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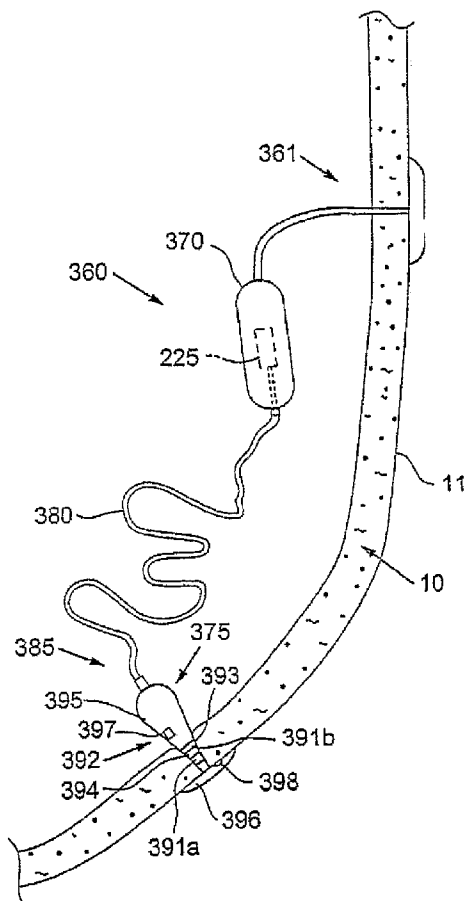
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(54) Title: SYSTEMS AND DEVICES FOR STIMULATING AN ORGAN WALL



(57) Abstract: An retaining device for attaching to a contractile organ such as a digestive tract organ or stomach is provided. One aspect may include a lead for stimulating a digestive organ. The device may be an electrical stimulation device configured to deliver electrical signals to the organ. Also, a pseudounipolar stimulator lead for anchoring to a digestive organ is provided.

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SYSTEMS AND DEVICES FOR STIMULATING AN ORGAN WALL

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. Patent Application Nos. 11/249,661; 11/249,290; and 11/249,291; which were all filed on October 12, 2006, the full disclosures of which are incorporated herein by reference.

STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER
FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] NOT APPLICABLE

REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER
PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK.

[0003] NOT APPLICABLE

BACKGROUND OF THE INVENTION

[0004] Field of the Invention

[0005] This invention relates to an anchor for attaching to the wall of a contractile organ such as, e.g., a stomach or other gastrointestinal tract organ. This invention also relates to an electrical lead or stimulator for attaching to the wall of a digestive organ.

Background of the Invention

[0006] Digestive organ and other contractile organ stimulation using electrodes coupled to the organ have been proposed in a variety of applications. Currently devices for stimulating digestive tract organs are typically delivered to the organ by way of a laparoscopic surgical procedure, i.e., in which an incision is made in the stomach and the leads are tunneled through the abdominal tissue.

[0007] Copending Patent Application No. 10/295,128, filed November 14, 2002; and its parent U.S. Patent Application No. 09/847,884, now U.S. Patent No. 6,535,764; both of which are incorporated in their entirety herein by reference, describe an endoscopically

delivered stimulation device that is attached to the inside of the stomach from within the stomach.

[0008] Generally bipolar or monopolar leads have been provided in the proposed devices. Monopolar stimulation may cause inadvertent stimulation of tissue adjacent the stimulating lead. Organs immediately adjacent the stomach may have an unintended physiological response to such stimulation.

[0009] Accordingly when stimulating the stomach or other digestive organs it may be desirable to concentrate stimulation to a small area. However, digestive organ walls are relatively thin (typically about 10 mm) so that placement of bipolar electrodes on or through the walls in a manner that maintains electrical contact may also cause shunting between the electrodes. Additionally, the mucosa of the stomach has a high impedance further reducing the effectiveness of bipolar electrodes stimulating through the mucosa.

[0010] It would be desirable to provide an improved device system or method for attaching a device to a contractile organ such a stomach. It would also be desirable to provide an improved lead for stimulating a contractile digestive organ.

BRIEF SUMMARY OF THE INVENTION

[0011] According to the present invention, a retention device, system and method are provided for attaching or coupling to a contractile organ. The device may be used to attach devices or elements such as, therapeutic or diagnostic devices or elements. According to one aspect of the invention a lead with such a retention device, is provided with at least one electrode for stimulating the organ. The retention device, system and method may also be used to couple devices or elements to a digestive tract organ such as a stomach. Such elements may include, but are not limited to, sensors for sensing conditions relating to the organ and therapeutic delivery systems such as drug delivery systems.

[0012] One aspect of the present invention provides a device, system and method for diagnosing and treating digestive related disorders or conditions. The present invention also provides a device, system and method for electrical stimulation of the digestive tract and related organs. Electrical stimulation is generally defined herein to mean any application of an electrical signal or of an electromagnetic field to tissue of the digestive organ for a therapeutic purpose. While the device system and method may be used with any digestive

tract organ and/or gastrointestinal tract organ, it is described with particular reference to use in a stomach.

[0013] In one variation, stimulation is applied to the stomach, for example, to treat digestive disorders or conditions, nausea, obesity or pain symptoms. The stimulation may affect the smooth muscle contractions and/or nerves associated with the stomach. Stimulation may also be used to affect motility. In one variation, the device is designed to facilitate or expedite mixing or breaking down of food matter or liquids in the stomach. In another variation, the device is designed to control, facilitate or expedite movement of food matter or liquids through the stomach and into the small intestine. In another variation, the device is designed to stimulate the stomach to delay passage of food from the stomach and into the small intestine.

[0014] The device of an embodiment of the present invention may reside in part or in whole within the patient's stomach. A device may include: a lead including at least one stimulating electrode in electrical contact with the stomach wall when implanted. It may also include an electronics unit containing the electronic circuitry of the device; or an attachment or coupling system for attaching or coupling a device or lead to the stomach.

[0015] The device of the present invention may be deployed from an abdominal approach (e.g., using open or laparoscopic surgery) or an endoscopic approach (through the esophagus), or a combination of approaches.

[0016] In one embodiment the device comprises an anchor that engages the wall on one side of an organ. The anchor may be a disc, a plate, a stop, or other attachment device. The device further comprises an elongate portion extending through the organ wall wherein the elongate portion comprises a tapered portion tapering from an distal location with respect to the anchor towards a proximal location with respect to the anchor.

[0017] According to one variation, the anchor is positioned on the outside of the stomach wall when deployed. When deployed, the tapered portion of the elongate portion is configured to extend at least in part into the stomach wall from within the stomach and to permit the stomach wall to thicken as it contracts while generally maintaining the anchor in an engaging relationship with the outside of the stomach wall. During stomach contractile behavior, the stomach muscle contracts about the circumference of the tapered portion of the anchor which acts to hold the anchor in place. The contraction force vector on the tapered portion tends to pull the anchor in towards the outer wall of the stomach. As the stomach wall

thickens it expands towards the wider portion of the taper and the anchor is held in place with gradually greater force as the stomach expands and the axial component of the contraction force increases.

[0018] A lead in accordance with the invention comprises the anchor and tapered member as described herein with an electrode or electrodes located thereon where the anchor and tapered member assist in maintaining electrical contact of the electrode(s) with the stomach wall. In pulling the engaging portion of the anchor towards the outer wall of the stomach as the stomach contracts, the anchor and tapered member accordingly act to reduce movement of the lead with respect to the stomach wall and thus to maintain electrode contact with the stomach wall.

[0019] According to one embodiment a device and method for laparoscopically implanting the device is provided. Such laparoscopically implantable device may include a subcutaneously implanted pulse generator coupled to a lead implanted through the stomach wall.

[0020] According to one embodiment, the stimulation device is constructed of size and shape such that it can be deployed through the mouth and esophagus with the aid of an endoscope. The device components may also be constructed of materials that allow it to withstand and function in the highly acidic environment of the stomach for two or more years.

[0021] In addition to the device being capable of stimulating the stomach wall, the device may also include diagnostic elements such as e.g., sensors for sensing various parameters of the stomach. The sensors may be mounted on the electronics unit, an attachment mechanism, the lead, or otherwise, for example, in an independently attached device. The stimulation device may include a mechanical sensor that senses, for example, stomach wall contractions. Alternatively, electrical sensors may detect changes in impedance due to changes in wall thickness from smooth muscle contractions. Other examples of such sensors may include, for example, pH sensors, impedance sensors, pressure sensors and temperature measuring devices. The stimulation device may be programmed to deliver stimulation in response to sensing stomach parameters. For example, a sensor may be used to determine when food has been ingested. When the sensor senses information indicating food has been ingested, the stimulation device may be instructed to deliver stimulation pulses to stimulate gastric motility, to slow the emptying of the stomach, or to provide a sensation of fullness or satiety.

