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Kirschenman

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(54) **PRINTED ELECTRODE CATHETER**

(2013.01); *A61B 2018/00642* (2013.01); *A61B 2018/00875* (2013.01); *A61M 2205/332* (2013.01)

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(58) **Field of Classification Search**
CPC *A61B 5/0422*
See application file for complete search history.

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 443 days.

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(21) Appl. No.: **14/879,575**

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(51) **Int. Cl.**

Primary Examiner — Lee S Cohen

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A61B 18/14 (2006.01)
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A61M 25/01 (2006.01)
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G01L 1/16 (2006.01)
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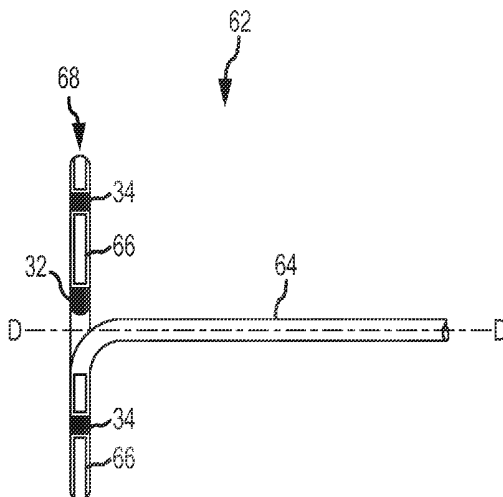
(57) **ABSTRACT**

(52) **U.S. Cl.**

CPC *A61B 5/0422* (2013.01); *A61B 18/1492* (2013.01); *A61M 25/01* (2013.01); *A61N 1/056* (2013.01); *G01L 1/005* (2013.01); *G01L 1/16* (2013.01); *G01L 5/00* (2013.01); *A61B 5/6885* (2013.01); *A61B 2018/00577*

An elongate medical device may comprise an elongate tubular body, an electrode, and a trace. The elongate tubular body may comprise a distal end portion and a proximal end portion, the body defining a longitudinal axis. The electrode may comprise electrically-conductive ink extending circumferentially about a portion of the distal end portion. The trace may comprise electrically-conductive ink, electrically coupled with the electrode, extending proximally from the electrode.

8 Claims, 12 Drawing Sheets



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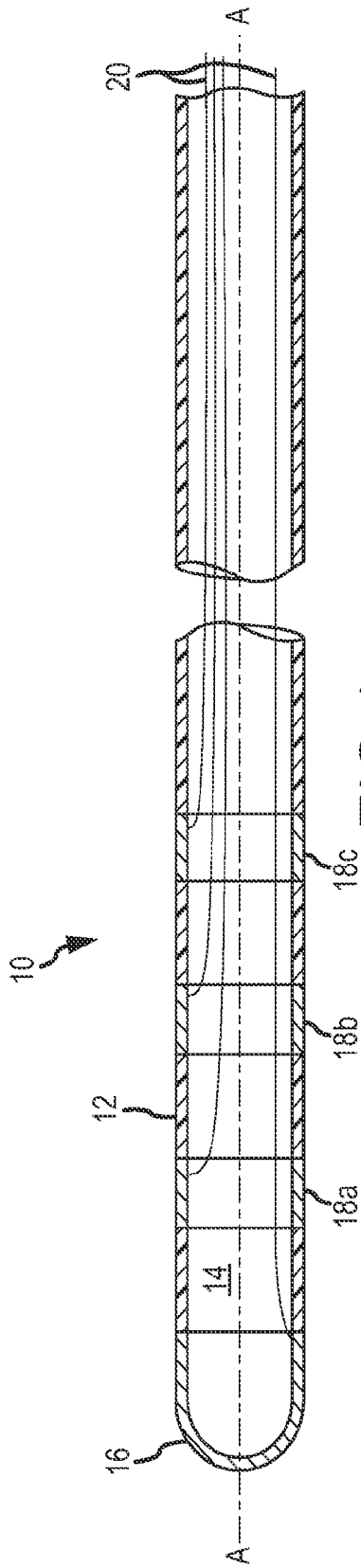


FIG. 1
(PRIOR ART)

