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(71) Applicant: ST. JUDE MEDICAL, CARDIOLOGY DIVISION, INC. [US/US]; 177 East County Road B, St. Paul, Minnesota 55117 (US).

(72) Inventors: VANSKOY, John; 13710 54th Avenue North, #305, Plymouth, Minnesota 55446 (US). SEFKOW, Ryan; 9939 Crown Ridge Drive, Frisco, Texas 75035 (US). ROSENBERG, Stuart; 31413 Arena Drive, Castaic, California 91384 (US). KEEL, Allen; 893 Rhode Island Street, San Francisco, California 94107 (US). SHAH, Riddhi; 4355 Renaissance Drive, Apt. 305, San Jose, Cali-

fornia 95134 (US). HOU, Wenbo; 27662 Briarcliff Place, Valencia, California 91354 (US).

(74) Agent: MARKS, Scott A.; St. Jude Medical, Cardiovascular and Ablation Technologies, 5050 Nathan Lane North, Plymouth, Minnesota 55442 (US).

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(54) Title: MEDIGUIDE-ENABLED RENAL DENERVATION SYSTEM FOR ENSURING WALL CONTACT AND MAPPING LESION LOCATIONS

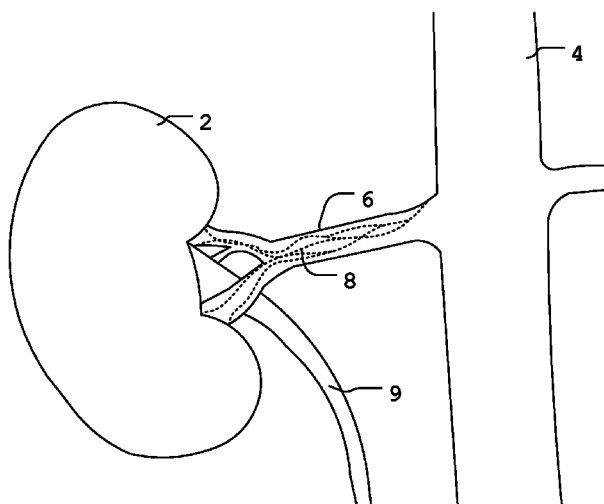


FIG. 1

(57) Abstract: An ablation catheter includes an elongated body having a proximal end and a distal end. At least one ablation element is disposed on the body between the proximal end and the distal end and configured to ablate renal tissue to control hypertension. At least one localization sensor is disposed on the body and configured to interact with a magnetic field. The at least one localization sensor aids in determining an appropriate target tissue for ablation.





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MEDIGUIDE-ENABLED RENAL DENERVATION SYSTEM FOR
ENSURING WALL CONTACT AND MAPPING LESION LOCATIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of the filing date of U.S. Patent Application No. 13/829,310, filed on March 14, 2013, the disclosure of which is hereby incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention is related to ablation devices, and more particularly to devices, systems, and methods for mediguid-enabled renal denervation.

[0003] Hypertension is a major global public health concern. An estimated 30-40% of the adult population in the developed world suffers from this condition. Furthermore, its prevalence is expected to increase, especially in developing countries. Diagnosis and treatment of hypertension remain suboptimal, even in developed countries. Despite the availability of numerous safe and effective pharmacological therapies, including fixed-drug combinations, the percentage of patients achieving adequate blood-pressure control to guideline target values remains low. Thus, the development of new approaches for the management of hypertension is a priority. These considerations are especially relevant to patients with so-called resistant hypertension (i.e., those unable to achieve target blood-pressure values despite multiple drug therapies at the highest tolerated dose). Such patients are at high risk of major cardiovascular events.

[0004] Renal sympathetic efferent and afferent nerves, which lie within and immediately adjacent to the wall of the renal artery, are crucial for initiation and maintenance of systemic hypertension. Indeed, sympathetic nerve modulation as a therapeutic strategy in hypertension had been considered long before the advent of modern pharmacological therapies. Radical surgical methods for thoracic, abdominal, or pelvic

sympathetic denervation has been successful in lowering blood pressure in patients with so-called malignant hypertension. However, these methods were associated with high perioperative morbidity and mortality and long-term complications, including bowel, bladder, and erectile dysfunction, in addition to severe postural hypotension. Renal denervation is the application of a chemical agent, or a surgical procedure, or the application of energy to partially or completely damage renal nerves so as to partially or completely block renal nerve activity. Renal denervation reduces or completely blocks renal sympathetic nerve activity, increases renal blood flow (RBF), and decreases renal plasma norepinephrine (NE) content.

[0005] The objective of renal denervation is to neutralize the effect of the renal sympathetic system, which is involved in arterial hypertension. One method to reach this objective is to use radio frequency (RF) ablation of renal sympathetic nerves to reduce the blood pressure of certain patients. There is a need for devices and techniques that are designed to improve the effectiveness of the procedure.

BRIEF SUMMARY OF THE INVENTION

[0006] To achieve these goals, a system and method that include a mediguide-enabled ablation catheter and specific techniques of overcoming these challenges are proposed.

[0007] In some embodiments, an ablation catheter includes an elongated body having a proximal end and a distal end, at least one ablation element disposed on the body between the proximal end and the distal end, and at least one localization sensor disposed on the body and configured to interact with a magnetic field.

[0008] In some embodiments, an ablation catheter includes a longitudinal rod, a plurality of arms disposed about the longitudinal rod, and being resiliently biased outwardly away from the longitudinal rod, at least one ablation element disposed on each of the arms, and at least

one localization sensor disposed on at least one of the longitudinal rod and one of the plurality of arms.

[0009] In some embodiments, a method for ablating vascular tissue includes introducing into an artery an ablation catheter including an elongated body having a proximal end and a distal end, at least one ablation element disposed on the body between the proximal end and the distal end, and at least one localization sensor disposed on the body, using the at least one localization sensor to determine an appropriate target tissue for ablation and ablating the target tissue to provide a therapeutic effect.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Various embodiments of the present system and method will now be discussed with reference to the appended drawings. It is to be appreciated that these drawings depict only some embodiments and are therefore not to be considered as limiting the scope of the present system and method.

[0011] FIG. 1 is a schematic illustration of a kidney, the renal artery and the aorta;

[0012] FIGS. 2A-D illustrate an assembly of staggered ablation elements for a catheter;

[0013] FIG. 3 is a cross-sectional view of an arm of an electrode assembly illustrating an example of a temperature sensor and an irrigation fluid channel;

[0014] FIGS. 4A and 4B are perspective views of an assembly of staggered ablation elements for a catheter;

[0015] FIGS. 5A and 5B are perspective views of another electrode assembly of staggered ablation elements for a catheter;

[0016] FIG. 6 is a perspective view of an over-the-wire configuration for introducing an assembly of staggered ablation elements on a catheter to the surgical site by passing a guide wire through an internal lumen of the catheter;

[0017] FIG. 7 is a perspective view of an over-the-wire configuration for introducing an assembly of staggered

ablation elements on a catheter to the surgical site by passing a guide wire through a hole provided at the distal end of the assembly of staggered ablation elements;

[0018] FIG. 8A is a schematic front view of a magnetic transmitter assembly;

[0019] FIG. 8B is a schematic exploded view of three coils forming a magnetic transmitter unit;

[0020] FIG. 8C is a schematic exploded view of a magnetic transmitter assembly and a corresponding motion box formed underneath the assembly;

[0021] FIGS. 9A-C are various configurations of an electrode assembly having localization sensors according to one embodiment of the present invention;

[0022] FIG. 9D is a schematic cross-sectional view of a localization sensor disposed under an ablation electrode according to one embodiment of the present invention;

[0023] FIG. 9E is a schematic cross-sectional view of a localization sensor disposed around an ablation electrode according to another embodiment of the present invention;

[0024] FIGS. 10A and 10B are perspective views of an assembly of staggered ablation elements for a catheter including a plurality of localization sensors according to another embodiment of the present invention; and

[0025] FIG. 11 diagrammatically illustrates real-time visual displays of the catheter location within the renal artery according to one embodiment of the present invention.

DETAILED DESCRIPTION

[0026] In the description that follows, the terms "proximal" and "distal" are to be taken as relative to a user (e.g., a surgeon or a physician) of the disclosed devices and methods. Accordingly, "proximal" is to be understood as relatively close to the user, and "distal" is to be understood as relatively farther away from the user.

[0027] FIG. 1 is a schematic representation of a kidney and its associated structures. The human body typically

includes two kidneys 2, one on each side of the vertebral column. The kidneys serve to filter waste products from the blood. After filtration, urine passes from each bean-shaped kidney 2 via ureter 9 to the bladder (not shown). As seen in FIG. 1, kidneys 2 receive blood from aorta 4 through renal artery 6. Though the main function of the kidneys 2 is to remove waste products from the body, they also play a role as a regulatory organ. Specifically, it has been determined that renal sympathetic efferent and afferent nerves 8, which lie within and adjacent to the wall of the renal artery 6, play a role in managing blood pressure. Elevated renal nerve activity is associated with the development of hypertension.

[0028] FIGS. 2A-D illustrate an assembly of staggered ablation elements for an ablation catheter. In the perspective view of FIG. 2A, an ablation catheter 10 includes an elongated catheter body 12 extending between a proximal end (not shown) and a distal end 14 along a longitudinal axis 16 of the body. An ablation element assembly 20 includes a plurality of ablation elements 22 connected to the catheter body 12. The ablation elements 22 are discretely spaced from one another longitudinally and/or laterally. At least two of the ablation elements 22 may be spaced from one another longitudinally.

