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(54) Title: DEVICES AND METHODS FOR ENDOLUMINAL GASTRIC RESTRICTION AND TISSUE MANIPULATION

(57) Abstract: An endoluminal treatment device and method includes introducing an endoluminal device into a lumen of a patient and engaging a wall of the lumen with a retractor of the endoluminal device. The wall is retracted such that outer surfaces of the lumen come into contact with each other and thereby form a plication. Following formation of the plication, the device is activated to deploy a securing device to secure the plication. Multiple plications can be introduced into the organ wall and then be approximated to reduce the volume of the lumen and to form a pouch, such as in a gastric reduction procedure.



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DEVICES AND METHODS FOR ENDOLUMINAL GASTRIC RESTRICTION AND TISSUE MANIPULATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This application is related to and claims priority to United States Provisional application no. 60/741,510, filed December 1, 2005 and United States Provisional application no. 60/849,414, filed October 4, 2006, each of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD OF THE INVENTION

[002] Generally, the present invention relates to endoluminal surgical devices and methods. More particularly, the devices and methods provide for endoluminal gastric restriction, closure of gastric and/or non-gastric wall openings, treatment of fistulas, tissue reconfiguration, and the like.

BACKGROUND OF THE INVENTION

[003] Laparoscopic surgery has greatly reduced the size and scope of incisions made in a patient and resulted in reduced morbidity and mortality rates. However, even with the reductions in size and scope of incisions as a result of laparoscopic surgery, complications in and during surgical procedures remain. A technique that is developing to further reduce surgical complications is to work through an endoluminal access port. An example of an endoluminal access port is the mouth and this access port can give a surgeon access to a patient's esophagus and stomach.

[004] Stomach tissue often needs surgical treatment to treat fistulas and to close transgastric incisions to stop stomach fluids from leaking from the stomach to surrounding tissue and to stop infectious matter from spreading from or to the stomach tissue. Other stomach treatments include stomach reduction procedures for obese patients. Traditionally, physicians have been placing devices such as the Lap Band® on the external surface of the gastric wall to create a restricted stomach capacity. Another traditional procedure for stomach reduction includes a laproscopic procedure in which surgeons protrude into the stomach from the exterior of the patient and staple the stomach into a smaller volume. This restriction creates a pouch inside the stomach which fills quickly when food is ingested and assists in generating a sensation of being full. However, these procedures have drawbacks such as complications from port punctures of

the stomach, large incisions, substantial recovery time, expense, lost productive work time, infection, and the like.

[005] The incisions created by the current surgical procedures also include a morbidity and mortality rate that can be reduced by reducing or eliminating the need for such incisions by accessing the surgical site endoluminally.

SUMMARY OF THE INVENTION

[006] According to some embodiments of the present invention, an endoluminal implant device includes a tissue anchor implant configured to be implanted into a lumen of a body without creating an incision in integument of the body. The tissue anchor implant is also configured to maintain a plication in a wall of the lumen. Further included with the implant device is a medical treatment associated with the tissue anchor implant. In some embodiments, the medical treatment includes a drug for delivery within the lumen, a biological stimulation device, or a monitoring device. In some embodiments, the biological stimulation device is selected from the group of an electrical stimulation device, mechanical stimulation device, vibratory device, sound device, ultra-sound device, chemical stimulatory device, neuro-transmitter stimulation device, thermal stimulation, sensory stimulatory device, and combinations thereof. In alternative embodiments, the monitoring device is selected from the group of a pH sensor, pressure sensor, chemical sensor, hormone sensor, dilation sensor, fluid sensor, ion sensor, tissue extension sensor, and combinations thereof. In some embodiments, the medical treatment includes material selected from the group of radioactive material, chemotherapy material, biological material, small molecule drug material, and combinations thereof. In alternative embodiments, the medical treatment is configured to treat a local gastric condition or a systemic condition. In other embodiments, the medical implant includes bioresorbable material. In some embodiments, the medical implant is selected from the group of PPI/H2 blockers, pain medication, cardiac medication, antihypertensives agents, insulin, hypoglycemic agents, antipsychotic medications birth control medications, pH sensor with or without antacid secretion, vascular sensor for oxygen, vascular sensor for carbon dioxide, vascular sensor for glucose, vascular sensor for blood pressure, sensor for defibrillation, cardiac rate sensor, cardiac rhythm sensor, medications to stimulate vagus nerve, or the like.

[007] In some embodiments, an endoscopic treatment method includes introducing an endoluminal device into a lumen of a patient without creating an incision in integument of the patient, engaging a wall of the lumen with an end effector of the endoluminal device to form a plication, and activating the end effector to secure the plication with an anchor object and a treatment device, wherein the treatment device is coupled with the anchor object. In some embodiments, the treatment device includes a drug delivery device, a biological stimulation device, or is configured to treat a local gastric condition or a systemic medical condition. In some embodiments, the treatment device includes material selected from the group of radioactive material, chemotherapy material, biological material, small molecule drug material, and combinations thereof. In other embodiments, the treatment device includes a feeding tube, a bioresorbable material, or a drug. In some embodiments, the anchor object further includes an attachment device for removably coupling the treatment device. In some embodiments, the attachment device is selected from the group of a hook, magnet, loop, and combinations thereof.

[008] In alternative embodiments, a non-invasive endosurgical device includes an endoluminal device having a longitudinally extending flexible shaft, a distal end of the longitudinally extending flexible shaft configured to engage tissue to be treated, a needle coupled with the distal end for piercing tissue, and a barb configured on the needle such that tissue pierced with the needle remains on the needle. In some embodiments, a distal tip of the needle defines a hole therethrough for receiving suture material or a plurality of holes defined in a distal tip of the needle. In other embodiments, the present invention includes suture material looped through the holes in the needle such that the suture material forms the barb or where the suture material extending through the hole is knotted on one side of the hole to form the barb.

[009] In alternative embodiments, a non-invasive endosurgical device includes an endoluminal device having a longitudinally extending flexible shaft having a distal end, a first arm and a second arm positioned near the distal end and configured to approximate together and deploy an implant, and a tissue grasper. In some embodiments, the tissue grasper includes a longitudinal flexible shaft having a proximal end and a distal end, a handle near the proximal end of the flexible shaft having a slidable member, an inner rod coupled between the slidable member and graspers configured near the distal end and a

rigid receiver near the distal end configured to receive the graspers, wherein when a user slides the slidable member proximally the graspers approximate as they are retracted into the rigid receiver. In some embodiments, the graspers further include hooks for attaching to tissue to be retracted and can be fabricated from a polymer material, a metal, an alloy, or shape memory metal. In some embodiments, the graspers are about 3.5 cm in length.

[0010] According to some embodiments, an endoluminal treatment method includes introducing an endoluminal device into a lumen of a patient without creating an incision in the patient, engaging a wall of the lumen with an end effector of the endoluminal device, forming a first plication in the wall of the lumen with the end effector, forming a second plication in the wall of the lumen with the end effector, the second plication being adjacent the first plication, and coupling the first plication with the second plication to thereby form a first double plication wherein an open pocket is formed between the first plication and the second plication. In some embodiments, after forming the first plication, the plicated tissue is pierced with a needle of the end effector and retained on the needle. Next, the second plication is pierced with the needle, and an implant is deployed to fix the first plication with the second plication and form the double plication. In other embodiments, a second double plication is formed adjacent the first double plication, wherein a second open pocket formed by the second double plication and the open pocket formed by the first double plication are axially aligned. In some embodiments, an artificial biological tube is formed by aligning multiple double plications such that open pockets formed by the multiple double plications axially align. In some embodiments, the first double plication is coupled with the second double plication.

[0011] In some embodiments, the artificial biological tube is formed in the stomach of a patient and fixes tissue of an anterior wall of the stomach to a posterior wall of the stomach on a lesser curve of the proximal stomach, such that when food passes through the tube and the tube stretches a sensation of fullness or satiety is induced. In alternative embodiments, the double plication is positioned near the gastro-esophageal-junction such as to function as an artificial gastric valve.

[0012] In some embodiments of the present invention, an endoluminal GERD treatment method includes introducing an endoluminal device into a lumen of a patient without creating an incision in the patient and engaging a wall of the lumen with an end effector of the endoluminal device to form two adjacent plications in the wall of the lumen near the gastro-esophageal-junction such that an artificial biologic tube is formed between the two adjacent plications and distal to the gastro-esophageal-junction to block gastric fluid from interfering with tissue of the esophagus. In some embodiments, a plurality of the two adjacent plications are formed and extend axially from near the gastro-esophageal-junction into the stomach. In some embodiments, the artificial biologic tube is between about 0.5 cm and about 5 cm in length or between about 0.5 cm and about 3 cm in diameter.

[0013] According to some embodiments of the present invention, an endoluminal obesity treatment method includes introducing an endoluminal device into a stomach of a patient without creating an incision in the patient and engaging a wall of the stomach with an end effector of the endoluminal device. Next, two adjacent plications are formed in the wall of the stomach such that an artificial biologic tube is formed between the two adjacent plications to thereby reducing a volume of the stomach to treat obesity. In some embodiments, a plurality of the two adjacent plications are formed in the wall of the stomach, wherein the plurality of the two adjacent plications are substantially axially aligned. In some embodiments, the plications are positioned distal to the patient's gastro-esophageal-junction such that a pouch of stomach tissue remains between the gastro-esophageal-junction and the artificial biologic tube. In alternative embodiments, the artificial biologic tube is between about 0.5 cm and about 10 cm in length, between about 1 cm and about 8 cm in length, between about 0.2 cm and about 5 cm in diameter, and/or between about 0.5 cm and about 3 cm in diameter. According to some embodiments, the artificial biologic tube is formed by fixing tissue of an anterior wall of the stomach to a posterior wall of the stomach on a lesser curve of the proximal stomach, such that when food passes through the tube and the tube stretches a sensation of fullness or satiety is induced.

[0014] According to other embodiments of the present invention, an endoluminal treatment method includes introducing an endoluminal device into a lumen of a patient

through a body cavity, forming a first plication from a first portion of a wall of the lumen by a first manipulation of the endoluminal device, attaching a suture to the first plication, forming a second plication from a second portion of the wall of the lumen by a second manipulation of the endoluminal device, attaching the suture to the second plication, and tightening the suture such that the first plication and the second plication are approximated. In some embodiments, the lumen is a lumen of a stomach of the patient and tightening of the suture and approximating the first and second plications reduces a volume within the lumen. According to some embodiments, the approximated plications augment a gastro-esophageal junction of a stomach of the patient and are positioned in the stomach and between about 2 cm and about 5 cm from the gastro-esophageal junction. In alternative embodiments, the volume of the reduced lumen is between about 5 mL and about 20 mL and in other embodiments, the volume of the reduced lumen is between about 10 mL and about 15 mL. According to some embodiments, the volume of the reduced lumen has an opening to a remaining portion of the hollow organ of between about 5 mm and about 15 mm in an average cross-sectional dimension.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 shows a schematic view of an endoluminal surgical device according to an embodiment of the present invention;

[0016] FIG. 2 shows a schematic view of a tissue engaging end effector of an endoluminal surgical device according to an embodiment of the present invention;

[0017] FIG. 3 shows an implanted device according to an embodiment of the present invention;

[0018] FIGS. 4A and 4B show implanted devices according to other embodiments of the present invention;

[0019] FIG. 5 shows a device positioned on an end effector prior to implantation according to an embodiment of the present invention;

[0020] FIG. 6 shows a tissue plication including an implanted device according to an embodiment of the present invention;

[0021] FIG. 7 shows another device positioned on an end effector prior to implantation according to an embodiment of the present invention;

[0022] FIG. 8 shows another tissue plication including an implanted device according to an embodiment of the present invention;

[0023] FIG. 9 shows yet device positioned on an end effector prior to implantation according to an embodiment of the present invention;

[0024] FIG. 10 shows another tissue plication including an implanted device according to an embodiment of the present invention;

[0025] FIG. 11 shows an implanted device according to another embodiment of the present invention;

[0026] FIG. 12 shows an end effector with a tissue plication formed on a needle of the end effector according to an embodiment of the present invention;

[0027] FIG. 13 shows an end effector with multiple tissue plications formed on a needle of the end effector according to an embodiment of the present invention;

[0028] FIGS. 14A-14C show embodiments of a tissue plication and corresponding open tissue pocket according to embodiments of the present invention;

[0029] FIG. 15 shows a distal end of an endoluminal device according to an embodiment of the present invention;

[0030] FIG. 16 shows another distal end of an endoluminal device according to an embodiment of the present invention;

[0031] FIG. 17 shows another distal end of an endoluminal device according to an embodiment of the present invention;

[0032] FIG. 18 shows a suture pusher according to an embodiment of the present invention;

[0033] FIG. 19 shows a cross-sectional plan view of plications formed within a hollow organ according to an embodiment of the present invention;

[0034] FIG. 20 shows yet another cross-sectional plan view of plications formed within a hollow organ according to an embodiment of the present invention;

[0035] FIG. 21 shows a further cross-sectional plan view of plications formed within a hollow organ according to an embodiment of the present invention;

[0036] FIG. 22 shows another cross-sectional plan view of plications formed within a hollow organ according to an embodiment of the present invention;

[0037] FIG. 23 shows another cross-sectional plan view of plications formed within a hollow organ according to an embodiment of the present invention;

[0038] FIG. 24 shows another cross-sectional plan view of plications formed within a hollow organ according to an embodiment of the present invention;

[0039] FIGS. 25A and 25B show a further cross-sectional plan views of plications formed within a hollow organ according to an embodiment of the present invention;

[0040] FIG. 26 shows a side view of a hollow organ following approximation of plications formed intraluminally according to an embodiment of the present invention;

[0041] FIG. 27 shows a tissue grasper according to an embodiment of the present invention;

[0042] FIG. 28 shows a distal end of a tissue grasper according to an embodiment of the present invention;

[0043] FIG. 29 shows a tissue grasper in association with an end effector according to an embodiment of the present invention;

[0044] FIG. 30 shows varying embodiments of needles for piercing tissue according to embodiments of the present invention;

[0045] FIG. 31 shows a needle with suture threaded through distal holes in the needle according to embodiments of the present invention;

[0046] FIG. 32 shows a tissue fixation device implanted on tissue according to embodiments of the present invention;

[0047] FIG. 33 shows a suture clip according to an embodiment of the present invention; and

[0048] FIG. 34 shows another view of a suture clip according to an embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0049] The present invention provides methods and devices for manipulate tissue, closing incisions, repairing fistulas, and the like in a hollow organ by accessing the tissue through a body orifice. The tissue of a hollow organ, such as for example, the stomach, can be manipulated to generate a fold or plication and a suture based tissue anchoring implant can be implanted to maintain the manipulated character of the tissue. In some embodiments, after the tissue is manipulated into several folds or plications, the suture

based implants are drawn together to position the folds in a predetermined orientation with respect to each other and result in restructuring the volume of the lumen. In some embodiments, a drug or device can also be introduced into the lumen of the organ and implanted or attached to the organ wall with a suture based implant. In some embodiments, multiple plications can be linearly aligned with respect to each other such as to form an artificial biological tube. Devices are also disclosed for manipulating the tissue in accord with the methods of the present invention.