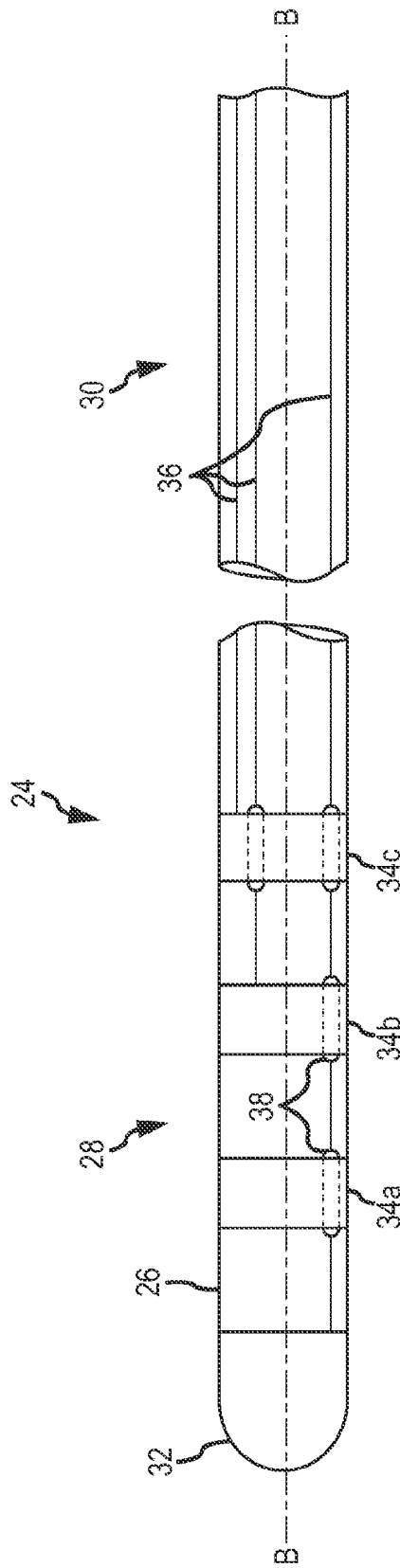


FIG. 2A

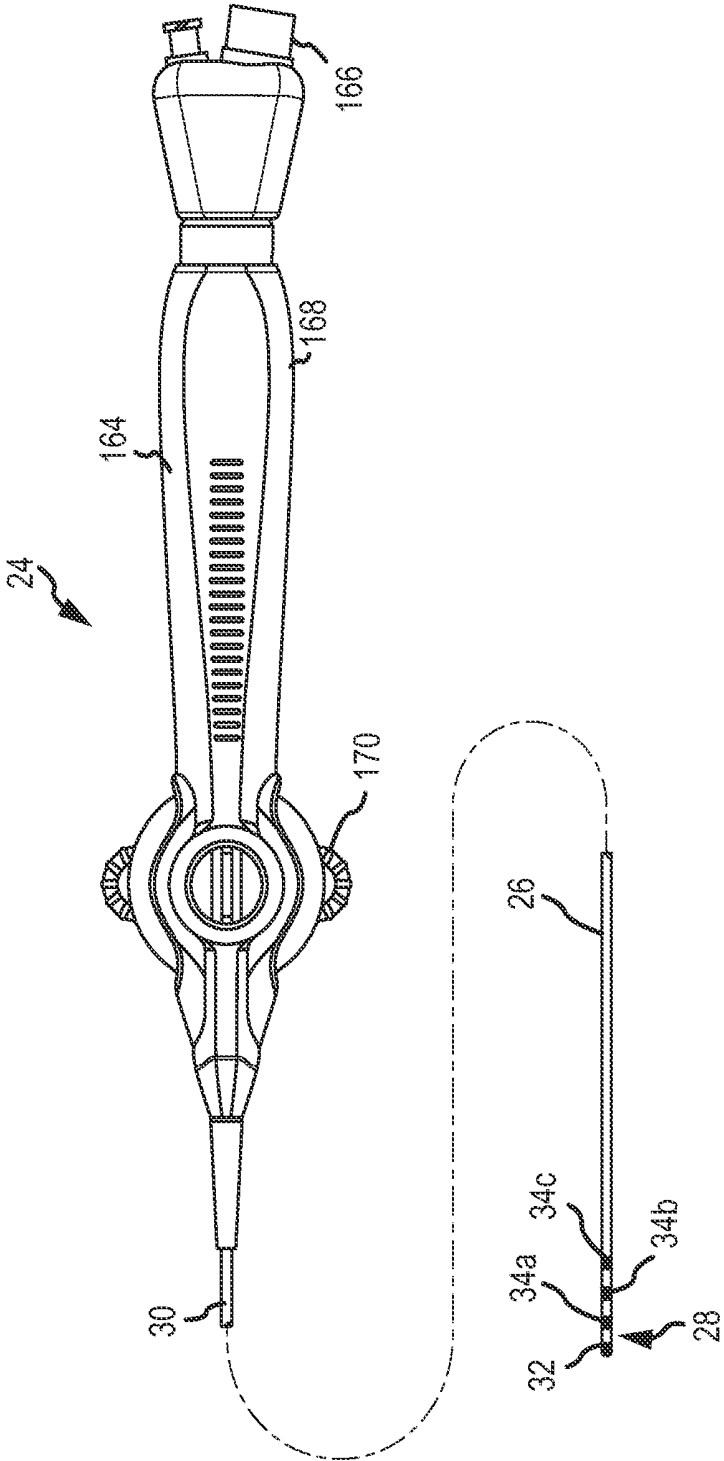


FIG. 2B

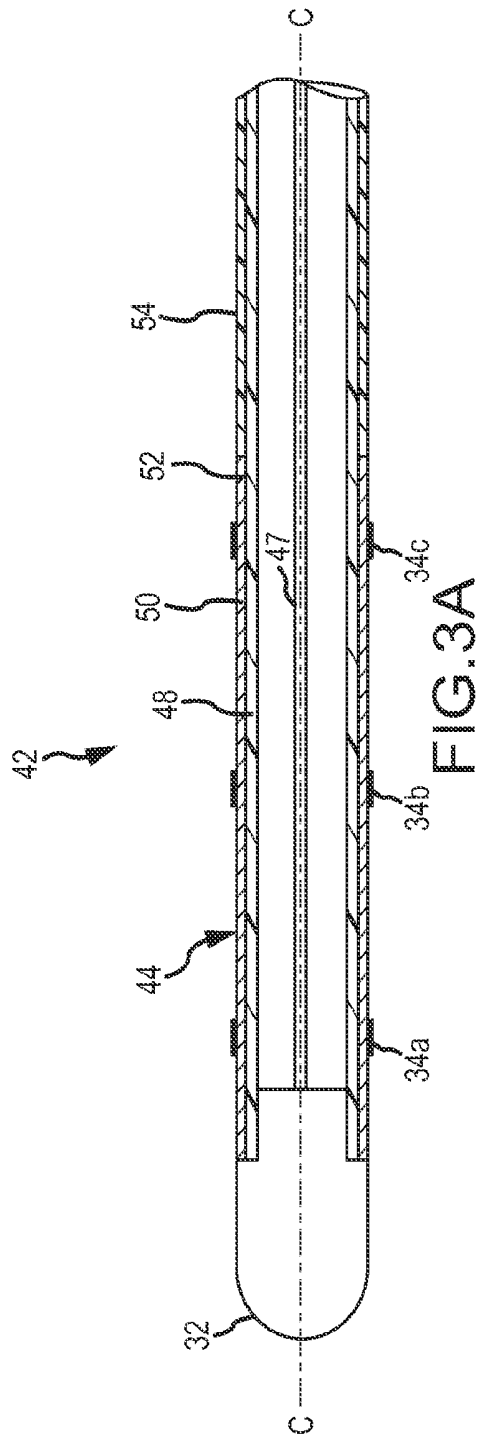


FIG. 3A

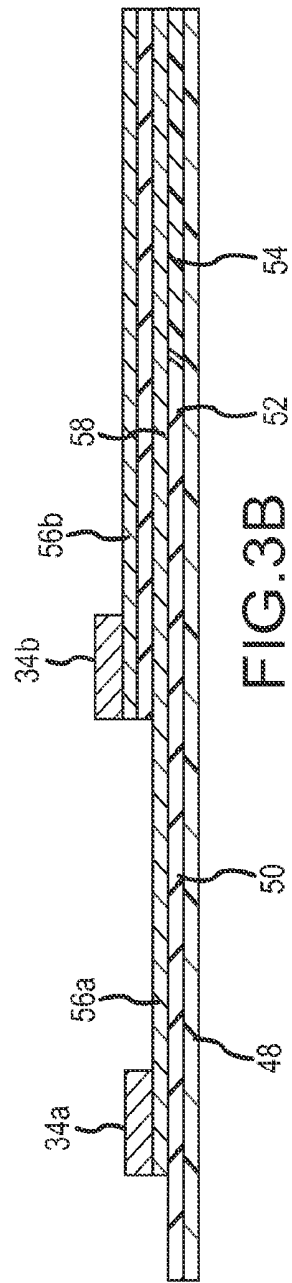


FIG. 3B

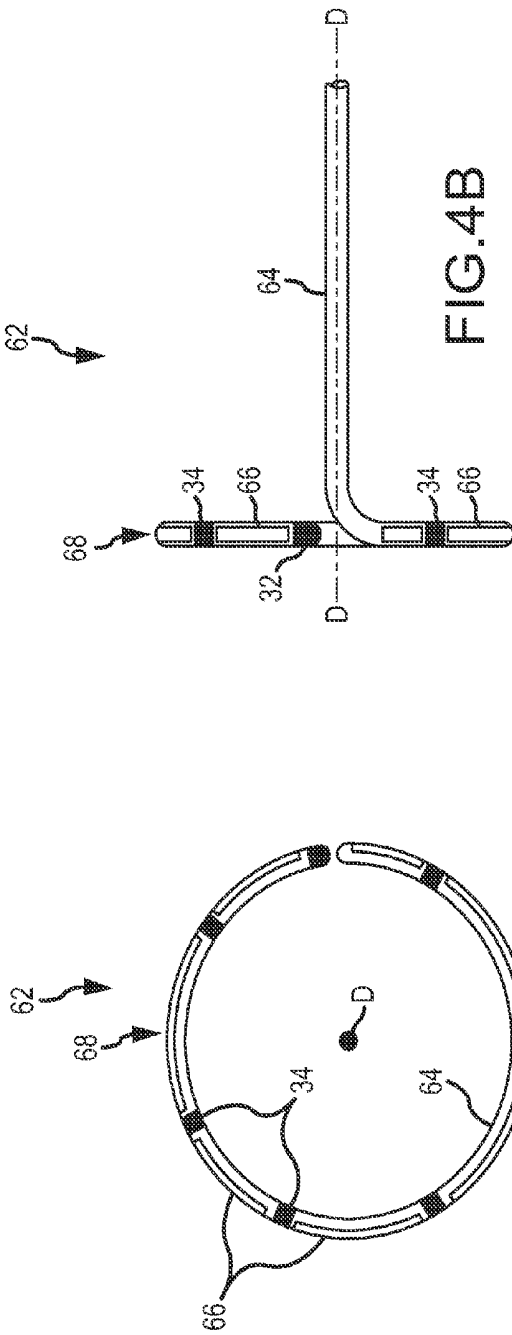


FIG. 4B

FIG. 4A

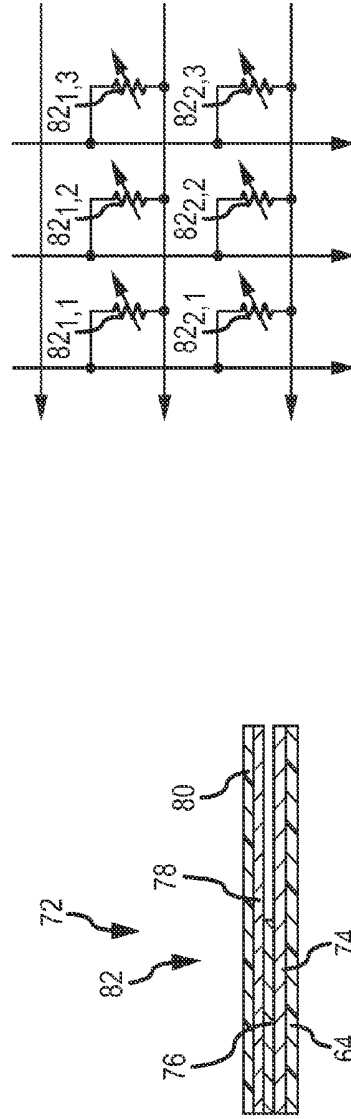


FIG. 5

FIG. 6

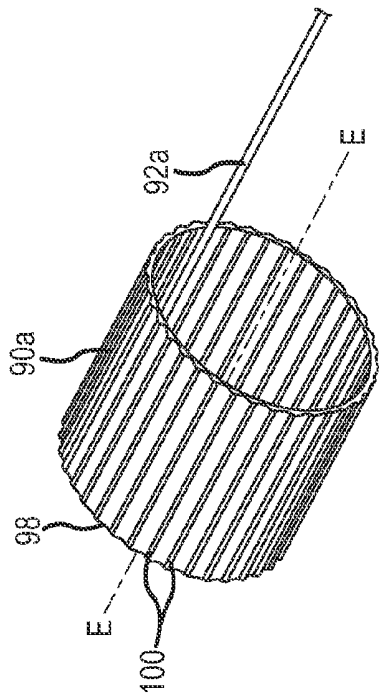


FIG. 7B

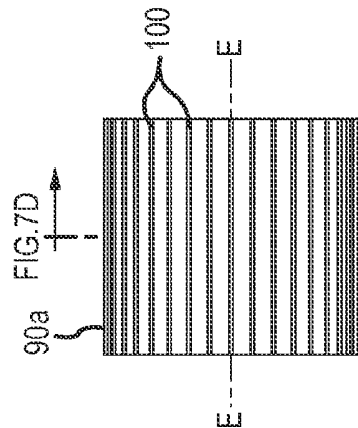


FIG. 7C

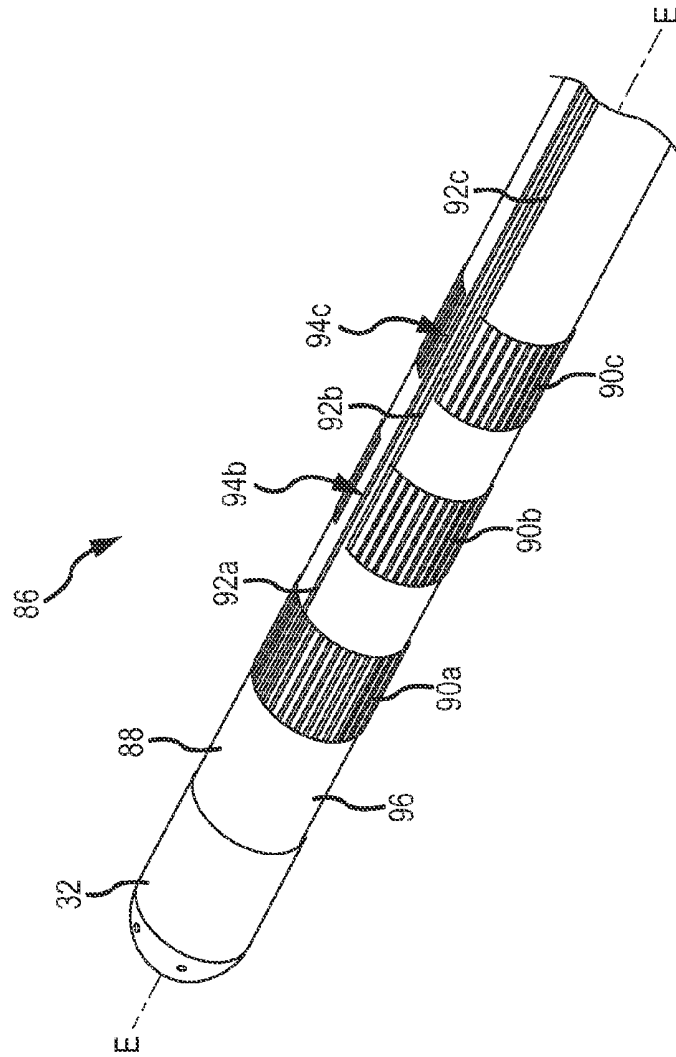


FIG. 7A

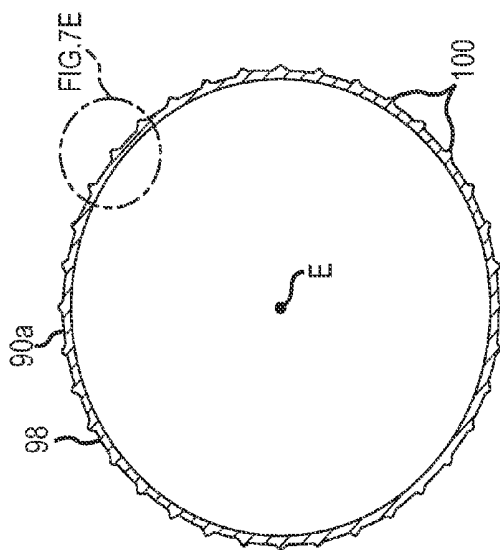


FIG. 7D

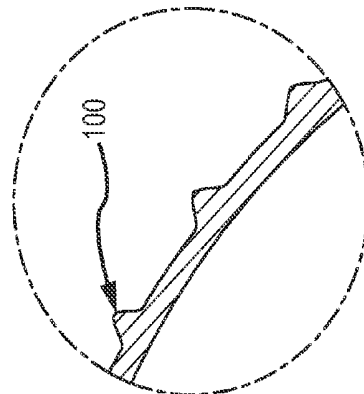


FIG. 7E

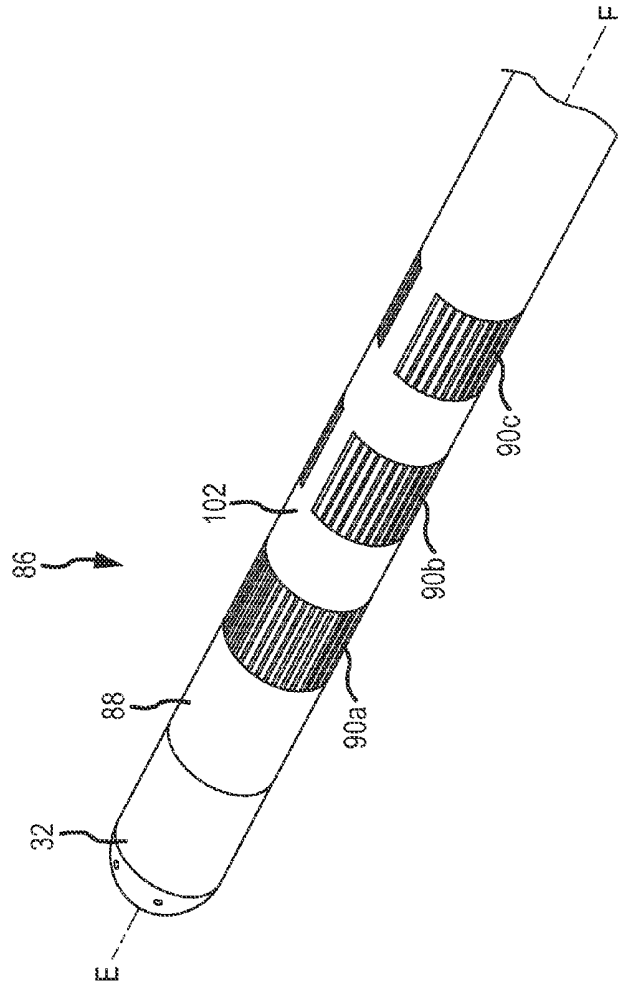


FIG. 7F

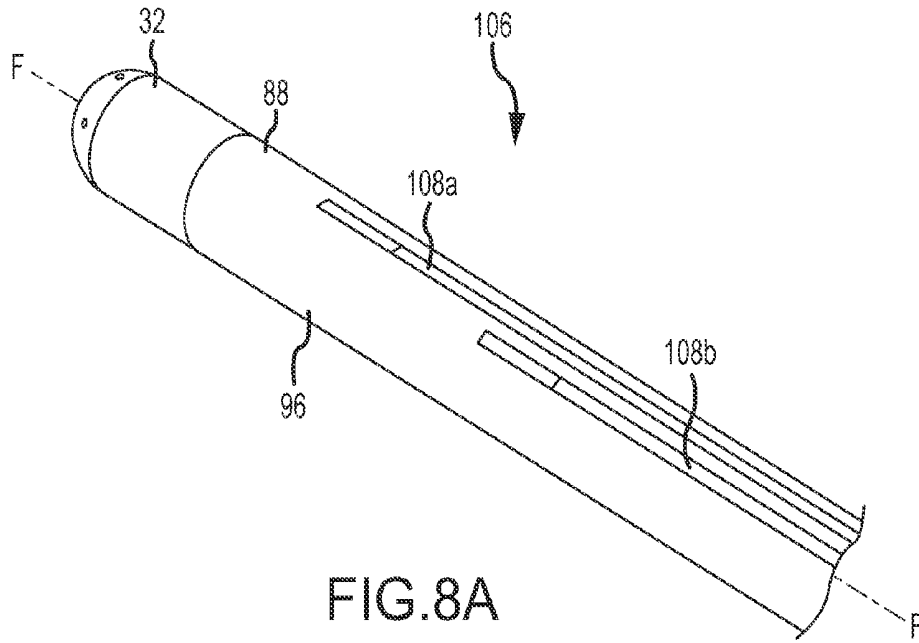


FIG. 8A

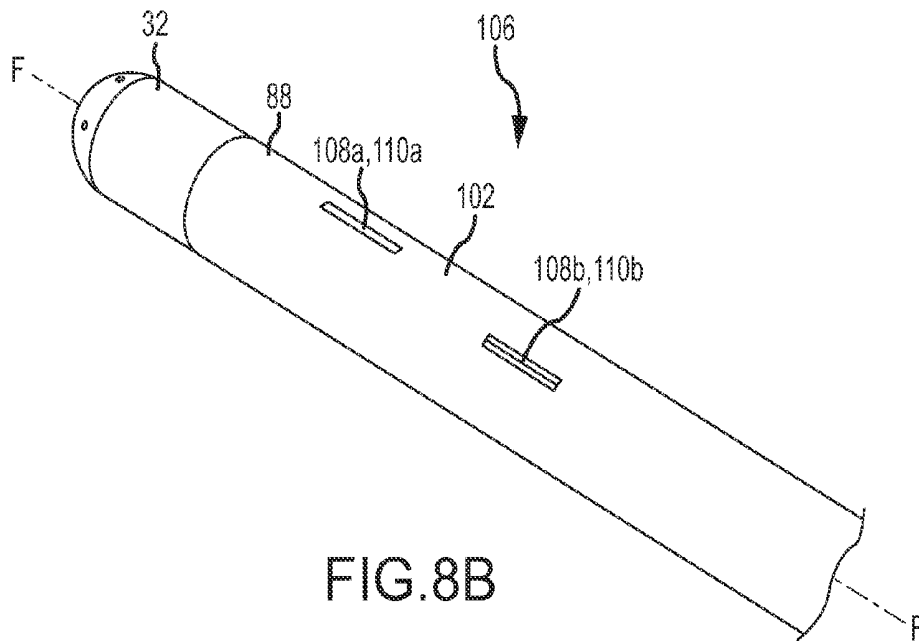


FIG. 8B

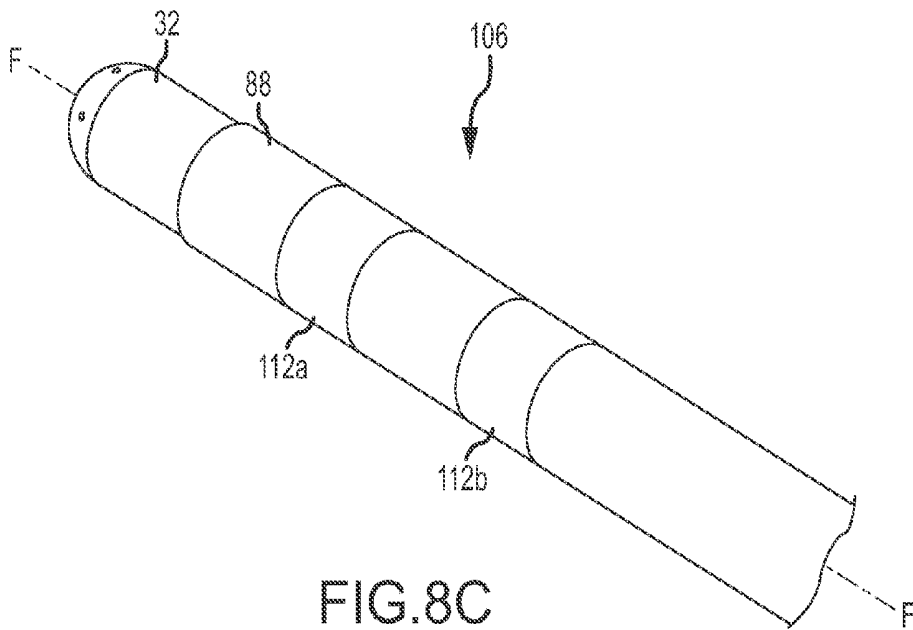


FIG. 8C

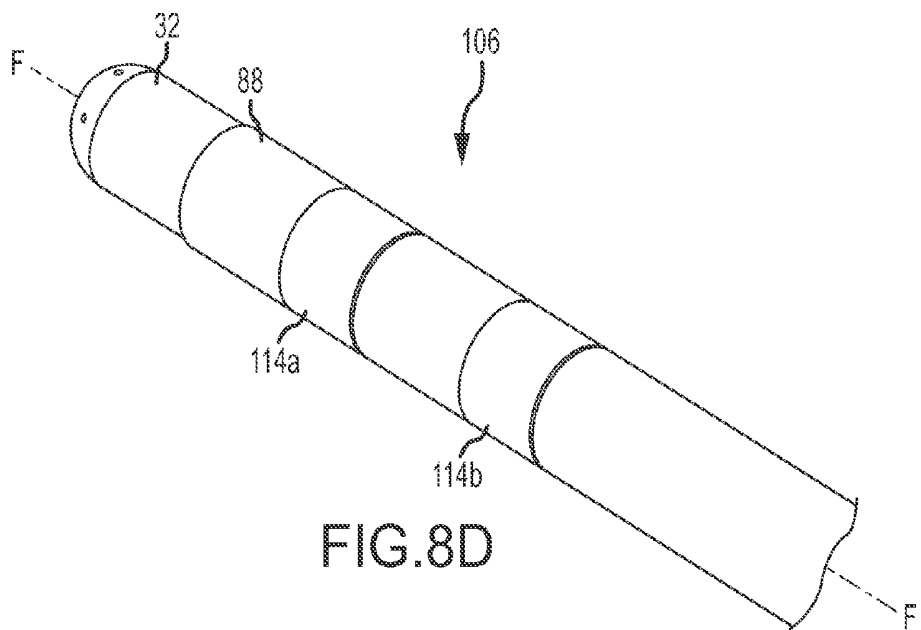


FIG. 8D

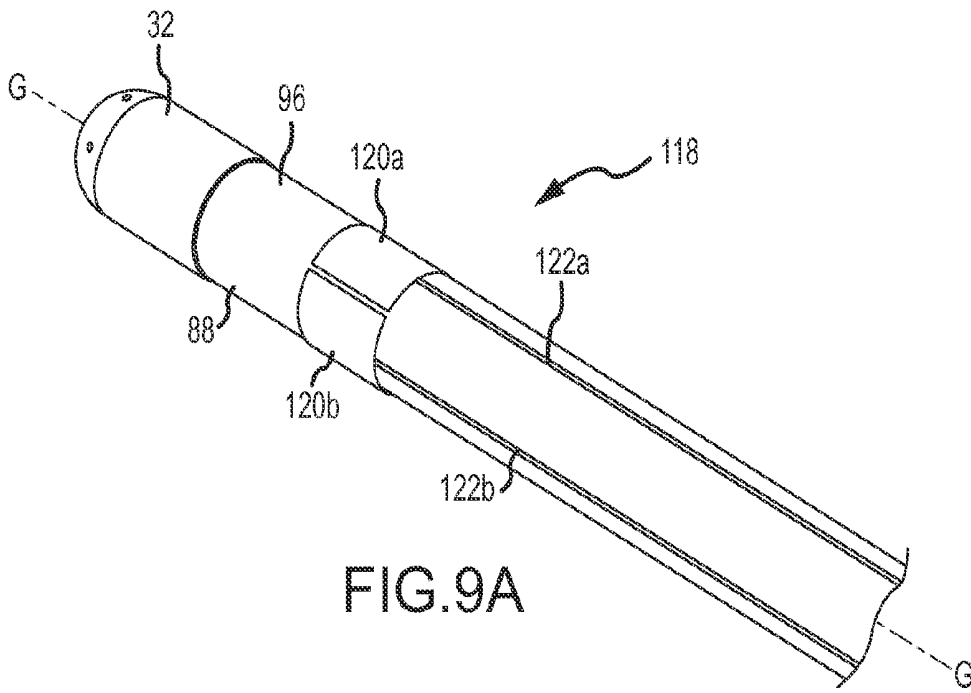


FIG. 9A

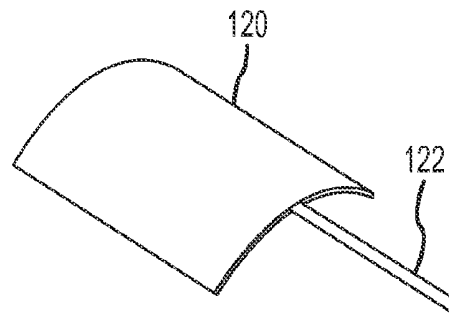


FIG. 9B

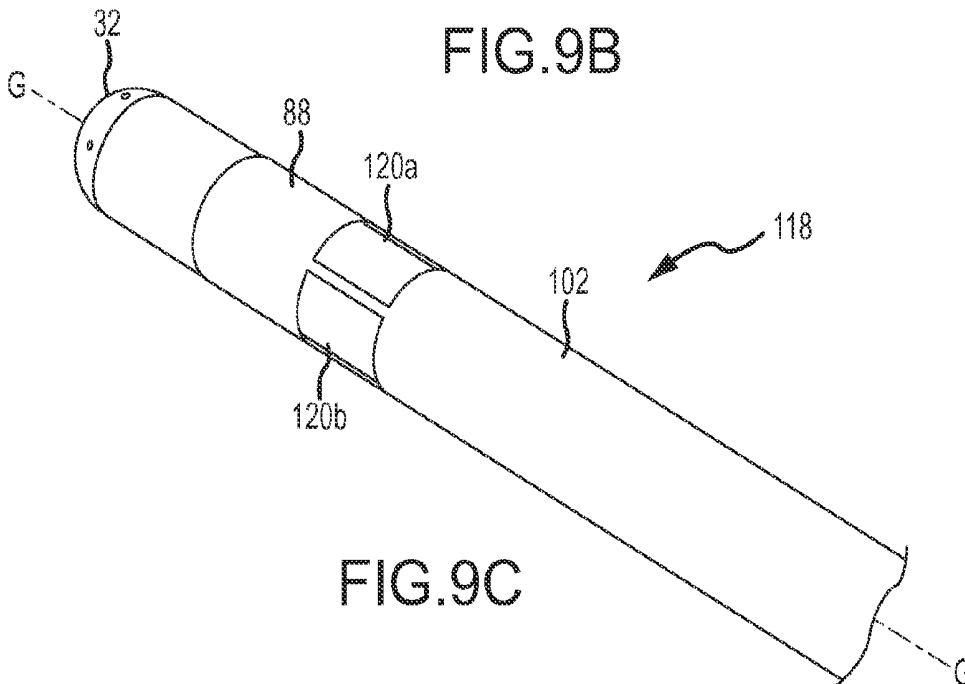


FIG. 9C

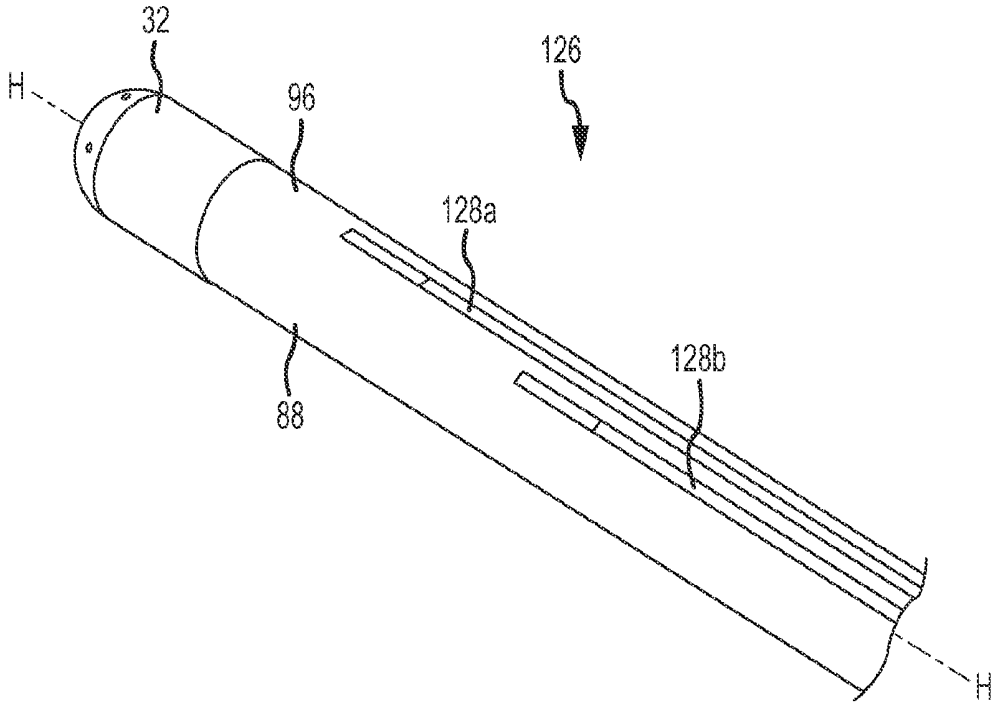


FIG. 10A

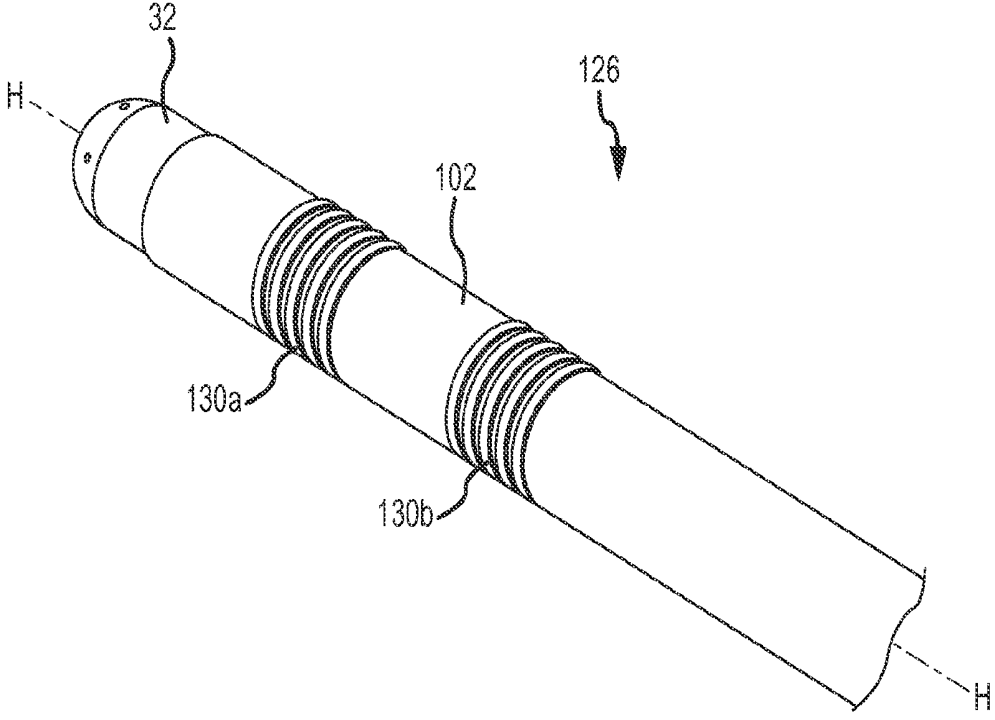


FIG. 10B

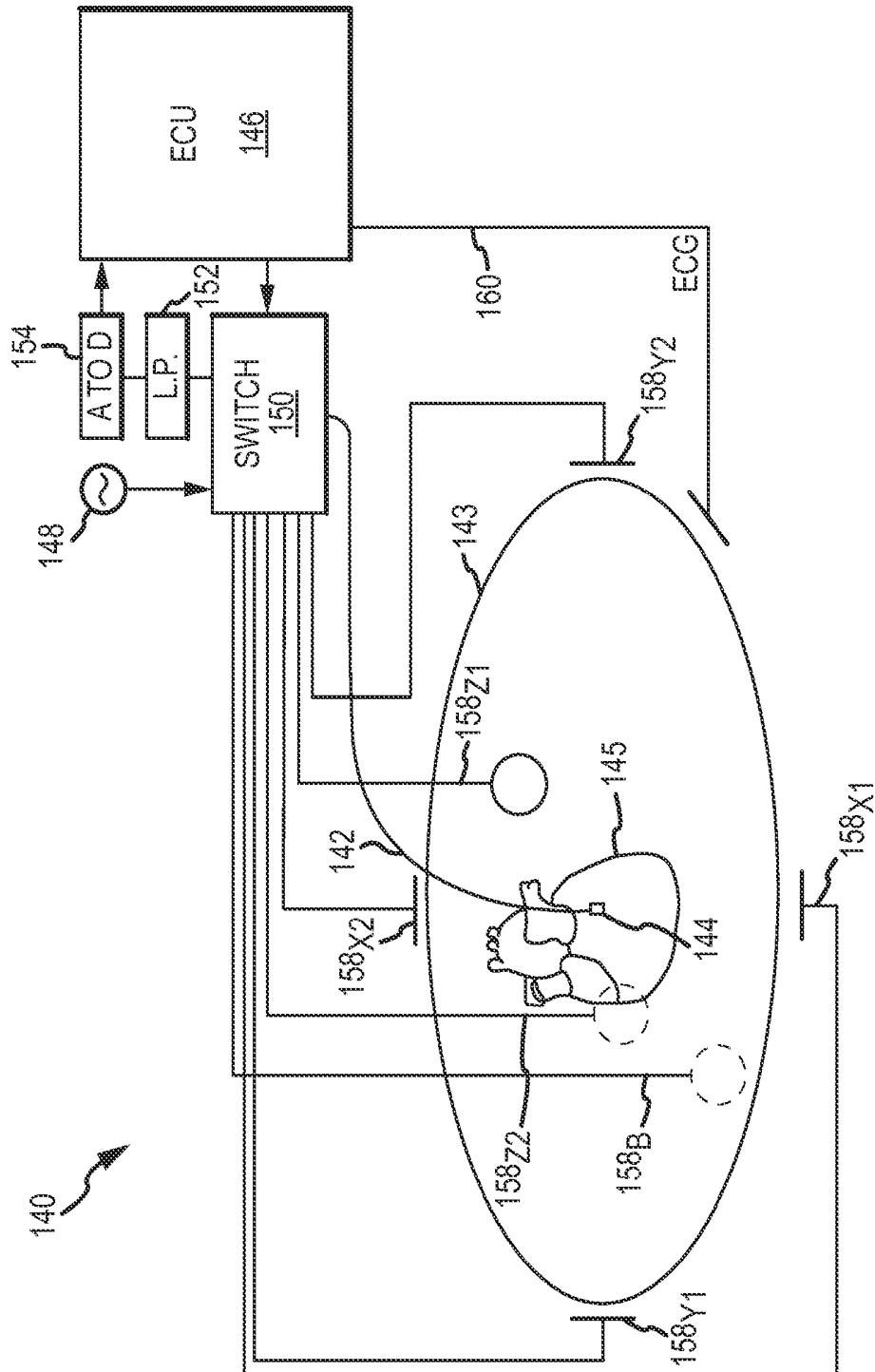


FIG.11

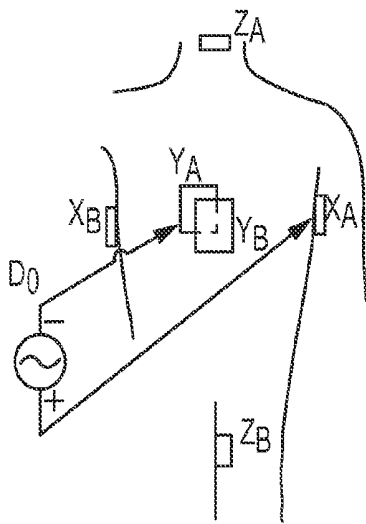


FIG. 12A

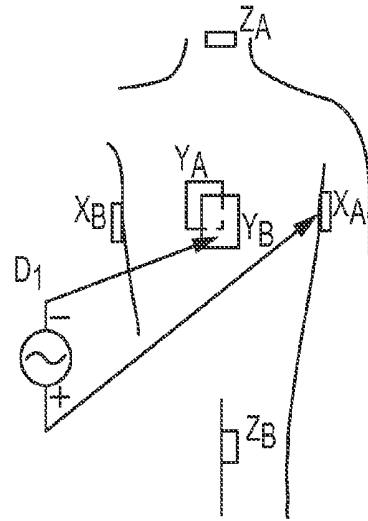


FIG. 12B

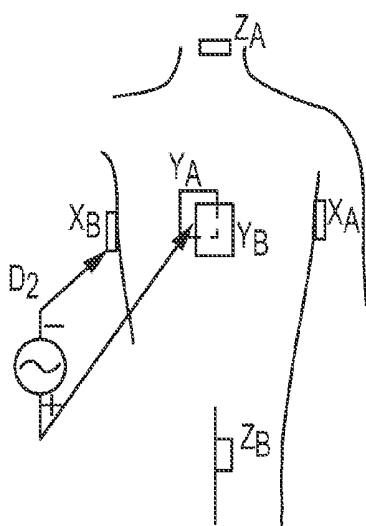


FIG. 12C

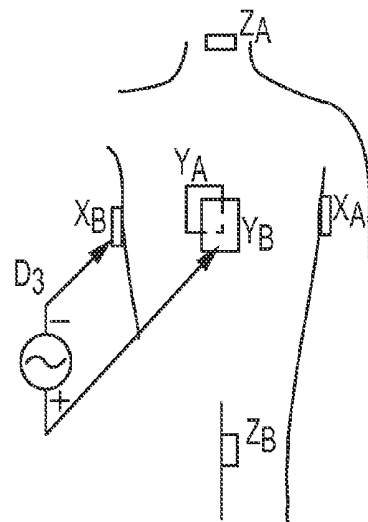


FIG. 12D

PRINTED ELECTRODE CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 13/764,189, filed 11 Feb. 2013, now U.S. pat. No. 9,179,971, which is hereby incorporated by reference as though fully set forth herein.

BACKGROUND

a. Field of the Disclosure

The instant disclosure relates to elongate medical devices, including the electrical infrastructure for elongate medical devices.

b. Background Art

Electrophysiology catheters are used for an ever-growing number of procedures. For example, electrophysiology catheters are used for diagnostic, therapeutic, and ablative procedures, to name just a few examples. Typically, the catheter is manipulated through the patient's vasculature and to the intended site, for example, a site within the patient's heart. The catheter typically carries one or more sensors, such as electrodes, which may be used for ablation, electrophysiology mapping, and the like.

A portion of an exemplary electrophysiology catheter **10** manufactured according to known methods is shown in cross-section in FIG. 1. The catheter **10** includes an elongate tubular body **12** defining a longitudinal axis A and an interior lumen **14**, a tip electrode **16**, and a number of ring electrodes **18a**, **18b**, **18c**. The catheter **10** may also include numerous other features (not illustrated), such as one or more pull wires coupled with the body, such as through one or more pull rings, to steer the catheter **10**, one or more fluid ports and lumens, and other known features. The body **12** may be made of a thermoplastic elastomer or another suitable material, such as Pebax™, Teflon™, or Kapton™. The ring electrodes **18** may be embedded in the body **12** during melt processing of the body **12** or through other known manufacturing steps or methods. The tip electrode **16** and the ring electrodes **18** may be electrically coupled with leads **20** extending to a proximal end of the catheter (not shown) for coupling with a mapping and navigation system, ablation generator, or other electrical system, for example. The leads **20** may extend longitudinally through the interior lumen **14** of the body, as shown in FIG. 1, or may extend through the wall of the body **12**.

