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(54) Title: ELECTRODE TREATMENT DEVICE WITH ACTUATABLE DEPLOYMENT SYSTEM AND RELATED METHODS OF DEPLOYMENT AND TREATMEN

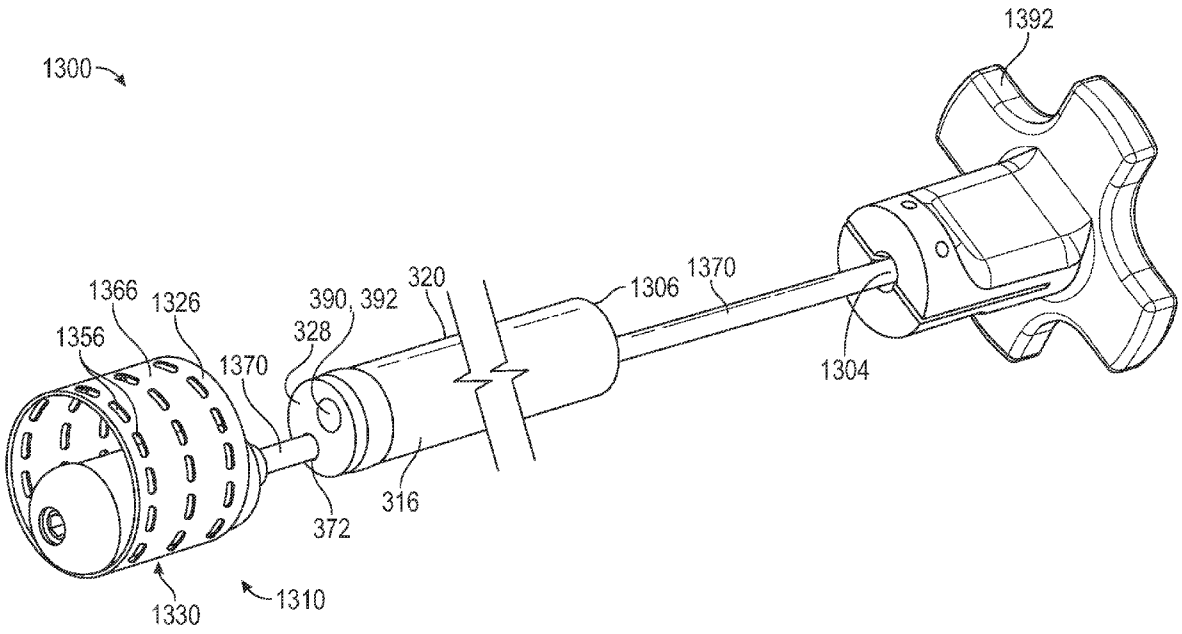

FIG. 23

(57) Abstract: An electrode treatment device (300, 600, 700, 800, 900, 902, 1000, 1100, 1200, 1300, 1400, 1400', 1400a, 1400b, 1400c, 1600, 1600', 1800, 1900, 2000, 2100, 2200, 2300, 2400) for treating gastrointestinal tissue or other tissue includes an actuatable electrode deployment system (310, 610, 710, 810, 910, 912, 1010, 1110, 1210, 1310, 1410, 1410', 1410a, 1410b, 1410c, 1610, 1610', 1810, 1910, 2010, 2110, 2210, 2310, 2410) that is attachable to an endoscope (320) and that moves a flexible electrode (366, 666, 766, 1066, 1166, 1266, 1366, 1466, 2466), such as a flexible printed circuit strip, from a stowed configuration to a deployed configuration in apposition with tissue. The electrode may be at least partially coiled within a housing (1316, 1416, 1616, 2016, 2116) when in the stowed configuration, and an actuation element (1314, 1414, 1414a, 1414b, 1414c, 1614) mounted at a proximal end (1306) of the endoscope or forwardly of a distal end (328) of the endoscope and at least partially within the housing. Deployment of the electrode may be automatically halted or controlled based on electric current drawn by the actuation element indicative of mechanical resistance

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encountered by the electrode. The electrode treatment system may include a shaft (370, 770, 870, 970, 972, 1370, 1470, 2470) threaded through a working channel (372) of the endoscope and electrically and/or mechanically connected to a controller (14) and/or actuation element at the proximal end.

ELECTRODE TREATMENT DEVICE WITH ACTUATABLE DEPLOYMENT SYSTEM AND RELATED METHODS OF DEPLOYMENT AND TREATMEN

TECHNICAL FIELD

[0001] The present disclosure relates generally to the field of internal tissue treatment and, in particular, to devices and methods with electrodes deployable from an endoscope or catheter to ablate cells for treating targeted tissues.

BACKGROUND

[0002] 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.

[0003] 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.

[0004] 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.

[0005] 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.

[0006] 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 for example.

SUMMARY

[0007] An electrode deployment system that is attachable to an endoscope includes an actuatable electrode deployment mechanism that moves a flexible electrode from a stowed configuration to a deployed configuration in apposition with tissue to be treated by electrolysis and/or electroporation, or to utilize the electrode for applying other or additional energy waveforms, or for sensing. The system is particularly useful for duodenum mucosal resurfacing (DMR). An actuation element of the electrode deployment mechanism, such as an electric motor, may be at least partially contained within a housing disposed distally of a distal end of the endoscope and the electrode array may be at least partially coiled within the housing when in the stowed configuration. The actuation element may be activated to rotatably drive a part of the mechanism to unfurl and furl the flexible electrode between the stowed and deployed configurations. Deployment of the electrode may be performed in an automatic or semi-automatic manner by sensing a current drawn by the actuation element during operation and automatically shutting off the actuation element in response to the current exceeding a predetermined threshold indicative of mechanical resistance being encountered by the electrode contacting the tissue. Further stepwise expansion of the electrode may be selectively initiated, for example by manually

pressing a button on a controller. Embodiments of the deployment mechanism may be closely integrated with an endoscope to achieve a relatively low overall profile to enhance maneuvering.

[0008] In some embodiments, the electrode deployment mechanism and its actuation element may be mounted forwardly of a distal end of the endoscope and may be positioned eccentrically of the endoscope to provide the endoscope with improved visibility of the electrode and the tissue treatment site during deployment and retraction. The system may include a shaft attached to the deployment mechanism that is threaded through a distal opening of the working channel at the distal end of the endoscope. After the shaft is threaded through the working channel of the endoscope, a proximal end of the shaft may be connected to a handle or a robotic manipulator and an electrical connector at the proximal end of the shaft can be connected a mating electrical connector that is coupled to a power supply of the system.

[0009] In other embodiments, the electrode deployment mechanism may be mounted forwardly of the distal end of the endoscope and driven by an actuation element mounted at a proximal end of the endoscope, for example via a drive shaft that is threaded through the working channel of the endoscope and that couples the electrode deployment mechanism to the actuation element to achieve mechanical power transmission from the actuation element to the electrode deployment mechanism. For example, the shaft may be rotatably driven by the actuation element. In another example, the shaft may be hollow and may serve as a conduit for transmitting hydraulic or pneumatic fluid from the actuation element through the shaft to the electrode deployment mechanism for hydraulic or pneumatic actuation.

[0010] Subsystems for cleaning and irrigation may also be included in electrode treatment systems disclosed herein.

[0011] 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

[0012] 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:

[0013] FIG. 1 is a schematic illustration of a system for electroporation and/or electrolysis in accordance with examples described herein.

[0014] FIG. 2 is a schematic illustration of a robotically-assisted manipulator system in accordance with examples described herein.

[0015] FIG. 3A is a schematic diagram of an instrument system in accordance with examples described herein.

[0016] FIG. 3B illustrates a distal portion of the instrument system of FIG. 3A with an extended example of an instrument in accordance with examples described herein.

[0017] FIG. 4 is a front-left isometric view of an electrode treatment device consistent with an embodiment of the present disclosure, with an endoscope, drive shaft, and electrical connection tab of the electrode treatment device shown truncated at the left rear side of the figure. In FIG. 4, an electrode strip of the electrode treatment device is illustrated in a stowed configuration.

[0018] FIG. 5A is a longitudinal cross section view of the electrode treatment device of FIG. 4 taken along line 5A—5A of FIG. 4.

[0019] FIG. 5B is a lateral cross section view of an electrode deployment system of the electrode treatment device of FIG 4 taken along line 5B—5B of FIG. 4, with the endoscope omitted.

[0020] FIG. 6 is a rear-left isometric view of the electrode treatment device of FIG. 4 showing an electrode strip of the electrode treatment device in a deployed configuration.

[0021] FIG. 7 is a cross section view of the electrode treatment device of FIG. 4 taken along line 7—7 of FIG. 6 and showing the electrode strip in the deployed configuration.

[0022] FIGS. 8A and 8B are cross sectional end views of the electrode treatment device of FIG. 4 taken along line 8—8 of FIG. 6, schematically showing the electrode strip in respective stowed and deployed configurations.

[0023] FIG. 9 is a layout view of an exemplary electrode strip of the electrode treatment device FIGS. 4-7 and 10.

[0024] FIG. 10 is an isometric view of an electrode treatment device and electrode deployment system according to an embodiment of the present disclosure in which

first and second members of the electrode deployment system are formed with a framework and windows to allow the endoscope visibility to a tissue treatment site.

[0025] FIG. 11 is an isometric view of an electrode treatment device and electrode deployment system according to an embodiment of the present disclosure in which an electrode coiling mechanism of the electrode deployment system is positioned eccentrically and distally of an endoscope to which it is attached.

[0026] FIG. 12 is a cross section view of the electrode treatment device of FIG. 11 taken along line 12—12 in FIG. 11.

[0027] FIGS. 13A and 13B are partial assembly views of the electrode coiling mechanism and electrode strip of the electrode treatment device of FIGS. 11-12 shown in respective stowed and deployed configurations.

[0028] FIG. 14 is a photograph taken from an optical imaging system of an electrode treatment device consistent with an embodiment of the present disclosure while the electrode treatment device is inserted endoluminally into a gastrointestinal organ.

[0029] FIG. 15 is a side view of an electrode treatment device according to an embodiment in which an electrode coiling mechanism of the instrument is angled relative to a longitudinal axis of an endoscope.

[0030] FIG. 16A is an isometric view of an electrode treatment device according to an embodiment in which the electrode deployment system is positioned eccentrically and distally of an endoscope to which it is attached, and in which a drive shaft of the electrode deployment system extends through a working channel of the endoscope.

[0031] FIG. 16B is an isometric view of an electrode treatment device according to an embodiment in which the electrode deployment system is positioned eccentrically and distally of an endoscope to which it is attached as well as angled relative to a longitudinal axis of the endoscope, and in which a drive shaft of the electrode deployment system extends through a working channel of the endoscope

[0032] FIG. 17 is an isometric view of an electrode treatment device including an electrode deployment system supported on an endoscope and including an electrode strip coiled around an inflatable bladder.

[0033] FIG. 18 is an isometric view of the electrode treatment device of FIG. 17 with the electrode strip and inflatable bladder illustrated in an inflated and deployed configuration.

[0034] FIGS. 19A and 19B are photographs of an embodiment of an inflatable electrode deployment system including an electrode with a braided sleeve surrounding an inflatable bladder, shown in respective stowed and deployed configurations.

[0035] FIG. 20 is a side schematic view of an electrode treatment device including an inflatable electrode deployment system surrounding a distal end portion of an endoscope.

[0036] FIGS. 21A and 21B are isometric views of an electrode treatment device according to an embodiment with an electrode of the electrode treatment device shown in respective stowed and deployed configurations.

[0037] FIG. 21C is a longitudinal cross section view of the electrode treatment device of FIG. 21A, illustrating a powered actuation element within an electrode deployment mechanism of the device, and showing an electrode of the device in the stowed configuration.

[0038] FIG. 22 is an isometric view of the electrode treatment device of FIGS. 21A, 21B, and 21C according to an embodiment wherein the electrode treatment device is positioned distally of a distal end of an endoscope and attached to the endoscope by a control shaft that extends through a working channel of the endoscope, with an electrode of the electrode treatment device shown in a stowed configuration.

[0039] FIG. 23 is an isometric view of the electrode treatment device of FIG. 22 shown with its electrode uncoiled and expanded laterally to a deployed configuration.

[0040] FIG. 24 is a longitudinal cross section view of the electrode treatment device of FIG. 22.

[0041] FIG. 25 is a longitudinal cross section view of a proximal end portion of the control shaft and handle of the electrode treatment device of FIG. 22, showing detail of an electrical connector.

[0042] FIG. 26 is a side view of an electrode treatment device according to another embodiment.

[0043] FIG. 27 is a longitudinal cross section view of the electrode treatment device of FIG. 26.

[0044] FIG. 28 is a partially exploded view of the electrode treatment device of FIG. 26 showing details of an electrode deployment mechanism of the electrode treatment device.

[0045] FIG. 29A is an enlarged section view of the electrode treatment device of FIG. 26 taken along line 29A—29A in FIG. 27, showing details of a planetary gearset of the electrode deployment mechanism.

[0046] FIG. 29B is an enlarged detail view of a planetary gearset of the electrode deployment mechanism of the electrode treatment device of FIG. 26 with the end cap and outer first member omitted to illustrate certain features in more detail.

[0047] FIG. 30 is a longitudinal cross section view of an electrode treatment device with an electrode deployment mechanism without a planetary gearset.

[0048] FIG. 31 is a side view of an electrode treatment device of the kind illustrated in FIGS. 26-30, wherein an actuation element is positioned within an electrode deployment mechanism of the device.

[0049] FIG. 32 is a side view of an electrode treatment device in which an actuation element is positioned proximally adjacent to an electrode deployment mechanism of the device.

[0050] FIG. 33 is a side view of an electrode treatment device in which an actuation element is positioned distally adjacent to an electrode deployment mechanism of the device.

[0051] FIG. 34 is a longitudinal cross section view of an electrode treatment device with an actuation element positioned at a proximal end of the device and coupled to an electrode deployment mechanism at a distal end of the device by a drive shaft extending through a working channel of an endoscope.

[0052] FIG. 35 is a longitudinal cross section view of an electrode treatment device with an actuation element positioned at a proximal end of the device and a shaft coupling the actuation element to a mechanical power transmission within the electrode deployment mechanism at a distal end of the device.

[0053] FIG. 36 is an isometric proximal end view of an inner, second member of the electrode deployment mechanism of FIG. 28 showing details of an electrode mounting channel with a textured adhesion surface.

[0054] FIG. 37 is an isometric distal end view of the second member of FIG. 36 showing an opposite side of the second member.

[0055] FIG. 38 is a side pictorial view of the second member of FIG. 36 with an electrode strip secured thereto via the electrode mounting channel of the second member.

[0056] FIG. 39 is a bottom view of an end portion of an electrode strip showing a roughened bottom surface for improved adhesive connection between the electrode strip an electrode deployment mechanism.

[0057] FIG. 40 is a pictorial view of an outer, first member and an end cap of the electrode deployment mechanism of FIG. 28, showing mating features for aligning and mechanically coupling the end cap to the first member.

[0058] FIG. 41A is an exploded assembly view of the second member of FIGS. 36-37 and a drive shaft, showing details of a keyed coupling for transmitting rotary force from the drive shaft to the second member and providing good tensile strength in the coupling.

[0059] FIG. 41B is an enlarged oblique distal end view of the second member of FIG. 41A showing internal details of the keyed coupling feature.

[0060] FIG. 42 is an isometric view of an embodiment of an electrode treatment device including a cleaning brush lining a slot of the electrode treatment device, wherein an electrode strip of the device is omitted to show details of the cleaning brush.

[0061] FIG. 43 is an isometric view of an embodiment of an electrode treatment device including a wiper lining a slot of the electrode treatment device, wherein an electrode strip of the device is omitted to show details of the wiper.

[0062] FIG. 44 is an embodiment of an electrode treatment device with an electrode strip of the device omitted and arrows illustrating fluid for cleaning of the electrode or irrigation of tissues flowing outwardly from the side of the electrode treatment device.

[0063] FIG. 45 is a longitudinal cross section view of the electrode treatment device of FIG. 44, showing a fluid flow path through a shaft of the device according to one embodiment.

[0064] FIG. 46 a longitudinal cross section view of the electrode treatment device according to an embodiment in which fluid is delivered via a secondary hose or tube laterally adjacent to the shaft.

[0065] FIG. 47 is a pictorial view of an embodiment of an electrode treatment device including irrigation nozzles for spraying fluid radially outward toward target tissue.

[0066] FIG. 48 is a pictorial view of another embodiment of an electrode treatment device with irrigation nozzles and a deflector for directing the spray of fluid longitudinally along the side of the device.

[0067] FIG. 49 is a pictorial view of another embodiment of an electrode treatment device including an indicator feature for reading a scale that indicates a diameter of a deployed electrode as illustrated in FIG. 50.

[0068] FIG. 50 is an illustration of a video display from an endoscope of the electrode treatment device of FIG. 49 while the electrode treatment device is in use with its electrode strip in a deployed condition, showing a scale on the inside of the electrode strip and indicator on the housing of the treatment device for reading the diameter of the deployed electrode strip.

[0069] FIG. 51 is a layout view of the electrode strip of FIGS. 49 and 50 showing details of a scale printed thereon in accordance with one embodiment.

DETAILED DESCRIPTION

[0070] 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.

[0071] 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.

[0072] 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/or 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/or 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.

[0073] 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, 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.

[0074] 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.

[0075] 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.

[0076] 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.

[0077] Examples of instruments and 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 electrolysis and/or electroporation in some examples, radiofrequency ablation in other examples, and other energy modalities in yet other examples. When the energy is 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 and current 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.

[0078] 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.

[0079] 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 reference to FIGS. 4-20. 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.

[0080] 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 circuity such as one or more application specific integrated circuits (ASICs) and/or field programmable gate arrays (FPGAs).

[0081] 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.

[0082] 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 32, such as a lumen, 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.

[0083] 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.

[0084] 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.

[0085] 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.

[0086] 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.

[0087] 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 20 for electrolysis and permeabilization. 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.

[0088] 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.

[0089] 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.

[0090] In some embodiments, examples of parameters 22 which may be used include a delivery of between 1 and 50 voltage pulses between 50 V and 1000 V. Those pulses may be delivered in a system having a capacitance between 50 μF and 1000 μF, and a resistance of greater than 0 ohms and less than 100 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, $Q = C \cdot V$. Also, charge is the product of current I (in amps) and time t (in seconds). That is, $I \cdot t = Q$. 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.

[0091] In some embodiments, the time constant (e.g., exponential decay time constant of the capacitive discharge) may range from 50 microseconds (μs) to 50 milliseconds (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.

[0092] 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.

[0093] 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.

[0094] 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.

[0095] 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.

[0096] 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.

[0097] 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.

[0098] 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.

[0099] 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.

[00100] 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.

[00101] 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.

[00102] 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.

[00103] FIG. 3A 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.

[00104] 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 may have an outer diameter in the range of approximately 6 mm to approximately 20 mm, or preferably in the range of approximately 9 mm to approximately 16 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.

[00105] 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.

[00106] 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.

[00107] The flexible body 216 includes one or more channels (e.g., passageways or ports) 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. 3B 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 portion 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.

[00108] 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.

[00109] 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.

[00110] Embodiments of a medical instrument system including an electrode deployment system illustrated in the context of an electrode treatment device for electrosurgery will now be described with reference to FIGS. 4-20. The various embodiments of an electrode treatment device and electrode deployment system disclosed herein may comprise an electrode instrument for electrosurgery, such as electrolysis and/or electroporation, or for sensing or other uses. In some embodiments, electrode deployment systems according to the present disclosure are slidably, removably, or permanently attached to an endoscope. In some embodiments, electrode deployment systems according to the present disclosure may be operably coupled, 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. 3A and 3B. In other embodiments, electrode deployment systems according to the present disclosure can be integrated with the body of an endoscope, catheter, or other elongate flexible device.

[00111] With reference to FIG. 4, an electrode treatment device 300 according to an embodiment includes an electrode deployment system 310 supported on a distal end portion 316 of an endoscope 320 or another elongate flexible device. Endoscope 320 includes an elongate flexible body 324 (that is shown truncated in FIG. 4 for purposes of illustration) having a distal end 328. In the illustrated embodiment, electrode deployment system 310 is fitted onto body 324 adjacent its distal end 328 so that an electrode coiling mechanism 330 of electrode deployment system 310 encircles distal end portion 316 of endoscope 320 and is mounted concentrically thereon. In some embodiments, electrode coiling mechanism 330 may be slip-fit or press-fit onto distal end portion 316 of body 324. In other embodiments, electrode coiling mechanism 330 may be snap-fit onto distal end portion 316 via an engagement groove or detent feature (not illustrated) on distal end portion 316 and/or a part of electrode coiling mechanism 330. In other embodiments, such as those illustrated in FIGS. 19A, 19B, and 20, the electrode deployment system includes a mechanism or means for electrode deployment other than a coiling mechanism. Electrode coiling mechanism 330 includes a first member 340 (also referred to herein as an outer member 340) and a second member 360 (also referred to herein as an inner member 360). As an example, the first member 340 is an outer housing and the second member 360 is an inner housing of the electrode coiling mechanism.

[00112] With reference to FIGS. 4, 5A, and 5B together, the electrode coiling mechanism 330 includes a first gear 344, such as a ring gear formed on an annular inner surface 348 of first member 340, and a second gear 354, such as a pinion gear. In other embodiments (not illustrated), first gear 344 may be a separate component attached to first member 340 and may be a ring gear or other type of gear, such as a crown gear. In the illustrated embodiment, first member 340 is generally tubular shaped and rotatably supported on the second member 360 of electrode coiling mechanism 330. In the illustrated embodiment, the second member 360 is a generally tubular shaped component interposed between first member 340 and body 324 and positioned at least partially within first member 340. The first member 340 overlaps second member 360 in an axially-overlapping region 362 where the second member 360 (or a portion thereof) is positioned within first member. An annular gap 368 (FIGS. 5A and 8B) is formed between the inner and outer members in the axially-overlapping region 362.

[00113] A first portion 364 of a flexible electrode strip 366 is wrapped around first member 340 and a remaining portion of electrode strip 366 is coiled around second member 360 in the gap 368 between the first and second members 340, 360. In alternative embodiments, all or nearly all of electrode strip 366 may be coiled around first member 340. Flexible electrode strips as described herein may include one, two, or any suitable number of electrodes (e.g., an array of electrodes). In the illustrated embodiment, second member 360 is longitudinally longer than first member 340 and electrode strip 366 (*e.g.,* second member 360 extends proximally relative a proximal end 369 of first member 340). In some embodiments, one or both the first and second members 340 and 360 may extend proximally relative to electrode strip 366. In some embodiments, such as the one illustrated in FIG. 10, the first and second members have approximately the same longitudinal length, which may be just long enough (e.g., sufficiently long) to support electrode strip 366 thereon.

[00114] In the embodiment illustrated, first and second members 340, 360 are made of a transparent material, such as clear thermoplastic resin, for reasons that are discussed in more detail below in reference to FIG. 6. When the respective electrode strips as described herein are in the stowed configurations, electrode treatment devices consistent with the present disclosure may have an overall outer diameter in the range of 10 mm to 17 mm. The relatively small diameter of such electrode treatment devices and their electrode deployment systems may facilitate

maneuverability and navigation in gastrointestinal regions, the duodenum, and particularly at the pylorus and duodenojejunal junction.

[00115] Second gear 354 is mounted on a drive shaft 370 for rotation therewith about a rotational axis 374 of drive shaft 370. Drive shaft 370 extends through and from a working channel 372 (e.g., also illustrated with respect to embodiment of FIGS. 12 and 16A-16B; sometimes referred to as a "working port"), which extends longitudinally through body 324 of endoscope 320. In other embodiments (not illustrated), drive shaft 370 may extend from working channel 372 or a working port of endoscope 320 while not extending entirely through body 324, for example if drive shaft 370 is driven from within body 324 of endoscope 320. Second gear 354 is meshed or otherwise mated with first gear 344 such that rotation of drive shaft 370 drives first member 340 to rotate relative to second member 360 about a common central axis 376 of first member 340 and distal end 328. In other words, second member 360 is fixed in rotation relative to first member 340. As first member 340 rotates relative to second member 360, electrode strip 366 deploys laterally outwardly from endoscope 320 as illustrated in FIGS. 6, 7, and 8B and further described below in reference to those figures. Thus, drive shaft 370 is operably coupled to first member 340 via first and second gears 344, 354 such that rotation of drive shaft 370 relative to body 324 of endoscope 320 imparts relative movement between the first and second members 340, 360 for transitioning electrode strip 366 between the stowed and deployed configurations (e.g., by unfurling and furling electrode strip 366). The gear ratio between second gear 354 and first gear 344, may be in the range of about 1:20 to 1:2. In the embodiment illustrated, first gear 354 has 48 teeth and second gear 344 has 18 teeth, for a gear ratio of 3:8.

[00116] A handle (see handle 792 in FIG. 11) may be attached to a proximal end portion of drive shaft 370 to facilitate manipulation of drive shaft 370 and operation of electrode deployment system 310. In some embodiments, the handle may be actuated manually by a user. In other embodiments, the handle 792 or a linkage or other coupling device or feature at the proximal end of drive shaft 370 may be coupled to an external device for actuation of electrode deployment system 310, such as a robotically-assisted manipulator system. In yet other embodiments, manual and robotically-assisted actuation may be provided.

[00117] The electrode treatment devices described herein may be coupled to an external device to provide actuation, control, and/or electrical power to the electrode treatment device. For example, electrode treatment device 300 and the other electrode

treatment devices described herein may be actuated by a robotically-assisted manipulator system (e.g., manipulator assembly 102). Electrode treatment device 300 (e.g., the handle, drive shaft 370, and/or control shaft 1370 (FIGS. 21A-25) 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 electrode treatment device 300 is coupled to the manipulator assembly, the drive inputs of electrode treatment device 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 electrode treatment device 300 may be coupled to distal end portion 316 of the electrode treatment device 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 distal end portion 316 of electrode treatment device 300 as well as expansion and/or retraction of the electrodes described herein (*e.g.,* electrode strip 366, electrode strip 1066 of FIGS. 17-18, braided electrodes 1166, 1266 of FIGS. 19A, 19B, and 20, and electrode strip 1366 of FIGS. 21A-24) to adjust the electrodes between the deployed configuration and a stowed configuration. In addition, 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 the electrodes of electrode treatment device 300. Drive unit 204 may be electrically coupled to the electrodes via one or more electrical cables, wires, or traces running along or through electrode treatment device 300. In alternative embodiments, the controller and power supply may provide power to the electrical cables, wires, or traces without coupling to the drive unit (e.g., the controller and power supply may be independent of the drive unit).

[00118] In the embodiments illustrated in FIGS. 4-10, first member 340, 640 rotates about second member 360, 660 and endoscope 320, and second member 360, 660 is constrained from rotating relative to endoscope 320. In other embodiments, such as the embodiment of FIGS. 11-16B, described below, an inner member is rotatable relative to the outer member. In still other embodiments, each of the first and second members (inner and outer members) may be rotatable about a central axis (e.g., central axis 376), or an eccentric axis, relative to the other of the first and second members to deploy the electrode (e.g., electrode strip 366) by uncoiling or otherwise. Accordingly, drive shaft 370 may be operatively coupled to one or both of the first and

second members of the coiling mechanisms of various embodiments to impart relative motion between the first and second members.

[00119] Returning to FIGS. 4, 5A, and 5B, second gear 354 is freely rotatable within a shroud 378 formed at a distal end of second member 360. With the exception of a meshed or mating portion of the first and second gears, shroud 378 may extend circumferentially to cover a substantial portion of the gear assembly of first gear 344 and second gear 354 while contouring around where the first and second gears 344, 354 mate, to thereby inhibit exposure of the gear teeth of the first and second gears 344, 354 to tissues when electrode treatment device 300 is in use. Shroud 378 may also provide support and guidance for second gear 354. In some embodiments, a guide wire 380 extends distally from drive shaft 370 and second gear 354. Guide wire 380 is marked with distance indicator marks 384 (FIG. 4) visible to an optical imaging system 109, 390 of endoscope 320.

[00120] Drive shaft 370 may include a torque tube or other flexible elongate torque-transferring device (e.g., a flexible drive shaft). In embodiments including a torque tube, guide wire 380 may extend through a lumen of the torque tube. Drive shaft 370 may be generally cylindrical in shape. Drive shaft 370 may include a shaped fitting 446 at a distal end of drive shaft 370, such as the hexagonal fitting illustrated, for mating with a similarly-shaped hole or socket in second gear 354 and for transferring torque to second gear 354, which transmits the torque to first member 340 via first gear 344. Second gear 354 may be press-fit onto fitting 446 or attached to drive shaft 370 by other means, such as welding or adhesive. Drive shaft 370, fitting 446, and second gear 354 may be made of a metal, such as stainless steel or titanium, high strength plastic, or another material. In some embodiments, drive shaft 370 and/or fitting 446 are made of metal and second gear 354 is made of high-strength thermoplastic resin or composite material, such as a glass-fiber or carbon-fiber reinforced resin. In other embodiments, a different type of mechanism or device for transmitting torque or power from drive shaft 370 to first member 340 may be utilized in place of first and second gears 344, 354. One or more bearings (not illustrated, but see bearings 796 in FIG. 12) may be interposed between first and second members 340, 360 at a bearing interface therebetween to reduce friction during relative rotation between first and second members 340, 360.

[00121] FIGS. 4, 5A, 5B, and 8A illustrate electrode treatment device 300 with electrode deployment system 310, electrode coiling mechanism 330 and electrode

strip 366 in a stowed configuration. Electrode strip 366, an embodiment of which is illustrated in FIG. 9 (shown laid out flat) and further described below, includes opposite first and second end portions 422, 424 and a middle portion 426 interposed between the first and second end portions 422, 424. A lead tab 428 extends transversely from the electrode strip 366. As shown in FIG. 4, first end portion 422 is fixedly attached, such as by welding, adhesives, fasteners, or other means of direct attachment for example, to an outside surface of first member 340 in the axially-overlapping region 362 (FIG. 5A) and wrapped at least partially around the outside of first member 340. Electrode strip 366 then passes through a slot 440 that extends longitudinally through a tubular section of first member 340 and the remainder of electrode strip 366 is coiled around second member 360 within the gap 368 in the axially-overlapping region 362 between the first and second members 340, 360 when electrode strip 366 is in the stowed configuration, as best illustrated in FIG. 8A further discussed below. Second end portion 424 is constrained from movement or rotation about central axis 376, such as by fixedly attaching second end portion 424 to second member 360, e.g., by welding, adhesives, fasteners, or other means of direct attachment, in the axially-overlapping region 362 as best illustrated in FIGS. 8A and 8B. Slot 440 may be approximately 20 mils wide, which is more than twice the thickness of electrode strip 366 in the embodiment illustrated.

[00122] FIGS. 6, 7, and 8B illustrate electrode treatment device 300 with electrode deployment system 310, electrode coiling mechanism 330 and electrode strip 366 in a deployed configuration in which middle portion 426 of electrode strip 366 is expanded laterally and radially outward from first member 340 relative to the stowed configuration illustrated in FIGS. 4, 5A, 5B, and 8A.

[00123] Electrode deployment system 310 may be advanced or otherwise moved axially from a first axial position (FIGS. 4 and 5A) to a second axial position (FIGS. 6 and 7) and vice versa, e.g., for deployment, retraction, and/or removal. The electrode deployment system 310 may be advanced or retracted longitudinally (axially) when electrode strip 366 is in the stowed configuration, and/or the deployed configuration, and/or during treatment. For example, portions of the electrode deployment system 310 may be telescopically extended beyond a distal end 328 of endoscope 320 or retracted back adjacent to the distal end 328 of the endoscope 320. Drive shaft 370 is moved distally relative to endoscope 320 to slidably move first member 340 axially more distal relative to endoscope 320 from the first axial position shown in FIGS. 4

and 5A and extended to the second axial position shown in FIGS. 6 and 7, which is different relative to the first axial position. In the second axial position, all or a portion of first member 340 and all or a portion of the electrode strip 366 are moved distally of the distal end 328 of endoscope 320 and optionally within a field of view of optical imaging system 390 (FIG. 4). In the embodiment illustrated, second member 360 is also slidably moved distally relative to endoscope 320. In other embodiments (not illustrated), second member 360 may be prevented from moving longitudinally relative to endoscope 320 and first member 340 may be telescopically movable longitudinally/distally relative to second member 360. In still other embodiments (not illustrated), first and second members 340, 360 may be slidably mounted on a stationary third member interposed between second member 360 and body 324 of endoscope 320, and in which the third member is securely supported on distal end portion 316 of endoscope 320, for example by press fitting, such that the third member provides a stationary platform or guideway for longitudinal sliding movement of first and second members 340, 360.

[00124] In some embodiments, the aforementioned telescoping extension or retraction is driven by drive shaft 370. Telescoping extension or other extension of electrode deployment system 310 may facilitate precise placement and deployment of electrode strip 366 into apposition with targeted tissues for electrosurgical treatment, by allowing an operator to use optical imaging system 109, 390 to view the position of electrode strip 366 during its lateral and/or radial deployment in relation to the targeted tissue. Distance indicator marks 384 on guide wire 380 may be utilized as a point of reference for the extent to which electrode deployment system 310 has been telescoped (i.e., the distance that first member 340 has been moved longitudinally relative to endoscope 320), or as a point of reference for placement of electrode treatment device 300, or as a reference for the distance by which first member 340 must be moved longitudinally relative to endoscope 320 to allow electrode strip 366 to reach the targeted tissue. Distance indicator marks 384 may be spaced apart by approximately the same width as the width W (FIG. 9) of electrode strip 366.

[00125] As previously noted, first member 340 may be made of a transparent material providing visibility therethrough for the optical imaging system 390 to image the electrode strip 366 when deployed. In some embodiments, second member 360 is also made of a transparent material for the same reason. In some embodiments, at least a portion of electrode strip 366 may be made of a transparent or translucent

flexible material, such as transparent polyimide (PI) or transparent polyethylene terephthalate (PET), allowing visibility through electrode strip 366 to the targeted tissue. And in some embodiments, electrode strip 366 may include one or more holes, windows, or other apertures 460 formed therein to provide visibility through electrode strip 366 (e.g., when the electrode strip 366 is made of an opaque material), particularly when electrode strip 366 is laterally expanded to the deployed (unfurled) configuration illustrated in FIG. 6.

[00126] Electrode treatment device 300 may be operated by first inserting the electrode treatment device 300, including endoscope 320 and electrode deployment system 310, into a patient, for example endoluminally, and guiding electrode treatment device via endoscope 320 to a treatment site, such as a location within the duodenum or other gastrointestinal site, for example. The position of electrode treatment device 300 relative to target tissue at the treatment site may be gauged visually by viewing distance indicator marks 384 on guide wire 380 through optical imaging system 390 of endoscope 320. Once positioned at the treatment site, electrode deployment system 310 may be advanced distally into view of optical imaging system 390 by moving drive shaft 370 distally relative to endoscope 320, followed by rotation of drive shaft 370 in a first direction 398 (FIG. 8B) to uncoil (unfurl) and deploy electrode strip 366 laterally outward from first member 340 to a deployed configuration in apposition to the targeted tissue. Once electrode strip 366 is deployed into contact with targeted tissue, electrical energy may be applied to electrode strip 366 to effect electrosurgical treatment of the tissue, such as by electrolysis, electroporation, or both. In some embodiments, electrode strip 366 may be utilized alone or in combination with one or more electronic sensors formed thereon (not shown) to sense a condition of the tissue or the patient by measuring electrical signals transmitted by electrode strip 366.

[00127] After completing an electrosurgical procedure or other procedure using electrode treatment device 300 at a treatment site or test site (*e.g.,* a first tissue treatment site), electrode strip 366 may be returned to the stowed configuration illustrated in FIGS. 4, 5, and 8A by rotating drive shaft 370 in a second direction opposite the first direction 398, causing electrode coiling mechanism 330 to coil the electrode strip 366 around second member 360 (*e.g.,* furling the electrode strip 366). Additional treatment or sensing may then be accomplished by advancing electrode strip 366, either by additional telescoping of electrode deployment system 310 relative to endoscope 320, or by moving endoscope 320 (*i.e.,* moving the entire electrode

treatment device 300) to a second tissue treatment site, which in some instances may overlap with the first treatment site. At the second treatment site, electrode strip 366 may again be deployed laterally outward from first member 340 as before, into apposition with tissue at the second treatment site, and energized for electrosurgical treatment or sensing. Upon completion of the treatment or treatments at one or more treatment sites, electrode strip 366 can be retracted to the stowed configuration via rotation of the drive shaft 370 in the second direction to coil the electrode strip 366. Additionally, the electrode deployment system 310 may be retracted proximally to the first axial position (e.g., adjacent distal end 328 of endoscope 320) by moving drive shaft 370 proximally relative to endoscope 320.

[00128] Turning now to FIG. 9, an exemplary electrode device 500 embodying electrode strip 366 comprises a flexible printed circuit 502 (aka flex-circuit) including conductive electrodes 510, 520 deposited on an outer surface of a flexible polymeric substrate 530. (Note: For simplicity of illustration, electrodes 510, 520 are omitted from the electrode strips 366 illustrated in FIGS. 4, 5, 6, 7, 10, 11, and 12.) In some embodiments, electrode device 500 may overall have a shape that is different from a simple strip configuration – for example, the L-shaped configuration illustrated in FIG. 9, in which the electrode strip 366 (*i.e.,* an "electrode strip portion" of device 500) forms one leg of the L shape and the lead tab 428 forms the other leg of the L shape. In other embodiments (not illustrated), the entire electrode device 500 may be shaped as a strip, such as a simple strip of foil operating as a monopolar electrode.

[00129] Substrate 530 of flexible printed circuit 502 may consist or comprise a film of polyimide, polyester, polyethylene terephthalate (PET), or another suitable flexible insulating material. The substrate 530 may have a thickness in the range of 2 mils to 10 mils or more (0.051 to 0.254 mm). The thickness of substrate may depend on the needed stiffness or relative flexibility of electrode strip 366 for purposes of preventing buckling during deployment, and achieving desired expansion size and tissue apposition forces, which may also be impacted by the width W of electrode strip 366 and other factors such as electrode configuration, material properties, etc. Electrode strip 366 may have a width W that is in the range of 5 to 50 mm or more, and preferably in the range of 10 to 30 mm. Making electrode strip 366 and the overall electrode deployment system 310 with a smaller width may improve maneuverability of endoscope 320 and electrode treatment device 300 during navigation through gastrointestinal passageways but decreases the tissue coverage area of electrode

strip 366, which may increase the amount of electrosurgical contact and energization steps required to treat a larger area of tissue. Depending on the diameter of the electrode coiling mechanism 330, electrode strip 366 may have a length L in the neighborhood of 40 to 200 mm, and more preferably in the range of approximately 80 mm to 140 mm. With an electrode coiling mechanism 330 having an outer diameter of about 32 mm, the length of electrode strip 366 may be in the range of about 110 mm to 130 mm.

[00130] The embodiment of electrode device 500 illustrated in FIG. 9 includes an array of two electrodes, namely first electrode 510 and second electrode 520, connected to respective first and second leads 512, 522 for bipolar operation. In other embodiments, more than two electrodes may be utilized. Each electrode 510, 520 of the illustrated embodiment includes one or more respective fingers 514, 524 extending over substrate 530 from bus regions 516, 526 of electrodes 510, 520 located at the respective second and first end portions 424, 422 of electrode strip 366. Fingers 514, 524 may extend along the majority of the length of electrode strip 366. Fingers 514, 524 may be interlaced and spaced apart along the width of the electrode strip 366 as illustrated, to provide a controlled fixed and consistently even distance between adjacent finger portions 514, 524 of the respective first and second electrodes 510, 520 (*i.e.,* between each pole along the surface of electrode strip 366). By alternating the fingers 514, 524 of first and second electrodes 510, 520, an electrode array having increased treatment area is possible while maintaining consistently small spacing between the first and second electrodes 510, 520, which may avoid the need to increase the voltage and/or power applied for electrosurgery. Apertures 460 formed in or through substrate 530 may be regularly spaced apart in the spaces between fingers 514, 524. In some embodiments, electrode strip 366 may include one, two, three, four, five, six, or more fingers 514 of first electrode 510 spaced apart across width W of substrate 530 and the same or slightly different number of fingers 524 of second electrode 520 arranged in alternating succession. Skilled persons will appreciate that the arrangement or array of electrodes on electrode strip 366 may be realized in a multitude of different shapes, patterns, and configurations different from those illustrated herein.

[00131] Electrodes 510, 520 (including fingers 514, 524) may be formed of one or more metals deposited on substrate 530 via a printing methodology as is well known in the art of manufacturing flex circuits. Suitable metals for electrodes 510 and 520

may include copper, nickel, gold, tin, alloys, or a laminate of two or more such metals, such as a base of copper, covered by a nickel layer, and then a gold top layer to prevent corrosion and any unwanted biochemical impacts of the copper or nickel layers. Segments 532, 534 of an insulating film of polyimide, PET, or another insulating resin material may be applied over electrodes 510, 520 at the respective first and second end portions 422, 424 of electrode strip 366, and segment 534 may also cover leads 512, 522 at lead tab 428. Insulating film segments 532, 534 may facilitate securement of electrode strip 366 to electrode coiling mechanism 330, or another deployment mechanism or means, and may prevent damage to or electrical shorting between first and second electrodes 510, 520 in those regions where the electrodes 510, 520 do not need to be exposed for contact with target tissue.

[00132] In some embodiments, electrode strip 366 may be heat treated or thermoformed to provide shape memory, preferably in the coiled stowed configuration. By heat treating or thermoforming electrode strip 366 in the stowed configuration, electrode strip 366 may tend to return to the stowed position when rotational force is removed from drive shaft 370, or in the event that either of the first or second end portions 422, 424 of electrode strip 366 should become detached from first or second members 340, 360, which may facilitate removal of electrode treatment device 300 from the patient's body.

