Abstract: An endoluminal lining system for internally lining a hollow organ (1) comprises a flexible tubular lining (2) and an anchoring device (5) for fastening the lining (2) in the hollow organ (1). The anchoring device (5) comprises an anchoring ring (6) forming a radially external anchoring surface (9), a plurality of barbs (10) arranged in the anchoring surface (9) and operable to protrude from the anchoring surface (9) radially outward and inclined with respect to a radial direction to the longitudinal axis (8) such that, upon rotation of the anchoring ring (6) in a first direction about the longitudinal axis (8), the barbs (10) penetrate into surrounding tissue (11) and acquire said tissue (11) towards the anchoring surface (9). Moreover, locking means are provided to prevent relative rotation between the anchoring ring and the surrounding tissue.

Title: An Endoluminal Lining System and a Method for Endoluminally Lining a Hollow Organ
DESCRIPTION
"AN ENDOLUMINAL LINING SYSTEM AND A METHOD FOR ENDOLUMINALLY LINING A HOLLOW ORGAN"

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 $\geq 40$) due to their complications, including the risk of death, leaving patients who are considered obese or moderately obese with few, if any, interventional options.

In addition to the above described gastrointestinal reduction surgery, endoluminal sleeves are known for partially or totally lining certain portions of the stomach and of the intestine with the aim to separate or bypass at least part of the food flow from the lined portions of the gastrointestinal tract. It has been observed that by creating a physical barrier between the ingested food and certain regions of the gastrointestinal wall by means of endoluminal sleeves, similar benefits for weight loss and improvement or resolution of type 2 diabetes may be achieved as with gastric bypass surgery. Physicians believe that by creating a physical barrier between the ingested food and selected regions of the gastrointestinal wall, it might be possible to purposefully influence the mechanism of hormonal signal activation originating from the intestine.
A known type of endoluminal sleeve relies on metallic expandable structures, such as a stent, to engage the surrounding hollow organ for holding the sleeve in the planned position. To improve anchoring and stability of the sleeve, it is further known to provide the stent with barbs which penetrate the surrounding tissue.

This notwithstanding, it has been observed that the endoscopic sleeves tend to move inside the GI tract and migrate away from their initially planned position. US patent n. 7,220,237 B2, Method and device for use in endoscopic organ procedures, to Gannoe et al. describes procedures for internally lining portions of the gastrointestinal tract, using tubular endoluminal sleeves and stapling devices for circumferentially acquiring tissue of the gastric wall and fixing a circular section of the acquired tissue to which an endoluminal sleeve is secured by shape interference.

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

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

**SUMMARY OF THE INVENTION**

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

At least part of the above identified needs are met by an endoluminal lining system for internally lining a hollow organ, particularly a section of the gastrointestinal tract, the system comprising a flexible tubular lining extending between a proximal end and a distal end and an anchoring device for fastening the flexible tubular lining in the hollow organ. The anchoring device is provided at one of the proximal end and distal end of the lining and comprises an anchoring ring defining a longitudinal ring axis which is an axis of symmetry of the ring, the ring having a radially external anchoring surface and a plurality
of barbs protruding from the anchoring surface. The barbs are inclined with respect to a radial direction to the longitudinal axis such that, upon rotation of the anchoring ring in a first direction about the longitudinal axis, the barbs penetrate into the surrounding tissue and acquire said tissue towards the anchoring surface and, upon rotation of the anchoring ring in a second direction opposite the first direction the barbs are withdrawn from the surrounding tissue. The anchoring device further comprises locking means adapted to prevent the ring from rotating with respect to the surrounding tissue. This allows to simply and reliably fasten the lining within a hollow organ, particularly a section of the GI tract, by endoluminal insertion of the lining system to the anchoring site, exposing of the ring with its anchoring surface and barbs to the surrounding tissue and rotation of the ring until the surrounded tissue is pierced and slid along the barbs towards and against the anchoring surface. After completion of the tissue fastening and acquisition the locking means are activated to prevent the ring from rotating with respect to the acquired tissue, thereby preserving the anchoring configuration of the lining system.

