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Long

(54) ELECTRICAL ABLATION APPARATUS, SYSTEM, AND METHOD

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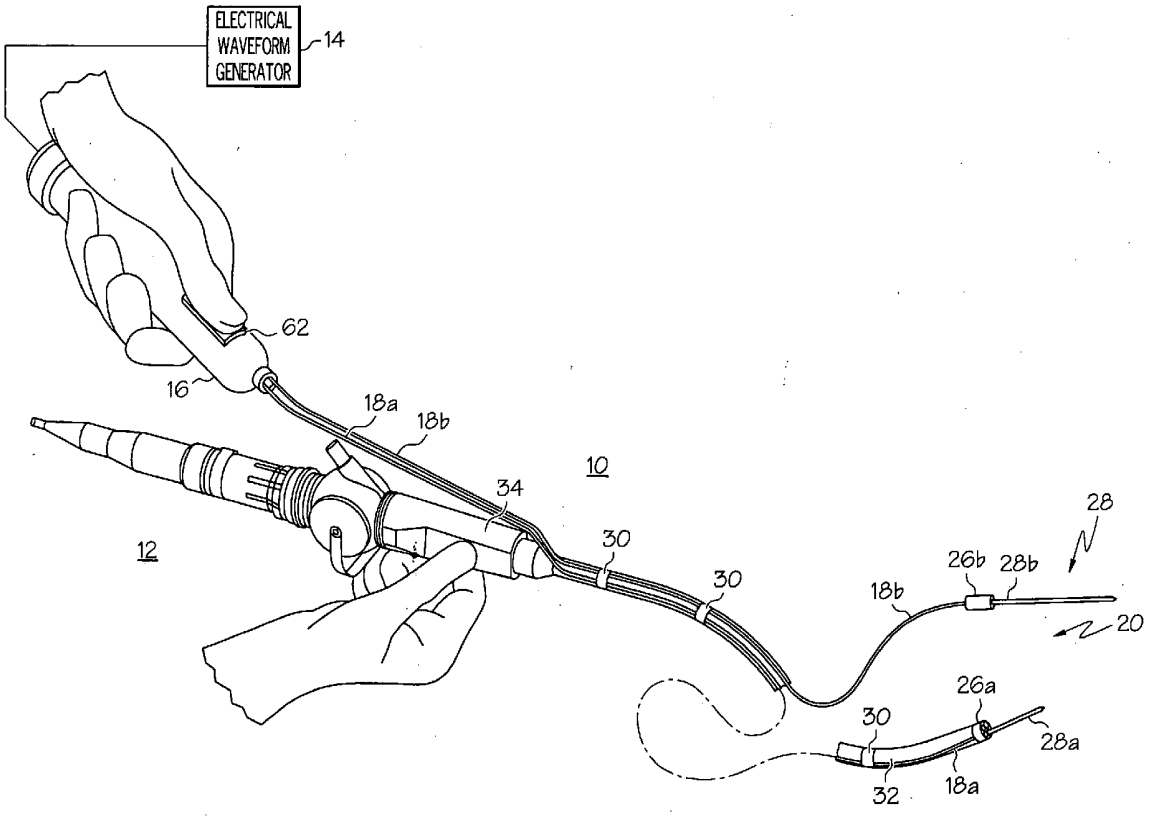
(57) **ABSTRACT**

A surgical instrument, such as an endoscopic or laparoscopic instrument, includes an ablation device. The ablation device includes an elongate relatively flexible member having a proximal end and a distal end. The flexible member includes a working channel. A first electrode extends from the working channel at the distal end of the flexible member and is adapted to be endoscopically located in a first position relative to a tissue treatment region. A second electrode is adapted to be percutaneously located in a second position of the tissue treatment region. The first and second electrodes are adapted to couple to an electrical waveform generator and to receive an electrical waveform sufficient to ablate tissue located between the first and second electrodes.



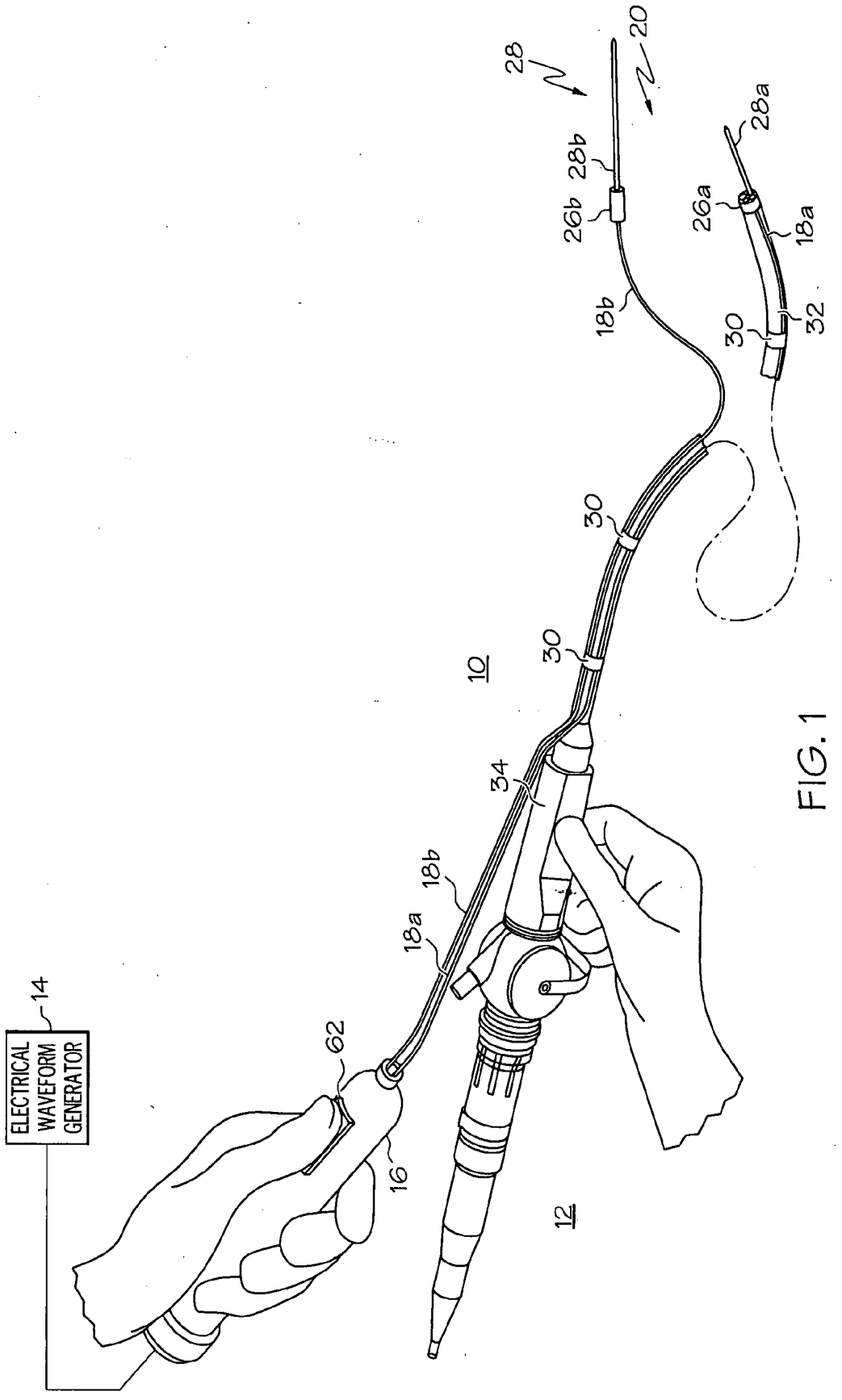

28
20
28a
28b
26b
26a
18a
18b
30
32
30
30
10
34
18b
18a
62
14
ELECTRICAL WAVEFORM GENERATOR
16
12