The device may also be user controlled, where the recipient of the device is able to externally activate the device, for example by using an external unit which delivers a control signal via telemetry. Pressure sensors may be used to sense motility patterns, e.g. presence, strength or frequency of contractions. Mean pressure shifts may be observed to identify fundal contractility. The stimulation device may also use sensed parameters to program or reprogram the device stimulation program. For example, measuring impedance changes through a circuit coupled to the electrodes (e.g., delivering a constant current or voltage across the electrodes to determine impedance) or determining the contractile behavior of the stomach using a strain gauge (or similar sensor such as a piezo-electric sensor) in response to stimulation pulses, the effectiveness of the stimulation pulses may be monitored and adjusted to provide optimal response. Examples of use of such sensors are described, for example in copending U.S. Patent Application No.10/950,345 filed September 23, 2004, which is incorporated in its entirety herein by reference.

[0022] According to another aspect of the invention the device may be programmed to randomly or pseudorandomly select or vary one or more stimulation parameters, for example, to reduce adaptation or desensitization of a digestive organ to stimulation, and especially stimulation at non-physiologic rates.

[0023] In accordance with one variation of the invention an electrical stimulator is provided for stimulating a digestive organ where a stimulating electrode and a return electrode are a sufficient distance apart to reduce shunting. In accordance with another variation of the invention, a return electrode having a sufficiently large area and a sufficiently low impedance so that stimulation is effective when positioned adjacent higher impedance tissue such as the mucosa of the stomach. In accordance with another variation of the invention a stimulator is provided with electrodes that may be positioned in close enough proximity to avoid unwanted stimulation of adjacent tissue.

[0024] One aspect of the present invention provides a pseudounipolar stimulation device and method. Pseudounipolar electrodes in accordance with the invention are electrodes that comprise a stimulation electrode and a larger area return electrode that are used in a relatively close proximity, e.g. in near field stimulation. Accordingly, current flow can be limited to a desired region, while reducing shunting and resulting suboptimal energy consumption typical of bipolar electrode pairs in some tissue stimulation applications. Thus, pseudounipolar electrodes allow for improved control of current flow and energy consumption.

[0025] A variation of the invention provides a lead for stimulating a digestive organ. Another aspect of the invention provides a device and method for electrically stimulating a digestive organ. Electrical stimulation is generally defined herein to mean any application of an electrical signal or of an electromagnetic field to tissue of the digestive organ for a therapeutic purpose. While the device system and method may be used with any digestive tract organ and/or gastrointestinal tract organ, it is described with particular reference to use in a stomach.

[0026] In one variation, stimulation is applied to the stomach, for example, to treat digestive disorders or conditions, nausea, obesity or pain symptoms. The stimulation may affect the smooth muscle contractions and/or nerves associated with the stomach. Stimulation may also be used to affect motility. In one variation, the device is designed to facilitate or expedite mixing or breaking down of food matter or liquids in the stomach. In another variation, the device is designed to control, facilitate or expedite movement of food matter or liquids through the stomach and into the small intestine. In another variation, the device is designed to stimulate the stomach to delay passage of food from the stomach and into the small intestine.

[0027] The device of an embodiment of the present invention may reside in part or in whole within the patient's stomach. A device may include: a lead including at least one stimulating electrode in electrical contact with the stomach wall when implanted. It may also include an electronics unit containing the electronic circuitry of the device; or an attachment or coupling system for attaching or coupling a device or lead to the stomach.

[0028] The device of the present invention may be deployed from an abdominal approach (e.g., using open or laparoscopic surgery) or an endoscopic approach (through the esophagus), or a combination of approaches.

[0029] A device in accordance with one aspect of the invention includes: a first stimulating electrode in electrical contact with the stomach wall and having a first surface area, and a second return electrode within the vicinity of the first electrode and having a second surface area significantly larger than the surface area of the first electrode. The device may further comprise a retention device and/or anchor configured to couple the first electrode to the wall or tissue of the organ. The retention device or anchor may also couple the second electrode to the organ, or a second device may couple the second electrode to the organ in the vicinity of the first electrode. The device may further comprise an attachment device configured to

attach the electronics housing to an organ wall. One or more of the first or second electrodes may also be located on an electronics unit housing coupled to the organ.

[0030] The device if used in the stomach comprises components are constructed of materials that allow it to withstand and function in the highly acidic environment of the stomach for two or more years.

[0031] In addition to the device being capable of stimulating the digestive organ, the electrodes of the device may also be used for diagnostic purposes. For example, the electrodes may be used to sense and observe electrical activity in the digestive organ. Such sensing may be used over time to identify patterns, diagnose diseases and evaluate effectiveness of various treatment protocols. For example irregular or lack of EGG (electrogastrogram) activity may be sensed. Stimulation may be provided in response to sensed EGG activity or lack of activity.

[0032] Various aspects of the invention are further described in the following detailed description and in the claims herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] Figure 1A is a schematic, partial cross section side view of a stimulator in accordance with the invention, implanted in a stomach.

[0034] Figures 1B-1D illustrate a method for deploying the lead of Figure 1A.

[0035] Figure 2 is a schematic, partial cross section side view of a stimulator in accordance with the invention, implanted in a stomach.

[0036] Figure 3 is a schematic, partial cross section side view of a stimulator in accordance with the invention, implanted in a stomach.

[0037] Figure 4 is a schematic side view of a stimulator in accordance with the invention, implanted in a stomach.

[0038] Figures 5A-5C are perspective views of a stimulator in accordance with the invention, implanted in a stomach.

[0039] Figure 6 is a schematic view of a stimulator being endoscopically implanted in a stomach.

DETAILED DESCRIPTION OF THE INVENTION

[0040] Referring to Figure 1A, a laparoscopically implantable stimulator 100 is illustrated implanted in a subject. The stimulator 100 includes a lead 110 (shown implanted in a stomach wall 10) coupled to stimulation electronic circuitry 120, (in this particular illustration, a subcutaneously implanted pulse generator). The lead 110 comprises a retaining portion 119 including an elongate portion 111 coupled to an expandable anchor 114 where the expandable anchor 114 engages the outside 11 of the stomach wall 10 and the elongate portion 111 extends through the stomach wall 10 and into the stomach. The lead 110 further comprises a lead wire 130 extending from the expandable anchor 114 to a connector 140 for connecting to the electronic circuitry 120 of the pulse generator.

[0041] The elongate portion 111 of the lead 110 includes a tapered portion 112 that tapers from an inward location 115 where the circumference of the tapered portion 112 is wider in a direction towards the outside of the stomach, to an outward location 116 where the circumference of the tapered portion 112 is narrower. When the lead 110 is deployed, the tapered portion 112 extends at least in part into the stomach wall. An electrode 113 is located on the elongate anchor 114 so that when the lead is implanted, the electrode 113 is located between the serosa 15 and mucosa 17 in one or more of the muscle layers 16a-c or submucosa 16d. A return electrode 117 is located on the elongate portion 111 within the stomach 10 (alternatively within the stomach wall 10). Return electrodes may be positioned in other locations. For example, a return electrode 118 may be located on the lead wire 130. A return electrode 119 may also be located on expandable anchor 114 (e.g., the outer surface of the anchor 114).

[0042] The expandable anchor 114 forms a plate that engages the outside 11 of the stomach wall 10 to prevent the lead from advancing further into the stomach and to maintain the relative position of the electrode 113 within the stomach wall. The expandable anchor 114 may alternatively or in addition include anchoring features such as, e.g., holes to receive sutures. The lead wire 130 includes some slack 130a to allow for movement of the patient, e.g. movement of the stomach during contractions or otherwise.

[0043] The tapered portion 112 of the elongate portion 111 operates to hold the electrode in place in the muscle layer during the stomach wall contraction. The contraction forces of the muscle layer translate into forces that hold the lead in the stomach. At the same time the

forces of contraction draw the tapered lead in towards the inside of the stomach, the plate or expandable anchor 114 prevents movement of the lead further into the stomach.

[0044] Thus, the tapered portion 112 of the elongate member 111 acts to reduce movement of the lead 110 with respect to the stomach wall 10. The tapered configuration of the elongate portion 111 further permits the stomach wall to thicken while the lead 110 is held in place with gradually greater force. The tapered portion 112 and expandable anchor 114 accordingly assist in maintaining electrical contact of the electrode with the stomach wall by reducing movement of the anchor with respect to the stomach wall.