[0029] In this embodiment, the ablation elements 22 are electrodes, such as RF electrodes. The ablation element assembly 20 is connected to the distal end 14 of the catheter body 12. As seen in FIGS. 2A-D, the electrode assembly 20 includes a plurality of arms 24, each of which may be oriented generally parallel to the longitudinal axis 16. Each arm 24 has a proximal end 26 connected to the catheter body 12 and a distal end 28. The distal ends 28 of the arms 24 are connected at a distal junction 30. Each arm 24 includes an intermediate segment 32, a proximal stiffness change between the proximal end 26 and the intermediate segment, and a distal stiffness change between the distal end 28 and the intermediate segment. The arms 24 include a plurality of

ablation electrodes 22 on the intermediate segments 32. A longitudinal rod 60 extends along the longitudinal axis 16. The distal end 28 of arm 24 may be coupled to longitudinal rod 60 while the proximal end 26 is coupled to distal end 14 of catheter body 12.

[0030] As shown in FIG. 2B, because of the attachment of arms 24 to rod 60 at one end and body 12 at the other end, the electrode assembly 20 is movable between a collapsed condition 20a and an expanded condition 20b, with the intermediate segments 32 of the arms 24 in the expanded condition moving outwardly relative to the proximal ends 26 and distal ends 28 of the arms in the collapsed condition.

[0031] Each arm 24 includes a proximal leg 34 coupled between the intermediate segment 32 and the proximal end 26 of the arm, and a distal leg 36 coupled between the intermediate segment and the distal end 28 of the arm. Each arm 24 also includes a proximal hinge 44 coupled between the proximal leg 34 and the intermediate segment 32 and a distal hinge 46 coupled between the distal leg 36 and the intermediate segment. The hinges 44, 46 represent the stiffness changes in this embodiment to facilitate movement of the intermediate segments 32 of the arms 24 between the collapsed condition 20a and the expanded condition 20b. In addition, each arm 24 may further include a proximal end hinge 40 coupled between the proximal leg 34 and the proximal end 26 and a distal end hinge 42 coupled between the distal leg 36 and the distal end 28 to further facilitate movement of the intermediate segments 32 of the arms between the collapsed condition 20a and the expanded condition 20b.

[0032] In use, the catheter 10 with the electrode assembly 20 is inserted into a blood vessel or the like in the collapsed condition 20a (inside a guiding sheath or the like) and deployed into the expanded condition 20b. To allow blood to flow past the electrode assembly 20 in the blood vessel and reduce or avoid obstruction, the arm 24 in FIG. 2C has a narrow intermediate segment 32, proximal leg 34, and distal

leg 36. In FIG 2D, the intermediate segment 32 is wider while the proximal leg 34 and distal leg 36 are tapered so as to be smaller in cross-section than the intermediate segment, thereby reducing obstruction. Furthermore, the electrode assembly 20 preferably has no sharp corners or edges, but has rounded corners and edges to facilitate easier and smoother movement within the blood vessel. Proximal leg 34 and distal leg 36 may also be hollow to allow blood to flow therethrough.

[0033] The ablation electrodes 22 in the expanded condition 20b contact the tissue and denervate nerves by raising the temperature and burning some of the nerves. To improve surface contact for the ablation electrodes 22, the intermediate segments 32 preferably have sufficient stiffness to avoid or minimize bending in the expanded condition 20b. The electrode assembly 20 may move from the collapsed condition 20a to the expanded condition 20b by any suitable mechanism. In one example, any or all of the proximal legs 34, the distal legs 36, the proximal end hinges 40, and the distal end hinges 42 of the arm 24 may be resiliently biased (e.g., with a spring or a memory material) to move the electrode assembly 20 toward the expanded condition 20b. In another example, a longitudinal rod 60 in the center of the electrode assembly 20 may be connected to the distal junction 30, and may be used to pull the distal junction 30 toward the distal end 14 of the catheter body 12 to move the electrode assembly 20 toward the expanded condition 20b.

[0034] A plurality of temperature sensors 50 may be thermally coupled with the plurality of ablation electrodes 22 to measure the temperatures of the ablation electrodes. FIG. 3 is a cross-sectional view of an arm 24 illustrating an example of a temperature sensor 50 disposed adjacent the electrode 22 supported on the arm. In addition, the arms 24 may include a plurality of irrigation fluid channels 54 near the plurality of ablation electrodes 22 to direct irrigation fluid toward the ablation electrodes 22, as seen in FIG. 3.

[0035] FIG. 4 illustrates an alternative configuration of a staggered ablation electrode assembly. FIG. 4A shows the electrode assembly 60 in a collapsed condition and FIG. 4B shows the electrode assembly 60 in an expanded configuration. The electrode assembly 60 may be connected to the distal end of a catheter body or may be disposed proximally from the distal end of the catheter body.

[0036] The electrode assembly 60 of FIG. 4 differs from the electrode assembly 20 of FIG. 2 in several respects. First, each ablation electrode 62 has a lateral dimension which is greater than its longitudinal dimension. The lateral dimension of the electrode 62 is greater than the lateral dimension of the arm 64 that supports the electrode. Each arm 64 has a proximal leg 66, a distal leg 68, and an intermediate segment 70. Each electrode 62 has the shape of a circumferential arch that produces an ablation zone that is oriented laterally with respect to the longitudinal axis. Such an ablation zone is more efficient and effective for ablating renal nerves that are oriented generally longitudinally.

[0037] Unlike the electrode assembly 20 of FIG. 2, the electrode assembly 60 of FIG. 4 does not include hinges on the arms. Rather, the arms 64 are configured to facilitate movement of the electrode assembly 60 from the collapsed condition to the expanded condition. For example, the proximal leg 66 has a lower stiffness than the intermediate segment 70 and the distal leg 68 has a lower stiffness than the intermediate segment. The arms may further include weakened portions 69, showed by dashed lines, to aid in bending. A longitudinal rod 65 in the center of the electrode assembly 60 may be connected to the distal junction 67, and can be used to pull the distal junction 67 in the proximal direction to move the electrode assembly 60 toward the expanded condition. Distal legs 68 may be attached to distal junction 67, while proximal legs 66 remain affixed to inner rod 65. As a result, by moving distal junction 57 relative to

rod 65, the proximal leg 66 and the distal leg 68 will bend or deform under a force that moves the electrode assembly 60 to the expanded condition. That force may be produced by forming at least one of the arms 64 of a shape memory material (e.g., nitinol).

[0038] The electrode assembly 60 of FIG. 5 is similar to the electrode assembly 60 of FIG. 4. They differ only in the arrangement of the ablation electrodes 62. In FIG. 4, the ablation electrodes 62 are staggered in a spiral manner in the longitudinal direction. In FIG. 5, the ablation electrodes 62 are arranged in nearly diametrically opposing pairs. These examples illustrate a few of the many different ways to arrange the staggered ablation electrodes 62 to form the electrode assemblies 60.

[0039] Guide wires may be used to introduce the aforementioned ablation assemblies into the body. FIGS. 6 and 7 illustrate two methods of guiding the ablation assembly over the guide wire. FIG. 6 shows an over-the-wire configuration for introducing the assembly 60 of staggered ablation electrodes 62 on a catheter 75 to the surgical site by passing a guide wire 77 through an internal lumen of the catheter. The guide wire 77 extends through an opening 61 at the distal end of the electrode assembly 60, and through a tube 63 that extends through the assembly 60 to the internal lumen of catheter 75 from the catheter's distal end 79 to catheter's proximal end (not shown). The distal end of the assembly 60 is disposed distally of the distal end 79 of the catheter 75.

[0040] FIG. 7 illustrates an alternative over-the-wire configuration for introducing the assembly 60 of staggered ablation electrodes 62 on a catheter 75 to the surgical site. A guide wire 77 is passed through an opening 61 provided at the distal end of the assembly 60. The guide wire 77 then passes into a tube 63 and out therefrom through an intermediate opening 73 therein. Guidewire 77 then extends externally of the catheter 75 toward the proximal end of the catheter. In FIG. 7, both the distal opening 61 and the

intermediate opening 73 are disposed distally of the distal end 79 of catheter 75.

[0041] As previously noted, ablation element localization may affect the efficacy of the treatment. To improve positioning, the electrode assembly 60 may include other structural components and materials, such as a magnetic material to enable sensing of the assembly through use with a magnetic location system, such as, for example, the guided Medical Positioning System ("gMPS") from MediGuide Ltd., and as generally shown in U.S. Patent No. 7,386,339 entitled "Medical Imaging and Navigation System," the disclosure of which is incorporated herein by reference in its entirety.

[0042] The gMPS is intended to enable real time positioning and navigation of a gMPS-enabled diagnostic or therapeutic invasive device used in vascular or cardiac procedures. The gMPS consists of a miniaturized gMPS localization sensor, which is assembled on a device interacting with a magnetic field. When the gMPS sensor is located in a controlled low-intensity surrounding magnetic field, it provides real-time tip location and orientation data. The system may acquire a series of angiographic images and merge the position and orientation signals of the gMPS sensor with these images.

[0043] A magnetic transmitter assembly (MTA) creates the requisite magnetic field. The MTA is installed on an x-ray detector, located at a distance of about 5 cm to about 30 cm above the relevant body part to be treated. The MTA's function is to generate a well-defined, changing magnetic field in a confined space, referred to as a motion box, above the target tissue. FIG. 8A is a schematic representation of a magnetic transmitter assembly 100, which is composed of three magnetic transmitter units (MTUs) 110A, 110B, 110C; two MTUs, 110A and 110C, are located on opposite sides of an x-ray detector 105 and one MTU, 110B, is located on the front of the x-ray detector.

