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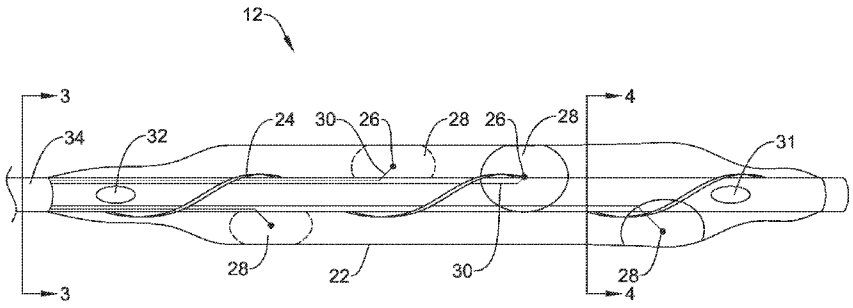


Figure 2

(57) Abstract: Medical devices and methods for making and using medical devices are disclosed. An example medical device may include a renal nerve modulation device. The renal nerve modulation device may include an elongate shaft. A balloon may be coupled to the shaft. The balloon may have a hydrophilic electrode region. A sensor may be coupled to the balloon and may be disposed adjacent to the hydrophilic electrode region. An electrode may be coupled to the catheter shaft and may be disposed within the balloon.

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RENAL NERVE MODULATION DEVICES

Cross-Reference to Related Applications

This application claims priority under 35 U.S.C. §119 to U.S. Provisional Application Serial No. 61/644,296, filed May 8, 2012, the entirety of which is incorporated herein by reference.

Technical Field

The present disclosure pertains to medical devices and methods for making and using medical devices. More particularly, the present disclosure pertains to medical devices for renal nerve modulation.

Background

A wide variety of intracorporeal medical devices have been developed for medical use, for example, intravascular use. Some of these devices include guidewires, catheters, and the like. These devices are manufactured by any one of a variety of different manufacturing methods and may be used according to any one of a variety of methods. Of the known medical devices and methods, each has certain advantages and disadvantages. There is an ongoing need to provide alternative medical devices as well as alternative methods for manufacturing and using medical devices.

Brief Summary

This disclosure provides design, material, manufacturing method, and use alternatives for medical devices. An example medical device may include a renal nerve modulation device. The renal nerve modulation device may include an elongate shaft. A balloon may be coupled to the shaft. The balloon may have a hydrophilic electrode region. A sensor may be coupled to the balloon and may be disposed adjacent to the hydrophilic electrode region. An electrode may be coupled to the catheter shaft and may be disposed within the balloon.

Another example renal nerve modulation device may include an elongate shaft. A balloon may be coupled to the shaft. An electrode may be coupled to the balloon. A sensor may be coupled to the balloon and disposed adjacent to the electrode.

Another example renal nerve modulation device may include an elongate catheter shaft. A balloon may be coupled to the shaft. The balloon may have a plurality of hydrophilic electrode regions defined thereon. A plurality of flexible sensors may be coupled to the balloon. At least one of the plurality of flexible sensors may be disposed adjacent to each of the hydrophilic electrode regions. A conductive fluid may be disposed within the balloon. A radiofrequency electrode may be disposed within the balloon. The conductive fluid may be configured to conduct radiofrequency energy from the radiofrequency electrode to the hydrophilic electrode regions.

The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present invention. The Figures, and Detailed Description, which follow, more particularly exemplify these embodiments.

Brief Description of the Drawings

The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings, in which:

Figure 1 is a schematic view illustrating a renal nerve modulation system in situ;

Figure 2 is a side view of a portion of an example medical device;

Figure 3 is a cross-sectional view taken through line 3—3 in Figure 2;

Figure 4 is a cross-sectional view taken through line 4—4 in Figure 2;

Figure 5 is a partially cross-sectional side view of the example medical device from Figure 2 disposed within a blood vessel;

Figure 6 is a side view of a portion of an example electrode and an example sensor;

Figure 7 is a side view of a portion of an example electrode and an example sensor;

Figure 8 is a side view of a portion of an example electrode and an example sensor;

Figure 9 is a side view of a portion of an example electrode and an example sensor;

Figure 10 is a side view of a portion of another example medical device;

Figure 11 is a side view of a portion of another example medical device;

Figure 12 is a side view of a portion of another example medical device;

Figure 13 is a side view of a portion of another example medical device;

Figure 14 is a side view of a portion of another example medical device; and

Figure 15 is a side view of a portion of another example medical device.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

Detailed Description

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term "about," whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g. 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Certain treatments require the temporary or permanent interruption or modification of select nerve function. One example treatment is renal nerve ablation, which is sometimes used to treat conditions related to congestive heart failure or hypertension. The kidneys produce a sympathetic response to congestive heart failure, which, among other effects, increases the undesired retention of water and/or

sodium. Ablating some of the nerves running to the kidneys may reduce or eliminate this sympathetic function, which may provide a corresponding reduction in the associated undesired symptoms.

While the devices and methods described herein are discussed relative to renal nerve modulation, it is contemplated that the devices and methods may be used in other treatment locations and/or applications where nerve modulation and/or other tissue modulation including heating, activation, blocking, disrupting, or ablation are desired, such as, but not limited to: blood vessels, urinary vessels, or in other tissues via trocar and cannula access. For example, the devices and methods described herein can be applied to hyperplastic tissue ablation, cardiac ablation, pulmonary vein isolation, tumor ablation, benign prostatic hyperplasia therapy, nerve excitation or blocking or ablation, modulation of muscle activity, hyperthermia or other warming of tissues, etc. In some instances, it may be desirable to ablate perivascular renal nerves with ultrasound ablation.

Figure 1 is a schematic view of an illustrative renal nerve modulation system *in situ*. System 10 may include one or more conductive element(s) 16 for providing power to a renal ablation system including a renal nerve modulation device 12 and, optionally, within delivery sheath 14, the details of which can be better seen in subsequent figures. A proximal end of conductive element(s) 16 may be connected to a control and power unit 18, which may supply the appropriate electrical energy to activate one or more electrodes disposed at or near a distal end of the renal nerve modulation device 12. In addition, control and power unit 18 may also be utilized to supply/receive the appropriate electrical energy and/or signal to activate one or more sensors disposed at or near a distal end of the renal nerve modulation device 12. When suitably activated, the electrodes are capable of ablating tissue as described below and the sensors may be used to sense desired physical and/or biological parameters. The terms electrode and electrodes may be considered to be equivalent to elements capable of ablating adjacent tissue in the disclosure which follows. In some instances, return electrode patches 20 may be supplied on the legs or at another conventional location on the patient's body to complete the circuit. A proximal hub (not illustrated) having ports for a guidewire, an inflation lumen and a return lumen may also be included.

The control and power unit 18 may include monitoring elements to monitor parameters such as power, voltage, pulse size, temperature, force, contact, pressure,

impedance and/or shape and other suitable parameters, with sensors mounted along renal nerve modulation device 12, as well as suitable controls for performing the desired procedure. In some embodiments, the power unit 18 may control a radiofrequency (RF) electrode and, in turn, may "power" other electrodes including so-called "virtual electrodes" described herein. The electrode may be configured to operate at a suitable frequency and generate a suitable signal. It is further contemplated that other ablation devices may be used as desired, for example, but not limited to resistance heating, ultrasound, microwave, and laser devices and these devices may require that power be supplied by the power unit 18 in a different form.

Figure 2 illustrates a distal portion of a renal nerve modulation device 12. Here it can be seen that renal nerve modulation device 12 may include an elongate member or catheter shaft 34, an expandable member or balloon 22 coupled to shaft 34, and an electrode 24 disposed within balloon 22. Additional electrodes 24 may also be utilized. When in use, balloon 22 may be filled with a conductive fluid such as saline to allow the ablation energy (e.g., radiofrequency energy) to be transmitted from electrode 24, through the conductive fluid, to one or more windows 28 disposed along balloon 22. While saline is one example conductive fluid, other conductive fluids may also be utilized including hypertonic solutions, contrast solution, mixtures of saline or hypertonic saline solutions with contrast solutions, and the like. The conductive fluid may be introduced through a fluid inlet 31 and evacuated through a fluid outlet 32, both in a central shaft 34. This may allow the fluid to be circulated within balloon 22. As described in more detail herein, windows 28 may be generally hydrophilic portions of balloon 22. Accordingly, windows 28 may absorb fluid (e.g., the conductive fluid) so that energy exposed to the conductive fluid can be conducted to windows 28 such that windows 28 to take the form of "virtual electrodes" capable of ablating tissue.

