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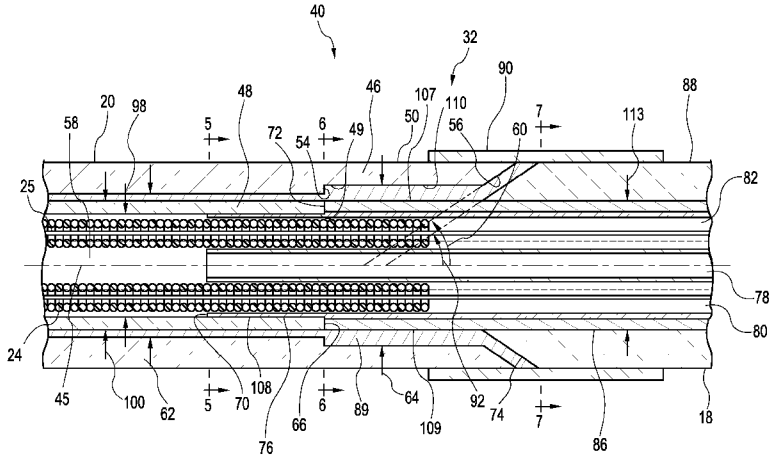


FIG.4A

(57) Abstract: A medical device for the diagnosis or treatment of tissue in a body and method for fabricating the same are provided. The device includes comprises a first shaft and a second shaft. The first shaft includes a longitudinal axis, and the second shaft includes a second shaft axial end disposed within the first shaft. The second shaft is connected to the first shaft by a first nested lap joint formed between the first shaft and the second shaft.

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MEDICAL DEVICE WITH A NESTED LAP JOINT AND A FUSED CONDUCTIVE ELEMENT AND METHOD FOR FABRICATING THE SAME

BACKGROUND

a. Technical Field

[0001] This disclosure generally relates to a medical device for diagnosis or treatment of tissue in a body and method for fabricating the same. In particular, the instant disclosure relates to the joining of various members and/or components in shafts of a medical device.

b. Background Art

[0002] This background description is set forth below for the purpose of providing context only. Therefore, any aspects of this background description, to the extent that it does not otherwise qualify as prior art, is neither expressly nor impliedly admitted as prior art against the instant disclosure.

[0003] Electrophysiology catheters are used in a variety of diagnostic, therapeutic, and/or mapping and ablative procedures to diagnose and/or correct conditions such as atrial arrhythmias, including for example, ectopic atrial tachycardia, atrial fibrillation, and atrial flutter. Arrhythmias can create a variety of conditions including irregular heart rates, loss of synchronous atrioventricular contractions, and stasis of blood flow in a chamber of a heart, which can lead to a variety of symptomatic and asymptomatic ailments and even death.

[0004] A catheter may be deployed and manipulated through a patient's vasculature to the intended site, for example, a site within a patient's heart or a chamber or vein thereof. The catheter may carry one or more electrodes that can be used for cardiac mapping or diagnosis, ablation and/or other therapy delivery modes, or both, for example. Once at the intended site, treatment can include, for example, radio frequency (RF) ablation, cryoablation, laser ablation, chemical ablation, high-intensity focused ultrasound-based ablation, microwave ablation, and/or other ablation treatments. The catheter may impart ablative energy to cardiac tissue to create one or more lesions in the cardiac tissue and oftentimes a contiguous or linear and transmural lesion. This lesion disrupts undesirable cardiac activation pathways and thereby limits, corrals, or prevents errant conduction signals that can form the basis for arrhythmias.

[0005] To position a catheter within the body at a desired site, some type of navigation may be used, such as using mechanical steering features incorporated into the catheter (or an introducer sheath). In some examples, medical personnel may manually manipulate and/or operate the catheter using the mechanical steering features.

[0006] In order to facilitate the advancement of catheters through a patient's vasculature, the simultaneous application of torque at the proximal end of the catheter and the ability to selectively deflect the distal tip of the catheter in a desired direction can permit medical personnel to adjust the direction of advancement of the distal end of the catheter and to position the distal portion of the catheter during an electrophysiological procedure. The proximal end of the catheter can be manipulated to guide the catheter through a patient's vasculature. The distal tip can be deflected by a pull wire attached at the distal end of the catheter that extends to a control handle that controls the application of tension on the pull wire.

[0007] Two of the mechanical considerations for a catheter shaft are that it transmit torque and resist compression during use. Substantial frictional forces sometimes resist transmission of torque across the length of the catheter. In some cases, these forces can cause the catheter shaft to twist about a longitudinal axis of the catheter shaft, storing energy in the process in a spring-like fashion. If the energy is released suddenly, the distal end of the catheter, which may be deflected by a steering mechanism, can be undesirably propelled with significant force.

[0008] With respect to resisting compression during use, it is important for medical personnel to be able to advance the catheter through a vessel, sometimes against significant frictional resistance, without undue axial compression or snaking of the catheter shaft. Shaft compression can result in a loss of control for the medical practitioner and can complicate the positioning of the distal end of the catheter shaft at a desired location for a medical procedure. In addition, medical personnel may rely on tactile feedback to attain and verify proper positioning of the catheter, and such feedback can be impaired by excessive compressibility.

[0009] The foregoing discussion is intended only to illustrate the present field and should not be taken as a disavowal of claim scope.

SUMMARY

[0010] Among other things, various embodiments disclosed herein are directed to a medical device for diagnosis or treatment of tissue in a body and a method for fabricating the same. In particular, the instant disclosure relates to a medical device with a nested lap joint and a fused conductive element and method for fabricating the same.

[0011] A medical device for the diagnosis or treatment of tissue in a body in accordance with one embodiment of the present teachings includes a first shaft and a second shaft. The first shaft includes a longitudinal axis, and the second shaft includes a second shaft axial end disposed within the first shaft. The second shaft is connected to the first shaft by a first nested lap joint formed between the first shaft and the second shaft.

[0012] A medical device for the diagnosis or treatment of tissue in a body in accordance with another embodiment of the present teachings includes a first shaft, a second shaft, and a conductive element disposed within at least one of the first and second shafts. The second shaft is connected to the first shaft by a first nested lap joint formed between the first shaft and the second shaft.

[0013] A method for fabricating a medical device in accordance with another embodiment of the present teachings includes providing a shaft with a shaft inner surface. The method further includes providing a conductive element. The method further includes inserting the conductive element into the shaft. The method further includes fusing at least a portion of the conductive element to the shaft inner surface to form a fused area. Fusing at least a portion of the conductive element comprises selectively heating the portion of the conductive element using an energy source.

[0014] A medical device and method for making the same in accordance with the present teachings is advantageous relative to conventional devices and methods. A medical device and method for making the same in accordance with the present teachings provide a more reliable and durable medical device with less kinking and a reduced risk of joint separation by spreading the loads over the various layers of the device. In addition, the method for making the device allows for more precise embedding of the conductive element and increased efficiency, which results in a decrease in cost.

[0015] The foregoing and other aspects, features, details, utilities, and advantages of the present disclosure will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Figure 1 is a schematic view of a medical device for diagnosis or treatment of tissue in a body in accordance with one embodiment of the present teachings.

[0017] Figure 2 is a close-up isometric view of the portion indicated as "2" of the medical device illustrated in Figure 1 in accordance with one embodiment of the present teachings (with some components omitted for clarity).

[0018] Figure 3 is an exploded view of the portion of the medical device illustrated in Figure 2 (with some components omitted for clarity).

[0019] Figure 4A is a cross-sectional view of the portion of the medical device of Figure 2 (with some components omitted for clarity).

[0020] Figure 4B is a semi-exploded, cross-sectional view of the portion of the medical device of Figure 2 (with some components omitted for clarity).

[0021] Figure 5 is a cross-sectional view of the portion of the medical device of Figure 4A taken along line 5-5.

[0022] Figure 6 is a cross-sectional view of the portion of the medical device of Figure 4A taken along line 6-6.

[0023] Figure 7 is a cross-sectional view of the portion of the medical device of Figure 4A taken along line 7-7.

[0024] Figure 8A is a schematic view of a distal portion of the medical device of Figure 1 in accordance with another embodiment of the present teachings.

[0025] Figure 8B is a schematic view of a distal portion of the medical device of Figure 1 in accordance with another embodiment of the present teachings.

[0026] Figure 9 is a flow chart diagram of a method for fabricating the medical device of Figure 1 in accordance with another embodiment of the present teachings.

[0027] Figure 10A is a schematic view of a portion of the medical device of Figure 1 in relation to an RF coil illustrating an embodiment of the method of Figure 9.

[0028] Figure 10B is a cross-sectional view of the portion of the medical device of Figure 10A taken along line 10B-10B.

DETAILED DESCRIPTION

[0029] An electrophysiology catheter may include an elongate proximal shaft portion and a deflectable distal shaft portion. The connection between the proximal and distal shaft portions must be sufficient enough to withstand tensile loads and other stresses. The proximal shaft portion may be relatively stiff, while the distal deflectable shaft portion may be relatively less stiff. When the connection or joint between the proximal and distal shaft portions transitions stiffness abruptly, the catheter may exhibit a non-uniform curvature during deflection and have inequitable stress profiles. However, a joint that transitions stiffness gradually across the catheter length may result in a catheter having uniform curvature and equitable stress profiles. Moreover, having multiple bonded layers in the catheter may result in even more gradual stiffness transitions. In addition, when using rigid adhesives, it may be desirable to spread the bond joints out (since the adhesive may be more rigid than the surrounding materials). However, if the bond joint with rigid adhesive is too long, the catheter may exhibit non-uniform curvature upon deflection or bending.

[0030] In order to provide the desired mechanical property of resisting compression during use, a catheter may further incorporate a compression coil and/or spring pack embedded within the catheter shaft, as discussed in greater detail in commonly owned co-pending U.S. Patent Application No. 13/838,124 filed March 15, 2013 (hereinafter "the '124 Application"), which is hereby incorporated by reference in its entirety as though fully set forth herein. Components, such as compression coils and spring packs, can be embedded into the catheter by heating (and subsequently cooling) the outer layer(s) of the catheter surrounding the components, as discussed in greater detail in commonly owned U.S. Patent No. 7,993,481 filed December 28, 2006 (hereinafter "the '481 Patent"), which is hereby incorporated by reference in its entirety as though fully set forth herein.

[0031] 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.

[0032] 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.

[0033] 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 a medical device or instrument used to treat a patient. The term "proximal" refers to the portion of the device closest to the clinician (or to a robotic control configured to manipulate the device) 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, medical devices may be used in many orientations and positions, and these terms are not

intended to be limiting or absolute. Furthermore, the terms "bonded," "affixed," and "fused" as used herein are intended to mean the same thing.

[0034] Referring now to the drawings wherein like reference numerals are used to identify identical or similar components in the various views, Figure 1 is a schematic view of a medical device 10 for diagnosis or treatment of tissue in a body in accordance with one embodiment of the present teachings. Device 10 is provided for examination, diagnosis, and treatment of internal body tissues. In accordance with one embodiment of the present teachings, device 10 comprises an electrophysiology ("EP") catheter. It should be understood that device 10 could be several types of EP catheters, such as a mapping catheter, an ablation catheter, and an intracardiac echocardiograph (ICE) catheter, and could use different types of energy (e.g., radio frequency (RF), cryoablation, ultrasound, laser, microwave, electroporation, etc.). Further, it should be understood that the present teachings can be used for other types of medical devices (and used in the diagnosis or treatment of tissue including, for example, introducer sheaths). Accordingly, one of ordinary skill in the art will recognize and appreciate that the medical device and method of fabricating the same disclosed herein can be used in any number of diagnostic and therapeutic applications. In its most general form, device 10 is generally cylindrical in shape with a proximal portion 12 and a distal portion 14 and comprises a tip assembly 16 at distal portion 14, a deflectable distal shaft 18 proximal to tip assembly 16, a proximal shaft 20 proximal to distal shaft 18, a handle assembly 22 at proximal portion 12, and pull wires 24, 25 (shown in Figures 4A-8B) extending from handle assembly 22 through proximal shaft 20 and distal shaft 18, in accordance with an embodiment.

