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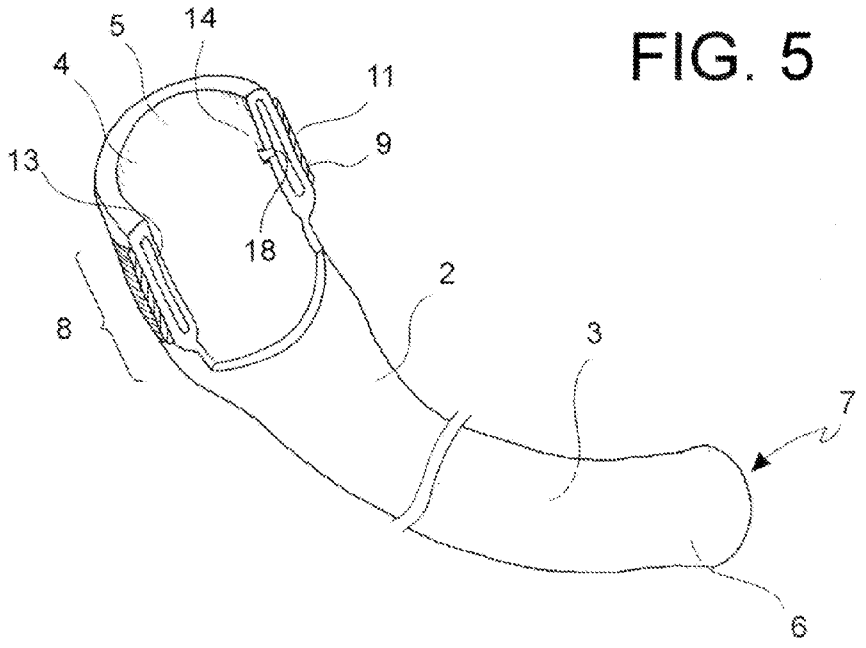

FIG. 5

(57) Abstract: An endoluminal sleeve (2) for internally lining a section of a GI tract comprises a wall 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), and a tubular anchoring collar (8) formed at the proximal sleeve end (4) and having an external anchoring surface (9) with an adhesive layer (11).

DESCRIPTION

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 an endoluminal sleeve configured for deployment inside a GI tract, particularly 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, a distal end defining a distal lumen opening, and a tubular anchoring collar formed at the proximal sleeve end and having an external anchoring surface with an adhesive layer.

Thanks to the adhesive layer, the anchoring collar can be glued to the surrounding wall of the GI tract, e.g. to a gastric wall or duodenal wall, and the glued connection reliably seals the proximal sleeve end with respect to the tissue.

In accordance with an aspect of the invention, the anchoring collar forms an inflatable chamber and an insufflating port adapted to detachably couple with an insufflating nozzle of an applier. The insufflating port may further comprise a stop valve which is adapted to seal the insufflating port after detachment of the insufflating nozzle.

Hence, by inflating the inflatable chamber the anchoring collar can be expanded until the anchoring surface with the adhesive layer is pressed against the surrounding gastrointestinal wall, so that the adhesive glues the sleeve in its planned position.

In accordance with a further aspect of the invention, there is provided a surgical system for internally lining a section of the GI tract, particularly of the duodenum, the system comprising the sleeve and an applier which can be coupled to an endoscope and which forms a sleeve seat adapted to receive the sleeve in a compacted configuration, and an insufflating device with an insufflating nozzle arranged in the sleeve seat and adapted to inflate the anchoring collar, thereby expanding the external anchoring surface with the adhesive layer.

In accordance with a yet further aspect of the invention, the sleeve seat is configured to receive the sleeve in such a position and shape that an internal surface of the anchoring collar defines together with a sealing surface of the sleeve seat a temporary insufflating space and wherein the insufflating nozzle extends into the temporary insufflating space. This allows the anchoring collar to be inflated and, hence, expanded, without any need to create a dedicated inflation chamber in the sleeve itself.

