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(54) **ELECTRICAL ABLATION DEVICES**

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(57) **ABSTRACT**

An electrical ablation apparatus comprises first and second electrodes. Each electrode comprises a first end configured to couple an energy source and a second end configured to couple to a tissue treatment region. An energy source is coupled to the first and second electrodes. At least one electrode is movable between a first position and a second position. A first necrotic zone having a first shape is created when the electrodes are energized in the first position and a second necrotic zone having a second shape is created when the electrodes are energized in the second position. At least one electrode may be pre-formed with a radius.

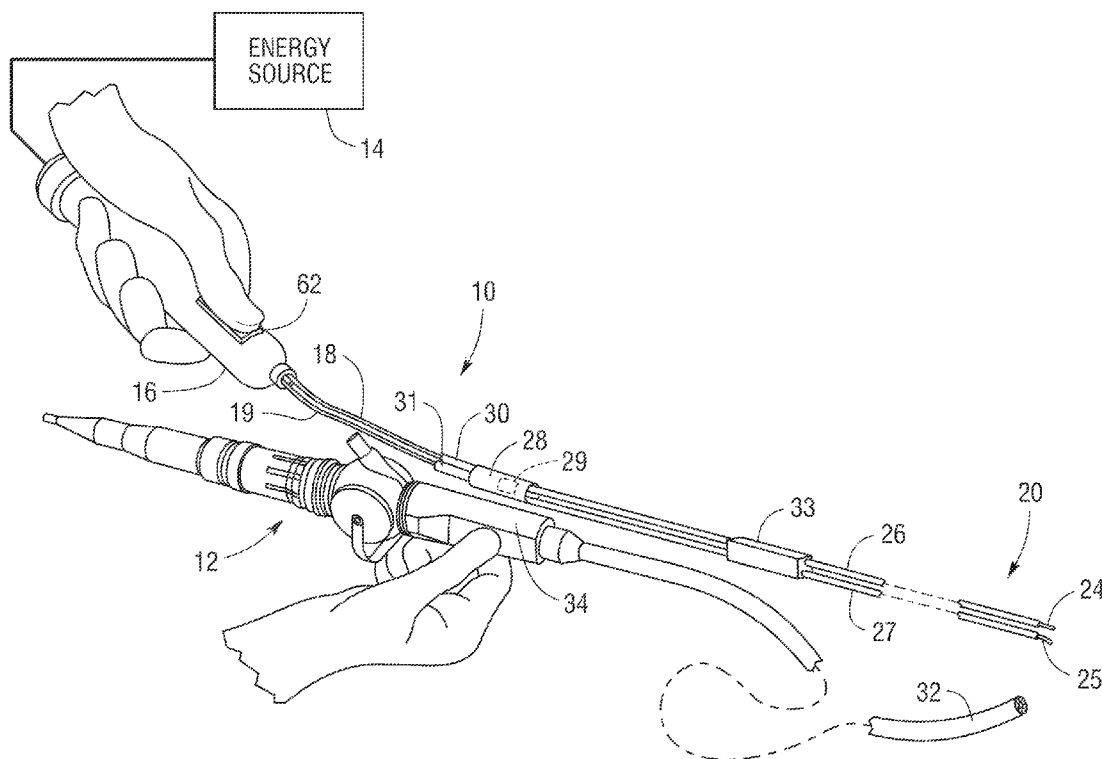
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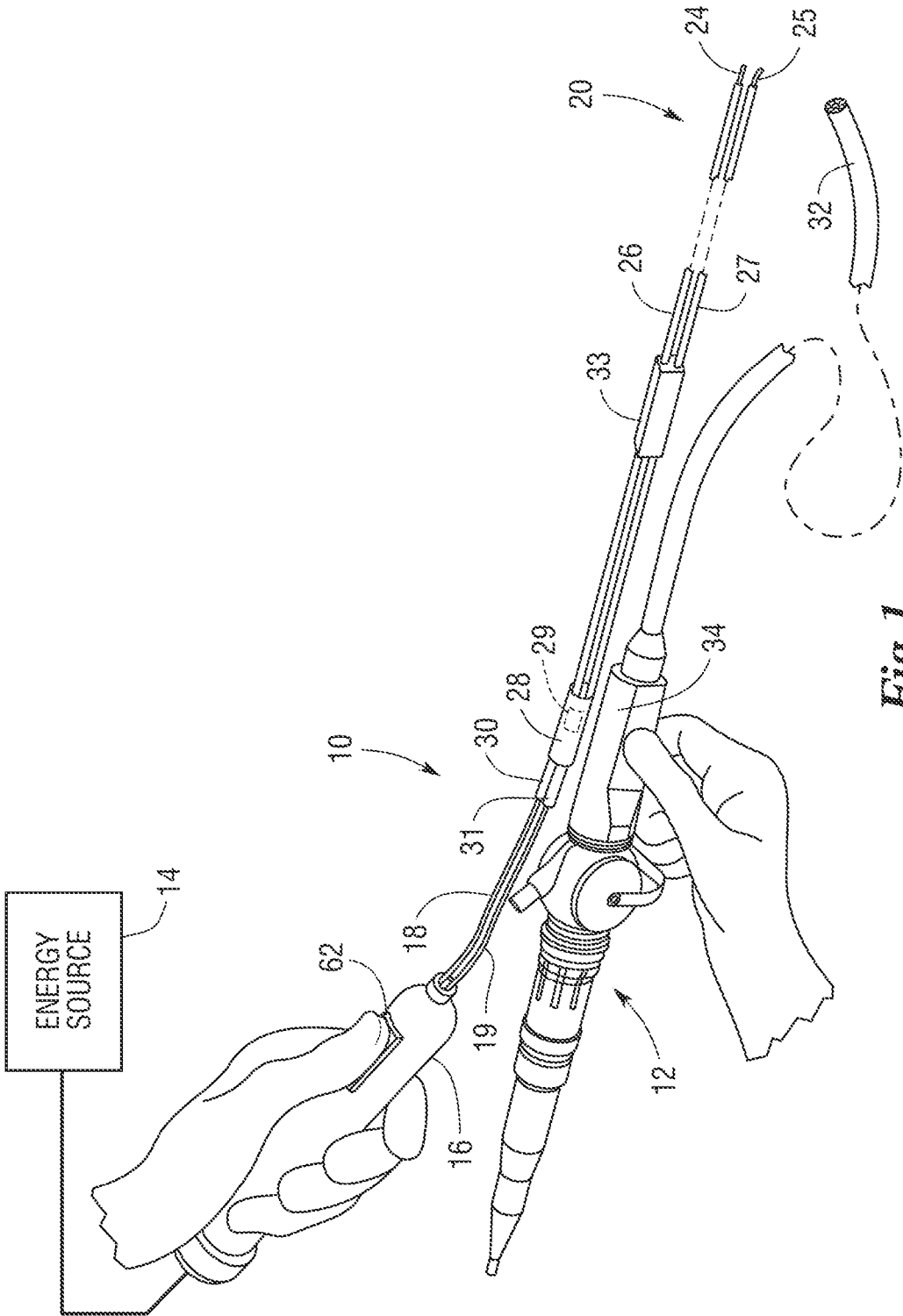


