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Title: AN APPLIER FOR ANCHORING A LINING TO A HOLLOW ORGAN

Abstract: An endoluminal applier (1) for anchoring a tubular lining (9) to a hollow organ (10), the applier (1) comprising a fastening assembly (4) forming a fastening cavity (5) adapted to receive a tissue portion (6) of the hollow organ (3) together with a portion of the lining (2), a suction device (7) with one or more suction apertures (8) opening into the fastening cavity (5) for acquiring the tissue portion (6) and lining (3) into the fastening cavity (5), a stitching mechanism (9) adapted to stitch into the fastening cavity (5) and to apply a running suture to the acquired tissue portion (6) and lining (2).
DESCRIPTION
"AN APPLIER FOR ANCHORING A LINING TO A HOLLOW ORGAN"

FIELD OF THE INVENTION

[0001] 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

[0002] 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.

[0003] 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.

[0004] 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.

[0005] 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.

[0006] 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.

[0007] 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.

[0008] 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 reliable anchoring and conservation of the planned position of the endoluminal sleeve.

[0009] Moreover, the known devices and methods do not sufficiently address the need of creating sealed or leak tight connection regions between the endoluminal sleeve and the hollow organ in order to obtain a desired flow scheme of the food flow and the flow of bodily fluids, such as gastric juices, bile and pancreatic fluid.

[0010] Accordingly, there is a need for improved devices and procedures for positioning and anchoring an endoluminal sleeve in the GI tract.

**SUMMARY OF THE INVENTION**

[0011] 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.

[0012] At least part of the above identified needs are met by an endoluminal applier for anchoring a tubular lining to a hollow organ, the applier comprising a fastening assembly having:

- a fastening cavity adapted to receive a tissue portion of said hollow organ together with a
portion of said lining,
- a suction device with one or more suction apertures opening into the fastening cavity and adapted to acquire the tissue portion and lining into the fastening cavity,
- a stitching mechanism adapted to stitch into said fastening cavity and to apply a running suture to the acquired tissue portion and lining.

[0013] This provides an instrumentation which may be used similarly to known circular staplers, but obviates the use of rigid staples and reduces the stiffness of the sutured seam with respect to fastening procedures with staplers. Moreover, the stitching force necessary to pierce a single perforating needle through the acquired tissue and lining is significantly lower than the forces normally required for stapling.

[0014] In accordance with an aspect of the invention, the fastening cavity has a first sewing surface defining a first slot extending along a stitching path and an opposite second sewing surface facing the first sewing surface and defining a second slot extending along the stitching path, and the stitching mechanism comprises a perforating needle arranged in the first slot, a thread catch arranged in the second slot, and a needle driving assembly adapted to:
- repeatedly moving the perforating needle and the thread catch with respect to each other to create a running suture through said fastening cavity, and
- moving the perforating needle and the thread catch along the first and second slots to extend the running suture along the stitching path.

[0015] In accordance with a further aspect of the invention, the stitching mechanism comprises:
- a continuous annular needle path, said needle path crossing the fastening cavity and being formed inside an unobstructed disentangling space;
- a needle and needle drive assembly arranged for movement of the needle along the needle path;
- a suture secured to the needle and extending from the needle through the disentangling space and through the fastening cavity outside the fastening assembly, so that the needle can repeatedly move along the entire needle path without winding the suture around any part of the fastening assembly.

[0016] This allows to position the applier with the fastening cavity over a portion of tissue and lining, acquire the tissue portion and lining in the fastening cavity, sending the needle with the suture through the acquired tissue portion and lining, releasing the tissue portion and lining from the fastening cavity, rotating or moving the fastening cavity to the next
portion of tissue and lining and moving the needle along the annular needle path to an initial
needle position (without tangling the suture), and repeating the sequence until a complete
running suture, e.g. a circumferential purse string suture, is created.

[0017] In accordance with a yet further aspect of the invention, the fastening assembly
forms a plurality of fastening cavities arranged along a circumference of the fastening
assembly, as well as a continuous annular needle path which crosses all fastening cavities
and which extends inside a continuously radially externally open annular sewing groove
formed along the circumference of the fastening assembly. The stitching mechanism
comprises a needle and needle drive assembly arranged for movement of the needle along
the needle path, as well as a suture secured to the needle and extending from the needle
inside the annular sewing groove, so that the needle can repeatedly move along the entire
needle path and the thus obtained suture loop can be moved radially out of the sewing
groove.

[0018] This embodiment allows to contemporaneously acquire a plurality of tissue portions
and lining portions along a circumference around the fastening assembly, then sending the
needle successively through all acquired tissue and lining portions, thereby obtaining a
(possibly closed loop) running purse string suture between the lining and the tissue of the
hollow organ, and eventually releasing the purse string sutured tissue and lining from the
applier.

