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FIG 1. A portion of a portion of a human gastro-
intestinal (GI) tract

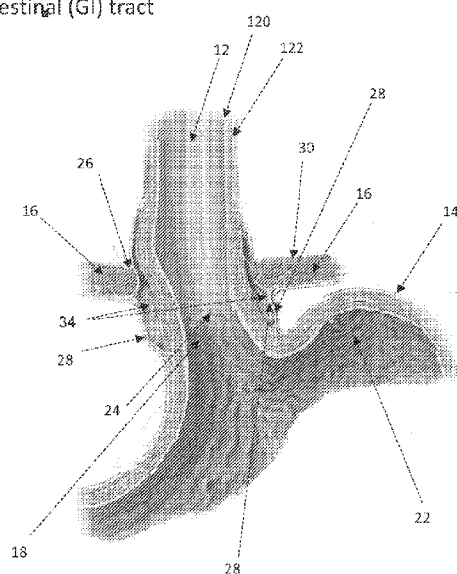


FIG. 1 A

(57) Abstract: Provided herein as a transoral minimally invasive method and a system thereof for the treatment of gastrointestinal diseases and/or obesity, which at least partially encircles a part of the gastrointestinal tract, such as esophagus of the patient by advancing a pre-shape dissector endoluminally, laterally, anteriorly or posteriorly to the subfascial area from outer wall outer wall of the esophagus and introducing the pre-shape dissector sub-fascially in the sub-fascial area, whereby at least one part of the encircled esophagus will be provided with an additional mechanical augmentation.



APPARATUS AND METHOD FOR DEPLOYING MEDICAL DEVICE FOR GASTROINTESTINAL DISEASES

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Application No. 16/910,233, filed October 3, 2019, which is hereby incorporated by reference herein in its entirety.

BACKGROUND

Field

[0002] The present specification relates to surgical apparatuses, systems and procedures used in treatment of gastrointestinal diseases and/or obesity. More specifically, the present specification is related to surgical apparatuses, systems and procedures for controlling, navigating and deploying medical devices to a targeted site.

Description of the Related Art

[0003] Gastrointestinal diseases refer to diseases involving the gastrointestinal tract, namely the esophagus, stomach, small intestine, large intestine and rectum, and the accessory organs of digestion, the liver, gallbladder, and pancreas, including such conditions as gastroesophageal reflux, abdominal pain, constipation, irritable bowel syndrome, hemorrhoids, anal fissures, perianal abscesses, anal fistulas, perianal infections, diverticular diseases, colitis, colon polyps and cancer.

[0004] Gastroesophageal reflux disease (GERD) is the most common gastrointestinal disease of the esophagus. It is a chronic, progressive disorder that presents most typically with heartburn and regurgitation and atypically with chest pain, dysphagia, chronic cough, globus, or sore throat. The mainstay for diagnosis and characterization of the disorder is esophagoduodenoscopy (EGD), high-resolution esophageal manometry, and symptom-associated ambulatory esophageal pH impedance monitoring. Epidemiological data have demonstrated that obesity is an important risk factor for the development of gastroesophageal reflux disease. There is also accumulating data that obesity is associated with complications related to longstanding reflux such as erosive esophagitis, Barrett's Esophagus, and esophageal adenocarcinoma.

[0005] Treatment regimens for GERD have included various dietary and lifestyle modifications (such as avoidance of acidic foods, carbonated beverages, alcohol, and tobacco), as well as pharmaceutical compositions (e.g. anti-secretory drugs, most commonly proton pump inhibitors (PPIs)) and surgery. Numerous surgical procedures for the treatment of GERD are known in the prior art. One surgical approach to GERD treatment is Laparoscopic Fundoplication, which is a minimally invasive procedure done to restore the function of the lower esophageal sphincter (the valve between the esophagus and the stomach) by wrapping the stomach around the esophagus, so that a new “functional valve” between the esophagus and the stomach and prevents reflux of the acid and bile (non-acidic fluid) from the stomach into the esophagus.

[0006] Another approach to the treatment of GERD is gastric bypass surgery, which is a type of weight-loss surgery that involves creating a small pouch from the stomach and connecting the newly created pouch directly to the small intestine, leading to decreased nutrient absorption by the patient and symptom alleviation of GERD. A further approach is the application of magnetic sphincter augmentation, which is designed to augment the lower esophageal sphincter (LES) through magnetomechanical means (such as The Linx™ Reflux Management System (Torax Medical, Shoreview, MN), consisting of magnetic beads that are connected by titanium links that allow the beads to open during a swallow or belch. The force of magnetic attraction exerts forces to strengthen the LES.). Yet another approach is Electrical Stimulation laparoscopically implanting electrodes in the LES (EndoStim LES Stimulation System; EndoStim BV, The Hague, The Netherlands), which automatically delivers tiny electronic pulses from the implanted pulse generator to the weak LES muscle. The pulses stimulate the muscle to function as a healthy LES, opening for swallowing, belching, and other normal behaviors, but remaining closed at other times.

[0007] Besides, several technologies have been developed to offer transoral minimally invasive methods for treatment of GERD. The procedures are typically performed endoscopically under general anesthesia. The Esophyx® device (Endogastric Solutions, Redmond, WA) claims to restore the dynamics of the angle of endoscopically with a greater than 270° internal wrap or fundoplication. The device utilizes a tissue grasping mechanism and proprietary stapling system that is passed over a standard endoscope. In contrast to the Esophyx® device, the MUSE™ system (Medigus, Israel) is

an ultrasonic surgical stapler embedded within a custom endoscope to perform a similar transoral fundoplication

[0008] The procedures outlined above have been limited by various factors. For example, patients undergoing Laparoscopic Fundoplication require hospitalization and a seven to ten-day recovery period. Also, various gastric bypass procedures, in which a portion of the gastro-intestinal tract is surgically excised, have led to under-nourished or malnourished patients, and furthermore such procedures are typically highly invasive and irreversible. Further, the use of magnetic sphincter augmentation has only been explored in small hiatal hernias where a primary crural repair is performed concurrently. Additionally, the Linx™ system, which employs a plurality of titanium beads with magnetic cores, is used to treat GERD. However, the Linx™ system is incompatible with magnetic resonance imaging (MRI).

[0009] As can be seen, there is a need for apparatuses, systems, and methods for the safe, reliable, cost-effective, and minimally invasive treatment of gastrointestinal diseases and/or obesity.

SUMMARY

[0010] The present invention provides systems, apparatus, and methods for the effective and minimally invasive treatment of gastrointestinal diseases (such as gastro-esophageal reflux disease (GERD)) and/or obesity. In an embodiment the invention provides a minimally invasive method to deploy a medical device for treatment of a patient. The device is adjustable (e.g., deformable, bendable or expandable) in at least one dimension to partially encircle one or more tissues or organs targeted for providing additional mechanical augmentation on the encircled portion.

[0011] According to the present invention, a method for deploying a medical device to a target site of a patient is provided, comprising: a) placing an endoscopic device endoluminally to a first location within an esophagus of the patient; b) introducing the flexible, elongated sheath to a second location at a subfascial area outside the esophagus in response to the image captured by the endoscopic device, wherein the sheath has a hollow interior and further comprises: a steerable guiding member moveably disposed within the interior of the sheath and comprising a guided portion and a shapeable portion

adjacent to the distal end of the guided portion, wherein the shapeable portion is steered to deflect from, and return to, a longitudinal axis thereof; and a pre-shape dissector comprising a deformable, elongated body, the pre-shape dissector being located over at least a part of the shapeable portion and deliverable from the guiding member; c) advancing the shapeable portion of the guiding member being deflected from the second location along the subfascial area, whereby the deformable, elongated body of the pre-shape dissector thereover forms a curved portion along the shapeable portion advancing path to at least partially encircle esophagus; and d) the curved portion of the dissector remaining at least partially around the esophagus when the guiding member is retracted, whereby a mechanical augmentation is applied to the esophagus via the curved portion.

[0012] In one embodiment, the flexible, elongated sheath of b) above can be introduced endoluminally to the second location. In another embodiment, the flexible, elongated sheath can further comprise a coupler connecting the sheath to the endoscopic device, the coupler comprising a first opening that allows the endoscopic device to extend therethrough and a second opening that allows the sheath to extend therethrough. Thus, the sheath and the endoscopic device can be deployed at the same time.

[0013] In some embodiments, the flexible, elongated sheath of b) above may be introduced to the second location via different locations of the patient's body. For example, in one embodiment, the sheath can be inserted laterally through a portion of a phrenoesophageal ligament (POL) to approach the second location. In another embodiment, the sheath may be inserted anteriorly through a portion of the phrenoesophageal ligament (POL) to approach the second location. In yet another embodiment, the sheath can be inserted posteriorly through a portion of the phrenoesophageal ligament (POL) to approach the second location.

[0014] In some embodiments, the method can further comprise a step of providing a first magnet at a distal end of the endoscopic device and a second magnet at a distal end of the flexible, elongated sheath. In other embodiments, the distal end of the sheath can be guided to the second location in response to the movement of the endoscopic device when a magnetic field is applied.

[0015] In some embodiments, the first location within the esophagus can be at esophagogastric junction, the esophageal-diaphragmatic junction, or the gastro-diaphragmatic junction.

[0016] In some embodiments, b) above can further comprises: creating an opening between the first location and the second location to advance and retract the flexible, elongated sheath therethrough; and providing at least one inflatable balloon at the distal end of the flexible, elongated sheath, whereby the subfascial area is dissected and supported when the balloon is inflated. In another embodiment, the opening can be created using a needle or a cannula.

[0017] In some embodiments, the shapeable portion of b) above can comprise a shape memory material such as a shape memory alloy including but not limited to an alloy containing both nickel and titanium.

[0018] In some embodiments, the pre-shape dissector can be a coil or spring like member.

[0019] These and other features, aspects, and advantages of the present invention will become better understood with reference to the following drawings, description, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG 1A is a sectional view of a portion of a human gastro-intestinal (GI) tract. FIG. 1B is a cross section of the GI tract of FIG.1A. FIG.1C is an enlarged view of FIG. 1B.

[0021] FIG. 2 is a schematic view of one step of a method of deploying a medical device according to one embodiment hereof, illustrating a “double barrel” shaped endoscope and introducer being introduced endoluminally with respect to esophagus of the patient to a targeted site closed to esophagogastric junction.

[0022] FIGS. 3 is schematic views of one step of a method of deploying a medical device according to one embodiment hereof, illustrating a catheter being advanced outwardly from a distal end of the introducer.