[0045] The lead 110 or a portion of the lead 110 (including, e.g. the tapered portion 112) may be constructed of a flexible or rigid material. According to one variation, a soft elastic material is used. When the stomach contracts the soft elastic material, the shape may change. Examples of such materials include, a fluoropolymer such as PTFE (polytetrafluoroethylene) or PVTF (polyvinylidene fluoride).

[0046] The lead 110 also includes a guidewire opening 150 and through hole 151 for guiding the lead 110 during deployment.

[0047] Figures 1B-1D illustrate deployment of the lead 110 using a laparoscopic system and method. As illustrated in Figure 1B, the stomach 10 is punctured with a hollow needle 155 from the outside of the stomach into the stomach. A guidewire 160 is positioned through the needle 155 and into the stomach.

[0048] As illustrated in Figure 1C, the needle 155 is removed leaving guidewire 160 in place extending through the abdomen into the stomach at a lead deployment site 20. A lead 110 with an expandable anchor 114 folded in a sheath 170 (Figure 1D) is placed over the guide wire 160 through the guidewire lumen 150 and through hole 151 in the elongate portion 111 of the lead 110. The lead 110 is pushed over the guidewire 160 into place through the stomach wall 10 with the expandable anchor 114 adjacent the outside 11 of the stomach 10 at the deployment site 20. The sheath 170 is torn off the expandable anchor 114 and remaining lead 110 to allow the expandable anchor 114 to expand adjacent the outside 11 of the stomach wall 10. The expandable anchor 114 may then be finally adjusted to be in a position flush against the outer wall 11. The expandable anchor 114 may be sutured to the outside of the stomach wall through suture holes (not shown) provided in the expandable member.

[0049] A plurality of such leads may be each separately placed according to this procedure and then may be connected to the pulse generator. Also a plurality of leads may be attached to a single lead wire connector and placed in series.

[0050] A sensor may be included at one or more locations on the lead 110 or housing of the electronic circuitry. A sensor 131 is positioned on the expandable anchor 114 and may include a motion sensor or contraction sensor that senses movement or contraction of the stomach. For example, a piezoelectric sensor or strain gauge may be used to sense contractions. A sensor 132 such as a temperature or other sensor is located on the lead 110 within the stomach to determine when food has been ingested and/or to identify the composition of materials within the stomach. Examples of the use of such sensors are described in copending U.S. Patent Application No.10/950,345, filed September 23, 2004, and entitled "Responsive Gastric Stimulator," which is incorporated herein by reference.

[0051] A number of variations are contemplated herein. For example, the electronic circuitry may be attached to the stomach wall in a housing or may include an external device in communication with electronic circuitry implanted in the patient. The return electrode or second electrode of a bipolar pair of stimulation electrodes may be located on the expandable member, along the lead inside or outside of the stomach or within the stomach wall. The return electrode may also be included in a separately implanted lead similar to lead 110. The return electrode may also be located on the electronics housing. The expandable member may alternatively comprise an anchor or attachment device that attaches to any portion of the stomach wall. The device may also be implanted in other digestive organs or contractile organs with cavities.

[0052] Referring to Figure 2, a stimulator 200 in accordance with the invention is illustrated attached to a stomach wall 10. The stimulator 200 comprises a housing 220 containing electronic circuitry 225 and attached with anchor 230 to the stomach wall 10. The anchor 230 comprises an elongate member 231 having an expandable distal portion 232. The expandable distal portion 232 may be deployed from the inside to the outside of the stomach wall where the expandable distal portion 232 is expanded to engage the outer surface 11 of the stomach wall 10. The elongate member 231 extends through the stomach wall between the expandable distal portion and the housing containing the electronic circuitry 225 to attach anchor 230 to the housing 220. An example of the deployment of an expandable member such as the expandable distal portion 232 is described, for example, in U.S. Patent No.

6,535,764 incorporated herein by reference. The expandable distal portion may comprise, for example, a shape memory alloy, a spring member, or an inflatable member. The electronic circuitry is sealed in the housing 220. The electronic circuitry 225 provides an electrical signal applied through electrodes to the stomach wall, and telemetry communication with an external unit such as a programmer, reader, recorder or controller. The outer shell of the housing 220 is constructed of an acid corrosion resistant material such as a suitable inert polymer that is stable in acidic environments, or an acid corrosion resistant metal such as Platinum, Gold, Tantalum, Titanium, or suitable alloys thereof.

[0053] The stimulator 200 further comprises a lead 235 in accordance with the invention. The lead 235 is coupled to the electronic circuitry 225 of the housing 220 with a flexible lead wire 240. The lead 235 extends out of the housing 220 and is positioned through the stomach wall 10 with at least one electrode in contact with tissue of the stomach.

[0054] The lead 235 comprises a retaining portion 250 including an elongate portion 252 that when deployed, extends through the stomach wall 10. The elongate portion 252 comprises a tapered portion 253 that when deployed, extends at least in part, through the stomach wall 10. The retaining portion 250 further comprises an expandable distal anchor portion 256 that may be deployed from the inside the stomach to the outside of the stomach wall in a manner similar to the deployment of the expandable distal portion 232. The expandable distal anchor portion 256 is expanded at the outside surface 11 of the stomach and is configured to engage the outer surface 11 of the stomach wall 10. The expandable distal anchor portion 256 acts as a stop to prevent the retaining portion 250 from pulling out and into the stomach. The elongate portion 252 extends at least in part through the stomach wall 10 and between the expandable distal anchor portion 256 and the housing 220.

[0055] The tapered portion 253 of the elongate portion 252 comprises a narrower portion 254 located outwardly towards the outside of the stomach with respect to a wider portion 255 which is more inward. The tapered portion 253 tapers from the wider portion 255 outwardly towards the narrower portion 254. The retaining portion 250 further comprises a first electrode 251a and a second electrode 251b, each electrode formed of a corrosion resistant metal conductor such as Platinum, Gold, Tantalum, Titanium or suitable alloys thereof. The first electrode 251a comprises a small ring electrode positioned on the narrower portion 254 and in electrical contact with the stomach wall 10. The second electrode 251b is located proximally of the first electrode 251a near the wider portion 255 of the elongate member 253.

The second electrode 251b has a significantly greater surface area than the first electrode 251a thus focusing the current density adjacent the first electrode 251a. The electrodes 251a, 251b are coupled to conductors extending through flexible lead wire 240, which are coupled to the electronic circuitry 225.

[0056] The tapered portion 253 of the elongate member 252 acts to reduce movement of the retaining portion 250 with respect to the stomach wall 10 in a manner similar to that described with reference to retaining portion 119 of Figure 1A. A sensor 257 may also be located on or adjacent the elongate portion 252 or other portion of the retaining portion 250. A sensor 258 may be located on a portion of the anchor adjacent the stomach wall, such as e.g. on the expandable distal portion 256. For example, sensor 257 or sensor 258 may comprise a temperature sensor or contraction sensor (such as a piezo-electric element or strain gauge), or other sensor indicating a condition relating to the stomach. Sensors 257, 258 may be coupled through a conductor extending through the lead wire 240 to the electronic circuitry 225 in the housing 220.

[0057] The lead 235 or a portion of the lead 235 (including, e.g. the tapered portion 253) may be constructed of a flexible or rigid material. According to one variation, a soft elastic material is used. When the stomach contracts the soft elastic material, the shape may change. Examples of such materials include, a fluoropolymer such as PTFE (polytetrafluoroethylene) or PVTF (polyvinylidene fluoride).

[0058] The circuitry 225 comprises, a microprocessor or controller for controlling the operations of the electronic circuitry 225, an internal clock, and device configured to power the various components of the circuit 225. The controller controls electrical stimulation delivered to stimulating electrodes 251a, 251b in accordance with programmed parameters.

[0059] Figure 3 illustrates a stimulator 360 in accordance with the invention attached to a stomach wall 10. The stimulator 360 comprises a housing 370 containing electronic circuitry 225 described above with reference to Figure 2. The housing 370 is constructed in a similar manner as housing 220 and is attached with anchor 361 to the stomach wall in a similar manner as the housing 220 is attached as described with respect to Figure 2.

[0060] The stimulator 360 further comprises a lead 375 in accordance with the invention. The lead 375 is coupled to the electronic circuitry 225 of the housing 370 with a flexible lead wire 380. The lead 375 extends out of the housing 370 and is positioned through the stomach wall 10 with a bipolar electrode pair 391a, 391b in contact with tissue of the stomach.