During an ablation procedure, it may be desirable to monitor one or more physical and/or biological parameter. For example, it may be desirable to monitor the temperature before, during, and after the procedure. This may include monitoring the temperature at balloon 22, along the vessel wall, within the blood vessel, and the like. In addition, temperature changes may also be present adjacent to calcified lesions and/or vulnerable plaques. It may be desirable to avoid ablation at or near calcified lesions and/or vulnerable plaques. It can also be appreciated that in a renal nerve ablation procedure it may be desirable to raise the temperature of the tissue surround

the blood vessel so as to desirably modulate (e.g., ablate) the renal nerves while minimizing damage to surrounding tissue. Thus, monitoring of temperature may improve the quality of the intervention.

In addition, it may also be desirable to monitor force (e.g., force, pressure, contact, and/or the like) before, during, and after the procedure. In general, a pressure sensor detects a force applied to it. This information may be used to confirm contact, or absence of contact, of balloon 22 with a wall of a vessel or cardiac chamber and/or the relative level of resistance encountered due to balloon 22 expansion by the vessel wall.

Furthermore, it may be desirable to monitor impedance before, during, and after the procedure. In an example, an impedance sensor can detect relative impedance in the tissue in the presence of RF energy delivery. The impedance information may be used to control or abort therapy (e.g., to increase or decrease the energy in response to a tissue impedance, or to stop therapy if the impedance exceeds a threshold). Certain impedance levels may be correlated with proximity and/or contact with the vessel wall, tissue modulation, denaturation, and/or alteration. In addition, impedance may differ adjacent to calcified lesion and/or vulnerable plaques. Thus, impedance levels may be used to aid in a given intervention.

In addition, it may also be desirable to have sensors that detect nerve activity, blood flow, device orientation, hormones and/or other chemical or biochemical entities, pH levels, ultrasonic signals, and the like.

Device 12 may include one or more sensors 26 that are designed to sense temperature, force/pressure/contact, impedance, and/or other physical and/or biological parameters. In at least some embodiments, sensors 26 may be coupled to balloon 22 (e.g., along an interior surface, exterior surface, or both). Alternatively, sensors 26 may be coupled to shaft 34. In general, sensors 26 may include a polymer material (e.g., sensors 26 may be polymer based), an applied sensor material (e.g., a material that is applied in a liquid stated and cured), a conductive material, or the like. These are just examples. Sensors 26 may be configured to sense the desired parameter at the balloon, tissue, or both as well as at locations between the balloon and tissue. The parameter sensed by sensors 26 may be displayed on an external device that is communicatively coupled to the device through a wired connection or lead 30, a wireless connection, or both.

In embodiments that utilize lead 30, lead 30 may take the form of a suitable wire. Alternatively, lead 30 may be a printed or applied lead that is disposed along, for example, the exterior of balloon 22 and/or shaft 34. In other embodiments, some portions of lead 30 may be applied or printed and other portions may include a wire. According to any of these embodiments, lead 30 may have an insulator or insulating mask to provide suitable insulation. In some of these and in other embodiments, balloon 22 and/or shaft 34 (and/or portions thereof) may include or otherwise be doped with an ionic or conductive material (e.g., which may form a "doped electrical circuit) so that electrical signals can be transitioned along balloon 22 and/or shaft 34. In some of these and in other embodiments, a flexible applied (and/or printed) lead, itself, may be used as sensor 26. For example, a flexible applied lead may define a conductive pathway that has a variable resistance when the material is flexed or strained. Such flexible applied leads may be used, for example, to sensor force or strain and the orientation of the lead may impact the force or orientation of the force sensed (e.g., tension vs. compression; radial vs. elongation; etc.).

The number, form, and configuration of sensors 26 may vary. For example, in some embodiments, balloon 22 includes one sensor 26. In other embodiments, balloon 22 includes two, three, four, five, six, seven, eight, nine, ten, or more sensors 26. When multiple sensors 26 are utilized, they all may be the same type of sensor or they may be different types of sensors. Various sensor geometries are also contemplated including, for example, circular, oval, polygonal, serpentine, having a variety of differing surface areas, including microtextures to increase surface area or being super-smooth, or the like.

As indicated above, sensors 26 may include pressure sensors (e.g., pressure, force, and/or contact sensors and the like), temperature sensors (e.g., thermocouples, thermistors, and the like), impedance sensors, or other suitable sensors. When sensors 26 include a temperature sensor, the sensor may include a thermocouple or a thermistor. In some embodiments, device 12 may include a thermally matched adhesive that may be highly thermally insulative to avoid changing sensing performance. When sensors 26 include an impedance sensor, the impedance sensors may be unipolar, bipolar, quadripolar, or some other similar configuration and/or a combination of these. The unipolar impedance sensors may be configured to sense the impedance between the impedance sensor 26 on the surface of balloon 22 and the blood, plaque or calcification, vessel wall, surrounding, tissue, and ground electrode

on the patient's body. The multi-polar electrodes may include multiple electrodes on balloon 22 and would sense the impedance of the blood, tissue, plaque, calcification, or other material between the plurality of electrodes – thereby detecting whether or not the electrodes were in contact with the vessel wall and whether or not ablation should occur. Although the impedance sensors 26 may not necessarily need to be operating at the same time as electrode 24, the impedance sensors 26 may operate at a frequency sufficiently different from electrode 24, and with appropriate signal processing, so that the targeted impedances can be measured.

Sensors 26 may be generally flexible and/or stretchable. This may allow sensors 26 to remain intact while being positioned at or on an expandable balloon 22. In at least some embodiments, flexible electronics technology may be used to form the sensors 26, to couple sensors 26 to balloon 22 and/or to electrical conductors in shaft 34, or both. For example, flexible electronics are available from MC10, Inc. Suitable sensor technology is described in US Patent Publication Numbers US 2011/0034912 and US 2011/0215931, the entire disclosures of which are herein incorporated by reference.

When sensors 26 include a temperature sensor, sensor 26 may be configured to sense temperatures in the range of about 0-140 °C or about 20-120 °C. The sensitivity of temperature sensor 26 may be about 0.1 °C to 5 °C or less or about 1 °C or less. The temperature sensor 26 may have an accuracy of about 0.1 °C to 5 °C or less or about 0.2 °C or less. The thermal response time of temperature sensor 26 may be about 0.1 to 5 seconds or less or about 0.5 to 1 second or less. The thickness of temperature sensor 26 (when disposed on balloon 22) may be about 0.0001 to 0.010 inches or about 0.0005 to 0.001 inches. The thickness of temperature sensor 26 (when disposed on shaft 34) may be about 0.0005 to 0.010 inches or about 0.005. These are just examples. The temperature sensor 26 may be electrically insulated so as to optimally sense the temperature of interest.

When sensors 26 include an impedance sensor, sensor 26 may have a range of about 50 Ω to 5 KΩ or about 100 Ω to 2 KΩ. The impedance sensitivity of impedance sensor 26 may be about 50 Ω to 200 Ω or less or about 100 Ω or less. The impedance accuracy of impedance sensor 26 may be ± about 1-10% or ± about 5-10%. These are just examples. When impedance sensors 26 are disposed on the surface of balloon 22, sensors 26 may be electrically insulated from the hydrophilic

balloon surface such that sensors 26 may optimally detect the anatomy and physiology of interest.

Balloon 22 may include protrusions, or other features, on which the sensors 26 may be mounted. Accordingly, when sensors 26 are pressed against a wall, the balloon feature and the sensor 26 may protrude into the vessel wall, allowing for a sensor reading at a depth that is dependent on the depth of penetration of the balloon feature into the wall. The features and sensors may be small enough so as to not impact vessel integrity. In one example, a temperature may be detected at a depth of 0.5 to 5 mm into a vessel wall.

Balloon 22 may also include (or have built thereon) micro-devices on the balloon surface that are configured to allow radiofrequency and/or ultrasound energy to be delivered to the vessel wall to enable nerve ablation.

Balloon 22 may also include (or have built thereon) micro-devices on the balloon surface that are configured to allow delivery of drugs for a variety of applications and electrical pulses to induce cell electroporation.

Device 12 may also be configured to provide feedback about the parameter sensed by sensors 26 during an intervention. For example, if the temperature exceeds a threshold, the intervention may be automatically altered, reduced, or aborted. For example, when ablating nerves, it may be generally desirable to achieve a target temperature (e.g., 50°C) at the nerve but avoid going over a temperature threshold (e.g., 65°C) at the vessel wall. Similarly, it may be desirable to alter, reduce, or abort an intervention based on information gathered through other types of sensors. The feedback may be incorporated into control unit 18 or other suitable devices. In addition, signal processing may be utilized for sensors 26 to enhance the signal to noise ratio and/or filter out the radiofrequency ablation signal, physiological noise, etc.