FIG. 1

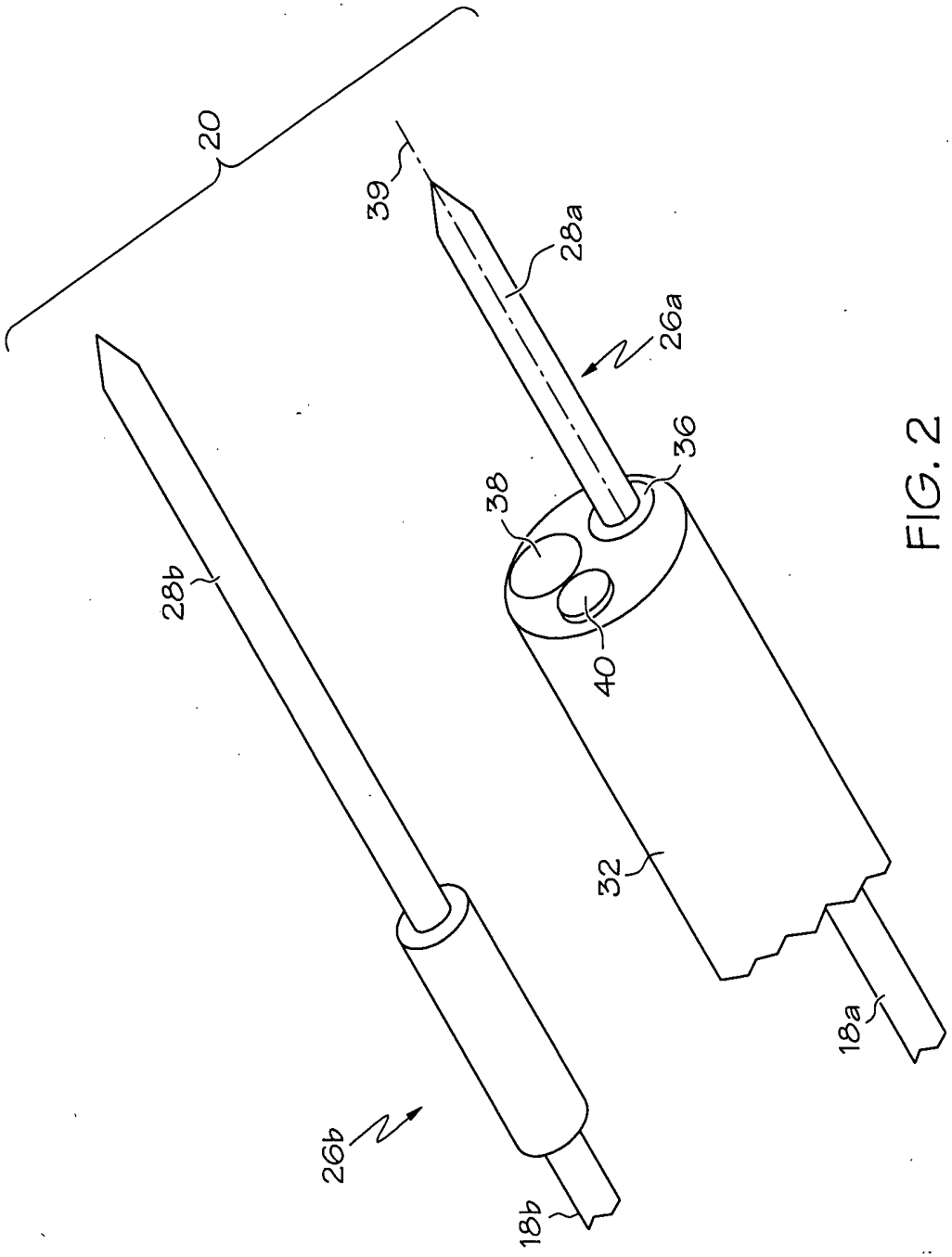


FIG. 2

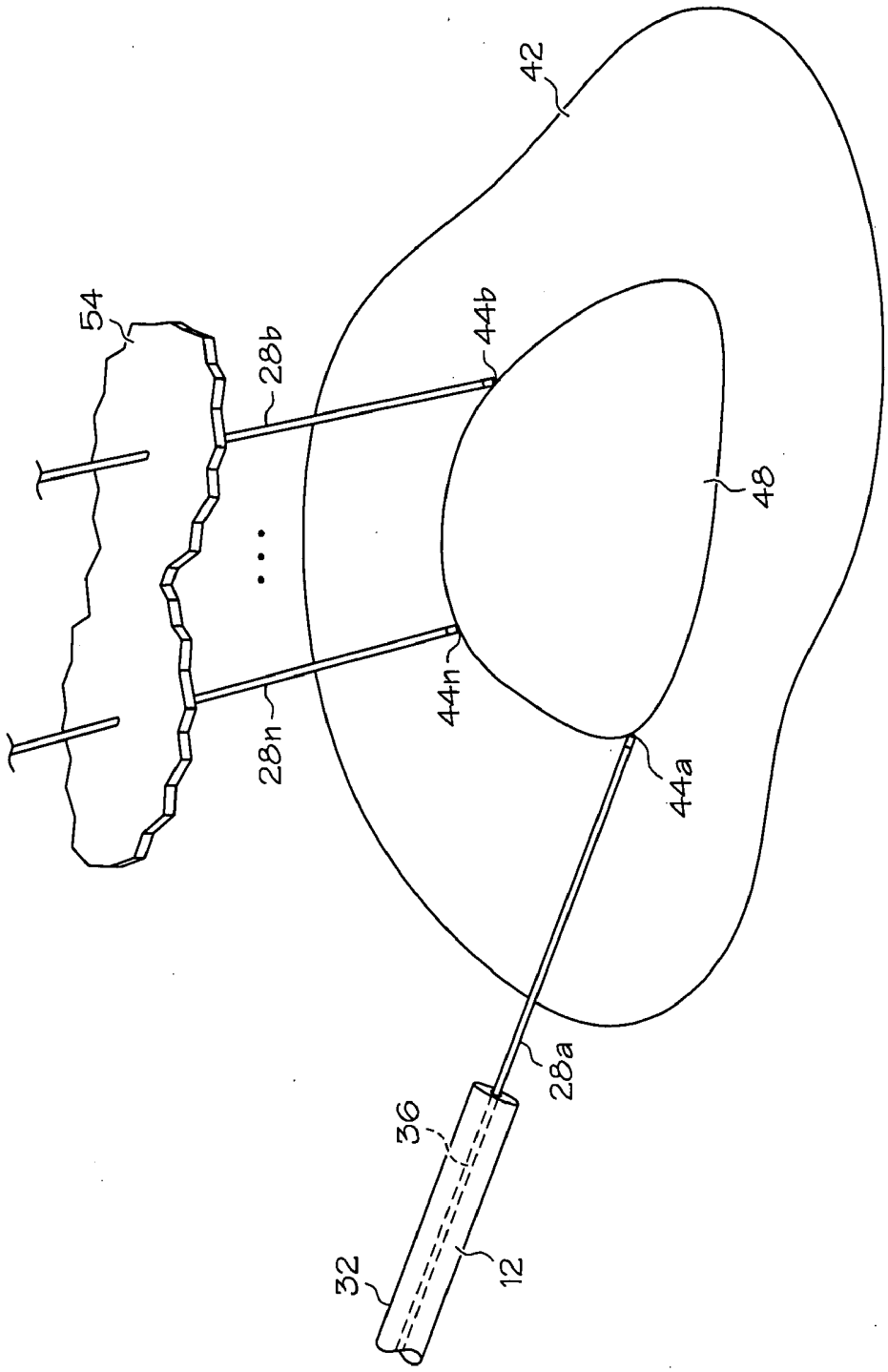


FIG. 3

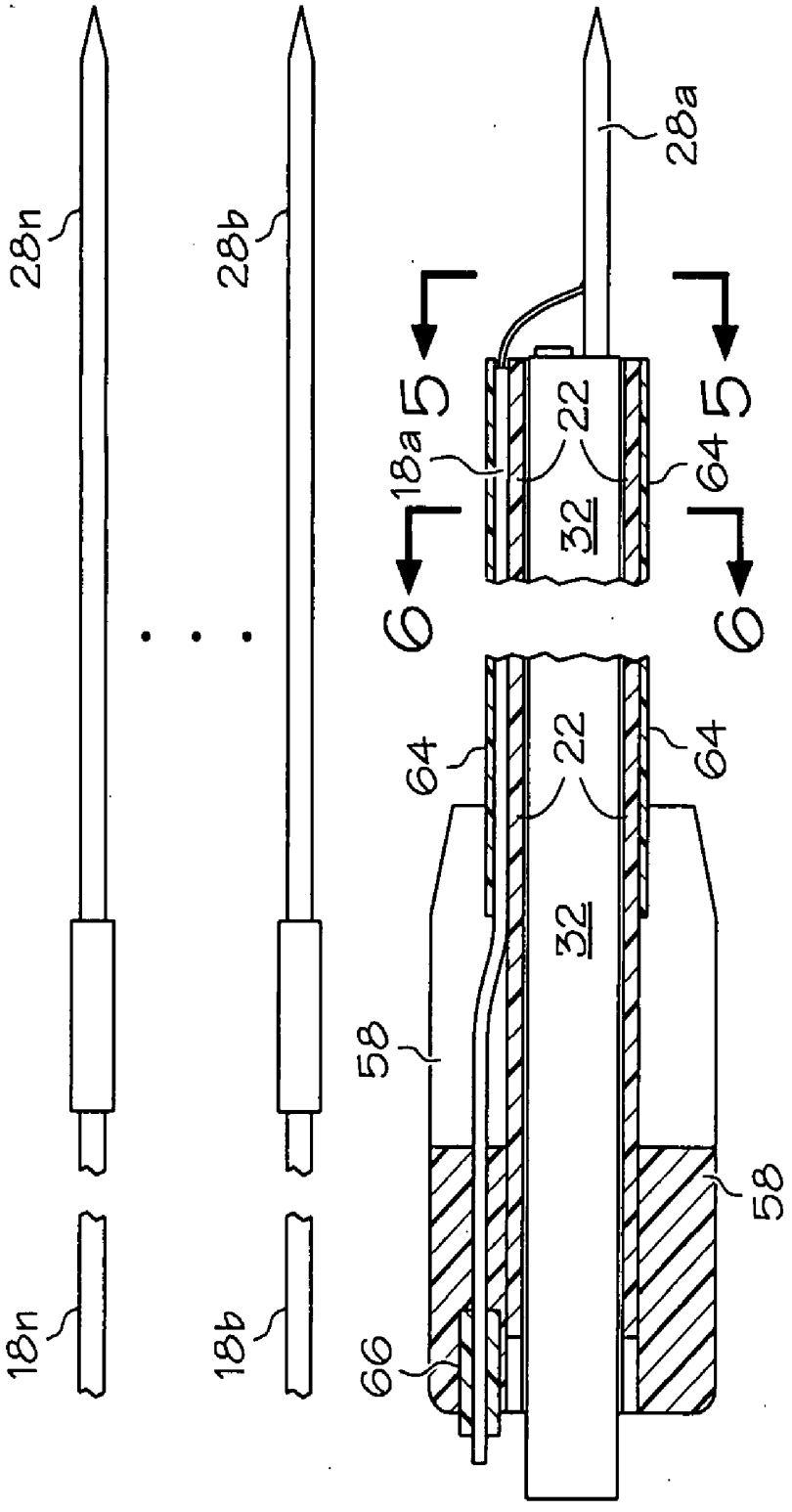


FIG. 4

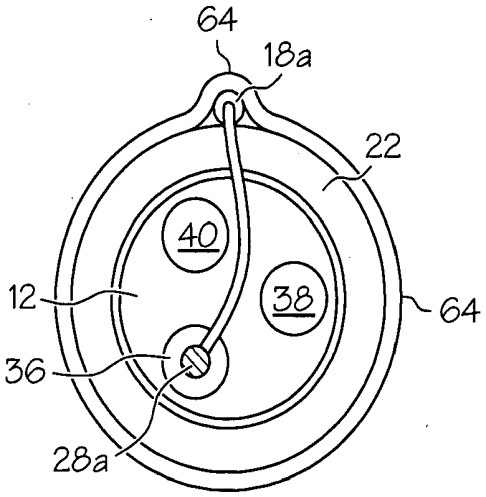


FIG. 5

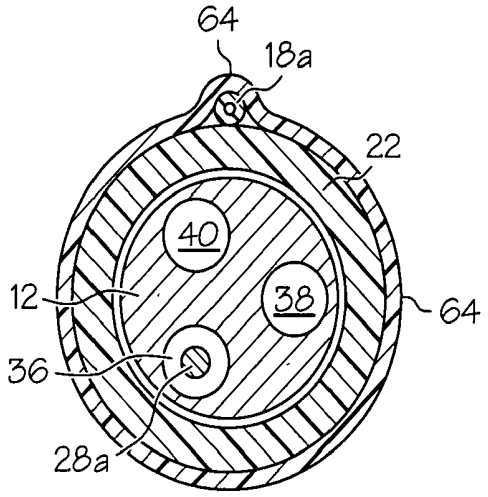


FIG. 6

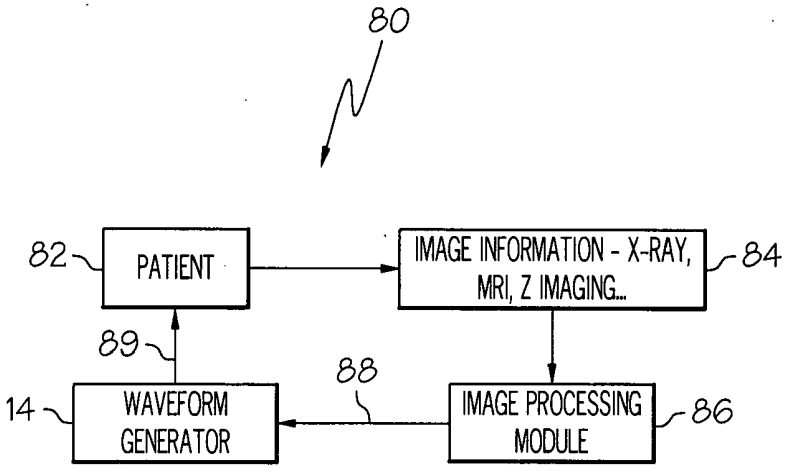


FIG. 8

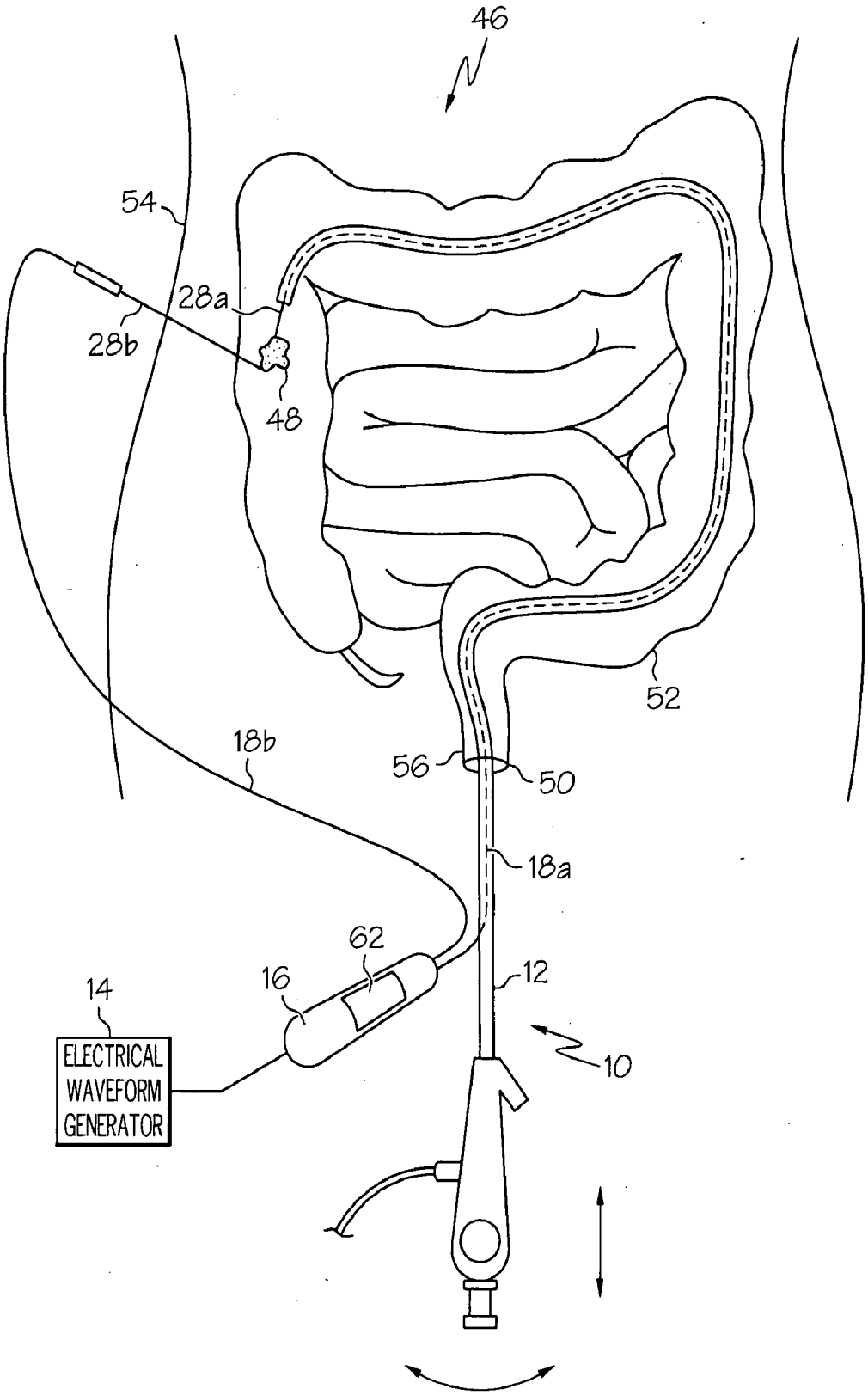

46
54
28a
28b
48
52
18b
56
50
18a
62
16
12
14
ELECTRICAL WAVEFORM GENERATOR
10

FIG. 7

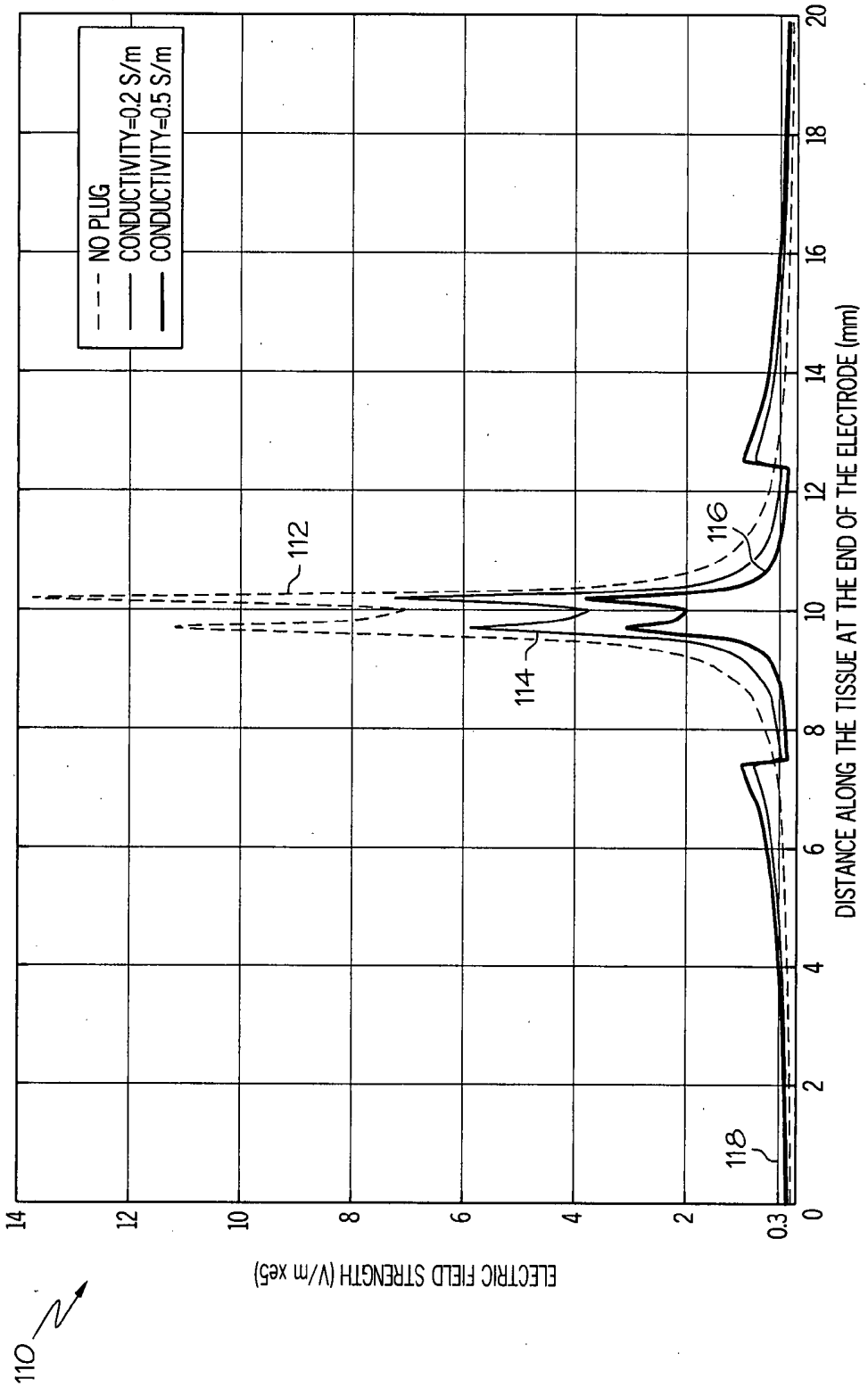
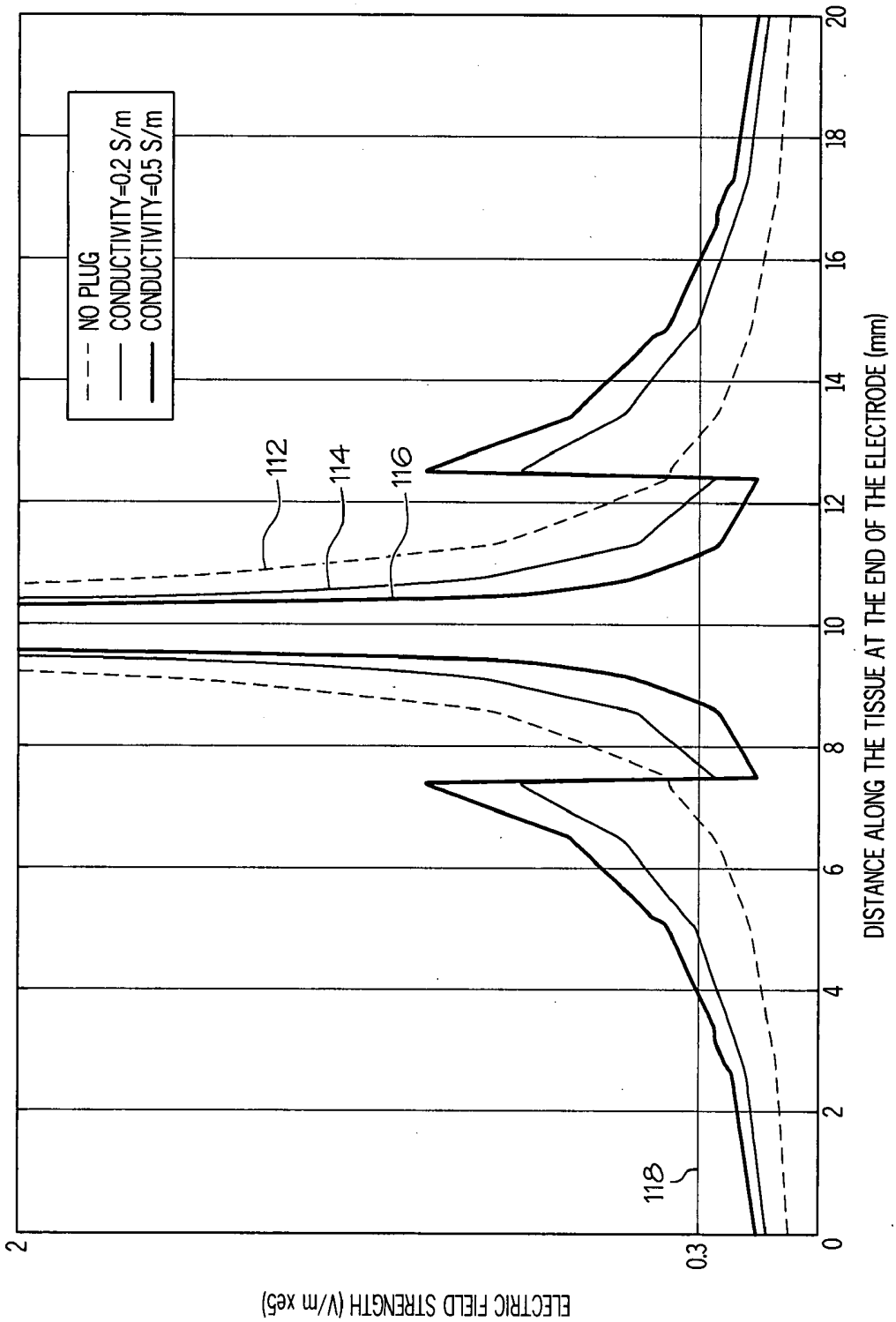

NO PLUG
CONDUCTIVITY=0.2 S/m
CONDUCTIVITY=0.5 S/m
ELECTRIC FIELD STRENGTH (V/m x e5)
DISTANCE ALONG THE TISSUE AT THE END OF THE ELECTRODE (mm)
0.3
2
4
6
8
10
12
14
16
18
20
110
112
114
116
118

