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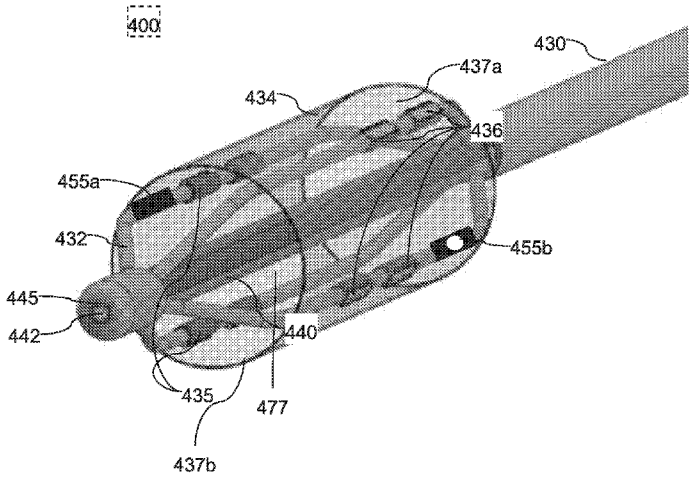
(54) **Title**: ABLATION CATHETER WITH INSULATION

(57) **Abstract**: An ablation device and/or method of ablation may include placing one or more ablation electrodes in contact with a target tissue in a lumen. An electrical insulator may be positioned between the electrode and a lumen fluid and an electrical signal (for example a radio frequency signal) may be conveyed between the electrodes to heat and/or ablate the target tissue. Ablation may be bipolar and/or an in lumen disperse electrode may be supplied for unipolar ablation. Ablation progress may be sensed and ablation may be adjusted to produce a desired level and/or geometry of ablation.

FIG. 4A



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ABLATION CATHETER WITH INSULATION

RELATED APPLICATION

This application claims the benefit of priority under 35 USC §119(e) of U.S. Provisional Patent Application No. 61/759,066 filed 31 January 2013, the contents of which are incorporated herein by reference in their entirety.

FIELD AND BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to an ablation catheter and, more particularly, but not exclusively, to a radio frequency ablation catheter that may optionally be suited for renal artery denervation.

SUMMARY OF THE INVENTION

According to an aspect of some embodiments of the present invention there is provided an ablation catheter fitting into a lumen of a patient comprising: a radially expanding tubular insulation member sized and shaped to fit in a lumen of a blood vessel in an expanded configuration;an expansion mechanism for radially expanding an inner passageway of the radially expanding tubular insulation member toward walls of the blood vessel, from a retracted configuration to the expanded configuration; and a plurality of ablation electrodes mounted along an outer surface of the radially expanding insulation tubular member. In the expanded configuration a hydraulic radius of the passageway is at least 50% of a hydraulic radius of the lumen.

According to some embodiments of the invention, the insulator fits into the lumen which is a blood vessel.

According to some embodiments of the invention, the expansion is by plastic deformation of the insulator.

According to some embodiments of the invention, at least one of the plurality of ablation electrodes is mounted with an active surface tangent to the outer surface of the expanding tubular insulator the active surface facing the inner surface of the lumen.

According to some embodiments of the invention, the insulator contacts an area on the inner surface of the lumen. The contact area may surround at least one of the plurality of ablation electrodes.

According to some embodiments of the invention, the insulator separates between at least one of the plurality of ablation electrodes and fluid in the passageway.

According to some embodiments of the invention, the plurality ablation electrodes include at least four pairs of ablation electrodes.

According to some embodiments the invention further includes a control unit selectively conveying an ablation signal between electrodes of each of the at least four pairs of ablation electrodes.

According to some embodiments the invention further includes a dispersive electrode, for conveying a signal to one or more of the ablation electrodes.

According to some embodiments the invention further includes the expansion mechanism includes a plurality of supports.

According to some embodiments the invention further includes the insulator transfers heat from the plurality of ablation electrodes to a heat sink.

According to some embodiments the invention further includes the heat sink includes the fluid flowing through the lumen.

According to some embodiments the invention further includes the heat sink includes the fluid flowing through the expandable passageway.

According to some embodiments the invention further includes an area of the inner surface of the lumen in contact with the insulator surrounding at least one ablation electrode of the plurality of ablation electrodes is at least 50 mm2.

According to some embodiments the invention further includes an area of target tissue in contact with the insulator surrounding at least one ablation electrode of the plurality of ablation electrodes includes a margin of at least 3 mm surrounding the at least one electrode.

According to some embodiments the invention further includes in the expanded configuration a cross sectional area of the passageway is at least 50% of a cross sectional area of the lumen.

According to some embodiments the invention further includes in the expanded configuration a hydraulic radius of the passageway is at least 70% of a hydraulic radius of the lumen.

According to an aspect of some embodiments of the present invention there is provided a method of ablation therapy in a lumen in a patient comprising: positioning

one or more electrodes in contact with a wall of the lumen; and expanding an insulator thereby contacting by an outer surface of a wall of the insulator an inner surface of a wall of the lumen; an area of the contacting surrounding at least one of the one or more electrodes defining by an inner surface of the insulator a passageway along the lumen for flow of a fluid through the lumen, and electrically insulating between the fluid and the at least one of the electrodes and heating the tissue by means of an electrical signal from the at least one electrode.

According to some embodiments the invention further includes cooling at least a portion of at least one of the tissue and the electrode simultaneous to the heating.

According to some embodiments of the invention, the cooling includes transferring heat between the portion and a heat sink.

According to some embodiments of the invention, the transferring includes conducting heat across the wall of the insulator.

According to some embodiments of the invention, the heat sink includes the fluid in the lumen.

According to some embodiments of the invention, the heat sink includes fluid in the passageway.

According to some embodiments of the invention, the passageway passes along a surface of the insulator opposite an ablation zone.

According to some embodiments of the invention, the contacting includes contacting an area of the inner surface of the wall of the lumen surrounding the electrode.

According to some embodiments of the invention, the area of the inner surface of the wall of the lumen surrounding the electrode includes an area of at least 50 mm2.

According to some embodiments of the invention, the contacting includes a margin around the electrode of at least 3 mm in every direction.

According to an aspect of some embodiments of the present invention there is provided an ablation catheter comprising: a plurality of ablation electrodes in contact with a target tissue in a lumen; a dispersive electrode provided in the lumen, the dispersive electrode having a conducting contact area at least 20 times a large as the ablation electrode, and a control unit conveying a first signal between a pair of the

plurality of ablation electrodes and a second signal between the dispersive electrode and at least one of the plurality of ablation electrodes.

According to some embodiments the invention further includes an insulator electrically insulating at least one of the ablation electrodes from a fluid in the lumen.

According to some embodiments the invention the dispersive electrode is not in contact with the target tissue.

According to some embodiments the invention further includes a passageway for a fluid to pass through the lumen.

According to some embodiments the invention a first side of the insulator is in contact with the target tissue in a vicinity of the ablation electrode and a second side of the insulator is in contact with the fluid in the passageway and heat transfer to the fluid across the insulator cools the target tissue in the vicinity of the ablation electrode.

According to some embodiments the invention the dispersive electrode is in contact with a fluid inside the lumen.

According to an aspect of some embodiments of the present invention there is provided a method of ablation therapy inside a lumen of a patient comprising: positioning a plurality of ablation electrodes in contact with a target tissue in the lumen; conveying through the target tissue a first electrical signal between a pair of the ablation electrodes; and conveying through the target tissue a second electrical signal between at least one of the plurality of ablation electrodes and the a dispersive electrode having an active surface area at least twenty times an active surface area of the ablation electrode.

According to some embodiments the invention further includes insulating electrically at least one of the ablation electrodes from a fluid in the lumen.

According to some embodiments the invention further includes placing the dispersive electrode into contact with a fluid in the lumen.

According to some embodiments the invention further includes placing at least part of the dispersive electrode into the lumen.

According to some embodiments the invention the placing is by means of a catheter.

According to an aspect of some embodiments of the present invention there is provided at least one ablation electrode in contact with a tissue on an inner wall of a lumen; an insulator including a tissue side in contact with an area of the tissue

surrounding the electrode and a lumen side in contact with fluid in the lumen, the insulator electrically insulating the at least one ablation electrode from a fluid in the lumen; and a passageway allowing fluid flow through the lumen.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

Implementation of the method and/or system of embodiments of the invention can involve performing or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of embodiments of the method and/or system of the invention, several selected tasks could be implemented by hardware, by software or by firmware or by a combination thereof using an operating system.

For example, hardware for performing selected tasks according to embodiments of the invention could be implemented as a chip or a circuit. As software, selected tasks according to embodiments of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks according to exemplary embodiments of method and/or system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions and/or data and/or a non-volatile storage, for example, a magnetic hard-disk and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally provided as well.

BRIEF DESCRIPTION OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the

drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the drawings:

FIG. 1 is a flowchart illustrating a method of ablation in accordance with some embodiments of the present invention;

FIG. 2 is a flowchart illustrating a method of bipolar ablation in accordance with some embodiments of the present invention;

FIG. 3 is a flowchart illustrating a method of unipolar ablation in accordance with some embodiments of the present invention;

FIGS. 4A-D are illustration of an ablation device in accordance with some embodiments of the present invention;

FIG. 5 illustrates a windsock type insulator in accordance with some embodiments of the present invention;

FIGS. 6A-B illustrate a laser-cut tube type support structure in accordance with some embodiments of the present invention;

FIG. 7 is an illustration of a support structure formed of spiral wire in accordance with some embodiments of the present invention;

FIG. 8 is a an illustration of an insulating frame in accordance with some embodiments of the present invention;

FIGS. 9A-B illustrate a support structure and insulator in accordance with some embodiments of the present invention;

FIG. 10 illustrates a laser-cut tube support structure and insulator in accordance with some embodiments of the present invention;

FIGS. 11A-B illustrate a laminar support structure in accordance with some embodiments of the present invention;

FIGS. 12A-B illustrate a support structure including braided wires in accordance with some embodiments of the present invention;

FIGS. 13A-C illustrate a support structure including a break out malecot in accordance with some embodiments of the present invention;

FIGS. 14A-C illustrate a support a distal-extending malecot in accordance with some embodiments of the present invention;

FIGS. 15A-B illustrate a hydraulic support structure in accordance with some embodiments of the present invention;

FIGS. 16A-C illustrate a printed circuit board support structure and insulator in accordance with some embodiments of the present invention;

FIG. 17 illustrates control unit in accordance with some embodiments of the present invention;

FIG. 18 is a flow chart illustration of a method of ablation and/or measuring evoked response in accordance with some embodiments of the present invention;

FIG. 19 illustrates simulated measurements of an evoked response in accordance with some embodiments of the present invention;

FIG. 20 illustrates a ablation device included sensors for evoked response in accordance with some embodiments of the present invention; and

FIGS. 21A-B illustrate an alternate ablation device included sensors for evoked response in accordance with some embodiments of the present invention;

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to an ablation catheter and, more particularly, but not exclusively, to a radio frequency ('RF') ablation catheter that may optionally be used for renal artery denervation.

In some embodiments, the present invention relates to methods and/or devices (e.g., control unit) for ablation using ablation catheter, e.g., RF ablation catheter.

Overview

1 Ablation device with electrical insulation and cooling

An aspect of some embodiments of the current invention relates to a method of catheter ablation wherein an ablation electrode is optionally introduced into a lumen and/or positioned in contact with a tissue to be ablated. For example the tissue may be part of the inner surface of the lumen. The ablation catheter may be provided with an insulator, for example a polyurethane membrane. In some embodiments the insulator may be tubular. For the sake of the current application a tubular insulator may have insulating wall surrounding one or more passageways. The wall and the passageways

may have a non-circular cross section. The cross section may change along the length (for example to fit a changing cross section of lumen in a patient). A tubular insulator may be elongated (the axis may be greater than the width) or short (the axis may shorter than the width). An outer surface of the insulator may be optionally pressed against tissue surrounding the location of the ablation electrode. The membrane may for example electrically insulate the ablation electrode and/or an ablation zone from a fluid in the lumen. The ablation zone may be heated and/or ablated by conveying an electrical signal (for example an RF signal) between the ablation electrode and a second electrode. A portion of the ablation zone may optionally be cooled. For example the insulator may transfer heat away from the electrode and/or the lesion formed by the ablation and/or the tissue in the vicinity of the electrode and/or tissue in the vicinity of the lesion. Optionally, the insulator may conduct the heat to a heat sink. For example a heat sink may include a fluid. The fluid may be in contact with the inner surface of the insulator that is opposite the ablation zone. For example the heat sink may include lumen fluid (for example blood) flowing across the inner surface of the insulator opposite the ablation zone and/or an artificial cooling fluid. The local thickness and/or heat conductivity of the insulator may optionally be adjusted to preferentially cool one portion of the ablation zone more than another portion.

In some embodiments, the insulator may optionally be pressed against the inner wall of the lumen and/or expanded by supports that open like a tent and/or an umbrella and/or an expandable basket and/or a malecot. The support structure may optionally include for example ribs and/or stretchers like an umbrella and/or other support (e.g., brace, buttress, stanchion, cantilever, strut, frame and/or spines). The supports may include, for example, inflatable (hydraulic and/or pneumatic) supports, supports made of nitinol, a folding basket, a malecot, a stent, a folding stent, a laminated structure, a balloon and/or an expandable woven structure. The insulator may allow fluid flow through the lumen. For example, the insulator may be open at a distal end, allowing blood to continue to flow through the delivery vessel. For example, the insulator may include a passageway to allow flow past the insulator. For example the insulator may have an open ended tubular geometry. Fluid may optionally flow along the lumen through a passageway along the axis of a tubular insulator while the insulator walls insulate the inner surface of the lumen from the fluid. Optionally, the insulator may be

expanded to fill the lumen. Optionally, as the insulator expands, the passageway may also expand. For example the passageway may have a cross section open to flow that has an area of least 50% of the area of the cross section of the lumen that is open to flow. Alternatively or additionally the hydraulic radius of the passageway (defined for example as the four times cross sectional area divided by the wetted perimeter) by may be 70% of the hydraulic radius of the lumen. In some embodiments the cross sectional area of flow the passageway may range between 25% and 50% of the cross sectional area of flow in the lumen and/or the hydraulic radius of the pathway way may range between 50% and 70% of the hydraulic radius of the lumen.

The expanding tent, basket and/or umbrella structure may for example have a expanded width ranging for example between 4 and 8 mm and/or ranging for example between 1 and 10 mm. The length of the basket, tent and/or umbrella structure may for example range between 10 and 40 mm and/or between 20 and 30 mm. optionally, in its expanded configuration the insulator may be spread against all wall of the lumen.

For example, the insulator may include a membrane of thickness ranging between for example 0.1 and 0.01 mm and/or may pose impedance (against isoconductive saline solution) for example ranging between 50 to 150 kΩ at 460 kHz (e.g., 50 to 100 kΩ, 100 to 150 kΩ etc.). The membrane may be made from, for example, Urethane and/or a polyurethane polymer. In some embodiments, the basket may have a diameter of less than 6 French (2 mm) when out of an intravascular delivery sheath but before expanding. In some embodiments, the basket may contract to a diameter of less than 6 French (2 mm) contracted but before being reinserted into the sheath that is commonly used to introduce a catheter to its intended delivery location within the vasculature.

2 General

Some embodiments of the current invention may include a multi-electrode ablation device. The device may be inserted into a body lumen via a catheter. At times the ablation device may be referred to as an ablation catheter or a catheter. A multi-electrode ablation catheter may be powered by a control unit (e.g., including an RF generator). The control unit may have a number of channels that convey an electrical signal bipolarly (for example from a first ablation electrode in contact with the target tissue at a first location to a second ablation electrode in contact with the target tissue at

a second location) through a target tissue between electrode pairs (for example, the ablation electrodes may be mounted on the catheter's working [distal] end), and/or unipolarly through a target tissue between an ablation electrode (that may optionally be in contact with the target tissue) and a dispersive (reference) electrode (e.g., a shaft electrode in contact with lumen fluid (for example blood) and/or an external electrode). The electrodes may be activated in accordance with a switch configuration set by a multiplexer. Multiplexer RF channels may be used to transmit radio frequency (RF) ablation energy to the electrodes. The RF channels may optionally include means to measure electrode/tissue impedance. In some embodiments, measurements may be made with high accuracy and/or repeatability. The RF channels may optionally be controlled by a controller (e.g., a microcontroller and/or single-board computer).

