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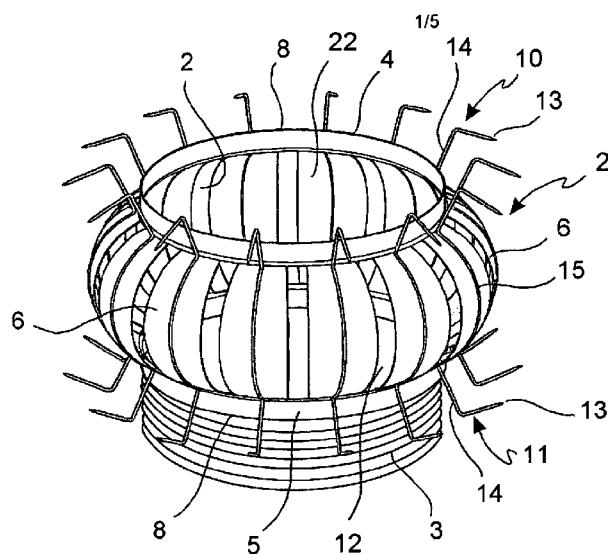


FIG. 1

(57) Abstract: An anchoring device (2) for fastening a flexible tubular lining (3) in the hollow organ includes a proximal compression ring (4), a distal compression ring (5) and elastic bridge elements (6) permanently biasing the proximal and distal compression rings (4, 5) against each other in a closed shape.



**"AN ENDOLUMINAL LINING SYSTEM AND A METHOD FOR
ENDOLUMINALLY LINING A HOLLOW ORGAN"**

DESCRIPTION

FIELD OF THE INVENTION

5 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

10 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
15 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.

20 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
25 obese or moderately obese with few, if any, interventional options.

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

be possible to purposefully influence the mechanism of hormonal signal activation originating from the intestine.

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

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

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

However, the known methods and devices for placing and securing endoluminal linings within hollow organs, particularly within the gastrointestinal tract, are not yet satisfactory with regard to a safe and reliable introduction, positioning and anchoring of the sleeve and with regard to the conservation of its planned position. Moreover, the known devices and methods do not sufficiently address the needs and specific problems arising in case of removal, substitution or relocation of endoluminal sleeves.

Moreover, the known devices and methods do not sufficiently address the need of a good visual control and verification of the correct target site for anchoring the endoluminal sleeves.

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

SUMMARY OF THE INVENTION

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

procedure can be performed entirely from within the patient's stomach or other intestinal tract, and does not necessarily require any external incision.

- At least part of the above identified needs are met by an endoluminal lining system for internally lining a hollow organ, particularly a section of the gastrointestinal tract,
- 5 the system comprising an anchoring device for fastening a flexible tubular lining in the hollow organ, the anchoring device comprising a distal compression ring and a proximal compression ring and at least one elastic bridge element connecting said distal ring to said proximal ring and permanently biasing the distal and proximal rings against each other in an activated shape adapted to clamp a tissue portion of
- 10 the hollow organ, wherein the anchoring device can be held, against an elastic preload of the bridge element, in a rest shape in which the proximal and distal compression rings are located at a distance to each other adapted to acquire said tissue portion therebetween and, upon releasing the anchoring device, the proximal and distal compression rings snap elastically in the activated shape.
- 15 The anchoring device can be held in the rest shape during endoluminal introduction into a target section of the GI tract and then released to elastically snap in the activated shape and clamp an annular tissue portion of the target section to which the tubular lining is intended to be fastened.

- In accordance with an aspect of the invention, in the activated shape, the bridge element protrudes radially inward with respect to the proximal and distal
- 20 compression rings and a radially outward displacement or deformation of the bridge element moves the proximal and distal compression rings from the activated shape to a spread apart rest shape which is adapted to release a previously clamped tissue portion.

- 25 This makes it possible to comfortably remove the anchoring device and the attached lining from the hollow organ or to relocate the lining within the hollow organ, e.g. the GI tract, in accordance with a therapy plan. This provides a high flexibility of therapy with regard to the selection and modification of the regions in which the contact between the food flow and the GI tract is prevented.

- 30 In accordance with a yet further aspect of the invention, the anchoring device comprises a proximal group of needles arranged at the proximal compression ring and a distal group of needles arranged at the distal compression ring, the distal and proximal needles having a shape adapted to pierce a surrounding tissue portion and to drag the pierced tissue portion into a clamping space between the

proximal and distal compression rings during the movement of the anchoring device from the rest shape to the activated shape.

Thanks to the tissue acquisition by means of the needles during reverting from the open shape to the closed shape of the anchoring device, the need of additional tissue acquisition devices and procedures is obviated.

In accordance with an aspect of the invention, the system comprises at least one flexible tubular lining extending between a proximal end and a distal end, the lining being connected to the coupling portion near one of the proximal end and distal end.

10 In accordance with a further aspect of the invention, the lining system comprises an endoluminal applier having a flexible insertion shaft and a distal ring fastening assembly, the ring fastening assembly comprising a ring spreader insertable into the anchoring device and adapted to engage the at least one bridge element from inside the anchoring device and movable between a radially expanded position in which the ring spreader captively connects the anchoring device to the ring fastening assembly while keeping the anchoring device in the open shape and a radially retracted position in which the ring spreader allows the anchoring device to snap in the closed shape and to be removed from the ring fastening assembly.

20 The applier can be used to endoluminally deploy the anchoring device of the lining system and also for endoluminally removing the anchoring device from the hollow organ.

In accordance with a further aspect of the invention, the endoluminal applier forms a central channel extending longitudinally through the ring fastening assembly the central channel being adapted for the passage of an endoscope to visualize the space distally ahead of the ring fastening assembly and, possibly, to slide the applier endoluminally along said endoscope to a target site in the hollow organ.

25 The applier allows an improved guidance through the GI tract and continuous visualization by the endoscope received in the central channel, both during endoluminal insertion and withdrawal of the applier and during inspection of the applied anchoring device or of the target site from which the anchoring device has been removed.

