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(54) **PERCUTANEOUS DEVICE TO VISUALIZE, TARGET AND ABLATE NERVES**

PERKUTANE VORRICHTUNG ZUR VISUALISIERUNG; ANVISIERUNG UND ABLATION VON NERVEN

DISPOSITIF PERCUTANÉS DE VISUALISATION, DE CIBLAGE ET D'ABLATION DE NERFS

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Description

TECHNICAL FIELD

[0001] The present invention is related to systems and methods for visualizing, targeting and ablating nerves including the disruption of sympathetic nerve activity. Some embodiments of the invention are related to systems and methods for improving renal and/or cardiac function through neuromodulation.

BACKGROUND

[0002] Nerve modulation therapies such as nerve ablation are beneficial for certain conditions. For example, sympathetic renal activity connected with congestive heart failure may cause unwanted symptoms such as fluid retention. Interrupting this sympathetic nerve activity may mitigate these symptoms. One technique for interrupting the renal sympathetic nerve activity is to ablate the sympathetic nerves, which are disposed in part around the renal arteries. Typical renal nerve ablation therapies involve the introduction of an ablation catheter into the renal arteries and ablating the arteries at various longitudinal and radial locations along the arteries.

[0003] Such a catheter is known from document US 2010/0280504 A1.

[0004] This procedure is done without identifying the specific location of the nerve tissue or identifying the nerve tissue.

SUMMARY

[0005] Being able to identify the nerve tissue may allow for more targeted and thus less traumatic therapies. A therapy which identifies the nerve tissue in conjunction (i.e. before, during and/or after) with a nerve modulation technique such as ablation may be useful in such renal procedures as well as procedures elsewhere in the body.

[0006] The invention is defined by apparatus claim 1.

[0007] One embodiment pertains to an apparatus for percutaneously identifying nerve tissue that includes an elongate shaft for percutaneous deployment and an active imaging structure disposed on the distal region of the elongate shaft. The imaging structure may be configured to remotely image nerve tissue by exciting a signal in nerve tissue from a percutaneous location and receiving the signal from a percutaneous location. The imaging structure may include a first percutaneous probe for exciting the signal and a second percutaneous probe for receiving the signal, or may include a single percutaneous probe that both excites and receives the signal.

[0008] The elongate shaft can also include, in the distal region, a fixation element that has a collapsed configuration and an expanded configuration. Examples of such fixation elements include inflatable balloons The probe or probes is mounted on a module at the distal region, and the module is rotatable with respect to the elongate shaft. The module is located within the fixation element, in which case, the module is rotatable with respect to the fixation element as well. An actuation device may be operatively connected to the module to provide such movement.

[0009] The probe may be a photo-acoustic sensor comprising a radio frequency-emitter such as a light emitter and a phased array of transducers. The light-emitter may be configured to emit light towards a defined location and to change the intensity of the emission and the location of the emission relative to the probe. The light-emitter may comprise an element that can emit discrete pulses of light and may comprise a phased array of light emitting elements that can emit coherent light. A signal processor is preferably operatively connected to the probe. The signal processor may be used to process the signals from the probe and may be used in conjunction with the probe to image the nerve tissue and can be configured to use the signal from the probe to measure temperature.

[0010] The elongate shaft can also include a nerve modulation element in the distal region such as, for example, an ablation element. The ablation element is preferably configured to focus energy at a distance from the nerve modulation element such that the energy can pass through a first tissue to modulate the nerve tissue. The nerve modulation element can be an ultrasonic ablation element and can be configured to ablate the nerve tissue.

[0011] One embodiment pertains to a method of nerve modulation that includes the steps of identifying nerve tissue to be modulated from a percutaneous location in the body and modifying the nerve tissue from a percutaneous location. The nerve tissue to be identified may be spaced apart from the probe doing the identification and may be separated from the probe by intervening tissue. The method can also include the step of identifying changes in the nerve tissue during the modulation of the nerve tissue such as changes in temperature.

[0012] In some variations of the method, a dye that preferentially dyes or is otherwise preferentially taken up by nerve tissue is introduced to the region of interest. The identification of nerve tissue may thus be aided by this dye, which may be more responsive to the excitation signals than the nerve tissue itself. One contemplated sensor to be used during identification is a photo-acoustic sensor.

[0013] The modulation of the nerve tissue may be done by a probe spaced apart from the nerve tissue. Energy may be passed through a first tissue non-destructively to focus on the nerve tissue to target and ablate nerve tissue. An ultrasonic ablator comprising a phased array of transducers may be used to focus ultrasonic energy for the nerve modulation.

[0014] Within the structure of the embodiment described above, and expanding from these embodiments, a wide variety of alternatives are contemplated. Elements of these alternative embodiments will be described below.

[0015] For example, the elongate shaft may be a catheter, stylus or needle configured for percutaneous deployment. The excitation probe may be a separate element that is either another percutaneous member or on a member designed to be used outside the body and in conjunction with the receiving probe on the elongate shaft. In general, the apparatus may be configured for percutaneous deployment, intravascular deployment or deployment through any body opening or lumen, natural or man-made.

[0016] The probe may be configured to preferentially excite a signal in nerve tissue while exciting substantially no signal in other body tissue such as the non-nerve tissue of a blood vessel wall. To preferentially excite such a signal, the probe may be configured to emit light, coherent light or laser light in an appropriate part of the spectrum such as in the infrared region of the spectrum, the near infrared region, the visible region or the ultraviolet region, and may thereby excite fluorescence or other return signal from the nerve tissue.

[0017] In some configurations, the apparatus may work with a dye that has been applied in the region of interest. The dye may be a dye that preferentially dyes nerve tissue or molecules found in greater concentration in nerve tissue and preferentially tails to dye non-nerve tissue. The probe may excite fluorescence from such a dye. Conversely, the dye may be one that preferentially avoids nerve tissue. The probe, when exciting an image from such a dye by fluorescing or other means, may thus create a sort of negative image of the nerve tissue.

[0018] The probe may be configured to receive a light signal or an acoustic signal. In some cases, the excitation signal is a light signal such as a laser and the receiving signal is a light signal. In some cases, the excitation signal is a light signal such as a laser or an RF signal and the receiving signal is an acoustic signal (e.g. photo-acoustics). In some cases, the excitation signal is an acoustic signal and the receiving signal is an acoustic signal (e.g. ultrasound).