[0023] FIG. 4 is a schematic view of one step of a method of deploying a medical device according to one embodiment, illustrating the distal end of the catheter being introduced to the subfascial area when a balloon area is insufflated.

[0024] FIG. 5 is a schematic view of a distal end of the catheter being placed in the subfascial area shown in FIG. 1C according to one embodiment, illustrating a first magnet at the distal end of the endoscope being manipulated to attract and guide a corresponding second magnet at the distal end of the catheter, thereby advancing the distal end of the catheter within subfascial area.

[0025] FIG. 6 is a schematic view of the distal end of the catheter being advanced in the subfascial area shown in FIG. 1C according to one embodiment, illustrating the distal end of the catheter being guided to move within the subfascial area to encircle the outer wall of esophagus.

[0026] FIG. 7 is a schematic view of one step of a method of deploying a medical device according to one embodiment, illustrating a steerable guidewire being introduced within and extending outwardly from the distal end of the catheter.

[0027] FIG. 8 is a schematic view of one step of a method of deploying a medical device according to one embodiment, illustrating a shapeable portion of the steerable guidewire regaining its shape in the subfascial area to encircle the outer wall of esophagus.

[0028] FIG. 9 is a schematic view of one step of a method of deploying a medical device according to one embodiment, illustrating a pre-shape dissector located over a shapeable portion of the guidewire encircling the outer wall of esophagus along the advancing path of the shapeable portion.

[0029] FIG. 10 is a schematic view of one step of a method of deploying a medical device according to one embodiment, illustrating that a pre-shape dissector remaining around the outer wall of esophagus when the guidewire is retracted.

[0030] FIGS. 11A and 11B are schematic views of one step of a method of deploying a medical device according to another embodiment, illustrating a delivery system being inserted laterally into a patient adjacent or through the patient's diaphragm and through

the POL into a subfascial area to deliver the medical device. FIG. 11 A is a cross section of the GI tract as shown in FIG. 1B. FIG. 11B is a sectional view of a portion of the GI tract as shown in FIG. 1A.

[0031] FIG. 12 is a schematic view of one step of a method of deploying a medical device according to another embodiment, illustrating a delivery system being inserted anteriorly into a subfascial area to deliver the medical device.

[0032] FIG. 13 is a schematic view of one step of a method of deploying a medical device according to another embodiment, illustrating a delivery system being inserted posteriorly into a subfascial area to deliver the medical device.

DETAILED DESCRIPTION

[0033] FIG 1A hereof is a sectional view of a portion of a human gastro-intestinal (GI) tract 10 (hereafter, GI tract 10), such as that disclosed in No. US 8,868,215 B2 and No. US 8,874,216 B2, which are incorporated herein by reference in their entireties, except for any definitions, subject matter disclaimers or disavowals, and except to the extent that the incorporated material is inconsistent with the express disclosure herein, in which case the language in this disclosure controls. FIG. 1B is a cross section of the GI tract 10 of FIG. 1A. FIG. 1C is an enlarged view of a portion of the GI tract 10 of FIG. 1B. The GI tract 10 includes the esophagus 12, the stomach 14, the diaphragm 16, and the cardiac orifice 18. The histology change between esophageal tissue 20 of the esophagus 12 and the gastric tissue 22 of the stomach 14 occurs at esophagogastric junction 24, which is also called the “z-line”. The esophagus 12 passes through an opening of the diaphragm 16 known as the esophageal hiatus 26. Proximally above the esophageal hiatus 26, the esophagus 12 is anchored to the diaphragm 16 by an upper limb of the phrenoesophageal ligament 28 (hereafter, POL 28). The POL 28 is formed from two closely aligned layers including a layer derived from the endothoracic fascia 30 and a layer derived from the transversalis fascia 32. A lower limb of the POL 28 attaches to the stomach 14 proximally below the esophageal hiatus 26. A subfascial area 34 (i.e. gastroesophageal (GE) space) is formed between an inner wall 280 of the POL 28 and outer wall 122 of the esophagus 12 and of the cardiac orifice 18. The subfascial area 34 is filled with adipose tissue and is traversed by blood vessels.

[0034] Herein, a method to deploy a medical device using a delivery system endoluminally into the esophagus 12 interiorly of an intended placement location thereof around the esophagus, then through the inner wall 120 of the esophagus 12 and outwardly of the outer wall 122 thereof (see, e.g. FIG. 4), and into the subfascial area 34, introducing a medical device (see, e.g. FIG. 9) sub-fascially in the subfascial area 34 to encircle or substantially encircle at least one part of the esophagus 12 so that mechanical augmentation (i.e. additional mechanical pressure from the medical device) can be applied to the encircled or substantially encircled part of the esophagus 12, is described and shown.

[0035] FIG. 2 is a schematic view of one step of a method of deploying a medical device according to one embodiment hereof, illustrating a “double barrel” shaped endoscope 50 and introducer being introduced endoluminally with respect to esophagus 12 of the patient to a targeted site closed to esophagogastric junction. As shown in FIGS. 1, the endoscopic device can be a conventional endoscope 50 or an ultrasound endoscope placed with respect to the interior of the esophagus 12 of the patient at the esophagogastric junction 24. The endoscope 50 can be any type known in the art, including, for example a device configured of: a flexible insertion tube 52 (partially shown) having a proximal end (not shown) and a distal end 54, the flexible insertion tube 52 configured for extending in a longitudinal direction and insertable into a body lumen, here the esophagus 12, thereby producing detailed images of the lining and walls 120, 122 of the esophagus 12. To accurately navigate a medical device to the targeted site, the flexible insertion tube 52 includes a first magnet 56 provided at the distal end 54 thereof, which is configured for attracting and guiding a corresponding second magnet 68 mounted at a distal end 66 of a catheter shaft 62 extending outwardly from an introducer 42 (see, e.g. FIG. 3). The first magnet 56 here is designed as a ring-shaped member to surround around a portion of the exterior wall 55 of the distal end 54 of the endoscope 50. The endoscope 50 further comprises a handle (not shown) provided at the proximal end of the flexible insertion tube 52. The handle includes a deflection control knob (not shown) which the operator moves to selectively and controllably bend the flexible insertion tube 52 at the distal end 54 thereof, so that an operator of the endoscope 50 can navigate the distal end 54 of the flexible insertion tube 52 to a targeted site within the esophagus 12 based on detailed image thereof provided by the endoscope 50. In an example, the distal end 54 of the

flexible insertion tube 52 includes a camera, one or more additional working channels for slidably providing tool access and control, an illuminating device (not shown) such as a LED or light bundle, as well as irrigation and suction ports (not shown), or inflatable devices such as one or more inflatable members such as balloons.

[0036] In FIG. 2, an introducer 42 is connected to the endoscope 50 via a coupler 44. The coupler 44 is manufactured of stainless steel or another biocompatible material, and it serves to relatively position the distal ends 54 of the flexible insertion tube 52 and the introducer 42 relative to each other. The coupler 44 includes a connecting part 440 surrounding the exterior walls 55 of the flexible insertion tube 52 and the introducer 42, and a plurality, in the embodiment described, two, openings 442, 444 extending generally side by side therethrough. The flexible insertion tube 52 extends through and tightly fits into the first opening 442 of the coupler 44 and the introducer 42 extends through and tightly fits into the second opening 444, forming a side by side, “double barrel”, structure of the flexible insertion tube 52 and the introducer 42. Thus, the introducer 42 is secured to move endoluminally together with the endoscope 50 to a targeted site close to the esophagogastric junction 24. Here, the introducer 42 is a tubular structure including a hollow interior 43 to receive a catheter 60 moveably disposed therein and an opening 430 at the distal end 420 thereof. In some examples, the introducer 42 can be an endoscopic trocar or a cannula.

[0037] FIGS. 3 includes schematic views of one step of a method of deploying a medical device according to one embodiment hereof, illustrating a catheter being advanced outwardly from a distal end of the introducer 42. The catheter 60 here includes a flexible, elongated catheter shaft 62 (Fig. 4), a proximal end (not shown) and a distal end 66. The catheter shaft 62 has a bore 620 such that a guidewire 70 (see. e.g. FIG. 7) is extendable or retractable through the bore 620 and is extendable outwardly from an opening (not shown) at the distal end thereof 66. A second magnet 68 is provided at the distal end 66 of the catheter 60 and configured to be attracted and guided by the first magnet 56. The second magnet 68 here is designed as a ring-shape member to surround around a portion of the exterior wall 61 of the distal end 66 of the catheter 60. Adjacent to the second magnet 68 is an inflatable balloon area 63 surrounding a portion of the exterior wall 61 of the catheter 60 at the distal end 66 thereof. The balloon area 63 is configured to open up or dissect the subfascial area 34 (see. e.g. FIG. 7) when it is

insufflated, and can be insufflated by any current technologies known in the art. For example the balloon techniques discloses in patents No. US 8,868,215 B2, which are incorporated herein by reference in their entireties, except for any definitions, subject matter disclaimers or disavowals, and except to the extent that the incorporated material is inconsistent with the express disclosure herein, in which case the language in this disclosure controls.

[0038] FIG. 4 is a schematic view of one step of a method of deploying a medical device according to one embodiment, illustrating the distal end 66 of the catheter 60 in the subfascial area 34 when the balloon area 63 is insufflated. The catheter shaft 62 is fed through the interior 43 of the introducer 42 from a location extending outwardly of the patients mouth (not shown) and is pushed along the interior 43 of the introducer 42, toward, and through, the inner wall 120 and outer wall 122 of esophagus 12. To deliver the distal end 66 of the catheter 60 to the subfascial area 34, an incision is created between the inner wall 120 and outer wall 122 of esophagus 12 at the esophagogastric junction 24. For example, a puncturing device (not shown) is advanced from one of the working channels (not shown) of the endoscope 50 toward, into, and through the inner wall at the esophagogastric junction 24, to create a connected channel 124 or opening through the structure of the esophagus 12 from and through the inner and outer walls thereof, forming the connected channel 124 to extend between the interior of the esophagus 12 and the subfascial area 34 of the POL 28. The puncturing device includes a flexible, elongated member, with a piercing part at its distal end. In an example, the puncturing device is a flexible needle, a cannula or an ablation catheter. Once the piercing part reaches the targeted site at the esophagogastric junction 24, the local inner wall 120 and outer wall 122 of esophagus 12 are perforated by the piercing part pushing into the inner wall 120 of the esophagus 12 as a result of mechanical force being applied thereat though the piercing part (e.g. a needle tip or a cannula tip) with an anchor (not shown). Alternatively, the inner wall 120 and the outer wall 122 of esophagus 12 can be perforated by thermal or cryo-energy applied though a piercing part (e.g. a tip of the ablation catheter). Thus, a connected channel 124 is created connecting the interior volume of the esophagus 12 with the subfascial area 34 of the POL 28. When the distal end of the catheter is introduced into the subfascial area 34, the inflatable balloon area 63 is insufflated to help open up or

dissect the subfascial area 34, thereby facilitating the advancement of the distal end 66 of the catheter 60 within the subfascial area 34.

