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(54) Title: ELECTRICAL ABLATION DEVICES AND METHODS

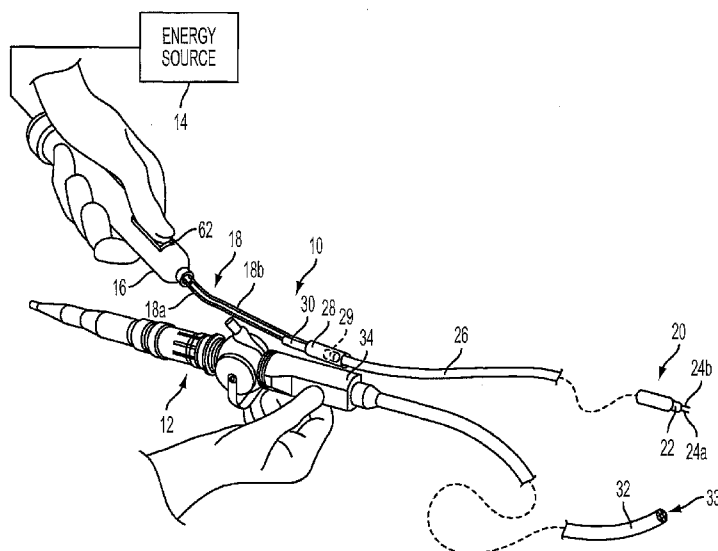


FIG. 1

(57) Abstract: An ablation apparatus may generally comprise an elongated body having a proximal end and a distal end and a non-conductive tip at the distal end, a conductive sheath at least partially surrounding a portion of the elongated body intermediate the proximal end and the tip, and an electrical conductor electrically connected to the conductive sheath. The ablation apparatus may comprise a first electrode having a first diameter and a plurality of second electrodes each having a second diameter, wherein the first diameter is greater than the second diameter. Methods of using the ablation apparatus are also described.

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- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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## **TITLE**

### **ELECTRICAL ABLATION DEVICES AND METHODS**

#### **BACKGROUND**

**[0001]** Electrical ablation therapy has been used in medicine for the treatment of undesirable tissue, such as, for example, diseased tissue, cancer, malignant and benign tumors, masses, lesions, and other abnormal tissue growths. Apparatuses, systems, and methods for conventional ablation therapies may include electrical ablation therapies, such as, for example, high temperature thermal therapies including, focused ultrasound ablation, radiofrequency (RF) ablation, and interstitial laser coagulation, chemical therapies in which chemical agents are injected into the undesirable tissue to cause ablation, surgical excision, cryotherapy, radiation, photodynamic therapy, Moh's micrographic surgery, topical treatments with 5-fluorouracil, and laser ablation.

**[0002]** Conventional electrical ablation therapies may suffer from some of the following limitations: cost, length of recovery, permanent damage to healthy tissue, and extraordinary pain inflicted on the patient. One drawback of conventional electrical ablation therapies may be high current density at the electrode tip. High current density at the electrode tip may contribute to thermal necrosis to tissue surrounding the electrode tip. High current density at the electrode tip may also contribute to induced muscle contractions in skeletal muscle, cardiac muscle, and/or smooth muscle due to the delivery of electrical pulses to the undesirable tissue during treatment. For example, the electrical pulses may induce strong and painful muscle contractions in skeletal muscles in proximity to the electrode. The induced muscle contraction may cause unwanted damage to the tissue due to electrode movement. The induced muscle contractions may also be problematic when provoked in heart muscle. Accordingly, electrical ablation apparatuses, systems, and methods for the treatment of undesirable tissue having reduced current density at the electrode tip are desirable.

## **FIGURES**

**[0003]** The various embodiments of electrical ablation devices and methods thereof described herein may be better understood by considering the following description in conjunction with the accompanying drawings.

**[0004]** FIG. 1 illustrates an electrical ablation system according to certain embodiments described herein.

**[0005]** FIGS. 2A-B illustrate an electrical ablation system according to certain embodiments described herein.

**[0006]** FIG. 3 illustrates an electrical ablation system according to certain embodiments described herein.

**[0007]** FIG. 4 illustrates an electrical ablation system according to certain embodiments described herein.

**[0008]** FIG. 5 is graphical representation of a cell necrosis by irreversible electroporation according to certain embodiments described herein.

**[0009]** FIG. 6 is graphical representation of a cell necrosis by irreversible electroporation according to certain embodiments described herein.

## **DESCRIPTION**

**[0010]** Various embodiments are directed to electrical ablation apparatuses, systems, and methods for the treatment of undesirable tissue having reduced current density at the electrode tip.

**[0011]** This disclosure describes various elements, features, aspects, and advantages of various embodiments of electrical ablation devices and methods thereof. It is to be understood that certain descriptions of the various embodiments have been simplified to illustrate only those elements, features and aspects that are relevant to a more clear understanding of the disclosed embodiments, while eliminating, for purposes of brevity or clarity, other elements, features and aspects. Any references to “various embodiments,” “some embodiments,” “one embodiment,”

or “an embodiment” generally means that a particular element, feature and/or aspect described in the embodiment is included in at least one embodiment. The phrases “in various embodiments,” “in some embodiments,” “in one embodiment,” or “in an embodiment” may not refer to the same embodiment. Persons having ordinary skill in the art, upon considering the description herein, will recognize that various combinations or sub-combinations of the various embodiments and other elements, features, and aspects may be desirable in particular implementations or applications. However, because such other elements, features, and aspects may be readily ascertained by persons having ordinary skill in the art upon considering the description herein, and are not necessary for a complete understanding of the disclosed embodiments, a description of such elements, features, and aspects may not be provided. As such, it is to be understood that the description set forth herein is merely exemplary and illustrative of the disclosed embodiments and is not intended to limit the scope of the invention as defined solely by the claims.

**[0012]** All numerical quantities stated herein are approximate unless stated otherwise, meaning that the term “about” may be inferred when not expressly stated. The numerical quantities disclosed herein are to be understood as not being strictly limited to the exact numerical values recited. Instead, unless stated otherwise, each numerical value is intended to mean both the recited value and a functionally equivalent range surrounding that value. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques.

**[0013]** Notwithstanding the approximations of numerical quantities stated herein, the numerical quantities described in specific examples of actual measured values are reported as precisely as possible.

**[0014]** All numerical ranges stated herein include all sub-ranges subsumed therein. For example, a range of “1 to 10” is intended to include all sub-ranges between and including the

recited minimum value of 1 and the recited maximum value of 10. Any maximum numerical limitation recited herein is intended to include all lower numerical limitations. Any minimum numerical limitation recited herein is intended to include all higher numerical limitations.

**[0015]** As generally used herein, the terms “proximal” and “distal” generally refer to a clinician manipulating one end of an instrument used to treat a patient. The term “proximal” generally refers to the portion of the instrument closest to the clinician. The term “distal” generally refers to the portion located furthest from the clinician. It will be further appreciated that for conciseness and clarity, spatial terms such as “vertical,” “horizontal,” “up,” and “down” may be used herein with respect to the illustrated embodiments. However, surgical instruments may be used in many orientations and positions, and these terms are not intended to be limiting and absolute.

**[0016]** In certain embodiments, electrical ablation devices may generally comprise one or more electrodes configured to be positioned into or proximal to undesirable tissue in a tissue treatment region (e.g., a target site or a worksite). The tissue treatment region may have evidence of abnormal tissue growth. In general, the electrodes may comprise an electrically conductive portion (e.g., medical grade stainless steel, gold plated, etc.) and may be configured to electrically couple to an energy source. The electrodes may have a diameter or radius from 0.5 mm to 1.5 mm, such as, for example, 0.5mm, 0.75mm, 1mm, and 1.5mm. Once the electrodes are positioned into or proximal to the undesirable tissue, an energizing potential may be applied to the electrodes to create an electric field to which the undesirable tissue is exposed. The energizing potential (and the resulting electric field) may be characterized by various parameters, such as, for example, frequency, amplitude, pulse width (duration of a pulse or pulse length), and/or polarity. Depending on the diagnostic or therapeutic treatment to be rendered, a particular electrode may be configured either as an anode or a cathode, or a plurality of electrodes may be configured with at least one electrode configured as an anode and at least one other electrode configured as a cathode. Regardless of the initial polarity

configuration, the polarity of the electrodes may be reversed by reversing the polarity of the output of the energy source.

