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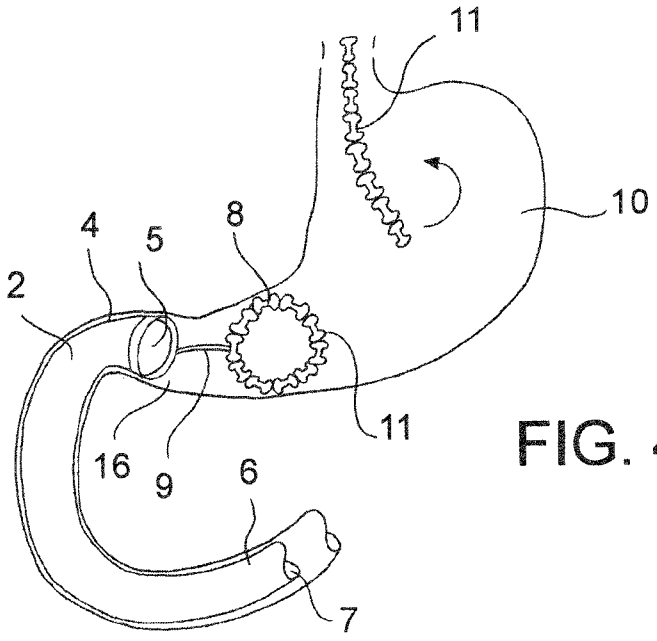

FIG. 4

(57) Abstract: An endoluminal sleeve device (1) for internally lining a section of the GI tract, comprises a sleeve (2) configured for deployment inside a duodenum, the sleeve (2) having walls of a flexible material defining a sleeve lumen (3), a proximal end (4) defining a proximal lumen opening (5), and a distal end (6) defining a distal lumen opening (7), an anchoring component (8) having a slender transport configuration and a bulky deployed configuration, wherein the anchoring component (8) is locatable at a distance from the proximal sleeve end (4) and connected thereto by an elongated tether (9).

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DEVICES FOR ANCHORING AN ENDOLUMINAL SLEEVE IN THE GI TRACT

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. It was observed that endoluminal sleeves in certain regions of the stomach and the duodenum contributed to improve glycemic control and to reduce or eliminate other co-morbidities of obesity. Moreover the lining of parts of the GI-tract by means of endosleeves provide an alternative or an additional therapy to traditional therapies of type II diabetes and obesity. Endosleeves may be placed in a brief and less invasive procedure and address the patient's fear of surgery. Contrary to traditional gastric bypass surgery, the result of endoluminal sleeve surgery is reversible and the sleeve can be removed after achievement of the clinical result, but also in case of the occurrence of undesired side effects or clinical complications.

A typical duodenal sleeve device is described in U.S. Pat. No. 7,267,694 where the proximal end of a flexible, floppy sleeve of impermeable material defining a sleeve lumen is endoscopically deployed and anchored with the help of a barbed stent in the pylorus or in the superior section of the duodenum, the stent also ensuring that the proximal lumen opening of the sleeve remains open. Chyme from the stomach enters the proximal lumen opening of the sleeve and passes through the sleeve lumen to the distal lumen opening. Digestive enzymes secreted in the duodenum pass through the duodenum on the outside of the sleeve. The enzymes and the chyme do not mix until the chyme exits from the distal lumen opening of the liner tube. In such a way, the efficiency of the process of digestion of the chyme is diminished, reducing the ability of the gastrointestinal tract to absorb calories from the food.

G.I. Dynamics, Inc., (Watertown, Mass., USA) produces the Endobarrier(R) device that is substantially a duodenal sleeve device configured so that the proximal end of the device is anchored inside the duodenal bulb with the help of a barbed anchoring stent that also keeps the proximal lumen opening open.

In US 2004/0148034 is taught a duodenal sleeve device attached to a funnel, the funnel configured for anchored to the gastric walls inside the gastric cavity in proximity to the lower esophageal sphincter. Food passing the lower esophageal sphincter is directed by the funnel into the proximal lumen opening of the duodenal sleeve device.

In U.S. Pat. No. 7,121,283 is taught a duodenal sleeve device attached to a large stent-like anchoring device that presses outwardly against the pyloric portion of the

stomach, the pyloric sphincter and the duodenal bulb.

In known endosleeves, it has been observed that the sleeve devices tend to move inside the GI tract and migrate away from their original anchoring position.

A further important issue with endoluminal sleeves is the risk of failure of sealing of the lined lumen and, hence, the risk of an undesired leakage of the partially digested food flow in the interstice between the lumen wall and the sleeve. Moreover, known endoluminal sleeve attachment devices and methods are not yet fully satisfying with regard to permitting normal biological events, including vomiting, to occur.

Further fields of desirable improvements related with endoluminal sleeves are their removal from the patient without injuring the involved tissues, the rapidity of deployment and removal of the sleeve, and the repeatability of the sleeve placement.

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

SUMMARY OF THE INVENTION

The present invention provides for an endoluminal, particularly duodenal, sleeve device and method for the transoral, or endoscopic, positioning and anchoring of an endoluminal sleeve device within a gastrointestinal tract, including, but not limited to, the pylorus, the esophagus, stomach, duodenum as well as other 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. Alternatively, the surgeon may insert devices as described below laparoscopically into the stomach or intestine as appropriate.

According to an aspect of the invention, there is provided a duodenal sleeve device, comprising:

- a sleeve configured for deployment inside a duodenum of a human subject, the sleeve having walls of a flexible material defining a sleeve lumen, a proximal end defining a proximal lumen opening, and a distal end defining a distal lumen opening;

- an anchoring component having a slender transport configuration and a bulky deployed configuration, the anchoring component being locatable at a distance from the proximal end of the sleeve and connected to the proximal end of the sleeve by an elongated tether.

The anchoring component can be endoluminally inserted in and removed from the stomach through the mouth and the esophagus while being in the slender transport configuration and, thanks to the distance between the anchoring component and the proximal end of the sleeve, the anchoring component can be deformed to the bulky deployed configuration without interfering with or influencing the shape of the proximal sleeve opening which is crucial for the sealing of the sleeve against the gastrointestinal wall. Moreover, thanks to the distance between the expandable anchoring component and the proximal sleeve end, the anchoring component can bear against selected robust structures of the stomach, such as for instance the cardiac portion or the antrum, while staying away from more delicate structures, such as the proximal duodenum and the pyloric valve. In this way the risk of obstruction and trauma by the anchoring components is reduced.

In accordance with an aspect of the invention, the anchoring component comprises a gastric coil which can change shape from an extended free-ended string shape adapted for transoral or transnasal transportation thereof into the stomach, to an arched or annular configuration adapted to shape connect with the stomach such as to provide an anchor for the pull resistant tether which is connected to the proximal sleeve end.

In accordance with a further aspect of the invention, the anchoring component comprises a gastric balloon which can be expanded from a collapsed shape to an expanded shape and which may be dimensioned to occupy a substantial volume of the stomach, thereby combining the weight loss effect due to stomach reduction with the function of anchoring the sleeve.

In accordance with a yet further aspect of the invention, the anchoring component comprises a set of individual initially separate segments which are adapted to be individually transportable into the stomach and which can be assembled, e.g. by snap fit and/or additional magnetic attraction to form a rigid body of greater dimensions than the individual segments, particularly a ring or a coil.

In accordance with a further aspect of the invention, the proximal sleeve end supports an elastic spread ring in a deformed wavy shape with undulations in a

sleeve longitudinal direction but with no or substantially no undulations in a sleeve radial or transverse direction, thereby elastically biasing the proximal sleeve end in a radially spread configuration while preserving a continuously convex outer contour. This contributes to reliably seal the proximal sleeve end against the surrounding tissue, e.g. against a proximal duodenal wall section.