In accordance with an aspect of the invention, the locking means comprise at least one fastener adapted to pierce the acquired tissue or tissue adjacent to the acquired tissue and at least one fastener seat formed in the ring and adapted to receive and hold the fastener so that the fastener extends in a transverse direction to the extension of the barbs, preferably in a direction parallel to the longitudinal ring axis.

Thanks to the transverse orientation of the fastener relative to the barbs, a rotation of the ring with respect to the fastened tissue and, hence, a withdrawal of the barbs from the acquired tissue is effectively prevented.

In accordance with a further aspect of the invention, the locking means comprise at least one suture hole formed in the ring and adapted to receive a suture for suturing a portion of the acquired tissue to the ring, thereby preventing the ring from rotating with respect to the acquired tissue about the longitudinal axis.

In accordance with a further aspect of the invention, the lining system comprises an endoluminal applier for endoluminially delivering and fastening the anchoring device of the lining system to the hollow organ, the applier comprising a flexible elongate applier shaft and a ring fastening assembly arranged at a distal end of the applier shaft and having a longitudinal axis. The ring fastening assembly comprises a ring holder adapted to engage the ring of the anchoring device by a shape coupling which prevents relative rotation therebetween, a rotation mechanism adapted to rotate the ring holder with respect to the insertion shaft about the longitudinal axis, and a pusher adapted to engage at least one
fastener and translatable with respect to the ring holder, wherein the pusher is operable to push the fastener towards the ring holder in a direction parallel to the longitudinal axis. The endoluminal applier allows to perform the ring rotation necessary for the tissue acquisition and the fastener translation necessary for rotationally locking the ring with respect to the acquired tissue by means of a single instrument, i.e. the ring fastening assembly, and without rotating or pushing or pulling the entire applier shaft. 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 in accordance with a first embodiment of the invention;
- Figure 2 illustrates an endoluminal lining system in accordance with a second embodiment of the invention;
- Figure 3 illustrates a longitudinal cross-section of the lining system of figure 2 during endoluminal fixation within a section of the GI tract of a patient;
- Figure 3A is a perspective illustration of the situation in figure 3, illustrating a "twisting"-type tissue acquisition in accordance with an embodiment of the invention;
- Figure 4 is a side view of an endoluminal lining system in accordance with a third embodiment of the invention;
- Figure 5 illustrates a longitudinal cross-section of the lining system of figure 4 during endoluminal fixation within a section of the GI tract of a patient;
- Figure 6 is a side view of an endoluminal lining system in accordance with a fourth embodiment of the invention;
- Figure 7 illustrates a longitudinal cross-section of the lining system of figure 6 during endoluminal fixation within a section of the GI tract of a patient;
- Figure 8 illustrates an endoluminal applier for endoluminally inserting and anchoring the lining system in a target site in a hollow organ, wherein the applier carries a lining and anchoring ring as illustrated in figure 3;
- Figure 9 illustrates an endoluminal applier for endoluminally inserting and anchoring the lining system in a target site in a hollow organ, wherein the applier carries a lining and anchoring ring as illustrated in figures 4 and 5;
- Figure 10 illustrates an endoluminal applier for endoluminally inserting and anchoring the lining system in a target site in a hollow organ, wherein the applier carries a lining and anchoring ring as illustrated in figures 6 and 7;
- Figures 11 and 12 illustrate different possible positions of the endoluminal 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, figure 1 depicts an endoluminal lining system for internally lining a hollow organ 1, particularly a section of the gastrointestinal tract. The system comprises a flexible tubular lining 2 extending between a proximal end 3 and a distal end 4 and an anchoring device 5 for fastening the flexible tubular lining 2 in the hollow organ 1.

The anchoring device 5 is provided at one of the proximal end 3 and distal end 4 of the lining and comprises an anchoring ring 6 defining a central passage opening 7 and developing about a longitudinal axis 8 of the anchoring device 5, which is an axis of symmetry of the ring 6. The anchoring ring 6 has a radially external anchoring surface 9 and a plurality of barbs 10 arranged in the anchoring surface 9 and operable to protrude from the anchoring surface 9 radially outward and inclined with respect to a radial direction to the longitudinal axis 8. In this way, upon rotation of the anchoring ring 6 in a first direction about the longitudinal axis 8, the barbs 10 penetrate into the surrounding tissue 11 of the hollow organ 1 and acquire and attract said tissue 11 towards the anchoring surface 9 and, upon rotation of the anchoring ring 6 in a second direction opposite the first direction the barbs 10 are withdrawn from the surrounding tissue 11 and allow the tissue 11 to detach from the anchoring surface 9.