**[0017]** In certain embodiments, a suitable energy source may comprise an electrical waveform generator. The electrical waveform generator may be configured to create an electric field that is suitable to create irreversible electroporation in undesirable tissue at various electric field amplitudes and durations. The energy source may be configured to deliver electrical pulses in the form of direct-current (DC) and/or alternating-current (AC) voltage potentials (*e.g.*, time-varying voltage potentials) to the electrodes. The energy source may also be configured to reverse the potential between the electrodes. The electrical pulses may be characterized by various parameters, such as, for example, frequency, amplitude, pulse width, polarity, total number of pulses, and delay between pulses bursts. The undesirable tissue may be ablated by exposure to the electric potential difference across the electrodes.

**[0018]** In certain embodiments, the apparatuses, systems, and methods may be configured for minimally invasive ablation treatment of undesirable tissue through the use of irreversible electroporation. Minimally invasive ablation treatment of undesirable tissue may be characterized by the ability to ablate undesirable tissue in a controlled and focused manner having reduced or no thermally damaging effects to the surrounding healthy tissue. The apparatuses, systems, and methods may be configured to ablate undesirable tissue through the use of electroporation or electropermeabilization. Electroporation refers to the application of electric pulses to a cell membrane to cause an increase in the permeabilization of the cell membrane. The external electric field (*i.e.*, electric potential/per unit length) applied to the cell may significantly increase the electrical conductivity and permeability of the plasma in the cell membrane.

**[0019]** More specifically, the apparatuses, systems, and methods may be configured to ablate undesirable tissue through the use of irreversible electroporation. Irreversible electroporation refers to the application of an electric field of a specific magnitude and duration to a cell

membrane such that the permeabilization of the cell membrane cannot be reversed. One of the primary parameters affecting the transmembrane potential is the potential difference across the cell membrane. The destabilizing potential may form pores in the cell membrane when the potential across the cell membrane exceeds its dielectric strength causing the cell to die under a process known as apoptosis and/or necrosis. Irreversible electroporation may lead to cell death without inducing a significant amount of heat in the cell membrane.

**[0020]** The application of irreversible electroporation pulses to cells may be an effective way for ablating large volumes of undesirable tissue with no or minimal detrimental thermal effects to the surrounding healthy tissue. Without wishing to be bound to any particular theory, it is believed that irreversible electroporation destroys cells with no or minimal heat, and thus, may not destroy the cellular support structure or regional vasculature. A destabilizing irreversible electroporation pulse, suitable to cause cell death without inducing a significant amount of thermal damage to the surrounding healthy tissue, may have amplitude in the range of several hundred to several thousand volts and may be generally applied across biological membranes over a distance of several millimeters, for example, for a relatively long duration of 1  $\mu$ s to 100 ms. Thus, the undesirable tissue may be ablated *in-vivo* through the delivery of destabilizing electric fields by quickly causing cell necrosis.

**[0021]** The apparatuses, systems, and methods for electrical ablation therapy may be adapted for use in minimally invasive surgical procedures to access the tissue treatment region in various anatomic locations, such as, for example, the brain, lungs, breast, liver, gall bladder, pancreas, prostate gland, and various internal body lumen defined by the esophagus, stomach, intestine, colon, arteries, veins, anus, vagina, cervix, fallopian tubes, and the peritoneal cavity. Minimally invasive electrical ablation devices may be introduced to the tissue treatment region through a small opening formed in the patient's body using a trocar or through a natural body orifice such as the mouth, anus, or vagina using transluminal access techniques known as Natural Orifice Transluminal Endoscopic Surgery (NOTES)<sup>TM</sup>. Once the electrical ablation

devices (e.g., electrodes) are located into or proximal to the undesirable tissue in the treatment region, electric field potentials may be applied by the energy source to the undesirable tissue. The electrical ablation devices may comprise portions that may be inserted into the tissue treatment region percutaneously (e.g., where access to inner organs or other tissue is done via needle-puncture of the skin). Other portions of the electrical ablation devices may be introduced into the tissue treatment region endoscopically (e.g., laparoscopically and/or thoracoscopically) through trocars or channels of the endoscope, through small incisions, or transcutaneously (e.g., where electric pulses are delivered to the tissue treatment region through the skin). An electrical ablation device is described in commonly owned U.S. Patent Publication No. 20100179530, entitled, "ELECTRICAL ABLATION DEVICES" filed January 12, 2009.

**[0022]** FIG. 1 illustrates one embodiment of an electrical ablation system 10. The electrical ablation system 10 may be employed to ablate undesirable tissue, such as, for example, diseased tissue, cancer, malignant and benign tumors, masses, lesions, and other abnormal tissue growths in a tissue treatment region using electrical energy. The electrical ablation system 10 may be configured to treat a number of lesions and osteopathologies comprising metastatic lesions, tumors, fractures, infected sites, and inflamed sites in a tissue treatment region using electrical energy. The electrical ablation system 10 may be configured to be positioned within a patient's natural body orifice, e.g., the mouth, anus, and vagina, and/or advanced through internal body lumen or cavities, e.g., the esophagus, stomach, intestines, colon, cervix, and urethra, to reach the tissue treatment region. The electrical ablation system 10 may be configured to be positioned and passed through a small incision or keyhole formed through the patient's skin or abdominal wall using a trocar to reach the tissue treatment region. The tissue treatment region may be located in the patient's brain, lung, breast, liver, gall bladder, pancreas, prostate gland, various internal body lumen defined by the esophagus, stomach, intestine, colon, arteries, veins, anus, vagina, cervix, fallopian tubes, and the peritoneal cavity. The electrical ablation system 10 may be used in conjunction with

endoscopic, laparoscopic, thoracoscopic, open surgical procedures via small incisions or keyholes, percutaneous techniques, transcutaneous techniques, and/or external non-invasive techniques, and any combinations thereof.

**[0023]** Once positioned into or proximate the tissue treatment region, the electrical ablation system 10 may be actuated (*e.g.*, energized) to ablate the undesirable tissue. In one embodiment, the electrical ablation system 10 may be configured to treat diseased tissue in the gastrointestinal tract, esophagus, lung, and/or stomach that may be accessed orally. In another embodiment, the electrical ablation system 10 may be adapted to treat undesirable tissue in the liver or other organs that may be accessible using transluminal access techniques, such as, for example, NOTES™ techniques where the electrical ablation devices may be initially introduced through a natural body orifice and then advanced to the tissue treatment site by puncturing the walls of internal body lumen. In various embodiments, the electrical ablation system 10 may be adapted to treat undesirable tissue in the brain, lung, breast, liver, gall bladder, pancreas, or prostate gland, using one or more electrodes positioned percutaneously, transcutaneously, translumenally, minimally invasively, and/or through open surgical techniques, or any combination thereof.

**[0024]** In one embodiment, the electrical ablation system 10 may be employed in conjunction with a flexible endoscope 12, as well as a rigid endoscope, laparoscope, or thoracoscope, such as the GIF-100 model available from Olympus Corporation. In one embodiment, the endoscope 12 may be introduced to the tissue treatment region trans-anally through the colon, trans-orally through the esophagus and stomach, trans-vaginally through the cervix, transcutaneously, or via an external incision or keyhole formed in the abdomen in conjunction with a trocar. The electrical ablation system 10 may be inserted and guided into or proximate the tissue treatment region using the endoscope 12. In other embodiments, the endoscope 12 is not utilized, and instead other techniques, such as, for example, ultrasound or a computerized tomography (CT) scan, may be used to determine proper instrument placement during the procedure.

**[0025]** In the embodiment illustrated in FIG. 1, the endoscope 12 comprises an endoscope handle 34 and an elongate relatively flexible shaft 32. The distal end of the flexible shaft 32 may comprise a light source and a viewing port. Optionally, the flexible shaft 32 may define one or more channels for receiving various instruments therethrough, such as, for example, electrical ablation devices. Images within the field of view of the viewing port may be received by an optical device, such as, for example, a camera comprising a charge coupled device (CCD) usually located within the endoscope 12, and transmitted to a display monitor (not shown) outside the patient. In one embodiment, the electrical ablation system 10 may comprise a plurality of electrical conductors 18, a handpiece 16 comprising an activation switch 62, and an energy source 14, such as, for example, an electrical waveform generator, electrically coupled to the activation switch 62 and the electrical ablation device 20. The electrical ablation device 20 may comprise a relatively flexible member or shaft 22 that may be introduced to the tissue treatment region using any of the techniques discussed above, such as, an open incision and a trocar, through one of more of the channels of the endoscope 12, percutaneously, or transcutaneously.