[0044] As seen in FIG. 8B, each MTU 110 includes three separate orthogonal coils 120A, 120B, 120C that are assembled together. Because magnetic transmitter assembly 110 utilizes three MTUs, there are nine total orthogonal coils in the assembly. The magnetic transmitter assembly 100 generates AC magnetic and electrical fields, typically in the range of 9-15 KHz. These nine coils within the MTA are driven by nine concurrent power amplifiers from a controller (not shown). The controller also supplies nine loadable sine signals that drive the nine coils at practical frequencies that range from about 9 kHz to about 15 kHz. Thus, every coil is driven at a fixed frequency. Table 1 below is an example of nine frequencies applied at the nine coils:

Table 1: Frequency table									
Channel	1	2	3	4	5	6	7	8	9
Frequency [kHz]	11.125	12.375	9.875	11.625	12.875	10.25	12.125	13.25	10.75

[0045] Exciting the nine coils creates a magnetic field in a virtual 3D space under MTA 100 called the motion box 130, shown in FIG. 8C. During system operation for clinical use, a treatment device includes any number of gMPS sensors that detect the magnetic fields from the nine coils and thus provide data relating to location and orientation of the gMPS sensors (e.g., x, y, and z components, roll, pitch and yaw). Thus, when such a device having multiple gMPS sensors is placed within the motion box it can be tracked inside the vasculature.

[0046] An electrode assembly may be constructed to ablate tissue while using the magnetic location system described above for localization. In a simple configuration shown in FIG. 9A, an electrode assembly 90 includes a single tubular body 92 and a single ablation electrode 62 for ablating tissue in the renal artery. A single localization sensor 100 is located circumferentially adjacent ablation electrode 62 and connected via a wire 102 through body 92 to a processor (not shown). Each localization sensor may be formed of an electric

conductor that winds to form a coil, or other shape to generate a stable signal. In one example, the localization sensor may be formed of a sub-millimeter copper wire. The localization sensor may include gMPS sensors or any other suitable sensor capable of determining a position, an orientation or both a position and an orientation of a medical device. In some examples, the localization sensor may be spaced away from an adjacent ablation electrode so as not to be in contact with the ablation electrode in order to avoid interference during ablation. Localization sensor 100 may be made of a radiopaque material or coated with such a material, thereby being detectable by an imaging device, such as radiographic, fluoroscopic, magnetic or sonographic devices. Localization sensor 100 detects an electromagnetic field from the MTUs and produces a respective electrical analog signal, which is then digitized and used to indicate the location and orientation of the sensor.

[0047] FIG. 9B illustrates a similar electrode assembly 90 but shows that the localization sensor 100 may be disposed at a distal end 94 of body 92 spaced from ablation electrode 62 rather than being located adjacent the ablation electrode. With the localization sensor 100 located at distal end 94, the position and orientation of the tip of the electrode assembly 90 may be identified within the renal artery. The location of localization sensor 100 may be varied and may depend on the type of sensor being used. For example, if localization sensor 100 is made of copper, it may be beneficial to isolate the sensor from blood flow, while keeping it as close to the surface of electrode assembly 90 as possible to maintain accurate localization.

[0048] In another configuration, shown in FIG. 9C, multiple ablation electrodes 62 are disposed on body 92. Each ablation electrode 62 may be circumferentially adjacent to a designated localization sensor 100, which is connected to a wire 102. Thus, multiple localization sensors 100 may be

disposed on body 92 to show the location of each ablation electrode 62.

[0049] It will be understood that while the preceding examples illustrate localization sensors 100 disposed on body 92 adjacent to or spaced from ablation electrodes 62, the localization sensors may be disposed under each ablation electrode and connected to a wire 102 disposed within the body (FIG. 9D). Alternatively, the localization sensors may be placed around each ablation electrode 62 (FIG. 9E).

[0050] FIGS. 10A and 10B illustrate an electrode assembly 90 including a plurality of ablation electrodes 62 and localization sensors 100 disposed on the intermediate segment 70 of arms 64. In this specific example, electrode assembly 90 includes four arms 64 and a localization sensor 100 disposed on each arm 64 near each of the ablation electrodes 62. Though FIG. 10 illustrates localization sensors 100 disposed immediately adjacent each of the ablation electrodes 62, it will be understood that localization sensors 100 may be disposed on less than all of the arms 64, at any location near the arms (e.g., anywhere between proximal leg 66 and distal leg 68) or at the distal tip of the electrode assembly 90 as shown in FIG. 9B.

[0051] The localization sensors 100 provide a number of benefits. First, the localization sensors 100 may facilitate the location of lesion sites by providing three-dimensional sensor location at higher precision than with the two-dimensional projections of conventional fluoroscopy. Second, the localization sensors 100 may further provide the relative positions of additional lesions after moving the ablation catheter as the old and new catheter positions may be registered on the same image or three-dimensional model of the renal artery. Third, localization sensors 100 may facilitate contact between the ablation electrodes and the arterial wall. This is because a rotational angiogram of the renal artery may allow construction of a three-dimensional model of the arterial lumen, and a localization sensor's precise location

is capable of indicating whether the ablation electrodes are in direct proximity to a vessel wall. Moreover, analysis of the sensors' motion characteristics, such as the position and orientation of the individual sensors, may distinguish between firm and inadequate contact with the arterial wall.

[0052] These principles are illustrated in more detail in FIG. 11. In this example, electrode assembly 90 is inserted into renal artery 6, the electrode assembly having a plurality of arms 64, each arm having an ablation electrode 62 and a localization sensor 100. The localization sensors 100 are coupled to multiple visual displays 72, 74, 76 to facilitate treatment.

[0053] For the sake of clarity, FIG. 11 illustrates three separate visual displays although it will be understood that a single visual display may display any of the techniques described below in multiple windows either at the same time or sequentially. Visual display 72 illustrates the position of the electrode assembly 90 within a three-dimensional angiogram model of the renal artery by utilizing localization sensors 100. Thus, the physician may obtain better visualization of the electrode assembly and more precisely locate same to form a lesion in the renal artery at a desired site.

[0054] Visual display 74 illustrates the technique of visualizing a first set of lesions 112 on the display and moving the electrode assembly 90 so that new lesions are formed at second positions. Specifically, the positions of old lesions 112 are registered using localization sensors 100 on the three-dimensional model and displayed using icons, colors, shading or the like, while the electrode assembly 90 is rotated and or translated within renal artery 6. A second set of lesions may then be formed in the renal artery while appreciating the positions of older lesions 112.

[0055] In one alternative, visual display 74 may register the positions of the first set of lesions 112 and display, using icons, colors or shading, preferred

positions 114 for creating the second set of lesions. Thus, the physician may ablate tissue to create a first set of lesions and the localization sensors 100 may guide the placement of the second set. Specifically, after forming the first set of lesions 112, the localization sensors may register the locations of this first set. A visual icon may automatically inform the physician where to create the second set of lesions and the physician may simply move and rotate the electrode assembly 90 so that the ablation electrodes 62 align with the preferred positions 114 and ablate at those sites, thereby creating two sets of lesions that provide the best therapeutic result. The system may provide an alert, such a visual, auditory or tactile alert, to confirm that the ablation electrodes 62 are properly aligned with the preferred positions 114.

[0056] Visual display 76 may provide an enlarged view showing the position of an ablation electrode 62 with respect to the wall of renal artery 6. Initially, a rotational angiogram of renal artery 6 may allow generation of a three-dimensional model and the precise localization of a localization sensor 100 may indicate the proximity of ablation electrode 62 to the arterial wall through visual inspection. Using the three-dimensional model, the distance between the localization sensor 100 and the arterial wall may be seen by the physician on the visual display 76 and adequate wall contact may be determined. Additionally, a reconstruction feature such as the AngioSurvey 3D Reconstruction feature or similar may be used to create a three-dimensional model of coronary vessels that can be overlaid and merged with the live three-dimensional tracking of the localization sensor. One such feature for three-dimensional reconstruction is described in U.S. Patent No. 7,840,252, which is incorporated herein by reference in its entirety. Using this technique or a similar one, the distance between the arterial wall and the localization sensors may be computed and adequate wall contact may be determined based on this computation.

[0057] In addition to visual inspection and distance analysis, through real-time analysis of the motion of localization sensors 100, proper contact with the arterial wall may be determined. The reason hypothesized for this phenomenon is that a localization sensor 100 will move less when it is in contact with the arterial wall. Specifically, sensors deployed but not fully in contact with the arterial wall will both translate and rotate cyclically as blood pressure pulses through the renal artery. Conversely, localization sensors deployed and adequately in contact with the arterial wall will exhibit some translational movement as the arterial wall distends with each pressure pulse, but the rotational component will be blunted. Thus, proper contact with the arterial wall is ensured, thereby reducing the risk of adverse complications when electrode wall contact is not monitored.

[0058] The electrode assembly 90 described above may be used for renal denervation to treat hypertension. Initially, a dye may be injected into the renal artery while utilizing biplane fluoroscopy or rotational fluoroscopy. Mediguide AngioSurvey 3D Reconstruction may be used to create a three-dimensional model of the renal artery. Once the model has been created, the remaining steps of the procedure may be fluoro-less, thereby limiting the exposure to fluoroscopy when compared to conventional methods where fluoroscopy is used throughout the procedure.

[0059] Following construction of the renal artery model, the electrode assembly may be introduced into the renal artery using the localization sensors 100 projected onto the three-dimensional model as a guide on a visual display. The electrode assembly 90 may be introduced into the body in the collapsed condition, such as, for example, that shown in FIG. 10A, using a transfemoral or other suitable approach. Electrode assembly 90 may be advanced until reaching the ostium of the renal artery. One or more localization sensors 100 may be used to facilitate advancing the

assembly 90 into the renal artery so that it is positioned at a point slightly proximal of the renal artery bifurcation.

[0060] The physician may then radially expand arms 64 into the expanded condition (FIG. 10B) while using localization sensors 100 and visual displays as described above to ensure proper positioning and orientation within the artery and proper contact of the ablation electrodes 62 with the arterial wall.