In accordance with a yet further aspect of the invention, a proximal edge of the proximal sleeve end funnels radially outward and tapers to a thin sealing lip.

Further spread rings may be connected to the sleeve along its length to expand the sleeve and prevent the sleeve from twisting on itself. These rings could be either inside the sleeve, outside the sleeve or build within the wall of the sleeve.

In accordance with a yet further aspect of the invention, an elastic spring is interposed between the anchoring component and the proximal sleeve end. The elastic spring provides some additional flexibility during placement of the sleeve end expansion of the anchoring component from the transport configuration to the deployed configuration.

In accordance with a further aspect of the invention, the sleeve device comprises a distance adjusting mechanism adapted to adjust the (non-stretched) length of the tether between the anchoring component and the proximal sleeve end.

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.

BRIEF DESCRIPTION OF THE DRAWINGS

- Figure 1 illustrates a duodenal sleeve device in accordance with an embodiment;
- Figure 2 is a longitudinal cross-section of a sleeve of a duodenal sleeve device in accordance with an embodiment;
- Figure 3 illustrates a method step for endoluminal placement of the sleeve of an endoluminal sleeve device within the GI tract;
- Figure 4 illustrates a duodenal sleeve device in accordance with a further embodiment and method steps for its endoluminal placement and anchoring in the GI tract;
- figure 5 illustrates a duodenal sleeve device in accordance with a further embodiment anchored within the stomach;

- figure 6 illustrates a duodenal sleeve device in accordance with a yet further embodiment anchored within the stomach;
- figure 7 illustrates a detail of a duodenal sleeve device in accordance with an embodiment;
- figure 8 illustrates a detail of a duodenal sleeve device in accordance with a further embodiment;
- figures 9 through 11 illustrate devices and methods for adjusting the length of a tether of a duodenal sleeve device in accordance with an embodiment;
- figure 12 illustrates devices and methods for anchoring a duodenal sleeve device in accordance with an embodiment;
- figure 13 illustrates a duodenal sleeve device implanted in a GI tract in accordance with a yet further aspect of the invention;
- figure 14 is a cross-sectional view in the plane XIV-XIV in figure 13 in accordance with an embodiment;
- figure 15 illustrates a detail of the anchored sleeve device in figure 13 in longitudinal cross-section in accordance with an embodiment;
- figure 16 illustrates a detail of an anchoring member 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, an endoluminal sleeve device 1 for internally lining a section of the GI tract, particularly a section of duodenum distally from the pylorus, comprises a sleeve 2 configured for deployment inside a duodenum of a human subject, the sleeve 2 having walls of a flexible material defining a sleeve lumen 3, a proximal end 4 defining a proximal lumen opening 5, and a distal end 6 defining a distal lumen opening 7. The device 1 comprises further an anchoring component 8 having a slender transport configuration and a bulky deployed configuration, the anchoring component 8 being locatable at a distance from the proximal sleeve end 4 and connected thereto by an elongated tether 9.

The anchoring component 8 can be endoluminally inserted in and removed from the stomach 10 through the mouth and the esophagus while being in the slender transport configuration and, thanks to the distance between the anchoring component 8 and the proximal sleeve end 4, the anchoring component 8 can be

deformed to the bulky deployed configuration without interfering with or influencing the shape of the proximal lumen opening 5 which is crucial for the sealing of the sleeve 2 against the gastrointestinal wall. Moreover, thanks to the distance between the expandable anchoring component 8 and the proximal sleeve end 4, the anchoring component 8 can bear against selected robust structures of the stomach 10, such as for instance the cardiac portion or the antrum, while staying away from more delicate structures, such as the proximal duodenum and the pyloric valve. In this way the risk of obstruction and trauma by the anchoring component 8 is reduced.

In accordance with an embodiment (Figure 4), the anchoring component 8 comprises a gastric coil 11 which can change shape from an extended free-ended string shape adapted for transoral or transnasal transportation thereof into the stomach, to an arched or annular configuration adapted to shape connect with the stomach 10 such as to provide an anchor for the pull resistant tether 9 which is connected to the proximal sleeve end 4.

In accordance with embodiments, the gastric coil 11 can comprise a sequence of rigid segments which are linked to one another by elastic or shape memory or phase changeable material links. Additionally or alternatively, the gastric coil 11 can be snap rigidizable in its arched deployed shape, e.g. by means of mutually snap connectable initially free ends, by a pull string activatable rigidizing mechanism.

In case of an open ended arched deployed shape, the free ends are preferably oriented radially inwardly with respect to an outer coil contour in order to not rub and irritate the surrounding tissue.

The free-ended string shape of the gastric coil 11 in the transport configuration provides an extremely slender structure which can be easily and mini-invasively moved through the mouth down the esophagus into the stomach or pushed through an endoluminally or laparoscopically inserted insertion tube.

A proximal tether end of the tether 9 can be connected to a free end of the gastric coil 11 or to an intermediate portion thereof at a distance from both free ends.

In accordance with a further embodiment (Figure 5), the anchoring component 8 comprises a gastric balloon 12 which can be expanded from a collapsed shape to an expanded shape and which may be dimensioned to occupy a substantial volume of the stomach 10, thereby combining the weight loss effect due to

stomach reduction with the function of anchoring the sleeve 2. In the expanded configuration, the gastric balloon 12 may define a through hole 13 that allows the food to flow through the balloon 12 which would otherwise obstruct the stomach 10. In this case a proximal end of tether 9 may be fastened to the gastric balloon 12 near or at a distal aperture 14 of the through hole 13 in order that the distal pulling force due to peristalsis correctly orients the gastric balloon 12 and prevents the through hole opening from being fully covered and obstructed by the gastric wall.

After initial endoscopic inspection of the stomach of a patient, the balloon 12 can be endoscopically passed through the mouth and down the esophagus into the stomach while it is in its smallest, deflated shape. Once the balloon is inside the stomach, it is filled with sterile saline solution through a filling catheter 15 attached to the balloon 12. Once filled, the catheter 15 is removed and the balloon 12, pulled distally by the attached tether 9 engages the stomach wall proximal to the pylorus 16.

The balloon 12 may be grafted of a soft and pliable silicone material similar to known intragastric balloons. Alternatively or additionally, the gastric balloon 12 may have a foldable or stretchable outer wall to which an internal frame (not shown) is attached which is expandable from a collapsed shape to an expanded shape.

In an embodiment, the internal frame can be expanded together with the gastric balloon 12 outer wall by insufflating the balloon e.g. with saline solution. The frame is configured that, after expansion thereof, it preserves the expanded shape of the balloon independently from the insufflating fluid and possible deflation. This will assure a much longer live cycle of the anchoring balloon 12 compared to known gastric balloons.

In a further embodiment, the internal frame may be elastically deformable from a released expanded shape to a compressed collapsed shape and the gastric balloon 12 may be held in the collapsed shape (transport configuration of the anchoring component) by an external retaining device, e.g. a stretch resistant outer sheath, a rigid capsule, a retaining string or retaining band. In this case, expansion of the gastric balloon 12 can be accomplished by removing the retaining device once the gastric balloon is positioned within the stomach. Hence, no insufflations is required.

The gastric balloon 12 can be removed together with the sleeve 2 or independently

from the sleeve 2, via the esophagus and mouth. For this purpose, the gastric balloon 12 is deformed, prior to removal, back to its collapsed shape, e.g. by deflation (by means of endoscopic puncturing) and/or external compression. Once the balloon 12 is collapsed it can be endoscopically grasped and removed from the stomach 10 through the esophagus and the mouth.

In accordance with a further embodiment, the anchoring component 8 comprises a non deformable monolithic rigid ring or coil which is placed within the stomach through a previously created gastrostomy. The rigid single piece anchoring component reduces the risk of undesired deformations even though it may require traditional surgery for deployment and removal.