[0035] Still referring to Figure 1, tip assembly 16 may comprise a tip electrode 26 having a distal end 28 and a proximal end 30. Tip electrode 26 may be configured for various functions including, without limitation, an active outer surface that is configured for exposure to blood and/or tissue. Tip electrode 26 of tip assembly 16 may have an aperture (not shown) formed therein that is sufficiently sized and configured to receive a wire (not shown) that is connected to tip electrode 26. One end of the wire is connected to tip electrode 26 and another end is configured to be connected to, for example, monitoring, recording, or ablation devices, such as a radiofrequency (RF) generator. The wire may be a pre-coated wire that is insulated from other components in tip assembly 16. Tip electrode 26 of tip

assembly 16 may further include another aperture (not shown) formed therein that is configured to receive a thermocouple (not shown). The thermocouple may be configured to measure the temperature of tip electrode 26, targeted tissue, and/or the interface therebetween and provide feedback to the monitoring , recording, or ablation devices described hereinabove. Tip electrode 26 may further include a fluid lumen (not shown) configured as a passageway for irrigation fluid. Tip electrode 26 may be affixed to deflectable distal shaft 18 in a number of ways. For instance, tip electrode 26 may be bonded to an inner radial surface of deflectable distal shaft 18 using an epoxy material. In another embodiment, tip electrode 26 is integral with distal shaft 18.

[0036] Still referring to Figure 1, deflectable distal shaft 18 can be configured for deflection independent of proximal shaft 20 (as shown in phantom lines). Distal shaft 18 is disposed between tip assembly 16 and proximal shaft 20. Distal shaft 18 has a proximal portion 32 and distal portion 34 and may comprise an elongated body extending from proximal portion 32 to distal portion 34 and one or more electrodes 36. The length and diameter of distal shaft 18 can vary according to the application. For example and without limitation, the length of distal shaft 18 can range from about two inches (50.8 millimeters) to about six inches (152.4 millimeters), and the diameter of distal shaft 18 can range from about five French to about twelve French. In an embodiment, the diameter of distal shaft 18 can be about seven French. Although these particular dimensions are mentioned specifically, the dimensions of distal shaft 18 can vary in accordance with various applications.

[0037] Electrodes 36 (such as, for example, ring electrodes) may be mounted on or affixed to distal shaft 18. In an embodiment, an active outer surface of each electrode 36 can be configured for exposure to blood and/or tissue. Each electrode 36 may be assembled with distal shaft 18 using any number of known processes. For instance, electrodes 36 may be built into distal shaft 18 using a reflow process. In such a process, electrodes 36 are placed at the appropriate/desired locations on distal shaft 18, and then at least a section of distal shaft 18 is exposed to a heating process in which electrodes 36 and polymeric material of distal shaft 18 become affixed, bonded, or fused together. Sufficiently sized aperture(s) (not shown) may be formed in distal shaft 18 proximate to each electrode 36 in order to allow for wires (not shown) connected to electrodes 36 to be threaded through distal shaft 18. The wires may be pre-coated wires such that they are insulated from each other and other

components in device 10. The wires may extend through distal shaft 18, proximal shaft 20, and handle assembly 22 and may be connected to, for example, monitoring and/or recording devices and/or ablation devices associated with or connected to device 10.

[0038] Still referring to Figure 1, elongate proximal shaft 20 has a proximal portion 38 and a distal portion 40. At proximal portion 38, proximal shaft 20 may be connected to handle assembly 22, and at distal portion 40, proximal shaft 20 may be connected to distal shaft 18.

[0039] Still referring to Figure 1, handle assembly 22 is operative to, among other things, effect movement (i.e., deflection) of distal shaft 18. Handle assembly 22 has a distal portion 42 and a proximal portion 44. At its distal portion 42, handle assembly 22 may be coupled to proximal shaft 20 at its proximal portion 38 (disposed within handle assembly 22 and not shown). Proximal portion 44 of handle assembly 22 may be configured to be coupled to a monitoring or recording or ablation device. Handle assembly 22 may comprise an actuator (not shown) that can be selectively manipulated to cause distal shaft 18 to deflect in one or more directions (e.g., up, down, left, and right).

[0040] In an embodiment, pull wires 24, 25 (seen in Figures 4A-8B) facilitate deflection of distal shaft 18. Pull wires 24, 25 generally may extend through proximal portion 12 to distal portion 14 of device 10. In an embodiment, pull wires 24, 25 may be attached to diametrically opposite locations on an inner radial surface of a pull ring 43 (shown in Figures 8A-8B) at distal portion 14 of device 10 by, for example and without limitation, a solder or weld joint. Pull wires 24, 25 then extend proximally from pull ring 43 toward handle assembly 22. Pulling of pull wires 24, 25 via handle assembly 22 during use of device 10 will cause pull ring 43 to tilt or rock, thereby deflecting distal shaft 18. Although device 10 is described and illustrated as including two opposing pull wires 24, 25, it should be noted that device 10 is not limited to two opposing pull wires 24, 25. Rather, device 10 may include a single pull wire arrangement. In other embodiments, device 10 may include more than two pull wires. Pull wires 24, 25 may be formed from a superelastic Nitinol wire, carbon fiber, para-aramid synthetic fiber generally available from DuPont under the brand name KEVLAR®, or other suitable material in accordance with various embodiments.

[0041] Figure 2 is a close-up isometric view of the portion indicated as "2" of the medical device illustrated in Figure 1 in accordance with one embodiment of the present teachings (with some components omitted for clarity). Specifically, Figure 2 shows device 10 in an assembled state and generally illustrates the connection points between the various components of device 10, namely between proximal shaft 20 and distal shaft 18. Figure 3 is an exploded view of the portion of the medical device 10 illustrated in Figure 2 (with some components omitted for clarity). Figure 4A is a cross-sectional view of the portion of the medical device 10 of Figure 2 (with some components omitted for clarity) and generally illustrates the overlapping of certain layers of device 10 defining nested lap joints. Figure 4B is a semi-exploded, cross-sectional view of the portion of the medical device of Figure 2 (with some components omitted for clarity). Figures 5-7 are various cross-sectional views of the portion of device 10 illustrated in Figure 4A.

[0042] With simultaneous reference to Figures 2 and 3, proximal shaft 18 may include an outer layer 46 and a tube or liner 48 disposed within outer layer 46. Distal shaft 20 may include a cylindrical member 76, a braided layer 86, and an outer jacket 88. In an embodiment, these aforementioned components of proximal shaft 20 and distal shaft 18 may be assembled in a layer-by-layer fashion to form nested lap joints, as will be described in more detail below.

[0043] Referring particularly to Figures 4A-4B, device 10 defines a longitudinal axis 45. Distal portion 40 of proximal shaft 20 may be configured to be coupled with proximal portion 32 of distal shaft 18. Proximal shaft 20 may comprise one layer or a series of layers. As previously discussed, in the illustrated embodiment, proximal shaft 20 comprises outer layer 46, tube or liner 48 disposed within outer layer 46, and a stepped inner surface 49 that extends from proximal portion 38 (Figure 1) to distal portion 40. In the illustrated embodiment, liner 48 and outer layer 46 define stepped inner surface 49 such that surface 49 comprises an inner surface of liner 48 and a portion of an inner surface of outer layer 46.

[0044] Outer layer 46 may have an outer surface 50, an inner edge 54 and a distal edge 56, and a lumen 58. Outer layer 46 may also be generally cylindrical in shape and have a round cross section. It should be understood, however, that outer layer 46 can have various cross-sections, including oval or square, or can have more than one type of cross-sectional shape at different points along its length. Inner edge 54 and distal edge 56 may generally

extend in a radial direction. Inner edge 54 is illustrated as extending perpendicular to axis 45, and distal edge 56 is illustrated as extending at an angle 60 relative to axis 45. One of ordinary skill in the art will appreciate, however, that inner edge 54 and distal edge 56 may be at any angle and may not be circumferentially uniform relative to axis 45. For example and without limitation, inner edge 54 and/or distal edge 56 may not be planar but, instead, include a slot that extends proximally. In another embodiment, outer layer 46 may have different lengths along its circumference about axis 45, measured from proximal portion 38 (Figure 1) to inner edge 54 and/or to distal edge 56. In an embodiment, outer layer 46 may be composed of braided stainless steel wire sandwiched between two layers of polymeric material, such as polyurethane, nylon, or various types of plastic materials (such as polyether block amides offered under the trademark PEBAX® (e.g., 72D Pebax), which is a registered trademark of Arkema France) or any other suitable material. In one embodiment, inner edge 54 may be the point at which one layer of polymeric material ends (i.e., distal of inner edge 54, outer layer 46 is composed of braided wire and only one layer of polymeric material). Regardless of the material used, the material should have the capability to be displaced or to shrink when subjected to a process, such as for example, a heating process that is performed (in accordance with an embodiment). The braided stainless steel wire provides increased stiffness to proximal shaft 20. In the illustrated embodiment, outer layer 46 generally has an inner diameter 62 proximal to inner edge 54 and an inner diameter 64 proximal to distal edge 56. It should be understood, however, that outer layer 46 may have one inner diameter or multiple inner diameters along its length. In one embodiment, proximal shaft 20 is sixty inches in length.

[0045] In an embodiment, stepped inner surface 49 defines lumen 58 of proximal shaft 20. Among other things, lumen 58 allows for components of device 10 and fluid to travel between proximal portion 38 and distal portion 40 of proximal shaft 20. As illustrated, lumen 58 extends along axis 45 in the longitudinal direction. In other embodiments, however, proximal shaft 20 may have more than one lumen, and the lumen(s) may be parallel or at an angle to axis 45.

[0046] Still referring particularly to Figures 4A-4B, liner 48 of proximal shaft 20 has an axial end 66 and may be generally cylindrical in shape. In accordance with an embodiment, liner 48 is disposed along axis 45 within a portion of outer layer 46 of proximal

shaft 20. In another embodiment, liner 48 may extend distally outside of outer layer 46. In the illustrated embodiment, axial end 66 of liner 48 is aligned with inner edge 54 of outer layer 46 in the radial direction. One of ordinary skill in the art will understand, however, that axial end 66 of liner 48 may be disposed proximally or distally to inner edge 54. Liner 48 may be composed of a polymeric material, such as polyurethane, nylon, or various types of plastic materials such as polyether block amides offered under the trademark PEBAX®, which is a registered trademark of Arkema France, or any other suitable material. Regardless of the material used, the material should have the capability to be displaced or to shrink when subjected to a process, such as for example, a heating process that is performed (in accordance with an embodiment). The mechanical properties of liner 48 can also be varied, for example, by varying the properties of the polymeric material (e.g., dimension of the cylindrical braid structure and/or durometers of the polymers). Additionally, the mechanical properties of liner 48 can be varied along its length in accordance with some embodiments or can be substantially constant along its entire length in accordance with other embodiments.

[0047] Still referring particularly to Figures 4A-4B, proximal portion 32 of distal shaft 18 may be configured to be coupled with distal portion 40 of proximal shaft 20. In the illustrated embodiment, a filler or epoxy layer 89 (described in more detail herein below) is sandwiched between portions of proximal shaft 20 and distal shaft 18. As discussed previously, in the illustrated embodiment, distal shaft 18 may extend along longitudinal axis 45, may have proximal edges 70, 72, 74, and may comprise cylindrical member 76 (best seen in Figure 3), lumens 78, 80, 82 (best seen in Figures 5-7), braided layer 86, and outer jacket 88. It should be understood that distal shaft 18 may consist of any number of layers with the same or different materials and have one or several edges at its proximal portion 32. Moreover, in one embodiment, distal shaft 18 is coaxial with proximal shaft 20.