[0019] When the probe is configured to generate an acoustic signal, the signal may be an ultrasound signal. The ultrasound signal may have a frequency of less than 100 MHz, or a frequency of less than 90 MHz, or a frequency of less than 80 MHz and may also have a frequency of greater than 20 MHz or a frequency of greater than 40 MHz, or a frequency of greater than 60 MHz or have other suitable frequencies. The probe may also be used to generate ultrasonic frequencies suitable for ablation.

[0020] The apparatus may generally include driver electronics coupled to the probe and coupled to the receiver probe. There may be a controller coupled to the driver electronics and configured to control activation of the probe.

[0021] In some cases, the probe may comprise a phased array of emitters and the controller may be configured to control activation of each of the emitters in the phased array of emitters. The controller may be configured to electronically adjust a depth of focus of the phased array of emitters by selective and timed activation of the individual emitters in the phased array. A location of a focal point of the phased array of emitters may be adjusted in similar fashion. For example, the control may be configured to move the focal point of the phased array of emitters longitudinally with respect to the catheter and/or configured to move the focal point of the phased array of emitters radially with respect to the catheter. In addition, the controller may adjust the angular orientation of the focal point.

[0022] The receiving probe may comprise a phased array of receiving elements operatively connected to the controller. The depth of focus, radial, longitudinal and angular location of the focal point of the phased array of receiving elements can be adjusted through the controller. The emitters, receiving elements, and/or unified probe elements may be transducers or other elements appropriate to the sensing technology used.

[0023] The apparatus may comprise a probe actuator for moving the probe on the catheter radially and/or longitudinally and/or rotationally. Further, any of the phased arrays may further comprise a plurality of element actuators for individually adjusting the elements in the phased array.

[0024] The apparatus may further comprise a positioning element such as a centering element that fixes the distal region of the catheter in the center of a blood vessel or against a vessel wall. The positioning element may comprise a balloon, a non-occluding balloon such as a multi-lobed balloon or a balloon comprising an expandable helical element. The balloon may have a transparent balloon wall and may have a transparent expansion fluid. Alternative positioning elements may be self-expanding positioning elements such as a plurality of struts biased to an expanded state or a stent-like element.

[0025] The probe may be located at any convenient location. For example, the probe may be located between the proximal and distal ends of the centering element, distal of the distal end of the centering element, or proximal of the proximal end of the centering element. The probe and the receiving probe may overlap longitudinally along the longitudinal axis of the catheter.

[0026] Some embodiments further include an ablation element disposed in the distal region. The ablation element may be configured to focus energy at a distance by producing energy that passes through a first body tissue and ablates a second body tissue at a predetermined point. In general, the energy focuses at the predetermined point and is thus too dispersed in the area of the first body tissue to modulation or otherwise affect the first tissue. The ablation element may use any suitable ablation technology such as ultrasound, electromagnetic energy such as radio frequency, microwave energy, laser light or cryogenic energy. In general, ultrasound and light are the technologies most suitable for use with systems that focus the ablation energy at a distance to pass through intervening tissue. The ablation element may

comprise an array of energy elements that are configured to be used cooperatively to ablate targeted tissue, such as a phased array of transducers. It is possible for the probe function and the ablation function to use the same transducers. The phased array has a focal point that may be adjusted as previously described.

[0027] One example embodiment is a needle or other percutaneous device having a renal modulation element and a sensing element such as an ultrasound element or a photo-acoustic element or portion of a photo-acoustic element. In the case of the photo-acoustic element, the excitation element may be on the probe or may be a separate component. The renal nerve modulation element may be an ultrasound element or other suitable element such as those described above or a drug delivery element.

[0028] Naturally, any of the apparatuses described above can be used in a method of moving the distal region of the apparatus percutaneously to the region of interest, exciting a signal, and receiving the signal. Further steps preferably include processing the receiving signal, and communicating the received signal from the apparatus by, for example, displaying the received signal on an electronic display. Ways of displaying the signal include displaying the received signal in a graph or on an image of the region of interest. The communication of the received signal may also include providing an auditory indication.

[0029] The probe may be moved rotationally and/or longitudinally through the region of interest while activating the probe to excite the signal. In some embodiments, the probe is moved after moving a positioning and/or fixation element to the expanded position, and the probe is moved relative to the positioning element.

[0030] The activation of the probe generally comprises exciting a signal in nerve tissue. The signal may be, for example, a fluorescing of the nerve tissue or an acoustic signal. In some methods, a dye that preferentially binds to nerve tissue is provided in the region of interest. The dye maybe provided percutaneously, intravascularly or orally and may be provided through a separate injection system.

[0031] The activation of the probe may comprise generating light such as laser light, ultraviolet light, infrared light or other suitable light or radiofrequency energy, or generating ultrasound energy. The ultrasound energy may be provided at a frequency of less than about 100 MHz or 80 MHz, and/or a frequency of greater than 20 MHz, 40 MHz, or 60 MHz. The activation of the probe may further comprise modulating emitted energy by, for example, emitting energy towards a focal point. One may select a focal point at a predetermined location at a distance from the probe and emitting energy to maximize the energy at the predetermined location. One may modulate by emitting energy towards the focal point while changing a characteristic of the focal point (e.g. changing a radial distance of the focal point to the probe, changing a longitudinal location relative the probe, changing a radial location relative the probe, changing an intensity of the energy at the focal point, widening the focal point, or changing an intensity of the energy at the focal point may comprise increasing or decreasing the amount of energy emitted by the probe).

[0032] The step of receiving the signal may comprise the step of receiving an acoustic wave. A controller can be used to selectively process the received signal to determine characteristics of the tissue at locations spaced away from the receiving element. For example, using a phased array of receiving elements, one can focus on receiving a signal from a particular location spaced away from the phased array. This location can be modified as described above and may be synchronized with the focal point of the excitation signal.

[0033] With those embodiments that include an ablation element, the method may further comprise the step of activating the ablation element. The ablation element may have a focal point like the excitation element above, and the focal point may be modified in like manner. One may track changes in the signals over time, and identify the differences in the signals. This may help identify the location of any ablation and the effectiveness of the ablation procedure. One can image the area prior to the ablation treatment and in some cases continue to image the area during the ablation treatment or intermittently image the area during or between ablation treatments. In some methods, one can use ultrasonic signals to measure temperature. One may sequentially determine a treatment location and then ablate at the treatment location, and then repeat the process as desired.