30 In accordance with a yet further aspect of the invention, the ring spreader is elastically deformable from the radially expanded position to the radially retracted position and, possibly permanently elastically biased in the retracted position, and

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the ring fastening assembly comprises a substantially rigid locking portion slidably coupled with the ring spreader and movable from a locking position in which the locking portion rigidly locks the ring spreader in the expanded position and a release position in which the ring spreader can move in the retracted position.

- 5 In accordance with a yet further aspect of the invention, the ring fastening assembly of the endoluminal applier forms a lining seat which is adapted to receive the tubular lining in a longitudinally compacted (substantially annulus) shape with regard to a lining longitudinal extension.

This assures a correct relative positioning of the anchoring device and the tubular lining during endoluminally transportation and during snap fastening of the anchoring device to the hollow organ, obviating the risk of damaging or entangling the lining during these operations.

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

DESCRIPTION OF THE DRAWINGS

- Figure 1 illustrates an endoluminal lining system with an anchoring device in a open shape according to an embodiment of the invention;
- Figure 2 is a partial perspective view of a ring fastening assembly of an applier carrying the anchoring device of figure 1;
- Figure 3 is a partial perspective view of the applier of figure 2 with a protective housing in accordance with an embodiment;
- Figure 4 illustrates a longitudinal cross-section of the endoluminal applier carrying the anchoring device in accordance with an embodiment;
- Figures 5 and 6 are longitudinal cross-sections of the applier and of the anchoring device, illustrating the fixation of the anchoring device to a section of the GI tract;
- Figures 7 to 9 illustrate method steps of an endoluminal deployment of the lining system in a target location in the GI tract;
- Figure 10 illustrates different possible positions of the tubular lining within the GI tract of a patient;

DETAILED DESCRIPTION OF EMBODIMENTS

Referring to the drawings where like numerals denote like anatomical structures

and components throughout the several views, figures 1 to 6 depict an endoluminal lining system for internally lining a hollow organ, particularly a section of the gastrointestinal tract 1. The system comprises an anchoring device 2 for fastening a flexible tubular lining 3 in the hollow organ. The anchoring device 2 includes a proximal compression ring 4, a distal compression ring 5 and at least one, preferably a plurality of elastic bridge elements 6 which connect the proximal compression ring 4 to the distal compression ring 5 and constitute a spring structure which permanently biases the distal and proximal rings 4, 5 against each other in a closed shape (Figure 6) adapted to clamp a tissue portion 7 of the hollow organ 1. The anchoring device 2 can be held, against an elastic preload of the bridge elements 6, in an open shape (Figure 5) in which the proximal and distal compression rings 4, 5 are located at a distance to each other adapted to acquire the tissue portion 7 therebetween. Upon releasing the anchoring device 2, the spring load of the bridge elements 6 snaps the proximal and distal compression rings 4, 5 elastically back in the closed shape.

The described configuration of the anchoring device 2 makes it possible to hold the latter in the open shape during endoluminal introduction and positioning in a target section of the GI tract and then release the anchoring device so that it snaps elastically in the closed shape, thereby clamping an annular tissue portion of the target section to which the tubular lining 3 is intended to be fastened.

In accordance with an embodiment, in the closed shape, the bridge elements 6 protrude radially inward with respect to the proximal and distal compression rings 4, 5 and a radially outward displacement or deformation of the bridge elements 6 moves the proximal and distal compression rings 4, 5 from the closed shape to the spread apart open shape which is adapted to detach the anchoring device 2 from a previously clamped tissue portion 7.

In the open shape, the anchoring device 2 and the attached lining 3 can be removed from the hollow organ or relocated within the hollow organ, e.g. the GI tract, in accordance with a therapy plan. This provides a high flexibility of therapy with regard to the selection and modification of the regions in which the contact between the food flow and the GI tract is prevented.

In accordance with an embodiment, the proximal and distal compression rings 4, 5 have a substantially circular shape and opposed annular tissue compression surfaces 8 adapted to clamp a ring shaped tissue portion of the hollow organ

along a substantially continuous line along which the tubular lining 3 is sealed to the hollow organ. The bridge elements 6 may be formed as a single piece with the compression rings 4, 5 and may comprise (initially) arch-shaped spring bands which, in the closed shape, extend radially inside the compression rings 4, 5 and have a convex internal side and a concave external side. The concave external sides of the bridge elements 6 in the closed shape form a circumferential cavity 9 adapted to receive a ring shaped tissue portion clamped by the compression rings 4, 5. When the anchoring device 2 is deformed in the open shape, the arch-shaped spring bands of the bridge elements 6 are bent radially outward with respect to the compression rings 4, 5 and define an arch with a concave internal side and a convex external side.

In accordance with an exemplary embodiment, the anchoring device 2 may comprise a proximal group of needles 10 arranged at the proximal compression ring 4 and a distal group of needles 11 arranged at the distal compression ring 5. The proximal and distal needles 10, 11 have a shape adapted to pierce a surrounding tissue portion and to drag the pierced tissue portion, during the movement from the open shape to the closed shape, into the circumferential cavity 9 and a clamping space between the proximal and distal compression rings 4, 5. Hence, during snap reverting of the anchoring device 2 from the open position to the closed position, the proximal and distal needles 10, 11 automatically acquire the tissue portion intended to be clamped, thereby obviating the need of additional tissue acquisition devices and procedures.

Alternatively, dedicated tissue acquisition means, such as grasping means or suction means may act on the surrounding tissue from inside the anchoring device 2 through free spaces or slots 12 formed between adjacent bridge elements 6 and attract and hold the acquired tissue against the bridge elements 6 while the anchoring device 2 reverts to the closed shape.

The needles 10, 11 may be generally hook shaped and have pointed ends oriented in a manner to move towards each other during the movement from the open shape to the closed shape. In accordance with an embodiment, in the open shape the free pointed ends 13 of the proximal needles 10 are oriented radially outward and inclined distally (i.e. towards the distal compression ring 5) and the free pointed ends 13 of the distal needles 11 are oriented radially outward and inclined proximally (i.e. towards the proximal compression ring 4). The pointed ends 13 of

the needles 10, 11 are preferably inclined by 5° to 45°, preferably by 10° to 30° with respect to a plane perpendicular to a longitudinal axis of the anchoring device 2.

