



(51) International Patent Classification:
A61N 1/00 (2006.01)

(21) International Application Number:
PCT/US2009/061547

(22) International Filing Date:
21 October 2009 (21.10.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/107,252 21 October 2008 (21.10.2008) US
61/162,241 20 March 2009 (20.03.2009) US
61/180,133 21 May 2009 (21.05.2009) US
61/222,409 1 July 2009 (01.07.2009) US

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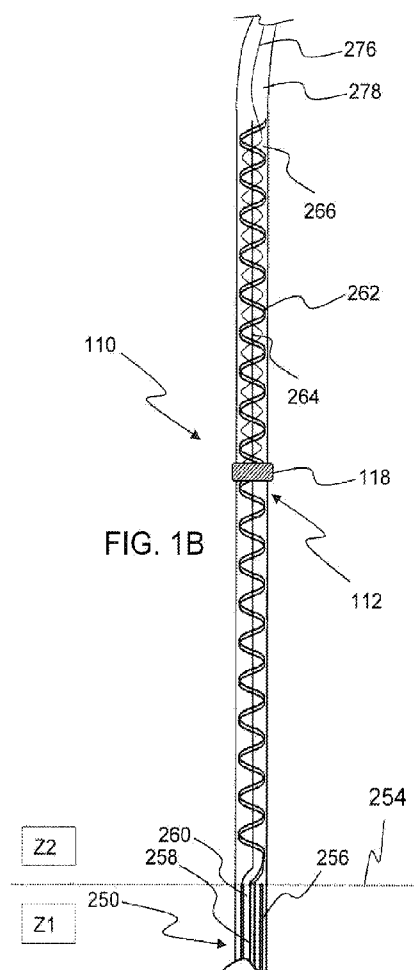
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(54) Title: MICROWAVE TREATMENT DEVICES AND METHODS

(57) Abstract: The present invention discloses medical systems and methods adapted for the delivery of various medical components such as microwave antennas within or on a body for performing one or more medical procedures. Several embodiments herein disclose medical systems comprising a combination of one or more medical components and one or more elongate steerable or non-steerable arms that are adapted to mechanically manipulate the one or more medical components. Several embodiments of microwave antennas are disclosed that comprise an additional diagnostic or therapeutic modality located on or in the vicinity of the microwave antennas.





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

(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

MICROWAVE TREATMENT DEVICES AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a nonprovisional of U.S. Patent Provisional Numbers: 61/107,252 filed on October 21, 2008, 61/162,241 filed on March 20, 2009, 61/180,133 filed on May 21, 2009, and 61/222,409 filed on July 1, 2009 the content of each of which are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

[0002] This invention relates to microwave antennas and delivery systems suitable for positioning various medical components such as microwave antennas within a patient's body.

BACKGROUND OF THE INVENTION

[0003] Microwave antennas have been designed to treat various medical conditions by microwave energy delivery. Such microwave antennas may be used for ablating or otherwise modifying tissue. For example, microwave antennas have been used for ablating cardiac tissue to treat cardiac arrhythmias. In several applications of microwave antennas including cardiac ablations, it is very advantageous to have an additional modality located on the microwave antenna. For example, it is very advantageous to have one or more electrophysiological mapping electrodes located on or near a microwave antenna used for cardiac ablation. Such a design enables the user to ablate cardiac tissue using the microwave antenna and also detect electrophysiological signals using the mapping electrodes. Simply adding an additional modality such as mapping electrodes and the conductive wires over a microwave antenna may create a microwave antenna that is unsuitable for clinical use. The additional modality and the conductive wires may absorb microwave energy and become hot. This in turn may causes problems such as burning or charring of tissue, creation of undesirable blood clots and adherence of the microwave antenna to tissue. In addition, additional modality and the conductive wires connected to the additional modality may change the shape of the microwave field emitted by the microwave antenna. This in turn may create a shaped microwave field that is no longer clinically useful. Such a shaped microwave field may also create additional safety issues by undesired microwave energy delivery to healthy tissue. The microwave field may also affect the functioning of the additional modality. Thus, there is a need for microwave antennas that comprise such additional modality such that the safety and the performance of such antennas is not compromised.

[0004] Medical diagnostic and surgical procedures generally require that physicians perform many increasingly complex functions within the body. In many of these procedures, the physicians must properly access tissue locations and precisely orient a medical component to perform a diagnostic or surgical procedure. In an ever increasing number of modern surgical procedures, elongate devices are introduced into the target tissue through surgically created access openings or natural openings in the body. Physicians deliberately keep such access openings small to minimize the trauma and the healing burden on the patient. For example, in many catheter-based cardiac procedures, a physician will access internal cardiac tissue by navigating a device through the vasculature until the device can engage the cardiac tissue (e.g. a chamber of the heart). In another example, a physician may create an opening (or rely upon a natural body opening) to access organs and tissues requiring a medical procedure. Traditionally, the desire to minimize trauma to the patient often comes at the expense of the maneuverability of the medical component when compared to a similar open surgical procedure. For instance, a physician working with his hands and having full access to a target site such as during an open surgery has much greater freedom to manipulate one or more medical devices to access target tissue and position and orient the medical devices as needed to perform many functions. Yet, such freedom is lost during minimally invasive procedures and in some open surgical procedures where the physician's access to the target site is limited due to obstructing tissue or organs (such as accessing the interior of an organ through a wall of the organ).

[0005] Many conventional approaches attempt to overcome these limitations on maneuverability by providing a device with a steerable distal end. However, these existing devices are unable to provide the optimal amount of articulation and/or manipulation needed within the body, especially when the procedure is performed under fluoroscopy.

[0006] To illustrate this point, consider the situation in an open surgical procedure, where a physician is able to use one or both arms to directly manipulate a treatment device onto or along a body structure. The numerous degrees of freedom offered by a single arm (including the hand, the wrist and fingers) enables satisfactory placement of the treatment device. When the physician attempts the same procedure through a limited access (either a smaller incision, use of access ports, intravascularly or even through dissection of other tissues/organs), conventional steerable devices do not provide sufficient maneuverability. For example, catheter-based interventional endocardiac ablations for treating Atrial Fibrillation suffer from shortcomings due to a lack of access to all target regions within the atria. For a successful procedure, it is critical to access specific target regions within the left atrium and create a series of ablations in a specific pattern. Existing steering devices are inadequate in providing this function. This reduces the efficacy of the procedure,

increases the procedure times and necessitates the use of very expensive accessory devices such as surgical navigation systems.

[0007] In view of the above, there remains a need for a device or system that offers improved positioning of one or more medical device components in various medical procedures. There also remains a need for a device or system that allows a physician the capability to position an appropriate medical component readily and predictably at all desired locations (where the locations may be 2 or 3 dimensional structures) for performing the required procedure such as catheter based cardiac ablation.

BRIEF SUMMARY OF THE INVENTION

[0008] The systems and methods described herein are useful in a variety of medical procedures including various diagnostic and therapeutic procedures. In addition, the invention is also useful in open surgical procedures, minimally invasive procedures, as well as procedures performed through natural body openings such as NOTES procedures.

[0009] In a significant amount of the disclosure, the heart is used an example of a target organ and cardiac ablation procedures are used as an example of procedures that may be performed using the current invention. However, it should be noted that the various methods and devices disclosed herein may also be used in medical procedures ranging from endovascular cardiac, thoracic cardiac, bronchial, lung, neurological, gynecological, gastro-intestinal, spinal, ENT, laparoscopic, arthroscopic and other endoscopic procedures, robotic including tele-robotic, oncological, etc. In several embodiments herein, portions of the heart are accessed by minimally invasive approach through the inferior vena cava or the superior vena cava. However, one or more portions of the heart may also be accessed through a sub-xiphoid approach (e.g. by penetrating a region such as the apex of a heart ventricle or after accessing the pericardial space) or through a Natural Orifice Transluminal Endoscopic access (e.g. through the stomach or esophagus) or through an open surgical approach (e.g. after a thoracotomy or a sternotomy). One or more portions of the medical systems herein may be introduced into a heart chamber through an atrial appendage of the heart.

[0010] In one example, the present disclosure describes methods of delivering microwave energy to tissue. Such methods can include positioning an elongate microwave antenna adjacent to a first region of tissue wherein the antenna comprises a proximal end, a distal end and an antenna axis and the electrode is located over the antenna and between the antenna and the first region of tissue where the the wire is connected to the electrode and is electrically isolated from the antenna and wherein a first portion of the wire is exposed to the microwave field emitted by the antenna such that every section of the first portion of

the wire is oriented non-parallel to the axis of the antenna; delivering microwave energy to the first location of tissue through the elongate microwave antenna to generate a microwave field where the position of the conductive wire reduces a distortion of the microwave field otherwise resulting from the electrode and to create a first lesion; applying energy through the electrode to diagnose or treat the tissue while maintaining a position of the antenna.

[0011] Devices for use in as described herein include microwave emitting systems for delivering microwave energy. In one example such a system includes a transmission line coupleable to a microwave energy source; an elongate microwave antenna having a proximal end, a distal end and an antenna axis, wherein the proximal end of the antenna is electrically coupled to the distal end of the transmission line and where the elongate microwave antenna generates a microwave field upon application of the microwave energy to the transmission line; an electrode positioned along the microwave antenna and between the proximal end and the distal end of the antenna, wherein the electrode is exposed to the microwave field emitted by the antenna and is electrically isolated from the antenna, where the electrode is coupleable to a second power supply; a conductive wire coupled to the electrode wherein the wire is electrically isolated from the antenna and wherein a first portion of the wire exposed to the microwave field emitted by the antenna is disposed relative to the antenna axis such that every section of the first portion of the wire is non-parallel to the axis of the antenna such that arrangement of the conductive wire relative to the antenna reduces distortion of the microwave field due to the electrodes.

[0012] Some of the embodiments herein may be broadly described as microwave devices comprising a transmission line such as a coaxial cable and an antenna connected to the coaxial cable. Further, an electrode is located adjacent to or over the antenna. The antenna comprises 1. a radiating element, 2. one or more shaping elements and 3. one or more antenna dielectrics covering one or more portions of the radiating element and/or the shaping element. The electrode can be any diagnostic or treatment modality that allows for a separate application of energy to the tissue region intended for treatment by the antenna.

[0013] In embodiments wherein transmission line is a coaxial cable, the radiating element may be a continuation of the inner conductor of the coaxial cable or may be an additional conductive element electrically connected to the inner conductor of the coaxial cable. The radiating element radiates a microwave field that is characteristic of its specific design. The radiated microwave field causes agitation of polarized molecules, such as water molecules, that are within target tissue. This agitation of polarized molecules generates frictional heat, which in turn raises the temperature of the target tissue. Further, the microwave field radiated by the radiating element may be shaped or otherwise redistributed by one or more shaping element(s) in the antenna. In one embodiment, the shaping

element(s) are made of an electrically conductive material (e.g. one or more metallic objects of various sizes, shapes, orientations, etc.). In this embodiment, the shaping element(s) may be electrically connected to the outer conductor or shielding element of the transmission line (e.g. the outer conductor of a coaxial cable). In an alternate embodiment, the shaping element(s) are not in direct electrical conduction with the outer conductor or shielding element of the transmission line e.g. the outer conductor of a coaxial cable. The one or more antenna dielectrics may cover one or more portions of one or both of: radiating element and shaping element. The antenna dielectrics may be used for changing the propagation of the microwave field from one or both of: radiating element and shaping element to the surrounding. The antenna dielectrics may be used for changing the matching of the antenna.

[0014] The one or more diagnostic or treatment modalities may be a part of the microwave device or may be located on an additional device that is located around the microwave device. One or more conductive wires may be connected to the diagnostic or treatment modalities that connect the diagnostic or treatment modalities to an external circuit. The diagnostic or treatment modalities and the conductive wires connected to the diagnostic or treatment modalities are located within the microwave field emitted by the antenna. The novel configuration and placement of such diagnostic or treatment modalities and their conductive wires ensures that the temperature of the additional modality and the conductive wires does not exceed a safe level during clinical use. Further, the presence of the additional modalities and the conductive wires does not affect or minimally affects the shape of the microwave field emitted by the microwave antenna. This in turn ensures that the safety and the performance of such antennas is not compromised.

[0015] Various additional features may be added to the devices disclosed herein to confer additional properties to the devices disclosed herein. Examples of such features include, but are not limited to one or more lumens, ability to apply a vacuum or suction to the target anatomy, ability to visualize one or more regions of the target anatomy, ability to limit the depth of insertion into the target anatomy, ability to deploy the antenna, ability to connect to a source of energy, etc.

[0016] The dimensions or other working parameters of the devices disclosed herein may be adjustable or programmable based on user inputs. The user input may be based on factors such as patient's anatomical data including anatomical dimensions and the desired level of safety and efficacy.

[0017] The various microwave antennas and the microwave engineering principles disclosed herein may be also used in a variety of non-medical applications. The near field of the microwave antennas disclosed herein may be used on target materials such as food,

industrial products, semiconductors, etc. The near field of the microwave antennas disclosed herein may be used for cooking or heating foods, in industrial processes for drying and curing products, in semiconductor processing techniques to generate plasma for processes such as reactive ion etching and plasma-enhanced chemical vapor deposition (PECVD).

[0018] The device and methods disclosed herein may be used with or without modifications to create one or more point, linear, area or volumetric lesions. The present invention discloses various embodiments of flexible, low-profile devices that can be inserted non-invasively or minimally invasively into or near the target tissue.

[0019] The present invention also comprises medical systems for steering medical components or devices in the anatomy. In one embodiment, the medical system comprises at least a first and second arm, each arm having a maneuverable distal portion and a proximal portion, where manipulation of the respective arm's proximal portion permits articulation of the arm's maneuverable distal portion independently of the other respective arm, and a medical component coupled to the first arm and extendable from the first arm's maneuverable distal portion, the medical component being engageable with the second arm's maneuverable distal portion, such that when coupled to both arms, movement of either maneuverable distal portion alters a profile or position of the medical component allowing for positioning of the medical component to perform the medical procedure.

[0020] In another embodiment, the invention includes a medical system for performing a medical procedure on or in a patient, the system comprising a first arm having a maneuverable distal portion and a proximal portion, wherein manipulation of the arm's proximal portion permits articulation of the arm's maneuverable distal portion and a medical component coupled to the first arm and extendable from the first arm's maneuverable distal portion. Movement of the maneuverable distal portion alters a profile or position of the medical component allowing for positioning of the medical component to perform the medical procedure.

[0021] In some variations, the medical components extend through an arm in a concentric or coaxial manner. However, the invention also includes components that extend parallel to the arm, or that extend along the arm or a portion thereof in a non-concentric manner. One or more arms may be removably coupled to the medical component(s) via a grasping structure. An example of such grasping structure includes a releasable hook, ring, or jaws. The arms can fully or partially hollow. One or more arms may be concentric with each another. One or more arm may be introduced via one or more access ports and pathways.

[0022] For purposes of this specification, the term medical component is intended to include a medical device or portion thereof that is adapted to provide a visual, diagnostic, or

treatment procedure. For example, and as described below, in one variation, the system can include a first medical component comprising an energy delivery device configured to deliver energy (e.g. microwave, radiofrequency, DC, ultrasound, laser, a cryogenic field) to or from tissue and a second medical component (such as a guidewire, rail, tether, etc.) that is used to direct the energy delivery device towards a target site. The first and second medical component can be parts of the same device or can be separate medical devices.

[0023] Examples of medical components, include, but are not limited to, therapeutic devices such as ablation devices for imparting a treatment relative to a target tissue, diagnostic devices such as mapping catheters for providing physiological information regarding a target tissue; positioning devices which include elements for providing additional positioning of additional functional devices (e.g., guidewires, rails, tethers, introducer catheters, sheaths, etc.), imaging devices, or non-imaging feedback devices (such as a Doppler catheter). The medical component need not have a specific physical structure, for example the arms of the inventive system can be adapted to deploy a simple tube that administers a chemical ablating agent at a desired location or deploy an additional fluid used during, and in support of, the medical procedure, for example deployment of contrast agent to provide a clearer view of the anatomy in support of a procedure performed within a patient's heart. In yet additional variations, the medical components can include separate components used to provide a single diagnostic procedure or medical of the same medical procedure. For instance, when using a radiofrequency energy modality, the medical component could include a first electrode while the second component can include a second electrode (either the opposite or same polarity).

[0024] The tether member may consist of a string or wire like structure that is used to simply pull the medical component through one or both arms. In additional variations, the tether member can include a flexible tether member that, when deflected, assumes a curvilinear shape based on the structural characteristics of the tether. As discussed below, this allows the medical component to assume a "U" shaped configuration that can assist in performing the medical procedure. The tether member may also comprise one or more conductive wires connected to one or more diagnostic or therapeutic modalities. In one embodiment, the one or more conductive wires are a part of the tether. In one embodiment, the one or more conductive wires extend along the tether and are attached to the tether at one or more regions. In one embodiment, the one or more conductive wires extend along the tether and are unattached to the tether.

[0025] Another aspect of the system is the ability to control movement of the distal portions of the arms from the proximal portions. In one embodiment, the arms include handle portions

on the proximal end. The handle portions can include one or more steering control mechanisms. The movement of the arms can occur in any three dimensional space.

[0026] In an addition embodiment, the devices and method described herein include a medical system for performing a medical procedure on or in a patient, the system comprising a medical component, a first arm having a distal portion and a proximal portion, where manipulation of the first arm's proximal portion permits articulation of the first arm's distal portion and where the medical component is coupled to and advanceable relative to the distal portion of the arm, a second arm having a distal portion and a proximal portion, where manipulation of the second arm's proximal portion allows for articulation of the second arm's distal portion, a rail member or tether coupled to the medical component and extending through the second arm, and where the first and second arms are configured to be manipulated independently, and where manipulation of the first or second arm alters a profile or position of the medical component allowing for positioning of the medical component.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0027] Fig. 1A shows a side view of an embodiment of a linear microwave antenna of the present invention comprising a radiating element and a microwave field shaping element.

[0028] Fig. 1B shows a side view of an embodiment of a microwave antenna comprising one or more electrophysiological mapping or pacing or RF ablation electrodes.

[0029] Fig. 1C shows a section through an embodiment of coaxial cable usable for the ablation device of Figs. 1A, 1B and for other ablation devices disclosed herein.

[0030] Fig. 1D shows a longitudinal section of the embodiment of the ablation device of Fig. 1A through the distal end of the coaxial cable.

[0031] Figs. 1E – 1G show the method steps of a method of creating two overlapping lesions in a tissue.

[0032] Fig. 1H shows a side view of an embodiment of a microwave antenna comprising multiple electrophysiological mapping or pacing electrodes that are spaced in regular intervals along the length of the antenna.

[0033] Fig. 1I shows a side view of an embodiment of a microwave antenna comprising multiple electrophysiological mapping or pacing electrodes that are spaced in pairs along the length of the antenna.

[0034] Fig. 1J shows a side view of a functional microwave antenna with a design similar to the design shown in Fig. 1A.

[0035] Fig. 1K shows a side view of a functional microwave antenna having additional electrodes.

- [0036] Fig. 1L and 1M show surface images of lesions obtained by ablating the surface of porcine muscle tissue using the antennas shown in Fig. 1J and 1K respectively.
- [0037] Fig. 1N and 1O show sections of the porcine tissue in Figs. 1L and 1M showing the depth of the lesions obtained by the antennas in Fig. 1J and 1K respectively.
- [0038] Fig. 1P shows a side view of a simulated SAR profile generated by an antenna similar to the antenna of Fig. 1A.
- [0039] Fig. 1Q shows a side view of a simulated SAR profile generated by an antenna similar to the antenna of Fig. 1A but having four extra electrodes spaced at regular intervals along the length of the antenna wherein each electrode is connected to a conductive wire arranged in a first configuration.
- [0040] Fig. 1R shows a side view of a simulated SAR profile generated by an antenna similar to the antenna of Fig. 1A but having four extra electrodes spaced at regular intervals along the length of the antenna wherein each electrode is connected to a conductive wire arranged in a second configuration.
- [0041] Fig. 1S shows a view of the distal region of the ablation device similar to the ablation device used in Figs. 1K, 1M and 1O.
- [0042] Figs. 1T shows an antenna similar to the antenna in Fig. 1A being slidably introduced through the lumen of a functional tube.
- [0043] Fig. 1U shows a side view of a simulated SAR profile generated by a 915 MHz monopole antenna.
- [0044] Fig. 1V shows a side view of a simulated SAR profile generated by a monopole antenna similar to the antenna of Fig. 1U but having four extra electrodes spaced at regular intervals along the length of the antenna wherein each electrode is connected to a conductive wire arranged in a first configuration.
- [0045] Fig. 1W shows a side view of a simulated SAR profile generated by a monopole antenna similar to the antenna of Fig. 1U but having four extra electrodes spaced at regular intervals along the length of the antenna wherein each electrode is connected to a conductive wire arranged in a second configuration.
- [0046] Fig. 1AA shows an embodiment of a medical system comprising a sheath or arm that is used to introduce and position a medical component.
- [0047] Fig. 1AB shows an embodiment of a working model of the medical system similar to that shown in Fig. 1A.
- [0048] Figs. 1AC and 1AD show two configurations of an embodiment of a medical system comprising a medical component introduced in the anatomy through an arm.

- [0049] Figs. 1AE and 1AF show two configurations of an embodiment of a medical system wherein a medical component and a second medical component are introduced in the anatomy through an arm.
- [0050] Figs. 1AG – 1AK show various steps of a method of introducing a medical component comprising a bendable or foldable region into the anatomy through an arm.
- [0051] Figs. 2A – 2D show various method steps of accessing and/or diagnosing and/or treating one or more regions of the left atrium.
- [0052] Fig. 2E shows an embodiment of a treatment assembly similar to the treatment assembly in Fig. 1AA.
- [0053] Fig. 2F shows an AP view of the right atrium showing a step of a method of ablating a portion to treat atrial flutter using the treatment assembly in Fig. 2E.
- [0054] Figs. 3A – 3B show an embodiment of an arm having a distal portion capable of being deflected from a planar configuration as shown in Fig. 3A to a non-planar configuration as shown in Fig. 3B.
- [0055] Fig. 4A illustrates a first embodiment of a medical system comprising two arms that allow for improved positioning of one or more medical components extending between the two arms.
- [0056] Fig. 4B illustrates one possible use of the medical system shown in Fig. 4A.
- [0057] Fig 4F – 4G shows a medical system comprising two arms with pre-shaped distal portions used to manipulate a medical component.
- [0058] Fig. 4C shows an alternate embodiment of the medical system of Fig. 4A showing a first medical component comprising six functional elements.
- [0059] Fig. 4D shows an alternate embodiment of the medical system of Fig. 4A showing a first medical component comprising a long, linear active region.
- [0060] Fig. 4E shows an alternate embodiment of the medical system of Fig. 4A showing a first medical component comprising a centrally located active region and multiple functional elements on both sides of the active region.
- [0061] Fig. 4F shows an alternate embodiment of the medical system of Fig. 4A showing a first medical component comprising multiple functional elements and a tether or spline.
- [0062] Fig. 4G shows an alternate embodiment of the medical system of Fig. 4A showing an assembly comprising two medical components comprising multiple functional elements joined at their distal ends by a tether or spline.
- [0063] Fig. 4H shows an alternate embodiment of the medical system of Fig. 4F showing a medical component comprising multiple branches, each branch containing multiple functional elements.

- [0064] Fig. 4I shows an alternate embodiment of the medical system of Fig. 4C showing a first medical component comprising a basket containing multiple functional elements.
- [0065] Fig. 4J shows an alternate embodiment of the medical system of Fig. 4A showing a first medical component comprising an active region wherein the active region comprises a balloon.
- [0066] Fig. 4K shows an alternate embodiment of the medical system of Fig. 4C showing a first medical component comprising a mesh basket.
- [0067] Figs. 5A – 5C show embodiments of a medical system comprising a first medical component comprising a tether or rail or guidewire or stylet.
- [0068] Fig 5D shows an embodiment of a medical system comprising a first medical component used to guide the introduction and/or the positioning of a second medical component, wherein the second medical component is enclosed within at least a portion of the first medical component.
- [0069] Fig 5E shows a variation of the embodiment of the medical system of Fig. 5C.
- [0070] Fig 5F shows an embodiment of a medical system comprising a hollow first medical component used to guide the introduction and/or the positioning of a second medical component, wherein second medical component is enclosed within at least a portion of the first medical component.
- [0071] Figs. 6A – 6G show various alternate embodiments of the medical system of Fig. 4A comprising an active region comprising one or more one or more functional elements in the form of radiofrequency electrodes.
- [0072] Figs. 6H – 6K show some examples of a medical system with several possible orientations of regions of a medical component.
- [0073] Figs. 6L and 6M illustrate an embodiment of a medical component and a second medical component having respective mating portions.
- [0074] Fig. 6N illustrates an embodiment of a medical system comprising a single medical component extending between adjacent arms.
- [0075] Figs. 6O – 6P illustrate a medical system comprising a medical component comprising a flexible tether and a joint member coupling the tether to the medical component.
- [0076] Fig. 6Q shows an embodiment of a medical system similar to the medical system shown in Fig. 6H, but further comprising a hollow second medical component.
- [0077] Figs. 7A – 7D show an embodiment of a method to treat an electrophysiological disease like atrial fibrillation in the heart using minimally invasive techniques.
- [0078] Figs. 7E and 7F show examples of lesion patterns created in the left atrium using a medical system similar to the medical system in Fig. 4C to treat atrial fibrillation.
- [0079] Fig. 7G show a step in the creation of the lesion pattern shown in Fig. 7E.

- [0080] Fig. 7H shows an embodiment of medical system deployed inside the left atrium such that a medical component substantially spans the entire left atrium.
- [0081] Figs. 8A and 8B show two embodiments of arm coupling elements 184 that may be used to mechanically couple two or more arms disclosed herein.
- [0082] Fig. 9A shows an example of a medical system comprising a second medical component that advances over a first medical component.
- [0083] Fig. 9B illustrates an embodiment of the present invention wherein a medical component is coupled adjacent to two arms via coupling portions rather than being introduced through the arms as shown in some of the previous figures.
- [0084] Figs. 10A – 10DA show various views of a first embodiment of a medical system comprising a hollow tube through which an elongate looped medical component is slidably introduced.
- [0085] Figs. 10E – 10HA show various views of a second embodiment of a medical system comprising a hollow tube through which an elongate looped medical component is slidably introduced.
- [0086] Figs. 10I – 10LA show various views of a third embodiment of a medical system comprising a hollow tube through which an elongate looped medical component is slidably introduced.

DETAILED DESCRIPTION OF THE INVENTION

- [0087] The present invention discloses devices and methods for treating tissue with microwave energy. In several method embodiments, microwave energy is used for ablating tissue e.g. for treating atrial fibrillation by controlled ablation of left atrial tissue, etc. The systems and methods described herein are useful in a variety of medical procedures including various diagnostic and surgical procedures. In addition, the invention is also useful in open surgical procedures, minimally invasive procedures, as well as procedures performed through natural body openings.
- [0088] In a significant amount of the disclosure, the heart is used an example of a target organ and cardiac ablation procedures are used as an example of procedures that may be performed using the current invention. However, it should be noted that the various methods and devices disclosed herein may also be used in medical procedures including, but not limited to: endovascular cardiac, thoracic cardiac, bronchial, lung, gynecological, gastro-intestinal, spinal, ENT, laproscopic, arthroscopic procedures, etc.

[0089] Microwave thermal ablation does not depend on the conduction of electricity to tissue unlike RF ablation. Thus, devices using microwave thermal ablation such as some of the devices disclosed herein don't need good contact with tissue. They can function well even without perfect contact with the target tissue. Thus, the devices disclosed herein do not require extremely precise placement in tissue, thereby reducing the dependence of procedure outcome on physician skills. In some embodiments, the devices herein are designed to have a proximal shaft and a distal microwave emitting portion comprising an antenna. The proximal shaft comprises a transmission line such as a flexible coaxial cable that delivers microwave energy from a microwave generator to the microwave emitting portion. The shaft can be designed to be slim (e.g. < 3 mm in diameter) to enable the introduction of the ablation device through narrow openings. The shaft can be designed to be flexible such that minimal forces are exerted on bodily tissues during the introduction of the ablation devices into the anatomy. The flexible nature of the shaft enables the shaft to take the natural shape of passage during introduction instead of distorting the passage by the shaft of the device. The designs of the coaxial cables disclosed herein confer sufficient flexibility to the device shaft such that the device shaft is capable of bending by more than 45 degrees when it experiences distorting forces by the anatomy. If desired, the device shaft may be made stiffer by adding one or more coatings, coverings, stylets and other stiffening elements.

[0090] Several of the experiments herein were performed at 0.915 GHz or 2.45 GHz ISM band. Antennas, methods, etc. disclosed herein may be used with or without modifications at other frequencies including, but not limited to ISM bands of 0.433 GHz, 5.8 GHz, etc. The microwave power generator may be magnetron based or solid state. The microwave power generator may be single or multi-channel. The microwave power generator used for the experiments comprised a Vector Network Analyzer (Agilent 8753 series) and amplifier modules build in-house using transistors from Freescale Semiconductor (Austin, Texas). The power measurement was made using a power meter (ML2438A Power Meter, Anritsu Company, Richardson, TX). Similar devices and components can be used to design the microwave generator for clinical use with the devices and methods disclosed herein.

[0091] In the experiments, where desired, a fiber optic thermometry system (FOT Lab Kit by LumaSense Technologies, Santa Clara, CA) was used to measure the temperature at several locations in the tissue. The fiber optic thermometry system was used since it has no metallic components that might interfere with the microwave field. Similar non-interfering thermometry may be used to measure the temperature at one or more locations during an ablation procedure.

[0092] Several devices and methods described herein provide a physician with an improved ability to remotely position one or more medical components on or in a target tissue location. The ability to position such medical components allows the physician to perform one or more medical procedures with improved accuracy and efficiency where direct use of the physician's arms is not possible. Although variations of the system described below primarily discuss placement of one or more energy delivery devices on tissue, such variations are for exemplary purposes only. The features of the system can be used to position any number or type of medical components including, but not limited to: implants or implant delivery devices, diagnostic devices, imaging devices, biopsy devices, radiation emitting devices, drug delivery devices, radio-opaque markers, valvular annuloplasty devices, suturing devices, etc.

[0093] The system could also be used as a stable platform to perform minimally invasive surgical procedures. In such procedures, the devices and methods disclosed herein may be used to cut, suture, coagulate or remove tissue for example. Any suitable imaging modality may be used to visualize the anatomy and/or one or more of the devices disclosed herein while performing any of the procedures disclosed herein. Examples of such imaging modalities include, but are not limited to endoscopes (e.g. colonoscopes, laparoscopes, thoroscopes, bronchoscopes, cystoscopes, colposcopes, hysteroscopes, arthroscopes, etc.), X-rays, Computed tomography (CT), fluoroscopy, ultrasound imaging including intravascular and intracardiac ultrasound imaging, intra-cardiac electrophysiological three dimensional mapping, MRI, PET, near infra-red imaging, etc.

[0094] In Fig. 1A, microwave ablation device **110** comprises a transmission line such as a coaxial cable **250**. A working element **112** such as an antenna **112** is connected to the distal end of coaxial cable **250**. Fig. 1A shows microwave ablation device **110** divided into a first zone Z1 and a second zone Z2 by an imaginary transition line **254**. First zone Z1 is proximal to second zone Z2. Transition line **254** is defined by the distal end of coaxial cable **250** and is substantially perpendicular to the axis of coaxial cable **250** at the distal end of coaxial cable **250**. In the embodiment shown in Fig. 1A, the distal region of coaxial cable **102** lies entirely within first zone Z1 and antenna **112** lies entirely within second zone Z2. In a one embodiment, a single microwave signal is fed to antenna **112** through coaxial cable **250**. Antenna **112** generates a microwave field. The near field of the microwave field generated by antenna **112** may be used for tissue ablation.

[0095] In Fig. 1A, antenna **112** comprises a radiating element **262** and a shaping element **264**. Radiating element **262** may be made of a variety of conducting materials e.g. metals, conductive polymers, materials with embedded conductive particles, etc. When microwave energy is delivered through coaxial cable **250** to antenna **112**, a first microwave field is

emitted by radiating element 262. The first microwave field interacts with shaping element 264. This interaction induces a leakage current on shaping element 264. The leakage current in turn creates a second microwave field. The first microwave field and the second microwave field together combine to produce a unique shaped microwave field of antenna 112 that is clinically more useful than the unshaped microwave field generated by an antenna 112 comprising only radiating element 262. Thus the original microwave field is redistributed by the design of shaping element 264.

[0096] Shaping element 264 alone is not capable of functioning as an antenna; rather shaping element 264 shapes or redistributes the electromagnetic or microwave field emitted by radiating element 262 to produce a clinically improved microwave field. It should be noted that there is no direct electrical conduction between radiating element 262 and shaping element 264. Antenna 112 further comprises one or more antenna dielectrics 266 covering one or more portions of one or both of: radiating element 262 and shaping element 264. In Fig. 1A, an antenna dielectric 266 covers the entire radiating element 262. Any of the antenna dielectrics 266 disclosed herein may be used to shape the microwave field and to optimize the performance of antenna 112. Any of the antenna dielectrics 266 disclosed herein may be replaced by one or more conducting polymers.

[0097] A microwave field couples to the nearest conductive path. In prior art monopole antennas, the nearest conductive path is provided by the shielding element of the transmission line (e.g. the outer conductor 256 of the feeding coaxial cable 250). This causes a strong concentration of the microwave field in the junction between antenna 112 and transmission line 250. However, in several embodiments of antenna 112 disclosed herein, the nearest conductive path is provided by shaping element 264. Thus the microwave field couples to shaping element 264 instead of coupling to the shielding element of the transmission line (e.g. the outer conductor 256 of the feeding coaxial cable 250). Therefore, minimal microwave field is coupled proximally to the shielding element of the transmission line. This in turn creates a unique, shaped or redistributed microwave field that does not significantly extend proximally to antenna 112 as shown in Fig. 1P and 1Q. Further, the combination of radiating element 262 and shaping element 264 improves the power deposition of antenna 112.

[0098] Antennas disclosed herein may comprise one or more shaping elements 264 made of a variety of conducting materials e.g. metals, conductive polymers, materials with embedded conductive particles, etc. Such shaping elements 264 may comprise one or more dielectrics layers to insulate the shaping element 264 from surrounding tissue. Examples of such shaping elements 264 include, but are not limited to: straight or curved segments of metallic elements, elements with a circular or oval shape, elements with a polygonal shape

(e.g. triangular, square, rectangular, pentagonal, etc.), multiple elements joined together by one or more electrically conducting joint(s), multiple elements joined together by a non-electrically conducting joint(s), elements with multiple curves, symmetrically arranged segments of elements, non-symmetrically arranged segments of elements, etc.

[0099] In one embodiment, radiating element **262** is a continuation of the inner conductor **258** of a coaxial cable **250**. In a one embodiment, shaping element **264** is made of an electrically conductive material e.g. a metal and is electrically connected to a region of outer conductor **256** of coaxial cable **250**. In an alternate embodiment, antenna **112** comprises one or more conductive shaping elements **264** that are electrically isolated from outer conductor **256**. In this embodiment, one or more shaping elements **264** function as passive radiators or parasitic elements of antenna **112**. In one embodiment, shaping element **264** is designed to act as a microwave shielding element and/or a microwave reflecting element.

[0100] Further, antenna **112** may be designed to be sufficiently flexible such that during and after introduction and deployment of antenna **112** in the anatomy, the anatomy experiences only slight forces from antenna **112**. This may be achieved by designing an antenna **112** comprising one or more flexible radiating elements **262**, one or more flexible shaping elements **264** and one or more flexible antenna dielectric materials. Sufficiently flexible antennas may reduce damage to healthy tissue as well as potentially reduce the pain experienced by the patient during the introduction and deployment. Antenna **112** may be introduced through a small lumen. This enables the introduction of antenna **112** through narrow catheters, shafts, introducers and other introducing devices. Further, this enables the introduction of antenna **112** through small natural or artificially created openings in the body. Further, antenna **112** may be designed to have an atraumatic distal end to reduce the risk of perforation of tissue. The flexible nature of antenna **112** enables antenna **112** to take the natural shape of an introduction passage during introduction instead of distorting the passage. In one embodiment, the length of straightened radiating element **262** measured along the radiating element **262** from the distal end of coaxial cable **250** or other transmission line until the distal end of radiating element **262** is an odd multiple of one quarter of the effective wavelength at one of: 433 MHz ISM band, 915 MHz ISM band, 2.45 GHz ISM band and 5.8 GHz ISM band. For example, the length of radiating element **262** may be three quarters of the effective wavelength at the 915 MHz ISM band. The effective wavelength is dependent on the medium surrounding the antenna and the design of a dielectric covering on the radiating element **262**. The design of the dielectric covering includes features such as the type of dielectric(s) and thickness of the dielectric layer(s). The exact length of the radiating element **262** may be designed to get good impedance matching.

[0101] In any of the embodiments herein, one or more outer surfaces of radiating element **262** may be covered with one or more layers of antenna dielectrics **266**. The thickness and type of antenna dielectrics **266** along the length of radiating element **262** may be designed to modify and optimize the microwave properties of the antenna **112**. For example, one or more antenna dielectrics **266** covering radiating element **262** may be used to shape the microwave field and to optimize the performance of antenna **112**. The one or more antenna dielectrics **266** covering radiating element **262** may be used to shape the microwave field by changing the local dielectric environment in the region adjacent to radiating element **262**. Examples of dielectric materials that can be used to design one or more embodiments disclosed herein include, but are not limited to EPTFE, PTFE, FEP and other fluoropolymers, Silicone, Air, PEEK, polyimides, cyanoacrylates, epoxies, natural or artificial rubbers and combinations thereof. In one embodiment, entire radiating element **262** is covered with a silicone dielectric. The layer of silicone used to coat a distal portion of radiating element **262** may be thinner than the layer of silicone used to coat a proximal portion of radiating element **262**. The thinner silicone dielectric may be used to compensate for the lower field strength that normally exists at the distal portion of a microwave antenna. Thus, the microwave field is made more uniform along the length of radiating element **262**.

[0102] In any of the embodiments herein, the shape of radiating element **262** may be that same or different from the shape of shaping element **264**. Further in any of the embodiments herein, both radiating element **262** and shaping element **264** may be non-linear. Further, in any of the embodiments herein, radiating element **262** and shaping element **264** may be non-parallel to each other.

[0103] Fig. 1A shows a side view of an embodiment of a linear microwave antenna of the present invention having a microwave antenna comprising a radiating element and a microwave field shaping element. In the embodiment shown in Fig. 1A, the novel microwave field shaping technique of the present invention is used to improve the performance of a helical antenna. The resultant antenna can be used to create a uniform lesion along the length of the antenna without adversely affecting tissues surrounding the transmission line. In the embodiment shown in Fig. 1A, the width of antenna **112** is substantially the same as the width of the coaxial cable **250**.

[0104] In one embodiment, a single microwave signal is fed to antenna **112** through coaxial cable **250**. Antenna **112** generates a microwave field. The near field of the microwave field generated by antenna **112** may be used for achieving the desired clinical outcome such as ablating tissue. In Fig. 1A, antenna **112** comprises a radiating element **262** and a shaping element **264**. In one embodiment, radiating element **262** is a continuation of the

inner conductor 258 of coaxial cable 250. Shaping element 264 shapes the microwave field emitted by radiating element 262. In one embodiment, shaping element 264 is made of an electrically conductive material e.g. a metal or a conductive polymer and is electrically connected to a region of outer conductor 256 of coaxial cable 250. In an alternate embodiment, a conductive shaping element 264 is electrically isolated from outer conductor 256. In this embodiment, shaping element 264 functions as a passive radiator or parasitic element of antenna 112. Shaping element 264 in this electrically isolated embodiment absorbs microwaves radiated from radiating element 262 and re-radiates microwaves.

[0105] It should be noted that there is no direct electrical conduction between radiating element 262 and shaping element 264. When microwave energy is delivered through coaxial cable 250 to antenna 112 in Fig. 1A, a first microwave field is emitted by radiating element 262. This first microwave field is a normal mode microwave field of a small diameter (antenna diameter D is much less than the microwave wavelength) helical antenna. The first microwave field interacts with shaping element 264. This interaction induces a leakage current on shaping element 264. The leakage current in turn creates a second microwave field. The second microwave field is an elongated, axial mode microwave field due to the elongate shape of shaping element 264. The first microwave field and the second microwave field together combine to produce a unique shaped microwave field of antenna 112 that is clinically more useful than the unshaped microwave field generated by an antenna 112 comprising only radiating element 262. Thus the original microwave field is redistributed by the design of shaping element 264. Shaping element 264 alone is not capable of functioning as an antenna; rather shaping element 264 shapes or redistributes the electromagnetic or microwave field emitted by radiating element 262 to produce a clinically improved microwave field. It should be noted that there is no direct electrical conduction between radiating element 262 and shaping element 264 in Fig. 1A.

[0106] Further, the specific design of shaping element 264 may be used to improve the power deposition of an antenna 112 comprising radiating element 262. Shaping element 264 may be made of one or more non-insulated or insulated conducting materials e.g. metals, conductive polymers, materials with embedded conductive particles, etc. The embodiments of the present invention may be designed wherein individual elements e.g. radiating element 262 have minimal or no sharp corners to avoid undesirable regions of concentrated microwave field.

[0107] Antenna 112 in Fig. 1A has a linear, elongate shape that is especially suited for the ablation of a linear region of tissue e.g. for the creation of a linear lesion in the left atrium.

[0108] In Fig. 1A, the surface of radiating element **262** is enclosed within one or more layers of dielectric materials. In this embodiment, every portion of radiating element **262** is covered with some dielectric material such that no metallic surface of radiating element **262** is exposed to tissue. Thus, in this embodiment, radiating element **262** is electrically insulated from tissue. Thus, in this embodiment, radiating element **262** is able to transmit a microwave field into tissue, but unable to conduct electricity to tissue. Thus, in this embodiment, there is no electrical conduction and no conductive path between radiating element **262** and shaping element **264**. Further, in this embodiment, there is no electrical conduction and no conductive path between radiating element **262** and the surrounding tissue. In one embodiment, the dielectric on a proximal portion of radiating element **262** is a continuation of the dielectric **260** of coaxial cable **250**. The thickness of a dielectric on radiating element **262** may vary along the length of radiating element **262**. Further, the cross-section of a dielectric on radiating element **262** may not be radially symmetric.

[0109] In the embodiment of Fig. 1A, radiating element **262** is made of a helically arranged length of a metallic conductor. The helix may be symmetric with a constant pitch and a constant diameter along the length of the helix. In one embodiment, the straightened length of the conductor used for constructing radiating element **262** is about three quarters of the effective wavelength at 915 MHz. In alternate embodiments, this length may be an odd multiple of one quarter of the effective wavelength at one of: 433 MHz ISM band, 915 MHz ISM band, 2.45 GHz ISM band and 5.8 GHz ISM band. Although in Fig. 1A, radiating element **262** has about 19 turns, embodiments of ablation devices **110** may be constructed wherein radiating element **262** has about 1 to 30 turns. The pitch of a helical radiating element **262** may range between 0.3 mm and 20 mm. Radiating element **262** may be made from a metallic element or alloy selected from the group comprising Nitinol, stainless steel or copper. Radiating element **262** may comprise a plating of a conducting metal such as Ag or Au on the outer surface of radiating element **262**. The metallic conductor used for constructing radiating element **262** may have a round, oval, rectangular or square cross-section.

[0110] In one embodiment, the metallic conductor used for constructing radiating element **262** has a round cross-section with a diameter of 0.5 mm +/- 0.4 mm. In another embodiment, the metallic conductor used for constructing radiating element **262** has a rectangular cross-section with cross-sectional dimensions of 10 mm +/- 9.5 mm by 0.5 mm +/- 0.4 mm. In another embodiment of a radiating element with a rectangular cross-section, the cross-sectional dimensions are 1 mm +/- 0.3 mm by 0.1 mm +/- 0.05 mm. In an alternate embodiment, radiating element **262** is made of a length of a metallic conductor that is arranged in a

substantially two dimensional configuration. For example, the length of a metallic conductor may be arranged in a substantially wavy or zigzag or serpentine configuration.

[0111] In the embodiment in Fig. 1A, radiating element **262** is arranged symmetrically around shaping element **264** and partially or fully encloses shaping element **264**. Shaping element **264** may be made of a linear or helical length of a metallic conductor. The outer diameter of shaping element **264** may be uniform or may be non-uniform along the length of antenna **112**. In the embodiment shown in Fig. 1A, shaping element **264** is made of a substantially linear length of a metallic conductor. Shaping element **264** may be made from a metallic element or alloy selected from the group comprising Nitinol, stainless steel or copper. Shaping element **264** may comprise a plating of a conducting metal such as Ag or Au on the outer surface of shaping element **264**. The metallic conductor used for constructing shaping element **264** may have a round, oval, rectangular or square crosssection. In one embodiment, the metallic conductor used for constructing shaping element **264** has a round crosssection with a diameter of 0.5 mm +/- 0.3 mm. In another embodiment, the metallic conductor used for constructing shaping element **264** has a rectangular crosssection with dimensions of 0.5 mm +/- 0.3 mm by 0.5 mm +/- 0.3 mm. Antenna **112** further comprises one or more antenna dielectrics **266** between radiating element **262** and shaping element **264**. In one embodiment, antenna dielectric **266** is sufficiently flexible to create a flexible antenna **112**. The flexibility of antenna **112** allows antenna **112** to bend from a substantially linear configuration to a substantially non-linear configuration and vice-versa during clinical use. The flexibility of antenna **112** also allows antenna **112** to bend relative to the distal end of the transmission line during clinical use. This in turn allows a user to introduce antenna **112** to the target location through tortuous or non-linear introduction paths such as blood vessels. In one embodiment, antenna dielectric **266** is sufficiently stiff to create a sufficiently stiff antenna **112**.

[0112] The stiffness of antenna **112** prevents antenna **112** from bending during clinical use. This in turn enables the user to use antenna **112** to puncture or penetrate through tissue such as tumor tissue. Examples of dielectrics that can be used between radiating element **262** and shaping element **264** include, but are not limited to EPTFE, PTFE, FEP and other fluoropolymers, Silicone, Air, PEEK, polyimides, natural or artificial rubbers and combinations thereof. Additionally the entire antenna **112** may be covered or encapsulated in a dielectric. Examples of dielectrics that can be used to cover or encapsulate antenna **112** include, but are not limited to EPTFE, PTFE, FEP and other fluoropolymers, Silicone, PEEK, polyimides, natural or artificial rubbers and combinations thereof. Antenna dielectric **266** may comprise one or more layers of such dielectrics. The dielectric used to cover or encapsulate antenna **112** may be porous or non-porous. In Fig. 1A, the length of antenna **112** is between 10 mm and 80 mm. In Fig. 1A, the width of antenna **112** is

between 1 mm and 40 mm. In one particular embodiment, antenna **112** has a length of 45 mm +/- 7 mm and a width of 2 mm +/- 0.5 mm. Radiating element **262** is electrically connected to inner conductor **258** of coaxial cable **250**. This may be done for example, by soldering or resistance welding radiating element **262** to inner conductor **258**. Shaping element **264** is electrically connected to outer conductor **256** of coaxial cable **250**. This may be done for example, by soldering or resistance welding shaping element **264** to outer conductor **256**. Antenna **112** may be floppy, flexible or substantially rigid. Antenna **112** may be malleable or have shape memory or elastic or super-elastic properties. The distal end of antenna **112** may be atraumatic. Antenna **112** may be designed such that the length of antenna **112** is adjustable. For example, length of antenna **112** may be increased or reduced to increase or reduce the length of an ablation zone. In this embodiment, shaping element **264** may have a helical or substantially wavy or zigzag or serpentine configuration. The length of antenna **112** may be increased or reduced intra-operatively or pre-operatively. In one embodiment, one or both of radiating element **262** and shaping element **264** are a part of a flexible circuit and are manufactured using commonly known techniques for manufacturing flexible circuits.

[0113] In Fig. 1A, the shape of radiating element **262** is different from the shape of shaping element **264**. Further in the embodiment in Fig. 1A, radiating element **262** is non-linear. Further in the embodiment in Fig. 1A, shaping element **264** is substantially linear. However radiating element **262** and shaping element **264** are generally oriented such that their axes are parallel to each other. Alternate embodiments of antenna **112** may be designed wherein radiating element **262** is substantially linear. Alternate embodiments of antenna **112** may be designed wherein shaping element **264** is substantially non-linear. Alternate embodiments of antenna **112** may be designed wherein radiating element **262** and shaping element **264** are generally oriented such that their axes are not parallel.

[0114] Although in the embodiment in Fig. 1A shaping element **264** is connected to the distal end of coaxial cable **250**, other embodiments of antenna **112** may be designed wherein shaping element **264** is connected to coaxial cable **250** at a region other than the distal end of coaxial cable **250**. For example, in one alternate embodiment, shaping element **264** is metallic and is electrically connected to a region of outer conductor **256** of coaxial cable **250** proximal to the distal end of the coaxial cable **250**.