In order to lock the acquired tissue 11 to the anchoring ring 6, the anchoring device 5 comprises locking means adapted to prevent the anchoring ring 6 from rotating with respect to the surrounding tissue 11.

This allows to simply and reliably fasten the lining 2 within the hollow organ 1, particularly a section of the GI tract, by endoluminal insertion of the lining system to the anchoring site, exposing of the anchoring ring 6 with its anchoring surface 9 and barbs 10 to the surrounding tissue 11 and rotation of the anchoring ring 6 until the surrounded tissue 11 is pierced and slid along the barbs 10 towards and against the anchoring surface 9. After completion of the tissue fastening and acquisition the locking means are activated to
prevent the anchoring ring 6 from rotating with respect to the acquired tissue 11, thereby
preserving the anchoring of the lining 2 in the planned position.
The barbs 10 may be movable between a rest position in which free pointed ends of the
barbs are retracted inside the anchoring ring 6, and an activated position in which the
barbs are protracted to extend outside the anchoring ring 6. This allows the lining system
to be inserted endoluminally with the barbs retracted and to protract the barbs 10 only
after positioning of the anchoring ring 6 in the planned anchoring site.
A moving mechanism may be provided in the anchoring ring 6 for actively moving the
barbs 10 from the rest position inside the anchoring ring 6 to the activated position outside
the anchoring surface 9. Alternatively, the barbs 10 may be permanently elastically biased
to the activated position and a releasable barb retaining mechanism may be provided at
the anchoring ring 6 which is adapted to retain the barbs in the rest position during
endoluminal insertion of the lining system and to release the barbs to elastically protract in
the activated position after positioning of the anchoring ring 6 in the planned anchoring
site inside the hollow organ 1.
Alternatively or additionally, a detachable or otherwise removable protective sheath may
be provided to protect the surrounding tissue from the barbs 10 during endoluminal
insertion of the lining system. In this case, the protective sheath is withdrawn from the
anchoring ring 6 after its positioning in the anchoring site, in order to expose the barbs to
the surrounding tissue.
In accordance with an embodiment (Figure 1), the locking means comprise at least one
suture hole 15 formed in the anchoring ring 6 and adapted to receive a suture 16 for
suturing a portion of the acquired tissue 11 to the anchoring ring 6, thereby preventing the
anchoring ring 6 from rotating about the longitudinal axis 8 with respect to the acquired
tissue 11.
In accordance with further embodiments (Figures 2, 4, 5), the locking means comprise at
least one pin or needle fastener 12 adapted to pierce the acquired tissue 11 or neighbor
tissue 13 adjacent to the acquired tissue 11 and at least one fastener seat 14 formed in
the anchoring ring 6 and adapted to receive and hold the fastener 12 so that the fastener
12 extends in a transverse direction to the extension of the barbs 10, preferably in a
direction parallel to the longitudinal ring axis 8.
Thanks to the transverse orientation of the pin or needle fastener 12 relative to the barbs
10, a rotation of the anchoring ring 6 with respect to the fastened tissue 11 and, hence, a
withdrawal of the barbs 10 from the acquired tissue 11 is effectively prevented.
With regard to the exemplary embodiment illustrated in figures 2 and 3, the locking means may comprise a fastening ring 17 having a central passage opening which can be aligned with the passage opening 7 of the anchoring ring 6 for the passage of the contents, e.g. food or chime, once the lining is anchored in the hollow organ 1, e.g. the jejunum. The fastening ring 17 is initially separate from the anchoring ring 6 and supports a plurality of uniformly circumferentially distributed needle or pin fasteners 12 arranged in a frontal surface 18 of the fastening ring 17 and protruding in an axial direction parallel to the longitudinal axis 8 towards the anchoring ring 6.