In accordance with a yet further embodiment, the anchoring component 8 comprises a set of individual initially separate segments which are adapted to be individually transportable into the stomach and which can be assembled, e.g. by snap fit and/or additional magnetic attraction to form a rigid body of greater dimensions than the individual segments, particularly a ring or a coil, as illustrated in figures 1, 6, 8.

In accordance with an embodiment (Figure 1), the anchoring component has an outer wall or external surface layer of non degradable material, such as an austenitic Chromium-Nickel stainless steel with superior corrosion resistance. An example for such a material is SS316L which permits usage in severe corrosive environments and which, for the intended use, may have a nominal composition of Chromium 17.2%, Manganese 1.6%, Nickel 10.9%, Carbon 0.02%, Molybdenum 2.1% + Iron Balance to complete 100%.

The proximal tether end 17 may be connected to the ring or coil shaped anchoring component 8 by a proximal connecting ring 18 which can slide along a section of the anchoring component 8 to assure that the connecting ring 18 can always slide to the most distal located portion of the anchoring component 8. In this way, a rotation of the anchoring component 8 due to movements of the gastric wall or of the pylorus will not substantially change the position of the proximal end 17 of tether 9 and undesired local displacements of the proximal end 4 of the sleeve 2 are significantly reduced.

The connecting ring 18 can be made of the same non degradable material as the anchoring component outer wall, e.g. a welded or braced SS316L wire annulus.

The tether 9 may be a flexible non-stretchable wire or braded cable made from a

non-degradable material, such as e.g. the above said SS316L steel alloy or other suitable high corrosion resistant material.

In accordance with an embodiment, an initially free tether end is routed through a crimping tube 19 (which is conveniently of the same material as the tether, i.e. SS316L steel alloy), then around the connecting ring 18 and back through (or into) the crimping tube 19, which is then crimped to lock the tether 9 within the tube and attached to the connecting ring 18. Conveniently, in order to reduce the risk of trauma, the free end of the tether 9 remains encapsulated inside the crimped crimping tube 19.

The described connection solution allows an easy and structurally reliable connection with a possibility to easily adjust the tether length prior to crimping.

The finished assembly can be additionally coated with a silicone coating for protection against the acid environment within the GI tract and for creating a smooth external surface which doesn't irritate the surrounding tissues. The silicone coating may be a combination of a tubing of flexible, inert silicone elastomer, a silicone sealant or adhesive or other protective materials which completely encapsulate the braided cable of the tether 9, the crimping tube 19 and the connecting ring 18.

In the deployed configuration, the tether 9 passes through the pylorus 16 and connects the proximal sleeve end 4 (located within the duodenum) to the anchoring component 8 within the stomach.

A distal tether portion may form junction point 20 from which a plurality of e.g. two to five, preferably 3 or 4, distal split tethers 21 extend which connect to the proximal sleeve end 4 in different locations along its circumference, in order to avoid an unilateral anchoring pull that would tilt the proximal lumen opening 5.

The junction point 20 may be embodied by means of a second crimping tube 19 into which the tether 9 and the split tethers 21 are inserted and locked by crimping. Here too, the free ends of wire or cable material are preferably encapsulated inside the crimping tube 19.

The junction point 20 and split tethers 21 can be coated for protection as described in connection with the proximal tether attachment.

The connection of the split tethers 21 with the proximal sleeve end 4 can be embodied by means of the above described crimping method and crimping tubes or, alternatively, by means of an enlarged e.g. T-shaped end section of the split

tethers 21 which may be received in a corresponding seat of a proximal mounting structure 22 of the sleeve 2.

The connection of the split tethers 21 with the proximal sleeve end 4 can be coated for protection as described in connection with the proximal tether attachment.

In accordance with an embodiment, an elastic spread ring 23 is supported by the proximal sleeve end 4 in a deformed wavy shape with undulations in a sleeve longitudinal direction but preferably with no or substantially no undulations in a sleeve radial or transverse direction, thereby elastically biasing the proximal sleeve end 4 in a radially spread configuration while preserving a continuously convex outer contour. This contributes to reliably seal the proximal sleeve end 4 against the surrounding tissue, e.g. a proximal duodenal wall section.

In order to exert the above said light outward pressure on the proximal end 4 of the sleeve 2 but avoid structural complexity due to excessive bending of the spread ring, the non-deformed circumferential length of the spread ring 23 is selected from 1.5 to 2.5, preferably about 2.0 times the diameter of the proximal sleeve end 4.

Within a proximal mounting structure 22 of the sleeve 2, two or more spread rings 23 may be arranged to increase the sealing area and to uniformly distribute the sealing pressure. The spread rings 23 and possible additional reinforcing inserts in the wall of the sleeve 2 can be e.g. grafted from NiTinol wire.

In order to further improve sealing, a proximal edge 24 (Figure 2) of the proximal sleeve end 4 funnels radially outward and tapers proximally to form a thin sealing lip.

Further spread rings 23 may be connected to the sleeve 2 along its length to expand the sleeve and prevent it from twisting on itself. These spread rings 23 could be connected either inside the sleeve, outside the sleeve or build within the wall of the sleeve.

In order to facilitate the connection of the spread ring 23 to the proximal sleeve end 4, a proximal reinforced semi-rigid tubular mounting structure 22 may be formed at the proximal sleeve end 4, which mounting structure 22 connects to the tether 9 or split tethers 21 and holds the spread ring 23. A less resistant and more flexible section of the sleeve (e.g. made of silicone with a durometer value of about 20 and a wall thickness of 0.125 inches or less) can be attached to or extend from a distal end of the mounting structure 22.

As shown in figure 3, during endoluminal placement of the duodenal sleeve device

1, the spread ring 23 or rings can be folded together with the sleeve 2 and packed inside a flexible insertion tube 25. A pusher 26 placed in the insertion tube 25 proximally (doctor's side) from the packed sleeve can then advance distally to push the sleeve out of the tube. The insertion tube 25 can be passed through an instrument channel of an endoscope or it can be attached laterally on the outside of the scope. The insertion tube 25 might also be introduced laparoscopically through a gastrostomy.

In accordance with some embodiments, the same insertion tube 25 may receive also the anchoring component 8 in its slender transport configuration either individually or together with the sleeve 2, so that also the anchoring component 8 or the entire sleeve device 1 can be transported into the GI tract by means of the insertion tube 25 and distally pushed out of the latter for deployment.

In accordance with a further embodiment, after placing and fastening of the proximal sleeve end 4 within the stomach or duodenum, the insertion tube 25 may be withdrawn and pulled endoluminally in a distal direction (e.g. by using an anal endoluminal access) to place the remaining sleeve section and spread rings 23 into the intestine. This method ensures that tension on the sleeve 2 is maintained during placement, preventing the sleeve from bunching up with a possible risk of blockage.

In accordance with embodiments, the spread ring 23 or rings can be either an add-on component to secure the sleeve 2 within the GI tract or it can be integrally connected to the sleeve 2.

The spread ring 23 can be additionally used to hold the sleeve lumen 3 and the gastric or duodenal wall open for ease of additional stapling and maintains the spacing of the fasteners. The spread ring 23 can carry markers showing planned locations for fasteners or for attachment of the split tethers 21.

In accordance with a further embodiment, additional spread rings 23 can be associated to the sleeve distally and proximally of the position of the sphincter of ODDI so that a sleeve wall between the two additional spread rings may create a bile collection space from which bile may be drained outside or inside the sleeve 2.

In accordance with a further embodiment, one or more (possibly adjustable) flanges 27, which might have an adjustable internal diameter, are connected inside the sleeve 2 for the purpose of varying the lumen size to influence gastric emptying or to create a torturous path for the chyme to slow the flow rate of the chyme

through the section of the GI tract lined by the sleeve 2. Such internal flange 27 can further be configured to act as an anti reflux device of the sleeve. Conveniently, the flange 27 or flanges may be connected to the wall of the sleeve 2 near or by means of the spread rings 23.