[0115] In Fig. 1A, since radiating element **262** is in electrical contact with inner conductor **258**, there is a first electrically conductive path extending from inner conductor **258** till the distal end of radiating element **262**. In the embodiments wherein shaping element **264** is made of a conductive material and is electrically connected to outer conductor **256** of coaxial cable **250**, there is a second electrically conductive path extending from outer

conductor **256** till the distal end of shaping element **264**. In such embodiments, even though there are two conductive paths that extend from first zone Z1 to the second zone Z2, the designs, materials and the microwave properties of the two conductive paths may be significantly different in first zone Z1 and second zone Z2 as described before. In first zone Z1, outer conductor **256** of coaxial cable **250** is located symmetrically around inner conductor **258** and at a constant distance from inner conductor **258**. However, in second zone Z2, radiating element **262** is located symmetrically around shaping element **264** and at a constant distance from shaping element **264**. In first zone Z1, outer conductor **256** of coaxial cable **250** always acts as a shield for the microwave field in first zone Z1 whereas in second zone Z2, shaping element **264** may or may not act as a shield for the microwave field in second zone Z2.

{0116} Fig. 1C shows a section through an embodiment of coaxial cable **250** usable for ablation device **110** of Fig. 1A, 1B and for other ablation devices **110** disclosed herein. In one embodiment, coaxial cable **250** used herein is flexible and comprises an inner conductor **258** made of Nitinol with a Ni content of 56 % +/- 5 %. The outer diameter of inner conductor **258** is 0.0172" +/- 0.004". Inner conductor **258** has a cladding or plating **270** of a highly conductive metal such as Ag or Au. In one embodiment, inner conductor **258** comprises a silver cladding **270** of thickness 0.000250" +/- 0.000050". Cladding **270** in turn is surrounded by dielectric material **260**. In one embodiment, dielectric material **260** is made of expanded PTFE with an outer diameter of 0.046" +/- 0.005". The dielectric material **260** in turn is surrounded by the outer conductor **256**. Outer conductor **256** acts as a shielding element to the microwave signals transmitted by inner conductor **258**. Further, outer conductor **256** shields the microwave signals transmitted by inner conductor **258** from external noise. In one embodiment, outer conductor **256** comprises multiple strands of Ag plated Cu. The multiple strands of outer conductor **256** are arranged such that the outer diameter of outer conductor **256** is 0.057" +/- 0.005". Outer conductor **256** in turn is covered by an outer jacket **268**. In one embodiment, outer jacket **268** is made of PTFE with an outer diameter of 0.065" +/- 0.005". Thus, the outer diameter of coaxial cable **250** is less than about 2 mm. The low profile of flexible coaxial cable **250** has tremendous clinical advantages since it can be inserted through narrow and/or tortuous anatomical paths or introducing device lumens. In one embodiment, a shaft comprising coaxial cable **250** is stiffened or strengthened by adding one or more stiffening or strengthening elements such as enclosing stiffening devices jackets, braids, or stiffening layers over coaxial cable **250**. In one embodiment, antenna **112** is stiffened or strengthened by adding one or more stiffening or strengthening elements such as jackets, braids or layers within or over antenna **112**.

[0117] Fig. 1D shows a longitudinal section of the embodiment of ablation device **110** of Fig. 1A through the distal end of coaxial cable **250**. In Fig. 1D, the identity of coaxial cable **250** ends at the distal end of outer conductor **256**. Transition line **254** in Fig. 1D is located at the distal end of outer conductor **256** and is substantially perpendicular to the axis of coaxial cable **250** at the distal end of outer conductor **256**. Outer jacket **268** of coaxial cable **250** terminates a small distance proximal to the distal end of outer conductor **256**. A conductive element attached to the distal end of inner conductor **258** forms radiating element **262**. In one embodiment, the proximal end of radiating element **262** is electrically connected to the distal end of inner conductor **258**. In one embodiment, the proximal end of radiating element **262** is soldered to inner conductor **258**. In another embodiment, the proximal end of radiating element **262** is laser welded to inner conductor **258**. The proximal end of radiating element **262** may be electrically connected to inner conductor **258** in various configurations including, but not limited to lap joint and butt joint. The proximal end of shaping element **264** is electrically connected to a region of outer conductor **256**. In one embodiment, the proximal end of shaping element **264** is electrically connected to the distal end of outer conductor **256**. In one embodiment, the proximal end of shaping element **264** is soldered to outer conductor **256**. In another embodiment, the proximal end of shaping element **264** is laser welded to outer conductor **256**. The proximal end of shaping element **264** may be electrically connected to outer conductor **256** in various configurations including, but not limited to lap joint and butt joint.

[0118] Fig. 1B shows a side view of an embodiment of a microwave antenna comprising one or more electrophysiological mapping or pacing or RF ablation electrodes. Antenna **112** in Fig. 1B is similar in design to antenna **112** of Fig. 1A. Antenna **112** in Fig. 1B has a proximal end connected to the distal end of the transmission line **250**, a distal end and an antenna axis. However, antenna **112** in Fig. 1B further comprises one or more electrodes **118**. Electrode **118** may be used for one or more of: sensing and/or measuring electrophysiological signals, electrically pacing a tissue and ablating an anatomical region. In the embodiment wherein antenna **112** is used to treat or ablate tissue, electrode **118** may be used for one or more of: identifying the site of treatment, confirming successful treatment and monitoring progress of the treatment. In one method embodiment, ablation device **110** introduced percutaneously into the heart and is used to ablate cardiac tissue to treat an arrhythmia such as atrial fibrillation, flutter, ventricular tachycardia, etc. In such methods, electrodes **118** are used for one or more of: identifying the site of the arrhythmia, identifying site(s) to be ablated, confirming successful ablation of the cardiac tissue, confirming uni-directional or bi-directional block and monitoring progress of the ablation. Thus electrodes **118** confer a clinical advantage to the physician since ablation and sensing can be done by a single slim and flexible device.

[0119] Electrodes **118** are made of a metallic material and are exposed to the surrounding tissue. In Fig. 1B, electrode **118** is located in the microwave field generated by antenna **112**. Electrode **118** is connected by an elongate conductive wire **276** that electrically connects electrode **118** to an external circuit. Wire **276** is located in the microwave field generated by antenna **112**. If improperly placed, both electrode **118** and wire **276** can cause unwanted coupling with the microwave field which in turn can cause unwanted distortion of the microwave field. Fig. 1B shows one embodiment of conductive wire **276** that are designed to cause minimal or no interference with the microwave energy emitted by antenna **112**. In Fig. 1B, electrode wire **276** is arranged in a helical configuration around shaping element **264**. This novel arrangement of conductive wire **276** reduces the coupling between the conductive wire **276** and the microwave field which in turn reduces the heating of conductive wire **276**. Conductive wire **276** may be made of one or more conductive materials. Examples of such materials include, but are not limited to: stainless steel (with or without a coating of copper or gold or silver), copper, gold, silver and alloys thereof and other conductive materials. The diameter of the conductive wire **276** helix in Fig. 1B is substantially uniform along the length of antenna **112**. Further, the pitch (distance between adjacent turns) is substantially similar to the pitch of radiating element **262**. Further, the axis of the conductive wire **276** helix in Fig. 1B is oriented substantially parallel to the axis of antenna **112**. In one embodiment, the diameter of the helical arrangement of conductive wire **276** is less than the diameter of radiating element **262**.

[0120] In an alternate embodiment, conductive wire **276** is substantially straight and is arranged non-parallel to the length of antenna **112**. In one embodiment, the axis of helically disposed conductive wire **276** is substantially parallel to the axis of one or both of: radiating element **262** and shaping elements **264**. In Fig. 1B, if conductive wire **276** is defined as a series of curved segments, all of the curved segments are oriented such that they are non-parallel to the axis of antenna **112**. The portion of wire **276** located on antenna **112** has about 9 turns. In alternate embodiments, the portion of wire **276** located on antenna **112** has about 0.5 to 30 turns. In another embodiment, coupling between the microwave field and conductive wire **276** is reduced by spacing conductive wire **276** from radiating element **262** by a sufficient amount of a dielectric material. In one embodiment, coupling between the microwave field and conductive wire **276** is used to purposely modify the shape and/or the size of the microwave field. In one embodiment, one or more conductive wires **276** pass along the proximal end of antenna **112**.

[0121] In one such embodiment, one or more conductive wires **276** are routed over and along coaxial cable **250** i.e. proximally from antenna **112**. In another embodiment, one or more conductive wires **276** pass along the distal end of antenna **112**. In one such embodiment,

one or more conductive wires 276 are routed distally from antenna 112 through a distal dielectric 278 as shown in Fig. 1B. Distal dielectric 278 is located on the distal end of ablation device 110. In one embodiment, one or more conductive wires 276 are embedded in distal dielectric 278. Distal dielectric 278 may or may not form a part of a pull wire or tether 114 arrangement located on the distal region of ablation device 110 as shown in Figs. 1AA and 1AB. In one embodiment, conductive wires 276 themselves are designed to be tethers 114 or pull wires. In another embodiment, a separate flexible tether 114 is attached to the distal region of ablation device 110 and conductive wires 276 are arranged along tether 114 such that there is no or minimal tension on conductive wires 276 during clinical use.

[0122] Electrode 118 is designed to be as small as possible. In one embodiment, electrode 118 is made of a metallic cylindrical ring with an outer diameter between 0.5 - 5 mm and a length between 0.1 - 4 mm. In one embodiment, coupling between the microwave field and electrode 118 is reduced by placing electrode 118 in a region of antenna 112 where the microwave field is relatively weak. In another embodiment, coupling between the microwave field and electrode 118 is reduced by spacing electrode 118 from radiating element 262 by a sufficient amount of a dielectric material. Although only a single electrode 118 is shown in Fig. 1B for clarity, embodiments of ablation device 110 may be designed that comprise more than one electrode 118. In one embodiment, an antenna 112 comprising multiple electrodes 118 is designed such that even though individual electrodes 118 may interact with and slightly distort the microwave field, the combined effect of multiple electrodes 118 causes minimal or no net microwave field distortion.

[0123] Figs. 1E – 1G show the method steps of a method of creating two overlapping lesions in a tissue. In Figs. 1E – 1G, the method is demonstrated in an experimental setup for demonstrating the utility of antenna 112 of Fig. 1A for intra-cardiac ablation and other applications. The experimental setup comprised a slice of porcine muscle tissue is kept in a water bath maintained at 37 C. Further, water is pumped in the water bath from a nozzle 272 and is continuously circulated through the water bath using a pump (not shown). This is to simulate the effect of blood flow within the heart chambers. In Fig. 1E, a linear antenna 112 similar in design to antenna 112 of Fig. 1A is placed in contact with the porcine tissue as shown. Thereafter, microwave power at 0.915 GHz is delivered to ablation device 110 at 80 W for 60 s.

[0124] Fig. 1E shows a first ablation created around antenna 112. In Fig. 1F, antenna 112 is moved to a new location. Thereafter, microwave power is delivered to ablation device 110 at 80 W for 60 s to create a second lesion as shown in Fig. 1G. In Fig. 1G, antenna 112 is being moved away after creating the second lesion. The tissue shows two overlapping

lesions that overlap lengthwise. Various patterns of multiple lesions may thus be created by repositioning any of the antennas **112** disclosed herein. Any of the antennas **112** disclosed herein may be repositioned by one or more of: rotating around an axis, moving proximally or distally, moving sideways, revolving around an axis, increasing or reducing in size, engaging a steering or deflecting mechanism on ablation device **110** and engaging a steering or deflecting mechanism on an accessory device. Further, any of the antennas **112** disclosed herein may be designed and used such that during clinical use the forces exerted by a flexible antenna **112** on surrounding tissues do not distort the surrounding tissue. In one embodiment, two lesions are created that do not intersect each other. In another embodiment, two elongate lesions are created that are joined lengthwise. In another embodiment, two elongate lesions are created that are joined breadthwise. In another embodiment, two elongate lesions are created that intersect each other to form an approximately X-shaped resulting lesion.

[0125] The lesions created in Fig. 1G were deep and overlapping lesions. The length of the combined lesion was about 9 cm and the visual depth of the lesion varied from 1 – 1.5 cm. Thus, long, deep lesions may be created by antenna **112**. The lesions may be created such that they span the entire thickness of the tissue such as a heart wall. Thus antenna **112** can be used to create trans-mural lesions. Further, there is a complete absence of charring in the lesion. Also, long, deep lesions were created even in the presence of flowing fluid. Thus antenna **112** may be used to create lesions in anatomical regions that contain flowing blood such as the vasculature (veins, arteries, etc.) and the heart chambers.

[0126] Fig. 1H shows a side view of an embodiment of a microwave antenna comprising multiple electrophysiological mapping or pacing electrodes that are spaced in regular intervals along the length of antenna **112**. Embodiments of ablation device **110** may be designed that comprise 1 – 64 such electrodes **118**. Electrodes **118** may be spaced at regular intervals or at non-regular intervals along the length of antenna **112**. In any of the embodiments of electrodes **118** disclosed herein wherein electrodes **118** are electrophysiological mapping electrodes; one or more electrodes **118** may be used in a uni-polar mode or a bi-polar mode. When such electrodes **118** are used in a bi-polar mode, any two electrodes **118** (e.g. two adjacent electrodes **118**) may be used for performing a mapping procedure. For example, in Fig. 1H, electrodes **118** may be used in the bi-polar mode by using first and second electrodes **118**, second and third electrodes **118**, third and fourth electrodes **118**, etc. In one embodiment, an antenna **112** comprising multiple electrodes **118** such as shown in Fig. 1H is designed such that even though individual electrodes **118** may interact with and slightly distort the microwave field, the combined effect of multiple electrodes **118** causes minimal or no net microwave field distortion.

[0127] Fig. 1I shows a side view of an embodiment of a microwave antenna comprising multiple electrophysiological mapping or pacing electrodes that are spaced in pairs along the length of antenna 112. Such an embodiment is especially suited for cardiac ablation using antenna 112 wherein electrodes 118 are used for electrophysiological mapping in a bi-polar mode. In such an embodiment, two electrodes 118 in a pair are used in a bi-polar mode for performing an electrophysiological mapping procedure. In Figs. 1H and 1I, conductive wires 276 are not shown for improved clarity.

[0128] Although in several figures, elements 118 are described as electrophysiological mapping electrodes 118, one or more of electrodes 118 in any of the embodiments shown herein (such as those shown in Figs. 1B, 1H, 1I, 1K, 1S, 1T, etc.) may be one or more diagnostic or therapeutic modalities including, but not limited to: radiofrequency ablation electrodes, electrophysiological pacing electrodes, electrophysiological mapping electrodes, temperature sensors, impedance sensors, pressure sensors, proximity sensors, flow sensors, moisture sensors, electromagnetic field sensors, etc. Such diagnostic or therapeutic modalities may comprise one or more metallic or conductive portions. In any of the devices disclosed herein comprising multiple such diagnostic or therapeutic modalities, all of the modalities may perform the same function. In any of the devices disclosed herein comprising multiple such diagnostic or therapeutic modalities, at least two modalities may perform different functions. For example, one modality may be an electrophysiological mapping electrode while another modality may be a temperature sensor. Such elements and the conductive wires 276 connected to such elements may be designed to have minimal or no coupling with the microwave field. Such elements and conductive wires 276 connected to such elements may be exposed to surrounding tissue or may be electrically insulated from surrounding tissue.

[0129] Fig. 1J shows a side view of a functional microwave antenna with a design similar to the design shown in Fig. 1A. Antenna 112 in Fig. 1J does not have any electrodes 118. Fig. 1K shows a side view of a functional microwave antenna having additional electrodes 118. The basic design of antenna 112 in Fig. 1K is similar to the basic design of the antenna 112 of Fig. 1J. It can be seen that the lengths of antenna 112 in Figs. 1J and 1K are similar (about 3.5 cm). Antenna 112 in Fig. 1K comprises three pairs of electrodes 118 (a proximal pair, a middle pair and a distal pair) arranged similar to the arrangement shown in Fig. 1I. The conductive wires 276 of electrodes 118 are routed through a tether 114 connected to the distal end of antenna 112. The conductive wires 276 in Fig. 1K are arranged in a helical configuration on antenna 112 as shown in Fig. 1B. Fig. 1L and 1M show surface images of lesions obtained by ablating the surface of porcine muscle tissue using the antennas shown in Fig. 1J and 1K respectively. The initial temperature of the

porcine muscle tissue was 37 C to simulate human body temperature. The ablation power used was 80 W and the ablation time was 80 s in both the studies in Fig. 1L and 1M. Fig. 1L and 1M show that the surface characteristics of the lesions are substantially similar. The length of both the lesions is about 3.8 cm. The width of both the lesions is about 7 – 10 mm. Fig. 1N and 1O show sections of the porcine tissue in Figs. 1L and 1M showing the depth of the lesions obtained by the antennas in Fig. 1J and 1K respectively. The maximum depth of both the lesions is about 7 – 8 mm. This further proves that the novel positioning of electrodes 118 and/or the novel positioning of conductive wires 276 causes minimal or no interference with the microwave field emitted by antenna 112. Further, the unique arrangement of electrodes 118 and wires 276 causes a clinically insignificant distortion of the thermal profile of the heat generated by antenna 112. Further, there are no regions of charring or burning of tissue along the lesion created in Figs. 1M and 1O. Thus, the novel placement of electrodes 118 and conductive wires 276 has not resulted in any “hot spots” or undesired zones of high temperature.

[0130] Non-interfering designs of electrodes 118 and conductive wires 276 will be further illustrated in Figs. 1P – 1R. Fig. 1P shows a side view of a simulated SAR profile generated by an antenna similar to the antenna of Fig. 1A. Fig. 1Q shows a side view of a simulated SAR profile generated by a first antenna similar to the antenna of Fig. 1A but having four extra electrodes 118 spaced at regular intervals along the length of the antenna. The conductive wires 276 in this embodiment are arranged in a non-interfering arrangement as shown in Fig. 1B.

[0131] Fig. 1Q demonstrates that the SAR profile generated by the device embodiment having four electrodes 118 is similar to the SAR profile in Fig. 1P. Thus, the unique arrangement of electrodes 118 and wires 276 causes a clinically insignificant distortion of the microwave field generated by antenna 112. Further, the unique arrangement of electrodes 118 and wires 276 causes a clinically insignificant distortion of the thermal profile of the heat generated by antenna 112. In this simulation, four conductive wires 276 were combined into a bundle of wires. Thus, the unique arrangement of conductive wires 276 causes an insignificant distortion of the microwave field generated by antenna 112. The SAR profiles in Figs. 1Q and 1P are substantially radially symmetric. Further, the SAR profiles in Figs. 1Q and 1P are substantially bilaterally symmetric on both sides of an imaginary plane oriented perpendicularly to the axis of antenna 112 and passing roughly through the center of antenna 112. Fig. 1Q demonstrates that the microwave field generated by antenna 112 is substantially restricted to second zone Z2. There is a clinically insignificant amount of the microwave field in first zone Z1 containing coaxial cable 250. Thus, there is negligible backward coupling between the microwave field and the distal portion of coaxial cable 250. This in turn reduces the risk of ablating tissue proximal to the

distal end of coaxial cable **250**. Further, the microwave field is substantially uniform along the length of antenna **112** as compared to a comparable monopole antenna. Thus the lesion formed by the microwave field in Fig. 1Q will be uniform and substantially localized.

Thus, embodiments of linear antenna **112** comprising one or more electrodes **118** and their corresponding conductive wires **276** designed to operate at **915** MHz and other microwave frequencies may be designed that can create uniform, symmetrical, continuous, linear lesions with a lesion length greater than 35 mm. Further, Fig. 1Q shows the absence of undesired concentration of microwave energy over the electrodes **118** or over conductive wires **276**. This in turn ensures that there will be no “hot spots” or undesired zones of high temperature along antenna **112** during clinical use.

[0132] Fig. 1R shows a side view of a simulated SAR profile generated by a second antenna similar to the antenna of Fig. 1A having four extra electrodes **118** spaced at regular intervals along the length of the antenna. The conductive wires **276** in this embodiment are linear and arranged parallel to the axis of antenna **112**. Fig. 1R demonstrates that the SAR profile generated by the device embodiment having four electrodes **118** is significantly different from the SAR profile in Fig. 1P. Thus, this arrangement of electrodes **118** and wires **276** has caused a clinically significant distortion of the microwave field and the thermal profile of the heat generated by antenna **112**. The microwave field is concentrated in a smaller zone located near the proximal end of antenna **112**. In this simulation, four conductive wires **276** were combined into a bundle of wires. The SAR profile in Fig. 1R is not bilaterally symmetric on both sides of an imaginary plane oriented perpendicularly to antenna **112** and passing roughly through the center of antenna **112**. Further, the microwave field is substantially non-uniform along the length of antenna **112**. Thus the lesion formed by the microwave field in Fig. 1R will be smaller than the lesion in Fig. 1Q. A comparison of the SAR profiles in Figs. 1Q and 1R illustrate the usefulness of this unique arrangement of electrodes **118** and wires **276**.

[0133] Fig. 1S shows a view of the distal region of the ablation device similar to the ablation device used in Figs. 1K, 1M and 1O. In Fig. 1S, ablation device **110** comprises an antenna **112** similar in design to antenna **112** of Fig. 1A. Antenna **112** further comprises three pairs of electrodes **118** - a proximal pair, a middle pair and a distal pair. In one embodiment, the proximal pair of electrodes **118** is located away from the junction region of antenna **112** and coaxial cable **250**. In one embodiment, the distal pair of electrodes **118** is located near or on the distal end of antenna **112**. A flexible coaxial cable **250** supplies power to antenna **112**. The distal end of antenna **112** is connected to a tether **114** comprising a transparent distal dielectric **278** made at least partially of silicone and conductive wires **276**. Such an ablation device **110** may be used in any suitable method and device embodiments disclosed herein including, but not limited to the embodiments shown in Figs. 1AA – 1AK, 2A – 2D,

4A – 4B, 6H – 6Q and 7E – 7H. It can be seen in Fig. 1S that the tether **114** is continuous with the remainder of ablation device **110**. Further, the tether is connected to the distal end of antenna **112**.

[0134] Electrodes **118** and wires **276** may or may not be physically located on the device that comprises antenna **112**. For example, electrodes **118** and wires **276** may be located on a separate device that is located around antenna **112**. Figs. 1T shows an antenna similar to the antenna in Fig. 1A being slidably introduced through the lumen of a functional tube. In Fig. 1T, functional tube **188** comprises four equally spaced electrodes **118**. Each electrode **118** is connected to a conductive wire **276**. The four conductive wires **276** are arranged on functional tube **188** such that every curved segment of the conductive wires **276** is non-parallel to the axis of the functional tube **188**. When antenna **112** is located within functional tube **188** such that antenna **112** is enclosed within electrodes **118**, both electrodes **118** and a portion of conductive wires **276** are exposed to the microwave field generated by antenna **112**. However, as discussed elsewhere in the specification, the novel arrangement of electrodes **118** and conductive wires **276** will not adversely affect the safety and efficacy of a procedure performed using antenna **112**. During a method, the relative positions of antenna **112** and functional tube **188** may be changed by a user. In one embodiment, functional tube **188** comprises a steering or deflecting mechanism. The embodiment in Fig. 1T differs from the embodiment in Fig. 1B. In Fig. 1B, electrodes **118** and wire **276** are attached to antenna **112** or embedded inside antenna dielectric **266** of antenna **112**. In Fig. 1T, electrodes **118** and wire **276** are slidable relative to antenna **112** and are not fixed to antenna **112**.

[0135] Non-interfering designs of electrodes **118** and conductive wires **276** will be further illustrated in Figs. 1U – 1W. Fig. 1U shows a side view of a simulated SAR profile generated by a 915 MHz monopole antenna. Fig. 1V shows a side view of a simulated SAR profile generated by a monopole antenna similar to the antenna of Fig. 1U but having four extra electrodes spaced at regular intervals along the length of the antenna. The conductive wires **276** in this embodiment are arranged in a non-interfering arrangement as shown in Fig. 1B. Fig. 1V demonstrates that the SAR profile generated by this device embodiment having four electrodes **118** is similar to the SAR profile in Fig. 1U. Thus, the unique arrangement of electrodes **118** and wires **276** causes a clinically insignificant distortion of the microwave field generated by antenna **112**.

[0136] Further, the unique arrangement of electrodes **118** and wires **276** causes a clinically insignificant distortion of the thermal profile of the heat generated by antenna **112**. In this simulation, four conductive wires **276** were combined into a bundle of wires. The SAR profiles in Figs. 1V and 1U are substantially radially symmetric. Further, the SAR profiles

in Figs. 1V and 1U are substantially bilaterally symmetric on both sides of an imaginary plane oriented perpendicularly to antenna **112** and passing roughly through the proximal end of antenna **112**. Fig. 1W shows a side view of a simulated SAR profile generated by a monopole antenna similar to the antenna of Fig. 1U but having four extra electrodes spaced at regular intervals along the length of the antenna wherein each electrode is connected to a conductive wire. The conductive wires **276** in this embodiment are linear and arranged parallel to the axis of antenna **112**. Fig. 1W demonstrates that the SAR profile generated by the device embodiment having four electrodes **118** is significantly different from the SAR profile in Fig. 1U. Thus, this arrangement of electrodes **118** and wires **276** has caused a clinically significant distortion of the microwave field generated by antenna **112**. The microwave field is concentrated in a smaller zone located near the proximal end of antenna **112**. In this simulation, four conductive wires **276** were combined into a bundle of wires. The SAR profile in Fig. 1W is not bilaterally symmetric on both sides of an imaginary plane oriented perpendicularly to antenna **112** and passing roughly through the proximal end of antenna **112**. Thus the lesion formed by the microwave field in Fig. 1W will be smaller than the lesion in Fig. 1V. A comparison of the SAR profiles in Figs. 1W and 1V illustrate the usefulness of this unique arrangement of electrodes **118** and wires **276**.

[0137] Further, the unique arrangement of electrodes **118** and wires **276** does not negatively affect the simulated return loss of a device with a monopole antenna. A simulated return loss of -14.90 was obtained at **915** MHz for a device with a monopole antenna of Fig. 1U. A simulated return loss of -19.52 was obtained at **915** MHz for a device with a monopole antenna and electrodes and electrode wire arrangement of Fig. 1V. This is actually a significant improvement over the return loss of the device of Fig. 1U. A simulated higher return loss of -12.86 was obtained at **915** MHz for a device with a monopole antenna and electrodes and electrode wire arrangement of Fig. 1W. Thus, the electrode and electrode wire arrangement of Fig. 1W has negatively affected the simulated return loss of a device with a monopole antenna.

[0138] In a first variation, the invention includes a medical system **100** for performing a medical procedure on or in a patient, the medical system **100** comprising at least a first hollow sheath or arm **102**. In the specification, the term "arm" is used to describe any elongate device that can be used to introduce and/or manipulate one or more components of medical system **100**. Thus, arm can be an introducing catheter, a cannula, a tubular sheath, etc. Arm **102** has a maneuverable distal portion **104** and a proximal portion **106**, wherein manipulation of proximal portion **106** of arm **102** permits articulation of maneuverable distal portion **104** of arm **102**. A medical component **110** is mechanically coupled to arm **102** and is adjustably extendable from maneuverable distal portion **104** of arm **102**. Medical component **110** is mechanically engaged to maneuverable distal portion **104** of

arm **102**, such that movement of maneuverable distal portion **104** alters the position and/or the orientation of medical component **110**.

[0139] Fig. 1AA shows an embodiment of a medical system **100** comprising a sheath or arm **102** that is used to introduce and position a medical component **110**. In Fig. 1AA, medical component **110** comprises a working element **112** (e.g. a flexible long antenna) located on a first portion of medical component **110** and a tether **114** that forms the second portion of medical component **110**. In this embodiment, the first portion is integrated with the second portion. The first portion comprises a device shaft **116** that may be twisted or torqued by the user. Device shaft **116** is slidably and rotatably positioned within a lumen of arm **102**. Device shaft **116** may comprise a first circuit that transmits energy to the distal region of medical component **110**. In one embodiment, working element **112** is a flexible long microwave antenna and the device shaft comprises a coaxial cable that transmits microwave energy (e.g. at 915 MHz ISM band or at 2.45 GHz ISM band) to working element **112**.

[0140] Examples of microwave ablation antennas that can be used in the present invention are given in US Provisional Patent Application Serial No. 61/162,241 filed on March 20, 2009 titled "Methods and devices for applying energy to bodily tissues", and in US Provisional Patent Application Serial No. 61/222,409 filed on July 1, 2009 titled "Steerable medical systems for positioning medical elements in or within a body"; the entire disclosures of which are incorporated herein by reference. In Fig. 1AA, medical component **110** forms a mechanically unsupported looped region beyond the distal end of arm **102**. The region of medical component **110** proximal to the distal end of arm **102** is mechanically supported by arm **102**. The size and/or the shape and/or the position and/or the orientation of the looped region is adjustable by one or more user directed movements. The first portion of medical component **110** comprises four pairs of mapping electrodes **118**. One or more mapping electrodes **118** may be located on one or more of the following locations: adjacent to an end of working element **112**, spaced apart from working element **112** and over the extent of working element **112**.

[0141] In the embodiment shown in Fig. 1AA, two pairs of mapping electrodes **118** are located adjacent to each end of working element **112**. Also in the embodiment shown in Fig. 1AA, two pairs of mapping electrodes **118** are located over the extent of working element **112** and surround working element **112**. Mapping electrodes **118** may be used to obtain electrophysiological signals from tissue. Embodiments of medical component **110** comprising mapping electrodes **118** located in close proximity to or over working element **112**, enables the user to perform both electrophysiological mapping by one or more mapping electrodes **118** and energy delivery by working element **112** without changing the

position of working element **112**. Thus in several method embodiments disclosed herein, working element **112** is positioned at a first location of a target tissue. Thereafter, working element **112** is used to deliver energy to the first location of the target tissue to ablate tissue and create a first lesion. One or more mapping electrodes **118** are used to map electrophysiological signals from the ablated tissue or other tissue at the first location of the target tissue while maintaining working element **112** at the first location of the target tissue. Thus, mapping electrodes **118** may be used to confirm desired ablation of tissue and/or to determine the need for additional energy delivery to tissue. When mapping electrodes **118** are present over working element **112**, the user can perform both energy delivery as well as mapping without moving working element **112** and without needing an additional device for mapping. This greatly simplifies the procedure while eliminating the cost of an additional device for mapping.

[0142] Tether **114** is slidably positioned within a lumen of arm **102**. In one embodiment of medical system **100** in Fig. 1AA, tether **114** has a sufficient stiffness to be pushable and/or torqueable. Tether **114** may be connected to a portion of device shaft **116** or to a working element **112**. Any of the tethers **114** disclosed herein may comprise one or more working elements **112** or mapping electrodes **118**. Tether **114** and other steering mechanisms disclosed herein may be used to change the shape of a flexible working element **112**. For example, the shape of working element **112** may be changed from one of: a linear shape, a planar non-linear shape and a non-planar non-linear shape (three dimensional) shape to one of: a linear shape, a planar non-linear shape and a non-planar non-linear shape (three dimensional) shape and vice versa.

[0143] Working element **112** may be used to create ablations that are similar or dissimilar to the shape of the working element **112**. For example, a working element **112** in a substantially circular configuration may be used to create a substantially circular lesion. Alternately, a working element **112** in a substantially circular configuration may be used to create a substantially round lesion. The round lesion may be created, for example, by using a higher power setting and/or higher time setting than that used for creating the substantially circular lesion. Similarly, working elements **112** in a substantially closed loop configuration may be used to create lesions that correspond to the shape of the perimeter of the substantially closed loop configuration or to the shape of the area enclosed by the substantially closed loop configuration. Thus, a linear working element **112** may be used to create one or more of: linear lesions, area ablations (e.g. by positioning linear working element **112** at multiple regions on a tissue surface or by using a bent working element **112** to create an area ablation) or volume ablations e.g. by creating deeper lesions over several regions on a target tissue.

[0144] In any of the embodiments herein, the stiffness of the region of tether **114** distal to the distal end of arm **102** may be the same as or more than or less than the stiffness of the region of shaft **116** distal to the distal end of arm **102**.

[0145] In one embodiment of the device in Fig. 1AA, mapping electrodes **118** and a second circuit electrically connected to mapping electrodes **118** are placed on working element **112** such that there is minimal interference from mapping electrodes **118** with a microwave field generated by working element **112**. In one embodiment, the second circuit comprises electrode wires made of copper or gold or silver or of stainless steel with or without a plating of copper/gold/or/silver. The electrode wires may be located on device shaft **116** or on tether **114**. In one embodiment, the electrode wires are electrically insulated from the first circuit and working element **112**. Mapping electrodes **118** may be made of standard radiopaque materials such as platinum. Thus, the user may use radiographic visualization to visualize mapping electrodes **118** or other radiopaque components of the devices disclosed herein during a procedure.

[0146] One or more mapping electrodes **118** may be substituted by one or more radiofrequency ablation electrodes or electrophysiological pacing electrodes that deliver controlled electrical energy for electrophysiological pacing of tissue such as cardiac tissue. Although in Fig. 1AA, mapping electrodes **118** are shown only on device shaft **116**, one or more mapping electrodes **118** may be present on one or more of: device shaft **116** and tether **114**. In one method embodiment, working element **112** and one or more mapping electrodes **118** are simultaneously used for delivering microwave energy and for electrophysiological mapping of tissue respectively. In another method embodiment, one or more mapping electrodes **118** are used for electrophysiological mapping of tissue after working element **112** has delivered microwave energy. In another method embodiment, one or more mapping electrodes **118** are used for electrophysiological mapping of tissue before working element **112** has delivered microwave energy.

[0147] In Fig. 1AA, the distal end of tether **114** is connected to a distal end of device shaft **116**. The connection is an end-to-end connection. In such a connection, there is a smooth transition between the curve of the distal end of tether **114** and the curve of the distal end of device shaft **116**. In such embodiments, when one of: shaft **116** and tether **114** is advanced distally by an amount and the other of: shaft **116** and tether **114** is withdrawn proximally by a substantially similar amount, the position of working element **112** on the looped region of medical component **110** is changed without substantially changing the shape of the looped region. In such embodiments, the stiffness of the region of tether **114** distal to the distal end of arm **102** may be substantially similar to the stiffness of the region of shaft **116** distal to the distal end of arm **102**.

[0148] In Fig. 1AA, arm 102 comprises an opening at the distal end of arm 102 through which medical component 110 exits. In alternate embodiments, arm 102 comprises one or more openings that are located on a side wall of arm 102 rather than at the distal end of arm 102. The one or more openings may be of the same size and shape or differ in size and/or shape. The one or more openings may be arranged on arm 102 such that medical component 110 exits arm 102 at an angle to arm 102.

[0149] Fig. 1AB shows an embodiment of a working model of the medical system 100 similar to that shown in Fig. 1AA. In Fig. 1AB, the medical component 110 comprises a first portion that comprises a microwave antenna 112. Microwave antenna 112 is supplied with microwave energy through a flexible coaxial cable that forms a shaft 116 of the first portion of medical component 110. Tether 114 forms the second portion of medical component 110. Antenna 112 and a portion of the coaxial cable are covered with a layer of dielectric material 120 such that antenna 112 is electrically insulated from the surrounding tissue. Arm 102 herein comprises three pull wires to deflect the distal portion 104 of arm 102 in three planes. However, medical component 110 in Fig. 1AB does not contain mapping electrodes 118.

[0150] Although many variations of medical system 100 are discussed and/or illustrated with a single arm 102, variations of medical system 100 may include any number of arms 102. In some variations, medical component 110 extends through arm 102 in a generally concentric or coaxial manner. However, the invention also includes arrangements of medical component 110 and arm 102 wherein medical component 110 extends parallel to arm 102, or extends along arm 102 or a portion thereof in a non-concentric manner. Arm 102 may be reversibly coupled to one or more medical component(s) 110 via a grasping structure. Examples of such grasping structures include, but are not limited to: releasable hooks, rings, or jaws. Arm 102 may be fully or partially hollow. One or more arms 102 may be arranged concentrically to manipulate medical component 110. Arm 102 may be introduced via one or more access ports and pathways.

[0151] For purposes of this specification, the term medical component 110 is intended to describe a medical device or portion thereof that is adapted to provide a visualization, diagnostic, or treatment procedure. For example, and as described below, in one variation, medical system 100 may include a medical component 110 comprising a first portion comprising a working element 112 configured to deliver energy (e.g., radiofrequency (monopolar or bipolar), resistively generated heat, microwaves, ultrasound energy, laser) to or from tissue and a second portion (such as a guidewire, rail, tether 114, etc.) that is used to manipulate the position and/or the orientation of the first portion. Alternatively, or in combination, medical component 110 may also comprise one or more sensors or

information receiving elements. For example, such elements can include one or more of: electrodes (that detect and/or measure voltage, current and/or impedance), temperature sensors, pressure sensors, light measurement devices, infrared sensors, chemical sensors, radiation sensors, deformation sensors, or any other type of sensors that observe and/or measure a state or condition of tissue or the body. In one embodiment, the first portion and the second portion are parts of the same medical component 110. In one embodiment, the first portion and the second portion are integrated with each other and are non-separable without destroying medical component 110. In another embodiment, first portion and second portion are separable from each other by one or more user generated actions. In one embodiment, the first portion can advance over the second portion which functions as a rail, guide, or tether. In such a case, the first portion and second portion may be separate medical devices.

[0152] Examples of medical components 110, include, but are not limited to, therapeutic devices such as ablation devices for imparting a treatment to a target tissue, diagnostic devices such as mapping catheters for providing physiological information regarding a target tissue; positioning devices which include elements for providing additional positioning of additional medical components 110 (e.g., guidewires, rails, tethers, introducer catheters, sheaths, etc.), imaging devices, or non-imaging feedback devices (such as a Doppler catheter). Medical component 110 need not have a specific physical structure, for example an arm 102 of the inventive medical system 100 can be adapted to deploy a simple tube that administers a chemical ablating agent at a desired location or delivers an additional fluid used during, and in support of, the medical procedure (e.g. a contrast agent delivered to provide a clearer view of the anatomy in support of a procedure performed within a patient's heart). In yet additional variations, medical system 100 may comprise multiple separate medical components 110 used to provide a single diagnostic procedure or different steps of the same medical procedure. For instance, when using a radiofrequency energy modality, a first medical component 110 could include a first electrode while a second medical component 110 can include a second electrode (either the opposite or same polarity). Alternatively, one medical component 110 can include an ablation element or electrode while a second medical component 110 contains one or more mapping electrodes to assess the ablation lesion created by the first medical component 110.

[0153] Any of the arms 102 may comprise a handle portion on the proximal end of arm 102. The handle portion enables the user to control movement of the distal portion 104 of arm 102. In one embodiment, the handle portion is connected to one or more steering control mechanisms e.g. pull wires, pre-shaped tubular sheaths, inflatable balloons, slidable stylets, etc. In one embodiment, the handle mechanism allows the physician to control the

maneuverable distal section **104** of arm **102** with a single hand. The movement of distal section **104** of arm **102** can occur in any three dimensional space. In a particular embodiment, arm **102** comprises two pairs of oppositely disposed pull wires. In another embodiment, arm **102** comprises three pull wires arranged **120** degrees apart around the circumference of arm **102**. Accordingly, embodiments of arm **102** comprising any number of steering mechanisms or steering control mechanisms are to be considered within the scope of this invention.

[0154] In several embodiments of the present invention, a single type of steering mechanism is shown on arm **102**. However, the invention is not limited to only a single type of steering mechanism on arm **102**. Instead, any of the arms **102** of the present invention may employ any number and/or type of steering mechanisms or controls or actuators to produce the desired steering capability of the arm **102**.

[0155] Any of the tethers **114** herein may have a circular, semicircular, oval, or a non-uniform cross section. In additional variations, a tether **114** may comprise a hollow cavity with any number of openings for delivery of one or more fluids such as gases or liquids such as contrast agents. In one such embodiment, a tether **114** comprises one or more lumens.

[0156] Tether **114** may be made of a metallic or non-metallic (e.g. polymeric) material. In one embodiment, tether **114** comprises a coating (e.g. a lubricious coating) on the outer surface of tether **114**. In one embodiment, tether **114** has an insignificant column strength i.e. tether **114** is floppy. In another embodiment, tether **114** is a wire-like member having a sufficient stiffness that allows for improved control of the remaining portion of medical component **110**.

[0157] Any of the tethers **114** disclosed herein may comprise a steering mechanism to steer or deflect a portion of tether **114**. In one such embodiment, a tether **114** comprises a lumen in which a steering device is slidable positioned. The steering mechanism may be one or more of: a sufficiently stiff stylet, a pull wire, a hollow tube and a deflectable elongate device.

[0158] In additional embodiments of the medical system **100**, the position and/or the orientation of one or more medical components **110** disclosed herein can be locked relative to an arm **102**. In one such embodiment, proximal portion **106** of arm **102** comprises a reversibly locking mechanism such as a rotating hemostasis valve. In another such embodiment, a handle **108** of an arm **102** can include such locking mechanisms.

[0159] In one embodiment, the position and/or the orientation of one or more arms **102** disclosed herein may be independently frozen in place to permit the physician to independently freeze the position and/or the orientation of each arm **102** into a desired

profile or orientation. This reduces or eliminates the need by the physician to continuously hold an arm 102 in any particular profile.

[0160] Any of the devices disclosed herein may have a varying degree of flexibility along the length of the device. For example, arm 102 may comprise a relatively stiff proximal portion 106 and relatively flexible distal portion 104. This permits ease of articulation of arm 102 at the treatment site but a relatively stable proximal portion 106 from which arm 102 can be maneuvered.

[0161] In additional variations of the system, one or more arms 102 may be configured to perform medical procedures as well. For instance, an arm 102 may comprise one or more electrodes, a fluid source, a suction source, a reservoir to collect tissue, etc. In another embodiment, distal portion 104 of arm 102 may be adapted to provide suction, irrigation, contrast agents, etc. to the target site. In yet another embodiment, distal portion 104 of arm 102 comprises vision capabilities such as a fiber optic, CCD camera, or another vision source enabling visualization of one or more portions of medical system 100 and/or the anatomy during a procedure.

[0162] In embodiments wherein medical component 110 is connected to an auxiliary component (e.g., a power supply, imaging monitor, fluid source, etc.), a handle connected to medical component 110 can include the desired connector.

[0163] Figs. 1AC and 1AD show two configurations of an embodiment of a medical system 100 wherein medical component 110 is introduced in the anatomy through arm 102. Medical component 110 comprises a shaft 116 having one or more working elements 112. In one embodiment, working elements 112 are selected from the group consisting of: radiofrequency ablation electrodes, microwave antennas, electrophysiological mapping electrodes, electrophysiological pacing electrodes, ultrasound emitting elements, cryoablative elements, laser emitting elements, electrocautery elements, electrosurgical cutting and/or coagulating elements and combinations thereof. The distal end of shaft 116 is coupled to a string or tether 114. The shape and/or the size and/or the position and/or the orientation of the region of medical component 110 distal to the distal region of arm 102 can be changed by one or more of: torquing arm 102, advancing or withdrawing arm 102, steering a steerable distal region of arm 102, torquing shaft 116 of medical component 110, advancing or withdrawing shaft 116 of medical component 110 and pulling or releasing tether 114. In one embodiment, arm 102 is steerable and is robotically controlled by a user. In this embodiment, the shape and/or the size and/or the position and/or the orientation of the region of medical component 110 distal to the distal region of arm 102 can be further changed by robotically manipulating the distal region of arm 102. In another embodiment, arm 102 is steerable and is further enclosed by a second steerable arm 102 (not shown). In

this embodiment arm 102 and second steerable arm 102 are telescopingly coupled together. In this embodiment, the shape and/or the size and/or the position and/or the orientation of the region of medical component 110 distal to the distal region of arm 102 can be further changed by one or more of: changing the relative positions of arms 102 and second arm 102, engaging a steerable distal region of second arm 102 and torquing arm 102 relative to second arm 102.

[0164] In Fig. 1AC, medical component 110 is in a “U-mode”. In this mode, there is a smooth profile transition from the distal end of first portion of medical component 110 to the distal portion of tether 114. This mode may be created by extending the shaft of medical component 110 by a sufficient distance from the distal region of arm 102 and pulling tether 114. In Fig. 1AD, medical component 110 is in a “V-mode”. In this mode, the distal end of first portion of medical component 110 is angled relative to the distal portion of tether 114. This mode may be created by releasing tether 114 sufficiently to enable shaft 116 of medical component 110 to acquire a comparatively linear shape due to the elasticity of shaft 116. In one embodiment, tether 114 is slidably coupled relative to shaft 116 of medical component 110. For example, tether 114 may slide within a lumen of shaft 116 of medical component 110. In another embodiment, tether 114 is fixed to a portion on shaft 116 of medical component 110.

[0165] Figs. 1AE and 1AF show two configurations of an embodiment of a medical system 100 wherein medical component 110 and second medical component 122 are introduced in the anatomy through arm 102. In Fig. 1AF, medical component 110 and second medical component 122 are introduced into the anatomy in a looped configuration as shown. The distal ends of medical component 110 and second medical component 122 are connected to each other by tether 114. In one embodiment, tether 114 or a portion thereof is flexible enough to assume an acute bend of about 180 degrees when medical component 110 and second medical component 122 are introduced in the anatomy through arm 102. This enables the introduction of medical component 110 and second medical component 122 through arm 102 in a folded configuration or “V-mode” as shown in Fig. 1AE. In one method embodiment, medical component 110 and second medical component 122 are introduced in the anatomy through arm 102 in the configuration shown in Fig. 1AE. Thereafter, one of medical component 110 and second medical component 122 is advanced distally while the other of medical component 110 and second medical component 122 is withdrawn proximally relative to arm 102. This is done such that tether 114 lies inside arm 102. Thereafter, a medical procedure is performed using medical system 100. Thus, the flexible part (e.g. a flexible portion of tether 114) of medical system 100 is used during introduction of medical component 110 and second medical component 122 through arm 102 and is withdrawn from the anatomy when the medical procedure is performed.

[0166] Medical component 110 comprises a shaft 116 having one or more working elements 112. Similarly, second medical component 122 comprises a shaft 116 having one or more working elements 112. Working elements 112 on medical component 110 or second medical component 122 may be any of the working elements disclosed elsewhere in this document. The shape and/or the size and/or the position and/or the orientation of the regions of medical component 110 and second medical component 122 distal to the distal region of arm 102 can be changed by one or more of: torquing arm 102, advancing or withdrawing arm 102, steering a steerable distal region of arm 102, torquing the shaft of medical component 110 or second medical component 122, advancing or withdrawing medical component 110 or second medical component 122 relative to arm 102 and engaging a steering modality on medical component 110 or second medical component 122. In one embodiment, arm 102 is steerable and is robotically controlled by a user.

[0167] In this embodiment, the shape and/or the size and/or the position and/or the orientation of regions of medical component 110 or second medical component 122 distal to the distal region of arm 102 can be further changed by robotically manipulating the distal region of arm 102. In another embodiment, arm 102 is steerable and is further enclosed by a second steerable arm 102 (not shown). In this embodiment arm 102 and second steerable arm 102 are telescopingly coupled together. In this embodiment, the shape and/or the size and/or the position and/or the orientation of regions of medical component 110 or second medical component 122 distal to the distal region of arm 102 can be further changed by one or more of: changing the relative positions of arm 102 and second steerable arm 102, steering a steerable distal region of second steerable arm 102 and torquing arm 102 relative to second steerable arm 102. In Fig. 1AF, medical component 110 is in a “U-mode”. This mode is created by extending the shafts of medical component 110 and second medical component 122 by a sufficient distance from the distal region of arm 102 and doing one of: pressing the distal regions of medical component 110 and second medical component 122 against tissue (as shown) and engaging a steering mechanism on medical component 110 or second medical component 122. In Fig. 1AE, medical component 110 is in a “V-mode”. This mode can be created by taking medical system 100 of Fig. 1AF away from the tissue thereby causing the shafts of medical component 110 and second medical component 122 to acquire a comparatively linear shape due to the elasticity of the shafts. Alternatively, the “V-mode” can be created by engaging a steering mechanism on medical component 110 or second medical component 122. In one embodiment, tether 114 is slidably coupled relative to the shaft of one or both of medical component 110 and second medical component 122. For example, tether 114 may slide within a lumen of one or both of medical component 110 and second medical component 122. In another embodiment,

tether **114** is fixedly coupled to the shafts of medical component **110** and second medical component **122**.

[0168] Any of the medical components **110** disclosed herein may comprise one or more bendable regions to enable the insertion of a folded medical component **110** into the anatomy. Figs. 1AG – 1AK show various steps of a method of introducing a medical component **110** comprising a bendable or foldable region into the anatomy through an arm **102**. In Figs. 1AG – 1AK, a portion of arm **102** has been cut out to show the orientation and position of the devices within arm **102**. In the embodiment shown, tether **114** comprises a bendable or foldable region **115**. In the embodiment shown, region **115** spans a short length of or a point on tether **114**. In an alternate embodiment, region **115** is a flexible connection between tether **114** and shaft **116** of medical component **110**. In another alternate embodiment, entire tether **114** is flexible enough to be bendable or foldable.

