



US009579030B2

(12) **United States Patent**
Scheuermann et al.

(10) **Patent No.:** **US 9,579,030 B2**
(45) **Date of Patent:** **Feb. 28, 2017**

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

USPC 600/439, 462, 466; 606/11
See application file for complete search history.

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/554,391**

(22) Filed: **Jul. 20, 2012**

(65) **Prior Publication Data**

US 2013/0165764 A1 Jun. 27, 2013

Related U.S. Application Data

(60) Provisional application No. 61/509,954, filed on Jul. 20, 2011.

(51) **Int. Cl.**

A61B 5/05 (2006.01)
A61B 5/04 (2006.01)
A61N 7/02 (2006.01)
A61B 5/00 (2006.01)
A61B 5/01 (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC **A61B 5/04001** (2013.01); **A61B 5/0095** (2013.01); **A61B 5/01** (2013.01); **A61B 5/201** (2013.01); **A61B 5/4029** (2013.01); **A61N 7/02** (2013.01); **A61B 8/4461** (2013.01); **A61B 18/26** (2013.01); **A61B 2018/0022** (2013.01); **A61B 2018/00214** (2013.01); **A61B 2018/00285** (2013.01); **A61N 1/403** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC **A61B 2018/00214**; **A61B 8/4461**;
A61B 18/26; **A61B 2018/0022**; **A61B 2018/00285**; **A61B 5/6853**; **A61N 7/02**;
A61N 2007/0082; **A61N 1/403**; **A61N 2007/0091**; **A61N 7/00**

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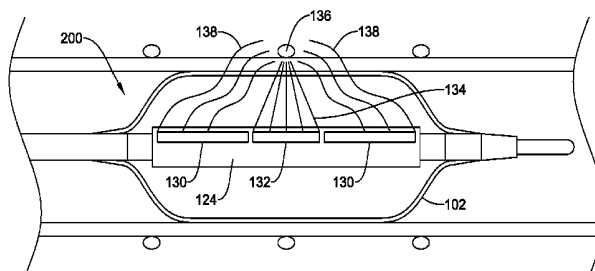
Primary Examiner — Long V Le

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(57) **ABSTRACT**

Apparatuses for identifying nerve tissue and methods for making and using the same are disclosed. An example apparatus may include an elongate shaft having a distal region configured to be percutaneously deployed within a patient. An active imaging structure may be disposed on the distal region. The active 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 active imaging structure may include one or more probes.