[00133] For ease of illustration, lead tab 428 and leads 512, 522 are illustrated in FIG. 9 as being relatively short in relation to the length of electrode strip portion 366. However, in some embodiments, lead tab 428 and leads 512, 522 may be made much longer, such as long enough to extend along the entirety of endoscope 320 to adjacent the operator controls for endoscope 320, or to a power supply. In other embodiments, wires may be coupled to leads 512, 522 to complete the electrical connection to a power supply.

[00134] FIG. 10 illustrates another embodiment of an electrode treatment device 600, electrode deployment system 610, and electrode coiling mechanism 630 carried by endoscope 320 and shown in an extended and deployed configuration. With reference to FIG. 10, electrode deployment system 610 is similar in configuration and operation to electrode deployment system 310 of FIGS. 4-8, except that first and second members 640 and 660 of system 610 are formed of a framework with openings 670 for purposes of allowing optical imaging system 390 visibility to an electrode strip 666 of system 610 and to the targeted tissue. In this manner, first and second

members 640, 660 need not be made of transparent material. Such a framework construction may also improve the flexibility of electrode coiling mechanism 630 along the axis of endoscope 320 which may improve maneuverability. Similarly, the first and second members 340 and 360 of system 310 of FIGS. 4-7 may be provided with a framework with openings rather than or in addition to being made of transparent material.

[00135] FIG. 11 illustrates a different embodiment of an electrode treatment device 700, including an electrode deployment system 710 supported by an endoscope 320 adjacent its distal end 328. Electrode deployment system 710 includes an electrode coiling mechanism 730 that is described below in further detail in reference to FIG. 12. Electrode coiling mechanism 730 is eccentrically offset from central axis 376 of endoscope 320 (e.g., central axis 774 of cylindrical cavity 750 of electrode coiling mechanism 730 is offset from the longitudinal central axis 376 of endoscope 320) and positioned distally of an objective lens of optical imaging system 390 to provide optical imaging system 390 with visibility to portions of the electrode deployment system 710 (e.g., electrode coiling mechanism 730), and to the outside of electrode strip 766 when in the stowed configuration illustrated in FIG. 11. Electrode deployment system 710 includes a mount section 732 to attach electrode deployment system to a distal end portion 316 of endoscope 320 in rotatably firm fashion, as described in more detail below.

[00136] FIG. 12 is a cross section view of electrode treatment device 700 taken along line 12—12 in FIG. 11. With reference to FIG. 12, electrode coiling mechanism 730 includes an outer first member 740 that is non-rotatable relative to mount section 732 and may be integrally formed therewith of a unitary one-piece construction. Mount section 732 and first member 740 may be molded of thermoplastic material, for example, or may be made of other structural materials such as metal. A spindle-shaped second member 760 (inner member) is positioned at least partially within a generally cylindrical cavity 750 formed in distal end 752 of first member 740. In other embodiments (not illustrated), cylindrical cavity 750 may be formed in a proximal end 754 of first member 740 opposite distal end 752. Cylindrical cavity 750 and second member 760 are aligned coaxially on a central axis 774. Central axis 774 is also the rotational axis of a drive shaft 770 that is operably coupled to second member 360 and offset from the longitudinal central axis 376 of endoscope 320. Drive shaft 770 extends through an opening in a proximal end of first member 740 and is fixedly coupled to

second member 760 so that rotation of drive shaft 770 directly drives second member 760 to rotate relative to first member 740 (which is rotatably fixed on endoscope 320 as described above) for deploying (expanding) and/or stowing (retracting) an electrode strip 766, as further described below. Drive shaft 770 may include a torque tube 778 covered by a sheath or insulating layer 782. Bearings 796 may be provided between first and second members 740, 760 to reduce friction therebetween during rotation of second member 760 relative to first member 740. Bearings 796 may comprise a dry sliding bearing, such as a solid polytetrafluoroethylene (PTFE) material commonly known by the trademark TEFLON, or another low friction material. In some embodiments, bearings 796 may comprise ring bearings, which may have an O-ring shape or a different shape or configuration.

[00137] The operation of electrode coiling mechanism 730 is illustrated in FIGS. 13A and 13B, which depict respective stowed and deployed configurations of the electrode coiling mechanism 730 of electrode deployment system 710 of FIGS. 11-12, and the electrode strip 766 deployed by electrode coiling mechanism 730. With reference to FIG. 13A, a first end portion 722 of electrode strip 766 is affixed, adhered or otherwise attached to an outer surface of first member 740 adjacent to a slot 744 formed therein, and a second end portion 724 of electrode strip 766 is affixed adhered or otherwise attached to an outer surface of second member 760. At least a portion of a middle portion 726 of electrode strip 766 between first and second end portions 722, 724 extends through slot 744 and is coiled around second member 760. As noted above, in reference to FIGS. 11-12, the outer first member 740 is rotationally fixed relative to endoscope 320 and the inner second member 760 is rotatable and attached to drive shaft 770 (FIGS. 11-12). From the stowed configuration of FIG. 13A, electrode strip 766 is transitioned to the laterally-extended deployed condition shown in FIG. 13B by rotating second member 760 in a first direction that is counterclockwise in the image of FIGS 13A and 13B. Counterclockwise rotation of second member 760 causes electrode strip 766 to be unwound and pushed out of slot 744. A desired stiffness of electrode strip 766 may be provided that prevents or reduces buckling of electrode strip 766 within an annular gap 746 between the first and second members 740, 760. Electrode strip 766 may rub along an inner cylindrical surface of first member 740 as it is being paid out, which creates friction due to a kind of capstan effect. Such a capstan effect is not an issue or is reduced with the electrode coiling mechanisms 330, 630 of FIGS. 4-10 in which the (outer) first members 340, 640 rotate around the (inner)

second members 360, 660. To reduce the capstan effect in the embodiments of FIGS. 11, 12, 13A, and 13B, in which the inner second member 760 rotates relative to the outer first member 740, the surface of cavity 750 (inner cylindrical surface of outer first member 740) may be coated with a lubricant, such as KRYTOX grease, or lined with PTFE tape or film, to reduce friction between the electrode strip 766 and inner cylindrical surface of outer first member 740 as electrode strip 766 is paid out). Additionally, a portion of first end portion 722 of electrode strip 766 may extend partially over slot 744 and rub against middle portion 726 of electrode strip 766 as electrode strip 766 is being deployed (uncoiled) and stowed (wound/coiled around second member 760).

[00138] In the illustrated embodiment of FIGS. 11 and 12, mount section 732 includes a collet 734 having an externally threaded tubular neck portion with longitudinal slots 736. Mount section 732 further includes an internally-threaded securement nut 738 that is threaded onto collet 734 and tightened to securely clamp and affix collet 734 of electrode deployment system 710 onto distal end portion 316 of endoscope 320. Various other mounting and clamping arrangements are also within the scope of the present disclosure. For example, mount section 732 could be slidably mounted to endoscope 320 to allow axial movement of electrode deployment system 710 relative to endoscope 320, similarly to the embodiments illustrated in FIGS. 6 and 7. In such embodiments, mount section 732 may be rotatably constrained to prevent mount section 732 and first member 740 from rotating relative to endoscope 320.

[00139] The drive shaft 770 of electrode deployment system 710 may extend alongside and immediately adjacent to the body of endoscope 320, as shown in FIGS. 11 and 12 (see also drive shaft 870 of FIG. 15) or may extend through the working channel 372 of endoscope 320 as illustrated in FIGS. 16A and 16B, described below. A guide wire 780 may extend from a soft nose cone 788 attached at a distal end of electrode coiling mechanism 730. A lead tab 728 with electrical leads extends in the proximal direction from electrode strip 766 for connection to a control system or power supply (not illustrated) of the electrode treatment device 700. A control handle 792 is connected to drive shaft 770 at a proximal end thereof for moving drive shaft relative to endoscope 320 (e.g., rotatably to move electrode strip 766 between the stowed and deployed configurations and/or axially to translate the electrode strip 766 distal or proximal relative to endoscope 320). A collar 794 is connected to a sheath around the drive shaft 770 to counter the torque applied to handle 792 and shaft 770. As described

above, in some embodiments, the handle 792 may be actuated manually by a user. In other embodiments, the handle 792 (or a different linkage or coupling at proximal end of drive shaft 770) may be coupled to an external device for actuation such as a robotically-assisted manipulator system. In yet other embodiments, manual and robotically-assisted actuation may be provided.

[00140] Electrode strip 766 is illustrated in FIGS. 13A and 13B as having four electrodes 714, which may alternate in polarity for bipolar operation in the manner described above with reference to FIG. 9, such that electrode strip 766 includes two pairs of interlaced electrode fingers. In other embodiments, electrode strip 766 can include one, two, or any number of suitable electrodes to provide for bipolar operation or monopolar operation as desired. To aid visibility via endoscope 320 (FIGS. 11-12), a series of oval slots 716 may be provided in the substrate of electrode strip 766 between adjacent pairs of electrodes 714.

[00141] FIG. 14 is a photograph taken from an optical imaging system of an electrode deployment system while inserted endoluminally into a gastrointestinal organ. The electrode deployment system of FIG. 14 has essentially the same design as the electrode deployment system 710 illustrated in FIGS. 11, 12, 13A and 13B, with its electrode coiling mechanism and electrode strip 766' mounted eccentrically offset from endoscope 320 and distally of the distal end 328 so as to avoid covering or occluding optical imaging system 390. (Note: The embodiment of FIG. 14 differs from the embodiment of FIGS. 11, 12, 13A, and 13B by the absence of oval slots 716 (FIG. 13A, 13B) in electrode strip 766'.) FIG. 14 illustrates how the exterior of the stowed electrode strip 766' and adjacent targeted tissue 786 are both within the field of view of optical imaging system 390 of endoscope 320, which may facilitate placement of electrode deployment system 710 prior to and/or during deployment and/or during electrosurgical treatment of targeted tissue 786.

[00142] FIG. 15 depicts an embodiment of an electrode treatment device 800 having an electrode deployment system 810 with an electrode coiling mechanism 830 that is similar in function to electrode coiling mechanism 730 of FIG. 12, but with an axis of rotation 874 that is angled (e.g., at a non-zero angle, oblique angle) relative to longitudinal axis 376 of endoscope 320 so that electrode coiling mechanism 830 extends distally from distal end 328 of endoscope 320 and converges toward longitudinal axis 376 (and may cross longitudinal axis 376 at a distal location, as illustrated). Angling of electrode deployment system 810 relative to endoscope 320

may make electrode treatment device 800 more maneuverable during endoluminal insertion and extraction, and particularly during navigation through tortuous regions such as the pylorus and duodenojejunal junction. Angling of electrode deployment system 810 may also aid in visibility of electrode deployment system 810 and its electrode (not illustrated) to optical imaging system 390 of endoscope 320.

[00143] Electrode deployment system 810 may include an elastomeric guide tip 844 extending distally from the distal end of electrode coiling mechanism 830. Such guide tips 844 can be incorporated in whole or in part to any of the electrode deployment systems described herein. Guide tip 844 may be made of any of various soft elastomeric materials, such as silicone, and may serve as a bumper to inhibit trauma when electrode treatment device 800 is being pushed "blindly" through gastrointestinal lumen during pink-outs (e.g., where tissue occludes the optical imaging system 390). A drive shaft 870 of electrode deployment system 810 extends proximally from electrode coiling mechanism 830 along the axis of rotation 874, but because drive shaft 870 is flexible it may be easily accommodated during insertion, maneuvering, and navigation of electrode treatment device 800 through gastrointestinal passageways.

[00144] FIG. 16A depicts an electrode treatment device 900 in accordance with another embodiment, with an electrode deployment system 910 mounted to a distal end portion of endoscope 320 and being eccentrically offset relative to a longitudinal axis 376 of endoscope 320. An electrode coiling mechanism 930 of electrode deployment system 910 is disposed distal of the distal end portion of endoscope 320 so that at least a portion of an electrode (not illustrated) of device 900 is within a field of view of optical imaging system 390 of endoscope 320. Electrode coiling mechanism 930 has an axis of rotation 940 that is substantially parallel to longitudinal axis 376 of endoscope 320. Electrode treatment device 900 may include one or more features, in whole or in part, identical or similar to the other electrode treatment devices described herein (e.g., electrode treatment devices 300, 600, 700, 800). In this embodiment, the electrode coiling mechanism 930 is driven by a drive shaft 970 that extends through the working channel 372 of endoscope 320.

[00145] FIG. 16B depicts an electrode treatment device 902 in accordance with yet another embodiment, in which an electrode deployment system 912 is mounted to a distal end portion 316 of endoscope eccentrically offset relative to longitudinal axis 376 so that at least a portion of an electrode (not illustrated) of electrode treatment device

902 is within a field of view of optical imaging system 390 of endoscope 320. An electrode coiling mechanism 932 of electrode treatment device 902 positioned distal of distal end portion 316 has an axis of rotation 942 that is angled (e.g., at a non-zero angle, oblique angle) so that electrode coiling mechanism 932 extends distally from distal end 328 of endoscope 320 and converges toward longitudinal axis 376 (and may cross longitudinal axis 376 at a distal location, as illustrated). A drive shaft 972 of electrode treatment device 902 extends through the working channel 372 (FIG. 16A) of endoscope 320 and is coupled to a rotating member of electrode deployment system 912, for example via a flexible linkage, universal joint, bevel gear arrangement, or other means capable of transmitting torque across the angle between drive shaft 972 and axis of rotation 942. Electrode treatment device 902 may include one or more features, in whole or in part, identical or similar to the other electrode treatment devices described herein (e.g., electrode treatment devices 300, 600, 700, 800).

[00146] FIGS. 17 and 18 illustrate an electrode treatment device 1000, including an electrode deployment system 1010 having an electrode coiling mechanism 1030 in which a preformed coiled electrode strip 1066 is coiled around an inflatable bladder 1040 such as an elastomeric or non-elastomeric balloon. FIG. 17 shows electrode deployment system 1010 in a contracted condition and FIG. 18 shows electrode deployment system 1010 in an expanded, partially deployed condition. With reference to FIG. 17, bladder 1040 is attached around an insufflation hose 1070, which extends alongside endoscope 320 and is supported by a mounting bracket 1032 attached at a distal end portion 316 of endoscope 320. Insufflation hose 1070 may comprise any tube capable of carrying air or another gas for inflating bladder 1040, such as a torque tube. Mounting bracket 1032 may include a tubular section 1034 abutting distal end portion 316 alongside the body 324 of endoscope 320, which may serve as a receiver socket for electrode deployment system 1010 in some embodiments. In other words, in some embodiments (not illustrated), the bladder 1040 and electrode strip 1066 may be retracted into tubular section 1034 when electrode deployment system 1010 is in a stowed configuration and extended distally of endoscope 320 when ready for expansion and deployment. A nose 1088 extends distally from bladder 1040 and may be attached to a distal end of insufflation hose 1070. A first end 1022 of electrode strip 1066 may be freely movable and unattached, so that when bladder 1040 is expanded by injecting air or another gas via insufflation hose 1070 electrode strip 1066 may uncoil freely around the expanding bladder 1040, as illustrated in FIG. 18. After

applying an electrical voltage and/or current to electrode strip 1066 to perform an electrosurgical procedure, bladder 1040 may be deflated to allow further movement or extraction of electrode treatment device. In some embodiments (not illustrated), deflation of bladder 1040 may allow electrode coiling mechanism 1030 to be retracted into tubular section 1034 of mounting bracket 1032 by retraction of insufflation hose 1070.

[00147] FIGS. 19A and 19B illustrate an alternative electrode deployment system 1110 with an inflatable bladder located within an electrode 1166 in the form of a flexible braided sleeve having conductive fibers. FIG. 19A shows electrode deployment system 1110 in a stowed configuration with its inflatable bladder deflated, and FIG. 19B shows electrode deployment system 1110 in a deployed configuration with its inflatable bladder inflated to expand the outer diameter of the braided sleeve electrode 1166. As shown in FIG. 19B, when the bladder is inflated, the length of the electrode 1166 shortens to accommodate for the lateral/radial expansion of the braided sleeve.

[00148] FIG. 20 depicts an electrode treatment device 1200 according to another embodiment, with an inflatable electrode deployment system 1210 mounted around a distal end portion of an endoscope 320. With reference to FIG. 20, an inflatable bladder 1240 of electrode deployment system 1210 surrounds a distal end portion 316 of endoscope 320 and an electrode 1266 of electrode deployment system 1210 encircles inflatable bladder 1240. Electrode 1266 may be of the braided sleeve type illustrated in FIGS. 19A and 19B. In an alternative embodiment (not illustrated), electrode 1266 may be of the preformed coil type electrode strip illustrated in FIGS. 17-18 or an electrode array of another type. In either case, when inflatable bladder 1240 is inflated via insufflation hose 1270, electrode 1266 is expanded laterally to a deployed configuration as illustrated. Electrical wires (not illustrated) may also run through insufflation hose 1270 and connect to a conductive cap 1280 at a distal end of electrode deployment system 1210 to make a reliable electrical connection with electrode 1266. Electrode deployment system 1210 may be slidable distally along endoscope by moving insufflation hose 1270 in a distal direction to facilitate treatment of tissues located beyond distal end 328 of endoscope 320. For this purpose, the electrode deployment system 1210 may include a rigid inner tubular cylinder (not illustrated) to support inflatable bladder 1240 and prevent it from inflating/encroaching

inwardly when electrode deployment system 1210 is moved distally of distal end 328 of endoscope 320.

[00149] FIGS. 21A and 21B depict an electrode treatment device 1300 according to yet another embodiment, with an electrode strip 1366 of electrode treatment device 1300 shown in respective stowed and deployed configurations. FIG. 21C is a longitudinal section view of an electrode deployment system 1310 of electrode treatment device 1300. As illustrated in FIGS. 22-25, electrode deployment system 1310 is attachable to an endoscope 320. With reference to FIGS. 22-24 and as described in more detail below, the electrode deployment system 1310 may be disposed distally of a distal end 328 of endoscope 320 and distally of an objective lens 392 of optical imaging system 390 that is proximate distal end 328, so that electrode deployment system 1310 is within a field of view of optical imaging system 390.

[00150] With reference to FIGS. 21A-21C together, the electrode deployment system 1310 includes an actuatable electrode coiling mechanism 1330 that moves a flexible electrode, such as electrode strip 1366, from a stowed configuration (FIG. 21A) to a deployed configuration (FIG. 21B), and vice-versa, wherein electrode strip 1366 is expanded in the deployed configuration relative to the stowed configuration. Electrode deployment system 1310 may be powered or otherwise driven to transition the electrode strip 1366 between the stowed configuration and the deployed configuration. When attached to an endoscope, the electrode deployment system 1310 and electrode coiling mechanism 1330 remain attached to the endoscope (e.g., the endoscope 320) as illustrated in FIGS. 22-23. Electrode strip 1366 may comprise a flexible printed circuit, as previously described above with respect to electrode strip 366. In some embodiments, at least a portion of electrode strip 1366 may be made of a transparent or translucent flexible material as described above. In other embodiments, electrode strip 1366 may optionally be provided with slot-shaped apertures 1356 cut through the flexible printed circuit to provide the optical imaging system 390 with better visibility to a tissue treatment site (not illustrated) outside of electrode strip 1366 when electrode strip 1366 is in the deployed configuration.

[00151] With reference to FIG. 21C, an actuation element 1314 (e.g., one or more electric motors, coil spring motors, hydraulic rotary actuators, pneumatic rotatory actuators, other motors or powered drive devices, gears, pistons, rotatable shafts, etc.) of electrode deployment system 1310 may be at least partially contained within a housing 1316 of electrode deployment system 1310, and electrode strip 1366 may be

at least partially coiled around and/or within housing 1316 when in the stowed configuration. Locating or positioning the actuation element 1314 (e.g., in particular a motor of an actuator) at least partially within the housing 1316 and electrode strip 1366, rather than at or near a proximal end portion 1304 of control shaft 1370, may provide a user or system (e.g., robotically-assisted or actuated) with more accurate or useful data including one or more of: current, torque, opening distance (e.g., of electrode strip 1366) for improved operation and/or treatment with electrode treatment system 1310 as described below (e.g., sufficient desired tissue apposition). Housing 1316 includes a first member 1340 (outer member) and a second member 1360 (inner member), with second member 1360 being disposed at least partially within a cylindrical cavity 1350 in first member 1340.

[00152] In the embodiment illustrated, a proximal end portion 1354 of first member 1340 is attached to a distal end portion 1372 of a control shaft 1370, for example by securely press-fitting, welding, fastening or otherwise securely affixing first member 1340 to control shaft 1370 so as to prevent first member 1340 from rotating relative to control shaft 1370. Control shaft 1370 may be, for example, a torque tube or other type of shaft or tube that can provide sufficient torsional and bending stiffness to furl and unfurl electrode strip 1366 and position electrode deployment system 1310 in a targeted position through tortuous anatomy as described in more detail below. Further, as discussed below, control shaft 1370 may be translatable or slidable to allow an operator to move electrode deployment system 1310 rotationally, distally, and/or proximally—*e.g.*, by manipulating a handle 1392 of electrode treatment device 1300 that is attached to a proximal end portion 1304 of control shaft 1370 (FIGS. 22-25), or by operating a robotically-assisted manipulator system attached to proximal end portion 1304 of control shaft 1370 and/or the handle 1392 as described above with respect to electrode treatment device 300. Actuation element 1314 is operably interposed between the first and second members 1340, 1360, for example by securing a first end 1318 of actuation element 1314 to first member 1340 and coupling the second member 1360 to an output shaft 1334 of actuation element (which is opposite first end 1318), so that the operation of actuation element 1314 rotates second member 1360 within cavity 1350 about a central axis 1374 relative to control shaft 1370 and first member 1340 for furling and unfurling of electrode strip 1366, as further described below.

[00153] Optionally, bearings 1376, such as a pair of PTFE O-rings as illustrated, may be interposed between first member 1340 and second member 1360, for example encircling proximal and distal ends of second member 1360, as illustrated. Bearings 1376 reduce friction between first and second members 1340, 1360 during operation of actuation element 1314 for deployment and transition of electrode strip 1366. Bearings 1376 also maintain second member 1360 centered within cylindrical cavity 1350 of first member 1340 and may provide a seal that inhibits or prevents fluids (e.g., from a patient's body) from reaching actuation element 1314.

[00154] Proximal end portion 1354 of first member 1340 may be necked for strength and to provide additional surface area for attachment to control shaft 1370 where it is press fit into an attachment hole 1308 in proximal end portion 1354. The necked attachment hole 1308 concentric with first member 1340 in the illustrated embodiment; and because working channel 372 is eccentric of longitudinal axis 376 of endoscope 320, the electrode deployment system 1310 is thus mounted to endoscope 320 eccentrically of distal end 328. Control shaft 1370 may be hollow to accommodate electrical wires 1380 or other control elements, as further described below, and may have a length in the range of 1 to 3 meters (m) or preferably approximately 1.8 m. Control shaft 1370 is preferably tubular, has sufficient torsional rigidity to support the delivery of torque to second member 1360, and is preferably sufficiently flexible/bendable to allow electrode deployment system to be displaced laterally during endoluminal navigation but stiff enough to retain shape, thereby facilitating maneuverability and navigation in gastrointestinal regions, the duodenum, and particularly at the pylorus and duodenojejunal junction. For example, control shaft 1370 may have a bending stiffness (flexural rigidity) in the range of 0.01 pound·inch^2 (lb·in^2) to 10 lb·in^2 (2.87×10^{-5} N·m^2 to 0.0287 N·m^2), and a ratio between absolute input rotation (from rest) to resultant output rotation at the distal end of a 1.8 m long control shaft 1370 in the range of between 10:1 and 1:1.

[00155] In some embodiments (not illustrated), the attachment hole 1308 in proximal end portion 1354 of first member 1340 maybe eccentrically offset, allowing the lateral position of electrode coiling mechanism 1330 to be adjusted relative to longitudinal axis 376 of endoscope 320 through manual or robotically-assisted rotation of control shaft 1370. For example, attachment hole 1308 may be offset eccentrically a sufficient distance from central axis 1374 such that electrode coiling mechanism 1330 can be aligned with longitudinal axis 376 of endoscope 320, which may facilitate endoluminal

navigation. In alternative embodiments, such as the embodiments described below with reference to FIGS. 26-46, control shaft 1370 is fixedly attached to second member 1360 such that first member 1340 is rotatable around and relative to control shaft 1370 and second member 1360. In some embodiments, actuation element 1314 may be directly attached to control shaft 1370 and may be connected to one or both of first and second members 1340, 1360, for example via a gear assembly, so that one or both of the first and second members 1340, 1360 are rotatable relative to control shaft 1370. In still other embodiments (not illustrated), attachment hole 1308 may be positioned or disposed at an oblique angle relative to longitudinal axis 376 so that electrode coiling mechanism 1330 and its axis of rotation (coincident with central axis 1374) are angled relative to longitudinal axis 376 of endoscope 320 in a manner similar to the embodiments illustrated in FIGS. 15 and 16B.

[00156] First member 1340 overlaps second member 1360 in an axially-overlapping region 1362 around which electrode strip 1366 is coiled. The first and second members 1340, 1360 are configured and arranged to form an annular gap 1346 between the first and second members 1340, 1360 in the axially-overlapping region 1362. At least a portion of electrode strip 1366 is coiled in the annular gap 1346 when in the stowed configuration. A first end portion 1322 of electrode strip 1366 is securely attached to an outer surface 1320 of first member 1340 adjacent a slot 1344 that extends longitudinally through first member 1340 in the axially-overlapping region 1362. A second end portion 1324 of electrode strip 1366 is securely attached to second member 1360. And a middle portion 1326 of electrode strip 1366 between the first and second end portions 1322, 1324 is uncoiled and paid out from the annular gap 1346 through slot 1344 when actuation element 1314 is operated, to thereby expand the arrangement of electrode strip 1366 so as to form a loop (or near-loop) around electrode coiling mechanism 1330 in the deployed configuration, as illustrated in FIG. 21B. In the embodiment illustrated, a first portion of electrode strip 1366 including second end portion 1324 is coiled around second member 1360 and a second portion of electrode strip 1366 including first end portion 1322 extends partially around first member 1340. To reduce the capstan effect described above with reference to FIGS. 13A and 13B, an inner cylindrical surface of first member 1340 may be lined with PTFE tape or film, or coated with coated with a lubricant, such as KRYTOX grease. In other embodiments (not illustrated), electrode strip 1366 may be coiled at least in part around first member 1340 or may be coiled around both of the first and second

members 1340, 1360. First end portion 1322 may partially or fully overlap slot 1344 in the same manner as illustrated in FIGS. 13A and 13B.

[00157] In the embodiment illustrated, actuation element 1314 is positioned within the first member 1340 and partially within the second member 1360. Thus, in embodiments when the electrode deployment system 1310 is attached to an endoscope 320 (FIGS. 22-25), actuation element 1314 is disposed distally of distal end 328, objective lens 392, and optical imaging system 390 of endoscope 320, and electrode strip 1366 is coiled around actuation element 1314. Other configurations may be possible: for example, in which actuation element 1314 is positioned at least partially within first member 1340 and outside of second member 1360, or in which actuation element 1314 is positioned at least partially within second member 1360 but outside of first member 1340 (or at least outside of cavity 1350). An electric motor of actuation element 1314 may have an outer diameter of approximately 6 to 8 mm and an internal gearbox having a gear ratio in the range of approximately 100:1 to 1000:1, or more preferably between approximately 550:1 and 700:1, for example. In some embodiments, actuation element 1314 may comprise a brushless DC motor including position encoding of the output shaft 1334 for control of electrode deployment. In still other embodiments (not illustrated), actuation element 1314 may include a miniaturized DC motor seated in control shaft 1370 and only the output shaft of the motor may extend beyond control shaft 1370 and distal end 328 of endoscope 320.

[00158] In the embodiment illustrated, actuation element 1314 is directly connected to first and second members 1340, 1360, with the output shaft 1334 of actuation element 1314 keyed to a hole 1336 in distal end portion 1338 of second member 1360, and optionally cemented or otherwise securely coupled thereto. In other embodiments, output shaft 1334 may be coupled to one or both of first and second members 1340, 1360 via a mechanical power transmission device, such as a belt or gear assembly. A cap 1332 is attached to a distal end portion 1352 of first member 1340 and includes an axial hole 1342 that rotatably supports second end portion 1338 for rotation therein.

[00159] Electrode strip 1366 may include a single electrode for monopolar operation or two electrodes for bipolar operation, or more than two electrodes, as described above with reference to FIG. 9, describing electrodes 510, 520 of electrode strip 366. The flexible printed circuit including electrode strip 1366 may further include a lead tab 1328 connected to and extending longitudinally from electrode strip 1366. Lead tab 1328 may extend into a pocket 1358 in proximal end portion 1354 of first member 1340

and may terminate in an electrical connector assembly 1382 to facilitate electrical connection of lead tab 1328 to one or more of the wires 1380 that extend through control shaft 1370. Electrical connector assembly 1382 may include a first connector 1384 attached to lead tab 1328 and configured to mate with a second connector 1386 attached to one or more wires 1380. In other embodiments, wires 1380 may be directly connected to lead tab 1328, for example by solder joints. The arrangement of pocket 1358 with an opening allows lead tab 1328 to be connected to wires 1380 outside of pocket 1358 (e.g., using electrical connector assembly 1386 or by directly connecting to wires) during manufacture of electrode deployment system 1310, followed by placing lead tab 1328 (and electrical connector assembly 1386, if any) into pocket 1358 and then threading wires 1380 through control shaft 1370. Additional wires 1380 extending through control shaft 1370 may be connected directly or indirectly to actuation element 1314 for operating actuation element 1314 as further described below. After assembly of electrode deployment system 1310 and connection of wires 1380 to actuation element 1314 (e.g., with electrical connector assembly 1382), pocket 1358 may be filled with resin or sealant to prevent fluids from reaching electrical connector assembly 1382 and actuation element 1314. Wires 1380 are connected at the proximal end portion 1304 of control shaft 1370 to a controller (such as controller 14 of FIG. 1 or control system 112 of FIG. 2) and a power supply of the system (e.g., power supply 12 in FIG. 1), either directly or indirectly. The controller and/or power supply provides energy to electrode strip 1366 for electrosurgical tissue treatment, such as electrolysis or electroporation, and/or senses an electro-physical condition of the tissue. The controller and/or power supply may also provide power for operating actuation element 1314. Alternatively, a separate second controller and second power supply may provide power for actuation element 1314.

[00160] As illustrated in FIGS. 22-25, electrode deployment system 1310 may be attached to endoscope 320 by control shaft 1370, which extends through working channel 372 of endoscope 320. Control shaft 1370 may be slidable within working channel 372 to allow an operator to move electrode deployment system 1310 rotationally, distally, and/or proximally relative to endoscope 320—either by manipulating a handle 1392 of electrode treatment device 1300 that is attached to a proximal end portion 1304 of control shaft 1370, or by operating a robotically-assisted manipulator system attached to proximal end portion 1304 of control shaft 1370 and/or the handle 1392 as described above with respect to electrode treatment device 300.

In other embodiments (not illustrated), electrode deployment system 1310 may be attached to endoscope 320 by attaching control shaft 1370 to a side of endoscope (similarly to how insufflation hose 1070 is mounted in the embodiment of FIGS. 17 and 18). In still other embodiments, electrode deployment system 1310 may be provided separate from endoscope 320 and used in conjunction therewith, mounted to endoscope 320, and/or both (e.g., separate, but used in conjunction therewith for certain procedures and mounted to endoscope for other procedures).

[00161] Turning to FIG. 25, wires 1380 that extend through control shaft 1370 are connected near or in proximal end portion 1304 of control shaft to an electrical connector 1390, which may be attached to proximal end portion 1304. Electrical connector 1390 may comprise a phone connector (also known as a headphone jack), such as a sub-miniature phone connector, for example a 4-conductor 2.5mm diameter TRRS phone connector plug. Axial mounting of sub-miniature electrical connector 1390 to control shaft 1370 enables control shaft 1370 to be installed and loaded into working channel 372 from distal end 328 of endoscope 320 (*e.g.,* in a distal to proximal direction). In other embodiments (not illustrated), a nano circular connector or other non-coaxial connector may be used for electrical connector 1390. After control shaft 1370 is slidably loaded into working channel 372, electrical connector 1390 is plugged into a control system (not illustrated) which controls a power supply to supply energy to actuation element 1314 and electrode strip 1366. The control system may be part of or adjacent to a robotically-assisted manipulator system. Because electrical connector 1390 is located at proximal end portion 1304 of control shaft 1370, when electrode treatment device 1300 is used with a robotically-assisted manipulation system, the mating socket connector of a controller (to which electrical connector 1390 is connected) need not be sterile. In some embodiments, handle 1392 is attached to control shaft 1370 before a cable of the controller is connected to the electrical connector 1390. An opening 1394 is provided in handle 1392 to allow a mating socket connector (not illustrated) on the cable to be coupled to electrical connector 1390.

[00162] Electrode treatment device 1300 may further or alternatively include one or more features, in whole or in part, identical or similar to the other electrode treatment devices described herein (e.g., electrode treatment devices 300, 600, 700, 800, 900, 902, 1000, 1200, 1400, 1400', 1400a-c, 1600, 1600' 2000, 2100, 2200, 2300, and 2400).

[00163] Accordingly, a method of deploying an electrode may include the steps of: (1) loading electrode treatment device 1300 onto endoscope 320 by: (a) inserting control shaft 1370 into working channel 372 via an opening at distal end 328 of endoscope 320 and (b) sliding the control shaft 1370 through working channel 372 (e.g., in a distal to proximal direction) until control shaft 1370 extends beyond a proximal end 1306 (FIG. 21) of endoscope 320 and electrode deployment device 1310 is positioned distally adjacent the distal end 328; then (b) electrically connecting a power supply to the proximal end portion 1304 of control shaft 1370, for example by joining electrical connector 1390 to a mating electrical socket connector of a controller which is connected to the power supply. Once connected, electrode deployment device 1310 may be operated to move electrode strip 1366 between the stowed and deployed configurations as described above with reference to FIGS. 21 and 22. To facilitate insertion of control shaft 1370 into a typical endoscope 320 and sliding through working channel 372, control shaft may have an outer diameter of between 2.5 mm and 4.0 mm, or more preferably approximately 2.7 mm (+/- 0.1 mm).

[00164] A method of deploying an electrode may also involve an automatic or semi-automatic method of controlling the transitioning of the electrode strip 1366 from the stowed configuration to the deployed configuration. In a first step, actuation element 1314 is initially activated, for example by an activation signal generated by a user depressing a control button (*e.g.,* with a short press). Once initially activated, the actuation element 1314 uncoils or otherwise unfurls the electrode strip 1366. While actuation element 1314 operates to unfurl electrode strip 1366, the controller (e.g., controller 14 of FIG. 1 or control system 112 of FIG. 2) senses and monitors an electrical current supplied to actuation element 1314. When electrode strip comes into apposition with tissue, a greater load is generated at actuation element 1314 which increases the electrical current drawn by actuation element 1314. The controller senses the electrical current supplied to actuation element 1314 and automatically switches off the electrical current (*i.e.,* switches off the power to an electrical motor of actuation element 1314) when the electrical current drawn by actuation element 1314 exceeds a predetermined threshold indicative of apposition with tissue. Monitoring the elapsed time and/or a visual observation may also be used in combination or in addition to sensing the current, to determine when to switch off the electrical current to achieve a targeted or desired apposition force or pressure against targeted tissue, and/or as a safety mechanism (e.g., over-unfurling of electrode strip 1366). Thus,

methods according to the present disclosure may automatically halt the unfurling of the electrode strip 1366. After the initial unfurling is halted, the user may further depress the control button one or more times (for example, with short presses identical to the short press utilized in the initial activation and deployment sequence) and, with each further short press of the button, to generate a stepping signal that selectively activates actuation element 1314 for a predetermined interval to further unfurl electrode strip 1366 in a stepwise manner until sufficient apposition with targeted tissue is confirmed by visual observation through endoscope 320 or otherwise. The initial activation signal and stepping signal(s) may be identical. The steps of activating the actuation element 1314 and further activating the actuation element 1314 stepwise will both cause the actuation element 1314 to operate in a first direction.

[00165] After deployment, electrical energy may be applied to electrode strip 1366 to perform a treatment or sensing operation on the targeted tissue. After treatment or sensing of tissue, the electrode strip 1366 may be returned to the stowed configuration by activating the actuation element 1314 in a second direction opposite the first direction to coil or otherwise furl the electrode strip 1366. The actuation element 1314 may be activated in the second direction at any time for retracting electrode strip 1366, by sending a stowage signal to the controller. The stowage signal may be generated by a user pressing the button for a long press (significantly different and longer than the short press), or by some other control means or methods, for example by a computerized response to an unsafe condition. For safety reasons, the stowage signal and operation in the second direction can be initiated at any time, including during the initial activation or subsequent stepping of motor in the first direction.

[00166] Methods of deployment and operation of electrode treatment device 1300 may further include many other optional steps and processes which will be appreciated by those of skill in the art.

[00167] Turning now to FIGS. 26-29B, another embodiment of an electrode treatment device 1400 includes an electrode deployment system 1410 with an actuation element 1414 (*e.g.,* one or more electric motors, coil spring motors, hydraulic rotary actuators, pneumatic rotatory actuators, other motors or powered drive devices, gears, pistons, rotatable shafts, etc.) positioned at least partially within an electrode coiling mechanism 1430 including a first member (outer member) 1440 that is arranged for rotation around a second member (inner member) 1460 that is fixed to a control shaft 1470 (*e.g.,* in contrast to the electrode coiling mechanism 1330).

[00168] With reference to FIGS. 27 and 28, the actuatable electrode coiling mechanism 1430 moves a flexible electrode, such as electrode strip 1466, from a stowed configuration (illustrated in FIGS. 26 and 27) to a deployed configuration (not shown, but see FIG. 21B), and vice-versa, wherein electrode strip 1466 is expanded in the deployed configuration relative to the stowed configuration. Electrode deployment system 1410 may be powered or otherwise driven to transition the electrode strip 1466 between the stowed configuration and the deployed configuration. Electrode strip 1466 may have one or more of any of the features described above with reference to electrode strip 1366 of FIGS. 9 and 22-24 or described below with reference to electrode strip 2466 of FIGS. 49-51; and actuation element 1414 may have one or more of any of the features of actuation element 1314 described above with reference to FIG. 21C. A housing 1416 includes first member 1440 and second member 1460, with the second member 1460 being disposed at least partially within a cylindrical cavity 1450 in first member 1440.

[00169] A proximal end portion 1454 of second member 1460 is attached to a distal end portion 1472 of control shaft 1470, for example by securely press-fitting, welding, fastening or otherwise securely affixing second member 1460 to the control shaft 1470 so as to prevent second member 1460 from rotating relative to control shaft 1470 (*e.g.,* such that the second member 1460 is rotatably fixed in position relative to the first member 1440 and control shaft 1470). In an embodiment illustrated in an exploded view in FIG. 41A, further described below, distal end portion 1472 of control shaft 1470, or of a flex shaft threaded therethrough, includes a key 1404 that mates with a corresponding keyway 1406 in proximal end portion 1454 of second member 1460, thereby facilitating the transfer of torque from control shaft 1470 (or a flex shaft threaded therethrough) to second member 1460. Control shaft 1470 is also securely connected to a shroud 1412 or boot (illustrated in broken lines in FIG. 26) of electrode treatment device 1410, for example by press fitting. Control shaft 1470 may be, for example, a torque tube or other type of shaft or tube. Control shaft 1470 may be translatable or slidable to allow an operator to move electrode deployment system 1410 rotationally, distally, and/or proximally—*e.g.*, by manipulating a handle of electrode treatment device 1400 that is attached to a proximal end portion of control shaft 1470, or by operating a robotically-assisted manipulator system attached to the proximal end portion of control shaft 1470 and/or the handle, as described above with respect to electrode treatment devices 300 and

1300. Control shaft 1470 may be hollow to accommodate electrical wires 1480 or other control elements, and may have one or more of any of the other features and characteristics described above with reference to control shaft 1370 of FIGS. 21C and 22-24. Similarly, wires 1480 may have the one or more of the same characteristics, functions, and purposes as wires 1380 of the embodiment of FIGS. 21C and 22-24 (*e.g.,* to couple electrode strip 1466 and/or actuation element 1414 to one or more controllers and/or power supplies to provide energy to electrode strip 1466 for electrosurgical tissue treatment, such as electrolysis or electroporation, and/or sense an electro-physical condition of the tissue and/or provide power for operating actuation element 1414).

[00170] As in the embodiments of electrode deployment system 1310 of FIGS. 22-24, electrode deployment system 1410 of FIGS. 25-29 is attachable to an endoscope 320. Upon attachment to the endoscope 320, the electrode deployment system 1410 is disposed distally of a distal end 328 of endoscope 320 and distally of an objective lens (392 in FIG. 24) that is proximate distal end 328, so that electrode deployment system 1410 is within a field of view of an optical imaging system (e.g., 109 in FIG. 2, and 390 in FIG. 24) or a visualization system (e.g., 231 in FIG. 3A) of the endoscope 320.

[00171] Electrode deployment system 1410 may be attached to endoscope 320 by threading control shaft 1470 through a working channel 372 of endoscope 320 in a manner similar to as described above with reference to FIGS. 22-25 (*e.g.,* in a distal to proximal direction), which provides the same or similar functionality as described above. In other embodiments, electrode deployment system 1410 may be attached to a side of endoscope 320. In still other embodiments, electrode deployment system 1410 may be provided separate from endoscope 320 and used in conjunction therewith, mounted to endoscope 320, and/or both (*e.g.,* separate, but used in conjunction therewith for certain procedures and mounted to endoscope for other procedures).

[00172] Actuation element 1414 is operably interposed between the first and second members 1440, 1460, for example by securing a first end 1418 of actuation element 1414 to second member 1460 and coupling an output shaft 1434 of actuation element (which is opposite first end 1418) to the first member 1440, so that the operation of actuation element 1414 rotates first member 1440 about a central axis 1474 relative to control shaft 1470, second member 1460, and shroud 1412, for furling and unfurling

of electrode strip 1466, as further described below. Output shaft 1434 may be coupled to first member 1440 via a gearset 1550 (or gear train) or other coupling, as described below with reference to FIGS. 28-30.

