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(54) **HELICAL ELECTRODE TREATMENT DEVICE AND RELATED METHODS OF TREATMENT**

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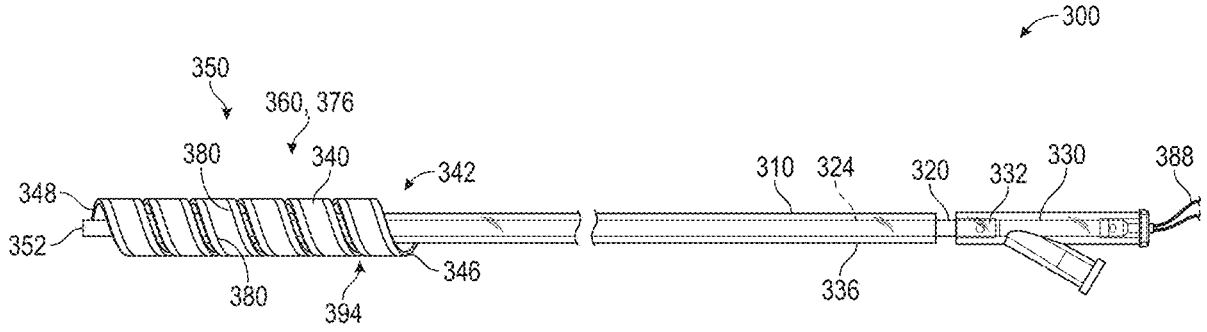
(57) **ABSTRACT**

An electrode treatment device includes an electrode strip arranged in the shape of a helix with a first end of the electrode strip attached to an elongate flexible body, such as a catheter tube, and a second end of the electrode strip attached to a flexible shaft that extends from the body. When the helical electrode is contracted around the body and/or shaft, the device may be less than 2 mm in diameter to facilitate endoluminal insertion and treatment of gastrointestinal or lung tissue, for example. The shaft is rotatable relative to the body to radially expand the helix to a deployed position in apposition to target tissue for electrosurgical treatment (e.g., treatment in a lumen). The electrode strip may consist of conductive foil or may comprise a flexible printed circuit with one or more electrodes formed thereon. The device may be operated by a robotic manipulator.



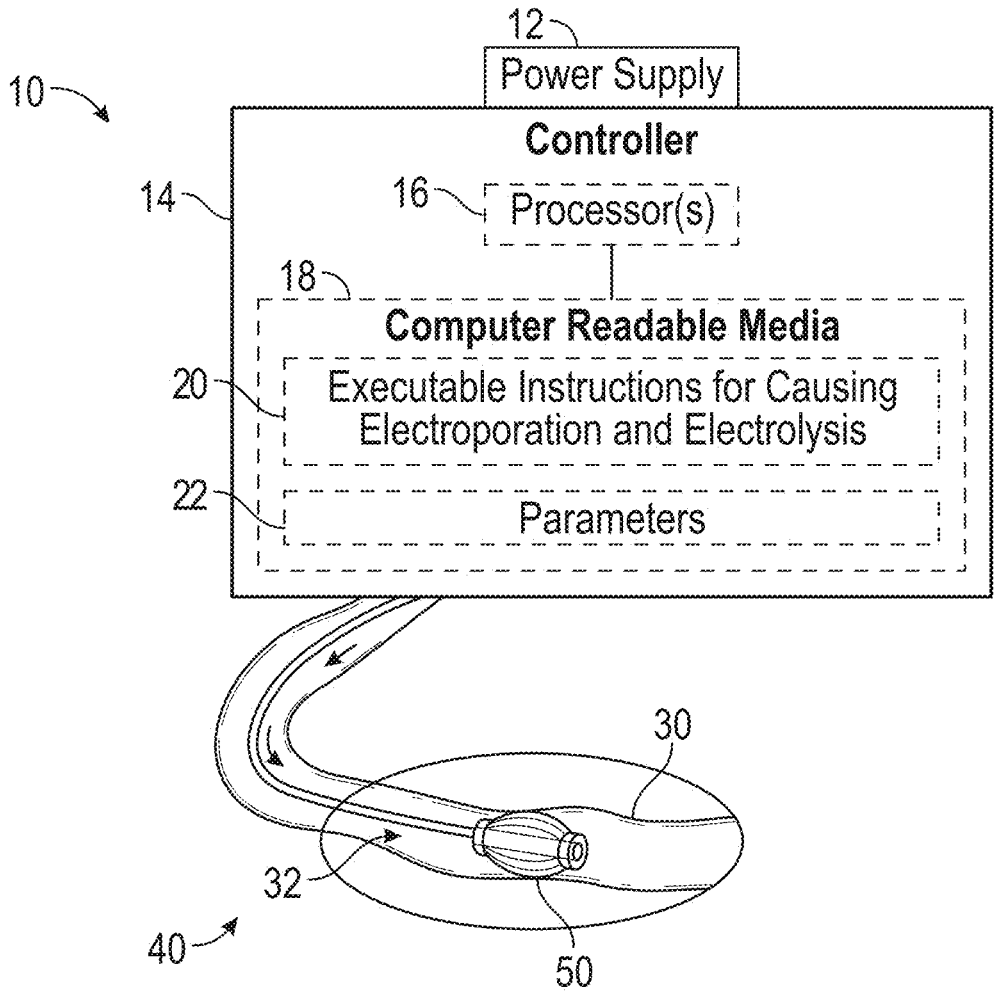

12
Power Supply
10
Controller
14
16
Processor(s)
18
Computer Readable Media
20
Executable Instructions for Causing Electroporation and Electrolysis
22
Parameters
30
32
40
50

FIG. 1

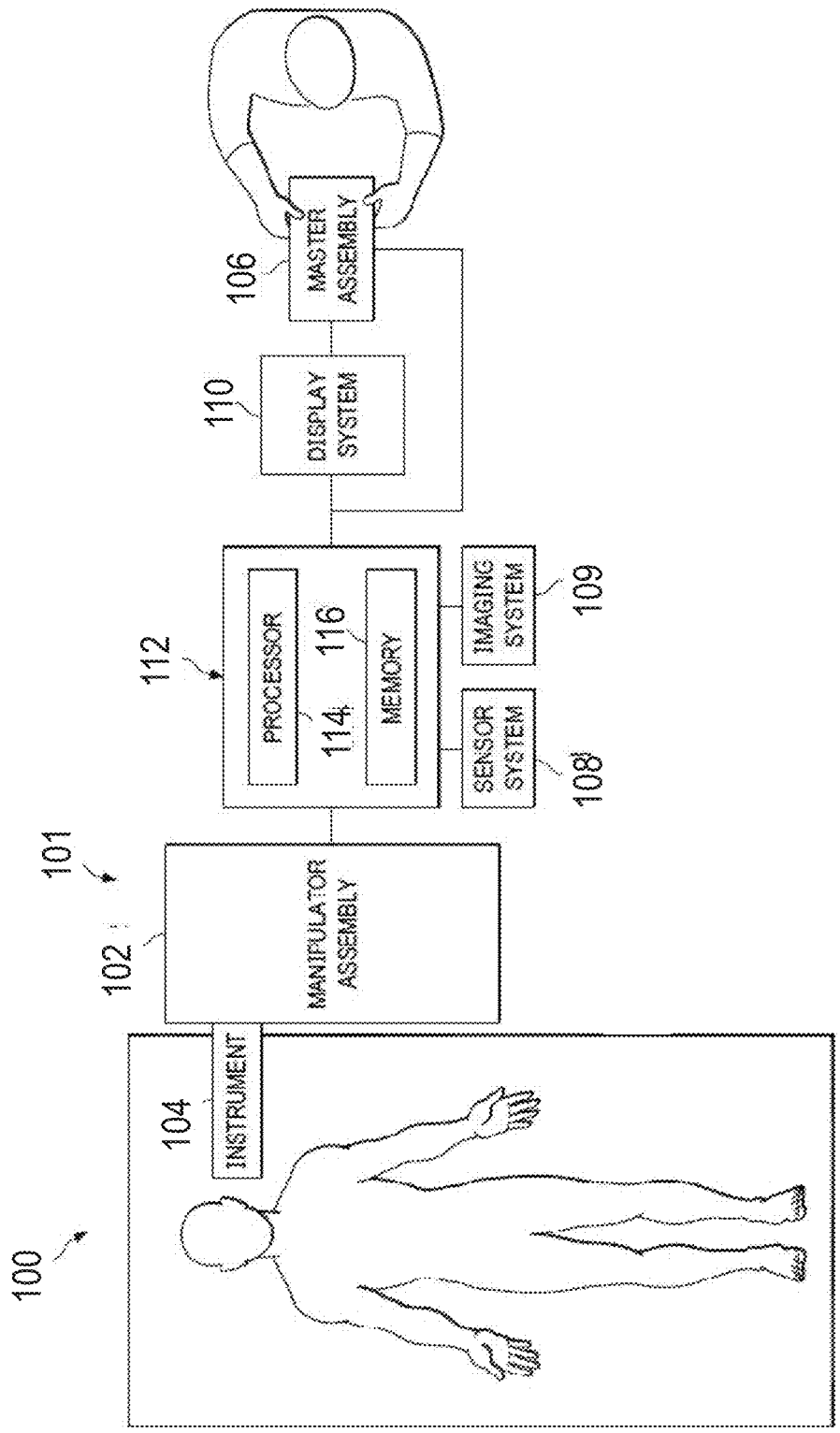

100
101
102
104
INSTRUMENT
MANIPULATOR ASSEMBLY
112
PROCESSOR
114
116
MEMORY
SENSOR SYSTEM
108
IMAGING SYSTEM
109
110
DISPLAY SYSTEM
106
MASTER ASSEMBLY

FIG. 2

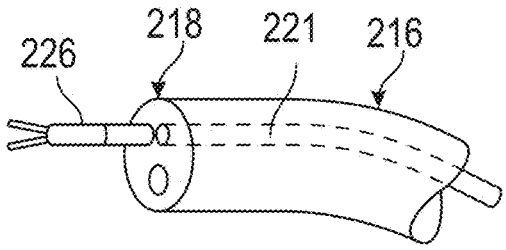
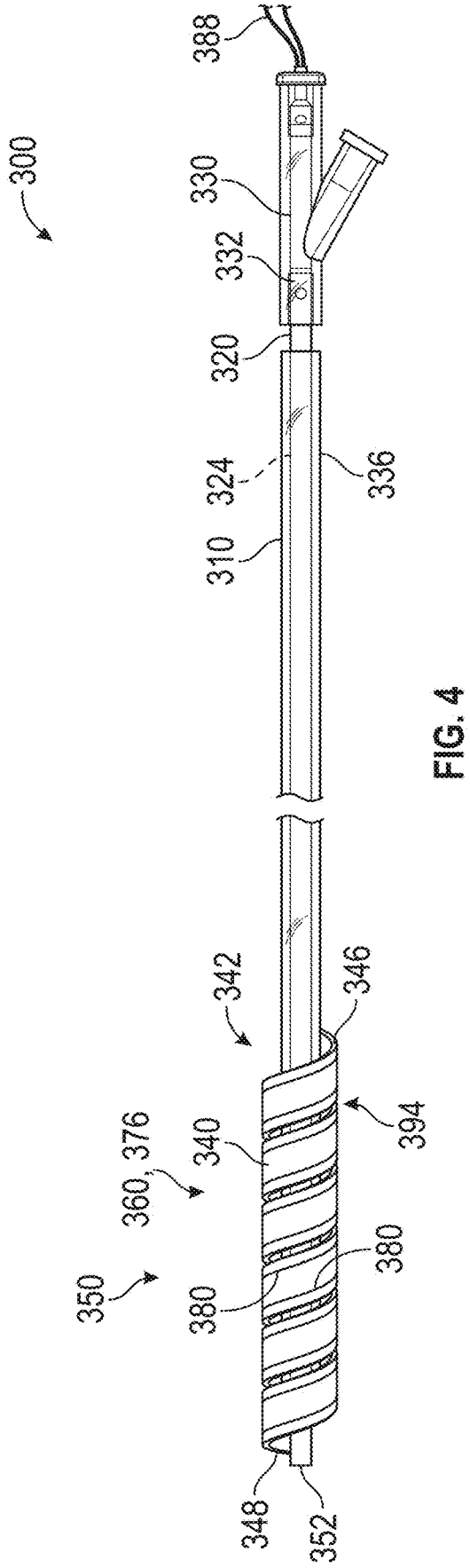