[0061] The lead 375 comprises a retaining portion 385 including an elongate portion 392 that when deployed, extends through the stomach wall 10. The elongate portion 392 comprises a tapered portion 393 that when deployed and when the stomach is contracting, extends at least in part, through the stomach wall 10. The retaining portion 385 further comprises an expandable distal anchor 396 that may be deployed from the inside the stomach to the outside of the stomach wall in a manner similar to the deployment of the expandable distal anchor 256 as described with respect to Figure 2. The expandable distal anchor 396 is expanded at the outside surface 11 of the stomach and is configured to engage the outer surface 11 of the stomach wall 10. The expandable distal anchor 396 acts as a stop to prevent the retaining portion 385 from pulling out and into the stomach. The elongate portion 392 extends at least in part through the stomach wall 10 and between the expandable distal anchor 396 and the housing 370. The tapered portion 393 of the elongate portion 392 comprises a narrower portion 394 located outwardly towards the outside of the stomach with respect to a wider portion 395 which is more inward. The tapered portion 393 tapers from the wider portion 395 outwardly towards the narrower portion 394. The retaining portion 385 further comprises a pair of bipolar electrodes, 391a, 391b, each electrode formed of a corrosion resistant metal conductor such as Platinum, Gold, Tantalum, Titanium, or suitable alloys thereof. The electrode pair 391a, 391b is positioned on the narrower portion 394 and in electrical contact with the stomach wall 10. The electrodes 391a, 391b are coupled to conductors extending through flexible lead wire 380, which are coupled to the electronic circuitry 225. The lead 375 may be constructed of similar materials as lead 253 as described herein.

[0062] The tapered portion 393 of the elongate member 392 acts to reduce movement of the retaining portion 385 with respect to the stomach wall 10 in a manner similar to that of retaining portion 119 described herein with reference to Figure 1.

[0063] A sensor 397 may also be located on or adjacent the elongate portion 392 or other portion of the anchor 390. A sensor 398 may be located on a portion of the anchor adjacent the stomach wall, such as e.g. on the expandable distal portion 396. For example, sensor 397 or sensor 398 may comprise a temperature sensor or contraction sensor (such as a piezo-electric element or strain gauge), or other sensor indicating a condition relating to the stomach. Sensors 397, 398 may be coupled through a conductor extending through the lead wire 380 to the electronic circuitry 225 in the housing 370.

[0064] Memory devices located in the electronic circuitry or implantable pulse generator (or alternatively in an external device in communication with the electronic circuitry) contain the program instructions for the controller and any other permanently stored information that allows the controller to operate. The memory device may also contain programmable memory. A telemetry coil or other communication device that communicates with an external control or programming device may also be provided. Thus information may be downloaded or uploaded from or to an external device. The electronic circuit 225 or pulse generator may also be coupled to one or more sensors.

[0065] The stimulation modes and parameters can either be set using the external programmer, or they may be set in response to sensory feedback.

[0066] According to one aspect of the invention, a device is provided that is programmed to randomly (or pseudorandomly) select or vary one or more stimulation parameters, and to deliver the stimulation to a digestive organ according to the selected parameters. In accordance with one aspect, stimulation is randomly (or pseudorandomly) selected or varied to reduce adaptation or desensitization of a digestive organ to stimulation, and especially to stimulation at non-physiologic rates. The programmed device may randomly (or pseudorandomly) select or generate parameters from within a window of acceptable parameters or a randomization window. Such parameters may include but are not limited to, e.g., pulse width, pulse repetition rate, burst frequency, burst repetition rate, pulses per burst. The programmed device may also randomly (or pseudorandomly) select or vary pulse amplitude, pulse shape and burst envelope within a window or according to selection criteria. The programmed device may randomly (or pseudorandomly) select or vary any one or more of these or other parameters prior to or during stimulation. The programmed device may also randomly (or pseudorandomly) select or vary stimulation from pulse to pulse or burst to burst. The programmed device may operate to periodically change parameters or may do so in response to sensing or receiving feedback that adaptation or desensitization is occurring, or that the stimulation is otherwise losing its effectiveness. According to one aspect of the invention, for example, the device may monitor stimulation response over time using a contraction monitoring device such as a strain gauge or other contraction sensor. If the device detects a sub optimal stimulation response, the device may then randomly or pseudorandomly select the next parameter(s) or sets of parameters. An example of such stimulation is described in co-pending U.S. Patent Application No. 11/219,004, filed on September 1, 2005, and entitled "Randomized Stimulation of A Gastrointestinal Organ."

[0067] The electronic circuitry 225 or pulse generator may communicate with an external device that may be capable of receiving, displaying, or analyzing data from the electronic circuitry and also may be capable of programming, controlling or other communications with the electronic circuitry 225 or pulse generator. The electronic circuitry 225 may also comprise a passive device that may be powered and controlled by an external device.

[0068] A lead as described herein is also set forth in copending U.S. Patent Application No. 11/249,661, filed on October 12, 2005, and entitled "Digestive Organ Retention Device," which is incorporated herein by reference.

[0069] Referring to Figure 4, a stimulator 10a in accordance with the invention is illustrated attached to a stomach wall 100a. The stimulator 10a comprises a housing 20a containing electronic circuitry 25. The stimulator 10a is attached with anchor 30 to the stomach wall 100a. The anchor 30 comprises an elongate member 31 having an expandable distal anchor portion 32. The expandable distal anchor portion 32 may be deployed from the inside to the outside of the stomach wall where the expandable distal anchor portion 32 is expanded to engage to the outer surface 110a of the stomach wall 100a. The elongate member 31 extends through the stomach wall between the expandable distal portion and the housing containing the electronic circuitry 25. An example of the deployment of an expandable member such as the expandable distal portion 32 is described, for example, in U.S. Patent No. 6,535,764. The expandable distal anchor portion 32 may comprise, for example, a shape memory alloy, a spring member, or an inflatable member. The electronic circuitry is sealed in the housing 20.

[0070] The electronic circuitry 25 provides sensing, stimulating electronic pulses through electrodes to the stomach wall, and telemetry communication with an external unit such as a programmer, reader, recorder or controller. The outer shell of the housing is constructed of an acid corrosion resistant material such as a suitable inert polymer or an acid corrosion resistant metal such as Platinum, Gold, Tantalum, Titanium, or suitable alloys thereof.

[0071] The stimulator 10a further comprises a lead 35 in accordance with the invention. The lead 35 is coupled to the electronic circuitry 25 of the housing 20 with a flexible lead wire 40. The lead 35 extends out of the housing 20a and is positioned through the stomach wall with at least one electrode in contact with the tissue of the stomach.

[0072] The lead 35 comprises a retaining portion 50 including an elongate portion 52 that when deployed extends through the stomach wall 100a. The elongate portion comprises a

tapered portion 53 that when deployed extends at least in part through the stomach wall 100a. The retaining portion 50 further comprises an expandable distal anchor portion 56 that may be deployed from the inside to the outside of the stomach wall in a manner similar to expandable distal portion 32. The expandable distal anchor portion 56 is expanded at the outside surface of the stomach and is configured to engage the outer surface 110a of the stomach wall. The expandable distal anchor portion acts as a stop to prevent the retaining portion 50 from pulling out and into the stomach. The elongate portion 52 extends at least in part through the stomach wall 100a and between the expandable distal anchor portion 56 and the housing 20a.

[0073] The tapered portion 53 of the elongate portion 52 comprises a narrower portion 54 located outwardly towards the outside of the stomach with respect to a wider portion 55 which is more inward. The tapered portion 53 tapers from the wider portion 55 outwardly towards the narrower portion 54. The retaining portion 50 further comprises a first electrode 51a and a second 51b electrode, each electrode formed of a corrosion resistant metal conductor such as Platinum, Gold, Tantalum, Titanium or suitable alloys thereof. The first electrode 51a comprises a small ring electrode positioned on the narrower portion 54 and in electrical contact with the stomach wall 100a. The electrode 51a may also be a partial ring of another configuration. The second electrode 51b is located proximally of the first electrode 51b near the wider portion 55 of the elongate member 53. The electrodes 51a, 51b are coupled to conductors extending through flexible lead wire 40 which are coupled to the electronic circuitry 25.

[0074] The second electrode 51b has a much greater surface area than the first electrode 51a thus focusing the current density between the electrodes, with a higher current density at the first electrode 51a. The second electrode 51b is shown positioned adjacent the mucosa of the stomach. The larger surface area of the second electrode 51b also provides a lower impedance, which compensates at least in part for the high impedance of the mucosa.

[0075] In a stimulator according to the invention and in use in a stomach, the second electrode 51b which is larger and more proximal may have a surface area between about 50 to 200 mm². The first electrode which is smaller and more distal may have a surface area between about 2 to 20 mm². The ratio of smaller to larger electrode area according to the invention may be between 1:40 and 2:5.