FIG. 9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CONDUCTIVITY=0.2 S/m
CONDUCTIVITY=0.5 S/m
112
114
116
118
2
0.3
0
2
4
6
8
10
12
14
16
18
20
ELECTRIC FIELD STRENGTH (V/m x e5)
DISTANCE ALONG THE TISSUE AT THE END OF THE ELECTRODE (mm)

FIG. 10

ELECTRICAL ABLATION APPARATUS, SYSTEM, AND METHOD

CROSS REFERENCE TO RELATED APPLICATION

[0001] The present application is related to concurrently-filed U.S. patent application Ser. No. _____, entitled ELECTROPORATION ABLATION APPARATUS, SYSTEM, AND METHOD, by Gary Long, Attorney Docket No. 07034/END6107USNP, which is incorporated herein by reference in its entirety.

BACKGROUND

[0002] Electrical therapy techniques have been employed in medicine to treat pain and other conditions. Electrical ablation techniques have been employed in medicine for removing diseased tissue or abnormal growths from the body. Electrical therapy probes comprising electrodes may be required to electrically treat diseased tissue. The electrodes may be introduced into the patient percutaneously to the tissue treatment region by passing the electrodes through the skin of the patient. If the at least two electrical therapy electrodes are introduced only percutaneously, however, the relative position between these electrodes may be limited. Nevertheless, there is a need for improved medical instruments to electrically ablate or destroy diseased tissue, such as cancer, or abnormal growths from the body. There may be a need for such electrical therapy techniques to be performed endoscopically.