More specifically, the proximal needles 10 may have a base portion 14 extending radially outward and inclined proximally and the pointed end 13 extending radially outward and inclined distally. Analogously, the distal needles 11 may have a base portion 14 extending radially outward and inclined distally and the pointed end 13 extending radially outward and inclined proximally. Both the base portion 14 and the pointed end 13 of the needles 10, 12 may be straight and form an angle therebetween.

Pairs of respectively a proximal needle 10 and an opposite distal needle 11 may be connected by a common bridge section 15 to form a single piece needle unit. The single piece needle unit is fixated to the anchoring device by the common bridge section 15 extending along and connected to a respective bridge element 6 (Figure 1).

The flexible tubular lining 3 extends between a proximal end 16 and a distal end 17 and is connected to the coupling portion 2 near one of the proximal end 16 and distal end 17.

In accordance with an embodiment, the lining 3 may be connected to one of the proximal and distal compression rings 4, 5. This assures a leak-tight connection of the lining 3 with the hollow organ, since the compression rings engage the hollow organ along a continuous clamping line.

The lining 3 and the anchoring device 2 may be connected to each other permanently or detachably in order to allow the lining 3 to be replaced and the anchoring device 2 to be re-used.

In order to facilitate the endoluminal introduction and anchoring of the lining 3, the anchoring device 2 may form a lining seat 18 adapted to receive and hold the tubular lining 3 in a packed (substantially ring shaped), e.g. wrapped, folded, compressed or rolled up, configuration with regard to a lining longitudinal extension. In accordance with an embodiment, the lining seat 18 may be adapted to hold the lining 3 in the packed configuration when the anchoring device 2 is in the open shape and to release the lining 3 and, possibly push at least a portion of the lining 3 distally out of the lining seat 18, when the anchoring device 2 snaps in the closed shape.

The lining system may further comprise an endoluminal applier 19 for fastening the anchoring device 2 with the lining 3 to the hollow organ, particularly to a section of the GI tract of a patient. The applier 19 has a flexible insertion shaft 31 extending between a proximal handle (not illustrated) and a distal shaft end at which a ring fastening assembly 20 is provided. The ring fastening assembly 20 comprises a ring spreader 21 insertable into a central passage aperture 22 of the anchoring device 2 and adapted to engage the at least one, preferably all bridge elements 6 from inside the anchoring device 2. The ring spreader 21 is movable between a radially expanded position in which it deforms the bridge elements 6 outward, thereby captively connecting the anchoring device 2 to the ring fastening assembly 20 and keeping the anchoring device 2 in the open shape, and a radially retracted position in which the ring spreader 21 allows (the bridge elements 6 to elastically deform inward, thereby allowing) the anchoring device 2 to snap in the closed shape and to be removed from the ring fastening assembly 20.

When the ring spreader 21 is in the expanded position the portions of the ring spreader engaging the bridge elements 6 are captured between the proximal and distal compression rings 4, 5, as the opening defined by the compression rings is smaller than the expanded ring spreader.

The applier 19 can be used for endoluminally deploying and removing the anchoring device 2 of the lining system within the hollow organ.

In accordance with an exemplary embodiment, the ring spreader 21 may be elastically deformable from the radially expanded position to the radially retracted position and vice versa and, possibly permanently elastically biased in the retracted position (which allows insertion of the ring spreader 21 into the anchoring device 2), and the ring fastening assembly 20 comprises a substantially rigid locking portion 25 slidably coupled with the ring spreader 21 and movable from a locking position in which the locking portion 25 rigidly locks the ring spreader 21 in the expanded position and a release position in which the ring spreader 21 is free to move in the retracted position.

The ring fastening assembly 21, particularly the ring spreader 21 may further form a lining seat (not illustrated) which is adapted to receive and hold the tubular lining 3 in a longitudinally compacted (substantially annulus) shape with regard to a lining longitudinal extension and to release the lining 3 when the ring spreader 21 moves in the retracted position and the ring fastening assembly 20 is withdrawn from the

clamped anchoring device 2.

The lining seat assures a correct relative positioning of the anchoring device and the tubular lining during endoluminally transportation and during snap fastening of the anchoring device to the hollow organ, thereby obviating the risk of damaging or entangling the lining during these operations.

In accordance with a preferred embodiment, the endoluminal applier 19 forms a central channel 24 extending longitudinally through the ring fastening assembly 20 and adapted for the passage of an endoscope 23 to visualize the space distally ahead of the ring fastening assembly 20 and, possibly, to slide the applier 19 endoluminally along the endoscope 23 to a target site in the hollow organ 1.

The endoscope 23 received within the central channel 24 allows an improved guidance of the applier 19 through the GI tract and continuous visualization both during endoluminal insertion and withdrawal of the applier and during inspection of the fastened anchoring device 2 or of the target site from which the anchoring device has been removed.

In accordance with the exemplary embodiment illustrated in figures 3 and 4, the ring spreader 21 is housed inside a distally open, substantially tubular, protective housing 26 and can slide distally out of the housing 26 to expose the anchoring device 2 to the surrounding tissue and back into the housing 26 to protect the surrounding tissue from the anchoring device 2, particularly from the needles 10, 11.

The ring spreader 21 may comprise a substantially tubular body defining a longitudinal channel and having a side wall 28 forming a plurality of longitudinally extending elastically flexible spreader fingers 27 arranged circumferentially about the longitudinal channel. Each spreader finger 27 forms a radially outwardly protruding spreader portion 29 near a free distal free end thereof. The spreader portions 29 are adapted to engage the inside of a corresponding bridge element 6 for holding the anchoring device 2 in the open shape. Proximally of the spreader portion 29, at least part of the spreader fingers 27 form a radially outwardly protruding abutment portion 30 which defines together with the spreader portions 29 an annular cavity adapted to captively receive the proximal compression ring 4 of the anchoring device 2. The abutment portions 30 define a distal and face against which the proximal compression ring 4 abuts during the snap movement from the open shape to the closed shape, thereby guiding the snap movement and

stabilizing the ring position.