226
218
221
216

FIG. 3B

219
219
218
200
220
221
221
202
222
226
216
224
224
102
Manipulator Assembly
204
231
Visualization System
Navigation System
232
230
Tracking System
Display System
110
217

FIG. 3A


300
388
330
332
320
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394
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360, 376
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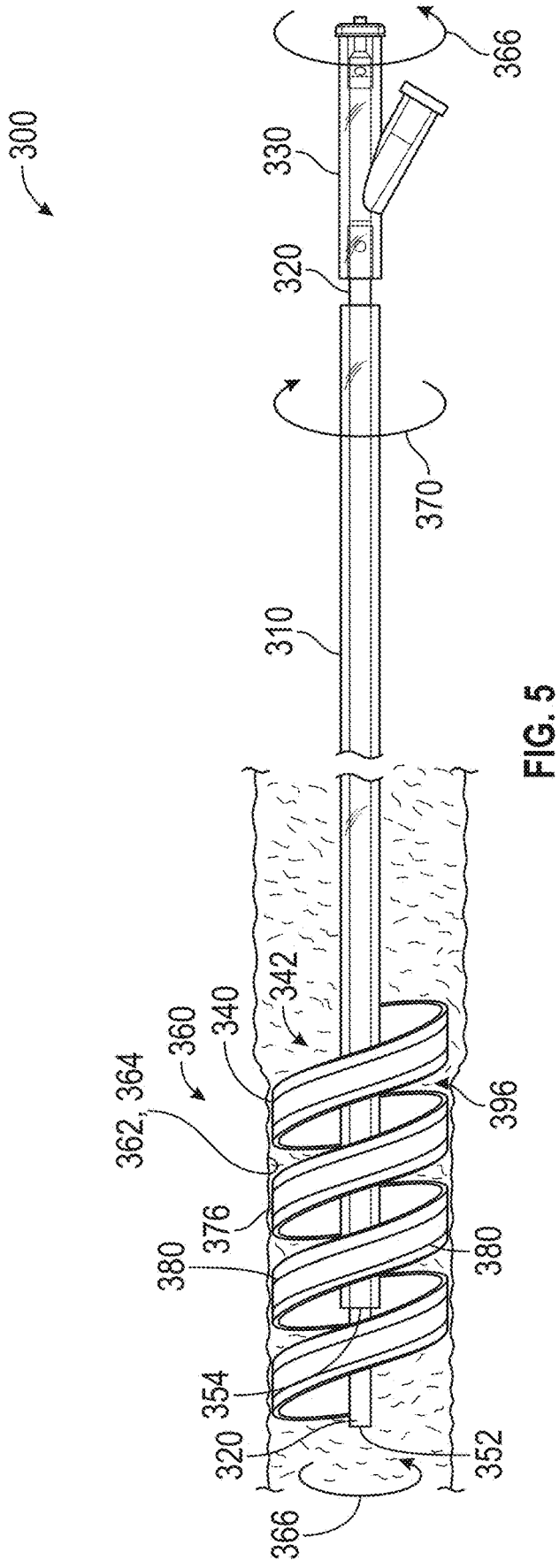
352

FIG. 4


300
330
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362, 364
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366

FIG. 5

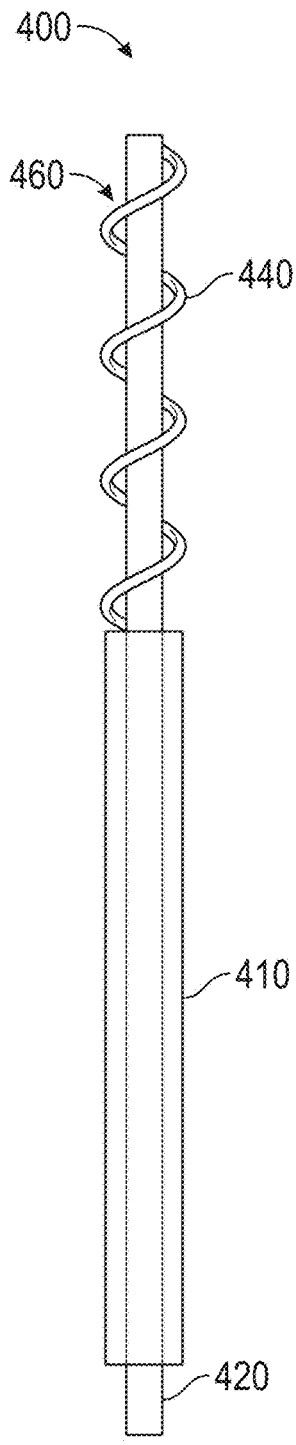

FIG. 6A

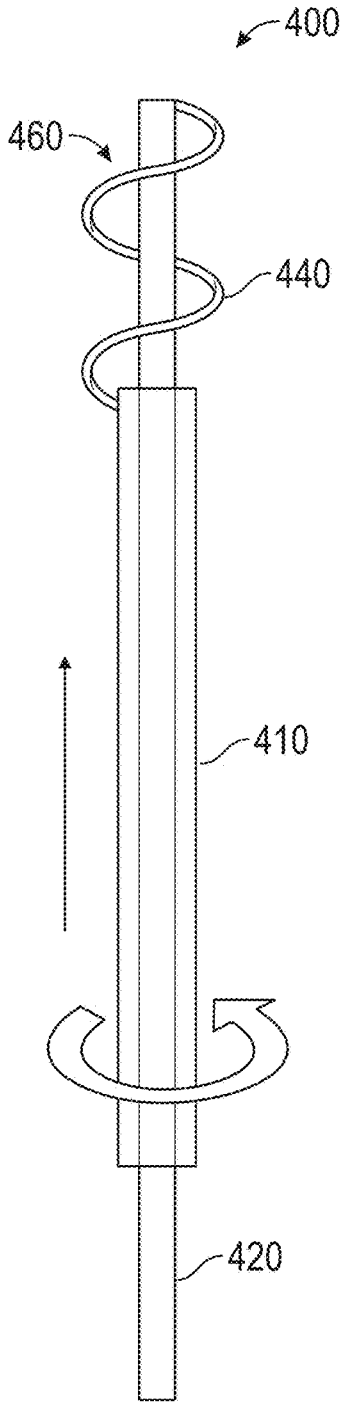

FIG. 6B

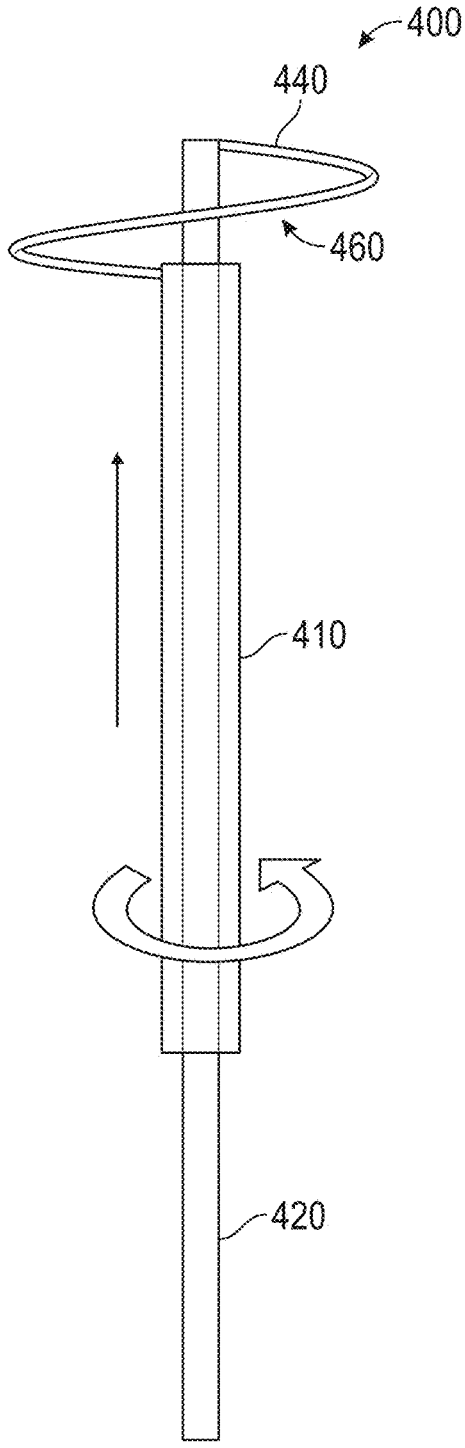

FIG. 6C

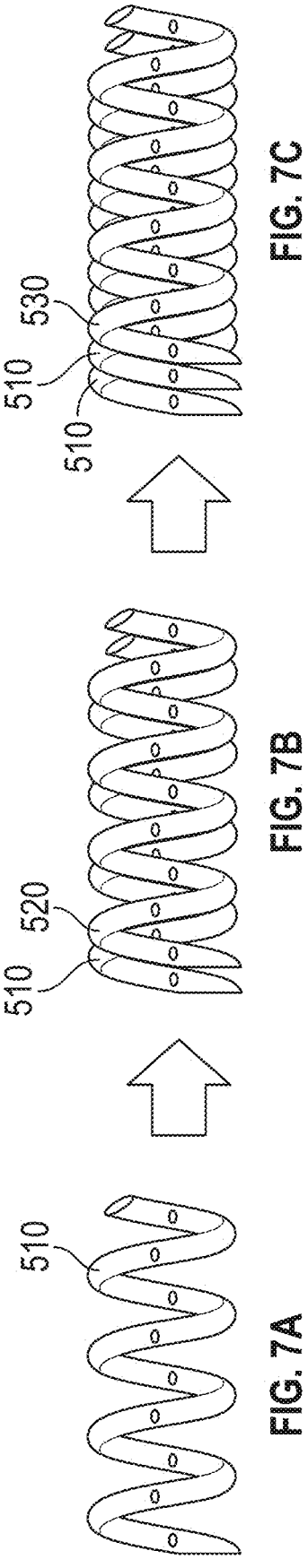

FIG. 7A

FIG. 7B

FIG. 7C

HELICAL ELECTRODE TREATMENT DEVICE AND RELATED METHODS OF TREATMENT

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority benefit under 35 U.S.C. § 119 (e) of U.S. Provisional Patent Application No. 63/579,822, filed Aug. 31, 2023, which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present disclosure relates generally to the field of tissue treatment. In particular, the disclosure relates to devices and methods with deployable electrodes to ablate cells for treating targeted tissues.