Optionally a catheter according to some embodiments of the current invention may be used for renal denervation. Renal denervation, is a minimally invasive, endovascular catheter based procedure using radiofrequency ablation aimed at treating resistant hypertension. Radiofrequency pulses may be applied to the renal arteries. Ablation in some embodiments may denude nerves in the vascular wall (adventitia layer) of nerve endings. This may causes reduction of renal sympathetic afferent and efferent activity and/or blood pressure can be decreased. During the procedure, a steerable catheter with a radio frequency (RF) energy electrode tip may deliver RF energy to a renal artery via standard femoral artery access. A series of ablations may be delivered along each renal artery.

As used herein, the term "controller" may include an electric circuit that performs a logic operation on input or inputs. For example, such a controller may include one or more integrated circuits, microchips, microcontrollers, microprocessors, all or part of a central processing unit (CPU), graphics processing unit (GPU), digital signal processors (DSP), field-programmable gate array (FPGA) or other circuit suitable for executing instructions or performing logic operations. The instructions executed by the controller may, for example, be pre-loaded into the controller or may be stored in a separate memory unit such as a RAM, a ROM, a hard disk, an optical disk, a magnetic medium, a flash memory, other permanent, fixed, or volatile memory, or any other mechanism capable of storing instructions for the controller. The controller may be

customized for a particular use, or can be configured for general-purpose use and can perform different functions by executing different software.

The controller may optionally be able to calculate the temperature of some or all of the electrodes and/or near some or all of the electrodes. For example, temperature measurements may be sensed by means of the thermocouple attached to each electrode and the output of the means is forwarded to the controller for calculation. Interaction with the user (e.g., a physician performing the ablation procedure) may optionally be via a graphical user interface (GUI) presented on for example a touch screen or another display.

In some embodiments, electrode impedance measurements may be used to estimate contact (estimated contact) between electrode and tissue as surrogate for thermal contact between electrode interface and target tissue. In some embodiments, power being converted to heat at electrode/tissue interface may be estimated (estimated power) for example based on the estimated contact, applied power and/or electrode temperature. Together with the time of RF application to the tissue, the estimated contact and/or estimated power and/or electrode temperature may optionally be used to calculate energy transferred to target tissue and/or resulting target tissue temperature locally at individual ablation electrode locations. Optionally, the results may be reported in real-time. Optionally, based for example on the calculated cumulative energy transferred to target tissue, the duration of ablation may be controlled to achieve quality of lesion formation and/or avoid undesirable local over-ablation and/or overheating. Control algorithms may deem to have completed lesion formation successfully for example when the quality of lesion at each electrode location reaches a predetermined range.

Some embodiments of the current invention may combine a multi-electrode ablation device with blood exclusion. In some embodiments, the distance from the proximal end of the insulating basket to the distal end (toward the catheter tip) of an in-catheter dispersive electrode may range for example between 10 to 75 mm (e.g., between 10 to 15 mm, between 10 to 25 mm, between 25 to 50 mm, between 50 to 75 mm etc.). For renal artery denervation, the distance between the dispersive electrode and the proximal end of the expandable structure may range preferably between 20 to 50mm

(e.g., 20mm, 30mm, 40mm, 50mm etc.) to ensure that the dispersive electrode is within the aorta, and away from the desired ablation area within the renal artery.

Various embodiments of the current invention may be configured to fit for example in a 5 French (1.33 mm diameter) catheter with a lumen extending from the handle through the distal tip making it possible to insert it with the aid of a standard 0.014 inch (0.36 mm) guide wire. The flexibility of the assembly may optionally be compatible with applicable medical standards. A catheter (for example the various embodiments described below) may include a guidewire. For example, the guidewire may be inserted through a lumen of the catheter. Optionally, the guidewire may help position the catheter. The guidewire may optionally be able to extend past an orifice at the distal end of the catheter.

3 Bipolar and unipolar ablation

An aspect of some embodiments of the current invention relates to a method of catheter ablation using bipolar and/or unipolar ablation, e.g., to achieve a desired lesion geometry. For example, bipolar ablation between a first and a second ablation electrode may be used to convey an electrical signal through a target tissue to produce a lesion. Ablation may progress more quickly at the location of the first electrode than at the location of the second electrode. Bipolar ablation may optionally be paused and unipolar ablation may be initiated between the second ablation electrode and a dispersive electrode to increase progress of ablation in the vicinity of the second electrode. A balance of unipolar and/or bipolar ablation may be used to adjust a geometry of a lesion. For example, bipolar ablation may be used to achieve spreading of a lesion along a tissue surface. For example, unipolar ablation may be used to deepen a lesion.

In some cases it may be desired to ablate tissue in a given area to an effective level (for example effective ablation may occur for heating to a temperature of between 60° and 70° C for a time between 20 and 180 sec.). Tissue and/or contact with electrodes may be heterogeneous. Tissue may heat and/or ablate unevenly. Overheating and/or over-ablating tissue may have serious consequences (for example heating to over 90° C and/or over-ablating may cause blood coagulation and/or blood clots and/or damage to arteries and/or internal bleeding etc.). In some embodiments, the current invention may facilitate monitoring and/or control of ablation within parts of a lesion. In some embodiments, local monitoring and/or control may produce more even ablation. For

example a desired level of ablation may be reached in multiple regions of a lesion without over ablating any region.

4 In-lumen dispersive electrode

An aspect of some embodiments of the current invention relates to an in-lumen dispersive electrode for unipolar ablation. The dispersive electrode may be introduced into a body lumen and/or electrical contact may be supplied by a fluid in the lumen. The dispersive electrode may be inserted into the same lumen as an ablation electrode. The dispersive electrode may be part of the same catheter as an ablation electrode. Optionally, a single catheter may include a dispersive electrode and a plurality of ablation electrodes. The catheter and/or electrodes may be configured to operate in unipolar and/or bipolar modes.

In some embodiments, a control unit may supply power for ablation (for example: a radio frequency (RF) generator). For example the control unit may be a rechargeable and/or battery-powered. The ablation generator may operate for example around the 460 kHz frequency and/or ranging for example between 400 and 600 kHz or other RF frequency ranges assigned to ISM (Industrial, Scientific, and Medical) applications within the low-frequency (LF: 30 to 300 kHz), medium-frequency (300 kHz to 3 MHz), and high-frequency (HF 3 to 30 MHz) portions of the RF spectrum. The control unit may have a number of channels that allow ablation to be conducted bipolarly between electrode pairs through the target tissue. The generator may optionally be able to deliver ablation energy to be conveyed simultaneously between one, some and/or all bipolar ablation electrode pairs in the catheter. For example a catheter may include four or more bipolar ablation electrode pairs. In some embodiments, the generator may supply a maximum power of, for example, between 3-10W per bipolar channel. The generator may optionally be able to ablate unipolarly between one, some and/or all of the contact electrodes and a dispersive electrode, e.g., catheter-borne reference in-lumen dispersive electrode. Lesion formation may for example take between 15 to 180 seconds. Each channel may have a minimum voltage compliance of 100 V. In some embodiments, the minimum voltage compliance may permit, for example, an average of between 2 and 10W to be delivered per bipolar electrode pair presenting an impedance for example ranging between 1.0 and 1.5 kΩ.

In some embodiments, an ablation electrode of the current invention may be made for example of between 80% and 95% Platinum and/or between 20% and 5% Iridium. The ablation electrodes may range for example between 0.5 and 4 mm long and/or have an electrically active area for example of between 0.1 and 1 mm^2 and/or have a diameter ranging from 0.01 to 0.05 inch (0.25 to 1.27 mm). The electrically active area of the ablation electrodes may be in contact with a target tissue. The distance between ablation electrodes may range for example between 0.5 and 3 mm or more.

In some embodiments, a dispersive electrode may for example have a length ranging for example between 4 to 20 mm and/or have a diameter ranging between 2 and 5 French (between 0.67 and 1.67 mm). The dispersive electrode may have an electrically active area ranging for example, 20 to 50 times or more than the electrically active area and/or surface of contact of the ablation electrodes. For example the electrically active area of the dispersive electrode may range between 50 to 150 mm^2 (e.g., between 50 to 100 mm2, between 100 to 150 mm2, between 75 to 120 mm2etc.). Optionally the electrically active surface of the disperse electrode may be in electrical contact with a fluid in a lumen of a patient. In some embodiments, the dispersive electrode may be coated with a material such as porous titanium nitride (TiN) or iridium oxide (IrOx). The coating may increase microscopic surface area of the electrode in electrical contact with lumen fluid.

5 Local measurement of ablation progress

An aspect of some embodiments of the current invention relates to a method of catheter ablation wherein ablation progress may be measured locally at the site of one, some and/or all ablation electrodes. For example, during a pause in the bipolar ablation signal, impedance may be measured locally at an ablation electrode for example by measuring impedance between the ablation electrode and a dispersive electrode.

For example, the system may measure the complex bipolar and unipolar electrode impedance at the ablation frequency. Optionally when not ablating, an auxiliary signal may include an auxiliary current not meant to cause significant physiological effect. Electrode Impedance measurements may optionally be possible within the 100Ω to 1kΩ range within a minimum accuracy ranging for example between 2 to 10%, and within the 100Ω to 2kΩ range with a minimum accuracy ranging for example between 5 to 20%. Minimum repeatability within the 100Ω to 2kΩ range may

range for example between 2 to 10%. Ablation interruptions may range from 1 to 100 ms when measuring unipolar impedance during bipolar ablation segments. Impedance measurements may be taken at a minimum rate ranging for example between 50 to 200 samples for use by the control algorithm.

In some embodiments, temperature may be measured individually at one, some and/or all of the contact electrodes. Temperature measurements may use, for example, a thermocouple. The thermocouple may optionally be formed between the main electrode's wire and an auxiliary thermocouple wire. Temperature measurement range may be for example between 30^0C to 100^0C or more. Temperature measurement accuracy range between ±0.2 to ±1 ^{0}C or may be more accurate. Temperature measurement repeatability may range for example between 0.1 to 0.5 ^{0}C or less. Target temperatures may range for example between 60 to 80 ^{0}C.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings and/or the Examples. The invention is capable of other embodiments or of being practiced or carried out in various ways.

Exemplary embodiments

1 Outline of method of ablation

Referring now to the drawings, Figure 1 is a flow chart illustration of a method of therapy using unipolar and/or bipolar ablation, in accordance with some embodiments of the invention. The exemplary method, illustrated for example in Fig. 1, of unipolar and bipolar ablation may be used to achieve a desired lesion geometry, to measure the progress of ablation locally near electrodes and/or in an area between electrodes and/or to adjust a geometry of a lesion. The method may be used to control power and duration of ablation at one or more electrodes, e.g., to ensure quality of lesion formation.

In some embodiments, an ablation device may be set up **101**. In some embodiments, a catheter with the ablation device may be inserted **102** into a patient. A dispersive electrode may optionally be placed **104** in contact with a large area of the patient. Optionally, the dispersive electrode may be inserted into the patient with the catheter (e.g., the dispersive electrode may be part of the catheter). Alternatively or

additionally the dispersive electrode may be independent of the catheter. The large contact area, for example the contact area may range between 50 to 150 cm^2 or more of the dispersive electrode may reduce tissue damage and/or impedance in the vicinity of the dispersive electrode.

In some embodiments, a two or more ablation electrodes may be positioned **106** in contact with a target tissue in an area to be ablated. The ablation electrodes may have a small contact area with the target tissue. Current flowing from the ablation electrode may be concentrated in the small contact area causing local ablation. The high current flowing through a small contact area in the vicinity of the ablation electrode may produce a high electrical impedance in the vicinity of the ablation electrode. For example, most of the impedance for current between the dispersive electrode and the ablation electrode may occur in the vicinity of the ablation electrode.

The ablation device may optionally include an insulator. The insulator may optionally be expanded **107** and/or spread **108** across a surface of a target tissue. Optionally, the insulator may isolate the electrode from a fluid in a lumen (for example blood in an artery). Optionally, the insulator may prevent leaking and/or or shunting of ablative energy away from a target.

In some embodiments, after positions **106** the ablation electrodes and/or expanding **107** and/or spreading **108** the insulator, the contact of the ablation electrodes with the target tissue may be tested **109**. For example, the impedance may be measured between the ablation electrode and the dispersive electrode and/or the temperature may be tested at the ablation electrode while applying current. If the contact is not good **110 (Step 110: no)** (for example the impendence is high) then the ablation electrode may be repositioned (for example by re-inserting **102** the catheter and/or moving and/or re-positioning **106** the ablation electrodes).

In some embodiments, once the ablation electrodes are proper positioned and/or contact is good **110 (Step 110:** yes), ablation may proceed. For example, bipolar ablation **112** may take place between two ablation electrodes (note as used herein bipolar ablation may also include multipolar ablation between more than two ablation electrodes). Optional details of bipolar ablation **112** are described, for example, in Fig. 2. In some embodiments, unipolar ablation **114** may take place between one or more ablation electrodes and a dispersive reference electrode. For example, if during bipolar

ablation **112** it is observed that ablation is proceeding faster near one of the ablation electrodes than near the other electrode of the pair and/or that one electrode is heating up too much and/or that ablation is taking place too near the surface etc., bipolar ablation **112** may be interrupted (for example not passing current and/or passing a reduced current) and/or optionally the fast and/or overheating electrode may be allowed to rest (for example not passing current or passing a reduced current). Unipolar ablation **114** may optionally continue at all or some of the electrodes. One or more rounds of bipolar ablation **112** and/or rest and/or unipolar ablation **114** may continue **(Step 115: no)** until the ablation is finished **(Step 115: yes).** When ablation is finished at a given location, the process may be repeated at another location **116**.

2 Bipolar ablation

Fig. 2 is a flow chart illustration of a method of bipolar ablation in accordance with some embodiments of the current invention. Bipolar ablation **112** may optionally start after prior processes **201** as illustrated for example in Fig. 1. Bipolar (or multipolar) ablation **112** may proceed by applying a high current **220**, e.g., resulting in the desired power delivered to the tissue, for example, an average of between 2 and 10W (e.g., 2W, 4W, 5W, 10W etc.) between one or more pairs of ablation electrodes. During the application of current **220**, the temperature at one, some or all of the ablation electrodes and/or the current and/or the impedance between pairs of electrodes may optionally be monitored. Application of current may continue for example between 5-200 milliseconds (e.g., 50-200 milliseconds, 100-200 milliseconds, 150-200 milliseconds etc.) at a power ranging for example between 2.0 to 10 WATT between each pair of ablation electrodes. Current application may be interrupted **221** for a short period, for example between 50-200 milliseconds at which time impedance and/or temperature may be tested **222** at the location of one or more of the ablation electrodes and/or other locations. For example, impedance may be tested **222** by applying a small current between the ablation electrode and a dispersive electrode. After testing **222**, application **220** of current may optionally continue (for example as long as bipolar ablation **112** has not been completed (step **224** "no") and/or if there are no signs of overheating and/or over-ablation). The interruption of current application **220** may optionally be short enough that the target tissue does not significantly cool and/or ablation **is** not adversely affected. Optionally, when bipolar ablation **112** at a particular location is completed

(step **224** yes), for example it reaches a desired level and/or ablation and/or temperature at a location reaches a safety limit, bipolar ablation **112** at that location may stop. Completion **224** of a lesion may, for example may be evaluated by a "quality of lesion formula" which may be some function of impedance, temperature, and energy delivered. The total length of the bipolar ablation **112** at a single location may range for example between 15-300 sec. Bipolar ablation may continue at other locations and/or a next process **214** may start.

3 Unipolar ablation

Fig. 3 is a flow chart illustration of a method of unipolar ablation in accordance with some embodiments of the current invention. Unipolar ablation may be performed by passing current between for example an ablation electrode (e.g., an ablation electrode of a pair) and a dispersive electrode. Optionally, the dispersive electrode may have a large area of contact with the patient. Typically the majority of the impedance and/or ablation occurs at the location and/or near the ablation electrode. Sometimes, unipolar ablation may cause deeper lesions than bipolar ablation. In some embodiments, unipolar ablation may be used to preferentially ablate tissue at a single location and/or to achieve preferred ablation geometry, for example to achieve a deeper lesion.

Unipolar ablation may optionally follow after a previous process **312**. For example, after bipolar ablation achieves a large and/or shallow and/or heterogeneous lesion, unipolar ablation may be used to ablate a small area and/or to achieve a deeper lesion and/or even out a lesion (for example to ablate a portion of a less well done portion of a lesion).