The foregoing discussion is intended only to illustrate the present field and should not be taken as a disavowal of claim scope.

BRIEF SUMMARY

An embodiment of an elongate medical device may comprise an elongate tubular body, an electrode, and a trace. The elongate tubular body may comprise a distal end portion and a proximal end portion, the body defining a longitudinal axis. The electrode may comprise electrically-conductive ink extending circumferentially about a portion of the distal end portion. The trace may comprise electrically-conductive ink, electrically coupled with the electrode, extending proximally from the electrode.

Another embodiment of an elongate medical device may comprise an elongate tubular body comprising a distal end portion and a proximal end portion, the body defining a longitudinal axis, a first electrode, and a first trace. The first

electrode may comprise electrically-conductive ink extending circumferentially about a first portion of the tubular body. The first trace may comprise electrically-conductive ink, electrically coupled with the first electrode, extending proximally from the first electrode. An electrically insulating layer may be radially inward of the first electrode and the first trace. The elongate medical device may further comprise a second electrode and a second trace. The second electrode may comprise electrically-conductive ink extending circumferentially about a second portion of the tubular body. The second trace may comprise electrically-conductive ink, electrically coupled with the second electrode, extending proximally from the second electrode. At least a portion of the second trace may be disposed radially inward of the electrically insulating layer.

Another embodiment of an elongate medical device may comprise an elongate tubular body comprising a distal end portion and a proximal end portion, the body defining a longitudinal axis, an electrode, a trace, and a force sensor. The electrode may comprise electrically-conductive ink extending circumferentially about a portion of the tubular body. The trace may comprise electrically-conductive ink, electrically coupled with the electrode, extending proximally from the electrode. The force sensor may comprise a semiconducting layer radially between a first electrically-conductive layer and a second electrically-conductive layer.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of an embodiment of a portion of a catheter constructed according to known methods.

FIG. 2A is a plan view of an embodiment of a portion of a catheter including electrodes and traces comprising printed ink.

FIG. 2B is a plan view of the catheter of FIG. 2A.

FIG. 3A is a partial cross-sectional view of an embodiment of a portion of a catheter including electrodes and traces comprising printed ink.