Fig. 1

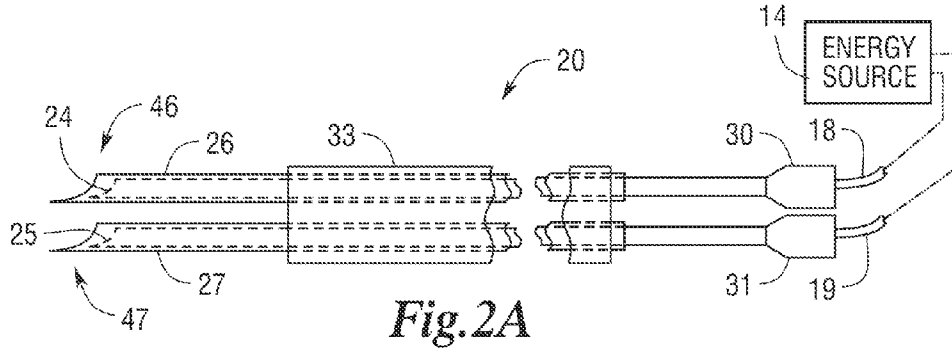


Fig. 2A

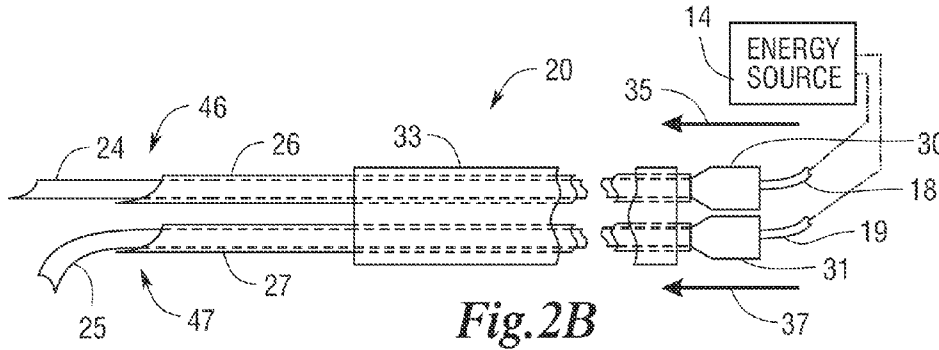


Fig. 2B

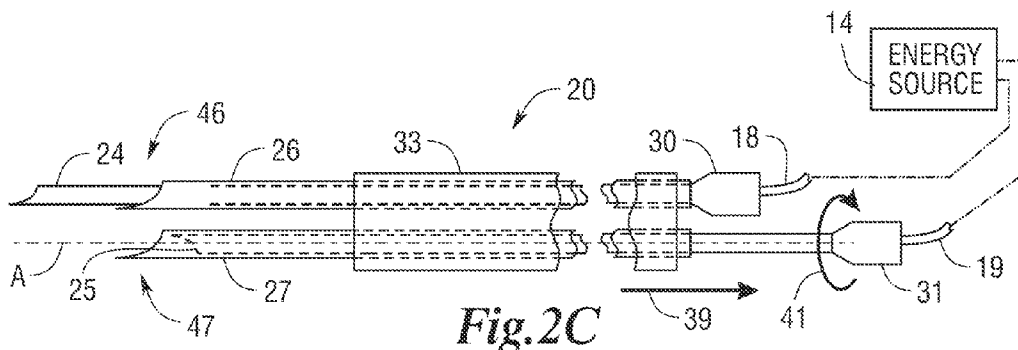


Fig. 2C

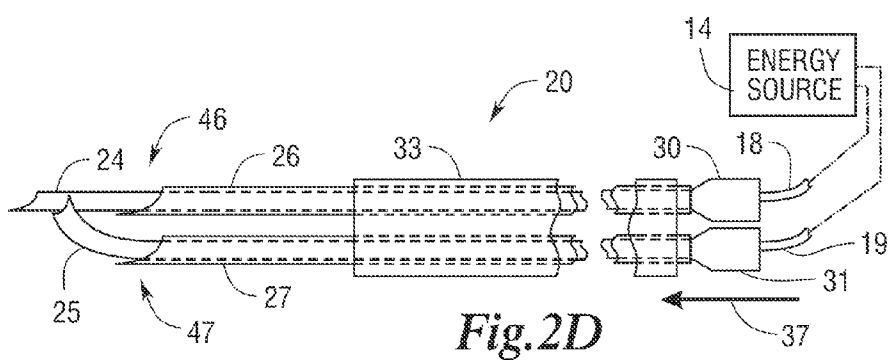


Fig. 2D

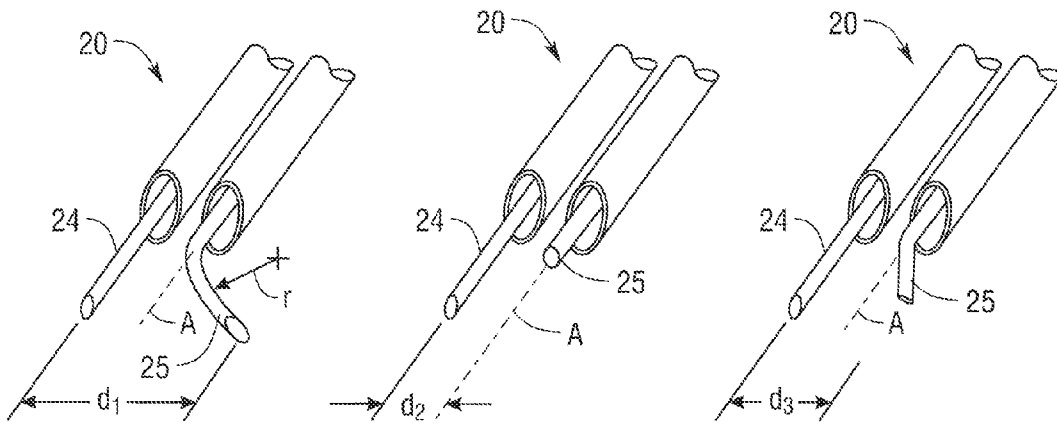


Fig.3A

Fig.3B

Fig.3C

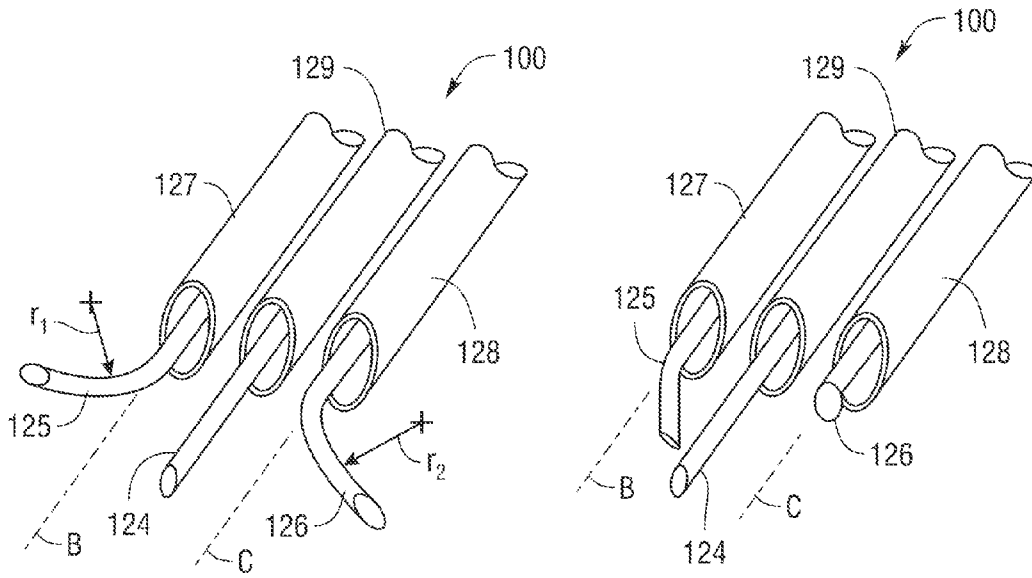


Fig.4A

Fig.4B

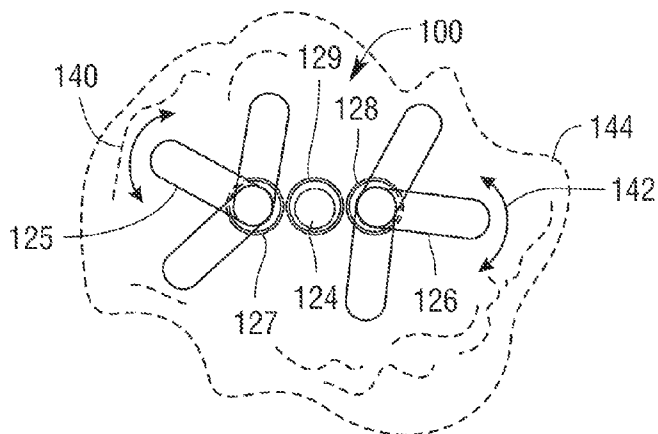


Fig. 5A

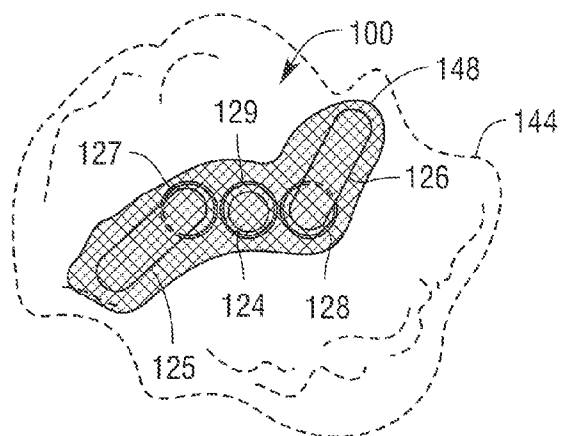


Fig. 5B

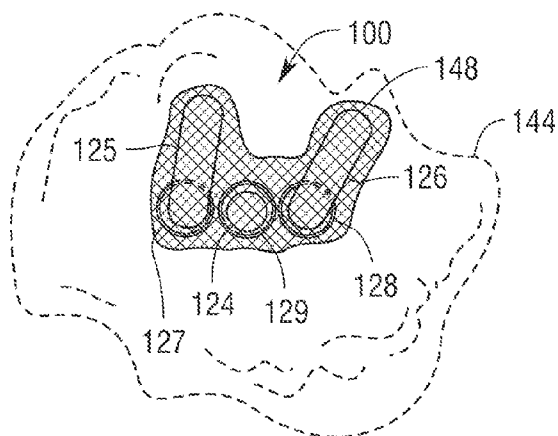


Fig. 5C

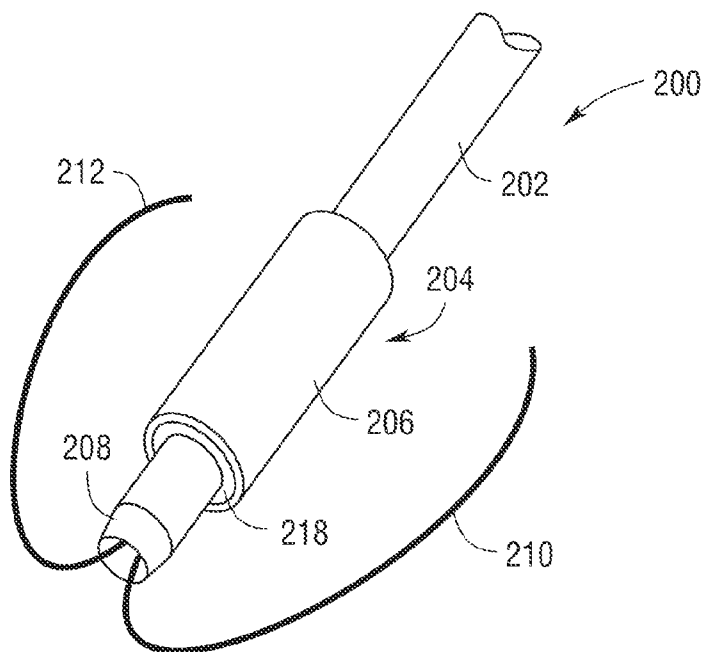


Fig. 6

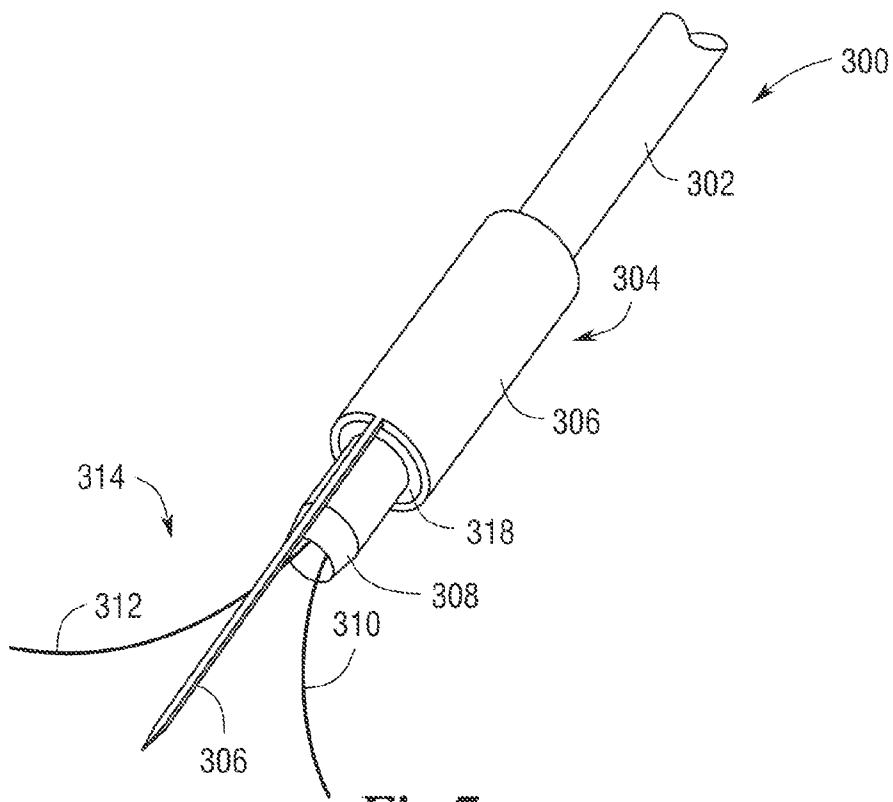


Fig. 7

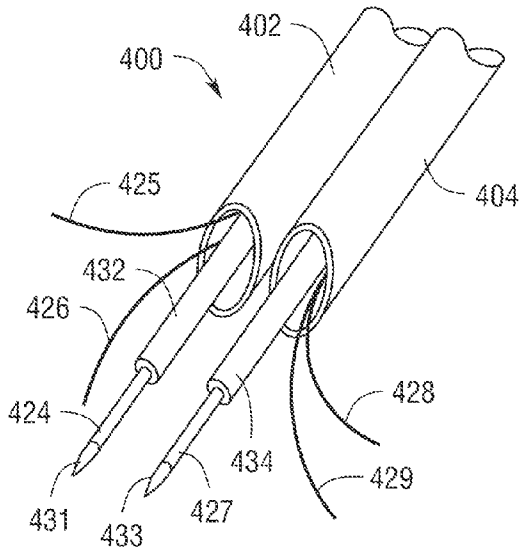


Fig. 8

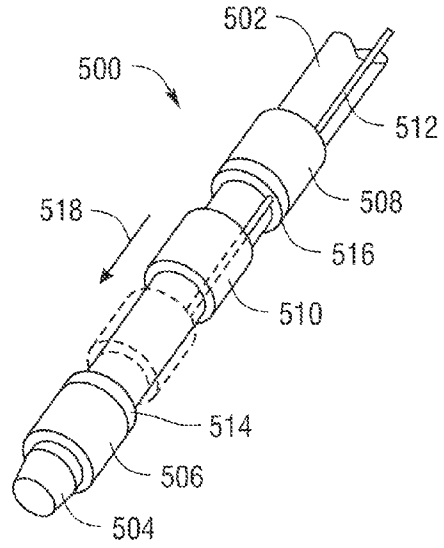


Fig. 9

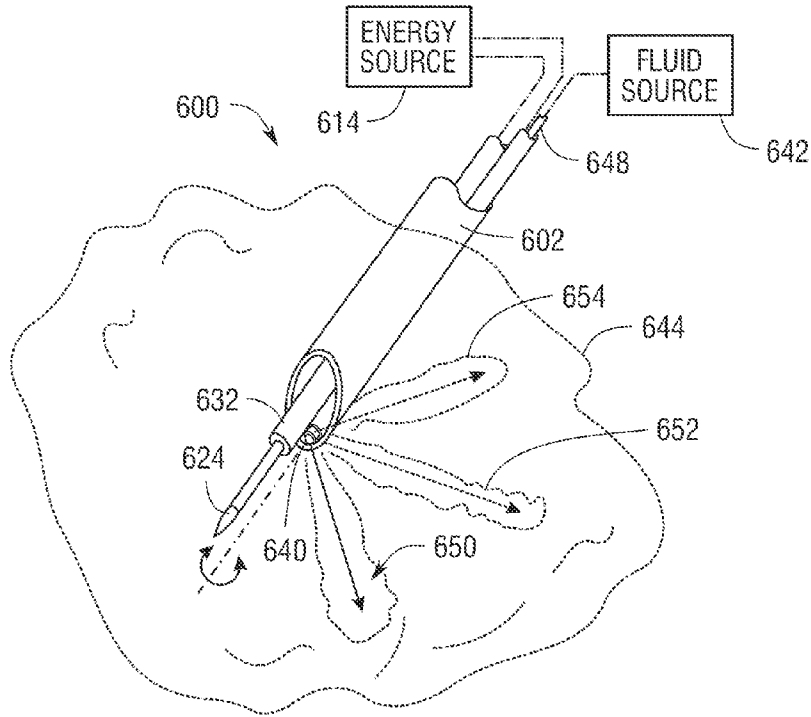


Fig. 10

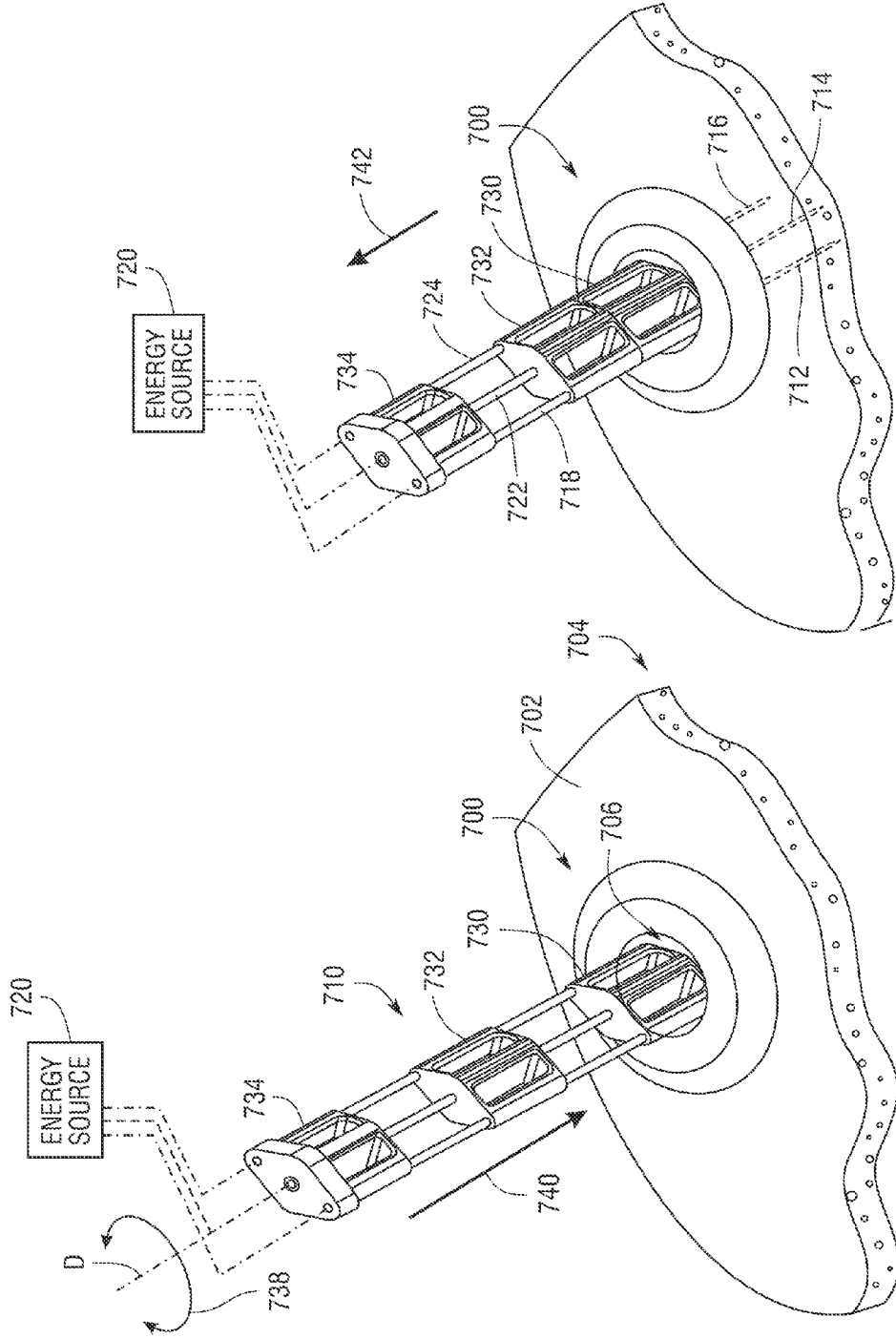


Fig. 11B

Fig. 11A

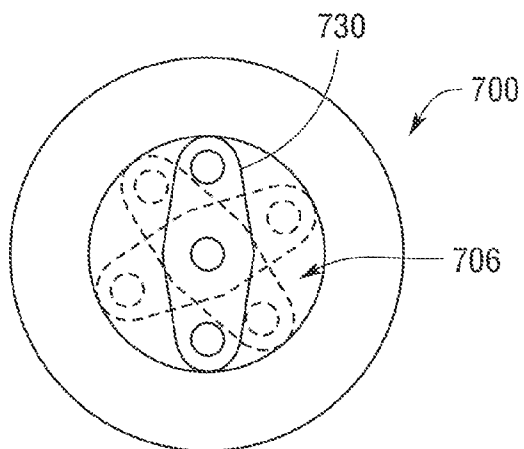


Fig. 12

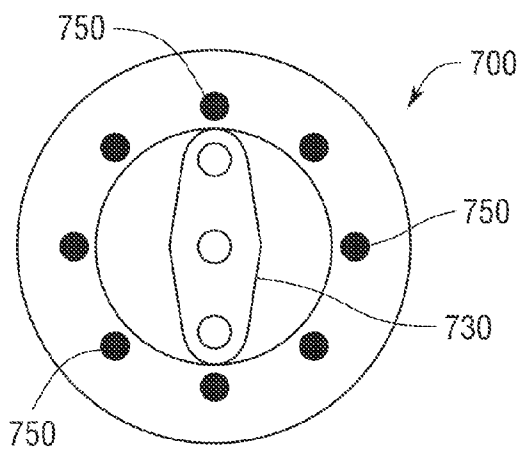


Fig. 13

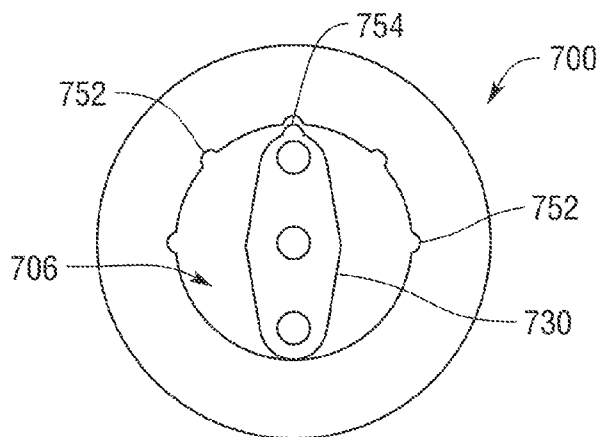


Fig. 14

ELECTRICAL ABLATION DEVICES

BACKGROUND

[0001] Electrical ablation therapy has been employed in medicine for the treatment of undesirable tissue such as diseased tissue, cancer, malignant and benign tumors, masses, lesions, and other abnormal tissue growths. While conventional apparatuses, systems, and methods for the electrical ablation of undesirable tissue are effective, one drawback with conventional electrical ablation treatment is the resulting permanent damage that may occur to the healthy tissue surrounding the abnormal tissue due primarily to the detrimental thermal effects resulting from exposing the tissue to thermal energy generated by the electrical ablation device. This may be particularly true when exposing the tissue to electric potentials sufficient to cause cell necrosis using high temperature thermal therapies including focused ultrasound ablation, radiofrequency (RF) ablation, or interstitial laser coagulation. Other techniques for tissue ablation include chemical ablation, in which chemical agents are injected into the undesirable tissue to cause ablation as well as surgical excision, cryotherapy, radiation, photodynamic therapy, Moh's micrographic surgery, topical treatments with 5-fluorouracil, laser ablation. Other drawbacks of conventional thermal, chemical, and other ablation therapy are cost, length of recovery, and the extraordinary pain inflicted on the patient.