[0039] FIG. 5 is a schematic view of the distal end 66 of the catheter 60 being placed in the subfascial area shown in FIG. 1C according to one embodiment, illustrating a first magnet 56 at the distal end of the endoscope 50 being manipulated to attract and guide a corresponding second magnet 68 at the distal end 66 of the catheter 60, thereby advancing the distal end of the catheter within subfascial area. FIG. 6 is a schematic view of the distal end of the catheter being advanced in the subfascial area shown in FIG. 1C according to one embodiment, illustrating the distal end 66 of the catheter 60 being guided to move within the subfascial area to encircle the outer wall of esophagus. As also shown in FIGs. 5 and 6, the operator can selectively and controllably use the handle (not shown) of the endoscope 50 to rotate the endoscope 50 about its longitudinal axis L so that the first magnet 56 surrounding around the distal end 54 of the endoscope 50 can be rotated accordingly, which attracts the second magnet 68 pulling the distal end 66 of the catheter 60 close to and move along the outer wall 122 of the esophagus 12 in the subfascial area 34. Once deployed, the deployed distal end 66 of the catheter 60 forms a guide 65 through which a guidewire 70 (see, e.g. FIG. 7) is guided to be located around, or substantially around, the outer wall 122 of esophagus 12.

[0040] FIG. 7 is a schematic view of one step of a method of deploying a medical device according to one embodiment, illustrating a steerable guidewire being introduced within and extending outwardly from the distal end 66 of the catheter 60. FIG. 8 is a schematic view of one step of a method of deploying a medical device according to one embodiment, illustrating a shapeable portion 74 of the steerable guidewire, formed of a shape memory material, regaining its shape in the subfascial area 34 to encircle the outer wall of esophagus. The catheter shaft 62 has a bore 620 to receive a steerable guidewire 70 and a pre-shape dissector 80 (see, e.g. FIG. 9) located over a portion of the guidewire 70. The guidewire 70 is moveably disposed within the bore 620 of the catheter 60 and extends outwardly from the distal end 66 of the catheter 60. The guidewire 70 includes a flexible, elongated shaft 72 and a shapeable portion 74 adjacent to and extending from a distal end 76 of the guidewire shaft 72. The guidewire shaft 72 is extendable or retractable through the bore 620 and extends outwardly from an opening (not shown) at the distal end 66 of the catheter 60 a distance sufficient, when deployed through the bore 620 of the

catheter 60, to extend to a location exterior of a patients mouth (not shown), plus at least the length of the shapeable portion 74. The shapeable portion 74 is configured of a shape memory material (such as shape memory alloy including nickel and titanium), which is maintainable in a roughly straight line configuration in a constrained state and regains its shape in an unconstrained state. Here, the guidewire shaft 72 need not be configured as a shape memory material, but can instead be any suitable biocompatible material for the guidewire 70. The operator can operate any guidewire controller (such as a hand-held controller) known in the art to selectively and controllably steer the movement or deflection of the shapeable portion 74. In an unconstrained state, the shapeable portion 74 with the guidewire shaft 72 is introduced from the proximal end 64 of the catheter 60 into the bore 620 and is advanced within the bore 620, and into the guide portion 65 of the catheter 60. The shapeable portion 74 is then constrained to the shape of the guide portion 60 to be deflected from its longitudinal axis L1 along the guidewire shaft 72 to create a bend 78, thereby extending generally along the circumference of a circle to be located around, or substantially around the outer wall 122 of esophagus 12. The operator guiding the guidewire 70 can also use the camera of the endoscope 50 and a monitor (not shown) adjacent to the working area exterior of the patient to visualize the locations of the connected channel 124, the guide portion 65 of the catheter 60 to effect the extending of the guidewire 70 inwardly of the guide portion 65. As the shapeable portion 74 is being deployed around the esophagus 12, the balloon area 63 of the catheter 60 is flattened and the catheter 60 is retracted inwardly of the opening 430 in the introducer 42, such as by pulling it from a location exterior of the patient. As a result, the shapeable portion 74 of the guidewire 70 remains around the esophagus 12 when the catheter 60 is retracted.

[0041] FIG. 9 is a schematic view of one step of a method of deploying a medical device according to one embodiment, illustrating a pre-shape dissector located over a shapeable portion of the guidewire encircling the outer wall of esophagus along the advancing path of the shapeable portion. FIG. 10 is a schematic view of one step of a method of deploying a medical device according to one embodiment, illustrating that a pre-shape dissector remaining around the outer wall of esophagus when the guidewire 74 has been retracted. The pre-shape dissector 80 is configured to open up or dissect the subfascial area 34 when it is advanced in the subfascial area 34, and provide additional mechanical augmentation squeezing the encircled portion of esophagus 12 when it is

deployed. Here, the pre-shape dissector 80 is designed as a coil or spring like member where a biocompatible shape memory material is wound as a coil around and longitudinally along a central axis, and the resulting coil is configured in its unconstrained state as a C-shaped member 82 as shown in FIGs 9 and 10. The outer diameter or span of the C-shaped member 82 across its circumference, in an unconstrained state, is less than the smallest width of the interior 43 of the introducer 42, while the inner diameter thereof is sized to be slightly greater than the greatest diameter of the guidewire shaft 72 and the shapeable portion 74 thereof. Thus, the C-shaped member 82 is unable to retract along the bend 78 of the shapeable portion 74, causing the C-shaped member 82 to deploy around the esophagus 12 at the same time the shapeable portion 74 is deployed around the esophagus 12. Thereafter, the guidewire 70 is retracted from the subfascial area 34, and the C-shaped member 82 remains in place as shown in FIG. 10. To prepare for deployment, the C-shaped member 82 is pushed by a push tube (not shown) extended from an location external to the patients mouth and through the interior 43 of the introducer 42, The distal end of the push tube bears against a first end 820 of the C-shaped member 82 to push the C-shaped member 82 and advance it outwardly of the catheter 70 along the guidewire shaft 72, and into the connected channel 124, and thence outwardly along the shapeable portion 74. Once the C-shaped member 82 has been deployed in the subfascial area 34 and around the esophagus 12 as shown in FIG. 9, the guidewire 70 is retracted inwardly of the opening 430 of the introducer 42 by pulling it from a location exterior of the patient. Because the C shaped member 82 can expand to increase the gap 84 between the first end 820 and second end 822 thereof, as material such as food or liquid passes through the esophagus 12, the outer wall of the esophagus 12 will push outwardly to increase the length of the gap 84, but once this material has passed the location of the C shaped member 82, it will spring back to its free shape to prevent material from leeching therepast in the opposite direction (stomach toward mouth direction). Thus, additional mechanical augmentation provided by the C shaped member 82 is applied to the muscular layer around the outer wall 122 of esophagus 12 (e.g. lower esophageal sphincter (LES)), thereby decreasing or preventing gastric reflux and effectively treats GERD

[0042] FIGS. 11A and 11B are schematic views of one step of a method of deploying a medical device according to another embodiment, illustrating a delivery system being

inserted laterally into a patient adjacent or through the patient's diaphragm and through the POL into a subfascial area 34 to deliver the medical device. FIG. 11 A is a cross section of the GI tract as shown in FIG. 1B. FIG. 11B hereof is a sectional view of a portion of the GI tract as shown in FIG. 1A. Here, the delivery system 90 includes an introducer, a catheter, a steerable guidewire and a pre-shape dissector as described above. An incision 94 is created at the lateral side 92 of the patient's abdomen using any suitable surgical tool known in the art, such as laparoscopic tools so that the introducer (e.g. a trocar) is allowed to be inserted laterally adjacent or through the diaphragm 16 and advanced toward, into and through the POL 28. Once the introducer being deployed, a catheter is advanced outwardly from a distal end of the introducer and the distal end thereof is introduced into the subfascial area 34 from the POL 28 when a balloon area 91 is insufflated according to the deploying method as described above. Thereafter, a steerable guidewire and a pre-shape dissector are deployed into the subfascial area 34 from the POL 28 similarly as described in the previous paragraphs, leaving the C-shaped member around the esophagus 12 as shown in FIG. 9.

[0043] FIG. 12 is a schematic view of one step of a method of deploying a medical device according to another embodiment, illustrating a delivery system being inserted anteriorly into a subfascial area to deliver the medical device. FIG. 13 is a schematic view of one step of a method of deploying a medical device according to another embodiment, illustrating a delivery system being inserted posteriorly into a subfascial area 34 to deliver the medical device. Alternatively, as shown in FIG 12, the delivery system 90 can be inserted at the front side 96 of the patient's abdomen using any suitable surgical tool known in the art, thereby being advanced toward an anterior portion of the cardiac orifice 18/esophagus 12, through the diaphragm 16 and the POL 28 into a subfascial area 34 to deliver the medical device using the method as described above. Also, in FIG 13, the delivery system can be inserted at the back side 98 of the patient's abdomen using any suitable surgical tool known in the art (such as a spinal needle), thereby being advanced into the diaphragm 16 proximate to the vertebral column 36 and through the POL 28 into a subfascial area 34 to deliver the medical device using the method as described above.

[0044] It is to be noted that various modifications or alterations can be made to the above-described exemplary embodiments of the invention without departing from the technical features of the invention as defined in the appended claims.

What is claimed is:

1. A method for deploying a medical device to a target site of a patient, comprising:
 - a) placing an endoscopic device endoluminally to a first location within an esophagus of the patient;
 - b) introducing the flexible, elongated sheath to a second location at a subfascial area outside the esophagus in response to the image captured by the endoscopic device, wherein the sheath has a hollow interior and further comprises:
 - a steerable guiding member moveably disposed within the interior of the sheath and comprising a guided portion and a shapeable portion is adjacent to the distal end of the guided portion, wherein the shapeable portion is steered to deflect from and return to a longitudinal axis thereof; and
 - a pre-shape dissector comprising a deformable, elongated body, the pre-shape dissector being located over at least a part of the shapeable portion and deliverable from the guiding member;
 - c) advancing the shapeable portion of the guiding member being deflected from the second location along the subfascial area, whereby the deformable, elongated body of the pre-shape dissector thereover forms a curved portion along the shapeable portion advancing path to at least partially encircle esophagus; and
 - d) the curved portion of the dissector remaining at least partially around the esophagus when the guiding member is retracted, whereby a mechanical augmentation is applied to the esophagus via the curved portion.
2. The method of claim 1, wherein the flexible, elongated sheath of the step b) is introduced endoluminally to the second location.
3. The method of claim 2, wherein the flexible, elongated sheath of the step b) further comprises a coupler connecting the sheath to the endoscopic device, the coupler comprising a first opening that allows the endoscopic device extending therethrough and a second opening that allows the sheath extending therethrough.

