(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 August 2012 (16.08.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/107079 A1

(51) International Patent Classification:
A61F 5/00 (2006.01)

(21) International Application Number:
PCT/EP2011/051814

(22) International Filing Date:
8 February 2011 (08.02.2011)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant *(for all designated States except US)*: **ETHICON ENDO-SURGERY, INC.** [US/US]; 4545 Creek Road, Cincinnati, Ohio 45242-2839 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **PASTORELLI, Alessandro** [IT/IT]; Via Francesco Sivori, 5, I-00136 Roma (IT). **HARRIS, Jason** [US/US]; 3896 Top Flite Lane, Mason, Ohio 45040 (US). **ORTIZ, Mark Steven** [US/US]; 1145 Glen Echo Ln, Milford, Ohio 45150 (US). **D'ARCANGELO, Michele** [IT/IT]; Via Benedetto Croce, 26, I-00142 Roma (IT).

(74) Agents: **LEIHKAUF, Steffen Falk** et al.; c/o Jacobacci & Partners S.p.A., Via Senato, 8, I-20121 Milano (IT).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: AN ENDOLUMINAL LINING SYSTEM

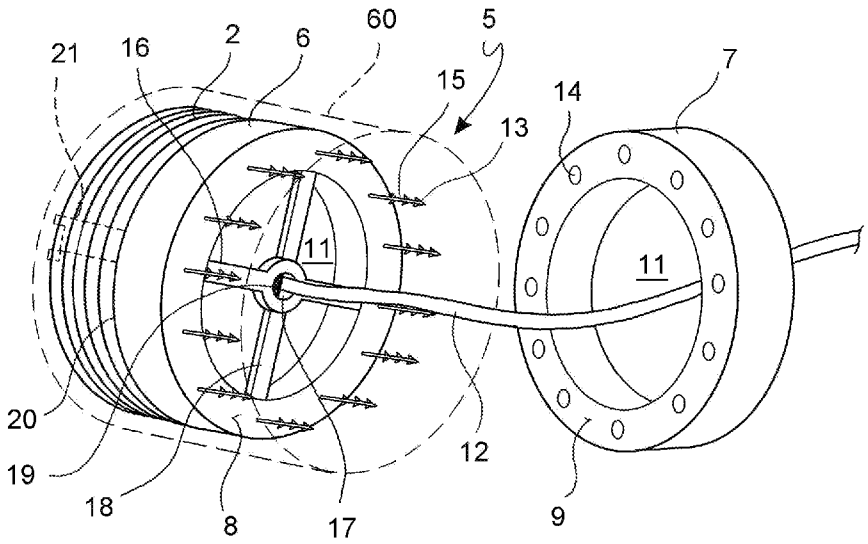

FIG. 1

(57) Abstract: An endoluminal lining system for internally lining a section of the gastrointestinal tract comprises a flexible tubular lining (2) and an anchoring device (5) connected to the lining (2). The anchoring device (5) comprises a distal compression ring (6) and a proximal compression ring (7) initially separate from the distal compression ring (6), the distal and proximal compression rings (6, 7) forming a central passage opening (11), co-operating opposite tissue clamping surfaces (8, 9) and locking means (13; 22) adapted to lock the distal compression ring (6) to the proximal compression ring (7) in a tissue clamping configuration.

WO 2012/107079 A1

AN ENDOLUMINAL LINING SYSTEM

DESCRIPTION

FIELD OF THE INVENTION

The present invention relates generally to medical apparatuses and methods and more particularly to devices and methods for positioning and anchoring a lining to a hollow body organ, such as a stomach, intestine or gastrointestinal tract.

BACKGROUND OF THE INVENTION

In cases of severe obesity, patients may currently undergo several types of surgery either to tie off or staple portions of the large or small intestine or stomach, and/or to bypass portions of the same to reduce the amount of food desired by the patient, and the amount absorbed by the gastrointestinal tract. The procedures currently available include laparoscopic banding, where a device is used to "tie off" or constrict a portion of the stomach, vertical banded gastroplasty (VBG), or a more invasive surgical procedure known as a Roux-En-Y gastric bypass to effect permanent surgical reduction of the stomach's volume and subsequent bypass of the intestine.

Although the outcome of these stomach reduction surgeries leads to patient weight loss because patients are physically forced to eat less due to the reduced size of their stomach, several limitations exist due to the invasiveness of the procedures, including time, general anesthesia, healing of the incisions and other complications attendant to major surgery. In addition, these procedures are only available to severely obese patients (morbid obesity, Body Mass Index >=40) due to their complications, including the risk of death, leaving patients who are considered obese or moderately obese with few, if any, interventional options.

In addition to the above described gastrointestinal reduction surgery, endoluminal sleeves are known for partially or totally lining certain portions of the stomach and of the intestine with the aim to separate or bypass at least part of the food flow from the lined portions of the gastrointestinal tract. It has been observed that by creating a physical barrier between the ingested food and certain regions of the gastrointestinal wall by means of endoluminal sleeves, similar benefits for weight loss and improvement or resolution of type 2 diabetes may be achieved as with gastric bypass surgery. Physicians believe that by creating a physical barrier between the ingested food and selected regions of the gastrointestinal wall, it might be possible to purposefully influence the mechanism of hormonal signal activation originating from the intestine.

A known type of endoluminal sleeve relies on metallic expandable structures, such as a stent, to engage the surrounding hollow organ for holding the sleeve in the planned position. To improve anchoring and stability of the sleeve, it is further known to provide the stent with barbs which penetrate the surrounding tissue.

This notwithstanding, it has been observed that the endoscopic sleeves tend to move inside the GI tract and migrate away from their initially planned position.

US patent n. 7,220,237 B2, Method and device for use in endoscopic organ procedures, to Gannoe et al. describes procedures for internally lining portions of the gastrointestinal tract, using tubular endoluminal sleeves and stapling devices for circumferentially acquiring tissue of the gastric wall and fixating a circular section of the acquired tissue to which an endoluminal sleeve is secured by shape interference.

However, the known methods and devices for placing and securing endoluminal linings within hollow organs, particularly within the gastrointestinal tract, are not yet satisfactory with regard to a safe and reliable introduction, positioning and anchoring of the sleeve and with regard to the conservation of its planned position.

Accordingly, there is a need for improved devices and procedures for positioning and anchoring an endoluminal sleeve in a hollow organ, particularly in the GI tract.

SUMMARY OF THE INVENTION

The present invention provides for an improved endoluminal lining system and method for the transoral, or endoscopic, positioning and anchoring of an endoluminal lining within a hollow body organ, particularly the gastrointestinal tract, including, but not limited to, the esophagus, stomach, portions of or the entire length of the intestinal tract, etc., unless specified otherwise. In the case of the present invention, the surgeon or endoscopist may insert devices as described below through the patient's mouth, down the esophagus and into the stomach or intestine as appropriate. The procedure can be performed entirely from within the patient's stomach or other intestinal tract, and does not necessarily require any external incision.

At least part of the above identified needs are met by an endoluminal lining system for internally lining a hollow organ, particularly a section of the gastrointestinal tract, the system comprising a flexible tubular lining extending between a proximal end and a distal end and an anchoring device for fastening the flexible tubular lining in the hollow organ, the anchoring device comprising a distal compression ring connected to the lining and a proximal compression ring initially separate from the distal compression ring, wherein the distal and proximal compression rings form co-operating opposite tissue clamping

surfaces adapted to clamp a ring shaped tissue portion of the hollow organ therebetween and locking means adapted to lock the distal compression ring to the proximal compression ring in a tissue clamping configuration.

Thanks to the initially separate proximal and distal compression rings, each of them can be endoluminally inserted and positioned within the hollow organ independently from the other compression ring and both rings can be approximated and moved towards each other over relatively great distances, thereby providing enough space and good visual and instrument access therebetween for the acquisition of tissue intended to be clamped.

In accordance with an aspect of the invention, the lining system comprises flexible guide means, such as a guide wire, which can be fastened to the distal compression ring in a pull resistant manner and slidably received by the proximal compression ring, thereby allowing the distal ring to be pulled towards and coupled with the proximal compression ring.

In accordance with an aspect of the invention, the distal compression ring comprises a support frame forming a guide seat for a pull resistant connection with a guide wire, wherein the guide seat is arranged radially inside the distal compression ring at a distance from the tissue clamping surfaces.

This allows to manipulate and pull the distal compression ring inside the hollow organ by acting on a guide wire, but without interference between the guide wire and the tissue portion intended to be clamped between the compression rings.

In accordance with a further aspect of the invention, the ring locking means comprise at least one pair of diametrically opposite locking pins protruding from one of the distal and proximal compression rings towards the other compression ring and adapted to be received by corresponding locking seats formed in the other compression ring, e.g. by snap fit, shape connection or interference fit. Both the locking seats and the locking pins form a guide channel adapted to receive a guide wire which allows the compression rings to be pulled towards each other and in engagement in a tissue clamping configuration.

In accordance with an aspect of the invention, the locking pins and the locking seats are formed in the tissue clamping surfaces of the distal and proximal compression rings, respectively, and the locking pins are intended to puncture and retain the clamped tissue portion between the compression rings.

After inserting the guide wire along a path within the wall of the hollow organ, e.g. the jejunum, the anchoring device and, hence, the endoluminal lining can be positioned very precisely by pulling or sliding the compression ring with the locking pins along the

predefined guide wire path through the hollow organ wall.

In accordance with a further aspect of the invention, the endoluminal lining system comprises a plurality of needles connected to one of the distal and proximal compression rings and movable from a rest position in which pointed free ends of the needles are received inside the compression ring and an activated position in which the pointed free ends of the needles protrude radially outward of the compression ring and are inclined towards the other compression ring. In the activated position, the needles can pierce and retain the organ wall adjacent the compression ring and, during movement of the compression ring towards the other compression ring, the pierced and retained organ wall is pushed together and folded over the clamping surface.

Thanks to the tissue acquisition by means of the needles during the ring approximation movement, the need of additional tissue acquisition devices and procedures is obviated.

Alternatively, the tissue acquisition means may also be separate from the anchoring device and comprise e.g. a plurality of anchoring hooks, e.g. so called T-tags, adapted to be fastened to the organ wall at the anchoring site and flexible pull strings connected to each one of the anchoring hooks and extended through a central passage opening of the proximal compression ring, thereby allowing the fastened organ wall to be pulled between the tissue clamping surfaces from inside the central passage opening.

In accordance with a further aspect of the invention, at least one of the distal and proximal compression ring is time-dependently bio-fragmentable or absorbable. This makes the endoluminal lining a temporary and reversible therapeutic treatment.

