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(54) Title: DEVICES AND METHODS FACILITATING SLEEVE GASTRECTOMY PROCEDURES

(57) Abstract: A device for use in bariatric surgery includes a tube member, a coupling member, and a rod member. The tube member includes a proximal portion and a distal portion having a distal end. The coupling member is affixed to the tube member. The rod member includes a proximal portion and a distal portion having a distal end. The rod member is slidably coupled with the coupling member. The distal end of the rod member is fixedly coupled to the distal end of the tube member. The proximal portion of the rod member is translatable relative to the tube member to transition the distal portion of the rod member between a contracted position, wherein the distal portion of the rod member extends along the distal portion of the tube member, and a deployed position, wherein the distal portion of the rod member bows outwardly relative to the tube member.

DEVICES AND METHODS FACILITATING SLEEVE GASTRECTOMY PROCEDURES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of and priority to U.S. Provisional Patent Application No. 61/716,109, filed on October 19, 2012, the entire contents of which are incorporated herein by reference.

BACKGROUND

Technical Field

[0002] The present disclosure relates generally to bariatric surgery and, more particularly, to devices and methods that facilitate performing sleeve gastrectomy procedures.

Background of Related Art

[0003] Obesity is reaching epidemic proportions in many regions of the world, particularly in the United States. In order to treat obesity, various surgical procedures have been developed including, for example, gastric bypass, adjustable gastric banding, and sleeve gastrectomy. The goal in each of these procedures is to reduce the patient's stomach capacity to restrict the amount of food that the patient can eat. The reduced stomach capacity, in turn, results in a feeling of fullness for the patient after ingesting a relatively smaller amount of food. Thus, the patient can achieve significant weight loss.

[0004] Sleeve gastrectomy involves transecting the stomach, e.g., using a stapling device or other suitable device, to reduce the patient's stomach volume. Sleeve gastectomy procedures are often aided by the use of a bougie, which serves as a guide or template for transecting the stomach to the appropriate configuration while inhibiting inadvertent transection of stomach or

esophageal tissue. Once the stomach has been appropriately transected, the bougie is removed and a leak test is performed to determine whether there are any areas of extravasation.

[0005] There is a need for a device and/or method of positioning the stomach, or other hollow organ, to avoid shifting of the sides of the organ with respect to one another during transection, stapling etc., in a surgical procedure. There is a need for a simpler, more convenient way to perform a leak test, visualize the transected tissue, etc.

SUMMARY

[0006] In an aspect of the present disclosure, a medical device comprises a flexible tube that is hollow and contains a channel extending from a proximal opening to a distal closed tapered end, a series of perforations or openings towards the distal end of the tube allowing for suction fixation of tissue a flexible component alongside the tube that when deployed allows for the stretching of a stomach to its original shape, the application of suction placing the tube along a lesser curvature of the stomach, fixing anterior and posterior walls of the stomach, and preventing their movement while the surgeon transects the stomach, the suction allowing for clear identification of the tube.

[0007] The flexible component is desirably an attached movable element. The tube can be made of silicone. A coupling device that holds the movable element to the tube can be provided. The movable element can be deployable to align the stomach by evening out the anterior and posterior walls of the stomach and by pushing the tube and a perforated area of the tube towards the lesser curvature of the stomach. Suction can be applied at a proximal end of the tube. Air or colored fluid can be instilled into a proximal end of the tube.

[0008] In a further aspect, a device for use in bariatric surgery provided in accordance with the present disclosure generally includes an elongated flexible tube member, a coupling

member, and an elongated resilient rod member. The tube member defines a proximal portion and a distal portion having a distal end. The coupling member is affixed to the tube member intermediate the proximal and distal portions of the tube member. The rod member defines a proximal portion and a distal portion having a distal end. The rod member is slidably coupled to the coupling member intermediate the proximal and distal portions of the rod member. The distal end of the rod member is fixedly coupled to the distal end of the tube member. The proximal portion of the rod member is translatable relative to the tube member to transition the distal portion of the rod member between a contracted position, wherein the distal portion of the rod member extends along the distal portion of the tube member, and a deployed position, wherein the distal portion of the rod member bows outwardly relative to the tube member.

[0009] In embodiments, the tube member defines a lumen extending therethrough and the distal portion of the tube member defines a plurality of apertures in fluid communication with the lumen.

[0010] In embodiments, a suction source is provided. The suction source is operably coupled to the tube member and configured to apply suction to the lumen of the tube member.

[0011] In embodiments, a fluid source is provided. The fluid source is operably coupled to the tube member and configured to supply fluid to the lumen of the tube member.

[0012] In embodiments, an end cap is affixed to the distal end of the tube member. The distal end of the rod member is affixed to the end cap. Further, the distal end of the rod member may be monolithically formed with the end cap. The cap can house a releasable connection of the rod member and tube member, or other mechanisms.

[0013] In embodiments, in the deployed position, the distal portion of the rod member defines a curvature complementary to a greater curvature portion of a patient's stomach.

[0014] In embodiments, the coupling member includes a ring disposed about the tube member. The ring slidably receives the rod member.