The locking portion 25 comprises a tube section slidably received inside the longitudinal channel of the ring spreader 21 such that a distal translation of the tube section into the region of the spreader portions 29 pushes the spreader portions 29 outward and a proximal translation of the tube section away from the spreader portions 29 allow the spreader fingers 27 to bend inward. The tubular section itself defines a portion of the central channel 24 for the endoscope 23.

The applier 19 comprises a ring exposing mechanism adapted to move the ring spreader 21 with respect to the protective housing 26 or vice versa. The ring exposing mechanism is connected through one or more flexible exposing movement transmitters with an extracorporeal exposing activation mechanism provided e.g. at a proximal handle portion of the applier 19.

The applier 19 further comprises a lock and release mechanism adapted to move the locking portion 25 with respect to the ring spreader 21. The lock and release mechanism is connected through one or more flexible lock and release movement transmitters with an extracorporeal lock and release activating mechanism provided e.g. at a proximal handle portion of the applier. Both the exposing movement transmitters and the lock and release movement transmitters are arranged inside the flexible shaft 31.

DETAILED DESCRIPTION OF A METHOD FOR ANCHORING AND REMOVING THE TUBULAR LINING WITHIN A HOLLOW ORGAN

A clinical work-up, including a physical and mental assessment of the patient may be performed to determine whether a transoral deployment and anchoring of an endoluminal lining is clinically indicated. This assessment may include inspecting the esophagus and stomach of the patient to determine whether any contraindications exist for undertaking the procedure such as ulcerations, obstructions, or other conditions that may preclude treatment. Once the assessment has been completed, either in an operating room with the patient under general anesthesia, or in an endoscopy suite with the patient under sedation, the operator can prepare the applier 19 with the anchoring device 2 with the attached ling 3 placed over the ring spreader 21, as shown in FIG. 3, and slide the applier 19 over the endoscope 23 to guide it under endoscopic visualization down the patient's esophagus and stomach to a target location in the GI tract, e.g. in the duodenum. Once in place, the physician uses the endoscope 23 placed in

the central channel of the applier 19 to view and select an area suitable for the application of the anchoring device 2.

Once the applier is positioned in the selected anatomical location, the ring spreader is advanced distally out of the protective housing to expose the anchoring device to the surrounding tissue within the duodenum. At this stage tissue acquisition mechanism, either vacuum or mechanical grasping, may be activated through the apertures of the ring spreader or tissue may be drawn into the clamping space through the action of needles 10, 11 in an entirely or partially circumferential manner.

For this purpose and for clamping the anchoring device to the target section of duodenum, the locking portion is moved from the locking position to a release position, allowing the ring spreader to bend to the retracted position and the anchoring device to move slowly or snap from the open shape to the closed shape. During this movement the needles 10, 11 penetrate and acquire the ring shaped tissue portion 7 which is then clamped by the proximal and distal compression rings, thereby fastening the anchoring device 2 in place in a circumferential fashion. Subsequently, the ring shaped anchoring place can be directly endoscopically visualized by passing the endoscope 23 distally through the ring fastening assembly. The tubular lining attached to the anchoring device can be now pulled distally to unfold it from the collapsed configuration to an extended substantially elongate tubular shape configuration. Then, applier 19 is removed.

After a period of time the anchoring device 2 may be removed from the duodenum by endoluminally inserting the applier, inserting the ring spreader into the passage opening of the anchoring device and moving the ring spreader to its expanded position, thereby deforming the bridge elements of the anchoring device outward and opening the anchoring device so that the compression rings and the needles detach from the clamped tissue. In the expanded position the ring spreader captively holds the detached anchoring device which can be now withdrawn into the protective housing of the applier and removed from the body or fastened to a different position in the GI tract.

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

Particularly, the described devices and procedures help to mimic the effects of

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

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

CLAIMS

1. An anchoring device (2) for fastening a flexible tubular lining (3) in the hollow organ, said anchoring device (2) including a proximal compression ring (4), a distal compression ring (5), a plurality of elastic bridge elements (6) extending between
5 the proximal and distal compression rings (4,5) and permanently biasing the proximal and distal compression rings (4, 5) against each other in a closed shape, in which said anchoring device (2) can be held in an open shape in which the proximal and distal compression rings (4, 5) are located at a distance to each other and, upon releasing the anchoring device (2), the spring load of the bridge
10 elements (6) snaps the proximal and distal compression rings (4, 5) back in the closed shape.
2. An anchoring device (2) according to claim 1, wherein, in the closed shape, the bridge elements (6) protrude radially inward with respect to the proximal and distal compression rings (4, 5) and a radially outward deformation of the bridge elements
15 (6) moves the proximal and distal compression rings (4, 5) from the closed shape to the spread apart open shape.
3. An anchoring device (2) according to claim 1 or 2, wherein the proximal and distal compression rings (4, 5) have a substantially circular shape and opposed annular tissue compression surfaces (8) adapted to clamp a ring shaped tissue
20 portion of the hollow organ along a continuous line for sealing said tubular lining (3) to the hollow organ (1).
4. An anchoring device (2) according to any preceding claim, wherein the bridge elements (6) are formed as a single piece with the compression rings (4, 5) and comprise arch-shaped spring bands which, in the closed shape, extend radially
25 inside the compression rings (4, 5) and form a circumferential cavity (9) adapted to receive a ring shaped tissue portion clamped by the compression rings (4, 5).
5. An anchoring device (2) according to any preceding claim, comprising a proximal group of needles (10) arranged at the proximal compression ring (4) and a distal group of needles (11) arranged at the distal compression ring (5) in a
30 manner to pierce a surrounding tissue portion and drag the pierced tissue portion into a clamping space between the proximal and distal compression rings (4, 5) during the movement from the open shape to the closed shape.
6. An anchoring device (2) according to claim 5, wherein the needles (10, 11) are hook shaped and have pointed ends oriented in a manner to move towards each

other during the movement from the open shape to the closed shape.