In accordance with further aspect of the invention (Figures 6, 7), an elastic spring 28 is interposed between the anchoring component 8 and the proximal sleeve end 4. The elastic spring 28 provides some additional flexibility during placement of the sleeve 2 end during expansion of the anchoring component 8 from the transport configuration to the deployed configuration. Moreover, the spring 28 can stretch and retract to adapt to gastric and duodenal peristaltic movements, while keeping the proximal sleeve end 4 in sealing engagement against the duodenal wall.

The spring 28 can be embodied by an elastic section of the tether 9 or of the split tethers 21 or may be interposed in series between the tether 9 and the proximal sleeve end 4 or between the tether 9 and the anchoring component 8. Also the spring 28 may be provided with an external protective layer as described for the tether assembly.

In accordance with an embodiment (Figure 7) the spring 28 comprises an elastic coil connected to the proximal sleeve end 4, particularly to the proximal mounting structure 22 of the sleeve 2, wherein the elastic coil may be advantageously tapered in a proximal direction (towards the anchoring component 8). In this embodiment, a distal end of the flexible tether 9 may be connected to a proximal end of the tapered elastic coil, e.g. by crimping. The spring 28 or elastic tapered coil can also be formed in a single monolithic piece with the mounting structure 22 of the sleeve 2.

A coiled elastic spring 28 directly connected to the proximal sleeve end 4 may also improve the access to the proximal lumen opening 5 in comparison to a multiple split tether approach, compare figures 1 and 7.

In an alternative embodiment, the elastic spring 28 is formed by a portion of the anchoring component 8 itself, e.g. by an elastic end section of the above described gastric coil 11 to which the proximal tether end 17 is connected.

The benefits of a large anchoring component 8 for anchoring the sleeve 2 and for obstruction prevention at the pylorus are thus combined with some desired elastic adjustment of the distance between the anchoring component 8 and the proximal sleeve end 4, thereby improving adaption to anatomy.

In accordance with a further aspect of the invention, the sleeve device 1 comprises a distance adjusting mechanism 29 adapted to adjust the (non-stretchable) length of the tether 9 between the anchoring component 8 and the proximal sleeve end 4.

In some embodiments (Figures 8, 12), a plurality of tethers 9 are provided to connect the proximal mounting structure 22 of the sleeve 2 (placed within the proximal duodenum) to the anchoring component 8 which is preferably shaped as a ring (and placed proximal to the pylorus within the stomach), and the tethers 9 may be extended through the tissue of the pylorus 16 itself or through the pyloric passage without piercing the bodily tissue.

The proximal ends 17 of the tethers 9 are inserted through holes in the anchoring component 22 and locked therein against distal withdrawal by collets or clamping slider 30 which can slide along the tether 9 and which can be locked in a selected position by a clamping mechanism 32, e.g. by a pusher which is elastically biased transversally into an internal channel of the clamping slider 30 through which the tether 9 is passed, said pusher having activating tabs which can be handled and activated by a grasper.

This allows to adjust the effective (non-stretchable) length of the tethers 9 and, thus, the distance between the anchoring component 8 and the proximal sleeve end 4.

In accordance with an embodiment (Figure 12) the length of the tethers 9 is adjusted to place and hold the proximal sleeve end 4 and the anchoring component 8 snugly fitted against both sides of the pylorus 16.

The length adjustment of the at least one tether 9 can also be used to tighten up the anchoring component 8 and the proximal sleeve end 4 against the pylorus 16 to clamp the latter therebetween.

When the tethers 9 do not extend through the pylorus tissue but through the pylorus passage, a plurality of tethers can be extended diagonally therethrough in order not to rub against and irritate the delicate tissue at the pylorus.

During anchoring of the sleeve device 1 in the GI tract, the tethers 9 can be distally driven through the pylorus tissue or, generally towards and in coupling engagement with the proximal sleeve end 4, by means of a pushing tube 31 which receives the tether 9 inside and provides stiffness against flexure.

Figure 12 illustrates a method and an endoscopic applier 33 comprising a flexible shaft and an applier head 34 arranged at a distal end of the flexible shaft. The

applier head 34 comprises a proximal coupler mount 36 adapted to carry the (ring shaped) anchoring component 8, a distal coupler mount 35 operable to translate with respect to the proximal coupler mount 36 and adapted to carry the proximal mounting structure 22 of sleeve 2, as well as one or more pushing tubes 31 positioned and operable to translate through tether holes 38 formed in the anchoring component 8 with respect to both the proximal and distal coupling mounts 36, 35 and adapted to receive the tethers 9 provided with a distal (snap-) coupling tip 39 which may be pointed for piercing through bodily tissue. The applier 33 allows to adjust the distance between the anchoring component 8 and the proximal sleeve mounting structure 22 by translating the distal coupling mount 35 with respect to the proximal coupling mount 36 and to apply and fasten the tethers 9 by pushing them with the pushing tube 31 through the tether holes 38 in the anchoring component 8 and distally (through the pyloric tissue and) in engagement with coupling seats 37 formed in the sleeve mounting structure 22. After coupling and proximal withdrawal of the pushing tubes 31, the collets or clamping slider 30 can be advanced, adjusted and locked to fasten the tethers 9 to the anchoring component 8.

In accordance with a further aspect of the invention (Figures 13 to 16) an endoluminal sleeve device 1 is provided for internally lining a section of the GI tract comprises a sleeve 2 configured for deployment inside a duodenum, the sleeve 2 having a wall of a flexible material defining a sleeve lumen 3, a proximal end 4 defining a proximal lumen opening 5, and a distal end 6 defining a distal lumen opening 7, as well as an anchoring component 8 having a slender transport configuration and a bulky deployed configuration, e.g. an expandable Nitinol ring, attached to the proximal sleeve end 4, e.g. by tethers as has been described herein before, or directly such that the anchoring component forms part of the proximal sleeve end 4. Anchoring of the sleeve device 1 can be accomplished by using an endoscopic applier to deliver a plurality of individual (plastic or metallic) hooking members 40 in a target anchoring location within the GI tract, e.g. near the pylorus 16, and to connect the individual anchoring members 40 along a circumferential row to the wall of the stomach 10 or of the intestine such that the hooking members 40 protrude radially into the lumen of the GI tract at the target anchoring location.

After placing the hooking members 40, the sleeve device 1 can be endoluminally

inserted in the GI tract (using e.g. the methods described in relation with the embodiments of figures 1 to 12) and the anchoring component 8 is positioned in the target anchoring location proximal to the circumferential row of hooking members 40. In response to a peristaltic distal pull, the anchoring component 8 will abut against the hooking members 40 and cannot pass distally through the target anchoring location. As illustrated in Figure 16, the hooking member 40 may comprise a e.g. coiled or corkscrew shaped a tissue anchor 41 and a hook shaped catching portion 42 adapted to hook into the anchoring component 8 from a distal and radially internal side.

The sleeve 2 itself is sufficiently flexible to follow the curvature of the duodenum. Further, in some embodiments the walls of the sleeve are sufficiently flexible and/or collapsible to allow duodenal peristalsis to drive chyme through the lumen of the sleeve. Sufficient collapsibility of the walls of the sleeve prevents continuous intimate contact of the outer surface of the sleeve with the duodenal mucosa, avoiding damage to the duodenal mucosa and allowing digestive secretions not collected into the sleeve lumen to pass through the duodenal lumen outside the sleeve lumen.

In some embodiments, at least a portion of the wall of a sleeve may be porous or semipermeable to allow entry of digestive secretions into the sleeve lumen and/or to allow the flow of fluids and digested matter out of the sleeve lumen.