[0076] The tapered portion 53 of the elongate member 52 of Figure 4 in combination with the expandable anchor portion 56 act to reduce movement of the retaining portion 50 with respect to the stomach wall 100 during stomach contractile behavior. Thus, the retaining portion 50 assists in maintaining electrical contact of the electrode 51a with the stomach wall. The anchor accordingly acts to reduce movement of the anchor and thus to maintain electrode contact with the stomach wall.

[0077] The circuitry 25 comprises, a microprocessor or controller for controlling the operations of the electronic circuitry 25, an internal clock, and device configured to power the various components of the circuit 25. The controller controls electrical stimulation delivered to stimulating electrodes 51, 52 in accordance with programmed parameters.

[0078] Referring to Figures 5A-5C, a stimulator 60 in accordance with the invention is illustrated. The stimulator 60 comprises an anchor 70 and a housing 61. The anchor 70 comprises an elongate member 71 having an expandable distal end 72. The housing 61 includes electronic circuitry 25 for supplying electrically stimulating signals through electrodes 65, 73 to the stomach wall tissue. The housing 61 further includes an opening 62 for receiving the elongate member 71 of the anchor 70 to removably couple the anchor 70 to the housing 60. A notch 76 in the elongate member 71 engages a catch in the opening 62 of the housing 61 to couple the anchor 70 to the housing 61.

[0079] As illustrated in Figure 5B, the anchor 70 is positioned through the stomach wall 100a and the expandable distal end 72 is expanded to anchor the anchor 70 on the stomach wall. The anchor 70 includes an electrode 73 positioned on the elongate member 71 so that when the anchor 70 is deployed, it is in electrical contact with the stomach wall 100a. The anchor 70 further includes an electrical contact that extends from the electrode 73 through the elongate member 71 to an external contact 77 on the elongate member 71 that couples with a contact within the opening 62 in the housing 61 to electrically couple the electrode to electronic circuitry 25 contained within the housing 61.

[0080] The housing 61 further contains a large area electrode 65. Electrode 73 on the anchor 70 and electrode 65 on the housing 61 form an electrode pair. The electrode 73 is a relatively smaller area electrode in comparison to electrode 65. According to one example of the invention in use in a stomach, the electrode 65 which is larger and more proximal may have a surface area between about 50 to 200 mm². The electrode 73 which is smaller and

more distal may have a surface area between about 2 to 20 mm². The ratio of smaller to larger electrode area may be between 1:40 and 2:5.

[0081] The electrodes 65, 73 are formed of a corrosion resistant metal conductor such as Platinum, Gold, Tantalum, Titanium or suitable alloys thereof.

[0082] A tether 79 is secured to the proximal end 78 of the elongate member 71. The tether 79 is used to guide the opening 62 of the housing 61 into place over the elongate member 71 of the anchor 70 which is anchored to the stomach wall 100a (See Figure 5B).

[0083] A sensor 80 for sensing various parameters of the stomach is located on the elongate member 71 of the anchor 70.

[0084] The sensor 80 is coupled through a conductor (not shown) to an electrical contact on the elongate member 73 so that when the housing 61 is coupled to the anchor 70, the sensor is in communication with the electronic circuitry in the housing 61 through an electrical contact in the opening 62 of the housing 61. A variety of different sensors may be used to sense parameters or conditions of the stomach or patient. For example, a sensor may be a mechanical sensor that senses stomach wall contractions. Alternatively, electrical sensors may detect changes in impedance due to changes in wall thickness from smooth muscle contractions. Other examples of such sensors may include, for example, pH sensors, impedance sensors, pressure sensors and temperature measuring devices.

[0085] Figure 6 illustrates the placement of a stimulator in accordance with the invention in the stomach an endoscope of the system of the present invention a flexible endoscope 120a is used to locate an attachment site in the stomach 100a and attach the stimulator device to the stomach wall of a patient. The flexible endoscope 120a is of the type that is typically used by gastroenterologists in accessing the esophagus or stomach. The endoscope allows the physician to visualize while performing procedures on the upper gastrointestinal tract. The flexible endoscope may be, for example, a flexible fiber optic endoscope utilizing optic fibers for imaging or a video endoscope that uses a CCD (charge coupled device) to provide video images. Such endoscopes typically include a fiber optic light guide and a complex objective lens at the distal end to focus the image.

[0086] Memory devices located in the electronic circuitry (or alternatively in an external device in communication with the electronic circuitry) contain the program instructions for the controller and any other permanently stored information that allows the controller to

operate. The memory devices may also contain programmable memory. A telemetry coil or other communication device that communicates with an external control or programming device may also be provided. Thus information may be downloaded or uploaded from or to an external device. The circuit 25 may also be coupled to one or more sensors.

[0087] The stimulation modes and parameters can either be set using the external programmer, or they may be set in response to sensory feedback.

[0088] The electronic circuitry 25 may communicate with an external device that may be capable of receiving, displaying, or analyzing data from the electronic circuitry and also may be capable of programming, controlling or other communications with the electronic circuitry 25. The electronic circuitry 25 may also comprises a passive device that may be powered and controlled by an external device.

[0089] The materials of the attachment devices, stimulators and housings of the present invention are preferably selected for long-term use in the stomach, i.e., two or more years. Suitable materials include the materials described herein.

[0090] While the invention has been described with reference to preferred embodiments and in particular to a gastric stimulator, the present invention contemplates that the attachment devices may be used to attach a number of functional devices to the wall of digestive organs.

[0091] While the invention has been described with reference to certain embodiments, it will be understood that variations and modifications may be made within the scope of the following claims. Such modifications may include substituting elements or components which perform substantially the same function in substantially the same way to achieve substantially the same result that the invention can be practiced with modification within the scope of the following claims.

WHAT IS CLAIMED IS:

1. An implantable system for stimulating a hollow organ having an organ wall and a cavity therein, the system comprising:
a pulse generator positionable outside of the organ; and
an implantable lead having at least one electrode, wherein the lead is connectable with the pulse generator so as to provide stimulation energy to the at least one electrode, and
wherein the lead is configured to be implanted so that a portion of the lead transects the organ wall and protrudes inside the cavity of the hollow organ while at least one of the at least one electrodes is in electrical contact with the organ wall.
2. A system as in claim 1, further comprising at least one sensor disposed on the implantable lead.
3. A system as in claim 2, wherein the at least one sensor is disposed on the portion of the lead that protrudes inside the cavity of the hollow organ.
4. A system as in claim 3, wherein the at least one sensor comprises a temperature sensor.
5. A system as in claim 2, wherein the at least one sensor includes a pH sensor, an impedance sensor, a pressure sensor, a temperature sensor, a mechanical sensor, or any combination of these.
6. A system as in claim 1, wherein the organ wall includes a muscle layer, and wherein electrical contact with the organ wall comprises positioning within the muscle layer of the organ wall.
7. A system as in claim 1, wherein at least one of the at least one electrode is disposed on the portion of the lead that protrudes inside the cavity of the hollow organ.
8. A system as in claim 1, wherein the lead includes an expandable anchor configured to engage an outside surface of the organ wall while the at least one electrode is in electrical contact with the organ wall.

9. A system as in claim 8, wherein the expandable anchor includes at least one hole through which the anchor is capable of being anchored to the organ wall.
10. A system as in claim 1, wherein the implantable lead includes a guidewire lumen configured to receive a guidewire for advancement of the lead over the guidewire.
11. A system as in claim 1, wherein the portion of the lead transecting the organ wall has a tapered shape.
12. A system as in claim 11, wherein the tapered shape tapers from a wider portion near the cavity to a narrower portion near the outside of the organ.
13. A system as in claim 1, wherein the at least one electrode comprises a pair of pseudounipolar electrodes.
14. A system as in claim 13, wherein the pseudounipolar electrodes include a first electrode having a first surface area and a second electrode having a second surface area; wherein the first surface area is about 2 to 20 mm² and wherein the second surface area is about 50 to 200 mm².
15. A system as in claim 13, wherein the pseudounipolar electrodes include a first electrode having a first surface area and a second electrode having a second surface area; wherein the ratio of the first surface area to the second surface area is about 2:5 or less.
16. A system as in claim 13, wherein the ratio of the first surface area to the second surface area is between about 1:40 and about 2:5.
17. An implantable device for attaching to a wall of a hollow organ, the device comprising:
an anchor configured to engage a first surface of the wall of the organ; and
an elongate portion coupled to the anchor and configured to be implanted so that a portion transects the organ wall and protrudes through an opposite surface of the wall of the organ, the elongate portion comprising a tapered portion that tapers from a wider

portion disposed near the opposite surface to a narrower portion near the first surface of the organ.