**[0026]** In one embodiment, one or more electrodes (*e.g.*, needle electrodes, balloon electrodes), such as first and second electrodes 24a, 24b may extend out from the distal end of the electrical ablation device 20. In one embodiment, the electrical ablation device may comprise multiple needle electrodes that may be employed to treat the undesirable tissue. In one embodiment, the first electrode 24a may be configured as the positive electrode and the second electrode 24b may be configured as the negative electrode. The first electrode 24a may be electrically connected to a first electrical conductor 18a, or similar electrically conductive lead or wire, which may be coupled to the positive terminal of the energy source 14 through the activation switch 62. The second electrode 24b may be electrically connected to a second electrical conductor 18b, or similar electrically conductive lead or wire, which may be coupled to the negative terminal of the energy source 14 through the activation switch 62. The electrical

conductors 18a, 18b may be electrically insulated from each other and surrounding structures, except for the electrical connections to the respective electrodes 24a, 24b.

**[0027]** In certain embodiments, the electrical ablation device 20 may be configured to be introduced into or proximate the tissue treatment region using the endoscope 12 (laparoscope or thoracoscope), open surgical procedures, and/or external and non-invasive medical procedures. The electrodes 24a, 24b may be referred to herein as endoscopic or laparoscopic electrodes, although variations thereof may be inserted transcutaneously or percutaneously. In various embodiments, one or both electrodes 24a, 24b may be adapted and configured to slideably move in and out of a cannula, lumen, or channel defined within the flexible shaft 22.

**[0028]** When the electrodes 24a, 24b are positioned at the desired location into or proximate the tissue treatment region, the electrodes 24a, 24b may be connected to or disconnected from the energy source 14 by actuating or de-actuating the activation switch 62 on the handpiece 16. The activation switch 62 may be operated manually or may be mounted on a foot switch (not shown), for example. The electrodes 24a, 24b may deliver electric field pulses to the undesirable tissue. The electric field pulses may be characterized by various parameters, such as, for example, pulse shape, amplitude, frequency, pulse width, polarity, total number of pulses and duration. The electric field pulses may be characterized by amplitudes in the range of  $\pm 100$  VDC to  $\pm 10,000$  VDC, pulse widths in the range of 1  $\mu$ s to 100 ms, and frequencies in the range of 1 Hz to 10,000 Hz. The electric field pulses may be sufficient to induce irreversible electroporation in the undesirable tissue. The induced potential may depend on a variety of conditions, such as, for example, tissue type, cell size, and electric field pulse parameters. The transmembrane potential of a specific tissue type may primarily depend on the amplitude of the electric field and pulse width. Without wishing to be bound to any particular theory, it is believed that an electric field strength of 200 V/cm to 2000 V/cm may be suitable for destroying living tissue by inducing irreversible electroporation. This procedure may be repeated to destroy

relatively larger portions of the undesirable tissue. At anytime, the surgeon or clinician may reposition at least one of the electrodes and begin the process anew.

**[0029]** In certain embodiments, a protective sleeve or sheath 26 may be slidably disposed over the flexible shaft 22 and within a handle 28. In another embodiment, the sheath 26 may be slidably disposed within the flexible shaft 22 and the handle 28. The sheath 26 may be slideable and may be located over the electrodes 24a, 24b to protect the trocar and prevent accidental piercing when the electrical ablation device 20 is advanced therethrough. One or both of the electrodes 24a, 24b may be adapted and configured to slideably move in and out of a cannula, lumen, or channel formed within the flexible shaft 22. One or both of the electrodes 24a, 24b may be fixed in place. One of the electrodes 24a, 24b may provide a pivot about which the other electrode may be moved in an arc to other points in the tissue treatment region to treat larger portions of the diseased tissue that cannot be treated by fixing both of the electrodes 24a, 24b in one location. In one embodiment, one or both of the electrodes 24a, 24b may be adapted and configured to slideably move in and out of a working channel formed within a flexible shaft 32 of the endoscope 12 or may be located independently of the endoscope 12.

**[0030]** In one embodiment, the first and second electrical conductors 18a, 18b may be provided through the handle 28. The first electrode 24a may be slideably moved in and out of the distal end of the flexible shaft 22 using a slide member 30 to retract and/or advance the first electrode 24a. The second electrode 24b may be slideably moved in and out of the distal end of the flexible shaft 22 using the slide member 30 or a different slide member to retract and/or advance the second electrode 24b. One or both electrodes 24a, 24b may be coupled to the slide member 30, or additional slide members, to advance and retract the electrodes 24a, 24b and position the electrodes 24a, 24b. In this manner, the first and second electrodes 24a, 24b which may be slidably movable within the cannula, lumen, or channel defined within the flexible shaft 22, may be advanced and retracted with the slide member 30. As shown in FIG. 1, the first electrical conductor 18a coupled to the first electrode 24a may be coupled to the slide

member 30. In this manner, the first electrode 24a, which is slidably movable within the cannula, lumen, or channel within the flexible shaft 22, may be advanced and retracted with the slide member 30. In one embodiment, various slide members, such as the slide member 30, may be rotatable. Thus rotation of the slide member 30, or additional slide members, may rotate the corresponding electrode(s) at the distal end of the electrical ablation device 20.

**[0031]** In various other embodiments, transducers and/or sensors 29 may be located in the handle 28 (or other suitable location) of the electrical ablation device 20 to sense the force with which the electrodes 24a, 24b penetrate the tissue in the tissue treatment region. This feedback information may be useful to determine whether one or both of the electrodes 24a, 24b have been properly inserted in the tissue treatment region. As is particularly well known, cancerous tumor tissue tends to be denser than healthy tissue, and thus greater force may be typically required to insert the electrodes 24a, 24b therein. The transducers or sensors 29 may provide feedback to the operator, surgeon, or clinician to physically sense when the electrodes 24a, 24b are placed within the cancerous tumor. The feedback information provided by the transducers or sensors 29 may be processed and displayed by circuits located either internally or externally to the energy source 14. The sensor 29 readings may be employed to determine whether the electrodes 24a, 24b have been properly located within the cancerous tumor thereby assuring that a suitable margin of error has been achieved in locating the electrodes 24a, 24b.

**[0032]** In one embodiment, the input to the energy source 14 may be connected to a commercial power supply by way of a plug (not shown). The output of the energy source 14 may be coupled to the electrodes 24a, 24b, which may be energized using the activation switch 62 on the handpiece 16, or an activation switch mounted on a foot activated pedal (not shown). The energy source 14 may be configured to produce electrical energy suitable for electrical ablation.

**[0033]** In one embodiment, the electrodes 24a, 24b may be adapted and configured to electrically couple to the energy source 14 (e.g., generator, waveform generator). Once

electrical energy is coupled to the electrodes 24a, 24b an electric field may be formed at a distal end of the electrodes 24a, 24b. The energy source 14 may be configured to generate electric pulses at a predetermined frequency, amplitude, pulse width, and/or polarity that are suitable to induce irreversible electroporation to ablate substantial volumes of undesirable tissue in the treatment region. For example, the energy source 14 may be configured to deliver DC electric pulses having a predetermined frequency, amplitude, pulse width, and/or polarity suitable to induce irreversible electroporation to ablate substantial volumes of undesirable tissue in the treatment region. The DC pulses may be positive or negative relative to a particular reference polarity. The polarity of the DC pulses may be reversed or inverted from positive-to-negative or negative-to-positive a predetermined number of times to induce irreversible electroporation to ablate substantial volumes of undesirable tissue in the treatment region.

**[0034]** In one embodiment, a timing circuit may be coupled to the output of the energy source 14 to generate electric pulses. The timing circuit may comprise one or more suitable switching elements to produce the electric pulses. For example, the energy source 14 may deliver a series of  $n$  electric pulses (where  $n$  is any positive integer) to the electrodes 24a, 24b of sufficient amplitude to induce irreversible electroporation suitable for tissue ablation. In one embodiment, the electric pulses may have a fixed or variable pulse width, amplitude, frequency, and/or polarity.

**[0035]** The electrical ablation device 20 may be operated either in bipolar or monopolar mode. In bipolar mode, the first electrode 24a may be electrically connected to a first polarity and the second electrode 24b may be electrically connected to the opposite polarity. In monopolar mode, the first electrode 24a may be coupled to a prescribed voltage and the second electrode 24b may be set to ground. The energy source 14 may be configured to operate in either the bipolar or monopolar modes with the electrical ablation system 10. In bipolar mode, the first electrode 24a may be electrically connected to a prescribed voltage of one polarity and the second electrode 24b may be electrically connected to a prescribed voltage of the opposite

polarity. When more than two electrodes are used, the polarity of the electrodes may be alternated so that any two adjacent electrodes may have either the same or opposite polarities.

