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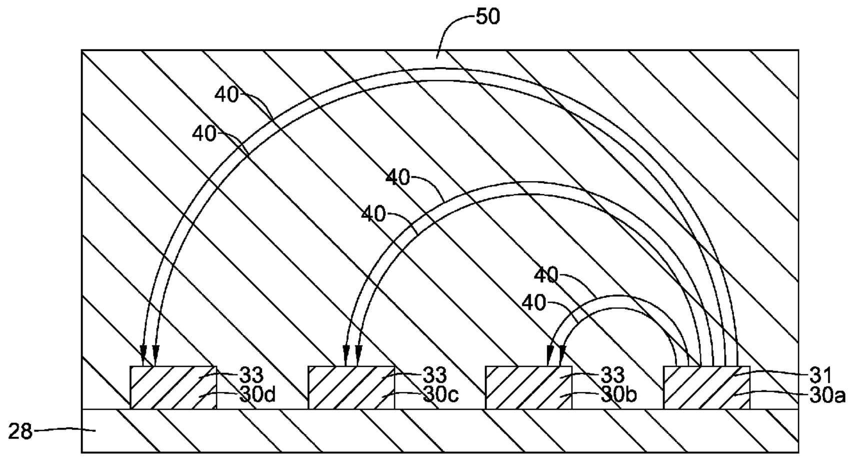

FIG. 2B

(57) Abstract: Medical devices and methods for making and using the same are disclosed. An example medical device may include a medical device for renal nerve ablation. The medical device may include an elongate shaft having a distal region. An expandable member may be coupled to the distal region. A plurality of electrodes may be coupled to the expandable member and a single conductive member may be coupled to each electrode. Where one of the plurality of electrodes is active, the remaining electrodes may be inactive and act as ground or return electrodes. The electrode of the plurality of electrodes that is active may change over time.

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MEDICAL DEVICES FOR RENAL NERVE ABLATION

Cross-Reference To Related Applications

This application claims priority under 35 U.S.C. §119 to U.S. Provisional Application Serial No. 61/841,669, filed July 1, 2013, the entirety of which is incorporated herein by reference.

Technical Field

The present disclosure pertains to medical devices, and methods for manufacturing medical devices. More particularly, the present disclosure pertains to medical devices for renal nerve ablation.

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 medical device for renal nerve ablation. The medical device may include an elongate shaft having a distal region. An expandable member may be coupled to the distal region. A plurality of electrodes may be coupled to the expandable member. A single conductive member may be connected to each of the electrodes, where each of the connected conductive members are capable of powering the electrode to which the conductive trace is connected. When one of the plurality of electrodes is active, the remaining unpowered electrodes act as ground electrodes.

Another example medical device for renal ablation may include an elongate shaft having a distal region. An expandable balloon may be coupled to the distal region. A plurality of electrodes may be coupled to the expandable member. A plurality of conductive traces may be coupled to the elongate shaft and a single conductive trace of the plurality of conductive traces is connected to each of the electrodes such that each of the connected single conductive traces is capable of powering the electrode to which the single conductive trace is connected. When one of the plurality of electrodes is active, one or more of the plurality of electrodes act as a ground electrode.

Methods for ablating renal nerves are also disclosed. An example method may include providing a medical device. The medical device may include an elongate shaft having a distal region. An expandable member may be coupled to the distal region. Two or more electrodes may be coupled to the expandable member. The medical device may include a plurality of conductive traces and a single conductive trace may be connected to each of the two or more electrodes. The method may also include advancing the medical device through a blood vessel to a position within a renal artery, expanding the expandable member, activating one of the two or more electrodes, and maintaining the remaining electrodes of the two or more electrodes as inactive to act as ground electrodes.

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

Brief Description of the Drawings

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

Figure 1 is a schematic view of an illustrative medical device;

Figure 2A is a schematic side view of a portion of an illustrative medical device;

Figure 2B is schematic cross-sectional view taken through line 2B-2B in Figure 2A;

Figure 3A is a schematic side view of a portion of an illustrative medical device;

Figure 3B is schematic cross-sectional view taken through line 3B-3B in Figure 23;

Figure 4A is a schematic side view of a portion of an illustrative medical device;

Figure 4B is schematic cross-sectional view taken through line 4B-4B in Figure 4A;

Figure 5A is a schematic side view of a portion of an example medical device;

Figure 5B is schematic cross-sectional view taken through line 5B-5B in Figure 5A;

Figure 6 is a schematic side view of a portion of an illustrative medical device;

Figure 7A is a schematic side view of a portion of an illustrative medical device;

Figure 7B is schematic cross-sectional view taken through line 7B-7B in Figure 7A; and

Figure 8 is schematic flow diagram showing an illustrative method of using a medical device.

While the disclosure 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 disclosure.

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.

It is noted that references in the specification to “an embodiment”, “some embodiments”, “other embodiments”, etc., indicate that the embodiment described may include one or more particular features, structures, and/or characteristics. However, such recitations do not necessarily mean that all embodiments include the particular features, structures, and/or characteristics. Additionally, when particular features, structures, and/or characteristics are described in connection with one embodiment, it should be understood that such features, structures, and/or characteristics may also be used connection with other embodiments whether or not explicitly described unless clearly stated to the contrary.

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 are aimed at 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 such as or related to hypertension, congestive heart failure, diabetes, or other conditions impacted by high blood pressure or salt retention. The kidneys produce a sympathetic response, which may increase the undesired retention of water and/or sodium. The result of the sympathetic response, for example, may be an increase in blood pressure. Ablating some of the nerves running to the kidneys (e.g., disposed adjacent to or otherwise along the renal arteries) may reduce or eliminate this sympathetic response, which may provide a corresponding reduction in the associated undesired symptoms (e.g., a reduction in blood pressure).

While the devices and methods described herein are discussed relative to renal nerve ablation and/or 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, pulmonary vein ablation, tumor ablation, benign prostatic hyperplasia therapy, nerve excitation or blocking or ablation, modulation of muscle activity, hyperthermia or other warming of tissues, etc.

Figure 1 is a schematic view of an example renal nerve modulation system 10. System 10 may include a renal nerve ablation medical device 12. The renal nerve ablation medical device 12 may be used to ablate nerves (e.g., renal nerves) disposed adjacent to the kidney K (e.g., renal nerves disposed about a renal artery RA). In use, renal nerve ablation device 12 may be advanced through a blood vessel such as the aorta A to a position within the renal artery RA. This may include advancing the renal nerve ablation device 12 through a guide sheath or catheter 14. When positioned as desired, the renal nerve ablation device 12 may be activated to activate one or more electrodes (not shown in Figure 1). This may include coupling renal nerve ablation medical device 12 to a generator or controller 16 so as to supply the desired activation energy to the electrodes. For example, renal nerve ablation medical device 12 may include a wire or conductive member 18 with a connector 20 that can be connected to a connector 22 on the generator or controller 16 and/or a wire 24 coupled to the generator or controller 16. In at least some embodiments, the generator or the controller 16 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 medical device 12. When activated, the electrodes may be capable of ablating tissue (e.g., renal nerves) as described below and the sensors may be used to sense desired physical and/or biological parameters.

Figure 2A is a side view illustrating a portion of the renal nerve ablation device 12. Here it can be seen that device 12 may include a tubular member or catheter shaft 26. An expandable member 28 may be coupled to catheter shaft 26 (e.g., the elongate catheter shaft 26 may have a distal region and the expandable member 28 may be coupled to the distal region of the elongate catheter shaft 26). In at least some embodiments, the expandable member 28 may be an expandable balloon. In other embodiments, the expandable member 28 may be and/or include a basket, a stent, a plurality of struts, or the like.

An electrode 30 or a plurality of electrodes 30 may be coupled to the expandable member 28. In at least some embodiments, the electrode(s) 30 may be ablation electrodes that are capable of delivering ablation energy to a suitable target. For example, the electrodes 30 may be capable of delivering ablation energy to tissue positioned adjacent to a blood vessel such as renal nerves positioned adjacent to a renal artery.

