



(51) International Patent Classification:
A61B 18/00 (2006.01)

(21) International Application Number:
PCT/US20 11/058138

(22) International Filing Date:
27 October 2011 (27.10.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/408,181 29 October 2010 (29.10.2010) US

(71) Applicant (for all designated States except US):
C.R.BARD, INC. [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **HE, Ding, Sheng** [US/US]; 377 Westford Rd., Tyngsboro, MA 01879 (US).
CIAVARELLA, David, J. [US/US]; 102 Fairfield Drive,

Short Hills, NJ 07078 (US). **BURNSIDE, Eddie, K.** [US/US]; 3107 Crestview Circle, Bountiful, Utah 84010 (US).

(74) Agent: **WIGHT, Todd, W.**; Rutan & Tucker LLP, 611 Anton Boulevard, Suite 1400, Costa Mesa, CA 92626 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,

[Continued on next page]

(54) Title: BIOIMPEDANCE-ASSISTED PLACEMENT OF A MEDICAL DEVICE

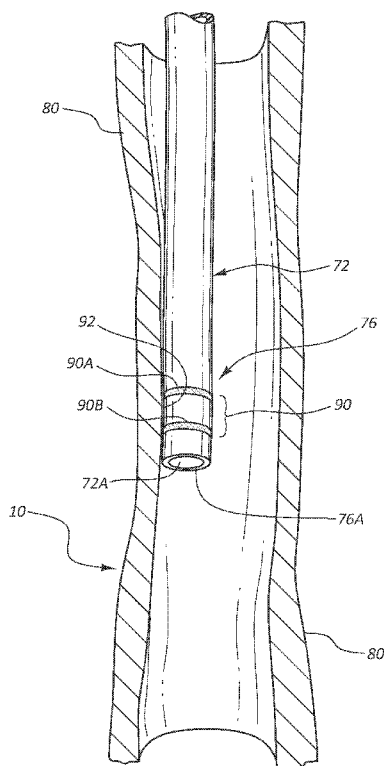


FIG. 3

(57) Abstract: A system and method for guiding a catheter or other medical device to a desired target destination within the vasculature of a patient via bioimpedance measurements is disclosed. The target destination in one embodiment includes placement of the catheter such that a distal tip thereof is disposed proximate the heart, e.g., the junction of the right atrium and superior vena cava. In one embodiment the method for guiding the catheter comprises introducing the catheter into a vessel of the patient, the catheter defining a lumen through which fluids can be infused into the vasculature of the patient. The catheter is advanced toward a target destination within the vasculature. A first impedance value based on intravascular detection of at least one electrical property related to a first tissue surface of the vessel is calculated to enable determination of the proximity of a distal end of the catheter to the target destination.

UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.1 7(ii))*
- *of inventorship (Rule 4.1 7(iv))*

Published:

- *with international search report (Art. 21(3))*

Declarations under Rule 4.17:

BIOIMPEDANCE-ASSISTED PLACEMENT OF A MEDICAL DEVICE**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 61/408,181, filed October 29, 2010, and entitled "Bioimpedance-Assisted Catheter Placement," which is incorporated herein by reference in its entirety.

BRIEF SUMMARY

[0002] Briefly summarized, embodiments of the present invention are directed to a system and method for guiding a catheter or other medical device to a desired target destination within the vasculature of a patient via bioimpedance measurements. The target destination in one embodiment includes placement of the catheter such that a distal tip thereof is disposed proximate the heart, *e.g.*, the junction of the right atrium and superior vena cava.

[0003] In one embodiment the method for guiding the catheter comprises introducing the catheter into a vessel of the patient, the catheter defining a lumen through which fluids can be infused into the vasculature of the patient. The catheter is advanced toward a target destination within the vasculature. A first impedance value based on intravascular detection of at least one electrical property related to a first tissue surface of the vessel, such as electrical current and voltage, is calculated to enable determination of the proximity of a distal end of the catheter to the target destination.

[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 the present disclosure 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. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0006] FIG. 1 is a block diagram of an example system with which embodiments of the present invention can be practiced;

[0007] FIG. 2 is a simplified view of a patient and a catheter being inserted therein using the system of FIG. 1;

[0008] FIG. 3 is a partial cutaway view of the catheter of FIG. 2 disposed in a vessel of a vasculature of the patient according to one embodiment;

[0009] FIG. 4 is a simplified schematic of portions of the system of FIG. 1, according to one embodiment;

[0010] FIG. 5 is a simplified view of a heart and surrounding vasculature of a patient together with the catheter of FIG. 2;

[0011] FIG. 6 is a perspective view of a distal portion of a catheter including a guiding stylet disposed therein according to one embodiment;

[0012] FIG. 7 is a side view of a distal portion of a catheter including a directional flap according to one embodiment;

[0013] FIG. 8 is a side view of a distal portion of a catheter including two directional flaps according to one embodiment;

[0014] FIGS. 9A and 9B are partial cross sectional side views showing a distal portion of a catheter disposed in a vessel and including a deployable wing according to one embodiment;

[0015] FIG. 10 is a partial cross sectional side view showing a catheter disposed in a vessel and including an electrode pair according to one embodiment;

[0016] FIG. 11 is a cross sectional bottom view of a catheter disposed in a vein according to one embodiment;

[0017] FIG. 12 is a cross sectional bottom view of a catheter disposed in an artery according to one embodiment; and

[0018] FIG. 13 is a partial cutaway view of the catheter of FIG. 2 disposed in a vessel of a vasculature of the patient according to one embodiment.

DETAILED DESCRIPTION OF SELECTED EMBODIMENTS

[00019] 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 present invention, and are neither limiting nor necessarily drawn to scale.

[00020] 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. Also, the words "including," "has," and "having," as used herein, including the claims, shall have the same meaning as the word "comprising."

[00021] Embodiments of the present invention are generally directed to a system and method for guiding to a desirable anatomic location a medical device, such as a peripherally inserted central catheter ("PICC") or other catheter. In particular, certain embodiments to be discussed describe assisting placement of a catheter or other medical device within the vasculature of the body of a patient such that a distal tip thereof is disposed proximate the heart, *e.g.*, the junction of the right atrium ("RA") and superior vena cava ("SVC"). In one embodiment, guidance of a catheter tip to such a location is achieved by using bio-impedance measurements, which can enhance clinical efficacy and improve patient safety. Thus, a mapping between body impedance and intravascular anatomic location can be achieved in one embodiment. Note that the catheters to be described for placement within the patient by way of the systems and methods discussed herein include those defining one or more lumens for the infusion and aspiration of fluids from the vasculature. It should be remembered, however, that other types of catheters and medical devices can be placed using the principles described herein. As such, the discussion to follow should not be construed as limiting in any way.

[00022] In brief, tissue impedance is a location-specific phenomenon within the patient vasculature. For example, in the thoracic cavity there is measurable tissue impedance difference between the different heart chambers as well as between atrial tissue and adjacent vessels, including the inferior vena cava ("IVC") and the SVC. Indeed, atrial tissue mainly includes myocardial tissue that exhibits a relatively high electrical conductivity, and thus a

relatively low impedance. In contrast, vascular tissue, *e.g.*, regions of the vena cava (the IVC and the SVC), includes mainly smooth muscle cells that are much thinner than the atrial tissue and therefore possess a relatively low electrical conductivity, and thus a relatively high impedance. At the junction of the RA and SVC, the atrial tissue and vascular tissue meet one another and thus define an impedance "border zone" where relatively low impedance tissue meets relative high impedance tissue. This region is but one example where relative differences in impedance are found within the patient vasculature.

[00023] In accordance with one embodiment, a system is disclosed for enabling such impedance variations to be monitored during advancement of a catheter or other medical device within the vasculature of the patient so as to enable positioning of a distal tip of the catheter at a desired target destination. The system in one embodiment includes, among other components, a purpose-specific electrical circuit, processor, and display for monitoring intravascular bioimpedance via electrodes disposed on a distal portion of the catheter. The system and methods described herein provide a clinician with guidance to assist in directing the distal tip of the catheter to the desired target destination via feedback of impedance detected by the electrodes during catheter advancement through the vasculature. Further, the system can be employed to confirm the catheter distal tip position after catheter advancement is complete. Again, note that the catheter positioned by the system and methods discussed herein is merely representative of one of many different types of catheters or other suitable indwelling medical devices.

[00024] Reference is first made to FIGS. 1 and 2 which depict various components of a catheter placement system ("system"), generally designated at 10, configured in accordance with one example embodiment of the present invention. As shown, the system 10 generally includes a console 20, display 30, ultrasound probe 40, sensor 50, and impedance components 60, each of which is described in further detail below.

[00025] Note that the particular components to be employed in guiding a catheter via impedance measurements are shown here in the system 10, which system also includes additional catheter insertion and guidance functionality, including a pre-insertion ultrasound-based vessel visualization modality and a magnetic-based catheter tip guidance modality, as will be discussed below. This notwithstanding, it is understood that the impedance-based catheter guidance modality, also discussed below, can be employed independent and apart from the other catheter insertion and advancement assistance features of the system 10.

Indeed, the system 10 may only include an impedance-based catheter guidance modality, in one embodiment. As such, the present discussion presents merely one example of an environment in which embodiments of the present invention can be practiced.

[00026] FIG. 2 shows the general relation of the above-referenced components to a patient 70 during a procedure to place a catheter 72 into the patient vasculature through a skin insertion site 73. FIG. 2 shows that the catheter 72 generally includes a proximal portion 74 that remains exterior to the patient and a distal portion 76 that resides within the patient vasculature after placement is complete. The system 10 is employed to ultimately position a distal tip 76A of the catheter 72 in a desired position within the patient vasculature. In one embodiment, the desired position for the catheter distal tip 76A is proximate the patient's heart, such as in the lower one-third (1/3rd) portion of the SVC. Of course, the system 10 can be employed to place the catheter distal tip in other locations. The catheter proximal portion 74 further includes a hub 74A that provides fluid communication between the one or more lumens of the catheter 72 and one or more extension legs 74B extending proximally from the hub.

