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(54) **METHODS AND APPARATUS FOR REVISION OF OBESITY PROCEDURES**

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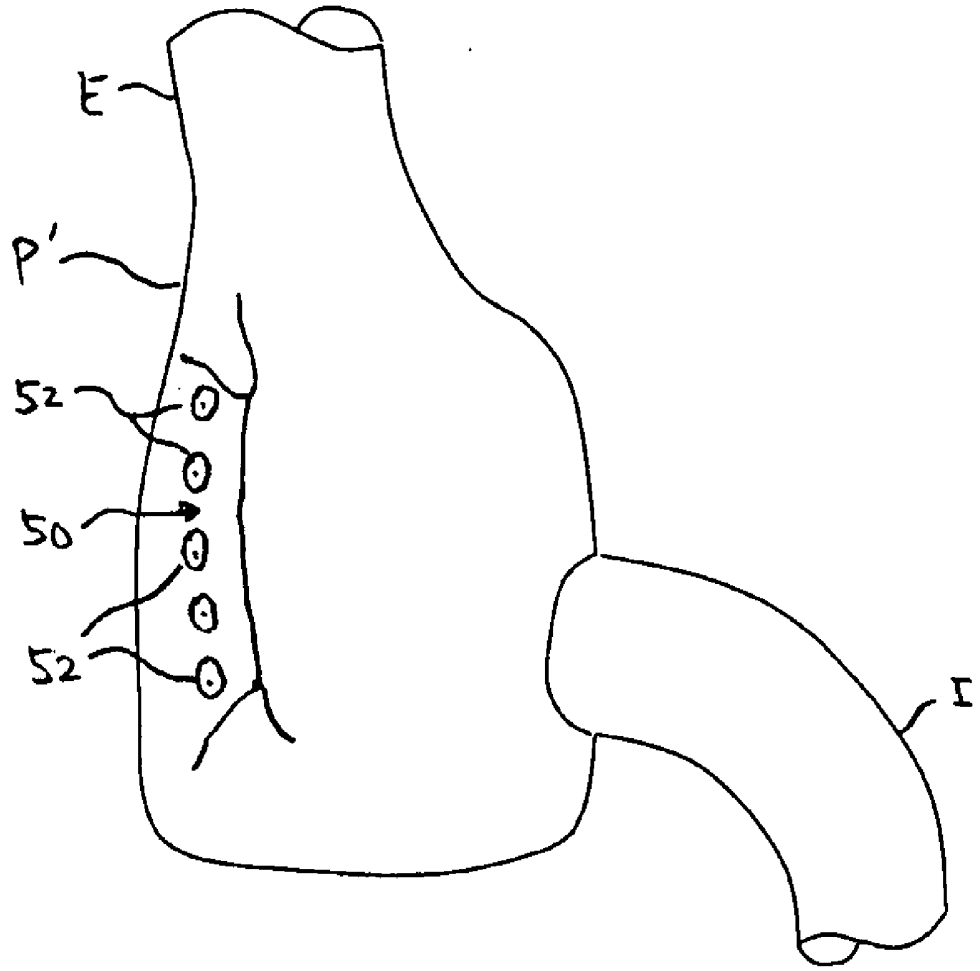
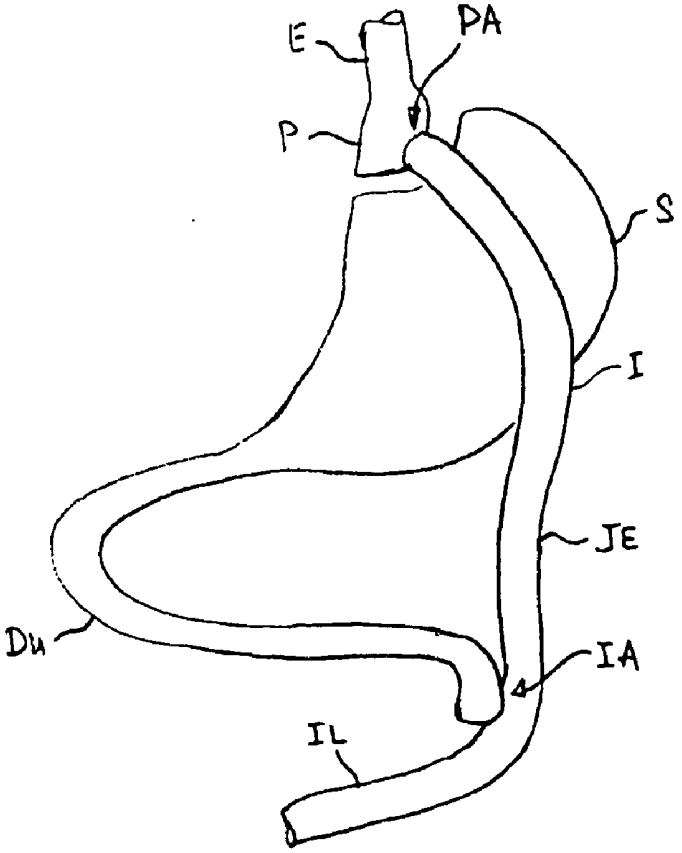
(52) **U.S. Cl.** **128/898**

(57) **ABSTRACT**

Methods and apparatus for the endoluminal revision of previously performed obesity procedures which have failed are described. One or more endoluminal instruments may be advanced per-orally into the previously formed failed pouch where a number of different procedures can be performed. One or more tissue folds can be formed and secured to reduce the size of the pouch, or the stoma connecting the pouch to the intestinal tract can be reduced in size using endoluminally deployed tissue anchors. These procedures can be performed entirely from within the pouch lumen or upon the exterior surface of the pouch via transgastric entry of the instruments into the peritoneal cavity of a patient. Alternatively, the interior tissue within the pouch can be injured or sclerosed to shrink the pouch lumen. In another alterative, a length of the Roux limb can be shortened endoluminally to create a malabsorptive region.





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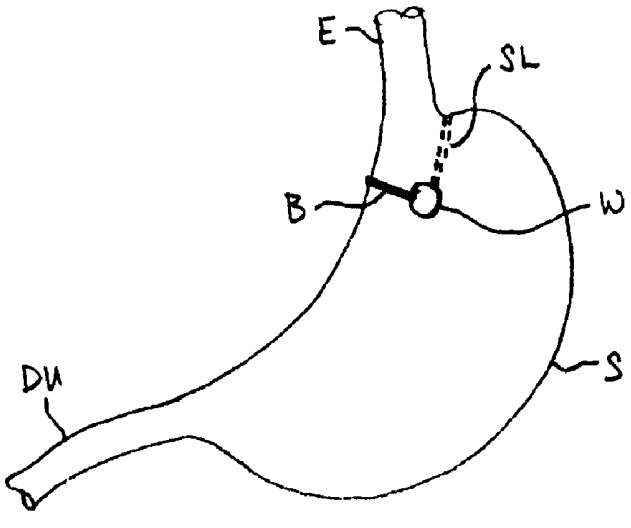