11 Claims, 4 Drawing Sheets



- (51) **Int. Cl.**
A61B 5/20 (2006.01)
A61B 18/00 (2006.01)
A61B 8/00 (2006.01)
A61N 7/00 (2006.01)
A61N 1/40 (2006.01)
A61B 18/26 (2006.01)
- (52) **U.S. Cl.**
 CPC *A61N 7/00* (2013.01); *A61N 2007/0082* (2013.01); *A61N 2007/0091* (2013.01)
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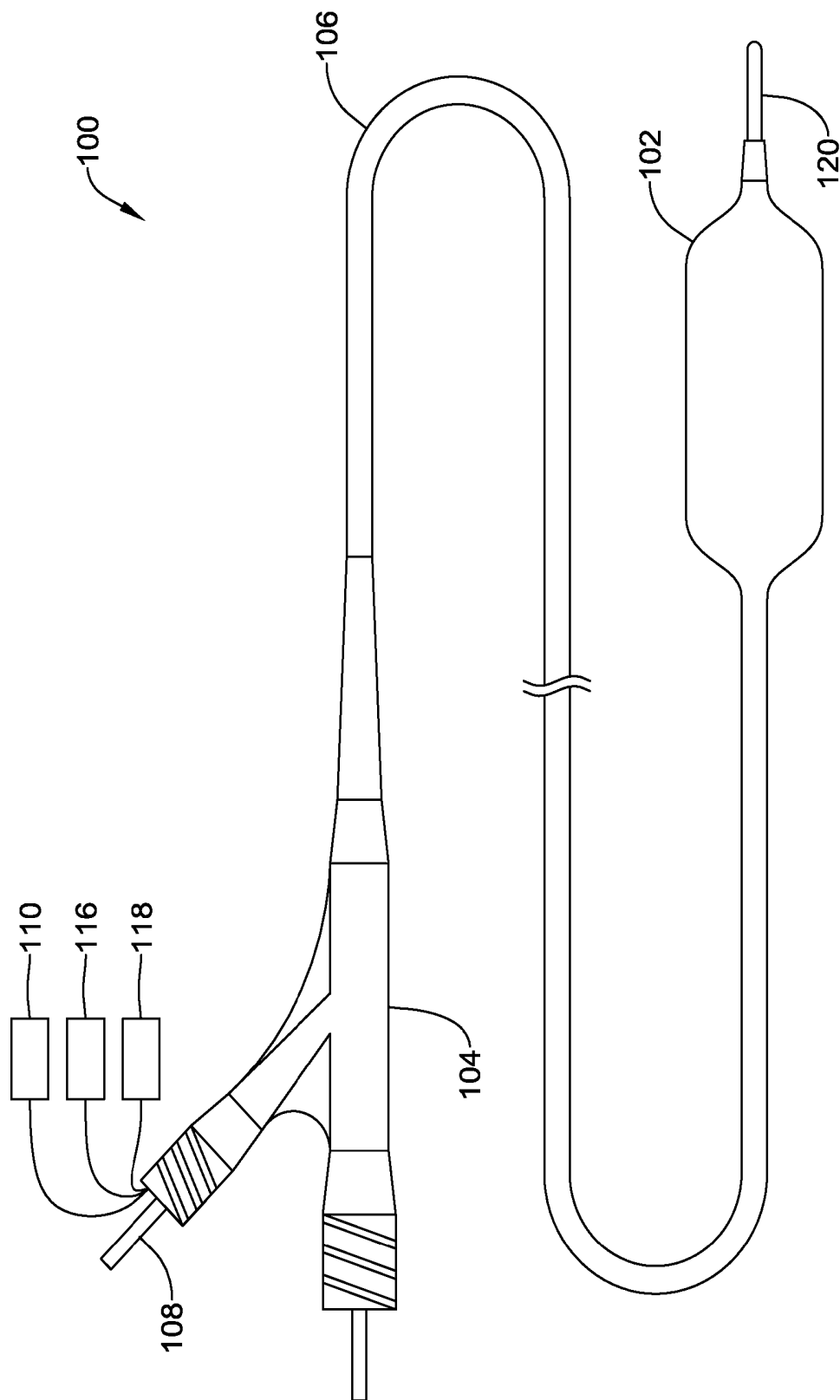