FIG. 3B is an enlarged cross-sectional view of an electrical infrastructure portion that may be used to construct the catheter of FIG. 3A.

FIGS. 4A and 4B are orthogonal plan views of an embodiment of a portion of a catheter including electrodes, traces, and contact sensors comprising printed ink.

FIG. 5 is an enlarged cross-sectional view of a contact sensor comprising printed ink that may be included in the catheter of FIGS. 4A and 4B.

FIG. 6 is a schematic view of an exemplary contact sensing circuit.

FIG. 7A is an isometric view of an embodiment of a portion of a catheter including electrodes and traces comprising printed ink in a first stage of construction.

FIG. 7B is an isometric view of an electrode and a portion of a trace of the catheter portion of FIG. 7A.

FIG. 7C is a side view of the electrode of FIG. 7B.

FIG. 7D is a cross-sectional view of the electrode of FIG. 7B.

FIG. 7E is an enlarged cross-sectional view of a portion of the electrode of FIGS. 7B-7D.

FIG. 7F is an isometric view of the catheter portion of FIG. 7A in a second stage of construction.

FIGS. 8A-8D are isometric views of an embodiment of a portion of a catheter including electrodes and traces comprising printed ink in various stages of construction.

FIG. 9A is an isometric view of an embodiment of a portion of a catheter including electrodes and traces comprising printed ink in a first stage of construction.

FIG. 9B is an isometric view of an electrode and a portion of a trace of the catheter portion of FIG. 9A.

FIG. 9C is an isometric view of the catheter portion of FIG. 9A in a second stage of construction.

FIGS. 10A and 10B are isometric views of an embodiment of a portion of a catheter including electrodes and traces comprising printed ink in first and second stages of construction, respectively.

FIG. 11 is a schematic view of a medical device mapping and navigation system.

FIGS. 12A-12D are diagrammatic views of exemplary dipoles created using the mapping and navigation system of FIG. 11.

DETAILED DESCRIPTION

Various embodiments are described herein to various apparatuses, systems, and/or methods. Numerous specific details are set forth to provide a thorough understanding of the overall structure, function, manufacture, and use of the embodiments as described in the specification and illustrated in the accompanying drawings. It will be understood by those skilled in the art, however, that the embodiments may be practiced without such specific details. In other instances, well-known operations, components, and elements have not been described in detail so as not to obscure the embodiments described in the specification. Those of ordinary skill in the art will understand that the embodiments described and illustrated herein are non-limiting examples, and thus it can be appreciated that the specific structural and functional details disclosed herein may be representative and do not necessarily limit the scope of the embodiments, the scope of which is defined solely by the appended claims.

