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(54) Title: APPARATUS FOR TREATING MEDICAL CONDITIONS OF HOLLOW ANATOMICAL STRUCTURES

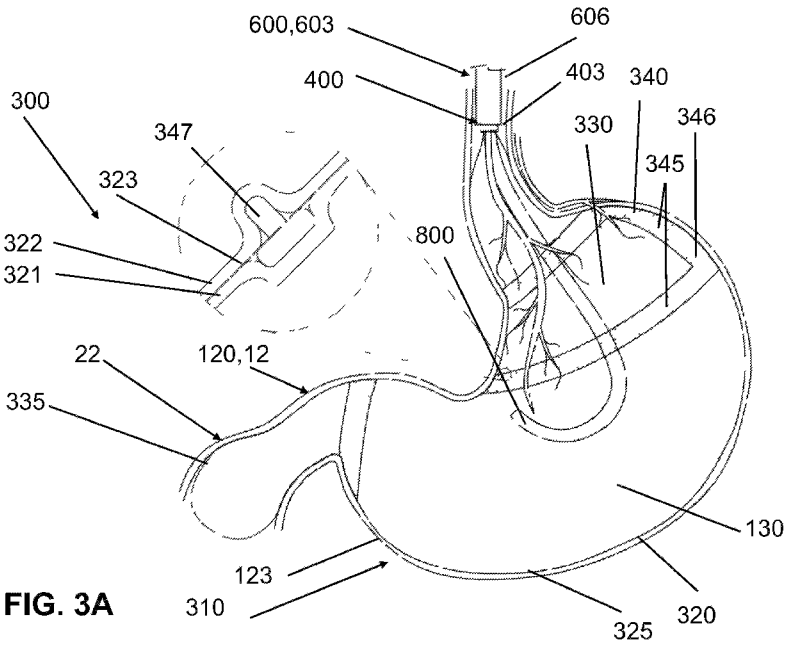

FIG. 3A

(57) Abstract: Minimally invasive apparatus and method for treating medical conditions of hollow anatomical structures. The treatment apparatus and method provide for delivery of energy from an expandable member having conductive regions with pointed contact electrodes, to the interior surface of the hollow anatomical structure in contact with the underlying glands, nerves, and muscle walls of the structure.

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Apparatus for treating medical conditions of hollow anatomical structures

RELATED APPLICATIONS

[0001] The present application is a continuation in part of U.S. Patent Application Serial No. 12/144,575, filed on June 23, 2008, by Edwards et al., entitled "Devices and Methods for Treatment of Hollow Organs," which is a continuation in part of U.S. Patent Application Serial No. 12/108,499, filed on April 23, 2008, by Edwards et al., entitled "Treating Medical Conditions of Hollow Organs," which is a continuation in part of U.S. Patent Application Serial No. 12/099,349, filed on April 8, 2008, by Edwards et al., entitled "Treating Medical Conditions of Hollow Organs;" all of which applications are assigned to the assignee of the present application; the full disclosures of which are all incorporated herein by reference. All patents and published patent applications referred to herein are incorporated herein by reference in their entirety.

Technical Field

[0002] The present invention is generally related to devices and methods for treating medical conditions of hollow anatomical structures, and more particularly, and by way of example, to devices and methods for treating the hollow anatomical structures of the digestive system to treat body-weight related conditions.

Background Art

[0003] The human body has several anatomical structures that are considered hollow, such as but not limited to: hollow anatomical structures of the GI tract (e.g., esophagus, stomach, small and large intestines), bladder, ear canal, nasal sinuses, female reproductive system (e.g., vagina, vaginal canal, uterus, fallopian tubes), and the lungs; as well as various veins and arteries.

[0004] Each of these and other hollow anatomical structures can be subject to medical conditions such as cancer or conditions resulting from loosening of the muscles underlying the HAS, tissue proliferation, and the like. Treatment for these medical conditions range from pharmaceutical therapies to highly invasive surgeries.

[0005] As an example, obesity is one major medical condition that affects several hollow structures of the GI tract. Obesity is directly associated with other medical disorders, such as: osteoarthritis (especially in the hips), sciatica, varicose veins, thromboembolism, ventral and hiatal hernias, hypertension, insulin resistance, and hyperinsulinemia; premature death; type 2 diabetes, heart disease, stroke, hypertension, gall bladder disease, GI tract cancers,

incontinence, psychological disorders, sleep apnea, gastro esophageal reflux disease (GERD), and liver disease. Reducing obesity reduces the effects of these conditions provided the weight loss is significant and enduring. This, of course, is the challenge to the patient and practitioner.

[0006] Current obesity treatments include behavior modification, pharmaceutical interventions, and invasive surgeries.

[0007] One problem with behavior modification is patient compliance. Significant and maintained weight loss demand enormous levels of patient compliance over a long time.

[0008] Problems with pharmaceutical intervention include drug dependence and adverse side effects. Amphetamine analog treatments involve habitual use of addictive drugs to produce and maintain significant weight loss. Dexfenfluramine and fenfluramine treatments often result in primary pulmonary hypertension and cardiac valve abnormalities. Drugs such as sibutramine substantially increase blood pressure in many patients.

[0009] Surgical obesity treatments include invasive surgical procedures such as: gastric banding, bariatric surgery, and liposuction. While current surgical procedures can be effective, the overall rates of surgical mortality and associated hepatic dysfunction are so high that surgical treatments are only indicated for younger patients who are morbidly obese.

[0010] The following table outlines various conventional treatments for obesity and issues associated therewith:

Treatment	Issues
Diet, Exercise and Behavior Modification	90% unsuccessful
Pharmacotherapy	Moderate benefits and risk of dependence
Very Low Calorie Diet and Medically Supervised Programs	Patients of regain weight
Gastric Banding	Invasive, risks, complications, long-term care, costly
Bariatric Surgery	Invasive, risks, complications,

Treatment	Issues
	long-term care, costly
Liposuction	Invasive, risks, complications, long-term care, costly

[0011] USP 7,326,207 proposes treating obesity by mapping (for example, using a visualization apparatus, such as but not limited to endoscopes or fluoroscopes) and ablating nerves in targeted stomach areas by creating patterns of thermal lesions. The nerves are ablated using electrodes that penetrate the nerves during energy application. Mapping is required to properly position the electrodes where they can penetrate the nerves. Physiological changes caused by tissue ablation create a sense of satiety in the patient by directly modulating nerves responsible for hunger sensation or by modulating the nerves inhibiting the let-down reflex of the stomach muscles that are digestion precursors.

[0012] Despite the treatment described in the '207 patent, there is room for further improvement in the field of obesity treatment and as well treatment of other medical conditions that affect hollow anatomical structures.

Summary

[0013] The present invention relates to devices and methods for treatment of hollow anatomical structures ("HAS"). In an embodiment, the present invention relates to devices and methods for treatment of the digestive system, such as the stomach, for weight-related conditions. Although the apparatus and methods of the present invention are described in the context of treating the stomach, it should be appreciated that the present devices and methods are applicable and useful in treatment of other hollow anatomical structures and may be adapted to suit the particular hollow anatomical structure under treatment. Exemplary hollow anatomical structures include, but are not limited to, the lungs, urinary tract, nasal passages, the reproductive tract, as well as body lumens and blood vessels such as, but not limited to, the perforator veins which connect the superficial veins to the deep veins in the leg, truncal superficial veins of the leg (e.g., great saphenous vein, short saphenous vein, and the like), superficial tributary veins of the leg, internal spermatic veins (varicoceles), ovarian veins, gonadal veins, hemorrhoidal vessels, fallopian tubes, a-v malformations, a-v fistula side branches, esophageal varices, and the like.

[0014] Methods of treatment embodying features of the present invention include applying

energy to, among other things, any one or more of muscles, nerves, mucosa (or tissue), or glands associated with and/or underlying the hollow anatomical structure (including vessels) to alter any one or more of the muscular profile of the structure, its biomechanical operation, or physiological properties (e.g., shrinkage, coagulation, ablation, constriction). The treatments embodying features of the present invention enable the modification of any one or more of the nerve signal transmission and the muscle profile to one more suitable for reaching treatment goals, or the gland's enzyme release. As used herein, the term "ablative energy" denotes energy to bring about any of such physiological or other changes mentioned above.

[0015] In each such application and others to treat the various hollow anatomical structures, the point of entry for the introduction of the present devices to access the structures, the accompanying components (e. g, visualization device), physical shape of the delivery system, as well as the treatment assembly embodying features of the present invention may differ to suit the particular application. The present apparatus and methods may be adapted for use in percutaneous, surgical, or laparoscopic procedures.

[0016] In the case of the stomach, the desired treatment sites of the hollow anatomical structure, are those of the stomach's and include any one or more areas corresponding to or in the vicinities of the greater curvature of the stomach, smaller curvature of the stomach, cardiac zone, gastric/fundic zone, pyloric zone, or the vagal nerve within the stomach. In an embodiment, the treatment site may include the small intestine. In an embodiment, the nerves, muscles, and/or glands are exposed to a source of ablative energy by expanding the structure beyond its normal volume until the structures mucosa (or tissue) is separated and the underlying nerves, muscles, and/or glands are exposable to the energy. The nerves, muscles, mucosa, and/or glands are exposed by way of expanding an expandable member ("expander member") sized and configured to expand within the structure, and conforming the structure's inner volume to that of the expanded member. In one embodiment, the expandable expander member is formed from non-compliant or semi-compliant material such that it cannot at least substantially expand beyond a pre-defined size. The expandable member, upon expansion, expands the structure to a size greater than its normal (e.g., as it is at least prior to the treatment) size, thus conforming the hollow structure's volume to that of the expandable member in the expanded configuration. The methods of treatment provide for guided delivery of energy to the desired treatment areas of the hollow anatomical structure.

[0017] An apparatus for treating medical conditions of hollow anatomical structures

embodying features of the present invention may include a treating assembly having an expander assembly including an expandable member configured for expansion in the structure to expose at least a portion of either or both the hollow structure's underlying nerves and muscle. In an exemplary configuration, the expandable member, such as an expandable balloon, is disposed at a distal end of an elongate body such as a catheter.