In some embodiments, at least a portion of the wall of a sleeve may be impermeable, analogous to the Endobarrier(R) by GI Dynamics Inc, Watertown, Mass., USA and as described in U.S. Pat. No. 7,267,694 which is included by reference as if fully set forth herein.

The diameter of the sleeve lumen may be substantially constant along the entire length of the liner tube. Although any suitable luminal diameter may be used, in some embodiments, the luminal diameter may be not more than about 30 mm, not more than about 25 mm and even not more than about 20 mm.

In some embodiments, the proximal end of the sleeve may be flared and may define a funnel-like structure.

The length of the sleeve may be any suitable length and may be selected in accordance with clinical decisions made by the treating physician. A typical sleeve is between about 25 cm and about 160 cm long. Generally, the sleeve is selected so that when the duodenal sleeve device is deployed, the distal lumen opening of

the sleeve is located distal to the duodenal-jejunal flexure and empties out into the jejunum. In some embodiments, the sleeve may be even longer.

Suitable materials from which the sleeve for implementing the invention are fashioned include silicone, polyurethane, polyethylene (e.g., low density polyethylene films) and fluoropolymers (e.g., expanded polytetrafluoroethylene). In some embodiments, the sleeve is fashioned from fluoropolymer or polyethylene film impregnated with polyurethane or silicone to reduce permeability, as taught in U.S. Pat. No. 7,267,694.

The sleeve may include one or more markers (e.g., barium) designed for viewing the position of the sleeve within the intestines through fluoroscopy, such as a longitudinal rib or other markers that are spaced along the length of sleeve. In addition, sleeve may further include components that inhibit twisting or kinking of the sleeve itself. In one embodiment, these components include one or more stiffening elements, such as rings, coupled to either the inside or the outside of the sleeve at spaced locations along its length. These rings can, for example, be made of a slightly thicker silicone material that would resist twisting or kinking of the sleeve around the ring. In other embodiments, the stiffening elements may be in spiral shape or extending lengthwise along at least a portion of the sleeve.

In an implantation method, the sleeve may be initially folded or rolled up and packed into the interior of an applier. The distal end of sleeve may be initially closed, e.g. with a small polymeric or silicone seal and forms a programmed tearing line, e.g. a perforation, along which the distal end can tear open by the internal pressure of the chyme flow.

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 obviate undesired migration of the sleeve away from its original anchoring position and addresses the need of reliable sealing of the lined lumen. Moreover, some embodiments of the described devices and methods are beneficial with regard to permitting normal biological events, including vomiting, to occur.

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. Endoluminal sleeve device (1) for internally lining a section of the GI tract, comprising:

- a sleeve (2) configured for deployment inside a duodenum, the sleeve (2) having walls of a flexible material defining a sleeve lumen (3), a proximal end (4) defining a proximal lumen opening (5), and a distal end (6) defining a distal lumen opening (7),

- an anchoring component (8) having a slender transport configuration and a bulky deployed configuration, the anchoring component (8) being locatable at a distance from the proximal sleeve end (4) and connected thereto by an elongated tether (9).

2. Endoluminal sleeve device (1) according to claim 1, in which the anchoring component (8) comprises a gastric coil (11) which can change shape from an extended free-ended string shape adapted for endoluminal transportation into the stomach, to a deployed arched shape adapted to shape connect with the stomach (10).

3. Endoluminal sleeve device (1) according to claim 2, in which the gastric coil (11) comprises means for locking thereof in the deployed arched shape.

4. Endoluminal sleeve device (1) according to claim 1, in which the anchoring component (8) comprises a gastric balloon (12) which can be expanded from a collapsed shape to an expanded shape.

5. Endoluminal sleeve device (1) according to claim 4, in which, the expanded configuration, the gastric balloon (12) may defines a through hole (13) and a proximal end of tether (9) is fastened at a distal aperture (14) of the through hole (13).

6. Endoluminal sleeve device (1) according to claim 1, in which the anchoring component (8) comprises a set of individual, initially separate segments adapted to be individually transportable into the stomach and which can be assembled to form a rigid body of greater dimensions than the individual segments.

7. Endoluminal sleeve device (1) according any one of the preceding claims, in which the anchoring component (8) has a ring shaped deployed configuration and a proximal end (17) of tether (9) is connected to circumferentially slide along it.

8. Endoluminal sleeve device (1) according any one of the preceding claims, comprising at least one elastic spread ring (23) supported by the proximal sleeve end (4) in a deformed wavy shape with undulations in a sleeve longitudinal

direction, wherein the spread ring (23) elastically biases the proximal sleeve end (4) in a radially spread configuration while preserving a continuously convex outer contour.

9. Endoluminal sleeve device (1) according to claim 8, in which a total circumferentially developed length of the spread ring (23) is between 1.5 and 2.5 times the diameter of the proximal sleeve end (4).

10. Endoluminal sleeve device (1) according to any preceding claim, in which a proximal edge (24) of the proximal sleeve end (4) forms a sealing lip funneled radially outward and tapered proximally.

11. Endoluminal sleeve device (1) according to any preceding claim, comprising an elastic spring (28) interposed between the anchoring component (8) and the proximal sleeve end (4).

12. Endoluminal sleeve device (1) according to claim 11, in which said spring (28) is formed by an elastic section of the tether (9).

13. Endoluminal sleeve device (1) according to claim 11, in which the spring (28) comprises an elastic coil connected to the proximal sleeve end (4) and tapered in a proximal direction towards the anchoring component (8).

14. Endoluminal sleeve device (1) according to any preceding claim, comprising a distance adjusting mechanism (29) adapted to adjust an non-stretched length of the tether (9) between the anchoring component (8) and the proximal sleeve end (4).

15. Endoluminal sleeve device (1) anchoring system, comprising an endoluminal sleeve device (1) according to claim 1 and an applier (33) with a flexible shaft and an applier head (34) arranged at a distal end of the flexible shaft, the applier head (34) comprising:

- a proximal coupler mount (36) adapted to carry the anchoring component (8),
- a distal coupler mount (35) operable to translate with respect to the proximal coupler mount (36) and adapted to carry a ring-shaped proximal mounting structure (22) of sleeve (2),
- at least one pushing tube (31) adapted to receive the tether (9) and operable to translate with respect to both the proximal and distal coupling mounts (36, 35) through tether holes (38) formed in the anchoring component (8) and towards a coupling seat (37) formed in the sleeve mounting structure (22),

the tether (9) being provided with a distal coupling tip (39) adapted to connect with

the coupling seats (37) in the sleeve mounting structure (22)

16. Method for internally lining a section of the GI tract, comprising:

- placing a sleeve (2) inside a duodenum, the sleeve (2) having walls of a flexible material defining a sleeve lumen (3), a proximal end (4) defining a proximal lumen opening (5), and a distal end (6) defining a distal lumen opening (7),
- inserting an anchoring component (8), which is deformed in a slender transport shape,
- deforming the anchoring component (8) inside the stomach from the slender transport shape to a bulky deployed shape,
- positioning the bulky shaped anchoring component (8) within the stomach at a distance from the proximal sleeve end (4),
- connecting the anchoring component (8) with the proximal sleeve end (4) by an elongated tether (9).

17. Method according to claim 16, comprising:

- after connecting the tether (9) to both the proximal sleeve end (4) and the anchoring component (8), adjusting the length of the tether (9) to adapt the distance between the proximal sleeve end (4) and the anchoring component (8) to the gastro-duodenal anatomy.