SUMMARY

[0003] In one general aspect, the various embodiments are directed to an ablation device. In one embodiment, the ablation device comprises an elongate relatively flexible member having a proximal end and a distal end. The flexible member comprises a working channel. A first electrode extends from the working channel at the distal end of the flexible member. The first electrode is adapted to be endoscopically located in a first position relative to a tissue treatment region. A second electrode is adapted to be percutaneously located in a second position of the tissue treatment region. The first and second electrodes are adapted to couple to an electrical waveform generator and to receive an electrical waveform sufficient to ablate tissue located between the first and second electrodes.

FIGURES

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

[0005] FIG. **1** illustrates one embodiment of an electrical ablation system.

[0006] FIG. **2** is an enlarged view of one embodiment of an electrical ablation probe of the electrical ablation system shown in FIG. **1**

[0007] FIG. **3** illustrates the use of one embodiment of the electrical ablation system to treat diseased tissue on the liver.

[0008] FIG. **4** is a sectional view taken along the longitudinal axis of one embodiment of the electrical ablation system shown in FIG. **1**.

[0009] FIG. **5** is a sectional view taken along line **5-5** of one embodiment of the electrical ablation system shown in FIG. **4**.

[0010] FIG. **6** is a sectional view taken along line **6-6** of the rotation tube of one embodiment of the electrical ablation system shown in FIG. **4**.

[0011] FIG. **7** shows a distal portion of one embodiment of the electrical ablation system shown in FIG. **1** inserted into a hollow body or natural opening of a patient.

[0012] FIG. **8** is a diagram of one embodiment of a control loop for one embodiment of an electrical (e.g., IRE or RF) therapy procedure to treat diseased tissue as described herein.

[0013] FIG. **9** is a graphical representation (graph) of the electric field strength (along the y-axis) as a function of the distance from an electrical therapy electrode under various conductivity environments near the diseased tissue.

[0014] FIG. **10** is a close up of the graph shown in FIG. **9**.

DESCRIPTION

[0015] The various embodiments described herein are directed to electrical therapy ablation devices. The electrical therapy ablation devices comprise probes and electrodes that can be positioned in a tissue treatment region of a patient either endoscopically or transcutaneously (percutaneously), and in some embodiments a combination thereof. An endoscopic electrode is inserted through a working channel of an endoscope. A transcutaneous or percutaneous electrode has a sharp point to facilitate insertion through the skin of a patient and to enhance local current density at a target site during treatment. The placement and location of the electrodes can be important for effective and efficient therapy. Once positioned, the electrical therapy electrodes deliver electrical current to the treatment region. The electrical current is generated by a control unit or generator external to the patient and typically has particular waveform characteristics, such as frequency, amplitude, and pulse width. Depending on the diagnostic or therapeutic treatment rendered, the probes may comprise one electrode containing both a cathode and an anode or may contain a plurality of electrodes with at least one serving as a cathode and at least one serving as an anode.

[0016] Electrical therapy ablation may employ electroporation or electropermeabilization techniques where an externally applied electric field (electric potential) significantly increases the electrical conductivity and permeability of a cell plasma membrane. Electroporation is the generation of a destabilizing electric potential across such biological membranes. In electroporation, pores are formed when the voltage across the cell plasma membrane exceeds its dielectric strength. Electroporation destabilizing electric potentials are generally in the range of several hundred volts across a distance of several millimeters. Below certain magnitude thresholds, the electric potentials may be applied across a biological membrane as a way of introducing some substance into a cell, such as loading it with a molecular probe, a drug that can change the function of the cell, a piece of coding DNA, or increasing the uptake of drugs in cells. If the strength of the applied electrical field and/or duration of exposure to it are suitably chosen, the pores formed by the electrical pulse reseal after a short period of time, during which extracellular compounds have a chance to enter into the cell. Thus, below a certain threshold, the process is reversible and the potential does not permanently damage the cell membrane. This process may be referred to as reversible electroporation (RE).

[0017] On the other hand, excessive exposure of live cells to large electric fields can cause apoptosis and/or necrosis—the processes that result in cell death. Thus, the excessive exposure of live cells to large electric fields may be referred to as irreversible electroporation (IRE) because the cells die when exposed to such excessive electrical fields or potentials across the cell membranes.

[0018] Electroporation may be performed with devices called electroporators. These appliances create the electric current and send it through the cell. Electroporators may comprise two or more metallic (e.g., aluminum) electrodes connected to an energy source. The energy source generates an electric field having a suitable characteristic waveform output in terms of frequency, amplitude, and pulse width.

[0019] Endoscopy means looking inside and refers to looking inside the human body for medical reasons. Endoscopy may be performed using an instrument called an endoscope. Endoscopy is a minimally invasive diagnostic medical procedure used to evaluate the interior surfaces of an organ by inserting a small tube into the body, often, but not necessarily, through a natural body opening. Through the endoscope, an operator may see abnormal or diseased tissue such as lesions and other surface conditions. The endoscope may have a rigid or a flexible tube and in addition to providing an image for visual inspection and photography, the endoscope may be adapted and configured for taking biopsies, retrieving foreign objects, and introducing medical instruments to a tissue treatment region. Endoscopy is a vehicle for minimally invasive surgery.

[0020] The embodiments of the electrical therapy ablation devices may be employed for treating diseased tissue, tissue masses, tissue tumors, and lesions (diseased tissue). More particularly, the electrical therapy ablation devices may be employed in minimally invasive therapeutic treatment of diseased tissue. The electrical therapy ablation devices may be employed to deliver energy to the diseased tissue to ablate or destroy tumors, masses, lesions, and other abnormal tissue growths. In one embodiment, the electrical therapy ablation devices and techniques described herein may be employed in the treatment of cancer by quickly creating necrosis and destroying live cancerous tissue in-vivo. Minimally invasive therapeutic procedures to treat diseased tissue by introducing medical instruments to a tissue treatment region through a natural opening of the patient are known as Natural Orifice Translumenal Endoscopic Surgery (NOTES)™.

[0021] FIG. **1** illustrates one embodiment of an electrical ablation system **10**. The electrical ablation system **10** may be employed to electrically treat diseased tissue such as tumors and lesions inside a patient. The electrical ablation system **10** may be configured to be positioned within a natural opening of the patient such as the colon or the esophagus and can be passed through the natural opening to reach a tissue treatment region. The illustrated embodiment of the electrical ablation system **10** may be used to treat diseased tissue via the colon or the esophagus of the patient, for example. The tissue treatment region may be located in the esophagus, colon, liver, breast, brain, and lung, among others. The electrical ablation system **10** can be configured to treat a number of lesions and ostepathologies comprising metastatic lesions, tumors, fractures, infected site, inflamed sites, and the like. Once positioned at the target tissue treatment region, the electrical ablation system **10** can be configured to treat and ablate diseased tissue in that region. In one embodiment, the electrical ablation system **10** may be adapted to treat diseased tissue, such as cancers, of the gastrointestinal (GI) tract or esophagus that may be accessed orally. In another embodiment, the electrical ablation system **10** may be adapted to treat diseased tissue, such as cancers, of the liver or other organs that may be accessible trans-anally through the colon and/or the abdomen.

[0022] One embodiment of the electrical ablation system **10** may be mounted on a flexible endoscope **12** (also referred to as endoscope **12**), such as the GIF-100 model available from Olympus Corporation. The flexible endoscope **12** includes an endoscope handle **34** and an elongate relatively flexible shaft **32**. The electrical ablation system **10** generally comprises an electrical ablation probe **20**, a plurality of electrical conductors **18**, a handpiece **16** having a switch **62**, and an electrical waveform generator **14**. The electrical ablation probe **20** is located at a distal end of the flexible shaft **32** and the electrical conductors **18** may attach to the flexible shaft **32** using a plurality of clips **30**. The electrical ablation probe **20** comprises electrical therapy probes **26***a,b* to deliver electrical energy to a desired tissue treatment region. The electrical therapy probes **26***a,b* comprise one or more electrical therapy electrodes **28***a,b*. A first electrical therapy probe **26***a* comprises a first electrical therapy electrode **28***a* and is electrically connected to a first electrical conductor **18***a*. The first electrical therapy electrode **28***a* extends through a bore in the flexible shaft **32** such as a working channel **36** (FIG. **2**) of the endoscope **12**. The first electrical therapy electrode **28***a* is introduced to the desired tissue treatment region endoscopically. The first electrical therapy probe **26***a* may be referred to herein as an endoscopic electrical therapy probe. A second electrical therapy probe **26***b* comprises a second electrical therapy electrode **28***b* and is electrically connected to a second electrical conductor **18***b*. The second electrical therapy electrode **28***b* is introduced to the desired tissue treatment region transcutaneously by piercing the skin covering the tissue treatment region. The second electrical therapy probe **26***b* may be referred to herein as a transcutaneous electrical therapy probe. Once the first and second electrical therapy electrodes **28***a,b* are located at respective first and second positions in the tissue treatment region, manual operation of the switch **62** of the handpiece **16** electrically connects or disconnects the electrical therapy electrodes **28***a,b* to the electrical waveform generator **14**. Alternatively, the switch **62** may be mounted on, for example, a foot switch (not shown).