[0018] The expandable balloon includes treatment areas corresponding to any one or more desired treatment sites of the HAS. In the case of the stomach, the desired treatment sites are those of the stomach and include any one or more areas corresponding to or in the vicinities of the greater curvature of the stomach, smaller curvature of the stomach, cardiac zone, gastric/fundic zone, pyloric zone, or the vagal nerve within the stomach. The balloon treatment areas include conductive regions adapted to deliver ablative energy to the surface of the hollow anatomical structure. The balloon treatment areas circumferentially surround the expandable balloon and are longitudinally positioned on an inner or preferably outer surface of the balloon. The conductive regions comprise a plurality of electrodes adapted to deliver ablative energy to the surface of the hollow anatomical structure, including the vagal nerve. At least a portion of the electrodes comprise pointed contact electrodes for providing an enhanced range of power delivery to selectively reach and ablate the surface of the hollow anatomical structure including nerves such as the vagal nerve. In an embodiment, a tissue facing surface of the pointed contact electrodes has a smaller surface area than the opposing surface. This smaller surface area enables a more targeted delivery of the ablative energy to the desired target area of the structure. In an embodiment, the expandable balloon is formed from two layers of material with the pointed contact electrodes positioned in an interior space between the two layers. The conductive regions may be continuous or include interruptions. The shape of the region may be uniform throughout or different regions may have different shapes. The conductive regions including the pointed contact electrodes form conductive areas for surface contact (e.g., physically non-penetrating) with and transferring energy to the inner surface of the hollow anatomical structure. Inflation of the expandable balloon expands the stomach to stretch the pleated mucosa of the stomach and expose underlying nerves and stomach muscle and brings the conductive regions into surface (e.g., substantially non-penetrating) contact with the treatment site. Leads 323 extend from the pointed contact electrodes by way of a conduit to an energy generator. The pointed contact electrodes may be formed of any suitable material such as stainless steel. The electrodes may further comprise other surface electrodes secured to the expandable balloon by suitable means such

as rivets piercing the expandable balloon surface, exposing the surface electrodes to the outside of the balloon, thus enabling the surface electrodes to be in surface contact with the stomach tissue. The surface electrodes may be formed from flexible circuitry etched onto the surface of expandable balloon 320 and are connectable to the energy source by way of leads. The source of energy may be energy in the form of electromagnetic energy (e.g., RF, microwave) and ultrasonic energy, infrared energy, visible laser energy, heat energy, or the like.

[0019] The energy source is provided by an energy generator controllable by a control assembly. The amount and level of energy at its source is set to provide a sufficient level of energy at the point of treatment. The desired energy levels differ for different hollow anatomical structures. The temperature at the point of treatment is sufficiently high to effectuate the desired treatment. The temperature at the point of treatment, for the stomach, may range from about 50 to about 100°C, from about 60° to about 95°C, from about 60° to about 80°C.

[0020] In order to monitor the amount of energy delivered and the amount of heat generated, the apparatus can also include one or more sensors. The one or more sensors may be located within or about the expandable member, at or near the conductive regions. These sensors can be used to detect a variety of operating parameters including the amount of energy delivered, and the temperature of a region adjacent the apparatus. These sensors can also be used to provide feedback for controlling the operation of an energy source which delivers energy to the energy transmitting regions. In addition, chemical or biochemical sensors can be used to detect ablation.

[0021] In one embodiment, the at least one temperature sensor is a thermocouple or thermistor. The temperature sensor is coupled to a communication link (such as a conductor), which is coupled to a processor. For example, in the case where the temperature sensor is a thermocouple, the communication link may comprise a D/A converter coupled to a register disposed for reading by the processor. The processor reads a sensor value from the sensor and, responsive thereto, controls the signal generator so as to achieve delivery of an effective amount of energy to a desired section of tissue to be ablated. The processor thus uses the information from the signal generator, the energy transmitting regions, and temperature sensor, as a feedback loop for controlled delivery of energy to a section of a stomach (or other treatment areas of a hollow anatomical structure). For example, the processor may control the level of energy to achieve a selected temperature, or to achieve a selected amount

of ablation of a section of a stomach. A variety of positionings for the sensors are possible. In one embodiment, the sensor is coupled to the expandable member.

[0022] As described above, the temperature or some other property of the tissue being ablated, or of the energy delivery device can be monitored using a variety of sensors. By way of example, open and a closed loop feedback systems may be utilized for coupling a sensor used in the apparatus to an energy source so that the output energy of the energy source is adjusted in relation to the property sensed by the sensor. One or more sensors may be located within or about the expandable member, or at or about the conductive regions. It should be appreciated that the sensor may take any appropriate form, as for example formed of wireless construction, and may further be configured to sense and convey the necessary information in any number of ways and formats and is not limited to direct thermal sensors. By way of example and not limitation, the temperature may be sensed by optical means which can assess a change in the color of at least a portion of expandable member (e.g., conductive regions). In this configuration, colorants may be present in the material forming the expandable member/regions or be painted or deposited on its material (on the inner or outer surface). Once the colored area is exposed to the elevated temperature, the colorant may change its characteristics. Information as to the temperature may then be conveyed to the practitioner. The information may be conveyed automatically by instrumentation or by direct visualization through the endoscopic device. As stated, such sensors may also be present on or in the expandable member.

[0023] The treatment assembly may further include a visualization device, such as an endoscope, disposable within the elongate body (e.g., catheter), or deliverable though any other suitable means. The endoscope may include an illumination source such as lights for visualization of the structure when it is disposed within its interior. In an embodiment, the endoscope is disposed within the expander assembly prior to advancement into the structure. The expander assembly and the endoscope are accessible through a disposable hand-piece at the proximal end of the treatment assembly.

[0024] The expandable member may be formed from any suitable material such as, but not limited to expandable, noncompliant (or semi-compliant) material including Mylar, Nylon, PET, PeBax, IEBA. In a preferred embodiment, the material for balloons is formed from non-compliant material. For example, Mylar, while expandable, is noncompliant and restricts expansion of the expandable balloon within the stomach. Therefore, an expandable balloon formed from Mylar cannot infinitely expand and patient injury resulting from

unintended over-inflation of expandable balloon 320 can be reduced. In an embodiment, when used for obesity treatment, expandable balloon 320 is constructed such that when inflated within the stomach, the stomach expands from its empty volume (about 1 liter) to at least about twice the stomach's empty volume (e.g. 2 liters). However, for other hollow anatomical structures and other species, the expandable member may have different profiles or volumes. In an embodiment, the expandable member is pre-shaped such that as the expandable member is expanded within the hollow anatomical structure, the interior of the hollow anatomical structure conforms to the profile of the expandable member.

[0025] Optional visual markings, corresponding to desired target areas of the HAS, may be located on the expandable member. The visual markings are used to aid in locating the desired treatment target areas. Such visual markings may be incorporated into or deposited on or within the material forming the member. In an embodiment, the visual markings may take the form of colorant, metallic or polymeric material. Although some sort of visual marking may be preferred, the practitioner may identify the necessary areas for transfer of energy using practitioner's experience. The visual markings may be positioned to correspond to any one or more areas corresponding to or in the vicinities of the greater curvature of the stomach, smaller curvature of the stomach, cardiac zone, gastric/fundic zone, pyloric zone, or the vagal nerve within the stomach.

[0026] In another embodiment, a treatment assembly may include a reference point positioner disposable at a distal end of the expander assembly. Preferably, reference point positioner comprises a positioning balloon adapted for inflation in the patient's body using means such as a conventional air or liquid tube that may also acts as a catheter guide. In operation, positioning balloon is inflated after passing through the pyloric sphincter and seats against the distal side of the pyloric sphincter. Once seated, inflated positioning balloon sets a reference point for tube and allows proper positioning of the balloon assembly without necessarily using a visualization apparatus. In an embodiment, the expanding balloon and its treatment sites may extend into the small intestine to provide treatment to at least a portion of the small intestine.

[0027] In an embodiment, the treatment assembly further includes an external treatment controller (portions of which were described above) for controlling various parameters useful in the treatment procedure. The external treatment controller includes any one or more of the following subassemblies: treatment energy source for providing and controlling energy source, input/output (I/O) device, inflation fluid delivery unit for inflating/deflating the

expandable member, and/or a positioning balloon when present.

[0028] In an exemplary method for treating the hollow anatomical structures embodying features of the present invention includes using a source of energy to apply energy to at least one surface of the HAS to affect its operation. In an embodiment energy, is thermal energy provided from a source of energy in the form of electromagnetic energy (e.g., RF, microwave), ultrasonic energy, infrared energy, visible laser energy, heat energy, or the like.

[0029] In an embodiment, the hollow anatomical structure is the stomach and the at least one surface of the HAS to which energy is applied is either or both stomach's muscle surface or the surface in the vicinity of at least a portion of a nerve communicating with the stomach and brain. In an embodiment, the treatment includes applying energy to at least one surface of the stomach's underlying glands to affect glandular emissions, such as ghrelin, pepsin, rennin, and/or HCl. In an exemplary method, the treatment includes transferring energy from the energy transmitting conductive regions on, in, or about the expandable member to the hollow anatomical structure's surface (or underlying muscles, nerves, glands, etc), by way of direct or indirect surface contact.

[0030] In an exemplary embodiment, a method for treating the hollow anatomical structure, such as the stomach in the digestive tract, includes introducing an expandable member into the hollow anatomical structure; expanding the hollow anatomical structure with the expandable member to bring into surface contact at least a portion of a surface of the expandable member (e.g., conductive regions) with at least a portion of a surface of the hollow anatomical structure to expose any one or more of the underlying nerves, muscles, or glands of the HAS. A source of energy, such as RF energy, is controllably provided, through the leads, to the conductive regions extending along at least a portion of the expandable balloon. As energy is provided to the conductive regions, energy is emitted (e.g., transmitted) from the conductive regions and the expandable member to the desired treatment area/s of the target hollow anatomical structure. In an embodiment, the expanded expandable member comes into direct surface contact with the desired target areas of the hollow anatomical structure. At least one or more of underlying nerve, muscle, or gland of the stomach are treated (e.g., ablated). In an embodiment, the at least one or more of underlying muscle is at least in one of the greater curvature of the stomach, smaller curvature of the stomach, cardiac zone, gastric/fundic zone, pyloric zone, or the vagal nerve within the stomach.

[0031] In an embodiment for treatment of the gastric tract, and in operation, a gastric

introducer is positioned in the patient's throat and protects the esophageal walls during the procedure. The expander assembly, preloaded with the endoscope (when present), is inserted into patient's body through the introducer. The expandable balloon is advanced distally positioning the shaped distal portion against the distal side of the pyloric sphincter. Using an inflation conduit, the expandable member is inflated until the stomach's volume reaches the desired volume, such as at least about twice its empty volume (e.g. to about 2 liters). The pre-shaped distal portion, at the expanded configuration, seats against the distal side of the pyloric sphincter, providing an anchor and aiding in position and placement of the expander assembly within stomach.

[0032] Once the expandable member has been positioned at the treatment site and expanded to the desired volume, the optional endoscope may be pulled back completely or partially into the introducer.

[0033] In an embodiment, the practitioner, using control unit 510 and a foot pedal, introduces energy, from an energy source, such as an RF generator, by way of leads to the conductive region/s. As energy is transmitted to the conductive regions, energy, such as thermal energy, is emitted from the conductive regions and the expandable member to the desired treatment area/s of the target hollow anatomical structure. In an embodiment, at least a portion of the expanded expandable member, including the conductive regions, comes into direct surface contact with the desired target areas of the hollow anatomical structure. The pointed contact electrodes enable better surface contact with the tissue and/or nerves and provide for a more targeted delivery of the energy. In an embodiment, the desired treatment area/s include any one or more areas corresponding to or in the vicinities of the greater curvature of the stomach, smaller curvature of the stomach, cardiac zone, gastric/fundic zone, pyloric zone, or the vagal nerve within the stomach.

[0034] In an embodiment, the emitted energy is sufficiently high to cause a change (e.g., physical, biochemical, physiological change) in the treatment target areas as described earlier.

[0035] During the procedure time, using GUI and feedback from corresponding sensor associated with such electrodes (conductive regions), the practitioner can monitor the temperature at the site. The duration of time and frequency of applied energy are, of course, responsive to judgments of medical personnel.