**[0036]** In monopolar mode, it may not be necessary that the patient be grounded with a grounding pad. Since a monopolar energy source 14 may be typically constructed to operate upon sensing a ground pad connection to the patient, the negative electrode of the energy source 14 may be coupled to an impedance simulation circuit. In this manner, the impedance circuit simulates a connection to the ground pad and thus may be able to activate the energy source 14. It will be appreciated that in monopolar mode, the impedance circuit may be electrically connected in series with either one of the electrodes 24a, 24b that may be otherwise attached to a grounding pad.

**[0037]** In one embodiment, the energy source may be configured to produce RF waveforms at predetermined frequencies, amplitudes, pulse widths, and/or polarities suitable for electrical ablation of cells in the tissue treatment region. One example of a suitable RF energy source may be a commercially available conventional, bipolar/monopolar electrosurgical RF generator, such as Model Number ICC 350, available from Erbe, GmbH.

**[0038]** In one embodiment, the energy source may be configured to produce destabilizing electrical potentials (*e.g.*, fields) suitable to induce irreversible electroporation. The destabilizing electrical potentials may be in the form of bipolar/monopolar DC electric pulses suitable for inducing irreversible electroporation to ablate tissue undesirable tissue with the electrical ablation device. A commercially available energy source suitable for generating irreversible electroporation electric field pulses in bipolar or monopolar mode is a pulsed DC generator such as Model Number ECM 830, available from BTX Molecular Delivery Systems Boston, MA. In bipolar mode, the first electrode 24a may be electrically coupled to a first polarity and the second electrode 25 may be electrically coupled to a second (*e.g.*, opposite) polarity of the energy source 14. Bipolar/ monopolar DC electric pulses may be generated at a variety of frequencies, amplitudes, pulse widths, and/or polarities. Unlike RF ablation systems, which may

require high power and energy levels delivered into the tissue to heat and thermally destroy the tissue, irreversible electroporation may require very little energy applied to the tissue to heat and kill the cells of the undesirable tissue using electric field potentials rather than heat.

Accordingly, irreversible electroporation systems may avoid the detrimental thermal effects caused by RF ablation systems.

**[0039]** In certain embodiments, the energy source may comprise a wireless transmitter to deliver energy to the electrodes using wireless energy transfer techniques via one or more remotely positioned antennas. Those skilled in the art will appreciate that wireless energy transfer or wireless power transmission refers to the process of transmitting electrical energy from an energy source to an electrical load without interconnecting wires. In one embodiment, the energy source 14 may be coupled to the first and second electrodes 24a, 24b by a wired or a wireless connection. In a wired connection, the energy source 14 may be coupled to the electrodes 24a, 24b by way of the electrical conductors 18a, 18b as shown. In a wireless connection, the electrical conductors 18a, 18b may be replaced with a first antenna (not shown) coupled the energy source 14 and a second antenna (not shown) coupled to the electrodes 24a, 24b, wherein the second antenna may be remotely located from the first antenna. In one embodiment, the energy source may comprise a wireless transmitter to deliver energy to the electrodes using wireless energy transfer techniques via one or more remotely positioned antennas. As previously discussed, wireless energy transfer or wireless power transmission is the process of transmitting electrical energy from the energy source 14 to an electrical load, *e.g.*, the abnormal cells in the tissue treatment region, without using the interconnecting electrical conductors 18a, 18b. An electrical transformer is the simplest example of wireless energy transfer. The primary and secondary circuits of a transformer may not be directly connected and the transfer of energy may take place by electromagnetic coupling through a process known as mutual induction. Power also may be transferred wirelessly using RF energy.

**[0040]** According to certain embodiments, the electrical ablation device 20 may be introduced into the tissue treatment region through a trocar, for example, or inserted to a tissue treatment region transcutaneously, percutaneously, or other suitable techniques. In one embodiment, the cannula, lumen, or channel defined within the flexible shaft 22 may comprise a cutting edge, such as a bevel or other sharp edge, to aid in the puncturing/piercing of tissue.

**[0041]** According to certain embodiments, an ablation apparatus may generally comprise an elongated body having a proximal end and a distal end and a non-conductive tip at the distal end, a conductive sheath at least partially surrounding a portion of the elongated body intermediate the proximal end and the tip, and an electrical conductor electrically connected to the conductive sheath coupled to an energy source operative to generate and deliver a sequence of electrical pulses to tissue to induce cell necrosis in the tissue by irreversible electroporation. Without wishing to be bound to any particular theory, it is believed that the non-conductive tip and/or the conductive sheath may reduce the current density at the tip relative to a similar apparatus having an electrode at the tip. The conductive sheath may delocalize the current density over a greater surface area. The conductive sheath may reduce thermal necrosis at the tip. The non-conductive tip may reduce thermal necrosis at the tip. The conductive sheath and/or non-conductive tip may reduce induced muscle contractions. The ablation apparatus may be operated either in bipolar mode or monopolar mode.

**[0042]** Referring to FIGS. 2A-B, an ablation apparatus 100 may generally comprise an elongated body 105 having a proximal end and a distal end and a non-conductive tip 110 at the distal end, a conductive sheath 120 at least partially surrounding a portion of the elongated body 105 intermediate the proximal end and the tip, and an electrical conductor 130 electrically connected to the conductive sheath 120. The ablation apparatus may comprise an energy source (not shown) coupled to the electrical conductor 130, the energy source configured to deliver a series of electrical pulses to tissue to induce cell necrosis in the tissue by irreversible electroporation. The ablation apparatus 100 may have an elongated body 105 comprising a

tapered segment 140. The tapered segment 140 may be intermediate the proximal end and the distal end. The tapered segment 140 may comprise a chamfer cut. The electrical conductor 130 may be positioned in the tapered segment 140. The electrical conductor 130 may be positioned in the chamfer cut. The ablation apparatus 100 may have an elongated body 105 comprising a tapered tip 110. The tip 110 may comprise a bevel cut. The tip 110 may comprise a cutting edge. In one embodiment, an ablation apparatus 100 may generally comprise an elongated body 105 comprising a tapered segment 140 having a chamfer cut including an electrical conductor 130 therein, and a tapered tip 110 having a bevel cut.

**[0043]** In certain embodiments, the non-conductive tip 110 may comprise a ceramic material, a polymer, a glass material, a carbon material, and any combinations thereof. In one embodiment, the non-conductive tip 110 may comprise polyalkenes, such as polyethylene and polypropylene, silicon, and polytetrafluoroethylene, such as TEFLON. The non-conductive tip may comprise a substantial portion of the distal end of the elongated body. The non-conductive tip may have an area less than the area of the conductive sheath. The area of the non-conductive tip may be 50%, 75%, or 90% less than the area of the conductive sheath.

**[0044]** In certain embodiments, the conductive sheath 120 may comprise a metal. In one embodiment, the conductive sheath 120 may comprise a metal selected from the group consisting of medical grade stainless steel, gold, platinum, and iridium. The conductive sheath may have a length, width, diameter, and thickness. In various embodiments, for example, the conductive sheath may have a length of 5 cm to 25 cm, a width or diameter of 0.5 mm to 1 mm, and a thickness of 0.5 mm to 1 mm. The conductive sheath may have any suitable shape, such as, for example, cylinder and cube. The conductive sheath may be deposited onto at least a portion of the ablation apparatus. The conductive sheath may be deposited onto at least a portion of a circumferential surface of the ablation apparatus. The conductive sheath may be deposited onto at least a portion of a circumferential surface of the ablation apparatus intermediate the proximal end and the tip. The conductive sheath may surround the tapered

segment of the elongated body. The conductive sheath may surround the chamfer cut of the elongated body. The electrical conductor 130 may be fixedly attached to the conductive sheath 120.

**[0045]** According to certain embodiments, an ablation apparatus may generally comprise a first electrode, a plurality of second electrodes, a grounding pad, and an energy source coupled to the first electrode and plurality of second electrodes, the energy source configured to deliver a series of electrical pulses to tissue to induce cell necrosis in the tissue by irreversible electroporation. The first electrode may be connected to the positive output of the generator, the plurality of second electrodes may be connected to the negative output of the generator, and the grounding pad may be connected to the negative output of the generator. In one embodiment, the ground pad may be replaced by an impedance simulation circuit. The polarity of the plurality of second electrodes and the polarity of the grounding pad may be the same. Without wishing to be bound to any particular theory, it is believed having the same polarity may reduce the current density at the electrode tips relative to a similar ablation apparatus having a different polarity. The grounding pad may delocalize the current density over a greater surface area. The grounding pad may reduce thermal necrosis at the tip. The grounding pad may reduce induced muscle contractions.