Unipolar ablation **114** may proceed by applying a high current **320**, e.g., resulting in the desired power delivered to the tissue, for example, an average of between 2 and 10W (e.g., 2W, 4W, 5W, 10W etc.) between one or more ablation electrodes and a dispersive electrode. During the application of current **320**, the temperature at one, some or all of the ablation electrodes and/or the current and/or the impedance between the electrodes (e.g., an ablation electrode and dispersive electrode) may optionally be monitored. Application of current may continue for example between 50-200 milliseconds and/or between 200 milliseconds and 20 seconds and/or between 20 seconds and 200 seconds at a power of 0.5-10 WATT between each ablation electrode and the dispersive electrode. High current application may be interrupted for a short

period for example between 0.5-100 milliseconds at which time impedance and/or temperature may be tested **322** at the location of one or more of the ablation electrodes and/or other locations. For example, testing **322** may include measuring local impedance for example by applying a small current between one of the ablation electrodes and the dispersive electrode. Alternatively or additionally testing **322** may include calculating a "quality of lesion". After testing **322**, application **320** of current may optionally be resumed (**step 324 no**) (for example if local ablation has not been completed and/or if there are no signs of local overheating and/or over-ablation). The interruption of current application **320** may optionally be short enough that the target tissue does not significantly cool and/or ablation is not adversely affected.

In some embodiments, when ablation at a particular location reaches a desired level and/or ablation and/or temperature at a location reaches a safety limit (**step 324 yes**) unipolar ablation **114** at that location may be stopped. Unipolar ablation **114** may continue at other locations or other ablation electrodes and/or a next process **316** may start. For example, bipolar ablation may proceed between two electrodes until ablation reached a desired limit and/or a safety limit (step **324 yes**) at some location (for example ablation may reach a limit near a first of two electrodes). Bipolar ablation may be stopped. Ablation may optionally be continued at the second of the two electrodes. For example, unipolar ablation may be used in order to "touch up" the ablation at each site of the second electrode. Alternatively or additionally, bipolar ablation may continue between the second electrode and another electrode for example as described herein below.

4 Exemplary ablation devices

Figs. 4A-16C illustrate various embodiments of ablation devices and/or insulators in accordance with some embodiments of the current invention. An ablation device may optionally include an insulator, for example the insulator may include a membrane and/or a frame. The membrane may optionally have a tubular form. In some embodiments, the insulator outer surface of the insulator may optionally be pressed against an inner surface of a wall of a lumen or vessel in the vicinity of an ablation target and or in an area surrounding an electrode. For example the insulator may exclude lumen fluid from an area on the inner wall of the lumen ranging between 0.1 mm^2 and 40 mm^2 around one or more electrodes. Optionally the insulator may electrically isolate

the electrode and/or the area of tissue surrounding the electrode from the lumen fluid. In some embodiments, expansion of a support structure may press an insulator against an inner wall of a lumen.

Figs. 4A-C illustrates a schematic view of an exemplary ablation device **400**, in accordance with some embodiments of the current invention. In some embodiments, an ablation catheter may be inserted into a lumen and/or opened to contact a target tissue. The ablation device may include an insulator that may optionally prevent shunting of ablation energy away from a target tissue and/or may cool a portion of the ablation zone. For example, the insulator may transfer heat to a heat sink. For example, heat transfer may be by conduction. For example the heat sink may include fluid to flowing past the ablation zone cooling a surface of the insulator opposite the ablation zone. Optionally, a highly heat conductive material (for example metal) may be added to the insulator in a certain location to preferentially cool that location and/or the insulator may be made thinner in a particular location to allow more heat conduction away from that location. In some embodiments, the ablation catheter may include a dispersive electrode with large surface area. The dispersive electrode may provide a unipolar reference. The dispersive electrode may optionally be inserted into the lumen with the ablation electrodes. Optionally, the dispersive electrode may be in electrical contact with fluid (for example blood) within the lumen. For example, the dispersive electrode may surround the ablation catheter's shaft.

Some embodiments of an ablation device may optionally include a tubular insulator. For example, an insulator may include a membrane **434** that has an tubular form. Membrane **434** may optionally be expanded and/or spread against a target tissue, for example an inner surface of a lumen. Membrane **434** may optionally prevent shunting of ablation energy away from the target tissue. For example, membrane **434** may optionally prevent shunting of ablation energy into a fluid (for example, blood) in vicinity of an ablation electrode **436**. In some embodiments, an ablation electrode **436** may optionally be coated with a non-electrically conductive material **435** except for the segment that protrudes through the blood-exclusion membrane to contact the target tissue. In some embodiments, decreasing shunting may decrease the power necessary for ablation and/or increase the control and/or precision of measurement of the power applied to the target tissue.

Membrane **434** may optionally allow fluid to flow **439** (for example see Fig. 4B) along the lumen. For example, membrane **434** may have a tubular form allowing fluid flow **439** along a passageway **477** along the axis of the insulator. Membrane **434** may be thin taking only a small portion of the cross section of the lumen. Passageway **477** may optionally include more than half the cross section of the lumen. The hydraulic radius of passageway may be more than 70% of the hydraulic radius of the lumen. Membrane **434** may optionally transfer heat away from the ablation zone. For example membrane **434** may conduct heat to fluid flowing **439** in passageway **477**. For example, blood flow **439** across the inside surface of the insulator (opposite the target tissue) may cool the outside surface that is against the target tissue and/or a portion of the target tissue. By cooling the target tissue, the lesion may be made deeper and/or more even (as has been observed for example in irrigated ablation procedures). Alternatively or additionally, blood flow **439** across the inside surface of the insulator may cool electrodes **436**. Reducing the temperature of the electrode may reduce the temperature in the interface between electrode **436** and the tissue. Reducing the temperature at the tissue electrode interface may allow more power to be delivered deeper into the tissue. Alternatively or additionally, allowing fluid flow **439** in the lumen may reduce pain and/or secondary tissue damage due to blockage of circulation during the ablation procedure.

In some embodiments, an ablation device may include one or more markers. For example, device **400** includes two individually recognizable radio opaque markers **455a,b**. Markers **455a,b** may optionally be easily recognized in radiographic and/or other extra body images (for example an image may be made using ultrasound and/or magnetic resonance MRI and/or x-ray and/or other imaging techniques). Distinguishing markers **455a,b** may help a clinician locate and/or determine the orientation of a catheter and/or a support structure and/or individual electrodes **436**.

In some embodiments, a guidewire **442** may be inserted through a lumen of the catheter. For example, guidewire **442** may help position the catheter. Guidewire **442** may optionally be able to extend past an orifice **445** at the distal end of the catheter.

In some embodiments, a dispersive electrode **440** may be inserted into a lumen in the patient being treated. For example, in device **400**, dispersive electrode **440** may be inserted into the same lumen as ablation electrodes **436**. Dispersive electrode **440** may optionally have a large surface of contact. For example, dispersive electrode **440** may be

in contact with fluid inside the lumen. The large contact area may decrease local impedance and/or heating near dispersive electrode **440**. Dispersive electrode **440** may optionally be coated with a material such as porous titanium nitride (TiN) or iridium oxide (IrOx) for example to increase its microscopic surface area in electrical contact with the fluid.

Ablation device **400** may include, for example a plurality of ablation electrodes **436**. Ablation electrodes may optionally be used in pairs for bipolar ablation. Optionally a signal may be transmitted between any two electrodes **436**. Dispersive electrode **440** may be used for example to pass a high current to one, some or all of the ablation electrodes to perform unipolar ablation. Dispersive electrode **440** may optionally be used for measuring the local impedance near one or more of the ablation electrodes **436**. For example a small current may be passed between dispersive electrode **440** and one of the ablation electrodes **436** to test impedance in the local area of the ablation electrode **436**. An optional multiplexed power source **441** (e.g., current source) (for example see Fig. 4B) may be used to supply current to a selected group of electrodes (for example including some or all of ablation electrodes **436** and/or dispersive electrode **440**) during a time slice and/or a different group of electrodes (for example including some or all of ablation electrodes **436** and/or dispersive electrode **440**) during a different time slice.

For example, ablation device **400** may optionally include a "basket" made out of nitinol wire spines and/or supports **432**. Ablation electrodes **436** may optionally be positioned on supports **432**. For example pairs of ablation electrodes **436** may be distributed along the periphery of the basket to ablate the intrabody target tissue. Optionally, each electrode may be fitted with a thermocouple and/or other suitable sensor.

For example, an insulator may include a polyurethane membrane **434**. Membrane **434** may be is placed onto the supports **432**. Upon deployment, the basket including supports **432** and/or membrane **434** may optionally open up like an umbrella. In the exemplary embodiment, ablation electrodes **436** may optionally be exposed to target tissue on the inner walls of the lumen into which the catheter is deployed.

The insulator may optionally include non-porous membrane **434** covering the mid-section of the expandable basket structure. The membrane may optionally separate blood from the treatment area. Membrane **434** may optionally increase the portion of

electrical ablation energy delivered to the target tissue for example by reducing the shunting of the ablation energy to the blood. In contrast to some occluding means to exclude blood (for example balloons), the basket and/or membrane **434** may be open at the distal and/or proximal ends, allowing blood to continue to flow **439** through the lumen (for example the delivery vessel and/or artery). During the ablation procedure tissue and/or organs may continue to receive blood. During the ablation procedure blood passing along the inside surface of membrane **434** may cool the surface of the target tissue.

In some embodiments, an ablation catheter may include a plurality of ablation electrode pairs. For example ablation device **400** may include four pairs of ablation electrodes **436** helically distributed around an open tubular basket near the end of a catheter shaft **430** (as illustrated for example in Fig. 4A). During ablation, some or all of the four pairs of ablation electrodes **436** may be activated simultaneously. For example, four lesions can be made simultaneously in a helical pattern along the wall of a lumen. Additionally, ablation current may be delivered between ablation electrodes on adjacent spines, for example between electrodes 436b and 436c, between electrodes 436d and 436e, etc.

In some embodiments, flow **439** in a lumen may help hold membrane **434** in an expanded configuration. For example, as shown in Fig. 4B, the downstream (distal) opening **437b** of membrane **434** may be narrower than the upstream (proximal) opening **437a**. When placed inside an artery, downstream opening **437b** may present resistance against blood flow **439**. Resistance to flow **439** exiting membrane **434** may cause pressure within membrane **434** to increase. Increased internal pressure may make membrane **434** expand against an artery wall and/or spread out, for example like a parachute and/or a windsock.

Fig. 5 illustrates a tubular insulator **534** having a form of a windsock and/or a parachute deployed from a catheter **530** in accordance with some embodiments of the current invention. Optionally fluid may flow **539** through a passageway **577** through insulator **534**. For example fluid may enter a large opening **537a** (illustrated for example at the proximal end of insulator **534**). Optionally the fluid may exit a smaller opening **537b** (for example windows at the distal end of insulator **534**). The dynamic pressure of the fluid flow **539** (for example blood flow in an artery) may help keep the insulator **534**

inflated. For example, fluid pressure may press insulator **534** against walls of a lumen. Optionally, insulator **534** and/or other structural members **532** may insulate electrodes **536** from lumen fluids. Internal pressure may optionally be used to cause expansion on its own or along with another mechanism. In some embodiments, pressure against an inner surface of a lumen may be augmented by structural members. Some structural members may carry an electrode. Alternatively or additionally some structural members that do not carry electrodes may be introduced for example to provide support for the insulator. For example, in the exemplary embodiment of Figs. 6A and 6B, a basket may be formed by cutting out from a nitinol tube. The deploying of the basket may optionally include supports springing out (where the direction of expansion has been determined by heat setting the memory of the nitinol wire). Fig. 6A illustrates the basket in a collapsed configuration and Fig. 6B illustrates the basket in an expanded configuration. Production of the tube and/or the cutting may optionally be similarly to production of a stent. The basket may include various structural elements, for example struts **632**, cross members **633**, support members **643**, end members **647** and/or cantilever members **645**. Supports **643** may for example retain a preferred geometry of other structural members and/or also provide a support for the geometry of the insulator. Cantilever members may for example supply pressure on parts of the insulator.

In some embodiments, support for electrodes and/or an insulator may be supplied by a spiral wire basket. For example as shown in the exemplary embodiment of Fig. 7 a spiral element **732** may be expanded by twisting in one direction **751** and/or collapsed by twisting in the opposite direction. Optionally, an axial wire **753** may be used for twisting spiral element **732**. For example, spiral element **732** may be located at the distal end of a catheter **730**. Catheter **730** may include multiple spiral elements and/or other elements that may be expanded and/or collapsed to form a desired shape. The expanding elements may optionally cause an insulating membrane to take a circular cross section and/or press an insulating membrane against the walls of a lumen. The resulting shape of the membrane in an expanded configuration may depend on the way in which the spiral elements of the basket deploy. In some embodiments, electrodes and/or markers and/or an insulating frame and/or an insulating membrane may be mounted and/or included on element **732**.

In some embodiments, support members for an insulator may extend around an electrode, for example as illustrated in Fig. 8. Optionally, a strut **832** may hold an electrode **836** and/or a frame **853** against a tissue to be ablated. Frame **853** may optionally electrically insulate electrode **836** and/or an area of tissue around electrode **836** from fluid in a lumen. In some embodiments, frame **853** may conduct heat away from electrode **836** and/or the tissue near electrode **836**. For example, the heat may be conducted to a heat sink cooling electrode **836** and/or the tissue around electrode **836**.

Figs. 9A-B, illustrate an insulating membrane **934** wrapped around a support structure in accordance with some embodiments of the current invention. Electrodes **836** may optionally protrude through holes in membrane **934** to contact the tissue. Frame **853** may hold membrane against the tissue around electrode **836** optionally insulating electrode **836** from a bodily fluid. Optionally, additional support members (for example members **943**) may supply further support to membrane **934**. Alternatively or additionally, frame **853** may be an insulator. In some embodiments may not a surrounding membrane **934**. Alternatively or additionally a nitinol stent type support structure may support electrodes **836** and/or a frame **853** and/or a membrane **934**. Exemplary nitinol stent type support structures are illustrated for in Figs. 6 and 10.

Fig. 10 illustrates a nitinol support structure with a surrounding membrane **934** and a frame **853** around electrodes **836** in accordance with some embodiments of the current invention. Optionally, an ablation device (for example as illustrated in Figs. 8 and/or Figs. 9A-B and/or Fig. 10) may include one or more markers for example similar to markers **455a,b**.

In some embodiments, a ablation device may include a laminated membrane. For example as shown in Figs. 11A-B, the membrane may be formed by laminating several layers of polymers with similar and/or different characteristics. Optionally, the laminated membrane may tend to expand outwardly. For example, the laminated membrane may push outward against a lumen wall, insulating the wall from fluid inside the lumen.

Fig. 11A illustrates a balloon **1134a** insulator in accordance with some embodiments of the current invention. In some embodiments, balloon **1134a** may be fitted inside a support structure **1132**. Optionally, support structure **1132** may include a stent type support (for example as illustrated in Fig. 6). As illustrated for example in Fig. 11B, balloon **1134a** may be welded to the support structure **1132**. For example, welding

may be by adhering balloon **1134a** to a layer of polymer film **1134b** in a lamination that sandwiches the support structure **1132** between the two layers (balloon **1134a** and film **1134b**). Further layers may optionally be added, for example to achieve a desired stiffness, elasticity, deformability, heat conductivity and/or electrical conductivity. Optionally, the ends of the balloon may be trimmed and/or removed to produce a tubular form and/or a passageway for fluid flow. Optionally, heat conducting elements may be introduced between the layers to preferentially cool particular areas of an ablation zone (for example a portion of the target tissue and/or an electrode).

In some embodiments, a braid of wires that forms a catheter shaft may be expanded to form a basket support for an insulator. For example, spiral element **732** of Fig. 7 may form part of a braided casing of a catheter. Figs. 12A-B illustrate a catheter having braided elements in accordance with some embodiments of the current invention. For example, the braided elements may include one or more insolated Copper wires **1232a** (for example copper with a polyimide insulation [Cu-Pi]) and/or one or more stainless steel [SST] wires **1232b**. Optionally, Cu-Pi wires **1232a** may be used to carry current and/or signals between a control unit, a signal generator and/or an antenna in the catheter. The catheter may also include one or more axial wires **1232c**. The axial wires **1232c** may for example be formed of Nitinol. For example, at a distal end of a catheter one or more nitinol wire **1232c** may form a support structure; for example as illustrated in Fig. 12B. One or more Cu-Pi wire **1232a** may carry a current and/or a signal between a signal generator and/or a receiver at a proximal end of the catheter and an electrode **1236** and/or a sensor and/or an electrode at a distal end of the catheter, for example as illustrated in Fig 12B. Alternatively or additionally an expanding basket may be made of radial and/or spiral elements. Alternatively or additionally, a pull wire **1257** may be provided to deploy an expanding support structure. For example, in some embodiments, a guidewire tube may be used as a pull wire.