[0050] An endoluminal device 100, such as that shown in FIG. 1 and disclosed in U.S. Patent No's. 6,835,200; 6,821,285; 6,773,441; 6,663,639; 6,506,196; and 6,494,888, and U.S. Published Application No's. 2005/0033328; 2004/0194790; 2004/0193194; 2004/0193193; 2004/0193184; 2004/0193117; 2002/0193816; and U.S. Provisional patent application no. 60/741,510 filed December 1, 2005, the disclosure of each is hereby incorporated by reference in its entirety, is utilized in the present invention to manipulate tissue of a patient. Generally, the endoluminal device 100 is configured such that it can be positioned within a hollow organ by entry through a body cavity opening, such as for example, positioning the device into the stomach via the mouth of a patient. Once introduced into the patient, the device is capable of manipulating tissue and implanting objects or devices.

[0051] Referring to FIG. 1, endoluminal surgical device 100 is shown according to an embodiment of the present invention. Endoluminal surgical device 100 includes a generally longitudinal and flexible shaft 102, an end effector 200 configured near the distal end of flexible shaft 102, and control mechanisms configured near the proximal end of flexible shaft 102. End effector 200, shown in FIG. 2, includes first arm 202 and second arm 204. First arm 202 and second arm 204 are configured to engage tissue and implant anchor object 220. According to some embodiments, anchor object 220 generally includes pledgets 222 and 224 which, according to some embodiments, are connected by suture 226. Generally anchor object 220 is configured to fix tissue and provide an increased surface area for approximating tissue over traditional tissue fixations such as staples or suture alone. In use, first arm 202 and second arm 204 are positioned with respect to tissue that is to be manipulated. The arms are manipulated by actuating controls on proximal end 104 of endoluminal surgical device 100. When first

arm 202 and second arm 204 are actuated, they move toward each other and tissue positioned between the arms is engaged and pierced with needle 206. In some embodiments, end effector 200 includes retractor for retracting tissue into range of first arm 202 and second arm 204. Endoluminal surgical device 100, end effector 200, and anchor object 220 are further disclosed in the referenced patent publications and patent applications incorporated herein by reference. As described in further detail in the publications and applications incorporated herein by reference, anchor object can be constructed from any biocompatible material, such as, but not limited to, stainless steel, cobalt chromium, titanium, alloys of such metals, biocompatible polymers, soluble polymers, non-soluble polymers, swellable polymers, absorbable polymers, suture material, bioresorbable suture, bioabsorbable suture, combinations thereof, or the like.

[0052] Referring now to FIG.3, endoluminal surgical device 100 is utilized to manipulate tissue 320 of a hollow organ, such as for example the stomach, and form plications, such as plication P1. Plication P1 is formed by gathering or manipulating tissue 320 of the wall of the organ with end effector 200 into a fold and piercing the folded tissue 320 with needles 206 of end effector 200. As needles 206 pierce the tissue of the first plication P1, suture material 312 is pushed through the tissue and first pledget 222 is deployed.

According to an embodiment, one end of suture 312 is attached to pledget 222 and the other end of suture 312 remains free and outside the patient. According to an alternative embodiment, both ends of suture 312 remain free and outside the patient's body. Pledget 222 can be loosely attached or securely attached to suture 312 by a knot, a suture clip, being integral with suture 312, combinations thereof, or the like. Following implantation of pledget 222, second pledget 224 is preferable positioned with respect to suture 312 outside the body and introduced into the hollow organ with endoluminal device 100. Second pledget 224 is then moved into the hollow organ and endoluminal device 100 is manipulated to form a second fold of tissue or plication P2. Second plication P2 is then pierced with needle 206, thereby pushing suture 312 through plication P2 and bringing second pledget 224 into position adjacent a side of plication P2. Following positioning of pledgets 222 and 224, suture 312 is tightened such that plication P1 and plication P2 are drawn together. Preferably, pledget 222 and pledget 224 are positioned on opposing sides of plication P1 and P2, respectively. In an alternative embodiment, pledget 222 and

second pledget 224 are positioned on the same side of plication P1 and plication P2, respectively.

[0053] After suture 312 is tightened such that plication P1 and plication P2 are approximated together, suture 312 is fixed. According to alternative embodiments, suture 312 can be either removably fixed or irremovably fixed to hold plication P1 and plication P2 in position. Suture 312 can be fixed with a knot, a suture clip, fused together, combinations thereof, or the like. Furthermore, a predetermined pressure can be applied through the tightening of suture 312 such as to generate a predetermined treatment condition between the plications. According to some embodiments, this procedure is performed in the stomach of a patient. According to a preferred embodiment of treating a stomach condition, plication P1 and plication P2 are formed approximately 2 cm from gastro-esophageal junction (GEJ) 310. According to alternative embodiments, plication P1 and plication P2 are formed between about 2 cm and about 5 cm from GEJ 310.

[0054] According to alternative embodiments, pledgets 222 and 224 may or may not be used to form plications P1 and P2, respectively. It should be appreciated that depending on a condition to be treated, tissue type being treated, location of treatment, size or area to be treated, combinations thereof, and the like, pledgets 222 and 224 may not be necessary, thereby, simply using suture 312 to form plications P1 and P2 and tighten plications P1 and P2 together. In some embodiments, multiple pledgets can be implanted adjacent one another such as to treat a large tissue disturbance, such as a large incision, re-incision, necrotic site, fistula, combinations thereof, or the like.

[0055] In some embodiments, a patch 318 can be introduced with endoluminal device 100 into the organ to be treated. Patch 318 can be associated with a tissue engaging portion of the device and placed on the wall of the organ 320 when the tissue engaging portions grasp the wall to form the plication. In some embodiments, patch 318 is coupled with a plication, such as plication P2, through pledget 224. According to alternative embodiments, patch 318 can be attached at a plurality of locations to the wall of the organ. Patch 318 can increase the integrity of the organ. In some embodiments, patch 318 includes therapeutic agents such as, for example, antibiotics, drugs, inhibiting agents, anti-inflammatory agents, combinations thereof, and the like. The therapeutic agents can

be coated on patch 318 or they can be dispersed throughout the material that forms patch 318. Patch 318 can also be fabricated from non-absorbable or bio-resorbable materials. [0056] In alternative embodiments, patch 318 can include a medical treatment such as, but are not limited to, PPI/H2 blockers associated with the medical implant; electrodes for gastric stimulation/electrical blockage of contraction; pain medication; cardiac medication, antihypertensives agents, insulin, hypoglycemic agents, and the like; antipsychotic medications; birth control medications; pH sensor with or without antacid secretion; GPS-like locator for people who get lost (e.g., Alzheimer's, etc.); vascular sensor for oxygen, carbon dioxide, glucose, blood pressure, and the like; sensor for defibrillation; cardiac rate/rhythm sensor that can stimulate vagus nerve to increase heart rate if necessary; combinations thereof; and the like.

[0057] According to another embodiment as shown in FIGS. 4A and 4B, patch 318 can be implanted onto tissue 320 with multiple attachments. According to some embodiments as shown in FIG. 4A, patch 318 can be located or held in position by coupling retractors 404A – 404D to tissue 320 and/or patch 318. In some embodiments, as shown in FIG. 4B, implant 318 may be such a shape or dimension that multiple anchor objects 220 are required for proper or secure attachment of implant 318 to tissue 320. As shown in FIG. 4B, multiple anchors 408A – 408D are implanted through tissue 320 and implant 318 to affix implant 318 as desired to tissue 320. According to some embodiments, anchors 408A – 408D include pledgets, such as pledgets 222 and 224 and suture 226.

[0058] Referring now to FIG. 5, end effector 200 is shown having second arm 204 configured with implant 318 associated with needle 206 through suture 226. In some embodiments implant 318 can be, but is not limited to, a drug delivery device, such as for example a delayed delivery material, delayed absorbable drug eluding material, selectively drug permeable material or membrane, time release delivery device, combination thereof, or the like. In alternative embodiments, implant 318 can be, but is not limited to a stimulator device, such as for example, an electrical stimulation device, mechanical stimulation device, vibratory device, sound stimulation device, ultra-sound stimulation device, combinations thereof, or the like. In some embodiments, the stimulation device can be configured to stimulate a sense of a patient. In a preferred

embodiment, the sense stimulated by the stimulation device can be a sense of satiety in the patient such that the patient's desire for eating is subsided. In further alternative embodiments, implant 318 can be, but is not limited to, a sensory device, such as for example, a device to monitor pH, pressure, temperature, salinity, hydration, cellular activity, protein levels, glucose levels, insulin levels, hormone levels, biological function, biological secretion, cellular uptake, cellular secretion, combinations thereof, and the like. In further embodiments, implant 318 can be, but is not limited to, a device to control biological activity, such as for example, inter or intra cellular pH, temperature, salinity, cellular function, cellular excretion, cellular uptake, glucose levels, insulin levels, combinations thereof, and the like. In alternative embodiments, suture 226 can be resorbable suture material or non-resorbable suture material.

[0059] According to FIG. 6, implant device 318 is shown implanted with respect to tissue 320 of a patient. According to an embodiment, tissue 320 can be stomach wall tissue 604 and stomach mucosa 602 and formed into plication 620. Plication 620 is affixed with an anchor object that includes pledgets 222 and 224. In some embodiments, pledgets 222 and 224 can be coupled together with a tee bar 608 and suture 226 and in other embodiments pledgets can be coupled together with suture 226. According to some embodiments, as shown in FIG 6, implant 318 can be integral with pledget 224, coupled with pledget 224, or removable coupled with pledget 224. In some embodiments, the coupling between pledget 224 and implant 318 can be degradable over a predetermined time such that implant 318 can become detached from pledget 224. According to other embodiments, implant 318 can be any of the implant devices, sensors, drugs, drug delivery devices, monitors, control devices, combinations thereof, and the like that are described herein and/or incorporated into this application by reference.

[0060] Referring now to FIG. 7, end effector 200 is shown having first arm 202 configured to couple with implant 318. Implant 318 further includes an affixing portion 716 for engaging with needle 206 and coupling thereto to bind tissue therebetween. In some embodiments, implant 318 can be any of the implant devices described herein or incorporated herein by reference. In other embodiments, suture 226 and pledget 224 can be fabricated according to other embodiments described herein or incorporated herein by reference.

[0061] According to FIG. 8, a plication 820 can be formed from a tissue wall or lining 320. Plication 820 is formed from binding tissue 320 with an anchor object that includes pledgets 222 and 224. In some embodiments, pledgets 222 and 224 can be coupled with suture 226 and tee bar 808. According to some embodiments, implant 318 can be implanted with anchor object by coupling implant 318 between tissue wall 320 and pledget 222. In some embodiments, the tips of needles 206 are configured to break upon activation of the device 100, and thereby form suture retaining t-bars as described in more detail herein.

[0062] According to other embodiments, as shown in FIG. 9, implant 318 can be implanted on a tether 916 such that implant 318 is relatively affixed to tissue but not rigidly affixed to any particular tissue. According to FIG. 9, needle 206 of second arm 204 includes suture 226 attached with pledget 224 for affixing tissue into a plication and suture 226 extends further beyond pledget 224 and couples with implant 318. According to such embodiments, implant 318 is implanted into a patient and affixed into a general location, however, implant 318 is semi-free to move within patient to the extent of tether 916 provided between pledget 224 and implant 318. FIG. 10 shows tethered implant 318 in an implanted position with respect to a tissue plication 1020. According to some embodiments, tether 916 can be an extension of suture material 226 used to secure the anchor object.