Figure 1

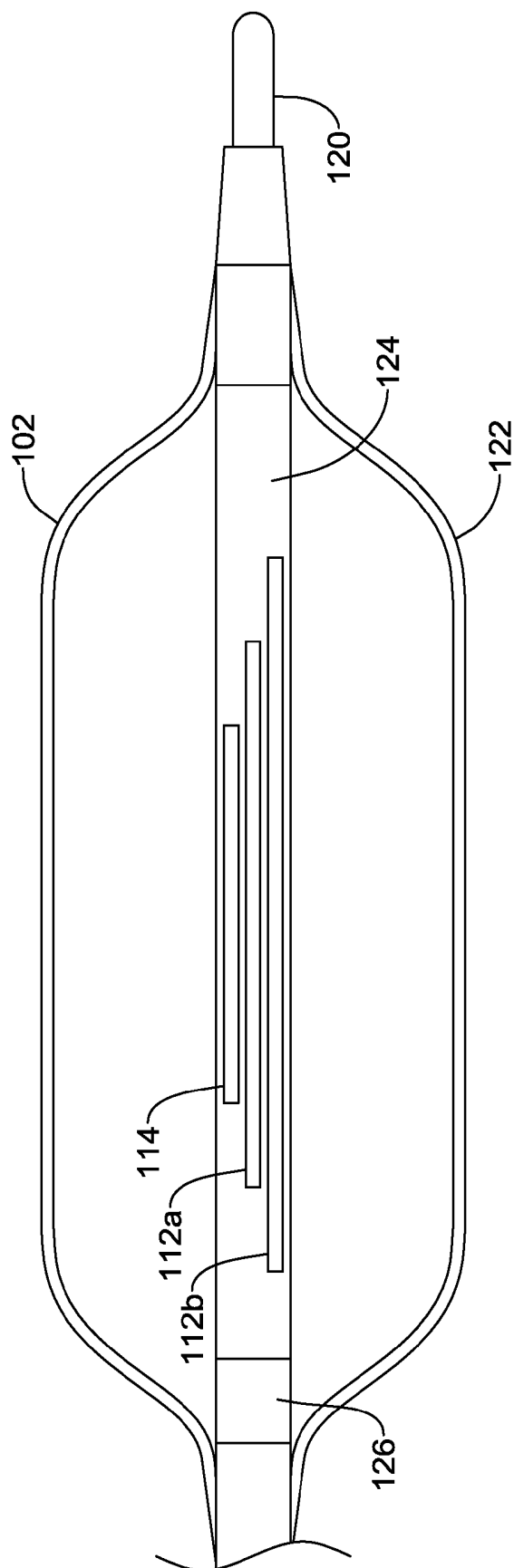


Figure 2

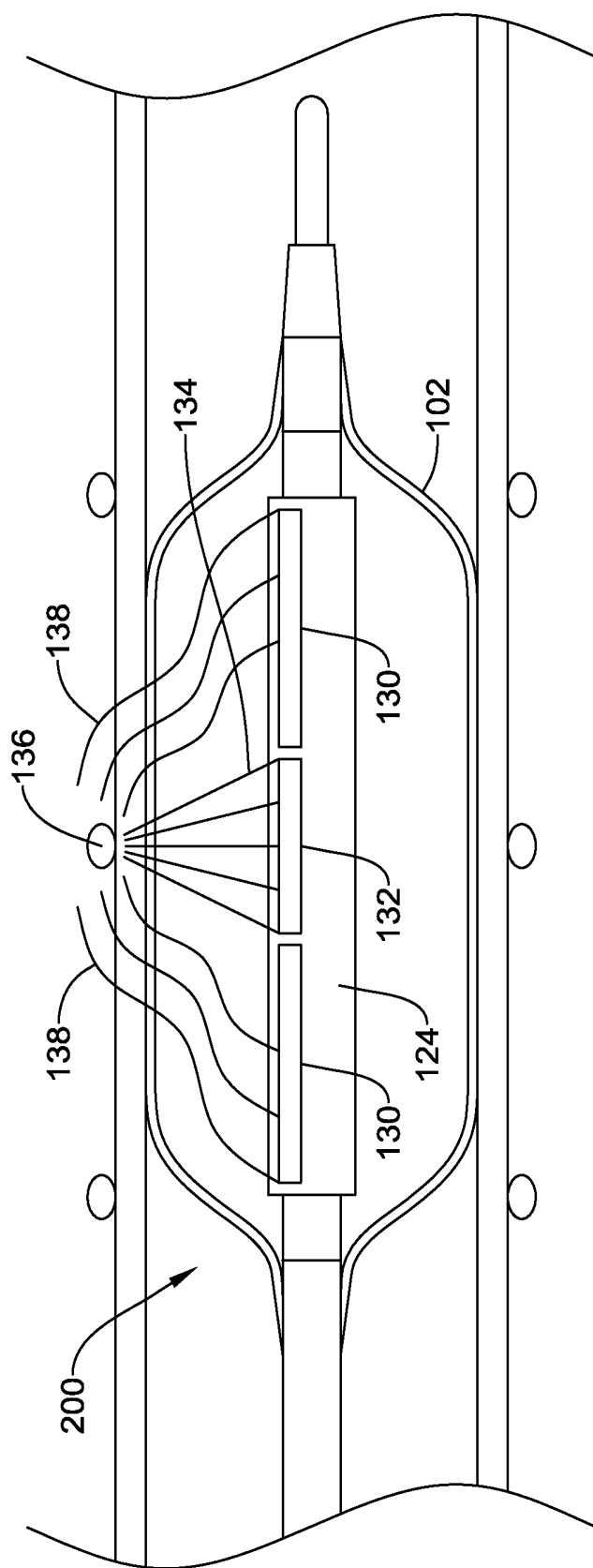


Figure 3A

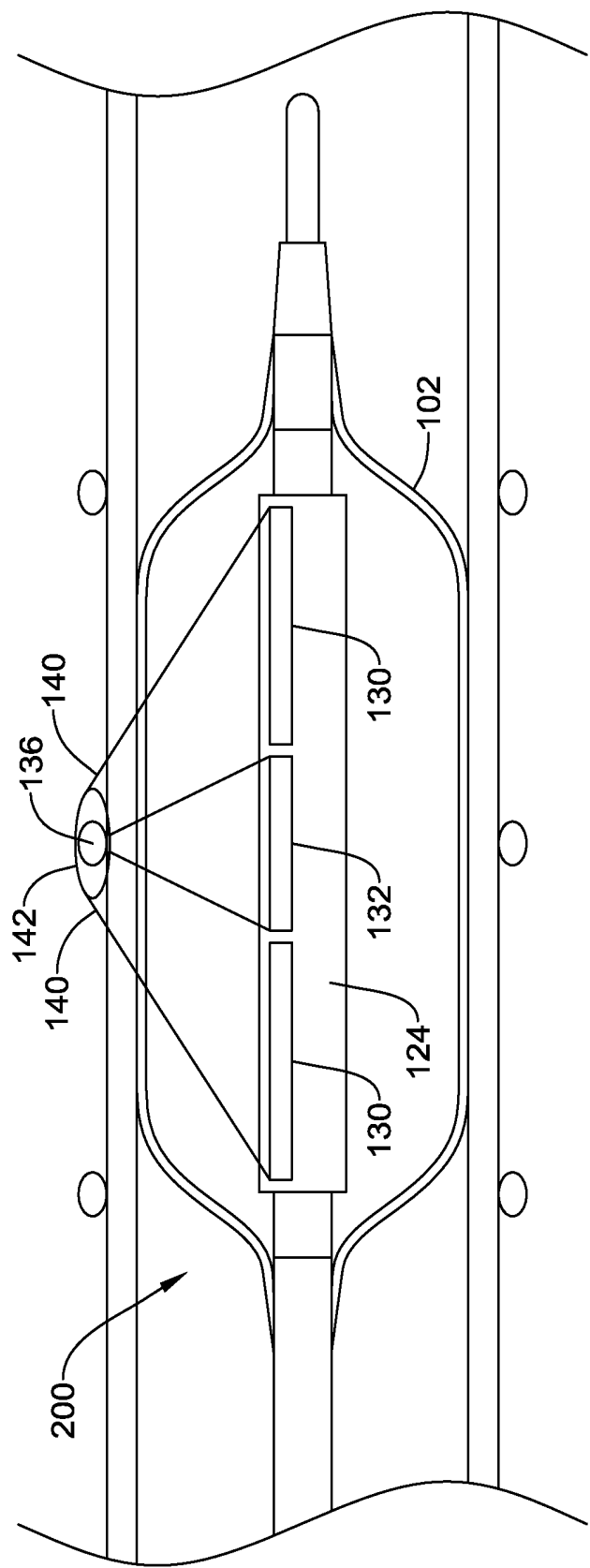


Figure 3B

PERCUTANEOUS DEVICES AND METHODS TO VISUALIZE, TARGET AND ABLATE NERVES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. §119 to U.S. Provisional Application Ser. No. 61/509,954, filed Jul. 20, 2011, the entirety of which is incorporated herein by reference.

TECHNICAL FIELD

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 neuro-modulation.

BACKGROUND

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

SUMMARY

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.

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. In another alternative, the signal excitation may be provided by an extracorporeal device and the probe may receive signal excited by the extracorporeal probe.

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 and self-expanding stent-like structures. The probe or probes may be mounted on a module at the distal region, and the module may be rotatable and/or longitudinally and/or radially movable with respect to

the elongate shaft. The module may be located within the fixation element, in which case, the module may be rotatable or longitudinally or radially movable with respect to the fixation element as well. An actuation device may be operatively connected to the module to provide such movement.

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.

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.

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.

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.

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.

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.

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.

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.

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 fails 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.

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 may be provided percutaneously, intravascularly or orally and may be provided through a separate injection system.

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 to the probe, changing a radial location relative to 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).

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.

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.

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.

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

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:

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

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

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

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

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

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

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

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

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.

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

The terms “preferential” and “preferentially” mean that the modified element is disproportionately 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.

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.

FIG. 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.

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**.

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).

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.

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.

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.

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.

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).

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.

FIG. 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** may be cylindrical and may be 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.

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.

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.

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.

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.

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 Ser. No. 61/324,164 and/or U.S. Patent Application Publication No. US 2011/0257523, the entire disclosures of which are herein incorporated by reference, may be used with either sensing elements **112a**, **112b** or, as described below, with ablation elements **114**.

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.

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

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ablation elements **114**. The ablation elements **114** may be focused to ablate only the targeted nerve tissue.