A conductive member 32 may be coupled to each electrode 30. The conductive member 32 may take the form of a conductive trace, a conductive wire, or the like. Conductive members 32 may be coupled to or be a region of conductive member 18 and, ultimately, may be coupled to generator or controller 16. Thus, a suitable energy (e.g., RF energy or other form of energy) may be delivered to the electrode 30 (e.g., an active electrode 31) via the conductive member 32. Illustratively, an active electrode 31 may be an electrode 30 actively receiving power through the conductive member 32 connected thereto.

In some instances, a single conductive member 32 may be connected to each of a plurality of electrodes 30, as shown in Figures 2A-7B. The single conductive member 32 connected to its respective electrode 30 may be capable of powering that respective electrode 30 to which the conductive member 32 is connected. When the electrode 30 is receiving power through the conductive member 32 connected thereto, the electrode 30 may be considered an "active electrode" 31. When the electrode 30 is not receiving power through its respective conductive member 32, the electrode 30 may be considered an "inactive electrode 33". Illustratively, the active electrode 31 is an electrode 30 that emits energy and the inactive electrode 33 is an electrode 30 that dissipates or disperses energy.

In instances where there are a plurality of electrodes 30 applied to the expandable member 28 or one or more other features of the medical device 12, one of the plurality of electrodes 30 may be an active electrode 31 and the remaining electrodes 30 may be inactive electrodes 33. In such instances, and/or other instances, the inactive electrodes 33 may act as return or ground electrodes, which may reduce or eliminate the need for a dedicated ground electrode and electrodes 30. Through the elimination of dedicated ground electrodes running to each electrode 30 and/or dedicated conductive member 32 return paths (e.g., second conductive members running to each electrode 30), a size, footprint, and/or complexity of a flex circuit or the electrode 30 and the conductive member 32, themselves, may be reduced and simplified, respectively. As a result, the reduced size of the flex circuits or the electrode 30 and the conductive member 32 may reduce the chances of the medical device 12 failing (e.g., the electrode 30 may delaminate from the flex circuit, etc.)

during insertion, withdrawal, or re-insertion of the catheter shaft 26 and/or the expandable member 28 in a blood vessel.

Return or ground electrodes may be capable of being a return electrical pathway for the active electrode 31. As a result, energy may be delivered to the active electrode 31 and the return or ground electrode may be the return electrical pathway. For example, Figures 2B, 3B, 4B, and 5B illustrates that energy 40 may be delivered to body tissue 50 (which may include renal nerves and/or other nerve tissue) from the active electrode 30 and then back to the return or ground electrodes (e.g., inactive electrodes 33).

When there are a plurality of electrodes 30 applied to the medical device 12, a single one of the plurality of electrodes 30 may be an active electrode 31 and the remaining electrodes 30 may be inactive electrodes 33 acting as return or ground electrodes, as shown in Figures 2A-5B for example, or one or more of the remaining electrodes 30 may be inactive electrodes 33. Over time (e.g., during a procedure), the electrode 30 of the plurality of electrodes 30 that is the active electrode 31 may remain active and the one or more electrodes 30 that are inactive electrodes 33 may remain inactive.

Alternatively, over time (e.g., during a procedure), the electrode 30 of the plurality of electrodes 30 that is the active electrode 31 may change or switch. For example, where there is a first electrode 30a, a second electrode 30b, a third electrode 30c, and a fourth electrode 30d, as shown in Figures 2A and 2B, the first electrode 30a may be the active electrode 31 and one or more of the remaining electrodes 30b-30d may be inactive electrodes 33 (e.g., all of the remaining electrodes 30b-30d may be inactive electrodes 33). In the example, the active electrode 31 may be switched from the first electrode 30a to one of the remaining electrodes 30b-d. As shown in Figures 3A and 3B, for example, the second electrode 30b may be the active electrode 31 and any one of the remaining electrodes 30a, 30c, 30d may be the inactive electrodes 33 (e.g., all of the remaining electrodes 30a, 30c, 30d may be the inactive electrodes 33). As shown in Figures 4A and 4B, for example, the third electrode 30c may be the active electrode 31 and any one of the remaining electrodes 30a, 30b, 30d may be the inactive electrodes 33 (e.g., all of the remaining electrodes 30a, 30b, 30d may be the inactive electrodes 33. As shown in Figures 5A and 5B, for example, the fourth electrode 30d may be the active electrode 31 and any one of the remaining electrodes 30a, 30b, 30c may be the inactive electrodes 33 (e.g., all of the remaining electrodes 30a, 30b, 30c may be the inactive electrodes 33).

The described order of which electrode 30 is an active electrode 31 and which electrode(s) 30 are inactive electrodes 33 is not required and any electrode 30 may be the active electrode 31 and any one or more of the remaining electrodes 30 may be inactive electrodes 31, as desired. Further, the numbering of the electrodes 30 (e.g., the first electrode 30a, the second electrode 30b, the third electrode 30c, the fourth electrode 30d, etc.) is used for clarity of description purposes and is not meant to be limiting. Additionally, more or fewer than four (4) electrodes may be utilized, as desired.

In some instances, each of the plurality of electrodes 30 may be active for an equal amount of time over defined (e.g., set) time period (e.g., a determined time for ablating tissue). In one illustrative example, where there are four electrodes 30a, 30b, 30c, and 30d, each electrode 30 may be active for a quarter of a set time period and inactive for three quarters of the set time period. Alternatively, or in addition, each of the plurality of electrodes 30 may be active for a set time period (e.g., ten (10) seconds, fifteen (15) seconds, twenty (20) seconds, etc.) before a different electrode 30 of the plurality of electrodes 30 becomes active.

In some illustrative instances, the conductive member 32 (e.g., conductive traces) may be covered or coated with a coating 42 for conductive member insulation, protection, and/or for other purposes, as shown in Figure 6. The coating 42 may be applied to the conductive traces 32 in any manner. For example, the coating 42 may be applied to the conductive traces 32 through a deposition method or other application method, as desired. In some instances, the electrodes 30 and/or other features (e.g., temperature sensors 44) may be masked prior to applying a coating to the conductive members 32 to facilitate ensuring the electrodes 30 and/or other features are not covered by the coating 42.

The coating 42 may be any type of insulating material (e.g., electrically and/or thermally insulating) and/or protective material. In some instances, the coating 42 may be a single material or multiple materials mixed together and/or applied to the medical device 12 separately. In one example, the coating 42 may be a thermoplastic polyurethane (TPU). In some instances, a single layer of coating 42 may be applied to the medical device 12. Alternatively, or in addition, multiple layers of coating 42 may be applied to the medical device 12. Where multiple layers of coating 42 may be applied to the medical device, the conductive members 32 may be stacked up at a proximal waist of the expandable member 28 (e.g., where the expandable member 28 meets the tubular member or catheter shaft 26).

In some illustrative instances, a non-conductive or insulator layer 34 may be disposed adjacent to the conductive member 32. The electrode 30 may be disposed along the non-conductive layer 34. The non-conductive layer 34 may insulate the electrode 30 and/or the conductive member 32 from other structures including conductive structures along the expandable member 28 (e.g., which may include one or more conductive members/electrodes acting as ground electrodes).

In some instances, the electrode(s) 30 may be disposed along a flexible circuit 46 (e.g., a "flex circuit"), as shown in Figures 7A and 7B. Some example flex circuits that may be utilized for device 12 (and/or other devices disclosed herein) may include or otherwise be similar to flex circuits disclosed in U.S. Patent Application No. 13/760,846, the entire disclosure of which is herein incorporated by reference. In one example flex circuit 46, the flex circuit 46 may include one or more polymeric layers (e.g., the insulation layer 34), such as polyimide or other polymeric layers with electrode(s) 30 and conductive member(s) 32 coupled thereto.