[0048] Proximal edges 70, 72, 74 of distal shaft 18 may extend in the radial direction. In one embodiment, proximal edge 74 corresponds in shape to distal edge 56 of proximal shaft 20, and proximal edge 72 of distal shaft 18 corresponds in shape to inner edge 54 of proximal shaft 20 and/or axial end 66 of liner 48. Proximal edges 70 and 72 are illustrated as extending perpendicular to axis 45, and proximal edge 74 is illustrated as extending at an angle 92 relative to axis 45. One of ordinary skill in the art will appreciate, however, that proximal edges 70, 72, 74 may be at any angle and may not be circumferentially uniform.

For example and without limitation, proximal edges 70, 72, 74 of distal shaft 18 may not be generally planar but, instead, include a slot or groove that extends in the longitudinal direction and corresponds to a key or protrusion on proximal shaft 20. Moreover, proximal edges 70, 72, 74 of distal shaft 18 may include a key or protrusion extending in the longitudinal direction that corresponds to a slot or groove in proximal shaft 20. In another embodiment, distal shaft 18 may have different lengths (from proximal edge 70, 72, and/or 74 to distal portion 34 shown in Figure 1) about axis 45 along its circumference.

[0049] In the illustrated embodiment, cylindrical member 76 extends from proximal edge 70 of distal shaft 18 to distal portion 34 (Figure 1) of distal shaft 18 and has two outer diameters: an outer diameter 94 (Figure 5) between proximal edges 70 and 72 and an outer diameter 96 (Figure 6) distal of proximal edge 72. However, it should be understood that cylindrical member 76 can have one diameter or more than two diameters. In the illustrated embodiment, proximal edge 70 is proximal to axial end 66 of liner 48 such that a portion of liner 48 overlaps a portion of cylindrical member 76 between proximal edges 70, 72 of distal shaft 18, and axial end 66 of liner 48 is aligned with proximal edge 72 of distal shaft 20 in the radial direction. In an embodiment, the length of cylindrical member 76 between proximal edge 70 and 72 is 0.100 inches. Moreover, in an embodiment, an inner diameter 98 of liner 48 (as best seen in Figures 4A-4B) may be slightly larger than or equal to outer diameter 94 (Figure 5) of cylindrical member 76 such that cylindrical member 76 is snug inside liner 48. In one embodiment, outer diameter 94 of cylindrical member 76 may be 0.064 inches. Furthermore, an outer diameter 100 of liner 48 (as best seen in Figures 4A-4B) may be substantially equal to outer diameter 96 (Figure 6) of cylindrical member 76 in accordance with some embodiments. An adhesive or epoxy may be used between liner 48 and cylindrical member 76 to better secure cylindrical member 76 inside liner 48, such as M-121 epoxy. Although cylindrical member 76 is shown as being cylindrical in shape, it should be understood that member 76 can have a variety of cross-sectional shapes. Moreover, member 76 can have different cross-sectional shapes across its length. In some embodiments, cylindrical member 76 is composed of a thermo-plastic, such as pellethane or polyether block amides offered under the trademark PEBAX®, which is a registered trademark of Arkema France, or any other suitable material. In the illustrated embodiment, lumens 78, 80, 82 are disposed entirely within cylindrical member 76; however, lumens 78, 80, 82 may be disposed

(partially or entirely) within other layers of distal shaft 18 in accordance with other embodiments.

[0050] Lumens 78, 80, 82 of distal shaft 18 may be configured such that various components or fluids required for performing the particular functionality of device 10 (e.g., recording electrograms, ablation, ultrasound, etc.) are disposed therein. Each lumen 78, 80, 82 may be fully formed or may share common spaces with one another. In accordance with the illustrated embodiment, lumens 78, 80, 82 may be disposed as proximate each other as manufacturally feasible, while allowing each lumen 78, 80, 82 to be fully formed. Depending upon the intended application of device 10, each lumen 78, 80, 82 may extend along an entire length of distal shaft 18 or may extend less than the entire length of distal shaft 18. Each lumen 78, 80, 82 may be formed to have a predetermined cross-sectional profile and shape. Furthermore, each lumen 78, 80, 82 may have various cross-sectional shapes at different points across the length of distal shaft 18.

[0051] Referring to Figure 5, in the illustrated embodiment, cylindrical member 76 has three lumens 78, 80, 82, each with a longitudinal axis 102, 104, 106 (Figure 2). In other embodiments, distal shaft 18 has one lumen, two lumens, or more than three lumens. In an embodiment, lumens 78, 80, 82 may be generally round or oval in cross-sectional shape and may extend from proximal portion 32 to distal portion 34 (Figure 1) of distal shaft 18 along their respective axes 102, 104, 106. In an embodiment, lumen 78 may be configured for housing wiring for electrodes 26, 36 (Figure 1) or for other electrical components and/or for use as an irrigation fluid passageway and the like. Axis 102 of lumen 78 may coincide with axis 45 of device 10 (Figures 4A-4B). In the illustrated embodiment, lumen 78 is lined with a liner 110 that serves the purpose of providing a lubricious surface and insulating the components within lumen 78. If provided, liner 110 may be constructed of a polymeric material, such as a polyimide or any other suitable material.

[0052] In an embodiment, lumen 80 may be located generally adjacent to or abutting lumen 78 and may be oriented such that its axis 104 is parallel to axis 102 of lumen 78. Lumen 82 may also be located generally adjacent to or abutting lumen 78 and may be oriented such that its axis 106 is parallel to axis 102 of lumen 78. Lumens 80, 82 may be configured to house pull wires 24, 25, respectively, to enable distal shaft 18 to deflect in two or more directions.

[0053] Referring back to Figures 4A-4B, braided layer 86 of distal shaft 18 has an outer diameter 113 and is configured to provide stiffness and torqueability to distal shaft 18. In the illustrated embodiment, braided layer 86 extends from proximal edge 72 to distal portion 34 (Figure 1) of distal shaft 18 and circumferentially surrounds a portion of cylindrical member 76. The length and diameter(s) of braided layer 86, however, can vary in accordance with other embodiments. In the illustrated embodiment, outer diameter 113 of braided layer 86 is slightly less than or equal to inner diameter 64 of outer layer 46 such that a portion of braided layer 86 is snug inside a portion of outer layer 46 of proximal shaft 20 between axial end 66 of liner 48 and/or inner edge 54 of outer layer 46 and distal edge 56 of outer layer 46. For example and without limitation, outer diameter 113 of braided layer 86 may be 0.076 inches, and inner diameter 64 of outer layer 46 of proximal shaft 20 may be between 0.076 and 0.078 inches. The length of overlap between layers 46, 86 in the axial direction may be 0.300 inches. Braided layer 86 can be composed of a polymeric material, such as polyurethane, nylon, or various types of plastic materials such as polyether block amides offered under the trademark PEBAX®, which is a registered trademark of Arkema France, or any other suitable material. Regardless of the material used, the material should have the capability to be displaced or to shrink when subjected to a process, such as for example, a heating process that is performed (in accordance with an embodiment). The polymeric material of braided layer 86 may be surrounded by braided stainless steel wire to provide increased stiffness to distal shaft 18. It should be understood that braided layer 86 can be omitted or consist of several layers in accordance with some embodiments. The mechanical properties of braided layer 86 can also be varied, for example, by varying the properties of the cylindrical braid structure(s) and the polymeric material (e.g., dimension of the cylindrical braid structure and/or durometers of the polymers). Additionally, the mechanical properties of braided layer 86 can be varied along its length in accordance with some embodiments or can be substantially constant along its entire length in accordance with other embodiments.

[0054] Outer jacket 88 of distal shaft 18 is configured to provide increased stiffness to distal shaft 18. In the illustrated embodiment, outer jacket 88 extends from proximal edge 74 to distal portion 34 (Figure 1) of distal shaft 18 and circumferentially surrounds a portion of braided layer 86. The length and diameter(s) of jacket, however, can vary in accordance with other embodiments. For example and without limitation, outer jacket 88 may extend distally

from proximal edge 70 or 72 of distal shaft 18. The mechanical properties of outer jacket 88 can also be varied along the length of outer jacket 88, for example, by varying the properties of the polymeric material (e.g., durometers of the polymers). For example and without limitation, most proximally, outer jacket 88 may have a segment composed of 65D Pellethane, followed by a segment composed of 55D or 90AE/55D Pellethane. Additionally, the mechanical properties of outer jacket 88 can be substantially constant along its entire length in accordance with other embodiments. It should be understood that outer jacket 88 can be omitted or consist of several layers in accordance with other embodiments.

[0055] Furthermore, in the illustrated embodiment, proximal edge 72 is distal of proximal edge 70, and proximal edge 74 is distal of proximal edge 72 in the axial direction such that member 76 extends proximally outside braided layer 86 and outer jacket 88, and braided layer 86 extends proximally outside outer jacket 88. One of ordinary skill in the art would understand, however, that proximal edges 70, 72, 74 may be proximally or distally disposed of one another. Additionally, in the illustrated embodiment device 10 further includes epoxy layer 89 between a portion of braided layer 86 of distal shaft 18 and outer layer 46 of proximal shaft 20 between proximal edges 72, 74 of distal shaft 18. Epoxy layer 89 may also extend in the radial direction between distal edge 56 of proximal shaft 20 and proximal edge 74 of distal shaft 18 and/or proximally of proximal portion 32 of distal shaft 18. In accordance with one embodiment, epoxy layer 89 may be M-121 epoxy. While epoxy layer 89 is configured to improve the bond strength between proximal shaft 20 and distal shaft 18, it should be understood that epoxy layer 89 is optional.

[0056] Device 10 may further include a sleeve 90. In the illustrated embodiment, sleeve 90 is disposed circumferentially around a portion of proximal shaft 20 and a portion of distal shaft 18 and may be configured to provide more strength to the joint(s) between proximal shaft 20 and distal shaft 18. In accordance with some embodiments, sleeve 90 may surround proximal and distal shafts 20, 18 at distal edge 56 of proximal shaft 20 and proximal edge 74 of distal shaft 18 and have a length of 0.400 inches. Sleeve 90 may be composed of polymeric material, such as polyurethane, nylon, or various types of plastic materials such as polyether block amides offered under the trademark PEBAX®, which is a registered trademark of Arkema France, or any other suitable material. Regardless of the material used, the material should have the capability to be displaced or to shrink when subjected to a

process, such as for example, a heating process that is performed (in accordance with an embodiment).

[0057] As best seen in Figures 4A-4B, distal shaft 18 may be connected to proximal shaft 20 by two nested lap joints formed between distal shaft 18 and proximal shaft 20. In the illustrated embodiment, cylindrical member 76, braided layer 86, and outer jacket 88 define a stepped outer surface 107 of distal shaft 18. Outer surface 107 includes steps 108, 109 extending in the axial direction. Step 108 may extend from proximal edge 70 to proximal edge 72. Step 109 may extend from proximal edge 72 to proximal edge 74. In the illustrated embodiment, a portion of liner 48 of proximal shaft 20 overlaps step 108 of distal shaft 18 in the radial direction to form a lap joint, and outer layer 46 of proximal shaft 20 nests this lap joint at edges 66, 72. Moreover, in the illustrated embodiment, inner surface 49 of proximal shaft 20 includes a step 110 extending in the axial direction from axial end 66 and/or inner edge 54 to distal edge 56. In an embodiment, inner step 110 of proximal shaft 20 overlaps step 109 of distal shaft 18 in the radial direction to form another lap joint, and sleeve 90 nests this lap joint at edges 56, 74. Although the nested lap joints are illustrated as extending circumferentially about axis 45, one of ordinary skill in the art will understand that the joints can instead extend partially about axis 45 (e.g., via slots and corresponding keys in proximal shaft 20 and distal shaft 18). The lap joints can be nested within each other to provide greater joint strength and to more effectively spread the loads and stresses across the various layers of device 10. Moreover, in the illustrated embodiment, the nested lap joints are staggered in the axial direction to spread the loads and stresses across the various layers of device 10 and to reduce the peak force experienced by any individual material. However, one of ordinary skill in the art will understand and appreciate that only one joint could be used, that nesting of the joints is optional, and that the lap joints do not have to be staggered in the axial direction in accordance with other embodiments.