BACKGROUND

[0003] Tissues in the body may be treated in surgical or medical procedures using resection and removal. While such procedures may be necessary to treat more extensive damage or resolve various medical conditions, minimally invasive procedures may be used as an alternative in some situations. Such procedures, where applicable, may be preferable to reduce overall patient risk, damage to surrounding tissue, recovery time, discomfort, and potentially harmful side effects as compared to more invasive, surgical procedures. In minimally invasive tissue ablation, targeted tissues may be treated inside the body (e.g., in situ) using procedures that do not involve resection or may require minimal resection. Some examples of minimally invasive tissue ablation techniques include electrolytic ablation, cryosurgery, chemical ablation (e.g., alcohol injection), thermal ablation (e.g., radiofrequency, microwave), and hydrothermal ablation. The primary aim of these ablation procedures is to destroy abnormal tissue in a targeted region and encourage the regrowth of healthy tissue.

[0004] Another known minimally invasive treatment technique involves electroporation of targeted tissues by localized application of an electrical field to increase permeability of cell membranes, which may then allow drugs or other chemicals to be introduced into the cells for treatment. Electroporation may also be used in combination with electrolysis as a method of tissue ablation, by a process also known as electrolytic electroporation, electroporation-electrolysis, or E2.

[0005] Tissue ablation is a therapeutic procedure used to treat abnormal or damaged tissues of various types, such as those of the gastrointestinal tract. Damage to intestinal tissue may arise from several sources but is commonly associated with chronic metabolic disorders such as diabetes. For patients with diabetes, damage to gastrointestinal tissues (particularly the duodenum) may create issues with insulin resistance and/or impair the ability for the body to process glucose. To help improve patient management of the disorder, duodenal mucosal resurfacing (DMR) has been proposed to resurface the patient's intestinal lining and help regenerate healthy lining to improve nutrient absorption at the duodenum. Improved health of the intestinal lining helps correct absorption issues and may yield a better therapeutic response to insulin for the patient, which in turn may allow some patients to replace more aggressive insulin therapies (e.g., injections) with oral medications to help manage the condition.

[0006] Generally, DMR is a procedure that involves introducing a catheter (or other suitable medical instrument) into the duodenum, typically under endoscopic guidance, and ablating the inner lining of the duodenum. However, various ablation techniques and ablation instrument designs may not be suitable for endoluminal ablation or may be challenging to control ablation to desired depths via application from within the duodenum lumen.

[0007] Tissue ablation also has potential as a minimally invasive therapeutic procedure for targeted treatment of lung cancer. However, the present inventors have recognized that deployment of electrodes for electrolysis and/or electroporation is complicated by size constraints and guidance issues associated with navigating a catheter through the tree of relatively small bronchioles leading to targeted lung tissues. Navigation of the bronchiole tree may require a steerable catheter having a diameter less than 3.5 mm. The present inventors have recognized the challenges associated with designing an electrode array small enough to be carried by such a catheter, but which can be deployed or expanded at the treatment site to contact a larger area of tissue.

[0008] The inventors have identified a need for an improved medical instrument with a flexible substrate having one or more electrodes to ablate cells for treating targeted tissues, such as gastrointestinal tissues or lung tissues for example.

SUMMARY

[0009] An electrode treatment device includes an elongate body, such as a catheter tube, having a distal end portion terminating in a tip, a shaft rotatably supported by the body and extending beyond the tip of the body, and an electrode strip, such as a flexible printed circuit with one or more electrodes extending along its length. The electrode strip has a first end portion attached to the distal end portion of the body and a second end portion attached to the shaft at a location distal to the tip of the body, and is wound around the body and/or the shaft to form a helix. The electrode strip may be coupled to an electrical power source via wires or other conductive pathways. The shaft is rotatable in a first direction relative to the body for radially expanding the helix to thereby deploy the electrode strip at a treatment site into apposition with targeted tissue for performing an electrosurgical procedure such as DMR or another function. The shaft is also rotatable relative to the body in a second direction opposite the first direction for radially contracting the helix around the body and/or shaft to facilitate extraction of the electrode strip from the treatment site. In some embodiments, the shaft is also slidably movable inwardly and distally outwardly relative to the body to adjust a pitch of the helix during expansion (deployment) and/or contraction.

[0010] In some embodiments, the electrode strip may be arranged to leave no gaps between turns of the helix when the electrode strip is contracted around the body and/or the shaft, or when in the expanded (deployed) position. And in some embodiments, the electrode strip is thermoformed or heat treated so that the electrode strip tends to return to the shape of the helix when no force is applied to the electrode strip via the shaft and/or the body.

[0011] In some embodiments, the shaft is movable relative to the body to cause the electrode strip to move between the contracted position and a maximally expanded position and the electrode strip has a maximum expansion ratio that exceeds 5:1 or 10:1 or 20:1, or is in the range of 5:1 to 30:1.

[0012] In some embodiments, the electrode treatment device is operated by a robotic manipulator. The robotic manipulator may include a rotational actuator and a translational actuator, which may be independently controlled in some embodiments. In some embodiments, the rotational and translational actuators are integrated into a single actuator.

[0013] Additional aspects and advantages will be apparent from the following detailed description of preferred embodiments, which proceeds with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The drawings depict only several examples in accordance with the disclosure and are therefore not to be considered limiting in scope. Exemplary embodiments will be described with additional specificity and detail through use of the accompanying drawings, in which:

[0015] FIG. **1** is a schematic illustration of a system for electroporation and/or electrolysis in accordance with examples described herein;

[0016] FIG. **2** is a schematic illustration of a robotically-assisted manipulator system in accordance with examples described herein;

[0017] FIG. **3**A is a schematic diagram of an instrument system in accordance with examples described herein;

[0018] FIG. **3**B illustrates a distal portion of the instrument system of FIG. **3**A with an extended example of an instrument in accordance with examples described herein;

[0019] FIG. **4** illustrates an electrode instrument with a helical electrode strip in a contracted position, accordance with an example described herein;

[0020] FIG. **5** illustrates the electrode instrument of FIG. **4** with the helical electrode strip deployed to an expanded position;

[0021] FIGS. **6**A, **6**B, and **6**C schematically illustrate an electrode instrument according to examples described herein, in which a body and shaft of the instrument are both rotatable and slidably translatable relative to each other to control a pitch of the helical electrode; and

[0022] FIGS. **7**A, **7**B, and **7**C illustrate incremental advancement of a helical electrode along a treatment site to a series of overlapping contact areas or treatment regions.

DETAILED DESCRIPTION

[0023] This disclosure is directed to apparatuses and systems for providing controlled delivery of one or more flexible electrodes to a targeted tissue site for treatment, such as ablation by electroporation and/or electrolysis, or for other purposes. Generally, a method for minimally invasive regenerative surgery is disclosed which includes subjecting a target area in living tissue to ablation delivered via the one or more electrodes. In some examples, the ablation energy may be in the form of a combination of one or more electric fields and electrolysis. However, it should be appreciated that the example systems and methods described herein may be utilized for the deployment of flexible substrates carrying electrodes using ablation modalities other than electroporation and/or electrolysis (e.g., radiofrequency ablation), or for purposes other than ablation, such as electrical stimulation or diagnostic methods.

[0024] During an example procedure utilizing electroporation and electrolysis, the electrode(s) are brought into proximity and/or contact with the target tissue, and the electric fields are generated by applying voltages and/or currents between the one or more electrodes. The electric fields may be generated to have a magnitude to permeabilize cell membranes in a region where ablation is desired. The electric fields may be generated to produce products of electrolysis of a magnitude that, by themselves, do not cause damage to cells or the extracellular matrix located in and around the target treatment region. However, when sufficient products of electrolysis are generated in the region of permeabilized cells, cellular death occurs within the region of the applied electric field without damaging the extracellular matrix or scaffolding to aid in promoting tissue regrowth in the treated tissue region.

[0025] In some examples, after applying ablative energy to one target region, the electrode(s) may be moved to other tissue locations by advancing and/or retracting a delivery catheter carrying the electrode(s) and repeating the process. In this manner, electroporation and electrolysis may be performed at multiple locations in a patient to cover a larger area of tissue. In some examples, multiple sets of electrodes may be positioned at multiple respective tissue sites such that electroporation and electrolysis may be performed at each site in parallel, reducing and/or eliminating a need to repeat the procedure as a catheter is moved through the patient.

[0026] In some embodiments of the present disclosure, the systems and methods disclosed herein may be used to treat tissue of the gastrointestinal tract. In other embodiments, lung tissue or any of a variety of other tissue may be treated using the systems and methods described herein. Generally, tissue may be treated where tissue regeneration is desirable or where it is desirable to replace one type of cells with another. Examples include intestine, duodenum, stomach, bladder, uterus, endometrial lining, ovaries, colon, rectum, sinuses, ducts, ureters, prostate, skin, muscle, nerve, diaphragm, momentum, kidney, follicles, brain, lymphatic vessels, breast, esophagus, lung, liver, kidney, lymph nodes, lymph node basins and/or heart. Replacement of one type of tissue with another may be in fibrotic areas where it is desired to replace fibrotic cells with stem cells that can remodulate the area or when pancreatic islets are injected in part of the liver to generate new sources of insulin. Other tissue may be treated in other examples. The following provides additional details relating to example processes of electroporation and/or electrolysis for tissue treatment in accordance with some embodiments.

[0027] As noted above, electroporation may be performed to permeabilize the cell membranes of targeted cells. Reversible electroporation may be used in which the permeabilization may cease after the electric fields are removed. Cells may survive reversible electroporation with the pores within the membrane resealing and returning to homeostasis. In irreversible electroporation, the permeabilization of the cell membrane is permanent leading to cell death. Typically for biological tissues, electric fields lower than about 1500 V/cm to about 200 V/cm are considered to produce reversible electroporation, while electric fields higher than about 1500 V/cm are considered to produce

irreversible electroporation. Examples of systems and methods described herein may utilize reversible electroporation to avoid disadvantages of irreversible electroporation, which may include heating and thermal damage, complexity of providing such large electric fields, and muscle contractions which may result from the large electric fields. It is to be understood that, although systems and methods described herein may be designed to utilize reversible electroporation, there may occur localities or incidental areas where conditions are such that irreversible electroporation, or even thermal ablation, may occur in limited parts of the treated tissue.