[0023] In one embodiment, the electrical waveform generator **14** may be a conventional, bipolar/monopolar electrosurgical IRE generator such as one of many models commercially available, including Model Number ECM 830, available from BTX Molecular Delivery Systems Boston, Mass. The IRE generator generates electrical waveforms having predetermined frequency, amplitude, and pulse width. The application of these electrical waveforms to the cell membranes of the diseased tissue causes the diseased cells to die. Thus, the IRE electrical waveforms may be applied to the cell membranes of diseased tissue in the tissue treatment region in order to kill the diseased cells and ablate the diseased tissue. IRE electrical waveforms suitable to destroy the cells of diseased tissues are generally in the form of direct current (DC) electrical pulses delivered at a frequency in the range of 1-20 Hz, amplitude in the range of 100-1000 VDC, and pulse width in the range of 0.01-100 ms. For example, an electrical waveform having amplitude of 500 VDC and pulse duration of 20 ms may be delivered at a pulse repetition rate or frequency of 10 HZ to destroy a reasonably large volume of

diseased tissue. Unlike RF ablation systems which require high powers and energy input into the tissue to heat and destroy, IRE requires very little energy input into the tissue, rather the destruction of the tissue is caused by high electric fields. It has been determined that in order to destroy living tissue, the electrical waveforms have to generate an electric field of at least 30,000 V/m in the tissue treatment region. The embodiments, however, are not limited in this context.

[0024] In one embodiment, the electrical waveform generator **14** may comprise a radio frequency (RF) waveform generator. The RF generator may be a conventional, bipolar/monopolar electrosurgical generator such as one of many models commercially available, including Model Number ICC 350, available from Erbe, GmbH. Either a bipolar mode or monopolar mode may be used. When using the bipolar mode with two electrodes, one electrode is electrically connected to one bipolar polarity, and the other electrode is electrically connected to the opposite bipolar polarity. If more than two electrodes are used, the polarity of the electrodes may be alternated so that any two adjacent electrodes have opposite polarities. Either the bipolar mode or the monopolar mode may be used with the illustrated embodiment of the electrical ablation system **10**. When using the bipolar mode with two electrical therapy electrodes **28***a,b* the first electrode **28***a* may be electrically connected to one bipolar polarity, and the second electrode **28***b* may be electrically connected to the opposite bipolar polarity (or vice-versa). If more than two electrical therapy electrodes **28** are used, the polarity of the electrodes **28** is alternated so that any two adjacent electrodes have opposite polarities.

[0025] In either case, the electrical (e.g., the IRE or RF) waveform generator **14**, when using the monopolar mode with two or more electrical therapy electrodes **28**, a grounding pad is not needed on the patient. Because a generator will typically be constructed to operate upon sensing connection of ground pad to the patient when in monopolar mode, it can be useful to provide an impedance circuit to simulate the connection of a ground pad to the patient. Accordingly, when the electrical ablation system **10** is used in monopolar mode without a grounding pad, an impedance circuit can be assembled by one skilled in the art, and electrically connected in series with one of the electrical therapy electrodes **28***a,b* that would otherwise be used with a grounding pad attached to a patient during monopolar electrosurgery. Use of an impedance circuit allows use of the IRE generator in monopolar mode without use of a grounding pad attached to the patient.

[0026] FIG. **2** is an enlarged view of one embodiment of an electrical ablation probe **20** of the electrical ablation system **10** shown in FIG. **1**. The first electrical therapy electrode **28***a* is introduced to the tissue treatment region endoscopically and extends through the distal end of the flexible shaft **32**. In one embodiment, the first electrode **28***a* protrudes from the distal end of an internal lumen extending between the proximal and distal ends of the flexible endoscope **12**. In one embodiment, the internal lumen may be the working channel **36** of the endoscope **12**. The first electrode **28***a* may be rotatable about a central axis **39** within the working channel **36** to facilitate locating the electrode **28***a* in a first position in the tissue treatment region. The second electrical therapy electrode **28***b* is introduced percutaneously to the target tissue treatment region. The second electrode **28***b* is located in a second position in the tissue treatment region. Introducing the second electrode **28***b* percutaneously allows the first and second electrodes **28***a,b* to be spaced further apart than if the two electrodes **28***a,b* were both introduced endoscopically. Spacing the first and second electrodes **28***a,b* further apart allows the electrodes to surround a larger diseased tissue region and generate an electric field over a much larger tissue treatment region. In this manner, the operator can surround the entire tissue treatment region of a cancerous lesion, a polyp, or a tumor, for example. Introducing at least one of the electrodes (e.g., the first electrode **28***a*) endoscopically enables the operator to accurately locate the target diseased tissue region using endoscopic visualization feedback by employing at least one light source **40** and a viewing port **38** located on the distal end of the endoscope **12**. The electrodes **28***a,b* may be energized with the electrical waveform generator **14** to deliver an IRE or an RF electrical waveform to treat the diseased tissue located between the first and second electrodes **28***a,b*. Because the electrodes **28***a,b* are located in the tissue treatment region independently, the operator has much more flexibility in positioning the electrodes **28***a,b* relative to the tissue treatment region.

[0027] The electrical conductors **18***a,b* are electrically insulated from each other and surrounding structures, except for the electrical connections the respective electrical therapy electrodes **28***a,b*. The distal end of the flexible shaft **32** of the flexible endoscope **12** may comprise the light source **40**, the viewing port **38**, and the working channel **36**, where the first electrode **28***a* may be passed therethrough. The viewing port **38** transmits an image within its field of view to an optical device such as a charge coupled device (CCD) camera within the flexible endoscope **12** so that an operator may view the image on a display monitor (not shown). In the embodiment shown in FIG. **2**, the distal end of flexible shaft **32** is proximal to the first electrode **28***a* within the field of view of the flexible endoscope **12** thus enabling the operator to see the tissue treatment region to be treated near the first electrode **28***a*. This technique provides a more accurate way to locate the first electrode **28***a* in the tissue treatment region.

[0028] FIG. **3** illustrates the use of one embodiment of the electrical ablation system **10** to treat a diseased tissue **48** on the liver **42**. In the embodiment illustrated in FIG. **3**, the flexible shaft **32** of the endoscope **12** has been introduced to the tissue treatment region trans-anally into the abdomen. The first electrical therapy electrode **28***a* is introduced through the working channel **36** of the flexible shaft **32**. The operator positions the first electrical therapy electrode **28***a* using endoscopic visualization so that the diseased tissue **48** to be treated lies within the field of view of the flexible endoscope **12**. The operator locates the first electrode **28***a* located in a first position **44***a* at a perimeter edge of the diseased tissue **48**. The operator then positions or introduces the second electrode **28***b* percutaneously through the skin **54** of the patient such that the second electrode **28***b* is located at a second position **44***b* at a perimeter edge of the diseased tissue **48**. Once the first and second electrodes **28***a,b* are located at the desired first and second positions **44***a,b*, the operator may energize the electrodes **28***a,b* with the electrical waveform generator **14** to deliver an IRE or an RF waveform suitable to destroy the diseased tissue **48**. For example, in an IRE embodiment, the first and second electrodes **28***a,b* may be energized with an electrical waveform having amplitude of approximately 500 VDC and a pulse width of approximately 20 ms at a frequency of approximately 10 Hz. In this manner, the diseased tissue **48** may be destroyed. This procedure may be efficient and repeated to destroy relatively larger portions of the diseased

tissue. Those skilled in the art will appreciate that similar techniques may be employed to treat any other diseased tissues accessed trans-anally through the colon and/or the abdomen and/or accessed orally through the esophagus or the stomach. Therefor, the embodiments are not limited in this context.

[0029] FIG. **4** is a sectional view taken along the longitudinal axis of one embodiment of the electrical ablation system **10** shown in FIG. **1**. The distal portion of the flexible shaft **32** is located inside a rotation tube **22** of the electrical ablation system **10**. The first electrical conductor **18***a* passes through a strain relief **66** of a rotation knob **58**. In the illustrated embodiment an external tube **64** or sheath may be located over the flexible shaft **32** such that the first electrical conductor **18***a* passes between the external tube **64** and the rotation tube **22**. The first electrical conductor **18***a* connects electrically to the first electrical therapy electrode **28***a*. The rotation tube **22** rotatably joins the rotation knob **58**. The operator can rotatably orient the first electrode **28***a*, even after insertion into the natural opening (e.g., trans-anally into the abdomen) by remotely rotating the probe **26***a*. The electrical ablation probe **20** is located within the field of view of the flexible endoscope **12** to enable the operator to see on a display monitor the tissue that is located between the electrodes **28**.