[0002] Conventional thermal, chemical, and other ablation techniques have been employed for the treatment of a variety of undesirable tissue. Thermal and chemical ablation techniques have been used for the treatment of varicose veins resulting from reflux disease of the greater saphenous vein (GSV), in which the varicose vein is stripped and then is exposed to either chemical or thermal ablation. Other techniques for the treatment of undesirable tissue are more radical. Prostate cancer, for example, may be removed using a prostatectomy, in which the entire or part of prostate gland and surrounding lymph nodes are surgically removed. Like most other forms of cancer, radiation therapy may be used in conjunction with or as an alternate method for the treatment of prostate cancer. Another thermal ablation technique for the treatment of prostate cancer is RF interstitial tumor ablation (RITA) via trans-rectal ultrasound guidance. While these conventional methods for the treatment of prostate cancer are effective, they are not preferred by many surgeons and may result in detrimental thermal effects to healthy tissue surrounding the prostate. Similar thermal ablation techniques may be used for the treatment of basal cell carcinoma (BCC) tissue, a slowly growing cutaneous malignancy derived from the rapidly proliferating basal layer of the epidermis. BCC tissue in tumors ranging in size from about 5 mm to about 40 mm may be thermally ablated with a pulsed carbon dioxide laser. Nevertheless, carbon dioxide laser ablation is a thermal treatment method and may cause permanent damage to healthy tissue surrounding the BCC tissue. Furthermore, this technique requires costly capital investment in carbon dioxide laser equipment. Undesirable tissue growing inside a body lumen such as the esophagus, large bowel, or in cavities formed in solid tissue such as the breast, for example, can be difficult to destroy using conventional ablation techniques. Surgical removal of undesirable tissue, such as a malignant or benign tumor, from the breast is likely to leave a cavity. Surgical resection of residual intraluminal tissue may remove only a portion of the undesirable tissue cells within a certain margin of healthy tissue. Accordingly, some undesirable tis-

sue is likely to remain within the wall of the cavity due to the limitation of conventional ablation instrument configurations, which may be effective for treating line-of-sight regions of tissue, but may be less effective for treating the residual undesirable tissue.

[0003] Accordingly, there remains a need for improved electrical ablation apparatuses, systems, and methods for the treatment of undesirable tissue found in diseased tissue, cancer, malignant and benign tumors, masses, lesions, and other abnormal tissue growths. There remains a need for minimally invasive treatment of undesirable tissue through the use of irreversible electroporation (IRE) ablation techniques without causing the detrimental thermal effects of conventional thermal ablation techniques.

FIGURES

[0004] The novel features of the various described embodiments are set forth with particularity in the appended claims. The various embodiments, however, both as to organization and methods of operation, together with advantages thereof, may be understood in accordance with the following description taken in conjunction with the accompanying drawings as follows.

[0005] FIG. 1 illustrates one embodiment of an electrical ablation system in accordance with one non-limiting embodiment.

[0006] FIGS. 2A-D illustrate one embodiment of the electrical ablation device in various phases of deployment.

[0007] FIGS. 3A-C illustrate perspective views of one embodiment of the electrical ablation device shown in FIGS. 2A-2D.

[0008] FIGS. 4A-C illustrate perspective views of one embodiment of the electrical ablation device.

[0009] FIGS. 5A-C illustrate the operation of electrical ablation device shown in FIGS. 4A-C in accordance with one non-limiting embodiment.

[0010] FIG. 6 illustrates an electrical ablation apparatus in accordance with one non-limiting embodiment.

[0011] FIG. 7 illustrates an electrical ablation apparatus in accordance with one non-limiting embodiment.

[0012] FIG. 8 illustrates an electrical ablation apparatus in accordance with one non-limiting embodiment.

[0013] FIG. 9 illustrates an electrical ablation apparatus in accordance with one non-limiting embodiment.

[0014] FIG. 10 illustrates an electrical ablation apparatus in accordance with one non-limiting embodiment.

[0015] FIGS. 11A-B illustrate the use of an alignment guide with an electrical ablation apparatus in accordance with one non-limiting embodiment.

[0016] FIG. 12 illustrates the engagement of the alignment guide shown in FIGS. 11A-B and a handle of the electrical ablation apparatus shown in FIGS. 11A-B.

[0017] FIG. 13 illustrates an alignment guide comprising a plurality of visual indicators in accordance with one non-limiting embodiment.

[0018] FIG. 14 illustrates an alignment guide comprising a plurality of detents in accordance with one non-limiting embodiment.

DESCRIPTION

[0019] Various embodiments are directed to apparatuses, systems, and methods for the electrical ablation treatment of undesirable tissue such as diseased tissue, cancer, malignant

and benign tumors, masses, lesions, and other abnormal tissue growths without causing any detrimental thermal effects to surrounding healthy tissue. Numerous specific details are set forth to provide a thorough understanding of the overall structure, function, manufacture, and use of the embodiments as described in the specification and illustrated in the accompanying drawings. It will be understood by those skilled in the art, however, that the embodiments may be practiced without the specific details described and illustrated herein. In other instances, well-known operations, components, and elements have not been described in detail so as not to obscure the embodiments described in the specification. Those of ordinary skill in the art will understand that the embodiments described and illustrated herein are non-limiting examples, and thus it can be appreciated that the specific structural and functional details disclosed herein may be representative and do not necessarily limit the scope of the embodiments, the scope of which is defined solely by the appended claims.

[0020] Reference throughout the specification to “various embodiments,” “some embodiments,” “one embodiment,” or “an embodiment” means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases “in various embodiments,” “in some embodiments,” “in one embodiment,” or “in an embodiment” in places throughout the specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. Thus, the particular features, structures, or characteristics illustrated or described in connection with one embodiment may be combined, in whole or in part, with the features structures, or characteristics of one or more other embodiments without limitation.

[0021] It will be appreciated that the terms “proximal” and “distal” may be used throughout the specification with reference to a clinician manipulating one end of an instrument used to treat a patient. The term “proximal” refers to the portion of the instrument closest to the clinician and the term “distal” 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.

[0022] Various embodiments of apparatuses, systems, and methods for the electrical ablation treatment of undesirable tissue such as diseased tissue, cancer, malignant and benign tumors, masses, lesions, and other abnormal tissue growths, are described throughout the specification and illustrated in the accompanying drawings. The electrical ablation devices in accordance with the described embodiments may comprise one or more electrodes configured to be positioned into or proximal to undesirable tissue in a tissue treatment region (e.g., target site, worksite) where there is evidence of abnormal tissue growth, for example. In general, the electrodes comprise an electrically conductive portion (e.g., medical grade stainless steel, gold plated, etc.) and are configured to electrically couple to an energy source. Once the electrodes are positioned into or proximal to the undesirable tissue, an energizing potential is 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 multiple parameters such as 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 may comprise a plurality of electrodes with at least one configured as an anode and at least one other configured as a cathode. Regardless of the initial polar configuration, the polarity of the electrodes may be reversed by reversing the polarity of the output of the energy source.

[0023] In various embodiments, a suitable energy source may comprise an electrical waveform generator, which 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 irreversible electroporation 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 irreversible electroporation pulses may be characterized by various parameters such as frequency, amplitude, pulse length, and/or polarity. The undesirable tissue may be ablated by exposure to the electric potential difference across the electrodes.

[0024] 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. Those skilled in the art will appreciate that wireless energy transfer or wireless power transmission is the process of transmitting electrical energy from an energy source to an electrical load without interconnecting wires. An electrical transformer is the simplest instance of wireless energy transfer. The primary and secondary circuits of a transformer are not directly connected and the transfer of energy takes place by electromagnetic coupling through a process known as mutual induction. Power also may be transferred wirelessly using RF energy. Wireless power transfer technology using RF energy is produced by Powercast, Inc. and can achieve an output of about 6 volts for a little over one meter. Other low-power wireless power technology has been proposed such as described in U.S. Pat. No. 6,967,462.

[0025] The apparatuses, systems, and methods in accordance with the described embodiments may be configured for minimally invasive ablation treatment of undesirable tissue through the use of irreversible electroporation to be able to ablate undesirable tissue in a controlled and focused manner without inducing thermally damaging effects to the surrounding healthy tissue. The apparatuses, systems, and methods in accordance with the described embodiments may be configured to ablate undesirable tissue through the use of electroporation or electropermeabilization. More specifically, the apparatuses, systems, and methods in accordance with the described embodiments may be configured to ablate undesirable tissue through the use of irreversible electroporation. Electroporation increases the permeabilization of a cell membrane by exposing the cell to electric pulses. The external electric field (electric potential/per unit length) to which the cell membrane is exposed to significantly increases the electrical conductivity and permeability of the plasma in the cell membrane. The primary parameter affecting the transmembrane potential is the potential difference across the cell membrane. Irreversible electroporation is 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, leading to cell death without inducing a significant amount of heat in the cell membrane. The destabilizing potential forms 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. The application of irreversible electroporation pulses to cells is an effective way for ablating large volumes of undesirable tissue without deleterious thermal effects to the surrounding healthy tissue associated with thermal-inducing ablation treatments. This is because irreversible electroporation destroys cells without heat and thus does 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 about several hundred to about several thousand volts and is generally applied across biological membranes over a distance of about several millimeters, for example, for a relatively long duration. Thus, the undesirable tissue may be ablated in-vivo through the delivery of destabilizing electric fields by quickly creating cell necrosis.

[0026] The apparatuses, systems, and methods for electrical ablation therapy in accordance with the described embodiments may be adapted for use in minimally invasive surgical procedures to access the tissue treatment region in various anatomic locations such as 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, for example, without limitation. Minimally invasive electrical ablation devices may be introduced to the tissue treatment region using a trocar inserted through a small opening formed in the patient's body 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)TM. Once the electrical ablation devices (e.g., electrodes) are located into or proximate to the undesirable tissue in the treatment region, electric field potentials can be applied to the undesirable tissue by the energy source. The electrical ablation devices 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 in commonly owned U.S. patent application Ser. No. 12/352,375 titled "ELECTRICAL ABLATION DEVICES," filed Jan. 12, 2009, the entire disclosure of which is incorporated herein by reference in its entirety.