4. The method of claim 1, the flexible, elongated sheath of the step b) is introduced to the second location by inserting the sheath laterally through a portion of a phrenoesophageal ligament (POL) to approach the second location.
5. The method of claim 1, the flexible, elongated sheath of the step b) is introduced to the second location by inserting the sheath anteriorly through a portion of the phrenoesophageal ligament (POL) to approach the second location.
6. The method of claim 1, the flexible, elongated sheath of the step b) is introduced to the second location by inserting the sheath posteriorly through a portion of the phrenoesophageal ligament (POL) to approach the second location.
7. The method of claim 1, further comprises: a step of providing a first magnet at a distal end of the endoscopic device and a second magnet at a distal end of the flexible, elongated sheath.
8. The method of claim 7, wherein the distal end of the sheath is guided to the second location in response to the movement of the endoscopic device when a magnetic field is applied.
9. The method of claim 1, wherein the first location of the step a) is at esophagogastric junction, the esophageal-diaphragmatic junction, or the gastro-diaphragmatic junction.
10. The method of the claim 1, the step b) further comprises:
 - creating an opening between the first location and the second location to advance and retract the flexible, elongated sheath therethrough; and
 - providing at least inflatable balloon at the distal end of the flexible, elongated sheath, whereby the subfascial area is dissected and supported when the balloon is inflated.
11. The method of claim 10, wherein the opening is created using a needle or a cannula.

12. The method of claim 1, wherein the shapeable portion of the step b) comprises a shape memory material.
13. The method of claim 1, wherein the pre-shape dissector is configured as a coil or spring like member.

FIG 1B

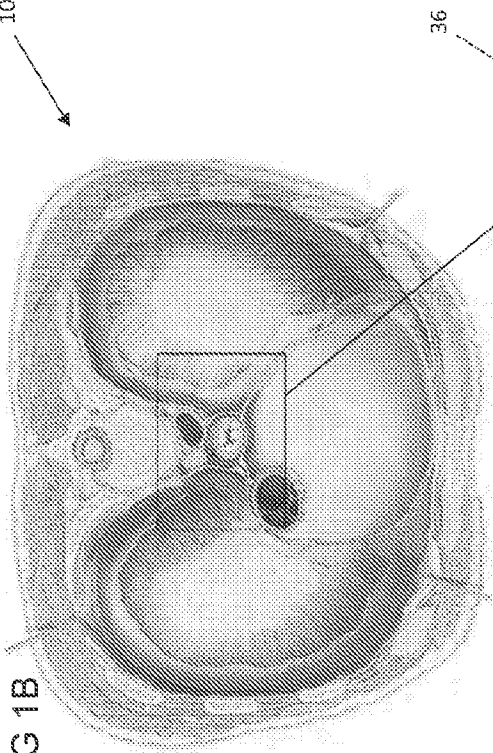


FIG 1. A portion of a human gastro-intestinal (GI) tract

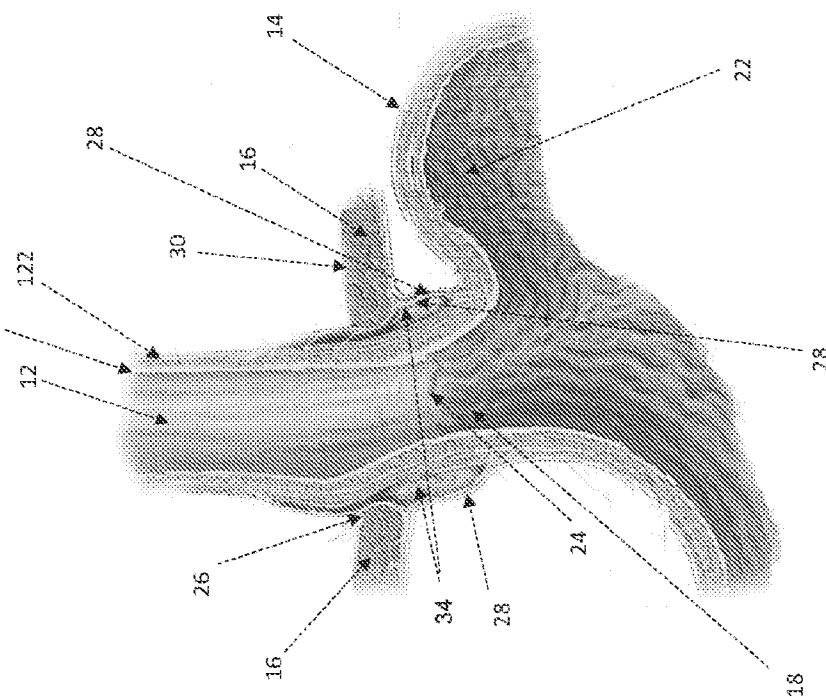


FIG. 1C

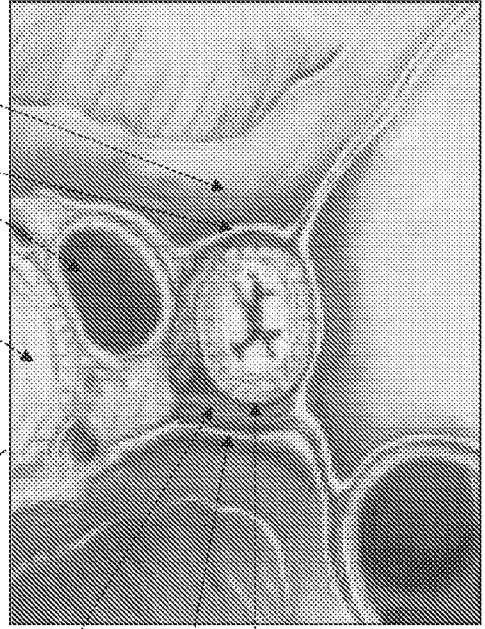


FIG. 2

- Locate the “double barrel” shaped endoscope and introducer to the target

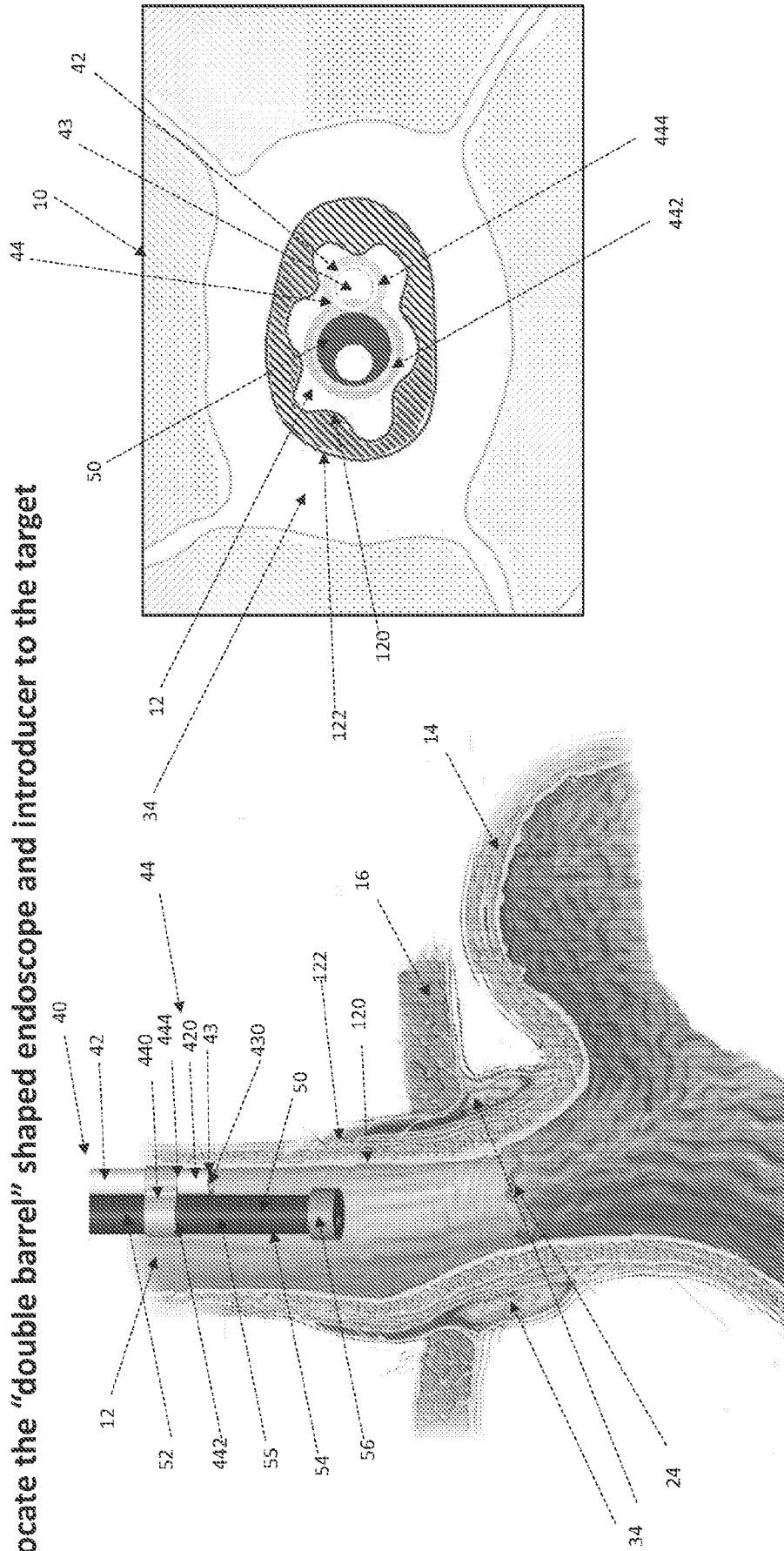


FIG.3

- Advancing the atraumatic balloon and magnet attached catheter through introducer