[0169] Region **115** is designed such that it can assume an acute bend of about **180** degrees when a folded medical component **110** is introduced in the anatomy through arm **102** as shown in Fig. 1AG. This enables the introduction of medical component **110** through arm **102** in a folded configuration or “V-mode” as shown in Fig. 1AG. In the step shown in Fig. 1AH, medical component **110** is advanced distally through arm **102**. Thereafter, in the step shown in Fig. 1AI, medical component **110** is further advanced distally such that region **115** and a portion of working element **112** are positioned distal to the distal end of arm **102**. Thereafter, in the step shown in Fig. 1AJ, shaft **116** is advanced distally while tether **114** is withdrawn proximally to position region **115** inside arm **102**. Thus, region **115** is used during introduction of medical component **110** through arm **102** and is withdrawn from the anatomy after introducing working element **112** into the anatomy through arm **102**. In the configuration shown in Fig. 1AJ, a looped region of medical component **110** comprising a portion of tether **114** and shaft **116** and working element **112** is located in the anatomy. In the embodiment shown in Fig. 1AJ, the looped region of medical component **110** is mechanically unsupported in the anatomy while the region of medical component **110** proximal to the distal end of arm **102** is supported by arm **102**. After medical component **110** is deployed as shown in Fig. 1AJ, a medical procedure may be performed using working element **112**. In one embodiment, working element may be used to deliver microwave energy to tissue. In one embodiment, the stiffness of the region of shaft **116** distal to the distal end of arm **102** is substantially the same as the stiffness of the region of tether **114** disposed distal to the distal end of arm **102**. In this embodiment, if one of: shaft **116** and tether **114** is pulled proximally by an amount and the other of: shaft **116** and tether **114** is advanced distally by the same amount, the position of working element **112** on looped region of medical component is changed without substantially

changing the size and/or the shape of the looped region of medical component **110**. In Fig. 1AK, working element **112** is repositioned by advancing shaft **116** distally by an amount and pulling tether **114** proximally by the same amount. This changes the position of working element **112** on looped region of medical component without substantially changing the size and/or the shape of the looped region of medical component **110**.

[0170] In another embodiment, medical component **110** comprises a sufficiently elastic joint between shaft **116** and tether **114**. The sufficiently elastic joint allows the joint to bend at an angle of about **180** degrees when folded medical component **110** is introduced through arm **102** as shown in Fig. 1AG. In one embodiment, the sufficiently elastic joint comprises a sleeve of stretchable material such as natural or artificial rubbers or polymers. Such a sleeve may enclose a support element such as a wire.

[0171] In another embodiment, a joint between shaft **116** and tether **114** has two configurations - a locked configuration and an unlocked configuration. The unlocked configuration loosely couples shaft **116** and tether **114** such that they can be advanced parallel to each other as shown in Fig. 1AG. After the joint exits the distal end of arm **102**, the joint is converted to a locked configuration in which shaft **116** and tether **114** are more tightly coupled together. After performing a procedure, the joint is converted to the unlocked configuration to enable the user to remove shaft **116** and tether **114** from the anatomy using arm **102**. In one such embodiment, the joint comprises two complementary fitting parts – one part is attached to tether **114** and the other part is attached to shaft **116**. In another such embodiment, the joint is a reversibly detachable ball and socket joint. The ball portion and the socket portion of the joint may be brought closer to each other to achieve the locked configuration. The ball portion and the socket portion of the joint may be moved apart from each other to achieve the unlocked configuration.

[0172] Figs. 2A – 2D show various method steps of accessing and/or diagnosing and/or treating one or more regions of the left atrium. In the embodiments shown in Fig. 2A – 2D, arm **102** and medical component **110** are inserted through the femoral vein and ultimately advanced into a left atrium of the heart via the inferior vena cava. In such methods, the position and/or the orientation of one or more regions of medical component **110** may be manipulated by one or more of: advancing or withdrawing medical component **110** relative to the distal region of arm **102**, torquing shaft **116** of medical component **110**, engaging one or more steering mechanisms (e.g. pull wires) on medical component **110**, pulling or releasing tether **114**, torquing tether **114**, advancing or withdrawing arm **102**, engaging one or more steering mechanisms (e.g. pull wires) on arm **102**, torquing arm **102** and increasing or decreasing the size of a looped portion of medical component **110**. One or more of the abovementioned manipulations may be performed simultaneously.

[0173] One or more of the method steps disclosed in Figs. 2A – 2D may be performed during a medical procedure. Further, one or more of the method steps disclosed in Figs. 2A – 2D may be performed more than once during a medical procedure. Further, one or more of the method steps disclosed in Figs. 2A – 2D and elsewhere in this document and one or more of the device embodiments disclosed herein may be used to perform one or more of: an electrophysiological ablation procedure, an electrophysiological mapping procedure and an electrophysiological pacing procedure. One or more of the method steps disclosed in Figs. 2A – 2D may be used to treat atrial fibrillation by ablating multiple regions in the left atrium and/or to treat atrial flutter by ablating one or more regions in the right atrium.

[0174] The system described herein is capable of reaching every desired target region of the left atrium during ablation procedures for treating atrial fibrillation. Further, if a long microwave antenna is used as a working element **112**, the resulting lesion is deep, long and transmural. Thus the present invention is capable of forming deep, long, transmural lesions in any orientation and in any location within the left or right cardiac atria for treating electrophysiological disorders such as atrial fibrillation and flutter. This dramatically reduces the time, cost and complexity of therapeutic procedures for treating electrophysiological disorders while increasing their effectiveness.

[0175] The figures in Fig. 2 series show various views of the heart showing the superior vena cava (SVC), inferior vena cava (IVC), the left superior pulmonary vein (LSPV), the left inferior pulmonary vein (LIPV), the right superior pulmonary vein (RSPV), the right inferior pulmonary vein (RIPV), the mitral valve annulus (MVA) and the tricuspid valve annulus (TVA). In Fig. 2A, medical system **100** comprising arm **102** and a looped medical component **110** is introduced through the inferior vena cava (IVC), the right atrium and through a single opening or puncture in the inter-atrial septum into the left atrium. The distal portion of arm **102** has been deflected to enable contact of working element **112** with a region on the left side of the left atrium. A portion of medical component **110** is oriented such that it extends from a region close to the ostium of the left inferior pulmonary vein to the annulus of the mitral valve. Thereafter, a suitable ablative energy e.g. microwave energy may be delivered to create one or more lesions extending from the left inferior pulmonary vein to the annulus of the mitral valve.

[0176] The size of the loop of medical component **110** may be reduced (as shown in Fig. 2B) or increased as desired. Further the deflection on the distal region of arm **102** may also be reduced or increased to position working element **112** at or near the left pulmonary veins (e.g. at or near the left pulmonary vein ridge). Thereafter, a lesion (e.g. an area ablation) on the left pulmonary vein ridge may be created. A small looped medical component **110** may be steered by arm **102** and used to ablate small regions of tissue to fill in any

electrophysiological “gaps” (if any) between adjacent ablations. The distal end of arm **102** may be positioned facing the roof of the left atrium. This position of working element(s) **112** is used to create a long “roof line” lesion on the roof of the left atrium. In Fig. 2F, tether **114** is manipulated to further position one or more working elements **112** on the roof of the left atrium. This step may be used to enable working element **112** to conform to any irregular surface of the left atrium. In Fig. 2G, the distal region of arm **102** is deflected by more than **180** degrees. In one embodiment, the distal region of arm **102** is deflected by about **200 – 280** degrees. This enables the distal end of arm **102** to point towards the right pulmonary vein ostia. In one method embodiment, this orientation of arm **102** wherein the distal end of arm **102** points towards the right pulmonary veins is achieved without torquing arm **102**. Thereafter, looped medical component **110** is advanced relative to the distal end of arm **102** to create one or more lesions around the right pulmonary vein ostia. In Fig. 2D, medical component **110** is partially deployed from the distal end of arm **102**. This arrangement may be used to create shorter lesions.

[0177] Alternate embodiments of medical systems and ablation devices **100** may be designed wherein medical component **110** does not comprise a tether **114**. Fig. 2E shows an embodiment of a medical system similar to the medical system in Fig. 1AA. In the embodiment in Fig. 2I, medical component **110** does not comprise a tether **114**. However, any of the medical components **110** disclosed herein such as shown in Fig. 2E and Fig. 1AA may comprise one or more steering mechanisms to steer or deflect a distal region of medical component **110**. Examples of such steering mechanisms include, but are not limited to one or more: sufficiently stiff stylets, pull wires, hollow tubes and deflectable elongate devices. Such steering mechanisms may be designed such that they cause none or minimal interference with the energy field emitted by elements such as working element **112**. In one such embodiment, one or more steering mechanism is made of a non-metallic material. For example, medical component **110** may comprise one or more internal pull wires made of a polymeric material. The embodiment shown in Fig. 2E may be used for accessing and/or diagnosing and/or treating one or more regions of the left atrium and other anatomical regions using methods similar to those described in Figs. 2A – 2D. In such methods, the position and/or the orientation of one or more regions of medical component **110** may be manipulated by one or more of: advancing or withdrawing medical component **110** relative to the distal region of arm **102**, torquing a shaft of medical component **110**, engaging one or more steering mechanisms (e.g. pull wires) on medical component **110**, advancing or withdrawing arm **102**, engaging one or more steering mechanisms (e.g. pull wires) on arm **102** and torquing or rotating arm **102**. One or more of the abovementioned manipulations may be performed simultaneously. Further, one or more of the abovementioned manipulations may be performed more than once during a medical

procedure. Further, one or more of the method steps disclosed in Figs. 2A – 2D and elsewhere in this document and one or more of the device embodiments disclosed herein may be used to perform one or more of: an electrophysiological ablation procedure, an electrophysiological mapping procedure and an electrophysiological pacing procedure.

[0178] Fig. 2F shows a view of the right atrium showing a step of a method of ablating a portion to treat atrial flutter using the medical system in Fig. 2E. In Fig. 2F, working element **112** is positioned such that it extends from the annulus of the tricuspid valve till the inferior vena cava. Thereafter, working element **112** is used to ablate an area extending from the annulus of the tricuspid valve till the inferior vena cava. In another embodiment, a substantially linear working element **112** is used to ablate a substantially linear region extending from the annulus of the tricuspid valve till the inferior vena cava.

[0179] Method embodiments similar to those shown in Fig. 2F may also be performed using any of the other embodiments of medical system **100** disclosed herein including the medical system **100** of Fig. 1AA.

[0180] Any of the medical systems herein such as those shown in Figs. 1AA and 2E may be used to ablate tissue around the coronary sinus. In one such embodiment, medical component **110** is introduced inside the coronary sinus to ablate tissue. In another embodiment, working element **112** is positioned inside the left atrium and is used to deliver energy such that the ablation extends from the endocardial surface at least till the coronary sinus. In one such embodiment, the ablation may be trans-mural extending from the endocardial surface till the epicardial surface.

[0181] Any of the sheaths or arms such as arm **102** may comprise a steering mechanism. Examples of such steering mechanisms include, but are not limited to pull wires, pre-shaped tubular sheaths and stylet structures. A physician may rotate an arm **102** to cause an articulated distal section **104** to move in an arc-type motion. An arm **102** may comprise a single steering member **128** e.g. a pull wire that extends through a wall of arm **102** so that steering member **128** does not interfere with any devices located in a working lumen **130** of arm **102**.

[0182] In some cases it may be desirable to reposition arm **102** along a three dimensional arc-type path, space, or area without requiring rotation of arm **102**. Since rotation of arm **102** might also rotate medical component **110** located therein, the ability to reposition arm **102** without rotation may be useful to avoid or minimize rotation of at least a proximal portion of medical component **110**. In one embodiment, the steering arm **102** includes a plurality of steering members **128** arranged symmetrically in a wall of the arm **102**. In one such embodiment, three steering member **128** are arranged symmetrically around lumen **130**. Such a symmetrical arrangement of three steering members **128** allows the user to deflect

distal portion **104** in three planes. Devices according to the present invention can include any number of steering members as desired without adversely impacting the size or flexibility of the arm **102**. In the embodiments herein wherein more than two steering members **128** are used, the distal end of arm **102** may be steerable to point in any direction in a three dimensional space without torquing or rotating arm **102**.

[0183] In one embodiment, two steering member **128** are arranged symmetrically around steering arm **102** on opposite sides of lumen **130**. The steering members **128** may be used to deflect distal portion **104** in a single plane. In another embodiment, two steering member **128** are arranged non-symmetrically on steering arm **102**. This enables the user to deflect or steer distal portion **104** of arm **102** in two planes.

[0184] In one embodiment, three steering member **128** are arranged non-symmetrically around lumen **130**. Two of the three steering members **128** are arranged on opposite sides of lumen **130**. Such a non-symmetrical arrangement of three steering members **128** allows the use to deflect distal portion **104** in two planes – a first plane enclosed by the oppositely arranged steering members **128** and a second plane different from the first plane.

[0185] In one embodiment, the four steering member **128** are arranged symmetrically around lumen **130**. Such a symmetrical arrangement of four steering members **128** allows the use to deflect distal portion **104** in two planes – each plane containing two oppositely located steering members **128**.

[0186] In one embodiment, steering member **128** are arranged such that there are two pairs of steering members **128** and the steering members **128** in each pair are located on opposite sides of lumen **130**. Such an arrangement of four steering members **128** allows the user to deflect distal portion **104** in two planes – each plane containing two oppositely located steering members **128**.

[0187] Thus distal portion **104** of arm **102** can be designed using appropriate number and position of steering members **128** to be steered in only a single direction, along two directions, along three directions or steered along four directions. Distal portion **104** of arm **102** can also be designed using appropriate number and position of steering members **128** to be steered in more than four directions. Distal portion **104** of arm **102** can be designed using appropriate number and position of steering members **128** to be steered along a single plane, along two planes and along three planes. Distal portion **104** of arm **102** can also be designed using appropriate number and position of steering members **128** to be steered in more than three planes.

[0188] In one embodiment, steering members **128** are pull wires. In another embodiment, any of the steering members **128** are stylets slidably positioned within arm **102**. The stylets have a sufficient stiffness to steer the distal region **104** of arm **102** when advanced or

withdrawn relative to arm **102**. One or more regions, especially one or more distal regions of the stylets may be pre-shaped. In another embodiment, the stylets can be twisted or torqued by the user to steer the distal regions of arm **102**.

[0189] Any arm **102** disclosed herein may comprise a handle **108** on the proximal region of arm **102**. Handle **108** enables the user to control movement of distal portion **104** of arm **102** by manipulating one or more regions or elements of handle **108**. In one embodiment, handle **108** is connected to one or more steering control mechanisms e.g. pull wires, pre-shaped tubular sheaths or stylet structures. A hub may be located on the proximal end of arm **102**. The proximal end of a lumen of arm **102** may open at the proximal end of hub. Hub may include one or more side ports. The one or more side ports may be used for example to introduce one or more liquids or devices into the lumen of arm **102**.

[0190] Any of the arms **102** may comprise longitudinal slots or passages. Each of the longitudinal slots may enclose a pull wire **128** or other steering member. In one embodiment, pull wires **128** are made of stainless steel coated with PTFE. A pull wire enclosure may be disposed around each pull wire **128**. Pull wire enclosures may be used to reduce friction during operation of the pull wires **128**. Further, pull wire enclosures may be used to prevent the longitudinal slots of arm **102** from collapsing. In one embodiment, a pull wire enclosure is made of a helix or coil of stainless steel coated with PTFE. A lumen of arm **102** may be strengthened by an inner coil. Inner coil may prevent the lumen of arm **102** from collapsing. This in turn reduces the risk of forming a kink or a localized sharp bend in the lumen of arm **102**, especially when distal region **104** of arm **102** is bent or deflected by a large angle such as **180** degrees or more. Such a kink or a localized sharp bend may substantially increase the friction between arm **102** and a device such as medical component **110** introduced through the lumen of arm **102**. Thus preventing the formation of a kink or a sharp bend enables the smooth movement (e.g. translation, rotation) of devices within the lumen of arm **102** even when distal region **104** of arm **102** is bent or deflected by a large angle. Inner coil may also provide sufficient strength to arm **102** such that arm **102** may be pushed or pulled or torqued when introduced inside the anatomy. In one embodiment, inner coil is made of stainless steel.

[0191] Figs. 3A – 3B show an embodiment of an arm **102** having a distal portion **104** capable of being deflected from a planar configuration as shown in Fig. 3A to a non-planar configuration as shown in Fig. 3B. The embodiment of arm **102** shown may comprise one or more steering mechanisms to steer distal portion **104**. In Fig. 3A, distal portion of arm **102** has been deflected from a substantially linear profile to a bent profile as shown. This may be achieved by engaging a first steering mechanism (e.g. a pull wire, a stylet, an inflatable balloon, etc.). Distal portion **104** of arm **102** is substantially planar as shown.

[0192] In Fig. 3B, distal portion of arm **102** has been deflected from a substantially planar, bent profile to a non-planar profile as shown. This may be achieved by engaging a second steering mechanism (e.g. a pull wire, a stylet, an inflatable balloon, etc.). Thus even if distal portion **104** is deflected by more than **180** degrees, the distal end of arm **102** does not get mechanically obstructed by a region of arm **102**. This configuration of arm **102** may be used to carry out any of the method steps disclosed herein. Any of the medical systems **100** disclosed herein may comprise arms **102** that can be converted from a substantially linear configuration to a configuration in which distal portion **104** comprises more than one curve. In one embodiment, a medical system **100** disclosed herein comprises an arm **102** that can be converted from a substantially linear configuration to a configuration in which distal portion **104** is spiral or helical. In the embodiments wherein arm **102** comprises multiple steering mechanisms, one or more steering mechanisms may be different. For example, an arm **102** may be designed using a pull wire and a slidable stylet. In one such embodiment, the distal most portion of the stylet is always located proximal to the distal most portion of the pull wire. In the embodiments wherein arm **102** comprises multiple steering mechanisms, one or more steering mechanisms may be similar or the same. For example, an arm **102** may be designed using two pull wires oriented at varying circumferential positions around arm **102**. Any of the pull wires disclosed herein may be oriented substantially parallel to the length of arm **102** spanned by the pull wire. Any of the pull wires may be oriented in a non-parallel orientation relative to the length of arm **102** spanned by the pull wires. Any of the medical systems **100** disclosed herein may comprise one or more bendable arms **102** wherein the radius of bending may be varied by the user.

[0193] Any of arms **102** disclosed herein may be pre-shaped. Various combinations of embodiments of arm **102** disclosed herein can be used to create medical systems **100**. For example, medical system **100** may be designed with a preshaped arm **102** comprising three steering members **128**.

[0194] Fig. 4A illustrates a first embodiment of a medical system **100** that allows for improved positioning of one or more medical components **110**. As shown, the system **100** includes a first maneuverable or steerable arm **102** and second maneuverable or steerable arm **102** that together manipulate medical component **110** extending between the distal end of the two arms. As discussed in detail below, the system **100** can be equipped to position any number of medical components. In most cases, at least one medical component **110** extends between first arm **102** and second arm **102**. In one embodiment, first maneuverable or steerable arm **102** can be non-movably coupled to the medical component **110**. In such a case, the combination of the first permanently mounted steerable arm **102** and medical

component **110** would itself become a first maneuverable or steerable medical device.

Medical component **110** may comprise one or more working elements.

[0195] Examples of such working elements are disclosed elsewhere in this document. Medical component **110** could also be passive with no working elements. Examples of medical component **110** with at least one working element include, but are not limited to steerable or non-steerable ablation catheters using ablative energies such as radiofrequency, microwave, ultrasound, cryoablative modalities or laser; electrocautery devices and electrosurgical cutting and/or coagulating devices. The working element may not have an electrical component. For example, medical component **110** may comprise a mechanical working element. Examples of such mechanical working elements include, but are not limited to forceps, needle drivers, scissors, graspers, retractors, hooks, obturators, hollow devices such as cannulas and delivery devices for delivering other devices, implants (e.g. artificial valves, occlusion devices, etc.), chemicals, drugs, biological material (stem cells, proteins, hormones, organs, tissues, etc.), etc. Examples of medical component **110** with no working element include, but are not limited to solid or hollow wires and hollow tubes made of polymeric and/or metallic materials.

[0196] Arms **102** as shown in Fig. 4A comprise radiopaque markers **132** located on distal portions **104** of arms **102**. Radiopaque markers **132** and/or other radiopaque components of the devices disclosed herein enable a user to track the location and/or the orientation of distal portions **104** of arms **102** under fluoroscopic visualization. Such radiopaque markers **132** may be located on any device disclosed herein. Alternately, any of the devices disclosed herein may comprise one or more regions of increased or decreased radio-opacity. Such regions of increased or decreased radio-opacity enable the user to accurately determine the location and/or the position and/or the extent of such regions under fluoroscopic visualization. Portions of increased radio-opacity may be created by additions of metallic segments or embedded contrast material into the devices disclosed herein. In one embodiment, at least two portions of medical component **110** or additional devices placed using medical component **110** deployed beyond distal portions **104** of arms **102** have differing radio-opacity. The differing radio-opacity may be used for example, to determine the position and/or the orientation of one or more working elements located on such devices.

[0197] Both the first and the second maneuverable or steerable arms **102** could be non-movably coupled to the medical component **110**. In such a case, the combination of the first and second permanently mounted steerable arms **102** and medical component **110** would itself become a first maneuverable or steerable medical device. Medical component **110**

could also include working elements as described earlier in this paragraph, or include no working element and be passive.

[0198] In any of the embodiments of medical systems **100** comprising multiple arms **102** disclosed herein, two or more of the multiple arms **102** may be similar. In one embodiment, all of the multiple arms **102** of a medical system **100** comprising multiple arms **102** are similar in design. In another embodiment, none of the multiple arms **102** of a medical system **100** comprising multiple arms **102** are similar in design.

[0199] Arms **102** are shown to be substantially parallel to each other in Fig. 4A. In alternate embodiments of medical system **100**, arms **102** may not be substantially parallel to each other. Arms **102** may be introduced into an anatomical region by similar or same paths. For example, arms **102** may both be introduced into the left atrium of the heart from the right femoral vein. In another embodiment, arms **102** may be introduced into an anatomical region by different paths. For example, first arm **102** may be introduced into the left atrium of the heart from the right femoral vein while second arm **102** may be introduced into the left atrium of the heart from the left femoral vein. In another embodiment, first arm **102** may be introduced into the left atrium of the heart from a subclavian vein while second arm **102** may be introduced into the left atrium of the heart from a femoral vein.

[0200] Arms **102** may be coupled to each other. For example, arms **102** may be introduced into the anatomy through a common sheath. In one embodiment, arms **102** are introduced into the anatomy through a single lumen of a sheath. In another embodiment, arms **102** are introduced into the anatomy through two different lumens of a sheath. In another embodiment, a coupling member such as an arm coupling element **184** may be used to couple arms **102** together as shown in Fig. 8A. Arm coupling element **184** may be made of a soft collapsible material. Fig. 8B shows an embodiment of an arm coupling element **184** comprising two lumens. One of the lumens is collapsible as shown, while the other lumen is substantially non-collapsible.

[0201] In those embodiments wherein medical component **110** requires connection to an auxiliary component (e.g., a power supply, imaging monitor, fluid source, etc.), medical component **110** can extend through handle **108** of either arm **102** for connection to a respective auxiliary unit **134**. In some embodiments, handle **108** can include the desired connector.

[0202] One or more regions of medical component **110** can be positioned at a desired location and orientation by performing one or more of the following actions: advancing or withdrawing one or both arms **102**, torquing one or both arms **102**, deflecting or maneuvering or steering the distal portions **104** of arms **102**; and advancing or withdrawing

medical component **110** relative to the distal portions **104** of arms **102**. After the one or more regions of medical component **110** are positioned at the desired location and orientation, a diagnostic or treatment procedure is performed. The diagnostic or treatment procedure can be performed by medical component **110** itself or by an additional device that is placed using medical component **110**. After the diagnostic or treatment procedure is performed, one or more regions of medical component **110** can be repositioned at a second desired location and orientation. Thereafter, a diagnostic or treatment procedure is performed. This sequence can be repeated as needed. Any of the medical components **110** disclosed herein may be used to perform a series of diagnostic and/or therapeutic procedures. In one embodiment, the series of diagnostic and/or therapeutic procedures comprise similar diagnostic and/or therapeutic procedures. For example, medical component **110** can be used to perform a series of therapeutic ablation procedures. In another embodiment, at least two procedures of the series of diagnostic and/or therapeutic procedures are different. For example, medical component **110** can be used to perform a combination of diagnostic electrophysiological sensing or mapping procedures and therapeutic ablation procedures.

[0203] In additional embodiments, any of the medical components **110** disclosed herein may be used to provide a path for a second medical component (not shown) that performs the medical procedure. For example, variations can include the first medical component **110** comprising a rail or guide-wire type of device. Once the physician positions the rail guidewire, the physician can then advance a second treatment or therapeutic component along the rail guidewire to perform a diagnostic or treatment procedure. In an alternate variation, the second treatment component can be a catheter with a working element (where such working element can comprise an electrode for mapping and/or ablation, a sensor, or other active portion).

[0204] In yet an additional variation, the medical component **110** can comprise a hollow sheath or rail, where a medical treatment component can be slidably located therethrough. For example, the medical treatment component can consist of an energy transfer device that delivers energy through the sheath or rail (or an opening located therein) to perform the surgical procedure. Various embodiments of medical system **100** may be configured as delivery systems for delivering a user-selected device using medical system **100**. For example, the combination of arms **102** and a hollow medical component **110** may be used to form a delivery system capable of accurately delivering a standard elongate device (e.g. diagnostic catheters, ablation catheters, imaging catheters, etc.) into the anatomy through hollow medical component **110**.

[0205] Various combinations of embodiments of arms 102 disclosed herein can be used to create medical systems 100 such as shown in Fig. 4A. For example, a medical system 100 may be designed with a first preshaped arm 102 and a second steerable arm 102 comprising three steering members 128. In another embodiment, a medical system 100 may be designed with a first steerable arm 102 comprising a single steering member 128 and a second steerable arm 102 comprising two steering members 128. In another embodiment, a medical system 100 may be designed with a first preshaped arm 102 steered by a single pre-shaped stylet and a second steerable arm 102 comprising two steering members 128.

[0206] Fig. 4B illustrates one possible use of a medical system 100 as shown in Fig. 4A. In this example, medical system 100 is used to perform an endovascular cardiac procedure using one or more medical components 110. As shown, a physician directs first and second arms 102 into the body 10. In this variation, the first and second arms 102 are inserted through the femoral vein 12 and ultimately advanced into a right atrium of the heart 14 via the inferior vena cava. However, any known access methods may be used to gain entry.

[0207] As noted above, arms 102 can be coupled via first and/or second medical components 110 when inserted into the body. Alternatively, medical system 100 is configured so that the medical component(s) 110 can be advanced in and out of (or distal and proximal to) first and second arms 102. This construction allows a physician to remove the medical component 110 from the first arm 102 or second arm 102 to ease insertion of the respective arms 102 into the patient's body. For example, the arms can be inserted into separate entry point or each arm can be separately maneuvered to the target site where the arms are ultimately coupled. In other words, medical system 100 can be inserted into a patient without the arms 102 being coupled by the medical component 110. Once the arms 102 are positioned at or near the target site, medical component 110 can be advanced from first steerable arm 102 to second arm 102. In some variations, medical component 110 can be affixed to one arm 102 so that it engages that arm 102 without extending through the entire length of that arm 102. Alternatively, medical component 110 can be advanced from first arm 102, through second arm 102 until medical component 110 extends out of handle 108 of second arm 102 as shown in Fig. 4B.

[0208] Fig. 4B also shows an optional third steerable arm 102A. As noted above, medical system 100 can include any number of additional steerable arms 102 that can be used to aid in positioning medical component 110. In any case, once the physician places medical system 100 within the target site (the right atrium), arms 102 provide the physician with the improved ability to maneuver the medical component or components 110 using distal portions 104 of arms 102.

[0209] Any of the arms **102** disclosed herein may comprise one or more plastically deformable distal portions **104**. The plastically deformable portions are designed such that they deform elastically while being introduced into the target tissue but can be deformed plastically by the user on application of a sufficient force. Thus, in this embodiment, distal portions **104** are user shapeable.

[0210] Fig. 4C shows an alternate embodiment of the medical system of Fig. 4A showing first medical component **110** comprising six functional elements **112**. In one embodiment, functional elements **112** are electrodes. In one embodiment, the electrodes are electrophysiological radiofrequency ablating electrodes. Although six electrodes are shown in the embodiment of Fig. 4C, additional variations of medical component **110** are possible comprising from one to ten or more electrodes. Thus medical component **110** of Fig. 4C comprises an array of electrodes. In the embodiment, spacing between adjacent functional elements **112** is the same. In an alternate embodiment, the spacing between adjacent functional elements **112** is not the same. In Fig. 4C, the radiofrequency ablating electrodes may be energized independently of each other. In an alternate embodiment, the radiofrequency ablating electrodes may function as an array of electrodes, two or more of which are energized by a single transmission line. In any case, variations of medical system **100** can include electrodes, or other energy delivery means (e.g., microwave antennas, resistive heating elements, or any other energy delivery means disclosed herein) that provide a physician with the ability to create discrete lesions as well as continuous or overlapping lesions.

[0211] In one embodiment, the length of the radiofrequency electrodes is between 0.1 mm and 10 mm. The radiofrequency electrodes may be adapted to transmit radiofrequency energy at a specified frequency lying between 0.1 KHz and 100 MHz. Alternately, instead of radiofrequency electrodes, medical component **110** may comprise other elements for ablating or destroying tissue or other working elements **112** disclosed elsewhere in the specification.

[0212] In any of the embodiments herein, medical component **110** may be adapted to deliver two or more treatment modalities. The two or more modalities may be selected from the group consisting of: radiofrequency energy, microwave energy, a cryogenic zone, laser, ultrasound energy, IR energy, visible light, thermal energy, X-rays and other ionizing radiation and chemicals.

[0213] Fig. 4D shows an alternate embodiment of the medical system of Fig. 4A showing first medical component **110** comprising a long, linear active region **142**. Such a design is useful to diagnose or treat a long segment of tissue. For example, medical component **110** in Fig. 4A and any of the embodiments of working element **112** or active region **142** herein

may be used to ablate a long, linear region of tissue to create a linear ablation. The long, linear active region **142** can be repositioned to another tissue location after a first treatment of tissue. Thereafter, the long, linear active region **142** may be used again to diagnose or treat tissue. In one embodiment shown in Fig. 4D, active region **142** comprises a long, linear microwave antenna. Although only a single microwave antenna is shown in Fig. 4D, embodiments of medical component **110** are possible comprising two or more microwave antennas.

[0214] The length of first medical component **110** extending between the distal regions of arms **102** is substantially uniform in outer diameter. Alternate designs of first medical component **110** are possible where the outer diameter of medical component **110** extending between the distal regions of arms **102** is non-uniform. Also, in Fig 4D, the stiffness of the region of first medical component **110** adjacent to the distal region **104** of one of arms **102** is substantially the same as the stiffness of the region of medical component **110** adjacent to the distal region **104** of the other of arms **102**. Alternate designs of medical component **110** are possible where the stiffness of the region of first medical component **110** adjacent to the distal region **104** of one of arms **102** is substantially different from the stiffness of the region of medical component **110** adjacent to the distal region **104** of the other of arms **102**. In this manner, designs of medical system **100** are possible where a physical property (e.g. stiffness, torquability, outer diameter, cross-sectional shape, radio-opacity, pushability/column strength, presence of one or more lumens, presence of one or more coatings, presence of one or more markers, lubricity, outer surface properties, porosity, storability, conductivity, presence of one or more metallic elements, dielectric constant, presence of one or more exit ports, color, elasticity, presence of one or more functional elements, etc.) of the region of first medical component **110** adjacent to the distal region **104** of one of arms **102** is substantially the same as or different from the physical property of the region of medical component **110** adjacent to the distal region **104** of the other of arms **102**. Embodiments of medical system **100** comprising long linear active regions **142** disclosed herein can be designed to enable a user to place long linear active region **142** in any orientation and any position on the surface of a bodily tissue. Some examples of orientations and positions of long linear active region **142** relative to arms **102** are shown in Figs. 6H – 6K. Such a medical system **100** is advantageous to treat the interior of hollow organs or anatomical cavities in a minimally invasive manner. Arms **102** are introduceable into such hollow organs or anatomical cavities (e.g. lumens) through small sized natural or artificial openings. Thereafter, active region **142** can be placed on one or more locations in the hollow organs or anatomical cavities (e.g. lumens) to treat one or more locations in the hollow organs or anatomical cavities (e.g. lumens).

[0215] Fig. 4E shows an alternate embodiment of the medical system of Fig. 4A showing first medical component **110** comprising a centrally located active region **142** and multiple functional elements **112** on both sides of active region **142**. In an alternate embodiment, one or more functional elements **112** are located only on one side of active region **142**. In Fig. 4E, active region **142** comprises a long, linear region. Such a design is useful to diagnose or treat a long segment of tissue. In Fig. 4E, functional elements **112** may be electrophysiological mapping electrodes. In an alternate embodiment, medical component **110** comprises a centrally located active region **142** and two functional elements **112**, one on each side of active region **142**. In one method embodiment, medical system **100** is introduced or created in the anatomy. Thereafter, active region **142** is used to treat tissue. The signals from treated and/or untreated tissue are obtained from functional elements **112**. Thereafter, active region **142** may be repositioned to treat other regions of the anatomy.

[0216] Fig. 4F shows an alternate embodiment of the medical system of Fig. 4A showing first medical component **110** comprising multiple functional elements **112** and a tether or spline **114**. In the embodiment shown in Fig. 4F, tether or spline **114** is permanently attached to medical component **110**. In an alternate embodiment, tether or spline **114** is attachable to and detachable from medical component **110** by a user. Tether **114** has stiffness less than the stiffness of the region of medical component **110** comprising functional elements **112**. This enables the user to pull or release tether **114** as desired to position first medical component **110** in a desired location and orientation. In Fig. 4F, first medical component comprises a first region containing functional elements **112** and a second region defined by tether **114**. In one embodiment, one or more functional elements **112** are located only on the portion of medical component **110** adjacent to the tether **114** i.e. only on the distal portion of the first region. In one embodiment, tether **114** is floppy or string-like.

[0217] Fig. 4G shows an alternate embodiment of the medical system of Fig. 4A showing an assembly comprising two medical components **110** comprising multiple functional elements **112** joined at their distal ends by a tether or spline **114**. In the embodiment shown in Fig. 4F, tether or spline **114** is permanently attached to medical components **110**. In an alternate embodiment, tether or spline **114** is attachable to and detachable from medical components **110** by a user. Tether **114** has stiffness less than the stiffness of the region of medical components **110** comprising functional elements **112**. This enables the user to collapse the assembly comprising two medical components **110** and tether **114** to a low profile for insertion through a narrow opening. In one embodiment, one or more functional elements **112** are located only on the portion of medical components **110** adjacent to tether **114**. In one embodiment, tether **114** is floppy or string-like.

[0218] Fig. 4H shows an alternate embodiment of the medical system of Fig. 4F showing medical component 110 comprising multiple branches, each branch containing multiple functional elements 112. Each branch is connected to a tether 114. Thus medical component 110 comprises multiple tethers 114. In the embodiment shown in Fig. 4H, tethers 114 are permanently attached to medical component 110. In an alternate embodiment, tethers 114 are attachable to and detachable from medical component 110 by a user. Tethers 114 have stiffness less than the stiffness of the region of medical component 110 comprising functional elements 112. This enables the user to pull tethers 114 and release tethers 114 as desired to position various branches of first medical component 110 in a desired location and orientation. In Fig. 4F, first medical component comprises a first region containing multiple branches, each containing multiple functional elements 112 and a second region defined by tethers 114. In one embodiment, one or more functional elements 112 are located only on the portion of medical component 110 adjacent to tethers 114 i.e. only on the distal portion of the first region. Any of the tethers 114 disclosed herein may be floppy or string-like. The first region of first medical component 110 is designed to be collapsible into an arm 102 for introduction into the anatomy. In the embodiment shown in Fig. 4H, first medical component 110 comprises three branches. Other embodiments are possible containing anywhere between two to ten branches. In an alternate embodiment, each of the branches is a spline that extends from the distal region of one of the arms 102 till the distal region of the other of the arms 102. The branches (splines) in this embodiment may or may not contain any tethers 114.

[0219] Fig. 4I shows an alternate embodiment of the medical system of Fig. 4C showing first medical component 110 comprising a basket containing multiple functional elements 112. The basket comprises multiple branches with each branch containing multiple functional elements 112. In the embodiment shown in Fig. 4I, the multiple branches are substantially parallel to each other. In one embodiment, one or more functional elements 112 are located only on the central portion of the branches. The basket is designed to collapse within an arm 102 for introduction into the anatomy. After exiting arm 102, the basket is designed to expand into an expanded configuration as shown. In the embodiment shown in Fig. 4I, first medical component 110 comprises three branches. Other embodiments are possible containing anywhere between two to ten branches. In an alternate embodiment, the length of the basket region is such that each of the branches extends from the distal region of one of arms 102 till the distal region of the other of arms 102. The branches (splines) in this embodiment do not contain any tethers 114. Features of any of the embodiments shown in Figs. 4C – 4K may be added to other embodiments disclosed herein.

[0220] Fig. 4J shows an alternate embodiment of the medical system of Fig. 4A showing first medical component **110** comprising an active region **142** wherein the active region **142** comprises a balloon. The balloon can be expanded to access target tissue not directly in the path of first medical component **110**. In one embodiment, active region **142** comprises a balloon with an ablation modality selected from the group consisting of: microwave energy, radiofrequency energy, cryo ablation, high intensity ultrasound energy, chemical ablation, laser ablation, ionizing radiation and thermal ablation. The balloon may be made of compliant, semi-compliant or non-compliant materials. The balloon may be inflated by gas or a liquid e.g. saline. In one embodiment, the ablation modality is located inside the balloon. Examples of such ablation modalities include, but are not limited to elements for delivering: lasers, focused ultrasound, cryogenic elements and microwave. The walls of the balloon in such case are adequately transparent to the passage of the energy. In another embodiment, the ablation modality is located on the surface the balloon. Examples of such ablation modalities include, but are not limited to elements for delivering: radiofrequency energy, thermal energy, lasers, focused ultrasound, cryogenic elements and microwave. The walls of the balloon in such case may be adequately resistant to the effects of the ablation modality.

[0221] Fig. 4K shows an alternate embodiment of the medical system of Fig. 4C showing first medical component **110** comprising a mesh basket. The basket comprises multiple branches. In the embodiment shown in Fig. 4K, the multiple branches intersect with each other. The basket is designed to collapse within an arm **102** for introduction into the anatomy. After exiting arm **102**, the basket is designed to expand into an expanded configuration as shown. One or more portions of the basket may have a layer of electrical insulation. In one embodiment, the mesh basket is energized by an energy source such that the energy can be delivered to the surrounding anatomy. For example, the mesh basket may be energized by radiofrequency energy such that the radiofrequency energy can be delivered to the surrounding anatomy.

[0222] Various embodiments of medical system **100** can be designed wherein first medical component **110** comprises only a single functional element **112** or active region **142**. Such embodiments may be adapted to deliver an ablation modality including, but not limited to an ablation modality selected from the group consisting of microwave energy, radiofrequency energy, cryo ablation, ultrasound energy, chemical ablation, laser ablation, IR energy, visible light, X-rays and other ionizing radiation and thermal ablation.

[0223] Any of the components disclosed herein that comprise electrodes may be designed such that the electrodes project out of the outer surface of the component to ensure better

proximity to target tissue. Alternately, the components may be designed such that the electrodes do not project out of the outer surface of the components.

[0224] In additional embodiments, a first medical component **110** may be used to guide the introduction and/or the positioning of a second medical component **122** in the anatomy. Examples of medical systems **100** comprising a first medical component **110** used to guide the introduction and/or the positioning of a second medical component **122** are shown in Figs. 5A – 5F. In Figs. 5A – 5C, first component **110** comprises a tether or rail or guidewire or stylet. First medical component **110** may have one or more coatings on its outer surface. Examples of such coatings include, but are not limited to radio-opaque coatings, lubricious coatings, hydrophilic coatings, hydrophobic coatings. The entire length of first medical component **110** may be radio-opaque. For example, a coaxial cable or other elements supplying microwave energy to working element **112** may be radiopaque. In another embodiment only a segment of first medical component **110** is radio-opaque. In one embodiment, first medical component **110** has a circular cross-section with an outer diameter between 0.5 mm and 3 mm. In one embodiment, first medical component **110** is sufficiently stiff such that the introduction of second medical component **122** over first medical component **110** does not substantially distort the position and the orientation of first medical component **110**.

[0225] As shown in Fig. 5A, second medical component **122** comprises a lumen and can be advanced over first medical component **110** which functions as a rail, guide, or tether. In this embodiment, the lumen is an end-to-end lumen. In such a case, the first and second medical components **110** and **122** comprise separate medical devices. In one embodiment, first medical component **110** is a guidewire. Alternate embodiments of second medical component **122** are possible that do not contain an end-to-end lumen. Fig. 5B shows a variation of the embodiment of Fig. 5A in which second medical component **122** comprises a rapid-exchange lumen. In the embodiments shown in Figs 5A and 5B, functional element **112** on second medical component **122** can be positioned in a desired location and orientation by one or more of: torquing one or both of arms **102**, deflecting a deflectable or steerable region of one or both of arms **102**, advancing or withdrawing one or both of arms **102**, advancing or withdrawing one or both segments of first medical component **110**, advancing or withdrawing second medical component **122** and engaging a steering or deflecting mechanism on second medical component **122**.

[0226] Fig. 5C shows an embodiment of a medical system **100** comprising a first medical component **110** used to guide the introduction and/or the positioning of a second medical component **122** wherein the distal portion of second medical component **122** is offset from the proximal region of second medical component **122**. This embodiment is useful to reach

tissue that does not lie directly on the path of first medical component **110**. In the embodiment shown in Fig. 5C, functional element **112** on second medical component **122** can be positioned in a desired location and orientation by one or more of: torquing one or both arms **102**, deflecting a deflectable or steerable region of one or both arms **102**, torquing second medical component **122**, advancing or withdrawing one or both arms **102**, advancing or withdrawing one or both segments of first medical component **110**, advancing or withdrawing second medical component **122** and engaging a steering or deflecting mechanism on second medical component **122**.

[0227] In Figs. 5A – 5C and Fig. 5E, second medical component **122** may be an energy transfer device having a functional element **112** adapted to transfer energy. Second medical component **122** could also include multiple functional elements **112**. Any of the functional elements **112** discussed herein may be an energy transfer element. For example, a functional element **112** may be one of: radiofrequency electrodes (monopolar or bipolar), a DC resistive heating source, a microwave antenna, ultrasound energy transfer element, laser source, a cryogenic element. Any of the functional elements **112** may be sensors or information receiving elements. For example, such elements can include electrodes (that detect voltage, current and/or impedance), temperature sensors, pressure sensors, light measurement devices, infrared sensors, chemical sensors, radiation sensors, deformation sensors, or any other type of sensors that observe or measure a state or condition of tissue or the body. Such sensors or information receiving elements can also be present on any of the devices disclosed herein. The combination of first medical component **110** and second medical component **122** may be designed such that first medical component **110** does not substantially interfere with the functioning of energy transfer elements **112**. In Figs. 5A – 5C and 5E – 5F, second medical component **122** and/or first medical component **110** may comprise one or more markers e.g. radio-opaque markers to enable a user to track the position of second medical component **122** and/or first medical component **110** in the anatomy. Any of the functional elements **112** herein may be a delivery element for delivering one or more drugs or chemicals (e.g. contrast agent) or biologicals (e.g. stem cells, fibroblasts, etc.). Any of the functional elements **112** may be a mechanical or electromechanical surgical tool.

[0228] In an alternative variation, the first and second medical components **110** and **122** can be integrated in a single device such that energy transfer device or second medical component **122** includes a rail or tether **114** that is affixed to a distal end. Rail or tether **114** can be used to either pull the device through an arm **102** (as a tether member) or provide sufficient column strength and flexibility to aid in positioning of a functional element **112** as desired (as a flexible member or flexible tether). In another variation of medical system **100**, the first and second medical components **110** and **122** can be integrated together as a single

device and a portion of second component **122** is torqueable and a rail or tether portion of component **122** is non-torqueable. Such a variation can be designed, for example, by having the rail or tether portion be more flexible than the torqueable portion of component **122**. Thus when the torqueable portion of second component **122** is twisted by a user, the twist is substantially transmitted to the distal region of first component **110**.

[0229] Fig 5D shows an embodiment of a medical system **100** comprising a first medical component **110** used to guide the introduction and/or the positioning of a second medical component **122** wherein second medical component **122** is enclosed within at least a portion of the first medical component. In the example shown in Fig. 5D, second medical component **122** is slidably enclosed within a lumen of first medical component **110**. The region of second medical component **122** distal to the distal ends of arms **102** is entirely enclosed within the region of first medical component **110** distal to the distal ends of arms **102**. In one embodiment, second medical component **122** comprises an energy transfer element. The energy transfer element of second medical component **122** and first medical component **110** are designed such that the energy can pass through first medical component. In one embodiment, energy transfer element of second medical component **122** comprises a microwave antenna and first medical component **110** is transmissible to microwave energy. In another embodiment, energy transfer element of second medical component **122** comprises one or more radiofrequency ablation electrodes and first medical component **110** is porous. The interior of first medical component **110** may be filled with saline or another suitable conductive medium.

[0230] In another embodiment, energy transfer element of second medical component **122** comprises a laser source and first medical component **110** is transmissible to laser. In the embodiment shown in Fig. 5D, first medical component **110** comprises multiple functional elements **112** on its surface. The design and location of the functional elements **112** of first medical component **110** is such that they do not interfere with the passage of energy emitted by the energy transfer element of second medical component **122**. For example, in one embodiment, second medical component **122** comprises a microwave antenna and multiple functional elements **112** are mapping electrodes. In this embodiment, first medical component **110** is designed such that the microwave energy can pass through first medical component **110** without substantial interference from the mapping electrodes.

[0231] In the embodiment shown in Fig. 5D, energy transfer element of second medical component **122** can be positioned in a desired location and orientation by one or more of: torquing one or both arms **102**, deflecting a deflectable or steerable region of one or both arms **102**, advancing or withdrawing one or both arms **102**, advancing or withdrawing one or both segments of first medical component **110**, advancing or withdrawing one or both

segments of second medical component **122**, engaging a steering or deflecting mechanism on second medical component **122** and engaging a steering or deflecting mechanism on first medical component **110**.

[0232] Fig 5E shows a variation of the embodiment of a medical system **100** of Fig. 5C. In the example shown in Fig. 5E, second medical component **122** further comprises a manipulating member capable of manipulating the distal region of second medical component **122**. In one embodiment, the manipulating member is a wire or tether or string **114** connected to the distal region of second medical component **122**. Manipulating member passes through a lumen of an arm **102**. Manipulating member can be used to deflect the distal end of second medical component **122** to further position functional element **112** in a desired region. In the embodiment shown in Fig. 5E, functional element **112** of second medical component **122** can be positioned in a desired location and orientation by one or more of: torquing one or both arms **102**, deflecting a deflectable or steerable region of one or both arms **102**, advancing or withdrawing one or both arms **102**, advancing or withdrawing one or both segments of first medical component **110**, advancing or withdrawing second medical component **122**, engaging a steering or deflecting mechanism on second medical component **122** and manipulating the manipulating member. In the embodiments where manipulating member has a sufficient stiffness, the step of manipulating the manipulating member comprises one or more of pulling manipulating member, pushing manipulating member and torquing manipulating member. In the embodiments where manipulating member is a wire or tether or string **114** with low stiffness, the step of manipulating the manipulating member comprises one or more of pulling manipulating member and releasing manipulating member. Second medical component **122** may comprise more than one manipulating members. Each of the multiple manipulating members may be attached to or cooperate with differing distal regions on second medical component **122**. One or more elongate medical devices (e.g. steerable sheaths) may slide over any manipulating member or any tether disclosed in this disclosure.

[0233] Fig 5F shows an embodiment of a medical system **100** comprising a hollow first medical component **110** used to guide the introduction and/or the positioning of a second medical component **122** wherein second medical component **122** is enclosed within at least a portion of the first medical component **110**. The region of second medical component **122** distal to the distal ends of arms **102** is entirely enclosed within first medical component **110**. Second medical component **122** comprises one or more functional elements **112** e.g. energy transfer elements. In the example shown in Fig. 5F, second medical component **122** is slidably enclosed within a lumen of first medical component **110**. Thus the position of one or more functional elements **112** is adjustable relative to the position of a region of first medical component **110** distal to the distal ends of arms **102**.

[0234] The energy transfer elements of second medical component **122** may be designed such that the energy can pass through first medical component **110**. In one embodiment, energy transfer element of second medical component **122** comprises a microwave antenna and first medical component **110** is transmissible to microwave energy. In another embodiment, energy transfer element of second medical component **122** comprises one or more radiofrequency ablation electrodes and first medical component **110** is porous. The interior of first medical component **110** may be filled with saline or another suitable conductive medium. In another embodiment, energy transfer element of second medical component **122** comprises a laser source and first medical component **110** is transmissible to laser. In the embodiment shown in Fig. 5D, first medical component **110** also comprises multiple functional elements **112** on its surface. The design and location of the functional elements **112** of first medical component **110** is such that they do not interfere with the passage of energy emitted by the energy transfer element of second medical component **122**. For example, in one embodiment, second medical component **122** comprises a microwave antenna and multiple functional elements **112** are mapping electrodes. In this embodiment, first medical component **110** is designed such that the microwave energy can pass through first medical component **110** without substantial interference from the mapping electrodes. First medical component **110** also encloses a sliding stiffening stylet **144**. In the embodiment shown in Fig. 5F, stiffening stylet **144** is enclosed in a lumen of first medical component **110**. The lumen containing stiffening stylet **144** is separated from the lumen containing second medical component **122** by a partition. The region of first medical component **110** that encloses stiffening stylet **144** is preferably softer than the region of first medical component **110** that encloses second medical component **122**. Thus sliding stiffening stylet **144** changes the shape of the region of first medical component **110** distal to the distal ends of arms **102**.