In accordance with a yet further aspect of the invention a method is provided for internally lining a section of a GI tract, particularly a section of a duodenum in a human subject, the method comprising providing a sleeve having walls of a flexible material defining a sleeve lumen, a proximal end defining a proximal lumen opening, a distal end defining a distal lumen opening, and a tubular anchoring collar formed at the proximal sleeve end and having an external anchoring surface with an adhesive layer, introducing the sleeve in a target section of the GI tract, pressing the anchoring collar with the adhesive layer against a wall of the GI tract

by inflating the anchoring collar.

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 surgical system with an endoluminal sleeve and an applier in accordance with an embodiment, the system being inside a target section of a GI tract;

- Figure 2 illustrates a detail of a surgical system with an endoluminal sleeve and an applier in accordance with a further embodiment, the system being inside a target section of a GI tract;

- Figure 3 illustrates a surgical system with an endoluminal sleeve and an applier after anchoring the sleeve inside a target section of a GI tract and during distal unfolding the sleeve;

- Figure 4 illustrates a surgical system with an endoluminal sleeve and an applier after deploying the sleeve inside a target section of a GI tract and during withdrawal of the applier;

- Figure 5 is a perspective, partially sectioned view of an endoluminal sleeve 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 2 for internally lining a section of the GI tract, particularly a section of duodenum distally from the pylorus, has 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, and a tubular anchoring collar 8 formed at the proximal sleeve end 4 and having an external anchoring surface 9 with an adhesive layer 11.

Thanks to the adhesive layer 11, the anchoring collar 8 can be glued to the surrounding wall of the GI tract, e.g. to a gastric wall 12 or duodenal wall, and the glued connection reliably seals the proximal sleeve end 4 with respect to the tissue.

In accordance with an aspect of the invention (Figure 5), the anchoring collar 8

forms an inflatable chamber 13 and an insufflating port 14 adapted to detachably couple with an insufflating nozzle 15 of an applier 17. The insufflating port 14 may further comprise a stop valve 18 which is adapted to seal the insufflating port 14 after detachment of the insufflating nozzle 15.

Hence, by inflating the inflatable chamber 13 the anchoring collar 8 can be expanded until the anchoring surface 9 with the adhesive layer 11 is pressed against the surrounding gastrointestinal wall, so that the adhesive glues the sleeve 2 in its planned position.

In accordance with an embodiment (Figures 2, 5), the inflatable chamber 13 forms an annular space which extends inside a tubular wall of the anchoring collar 8 circumferentially around the proximal sleeve end 4 and the insufflating port 14 is preferably arranged at a radially internal side of the tubular wall inside the sleeve lumen 3, thereby avoiding any risk of trauma to the tissue of the GI tract during manipulation, e.g. coupling and detaching of the insufflating port 14 and nozzle 15.

In accordance with a further aspect of the invention (Figures 1, 2), there is provided a surgical system 1 for internally lining a section of the GI tract, particularly of the duodenum, the system 1 comprising the sleeve 2 and an applier 17 which can be coupled to an endoscope 19 and which forms a sleeve seat 20 adapted to receive the sleeve 2 in a compacted configuration, and an insufflating device with an insufflating nozzle 15 arranged in the sleeve seat 20 and adapted to inflate the anchoring collar 8, thereby expanding the external anchoring surface 9 with the adhesive layer 11.

The insufflating nozzle 15 of the applier 17 can be connected or connectable by an insufflating line 28 to an extracorporeal insufflating pump (not illustrated) and the applier 17 carrying the sleeve 2 can be endoluminally introduced together with the endoscope 19 and, after positioning of the applier 17 in the planned anchoring location, the insufflating nozzle 15 can inject an insufflating fluid, e.g. saline solution or CO_2, in the anchoring collar 8 of the sleeve 2 to inflate it and to press the external anchoring surface 9 with the adhesive layer 11 against the surrounding tissue, e.g. a gastric wall 12 or duodenal wall.

In accordance with a further aspect of the invention, the sleeve seat 20 comprises a male surface 21 over which the sleeve 2 can be inserted, and retaining means, e.g. an annular retaining groove 22, adapted to receive a portion of the anchoring collar 8 and retain it in the sleeve seat 20 during inflation of the anchoring collar 8.