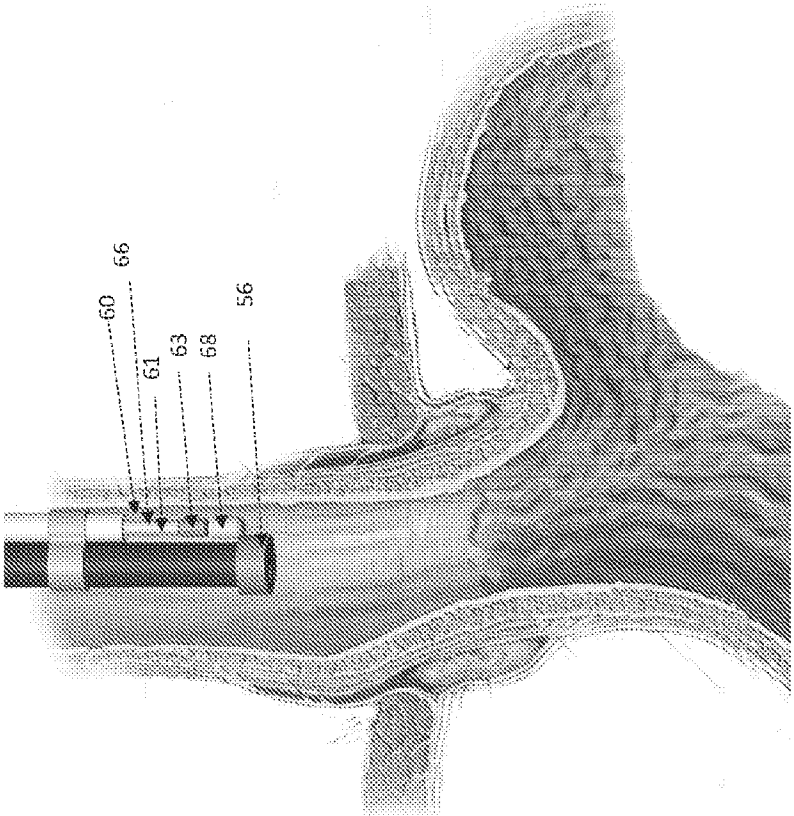
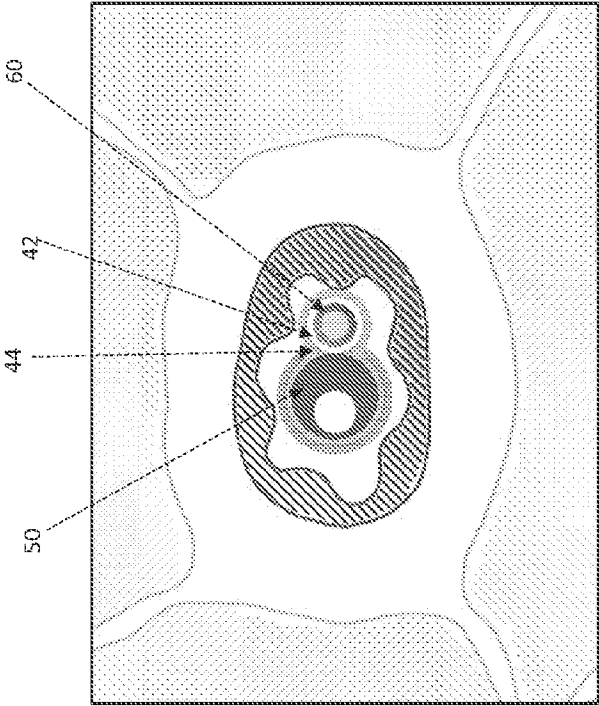


FIG.4

- Insufflating attached balloon to dissect submucosal layers and place a catheter to the target

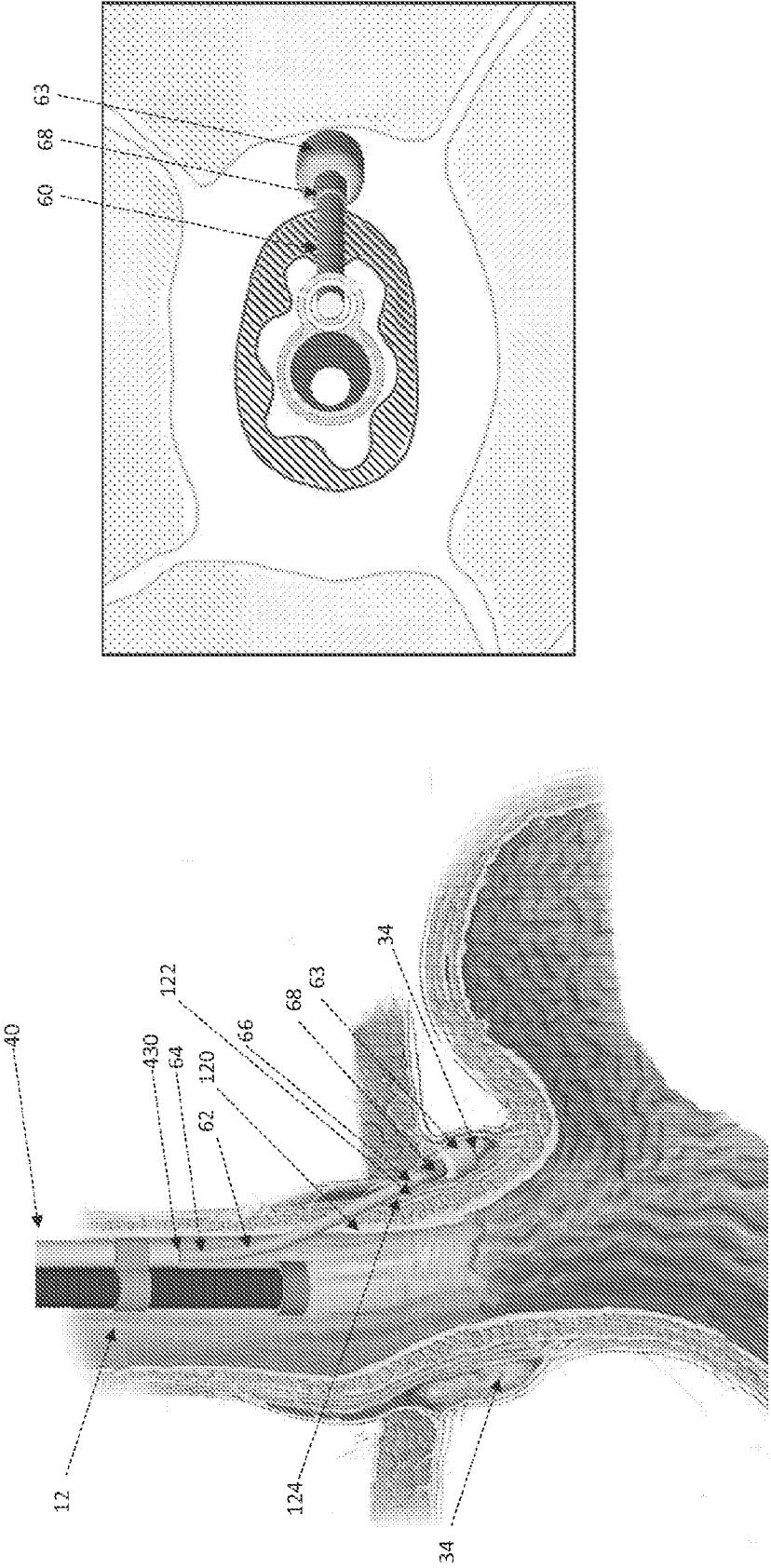


FIG.5

- Rotating a magnet ring attached endoscope to drag and pull the magnet attached catheter along to the esophagus

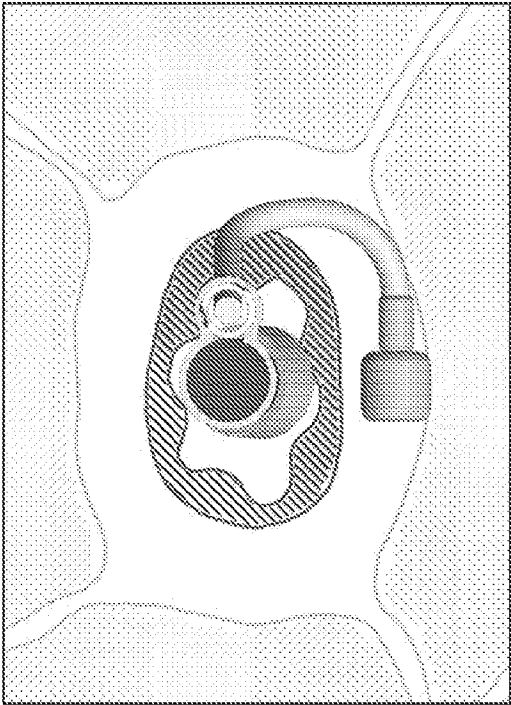
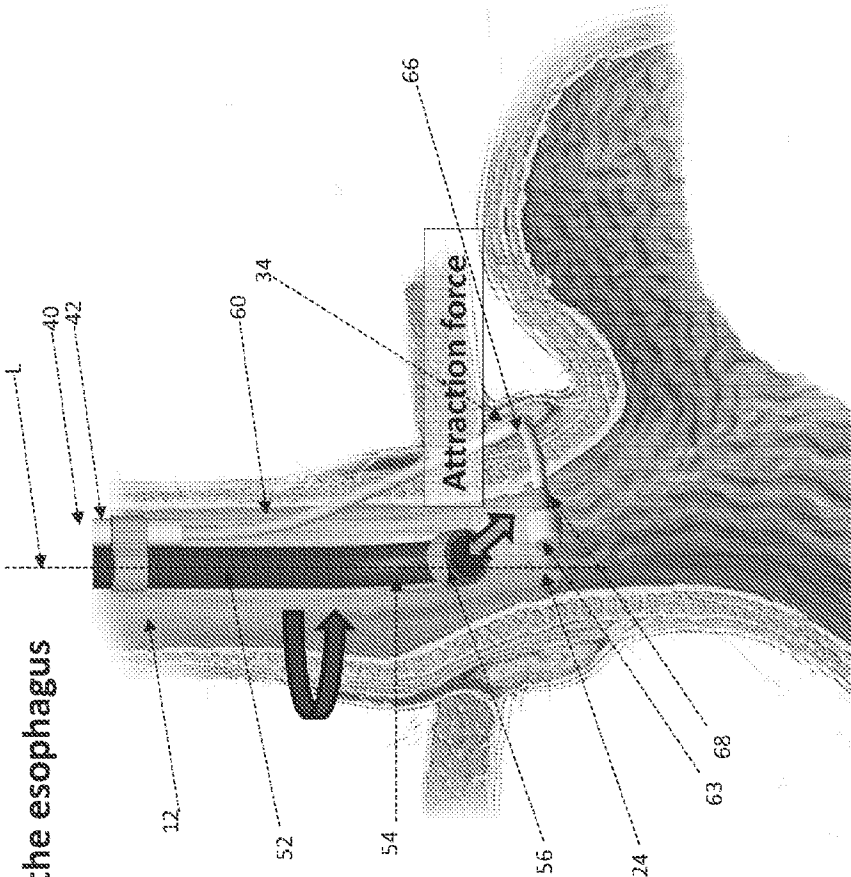