[0015] Also provided in accordance with the present disclosure is a system for use in bariatric surgery. The system includes a device having an elongated flexible tube member, a coupling member, and an elongated resilient rod member. The tube member includes a lumen extending therethrough and defines a proximal portion and a distal portion having a distal end. The distal portion of the tube member defines a plurality of apertures therethrough in fluid communication with the lumen. The coupling member is affixed to the tube member intermediate the proximal and distal portions of the tube member. The rod member defines a proximal portion and a distal portion having a distal end. The rod member is slidably coupled with the coupling member intermediate the proximal and distal portions of the rod member. The distal end of the rod member is fixedly coupled to the distal end of the tube member. The proximal portion of the rod member is translatable relative to the tube member to transition the distal portion of the rod member between a contracted position, wherein the distal portion of the rod member extends along the distal portion of the tube member, and a deployed position, wherein the distal portion of the rod member bows outwardly relative to the tube member. The system further includes a suction source and a fluid source. The suction source is operably coupled to the tube member and configured to apply suction to the lumen for suctioning stomach contents through the apertures and into the lumen and/or for suctioning stomach tissue to the distal portion of the tube member. The fluid source is operably coupled to the tube member and configured to supply fluid to the tube member for delivery to a patient's stomach via the plurality of apertures.

[0016] In embodiments, the device further includes an end cap affixed to the distal end of the tube member. The distal end of the rod member is affixed to the end cap. The system end cap may further be configured to seal the lumen at the distal end of the tube member. The distal end of the rod member may be monolithically formed with the end cap.

[0017] In embodiments, in the deployed position, the distal portion of the rod member defines a curvature complementary to a greater curvature portion of a patient's stomach.

[0018] In embodiments, one or more control members is provided for controlling a suction pressure applied by the suction source and/or controlling a flow rate of fluid provided from the fluid source.

[0019] A method of bariatric surgery provided in accordance with the present disclosure includes inserting a device, e.g., a device similar to any of the embodiments detailed above, at least partially into a patient's stomach and transitioning the device from a contracted condition to a deployed condition. In the deployed condition, the distal portion of the rod member bows outwardly relative to the tube member to complementarily mate with a greater curvature portion of the patient's stomach. The method further includes applying suction to retain a lesser curvature portion of the patient's stomach in complementary mating relation with the distal portion of the tube member, transitioning the device from the deployed condition back to the contracted condition, and transecting the patient's stomach adjacent the tube member.

[0020] In embodiments, the proximal portion of the rod member is translated distally relative to the tube member to transition the device from the contracted condition to the deployed condition. In embodiments, the proximal portion of the rod member is translated proximally relative to the tube member to transition the device from the deployed condition back to the contracted condition.

[0021] In embodiments, the method further includes introducing fluid through the tube member and into the patient's stomach to perform a leak test.

[0022] In embodiments, transecting the patient's stomach includes transecting the patient's stomach to form a tubular structure disposed about the distal portion of the tube member and having a diameter similar to a diameter of the distal portion of the tube member.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] Various aspects and features of the present disclosure are described herein with reference to the drawings wherein:

[0024] Fig. 1 is a schematic illustration showing a device provided in accordance with the present disclosure inserted into a patient's stomach;

[0025] Fig. 2 is a perspective view of a system provided in accordance with the present disclosure including the device of Fig. 1 disposed in a first condition;

[0026] Fig. 3 is a perspective view of the device of Fig. 1, disposed in a second condition; and

[0027] Fig. 4 is a flow diagram illustrating a method of performing a bariatric surgical procedure provided in accordance with the present disclosure.

DETAILED DESCRIPTION OF EMBODIMENTS

[0028] Embodiments of the present disclosure are detailed below with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views. Throughout this description, the term "proximal" will refer to the portion of the device or component thereof that is closest to the user and the term "distal" will refer to the portion of the device or component thereof that is farthest from the user.

[0029] Turning now to Figs. 1-3, a device provided in accordance with the present disclosure and configured for use during a sleeve gastrectomy procedure is shown generally identified by reference numeral 10. As best shown in Figs. 2-3, device 10 includes an elongated tube member 20 and an elongated rod member 40 coupled to tube member 20. The materials for the tube member 20 and the rod member are generally polymeric materials appropriate for surgical applications, such as the materials used to make a bougie or catheter. The tube member is hollow, whereas the rod member can be hollow or solid. Tube member 20 is formed from flexible materials such as silicone and rubber, although other suitable flexible materials are also contemplated. Tube member 20 has a distal portion 22 and a proximal portion 24 and defines a lumen 26 extending therethrough. A plurality of perforations or apertures 28 are defined through an outer wall of distal portion 22 of tube member 20. Apertures 28 enable fluid communication through the outer wall of tube member 20 between lumen 26 and the exterior of tube member 20. Tube member 20 further includes a distal end cap 30. The distal end of the tubular member 20 is closed in any appropriate manner. Distal end cap 30 may define a rounded tapered configuration, blunt conical configuration, or any other suitable configuration that facilitates atraumatic insertion into a patient's stomach "ST" (Fig. 1). Distal end cap 30 is affixed to the

distal end of tube member 20 in sealing engagement therewith to seal off lumen 26 at the distal end of tube member 20.

[0030] Tube member 20 is configured to connect to a suction source "S" and a fluid source "F." Suction source "S" is operable to provide suction within lumen 26 for suctioning fluids, stomach contents, etc. through apertures 28 and into lumen 26 for removal and/or for suctioning stomach tissue into contact with tube member 20. One or more control members 32, e.g., a valve, may interdisposed between tube member 20 and the suction source "S" to control the suction force being applied, although controls may alternatively or additionally provided on a user interface (not shown) of the suction source "S." Fluid source "F" is configured to pump fluid, e.g., water or air, into lumen 26 of tube member 20 and out through apertures 28 into the stomach "ST" (Fig. 1). Similar to suction source "S," the fluid source "F" may include one or more control members 34, e.g., a valve, interdisposed between tube member 20 and the fluid source "F" to control the flow rate and/or pressure of fluid being pumped through lumen 26 of tube member 20, although controls may alternatively or additionally provided on a user interface (not shown) of the fluid source "F." The tube member 20 can have one or more passageways.