[00027] The console 20 of FIGS. 1 and 2 can take one of a variety of forms and optionally houses various system components. A processor 22, including non-volatile memory such as EEPROM for instance, is included in the console 20 for controlling system function and intravascular impedance calculations during operation of the system 10, thus acting as a control processor. A digital controller/analog interface 24 is also included with the console 20 and is in communication with both the processor 22 and other system components to govern interfacing between the ultrasound probe 40, sensor 50, the impedance components 60, and other system components.

[00028] In greater detail, the impedance components 60 of the console 20 include means for measuring electrical current delivered to electrodes disposed on the catheter 72, as will be described. In the present embodiment, the means for measuring current includes an ammeter 64 implemented as a sampling circuit or other suitable form. Means for measuring voltage across the electrodes is also included. In the present embodiment, the means for measuring voltage includes a voltmeter 66 implemented as a sampling circuit or other suitable form. Of course, other devices can be employed to achieve the functionality of the aforementioned means. A radiofrequency (RF) or current source 62 is also included for providing an electrical current to the catheter electrodes, as will be described. In addition to these

components, other components for enabling impedance intravascular detection can also be added to the system 10, catheter 72, or both. As shown in FIG. 1, the ammeter 64, the voltmeter 66, and the RF source 62 are operably connected to the processor 22 and ports 52 to enable interoperability therewith. Note that the aforementioned components can be disposed in locations other than the console 20.

[00029] As mentioned, the system 10 further includes ports 52 for connection of console components with the sensor 50 and optional components 54 including a printer, storage media, keyboard, audio speaker, etc. The ports 52 in one embodiment are USB ports, though other port types or a combination of port types can be used for this and the other interfaces connections described herein. A power connection 56 is included with the console 20 to enable operable connection to an external power supply 58. A battery or other suitable internal power supply 57 can also be employed, either with or exclusive of the external power supply 58. Power management circuitry 59 is included with the digital controller/analog interface 24 of the console to regulate power use and distribution.

[00030] The display 30 in the present embodiment is integrated into the console 20 and is used to display impedance and other information to the clinician during the catheter placement procedure. In another embodiment, the display may be separate from the console. As will be seen, the content depicted by the display 30 changes according to which mode the catheter placement system is in: ultrasound vessel visualization, magnetic-based catheter guidance, impedance-based catheter guidance, etc. In one embodiment, a console button interface 32 and buttons included on the ultrasound probe 40 can be used to immediately call up a desired mode to the display 30 by the clinician to assist in the placement procedure. In one embodiment, information from multiple modes, such as magnetic and impedance-based catheter guidance, may be displayed simultaneously. Thus, the single display 30 of the system console 20 can be employed for ultrasound guidance in accessing a patient's vasculature, magnetic-based guidance during catheter advancement through the vasculature, and impedance-based guidance and/or confirmation of catheter distal tip placement with respect to a desired target destination within the vasculature, for instance. In one embodiment, the display 30 is an LCD device.

[00031] The ultrasound probe 40 is employed in connection with the first modality mentioned above, *i.e.*, ultrasound ("US")-based visualization of a vessel, such as a vein, in preparation for insertion of the catheter 72 into the vasculature. Such visualization gives real

time ultrasound guidance for introducing the catheter into the vasculature of the patient and assists in reducing complications typically associated with such introduction, including inadvertent arterial puncture, hematoma, pneumothorax, etc.

[00032] The handheld probe 40 includes a head that houses a piezoelectric array for producing ultrasonic pulses and for receiving echoes thereof after reflection by the patient's body when the head is placed against the patient's skin proximate the prospective insertion site 73 (FIG. 2). The probe 40 further includes a plurality of control buttons, which can be included on a button pad. In one embodiment, the modality of the system 10 can be controlled by the control buttons, thus eliminating the need for the clinician to reach out of the sterile field, which is established about the patient insertion site prior to catheter placement, to change modes via use of the console button interface 32 (FIG. 1).

[00033] As such, in one embodiment a clinician employs the first (US) modality to determine a suitable insertion site and establish vascular access, such as with a needle or introducer, then with the catheter. The clinician can then seamlessly switch, via button pushes on the probe button pad, to another modality, such as magnetic-based or impedance-based catheter guidance, without having to reach out of the sterile field. These latter modes can then be used to assist in advancement of the catheter 72 through the vasculature toward an intended target destination.

[00034] FIG. 1 shows that the probe 40 further includes button and memory controller 42 for governing button and probe operation. The button and memory controller 42 can include non-volatile memory, such as EEPROM, in one embodiment. The button and memory controller 42 is in operable communication with a probe interface 44 of the console 20, which includes a piezo input/output component 44A for interfacing with the probe piezoelectric array and a button and memory input/output component 44B for interfacing with the button and memory controller 42. Note that the console button interface and probe interface can, in one embodiment, include a touch screen, voice command, or other suitable functionality to enable ease of system control for the clinician.

[00035] The sensor 50 is employed by the system 10 during operation in the magnetic sensing mode to detect a magnetic field produced by magnetic elements included in a stylet that is removably received in the lumen of the catheter 72. As seen in FIG. 2, the sensor 50 is placed on the chest of the patient during catheter insertion. The sensor 50 is placed on the

chest of the patient in a predetermined location, such as through the use of external body landmarks, to enable the magnetic field of the stylet magnetic elements, disposed in the catheter 72 as described above, to be detected during catheter transit through the patient vasculature. The magnetic elements of the stylet magnetic assembly are co-terminal with the distal end 76A of the catheter 72 (FIG. 2) such that detection by the sensor 50 of the magnetic field of the magnetic elements provides information to the clinician as to the position and orientation of the catheter distal end during its transit within the vasculature.

[00036] In greater detail, the sensor 50 is operably connected to the console 20 of the system 10 via a cable and one or more of the ports 52, as shown in FIG. 1. Note that other connection schemes between the sensor and the system console can also be used without limitation. As just described, the magnetic elements are employed in the stylet 100 to enable the position of the catheter distal end 76A (FIG. 2) to be observable relative to the sensor 50 placed on the patient's chest. Detection by the sensor 50 of the stylet magnetic elements is graphically displayed on the display 30 of the console 20 during magnetic guidance mode.

[00037] In this way, a clinician placing the catheter is able to generally determine the location and/or orientation (*e.g.*, which way the distal tip 76A of the catheter 72 is pointing) of the catheter distal end 76A within the patient vasculature relative to the sensor 50 and detect when catheter malposition, such as advancement of the catheter along an undesired vein, is occurring. In one embodiment, the magnetic assembly can be tracked using the teachings of one or more of the following U.S. patents: 5,775,322; 5,879,297; 6,129,668; 6,216,028; and 6,263,230. The contents of the afore-mentioned U.S. patents are incorporated herein by reference in their entireties. Note again that buttons included on either the console 20 or the ultrasound probe 40 can be used to control system functionality during ultrasound mode, magnetic-based catheter guidance mode, or impedance-based catheter guidance mode.

[00038] Note that the system described herein in one embodiment can include additional functionality wherein determination of the proximity of the catheter distal tip relative to a sino-atrial ("SA") or other electrical impulse-emitting node of the heart of the patient can be determined, thus providing enhanced ability to accurately place the catheter distal tip in a desired location proximate the node. Also referred to herein as "ECG" or "ECG-based tip confirmation," this additional modality of the system enables detection of ECG signals originating from the SA node in order to place the catheter distal tip in a desired location within the patient vasculature. Note that the ECG modality can be seamlessly combined with

the other modalities of the system as described herein, namely ultrasound, magnetic-based catheter tracking, and impedance-based tracking to be described further below. Further details regarding this ECG modality and the other modalities described above can be found in U.S. Patent Application Publication No. 2011/0015533, filed September 29, 2010, and entitled "Stylets for use with Apparatus for Intravascular Placement of a Catheter," which is incorporated herein by reference in its entirety.

[00039] FIG. 2 shows that the catheter 72 is operably connected to the sensor 50 atop the patient's chest via a tether 78, with the sensor in turn operably connected to the console 20 and its included components via a cable. In this way, the electrode is operably connected to the RF source 62, the ammeter 64, the voltmeter 66, the processor 22, the display 30, and the other system components employed during operation thereof.

[00040] FIG. 3 shows a distal portion 76 of the catheter 72 disposed in a vessel 80 of the patient 70, as inferred in FIG. 2. As shown, the distal portion 76 includes the electrode array 90, including first and second electrodes 90A and 90B that are operably connected to conductive wires or the like longitudinally extending proximally in the catheter wall, for instance, and operably connecting to the tether 78 (FIG. 2) so as to operably connect the electrodes 90A, 90B of the electrode array 90 with the RF source 62 (FIG. 1). It is appreciated that the electrode array and constituent electrodes can be configured in a variety of ways and that the shape, number, position, and type of electrodes can vary from what is depicted and described herein. For example, the electrodes can be included proximate a distal end of a stylet that is removably received within a lumen of the catheter. These and other possible configurations are therefore contemplated.

[00041] FIG. 4 depicts a simplified schematic of the various components directly involved in measuring an impedance of the tissue surface 92 of a vessel and the operating relationship to one another, according to one embodiment. The components include the RF source 62, which provides an RF current to the electrode array 90, including the electrodes 90A and 90B that bound either side of the tissue surface 92 under evaluation. The magnitude of the current provided by the RF source 62 can be measured by the ammeter 64 and forwarded to the processor 22 of the console 20. The magnitude of the voltage difference between the two electrodes 90A and 90B across the tissue under evaluation can be measured by the voltmeter 66 and forwarded to the processor 22.