[0058] Figure 8A is a schematic view of a portion of the medical device of Figure 1 in accordance with another embodiment of the present teachings. As illustrated, device 10 can further include compression coils 114, 116 disposed around pull wires 24, 25 in the one or more lumens of proximal shaft 20 that extend from proximal portion 38 (Figure 1) to distal portion 40 of proximal shaft 20 or slightly into proximal portion 32 of distal shaft 18. Device 10 may also include one or more spring packs 117 disposed around pull wire(s) 24, 25 in

lumens 80, 82 of distal shaft 18. Compression coils 114, 116 and/or spring pack 117 may be configured to provide the desired mechanical property of resisting compression during use as described in more detail in the '124 Application. Because compression coils 114, 116 and spring pack 117 are generally not easily compressible, tension on pull wires 24, 25 will not translate into compressive tension on proximal shaft 20 and/or distal shaft 18. Compression coils 114, 116 and spring pack 117 are therefore configured to help assure that proximal shaft 20 and/or distal shaft 18 does not bend as a result of tension on pull wires 24, 25 and that rotational control of device 10 is not adversely affected when pull wires 24, 25 are under tension. In an embodiment, each of compression coils 114, 116 and/or spring pack 117 is tightly wound so it can bend, but is generally non-compressible. While pull wires 24, 25 may extend from handle assembly 22 (Figure 1) to pull ring 43, compression coils 114, 116 may generally extend only through proximal shaft 20 and perhaps slightly into proximal portion 32 of distal shaft 18, in accordance with some embodiments. Compression coils 114, 116 can extend the entire length of proximal shaft 20 in accordance with some embodiments. Each of the compression coils 114, 116 comprises a distal end 118, 120. The distance between distal end 118, 120 of coils 114, 116 and pull ring 43 may generally affect the curvature of distal shaft 18. As best seen in Figure 6, an outer diameter 122 of compression coils 114, 116 may be about 0.015 inches (0.38 millimeters) to about 0.030 inches (0.76 millimeters), and an inner diameter 124 of compression coils 114, 116 may be about 0.004 inches (0.10 millimeters) to about 0.015 inches (0.38 millimeters). Each of compression coils 114, 116 can comprise stainless steel in accordance with an embodiment. Where not disposed within a spring pack 117, pull wires 24, 25 may be surrounded by a tube 121 made of a material, such as PTFE.

[0059] In accordance with some embodiments, compression coils 114, 116 and/or spring pack 117 may include fused areas 125 with a fused coil pitch and unfused areas 127 with an unfused coil pitch. By allowing compression coils 114, 116 and/or spring pack 117 to have unfused areas 127 and fused areas 125 within proximal shaft 20 and/or distal shaft 18, proximal shaft 20 and/or distal shaft 18 may be configured to provide pushability and torqueability for device 10, while no longer being necessary to address shaft compression and/or snaking. Unfused areas 127 are configured to provide strain relief to device 10 and may be located between fused areas 125, at a proximal end 128a and/or a distal end 128b of spring pack 117, at proximal ends (not shown) of compression coils 114, 116, and/or at distal

ends 118, 120 of compression coils 114, 116. In an embodiment, the coil pitch at proximal and/or distal ends of compression coils 114, 116 and/or spring pack 117 may have a greater coil pitch than the coil pitch(es) disposed therebetween to reduce stress at the proximal and distal ends of the compression coils 114, 116 and/or spring pack 117. By separating compression coils 114, 116 from proximal shaft 20 and distal shaft 18 themselves, device 10 can undergo bench testing for assessing deflection of device 10 prior to formation of device 10 through a reflow process as described in more detail hereinbelow (and in the '124 Application). Moreover, by not fixedly attaching compression coils 114, 116 to device 10 or components thereof, device 10 may exhibit improved ease of assembly. Although compression coils 114, 116 and spring pack 117 are mentioned as having two coil pitches (fused coil pitch and unfused coil pitch), compression coils 114, 116 and/or spring pack 117 may have one coil pitch or multiple coil pitches throughout their respective lengths in accordance with other embodiments.

[0060] Referring to Figure 8A, fused areas 125 of compression coils 114, 116 and/or spring pack 117 may be fused to or embedded within inner surfaces 129, 130 (Figure 7) of lumens 80, 82 of cylindrical member 76 and/or inner surface 49 of proximal shaft 20 (such as, for example and without limitation, an inner surface of liner 48 or an inner wall of the polymeric material of outer layer 46 of proximal shaft 20, as seen in Figures 4A-4B). Moreover, the location of fused areas 125 relative to pull ring 43 disposed in distal portion 32 of distal shaft 18 may generally affect the curvature of distal shaft 18. In the illustrated embodiment in Figure 8A, pull wire 24 may exhibit a first radius of curvature upon tension, while pull wire 25 may exhibit a second radius of curvature upon tension. In the illustrated embodiment in Figure 8A, the first and second radii of curvature exhibited by pull wires 24, 25 upon tension are different. It should be understood that pull wires 24, 25 can be configured to have any curvature known in the art and that such curvature can be configured by fusing various portion(s) of compression coils 114, 116 and/or spring pack 117 along their respective lengths. In accordance with some embodiments, fused areas 125 may have a fused coil pitch that is smaller than an unfused coil pitch of unfused areas 127 of compression coils 114, 116. In an embodiment, proximal portion 38 (Figure 1) of proximal shaft 20 is filled with adhesive to prevent coils 114, 116 from moving more proximally. In accordance with some embodiments, the proximal ends of each of compression coils 114, 116 is not fixedly

attached to handle assembly 22, but instead abuts or stops at or is constrained by an axial end surface (e.g., of an adhesive) of proximal portion 38 (Figure 1) of proximal shaft 20.

[0061] In accordance with other embodiments, areas 125 of compression coils 114, 116 and/or spring pack 117 (to be fused) may each be circumferentially surrounded by and/or fused to a jacket of polymeric material, and the jacket may be fused to proximal shaft 20 and/or distal shaft 18 (as described hereinabove). In some embodiments, prior to fusion with proximal shaft 20 and/or distal shaft 18, fused areas 125 may be stretched, and then the jackets may be heated such that the material of the jacket melts and flows in between the stretched coil gaps of compression coils 114, 116 and/or spring pack 117. Use of a jacket may aid in subsequent fusion with proximal shaft 20 and/or distal shaft 18. Flowing the jacket material into the stretched coil gaps may prevent the material of proximal shaft 20 or distal shaft 18 from sinking into the coil gaps causing sink holes. The jackets can be composed of polymeric material, such as polyurethane, nylon, or various types of plastic materials such as polyether block amides offered under the trademark PEBAX®, which is a registered trademark of Arkema France, or any other suitable material. Regardless of the material used, the material should have the capability to be displaced or to shrink when subjected to a process, such as for example, a heating process that is performed (in accordance with an embodiment).

[0062] Referring to Figure 8B, device 10′ includes compression coils 114′, 116′ with fused areas 125′ and unfused areas 127′. In this illustrated embodiment, compression coils 114′, 116′ are generally the same length (i.e., their respective distal ends 118′, 120′ are aligned in the radial direction) such that pull wires 24′, 25′ generally exhibit the same radius of curvature upon tension.

[0063] With reference to Figure 9, a method of fabricating device 10 will now be described. The method may begin with the process 131 of providing liner 48. As set forth hereinabove, liner 48 may have axial end 66.

[0064] The method may continue with the process 132 of providing distal shaft 18 with proximal portion 32 and steps 108, 109 on outer surface 107 (see Figures 4A-4B). Process 132 may include several subprocesses. In accordance with one embodiment, process 132 may begin with the process of providing cylindrical member 76 with lumens 78, 80, 82,

the process of which is discussed in more detail in the '124 Application. Then, braided layer 86 may be formed by braiding a wire around an Acetyl core and thereafter removing the core. Next, formed braided layer 86 may be slid over cylindrical member 76. Thereafter, outer jacket 88 may be slid over braided layer 86. Next, some of the material of braided layer 86 and outer jacket 88 (and optionally a portion of cylindrical member 76) may be removed or machined off to form the stepped outer surface 107 (and proximal edges 70, 72, 74). Moreover, outer jacket 88 may be removed distally of proximal edge 72 to form proximal edge 74.

[0065] The method may continue with the process 134 of inserting cylindrical member 76 into axial end 66 of liner 48 such that liner 48 overlaps step 108 of distal shaft 18 in the radial direction, thus, forming a lap joint. Process 134 may include several subprocesses. In certain embodiments, an adhesive or epoxy (not shown) may be applied to one or both of an inner surface of liner 48 and step 108 of cylindrical member 76. In an embodiment, axial end 66 of liner 48 abuts and/or aligns with proximal edge 72 of distal shaft 18.

[0066] The method may continue with the process 136 of providing outer layer 46 of proximal shaft 20. Process 136 may include several subprocesses. In one embodiment, outer layer 46 is formed by coating an Acetyl plastic core with a polymeric material using extrusion equipment. Wire may then be braided around the coated core. Thereafter, another layer of polymer or plastic coats the braid. Finally, the core is removed to produce a hollow braided shaft.

[0067] The method may continue with the process 138 of applying an epoxy layer 89 around liner 48 and proximal portion 32 of distal shaft 18. In some embodiments, epoxy layer 89 may be applied between proximal edges 72, 74 of distal shaft 18. In accordance with one embodiment, epoxy layer 89 may be M-31 epoxy.

[0068] The method may continue with the process 140 of pushing outer layer 46 over liner 48 and proximal portion 32 of distal shaft 18 to form step 110 such that step 110 overlaps step 109 in the radial direction, thus nesting the lap joint formed in process 134 and forming another lap joint. Epoxy layer 89 may extend partially in the radial direction between distal edge 56 of proximal shaft 20 and proximal edge 74 of distal shaft 18, as a

result of this process 140. In an embodiment, distal edge 56 of outer layer 46 abuts and/or aligns with proximal edge 74 of distal shaft 18. Moreover, in an embodiment, inner edge 54 of outer layer 46 is radially aligned with axial end 66 of liner 48.

[0069] The method may continue with the process 142 of pushing sleeve 90 over proximal shaft 20 and distal shaft 18, thus, nesting the lap joint formed in process 140. In an embodiment, sleeve 90 circumferentially surrounds proximal shaft 20 and distal shaft 18 at distal edge 56 of proximal shaft 18 and proximal edge 74 of distal shaft 18.

[0070] The method may continue with the process 144 of subjecting device 10 to a reflow process, the details of which are discussed in the '124 Application.

[0071] The method may continue with the process 146 of providing compression coils 114, 116 and/or spring pack 117. Process 146 may include several subprocesses. In one embodiment, compression coils 114, 116 and spring packs 117 are pre-made to have multiple coil pitches throughout their lengths, for example and without limitation, a fused coil pitch and an unfused coil pitch. In another embodiment, jackets are slid over the portions of compression coils 114, 116 to be fused (denoted as 125), as described in more detail hereinabove in connection with Figures 8A-8B. Then, the portions that are to be fused (125) are stretched (forming the fused coil pitch) and heated such that the material of the jacket melts and flows in between the individual coil sections, thus, retaining the fused coil pitch. Flowing the jacket material into the stretched coil gaps may prevent the material of proximal shaft 20 or distal shaft 18 (in subsequent fusion) from sinking into the coil gaps causing sink holes.

[0072] The method may continue with the process 148 of inserting compression coils 114, 116 and/or spring pack 117 into device 10. In an embodiment, compression coils 114, 116 are disposed within proximal shaft 20 and may extend slightly into distal shaft 18. In an embodiment, spring pack 117 is disposed within distal shaft 18.