[0063] Referring now to FIG. 11, anchor implant 220 includes a coupling 1102 and pledgets 222 and 224 coupled together by suture 226. Anchor implant 220 is configured to couple tissue 320 to itself or to an implanted device. According to some embodiments, coupling 1102 is configured to provide a site on anchor implant 220 for attaching an implantable device, mechanical tool, drug eluding device, sensor, other device described or incorporated herein, combinations thereof, or the like. In some embodiments, coupling 1102 can be, but is not limited to a hook, clip, Velcro, magnet, loop, combinations thereof, or the like. According to some embodiments, coupling 1102 can be formed from a non-resorbable polymer, resorbable polymer, biodegradable polymer, drug eluding polymer, stainless steel, titanium, cobalt chromium, surgical material, combinations thereof, or the like.

[0064] Referring now to FIGS. 12-14, an open pocket or biologic tube is formed between multiple plications. In FIG. 12, end effector 200 is used to form a first plication 1206. Plication 1206 is formed by grasping tissue with retractor 1214 and manipulating first arm 202 and second arm 204 together such that needle 206 pierces the tissue. Suture 226 is associated with needle 206 such that suture 226 is pierced through tissue with needle 206. After piercing the tissue with needle 206, the tissue is retained on needle 206. In some embodiments, suture 226 is positioned through a hole in needle 206, as described herein, such that a quantity of suture material 226 forms a barb on one side of needle 206 (shown in FIG. 31). The barb can function to hold tissue on needle 206 after needle 206 has been penetrated through a first quantity of tissue. In other embodiments, the barb can be a loop of suture material 226, a knot tied in suture material 226 on one side of needle 206, or the like.

[0065] Referring now to FIG. 13, while first tissue plication 1206 remains on needle 206, retractor 1214 is used a second time to grasp a second portion of tissue to form second plication 1302. By forming two adjacent plications 1206 and 1302, an open pocket 1304 is formed therebetween. In some embodiments, an implant 1306 is housed in open pocket 1304.

[0066] In some embodiments, end effector 200 can have multiple retractors 1214 such that two plications can be formed simultaneously. In other words, a first retractor can grasp tissue and form a first plication while a second retractor grasps other tissue and forms a second plication. Next, the two plications can be anchored together such that an open pocket 1304 is formed therebetween. In yet other embodiments, tissue graspers are introduced into the surgical site percutaneously for grasping tissue and manipulating it into adjacent plications that form the tube or open pocket 1304. In some embodiments, the tissue graspers pull tissue around the flexible shaft 102 of the surgical device 200 and position the tissue for implantation of the anchor object. Next, an anchor object is implanted to fasten the plications around the shaft of the surgical device. After the desired number of plications are fixed around the shaft of the surgical device, the end effector 200 is straightened such as to be axially aligned with shaft 102 and the shaft 102 and end effector 200 are removed through the open pocket 1304 of the tissue plications.

leaving behind open pocket 1304, or as shown in FIGS. 14B and 14C artificial tissue tube 1450.

[0067] According to some embodiments, as shown in FIG. 14A, tissue 320 that forms an open pocket 1304 between plications 1206 and 1302 may be tissue that requires treatment. According to such embodiments, implant 1306 positioned in pocket 1304 is configured to treat tissue 320. In other embodiments, tissue 320 can be removed following the double plication procedure described with respect to FIGS. 12-14. In other embodiments, tissue 320 may dissolve or resorb following the double plication procedure.

[0068] In other embodiments, multiple double plication procedures, such as the double plication procedure described with respect to FIGS. 12-14 can be performed on adjacent tissue, in the same organ, or the like. In some embodiments, as shown in FIGS. 14B-14C axially aligned double plications 1440, 1442, 1444, and 1446 can be positioned adjacent to each other such that each open pocket 1304, formed between the double plications 1440, 1442, 1444, and 1446, is generally axially aligned and forms an artificial biological tube 1450. In some embodiments, artificial biological tube 1450 is formed by drawing each double plication together. In some embodiments, each plication 1440, 1442, 1444, and/or 1446 can be drawn together using surgical glue, suture material, surgical wire, staples, scoring the tissue such that the tissue reforms together, combinations thereof, or the like.

[0069] In some embodiments, linearly aligned double plications 1440, 1442, 1444, and 1446 are positioned, beginning at or distally near the gastro-esophageal-junction (GEJ) 1452 and extend into the stomach, thereby forming an artificial GEJ or gastric tube 1450. In some embodiments, when the artificial gastric tube is flaccid, *i.e.*, empty, the artificial gastric tube acts as a gastric flap or valve for protecting the esophagus from gastric fluids. Thus, the formation of such an artificial gastric tube can be a treatment for gastro-esophageal reflux disorder (GERD). In other embodiments, the formation of an artificial gastric tube can be a technique for gastric reconstruction or reduction surgery. According to such embodiments, the formation of such an artificial gastric tube effectively reduces the volume of the stomach of a patient, and thereby, stimulates the stomach into providing a sense of satiety with consumption of a smaller amount of food. In some

embodiments, the gastric tube forms a sleeve gastropasty by fixing tissue of the anterior wall to the posterior wall on the lesser curve or proximal stomach, such that when food passes through the sleeve and the sleeve stretches the sensation of fullness or satiety is induced.

[0070] According to some embodiments, between 1 and about 10 plications are positioned adjacent each other to form artificial tube 1450. In other embodiments, between 1 and about 8 plications are positioned adjacent each other to form artificial tube 1450. In yet other embodiments, between 1 and about 5 plications are positioned adjacent each other to form artificial tube 1450. In yet other embodiments, between 1 and about 3 plications are positioned adjacent each other to form artificial tube 1450. In still other embodiments, a single plication is positioned adjacent the GEJ to form artificial tube 1450 or GERD treatment. According to other embodiments, between about 5 and about 8 plications are positioned adjacent each other to form artificial tube 1450.

According to some embodiments, when artificial tube 1450 is formed with between one and two tissue plications, artificial tube 1450 is about 1 cm in length. In other embodiments, when artificial tube 1450 includes between about 10 to about 20 tissue plications, artificial tube 1450 is about 10 cm in length. In some embodiments, the diameter of artificial tube 1450 is between about 0.2 cm and about 10 cm. In other embodiments, the diameter of artificial tube 1450 is between about 0.5 cm and about 5 cm. In some embodiments, the diameter of artificial tube 1450 is between about 0.5 cm and about 3 cm. In some embodiments, the diameter of artificial tube 1450 is between about 0.5 cm and about 2 cm. According to some embodiments, linear placement of multiple plications 1440, 1442, 1444, and 1446 can be utilized to close an incision in a tissue wall, such as for example, following abdominal or thoracic surgery accessed through the gastric wall, colon, intestine, or esophagus as in N.O.T.E.S. procedures.

[0071] Referring now to FIGS. 15-18, a distal end 90 of the endoscope device is shown. Distal end 90 includes needles 91 and 92 which include holes 88 for receiving suture material. As shown in FIG. 15, needles 91 and 92 each receive separate suture material 94 and 96, respectively. FIG. 16 shows distal end 90, needles 91 and 92, suture 94 and 96, and pledget 222. According to such embodiments, suture 94 is looped through needle 91 and is secured through a pair of openings 102 in pledget 222. Another strand of

suture, suture 96 is looped through the second needle 92 and passes through a third hole 103 in pledget 222. In use, pledget 222 is positioned with respect to a plication and suture 94 and 96 is pierced through the plication. The free end of suture 96 extends outside of the patient's body for receiving a second pledget as described herein. FIG. 17 shows another embodiment of the present invention, wherein suture 94 and 96 both loop through pledget 222, through their respective needles 91 and 92 of distal end 90 and extend out of the patient's body for further manipulation. FIG. 18 shows a knot pusher 110 that can be utilized to tighten and secure suture 226 affixed between plications.

[0072] The present invention also discloses methods for restricting a hollow organ. Referring to FIG. 19, a single suture crisscross loop is shown. Plications P1 and P2 are formed similar to the methods described with respect to FIG. 3 and elsewhere herein, however, suture 226 is crossed. According to methods where suture 226 is crossed, plications P1 and P2 are twisted or rotated during tightening of suture 226. In some embodiments twisting or rotation of plications P1 and P2 result in a predetermined interface between plications P1 and P2.

[0073] Referring now to FIG. 20, double suture circular loop methods are disclosed. According to double suture circular loop methods, plications P1 and P2 are formed similar to those described with reference to FIG. 3, however, each plication P1 and P2 is formed with a pledget 222 and 224, respectively, attached to an independent loop of suture 226 and 227, respectively. According to methods using individual suture loops 226 and 227, for respective plications P1 and P2, each plication can be tightened independently of the other. Therefore, each plication P1 and P2 can be tightened and treated independently as needed, then plications P1 and P2 can be brought into contact with each other and subjected to a third independent tightening when suture loop 226 and 227 are tightened together and fixed.

[0074] According to FIG. 21, methods of the present invention also include forming plications P1 and P2 through the use of straight strands of suture material. According to such embodiments, pledget P1 is formed by manipulating tissue into a fold and piercing the tissue with needle 206 and suture 226 affixed to pledget 222. Similarly, but independently, plication P2 is formed by manipulating tissue into a fold and piercing through the fold with suture 227 attached to pledget 224. After formation of plication P1

and P2, suture 226 and suture 227 are tightened such that plications P1 and P2 are approximated together. According to alternative embodiments, pledgets 222 and 224 can be positioned on similar sides of plications P1 and P2 or on opposing sides. Pledgets positioned on opposing sides of plications P1 and P2 are shown in FIG. 22.

Approximating plications P1 and P2 together reduces the volume of the hollow organ, such as the stomach, as shown in FIG. 26.

[0075] According to alternative embodiments, disturbed tissue of the hollow organ, such as resected tissue or fistulas tissue can be treated with methods of the present invention. Referring to FIG. 23, plications P1 and P2 are affected with resections 66 and 68, respectively. Resections 66 and 68 can be, but are not limited to, intentional tissue resections, resection from removal of a tumor, fistulas, resection from removal of necrotic tissue, combinations thereof, and the like. According to methods of the present invention, plications P1 and P2 are formed, as described in any of the methods described herein. Preferably, suture 226 and pledgets 222 and 224 are positioned such that when suture 226 is tightened, resections 66 and 68 of plications P1 and P2, respectively, will be brought into contact with each other. Methods such as these presently described methods assists in healing of plications P1 and P2 together following their approximation. Therefore, in such embodiments, suture 226 and pledgets 222 and 224 can be absorbable, such that they are dissolved by the body tissue after a predetermined implant period. According to other embodiments, suture 226 and pledgets 222 and 224 can be non-absorbable, and the healing of resections 66 and 68 to each other provides additional support to the adjoined plications.

[0076] Referring now to FIG. 24, methods of forming and adjoining multiple plications are shown. According to such methods, multiple plications, P1, P2, P3, and P4 can be formed with a single suture 226. All plications P1-P4 will be drawn together upon tightening of suture 226. According to methods with a plurality of plications, a hollow organ, such as the stomach for example, can be approximated together in a uniform manner. According to embodiments for forming plications in the stomach tissue, it is preferable to form the plications in regions of the stomach not adjacent the heart such that the chance of injuring heart tissue is reduced.

[0077] Referring now to FIGS. 25A and 25B, other embodiments of the present invention include methods of forming multiple plications P1-P4 with multiple suture 226 and 227. According to such embodiments, plications P1-P4 are formed in accord with methods described herein, however, plications P1 and P2 are connected with suture 226 and plications P3 and P4 are connected with suture 227, which is independent from suture 226. FIG. 25A shows sutures 226 and 227 implanted but not tightened and FIG. 25B shows the tissue after the plications P1-P4 are tightened. According to FIG. 25A, plications P1 and P3 are formed with suture 226 threaded there through with pledgets 2521 and 2523, respectively, abutting plications P1 and P3. Plications P2 and P4 are formed with suture 227 threaded there through with pledgets 2522 and 2524, respectively, abutting the plications P2 and P4. According to FIG. 25B, suture 226 can be tightened such that plication P1 and P3 are brought into position adjacent each other with pledgets 2521 and 2523 on opposite sides of their respective plications. Similarly, suture 227 can be tightened such that plication P2 and P4 are drawn together resulting in pledgets 2522 and 2524 being on opposite of their respective plications. According to such embodiments, plications P1 and P3 can be formed at a first distance from GE junction 10 and plications P2 and P4 can be formed at a second distance from GE junction 10. According to such embodiments, when plications P1 and P3 are approximated together and plications P2 and P4 are approximated together, the respective plications do not interfere with each other and the hollow organ can be reduced to a predetermined size. According to some embodiments, a distance is left between the sets of plications.

[0078] Referring now to FIG. 26, following implantation of plications P1-P4 as shown in FIGS. 19-25 a hollow organ 2600 is configured with a restricted pouch 2602 via a restriction 2604. According to some embodiments, hollow organ 2600 can be a stomach for example, and restriction 2604 can function as a gastric reduction procedure for treating obesity for example.

[0079] Referring now to FIGS. 27-29, tissue grasper 2700 is shown configured to be used in association with endoluminal device 100. Tissue grasper 2700 includes a proximal end 2702 that remains outside a patient's body and is configured to be operated by a surgeon or other medical provider. Proximal end 2702 includes a slidable member 2704 which

slides over a frame 2706 and is connected to an inner rod 2708. The frame 2708 terminates proximally in a graspable end or handle 2710 for manipulation by the medical provider. Slidable member 2704 also includes graspable portions such as rings 2712 and 2714.

