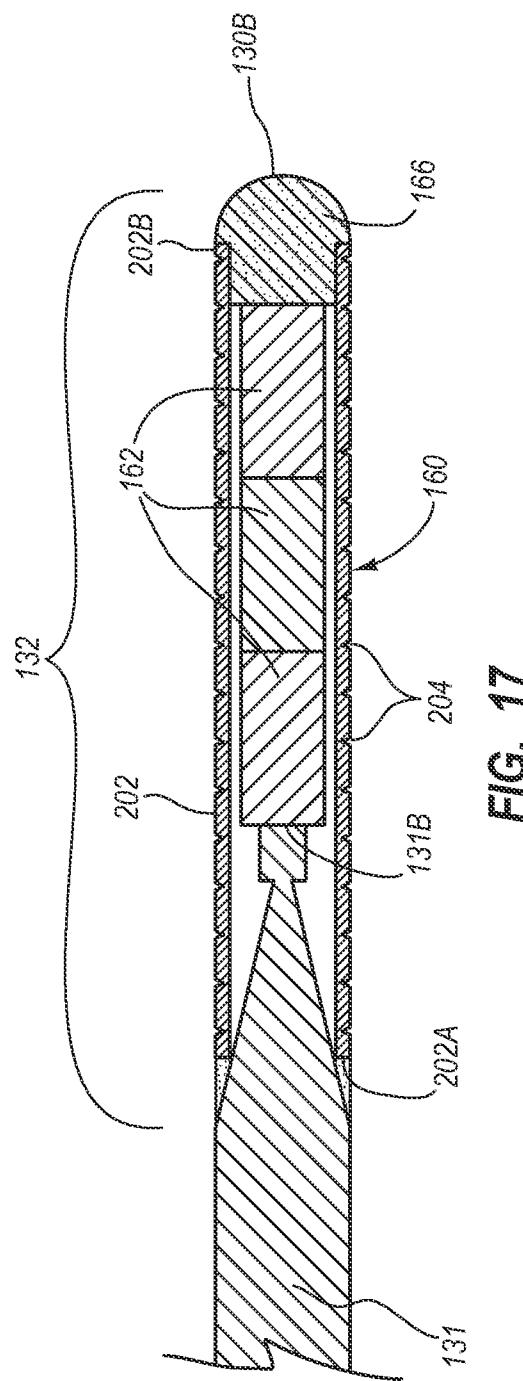
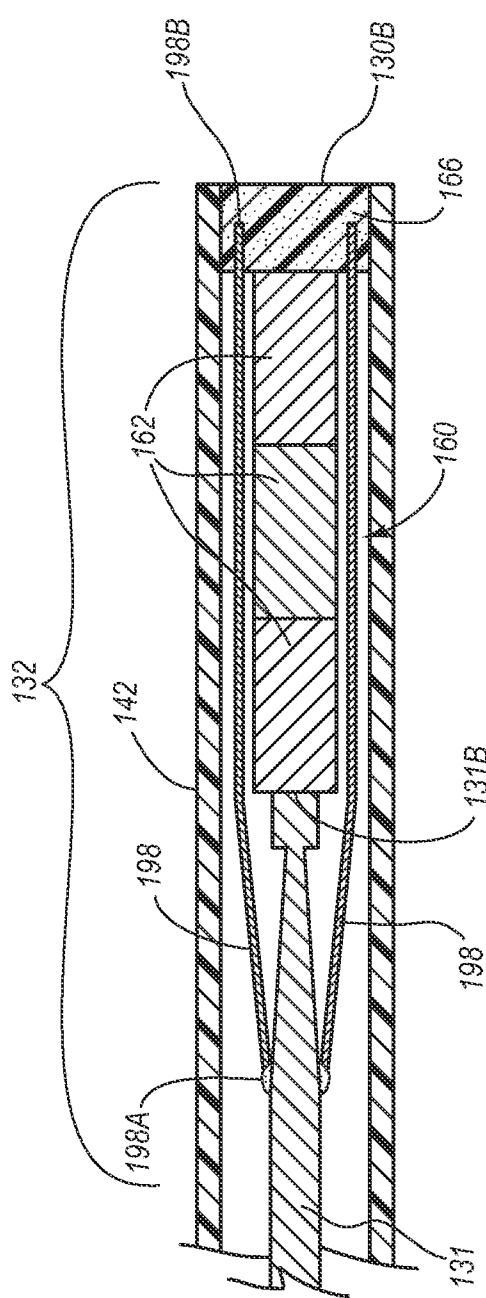