[00173] As with the embodiment of FIGS. 22-24, first member 1440 of the embodiment of FIGS. 26-28 overlaps second member 1460 in an axially-overlapping region 1462 around which electrode strip 1466 is coiled. The first and second members 1440, 1460 are configured and arranged to form an annular gap 1446 between the first and second members 1440, 1460 in the axially-overlapping region 1462. At least a portion of electrode strip 1466 is coiled in the annular gap 1446 when in the stowed configuration. A first end portion 1422 of electrode strip 1466 is securely attached to an outer surface 1420 of first member 1440 adjacent a slot 1444 that extends longitudinally through first member 1440 in the axially-overlapping region 1462. A second end portion 1424 of electrode strip 1466 is securely attached to second member 1460. And a middle portion 1426 of electrode strip 1466 between the first and second end portions 1422, 1424 is uncoiled and paid out from the annular gap 1446 through slot 1444 when actuation element 1414 is operated, to thereby expand the arrangement of electrode strip 1466 so as to form a loop (or near-loop) around electrode coiling mechanism 1430 in the deployed configuration. In the embodiment illustrated in FIGS. 26-28, a first portion of electrode strip 1466 including second end portion 1424 is coiled around second member 1460 and a second portion of electrode strip 1466 including first end portion 1422 extends partially around first member 1440. To reduce the capstan effect described above with reference to FIGS. 13A and 13B, an inner cylindrical surface of first member 1440 may be lined with a sleeve 1448 or film of PTFE or another low friction material, or coated with coated with a lubricant, such as KRYTOX grease. First end portion 1422 may partially or fully overlap slot 1444 in the same manner as illustrated in FIGS. 13A and 13B.

[00174] Electrode strip 1466 may include a single electrode for monopolar operation or two electrodes for bipolar operation, or more than two electrodes, and may have the same characteristics or features as described above with reference to electrode strip 1366 of FIGS. 22-24 or electrode strip 366 of FIG. 9.

[00175] Bearings 1476, such as a pair of PTFE O-rings as illustrated, may be interposed between first member 1440 and second member 1460, for example encircling proximal and distal ends of second member 1460, as illustrated. Each of

the bearings 1476 may be seated in a retainer, such as an annular recess 1478 (FIG. 37) formed in either an outer surface of second member 1460 (as illustrated in FIG. 27) or an inner surface of first member 1440 (not illustrated). Bearings 1476 reduce friction between first and second members 1440, 1460 during operation of actuation element 1414 for deployment and transition of electrode strip 1466. Bearings 1476 may also allow first member 1440 to rotate relative to second member 1460. Bearings 1476 also maintain second member 1460 centered within cylindrical cavity 1450 of first member 1440 and may provide a seal that inhibits or prevents fluids (e.g., from a patient's body) from reaching actuation element 1414. A further O-ring seal 1488 may create a fluid seal between the gearset 1550 and first member 1440 when in the position illustrated in FIG. 27. O-ring seal 1488 may be seated in an annular groove 1468 (FIGS. 28-29) formed in a component of the gearset 1550 to help retain second member 1460 adjacent a distal end portion 1452 of first member 1440 during normal operation.

[00176] With reference to FIGS. 27, 28 and 40, a cap 1432 is attached to a distal end portion 1452 of first member 1440, for example, by cementing, welding, or otherwise removably or fixedly securing the cap 1432 against the distal end portion 1452. Cap 1432 may include an axially-centered aperture 1442 (FIGS. 27 and 40). When cap 1432 is attached to distal end portion 1452 of first member 1440, a retaining groove 1428 (FIG. 27) is formed therebetween in which the O-ring seal 1488 is partially received or seated. As best illustrated in FIG. 40, cap 1432 and distal end portion 1452 may include keying features that mate together during assembly to ensure proper alignment. For example, cap 1432 may include one or more keying tabs 1456 (two in the embodiment shown) that each slidably mates with a corresponding keying slot 1458 formed on distal end portion 1452 of first member; and distal end portion 1452 may include one or more keying pins 1482 (two in the embodiment shown) that each slidably inserts into a corresponding keying hole 1484 in cap 1432.

[00177] Actuation element 1414 may be positioned within or partially within the first member 1440 and within or partially within the second member 1460. Thus, in embodiments wherein the electrode deployment system 1410 is attached to an endoscope 320, actuation element 1414 is disposed distally of distal end 328 of endoscope 320, and electrode strip 1466 is coiled around actuation element 1414. Other configurations may be possible: for example, in which actuation element 1414

is positioned at least partially within first member 1440 and outside of second member 1460, or in which actuation element 1414 is positioned at least partially within second member 1460 but outside of first member 1440 (or at least outside of cavity 1450), or adjacent first and second members 1440, 1460, as is described below with reference to FIGS. 31-33. Actuation element 1414 may include an electric motor having the same characteristics as those described above with respect to the motor of actuation element 1314 of the embodiment of FIGS. 21C and 22-24.

[00178] In the embodiment illustrated in FIGS. 27-29, actuation element 1414 is positioned within second member 1460 and secured thereto, for example, by cementing or with a potting material 1496. The output shaft 1434 of actuation element 1414 extends in the distal direction through an opening 1436 (FIG. 37) at the distal end portion 1438 of second member 1460 and engages the gearset 1550, which will now be described.

[00179] In the embodiment illustrated in FIGS. 27, 28, 29A and 29B, and with particular reference to FIGS. 28, 29A, and 29B, gearset 1550 comprises an epicyclic gear train in the form of a planetary gearset including a sun gear 1560 affixed to output shaft 1434 of the electric motor of actuation element 1414 and a plurality of planet gears 1570 carried on second member 1460 and meshed with the sun gear 1560. The planet gears 1570 are also meshed with a ring gear 1580 that is formed on an inner annular surface of the distal end portion 1452 of first member 1440 and encircles the set of sun and planet gears. Output shaft 1434 may be keyed to a hole 1562 in sun gear 1560 for torque transfer without slippage. For example, output shaft 1434 and hole 1562 may both have a D-shaped cross section. Hole 1562 may extend entirely through sun gear 1560 and may be axially longer than output shaft 1434, leaving a distal end of hole 1562 accessible at a distal end portion 1568 of sun gear 1560. Sun gear 1560 is preferably affixed to output shaft 1434, for example by press fitting, cementing or fastening, to prevent sun gear 1560 from sliding off output shaft 1434. In the example illustrated, gearset 1550 includes five planet gears 1570, each mounted on an axle pin 1572 that is secured into one of a series of holes or grooves 1574 (FIGS. 28, 37) formed in distal end portion 1438 of second member 1460. However, in other embodiments a larger or smaller number of planet gears 1570 may be used, depending on the desired gear reduction ratio. Sun gear 1560 may include a flange 1564 or other retention feature that retains planet gears 1570 on pins 1572 and on second member 1460. Sun gear 1560 may also include an annular groove 1468 into

which O-ring seal 1488 (FIG. 27) is normally seated. Rotation of output shaft 1434 causes sun gear 1560 to rotate relative to second member 1460, but because planet gears 1570 are carried by pins 1572 affixed to second member 1460 the planet gears 1570 do not orbit or revolve around sun gear 1560. Instead, the rotation of planet gears 1570 and their engagement with ring gear 1580 cause first member 1440 to rotate around second member 1460.

[00180] The gear reduction provided by gearset 1550 slows the unfurling and furling of electrode strip 1466 between the stowed and deployed conditions, decreases the load on actuation element 1414, and increases the effective output torque on first member 1440, which may provide improved control over the deployment of electrode strip 1466.

[00181] Another embodiment of an electrode treatment device 1400', illustrated in FIG. 30, is identical to the electrode treatment device 1400 of FIGS. 26-29 except that the planetary gearset 1550 is replaced by a direct drive coupling to rotatably couple the output shaft 1434 and first member 1440. For example, the planetary gearset 1550 may be replaced with a single spur gear 1550'. With reference to FIG. 30, spur gear 1550' is affixed to output shaft 1434 of actuation element 1414 and meshes with ring gear 1580 in first member 1440 via a splined structure to establish a direct-drive coupling between the output shaft 1434 and first member 1440. Spur gear 1550' is preferably affixed to output shaft 1434, for example by press fitting, cementing or fastening, to prevent spur gear 1550' from sliding off output shaft 1434.

[00182] In still other embodiments (not illustrated), output shaft 1434 may be coupled to first member 1440 via a different mechanical power transmission device, such as a drive belt or different type of gear assembly for example.

[00183] Turning now to FIGS. 31-33, the actuation element (*e.g.,* an electric motor) may be conjoined with electrode coiling mechanisms of the electrode deployment systems described herein in various ways. For example, as illustrated in FIG. 31, actuation element 1414a of electrode deployment system 1410a of electrode treatment device 1400a is positioned within electrode coiling mechanism 1430a, in the same or similar manner as with the embodiments of FIGS. 21C, 22-24, and 27-30. Alternatively, as illustrated in FIG. 32, actuation element 1414b may be positioned adjacent a proximal end portion 1408b of electrode coiling mechanism 1430b and the first and second members thereof, allowing the overall diameter of electrode treatment device 1400b to be smaller (*e.g.,* relative to electrode treatment device 1400a of FIG.

31). An output shaft 1434b of the actuation element 1414b, which is much thinner than its main body, may extend partially into or through electrode coiling mechanism 1430b to couple with first and/or second members of electrode coiling mechanism 1430b, *e.g.,* via a power transmission device such as a gearset (not illustrated), to thereby actuate an inner first member and/or an outer second member of the electrode coiling mechanism 1430b for deployment of the electrode strip 1466b. A further alternative embodiment is illustrated in FIG. 33, wherein actuation element 1414c is positioned adjacent a distal end of electrode coiling mechanism 1430c and the first and second members thereof. As with the embodiment of FIG. 32, output shaft 1434c of actuation element 1414c may extend partially into or through electrode coiling mechanism 1430c to couple with first and/or second members of electrode coiling mechanism 1430c, optionally via a power transmission device (not illustrated). The smaller diameter profile of electrode treatment devices 1400b, 1400c, relative to electrode treatment device 1400a, may improve the ability of devices 1400b and 1400c to pass through narrow cavities, passageways, or lumens in a patient to better reach some treatment locations, but at a cost of increased overall length relative to electrode treatment device 1400a, which may impact maneuverability in some cases.

[00184] In still other embodiments (not illustrated), a standalone motor or other standalone actuation element may be provided as a separate tool and carried by a second shaft that is inserted through a second working channel of a dual-channel endoscope. The standalone actuation element would be coupled with a separate unpowered electrode coiling mechanism or electrode deployment mechanism to provide motive force for deploying and retracting an electrode of the combination device. Such an arrangement may allow the overall width profile of the combination device to be greatly reduced relative to other arrangements.

[00185] FIG. 34 illustrates yet another embodiment of an electrode treatment device 1600, including an electrode deployment system 1610 optionally carried by an endoscope 320 wherein an instrument head 1602 (*e.g.,* an electrode coiling mechanism) of the electrode deployment system 1610 is positioned distally of a distal end 328 of endoscope 320. With reference to FIG. 34, an actuation element 1614 of electrode deployment system 1610 is positioned at a proximal end 1606 of electrode treatment device 1600 (*e.g.,* proximal end of the endoscope 320 or catheter tube 1670) rather than inside, adjacent, or partially inside of the instrument head 1602. This configuration creates the opportunity for size reduction of the instrument head 1602

because space is no longer needed therein for an actuation element, enabling the electrode treatment device 1600 to be used within smaller diameter anatomical structures. In this implementation, a rotational output of actuation element 1614 is transferred to an electrode coiling device 1630 at the distal instrument head 1602 of electrode deployment system 1610 by means of a flexible torque-transmitting shaft 1608 (commonly referred to as a flex shaft) that is threaded through a catheter tube 1670. These types of flexible drive shafts are commonly used in medical devices such as rotating atherectomy devices running with rotational shaft speeds in excess of 100,000 RPM, delivering substantial mechanical power to the distal end of the device. Shaft 1608 may be constructed of multiple, typically metallic, filaments helically wound in one or more layers around a central wire core or around a central wire rope core also comprised of multiple wound filaments. Alternatively, shaft 1608 could be constructed as a torque coil having a one or more filament layers wound around a central hollow lumen. In still other embodiments, shaft 1608 may comprise a flexible hypotube made of stainless steel or nitinol, which may be laser cut for improved flexibility. In the simplest case, shaft 1608 could comprise a single, solid wire, made of Nitinol for example, routed through catheter tube 1670. In yet other embodiments, a combination of different types of flex shafts may be utilized for shaft 1608, such as, for example, a hypotube with a torque coil welded onto its distal end for improved flexibility where shaft 1608 exits the distal end 328 of endoscope 320. The diameter of such solid or hollow, flexible drive shafts may range in diameter from 0.2 mm, to as much as 6mm, depending on the anatomy being treated and the torques required (*e.g.,* to deploy the electrode strip).

[00186] Actuation element 1614 may comprise a DC electric motor or other suitable motor, for example, mounted inside of a handle 1692 of electrode treatment device 1600 or as part of a robotic manipulator. Due to its placement outside of instrument head 1602, the motor of actuation element 1614 may be larger and more powerful (*e.g.,* relative to the actuation elements 1414 of the embodiments of FIGS. 21C, 22-24, and 27-30, wherein the actuation elements 1414 are positioned at least partially within the instrument head or coiling mechanism). This increased power can be delivered through higher-speed, low-torque rotation of shaft 1608, then converted to low-speed, high-torque rotation by means of a compact system of speed-reduction gearing located in the instrument head 1602.

[00187] In the embodiment illustrated in FIG. 34, the shaft 1608 drives a sun gear 1622 of a planetary gearset 1624 located inside the instrument head 1602, which is in turn coupled to first member 1640 via a ring gear 1626 formed on an inner annular surface of first member 1640. The planetary gearset 1624 may be constructed similarly to the gearset 1550 illustrated in FIGS. 27-29.

[00188] Other types of torque-increasing mechanical power transmission systems could also be utilized with actuation element 1614 and shaft 1608. For example, as illustrated in the electrode treatment device 1600' of FIG. 35, shaft 1608 may be coupled to a gearbox 1628 located within second member 1660, which engages with gearset 1624' (which may be either a direct-drive coupling or torque-reducing planetary gearset). Gearbox 1628 may be a custom set of spur gears or a packaged commercial gearbox, for example. Other types of torque-increasing gear systems could be used for gearbox 1628. Such gearing systems are well known in the art, and include worm gears, bevel gears, miter gears, strain-wave gearing, traction drives, or combinations of such gear systems.

[00189] In the embodiments illustrated in FIGS. 34 and 35, an output shaft 1634 of actuation element 1614 is directly connected to the drive shaft 1680. However, in other embodiments, the location of actuation element 1614 at proximal end 1606 of electrode treatment device 1600, 1600' may allow use of an output gearset (not illustrated) to couple output shaft 1634 to shaft 1680 and to step up the torque output by output shaft 1634, for ensuring sufficient torque is delivered to electrode coiling mechanism 1630, 1630'.

[00190] In another embodiment (not illustrated), shaft 1608 may drive rotation of first member 1640 or second member 1660 directly, so that one rotation of the shaft 1608 imparts one rotation of the first or second member. For example, shaft 1608 may be coupled to first member 1640 via a direct-drive coupling, such as the spur gear and ring gear coupling illustrated in FIG. 30.

[00191] Placing actuation element 1614 outside of instrument head 1602 and at a proximal end 1606 of electrode treatment device 1600 may also enable different types of actuation other than shaft-driven, such as hydraulic or pneumatic actuation. For example, in place of a torque-transmitting shaft 1608, power could be transmitted from actuation element 1614 to electrode coiling mechanism 1630 via a fluid charge within catheter tube 1670 (with shaft 1608 omitted). In such embodiments, the fluid would be pumped or its pressure otherwise controlled via actuation element 1614 and converted

to mechanical drive force via a hydraulic or pneumatic power transmission element at electrode coiling mechanism 1630.

[00192] FIGS. 36-39 illustrate details of second member 1460 and electrode strip 1466 for facilitating secure attachment of second end portion 1424 of electrode strip 1466 to second member 1460. In some embodiments, similar methods and structures as described below may be utilized for facilitating secure attachment of first end portion 1422 of electrode strip 1466 to first member 1440. With reference to FIG. 36, an outer surface of second member 1460 may include an anchoring surface 1702. Anchoring surface may include an array or pattern of dimples 1704, which may be molded into the anchoring surface 1702. The dimples 1704 or other texturing on anchoring surface 1702 may improve adhesion of an adhesive material or other substrate material that secures second end portion 1424 of electrode strip 1466 to second member 1460 in some embodiments, as further described below. In other embodiments, second end portion 1424 of electrode strip 1466 may be secured to anchoring surface 1702 by heat staking, ultrasonic welding, laser welding, overmolding, or another method. Anchoring surface 1702 may be bordered by a rib or shelf 1708 for aligning an edge of second end portion 1424 with second member 1460 during assembly.

[00193] Retention slots 1712, 1714 formed at the respective proximal and distal end portions 1454,1438 of second member 1460 may adjoin the anchoring surface 1702. One or more of the retention slots 1712, 1714 may be a closed slot (as illustrated by retention slot 1714) and one or more of retention slots 1712, 1714 may be an open slot (as illustrated by retention slot 1712). Retention tabs 1722, 1724 are sized to fit in the respective retention slots 1712, 1714 when attaching electrode strip to second member 1460, as illustrated in FIG. 38, for improved mechanical coupling and retention during unfurling and furling of electrode strip 1466. Electrode contact pads 1730 for each of the electrodes of electrode strip 1466 may be positioned on or over the proximal one of the retention tabs 1724 and staggered to prevent shorting of electrical connections made thereto, e.g., by soldering, electrical connectors, or another means for electrical connection of wires or other electrical conductors.

[00194] In some embodiments, electrode strip 1466 may be secured to anchoring surface 1702 by an adhesive material, such as epoxy or other resin for example, and the dimples 1704 or other texture on anchoring surface 1702 may improve adhesion and shear strength of the adhesive connection. Similarly, an inwardly-facing bottom surface 1746 of second end portion 1424 of electrode strip 1466 may be textured for

improved adhesion, *e.g.,* by molding, punching holes, laser etching, chemical etching, or grit blasting of bottom surface 1746, as depicted in FIG. 39. Injection ports 1750 may be provided in second member 1460 for injecting an adhesive material or other substrate material, or a component of a multi-component adhesive or substrate material such as epoxy, to the interface between bottom surface 1746 and anchoring surface 1702. Injection ports 1750, 1752 may allow delivery of adhesive or other substrate after proper assembly and alignment of electrode strip 1466 on second member 1460, thereby allowing additional time for assembly and alignment of components before the application of adhesive or other fast-curing substrate materials, as well as allowing additional time for final assembly after application of the adhesive or other substrate material. Injection ports 1750, 1752 may also allow some components of electrode deployment system 1410 to be sealed off from others; may allow for a more targeted and consistent dispensing of adhesive or other substrate material; and may prevent excess adhesive or other substrate material from being expelled or transferred from the anchoring surface 1702 onto other adjacent surfaces. An access opening 1756 may be located on an opposite side of second member 1460 from injection port 1750 to allow an injector spout of an adhesive applicator (not shown) to be inserted therethrough to reach injection port 1750 from inside of second member 1460. Injection ports 1750, 1752 and access opening 1756 may also allow for targeted dispensing of a lubricating grease during assembly of electrode deployment system 1410.

[00195] With reference to FIGS. 41A and 41B, control shaft 1470 may include a key 1404 at its distal end portion 1472. The key 1404 is sized to fit through a keyway 1406 in the proximal end portion 1454 of second member 1460. The control shaft 1470 is coupled to second member 1460 by first inserting control shaft 1470 into second member 1460 by inserting key 1404 through completely keyway 1406, and then rotating control shaft 1470 to offset key 1404 rotationally relative to keyway. With reference to FIG. 41B, a notch 1486 is formed in an end wall inner surface 1490 of proximal end portion 1454 and adjacent to keyway 1406. Notch 1486 is sized to receive key 1404 and includes a stop 1492 for limiting the rotation of key 1404. After the control shaft 1470 and key 1404 are rotated in place with key 1404 adjacent stop 1492, an internal cavity 1494 of second member 1470 (or proximal end portion thereof) can be filled with a resin, adhesive, or other curable substance (not illustrated) to secure the control shaft 1470 to second member 1460 with key 1404 seated in notch

1486. The keyway 1406 may also be filled with resin or other curable substance. The resin or other curable substance can be injected, for example via access opening 1756 or via the distal end of second member 1460. The secure mechanical connection achieved by this coupling arrangement may provide improved tensile strength and good transfer of torque from control shaft 1470 to second member 1460. The twisting manner of coupling between control shaft 1470 and second member 1460, with the radially extending key 1404 on control shaft 1470 mating with notch 1486, may be considered as a type of bayonet mount or half bayonet mount. Other twisting or non-twisting mechanical coupling arrangements may alternatively be utilized for a secure connection between control shaft 1470 and second member 1460.

[00196] Turning now to FIGS. 42-43, embodiments of electrode treatment devices 1800, 1900 with cleaning features will be described. With reference to FIGS. 42 and 43, each of the electrode treatment devices 1800, 1900 includes an electrode deployment system 1810, 1910, respectively, with a cleaning strip 1820, 1920, respectively, but may otherwise be configured in the same or similar manner as any of the electrode deployment systems 310, 610, 710, 810, 910, 912, 1010, 1110, 1210, 1310, 1410, 1410', 1610, 1610', 2010, 2110, 2210, 2310, 2410 disclosed herein. The cleaning strips 1820, 1920 are provided for mechanically wiping and cleaning electrode strip 1466 (omitted from FIGS. 42-43 for clarity) as the electrode strip 1466 is being uncoiled and coiled between the deployed and stowed conditions. In the embodiment of FIG. 42, cleaning strip 1820 of electrode deployment system 1810 comprises a cleaning brush mounted to first member 1440 along one or both side of the slot 1444 formed in first member 1440 (only one brush is illustrated in FIG. 42 for clarity). The cleaning brushes may be the same as or similar to the brush section of a medical cleaning brush, endoscopic cleaning brush, or endoscopic cytology brush, for example. In the embodiment of FIG. 43, cleaning strip 1920 of electrode deployment system 1910 may comprise one or more resilient wiper blades mounted to first member 1440 along one or both sides of slot 1444.

[00197] With reference to FIGS. 44-46, an electrode treatment device 2000, 2100 (which may otherwise be the same as or similar to any of the electrode treatment devices 300, 600, 700, 800, 900, 902, 1000, 1100, 1200, 1300, 1400, 1400', 1600, 1600', 1800, 1900, 2000, 2100, 2200, 2300, 2400 disclosed herein), may include passageways for delivery and application of a cleaning fluid to the electrode deployment systems 2010, 2110 thereof. Note that an electrode strip of electrode

treatment devices 2000, 2100 is omitted to reveal details of the cleaning system. FIG. 44 illustrates how cleaning fluid (indicated by arrows) may be expelled from slot 1444 of first member 1440 as the cleaning fluid exits a housing 2016, 2116 of electrode deployment system 2100 or 2110. FIG. 44 illustrates cleaning fluid being supplied to electrode deployment system 2010 via its control shaft 1470. FIG. 45 illustrates how cleaning fluid may be supplied to electrode deployment system 2110 via a separate fluid conduit 2120 (separate from control shaft 1470) which is connected to a port in shroud 2112 of electrode deployment system 2110. In either case, cleaning fluid may be routed and directed by the shapes of various elements of the electrode deployment system 2010, 2110 to provide an even flow over the electrode strip 1466.

[00198] With reference to FIGS. 47-48 electrode treatment devices 2200, 2300 include electrode deployment systems 2210, 2310 that may be the same as or similar to any of the electrode deployment systems 310, 610, 710, 810, 910, 912, 1010, 1110, 1210, 1310, 1410, 1410', 1610, 1610' disclosed herein. Electrode treatment devices 2200, and 2300 further include respective irrigation systems 2230, 2230 deployed with or integrated into endoscope 320, for irrigation of targeted tissues and/or the electrode strip 1466 (not illustrated). With reference to FIG. 47, irrigation system 2230 of electrode treatment device 2200 includes one or more spray nozzles 2240 configured and positioned to direct a spray 2260 of irrigation fluid laterally from distal end portion 316 of endoscope 320. In the embodiment of FIG. 48, electrode treatment device 2300 is provided with one or more spray nozzles 2340 that directs an irrigation fluid spray 2360 longitudinally forward (in the distal direction) toward electrode treatment device 2310. A deflector plate 2350 or other deflector structure or device may optionally be provided adjacent one or more of the spray nozzles 2340 to redirect and control the direction of irrigation spray. In either embodiment of electrode treatment device 2200, 2300, spray nozzles 2240, 2340 may be attached to the ends of fluid conduits threaded through or formed in endoscope 320.

[00199] FIGS. 49-51 illustrate an electrode treatment device 2400 including a measuring device 2404 and system for indicating the extent to which an electrode strip 2466 of electrode treatment device 2400 has been deployed, which may also indicate the size (*e.g.,* diameter) of the unfurled electrode strip 2466 and of the lumen or cavity 2420 (FIG. 50) of the patient or tissue site within which the electrode strip 2466 is deployed. Electrode treatment device 2400 is illustrated in a form and arrangement consistent with the electrode treatment device 1400 illustrated in FIGS. 26-28, and

may include some or all of the same components and functional elements as electrode treatment device 1400, in addition to the measuring device 2404 further described below. Electrode treatment device may further or alternatively include one or more features, in whole or in part, identical or similar to any of the electrode treatment devices 300, 600, 700, 800, 900, 902, 1000, 1200, 1300, 1400, 1400', 1400a-c, 1600, 1600' 2000, 2100, 2200, 2300 described herein.

[00200] FIG. 49 illustrates an electrode deployment system 2410 of electrode treatment device 2400 attached to a distal end of a shaft 2470 which extends from a distal end 328 of an endoscope 320 of the electrode treatment device 2400. FIG. 50 illustrates a video image from endoscope 320 showing electrode 2466 of electrode treatment device 2466 in a deployed condition. With reference to FIGS. 49-50, an indicator 2422 of measuring device 2404 is provided along an exterior surface of a shroud 2412 located at a proximal end of electrode deployment system 2410. In the embodiment illustrated, indicator 2422 takes the form of an embossed line that runs longitudinally along the surface of shroud 2412. In some embodiments, the embossed line of indicator 2422 may be tapered in width (as shown in FIG. 49) so as to appear of uniform width when viewed in a video image generated by the optical imaging system 390 (FIG. 4) of endoscope 390 (*e.g.,* a wide angle or fisheye lens thereof), as depicted in the video image of FIG. 50. In other embodiments, indicator 2422 may be some other indicia or datum feature, such as an arrow, notch, circle, dot, or other shape or visual feature, which may be raised, embossed, printed, marked or otherwise placed on shroud 2412 or on another component of electrode deployment system 2410 which is visible to the optical imaging system 390 (FIG. 4) of endoscope 320.

[00201] FIG. 51 illustrates a layout of an inner surface 2434 of electrode strip 2466. With reference to FIGS. 50 and 51, the inner surface 2434 of electrode strip 2466 is marked with a measuring scale 2450, which includes hash marks 2452 as best illustrated in FIG. 51. The hash marks 2452 of scale 2450 may include sets of major and minor hash marks that delimit various increments of distance along or length of electrode strip 2466. The hash marks may be spaced evenly and regularly, or may be spaced in a different manner, such as logarithmically. Scale 2450 may further include numerals 2454 or other indicia indicating the measure of distance along electrode strip and the circumference or diameter or other measure of the deployment of electrode strip 2466. With reference to FIG. 50, the position of a distal end portion 2424 of indicator 2422 relative to the electrode strip 2466 and scale 2450 indicates the extent

of unfurling and deployment of electrode strip, and may represent the diameter, circumference, and or other measure of the size of deployed electrode strip 2466, and/or the size of the lumen or cavity 2420 when electrode strip 2466 is in a deployed condition in contact with the lumen or cavity 2420. Thus, the scale 2450 and indicator 2422 cooperate to form the measuring device 2404. For example, FIG. 50 illustrates a measurement of approximately 5 on the scale 2450. In other embodiments, scale may be arranged in a different place or manner, and indicator 2422 may be located in a different manner. In some embodiments (not illustrated), scale 2450 and/or indicator 2422 may be projected onto electrode deployment system 2410 and/or electrode strip 2466 and/or cavity 2420, *e.g.,* via a laser emitted from endoscope 320 or by some other optical technique.

[00202] The diameter or size of the deployment of electrode strip 2466 measured using measuring device 2404 may be utilized to inform the magnitude of an electrical signal or power delivered to one or more electrodes on electrode strip 2466, so as to ensure uniform delivery of charge for electrosurgery or sensing, regardless of the extent of the deployment of electrode strip 2466. The accuracy of the measurement by measuring device 2404 utilizing the measuring scale 2450 and indicator 2422 illustrated may be accurate within approximately +/- 10% regardless of the rotational orientation of electrode deployment system 2410 and shroud 2412 relative to endoscope 320 and the placement of indicator 2422 (*e.g.,* up, down, right, left) relative to the cavity 2420 and/or the measuring scale 2450.

[00203] Embodiments of an electrode deployment system are illustrated herein in the context of an electrode treatment device for electrosurgery and soft tissue ablation. 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. For example, devices comprising the electrode deployment systems disclosed herein could be used as stabilization devices, such as for an ultrasound element, wherein the device deploys an ultrasound emitter and/or sensor package into apposition with tissue for imaging.

[00204] 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.

[00205] Further embodiments of the present disclosure are described by the following numbered examples and elements thereof, which can stand alone or be combined with the solution according to the main-claim(s) in any selective and combinatorial manner:

1. An electrode deployment system, comprising:

a first member;

a second member;

an electrode coupled to the first and second members; and

an actuation element operable to move at least one of the first and second members relative to the other to move the electrode between a stowed configuration and a deployed configuration, wherein the electrode is expanded in the deployed configuration relative to the stowed configuration and is coiled around one or both of the first and second members when in the stowed configuration, and wherein the actuation element is operable to rotate at least one of the first and second members relative to the other to uncoil the electrode and expand it to the deployed configuration from the stowed configuration.

2. The system of example 1, wherein a main body of the actuation element is disposed in one of: at least partially within the first member, proximally adjacent a proximal end of the first member, distally adjacent a distal end of the first member, and proximally of a proximal end of an endoscope coupled to the first member.

3. The system of example 1 or 2, wherein the actuation element includes an output shaft, wherein the output shaft is one of: coupled to the second member for rotating the second member relative to the first member and coupled to the first member for rotating the first member relative to the second member.

4. The system of example 3, wherein the output shaft is coupled to the first member via a gearset.

5. The system of example 4, wherein the gearset comprises a sun gear affixed to output shaft of actuation element and a plurality of planet gears carried on

second member, wherein the plurality of planet gears are meshed with the sun gear and a ring gear on an inner annular surface of a distal end portion of first member, and wherein the ring gear encircles the sun and planet gears.

6. The system of any one of examples 1 to 5, wherein:

the first member has a slot formed therein;

the second member is disposed at least partially within the first member; and

the electrode includes opposite first and second end portions, the first end portion is secured to the first member, the second end portion is secured to the second member, and the electrode extends through the slot and is coiled around one or both of the first and second members.

7. The system of any one of examples 1 to 6, wherein:

the first member overlaps the second member in an axially-overlapping region;

the first and second members are configured and arranged to form an annular gap between the first and second members in the axially-overlapping region, and

at least a portion of the electrode is coiled in the annular gap.

8. The system of any one of examples 1 to 7, further comprising a control shaft sized to be inserted through a working channel of an endoscope, the control shaft being attached to one of the first and second members, and the other of the first and second members is driven by the actuation element for rotation relative to the control shaft.

9. The system of example 8, wherein the control shaft is hollow and further comprises one or more wires, each wire being electrically connected to the actuation element or the electrode, and the wires extend through the control shaft for connection to a controller.

10. The system of example 8, further comprising the endoscope, the control shaft configured to be inserted through the working channel of the endoscope in a distal to proximal direction.

11. The system of example 10, wherein the main body of the actuation element is disposed proximally of the proximal end of the endoscope.

12. The system of any one of examples 1 to 11, wherein the actuation element includes an electric motor.

13. The system of any one of examples 1 to 12, further comprising a cleaning strip for cleaning the electrode as it is transitioned between the deployed and stowed conditions.

14. The system of any one of examples 1 to 13, further comprising a system for emitting fluid in the vicinity of the electrode or a tissue treatment site, or both.

15. The system of any one of examples 1 to 14, further comprising a measuring scale on the electrode and an indicator on a shroud positioned proximally of the first and second members.

16. An electrode treatment device, comprising:

an endoscope including an optical imaging system with an objective lens proximate a distal end of the endoscope;

an electrode deployment system attached to the endoscope such that an electrode of the electrode deployment system is disposed distal of the objective lens, the electrode deployment system being operable to transition the electrode between a stowed configuration and a deployed configuration while the electrode deployment system remains attached to the endoscope, wherein the electrode is laterally expanded in the deployed configuration relative to the stowed configuration.

17. The device of example 16, wherein the electrode deployment system is disposed within a field of view of the optical imaging system.

18. The device of example 16 or 17, wherein the electrode deployment system is mounted to the endoscope eccentrically of the distal end.

19. The device of any of the preceding examples, wherein the electrode comprises a flexible printed circuit.

20. The device of example 19, wherein the flexible printed circuit includes apertures formed therein, the apertures allowing the optical imaging system visibility through the flexible printed circuit to a tissue treatment site outward of the flexible printed circuit.

21. The device of any of the preceding examples, further comprising an elastomeric guide tip extending distally of the electrode deployment system.

22. The device of any of the preceding examples, wherein the electrode deployment system has an axis that is disposed at an angle relative to a longitudinal axis of the endoscope, so the axis of the electrode deployment system converges toward the longitudinal axis of the endoscope.

23. The device of any one of examples 16 to 22, wherein the electrode deployment system includes an inflatable bladder encircled by the electrode.

24. The device of any one of examples 16 to 23, wherein:

the electrode deployment system includes a first member and a second member, at least one of the first and second members being movable relative to the other; and

the electrode includes a first end portion and a second end portion opposite the first end portion, and the first end portion is attached to the first member and the second end portion is attached to the second member, and at least one of the first and second members includes a textured anchoring surface to which the respective first or second end portion of the electrode is attached.

25. The device of any one of examples 16 to 24, wherein:

the electrode deployment system includes a first member and a second member, at least one of the first and second members being movable relative to the other; and

the electrode includes a first end portion and a second end portion opposite the first end portion, and the first end portion is attached to the first member and the second end portion is attached to the second member, and the electrode includes retention tabs at the first and/or second end portions which mechanically engage with at least one of the first and second members.

26. The device of any one of examples 16 to 23, wherein the electrode deployment system includes a rotatable member and wherein the electrode includes a first end portion attached to the rotatable member and a second end portion opposite the first end portion, the second end portion constrained to prevent rotational movement relative to the endoscope, whereby rotation of the rotatable member expands the electrode to the deployed configuration.

27. The device of any one of examples 16 to 26, further comprising a drive shaft operatively coupled to the electrode deployment system, the drive shaft extending through a working channel of the endoscope.

28. The device of any one of examples 16 to 26, further comprising a drive shaft operatively coupled to the electrode deployment system, the drive shaft extending alongside the endoscope.

29. The device of example 27 or 28, wherein the drive shaft is operatively coupled to the electrode deployment system via a gearset.

30. The device of any of the preceding examples, further comprising an actuation element, the actuation element being operable to move the electrode between the stowed configuration and the deployed configuration.

31. The device of example 28 or 29, further comprising an actuation element disposed proximally of the endoscope and the actuation element is coupled to the drive shaft.

32. The device of any one of examples 16 to 26, further comprising an actuation element disposed distally of the objective lens, the actuation element being operable to move the electrode between the stowed configuration and the deployed configuration.

33. The device of example 32, wherein the electrode is coiled around the actuation element.

34. The device of any one of examples 30 to 33, wherein the actuation element includes a motor.

35. The device of any one of examples 30 to 34, wherein the electrode deployment system is attached to the endoscope by a control shaft that extends through a working channel of the endoscope.

36. The device of example 35, wherein the electrode deployment system includes:

an outer member; and

an inner member disposed at least partially within the outer member; and

wherein the control shaft is attached to one of the outer and inner members, and the other of the outer and inner members is driven by the actuation element for rotation relative to the control shaft.

37. The device of example 36, wherein the actuation element is disposed at least partially within the outer member, at least partially within the inner member, or both.

38. The device of example 36 or 37, wherein:

the outer member has a generally cylindrical cavity with a central axis, the outer member having a slot formed therein;

the inner member is disposed at least partially within the cylindrical cavity of the outer member; and

the electrode includes an electrode strip having opposite first and second end portions, the first end portion is secured to the outer member, the second end portion

is secured to the inner member, the electrode strip extends through the slot, the electrode strip is coiled around one or both of the outer and inner members when in the stowed configuration, and the actuation element is operatively coupled to the outer and inner members to rotate at least one of outer and inner members about the central axis relative to the other to thereby transition the electrode strip between the stowed and deployed configurations.

39. The device of example 38, wherein the first end portion of the electrode strip is attached to an outer surface of the outer member adjacent the slot.

40. The device of any one of examples 36 to 39, wherein the outer member overlaps the inner member in an axially-overlapping region, the electrode deployment system is configured to form an annular gap between the inner and outer members in the axially-overlapping region, and wherein at least a portion of the electrode is coiled in the annular gap.

41. The device of any one of examples 36 to 40, wherein the inner and outer members have proximal and distal end portions, and the actuation element is disposed either adjacent the distal end portions of the inner and outer members, or adjacent the proximal end portions of the inner and outer members.

42. The device of any one of examples 16 to 41, further comprising a cleaning strip for cleaning the electrode as it is transitioned between the deployed and stowed conditions.

43. The device of any one of examples 16 to 42, further comprising a system for emitting fluid in the vicinity of the electrode or a tissue treatment site, or both.

44. An electrode deployment system, comprising:

a first member;

a second member;

an electrode coupled to the first and second members; and

an actuation element housed at least partially within the first member, the actuation element operable to move at least one of the first and second members relative to the other to move the electrode between a stowed configuration and a deployed configuration, wherein the electrode is expanded in the deployed configuration relative to the stowed configuration.

45. The system of example 44, wherein the electrode is coiled around one of the first and second members when in the stowed configuration, and the actuation

element is operable to rotate at least one of the first and second members relative to the other to uncoil the electrode and expand it to the deployed configuration.

46. The system of example 44 or 45, wherein the actuation element is mounted on the first member and includes an output shaft coupled to the second member for rotating the second member relative to the first member.

47. The system of example 44 or 45, wherein the actuation element is mounted on the second member and includes an output shaft coupled to the first member for rotating the first member relative to the second member.

48. The system of example 47, wherein the output shaft is coupled to the first member via a gearset.

49. The system of any one of examples 44 to 48, further comprising a measuring scale on the electrode and an indicator positioned proximally of the first and second members.

50. The system of any one of examples 44 to 49, wherein:

the first member has a slot formed therein;

the second member is disposed at least partially within the first member; and

the electrode includes opposite first and second end portions, the first end portion is secured to the first member, the second end portion is secured to the second member, and the electrode extends through the slot and is coiled around one or both of the first and second members.

51. The system of any one of examples 44 to 50, wherein:

the first member overlaps the second member in an axially-overlapping region;

the first and second members are configured and arranged to form an annular gap between the first and second members in the axially-overlapping region, and

at least a portion of the electrode is coiled in the annular gap.

52. The system of any one of examples 44 to 51, further comprising a control shaft sized to be inserted through a working channel of an endoscope, the control shaft being attached to one of the first and second members, and the other of the first and second members is driven by the actuation element for rotation relative to the control shaft.

53. The system of example 52, further comprising an electrical connector attached to a proximal end portion of the control shaft and electrically coupled to the actuation element and the electrode.

54. The system of example 53, wherein the electrical connector comprises a sub-miniature phone plug connector extending coaxially from the proximal end portion of the control shaft.

55. The system of any one of examples 52 to 54, wherein the control shaft is hollow and further comprising one or more wires, each wire being electrically connected to the actuation element or the electrode, and the wires extend through the control shaft for connection to a controller.

56. The system of any one of examples 44 to 55, wherein the actuation element includes an electric motor.

57. The system of any one of examples 44 to 56, wherein the electrode includes a flexible printed circuit having at least first electrode and a second electrode that are formed on the flexible printed circuit.

58. The system of example 57, wherein the electrode strip includes a first end portion and a second end portion opposite the first end portion, and the first end portion is attached to the first member and the second end portion is attached to the second member, and at least one of the first and second members includes a textured anchoring surface to which the respective first or second end portion of the electrode strip is attached.

59. The system of example 57 or 58, wherein the electrode strip includes retention tabs at the first and/or second end portions, and the retention tabs mechanically engage with at least one of the first and second members.

60. The system of any one of examples 44 to 59, wherein the first and second members have proximal and distal end portions, and the actuation element is disposed either adjacent the distal end portions of the inner and outer members, or adjacent the proximal end portions of the inner and outer members.

61. The system of any one of examples 44 to 60, further comprising a cleaning strip for cleaning the electrode as it is transitioned between the deployed and stowed conditions.

62. The system of any one of examples 44 to 61, further comprising a system for emitting fluid in the vicinity of the electrode or a tissue treatment site, or both.

63. A method of deploying an electrode, comprising the steps of:

loading an electrode deployment system onto an endoscope by inserting a shaft of the electrode deployment system into a working channel of the endoscope via an opening at a distal end of the endoscope and sliding the shaft through the

working channel until the shaft extends beyond a proximal end of the endoscope and an electrode deployment device of the electrode deployment system that is attached to a distal end portion of the shaft is positioned distally adjacent the distal end of the endoscope;

operating the electrode deployment device to move a flexible electrode of the electrode deployment system between a stowed configuration and a deployed configuration.