In accordance with a further aspect of the invention, the lining system comprises an endoluminal applier for endoluminally delivering and fastening the anchoring device of the lining system to the hollow organ, the applier comprising a ring fastening assembly with a proximal ring holder adapted to hold the proximal compression ring, and a distal ring holder adapted to hold the distal compression ring. The distal ring holder is translatable relative to proximal ring holder and adapted to cooperate with the proximal ring holder for approximating the proximal and distal compression rings and pressing them together. The ring fastening assembly forms a central channel extending longitudinally through the proximal ring holder and through the distal ring holder and, preferably, opening laterally into the space between the proximal and distal ring holders, the central channel being adapted for the passage of an endoscope to visualize both the space between the proximal and distal rings received by the corresponding ring holders and the space distally ahead of the ring fastening assembly and, possibly, to slide the applier endoluminally

along the endoscope to a target site in the hollow organ.

The applier assures a correct relative positioning of the compression rings during fastening of the anchoring device and allows an improved guidance through the GI tract and continuous visualization by the endoscope received in the central channel, both during endoluminal insertion and withdrawal of the applier and during fastening of the compression rings.

These and other aspects and advantages of the present invention shall be made apparent from the accompanying drawings and the description thereof, which illustrate embodiments of the invention and, together with the general description of the invention given above, and the detailed description of the embodiments given below, serve to explain the principles of the present invention.

DESCRIPTION OF THE DRAWINGS

- Figure 1 illustrates an endoluminal lining system with an anchoring device in a disengaged configuration according to an embodiment of the invention;
- Figure 2 illustrates an insertion step for endoluminally placing a tubular lining in a portion of a GI tract, using a lining system according to an embodiment;
- Figure 3 illustrates a tissue fastening step for endoluminally placing a tubular lining in a portion of a GI tract, using a lining system according to an embodiment;
- Figure 4 illustrates a target portion of intestine after completion of the tissue fastening step in figure 3;
- Figure 5 illustrates a further step of a method for endoluminally placing a tubular lining in a portion of the GI tract, using a lining system according to an embodiment;
- Figure 6 illustrates the target portion of intestine and the tubular lining after completion of the endoluminal placement and anchoring procedure;
- Figure 7 illustrates an endoluminal lining system with an anchoring device in a disengaged configuration in accordance with a further embodiment of the invention;
- Figure 8 illustrates a tissue fastening and acquisition step of a method for endoluminally placing a tubular lining in a portion of the GI tract, using a lining system according to an embodiment;
- Figure 9 is an enlarged view of a detail in figure 8;
- Figure 10 illustrates guide wire material inserted in a target portion of a hollow organ wall along a predetermined path for a subsequent tissue acquisition and anchoring of a tubular lining;
- Figures 11 through 13 illustrate further steps of a method for endoluminally anchoring a

tubular lining in a portion of the GI tract, using the lining system in Figure 7;

- Figure 14 illustrates a distal compression ring with an attached tubular lining of an endoluminal lining system in accordance with a further embodiment of the invention;
- Figure 15 illustrates a tissue acquisition step of a method for endoluminally anchoring a tubular lining in a portion of the GI tract, using the lining system in figure 14;
- Figure 16 illustrates a tissue fastening and clamping step of a method for endoluminally anchoring a tubular lining in a portion of the GI tract, using the lining system in figure 14;
- Figures 17 and 18 illustrate different possible positions of the tubular lining within the GI tract of a patient;
- Figure 19 illustrates an applier of the endoluminal lining system in accordance with an embodiment.

DETAILED DESCRIPTION OF EMBODIMENTS

Referring to the drawings where like numerals denote like anatomical structures and components throughout the several views, figures 1 to 6 depict an endoluminal lining system for internally lining a hollow organ 1, particularly a section of the gastrointestinal tract. The system comprises a flexible tubular lining 2 extending between a proximal end 3 and a distal end 4 and an anchoring device 5 for fastening the flexible tubular lining 2 in the hollow organ 1. The anchoring device 5 comprises a distal compression ring 6 connected to the lining 2 and a proximal compression ring 7 initially separate from the distal compression ring 6. The distal and proximal compression rings 6, 7 form both a central passage opening 11 and co-operating opposite tissue clamping surfaces 8, 9 adapted to clamp a ring shaped tissue portion 10 of the hollow organ 1 therebetween, as well as locking means adapted to lock the distal compression ring 6 to the proximal compression ring 7 in a tissue clamping configuration.

Thanks to the initially separate proximal and distal compression rings, each of them can be endoluminally inserted and positioned within the hollow organ independently from the other compression ring and both rings can be approximated and moved towards each other over relatively great distances, thereby providing enough space and good visual and instrument access therebetween for the acquisition of tissue intended to be clamped.

In accordance with an embodiment, the lining system comprises flexible guide and traction means, such as at least one guide wire 12, which is fastened or can be fastened to the distal compression ring 6 in a pull resistant manner and which can be slidably received by the proximal compression ring 7 in a manner to allow the distal compression ring 6 to be pulled towards and coupled with the proximal compression ring 7.

The anchoring device may further comprise a plurality of needle fasteners 13 protruding from the clamping surface 8 of one of the proximal and distal compression rings 6, 7 towards the other compression ring and adapted to pierce and penetrate the tissue portion 10 clamped therebetween. The needle fasteners 13 improve the anchoring of the lining 2 within the hollow organ 1 and prevent tissue from slipping away from the clamping surfaces 8, 9 both during approximation of the compression rings and after completion of the anchoring.

In accordance with an embodiment, the needle fasteners 13 are configured to be received in corresponding locking seats 14, e.g. internally stepped or riffled holes, formed in the clamping surface 9 of the opposite compression ring (preferably the proximal ring 7) and form one or more barbs 15 which block the needle fasteners 13 inside the locking seats 14 to prevent separation of the interlocked compression rings and to maintain the achieved tissue clamping configuration. In this configuration the needle fasteners 13 act both as tissue retaining means and as ring locking means.

In accordance with an embodiment, the distal compression ring 6 may comprise a support frame 16 forming a guide seat 17 for a pull resistant connection of the distal compression ring 6 with the guide wire 12, wherein the guide seat 17 is arranged radially inside the distal compression ring 6 at a distance from the tissue clamping surface 8. This allows to manipulate and pull the distal compression ring 6 inside the hollow organ 1 by acting on a guide wire 12, but without interference between the guide wire 12 and the tissue portion 10 intended to be clamped between the compression rings 6, 7.

The support frame 16 comprises two crosswise (preferably perpendicularly) arranged beams 18 bridging the central passage opening 11 and connected to respectively diametrically opposite portions of the ring body of the distal compression ring 6. The beams 18 are connected to each other in a connecting region in a centre of a circle defined by the compression ring and this connection region forms the above said guide seat 17. The guide seat 17 may comprise a through hole adapted to slidably receive the guide wire 12 and a clamping jaw or a clamping wedge 19 for locking the guide wire 12 in a pull resistant manner.

Alternatively or additionally, a locking ring or clip (not illustrated) may be provided which can be fastened to the guide wire 12 to create a local increase of the guide wire thickness which interferes with the shape of the guide seat 17 to lock the guide wire 12 by shape coupling.

In accordance with an embodiment, the distal compression ring 6 comprises ring releasing

means which detach the support frame 16 from the distal ring 6 when the pulling force transmitted by the support frame 16 to the ring body of the distal compression ring 6 exceeds a predetermined target value sufficient for an adequate tissue clamping pressure and locking pressure between the compression rings 6, 7. The ring releasing means can be adapted to pulling force-dependently separating the support frame 16 from the distal ring body by resilient radially inward retraction or deformation of the support frame 16, particularly the cross beams 18, or by pulling force-dependently breaking the support frame 16, in predetermined breaking points, preferably near opposite end portions of the cross beams 18. This allows to automatically detach the guide wire 12 together with the support frame 18 from the distal compression ring 6 and withdraw them in proximal direction through the central passage openings 11 of the compression rings 6, 7 and endoluminally out of the patients' body.

In accordance with a further embodiment, the lining system comprises a lining seat 20 arranged at the distal compression ring 6 and adapted to receive and hold the pliable tubular lining 2 in a packed (substantially ring shaped), e.g. wrapped, folded, compressed or rolled up, configuration with regard to a lining longitudinal extension. The lining seat 20 may co-operate with the support frame 16 to release the lining 2 and, possibly to push at least a portion of the lining 2 distally out of the lining seat 20, when the support frame 16 is detached from the distal ring body. For this purpose the lining seat 20 may comprise one or more brackets 21 which are directly or indirectly held by the support frame 16 in a retaining position (suitable to retain the packed lining 2) as long as the support frame 16 is coupled to the ring body. Upon detachment of the support frame 16 from the ring body, the brackets 21 move in a release position in which the lining 2 is released to unfold distally.

In accordance with an embodiment, the brackets 21 are formed integrally (as a single piece) with the support frame 16.

The endoluminal lining system further comprises tissue acquisition means which may be incorporated in the anchoring device 5 or separate from the anchoring device 5.

In accordance with an embodiment, the tissue acquisition means comprise e.g. a plurality of anchoring hooks 30, e.g. so called T-tags, adapted to be fastened to the tissue portion 10 at the anchoring site and flexible pull strings 31 connected to each one of the anchoring hooks 30 and adapted to be extended through the passage opening 11 of the proximal compression ring 7 to pull the fastened tissue portion 10 between the tissue clamping surfaces 8, 9 from inside the passage opening 11.

An endoluminal applier 26 may be provided for both the tissue acquisition and the fastening of the anchoring device 5. The applier 26 (Figures 3, 5) has a flexible elongate insertion shaft 27 and a fastening assembly 28 arranged at a distal end 29 of the insertion shaft 27. The fastening assembly 28 includes a fastener driver 32 adapted to hold the anchoring hooks 30 during endoluminal insertion of the applier 26 and operable to drive the anchoring hooks 30, e.g. T-tags into the tissue portion 10. The applier 26 may further comprise a pulling mechanism 33 connected to the pull strings 31 of the anchoring hooks 30 and operable to pull the pull strings 31 into the fastening assembly 28, thereby acquiring the fastened tissue portion 10 between the clamping surfaces 8, 9 of the compression rings 6, 7. Alternatively or additionally, the applier 26 comprises an instrument channel 34 extending from the fastening assembly 28 to a proximal end of the insertion shaft 27 and adapted to receive the pull strings 31 so that the proximal string ends emerge extracorporeally from the proximal end of the applier 26 and can be directly pulled by the doctor.

The fastening assembly 28 may further comprise a ring seat 35 adapted to detachably receive the proximal compression ring 7 (for endoluminally inserting the proximal ring to the anchoring site in the hollow organ 1) and to support the proximal compression ring 7 while the distal compression ring 6 is pulled against it.

The guide wire 12 attached to the distal compression ring 6 may be received in the above described instrument channel 34 of the applier and a proximal guide wire end may be pulled from outside the body in order to approximate the compression rings 6, 7 and lock them together.