FIG. 1B

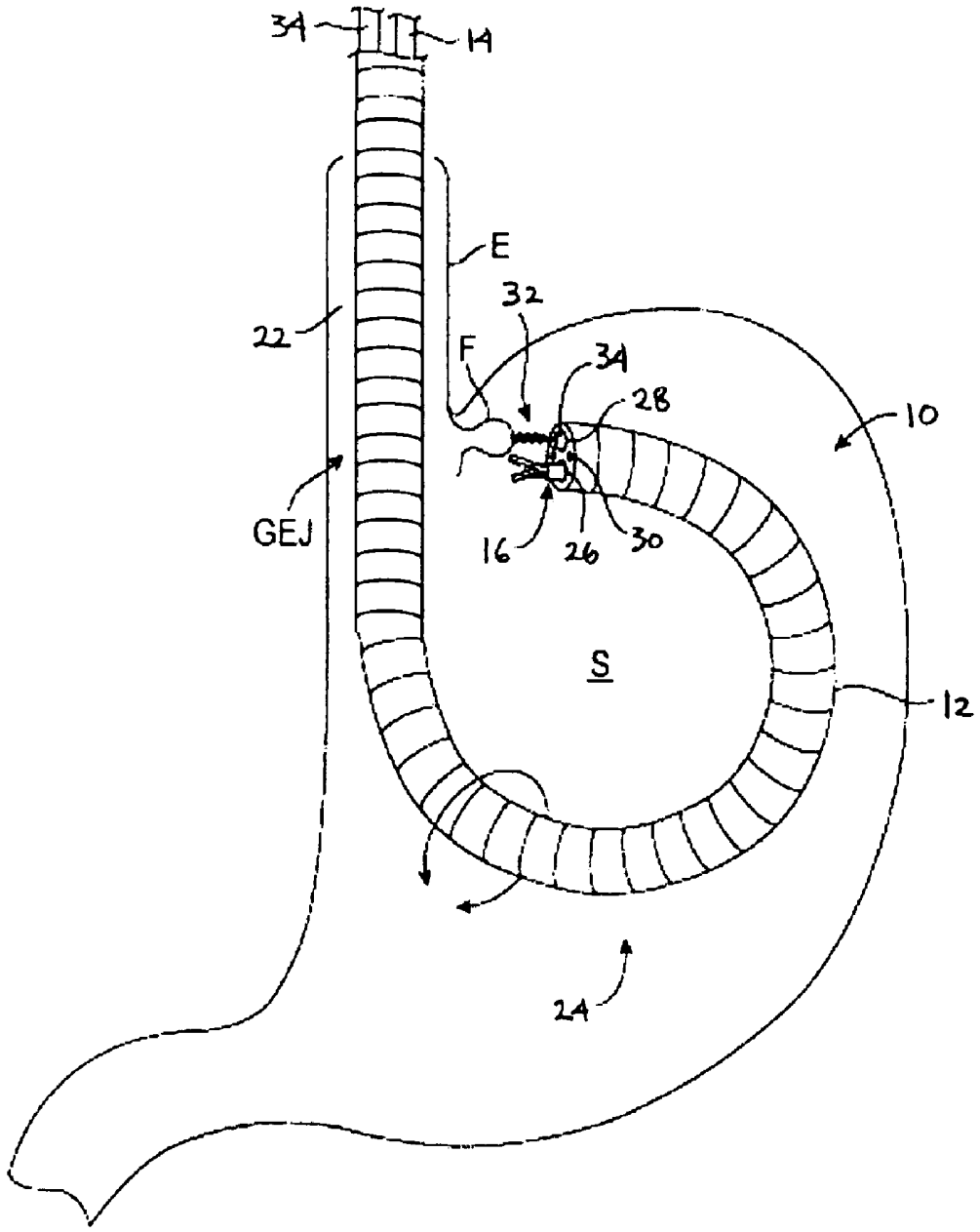


FIG. 2

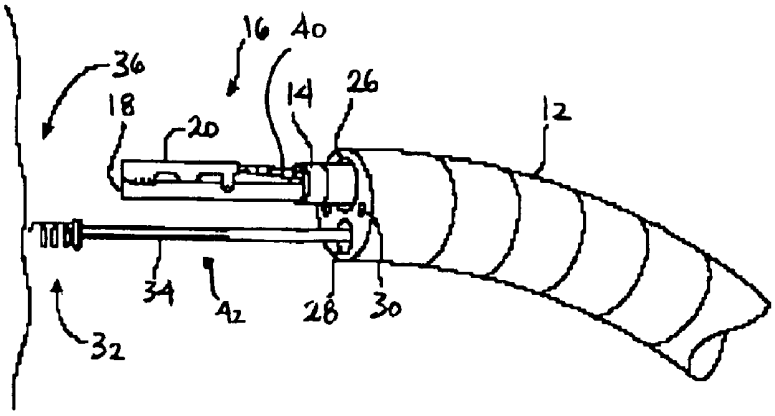


FIG. 3A

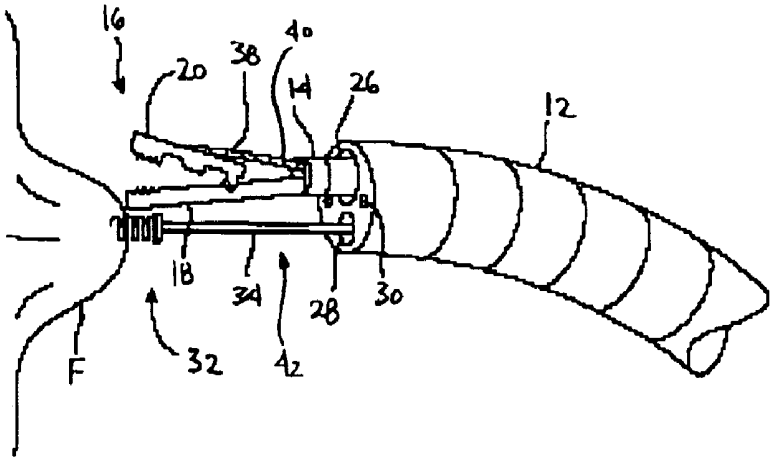


FIG. 3B

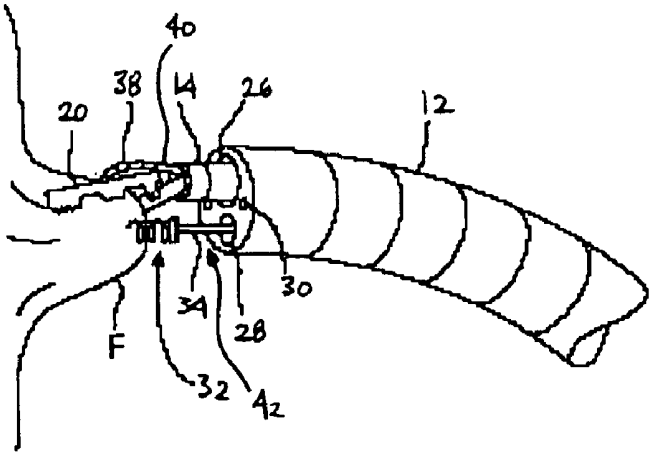


FIG. 3C

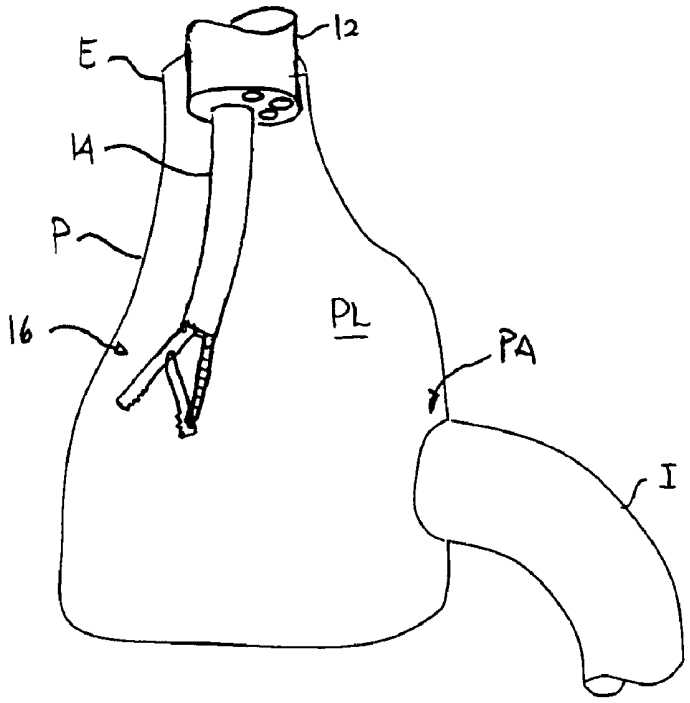


FIG. 4A

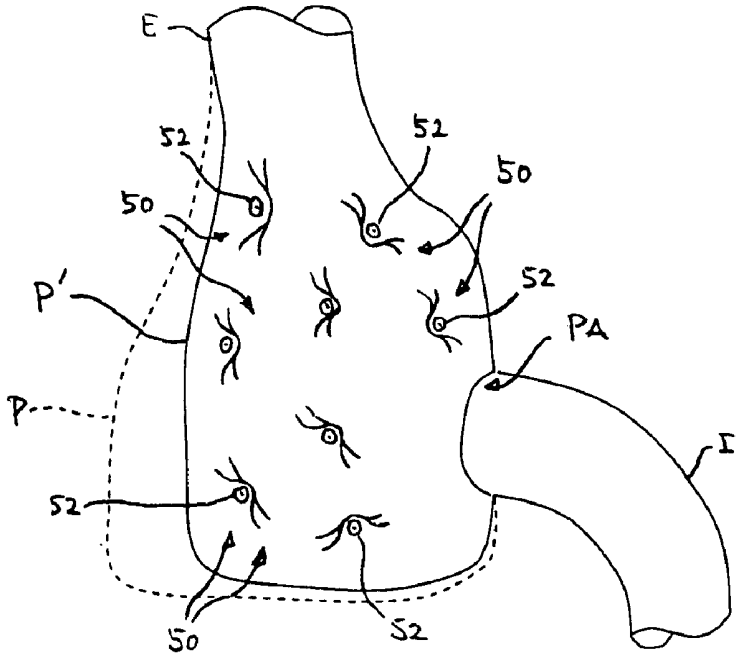
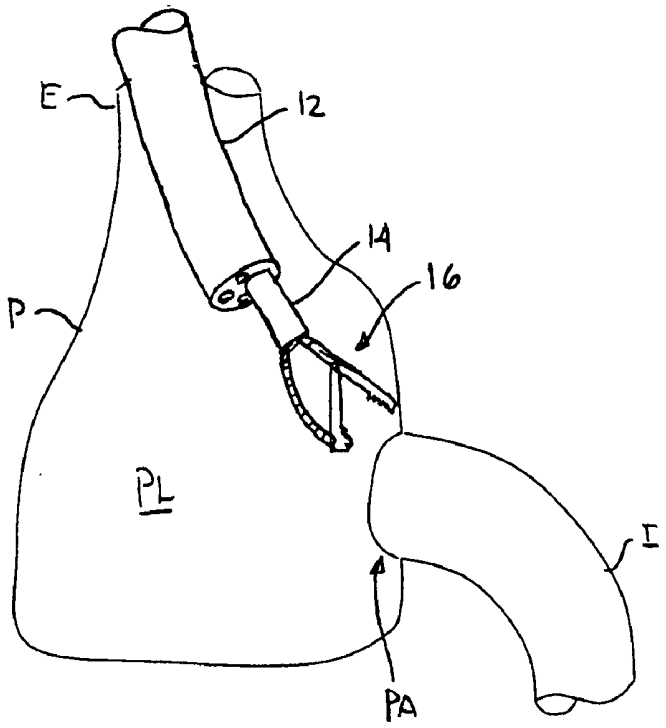


FIG. 4B



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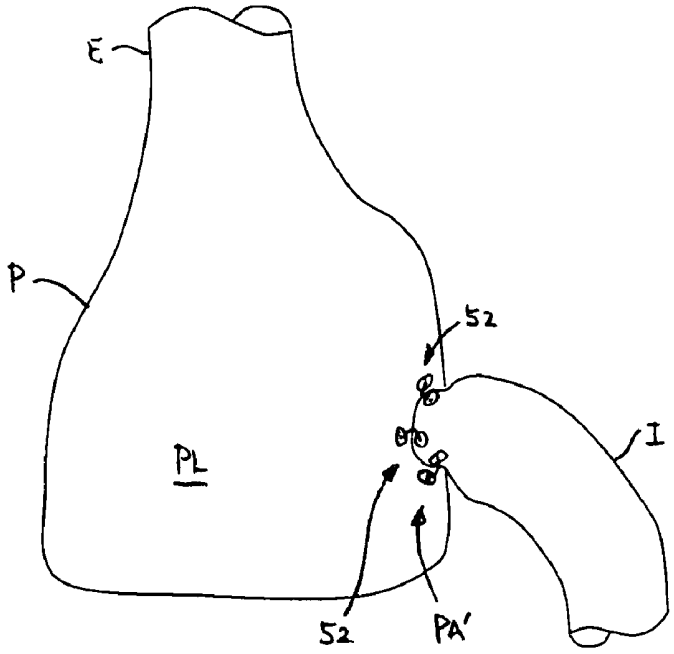