[0027] 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 diseased tissues, cancers, tumors, masses, lesions, abnormal tissue growths inside a patient using electrical energy. The electrical ablation system 10 may be used in conjunction with endoscopic, laparoscopic, thoracoscopic, open surgical procedures via small incisions or keyholes, percutaneous tech-

niques, transcutaneous techniques, and/or external non-invasive techniques, or any combinations thereof without limitation. The electrical ablation system 10 may be configured to be positioned within a natural body orifice of the patient such as the mouth, anus, or vagina and advanced through internal body lumen or cavities such as the esophagus, colon, cervix, urethra, for example, to reach the tissue treatment region. The electrical ablation system 10 also may be configured to be positioned and passed through a small incision or keyhole formed through the skin or abdominal wall of the patient to reach the tissue treatment region using a trocar. The tissue treatment region may be located in the brain, lungs, 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, for example, without limitation. The electrical ablation system 10 can be configured to treat a number of lesions and osteopathologies comprising metastatic lesions, tumors, fractures, infected sites, inflamed sites. Once positioned into or proximate the tissue treatment region, the electrical ablation system 10 can 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 (GI) tract, esophagus, lung, 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, without limitation, NOTESTM techniques, where the electrical ablation devices may be initially introduced through a natural orifice such as the mouth, anus, or vagina and then advanced to the tissue treatment site by puncturing the walls of internal body lumen such as the stomach, intestines, colon, cervix. In various embodiments, the electrical ablation system 10 may be adapted to treat undesirable tissue in the brain, liver, breast, gall bladder, pancreas, or prostate gland, using one or more electrodes positioned percutaneously, transcutaneously, transluminally, minimally invasively, and/or through open surgical techniques, or any combination thereof.

[0028] 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, an endoscope 12 is not utilized, and instead other technique, such as ultrasound or a computerized tomography (CT) scan, for example, is used to determine proper instrument placement during the procedure.

[0029] 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 electrical ablation devices, for example. Images within the field of view of the viewing port are received by an optical device, such as

a camera comprising a charge coupled device (CCD) usually located within the endoscope 12, and are transmitted to a display monitor (not shown) outside the patient.

[0030] In one embodiment, the electrical ablation system 10 may comprise an electrical ablation device 20, a plurality of electrical conductors 18, a handpiece 16 comprising an activation switch 62, and an energy source 14, such as 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 first lumen 26 and a second lumen 27. The first lumen 26 and the second lumen 27 may be introduced to the tissue treatment region using a variety of known techniques such as an open incision and a trocar, through one of more of the channels of the endoscope 12, percutaneously, or transcutaneously. In some embodiments, the first lumen 26 and the second lumen 27 may be relatively rigid or flexible. Additionally, additional lumens may be utilized, such as a larger lumen (not shown) surrounding the first lumen 26 and the second lumen 27. Further, a housing 33, or other suitable structure, may be utilized to maintain the relative position of the first lumen 26 and the second lumen 27.

[0031] In one embodiment, one or more electrodes (e.g., needle electrodes, balloon electrodes), such as a first electrode 24 and a second electrode 25, extend out from the distal end of the electrical ablation device 20. In one embodiment, the first electrode 24 may be configured as the positive electrode and the second electrode 25 may be configured as the negative electrode. The first electrode 24 is electrically connected to a first electrical conductor 18, or similar electrically conductive lead or wire, which is coupled to the positive terminal of the energy source 14 through the activation switch 62. The second electrode 25 is electrically connected to a second electrical conductor 19, or similar electrically conductive lead or wire, which is coupled to the negative terminal of the energy source 14 through the activation switch 62. The electrical conductors 18, 19 are electrically insulated from each other and surrounding structures except for the electrical connections to the respective electrodes 24, 25. In various 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, or external and non-invasive medical procedures. The electrodes 24, 25 may be referred to herein as endoscopic or laparoscopic electrodes, although variations thereof may be inserted transcutaneously or percutaneously. As previously discussed, either one or both electrodes 24, 25 may be adapted and configured to slideably move in and out of lumens 26, 27, respectively. In one embodiment, either one or both of the electrodes 24, 25 may be formed in a radius (i.e., arcuate, curved). Additionally, as discussed in more detail below, either one or both of the electrodes 24, 25 may be rotatable within their respective lumens 26, 27. Various features of one embodiment of the first and second electrodes 24, 25 are described in more detail in FIGS. 2A-D.

[0032] Once the electrodes 24, 25 are positioned at the desired location into or proximate the tissue treatment region, the electrodes 24, 25 may be connected to or disconnected from the energy source 14 by actuating or de-actuating the switch 62 on the handpiece 16. The switch 62 may be operated manually or may be mounted on a foot switch (not shown), for example. The electrodes 24, 25 deliver electric field pulses to the undesirable tissue. The electric field pulses

may be characterized based on various parameters such as pulse shape, amplitude, frequency, and duration. The electric field pulses may be sufficient to induce irreversible electroporation in the undesirable tissue. The induced potential depends on a variety of conditions such as tissue type, cell size, and electrical pulse parameters. The primary electrical pulse parameter affecting the transmembrane potential for a specific tissue type is the amplitude of the electric field and pulse length that the tissue is exposed to.

[0033] In one embodiment, the first and second electrical conductors 18, 19 may be provided through the handle 28. In the illustrated embodiment, the electrode 24 can be slideably moved in and out of the distal end of the first lumen 26 using a slide member 30 to retract and/or advance the first electrode 24. The electrode 25 can be slideably moved in and out of the distal end of the second lumen 27 using a slide member 31 to retract and/or advance the second electrode 25. In various embodiments either or both electrodes 24, 25 may be coupled to a single slide member, or additional slide members, to advance and retract the electrodes 24, 25, e.g., position the electrodes 24, 25. In the illustrated embodiment, the first electrical conductor 18 coupled to the first electrode 24 is coupled to the slide member 30. In this manner, the first electrode 24, which is slidably movable within the cannula, lumen, or channel defined by the first lumen 26, can be advanced and retracted with the slide member 30. In the illustrated embodiment, the second electrical conductor 19 coupled to the second electrode 25 is coupled to the slide member 31. In this manner, the second electrode 25, which is slidably movable within the cannula, lumen, or channel defined by the second lumen 27, can be advanced and retracted with the slide member 31. In one embodiment, various slide members, such as the slide member 31, are rotatable. Thus rotation of the slide member 30, 31 rotates the corresponding electrode 24, 25, respectively, at the distal end of the electrical ablation device 20.

[0034] In various other embodiments, transducers 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 24, 25 penetrate the tissue in the tissue treatment zone. This feedback information may be useful to determine whether either one or both of the electrodes 24, 25 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 is required to insert the electrodes 24, 25 therein. The transducers or sensors 29 can provide feedback to the operator, surgeon, or clinician to physically sense when the electrodes 24, 25 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 24, 25 have been properly located within the cancerous tumor thereby assuring that a suitable margin of error has been achieved in locating the electrodes 24, 25.

[0035] 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 is coupled to the electrodes 24, 25, which may be energized using the activation switch 62 on the handpiece 16, or in one embodiment, an activation switch mounted on a foot activated pedal (not shown). The energy source 14 may be con-

figured to produce electrical energy suitable for electrical ablation, as described in more detail below.

[0036] In one embodiment, the electrodes **24**, **25** are adapted and configured to electrically couple to the energy source **14** (e.g., generator, waveform generator). Once electrical energy is coupled to the electrodes **24**, **25**, an electric field is formed at a distal end of the electrodes **24**, **25**. The energy source **14** may be configured to generate electric pulses at a predetermined frequency, amplitude, pulse length, 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 length, 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.

[0037] 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 produce a series of n electric pulses (where n is any positive integer) of sufficient amplitude and duration to induce irreversible electroporation suitable for tissue ablation when the n electric pulses are applied to the electrodes **24**, **25**. In one embodiment, the electric pulses may have a fixed or variable pulse length, amplitude, and/or frequency.

[0038] The electrical ablation device **20** may be operated either in bipolar or monopolar mode. In bipolar mode, the first electrode **24** is electrically connected to a first polarity and the second electrode **25** is electrically connected to the opposite polarity. For example, in monopolar mode, the first electrode **24** is coupled to a prescribed voltage and the second electrode **25** is set to ground. In the illustrated embodiment, 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 **24** is electrically connected to a prescribed voltage of one polarity and the second electrode **25** is 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, for example.

[0039] In monopolar mode, it is not necessary that the patient be grounded with a grounding pad. Since a monopolar energy source **14** is 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 is able to activate the energy source **14**. It will be appreciated that in monopolar mode, the impedance circuit can be electrically connected in series with either one of the electrodes **24**, **25** that would otherwise be attached to a grounding pad.

[0040] In one embodiment, the energy source **14** may be configured to produce RF waveforms at predetermined frequencies, amplitudes, pulse widths or durations, and/or polarities suitable for electrical ablation of cells in the tissue

treatment region. One example of a suitable RF energy source is a commercially available conventional, bipolar/monopolar electrosurgical RF generator such as Model Number ICC 350, available from Erbe, GmbH.

[0041] In one embodiment, the energy source **14** 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 **20**. 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, Mass. In bipolar mode, the first electrode **24** 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 produced at a variety of frequencies, amplitudes, pulse lengths, and/or polarities. Unlike RF ablation systems, which require high power and energy levels delivered into the tissue to heat and thermally destroy the tissue, irreversible electroporation requires very little energy applied to the tissue to kill the cells of the undesirable tissue using electric field potentials rather than heat. Accordingly, irreversible electroporation systems avoid the detrimental thermal effects of RF ablation systems.

[0042] In one embodiment, the energy source **14** may be coupled to the first and second electrodes **24**, **25** by either a wired or a wireless connection. In a wired connection, the energy source **14** is coupled to the electrodes **24**, **25** by way of the electrical conductors **18**, **19**, as shown. In a wireless connection, the electrical conductors **18**, **19** may be replaced with a first antenna (not shown) coupled the energy source **14** and a second antenna (not shown) coupled to the electrodes **24**, **25**, wherein the second antenna is 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 **18**, **19**.

[0043] In one embodiment, the energy source **14** may be configured to produce DC electric pulses at frequencies in the range of about 1 Hz to about 10,000 Hz, amplitudes in the range of about ± 100 to about $\pm 3,000$ VDC, and pulse lengths (e.g., pulse width, pulse duration) in the range of about 1 μ s to about 100 ms. The polarity of the electric potentials coupled to the electrodes **24**, **25** may be reversed during an electrical ablation therapy procedure. For example, initially, the DC electric pulses may have a positive polarity and an amplitude in the range of about +100 to about +3,000 VDC. Subsequently, the polarity of the DC electric pulses may be reversed such that the amplitude is in the range of about -100 to about -3,000 VDC. In one embodiment, the undesirable cells in the tissue treatment region may be electrically ablated with DC pulses suitable to induce irreversible electroporation at frequencies of about 10 Hz to about 100 Hz, amplitudes in the range of about +700 to about +1,500 VDC, and pulse lengths of about 10 μ s to about 50 μ s. In another embodiment, the

abnormal cells in the tissue treatment region may be electrically ablated with an electrical waveform having an amplitude of about +500 VDC and pulse duration of about 20 ms delivered at a pulse period T or repetition rate, frequency $f=1/T$, of about 10 Hz. It has been determined that an electric field strength of about 1,000 V/cm is suitable for destroying living tissue by inducing irreversible electroporation.