Reference throughout the specification to “various embodiments,” “some embodiments,” “one embodiment,” or “an embodiment”, or the like, means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases “in various embodiments,” “in some embodiments,” “in one embodiment,” or “in an embodiment”, or the like, in places throughout the specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. Thus, the particular features, structures, or characteristics illustrated or described in connection with one embodiment may be combined, in whole or in part, with the features structures, or characteristics of one or more other embodiments without limitation given that such combination is not illogical or non-functional.

It will be appreciated that the terms “proximal” and “distal” may be used throughout the specification with reference to a clinician manipulating one end of an instrument used to treat a patient. The term “proximal” refers to the portion of the instrument closest to the clinician and the term “distal” refers to the portion located furthest from the clinician. It will be further appreciated that for conciseness and clarity, spatial terms such as “vertical,” “horizontal,” “up,” and “down” may be used herein with respect to the illustrated embodiments. However, surgical instruments may be used in many orientations and positions, and these terms are not intended to be limiting and absolute.

The manufacture of electrophysiology catheters according to known methods, such as the catheter 10 shown in FIG.

1, presents certain difficulties. For example, the large number of wires (e.g., pull wires and electrical leads for numerous electrodes) and potential for breakage of any of those wires may result in difficulty routing the wires through the numerous internal features of the catheter and handling of those wires during manufacturing. Therefore, according to at least one embodiment, a method for simplifying the construction and manufacturing of the catheter includes replacing known electrodes and leads with electrodes and leads comprising conductive ink printed directly on one or more layers of the catheter body.

Referring again to the Figures, in which like reference numerals refer to the same or similar features in the various views, FIG. 2A is a plan view of an embodiment of a portion of an elongate medical device 24. The medical device 24, like all ell elongate medical devices shown and described herein, may be a catheter, introducer, or other elongate medical device type. The elongate medical device 24, like all elongate medical devices shown and described herein, will be referred to as a catheter for ease of description (i.e., catheter 24). It should be understood, though, that the elongate medical device 24, like all elongate medical devices described herein, is not limited to a catheter.

The catheter 24 may include an elongate tubular body 26 defining an axis B and having a distal end portion 28 and a proximal end portion 30, a tip electrode 32, a number of ring electrodes 34a, 34b, 34c, a number of electrically-conductive traces 36, and a number of masks 38. The traces 36 may each be electrically coupled to a respective one of the tip electrode 32 and the ring electrodes 34 for electrically connecting the respective electrode 32, 34 to, for example, a mapping and navigation system, an ablation generator, and/or another known electrical system. Though not shown, the traces 36 may be radially covered by an outer layer of the body, in an embodiment.