[0080] A flexible shaft 2720 extends from proximal end 2701 and connects the proximal end 2702 with distal end 2722. Flexible shaft 2720 includes an outer housing 2722 that is configured to house inner rod 2708. Flexible shaft 2720 can be, for example, a flexible metal coil or plastic housing. Preferably flexible shaft 2720 is compatible with biological solutions and tissues such that flexible shaft 2720 is not degraded or affected by interaction with the biological solutions or tissues.

[0081] Referring now to FIG. 28, distal end 2724 of flexible shaft 2720 includes a rigid receiver 2730 and graspers 2726 and 2728. Rigid receiver 2730 forms the distal most portion of flexible shaft 2708 and includes a longitudinal opening through which inner rod 2708 and/or graspers 2726 and 2728 can pass. Graspers 2726 and 2728 couple with or are integral with inner rod 2708 on a proximal end and are angled or hooked on a distal working end to form tissue hooks 2727, 2729 to grasp tissue.

[0082] Graspers 2726 and 2728 are fabricated from flexible material such that graspers 2726 and 2728 can flex and be approximated together. Graspers 2726 and 2728 further include tissue hooks 2727 and 2729, respectively, for attaching to tissue. In some embodiments, graspers 2726 and 2728 are fabricated from a polymer based material, a metal, combinations thereof, or the like. According to a preferred embodiment, graspers 2726 and 2728 are fabricated from memory metal such as nickel-titanium alloys. In use, when rings 2712 and 2714 of the slidable member 2704 are moved toward handle 2710, inner rod 2708 is pulled proximally and because inner rod 2708 is coupled with or integral with graspers 2726 and 2728, the graspers are pulled proximally the same distance. As graspers 2726 and 2728 are pulled proximally they retreat into rigid receiver 2730 and are forced to approximate. In use, prior to retracting the graspers into rigid receiver 2730, the distal end of tissue grasper 2700 is positioned with respect to tissue such that tissue hooks 2727 and 2729 become attached to tissue to be treated. Next, the medical provider moves rings 2712 and 2714 proximally, thereby retracting and approximating graspers 2726 and 2728 into rigid receiver 2730 and retracting and

approximating tissue attached to tissue hooks 2727 and 2729. When the tissue to be treated is appropriately retracted and approximated with the tissue grasper 2700, the medical provider then activates end effector 200 which engages first arm 202 with second arm 204, piercing the tissue with the needles and suture, deploying the anchor implant and thereby retaining tissue in the approximated position. To release tissue that is attached to tissue hooks 2727 and 2729, the user pushes rings 2712 and 2714 distally, thereby moving graspers 2726 and 2728 distally, relaxing the grasped tissue and releasing it from tissue hooks 2727 and 2729.

[0083] According to some embodiments, tissue grasper 2700 can be used independently of endoluminal surgical device 100 such as through a trocar/cannula surgical port. In preferred embodiments, the tissue grasper 2700 is used in combination with endoluminal surgical device 100 and introduced endoluminally into the lumen of an organ needing treatment, such as shown in FIG. 29. End effector 200 includes a port 2902 between first arm 202 and second arm 204 through which distal end of tissue grasper 2700 passes. Therefore, in use, when tissue is retracted and approximated with tissue hooks 2727 and 2729 the tissue is positioned within the proper working space of first arm 202 and second arm 204 for implantation of a tissue anchor as described herein. In other embodiments, the tissue grasper 2700 can be used through an opening in an endoscope or along side the endoluminal surgical device or endoscope. Methods of using the tissue graspers 2700 include approximating two portions of tissue that are between about 2 centimeter and about 5 centimeter and need to be approximated before end effector 200 can effectively deploy the anchor implant. The tissue grasper 2700 also help present full tissue thickness, such as for example stomach mucosa and muscle tissues to the end effector 200 for secure implantation of the anchor object. According to some embodiments, the total length of the tissue grasper 2700 is about 50 inches, the graspers 2726 and 2728 open about 1.5 inches wide, and the graspers are about 0.030 inches in diameter.

[0084] According to some embodiments, tissue graspers 2700 can be used during procedures where tissue of an organ wall is resected, *e.g.*, to removal of a mass or damage in the tissue. During such procedures, perforation of the organ wall can occur, thereby, resulting in an opening in the organ wall that needs closure. The tissue grasper 2700 can then be used to bring together opposite edges of the perforation before

deploying an anchor implant to close the opening. Other procedures the tissue grasper 2700 can be useful in includes restructuring of gastric bypass procedures, such as a ROUX-en-Y procedure. Often after such procedures the pouch of stomach tissue left functional begins to stretch and deform over time and the anastomosis or the pouch adjacent to the anastomosis becomes dilated. The tissue grasper 2700 will be useful in bring together opposite edges of such an anastomosis or pouch before deploying an anchor implant to fix the tissue. Yet another procedure in which tissue grasper 2700 can be useful includes a NOTES (Natural Orifice Transluminal Endoscopic Surgery) procedure in which an incision is made in the stomach, colon, or other orifice to facilitate passage into the abdominal or thoracic cavity. The tissue grasper 2700 will be useful in bring together the opposite edges of the incision through which the NOTES procedure passed for entry into the abdominal or thoracic cavity.

[0085] Referring now to FIGS. 30-31, needle 206 is shown in more detail. It should be appreciated that needles 91, 92, 206, and other needles shown and discussed throughout this application can include the features of needle 206 described in FIGS. 30-31. Needle 206 generally includes holes 88 for receiving suture material, a tissue piercing distal tip 3004, and a scored section 3002. Holes 88 are configured to receive suture material 312, as shown in FIG. 31. The scored section 3002 is configured to break after needle 206 is passed through pledget 222 or 224 when first arm 202 is approximated with second arm 204. After needle 206 passes through pledget 222 or 224, a deflector in second arm 204 deflects the distal tip 3004 of needle 206, which causes the distal tip 3004 to break at scored section 3002. As shown in FIG. 32, when distal tip 3004, containing suture material 312, and is passed through pledget 222 or 224 and caused to break at scored section 3002, distal tip 3004 acts as a T-bar restricting suture material 312 from reversibly passing through the pledget and thereby anchoring tissue between the pledgets 222 and 224.

[0086] In some embodiments, suture 312 is positioned through hole 88 such that a quantity of suture material forms a barb 3102 of suture material on one side of needle 206, as shown in FIG. 31. Barb 3102 can function to hold tissue on needle 206 after needle 206 has been penetrated through a first quantity of tissue, such as described with

respect to FIGS. 12-14. Barb 3102 can be a loop of suture material 312 such as shown in FIG. 31 or a knot tied in suture material 312 on one side of needle 206 or the like.

[0087] Referring now to FIGS. 32, 33, and 34, methods and devices for tightening an anchor implant are shown. According to some embodiments, a pledget based implant as shown in FIG. 32 can be implanted to close an incision, such as incision 3202 in tissue. According to such embodiments, the tissue having the incision or damage to be closed is brought together as a plication with the endoluminal surgical device 100, as described herein. Next, pledgets 222 and 224 are implanted, as described herein, such that suture material 312 couples pledget 222 with pledget 224 and is bound on one side of pledget 222 with distal needle tip 3004. The other end of suture material 312 can include a slip knot 3200 that can remain loose after implanting pledgets onto the tissue and then be tightened to a selected tension when appropriate, such as following completion of the NOTES procedure. One advantage of utilizing the adjustable slip knot type of procedure is to provide the medical provider with the option to close different thicknesses of material and apply different pressures to different closed tissues. According to alternative embodiments, a suture clip, such as suture clip 3300 can be used to tighten suture 312 onto tissue to be closed. FIGS. 33 and 34 show a suture clip 3300 having biasing arms 3302 configured to engage suture material 312 and maintain pressure against tissue to be approximated or closed.

[0088] The foregoing brief descriptions are intended to facilitate the disclosure of embodiments of methods and devices of the present invention. The examples are intended as illustrations only and are in no way intended to limit the breadth of the invention, the scope of which is determined by the appended claims.

EXAMPLES

[0089] Example 1: Endoscopic fistula repair using full-thickness plication in the porcine stomach model.

[0090] Iatrogenic gastric perforations and fistulae often require surgical repair. A durable endoscopic alternative to surgical repair is desirable. In this example, an endoscopic technique is developed and evaluated to repair an iatrogenic gastric perforation using the Full-Thickness Plicator® (NDO Surgical, Mansfield, MA) in the porcine stomach model.

[0091] Gastric perforations of between about 10 mm to 15 mm in length were made along the greater curvature and fundus of 5 excised porcine stomachs. A plicator implant was created whereby suture lengths between pledgets of the implant were about 4 mm long. Using the tissue retractor of the plicator, the gastric wall at the edge of the perforation was retracted into the arms of the plicator. A full-thickness single plication was performed to seal the perforation. Supplemental oxygen was connected to the endoscope to maintain gastric distension when required. Following plication, the integrity of the closure was tested by holding the stomachs vertical and instilling a colored, carbonated liquid through the esophagus to fill and distend the stomach.

[0092] This technique resulted in a full-thickness, transmural suture that provided a secure closure of all gastric perforations up to about 15 mm in length with a single plication. There was no leakage of fluid upon complete distension of the stomach.

[0093] Example 2: Endoscopic creation of a restrictive gastric pouch using full-thickness plication.

[0094] Laparoscopic gastric banding has been successful in treating morbid obesity. The following example provides an endoscopic creation of a restrictive gastric pouch. A durable restrictive gastric pouch was generated endoscopically in a porcine stomach model using the Full-Thickness Plicator® (NDO Surgical, Mansfield, MA).

[0095] Five ex-vivo porcine stomachs were used in this study. A plicator implant was threaded with a 2-0 polypropylene suture through the holes of one of the pledgets of the implant to form a long U-shaped suture. The plicator was loaded with an implant and passed endoluminally into the stomach. Using the tissue retractor, the anterior/fundal gastric wall, roughly 2 cm below the GE junction was retracted and a full-thickness transmural plication performed. After removing the instrument, the suture loop remained through the pledget with both ends of the suture extending outside of the esophagus. One end of the suture was then passed through the pledget holes of a second implant. The plicator was reloaded and a similar plication was performed roughly 2 cm below the GE junction at the posterior/lesser curvature gastric wall. Both ends of the sutures extended outside of the esophagus. This process was repeated with a third and fourth plication at the posterior/fundus and anterior/lesser curvature of the stomach roughly 2 cm below the GE junction. Using an external knot pusher, the first and second plications were

approximated, secured and the suture cut. Similarly, the third and fourth plications were approximated, secured, and the suture cut.

[0096] Figures 25A and 25B show a cross-sectional schematic of the four opposing plications formed endoscopically within the stomach. After creation of the full-thickness plication locations within the stomach, the opposing plications are approximated together to create a gastric pouch, as shown schematically in Figure 26.

[0097] The 4 approximated and secured full-thickness, transmural plications created a durable restrictive gastric pouch. The capacity of the pouch in all 5 porcine stomachs was consistently between about 10-15 ml with the opening diameter between about 8-10 mm.

[0098] Example 3: Endoscopic transmural resection of gastric wall using full-thickness plication.

[0099] Endoscopic mucosal resection allows removal of premalignant mucosal lesions. Lesions invading into the submucosa and muscularis propria were resected endoscopically by transmural resection of the gastric wall using the Full-Thickness Plicator® (NDO Surgical, Mansfield, MA) in the porcine stomach model.

[00100] Five excised porcine stomachs were used in this experiment. A plicator cartridge was created with suture length of about 4 mm between the pledgets. The plicator was inserted into the stomach and the tissue retractor was extended into targeted gastric wall. The gastric cardia was retracted into the open arms of the plicator and a full-thickness plication was created to allow serosa to serosa contact. A stiff snare was used to resect the plicated gastric wall above the implant using electrocautery. The serosa to serosa tissue union was left intact. The excised wall was examined to ensure a full-thickness resection and the size was measured. The integrity of the plication was tested by instilling a colored, carbonated liquid to distend the stomach. A transmural, full-thickness gastric wall resection was achieved in all 5 porcine stomachs. The diameter of the excised specimen ranged from about 2 cm to about 3 cm. The gastric wall was securely closed with no leaks observed after the full-thickness resection was performed.

WHAT IS CLAIMED IS:

1. An endoluminal implant device, comprising:
a tissue anchor implant configured to be implanted into a lumen of a body without creating an incision in integument of the body and wherein the tissue anchor implant is configured to maintain a plication in a wall of the lumen; and
a medical treatment associated with the tissue anchor implant.
2. The implant of claim 1, wherein the medical treatment includes a drug for delivery within the lumen.
3. The implant of claim 1, wherein the medical treatment includes a biological stimulation device or a monitoring device.
4. The implant of claim 3, wherein the biological stimulation device is selected from the group consisting of an electrical stimulation device, mechanical stimulation device, vibratory device, sound device, ultra-sound device, chemical stimulatory device, neurotransmitter stimulation device, thermal stimulation, sensory stimulatory device, and combinations thereof.
5. The implant of claim 3, wherein the monitoring device is selected from the group consisting of a pH sensor, pressure sensor, chemical sensor, hormone sensor, dilation sensor, fluid sensor, ion sensor, tissue extension sensor, and combinations thereof.
6. The implant of claim 1, wherein the medical treatment includes material selected from the group consisting of radioactive material, chemotherapy material, biological material, small molecule drug material, and combinations thereof.
7. The implant of claim 1, wherein the medical treatment is configured to treat a local gastric condition.
8. The implant of claim 1, wherein the medical treatment is configured to treat a systemic condition.
9. The implant of claim 1, wherein the medical implant includes bioresorbable material.
10. The implant of claim 1, wherein the medical implant is selected from the group consisting of PPI/H2 blockers, pain medication, cardiac medication, antihypertensives agents, insulin, hypoglycemic agents, antipsychotic medications birth control medications, pH sensor with or without antacid secretion, vascular sensor for oxygen,

vascular sensor for carbon dioxide, vascular sensor for glucose, vascular sensor for blood pressure, sensor for defibrillation, cardiac rate sensor, cardiac rhythm sensor, medications to stimulate vagus nerve, or the like.