The anchoring ring 6 forms a plurality of fastener seats 14, e.g. internally stepped or riffled holes provided in a back surface 19 of the anchoring ring 6, intended to face towards the fastening ring 17 during application of the anchoring device 5. The fastener seats 14 are positioned and shaped to receive the pin or needle fasteners 12 by means of a snap-on shape coupling or interference fit, thereby holding the fasteners 12 (which are preferably straight) oriented transversely with respect to the barbs 10 and, preferably, parallel to the longitudinal axis 8.

The lining 2 and anchoring device 5 with the barbs 10 retracted in the rest position are endoscopically inserted through the mouth, esophagus, stomach and duodenum to the planned anchoring site, e.g. a section of the jejunum. Then, the anchoring ring 6 is positioned so that the longitudinal axis 8 coincides substantially with a longitudinal direction of the intestine and the barbs 10 are exposed by actively moving or releasing them from the rest position to the protracted activated position outside the anchoring surface 9. With the barbs 10 activated, the anchoring ring 6 is rotated about the longitudinal axis 8 in the first direction so that the barbs pierce the surrounding tissue 11 (Figure 3) and make it slide towards a base of the barbs and the anchoring surface 9. By further rotating the anchoring ring 6 in the first direction, the neighbor tissue 13 adjacent to the tissue 11 pierced by the barbs 10 is twisted and narrowed and, hence, pulled over the back surface 19 of the anchoring ring 6. It is now possible to move the fastening ring 17 parallel to the longitudinal axis 8 towards and in engagement with the anchoring ring 6. By pushing the fastening ring 17 and the anchoring ring 6 together, the pin or needle fasteners 12 pierce through the twisted neighbor tissue 13 arranged over the back surface 19 of anchoring ring 6 and are received by the fastener seats 14. In this way, any backward rotation of the anchoring ring 6 with respect to the surrounding tissue 11 is effectively prevented and the anchoring device of the lining system is reliably fixated in the planned anchoring site of the intestine. In this configuration the pin or needle fasteners 12
act both as anti-rotation means and, together with the barbs 10, as tissue retaining means.

With regard to the exemplary embodiment illustrated in figures 4 and 5, the locking means comprise a fastening ring 20 having a central passage opening aligned with the passage opening 7 of the anchoring ring 6 for the passage of the contents, e.g. food or chime, once the lining is anchored in the hollow organ 1, e.g. the jejunum. The fastening ring 20 is inseparably connected to the anchoring ring 6 and translatable parallel to the longitudinal axis 8 from an open position (Figure 4) to a closed position (Figure 5). The fastening ring 20 supports a plurality of uniformly circumferentially distributed needle or pin fasteners 12 arranged in a frontal surface 18 of the fastening ring 20 and protruding in an axial direction parallel to the longitudinal axis 8 towards the anchoring ring 6.

The anchoring ring 6 comprises a circumferential groove 21 formed in the anchoring surface 9, wherein the barbs 10 are arranged in the groove 21 and may be retractable inside the groove 21 (rest position) and retractable outside the groove 21 (activated position). In this configuration, by rotating the anchoring ring 6 in the first direction the surrounding tissue 11 is pierced and slides along the barbs into the groove 21.

The anchoring ring 6 further forms a plurality of fastener seats 14, e.g. internally stepped or rifled holes provided in a back surface 19 of the anchoring ring 6 and facing toward the fastening ring 20. The fastener seats 14 are positioned and shaped to hold the pin or needle fasteners 12 by means of shape coupling, thereby connecting the fastening ring 20 inseparably with the anchoring ring 6.

Moreover, the fastener seats 14 extend (in the longitudinal direction of axis 8) transversally through the circumferential groove 21 and guide the pin or needle fasteners 12, in the closed position, to extend through said circumferential groove 21.