Each of the ring electrodes 34 may extend about the entire circumference of the body 26, in an embodiment. In other embodiments, one or more of the ring electrodes 34 may extend about only a portion of the circumference of the body 26. Each of the traces 36 may extend proximally from a respective one of the electrodes 32, 34 over the longitudinal length of the body 26. At the proximal tip of the body (not shown), each of the traces 36 may be electrically coupled with a lead extending through a handle that is coupled with the body 26.

The tip electrode 32 may comprise a unitary metal element coupled with the body, in an embodiment. In other embodiments, the tip electrode 32 may comprise printed ink, like the ring electrodes 34, as described below.

The ring electrodes 34 and traces 36 may comprise electrically-conductive printed ink, in an embodiment. Like all printed ink elements shown and/or described herein, the ring electrodes 34 and traces 36 may be deposited or printed directly on the body 26, in an embodiment, according to an ink printing or deposition process, such as aerosol jet deposition, for example. The ring electrodes 34 and traces 36 may comprise the same materials (i.e., the same types of ink), in an embodiment. In other embodiments, the ring electrodes 34 and traces 36 may comprise different materials (i.e., different types of ink). Different inks may be used because different properties may be desirable and/or permissible for the ring electrodes 34 and the traces 36. For example, it may be desirable for the traces 36 to be more flexible to bend as the body 26 bends, while relatively stiffer ring electrodes 34 may be acceptable. In addition, it may be desirable for the ring electrodes 34 to have low impedance for more accurate electrical measurements, while relatively

higher impedance traces **36** may be acceptable. Accordingly, a relatively rigid, low impedance metallic ink may be used for the ring electrodes **34** and a more flexible ink such as one comprising nanotubes or graphene, for example, may be used for the traces **36**.

The masks **38** may be provided for extending the traces **36** past ring electrodes **34** without electrically coupling a ring electrode **34** with a trace **36** that is coupled with a more distal electrode. For example, three separate masks **38** may prevent the trace **36** that is electrically coupled with the tip electrode **32** from being electrically coupled with the first, second, and third ring electrodes **34a**, **34b**, **34c**, respectively.

FIG. 2B is a plan view of catheter **24**. In addition to the elements described in conjunction with FIG. 2A, the catheter **24** may include a handle assembly or handle **164** coupled with the catheter body **26** and one or more electromechanical connectors **166** configured to allow the catheter **24**, and the electrodes **32**, **34** thereof, in particular, to be coupled with components or subsystems of, for example, an electrophysiology (EP) laboratory system. Such components or subsystems may comprise, for example and without limitation, a visualization, navigation, and/or mapping system, an EP monitoring and recording system (e.g., for monitoring and/or recording electrocardiograms (ECG), cardiac signals, etc.), a tissue contact sensing system, an ablation system, a cardiac stimulation system (i.e., EP stimulator), and the like. An exemplary system is shown in U.S. patent application publication no. 2012/0029504, which is hereby incorporated by reference in its entirety as though fully set forth herein.

The handle **164** may be disposed at the proximal end portion **30** of the shaft body portion **26**. The handle **164** may provide a location for the clinician to hold the catheter **24** and may further provide means for steering or guiding the shaft body **26** within the body of a patient.

The handle **164** may comprise a housing **168**. The housing **168** may be of a unitary construction or may be constructed of a plurality of pieces that are configured to be assembled together. In a multi-piece embodiment, the housing **168** may be coupled together in any number of ways known in the art, such as, for example, by press fit or interference coupling techniques, by complementary interlocking members, by conventional fasteners or adhesives, or any other techniques known in the art.

In addition to the components described above, in an exemplary embodiment, the catheter **24** may further comprise a deflection mechanism **170** associated with the handle **164** of the catheter **24**. The deflection mechanism **170** may be coupled with a pull assembly (not shown) disposed at or in the distal end portion **28** of the shaft body **26**. The combination of the deflection mechanism **170** and the pull assembly provides a means by which a user or physician can effect movement (e.g., deflection) of the distal end portion **28** in one or more directions, and therefore, allows the physician to steer the catheter **24**.

FIG. 3A is a partial cross-sectional view of another embodiment of a portion of a catheter **42**. The catheter **42** may comprise an elongate tubular body **44** defining an axis C and an interior lumen **46**, a tip electrode **32**, a number of ring electrodes **34a**, **34b**, **34c**, and an electrical connection **47** extending through the lumen **46**. The ring electrodes **34** may each be coupled with a respective electrically-conductive trace, as will be described in conjunction with FIG. 3B. The body **44** may comprise an inner braid layer **48** and an outer polymer layer **50**. The outer polymer layer may

inner braid layer **48**, outer polymer layer **50**, and ring electrodes **34** are shown in cross-section.

The distal segment **52** and the proximal segment **54** of the outer polymer layer **50** of the body **44** may comprise different materials, in an embodiment. The distal segment **52** may comprise Teflon™, for example, and the proximal segment may comprise Pebax™, for example. Different materials may be provided, in an embodiment, because deposition or printing of the ring electrodes **34** and/or traces may require curing the printed ink at a temperature that is higher than the melting point of certain melt-processing polymers. For example, traces coupled with the ring electrodes **34** may comprise carbon nanotube (CNT) printed ink with a cure temperature of about 150° Celcius (C). A polymer comprising the proximal segment **54**, such as Pebax™, may have a melting temperature, such as about 130-174° C., that is lower than the temperature required for curing the printed ink. Accordingly, the distal segment **52** may comprise Teflon™, for example, which has a melting temperature of about 320° C., or another suitable material which has an acceptably high melting point. In addition, the portions of the traces over the proximal segment **54** may be laser sintered, rather than cured, in an embodiment, to avoid melting the proximal segment **54**. The distal segment **52** may be about six centimeters (6 cm) in length, in an embodiment. The length of the distal segment **52** may be selected according to the desired length of the portion of the catheter **42** on which ring electrodes **34** are to be disposed.

FIG. 3B is cross-sectional view of an exemplary electrode and trace infrastructure which may be used, for example, to print the ring electrodes **34** and traces of the catheter **42**. The illustrated infrastructure comprises the first ring electrode **34a**, the second ring electrode **34b**, and first and second traces **56a**, **56b** electrically coupled with the first and second ring electrodes **34a**, **34b**, respectively.

The infrastructure may include, in an embodiment, a radial layer for each ring electrode and trace, each separated by an electrically-insulating layer **58**. Thus, in an embodiment, the electrically-insulating layer **58** may be radially-inward of the second electrode **34b** and the second trace **56b**, and a portion of the first trace **56a** may be radially-inward of the electrically-insulating layer **58**. The ring electrodes **34** and traces **56** may comprise electrically-conductive printed inks substantially as described above. The electrically-insulating layer **58** may comprise acrylic cured with ultraviolet (UV) light (i.e., UV acrylic), in an embodiment, and/or another suitable electrical insulator.

Referring to FIGS. 3A and 3B, in build-up, the electrodes **34**, traces **56**, and one or more electrically-insulating layers **58** may be deposited or printed in an alternating sequence. For example, a first trace **56a** may be deposited in a line along the length of the distal segment **52** of the outer polymer layer **50** of the catheter body **44**. The first electrode **34a** may then be deposited about the circumference of the body **44**, including over a portion of the first trace **56a**, such that the first trace **56a** and the first electrode **34a** are electrically coupled. Next, a first electrically-insulating layer **58** may be deposited over at least a portion of the first trace **56a** (i.e., the portion of the first trace **56a** not covered by the first electrode **34a**) along the length of the catheter body **44** and, in an embodiment, about the circumference of the catheter body **44**. A second trace may **56b** then be deposited along the length of the first electrically-insulating layer **58**, then a second electrode **34b** about the circumference of the body **44**, and so on for as many ring electrodes **34** are desired. As a result, each of the ring electrodes **34** may each extend about the entire circumference of the body, if desired,

and each ring electrode may be electrically coupled to an independent electrical trace 56.

FIGS. 4A and 4B are plan views of an embodiment of a catheter 62. The catheter 62 may comprise an elongate tubular body 64 defining a longitudinal axis D, a tip electrode 32, a number of ring electrodes 34, and a number of resistive or capacitive force sensors 66. For clarity of illustration, not all electrodes 34 or force sensors 66 are designated. A distal end portion 68 of the body 64 (i.e., a portion including the electrodes 32, 34 and force sensors 66) may be configured to curl about the axis D to substantially form a circle about the axis D (FIG. 4A shows the distal end portion 68 only, for clarity of illustration). Such a circular configuration may be desired and used for particular mapping and ablation procedures, among other things. The ring electrodes 34 may comprise printed ink, printed and/or deposited according to one or more methods and/or configurations described herein.

One or more of the force sensors 66 may also comprise printed ink, in an embodiment. A force sensor 66 may comprise, in an embodiment, a semiconductive grid layered between separate conductive layers. FIG. 5 is a cross-sectional view of a portion 72 of a force sensor 66, taken transverse to the length of the force sensor portion. The force sensor portion 72 may include the catheter body 64, a first electrically-conductive printed ink layer 74, a semiconductor printed ink layer 76, a second electrically-conductive printed ink layer 78, and an external electrically-insulating printed ink layer 80.

The grid of the semiconductive layer 76 of the force sensor 66 may include grid lines, with each line having a corresponding conductive grid line on one or both of the conductive layers 74, 78. Each junction point where a grid line from the first conductive layer 74 crosses a grid line from the second conductive layer 78 with a semiconductive grid line in between forms a piezoresistive force sensor. FIG. 5 illustrates one such junction 82. Application of external force to the junction 82 changes the conductance of the junction 82. Each force sensor 66 shown in FIG. 4A may comprise a plurality of sensing junctions 82. In an embodiment, the plurality of sensing junctions 82 may be arranged in a grid, as noted above.

A plurality of force sensor junctions 82 may effectively form an electrical circuit similar to that shown in FIG. 6. The force sensor junctions 82 may be arranged in a plurality of rows (two are shown in FIG. 6) and columns (three are shown in FIG. 6). The rows and/or columns of force sensor junctions 82 may be interrogated (i.e., have their respective resistances/conductances checked), or the sensor junctions may be interrogated individually by, for example, driving a test voltage through a single row and/or a single column at a time while grounding other rows and/or columns. Accordingly, by cycling through the rows and columns in a sequence, each force sensor junction 82 may be interrogated individually (either directly, or indirectly by mathematical combination of row and column measurements) to assess the force at that junction 82. Detected forces may be displayed by a connected mapping and navigation system, for example, to inform a physician of what portions of the catheter 62 are contacting the patient's body.

Force sensors 66 such as those illustrated in FIGS. 4A-6 may be used in a number of applications. For example, a plurality of force sensors 66 may be disposed about the circular portion of a circular mapping catheter, as shown in FIG. 4A. In another application, a plurality of force sensors 66 may be disposed along the length of a sheath or introducer to assess the position of the sheath or introducer

relative to a transeptal puncture. Of course, other applications are possible, as well. Accordingly, the features illustrated in FIGS. 4A-6 are not limited to use in the embodiment illustrated in FIGS. 4A-4B.