64. The method of example 63, wherein the electrode deployment device includes an electric motor.

65. The method of example 63 or 64, wherein the shaft has an outer diameter between 2.5 mm and 4.0 mm.

66. The method of example 65, wherein the shaft has outer diameter of approximately 2.7 mm.

67. The method of any one of examples 63 to 66, further comprising the step of electrically connecting a power supply to a proximal end portion of the shaft.

68. The method of example 67, wherein an electrical connector is provided at the proximal end portion of the shaft, and wherein the step of electrically connecting the power supply to the proximal end portion of the shaft includes joining the electrical connector to a mating electrical connector that is electrically connected to the power supply.

69. The method of example 68, wherein the electrical connector comprises a sub-miniature phone plug connector extending coaxially from the proximal end portion of the shaft.

70. The method of any one of examples 67 to 69, wherein the step of electrically connecting the power supply to the proximal end portion of the shaft includes connecting a handle or a robotic manipulator to the proximal end portion of the shaft.

71. The method of example 70, further comprising rotating the shaft by manipulating the handle or by operating the robotic manipulator.

72. The method of any one of examples 63 to 71, wherein:

the flexible electrode includes an electrode strip that is coiled when in the stowed configuration; and

the step of operating the electrode deployment device includes moving the electrode strip from the stowed configuration to the deployed configuration by at least partially uncoiling the electrode strip.

73. A method of deploying an electrode, comprising the steps of:

activating an actuation element operatively coupled to a coiled flexible electrode strip to unfurl the electrode strip; and

sensing an electrical current supplied to the actuation element to drive the actuation element for unfurling of the electrode strip, and automatically switching off the electrical current when it exceeds a predetermined threshold to thereby halt the unfurling of the electrode strip.

74. The method of example 73, further comprising the step of applying energy to the electrode strip to perform a treatment or sensing operation on internal tissue.

75. The method of example 73 or 74, further comprising, after the step of automatically switching off the electrical current, selectively activating the actuation element for one or more additional predetermined intervals, to thereby further unfurl the flexible electrode strip in a stepwise manner.

76. The method of example 75, wherein the step of selectively activating the actuation element is performed in response to a controller receiving a stepping signal initiated by a user.

77. The method of example 76, wherein the step of activating the actuation element is performed in response to the controller receiving an activation signal initiated by the user.

78. The method of example 77, wherein the activation signal and the stepping signal are each generated by the user pressing a button in a similar manner.

79. The method of any one of examples 73 to 78, wherein the step of activating the actuation element causes the actuation element to operate in a first direction, and the method further comprises, after unfurling the electrode strip, activating the actuation element in a second direction opposite the first direction to furl the electrode strip.

80. The method of example 79, wherein the step of activating the actuation element in the second direction is performed in response to a controller receiving a second signal different from the activation signal.

81. The method of example 80, wherein the second signal is user-initiated.

82. The method of any one of examples 73 to 81, wherein the actuation element includes an electric motor.

83. An electrode treatment device, comprising:

an endoscope including a body having a distal end, the body having a working port extending longitudinally through the body;

an electrode deployment system supported by the endoscope adjacent its distal end;

an electrode supported on the electrode deployment system; and

a drive shaft extending through the working port, the drive shaft operatively coupled to the electrode deployment system and movable within the working port relative to the body to drive the electrode deployment system for moving the electrode between a stowed configuration and a deployed configuration, wherein the electrode is laterally expanded in the deployed configuration relative to the stowed configuration.

84. The device of example 83, wherein the electrode comprises a flexible printed circuit.

85. The device of example 84, wherein the flexible printed circuit includes multiple electrodes formed on an outer surface of the flexible printed circuit.

86. The device of any one of examples 83 to 85, wherein the drive shaft includes a torque tube.

87. The device of any one of examples 83 to 86, wherein the electrode deployment system includes:

an outer member, and

an inner member positioned at least partially within the outer member, the drive shaft being coupled to at least one of the inner and outer members so that movement of the drive shaft relative to the body of the endoscope imparts relative movement between the inner and outer members for transitioning the electrode between the stowed and deployed configurations.

88. The device of example 87, wherein the electrode is attached to the inner and outer members.

89. The device of example 87, wherein the electrode includes an electrode strip having opposite first and second end portions, wherein the first end portion is directly attached to the outer member and the second end portion is directly attached to the inner member.

90. The device of example 89, wherein at least one of the inner and outer members includes a textured anchoring surface to which the respective first or second end portion of the electrode strip is attached.

91. The device of example 89 or 90, wherein the electrode strip includes retention tabs at the first and/or second end portions, and the retention tabs mechanically engage with at least one of the inner and outer members.

92. The device of any one of examples 89 to 91, wherein the outer member overlaps the inner member in an axially-overlapping region and wherein opposite first and second end portions of the electrode are attached to the respective inner and outer members in the axially-overlapping region.

93. The device of example 92, further comprising an annular gap formed between the inner and outer members in the axially-overlapping region, and wherein the relative movement of the inner and outer members causes the electrode to be coiled in the annular gap.

94. The device of any one of examples 83 to 93, wherein at least a portion of the electrode deployment system including the electrode is movable from proximal of the distal end of the endoscope to distally forward of the distal end of the endoscope.

95. The device of any one of examples 83 to 94, wherein the electrode deployment system is concentric with the distal end of the endoscope.

96. The device of any one of examples 83 to 94, wherein the electrode deployment system is mounted to the endoscope eccentrically of the body of the endoscope.

97. The device of any one of examples 83 to 96, wherein at least one electrical conductor is coupled to the electrode and extends along the body toward a proximal end of the body.

98. The device of any one of examples 83 to 97, further comprising an electric motor coupled to the drive shaft for rotating the drive shaft within the working port to move the electrode between the stowed configuration and the deployed configuration.

99. An electrode deployment system for treating tissue, comprising:

an outer member having a generally cylindrical cavity with a central axis, the outer member having a slot formed therein;

an inner member positioned at least partially within the cylindrical cavity of the outer member and coaxially with the outer member, one of the inner and outer

members being configured for attachment to a distal end portion of an endoscope; and

an electrode strip having opposite first and second end portions, the first end portion is secured to the outer member, and the electrode strip is wrapped at least partially around the outer member, passes through the slot, and is coiled around the inner member, and the second end portion of the electrode strip is secured to the inner member,

at least one of the inner and outer members being rotatable about the central axis relative to the other to uncoil the electrode strip, thereby deploying at least a portion of the electrode strip through the slot and radially outward from the outer member.

100. The system of example 99, wherein the outer member is attachable to an endoscope and the inner member is rotatable about the central axis relative to the outer member.

101. The system of example 100, further comprising a drive shaft directly coupled to the inner member so that rotation of the drive shaft rotates the inner member relative to the outer member to deploy the electrode strip.

102. The system of example 99, further comprising a drive shaft coupled to at least one of the inner and outer members so that rotation of the drive shaft imparts the relative rotation between the inner and outer members.

103. The system of example 102, further comprising a first gear on at least one of the inner and outer members, and a second gear mounted on the drive shaft for rotation with the drive shaft, and the second gear meshes with the first gear to drive the first gear rotationally relative to the endoscope in response to rotation of the drive shaft to uncoil the electrode strip.

104. The system of example 103, wherein the first gear comprises a ring gear on the outer member, the ring gear having teeth disposed on an inner annular surface.

105. The system of any one of examples 99 to 104, wherein the first end portion of the electrode strip is attached to an outer surface of the outer member adjacent the slot.

106. The system of any one of examples 99 to 105, wherein the outer member overlaps the inner member in an axially-overlapping region and wherein the

first and second end portions of the electrode strip are secured to the respective outer and inner members in the axially-overlapping region.

107. The system of example 106, further comprising an annular gap formed between the inner and outer members in the axially-overlapping region, and wherein the electrode is coiled in the annular gap.

108. The system of any one of examples 99 to 107, wherein the inner member is attachable to an endoscope and outer member is mounted on the inner member for rotation relative to the inner member about the central axis.

109. The system of any one of examples 99 to 108, wherein the electrode strip comprises a flexible printed circuit.

110. The system of example 109, wherein the flexible printed circuit includes a pair of electrodes formed on an outer surface of the flexible printed circuit in a bi-polar arrangement.

111. The system of example 109, wherein the flexible printed circuit is formed on a polymer substrate having a thickness in a range of 2 mils to 10 mils.

112. An electrode treatment device, comprising:

an endoscope including an optical imaging system with an objective lens proximate a distal end of the endoscope; and

an electrode deployment system attached to the endoscope such that an electrode of the electrode deployment system is disposed distal of the objective lens, the electrode deployment system being operable to transition the electrode between a stowed configuration and a deployed configuration while the electrode deployment system remains attached to the endoscope, wherein the electrode is laterally expanded in the deployed configuration relative to the stowed configuration.

113. The device of example 112, wherein the electrode deployment system is disposed within a field of view of the optical imaging system.

114. The device of example 112 or 113, wherein the electrode deployment system is mounted to the endoscope eccentrically of the distal end.

115. The device of any one of examples 112 to 114, wherein the electrode comprises a flexible printed circuit with apertures formed therein, the apertures allowing the optical imaging system visibility through the flexible printed circuit to a tissue treatment site outside of the flexible printed circuit.

116. The device of any one of examples 112 to 115, further comprising an elastomeric guide tip extending distally of the electrode deployment system.

117. The device of any one of examples 112 to 116, wherein the electrode deployment system has an axis that is disposed at an angle relative to a longitudinal axis of the endoscope, so the axis of the electrode deployment system converges toward the longitudinal axis of the endoscope.

118. The device of any one of examples 112 to 117, wherein the electrode deployment system includes an inflatable bladder encircled by the electrode.

119. The device of any one of examples 112 to 118, wherein the electrode deployment system includes a rotatable member and wherein the electrode includes a first end portion attached to the rotatable member and a second end portion opposite the first end portion, the second end portion constrained to prevent rotational movement relative to the endoscope, whereby rotation of the rotatable member expands the electrode to the deployed configuration.

120. The device of any one of examples 112 to 119, further comprising a drive shaft operatively coupled to the electrode deployment system, the drive shaft extending through a working port of the endoscope.

121. The device of any one of examples 112 to 119, further comprising a drive shaft operatively coupled to the electrode deployment system, the drive shaft extending alongside the endoscope.

122. A method of deploying an electrode, comprising:

with an inner member positioned at least partially within a cylindrical cavity of an outer member, rotating one of the inner and outer members relative to the other while a flexible electrode strip having opposite first and second end portions is secured at its first end portion to an outside surface of the outer member and at its second end portion to the inner member with the electrode strip passing through a slot in the outer member, the step of rotating including:

rotating of at least one of the inner and outer members in a first direction causing a portion of the electrode strip to be deployed through the slot outwardly from the outer member to a deployed configuration, and

rotating the at least one of the inner and outer members in a second direction opposition the first direction causing a portion of the electrode strip to be moved laterally inwardly and coiled around the inner member to a stowed configuration.

123. The method of example 122, further comprising supporting the inner and outer members and the electrode strip on an endoscope adjacent a distal end of the endoscope and inserting the endoscope, the inner and outer members, and the

electrode strip into a patient endoluminally and positioning the electrode strip proximate a first tissue treatment site.

124. The method of example 123, further comprising moving the inner and outer members distally relative to the endoscope into a field of view of an optical imaging system of the endoscope.

125. The method of example 124, wherein the rotation of the at least one of the inner and outer members causes the electrode strip to be deployed into apposition with targeted tissue at the first tissue treatment site, and further comprising:

while the electrode strip is in apposition to the targeted tissue, applying energy to the electrode strip to treat the targeted tissue.

126. The method of example 125, further comprising, after the step of rotating the at least one of the inner and outer members in the second direction, endoluminally advancing the inner and outer members and the electrode strip to a second tissue treatment site different from the first tissue treatment site.

127. An electrode treatment device, comprising:

an endoscope including an elongate body having a distal end;

a drive shaft that is rotatable relative to the endoscope; and

an electrode coiling mechanism supported by the endoscope near its distal end, the electrode coiling mechanism including:

a first member supported on the endoscope adjacent the distal end for rotation relative to the endoscope, the first member having a first gear;

an electrode strip having opposite first and second end portions, the first end portion being attached to the first member and the second end portion being constrained to prevent rotational movement relative to the endoscope; and

a second gear mounted on the drive shaft for rotation with the drive shaft, and the second gear meshes with the first gear to drive the first member rotationally relative to the endoscope in response to rotation of the drive shaft, to thereby move the electrode strip between a stowed configuration and a deployed configuration, wherein the electrode strip is laterally expanded relative to the stowed configuration.

128. The device of example 127, wherein the first gear comprises a ring gear on the first member.

129. The device of example 127 or 128, wherein the electrode strip comprises a flexible printed circuit.

130. The device of example 129, wherein the flexible printed circuit includes multiple electrodes formed on an outer surface of the flexible printed circuit.

131. The device of any one of examples 127 to 130, wherein the electrode coiling mechanism further includes a second member positioned at least partially within the first member and rotationally constrained relative to the endoscope.

132. The device of example 131, wherein the second end portion of the electrode strip is attached to the second member.

133. The device of any one of examples 127 to 132, wherein the electrode coiling mechanism is concentric with the distal end of the endoscope.

134. The device of any one of examples 127 to 132, wherein the electrode coiling mechanism is mounted to the endoscope eccentrically of the body of the endoscope.

135. The device of any one of examples 127 to 134, wherein the drive shaft extends through a working channel of the endoscope.

136. An electrode deployment system configured to be carried by an endoscope including an optical imaging system having a field of view beyond a distal end of the endoscope, the system comprising:

a first member carrying an electrode attached to the first member, the first member configured to be slidably mounted on an endoscope for movement in a longitudinal direction relative to the endoscope from a retracted configuration, wherein a majority of the first member and the electrode are positioned proximally of the distal end of the endoscope, to an extended configuration, wherein the first member is moved distally relative to the endoscope to a position where at least a portion of the electrode is deployed distally of the distal end of the endoscope and within a field of view of an optical imaging system of the endoscope while the first member remains mounted on the endoscope.

137. The system of example 136, further comprising an elongate drive device coupled to the first member and slidable relative to the endoscope to move the first member between the retracted and extended configurations.

138. The system of example 137, the drive device extends through a working port of the endoscope and is slidably longitudinally relative to the endoscope.

139. The system of example 137 or 138, wherein the drive device comprises a flexible drive shaft.

140. The system example 139, wherein the drive device further includes a first gear attached to the drive shaft, and the first member includes a second gear thereon that meshes with the first gear so that rotation of the drive shaft drives the first member rotatably relative to the endoscope.

141. The system of example 137 or 138, further comprising an inflatable bladder carried by the first member and wherein the drive device comprises an insufflation tube.

142. The system of any one of examples 136 to 140, further comprising a second member configured to be slidably mounted on the endoscope for movement in the longitudinal direction relative to the endoscope, the first member being mounted on the second member for movement with the second member in the longitudinal direction, one of the first and second members being rotatable relative to the other and relative to the endoscope.

143. The system of example 142, further comprising a third member configured to be securely mounted on the endoscope proximate the distal end, the first and second members being slidably mounted on the third member and movable in the longitudinal direction relative thereto.

144. The system of example 142 or 143, wherein the electrode includes an electrode strip having a first end portion attached to the first member and a second end portion opposite the first end portion and attached to the second member.

145. The system of example 144, wherein the electrode strip includes a middle portion interposed between opposite first and second end portions of the electrode strip, the first end portion attached to the rotatable one of the first and second members and the second end portion constrained to prevent rotational movement relative to the endoscope, whereby rotation of the rotatable one of the first and second members expands the electrode strip to a deployed configuration, in which a middle portion of the electrode strip is expanded outwardly from the first and second members.

146. The system of any one of examples 136 to 145, wherein the electrode comprises a flexible printed circuit with apertures formed therein, the apertures allowing the optical imaging system a view through the flexible printed circuit to a tissue treatment site outside of the flexible printed circuit, when the system is in use.

147. A method of deploying an electrode, comprising:

supporting an electrode deployment system on an endoscope adjacent a distal end of the endoscope, the electrode deployment system having:

a first member that is rotatable relative to the endoscope, the first member having a first gear,

a flexible electrode strip with opposite first and second end portions, the first end portion attached to the first member and the second end portion being constrained to prevent rotational movement relative to the endoscope,

a drive shaft, and

a second gear mounted on the drive shaft for rotation with the drive shaft, the second gear meshing with the first gear;

inserting the endoscope and the electrode deployment system into a patient endoluminally and positioning the electrode deployment system proximate a first tissue treatment site; and

rotating the drive shaft to thereby cause the first member to rotate relative to the endoscope via the first and second gears and to move the electrode strip laterally relative to the endoscope between a stowed configuration and a deployed configuration, wherein the electrode strip is laterally expanded in the deployed configuration relative to the stowed configuration.

148. The method of example 147, further comprising moving the drive shaft distally relative to the endoscope to thereby extend the first member and electrode strip distally of the distal end of the endoscope into a field of view of an optical imaging system of the endoscope.

149. The method of example 148, wherein the step of rotating the drive shaft is performed after moving the drive shaft in the distal direction, and the step of rotating the drive shaft includes rotating the drive shaft in a first direction to move the electrode strip laterally outwardly to the deployed configuration in apposition to targeted tissue at the first tissue treatment site, and subsequently rotating the drive shaft in a second direction opposite the first direction to move the electrode strip laterally inwardly, and further comprising applying energy to the electrode strip while the electrode strip is in apposition to the targeted tissue.

150. The method of example 149, further comprising, after rotating the drive shaft in the second direction, endoluminally advancing the electrode deployment system to a second tissue treatment site different from the first tissue treatment site.

151. A method of deploying an electrode comprising:

slidably supporting an electrode deployment system on an endoscope adjacent a distal end of the endoscope, the electrode deployment system including a first member carrying an electrode;

moving the first member and the electrode in a longitudinal direction relative to the endoscope from a retracted configuration, wherein a majority of the first member and the electrode are positioned proximally of the distal end of the endoscope, to an extended configuration, wherein the first member is moved distally relative to the endoscope to a position where at least a portion of the electrode is deployed distally of the distal end of the endoscope and within a field of view of an optical imaging device of the endoscope; and

while the first member remains supported on the endoscope, deploying the electrode laterally outwardly from the first member into apposition with targeted tissue at a first tissue treatment site.

152. The method of example 151, further comprising, operably coupling a drive device to the first member, and wherein the step of moving the first member and the electrode in the longitudinal direction includes moving the drive device in the longitudinal direction.

153. The method of example 152, further comprising slidably inserting the drive device through a working port of the endoscope before operably coupling the drive device to the first member.

154. The method of example 152 or 153, wherein the electrode deployment system further includes a second member movable longitudinally relative to the endoscope and the first member is rotatable relative to the second member, and the drive device includes a drive shaft, and the step of deploying the electrode laterally outwardly includes rotating the drive shaft relative to the endoscope to rotate the first member relative to the second member.

155. The method of any one of examples 152 to 154, wherein operably coupling the drive device to the first member includes coupling the drive shaft to a gear assembly.

156. The method of example 152 or 153, wherein the drive device includes an insufflation tube and operably coupling the drive device to the first member includes coupling the insufflation tube to a bladder of the electrode deployment system.

157. The method of any one of examples 151 to 156, further comprising applying energy to the electrode while the electrode is in apposition with the targeted tissue.

158. The method of example 157, further comprising, after applying the energy to the electrode, moving the electrode laterally inwardly toward the first member and endoluminally advancing the first member and electrode to a second tissue treatment site different from the first tissue treatment site.

[00206] 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.

CLAIMS

The invention claimed is:

1. An electrode deployment system, comprising:

a first member;

a second member;

an electrode coupled to the first and second members; and

an actuation element operable to move at least one of the first and second members relative to the other to move the electrode between a stowed configuration and a deployed configuration, wherein the electrode is expanded in the deployed configuration relative to the stowed configuration and is coiled around one or both of the first and second members when in the stowed configuration, and wherein the actuation element is operable to rotate at least one of the first and second members relative to the other to uncoil the electrode and expand it to the deployed configuration from the stowed configuration.

2. The system of claim 1, wherein a main body of the actuation element is disposed in one of: at least partially within the first member, proximally adjacent a proximal end of the first member, distally adjacent a distal end of the first member, and proximally of a proximal end of an endoscope coupled to the first member.

3. The system of claim 1 or 2, wherein the actuation element includes an output shaft, wherein the output shaft is one of: coupled to the second member for rotating the second member relative to the first member and coupled to the first member for rotating the first member relative to the second member.

4. The system of claim 3, wherein the output shaft is coupled to the first member via a gearset.

5. The system of claim 4, wherein the gearset comprises a sun gear affixed to output shaft of actuation element and a plurality of planet gears carried on second member, wherein the plurality of planet gears are meshed with the sun gear and a ring gear on an inner annular surface of a distal end portion of first member, and wherein the ring gear encircles the sun and planet gears.

6. The system of any one of claims 1 to 5, wherein:

the first member has a slot formed therein;

the second member is disposed at least partially within the first member; and

the electrode includes opposite first and second end portions, the first end portion is secured to the first member, the second end portion is secured to the second member, and the electrode extends through the slot and is coiled around one or both of the first and second members.

7. The system of any one of claims 1 to 6, wherein:

the first member overlaps the second member in an axially-overlapping region;

the first and second members are configured and arranged to form an annular gap between the first and second members in the axially-overlapping region, and

at least a portion of the electrode is coiled in the annular gap.

8. The system of any one of claims 1 to 7, further comprising a control shaft sized to be inserted through a working channel of an endoscope, the control shaft being attached to one of the first and second members, and the other of the first and second members is driven by the actuation element for rotation relative to the control shaft.

9. The system of claim 8, wherein the control shaft is hollow and further comprises one or more wires, each wire being electrically connected to the actuation element or the electrode, and the wires extend through the control shaft for connection to a controller.

10. The system of claim 8, further comprising the endoscope, the control shaft configured to be inserted through the working channel of the endoscope in a distal to proximal direction.

11. The system of claim 10, wherein the main body of the actuation element is disposed proximally of the proximal end of the endoscope.

12. The system of any one of claims 1 to 11, wherein the actuation element includes an electric motor.

13. The system of any one of claims 1 to 12, further comprising a cleaning strip for cleaning the electrode as it is transitioned between the deployed and stowed configurations, or a system for emitting fluid in the vicinity of the electrode or of a tissue treatment site, or both.

14. The system of claim 8, wherein a distal end portion of the control shaft includes a first engagement member configured to be secured to a corresponding second engagement member of a proximal end portion of the second member to fixedly secure the control shaft to the second member.

15. The system of any one of claims 1 to 14, further comprising a measuring scale on the electrode and an indicator positioned proximally of the first and second members.

16. An electrode treatment device, comprising:

an endoscope including an optical imaging system with an objective lens proximate a distal end of the endoscope;

an electrode deployment system attached to the endoscope such that an electrode of the electrode deployment system is disposed distal of the objective lens, the electrode deployment system being operable to transition the electrode between a stowed configuration and a deployed configuration while the electrode deployment system remains attached to the endoscope, wherein the electrode is laterally expanded in the deployed configuration relative to the stowed configuration.

17. The device of claim 16, wherein the electrode deployment system is disposed within a field of view of the optical imaging system.

18. The device of claim 16 or 17, wherein the electrode deployment system is mounted to the endoscope eccentrically of the distal end.

19. The device of any of the preceding claims, wherein the electrode comprises a flexible printed circuit.

20. The device of claim 19, wherein the flexible printed circuit includes apertures formed therein, the apertures allowing the optical imaging system visibility through the flexible printed circuit to a tissue treatment site outward of the flexible printed circuit.

21. The device of any of the preceding claims, further comprising an elastomeric guide tip extending distally of the electrode deployment system.

22. The device of any of the preceding claims, wherein the electrode deployment system has an axis that is disposed at an angle relative to a longitudinal axis of the endoscope, so the axis of the electrode deployment system converges toward the longitudinal axis of the endoscope.

23. The device of any one of claims 16 to 22, wherein the electrode deployment system includes an inflatable bladder encircled by the electrode.

24. The device of any one of claims 16 to 23, wherein:

the electrode deployment system includes a first member and a second member, at least one of the first and second members being movable relative to the other; and

the electrode includes a first end portion and a second end portion opposite the first end portion, and the first end portion is attached to the first member and the second end portion is attached to the second member, and at least one of the first and second members includes a textured anchoring surface to which the respective first or second end portion of the electrode is attached.

25. The device of any one of claims 16 to 24, wherein:

the electrode deployment system includes a first member and a second member, at least one of the first and second members being movable relative to the other; and

the electrode includes a first end portion and a second end portion opposite the first end portion, and the first end portion is attached to the first member and the second end portion is attached to the second member, and the electrode includes retention tabs at the first and/or second end portions which mechanically engage with at least one of the first and second members.

26. The device of any one of claims 16 to 23, wherein the electrode deployment system includes a rotatable member and wherein the electrode includes a first end portion attached to the rotatable member and a second end portion opposite the first end portion, the second end portion constrained to prevent rotational movement relative to the endoscope, whereby rotation of the rotatable member expands the electrode to the deployed configuration.

27. The device of any one of claims 16 to 26, further comprising a drive shaft operatively coupled to the electrode deployment system, the drive shaft extending through a working channel of the endoscope.

28. The device of any one of claims 16 to 26, further comprising a drive shaft operatively coupled to the electrode deployment system, the drive shaft extending alongside the endoscope.

29. The device of claim 27 or 28, wherein the drive shaft is operatively coupled to the electrode deployment system via a gearset.

30. The device of any of the preceding claims, further comprising an actuation element, the actuation element being operable to move the electrode between the stowed configuration and the deployed configuration.

31. The device of claim 28 or 29, further comprising an actuation element disposed proximally of the endoscope and the actuation element is coupled to the drive shaft.

32. The device of any one of claims 16 to 26, further comprising an actuation element disposed distally of the objective lens, the actuation element being operable to move the electrode between the stowed configuration and the deployed configuration.

33. The device of claim 32, wherein the electrode is coiled around the actuation element.

34. The device of any one of claims 30 to 33, wherein the actuation element includes a motor.

35. The device of any one of claims 30 to 34, wherein the electrode deployment system is attached to the endoscope by a control shaft that extends through a working channel of the endoscope.

36. The device of claim 35, wherein the electrode deployment system includes:

an outer member; and

an inner member disposed at least partially within the outer member; and

wherein the control shaft is attached to one of the outer and inner members, and the other of the outer and inner members is driven by the actuation element for rotation relative to the control shaft.

37. The device of claim 36, wherein the actuation element is disposed at least partially within the outer member, at least partially within the inner member, or both.

38. The device of claim 36 or 37, wherein:

the outer member has a generally cylindrical cavity with a central axis, the outer member having a slot formed therein;

the inner member is disposed at least partially within the cylindrical cavity of the outer member; and

the electrode includes an electrode strip having opposite first and second end portions, the first end portion is secured to the outer member, the second end portion is secured to the inner member, the electrode strip extends through the slot, the electrode strip is coiled around one or both of the outer and inner members when in the stowed configuration, and the actuation element is operatively coupled to the outer and inner members to rotate at least one of outer and inner members about the central axis relative to the other to thereby transition the electrode strip between the stowed and deployed configurations.

39. The device of claim 38, wherein the first end portion of the electrode strip is attached to an outer surface of the outer member adjacent the slot.

40. The device of any one of claims 36 to 39, wherein the outer member overlaps the inner member in an axially-overlapping region, the electrode deployment system is configured to form an annular gap between the inner and outer members in the axially-overlapping region, and wherein at least a portion of the electrode is coiled in the annular gap.

41. The device of any one of claims 36 to 40, wherein the inner and outer members have proximal and distal end portions, and the actuation element is disposed either adjacent the distal end portions of the inner and outer members, or adjacent the proximal end portions of the inner and outer members.

42. The device of any one of claims 16 to 41, further comprising a cleaning strip for cleaning the electrode as it is transitioned between the deployed and stowed conditions.

43. The device of any one of claims 16 to 42, further comprising a system for emitting fluid in the vicinity of the electrode or a tissue treatment site, or both.

44. The device of any one of claims 16 to 43, further comprising a measuring scale on the electrode and an indicator at a proximal end portion of the electrode deployment system.

45. An electrode deployment system, comprising:

a first member;

a second member;

an electrode coupled to the first and second members; and

an actuation element housed at least partially within the first member, the actuation element operable to move at least one of the first and second members relative to the other to move the electrode between a stowed configuration and a deployed configuration, wherein the electrode is expanded in the deployed configuration relative to the stowed configuration.

46. The system of claim 45, wherein the electrode is coiled around one of the first and second members when in the stowed configuration, and the actuation element is operable to rotate at least one of the first and second members relative to the other to uncoil the electrode and expand it to the deployed configuration.

47. The system of claim 45 or 46, wherein the actuation element is mounted on the first member and includes an output shaft coupled to the second member for rotating the second member relative to the first member.

48. The system of claim 45 or 46, wherein the actuation element is mounted on the second member and includes an output shaft coupled to the first member for rotating the first member relative to the second member.

49. The system of claim 48, wherein the output shaft is coupled to the first member via a gearset.

50. The system of any one of claims 45 to 49, further comprising a measuring scale on the electrode and an indicator positioned proximally of the first and second members.

51. The system of any one of claims 45 to 50, wherein:

the first member has a slot formed therein;

the second member is disposed at least partially within the first member; and

the electrode includes opposite first and second end portions, the first end portion is secured to the first member, the second end portion is secured to the second member, and the electrode extends through the slot and is coiled around one or both of the first and second members.

52. The system of any one of claims 45 to 51, wherein:

the first member overlaps the second member in an axially-overlapping region;

the first and second members are configured and arranged to form an annular gap between the first and second members in the axially-overlapping region, and

at least a portion of the electrode is coiled in the annular gap.

53. The system of any one of claims 45 to 52, further comprising a control shaft sized to be inserted through a working channel of an endoscope, the control shaft being attached to one of the first and second members, and the other of the first and second members is driven by the actuation element for rotation relative to the control shaft.

54. The system of claim 53, further comprising an electrical connector attached to a proximal end portion of the control shaft and electrically coupled to the actuation element and the electrode.

55. The system of claim 54, wherein the electrical connector comprises a sub-miniature phone plug connector extending coaxially from the proximal end portion of the control shaft.

56. The system of any one of claims 53 to 55, wherein the control shaft is hollow and further comprising one or more wires, each wire being electrically connected to the actuation element or the electrode, and the wires extend through the control shaft for connection to a controller.

57. The system of any one of claims 45 to 56, wherein the actuation element includes an electric motor.

58. The system of any one of claims 45 to 57, wherein the electrode includes a flexible printed circuit having at least first electrode and a second electrode that are formed on the flexible printed circuit.

59. The system of claim 58, wherein the electrode strip includes a first end portion and a second end portion opposite the first end portion, and the first end portion is attached to the first member and the second end portion is attached to the second member, and at least one of the first and second members includes a textured anchoring surface to which the respective first or second end portion of the electrode strip is attached.

60. The system of claim 58 or 59, wherein the electrode strip includes retention tabs at the first and/or second end portions, and the retention tabs mechanically engage with at least one of the first and second members.

61. The system of any one of claims 45 to 60, wherein the first and second members have proximal and distal end portions, and the actuation element is disposed either adjacent the distal end portions of the inner and outer members, or adjacent the proximal end portions of the inner and outer members.

62. The system of any one of claims 45 to 61, further comprising a cleaning strip for cleaning the electrode as it is transitioned between the deployed and stowed conditions.

63. The system of any one of claims 45 to 62, further comprising a system for emitting fluid in the vicinity of the electrode or a tissue treatment site, or both.

64. A method of deploying an electrode, comprising the steps of:

loading an electrode deployment system onto an endoscope by inserting a shaft of the electrode deployment system into a working channel of the endoscope via an opening at a distal end of the endoscope and sliding the shaft through the

working channel until the shaft extends beyond a proximal end of the endoscope and an electrode deployment device of the electrode deployment system that is attached to a distal end portion of the shaft is positioned distally adjacent the distal end of the endoscope;

operating the electrode deployment device to move a flexible electrode of the electrode deployment system between a stowed configuration and a deployed configuration.

65. The method of claim 64, wherein the electrode deployment device includes an electric motor.

66. The method of claim 64 or 65, wherein the shaft has an outer diameter between 2.5 mm and 4.0 mm.

67. The method of claim 66, wherein the shaft has outer diameter of approximately 2.7 mm.

68. The method of any one of claims 64 to 67, further comprising the step of electrically connecting a power supply to a proximal end portion of the shaft.

69. The method of claim 68, wherein an electrical connector is provided at the proximal end portion of the shaft, and wherein the step of electrically connecting the power supply to the proximal end portion of the shaft includes joining the electrical connector to a mating electrical connector that is electrically connected to the power supply.

70. The method of claim 69, wherein the electrical connector comprises a sub-miniature phone plug connector extending coaxially from the proximal end portion of the shaft.

71. The method of any one of claims 68 to 70, wherein the step of electrically connecting the power supply to the proximal end portion of the shaft includes connecting a handle or a robotic manipulator to the proximal end portion of the shaft.

72. The method of claim 71, further comprising rotating the shaft by manipulating the handle or by operating the robotic manipulator.

73. The method of any one of claims 64 to 72, wherein:

the flexible electrode includes an electrode strip that is coiled when in the stowed configuration; and

the step of operating the electrode deployment device includes moving the electrode strip from the stowed configuration to the deployed configuration by at least partially uncoiling the electrode strip.

74. A method of deploying an electrode, comprising the steps of:

activating an actuation element operatively coupled to a coiled flexible electrode strip to unfurl the electrode strip; and

sensing an electrical current supplied to the actuation element to drive the actuation element for unfurling of the electrode strip, and automatically switching off the electrical current when it exceeds a predetermined threshold to thereby halt the unfurling of the electrode strip.

75. The method of claim 74, further comprising the step of applying energy to the electrode strip to perform a treatment or sensing operation on internal tissue.

76. The method of claim 74 or 75, further comprising, after the step of automatically switching off the electrical current, selectively activating the actuation element for one or more additional predetermined intervals, to thereby further unfurl the flexible electrode strip in a stepwise manner.

77. The method of claim 76, wherein the step of selectively activating the actuation element is performed in response to a controller receiving a stepping signal initiated by a user.

78. The method of claim 77, wherein the step of activating the actuation element is performed in response to the controller receiving an activation signal initiated by the user.

79. The method of claim 78, wherein the activation signal and the stepping signal are each generated by the user pressing a button in a similar manner.

80. The method of any one of claims 74 to 79, wherein the step of activating the actuation element causes the actuation element to operate in a first direction, and the method further comprises, after unfurling the electrode strip, activating the actuation element in a second direction opposite the first direction to furl the electrode strip.

81. The method of claim 80, wherein the step of activating the actuation element in the second direction is performed in response to a controller receiving a second signal different from the activation signal.

82. The method of claim 81, wherein the second signal is user-initiated.

83. The method of any one of claims 74 to 82, wherein the actuation element includes an electric motor.

84. An electrode treatment device, comprising:

an endoscope including a body having a distal end, the body having a working port extending longitudinally through the body;

an electrode deployment system supported by the endoscope adjacent its distal end;

an electrode supported on the electrode deployment system; and

a drive shaft extending through the working port, the drive shaft operatively coupled to the electrode deployment system and movable within the working port relative to the body to drive the electrode deployment system for moving the electrode between a stowed configuration and a deployed configuration, wherein the electrode is laterally expanded in the deployed configuration relative to the stowed configuration.

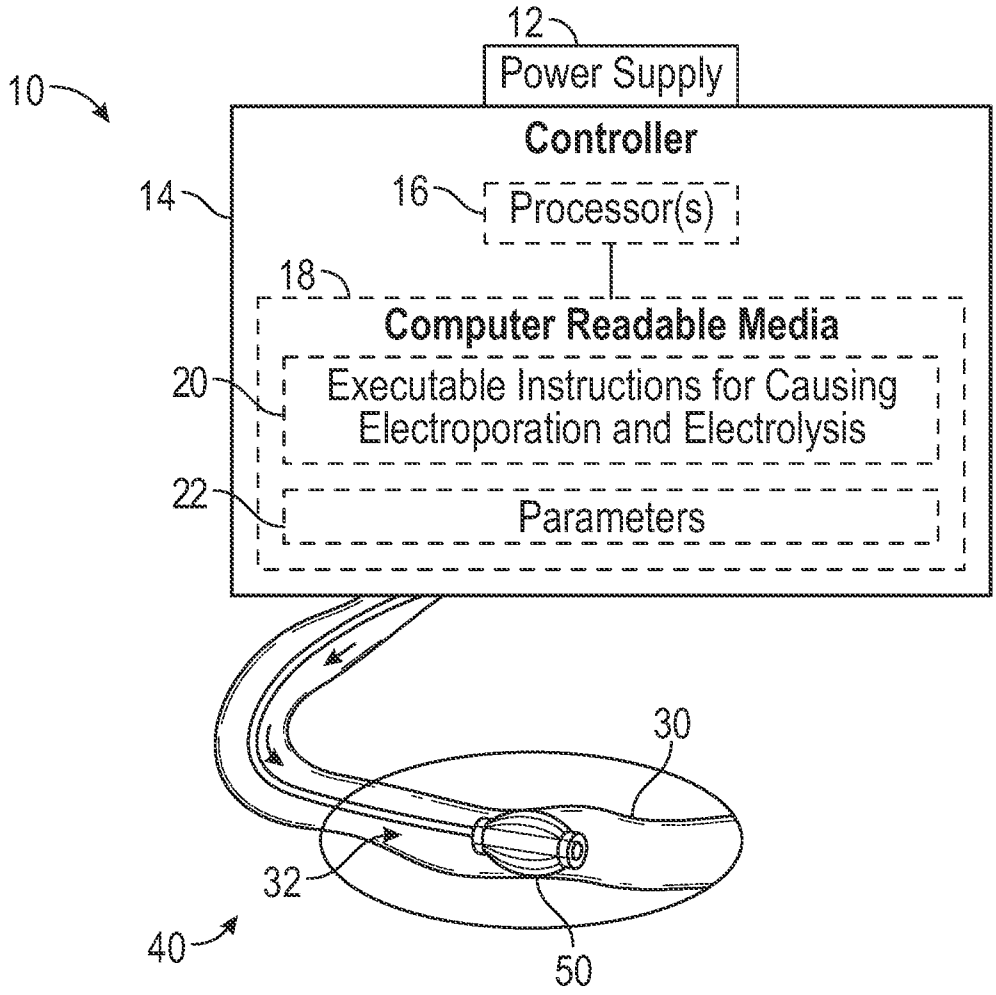
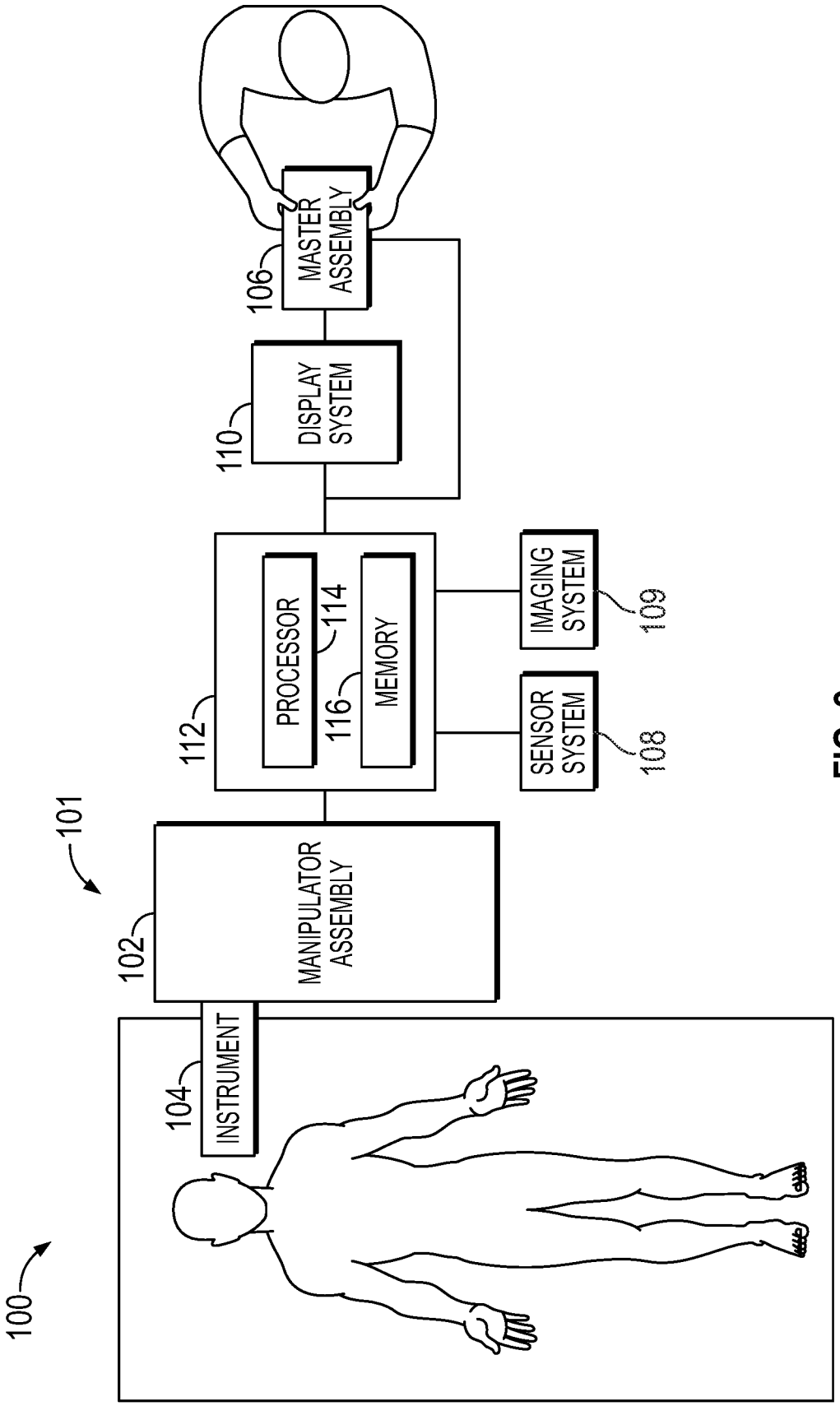