[0034] These methods may be used in any region of the body, including but not limited to a renal artery, a coronary artery, a vein, a descending aorta, an organ, a stomach, a colon, a trachea or other area of interest.

[0035] The above summary of some example embodiments is not intended to describe each disclosed embodiment or every implementation of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] Embodiments of the invention may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

Figure 1 is a diagram of an example nerve imaging and modulation catheter;

Figure 2 is a cut-away diagram illustrating details at the distal end of the catheter;

Figure 3A illustrates the distal end of an example catheter in situ;

Figure 3B illustrates the distal end of the example catheter of Fig. 3A in situ.

[0037] While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however,

that the intention is not to limit aspects of the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

DETAILED DESCRIPTION

[0038] For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

[0039] All numeric values are herein assumed to be modified by the term "about", whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the term "about" may be indicative as including numbers that are rounded to the nearest significant figure.

[0040] The recitation of numerical ranges by endpoints includes all numbers within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

[0041] Although some suitable dimensions ranges and/or values pertaining to various components, features and/or specifications are disclosed, one of skill in the art, incited by the present disclosure, would understand desired dimensions, ranges and/or values may deviate from those expressly disclosed.

[0042] As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

[0043] The terms "preferential" and "preferentially" mean that the modified element is disproportionally affected relative to other elements. For example, the phrase "preferentially exciting a signal in nerve tissue" means the excitation of the signal in nerve tissue is greater than in other tissue. This is in contrast to merely exciting a signal in nerve tissue, which may be understood to mean that other tissues may be equally excited, or non-preferentially exciting a signal in nerve tissue, which may be understood to mean that other tissues are equally excited

[0044] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The detailed description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention. The illustrative embodiments depicted are intended only as exemplary. Selected features of any illustrative embodiment may be incorporated into an additional embodiment unless clearly stated to the contrary.

[0045] Figure 1 is a diagram of an example imaging and nerve modulation catheter 100 that can be employed to identify nerve tissue and deliver a localized therapy to the nerve tissue. As shown in one implementation, the catheter 100 includes a distal inflatable balloon portion 102 that can be routed to a treatment site inside a patient to image and deliver therapy to that treatment site; a proximal end 104 that remains outside a patient during treatment and facilitates connection of various equipment to the catheter 100; and an elongate member or catheter shaft 106 that couples the proximal-end equipment to the distal inflatable balloon portion.

[0046] The catheter's elongate member 106 may include one or more internal lumens (not shown in FIG. 1). The lumens allow inflation fluid to be delivered distally from an external inflation fluid source 108 to an internal chamber of the balloon 102. The elongate member 106 also includes conductors (not shown) that carry electrical signals from components such as sensing elements (e.g., sensing elements 112a/112b, which can be seen in FIG. 2) and ablation elements (e.g., ablation element 114, which can be seen in FIG. 2) in the balloon 102 to a signal processor 110 at the proximal end of the catheter 100.

[0047] The signal processor 110 can process the electrical signals to electrically characterize signals from the sensing elements 112a/112b. In particular, the signal processor 110, in some implementations, generates visual displays, such as isochronal or isopotential maps of the tissue, which a physician may use to identify aberrant electrical pathways at locations in the body tissue that may be candidates for nerve modulation or maps which a physician may use to identify nerve tissue. The visual displays may be provided in a user interface 116 (e.g., a flat panel display, or other suitable output device).

[0048] The signal processor 110 can include circuitry for receiving acoustic or light signals or biopotential signals (e.g., differential amplifiers or other amplifiers that sense biopotential signals and amplify them to levels that can be used in further processing) and processing the signals in a manner that permits their subsequent analysis, for example by a medical professional delivering or considering delivering therapy to a patient.

[0049] In some implementations, the signal processor 110 includes dedicated circuitry (e.g., discrete logic elements and one or more microcontrollers; application-specific integrated circuits (ASICs); or specially configured programmable devices, such as, for example, programmable logic devices (PLDs) or field programmable gate arrays (FPGAs)) for processing biopotential signals and displaying a graphical representation of the signals in a user interface. In some implementations, the signal processor 110 includes a general purpose microprocessor and/or a specialized microprocessor (e.g., a digital signal processor, or DSP, which may be optimized for processing graphical or a biometric information) that executes instructions to receive, analyze and display information associated with the received signals. In such implementations, the signal processor 110 can include program instructions, which when executed, perform part of

the signal processing. Program instructions can include, for example, firmware, microcode or application code that is executed by microprocessors or microcontrollers. The above-mentioned implementations are merely exemplary, and the reader will appreciate that the signal processor 110 can take any suitable form.

[0050] A controller 118 at the proximal end can control the sensing elements 112a/112b and/or the nerve modulation elements 114 to generate probing signals and/or therapeutic emissions. In some embodiments, a separate controller may be used for controlling the nerve modulation elements 114. The controller 118 itself can take many different forms. In some implementations, the controller 118 is a dedicated electrical circuit employing various sensors, logic elements and actuators. In other implementations, the controller 118 is a computer-based system that includes a programmable element, such as a microcontroller or microprocessor, which can execute program instructions stored in a corresponding memory or memories. Such a computer-based system can take many forms, include many input and output devices (e.g., a user interface and other common input and output devices associated with a computing system, such as keyboards, point devices, touch screens, discrete switches and controls, printers, network connections, indicator lights, etc.) and may be integrated with other system functions, such as monitoring equipment, a computer network, other devices that are typically employed during a procedure, etc. For example, a single computer-based system may include a processor that executes instructions to provide the controller function, display imaging information associated with a procedure (e.g., from an imaging device); display pressure, temperature and time information (e.g., elapsed time since a given phase of treatment was started); and serve as an overall interface to the catheter 100. In general, various types of controllers are possible and contemplated, and any suitable controller 118 can be employed. Moreover, in some implementations, the controller 118 and the signal processor 110 may be part of a single computer-based system, and both control and signal processing functions may be provided, at least in part, by the execution of program instructions in a single computer-based system.