FIG. 3A illustrates the distal portion of an example 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 FIG. 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.

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 and spirit of the present invention as described in the appended claims.

What is claimed is:

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

an elongate shaft having a distal region configured to be percutaneously deployed within a patient;

wherein the elongate shaft comprises an inflatable balloon in the distal region, the balloon having a collapsed configuration and an expanded configuration;

an active imaging structure disposed on the distal region, the active imaging structure 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;

wherein the active imaging structure includes one or more probes;

wherein the elongate shaft further comprises a module disposed in the distal region, wherein the one or more probes are disposed on said module, wherein said one or more probes include a photo-acoustic sensor comprising a light-emitter that is configured to emit pulses of coherent light towards targeted nerve tissue and a phased array of ultrasonic transducers configured to detect acoustic return signals generated by the pulses of

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coherent light in the targeted nerve tissue, wherein said phased array is configured to focus ablation energy onto the targeted tissue at a distance from the phased array such that the ablation energy can pass through a first tissue to ablate the targeted nerve tissue, wherein the module is configured to change a first focal point of the ablation energy during use, and wherein the module further comprises an electrical actuation element disposed within the balloon for rotating the module within the balloon and about a central axis with respect to the balloon and with respect to the elongate shaft; and wherein the module is disposed within a cavity of the balloon and attached to an outer surface of the elongate shaft.

2. The apparatus of claim 1, wherein the light-emitter includes a laser diode.

3. The apparatus of claim 1, wherein the light-emitter is configured to emit coherent light towards a second focal point.

4. The apparatus of claim 3, wherein the light-emitter is configured to change the depth of focus of the second focal point.

5. The apparatus of claim 3, wherein the light-emitter comprises a phased array of light emitting elements.

6. The apparatus of claim 1, further comprising signal processing circuitry configured to use the signal to measure temperature.

7. The apparatus of claim 4, wherein the first focal point of the ablation energy and the second focal points of the coherent light are the same.

8. The apparatus of claim 5, wherein the phased array of light emitting elements is configured to change the radial, longitudinal and angular location of the second focal point and to change the depth of focus of the second focal point.

9. The apparatus of claim 1, wherein the phased array of ultrasonic transducers is configured to change the radial, longitudinal and angular location of the first focal point and to change the depth of focus of the first focal point.

10. The apparatus of claim 8, wherein the phased array of ultrasonic transducers is configured to change the radial, longitudinal and angular location of the first focal point and to change the depth of focus of the first focal point.

11. The apparatus of claim 10, wherein the phased array of light emitting elements and the phased array of ultrasonic transducers are configured to change the first focal point and the second focal point to the same radial, longitudinal and angular location.

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专利名称(译)	经皮装置和可视化，靶向和消融神经的方法		
公开(公告)号	US9579030	公开(公告)日	2017-02-28
申请号	US13/554391	申请日	2012-07-20
[标]申请(专利权)人(译)	伊尔曼TORSTEN TEO TAT金 黑斯廷斯ROGER N		
申请(专利权)人(译)	休门，TORSTEN TEO，TAT-JIN 黑斯廷斯，ROGER N.		
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IPC分类号	A61B5/05 A61N7/02 A61B5/20 A61B5/00 A61B5/01 A61B5/04 A61B8/00 A61B18/00 A61N7/00 A61N1/40 A61B18/26		
CPC分类号	A61B5/04001 A61B5/0095 A61B5/01 A61B5/201 A61B5/4029 A61N7/02 A61B8/4461 A61B18/26 A61B2018/0022 A61B2018/00214 A61B2018/00285 A61N1/403 A61N7/00 A61N2007/0082 A61N2007/0091 A61B5/0071 A61B18/02 A61B18/1492 A61B18/24 A61B2018/00023 A61B2018/00386 A61B2018/00404 A61B2018/00494 A61B2018/00511 A61B2018/00577 A61B2018/00791 A61B2090/3966 A61N2007/003		
优先权	61/509954 2011-07-20 US		
其他公开文献	US20130165764A1		
外部链接	Espacenet USPTO		

摘要(译)

公开了用于识别神经组织的装置及其制造和使用方法。示例性装置可包括细长轴，细长轴具有远端区域，远端区域构造成经皮部署在患者体内。有源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发神经组织中的信号并从经皮位置接收信号来远程成像神经组织。主动成像结构可包括一个或多个探针。