12
Power Supply
10
Controller
14
16
Processor(s)
18
Computer Readable Media
20
Executable Instructions for Causing Electroporation and Electrolysis
22
Parameters
30
32
40
50

FIG. 1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104
INSTRUMENT
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MASTER ASSEMBLY
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DISPLAY SYSTEM
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PROCESSOR
114
MEMORY
116
IMAGING SYSTEM
109
SENSOR SYSTEM
108

FIG. 2

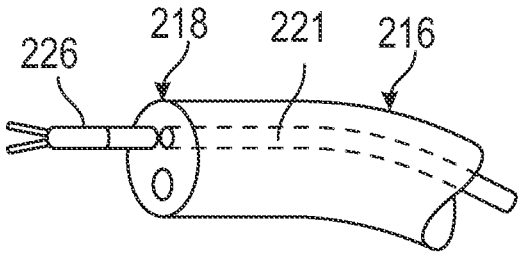
226
218
221
216

FIG. 3B

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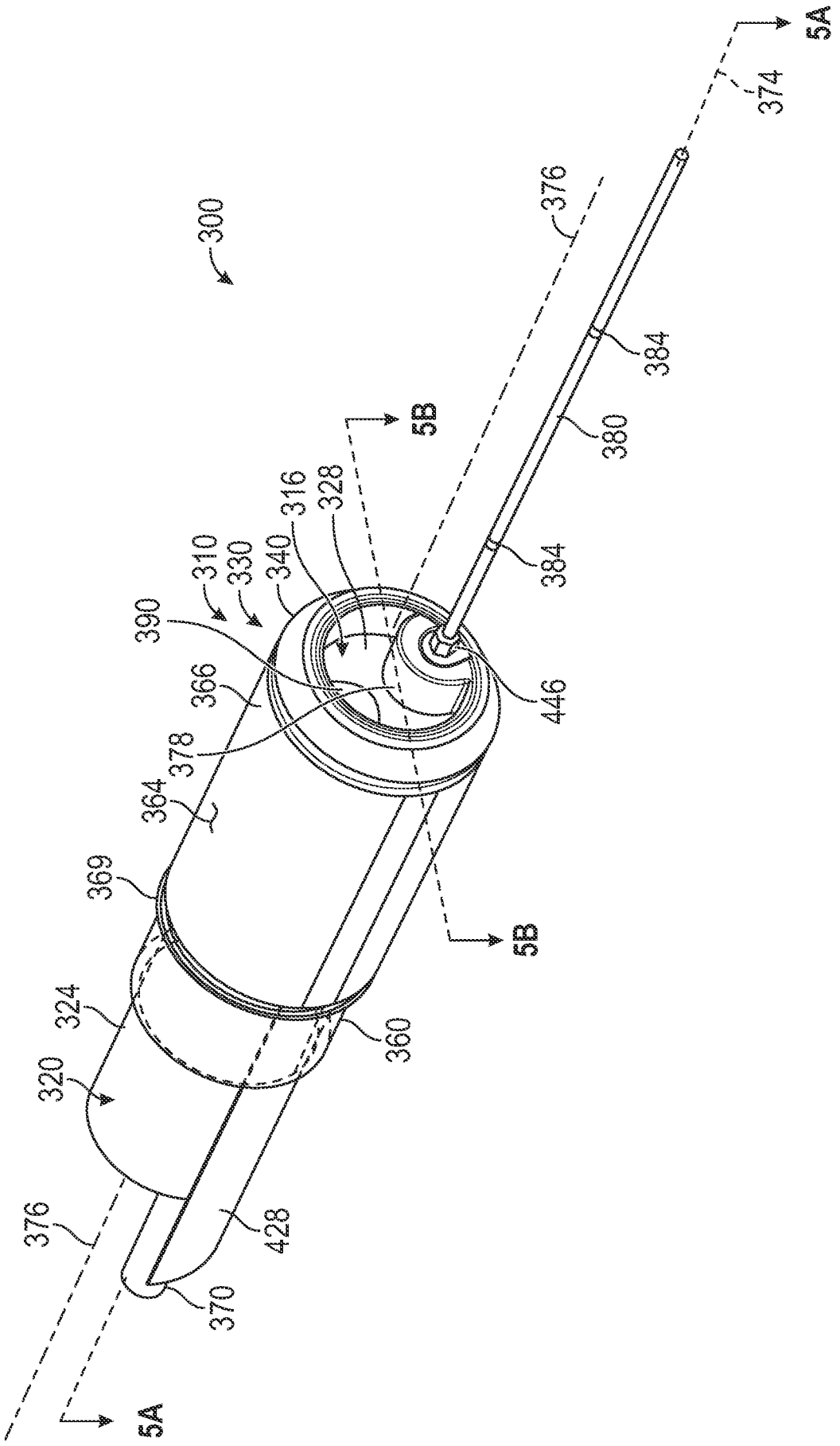
221
202
222
226
216
224
224
102
Manipulator Assembly
204
231
Visualization System
Navigation System
232
230
Tracking System
Display System
110
217

FIG. 3A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374
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446
5A
5B

FIG. 4

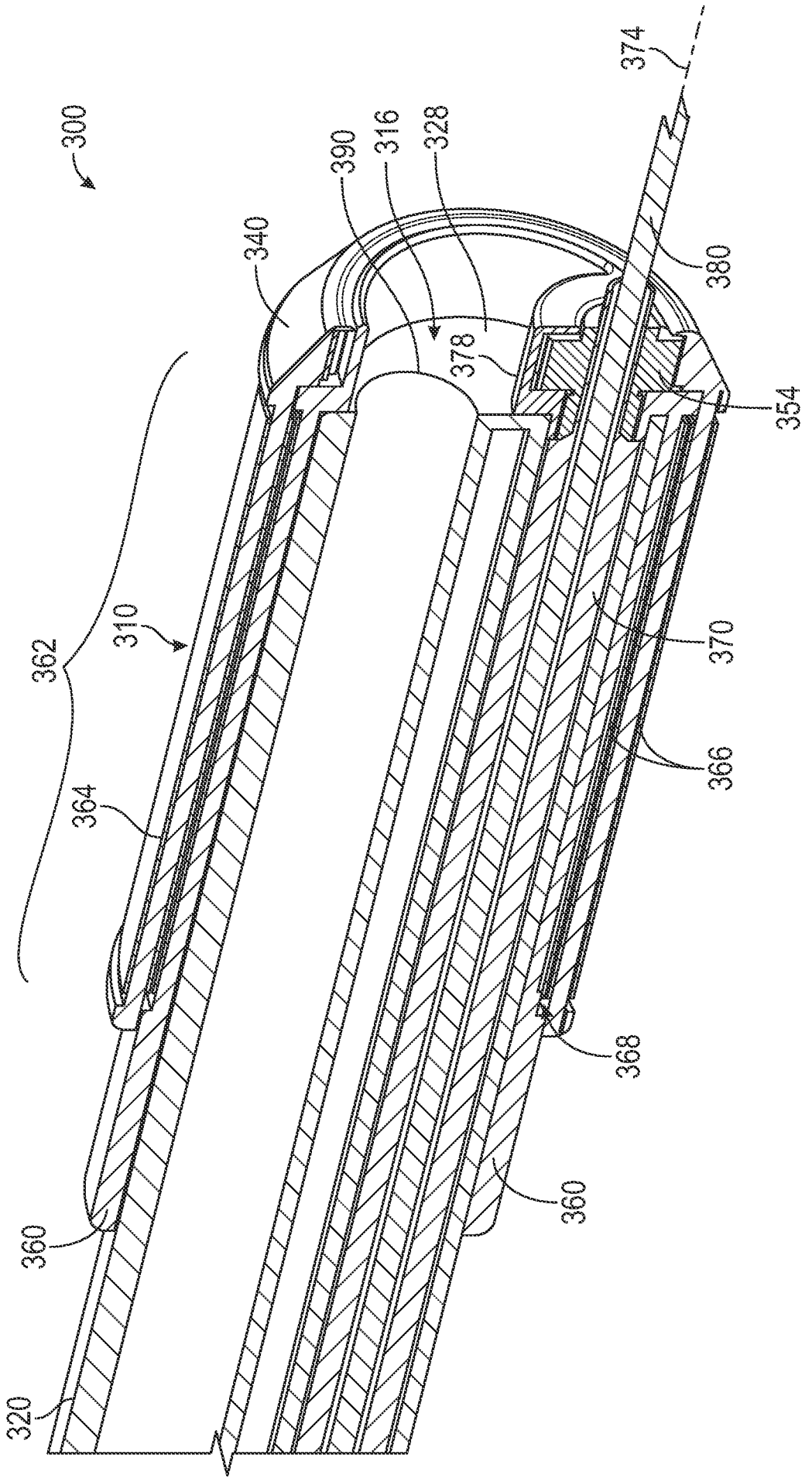
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FIG. 5A

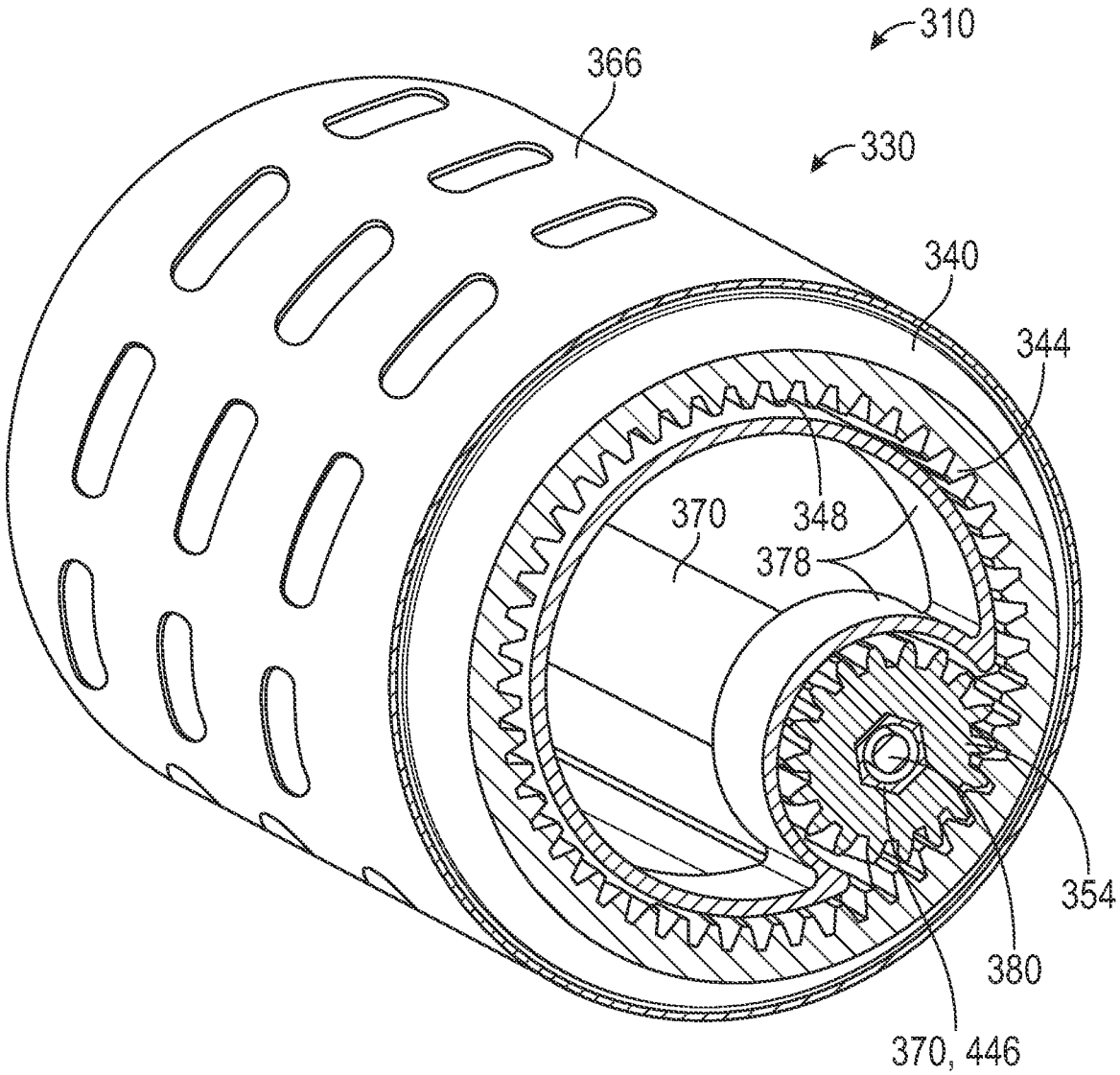


FIG. 5B

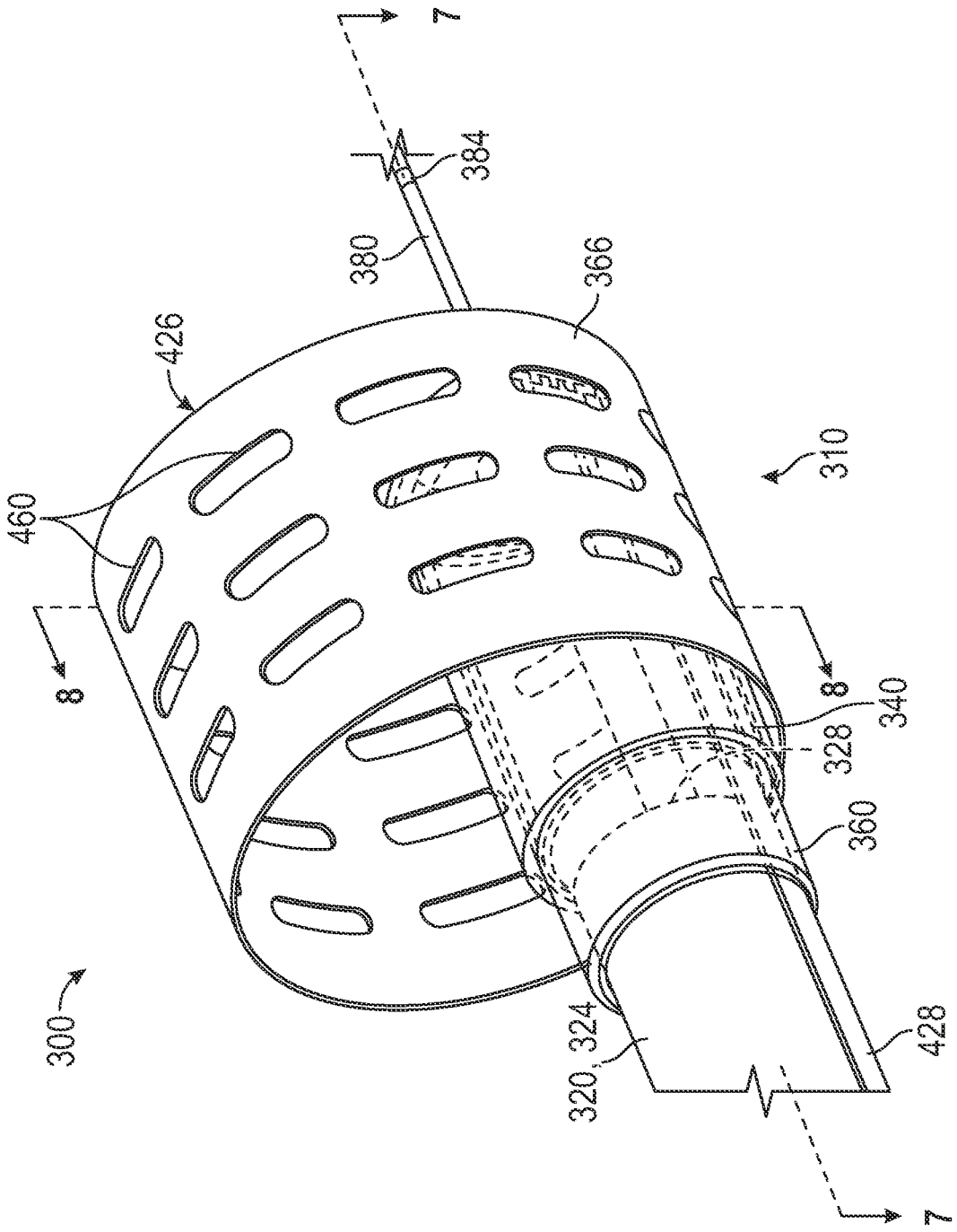


FIG. 6

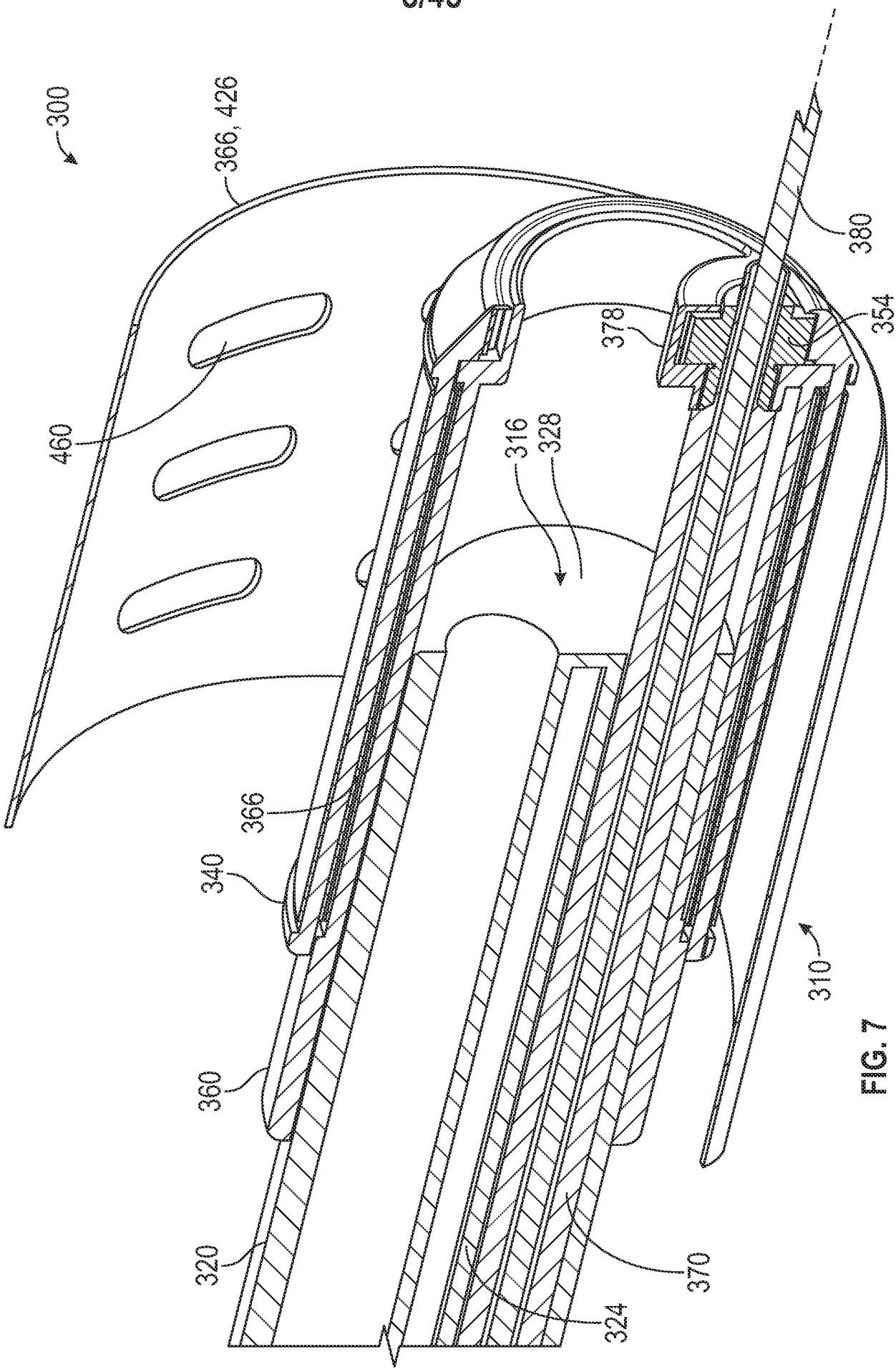
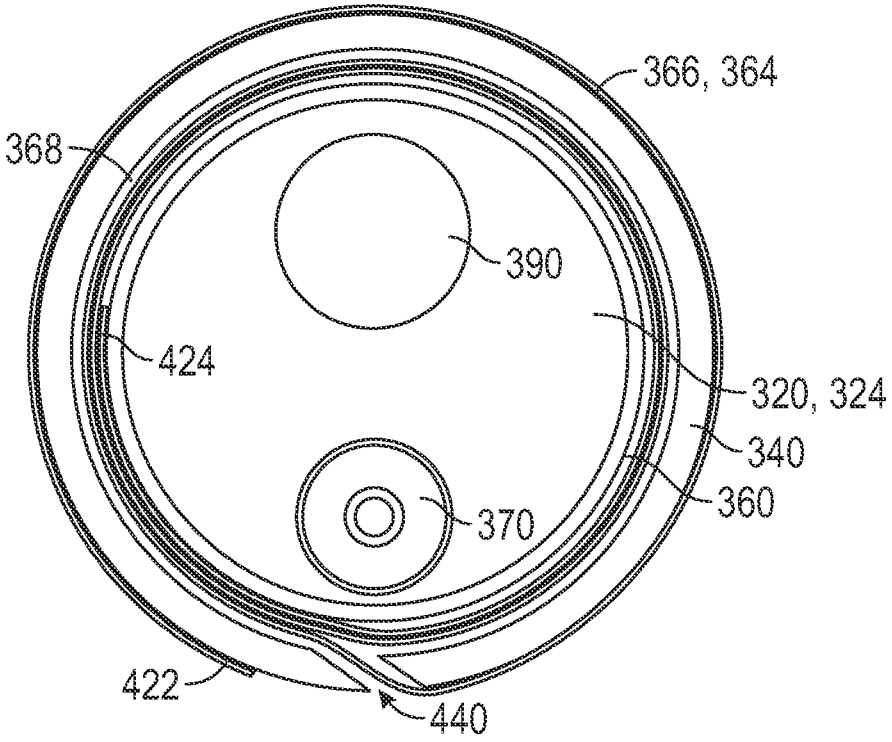


FIG. 7


366, 364
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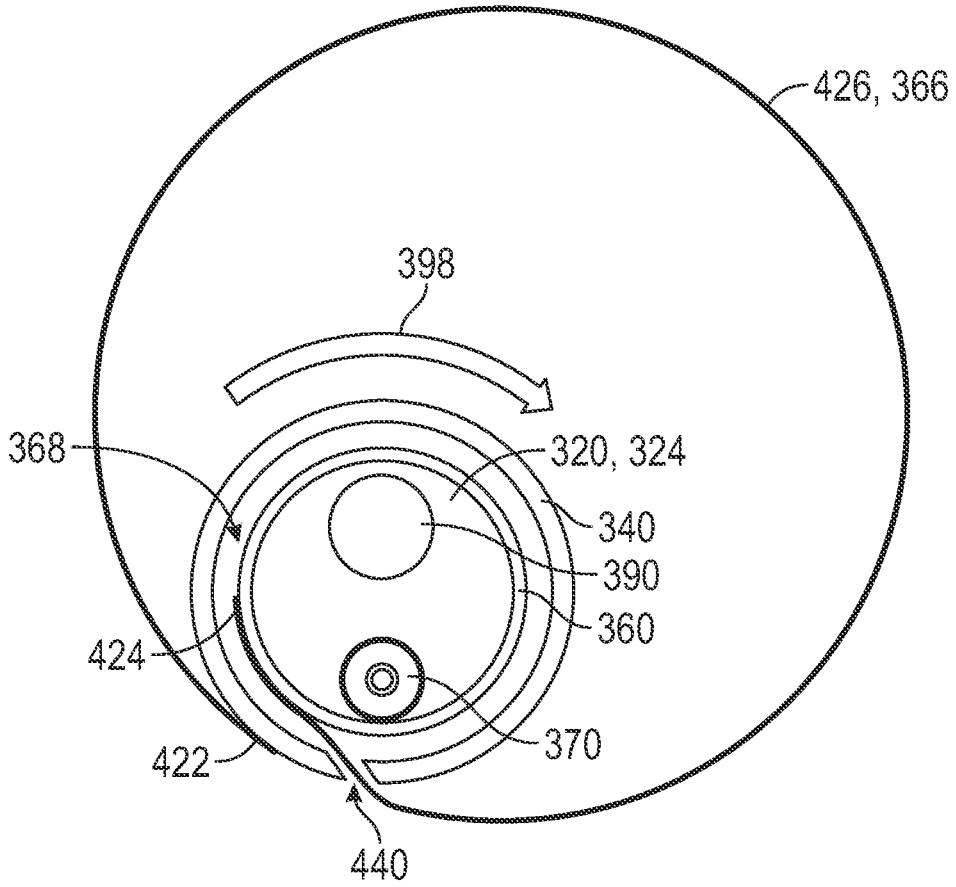
390
424
320, 324
340
360
370
422
440

FIG. 8A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422
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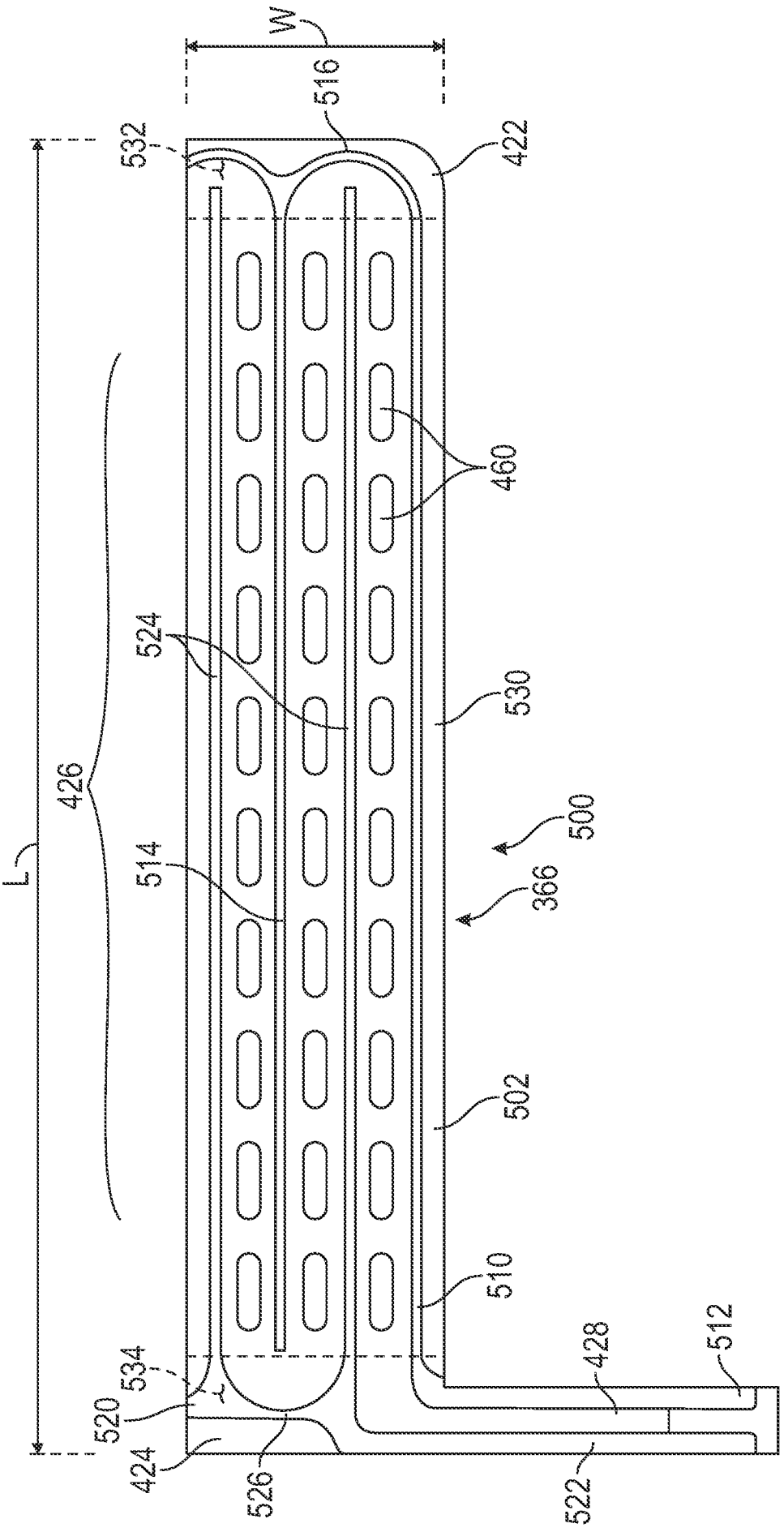
FIG. 8B


W
516
532
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L
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526
522

FIG. 9

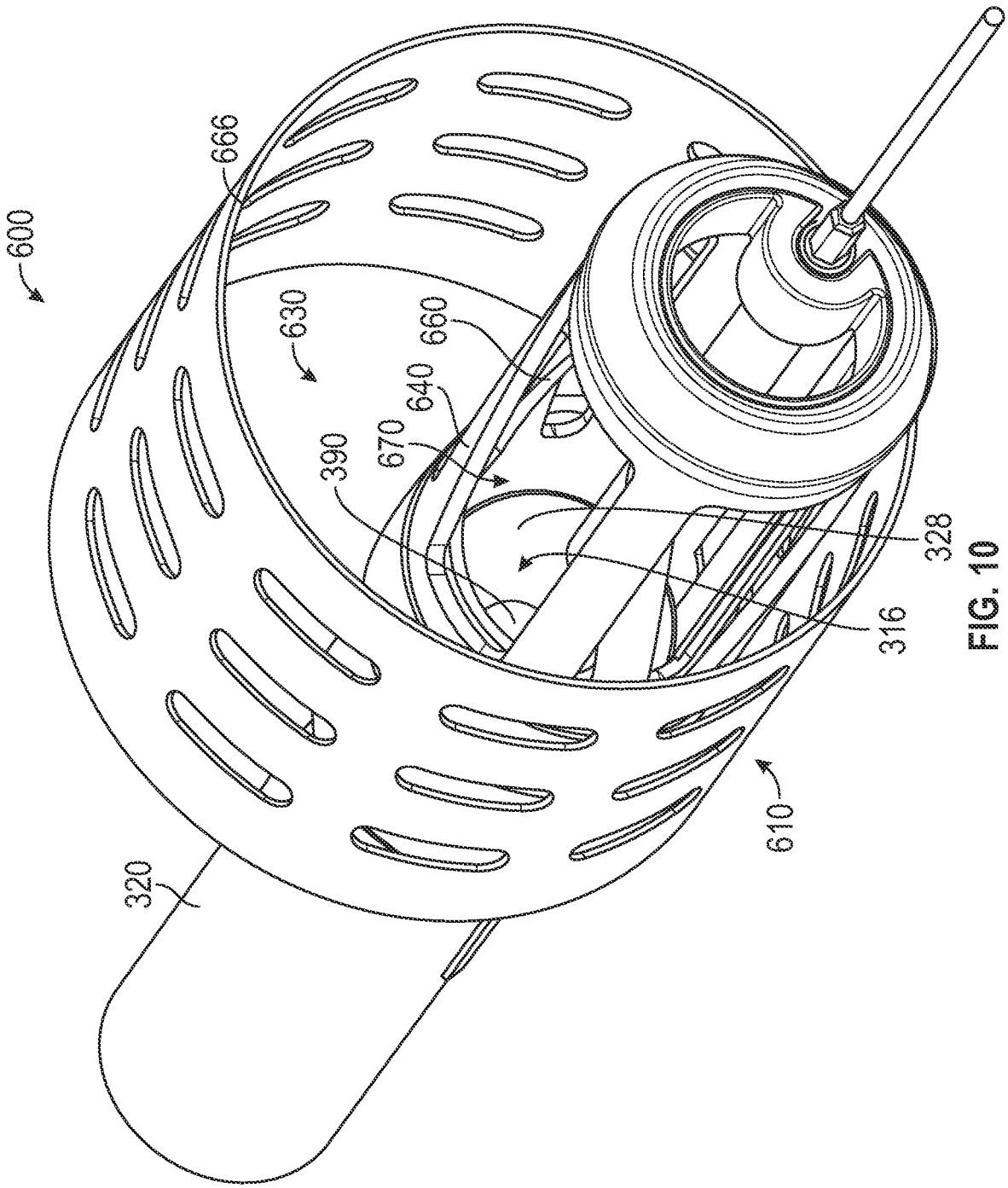


FIG. 10

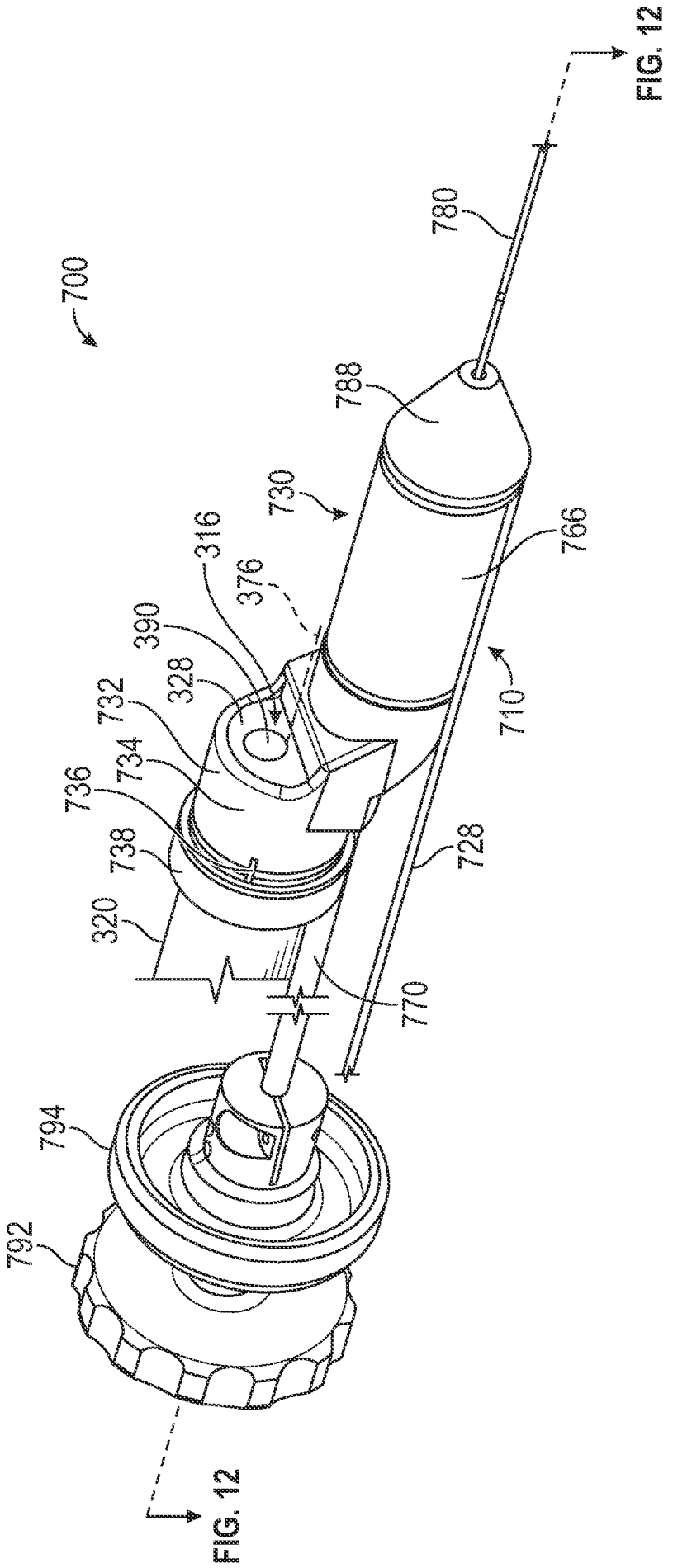
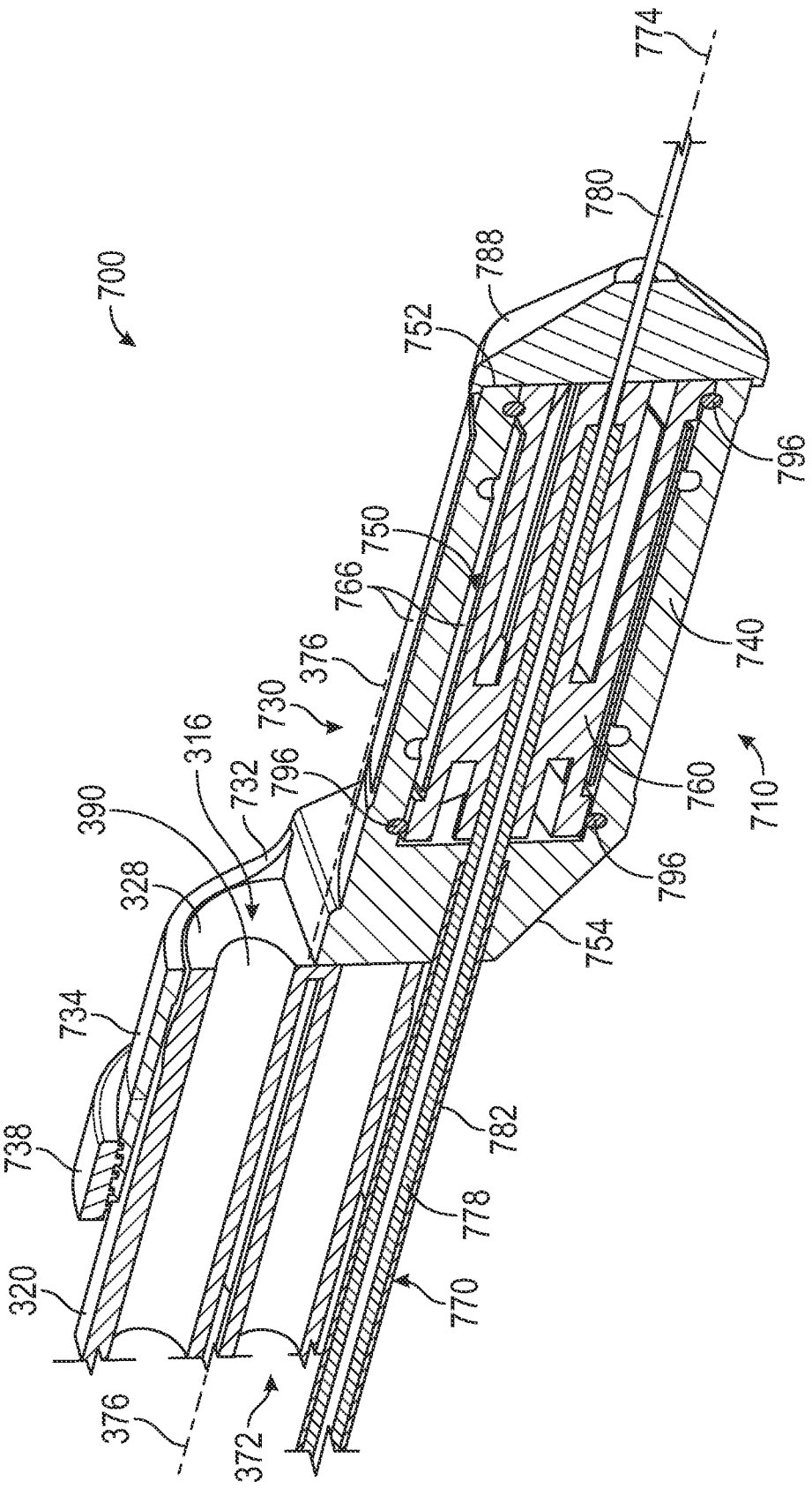