[0235] In the embodiment shown in Fig. 5F, energy transfer elements of second medical component **122** can be positioned in a desired location and orientation by one or more of: torquing one or both arms **102**, deflecting a deflectable or steerable region of one or both arms **102**, advancing or withdrawing one or both arms **102**, advancing or withdrawing one or both segments of first medical component **110** relative to one or both arms **102**, advancing or withdrawing second medical component **122**, sliding stiffening stylet **144** and torquing stiffening stylet **144**.

[0236] Although in Figs. 5A – 5F, first medical component **110** is shown to introduce a single second medical component **122**, first medical component **110** can comprise features (e.g. extra lumens, larger lumens, positioning elements, etc.) that enable the user to introduce more than one second medical components **122** along the first medical component **110**. In

one method embodiment, multiple second medical components **122** may be introduced simultaneously along the first medical component **110**. For example, two second medical components **122** may be introduced simultaneously through a single lumen of first medical component **110**. In another method embodiment, multiple second medical components **122** may be introduced sequentially along the first medical component **110**. In one such method embodiment, a second medical component **122** is introduced through a lumen of first medical component **110**; the second medical component **122** is used to perform a procedure; the second medical component is removed from the lumen and another second medical component **122** is introduced through the lumen of first medical component **110**.

[0237] Active region **142** in the present invention may be designed to emit any of the energies (e.g. microwave, radiofrequency, ionizing radiation, infra-red light, etc) disclosed herein. Figs. 6A – 6G show various alternate embodiments of the medical system **100** of Fig. 4A wherein elongate active region **142** comprises one or more one or more functional elements **112** in the form of radiofrequency electrodes **112**. Although the embodiments in Figs. 6A – 6G have been substantially described in terms of radiofrequency ablation methods and devices, several microwave ablation devices and methods are also a part of the present invention. The embodiments of Figs. 6A – 6G may also comprise a second medical component **122** that slides over tether **114** of first medical component **110**. In one embodiment, second medical component **122** is a mapping sheath comprising mapping electrodes **118** and a lumen through which one or more fluids such as contrast agents can be introduced into the anatomy. Second medical component **122** may be used to collect electrophysiological information. The electrophysiological information may be used for diagnosis of a disease and/or for determining the outcome of a procedure. As shown in Fig. 6M, the distal ends of first medical component **110** and second medical component **122** in Figs. 6A – 6G may be detachably attachable to each other to create a “U-mode”.

[0238] Fig. 6A shows medical system **100** wherein medical component **110** comprises multiple radiofrequency electrodes. Although Fig. 6A shows medical component **110** comprising four working elements **112** in the form of radiofrequency electrodes, variations of medical system **100** are possible comprising anywhere from 2 – 32 electrodes. Two or more radiofrequency electrodes **112** may be coupled together or energized by a single source. Radiofrequency electrodes **112** may be designed for multi-phase radio-frequency ablation by having multiple radiofrequency electrodes **112** capable of producing multiple current paths in the ablation zone. Radiofrequency electrodes **112** are fed by one or more conducting wires extending through a length of medical component **110**.

[0239] In the embodiments disclosed herein, radiofrequency electrodes **112** are fed by anywhere from one to thirty two conducting wires. Several variations are possible wherein

more than one radiofrequency electrodes **112** are fed by a single conducting wire. In the embodiments herein comprising multiple radiofrequency electrodes **112**, adjoining radiofrequency electrodes **112** may be spaced apart such that the treatment zones formed by adjacent radiofrequency electrodes **112** overlap. For example, the ablation zone formed by two adjoining radiofrequency ablation electrodes **112** may overlap due to heat spread in target tissue to form a single large ablation zone. The multiple radiofrequency ablation electrodes **112** may operate in a monopolar or bipolar configuration. In another embodiment, multiple radiofrequency ablation electrodes **112** are capable of operating in two modes: a monopolar mode or a bipolar mode. A user selects the mode (monopolar or bipolar) depending on his need. For example, the user may select the monopolar mode for creating deep lesions and the bipolar mode for creating surface lesions. In the case of bipolar radiofrequency electrodes **112**, adjacent radiofrequency electrodes **112** may be electrically coupled. In an alternate embodiment of bipolar radiofrequency electrodes **112**, non-adjacent radiofrequency electrodes **112** may be electrically coupled. Multiple radiofrequency ablation electrodes **112** may be energized simultaneously. In another embodiment, multiple radiofrequency ablation electrodes **112** are energized sequentially. In another embodiment, only a few selected multiple radiofrequency ablation electrodes **112** are energized at a time. When one or more of the multiple radiofrequency ablation electrodes **112** are not energized, the non-energized electrodes may have a high impedance. This is useful, for example, to reduce interference from the non-energized radiofrequency ablation electrodes **112**. In one embodiment, medical component **110** comprises multiple radiofrequency electrodes **112** coupled to a reference electrode that is located in the pericardial region. In an alternate embodiment, medical component **110** comprises a single reference electrode coupled to an array of multiple radiofrequency electrodes **112** located in the pericardial region. The voltages used to energize the multiple radiofrequency ablation electrodes **112** may be same or different. The frequencies of radiofrequency energy used to energize the multiple radiofrequency ablation electrodes **112** may be same or different. In one embodiment, the action of one or more multiple radiofrequency ablation electrodes **112** is controlled by controlling the voltage applied to the one or more multiple radiofrequency ablation electrodes **112**.

{0240} The one or more radiofrequency electrodes **112** disclosed in Figs. 6A – 6G may be energized by a variety of controlled waveforms. In one embodiment, the waveforms used to energize one or more radiofrequency electrodes **112** are changeable. The one or more electrodes **112** and associated waveforms may be designed to provide one of the following actions: cutting, coagulating, desiccating and fulgurating tissue. The one or more electrodes **112** and associated waveforms may also be designed to provide multiple actions described above, for example a combination of cutting and coagulating. One or more

electrodes **112** may be designed such that they transmit and/or receive energy uniformly over their surface. Alternately, one or more electrodes **112** may be designed such that they transmit and/or receive energy non-uniformly over their surface. For example, a portion of one or more electrodes **112** may be insulated such that one or more electrodes **112** transmit and/or receive energy only along particular regions.

[0241] Fig. 6B shows medical system **100** wherein medical component **110** comprises a single, long radiofrequency electrode. Radiofrequency electrode **112** may have a length ranging from 5 to 80 mm. Medical component **110** may further comprise additional long radiofrequency electrodes **112**.

[0242] Fig. 6C shows medical system **100** wherein medical component **110** comprises multiple radiofrequency electrodes adapted to function in a monopolar configuration. Radiofrequency electrodes **112** may be energized singly or as a group. More than one radiofrequency electrode **112** may be energized at a time. The medical system **100** in Fig. 6C cooperates with a ground pad **146** that is connected to the patient.

[0243] Fig. 6D shows medical system **100** wherein medical component **110** comprises a steering modality adapted to deflect or otherwise change the shape of active region **142**.

[0244] Fig. 6E shows medical system **100** wherein medical component **110** comprises a single, long radiofrequency electrode arranged in a spiral configuration. Radiofrequency electrode **112** may have a length ranging from 5 to 300 mm. Medical component **110** may further comprise additional radiofrequency electrodes **112** also arranged in spiral configuration.

[0245] Fig. 6F shows medical system **100** wherein medical component **110** comprises multiple long radiofrequency electrodes arranged parallel to each other. In one embodiment, medical component **110** comprises multiple radiofrequency electrodes **112** in the form of multiple parallel splines. Fig. 6G shows a cross sectional view of the embodiment of Fig. 6F through the plane 6G - 6G.

[0246] Any of the functional elements **112** disclosed herein may be heated using resistive heating by an electrical current. The resistively heated electrode may then be used for thermal treatment of tissue.

[0247] One or more radiofrequency electrodes **112** in Figs. 6A – 6G may be slidably positioned on medical component **110**. This allows the user to change the position of one or more radiofrequency electrodes **112** relative to medical component **110**. This can be used, for example, to access multiple target regions of the anatomy without changing the position of medical component **110**. Thus multiple target regions of the anatomy may be treated without changing the position of medical component **110**. In one embodiment, a slidable shaft comprising a single radiofrequency electrode **112** or an array or radiofrequency electrodes **112** is located within a portion of medical component **110**.

[0248] Although most of the embodiments in Figs. 6A – 6G are described in terms of radiofrequency ablation electrodes **112**, it should be noted that one or more of such electrodes may also be electrophysiological mapping electrodes or electrophysiological pacing electrodes. Further an additional ablation modality e.g. microwave ablation, cryoablation, laser ablation, HIFU ablation may be present along with one or more radiofrequency ablation electrodes **112**. In alternate embodiments, the one or more radiofrequency ablation electrodes **112** on the devices disclosed in Figs. 6A – 6G as well as in other devices disclosed herein may be replaced by one or more of: basket electrodes and balloon electrodes. Such basket electrodes and balloon electrodes may have one or more of: elements for delivering HIFU, cryoablation elements, radiofrequency ablation electrodes, microwave antennas and laser ablation elements.

[0249] Any of the embodiments in Figs. 6A – 6G may comprise a sliding second medical component **122** that slides over tether **114** as shown in Figs. 6L and 6M. In one embodiment, second medical component **122** is a mapping sheath comprising one or more mapping electrodes **118**. Any of the embodiments in Figs. 6A – 6G may comprise a modality for obtaining feedback about a procedure or for sensing a patient parameter. For example, medical system **100** may comprise one or more of an impedance measuring modality, temperature measuring modality and pressure measuring modality. Any of the embodiments in Figs. 6A – 6G may comprise a cooling mechanism. Examples of such cooling mechanisms include, but are not limited to: active cooling and passive cooling. Any of the embodiments in Figs. 6A – 6G may be cooled by irrigation with a coolant such as saline. The coolant may be released into the exterior of the embodiment or may be circulated within the interior of the embodiment.

[0250] Active region **142**, functional elements **112** and other regions of the devices disclosed herein may be used to treat a variety of internal organs including, but not limited to stomach, gall bladder, colon, rectum, urinary bladder, uterus and other regions of the female reproductive tract, regions of the male reproductive tract, esophagus, heart, lungs, liver, spleen, small intestine, and other pleural, visceral or peritoneal organs. The procedures may be performed on the surface of such organs, inside lumens or cavities of such organs or within an interior portion of such organs.

[0251] Arms **102** and medical component **110** may be manipulated to position active region **142** and/or functional element(s) **112** in several desired positions and orientations relative to arms **102**. Figs. 6H – 6K show some examples of the medical system **100** with several possible orientations of regions of medical component **110**. In Figs. 6H – 6K, arms **102** are introduced through a single opening or region into an anatomical cavity (e.g. the heart) such that they are introduced substantially parallel to each other. The distal regions of arms

102 have a steering region as shown. In Fig. 6H, arms **102** are introduced in the anatomy (e.g. inside a heart chamber) such that a looped medical component **110** extends between the distal regions of arms **102** as shown. Arms **102** may be advanced relative to one another and then articulated to orient the medical component **110** in a first profile as shown. Medical component **110** comprises an active region **142** (e.g. enclosing a microwave antenna) and multiple functional elements **112** (e.g. mapping electrodes). Active region **142** is spaced away from the shaft of arms **102** and is oriented at an angle of approximately 45 degrees to the length of arms **102** immediately proximal to the distal steering region of arms **102**.

[0252] In the embodiment shown in Fig. 6H, medical component **110** comprises an integral tether **114**. In an alternate embodiment, the distal end of the medical component **110** is reversibly attached to tether **114**. In one such embodiment, the distal end of the medical component **110** comprises an opening. The opening functions essentially like the eye of a needle and allows a user to introduce a looped tether **114** through the opening. An advantage of this construction is the ability to disconnect tether **114** from medical component **110** remotely by opening tether **114** loop at a remote location (e.g. at a proximal region of tether **114**) and pulling a free end of the tether **114**. Tether **114** may be made of suitable metallic or non metallic materials. In one embodiment, tether **114** is made of a radiopaque metallic material such as Nitinol. As with other embodiments shown herein, one or both of arms **102** may be translated and the position of medical component **110** may be adjusted relative to the position of arms **102** to place the component **110** as desired against a contoured surface of tissue.

[0253] In Fig. 6I, arms **102** are manipulated such that active region **142** is oriented substantially perpendicular to arms **102**. In particular, active region **142** is oriented substantially perpendicular to the regions of arms **102** proximal to the steering region. This embodiment may be used, for example, to ablate an ostium of a pulmonary vein. In Fig. 6J, arms **102** are manipulated such that active region **142** is oriented substantially parallel to arms **102**. In particular, active region **142** is oriented substantially parallel to the regions of arms **102** proximal to the steering region. This embodiment may be used, for example, to ablate a linear region of tissue oriented parallel to arms **102**. Fig. 6K shows an embodiment of arms **102** and medical component **110** wherein active region **142** is oriented substantially perpendicular to arms **102**. This embodiment differs from the embodiment shown in Fig. 6I. In Fig. 6I, active region **142** is spaced away from regions of arms **102** proximal to the distal steering regions of arms **102**.

[0254] In Fig. 6K, active region **142** is located in the vicinity of or immediately adjacent to regions of arms **102** proximal to the distal steering regions of arms **102**. Thus active region

142 in Fig. 6K can be used to ablate tissue in the vicinity of arms **102**. In a particular embodiment, arms **102** are introduced in the left atrium of the heart through a trans-septal opening or puncture. Active region **142** is used to treat tissue adjacent to the trans-septal opening or puncture e.g. tissue around the fossa ovalis. Thus active region **142** and regions of medical component **110** containing multiple functional elements **112** can be positioned at various distances from the shafts of arms **102**. The average distance of active region **142** or regions of medical component **110** containing multiple functional elements **112** from the regions of arms **102** proximal to the distal steering regions of arms **102** can range anywhere from 0 to 15 centimeters. Also, active region **142** and regions of medical component **110** containing multiple functional elements **112** can be oriented at various angles relative to the shafts of arms **102**. The average angle of active region **142** or regions of medical component **110** containing multiple functional elements **112** relative to the regions of arms **102** proximal to the distal steering regions of arms **102** can range anywhere from zero to **180** degrees. Similarly, in the embodiments wherein medical component **110** acts as a guide (guidewire, stylet, hollow tube, etc.), regions of second medical component **122** may be positioned at various angles and distances relative to arms **102**.

[0255] The embodiments of Figs. 6H – 6K may also comprise a second medical component **122** (not shown) that slides over tether **114** of medical component **110**. In one embodiment, second medical component **122** is a mapping sheath comprising mapping electrodes **112**. In another embodiment, mapping sheath comprises a lumen through which one or more fluids such as contrast agents can be introduced into the anatomy. Second medical component **122** may be used to collect electrophysiological information. The electrophysiological information may be used for diagnosing a disease and/or for determining the outcome of a procedure. In one embodiment, the region of second medical component **122** emerging from an arm **102** is stiffer than tether **114**. The stiffness of the combination of second medical component **122** and tether **114** may be greater than, equal to or less than the stiffness of the region of medical component **110** distal to the distal region of an arm **102**. Such second medical components **122** may be slidably present over any flexible string or tether **114** disclosed herein.

[0256] While some variations of medical system **100** comprises a tether **114** that has little column strength (essentially used to pull the device), alternate variations of tether **114** include a wire-like member having a sufficient stiffness that allows for improved control of an end of a medical component **110** that is coupled to tether **114**.

[0257] Fig. 6L illustrates a second variation of a medical system **100** according to the present invention. In this variation, a second medical component **122** is advanced over tether **114** of the medical component **110**. Second medical component **122** may comprise any number

of medical devices as described herein. In the illustrated variation, second medical component **122** comprises a catheter tube having working elements **112** such as mapping electrodes. As noted above, second medical component **122** can be coupled to any number of auxiliary sources to deliver fluid (such as saline or a contrast agent), provide suction, deliver additional medical devices/components, or provide visualization.

[0258] Fig. 6L also illustrates an example of the medical component **110** and second medical component **122** having respective mating portions **148** and **150**. When the medical component **110** and second medical component **122** are advanced together, the mating portions **148** and **150** couple together allowing for the combination of medical component **110** and second medical component **122** to behave as a single unitary device as shown in Fig 6M. Medical component **110** and second medical component **122** and the mating portions **148** and **150** maybe be designed to ensure a smooth transition of the outer surface of medical component **110** and second medical component **122** when the mating portions **148** and **150** couple together. In one embodiment, mating portion **148** comprises a tapering region and mating portion **150** comprises a hollow region. In the illustrated embodiment, medical component **110** comprises a microwave ablation device with electrodes **118**.

[0259] In one embodiment, the crosssectional profile of integral tether **114** is smaller than the crosssectional profile of the rest of medical component **110**. Thus the loop formed in the target anatomy by medical component **110** beyond the distal ends of arms **102** is asymmetric – having a slimmer tether **114** and a thicker rest of the medical component **110**. In this embodiment, second medical component **122** comprises a hollow region adapted to slide over tether **114**. When medical component **110** and second medical component **122** are advanced together with a force, the mating portions **148** and **150** couple together allowing for the combination of medical component **110** and second medical component **122** to behave as a single unitary device. Similarly, when the coupled medical component **110** and second medical component **122** are pulled apart with a force, the mating portions **148** and **150** decouple. In an embodiment, the coupling force is substantially the same as the decoupling force.

[0260] As shown in Fig. 6M, the coupled medical component **110** and second medical component **122** can advance between adjacent arms **102** in a similar manner as a single unitary device. Naturally, additional variations of medical system **100** described herein can include a single medical component **110** extended between adjacent arms **102** (as shown in Fig. 6N). In such a case, the medical component **110** can extend fully through arms **102** and exit at the proximal portions of arms **102**. Alternatively, one or more ends of the medical component **110** can terminate inside the arms **102** so that medical component **110** does not need to extend through the entirety of both arms **102**. In one embodiment,

medical component **110** of Fig. 6N comprises one or more working elements. Examples of such working elements include, but are not limited to diagnostic electrodes (e.g. mapping electrodes), ablating elements (radiofrequency ablation electrodes, microwave ablation antennas, cryogenic ablation elements, laser ablation elements, thermal ablation elements, high intensity ultrasound ablation elements, etc.)

[0261] A joint member may be used to mechanically couple tether **114** to medical component **110**. Generally, the joint member allows for increased articulation between flexible tether **114** and medical component **110**. This permits the medical component **110** and tether **114** to form a smaller angle between the joint member **152** and the medical component than would otherwise be attainable given a flexible tether **114**. Basically, such a “V” configuration allows for the medical component **110** and tether **114** (or other component that is joined to medical component **110**) to be inserted into a smaller opening or passage including, but not limited to: coronary sinus and a lumen of any of the anatomical systems (e.g. cardiovascular, gastrointestinal, etc.) disclosed herein. In some cases, the components joined by joint member **152** can be placed parallel to each other (as shown in Fig. 6O). Joint member **152** can be a flexible joint or it can simply be a “string-like” structure that allows for the joined medical components to be connected but easily positioned into the “V” configuration.

[0262] In some circumstances, a physician needs the ability to temporary use a joint member. For example, a joint member may be useful when advancing the medical components to a target site using a narrow profile (as shown in Fig. 6O), but not desired or needed when the components are positioned at the target site. Accordingly, in some variations of medical system **100**, one or more of the components are moveable relative to the joint member to cover the joint member. In one embodiment, tether **114** is axially moveable relative to the joint member. When joint member is covered by tether **114**, medical component **110** mechanically couples to second medical component **122** through tether **114**. When joint member is uncovered by tether **114**, medical component **110** mechanically couples to a second medical component **122** through more flexible joint member. In this configuration, medical component **110** and second medical component **122** can be advanced in the target area in the “V” configuration (as shown in Fig. 6O).

[0263] Fig. 6P illustrates a system **100** wherein a medical component **110** is detachably coupled to a second medical component **122** directly through a joint member **152** but without any rail or tether **114**. As illustrated, medical component **110** and second medical component **122** can include mating portions **148** and **150** so that upon joining mating portions **148** and **150**, joint member **152** is rendered ineffective.

[0264] Figs. 7A – 7D show an embodiment of a method to treat an electrophysiological disease like atrial fibrillation in the heart using minimally invasive techniques. The steps shown in Figs. 7A – 7D need not be performed in the sequence as shown in the figures. The performing physician may alter the treatment sequence. Also, all of the steps shown in Figs. 7A – 7D may not be performed during a treatment. One or more steps shown in Figs. 7A – 7D may be omitted and one or more additional steps be added during the treatment by the performing physician.

[0265] The medical system used for the procedure in Figs. 7A – 7D is shown in detail in Fig. 6Q. The medical system shown in Fig. 6Q while being generally similar to the medical system shown in Fig. 6H, further comprises a hollow second medical component 122. Second medical component 122 slides over a tether or spline 114 of medical component 110. In the embodiment shown in Fig. 6Q, second medical component 102 is a mapping sheath comprising a lumen through which one or more fluids such as contrast agents can be introduced into the anatomy. Second medical component 122 may be used to collect electrophysiological information about a disease and/or the outcome of a procedure. Medical component 110 comprises a long, linear active region 142. In one embodiment, active region 142 comprises a microwave antenna that is capable of ablating a long segment of tissue. The distal ends of medical component 110 and second medical component 122 are reversibly attachable in the anatomy. Medical component 110 is introduced through a first arm 102 and second medical component 122 is introduced through a second arm 102. In medical system 100 shown in Fig. 6Q, the distal end of medical component 110 is reversibly attached to the distal end of second medical component 122 forming a “U-mode” configuration.

[0266] In Fig. 7A, medical system 100 is introduced through an opening into the left atrium (e.g. a trans-septal puncture from the right atrium). Medical system 100 is positioned such that active region 142 of medical system 100 is placed adjoining the left pulmonary vein ostia in the left atrium. In the method embodiment shown in Fig. 7A, the distal end of first arm 102 lies distal to the distal end of second arm 102. Arms 102 may be manipulated by one or more of: torquing one or both arms 102, pulling and/or pushing one or both arms 102, steering the steerable distal end of one or both arms 102. The size and shape of a looped region of medical system 100 can also be further adjusted by advancing and/or withdrawing medical component 110 and/or second medical component 122. Energy (e.g. microwave energy) is applied to ablate a portion of the left atrium adjacent to the left pulmonary vein ostia. In one embodiment, active region 142 creates a long lesion. As with other method embodiments disclosed herein, active region 142 may be repositioned several times to create several long lesions. The lesions are preferably created such that there is

substantial overlap between at least two lesions. In one method embodiment, only a single long lesion is created in the region of the left atrium adjacent to the left pulmonary vein ostia.

[0267] Medical system **100** may be positioned such that active region **142** is placed adjoining the inferior region of the left atrium. This may be done by positioning the distal ends of medical component **110** and second medical component **122** along the proximal direction i.e. opposite to the direction of introduction of arms **102**. In order to achieve this configuration, the distal ends of arms **102** may be designed to deflect more than 90 degrees. Medical system **100** may be positioned such that active region **142** of medical system **100** is placed adjoining the superior region of the left atrium. Thereafter, energy (e.g. microwave energy) is applied to ablate a portion of the left atrium. In one embodiment, active region **142** creates a long lesion.

[0268] In Fig. 7B, medical system **100** is positioned such that active region **142** of medical system **100** is placed adjoining the right pulmonary vein ostia in the left atrium. As with other method embodiments shown in Figs. 7A – 7D, arms **102** may be further manipulated by one or more of: torquing one or both arms **102**, pulling and/or pushing one or both arms **102**, steering the steerable distal end of one or both arms **102**. The size and shape of a looped region of medical system **100** can also be further adjusted by advancing and/or withdrawing medical component **110** and/or second medical component **122**. Thereafter, energy (e.g. microwave energy) is applied to ablate a portion of the left atrium adjacent to the right pulmonary vein ostia.

[0269] In Fig. 7C, medical system **100** is positioned such that active region **142** of medical system **100** is placed adjoining the region between an ostium of the inferior left pulmonary vein and the mitral valve annulus of the left atrium. In medical system **100** shown in Fig. 7C, the distal end of medical component **110** is detached from the distal end of second medical component **122** forming a V-mode. In one method embodiment, the position of active region **142** is changed from that in Fig. 7A to that in Fig. 7C by pulling apart the distal end of medical component **110** from the distal end of second medical component **122** and pushing second arm **102** distally and/or steering the distal end of second arm **102**. As with other method embodiments shown in Figs. 7A – 7D, arms **102** may be further manipulated by one or more of: torquing one or both arms **102**, pulling and/or pushing one or both arms **102**, steering the steerable distal end of one or both arms **102**. The size and shape of a looped region of medical system **100** can also be further adjusted by advancing and/or withdrawing medical component **110** and/or second medical component **122**. Active region **142** is placed on or near the region between an ostium of the inferior left pulmonary vein and the mitral valve annulus of the left atrium. Thereafter, energy (e.g.

microwave energy) is applied to ablate a portion of the left atrium. In one embodiment, active region **142** creates a long lesion. Active region **142** may be repositioned several times to create several long lesions. Multiple lesions may be created using the steps shown in Fig. 7 series such that there is substantial overlap between at least two lesions.

[0270] In one method embodiment, a first lesion is created that isolates the posterior region of the heart (having two left pulmonary veins and two right pulmonary veins) from the rest of the heart (having the mitral valve). It should be noted that the first lesion may comprise multiple overlapping lesions e.g. multiple long overlapping lesions. First lesion may be created using the steps shown in Figs. 7A – 7B. Further, a second lesion may be created that extends from first lesion to a region on the mitral valve annulus of the left atrium. It should be noted that second lesion may comprise multiple overlapping lesions e.g. multiple long overlapping lesions. Second lesion may be created using the step shown in Fig. 7C.

[0271] In Fig. 7D, medical system **100** is positioned such that active region **142** of medical system **100** is placed in the right atrium between a region of the superior vena cava and a region of the inferior vena cava. In the configuration of medical system **100** shown in Fig. 7D, the distal end of medical component **110** is detached from the distal end of second medical component **122** forming a V-mode. As with other method embodiments, arms **102** may be further manipulated by one or more of: torquing one or both arms **102**, pulling and/or pushing one or both arms **102**, steering the steerable distal end of one or both arms **102**. The size and shape of a looped region of medical system **100** can also be further adjusted by advancing and/or withdrawing medical component **110** and/or second medical component **122**. The combination of arm **102** and second medical component **122** may be used to push active region **142** to contact the target tissue. Thereafter, energy (e.g. microwave energy) is applied to ablate a portion of the right atrium. In one embodiment, active region **142** creates a long lesion. Active region **142** may be repositioned several times to create several long lesions. The lesions are preferably created such that there is substantial overlap between at least two lesions. In one method embodiment, only a single long lesion is created in the right atrium between a region of the superior vena cava and a region of the inferior vena cava. In another method embodiment, a first superior long lesion and a second inferior long lesion are created in the right atrium between a region of the superior vena cava and a region of the inferior vena cava such that the first superior long lesion and the second inferior long lesion overlap.

[0272] In one method embodiment, a third lesion is created that extends from the tricuspid valve annulus to a region of the inferior vena cava inferior to the tricuspid valve annulus. It should be noted that third lesion may comprise multiple overlapping lesions e.g. multiple long overlapping lesions. Further, a fourth lesion may be created that extends between a

region of the superior vena cava and a region of the inferior vena cava. It should be noted that fourth lesion may comprise multiple overlapping lesions e.g. multiple long overlapping lesions. Fourth lesion may be created using the step shown in Fig. 7D.

[0273] Although Figs. 7A – 7D mostly disclose the use of devices and methods for creating long linear lesions, various devices and methods of Figs. 7A – 7D may be designed to create point lesions, long curvilinear lesions, lesions covering an area of tissue and lesions covering a volume of tissue. Two or more of such lesions may overlap. When such lesions are created in the heart, one or more of the lesions disclosed herein may be transmural. One or more of the devices and methods disclosed herein may be used to perform variations of the Maze procedure to treat atrial fibrillation. Further, any suitable medical system **100** disclosed herein may be used to perform any of the method steps disclosed herein (e.g. method steps shown in Figs. 7A – 7D) and/or create any of the lesions disclosed herein. Thus medical system **100** of Fig. 6Q is advantageous over current systems that do not allow easy access to all regions of the left atrium and do not allow the positioning of points and/or segments of medical system **100** at any desired orientation on the inner surface of the left atrium. For example, with current radiofrequency ablation systems for treating atrial fibrillation, it is difficult to access the area around the right pulmonary veins in the left atrium and create multiple overlapping lesions.

[0274] Several alternate embodiments of lesions patterns and methods are possible with the present invention. For example, Fig. 7E shows a view of an example of a lesion pattern created in the left atrium using the medical system **100** similar to medical system **100** in Fig. 4C or Fig. 1AA to treat atrial fibrillation. The figure shows a first left pulmonary vein lesion **164** and a second left pulmonary vein lesion **166** that together electrically isolate the left pulmonary veins of the heart from the rest of the heart. First left pulmonary vein lesion **164** and second left pulmonary vein lesion **166** overlap at at least two regions. The figure also shows a first right pulmonary vein lesion **168** and a second right pulmonary vein lesion **170** that together electrically isolate the right pulmonary veins of the heart from the rest of the heart. First right pulmonary vein lesion **168** and a second right pulmonary vein lesion **170** overlap at at least two regions. It should be noted that lesions **164**, **166**, **168**, **170** may comprise multiple overlapping lesions e.g. multiple long overlapping lesions.

[0275] Fig. 7F shows a view of an alternate lesion pattern created in the left atrium using the medical system **100** similar to medical system **100** in Fig. 4C or Fig. 1AA to treat atrial fibrillation. The figure shows a first left pulmonary vein lesion **164**, a second left pulmonary vein lesion **166**, a first right pulmonary vein lesion **168** and a second right pulmonary vein lesion **170** similar to those in Fig. 7E. Further, one of first left pulmonary vein lesion **164** and second left pulmonary vein lesion **166** overlaps with one of first right

pulmonary vein lesion **168** and a second right pulmonary vein lesion **170**. The lesion pattern further comprises a mitral valve lesion **172** that connects a region of the mitral valve annulus to one of first left pulmonary vein lesion **164** and second left pulmonary vein lesion **166**. It should be noted that lesions **164**, **166**, **168**, **170** and **172** may comprise multiple overlapping lesions e.g. multiple long overlapping lesions.

[0276] Fig. 7G show a step in the creation of the lesion pattern as shown in Fig. 7E. In Fig. 7N, a medical system **100** e.g. medical system **100** in Fig. 4C or Fig. 1AA is positioned in the left atrium such that a region of medical component **110** is positioned anterior to the left pulmonary veins as shown. Thereafter, one or more lesions are created anterior to the left pulmonary veins. Medical system **100** may be repositioned in the left atrium such that a region of medical component **110** is positioned posterior to the left pulmonary veins. Thereafter, one or more lesions are created posterior to the left pulmonary veins such that the lesions created in this step overlap with the lesions created previously in the step in Fig. 7N. Thereafter, medical system **100** may be repositioned in the left atrium to create one or more lesions posterior to the left pulmonary veins and anterior to the right pulmonary veins as shown. The steps of repositioning medical system **100** can be made using any of the steps and devices disclosed elsewhere in the specification.

[0277] In any of the embodiments disclosed herein, a looped medical component **110** and/or looped second medical component **122** may be deployed in an anatomical region such that the looped medical component **110** and/or looped second medical component **122** substantially span the entire anatomical region. In one method embodiment, this is done by deploying arms **102** in the anatomical region with a looped medical component **110** and/or looped second medical component **122** connecting the distal regions of arms **102**. Thereafter, looped medical component **110** and/or looped second medical component **122** are expanded in the anatomical region till looped medical component **110** and/or looped second medical component **122** substantially span the entire anatomical region. For example, Fig. 7H shows an embodiment of medical system **100** deployed inside the left atrium such that looped medical component **110** substantially spans the entire left atrium.

[0278] Although a significant amount of the disclosure discloses various embodiments of medical systems **100** used for treating regions of the heart, any device embodiment described herein may also be used to treat other anatomical regions. The devices and methods disclosed herein are especially suited for minimally invasive surgery inside hollow organs, openings or lumens. Examples of such lumens include, but are not limited to lumens in the vasculature, lumen of the gastrointestinal tract, lumens in the mouth or other oropharyngeal regions and lumens in the respiratory system. Medical system **100** may be collapsed for introduction through narrow passages or openings. Embodiments of medical

system **100** may be used to ablate tissue inside or around the coronary sinus. In a particular embodiment medical system **100** is used in the V-mode to ablate tissue inside a coronary sinus.

[0279] Medical system **100** comprising one or more arms **102** and medical component **110** may be introduced non-invasively into the lower esophagus through the nose or mouth to destroy Barrett's tissue. The position and/or the orientation of one or more regions of medical system **100** is tracked using an endoscope. The position and/or the orientation of one or more regions of medical system **100** can also be tracked using fluoroscopy, ultrasound or other imaging modalities disclosed herein. Medical component **110** comprising an active region **142** is manipulated such that active region **142** is adjacent to or in contact with the target tissue. Thereafter, active region **142** is used to treat tissue. The treatment may be tracked using endoscope and/or fluoroscopy or other imaging modalities disclosed herein. After a first region of target tissue is treated, active region **142** may be moved to a second region. The repositioning can be made by any one of the methods disclosed herein. More specifically, active region **142** may be rotated circumferentially along the esophagus or moved along the length of the esophagus. Medical component **110** may be deployed in a helical or spiral configuration inside the esophagus. In one embodiment, medical component **110** has a pre-shaped region that enables medical component to achieve such a helical or spiral configuration. In another embodiment, medical component **110** is twisted by twisting or torquing one of arms **102** such that medical component **110** achieves such a helical or spiral configuration.

[0280] Medical system **100** comprising one or more arms **102** and medical component **110** may be introduced non-invasively into the uterus through the vagina and the cervix for endometrial ablation. The position and/or the orientation of one or more regions of medical system **100** may be tracked using an external ultrasound device. The position and/or the orientation of one or more regions of medical system **100** can also be tracked using fluoroscopy, hysteroscopy, trans-vaginal ultrasound or any other imaging modalities disclosed herein. Arms **102** may have one or more distance markers along the length of arms **102** to indicate the depth of insertion of arms **102** into the uterine cavity. Active region **142** may be positioned inside the uterus and oriented perpendicular to the path of insertion of arms **102**. In one embodiment, the configuration of medical system **100** is similar to the configuration of medical system **100** in Fig. 4C. After a first region of target tissue is destroyed, active region **142** may be moved to a second region and a second region of the endometrium may be ablated. More specifically, active region **142** may be pulled proximally towards the cervix.

[0281] Medical system **100** comprising one or more arms **102** and medical component **110** may be introduced non-invasively into the lower esophageal region enclosed by the lower esophageal sphincter through the nose or mouth for treating GERD (Gastroesophageal reflux disease). The method may be similar to the method used for treating Barrett's tissue. Arms **102** may have one or more distance markers along the length of arms **102** to indicate the depth of insertion of arms **102** into the esophagus. In this embodiment, active region **142** is used to deliver energy that causes shrinkage of tissue. Active region **142** may be rotated within the esophagus if needed.

[0282] Figs. 8A and 8B show two embodiments of arm coupling elements **184** that may be used to mechanically couple two or more arms **102** disclosed herein. Such arm coupling elements **184** may be used along with any of the arms **102** in any of the medical systems **100** disclosed herein. In Fig. 8A, an arm coupling element **184** comprises two lumens. A first arm **102** is located within a lumen of arm coupling element **184** and a second arm **102** is located within another lumen of arm coupling element **184**. Arm coupling element **184** in this embodiment is made of a sufficiently stiff material such that the lumens of arm coupling element **184** are substantially non-collapsible. The inner lining of any of the lumens of devices herein such as that of arm coupling elements **184** may be lined with a layer of PTFE or other materials to reduce friction. Fig. 8B shows an embodiment of an arm coupling element **184** comprising a non-collapsible lumen **184A** and one or more collapsible lumens **184B**. Collapsible lumen **184B** is substantially collapsed when it does not enclose a device. This allows the reduction of the overall cross sectional profile of arm coupling element **184**. In one embodiment, an arm **102** is introduced through non-collapsible lumen **184A**. Thereafter, if needed, a second arm **102** is introduced through collapsible lumen **184B**. Such a design comprising one or more collapsible lumens may be used to design any of the arms **102** disclosed herein. In such embodiments, a portion of medical component **110** may pass through a lumen of arm **102** and one or more portions of medical system **100** may pass through the one or more collapsible lumens.

[0283] Fig. 9A shows another example of a system **100** where a second medical component **122** advances over a medical component **110**. Second medical component **122** is introduced through a first arm **102** and medical component **110** is introduced through second arm **102**. In the illustrated variation second medical component **122** is an energy delivery catheter and medical component **110** comprises a tether or rail. As noted herein, the system **100** can be used with any number of medical components. In the illustrated variation, second medical component **122** comprises an energy transfer device having an active region **142** along with one or more additional working elements **112**. Examples of working elements **112** are disclosed elsewhere in the specification. In one embodiment,

working elements **112** are selected from the group comprising of one or more: radiofrequency electrodes (monopolar or bipolar), mapping electrodes, DC resistive heating sources, microwave antennas, ultrasound energy transfer elements, laser sources and cryogenic elements.

[0284] As shown, the second medical component **122** can advance over the medical component **110** which functions as a rail, guide, or tether. In such a case, the first and second medical components **110** and **122** comprise separate medical devices. In an alternative variation, the first and second medical components **110** and **122** can be integrated together as a single device where the energy transfer device or component **122** includes a rail or tether that is affixed to a distal end. In such a case, rail or tether can be used to either pull the device through the second arm **102** (as a tether member) or provide sufficient column strength and flexibility to aid in positioning of the active region **142** as desired (as a rail member or flexible tether).

[0285] Fig. 9A also illustrates the use of an optional third arm **102** that is coupled to either medical component **110** or second medical component **122**. In the illustrated variation, third arm **102** comprises a grasping structure **178** used to removably engage either of medical component **110** or second medical component **122**. Third arm **102** allows a physician with another means of positioning medical component **110** and/or second medical component **122** to perform the desired procedure. Grasping structure **178** allows third arm **102** to be introduced into or removed from the operative space at any point during the procedure. Any number of grasping mechanisms can be employed including hooks, rings, grasping jaws, etc. Instead of a third arm **102**, any other accessory positioning device such as a magnetic device may be used to position medical component **110** and/or second medical component **122**.

[0286] Fig. 9B illustrates a variation of a system **100** under the present invention where the medical component **110** is coupled adjacent to the arms **102** via coupling portions **180** rather than being introduced through the arms as shown in some of the previous figures. As noted above, coupling portions **180** can comprise ring or tube structures. Alternatively, the coupling portions **180** can consist of a grasping mechanism such as grasping structure **178** discussed above. In this variation, medical component **110** comprises an energy transfer region **142**.

[0287] Figs. 10A – 10DA show various views of a first embodiment of a medical system comprising a hollow tube through which an elongate looped medical component is slidably introduced. Fig. 10A shows a side view of a medical system **100** comprising an introducer sheath **186**. Introducer sheath **186** encloses a lumen through which an elongate functional tube **188** is introduced. Any functional tube **188** disclosed herein may comprise one or

more working elements **112**. In one embodiment, functional tube **188** comprises one or more mapping electrodes. In an alternate embodiment, functional tube **188** does not comprise any functional elements **112**. Any functional tube **188** disclosed herein may be porous or non-porous. Functional tube **188** is looped such that the two ends of functional tube **188** pass through introducer sheath **186** and exit through the proximal end of introducer sheath **186**. One or both of the two ends of functional tube **188** may be advanced and/or retracted and/or torqued or twisted to position functional tube **188** as desired in the anatomy. The looped region of functional tube **188** distal to the distal end of introducer sheath **186** may be twisted or turned or otherwise distorted. The size of the looped region of functional tube **188** distal to the distal end of introducer sheath **186** may be increased or decreased as needed. In the embodiment shown in Fig. 10A, functional tube **188** comprises an integral steering mechanism **190** integral to a portion of functional tube **188**.

[0288] In one embodiment as shown in Fig. 10A, integral steering mechanism **190** is a pre-shaped, sufficiently rigid portion of functional tube **188**. In another embodiment, integral steering mechanism comprises one or more displaceable elements such as pull wires, tethers, stylets, etc. Integral steering mechanism **190** may be used to further manipulate the section of functional tube **188** enclosed by integral steering mechanism **190**. Functional tube **188** encloses a medical component **110** comprising an active region **142**. Medical component **110** is slidably located within functional tube **188**. In the embodiment shown in Fig. 10A, medical component **110** comprises a tether **114**. Medical component **110** may be pulled and/or pushed and/or torqued or twisted to position medical component **110** relative to functional tube **188**. In one embodiment, manipulation of medical component **110** leads to a change in the position and/or orientation of one or more portions of functional tube **188**. In another embodiment, manipulation of medical component **110** does not change the position and/or orientation of one or more portions of functional tube **188**. Medical system **100** further comprises an arm **102** located within functional tube **188**. Arm **102** comprises a lumen that encloses tether **114** of medical component **110**. Arm **102** is slidably positioned relative to tether **114**. Arm **102** may be advanced and/or retracted and/or torqued or twisted to position functional tube **188** as desired in the anatomy. Further, arm **102** may comprise a steering modality to further position functional tube **188**. Examples of such steering modalities are disclosed elsewhere in the specification. In one embodiment, medical component **110** is a microwave ablation catheter and functional tube **188** is designed such that microwave energy passes through functional tube **188** to ablate surrounding anatomical regions. In this embodiment, working elements **112** on functional tube **188** are designed such that they do not substantially interfere with the microwave energy emitted by medical component **110**. In the embodiment in Fig. 10A, one or more

regions of medical component **110** may be positioned in the anatomy by one or more of: pulling or releasing tether **114**; pulling and/or pushing and/or torquing or twisting medical component **110**; advancing and/or retracting and/or torquing or twisting one or both of the two ends of functional tube **188**; engaging integral steering mechanism **190**; engaging a steering mechanism on arm **102**; advancing and/or withdrawing and/or torquing or twisting arm **102** and advancing and/or withdrawing and/or torquing or twisting introducer sheath **186**. One or more regions of medical component **110** may be repositioned as needed to access and treat one or more anatomical regions. In one embodiment shown in Fig. 10B, integral steering mechanism **190** and arm **102** are manipulated such that a portion of functional tube **188** extends in the proximal direction proximal to the distal end of introducer sheath **186**. In Fig. 10B, a portion of functional tube **188** lies adjacent to or in contact with a portion of introducer sheath **186** proximal to the distal end of introducer sheath **186**.

[0289] Fig. 10C shows a cross sectional view through the medical system of Fig. 10A through plane 10C – 10C. Fig. 10C shows introducer sheath **186** enclosing two segments of functional tube **188**. One of the segments of functional tube **188** comprises integral steering mechanism **190** in the form of a sufficiently stiff, bent or pre-shaped region of functional tube **188**. This segment of functional tube **188** encloses medical component **110**. The other of the segments of functional tube **188** encloses arm **102** which in turn encloses tether **114**. Fig. 10D shows a cross sectional view through the medical system of Fig. 10A through plane 10D – 10D. Fig. 10DA shows a cross sectional view through the medical system of Fig. 10A through plane 10DA – 10DA.

[0290] Figs. 10E – 10HA show various views of a second embodiment of a medical system comprising a hollow tube through which an elongate looped medical component is slidably introduced. In Fig. 10E, introducer sheath **186** encloses a lumen through which an elongate functional tube **188** is introduced. Functional tube **188** is looped such that the one end of functional tube **188** passes through introducer sheath **186** and exits through the proximal end of introducer sheath **186**. The other end of functional tube **188** terminates outside introducer sheath **186** and is located adjacent to the distal end of introducer sheath **186**. The end of functional tube **188** passing through introducer sheath **186** may be advanced and/or retracted and/or torqued or twisted to position functional tube **188** as desired in the anatomy. The looped region of functional tube **188** distal to the distal end of introducer sheath **186** may be twisted or turned or otherwise distorted.

[0291] The size of the looped region of functional tube **188** distal to the distal end of introducer sheath **186** may be increased or decreased as needed. In the embodiment shown in Fig. 10E, a first arm **102** comprising a steering mechanism is slidably positioned over a

portion of functional tube **188** distal to the distal end of introducer sheath **186**. First arm **102** may be pre-shaped and have sufficient rigidity to manipulate a portion of functional tube **188**. In another embodiment, first arm **102** comprises one or more displaceable steering elements such as pull wires, tethers, stylets, etc. First arm **102** may be used to further manipulate the section of functional tube **188** enclosed by first arm **102**. Functional tube **188** encloses a medical component **110** comprising an active region **142**. Medical component **110** is slidably located within functional tube **188**. In the embodiment shown in Fig. 10E, medical component **110** comprises a tether **114**.

[0292] Medical component **110** may be pulled and/or pushed and/or torqued or twisted to position medical component **110** relative to functional tube **188**. In one embodiment, manipulation of medical component **110** leads to a change in the position and/or orientation of one or more portions of functional tube **188**. In another embodiment, manipulation of medical component **110** does not change the position and/or orientation of one or more portions of functional tube **188**. Medical system **100** further comprises a second arm **102** located within functional tube **188**. Second arm **102** comprises a lumen that encloses tether **114** of medical component **110**. Second arm **102** is slidably positioned relative to tether **114**. Second arm **102** may be advanced and/or retracted and/or torqued or twisted to position functional tube **188** as desired in the anatomy. Further, second arm **102** may comprise a steering modality to further position functional tube **188**. Examples of such steering modalities are disclosed elsewhere in the specification.

[0293] In one embodiment, medical component **110** is a microwave ablation catheter and functional tube **188** is designed such that microwave energy passes through functional tube **188** to ablate surrounding anatomical regions. In this embodiment, working elements **112** on functional tube **188** are designed such that they do not substantially interfere with the microwave energy emitted by medical component **110**. In the embodiment in Fig. 10E, one or more regions of medical component **110** may be positioned in the anatomy by one or more of: pulling or releasing tether **114**; pulling and/or pushing and/or torquing or twisting medical component **110**; advancing and/or retracting and/or torquing or twisting one end of functional tube **188**; engaging a steering modality on first arm **102** and/or second arm **102**; advancing and/or withdrawing and/or torquing or twisting first arm **102** and/or second arm **102** and advancing and/or withdrawing and/or torquing or twisting introducer sheath **186**. One or more regions of medical component **110** may be repositioned as needed to access and treat one or more anatomical regions. In one embodiment shown in Fig. 10F, first arm **102** and second arm **102** are manipulated such that a portion of functional tube **188** extends in the proximal direction proximal to the distal end of introducer sheath **186**. In Fig. 10F, a portion of functional tube **188** lies adjacent to or in contact with a portion of introducer sheath **186** proximal to the distal end of introducer sheath **186**. Fig. 10G shows a cross

sectional view through the medical system of Fig. 10E through plane 10G – 10G. Fig. 10G shows two portions of functional tube **188**. One of the portions of functional tube **188** is enclosed within first arm **102**. This segment of functional tube **188** encloses medical component **110**. The other of the segments of functional tube **188** encloses second arm **102** which in turn encloses tether **114**. Fig. 10H shows a cross sectional view through the medical system of Fig. 10A through plane 10H – 10H. In Fig. 4C, only one segment of functional tube **188** is seen enclosed within introducer sheath **186**. Fig. 10HA shows a cross sectional view through the medical system **100** of Fig. 10A through plane 10HA – 10HA.

[0294] Figs. 10I – 10LA show various views of a third embodiment of a medical system comprising a hollow tube through which an elongate looped medical component is slidably introduced. In Fig. 10I, introducer sheath **186** encloses a lumen through which an elongate functional tube **188** is introduced. Functional tube **188** is looped such that the one end of functional tube **188** passes through introducer sheath **186** and exits through the proximal end of introducer sheath **186**. The other end of functional tube **188** terminates outside introducer sheath **186** and is located distal to the distal end of introducer sheath **186**. The end of functional tube **188** passing through introducer sheath **186** may be advanced and/or retracted and/or torqued or twisted to position functional tube **188** as desired in the anatomy.

[0295] The looped region of functional tube **188** distal to the distal end of introducer sheath **186** may be twisted or turned or otherwise distorted. The size of the looped region of functional tube **188** distal to the distal end of introducer sheath **186** may be increased or decreased as needed. In the embodiment shown in Fig. 10I, a first arm **102** comprising a steering mechanism is slidably positioned over a portion of functional tube **188** distal to the distal end of introducer sheath **186**. First arm **102** may be pre-shaped and have sufficient rigidity to manipulate a portion of functional tube **188**. In another embodiment, first arm **102** comprises one or more displaceable steering elements such as pull wires, tethers, stylets, etc. First arm **102** may be used to further manipulate the section of functional tube **188** enclosed by first arm **102**. Functional tube **188** encloses a medical component **110** comprising an active region **142**. Medical component **110** is slidably located within functional tube **188**. Medical component **110** may be pulled and/or pushed and/or torqued or twisted to position medical component **110** relative to functional tube **188**. In one embodiment, manipulation of medical component **110** leads to a change in the position and/or orientation of one or more portions of functional tube **188**. In another embodiment, manipulation of medical component **110** does not change the position and/or orientation of one or more portions of functional tube **188**.