The lining 2 and anchoring device 5 with the barbs 10 retracted in the circumferential groove 21 or covered by a protective sheath are endoscopically inserted through the mouth, esophagus, stomach and duodenum to the planned anchoring site, e.g. a section of the jejunum. Then, the anchoring ring 6 with the attached fastening ring 20 is positioned so that the longitudinal axis 8 coincides substantially with a longitudinal direction of the intestine and the barbs 10 are exposed by actively moving or releasing them from the rest position to the protracted activated position outside the anchoring surface 9. With the barbs 10 activated, the anchoring ring 6 is rotated about the longitudinal axis 8 in the first direction so that the barbs pierce the surrounding tissue 11 and make it slide towards a base of the barbs inside the groove 21. It is now possible to push the fastening ring 20
from the open position to the closed position. By pushing the fastening ring 20 and the anchoring ring 6 together, the pin or needle fasteners 12 pierce through the surrounding tissue 11 arranged inside the circumferential groove 21 of anchoring ring 6 and are locked in the closed position by the fastener seats 14 (Figure 5). In this way, any backward rotation of the anchoring ring 6 with respect to the surrounding tissue 11 is effectively prevented and the anchoring device of the lining system is reliably fixated in the planned anchoring site of the intestine. Similarly to the embodiment of figures 2 and 3, also in this embodiment the pin or needle fasteners 12 act both as anti-rotation means and, together with the barbs 10, as tissue retaining means.

Figures 6 and 7 illustrate a further exemplary embodiment, in which the anchoring ring 6 and the fastening ring 20 are substantially shaped as described in connection with figure 4 and 5, but initially separate and adapted to be connected by moving the fastening ring 20 parallel to the longitudinal axis 8 towards and in engagement with the anchoring ring 6. By pushing the fastening ring 20 and the anchoring ring 6 together, the pin or needle fasteners 12 pierce through the surrounding tissue 11 arranged in the groove 21 of anchoring ring 6 and are received by the fastener seats 14.

In accordance with a further embodiment, the lining system comprises a lining seat 22 arranged at the anchoring ring 6 and adapted to receive and hold the pliable tubular lining 2 in a packed (substantially ring shaped), e.g. wrapped, folded, compressed or rolled up, configuration with regard to a lining longitudinal extension. The lining seat 22 may cooperate with the locking means, i.e. with the pin or needle fasteners 12 to release the lining 2 and, possibly to push at least a portion of the lining 2 distally out of the lining seat 22, when the locking means are activated (e.g. when the fasteners 12 are received by the fastener seats 14 in the closed position).

With regard to all described embodiments, the anchoring device 5 may be grafted at least partially of bioabsorbable material and the anchoring ring 6 and fastening ring 17, 20 may be substantially rigid. At least part of the anchoring device 5 may be protected by a protective sheath during endoluminal insertion in the hollow organ 1.

In accordance with a further embodiment of the invention, the lining system comprises an endoluminal applier 23 (Figures 8, 9, 10) for endoluminally delivering and fastening the anchoring device 5 of the lining system to the hollow organ 1. The applier 23 comprises a flexible elongate applier shaft 24 extending from a proximal handle (not illustrated) and a distal shaft end 26 at which a ring fastening assembly 25 is provided. The ring fastening assembly 25 defines a longitudinal assembly axis 27 and comprises a ring holder 28
adapted to detachably engage the anchoring ring 6 of the anchoring device 5 by means of shape coupling which prevents relative rotation therebetween, and a rotation mechanism 29 operable to rotate the ring holder 28 with respect to the applier shaft 24 about the assembly axis 27. The ring fastening assembly 25 further comprises a pusher 30 translatable parallel to the assembly axis 27 with respect to the ring holder 28 and adapted to engage at least one fastener 12, 17, 20 and operable to push the fastener axially towards the ring holder 28.

The endoluminal applier 23 allows to rotate the anchoring ring 6 for the tissue acquisition and to drive the fasteners 12 in the tissue 11, 13 and into the anchoring ring 6 for rotationally locking the ring 6 with respect to the acquired tissue. All these functions are accomplished by means of a single instrument, i.e. the ring fastening assembly 25, and without rotating or pushing or pulling the entire applier shaft 24.

In accordance with embodiments, the pusher 30 may form an annular fastening ring seat 32 adapted to detachably hold the fastening ring 17, 20 if provided.

In accordance with a further embodiment, the ring fastening assembly 25 comprises a barb activating mechanism 33 adapted to co-operate with the barb moving mechanism of the anchoring ring 5 received by the ring holder 28 and operable to move the barbs 10 from the rest position in the activated position or to release the barbs 10 to allow them to snap in the activated position. The barb activating mechanism 33 may comprise an activating tooth 34 arranged near the ring holder 28 and acting on a corresponding activating button 35 of the barb movement mechanism.