FIG. 5B

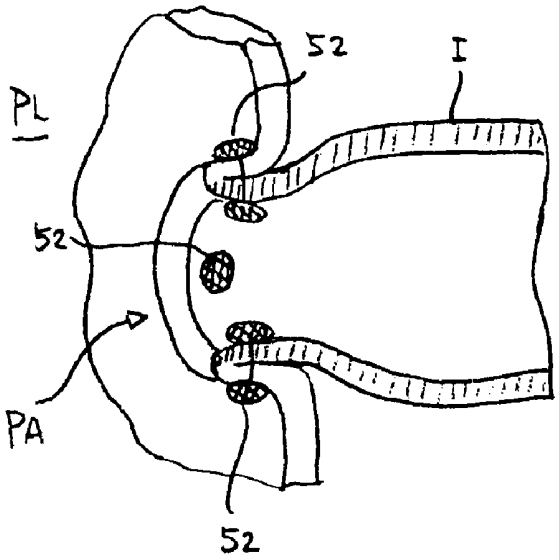


FIG. 5C

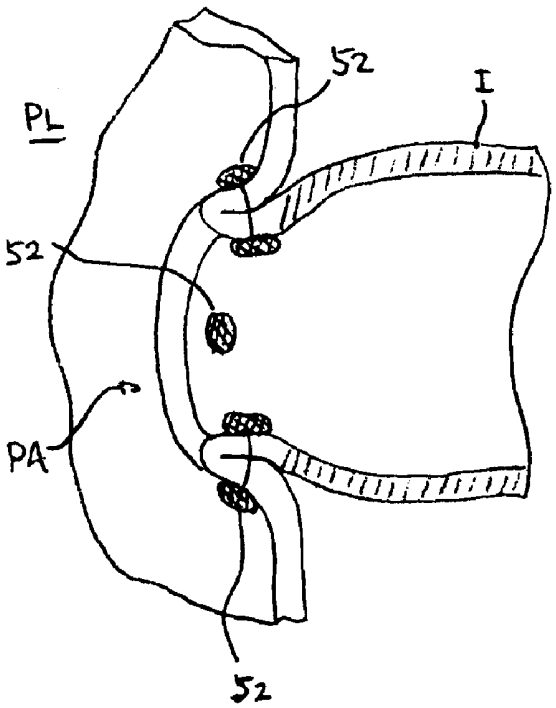


FIG. 5D

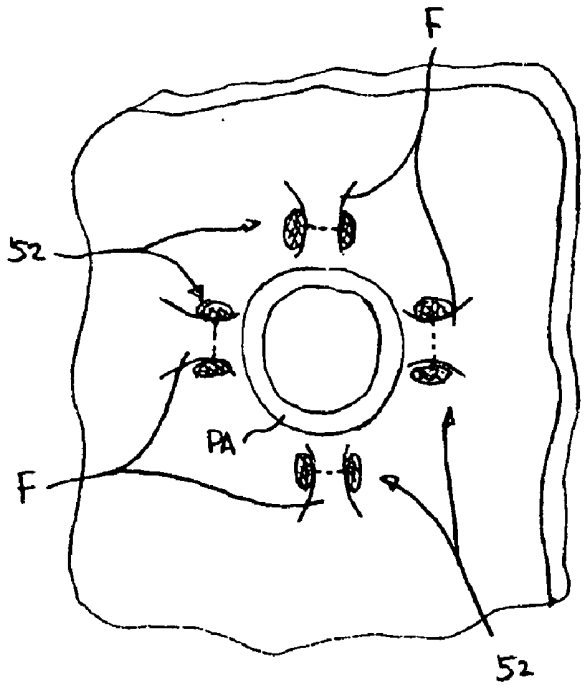


FIG. 5E

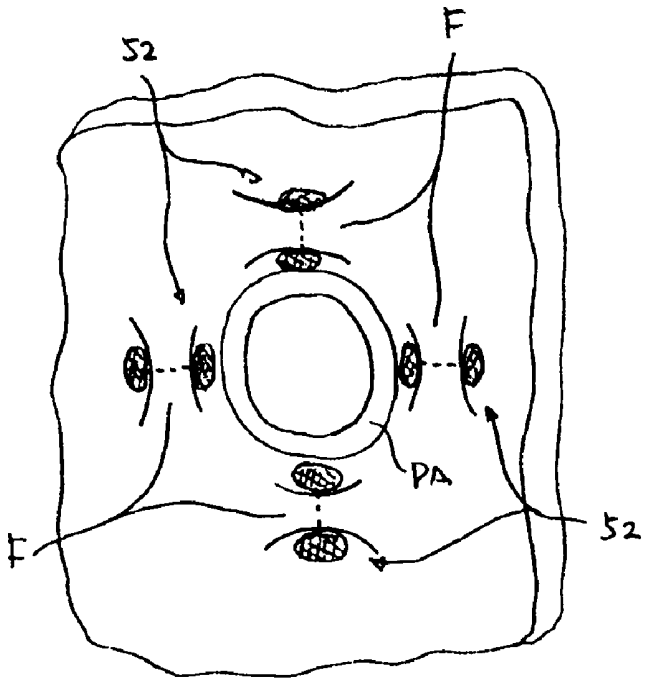


FIG. 5F

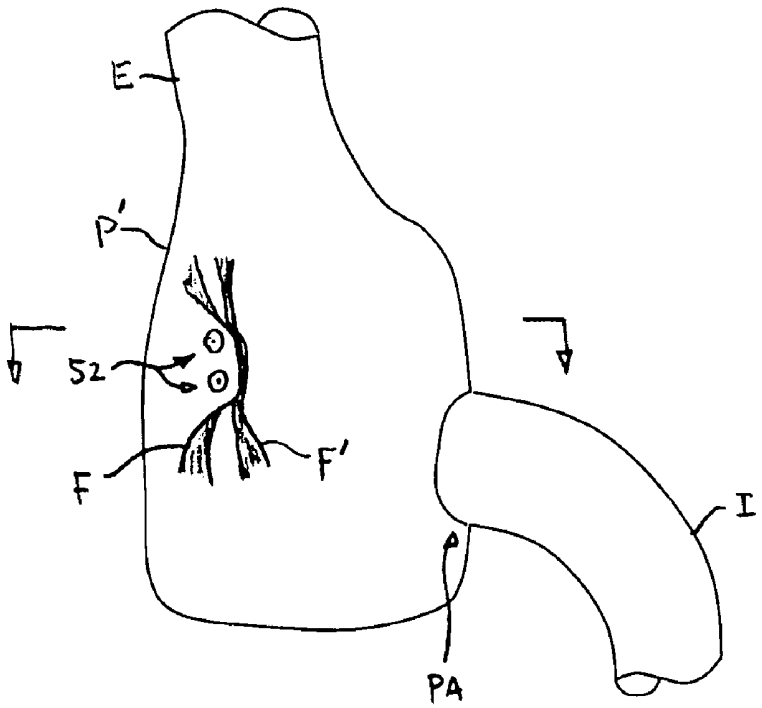


FIG. 6A

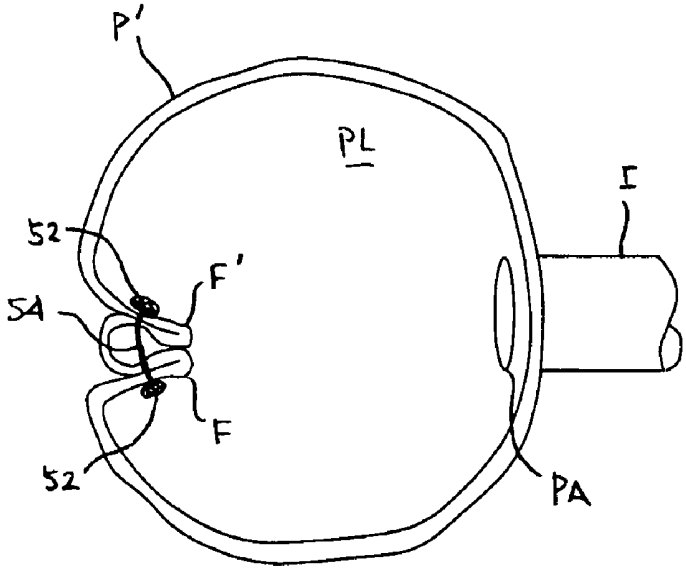


FIG. 6B

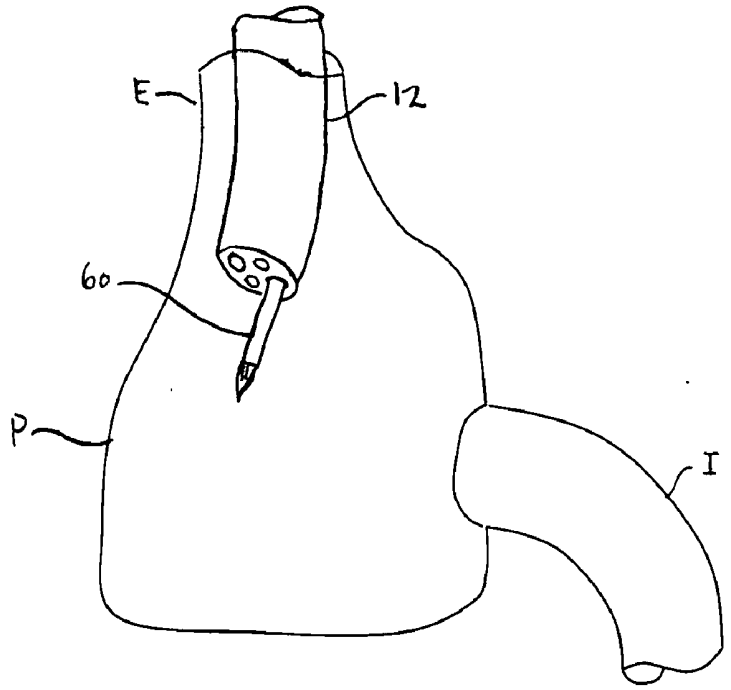


FIG. 7A

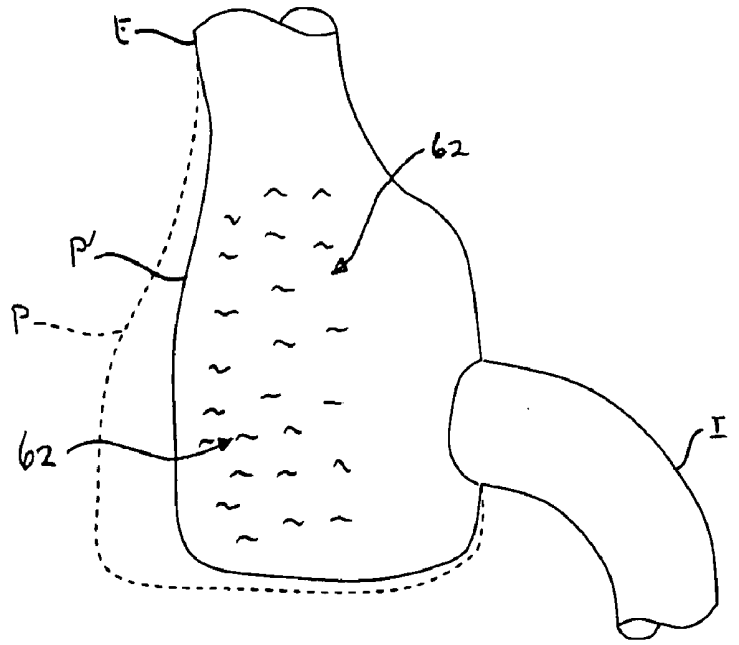


FIG. 7B

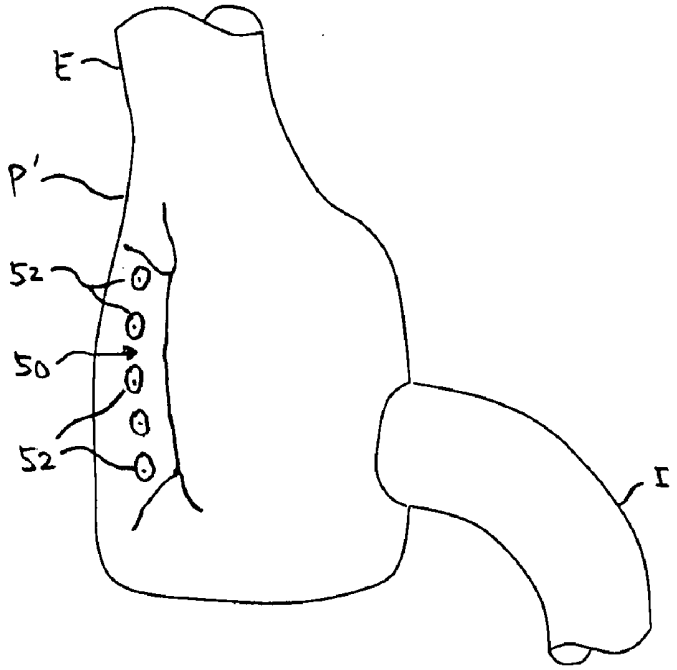


FIG. 8A

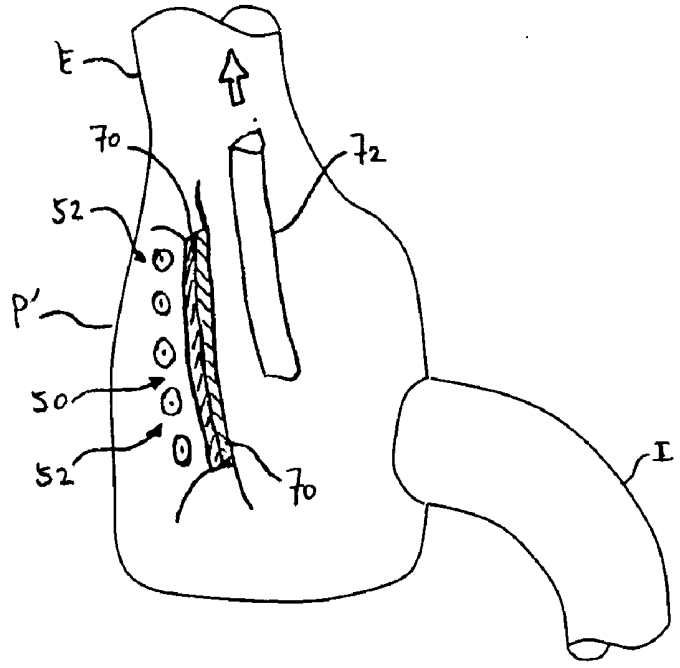
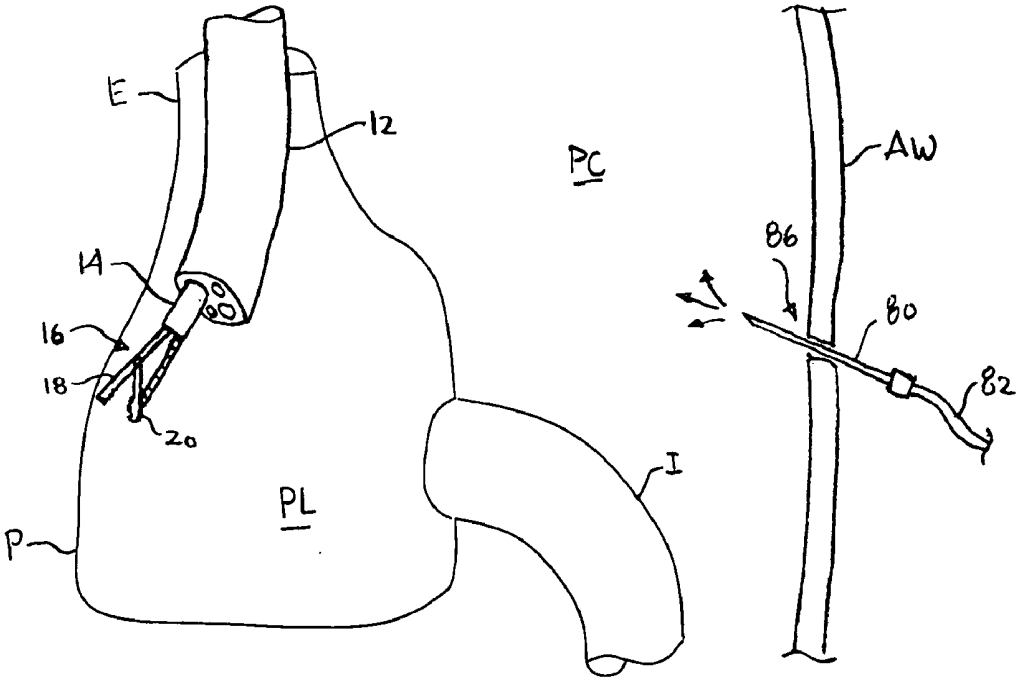


FIG. 8B



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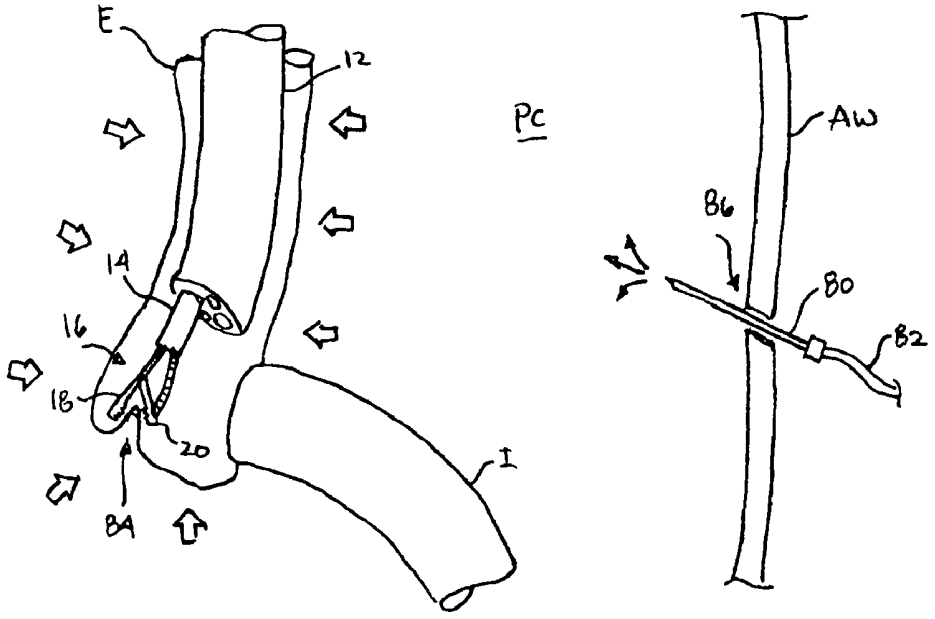