7. An anchoring device (2) according to claim 5 or 6, wherein, in the open shape, free pointed ends (13) of the proximal needles (10) are oriented radially outward and inclined distally and free pointed ends (13) of the distal needles (11) are oriented radially outward and inclined proximally.

8. An anchoring device (2) according to any of claims 5 to 7, wherein the proximal needles (10) have a base portion (14) extending radially outward and inclined proximally and a pointed end (13) extending radially outward and inclined distally, and the distal needles (11) have a base portion (14) extending radially outward and inclined distally and a pointed end (13) extending radially outward and inclined proximally.

9. An anchoring device (2) according to any of claims 5 to 8, wherein pairs of respectively a proximal needle (10) and an opposite distal needle (11) are connected by a common bridge section (15) to form a single piece needle unit, said common bridge section (15) is extended along and connected to a respective bridge element (6).

10. An anchoring device (2) according to any preceding claim, forming a lining seat (18) adapted to hold the lining (3) in a packed configuration when the anchoring device (2) is in the open shape and to release the lining (3) allowing it to unwrap when the anchoring device (2) moves in the closed shape.

11. An endoluminal lining system, comprising the anchoring device (2) according to any preceding claim and a flexible tubular lining (3) connected to one of the proximal and distal compression rings (4, 5).

12. An endoluminal applier (19) for deploying an anchoring device (2) according to any preceding claim, the applier (19) comprising a flexible insertion shaft (31) and a ring fastening assembly (20) with a ring spreader (21) insertable into a central passage aperture (22) of the anchoring device (2) and adapted to engage the bridge elements (6) from inside the anchoring device (2), wherein said ring spreader (21) is movable between a radially expanded position in which it deforms the bridge elements (6) outward, thereby captively connecting the anchoring device (2) to the ring fastening assembly (20) and keeping the anchoring device (2) in the open shape, and a radially retracted position allowing the anchoring device (2) to snap in the closed shape and to be removed from the ring fastening assembly (20).

13. Endoluminal applier (19) according to claim 12, forming a central channel (24)

extending longitudinally through the ring fastening assembly (20) and adapted for the passage of an endoscope (23) to visualize the space distally ahead of the ring fastening assembly (20) and to slide the applier (19) along the endoscope (23).

5 **14.** Endoluminal applier (19) according to claim 12 or 13, in which the ring spreader (21) is housed inside a distally open housing (26) and can slide distally out of the housing (26) to expose the anchoring device (2) to the surrounding tissue and back into the housing (26) to protect the surrounding tissue from the anchoring device (2).

10 **15.** Endoluminal applier (19) according to any one of claims 12 to 14, in which the ring spreader (21) comprises a tubular body defining a longitudinal channel and a side wall (28) forming a plurality of longitudinally extending spreader fingers (27), each spreader finger (27) forming a radially outwardly protruding spreader portion (29) adapted to engage the inside of a corresponding bridge element (6) and at least part of the spreader fingers (27) form a radially outwardly protruding abutment
15 portion (30) proximal of the spreader portions (29) and defining together with the spreader portions 29 an annular cavity for captively receiving the proximal compression ring (4).

16. Method for endoluminally anchoring a tubular lining to a hollow organ, comprising:

- 20 - providing an anchoring device (2) having a proximal compression ring (4), a distal compression ring (5) and elastic bridge elements (6) permanently biasing the proximal and distal compression rings (4, 5) against each other in a closed shape;
- connecting the tubular lining to the anchoring device;
- deforming the anchoring device in an open shape in which the compression rings
25 are spaced apart and holding the anchoring device in the open shape on an applier;
- endoluminally inserting the applier with the open shaped anchoring device to a target location of a hollow organ;
- clamping the anchoring device to said target location by releasing the anchoring
30 device from the applier, thereby allowing the anchoring device to snap in the closed shape and clamp a tissue portion of the hollow organ between said proximal and distal ring;
- removing the applier from the body.

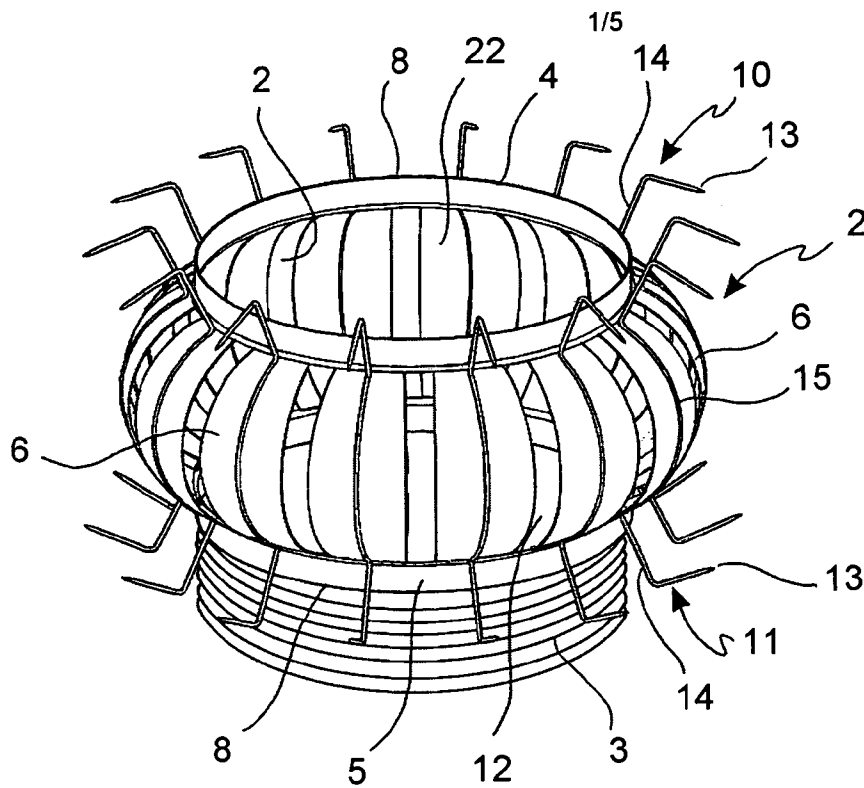
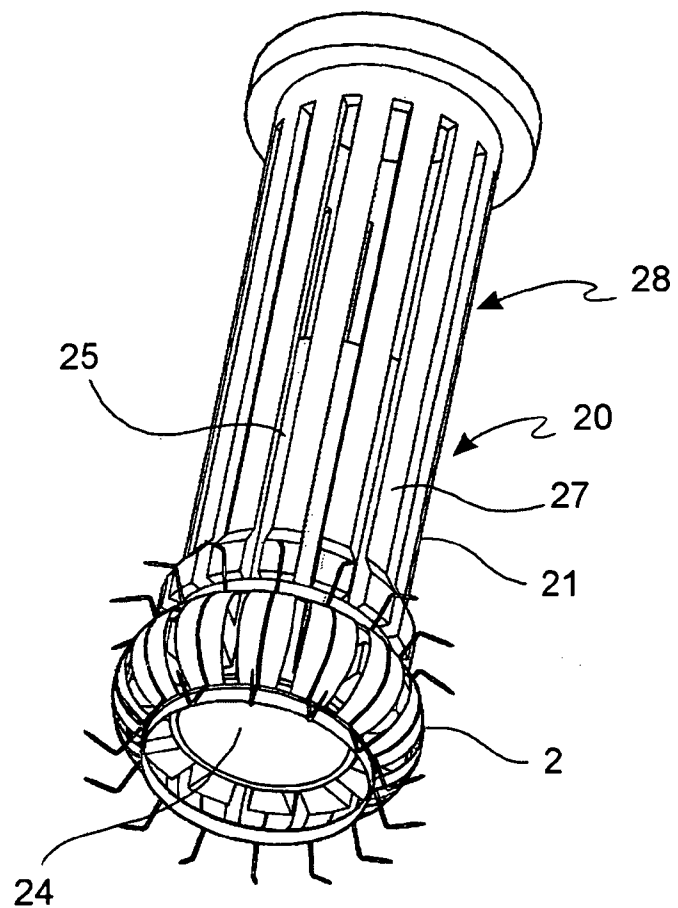