In accordance with an embodiment, the applier 26 comprises an endoscope defining the instrument channel 34 and a distal end to which the fastening assembly 28 is attached.

In accordance with a further embodiment (Figures 7 through 13), the ring locking means comprise at least one pair of diametrically opposite locking pins 22 protruding from one of the distal and proximal compression rings 6, 7 towards the other compression ring and adapted to be received by corresponding locking seats 14 formed in the other compression ring, e.g. by snap fit, shape connection or interference fit. Both the locking seats 14 and the locking pins 22 may form a guide channel 23, 24 adapted to receive a guide wire 25 which allows the compression rings 6, 7 to be pulled towards each other and in engagement in a tissue clamping configuration.

In this embodiment, the above described support frame is not necessary and the guide wires 25 are fastened in a pull resistant manner to the locking pins 22, e.g. by means of a

wedge or a clamp (not illustrated) adapted to clamp the guide wire against the guide channel 23 and/or a locking ring or clip (not illustrated) which can be fastened to the guide wire 25 to create a local increase of the guide wire thickness which interferes with the shape of the guide channel 23 to lock the guide wire 25 by shape coupling.

The locking pins 22 and the corresponding locking seats 14 are formed in the tissue clamping surfaces 8, 9 of the distal and proximal compression rings 6, 7, respectively, and the locking pins 22 are intended to puncture and retain the clamped tissue portion 10 between the compression rings 6, 7.

After inserting the guide wires 25 along a path within the wall of the hollow organ 1, e.g. the jejunum, the anchoring device 5 and, hence, the endoluminal lining 2 can be positioned very precisely by pulling or sliding the compression ring 6 with the locking pins 22 along the predefined guide wire path through the hollow organ wall.

The insertion of the guide wires 25 along predetermined paths in the lumen wall can e.g. be accomplished by means of a device 36 having a flexible insertion shaft 37 and a guide wire fastening head 38 with an arch shaped hollow needle 39 having a sharp free end suitable to pierce tissue and an internal channel opening near the free end and adapted to receive the guide wire 25. The guide wire fastening head 38 comprises a guide wire feeding mechanism operable to move the needle 39 out of the head 38 along an arch-shaped path in order to pierce the surrounding tissue, feed a portion of the guide wire 25 through the internal channel and, subsequently, withdraw the needle 39 along the arch shaped path back into the head 38, leaving the guide wire portion extended along the thus created path through the pierced tissue (Figures 9 and 10).

In this manner a plurality of individual open, endoluminally extended guide wire loops 40 can be placed in the hollow organ 1, each open guide wire loop 40 having a distal guide wire end 41, a proximal guide wire end 42 (which may at least initially extend outside the body of the patient) and an intermediate guide wire section 43 between the proximal guide wire end 42 and the distal guide wire end 41 which extends along the pierced path through the tissue portion 10 (Figure 10).

The distal guide wire end 41 of each individual guide wire 25 loop 40 is fastened in a pull resistant manner to the locking pins 22 of the distal compression ring 6 and the proximal guide wire end 41 (which emerges extracorporeally or which may be grasped by an endoluminal pulling instrument) can be pulled, thereby dragging the distal compression ring 6 from outside the body endoluminally (e.g. through the esophagus, stomach and duodenum) into the hollow organ 1 (e.g. the jejunum) near the target section intended for

anchoring the lining 2 (Figure 11). By further pulling the proximal guide wire end 41 in a proximal direction, the locking pins 22 of the distal compression ring 6 are pulled from a distal side of the target section 10 into and through the predefined guide wire path within the hollow organ wall.

In this embodiment, the proximal compression ring 7 can be delivered to the anchoring site and fastened to the tissue portion 10 and to the distal compression ring 6 by means of an endoluminal applier 44 (Figure 12) which is very similar to the previously described applier 26 (Figure 5).

The applier 44 (Figure 12) comprises a flexible elongate insertion shaft 27 and a fastening assembly 28 arranged at a distal end 29 of the insertion shaft 27. The fastening assembly 28 may further comprise a ring seat 35 adapted to detachably receive the proximal compression ring 7 (for endoluminally inserting the proximal ring to the anchoring site in the hollow organ 1) and to support the proximal compression ring 7 while the distal compression ring 6 is pulled against it.

The guide wires 25 fastened to the locking pins 22 of the distal compression ring 6 are slidably extended through the corresponding guide channels 24 of the locking seats 14 of the proximal compression ring 7.

The applier 44 may comprise an instrument channel 34 extending from the fastening assembly 28 to a proximal end of the insertion shaft 27 and adapted to receive the guide wires 25 so that the proximal guide wire ends 42 emerge extracorporeally from the proximal end of the applier 44 and can be directly pulled by the doctor.

Alternatively or additionally, the ring seat 35 defines a plurality of at least 2 guide wire channels 45 aligned with the guide channels 24 of the locking seats 14 of the proximal compression ring 7 and adapted to slidingly receive the guide wires 25 so that the fastening assembly 28 together with the proximal compression ring 7 are aligned with the predefined guide wire path during ring approximation and press-coupling (Figures 12 and 13).

The press coupling and mutual locking of the compression rings is brought about by pushing the proximal compression ring 7 by the applier 44 distally and contemporaneously pulling the distal compression ring 6 by means of the guide wires 25 in a proximal direction against the proximal ring 7.

In accordance with an embodiment, the applier 44 comprises an endoscope defining e.g. the instrument channel 34 and a distal end to which the fastening assembly 28 is attached.

In the embodiment illustrated in figures 7 through 13, the lining seat 20 may co-operate with the guide wires 25 to release the lining 2 when the guide wires 25 are detached from the distal compression ring 6. For this purpose the lining seat 20 may comprise one or more brackets 21 which are directly or indirectly held by the guide wires 25 in a retaining position (suitable to retain the packed lining 2) as long as the guide wires 25 are coupled to the distal compression ring 6. Upon detachment of the guide wires from the distal compression ring 6, the brackets 21 move in a release position in which the lining 2 is released to unfold distally.

In accordance with an embodiment, the brackets 21 are formed integrally (as a single piece) with guide wire locking means 19, e.g. with the above described clamping jaw or a clamping wedge or locking ring or clip which fixate the guide wire 25 to the compression ring.

In accordance with an embodiment, the distal compression ring 6 comprises ring releasing means which detach the guide wire 25 from the distal ring 6 when the pulling force transmitted by the guide wire 25 to the ring body of the distal compression ring 6 exceeds a predetermined target value sufficient for an adequate tissue clamping pressure and locking pressure between the compression rings 6, 7. The ring releasing means can be adapted to pulling force-dependently separating the guide wire 25 from the distal ring body by pulling force-dependently slipping out or tensile failure (rupture) of the guide wire 25 or by pulling force-dependently breaking the locking means 19, in predetermined breaking points. This allows to automatically detach the guide wire 25 from the distal compression ring 6 and withdraw them in proximal direction through the guide channels 23, 24 of the compression rings 6, 7 and endoluminally out of the patients' body.

As already explained above, by separating the guide wire 25 from the distal ring body the lining 2 may be automatically released to unfold.

Figures 14 through 16 illustrate an exemplary embodiment of onboard tissue acquisition means adapted to acquire the ring shaped tissue portion 10 of the hollow organ 1 between the clamping surfaces of the distal and proximal compression rings 6, 7 during ring approximation without any need of additional tissue acquisition devices and procedures.

Such tissue acquisition means may be advantageously used in connection with the anchoring device 5 illustrated in figure 1.

The tissue acquisition means comprise a plurality of needles 46 connected to one of the distal and proximal compression rings 6, 7 and movable, preferably tiltable or rotatable,

from a rest position in which pointed free ends 47 of the needles 46 are received inside the ring body of the compression ring, particularly within radially extending grooves 48 formed in the tissue clamping surface 8; 9, and an activated position in which the pointed free ends 47 of the needles 46 protrude radially outward of the compression ring 6 or 7 and are inclined towards the other compression ring, i.e. in the same direction in which the clamping surface faces. In other words, when the needles 46 are arranged at the proximal compression ring 7, the pointed free ends 47 of the needles 46 protrude in the activated position radially outward and distally. Alternatively or additionally, when the needles 46 are arranged at the distal compression ring 6, the pointed free ends 47 of the needles 46 protrude in the activated position radially outward and proximally.

In this manner, in the activated position, in response to an approximating movement e.g. of the distal compression ring 6 towards the proximal compression ring 7, the pointed needle ends 47 are driven in the tissue adjacent and ahead of the distal compression ring 6 such that the needles 46 pierce and retain the hollow organ wall which is progressively pushed together and folded over the clamping surface 8 (Figure 15).

The thus “automatically” acquired ring shaped tissue portion 10 is clamped and fastened between the distal and proximal compression rings 6, 7 in response to a further ring approximation and locking, as previously described.

The tissue acquisition can be further improved by moving the needles 46 together with the pierced tissue from the activated position radially inward to an intermediate position between the opposite tissue clamping surfaces 8, 9 of the compression rings 6, 7.

In accordance with an embodiment, the needles 46 are permanently elastically biased towards their activated position and connected to a needle moving mechanism 49 having an adjusting member, e.g. a lever mechanism with an adjusting lever. The adjusting member is adapted to be moved between a resting position in which the needle moving mechanism 49 holds the needles 46 in the rest position and an activating position in which the needle moving mechanism 49 allows the needles 46 to move in the activated position.

During endoluminal insertion of the compression ring 7, the adjusting member is locked or actively held in the resting position to hold the needles 46 in the radial grooves 48 and, after positioning of the compression ring 7 near the lining anchoring location in the hollow organ, e.g. in the jejunum, the adjusting member is actively displaced or released to move in the activating position, so that the needles 46 are driven out of the grooves 48 into their activated position.

Moreover, the compression rings 6, 7 or a ring applier may be configured that, during

approximation of the distal and proximal compression rings 6, 7, the adjustment member of the needle moving mechanism 49 is displaced from the activating position in the direction of the rest position, so that the needles 46 together with the pierced tissue move from the activated position radially inward to an intermediate position between the tissue clamping surfaces 8, 9 of the compression rings 6, 7.

For the purpose of moving the needles 46, the needle moving mechanism 49, particularly the adjusting member thereof, may cooperate with the ring coupling means, e.g. needle fasteners 13 or locking pins 22, with the support frame 16, with a dedicated protrusion formed on the opposite compression ring or with a ring applier for the endoluminal deployment of the lining system.

For example, in response to a compression ring (6, 7) approximation to a predetermined distance therebetween, the needle moving mechanism (49) is moved by at least one of the ring locking means and the support frame (16) in a manner to move the needles (46) together with the pierced tissue from the activated position radially inward to the intermediate position.