[00042] With the system 10 and catheter 72 configured as shown in FIGS. 3 and 4, the catheter 72 can be accurately positioned within the patient vasculature by first disposing the catheter within a vessel of the vasculature such that the electrode array 90 proximate the distal tip 76A thereof is adjacent to a tissue surface, such as the tissue surface 92 of FIG. 3, thus providing electrical communication between the electrode array 90 and the tissue surface 92 of the vessel 80. In one embodiment, such electrical communication is achieved by positioning the catheter 72 within the vessel 80 such that the electrodes 90A, 90B physically touch the tissue surface 92 of the vessel 80, as in FIG. 3. An electrical RF current produced by the RF source 62 can then be provided to the electrode array 90. In one embodiment, the current includes a predetermined frequency and is of relatively low power. Thus, with the distal portion 76 of the catheter disposed against a tissue surface 92, *i.e.*, the inner wall of the vessel 80 in the present embodiment and as shown in FIG. 3, the RF current is provided to the electrode array 90 and measured by the ammeter 64. The resultant voltage difference between the electrodes 90A and 90B across the tissue surface 92 is measured by the voltmeter. The magnitudes of the RF current and voltage are forwarded to the processor 22.

[00043] Upon receipt of the current and voltage data from the ammeter 64 and voltmeter 66 respectively, the processor can calculate the impedance in the region of the tissue surface under evaluation, also referred to herein as bioimpedance, according to the equation:

$$\text{Impedance (Z)} = \text{Volts (V)} / \text{Current (I)}. \quad (1)$$

[00044] As such, in the present embodiment, the processor includes suitable control algorithms with embedded software to sample the current and voltage data (and any other biophysical parameters), in order to automatically calculate the bioimpedance. The resulting impedance data as calculated by the processor 22 or other suitable system component can be depicted on the display 30 for observation by the clinician. In addition, audio tones or other suitable signals can be output by the speaker 54 or other suitable output device so as to provide additional feedback to the clinician. For instance, upon reaching the junction of the RA and the SVC, an area where a significant change in tissue impedance is encountered, the display can indicate the detected position of RA/SVC junction, and the audio speaker 54 can emit a predetermined audio tone to indicate the desired anatomic target location.

[00045] The above process can be iterated in real time as the catheter distal tip 76A is advanced in the vessel so as to provide real-time updating as to the calculated impedance

value according to the present position of the distal tip of the catheter 72. For instance, a first impedance calculation is calculated and displayed for a first location within the vessel of the catheter distal tip, then a second impedance calculation is calculated and displayed for a second distal tip location. Such a process can be iteratively performed and the resultant impedance values compared so as to enable a clinician to discern when the catheter distal tip is disposed at a desired target location, such as the RA/SVC junction, for instance.

[00046] FIG. 5 shows a heart 96 of a patient, including areas in and proximate thereto of varying impedance, including the SVC 98, the RA/SVC junction 100, and the RA 102. The SVC 98, for instance includes a relatively high impedance, such as about 130-140 ohms, in one example, while the RA/SVC junction 100 is at a relatively lower impedance of about 118 ohms for instance. The RA 102 is of even lower impedance, such as about 84 ohms in one example. Such location-based variations in tissue impedance values can be employed by the system 10 to determine the location of the electrode array 90 of the catheter 72 (FIGS. 1, 3). Further, knowledge of the distance from the electrode array 90 to the distal tip 76A of the catheter enables the position of the catheter tip to be determined within the vasculature, thus enabling its precise placement at a desired target location. Note that the above impedance values are for purposes of illustration and should not be considered limiting.

[00047] In light of the above, therefore, comparison of subsequent impedance calculations for successive catheter distal tip locations in the vessel can indicate proximity to a desired target location. For instance, a relatively small decrease in impedance values between first and second tissue surfaces can indicate that the electrodes have passed from the SVC 98 to the RA/SVC junction 100 (FIG. 5), while a relatively larger impedance decrease between the first and second interior surfaces can indicate that the electrodes have passed from the SVC to the RA 102. This or other suitable processes can be expanded to use multiple electrode arrays, multiples impedance readings, etc. In one embodiment, only a single impedance reading may be necessary to determine the location of the catheter distal tip with respect to the RA/SVC or RA, for instance.

[00048] As indicated above, measurement of impedance values at a given catheter location, followed by movement of the catheter and subsequent measurement at the new location, can be iteratively performed so as to determine when the catheter has been desirably placed, such as proximate the RA/SVC junction, for instance. It is appreciated that in one embodiment, the system 10 includes suitable algorithms to calculate, track, store, and display

the impedances at the various discrete catheter locations and the impedance change as the catheter is advanced within the vasculature. Further the system 10 can include various functionality to depict and display the tracked data in a user-friendly visual format for depiction on the display 30, including electronic circuits for displaying the impedance data and/or other biophysical parameters in digital and/or analog format. Note that example insertion sites for the catheter into the patient's vasculature include the arm (cephalic vein), neck (jugular vein) and the groin (femoral artery). Other insertion sites can, of course, be used.

[00049] In one embodiment, communication ports and software can be included with the system 10 to enable biophysical parameters sensed and/or employed by the system, *e.g.*, impedance, current, and voltage, to be exported for use by other medical equipment, such as clinical vital sign equipment, hemodynamic systems, anesthesia systems, electrophysiology lab systems, computers, storage systems, data analysis systems, etc.

[00050] In other embodiments, the electrode array of the system can vary from what is described herein for use in identifying and confirming the specific anatomic location within the vasculature and proximate the heart, including bipolar and/or monopolar electrodes that are included with a catheter, included stylet, or other indwelling medical device. Further, in one embodiment, the impedance values detected by the system described herein can be used to map the vasculature about the heart, which data can be correlated with radiographically acquired landmarks of the patient's anatomy.

[00051] As mentioned above, the electrodes 90A, 90B are operably connected to the console 20 by the tether 78 via the sensor 50, in one embodiment. In this case, the tether 78 and/or associated connectors are configured to penetrate through a sterile barrier surrounding a sterile field established about the patient's catheter insertion site without compromising the sterile field so as to enable the electrodes 90A, 90B to operably connect with the console 20. Examples of and further details regarding such sterile field breaching can be found in U.S. Patent Application Publication No. 2011/0015533, which is incorporated by reference above.

[00052] In a further embodiment, it is appreciated that multiple electrodes or electrode arrays can be included or associated with the catheter such that multiple impedance measurements can be made simultaneously at differing locations along the length of the distal portion of the catheter. In yet another embodiment and as mentioned above, it is appreciated

that ECG-based catheter tip location can be used in concert with the impedance-based location techniques described herein. In such a configuration, the ECG-based location method can be used to direct the catheter distal tip to a generally preferred area, after which impedance-based location can be employed to precisely place the catheter distal tip at a desired location within the vasculature. Further details regarding such ECG-based location can be found in U.S. Patent Application Publication No. 2011/0015533, incorporated by reference above.

[00053] As mentioned, in one embodiment it is necessary to position the catheter 72 within the vessel 80 such that the electrodes 90A, 90B of the electrode array 90 are in physical contact with the interior tissue surface 92 of the vessel, as seen in FIG. 3. In one embodiment, this can be achieved by deviating the distal portion of the catheter within the blood stream of the vessel in which it is disposed. FIG. 6 shows an example of an apparatus for such a deviation, including a stylet 110 disposed within the lumen 72A of the catheter 72 such that a distal portion of the stylet extends distal to the distal tip 76A of the catheter. The stylet 110 includes a diversion flap 112 pivotably mounted at a distal end of the stylet so as to be able to be selectively moved between an aligned position and the deviated positions shown in phantom in FIG. 6. An actuating wire 114 is attached to the flap 112 and extends through the length of the stylet 110 so as to enable a clinician external to the patient to selectively deviate the flap. Deviation of the flap from its aligned position of FIG. 6 causes the flap to interfere with the blood flow through the vessel, which in turn causes the stylet 110 and the distal portion 76 of the catheter 72 to be pushed to one side of the vessel, thus enabling the electrodes 90A, 90B to physically contact the interior surface of the vessel. Once physical contact of the electrodes 90A, 90B is no longer needed, the actuating wire 114 can be moved to bring the flap 112 into alignment, thus stopping interfering engagement of the flap with the vessel blood flow. Note that the particular configuration and shape of the flap and stylet can vary from what is shown and described herein. Also, the stylet can be extended from the catheter distal tip 76A either less or further than what is shown in FIG. 6.

[00054] FIG. 7 shows a catheter diversion feature according to another embodiment, wherein a diversion flap 122 is included at the distal tip 76A of the catheter 72 and has operably connected thereto an actuating wire 124 for enabling a clinician to selectively fold the flap from the aligned position to the phantom deviated position shown in FIG. 7. The flap 122 operates in similar fashion to the flap 112 of FIG. 6 in causing deviation of the

catheter 72 in the blood stream so that at least a portion of the electrodes 90A, 90B can contact the vessel interior surface.

[00055] FIG. 8 shows a catheter diversion feature according to another embodiment, wherein two diversion flaps 122 are included at the catheter distal end 76A, each being operably connected to a separate actuating wire 124 so that deviation of the catheter distal portion is selectively achieved by actuating one or both of the flaps in order to deviate the distal portion in a particular direction. In one embodiment, the flaps can be used in concert to maintain the catheter in a central portion of the vessel so as to enable the catheter to be guided past difficult or tortuous vascular anatomy and to reduce vessel wall damage. Note that the number, shape, size, and particular design of the flaps disclosed herein can vary from what is shown and described.