[0028] In some treatment procedures, products of electrolysis may be applied to permeabilized cells to cause cell death of the permeabilized cells within the applied electrical field while leaving the extracellular matrix of the permeabilized cells intact. The extracellular matrix generally refers to a three-dimensional network of proteins and/or other molecules (e.g., collagen fibers, proteoglycans, and/or proteins such as fibronectin and/or laminin) which provide structure for cells and tissues and may additionally provide signaling for cell growth and development. Extracellular matrices may be used as scaffolds for tissue regeneration and/or engineering. For example, cells may be regenerated, grown, transplanted, or otherwise nurtured, on the extracellular matrix. By retaining the extracellular matrix in regions of otherwise ablated cells described herein, cell regeneration and/or tissue engineering may occur in the region of ablated cells. In some procedures, the extracellular matrix may be transplanted from a region of ablated cells to another region (which may be another region of ablated cells), to promote regeneration and/or tissue engineering in the transplanted region. In some cases, once the extracellular matrix is present, material may be injected into the extracellular matrix to enhance regrowth.

[0029] Example systems and methods described herein may utilize electrolysis products to cause cell death together with electroporation to permeabilize the cell membrane. The electrolysis products are sufficient to ablate (e.g., cause cell death) permeabilized cells in a relatively short time frame. However, the concentration of electrolysis products and exposure time are insufficient to cause cell death of non-permeabilized cells, thereby minimizing or avoiding the formation of scar tissue, fibrotic tissue, or ulceration in the treated region. Scar tissue and fibrosis is an indication that the extracellular matrix has been affected, and the ability for cells to regenerate and/or tissue engineering to occur in the ablated region may be inhibited. Accordingly, the electrolysis products are used to ablate permeabilized cells only, while leaving the extracellular matrix intact to promote tissue regrowth. Electrolysis products may include products toxic to cells (cytotoxic). Electrolysis preferentially utilizes one or more inert electrodes that do not participate in the process of electrolysis except as a source or sink of electrons or as catalysts. When participating non-inert electrodes are used in the process, they can generate metal ions that may cause systemic damage to the body, such as excess of iron or even metallic fragments.

[0030] Examples of systems disclosed herein include one or more electrodes, a power supply, and a controller to apply energy for treating internal tissue. The energy applied may be for electrolysis and/or electroporation in some examples, radiofrequency ablation in other examples, and other energy modalities in yet other examples. When the energy is for electroporation with or without electrolysis, the controller controls a charge delivered to the electrode(s) to induce one or more electric fields. Where electroporation and electrolysis are included, the electrode(s) are used to generate a current to produce electrolysis products and a voltage difference to produce an electric field that induces electroporation. The duration and magnitude of the charge applied determines the dose of the electrolytic products and the degree of the permeabilization of cells in the treatment site. Accordingly, a region of cell ablation may be determined by a region in which cells are exposed to the combination of permeabilization and to electrolysis products that cause ablation. The ablation, however, may leave the extracellular matrix intact in the region of ablated cells where the electrical field has been applied. The composition of the electrode(s) may be chosen in accordance with the desired products produced and electroporation effects.

[0031] With reference to FIG. **1**, the following provides a brief overview of an example system for delivering a catheter with electrodes to a targeted tissue site for treatment via electroporation and/or electrolysis. For clarity, the written description and the associated figures of various example embodiments generally references a catheter for use with the systems and methods described herein. However, it should be understood that other suitable medical instruments (e.g., instruments that may not be specifically classified as catheters) and other suitable energy modalities (e.g., radiofrequency ablation) may be used in conjunction with the disclosed systems and methods without departing from the principles of the disclosed subject matter.

[0032] FIG. **1** is a schematic illustration of a system **10** arranged in accordance with example embodiments described herein. Generally, example systems described herein may include a delivery system and a controller. In the example of FIG. **1**, the system **10** includes a power supply **12** coupled to a controller **14**, and a catheter **40**. Examples of other suitable catheters which may be used with the system **10** are described in further detail below with respect to FIGS. **4-7**. With reference to FIG. **1**, the controller **14** may include a processor **16**, computer readable media **18**, and other computing system components, such as one or more input devices, output devices, sensors, and/or communication devices in some examples. Additional, fewer, and/or different components may be used in other examples. The computer readable media **18** includes executable instructions **20** for modulating the output of power supply **12** for causing electroporation and electrolysis with the catheter **40** and may include stored parameters **22** which may be used in the process for causing electroporation and electrolysis, such as electric field strengths, voltage and/or current levels, waveform shapes, exposure duration parameters, and any other suitable parameters. In the example of FIG. **1**, the circle depicted around an end of the catheter **40** may indicate a region of cells that may be permeabilized via an applied electric field.

[0033] The controller **14** may be implemented using a computing device. Examples of computing devices include controllers, microcontrollers, computers, servers, medical devices, smart phones, tablets, wearable devices, and the like. The computing device may be handheld and may have other uses as well. The controller **14** may include one or more processors, such as the processor **16**. Any kind or number of processors may be present, including one or more central processing unit(s) (CPUs) or graphics processing

unit(s) (GPUs) having any number of cores, controllers, microcontrollers, and/or custom circuitry such as one or more application specific integrated circuits (ASICs) and/or field programmable gate arrays (FPGAs).

[0034] The controller **14** described herein may include computer readable media **18**, such as memory. Any type or kind of memory may be present (e.g., read only memory (ROM), random access memory (RAM), solid state drive (SSD), secure digital card (SD card), and the like). While a single box is depicted as the computer readable media **18** in FIG. **1**, any number of computer readable media **18** devices may be present. The computer readable media **18** may be in communication with (e.g., electrically connected to) the processor **16**.

[0035] The executable instructions **20** for electroporation and electrolysis may include instructions to control a charge delivered to electrodes, such as electrodes **50** of the catheter **40**. Accordingly, the controller **14** may induce a voltage difference across the targeted tissue to generate an electric field that causes permeabilization of cells in an area of tissue targeted for treatment. The electrodes **50** are illustrated in a cavity or lumen **32** formed within tissue **30**. Although the catheter **40** is shown disposed within a cavity **32** of tissue **30**, the catheter **40** may be on the surface of the tissue **30**, inside the tissue **30**, and/or proximate to the tissue **30**. Moreover, although a catheter **40** is shown for delivering and arranging the electrodes **50** for permeabilization and/or the generation of electrolysis products to treat tissue **30**, in other embodiments, other suitable delivery systems may be used.

[0036] A controller, such as controller **14** of FIG. **1**, may activate one or more selected electrodes **50** to provide an electric field. In some embodiments, the controller **14** may alternate or otherwise select a pattern of activated electrodes **50** (e.g., activating pairs of electrodes in sequence) to shape or deliver a particular electric field. In some examples, fluids or other substances may be injected into, brought into contact with, or otherwise placed in or around the tissue **30** to aid in shaping the electric field generated in the tissue **30**. For example, conductive fluids may aid in shaping the field (e.g., by extending the field). In other examples, non-conductive fluids may aid in shaping the field (e.g., by attenuating the field). In some examples, non-conductive fluids or other substances may be injected or otherwise placed in tissue to protect areas where ablation is not desired. The electric field may not penetrate and/or not be carried through the non-conductive fluid, such that the field would not reach tissue where ablation is not desired, or at least be present in insufficient strength to cause permeabilization or other cellular change.

[0037] The controller **14** may also be used to induce a current through the tissue **30**, such as between electrodes **50**, to generate products of electrolysis. The products of electrolysis may cause ablation of the permeabilized cells but are preferably insufficient to destroy the extracellular matrix in the region of the permeabilized cells. The remaining intact extracellular matrix may allow for regeneration of the tissue and tissue engineering as described previously.

[0038] In some embodiments, one or more of the electrodes **50** used to apply electroporation may also be used to generate products of electrolysis (in other words, some or all of the electrodes may be used for both electroporation and electrolysis). In other embodiments, a first subset of electrodes **50** used to apply electroporation may be different from a second subset of electrodes **50** used to generate products of electrolysis.

[0039] In some embodiments, the power supply **12** is integrated with the controller **14**. The power supply **12** may be implemented using any suitable power source, such as one or more AC power sources, DC power sources, batteries, and/or waveform generators. The power supply **12** may supply power to the electrodes **50** to generate a voltage and/or current and, therefore, an electric field and/or electrolysis products in the tissue **30**. In some examples, the power supply **12** may be implemented using a signal generator, such as an exponential decay wave generator.

[0040] The controller **14** may control the timing, strength, and duration of electric fields and/or electrolysis products provided via the catheter **40**. The controller **14** may, for example, be programmed to provide an electronic signal to the catheter **40**, via power supply **12**, where the electronic signal may be indicative of a dose of treatment, for example, a dose of electrolysis products and/or permeability level of cell. The electronic signal may control the timing and magnitude of the generated electric field, which may allow a user to customize treatment of the tissue **30** as desired. In some embodiments, the controller **14** may include such a program, or include one or more processing devices (e.g., processors), coupled to the computer readable media **18** encoded with executable instructions for electrolysis and permeabilization **20**. Although shown as a separate component coupled to the catheter **40** in FIG. **1**, in some embodiments, the controller **14** may be integrated as part of the catheter **40**. In other embodiments, the controller **14** may include programmable circuitry coupled to the catheter **40** via a wired or wireless connection.

[0041] As noted previously, the system **10** may include any suitable parameters **22** for controlling various aspects of the electroporation and electrolysis processes, such as electric field strengths, voltage levels, current levels, waveform shapes, exposure duration parameters, and any other suitable parameters. The parameters **22** may be stored in computer readable media **18** or in other suitable databases in communication with the controller **14**. In some embodiments, the controller **14** may be used to calculate the parameters **22**, or the controller **14** may be in communication with another system operable to calculate the parameters **22**.

[0042] In some example embodiments, the parameters **22** for a specific treatment protocol may be determined based on measurements taken in the tissue of interest or from a different sample of similar tissue. For example, measurements may be taken at various voltage levels with particular electrode configurations, and a target voltage level, current, pulse pattern, time constant, and other factors may be identified which cause reversible electroporation and the delivery of electrolysis products to result in cell death of the permeabilized cells as desired.

[0043] In some embodiments, examples of parameters **22** which may be used include a delivery of between 1 and 10 voltage pulses between 100 V and 1000 V. Those pulses may be delivered in a system having a capacitance between 50 μF and 100 μF, and a resistance of between 15-20 ohms. A quantity of electrolysis products generated may be related to the delivered charge in Coulombs. There are several ways to calculate the delivered charge. For example, the stored electric charge in a capacitor Q (in coulombs) is equal to the product of the capacitance C (in farads) of the capacitor and

the voltage V (in volts) across its terminals. That is, Q=C·V. Also, charge is the product of current I (in amps) and time t (in seconds). That is, I·t=Q. By defining the capacitance and the voltage across the capacitance, the charge may be defined, and accordingly the electrolysis performance determined. When a capacitor is discharged, it generates current and the current multiplied by time must be equal to the charge in the capacitor. When a capacitor is being discharged the current is not constant—it decays exponentially. Therefore, the time measure is given as the exponential decay time constant. The capacitance which controls the time constant is generally obtained from capacitors incorporated in the power supply, such as power supply **12** of FIG. **1**.

[0044] In some embodiments, the time constant (e.g., exponential decay time constant of the capacitive discharge) may be between 1.7 milliseconds (ms) and 1.8 ms. In other embodiments, the time constant may range from 50 microseconds (μs) to 3 ms. Generally, the lower limit of the time constant is related to a time sufficient to ensure electrolytic species (e.g., products of electrolysis) permeate the targeted area of permeabilized cells. The upper limit of the time constant is generally related to the production of electrolytic species (e.g., products of electrolysis) that can cause ablation on their own. Accordingly, electrolysis is generally targeted for an amount of time sufficient to allow diffusion of electrolysis products through a region of permeabilized cells. However, the amount of time electrolysis is provided should be limited to ensure the process does not result in ablation of non-permeabilized cells or otherwise damages the extracellular matrix in the region of the ablated cells.