FIG. 12
780
700
788
730
316
766
376
390
328
732
710
734
736
738
728
320
770
794
792
FIG. 12

FIG. 11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372

FIG. 12

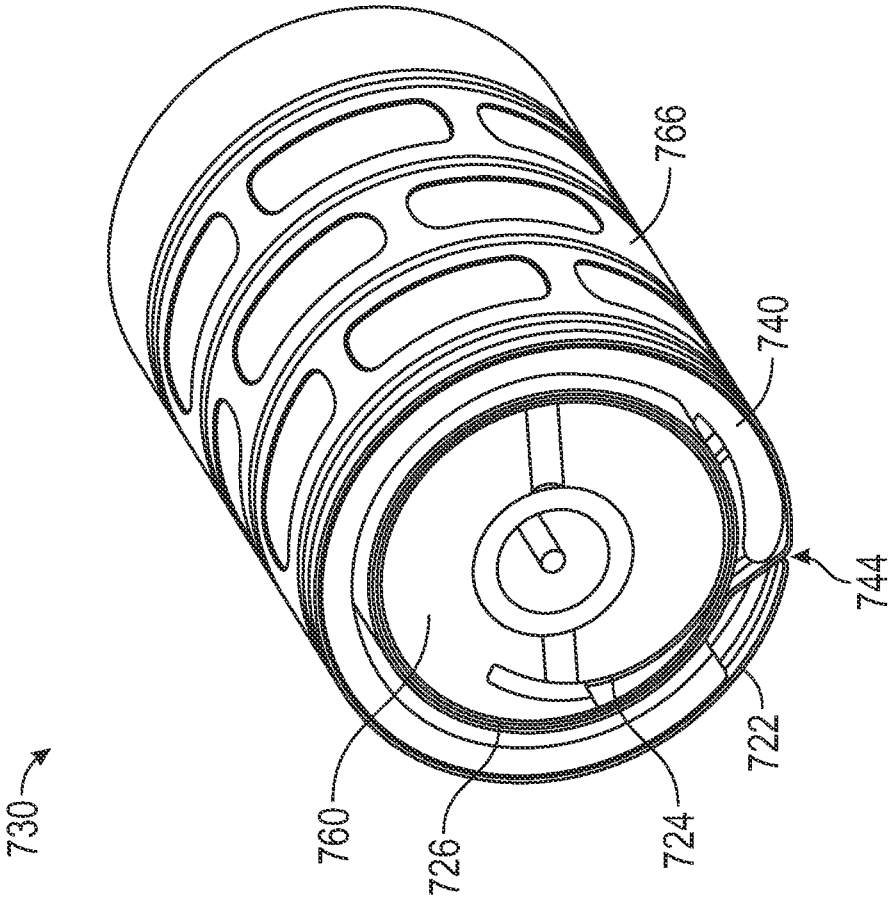

FIG. 13A

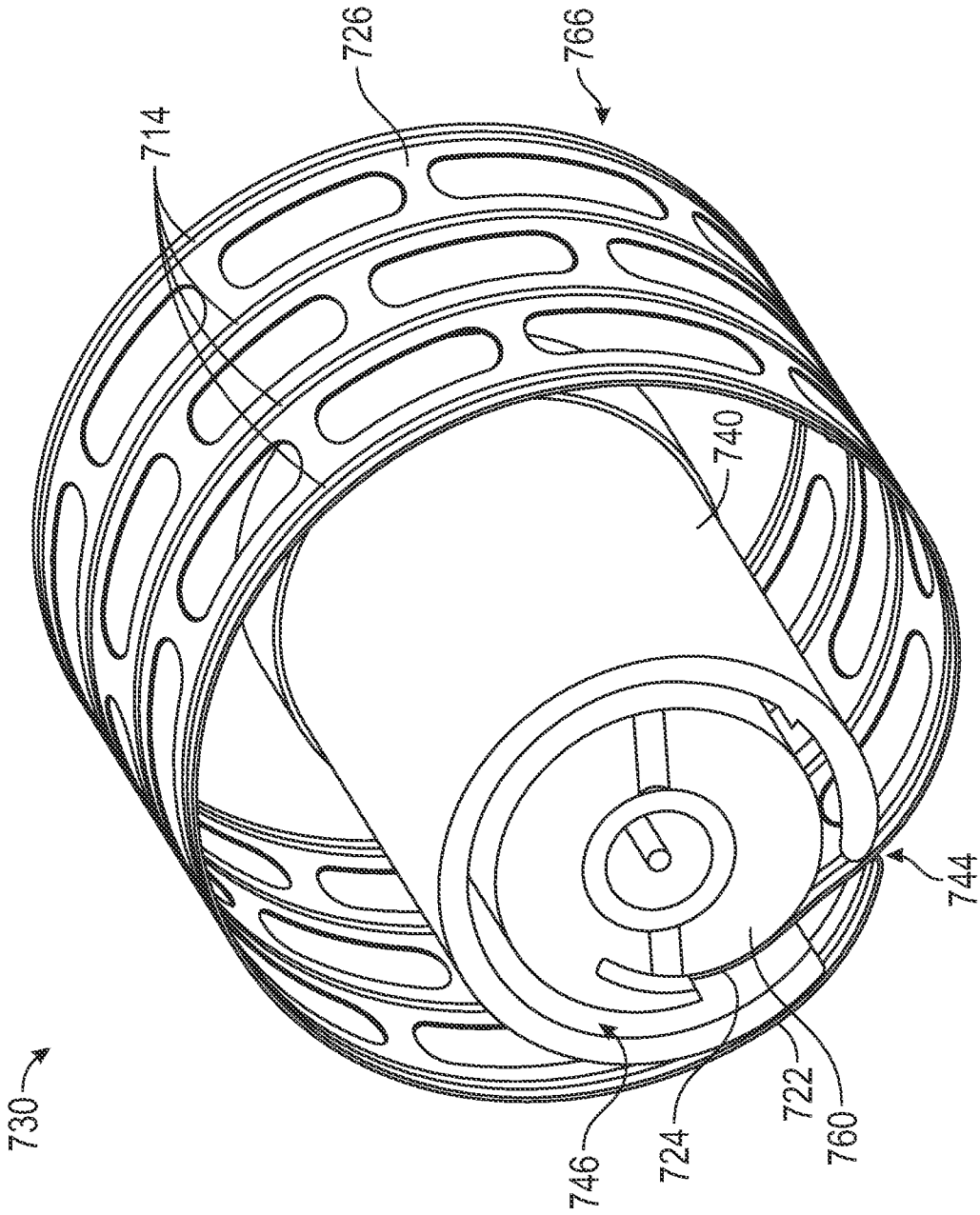

FIG. 13B

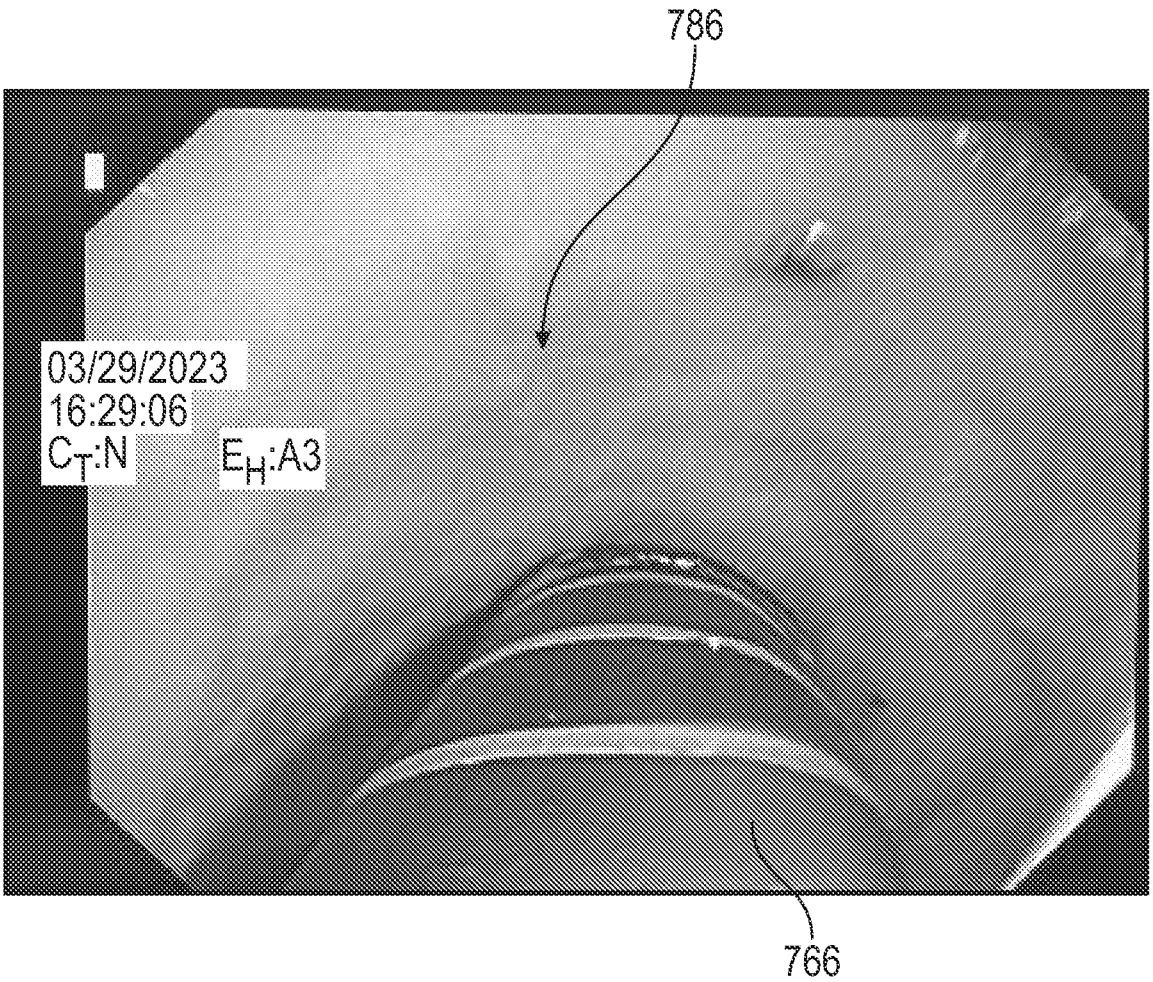

FIG. 14

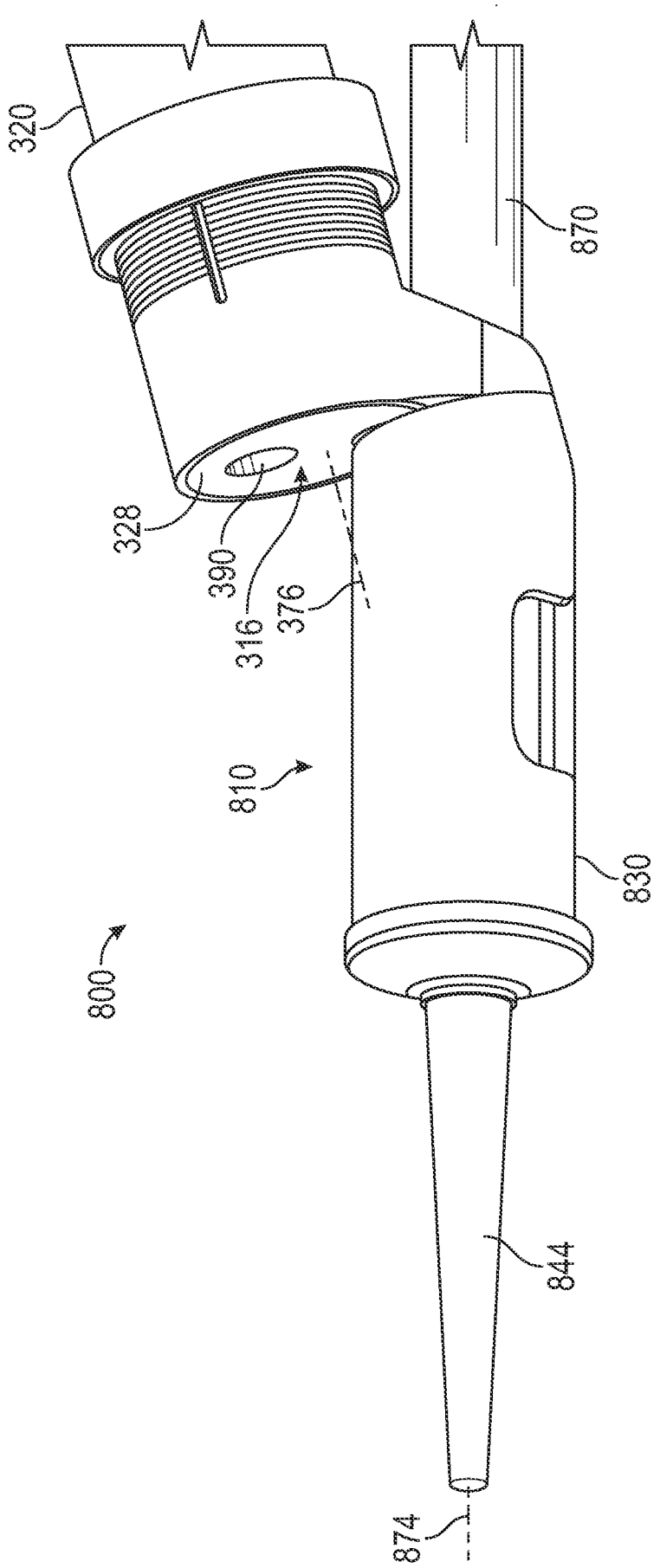

FIG. 15

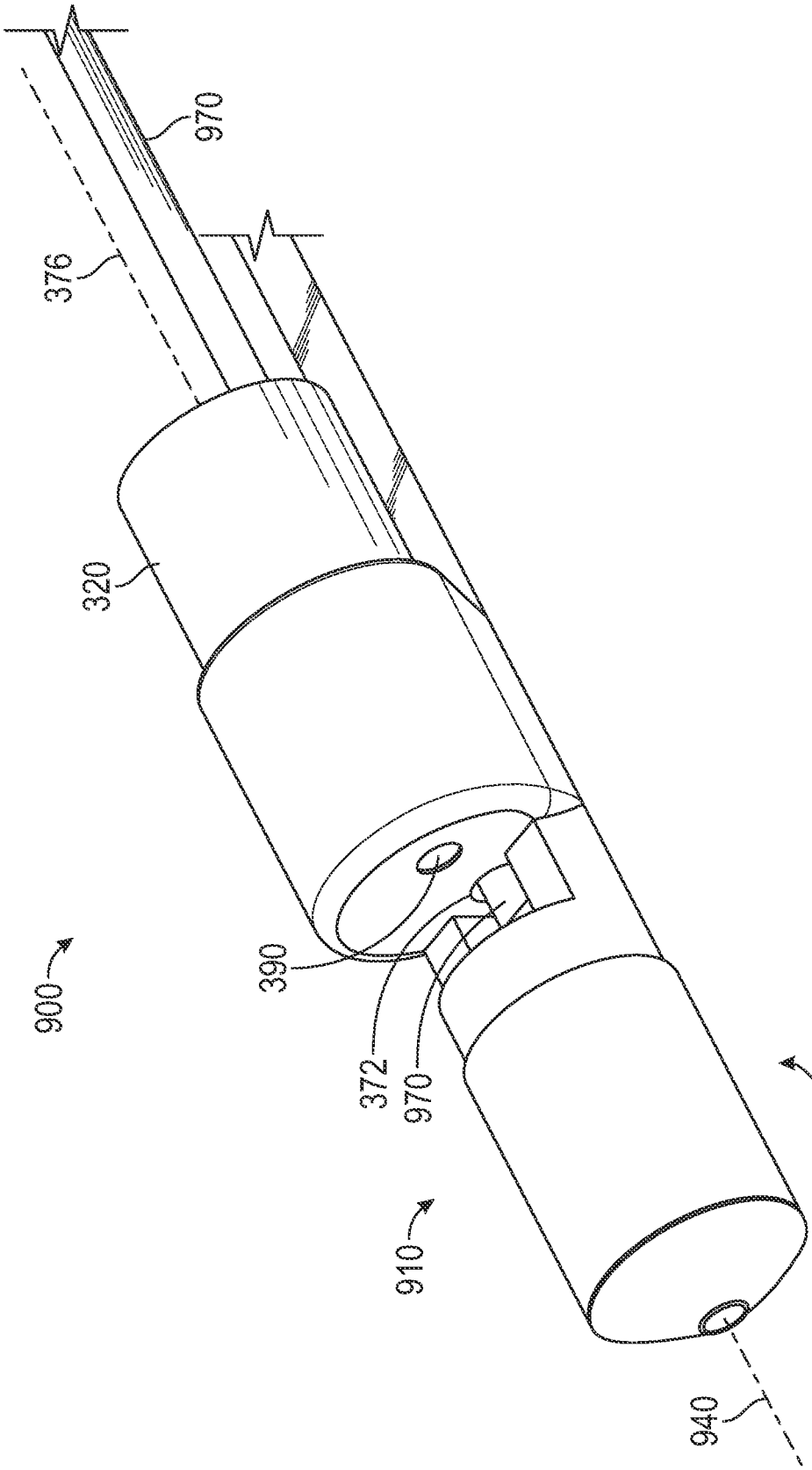

FIG. 16A

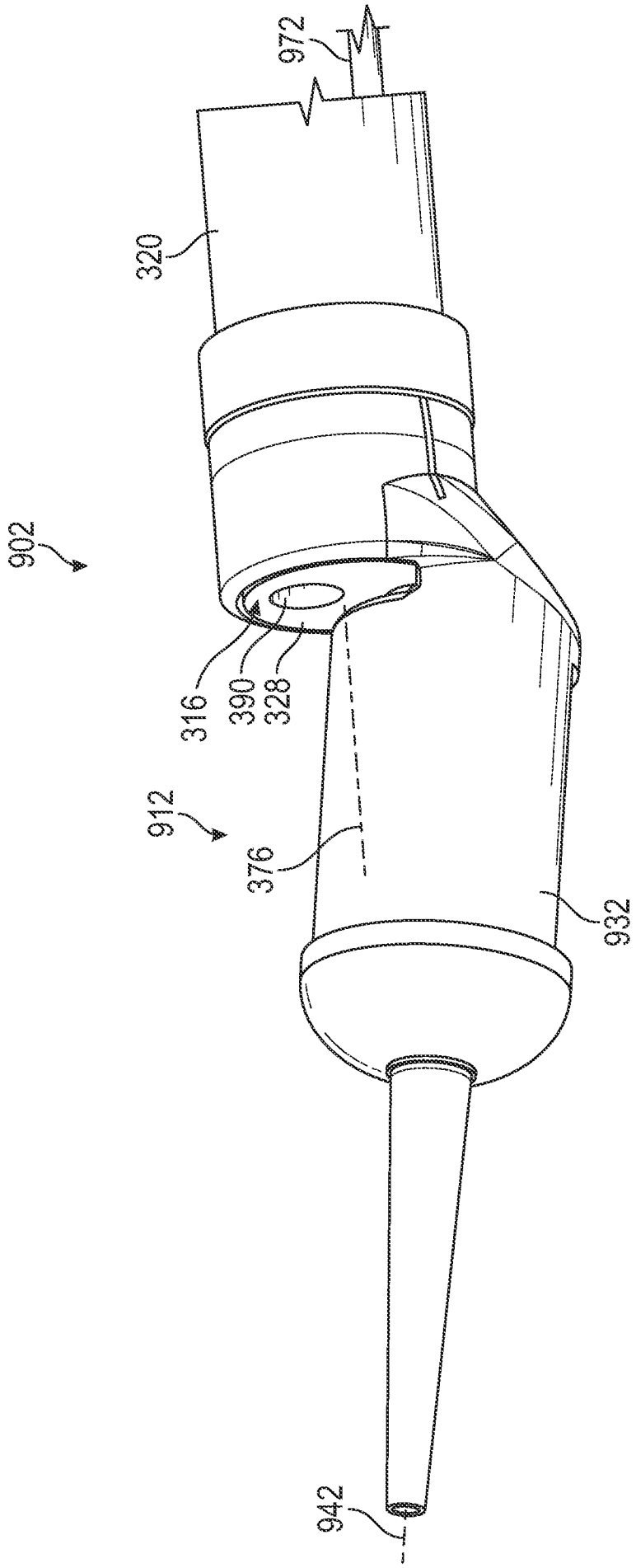

FIG. 16B

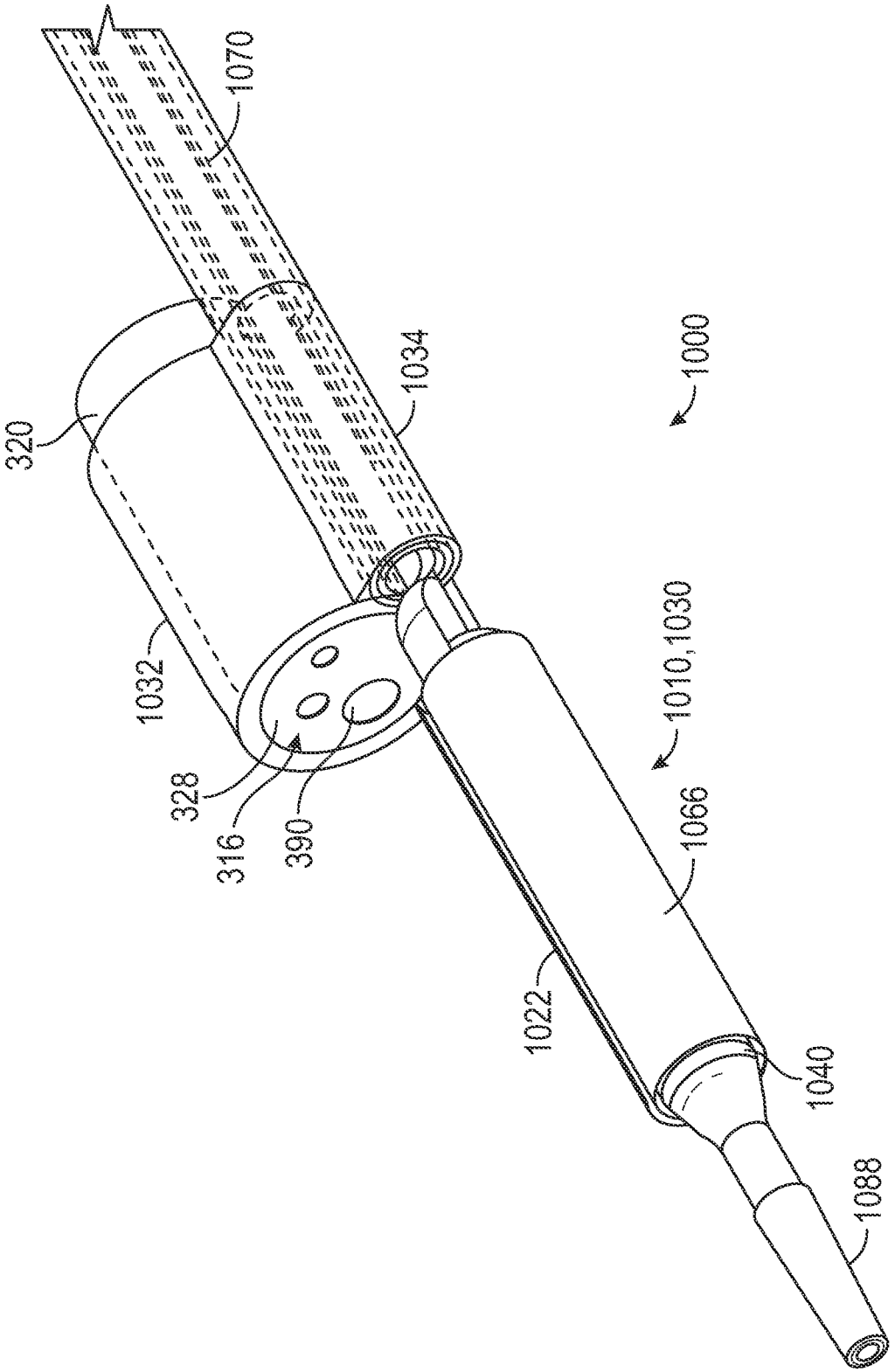
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FIG. 17

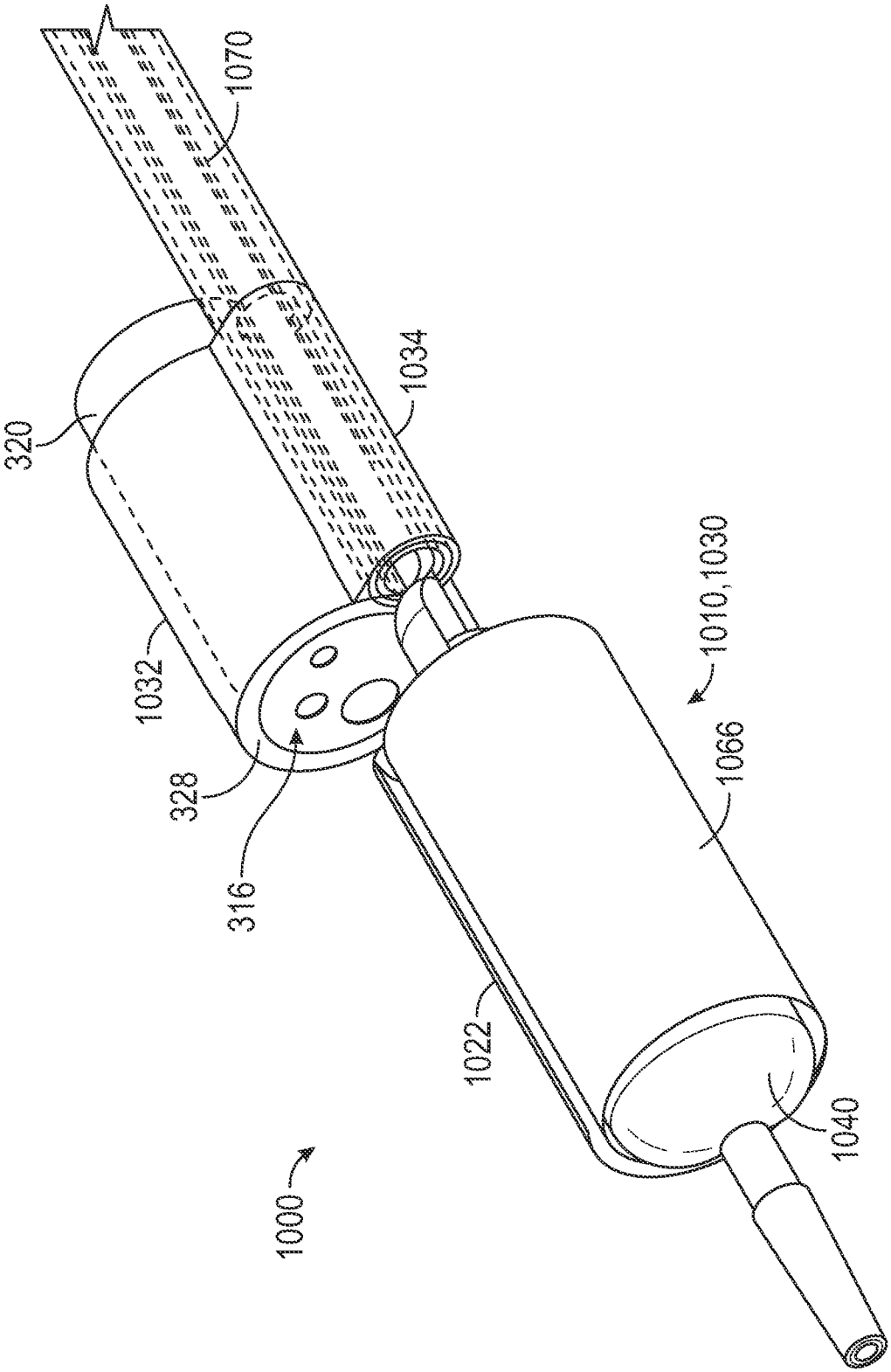

FIG. 18

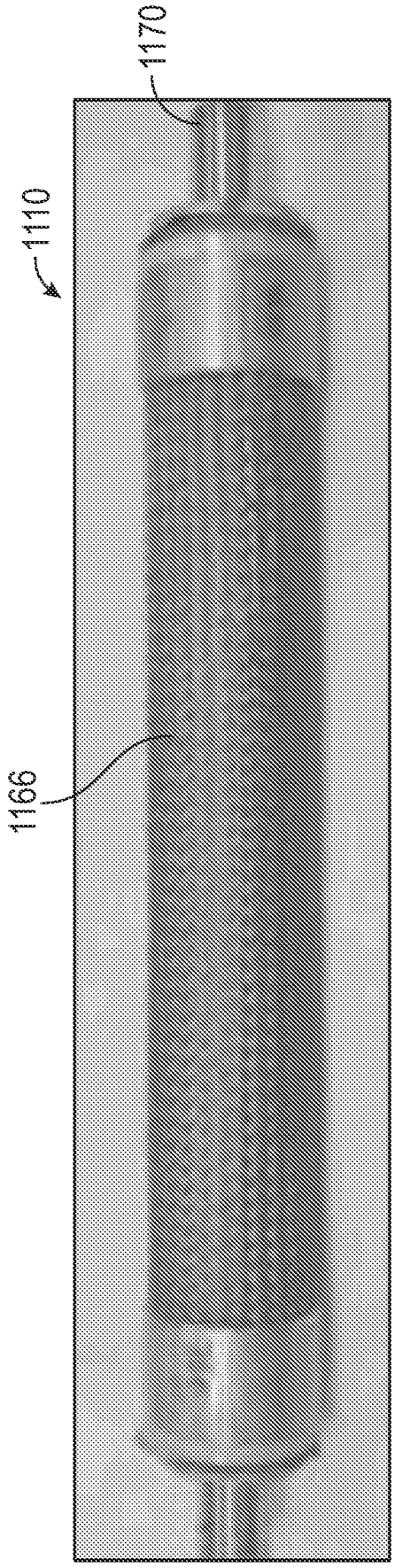

FIG. 19A

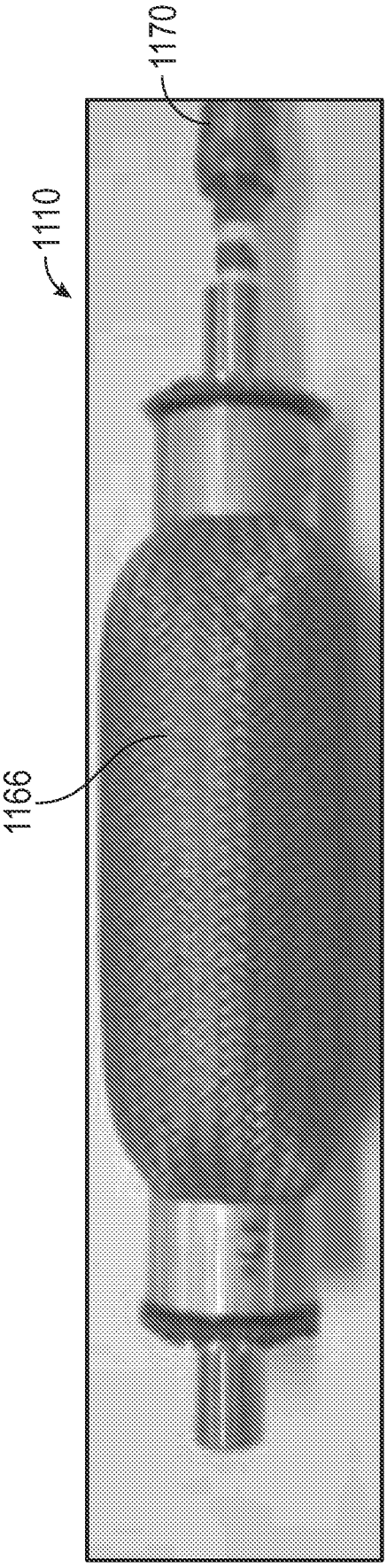

FIG. 19B

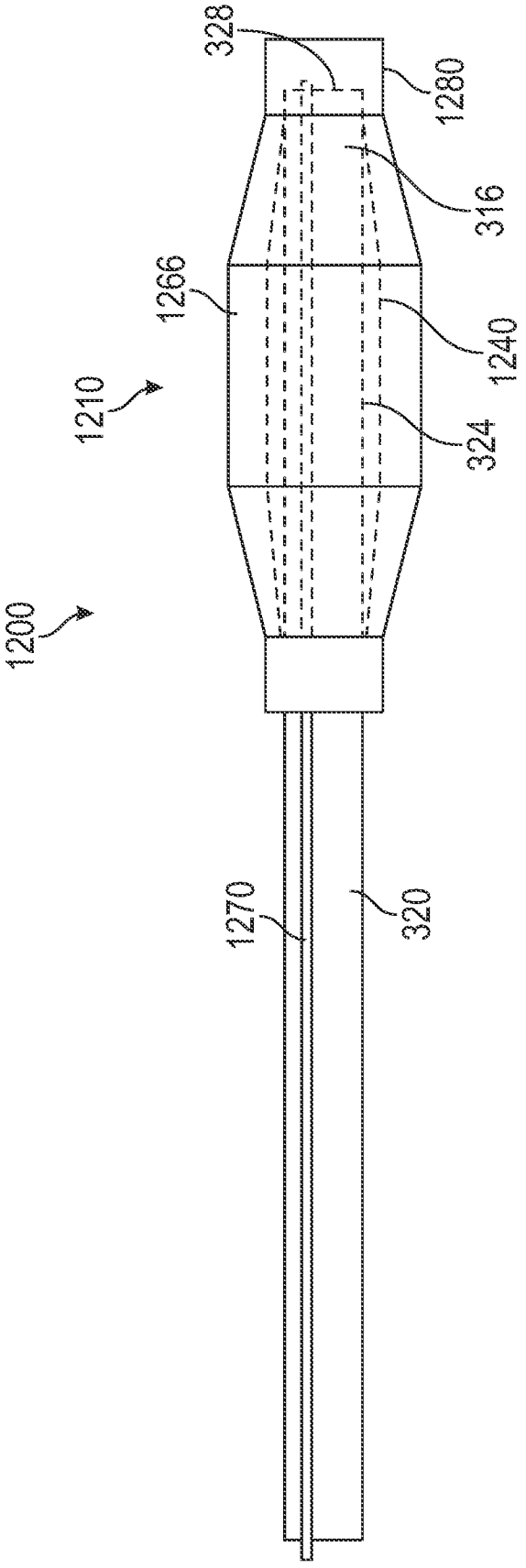

FIG. 20

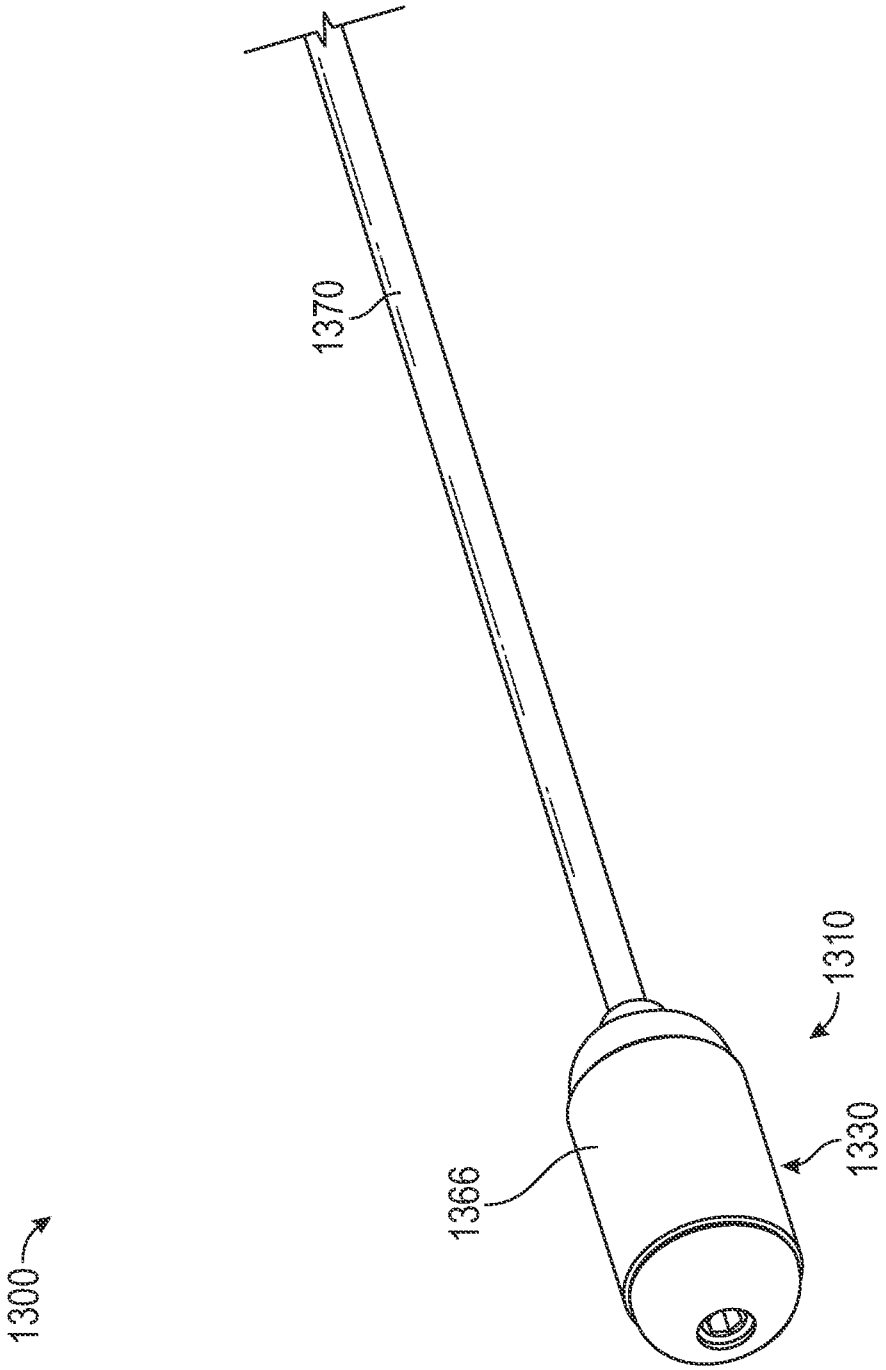

FIG. 21A

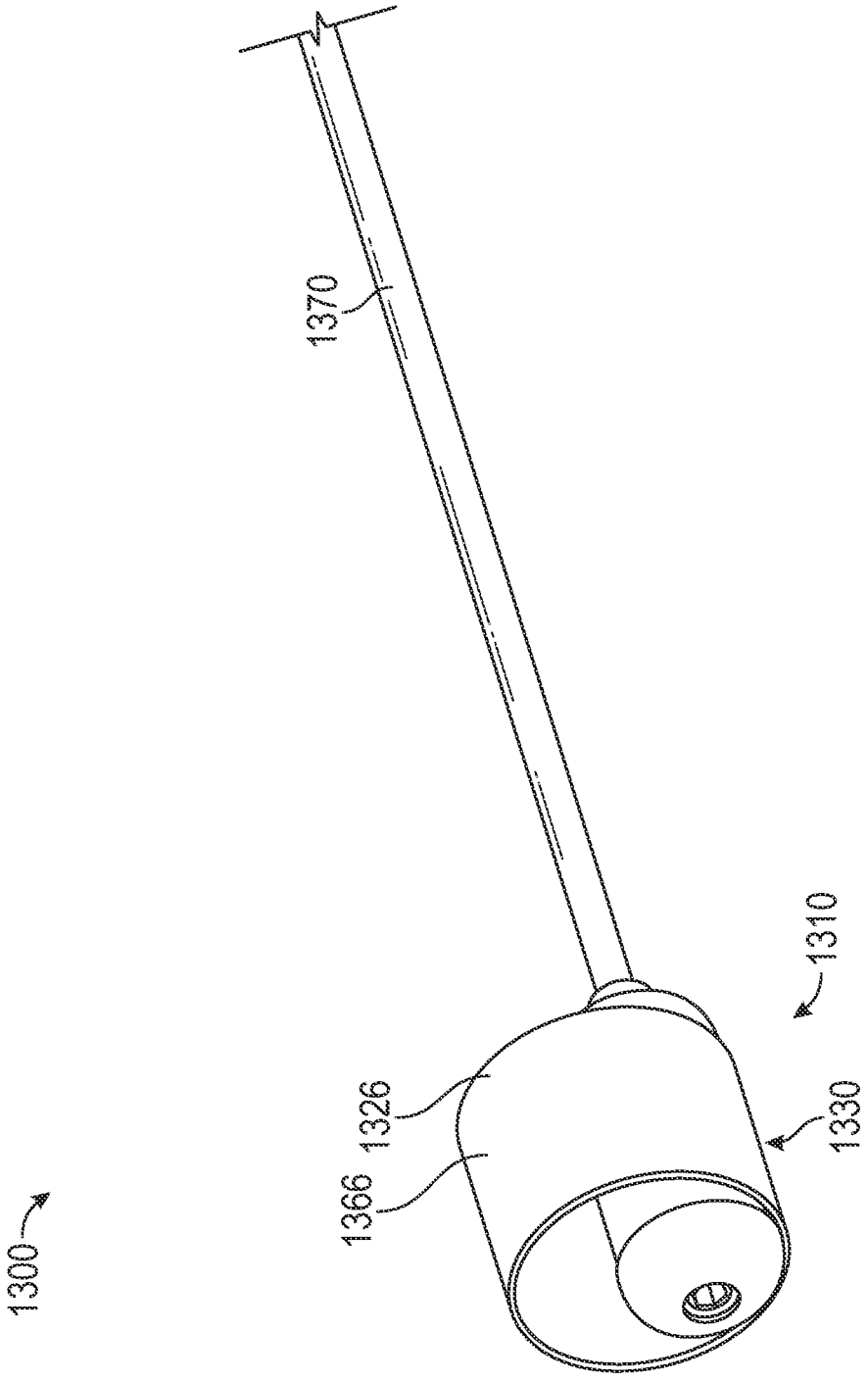

FIG. 21B

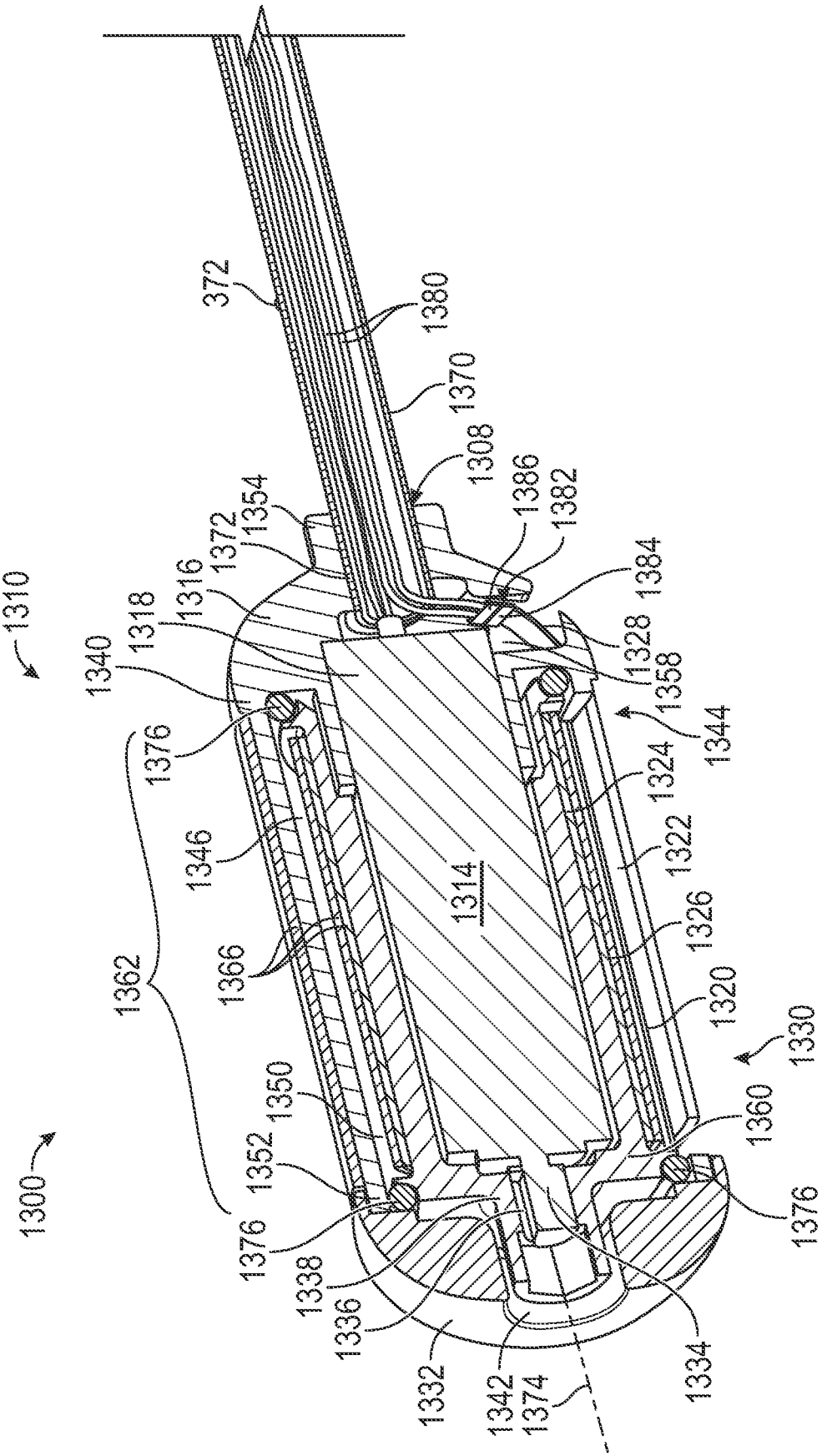
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FIG. 21C