[0051] The catheter 100 shown in FIG. 1 is an over-the-wire type catheter. Such a catheter 100 uses a guidewire 120, extending from the distal end of the catheter 100. In some implementations, the guidewire 120 may be pre-positioned inside a patient's body; once the guidewire 120 is properly positioned, the balloon 102 (in a deflated state) and the elongate member 106 can be routed over the guidewire 120 to a treatment site. In some implementations, the guidewire 120 and balloon portion 102 of the catheter 100 may be advanced together to a treatment site inside a patient's body, with the guidewire 120 leading the balloon 102 by some distance (e.g., several inches). When the guidewire portion 120 reaches the treatment site, the balloon 102 may then be advanced over the guidewire 120 until it also reaches the treatment site. Other implementations are contemplated, such as steerable catheters that do not employ a guidewire. Moreover, some implementations include an introducer sheath that can function similar to a guidewire, and in particular, that can be initially advanced to a target site, after which other catheter portions can be advanced through the introducer sheath.

[0052] The catheter 100 can include a manipulator (not shown), by which a medical practitioner may navigate the guidewire 120 and/or balloon 102 through a patient's body to a treatment site. In some implementations, release of cryogenic fluid into a cooling chamber may inflate the balloon 102 to a shape similar to that shown in FIG. 1. In other implementations, a pressure source 108 may be used to inflate the balloon 102 independently of the release of cryogenic fluid into the internal chamber of the balloon 102. The pressure source 108 may also be used to inflate an anchor member on the end of the guidewire 120 (not shown).

[0053] The catheter 100 includes a connector for connecting to the user interface 116, the controller 118 and the signal processor 110. The user interface may include monitoring equipment that may be used, for example, to monitor temperature or pressure at the distal end of the catheter 100. As indicated above, the monitoring equipment may be integrated in a single system that also provides the controller and signal processor. To aid in positioning the balloon 102 of the catheter 100 inside a patient's body, various marker bands (not shown) can also be disposed at the distal and proximal ends of the catheter 100. The marker bands may be radio-opaque when the catheter is viewed by x-ray or other imaging techniques. Other variations in the catheter 100 are contemplated. A guidewire may be arranged differently than shown, and may be separately controlled from the balloon portion of the catheter. Moreover, in some implementations, a guidewire may not be used.

[0054] Figure 2 illustrates some of the internal details of balloon 102. The balloon 102 includes a balloon wall 122 that may be formed from a polymer including, but not limited to, polyolefin copolymer, polyester, polyethylene terephthalate, polyethylene, polyether-block-amide, polyamide, polyimide, nylon, latex, or urethane. Balloon wall 122 is preferably transparent and is also preferably compliant. Balloon 102 includes an inner module 124 that may carry the sensing element 112a/112b and the nerve modulation elements 114. The inner module 124 is cylindrical and is rotatably mounted with respect to the balloon. An electrical actuation element 126 may allow rotation of the inner module 124 with respect to the balloon.

[0055] The sensing elements 112a/112b may be configured to identify nerve tissue and may comprise photo-acoustic elements, ultrasound elements, light sensors or other suitable nerve detection elements.

[0056] Photo-acoustic imaging uses the physical phenomenon of an acoustic wave being produced from a sample that is stimulated using electromagnetic energy. Generally, the tissue is irradiated using high-intensity

pulses of light or radiofrequency energy. These pulses are preferably short (1-100 ns). The wavelength of the pulsed of light may vary and, in some embodiments, may be in the range of about 400-500 nm (e.g., 450 nm) or, in some other embodiments, may be about 1200 nm or greater. These are just examples. Broadband acoustic waves are then generated from absorption of the energy in the tissue within the irradiated volume. Short (e.g. nanosecond) pulses may generate the highest resolution acoustic return signals. The acoustic return signals can be detected using an ultrasound detector and subsequently processed to provide spatial organization to generate an image of the target tissue. The strength of the acoustic return signal is related to the intensity and the wave-length of the pulses of coherent light and also related to the local optical absorption coefficient of the target tissue. Using photo-acoustic imaging, it is possible to distinguish between different tissue types at a high level of resolution (e.g. on the order of about 20-200 micrometers). Using preferential contrast dyes that have high optical absorption coefficients, photo-acoustic imaging techniques may be performed on the cellular and molecular level.

[0057] Sensing elements 112a may be configured to emit pulses of coherent light (e.g., having a wavelength in the range of about 400-500 or having a wavelength of about 1200 nm or greater) and sensing elements 112b may be configured to receive acoustic signals generated by the pulses of coherent light in the nerve tissue. For example, sensor elements 112a may be laser diodes and sensor elements 112b may be transducers. Sensor elements 112a preferably are configured to focus the coherent light at a focus point. The focus point may be a predetermined focus point or may be movable. The focus point may, for example be moved through the use of element actuators (not shown) under each of the sensor elements 112a, through using sensor elements 112a as a phased array, through the use of one or more lenses or other suitable means. The sensor elements 112b (the receiving elements) may be configured as a phased array, which allows either the elements or the controller 118 or signal processor 110 to determine where the reflected signals are coming from. In this manner, a three dimensional map that includes depth through the vessel wall can be created to identify the presence of nerve tissue.

[0058] In some embodiments, the sensor elements 112b can also measure temperature and detect temperature changes. Ultrasonic signals generated in the tissue are a function of the material properties of the tissue. Pertinent properties are the speed of sound through the material, which changes with temperature, and the thermal expansion of the material with temperature. These properties change as temperature changes and affect, in a predictable manner, the ultrasonic waves generated by the tissue. The signal processor 110 can therefore be configured to measure temperature deep in the tissue and/or detect temperature changes in the tissue. Such measurements may be useful in temperature dependent nerve modulation techniques to determine the temperatures at locations and the amount of time the tissue at those locations is exposed to particular temperatures.

[0059] A dye that preferentially attaches to nerve tissue or to molecules found in higher concentrations in nerve tissue may be used in conjunction with the sensing elements 112. The dye may have a high-optical absorption coefficient at a predetermined frequency and the sensing elements 112a may emit coherent light at that frequency. In this manner, the sensitivity of the system to the dye and the corresponding nerve tissue may be heightened resulting in more effective or deeper imaging of the nerve tissue. Such a dye may be injected by a separate needle into the area of interest prior to introduction of the catheter into the patient's body, may be introduced through a lumen of the catheter into the body vessel or may be introduced through another suitable manner such as topically or orally.

Other focusing elements such as those described in commonly owned U.S. Patent Application Serial No. 61/324,164 and/or U.S. Patent Application Publication No. US 2011/0257523 may be used with either sensing elements 112a, 112b or, as described below, with ablation elements 114.