**[0046]** In certain embodiments, the first electrode may have a first diameter and each of the plurality of second electrodes may have a second diameter. The first diameter may be greater than or equal to the second diameter. The first diameter may be greater than the second diameter. For example, the first diameter may be 18 gage and the second diameter may be 25 gage. Without wishing to be bound to any particular theory, it is believed that the smaller diameter of the plurality of second electrodes may reduce the current density at the tip relative to a similar electrode having a larger diameter. For example, the smaller diameter may divide the current into smaller amounts flowing from the multiple second electrodes. The current flowing from the first electrode generally equals the sum of the current flowing to the second

electrodes when the electrodes are electrically connected. The smaller diameter may reduce thermal necrosis at the electrode tip. The smaller diameter may reduce induced muscle contractions.

**[0047]** Referring to FIGS. 3 and 4, in certain embodiments, an ablation apparatus may generally comprise a first electrode 310 having a first diameter, a plurality of second electrodes 320 each having a second diameter comprising a proximal end and a distal end and a first conductive portion 312 intermediate the proximal end and the distal end, a non-conductive portion 314 intermediate the first conductive portion 312 and the distal end, and a second conductive portion 316 at the distal end, a grounding pad 330 comprising a non-conductive outer region 332 and a conductive inner region 334, and an energy source (not shown) coupled to the first electrode 310 and plurality of second electrodes 320, the energy source configured to deliver a series of electrical pulses to tissue 350 to induce cell necrosis 360 in the tissue 350 by irreversible electroporation, wherein the first diameter is greater than or equal to the second diameter. The ground pad may comprise a central hole 340. In one embodiment, the first electrode 310 may be positioned in the central hole 340 and the plurality of second electrodes 320 may be randomly positioned around the central hole 340. The plurality of second electrodes may comprise 1-10 electrodes and 2-8 electrodes, such as, for example, 2 electrodes, 4 electrodes, and 6 electrodes.

**[0048]** In certain embodiments, the grounding pad 330 may comprise a non-conductive outer region 332 and a conductive inner region 334. The first electrode 310 may contact the non-conductive outer region 332. The first electrode 310 may not contact the conductive inner region 334. Each of the plurality of second electrodes 320 may contact the non-conductive outer region 332 and the conductive inner region 334. The first conductive portion 312 of each of the plurality of second electrodes 320 may contact the conductive inner region 334. The second conductive portion 316 of each of the plurality of second electrodes 320 may contact the

tissue 350. The non-conductive portion 314 of each of the plurality of second electrodes 320 may contact the patient's abdominal wall.

**[0049]** According to certain embodiments, an ablation apparatus may generally comprise a first electrode 310 contacting the tissue 350 at a first distance and each of the plurality of second electrodes 320 contacting the tissue at a second distance. In one embodiment, the first electrode 310 may be positioned in the central hole 340 and advanced into the tissue 350 under ultrasound guidance a first distance, and the plurality of second electrodes 320 may be randomly positioned around the central hole 340 and advanced into the tissue 350 without ultrasound guidance a second distance. In one embodiment, the first distance may be greater than or equal to the second distance. In various embodiments, the distance between the electrodes may be from 0.5 cm to 15 cm. The plurality of second electrodes 320 may be positioned around and/or above bone and other solid structures. For example, the first electrode may be positioned in the liver a first distance suitable to create a zone of cell necrosis 360 and the second electrodes may be positioned in the liver around ribs at a second distance, such as, for example, 1-2 cm. The treatment of the patient may be more efficient without the need to place all electrodes under ultrasound guidance and/or the need to position all electrodes at the same distance.

**[0050]** According to certain embodiments, a method of treating tissue of a patient may generally comprise positioning a grounding pad adjacent the patient, inserting a first electrode under ultrasound guidance into the tissue to a first distance, inserting a plurality of second electrodes into the tissue to a second distance, and delivering a series of electrical pulses to tissue to induce cell necrosis in the tissue by irreversible electroporation. The method may comprise inserting a first electrode under ultrasound guidance through the central hole and into the tissue. The method may comprise inserting a plurality of second electrodes through the grounding pad into the tissue. The plurality of second electrodes may be inserted without ultrasound guidance. The method may comprise contacting the first conductive portion of each

of the second electrodes and the conductive inner region of the grounding pad. The method may comprise conducting energy from the first electrode to each of the plurality of second electrodes and the conductive inner region of the grounding pad. The first electrode may have a first polarity and the grounding pad and the plurality of second electrodes may have a different polarity. The polarity of the grounding pad and the polarity of the plurality of second electrodes may be the same.

**[0051]** FIGS. 5 and 6 illustrate a finite element model of the electric field created in the undesirable tissue when the electrodes are energized. As shown in FIGS. 5 and 6, the horizontal and the vertical axes represent distance in meters (m) with the center defined at by the location of the first electrode located directly in the undesirable tissue. A vertical scale shown to the right of the graph represents the electric field strength in a range from a minimum of about 500 V/m (bottom) to a maximum of about 5500 V/m (top). With the electrodes positioned as described in FIG. 4, when the DC pulses are applied to the first electrode 410 located directly in the undesirable tissue a necrotic zone 460 may be created around the first electrode 410. Although a small amount of necrosis 462 may occurs at the second electrode/tissue interface 416, it will likely not be a clinically significant amount. Irreversible electroporation energy in the range of 200 V/cm to 1500 V/cm is generally suitable for efficient and effective treatment of medical conditions that require the ablation of undesirable tissue from a localized region.

**[0052]** The embodiments of the electrical ablation devices described herein may be introduced inside a patient using minimally invasive or open surgical techniques. In some instances it may be advantageous to introduce the electrical ablation devices inside the patient using a combination of minimally invasive and open surgical techniques. Minimally invasive techniques may provide more accurate and effective access to the treatment region for diagnostic and treatment procedures. To reach internal treatment regions within the patient, the electrical ablation devices described herein may be inserted through natural openings of the

body such as the mouth, anus, and/or vagina, for example. Minimally invasive procedures performed by the introduction of various medical devices into the patient through a natural opening of the patient are known in the art as NOTES™ procedures. Surgical devices, such as an electrical ablation devices, may be introduced to the treatment region through the channels of the endoscope to perform key surgical activities (KSA), including, for example, electrical ablation of tissues using irreversible electroporation energy. Some portions of the electrical ablation devices may be introduced to the tissue treatment region percutaneously or through small – keyhole – incisions.

**[0053]** Endoscopic minimally invasive surgical and diagnostic medical procedures are used to evaluate and treat internal organs by inserting a small tube into the body. The endoscope may have a rigid or a flexible tube. A flexible endoscope may be introduced either through a natural body opening (e.g., mouth, anus, and/or vagina). A rigid endoscope may be introduced via trocar through a relatively small – keyhole – incision incisions (usually 0.5 - 1.5cm). The endoscope can be used to observe surface conditions of internal organs, including abnormal or diseased tissue such as lesions and other surface conditions and capture images for visual inspection and photography. The endoscope may be adapted and configured with channels for introducing medical instruments to the treatment region for taking biopsies, retrieving foreign objects, and/or performing surgical procedures.

**[0054]** Once an electrical ablation device is inserted in the human body internal organs may be reached using trans-organ or transluminal surgical procedures. The electrical ablation device may be advanced to the treatment site using endoscopic transluminal access techniques to perforate a lumen, and then, advance the electrical ablation device and the endoscope into the peritoneal cavity. Transluminal access procedures for perforating a lumen wall, inserting, and advancing an endoscope therethrough, and pneumoperitoneum devices for insufflating the peritoneal cavity and closing or suturing the perforated lumen wall are well known. During a transluminal access procedure, a puncture must be formed in the stomach

wall or in the gastrointestinal tract to access the peritoneal cavity. One device often used to form such a puncture is a needle knife which is inserted through the channel of the endoscope, and which utilizes energy to penetrate through the tissue. A guidewire is then feed through the endoscope and is passed through the puncture in the stomach wall and into the peritoneal cavity. The needle knife is removed, leaving the guidewire as a placeholder. A balloon catheter is then passed over the guidewire and through the channel of the endoscope to position the balloon within the opening in the stomach wall. The balloon can then be inflated to increase the size of the opening, thereby enabling the endoscope to push against the rear of the balloon and to be feed through the opening and into the peritoneal cavity. Once the endoscope is positioned within the peritoneal cavity, numerous procedures can be performed through the channel of the endoscope.