In addition, the virtual window electrodes 28 may be independently controllable. For example, balloon 22 may be partitioned so that each window 28 can be independently activated/deactivated. In some embodiments, an external RF generator may include logic and switching circuitry to deactivate individual electrodes or groups of electrodes when a particular sensor reading is achieved. For example, therapy to an electrode may be aborted when a temperature threshold is achieved. In another example, the rate of RF therapy energy delivery (e.g., power) may be reduced in response to increasing temperature.

A cross-sectional view of shaft 34 of the renal nerve modulation device 12 proximal to balloon 22 is illustrated in Figure 3. Shaft 34 may include a guidewire lumen 36, a lumen 38 connected to the fluid inlet 31, and a lumen 40 connected to the fluid outlet 32. Other configurations are contemplated. Electrode 24 (or a conductive element to supply power to electrode 24) may extend along the outer surface of shaft 34 or may be embedded within the shaft. Electrode 24 proximal to the balloon may be electrically insulated and may be used to transmit power to the portion of the electrode 24 disposed within balloon 22. Lead 30 may also be disposed along the outer surface of shaft 34 and may include a suitable insulator. In some embodiments, the guidewire lumen and/or one of the fluid lumens 38/40 may be omitted. In some embodiments, guidewire lumen 36 may extend from the distal end of device 12 to a proximal hub. In other embodiments, the guidewire lumen can have a proximal opening that is distal the proximal portion of the system. In some embodiments, the fluid lumens 38/ 40 can be connected to a system to circulate the fluid through the balloon 22 or to a system that supplies new fluid and collects the evacuated fluid. It can be appreciated that embodiments may function with merely a single fluid lumen and a single fluid outlet into the balloon.

A cross-sectional view of the shaft 34 distal to fluid outlet 32 is illustrated in Figure 4. The guidewire lumen 36 and the fluid inlet lumen 40 are present, as well as electrode 24. In addition, balloon 22 is shown in cross-section as having a first layer 44 and a second layer 46. Window 28 is formed in balloon 22 by the absence of second layer 46. First layer 44 may include an RF permeable material. One suitable material is a hydrophilic polyurethane. Other suitable materials include other hydrophilic polymers such as hydrophilic PEBAX, hydrophilic nylons, hydrophilic polyesters, block co-polymers with built-in hydrophilic blocks, polymers including ionic conductors, polymers including electrical conductors, metallic or nanoparticle filled polymers, and the like. Suitable hydrophilic polymers may exhibit between 20% to 50% hydrophilicity (or % water absorption). The second layer 46 may include an electrically non-conductive polymer such as a non-hydrophilic polyurethane, PEBAX, nylon, polyester or block-copolymer. Other suitable materials include any of a range of electrically non-conductive polymers. The materials of the first layer and the second layer may be selected to have good bonding characteristics between the two layers. For example, a balloon 22 may be formed from a first layer 44 made from a hydrophilic PEBAX and a second layer 46 made from a regular or

non-hydrophilic PEBAX. In other embodiments, a suitable tie layer (not illustrated) may be provided between the two layers.

In some of these and in other embodiments, a mask may be applied over hydrophilic material to reveal hydrophilic portions or windows 28. In an example, the mask can be a separate component into which balloon 22 is inserted. In another example, the mask may be applied onto the balloon 22. Some other details regarding masks and masking may be found in U.S. Patent No. 7,736,362, the entire disclosure of which is herein incorporated by reference. Other details regarding masks and masking can be found appended at the end of this disclosure.

Electrode 24 may be a flat ribbon electrode made from platinum, gold, stainless steel, cobalt alloys, or other non-oxidizing materials. In some instances, titanium, tantalum, or tungsten may be used. Electrode 24 may extend along substantially the whole length of the balloon 22 or may extend only as far as the distal edge of the most distal window 28. The electrode 24 may have a generally helical shape and may be wrapped around shaft 34. Alternatively, electrode 24 may have a linear or other suitable configuration. In some cases, electrode 24 may be bonded to shaft 34. The electrode 24 and windows 28 may be arranged so that the electrode extends directly under the windows 28. In some embodiments, electrode 24 may be a wire or may be a tubular member disposed around shaft 34. In some embodiments, a plurality of electrodes 24 may be used and each of the plurality may be fixed to the shaft 34 under windows 28 and may share a common connected to conductive element 16. In other embodiments that include more than one electrode, each electrode may be separately controllable. In such embodiments, balloon 22 may be partitioned into more than one chamber and each chamber may include one or more electrodes. The electrode 24 may be selected to provide a particular level of flexibility to the balloon to enhance the maneuverability of the system. It can be appreciated that there are many variations contemplated for electrode 24.

Figure 5 illustrates the distal end of device 12 in situ. Device 12 may be available in various sizes, and a size is selected that will allow the windows 28 of the balloon 22 to contact the wall of a blood vessel 48. The balloon may be somewhat compliant so that a balloon having a nominal 4 mm diameter can be expanded to fit a blood vessel of between 3.5 mm and 5 mm. These are just examples.

The particular balloon illustrated in Figure 5 may be suitable for use in a renal nerve modulation application. Renal nerves extend generally longitudinally around

the outside of a renal artery. This means that one can vary the longitudinal position of any particular circumferential treatment and achieve the same nerve modulation effect. Thus windows 28 are arranged to achieve complete circumferential coverage of the blood vessel while spaced apart longitudinally. In this particular case, the four windows 28 each cover a different 90 degree arc of the blood vessel 48. Each window may cover more than a 90 degree arc. For example, the windows 28 may cover a 100 or 110 degree arc to allow for some overlapping coverage of the windows 28. Windows 28 of this embodiment are four in number and generally circular in shape. It can be appreciated that variations in the number of windows and the shape of the windows are contemplated. For example, embodiments are contemplated which include 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or more windows and which include windows that are circular, oval, rectangular, or polygonal. Moreover, the windows having a different length and width may be oriented so that the largest dimension is parallel to the longitudinal axis, perpendicular to the longitudinal axis or at another angle with respect to the longitudinal axis such as a 45 degree angle. In some embodiments, each window may have an aspect ratio of 2:1, 3:1 or 4:1, where the major dimension is perpendicular to the longitudinal axis of the balloon. In some embodiments, the window or windows may have a custom pattern to provide a particular treatment pattern.

Prior to use, balloon 22 may be hydrated as part of the preparatory steps. Hydration may be effected by soaking the balloon in a saline solution. During ablation, a conductive fluid may be infused into balloon 22, for example via outlet 32. The conductive fluid may expand the balloon to the desired size. The balloon expansion may be monitored indirectly by monitoring the volume of conductive fluid introduced into the system or may be monitored through radiographic or other conventional means. Optionally, once the balloon is expanded to the desired size, fluid may be circulated within the balloon by continuing to introduced fluid through the fluid inlet 31 while withdrawing fluid from the balloon through the fluid outlet 32. The rate of circulation of the fluid may be between 2 and 20 ml/min, between 3 and 15 ml/min, between 5 and 10 ml/min or other desired rate of circulation. These are just examples. The circulation of the conductive fluid may mitigate the temperature rise of the tissue of the blood vessel 48 in contact with the windows 28.

Electrode 24 may be activated by supplying energy to electrode 24. The energy may be supplied at 400-500 KHz at about 5-30 watts of power. These are just

examples, other energies are contemplated. The energy may be transmitted through the medium of the conductive fluid and through windows 28 to the blood vessel wall to modulate or ablate the tissue. The second layer 46 of the balloon prevents the energy transmission through the balloon wall except at windows 28 (which lack second layer 46). The progress of the treatment may be monitored by monitoring changes in impedance through the electrode.

The electrode 24 may be activated for an effective length of time, such as 1 minute or 2 minutes. One the procedure is finished at a particular location, the balloon 22 may be partially or wholly deflated and moved to a different location such as the other renal artery, and the procedure may be repeated at another location as desired using conventional delivery and repositioning techniques.

Before, during, and/or after an ablation procedure, sensors 26 may be utilized to sense desirable physical and/or biological parameters.

The position of sensors 26 along 22 can vary as depicted schematically in Figures 6-9. For example, Figure 6 illustrates a sensor 26a that is positioned along an interior surface 25 of balloon 22 at window 28a. Lead 30a may also extend along interior surface 25. Conversely, Figure 7 illustrates sensor 26b that is positioned along an exterior surface 23 of balloon 22 at window 28b. Lead 30b may also extend along exterior surface 23. As shown, sensors 26a/26b (as well as other sensors disclosed herein) may be positioned generally adjacent to windows 28a/28b. However, this is not intended to be limiting. For example, Figure 8 illustrates sensor 26c position adjacent to window 28c and lead 30c extending along interior surface 25. Similarly, Figure 9 illustrates sensor 26d position adjacent to window 28d and lead 30d extending along exterior surface 23. The configurations illustrated in Figures 6-9 may be utilized for any of the sensors disclosed herein. In some of these and in other embodiments, the sensors (and/or additional sensors) may be positioned along shaft 34.