In some embodiments, the wires that form the basket may not be formed as a separate distal head to the catheter. Optionally, the wires that form the basket may be part of the conductors that come all the way through a catheter's shaft **1230**. For example, a conductor (for example bringing current and/or a signal to or from an electrode) may be an insulation-coated nitinol wire. The wire may provide structural

support, for example forming a spline strut. The same wire may also serve as an electrical conductor.

Figs. 13A-C and Figs 14A-C illustrate embodiments of insulators and support structures formed as a malecot in accordance with some embodiments of the current invention. For example in Figs. 13A-C tubing inside of a catheter expands out of slits in a malecot break configuration. Alternatively or additionally in Figs. 14A-C a malecot extends out a distal end of a catheter.

In some embodiments, for example as illustrated in Figs. 13A-C a catheter may have malecot **1363** and/or a multi-lumen profile with wire breakout slits **1359**. Fig. 13A illustrates malecot **1363** in an expanded configuration in accordance with some embodiments of the present invention. At slits **1359** an outer sheath **1330** of the catheter may allow an inner tubing **1332** to expand into a basket shape during actuation. Conducting wires may optionally run through a lumen of tubing **1332.** Electrodes **1336** and/or markers may be mounted on tubing **1332** and/or connected to a signal generator and/or signal receiver via the conducting wires. An insulator may include a tubular membrane **1334** surrounding sheath **1330** at the location of slits **1359**. When malecot **1363** expands it may be surrounded by membrane **1334**. Membrane **1334** may have openings through which electrodes **1336** protrude to contact the tissue to be ablated. Figs. 13B,C illustrate malecot **1363** in a retracted configuration. An inner lumen of the catheter may include a pull wire **1357** that may be used to expand and/or retract malecot **1363**. Alternately or additionally the insulator may include a frame mounted on tubing **1332** surrounding electrodes **1336** for example similar to frame **853** of Fig. 8. Alternately or additionally an insulating membrane may surround tubing **1332** on the inside of sheath **1330**. When the malecot **1363** is expanded, the alternative membrane may expand out of slits **1359** in a star shape.

Figs. 14A-C illustrate a malecot **1463** extending out of a distal end of a catheter in accordance with some embodiments of the current invention. Optionally malecot **1463** may be formed of a laser-cut Nitinol tube. Optionally malecot **1463** may have an retracted configuration where it fits in a catheter **1430** with an outer diameter of less than 2 mm and/or an extended configuration wherein malecot **1463** extends out of the distal end of catheter **1430**. In some embodiments in the extended configuration malecot may have a diameter of less than 3 mm. For example malecot **1463** is illustrated in an

extended configuration in Figs. 14A and 14B. In the extended configuration struts **1432** of malecot **1463** may be slightly expanded. Optionally malecot **1463** may have an expanded configuration. For example, Fig. 14C illustrates malecot **1463** in an expanded configuration. For example, an axial compressing force (for example exerted by pulling a pull wire) may cause malecot **1463** to expand radially from the extended configuration to the expanded configuration. The degree of expansion and/or pressure on the tissue to be ablated may optionally be user controllable according to the tension on the pull cord. In the expanded configuration the diameter of malecot **1463** may be larger than the diameter in the extended configuration and less than for example 7.5 mm. Malecot **1463** may carry electrodes **4136** and/or markers. Malecot **1463** may include an insulating sleeve for example similar to membrane**1334** and/or an insulating frame (for example similar to frame **854**) for insulating electrodes **1336**.

Figs. 15A-B illustrate insulators for an ablation device that may be expanded by hydraulic pressure in accordance with some embodiments of the current invention. For example, Fig. 15A illustrates an exemplary support structure including a hydraulic struts **1532a**. Fig. 15B illustrates an exemplary insulator for an ablation device including a tube formed as a double hydraulic sleeve **1532c** which may be inflated by increasing hydraulic pressure between the sleeves. Lumen fluids (for example blood) may flow **1539** through a passageway in the inner sleeve. Struts **1532a** and or sleeve **1532c** may optionally carry electrodes **1536** and/or an insulator (for example a membrane sleeve and/or a frame around electrodes **1536** and/or wires **1532b** and/or markers.

Insulating sleeves and/or hydraulic sleeves may be constructed for example by blow molding. Blow molding may optionally allow for secure mounting of a membrane proximal and distal to an expandable support.

Fig. 16A-C illustrate a flexible circuit board ablation device in accordance with some embodiments the present invention. For example a flexible printed circuit board (PCB) may be made of polyimide (PI). Circuits may optionally be printed on one or more surfaces. Fig. 16A illustrates a flexible circuit board **1663** for an ablation device laid out flat, according to some embodiments of the present invention. Board **1663** may include electrodes **1636** that may optionally be mounted on flexible struts **1632**. The ablation device may optionally be connected to a support structure, for example a nitinol basked and/or an inflatable strut. The ablation device may include connections to other

devices for example electrical leads and/or rings **1565** for connecting to structural supports and/or shaft transition pads **1667** through which electrical connection is made between the printed circuit board and the wires within the catheter's shaft that transmit and/or receive energy to/from an RF generator and/or receiver.. Fig. 16B illustrates circuit board **1663** rolled up as a tube in a retracted configuration for mounting into a catheter. Fig. 16C illustrates a cross sectional view of an embodiment of board **1663** inserted in a body lumen **1669** in an expanded configuration. Electrodes **1636** may optionally contact with the inner surface of the walls of lumen **1669**. Struts **1632** may optionally serve as an insulator. For example, the outer surface of struts **1632** may contact the wall of lumen **1669** in an area surrounding electrodes **1636**. For example, struts **1632** may prevent shunting of current from electrodes **1636** to fluid inside of lumen **1669**. Alternatively and/or additionally, struts **1632** may transfer heat from electrodes **1636** and or the wall of lumen **1669** to the lumen fluid. The lumen fluid may flow across the inner surface of struts **1632**. For example the thickness and/or material of struts **1632** may be adjusted to achieve a desired conductivity and/or resistance to electrical current and/or heat flow. For example, a heat sink may be printed on board **1663** and/or a channel may be printed to conduct heat from one or more electrodes **1636** and/or tissue in contact with board **1663** to a heat sink and/or lumen fluid. For example heat may be conducted and/or absorbed by a high heat conductivity channel and/or a high heat capacity element such as a metal insert and or channel in the insulator. Optionally the geometry of a heat sink and/or heat conduction channel may be adjusted to cool a particular area more than another area. For example, a highly heat conductive region may be formed near an electrode, preferentially cooling an area near the electrode. Further from the electrode the heat conductivity may be smaller. Thus, cooling may be increased near the electrode where overheating is more prevalent.

5 Control unit

Fig. 17 illustrated a control unit for an ablation device in accordance with some embodiments of the current invention. For example a control unit may include one or more radio frequency (RF) channels **1776**. The control unit may optionally have a number of channels **1776** that convey electrical signals for bipolar ablation between multiple electrode pairs (for example between specific pairs and/or any combination of a large number of electrodes, e.g., electrodes **436a-h**, electrodes **1336** etc., mounted for

example on a spine of the catheter's working end). Alternatively or additionally, RF channels **1776** may convey a signal for unipolarly ablation (for example between one or more ablation electrodes e.g., electrodes **1336** and a dispersive electrode, e.g., electrode **440**). In some embodiments the dispersive electrode may be located inside a catheter (for example a shaft electrode). For example, an internal dispersive electrode may be placed in contact with fluid (e.g. blood) inside a lumen (e.g. a blood vessel) wherein the ablation is taking place.

In some embodiments, signal of a single frequency may be conveyed for one or more electrodes, e.g., to pair of electrodes in bipolar ablation or one or more electrodes in unipolar ablation). In some embodiments, signals of a plurality of frequencies may be conveyed for one or more electrodes. For example, in bipolar ablation: a first pair of electrodes may receive signal of a first frequency and a second pair of electrodes may receive signal of a second frequency. For example, in unipolar ablation: a first electrode may receive signal of a first frequency and a second electrode may receive signal of a second frequency.

In some embodiments, a phase difference of the signal conveyed to a pair of electrodes may be controlled, e.g., by controller **1774**. Optionally, the phase difference may be controlled based on impedance and/or temperature measurements. In some embodiments, other parameters of a signal conveyed to one or more electrodes may be controlled, e.g., based on impedance and/or temperature measurements.

Selecting electrodes may optionally be according to a switch configuration. The selection may optionally be set by a multiplexer **1778**. Optionally, RF channels **1776** may have the means to measure electrode/tissue impedance under whatever selection is set by the switch configuration of the multiplexer **1778**. The RF channels **1776**, the switches and/or multiplexor **1778** may be controlled by a central controller **1774** (for example the central controller **1774** may include a processor, for example a microcontroller and/or single-board computer). The control unit may include receiver that is able to measure temperature inside the lumen (for example by means of a thermocouple attached at the location of one, some or all of the electrodes and/or at other locations). The control unit may include a user interface **1780**, for example a graphical user interface (GUI), e.g. presented on a touch screen.

In some embodiments, electrode impedance measurements may be used to estimate contact between electrode and tissue. Alternatively or additionally impedance measurements may be used as surrogate for thermal contact between electrode interface and target tissue. Optionally, RF power, electrode temperature, and electrode impedance may be used to estimate power being converted to heat at electrode/tissue interface. The estimated contact and/or estimated power may optionally be used to calculate energy transferred to target tissue and/or resulting target tissue temperature. Temperature and/or impedance measurements may be used in real-time to determine whether to apply unipolar or bipolar ablation. Optionally, other sensors inputs may be used in real-time to determine whether to apply unipolar or bipolar ablation. In some embodiments, the operator (e.g., a physician) may determine whether to apply unipolar or bipolar ablation, optionally based on temperature and/or impedance measurements which may be displayed to the operator. Additionally or alternatively, temperature and/or impedance measurements may be used in real-time to control power and duration of ablation. The power and/or duration of ablation may optionally be used to ensure quality of lesion formation. The generator may estimate lesion quality for an individual electrode and/or for an area between electrodes. The algorithms may optionally alert a user that lesion formation has been completed when the quality of lesion at each electrode location reaches a predetermined range. The algorithm may change the electrodes being powered and/or the power level and/or frequency dependent on the differential progress of ablation. In some embodiments, the algorithm may recommend changes to a use and wait for user input before making changes. For example, if ablation is progressing faster at a first electrode of a pair of electrodes than at a second electrode, the algorithm may recommend switching to unipolar ablation at the second electrode and/or may automatically switch. For example, if ablation is localized too much at the electrode locations, the algorithm may recommend changing to a frequency that penetrates tissue better.

In some embodiments, the control unit may measure complex bipolar and/or unipolar electrode impedance. For example impedance may be measured at the ablation frequency and/or at another frequency. Optionally, measurements may be made while ablating based on the ablation signal. Alternatively or additionally, impedance measurements may be made when not ablating. For example, during a interruption in

ablation, impedance may be measured using an auxiliary signal. The auxiliary signal may be generated by an RF generator of one or more of channels **1776**. The auxiliary signal may optionally meet the requirements of an auxiliary current not meant to cause any physiological effect. In some embodiments, electrode Impedance measurements shall be possible within the 100Ω to 1kΩ range with a minimum accuracy of 5%, and within the 1001Ω to 2kΩ range with a minimum accuracy of 10%. Minimum repeatability within the 100Ω to 2kΩ range may optionally be 5%. In some embodiments, ablation interruptions of less than 100 ms may be made for measuring impedance during ablation segments. Optionally, an auxiliary signal for impedance measurements may have the same frequency as ablation signals and/or an auxiliary signal for impedance measurements may have a different frequency from an ablation signal. Optionally, impedance measurements may be conveyed between a pair of electrodes being used for an ablation and/or an impedance measurement may be conveyed between electrodes between which there is no current ablation treatment. For example, during an interruption in bipolar ablation impedance may be measured between a disperse electrode and one ablation electrode of the active bipolar pair. Optionally, impedance measurements may be taken at a rate greater than 100 samples/s.

6 Evoked response

In some embodiments, evoked response may be used for determining a treatment location and/or measuring ablation progress. For example a catheter may be supplied with an apparatus for measuring vasoconstriction (for example through balloon pressure, strain on supports, pressure on a transducer [for example measuring blood pressure in the lumen being ablated and/or elsewhere], electrical signals [picked up for example by an antenna and/or an electrode in the catheter or elsewhere] and/or impedance measurements, for example as illustrated in Figs 20 and Figs. 21A-B). Target sites may optionally be located by finding regions where electrical stimulation delivered through the electrodes causes a significant vasocontractile response. Once ablation is started, changes in vasocontractile response to stimulation may be used to control the delivery of energy until a certain dampening of the vasocontractile response indicates desired extent of the effect of the ablation. Alternatively or additionally, the evoked electrical response to stimulus may be measured to find ablation sites and/or to estimate the extent of the effect of the ablation.

Fig. 18 illustrates an exemplary method of finding a receptor (for example a receptor may include perivascular renal nerve) and/or ascertaining ablation progress via evoked response, in accordance with some embodiments of the invention. In some embodiments, a stimulation electrode (which could include for example an ablation electrode) is positioned **1844** at a location wherein there may be an ablation candidate receptor and the tissue may be stimulated **1846** for example via an electrical signal. The response may be measured **1848** (for example the vasoconstriction and/or the electrical response). For example, a fast and/or strong response may indicate the presence of a receptor. If a receptor is not found **1850**, then the simulation electrode is positioned **1844** at a new location. If a receptor is found **1850**, then the ablation **1813** may proceed. Ablation **1813** may include bipolar ablation (for example bipolar ablation **112** as described hereinabove) and/or unipolar ablation (for example unipolar ablation **114** as described hereinabove). In place of and/or in addition to the tests described herein above evoked response may be used to measure ablation progress. During ablation, current application may be interrupted and an electrical signal may be transmitted to stimulate **1852** the tissue. The evoked response to stimulation may then be measured **1854** (for example the vasoconstriction and/or the electrical response). If the response is not yet damped **1856** enough, then ablation **1813** may continue. If the response is damped **1856** enough, then the process ends (for example either the ablation session ends and/or the process restarts finding another site and optionally ablating that site).

In some embodiments, the method illustrated in Fig. 18 may be used for determining a treatment location in a body of a treated patient e.g., by stimulating a tissue and detecting the elicited vasocontractile response. Treatment locations may be located by finding regions where electrical stimulation delivered through the electrodes causes a significant vasocontractile response. Once ablation is started, changes in vasocontractile response to stimulation may be used to control the delivery of energy for example until a certain dampening of the vasocontractile response indicates desired extent of lesion formation. Optionally, the evoked response may be measured in the intravascular space (for example by a blood pressure sensor in the catheter) and/or elsewhere in the body (for example through a blood pressure or blood flow sensor elsewhere in the body and/or from a location external to the body, for example through a blood pressure sensor, heart rate sensor, or plethysmography sensor).

In some embodiments, an evoked response may include an electrical reaction signal produced in response to a stimulus. Optionally, the stimulus may be applied inside a lumen of the patient, for example by a device on the ablation catheter. Optionally, a target site may be identified as a region where delivering a stimulation causes a significant evoked response. For example, a target for ablation may include a nerve terminal. Optionally, the stimulus may include an electrical signal. The evoked response may be measured for example as an electrogram. Optionally, the evoked response may be measured in the intravascular space (for example by electrodes of the catheter) and/or elsewhere in the body (for example at a nerve location elsewhere in the body and/or external to the body (for example using an external electrode). Once ablation is started, changes in evoked response to stimulation may optionally be used to control the delivery of energy until a certain dampening of the evoked response is detected. The dampened response may optionally indicate a desired extent of lesion formation. When sufficient dampening is detected, ablation may optionally be stopped.

Fig. 19 illustrates an exemplary stimulation and evoked response, in accordance with some embodiments of the invention. For example, curve **1961a** illustrates a stimulation to the receptors before ablation (either while searching for receptors or at the beginning of ablation). The abscissa shows time (for example a few milliseconds) and the ordinate may include for example the voltage of the signal and/or the current. The measured return signal is represented by graph **1962**. The measured signal may include a change in pressure in a balloon due to vasoconstriction and/or a stress and/or a strain on a support of a basket (for example support **432**) and/or a change electrical potential and/or impedance measured on the tissue. For example, curve **1961b** illustrates a stimulation to the receptors after ablation. For example, curve **1964** illustrates the dampening of the return signal after successful ablation.