FIG.6

- Rotating a magnet ring attached endoscope until the catheter fully encircling along to the esophagus

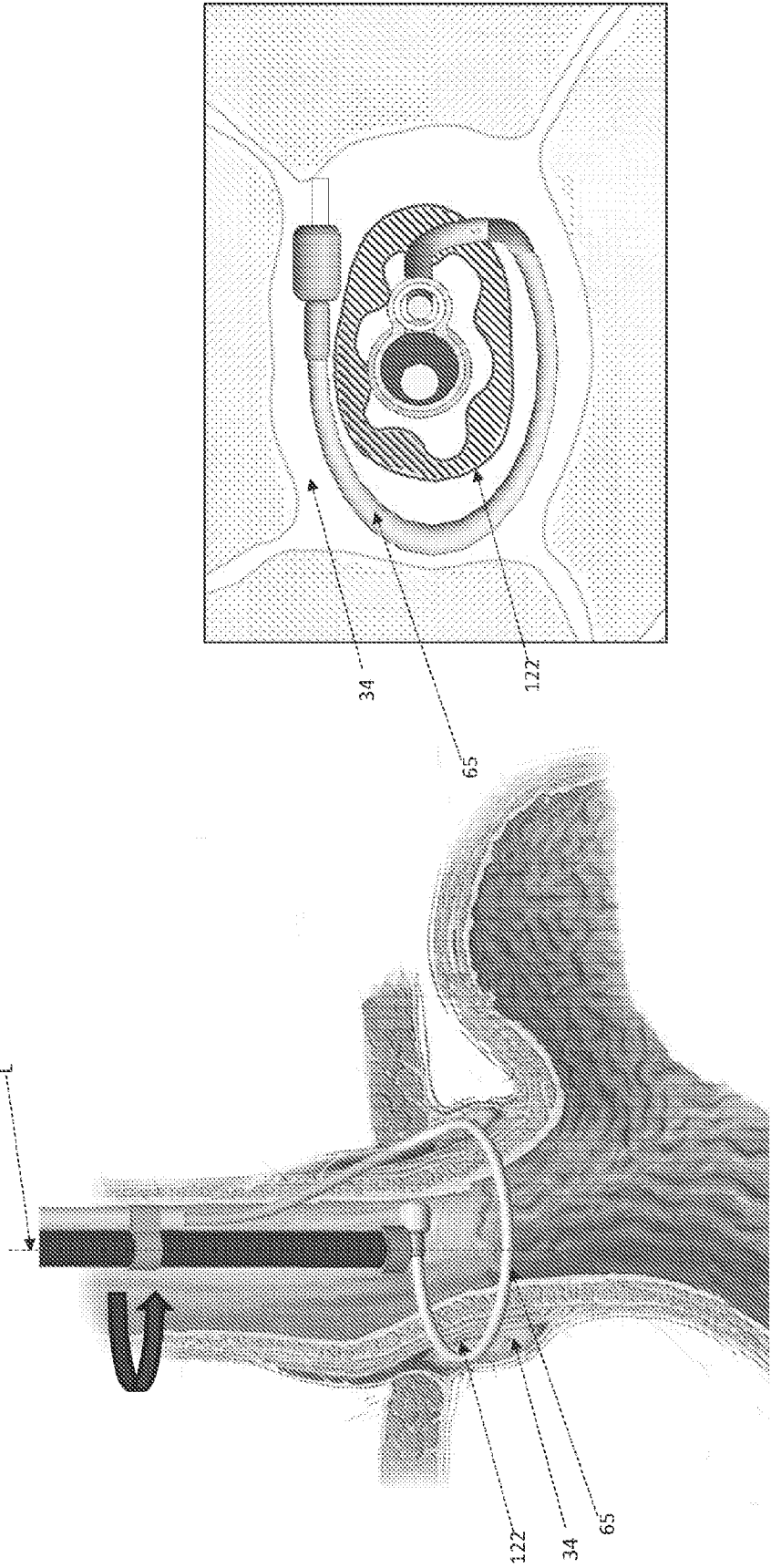


FIG.7

- Inserting guide wire through the catheter

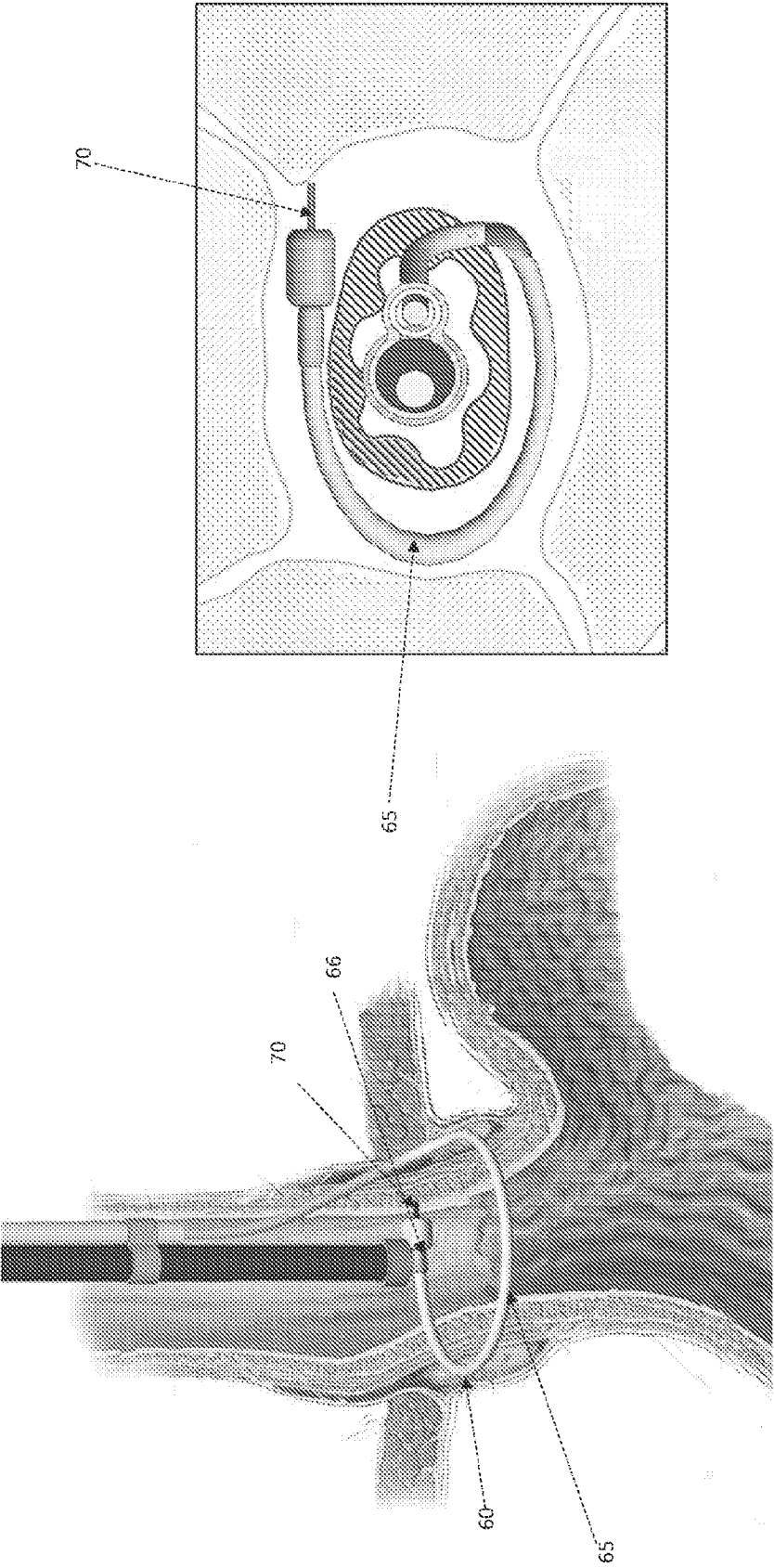


FIG.8

- Flattening atraumatic balloon and removing the catheter