[0060] The inner module 124 also includes ablation elements 114. Preferably, ablation elements that can ablate at depth without disrupting intervening tissue are used. Such ablation elements may include laser ablation elements and ultrasonic ablation elements. In some embodiments, sensing elements 112a or 112b can also function as the ablation elements. However, other ablation elements, such as radiofrequency ablation elements or cryogenic ablation elements may also be used. In the embodiment shown in Fig. 2, ablation elements 114 are ultrasonic ablation elements and are in the form of a phased array, which allows the ablation element to target the tissue at a selected depth of focus and may also allow the focal point to be moved laterally.

[0061] In use, the catheter may be deployed percutaneously or intravascularly to a region of interest, and the balloon 102 may be expanded to fix the distal end of the catheter in place during the procedure. The balloon may preferably be expanded using a clear inflation fluid such as saline. Sensing elements 112a/112b may then be activated to create an image of the region of interest preferentially identifying the nerve tissue. In renal arteries, for example, nerve tissue generally lies at depths of between 2 and 8 mm. The inner module 124 may be rotated during imaging to create an image of the body vessel on all sides of the balloon to identify nerve tissue in the region proximate the balloon. Once the nerve tissue is identified, the inner module may be rotated to aim the ablation elements 114 at the nerve tissue. The nerve tissue may then be ablated by activating the ablation elements 114. The ablation elements 114 may be focused to ablate only the targeted nerve tissue.

[0062] Figure 3A illustrates the distal portion of an ex-

ample catheter 200 in a body vessel lumen. Catheter 200 includes a balloon 102 and a module 124. The module 124 may be rotatable using actuation element 126. Module 124 includes ultrasonic phased arrays 130 and light emitting element 132. Light emitting element 132 emits short pulses of light 134, which are selected to preferentially excite nerve tissue 136. Any nerve tissue 136 thereby emits acoustic waves 138, which can be picked up by ultrasonic arrays 130. The module may be rotated during this process to identify nerve tissue in the area of interest. As illustrated in Figure 3B, once nerve tissue has been identified, the ultrasonic arrays can then focus ablation energy 140 to a focal point 142 to ablate the nerve tissue 136. The module 124 can be rotated to ablate additional nerve tissue. The depth of field of the focal point may be modified altered, depending on the depth and location of the nerve tissue.

[0063] Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departure in form and detail may be made without departing from the scope of the present invention as described in the appended claims.

Claims

1. An apparatus (100) for identifying nerve tissue, the apparatus comprising:

   an elongate shaft (106) having a distal region configured to be percutaneously deployed within a patient; and
   an active imaging structure disposed on the distal region, the active imaging structure configured to remotely image nerve tissue by exciting a signal in a nerve tissue from a percutaneous location and receiving the signal from a percutaneous location;
   wherein the active imaging structure includes one or more probes (112a, 112b);
   wherein the elongate shaft (106) comprises a fixation element in the distal region, the fixation element having a collapsed configuration and an expanded configuration,
   wherein the fixation element is an expandable balloon (102),
   characterized in that the elongate shaft (106) further comprises a cylindrical module (124) disposed in the distal region, said cylindrical module being provided at an outer surface of the elongate shaft, wherein the one or more probes (112a, 112b) are disposed on said cylindrical module (124), wherein the cylindrical module is rotatable with respect to the fixation element and with respect to the elongated shaft, and the cylindrical module (124) is disposed within a cavity of the balloon.

2. The apparatus of claim 1, wherein the active imaging structure comprises a first percutaneous probe for exciting the signal and a second percutaneous probe for receiving the signal.

3. The apparatus of claim 1, wherein the active imaging structure comprises a single percutaneous probe for exciting and receiving the signal.

4. The apparatus of any one of claims 1-3, wherein the one or more probes include a photo-acoustic sensor comprising a light emitter and a phased array of transducers.

5. The apparatus of claim 4, wherein the light-emitter includes a laser diode.

6. The apparatus of claim 4, wherein the light-emitter is configured to emit coherent light towards a focal point.

7. The apparatus of claim 6, wherein the light-emitter is configured to change the depth of focus of the focal point.

8. The apparatus of claim 6, wherein the light-emitter comprises a phased array of light emitting elements.

9. The apparatus of any one of claims 1-8, further comprising a signal processor (110) configured to use the signal to measure temperature.

10. The apparatus of any one of claims 1-9, further comprising an ablation element (114) configured to focus energy at a distance from the ablation element such that the energy can pass through a first tissue to ablate a second tissue.

11. The apparatus of claim 10, wherein the ablation element is an ultrasonic ablation element.

Patentansprüche

1. Vorrichtung (100) zum Identifizieren von Nervengewebe, wobei die Vorrichtung aufweist:

   einen länglichen Schaft (106), der einen distalen Bereich aufweist, der konfiguriert ist, perkutan innerhalb eines Patienten eingesetzt zu werden; und
   eine aktive Abbildungsstruktur, die am distalen Bereich angeordnet ist, wobei die aktive Abbildungsstruktur konfiguriert ist, Nervengewebe durch Anregen eines Signals in einem Nervengewebe von einer perkutanen Stelle aus und Empfangen des Signals an einer perkutanen Stelle aus der Ferne abzubilden;

wobei die aktive Abbildungsstruktur eine oder mehrere Sonden (112a, 112b) umfasst;
wobei der längliche Schaft (106) ein Befestigungselement im distalen Bereich aufweist,
wobei das Befestigungselement eine kollabierte Konfiguration und eine ausgedehnte Konfiguration aufweist,
wobei das Befestigungselement ein ausdehnbarer Ballon (102) ist,
dadurch gekennzeichnet, dass der längliche Schaft (106) ferner ein zylindrisches Modul (124) aufweist, das im distalen Bereich angeordnet ist, wobei das zylindrische Modul an einer Außenfläche des länglichen Schafts vorgesehen ist, wobei die eine oder die mehreren Sonden (112a, 112b) am zylindrischen Modul (124) angeordnet sind, wobei das zylindrische Modul bezüglich des Befestigungselements und bezüglich des länglichen Schafts drehbar ist, und das zylindrische Modul (124) innerhalb eines Hohlraums des Ballons angeordnet ist.

2. Vorrichtung nach Anspruch 1, wobei die aktive Abbildungsstruktur eine erste perkutane Sonde zum Anregen des Signals und eine zweite perkutane Sonde zum Empfangen des Signals aufweist.