[0061] A controller (not shown) may be used to provide power to ablate target tissue for a predetermined period of time (e.g., about 15 seconds). A transneural lesion is created across the renal nerves at the ablation electrode 62 to disrupt nerve impulses through the nerves. This step may be performed by simultaneously delivering energy to each of the ablation electrodes 62 or through a quick switching application. The location of each of the localization sensors 100 (and thus the location of each of the ablation electrodes) may be registered and annotated on the three-dimensional model, for example, by changing the color in proximity to the formed lesion. Further information such as time, temperature, total energy delivered, lesion depth and the like may also be encoded by gradations in color, shading or transparency on the visual display. Such information may also be stored and linked to a data table for further analysis.

[0062] Following the formation of the first set of lesions, the electrode assembly may be pulled back proximally slightly and positioned for forming a second set of lesions. Visualization of the first set of lesions on the visual display may aid the physician in properly positioning the electrode assembly for forming the second set of lesions. The localization sensor locations upon pulling back the electrode assembly are also rendered on the three-dimensional model. The distance that the catheter was pulled back, any rotation that the catheter has undergone during pullback and other information about the new catheter location in relation to the

old location is shown on the visual display. If the distance is not far enough or too far, the physician may be alerted. Moreover, if the rotation is incorrect such that the second set of lesions would overlap with the first set of lesions, the physician may be alerted that an ineffective ablation may be performed. Additionally, icons or graphical indicators may be used to help guide the ablation catheter to the preferred site for the second set of lesions.

[0063] Ablation electrode wall contact may be confirmed again via dimensional and motion analysis of the localization sensors. Energy may then be delivered to the ablation electrodes and the location and information such as time, temperature, total energy delivered, lesion depth and the like for forming the second set of lesions may then be encoded by gradations in color, shading or transparency on the visual display. Such information may also be stored and linked to a data table for further analysis.

[0064] After forming the desired number of lesions in the renal artery, electrode assembly 90 may be retracted from the ostium of the renal artery. Electrode assembly 90 may then be repositioned in the ostium of the contralateral renal artery and the ablation process repeated. When finished, electrode assembly 90 may be retracted and removed from the patient's body.

[0065] Although the systems and methods herein have been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present systems and methods. For example, the foregoing embodiments have illustrated the use of localization sensors in conjunction with radiofrequency ablation electrodes. It will be understood, however, that localization sensors may likewise be used in conjunction with laser-based ablation devices having one more optical fibers disposed within an elongated body and extending longitudinally therethrough. Such optical fibers may be optically coupled to a light source at one end and to a

diffuser at another end and configured to focus energy from the light source on target tissue of a blood vessel to ablate the target tissue. For example, the laser energy may be focused on the renal nerves to create lesions therein in the same manner as described above in order to control hypertension in patients. The light source may include a diode laser or a doped fiber laser pumped with a diode laser. It is, therefore, to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present systems and methods as defined by the appended claims.

[0066] It will be appreciated that the various dependent claims and the features set forth therein can be combined in different ways than presented in the initial claims. It will also be appreciated that the features described in connection with individual embodiments may be shared with others of the described embodiments.

CLAIMS

1. An ablation catheter, comprising:
an elongated body having a proximal end and a distal end;
at least one ablation element disposed on the body
between the proximal end and the distal end; and
at least one localization sensor disposed on the body and
configured to interact with a magnetic field.
2. The ablation catheter of claim 1, wherein the at
least one localization sensor is disposed near the distal end
of the elongated body.
3. The ablation catheter of claim 1, wherein the at
least one ablation element is a radiofrequency ablation
electrode.
4. The ablation catheter of claim 3, wherein the at
least one localization sensor is disposed adjacent the
ablation electrode.
5. The ablation catheter of claim 1, wherein the at
least one ablation element includes four ablation elements.
6. The ablation catheter of claim 1, further comprising
a plurality of localization sensors.
7. The ablation catheter of claim 1, further comprising
a plurality of ablation elements and at least one localization
sensor for each of the ablation elements.
8. The ablation catheter of claim 7, wherein each
ablation element is a radio frequency ablation electrode, and
each localization sensor is disposed under a corresponding one
of the ablation electrodes.

9. The ablation catheter of claim 1, wherein each localization sensor is connected to a processor via a wire.

10. The ablation catheter of claim 1, wherein the ablation element includes a diffuser and an optical fiber having a proximal end and a distal end, the optical fiber being disposed within the elongated body and extending longitudinally therethrough, the proximal end of the optical fiber being optically coupleable to a light source, the diffuser being coupled to the distal end of the optical fiber and configured to focus energy from the light source on target tissue of a blood vessel to ablate the target tissue.

11. The ablation catheter of claim 10, wherein the light source is selected from the group consisting of a diode laser and a doped fiber laser pumped with a diode laser.

12. An ablation catheter, comprising:
a longitudinal rod;
a plurality of arms disposed about the longitudinal rod, and being resiliently biased outwardly away from the longitudinal rod;
at least one ablation element disposed on each of the arms; and
at least one localization sensor disposed on at least one of the longitudinal rod and one of the plurality of arms.

13. The ablation catheter of claim 12, wherein the plurality of arms form a collapsible, basket-like arrangement.

14. The ablation catheter of claim 12, wherein the plurality of arms includes four arms arranged circumferentially apart by 90 degrees.

15. The ablation catheter of claim 12, wherein the at least one ablation element is a radiofrequency ablation electrode.

16. The ablation catheter of claim 12, further comprising a localization sensor disposed on each one of the plurality of arms.

17. A method for ablating vascular tissue, comprising:
introducing into an artery an ablation catheter including an elongated body having a proximal end and a distal end, at least one ablation element disposed on the body between the proximal end and the distal end, and at least one localization sensor disposed on the body;

using the at least one localization sensor to determine an appropriate target tissue for ablation; and

ablating the target tissue to provide a therapeutic effect.

18. The method of claim 17, further comprising injecting a dye into the artery, using a visualization technique to create a three-dimensional model of the artery and using the at least one localization sensor to track the ablation catheter through the three-dimensional model.

19. The method of claim 17, further comprising displaying a location of the ablation catheter within the artery on a visual display.

20. The method of claim 19, wherein the visual display indicates locations of previous ablations.

21. The method of claim 19, further comprising registering locations of a first set of lesions using the at least one localization sensor, computing preferred locations of a second set of lesions based on locations of the first set

of lesions using a process, and displaying the preferred locations on the visual display.

22. The method of claim 17, further comprising ensuring adequate wall contact between the at least one ablation element and a wall of the artery using the at least one localization sensor.

23. The method of claim 22, wherein the ensuring step includes visual inspection of the ablation element and the wall of the artery.

24. The method of claim 22, wherein the ensuring step includes calculating a distance between the at least one localization sensor and the wall of the artery.

25. The method of claim 22, wherein the ensuring step includes performing motion analysis of the at least one localization sensor.

26. The method of claim 17, wherein the artery is a renal artery.

27. The method of claim 17, wherein the ablating step includes ablating tissue in the renal artery to treat hypertension.