Thanks to the retaining means, the anchoring position of the sleeve 2 can be controlled, maintained and adjusted by means of the applier 17 also during expansion of the glued anchoring collar 8 and during setting of the adhesive.

In accordance with an embodiment (Figures 1, 2) the male surface 21 of the sleeve seat 20 is formed by a radially external surface of a tubular, preferably cylindrical, wall section of an applier head 23 and the retaining means comprise an annular flange 24 which protrudes outward from the male surface 21 and which has a retaining edge 25 bent towards the male surface 21, thereby forming an annular retaining groove 22 between the retaining edge 25 and the male surface 21 adapted to receive and retain the portion of the anchoring collar 8.

In accordance with a further embodiment, the retaining edge 25 may be formed by an elastic clip or by a plurality of elastic clips adapted to elastically pressing the portion of the anchoring collar 8 against the male surface 21 of sleeve seat 20.

In accordance with a yet further aspect of the invention (Figure 1), the sleeve seat 21 is configured to receive the sleeve 2 in such a position and shape that an internal surface 26 of the anchoring collar 8 defines together with a sealing surface of the sleeve seat 21 a temporary insufflating space 27 and wherein the insufflating nozzle 15 extends into the temporary insufflating space 27. This allows the anchoring collar 8 to be inflated and, hence, expanded, without any need to create a dedicated inflation chamber in the sleeve 2 itself.

In an exemplary embodiment, the temporary insufflating space 27 can be sealed from an external environment, e.g. by the above described retaining means, in a distal circumferential clamping line distally to the anchoring surface 9 and in a proximal circumferential clamping line proximal to the anchoring surface 9 along which distal and proximal clamping lines the sleeve 2 is clamped against the sleeve seat 20.

In accordance with a yet further aspect of the invention (Figure 3), the anchoring collar 8 of the sleeve 2 forms a permanent inflatable chamber 13 with an insufflating port 14 and the insufflating nozzle 15 of the applier 17 is adapted to detachably couple with the insufflating port to expand the anchoring collar 8 by injecting an insufflating fluid in the inflatable chamber 13. In this embodiment, the inflated anchoring collar 8 will remain permanently inflated also after deployment and withdrawal of the applier 17, thereby further improving anchoring and sealing of the sleeve 2 within the GI tract.

In accordance with a yet further aspect of the invention a method is provided for internally lining a section of a GI tract, particularly a section of a duodenum in a human subject, the method comprising providing a 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, and a tubular anchoring collar 8 formed at the proximal sleeve end 4 and having an external anchoring surface 9 with an adhesive layer 11, introducing the sleeve 2 in a target section of the GI tract, pressing the anchoring collar 8 with the adhesive layer 11 against a wall of the GI tract by inflating the anchoring collar 8.

In accordance with an embodiment, the anchoring collar 8 may be inflated by creating a temporary insufflating space 27 by retaining a portion of the anchoring collar 8 in sealing contact with a sleeve seat 20 of an applier 17 and injecting an insufflating fluid inside the temporary insufflating space 27.

In accordance with a further embodiment, the anchoring collar 8 may be inflated by detachably coupling an insufflating nozzle 15 with an insufflating port 14 of a permanent inflatable chamber 13 formed inside a wall of the anchoring portion 8 and injecting an insufflating fluid by means of the insufflating nozzle 15 through the insufflating port 14 into the permanent inflatable chamber 13, and then detaching the insufflating nozzle 15 from the insufflating port 14.

After anchoring, the sleeve 2 may be distally extended or rolled out, e.g. under endoscopic assistance or by means of a ballast weight (not shown) fastened at the distal end 6 of the sleeve 2.

In accordance with embodiments of the invention, the adhesive layer 11 may comprise surgical glue selected in the group consisting of fibrin sealants, cyanoacrylates, collagen-based compounds, glutaraldehyde glues and hydrogels.

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 (2) for internally lining a section of a GI tract, comprising a wall 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), and a tubular anchoring collar (8) formed at the proximal sleeve end (4) and having an external anchoring surface (9) with an adhesive layer (11).