**[0055]** The endoscope may be connected to a video camera (single chip or multiple chips) and may be attached to a fiber-optic cable system connected to a “cold” light source (halogen or xenon), to illuminate the operative field. The video camera provides a direct line-of-sight view of the treatment region. If working in the abdomen, the abdomen may be insufflated with carbon dioxide (CO<sub>2</sub>) gas to create a working and viewing space. The abdomen is essentially blown up like a balloon (insufflated), elevating the abdominal wall above the internal organs like a dome. CO<sub>2</sub> gas is used because it is common to the human body and can be removed by the respiratory system if it is absorbed through tissue.

**[0056]** Once the electrical ablation devices are located at the target site, the diseased tissue may be electrically ablated or destroyed using the various embodiments of electrodes discussed herein. The placement and location of the electrodes can be important for effective and efficient electrical ablation therapy. For example, the electrodes may be positioned proximal to a treatment region (e.g., target site or worksite) either endoscopically or transcutaneously (percutaneously). In some implementations, it may be necessary to introduce the electrodes inside the patient using a combination of endoscopic, transcutaneous, and/or open techniques.

The electrodes may be introduced to the tissue treatment region through a channel of the endoscope, an overtube, or a trocar and, in some implementations, may be introduced through percutaneously or through small – keyhole – incisions.

**[0057]** Preferably, the various embodiments of the devices described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK® bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

**[0058]** It is preferred that the device is sterilized prior to use. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, steam.

**[0059]** Although the various embodiments of the devices have been described herein in connection with certain disclosed embodiments, many modifications and variations to those embodiments may be implemented. For example, different types of end effectors may be employed. Also, where materials are disclosed for certain components, other materials may be used. The foregoing description and following claims are intended to cover all such modification and variations.

**[0060]** Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which

conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

**CLAIMS**

What is claimed is:

1. An electrical ablation apparatus comprising:  
an elongated body having a proximal end and a distal end and a non-conductive tip at the distal end;  
a conductive sheath at least partially surrounding a portion of the elongated body intermediate the proximal end and the tip; and  
an electrical conductor electrically connected to the conductive sheath.
2. The apparatus of claim 1, wherein the tip comprises a ceramic material, a polymer, a glass material, a carbon material, and any combinations thereof.
3. The apparatus of claim 2, wherein the polymer comprises polytetrafluoroethylene.
4. The apparatus of claim 1, wherein the conductive sheath comprises a metal.
5. The apparatus of claim 4, wherein the metal is selected from the group consisting of medical grade stainless steel and gold.
6. The apparatus of claim 1, wherein the elongated body comprises a tapered segment intermediate the proximal end and the tip.
7. The apparatus of claim 1, wherein the elongated body comprises a tapered segment including a chamfer cut the proximal end and the tip.
8. The apparatus of claim 1, wherein the tip is tapered.
9. The apparatus of claim 1, wherein the elongated body comprises a tapered segment having a chamfer cut intermediate the proximal end and the tip and the tip has a bevel cut.
10. The apparatus of claim 9, wherein the conductive sheath at least partially surrounds a portion of the chamfer cut.

11. The apparatus of claim 1, wherein the tip comprises a cutting edge.
12. The apparatus of claim 1, wherein the device is electrically monopolar.
13. An ablation apparatus comprising:
  - a first electrode having a first diameter;
  - a plurality of second electrodes each having a second diameter comprising a proximal end and a distal end and a first conductive portion intermediate the proximal end and the distal end, a non-conductive portion intermediate the first conductive portion and the distal end, and a second conductive portion at the distal end;
  - a grounding pad comprising a non-conductive outer region and a conductive inner region;
  - an energy source coupled to the first electrode and plurality of second electrodes, the energy source configured to deliver a series of electrical pulses to tissue to induce cell necrosis by irreversible electroporation;
  - wherein the first diameter is greater than the second diameter.
14. The apparatus of claim 13, wherein the grounding pad comprises a central hole including the first electrode therein.
15. The apparatus of claim 13, wherein the first electrode does not contact the conductive inner region of the grounding pad.
16. The apparatus of claim 15, wherein the first conductive portion of each of the plurality of second electrodes contacts the conductive inner region of the grounding pad.
17. The apparatus of claim 16, wherein the first electrode contacts the tissue at a first distance and each of the plurality of second electrodes contacts the tissue at a second distance, and wherein the first distance is greater than the second distance.
18. The apparatus of claim 13, wherein the electrical pulses are characterized by amplitudes in the range of about  $\pm 100$  VDC to about  $\pm 10,000$  VDC, pulse widths in the range of about 1  $\mu$ s to about 100 ms, and frequencies in the range of about 1 Hz to about 10,000 Hz.

19. The apparatus of claim 13, wherein the apparatus is electrically monopolar.
20. A method of treating tissue of a patient, the method comprising:  
positioning a grounding pad adjacent the patient, wherein the grounding pad comprises a central hole, a non-conductive outer region, and a conductive inner region;  
inserting a first electrode under ultrasound guidance through the central hole and into the tissue to a first distance, wherein the first electrode has a first diameter;  
inserting a plurality of second electrodes through the grounding pad into the tissue to a second distance, wherein each second electrode has a second diameter and comprises a proximal end and a distal end and a first conductive portion intermediate the proximal end and the distal end, a non-conductive portion intermediate the first conductive portion and the distal end, and a second conductive portion at the distal end;  
contacting the first conductive portion of each of the second electrodes and the conductive inner region of the grounding pad; and  
delivering a series of electrical pulses to tissue to induce cell necrosis in the tissue by irreversible electroporation;  
wherein the first diameter is greater than the second diameter; and  
wherein the first distance is greater than the second distance.