3. Vorrichtung nach Anspruch 1, wobei die aktive Abbildungsstruktur eine einzige perkutane Sonde zum Anregen und Empfangen des Signals aufweist.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, wobei die eine oder die mehreren Sonden einen photoakustischen Sensor umfassen, der einen Lichtemitter und eine phasengesteuerte Transduceranordnung aufweist.

5. Vorrichtung nach Anspruch 4, wobei der Lichtemitter eine Laserdiode aufweist.

6. Vorrichtung nach Anspruch 4, wobei der Lichtemitter konfiguriert ist, kohärentes Licht auf einen Brennpunkt zu emittieren.

7. Vorrichtung nach Anspruch 6, wobei der Lichtemitter konfiguriert ist, die Tiefenschärfe des Brennpunkts zu ändern.

8. Vorrichtung nach Anspruch 6, wobei der Lichtemitter eine phasengesteuerte Anordnung von lichtemittierenden Elementen aufweist.

9. Vorrichtung nach einem der Ansprüche 1 bis 8, die ferner einen Signalprozessor (110) aufweist, der konfiguriert ist, das Signal zu verwenden, um die Temperatur zu messen.

10. Vorrichtung nach einem der Ansprüche 1 bis 9, die ferner ein Ablationselement (114) aufweist, das konfiguriert ist, Energie in einem Abstand vom Ablationselement so zu fokussieren, dass die Energie durch ein erstes Gewebe gehen kann, um ein zweites Gewebe zu abladieren.

11. Vorrichtung nach Anspruch 10, wobei das Ablationselement ein Ultraschall-Ablationselement ist.

Revendications

1. Dispositif (100) pour l'identification d'un tissu nerveux, ledit dispositif comprenant :

une tige allongée (106) ayant une partie distale prévue pour être déployée par voie percutanée dans le corps d'un patient ; et
une structure d'imagerie active disposée dur la partie distale, la structure d'imagerie active étant prévue pour représenter à distance le tissu nerveux par excitation d'un signal dans le tissu nerveux d'un emplacement percutané et réception du signal d'un emplacement percutané ;
où la structure d'imagerie active comprend une ou plusieurs sondes (112a, 112b) ;
où la tige allongée (106) comprend un élément de fixation dans la partie distale, ledit élément de fixation présentant une configuration contractée et une configuration expansée,
où l'élément de fixation est un ballonnet expansible (102)
caractérisé en ce que la tige allongée (106) comprend en outre un module cylindrique (124) disposé dans la partie distale, ledit module cylindrique étant prévu sur une surface extérieure de la tige allongée, la ou les sondes (112a, 112b) étant disposées sur le module cylindrique (124), le module cylindrique étant rotatif par rapport à l'élément de fixation et par rapport à la tige allongée, et
le module cylindrique (124) est disposé dans une cavité du ballonnet.

2. Dispositif selon la revendication 1, où la structure d'imagerie active comprend une première sonde percutanée pour l'excitation du signal et une deuxième sonde percutanée pour la réception du signal.

3. Dispositif selon la revendication 1, où la structure d'imagerie active comprend une seule sonde percutanée pour l'excitation et la réception du signal.

4. Dispositif selon l'une des revendications 1 à 3, où la ou les sondes sont pourvues d'un capteur photoacoustique comprenant un émetteur de lumière et un réseau de transducteurs à commande de phase.

5. Dispositif selon la revendication 4, où l'émetteur de lumière comprend une diode laser.

6. Dispositif selon la revendication 4, où l'émetteur de lumière est prévu pour émettre une lumière cohérente vers un point focal.

7. Dispositif selon la revendication 6, où l'émetteur de lumière est prévu pour varier la profondeur de champ du point focal.

8. Dispositif selon la revendication 6, où l'émetteur de lumière comprend un réseau d'éléments émetteurs de lumière à commande de phase.

9. Dispositif selon l'une des revendications 1 à 8, comprenant en outre un processeur de signal (110) prévu pour exploiter le signal afin de mesurer une température.

10. Dispositif selon l'une des revendications 1 à 9, comprenant en outre un élément d'ablation (114) prévu pour focaliser l'énergie à distance de l'élément d'ablation de sorte que l'énergie puisse traverser un premier tissu pour procéder à l'ablation d'un deuxième tissu.