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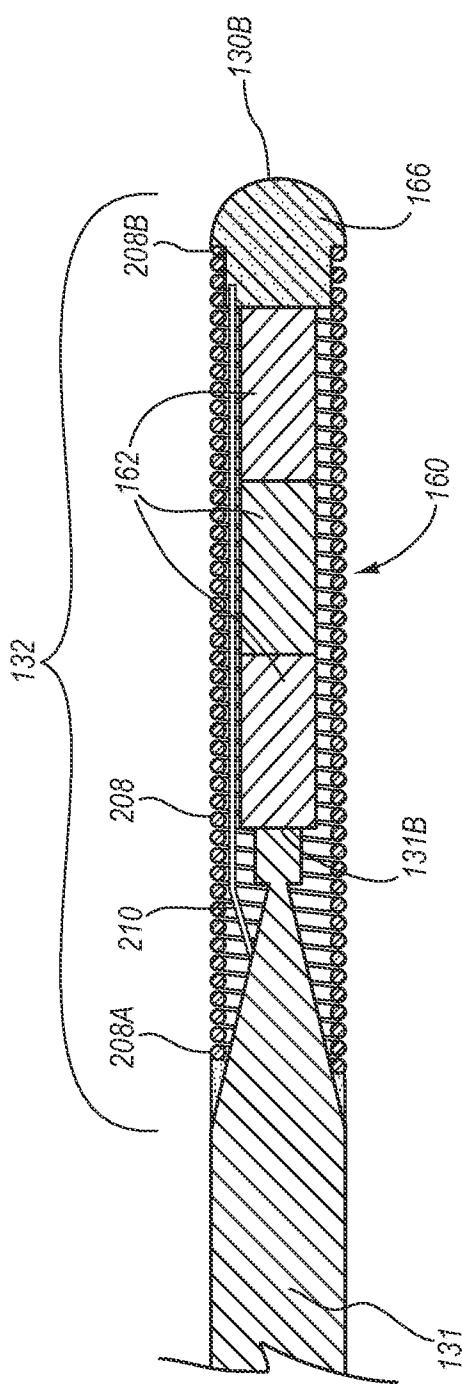