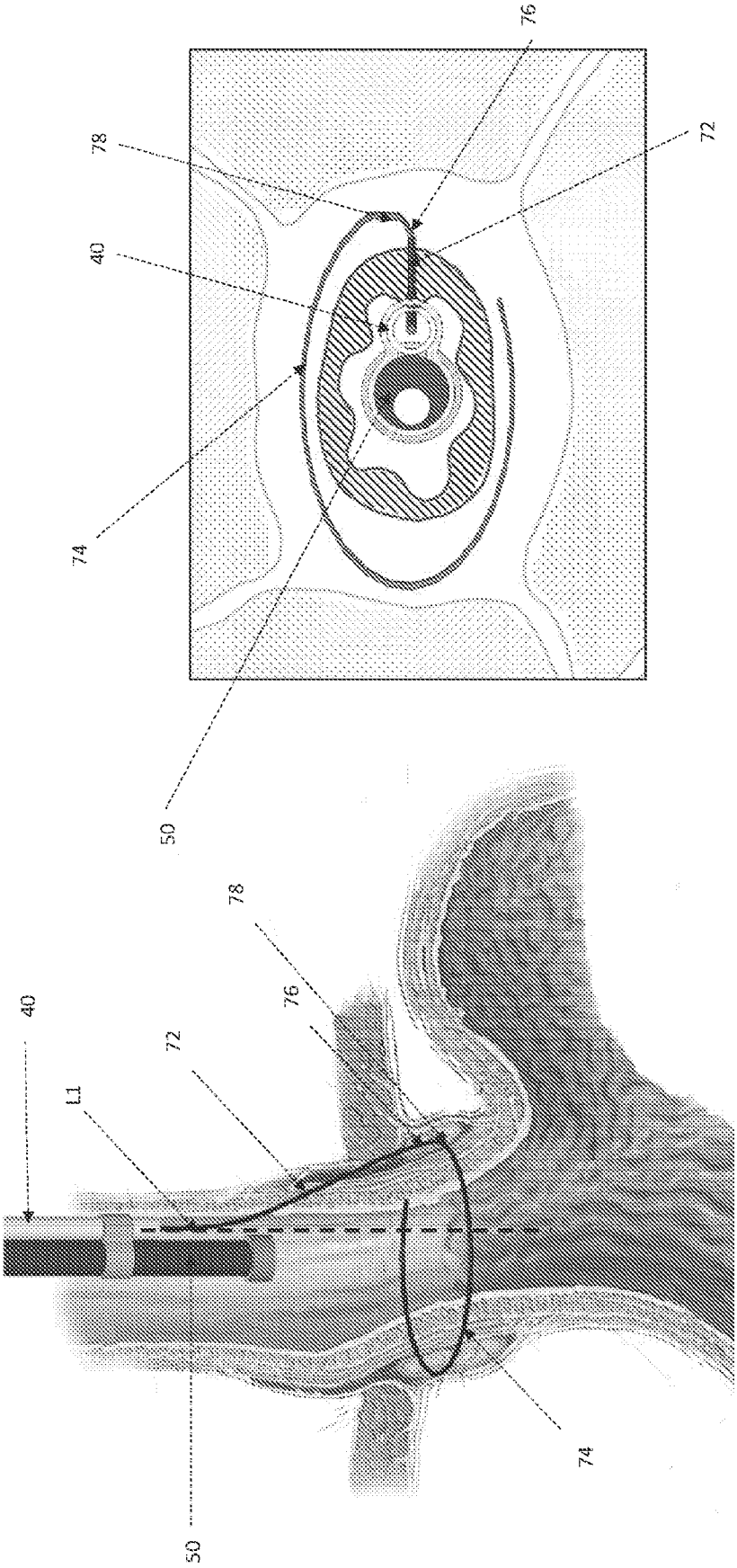


FIG.9

- Inserting the C-shaped coil along to the guide wire

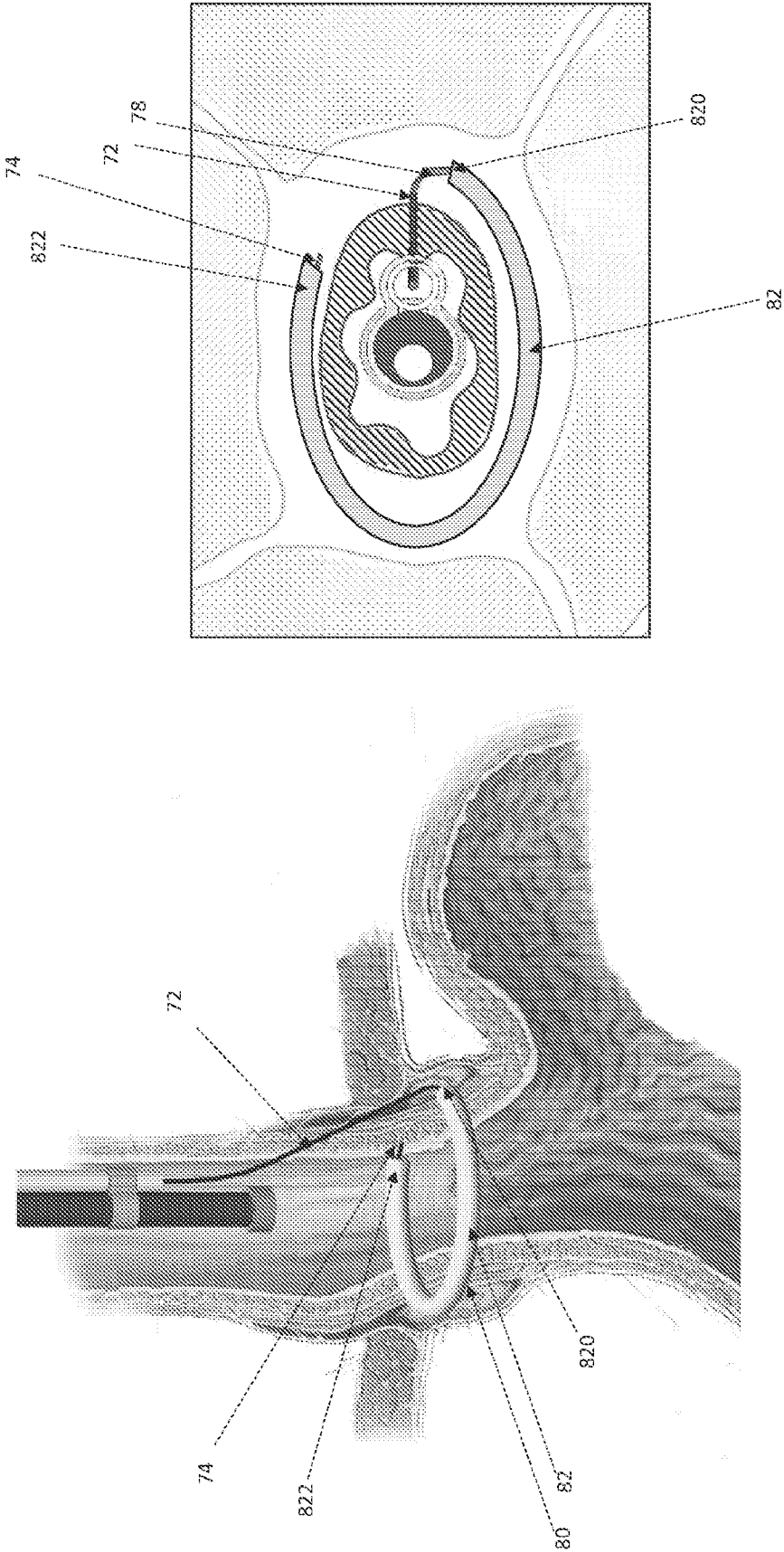


FIG.10

- Finishing the installment of C-shape coil and removing “double barrel” shaped endoscope and introducer

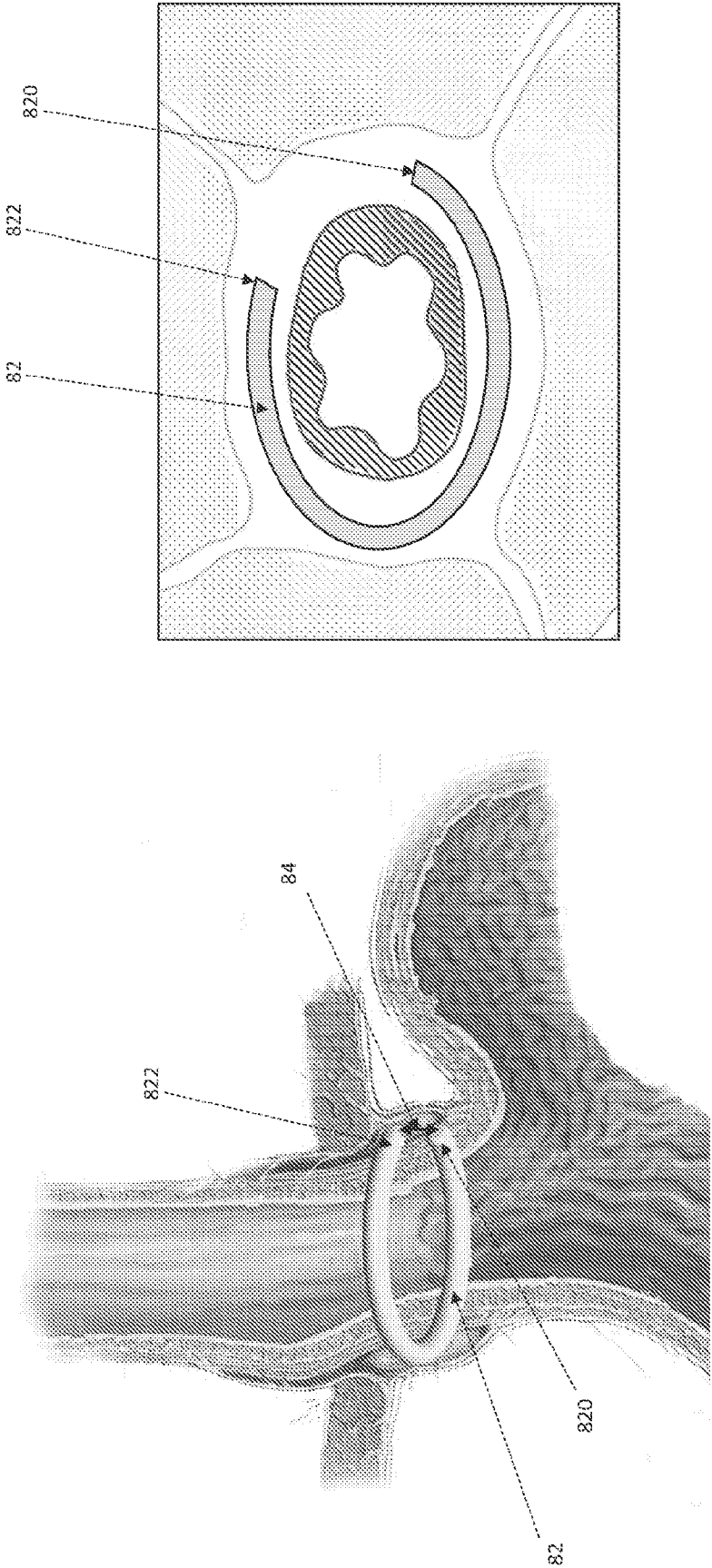
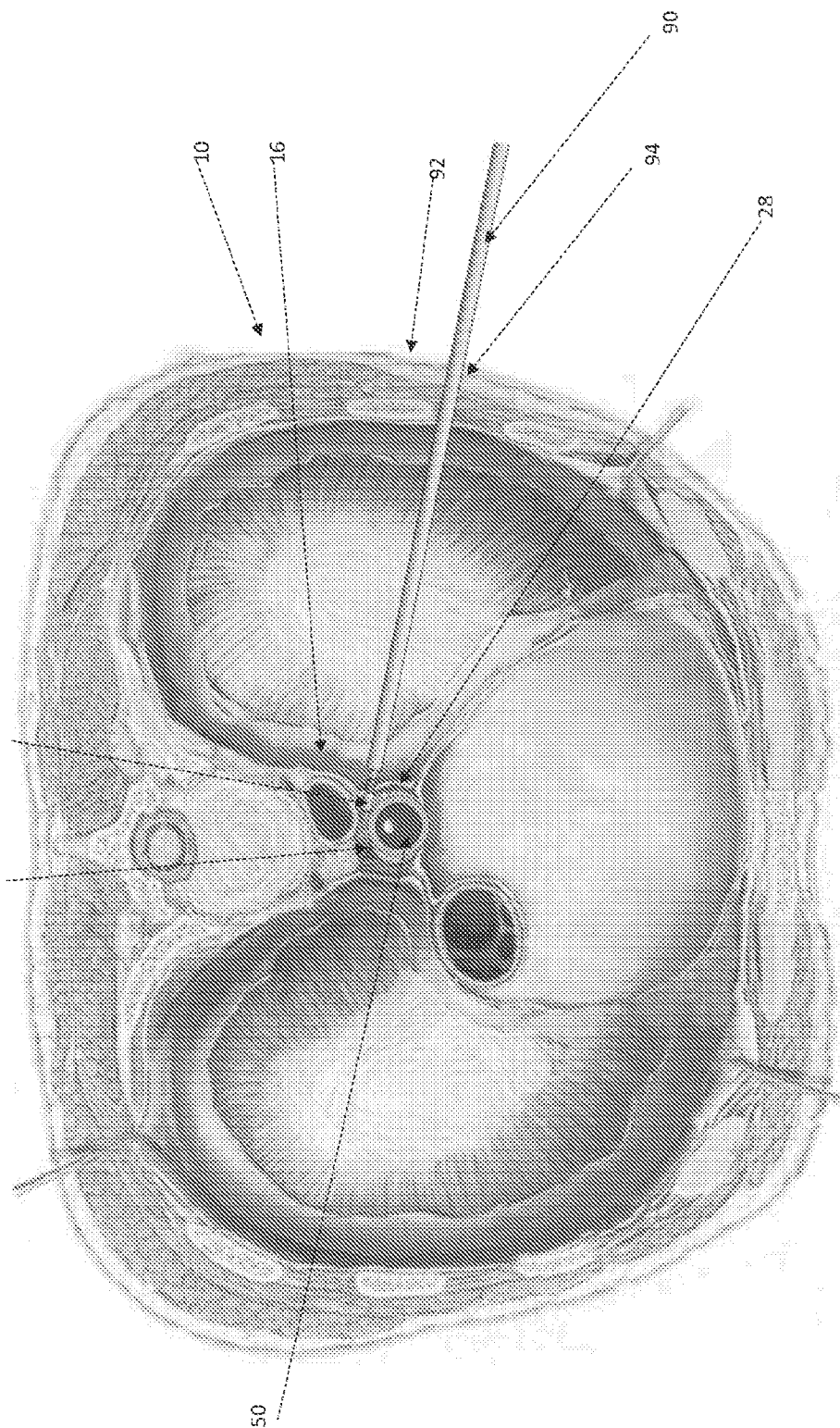