[0045] In some embodiments, the generated electric field ranges between 100 V/cm and 3500 V/cm. In other embodiments, the electric field may be between 100 V/cm and 1500 V/m or between 200 V/cm and 850 V/cm. In still other embodiments, the electric field may be less than 1400 V/cm in some examples, less than 1300 V/cm in some examples, less than 1000 V/cm in some examples, less than 800 V/cm in some examples, or less than 600 V/cm in some examples.

[0046] The system **10** may further include one or more sensors (not shown) for measurement of pH, temperature, electric field strength, tissue electrical resistivity or impedance, and/or other suitable properties of the tissue **30** for optimizing treatment. For example, in one embodiment, a pH sensor may be incorporated with the system **10**. The pH sensor may be arranged in any one of several configurations, such as coupled to the catheter **40** adjacent the electrodes **50** to detect a pH value near the electrodes **50**. In another embodiment, a pH sensor may be provided at an outer edge of a targeted region of tissue. In either configuration, the pH sensor may be in communication with the controller **14**, where the controller **14** may utilize one or more received pH values as an indication of tissue ablation and/or to monitor the occurrence of tissue damage based on detected pH levels at the treatment site and surrounding regions of tissue. In some embodiments, the controller **14** may adjust the voltage, current, and/or electric field applied to the tissue responsive to the detected pH levels. For example, if pH values for tissue located outside the treatment site are at or exceed a threshold for tissue damage, the controller **14** may reduce a magnitude of electric field, a duration between pulses, or cease application of the electric field. Similarly, if pH values for tissue within a targeted region are at or exceed a threshold for tissue ablation, the controller **14** may cease application of current through electrodes immediately and/or after a desired elapsed electrolysis time to cease the electrolysis process.

[0047] In some embodiments, a resistivity meter may be used to determine a resistance of the target tissue. For example, the controller **14** and/or power supply **12** of FIG. **1** may provide an impedance measurement. The impedance measurement may determine a resistivity of the tissue **30** contacted by electrodes **50** of the system **10**. For example, the controller **14** and/or power supply **12** may provide a nominal amount of current, such as DC current, through the tissue **30** and receive a resistivity measurement and/or calculate resistivity of the tissue **30**. In some examples, an applied voltage, current, and/or electric field may be selected, determined, and/or allowed based on a measured resistance of the tissue **30**. In some examples, a number of pulses of applied voltage may be selected, determined, and/or otherwise used based on a measured resistance of the tissue.

[0048] In some embodiments, a sensor, such as a Gauss meter and/or Tesla meter, for detecting and/or determining electric field strength may also be used. In such embodiments, the sensor may be in operable communication with the controller **14** for ensuring that the electric field strength remains at a target level for a desired treatment protocol.

[0049] In some embodiments, the ablation instrument for delivering electrolytic electroporation (e.g., catheter **40** of FIG. **1**) may be delivered via a computer-assisted, teleoperational manipulator system, sometimes referred to as a robotically assisted system or a robotic system. The manipulator system comprises one or more manipulators that can be operated with the assistance of an electronic controller (e.g., computer) to move and control functions of one or more instruments when coupled to the manipulators. FIG. **2** illustrates one example embodiment of a robotically-assisted manipulator system **100** for use with the systems and methods described herein. The manipulator system can be used, for example, in surgical, diagnostic, therapeutic, biopsy, or non-medical procedures.

[0050] With reference to FIG. **2**, a robotically-assisted manipulator system **100** may include one or more manipulator assemblies **102** for operating one or more medical instrument systems **104** in performing various procedures on a patient P positioned on a table T in a medical environment **101**. For example, the manipulator assembly **102** may drive catheter or end effector motion, may apply treatment to target tissue, and/or may manipulate control members. The manipulator assembly **102** may be teleoperated, non-teleoperated, or a hybrid teleoperated and non-teleoperated assembly with select degrees of freedom of motion that can be motorized and/or teleoperated and select degrees of freedom of motion that may be non-motorized and/or non-teleoperated. An operator input system **106**, which may be inside or outside of the medical environment **101**, generally includes one or more control devices for controlling manipulator assembly **102**. The manipulator assembly **102** supports a medical instrument system **104** and may optionally include a plurality of actuators or motors that drive inputs on the medical instrument system **104** in response to commands from a control system **112**. The actuators may optionally include drive systems that when coupled to the medical instrument system **104** advance the medical instrument system **104** into a naturally or surgically created anatomic orifice. Other drive systems can move the distal end of the

medical instrument system **104** in multiple degrees of freedom, which may include three degrees of linear motion (e.g., linear motion along the X, Y, Z Cartesian axes) and in three degrees of rotational motion (e.g., rotation about the X, Y, Z Cartesian axes). The manipulator assembly **102** may support various other systems for irrigation, treatment, or other purposes. Such systems may include fluid systems (including, for example, reservoirs, heating/cooling elements, pumps, and valves), generators, lasers, interrogators, and ablation components.

[0051] The robotically-assisted manipulator system **100** also includes a display system **110** for displaying an image or representation of the surgical site and the medical instrument system **104** generated by an imaging system **109** which may include an imaging system, such as an endoscopic imaging system. The display system **110** and the operator input system **106** may be oriented so an operator O can control the medical instrument system **104** and the operator input system **106** with the perception of telepresence. A graphical user interface may be displayable on the display system **110** and/or a display system of an independent planning workstation.

[0052] In some examples, the endoscopic imaging system components of the imaging system **109** may be integrally or removably coupled to the medical instrument system **104**. However, in some examples, a separate imaging device, such as an endoscope, attached to a separate manipulator assembly may be used with the medical instrument system **104** to image the surgical site. The endoscopic imaging system **109** may be implemented as hardware, firmware, software, or a combination thereof which interact with or are otherwise executed by one or more computer processors, which may include the processors of the control system **112**.

[0053] The robotically-assisted manipulator system **100** may also include a sensor system **108**. The sensor system **108** may include a position/location sensor system (e.g., an actuator encoder or an electromagnetic (EM) sensor system) and/or a shape sensor system (e.g., an optical fiber shape sensor) for determining the position, orientation, speed, velocity, pose, and/or shape of the medical instrument system **104**. The sensor system **108** may also include temperature, pressure, force, or contact sensors or the like.

[0054] The robotically-assisted manipulator system **100** may also include a control system **112**. The control system **112** includes at least one memory **116** and at least one computer processor **114** for effecting control between the medical instrument system **104**, the operator input system **106**, the sensor system **108**, and the display system **110**. The control system **112** also includes programmed instructions (e.g., a non-transitory machine-readable medium storing the instructions) to implement a procedure using the robotically-assisted manipulator system including for navigation, steering, imaging, engagement feature deployment or retraction, applying treatment to target tissue (e.g., via the application of energy), or the like.

[0055] The control system **112** may optionally further include a virtual visualization system to provide navigation assistance to operator O when controlling the medical instrument system **104** during an image-guided surgical procedure. Virtual navigation using the virtual visualization system may be based upon reference to an acquired pre-operative or intra-operative dataset of anatomic passageways. The virtual visualization system processes images of the surgical site imaged using imaging technology such as computerized tomography (CT), magnetic resonance imaging (MRI), fluoroscopy, thermography, ultrasound, optical coherence tomography (OCT), thermal imaging, impedance imaging, laser imaging, nanotube X-ray imaging, and/or the like. The control system **112** may use a pre-operative image to locate the target tissue (using vision imaging techniques and/or by receiving user input) and create a pre-operative plan, including an optimal first location for performing treatment. The pre-operative plan can include, for example, a planned size to expand an expandable device, a treatment duration, a treatment temperature, and/or multiple deployment locations.

[0056] FIG. **3**A illustrates a medical instrument system **200** according to some example embodiments. The medical instrument system **200** may be used in an image-guided medical procedure. In some embodiments, the medical instrument system **200** may be used for non-teleoperational exploratory procedures or in procedures involving traditional manually operated medical instruments, such as endoscopy. In other embodiments, the medical instrument system **200** is interchangeable with, or a variation of, the medical instrument system **104** of FIG. **2**.

[0057] The medical instrument system **200** includes an elongate flexible device **202**, such as a flexible catheter, endoscope (e.g., gastroscope, bronchoscope, duodenoscope), or other suitable device coupled to a drive unit **204**. The elongate flexible device **202** includes a flexible body **216** having a proximal end portion **217** and a distal end portion **218**, including a tip portion. In some embodiments, the flexible body **216** has an outer diameter of approximately 14-20 mm. Other embodiments of the flexible body **216** may have larger or smaller outer diameters. The flexible body **216** may have an appropriate length to reach certain portions of the anatomy, such as the lungs, sinuses, throat, or the upper or lower gastrointestinal region, when the flexible body **216** is inserted into a patient's oral or nasal cavity.

[0058] The medical instrument system **200** optionally includes a tracking system **230** for determining the position, orientation, speed, velocity, pose, and/or shape of the distal end portion **218** and/or of one or more segments **224** along the flexible body **216** using one or more sensors and/or imaging devices. The entire length of the flexible body **216**, between the distal end portion **218** and the proximal end portion **217**, can be effectively divided into segments **224**. The tracking system **230** may optionally be implemented as hardware, firmware, software or a combination thereof which interact with or are otherwise executed by one or more computer processors, which may include the processors of the control system **112** in FIG. **2**.

[0059] The tracking system **230** may optionally track the distal end portion **218** and/or one or more of the segments **224** using a shape sensor **222**. In some embodiments, the tracking system **230** may optionally and/or additionally track the distal end portion **218** using a position sensor system **220**, such as an electromagnetic (EM) sensor system. In some examples, the position sensor system **220** may be configured and positioned to measure six degrees of freedom, e.g., three position coordinates X, Y, Z and three orientation angles indicating pitch, yaw, and roll of a base point or five degrees of freedom, e.g., three position coordinates X, Y, Z and two orientation angles indicating pitch and yaw of a base point.

[0060] The flexible body **216** includes one or more channels (e.g., passageways) sized and shaped to receive one or

more medical instruments **226**. In some embodiments, the flexible body **216** includes two channels **221** for separate instruments **226**, however, a different number of channels **221** may be provided. FIG. **3**B is a simplified diagram of an end portion of the flexible body **216** with the medical instrument **226** extended outwardly therefrom according to some embodiments. In some embodiments, the medical instrument **226** may be used for procedures and aspects of procedures, such as surgery, biopsy, ablation, mapping, imaging, illumination, irrigation, or suction. The medical instrument **226** may be deployed through the channel **221** of the flexible body **216** and used at a target location within the anatomy. In other embodiments, the medical instrument may be integrated with flexible body **216**, rather than being received in or deployed through a channel of the flexible body **216**. The medical instrument **226** can include, for example, image capture devices, biopsy instruments, ablation instruments, catheters, laser ablation fibers, and/or other surgical, diagnostic, or therapeutic tools. Medical tools can include end effectors having a single working member such as a scalpel, a blunt blade, a lens, an optical fiber, an electrode, and/or the like. Other end effectors can include, for example, forceps, graspers, balloons, needles, scissors, clip appliers, and/or the like. Other end effectors can further include electrically activated end effectors such as electrosurgical electrodes, expandable ablation members, transducers, sensors, imaging devices and/or the like. The medical instrument **226** may be advanced from the opening of channel **221** to perform the procedure (e.g., electroporation and/or electrolysis in the present disclosure) and then retracted back into the channel **221** when the procedure is complete. The medical instrument **226** may be removed from the proximal end **217** of the flexible body **216** or from another optional instrument port (not shown) along the flexible body **216**. The medical instrument **226** may be used with an image capture device (e.g., an endoscopic camera) also within the elongate flexible device **202**. Alternatively, the medical instrument **226** can itself be the image capture device.