Fig. 20 illustrates an ablation device **2000** capable of measuring evoked response in accordance with some embodiments of the current invention. Ablation device **2000** may, for example, include a support structure similar to that of Fig. 4C (for example including struts **432**). Ablation device **2000** may option include markers (for example similar to markers **455a,b** – not illustrated), electrodes **436,** an insulator (for example a membrane **434**) and/or other components or structures described above. For example, the support structure, markers, electrodes **436** and/or insulator may be similar to one,

some and/or any of the embodiments above. Optionally, ablation device **2000** may include one or more sensors to sense evoked response. For example, a strain gauge **2070** may measure evoked vasoconstriction response and/or resultant squeezing of the support structure. Alternately or additionally, ablation device **2000** may include a pressure transducer to measure the fluid pressure inside a lumen. Ablation device **2000** may include exemplary thermocouples **2072** for measuring temperature near the ablation electrodes **436**.

Figs. 21A-B illustrate a perspective and a cross sectional view respectively of an alternate ablation device **2100** capable of measuring evoked response in accordance with some embodiments of the invention. Ablation device **2100** may, for example, include a malecot support structure similar to that of Figs. 14A-C (for example including struts **1432**). Ablation device may option include markers (for example similar to markers **455a,b** – not illustrated), electrodes **1336** and/or an insulator **2134**. Ablation device **2100** may include other components or structures described above. For example, the support structure, markers, sensors, electrodes sensors and/or insulator may be similar to one, some and/or any of the embodiments above. Optionally, ablation device **2100** may be configured to sense evoked response. For example, insulator may be configured to sense pressure and/or shape changes caused by evoked vasoconstriction response and/or resultant squeezing of the support structure. For example, insulator **2134** may include an internal liquid filled cavity **2179**. Changes in the shape of insulator **2134** may induce changes in the internal pressure in cavity **2179** and may be sensed by a pressure transducer. Alternately or additionally, ablation device **2100** may be constructed of multiple layers of material which may produce an electrical response (for example a change in resistance) under strain. The electrical response may be sensed and/or used detect an evoked response. The materials of insulator **2134** and or the fluid between layers may be chosen to provide a heat sink and/or heat conductor, for example for conducting heat away from the ablation zone. Insulator **2134** may include a central passageway **2177** through which lumen fluids may flow **2139**. Optionally, struts **1432** may pass through support lumens **2175** in insulator **2134**.

It is expected that during the life of a patent maturing from this application many relevant technologies will be developed and the scope of the terms used herein is

intended to include all such new technologies *a priori*. As used herein the term “about” refers to ± 10 %.

The terms "comprises", "comprising", "includes", "including", “having” and their conjugates mean "including but not limited to".

The term “consisting of” means “including and limited to”.

The term "consisting essentially of" means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular form "a", "an" and "the" include plural references unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

Throughout this application, various embodiments of this invention may be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein, it is meant to include any cited numeral (fractional or integral) within the indicated range. The phrases “ranging/ranges between” a first indicate number and a second indicate number and “ranging/ranges from” a first indicate number “to” a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numerals therebetween.

As used herein the term "method" refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques and procedures either known to, or readily developed from known

manners, means, techniques and procedures by practitioners of the chemical, pharmacological, biological, biochemical and medical arts.

As used herein, the term "treating" includes abrogating, substantially inhibiting, slowing or reversing the progression of a condition, substantially ameliorating clinical or aesthetical symptoms of a condition or substantially preventing the appearance of clinical or aesthetical symptoms of a condition.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

WHAT IS CLAIMED IS:

1. An ablation catheter fitting into a lumen of a patient comprising:

a radially expanding tubular insulation member sized and shaped to fit in a lumen of a blood vessel in an expanded configuration;

a plurality of ablation electrodes mounted along an outer surface of said radially expanding insulation tubular member;

an expansion mechanism for radially expanding an inner passageway [not the passageway..] of said radially expanding tubular insulation member toward walls of said lumen, from a retracted configuration to said expanded configuration; and wherein when said expanded configuration a hydraulic radius of said passageway is at least 50% of the a hydraulic radius of said lumen.

2. The ablation catheter of claim 1 wherein, said expanding tubular insulator fits into said lumen which is a lumen of a blood vessel.

3. The ablation catheter any of claims 1 and 2, wherein said expansion is by plastic deformation of said expanding tubular insulator.

4. The ablation catheter any of claims 1, 2 and 3, wherein at least one of said plurality of ablation electrodes is mounted with an active surface tangent to said outer surface of said expanding tubular insulator said active surface facing said inner surface of said lumen.

5. The ablation catheter of any of claims 1 - 4, wherein said expanding tubular insulator is configured to contact an area of an inner surface of said walls of the lumen surrounding at least one of said plurality of ablation electrodes.

6. The ablation catheter of any of claims 1 - 5, wherein said expanding tubular insulator separates between at least one of said plurality of ablation electrodes and fluid in said passageway.

7. The ablation catheter of any of claims 1 - 6, wherein said plurality ablation electrodes include at least four pairs of ablation electrodes.

8. The ablation catheter of claim 7 further comprising

a control unit selectively conveying an ablation signal between electrodes of each of said at least four pairs of ablation electrodes.

9. The ablation catheter of any of claims 7 and 8 wherein said at least four pairs of ablation electrodes are helically distributed around said expanding tubular insulator.

10. The ablation catheter according to any of claims 1-9 wherein said expansion mechanism includes a plurality of supports.

11. The ablation catheter according to any of claims 1-10, wherein said expanding tubular insulator transfers heat from the plurality of ablation electrodes to a heat sink.

12. The ablation catheter of claim 11, wherein said heat sink includes said fluid flowing through the lumen.

13. The ablation catheter of any of claims 11 - 12, wherein said heat sink includes said fluid flowing through said expandable passageway.

14. The ablation catheter according to any of claims 1-13, wherein an area of said inner surface of said lumen in contact with said expanding tubular insulator surrounding at least one ablation electrode of said plurality of ablation electrodes is at least 50 mm^2.

15. The ablation catheter according to any of claims 1-14, wherein an area of target tissue in contact with said expanding tubular insulator surrounding at least one ablation electrode of said plurality of ablation electrodes includes a margin of at least 3 mm surrounding said at least one electrode.

16. The ablation catheter according to any of claims 1-15, wherein in said expanded configuration a cross sectional area of said passageway is at least 50% of a cross sectional area of said lumen.

17. The ablation catheter according to any of claims 1-16, wherein in said expanded configuration a hydraulic radius of said passageway is at least 70% of a hydraulic radius of said lumen.

18. A method of ablation therapy in a lumen in a patient comprising:

positioning one or more ablation electrodes in contact with a wall of the lumen; and

expanding an insulator thereby contacting by an outer surface of a wall of said expanding tubular insulator an inner surface of the wall of the lumen;

an area of said contacting surrounding at least one of said one or more ablation electrodes,

defining by an inner surface of said expanding tubular insulator a passageway along said lumen for flow of a fluid through said lumen, and

electrically insulating between said fluid and said at least one ablation electrode of the one or more ablation electrodes and

heating said tissue by means of an electrical signal from said at least one ablation electrode.

19. The method of claim 18, further comprising:

cooling at least a portion of at least one of said tissue and said at least one ablation electrode by heat transfer to said insulator simultaneous to said heating.

20. The method of claim 19, wherein said cooling includes said insulator conducting heat from said portion to a heat sink.

21. The method of claim 20, wherein said transferring includes conducting heat across said wall of said expanding tubular insulator.

22. The method of any of claims 20 and 21, wherein said heat sink includes fluid in said lumen.

23. The method of any of claims 20 and 21, wherein said heat sink includes fluid in said passageway.

24. The method any of claims 18-23, wherein said passageway passes along a surface of said expanding tubular insulator opposite an ablation zone.

25. The method of any of claims 18-24, wherein said contacting includes contacting an area of said inner surface of said wall of said lumen surrounding at least one ablation electrode of the one or more ablation electrodes.

26. The method of claim 25, wherein said area of said inner surface of said wall of said lumen surrounding said electrode includes an area of at least 50 mm^2.

27. The method of claim 25, wherein said contacting includes a margin around said at least one ablation electrode of at least 3 mm in every direction.

28. An ablation catheter comprising:

a plurality of ablation electrodes in contact with a target tissue in a lumen;

a dispersive electrode provided in the lumen, the dispersive electrode having a conducting contact area at least 20 times a large as the ablation electrode, and

a control unit conveying

a first signal between a pair of said plurality of ablation electrodes and

a second signal between said dispersive electrode and at least one of said plurality of ablation electrodes.

29. The ablation catheter of claim 28, further comprising:

an insulator electrically insulating at least one of the plurality of ablation electrodes from a fluid in said lumen.

30. The ablation catheter of any claim 28 - 29, wherein the dispersive electrode is not in contact with said target tissue.

31. The ablation catheter according to any of claims 28-30, further including:

a passageway for a fluid to pass through the lumen.

32. The ablation catheter according to any of claims 28-31, wherein a first side of the insulator is in contact with the target tissue in a vicinity of said ablation electrode and a second side of the insulator is in contact with said fluid in said passageway and heat transfer to said fluid across said expanding tubular insulator cools said target tissue in said vicinity of said ablation electrode.

33. The ablation catheter according to any of claims 28-32, wherein the dispersive electrode is in contact with a fluid inside said lumen.

34. A method of ablation therapy inside a lumen of a patient comprising:

positioning a plurality of ablation electrodes in contact with a target tissue in said lumen;

conveying through said target tissue a first electrical signal between a pair of said ablation electrodes;

conveying through said target tissue a second electrical signal between at least one of said plurality of ablation electrodes and said a dispersive electrode having an active surface area at least twenty times an active surface area of said ablation electrode; and

cooling said ablation electrode by heat transfer across said insulator.

35. The method of claim 34, further comprising:

insulating electrically at least one of said ablation electrodes from a fluid in said lumen.

36. The method of any of claims 34-35, further comprising

placing said dispersive electrode into contact with a fluid in said lumen.

37. The method according to any of claims 34-36, further comprising

placing at least part of said dispersive electrode into said lumen.

38. The method according to any of claims 34-37, wherein said placing is by means of a catheter.

39. An ablation catheter comprising:

at least one ablation electrode in contact with a tissue on an inner wall of a lumen;

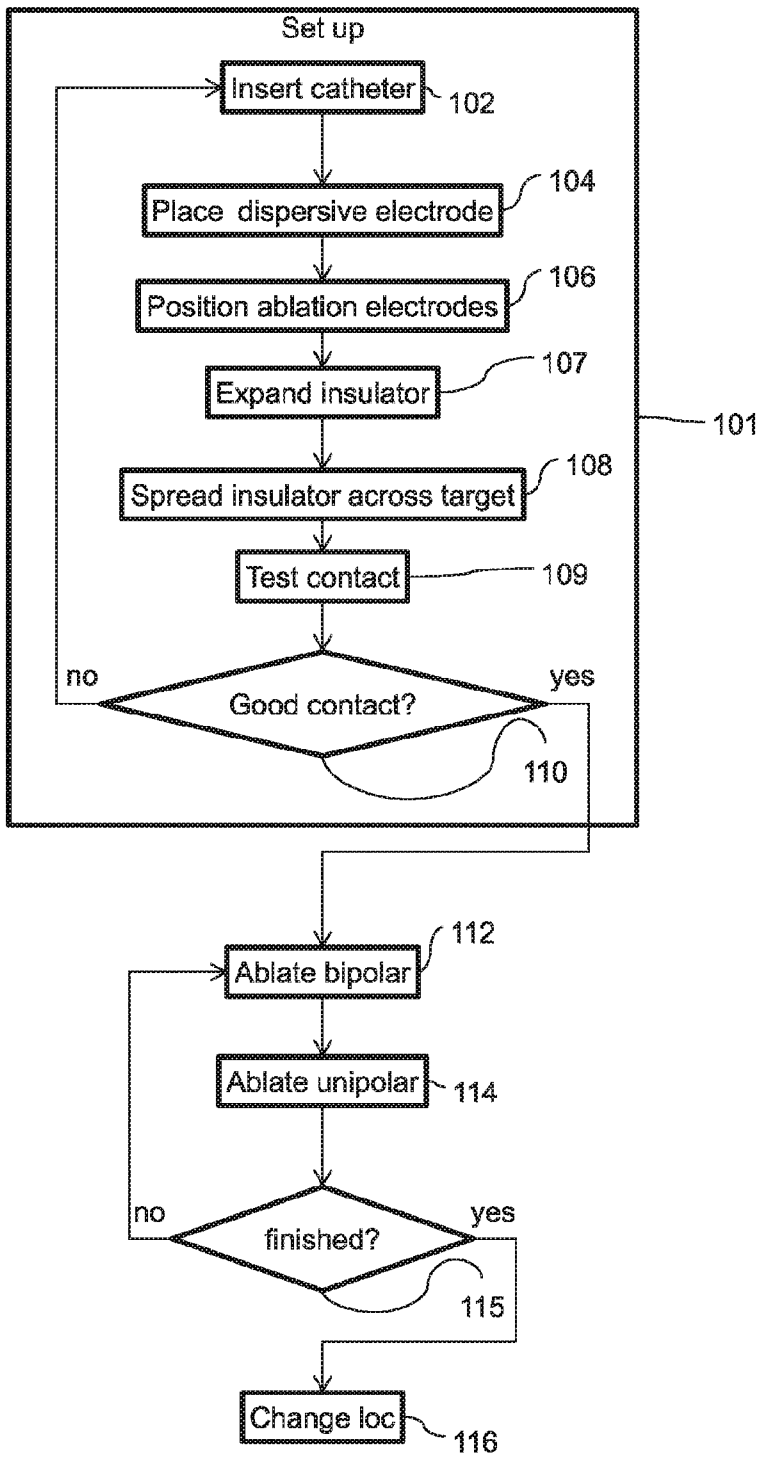
an insulator including

a tissue side in contact with an area of said tissue surrounding said electrode and

a lumen side in contact with fluid in the lumen, the insulator electrically insulating the at least one ablation electrode from a fluid in the lumen and cooling said at least one electrode ablation electrode by conducting heat to said fluid in the lumen; and

a passageway allowing fluid flow through the lumen.