FIG. 18

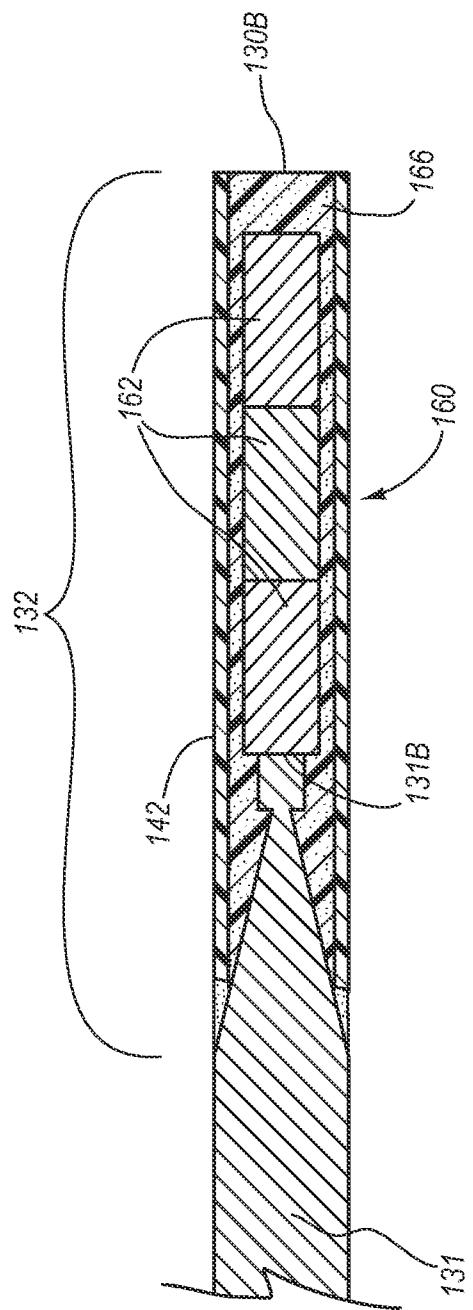


FIG. 19

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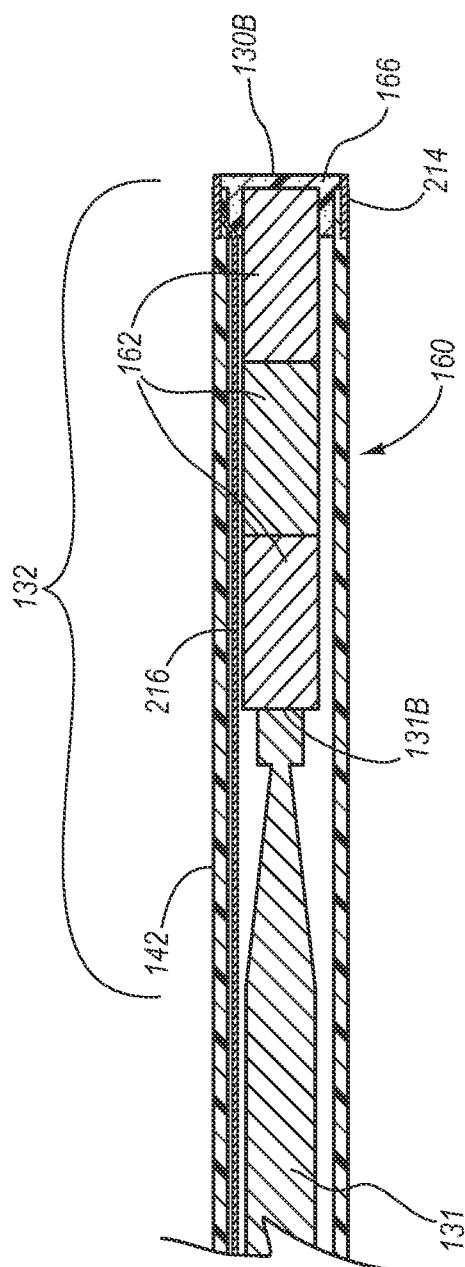