Figure 10 illustrates another example renal nerve modulation device 112 that may be similar in form and function to other devices disclosed herein. Device 112 may include shaft 134 and balloon 122. Also shown are ports 131/132 and electrode 124. According to this embodiment, balloon 122 may include only a single window 128. Sensor 126 having lead 130 coupled thereto may be positioned adjacent to window 128. Additional sensors may also be utilized.

Figure 11 illustrates another example renal nerve modulation device 212 that may be similar in form and function to other devices disclosed herein. Device 212 may include shaft 234 and balloon 222. According to this embodiment, balloon 222 may have a plurality of electrodes 228 coupled thereto (e.g., along an exterior surface thereof). One or more leads 229 may be coupled to electrodes 228. One or more sensors 226 having lead 230 coupled thereto may be positioned adjacent to electrodes 228. Additional sensors may also be utilized.

Sensors 226 may be configured to be independently controllable. Thus, each individual sensor 226 may be independently activated and/or deactivated. In addition, device 212 may also be configured to provide feedback about the parameter sensed by each individual sensor 226 during an intervention. For example, if the temperature exceeds a threshold, the intervention may be automatically altered, reduced, or aborted. Similarly, it may be desirable to alter, reduce, or abort an intervention based on information gathered through other types of sensors.

Figure 12 illustrates another example renal nerve modulation device 312 that may be similar in form and function to other devices disclosed herein. Device 312 may include shaft 334 and balloon 322. According to this embodiment, balloon 322 may have a single electrode 328 coupled thereto (e.g., along an exterior surface thereof). Lead 329 may be coupled to electrode 328. One or more sensors 326 having lead 330 coupled thereto may be positioned adjacent to electrode 328. Additional sensors may also be utilized.

Figure 13 illustrates another example renal nerve modulation device 412 that may be similar in form and function to other devices disclosed herein. Device 412 may include shaft 434 and balloon 422. According to this embodiment, balloon 422 may have a plurality of windows 428. One or more sensors 426 having lead 430 coupled thereto may be positioned adjacent to windows 428. Additional sensors may also be utilized. According to this embodiment, windows 428 may be expandable. As such, inflation of balloon 422 may result in expansion of windows 428 radially outward as shown in Figure 14. This configuration may allow sensing via sensors 426 to take place at the vessel wall or at location slightly within the vessel wall.

Figure 15 illustrates another example renal nerve modulation device 512 that may be similar in form and function to other devices disclosed herein. Device 512 may include shaft 534 and balloon 522. Balloon 522 may include one or more windows such as window 528a and window 528b. Device 512 may also include one

or more sensors that may take the form of printed sensors. For example, printed sensor 548 may be disposed adjacent to window 528a. Printed sensor 548 may include a pressure sensitive ink that can sense pressure and can be transmitted electrically. This may allow pressure to be measured along balloon 522 (which may allow contact with the vessel wall to be determined). Alternatively, printed sensor 548 may take the form of a printed thermocouple. In some embodiments, additional sensors may also be utilized. For example, a first printed sensor 550 and a second printed sensor 552 may be utilized (e.g., positioned at or adjacent to window 528b. One of sensors 550/552 may include a printed pressure sensor and the other sensor 550/552 may include a printed thermocouple. Additional sensors may also be utilized.

The materials that can be used for the various components of medical device 12 (and/or other medical devices disclosed herein) may include those commonly associated with medical devices. For simplicity purposes, the following discussion makes reference to medical device 12. However, this is not intended to limit the devices and methods described herein, as the discussion may be applied to other similar medical devices disclosed herein.

Medical device 12 may be made from a metal, metal alloy, polymer (some examples of which are disclosed below), a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable material. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the

like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

As alluded to herein, within the family of commercially available nickel-titanium or nitinol alloys, is a category designated "linear elastic" or “non-super-elastic” which, although may be similar in chemistry to conventional shape memory and super elastic varieties, may exhibit distinct and useful mechanical properties. Linear elastic and/or non-super-elastic nitinol may be distinguished from super elastic nitinol in that the linear elastic and/or non-super-elastic nitinol does not display a substantial "superelastic plateau" or "flag region" in its stress/strain curve like super elastic nitinol does. Instead, in the linear elastic and/or non-super-elastic nitinol, as recoverable strain increases, the stress continues to increase in a substantially linear, or a somewhat, but not necessarily entirely linear relationship until plastic deformation begins or at least in a relationship that is more linear that the super elastic plateau and/or flag region that may be seen with super elastic nitinol. Thus, for the purposes of this disclosure linear elastic and/or non-super-elastic nitinol may also be termed “substantially” linear elastic and/or non-super-elastic nitinol.

In some cases, linear elastic and/or non-super-elastic nitinol may also be distinguishable from super elastic nitinol in that linear elastic and/or non-super-elastic nitinol may accept up to about 2-5% strain while remaining substantially elastic (e.g., before plastically deforming) whereas super elastic nitinol may accept up to about 8% strain before plastically deforming. Both of these materials can be distinguished from other linear elastic materials such as stainless steel (that can also can be distinguished based on its composition), which may accept only about 0.2 to 0.44 percent strain before plastically deforming.

In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy is an alloy that does not show any martensite/austenite phase changes that are detectable by differential scanning calorimetry (DSC) and dynamic metal thermal analysis (DMTA) analysis over a large temperature range. For example, in some embodiments, there may be no martensite/austenite phase changes detectable by DSC and DMTA analysis in the range of about –60 degrees Celsius (°C) to about 120 °C in the linear elastic and/or non-super-elastic nickel-titanium alloy. The mechanical bending properties of such material may therefore be generally inert to the effect of temperature over this very broad range of temperature. In some embodiments, the mechanical bending properties of the linear elastic and/or non-super-elastic nickel-

titanium alloy at ambient or room temperature are substantially the same as the mechanical properties at body temperature, for example, in that they do not display a super-elastic plateau and/or flag region. In other words, across a broad temperature range, the linear elastic and/or non-super-elastic nickel-titanium alloy maintains its linear elastic and/or non-super-elastic characteristics and/or properties.

In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy may be in the range of about 50 to about 60 weight percent nickel, with the remainder being essentially titanium. In some embodiments, the composition is in the range of about 54 to about 57 weight percent nickel. One example of a suitable nickel-titanium alloy is FHP-NT alloy commercially available from Furukawa Techno Material Co. of Kanagawa, Japan. Some examples of nickel titanium alloys are disclosed in U.S. Patent Nos. 5,238,004 and 6,508,803, which are incorporated herein by reference. Other suitable materials may include ULTANIUM™ (available from Neo-Metrics) and GUM METAL™ (available from Toyota). In some other embodiments, a superelastic alloy, for example a superelastic nitinol can be used to achieve desired properties.

In at least some embodiments, portions or all of medical device 12 may also be doped with, made of, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. This relatively bright image aids the user of medical device 12 in determining its location. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like. Additionally, other radiopaque marker bands and/or coils may also be incorporated into the design of medical device 12 to achieve the same result.

In some embodiments, a degree of Magnetic Resonance Imaging (MRI) compatibility is imparted into medical device 12. For example, medical device 12 or portions thereof, may be made of a material that does not substantially distort the image and create substantial artifacts (i.e., gaps in the image). Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. Medical device 12 or portions thereof, may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS:

R30003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nitinol, and the like, and others.

Some examples of suitable polymers for medical device 12 may include polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM, for example, DELRIN® available from DuPont), polyether block ester, polyurethane (for example, Polyurethane 85A), polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL® available from DSM Engineering Plastics), ether or ester based copolymers (for example, butylene/poly(alkylene ether) phthalate and/or other polyester elastomers such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), Marlex high-density polyethylene, Marlex low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide (PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly paraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID® available from EMS American Grilon), perfluoro(propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), poly(styrene-*b*-isobutylene-*b*-styrene) (for example, SIBS and/or SIBS 50A), polycarbonates, ionomers, biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like.

U.S. Patent No. 5,860,974 and U.S. Patent Application No. 13/711,231 are herein incorporated by reference.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A renal nerve modulation device, comprising:

an elongate shaft;

a balloon coupled to the shaft, the balloon having a hydrophilic electrode region;

a sensor coupled to the balloon and disposed adjacent to the hydrophilic electrode region; and

an electrode coupled to the shaft and disposed within the balloon.