Fig. 11A is a cross section of the GI tract where a delivery system is inserted laterally into a subfascial area to deliver the medical device.



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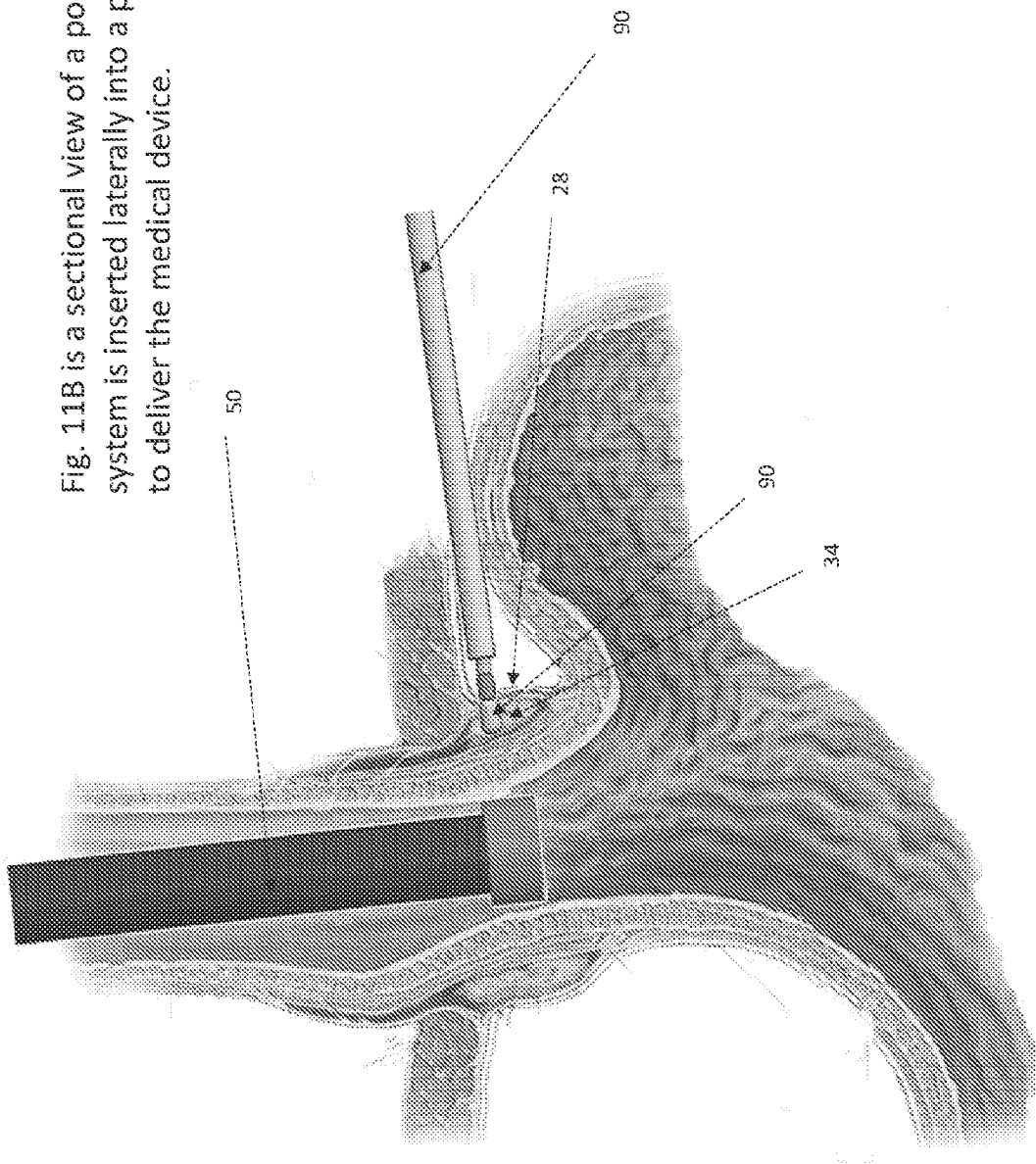


Fig. 11B is a sectional view of a portion of the GI where a delivery system is inserted laterally into a patient into a subfascial area to deliver the medical device.

Fig. 12 is a cross section of the GI tract where a delivery system is inserted anteriorly into a subfascial area to deliver the medical device.

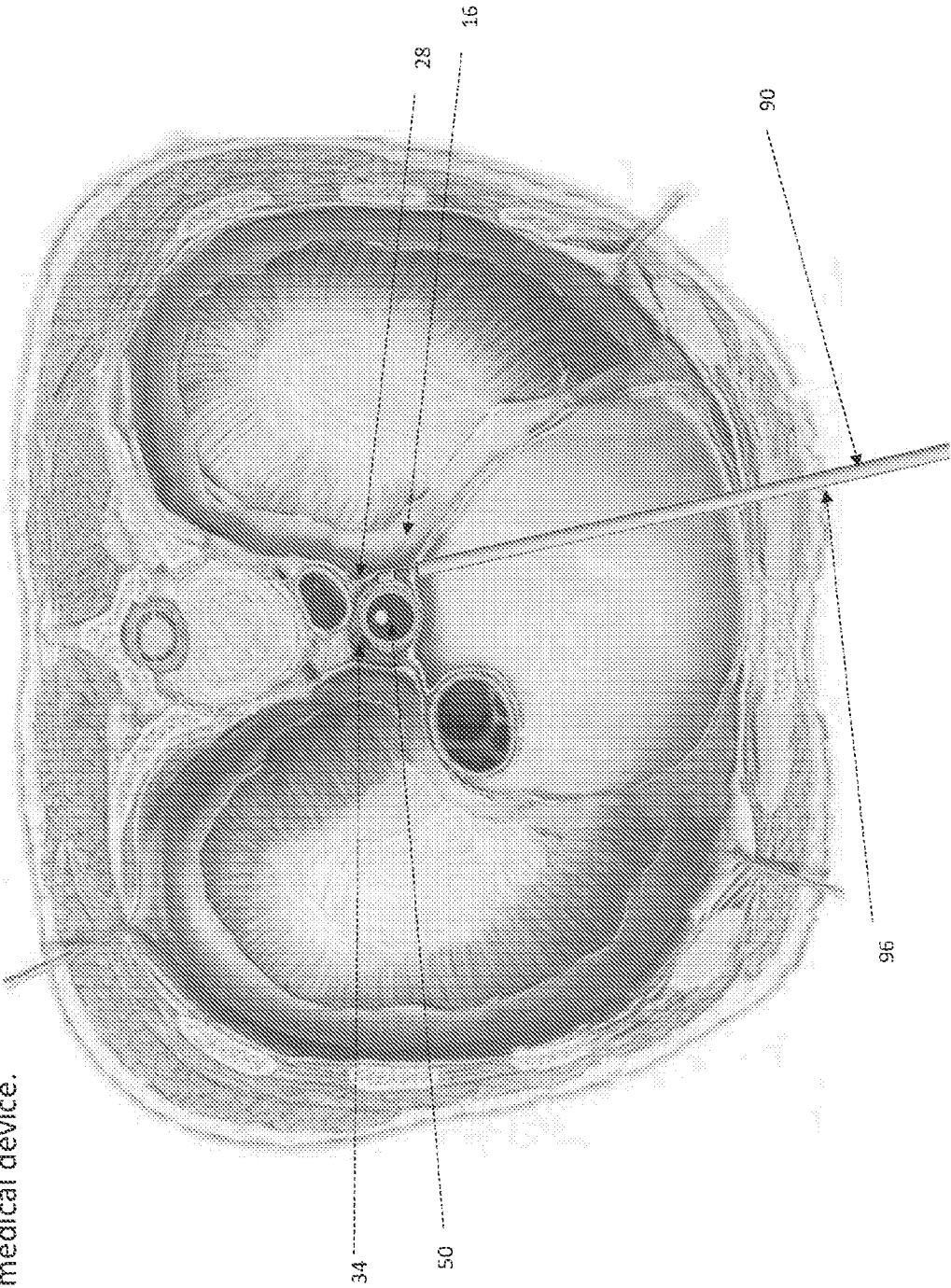


Fig. 13 is a cross section of the GI tract where a delivery system is inserted posteriorly into a subfascial area to deliver the medical device.