FIG. 1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Place dispersive electrode
104
Position ablation electrodes
106
Expand insulator
107
Spread insulator across target
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Test contact
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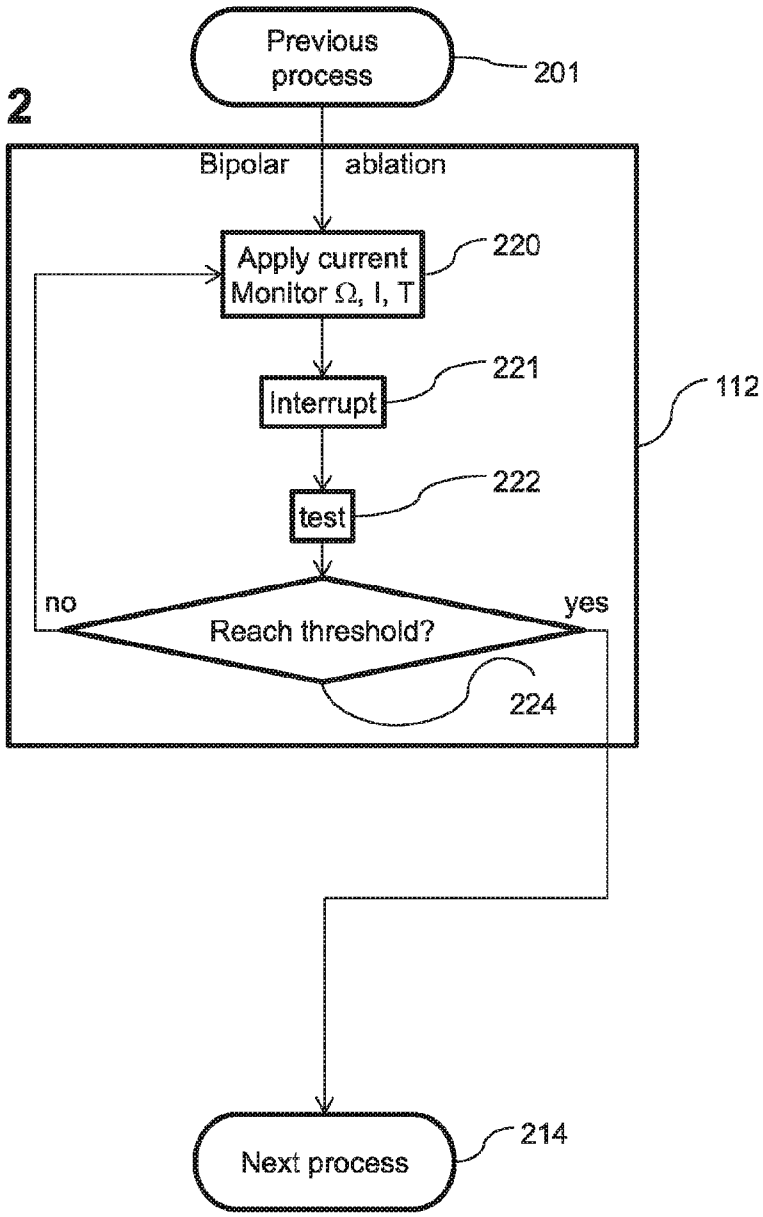
110
101
Ablate bipolar
112
Ablate unipolar
114
no
finished?
yes
115
Change loc
116

FIG. 2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Interrupt
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112
test
222
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Reach threshold?
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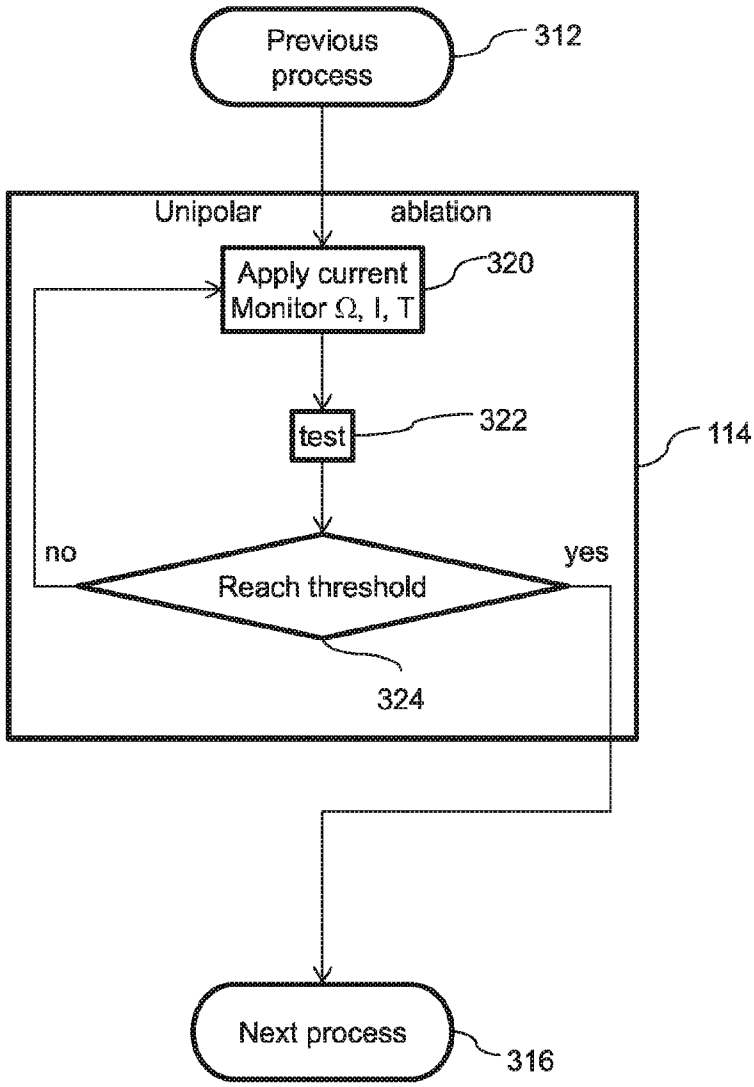
Next process
214

FIG. 3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320
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322
114
no
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Reach threshold
324
Next process
316

FIG. 4A

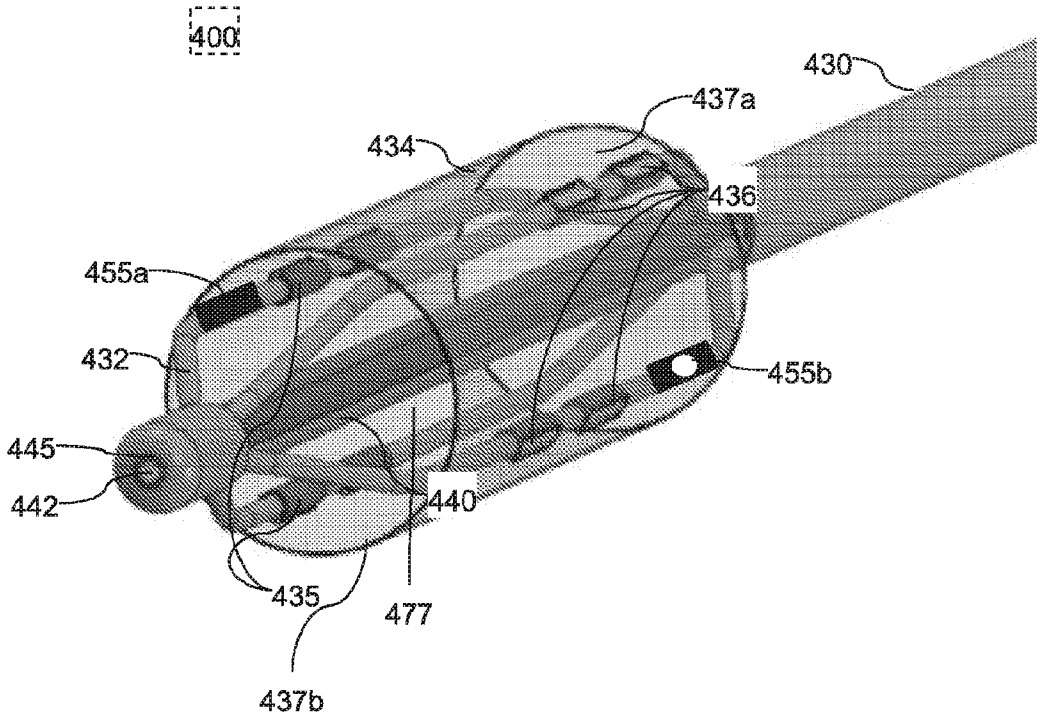


FIG. 4B

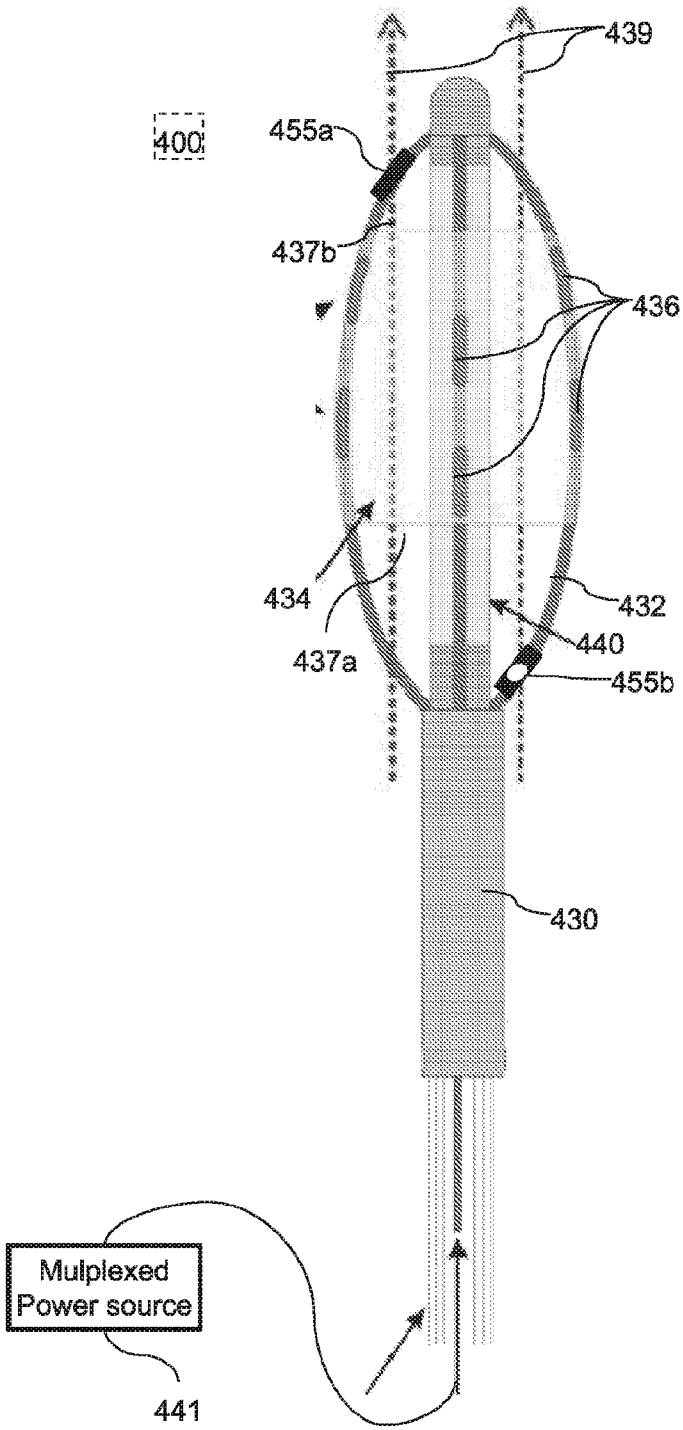

439
400
455a
437b
436
434
437a
432
440
455b
430
Mulplexed
Power source
441

FIG. 4C

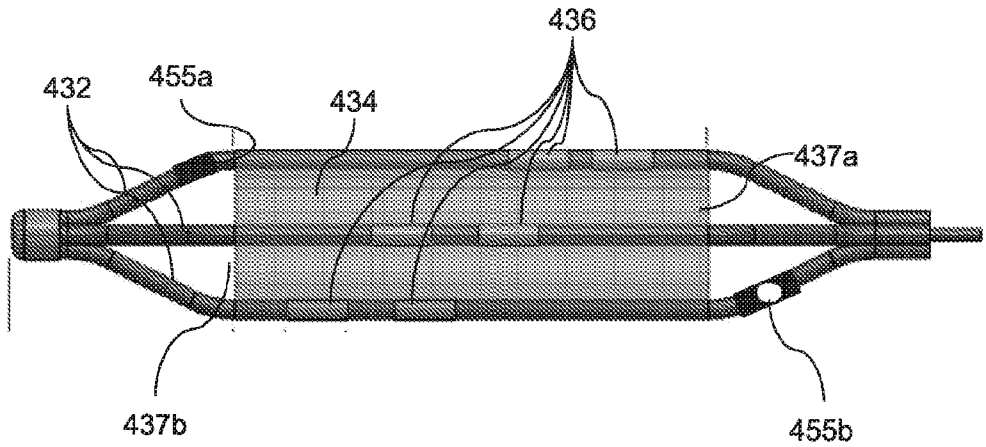
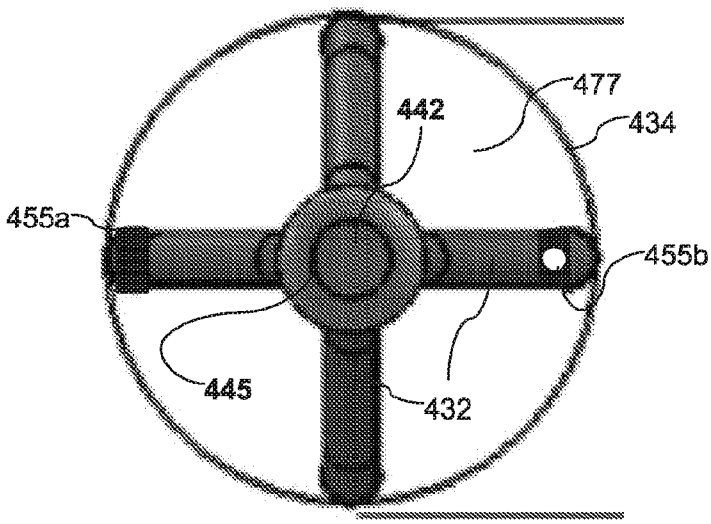