For the purpose of coupling the compression rings together and fastening the tissue between the tissue clamping surfaces of the compression rings, needle fasteners 13 similar to those previously described in connection with figure 1 or locking pins 22 similar to those previously described in connection with figure 7 may be provided at the proximal compression ring 7 or, more generally spoken, at the compression ring opposite the one having the tissue acquisition needles 46. As already described in relation with the embodiments of figure 1 and 7, the needle fasteners 13 or locking pins 22 are configured to be received in corresponding locking seats 14, e.g. internally stepped or riffled holes, formed in the clamping surface of the opposite compression ring (in the figure 16 embodiment, preferably the distal ring 7) and form one or more barbs 15 which block the needle fasteners 13 or locking pins 22 inside the locking seats 14 to prevent separation of the interlocked compression rings and to maintain the achieved tissue clamping configuration.

In accordance with a further exemplary embodiment, at least one of the distal 6 and proximal compression ring 7 is time-dependently bio-fragmentable or absorbable. This makes the endoluminal lining a temporary and reversible therapeutic treatment. The tubular lining 2 may be detachably connected to one of the compression rings 6, 7 and can be substituted by another tubular lining, e.g. of different length. For example, the proximal end 3 of the lining 2 may be detachably inserted in a connecting groove 50 of the

lining seat 20 formed in one of the distal and proximal compression rings 6, 7 and clamped against the connecting groove 50 by means of a possibly elastically deformable clamping ring 51 having a shape substantially complementary with the shape of the connecting groove 50 (Figures 15, 16).

With regard to all described embodiments, the anchoring device 5 may be grafted at least partially of bioabsorbable material and the compression rings 6, 7 are substantially rigid, while the guide wires 12, 25 are flexible and substantially inextensible. At least part of the anchoring device 5 may be protected by a protective sheath 60 during endoluminal insertion in the hollow organ 1.

Figure 19 illustrates an exemplary embodiment of an endoluminal applier 52 for endoluminally delivering and fastening the anchoring device 5 of the lining system to the hollow organ 1. The applier 52 has a flexible insertion shaft 59 extending between a proximal handle (not illustrated) and a distal shaft end at which a ring fastening assembly 28' is provided. The ring fastening assembly 28' comprises a proximal ring holder 53 adapted to hold the proximal compression ring 7, and a distal ring holder 54 adapted to hold the distal compression ring 6. The distal ring holder 54 is translatable relative to proximal ring holder 53 and adapted to cooperate with the proximal ring holder 53 for approximating the proximal and distal compression rings 7, 6 and pressing them together. The ring fastening assembly 28' forms a central channel 55 extending longitudinally through the proximal ring holder 53 and through the distal ring holder 54 and, preferably, opening laterally into a clamping space 56 between the proximal and distal ring holders 53, 54. The central channel 55 is adapted to slidingly receive an endoscope to visualize both the space between the proximal and distal rings 7, 6 received by the corresponding ring holders 53, 54 and the space distally ahead of the ring fastening assembly 28' and, possibly, to slide the applier 52 endoluminally along the endoscope to the lining anchoring site in the hollow organ 1.

The applier 52 assures a correct relative positioning of the compression rings 6, 7 during fastening of the anchoring device 5 and allows an improved guidance through the GI tract and continuous visualization by the endoscope received in the central channel 55, both during endoluminal insertion and withdrawal of the applier 52 and during fastening of the compression rings 6, 7.

In accordance with an embodiment, the applier 52 comprises a tissue acquisition mechanism 57 adapted to acquire a substantially ring shaped tissue portion 10 of the hollow organ 1 in the clamping space 56 between the proximal and distal ring holders 53,

54. The tissue acquisition mechanism 57 may be arranged in the ring fastening assembly 28' between the central channel 55 and one of the ring holders 53, 54, i.e. radially external of the central channel 55 and radially internal of the ring holder, thereby allowing complete visual access also during tissue acquisition. Alternatively, the tissue acquisition mechanism 57 and the endoscope may be configured to be received together and contemporaneously in the central channel 55, e.g. by passing the tissue acquisition mechanism through an instrument channel of the endoscope while the endoscope is received in the central channel 55 of the ring fastening assembly 28'. The tissue acquisition mechanism 57 may comprise mechanical gaspers or suction means.

In accordance with an embodiment, the distal ring holder 54 comprises ring releasing means which detach the distal ring holder 54 from the distal ring 6 when the force transmitted by the distal ring holder 54 to the ring body of the distal compression ring 6 exceeds a predetermined target value sufficient for an adequate tissue clamping pressure and locking pressure between the compression rings 6, 7. The ring releasing means can be adapted to force-dependently separating the distal ring holder 54 from the distal compression ring 6 by resilient radially inward retraction or deformation of the distal ring holder 54 or by force-dependently breaking the distal ring holder 54 in predetermined breaking points. This allows to automatically detach the distal ring holder 54 from the distal compression ring 6 and withdraw it in proximal direction through the central passage openings 11 of the compression rings 6, 7 and endoluminally out of the patients' body.

In accordance with a further embodiment, the applier 52 comprises a lining seat 58 arranged at the distal ring holder 54 and adapted to receive and hold the pliable tubular lining 2 in a packed (substantially ring shaped), e.g. wrapped, folded, compressed or rolled up, configuration with regard to a lining longitudinal extension. The lining seat 58 may co-operate with the distal compression ring 6 received by the distal ring holder 54 to release the lining 2 and, possibly to push at least a portion of the lining 2 distally out of the lining seat 58, when the distal ring holder 54 is detached from the distal compression ring 6.

In this way bypass conduits can be created in the GI tract of a patient to achieve a malabsorptive effect in cases where such an effect may enhance weight loss, as well as the initially described effects on hormonal signaling in general.

Particularly, the described devices and procedures help to mimic the effects of gastric bypass in resolution of type 2 diabetes and facilitating weight loss, improve glycemic control and reduce or eliminate other co-morbidities of severe obesity. Moreover, the

described devices and procedures may be advantageously used in conjunction with other therapeutic regimes for the treatment of type 2 diabetes and its co-morbidities and address the patients fear of invasive surgery. Last but not least, the described procedures and devices allow a reversible procedure with an easy removal and replacement of the endoluminal lining or sleeve once the desired effect has been achieved or a modification of the endoluminal lining is desired.

Although preferred embodiments of the invention have been described in detail, it is not the intention of the applicant to limit the scope of the claims to such particular embodiments, but to cover all modifications and alternative constructions falling within the scope of the invention.

CLAIMS

1. An endoluminal lining system for internally lining a hollow organ (1), particularly a section of the gastrointestinal tract, the system comprising a flexible tubular lining (2) and an anchoring device (5) connected to the lining (2) and suitable for fastening the lining (2) in the hollow organ (1), said anchoring device (5) comprising:

- a distal compression ring (6) and
- a proximal compression ring (7) initially separate from the distal compression ring (6),

said distal and proximal compression rings (6, 7) forming a central passage opening (11) and co-operating opposite tissue clamping surfaces (8, 9), as well as locking means (13; 22) adapted to lock the distal compression ring (6) to the proximal compression ring (7) in a tissue clamping configuration,

2. The system according to claim 1, comprising flexible guide and traction means (12, 25) fastened to the distal compression ring (6) in a pull resistant manner and slidably received by the proximal compression ring (7) in a manner to allow the distal compression ring (6) to be pulled towards and coupled with the proximal compression ring (7).

3. The system according to claim 2, in which the distal compression ring (6) comprises ring releasing means which detach the guide and traction means (12; 25) from the distal ring (6) when the pulling force transmitted by the guide and traction means (12; 25) to the ring body of the distal compression ring (6) exceeds a predetermined target value sufficient for an adequate tissue clamping pressure and locking pressure between the compression rings (6, 7).

4. The system according to any one of the preceding claims, comprising a lining seat (20) arranged at the distal compression ring (6) and adapted to receive and hold the lining (2) in a packed configuration.

5. The system according to claim 4, in which the lining seat (20) is at least indirectly linked with the guide and traction means (12, 25) such as to release the lining (2) when the guide and traction means (12, 25) are detached from the distal compression ring (6).

6. The system according to any one of the preceding claims, comprising a plurality of needles (46) arranged at one of the distal and proximal compression rings (6, 7) and movable from a rest position in which pointed free ends (47) of the needles (46) are received inside grooves (48) formed in the tissue clamping surface (8), and an activated position in which the pointed free ends (47) protrude radially outward of the compression ring (6) and are inclined towards the other compression ring.

7. The system according to claim 6, in which the needles (46) are connected to a needle

moving mechanism (49) operable to:

- holding the needles (46) in the rest position during endoluminal insertion of the compression ring (6),
- moving the needles (46) in the activated position,
- moving the needles (46) together with the pierced tissue from the activated position radially inward to an intermediate position between the tissue clamping surfaces (8, 9) of the compression rings (6, 7).

8. The system according to claim 7, in which the needle moving mechanism (49) is adapted to move the needles (46) from the activated position radially inward to an intermediate position between the tissue clamping surfaces (8, 9) of the compression rings (6, 7) in response to a compression ring (6, 7) approximation to a predetermined distance therebetween.

9. The system according to any preceding claim, in which the distal compression ring (6) comprises a support frame (16) forming a guide seat (17) for a pull resistant connection of the distal compression ring (6) with a guide wire (12) forming said guide and traction means (12, 25), wherein the guide seat (17) is arranged radially inside the distal compression ring (6) at a distance from the tissue clamping surface (8).

10. The system according to claim 9, in which said support frame (16) comprises two crosswise arranged beams (18) bridging the central passage opening (11) and connected to respectively opposite portions of a ring body of the distal compression ring (6), the beams (18) being connected to each other in a connecting region forming the guide seat (17) coaxial with the ring body.

11. The system according to claim 9, in which the guide seat (17) comprise a through hole adapted to slidably receive the guide wire (12) and a clamping jaw or wedge (19) for locking the guide wire (12) in a pull resistant manner.

12. The system according to any one of claims 9 to 11, in which the distal compression ring (6) comprises ring releasing means which detach the support frame (16) from the distal ring (6) when the pulling force transmitted by the support frame (16) to the ring body of the distal compression ring (6) exceeds a predetermined target value sufficient for an adequate tissue clamping pressure and locking pressure between the compression rings (6, 7).

13. The system according to claim 12, in which said ring releasing means are adapted to pulling force-dependently separating the support frame (16) from the ring body of the distal compression ring (6) by resilient radially inward retraction of the support frame (16).

14. The system according to claim 12, in which said ring releasing means are adapted to pulling force-dependently separating the support frame (16) from the distal ring body by breaking the support frame (16) in predetermined breaking points.

15. The system according to any one of claims 2 to 8, in which the ring locking means (13; 22) comprise at least one pair of diametrically opposite locking pins (22) protruding from one of the distal and proximal compression rings (6, 7) towards the other compression ring and adapted to be received by corresponding locking seats (14) formed in the other compression ring, wherein the locking seats (14) and the locking pins (22) form guide channels (23, 24) adapted to receive guide wires (25) forming said guide and traction means (12, 25), said guide wires (25) being fastened in a pull resistant manner with respect to the locking pins (22).