11. An endoscopic treatment method, comprising:

introducing an endoluminal device into a lumen of a patient without creating an incision in integument of the patient;

engaging a wall of the lumen with an end effector of the endoluminal device to form a plication;

activating the end effector to secure the plication with an anchor object and a treatment device, wherein the treatment device is coupled with the anchor object.

12. The method of claim 11, wherein the treatment device includes a drug delivery device.

13. The method of claim 11, wherein the treatment device is configured to treat a local gastric condition or a systemic medical condition.

14. The method of claim 11, wherein the treatment device includes a biological stimulation device.

15. The method of claim 14, wherein the biological stimulation device is selected from the group consisting of an electrical stimulation device, mechanical stimulation device, vibratory device, sound device, ultra-sound device, chemical stimulatory device, neuro-transmitter stimulation device, thermal stimulation, sensory stimulatory device, and combinations thereof.

16. The method of claim 11, wherein the treatment device includes a monitoring device.

17. The method of claim 16, wherein the monitoring device is selected from the group consisting of a pH sensor, pressure sensor, chemical sensor, hormone sensor, dilation sensor, fluid sensor, ion sensor, tissue extension sensor,

18. The method of claim 11, wherein the treatment device includes material selected from the group consisting of radioactive material, chemotherapy material, biological material, small molecule drug material, and combinations thereof.

19. The method of claim 11, wherein the treatment device includes a feeding tube.

20. The method of claim 11, wherein the treatment device includes a bioresorbable material.
21. The method of claim 20, wherein the bioresorbable material includes a drug.
22. The method of claim 11, wherein the anchor object further includes an attachment device for removably coupling the treatment device.
23. The method of claim 22, wherein the attachment device is selected from the group consisting of a hook, magnet, loop, and combinations thereof.
24. The method of claim 11, further comprising before engaging a wall of the lumen with the end effector, engaging a wall of the lumen with a guide wire such that the end effector is guided to a desired location.
25. A non-invasive endosurgical device, comprising:
 - an endoluminal device having a longitudinally extending flexible shaft;
 - a distal end of the longitudinally extending flexible shaft configured to engage tissue to be treated;
 - a needle coupled with the distal end for piercing tissue; and
 - a barb configured on the needle such that tissue pierced with the needle remains on the needle.
26. The non-invasive endosurgical device of claim 25, wherein a distal tip of the needle defines a hole therethrough for receiving suture material.
27. The non-invasive endosurgical device of claim 26, further comprising a plurality of holes defined in a distal tip of the needle.
28. The non-invasive endosurgical device of claim 27, further comprising suture material looped through the holes such that the suture material forms the barb.
29. The non-invasive endosurgical device of claim 26, further comprising suture material extending through the hole and knotted on one side of the hole, wherein the knot forms the barb.
30. A non-invasive endosurgical device, comprising:
 - an endoluminal device having a longitudinally extending flexible shaft, wherein the endoluminal device has a distal end;
 - a first arm and a second arm positioned near the distal end, wherein the first arm and the second arm are configured to approximate together and deploy an implant; and

a tissue grasper comprising:

a longitudinal flexible shaft having a proximal end and a distal end;

a handle near the proximal end of the flexible shaft, wherein the handle includes a slidable member;

an inner rod coupled between the slidable member and graspers configured near the distal end; and

a rigid receiver near the distal end configured to receive the graspers, wherein when a user slides the slidable member proximally the graspers approximate as they are retracted into the rigid receiver.

31. The non-invasive endosurgical device of claim 30, wherein the graspers further comprise hooks for attaching to tissue to be retracted.

32. The non-invasive endosurgical device of claim 30, wherein the grasper comprise a polymer material, a metal, or an alloy.

33. The non-invasive endosurgical device of claim 30, wherein the grasper comprises shape memory metal.

34. The non-invasive endosurgical device of claim 30, wherein the graspers are about 3.5 cm in length.

35. An endoluminal treatment method, comprising:

introducing an endoluminal device into a lumen of a patient without creating an incision in the patient;

engaging a wall of the lumen with an end effector of the endoluminal device;

forming a first plication in the wall of the lumen with the end effector;

forming a second plication in the wall of the lumen with the end effector, the second plication being adjacent the first plication;

coupling the first plication with the second plication to thereby form a first double plication;

wherein an open pocket is formed between the first plication and the second plication.

36. The method of claim 35, further comprising after forming the first plication, piercing the plicated tissue with a needle of the end effector;

retaining the first plication on the needle;

piercing the second plication with the needle; and

deploying an implant to fix the first plication with the second plication and form the double plication.

37. The method of claim 35, further comprising forming a second double plication adjacent the first double plication, wherein a second open pocket formed by the second double plication and the open pocket formed by the first double plication are axially aligned.

38. The method of claim 35, further comprising forming an artificial biological tube by aligning multiple double plications such that open pockets formed by the multiple double plications axially align.

39. The method of claim 37, further comprising coupling the first double plication with the second double plication.

40. The method of claim 38, wherein the artificial biological tube is formed in the stomach of a patient.

41. The method of claim 40, wherein the artificial biological tube fixes tissue of an anterior wall of the stomach to a posterior wall of the stomach on a lesser curve of the proximal stomach, such that when food passes through the tube and the tube stretches a sensation of fullness or satiety is induced.

42. The method of claim 35, wherein the double plication is positioned near the gastro-esophageal-junction such as to function as an artificial gastric valve.

43. The method of claim 35, further comprising coupling an implant device with the first or second plication.

44. The method of claim 43, wherein the implant device is a drug delivery device.

45. The method of claim 43, wherein the implant device is selected from the group consisting of an electrical stimulation device, mechanical stimulation device, vibratory device, sound device, ultra-sound device, chemical stimulatory device, neuro-transmitter stimulation device, thermal stimulation, sensory stimulatory device, and combinations thereof.

46. An endoluminal GERD treatment method, comprising:

introducing an endoluminal device into a lumen of a patient without creating an incision in the patient;

engaging a wall of the lumen with an end effector of the endoluminal device;
forming two adjacent plications in the wall of the lumen near the gastro-esophageal-junction such that an artificial biologic tube is formed between the two adjacent plications and distal to the gastro-esophageal-junction to block gastric fluid from interfering with tissue of the esophagus.

47. The method of claim 46, further comprising forming a plurality of the two adjacent plications extending axially from near the gastro-esophageal-junction into the stomach.

48. The method of claim 46, wherein the artificial biologic tube is between about 0.5 cm and about 5 cm in length.

49. The method of claim 46, wherein the artificial biologic tube is between about 0.5 cm and about 3 cm in diameter.

50. The method of claim 47, further comprising coupling the plurality of plications together.

51. The method of claim 47, wherein the plications are coupled with glue, suture, wire.

52. An endoluminal obesity treatment method, comprising:

introducing an endoluminal device into a stomach of a patient without creating an incision in the patient;

engaging a wall of the stomach with an end effector of the endoluminal device;
forming two adjacent plications in the wall of the stomach such that an artificial biologic tube is formed between the two adjacent plications to thereby reducing a volume of the stomach to treat obesity.

53. The method of claim 52, further comprising forming a plurality of the two adjacent plications in the wall of the stomach, wherein the plurality of the two adjacent plications are substantially axially aligned.

54. The method of claim 52, wherein the plications are positioned distal to the patient's gastro-esophageal-junction such that a pouch of stomach tissue remains between the gastro-esophageal-junction and the artificial biologic tube.

55. The method of claim 52, wherein the artificial biologic tube is between about 0.5 cm and about 10 cm in length.

56. The method of claim 52, wherein the artificial biologic tube is between about 1 cm and about 8 cm in length.
57. The method of claim 52, wherein the artificial biologic tube is between about 0.2 cm and about 5 cm in diameter.
58. The method of claim 52, wherein the artificial biologic tube is between about 0.5 cm and about 3 cm in diameter.
59. The method of claim 52, wherein the plurality of the two adjacent plications are coupled together.
60. The method of claim 59, wherein the coupling includes glue, suture, or wire.
61. The method of claim 52, wherein the artificial biologic tube is formed by fixing tissue of an anterior wall of the stomach to a posterior wall of the stomach on a lesser curve of the proximal stomach, such that when food passes through the tube and the tube stretches a sensation of fullness or satiety is induced.
62. An endoluminal treatment method, comprising:
 introducing an endoluminal device into a lumen of a patient through a body cavity;
 forming a first plication from a first portion of a wall of the lumen by a first manipulation of the endoluminal device;
 attaching a suture to the first plication;
 forming a second plication from a second portion of the wall of the lumen by a second manipulation of the endoluminal device;
 attaching the suture to the second plication; and
 tightening the suture such that the first plication and the second plication are approximated.
63. The method of claim 62, wherein the lumen is a lumen of a stomach of the patient.
64. The method of claim 62, wherein tightening the suture and approximating the first and second plications reduces a volume within the lumen.
65. The method of claim 62, further comprising:
 forming a plurality of plications at substantially the same plane of the lumen.
66. The method of claim 65, further comprising:

attaching pairs of the plurality of plications to each other with a suture.

67. The method of claim 65, further comprising:
tightening the suture connecting pairs of plications independently from other pairs of plications.
68. The method of claim 66, further comprising:
attaching the plurality of plications together with a single suture.
69. The method of claim 62, wherein the approximated plications augment a gastro-esophageal junction of a stomach of the patient.
70. The method of claim 62, wherein the plications are positioned in the stomach and between about 2 cm and about 5 cm from the gastro-esophageal junction.
71. The method of claim 62, wherein the plications are positioned in the stomach and about 2 cm from the gastro-esophageal junction.
72. The method of claim 64, wherein the volume is between about 5 mL and about 20 mL.
73. The method of claim 64, wherein the volume is between about 10 mL and about 15 mL.
74. The method of claim 64, wherein the volume has an opening to a remaining portion of the hollow organ of between about 5 mm and about 15 mm in an average cross-sectional dimension.

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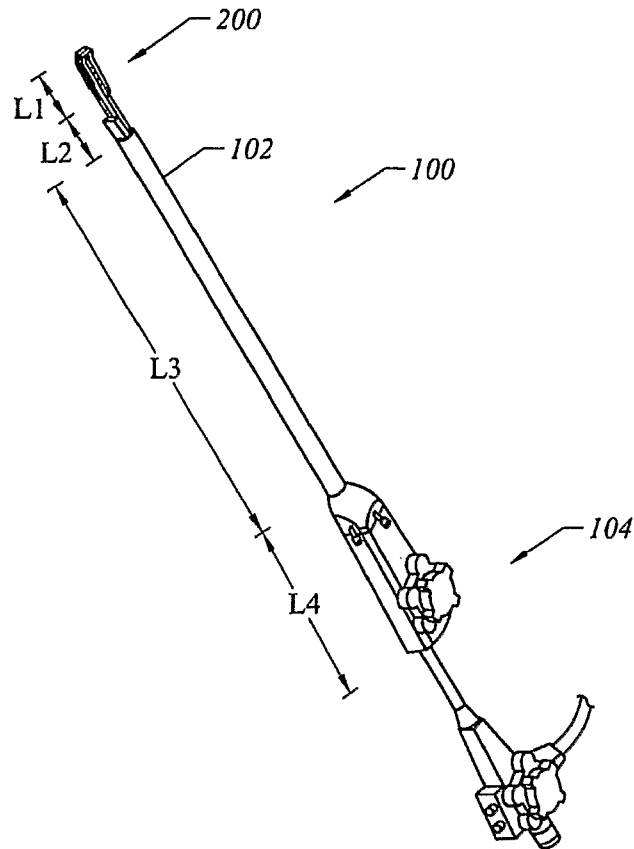