[0044] FIGS. 2A-D illustrate one embodiment of the electrical ablation device 20 in various phases of deployment. The electrical ablation device 20 may be used in conjunction with the electrical ablation system 10 shown in FIG. 1. It will be appreciated that other devices and electrode configurations may be employed without limitation. FIG. 2A illustrates an initial phase of deployment in which the first electrode 24 is retracted into the first lumen 26 and the second electrode 25 is retracted into the second lumen 27. The electrodes 24, 25 may have dimensions of about 0.5 mm, about 0.75 mm, about 1 mm, or about 1.5 mm in diameter. It will be appreciated that the dimensions of the electrodes 24, 25 may be anywhere from about 0.5 mm to about 1.5 mm in diameter. In various embodiments, the diameter of the first electrode 24 may be different from the diameter of the second electrode 25. 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 distal end 46 of the first lumen 26 may comprise a cutting edge, such as a bevel or other sharp edge, to aid in the puncturing/piercing of tissue. The distal end 47 of the second lumen 27 may have a similar configuration.

[0045] FIG. 2B illustrates another phase of deployment in which the first electrode 24 is extended distally from the first lumen 26 and the second electrode 25 is extended distally from the second lumen 27. As illustrated, the electrodes 24, 25 may comprise a cutting edge, such as a bevel, on their distal ends to aid in the puncturing/piercing of tissue. In one embodiment, movement of the slide member 30 in the direction indicated by arrow 35 extends the first electrode 24 distally from the first lumen 26 and movement of the slide member 31 in the direction indicated by arrow 37 extends the second electrode 25 distally from the second lumen 27. In various embodiments, other techniques of extending the electrodes 24, 25 may be utilized, such as a linear drive motor, for example. In this phase of deployment, the first and second electrodes 24, 25 may extend distally through the distal end of the electrical ablation device 20 into or proximate the tissue treatment region. In one embodiment, the second electrode 25 may be formed with a radius, such that it curves or splays when it extends from the second lumen 27, as illustrated in FIG. 2B.

[0046] The first electrode 24 may be retracted into the second lumen 27 by pulling proximally on the slide member 31 in the direction indicated by arrow 39 in FIG. 2C. During a medical procedure, the first electrode 24 may remain inserted into the tissue treatment area. In a retracted position, the first electrode 24 may be rotated about its longitudinal axis (shown as "A") as indicated by arrow 41. In the illustrated embodiment, the slide member 31 may be rotated to rotate the first electrode 24. The first electrode 24 may be rotated in any suitable direction and any suitable number of degrees, such as 45°, 90°, or 135°, for example. FIG. 2D illustrates another phase of deployment in which the first electrode 24 is in a fully extended position after it has been rotated. To achieve

this position, the slide member 31 may be moved in the direction indicated by arrow 37.

[0047] One or more of the electrodes 24, 25 may be retracted, rotated, and then placed in a new location in the tissue treatment region. FIGS. 3A-C are perspective views of one embodiment of the electrical ablation device 20 in various stages of rotation about axis "A." Such rotation enables the surgeon or clinician to target and treat a larger tissue treatment region without having to remove the electrical ablation device 20 from the tissue treatment area. Thus, the second electrode 25, for example, may be located in a plurality of positions in and around the tissue treatment region in order to change the distance between the first electrode 24 and the second electrode 25 and treat much larger regions of tissue. As shown in FIG. 3A, in a first position, the distal tip of the first electrode 24 may be separated by a distance "d₁" from the distal tip of the second electrode 25. As shown in FIG. 3B, in a second position, the distal tip of the first electrode 24 may be separated by a distance "d₂" from the distal tip of the second electrode 25. As shown in FIG. 3C, in a third position, the distal tip of the first electrode 24 may be separated by a distance "d₃" from the distal tip of the second electrode 25. Furthermore, increasing the radius "r" (FIG. 3A) of the second electrode 25 and/or the spacing between the electrodes 24, 25 enables the generation of an electric field over much larger tissue treatment regions and thus the ablation of larger volumes of undesirable tissue. In this manner, the operator can treat a larger tissue treatment region comprising cancerous lesions, polyps, or tumors, for example.

[0048] It will be appreciated that the electrical ablation device 20 described with reference to FIGS. 1, 2A-E, and 3A-C may be introduced inside a patient transcutaneously, percutaneously, through an open incision, through a trocar, through a natural orifice, or any combination thereof. In one embodiment, the outside diameter of the electrical ablation device 20 may be sized to fit within a channel of an endoscope and in other embodiments the outside diameter of the electrical ablation device 20 may be sized to fit within a hollow outer sleeve, or trocar, for example. The hollow outer sleeve or trocar may be inserted into the upper gastrointestinal tract of a patient and may be sized to also comprise a flexible endoscopic portion of an endoscope (e.g., gastroscope), similar to the endoscope 12 described in FIG. 1.

[0049] Although the electrical ablation electrodes according to the described embodiments have been described in terms of the particular needle type electrodes 24, 25 as shown and described in FIGS. 1, 2A-D, and 3A-C those skilled in the art will appreciate that other configurations of electrical ablation electrodes may be employed for the ablation of undesirable tissue, without limitation. In another embodiment, the electrical ablation device 20 may comprise three or more retractable electrodes, one embodiment of which is described below with reference to FIGS. 4A and 4B. In another embodiment, the electrical ablation device 20 may comprise at least one slidable electrode disposed within at least one channel of the flexible shaft 32 of the endoscope 12. In another embodiment, the electrical ablation device 20 may comprise at least one electrode may be configured to be inserted into the tissue treatment region transcutaneously or percutaneously. Still in various other embodiments, the electrical ablation device 20 may comprise at least one electrode configured to be introduced to the tissue treatment region transcutaneously or percutaneously and at least one other electrode may be configured to be introduced to the tissue treatment region through at

least one channel of the flexible shaft **32** of the endoscope **12**. The embodiments, however, are not limited in this context.

[0050] FIGS. 4A-4B illustrate one embodiment of an electrical ablation device **100** comprising multiple needle electrodes. In the illustrated embodiment, the electrical ablation device **100** comprises three electrodes **124**, **125**, **126**. It will be appreciated that in one embodiment, the electrical ablation device **100** also may comprise a greater number of needle electrodes. One or more needle electrodes of the electrical ablation device **200** may be formed with a radius. In the illustrated embodiment the electrode **125** and the electrode **126** are both formed with a radius r_1 and r_2 (FIG. 4A), respectively, such that they curved when extended distally from the electrical ablation device **100**.

[0051] The electrical ablation device **100** may be used in conjunction with the electrical ablation system **10** shown in FIG. 1. It will be appreciated that other devices and electrode configurations may be employed without limitation. The electrodes **124**, **125**, **126** each may have dimensions of about 0.5 mm, about 0.75 mm, about 1 mm, or about 1.5 mm in diameter. It will be appreciated that the dimensions of each of the electrodes **124**, **125**, **126** may be anywhere from about 0.5 mm to about 1.5 mm in diameter. The electrical ablation device **100** may be introduced into the tissue treatment region through a trocar, transcutaneously, percutaneously, or using other suitable techniques.

[0052] The electrical ablation device **100** comprises essentially the same components as the electrical ablation device **20** described with reference to FIGS. 2A-D. The electrical ablation device **100** comprises electrodes **124**, **125**, **126** that may be individually or simultaneously deployable, retractable, and/or rotatable with respect to the corresponding lumens **126**, **127**, **128**. The electrodes **124**, **125**, **126** extend distally from the distal end of the electrical ablation device **100**. In one embodiment, the electrode **124** may be configured as the positive electrode coupled to the anode of the energy source **14** (FIG. 1) and the electrodes **125**, **126** may be configured as the negative electrode coupled to the cathode of the energy source **14** (FIG. 1). Once the electrodes **124**, **125**, **126** are positioned at the desired location into or proximate the tissue treatment region, the electrodes **124**, **125**, **126** may be connected/disconnected from the energy source **14** by actuating/de-actuating the switch **62** (FIG. 1).

[0053] Similar to the electrical ablation device **20**, the various electrodes **124**, **125**, **126** may be rotatable and the distance between the various electrodes and/or relative positions of the electrodes **124**, **125**, **126** may be may be changed. In the illustrated embodiment, two of the electrodes **125**, **126** are rotatable whereas the other electrode **124** is non-rotatable. For example, one of the electrodes **125** may be rotatable about its longitudinal axis (illustrated as "B") and the other electrode **126** may be rotatable about its longitudinal axis (illustrated as "C"). FIG. 4A illustrates the rotatable electrodes **125**, **126** in a first position and FIG. 4B illustrates the rotatable electrodes **125**, **126** in a second position (i.e., after rotation). The rotatable electrodes **125**, **126** may be rotated using any suitable method, such as by slide members similar to slide member **31** (FIGS. 2A-2B). As is to be appreciated, the rotatable electrodes **125**, **126** may be retracted into their respective lumens **127**, **128** prior to rotation. Once rotated to a desired position, the rotatable electrodes **125**, **126** then may be extended distally from the distal end of the ablation device **100**. Such rotation of the rotatable electrodes **125**, **126** enables the surgeon or clinician to target and treat a larger tissue treatment

region without having to remove the electrical ablation device **100** from the tissue treatment area. Additionally, for embodiments with multiple rotating electrodes, each electrode may be retracted, extended, and rotated independently from the other electrodes.

[0054] FIGS. 5A-5B illustrate the operation of electrical ablation device **100** in accordance with one non-limiting embodiment. The electrodes **124**, **125**, **126** may be inserted into a tissue treatment region **144**. The tissue treatment region **144** may be representative of a variety of diseased tissues, cancers, tumors, masses, lesions, abnormal tissue growths, for example. In one embodiment, one of the rotatable electrodes **125** may be rotated in the directions indicated by arrow **140** and the other rotatable electrode **126** may be rotated in the directions indicated by arrow **142**. One of the rotatable electrodes **125** may be retracted into the lumen **127** prior to rotation and the other rotatable electrode **126** may be retracted into the lumen **128** prior to rotation. As shown in FIG. 5B, to ablate a portion of the tissue treatment region **144**, the operator initially may locate one of the rotatable electrodes **125** at a first position and the other rotatable electrode **126** at a second position. Once the rotatable electrodes **125**, **126** are located into or proximate the tissue treatment region **144**, all of the electrodes **124**, **125**, **126** are energized with irreversible electroporation pulses to create a first necrotic zone **146** having a first shape substantially similar to that shown in FIG. 5B. For example, once the rotatable electrodes **125**, **126** are located in the desired positions, the tissue treatment region **144** may be exposed to an electric field generated by energizing all of the electrodes **124**, **125**, **126** with the energy source **14** (FIG. 1). The electric field may have a magnitude, frequency, and pulse length suitable to induce irreversible electroporation in the tissue treatment region **144** to create the first necrotic zone **146** having a first shape. The size of the necrotic zone **146** is substantially dependent on the size, separation, and orientation of the rotatable electrodes **125**, **126**, as previously discussed. The treatment time is defined as the time that the rotatable electrodes **125**, **126** are activated or energized to generate the electric pulses suitable for inducing irreversible electroporation in the tissue treatment region **144**.