16. The system according to claim 15, comprising an applier (44) having a flexible elongate insertion shaft (27) and a ring fastening assembly (28) arranged at a distal end (29) of the insertion shaft (27), wherein the ring fastening assembly (28) comprises a ring seat (35) adapted to detachably support the proximal compression ring (7) and forms at least two guide wire channels (45) aligned with the guide channels (24) of the locking seats (14) of the proximal compression ring (7) and adapted to slidingly receive the guide wires (25).

17. The system according to claim 1, comprising an endoluminal applier (52) for endoluminally delivering and fastening the anchoring device (5) of the lining system to the hollow organ (1), the applier (52) comprising a flexible insertion shaft (59) and a ring fastening assembly (28') arranged at a distal end of the insertion shaft and having:

- a proximal ring holder (53) adapted to hold the proximal compression ring (7),
- a distal ring holder (54) adapted to hold the distal compression ring (6) and translatable relative to proximal ring holder (53) for approximating the proximal and distal compression rings (7, 6) and pressing them together,
- a central channel (55) extending longitudinally through the proximal ring holder (53) and through the distal ring holder (54) and adapted to receive an endoscope,
- a tissue acquisition mechanism (57) adapted to acquire a substantially ring shaped tissue portion (10) of the hollow organ (1) in the clamping space (56) between the proximal and distal ring holders (53, 54).

18. The system according to claim 17, in which the distal ring holder (54) comprises ring releasing means which detach the distal ring holder (54) from the distal ring (6) when the force transmitted by the distal ring holder (54) to the distal compression ring (6) exceeds a

predetermined target value sufficient for an adequate tissue clamping pressure and locking pressure between the compression rings (6, 7).

19. The system according to claim 17, in which the ring releasing means are adapted to force-dependently separating the distal ring holder (54) from the distal compression ring (6) by resilient radially inward retraction of the distal ring holder (54).

20. The system according to claim 17, in which the ring releasing means are adapted to force-dependently separating the distal ring holder (54) from the distal compression ring (6) by force-dependently breaking the distal ring holder (54) in predetermined breaking points.

21. The system according to claim 17, in which the applier (52) comprises a lining seat (58) arranged at the distal ring holder (54) and adapted to hold the lining (2) in a packed configuration, said lining seat (58) co-operates with the distal compression ring (6) received by the distal ring holder (54) such that the lining (2) is released to unfold when the distal ring holder (54) is detached from the distal compression ring (6).

22. The system according to claim 1, in which the tubular lining (2) is detachably connected to one of the compression rings (6, 7)

23. The system according to claim 22, in which the proximal end (3) of the lining (2) is detachably inserted in a connecting groove (50) of one of the distal and proximal compression rings (6, 7) and clamped against the connecting groove (50) by means of an elastically deformable clamping ring (51) having a shape substantially complementary with the shape of the connecting groove (50).

24. The system according to claim 1, in which the anchoring device (5) is at least partially made of bioabsorbable material.

25. A method for applying a tubular lining to a lumen of a gastrointestinal tract, the method comprising:

- placing an applier comprising a tubular lining, an endoscope, and a first ring member into the lumen;
- endoscopically obtaining visibility to an area suitable for fastening the first ring member;
- fastening the first ring member together with the tubular lining to a wall of the lumen by:

a) deploying a second ring member within the lumen;

b) acquiring a ring shaped tissue portion of the lumen between the first ring member and the second ring member;

c) approximating the first and second ring members to clamp the acquired tissue portion therebetween;

d) extending a ring locking means at least partially parallel to the lumen from one of the first and second ring members to into the other ring member to lock the first and second ring members together with the acquired tissue portion clamped therebetween.