2. The renal nerve modulation device of claim 1, wherein the balloon includes an inner layer and an outer layer.

3. The renal nerve modulation device of claim 2, wherein the hydrophilic electrode region is defined by the absence of the outer layer along a portion of the balloon.

4. The renal nerve modulation device of claim 3, wherein the balloon includes one or more additional hydrophilic electrode regions.

5. The renal nerve modulation device of claim 4, further comprising an additional sensor disposed adjacent to the each of one or more additional hydrophilic electrode regions.

6. The renal nerve modulation device of any one of claims 1-5, wherein the sensor includes an applied sensor lead extending proximally therefrom.

7. The renal nerve modulation device of claim 6, further comprising an insulating member disposed over the lead.

8. The renal nerve modulation device of any one of claims 1-7, wherein the sensor includes a temperature sensor.

9. The renal nerve modulation device of any one of claims 1-8, wherein the sensor includes a pressure sensor.

10. The renal nerve modulation device of any one of claims 1-9, wherein the sensor includes a force sensor.

11. The renal nerve modulation device of any one of claims 1-10, wherein the sensor includes an impedance sensor.

12. The renal nerve modulation device of any one of claims 1-11, wherein a conductive fluid is disposed within the balloon.

13. The renal nerve modulation device of any one of claims 1-12, wherein the electrode is a radiofrequency electrode.

14. A renal nerve modulation device, comprising:

an elongate shaft;

a balloon coupled to the shaft;

an electrode coupled to the balloon; and

a sensor coupled to the balloon and disposed adjacent to the electrode.

15. A renal nerve modulation device, comprising:

an elongate catheter shaft;

a balloon coupled to the shaft, the balloon having a plurality of hydrophilic electrode regions defined thereon;

a plurality of flexible sensors coupled to the balloon, wherein at least one of the plurality of flexible sensors is disposed adjacent to each of the hydrophilic electrode regions;

a conductive fluid disposed within the balloon;

a radiofrequency electrode disposed within the balloon; and

wherein the conductive fluid is configured to conduct radiofrequency energy from the radiofrequency electrode to the hydrophilic electrode regions.