[0036] After the practitioner is satisfied that the desired amount of tissue has been treated (for example ablated) and/or the pulse transmissions between nerves and the brain have been affected by the desired amount, energy application is stopped. The expandable member is

deflated the expander assembly and withdrawn from the patient, as is the gastro introducer.

[0037] In another embodiment embodying features of the present invention, after patient sedation, the endoscope introduces the reference point positioner (e.g., reference point balloon), into the patient's alimentary canal. The endoscope forwards positioning balloon through the stomach and onto the distal side of the pyloric sphincter. The endoscope is retracted and positioning balloon inflated to seal against the distal side of the pyloric sphincter. This sets a fixed reference point for the tube. A gastric introducer positioned in the patient's throat, protects the esophageal walls during the next steps in the process.

[0038] The expander assembly is now introduced into the patient's digestive system through the gastric introducer and by the catheter riding over tube. When distal tip of the catheter contacts the positioning balloon and the closed pyloric sphincter, the practitioner stops inserting the stomach expander into the patient. Balloon member is then inflated until the stomach's volume becomes about twice its empty volume. The desired target areas are treated as described above.

[0039] After the practitioner is satisfied that the desired amount of tissue has been treated (for example ablated) and/or the pulse transmissions between nerves and the brain have been affected by the desired amount, energy application is stopped. The reference positioner and the expandable member are deflated and withdrawn from the patient, as is the gastro introducer.

Brief Description of Drawings

[0040] FIGs. IA and IB are simplified illustrations of a mammalian digestive system.

[0041] FIG. 2A illustrates an exemplary assembly embodying features of the present invention for treating hollow anatomical structures.

[0042] FIGs. 3A and 3B are schematic representations of different expandable members embodying features of the present invention.

[0043] FIG. 4A is a schematic representation of a treatment assembly embodying features of the present invention and for treating hollow anatomical structure.

[0044] FIGs. 4AA-AC are cross sectional views of portions of the HAS expander assembly, endoscope, and the introducer of FIG. 4A.

[0045] FIG. 4B is a schematic representation of another treatment assembly embodying features of the present invention and for treating hollow anatomical structure.

[0046] FIG. 5 illustrates a schematic of an exemplary external control unit embodying features of the present invention for use with the stomach treatment assembly of FIGS. 4A and 4B.

[0047] FIGs. 6A and 6B are schematic representations of neural communication between the stomach and the brain.

[0048] FIG. 7 illustrates a schematic profile of a treated stomach about 8-12 weeks, post-op.

Description of Embodiments

Anatomical Background

[0049] In describing features of the present invention, the hollow organ of the digestive system, such as the stomach, will be used. However, it should be appreciated by those skilled in the art that the use of this exemplary organ is not intended to limit the scope of the present invention.

[0050] FIGS. IA and IB are simplified depictions of a mammalian digestive system. These FIGS. are not intended to be strictly accurate in an anatomic sense or imply that the teachings of this patent application are limited strictly to treating the digestive system. The drawings show the digestive system in somewhat diagrammatic form for purposes of discussion.

[0051] FIG. IA, illustrates esophagus 10, a muscular tube, for carrying food from the mouth to the stomach 12, by way of wavelike contractions of the muscles in the walls of the esophagus 10. The interior esophagus walls include glands that secrete mucus, which further aid the movement of food by acting as lubricants.

[0052] Stomach 12, located in the upper left hand side of the abdomen, lies between the esophagus 10 and the small intestine 14. In humans and most other animals, stomach 12 is a simple baglike organ.

[0053] FIG. IB depicts branches 15 of the vagal nerve that connect stomach 12 with the hindbrain H which is believed to be the neurological source for the hunger sensation. The upper end of stomach 12 connects with the esophagus 10 at cardiac notch 16 (FIG. IA). The muscular ring called the lower esophageal sphincter 18 surrounds the opening between the esophagus 10 and the stomach 12. The funnel-shaped region of the stomach 12 immediately next to sphincter 18 is the cardia. The cardia (also known as Z-line or esophagogastric junction or gastroesophageal junction) is the anatomical term for the junction orifice of the stomach and the esophagus. At the cardia, the mucosa of the esophagus transitions into gastric mucosa. The cardia is also the site of the lower esophageal sphincter 18 (LES which is also termed cardiac sphincter). The greater curvature of the stomach, 26, starts from the cardiac orifice at the cardiac notch, and forms an arch backward, upward, and to the left; the highest point of the convexity is on a level with the sixth left costal cartilage. The lesser curvature 27 of the stomach is opposite the greater curvature and extends between the cardiac and pyloric orifices, forming the right or posterior border of the stomach. It descends as a continuation of the right margin of the esophagus in front of the fibers of the right crus of the diaphragm, and then, turning to the right, it crosses the first lumbar vertebra and ends at the

pylorus.

[0054] From this level it may be followed downward and forward, with a slight convexity to the left as low as the cartilage of the ninth rib; it then turns to the right, to the end of the pylorus. Positioned below the cardia is the fundus 25 of the stomach.

[0055] The volume of an average adult stomach, an organ for storing and digesting food, is a little over one quart (~0.95 liter). Pyloric sphincter 22, located distal of pylorus 23, surrounds and controls the size of the duodenal opening disposed between stomach 12 and small intestine 14. Pyloric sphincter 22 keeps non-liquid food in stomach 12 until the food is processed into a more flowable liquid form, thereafter allowing for the flow of the liquefied food from stomach 12 into the intestine 14. The time food spends in stomach 12 varies and usually ranges from about three to about five hours.

[0056] Using these anatomical features as landmarks or guides, the human stomach is often described as having three zones, namely: cardiac zone, gastric/fundic zone, and pyloric zone. In an embodiment, A treatment according to the body-weight related conditions, according to the present invention, is achieved by applying energy to or in the vicinities of any one or more of:

[0057] (1) nerve tissue which allows nerve pulse communication between the hindbrain H and stomach 12; or

[0058] (2) stomach tissue to ablate tissue in one or more areas where food is either processed and/or absorbed by the body, for example, the cardiac, gastric/fundic, and pyloric zones.

[0059] Additionally, treatment may be expanded to other areas, such as the small intestine (and associated nerves), where about 95% of all food absorption occurs. Ablation, or causing cell death, produces lesions which when large enough, evoke tissue-healing and intervention of fibroblasts, myofibroblasts, macrophages, and other cells. Healing results in tissue contraction (shrinkage), decreased volume, and/or altered biomechanical properties. In contrast with other treatments for conditions such as obesity which merely try to prolong patient satiety, the current devices and methods embodying features of the present invention, further provide for directly affecting the digestive process and may reduce food absorption. Without intending any limitations on the scope of the present invention, it is believed by the present inventors that ablation of cells in the cardiac, gastric/fundic, and/or pyloric zones enables treatment of weight-related conditions and reduces a patient's body weight, among other things, for the following reasons:

[0060] CARDIAC AND FUNDIC-GASTRIC ZONES - The cardia and fundic-gastric zone

contain, respectively, the cardiac glands (not shown) and the fundic glands (not shown). The cardiac and fundic glands release digestive enzymes (e.g., ghrelin, pepsin and rennin) and hydrochloric acid (HCl) which are used during digestion to break down food. Ablating a portion of the cardiac and gastric-fundic zones, e.g., the cardiac and fundic glands, therefore, reduces the release of ghrelin, pepsin, rennin and HCl, thereby reducing the amount of food digested by the body and resulting in more undigested food particles passing through the patient's body.

[0061] PYLORIC ZONE - The pyloric sphincter controls the size of food particles and their flow from the stomach (emptying cycle). The wider the opening of the sphincter, the larger the size of the food particles that may flow out of the stomach. Without limiting the scope of the present invention, it is believed that ablating the pyloric muscle tissue decreases the size of the pyloric opening and the size of food particles that may flow out, thereby lengthening the emptying cycle (longer sensation of satiety).

[0062] The gastric zone also includes the lesser curvature of the stomach which contains nerves that control peristalsis of the stomach walls. Peristalsis contributes to digestion by physically reducing the size of food particles in the stomach. It is also believed, without limiting the scope of the present invention, that ablating portions of the muscles of the lesser curvature reduces peristalsis and increases food particle size. These larger food particles, when passed through the pyloric sphincter, cannot be digested through the small intestine and therefore would pass through the patient's body undigested. Finally, ablating gastric zone tissue may also affect the gastric glands and reduce HCl production in the stomach (see above).

[0063] Against this anatomical and physiological background, exemplary apparatus, assemblies, and methods for treating body-weight related medical conditions associated with the digestive hollow organs will be described. It should be appreciated by those skilled in the art that using the digestive hollow organ, such as the stomach, for describing features of the present invention, is not intended to limit the scope of the present invention.

Treatment Apparatus

[0064] FIGS. 2A through 5 show features of an exemplary embodiment of apparatus 80 for treating hollow anatomical structures ("HAS").

[0065] Assembly 80 (FIG. 2) includes a hollow anatomical structures treating assembly 100 (FIG. 4A and 4B) and an external control assembly 500 (FIG. 5). At least a portion of the HAS treating assembly 100 works inside the patient's body for treatment of the hollow

anatomical structures such as hollow organs and blood vessels. For purposes of describing the present invention the digestive tract, e.g., stomach 12 (FIGS. IA and IB) will be used. External control assembly 500 (FIG. 5) includes components for, among other things, controlling, monitoring, and viewing at least parts of the HAS treating assembly 100.

Although the apparatus and methods of the present invention are described in the context of treating the digestive tract (e.g., stomach), it should be appreciated that the present devices and methods are applicable and useful in treatment of other hollow anatomical structures. Furthermore, it should be appreciated that the shape, size, and specific configuration of the various components may be modified and adapted for use in the particular application and the anatomical structure (e.g., respiratory tract, lung, reproductive tract and/or organ, urinary tract and organs, nasal passage, sinus, veins, artery, tunsile, tympanic membrane, or joints).

[0066] Now referring to FIG. 3A, portion of a HAS treating assembly 100, such as treatment assembly 100', is shown including; an expander assembly 300, 300' such as balloon assembly 310; embodying features of the present invention. As shown in FIG. 3A, the balloon assembly 310' including an expandable member such as expandable balloon 320, is disposed, in an expanded configuration, in the stomach 12. The expandable balloon is adapted for expansion within the interior of the HAS conforming an inner wall 123 of the HAS 120 to the shape and volume of the expanded expandable member such that at least portions of the outer surface 325 of the balloon 320 are in surface contact with the inner wall 123 of the HAS.

[0067] An interior 330 of balloon 320 is in fluid communication with an inflation/deflation source (FIG. 4B) through a conduit, such as lumen of an elongate body, such as catheter 400 (by way of example and not limitation, inflation deflation may be achieved through the same or different lumens). Balloon 320, as shown, is disposed at a distal end 403 of the catheter 400.

[0068] Now returning to FIG. 3A, a distal portion 335' of the balloon 320 is shaped to conform, upon expansion, to a portion of the HAS, preferably, distal to the desired treatment site; such as the pyloric sphincter 22. In operation the shaped distal portion 335' is inflated and seats against the distal end of the pyloric sphincter.