[0031] Continuing with reference to Figs. 2-3, rod member 40 is formed from a semi-rigid, resiliently flexible material, e.g., a suitable elastomer, and defines a length greater than the length of tube member 20 such that rod member 40 can be accessed outside the patient and/or remotely of the surgical site. Rod member 40 defines a distal portion 42 having a distal end 43 and a proximal portion 44. Distal end 43 of rod member 40 is integrally, i.e., monolithically, formed with or otherwise affixed to distal end cap 30. A coupling 50, e.g., a ring, sleeve, hook, latch, etc., affixed to tube member 20 slidably receives a portion of rod member 40 therethrough to slidably couple rod member 40 to tube member 20 intermediate the distal and proximal

portions 22, 24, respectively, of tube member 20. As a result of the above-configuration, rod member 40 is slidable through coupling 50 and relative to tube member 20 between a contracted position corresponding to a first condition of device 10 (Fig. 2), wherein distal portion 42 of rod member 40 extends along and abuts the outer surface of tube member 20 is substantially parallel relation relative thereto, and a deployed position corresponding to a second condition of device 10 (Fig. 3), wherein distal portion 42 of rod member 40 is bowed outwardly from tube member 20 and is spaced therefrom. In the deployed position, rod member 40 defines a configuration that generally complements the curvature of the greater curvature portion "C2" of the stomach "ST" (Fig. 1). Preferably, the flexibility and resilience and dimensioning of the member 40 is such that member 40 automatically forms a half-heart shape, with a large, bowed, curvature adjacent the proximal portion 44. Such a shape complements the greater curvature of the stomach. These features can be adapted to applications in other hollow organs as well. The rod member should be strong enough to stretch out the stomach, and reposition the anterior and posterior walls of the stomach. Proximal portion 44 of rod member 40 may be grasped and manipulated relative to tube member 20 to transition rod member 40 between the contracted and deployed positions. As mentioned above, rod member 40 is dimensioned such that proximal portion 44 is accessible from outside the patient, thus readily enabling manipulation thereof. More specifically, translating rod member 40 distally relative to tube member 20 and coupling 50 urges rod member 40 distally through coupling 50 such that distal portion 42 of rod member 40 is bowed outwardly relative to tube member 20 towards the deployed position. Translating rod member 40 proximally relative to tube member 20 pulls rod member 40 proximally through coupling 50 such the distal portion 42 of rod member 40 is pulled inwardly relative to tube member 20 towards the contracted position. As an alternative to manually manipulating rod

member 40, an actuator or actuation assembly (not shown) may be coupled to the proximal ends of tube member 20 and rod member 40 to enable selective translation of rod member 40 relative to tube member 20.

[0032] Referring to Fig. 4, in conjunction with Figs. 1-3, the use of device 10 during the course of a sleeve gastrectomy procedure is described. However, it is also envisioned that device 10 be capable of use in other similar surgical procedures, within hollow organs other than the stomach, etc. Initially, with rod member 40 disposed in the contracted condition, device 10, lead by distal end cap 30, is inserted through the patient's mouth, esophagus, and into the patient's stomach "ST" to the position shown in Fig. 1, wherein at least distal portion 22 of tube member 20, coupling 50, and distal portion 42 of rod member 40 are disposed within the patient's stomach "ST" (step S410). Once this position has been achieved, proximal portion 44 of rod member 40 is translated distally relative to tube member 20 such that distal portion 42 of rod member bows outwardly relative to tube member 20 towards the deployed position. As distal portion 42 of rod member 40 bows outwardly towards the deployed position, tube member 20 is urged towards and into complementary mating relation with the lesser curvature portion "C1" of the stomach "ST," while distal portion 42 of rod member 40 is urged towards and into complementary mating relation with the greater curvature portion "C2" of the stomach "ST" (step S420), engaging and flattening the stomach. As such, the orientation of device 10 with tube member 20 extending along the lesser curvature portion "C1" of the stomach "ST" between the esophageal sphincter "E" and the pyloric sphincter "P" can be readily achieved. As a result of this configuration of device 10 in the second condition, the above-described orientation of device 10 within the stomach is maintained despite spasms, folding, spiraling, and/or shifting of the stomach "ST." Further, the configuration of device 10 allows for proper positioning within

the stomach "ST" without the assistance of an viewing instrument, e.g., an endoscope (not shown).

[0033] Once the proper orientation of tube member 20 of device 10 has been achieved, suction source "S" may be activated to apply suction within lumen 26 for suctioning any remaining contents within the stomach "ST" into lumen 26 of tube member 20 through apertures 28. Application of suction within lumen 26 also suctions the lesser curvature portion "C1" of the stomach "ST" to the outer periphery of tube member 20, to ensure and maintain the complementary mating relation of tube member 20 with the lesser curvature portion "C1" of the stomach "ST" (step S430). Control member 32 may be manipulated or otherwise controlled to apply sufficient suction to maintain the relative position of tube member 20 without damaging surrounding tissue.