- [0296] Medical system **100** further comprises a second arm **102** that encloses first arm **102**. Second arm **102** comprises a lumen that encloses first arm **102** which in turn encloses functional tube **188** which in turn encloses medical component **110**. Second arm **102** is slidably positioned relative to first arm **102**. A distal region of second arm **102** is connected to the distal end of functional tube **188** by a flexible connector **192**. Second arm **102** may be advanced and/or retracted and/or torqued or twisted to position functional tube **188** as desired in the anatomy. Further, second arm **102** may comprise a steering modality to further position functional tube **188**. Examples of such steering modalities are disclosed elsewhere in the specification. In one embodiment, medical component **110** is a microwave ablation catheter and functional tube **188** is designed such that microwave energy passes through functional tube **188** to ablate surrounding anatomical regions. In this embodiment, working elements **112** on functional tube **188** are designed such that they do not substantially interfere with the microwave energy emitted by medical component **110**.
- [0297] In the embodiment in Fig. 10I, one or more regions of medical component **110** may be positioned in the anatomy by one or more of: pulling and/or pushing and/or torquing or twisting medical component **110**; advancing and/or retracting and/or torquing or twisting one end of functional tube **188**; engaging a steering modality on first arm **102** and/or second arm **102**; advancing and/or withdrawing and/or torquing or twisting first arm **102** and/or second arm **102** and advancing and/or withdrawing and/or torquing or twisting introducer sheath **186**. One or more regions of medical component **110** may be repositioned as needed to access and treat one or more anatomical regions. In one embodiment shown in Fig. 10J, first arm **102** and second arm **102** are manipulated such that a portion of functional tube **188** extends in the proximal direction proximal to the distal end of introducer sheath **186**. In Fig. 10J, a portion of functional tube **188** lies adjacent to or in contact with a portion of introducer sheath **186** proximal to the distal end of introducer sheath **186**. Fig. 10K shows a cross sectional view through the medical system of Fig. 10I through plane 10K – 10K. Fig. 10K shows introducer sheath **186** enclosing two arms **102** that in turn enclose functional tube **188** which in turn encloses medical component **110**. Fig. 10L shows a cross sectional view through the medical system of Fig. 10I through plane 10L – 10L. Fig. 10LA shows a cross sectional view through the medical system of Fig. 10I through plane 10LA – 10LA.
- [0298] Several embodiments described herein have a looped medical system **100** comprising two arms **102** and an elongate device or devices that connect the distal regions of arms **102**. For example, Fig. 4A shows a looped medical system **100** comprising arms **102** and a single elongate medical component **110** that connects the distal regions of arms **102**. Fig. 5A shows a looped medical system **100** comprising arms **102** and a combination of

elongate medical component **110** and second medical component **122** that connects the distal regions of arms **102**. In such looped medical system **100** embodiments, the looped medical system **100** may be introduced into the target anatomical site as a pre-assembled system. Such a pre-assembled medical system **100** may be collapsible and flexible for introduction through narrow lumens and cavities. In an alternate method embodiment, two arms **102** are introduced in the body. Thereafter, the distal regions of arms **102** are connected by one or more elongate devices to create a looped medical system **100** in the body.

[0299] In another method embodiment, a looped access is created between 2 openings in the body using a looped auxiliary device. Thereafter, the looped auxiliary device is used to create looped medical system **100** in the body such that arms **102** exit the body through the 2 openings. In one method embodiment of using a looped auxiliary device to create looped medical system **100** in the body, a looped access is created between 2 openings in the body using the looped auxiliary device. Thereafter, arms **102** are introduced through the 2 openings over the looped auxiliary device. Thereafter, arms **102** are navigated to the target anatomy. Thereafter, looped auxiliary device is exchanged for medical component **110** or a combination of medical component **110** and second medical component **122**. To illustrate this example, consider the location of medical system **100** in medical Fig. 7A. Medical system **100** can be deployed in this position by creating a looped access between 2 openings to the femoral vein using the looped auxiliary device. Thereafter, arms **102** are introduced through the 2 femoral vein openings over the looped auxiliary device. Arms **102** are navigated through the inferior vena cava and the right atrium to the left atrium through a previously created trans-septal puncture. Thereafter, looped auxiliary device is exchanged for medical component **110** or a combination of medical component **110** and second medical component **122**.

[0300] Any of the embodiments of medical system **100** described herein that comprise more than one arm **102** (e.g. medical system **100** in Fig. 4A) may be modified such that a single arm **102** is used to introduce medical component **110** and other components of medical system **100** disclosed herein. In one such embodiment, a medical component **110** is disposed within an arm **102** such that two elongate regions of medical component **110** are enclosed within arm **102** and a looped portion of medical component **110** extends beyond the distal end of arm **102**. In another such embodiment, a medical component **110** is disposed within an arm **102** such that one of the elongate regions of medical component **110** is enclosed within arm **102** and the other of the elongate regions of medical component **110** is located outside arm **102**. The two elongate regions of a looped medical component **110** may be present in a single lumen or in two separate lumens or compartments of arm **102**. For example, the medical system **100** in Fig. 4F may be redesigned such that a single

arm 102 is used to introduce entire medical component 110 including tether 114 into the anatomy. In another example, the medical system 100 of Fig. 4G may be modified such that both medical components 110 are introduced through a single arm 102. Two medical components 110 of Fig 4G may be located within a single lumen or in two separate lumens or compartments of arm 102.

[0301] Further, any of the embodiments of medical system 100 described herein that comprise a single arm 102 (e.g. medical system 100 in Fig. 1AA) may be modified such that more than one arm 102 is used to introduce medical component 110 and other components of medical system 100 disclosed herein. In one such embodiment, an additional arm 102 mechanically cooperating with a first arm 102 is used to manipulate the position and/or the orientation of one or more regions of a medical component 110.

[0302] Embodiments of medical system 100 herein may provide many degrees of freedom to position medical component 110 and/or working element 112 in any number of positions or profiles from a linear shape to simple two dimensional curves to complex three dimensional profiles that conform to a targeted region of tissue.

[0303] Any of devices disclosed herein such as medical component 110 or arm 102 may comprise one or more of any of the steering mechanisms disclosed herein. Such steering mechanisms may be designed such that they do not interfere with the working of medical component 110. For example, in embodiments wherein medical component 110 emits microwave energy, medical component 110 may comprise one or more pull wires or other steering mechanisms made of non-metallic materials such as plastic or polymer materials.

[0304] Any of the devices (e.g. medical component 110 or an arm 102) or components (e.g. a tether 114) disclosed herein may have additional features that enable the user to obtain information about one or more of: position and/or orientation of one or more components of medical system 100, contact and/or proximity of one or more components of medical system 100 to anatomical regions, images of anatomical regions, real-time information of tissue properties (e.g. temperature, electrical activity, viability, echogenicity, etc.), a physiological parameter of the patient's body, presence of one or more devices, feedback of the success or efficacy of a procedure and risky situations arising from too much force or pressure on the anatomy. In one embodiment, a component of medical system 100 comprises a force sensor to measure forces transmitted along the shaft or the one or more components of medical system 100. This may be used to determine tissue contact by the one or more components. In another embodiment, a component of medical system 100 comprises a temperature sensing modality such as a thermocouple. In another embodiment, a component of medical system 100 comprises a pressure sensor. In another embodiment, a component of medical system 100 comprises an impedance sensor. Such an impedance

sensor can be used to determine the success or efficacy of an ablation procedure. In another embodiment, a component of medical system **100** comprises an embedded intra-cardiac echography probe. In another embodiment, a component of medical system **100** comprises an embedded imaging probe capable of imaging in the non-visible electromagnetic spectrum. In an embodiment, a device or component disclosed herein comprises one or more electrodes. In one such embodiment, a device or component disclosed herein comprises multiple electrodes wherein at least two of the multiple electrodes differ in their design. In another such embodiment, a device or component disclosed herein comprises multiple electrodes wherein at least three of the multiple electrodes differ in their design.

[0305] Any of the devices or components herein may comprise a position feedback mechanism to determine the position of the device or components inside the anatomy. In one embodiment, the position feedback mechanism is a means for introducing a dye (e.g. a visually detectable dye) or a contrast agent (e.g. a radiopaque or ultrasound contrast agent) inside the anatomy. In another embodiment, the position feedback mechanism comprises one or more electrodes. In another embodiment, the position feedback mechanism comprises one or more distance markers located on an outer surface of the device or component. In one such embodiment, a medical component **110** introduceable through an arm **102** comprises one or more distance markers on the proximal region of medical component **110**. In clinical use, the distance markers lie outside the body of the patient. The relative distance between the distance markers and a proximal portion of arm **102** enables the user to determine the relative distance between the distal ends of arm **102** and medical component **110**. This in turn may be used to determine the degree of deployment of the distal region of medical component **110** relative to arm **102**.

[0306] Any of the devices and methods disclosed herein may be used for electrophysiological isolation of the pulmonary veins (PVs) to treat atrial fibrillation. This may be done by creating one or more lesions around the pulmonary vein ostia. In one such embodiment, an anchoring mechanism is used to reversibly anchor to a region inside or around the pulmonary vein ostia. Thereafter, a medical system **100** mechanically coupled to the anchoring mechanism is used to create a series of lesions around one or more pulmonary vein ostia. The anchoring mechanism may be one or more of: anchoring balloons that may be anchored inside the pulmonary veins, guidewires that are inserted inside the pulmonary veins, magnetic devices, devices comprising a means for applying a vacuum, etc. The medical system **100** may be pivoted around such an anchoring mechanism.

[0307] Several embodiments of user interfaces may be designed to manipulate one or more regions of medical system **100** in the anatomy. In one embodiment, the user interface is a

haptic system. The haptic system may have one or more of: force-feedback ability, ability to apply vibrations to the user and ability to apply one or more motions to the user. In another embodiment, the user interface comprises a joystick. The joystick may have a force feedback capability. The joy stick may be configured to have one, two, three or more planes of motion. In a particular embodiment, the planes of motion of the joystick correspond to the planes of steering of one of arms **102**. In one embodiment, medical system **100** comprises 2 joysticks – each joystick controlling the movement of the distal portion of an arm **102**. The joystick(s) may be mounted on a console. The console may contain additional features such as displays for fluoroscopy, displays for pre-procedure imaging results, results of a real-time diagnostic modality, displays of the medical system **100** position, etc.

[0308] In one embodiment, the user interface is similar to the SenseiTM System made by Hansen Medical, Mountain View, CA. In this embodiment, the user interface of medical system **100** comprises one or two robotic controllers along with several displays. The displays may display one or more of the following: fluoroscopic images, EKG data, X-ray images, intra-cardiac ultrasound images, external ultrasound images, pre-procedure electrophysiology maps, pre-procedure anatomical maps created from pre-procedure imaging, etc. Such a medical system **100** can be designed to introduce a user selected catheter into the anatomy as disclosed elsewhere in this document. The user selected catheter may be a catheter or device for accessing, diagnosing or treating the heart. Examples of such catheters include, but are not limited to ablation catheters, mapping catheters, pacing catheters, ultrasound imaging catheters (ICE catheters), guidewires, sheaths, needles, prosthetic valve delivery catheters, pacing leads and angioplasty catheters.

[0309] In another embodiment, the user interface is similar to the da Vinci[®] Surgical System made by Intuitive Surgical, Sunnyvale, CA. In this embodiment, the user interface of medical system **100** comprises one, two or more robotic controllers along with several displays. The displays may display one or more of the following: endoscopic images, fluoroscopic images, EKG data, X-ray images, intra-cardiac ultrasound images, external ultrasound images, pre-procedure electrophysiology maps, pre-procedure anatomical maps created from pre-procedure imaging, etc. Such a medical system **100** comprising a robotic user interface can be used to treat a variety of internal organs including, but not limited to stomach, gall bladder, colon, rectum, urinary bladder, uterus and other regions of the female reproductive tract, regions of the male reproductive tract, esophagus, heart, lungs, liver, spleen, small intestine, and other pleural, visceral or peritoneal organs. The procedures may be performed on the surface of such organs, inside lumens or cavities of such organs or within an interior portion of such organs.

[0310] Any of the intra-cardiac procedures disclosed herein may be performed in conjunction with an accessory device placed inside the esophagus or on the external surface of the heart or the pericardium. Such accessory devices may be selected from the group including, but not limited to: imaging devices such as Intracardiac Echocardiography (ICE) probes, temperature sensing devices, shields for shielding microwave energy and components of a surgical navigation system.

[0311] MRI imaging may be used along with any of the devices disclosed herein to visualize one or both of: portions of the devices disclosed herein and portions of the anatomy. One or more components of the devices disclosed herein may be made of non-ferrous or non-ferromagnetic materials.

[0312] It is important to note that the embodiments shown herein may be designed to be used in the left atrium of the heart to perform one or more diagnostic procedures (e.g. electrophysiology mapping procedures), one or more treatment procedures (e.g. ablation procedures) and combinations thereof. In such designs, one of arms **102** may be translated relative to the other of arms **102**. This allows the user to change the relative positions of regions of arms **102**. Also, in such designs, one or more arms **102** may have multiplanar steering ability. The multiplanar steering may be used to deflect or steer the distal region of arms **102** in multiple planes without torquing arms **102**. Arms **102** may be introduced in the heart using an auxiliary device loop such that each arm **102** is introduced through a single femoral puncture. Thereafter, auxiliary device loop may be exchanged for medical component **110** to create the looped medical system **100** inside the body. Embodiments of medical system **100** comprising arms **102** and medical component **110** may be sufficiently flexible and have a sufficiently low profile to enable a user to introduce the medical system **100** through the vasculature. For example, medical system **100** may be introduced through the femoral vein into the right atrium and thereafter through a trans-septal puncture into the left atrium. Medical system **100** can be used to treat various tissue regions of the heart including, but not limited to right atrium, left atrium, right ventricles, left ventricles, ostia of pulmonary veins and other vasculature connected to the heart and valves. In embodiments where medical component **110** is the only device between two arms **102** in the heart, medical component **110** may comprise an electrical working element. Examples of such electrical working elements include, but are not limited to linear or non-linear ablation electrode(s) or antenna(s), linear or non-linear mapping electrode(s) or antenna(s), linear or non-linear pacing electrode(s) or antenna(s) and linear or non-linear electrosurgical cutting elements. In embodiments where medical component **110** is used to introduce second medical component **110** between two arms **102** in the heart, second medical component may comprise an electrical working element. Examples of such

electrical working elements include, but are not limited to linear or non-linear ablation electrode(s) or antenna(s), linear or non-linear mapping electrode(s) or antenna(s), linear or non-linear pacing electrode(s) or antenna(s) and linear or non-linear electrosurgical cutting elements. In the embodiments where electrical working elements are used for ablation, mapping or pacing, physical motion of a component of medical system 100 may not be necessary for the medical action. For example, medical system 100 may be used to position an ablation antenna of medical component 110 adjacent to a target tissue in the heart and thereafter ablate the target tissue without moving any of arms 102 and medical component 110.

[0313] The region of medical system 100 extending between the distal regions of arms 102 may or may not have a uniform cross sectional profile throughout the region of medical system 100 extending between the distal regions of arms 102. For example, Fig. 4A shows a medical system 100 comprising a medical component 110 extending between the distal regions of arms 102 such that the region of medical component 110 extending between the distal regions of arms 102 has a substantially uniform cross sectional profile. Fig. 6K shows a medical system 100 comprising a medical component 110 extending between the distal regions of arms 102 such that the region of medical component 110 extending between the distal regions of arms 102 has a non-uniform cross sectional profile. As shown in Fig. 6K, the cross section of the region of medical component 110 adjacent to the distal region of one of arms 102 is larger than the cross section of the region of medical component 110 adjacent to the distal region of the other of arms 102.

[0314] In one embodiment, medical component 110 or one or more devices introduced by medical component 110 are magnetically enabled devices capable of being magnetically navigated in the anatomy. Such magnetic navigation may be used to further aid the precise positioning and orientation of medical component 110 or one or more devices introduced by medical component 110. In one embodiment, the distal region of medical component 110 such as an arm 102 or one or more devices introduced by medical component 110 are capable of being magnetically navigated by a magnetic navigation system such as the Stereotaxis Magnetic Navigation System made by Stereotaxis Inc., St. Louis, MO. One or more movements of such devices can be computer controlled.

[0315] One or more arms 102 disclosed herein may be controlled robotically by a user. For example, one or more arms 102 may be Artisan™ Control Catheters controlled by the Sensei™ Robotic Catheter System made by Hansen Medical, Mountain View, CA.

[0316] Any of the steering mechanisms disclosed herein may be designed such that a distal end of the steered device replicates a user motion applied to the proximal region of the device. In another embodiment, any of the steering mechanisms herein may be designed

such that a distal end of the steered device replicates the mirror image of a user motion applied to the proximal region of the device.

[0317] Several examples or embodiments of the invention have been discussed herein, but various modifications, additions and deletions may be made to those examples and embodiments without departing from the intended spirit and scope of the invention. Thus, any element, component, method step or attribute of one method or device embodiment may be incorporated into or used for another method or device embodiment, unless to do so would render the resulting method or device embodiment unsuitable for its intended use. If the various steps of a method are disclosed in a particular order, the various steps may be carried out in any other order unless doing so would render the method embodiment unsuitable for its intended use. Various reasonable modifications, additions and deletions of the described examples or embodiments are to be considered equivalents of the described examples or embodiments.

CLAIMS

We claim:

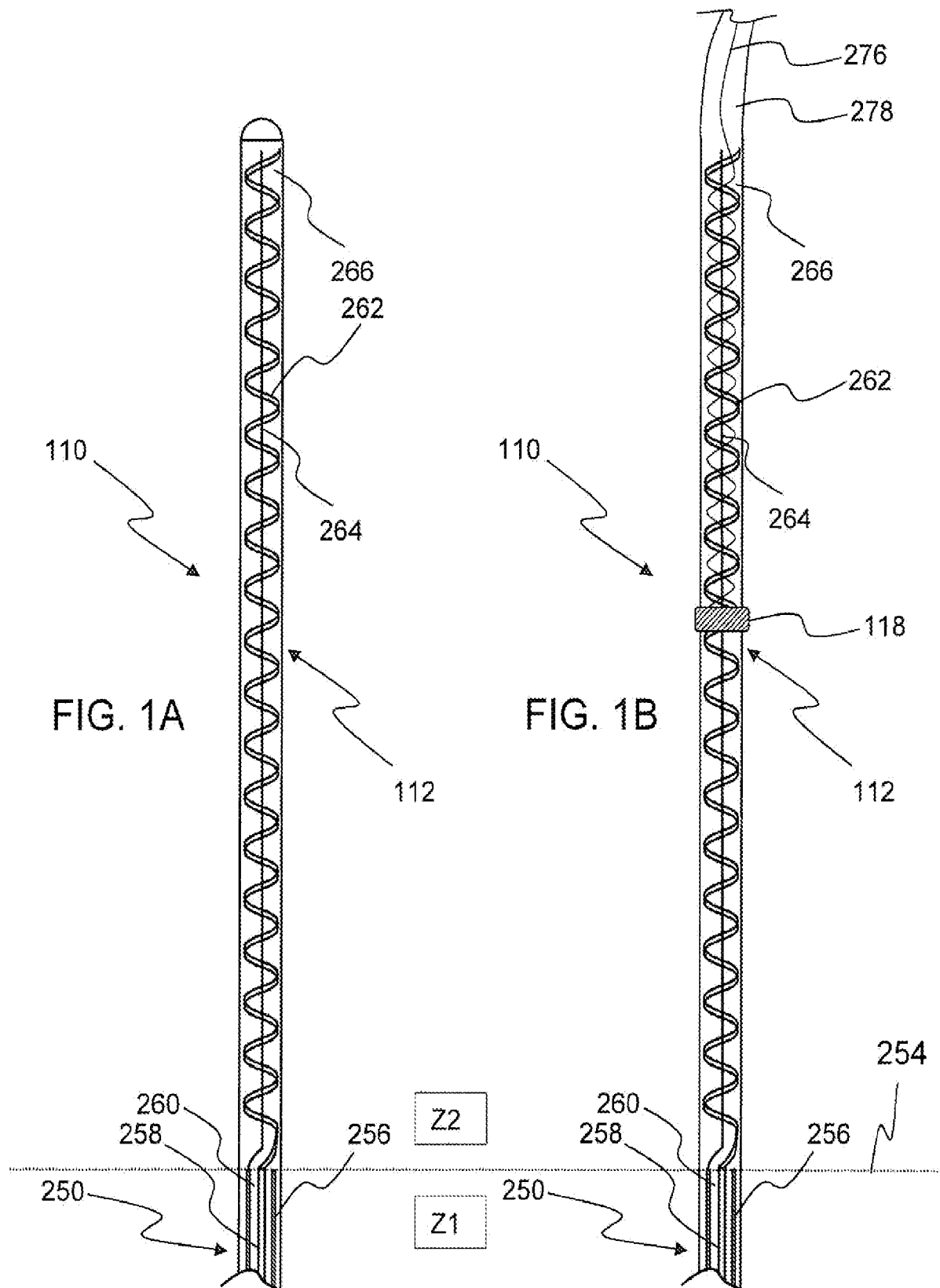
1. A microwave emitting system for delivering microwave energy comprising:
 - a transmission line coupleable to a microwave energy source;
 - an elongate microwave antenna having a proximal end, a distal end and an antenna axis, wherein the proximal end of the antenna is electrically coupled to the distal end of the transmission line and where the elongate microwave antenna generates a microwave field upon application of the microwave energy to the transmission line;
 - an electrode positioned along the microwave antenna and between the proximal end and the distal end of the antenna, wherein the electrode is exposed to the microwave field emitted by the antenna and is electrically isolated from the antenna, where the electrode is coupleable to a second power supply; and
 - a conductive wire coupled to the electrode wherein the wire is electrically isolated from the antenna and wherein a first portion of the wire exposed to the microwave field emitted by the antenna is disposed relative to the antenna axis such that every section of the first portion of the wire is non-parallel to the axis of the antenna such that arrangement of the conductive wire relative to the antenna reduces distortion of the microwave field due to the electrodes.
2. The system of claim 1, where the electrode is located externally over the microwave antenna.
3. The system of claim 1, wherein the first portion of the wire is non-linear.
4. The system of claim 1, wherein the first portion of the wire is helical and has a helix axis.
5. The system of claim 1, wherein the outer diameter and the pitch of the first portion of the helical wire are substantially constant.
6. The system of claim 1, wherein the first portion of the wire is shaped in a helix having an axis and is disposed such that the helix axis is parallel to the antenna axis.
7. The system of claim 1, wherein the portion of the wire covers at least one turn around the antenna.
8. The system of claim 1, wherein the portion of the wire is symmetrically disposed around the antenna.

9. The system of claim 1, wherein the microwave antenna generates a radially symmetric microwave field.
10. The system of claim 1, wherein the conductive wire is placed such that the electrode does not change a symmetry of the microwave field generated by the elongate microwave antenna.
11. The system of claim 1, wherein a majority of the microwave field is located distal to the distal end of the transmission line.
12. The system of claim 1, wherein a portion of the conductive wire is located distal to the distal end of the microwave antenna.
13. The system of claim 1, wherein a portion of the conductive wire is located proximal to the proximal end of the microwave antenna.
14. The system of claim 1, wherein the electrode and the conductive wire are fixed relative to the antenna.
15. The system of claim 1, wherein the antenna comprises an antenna dielectric and the electrode and the conductive wire are located inside the antenna dielectric.
16. The system of claim 1, wherein the electrode and the conductive wire are located on a device having a lumen and the antenna is slidably located in the lumen.
17. The system of claim 1, wherein the electrode comprises a metallic portion.
18. The system of claim 1, wherein the electrode comprises an electrode selected from the group consisting of: radiofrequency ablation electrodes, electrophysiological pacing electrodes, electrophysiological mapping electrodes, temperature sensors, impedance sensors, pressure sensors, proximity sensors, flow sensors, moisture sensors and electromagnetic field sensors.
19. The system of claim 1, further comprising an introducing device coupled to the antenna.
20. The system of claim 19, where the introducing device is steerable or deflectable.
21. The system of claim 1, further comprising at least a second electrode positioned along the microwave antenna.

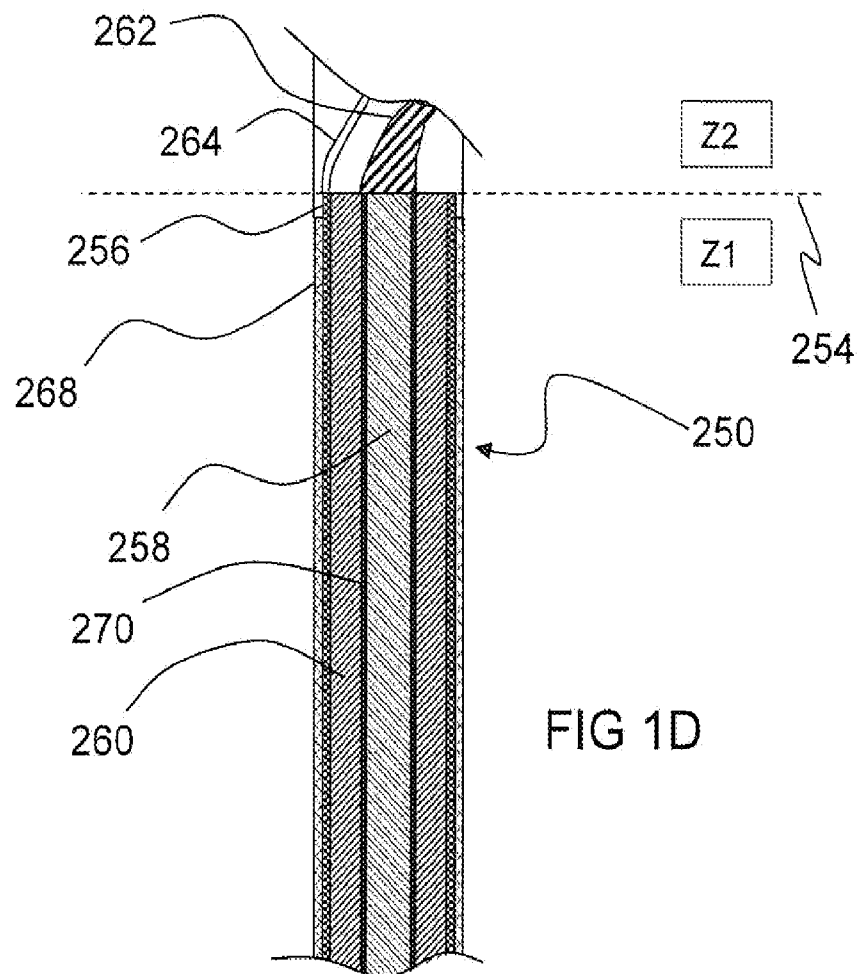
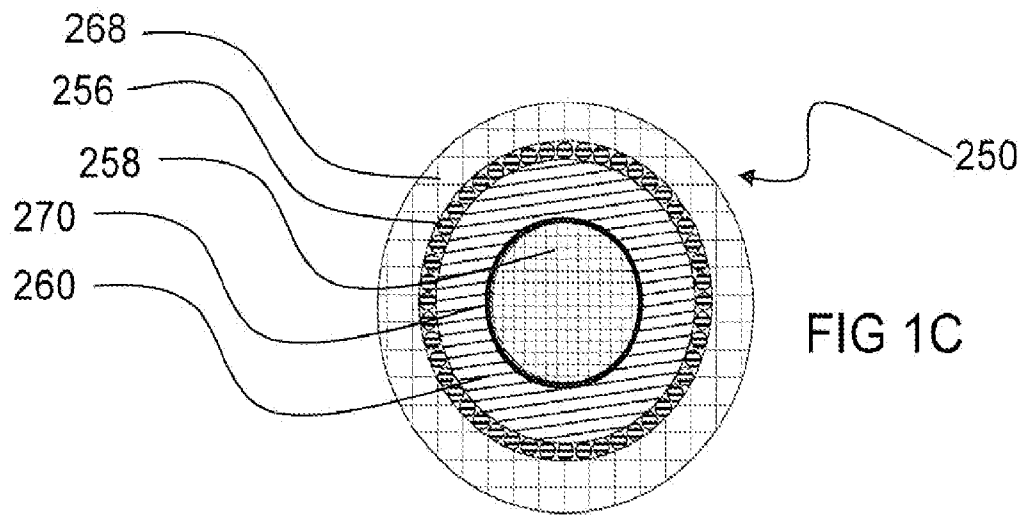
22. A method of delivering microwave energy to tissue comprising the steps of:
- positioning an elongate microwave antenna adjacent to a first region of tissue wherein the antenna comprises a proximal end, a distal end and an antenna axis and the electrode is located over the antenna and between the antenna and the first region of tissue where the the wire is connected to the electrode and is electrically isolated from the antenna and wherein a first portion of the wire is exposed to the microwave field emitted by the antenna such that every section of the first portion of the wire is oriented non-parallel to the axis of the antenna;
 - delivering microwave energy to the first location of tissue through the elongate microwave antenna to generate a microwave field where the position of the conductive wire reduces a distortion of the microwave field otherwise resulting from the electrode and to create a first lesion; and
 - applying energy through the electrode to diagnose or treat the tissue while maintaining a position of the antenna.
23. The method of claim 22, further comprising repositioning the antenna adjacent to a second region of tissue and delivering microwave energy to the second region of tissue.
24. The method of claim 23, further comprising creating a second lesion at the second region of tissue such that the first and second lesions overlap.
25. The method of claim 22, further comprising altering the shape of the antenna after creating the first lesion such that the shape of the antenna at the first region of tissue is different than the shape of the antenna at the second region of tissue.
26. The method of claim 22, wherein a second lesion is created at a second region of tissue such that the shape of the first lesion corresponds to the shape of the antenna at the first region and the shape of the second lesion corresponds to the shape of the antenna at the second region.
27. The method of claim 22, where positioning the elongate microwave antenna comprises positioning the elongate microwave antenna adjacent to cardiac tissue and where delivering microwave energy to the first location of tissue creates a lesion in cardiac tissue.
28. The method of claim 22, where delivering microwave energy and applying energy to the electrode occur simultaneously.
29. The method of claim 22, wherein the electrode and the wire are located on an elongate outer device comprising a lumen and the antenna is slidably positioned within the lumen

and the method further comprises the step of changing the relative positions of the antenna and the outer device.

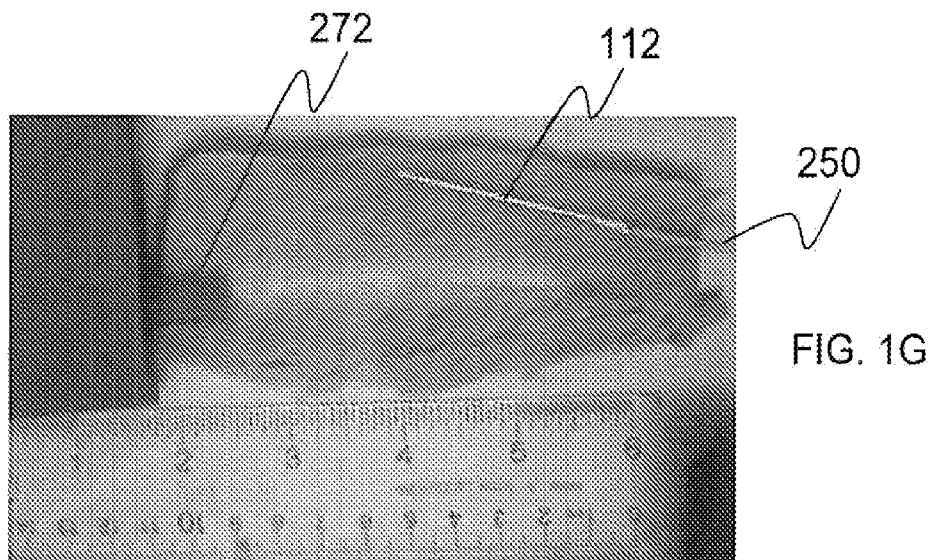
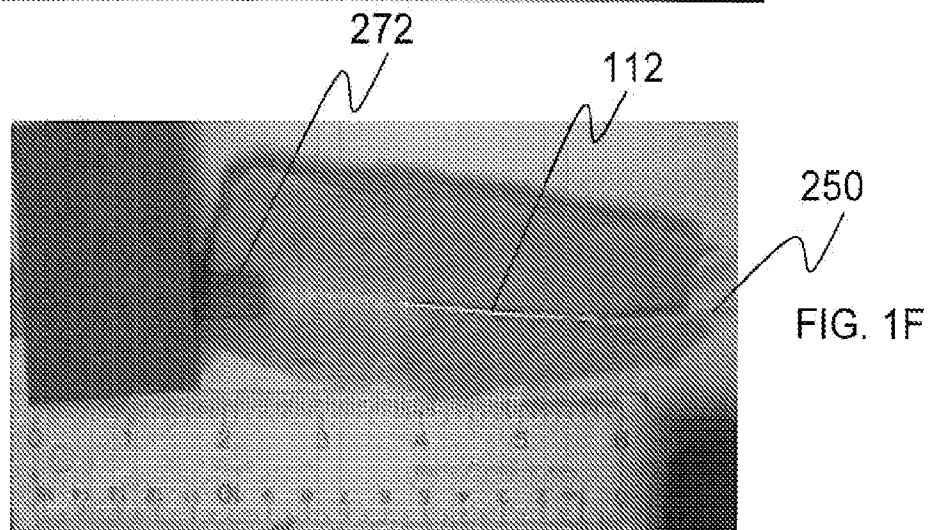
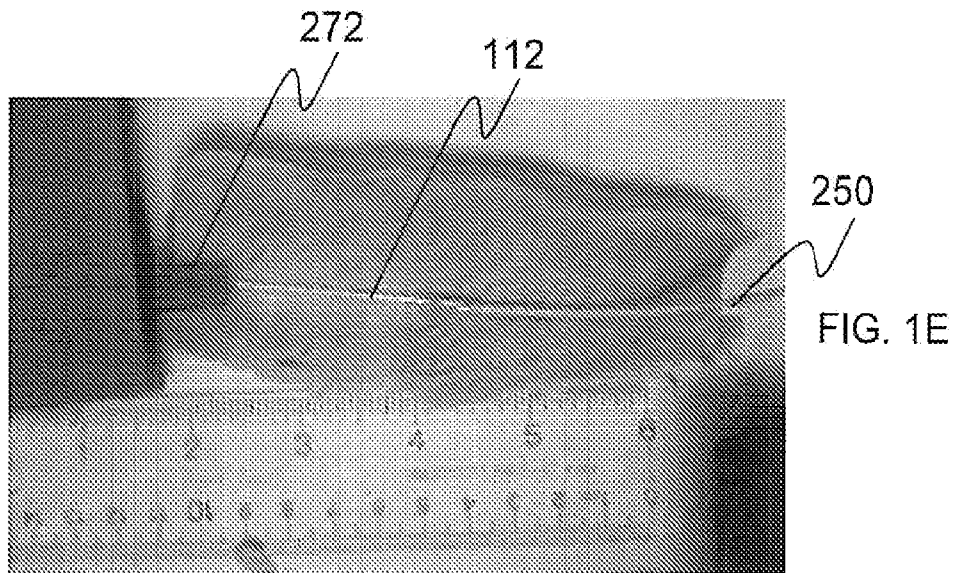
30. The method of claim 22, wherein the antenna is mechanically attached to a tether, and further comprising pulling or releasing the tether to change the shape of the antenna.
31. The method of claim 22, further comprising delivering the antenna through an elongate introducer device.
32. The method of claim 31, wherein the introducer device comprises a steering or deflecting mechanism.
33. The method of claim 22, where applying energy through the electrode comprises measuring electrophysiological signals in the tissue.
34. The method of claim 22, where applying energy through the electrode comprises delivering pacing signals to the tissue.
35. The method of claim 22, where applying energy through the electrode comprises delivering RF energy to the tissue.
36. The method of claim 22, where applying energy through the electrode comprises placing the electrode in contact with the first region of tissue.
37. The method of claim 22, where applying energy through the electrode comprises spacing the electrode from the first region of tissue.
38. A microwave emitting system for delivering microwave energy comprising:
 - a transmission line coupleable to a microwave energy source; and
 - an elongate microwave antenna having a proximal end, a distal end and an antenna axis, wherein the proximal end of the antenna is electrically coupled to the distal end of the transmission line,
 - a diagnostic or therapeutic modality located over the microwave antenna and between the proximal end and the distal end of the antenna, wherein the diagnostic or therapeutic modality is exposed to the microwave field emitted by the antenna and is electrically isolated from the antenna
 - a conductive wire connected to the diagnostic or therapeutic modality wherein the wire is electrically isolated from the antenna and wherein a first portion of the wire exposed to the microwave field emitted by the antenna is disposed relative to the antenna axis such that every section of the first portion of the wire is non-parallel to the axis of the antenna.



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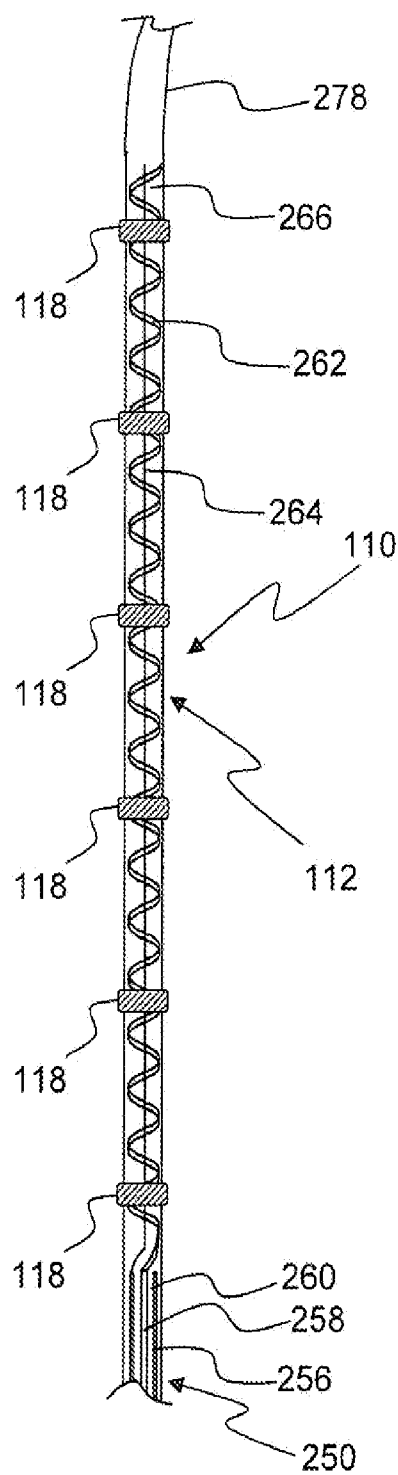


FIG. 1H

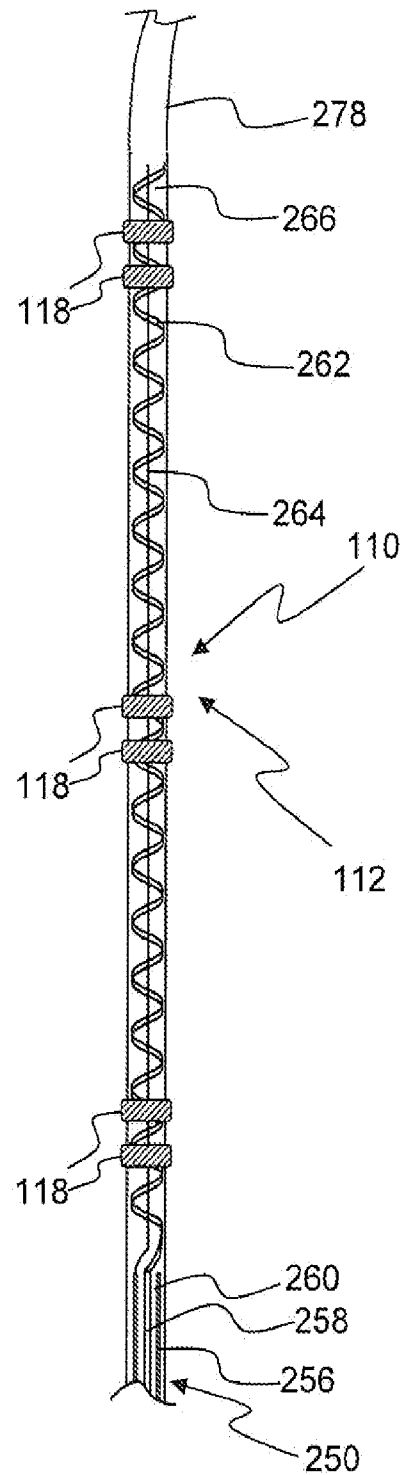


FIG. 1I

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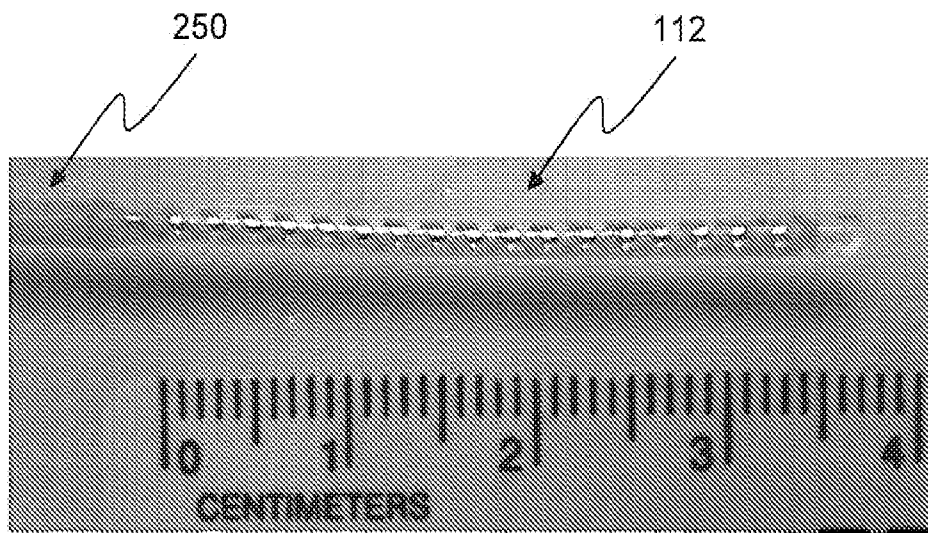


FIG 1J

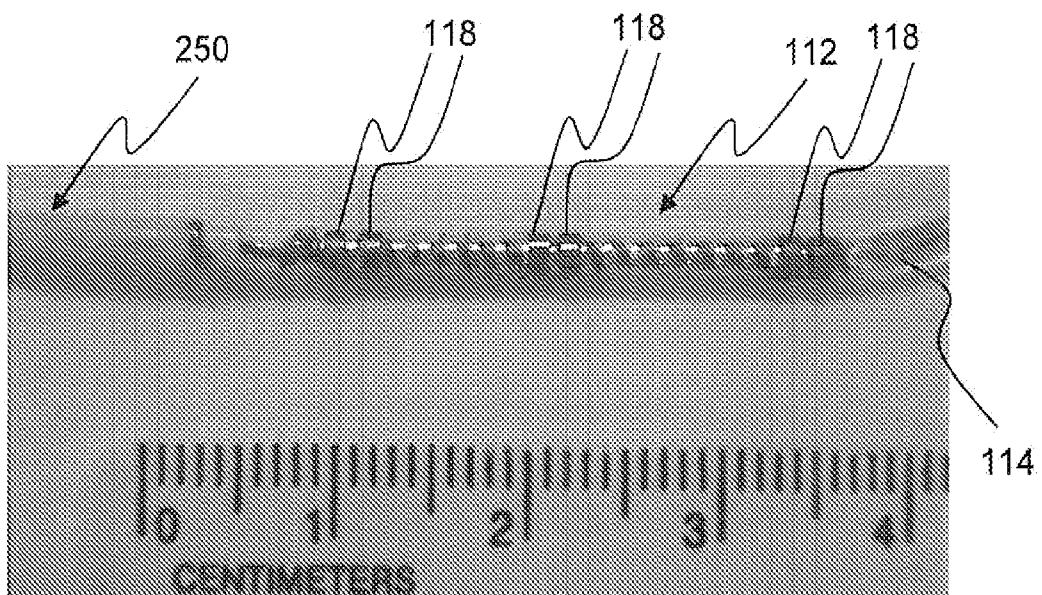
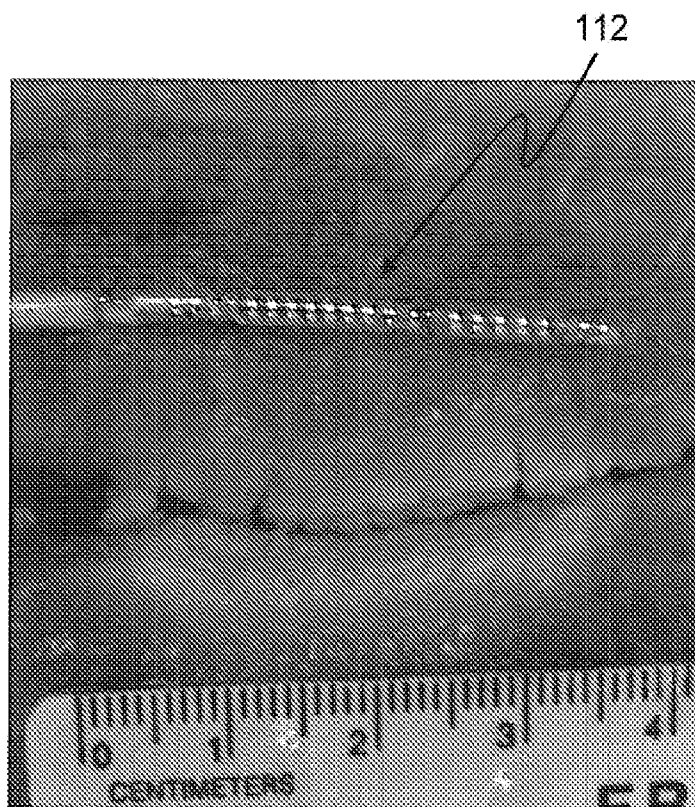
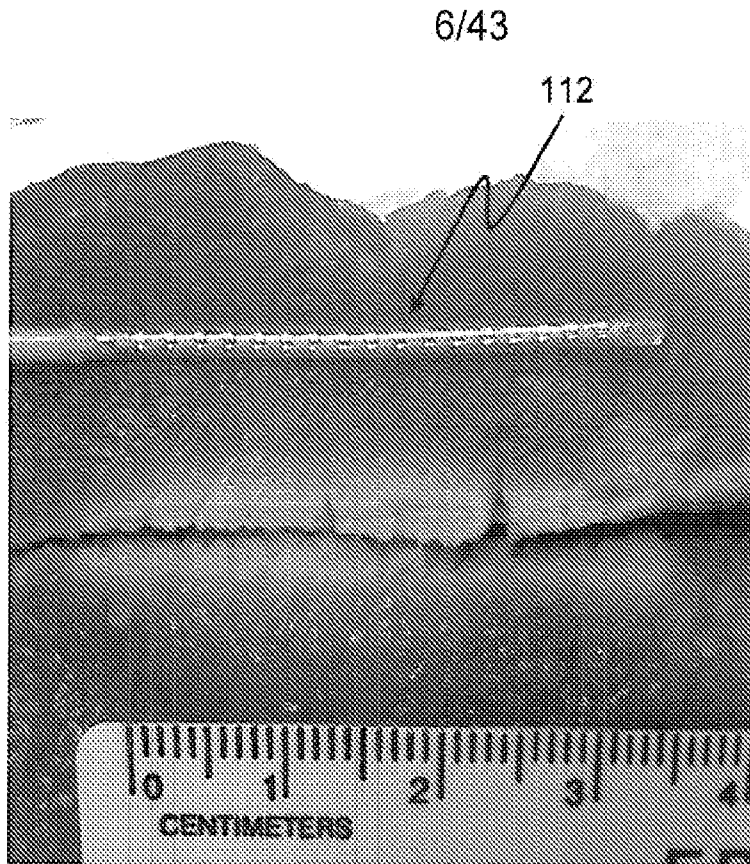


FIG 1K



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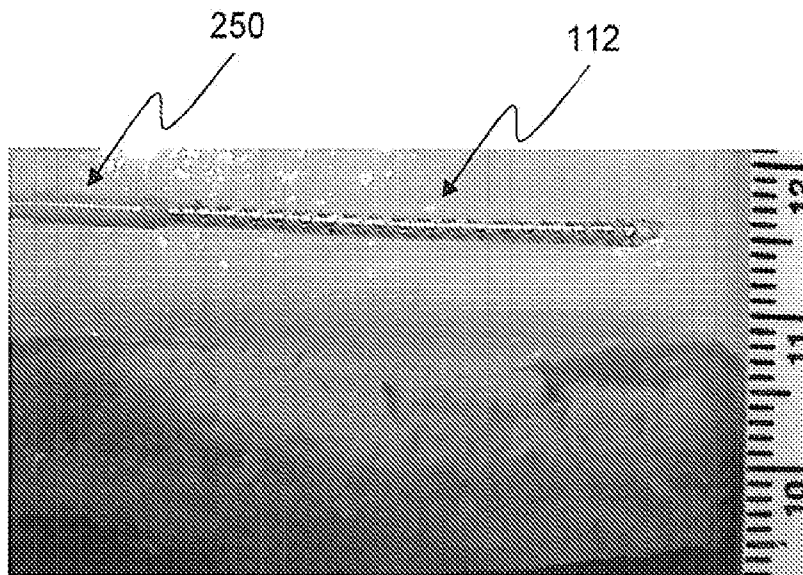