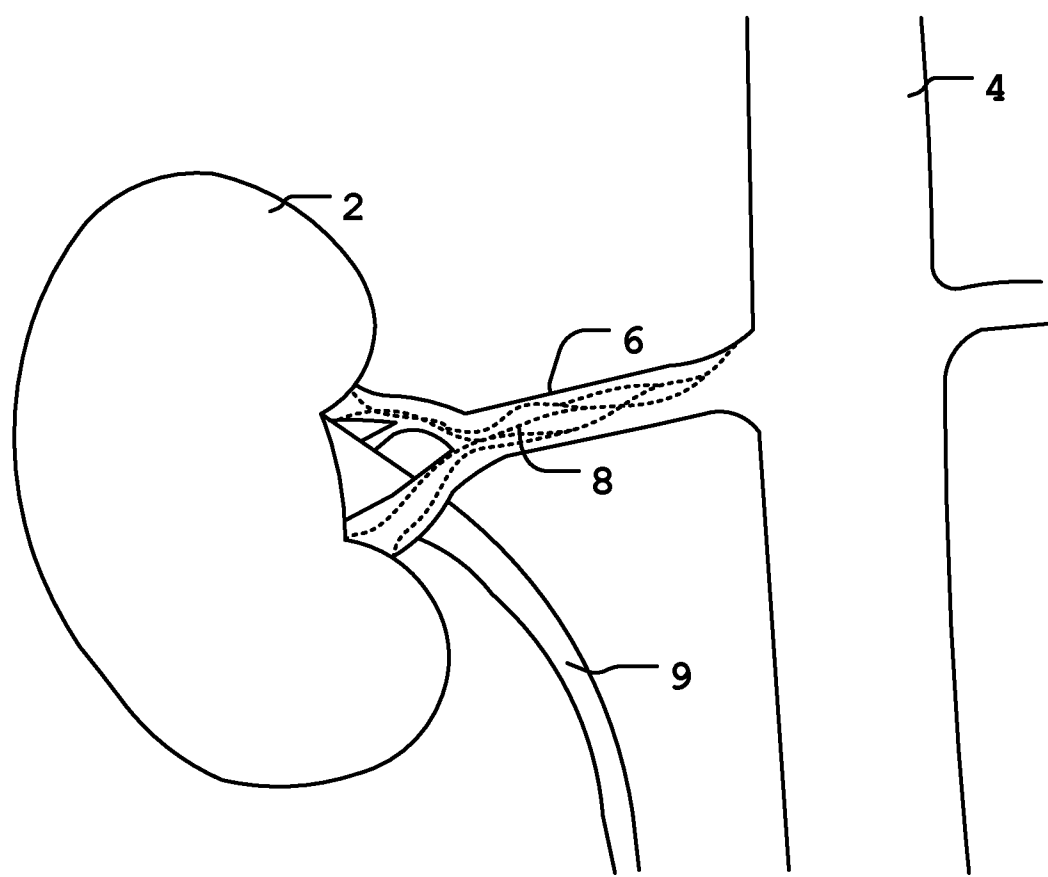


FIG. 1

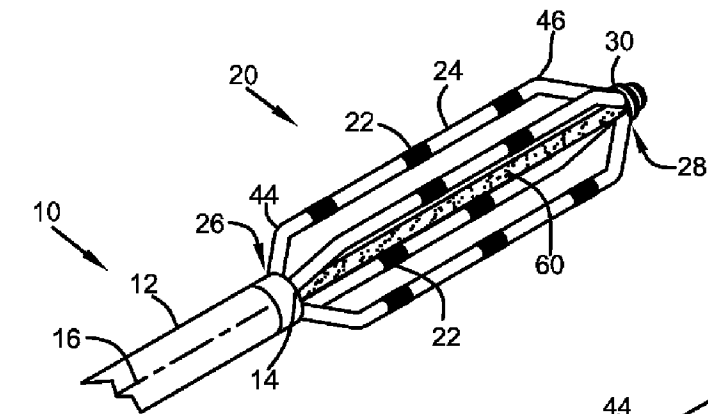


FIG. 2A

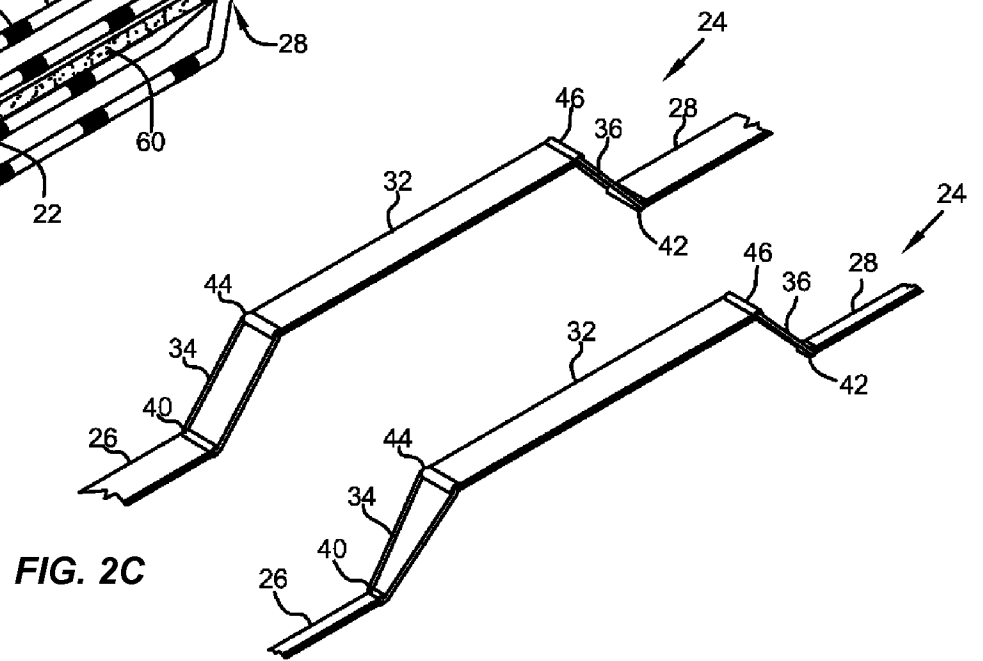


FIG. 2C

FIG. 2D

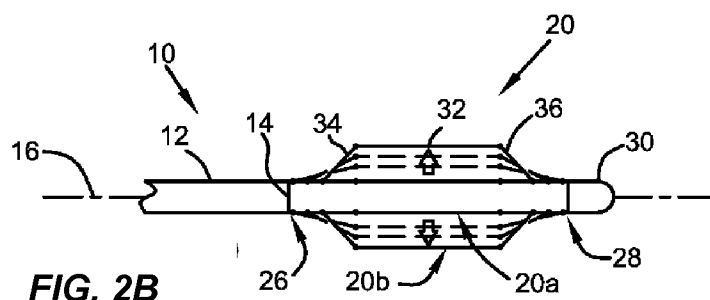


FIG. 2B

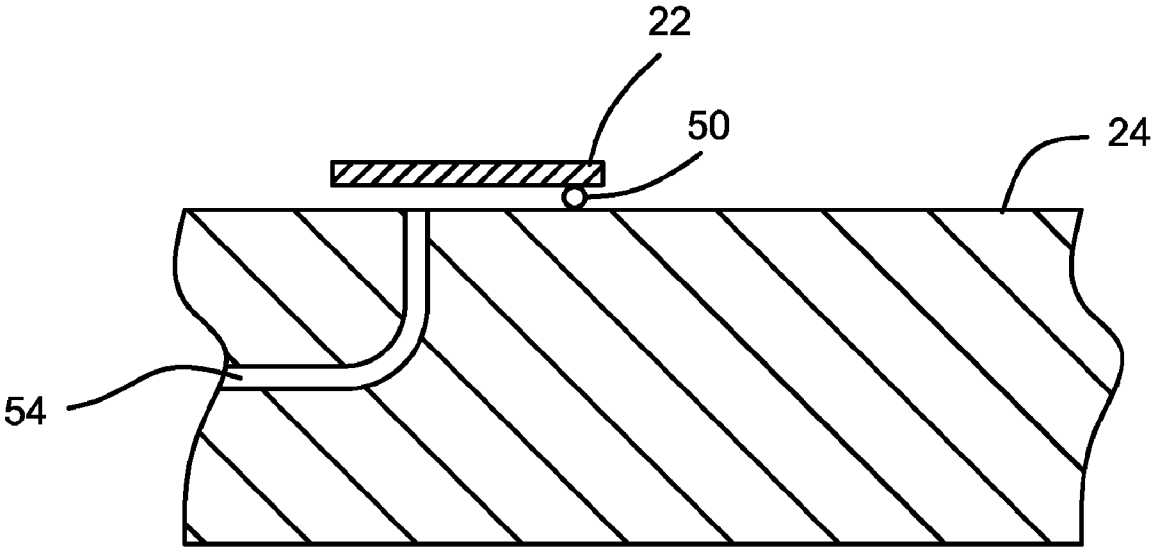


FIG. 3