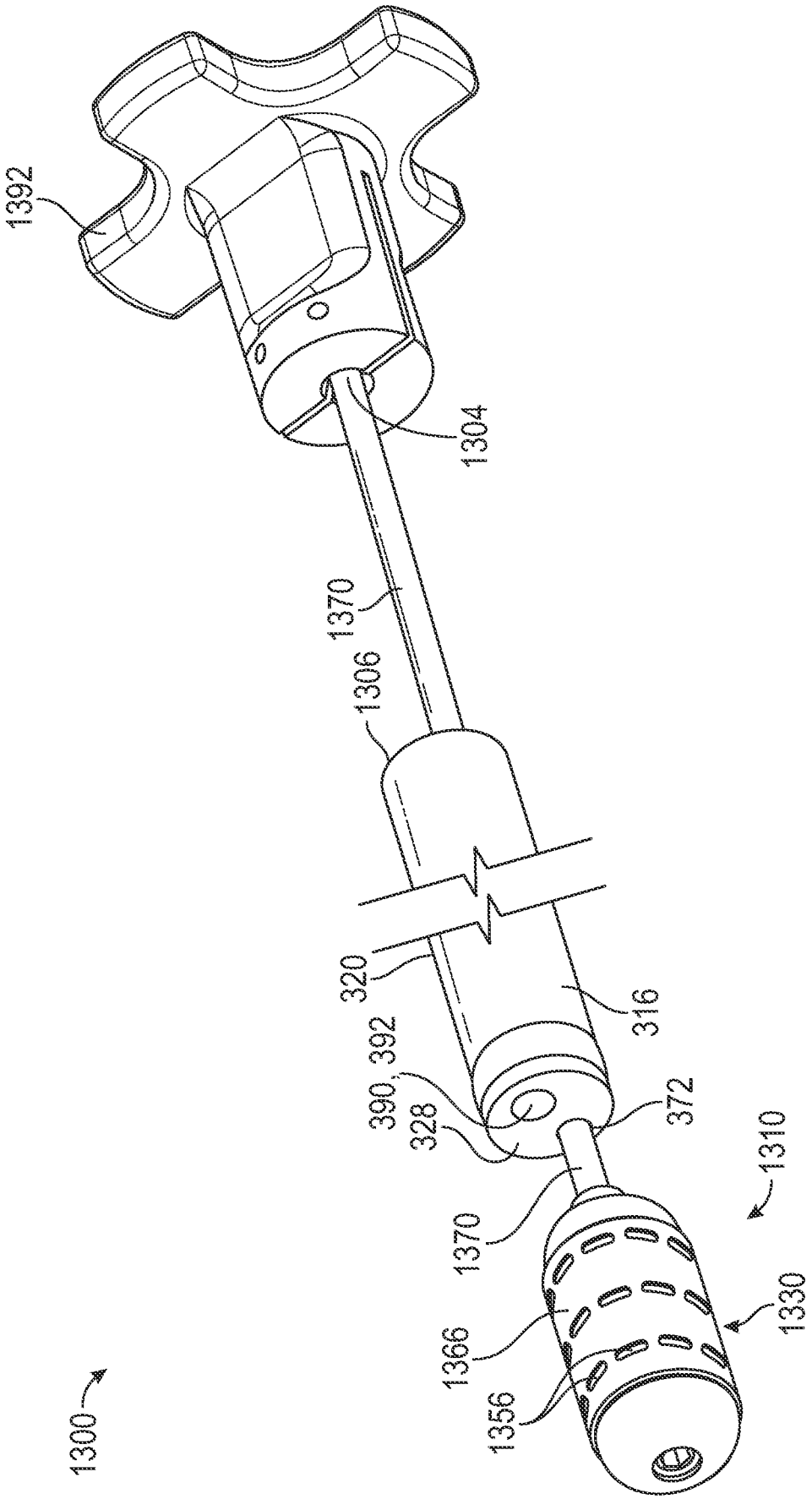
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FIG. 22

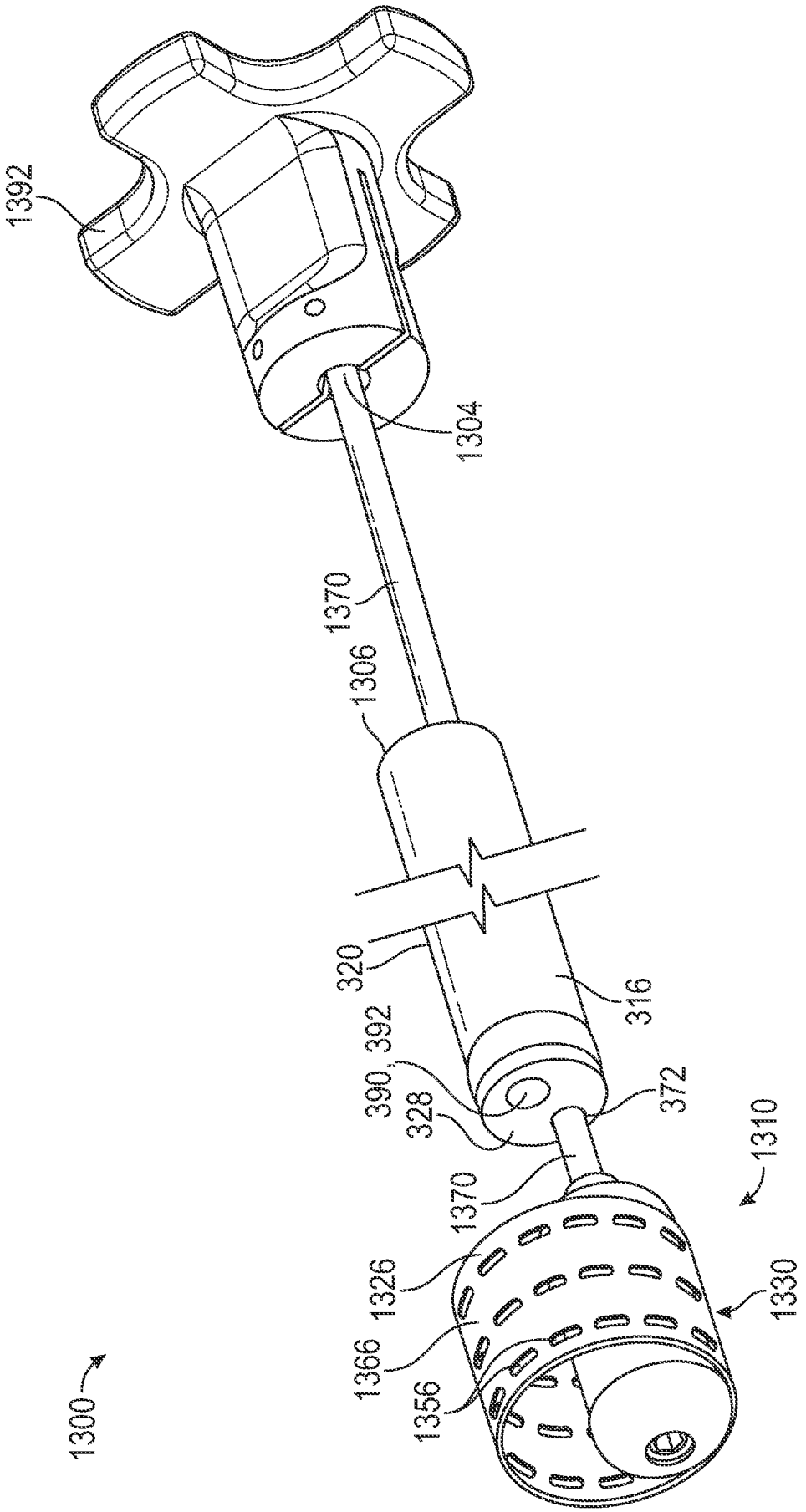
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FIG. 23

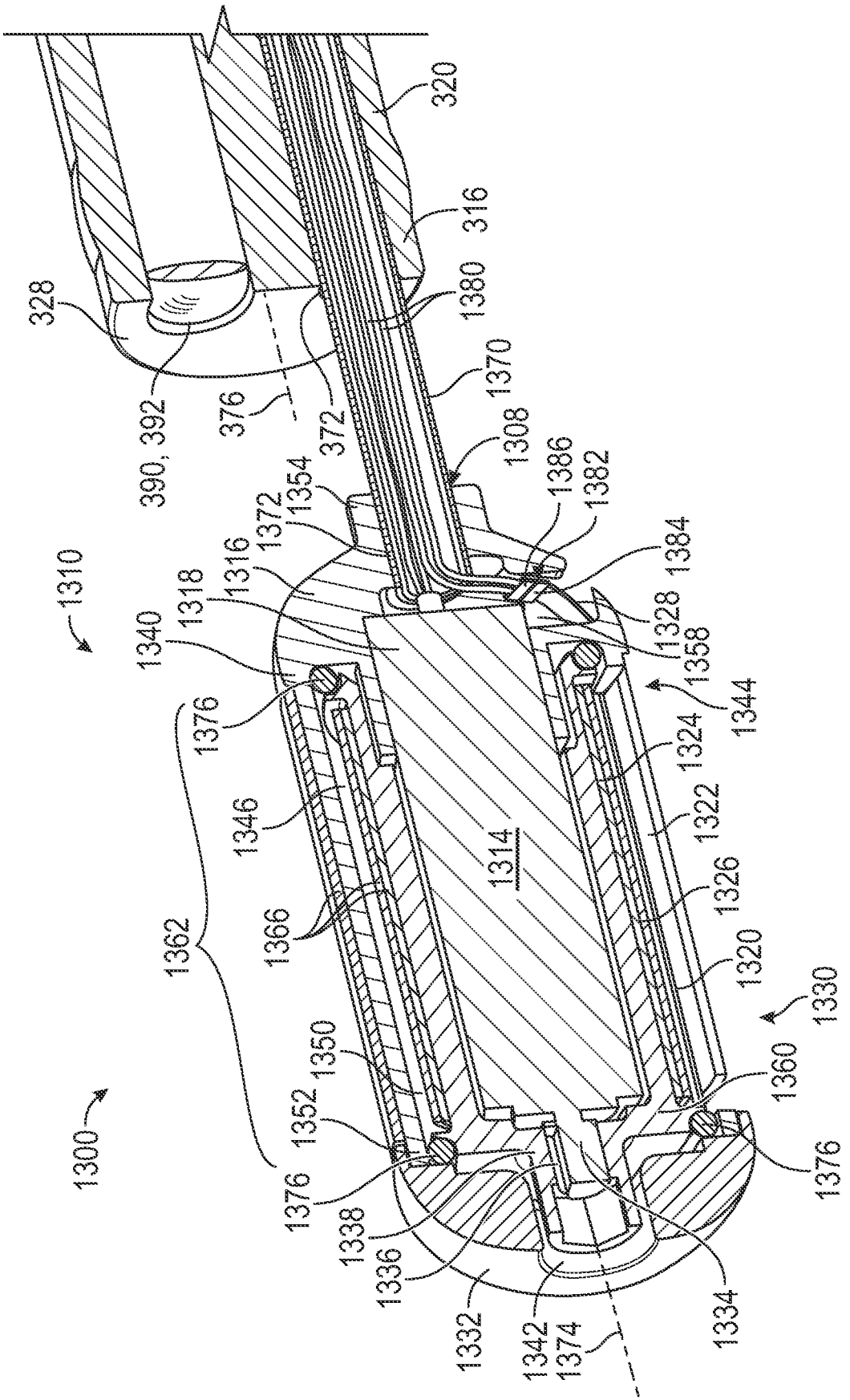
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FIG. 24

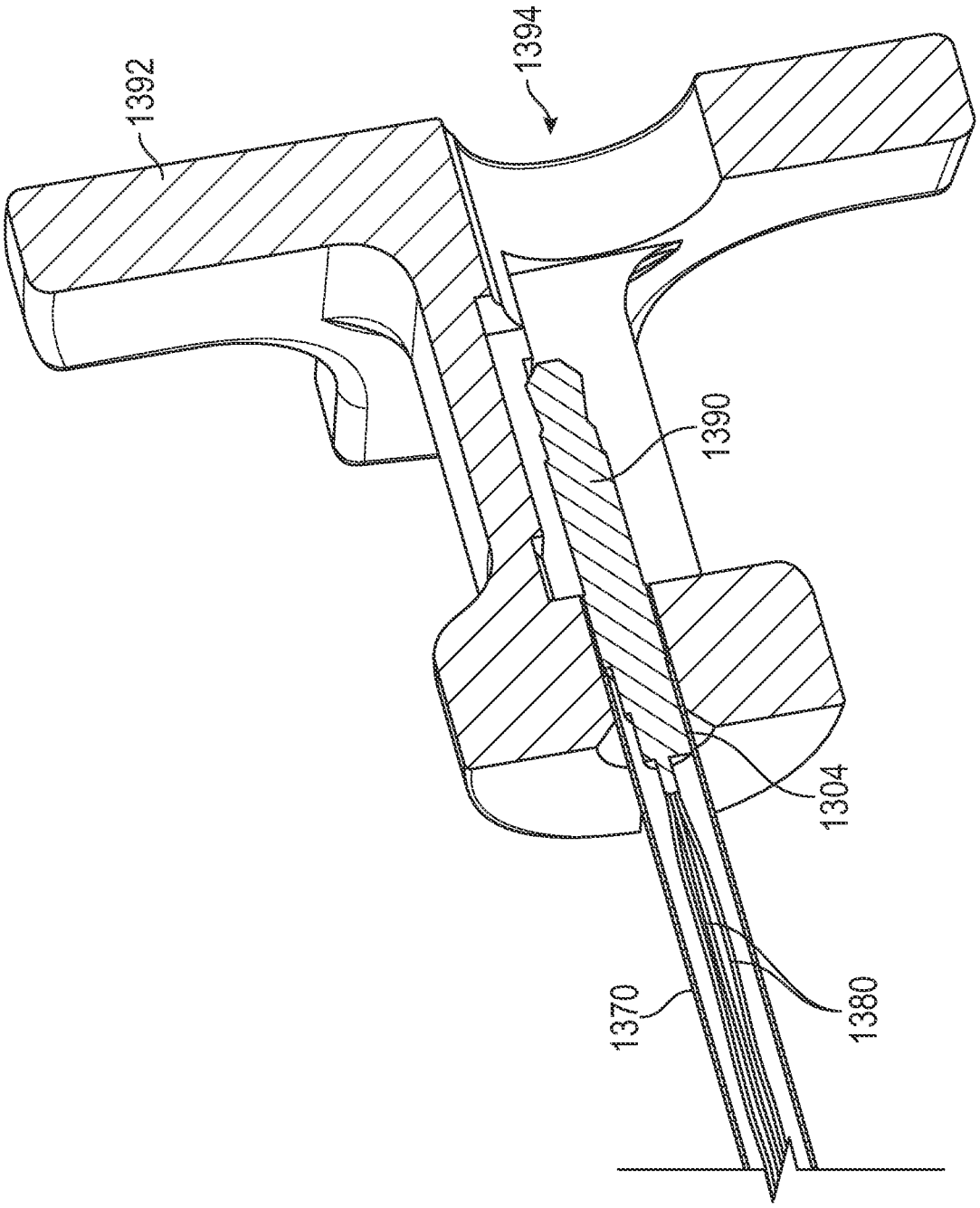

FIG. 25

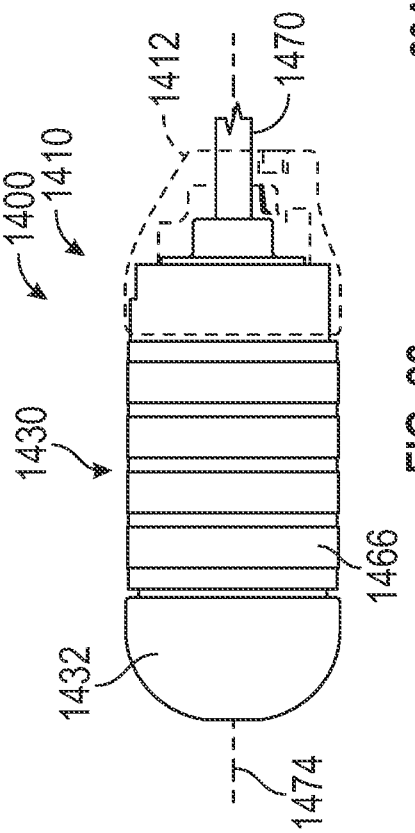
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FIG. 26

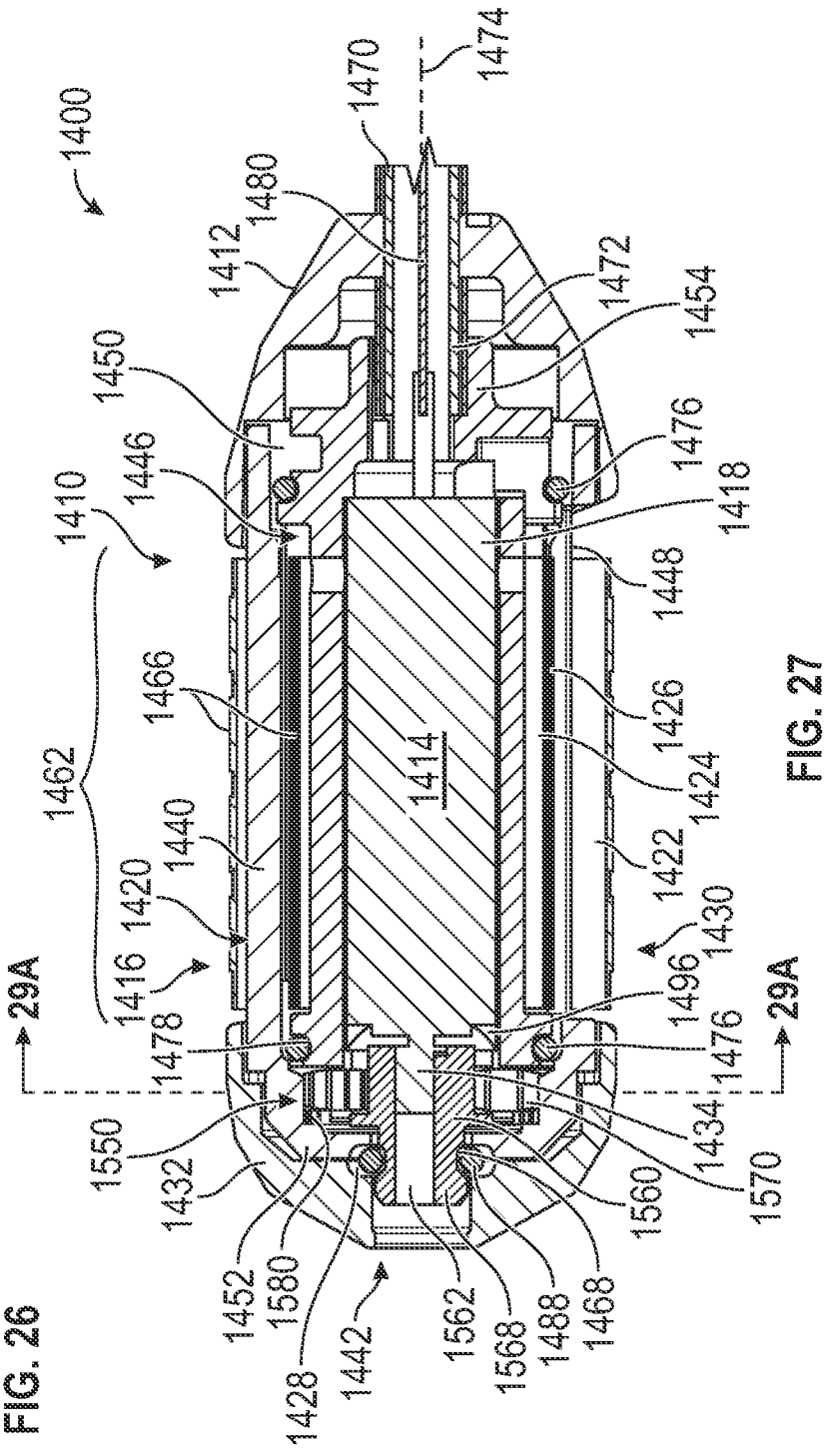
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FIG. 27

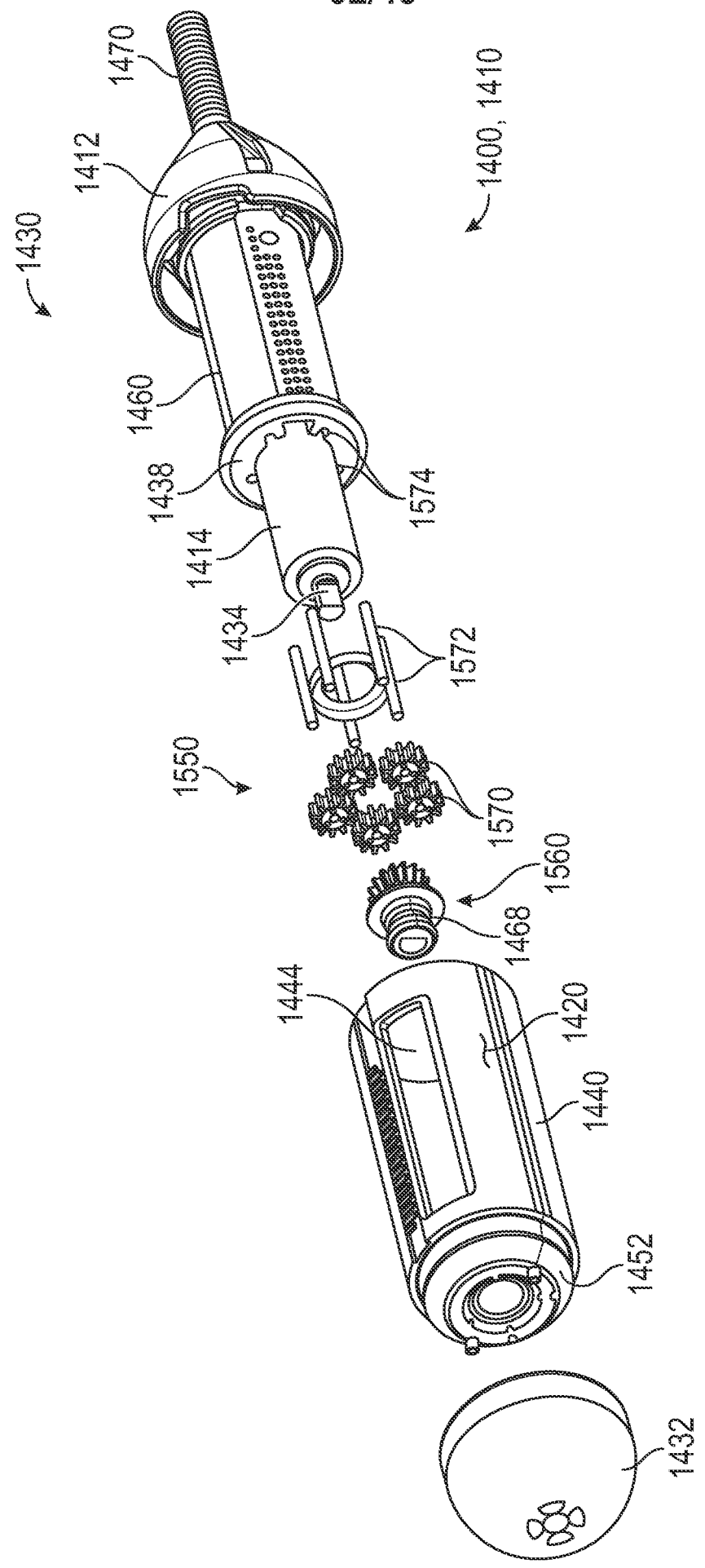
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FIG. 28

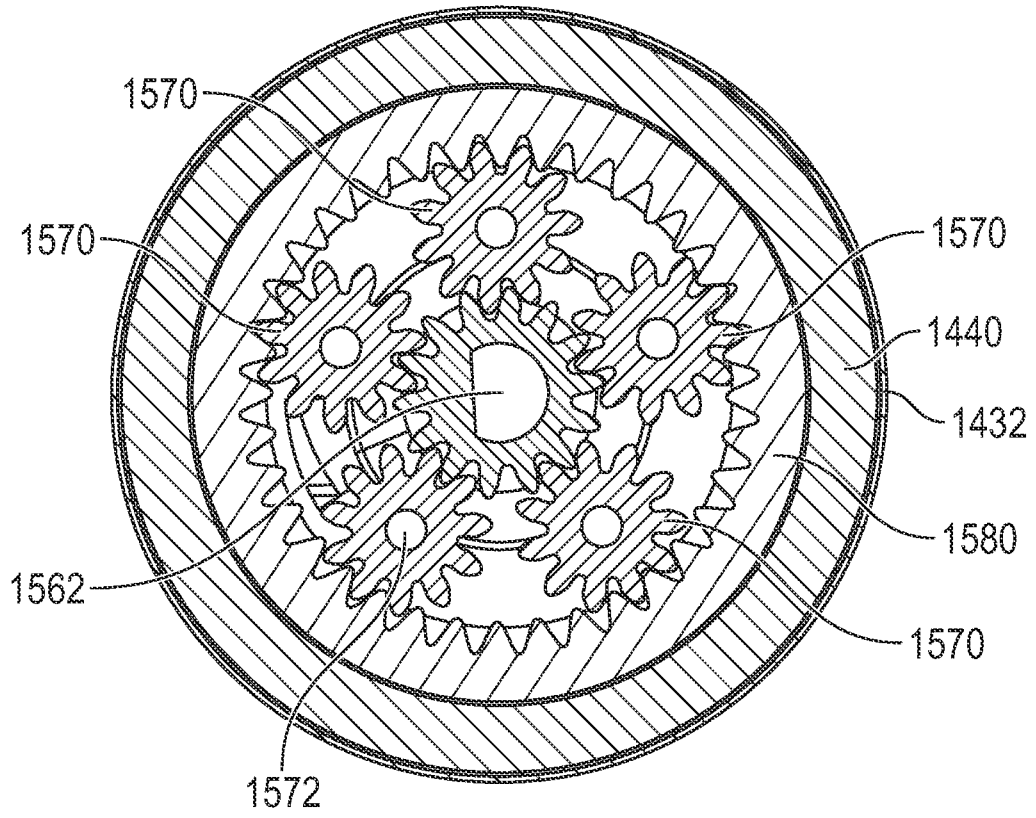

FIG. 29A

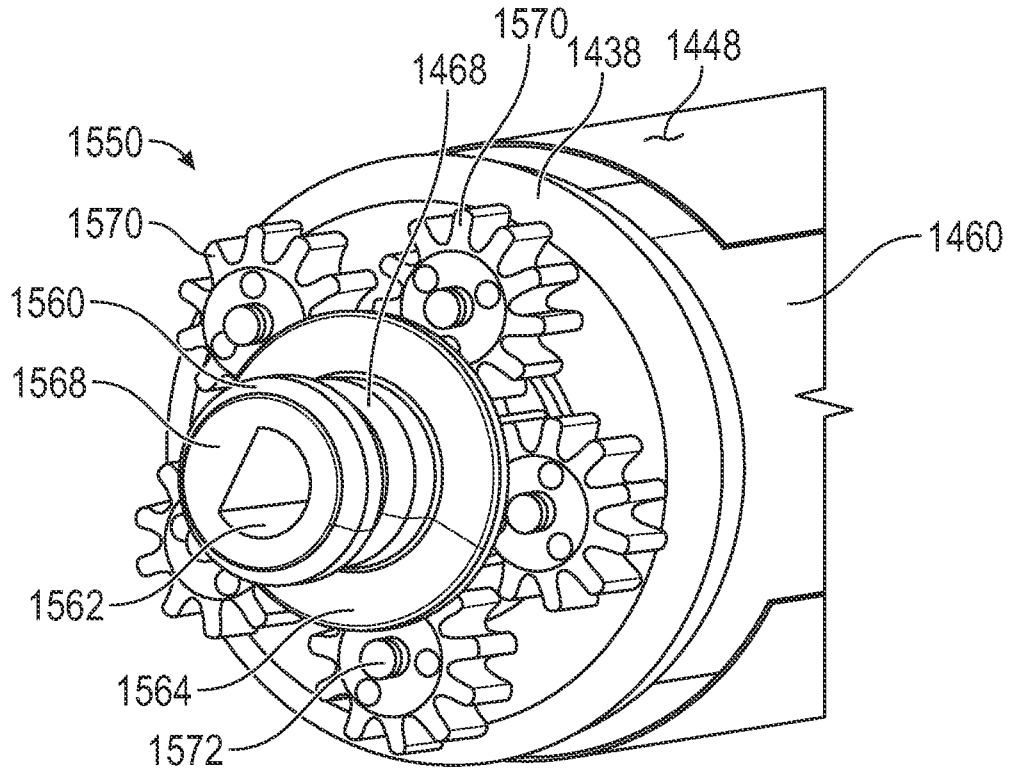

FIG. 29B

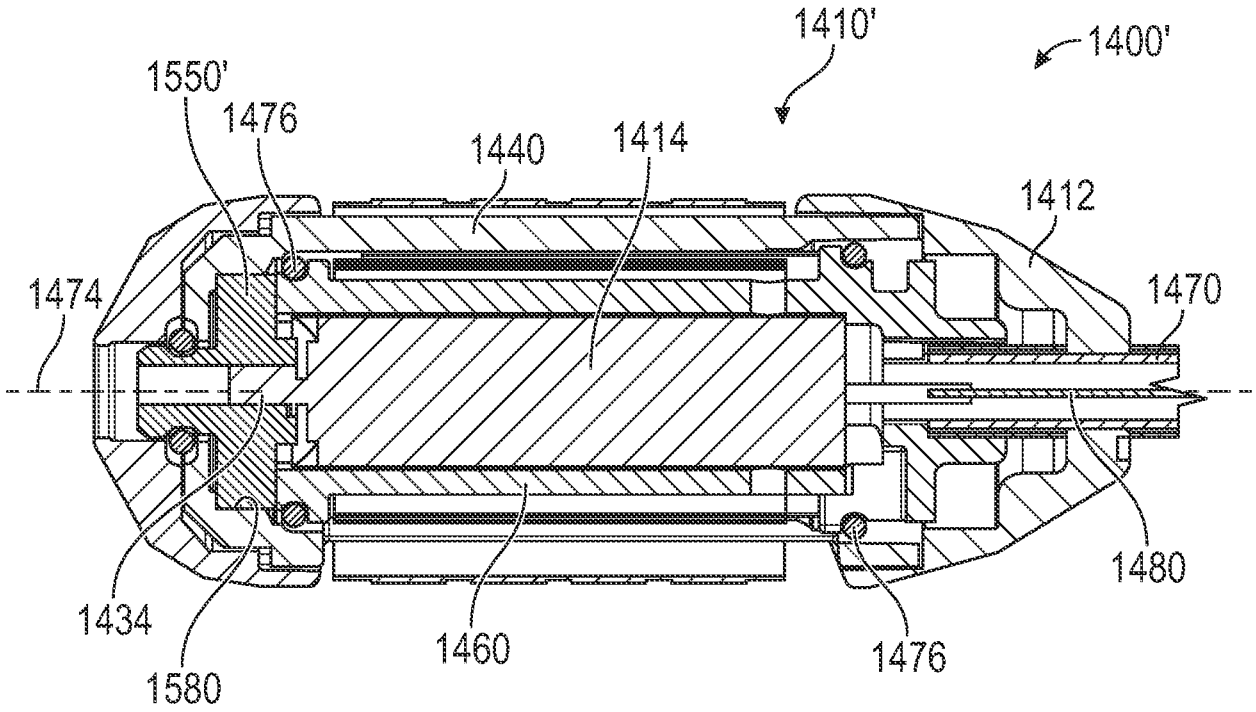
1410'
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FIG. 30

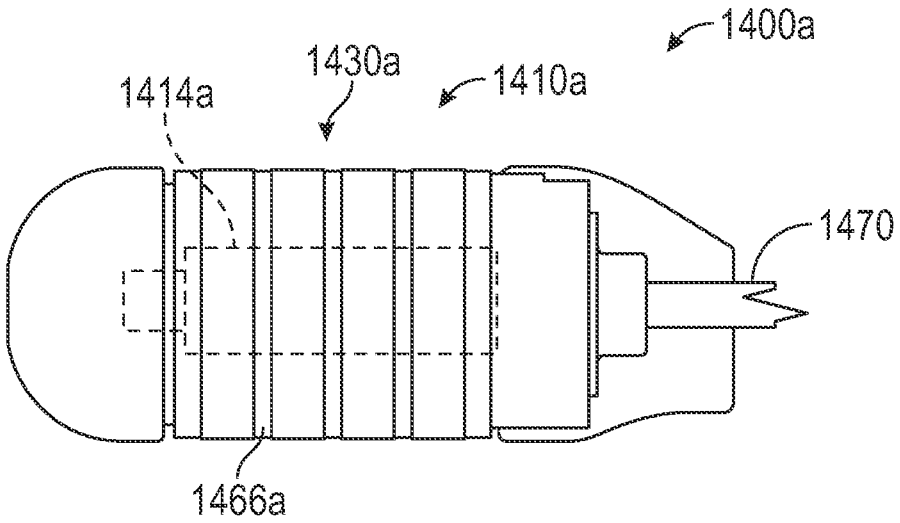

FIG. 31

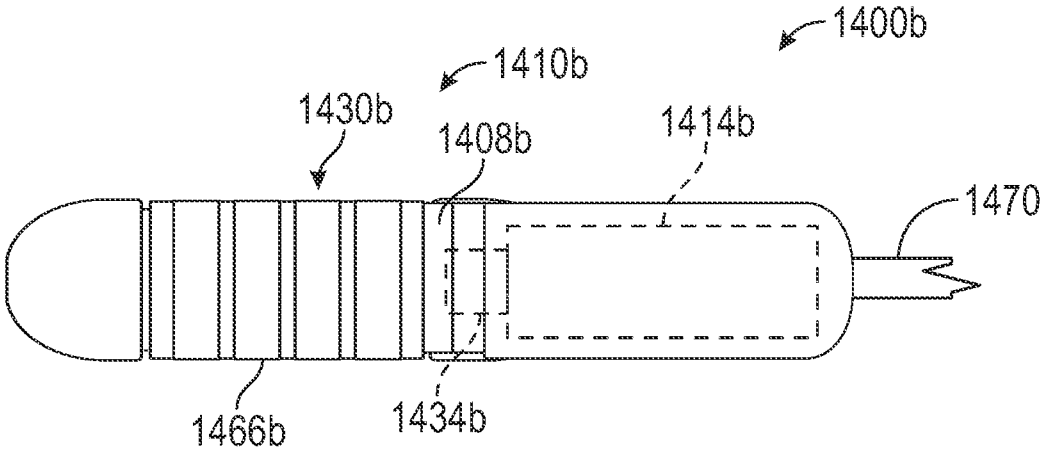

FIG. 32

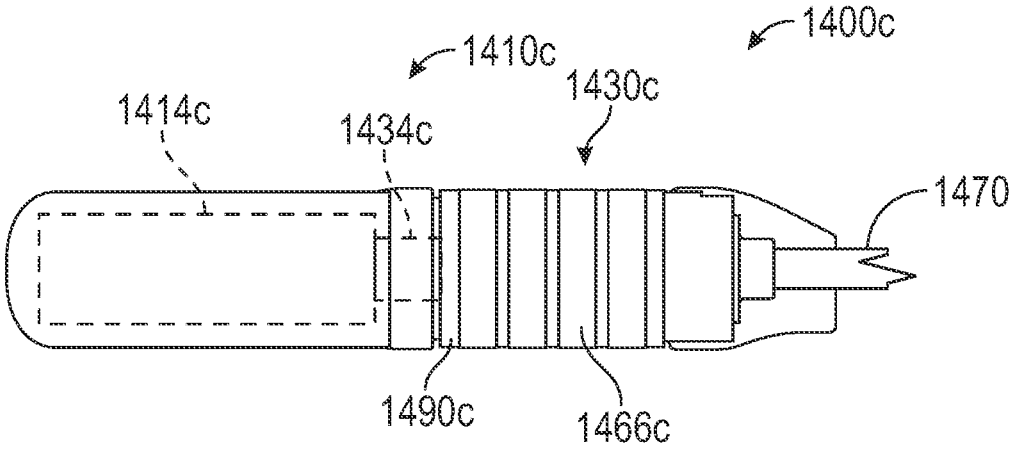

FIG. 33

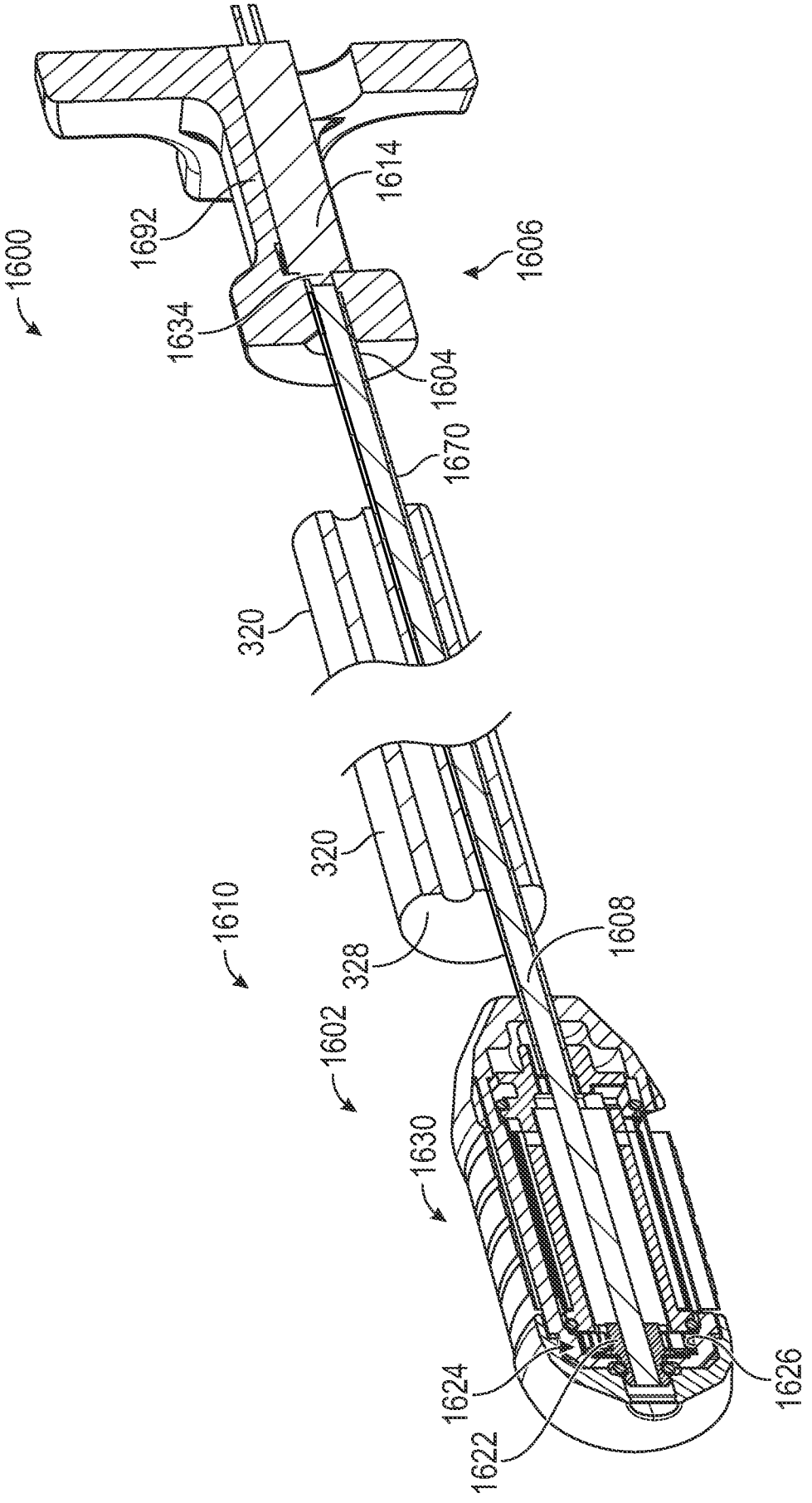
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FIG. 34