2. Endoluminal sleeve (2) according to claim 1, wherein the anchoring collar (8) forms an inflatable chamber (13) with an insufflating port (14) adapted to detachably couple with an insufflating nozzle (15) of an applier (17).

3. Endoluminal sleeve (2) according to claim 2, wherein the insufflating port (14) comprises a stop valve (18) adapted to seal the insufflating port (14) when not coupled with an insufflating nozzle (15).

4. Endoluminal sleeve (2) according to claim 2 or 3, wherein the inflatable chamber (13) forms an annular space which extends inside a tubular wall of the anchoring collar (8) circumferentially around the proximal sleeve end (4) and the insufflating port (14) is arranged at a radially internal side of the tubular wall inside the sleeve lumen (3).

5. Surgical system (1) for internally lining a section of the GI tract, the system (1) comprising:

- a sleeve (2) with a wall 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), and a tubular anchoring collar (8) formed at the proximal sleeve end (4) and having an external anchoring surface (9) with an adhesive layer (11),
- an applier (17) forming a sleeve seat (20) adapted to receive the sleeve (2) in a compacted configuration, and an insufflating device with an insufflating nozzle (15) arranged in the sleeve seat (20) and adapted to inflate the anchoring collar (8), thereby expanding the external anchoring surface (9) with the adhesive layer (11).

6. Surgical system (1) according to claim 5, wherein the sleeve seat (20) comprises a male surface (21) over which the sleeve (2) can be inserted, and retaining means adapted to receive a portion of the anchoring collar (8) of the sleeve (2) and retain said portion of the anchoring collar (8) in the sleeve seat (20) during inflation of the anchoring collar (8).

7. Surgical system (1) according to claim 6, wherein the retaining means comprise

an annular retaining groove (22) formed between a retaining edge (25) and the male surface (21).

8. Surgical system (1) according to claim 6, wherein the retaining means comprise at least one elastic clip adapted to elastically pressing the portion of the anchoring collar (8) against the male surface (21) of sleeve seat (20).

9. Surgical system (1) according to claim 5, wherein the sleeve seat (21) receives the sleeve (2) in such a position and shape that an internal surface (26) of the anchoring collar (8) defines together with a sealing surface of the sleeve seat (21) a temporary insufflating space (27), wherein said insufflating nozzle (15) extends into said temporary insufflating space (27).

10. Surgical system (1) according to claim 9, in which the temporary insufflating space (27) is sealed from an external environment in a distal circumferential clamping line distally to the anchoring surface (9) and in a proximal circumferential clamping line proximal to the anchoring surface (9) along which distal and proximal clamping lines the sleeve (2) is clamped against the sleeve seat (20).

11. Surgical system (1) according to claim 5, in which the anchoring collar (8) of the sleeve (2) forms a permanent inflatable chamber (13) with an insufflating port (14) and the insufflating nozzle (15) of the applier (17) is adapted to detachably couple with the insufflating port to expand the anchoring collar (8) by injecting an insufflating fluid in the inflatable chamber (13).

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

- providing a sleeve (2) having a wall 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), and a tubular anchoring collar (8) formed at the proximal sleeve end (4),
- applying an adhesive layer (11) on the anchoring collar (8),
- introducing the sleeve (2) in a target section of the GI tract,
- pressing the anchoring collar (8) with the adhesive layer (11) against a wall of the GI tract by inflating the anchoring collar (8).

13. Method according to claim 12, in which the step of inflating the anchoring collar (8) comprises:

- creating a temporary insufflating space (27) by retaining a portion of the anchoring collar (8) in sealing contact with a sleeve seat (20) of an applier (17), and

- injecting an insufflating fluid inside the temporary insufflating space (27).

14. Method according to claim 12, in which the step of inflating the anchoring collar (8) comprises:

- detachably coupling an insufflating nozzle (15) with an insufflating port (14) of a permanent inflatable chamber (13) formed inside a wall of the anchoring portion (8), and

- injecting an insufflating fluid by means of the insufflating nozzle (15) through the insufflating port (14) into the permanent inflatable chamber (13), and

- after injecting the insufflating fluid, detaching the insufflating nozzle (15) from the insufflating port (14).