[0061] The medical instrument **226** may additionally house cables, linkages, or other actuation controls (not shown) that extend between its proximal and distal end portions **217**, **218** to controllably bend the distal end portion **218** of the medical instrument **226**. The flexible body **216** may also house cables, linkages, or other steering controls (not shown) that extend between the drive unit **204** and the distal end portion **218** to controllably bend the distal end portion **218** as shown, for example, by the broken dashed line depictions **219** of the distal end portion **218**. In some examples, at least four cables are used to provide independent "up-down" steering to control a pitch motion of the distal end portion **218** and "left-right" steering to control a yaw motion of the distal end portion **218**. In embodiments in which the medical instrument system **200** is actuated by a robotically-assisted assembly, the drive unit **204** can include drive inputs that removably couple to and receive power from drive elements, such as actuators, of the teleoperational assembly. In some embodiments, the medical instrument system **200** can include gripping features, manual actuators, or other components for manually controlling the motion of the medical instrument system **200**. The information from the tracking system **230** can be sent to a navigation system **232** where it is combined with information from the visualization system **231** and/or the preoperatively obtained models to provide the physician or other operator with real-time position information.

[0062] In some embodiments, the medical instrument system **200** may be guided manually or via the robotically-assisted manipulator system **100** to deliver the medical instrument **226** to a target tissue site for treatment. In some procedures, the selection between a manual or robotic delivery and the approach may be determined based on the medical application. For example, in some gastrointestinal applications, the medical instrument system **200** (or standalone medical instrument **226**) may be delivered via a manual or robotic delivery device endoluminally through a trans-oral or trans-anal approach. A trans-abdominal approach with integrated monopolar or bipolar instrumentation, drop in probes or via catheters may also be used. For urological applications, the medical instrument system **200** (or standalone medical instrument **226**) may be delivered via a manual or robotic delivery device endoluminally through a trans-urethral approach, trans-perineal, pre-peritoneal or trans-abdominally with integrated bipolar instrumentation, drop in probes or via catheters. Similarly, for gynecological applications, the medical instrument system **200** (or standalone medical instrument **226**) may be delivered via a manual or robotic delivery device endoluminally through a trans-vaginal approach, trans-perineal, or trans-abdominally with integrated bipolar instrumentation, drop in probes or via catheters. For hepatobiliary applications, the medical instrument system **200** (or standalone medical instrument **226**) may be delivered via a manual or robotic delivery device endoluminally through a trans-oral approach to reach the ampulla or to go externally into the liver via a trans-gastrointestinal wall route or trans-abdominally with integrated bipolar instrumentation, drop in probes or via catheters. For neurovascular applications, the medical instrument system **200** (or standalone medical instrument **226**) may be delivered via a manual or robotic delivery device through an endovascular approach or through a keyhole craniotomy with integrated bipolar instrumentation, drop in probes or via catheters. For cardiac applications, the medical instrument system **200** (or standalone medical instrument **226**) may be delivered via a manual or robotic delivery device through an endovascular approach or trans-thoracic with integrated bipolar instrumentation, drop in probes or via catheters.

[0063] Embodiments of an electrode deployment system and electrode treatment device, illustrated in the context of an electrode instrument **300** for electrosurgery such as electrolysis and/or electroporation, will now be described with reference to FIGS. **4**, **5**, **6**A, **6**B, **6**C, **7**A, **7**B and **7**C. In some embodiments, electrode treatment devices and electrode deployment systems according to the present disclosure, such as electrode instruments **300**, may be received in and/or deployed from a channel of an endoscope, catheter, or any of the other elongate flexible devices **202** described above in reference to FIGS. **3**A and **3**B. In other embodiments, electrode instruments **300** according to the present disclosure can be integrated with the body of an endoscope, catheter, or other elongate flexible device.

[0064] With reference to FIG. **4**, electrode instrument **300** includes an elongate body **310** illustrated as a flexible catheter tube, but which may comprise other types of tubular or hollow structures adapted for insertion into a patient, such as a torque tube or an endoscope with a channel or passageway therethrough. A flexible shaft **320**, such as a wire, cable,

small torque tube, or other drive element, extends through a lumen **324** of body **310** and is movable relative to body **310** rotationally about a longitudinal axis of shaft **320**. In some embodiments, shaft **320** is also slidable longitudinally relative to body **310**, as described below in reference to FIGS. **6**A, **6**B, and **6**C. A handle **330** is attached to a proximal end portion **332** of shaft **320** to facilitate manipulation of shaft **320**. In some embodiments, the handle **330** may be actuated manually by a user. In other embodiments, the handle **330** may be coupled to an external device for actuation such as a robotically-assisted manipulator system. In yet other embodiments, a combination of manual and robotically-assisted actuation may be provided.

[0065] The electrode instruments described herein may be coupled to an external device to provide actuation, control, and/or electrical power to the electrode instrument. For example, the electrode instrument **300** and the other electrode instruments described herein may be actuated by a robotically-assisted manipulator system (e.g., manipulator assembly **102**). The electrode instrument **300** (e.g., the handle **330**, the body **310**, and/or the shaft **320**) may include or be coupled to a drive unit (e.g., drive unit **204**) having one or more drive inputs that removably couple to and receive power from drive elements, such as actuators, of the manipulator assembly. When the electrode instrument **300** is coupled to the manipulator assembly, the drive inputs of the electrode instrument **300** may be coupled to drive outputs of the manipulator assembly that are driven by the drive elements of the manipulator assembly. In addition, the drive inputs of the electrode instrument **300** may be coupled to the distal end portion of the electrode instrument **300** via one or more actuation drive members (e.g., actuation cables, actuation rods, tension members, and the like) to perform actions such as advancing, retracting, or articulating the distal end of the electrode instrument **300** as well as expansion and/or retraction of the electrode strips described herein (e.g. electrode strip **340**) to adjust the electrode strip between a deployed position and a contracted position. In some embodiments, the body **310** and/or shaft **320** of the electrode instrument **300** may be coupled to the drive unit **204** for adjusting the electrode strip between the deployed and contracted positions. In addition, the drive unit **204** may be coupled to a controller (e.g., controller **14**) and/or power supply (e.g., power supply **12**) to provide electrical power to electrodes of electrode instrument **300**. The drive unit **204** may be electrically coupled to the electrodes via one or more electrical cables running along or through the electrode instrument **300**. In alternative embodiments, the controller and power supply may provide power to the electrical cables without coupling to the drive unit (e.g., the controller and power supply may be independent of the drive unit).

[0066] An electrode strip **340** is coiled around a distal end portion **342** of body **310**, with a first end portion **346** of electrode strip **340** attached to distal end portion **342** of body **310** and a second end portion **348** of electrode strip **340** attached to a distal end portion **352** of shaft **320** located distal to a tip **354** (FIG. **5**) of distal end portion **342** of body **310**. The first end portion **346** is a proximal end portion of the electrode strip **340** and the second end portion **348** is a distal end portion of the electrode strip **340**. The connection locations of the first and second end portions **346** and **348** of electrode strip **340** are spaced apart longitudinally from each other such that the electrode strip **340** is coiled in the configuration of a helix **360**. Helix **360** is formed in a middle portion **376** of electrode strip **340** between first and second end portions **346**, **348** which curve away from the middle portion **376** toward their connections to body **310** and shaft **320**.

[0067] FIG. **4** illustrates the helically-arranged electrode strip **340** in a contracted position or configuration, with electrode strip **340** wrapped closely around body **310** and shaft **320**. For clarity of illustration, FIG. **4** shows electrode strip **340** expanded slightly from a fully contracted position wherein the electrode strip **340** is wound tightly around body **310**. In the contracted position, electrode instrument **300** is insertable endoluminally into a patient's body for treating tissue. The contracted position also facilitates movement of electrode instrument **300** within the patient's body and removal of electrode instrument **300** from the patient's body. In some embodiments, the entire distal portion **350** of electrode instrument **300**, including electrode strip **340**, may be retractable into a sheath or shield, for example into a channel **221** of an endoscope **202** (FIGS. **3**A and **3**B). Retraction of the distal portion **350** of electrode instrument **300** into a sheath may facilitate insertion and navigation of the electrode instrument **300** in a patient by covering the edges of the electrode strip **340** which may otherwise increase friction or catch on surrounding tissue during insertion or navigation. When electrode instrument **300** is carried in working channel **221** of an endoscope and distal portion **350** of electrode instrument **300** is retracted into the endoscope's working channel **221**, the endoscope provides a robust vehicle for delivering electrode instrument **300** to the target tissue and for removing electrode instrument **300** from the patient's body.

[0068] Shaft **320** is capable of transmitting torque to move second end portion **348** of electrode strip **340** relative to body **310** for deploying electrode strip **340**. With reference to FIG. **5**, after electrode instrument **300** is positioned in the patient with electrode strip **340** at a treatment site **362** adjacent targeted tissue **364**, and with the electrode strip moved outwardly from its sheath, if any, the shaft **320** is then rotated via handle **330** or via a robotic manipulator in a first direction indicated by arrow **366** relative to body **310** for radially expanding the helix **360**, to thereby deploy the electrode strip **340** into apposition with targeted tissue **364** at the treatment site. Conversely, the rotation of shaft **320** in the first direction relative to body **310** may be accomplished by rotating body **310** in an opposite direction indicated by arrow **370**, relative to shaft **320**. In some embodiments (not illustrated), shaft **320** is driven by a motor or other mechanism. In some embodiments, shaft **320** does not extend entirely through body **310** but projects from tip **354** of body **310** and is rotationally driven from within body **310** or by other means. In the embodiment illustrated in FIG. **5**, the first direction **366** of rotation of handle **330** is counterclockwise and the relative direction of rotation **370** of body **310** is clockwise for expanding the helix **360**. In another embodiment (not illustrated), the direction (i.e., handedness) of the helix may be reversed so that the first direction of rotation of handle **330** is clockwise and the relative direction of rotation of body **310** is counterclockwise.