FIG. 7A is an isometric view of an embodiment of a catheter 86 in a first stage of construction. The catheter 86 may include an elongate tubular body 88 defining an axis E, a tip electrode 32, a number of ring electrodes 90a, 90b, 90c, and a number of electrically-conductive traces 92a, 92b, 92c. The second and third ring electrodes 90b, 90c do not extend around the entire circumference of the body 88, but instead include respective gaps 94b, 94c through which traces 92 coupled with more distal electrodes 32, 92 extend.

FIG. 7A illustrates the catheter 86 after the tip electrode 32 has been coupled with the catheter body 88 and the ring electrodes 90 and traces 92 have been printed on a first layer 96 of the catheter body 88. The body first layer 96 may include one or more melt processing polymers and/or another appropriate material, such as Pebax™, Teflon™, or Kapton™. The body first layer 96 may be constructed, in an embodiment, similarly to the catheter body in FIG. 3A (i.e., with a distal segment of a first material and a proximal segment of a second material). The body 88 may also be constructed according to other methods known in the art, in embodiments. The ring electrodes 90 and traces 92 may comprise electrically-conductive printed ink.

FIG. 7B is an isometric view of a first ring electrode 90a and a portion of its trace 92a. FIGS. 7C and 7D are plan views of the first ring electrode 92a. FIG. 7E is an enlarged plan view of a portion of the first ring electrode 92a. Referring to FIGS. 7B-7E, the first ring electrode 92a, like each ring electrode 92, may include a body portion 98 and a plurality of longitudinally-extending ribs 100. In an embodiment, ribs 100 may additionally or alternatively extend circumferentially and/or in another direction or pattern. Furthermore, in addition to or instead of ribs 100, different protrusions or structures may be provided.

The ribs 100 (or other protrusions or patterns) may be provided to increase the surface area of the electrode 92. When measuring the impedance between the electrode 92 and a given point in an electrolyte (i.e., a patient's blood pool), the total impedance can be reduced by increasing the surface area of the electrode 92. Lower impedance, in turn, may allow for more accurate measurements. Accordingly, by providing ribs 100 on the electrode 92a, impedance may be reduced, and measurement accuracy may be improved.

The ribs 100 may be printed, in an embodiment, using a relatively high viscosity ink or multiple layers of ink. The ribs 100 may comprise the same material (i.e., the same ink) as the electrode body portion 98, in an embodiment. The ribs 100 may comprise a different material (i.e., a different ink) than the electrode body portion 98, in other embodiments. The ribs 100 may have a transverse (i.e., transverse to the axis E) height of about 1 thousandth of an inch (0.001 in) or less, in an embodiment, so as not to damage a patient's vasculature.

FIG. 7F is an isometric view of the catheter 86 in a second stage of construction. Referring to FIGS. 7A and 7F, after the ring electrodes 90 and traces 92 have been printed, a second layer 102 of the body 88 may be printed. The second body layer 102 may cover (i.e., be radially-outward of) the traces 92. The second body layer 102 may also cover portions of the first body layer 96 not covered by the ring electrodes 92. In an embodiment, the second body layer 102 may comprise a dielectric ink.

FIGS. 8A-8D are isometric views of an embodiment of a catheter 106 in various stages of construction. In a first stage,

the result of which is shown in FIG. 8A, a first layer 96 of an elongate tubular body 88 defining an axis F may be provided, a tip electrode 32 may be coupled to a distal end of the first layer 96, and electrical traces 108a, 108b may be printed on the first layer 96. The body first layer 96 may comprise Pebax™ or another melt-processing polymer or appropriate material as described herein. The traces 108 may comprise electrically-conductive printed ink, in an embodiment.

In a second stage of construction, the result of which is shown in FIG. 8B, a second body layer 102 may be printed over most of the traces 108, but for pass-through points 110a, 110b where electrodes will contact the traces 108a, 108b. In an embodiment, the second body layer 102 may be a dielectric printed ink.

In a third stage of construction, the result of which is shown in FIG. 8C, electrodes 112a, 112b may be printed. The electrodes 112 may comprise electrically-conductive printed ink. Each electrode 112a, 112b may be printed so as to be electrically coupled with a respective one of the traces 108a, 108b. In an embodiment, each electrode 112a, 112b may be printed to cover (i.e., be radially-outward of) a respective trace pass-through 110a, 110b. The electrodes 112 may comprise the same materials (i.e., the same electrically-conductive printed ink or inks) as the traces 108, in an embodiment.

In a fourth stage of construction, the result of which is shown in FIG. 8D, the electrodes 112 may be electroplated with platinum, gold, or another biologically-inert metal to create a metal outer electrode layer 114a, 114b. The printed-ink layer 112 of the electrodes may be used to apply a negative charge to draw in the plating ions during electroplating.

The embodiment of FIGS. 8A-8D may be preferred because it may allow the same materials (i.e., the same printed ink) to be used for the traces 108 and for the electrodes 112, simplifying manufacturing. Because the electroplated metal layer 114 may provide the low-impedance interface desirable for accurate measurements, the electrically-conductive ink used to print the electrodes 112 may be a more flexible, higher-impedance ink that may also be used to print the traces 108.

FIG. 9A is an isometric view of an embodiment of a catheter 118 in a first stage of construction. FIG. 9B is an enlarged isometric view of an electrode 120 and portion of a trace 122 of the catheter 118. Referring to FIGS. 9A and 9B, the catheter 118 may include an elongate tubular body 88 defining an axis G, a tip electrode 32, a number of electrodes 120a, 120b, and a number of traces 122a, 122b. One or more of the electrodes 120 may not extend around the entire circumference of the body 88, but may instead extend around separate respective circumferential portions of the body 88. In an embodiment, each electrode 120 may extend around about a quarter or a third of the circumference of the body 88. In an embodiment, multiple electrodes 120 may be arranged in a circumferential set at substantially the same longitudinal position on the body 88. Although only a single circumferential set of electrodes 120 is illustrated in FIG. 9A, multiple such sets may be provided, in an embodiment. Such multiple sets (and the traces 122 electrically coupled with those sets) may be arranged (i.e., for traces of more distal electrodes 120 to extend longitudinally past more proximal electrodes 120) according to, for example only, one or more of the schemes shown in FIG. 3B (i.e., layered radially), in FIG. 7A (i.e., with traces routed through electrode gaps), or in FIGS. 8A-8D (i.e., with the majority of the length of the traces covered by an exterior layer).

FIG. 9A illustrates the catheter 118 after the tip electrode 32 has been coupled with the catheter body 88 and the electrodes 120 and traces 122 have been printed on a first layer 96 of the catheter body 88. The body first layer 96 may include one or more melt processing polymers, such as Pebax™, and/or another known appropriate material, such as Teflon™ or Kapton™. The body first layer 96 may be constructed, in an embodiment, similarly to the catheter body in FIG. 3A (i.e., with a distal segment of a first material and a proximal segment of a second material). The electrodes 120 and traces 122 may comprise electrically-conductive printed ink substantially as described herein.

FIG. 9C is an isometric view of the catheter 118 in a second stage of construction. Referring to FIGS. 9A and 9C, after the electrodes 120 and traces 122 have been printed, a second body layer 102 may be printed. The second body layer 102 may cover (i.e., be radially-outward of) the traces 122. The second body layer 102 may also cover portions of the first body layer 96 not covered by the electrodes 120. In an embodiment, the second body layer 102 may comprise a dielectric ink.

The catheter and electrode arrangement illustrated in FIGS. 9A-9C may be preferred for directional position sensing—i.e., more localized positions of particular sides of the catheter. Such directional position sensing may be advantageous, for example, in a remote catheter guidance system (RCGS), such as one based on robotic movement of one or more medical devices. An exemplary embodiment of one such RCGS is shown in U.S. patent application publication no. 2009/0247993, which is hereby incorporated by reference in its entirety as though fully set forth herein.

FIG. 10A is an isometric view of an embodiment of a catheter 126 in a first stage of construction. The catheter 126 may include an elongate tubular body 88 defining an axis H, a tip electrode 32, and a number of electrical traces 128a, 128b.

FIG. 10A illustrates the catheter 126 after the tip electrode 32 has been coupled with the catheter body 88 and the traces 128 have been printed on a first layer 96 of the catheter body 88. The body first layer 96 may include one or more melt processing polymers and/or another known appropriate material, such as Pebax™, Teflon™, or Kapton™. The body first layer 96 may be constructed, in an embodiment, similarly to the catheter body in FIG. 3A (i.e., with a distal segment of a first material and a proximal segment of a second material). The traces 128 may comprise electrically-conductive printed ink substantially as described herein.

FIG. 10B is an isometric view of the catheter 126 in a second stage of construction. Referring to FIGS. 10A and 10B, after the traces 128a, 128b have been printed, electrodes 130a, 130b may be printed such that each electrode 130a, 130b is electrically coupled with a respective one of the traces 128a, 128b. Each electrode 130 may be printed as a series of rings, as a continuous spiral, or otherwise in a longitudinally-segmented arrangement. The electrodes 130 may comprise electrically-conductive ink, substantially as described herein. After the electrodes 130 are printed, a second body layer 102 may be printed. The second body layer 102 may cover (i.e., be radially-outward of) the traces 128, including the portions of the traces 128 longitudinally between segments of a given electrode 130. The second body layer 102 may also cover portions of the first body layer 96 not covered by the electrodes 130. In an embodiment, the second body layer 102 may comprise a dielectric ink.

The catheter 126 may be preferred for a relatively more flexible distal end. The electrodes 130, by virtue of the

longitudinal gaps between segments, may flex and bend with the catheter body more than would a more longitudinally-continuous electrode, such as the electrodes **90** shown in FIGS. 7A-7F.

It should be understood that the features of the catheter embodiments **24**, **42**, **62**, **86**, **106**, **118**, **126** described and illustrated herein are not mutually-exclusive. Instead, features from different embodiments may be combined as desired for a given application. For example, the ring electrodes **90** of FIGS. 7A-7F may each extend about the entire circumference of the catheter body **88**, in an embodiment, by radially layering their respective traces **92** according to the scheme illustrated in FIG. 3B. In another example, the electrodes **120** of FIGS. 9A-9C may be provided with the ribs **100** illustrated in FIGS. 7A-7F. Of course, numerous other combinations are possible and contemplated.

The aforementioned catheter embodiments **24**, **42**, **62**, **86**, **106**, **118**, **126** may operate with a variety of catheter systems such as visualization systems, mapping systems, and navigation support and positioning systems (i.e., for determining a position and orientation (P&O) of a flexible elongate member or other medical device). One such system is illustrated in FIG. 11.

FIG. 11 is a schematic and diagrammatic view of an embodiment of a medical device mapping and navigation system **140**. The system **140** is coupled with a catheter **142** that can be guided to and disposed in a portion of a body **143**, such as a heart **145**. The catheter **142** can include one or more sensors **144** for, e.g., collecting electrophysiology data, applying ablation energy, and/or determining a location of the catheter within the body. The system may include, at least in part, an electronic control unit (ECU) **146**, a signal generator **148**, a switch **150**, a low-pass filter **152**, an analog-to-digital (A-to-D) converter **154**, a plurality of body surface electrode patches **156**, and electrocardiogram (ECG) patches **160**.