18. Method for internally lining a section of the GI tract, comprising:

- connecting a plurality of individual anchoring members (40) along a circumferential row to a gastrointestinal wall in a target anchoring location within the GI tract such that the hooking members (40) protrude radially into the lumen of the GI tract;
- placing a sleeve (2) inside the GI tract, the sleeve (2) having walls of a flexible material defining a sleeve lumen (3), a proximal end (4) defining a proximal lumen opening (5), a distal end (6) defining a distal lumen opening (7),
- placing an anchoring component (8) in the target anchoring location in the GI tract, the anchoring component being connected to the sleeve (2) and deformed in a slender transport shape,
- expanding the anchoring component (8) inside the target anchoring location from the slender transport shape to a deployed ring shape,
- abutting the deployed ring shaped anchoring component (8) from a proximal side of the circumferential row of hooking members (40) against said hooking members 40.

FIG. 1

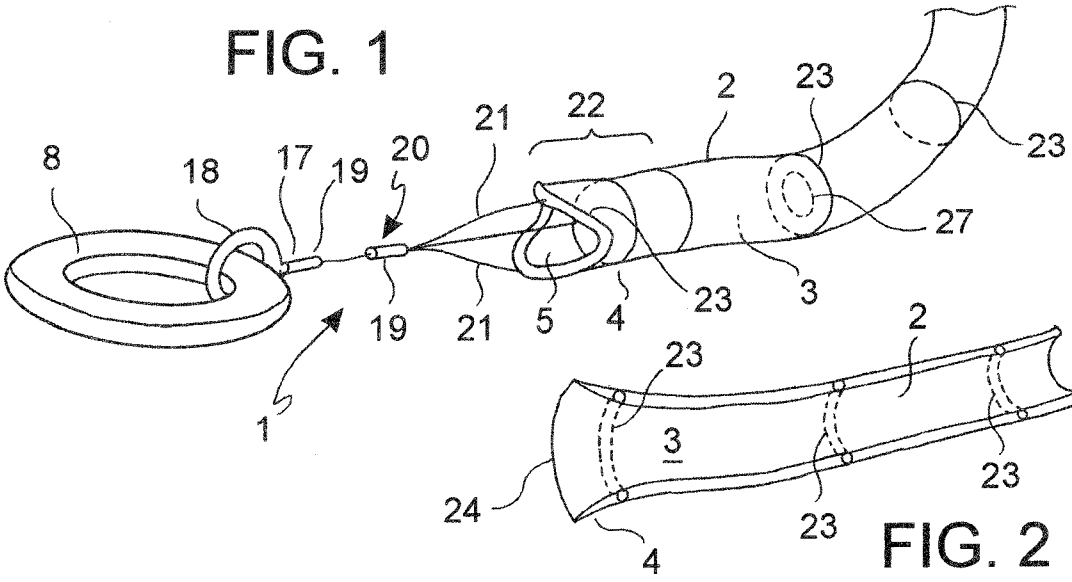


FIG. 2

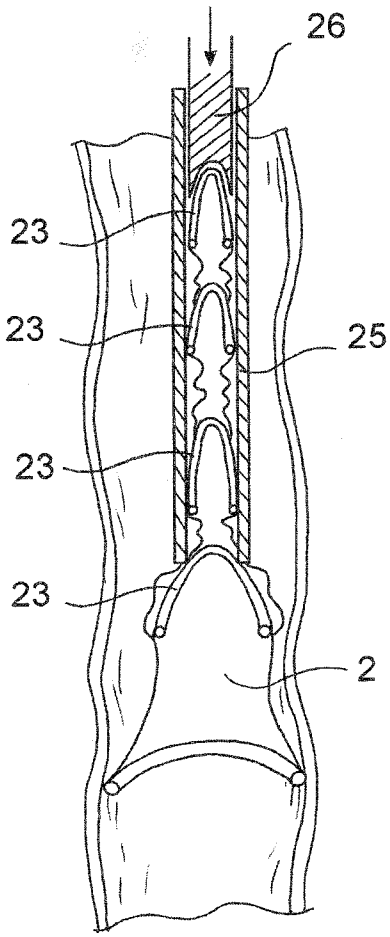


FIG. 3

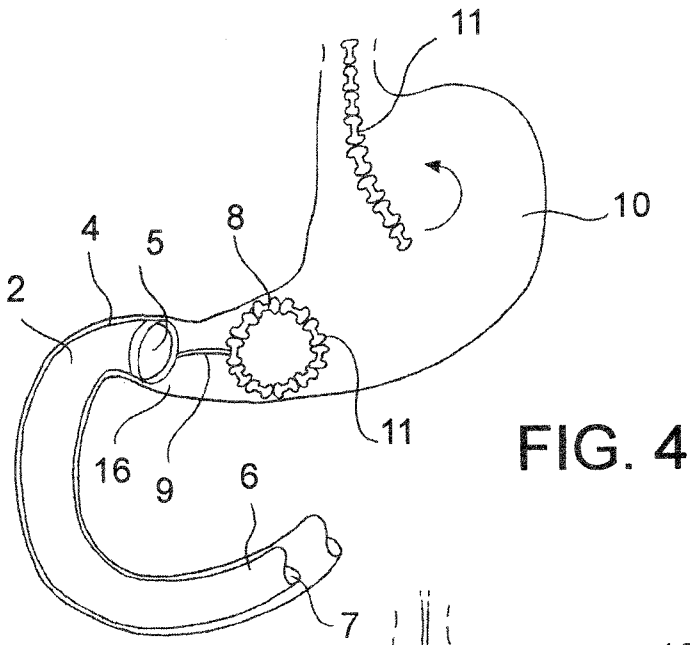


FIG. 4

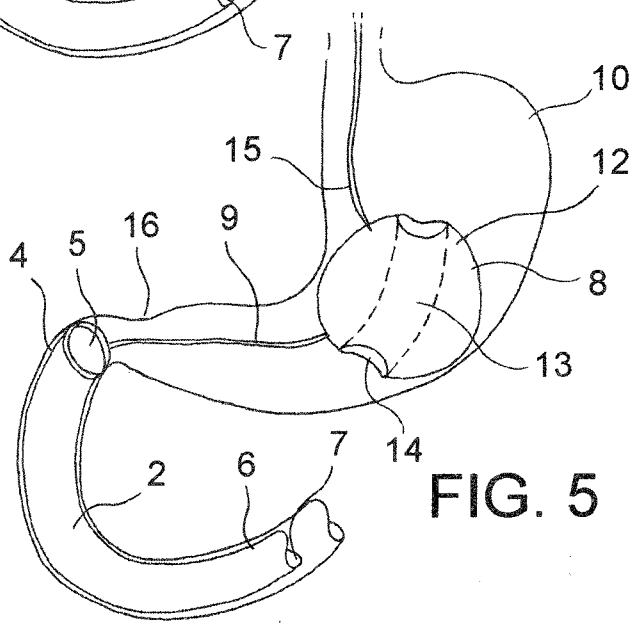
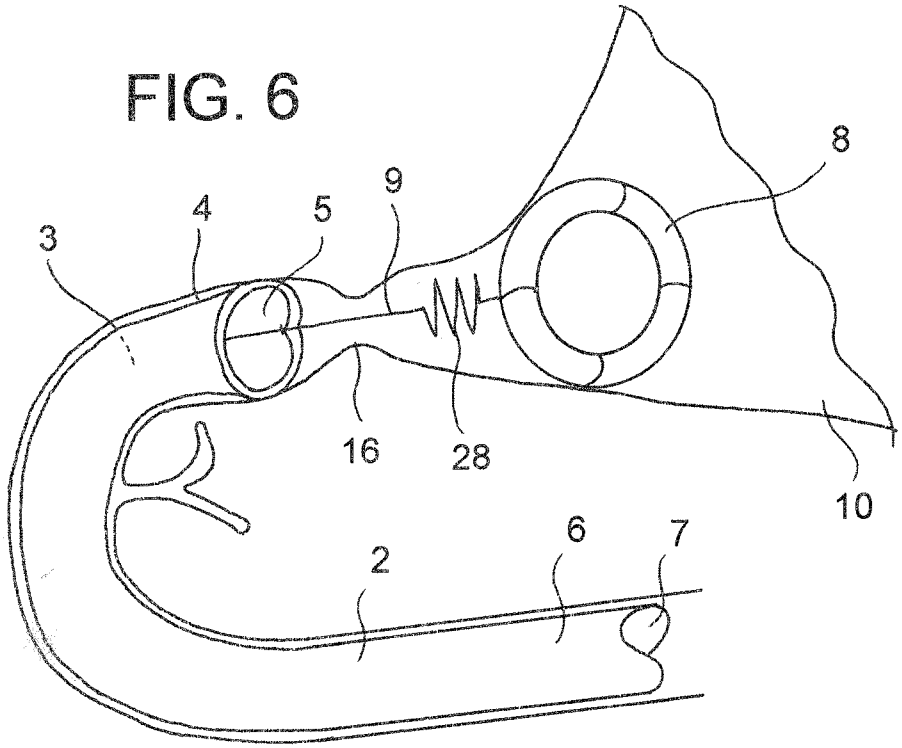