[0034] With tube member 20 maintained in position relative to the lesser curvature portion "C1" of the stomach "ST" as a result of the applied suction, proximal portion 44 of rod member 40 is translated proximally relative to tube member 20 such the distal portion 42 of rod member 40 is pulled inwardly relative to tube member 20 back to the contracted position (step S440). As suction is maintained at this point, tube member 20 is maintained in the positioned detailed above despite contraction of distal portion 42 of rod member 40.

[0035] Once distal portion 42 of rod member 40 has been returned to the contracted position, transection of the stomach "ST" adjacent tube member 20 on a opposite side of tube member 20 relative to the lesser curvature portion "C1" of the stomach "ST" may be effected in any suitable fashion (step S450), e.g., using a stapling device or other suitable device. Transection in this manner reforms the stomach "ST" to a tubular-shaped configuration that slightly larger than the outer dimension of tube member 20 and extends between the esophageal

sphincter "E" and the pyloric sphincter "P." The suction is maintained while the stomach tissue is transected and stapled, the shape of the tube member 20 forming a visible bulge. As can be appreciated, the diameter of tube member 20 may be selected in accordance with a desired diameter of the tubular-shape reformed stomach. The remaining stomach tissue is removed from the patient.

[0036] Upon completion of the stomach transection, the applied suction is removed and a leak test is performed (step S460). The leak test is performed by activating the fluid source "F" to pump fluid through lumen 26 of tube member 20 and into the stomach via apertures 28. The fluid may be air, colored water, or other suitable gaseous or liquid leak test agent. The fluid is pumped into the stomach "ST," e.g., via controlling control member 34, to achieve a pressure within the stomach "ST" sufficient to test the transected stomach tissue for extravasation. If extravasation is detected, the leak is repaired prior to completing the procedure, by suturing or any other appropriate method. The leak test is repeated after repairing the portion or portions of transected tissue where extravasation is detected, until no further extravasation is detected. Ultimately, device 10 is withdrawn from the patient's stomach "ST." A scope can be provided with the device, and the tube member may have a separate passageway for the scope or other devices. Alternatively, the user of the device may pass a scope through the singular passageway as needed.

[0037] In any of the embodiments disclosed herein, the tube member can be made of a clear polymer and a scope or camera is provided. In any of the embodiments disclosed herein, an ultrasound probe can be provided.

[0038] In any of the embodiments disclosed herein, the rod member 40 can be detachable from the tube member 20. The attachment or connection at the distal end of the tube member 20

can be frangible, releasable, etc., to allow the rod member 40 to be detached from the tube member 20. In this way, the user of the device has removed the rod member 40 from the site, while maintaining the position of the stomach (using suction, as discussed, avoiding transecting or stapling the rod member 40.

[0039] It will be understood that various modifications may be made to the embodiments of the present disclosure herein. Therefore, the above description should not be construed as limiting, but merely as exemplifications of embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

WHAT IS CLAIMED IS:

1. A medical device, comprising:

a flexible tube that is hollow and contains a channel extending from a proximal opening to a distal closed tapered end;

a series of perforations or openings towards the distal end of the tube allowing for suction fixation of tissue;

a flexible component alongside the tube that when deployed allows for the stretching of a stomach to its original shape;

the application of suction placing the tube along a lesser curvature of the stomach, fixing anterior and posterior walls of the stomach, and preventing their movement while the surgeon transects the stomach, the suction allowing for clear identification of the tube.

2. The medical device of claim 1, wherein the flexible component is an attached movable element.

3.The medical device of claim 1, wherein the tube is made of silicone.

4.The medical device of claim 2, further comprising a coupling device that holds the movable element to the tube.

5.The medical device of claim 2, the movable element being deployable to align the stomach by evening out the anterior and posterior walls of the stomach and by pushing the tube and a perforated area of the tube towards the lesser curvature of the stomach.

6.The medical device of claim 2, wherein suction is applied at a proximal end of the tube.

7.The medical device of claim 2, wherein air or colored fluid is instilled into a proximal end of the tube.

8. A device for use in bariatric surgery, comprising:

an elongated flexible tube member defining a proximal portion and a distal portion having a distal end;

a coupling member affixed to the tube member intermediate the proximal and distal portions of the tube member; and

an elongated resilient rod member defining a proximal portion and a distal portion having a distal end, the rod member slidably coupled with the coupling member intermediate the proximal and distal portions of the rod member, the distal end of the rod member fixedly coupled to the distal end of the tube member, the proximal portion of the rod member translatable relative to the tube member to transition the distal portion of the rod member between a contracted position, wherein the distal portion of the rod member extends along the distal portion of the tube member, and a deployed position, wherein the distal portion of the rod member bows outwardly relative to the tube member.

9. The device according to claim 8, wherein the tube member defines a lumen extending therethrough and wherein the distal portion of the tube member defines a plurality of apertures in fluid communication with the lumen.

10. The device according to claim 8, further including a suction source operably coupled to the tube member and configured to apply suction to the lumen of the tube member.

11. The device according to claim 8, further including a fluid source operably coupled to the tube member and configured to supply fluid to the lumen of the tube member.

12. The device according to claim 8, further including an end cap affixed to the distal end of the tube member, the distal end of the rod member affixed to the end cap.

13. The device according to claim 12, wherein the distal end of the rod member is monolithically formed with the end cap.