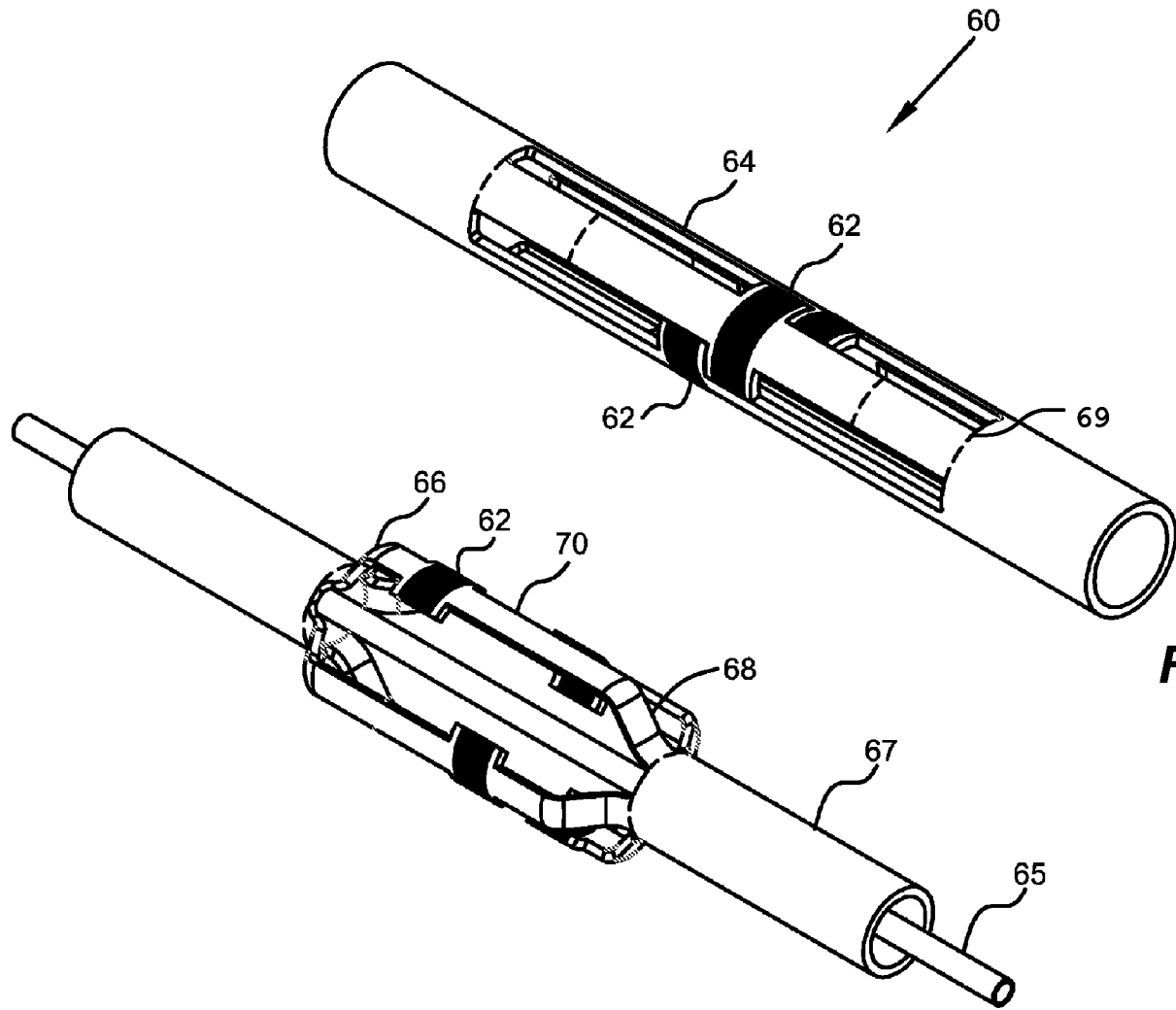


FIG. 4A

FIG. 4B

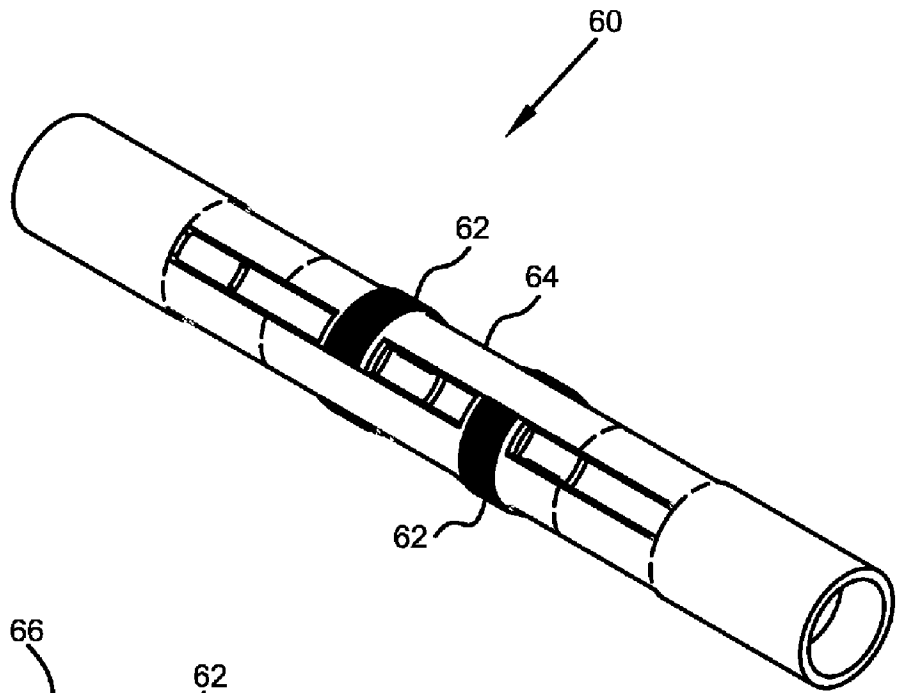


FIG. 5A

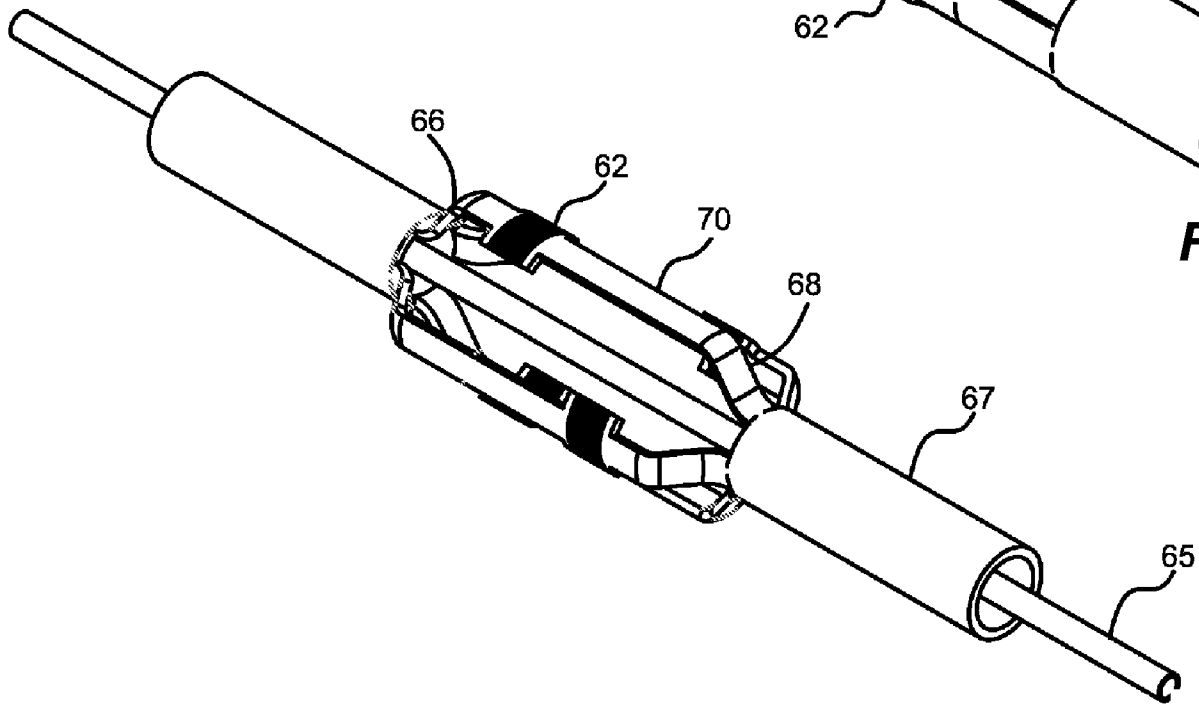


FIG. 5B

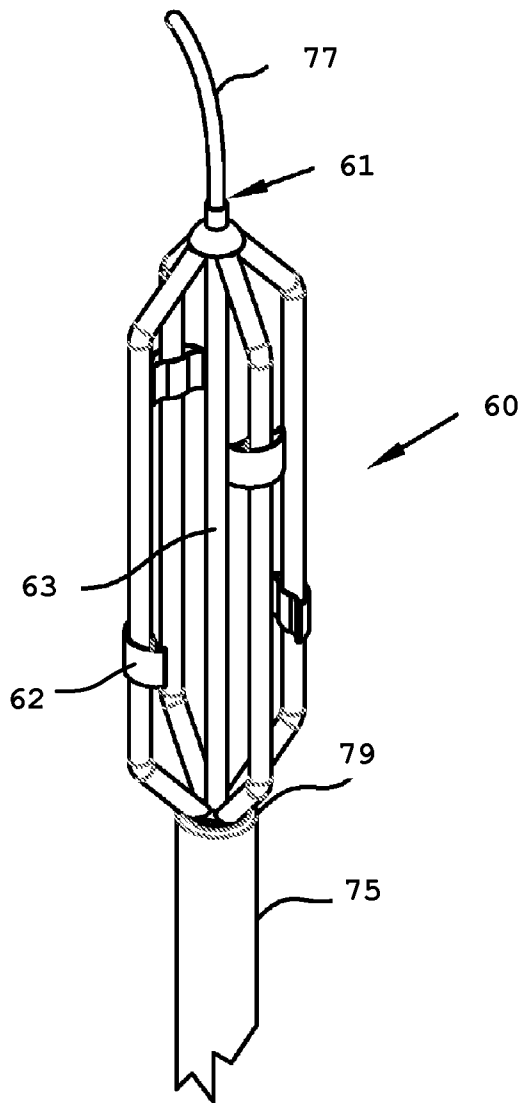


FIG. 6

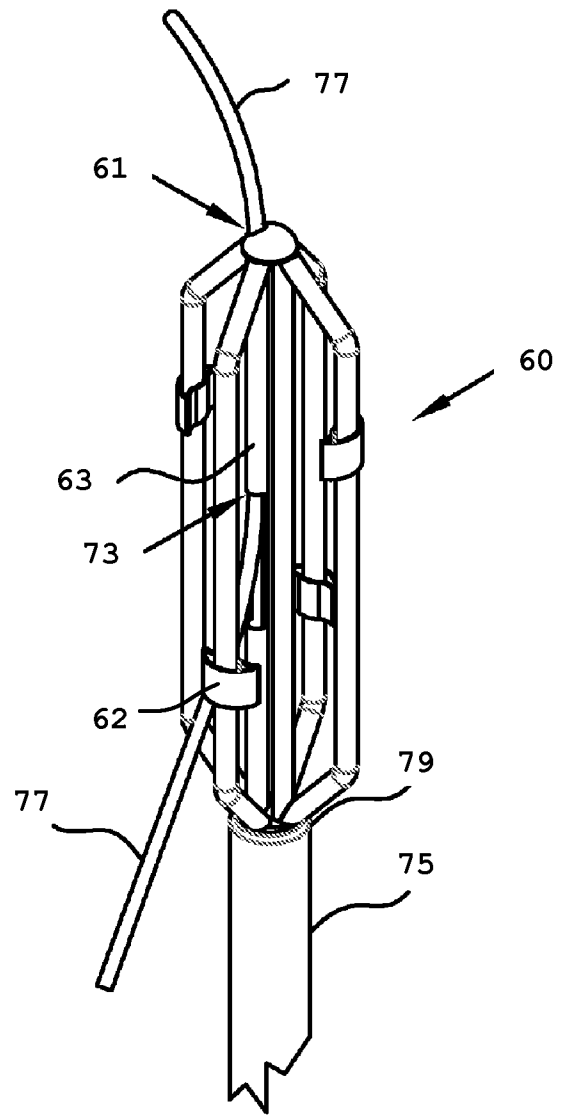
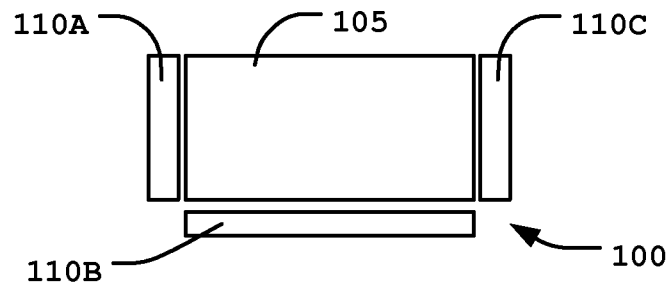