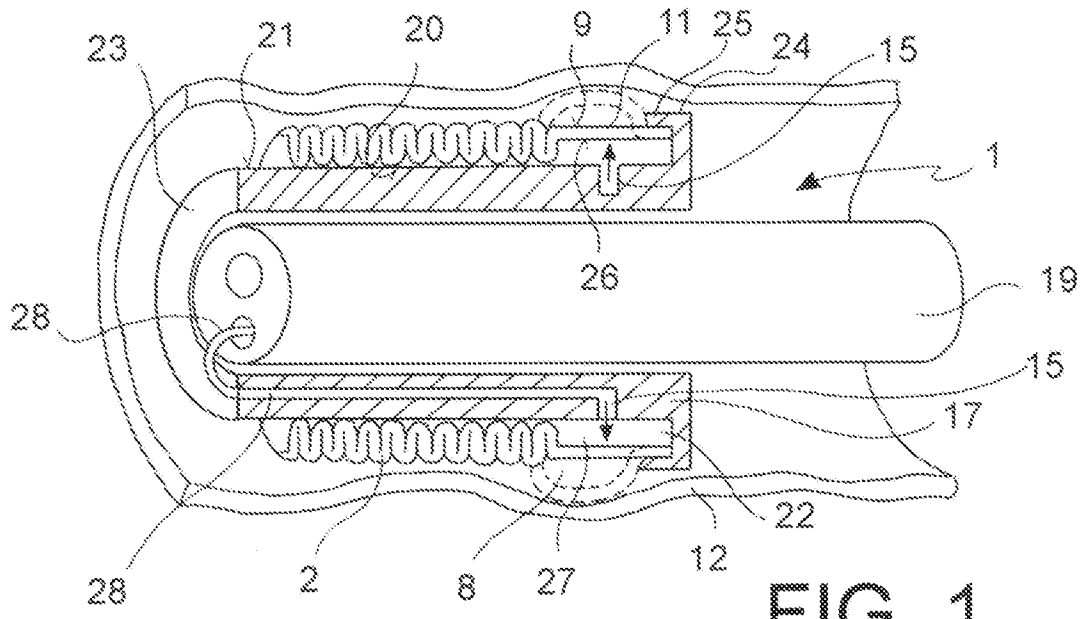

FIG. 1

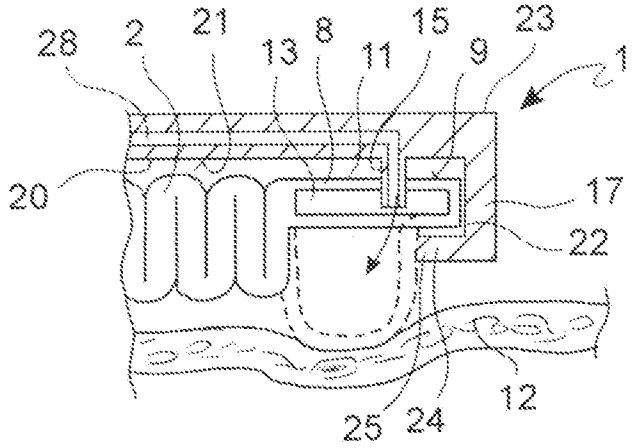

FIG. 2

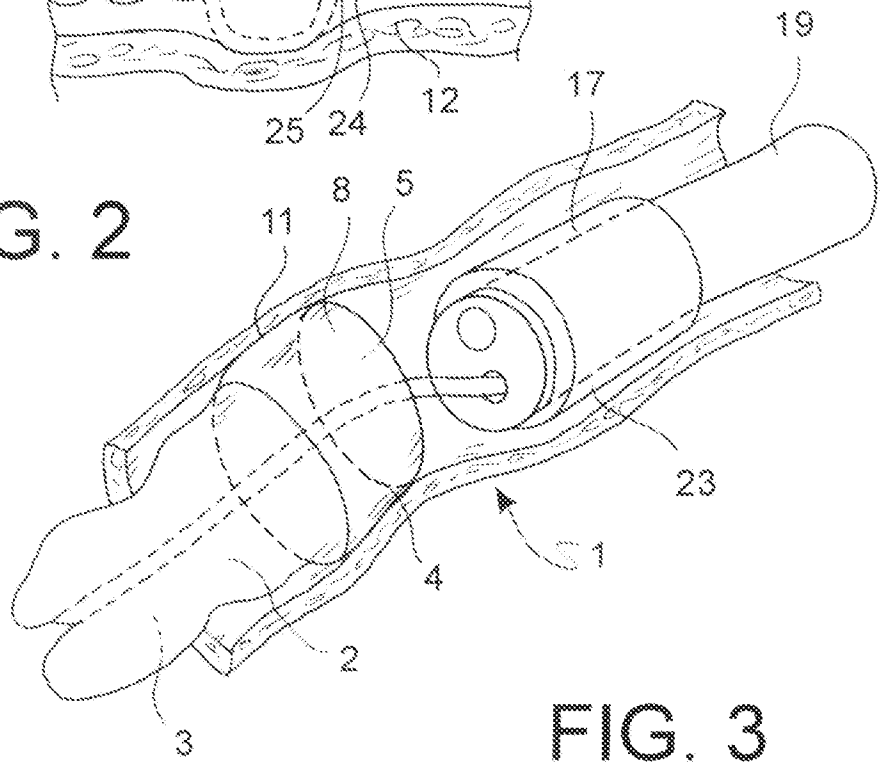

FIG. 3

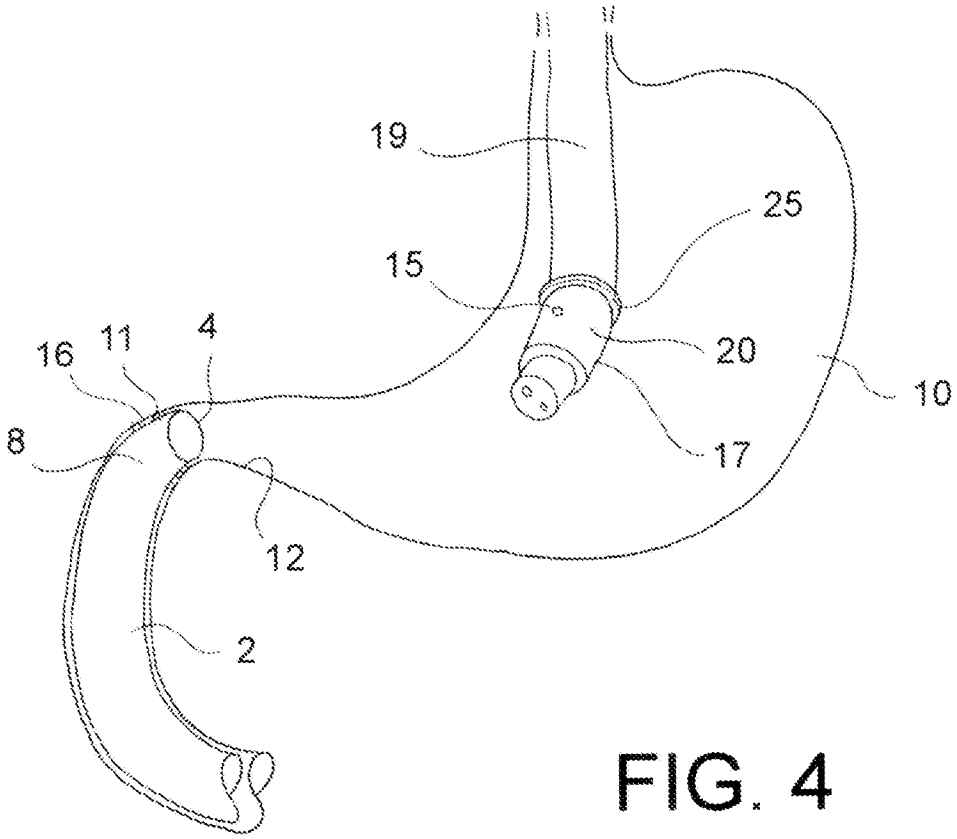

FIG. 4

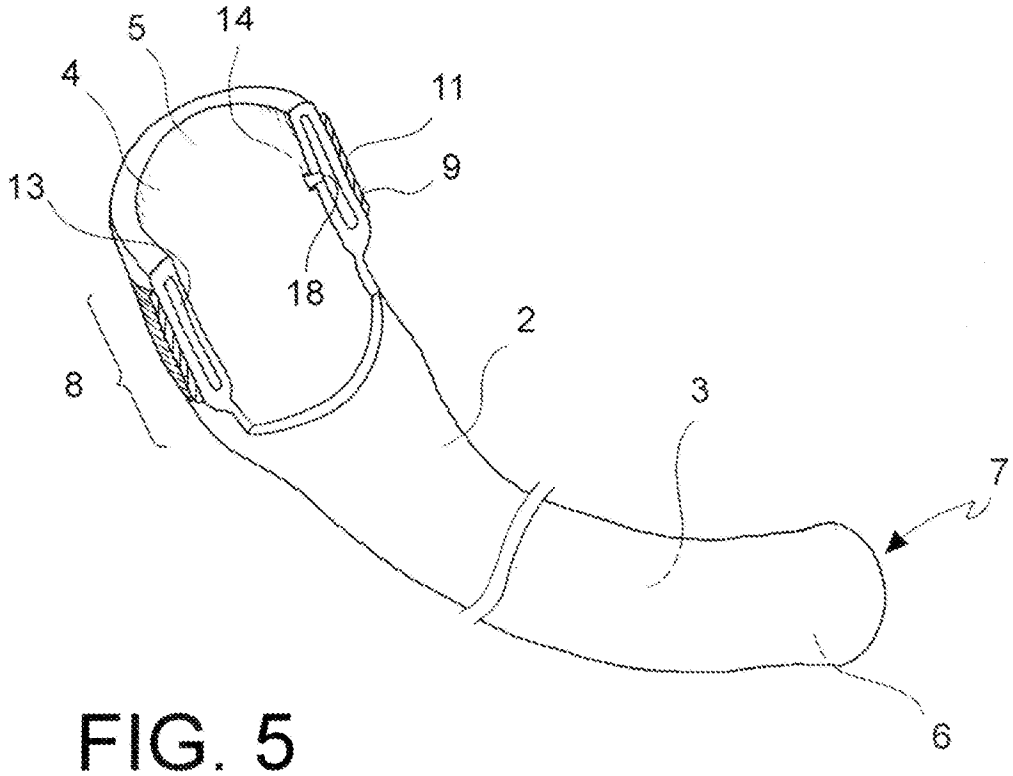

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/063946

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/00 A61F2/04
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/273060 A1 (LEVY MICHALE J [US] ET AL LEVY MICHAEL J [US] ET AL) 8 December 2005 (2005-12-08) paragraphs [0128], [0133], [0187], [0188], [0195], [0206]; figures 10,24	1-4
X	US 2004/172141 A1 (STACK RICHARD S [US] ET AL) 2 September 2004 (2004-09-02)	1-4
A	paragraphs [0063], [0078], [0094]; figures 15,16	5-11
X	WO 2004/080336 A2 (SYNECOR LLC [US]) 23 September 2004 (2004-09-23) page 6, lines 4-10; figures 10-12 page 11, lines 6-27	1-4

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
15 March 2012	30/03/2012

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	Grieb, Christian

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/063946

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 2004/148034 A1 (KAGAN JONATHAN [US] ET AL) 29 July 2004 (2004-07-29) cited in the application paragraphs [0136], [0158], [0167], [0183]; figure 5A	1-4
X	WO 2005/097012 A2 (SATIETY INC [US]) 20 October 2005 (2005-10-20) pages 8,9; figure 2 page 13, paragraph 3	1
X	US 2008/255678 A1 (CULLY EDWARD H [US] ET AL) 16 October 2008 (2008-10-16)	1
A	figure 1A	5-11

INTERNATIONAL SEARCH REPORT

Information on patent family members

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