[00056] FIGS. 9A and 9B show a catheter diversion feature according to another embodiment, wherein a distal portion of the catheter 72 includes a deployable flap, or wing 132, for interacting with the vessel blood flow to cause deviation of the distal portion 76 of the catheter toward the wall of the vessel 80 in which the catheter is disposed. In turn, this enables contact to be made between the interior wall of the vessel 80 and the catheter electrodes of the electrode array 90. As shown in FIG. 9B, in the present embodiment the wing 114 is triangular or semi-pyramidal in shape, though in other embodiments other wing shapes are possible. The wing can be selectively extensible/collapsible in one embodiment.

[00057] In one embodiment, it is appreciated that impedance-based guidance and measurement within a vasculature can be employed to detect regions of abnormality within vessels. For instance, an impedance measuring catheter or other intravascular device employing the methods as described herein can be used to detect plaque locations within coronary arteries, such as early-stage atherosclerotic lesions including foam cells and fatty deposits within intima. Such plaque deposits are unstable and are prone to rupture, which can expose the subendothelial plaque to blood flow. This in turn can lead to platelet clot formation and unstable angina or acute myocardial infarction. Detection of such regions via impedance difference measurement with respect to surrounding vessel tissue can enable prophylactic treatment (e.g., angioplasty, stents) to be commenced to alleviate any danger therefrom.

[00058] Impedance-based guidance and measurement can also be employed in one embodiment to detect pre-stenotic lesions in veins and/or arteries. It is noted that stenosis of atherosclerotic coronary and peripheral arteries, as well as central and peripheral veins (including veins included in an AV access circuit for hemodialysis) is a common problem often treated with angioplasty. Detection of such regions via impedance difference measurement ("mapping") as described herein with respect to surrounding vessel tissue can enable prophylactic treatment to be commenced to prevent problems in risk areas such as those prone to restenosis and/or de novo stenosis while still in early-stage development in the vessel wall and prior to significant vessel constriction. In one embodiment, a solid body catheter or catheter including a lumen is employed for carrying the impedance electrodes for detecting stenotic and/or pre-stenotic lesions. An example configuration is shown in FIG. 10, wherein the catheter 72 including the electrodes 90A, 90B is disposed within the vessel 80 such that the electrodes are positioned adjacent a pre-stenotic lesion 140. Differing impedance measurements on and around the lesion 140 can indicate its presence to a clinician, who may then treat the area as needed. In another embodiment, the impedance electrodes are included on an angioplasty balloon assembly, a stent assembly, or a drug-eluting balloon assembly so that the appropriate treatment (e.g., angioplasty, stenting, drug delivery) can be administered immediately after detection of the pre-stenosis region. Note that the detection of stenotic and/or pre-stenotic lesions may require, in one embodiment, the use of an RF source frequency distinct from that for impedance-based catheter tip placement.

[00059] In yet another embodiment, it is appreciated that impedance measurement within a vessel can be employed to ensure that access to an intended one of an artery or vein has been achieved. It is appreciated that during endovascular procedures inadvertent cannulation of a vein instead of an intended artery (or vice versa) can produce adverse effects during procedures including cardiac catheterization, central venous catheter placement, etc. Measurement of impedance values for portions of an interior wall of a vessel after access thereto is achieved can indicate whether the vessel is an artery or vein, thus enabling a clinician to confirm that the proper vessel type has been accessed. It is noted that impedance values for arteries generally fall between those of veins and myocardial tissue. This relationship enables discrimination between veins and arteries to be achieved. Thus, arteries, such as those typically cannulated during endovascular procedures (femoral, subclavian, brachial, etc.) can be identified by their impedance. Veins can be similarly identified, thus reducing the potential for adverse events related to incorrect vessel puncture.

[00060] The above impedance relationship is depicted in FIGS. 11 and 12, wherein in FIG. 11 a relatively thick-walled vein vessel 80 having a thickness t_1 is shown. The catheter 72 including electrodes such as the electrode 90B is disposed within the vein vessel 80. Impedance measurements taken by the electrodes can enable the clinician to determine whether the catheter 72 is disposed within a vein or artery, as described above. FIG. 12 shows a corresponding situation for the catheter 72 disposed in an artery vessel 80 having a thickness t_2 that is thinner relative to the thickness t_1 of the vein. As mentioned, the measured impedance of the artery will be generally lower than that for the vein but higher than that for heart-related tissue.

[00061] FIG. 13 shows that, in one embodiment, extended electrode wires 150 can be added to one or both of the electrodes 90A, 90B so as to enable the electrode array 90 to be in operable contact with the tissue surface 92 when the catheter 72 itself is not disposed adjacent the surface of the vessel. The extended electrode wires can be configured in a compliant manner so as to enable the wires to deform as necessary during advancement of the catheter 72 through the vasculature yet maintain contact with the tissue surface 92 so that impedance measurements can be taken when desired. In the present embodiment, four curved electrode wires 150 are attached to each electrode 90A, 90B. Note, however, that the number, size, shape, extension, and other configurations of the extended electrode wires can vary from what is shown and described herein.

[00062] Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the embodiments 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 method for guiding a catheter within a vasculature of a patient, the method comprising:
introducing the catheter into a vessel of the patient, the catheter defining a lumen through which fluids can be infused into the vasculature of the patient;
advancing the catheter toward a target destination within the vasculature; and
calculating at least a first impedance value based on intravascular detection of at least one electrical property related to a first tissue surface of the vessel to enable determination of the proximity of a distal end of the catheter with respect to the target destination.
2. The method for guiding a catheter as defined in claim 1, wherein calculating the at least first impedance value is performed by a processor based on detection of the at least one electrical property by at least one electrode pair associated with the catheter, the at least one electrode operably connected to the processor, the at least one electrical property including a voltage value across the electrode pair, the electrode pair disposed proximate to the first tissue surface.
3. The method for guiding a catheter as defined in claim 2, wherein calculating the at least first impedance value further comprises:
providing an electrical current to an electrode pair disposed proximate to the first tissue surface;
detecting a voltage value across the electrode pair; and
calculating the at least first impedance value based on the provided electrical current and the detected voltage.
4. The method for guiding as defined in claim 3, further comprising:
establishing physical contact of the electrode pair with the tissue surface before providing the electrical current.
5. The method for guiding as defined in claim 4, further comprising:
depicting data relating to the calculated at least one impedance value on a display for observation by a clinician.

6. The method for guiding as defined in claim 5, further comprising:
advancing the catheter so that the electrode pair is proximate a second tissue surface in the vessel;
providing an electrical current to the electrode pair;
detecting a voltage value across the electrode pair; and
calculating a second impedance value based on the provided electrical current and the detected voltage.
7. The method for guiding as defined in claim 6, wherein the target destination is proximate a junction of the superior vena cava and the right atrium of the heart of the patient, and wherein an impedance drop between the first impedance value and the second impedance value indicates advancement of a distal end of the catheter toward the junction from the superior vena cava.
8. A catheter guidance system, comprising:
a catheter for disposal within a vessel of a patient, the catheter defining at least one lumen through which a fluid may be infused into the vasculature;
an RF source for providing an electrical current;
at least one electrode pair included proximate a distal tip of the catheter to which the electrical current is provided;
means for measuring voltage values across the electrode pair when the electrical current is provided to the electrode pair and the electrode pair is disposed proximate a tissue surface of the vessel;
a processor for calculating impedance values according to the provided current and the voltage values; and
a display for depicting data relating to the calculated impedance values to assist a clinician in determining a location of the distal tip of the catheter within the vasculature.
9. The catheter guidance system as defined in claim 8, wherein the means for measuring voltage values is a voltmeter, the voltmeter being operably connected to the processor, and wherein the system further includes an ammeter for measuring the magnitude of the electrical current, the ammeter being operably connected to the processor.

10. The catheter guidance system as defined in claim 9, wherein the RF source, the voltmeter, the processor, and the display are included in a console.

11. The catheter guidance system as defined in claim 8, further including a magnetic tracking system for magnetically tracking the catheter within the vasculature and an ultrasound imaging system for ultrasonically imaging at least a portion of the vessel.

12. The catheter guidance system as defined in claim 8, wherein the electrode pair is disposed on an outer surface of the catheter proximate the distal tip thereof.

13. The catheter guidance system as defined in claim 8, wherein the electrode pair is included on a stylet removably received in the at least one lumen of the catheter.

14. The catheter guidance system as defined in claim 8, wherein the catheter further includes a diversion component for selectively diverting the electrode pair into physical contact with the tissue surface of the vessel.

15. The catheter guidance system as defined in claim 14, wherein a stylet is disposed within the at least one lumen of the catheter, and wherein the diversion component includes a movable diversion flap disposed on a distal portion of the stylet extending distal to the distal tip of the catheter.

16. The catheter guidance system as defined in claim 14, wherein the diversion component includes a single movable diversion flap disposed proximate the distal tip of the catheter.

17. The catheter guidance system as defined in claim 14, wherein the diversion component includes first and second movable diversion flaps disposed proximate the distal tip of the catheter, each diversion flap operably connected to an actuating wire for selective actuation of the diversion flap by a clinician, the diversion flaps movable to center the distal tip of the catheter in a center region of the vessel.

18. The catheter guidance system as defined in claim 14, wherein the diversion component includes a deployable flap defining a generally triangular shape.

19. The catheter guidance system as defined in claim 8, wherein the calculated impedance values further enable a clinician to determine placement of the catheter in one of a vein and an artery.