A flex circuit 46 may include a single electrode 30 and a single temperature sensor 44 applied to the insulation layer 34 and one or more flex circuits 46 may be applied to the expandable member 28. Alternatively, or in addition, a flex circuit 46 may include a plurality of electrodes 30 and one or more temperature sensors 44 applied to the insulation layer and one or more flex circuits 46 may be applied to the expandable member 28, as shown in Figures 7A and 7B. In other instances, the electrode 30 may be disposed along a printed circuit applied to the expandable member 28 or placed on a strut of a basket (e.g., where the basket is an expandable member 28) and attached to a conductive wire (e.g., where the conductive wire is a conductive member 32).

In some instances, one or more temperature sensor 44 may be coupled to the expandable member 28 and/or the flex circuit. The temperature sensors 44 may include a thermistor, thermocouple, or any other suitable temperature sensor. In some cases, a conductive member 36 may be coupled to the temperature sensor 44. As shown in Figures 2A, 3A, 4A, 5A, 6, and 7A, a single conductive member 36 may be coupled to each temperature sensor 44. Illustratively, the conductive member 36 coupled to the temperature sensor 44 may be the same as or different than the conductive member 32 coupled to the electrode 30. For example, the conductive member 32 may take the form of a conductive trace, a conductive wire, or the like, which may be capable of and/or configured to transmit electrical signals and/or electrical power to and from the temperature sensor 44.

In some instances, the conductive traces 36 may be covered or coated with a coating 42 for conductive member insulation, protection, and/or for other purposes. The coating 42 may be applied to the conductive traces 36 in any manner. For example, the coating 42 may be applied to the conductive traces 36 through a deposition method or other application method, as desired. In some instances, the temperature sensors 44 and/or other features (e.g., electrodes 30) may be masked prior to applying a coating to the conductive members 32 to facilitate ensuring the temperature sensors 44 and/or other features are not covered by the coating 42.

The coating 42 may be any type of insulating (e.g., electrically and/or thermally insulating) and/or protective material. In some instances, the coating 42 may be a single material or multiple materials that may be mixed together and/or applied to the medical device 12 separately. In one example, the coating 42 may be a thermoplastic polyurethane (TPU). In some instances, a single layer of coating 42 may be applied to the medical device 12. Alternatively, or in addition, multiple layers of coating 42 may be applied to the medical device 12. Where multiple layers of coating 42 may be applied to the medical device, the conductive members 32 may be stacked up at a proximal waist of the expandable member 28 (e.g., where the expandable member 28 meets the tubular member or catheter shaft 26.

In use, as shown in Figure 8, the renal nerve modulation system 10 may be utilized in a method 100 for ablating renal nerves or in other ablation methods,. In one example, the method 100 may include providing 102 a medical device, such as the renal nerve ablation medical device 12. The provided medical device 12 may include the elongate shaft (e.g., the tubular member or catheter shaft 26) having a distal end and/or region and an expandable member 28 coupled to the distal region of the catheter shaft 26. Further, in some instances, two or more (e.g., a plurality) of the electrodes 30 may be coupled to the expandable member 28 and a plurality of conductive members 32 (e.g., conductive traces) may be coupled to the elongate catheter shaft 26 or expandable member 28, where a single conductive member 32 may be connected to each of the two or more electrodes 30.

The method 100 may include advancing 104 the provided medical device 12 through a blood vessel (e.g., the aorta A or other blood vessel) to a position within the renal artery RA or other vessel and expanding 106 the expandable member 28 and placing the expandable member 28 adjacent or near a target tissue. Once the expandable member 28 has been expanded, one of the electrodes 30 may be activated 108. While activating 108 the one electrode 30 to create an active electrode 31, the remaining electrodes 30 may be maintained 110 as inactive to form ground electrodes. In some instances, the active electrode 31 may be deactivated 112 and one of the other electrodes 30 (e.g., inactive electrodes 33) may be activated 114 to form an active electrode, such that a different one of the two or more electrodes 30 is active and the remaining electrodes, including the electrode 30 that was formerly the active electrode 31 may now be inactive electrodes 33. The deactivating an active electrode 31 and activating an inactive electrode 33 may be optional, as depicted in Figure 8 with a dotted box.

In some instances, the activation and/or deactivation of electrodes 30 may be manually controlled or automatically controlled through one or more activation or deactivations devices. In one example, the generator or controller 16 may be utilized to manually and/or automatically control which electrode 30 is the active electrode. The generator or controller 16, which may include or communicate with a processor and a memory, may activate and deactivate electrodes 30 with the processor based on a computer program stored in its memory for a particular procedure. The program utilized by the generator or controller 16 deactivate or activate an electrode 30 after a set time period, after a temperature of a body tissue 50 or other feature is achieved, or any other criteria is achieved. In some cases, the program utilized by the generator or controller 16 may be manually overridden by a user and a user may manually dictated which electrode(s) 30 are active (e.g., one or more electrode 30 may be active electrodes 31 and/or one or more electrode 30 may be inactive electrodes 33). The electrodes 30 may be activated or deactivated via the generator or controller 16 in any manner, as desired.

In one example, the two or more electrodes may include the first electrode 30a, the second electrode 30b, the third electrode 30c, and the fourth electrode 30d. Illustratively, one of the electrodes 30a-30d may be activated (e.g., the first electrode 30a) to form an active electrode 31 and the remaining electrodes 30 (e.g., the second electrode 30b, the third electrode 30c, the fourth electrode 30d) may be inactive electrodes 33 and act as ground electrodes. Then, after a first period of time (e.g., one second, two seconds, five seconds, ten seconds, fifteen second, thirty seconds, one minute, two minutes, five minutes, etc.) the active electrode 31 (e.g., the first electrode 30a) may be deactivated, another electrode 30 (e.g., the second electrode 30b) may be activated to form an active electrode 31, and the remaining electrodes 30 (e.g., the first electrode 30a, the third electrode 30c, and the fourth electrode 30d) may be maintained as inactive electrodes 33 to form ground electrodes. Further, after a second period of time, which may be the same as the first period of time or any other amount or period of time, the active electrode 31 (e.g., the second electrode 30b) may be deactivated, another electrode 30 (e.g., the third electrode) may be active to form an active electrode 31, and the remaining electrodes 30 (e.g., the first electrode 30a, the second electrode 30b, and the fourth electrode 30d) may be maintained as an inactive electrode 33 to form ground electrodes.

The method 100 of switching which electrode(s) 30 are active may go on for any period or length of time. In one example, this method may continue and/or may repeat itself until a renal nerve modulation procedure or any other ablation procedure or a portion thereof is completed. In some instances, each electrode 30 of the medical device 12 will be an active electrode for a set period of time, where the set period of time for each electrode 30 may be the same as the set period of time for each electrode 30, may be different from a set period of time for at least one electrode 30, or may be different from the set period of time of all other electrodes 30. Alternatively, or in addition, an electrode 30 may remain the active electrode 31 until body tissue 50 adjacent the active electrode 31 reaches a threshold temperature as measured by a temperature sensor 44 associated with the active electrode 31 or a different temperature sensor 44, as desired.

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

Device 12 and the various components thereof 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 polymers 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. In some embodiments the sheath can be blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 6 percent LCP.

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 device of 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 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 device 12 to achieve the same result.

In some embodiments, a degree of Magnetic Resonance Imaging (MRI) compatibility may be imparted into device 12. For example, portions of device, 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. In some of these and in other embodiments, portions of device 12 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.

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 disclosure. 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 medical device for performing ablation procedures, comprising:

an elongate shaft having a distal region;

an expandable member coupled to the distal region;

a plurality of electrodes coupled to the expandable member;

a conductive member connected to each of the electrodes, where each of the connected conductive members are capable of powering the electrode to which the conductive member is connected; and

wherein when one of the plurality of electrodes is active, the remaining unpowered electrodes act as ground electrodes.

2. The medical device of claim 1, further comprising:

one or more temperature sensors coupled to the expandable member; and

a single conductive member connected to each of the one or more temperature sensors.