18. A device as in claim 17, wherein the anchor comprises an expandable member configured to expand from a narrower configuration to a wider configuration.

19. A device as in claim 17, wherein the elongate portion includes at least one electrode.

20. A device as in claim 17, wherein the anchor includes at least one electrode.

21. A device as in claim 17, further comprising at least one electrode, wherein the elongate portion and the anchor in combination are configured to maintain the electrode in electrical contact with the wall of hollow organ while permitting contractile activity of the wall.

22. A device as in claim 17, further comprising at least one sensor.

23. A device as in claim 22, wherein the sensor comprises a contraction sensor configured to sense information corresponding to contraction of the wall.

24. An implantable system for stimulating a hollow organ having an organ wall, the system comprising:

a lead having a pair of pseudounipolar electrodes; and

a pulse generator connectable with the lead so as to provide stimulation energy to at least one of the pair of pseudounipolar electrodes,

wherein the lead is configured to position at least one of the pseudounipolar electrodes in electrical contact with the organ wall.

25. A system as in claim 24, wherein the pair of pseudounipolar electrodes includes a first electrode having a first surface area and a second electrode having a second surface area; wherein the first surface area is about 2 to 20 mm² and wherein the second surface area is about 50 to 200 mm².

26. A system as in claim 24, wherein the pair of pseudounipolar electrodes includes a first electrode having a first surface area and a second electrode having a second

surface area; wherein the ratio of the first surface area to the second surface area is about 2:5 or less.

27. A system as in claim 26, wherein the ratio of the first surface area to the second surface area is between about 1:40 and about 2:5.

28. A system as in claim 24, wherein the lead includes a retention device having at least one of the pseudounipolar electrodes thereon, wherein the retention device is configured to be attached to the wall of the organ so that the at least one of the pair of pseudounipolar electrodes thereon is in contact with the organ.

29. A system as in claim 28, wherein the retention device comprises an expandable distal portion, and an elongate portion coupled to the expandable distal portion wherein the elongate portion is configured to extend at least in part through the wall of the organ, the elongate portion comprising a narrower more distal portion and a wider more proximal portion.