20. The catheter guidance system as defined in claim 8, wherein the calculated impedance values further enable a clinician to identify areas in the vessel where pre-stenoses or early plaque formation are present.

21. A method for guiding a catheter within a vasculature of a patient, the catheter defining a lumen through which fluids can be infused into the vasculature of the patient, the catheter including at least a first electrode pair disposed on an outer surface thereof, the method comprising:

- introducing the catheter into a vessel of the patient;
- advancing the catheter toward a target destination within the vasculature;
- providing an electrical current to the electrode pair with the electrode pair disposed proximate a first tissue surface;
- calculating at least a first impedance value according to the electrical current and a voltage value of the electrode pair at the first tissue surface; and
- conveying to a user the first impedance value to determine proximity of a distal tip of the catheter to the target destination.

22. The method for guiding as defined in claim 21, further comprising:

- further advancing the catheter such that the electrode pair is disposed proximate a second tissue surface;
- providing the electrical current to the electrode pair with the electrode pair disposed proximate the second tissue surface;
- calculating a second impedance value according to the electrical current and a voltage value of the electrode pair at the second tissue surface; and
- comparing the first impedance value with the second impedance value to determine proximity of the distal tip of the catheter to the target destination.

23. The method for guiding as defined in claim 22, further comprising:

- storing the first and second impedance values for future use.

24. The method for guiding as defined in claim 22, wherein when the second impedance value is smaller relative to the first impedance value, the clinician can infer the distal tip of the catheter is approaching the right atrium of the heart of the patient.

25. The method for guiding as defined in claim 22, wherein the electrode pair physically touches the first tissue surface and the second tissue surface when the electrical current is provided.

26. The method for guiding as defined in claim 22, wherein at least one electrode of the electrode pair includes at least one extended electrode wire that compliantly engages one of the first tissue surface and the second tissue surface.