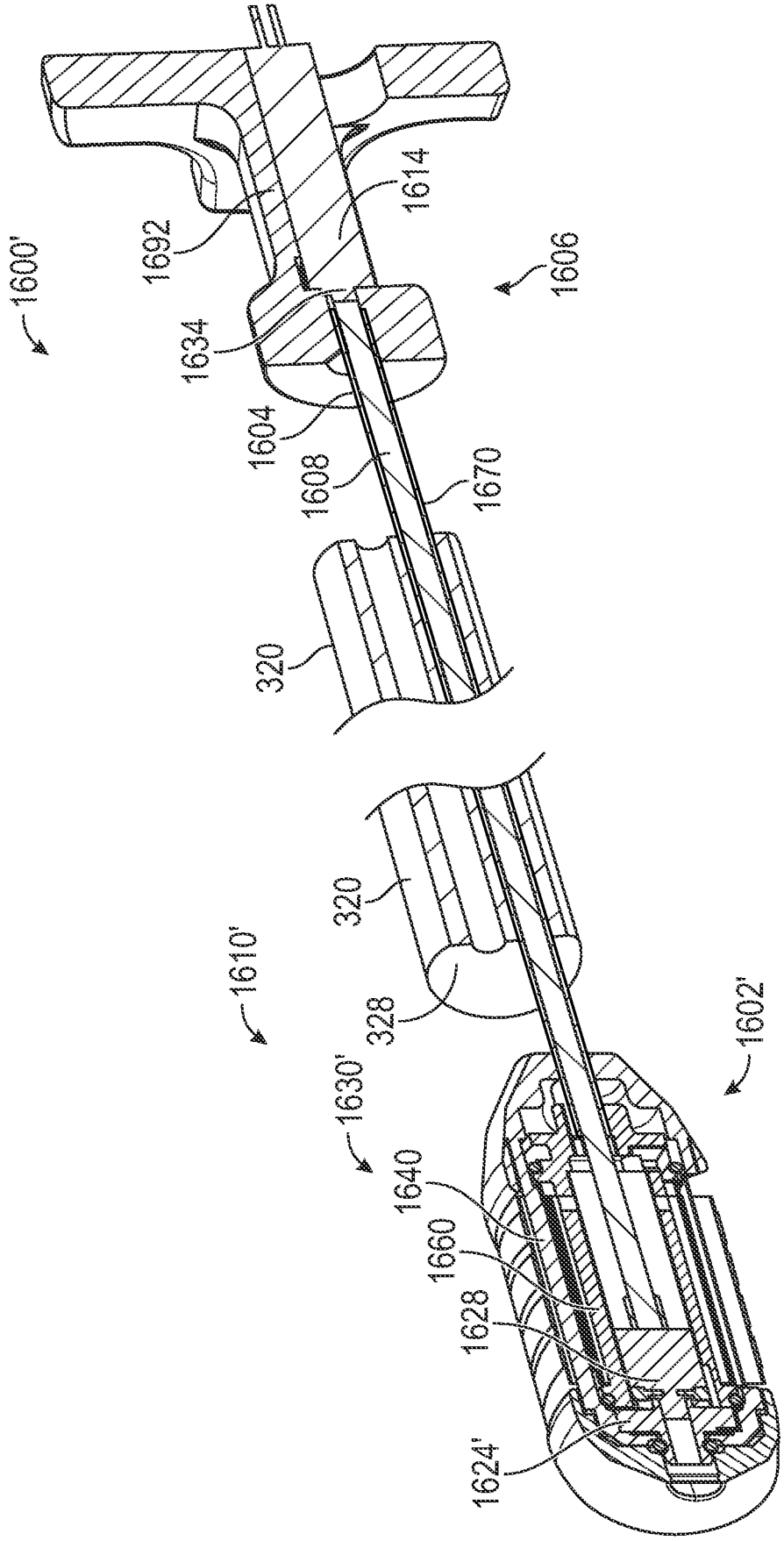
1600'
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FIG. 35

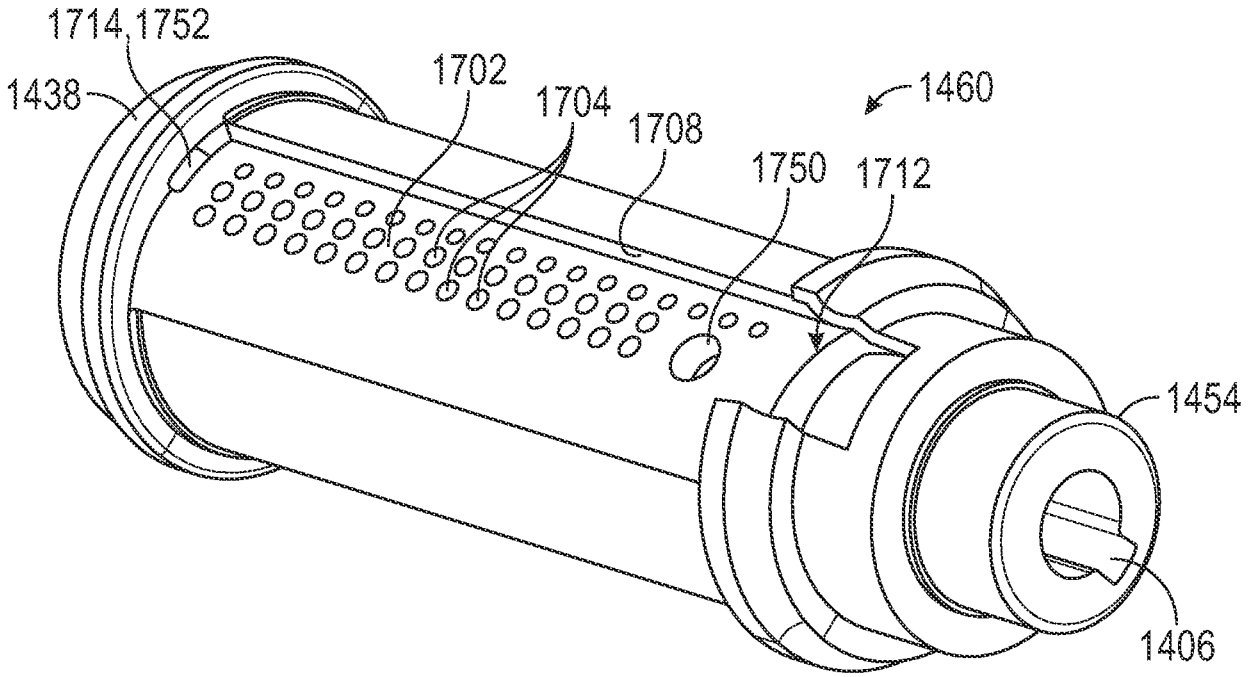
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FIG. 36

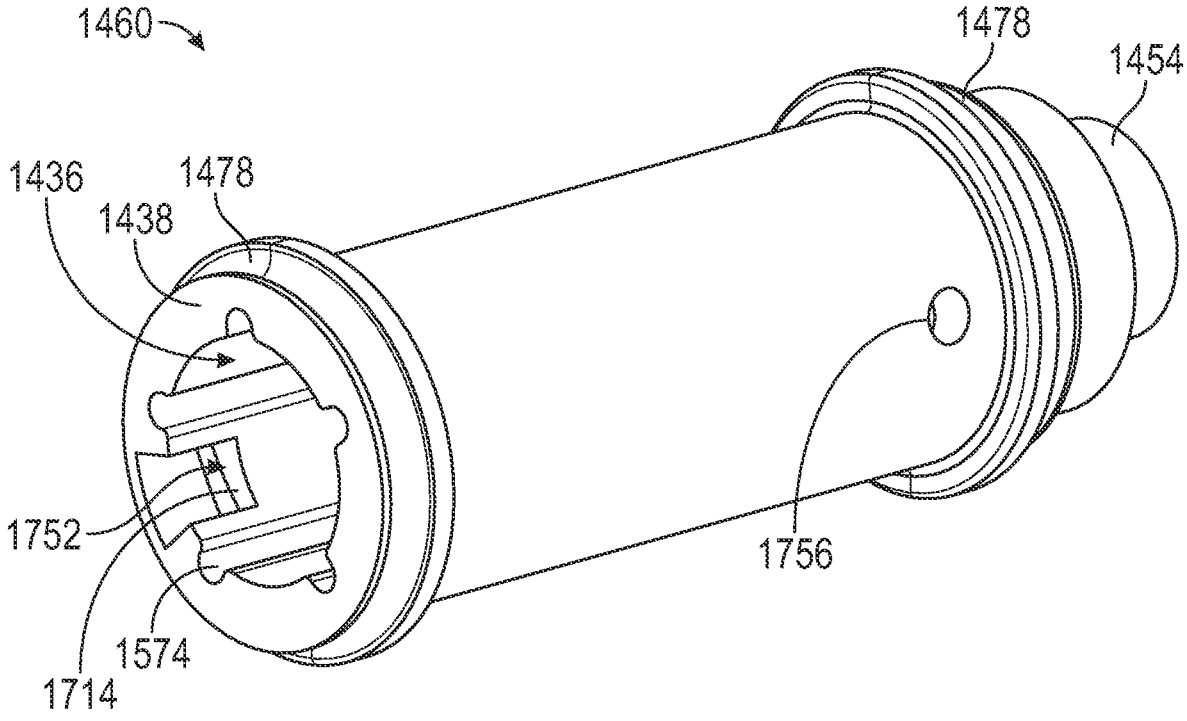
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FIG. 37

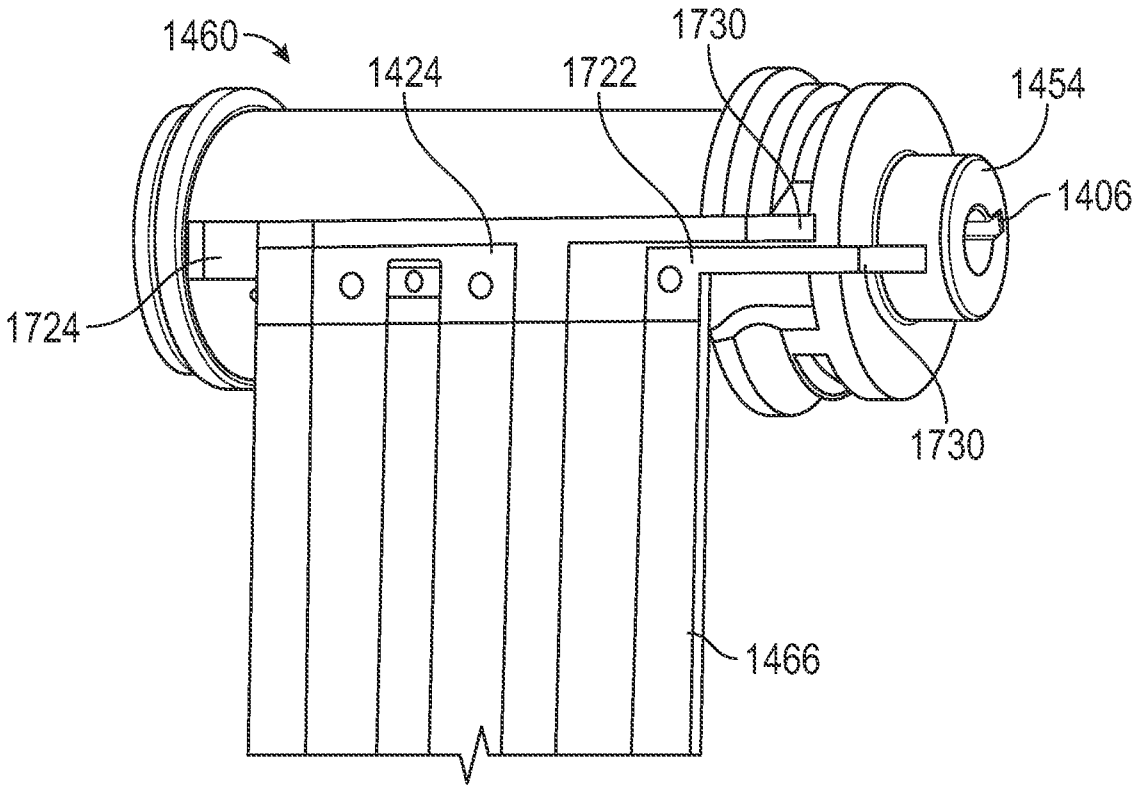
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FIG. 38

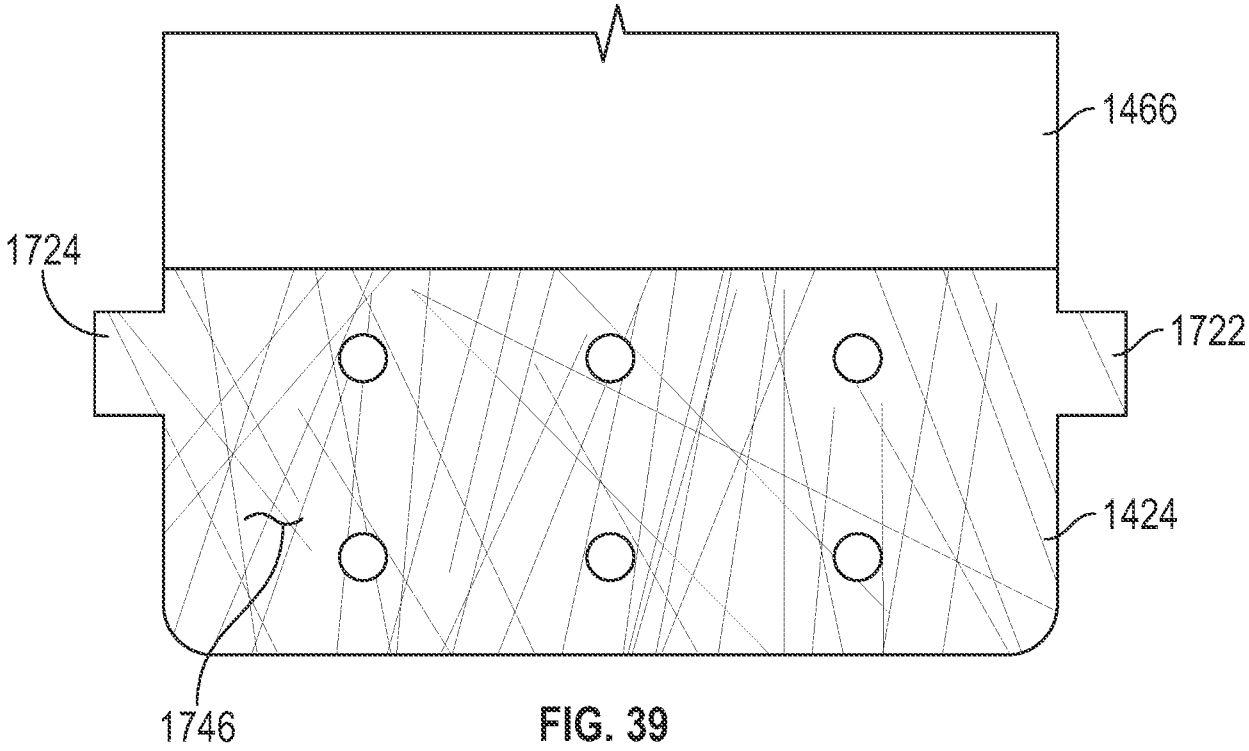
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FIG. 39

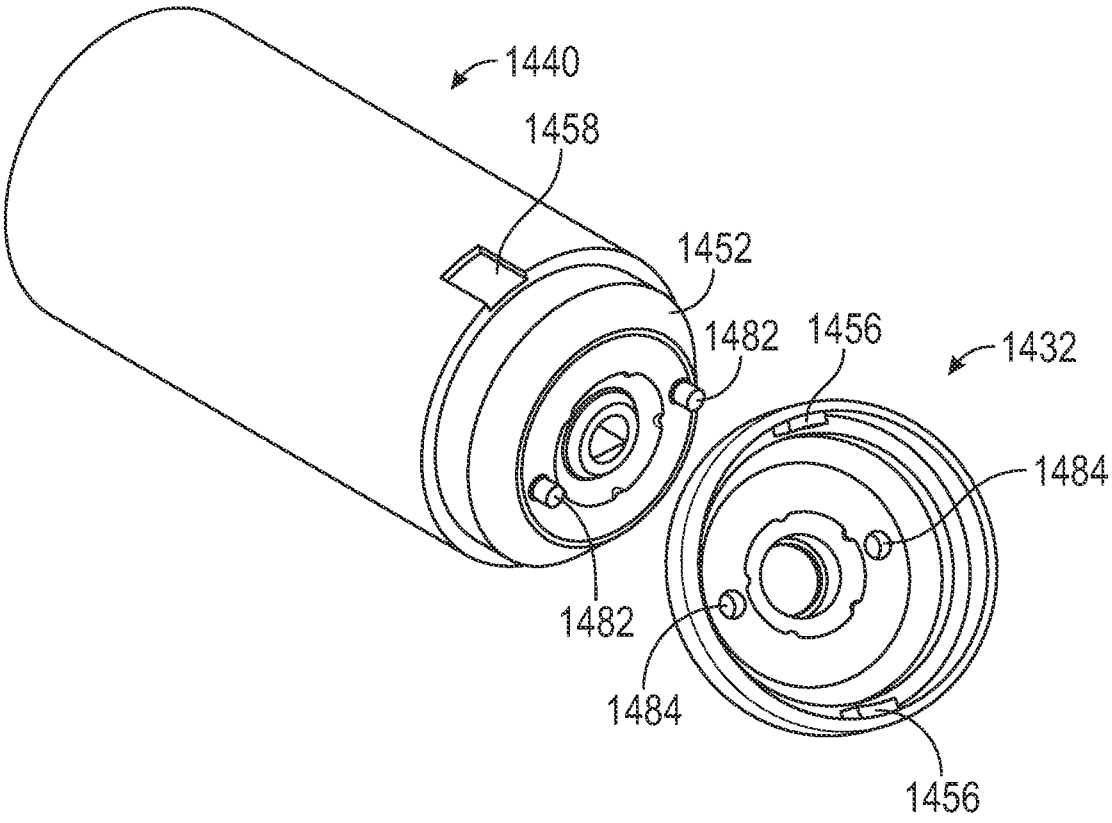

FIG. 40

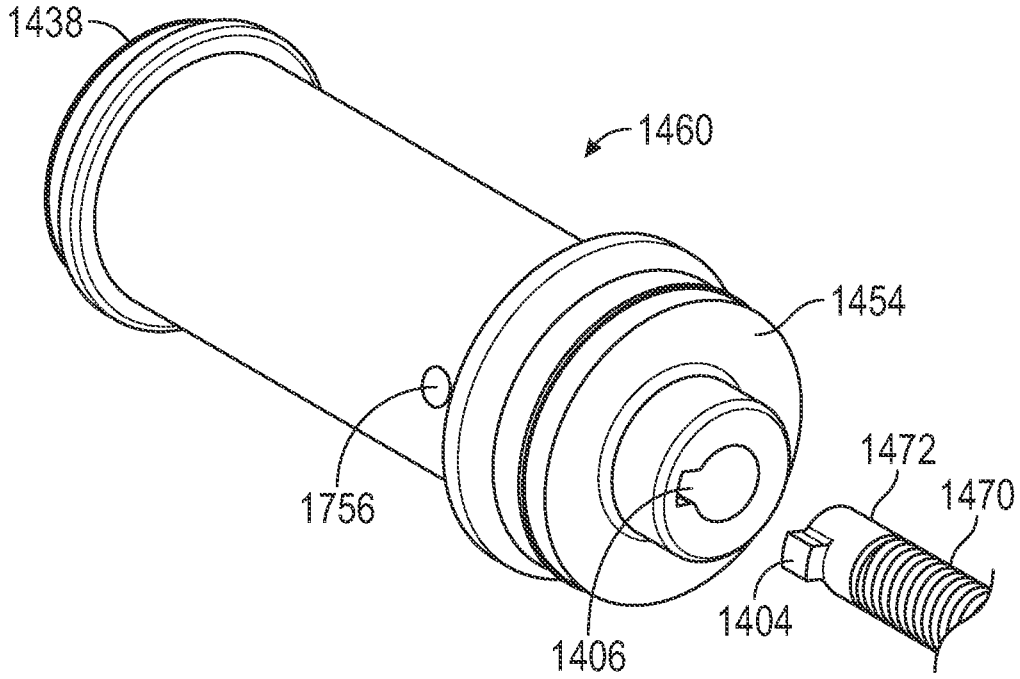

FIG. 41A

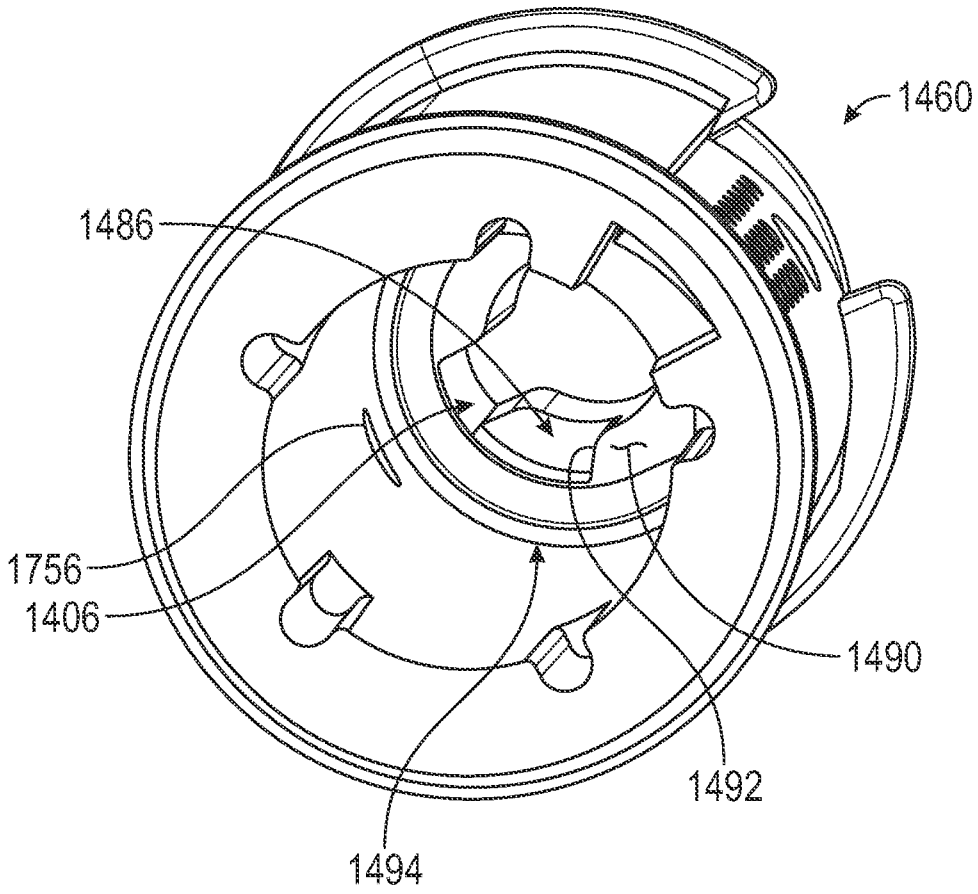

FIG. 41B

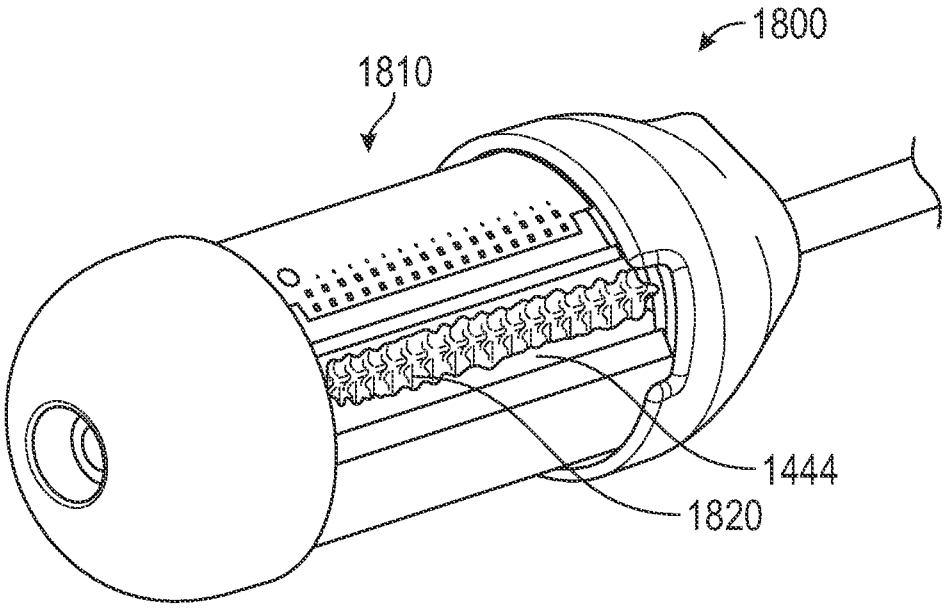

FIG. 42

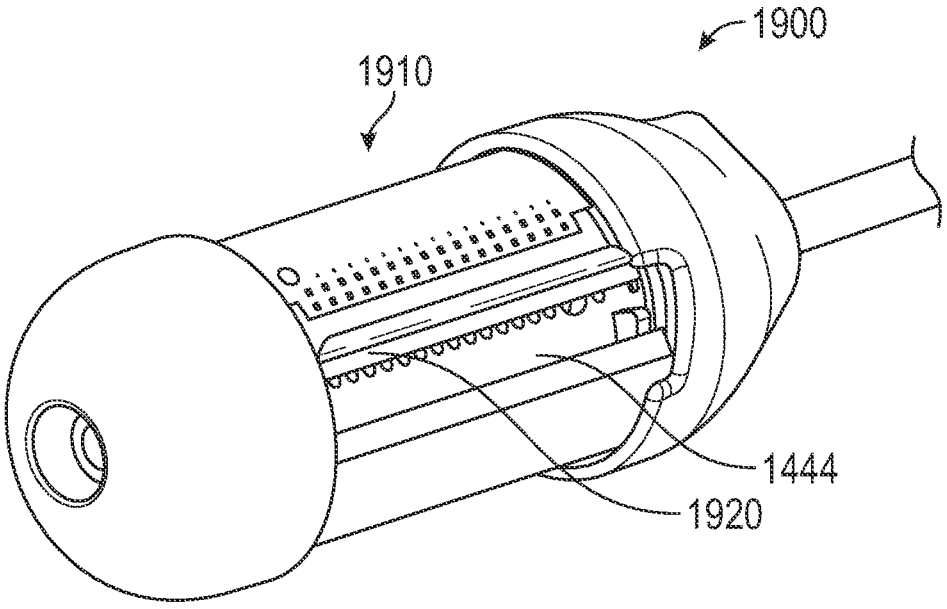

FIG. 43

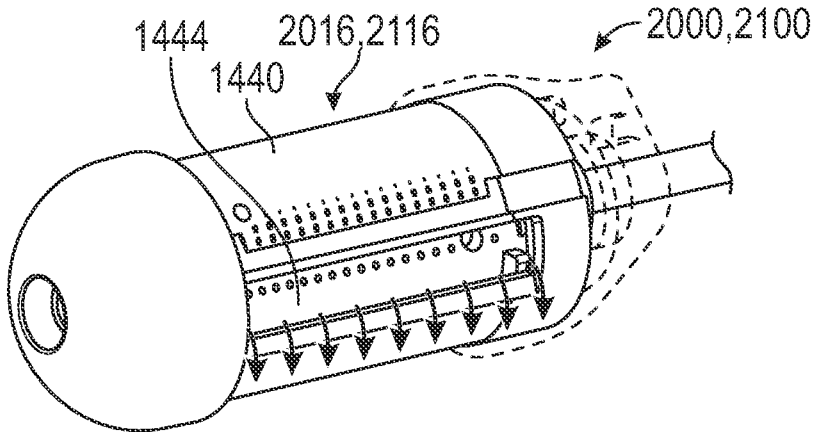

FIG. 44

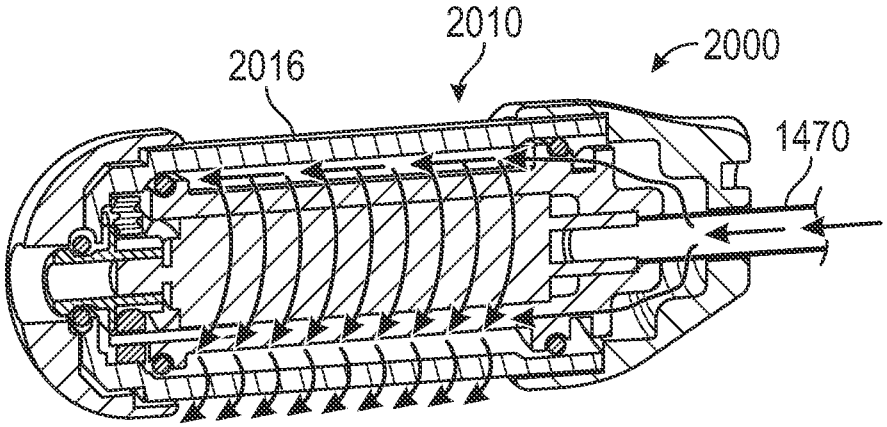

FIG. 45

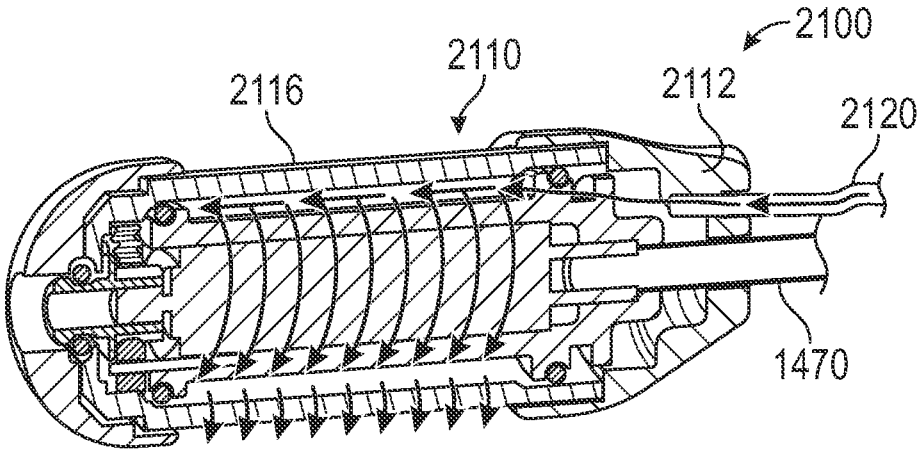

FIG. 46

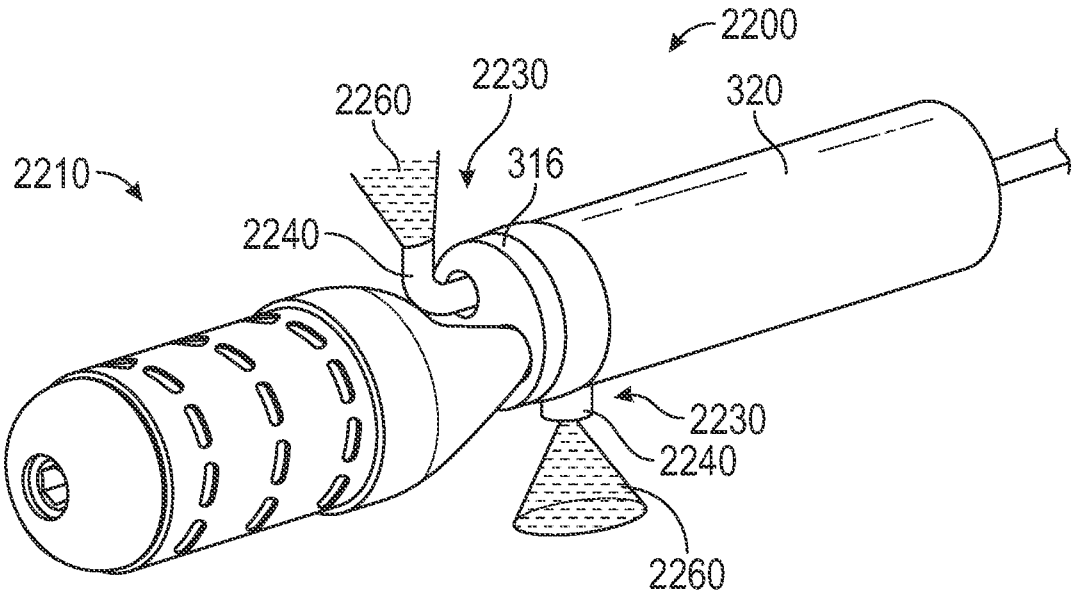
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FIG. 47

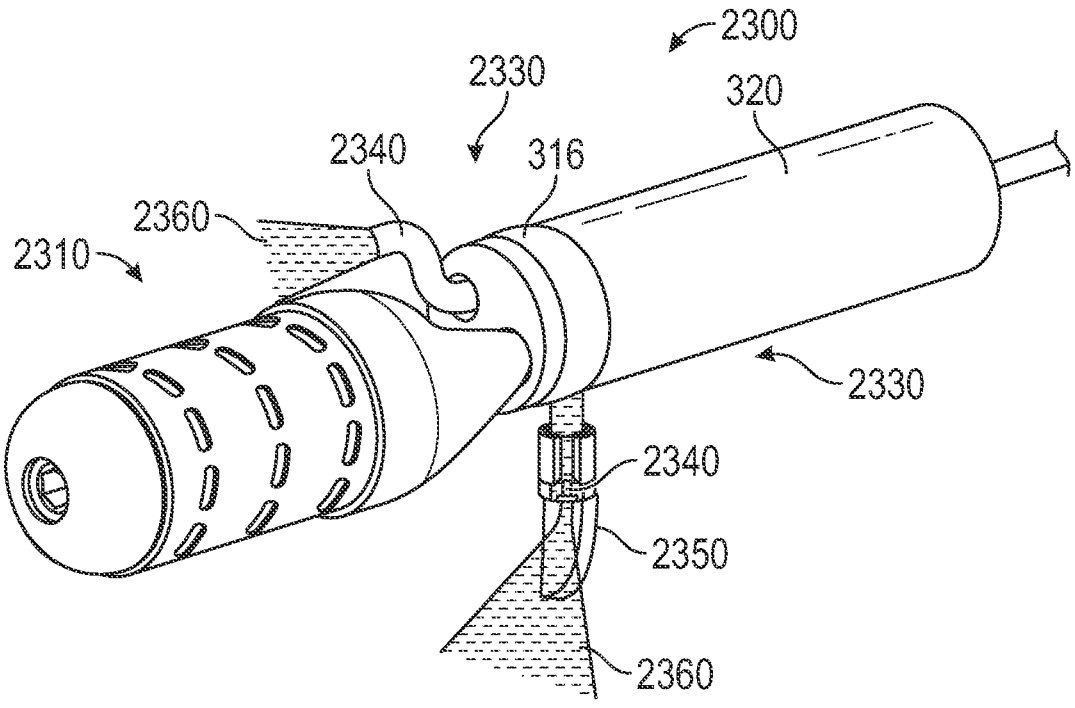
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FIG. 48

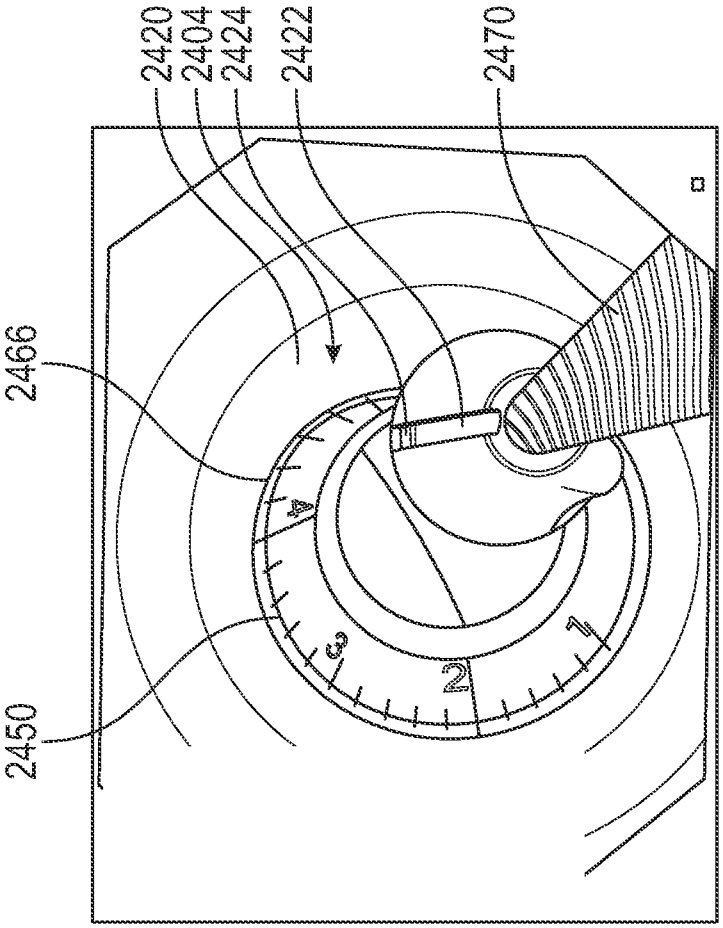

FIG. 50

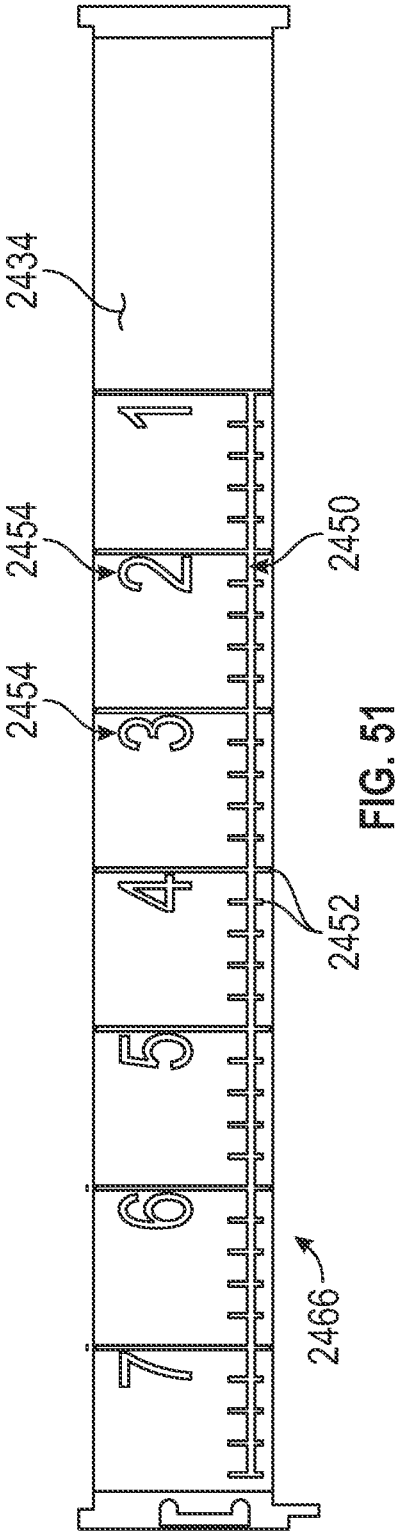

FIG. 51

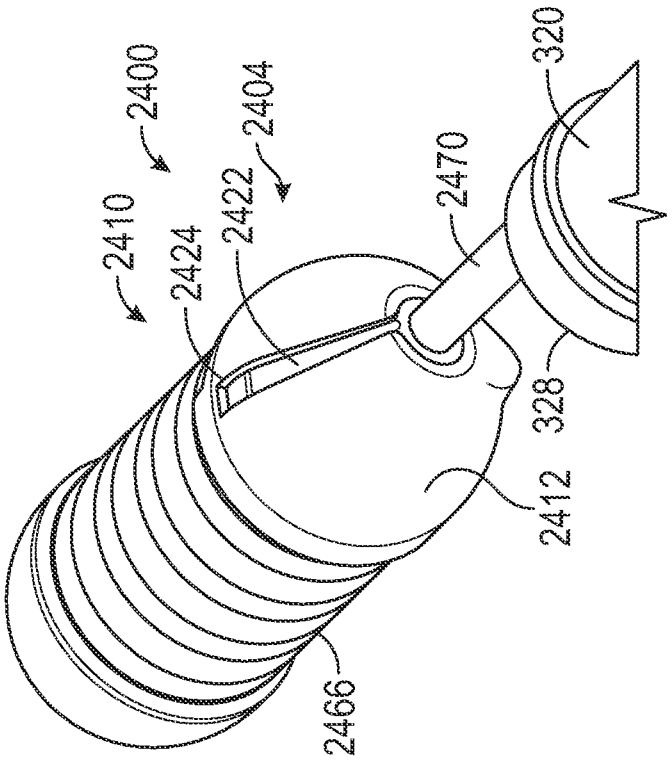

FIG. 49

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2024/052087

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B18/14 A61B1/00 A61B18/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2021/081131 A1 (DYAMX INC [US]) 29 April 2021 (2021-04-29) figures 5a-79c	1-3,6-15
X	WO 2022/104158 A2 (PULSE BIOSCIENCES INC [US]) 19 May 2022 (2022-05-19) figures 19a,19b	1
X	WO 2020/086677 A1 (BOSTON SCIENT SCIMED INC [US]) 30 April 2020 (2020-04-30) figure 8	1

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 January 2025	10/02/2025

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Cornelissen, P

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/052087

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 16-84
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 16-84

The present application contains 84 claims, of which 6 are independent. There is no clear distinction between the independent claims because of overlapping scope. There are so many claims, and they are drafted in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness (Art. 6 PCT), as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought. The non-compliance with the substantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search (PCT Guidelines, 9.19 and 9.25).
The search was based on the subject-matter, as far as can be understood, that could reasonably be expected to be claimed later in the procedure, and the corresponding claims, namely 1-15

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.3), should the problems which led to the Article 17(2) PCT declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/US2024/052087

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