3. The medical device of claims 1 or 2, wherein the conductive member is a conductive trace.

4. The medical device of any one of claims 1-3, wherein the one of the plurality of electrodes that is active changes over time.

5. The medical device of any one of claims 1-4, wherein each of the plurality of electrodes is active for an equal amount of time.

6. The medical device of any one of claims 1-5, wherein an active electrode is an electrode actively receiving power through the conductive member connected thereto.

7. The medical device of any one of claims 1-6, further comprising:

a coating covering each of the conductive members.

8. The medical device of claim 7, wherein the coating comprises a thermoplastic polyurethane (TPU).

9. The medical device of claims 7 or 8, wherein the coating comprises a plurality of layers of material.

10. The medical device of any one of claims 1-9, wherein the expandable member includes a balloon.

11. The medical device of any one of claims 1-10, wherein the active electrode of the plurality of electrodes is emitting energy and the remaining electrodes are dispersing energy.

12. The medical device of any one of claims 1-11, wherein:

the plurality of electrodes coupled to the expandable member includes four electrodes; and

one electrode is active and three electrodes are inactive and act as ground electrodes.

13. The medical device of any one of claims 1-12, further comprising:

a flex circuit disposed along the expandable member; and

wherein at least one of the plurality of electrodes is disposed along the flex circuit.

14. The medical device of any one of claims 1-13, further comprising:

a plurality of temperature sensors coupled to the expandable member; and

a single conductive member connected to each of the plurality of temperature sensors.

15. The medical device of any one of claims 1-14, wherein a single conductive member is connected to each of the electrodes such that each of the connected single conductive members is capable of powering the electrode to which the single conductive member is connected.

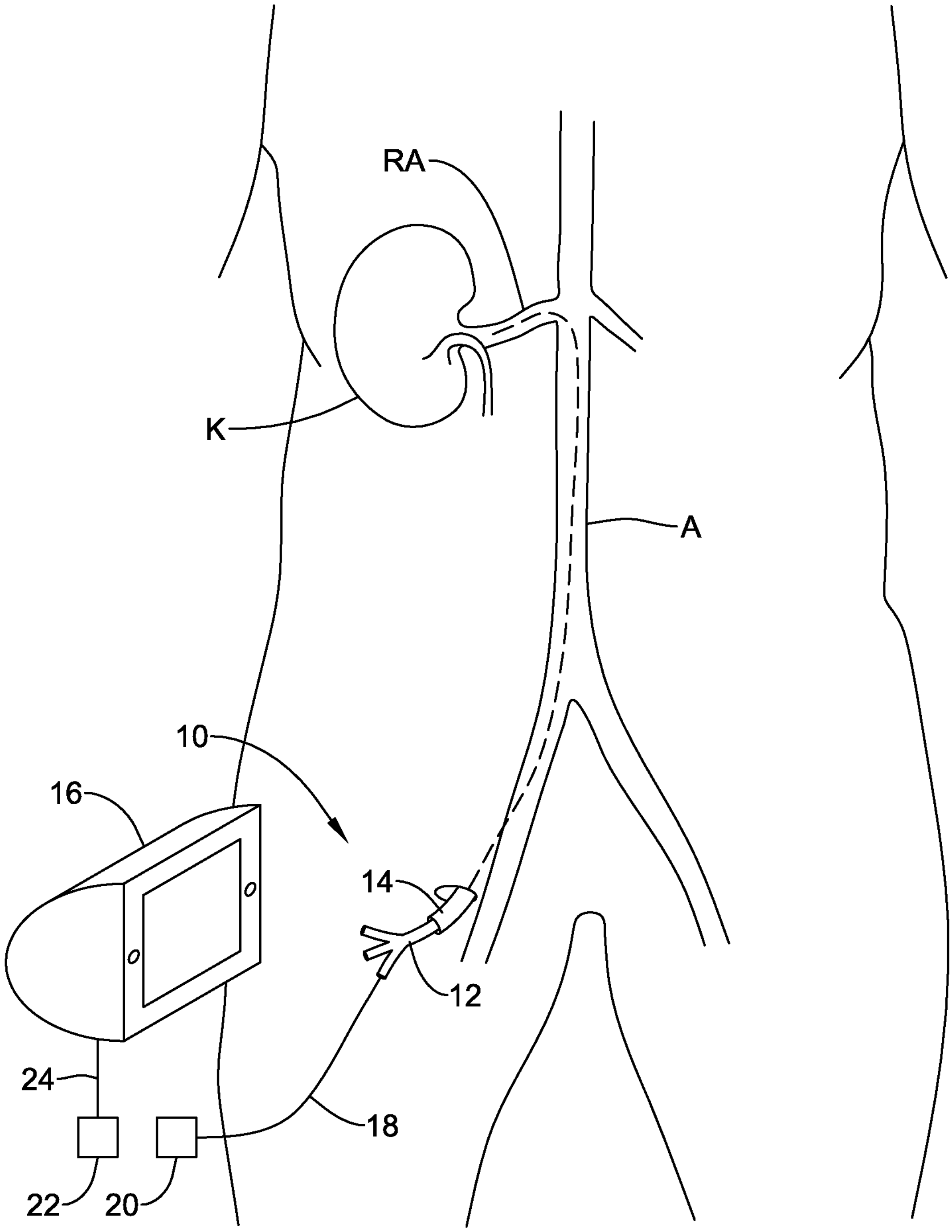

FIG. 1

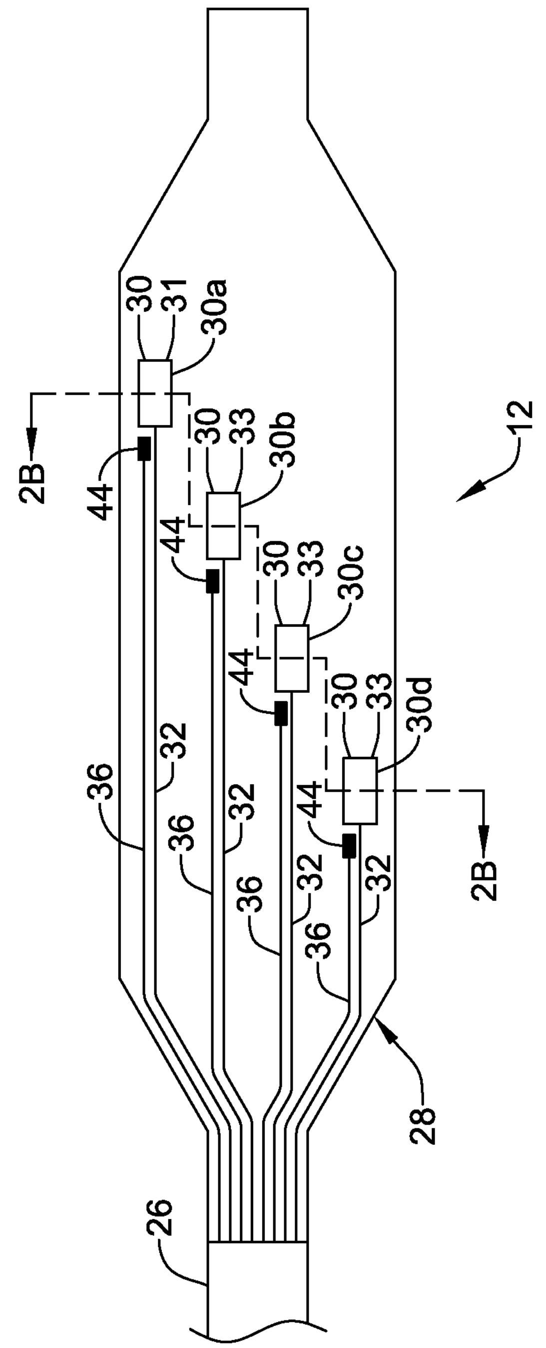
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FIG. 2A