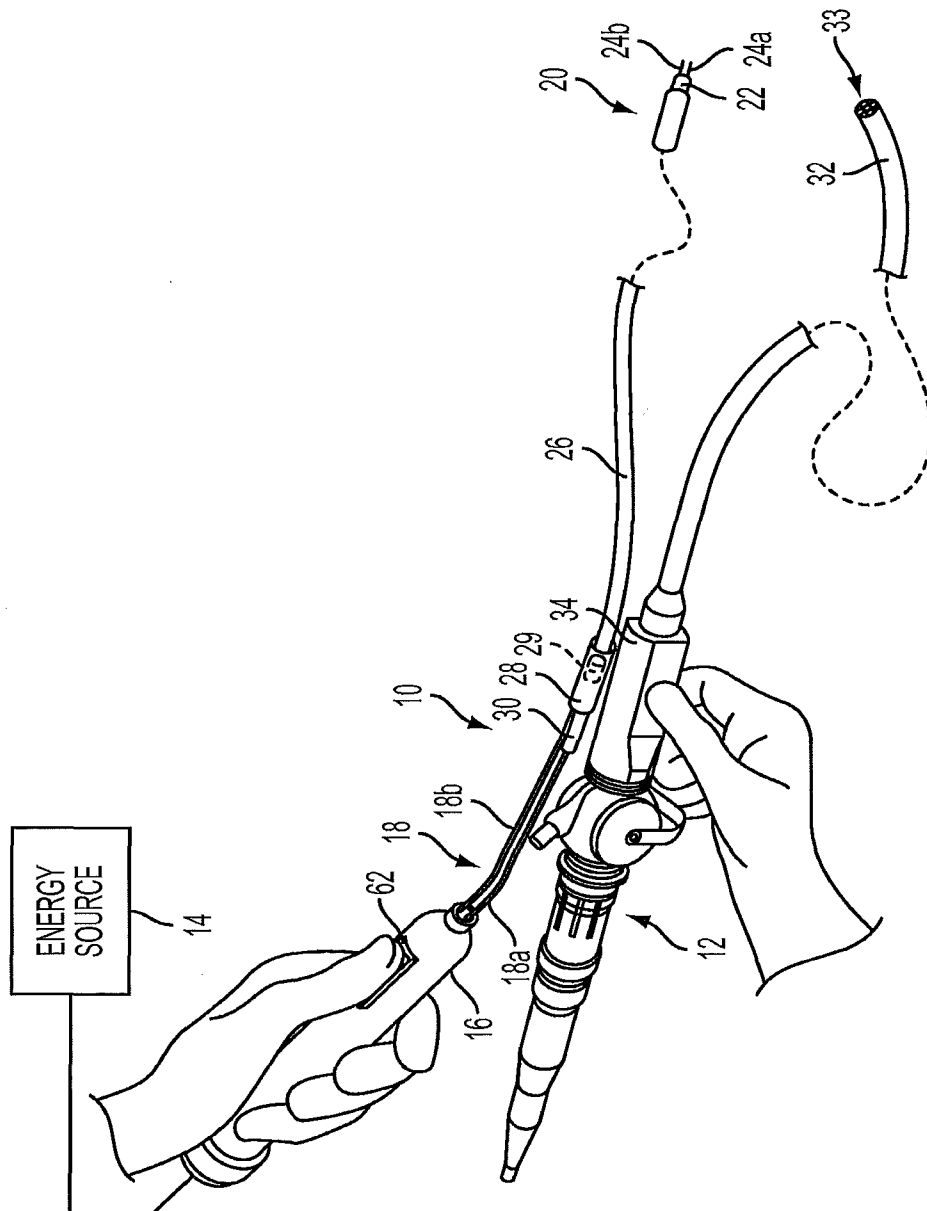


FIG. 1

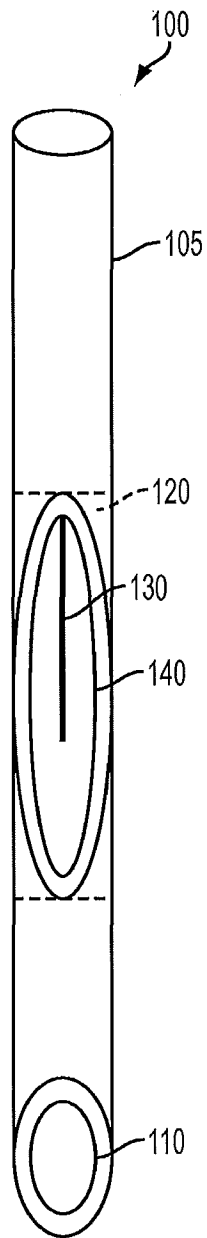


FIG. 2A

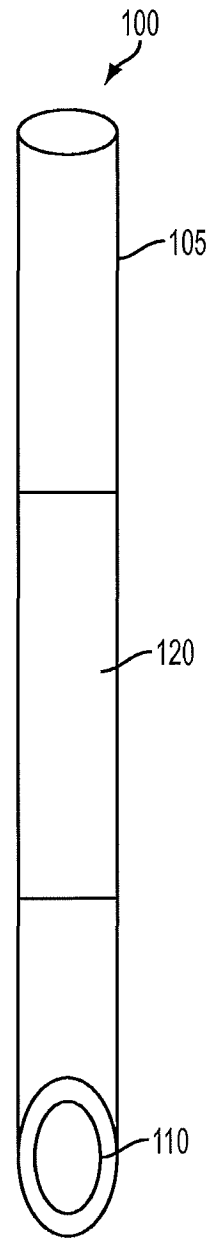


FIG. 2B

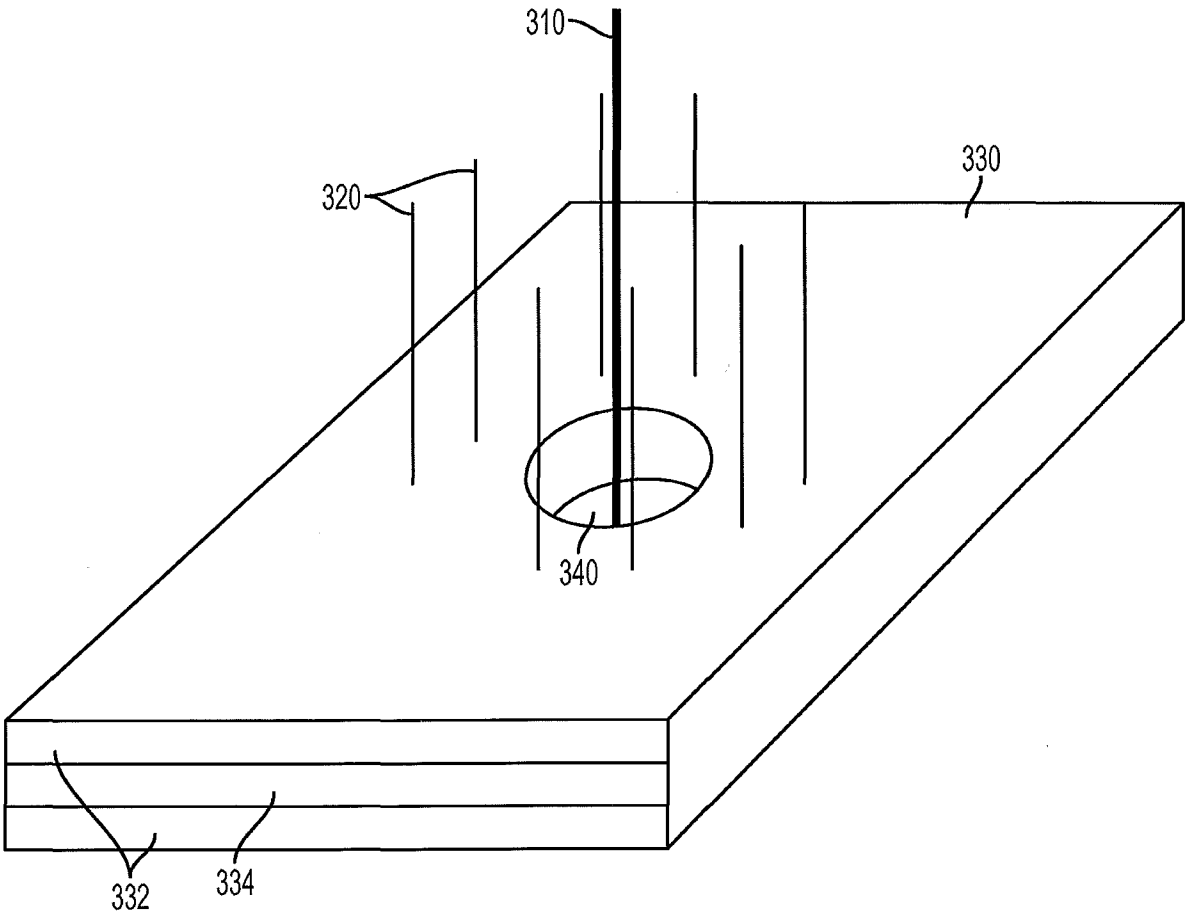


FIG. 3