FIG. 9B

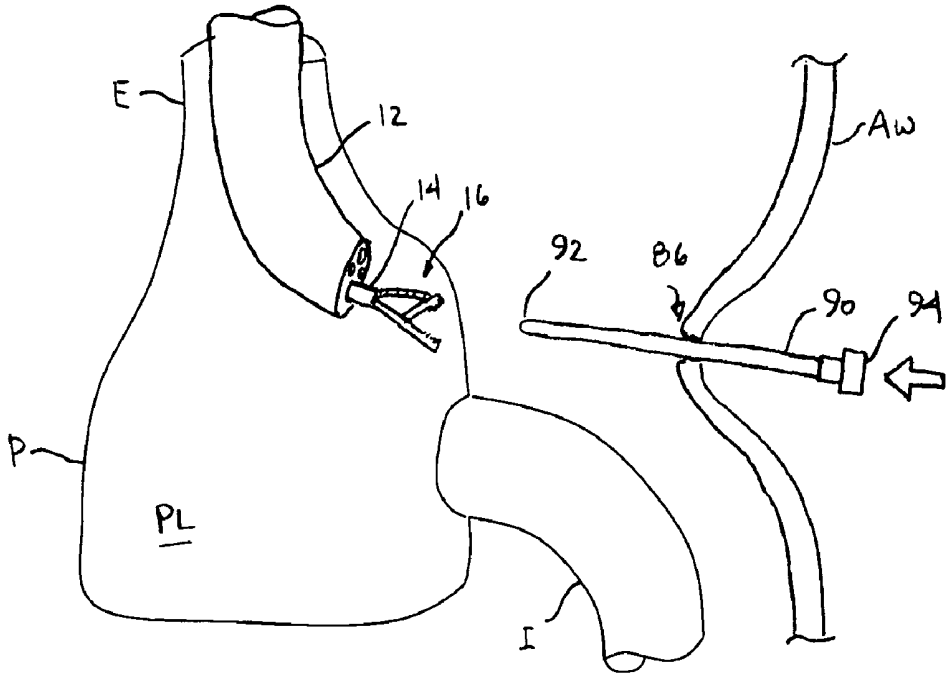

FIG. 10A

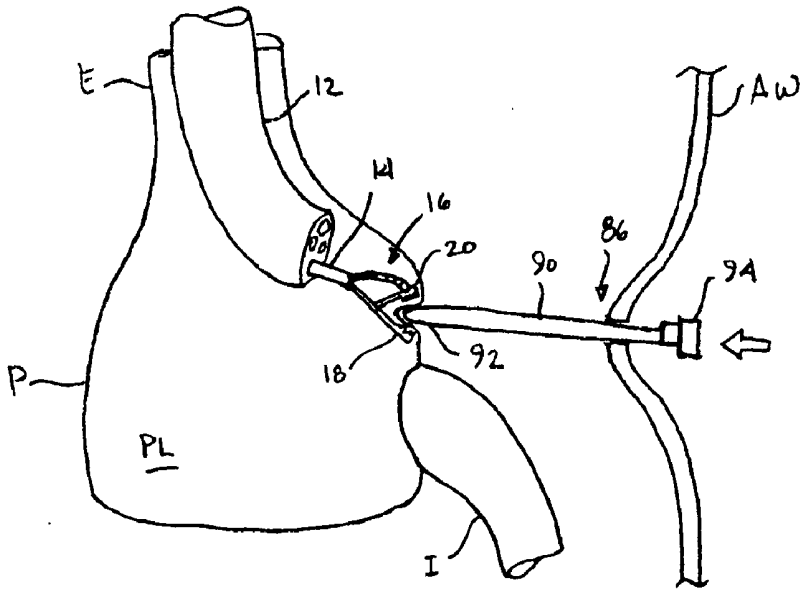

FIG. 10B

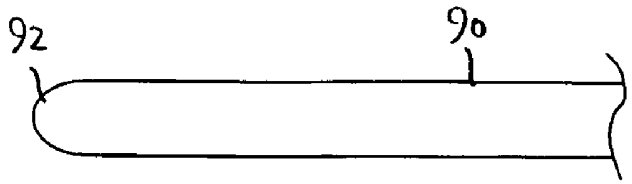

FIG. 11A

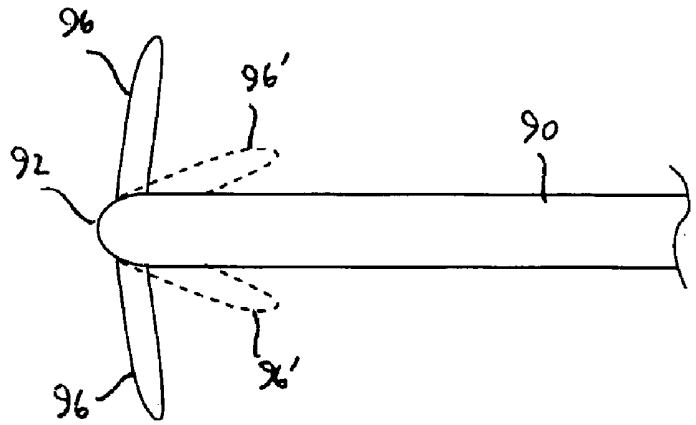

FIG. 11B

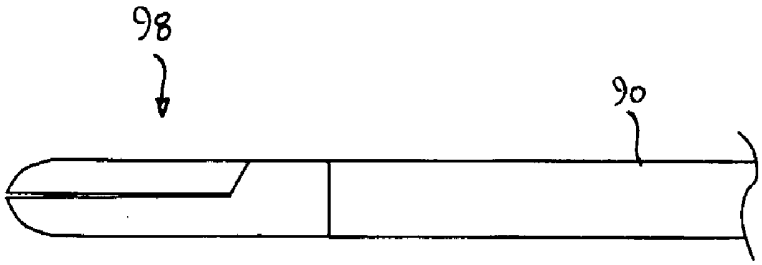

FIG. 11C

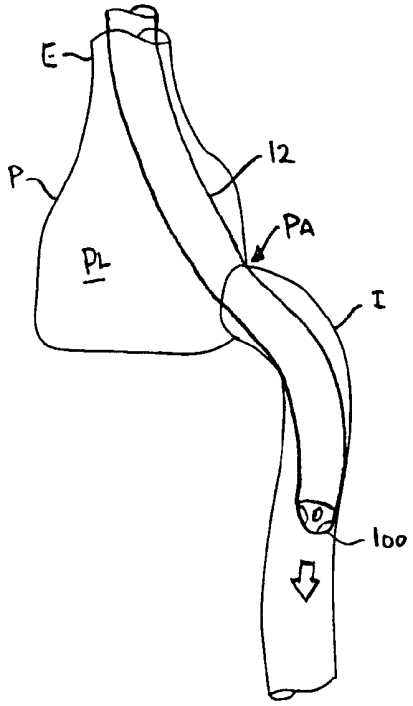

FIG. 12A

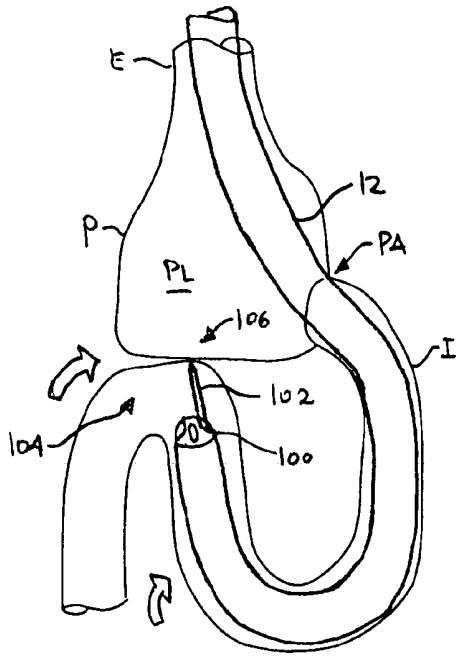

FIG. 12B

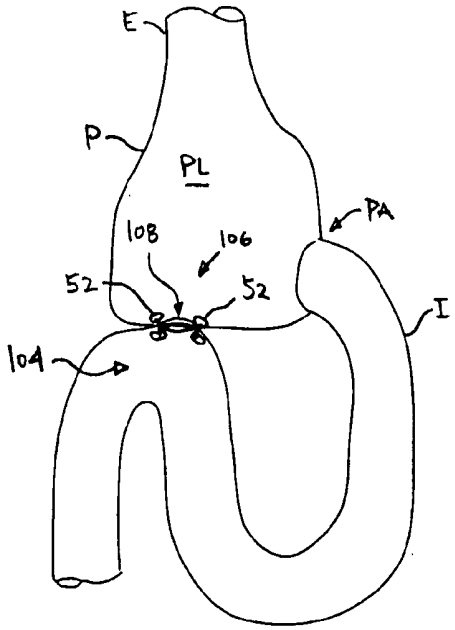

FIG. 12C

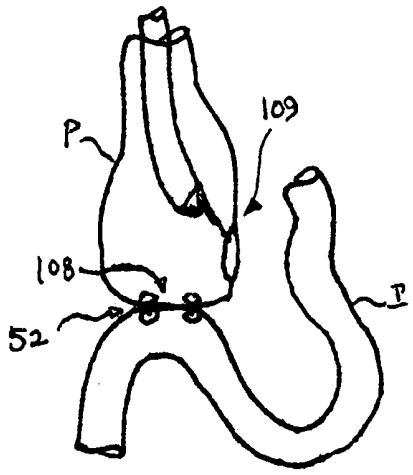

FIG. 12D

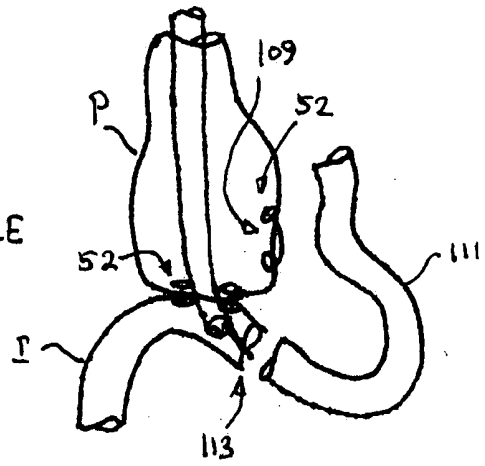

FIG. 12E

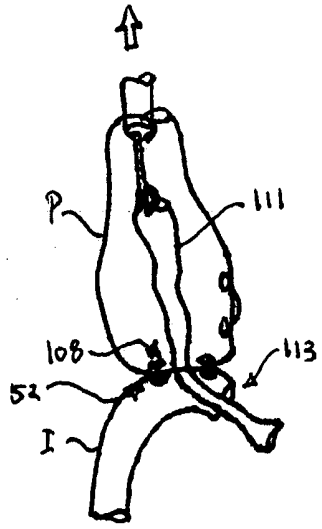

FIG. 12F

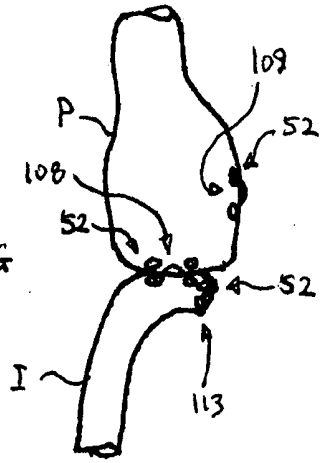

FIG. 12G

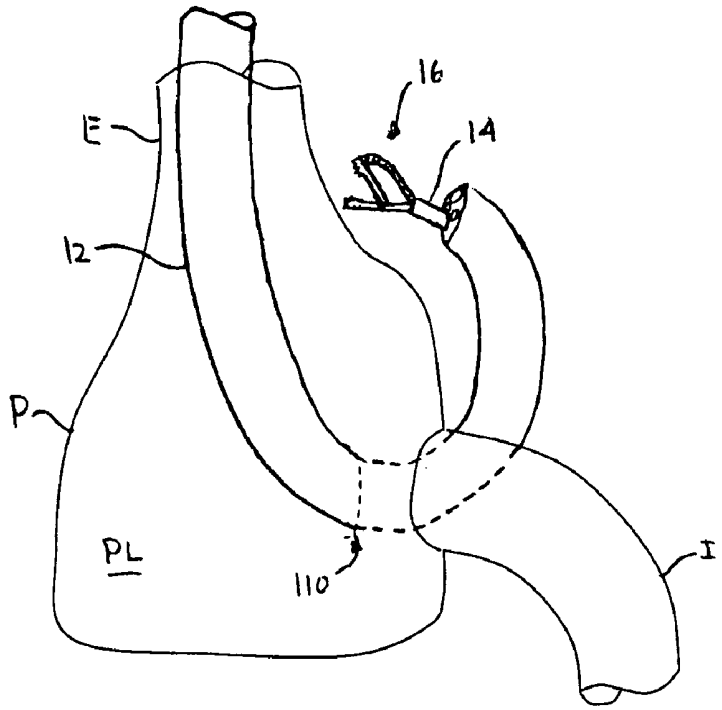

FIG. 13A

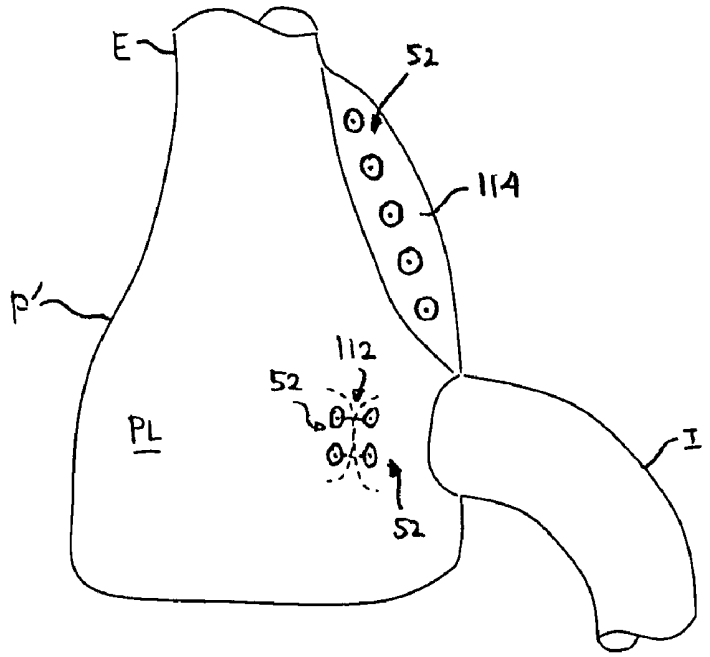

FIG. 13B

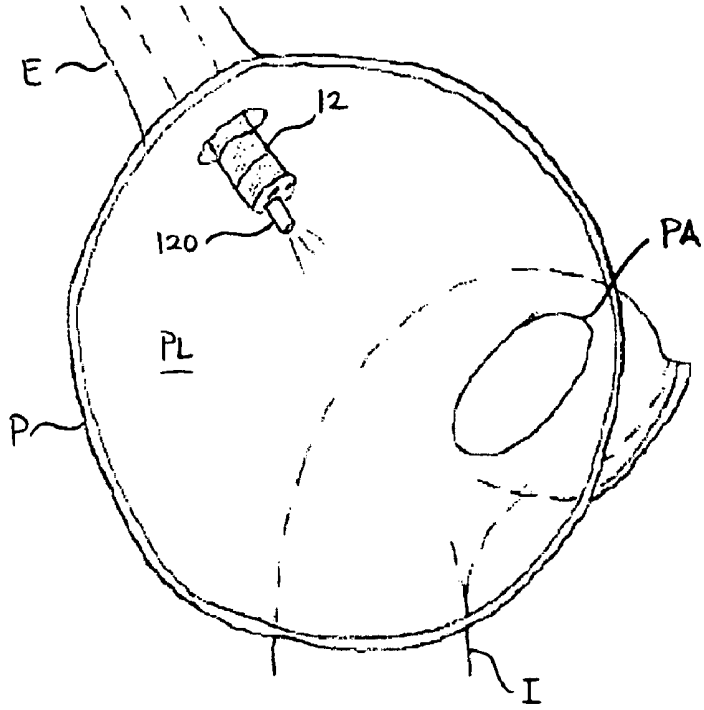

FIG. 14A

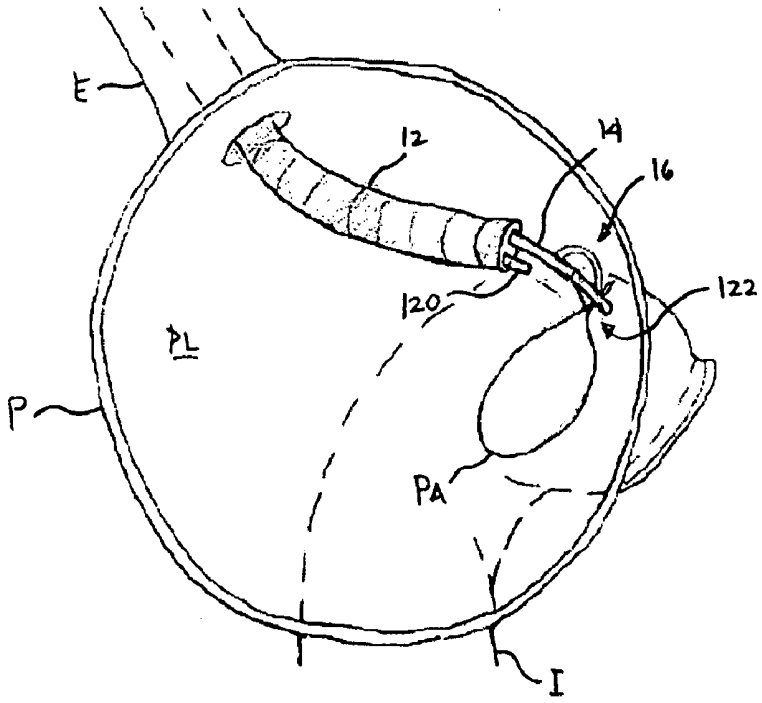

FIG. 14B

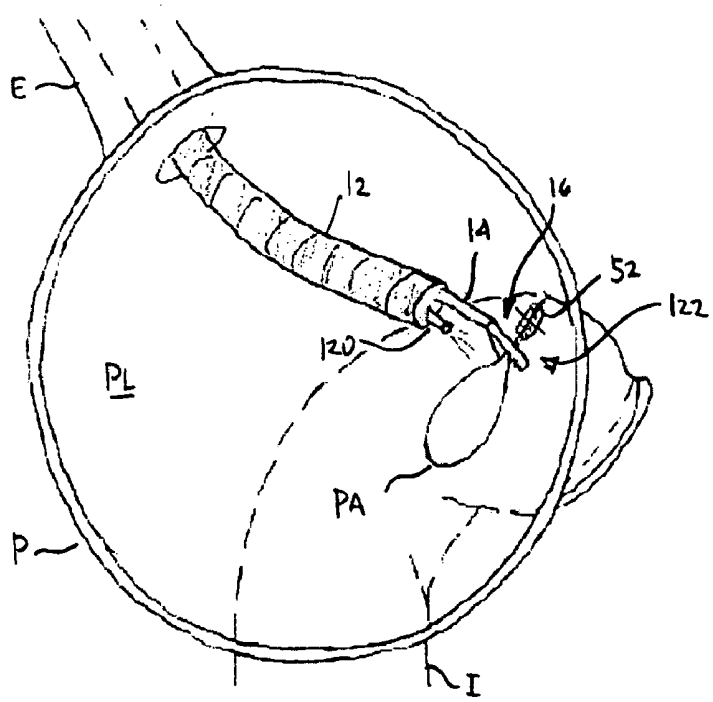

FIG. 14C

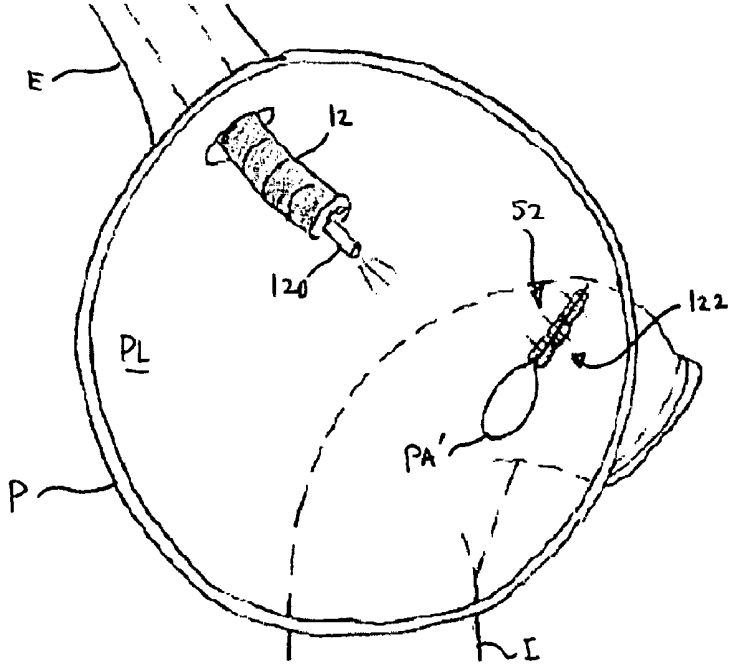

FIG. 14D

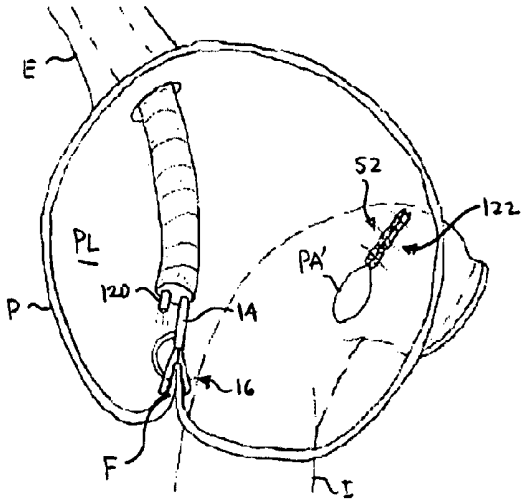

FIG. 15A

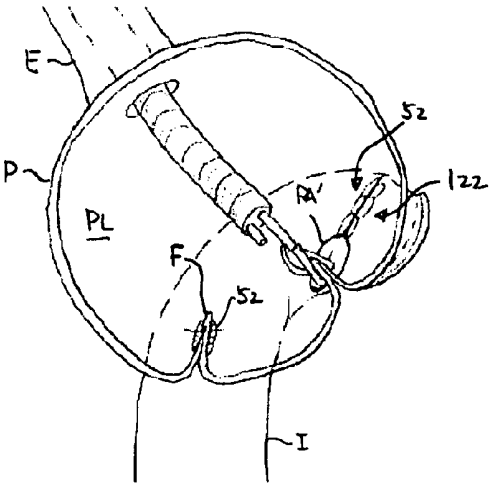

FIG. 15B

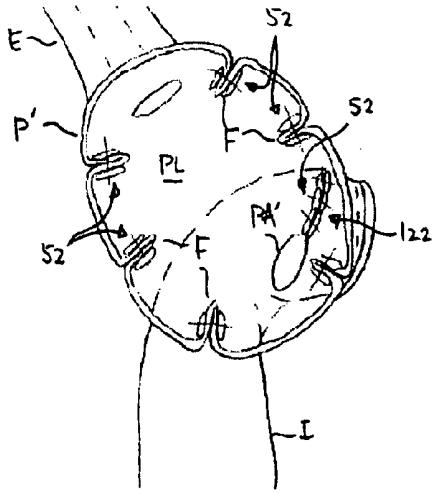

FIG. 15C

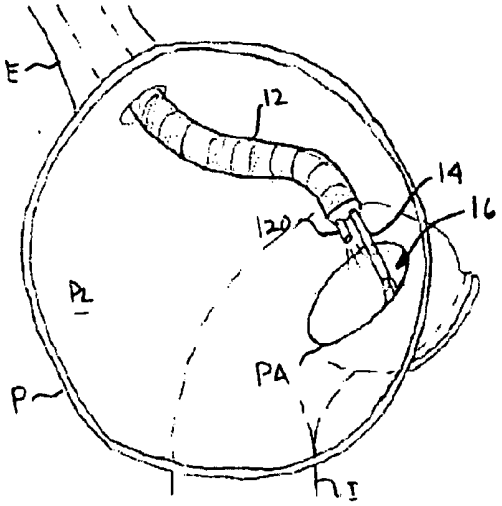

FIG. 16A

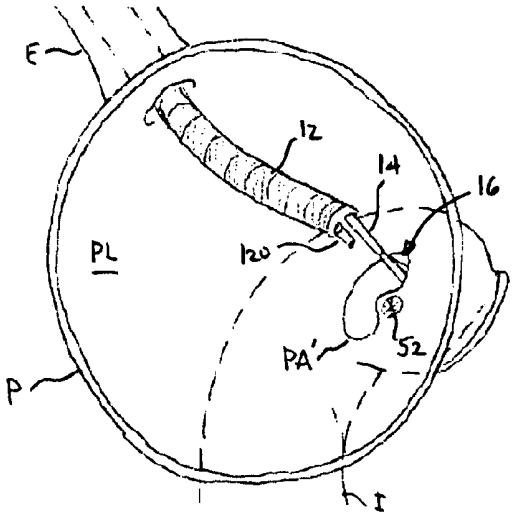

FIG. 16B

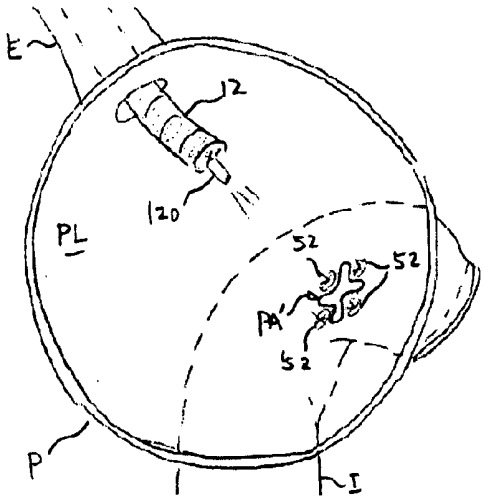

FIG. 16C

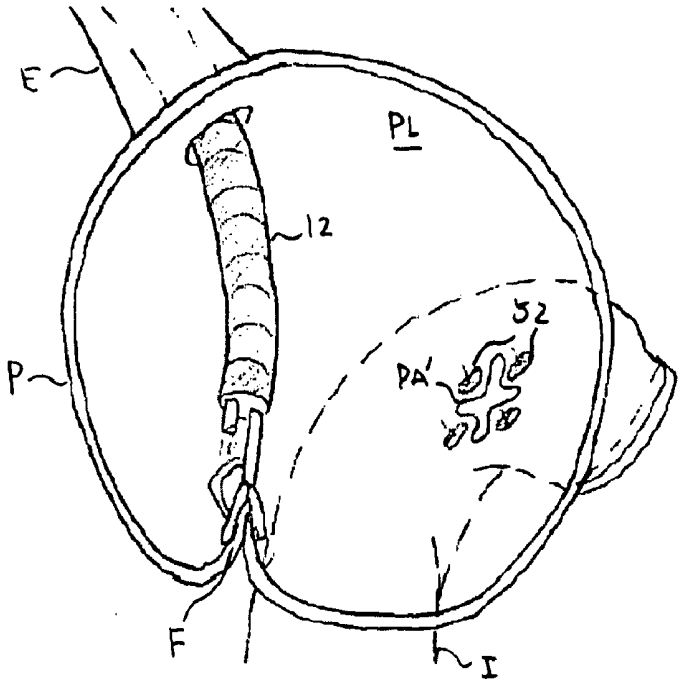

FIG. 17A

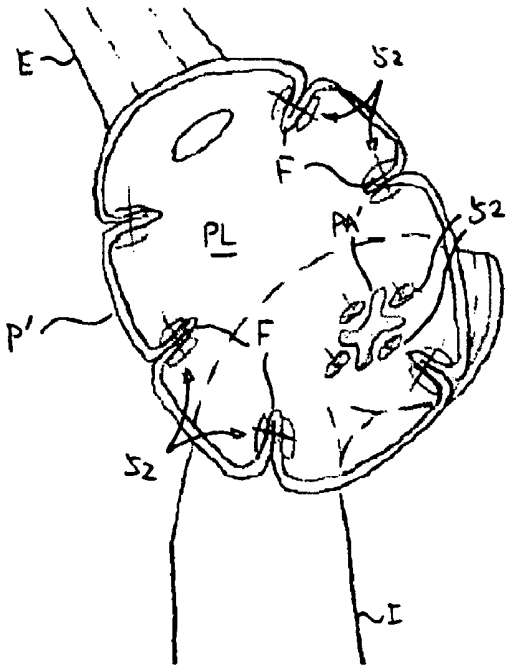

FIG. 17B

METHODS AND APPARATUS FOR REVISION OF OBESITY PROCEDURES

[0001] The present invention relates to methods and apparatus for the revision of obesity-related surgical procedures. More particularly, the present invention relates to the revision and/or correction of surgically altered anatomy within a patient body which has been surgically altered for the treatment of morbid obesity. The methods and apparatus utilize endoluminal procedures and instruments.

BACKGROUND OF THE INVENTION

[0002] Generally, three types of bariatric procedures are typically performed on patients for the treatment of morbid obesity. The various surgical procedures include vertical banded gastroplasty ("VBG"), laparoscopic gastric banding ("Lap-Band"), and the Roux-en-Y gastric bypass ("RYGB").

[0003] The RYGB procedure is a complex surgical procedure in which a small upper pouch P is created by stapling the stomach S and separating the pouch P from the remaining stomach S, which is left in place in the patient body. A Y-shaped segment of the intestines I (Roux limb), such as the upper jejunum JE or ilium IL, is rerouted and attached to the newly created pouch P via an anastomosis PA, as shown in FIG. 1A. The remaining portion of the jejunum JE is then reattached to the Roux limb at a lower point via an anastomosis IA. This rerouting causes food to pass through the esophagus E, through the pouch anastomosis PA, and into the Roux limb to bypass the stomach S. The pouch P further restricts the food intake and interferes with absorption to result in consistent weight loss.

[0004] In creating a VBG, a surgical stapler is used to form a staple line SL to create a small gastric pouch out of the stomach S just below the esophagus E. A non-adjustable polypropylene mesh band B is placed around the bottom of the pouch and through a circular window W created through the stomach S to restrict the size of its outlet, as shown in FIG. 1B. The small pouch and narrow outlet restricts the amount of food the patient can comfortably consume and delays the emptying of food into the remaining portion of the stomach S and duodenum DU.

[0005] However, in these types of surgical procedures, there is typically a failure rate of about 20% which is categorized into two types: acute and chronic failures. Acute failures are generally due to patient intolerance, leaks from either the pouch P or anastomoses PA and/or IA, and other complications. Chronic failures generally occur in about 10-20% of patients who fail to lose any significant amount of weight. The typical two failure modes occur from either (1) dilation of the pouch P, for example, where the pouch P expands from a 20-30 cc pouch to a 100-300 cc pouch; or from (2) dilation of the stoma through the pouch anastomosis PA, for example, where the stoma dilates from a 10-12 mm diameter to a 3-5 cm diameter.

[0006] Options for correcting these failures are limited to either simply leaving the dilated tissue or to perform an open surgical revision procedure to alter the length of the Roux limb to decrease absorption. However, such a procedure is typically accompanied by a 2-5% mortality rate and a 50% failure rate and is extremely difficult to perform due to the altered tissue anatomy. Moreover, minimally invasive laparoscopic surgical revision procedures are also extremely difficult because of the altered tissue anatomy and scar tissue.

[0007] Accordingly, in view of the foregoing, it would be desirable to provide minimally invasive methods and apparatus for performing endoluminal revision procedures to correct failed surgical procedures for obesity.

BRIEF SUMMARY OF THE INVENTION