[0069] Balloon 320 includes treatment areas 340 (shown as dotted pattern) corresponding to any one or more of desired treatment sites of the HAS. In the case of the stomach, in the embodiment shown, the desired treatment sites are those of the stomach's and include any one or more areas corresponding to or in the vicinities of the greater curvature of the

stomach, smaller curvature of the stomach, cardiac zone, gastric/fundic zone, pyloric zone, or the vagal nerve within the stomach. The balloon treatment areas circumferentially surround the expandable balloon and are longitudinally positioned on an inner or preferably outer surface of the balloon. The balloon treatment areas 340 include conductive regions 345 comprising a plurality of electrodes 346 (denoted by the dots although the location, density, and shape of the electrodes are not limited to that illustrated) adapted to deliver ablative energy to the surface of the hollow anatomical structure, including the vagal nerve. At least a portion of the electrodes 346 comprise pointed contact electrodes 347 for providing an enhanced range of power delivery to selectively reach and ablate the surface of the hollow anatomical structure including nerves such as the vagal nerve. In an embodiment, the expandable balloon is formed from two layers of material, 321 and 322. The pointed contact electrodes are positioned in an interior space between the two layers. The conductive regions may form a continuous band or multiple interrupted bands. The shape of the region may be uniform throughout or different regions may have different shapes. Inflation of expandable balloon 320 expands the stomach to stretch the pleated mucosa of the stomach and expose underlying nerves and stomach muscle and brings the electrodes including the pointed contact electrodes into surface (e.g., substantially non-penetrating) contact with the treatment site .

[0070] Leads 323 extend from the pointed contact electrodes to an energy source 900 connectable to an energy generator 520 by way of conduit 512, as described further below. The pointed contact electrodes may be formed of any suitable material such as stainless steel. The electrodes 346 may further comprise other surface electrodes secured to the expandable balloon by suitable means such as rivets piercing the expandable balloon surface, exposing the surface electrodes to the outside of the balloon, thus enabling the surface electrodes to be in surface contact with the stomach tissue. The surface electrodes may be formed from flexible circuitry etched onto the surface of expandable balloon 320 and are connectable by way of leads to the energy source.

[0071] As shown in FIG. 4A, the expanded balloon 320 extends from a distal end 606 of an introducer 600, such as gastric introducer 603. In an embodiment, the expanding balloon and its treatment areas may extend into the small intestine to provide treatment to at least a portion of the small intestine.

[0072] In another embodiment, **as** shown in **FIG.** 3B, **a HAS** treatment assembly 100" may include **a** reference point positioner 700 disposable **at a** distal end 103" of **the** expander

assembly 300". Preferably, reference point positioner 700 comprises a positioning balloon 703 adapted for inflation in the patient's body using means such as a conventional air or liquid tube 710 that may also acts as a catheter guide. In operation, positioning balloon 703 is inflated after passing through the pyloric sphincter 22 and seats against the distal side of the pyloric sphincter 22. Once seated, inflated positioning balloon 703 sets a reference point for tube 710 and allows proper positioning of the balloon assembly 310' without necessarily using a visualization apparatus. In an embodiment, the expanding balloon and its treatment sites may extend into the small intestine to provide treatment to at least a portion of the small intestine.

[0073] Now referring to FIG. 4A, the expander assembly 300' of FIG. 3A, is shown as part of a HAS treating assembly 100'. In the embodiment shown, the expander assembly 300' includes an elongate body such as catheter 400with proximal and distal ends, 406 and 403, respectively; and at least one lumen, such as lumen 410 extending along at least a distal portion thereof. (FIG. 4A). The balloon member 320 is disposed at the distal end of the HAS catheter 400 and extends from a distal end 606 of the introducer 600. As shown in FIG. 4A and cross-sections 4AA and 4AB, an endoscope 800 may optionally be disposable within the catheter 400. Endoscope (or other visualization tool) 800, during a procedure, may be extended into the interior 330 of the expandable balloon 320 for better visualization of the treatment site. Endoscope 800 may include an illumination source such as lights (not shown) for visualization of the HAS when it is disposed within the HAS interior 130. The expander assembly and endoscope are accessible through hand-piece 750 disposed at the proximal end 110 of the treatment assembly 100, 100'. For purposes of clarity in FIGS. 4AA-4AC, only the overall structure of the introducer, catheter, and/or endoscope are shown (the conductive regions are not shown).

[0074] Now referring to FIG. 4B, wherein like references denote like elements, expander assembly of FIG. 3B is shown as part of a HAS treating assembly 100". A distal end 103 of HAS treating assembly 100 includes the reference point positioner 700 with the positioning balloon 703 adapted for inflation in the patient's body using the conventional air or liquid tube 710 that also acts as a catheter guide.

[0075] The expander assembly 300 comprises, for example, the balloon assembly 310" integrated with the catheter 400 having a distal tip 420. In FIG. 4B, balloon assembly 310 is collapsed. Catheter 400 allows balloon assembly 310 to be inserted into the patient's body over tube 710. Then, using an air line in handpiece 750 disposable at the proximal end 110 of

the treating assembly 100", balloon member 320 is inflated to expand the stomach's volume. The HAS expander assembly, the reference point positioner, and tube 710 (and the endoscope when present) are accessible through hand-piece 750 disposed at the proximal end of the HAS treatment assembly.

[0076] The electrodes 346 are configured for communication with the energy source 900 which is connectable to energy generator 520 by way of conduit 512 controllable by the control assembly 500. The amount and level of energy at its source is set to provide a sufficient level of energy at the point of treatment. The desired energy level differs for different hollow anatomical structures. The temperature at the point of treatment is sufficiently high to effectuate the desired treatment. The temperature at the point of treatment, for the stomach, may range from about 50 to about lOO°C, from about 60° to about 95°C, from about 60° to about 80°C.

[0077] One or more sensors may be located within or about the expandable member, at or near the conductive regions. In an embodiment, the sensor is a thermocouple or thermistor. The temperature sensor is coupled to a communication link (such as a conductor), which is coupled to a processor. For example, in the case where the temperature sensor is a thermocouple, the communication link may comprise a D/A converter coupled to a register disposed for reading by the processor. The processor reads a sensor value from the sensor and, responsive thereto, controls the signal generator so as to achieve delivery of an effective amount of energy to a desired section of tissue to be ablated. The processor thus uses the information from the signal generator, the information from the conductive regions, and temperature sensor, as a feedback loop for controlled delivery of energy to a section of the stomach (or other treatment areas of a hollow anatomical structure). For example, the processor may control the delivery of energy to achieve delivery of a selected amount of energy, to achieve a selected temperature, or to achieve a selected amount of ablation of a section of a stomach. A variety of positionings for the sensors are possible. In one embodiment, the sensor is coupled to the expandable member.

[0078] As described above, the temperature or some other property of the tissue being ablated, or of the energy, can be monitored using a variety of sensors. By way of example, open and a closed loop feedback systems may be utilized for coupling a sensor used in the apparatus to an energy source so that the output energy of the energy source is adjusted in relation to the property sensed by the sensor. One or more sensors may be located within or about the expandable member, or at or about the conductive regions. It should be appreciated

that the sensor may take any appropriate form, as for example formed of wireless construction, and may further be configured to sense and convey the necessary information in any number of ways and formats and is not limited to direct thermal sensors. By way of example and not limitation, the temperature may be sensed by optical means which can assess a change in the color of at least a portion of expandable member (e.g., conductive regions). In this configuration, colorants may be present in the material forming the expandable member/regions or be painted or deposited on its material (on the inner or outer surface). Once the colored area is exposed to the elevated temperature, the colorant may change its characteristics. Information as to the temperature may then be conveyed to the practitioner. The information may be conveyed automatically by instrumentation or by direct visualization through the endoscopic device. As stated, such sensors may also be present on or in the expandable member.

[0079] Regardless of the configuration, HAS expandable member 320 may be formed from any suitable material such as, but not limited to expandable, noncompliant (or semi-compliant) material including Mylar, Nylon, PET, PeBax, IEBA. In a preferred embodiment, the material for balloons 320 is formed from non-compliant material. For example, Mylar, while expandable, is noncompliant and restricts expansion of the expandable balloon within the stomach. Therefore, an expandable balloon formed from Mylar cannot infinitely expand and patient injury resulting from unintended over-inflation of expandable balloon 320 can be reduced. In an embodiment, when used for obesity treatment, expandable balloon 320 is constructed such that when inflated within the stomach, the stomach expands from its empty volume (about 1 liter) to at least about twice the stomach's empty volume (e.g. 2 liters). However, for other hollow anatomical structures and other species, the expandable member may have different profiles or volumes. In an embodiment, the expandable member is pre-shaped such that as the expandable member is expanded within the hollow anatomical structure, the interior of the hollow anatomical structure conforms to the profile of the expandable member.

[0080] Optional visual markings, corresponding to desired target areas of the HAS, may be located on the expandable member. The visual markings are used to aid in locating the desired treatment target areas. Such visual markings may be incorporated into or deposited on or within the material forming the member. In an embodiment, the visual markings may take the form of colorant, metallic or polymeric material. Although some sort of visual marking may be preferred, the practitioner may identify the necessary areas for transfer of

energy using practitioner's experience. The visual markings may be positioned to correspond to any one or more areas corresponding to or in the vicinities of the greater curvature of the stomach, smaller curvature of the stomach, cardiac zone, gastric/fundic zone, pyloric zone, or the vagal nerve within the stomach.

External Control

[0081] Now referring back to FIGS. 2 and 5, the external control portion 500 for apparatus 80 is shown and including a control unit 510. Control unit 510 may include any one or more of the following subassemblies: treatment energy source 520 for providing and controlling energy source 900, controller 530, I/O device 540, inflation fluid delivery unit 250, and GUI 560.

[0082] Summarily, control unit 510 governs the power levels, cycles, and duration of energy transmitted through line 512 to the energy source and the conductive regions to achieve and maintain temperature levels that achieve treatment objectives. Foot switch 511 allows hands-free control of energy delivery. In tandem, control unit 510 controls delivery of processing (inflation) fluid and, if needed, the removal of aspirated material through fluid lines 555.

[0083] Controller 510 includes an Input/Output (I/O) device 540. The I/O device 540 allows practitioners to enter control and processing factors enabling control unit 510 to generate correct command signals. The I/O device 540 also receives real time processing feedback information from the one or more sensors associated with the expandable member or the conductive regions, as well as the endoscope (e.g., visualization data) when present. The feedback information is processed by the controller 530, to govern energy application and processing inflation fluid as well as energy delivery. The I/O device 540 also includes a graphical user interface (GUI) 560 that graphically presents processing information to the practitioner for viewing and/or analysis. The energy may be in the form of electromagnetic energy (e.g., RF, microwave) and ultrasonic energy, infrared energy, visible laser energy, heat energy, or the like.

Therapeutic Procedure/Method

[0084] For purposes of discussion, exemplary therapeutic methods embodying features of the present invention will be described in the context of the treatment of the stomach. However, it should be noted that the methods of the present invention are equally applicable in the treatment of other hollow anatomical structures and variations as to the steps, complementary components, visualization tools, introducers, and points of access to the anatomical structure may be modified as necessary. Because practitioners need not make any incisions (or in the

case of transcutaneous or laparoscopic procedures the incision is minimal), and in far contrast to the complex and highly invasive bariatric surgeries currently practiced, the treatment according to the present invention is minimally invasive. In an embodiment, the procedure takes about one hour, including preparation and minimal recovery times. In an embodiment, patients can be treated on an out-patient basis using conscious sedation and since the risk of serious problems during the treatment is low it does not necessarily require the complete back-up of a hospital for emergencies.