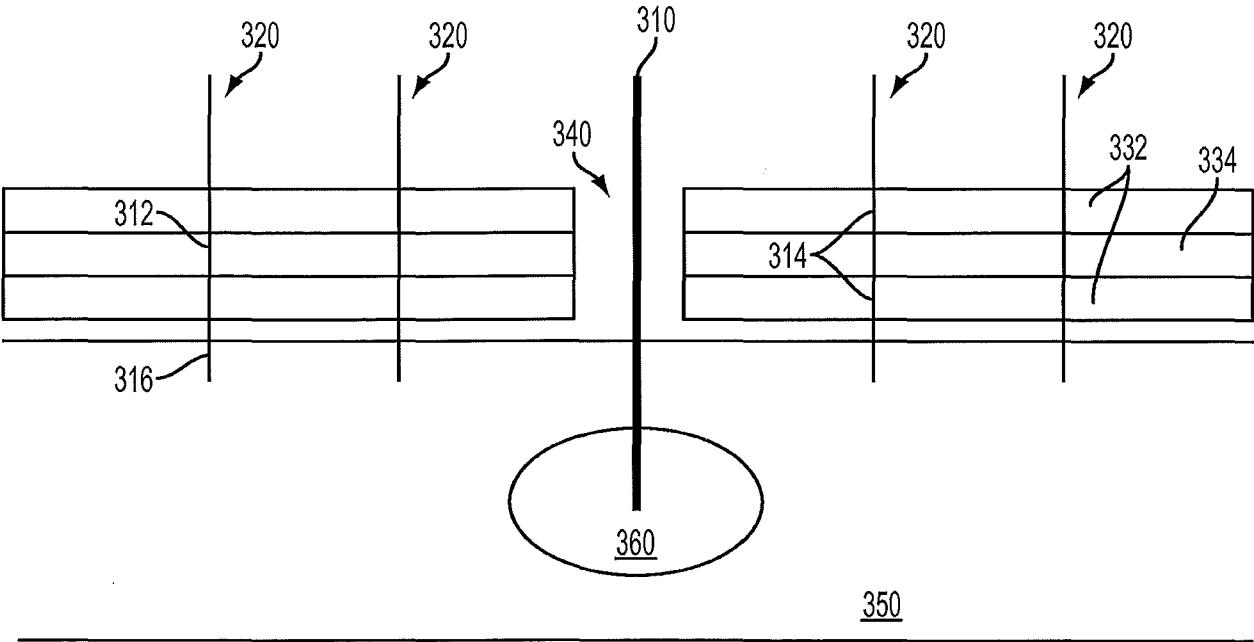


FIG. 4

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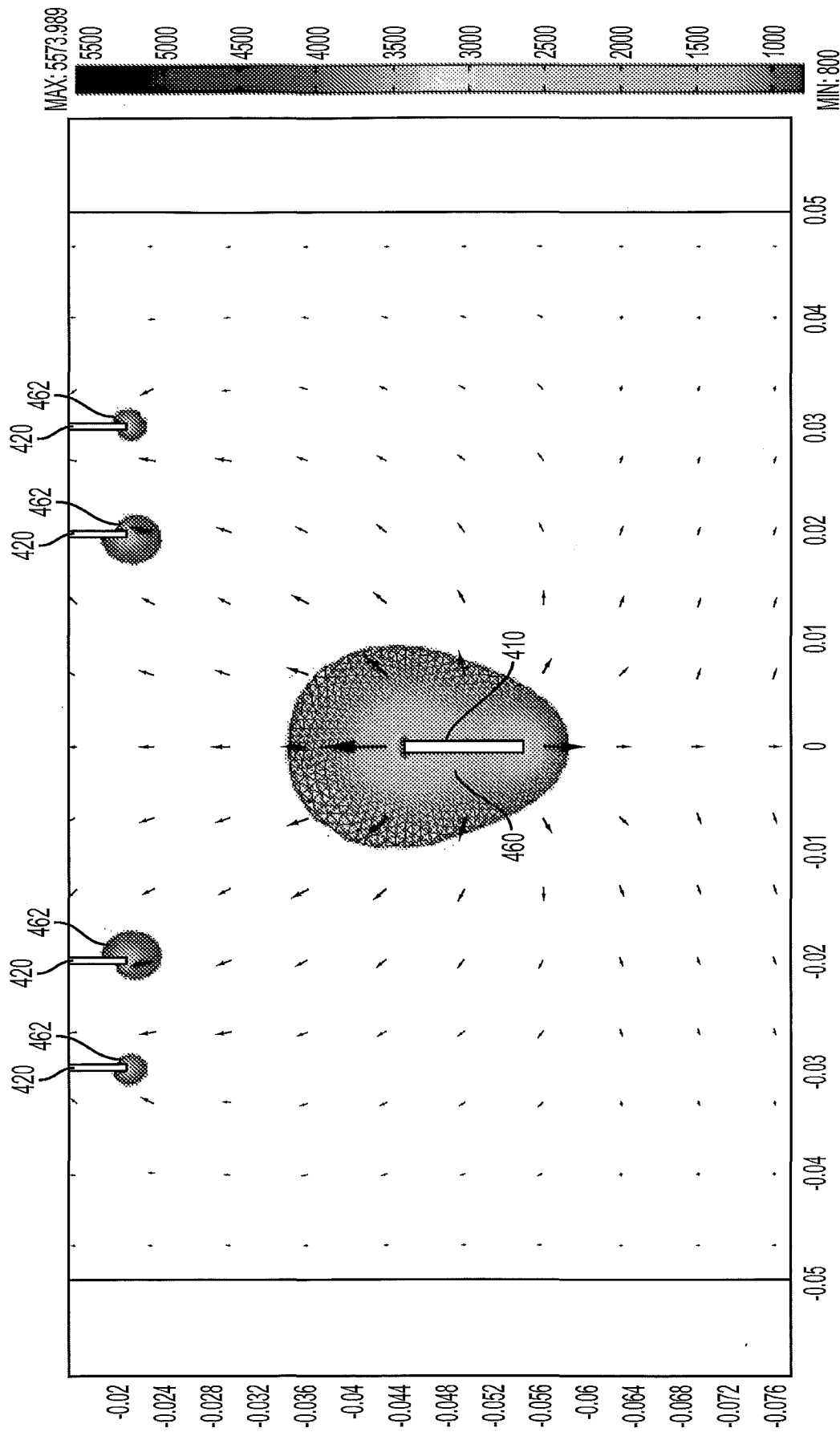


FIG. 5

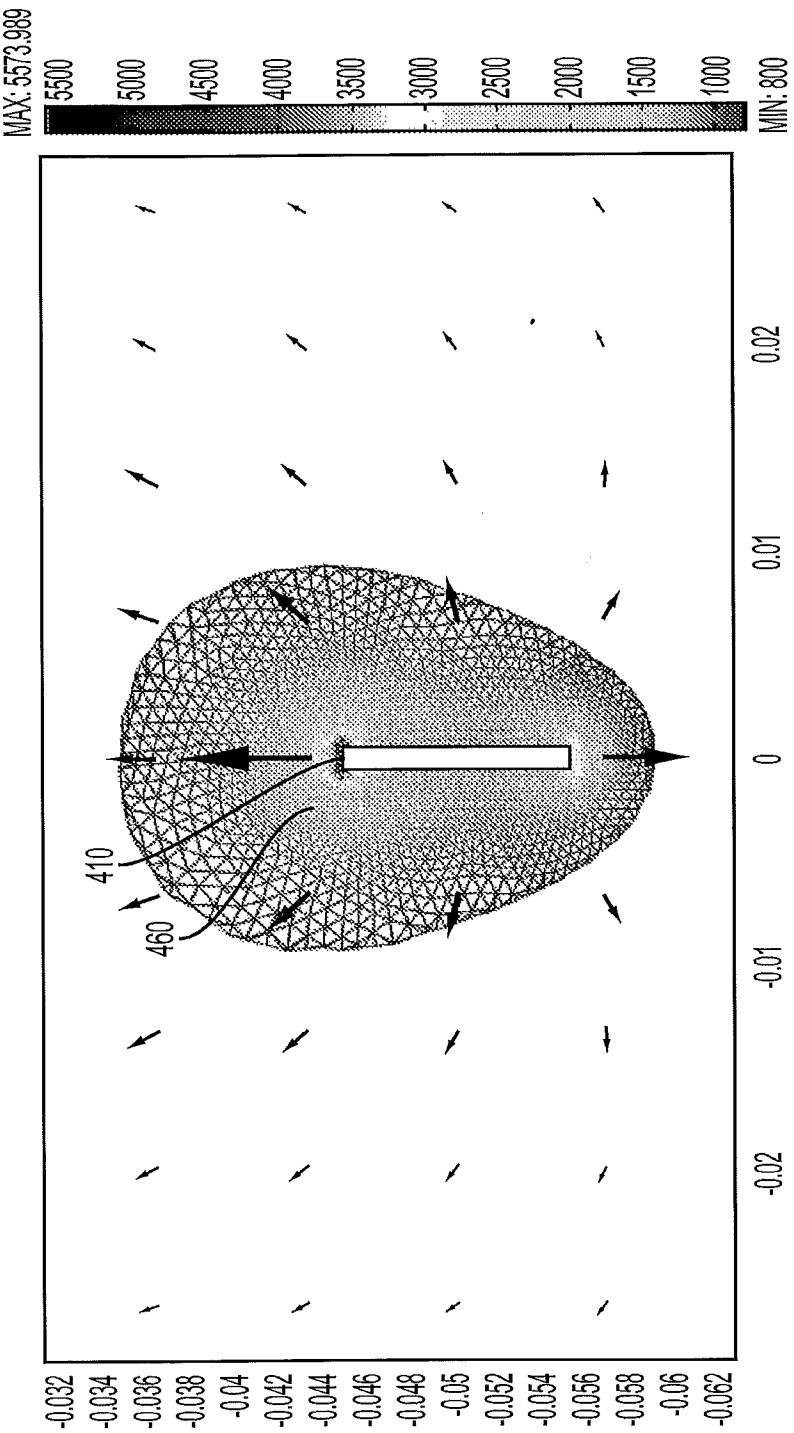


FIG. 6