FIG. 1

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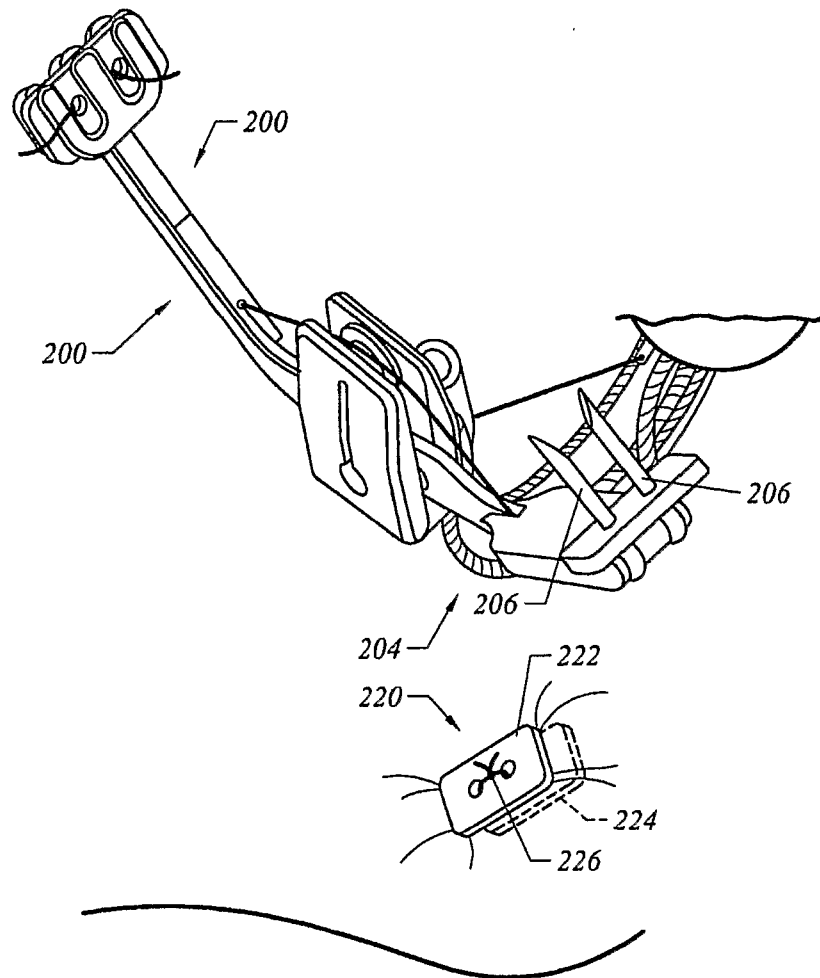


FIG. 2

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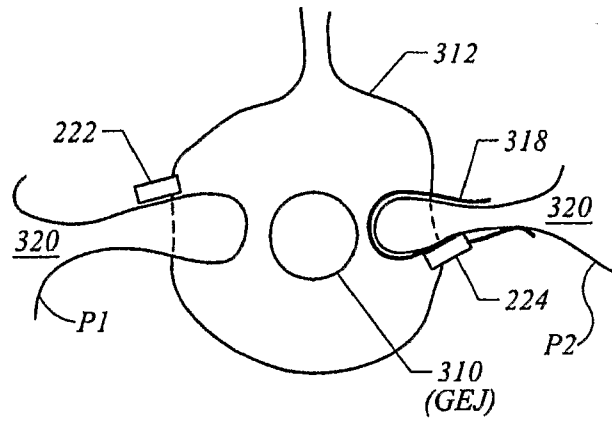


FIG. 3

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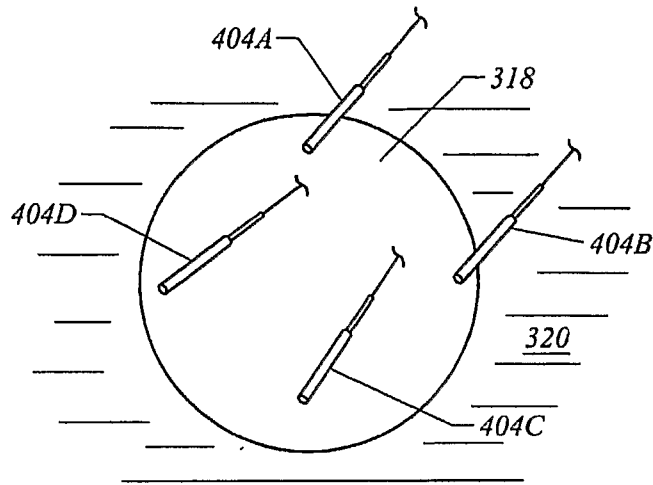


FIG. 4A

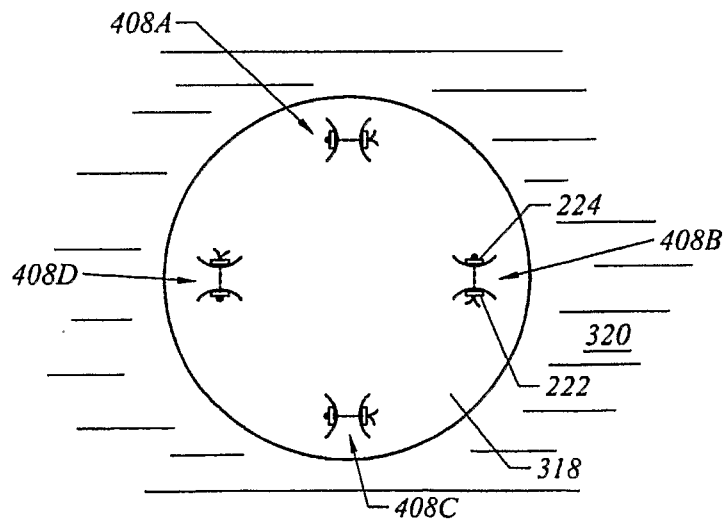


FIG. 4B

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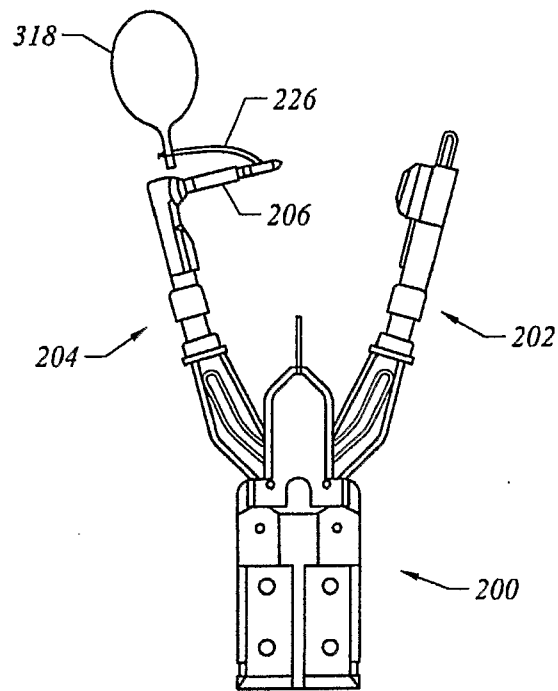


FIG. 5

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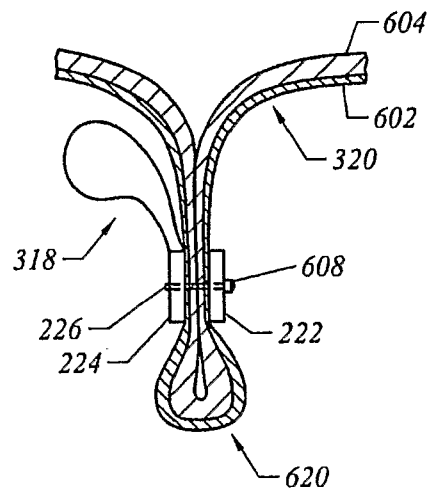


FIG. 6

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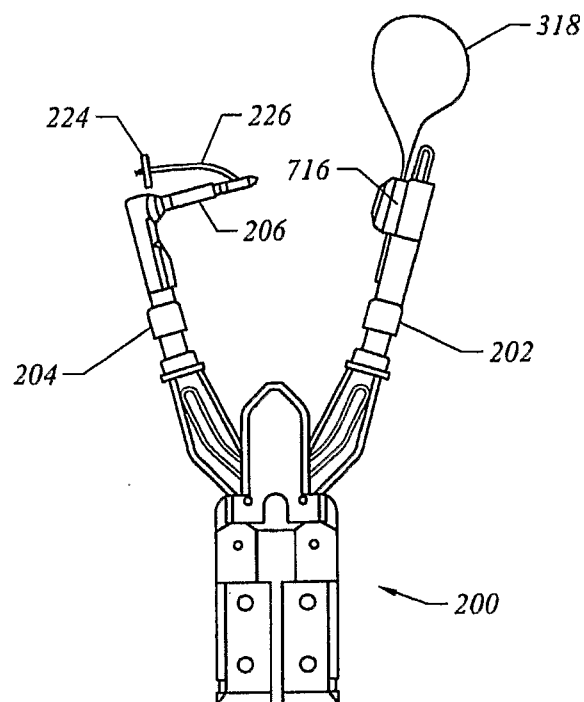


FIG. 7

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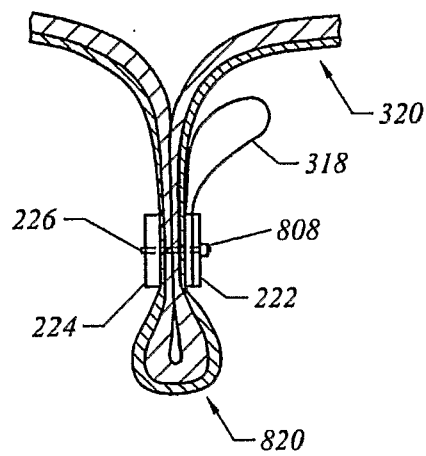


FIG. 8

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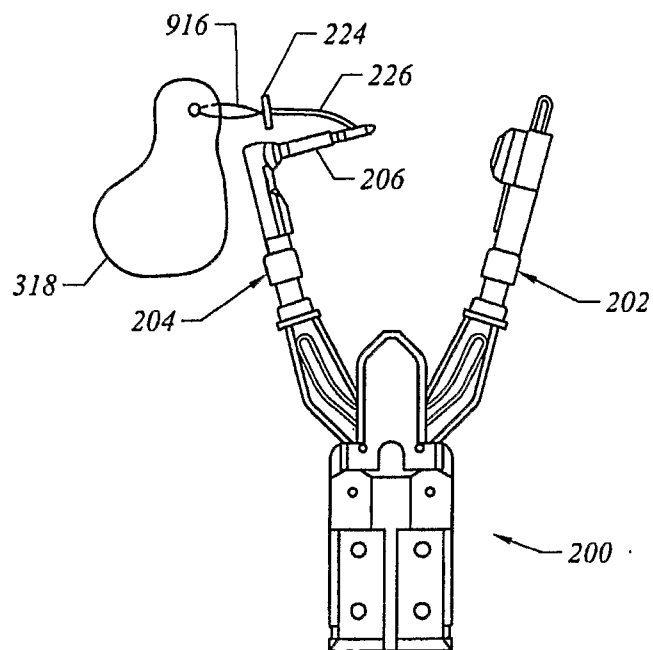


FIG. 9

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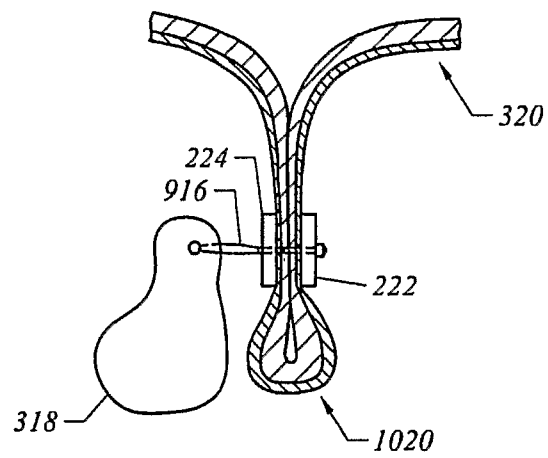


FIG. 10

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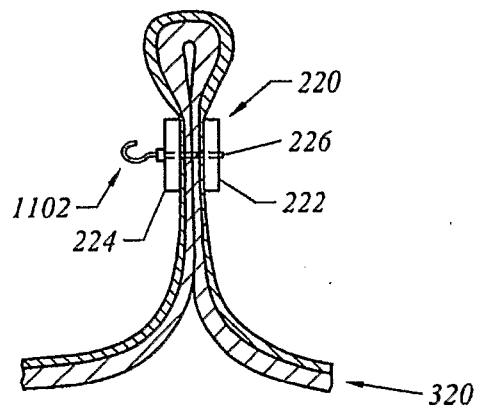


FIG. 11

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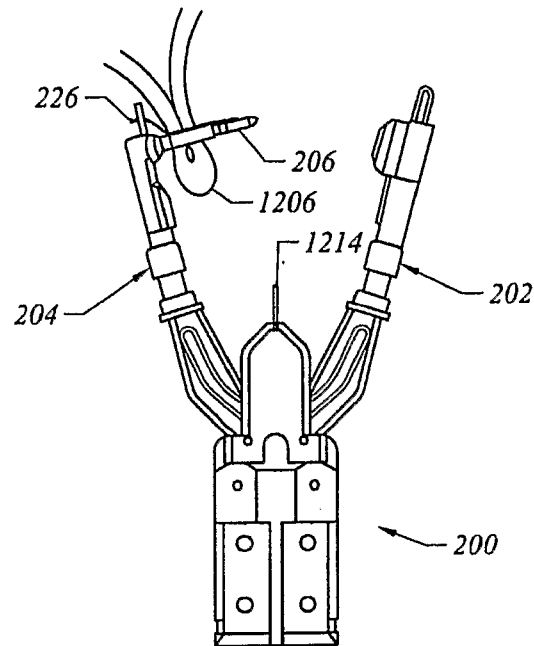


FIG. 12

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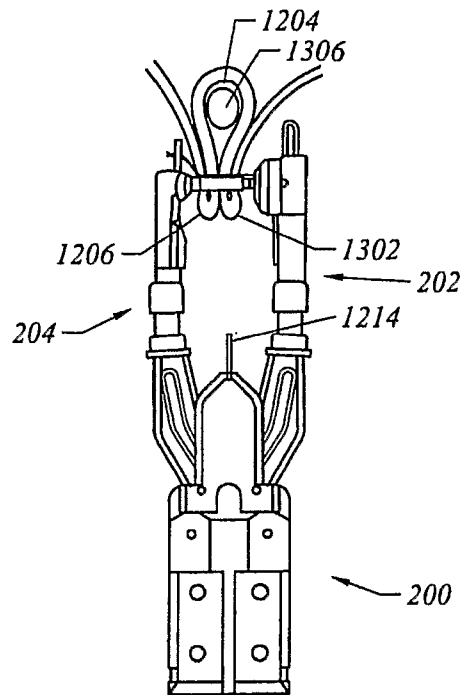