1/9

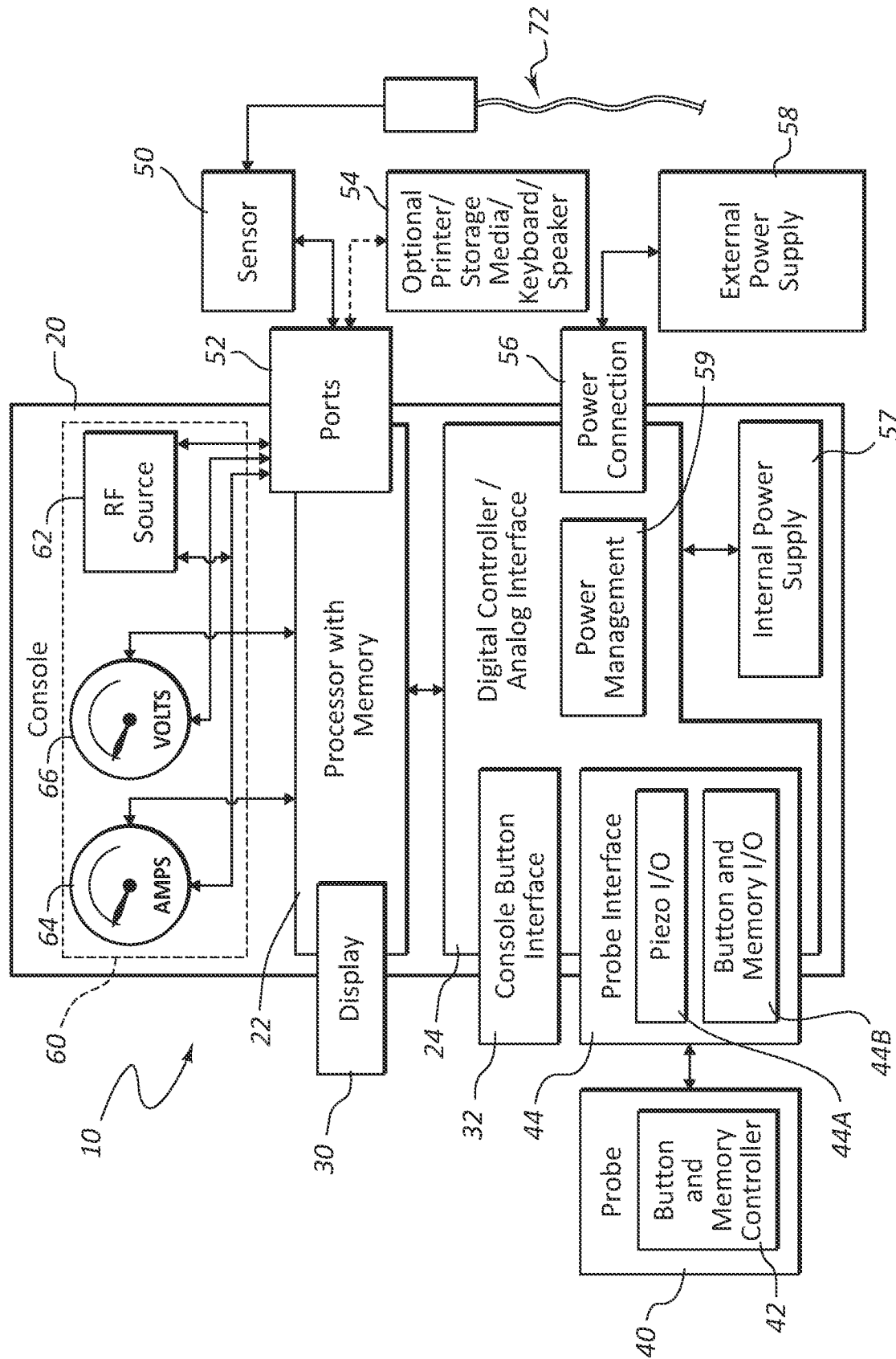


FIG. 1

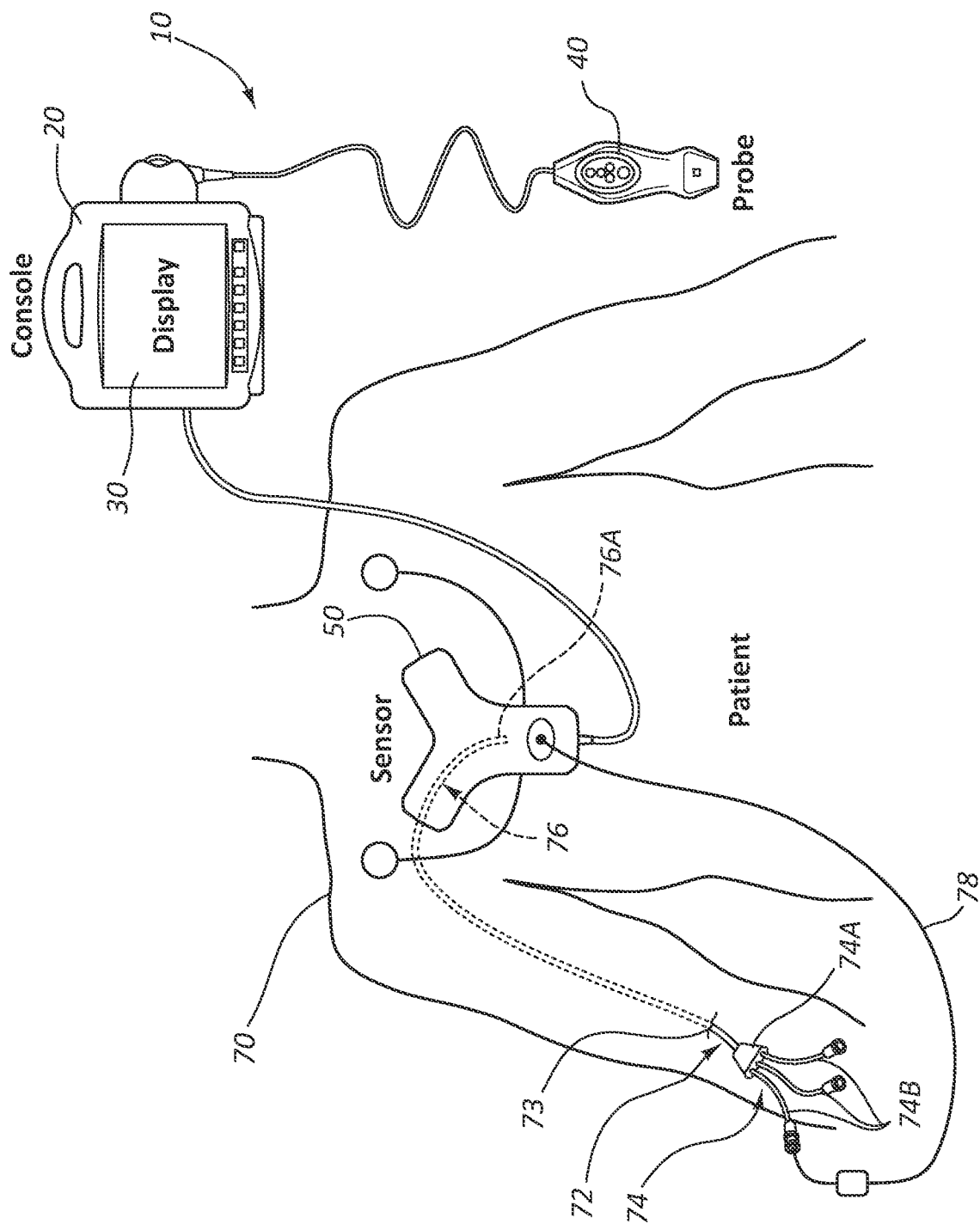


FIG. 2

3/9

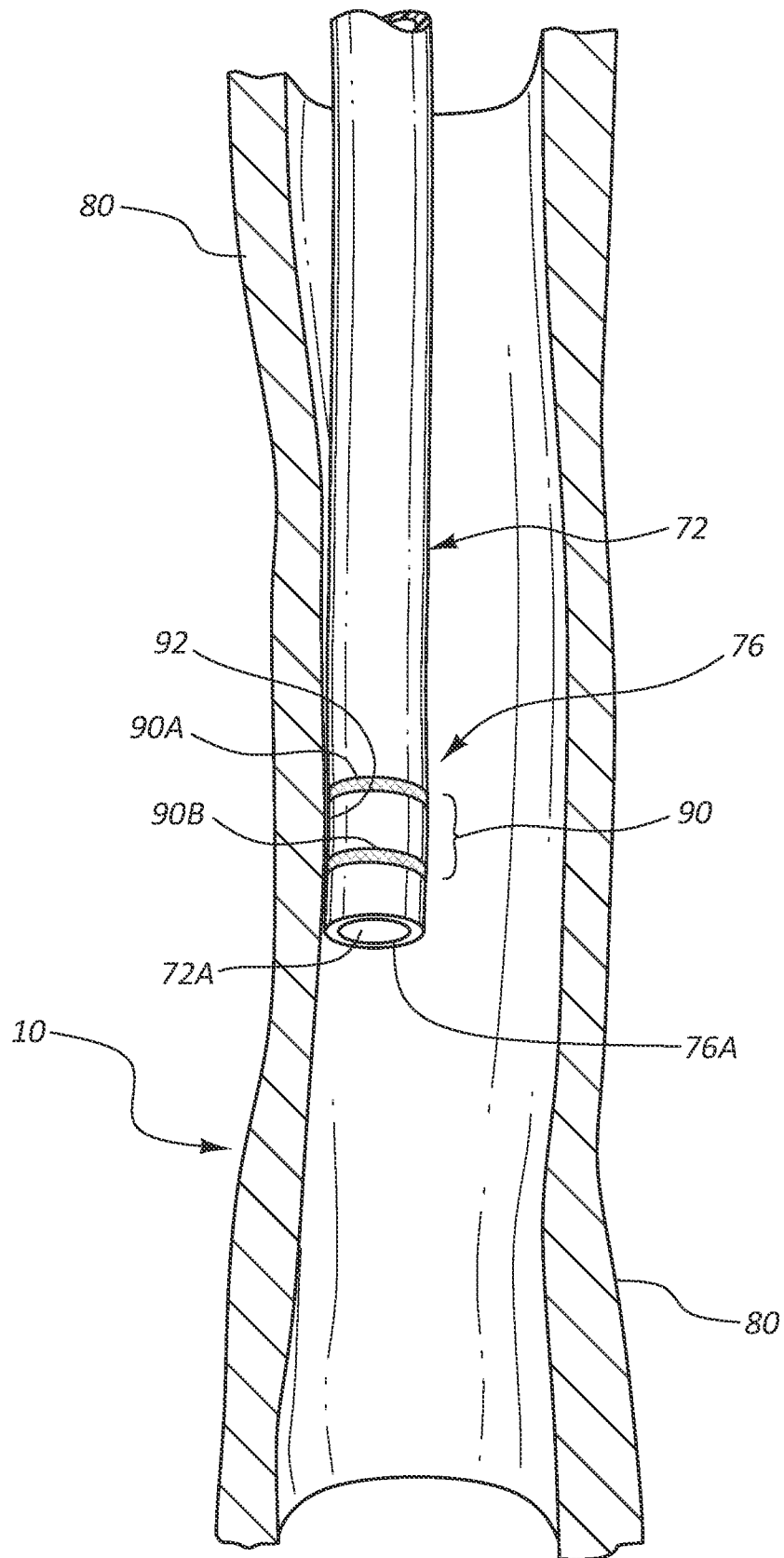


FIG. 3

4/9

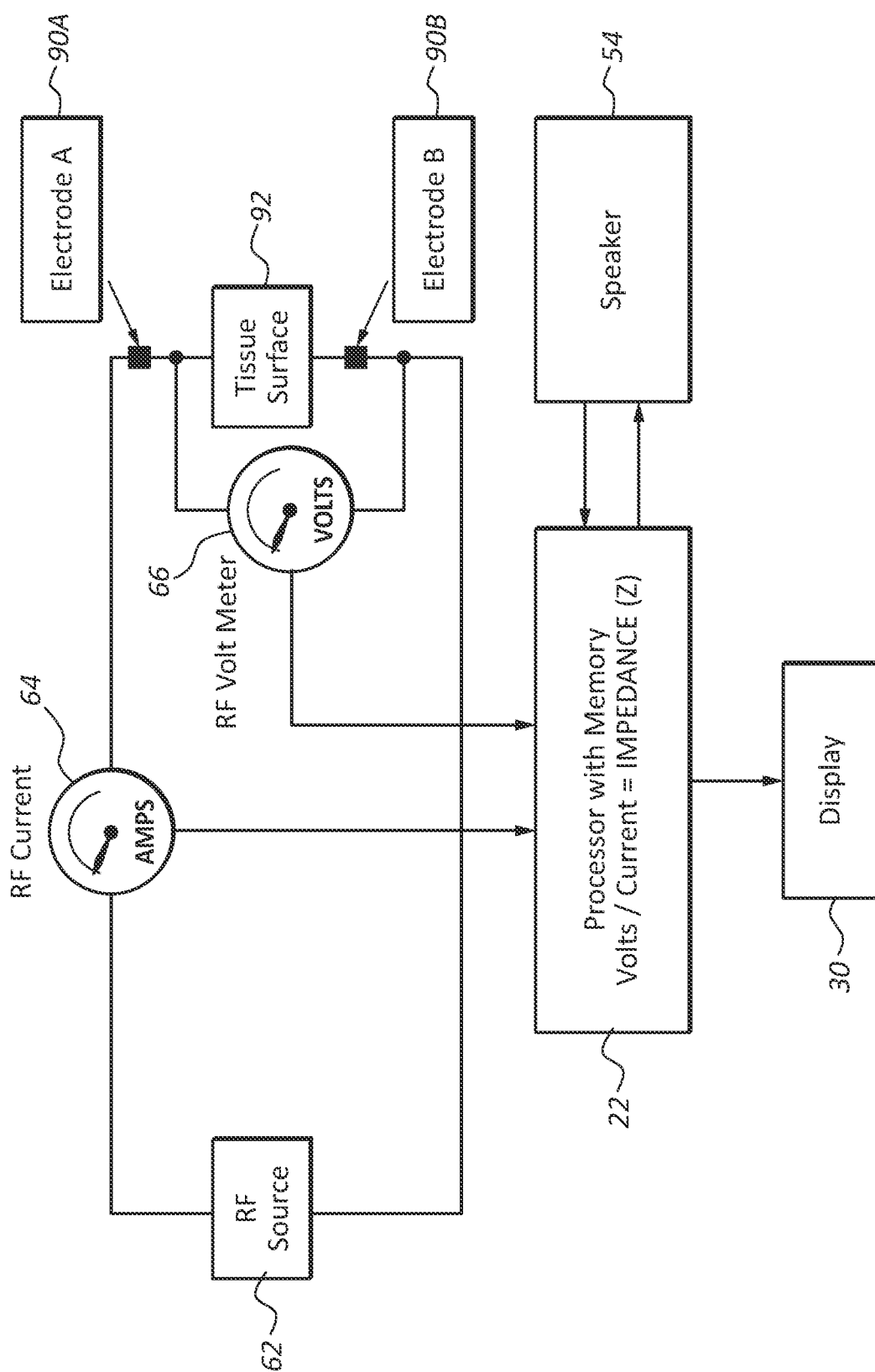


FIG. 4

5/9

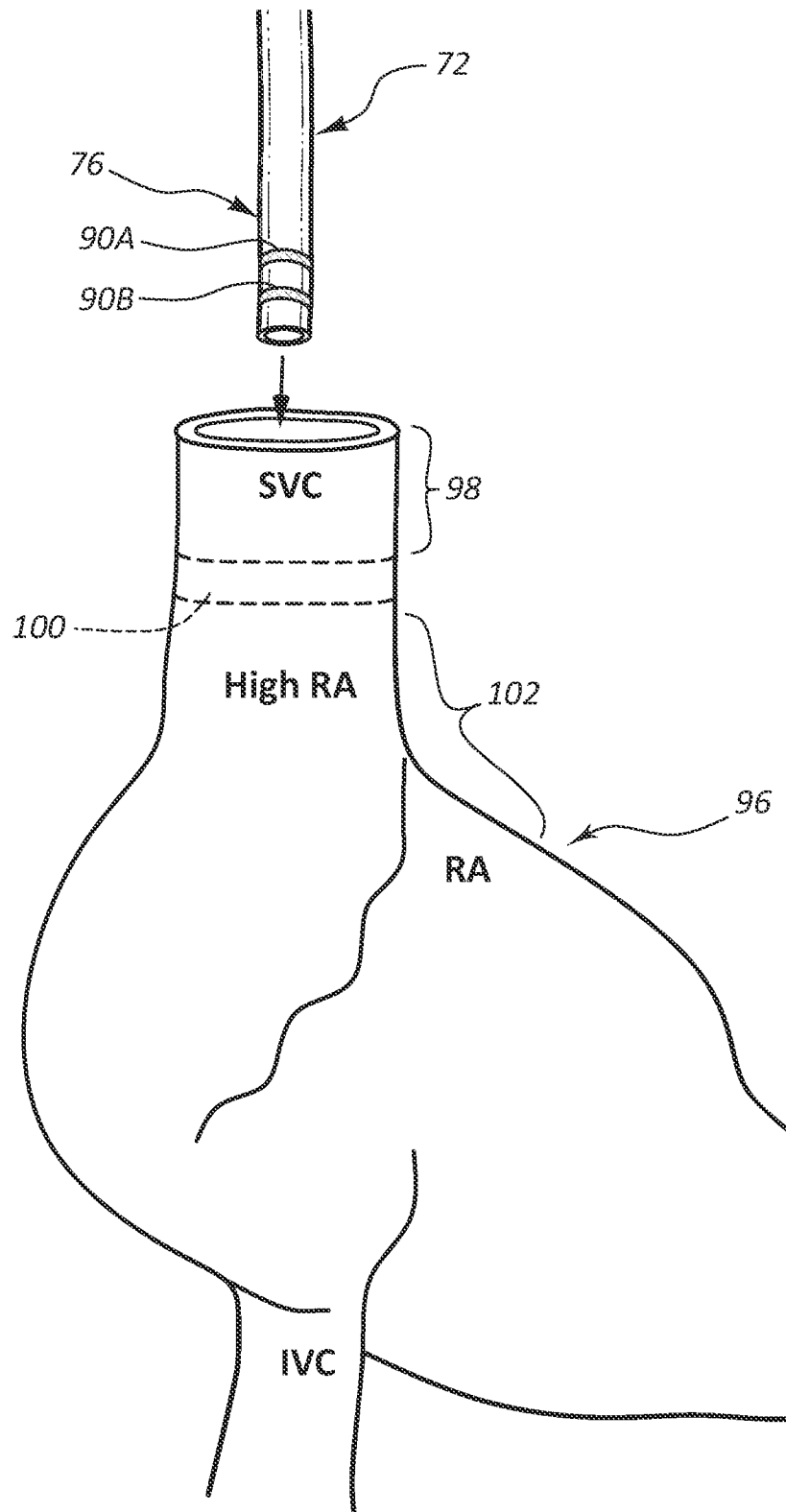


FIG. 5

6/9

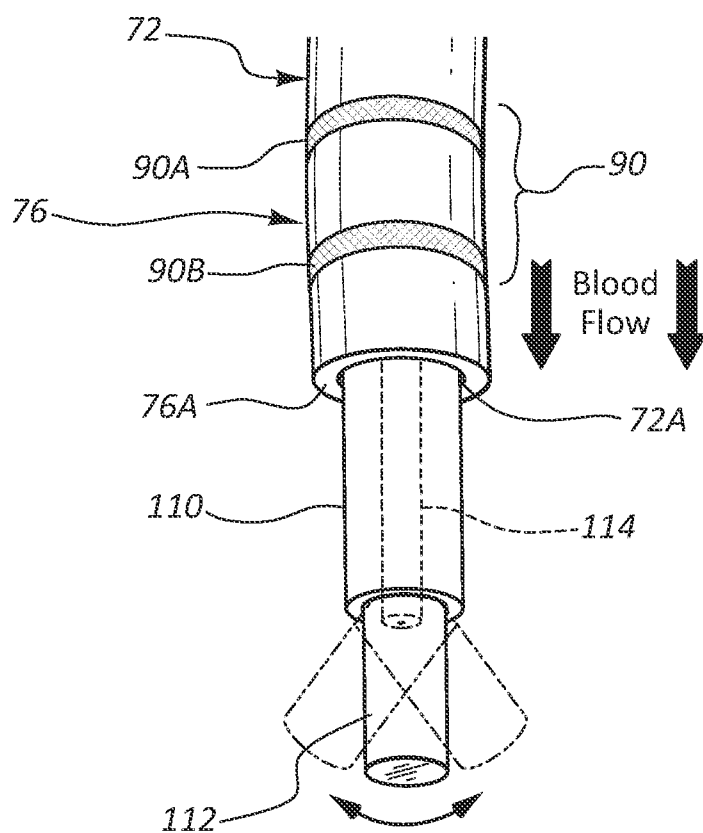


FIG. 6

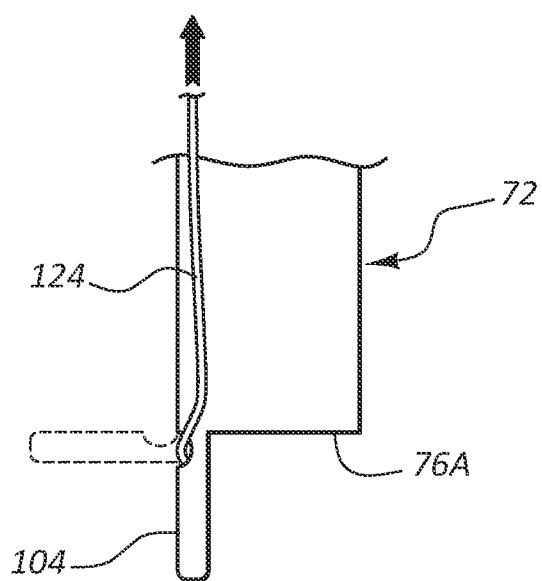


FIG. 7

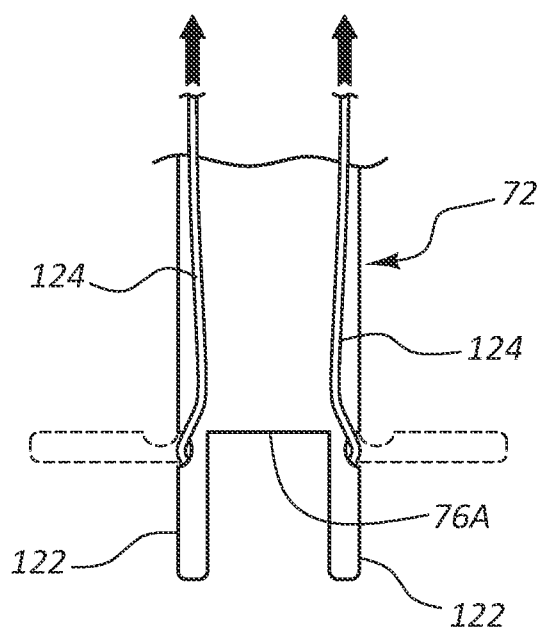


FIG. 8

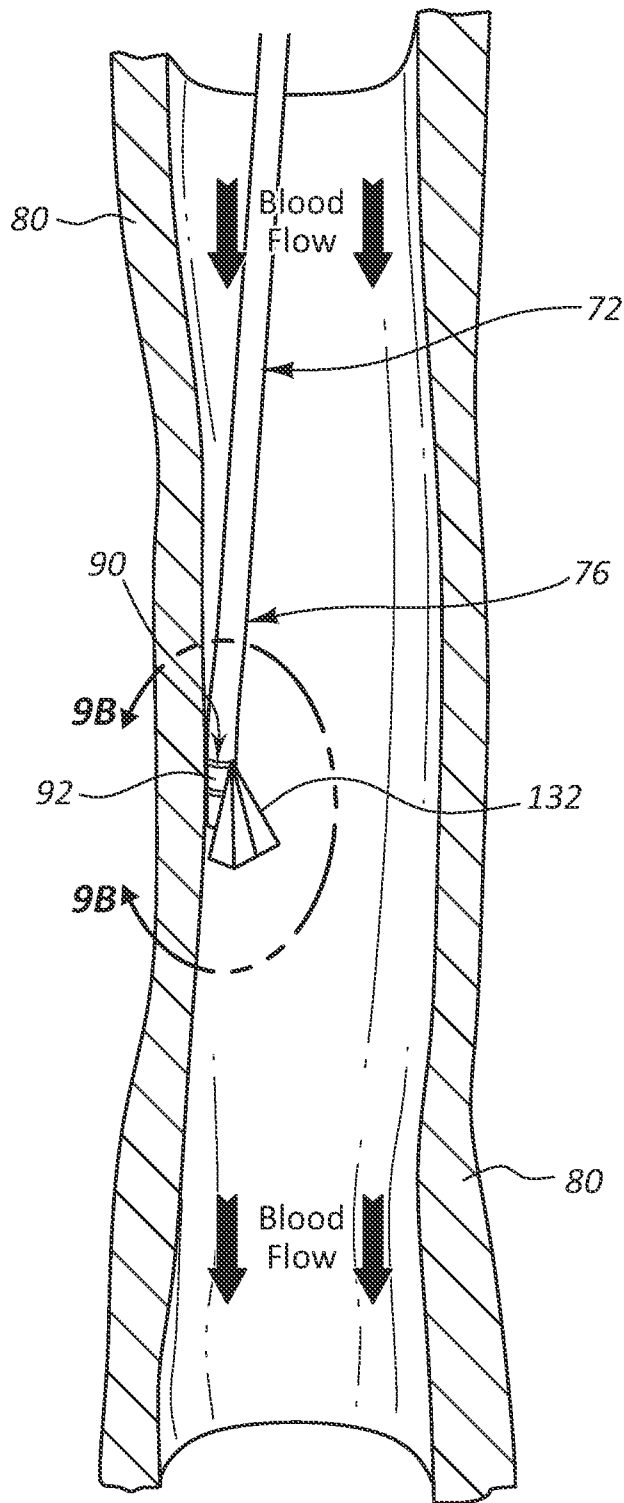


FIG. 9A

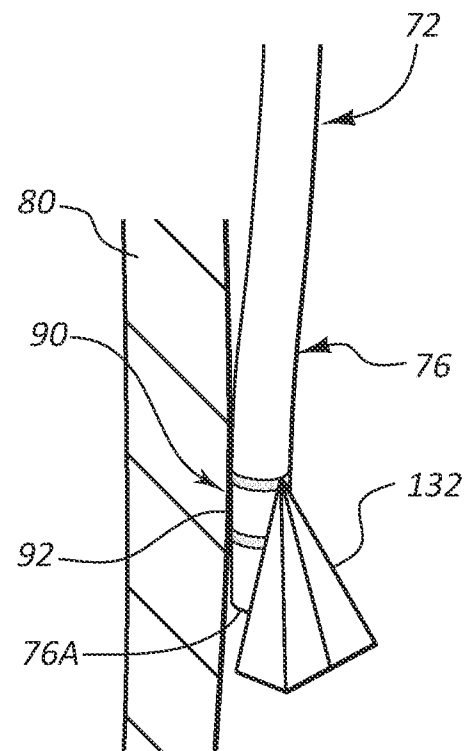


FIG. 9B

8/9

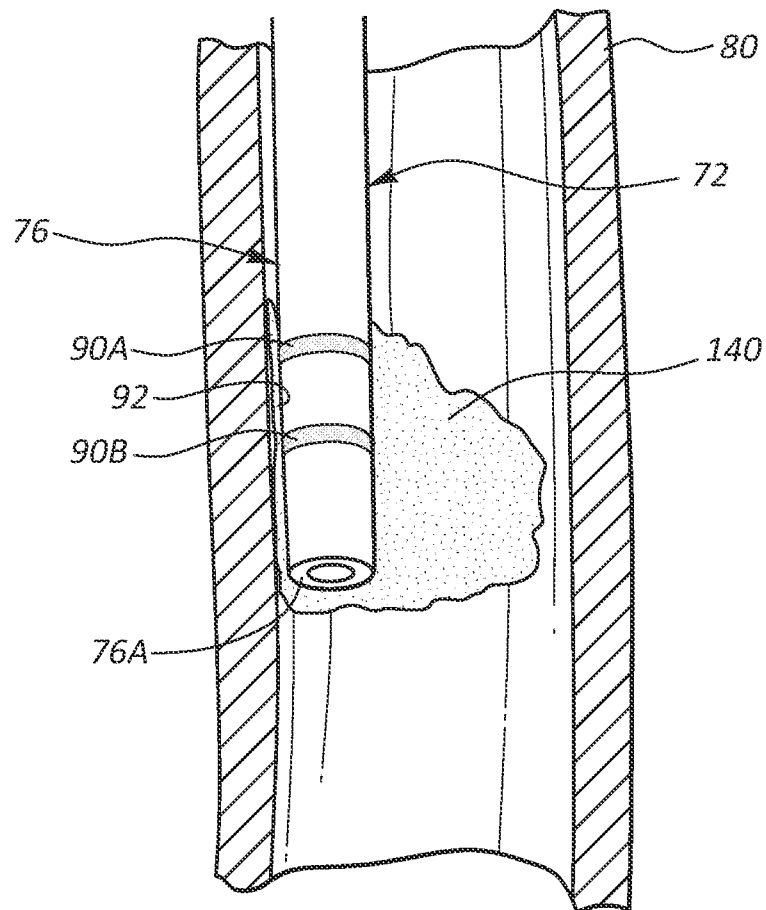


FIG. 10

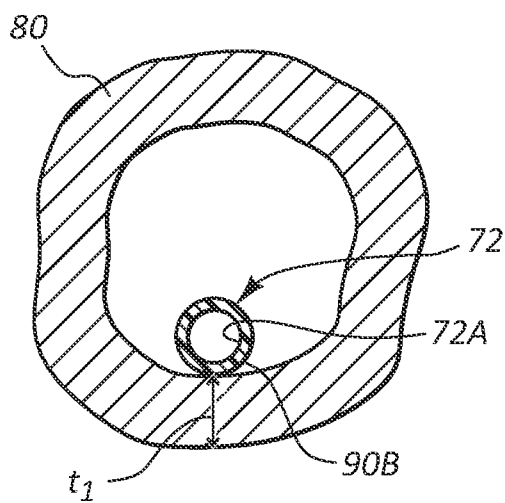