[0055] This procedure may be repeated to destroy relatively larger portions of the tissue treatment region **144** through rotation of at least one of the rotatable electrodes **125**, **126**. As illustrated in FIG. 5C, one of the rotatable electrodes **125** has been rotated to a second position. Prior to rotating, one of the rotatable electrodes **125** is retracted by pulling on an associated slide member (not shown) in a direction toward the proximal end. The rotatable electrode **125** may then be rotated within the corresponding lumen **127** to the second position. Once the rotatable electrode **125** is rotated to the second position, it may be advanced to engage the tissue treatment region **144** by pushing on the slide member (not shown) in a direction towards the distal end of the electrical ablation device **100**. A second necrotic zone **148** having a second shape substantially as shown is formed upon energizing all of the electrodes **124**, **125**, **126**. As is to be appreciated, a plurality of necrotic zones having a plurality of shapes may be formed by retracting the at least one of the rotatable electrodes **125**, **126**, rotating the first electrode(s) to a new location, advancing the first electrode(s) into the tissue treatment region **144** and energizing all of the electrodes **124**, **125**, **126**. This process may be repeated as often as necessary to create any number of necrotic zones. At anytime, the surgeon or

clinician can reposition the non-rotatable electrode **124** and begin the process anew. Those skilled in the art will appreciate that similar techniques may be employed to ablate any other undesirable tissues that may be accessible trans-anally through the colon, and/or orally through the esophagus and the stomach using transluminal access techniques. Therefore, the embodiments are not limited in this context.

[0056] FIG. 6 illustrates an electrical ablation apparatus **200** in accordance with various embodiments. The electrical ablation apparatus **200** may comprise an elongate sheath **202**. The distal end of the elongate sheath **202** may have a cutting edge, such as a bevel **208**, to aid in the puncturing or piercing of tissue. A first and second electrode **210**, **212** may be deployable from the distal end of the elongate sheath **202**. In various embodiments, a greater number of electrodes or lesser number of electrodes may be deployable from the distal end of the elongate sheath **202**. In one embodiment, a sleeve **204** at least partially surrounds the elongate sheath **202**. The sleeve **204** comprises the second electrode **206**. An insulator **218** may be utilized to electrically isolate the electrode **206** from the elongate sheath **202**. While the sleeve **204** is illustrated as a cylinder, it is to be appreciated that the sleeve **204** may be any suitable size, shape, or configuration. The first and second electrodes **210**, **212** may be pre-formed with a radius. Upon deployment from the distal end of the elongate sheath **202**, the first and second electrodes **210**, **212** may generally bend toward the proximal end of the electrical ablation apparatus **200** due to their pre-formed radius.

[0057] In one embodiment, at least one of the first and second electrodes **210**, **212** is rotatable within the elongate sheath **202**. Similar to previously discussed embodiments, the electrical ablation apparatus **200** may be inserted into a tissue treatment region and a plurality of necrotic zones having a plurality of shapes may be formed by retracting at least one of the electrodes **210**, **212**, rotating the electrode(s) to a new location, advancing the electrode(s) into the tissue treatment region and energizing the electrodes **206**, **210**, **212**. This process may be repeated as often as necessary to create any number of necrotic zones, each with a varying shape.

[0058] FIG. 7 illustrates an electrical ablation apparatus **300** in accordance with various embodiments. The electrical ablation apparatus **300** comprises features similar to the electrical ablation apparatus **200**. The electrical ablation apparatus **300** comprises an elongate sheath **302** having a bevel **308** at the distal end to aid in the puncturing or piercing of tissue. The illustrated embodiment also comprises first and second electrodes **310**, **312**, each with a pre-formed radius, that are deployable from the elongate sheath **302**. The sleeve **304** comprises an extension **314** extending distally from the distal end of the electrical ablation apparatus **300**. The extension **314** may have a sharp distal end. The sleeve **304** and the extension **314** may comprise the second electrode **306**. An insulator **318** may be utilized to electrically isolate the electrode **306** from the elongate sheath **302**. The extension **314** may be used to pierce tissue and positionally secure the electrical ablation apparatus **300** proximate to a tissue treatment region. At least one of the first and second electrodes **310**, **312** may be rotatable within the elongate sheath **302**. Similar to the electrical ablation device **200** described with reference to FIG. 6, the electrical ablation apparatus **300** may be inserted into a tissue treatment region to create a plurality of necrotic zones having a plurality of shapes by retracting the at least one of the electrodes **310**, **312**, rotating the electrode(s) to a new location, advancing the electrode(s) into the tissue treat-

ment region and energizing the electrodes **306**, **310**, **312**. This process may be repeated as often as necessary to create any number of necrotic zones, each with a varying shape. The extension **306** is used to anchor the electrical ablation device **300** during the procedure.

[0059] FIG. 8 illustrates another embodiment of an electrical ablation apparatus **400**. The electrical ablation apparatus **400** may comprise a first elongate sheath **402** and a second elongate sheath **404**. The first elongate sheath **402** may be substantially parallel to the second elongate sheath **404**. In some embodiments, the first elongate sheath **402** and the second elongate sheath **404** may be coupled together or otherwise formed together. First, second, and third electrodes **424**, **425**, **426** are deployable from the first elongate sheath **402**. Fourth, fifth, and sixth electrodes **427**, **428**, **429** are deployable from the second elongate sheath **404**. Each electrode **424**, **425**, **426**, **427**, **428**, **429** may be coupled to an energy source (not shown) at a proximal end and configured to couple to a tissue treatment region at the distal end. As illustrated, in various embodiments, some electrodes, such as the first electrode **424** and the fourth electrode **427** may be electrically isolated from the other electrodes. In one embodiment, the first electrode **424** is at least partially surrounded by an insulative sleeve **432** and the fourth electrode **427** is at least partially surrounded by an insulative sleeve **434**. In one embodiment, the first electrode **424** comprises a non-conductive distal end **431** and the second electrode **427** also comprises a non-conductive distal end **433**. In various embodiments, the non-conductive distal ends **431**, **433** comprise ceramic, or another non-conductive material. The use of the non-conductive distal ends **431**, **433** reduces the current density present at the distal end of the electrodes **424**, **427** when energized.

[0060] Various electrodes of the electrical ablation apparatus **400** may be pre-formed with a radius. In the illustrated embodiment, the second and third electrodes **425**, **426** and the fifth and sixth electrodes **428**, **429** are formed with a pre-formed radius. Therefore, similar to the previously discussed embodiments, after an initial energization, these electrodes may be retraced into their respective elongate sheaths and rotated in order to change the shape of the necrotic zone when the electrodes are re-introduced into a tissue treatment region and energized.

[0061] In various embodiments, other electrode configurations may be implemented to create necrotic zones of various shapes within a tissue treatment region. Yet another embodiment of an electrical ablation apparatus **500** is illustrated in FIG. 9. The electrical ablation apparatus **500** comprises an elongate shaft **502**. The distal end of the elongate shaft **502** may be sharpened, or otherwise contain a cutting edge, such as a bevel **504**. A plurality of electrodes may be disposed along the elongate shaft, alternating in polarity when in an energized state. In one embodiment, the first and second electrodes **506**, **508** may be at a first polarity and a third electrode **510** may be at a second polarity when energized. Regardless of the initial polar configuration, the polarity of the electrodes may be reversed by reversing the polarity of the output of the energy source. The third electrode **510** may be coupled to an energy source (not shown) via any suitable connection, such as an insulated conductor **512**, for example. Similarly, the first and second electrodes **506**, **508** may be coupled to an energy source, such as with conductors positioned internal to the elongate shaft **502**, for example. A first insulator **514** may be positioned intermediate the first elec-

trode 506 and the third electrode 510 and a second insulator 516 may be positioned intermediate the second electrode 508 and the third electrode 510. In some embodiments, the insulators 514, 516 may be coupled to the third electrode 510. The insulators 514, 516 prohibit an electrically conductive connection between two adjacent electrodes having opposite polarities.

[0062] In one embodiment, the third electrode 510 is slidably engaged with the elongate sheath 502. The position along the elongate sheath 502 may be controlled by the user at the proximal end of the electrical ablation apparatus 500, such as with a slide member similar to previously discussed embodiments. During a tissue treatment procedure, the third electrode 510 is placed in a first position and the electrical ablation apparatus 500 is positioned within a tissue treatment region. As is to be appreciated, the electrical ablation apparatus 500 may be introduced inside a patient endoscopically, transcutaneously, percutaneously, through an open incision, through a trocar, through a natural orifice, or any combination thereof. Once positioned by the user, the electrodes 506, 508, 510 may be energized to form a necrotic zone having a first shape in the tissue treatment region. The shape of the necrotic zone will be dependent on the position of the third electrode 510 relative to the first and second electrodes 506, 508. The user may slide the third electrode 510 in the direction indicated by arrow 518 to change the relative position of the third electrode 510. When the electrodes 506, 508, 510 are re-energized, a necrotic zone having a second shape is formed in the tissue treatment region. This process may be repeated as often as necessary to create any number of necrotic zones using the electrical ablation apparatus 500. At anytime, the surgeon or clinician can reposition the electrical ablation apparatus 500 within the tissue treatment region and begin the process anew. Further, as is to be appreciated, the electrodes 506, 508, 510 may be formed in any suitable configuration. For example, in one embodiment, the third electrode 510 comprises a cutting edge to assist in the movement of the third electrode 510 through tissue.