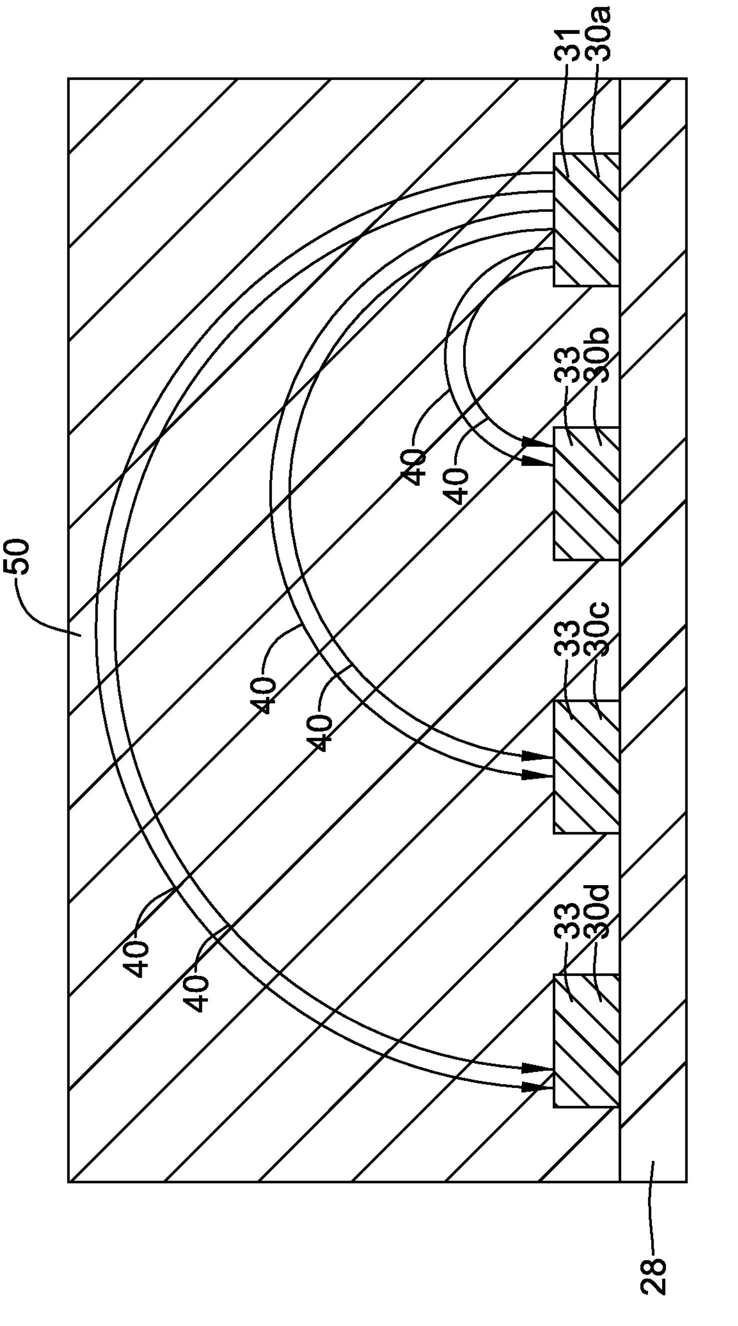

FIG. 2B

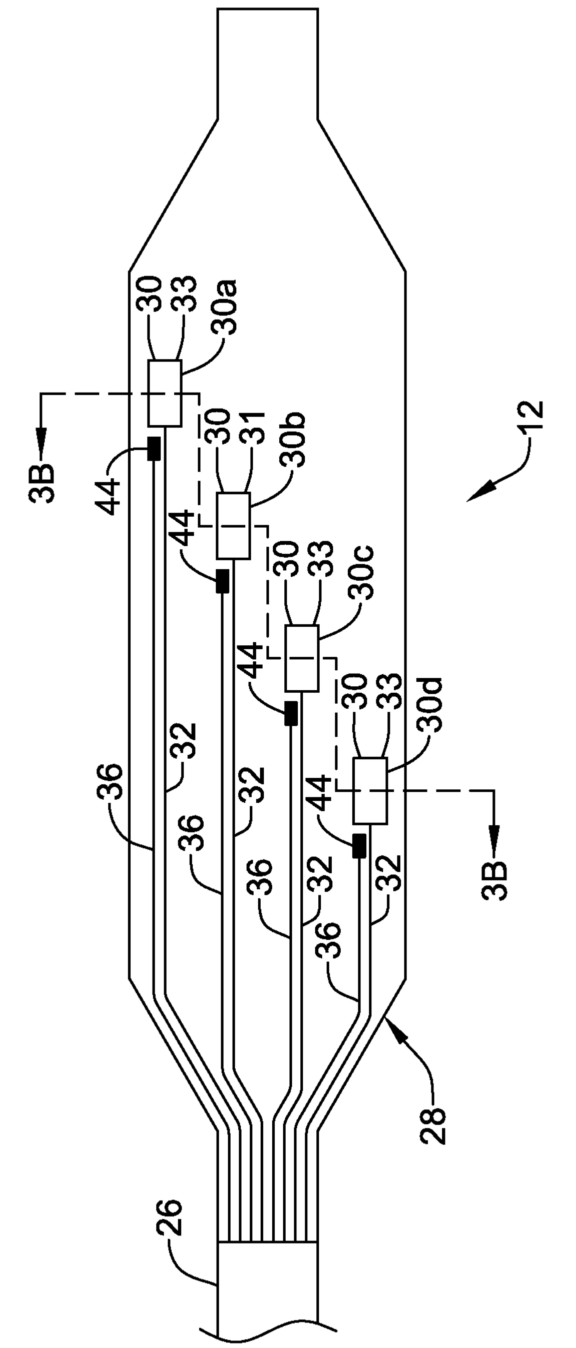
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FIG. 3A