FIG. 5

FIG. 6



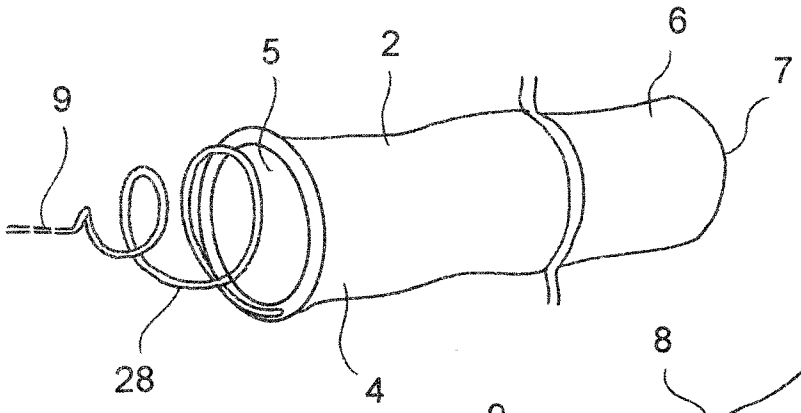


FIG. 7

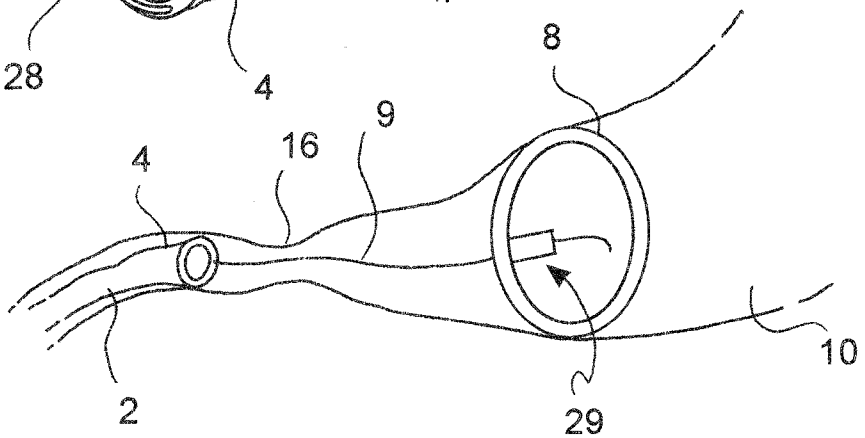
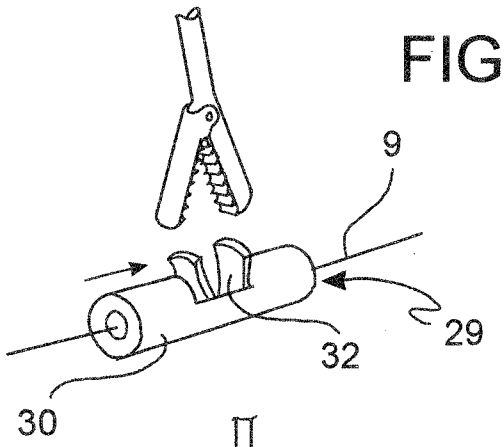