[0085] In an embodiment for treatment of the gastric tract, and in operation, a gastric introducer is positioned in the patient's throat and protects the esophageal walls during the procedure.

[0086] The expander assembly, preloaded with the endoscope (when present) is inserted into patient's body through the introducer. The expandable balloon is advanced distally positioning the shaped distal portion against the distal side of the pyloric sphincter. Using an inflation fluid line, such as an air line (e.g., extending along an inner lumen of catheter 400), through a hand-piece disposed at the proximal end of the HAS treatment assembly, expandable member is inflated until the stomach's volume reaches the desired volume, such as at least about twice its empty volume (e.g. to about 2 liters). The pre-shaped distal portion, at the expanded configuration, seats against the distal side of the pyloric sphincter, providing an anchor and aiding in position and placement of the expander assembly within stomach.

[0087] Once the expandable member has been positioned at the treatment site and expanded to the desired volume, the optional endoscope may be pulled back completely or partially into the introducer.

[0088] In an embodiment, the practitioner, using control unit 510 and a foot pedal, delivers energy from an energy source through leads to the conductive regions extending along at least portions of expandable balloon 320. As energy is provided to the conductive regions, energy is emitted (e.g., transmitted) from the conductive regions and the expandable member to the desired treatment area/s of the target hollow anatomical structure. In an embodiment, the expanded expandable member comes into direct surface contact, preferably at least substantially non-penetrating physical contact, with the desired target areas of the hollow anatomical structure. The pointed contact electrodes enable better surface contact with the tissue and/or nerves and provide for a more targeted delivery of the energy. In an embodiment, the desired treatment area/s include any one or more areas corresponding to or in the vicinities of the greater curvature of the stomach, smaller curvature of the stomach,

cardiac zone, gastric/fundic zone, pyloric zone, or the vagal nerve within the stomach.

[0089] In an embodiment, the transferred energy is sufficiently high to cause a change (e.g., physical, biochemical, physiological change) in the treatment target areas as described earlier.

[0090] As stated earlier, the energy may be in the form of electromagnetic energy (e.g., RF, microwave) and ultrasonic energy, infrared energy, visible laser energy, heat energy, or the like. During the treatment period, using GUI and feedback from corresponding sensor associated with such conductive regions, the practitioner can monitor the temperature at the site. The duration of time and frequency of applied energy are, of course, responsive to judgments of medical personnel.

[0091] After the practitioner is satisfied that the desired amount of tissue has been treated (for example ablated) and/or the pulse transmissions between nerves and the brain have been affected by the desired amount, energy application is stopped. The expandable member is deflated the expander assembly and withdrawn from the patient, as is the gastro introducer.

[0092] In another embodiment embodying features of the present invention, after patient sedation, the endoscope introduces the reference point positioner (e.g., reference point balloon), into the patient's alimentary canal. The endoscope forwards positioning balloon through the stomach and onto the distal side of the pyloric sphincter. The endoscope is retracted and positioning balloon inflated to seal against the distal side of the pyloric sphincter. This sets a fixed reference point for the tube. A gastric introducer positioned in the patient's throat, protects the esophageal walls during the next steps in the process.

[0093] The expander assembly is now introduced into the patient's digestive system through the gastric introducer and by the catheter riding over tube. When distal tip of the catheter contacts the positioning balloon and the closed pyloric sphincter, the practitioner stops inserting the stomach expander into the patient. Balloon member is then inflated until the stomach's volume becomes about twice its empty volume.

[0094] The practitioner, using same or similar methodology as that described above treats the desired areas of the hollow anatomical structure. After the practitioner is satisfied that the desired amount of tissue has been treated (for example ablated) and/or the pulse transmissions between nerves and the brain have been affected by the desired amount, energy application is stopped. The reference positioner and the expandable member are deflated and withdrawn from the patient, as is the gastro introducer.

[0095] FIGS. 6A and 6B very schematically show the disruption and slowing of the travel of nerve pulses S, S' between the stomach 12, the small intestine 14, and the brain. In FIG. 5A,

smaller ablated portions Q of exemplary nerve 15 disrupt the straight flow of nerve signal impulses S between the stomach, small intestine, and brain. In FIG. 5B, larger ablated portions Q' of exemplary nerve 15 more greatly disrupt the straight flow of nerve signal impulses S' between the stomach, small intestine, and brain. The size of ablated portions Q, Q' and the desired degree of associated signal disruption are left to the sound judgment of the practitioner after considering, for example, the degree of patient's obesity, strength of patient's hunger sensations, and variation in nerve size from patient to patient.

[0096] FIG. 7 is an exemplary depiction of the appearance of the muscle profile of a treated stomach about 3 months post-op. There will now be major muscular constrictions and lesions (dead tissue) 121 in the areas of the fundus 25, peritoneum 30 and pylorus 23. These muscular constrictions and associated lesions should cause patient weight loss for the reasons discussed above. Because the procedure does not cause complete cell death in the treated areas, over long periods of time continued healing may cause the stomach's muscle profile to return to normal. Accordingly, follow-up treatments may be required. However, due to the process' simplicity, this should not pose any undue risk or inconvenience to the patient.

Conclusion

[0097] While this application describes certain exemplary embodiments of treatments for weight-based medical conditions and apparatus useful for carry out the treatments, only the attached claims define the scope of the invention.

Claims

Claim 1. An apparatus for treating medical conditions of hollow anatomical structures, comprising:

an expandable member adapted for expansion within the hollow anatomical structure and conforming an interior of the hollow organ to an expandable member's profile in an expanded configuration and exposing at least a portion of either or both the structure's underlying nerves or muscle; and

conductive regions including pointed conductive electrodes disposed in, on, or about the expandable member and adapted to transmit ablative energy to the structure.

Claim 2. An apparatus according to claim 1, wherein the conductive regions of the expandable member are adapted for substantially non-penetrating surface contact with an interior of the structure.

Claim 3. An apparatus according to claim 1, wherein the structure is the stomach and the expandable member is adapted and sized to expand the stomach and expose one or more of greater curvature of the stomach, smaller curvature of the stomach, cardiac zone, gastric/fundic zone, or pyloric zone.

Claim 4. An apparatus according to claim 2, wherein the conductive regions of the expandable member are formed from a material comprising conductive metal.

Claim 5. An apparatus according to claim 3, further comprising a visualization assembly for viewing the interior of the structure during a medical procedure.

Claim 6. An apparatus according to claim 1, wherein the expandable member is formed from expandable semi-compliant or non-compliant material.

Claim 7. An apparatus according to claim 1, wherein the expandable member is formed from a non-compliant material.

Claim 8. An apparatus according to claim 1, further comprising a control assembly including components for any one or more of providing energy, controlling, monitoring, and viewing at least part of the apparatus.

Claim 9. A hollow anatomical structure treatment assembly comprising:
an expander assembly including
a catheter, and
an expandable member having
an inner surface forming an expandable space,
an outer surface, and
at least one treatment area having a conductive region with a plurality of electrodes for delivering ablative energy to a surface of the hollow anatomical structure.

Claim 10. A treatment assembly as in claim 9 wherein: at least some of the electrodes comprise pointed contact electrodes each having a point directed outward from the expandable member.

Claim 11. A treatment assembly as in claim 10 wherein: the pointed contact electrodes are formed of a suitable material such as stainless steel.

Claim 12. A treatment assembly as in claim 10 wherein: the expandable member is formed from two layers of material between which are disposed the pointed contact electrodes.

Claim 13. A treatment assembly as in claim 9 wherein at least one treatment area circumferentially surrounds the expandable member.

Claim 14. A treatment assembly as in claim 9 wherein: the expandable member has a plurality of conductive regions of different shapes.

Claim 15. A treatment assembly as in claim 9 wherein: the expandable member further comprises flexible electrode circuitry etched onto a surface of the expandable member.