FIG. 20

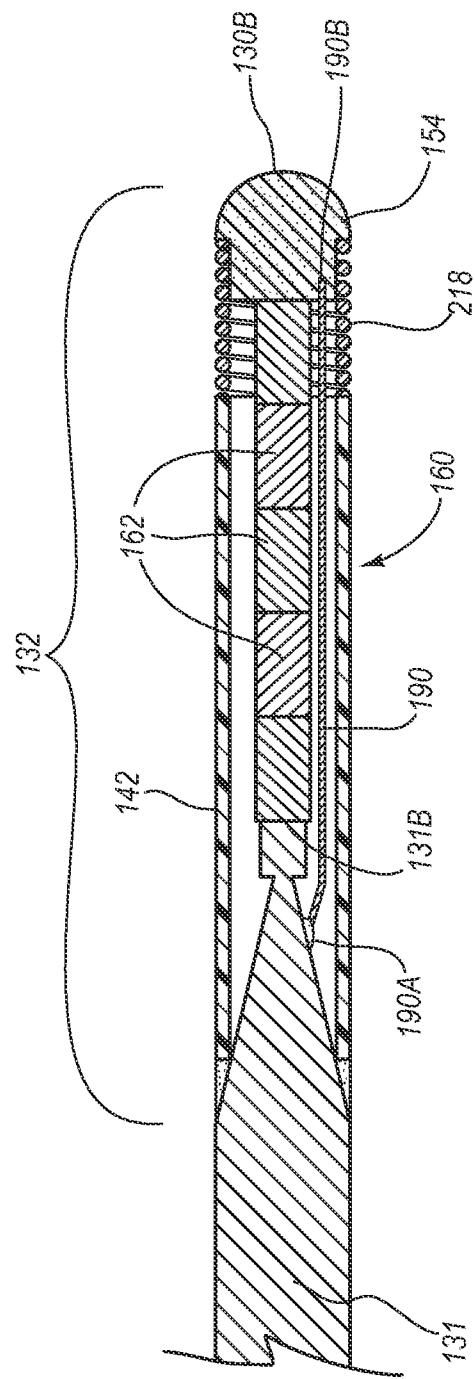


FIG. 21

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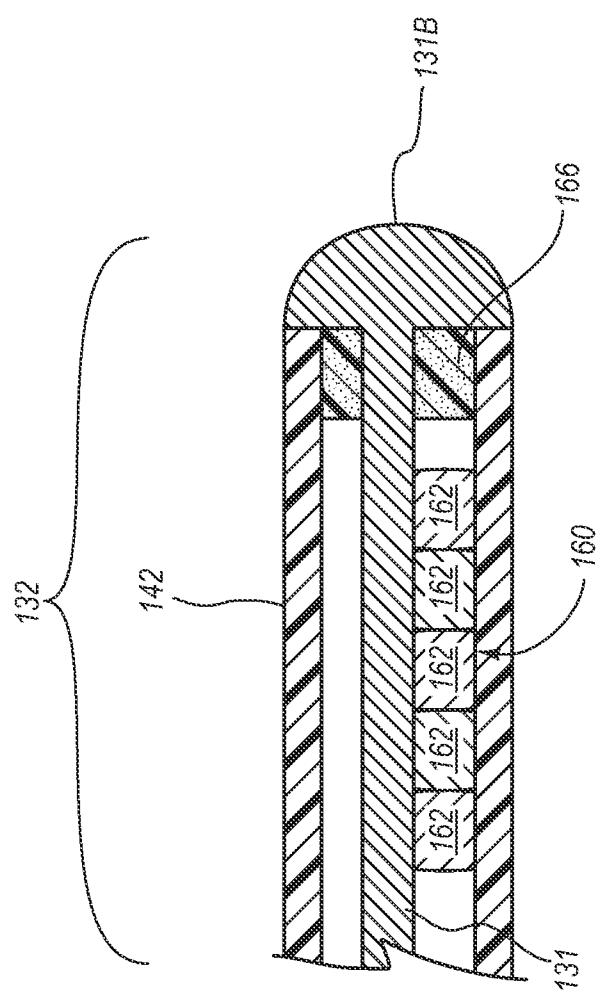


FIG. 22

**INTERNATIONAL SEARCH REPORT**

International application No

PCT/US2009/054687

**A CLASSIFICATION OF SUBJECT MATTER**  
 IPC(8) - A61M 25/01 (2009.01)  
 USPC - 607/122

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)

IPC(8) - A61M 25/01 (2009.01)  
 USPC - 600/407, 604/507, 508, 509, 510, 511, 607/122

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)

PatBase, Google Scholar

**C DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	US 5,824,031 A (COOKSTON et al) 20 October 1998 (20 10 1998) entire document	1, 2, 4, 5
Y		3, 6-20
Y	US 2007/0232882 A 1 (GLOSSOP et al) 04 October 2007 (04 10 2007) entire document	6-20
Y	US 7,107,105 B2 (BJORKLUND et al) 12 September 2006 (12 09 2006) entire document	3, 18-20

**D** Further documents are listed in the continuation of Box C

* Special categories of cited documents	"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
"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	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search	Date of mailing of the international search report
29 September 2009	<b>06 OCT 2009</b>

Name and mailing address of the ISA/US Mail Stop PCT, Attn ISA/US, Commissioner for Patents P O Box 1450, Alexandria, Virginia 22313-1450 Facsimile No 571-273-3201	Authorized officer Blame R. Copenheaver PCT Helpdesk 571 272-4300 PCT OSP 571 272-7774
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