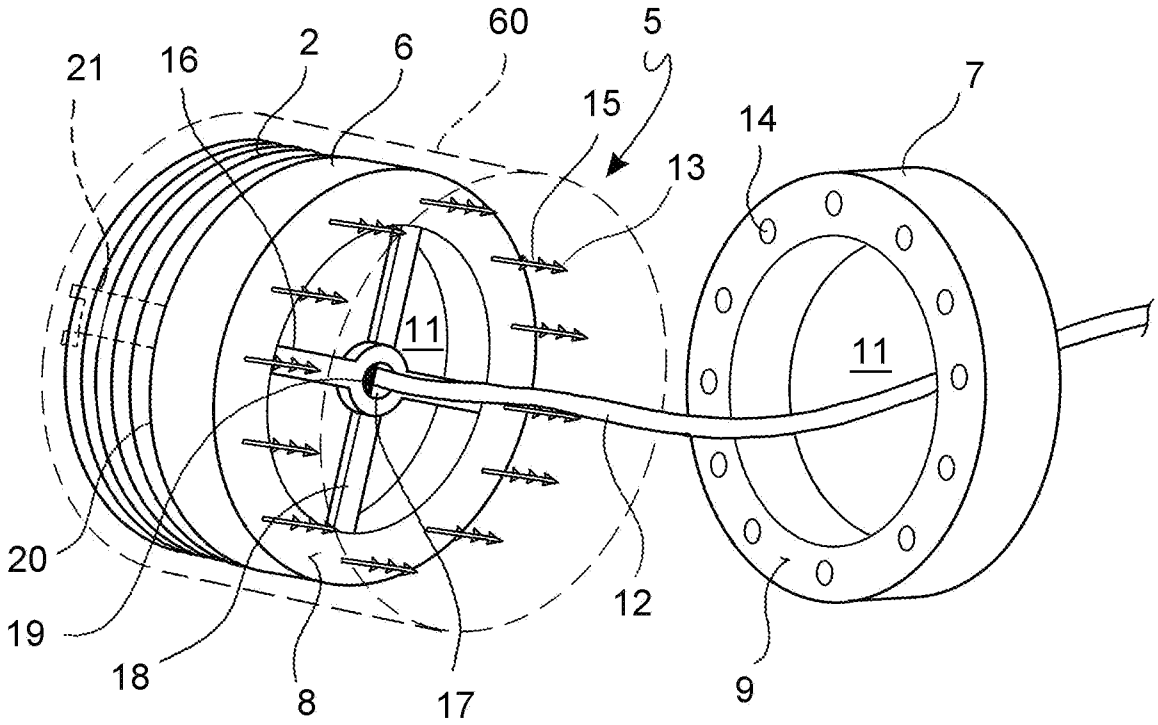

FIG. 1

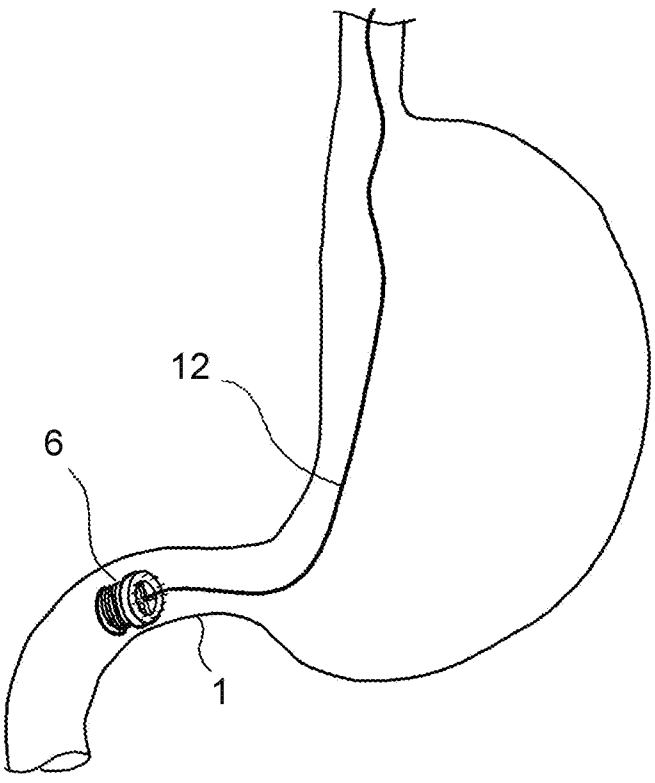

FIG. 2

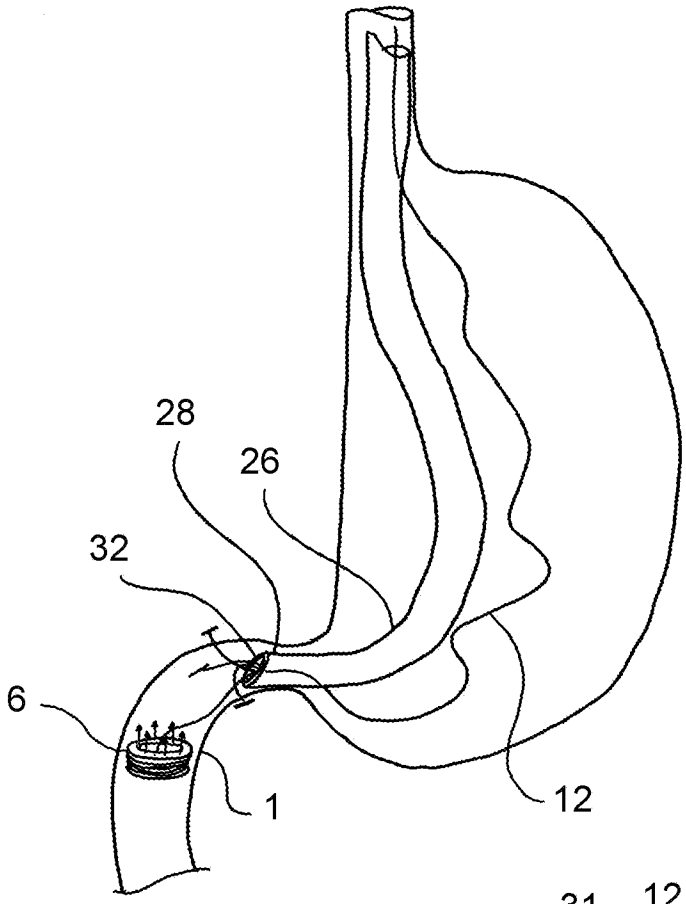

FIG. 3

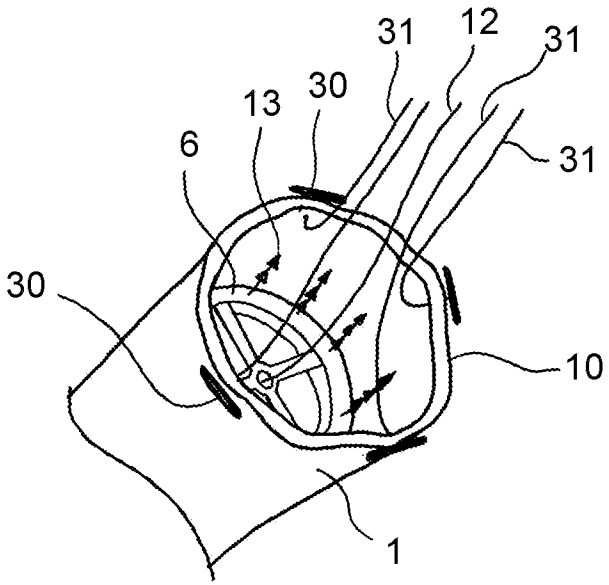

FIG. 4

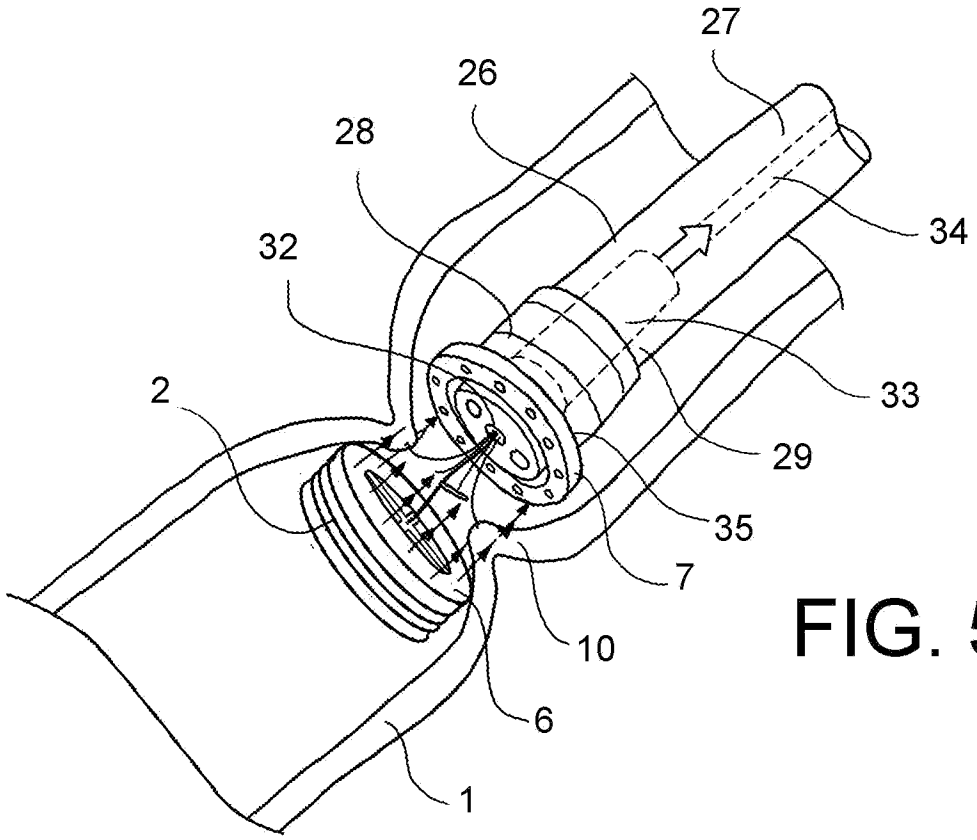

FIG. 5

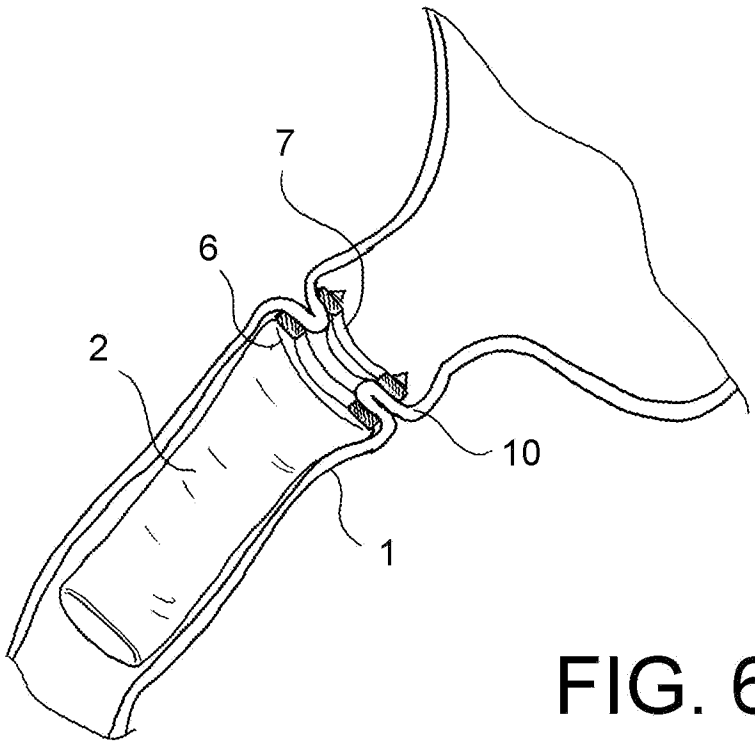

FIG. 6

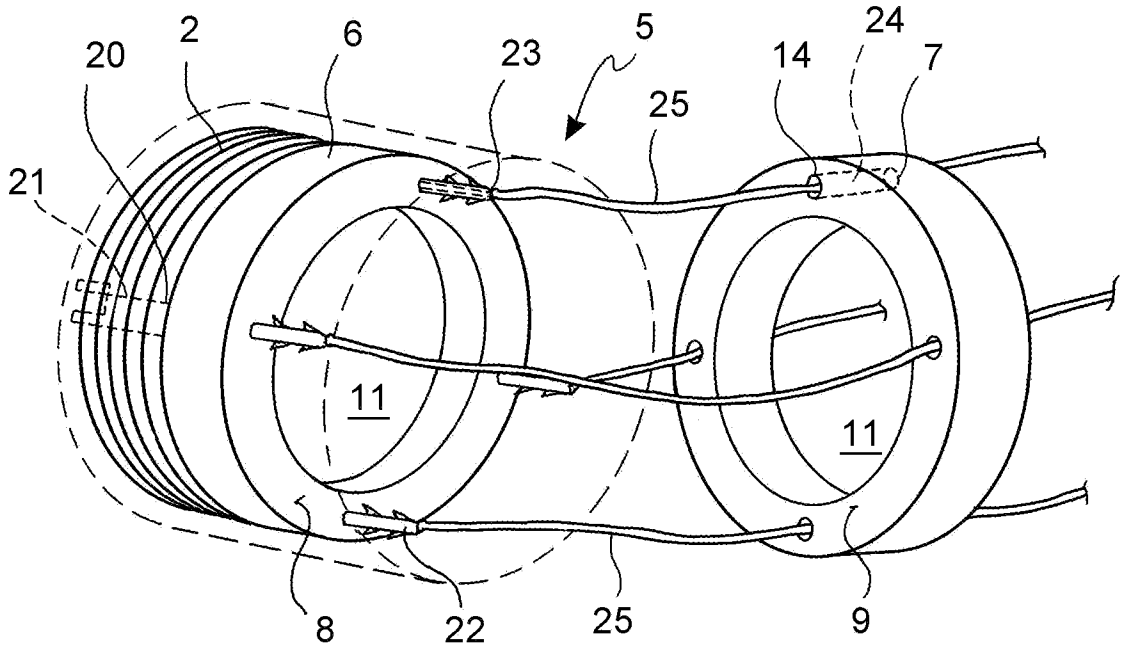

FIG. 7

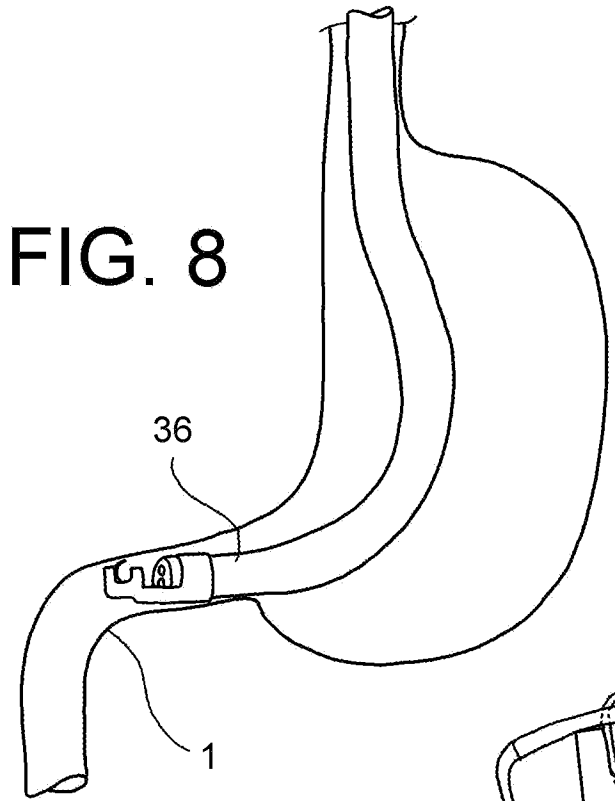

FIG. 8

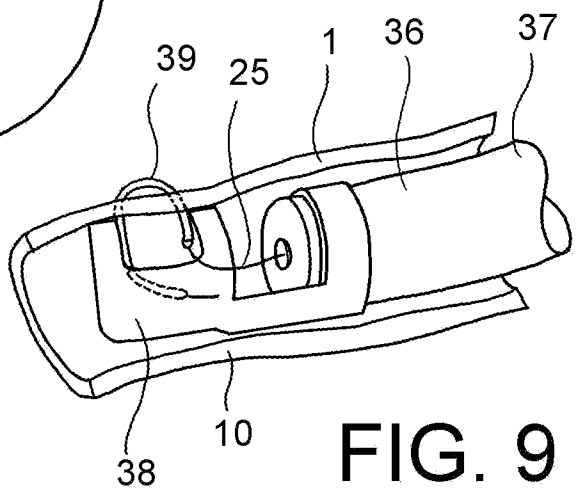

FIG. 9

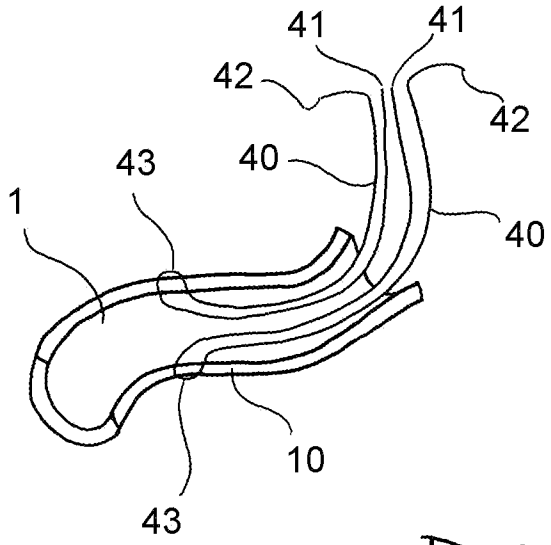

FIG. 10

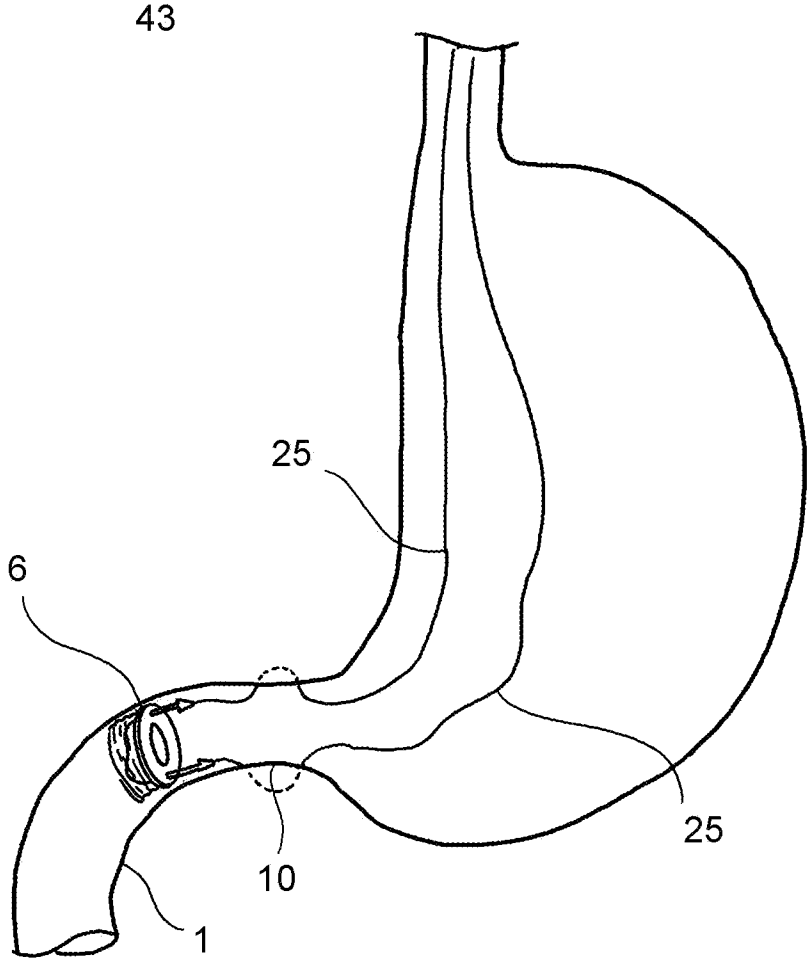

FIG. 11

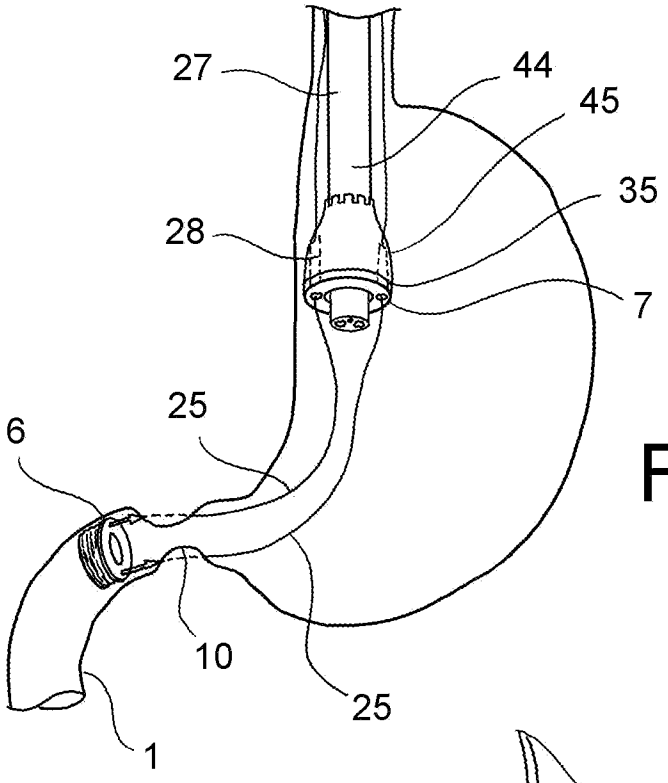

FIG. 12

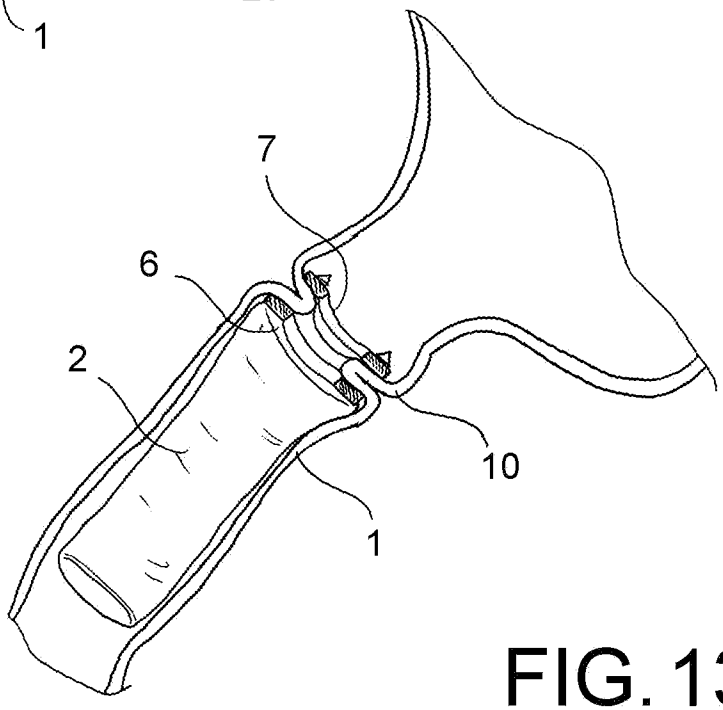

FIG. 13

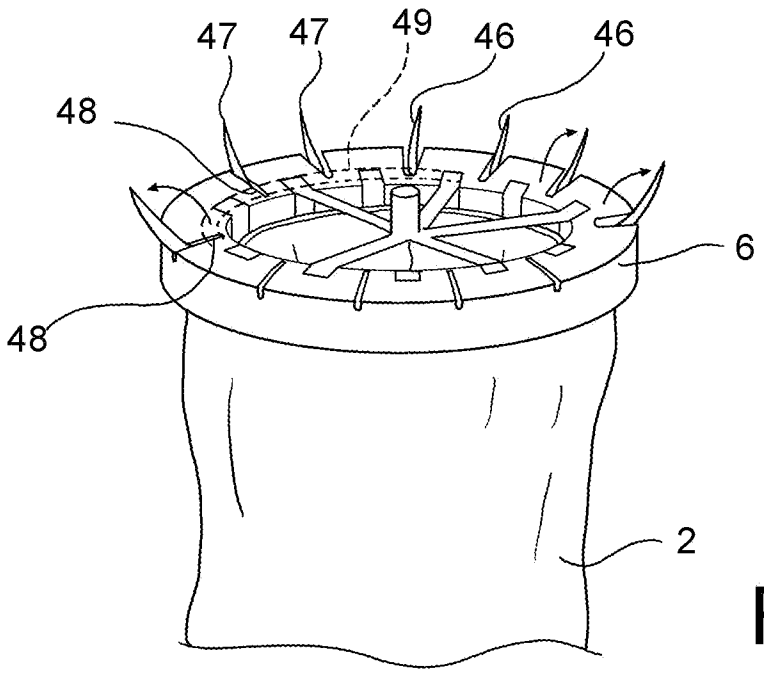

FIG. 14

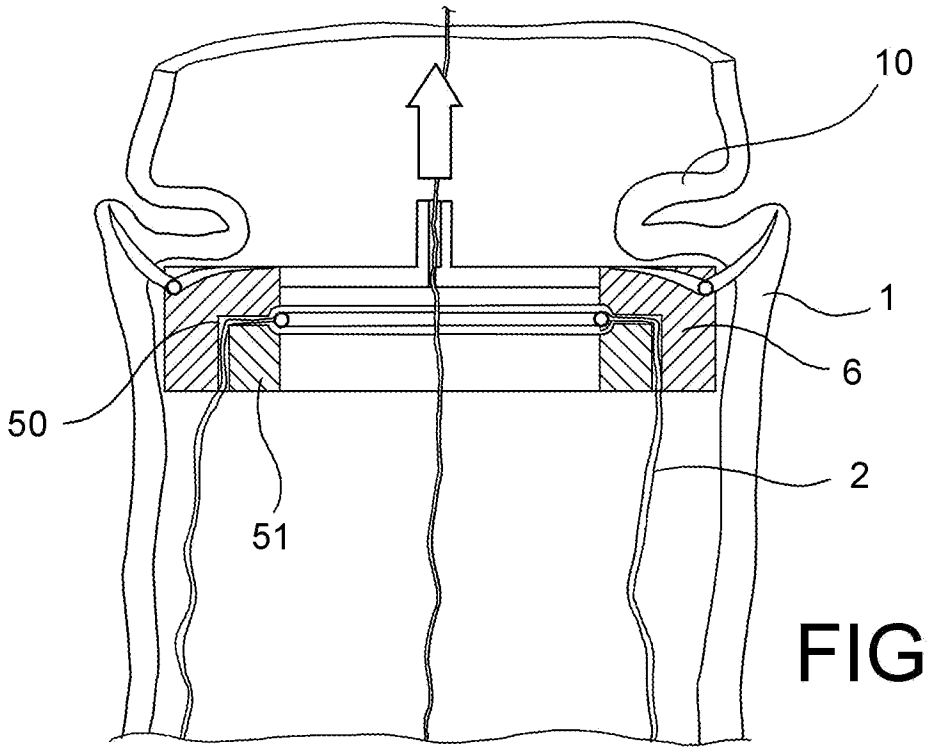

FIG. 15