[0008] Correction of failed obesity procedures in a minimally invasive manner may involve a number of different methods and instruments. The instruments may be introduced transgastrically, percutaneously, etc., into the patient's body and into or around a failed pouch previously created through a surgical procedure such as a RYGB, VBG, etc. Once the instruments are positioned within or adjacent to the pouch, tissue within or from the pouch may be temporarily engaged or grasped and the engaged tissue may be manipulated by a surgeon or practitioner from outside the patient's body.

[0009] In engaging, manipulating, and/or securing the tissue, various methods and devices may be implemented. For instance, tissue securement devices may be delivered and positioned via an endoscopic apparatus for contacting a tissue wall of the pouch lumen, creating one or more tissue folds, and deploying one or more tissue anchors through the tissue fold(s). The tissue anchor(s) may be disposed through the muscularis and/or serosa layers of the pouch lumen. A shape-lockable or rigidizable endoscopic assembly having an elongate body, a steerable distal portion, and multiple lumens defined therethrough may be advanced into a pouch per-orally and through the esophagus. A tissue manipulation assembly positioned at the distal end of a tubular body may be passed through the endoscopic assembly for engaging and securing the tissue.

[0010] Utilizing one or more of the instruments, the rigidizable endoscopic body may be used to pass the flexible body therethrough and into the pouch where it may be used to approximate folds of tissue which are secured via expandable tissue anchors expelled from the tissue manipulation assembly. Any number of tissue folds, i.e., one or more, may be created in a uniform pattern or randomly throughout the pouch lumen such that the enlarged pouch is reduced in size to a pouch having a smaller volume.

[0011] The instruments may be utilized endoluminally entirely within the pouch or transgastrically, where one or more tissue ridges may be formed from an exterior surface of the pouch. In this case, a transgastric opening may be created through the pouch to allow for passage of the instruments into the peritoneal cavity.

[0012] Another method may include reducing a diameter of the stoma between the pouch lumen and the intestinal tract through the pouch anastomosis. The tissue manipulation assembly may be directed to the tissue circumferentially around the anastomotic connection where one or several pairs of tissue anchors may be deployed into the tissue randomly or in a uniformly spaced configuration around the pouch anastomosis to reduce the opening to a smaller anastomosis which is more effective in restricting the passage of food received within the pouch lumen.

[0013] Another method may utilize an endoluminal tissue ablation instrument, e.g., plasma torch, laser, radio-fre-

quency probe, etc., to ablate one or more regions of tissue within the pouch to shrink the tissue and ultimately shrink the size of the pouch.

[0014] To facilitate the grasping and manipulation of the tissue within the pouch, various methods and instruments may be utilized. In one example, a tissue engagement member may be positioned through the elongate body and utilized with the tissue manipulation assembly. In another example, the tissue manipulation assembly may be positioned within the pouch lumen with the lower and upper jaw members positioned in an open configuration for receiving tissue therebetween. The air, along with any other fluids, contained within the pouch lumen may be evacuated out, e.g., through one of the lumens defined through the elongate body or through a catheter advanced through the body. The evacuation of air and fluids from the pouch lumen may collapse the pouch tissue onto the flexible body and between the jaw members.

[0015] In yet another example, a Verres needle may be advanced percutaneously and positioned through the abdominal wall of a patient. A gas (e.g., air, carbon dioxide, nitrogen, etc.) may be pumped into the peritoneal cavity of the patient body to collapse the tissue of the pouch onto and over the tissue manipulation assembly, particularly between the jaw members positioned within the pouch lumen. The collapsed pouch tissue positioned between the jaw members may then be easily grasped and secured by deploying one or more tissue anchors through the collapsed pouch tissue. **1**

[0016] In yet another method for facilitating engagement of the interior tissue, an elongate laparoscopic instrument having a blunted atraumatic tip may be advanced through a percutaneous opening and into contact with an outer surface of the pouch. Once the atraumatic tip contacts the outer surface of the pouch, the laparoscopic instrument may be pushed against the outer surface such that a fold of tissue is formed within the pouch lumen in the proximity of the tissue manipulation assembly. With the tissue fold formed within the pouch lumen, the jaw members of the tissue manipulation assembly may be positioned on either side of the tissue fold to grasp and secure the tissue. Once the tissue fold has been secured, the laparoscopic instrument may be repositioned at another location on the outer surface of the pouch.