FIG. 13

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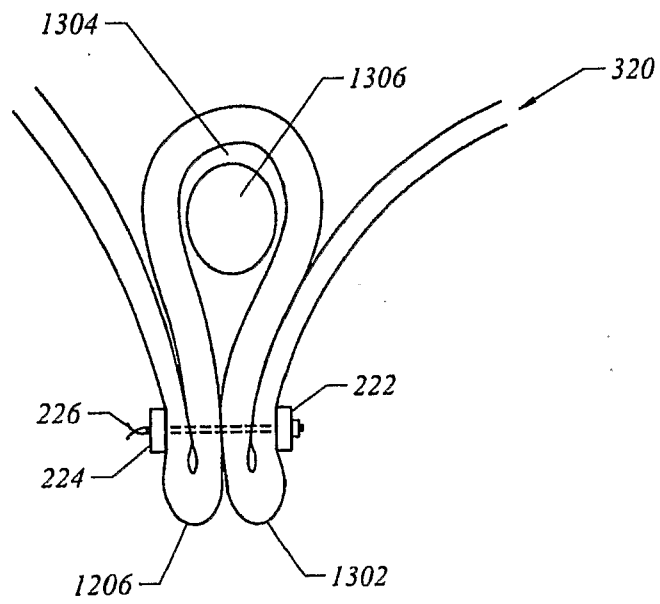


FIG. 14A

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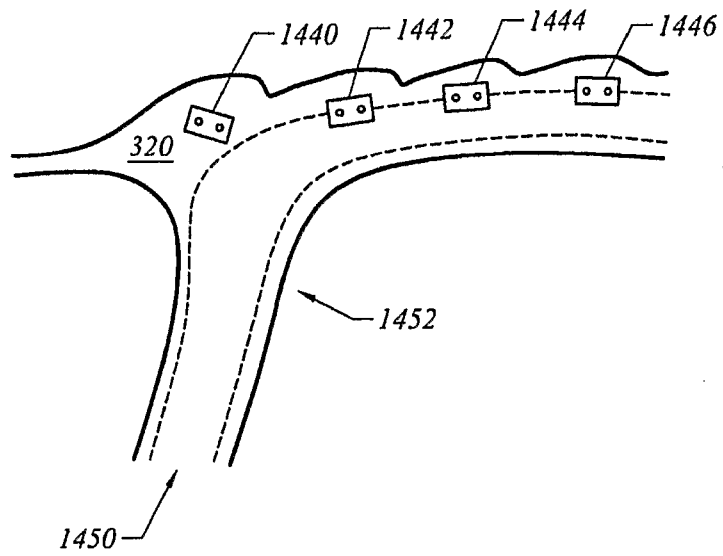


FIG. 14B

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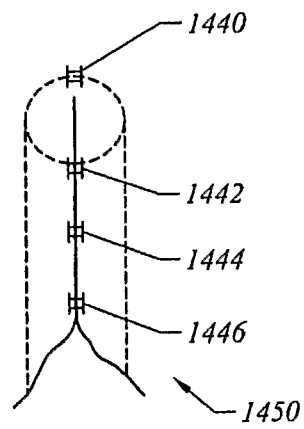


FIG. 14C

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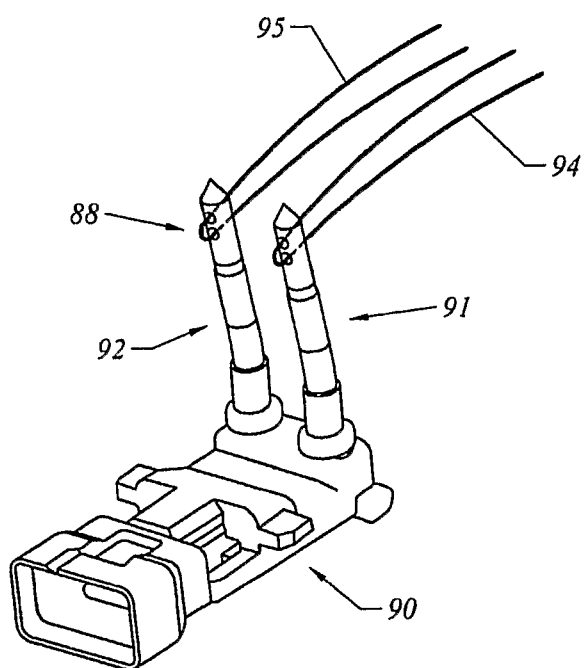


FIG. 15

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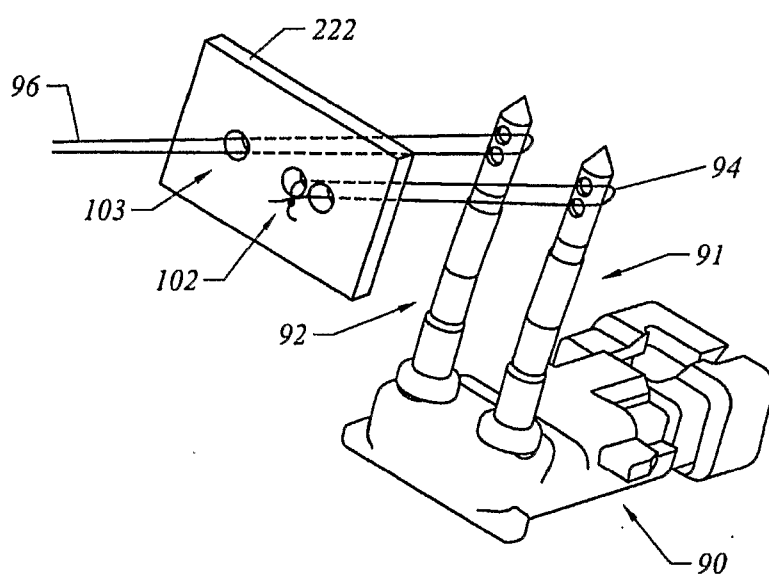


FIG. 16

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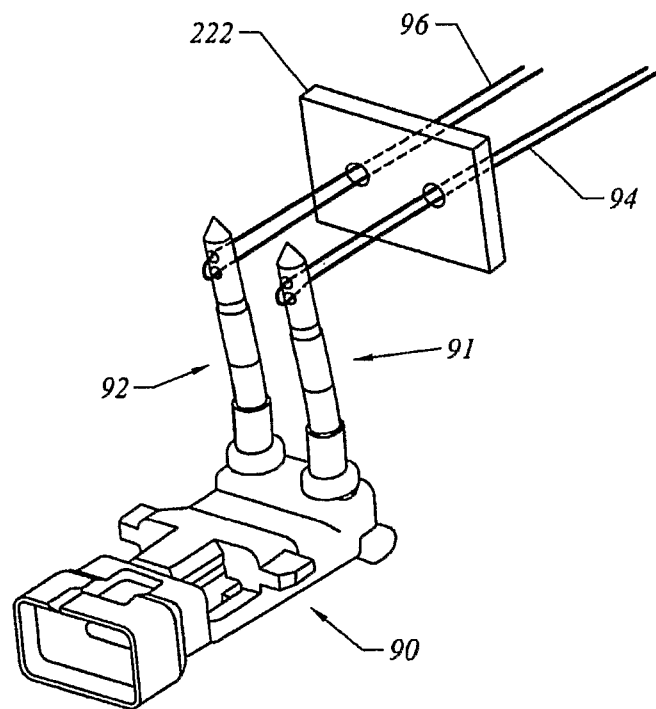


FIG. 17

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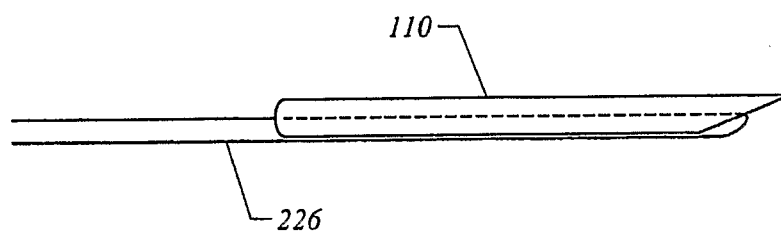


FIG. 18

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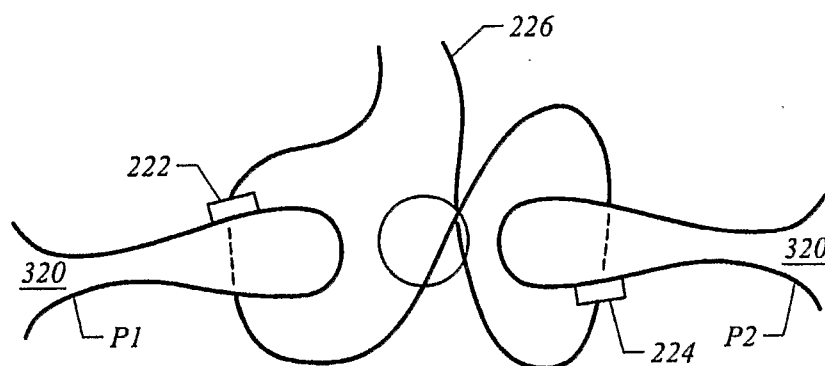


FIG. 19

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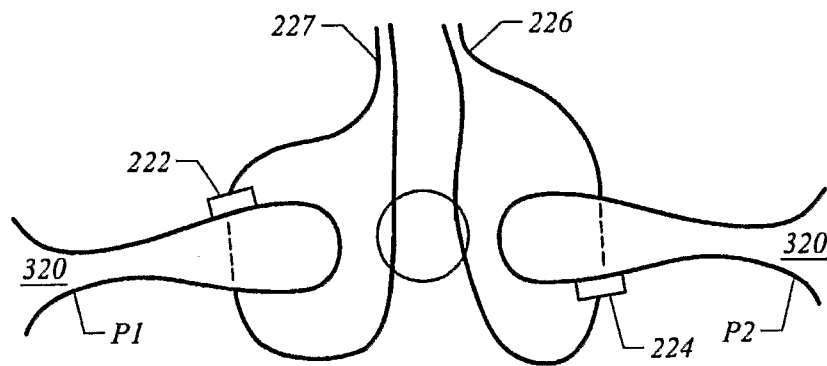


FIG. 20

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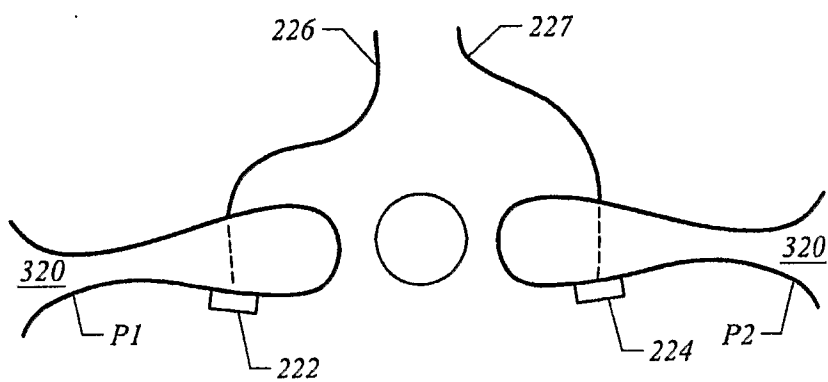


FIG. 21

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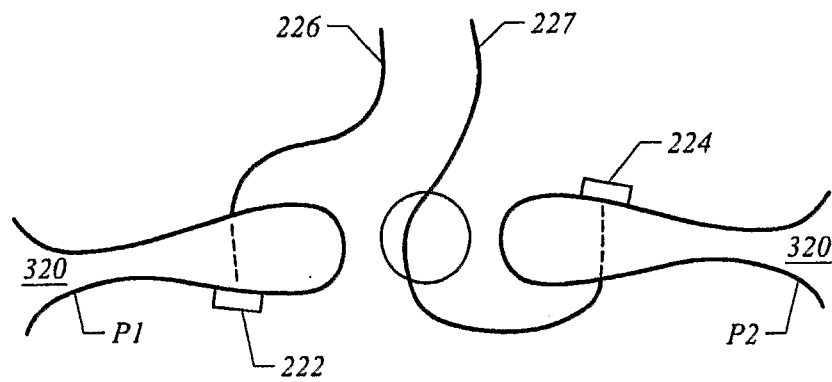


FIG. 22

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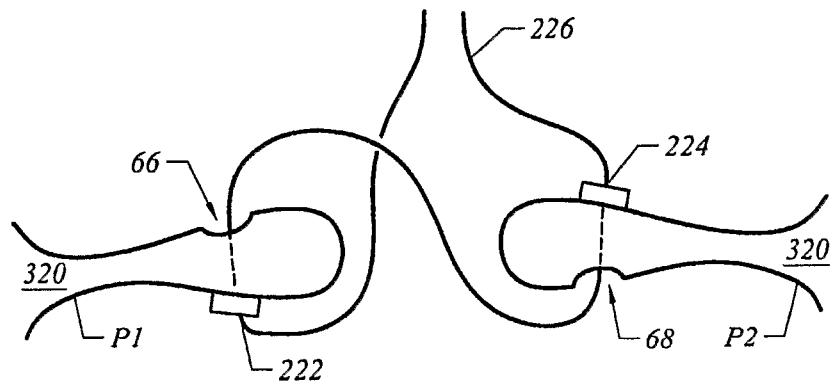