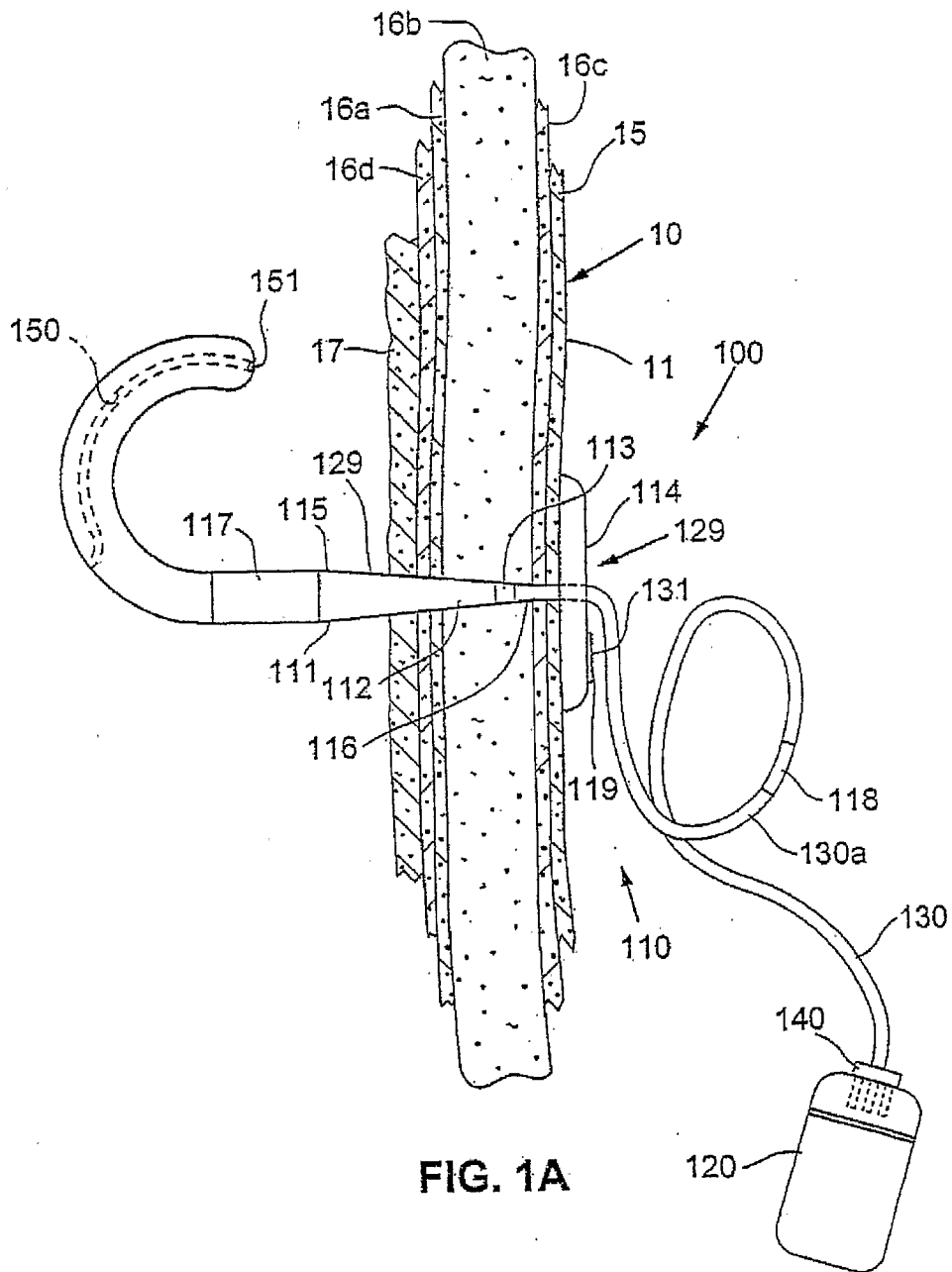


FIG. 1B

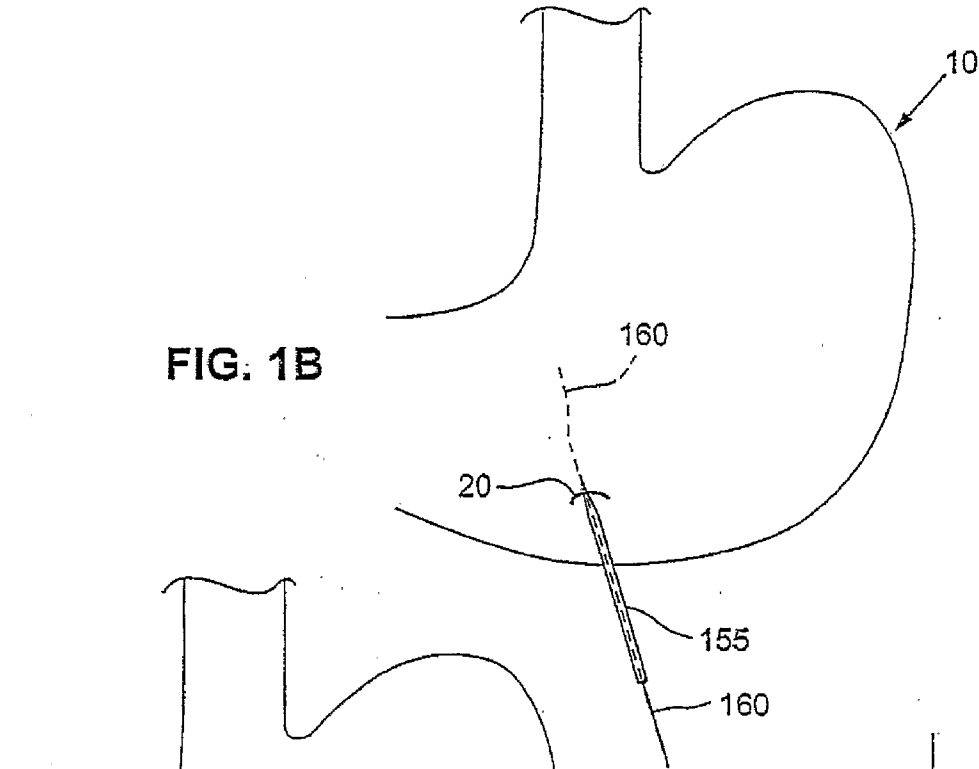


FIG. 1C

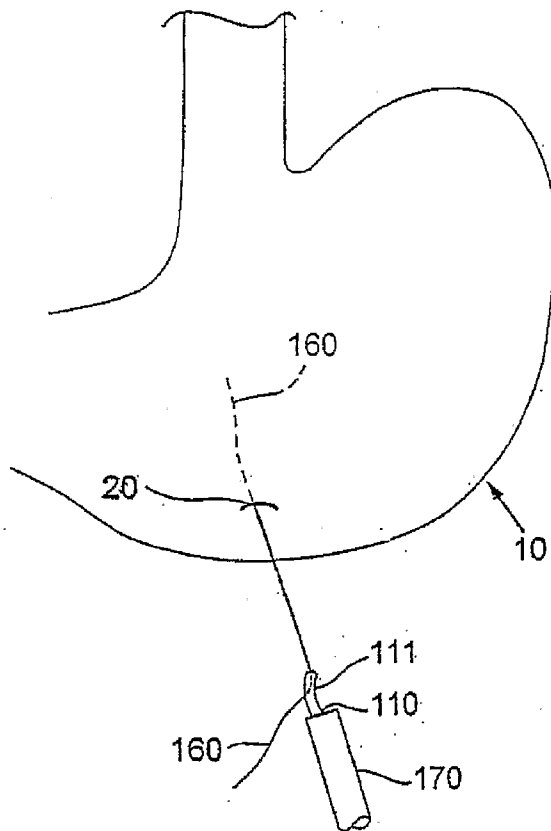
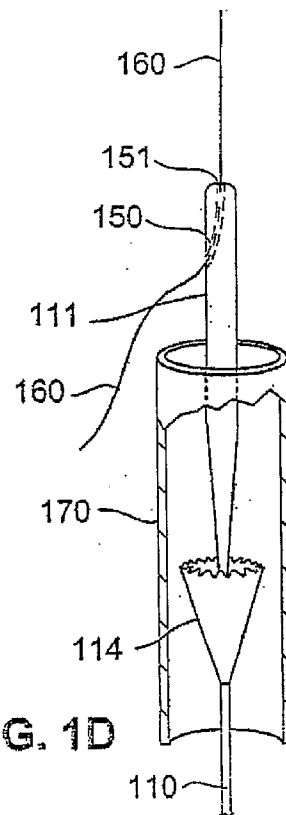