FIG 1N

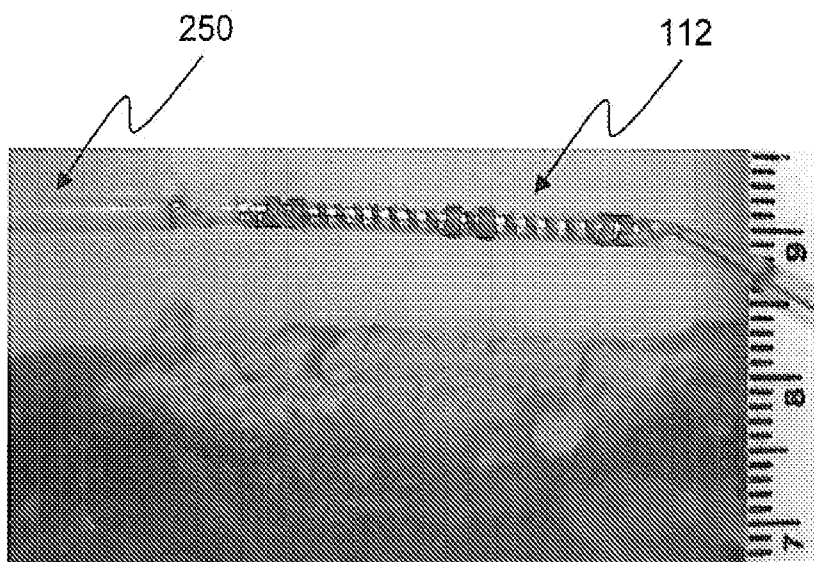


FIG 10

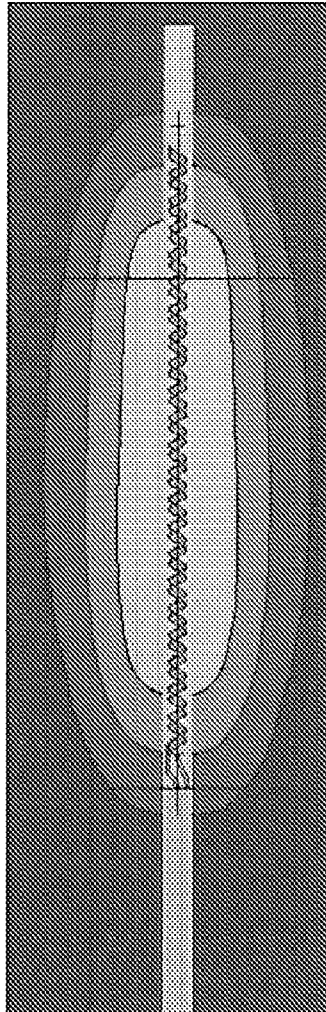
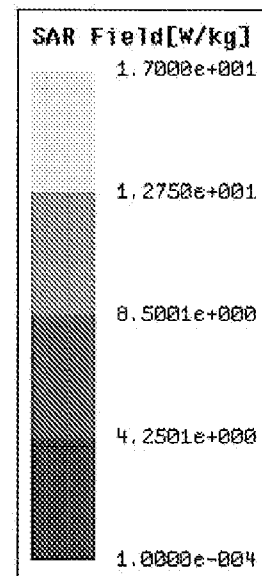
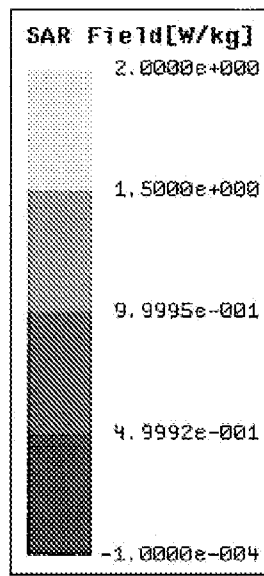
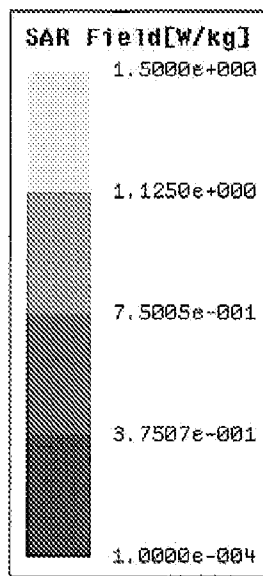


FIG 1P

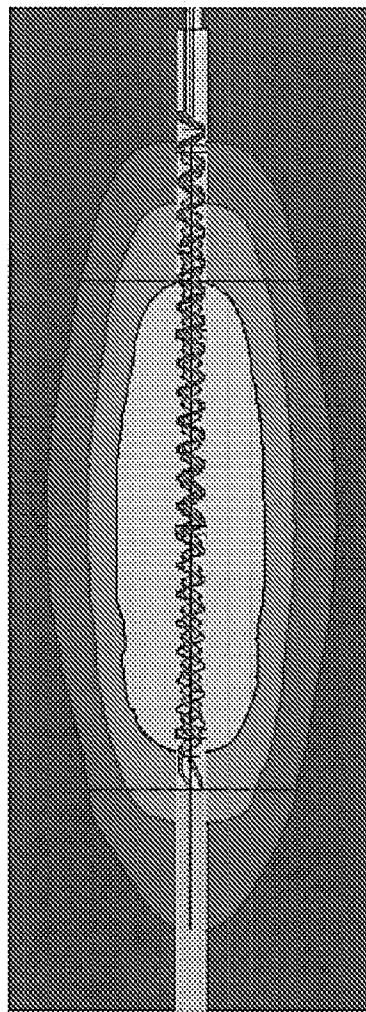


FIG 1Q

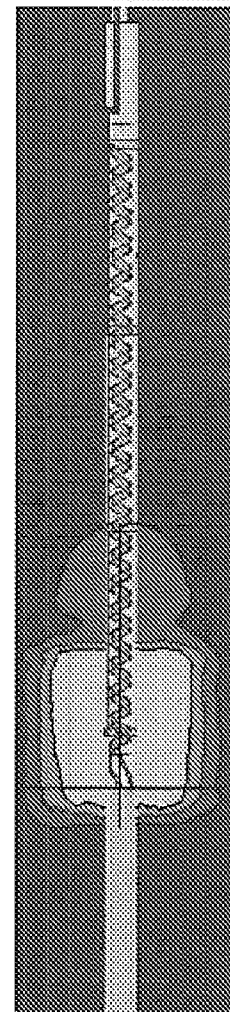
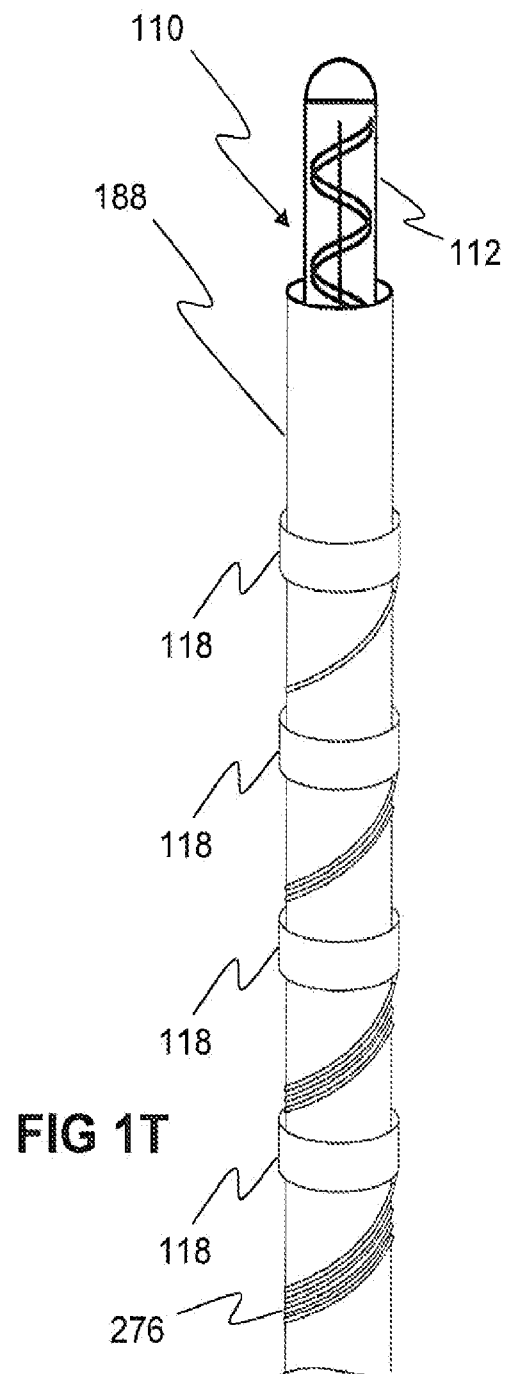
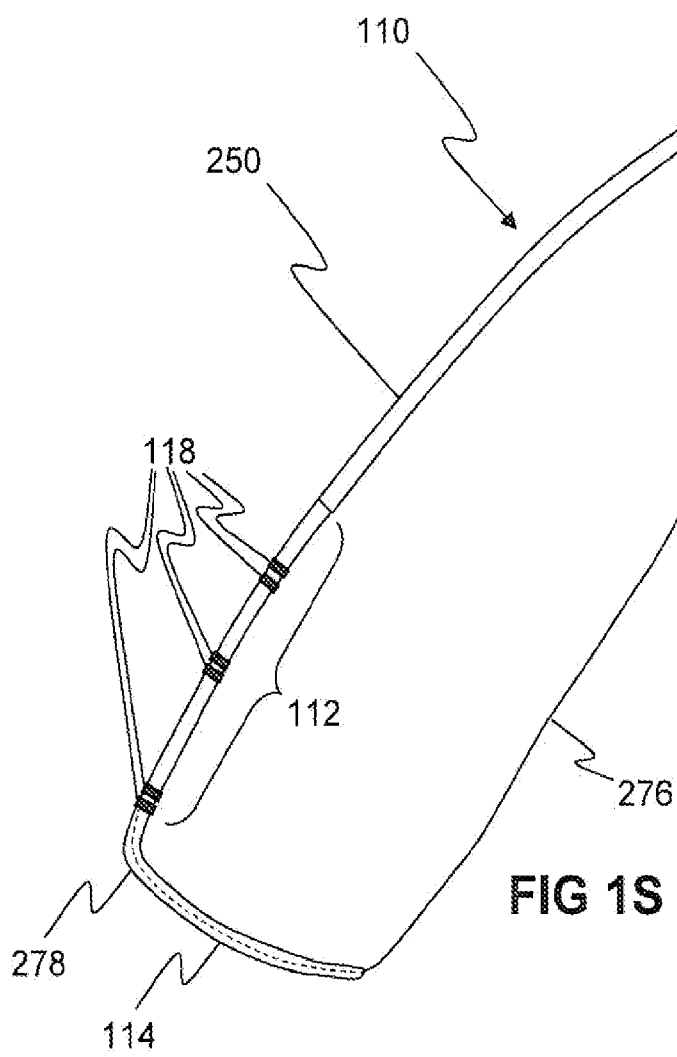


FIG 1R

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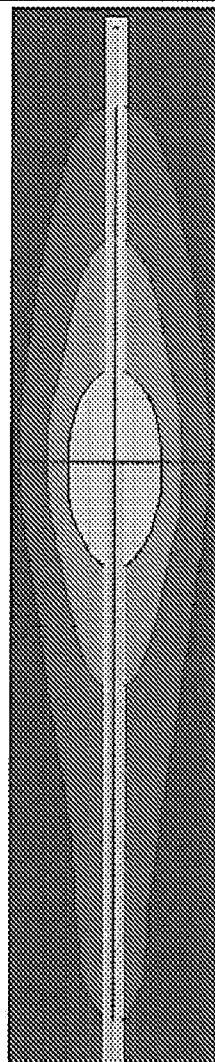
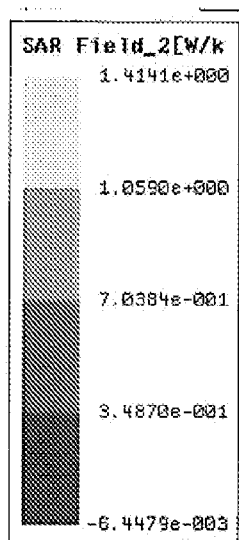


FIG 1U

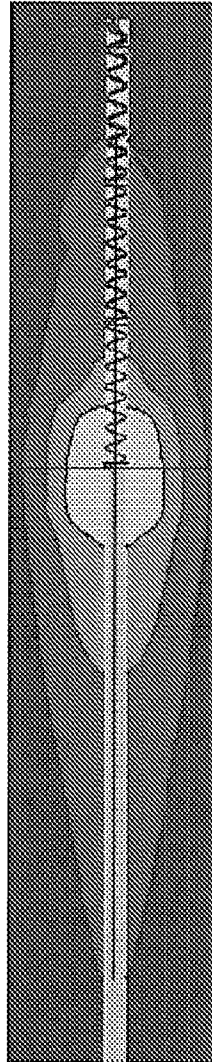
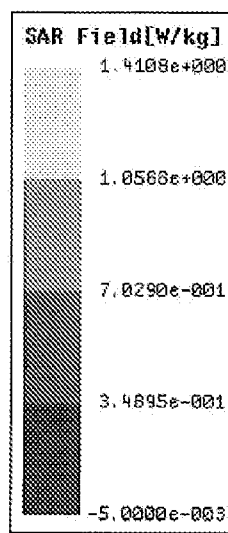


FIG 1V

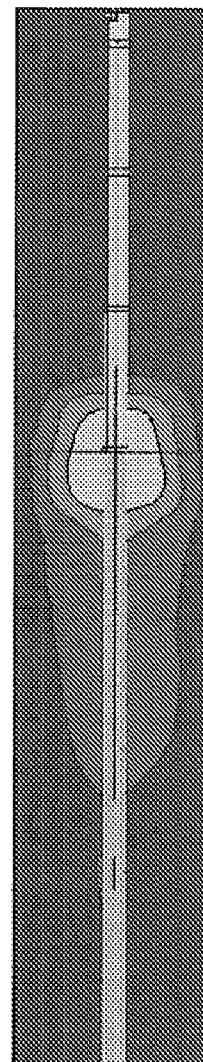
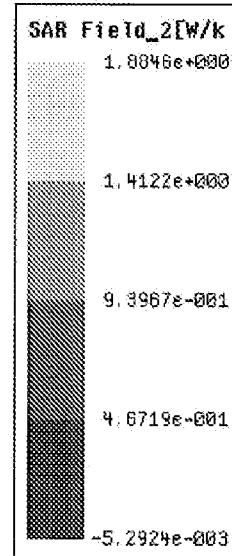
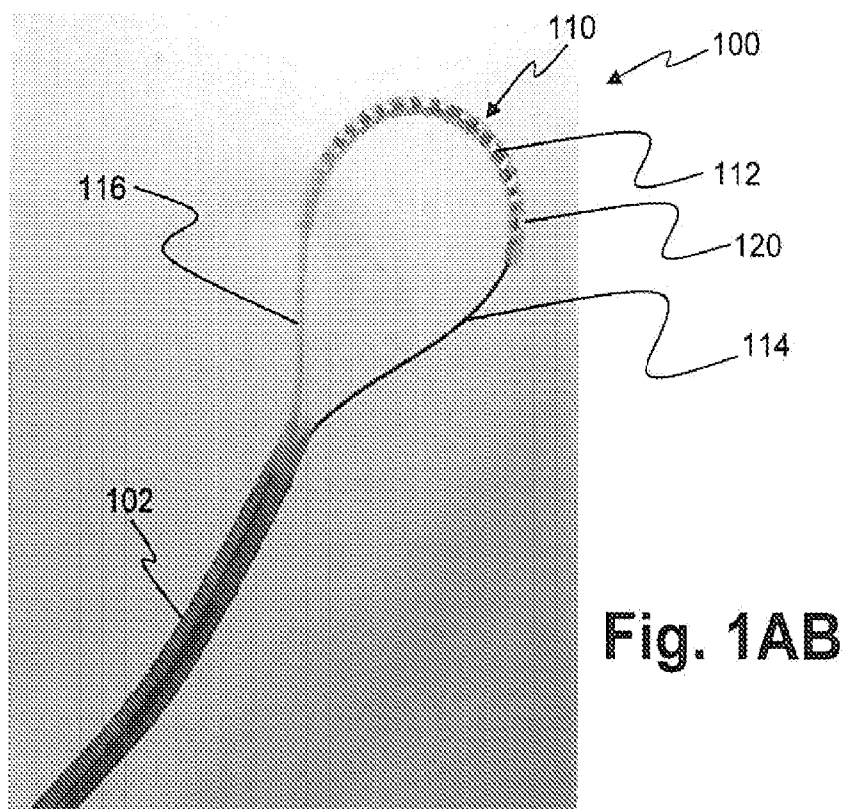
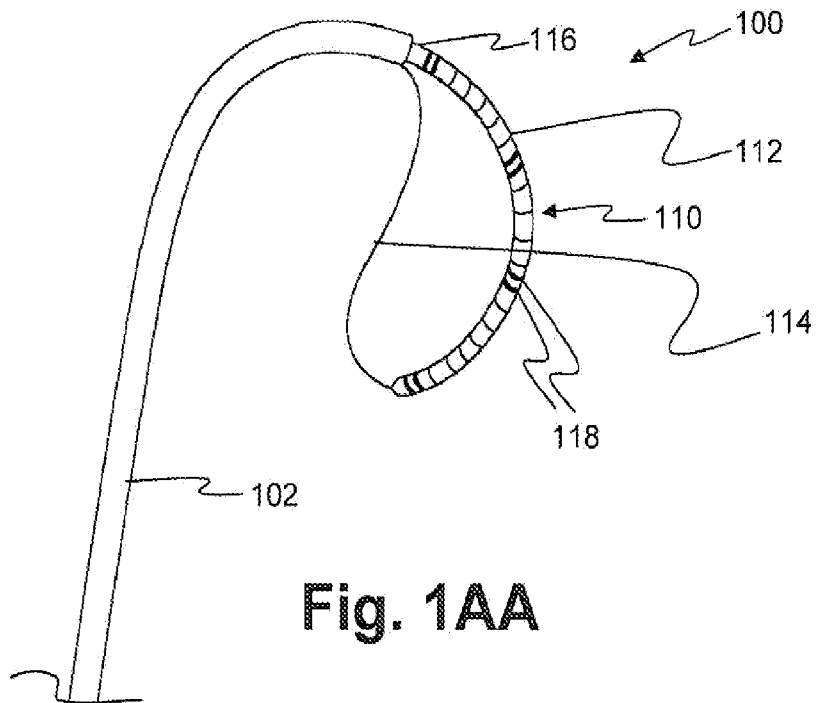
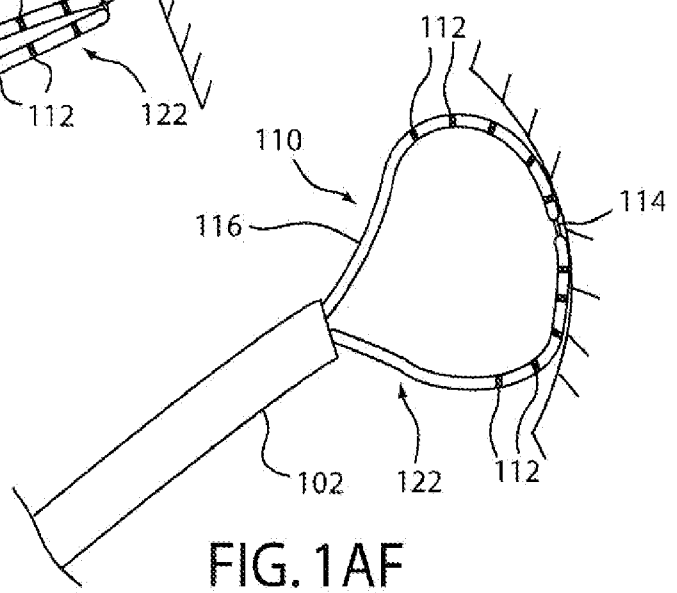
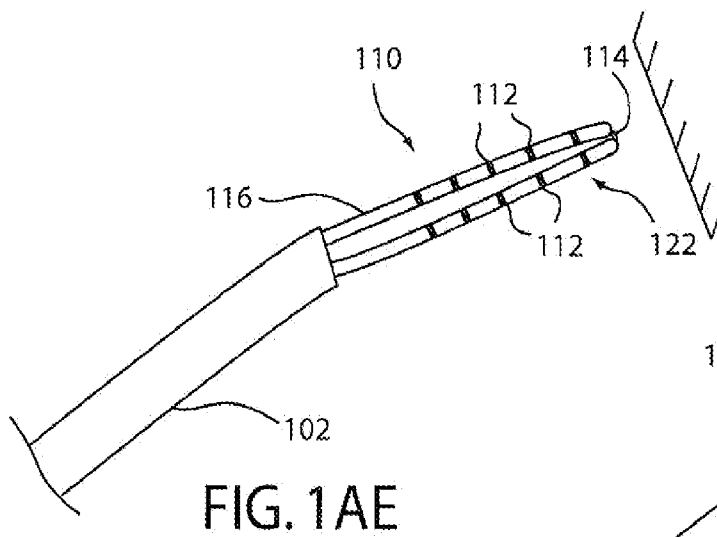
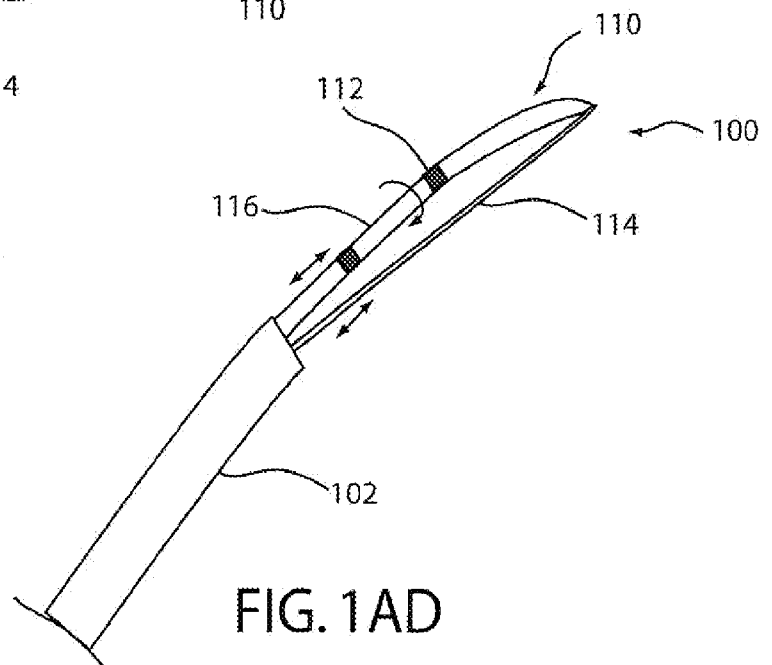
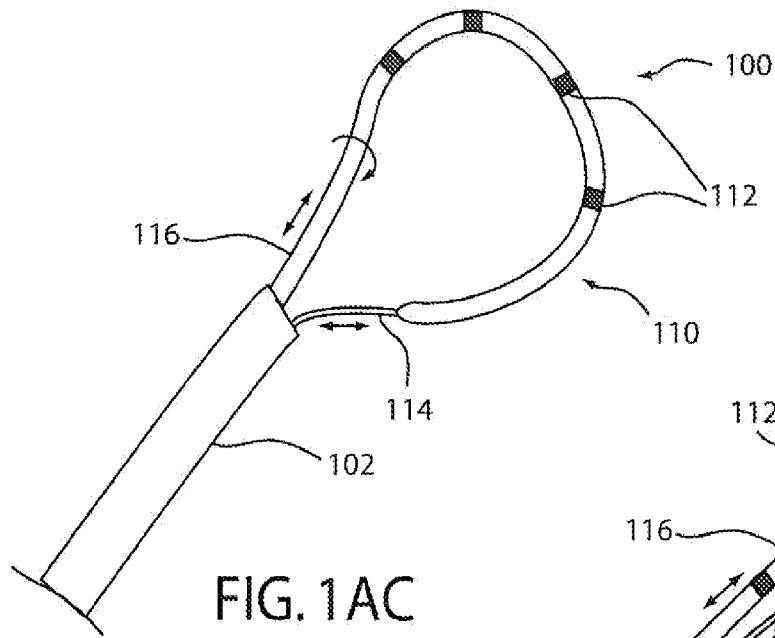


FIG 1W

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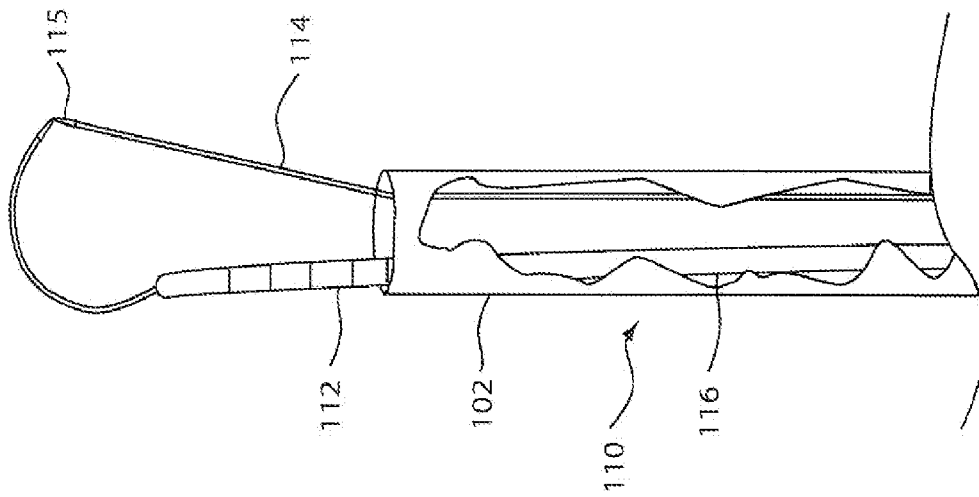


FIG. 1AI

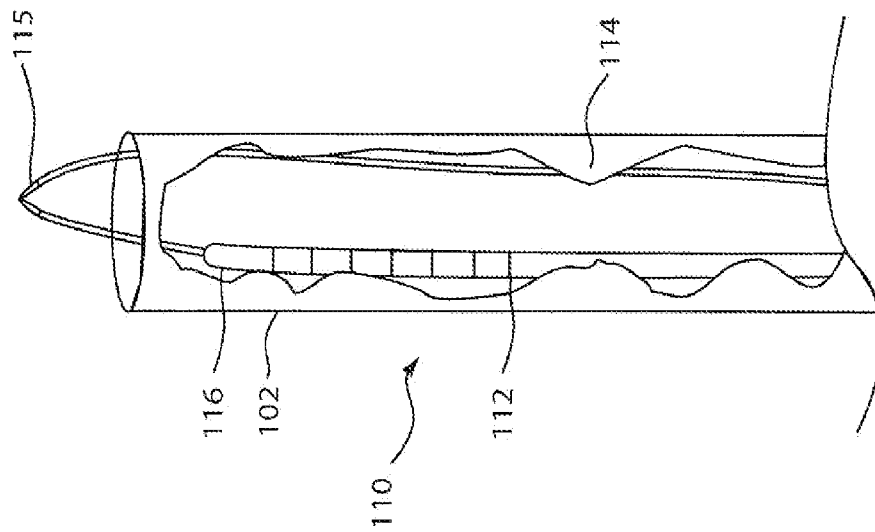


FIG. 1AH

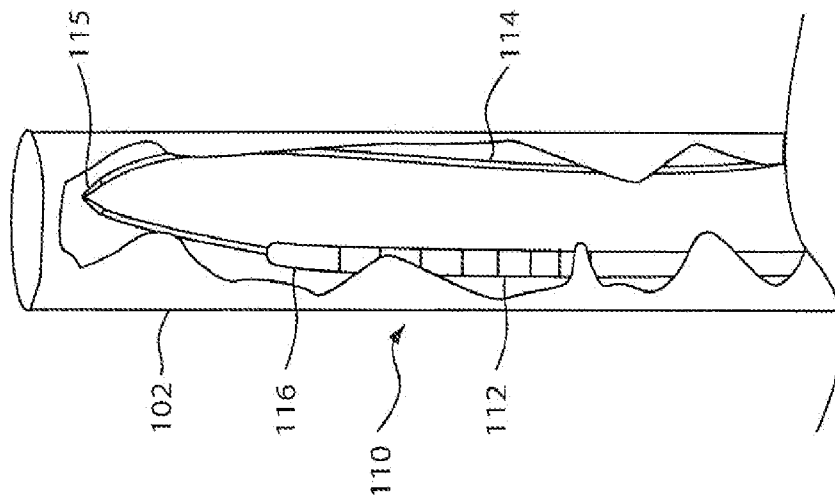


FIG. 1AG

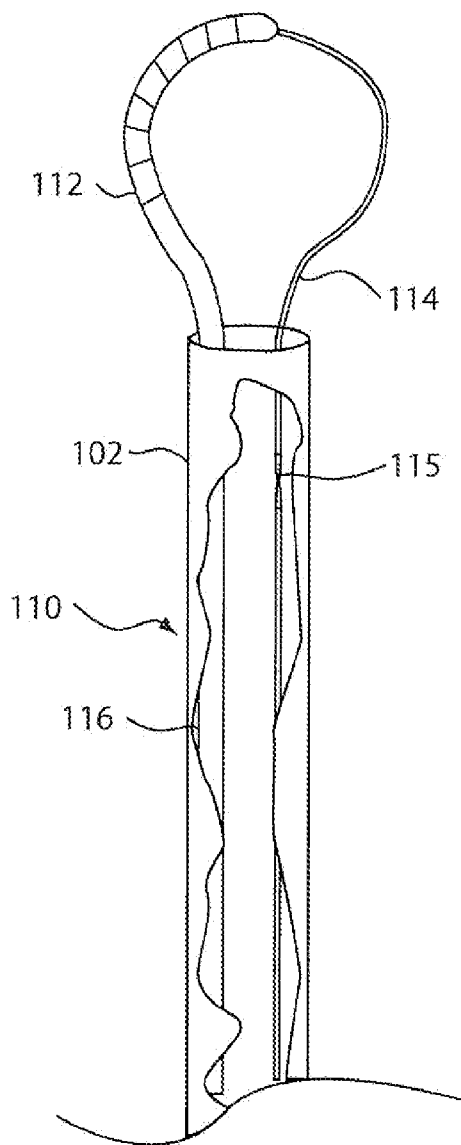


FIG. 1AJ

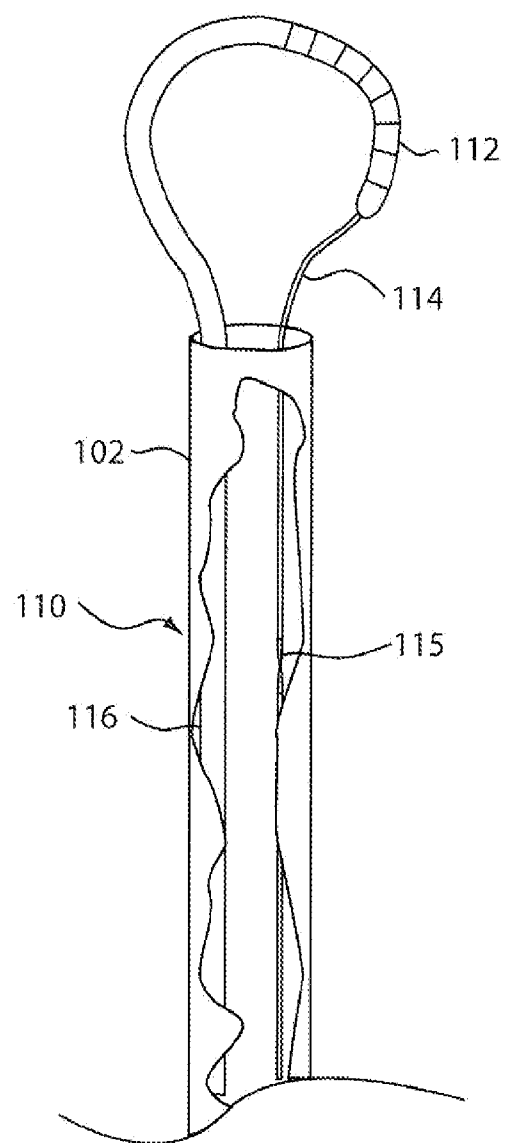


FIG. 1AK

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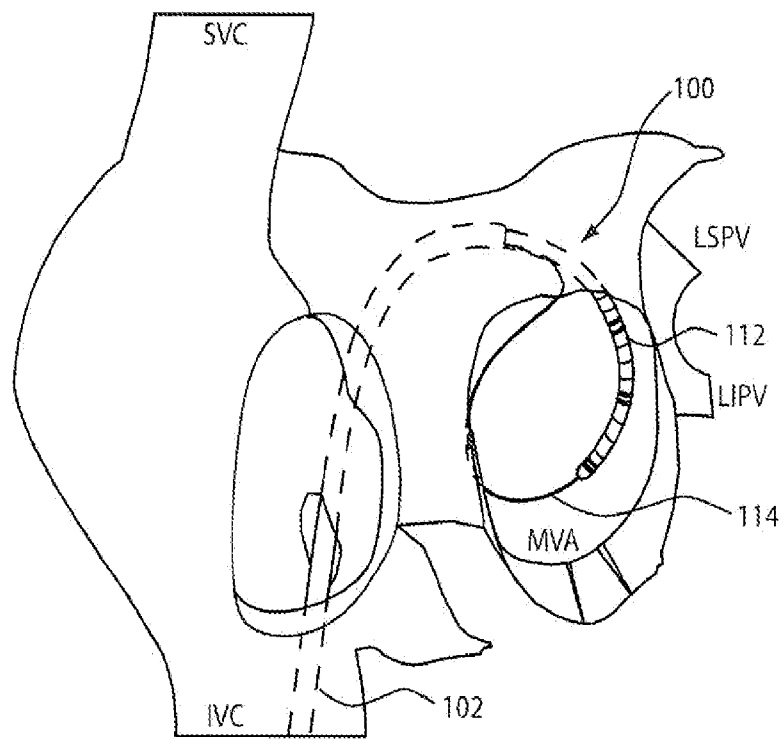


FIG. 2A

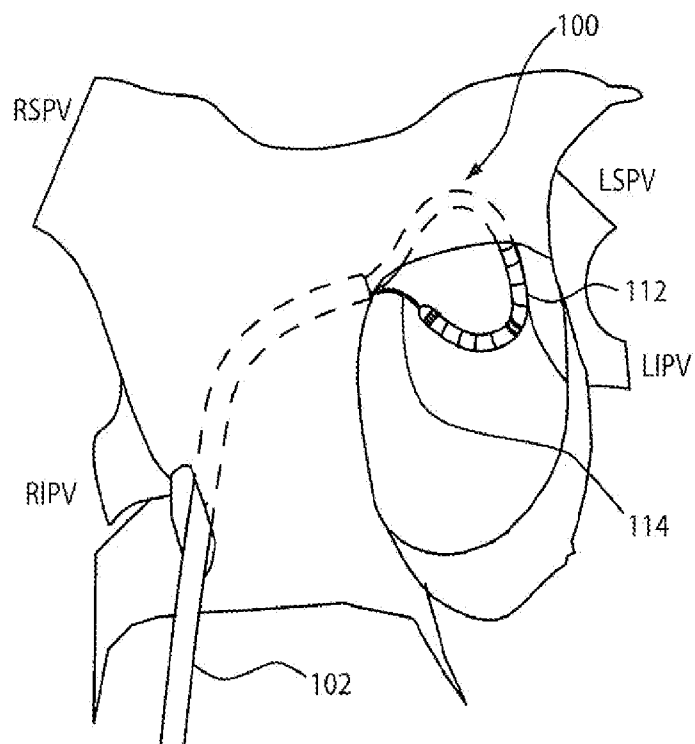
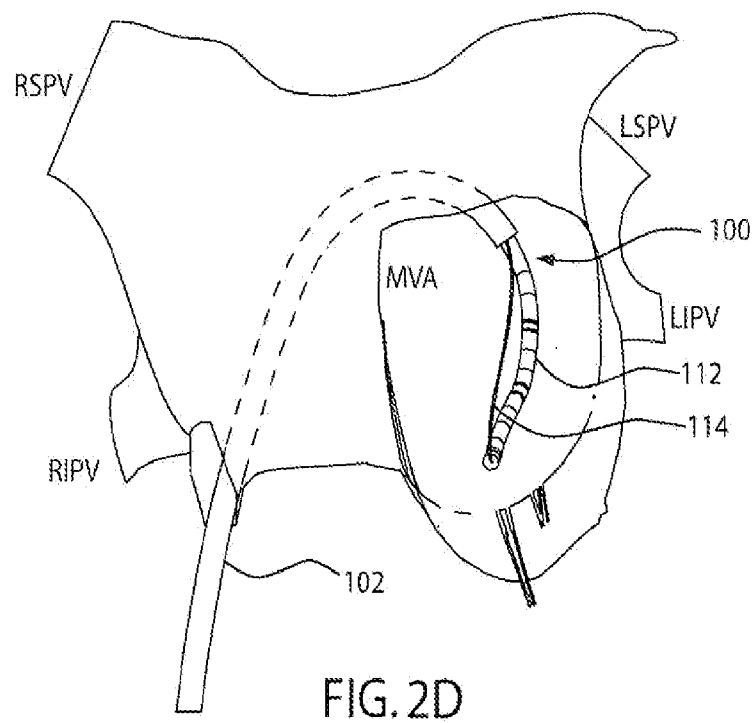
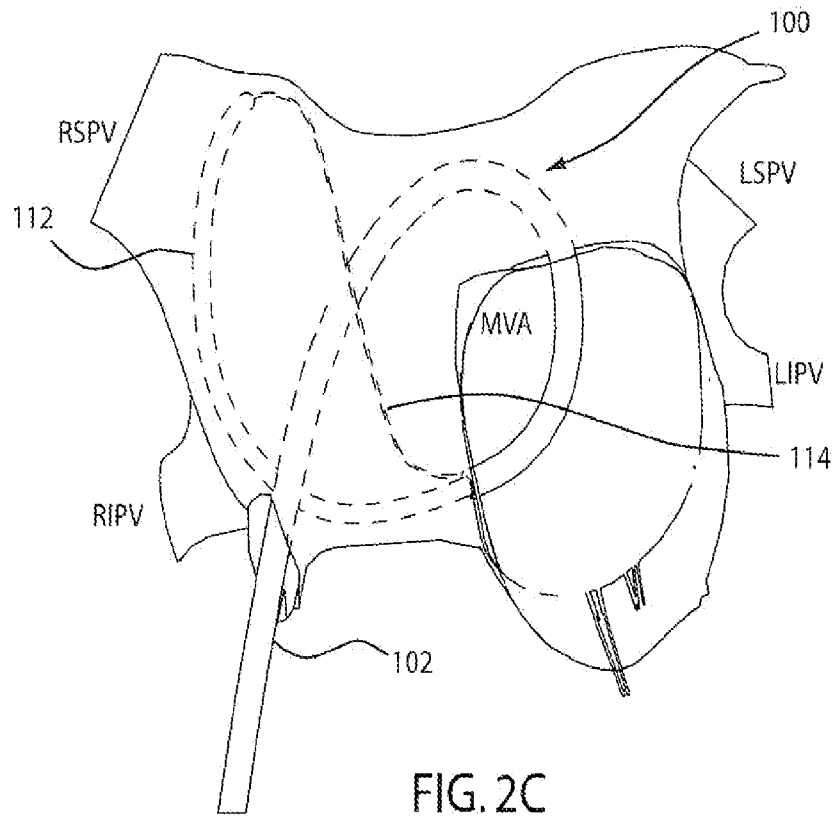


FIG. 2B

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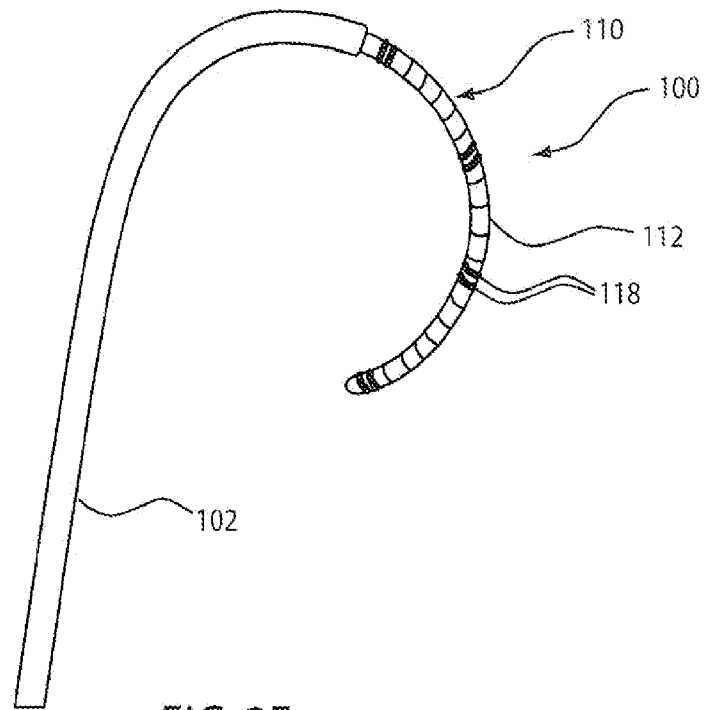