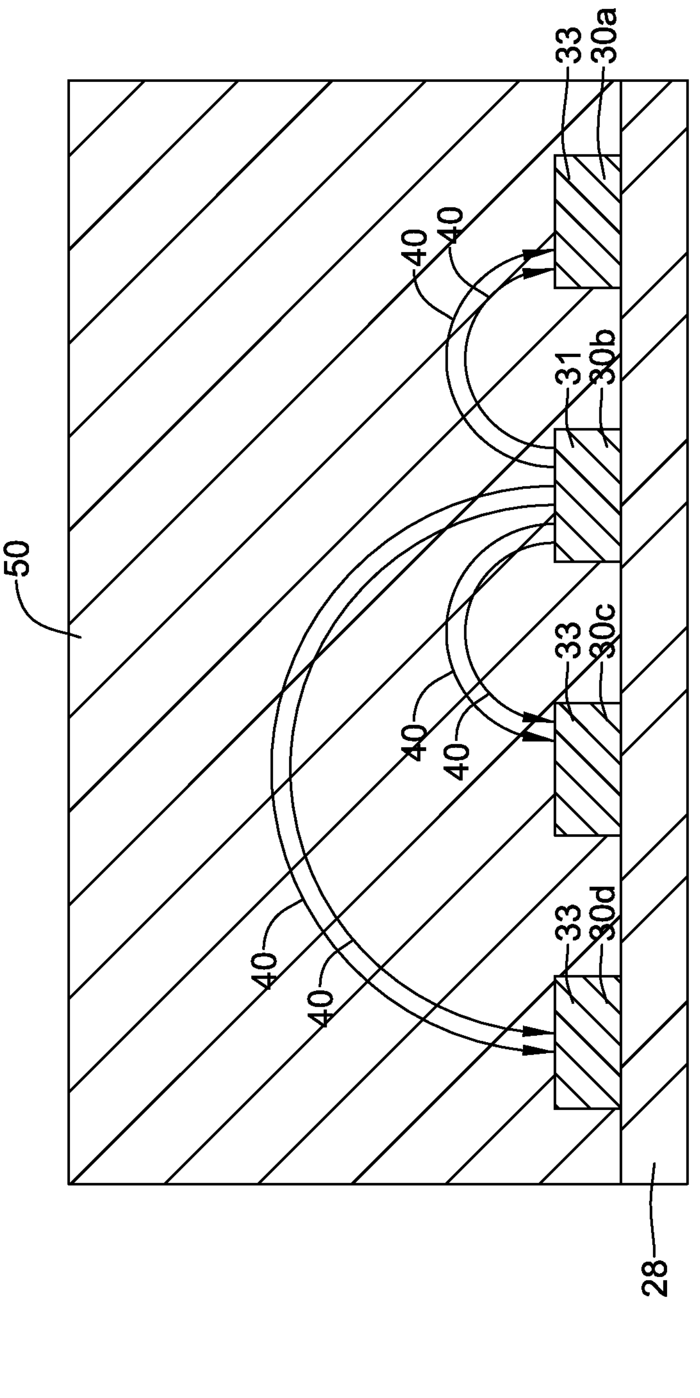

FIG. 3B

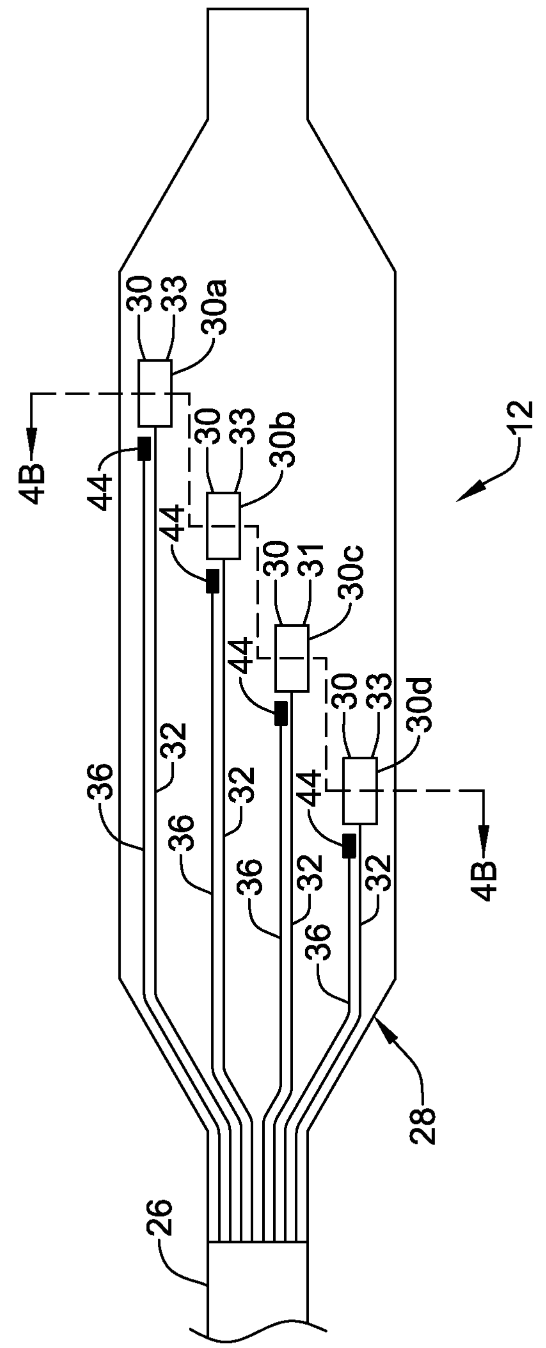
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FIG. 4A