[0073] The method may continue with the process 150 of inserting pull wires 24, 25 into device 10. In an embodiment, pull wires 24, 25 extend through lumen(s) of proximal shaft 20, lumens 80, 82 of distal shaft 18 (respectively), compression coils 114, 116 (respectively), and pull wire 24 may extend through spring pack 117 (see Figure 8A).

[0074] The method may continue with the process 152 of fusing portions 125 of compression coils 114, 116 and/or spring pack 117 to proximal shaft 20 and/or distal shaft 18. In an embodiment, process 152 comprises selectively heating portions 125 using an energy source. In accordance with one embodiment, such fusion is accomplished by using RF energy. For example and without limitation, an RF energy source is placed around device 10 in the area to be fused. The focused RF energy (in the form of electro-magnetic fields) passes through the non-conductive, non-RF-absorbent materials (i.e., outer layer 46 and liner 48 of proximal shaft 20 and member 76, braided layer 86, and outer jacket 88 of distal shaft 18) and, thus, selectively targets the conductive, RF-absorbent materials (i.e., compression coils 114, 116 and spring pack 117). The RF energy induces a current in compression coils 114, 116 and/or spring pack 117 and, thus, causes them to heat up. The material in close proximity to compression coils 114, 116 and/or spring pack 117 (e.g., pellethane of cylindrical member 76) is heated as a result, melts, and flows within and around the individual coil/spring sections. The material is permitted to cool, thus, resulting in the embedding or fusing of fused areas 125 within proximal shaft 20 and/or distal shaft 18. Process 152 allows for compression coils 114, 116 and/or spring pack 117 to become fused to proximal shaft 20 and/or distal shaft 18 without making any physical contact and without making any holes in device 10. Moreover, process 152 allows for fusing without causing any physical changes to outer layer 46 of proximal shaft 20 and braided layer 86 and outer jacket 88 of distal shaft 20. Additionally, the process 152 is highly precise and easily controllable (e.g., within ± 0.1 inches). Although processes 146, 148, 150 are described as occurring after process 152 of subjecting device 10 to a reflow process, one of ordinary skill in the art will understand that such processes can occur in several different orders in accordance with other embodiments. Additionally, it should be understood that other conductive elements of device 10 can be fused or embedded to a layer(s) within device 10, such as thermal sensors.

[0075] Figure 10A is a schematic view of a distal portion of the medical device of Figure 1 illustrating an embodiment of the method of Figure 9. Figure 10B is a cross-sectional view of the distal portion of the medical device of Figure 10A taken along line 10B-10B. Specifically, Figures 10A and 10B show an embodiment of the process 152 of fusing portions 125 of compression coils 114, 116 and/or spring pack 117 to proximal shaft 20 and/or distal shaft 18. As illustrated, RF energy may be applied using an RF coil 154 with an intensifier 156. Referring to Figure 10B, RF coil 154 may be circular in shape with an inner

diameter 158. Inner diameter 158 may be large enough such that coil 154 may circumferentially surround device 10 without contacting device 10. One of ordinary skill in the art will understand that other RF tools with various shapes may be used to apply RF energy (or another energy that selectively heats compression coils 114, 116 and spring pack 117) in accordance with other embodiments.

[0076] In one embodiment, device 10 is fabricated using the method described in connection with Figure 9. In another embodiment, device 10 is fabricated using process 152 of fusing portions 125 of compression coils 114, 116 and/or spring pack 117 to proximal shaft 20 and/or distal shaft 18, but does not include the nested lap joint(s) described hereinabove. In yet another embodiment, device 10 is fabricated to include the nested lap joint(s) but is not fabricated according to process 152 of fusing portions 125 of compression coils 114, 116 and/or spring pack 117 to proximal shaft 20 and/or distal shaft 18. One of ordinary skill in the art will understand that each improvement disclosed herein is not necessary to the other in order to function and improve device 10.

[0077] Although only certain 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 scope of this disclosure. All directional references (*e.g.*, plus, minus, upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present disclosure, and do not create limitations, particularly as to the position, orientation, or use of embodiments. 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 imply that two elements are directly connected/coupled and in fixed relation to each other. Additionally, the terms "electrically connected" and "in communication" are meant to be construed broadly to encompass both wired and wireless connections and communications. 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 the disclosure.

[0078] 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.

[0079] While one or more particular embodiments have been shown and described, it will be understood by those of skill in the art that various changes and modifications can be made without departing from the spirit and scope of the present teachings.

CLAIMS

What is claimed is:

1. A medical device for diagnosis or treatment of tissue in a body, comprising:

a first shaft including a longitudinal axis; and

a second shaft including a second shaft axial end disposed within the first shaft,

wherein the second shaft is connected to the first shaft by a first nested lap joint formed between the first shaft and the second shaft.

2. The device of claim 1, wherein the second shaft includes an outer surface, such outer surface including a first outer step extending in the axial direction, and the first nested lap joint corresponds to the first outer step of the second shaft.

3. The device of claim 2, wherein the first shaft overlaps the first outer step of the second shaft in the radial direction.

4. The device of claim 2, wherein the first and second shafts are connected by a second nested lap joint formed between the first shaft and the second shaft, the first shaft includes a first shaft axial end and a first shaft inner surface with an inner step extending axially from the first shaft axial end to an inner edge of the first shaft inner surface extending radially, the outer surface of the second shaft further includes a second outer step extending in the axial direction, and the second nested lap joint corresponds to the second outer step of the second shaft and the inner step of the first shaft.

5. The device of claim 4, wherein the inner step of the first shaft overlaps the second outer step of the second shaft in the radial direction.

6. The device of claim 4, wherein the first shaft further comprises a tube with a tube axial end and an outer layer disposed around the tube, the outer layer comprises an outer layer axial end corresponding to the first shaft axial end, and the inner edge of the first shaft corresponds to at least one of the tube axial end and an outer layer inner edge axially offset from the outer layer axial end and extending in the radial direction.

7. The device of claim 6, wherein the outer layer inner edge is aligned with the tube axial end in the radial direction.

8. The device of claim 4, wherein the second shaft further includes a first radially extending edge and a second radially extending edge, the first outer step extends from the second shaft axial end to the first radially extending edge, and the second outer step extends from the first radially extending edge to the second radially extending edge.

9. The device of claim 8, wherein the second shaft comprises:

a cylindrical member extending axially from the second shaft axial end;

a braided layer disposed around the cylindrical member and extending axially from the first radially extending edge of the second shaft; and

an outer jacket disposed around the braided layer and extending axially from the second radially extending edge of the second shaft.

10. The device of claim 4, wherein the first and second nested lap joints extend circumferentially about the longitudinal axis.

11. The device of claim 6, wherein the outer layer of the first shaft is configured to at least partially nest the first nested lap joint.

12. The device of claim 1, further comprising a filler disposed between the first shaft and the second shaft.

13. The device of claim 4, further comprising a sleeve disposed around the first shaft and the second shaft and configured to at least partially nest the second nested lap joint.

14. A medical device for diagnosis or treatment of tissue in a body, comprising:

a first shaft;

a second shaft; and

a conductive element disposed within at least one of the first and second shafts,

wherein the second shaft is connected to the first shaft by a first nested lap joint formed between the first shaft and the second shaft.

15. The device of claim 14, wherein the conductive element includes a fused portion fused to at least one of an inner surface of the first shaft and an inner surface of the second shaft.

16. The device of claim 14, wherein the first shaft includes a distal end, the second shaft extends distally of the distal end of the first shaft, and the conductive element is disposed at least partially in the second shaft.

17. The device of claim 14, wherein the conductive element is a spring pack with a longitudinal axis.

18. The device of claim 17, wherein the spring pack includes a fused portion with a fused coil pitch and an unfused portion with at least one unfused coil pitch, and the fused coil pitch is greater than the at least one unfused coil pitch.

19. The device of claim 18, wherein the fused portion of the spring pack is disposed between a first and second axial end of the spring pack such that the spring pack includes at least one strain-relief zone.

20. A method for fabricating a medical device, comprising:

providing a shaft with a shaft inner surface;

providing a conductive element;

inserting the conductive element into the shaft; and

fusing at least a portion of the conductive element to the shaft inner surface to form a fused area,

wherein fusing at least a portion of the conductive element comprises selectively heating the portion of the conductive element using an energy source.

21. The method of claim 20, wherein the shaft is made from a non-conductive material and selectively heating the portion of the conductive element comprises passing energy through the shaft to the portion of the conductive element.

22. The method of claim 21, wherein the energy is in the form of an electro-magnetic field.

23. The method of claim 20, wherein the energy source is an RF energy source and selectively heating the portion of the conductive element comprises inducing a current in the portion of the conductive element.

24. The method of claim 20, wherein fusing the portion of the conductive element further comprises heating a portion of the shaft inner surface via selectively heating of the portion of the conductive element to form the fused area.

25. The method of claim 20, wherein providing the conductive element comprises:

sliding a jacket over the portion of the conductive element; and

fusing the jacket to the portion of the conductive element.

26. The method of claim 25, wherein the conductive element is a spring pack with a coil pitch and fusing the jacket comprises stretching the portion of the conductive element to form a stretched coil pitch.

27. The method of claim 26, wherein fusing the jacket further comprises heating the portion of the conductive element.

28. The method of claim 27, wherein fusing the jacket further comprises cooling the jacket to maintain the stretched coil pitch of the portion of the conductive element.

29. The method of claim 20, wherein the shaft comprises a proximal shaft and a distal shaft and the method further includes connecting the proximal shaft and the distal shaft by forming a nested lap joint between the proximal shaft and the distal shaft.