[0017] In endoluminally revising a failed surgical procedure for the treatment of obesity, aside from reducing a volume of the pouch lumen, or reducing a diameter of the stoma through the pouch anastomosis, or even ablating the interior of the pouch lumen tissue surface, a length of the Roux limb may also be altered endoluminally. Altering the length of the Roux limb may create an additional malabsorptive portion of intestinal tissue and further reduce the ability of the patient body to absorb food passing therethrough. A rigidizable endoscopic body having a rounded atraumatic distal end may be advanced per-orally, through the patient's esophagus and pouch lumen, through the patient's pouch anastomosis and into the length of the intestinal tract.

[0018] The steerable distal portion of the endoscopic body may be articulated to curve into a retroflexed configuration relative to its proximal length while pulling a distal portion of the intestinal tract along with the endoscopic body into contact against or in proximity to the outer surface of the pouch. With the atraumatic distal end desirably positioned and the endoscopic body optionally rigidized, an endoscopic piercing or ablative instrument, e.g., an energizable needle knife, may be advanced through the distal portion of intestinal tissue and through the portion of pouch tissue to create an opening therebetween.

[0019] Once an opening through both tissue portions has been achieved, one or more tissue anchors may be deployed around the circumference of the openings using, e.g., tissue manipulation assembly, to secure the intestinal tissue to the pouch to create a side-to-side anastomotic connection. The anastomotic connection may be further dilated, if desired. Once the anastomotic connection has been formed, the endoscopic body may be transitioned into its flexible state (if initially rigidized) and withdrawn from the patient body. Optionally, the original pouch anastomosis may be closed using tissue anchors, if so desired, to ensure that food received within the pouch is shunted through the newly created anastomosis and bypasses the length of intestinal tissue. As a further option, the shunted portion of intestinal tissue may be endoluminally (or laparoscopically) excised and removed entirely from the patient body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. **1**A shows the resulting anatomy of the stomach and intestinal tract from a Roux-en-Y gastric bypass procedure.

[0021] FIG. **1**B shows the resulting anatomy of the stomach from a vertical banded gastroplasty procedure.

[0022] FIG. **2** illustrates one example in which a rigidizable endoscopic assembly may be advanced into a patient's stomach per-orally and through the esophagus with a tissue manipulation assembly advanced through a first lumen and a helical tissue engagement instrument advanced through a second lumen.

[0023] FIGS. **3**A to **3**C illustrate an example for performing an endoluminal tissue manipulation and securement procedure utilizing a tissue manipulation assembly in combination with a helical tissue engagement instrument within, e.g., a patient's altered stomach in a revision procedure.

[0024] FIGS. **4**A and **4**B show detail views, respectively, of a failed pouch and a repaired pouch having a plurality of tissue folds secured throughout an interior of the pouch to reduce its size.

[0025] FIGS. **5**A and **5**B show detail views, respectively, of a failed pouch and a pouch with its anastomotic opening reduced in diameter to further restrict the passage of food therethrough.

[0026] FIGS. **5**C and **5**D show partial cross-sectional views of reduced stomas where a portion of the anastomosed intestinal tissue is approximated with respect to the pouch and where a portion of the pouch tissue is plicated leaving the anastomosed intestinal tissue untouched, respectively.

[0027] FIGS. **5**E and **5**F show end views from within the pouch of the stoma and pouch anastomosis where the pouch tissue adjacent to the stoma may be approximated in a radial configuration and/or a circumferential or annular configuration, respectively.

[0028] FIGS. **6**A and **6**B show detail views, respectively, of a pouch having a portion of its interior approximated and a cross-sectional top view of the same.

[0029] FIGS. 7A and 7B show detail views, respectively, of a failed pouch and a pouch having at least a portion of its interior surface injured and/or ablated to reduce the pouch size.

[0030] FIGS. 8A and 8B show detail views, respectively, of a pouch having a portion of its interior approximated and removed to promote healing of the plicated tissue.

[0031] FIGS. 9A and 9B illustrate detail views of one method for facilitating the grasping and engagement of the tissue within the interior of the tissue pouch by insufflating a patient's peritoneal cavity to collapse the pouch tissue upon the tissue manipulation assembly.

[0032] FIGS. 10A and 10B illustrate another method for facilitating tissue grasping and engagement within the pouch lumen by advancing an elongate laparoscopic instrument through a percutaneous opening and into contact with an outer surface of the pouch.

[0033] FIGS. 11A to 11C show examples of various laparoscopic instruments which may be passed through the patient body into contact with the pouch exterior.

[0034] FIGS. 12A to 12C illustrate an example for altering a length of the Roux limb by advancing an optionally rigidizable elongate body through the pouch and intestinal tract and retroflexing a distal portion of the intestinal tissue for connection with the pouch.

[0035] FIGS. 12D to 12G illustrate an optional procedure for endoluminally excising and removing a portion of the Roux limb proximally through the pouch and esophagus and from the patient's mouth.

[0036] FIGS. 13A and 13B show another example for reducing a size of a pouch by creating at least one externally formed tissue ridge along the outer surface of the pouch.

[0037] FIGS. 14A to 14D illustrate one method where the pouch stoma may be reduced in size by approximating the edges of a portion of the stoma.

[0038] FIGS. 15A to 15C illustrate a combination of various methods where the pouch having a reduced stoma from FIGS. 14A to 14D may be further reduced in pouch size by engaging and securing one or more tissue folds throughout the lumen.

[0039] FIGS. 16A to 16C illustrate another method where the pouch stoma may be reduced in size by deploying one or more tissue anchors around a periphery of the stoma.

[0040] FIGS. 17A and 17B illustrate another combination of various methods where the pouch having a reduced stoma from FIGS. 16A to 16C may be further reduced in pouch size by engaging and securing one or more tissue folds throughout the lumen.

DETAILED DESCRIPTION OF THE INVENTION

[0041] To correct failed obesity procedures in a minimally invasive manner, a tissue manipulation and/or securement instrument may be introduced per-orally through the patient's esophagus and into the created pouch to perform a number of procedures. The pouch may have been previously formed by any number of procedures, e.g., RYGB, VBG, etc., for the treatment of obesity. Alternatively, the instrument may be introduced transgastrically, percutaneously, etc., into the patient's body and into or around the pouch. Once the instrument is positioned within or adjacent to the pouch, tissue within or from the pouch may be temporarily engaged or grasped and the engaged tissue may be manipulated by a surgeon or practitioner from outside the patient's body. Examples of creating and forming tissue plications may be seen in further detail in U.S. patent application Ser. No. 10/955,245 filed Sep. 29, 2004 as well as in U.S. patent application Ser. No. 10/735,030 filed Dec. 12, 2003, each of which is incorporated herein by reference in its entirety.

[0042] In engaging, manipulating, and/or securing the tissue, various methods and devices may be implemented. For instance, tissue securement devices may be delivered and positioned via an endoscopic apparatus for contacting a tissue wall of the pouch lumen, creating one or more tissue folds, and deploying one or more tissue anchors through the tissue fold(s). The tissue anchor(s) may be disposed through the muscularis and/or serosa layers of the pouch lumen. When manipulating and securing tissue within a patient's body, a separate elongate shaft having a helical tissue engager on or near the distal end of the shaft may be utilized in conjunction with a tissue manipulation assembly. Such an instrument may be generally utilized in endoluminal procedures where the tools are delivered through an endoscopic device.

[0043] As illustrated in FIG. 2, one such example is shown in which a shape-lockable or rigidizable endoscopic assembly 10 may be advanced into a patient's stomach S per-orally and through the esophagus E. Such an endoscopic assembly 10 may generally comprise an endoscopic device which may have a distal portion which may be articulated and steered to position its distal end anywhere within the stomach S. Once desirably configured, assembly 10 may then be locked or rigidized to maintain its shape or configuration to allow for procedures to be performed on the tissue utilizing any number of tools delivered through the assembly 10. Shape-lockable or rigidizable assembly 10 and its variations are described in further detail in U.S. patent application Ser. No. 10/734,562 filed Dec. 12, 2003 and in U.S. patent application Ser. No. 10/346,709 filed Jan. 15, 2003, both of which are incorporated herein by reference in its entirety.

[0044] Shape-lockable assembly 10 may be generally comprised of shape-lockable endoscopic body 12 having an articulatable distal portion 24. The endoscopic body 12 may define at least first and second lumens 26, 28, respectively, through the endoscopic body 12 through which one or more tools may be deployed into the stomach S. Additional lumens may be provided through shape-lockable endoscopic body 12, such as a visualization lumen 30, through which an endoscope may be positioned to provide visualization of the region of tissue. Alternatively, an imager such as a CCD imager or optical fibers may be provided in lumen 30 to provide visualization. An optional thin wall sheath may be disposed through the patient's mouth, esophagus E, and possibly past the gastroesophageal junction GEJ into the stomach S. Shape-lockable body 12, having a covering 22 thereon, may be advanced through esophagus E and into stomach S while disposed in a flexible state.

[0045] Distal steerable portion 24 of endoscopic body 12 may be then articulated to an orientation, e.g., whereby distal portion 24 facilitates engagement of tissue near and/or

inferior to the patient's gastroesophageal junction GEJ. Accordingly, distal steerable portion **24** may comprise a number of steering features, as described in further detail in U.S. patent application Ser. Nos. 10/734,562 and 10/346,709, incorporated above. With distal steerable portion **24** disposed in a desired configuration or orientation, endoscopic body **12** may be reversibly shape-locked to a rigid state such that the endoscopic body **12** maintains its position within the stomach S. Various methods and apparatus for rigidizing endoscopic body **12** along its length are also described in further detail in U.S. patent application Ser. Nos. 10/734,562 and 10/346,709, incorporated above.

[**0046**] FIG. **2** further shows tissue manipulation assembly **16** having been advanced through first lumen **26** and a helical tissue engagement member **32** positioned upon flexible shaft **34** advanced through second lumen **28**. As the tissue wall of a body lumen, such as the stomach, typically comprises an inner mucosal layer, connective tissue, the muscularis layer and the serosa layer. To obtain a durable purchase, e.g., in performing a stomach reduction procedure, helical tissue engagement member **32** may be advanced into contact with the tissue and preferably engages the tissue F such that when the tissue engagement member **32** is pulled proximally to draw the engaged tissue F between the jaw members **18**, **20** of tissue manipulation assembly **16**, at least the muscularis tissue layer and the serosa layer is drawn into tissue manipulation assembly **16**. As tissue manipulation assembly **16** may be utilized to grasp and secure the engaged tissue, any number of tools may be utilized with tissue manipulation assembly **16**, e.g., through shape-lockable endoscopic body **12**, to engage and manipulate the tissue of interest relative to tissue manipulation assembly **16**.

[**0047**] An illustrative example of a tissue manipulation instrument which may be utilized for endoluminally accessing tissue is described in further detail in U.S. patent application Ser. No. 11/070,863 filed Mar. 1, 2005 (US Pat. Pub. 2005/0251166 A1), which is incorporated herein by reference in its entirety. Such an instrument assembly generally comprises a flexible catheter or tubular body **14** which may be configured to be sufficiently flexible for advancement into a body lumen, e.g., transorally, percutaneously, laparoscopically, etc. Tubular body **14** may be configured to be torqueable through various methods, e.g., utilizing a braided tubular construction, such that when a proximally-located handle is manipulated and/or rotated by a practitioner from outside the patient's body, the longitudinal and/or torquing force is transmitted along body **14** such that the distal end of body **14** is advanced, withdrawn, or rotated in a corresponding manner.

[**0048**] As shown in FIGS. **3**A to **3**C, tissue manipulation assembly **16** is located at the distal end of tubular body **14** and is generally used to contact and form tissue folds, as mentioned above. The tissue manipulation assembly **16** may be connected to the distal end of tubular body **14** via a pivotable coupling. Lower jaw member **18** extends distally from the pivotable coupling and upper jaw member **20**, in this example, may be pivotably coupled to lower jaw member **18** via a jaw pivot. The location of the jaw pivot may be positioned at various locations along lower jaw **18** depending upon a number of factors, e.g., the desired size of the "bite" or opening for accepting tissue between the jaw members, the amount of closing force between the jaw members, etc. One or both jaw members **18**, **20** may also have a number of protrusions, projections, grasping teeth, textured surfaces, etc., on the surface or surfaces of the jaw members **18**, **20** facing one another to facilitate the adherence of tissue between the jaw members **18**, **20**.

[**0049**] Launch tube **40** may extend from the handle, through tubular body **14**, and distally from the end of tubular body **14** where a distal end of launch tube **40** is pivotally connected to upper jaw member **20** at a launch tube pivot. A distal portion of launch tube **40** may be pivoted into position within a channel or groove defined in upper jaw member **20**, to facilitate a low-profile configuration of tissue manipulation assembly **16**. When articulated, either via launch tube **40** or other mechanism, as described further below, jaw members **18**, **20** may be urged into an open configuration to receive tissue in the jaw opening between the jaw members **18**, **20**.

[**0050**] Launch tube **40** may be advanced from its proximal end at the handle such that the portion of launch tube **38**, which extends distally from body **14**, is forced to rotate at a hinge or pivot and reconfigure itself such that the exposed portion forms a curved or arcuate shape that positions the launch tube opening perpendicularly relative to upper jaw member **20**. Launch tube **40**, or at least the exposed portion of launch tube **38**, may be fabricated from a highly flexible material or it may be fabricated, e.g., from Nitinol tubing material which is adapted to flex, e.g., via circumferential slots, to permit bending.

[**0051**] FIGS. **3**A to **3**C further illustrate one method for articulating a tissue manipulation assembly into an opened and closed configuration. As shown in FIG. **3**A, the assembly may be delivered into a patient while in a low-profile configuration **40**, e.g., trans-orally, trans-anally, percutaneously, through an endoscope, an endoscopic device, directly, etc., and desirably positioned relative to a tissue region of interest **36**. The endoscopic body **12** may be rigidized to maintain its configuration within the patient body. Alternatively, it may be left in a flexible state during the procedure.

[**0052**] The tissue region of interest **36** as well as the procedure may be visualized through visualization lumen **30** or a separate imager. In either case, tissue manipulation assembly **16** and helical tissue engagement member **32** may be advanced distally out from endoscopic body **12** through their respective lumens **26**, **28**. Tissue engagement member **32** may be advanced into contact against the tissue surface, as shown in FIG. **3**A, and then rotated via its proximal handle until the tissue is engaged. The engaged tissue F may be pulled proximally relative to endoscopic body **12** and tissue manipulation assembly **16** may be actuated via its proximally located handle into an open expanded jaw configuration for receiving the engaged tissue F, as shown in FIG. **3**B.

[**0053**] Once desirably positioned, launch tube **40** may be urged proximally via its proximal end at the handle. Because of the jaw assembly pivot and the relative positioning of the upper jaw **20** along lower jaw member **18** and the launch tube pivot along upper jaw member **20**, the proximal movement of launch tube **40** may effectively articulate upper jaw **20** into an expanded jaw configuration, as shown in FIG. **3**B. Proximally urging launch tube **40** may also urge lower jaw member **18** to pivot and form an angle relative to a longitudinal axis of tubular body **14**. The opening of upper jaw **20** relative to lower jaw **18** creates a jaw opening for grasping,

receiving, and/or manipulating tissue. Moreover, the tissue manipulation assembly may also include a stop located adjacent to the jaw assembly pivot or within the pivot itself.