FIG. 2E

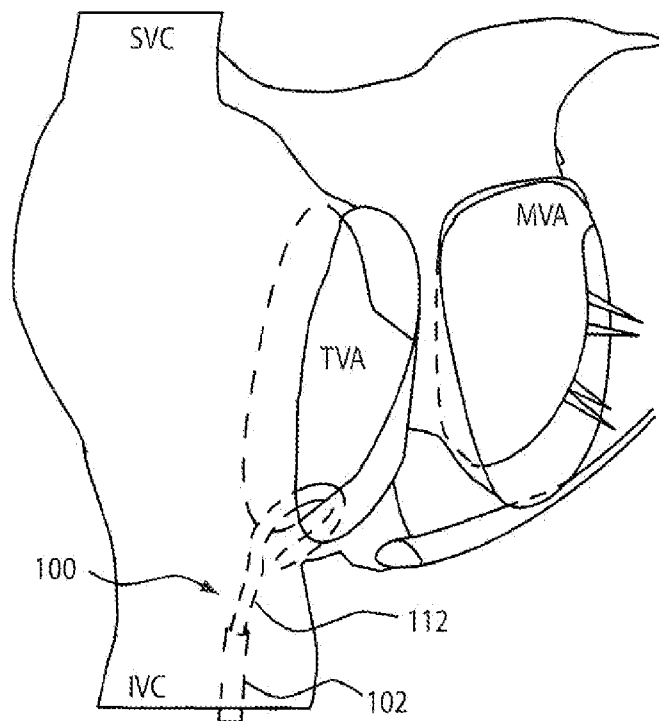


FIG. 2F

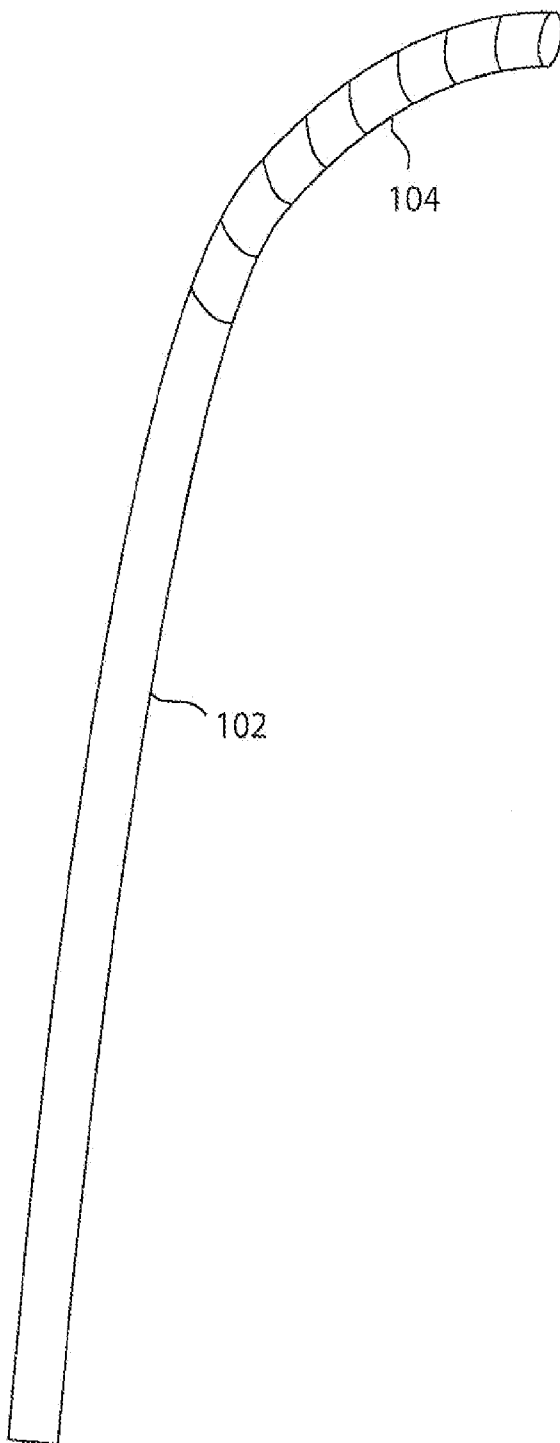


FIG. 3A

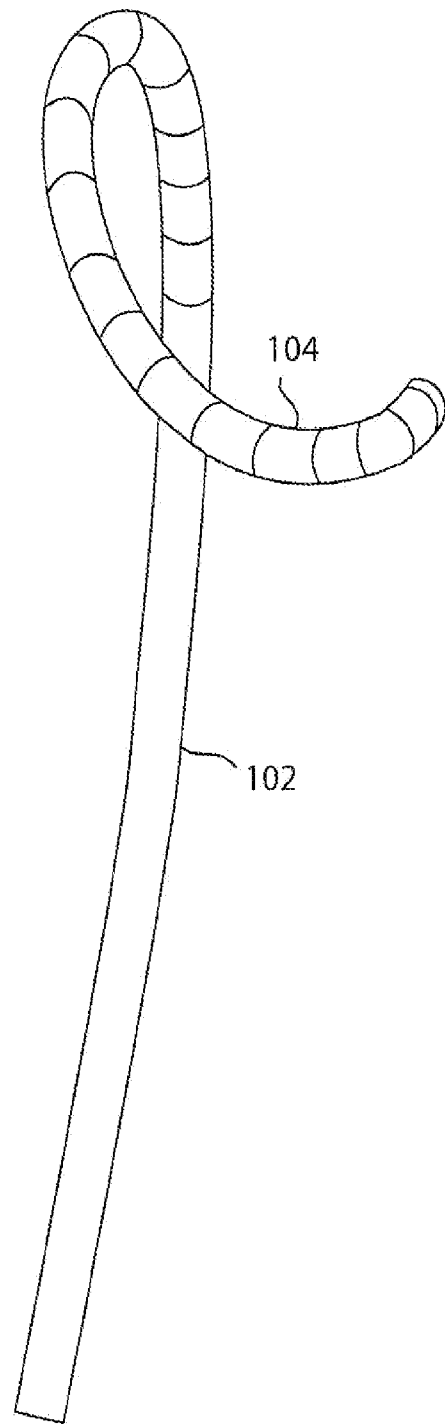


FIG. 3B

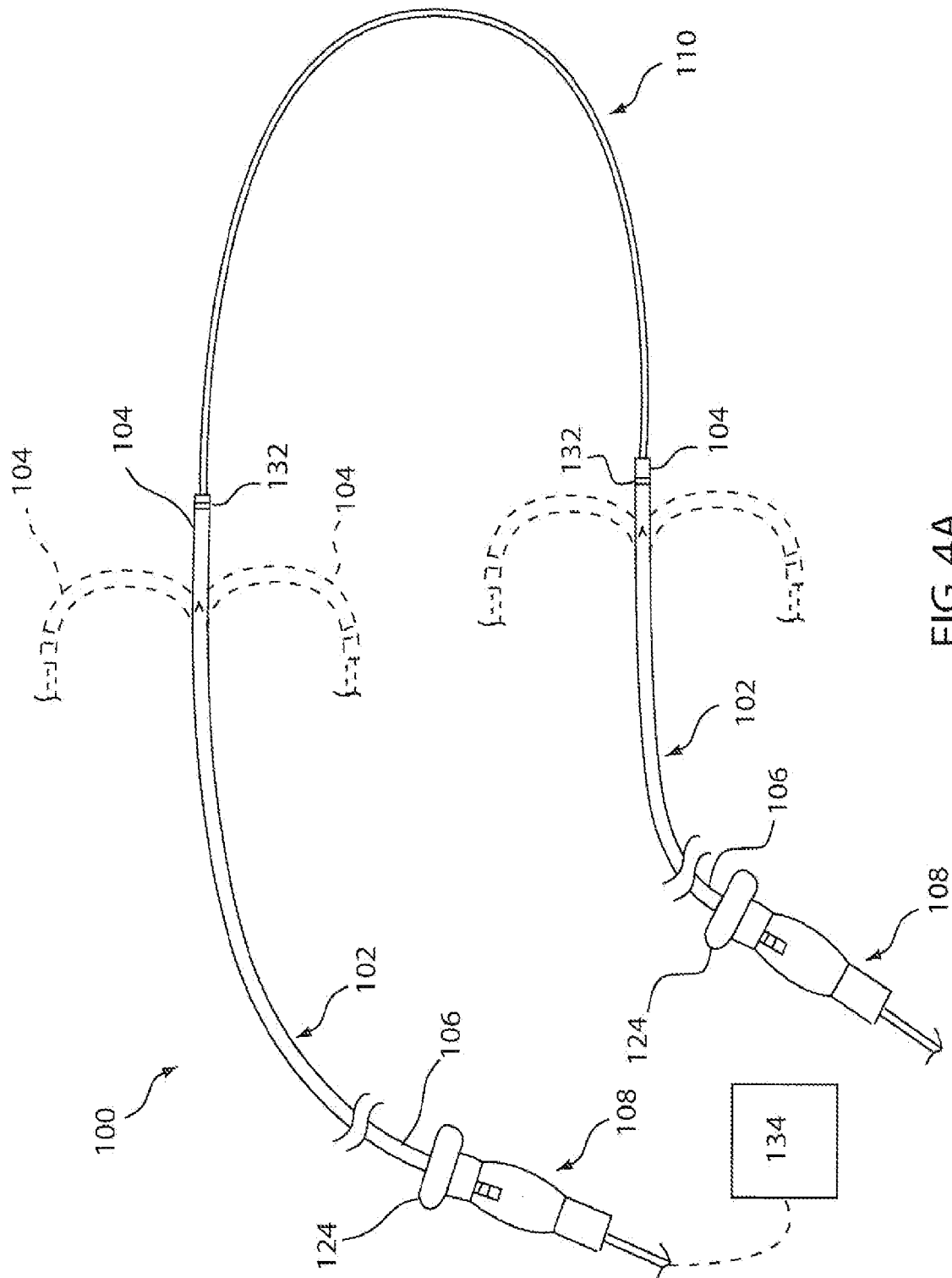


FIG. 4A

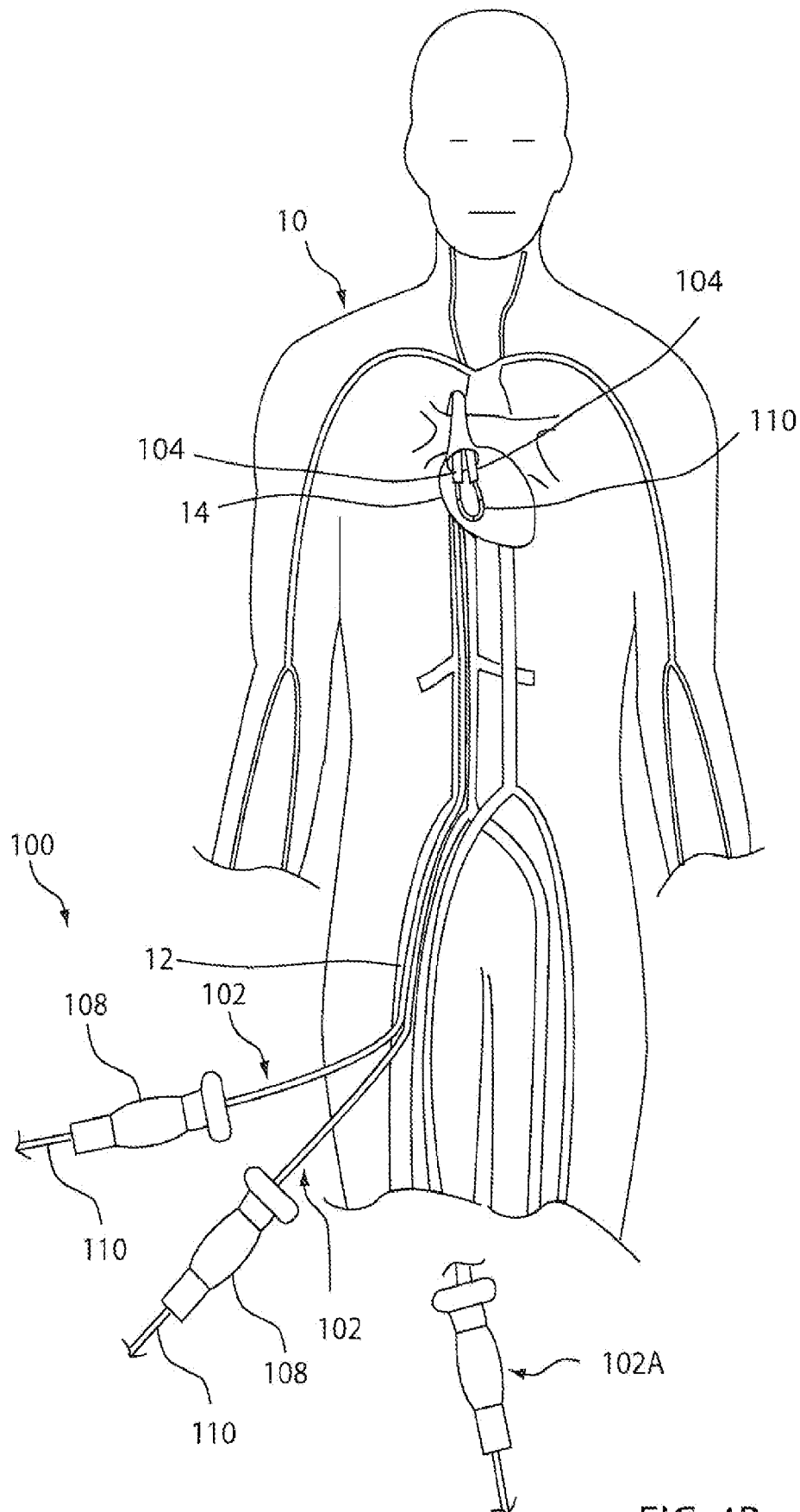


FIG. 4B

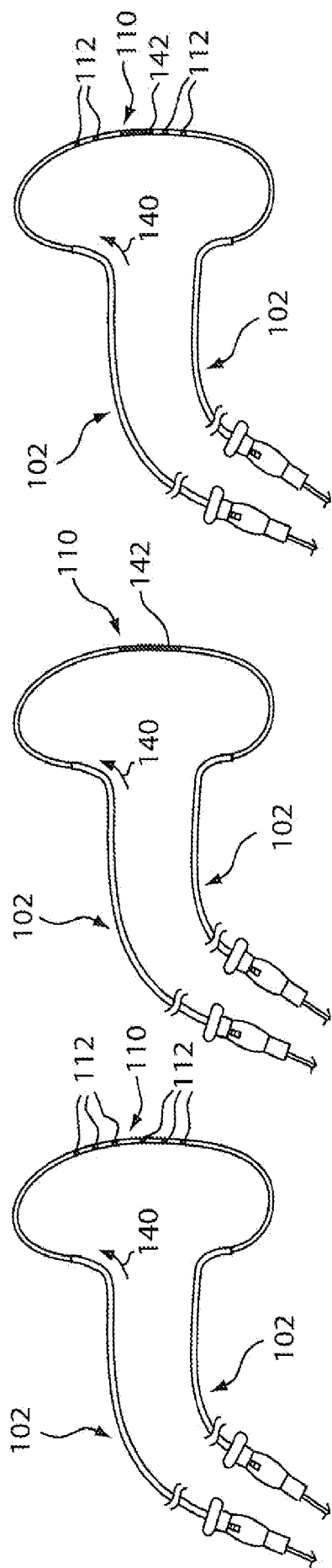


FIG. 4E

FIG. 4D

FIG. 4C

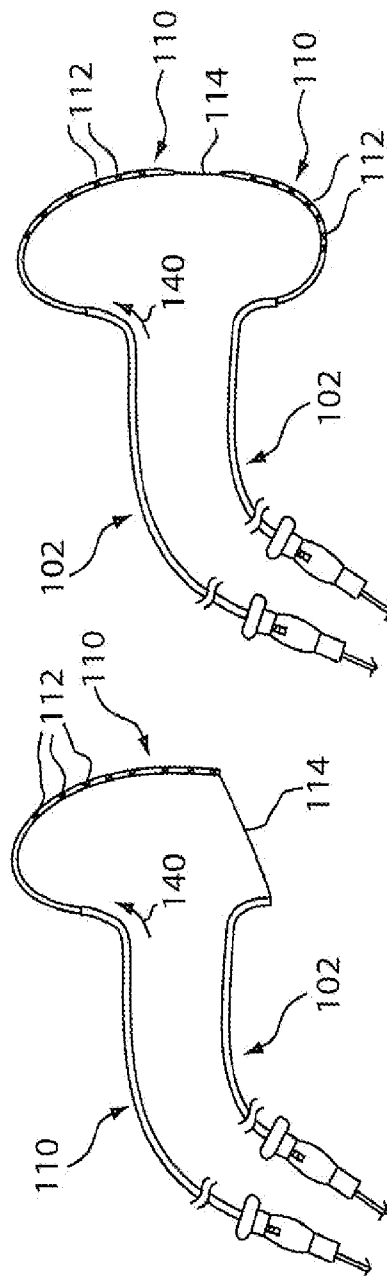
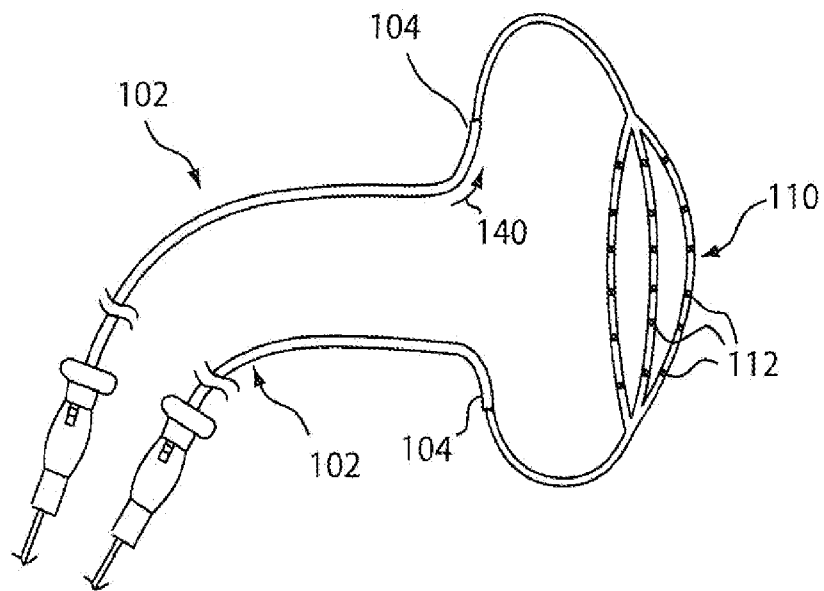
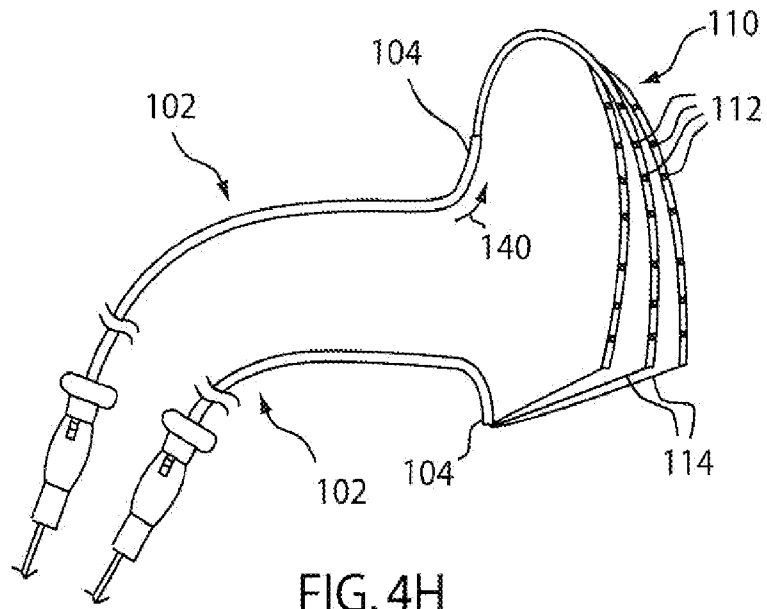


FIG. 4G

FIG. 4F

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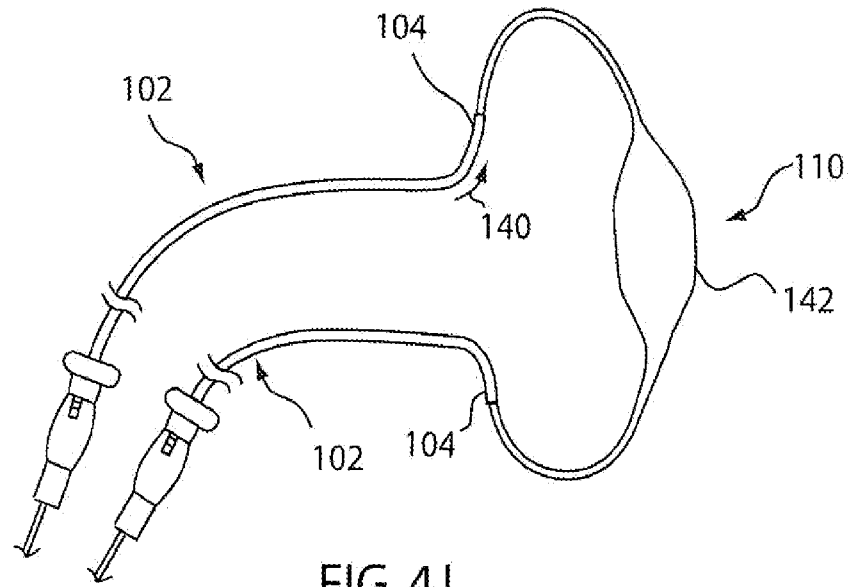


FIG. 4J

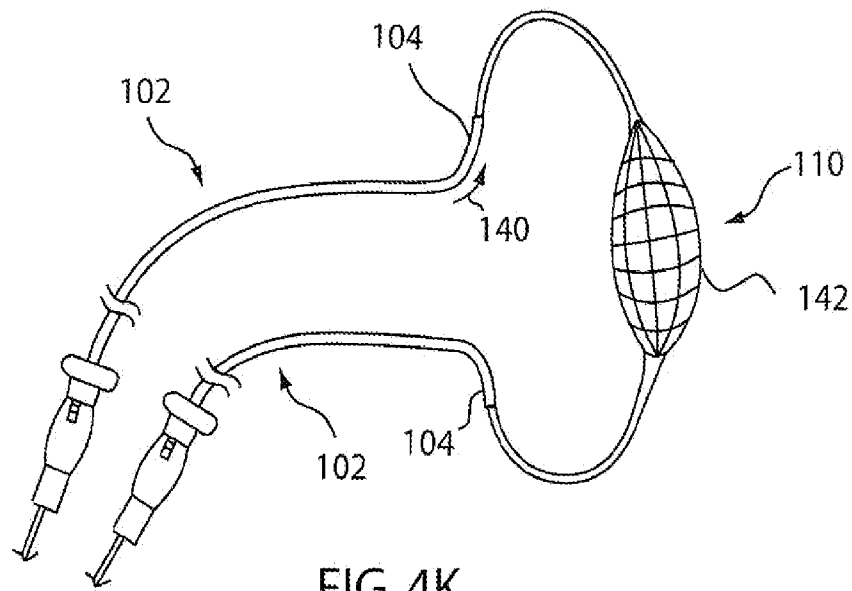


FIG. 4K

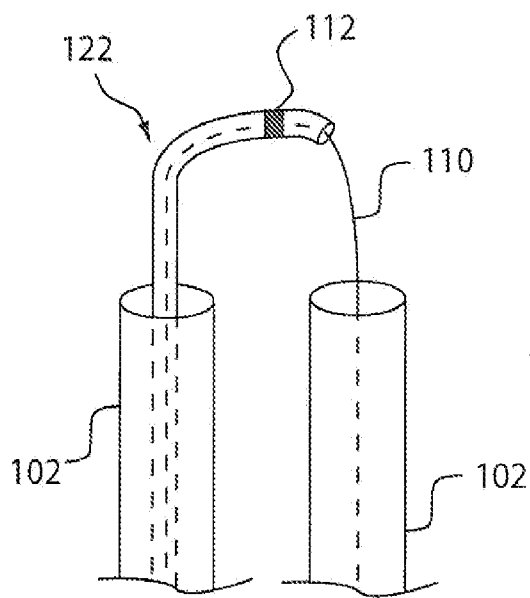


FIG. 5A

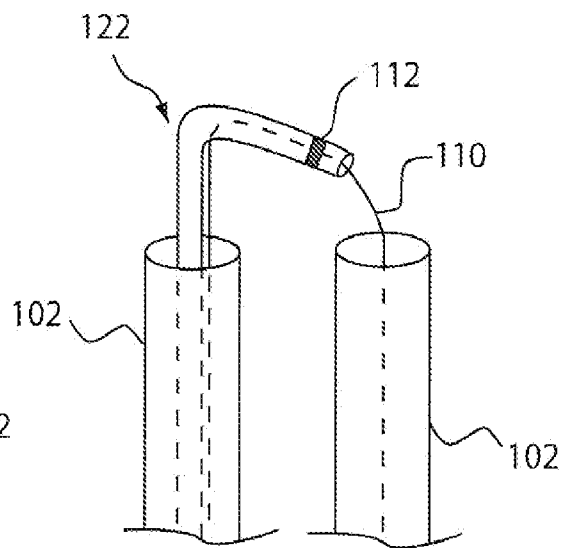


FIG. 5B

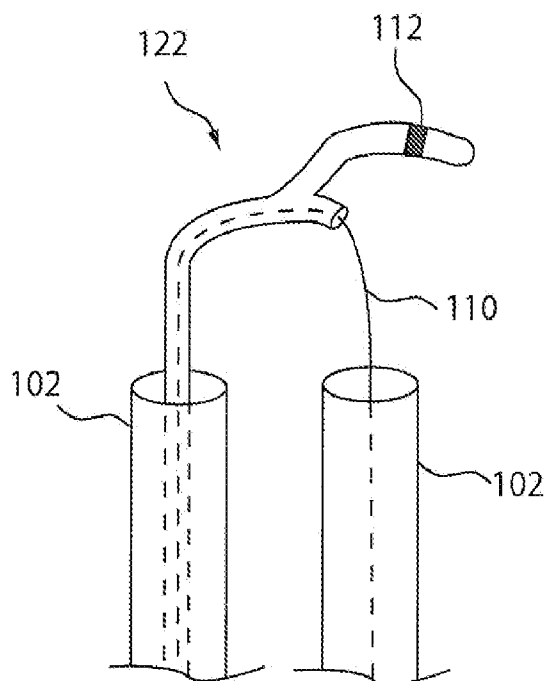


FIG. 5C

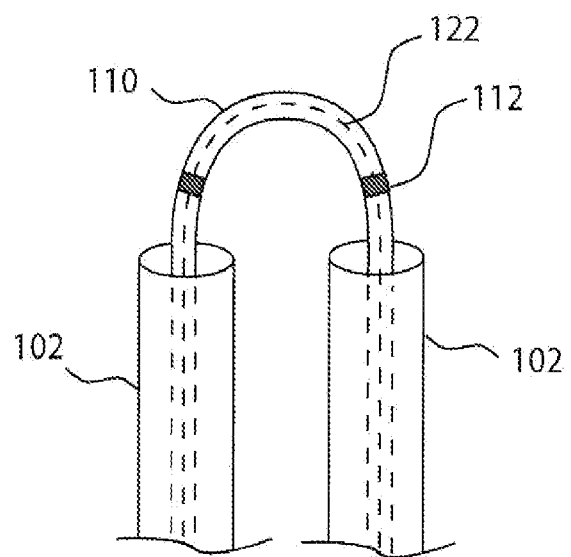


FIG. 5D

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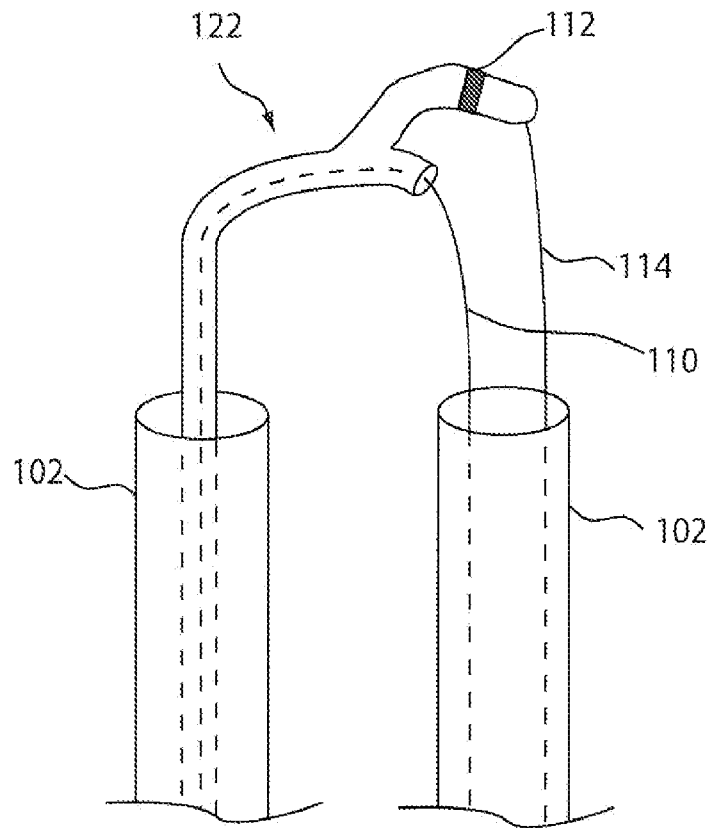


FIG. 5E

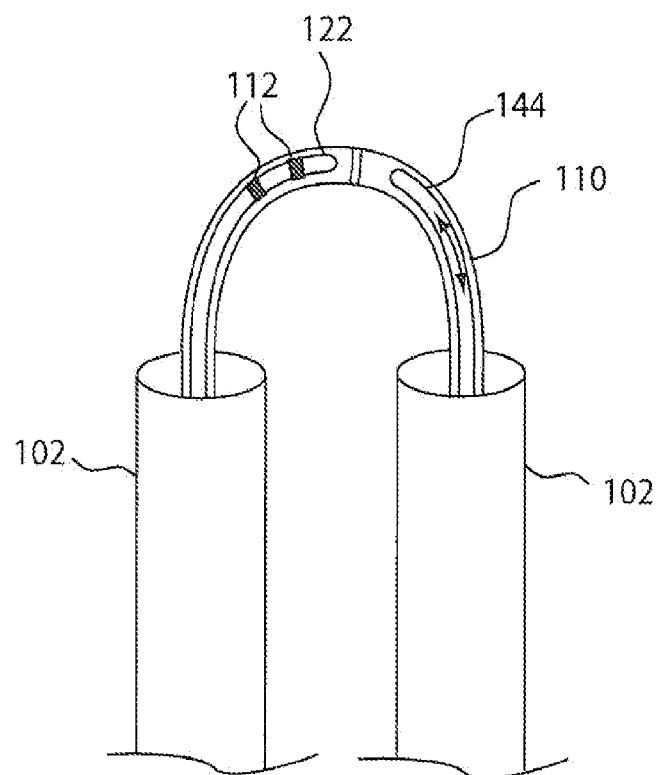


FIG. 5F

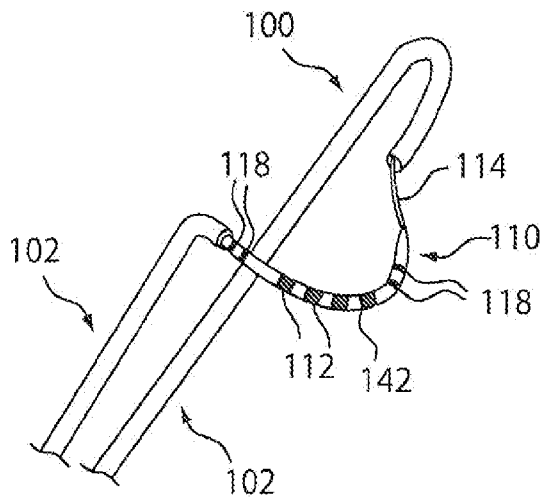


FIG. 6A

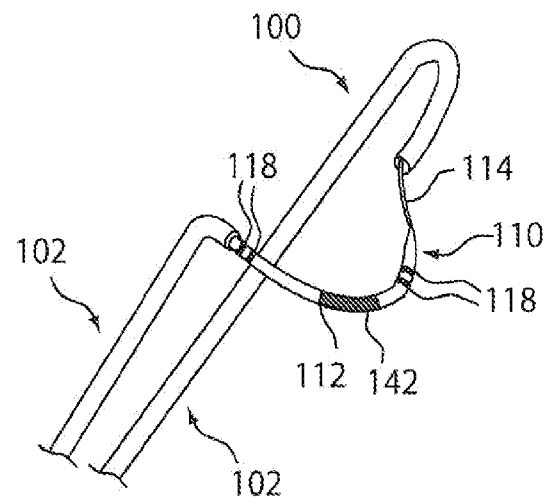


FIG. 6B

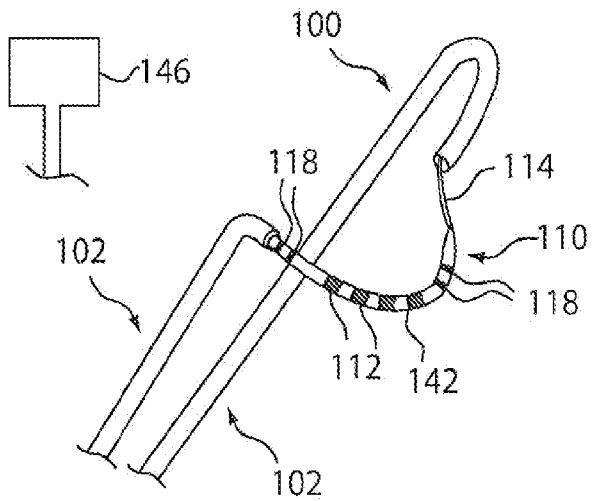


FIG. 6C

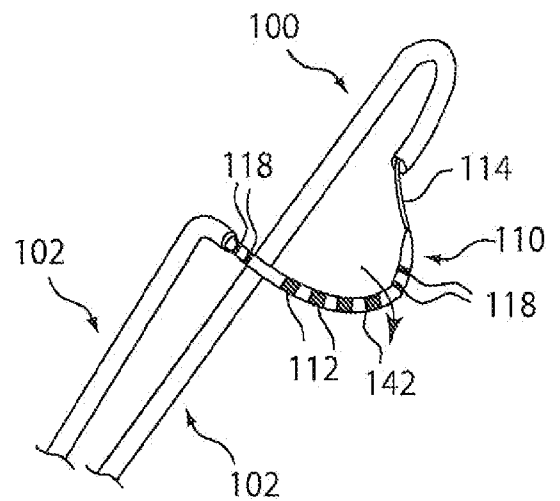


FIG. 6D

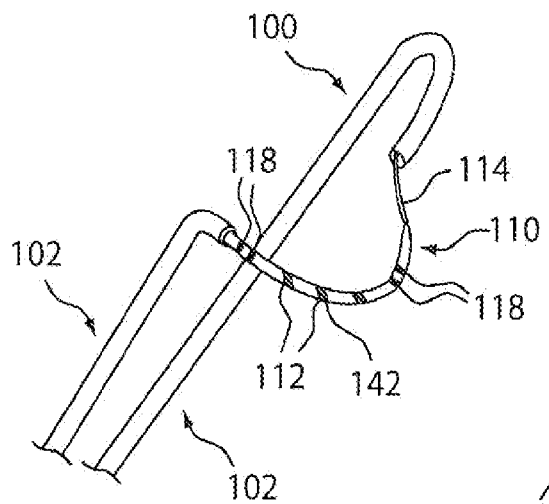


FIG. 6E

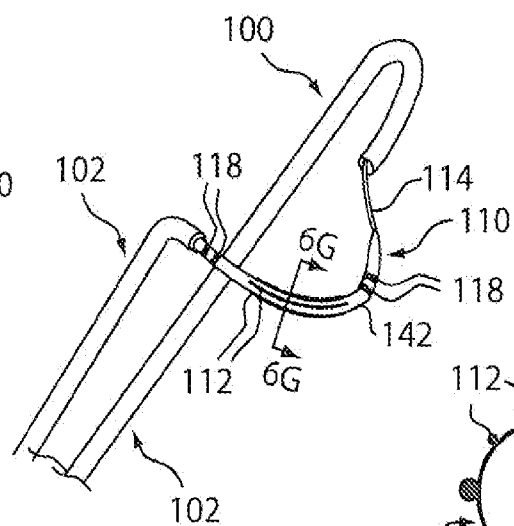


FIG. 6F

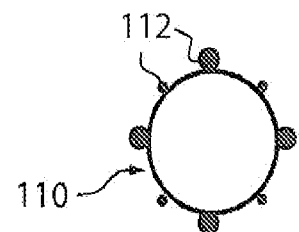


FIG. 6G

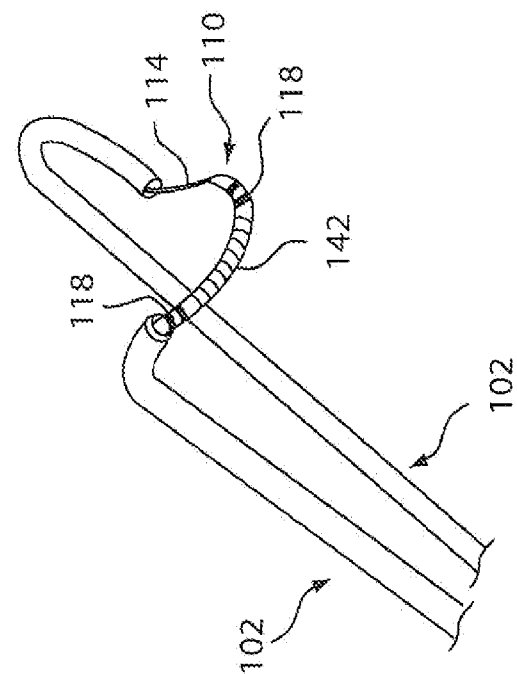


FIG. 6I

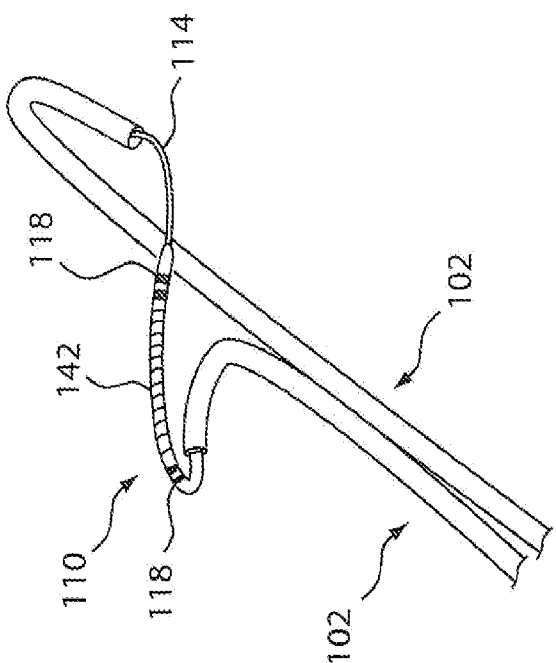


FIG. 6H

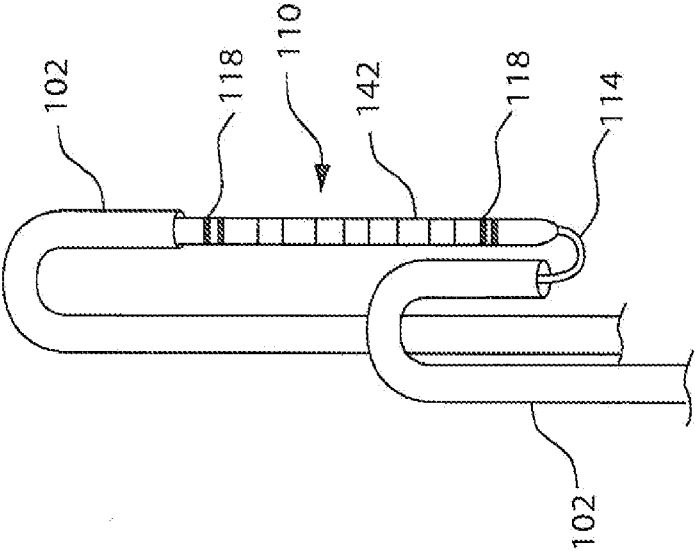


FIG. 6J

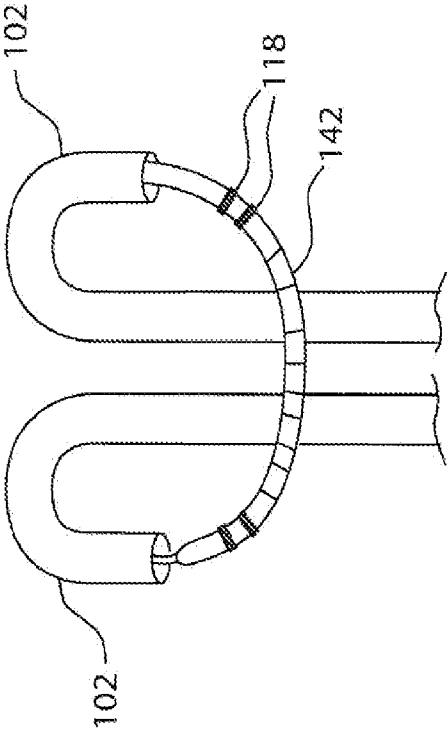


FIG. 6K

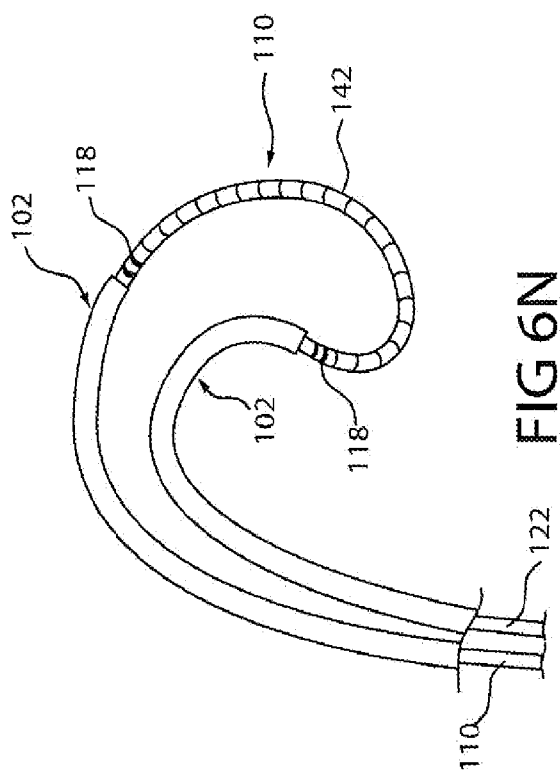


FIG 6N

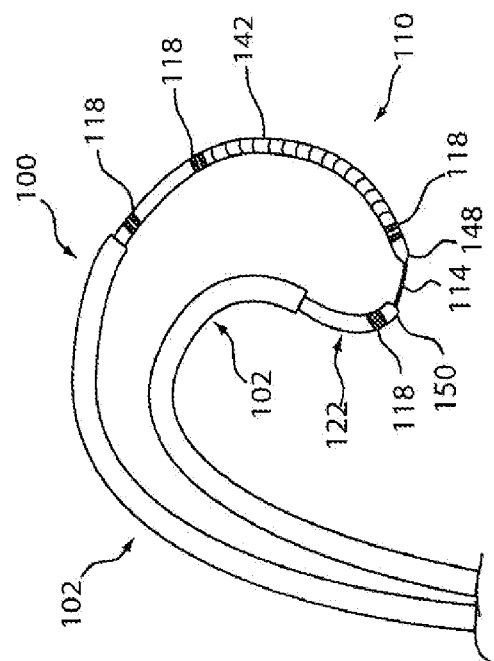


FIG 6L

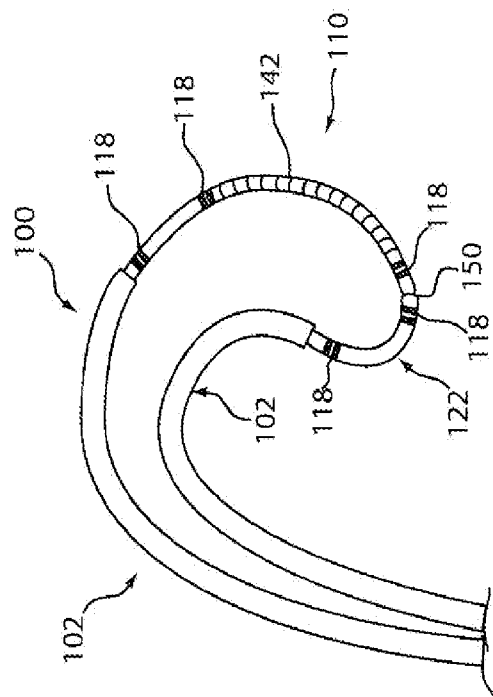


FIG 6M

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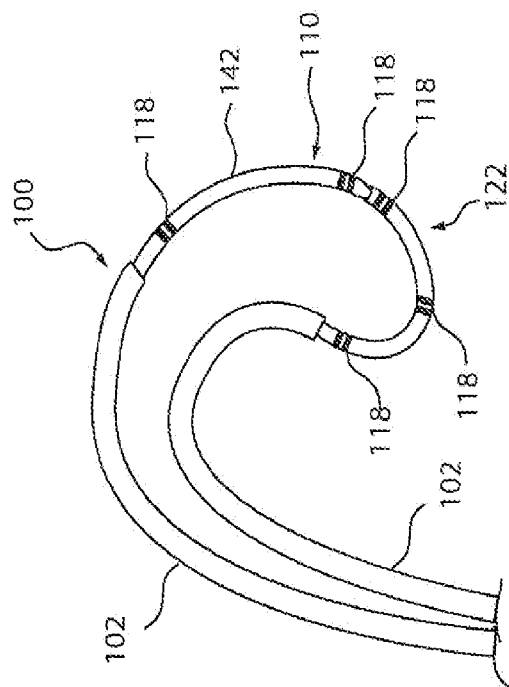


FIG. 60Q

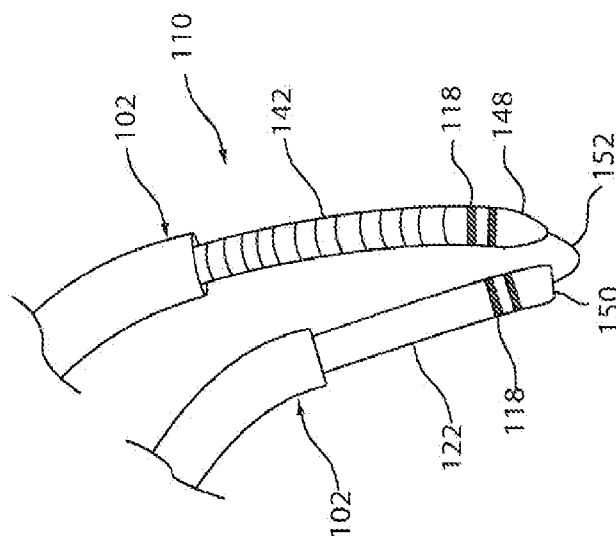


FIG. 60P

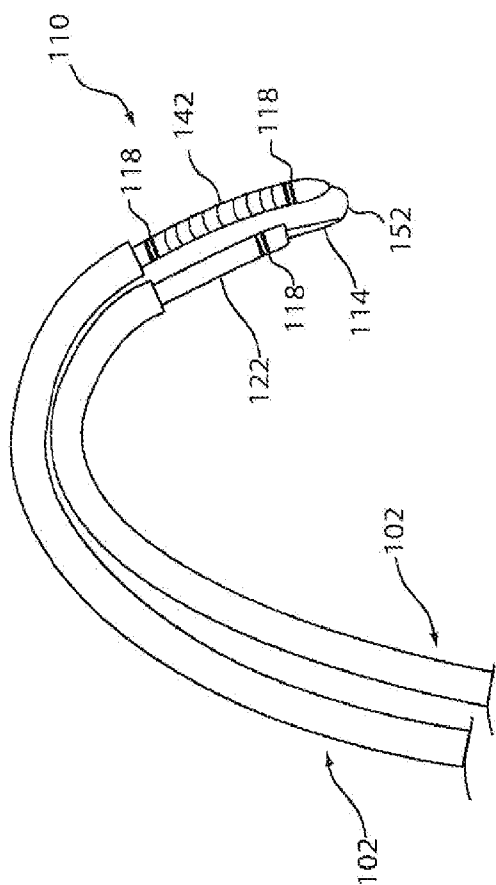
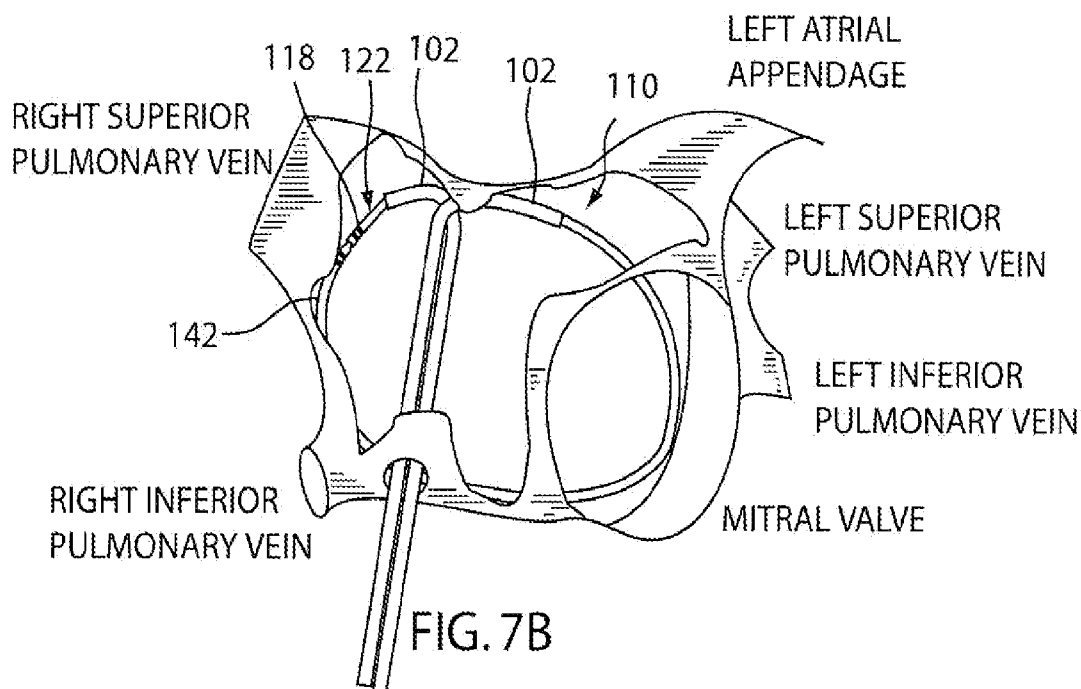
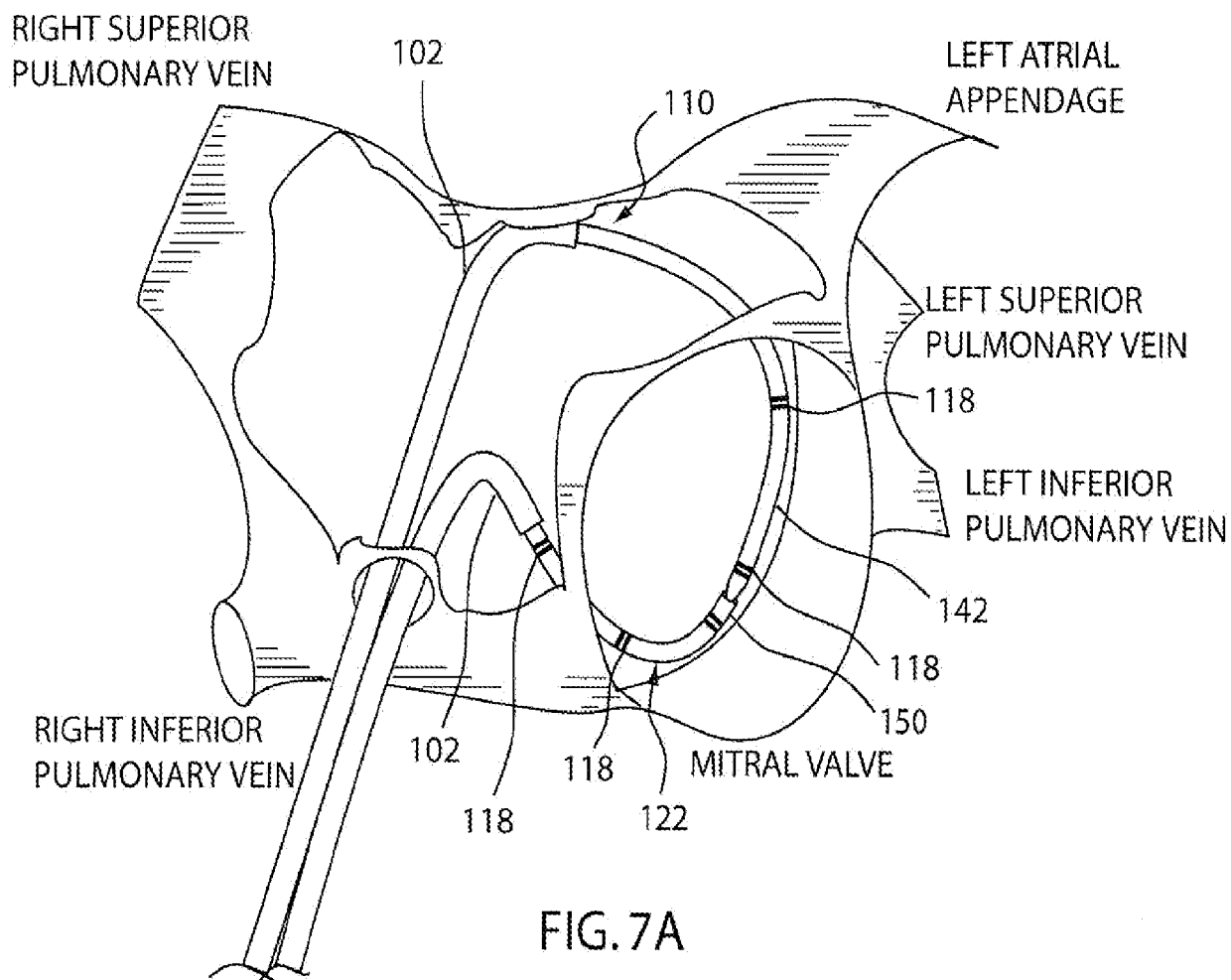
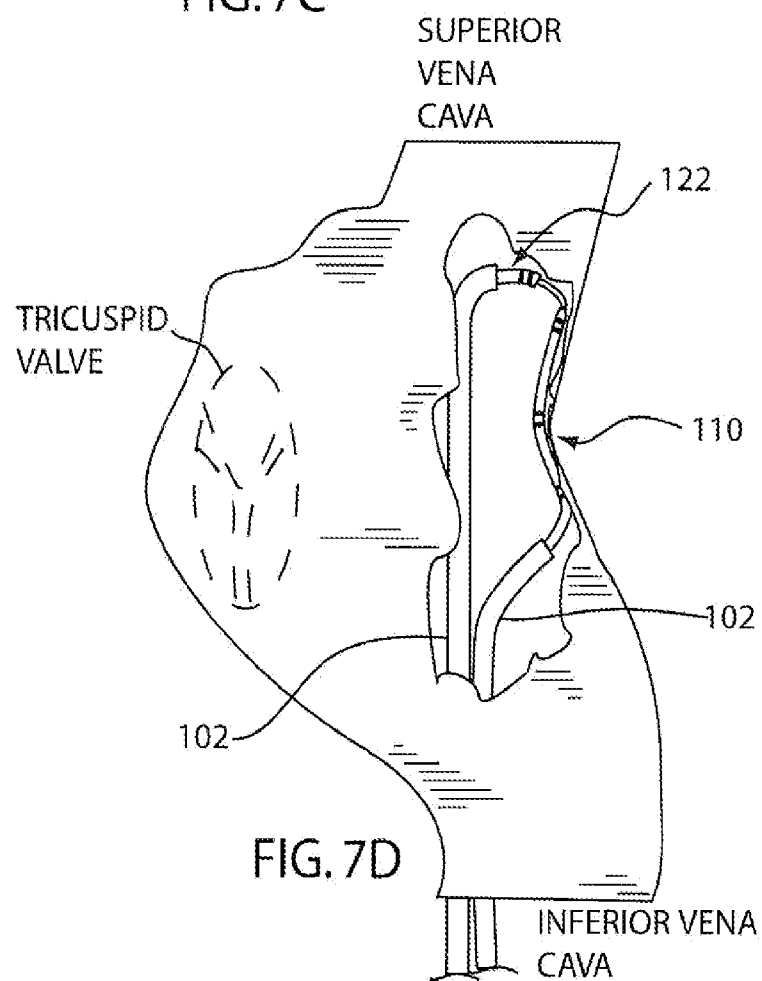
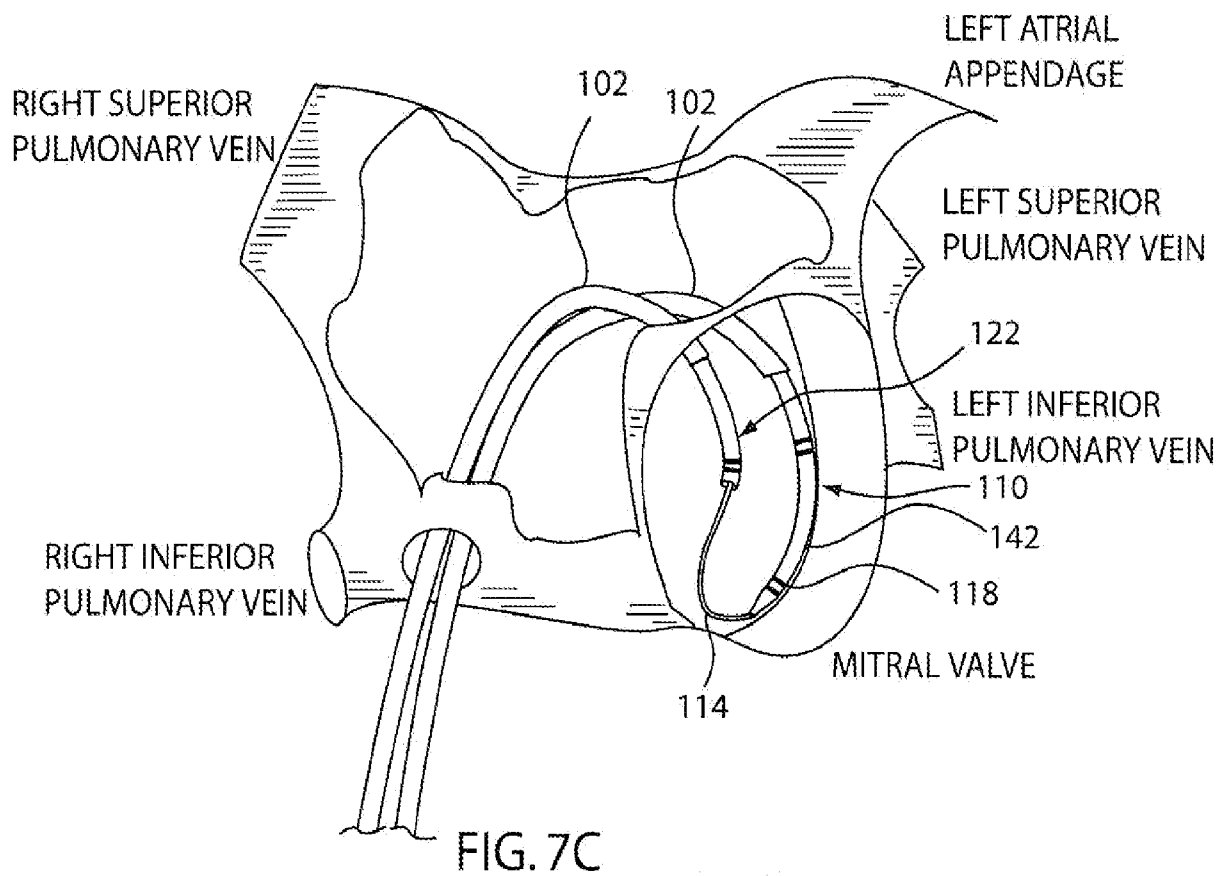