14. The device according to claim 8, wherein, in the deployed position, the distal portion of the rod member defines a curvature complementary to a greater curvature portion of a patient's stomach.

15. The device according to claim 8, wherein the coupling member includes a ring disposed about the tube member and slidably receiving the rod member.

16. A system for use in bariatric surgery, comprising:

a device, including:

an elongated flexible tube member having a lumen extending therethrough and defining a proximal portion and a distal portion having a distal end, the distal portion of the tube member defining a plurality of apertures therethrough in fluid communication with the lumen;

a coupling member affixed to the tube member intermediate the proximal and distal portions of the tube member; and

an elongated resilient rod member defining a proximal portion and a distal portion having a distal end, the rod member slidably coupled to the coupling member intermediate the proximal and distal portions of the rod member, the distal end of the rod member fixedly coupled to the distal end of the tube member, the proximal portion of the rod member translatable relative to the tube member to transition the distal portion of the rod member between a contracted position, wherein the distal portion of the rod member extends along the distal portion of the tube member, and a deployed position, wherein the distal portion of the rod member bows outwardly relative to the tube member;

a suction source operably coupled to the tube member and configured to apply suction to the lumen for suctioning stomach contents through the apertures and into the lumen and for suctioning stomach tissue to the distal portion of the tube member; and

a fluid source operably coupled to the tube member and configured to supply fluid to the tube member for delivery to a patient's stomach via the plurality of apertures.

17. The system according to claim 16, further including an end cap affixed to the distal end of the tube member, the distal end of the rod member affixed to the end cap.

18. The system according to claim 17, wherein the end cap seals the lumen at the distal end of the tube member.

19. The system according to claim 17, wherein the distal end of the rod member is monolithically formed with the end cap.

20. The system according to claim 16, wherein, in the deployed position, the distal portion of the rod member defines a curvature complementary to a greater curvature portion of a patient's stomach.

21. The system according to claim 16, further including a first control member configured to control a suction pressure applied by the suction source.

22. The system according to claim 16, further including a second control member configured to control a flow rate of fluid provided from the fluid source.

23. A method of bariatric surgery, comprising:

inserting a device at least partially into a patient's stomach, the device including:

an elongated flexible tube member defining a proximal portion and a distal portion having a distal end; and

an elongated resilient rod member defining a proximal portion and a distal portion having a distal end, the rod member slidably coupled to the tube member intermediate the

proximal and distal portions of the tube member, the distal end of the rod member fixedly coupled to the distal end of the tube member;

transitioning the device from a contracted condition to a deployed condition wherein, in the deployed condition, the distal portion of the rod member bows outwardly relative to the tube member to complementarily mate with a greater curvature portion of the patient's stomach;

applying suction to retain a lesser curvature portion of the patient's stomach in complementary mating relation with the distal portion of the tube member;

transitioning the device from the deployed condition back to the contracted condition; and

transecting the patient's stomach adjacent the tube member.

24. The method according to claim 23, wherein the proximal portion of the rod member is translated distally relative to the tube member to transition the device from the contracted condition to the deployed condition.

25. The method according to claim 23, wherein the proximal portion of the rod member is translated proximally relative to the tube member to transition the device from the deployed condition back to the contracted condition.

26. The method according to claim 23, further including introducing fluid through the tube member and into the patient's stomach to perform a leak test.

27. The method according to claim 23, wherein transecting the patient's stomach includes transecting the patient's stomach to form a tubular structure disposed about the distal portion of the tube member and having a diameter similar to a diameter of the distal portion of the tube member.