FIG. 23

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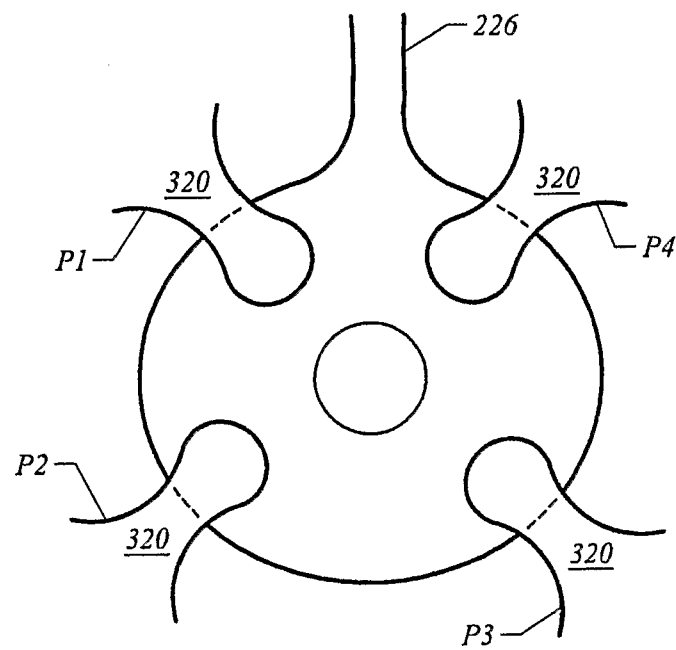


FIG. 24

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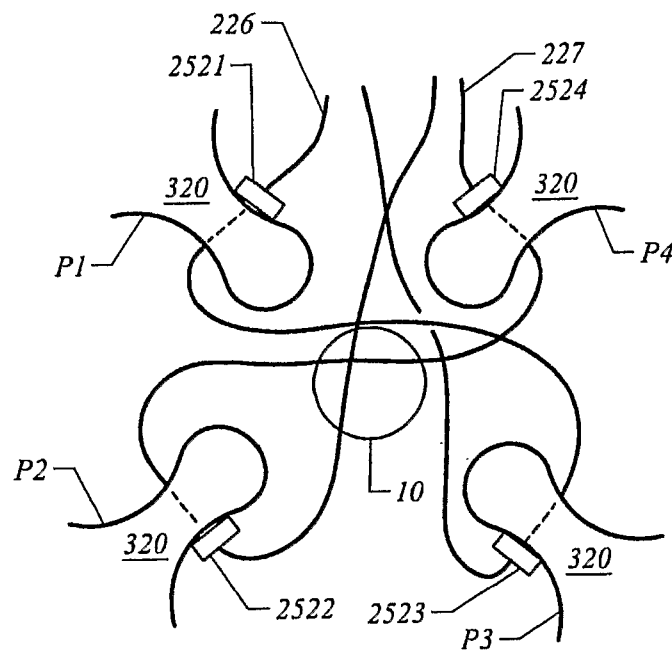


FIG. 25A

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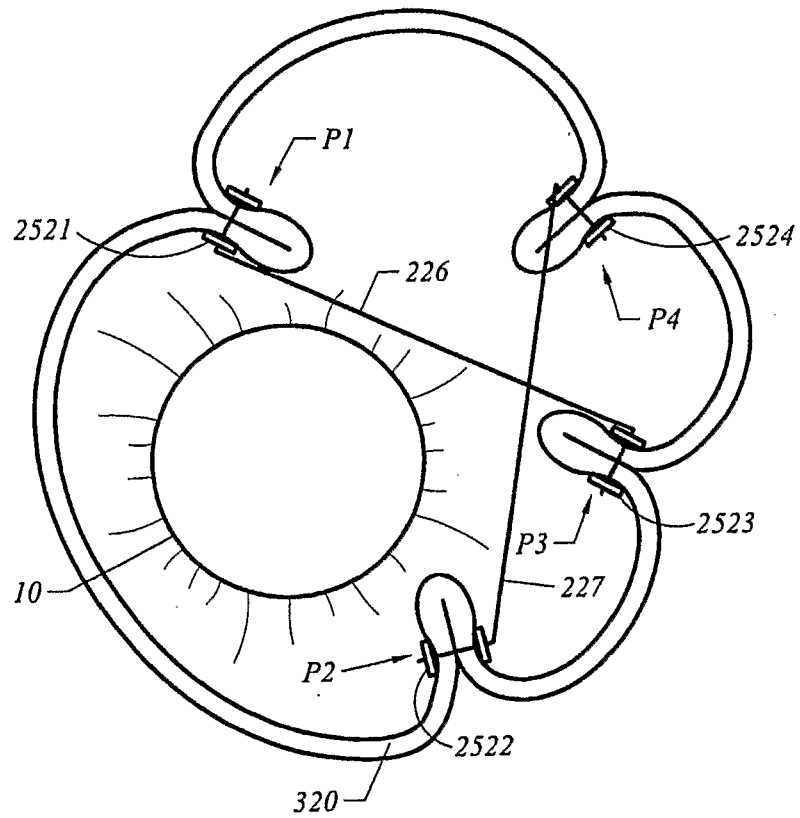


FIG. 25B

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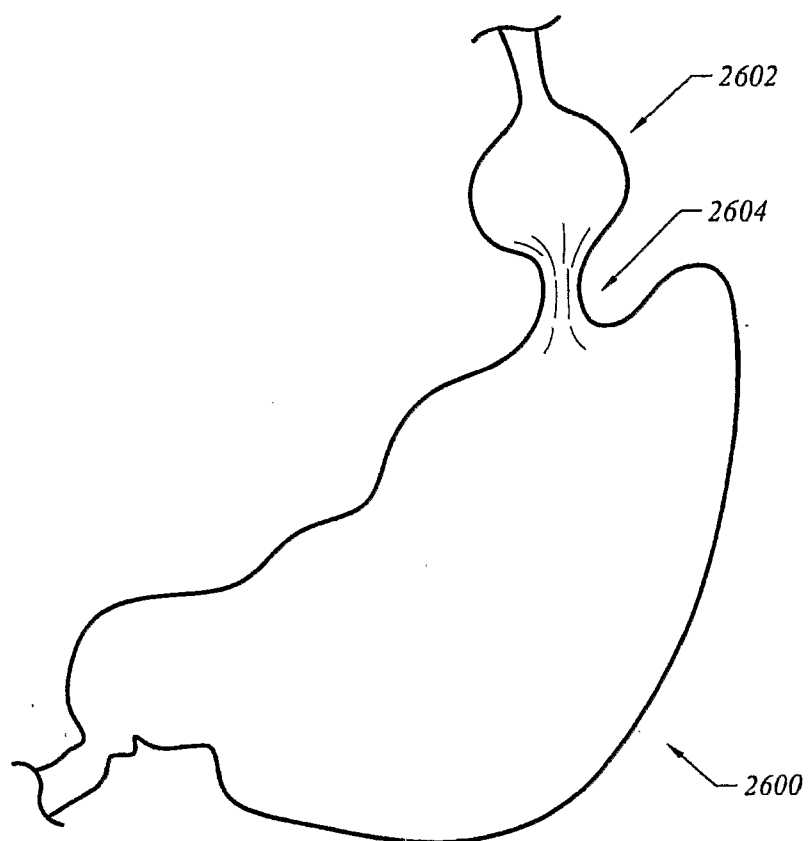


FIG. 26

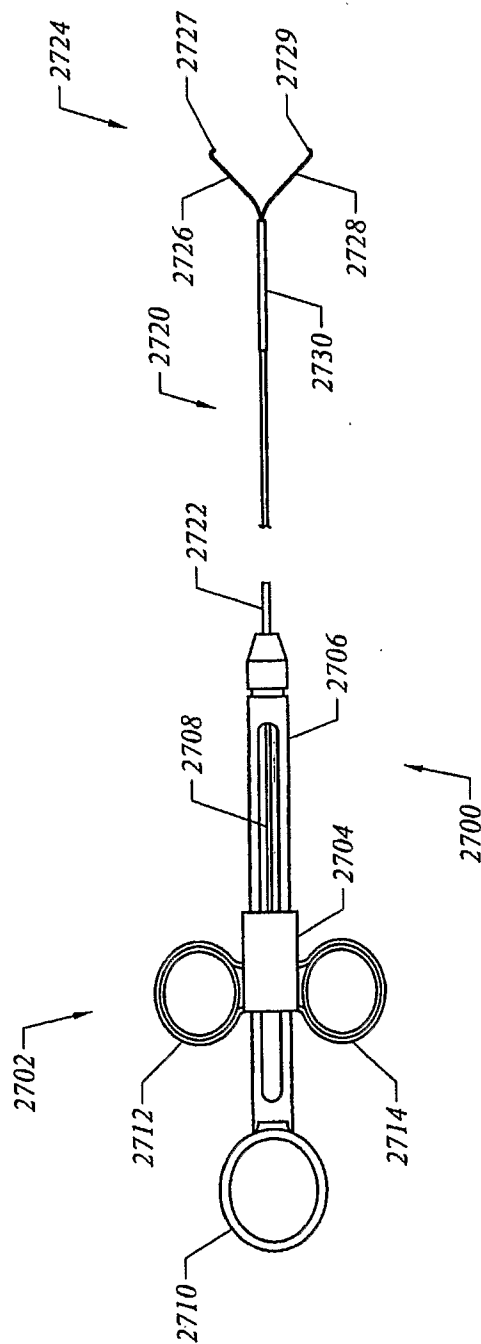


FIG. 27

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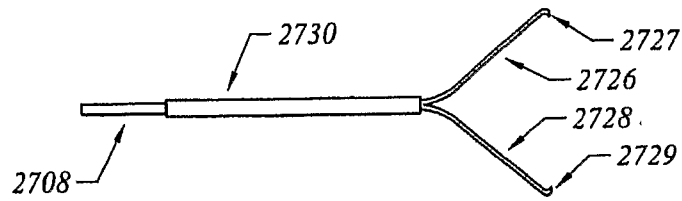


FIG. 28

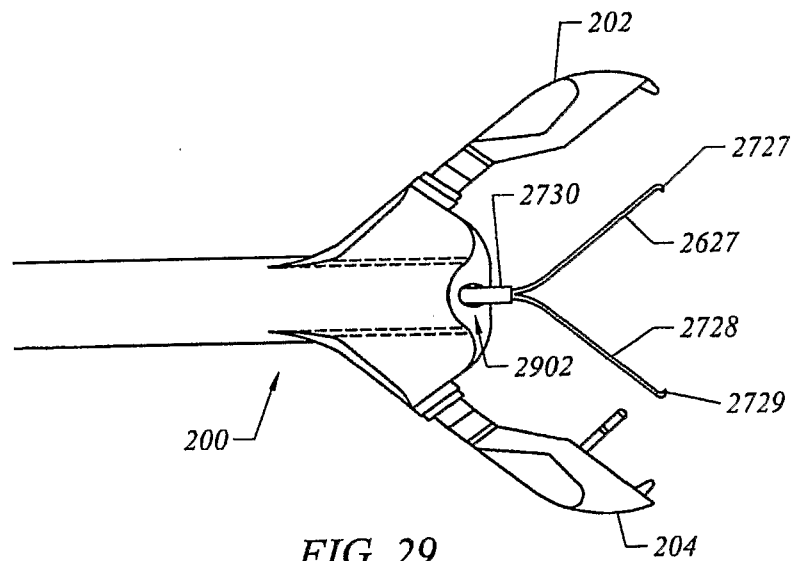


FIG. 29

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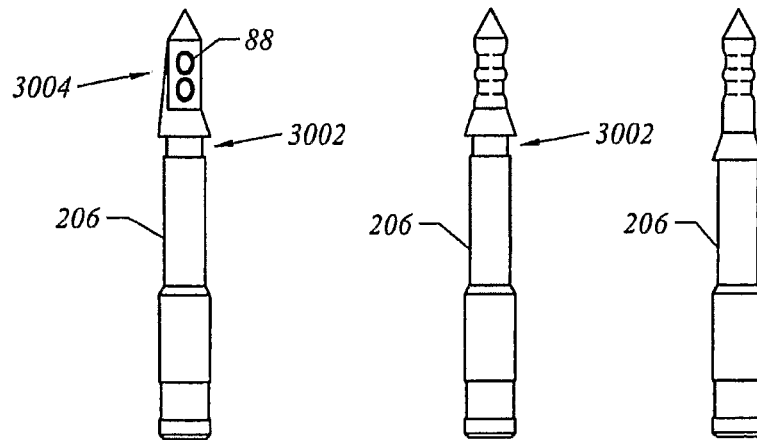


FIG. 30

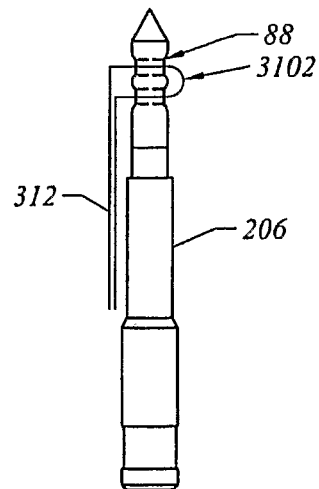


FIG. 31

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