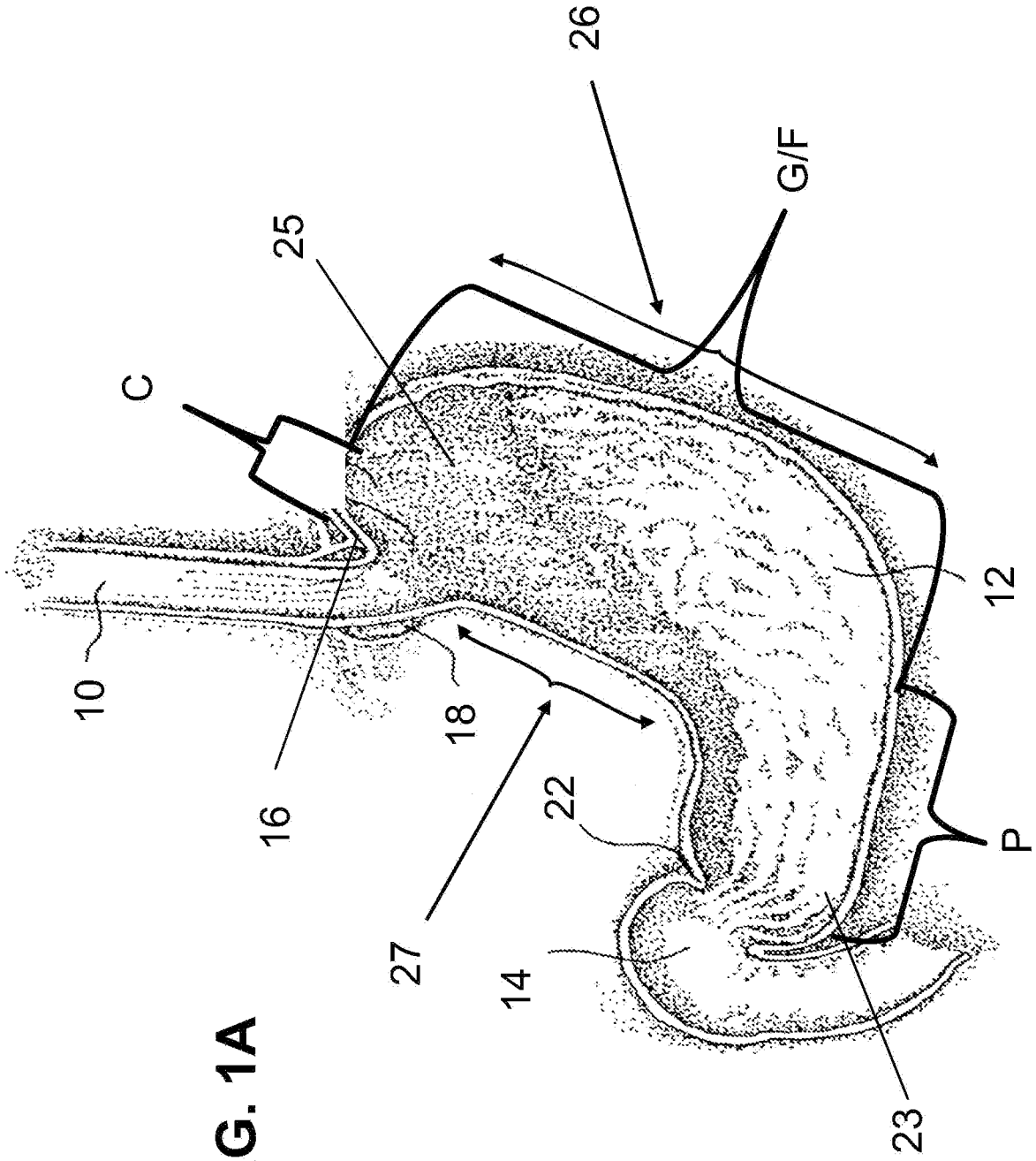


FIG. 1A

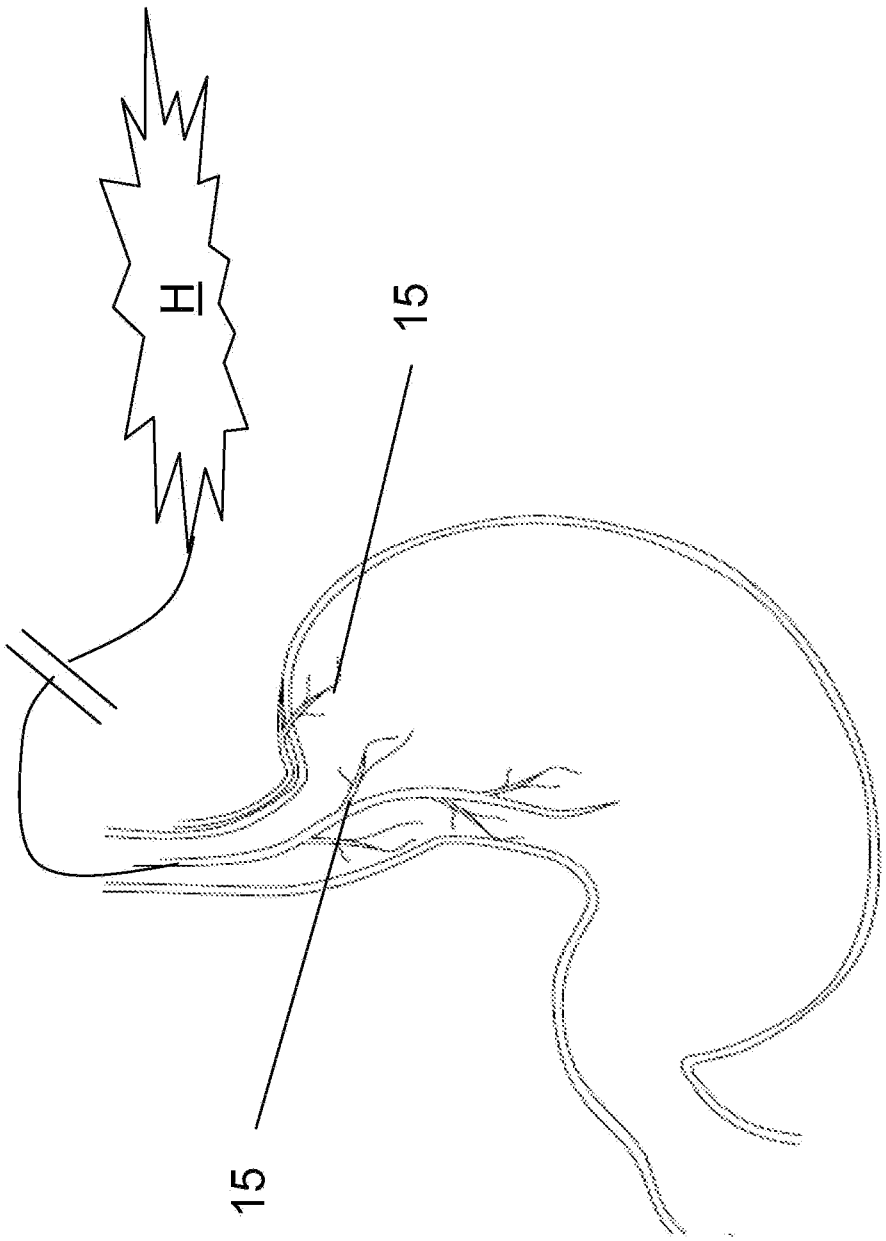


FIG. 1B

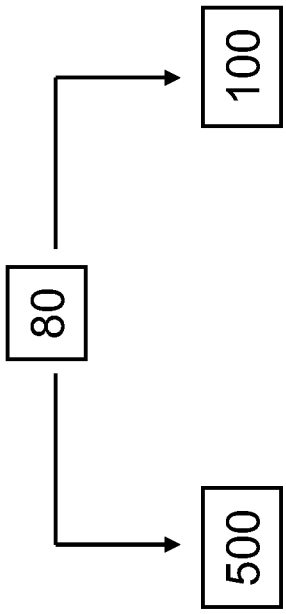
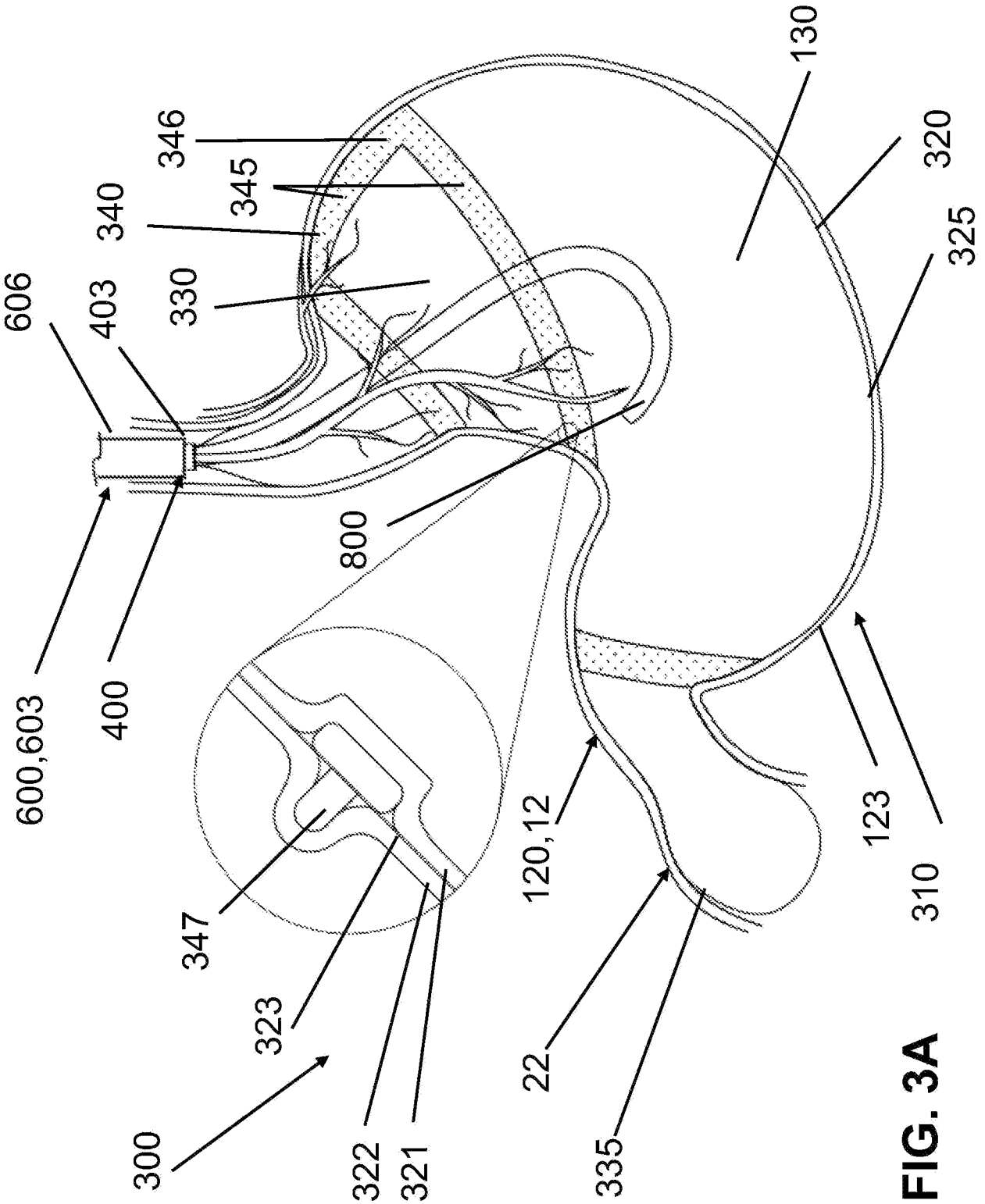


FIG. 2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340
330
606
403
600,603
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325
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323
322
321
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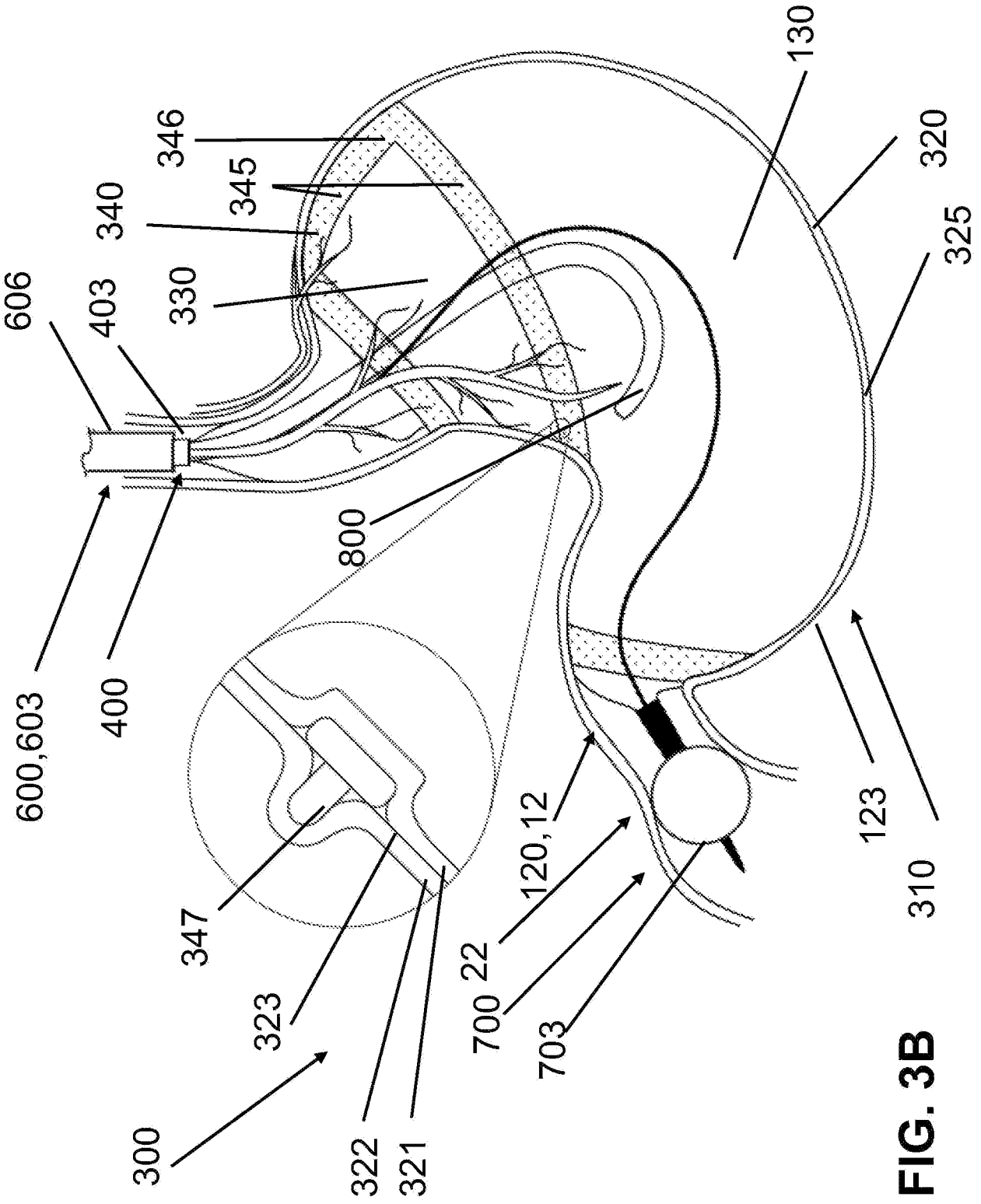
120,12
22
335
123
310