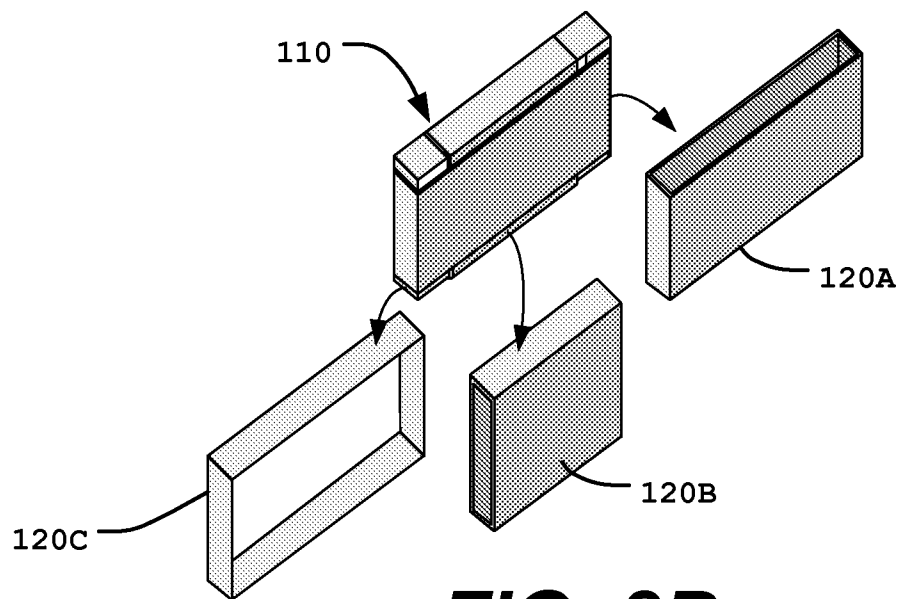
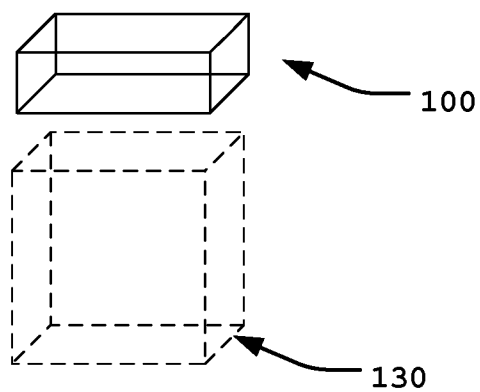
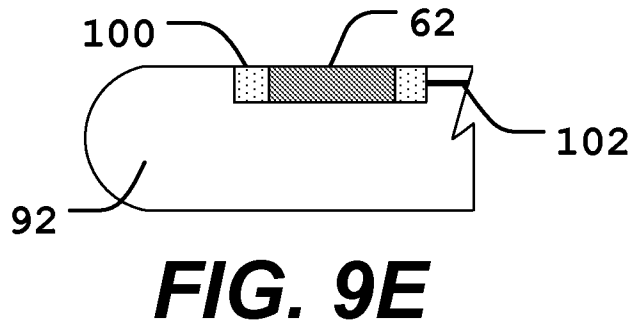
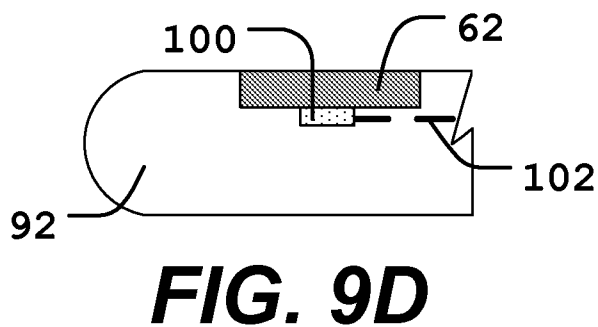
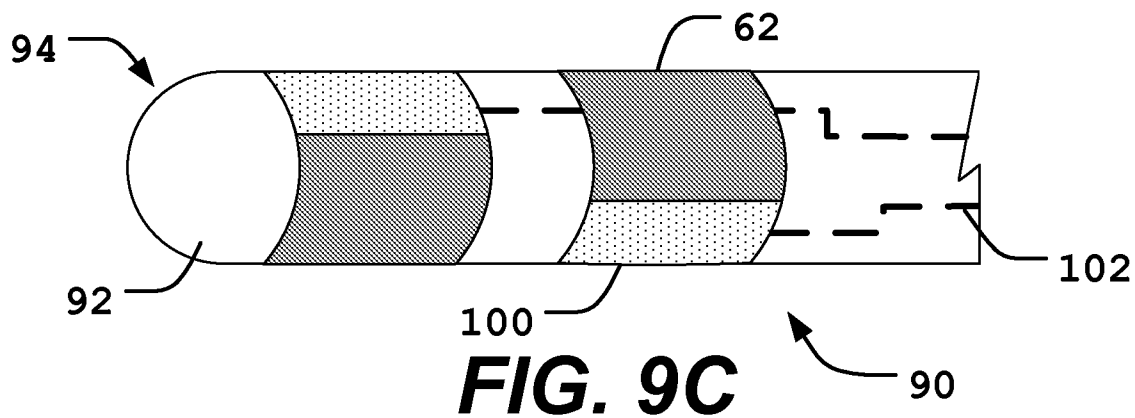
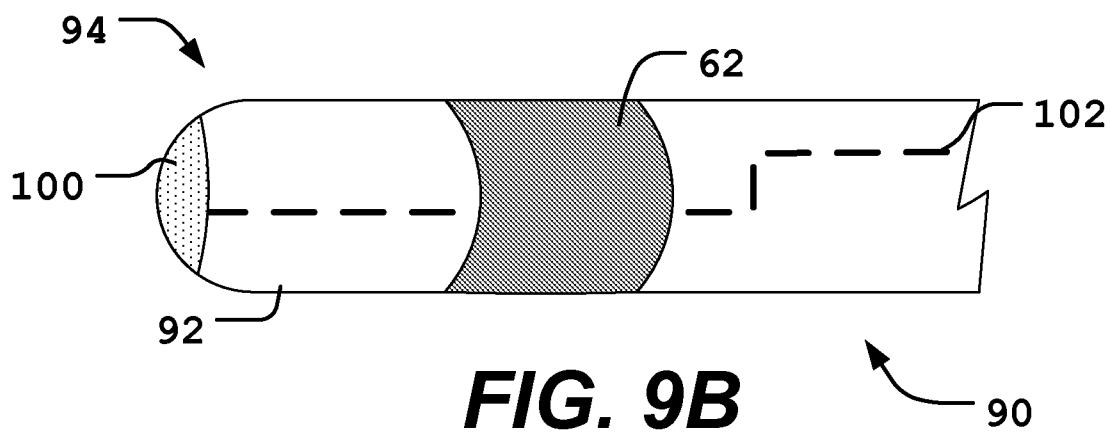
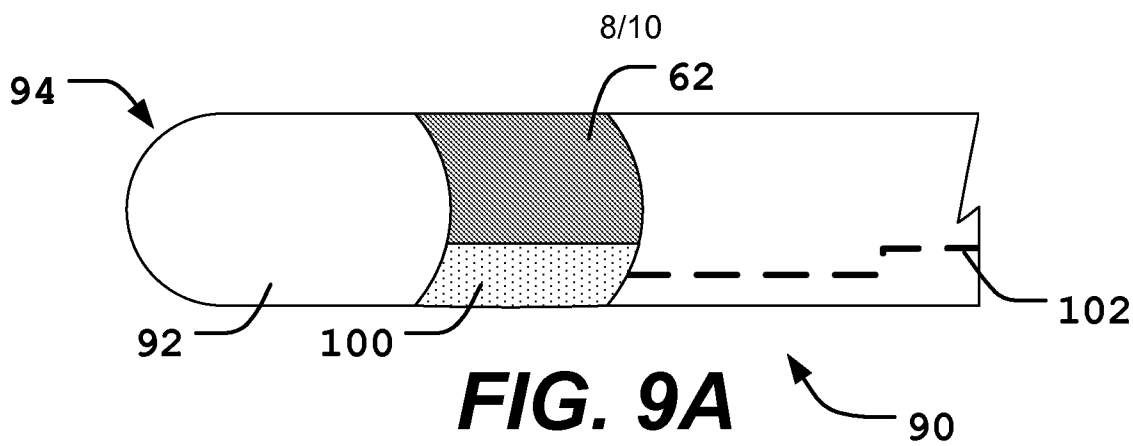