FIG. 4D



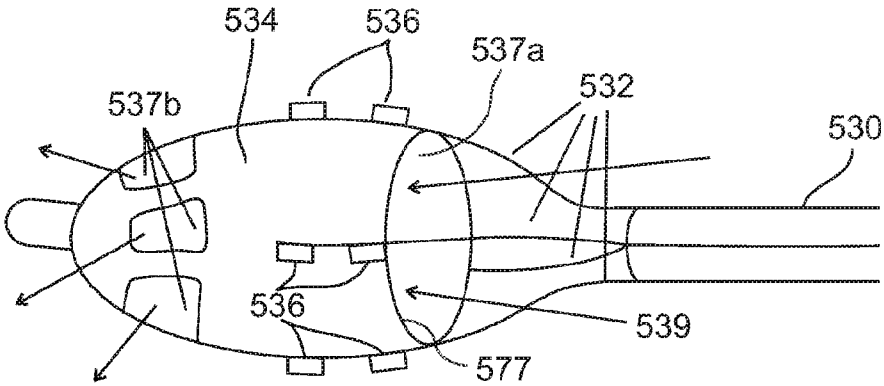


FIG. 5

FIG. 6A

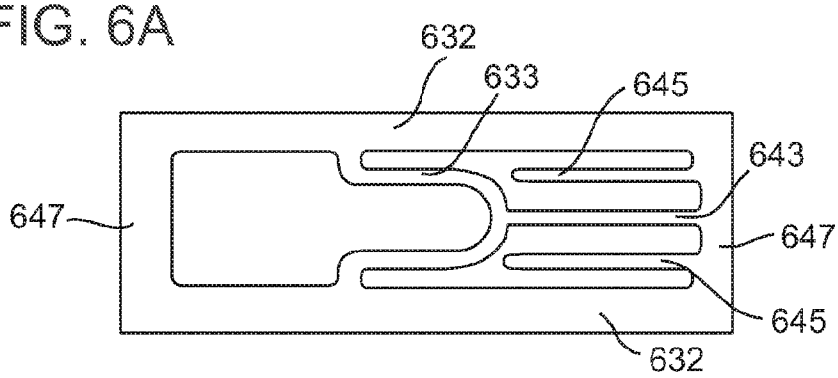


FIG. 6B

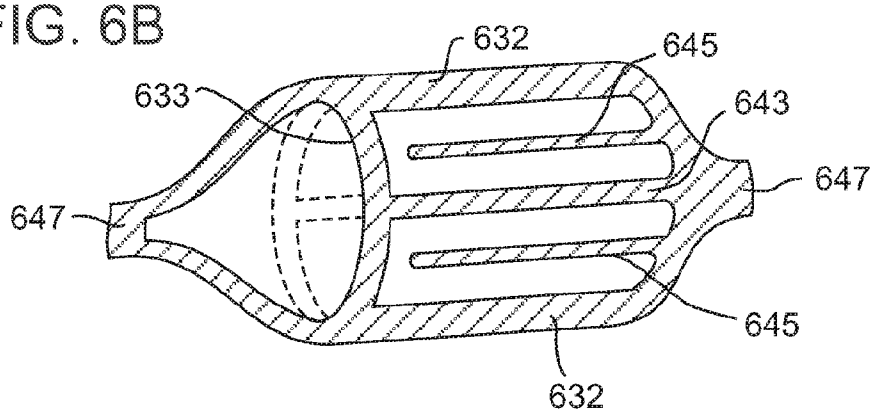


FIG. 7

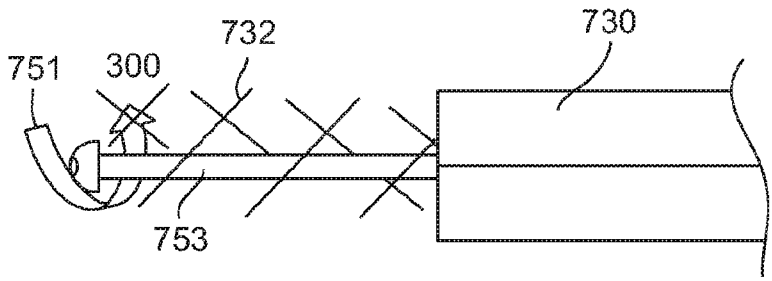


FIG. 8

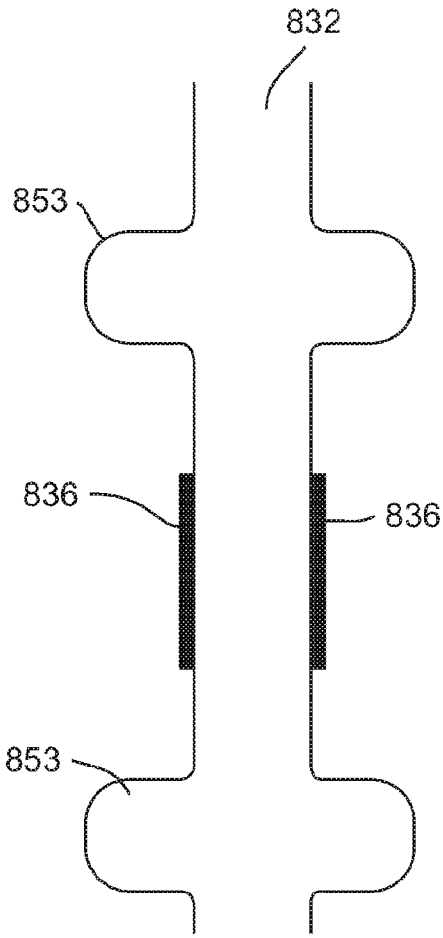


FIG. 9A

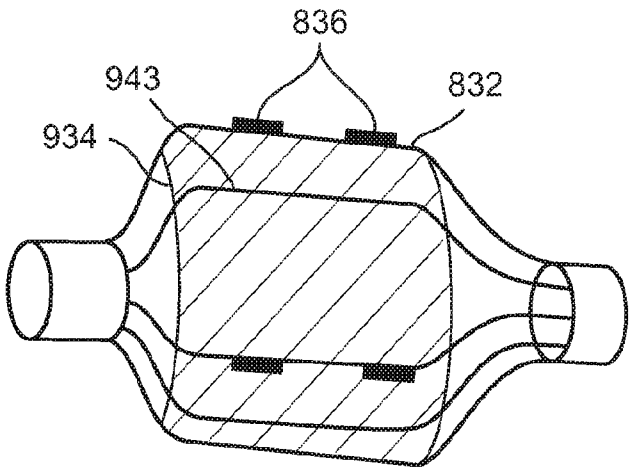
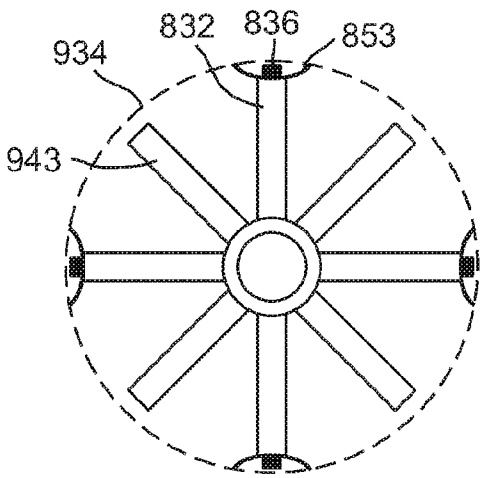


FIG. 9B



(++)