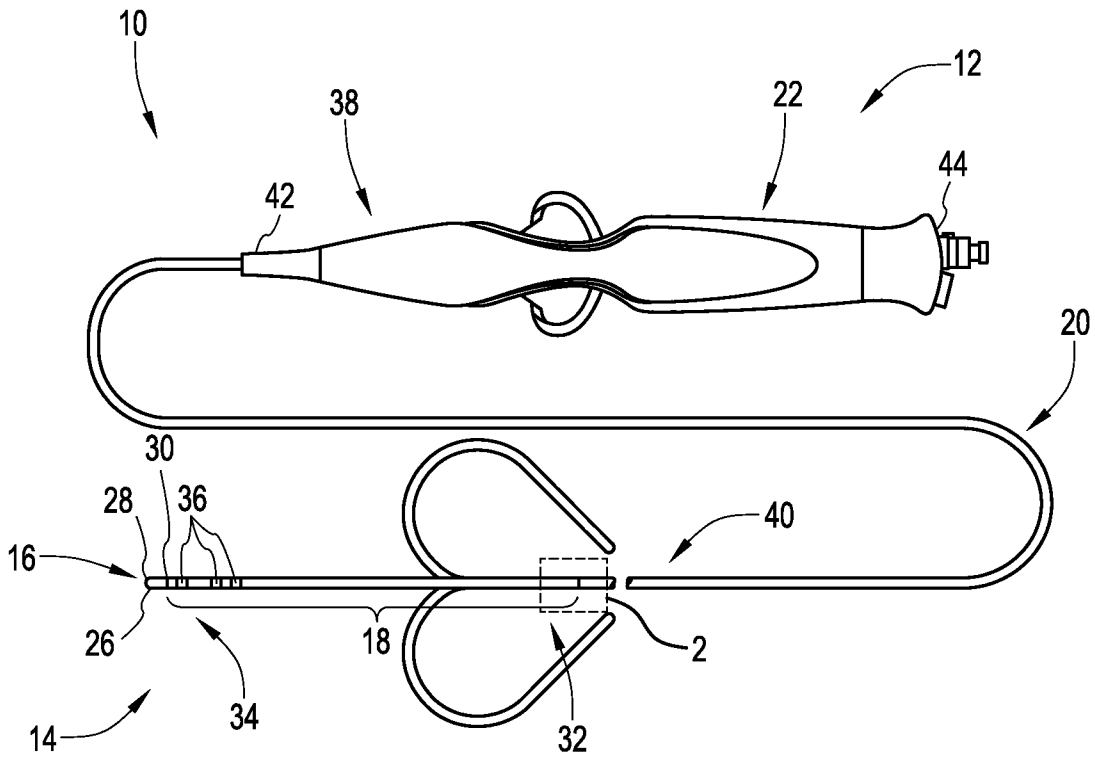


FIG.1

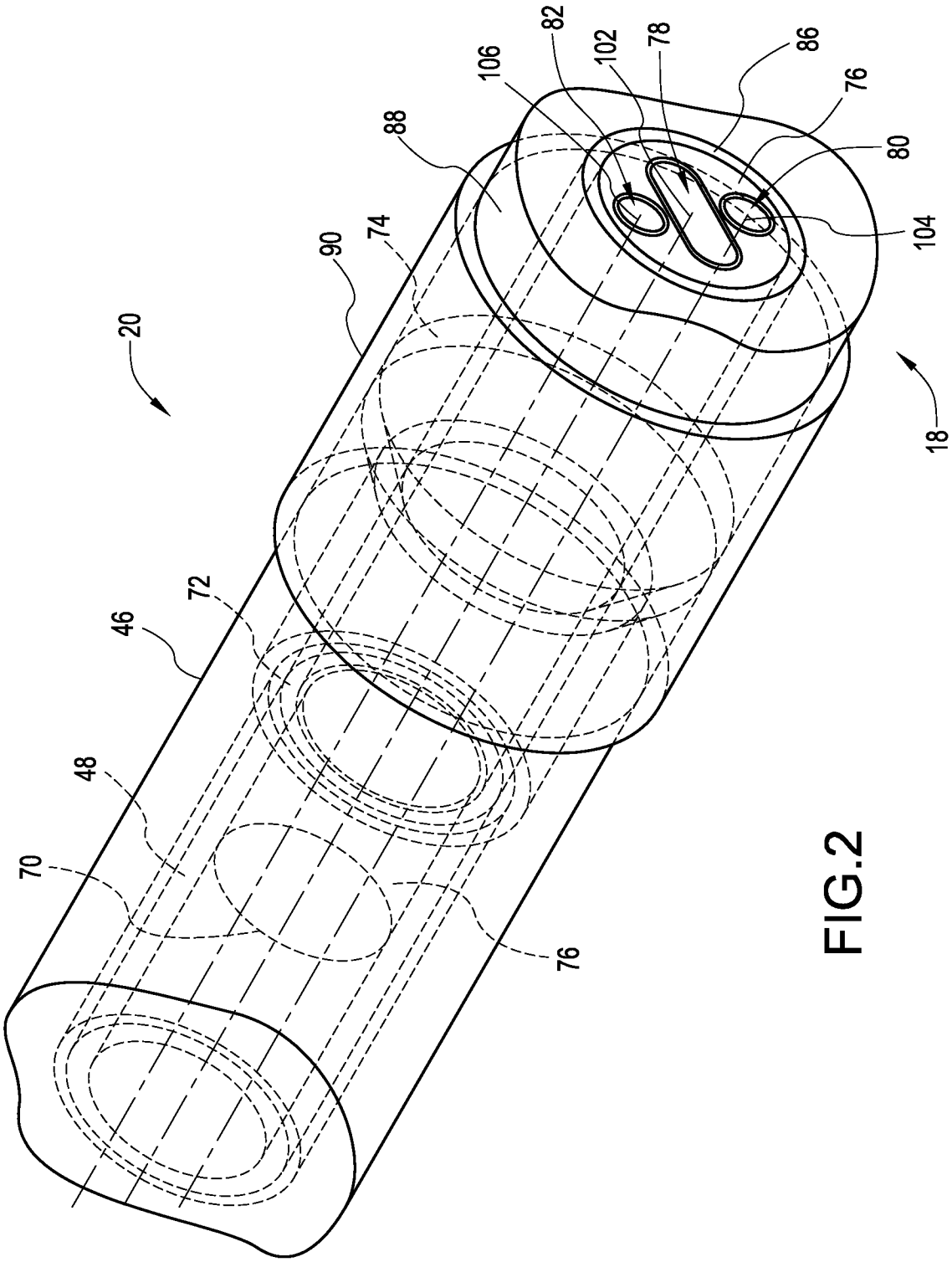


FIG.2

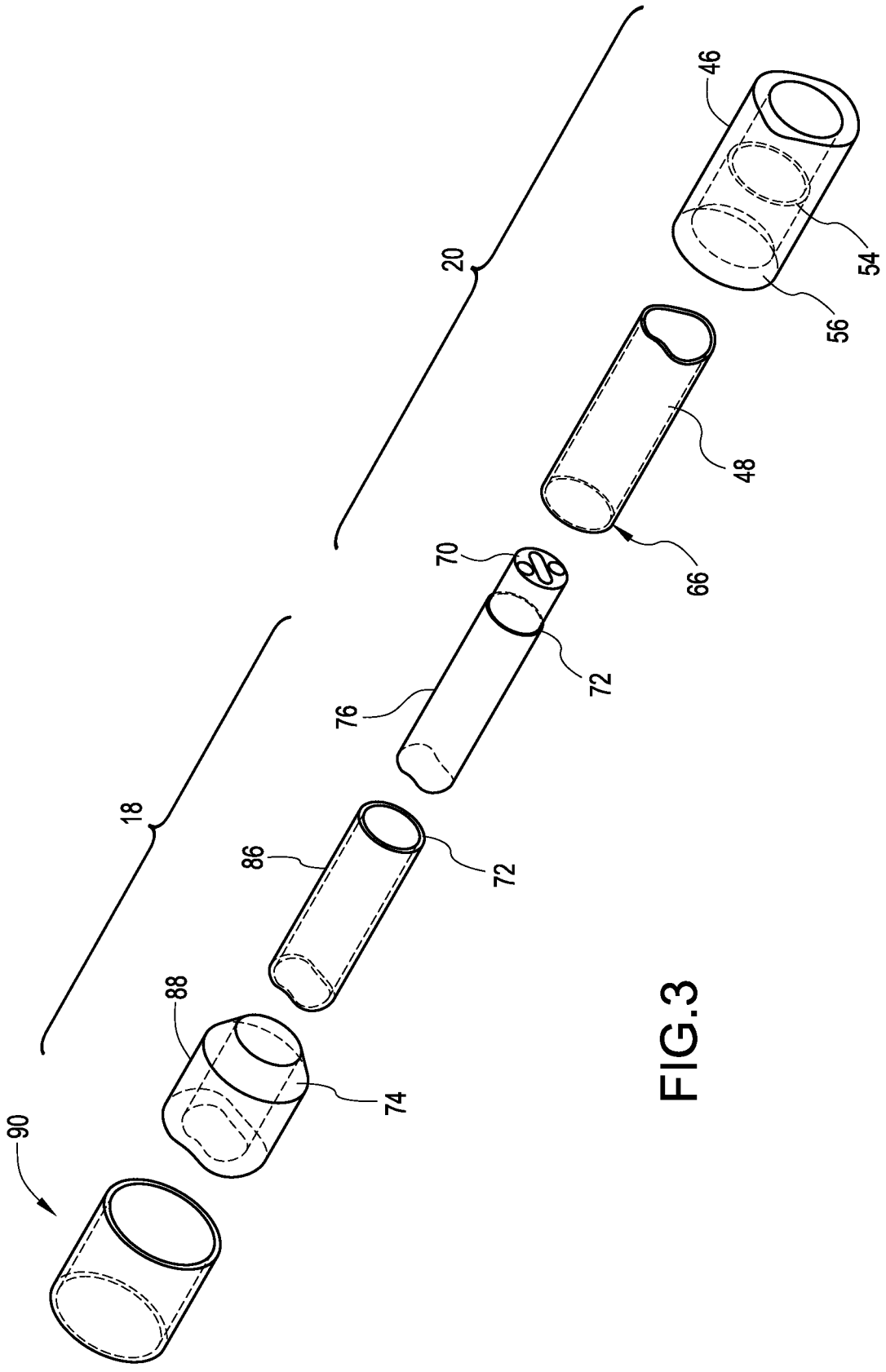


FIG.3

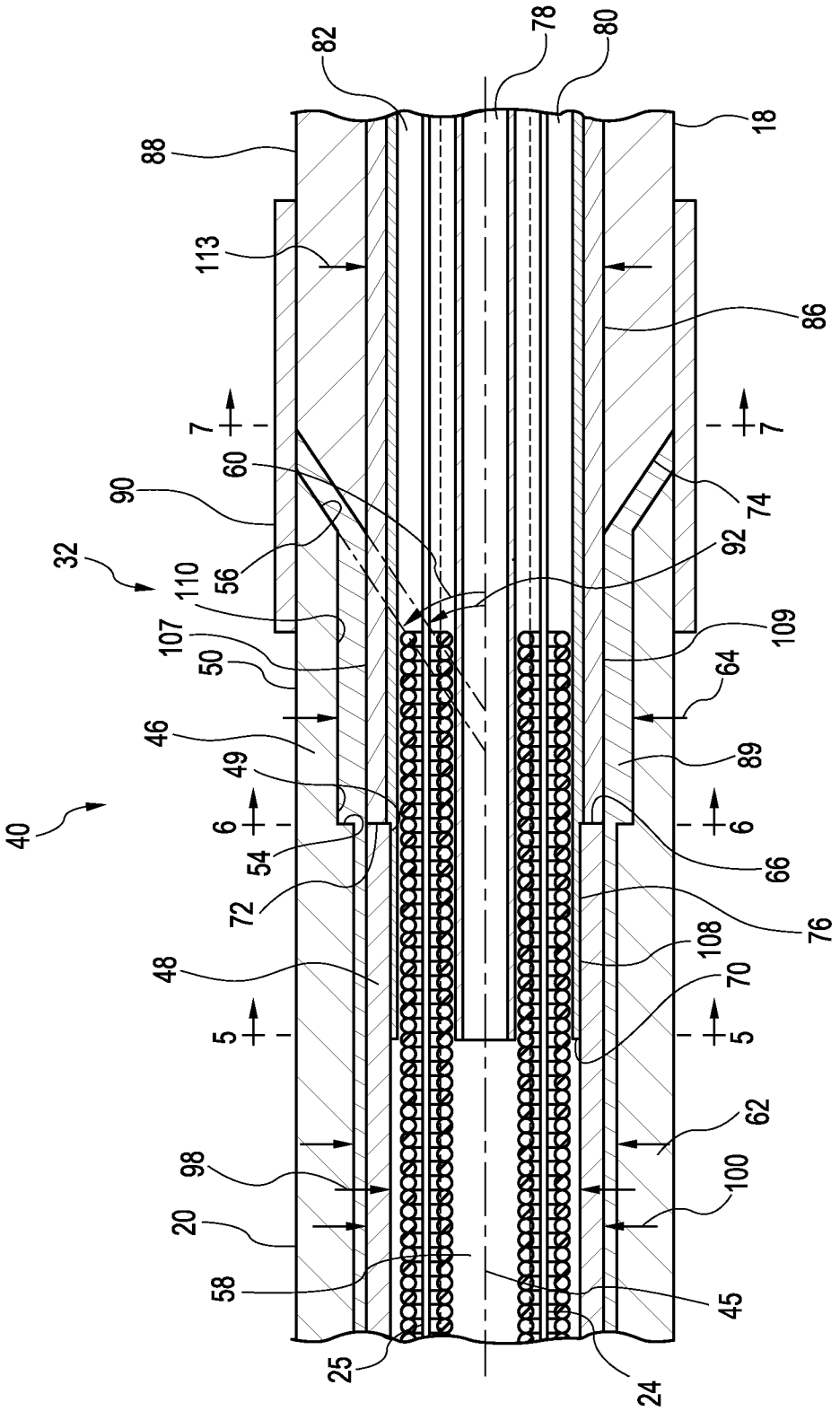

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FIG.4A

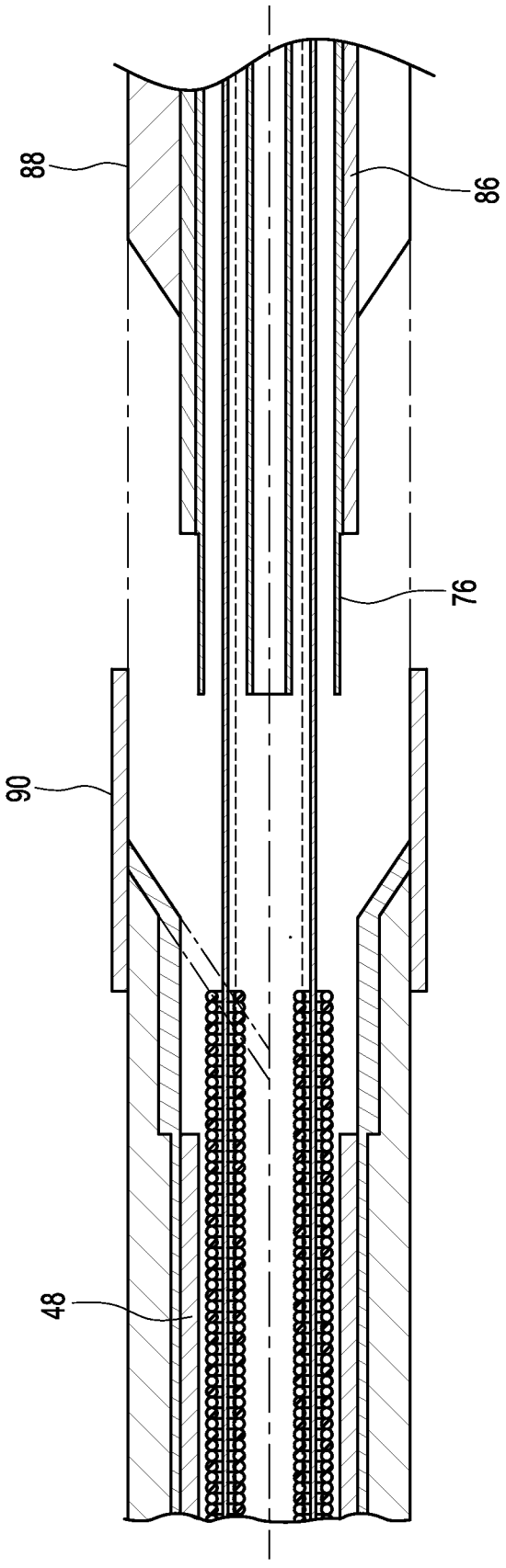


FIG.4B

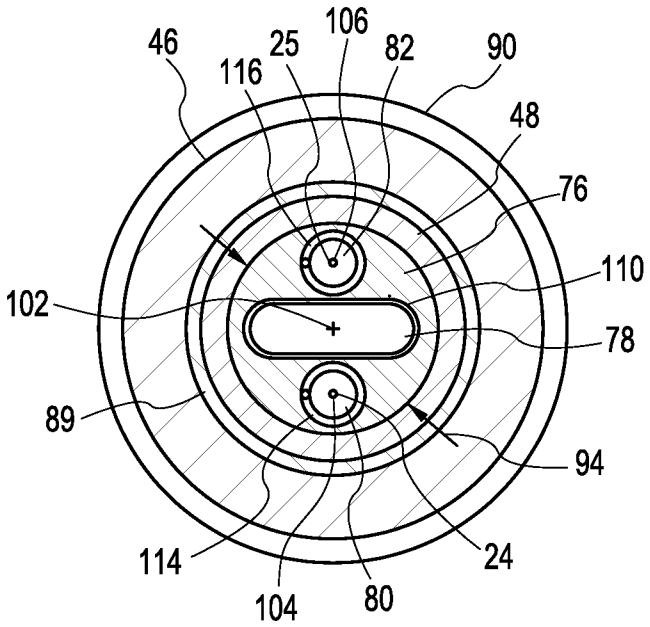


FIG.5

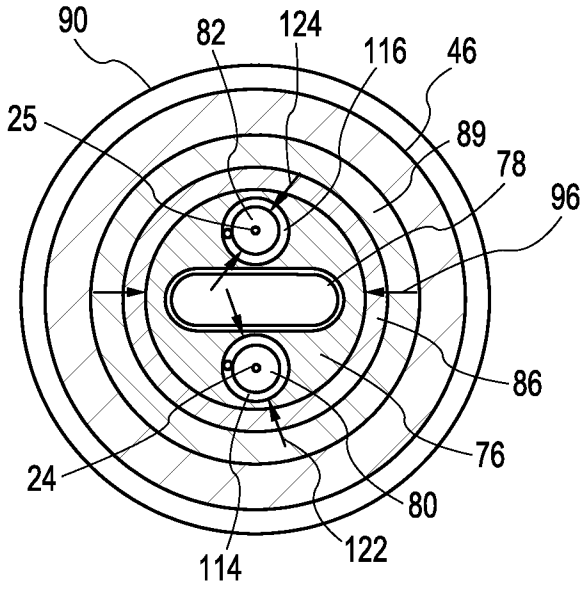


FIG.6

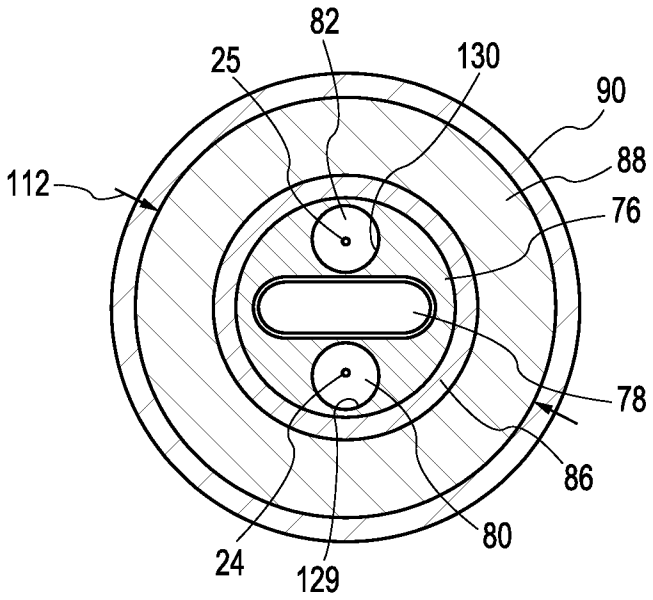


FIG.7

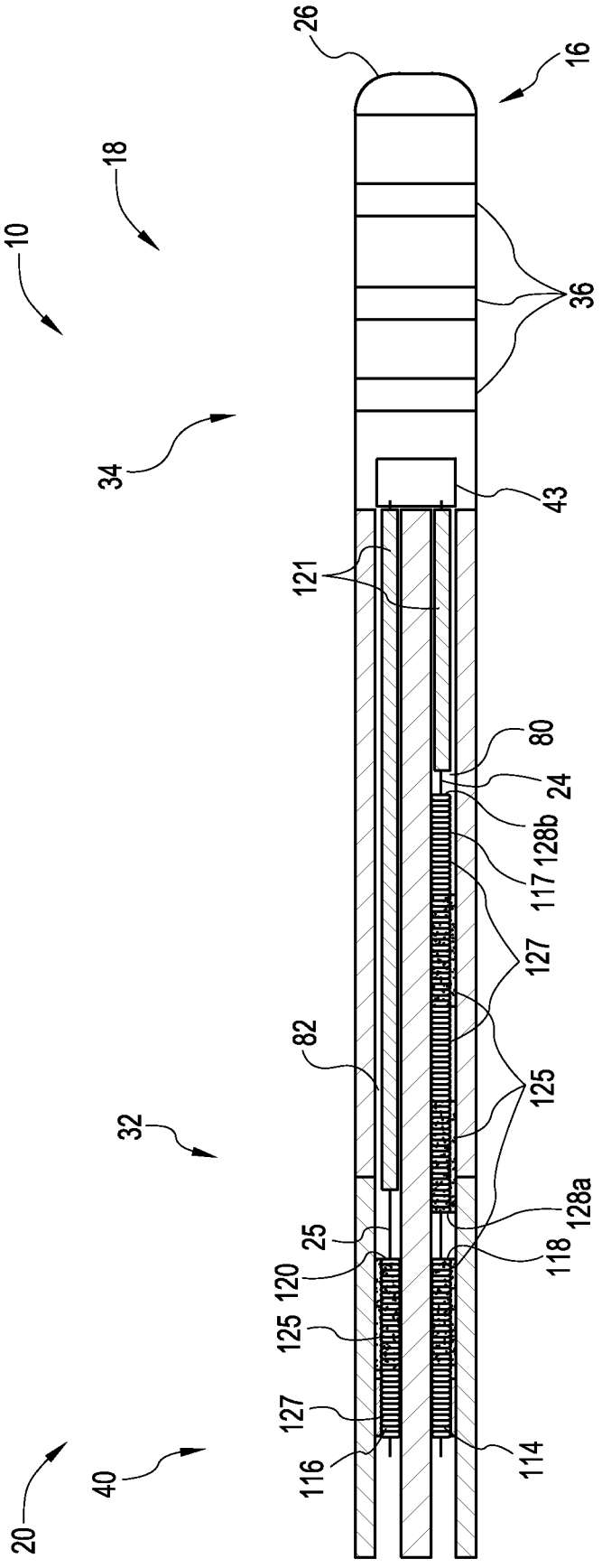

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18