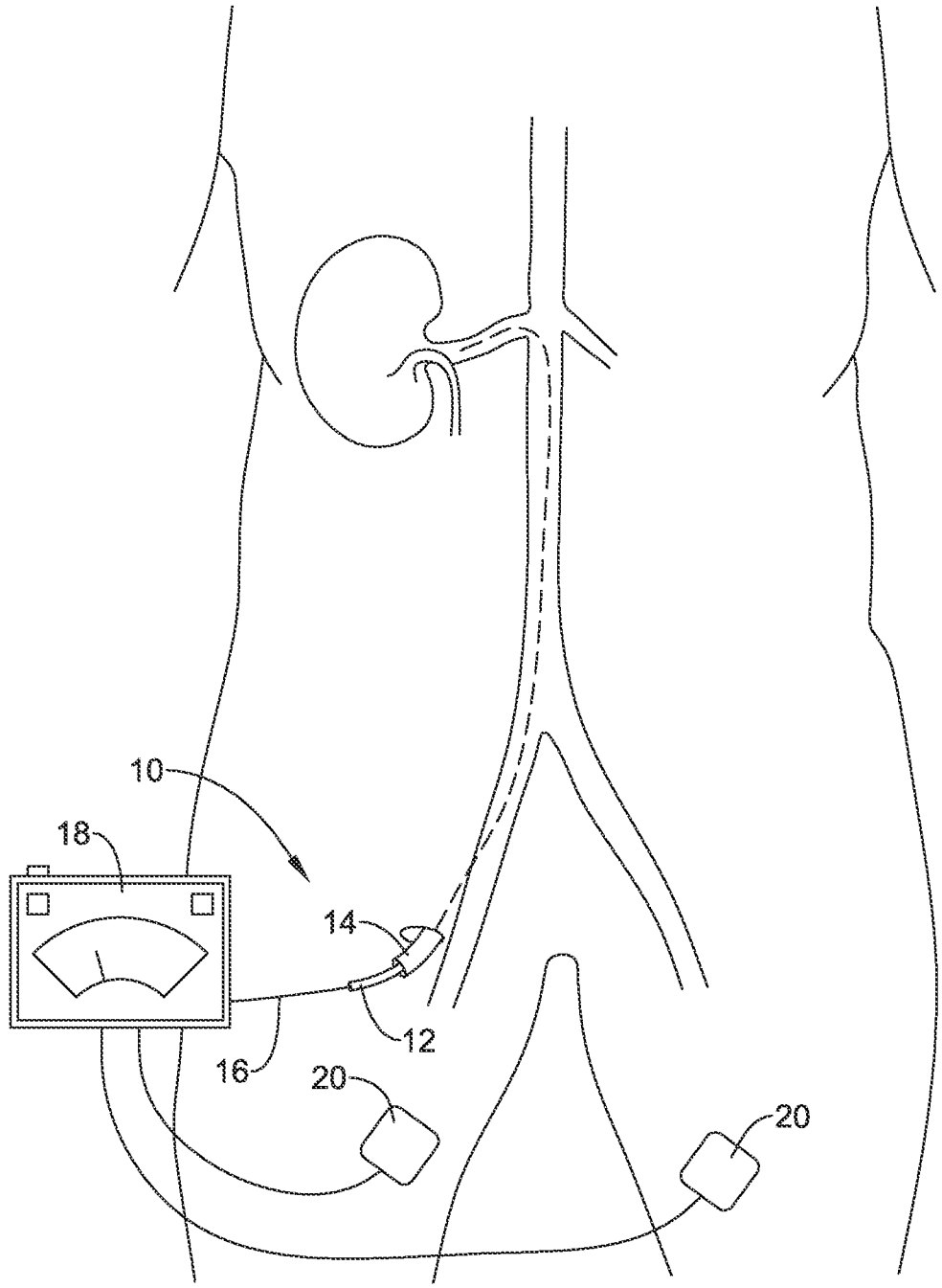


Figure 1

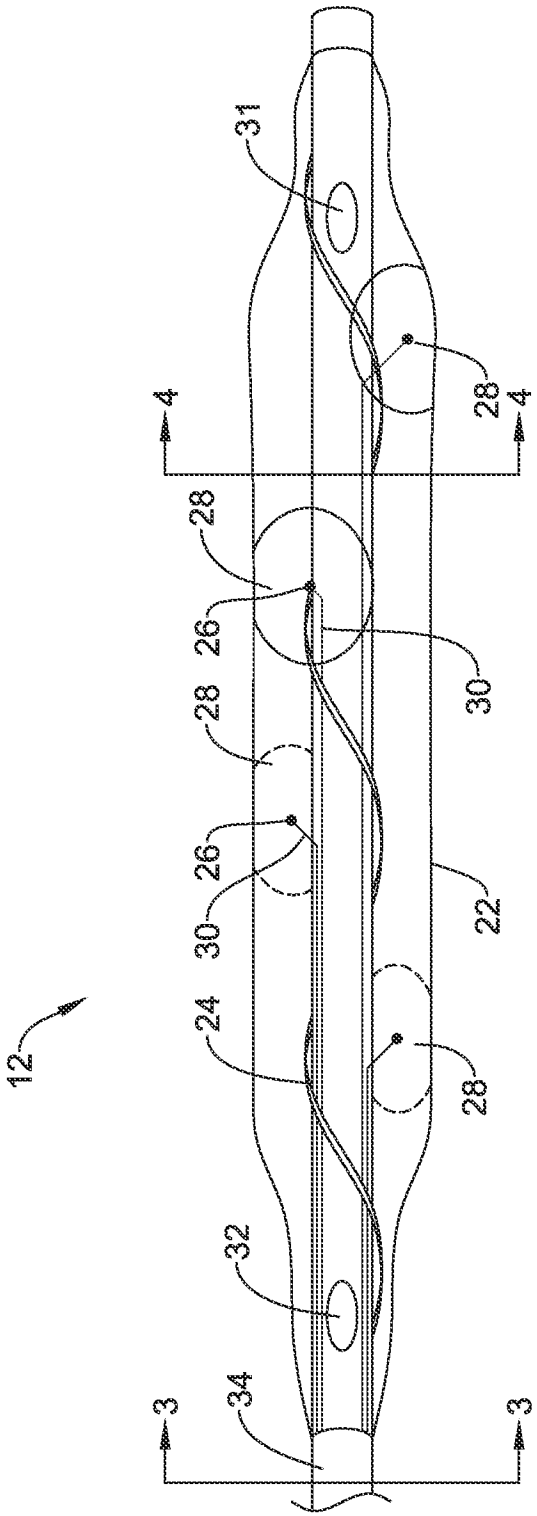


Figure 2

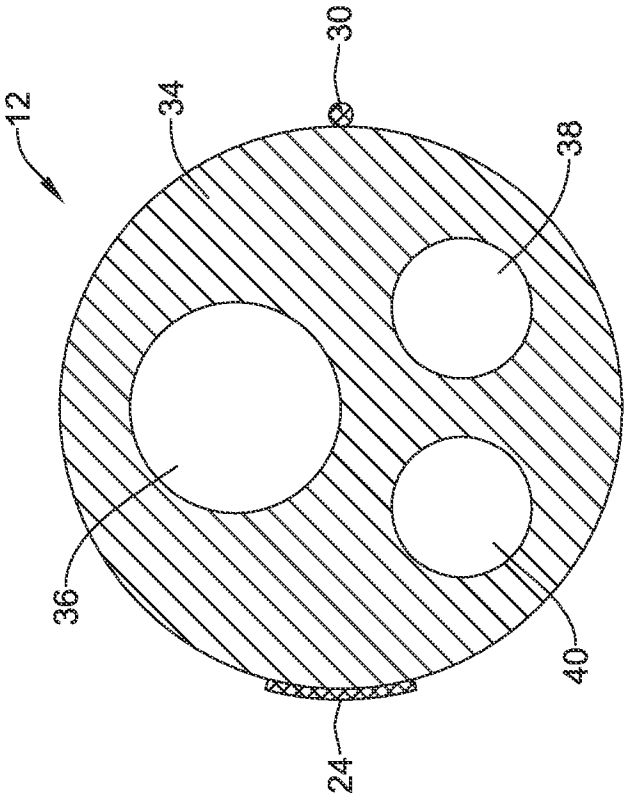


Figure 3

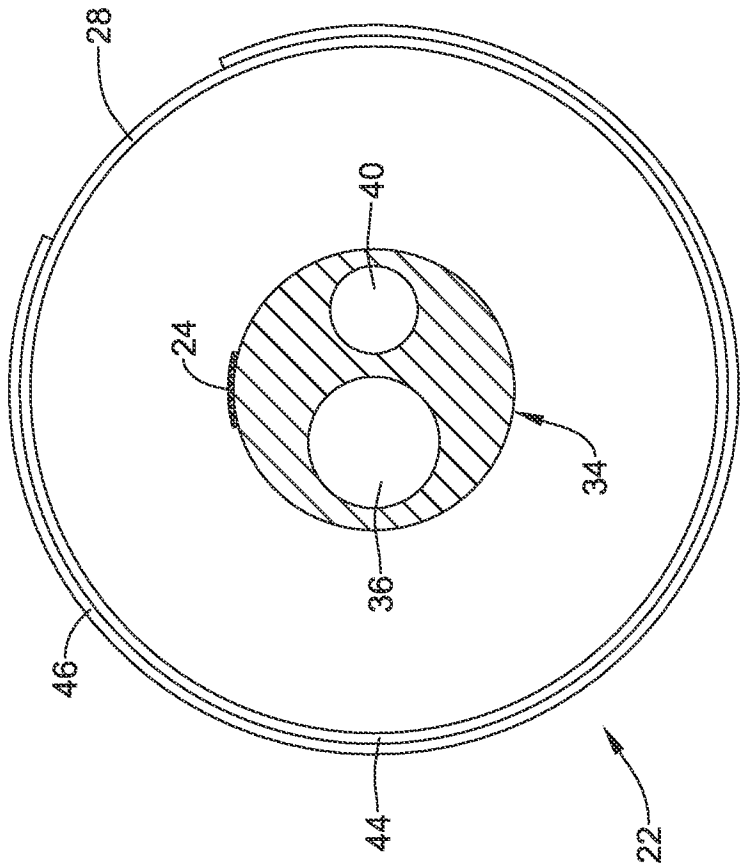


Figure 4

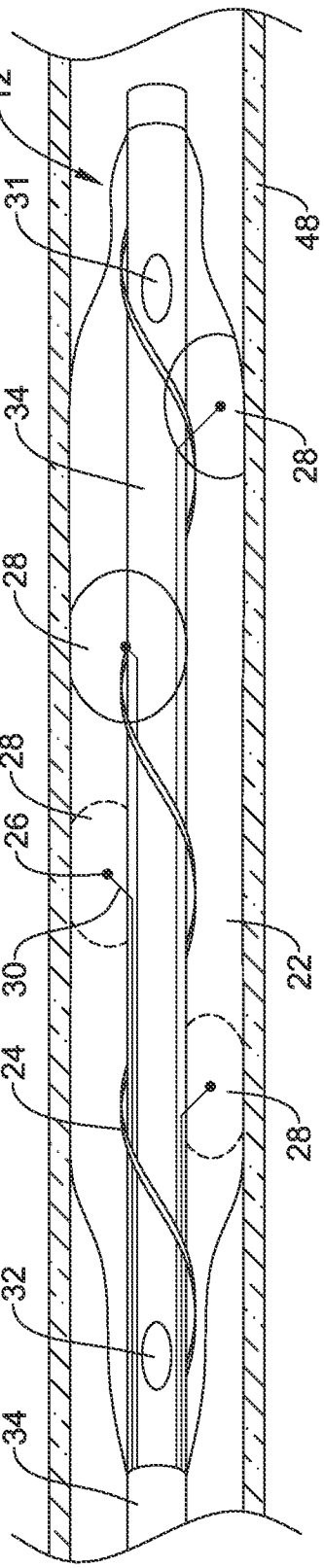


Figure 5

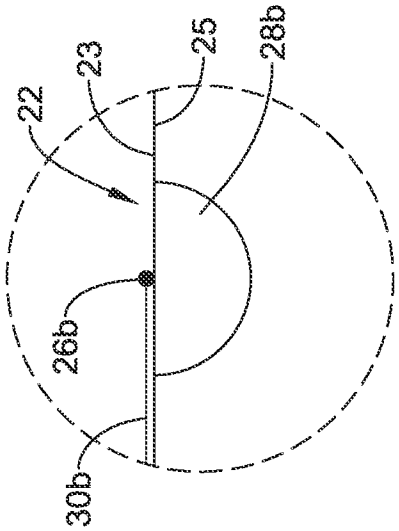


Figure 7

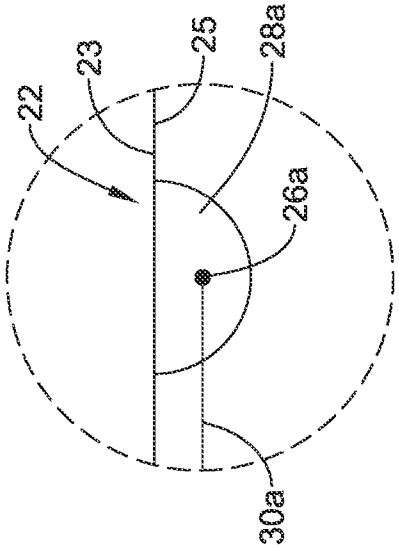


Figure 6

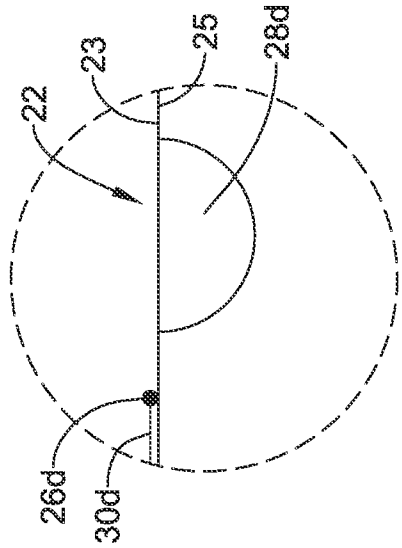


Figure 9

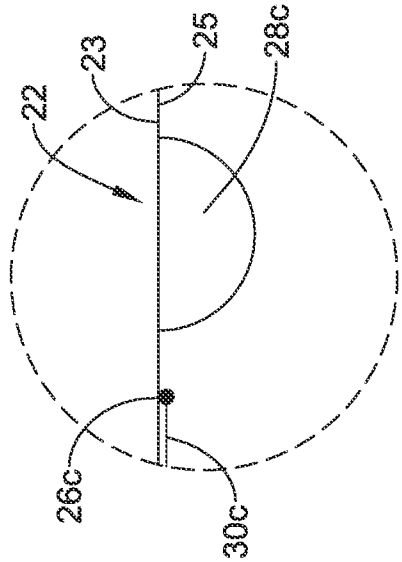


Figure 8

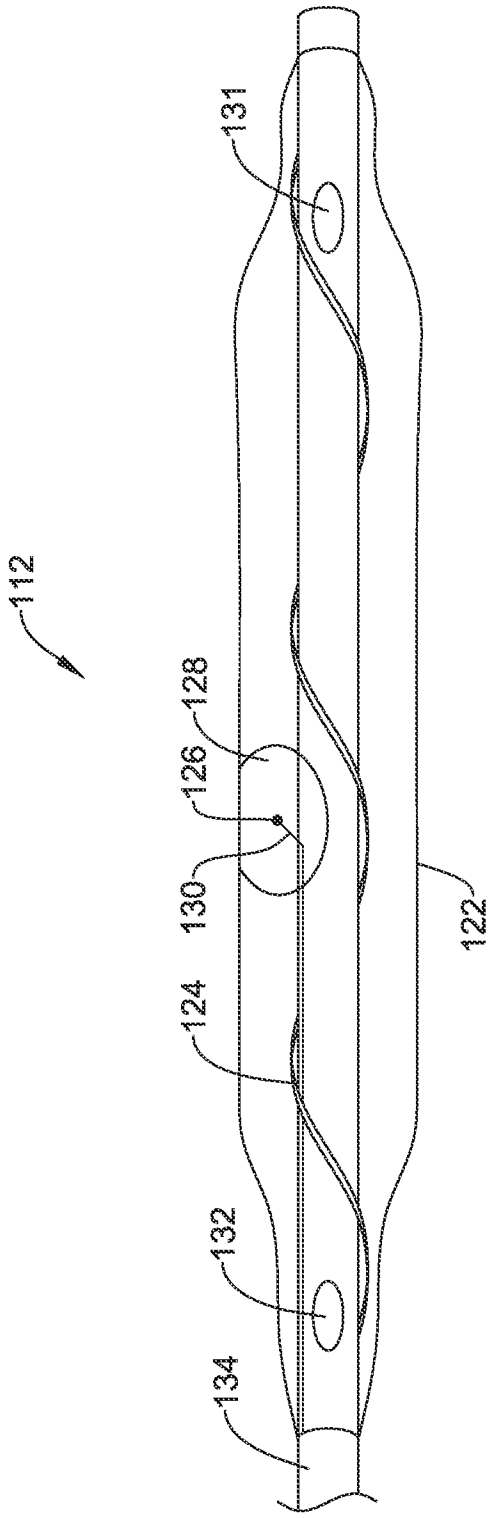


Figure 10

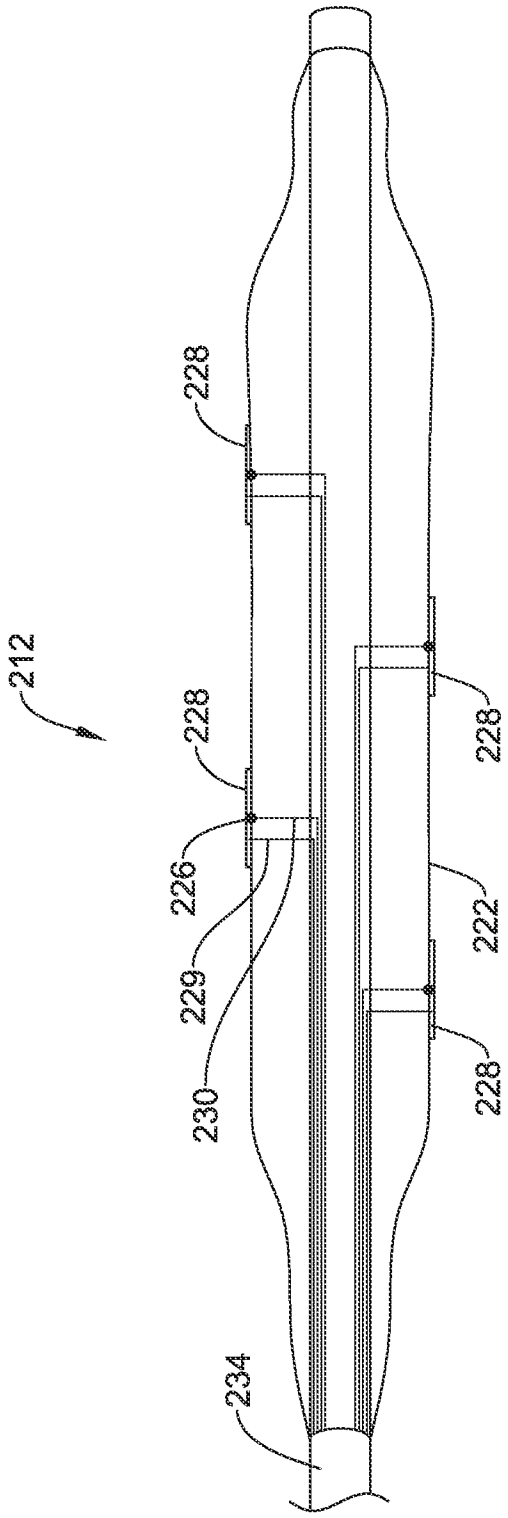


Figure 11

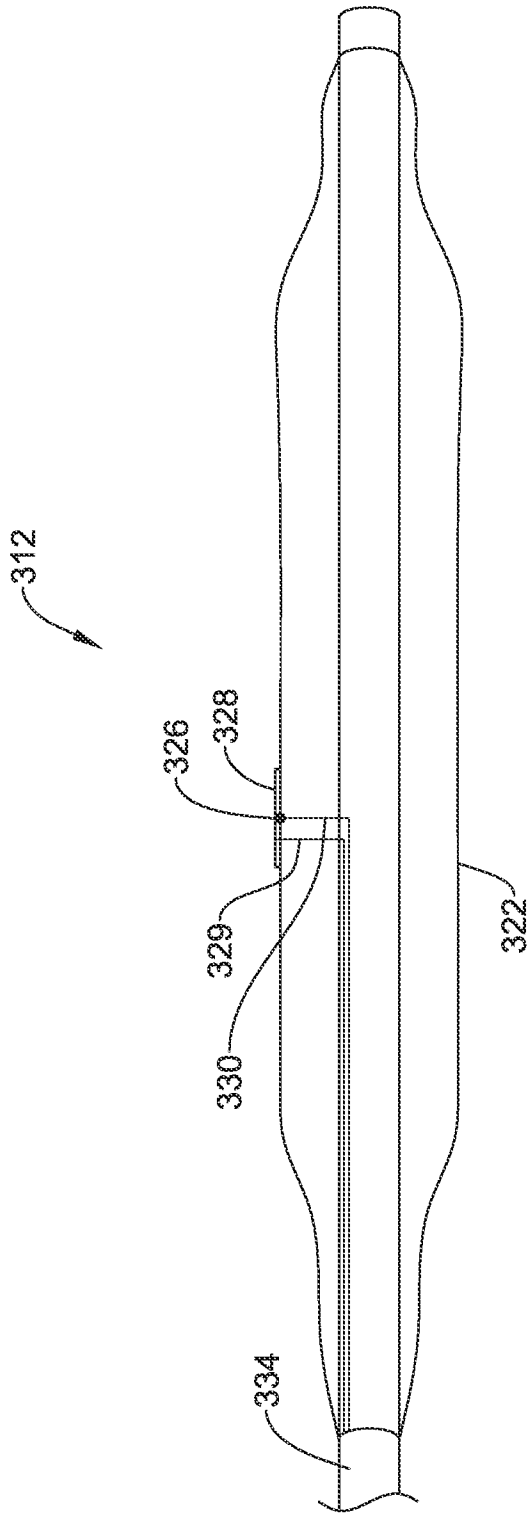


Figure 12

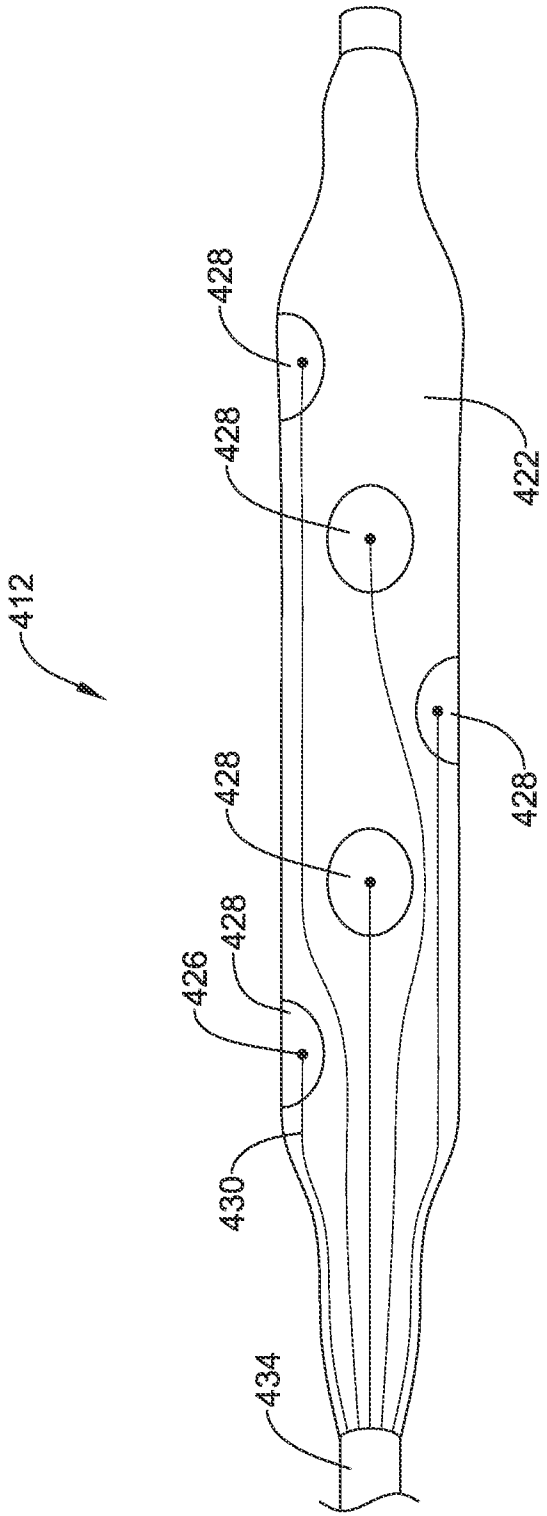


Figure 13

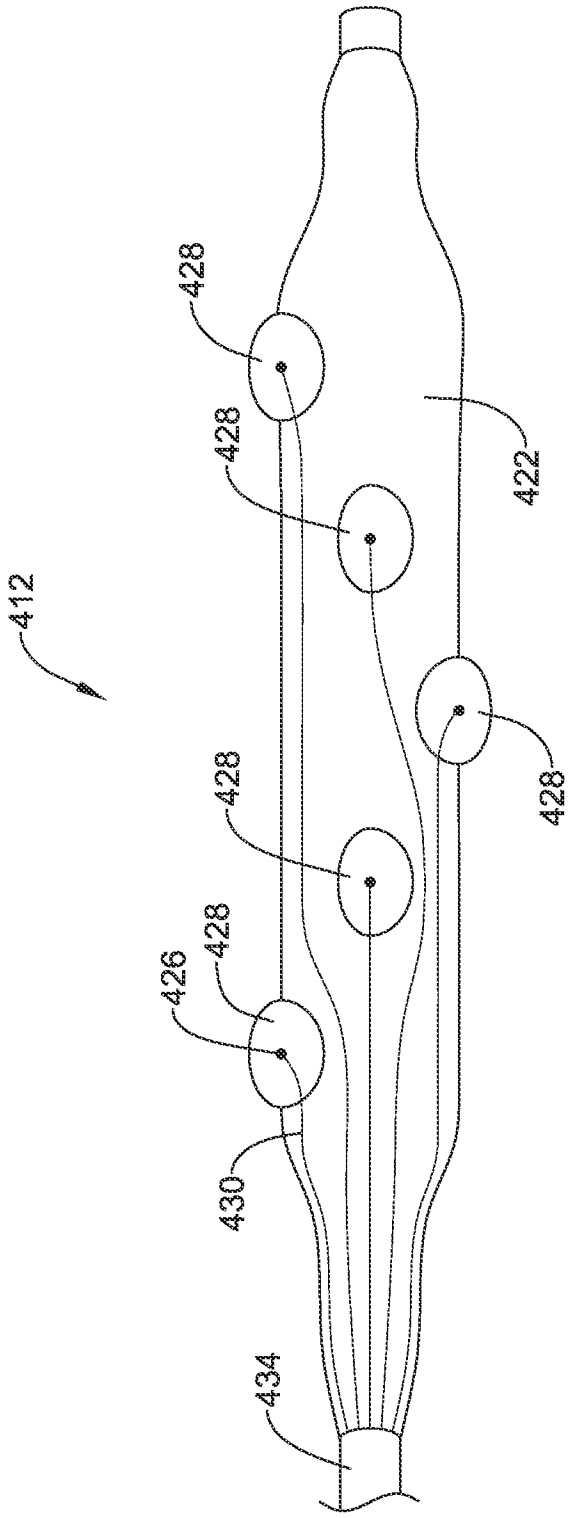


Figure 14

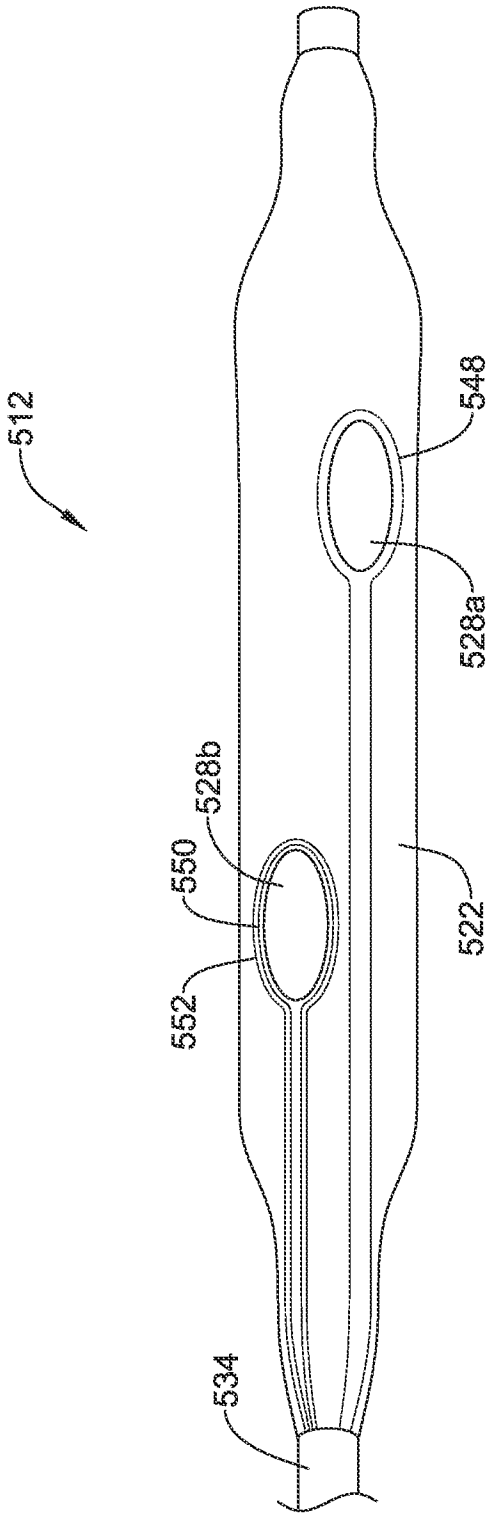