[0054] Once launch tube **40** has been urged proximally, it may be locked into place thus locking the jaw configuration as well. Moreover, having the launch tube **40** articulate the jaw members **18**, **20** in this variation eliminates the need for a separate jaw articulation and/or locking mechanism. Once the tissue has been pulled or manipulated between jaw members **18**, **20**, launch tube **40** may be pushed distally to actuate the jaw members **18**, **20** into a closed, grasping configuration, as shown in FIG. **3**C, for engagement with the tissue. As launch tube **40** is urged distally through elongate body **12**, lower jaw member **18** may be maintained at an angle relative to the tissue to further facilitate manipulation of the grasped tissue.

[0055] Although launch tube **40** may be fabricated from different materials having differing flexibilities, it may also be fabricated from a single material, as mentioned above, where the flexible portion **38** may be configured, e.g., by slotting, to allow for bending of the launch tube **40** in a plane to form a single curved or arcuate section while the proximal rigid section may extend at least partially into tubular body **14** to provide column strength to launch tube **40** while it is urged distally upon upper jaw member **20** and upon any tissue engaged thereby, as seen in the FIG. **3**C.

[0056] Once the tissue has been engaged between jaw members **18**, **20**, a needle assembly may be urged through the handle and out through launch tube **40**. The needle assembly may pass through lower jaw member **18** via a needle assembly opening defined in lower jaw member **18** to pierce through the grasped tissue. Once the needle assembly has been passed through the engaged tissue, one or more tissue anchors may be deployed for securing the tissue, as described in further detail in U.S. patent application Ser. No. 10/955,245, which has been incorporated by reference above.

[0057] Helical tissue engagement member **32** may be retracted from the tissue F or it may be left within the tissue while the tissue manipulation assembly engages and secures the tissue F. The helical tissue engagement member **32** is shown as a tissue piercing helix or corkscrew structure upon flexible shaft **34**. Tissue engagement member **32** may be rotated about its longitudinal axis to engage the tissue of interest by rotating its handle located on the proximal end of flexible shaft **34**.

[0058] A distal portion of shaft **34** proximal to engagement member **32** (or the entire length or a majority of the length of shaft **34** in other variations) may include a marked section **42**, as shown in FIGS. **3**A to **3**C. Helical tissue engagement member **32** and flexible shaft **34** are rotated about its longitudinal axis to advance engagement member **32** into the tissue region of interest **36**. Accordingly, marked section **42** may comprise any number of markings, designs, patterns, projections, textures, etc., which acts to provide a visual indication to the user as to the translational movement, rotation, direction of rotation, etc., of engagement member **32** and shaft **34** relative to tissue region **36** when viewed from outside the patient body laparoscopically or endoluminally, for instance, through visual lumen **30**.

[0059] Utilizing the instruments described above, various endoluminal procedures may be performed to correct failures in obesity-related procedures. For example, FIG. **4**A shows a detail view of a pouch P which may have failed, e.g., through a stretched and enlarged pouch lumen PL. The remaining anatomy, such as the remainder of the stomach S, has been omitted only for clarity. The flexible body **14** and tissue manipulation assembly **16**, described above, may be advanced per-orally, through the esophagus E, and into the enlarged pouch lumen PL. The rigidizable endoscopic body **12** may be used to pass the flexible body **14** therethrough and into pouch P, as shown in the figure. In an alternative method (and for methods described below), the endoscopic body **12** may be omitted entirely and flexible body **14** and tissue manipulation assembly **16** may be passed directly into the pouch P.

[0060] Once within the pouch lumen PL, the tissue manipulation assembly **16** may be used to create within the pouch P approximated folds of tissue **50** which are secured via expandable tissue anchors **52** expelled from the tissue manipulation assembly **16**, as described above. Any number of tissue folds **50**, i.e., one or more, may be created in a uniform pattern or randomly throughout the pouch lumen PL, as shown in FIG. **4**B, such that the enlarged pouch P is reduced in size to a pouch P' having a smaller volume.

[0061] Another method may involve endoluminally reducing a diameter or size of the stoma created between the pouch lumen PL and the intestinal tract I through the pouch anastomosis PA. As shown in FIG. **5**A, flexible body **14** and tissue manipulation assembly **16** may be advanced through the patient's esophagus E and into the pouch lumen PL either alone or optionally through endoscopic body **12**, as illustrated. Once within the pouch P, tissue manipulation assembly **16** may be directed to the tissue circumferentially around the anastomotic connection PA, where the tissue from pouch P and a portion of the tissue from the intestinal tract I around the pouch anastomosis PA may be approximated by tissue manipulation assembly **16** and secured by one or more pairs of tissue anchors **52**, as shown in FIG. **5**B. One pair or several pairs of tissue anchors **52** may be deployed into the tissue randomly or in a uniformly spaced configuration around the pouch anastomosis PA provided that the enlarged opening through pouch anastomosis PA is reduced in size to a smaller pouch anastomosis PA' opening which is more effective in restricting the passage of food received within pouch lumen PL.

[0062] There are a number of methods for reducing the stoma size by varying the configuration of the tissue anchors deployed around the stoma. For instance, the example illustrated in FIG. **5**C shows a partial cross-sectional side view of a reduced stoma through a pouch anastomosis PA where a portion of the anastomosed intestinal tissue I and a portion of the pouch tissue may be approximated around the stoma via one or more anchor pairs **52** deployed and secured against the tissue. In another variation, rather than approximating the intestinal tissue I, the portion of pouch tissue adjacent to or in proximity to the pouch anastomosis PA may be plicated such that the intestinal tissue I remains untouched, as shown in FIG. **5**D.

[0063] In yet other examples, the tissue from the pouch adjacent to the pouch anastomosis PA may be approximated and secured to reduce the stoma size. As shown in the end view from within the pouch of the stoma and pouch anastomosis PA in FIG. **5**E, one or more anchor pairs **52** may be

deployed into the pouch tissue to form one or more folds of tissue F which are formed radially with respect to the pouch anastomosis PA. In another example shown in FIG. **5**F, one or more tissue folds F may be formed and secured such that the tissue folds F are circumferentially or more annularly aligned with respect to the stoma and pouch anastomosis PA.

[**0064**] FIGS. **6**A and **6**B show detail perspective and cross-sectional top views of a reduced pouch lumen PL by approximating multiple folds of tissue within the pouch P. The tissue manipulation assembly **16** may be advanced into the pouch P and at least a first fold of tissue F may be approximated to at least a second fold of tissue F' and secured via one or more pairs of tissue anchors **52**. FIG. **6**B shows a cross-sectional view of the reduced pouch P' where the first fold of tissue F and the second fold of tissue F' are secured to one another by the tissue anchors **52** one either side of the respective tissue folds F, F' via a length of suture **54** passing through and securing each fold F, F'. Although a single tissue apposition is shown in this example, multiple folds of tissue may be approximated towards one another around the pouch lumen PL until the desired reduction in the pouch lumen volume has been achieved.

[**0065**] FIG. **7**A shows an example of a method where an endoluminal tissue ablation instrument **60**, e.g., plasma torch, laser, radio-frequency probe, etc., may be advanced through the endoscopic body **12** and into the pouch P. This ablation instrument **60** may be activated to ablate one or more regions of tissue **62** within pouch P, particularly the mucosal tissue, such that the shrinkage of the ablated tissue within pouch lumen PL shrinks the size of the pouch P to a reduced pouch P', as shown in FIG. **7**B. Examples of other tools and instruments for injuring regions of tissue and mucosa are shown and described in further detail in U.S. patent application Ser. No. 10/898,683 filed Jul. 23, 2004, which is incorporated herein by reference in its entirety.

[**0066**] FIG. **8**A shows an example of another method where one or more ridges of tissue may be plicated to form at least one tissue fold which is secured by one or more tissue anchors **52** to reduce the side of a pouch P'. To enhance the healing of the tissue fold, a portion of the tissue **72** may be optionally resected or otherwise injured to leave a region of injured or sclerosed tissue **70** along the tissue fold, as shown in FIG. **8**B. Injuring or removing tissue **72** is optional and may be performed on any of the tissue folds created within pouch lumen PL if additional healing of the tissue is desired. Examples of methods and instruments which may be utilized to resect and/or remove tissue from within a lumen, such as pouch lumen PL, may be seen in U.S. patent application Ser. No. 11/069,890 filed Feb. 28, 2005, which is incorporated herein by reference in its entirety.

[**0067**] To facilitate the grasping and manipulation of the tissue within the pouch P, various methods and instruments may be utilized. In one example, a tissue engagement member, such as member **32**, may be positioned through elongate body **12** and utilized with tissue manipulation assembly **16**, as described above. In another example, the tissue manipulation assembly **16** may be positioned within pouch lumen PL with lower and upper jaw members **18**, **20** positioned in an open configuration for receiving tissue therebetween. The air, along with any other fluids, contained within pouch lumen PL may be evacuated out, e.g., through one of the lumens defined through elongate body **12** or through a catheter advanced through body **12**. The evacuation of air and fluids from pouch lumen PL may collapse the pouch tissue onto the flexible body **14** and between the jaw members **18**, **20**.

[**0068**] In yet another example shown in FIG. **9**A, a hollow instrument, such as Verres needle **80**, may be advanced percutaneously and positioned through an opening **86** defined through the abdominal wall AW of a patient. Verres needle **80** may be fluidly connected via tubing **82** to a pump (not shown) such that a gas (e.g., air, carbon dioxide, nitrogen, etc.) may be pumped into the peritoneal cavity PC of the patient body. As more gas is introduced into the peritoneal cavity PC, the tissue of pouch P may become collapsed due to a pressure differential onto and over the tissue manipulation assembly **16**, particularly between jaw members **18**, **20** which may be positioned within pouch lumen PL prior to insufflating the peritoneal cavity PC with a gas, as shown in FIG. **9**B. The collapsed pouch tissue **84** positioned between jaw members **18**, **20** may then be easily grasped and secured by deploying one or more tissue anchors through the collapsed pouch tissue **84**. The gas within the peritoneal cavity PC may be evacuated to allow for the tissue manipulation assembly **16** to be repositioned within the pouch and the process of re-filling the peritoneal cavity PC with gas may be repeated. This method of insufflating the peritoneal cavity PC may be utilized either alone or in conjunction with insufflating and exsufflating the gas and fluids within the pouch lumen PL itself through the elongate body **12**, as described above.

[**0069**] In yet another method for facilitating engagement of the interior tissue, an elongate laparoscopic instrument **90** having a blunted atraumatic tip **92** may be advanced through a percutaneous opening **86** and into contact with an outer surface of the pouch P. As shown in FIG. **10**A, laparoscopic instrument **90** may be advanced distally through the peritoneal cavity via handle **94** with tissue manipulation assembly **16** positioned within the pouch lumen PL. Once the atraumatic tip **92** contacts the outer surface of the pouch P, laparoscopic instrument **90** may be pushed against the outer surface of pouch P such that a fold of tissue is formed within the pouch lumen PL in the proximity of the tissue manipulation assembly **16**, as shown in FIG. **10**B. To further facilitate the formation of the tissue fold, the interior of the pouch lumen PL may be insufflated with a gas to present a taut surface of the pouch tissue around the tissue fold.

[**0070**] With the tissue fold formed within the pouch lumen PL around the atraumatic tip **92**, the jaw members **18**, **20** of tissue manipulation assembly **16** may be positioned on either side of the tissue fold to grasp and secure the tissue, as further shown in FIG. **10**B. Once the tissue fold has been secured, laparoscopic instrument **90** may be repositioned at another location on the outer surface of the pouch P. This process may be repeated as many times as necessary until a desired reduction in the pouch size has been attained. Moreover, the tissue folds may be formed in a uniform manner around the pouch lumen PL or in a random manner, as desired and as described above.

[**0071**] Various laparoscopic instruments may be utilized for forming the tissue bulges within the pouch lumen PL. An elongate shaft **90** having a simple blunted or rounded atraumatic tip **92**, as described above and as shown in FIG.

11A, may be utilized. Alternatively, an elongate laparoscopic instrument having a variable geometry on its distal end may be utilized. Having such a variable geometry may be useful when advancing the instrument in the patient body in a low profile and expanded prior to contacting the pouch outer surface to form tissue folds having various geometries within the pouch. One example is shown in FIG. **11**B where an elongate shaft **90** may have one or more retractable arms **96** which can pivot into a deployed configuration for contacting against the pouch outer surface and retracted **96'** during delivery and withdrawal of the instrument **90** within the patient body. In another alternative, any laparoscopic instrument having a blunted distal shape may be utilized in forming the tissue folds. For example, FIG. **11**C shows an elongate shaft **90** having a conventional laparoscopic grasper **98** attached thereto. The grasper **98** may be utilized in its closed configuration to press against the pouch outer surface, as described above.

[**0072**] In yet another alternative, rather than using a laparoscopic instrument, the finger or fingers of the surgeon or practitioner may simply be used to press against the outer surface of the patient body and against the pouch tissue surface to form the tissue folds within the pouch for securement by the tissue manipulation assembly **16**. In any of the above described examples, the interior of the pouch lumen PL may be optionally insufflated by a gas during the tissue forming procedure.

[**0073**] In endoluminally revising a failed surgical procedure for the treatment of obesity, aside from reducing a volume of the pouch lumen, or reducing a diameter of the stoma through the pouch anastomosis PA, or even ablating the interior of the pouch lumen PL tissue surface, a length of the Roux limb may also be altered endoluminally. Altering the length of the Roux limb may create an additional malabsorptive portion of intestinal tissue and further reduce the ability of the patient body to absorb food passing therethrough.

[**0074**] As shown in FIG. **12**A, a failed RYGB procedure with a pouch P and its anastomosed intestinal tract I is illustrated. A rigidizable endoscopic body **12** having a rounded atraumatic distal end **100** may be advanced perorally, through the patient's esophagus E and pouch lumen PL, through the patient's pouch anastomosis PA and into the length of the intestinal tract I.

[**0075**] As described above, at least a portion of a length of endoscopic body **12** is transitionable between a flexible state and a rigid state and may have an articulatable or steerable distal portion **24**. As the endoscopic body **12** in its flexible state is advanced a distance through the intestinal tract I, its steerable distal portion may be articulated to curve into a retroflexed configuration relative to its proximal length. As the endoscopic body **12** is retroflexed, a distal portion **104** of the intestinal tract I along the jejunum JE or ilium IL may be pulled along by the endoscopic body **12** into contact against or in proximity to the outer surface of the pouch P, as shown in FIG. **12**B.