[0069] When in the expanded position or configuration illustrated in FIG. **5**, a middle portion **376** of electrode strip **340** between the first and second end portions **346**, **348** is spaced apart from shaft **320** and body **310** and into apposition with targeted tissue **364**. Once the electrode strip **340** is in contact with targeted tissue **364**, electrical potential and/or

current may be applied to electrode strip **340** to complete an electrosurgical procedure, as further described below. After completion of the electrosurgical procedure, the electrode strip **340** can be returned to the contracted position (FIG. **4**) by rotating shaft **320** relative to body **310** in a second direction opposite first direction **366**. Conversely, rotation of shaft **320** in the second direction may be accomplished by rotating body **310** relative to shaft **320** in an opposing second direction opposite from arrow **370**. After returning electrode strip **340** to the contracted position, electrode instrument **300** can be moved longitudinally forward or rearward along the treatment site **362** or to a different treatment site, or removed from the patient. In some cases, the electrode strip **340** may be retracted into a sheath, such as into the working channel **221** of an endoscope, before electrode instrument **300** is moved within or removed from the patient.

[0070] An expansion ratio of electrode instrument **300** is defined as the diameter of helix **360** when in the expanded position divided by the diameter of helix **360** when in its contracted position. To account for distortions at the first and second end portions **346**, **348** of electrode strip **340**, the diameter of helix **360** is measured as the diameter of a circle circumscribing an axial projection of the helix **360**. Thus, a "maximum expansion ratio" of electrode instrument **300** is defined as the maximum diameter of electrode strip **340** in its maximally expanded position divided by the minimum diameter of electrode strip **340** in its fully contracted position. For clarity, in the maximally expanded position the electrode strip **340** must still extend at least one full rotation or turn (at least 360 degrees), it being understood that less than one full turn or rotation of helix **360** may cause electrode strip **340** to extend radially a greater distance, but primarily or solely from one side of body **310**. In some embodiments, the maximum expansion ratio of electrode instrument **300** may exceed 5:1 or may exceed 10:1 or 20:1. In some embodiments, the maximum expansion ratio may be in the range of 5:1 to 30:1. Notably, a usable expansion ratio or "maximum usable expansion ratio" may be somewhat less than the maximum expansion ratio and may depend on mechanical properties of electrode strip **340**. For example, a very flexible electrode strip **340** may be tightly wound around body **310** to a very small minimum diameter and when expanded may desirably conform to tissues **362** lining irregular luminal shapes, but when expanded to its maximum diameter the electrode strip **340** may not be able to generate sufficient force in apposition to tissue **362** so as to effect sufficient electrical contact needed to perform a particular electrosurgical function, such as electrolysis and/or electroporation. Conversely, a stiffer electrode strip **340** may be expanded to a greater overall diameter while still providing sufficient apposition force and sufficient electrical contact with tissue for electrosurgical functionality but may be less able to conform to irregular luminal shapes and may be more difficult or impossible to coil tightly around body **310**, resulting in a larger minimum diameter in its contracted position. Thus, the term "maximum expansion ratio" should be understood as potentially different from the maximum usable expansion ratio.

[0071] In some embodiments, electrode strip **340** comprises a foil strip forming a single electrode of the electrode instrument for monopolar operation. In some embodiments, electrode strip **340** may comprise a flexible printed circuit (FPS) with one or more conductive lines or patterns (e.g., metal layers) exposed on the outer surface of FPS, forming one or more electrodes of the electrode instrument **300**. When multiple electrodes are utilized, electrode instrument **300** may be capable of bipolar operation, such as for electrolysis and/or electroporation. In the embodiment illustrated in FIGS. **4** and **5**, electrode strip **340** comprises an FPS with two conductors forming two electrodes **380** running the entire length of electrode strip **340**. Various conductor shapes and electrode configurations are possible on the surface of FPS. In some embodiments, each electrode **380** is connected to a power source (e.g., power source **12** of FIG. **1**) by a wire **388** (FIG. **4**) which may extend within shaft and/or body, or along the outside of body **310**, for example. When electrodes are implemented in an FPS, the FPS may include a narrow elongate tab or extension having conductive lines extending along the length of body **310** in place of wires, either inside of shaft **320** and/or body **310** or along the outside of body **310**. In other embodiments, each electrode **380** is connected to power source **12** via a different conductive pathway, such as via shaft **320** or body **310** (e.g., if made of or including a conductive material). When shaft **320** and/or body **310** forms the conductive pathway for one or more electrodes **380**, the shaft **320** and/or body **310** may have an electrically insulated surface to prevent electrical short circuits as between the shaft **320** and body **310**, to prevent electrical contact between the body **310** and tissues, and/or to prevent electrical contact or short circuits with electrode strip (e.g., when a foil strip) at unwanted locations beneath helix **360**. When shaft **320** and/or body **310** forms the conductive pathway for one or more electrodes **380**, in some embodiments the electrical connections to power supply **12** may be achieved through contact pads (not illustrated) formed on proximal end portion **336** of body **310** and/or proximal end portion **332** of shaft **320**, and/or in handle **330**, which may be electrically coupled to power supply **12** by corresponding contacts, wipers, or other means, such as inductive coupling (not illustrated). In other embodiments, wires **388** may be connected to handle **330** and/or one or both proximal end portions **336** and/or **332** of the respective body **310** and/or shaft **320**.

[0072] FIG. **4** illustrates electrode strip **340** in the contracted position with at least part of its first end portion **346** closely wrapped around of the distal end portion **342** of body **310** and at least part of its second end portion closely wrapped around the distal end portion **352** of shaft **320** that extends from tip **354** (FIG. **5**) of body **310**. In some embodiments, all or nearly all of the electrode strip **340** may be helically wrapped around body **310**, and in most embodiments at least a small portion of the second end portion **348** of electrode strip **340** is wrapped around the distal end portion **352** of shaft **320** that extends from tip **354** (FIG. **5**) of body **310**. In most embodiments, the entirety of electrode strip **340** is wrapped around shaft **320**, with the distal end portion **342** of body **310** being interposed between the electrode strip **340** and the shaft **320** along at least some of the length of the helix **360** of electrode strip **340**. In some embodiments, such as illustrated schematically in FIGS. **6**A, **6**B and **6**C described below, the shaft **320** extends a substantial distance from tip **354** of body **310** and the first end **346** of electrode strip **340** is attached to distal end portion **342** of body at or near tip **354** such that most or all of the electrode strip **340** is wrapped directly around shaft **320**. In some embodiments, distal portion **350** of electrode instrument **300** may be smaller than 2 mm in diameter, or smaller than 1.2 mm in diameter, or between 0.8 and 3 mm in

diameter, or between 1.2 and 2 mm in diameter. Such a small profile of electrode instrument **300** may facilitate its use for treatment of the duodenum, small intestines, nasal passageways, lung tissue in primary, secondary, or tertiary bronchi or bronchioles, or other narrow luminal regions of a patient's body.

[0073] First and second end portions **346**, **348** of electrode strip **340** may be attached to the respective body **310** and shaft **320** by various means. In some embodiments, at least one end of electrode strip **340** is attached to body **310** or shaft **320** via an adhesive. In some embodiments, at least one end of electrode strip **340** is welded to body **310** or shaft **320**. In some embodiments, at least one end of electrode strip **340** is tacked or pinned to body **310** or shaft **320**. In some cases, the attachment means are different for first and second end portions **346**, **348**, and in some cases the attachment means are the same.

[0074] In some embodiments, electrode strip **340** may be heat treated or thermoformed to provide shape memory, preferably in the contracted position. By heat treating or thermoforming electrode strip **340** in the contracted position, electrode strip **340** will tend to return to the contracted position when rotational force is removed from body **310** and/or shaft **320**, or in the event that either of the first or second end portions **346**, **348** of electrode strip **340** should become detached from body **310** or shaft **320**, which may facilitate removal of the instrument from the patient's body.

[0075] With reference to FIGS. **4** and **5**, electrode strip **340** may be arranged to leave a small gap **394** between adjacent turns of helix **360** when electrode strip **340** is in the contracted position, as illustrated in FIG. **4**, but when electrode strip **340** is rotationally deployed the gap increases, as illustrated by the enlarged gaps **396** in FIG. **5**. In some embodiments, electrode strip **340** may be arranged to leave no gaps or no substantial gaps between turns of the helix **360** when in in the contracted position. In some embodiments electrode strip **340** is arranged to leave no or little gap between adjacent turns of helix **360** when deployed at the treatment site **362** in the expanded position. When arranged to leave little or no gap between turns of the helix **360** in the expanded position, electrode strip **340** may overlap in the contracted position.

[0076] In some embodiments, shaft **320** is slidably movable proximally or inwardly (e.g., retractable) and distally outwardly (e.g., extendable) relative to body **310**, and/or body **310** is slidable longitudinally along shaft **320**, to adjust a pitch of helix **360** during deployment and/or retraction, as illustrated schematically in FIGS. **6**A, **6**B, **6**C. Such longitudinal sliding movement of shaft **320** may be performed independently of or simultaneously with rotation of shaft **320**. FIG. **6**A illustrates electrode instrument **400** with a first end of an electrode strip **440** connected to a body **410** and a second end of the electrode strip attached to a shaft **420**, and wherein electrode strip **440** is arranged to form a helix **460** and illustrated in FIG. **6**A in a contracted position. FIG. **6**B illustrates a partially deployed electrode strip **440**, wherein the body **410** is rotated relative to shaft **420** and slidably advanced, as indicated by arrows, so shaft **420** is retracted somewhat relative to body **410** as compared to FIG. **6**A. And FIG. **6**C illustrates electrode strip **440** in an expanded position with body **410** further rotated relative to shaft **420** and slidably advanced along shaft **420**. In each case of FIGS. **6**A, **6**B, and **6**C, the pitch of helix **460** may be kept constant by moving body **410** in a distally outward direction relative to shaft **420** (moving shaft **420** inwardly in retraction relative to body **410**) as the body **410** and shaft **420** are relatively rotated to expand helix **460**. By controlling the pitch of helix **360**, **460** by the combination of rotation and sliding inward/outward movement of shaft **320**, **420**, smaller gaps or no gaps between turns and improved electrical contact with targeted tissue **364** may be achieved in the deployed position, while allowing the electrode to be contracted to a small diameter in the contracted position.

[0077] In some cases, the angle of the connection between first and second end portions of electrode strip **340**, **440** may be variable by virtue of pivoting connections between the ends of electrode strip **340**, **440** and the respective body **310**, **410** and shaft **320**, **420**, so that electrode strip **340**, **440** does not buckle when expanded and/or contracted. Such a variable connection angle may instead allow helix **360**, **460** to maintain an approximately cylindrical outer profile when shaft **320**, **420** is moved distally outwardly or moved inwardly relative to body **310**, **410** during respective deployment and retraction.

[0078] In various embodiments, deployment and contraction of the electrode strip **340** may be achieved by any combination of sliding (e.g., axial) movement of the shaft **320** and/or body **310** relative to each other and/or rotation relative to each other.

[0079] In some embodiments, the shaft **320** and/or body **310** may be slidable (e.g., axially movable) relative to each other for electrode strip **340** deployment/contraction without relative rotation between the shaft **320** and the body **310** (e.g., relative rotation is fixed or prevented). For example, the shaft **320** and/or the body **310** may have a keyed or interlocking relationship that prevents relative rotation between the two, such as one of the shaft **320** and/or the body **310** having a slot and the other having a protrusion or key that slides within the slot but prevents or hinders rotation. As another example, the shaft **320** and/or the body **310** may have corresponding non-circular cross sections (such as multisided shape, such as a triangle, square, rectangle, parallelogram, pentagon, hexagon, etc.) that prevent or hinders relative rotation. In another example, the shaft **320** and/or body **310** may be in the form of a spline shaft (e.g., with ridges or teeth) that allows for relative translation but prevents rotation. As another example, the shaft **320** and/or the body **310** may each have a separately actuatable proximal portions (e.g., handles or the like) that are actuatable by a user and/or by a robotic manipulator when operative coupled to the manipulator. The proximal portions may have interlocking features described above to prevent relative rotation, which may be selectively activated.