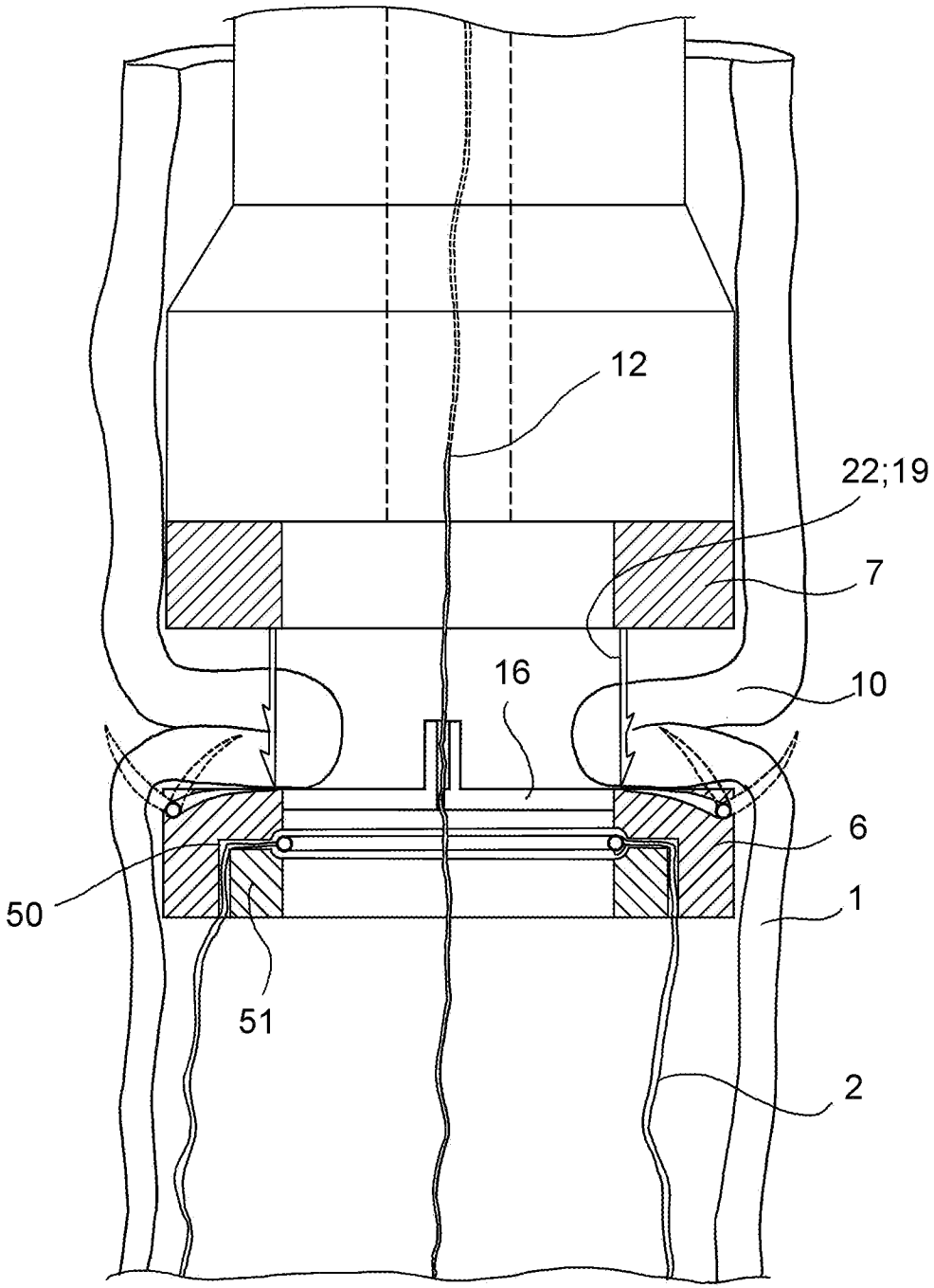

FIG. 16

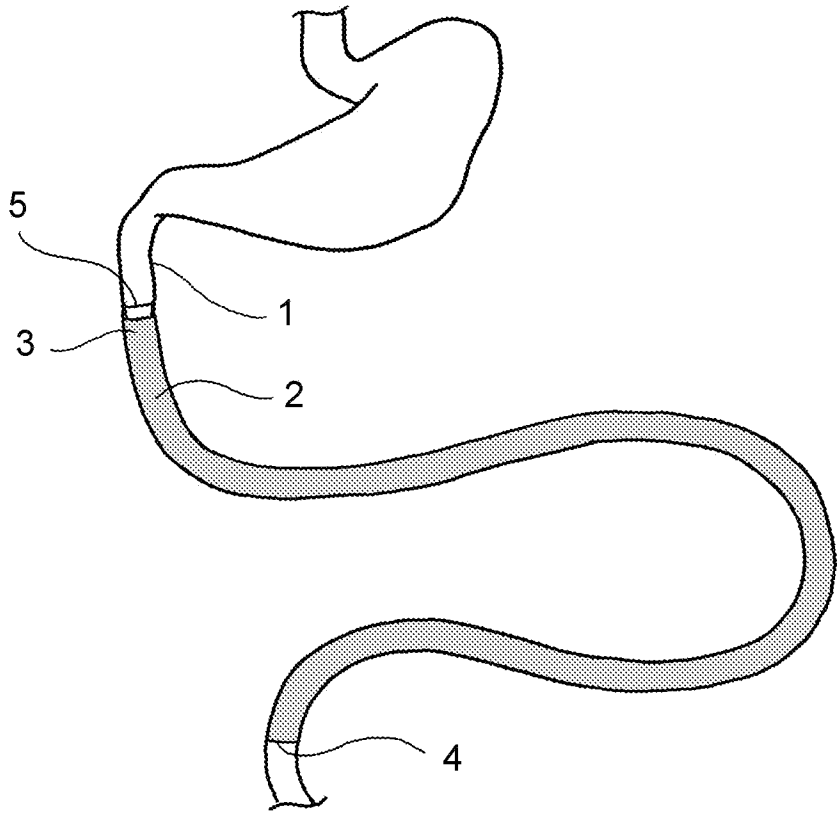

FIG. 17

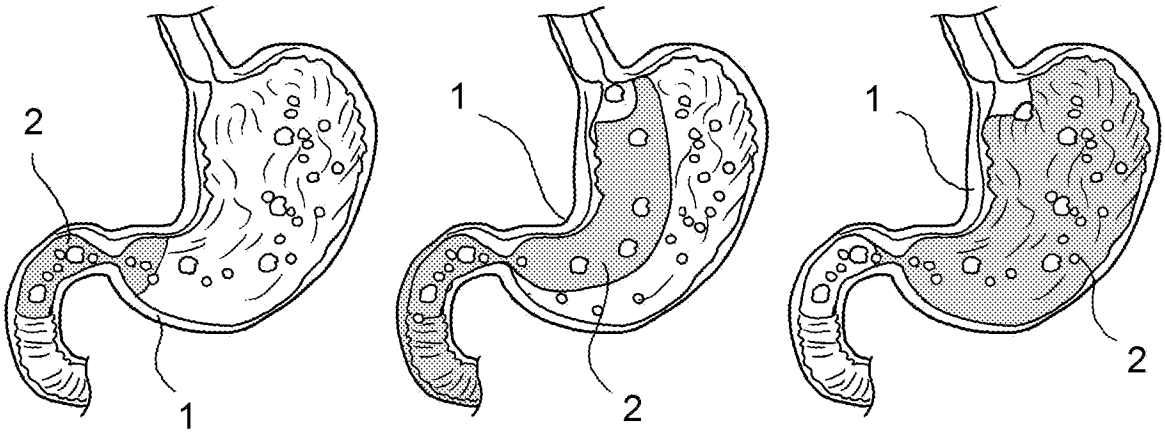

FIG. 18

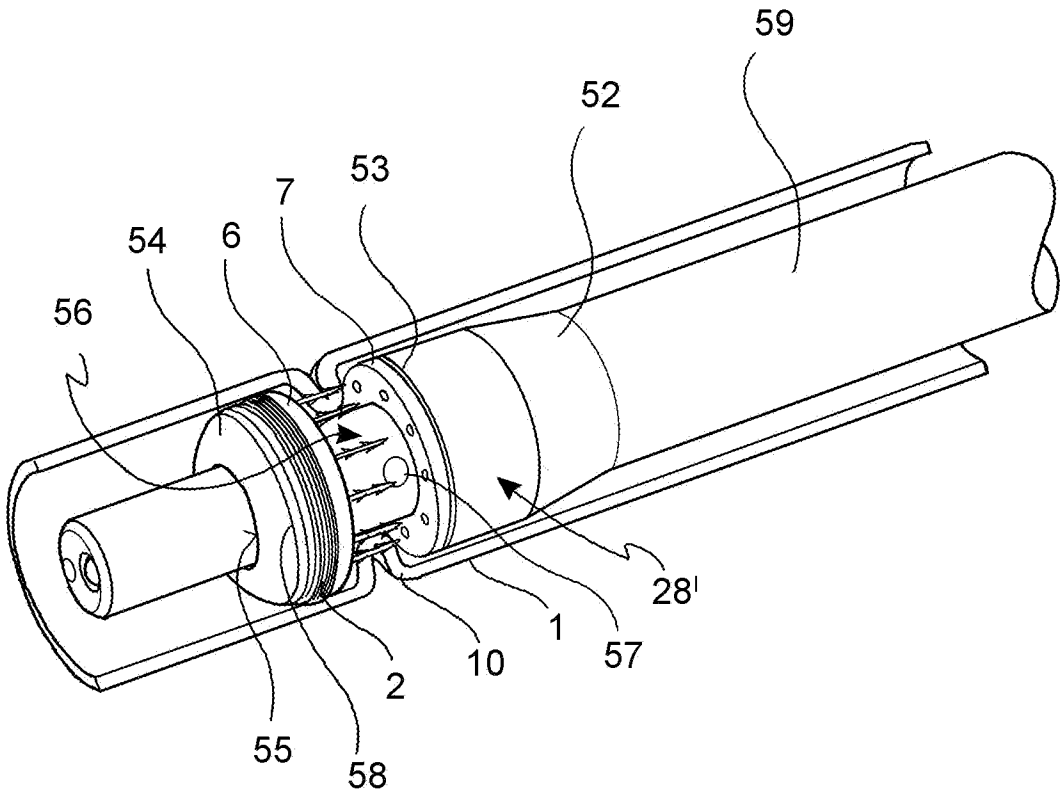

FIG.19

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/051814

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/00
ADD.

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)
A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/041133 A1 (VALENTX INC [US]) 21 May 2004 (2004-05-21) paragraphs [0274], [0284], [0416] - [0421]; figures 24D,68,69	1,2,4, 15,22-24
A	US 7 220 237 B2 (GANNOE JAMY [US] ET AL) 22 May 2007 (2007-05-22) cited in the application the whole document	1-24

☐ 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 document 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
6 October 2011	13/10/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Grieb, Christian

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/051814

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. [X] Claims Nos.: 25
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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 additional 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 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/EP2011/051814

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2004041133 A1	21-05-2004	AU 2003287436 A1	07-06-2004
		EP 1555970 A1	27-07-2005
US 7220237 B2	22-05-2007	US 2004082963 A1	29-04-2004
		US 2004092974 A1	13-05-2004
		US 2005101977 A1	12-05-2005