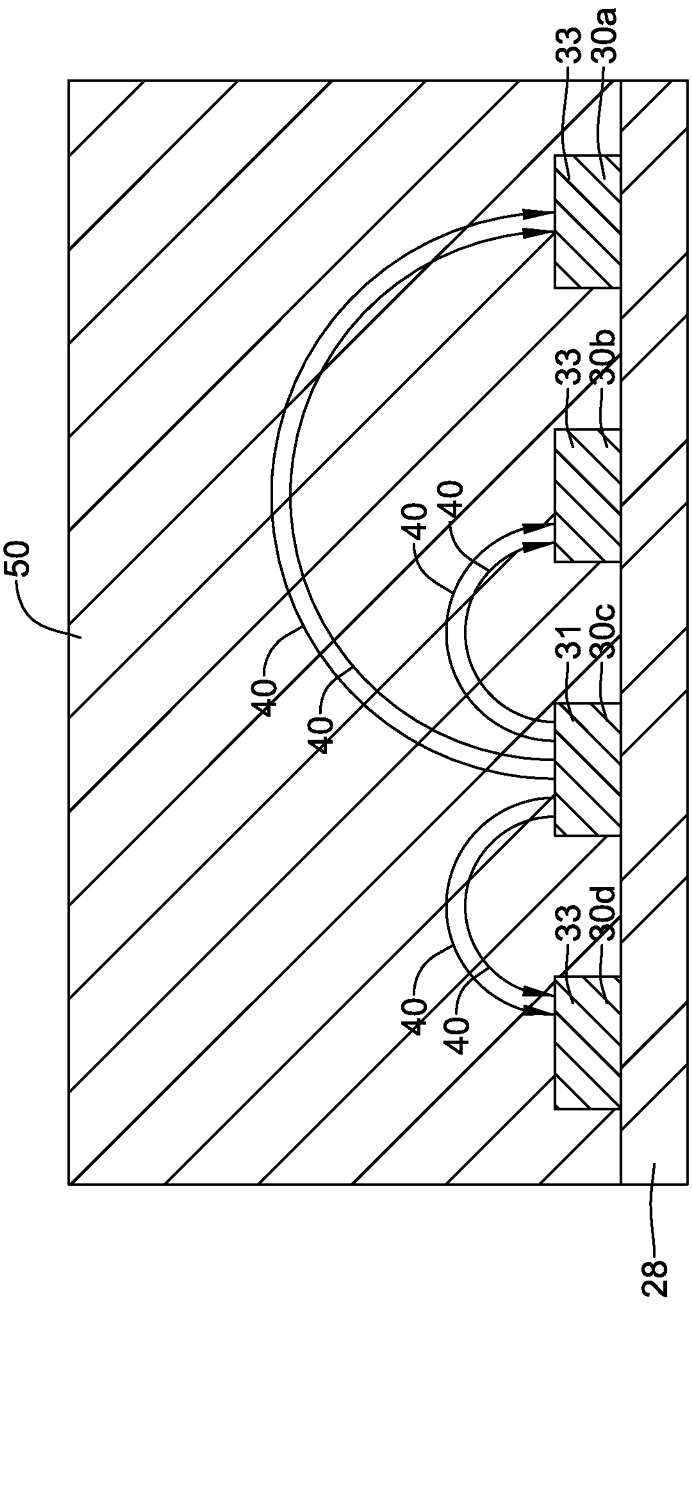

FIG. 4B

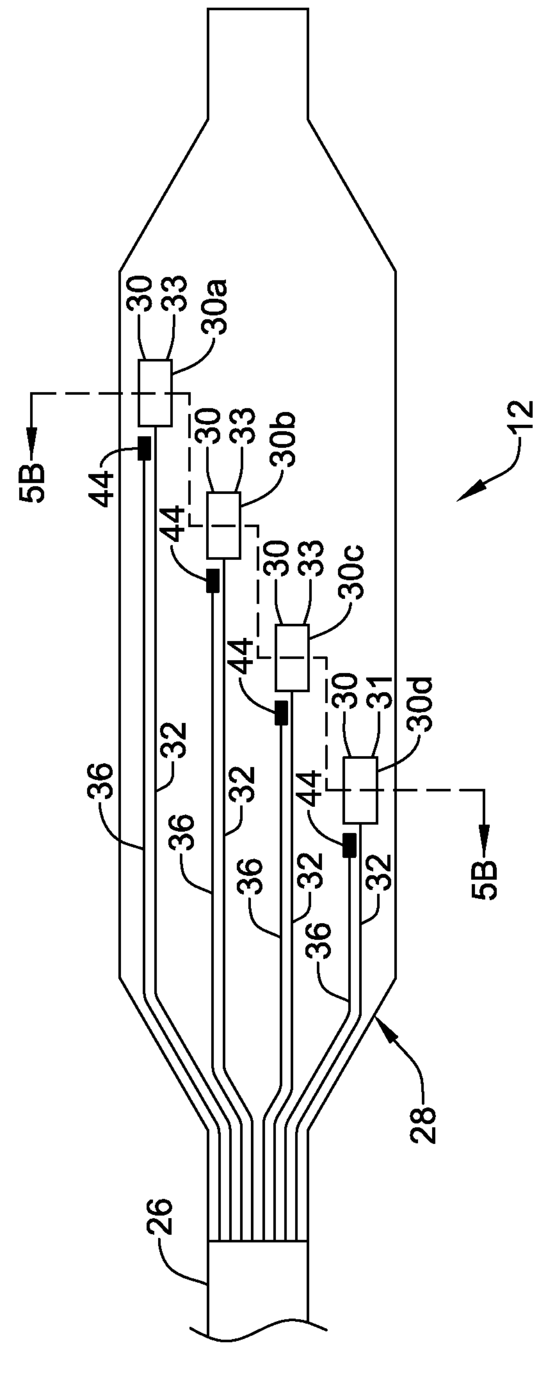
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FIG. 5A

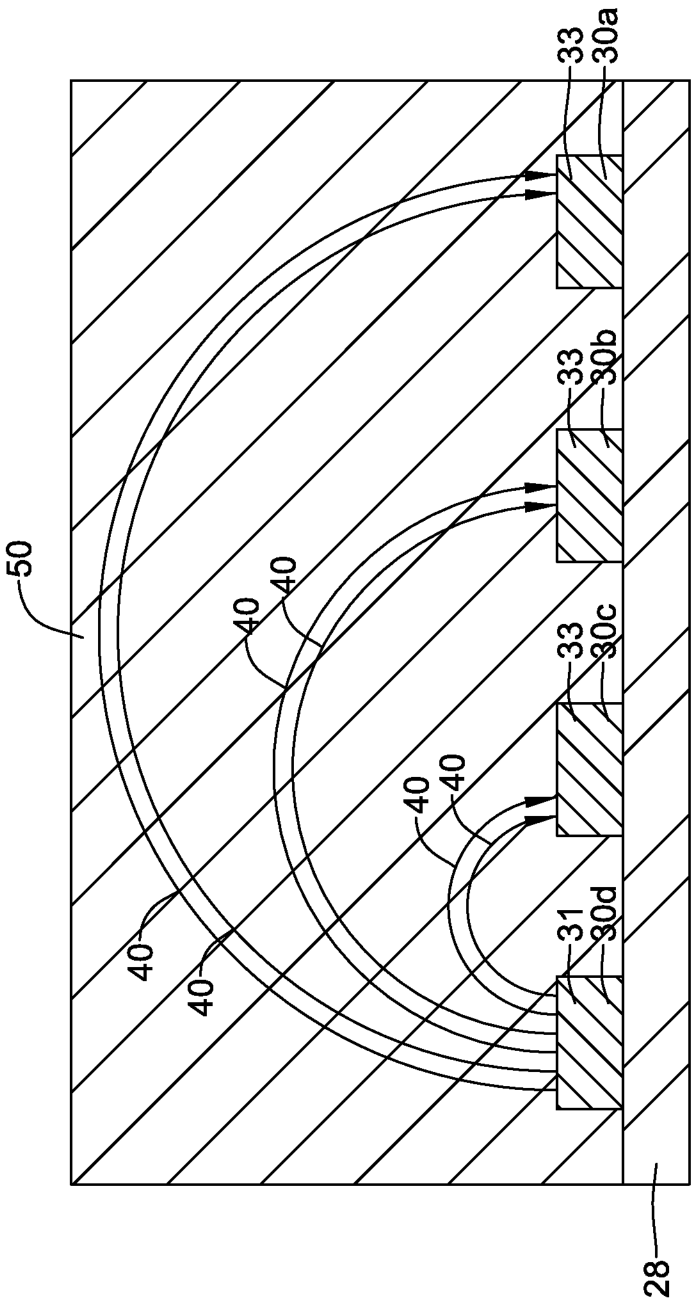

FIG. 5B

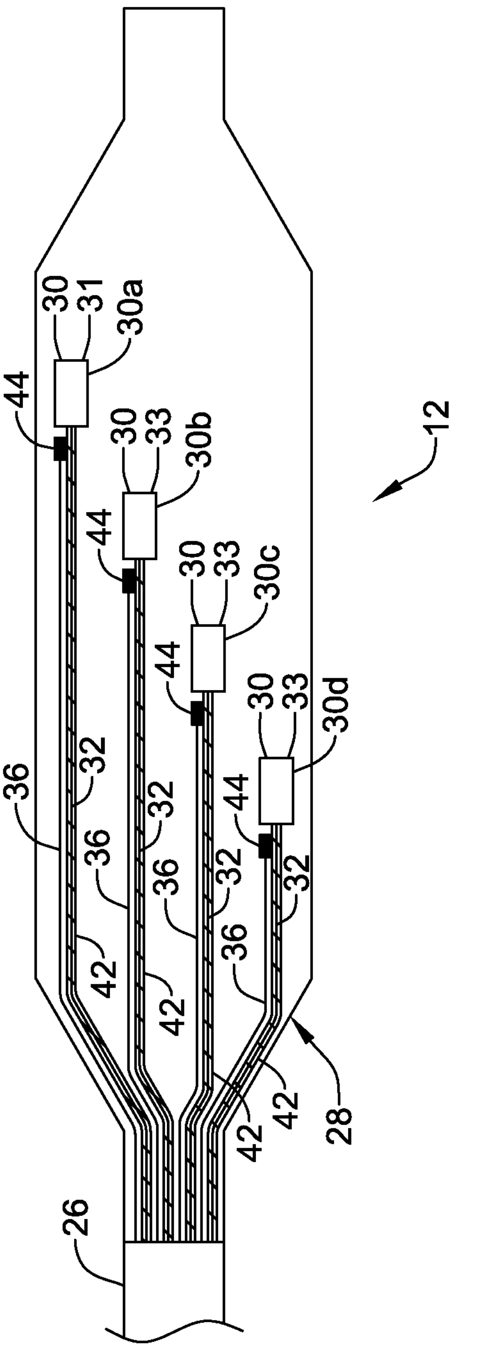

FIG. 6

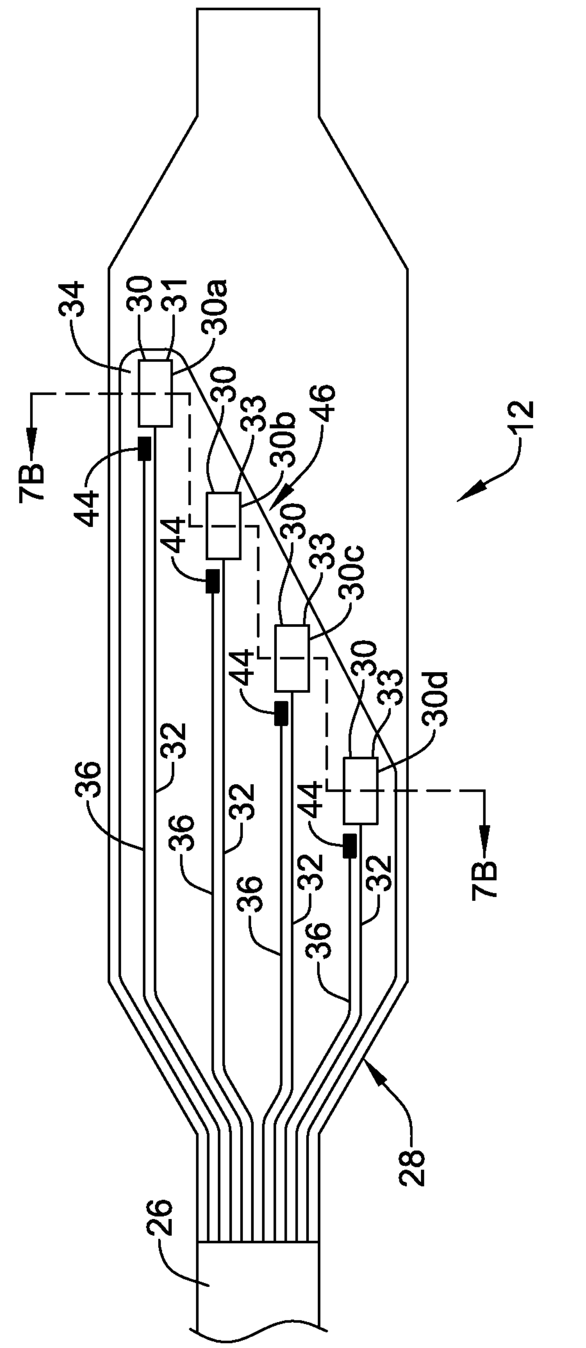
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FIG. 7A