FIG. 7

**FIG. 8A****FIG. 8B****FIG. 8C**



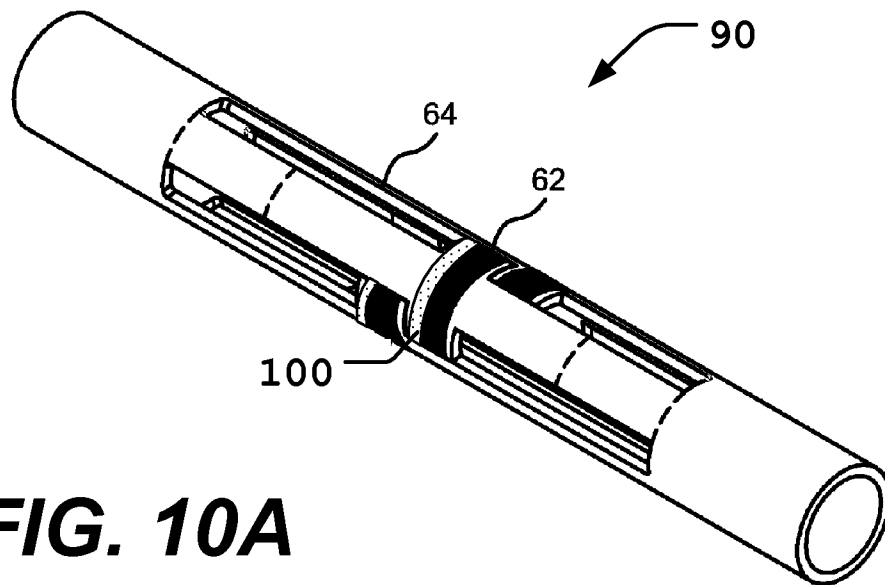


FIG. 10A

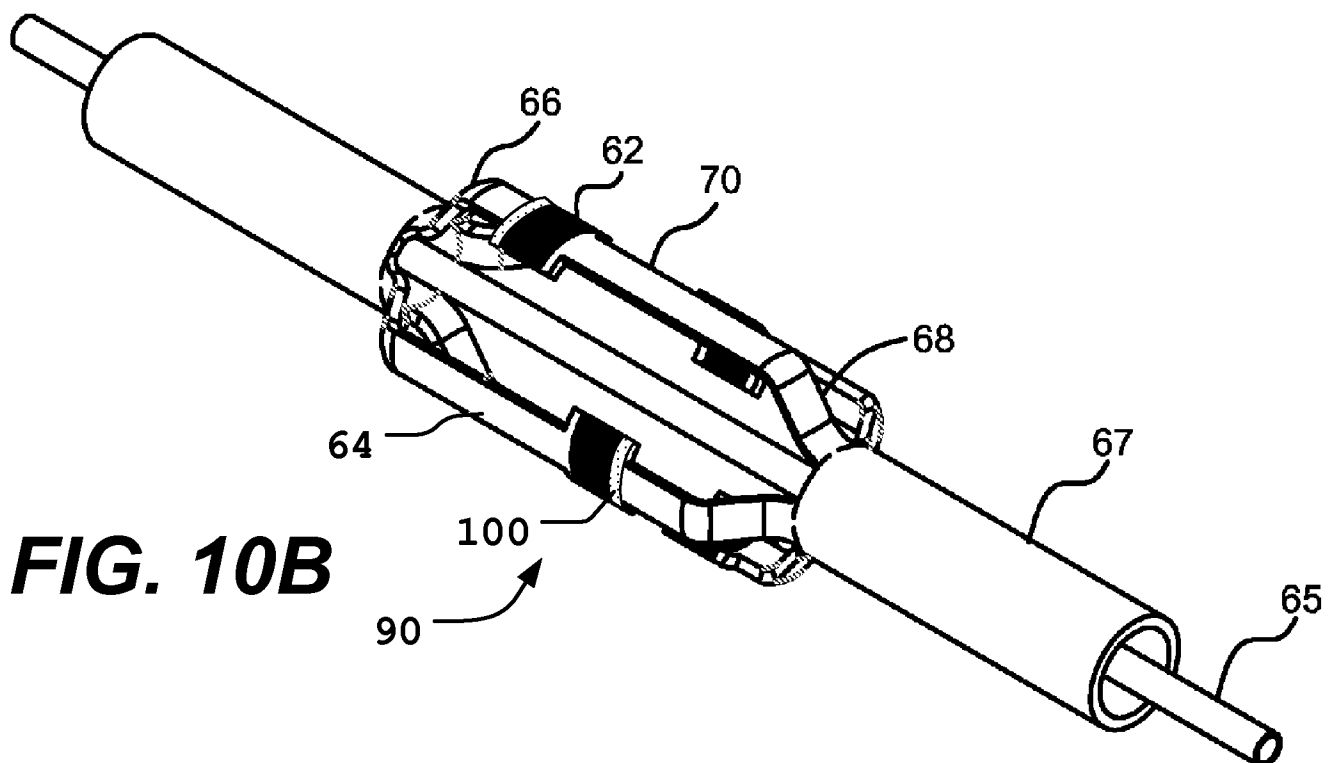
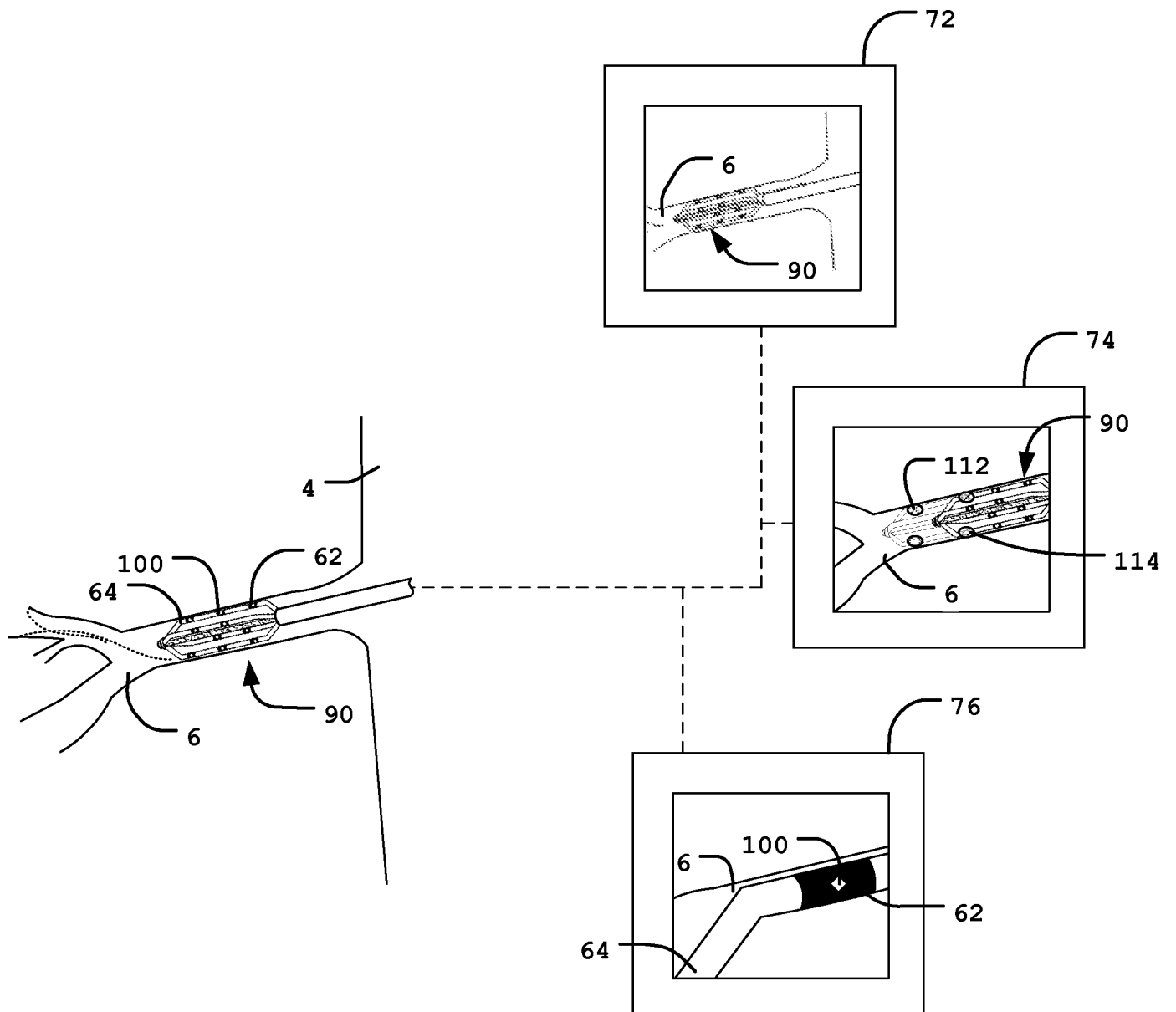


FIG. 10B

**FIG. 11**

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/019435

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/14 A61B19/00 A61B18/20
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 401 980 A1 (BIOSENSE WEBSTER ISRAEL LTD [IL]) 4 January 2012 (2012-01-04) paragraphs [0018] - [0021]; figures 1-2 paragraphs [0025] - [0029] paragraph [0042] -----	1-9, 12-16
X	EP 1 319 365 A2 (BIOSENSE WEBSTER INC [US]) 18 June 2003 (2003-06-18) paragraphs [0010] - [0016]; figures 1-2 -----	1-6,9, 12,13,15
X	WO 2012/092016 A1 (ST JUDE MEDICAL ATRIAL FIBRILL [US]; AFONSO VALTINO X [US]; SHI JIAZHE) 5 July 2012 (2012-07-05) paragraphs [0041] - [0069]; figures 1-6 ----- -/-	1-4,6,9



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

6 June 2014

Date of mailing of the international search report

15/09/2014

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Schnurbusch, Daniel

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/019435

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 279 692 A2 (SUPER DIMENSION LTD [IL]) 2 February 2011 (2011-02-02) paragraphs [0045] - [0047]; figure 1 paragraphs [0063] - [0069]; figures 12A-13B -----	1-4,6,9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2014/019435

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/019435

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

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

1. ☒ Claims Nos.: 17-27
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-9, 12-16

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-9, 12-16

an ablation catheter comprising an elongated body, at least one ablation element and at least one localization sensor interacting with a magnetic field,
and further specifying that the ablation elements are radio frequency ablation electrodes.

2. claims: 10, 11

an ablation catheter comprising an elongated body, at least one ablation element and at least one localization sensor interacting with a magnetic field,
and further specifying that the ablation elements are laser ablation systems, comprising a diffuser and an optical fiber coupleable to a light source and configured to focus energy from the light source to a target.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 17-27

Method claim 17 defines a method for treatment of the human or animal body by therapy and surgery practised on the human or animal body, because "[...] a method for ablating vascular tissue comprising: introducing into an artery an ablation catheter [...] ablating the target tissue [...]" (claim 17) is seen as a surgical and therapeutical step performed on a patient. Therefore no search has been performed for the subject-matter of this claim and the corresponding dependent claims (see Article 17 (2) PCT and Rule 39.1.(iv) PCT) and no written opinion is required for the subject-matter of these method claims (see Rule 43bis.1 and Rule 67.1 (iv) PCT).