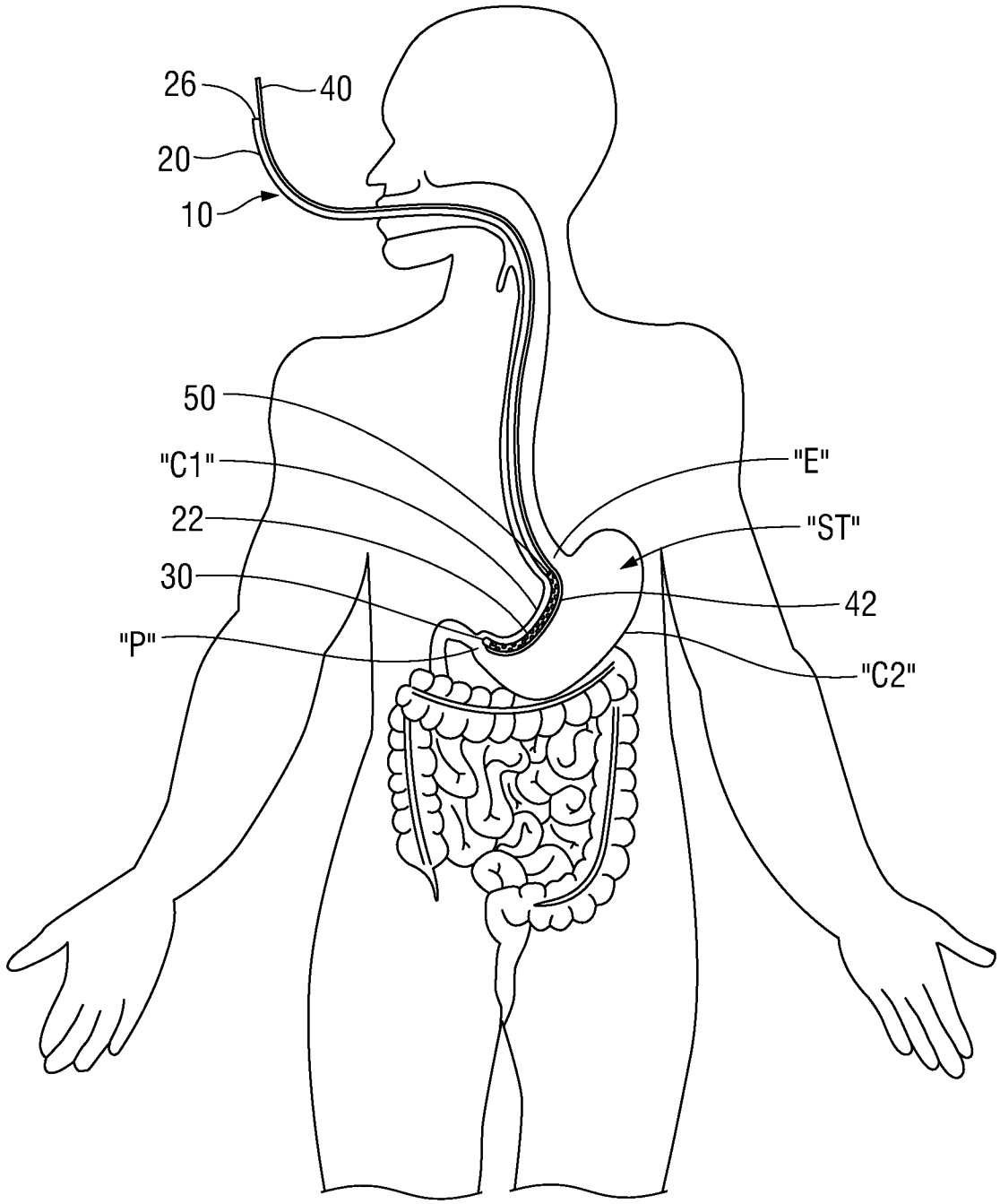

FIG. 1

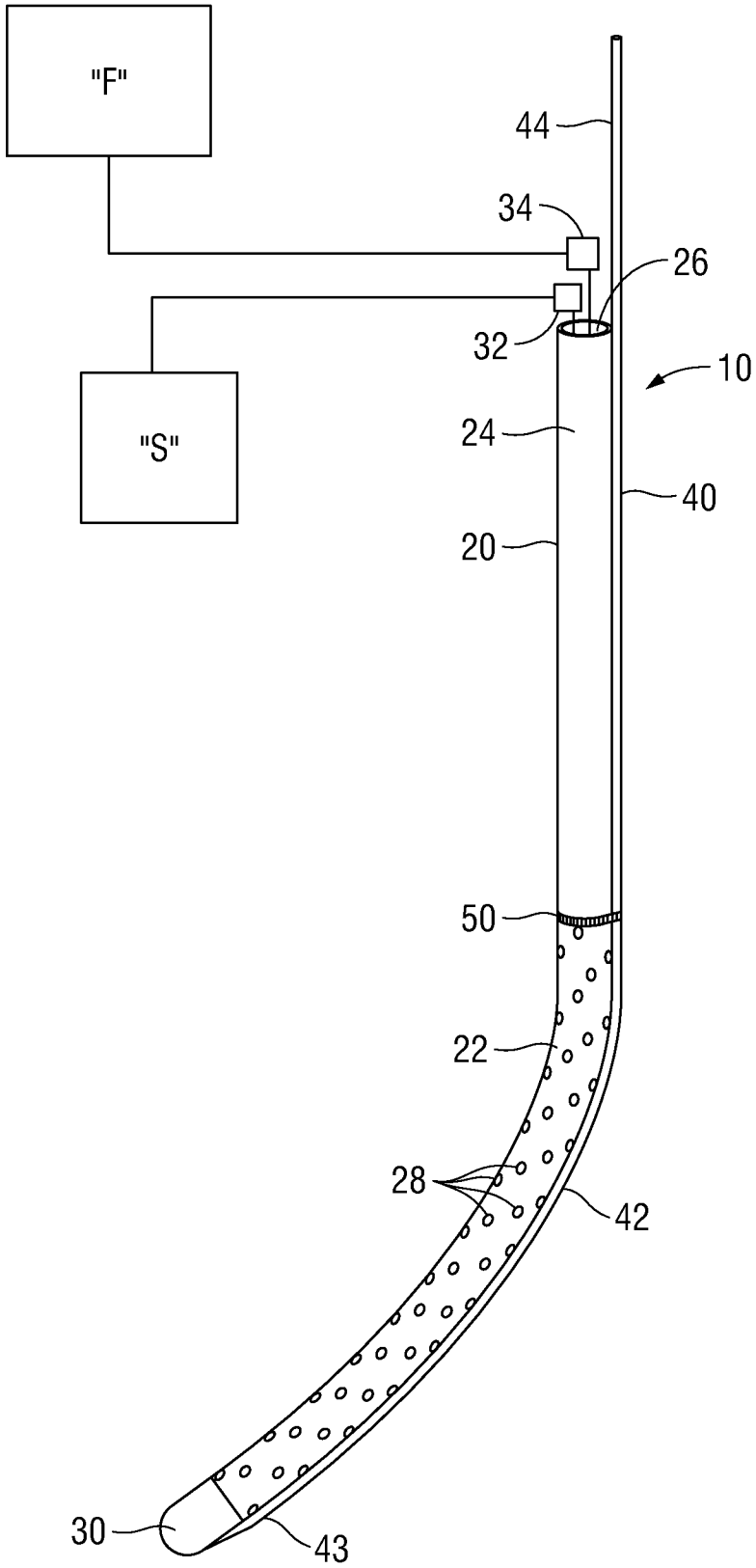

FIG. 2

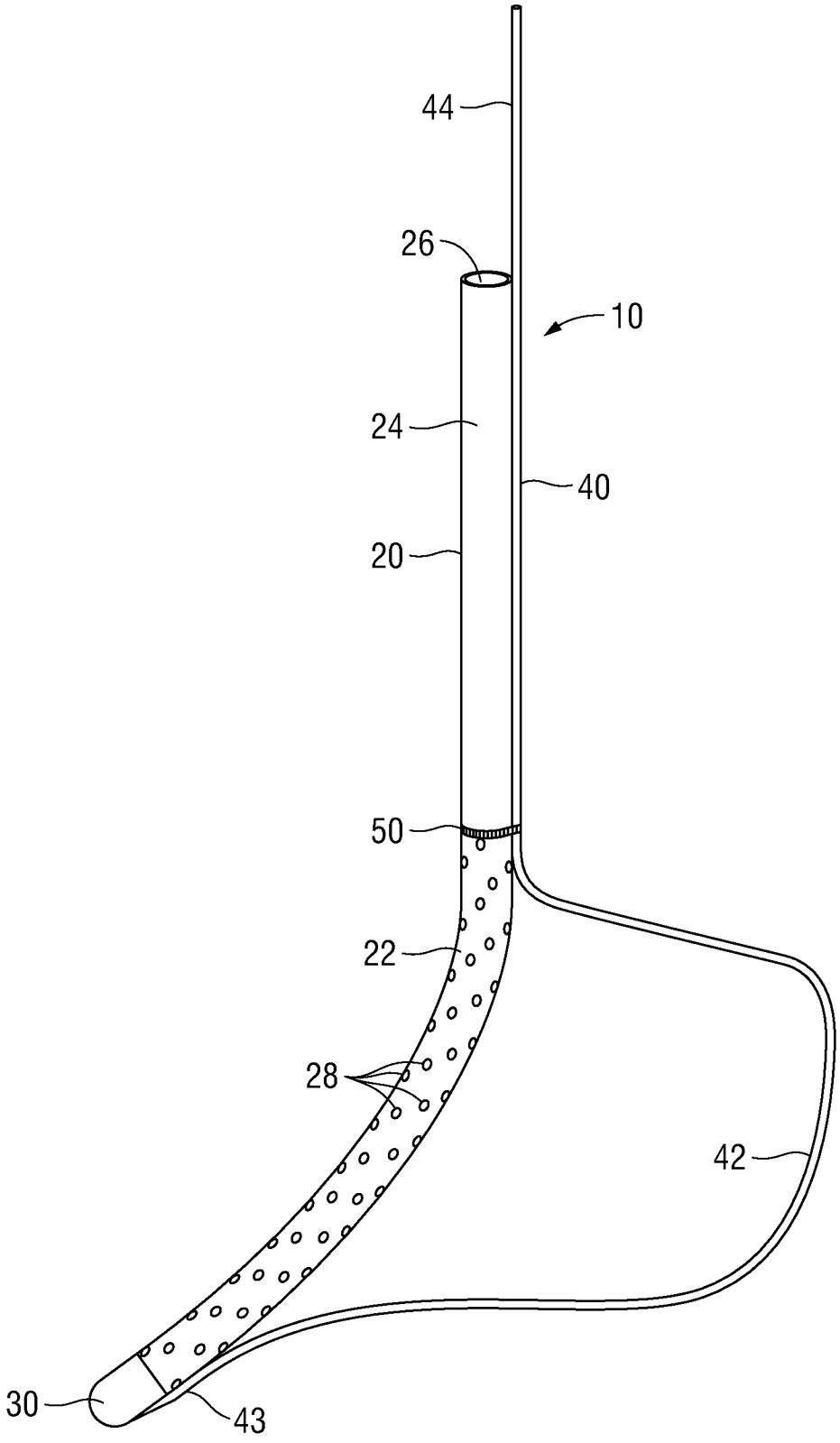

FIG. 3

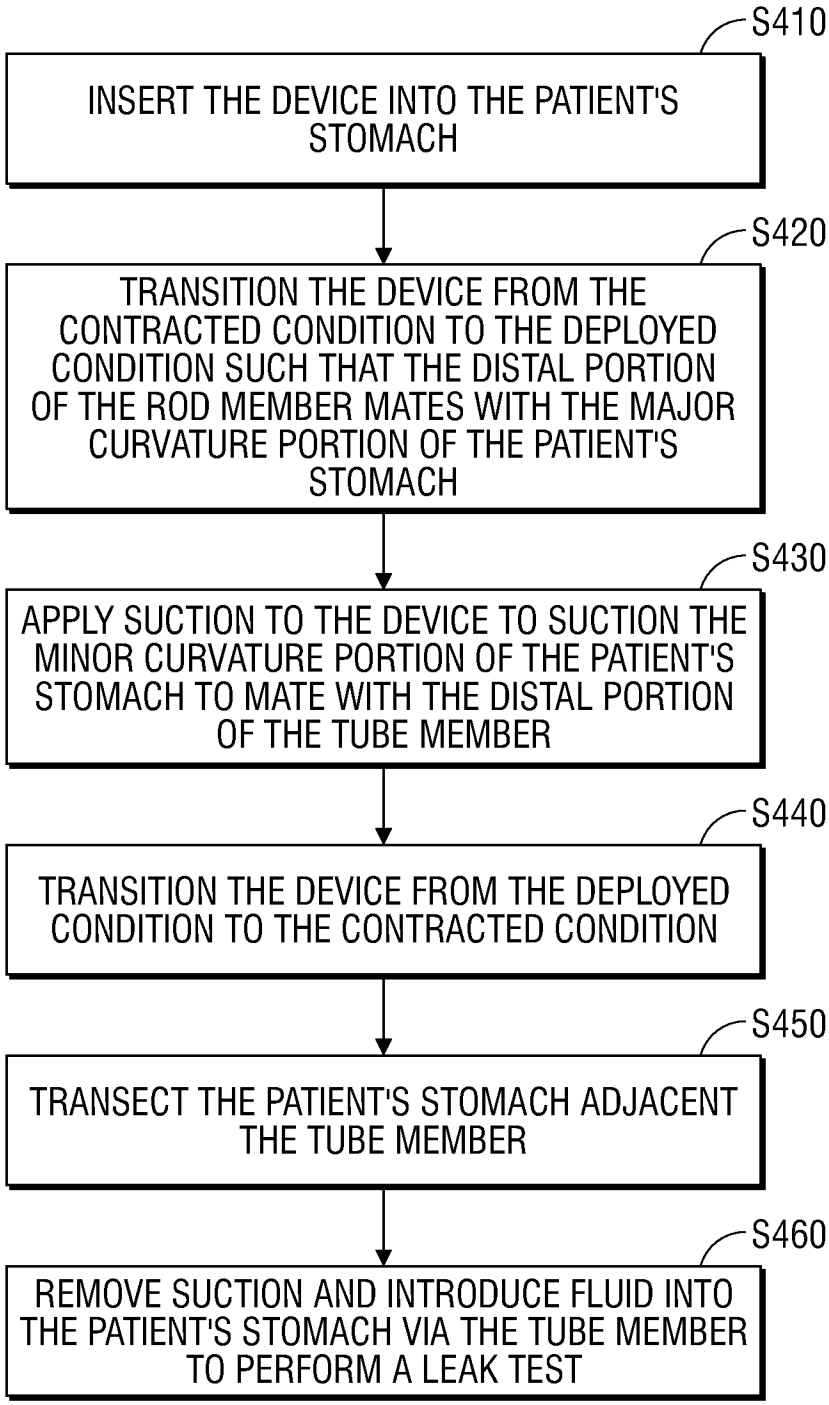
S410
INSERT THE DEVICE INTO THE PATIENT'S STOMACH
S420
TRANSITION THE DEVICE FROM THE CONTRACTED CONDITION TO THE DEPLOYED CONDITION SUCH THAT THE DISTAL PORTION OF THE ROD MEMBER MATES WITH THE MAJOR CURVATURE PORTION OF THE PATIENT'S STOMACH
S430
APPLY SUCTION TO THE DEVICE TO SUCTION THE MINOR CURVATURE PORTION OF THE PATIENT'S STOMACH TO MATE WITH THE DISTAL PORTION OF THE TUBE MEMBER
S440
TRANSITION THE DEVICE FROM THE DEPLOYED CONDITION TO THE CONTRACTED CONDITION
S450
TRANSECT THE PATIENT'S STOMACH ADJACENT THE TUBE MEMBER
S460
REMOVE SUCTION AND INTRODUCE FLUID INTO THE PATIENT'S STOMACH VIA THE TUBE MEMBER TO PERFORM A LEAK TEST

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/065368