FIG. 1

FIG. 2



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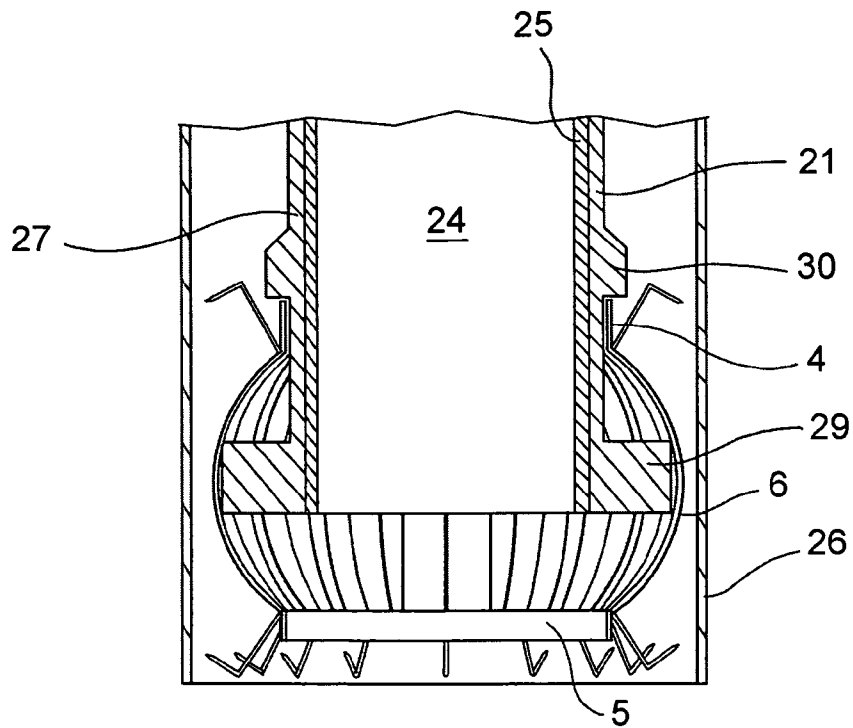
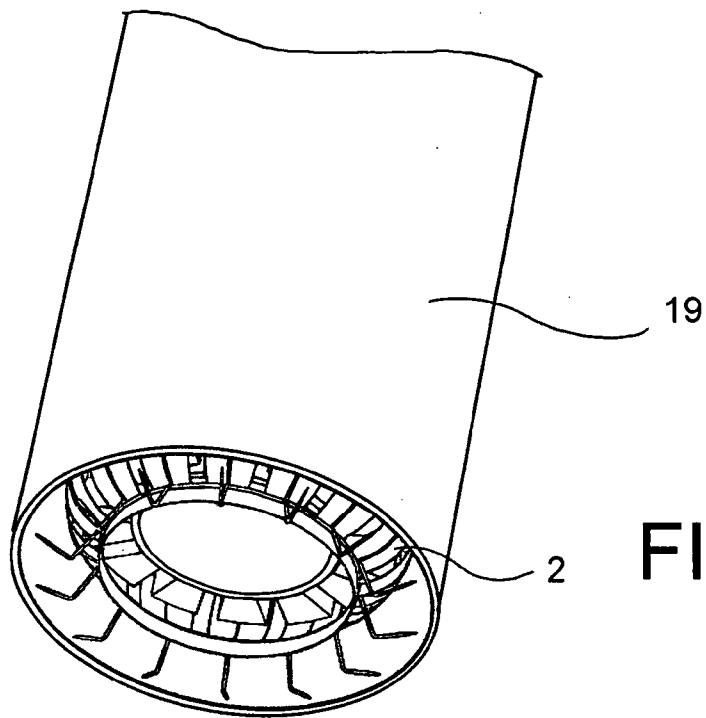