11. Dispositif selon la revendication 10, où l'élément d'ablation est un élément d'ablation à ultrasons.

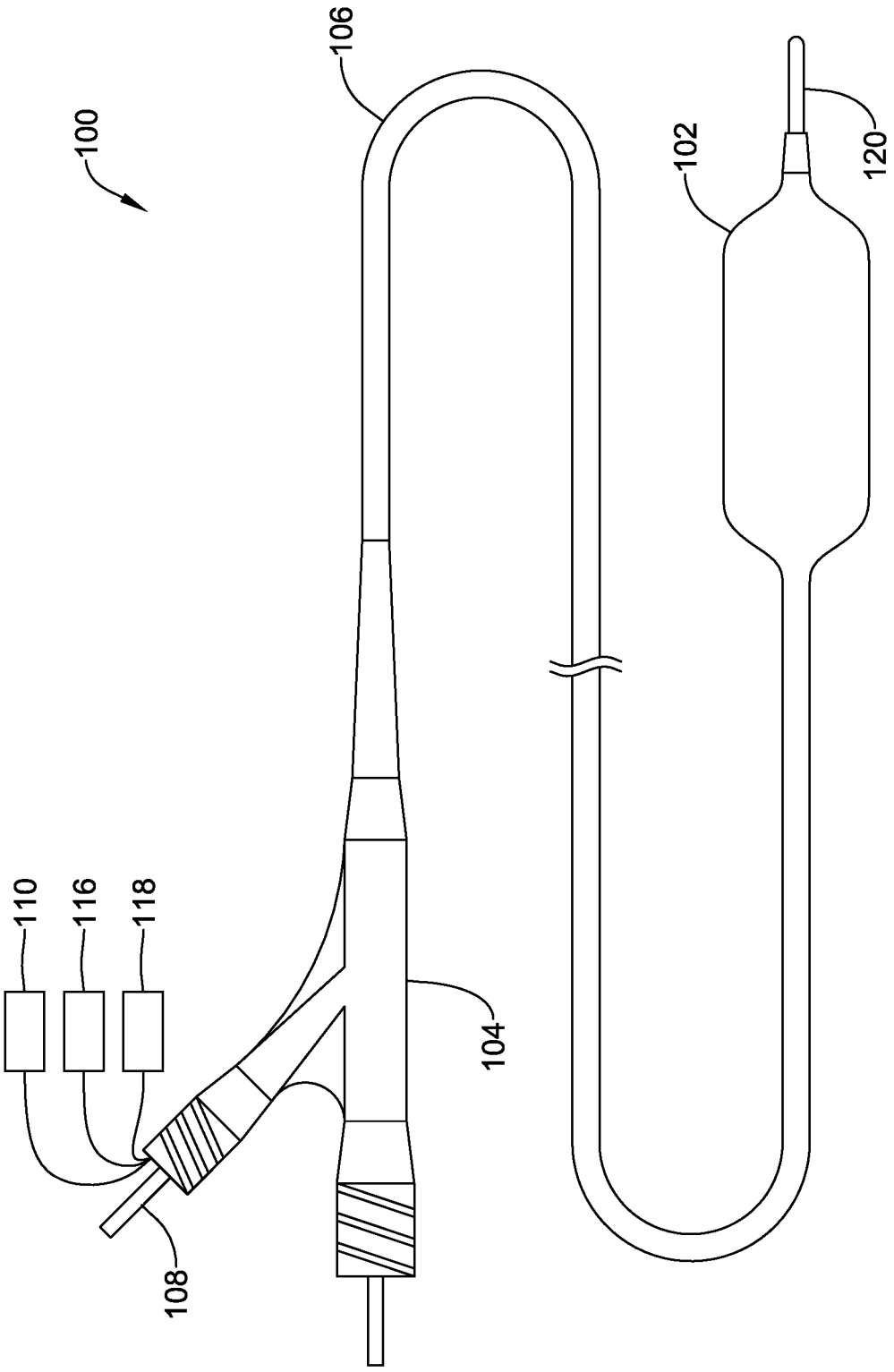

Figure 1

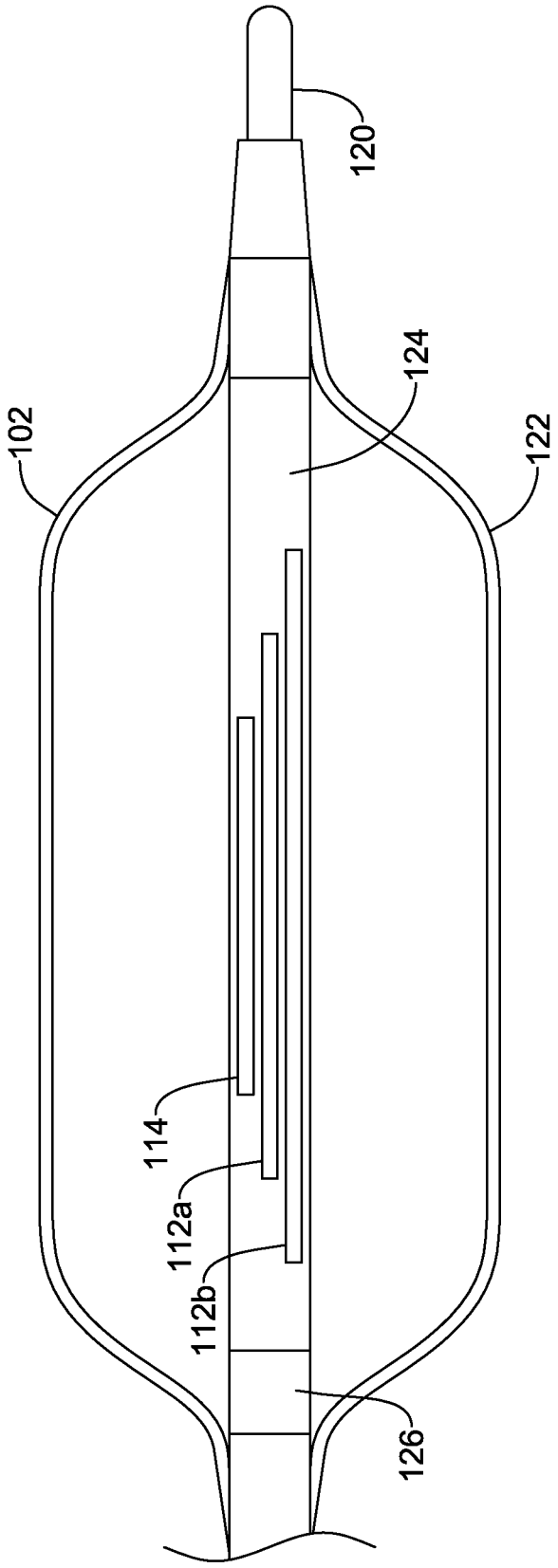

Figure 2

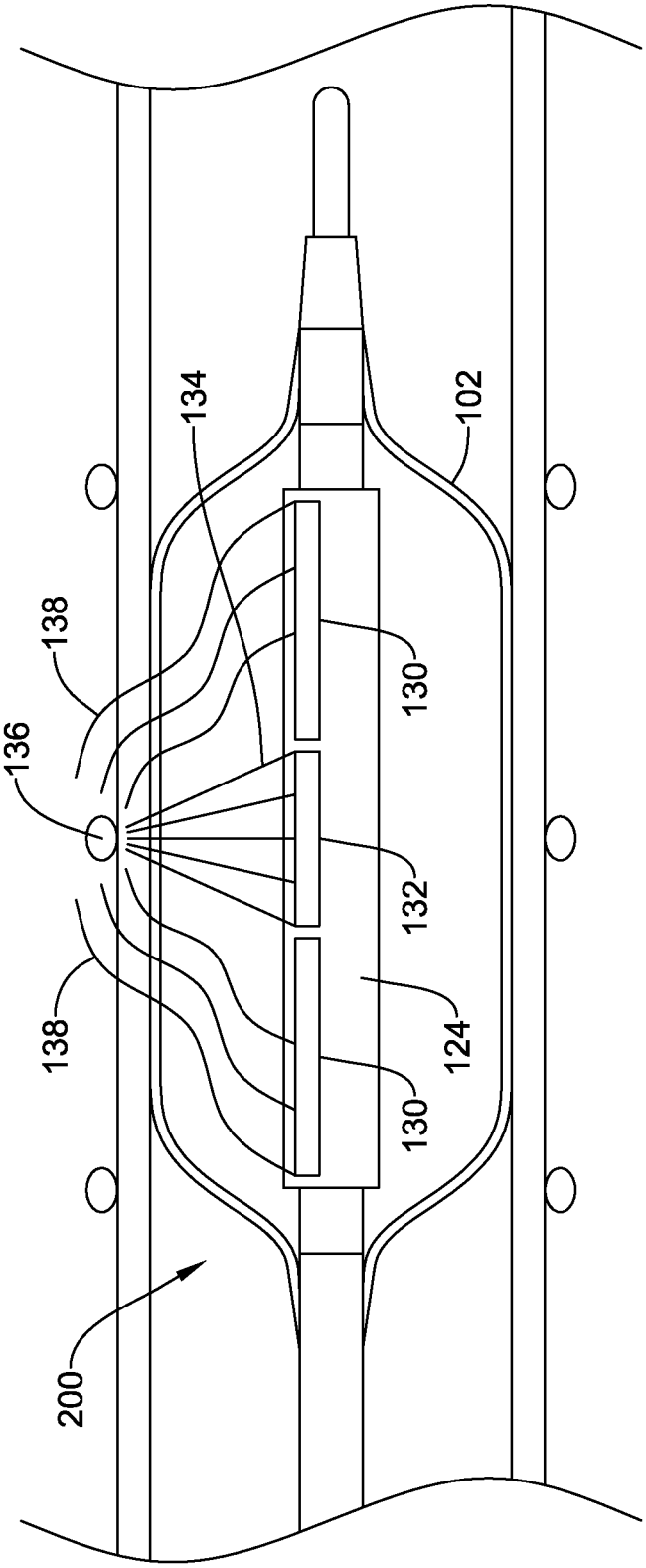

Figure 3A

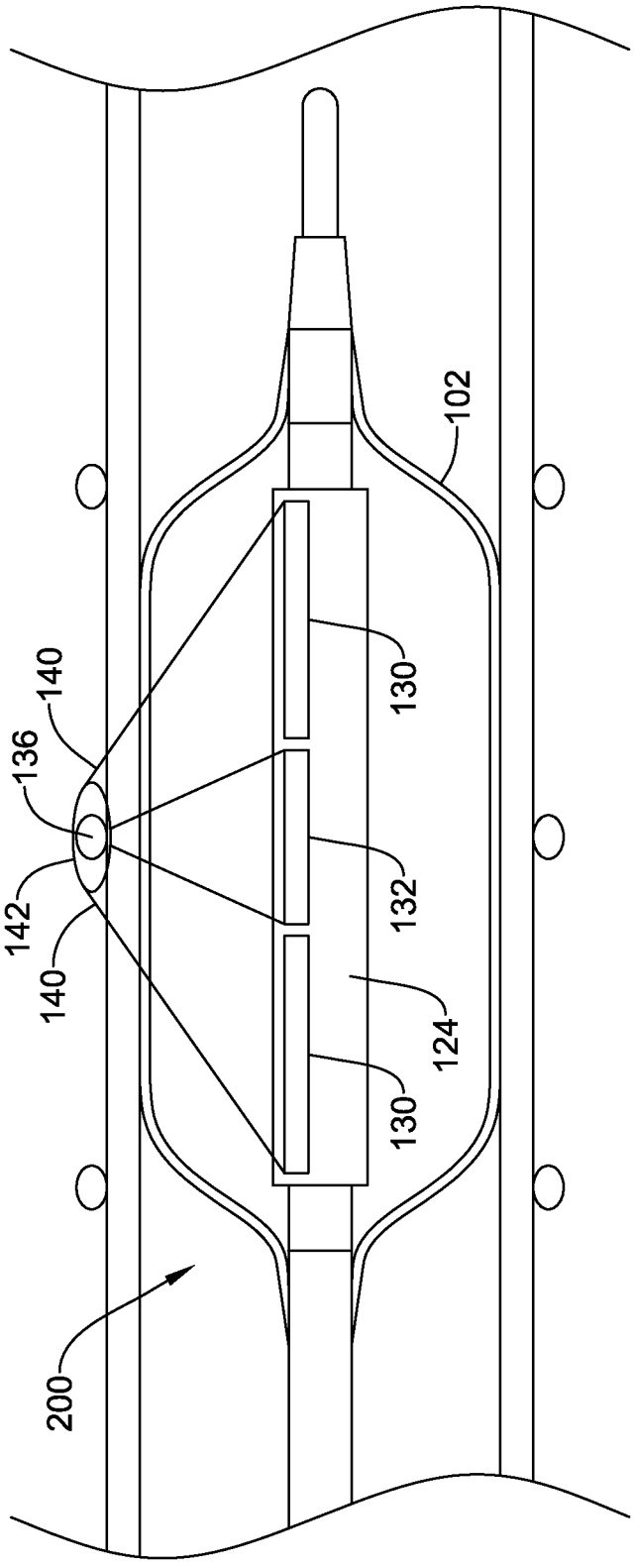

Figure 3B

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	经皮装置可视化，瞄准和消融神经		