Alternatively or additionally, the barb activating mechanism 33 may comprise a protection slider adapted to slide a protection casing 36 with respect to the ring holder 28 from a first position in which the protection casing covers the anchoring ring 6 received by the ring holder 28, to a second position in which the protection casing 36 exposes the anchoring ring 6.

The applier 23 may further comprise an instrument channel 31 extending longitudinally through the ring fastening assembly 25

The instrument channel 31 is adapted to slidingly receive an endoscope 37 to visualize the space distally ahead of the ring fastening assembly 25 and, possibly, to slide the applier 23 endoluminally along the endoscope 37 to the lining anchoring site in the hollow organ 1.

In accordance with an embodiment, the ring holder 28 comprises ring releasing means which detach the ring holder 28 from the anchoring ring 6 when the force transmitted by
the ring holder 28 to the anchoring ring 6 exceeds a predetermined target value sufficient for an adequate locking pressure between the pin or needle fasteners 12 and the anchoring ring 6. The ring releasing means can be adapted to force dependency separate the ring holder 28 from the anchoring ring 6 by resilient radially inward retraction or deformation of the ring holder 28 or by force dependency breaking the ring holder 28 in predetermined breaking points. This allows to automatically detach the ring holder 28 from the anchoring ring 6 and withdraw it in proximal direction through the central passage opening 11 of the anchoring ring 6 and, possibly, the fastening ring 17, 20, and endoluminally out of the patients' body.

The rotating mechanism 29 is connected through one or more flexible rotation transmitters with an extracorporeal rotation activation mechanism provided e.g. at the proximal handle portion of the applier 23. The pusher 30 is connected through one or more flexible pushing movement transmitters with an extracorporeal pushing mechanism provided e.g. at the proximal handle portion of the applier 23. Alternatively, the ring holder 28 is connected through one or more flexible pulling movement transmitters with an extracorporeal pushing mechanism provided e.g. at the proximal handle portion of the applier 23, so that the ring holder 28 can be pulled towards a stationary pusher 30.

Also the barb activating mechanism 33 may comprise one or more flexible activating movement transmitters connected to an extracorporeal barb activator button provided e.g. at the proximal handle portion of the applier 23. The rotation movement transmitters, the pushing movement transmitters and the barb activating movement transmitters are arranged inside the flexible applier shaft 24.

**DETAILED DESCRIPTION OF A METHOD FOR ANCHORING 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 23 with the anchoring device 5 with the attached lining 3 placed over the ring fastening assembly 25, as shown in FIGs 8, 9, 10. Particularly, the anchoring ring 6 is attached by detachable shape coupling to the ring
holder 28 and the fastening ring 17, 20 (if provided) or fasteners 12 are brought in engagement with the pusher 30. The barbs may be retracted in their rest position or covered by the protection casing 36. After preparation of the applier 23, the latter is moved over the endoscope casing 37 and guided 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 37 placed in the instrument channel 31 of the applier 23 to view and select an area suitable for the application of the lining 2.

Once the applier is positioned in the selected anatomical location, the barbs 10 of the anchoring ring 5 are exposed to the surrounding tissue 11 within the duodenum by operating the barb activating mechanism and, possibly, sliding the protection casing 36 away from the anchoring ring 6.

At this stage the ring rotation mechanism may be activated to rotate the ring holder 25 together with the anchoring ring 6 in the first direction and pierce and twist the surrounding tissue 11:

- to pull the adjacent neighbor tissue 13 over the back surface 19 of the anchoring ring 6 (Figure 3 and 8) or, - to move the surrounding tissue 11 in the circumferential groove 21 of the anchoring surface 9 (Figures 5, 9 and 6, 10).

Then the pin or needle fasteners 12 are pushed by means of pusher 30 through the acquired tissue into the fastener seats 14. In this way, any backward rotation of the anchoring ring 6 with respect to the surrounding tissue 11 is effectively prevented and the anchoring device of the lining system is reliably fixated in the planned anchoring site of the intestine.