[**0076**] Once the endoscopic body **12** and distal portion **104** of the intestinal tract has been desirably positioned relative to the pouch P, endoscopic body **12** may be optionally transitioned into its rigid state to provide a stable platform for cutting or piercing through the distal portion **104** and pouch P for creating an anastomotic connection therebetween. With the atraumatic distal end **100** desirably positioned and endoscopic body **12** optionally rigidized, an endoscopic piercing or ablative instrument **102**, e.g., an energizable needle knife, may be advanced through the distal portion **104** of intestinal tissue and through the portion of pouch tissue **106**. Once an opening through both tissue portions has been achieved, one or more tissue anchors **52** may be deployed around the circumference of the openings using, e.g., tissue manipulation assembly **16**, to secure the intestinal tissue I to the pouch P to create a side-to-side anastomotic connection **108**, as shown in FIG. **12**C. The anastomotic connection **108** may be further dilated, if desired, by utilizing additional instruments such as balloons, sphincterotomes, etc. Once the anastomotic connection **108** has been formed, the endoscopic body **12** may be transitioned into its flexible state (if initially rigidized) and withdrawn from the patient body.

[**0077**] Optionally, the original pouch anastomosis PA may be closed using tissue anchors **52**, if so desired, to ensure that food received within the pouch P is shunted through the newly created anastomosis **108** and bypasses the length of intestinal tissue I.

[**0078**] Additionally and/or optionally, one or more portions of the intestinal tissue may be excised and removed entirely from the patient body by withdrawing the excised tissue proximally through a natural orifice of the patient body, for instance, from and/or through the pouch, esophagus, and out of the patient's mouth. One example is shown in FIGS. **12**D to **12**G where after the pouch P has been shunted through the newly created anastomosis **108**, the rigidizable endoscopic body **12** may be directed towards the pouch anastomosis PA where a cutting or piercing instrument, such as instrument **102**, may be used to cut away the anastomosed intestinal portion I from the pouch P to leave a pouch opening **109**, as shown in FIG. **12**D.

[**0079**] With the previously anastomosed intestinal tissue I cut from pouch P, the pouch opening **109** may be closed via one or more tissue anchors **52**, as shown in FIG. **12**E, using the tissue manipulation assembly **16**. The endoscopic body **12** may be redirected through the anastomosis **108** where instrument **102** may be advanced at least partially into the intestinal tissue I to completely excise the portion of intestinal tissue **111**. As shown in FIG. **12**F, the excised intestinal tissue **111** may be grasped or otherwise secured via the tissue manipulation assembly **16** (or endoscopic graspers or other engaging instrument) and withdrawn proximally through the intestinal opening **113**, anastomosis **108**, pouch P, and through the patient esophagus and out of the patient's mouth. After the excised intestinal tissue **111** has been removed from the patient body, the endoscopic body **12** (or just the tissue manipulation assembly **16**) may be advanced back into pouch P and through the anastomosis **108** to deploy one or more additional tissue anchors **52** to close the intestinal tissue opening **113**, as shown in FIG. **12**G. The instruments may then be withdrawn proximally and removed from the patient body entirely.

[**0080**] In yet another method for reducing a size of the pouch lumen PL, endoscopic body **12** may be advanced through a transgastric opening **110** created along the pouch wall. The transgastric opening **110** may be formed by utilizing endoluminal cutting and/or piercing instruments or by utilizing laparoscopic instruments passed through the

patient's abdominal wall. In either case, the endoscopic body **12** may be passed through the transgastric opening **110** and into the peritoneal cavity of the patient body.

[**0081**] Once within the peritoneal cavity, the endoscopic body **12** may be steered and/or retroflexed to direct the tissue manipulation assembly **16** adjacent to the outer surface of the pouch P, as shown in FIG. **13**A. From there, tissue manipulation assembly **16** may be utilized to create at least one (or more) externally formed tissue ridge **114** by deploying one or more tissue anchors **52** along the outer surface of the pouch P. As the tissue is plicated and secured, the interior of the pouch lumen PL may be reduced in size to form a smaller pouch P', as shown in FIG. **13**B. Once the pouch P' has been desirably reduced in size, the endoscopic body **12** may be withdrawn proximally through the transgastric opening **110**, which may then be closed by deploying one or more tissue anchors **52** to close the opening **112**.

[**0082**] Examples for creating and/or closing transgastric openings as well as passing endoluminal instruments through the transgastric openings may be seen in further detail in U.S. patent application Ser. No. 11/238,279 filed Sep. 28, 2005 and U.S. Prov. Pat. App. Ser. No. 60/728,382 filed Oct. 18, 2005, each of which is incorporated herein by reference in its entirety.

[**0083**] As mentioned above, various combinations of different methods and procedures described herein may be combined with one another as practicable. For example, as shown in FIGS. **14**A and **14**B, an elongate rigidizable endoscopic body **12** may be advanced per-orally and trans-esophageally into the pouch lumen PL. The distal end of endoscopic body **12** may be directed towards the stoma defined by the pouch anastomosis PA, where flexible body **14** and tissue manipulation assembly **16** may be manipulated to grasp, e.g., the edges **122** of the pouch anastomosis PA, to approximate and secure the tissue, as shown in FIG. **14**B. The procedure may be viewed via an imaging assembly, such as fiber optic or CCD or CMOS electronic imager, or endoscope **120**.

[**0084**] As further shown in FIGS. **14**C and **14**D, one pair or several pairs of anchors **52** may be deployed into the pouch and/or intestinal tissue to approximate the edges **122** of the pouch anastomosis PA to create a smaller opening through a reduced pouch anastomosis PA'. Once the stoma size has been reduced, the tissue may be viewed via the endoscope **120** and the elongate rigidizable body **12** may be withdrawn from the pouch P. Alternatively and/or optionally, the pouch interior may be further reduced in size by re-directing the elongate body **12** and tissue manipulation assembly **16** to regions around the pouch lumen PL to create and secure with anchors **52** one or more tissue folds F, as shown in FIG. **15**A.

[**0085**] Although at least one tissue fold F may be formed and secured, multiple tissue folds F may be formed and secured around a periphery of the pouch lumen by manipulating the elongate body **12** and tissue manipulation assembly **16**, as shown in FIGS. **15**B and **15**C, to result in a revised pouch P' which not only has a reduced anastomotic opening PA' but also a reduced pouch P' size. The tissue anchors **52** may be deployed in tissue folds F formed randomly throughout the pouch lumen PL or in a circumferential or uniform manner. Furthermore, one or more of the tissue folds and anchors **52** may optionally be interconnected with one another via a drawstring-type mechanism, e.g., a loop suture, made from a suture or biocompatible wire to optionally tighten the tissue folds relative to one another in a purse-string manner. This type of looped suture and anchor assembly allows for the surgeon to manually adjust the size of the restriction opening.

[**0086**] In yet another example for creating a combination of various methods, FIGS. **16**A to **16**C illustrate the deployment of tissue anchors **52** around a periphery of the pouch anastomosis PA to result in a reduced anastomotic connection PA', as described above. The rigidizable elongate body **12** may be advanced adjacent to the pouch anastomosis PA, as shown in FIG. **16**A, where the tissue manipulation assembly **16** may be used to deploy one or more tissue anchor pairs **52** around the pouch anastomosis PA, as shown in FIGS. **16**B and **16**C. The tissue anchors **52** may be deployed in a radial or circumferential configuration, as described above.

[**0087**] Once the stoma has been reduced in size, the elongate body **12** may optionally be redirected to regions of tissue around the pouch lumen PL to create and secure one or more tissue folds F to result in a reduced pouch P' also having a reduced pouch anastomosis PA'. As described above, the tissue folds F may be formed uniformly or randomly through the pouch lumen PL and may be further interconnected, as desired.

[**0088**] These examples are intended to illustrate the various types of procedures and methods which may be combined as practicable and are not intended to be limiting in any way. Moreover, the elongate body **12** may be transitioned between a rigid state and a flexible state at any time during a procedure depending upon the desired degree of platform stability during tissue manipulation and securement within the pouch lumen PL.

[**0089**] Although various illustrative embodiments are described above, it will be evident to one skilled in the art that a variety of combinations of aspects of different variations, changes, and modifications are within the scope of the invention. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What is claimed is:

1. A method for correcting a failed surgically-created pouch within a patient body, comprising:

advancing a tissue manipulation assembly endoluminally into the failed surgically-created pouch;

forming at least one tissue fold within the pouch via the tissue manipulation assembly; and

securing the at least one tissue fold formed by the tissue manipulation assembly via at least one tissue anchor such that a volume of the pouch is reduced.

2. The method of claim 1 wherein advancing a tissue manipulation assembly endoluminally comprises advancing the assembly per-orally and trans-esophageally into the pouch.

3. The method of claim 1 wherein advancing a tissue manipulation assembly endoluminally comprises advancing a rigidizable elongate body endoluminally into the pouch and advancing the tissue manipulation assembly through at least one lumen defined through the elongate body.

4. The method of claim 3 further comprising rigidizing the elongate body to maintain a configuration after advancing the rigidizable elongate body endoluminally into the pouch.

5. The method of claim 1 wherein advancing a tissue manipulation assembly endoluminally comprises directing the assembly to a region of tissue within the pouch.

6. The method of claim 1 wherein forming at least one tissue fold comprises engaging a tissue region within the pouch via articulatable jaw members of the tissue manipulation assembly.

7. The method of claim 1 wherein forming at least one tissue fold comprises collapsing the tissue of the pouch onto the tissue manipulation assembly.

8. The method of claim 7 wherein collapsing the tissue of the pouch comprises evacuating air from within the pouch.

9. The method of claim 7 wherein collapsing the tissue of the pouch comprises insufflating a peritoneal space exterior to the pouch.

10. The method of claim 1 wherein forming at least one tissue fold comprises pushing a region of tissue into the pouch via a laparoscopic instrument pressed against an outer surface of the pouch.

11. The method of claim 1 wherein forming at least one tissue fold comprises pushing a region of tissue into the pouch via a finger pressed against an outer surface of the pouch.

12. The method of claim 1 further comprising forming a plurality of additional tissue folds within the pouch.

13. The method of claim 1 wherein forming at least one tissue fold comprises injuring and/or removing a portion of the tissue fold to promote healing of the tissue fold.

14. The method of claim 1 further comprising removing a portion of the tissue fold such that the volume of the pouch is further reduced.

15. The method of claim 1 further comprising deploying at least one additional tissue anchor into a region of tissue around an opening between the pouch and a length of anastomosed intestinal tissue via the tissue manipulation assembly.

16. The method of claim 15 further comprising approximating the at least one additional tissue anchor such that the opening between the pouch and the intestinal tissue is reduced in size.

17. The method of claim 1 further comprising deploying at least one additional tissue anchor into a region of tissue within the pouch and purse-stringing the tissue anchor and the at least one additional tissue anchor together.

18. A method for correcting a failed surgically-created pouch within a patient body, comprising:

advancing a tissue manipulation assembly endoluminally into the failed surgically-created pouch;

deploying at least one tissue anchor into a region of tissue around an opening between the pouch and a length of anastomosed intestinal tissue via the tissue manipulation assembly; and

approximating the at least one tissue anchor such that the opening between the pouch and the intestinal tissue is reduced in size.

19. The method of claim 18 wherein advancing a tissue manipulation assembly endoluminally comprises advancing the assembly per-orally and trans-esophageally into the pouch.

20. The method of claim 18 wherein advancing a tissue manipulation assembly endoluminally comprises advancing a rigidizable elongate body endoluminally into the pouch and advancing the tissue manipulation assembly through at least one lumen defined through the elongate body.

21. The method of claim 20 further comprising rigidizing the elongate body to maintain a configuration after advancing the rigidizable elongate body endoluminally into the pouch.

22. The method of claim 18 wherein deploying at least one tissue anchor comprises passing the at least one tissue anchor between the pouch and the intestinal tissue around the opening via a needle assembly delivered by the tissue manipulation assembly.

23. The method of claim 18 further comprising deploying a plurality of additional tissue anchors into the region of tissue around the opening.

24. The method of claim 18 wherein the at least one tissue anchor is deployed into at least a portion of pouch tissue and at least a portion of intestinal tissue.

25. The method of claim 18 wherein the at least one tissue anchor is deployed into a portion of pouch tissue surrounding the opening.

26. The method of claim 25 wherein the at least one tissue anchor is deployed in a radial configuration with respect to the opening.

27. The method of claim 25 wherein the at least one tissue anchor is deployed in a circumferential or annular pattern with respect to the opening.

28. The method of claim 18 further comprising forming at least one tissue fold within the pouch via the tissue manipulation assembly.

29. The method of claim 28 further comprising forming a plurality of additional tissue folds within the pouch.

30. The method of claim 18 wherein approximating the at least one tissue anchor comprises drawing tissue anchors towards one another such that the opening between the pouch and the intestinal tissue is reduced in size.

31. The method of claim 18 further comprising forming at least one tissue fold within the pouch via the tissue manipulation assembly.

32. The method of claim 31 further comprising securing the at least one tissue fold formed by the tissue manipulation assembly via at least one additional tissue anchor such that a volume of the pouch is reduced.

33. The method of claim 31 further comprising purse-stringing the tissue anchor and the at least one additional tissue anchor together.

34. A method for correcting a failed surgically-created pouch within a patient body, comprising:

advancing an elongate body endoluminally through the pouch and into a length of intestinal tissue connected to the pouch via a pouch anastomosis;

retroflexing a distal portion of the elongate body relative to a proximal length of the elongate body such that a distal portion of the intestinal tissue is brought into proximity of the pouch;

forming an opening endoluminally between the distal portion of intestinal tissue and the pouch; and

securing the distal portion of intestinal tissue to the pouch.

35. The method of claim 34 wherein advancing an elongate body endoluminally comprises rigidizing at least a portion of the elongate body to maintain a configuration of the elongate body within the pouch.

36. The method of claim 34 wherein forming an opening endoluminally comprises advancing a tissue piercing and/or ablating instrument through the elongate body and creating the opening between the distal portion of intestinal tissue and the pouch.

37. The method of claim 34 further comprising advancing a tissue manipulation assembly through at least one lumen defined through the elongate body.

38. The method of claim 37 wherein securing the distal portion comprises deploying at least one tissue anchor from the tissue manipulation assembly into the distal portion of intestinal tissue and the pouch.

39. The method of claim 34 wherein forming an opening further comprises dilating the opening.

40. The method of claim 34 further comprising closing the pouch anastomosis between the pouch and the length of intestinal tissue.

41. The method of claim 34 further comprising withdrawing the elongate body from the pouch and the length of intestinal tissue.

42. The method of claim 34 further comprising cutting a first portion of the intestinal tissue from the pouch anastomosis.

43. The method of claim 42 further comprising cutting a second portion of the intestinal tissue proximal to the distal portion of intestinal tissue.

44. The method of claim 43 further comprising endoluminally removing an excised portion of the intestinal tissue proximally through the pouch.

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摘要(译)

描述了用于对先前进行的失败的肥胖程序进行腔内修正的方法和装置。一个或多个腔内器械可以口服进入先前形成的失效袋中，其中可以进行许多不同的手术。可以形成并固定一个或多个组织折叠以减小小袋的尺寸，或者可以使用经腔内展开的组织锚定器来减小将小袋连接到肠道的造口的尺寸。这些手术可以完全从袋腔内或袋的外表面上进行，通过器械进入患者的腹膜腔进入胃腔。或者，小袋内的内部组织可能受伤或硬化以使小袋内腔收缩。在另一个替代方案中，Roux肢体的长度可以在腔内缩短以产生吸收不良区域。