FIG. 3A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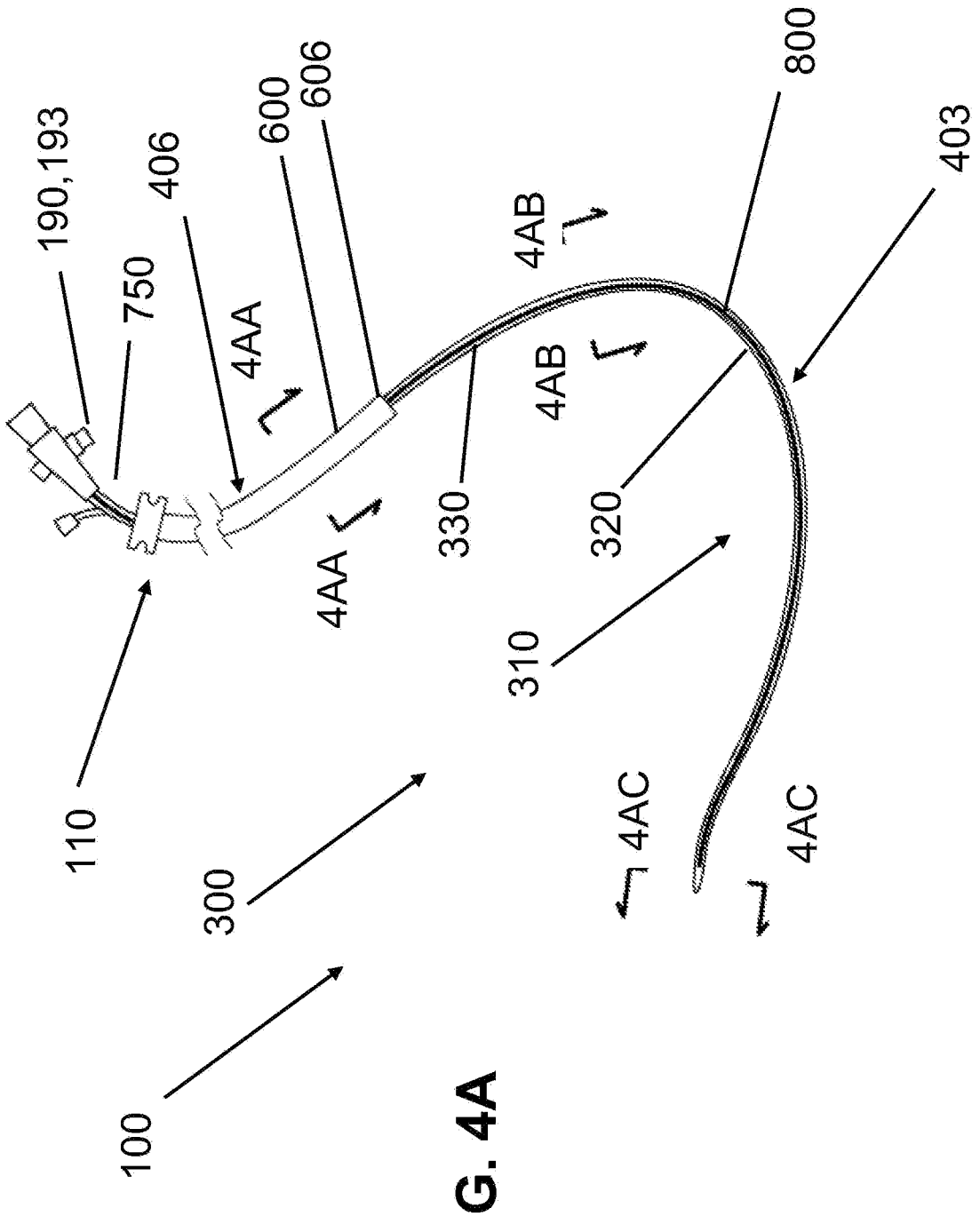
703
123
310

FIG. 3B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4AC
4AC
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406
600
606
750
800
190,193