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36
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43
121
80
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128b
117
127
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125
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128a
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116
114
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FIG.8A

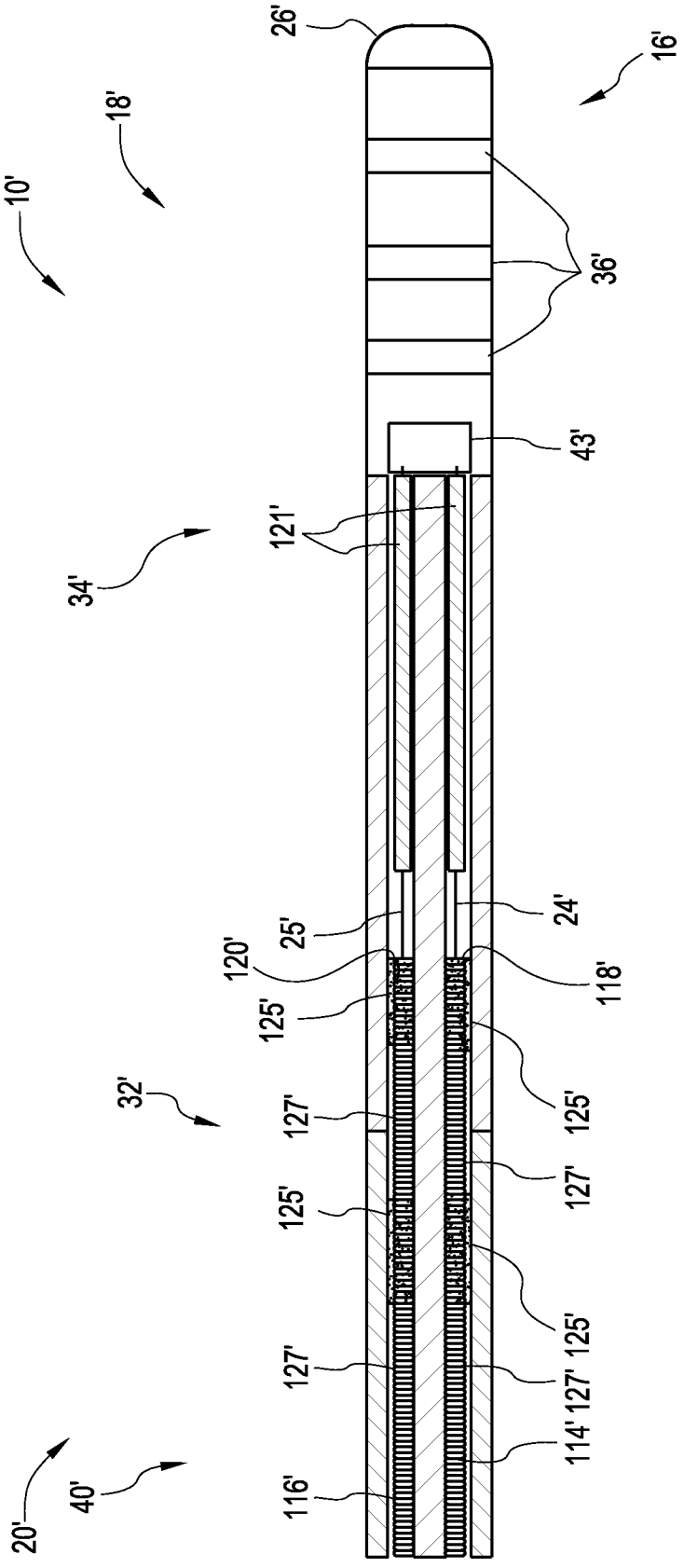

26'
16'
18'
10'
36'
43'
121'
34'
24'
25'
120'
118'
125'
32'
127'
125'
127'
125'
125'
127'
127'
114'
116'
40'
20'