The tubular lining attached to the anchoring ring 6 can be now released or pulled distally to unfold it from the collapsed configuration to an extended substantially elongate tubular shape configuration. For this purpose, the distal end 4 of the lining 2 may be provided with an inertial mass adapted to promote unfolding of the lining due to gravity or with a rigid or semi-rigid ring element adapted to be moved distally by the intestinal peristalsis. After completion of the procedure, the applier 23 is endoluminally removed from the patient.

Removal of the lining 2 from the hollow organ can be accomplished by separating, e.g. cutting the lining 2 from the anchoring device 5 or by detaching the needle or pin fasteners 12 from the fastening seats 14 of the anchoring ring 5 (e.g. by axially withdrawing the fastening ring 17, 20) and rotation of the anchoring ring (6) in the second direction opposite the first direction, so that the barbs 10 are withdrawn from the surrounding tissue 11 and allow the tissue 11 to detach from the anchoring surface 9.
In this way bypass conduits can be created in the GI tract of a patient to achieve a malabsorptive effect in cases where such an effect may enhance weight loss, as well as the initially described effects on hormonal signaling in general.

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

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

1. An endoluminal lining system for internally lining a hollow organ (1), particularly a section of the gastrointestinal tract, the system comprising a flexible tubular lining (2) and an anchoring device (5) connected to the lining (2) and suitable for fastening the lining (2) in the hollow organ (1), said anchoring device (5) defining a longitudinal axis (8) and comprising:
   - an anchoring ring (6) forming a central passage opening (7) and a radially external anchoring surface (9),
   - a plurality of barbs (10) arranged in the anchoring surface (9) and operable to protrude from the anchoring surface (9) radially outward and inclined with respect to a radial direction to the longitudinal axis (8) such that, upon rotation of the anchoring ring (6) in a first direction about the longitudinal axis (8), the barbs (10) penetrate into surrounding tissue (11) of the hollow organ (1) and acquire said tissue (11) towards the anchoring surface (9) and, upon rotation of the anchoring ring (6) in a second direction opposite the first direction the barbs (10) are withdrawn from the surrounding tissue (11).
   - locking means adapted to engage the anchoring ring (6) and the surrounding tissue (11) to prevent relative rotation therebetween.

2. Endoluminal lining system according to claim 1, in which the barbs (10) are movable between a rest position in which the barbs are retracted inside the anchoring ring (6), and an activated position in which the barbs are protracted outside the anchoring ring (6).

3. Endoluminal lining system according to claim 2, wherein the barbs (10) are permanently elastically biased to the activated position.

4. Endoluminal lining system according to claim 1, in which the locking means comprise at least one suture hole (15) formed in the anchoring ring (6) and adapted to receive a suture (16) for suturing a portion of the acquired tissue (11) to the anchoring ring (6).

5. Endoluminal lining system according to claim 1, in which the locking means comprise:
   - at least one pin or needle fastener (12) adapted to pierce the acquired tissue (11) or neighbor tissue (13) adjacent to the acquired tissue (11), and
   - at least one fastener seat (14) formed in the anchoring ring (6) and adapted to receive and hold the fastener (12) so that the fastener (12) extends in a transverse direction to the extension of the barbs (10).

6. Endoluminal lining system according to claim 5, in which the fastener seat (14) is configured to hold the fastener (12) to extend parallel to the longitudinal ring axis (8).

7. Endoluminal lining system according to claim 6, comprising a fastening ring (17; 20)
having a frontal surface (18) and a plurality of said needle or pin fasteners (12) protruding from said frontal surface (18),
the anchoring ring (6) forming a plurality of said fastener seats (14) positioned and shaped to receive the pin or needle fasteners (12) by means of shape coupling.

8. Endoluminal lining system according to claim 7, wherein the anchoring ring (6) comprises a circumferential groove (21) formed in the anchoring surface (9) and the barbs (10) are connected inside the groove (21) such that by rotating the anchoring ring (6) in the first direction the surrounding tissue (11) is pierced and slides along the barbs into the groove (21),
wherein the fastener seats (14) extend transversally through the circumferential groove (21) and guide the pin or needle fasteners (12) to extend, in a closed position, through said circumferential groove (21).