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其他公开文献	EP2734259A2		
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摘要(译)

公开了用于识别神经组织的设备及其制造和使用方法。示例设备可以包括具有远端区域的细长轴，该远端区域被配置为在患者体内经皮部署。主动成像结构可以设置在远端区域上。主动成像结构可以被配置为通过从经皮位置激励神经组织中的信号并从经皮位置接收信号来对神经组织进行远程成像。主动成像结构可以包括一个或多个探针。

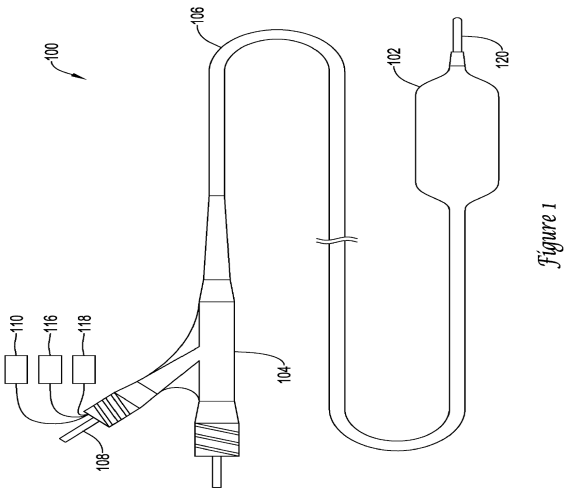

Figure 1