FIG.8B

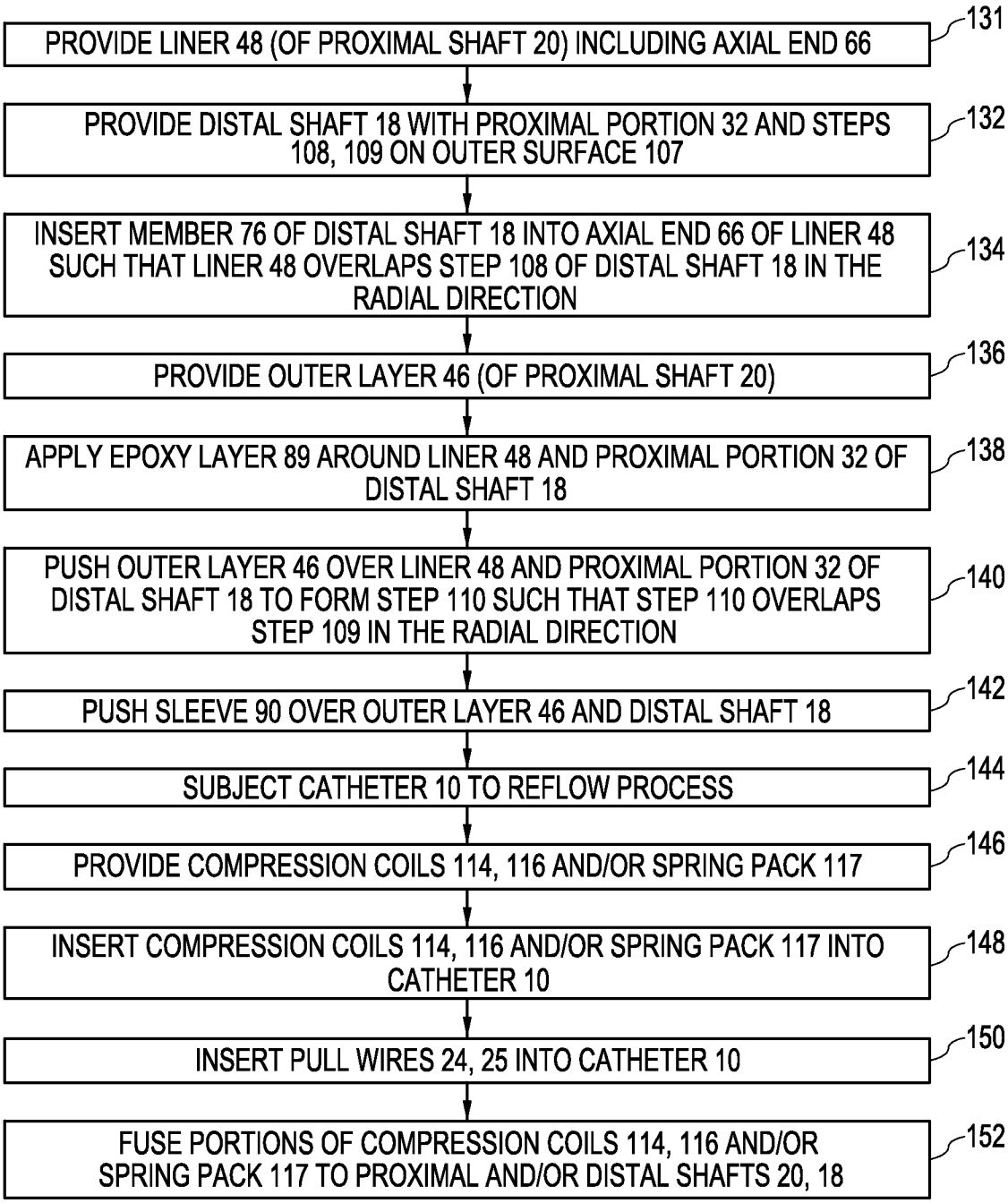

PROVIDE LINER 48 (OF PROXIMAL SHAFT 20) INCLUDING AXIAL END 66
131
PROVIDE DISTAL SHAFT 18 WITH PROXIMAL PORTION 32 AND STEPS 108, 109 ON OUTER SURFACE 107
132
INSERT MEMBER 76 OF DISTAL SHAFT 18 INTO AXIAL END 66 OF LINER 48 SUCH THAT LINER 48 OVERLAPS STEP 108 OF DISTAL SHAFT 18 IN THE RADIAL DIRECTION
134
PROVIDE OUTER LAYER 46 (OF PROXIMAL SHAFT 20)
136
APPLY EPOXY LAYER 89 AROUND LINER 48 AND PROXIMAL PORTION 32 OF DISTAL SHAFT 18
138
PUSH OUTER LAYER 46 OVER LINER 48 AND PROXIMAL PORTION 32 OF DISTAL SHAFT 18 TO FORM STEP 110 SUCH THAT STEP 110 OVERLAPS STEP 109 IN THE RADIAL DIRECTION
140
PUSH SLEEVE 90 OVER OUTER LAYER 46 AND DISTAL SHAFT 18
142
SUBJECT CATHETER 10 TO REFLOW PROCESS
144
PROVIDE COMPRESSION COILS 114, 116 AND/OR SPRING PACK 117
146
INSERT COMPRESSION COILS 114, 116 AND/OR SPRING PACK 117 INTO CATHETER 10
148
INSERT PULL WIRES 24, 25 INTO CATHETER 10
150
FUSE PORTIONS OF COMPRESSION COILS 114, 116 AND/OR SPRING PACK 117 TO PROXIMAL AND/OR DISTAL SHAFTS 20, 18
152

FIG.9

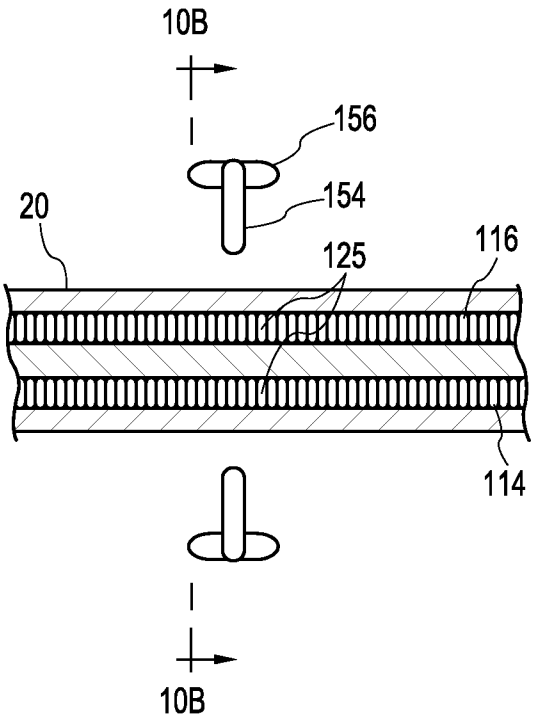


FIG.10A

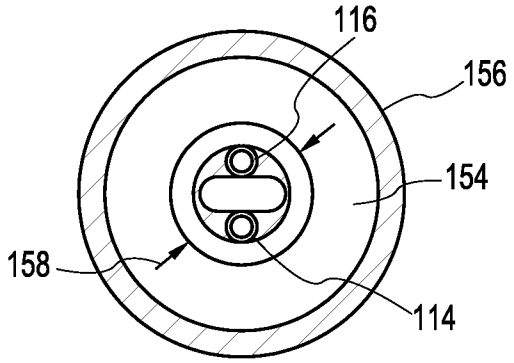


FIG.10B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/032907

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/14 A61B5/04 A61M25/00 B29C65/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M B29C A61N

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 187 130 B1 (BERARD JOHN [US] ET AL) 13 February 2001 (2001-02-13)	1-3,12
A	abstract; figures 1-7 column 3, line 17 - column 7, line 42	4-11
A	US 6 224 803 B1 (TIERNAN STEPHEN J [US]) 1 May 2001 (2001-05-01) abstract; figures 1-15 column 4, line 16 - column 5, line 35	1-13
A	US 2010/217234 A1 (GROVENDER ADAM D [US] ET AL) 26 August 2010 (2010-08-26) abstract; figures 1-11 paragraphs [0051] - [0124]	1-13

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 August 2015	24/11/2015

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/032907

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2011/125134 A1 (SCHWAGER MICHAEL [CH]) 26 May 2011 (2011-05-26) abstract; figures 1-4 paragraphs [0084] - [0127]	1-13
A	US 2004/140585 A1 (STERUD MICHAEL W [US] ET AL) 22 July 2004 (2004-07-22) abstract; figures 1-11 paragraphs [0026] - [0048]	1-13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/032907

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

see additional sheet

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

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

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

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

1-13

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2015/032907

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6187130 B1	13-02-2001	NONE	
US 6224803 B1	01-05-2001	US 6224803 B1	01-05-2001
		US 2001004703 A1	21-06-2001
US 2010217234 A1	26-08-2010	EP 2398541 A1	28-12-2011
		ES 2407646 T3	13-06-2013
		JP 5469680 B2	16-04-2014
		JP 2012518481 A	16-08-2012
		US 2010217234 A1	26-08-2010
		US 2012059336 A1	08-03-2012
		US 2013331782 A1	12-12-2013
		WO 2010096697 A1	26-08-2010
US 2011125134 A1	26-05-2011	CA 2730330 A1	21-01-2010
		CH 699220 A1	29-01-2010
		EP 2329180 A1	08-06-2011
		JP 5603332 B2	08-10-2014
		JP 2011528091 A	10-11-2011
		US 2011125134 A1	26-05-2011
		WO 2010006456 A1	21-01-2010
US 2004140585 A1	22-07-2004	AT 390164 T	15-04-2008
		CA 2513456 A1	12-08-2004
		DE 602004012708 T2	16-04-2009
		EP 1583578 A1	12-10-2005
		ES 2300739 T3	16-06-2008
		JP 4744432 B2	10-08-2011
		JP 2006516218 A	29-06-2006
		US 2004140585 A1	22-07-2004
		WO 2004067076 A1	12-08-2004

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-13

   medical device with proximal shaft and distal shaft portions connected by a nested lap joint

   ---

2. claims: 14-29

   medical device and corresponding fabrication method including a conductive element within a shaft

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