[0030] With reference to FIGS. **3** and **4**, in one embodiment, multiple electrical therapy probes **26***a-n* each connected to respective electrical conductors **18***a-n* and electrical therapy electrodes **28***a-n* may be employed to surround the diseased tissue region around multiple points **44***a-n*. This may be beneficial in destroying relatively larger portions of the diseased tissue. Once the electrodes **28***a-n* are located at the desired positions **44***a-n*, the operator may energize the electrodes **28***a-n* with the electrical waveform generator **14** to deliver an IRE or an RF waveform suitable to destroy the diseased tissue **48**. For example, in an IRE embodiment, the electrodes **28***a-n* may be energized with an electrical waveform having amplitude of approximately 500 VDC and a pulse width of approximately 20 ms at a frequency of approximately 10 Hz. In this manner, the diseased tissue **48** may be destroyed.

[0031] FIG. **5** is a sectional view taken along line **5-5** of one embodiment of the electrical system **10** shown in FIG. **4**. The electrical conductors **18***a,b* connect to the respective electrical therapy electrodes **28***a,b*. The rotation tube **22** retains the flexible shaft **32**. The inside diameter of the rotation tube **22** is larger than the outer diameter of the flexible endoscope **12** to allow rotation of the rotation tube **22** while holding the flexible endoscope **12** stationary, or vice versa. The first electrode **28***a* extends outwardly from the distal end of the flexible shaft **32** through the working channel **36**. The second electrode **28***b* is connected to the waveform generator **14** through the electrical conductor **18***b* and is provided outside of the flexible endoscope **12** to be introduced to the tissue treatment region percutaneously. In this embodiment, the operator may endoscopically view the tissue between the electrodes **28***a,b* as illuminated by the light source **40** and viewed through the viewing port **38**.

[0032] FIG. **6** is a sectional view taken along line **6-6** of the rotation tube **22** of one embodiment of the electrical ablation system **10** shown in FIG. **4**. The external tube **64** or sheath and the rotation tube **22** assemble and retain the first electrical conductor **18***a* as already described. The light source **40**, the viewing port **38**, and the working channel **36** of the flexible endoscope **12** are shown.

[0033] FIG. **7** shows a distal portion of one embodiment of the electrical ablation system **10** shown in FIG. **1** inserted into a hollow body or natural opening of a patient. The electrical ablation system **10** is inserted into the colon **46** through the anus **50**. The colon **46** includes a sphincter muscle **52** disposed between the anus **50** and the rectum **56**. The electrical ablation system **10** is maneuvered through several turns through the colon **46**. The electrical ablation system **10** is introduced to the diseased tissue **48** through the colon **46**.

[0034] The operator may treat the diseased tissue **48** using the embodiment of the electrical ablation system **10** comprising the electrical ablation probe **20** with the electrical therapy electrode **28***a* introduced endoscopically and the electrical therapy electrode **28***b* introduced transcutaneously or percutaneously through the skin **54** as previously discussed with reference to FIGS. **1-7** as follows. The operator inserts the flexible shaft **32** of the endoscope **12** into the anus **50** and maneuvers it through the colon **46**. The operator uses endoscopic visualization through the viewing port **38** to position the first electrical therapy electrode **28***a* next to the diseased tissue **48** on the liver **42** to be treated. If the diseased tissue **48** is on the liver **42**, the distal end of the endoscope **12** can be advanced into the sigmoid colon. Once in the sigmoid colon an instrument such as a needle knife can be advanced through the lumen of the endoscope. The needle knife can then cut an opening through the sigmoid colon and into the peritoneal space (under visualization). The endoscope can then be advance into the peritoneal space and manipulate until the liver is in view. The operator then introduces the second electrical therapy electrode **28***b* transcutaneously though the skin **54** to the diseased tissue **48**. This can be done under visualization using the view from the endoscope or with fluoroscopy. The transcutaneous electrode is then advanced into the liver. The first and second electrodes **28***a,b* are placed in intimate contact with the diseased tissue **48** to be treated within the field of view of the flexible endoscope **12**. While watching through the viewing port **38**, the operator actuates the switch **62**, electrically connecting the electrodes **28***a,b* to the waveform generator **14** through the conductors **18***a,b*. Electric current then passes through the portion of the diseased tissue **48** positioned between the electrodes **28***a,b* and within the field of view. When the operator observes that the tissue in the field of view has been ablated sufficiently, the operator deactuates the switch **62** to stop the ablation. The operator may reposition either the endoscopic electrode **28***a* or the transcutaneous electrode **28***b* for subsequent tissue treatment, or may withdraw the electrical ablation probe **20** (together with the flexible endoscope **12**).

[0035] FIG. **8** is a diagram of one embodiment of a control loop **80** for one embodiment of an electrical (e.g., IRE or RF) therapy procedure to treat diseased tissue as described herein. As previously discussed, the electrical therapy procedure may be effective in quickly creating necrosis of live tissue and destroying diseased (e.g., cancerous) tissue in-vivo. Real time information feedback about the size in volume of a necrotic zone may be helpful during an electrical therapy procedure for focal treatment of diseased tissue **48**.

[0036] Prior to an electrical therapy procedure, a patient **82** will have an image of the diseased tissue **48** taken for clinical purposes in an effort to reveal, diagnose, or examine the diseased tissue **48** and to identify its location more precisely. The image information **84** will generally include geometric information about the volume of the diseased tissue **48**. The image information **84** is provided to an image processing

module **86** to calculate the volume of the diseased tissue **48** and to display a virtual model of the diseased tissue **48** on a monitor. The image processing module **86** may comprise, for example, image processing software applications such as Comsol Multiphysics available by Comsol, Inc. to receive the image information **84**, extract the geometric information, and determine (e.g., calculate) the voltage required to treat the proper volume and outline of the necrotic zone required to treat the diseased tissue **48**. The image processing module **86** creates a virtual model of a treatment zone necessary to treat the diseased tissue **48**. The image processing module **86** then determines waveform parameters **88** of a suitable electrical waveform necessary to destroy the diseased tissue **48**. The waveform parameters **88** include the frequency, amplitude, and pulse width of the electrical waveform to be generated by the waveform generator **14**. The waveform generator **14** would then generate the suitable electrical waveform to destroy the diseased tissue **48** based on the calculated electrical waveform parameters **88**.

[0037] The image processing module **86** also comprises image processing software applications such as Matlab available by MathWorks, Inc. to receive the image information **84** and the virtual model and display an image of the diseased tissue **48** overlaid with an image of the virtual model. The overlaid images enable the operator to determine whether the calculated electrical waveform parameters **88** are suitable for destroying the diseased tissue **48**, whether too strong or too weak. Thus, the electrical waveform parameters **88** may be adjusted such that the virtual model image substantially overlays the entire diseased tissue image. The calculated **88** parameters are provided to the waveform generator **14** and the diseased tissue may be treated with an electrical waveform **89** based on the calculated parameters **88** as discussed herein. After the diseased tissue **48** is treated with the electrical waveform **89**, a new image of the diseased tissue **48** can be generated to determine the extent or effectiveness of the treatment. The cycle may be repeated as necessary to ablate the diseased tissue **48** as much as possible.

[0038] FIG. **9** is a graphical representation **110** (graph) of the electric field strength (along the y-axis) as a function of the distance from an electrical therapy electrode **28***a,b* under various conductivity environments near the diseased tissue **48**. FIG. **10** is a close up of the graph **110** shown in FIG. **9**. In electrical therapy of diseased tissue **48**, the volume of tissue that can be destroyed by an electrical waveform (e.g., the necrotic zone) may be defined by a minimum electric field strength applied to the tissue treatment region. The electric field strength in the tissue treatment region varies throughout the tissue as a function of the applied electrical waveform parameters such as frequency, amplitude, and pulse width as well as the conductivity of the tissue in the treatment region. When a single electrical therapy electrode **28***a* or **28***b* is located in a first position in the tissue treatment region of interest and a return pad is placed at a distance relatively far from the first position, an electric field is generated around the respective electrode **28***a* or **28***b* when it is energized with a particular electrical waveform. The magnitude of the electric field, however, diminishes rapidly in the radial direction away from the electrode **28***a,b*. When the electrodes **28***a,b* are placed relatively close together, a larger pattern of tissue can be destroyed. Injecting a fluid having a higher conductivity than the tissue into the tissue treatment region extends the electric field of sufficient strength to destroy the tissue radially outwardly from the electrode **28***a,b*. Thus, the addition of a fluid having higher conductivity than the tissue to be treated creates a larger tissue destruction zone (e.g., necrotic zone) by extending the electric field radially outwardly from the electrodes **28***a,b*.