FIG. 10

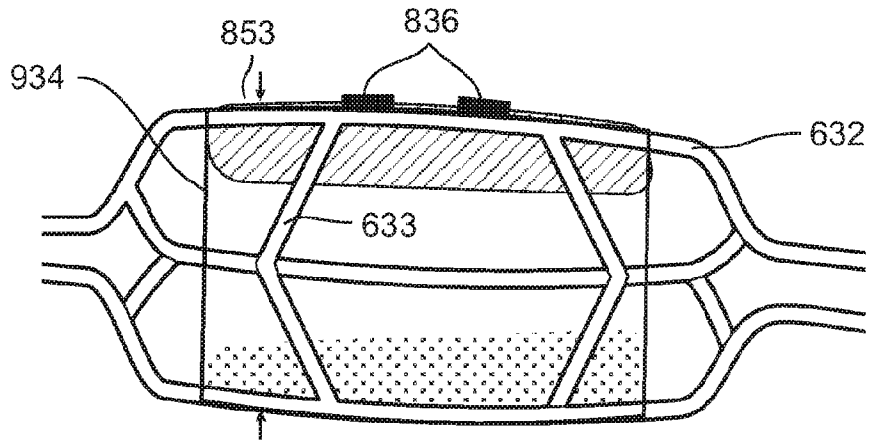


FIG. 11A

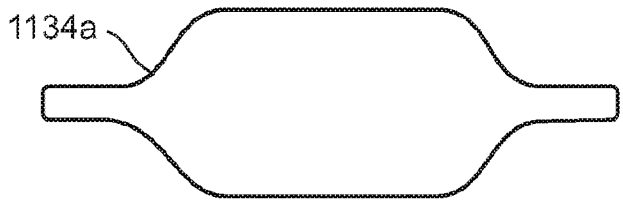


FIG. 11B

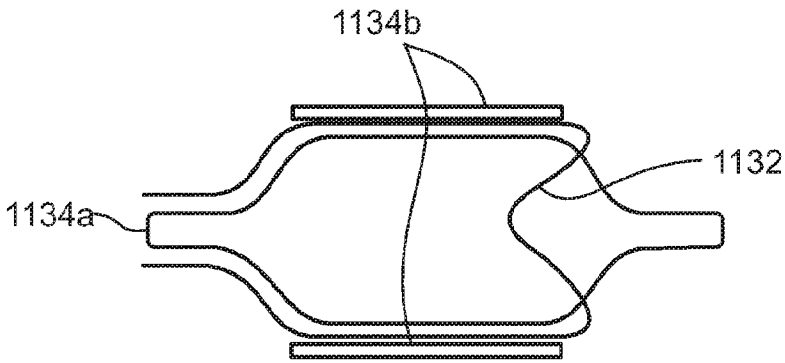


FIG. 12A

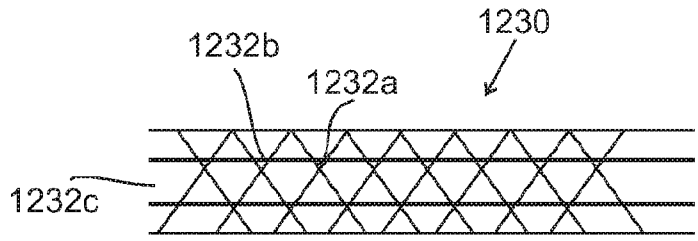


FIG. 12B

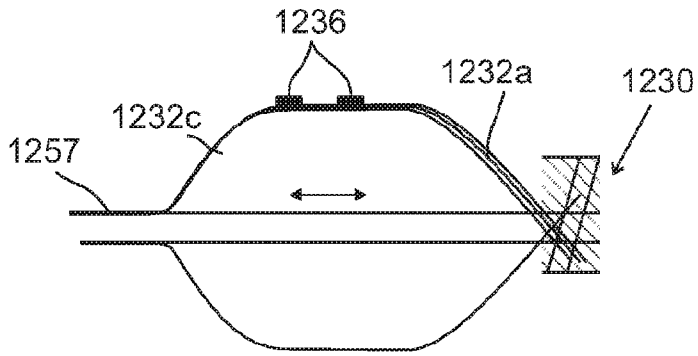


FIG. 13A

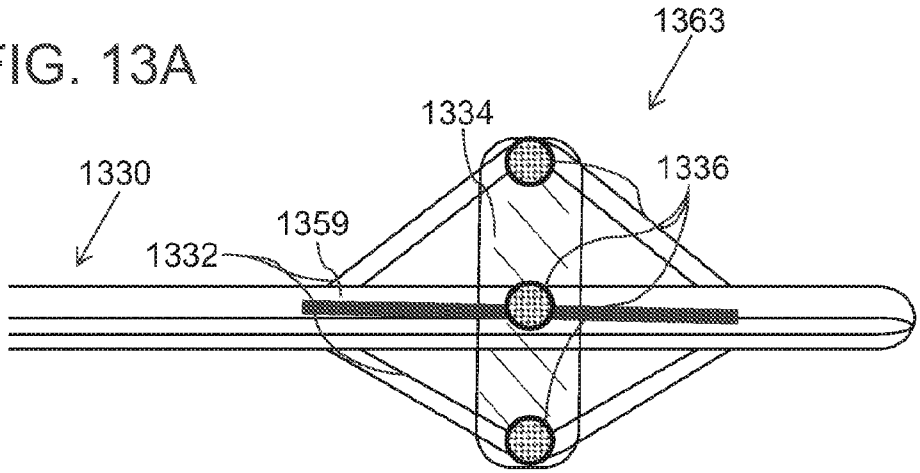


FIG. 13B

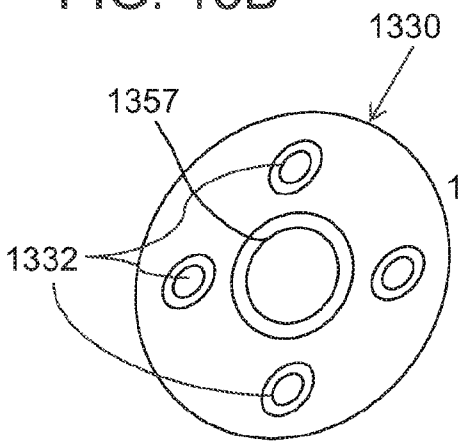


FIG. 13C

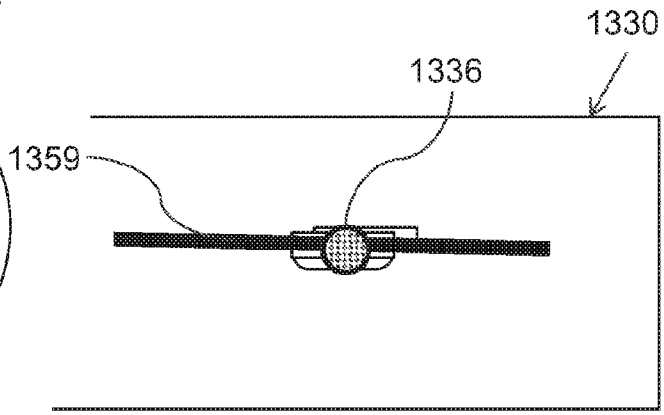


FIG. 14A

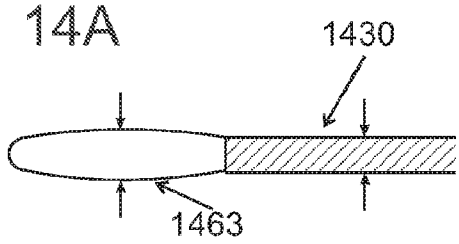


FIG. 14B

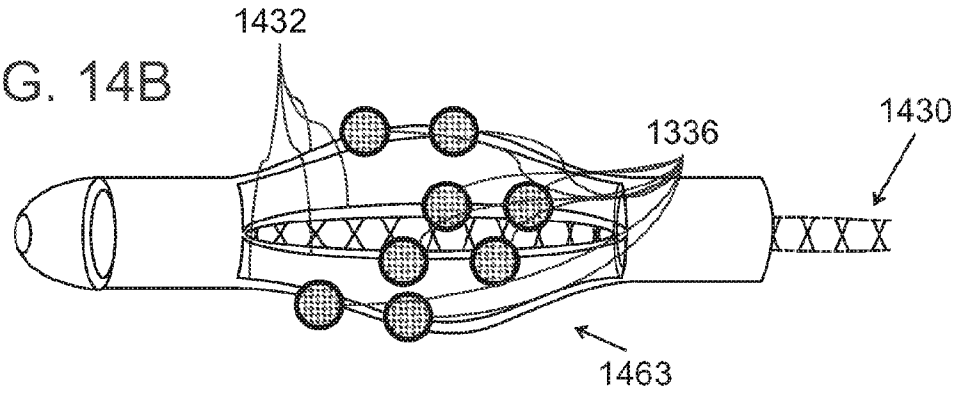


FIG. 14C

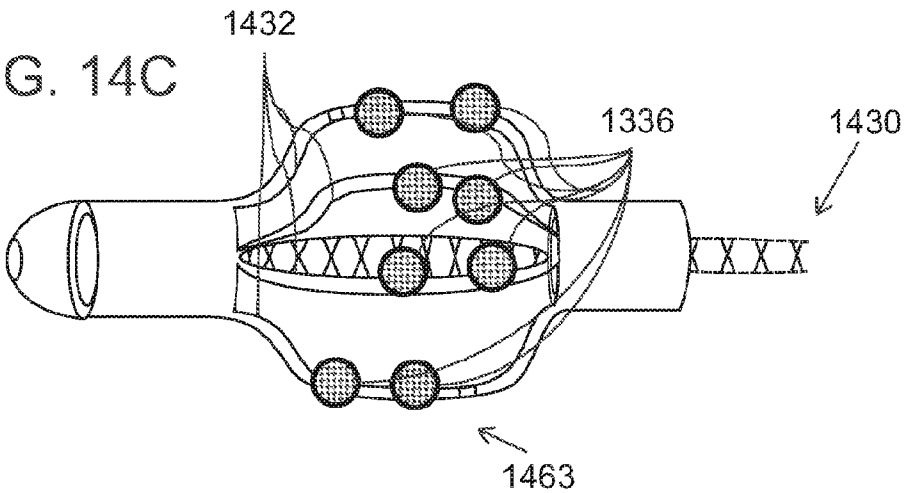


FIG. 15A

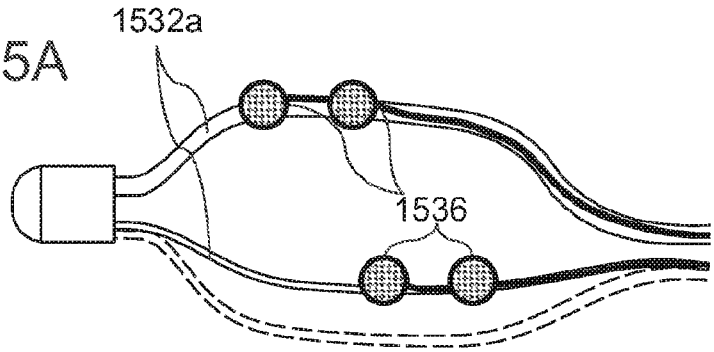


FIG. 15B

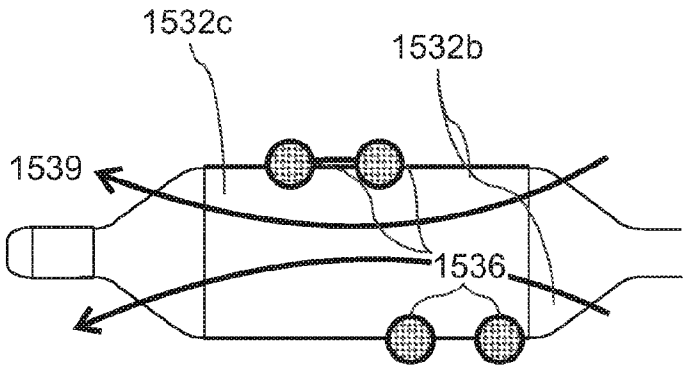


FIG. 16A

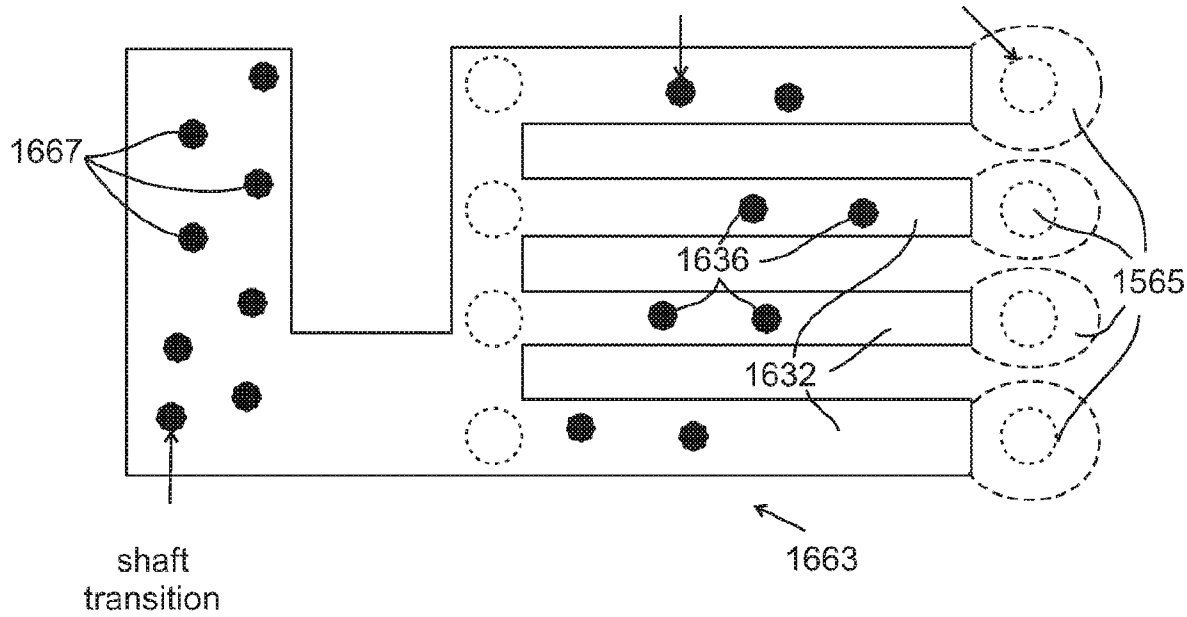


FIG. 16B

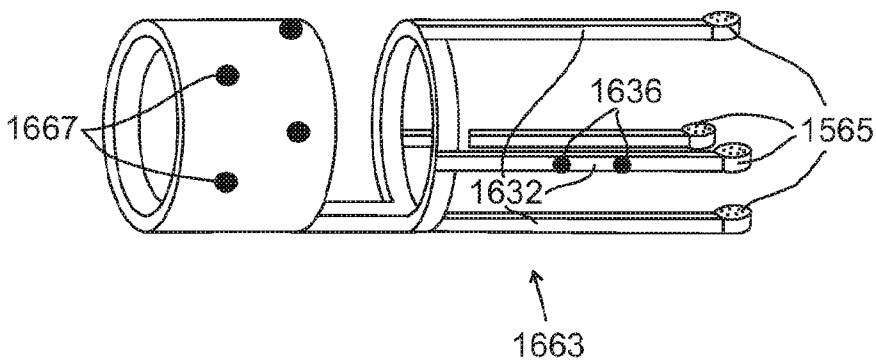


FIG. 16C

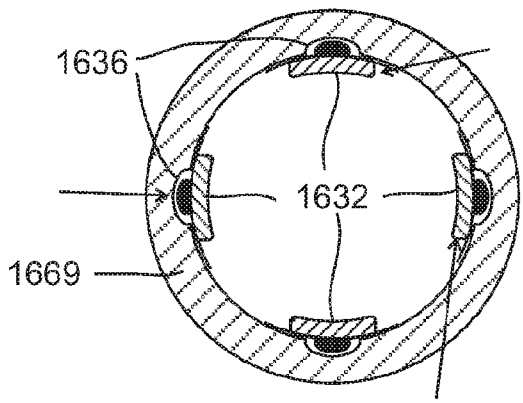


FIG. 17

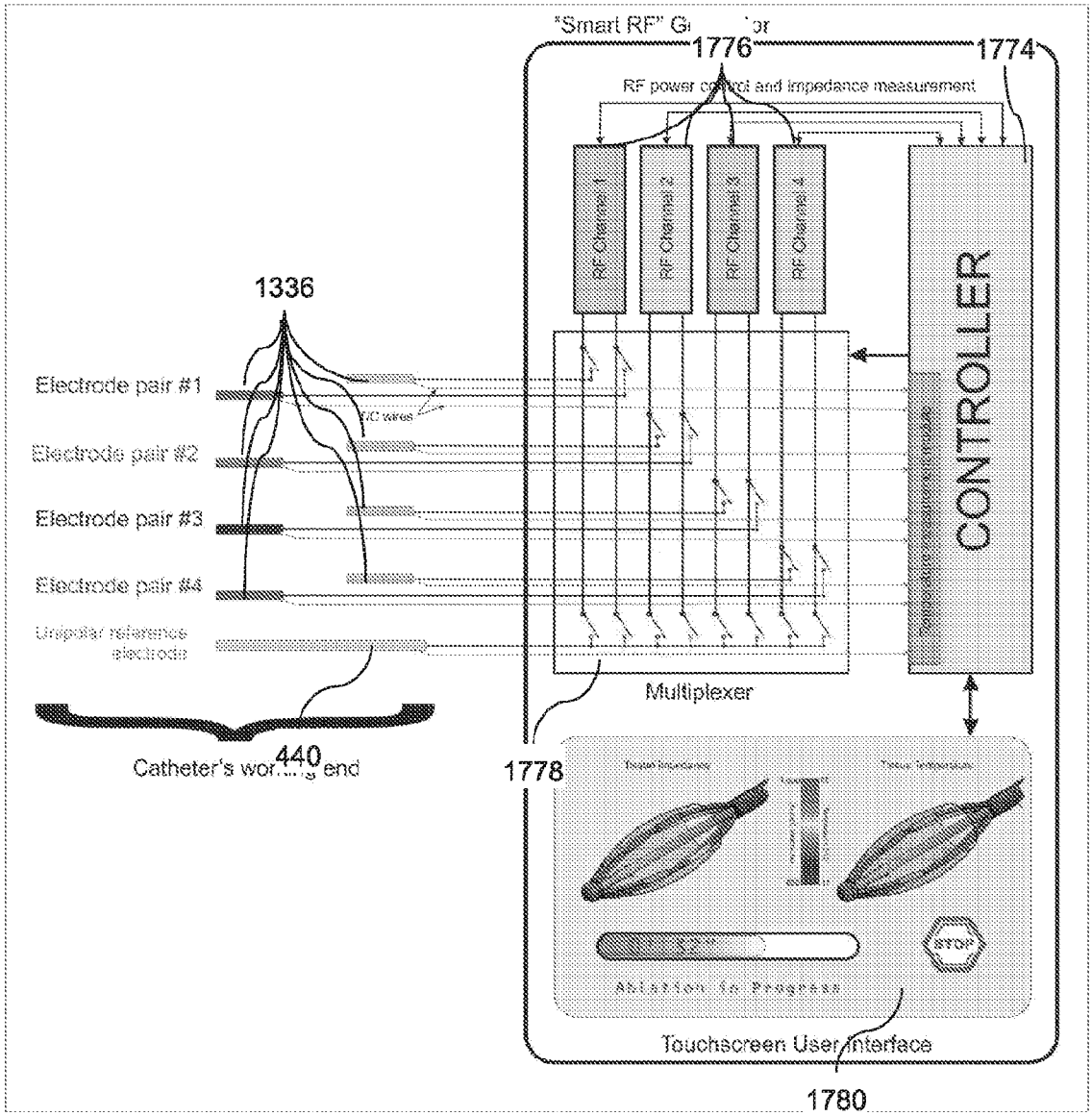

"Smart RF" G or
1776
1774
RF power control and impedance measurement
RF Channel 1
RF Channel 2
RF Channel 3
RF Channel 4
CONTROLLER
1336
Electrode pair #1
Electrode pair #2
Electrode pair #3
Electrode pair #4
Unipolar reference electrode
T/C wires
Multiplexer
Catheter's working end
440
1778
Tissue Impedance
Tissue Temperature
STOP
Ablation in Progress
Touchscreen User Interface
1780

FIG. 18

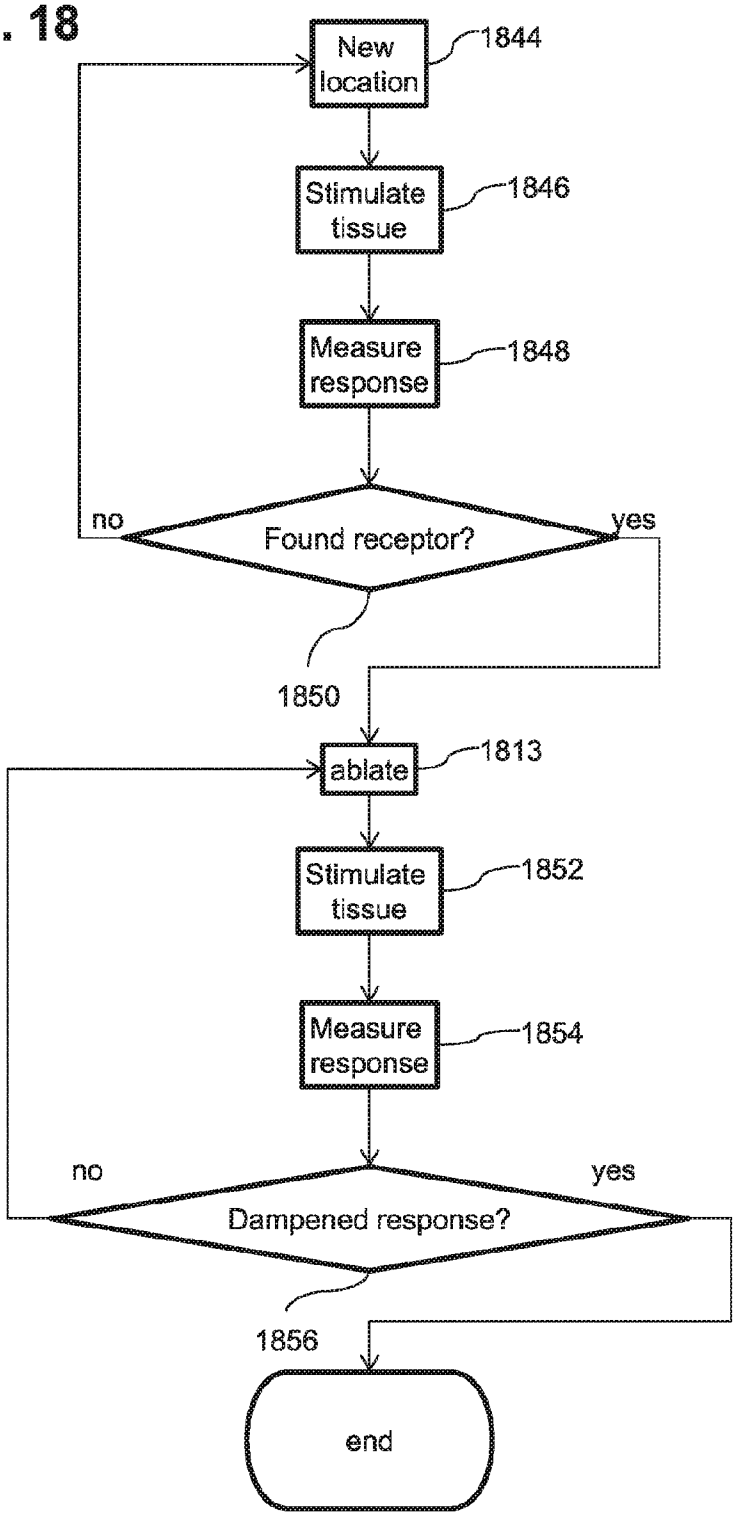

New location
1844
Stimulate tissue
1846
Measure response
1848
no
Found receptor?
yes
1850
ablate
1813
Stimulate tissue
1852
Measure response
1854
no
Dampened response?
yes
1856
end

FIG. 19

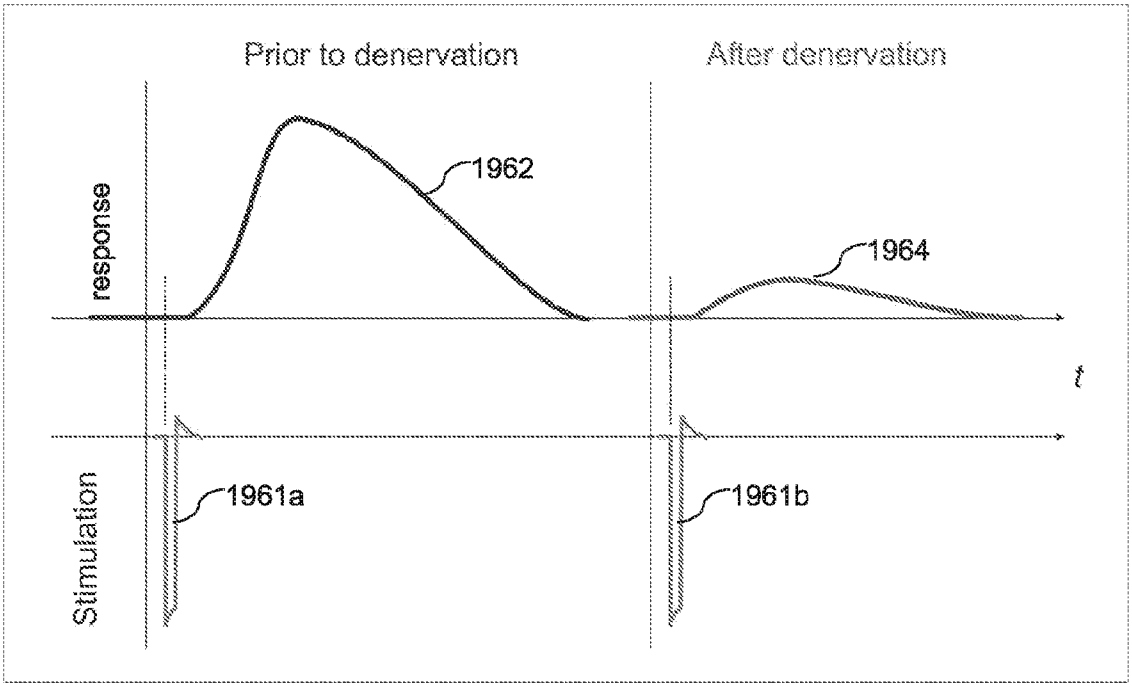

Prior to denervation
After denervation
response
1962
1964
t
Stimulation
1961a
1961b

FIG. 20

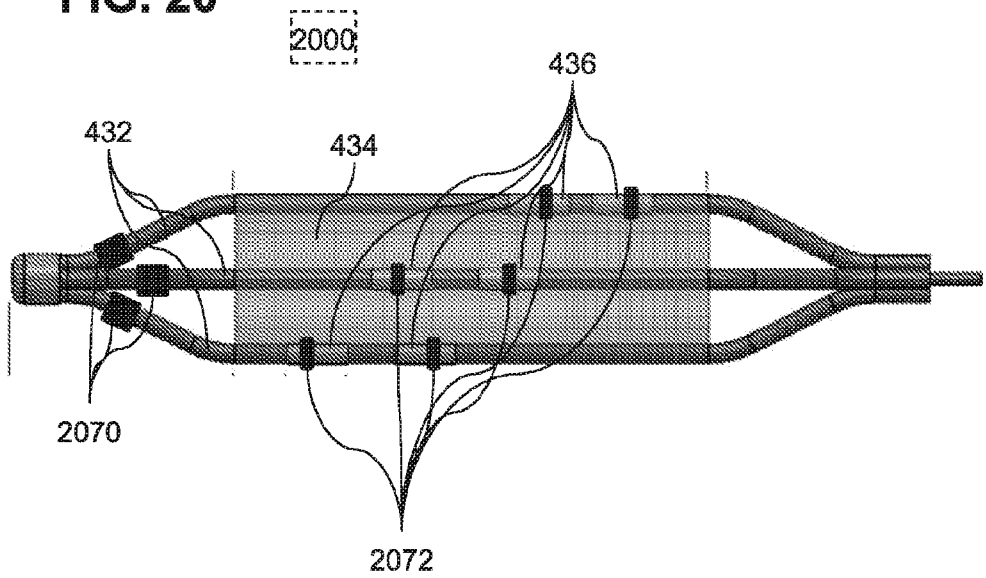


FIG. 21A

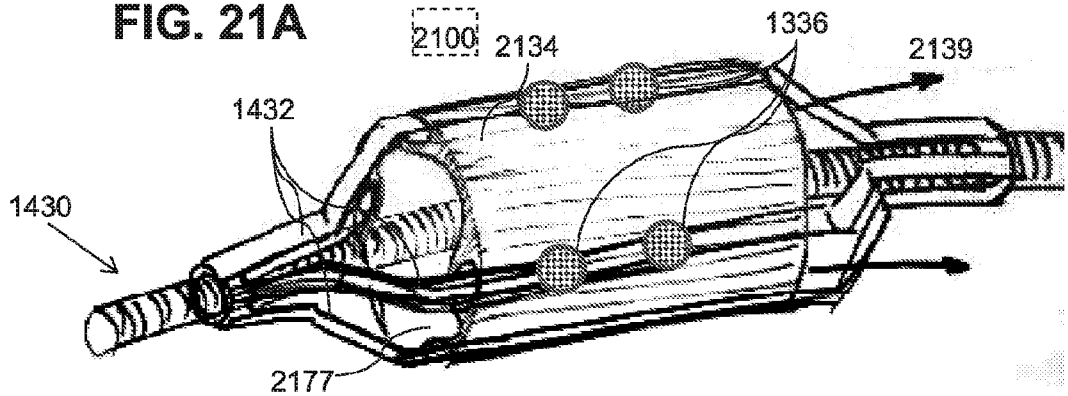


FIG. 21B