FIG. 8

FIG. 9



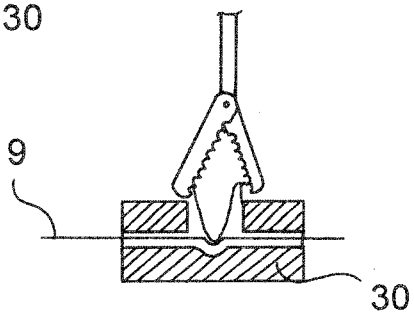


FIG. 10

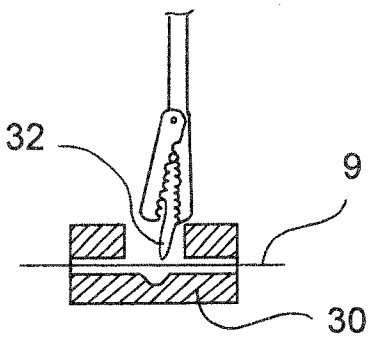


FIG. 11

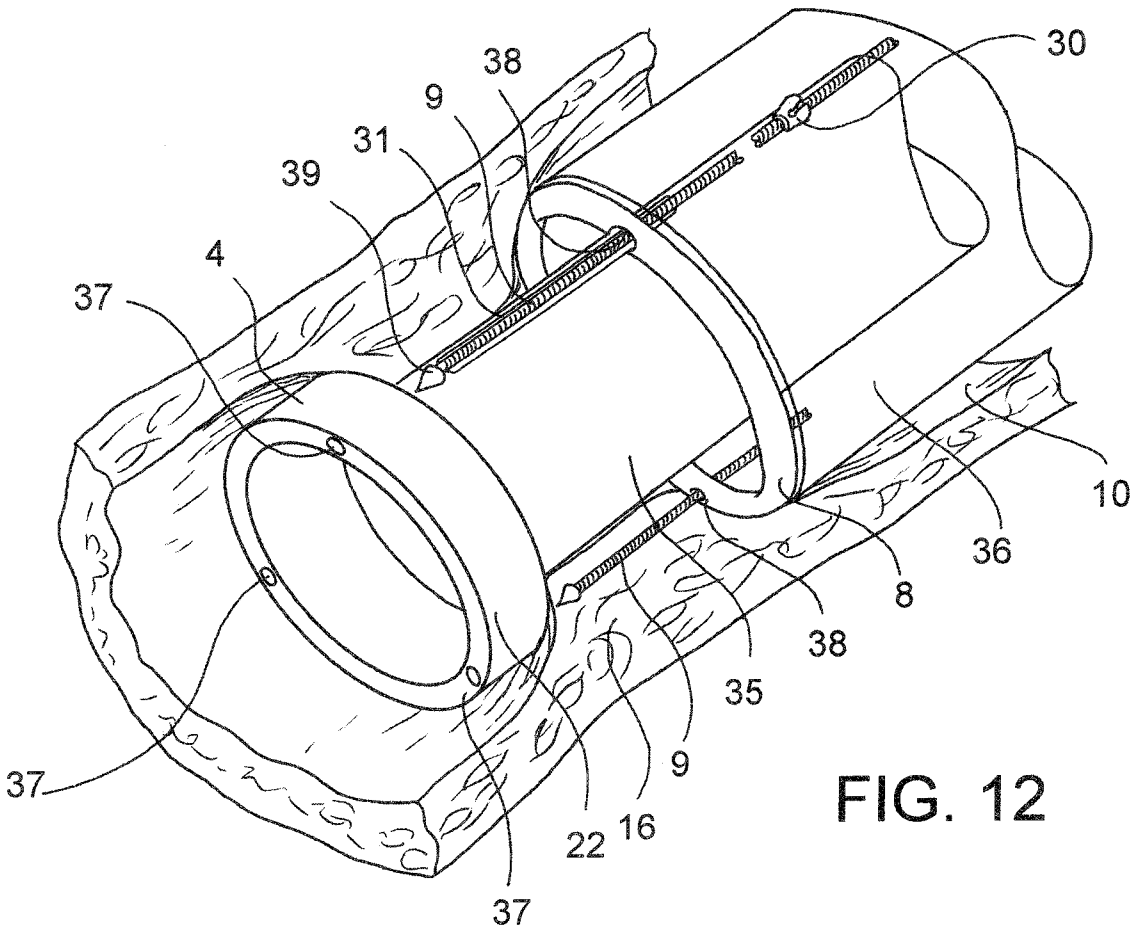
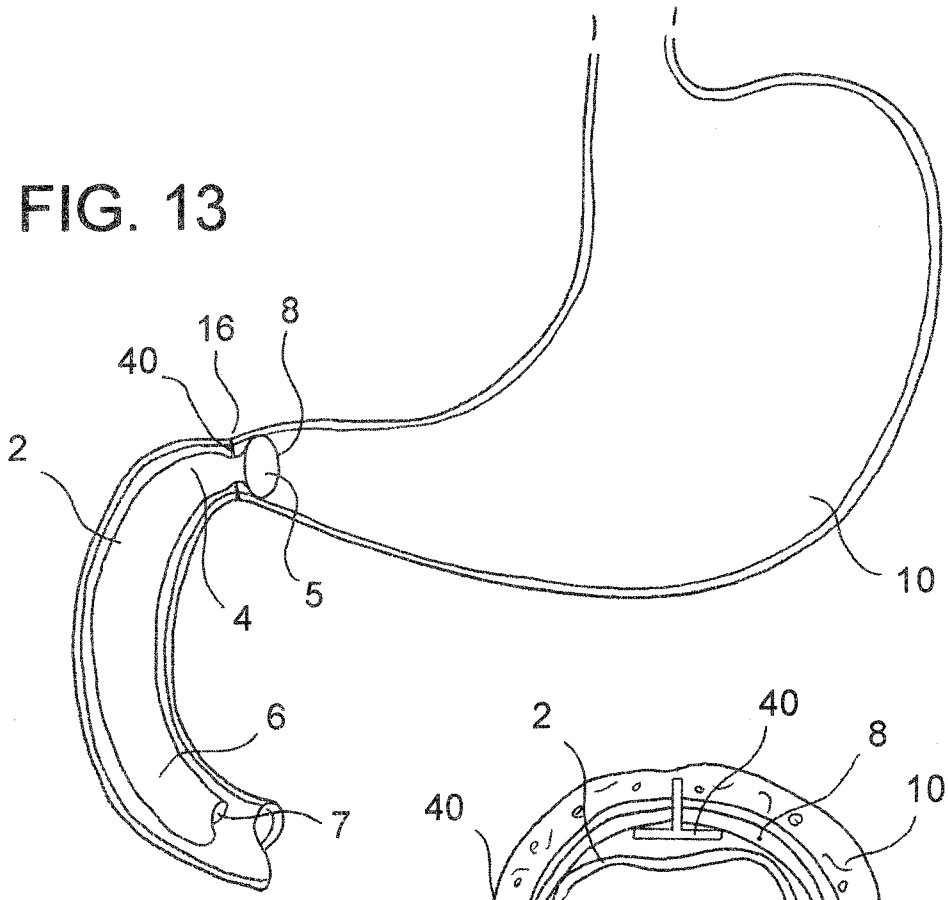


FIG. 12

FIG. 13



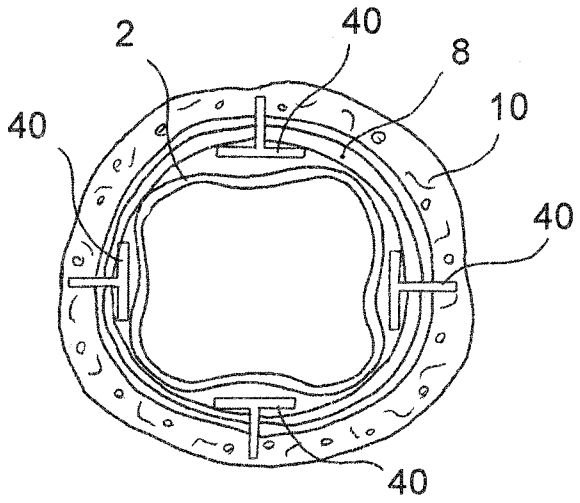


FIG. 14

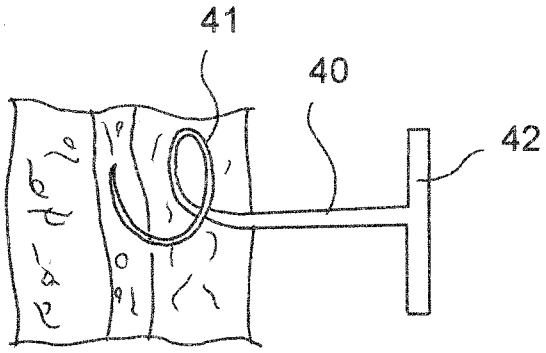


FIG. 16

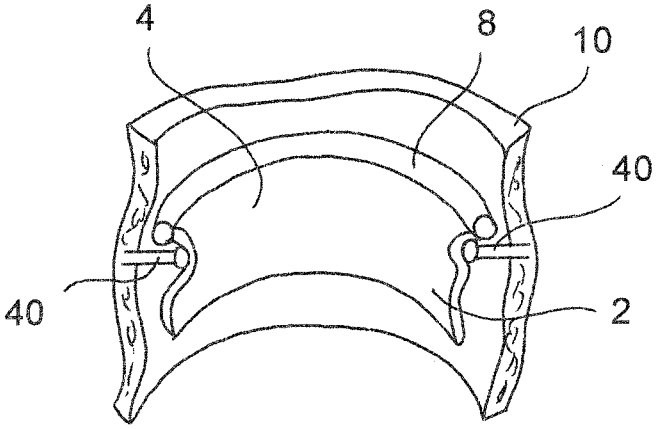


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/063945

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

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/004228 A1 (PRIPLATA ATTILA A [US] ET AL) 6 January 2011 (2011-01-06)	1-10
Y	paragraph [0099] - paragraph [0101]	11,12
A	paragraph [0118] - paragraph [0123]	15
	paragraph [0167] - paragraph [0170]; figures 1-39	

Y	US 2004/172142 A1 (STACK RICHARD S [US] ET AL) 2 September 2004 (2004-09-02)	11,12
A	paragraph [0054]; figure 10a	13,14

A	US 2011/066175 A1 (GROSS YOSSI [IL]) 17 March 2011 (2011-03-17)	1-7
	paragraph [0197] - paragraph [0201]; figures 1-19b	

☐ 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
3 April 2012	12/04/2012

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	Jansson Godoy, Nina

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/063945

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.: 16-18
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 16-18 relate to a method for treatment of the human or animal body by surgery according to Rule 39.1(iv) PCT.

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/EP2011/063945

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011004228 A1	06-01-2011	US 2011000496 A1	06-01-2011
		US 2011004228 A1	06-01-2011
		US 2011004229 A1	06-01-2011
		US 2011004236 A1	06-01-2011
		WO 2011100006 A1	18-08-2011
US 2004172142 A1	02-09-2004	US 2004172142 A1	02-09-2004
		US 2005004681 A1	06-01-2005
US 2011066175 A1	17-03-2011	US 2011066175 A1	17-03-2011
		WO 2011151830 A2	08-12-2011