9. Endoluminal lining system according to claim 8, wherein the fastening ring (20) is inseparably but slidably connected to the anchoring ring (6) and translatable with respect to the anchoring ring (6) parallel to the longitudinal axis (8) from an open position to said closed position,

10. Endoluminal lining system according to any one of the preceding claims, comprising a lining seat (22) arranged at the anchoring ring (6) and adapted to receive and hold the tubular lining (2) in a packed configuration with regard to a lining longitudinal extension.

11. Endoluminal lining system according to claim 10, wherein the lining seat (22) cooperates with the locking means (12) to release the lining (2) in response to the activation of the locking means (12).

12. Endoluminal lining system according to any one of the preceding claims, comprising an endoluminal applier (23) for endoluminally delivering and fastening the anchoring device (5) to the hollow organ (1), the applier (23) comprising:
- a flexible elongate applier shaft (24),
- a ring fastening assembly (25) provided at a distal end of the applier shaft (24) and defining a longitudinal assembly axis (27), the ring fastening assembly comprising:
  - a ring holder (28) adapted to detachably engage the anchoring ring (6) by means of shape coupling which prevents relative rotation therebetween,
  - a rotation mechanism (29) operable to rotate the ring holder (28) with respect to the applier shaft (24) about the assembly axis (27),
  - a pusher (30) translatable parallel to the assembly axis (27) with respect to the ring holder (28) and adapted to engage at least one fastener (12, 17, 20) and operable to push
the fastener axially towards the ring holder (28).

13. Endoluminal lining system according to claim 12, in which the ring fastening assembly (25) comprises a barb activating mechanism (33) adapted to co-operate with a barb moving mechanism of the anchoring ring (5) received by the ring holder (28) and operable to move the barbs (10) from the rest position in the activated position.

14. Endoluminal lining system according to claim 13, in which the barb activating mechanism (33) comprises an activating tooth (34) arranged near the ring holder (28) and acting on a corresponding activating button (35) of the barb movement mechanism.

15. Endoluminal lining system according to claim 13 or 14, in which the barb activating mechanism (33) comprises a protection slider adapted to slide a protection casing (36) with respect to the ring holder (28) from a first position in which the protection casing (36) covers the anchoring ring (6) received by the ring holder (28), to a second position in which the protection casing (36) exposes the anchoring ring (6).

16. Endoluminal lining system according to claim 12, in which the applier (23) comprises an instrument channel (31) extending longitudinally through the ring fastening assembly (25) and adapted to slidably receive an endoscope.

17. Method for endoluminally anchoring a tubular lining to a hollow organ, comprising:
- providing an anchoring ring (6) with a plurality of barbs (10) protruding from a radially external anchoring surface (9) of the anchoring ring (6) radially outward and inclined with respect to said radial direction,
- connecting the tubular lining (2) to the anchoring ring (6),
- inserting the anchoring ring (5) together with the tubular lining (2) endoluminally in the hollow organ,
- under endoscopic visualization positioning the anchoring ring (6) in a target location within the hollow organ (1),
- after positioning of the anchoring ring (6) in the target location, exposing the barbs (10) of the anchoring ring (6) to a surrounding tissue (11), and
- piercing and twisting the surrounding tissue (11) by rotating the anchoring ring (6) in a first direction;
- pushing at least one fastener (12) through the pierced and twisted surrounding tissue (11) tissue into the anchoring ring (6) so that the fastener extends transversally with respect to the extension of the barbs (10), thereby preventing the anchoring ring (6) from backward rotation with respect to the surrounding tissue (11).
INTERNATIONAL SEARCH REPORT

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

1. ☒ Claims Nos.: 17
   because they relate to subject matter not required to be searched by this Authority, namely:
   The subject-matter of claim 17, which is related to a method of endoluminally anchoring a tubular lining to a hollow organ, is considered to be covered by the provisions of Rule 39.1(iv) PCT (methods for treatment of the human or animal body by surgery).

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

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

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.
A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F5/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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[X] Further documents are listed in the continuation of Box C.  
[X] See patent family annex.

* Special categories of cited documents:

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"A" document member of the same patent family

Date of the actual completion of the international search: 22 February 2012

Date of mailing of the international search report: 06/03/2012

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

Authorized officer:
Dennler, Samuel
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