[0039] The graph **110** illustrates the electric field strength, along the y-axis, as a function of the radial distance from the electrical therapy electrode **28***a,b*. The y-axis is labeled in units of volts/meter ($V/m \times e^5$) and the x-axis is labeled in units of mm. The graph **110** illustrates a family of three functions with conductivity as a parameter. A first function **112** illustrates the electric field strength as a function of the radial distance from one of the electrodes **28***a,b* with no conductivity plug introduced into the tissue treatment region. A second function **114** illustrates the electric field strength as a function of the radial distance from one of the electrodes **28***a,b* with a conductivity plug of 0.2 S/m introduced in the tissue treatment region. A third function **116** illustrates the electric field strength as a function of the radial distance from one of the electrodes **28***a,b* with a conductivity plug of 0.5 S/m introduced in the tissue treatment region. As shown in the graph **110**, the peak electric field strength of each of the functions **112**, **114**, **116** decreases with increased conductivity in the tissue treatment region in proximity to the electrode **28***a,b*. However, the threshold **118** of each of the functions **112**, **114**, **116** where the electric field strength drops below the minimum threshold **118** of electric field strength required for tissue destruction becomes wider as the conductivity increases. In other words, increasing the conductivity of the tissue in the tissue treatment region extends the range of an effective electric field to destroy tissue or creates a larger necrotic zone. In one embodiment, the minimum electric field strength threshold **118** is approximately 30,000 V/m.

[0040] The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[0041] Preferably, the various embodiments of the invention 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.

[0042] It is preferred that the device is sterilized. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, steam.

[0043] Although the various embodiments of the invention 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.

[0044] 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.

What is claimed is:

1. An ablation device comprising:

an elongate relatively flexible member having a proximal end and a distal end, the flexible member comprising a working channel;

a first electrode extending from the working channel at the distal end of the flexible member, the first electrode is adapted to be endoscopically located in a first position relative to a tissue treatment region; and

a second electrode adapted to be percutaneously located in a second position of the tissue treatment region;

wherein the first and second electrodes are adapted to couple to an electrical waveform generator and to receive an electrical waveform sufficient to ablate tissue located between the first and second electrodes.

2. The ablation device of claim **1**, wherein the first and second electrodes are adapted to receive an irreversible electroporation (IRE) waveform from an IRE generator.

3. The ablation device of claim **1**, wherein the first and second electrodes are adapted to receive a radio frequency (RF) waveform from an RF generator.

4. The ablation device of claim **1**, comprising:

at least a third electrode adapted to be percutaneously located in a third position of the tissue treatment region, wherein the third electrode is adapted to couple to the electrical waveform generator and to receive an electrical waveform sufficient to ablate tissue located between the first, the second, and the at least third electrodes.

5. The ablation device of claim **1**, comprising:

at least one illuminator supported on the device and positioned to illuminate tissue; and

an image sensor supported on the device and positioned to image tissue therethrough.

6. A method comprising:

receiving image information of a diseased tissue region in a patient;

determining a volume and outline of a necrotic zone required to treat the diseased tissue based on the image information; and

determining waveform parameters to be generated by an electrical waveform generator suitable to destroy the diseased tissue.

7. The method of claim **6**, comprising:

extracting geometric information from the image information; and

determining the volume and outline of the necrotic zone required to treat the diseased tissue based on the geometric information.

8. The method of claim **6**, comprising:

providing the waveform parameters to an electrical waveform generator.

9. The method of claim **6**, comprising:

determining amplitude, frequency, and pulse width waveform parameters suitable to destroy the diseased tissue.

10. An ablation system, comprising:

an ablation device comprising:

an elongate relatively flexible member having a proximal end and a distal end, the flexible member comprising a working channel;

a first electrode extending from the working channel at the distal end of the flexible member, the first electrode is adapted to be endoscopically located in a first position relative to a tissue treatment region; and

a second electrode adapted to be percutaneously located in a second position of the tissue treatment region; and

an electrical waveform generator electrically coupled to the ablation device;

wherein the first and second electrodes are adapted to receive an electrical waveform sufficient to ablate tissue located between the first and second electrodes.

11. The ablation system of claim **10**, wherein the electrical waveform generator comprises an irreversible electroporation waveform generator.

12. The ablation system of claim **10**, wherein the electrical waveform generator comprises a radio frequency generator.

13. The ablation system of claim **10**, wherein the ablation device comprises at least a third electrode adapted to be percutaneously located in a third position of the tissue treatment region, wherein the third electrode is adapted to couple to the electrical waveform generator and to receive an electrical waveform sufficient to ablate tissue located between the first, the second, and the at least third electrodes.

14. The ablation system of claim **10**, wherein the ablation device comprises at least one illuminator supported on the device and positioned to illuminate tissue; and an image sensor supported on the device and positioned to image tissue therethrough.

15. The system of claim **10**, wherein the electrical waveform generator is to receive electrical waveform parameters from an image processing module; the electrical waveform parameters are suitable to destroy the diseased tissue; and the electrical waveform parameters are determined based image information of the diseased tissue region in a patient.

16. The system of claim **15**, wherein the electrical waveform parameters are determined based on a volume and outline of a necrotic zone required to treat the diseased tissue based on the image information; and the waveform parameters are to be generated by the electrical waveform generator.

17. The system of claim 16, wherein the volume and outline of the necrotic zone are determined from geometric information extracted from the image information.

18. The system of claim 15, wherein the electrical waveform parameters comprise amplitude, frequency, and pulse width of an electrical waveform suitable to destroy the diseased tissue.

19. A method comprising:

introducing an elongate relatively flexible member having a proximal end and a distal end into a natural opening of a patient, the flexible member comprising a working channel and a first electrode extending from the working channel at the distal end of the flexible member, the first electrode is adapted to be endoscopically located in a first position relative to a tissue treatment region;

introducing a second electrode percutaneously in a second position of the tissue treatment region; and

ablating the tissue located between the first and second electrodes.

20. The method of claim 19, comprising:

ablating the tissue with an irreversible electroporation (IRE) waveform from an IRE generator electrically coupled to the first and second electrodes.

21. The method of claim 19, comprising:

introducing at least a third electrode percutaneously in a third position of the tissue treatment region, wherein the third electrode is adapted to couple to the electrical waveform generator and to receive an electrical waveform sufficient to ablate tissue located between the first, the second, and the at least third electrodes.

22. The method of claim 19, comprising:

obtaining image information of the tissue treatment region in the patient;

determining a volume and outline of a necrotic zone required to treat the tissue in based on the image information; and

determining waveform parameters to be generated by an electrical waveform generator suitable to destroy the diseased tissue.

23. The method of claim 22, comprising:

extracting geometric information from the image information; and

determining the volume and outline of the necrotic zone required to treat the diseased tissue based on the geometric information.

24. The method of claim 23, comprising:

providing the waveform parameters to an electrical waveform generator.

25. The method of claim 23, comprising:

determining amplitude, frequency, and pulse width waveform parameters suitable to destroy the diseased tissue.

26. The method of claim 19, comprising:

ablating the tissue device with a radio frequency (RF) waveform from an RF generator electrically coupled to the first and second electrodes.

27. The method of claim 19, comprising introducing a conductive liquid into the tissue treatment region, wherein the conductive liquid has a conductivity that is relatively higher than the conductivity of the tissue in the tissue treatment region.

28. A method comprising:

obtaining a surgical instrument, wherein the surgical instrument comprises:

an elongate relatively flexible member having a proximal end and a distal end, the flexible member comprising a working channel;

a first electrode extending from the working channel at the distal end of the flexible member, the first electrode is adapted to be endoscopically located in a first position relative to a tissue treatment region; and

a second electrode adapted to be percutaneously located in a second position of the tissue treatment region;

wherein the first and second electrodes are adapted to couple to an electrical waveform generator and to receive an electrical waveform sufficient to ablate tissue located between the first and second electrodes;

sterilizing the surgical instrument; and

storing the surgical instrument in a sterile container.

* * * * *

专利名称(译)	电消融装置，系统和方法		
公开(公告)号	US20080200911A1	公开(公告)日	2008-08-21
申请号	US11/706591	申请日	2007-02-15
[标]申请(专利权)人(译)	LONG GARY大号		
申请(专利权)人(译)	LONG GARY大号		
当前申请(专利权)人(译)	爱惜康内镜手术，INC.		
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IPC分类号	A61B18/18		
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摘要(译)

诸如内窥镜或腹腔镜器械的手术器械包括消融装置。消融装置包括细长的相对柔性的构件，该构件具有近端和远端。柔性构件包括工作通道。第一电极从柔性构件的远端处的工作通道延伸，并且适于内窥镜地定位在相对于组织治疗区域的第一位置。第二电极适于经皮定位在组织治疗区域的第二位置。第一和第二电极适于耦合到电波形发生器并接收足以消融位于第一和第二电极之间的组织的电波形。