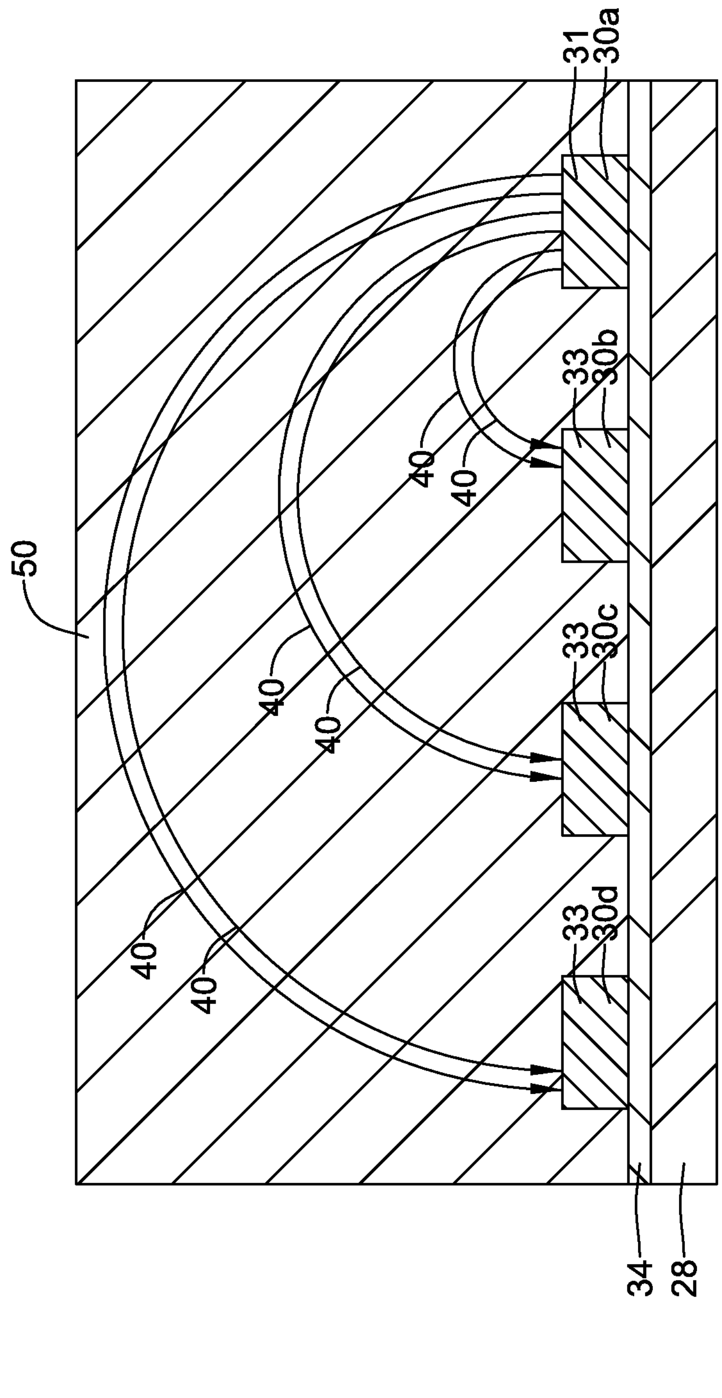

FIG. 7B

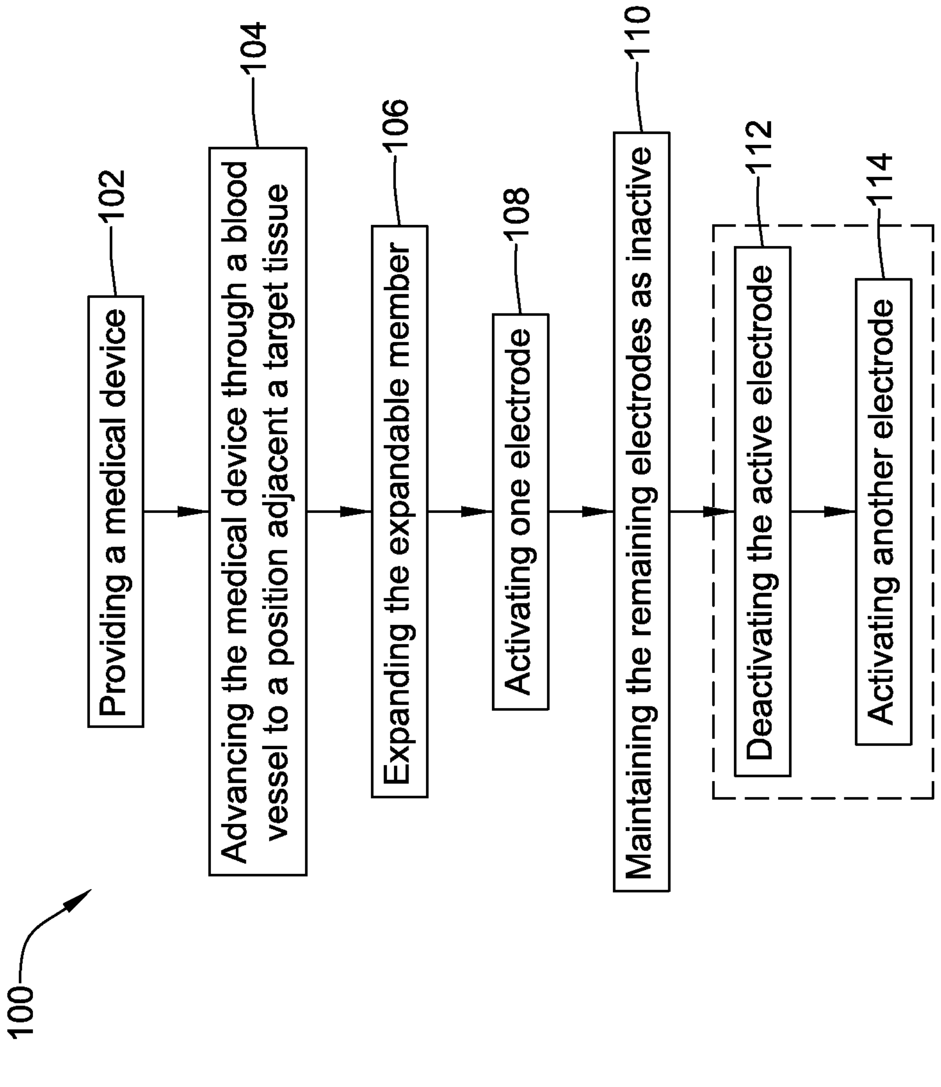
100
102
Providing a medical device
104
Advancing the medical device through a blood vessel to a position adjacent a target tissue
106
Expanding the expandable member
108
Activating one electrode
110
Maintaining the remaining electrodes as inactive
112
Deactivating the active electrode
114
Activating another electrode

FIG. 8