FIG. 4A

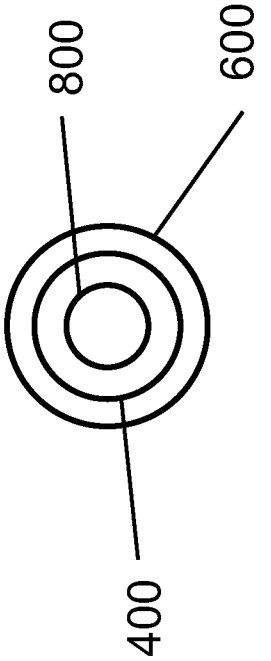

FIG. 4AA

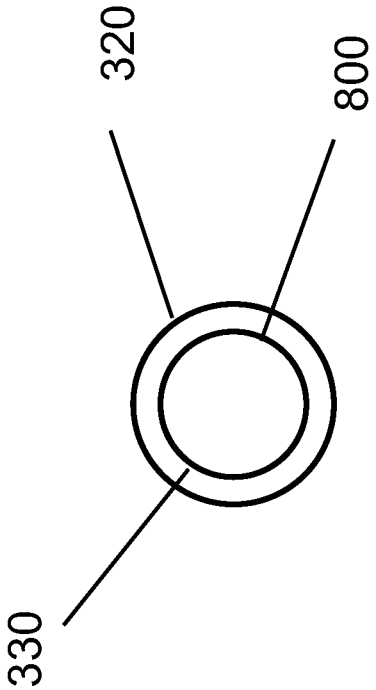

FIG. 4AB

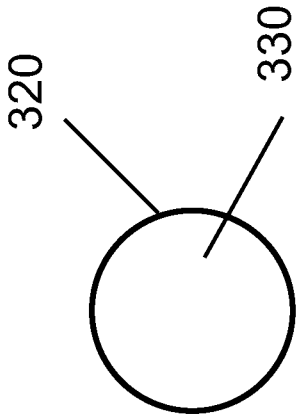

FIG. 4AC

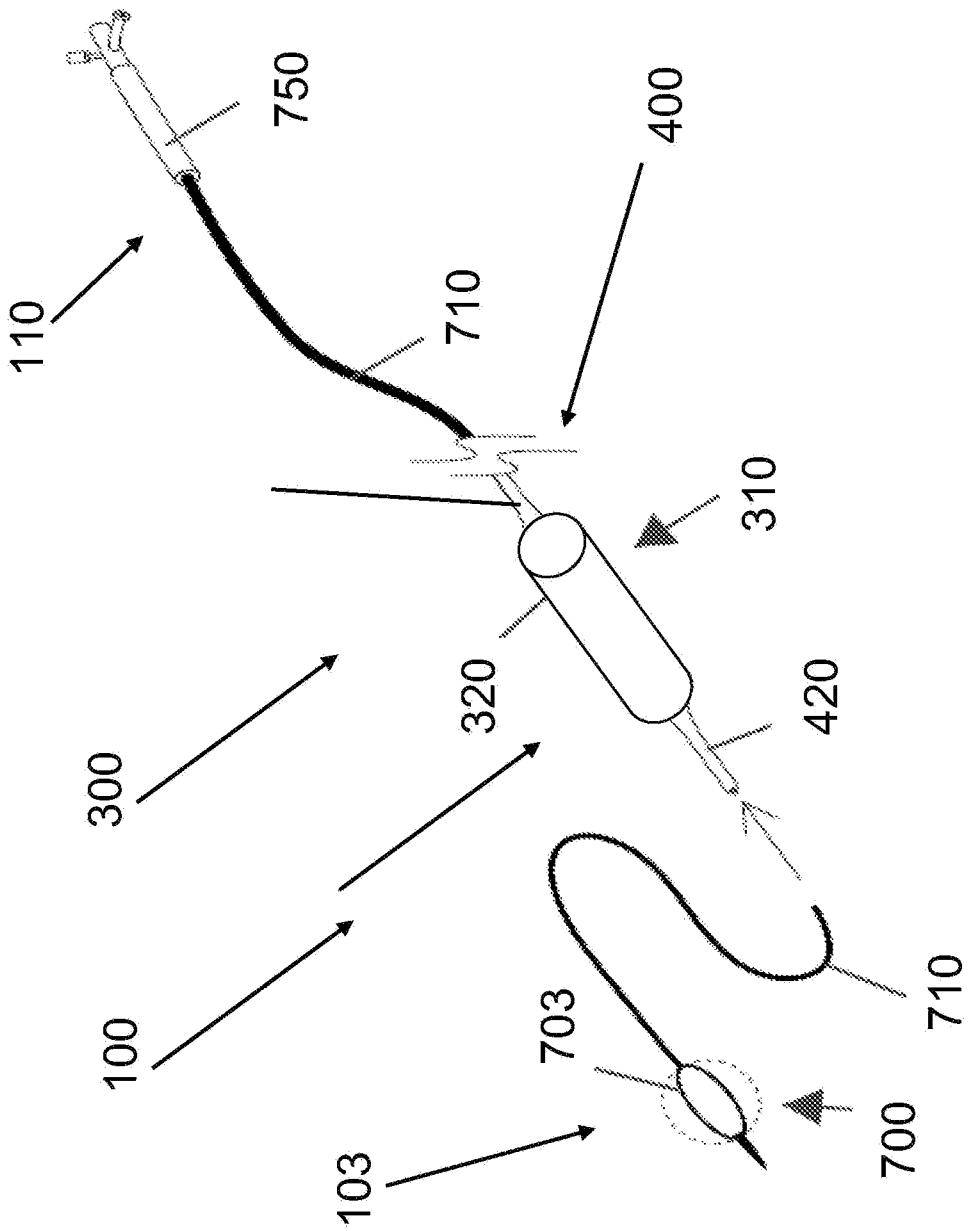

FIG. 4B

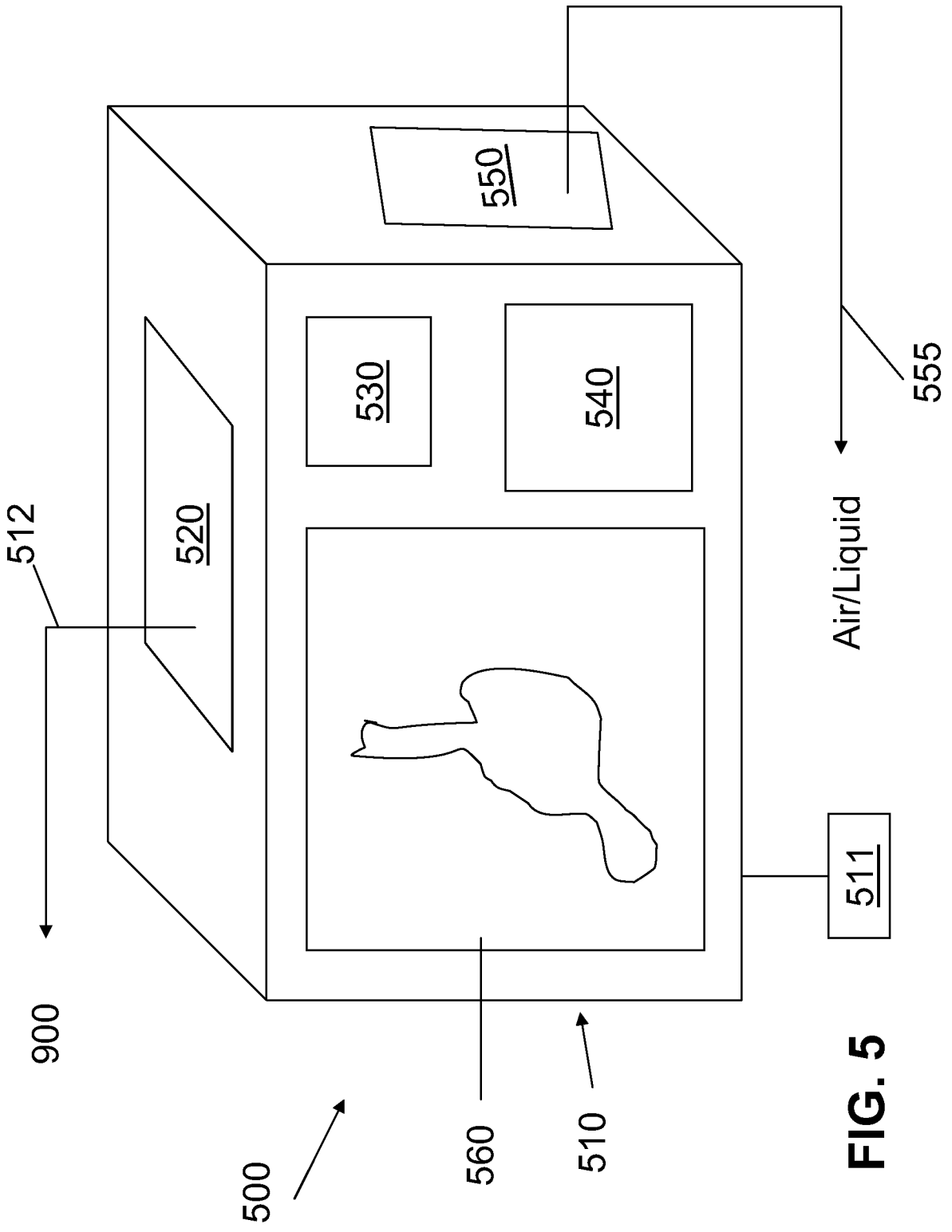

FIG. 5

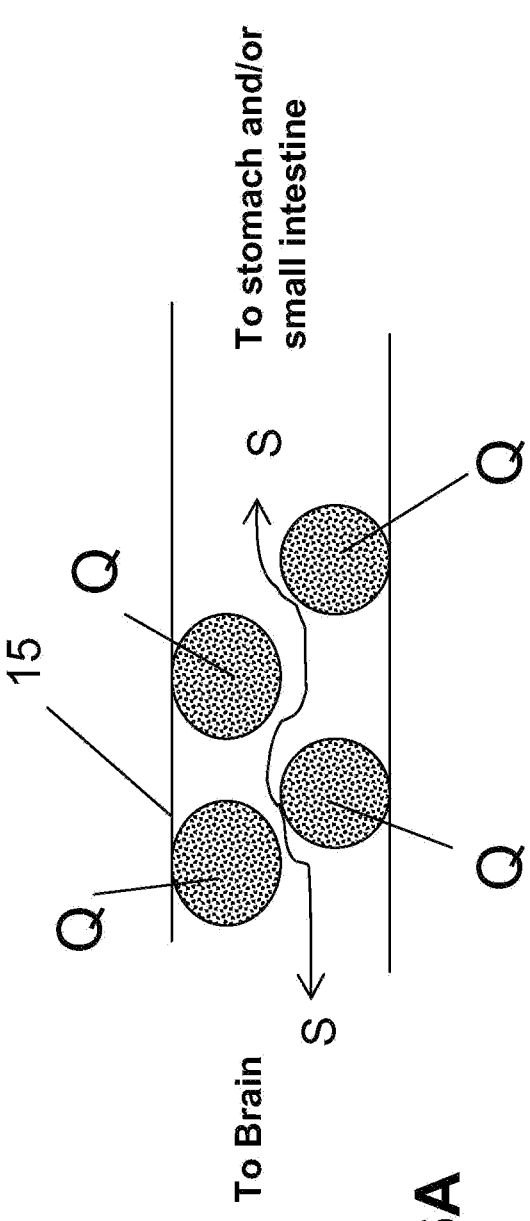
15
Q
Q
Q
Q
S
S
To stomach and/or
small intestine
To Brain

FIG. 6A

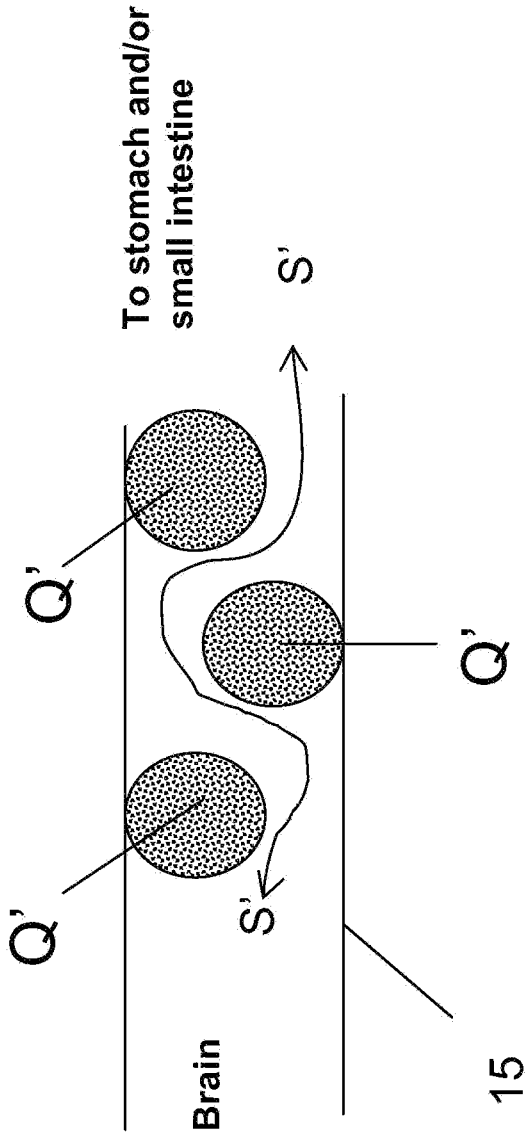
Q'
Q'
Q'
S'
S'
To stomach and/or
small intestine
To Brain
15

FIG. 6B

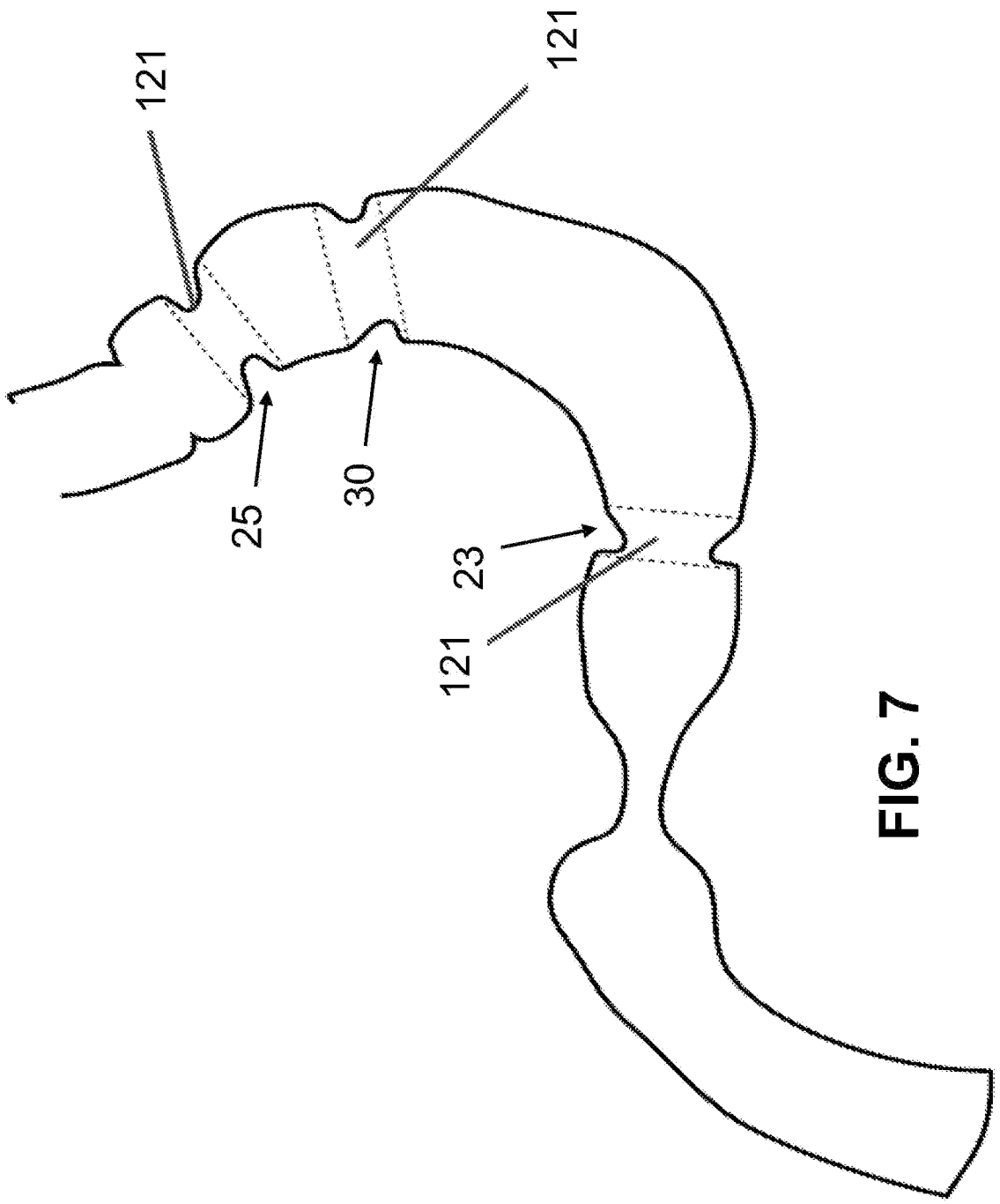

FIG. 7