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/00(2006.01)i, A61B 17/32(2006.01)i, A61B 17/22(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 17/00; A61N 1/18; A61F 2/06; A61M 5/00; A61F 5/00; A61B 17/04; A61B 17/08; A61B 17/32; A61B 17/22

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: gastrectomy, obesty, bariatric, bougie, suction

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007-0032800 A1 (ORTIZ, M. S. et al.) 8 February 2007 See abstract; paragraphs [0012], [0029], [0032]; claims 1, 6, 10, 15; and figures 1, 3, 5.	1-7
A		8-22
Y	WO 2008-121409 A1 (VARGAS, J.) 9 October 2008 See abstract; paragrpaphs [0037], [0048]; claims 1, 8; and figures 1, 3B-4A.	1-7
A		8-22
A	US 2011-0178454 A1 (GAGNER, M. et al.) 21 July 2011 See abstract; paragraphs [0021]-[0024]; claims 1-2, 12-13; and figures 1-4.	1-22
A	US 2006-0015151 A1 (ALDRICH, W. N.) 19 January 2006 See abstract; paragraphs [0040], [0058]-[0059]; claims 1-2, 40; and figures 2, 13A-13B.	1-22
A	US 2005-0119674 A1 (GINGRAS, P.) 2 June 2005 See abstract; paragraphs [0177]-[0179], [0181]-[0182]; claims 1, 76-77, 81, 83; and figures 3-4, 6-7.	1-22

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
05 February 2014 (05.02.2014)	**06 February 2014 (06.02.2014)**

Name and mailing address of the ISA/KR
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/065368

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23-27
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 23-27 pertain to methods for treatment of the human body and thus relate to a subject-matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/065368

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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