FIG. 4

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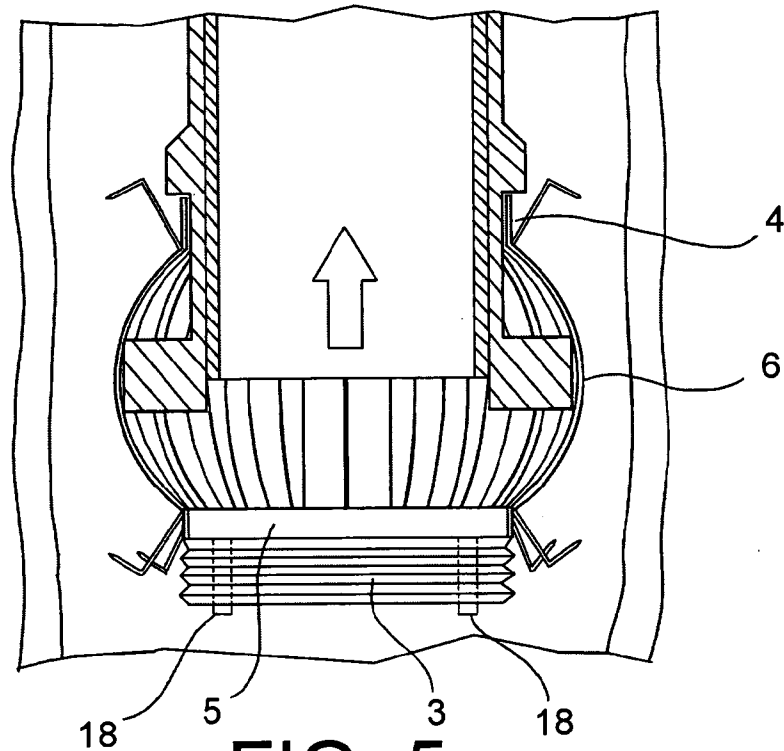


FIG. 5

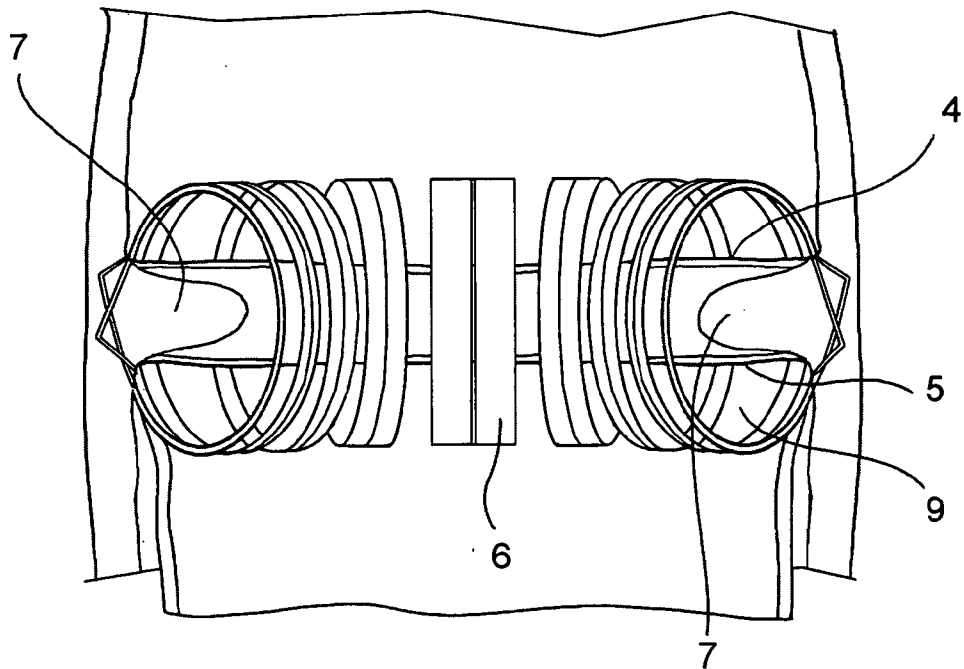


FIG. 6

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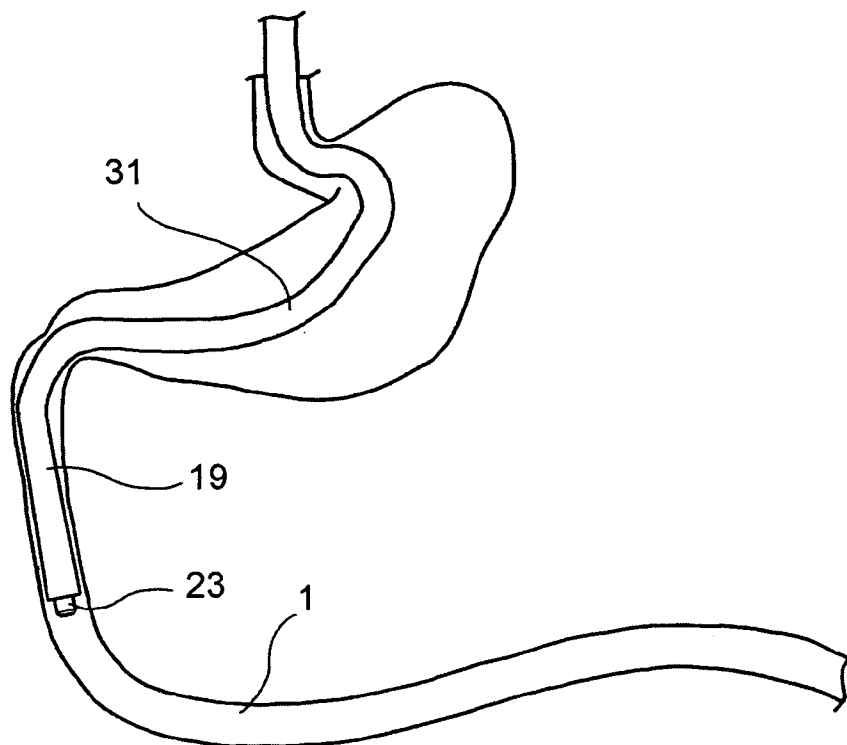
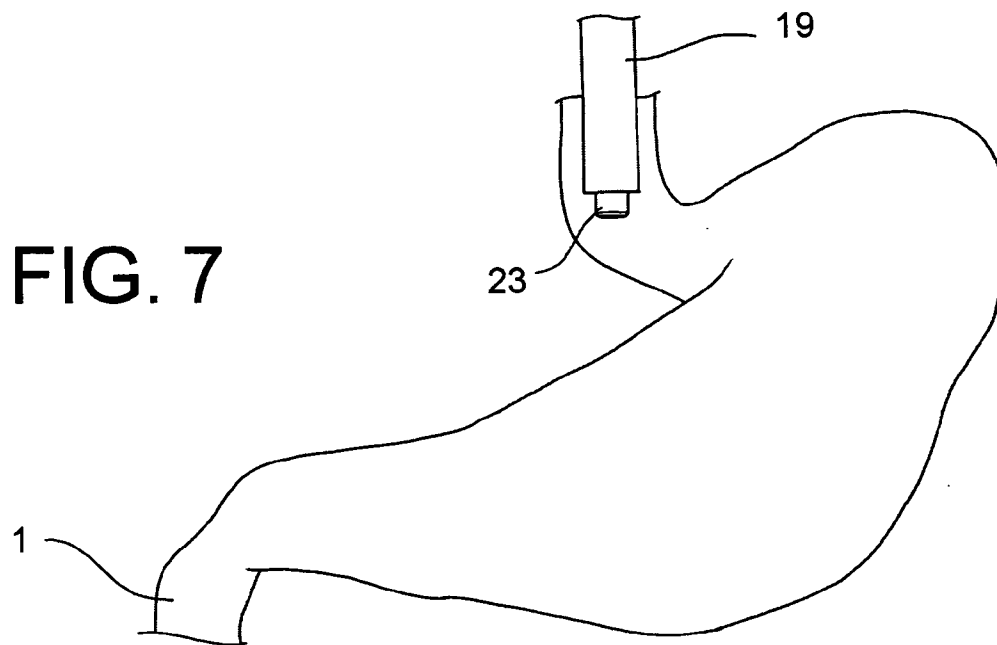