FIG. 11

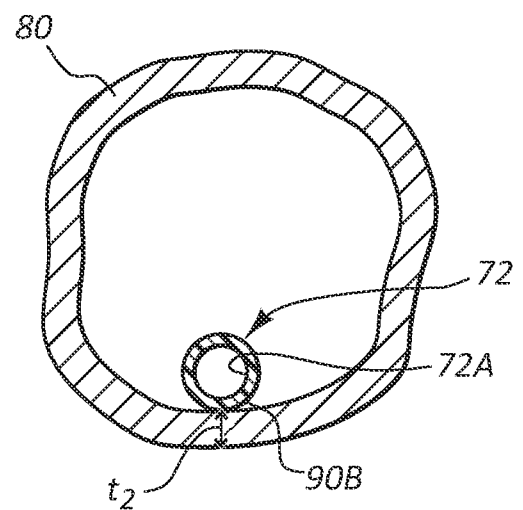


FIG. 12

9/9

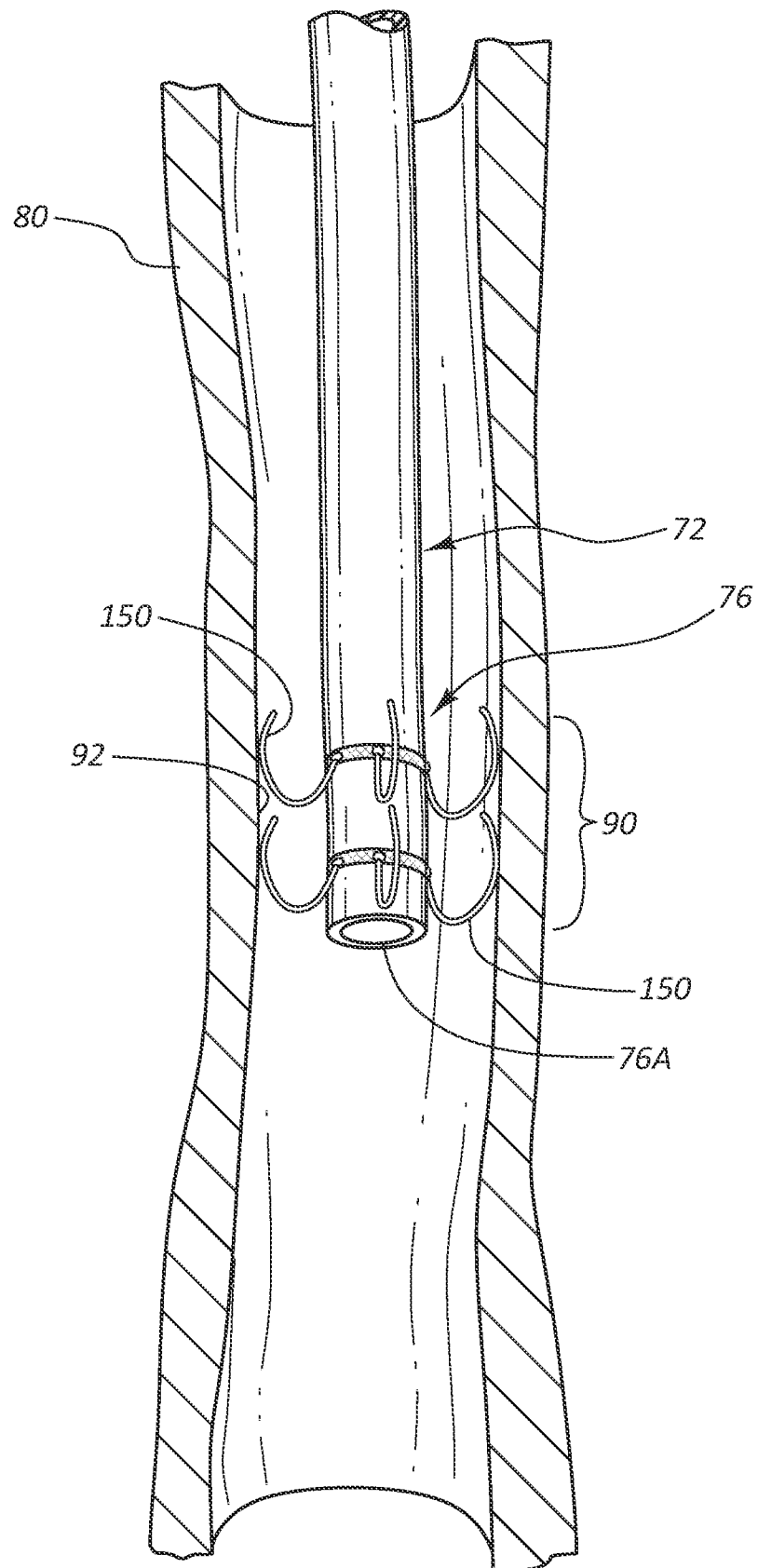


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US201 1/058138

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61 B 18/00 (2012.01)

USPC - 606/41

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) - A61B 18/00 (2012.01)

USPC - 604/41, 46, 66, 96.01, 523, 528, 536, 537; 606/32, 41

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)

Minesoft PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/0209950 A1 (STARKSEN) 20 August 2009 (20.08.2009) entire document	1-4
Y		5-26
Y	US 2007/0016007 A1 (GOVARI et al) 18 January 2007 (18.01.2007) entire document	5-26
Y	US 2005/0256541A1 (STYPULKOWSKI) 17 November 2005 (17.11.2005) entire document	13, 15
Y	US 6,491,671 B1 (LARSON, III et al) 10 December 2002 (10.12.2002) entire document	14-18
Y	US 5,025,799 A (WILSON) 25 June 1991 (25.06.1991) entire document	17
Y	US 2008/0125772 A1 (STONE et al) 29 May 2008 (29.05.2008) entire document	20

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

20 January 2012

Date of mailing of the international search report

07 FEB 2012

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:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774