FIG. 1D



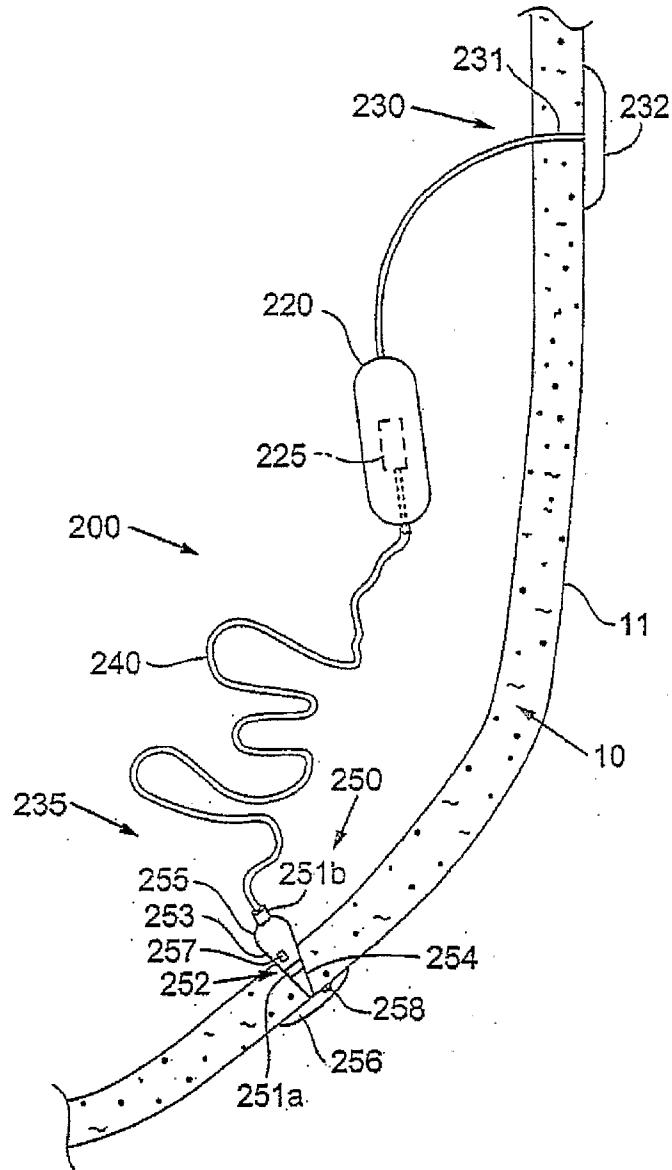


FIG. 2

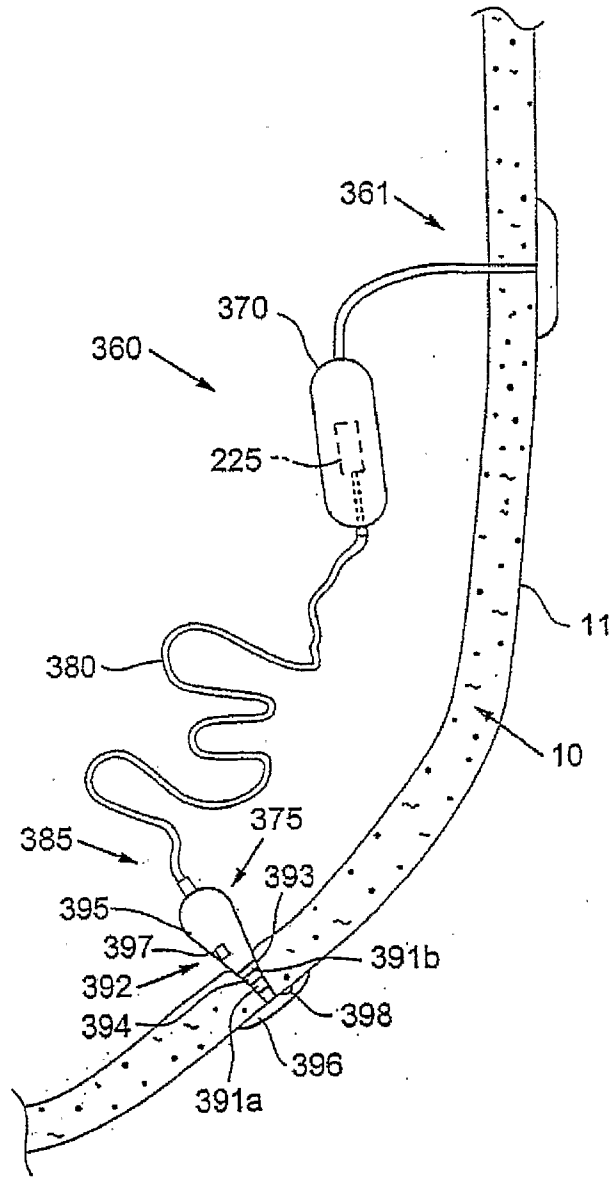


FIG. 3

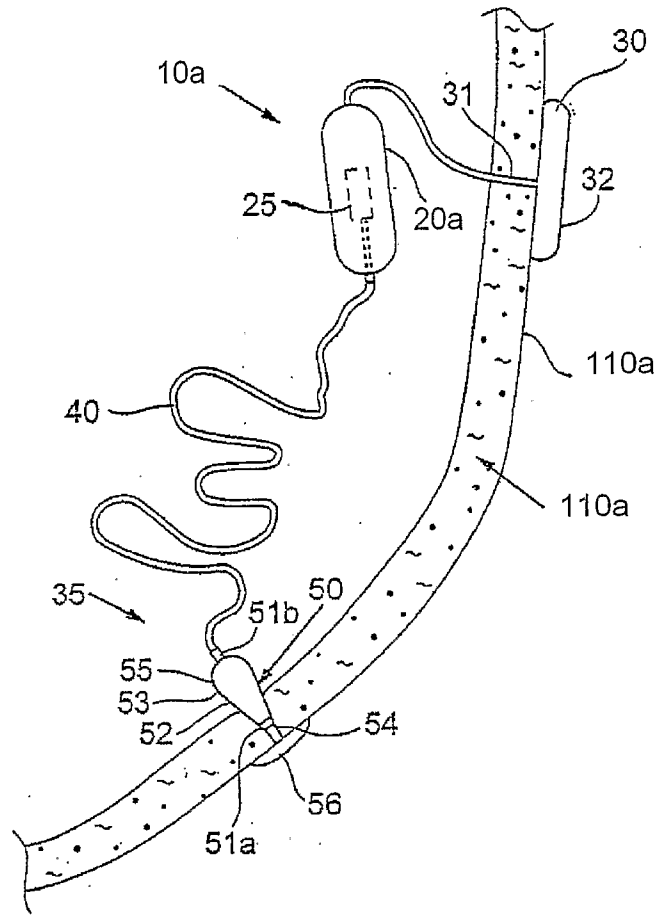
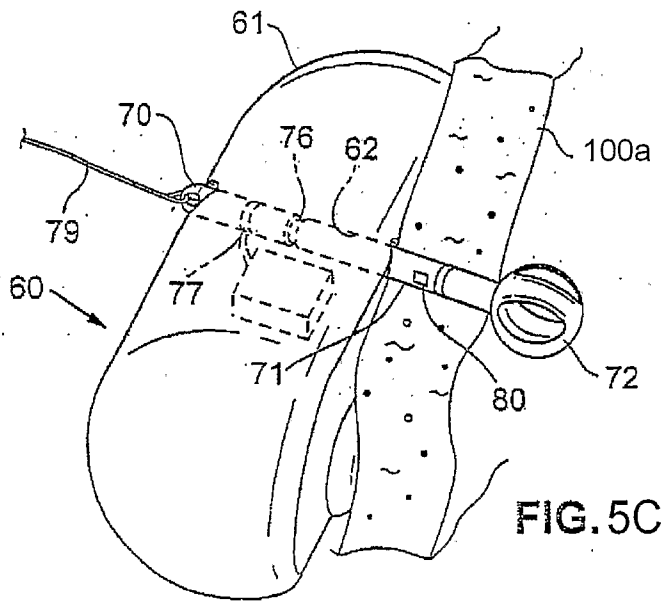
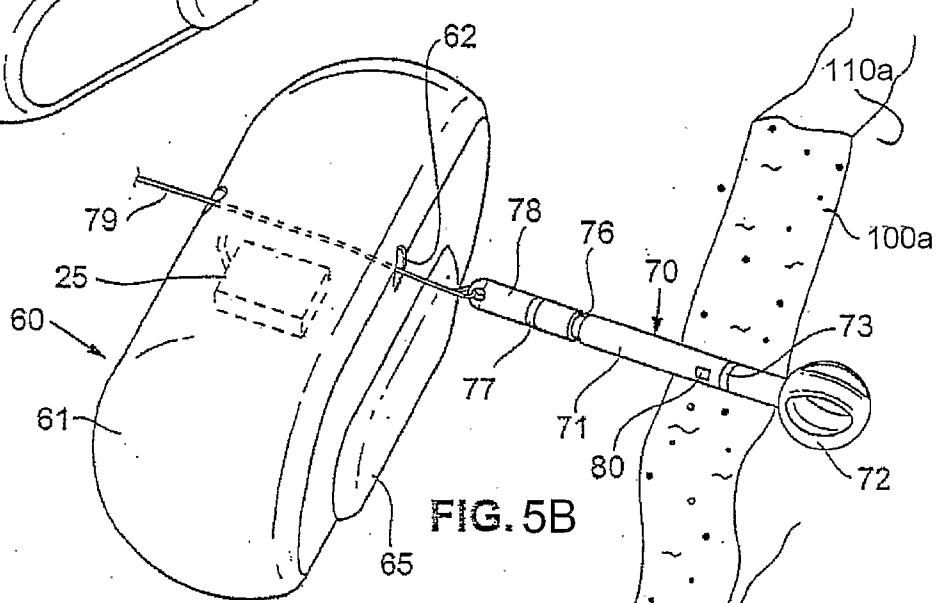
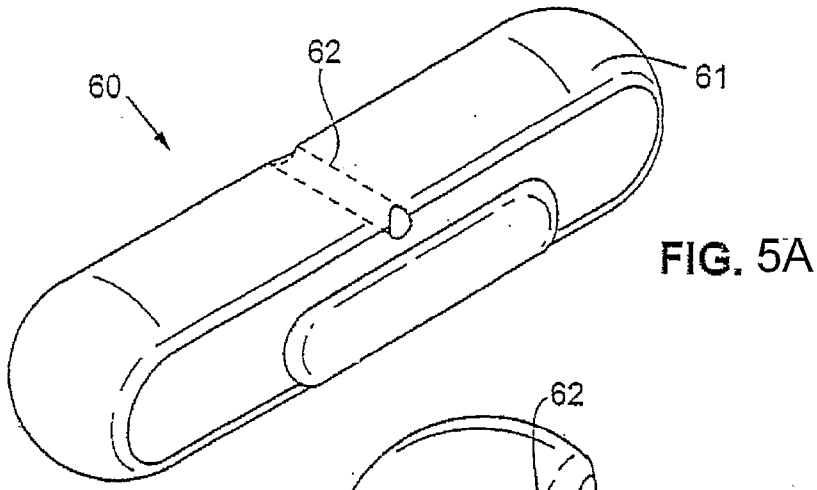


FIG. 4



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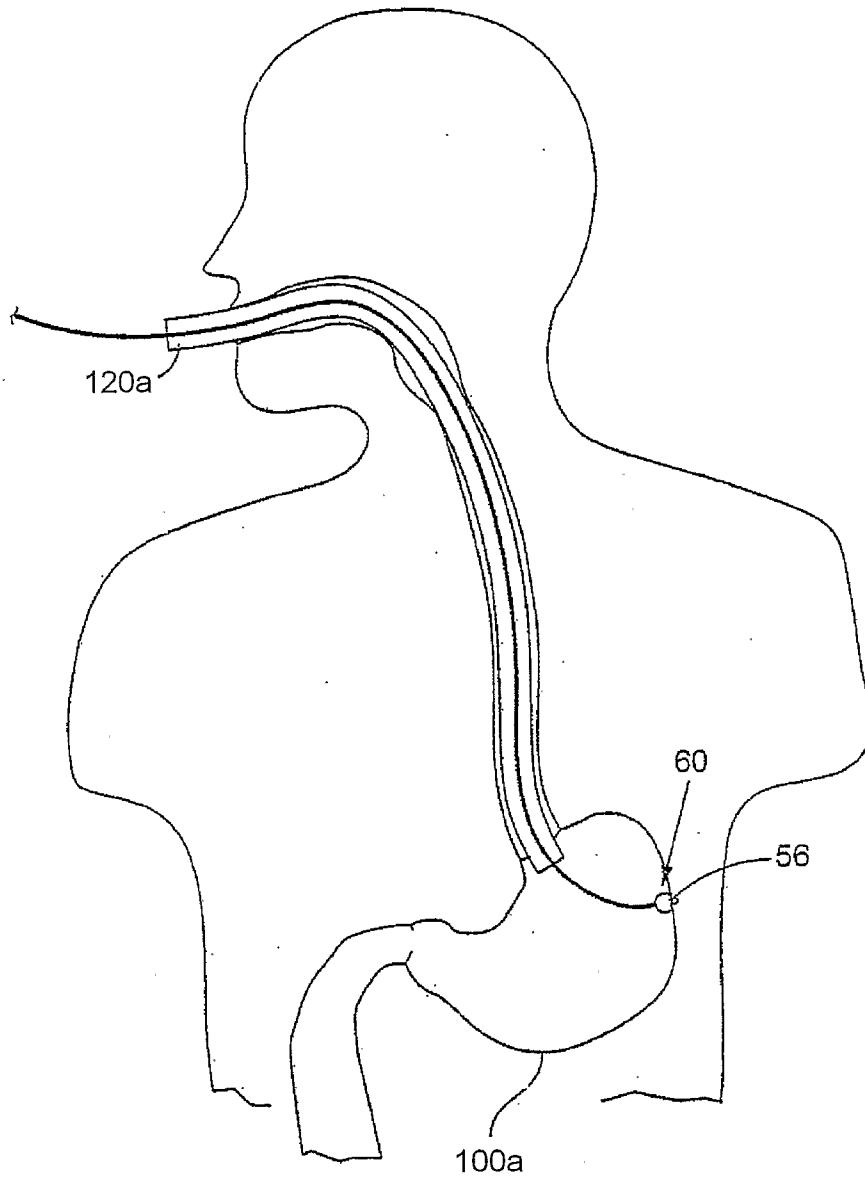


FIG. 6