FIG. 60

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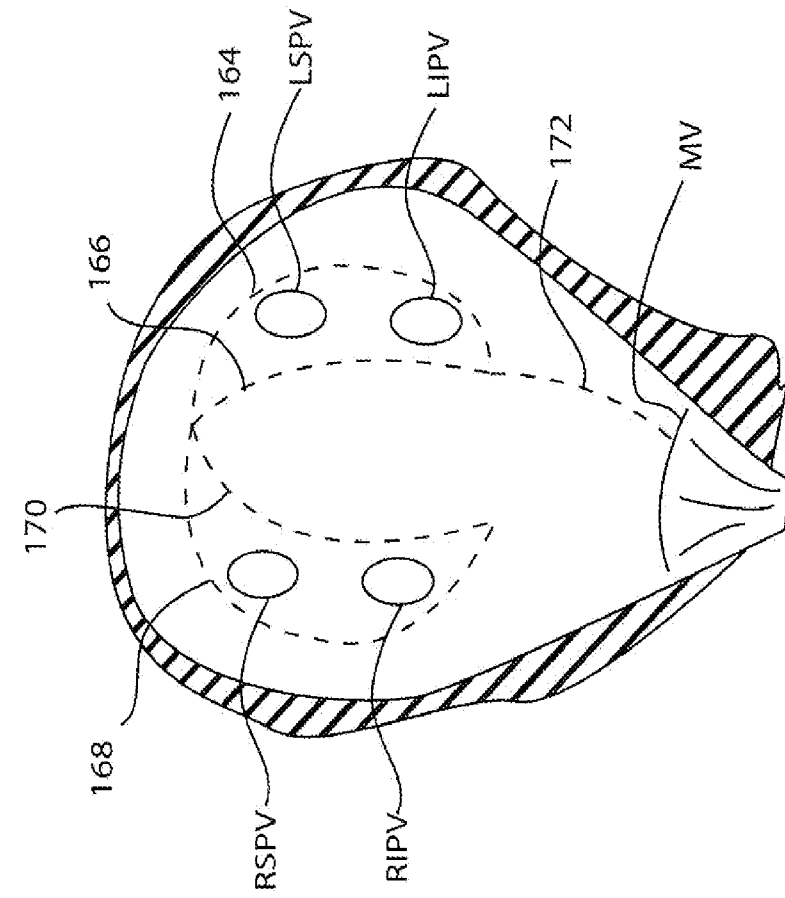


FIG. 7F

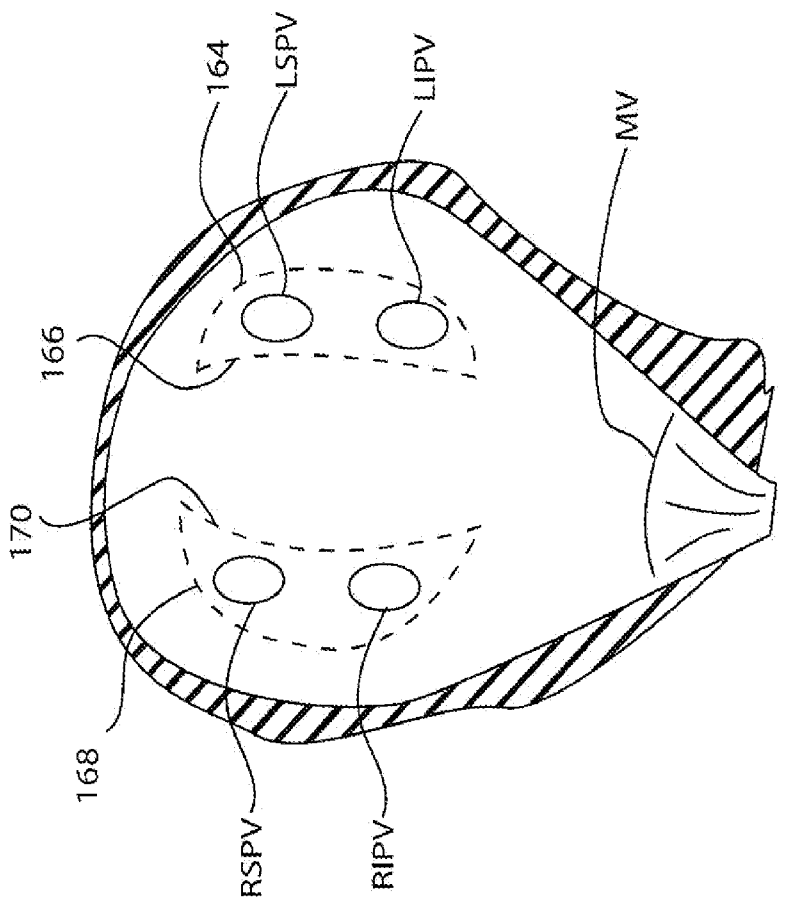


FIG. 7E

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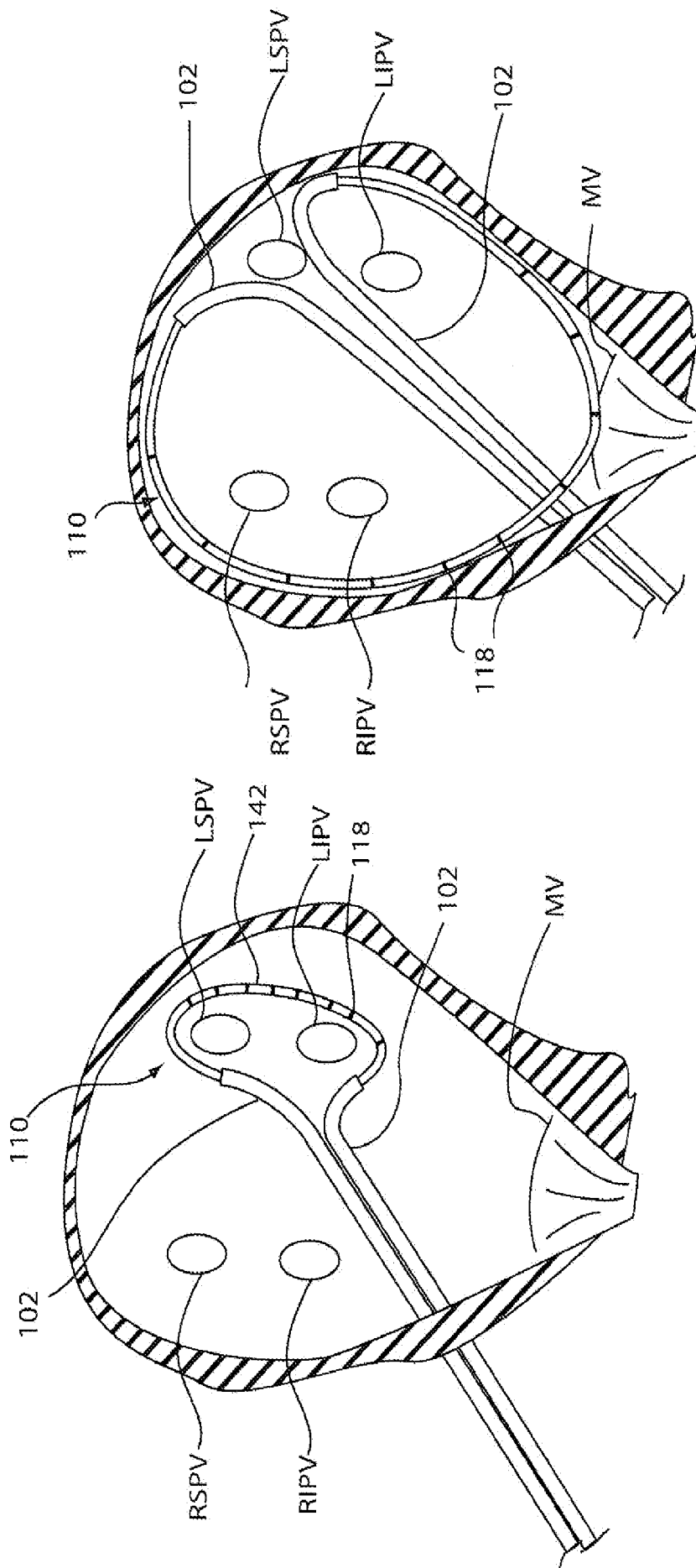


FIG. 7H

FIG. 7G

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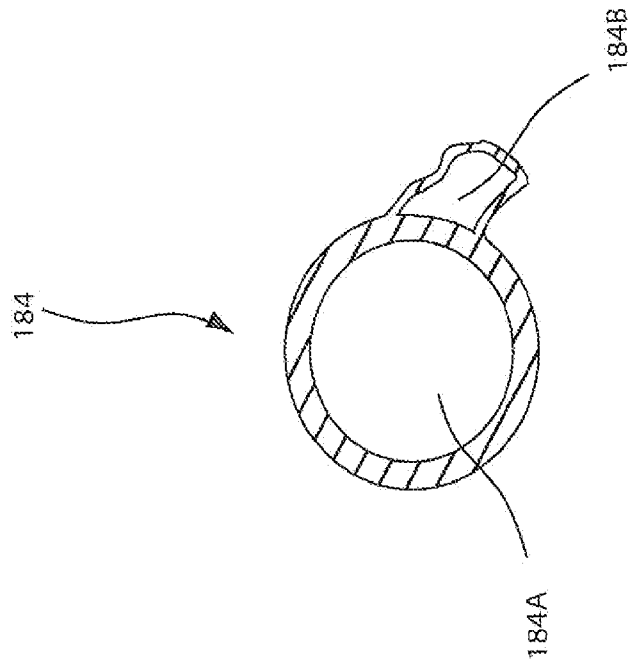


FIG. 8B

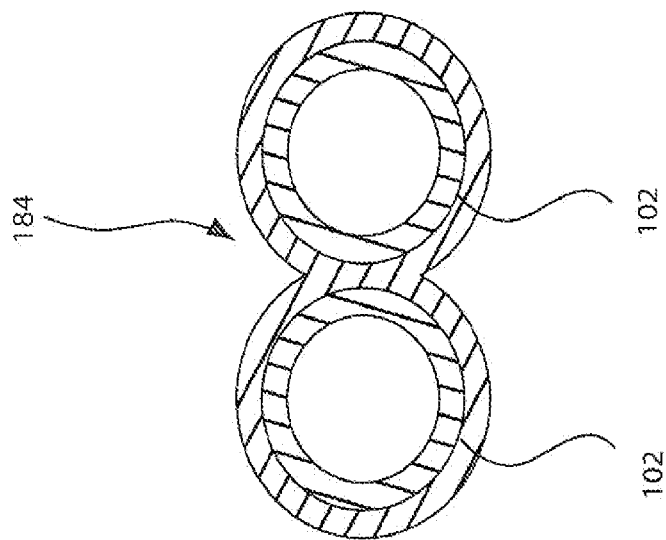


FIG. 8A

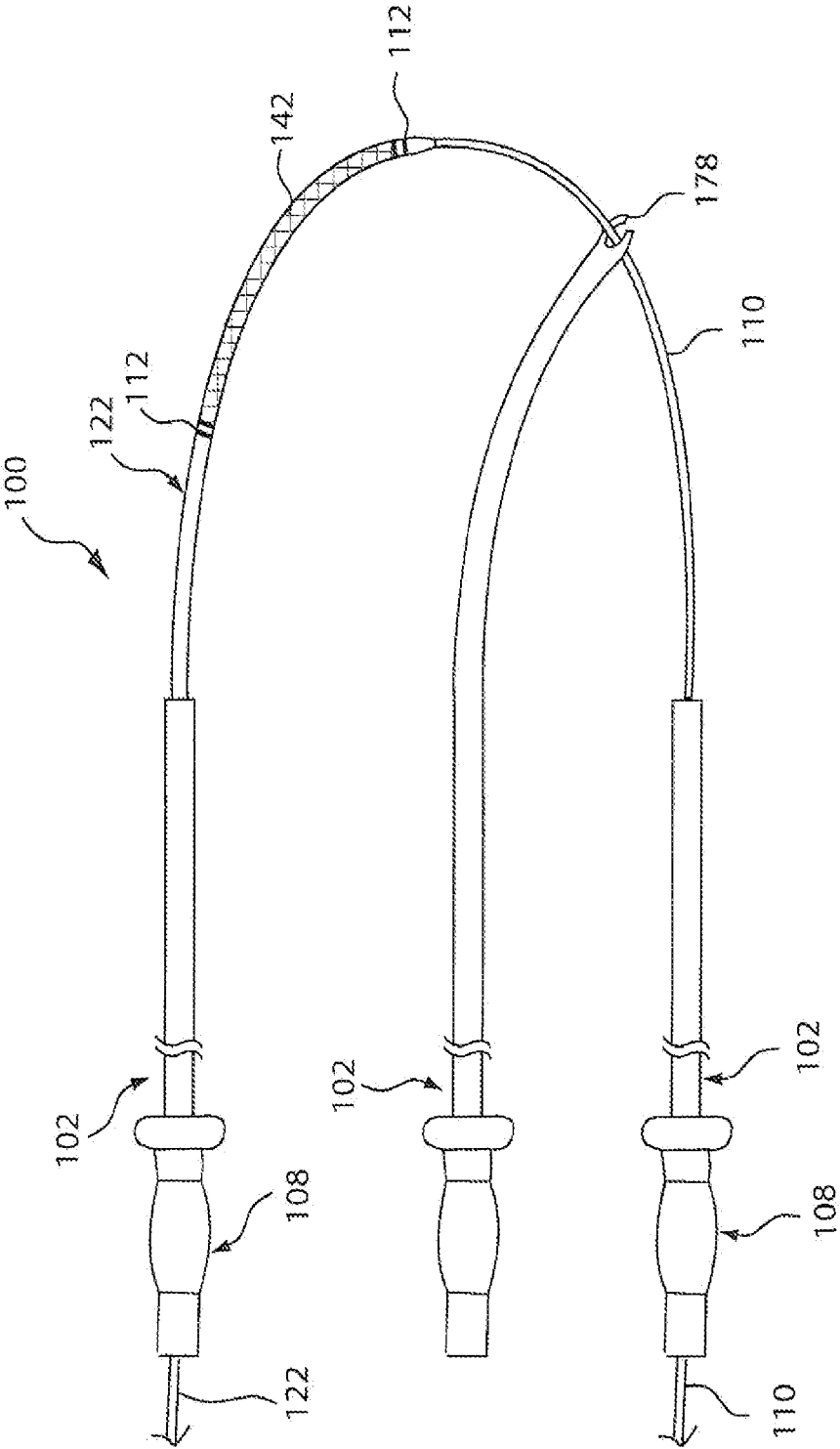


FIG. 9A

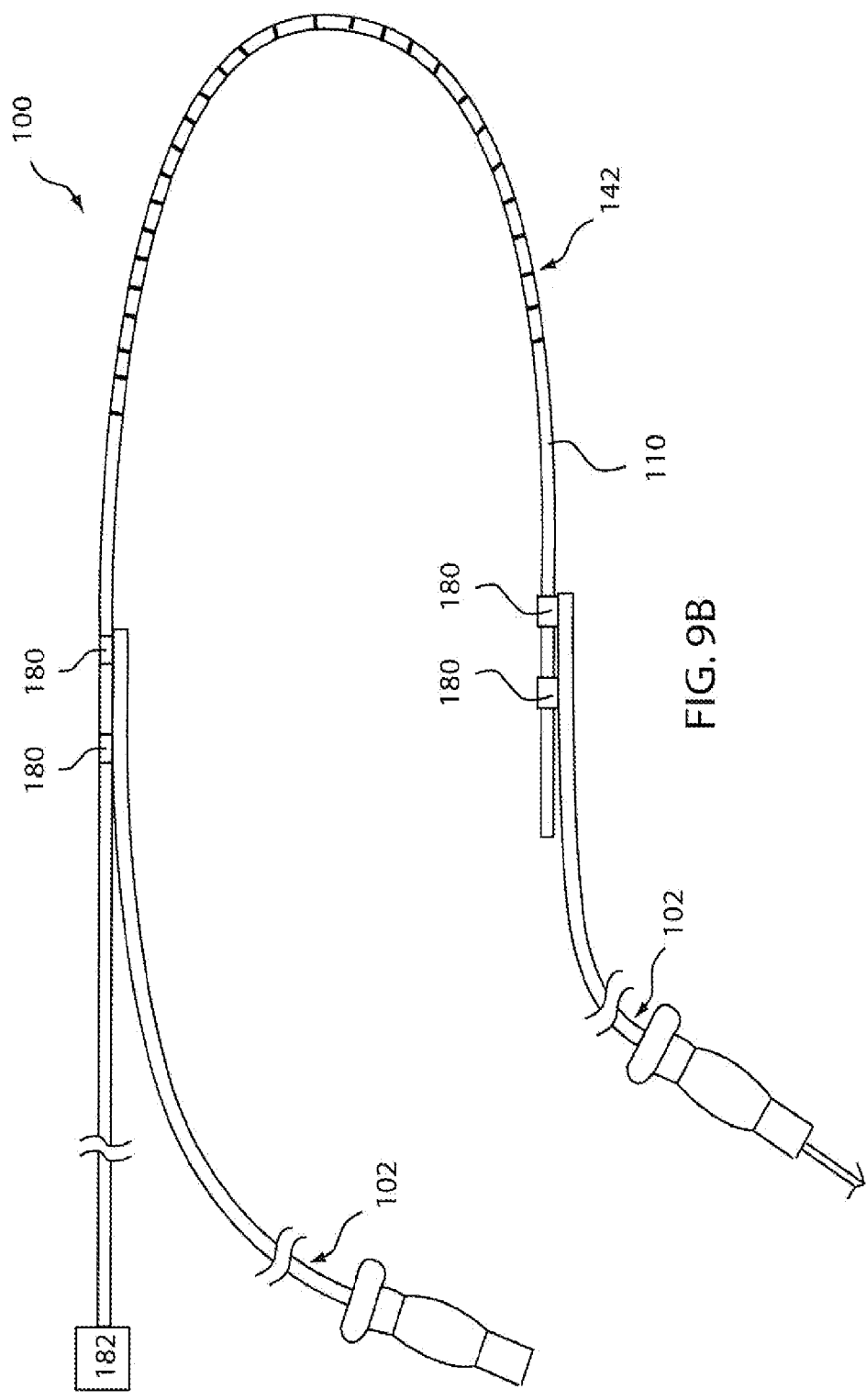


FIG. 9B

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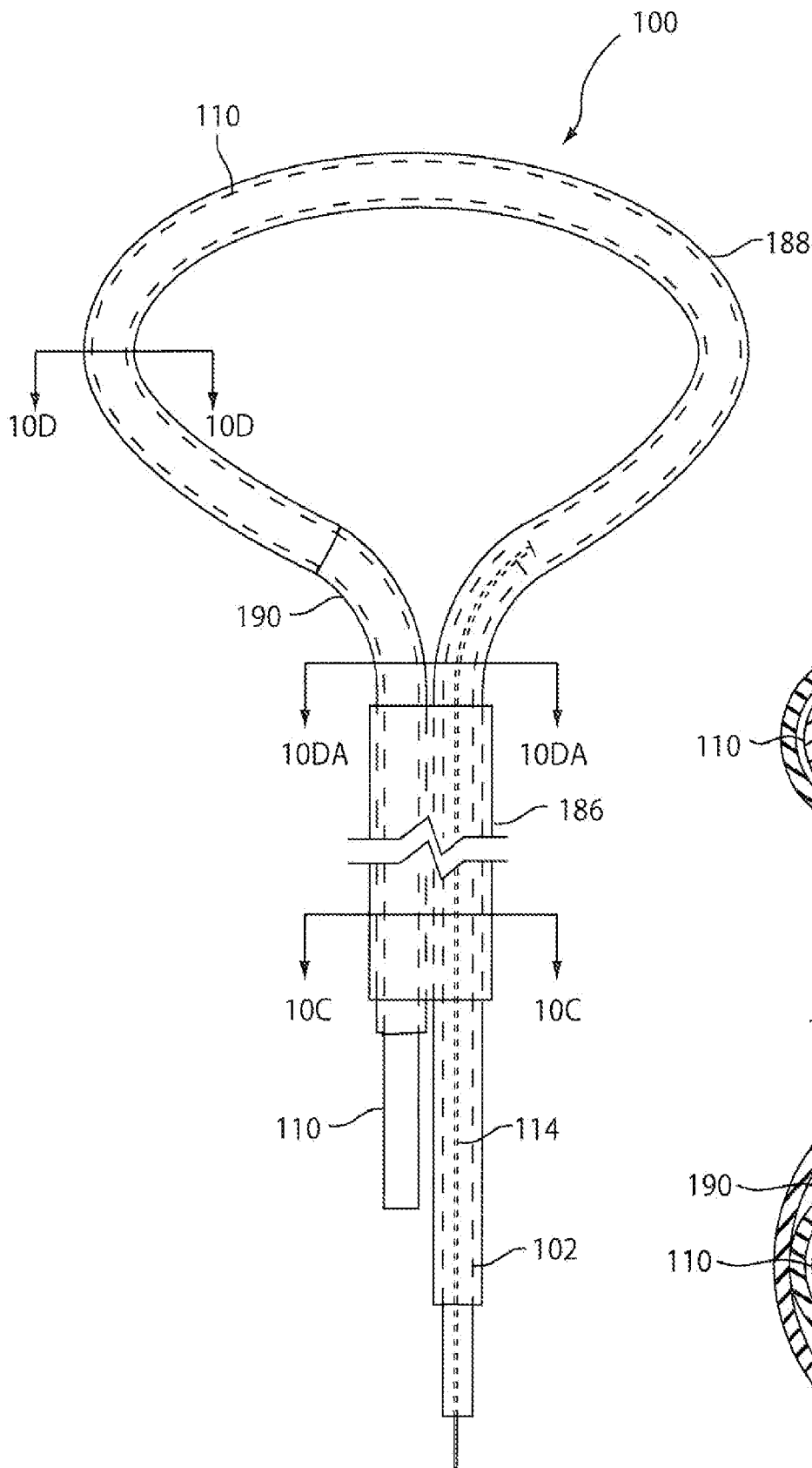


FIG. 10A

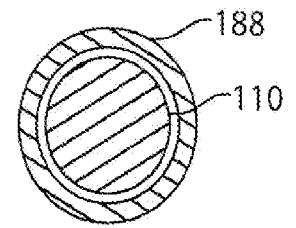


FIG. 10D

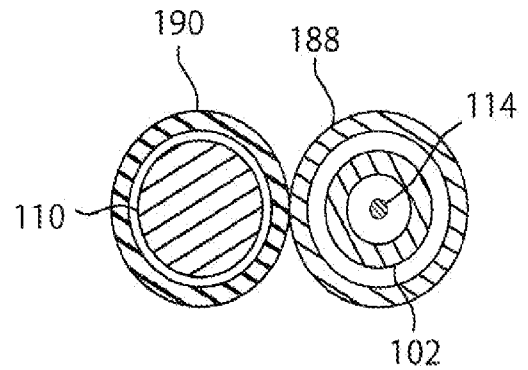


FIG. 10DA

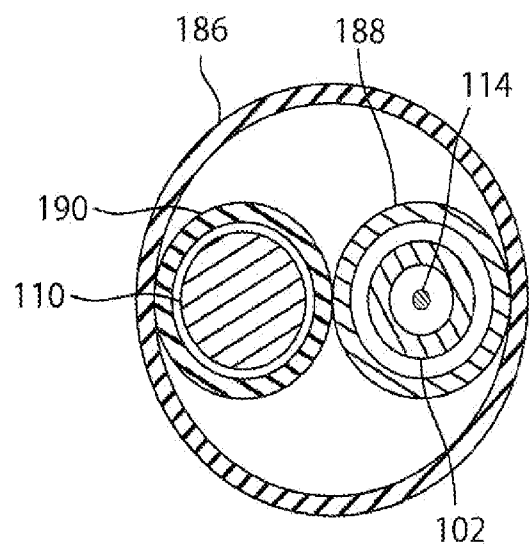


FIG. 10C

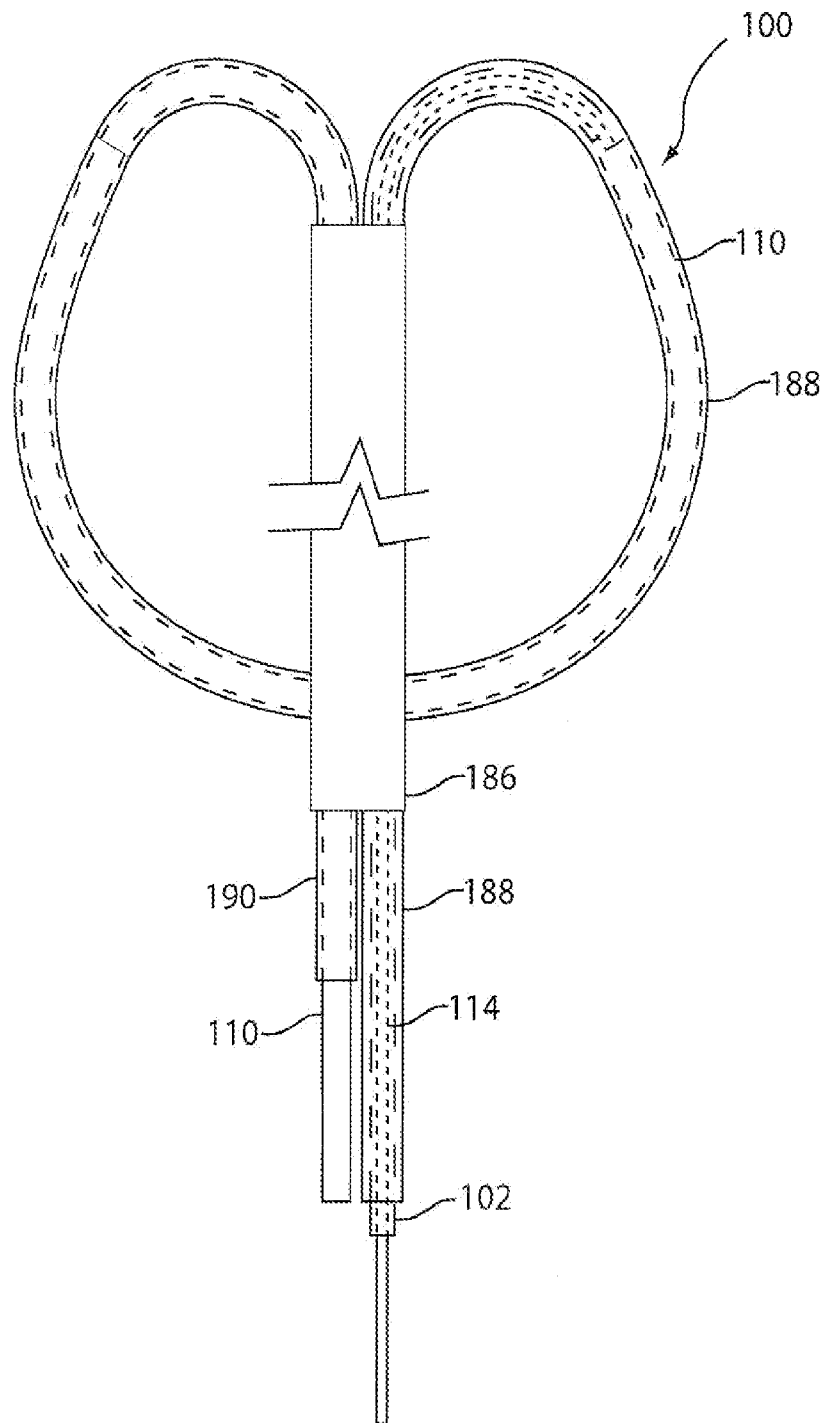


FIG. 10B

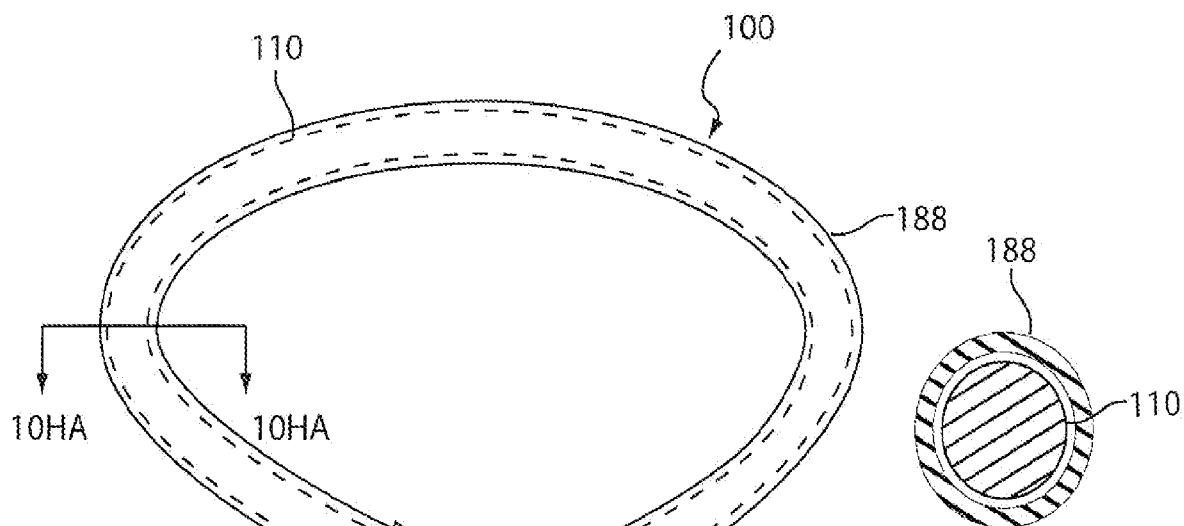


FIG. 10HA

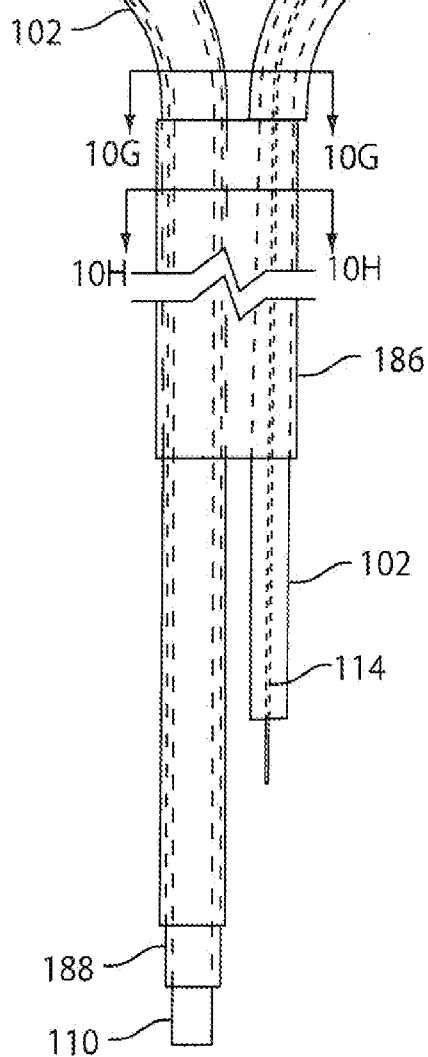


FIG. 10E

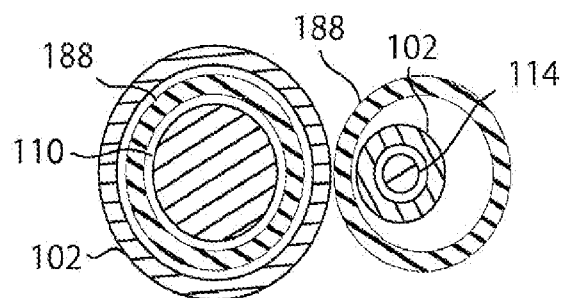


FIG. 10G

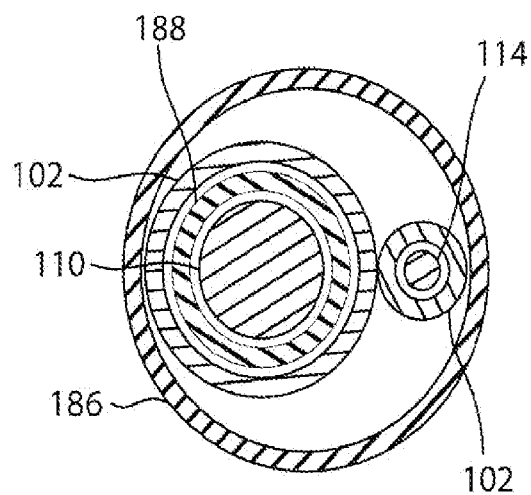


FIG. 10H

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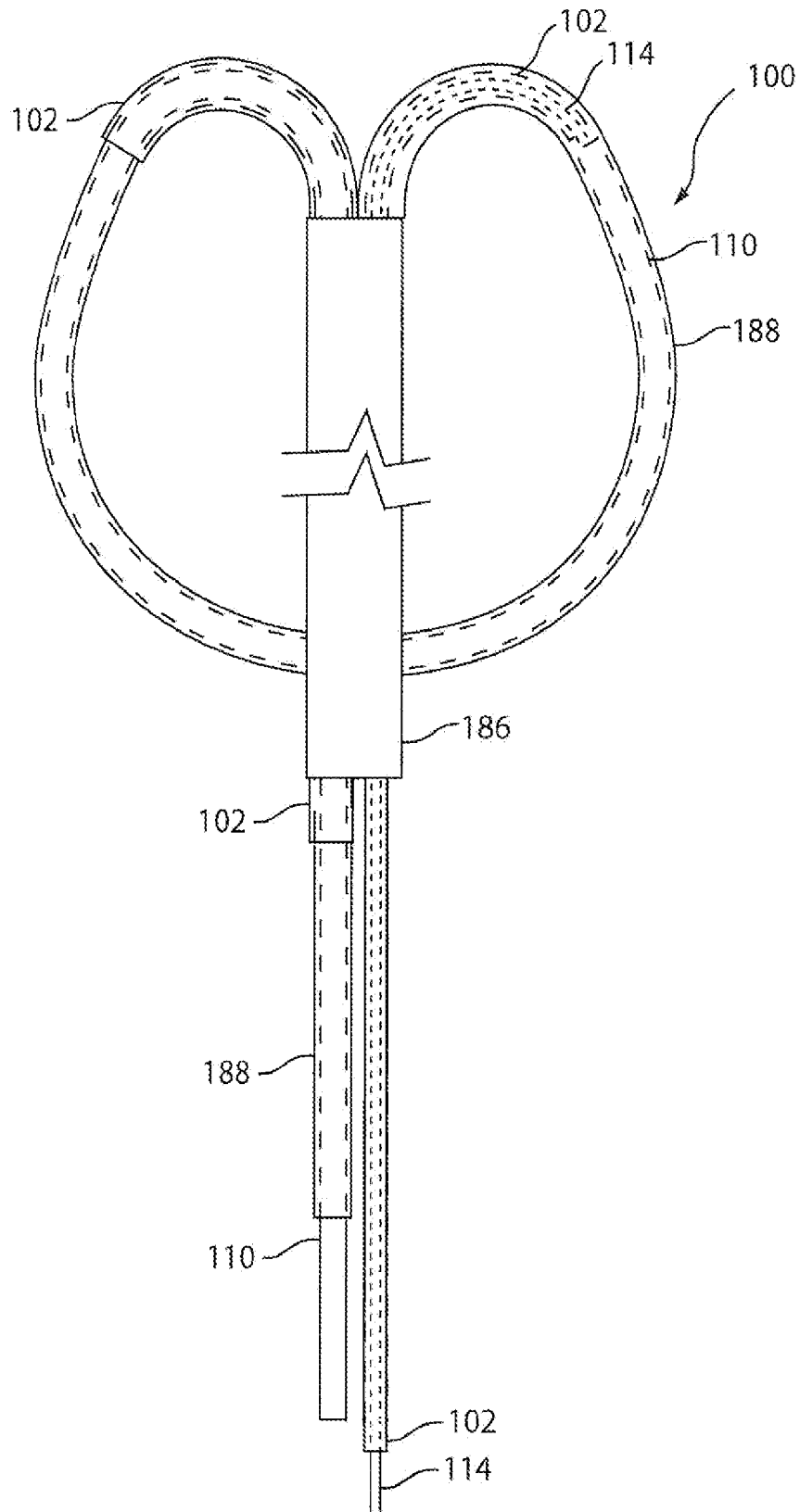


FIG. 10F

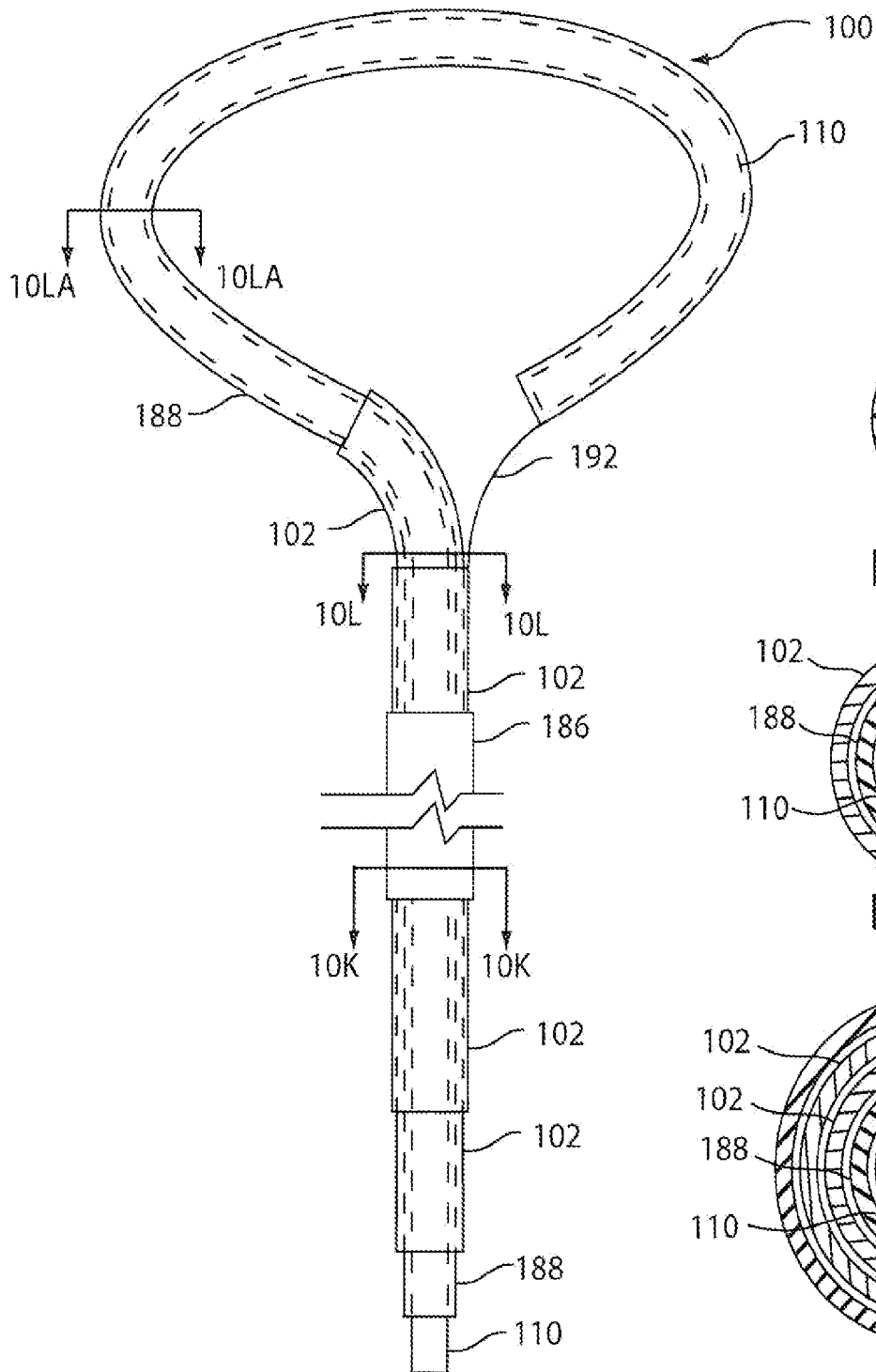


FIG. 10I

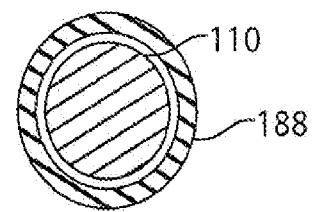


FIG. 10LA

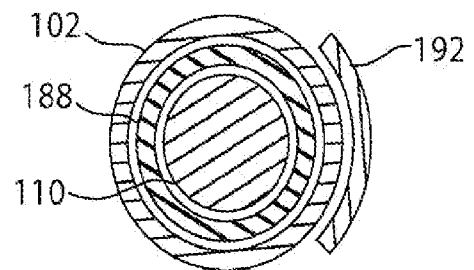


FIG. 10L

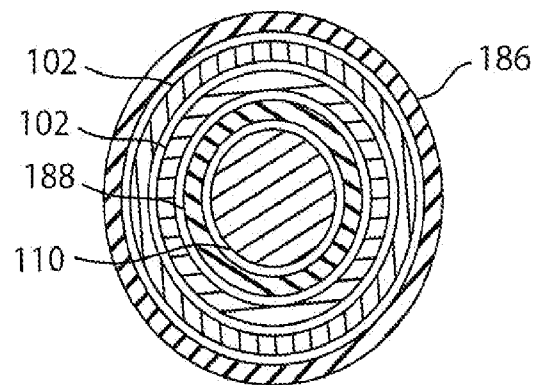


FIG. 10K

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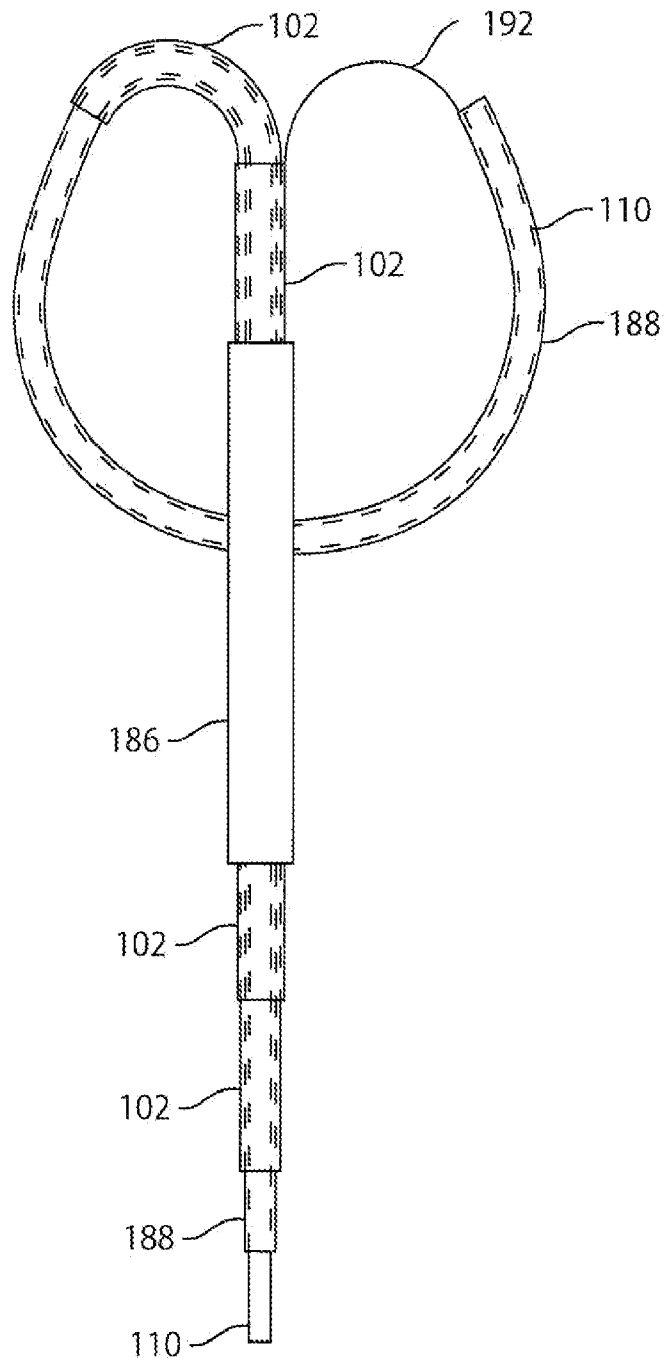


FIG. 10J

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2009/061547

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61N 01/00 (2009.01)

USPC - 607/009

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61N 01/00 (2009.01)

USPC - 607/009

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)

MicroPatent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/0203480 A1 (MODY et al) 30 August 2007 (30.08.2007) entire document	22-29, 31-33 and 35-38
Y		1-21, 30 and 34
Y	US 2007/0179552 A1 (DENNIS et al) 02 August 2007 (02.08.2007) entire document	1-21, 30 and 34
A	US 5,861,021 A (THOME et al) 19 January 1999 (19.01.1999) entire document	1-38
A	US 5,928,145 A (OCALI et al) 27 July 1999 (27.07.1999) entire document	1-38
A	US 7,226,446 B1 (MODY et al) 05 June 2007 (05.06.2007) entire document	1-38

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


* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

03 December 2009

Date of mailing of the international search report

11 DEC 2009

Name and mailing address of the ISA/US

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