[0063] FIG. 10 illustrates an electrical ablation apparatus 600 in accordance with one non-limiting embodiment. The electrical ablation apparatus 600 comprises an elongate sheath 602 and an electrode 624 deployable from the distal end of the elongate sheath 602. As illustrated, in various embodiments, the electrode 624 may be at least partially surrounded by an insulative sleeve 632. The electrical ablation apparatus 600 further comprises a fluid nozzle 640 configured to deploy a fluid into a tissue treatment region 644. The fluid nozzle 640 may be coupled to a fluid source 642 via a fluid conduit 648. Upon deployment, the fluid 640 bores a path in the tissue treatment region 644 to create a cavity 650. The fluid 640 may be any suitable conductive solution (e.g., saline solution). After the formation of the cavity 650, the fluid 640 located in the cavity 650 may be electrically connected to a first polarity of an energy source 614 to function as an electrode. The electrode 624 is supplied energy having an opposite polarity through an electrical coupling to the energy source 614. As current flows through the tissue treatment region 644 from the first electrode 624 to the fluid 640 in the cavity 650, a necrotic zone having a first shape is formed in the tissue treatment region 644. The user of the electrical ablation apparatus 600 then can rotate, or otherwise reposition the fluid nozzle 640, and deploy the fluid 640 to create a second cavity 652 and the process may be repeated to form a third necrotic zone having a second shape. As illustrated, a

third cavity 654 may be created to form yet a third necrotic zone having a third shape. Various parameters of the fluid and the fluid deployment process, such as a pressure, temperature, duration, may be altered or adjusted according to the type of tissue in the tissue treatment region 644 and the desired size of the cavity created. Furthermore, in various embodiments, a plurality of fluid nozzles 640 and/or a plurality of electrodes 624 may be utilized by the electrical ablation apparatus 600.

[0064] FIGS. 11A-B illustrate an alignment guide 700 in accordance with one non-limiting embodiment. The alignment guide 700 assists in the placement and delivery of electrodes to a treatment site inside a patient. As illustrated, the alignment guide 700 is positioned on the surface 702 of the skin 704 of a patient. The center of the alignment guide 700 may be positioned above the center of the targeted tissue (e.g., a tumor). Once placed in the proper position, the alignment guide 700 may be secured to the surface 702 of the skin 704 using any suitable attachment technique, such as surgical tape. In one embodiment, the alignment guide 700 comprises an adhesive on the skin contacting portion to adhere the alignment guide to the patient. The alignment guide 700 may be radio-opaque to allow proper placement through the use of ultrasound, CT guidance, or other techniques, proximate to the target tissue.

[0065] The alignment guide 700 defines a passageway 706 configured to receive an electrical ablation apparatus 710. In one embodiment, the electrical ablation apparatus 710 comprises first and second electrodes 712, 714, with each electrode 712, 714 comprising a first end configured to couple to an energy source 720 and a second end configured to couple to a tissue treatment region. In some embodiments, more electrodes, such as a third electrode 716, may be utilized. Furthermore, one or more of the electrodes may be preformed with a radius so that they curve or splay upon deployment from the distal end of the electrical ablation apparatus 710. According to one embodiment, the electrical ablation apparatus 710 comprises a first lumen 718 configured to receive the first electrode 712 and a second lumen 722 configured to receive the second electrode 714. If additional electrodes are utilized, the electrical ablation apparatus 710 also may comprise additional lumens, such as a third lumen 724 configured to receive a third electrode 716. The first electrode 712 may be movable between a first position and a second position with respect to the second electrode 714 (e.g., through rotation of the electrical ablation apparatus 710). A zone of cell necrosis in a first shape is created in a tissue treatment-region when the first electrode 712 is in a first position and a zone of necrosis in a second shape is created when the first electrode 712 is in the second position (e.g., subsequent to rotation).

[0066] The electrical ablation apparatus 710 may further comprise a first handle 730, a second handle 732, and a third handle 734. The handles 730, 732, 734 are configured to receive the lumens 718, 722, 724. In the illustrated embodiment, the first handle 730 is configured to be placed against the surface 702 of the skin 714 through the passageway 706 of the alignment guide 700. The electrical ablation apparatus 710 is rotatable about the longitudinal axis (shown as "D") in the directions indicated by arrow 738. The second and third handles 730, 732 may be moved in the direction indicated by arrow 740 in order to pass the electrodes 712, 714, 716 through the skin 704 and into a tissue treatment region (not shown). Once the electrodes 712, 714, 716 are coupled to the target tissue, the electrodes 712, 714, 716 may be energized

with the energy source 720 using previously discussed techniques to create a necrotic zone having a first shape. The user may then move the second and third handles 730, 732 in the direction indicated by arrow 742 (FIG. 11B) to remove at least one electrode from the target treatment region. In one embodiment, the center electrode (i.e., the second electrode 714) remains engaged with the tissue treatment region to serve as a central pivot as the electrical ablation apparatus 710 is rotated about axis A by the user. Once rotated, the user may once again move the second and third handles 730, in the direction indicated by arrow 740 in order to pass the rotated electrodes 714, 716 through the skin 704 and into a tissue treatment region at a different location. Once the electrodes 712, 714, 716 are again coupled to the target tissue, the electrodes may be energized with the energy source 720 to create a necrotic zone having a second shape. This process may be repeated as often as necessary to create any number of necrotic zones using the electrical ablation apparatus 700. The alignment guide 700 serves to ensure proper position of the electrical ablation apparatus 700 during the procedure.

[0067] As illustrated in FIG. 12, the handle 730 may be configured to rotate within the passageway 706 of the alignment guide 700. In order to assist the user in the rotation of the handle 730, various alignment aids may be used. For example, the skin contacting portion of the handle 730 may comprise a dye to mark the surface of the skin upon contact. As the user rotates the handle 730 and places it against the skin, a series of marks indicative of previous contacts will be imprinted on the skin. Additionally, as illustrated in FIG. 13, a plurality of visual indicators 750 may be distributed around the periphery of the alignment guide 700. Throughout a procedure, the user lines the handle 730 with the various visual indicators 750 prior to piercing the skin and underlying target tissue with the electrodes. Through the use of the visual indicators 750, the user can create necrotic zones of varying shapes within the target treatment region.

[0068] In some embodiments, as illustrated in FIG. 14, a plurality of detents may be used to assist the user in positioning the handle 730 during rotation. For example, the alignment guide 700 may define a plurality of notches 752 distributed around the periphery of the passageway 706. The notches 752 are configured to receive a portion of the handle 730, such as a protrusion 754, during rotation.

[0069] 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 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 NOTESTTM 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.

[0070] 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 0.5-1.5 cm). 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.

[0071] 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.

[0072] 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 (CO₂) 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. CO₂ 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.

[0073] 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 posi-

tioned 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.

[0074] 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.

[0075] 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.

[0076] 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.

[0077] 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.

1. An electrical ablation apparatus, comprising:
 - first and second electrodes, each electrode comprising a first end configured to couple to an energy source and a second end configured to couple to a tissue treatment region;
 - wherein the first electrode is movable between a first position and a second position with respect to the second electrode;
 - wherein the first and second electrodes are configured to induce a zone of cell necrosis in a first shape when the first electrode is in the first position; and
 - wherein the first and second electrodes are configured to induce a zone of necrosis in a second shape when the first electrode is in the second position.

2. The electrical ablation apparatus of claim 1, further comprising:

- a third electrode;
- a first lumen configured to receive the first electrode;
- a second lumen configured to receive the second electrode;
- and
- a third lumen configured to receive the third electrode.

3. The electrical ablation apparatus of claim 2, wherein the first electrode is pre-formed with a radius and rotatable within the first lumen and the third electrode is pre-formed with a radius and rotatable with the third lumen.

4. The electrical ablation apparatus of claim 2, wherein the first, second, and third lumens each have a distal end comprising a cutting edge.

5. The electrical ablation apparatus of claim 1, further comprising:

- an elongate sheath; and
- a sleeve at least partially surrounding the elongate sheath, wherein the sleeve comprises the second electrode.

6. The electrical ablation apparatus of claim 5, wherein the first electrode is deployable from a distal end of the elongate sheath and pre-formed with a radius.

7. The electrical ablation apparatus of claim 6, wherein the first electrode is rotatable within the elongate sheath.

8. The electrical ablation apparatus of claim 1, further comprising:

- a first elongate sheath;
- a second elongate sheath; and
- third and fourth electrodes, each electrode comprising a first end configured to couple to the energy source and a second end configured to couple to the tissue treatment region;

wherein the first and second electrodes are deployable from the first elongate sheath and the third and fourth electrodes are deployable from the second elongate sheath.

9. The electrical ablation apparatus of claim 8, wherein the first and third electrodes each are pre-formed with a radius.

10. The electrical ablation apparatus of claim 8, wherein the first elongate sheath and the second elongate sheath are substantially parallel.

11. The electrical ablation apparatus of claim 1, further comprising:

- a fluid nozzle configured to deploy a fluid to bore a path in the tissue treatment region using a fluid, wherein the first electrode is configured to couple to the fluid in the path.

12. The electrical ablation apparatus of claim 11, wherein the fluid nozzle is movable.

13. The electrical ablation apparatus of claim 11, further comprising a plurality of fluid nozzles.

14. The electrical ablation apparatus of claim 1, further comprising:

- an elongate shaft, wherein the first electrode is slidably engaged with the elongate sheath.

15. The electrical ablation apparatus of claim 14, wherein the second electrode comprises a distal electrode and a proximal electrode each disposed along the elongate shaft.

16. The electrical ablation apparatus of claim 15, wherein the first electrode is disposed on the elongate shaft intermediate the distal electrode and the proximal electrode.

17. The electrical ablation apparatus of claim 16, further comprising:

- a first insulator disposed on the elongate shaft intermediate the distal electrode and the first electrode; and

a second insulator disposed on the elongate shaft intermediate the first electrode and the proximal electrode.

18. An electrical ablation system, comprising:

first and second electrodes, each electrode comprising a first end configured to couple to an energy source and a second end configured to couple to a tissue treatment region, wherein the first electrode is movable between a first position and a second position with respect to the second electrode, wherein the first and second electrodes are configured to induce a zone of cell necrosis in a first shape when the first electrode is in the first position, and wherein the first and second electrodes are configured to induce a zone of necrosis in a second shape when the first electrode is in the second position;

a first lumen configured to receive the first electrode;

a second lumen configured to receive the second electrode;

an alignment guide defining a passageway, wherein the passageway is configured to receive the first and second lumens; and

a handle coupled to the first and second lumens, wherein the handle is configured to rotatably move the first electrode from the first position to the second position.

19. The electrical ablation system of claim **18**, wherein the alignment guide comprises a plurality of position indicators positioned proximate to the passageway.

20. An electrical ablation apparatus, comprising:

first and second electrodes, each electrode comprising a first end configured to couple to an energy source and a second end configured to couple to a tissue treatment region;

wherein the first electrode is movable between a first position and a second position with respect to the second electrode;

wherein the first and second electrodes are configured to induce a zone of cell necrosis in a first shape when the first electrode is in the first position;

wherein the first and second electrodes are configured to induce a zone of necrosis in a second shape when the first electrode is in the second position; and

wherein a distance between the first and second electrodes is adjustable by rotating at least one of the first and second electrodes about a central axis of the at least one of the first and second electrodes.

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