The system **140** is provided for visualization, mapping, and/or navigation of internal body structures and may be referred to herein as "the navigation system." The navigation system **140** may comprise an electric field-based system, such as, for example, an EnSite™ Velocity™ cardiac electro-anatomic mapping system running a version of EnSite™ NavX™ navigation and visualization technology software commercially available from St. Jude Medical, Inc., of St. Paul, Minn. and as also seen generally by reference to U.S. Pat. No. 7,263,397, or U.S. Patent Application Publication No. 2007/0060833 A1, both hereby incorporated by reference in their entireties as though fully set forth herein. In other exemplary embodiments, the navigation system **140** may comprise systems other than electric field-based systems. For example, the navigation system may comprise a magnetic field-based system such as the Carto™ system commercially available from Biosense Webster, and as generally shown with reference to one or more of U.S. Pat. Nos. 6,498,944; 6,788,967; and 6,690,963, the disclosures of which are hereby incorporated by reference in their entireties as though fully set forth herein. In another exemplary embodiment, the navigation system **140** may comprise a magnetic field-based system based on the MediGuide™ technology available from St. Jude Medical, Inc., and as generally shown with reference to one or more of U.S. Pat. Nos. 6,233,476; 7,197,354; and 7,386,339, the disclosures of which are hereby incorporated by reference in their entireties as though fully set forth herein. In yet another embodiment, the navigation system **140** may comprise a combination electric field-based and magnetic field-based system, such as, for example and without limitation, the

system described in pending U.S. patent application Ser. No. 13/231,284, or the Carto™ 3 system commercially available from Biosense Webster, and as generally shown with reference to U.S. Pat. No. 7,536,218, the disclosures of which are hereby incorporated by reference in their entireties as though set forth herein. In yet still other exemplary embodiments, the navigation system **140** may comprise or be used in conjunction with other commonly available systems, such as, for example and without limitation, fluoroscopic, computed tomography (CT), and magnetic resonance imaging (MRI)-based systems. For purposes of clarity and illustration only, the navigation system **140** will be described hereinafter as comprising an electric field-based system, such as, for example, the EnSite™ NavX™ system identified above.

The catheter **142** and sensors **144** may be provided for a variety of diagnostic and therapeutic purposes including, for example, electrophysiological studies, pacing, cardiac mapping, and ablation. In an embodiment, the catheter **142** can be an ablation catheter, mapping catheter, or other elongate medical device. The number, shape, orientation, and purpose of the sensors **144** may vary in accordance with the purpose of the catheter **142**. In an embodiment, at least one sensor **144** can be an electrode. For purposes of illustration, the description below will be with respect to an embodiment in which the sensors **144** comprise one or more electrodes, but the disclosure is not limited to such an embodiment.

The catheter **142** may comprise any catheter embodiment **24**, **42**, **62**, **86**, **106**, **118**, **126** described herein, or another catheter including one or more features illustrated and/or described herein. Accordingly, the sensor **144** may comprise a printed-ink electrode (such as one or more of electrodes **32**, **34**, **90**, **112**, **120**, **130** and/or another electrode including one or more features illustrated and/or described herein) and/or a printed-ink force sensor (such as force sensor **66**).

With the exception of the patch electrode **158_B** called a "belly patch," the patch electrodes **158** are provided to generate electrical signals used, for example, in determining the position and orientation of the catheter **142** and in the guidance thereof. In one embodiment, the patch electrodes **158** are placed generally orthogonally on the surface of the body and are used to create axes-specific electric fields within the body. For instance, in one exemplary embodiment, patch electrodes **158_{X1}**, **158_{X2}** may be placed along a first (x) axis. Patch electrodes **158_{Y1}**, **158_{Y2}** may be placed along a second (y) axis, and patch electrodes **158_{Z1}**, **158_{Z2}** may be placed along a third (z) axis. Each of the patch electrodes **158** may be coupled to the multiplex switch **150**. In an exemplary embodiment, the ECU **146** is configured, through appropriate software, to provide control signals to the multiplex switch **150** to thereby sequentially couple pairs of electrodes **158** to the signal generator **148**. Excitation of each pair of electrodes **158** (e.g., in either orthogonal or non-orthogonal pairs) generates an electrical field within the patient's body **143** and within an area of interest such as the heart **145**. Voltage levels at non-excited electrodes **158**, which are referenced to the belly patch **158_B**, are filtered by low-pass filter **152** and converted by A-to-D converter **154** and provided to the ECU **146** for use as reference values.

As noted above, one or more electrodes **144** are mounted in or on the catheter **142**. In an exemplary embodiment, at least one of the electrodes **144** comprises a positioning electrode and is configured to be electrically coupled to the ECU **146**. With a positioning electrode **144** electrically coupled to the ECU **146**, the electrode **144** is placed within electrical fields created in the body **143** (e.g., within the heart **145**) by exciting the patch electrodes **158**. The posi-

tioning electrode 144 experiences voltages that are dependent on the position of the positioning electrode 144 relative to the locations of the patch electrodes 158. Voltage measurement comparisons made between the electrode 144 and the patch electrodes 158 may be used to determine the position of the positioning electrode 144 relative to the heart 145 or other tissue. Movement of the positioning electrode 144 proximate a tissue (e.g., within a chamber of the heart 145) may produce information regarding the geometry of the tissue. This information may be used, for example, to generate models and maps of anatomical structures. Such maps and models may reflect a particular state of the anatomical structure such as, for example, the shape of the heart 145 at a particular point in the cardiac cycle. Position information determined according to measurements made with the electrode 144 may thus be associated with a particular portion of the cardiac cycle based on readings from the ECG patches 160. Information received from the positioning electrode 144 can also be used to display on a display device, the location and orientation of the positioning electrode 144 and/or a portion of the catheter 142 relative to the heart 145 or other tissue. Accordingly, among other things, the ECU 146 of the navigation system 140 may provide a means for generating display signals used to control a display and the creation of a graphical user interface (GUI) on the display.

The ECU 146 may comprise a programmable microprocessor or microcontroller, or may comprise an application specific integrated circuit (ASIC). The ECU 146 may include an input/output (I/O) interface through which the ECU 146 may receive a plurality of input signals including, for example, signals generated by patch electrodes 158 and the positioning electrode 144 (among others), and generate a plurality of output signals including, for example, those used to control a display and other user interface components. The ECU 146 may be configured to perform various functions with appropriate programming instructions or code (i.e., software). Accordingly, the ECU 144 can be programmed with one or more computer programs encoded on a computer-readable storage medium for performing functionality described herein.

FIGS. 12A-12D show a plurality of exemplary non-orthogonal dipoles, designated D_0 , D_1 , D_2 and D_3 . Referring to FIGS. 11 and 12A-12D, for any desired axis, the potentials measured across an intra-cardiac positioning electrode 144 resulting from a predetermined set of drive (source-sink) configurations may be combined algebraically to yield the same effective potential as would be obtained by simply driving a uniform current along the orthogonal axes. Any two of the surface electrodes 158 may be selected as a dipole source and drain with respect to a ground reference, e.g., belly patch 158_b, while the unexcited body surface electrodes measure voltage with respect to the ground reference. The positioning electrode 144 placed in heart 145 is also exposed to the field from a current pulse and is measured with respect to ground, e.g., belly patch 158_b. In practice, a catheter or multiple catheters within the heart may contain multiple positioning electrodes 144 and each positioning electrode 144 potential may be measured separately.

Data sets from each of the patch electrodes and the positioning electrode 144 are used to determine the location of the positioning electrode 144 within heart 145. After the voltage measurements are made, a different pair of surface electrodes is excited by the current source and the voltage measurement process of the remaining patch electrodes and positioning electrode 144 takes place. The sequence occurs rapidly, e.g., on the order of 100 times per second, in an

embodiment. To a first approximation the voltage on the positioning electrode 144 within the heart bears a linear relationship with position between the patch electrodes that establish the field within the heart, as more fully described in U.S. Pat. No. 7,263,397 referred to above.

In summary, FIG. 11 shows an exemplary navigation system 140 that employs seven body surface electrodes (patches), which may be used for injecting current and sensing resultant voltages. Current may be driven between two patches at any time; some of those driven currents are illustrated in FIGS. 12A-12D. Measurements may be performed between a non-driven patch and, for example, belly patch 158_b as a ground reference. A patch bio-impedance, also referred to as a "patch impedance" may be computed according to the following equation:

$$\text{BioZ}[c \rightarrow d][e] = \frac{V_e}{I_{c \rightarrow d}} \quad (1)$$

where V_e is the voltage measured on patch e and $I_{c \rightarrow d}$ is a known constant current driven between patches c and d, where patches c, d, and e may be any of the patch electrodes 158. The position of an electrode may be determined by driving current between different sets of patches and measuring one or more patch impedances along with the voltage on the positioning electrode. In one embodiment, time division multiplexing may be used to drive and measure all quantities of interest. Position determining procedures are described in more detail in U.S. Pat. No. 7,263,397 and publication no. 2007/0060833 referred to above, as well as other references.

Although a number of embodiments have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this disclosure. For example, all joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure may be made without departing from the spirit of this disclosure as defined in the appended claims.

Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

What is claimed is:

1. An elongate medical device comprising: an elongate tubular body defining a longitudinal axis with a body proximal portion and a body distal portion;

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an electrode comprising an electrically-conductive ink extending circumferentially about an exterior portion of the elongate tubular body, wherein the electrode is located on the body distal portion;

a trace comprising electrically-conductive ink electrically coupled with the electrode, the trace extending longitudinally from the electrode, wherein a first portion of the trace is on the body distal portion and a second portion of the trace is on the body proximal portion; and

a force sensor comprising a semiconductive layer radially disposed between a first electrically-conductive layer and a second electrically-conductive layer, the force sensor extending along a portion of the elongate tubular body,

wherein the body proximal portion comprises a first material with a first melting temperature and the body distal portion comprises a second material with a second melting temperature where the second melting temperature is higher than the first melting temperature.

2. The elongate medical device of claim 1, wherein the force sensor further comprises a first electrically insulative layer radially disposed outward of the first conductive layer.

3. The elongate medical device of claim 1, wherein a distal end portion of the elongate tubular body comprises a circular shape configured to curl about the longitudinal axis.

4. The elongate medical device of claim 1, further comprising:

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a plurality of electrodes, each electrode comprising electrically-conductive ink extending circumferentially about an exterior portion of the elongate tubular body;

a plurality of traces, each comprising electrically-conductive ink, each trace electrically coupled with a respective one of the plurality of electrodes, each trace extending longitudinally from the respective one of the plurality of electrodes; and

a plurality of force sensors, each force sensor comprising a semiconductive layer disposed radially between a first conductive layer and a second conductive layer extending along a portion of the elongate tubular body.

5. The elongate medical device of claim 4, wherein the plurality of force sensors and the plurality of electrodes are disposed in an alternating pattern along the length of the elongate tubular body.

6. The elongate medical device of claim 1, wherein the semiconductive layer further comprises semiconductive layer grid lines.

7. The elongate medical device of claim 6, wherein at least one of the first electrically-conductive layer and the second electrically-conductive layer comprise conductive grid lines corresponding to the semiconductive layer grid lines.

8. The elongate medical device of claim 1, wherein a portion of the trace comprises laser sintered ink.

* * * * *

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摘要(译)

细长医疗装置可包括细长管状主体, 电极和迹线。细长管状主体可包括远端部分和近端部分, 主体限定纵向轴线。电极可包括围绕远端部分的一部分周向延伸的导电墨水。迹线可包括导电墨水, 其与电极电耦合, 从电极向近侧延伸。