[0080] In some embodiments, the shaft **320** and/or the body **310** may be rotatable relative to each other for electrode strip **340** deployment/contraction without relative translation between the shaft **320** and the body **310** (e.g., relative axial movement is fixed or prevented). For example, the shaft **320** and/or the body **310** may have mechanical constraints that permit rotation but prevent relative axial movement. As another example, the shaft **320** and/or the body **310** may each have a separately actuatable proximal portions (e.g., handles or the like) that are actuatable by a user and/or by a robotic manipulator when operative coupled to the manipulator. The proximal portions may have interlocking features to prevent relative axial motion, which may be selectively activated.

[0081] In some embodiments, the shaft **320** and/or the body **310** may be movable in both relative translation and relative rotation for electrode strip **340** deployment/contraction. For example, the shaft **320** and/or the body **310** may move for relative rotation during a portion of the deployment/contraction and may move in relative translation during another portion of the deployment/contraction. In such embodiments, the shaft **320** and body **310** may be joined by a helical cam slot arrangement or threaded engagement to coordinate the rotational and longitudinal movement. For example, body **310** may include a cam slot and shaft **320** may include a follower that rides in the cam slot.

[0082] In embodiments where the electrode instrument **300** is coupled to a robotic manipulator (such as manipulator assembly **102** of FIG. **2**) and receives actuation forces from the manipulator, in some embodiments, translation and rotation may be independently driven by separate actuators. That is, the system may include a first actuator to drive rotation and a second actuator to drive translation. A control system may send signals to the respective actuators to drive relative axial motion and/or relative rotation for deployment/contraction of the electrode strip **340**. In some examples, the translation and rotation degrees of freedom are independently actuated. During deployment/contraction, both the translation actuator and the rotation actuator may be simultaneously or sequentially actuated to cause deployment and contraction. As one example for sequential actuation, during contraction, the first rotation actuator may be driven to wind down the electrode strip **340** to a preset amount (e.g., wind down from full deployment to 20% deployment, or to 15% deployment, or 25% deployment, etc.), then the second translation actuator may be driven to stretch the helix **360** axially (i.e., change its pitch), then the first rotation actuator may be driven to wind down the remainder of the electrode strip **340** deployment. In some embodiments, the system may include separate actuators for driving translation and rotation with coupled control between the actuators. That is, control of each degree of freedom is coupled such that actuating the rotation actuator for a specified amount of movement will cause the translation actuator to move with a corresponding length. In some examples, the control system may send signals to drive axial motion via the translation actuator without driving rotation or may send signals to drive rotation via the rotation actuator without driving translation. For example, the control system may send signals to the actuator that drives relative axial movement between the shaft **320** and the body **310**. The control system may optionally send signals to lock, disengage, or otherwise not drive the actuator that drives relative rotation between the shaft **320** and the body **310**. Similarly, the control system may send signals to the actuator that drives relative rotation movement between the shaft **320** and the body **310**. The control system may optionally send signals to lock, disengage, or otherwise not drive the actuator that drives relative axial movement between the shaft **320** and the body **310**.

[0083] In some embodiments where the electrode instrument **300** is coupled to a robotic manipulator and receives actuation forces from the manipulator, one actuator of the manipulator is coupled to drive both translation and rotational movements.

[0084] In some embodiments, the robotic manipulator may infer the diameter of helix **360** based on an algorithmic model of the electrode treatment device and the amount of rotational and/or translational actuation of shaft **320** and/or body **310** relative to the other. The amount of rotational and/or translational movement may be determined by encoders on the actuator(s) or inferred by the time and rate at which the actuator(s) drive the electrode instrument **300**. In some embodiments, electrical contact of electrode strip **340** with tissue may be detected by measuring resistance across the electrodes **380** of the electrode strip **340**. In some embodiments, the electrical inputs to, or electrical characteristics of, the robotic actuators may be monitored to detect a complete deployment of electrode strip **340** into sufficient apposition with tissue. For example, the robotic manipulator may monitor actuator drive torque by measuring the absolute current value(s) and/or the rate of change (slope) of the drive current(s) during rotation and/or translation of the electrode device. In some embodiments, apposition may be detected by sensing that the actuator is drawing current, but not rotating (as may be detected by an encoder on the actuator).

[0085] FIGS. **7**A, **7**B, and **7**C schematically illustrate steps in a treatment technique to address the presence of large gaps **396** between turns of the helix **360** when in the deployed position. FIG. **7**A illustrates a first contact region or treated region **510** of a helical electrode (not illustrated, but in the same shape as contact region), wherein the treated region is effected by application of electrical potential and/or current to electrode to perform an electrosurgical technique such as electrolysis and/or electroporation. FIG. **7**B illustrates a second contact region or treated region **520** that overlaps along its edges with the first contact region or treated region **510**. Similarly, FIG. **7**C illustrates a third contact region or treated region **530** that overlaps along its edges with the second contact region or treated region **520**. Between the treatment steps of FIGS. **7**A and **7**B, and between the treatment steps of FIGS. **7**B and **7**C, the electrode strip is contracted, then advanced along the treatment site incrementally by a distance less than the pitch of the helix, then expanded again into apposition with tissue. In the embodiment illustrated in FIGS. **7**A-**7**B-**7**C, each advancement is approximately ⅓ of the pitch of the deployed helix.

[0086] Embodiments of an electrode deployment system are illustrated herein in the context of an electrode instrument **300** for electrosurgery. However, electrode deployment systems consistent with the disclosed embodiments may be utilized for purposes of electrical stimulation, electrical sensing, or as part of other instruments or mechanisms for medical uses, or as parts of instruments or mechanisms for non-medical uses.

[0087] Thus, it should be understood that the exemplary embodiments described herein of both the design of catheter delivery systems and the potential clinical applications associated therewith are not intended to be limiting. In addition, it is to be appreciated that any one of the above embodiments or processes, or specific features associated therewith, may be combined with one or more other embodiments and/or processes or be separated and/or performed amongst separate devices or device portions in accordance with the present systems, devices, and methods. Finally, the disclosure is intended to be merely illustrative of the present devices, apparatuses, systems, and methods and should not be construed as limiting the appended claims to any particular embodiment or group of embodiments.

[0088] It will be obvious to those having skill in the art that many changes may be made to the details of the above-described embodiments without departing from the underlying principles of the invention. The scope of the present invention should, therefore, be determined only by the following claims.

1-40. (canceled)

41. An electrode treatment device, comprising:

an elongate body having a distal end portion terminating in a tip;

a shaft rotatably supported by the body and extending beyond the tip of the body; and

an electrode strip having a first end portion attached to the body, and a second end portion attached to the shaft at a location distal to the tip of the body, the electrode strip wound around the body and/or the shaft to form a helix, the shaft being rotatable in a first direction relative to the body for radially expanding the helix to thereby deploy the electrode strip at a treatment site, and the shaft being rotatable relative to the body in a second direction opposite the first direction for radially contracting the helix around the body and/or shaft to facilitate extraction of the electrode strip from the treatment site.

42. The electrode treatment device of claim **41**, wherein the shaft is slidably movable inwardly and distally outwardly relative to the body.

43. The electrode treatment device of claim **41**, wherein the electrode strip comprises a flexible printed circuit.

44. The electrode treatment device of claim **41**, wherein the body or the shaft, or both, provide a conductive path to the electrode strip, and wherein the body or the shaft, or both, have an electrically insulated surface.

45. The electrode treatment device of claim **41**, wherein the electrode strip is arranged to leave no gaps between turns of the helix when deployed at the treatment site.

46. The electrode treatment device of claim **41**, wherein the electrode strip is arranged to leave no gaps between turns of the helix when the electrode strip is contracted around the body and/or the shaft.

47. The electrode treatment device of claim **41**, wherein the electrode strip is thermoformed or heat treated to return to the shape of the helix when no force is applied to the electrode strip via the shaft and/or the body.

48. The electrode treatment device of claim **41**, further comprising a robotic manipulator coupled to the shaft and/or the body, and wherein the robotic manipulator includes a rotational actuator that rotates the shaft relative to the body and a translational actuator that moves the shaft axially relative to the body.

49. The electrode treatment device of claim **48**, wherein the rotational actuator and translational actuator are integrated in a single actuator device.

50. The electrode treatment device of claim **48**, further comprising a control device that controls the rotational and translational actuators independently.

51. The electrode treatment device of claim **48**, wherein a deployment control device detects when the electrode strip is deployed into apposition with targeted tissue by sensing an electrical input and/or characteristic of at least one of the rotational and translational actuators.

52. An electrode treatment device comprising:

an elongate body having a distal end portion terminating in a tip;

a shaft extending from the tip of the body and movable relative to the body; and

an electrode strip having a first end portion attached to the body, a second end portion attached to the shaft at a location distal to the tip of the body, and a middle portion between the first and second end portions, the electrode strip being coiled around the shaft or the body, or both, and the shaft being movable relative to the body to cause the electrode strip to move between a contracted position in which the electrode strip is wrapped closely around the shaft or the body, or both, and a maximally expanded position in which the middle portion of the electrode strip is spaced apart from the shaft and the body, wherein the electrode strip has a maximum expansion ratio that exceeds 5:1.

53. The electrode treatment device of claim **52**, wherein the shaft is rotatable relative to the body.

54. The electrode treatment device of claim **52**, wherein the shaft is slidably movable inwardly and distally outwardly relative to the body.

55. The electrode treatment device of claim **52**, wherein the electrode strip comprises a flexible printed circuit.

56. The electrode treatment device of claim **52**, wherein the body or the shaft, or both, provide a conductive path to the electrode strip, and wherein the body or the shaft, or both, have an electrically insulated surface.

57. The electrode treatment device of claim **52**, wherein the maximum expansion ratio exceeds 10:1.

58. The electrode treatment device of claim **52**, wherein the expansion ratio is in the range of 5:1 to 30:1.

59. The electrode treatment device of claim **52**, wherein the electrode strip is helically coiled around the shaft or the body, or both.

60. The electrode treatment device of claim **59**, wherein the electrode strip is thermoformed or heat treated to return to the contracted position of the helix when no force is applied to the electrode strip via the shaft and/or the body.

61. The electrode treatment device of claim **52**, further comprising a robotic manipulator coupled to the shaft and/or the body, and wherein the robotic manipulator includes a rotational actuator that rotates the shaft relative to the body and a translational actuator that moves the shaft axially relative to the body.

62. The electrode treatment device of claim **61**, wherein the rotational actuator and translational actuator are integrated in a single actuator device.

63. The electrode treatment device of claim **61**, further comprising a control device that controls the rotational and translational actuators independently.

64. The electrode treatment device of claim **61**, wherein a deployment control device detects when the electrode strip is deployed into apposition with targeted tissue by sensing an electrical input and/or characteristic of at least one of the rotational and translational actuators.

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