FIG. 8

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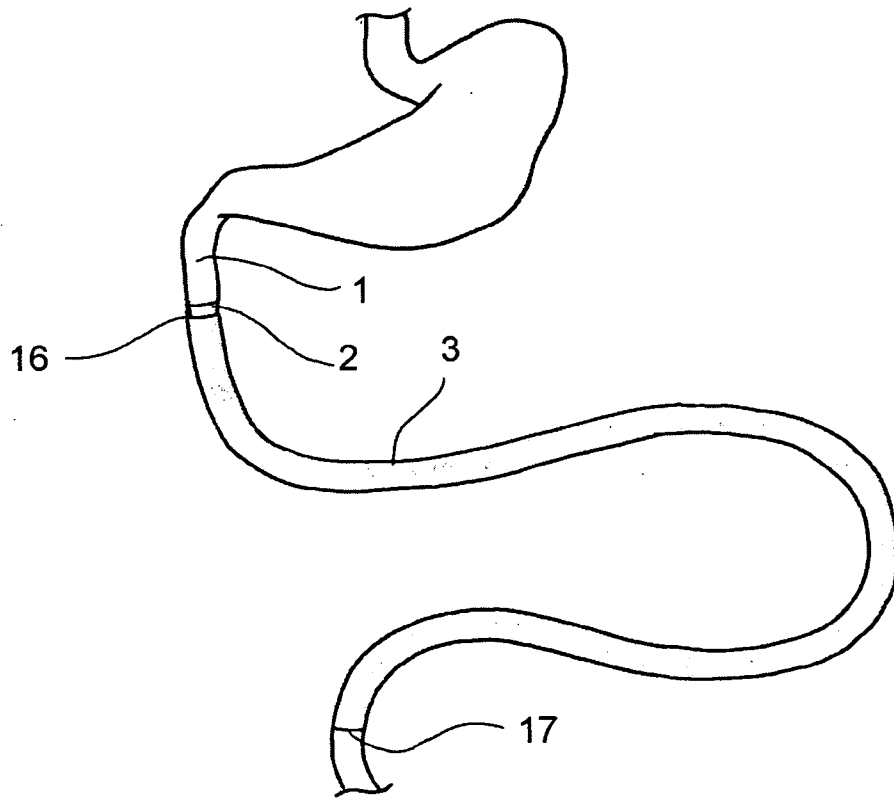


FIG. 9

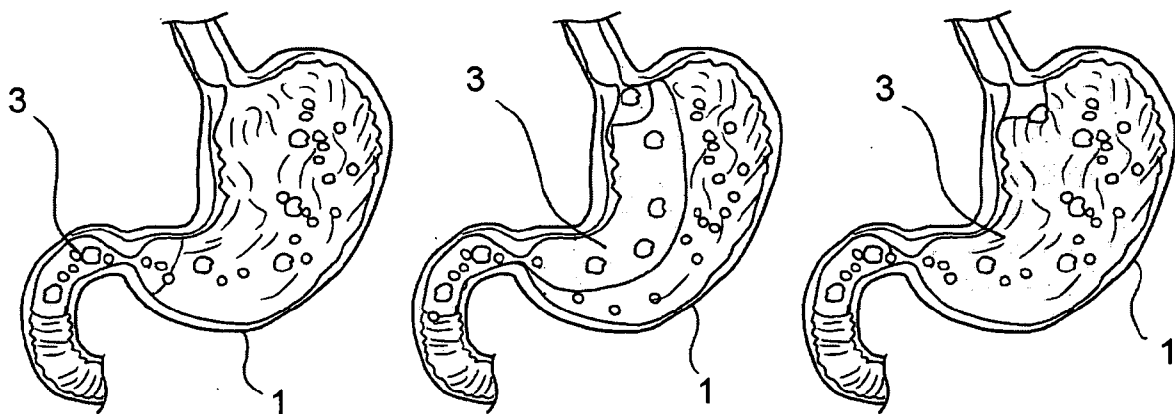


FIG. 10