Figure 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/040177

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/14
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 A61N

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 846 239 A (SWANSON DAVID K [US] ET AL) 8 December 1998 (1998-12-08) column 10, line 60 - column 11, line 14 page 18, line 54 - page 20, line 19 column 21, line 27 - line 55; figures 11,14	1-13,15
X	US 6 500 174 B1 (MAGUIRE MARK A [US] ET AL) 31 December 2002 (2002-12-31) column 19, line 22 - column 20, line 4 column 41, line 18 - line 37; figure 2	1-13,15
X	US 2012/065554 A1 (PIKUS MICHAEL [US]) 15 March 2012 (2012-03-15)	14
A	paragraphs [0057], [0067] - [0070], [0078]; figures 8,9	1-13,15

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

[X] See patent family annex.

* Special categories of cited documents :

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 August 2013	28/08/2013

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/040177

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/059965 A1 (EBERL GREGORY RICHARD [US] ET AL EBERL GREGORY R [US] ET AL) 17 March 2005 (2005-03-17) cited in the application paragraphs [0049], [0065]; figure 2	1-15
X,P	WO 2013/040201 A2 (BOSTON SCIENT SCIMED INC [US]; SUBRAMANIAM DR RAJ [US]; KOBLISH JOSEF) 21 March 2013 (2013-03-21) paragraphs [0065] - [0068]; figures 2,3	1-8,12, 13
E	WO 2013/101452 A1 (BOSTON SCIENT SCIMED INC [US]) 4 July 2013 (2013-07-04) page 7, line 14 - page 9, line 3; figure 2	1-4,6-8, 14

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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