[0019] 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 applier for anchoring a tubular lining to a hollow organ,
the applier being in a closed configuration;
- Figure 2 illustrates the applier of figure 1 in an open configuration;
- Figure 3 illustrates a transoral introduction of the applier of figure 1 to the duodenum;
- Figure 4 illustrates a method step in which the applier is opened after positioning in the
target location in the GI tract;
- Figure 5 illustrates the applier and a method for acquiring tissue of the hollow organ to
which the tubular lining is intended to be secured in accordance with an embodiment;
- Figure 6 illustrates the applier in a closed configuration in which the acquired tissue and
an anchoring portion of the lining is clamped between opposite sewing surfaces of a fastening cavity of the applier and ready for the application of a running suture; 
- Figure 7 is a schematic cross-sectional view of a tubular lining sutured to a target location of the hollow organ, but still in a collapsed or packed shape;
- Figure 8 illustrates the tubular lining after anchoring and full extension within a section of the GI tract;
- Figure 9 is a partially sectioned side view of the applier in accordance with a further embodiment;
- Figure 10 is sectional view in plane X-X in figure 9;
- Figures 11A through 11E illustrate a sequence of movements accomplished by a stitching mechanism of the applier in accordance with an embodiment;
- Figure 12 illustrates an endoluminal applier for securing a tubular lining to a hollow organ in accordance with a further embodiment;
- Figure 13 is a sectional view in plane XIII-XIII in figure 12;
- Figure 13A illustrates a sequence of an open loop suture disentangling implemented by the applier of Figure 12;
- Figure 14 is sectional view in plane XIV-XIV in figure 12;
- Figure 15 is a sectional view of a purse string suture through an endoluminal lining and an intestinal wall created by means of the applier in figure 12;
- Figure 16 illustrates an endoluminal applier for securing a tubular lining to a hollow organ in accordance with a further embodiment;
- Figure 17 is sectional view in plane XVII-XVII in figure 16 during a suturing step;
- Figure 18 is sectional view in plane XVII-XVII in figure 16 during a tissue releasing step;
- Figures 19 and 20 illustrate further devices and methods for endoluminally securing a lining inside a GI tract.

**DETAILED DESCRIPTION OF EMBODIMENTS**

[0020] Referring to the drawings where like numerals denote like anatomical structures and components throughout the several views, figure 1 depicts an endoluminal applier 1 for anchoring a tubular lining 2 to a hollow organ 3, particularly to a section of the GI tract of a patient.

[0021] The applier 1 comprises a fastening assembly 4 which has a fastening cavity 5 adapted to receive a tissue portion 6 of the hollow organ 3 together with a portion of the lining 2, a suction device 7 with one or more suction apertures 8 opening into the fastening cavity 5 and adapted to acquire the tissue portion 6 and lining 3 into the fastening cavity 5.
The fastening assembly 4 further comprises a stitching mechanism 9 adapted to stitch into the fastening cavity 5 and to apply a running suture to the acquired tissue portion 6 and lining 2.

[0022] In accordance with an embodiment, the fastening cavity 5 has a first sewing surface 10 defining a first sewing slot 11 extending along a stitching path and an opposite second sewing surface 12 facing the first sewing surface 10 and defining a second sewing slot 13 extending along the stitching path. The stitching mechanism 9 comprises a perforating needle 14 arranged in the first sewing slot 11, a thread catch 15 arranged in the second sewing slot 13, and a needle driving assembly 16. The needle driving assembly 16 is adapted to repeatedly moving the perforating needle 14 and the thread catch 15 with respect to each other to create a running suture through the fastening cavity 5, and to moving the perforating needle 14 and the thread catch 15 along the first and second sewing slots 11, 13 in a manner to extend the running suture along the stitching path.

[0023] More specifically, the needle driving assembly 16 can be adapted to repeatedly moving the perforating needle 14 with a suture loop forward through the fastening cavity 5 into the second sewing slot 13 and then backward in the first sewing slot 11, and repeatedly moving the thread catch 15 in engagement with the suture loop 17 to hold the suture loop in the second sewing slot 13 during the backward movement of the perforating needle 14, and moving the perforating needle 14 and the thread catch 15 along the stitching path with respect to the first and second sewing surfaces 10, 12 while the suction device 7 or clamping means which will be described further below constrain the tissue portion 6 and the lining 2 stationarily within the fastening cavity 5.

[0024] Figures 11A to 11E illustrate an exemplary embodiment of a movement sequence of the stitching mechanism 9, in which a basic chain stitch is created through the lining 2 and tissue portion 6 by first sending the perforating needle 14 forward through the tissue portion and lining held between the first and second sewing surfaces 10, 12. Then, as the perforating needle 14 is moved backward, the friction of the suture 17 against the tissue 6 and lining 2 is sufficient to form a small loop on their side facing the second sewing slot 13. That loop is caught by the hook shaped thread catch 15 housed within the second sewing slot 13. The needle driving assembly 16 then moves both the perforating needle 14 and the thread catch 15 forward along the stitching path, thereby projecting the previously caught loop of suture in the position of the subsequent stitch. In this manner, the next forward movement of the perforating needle 14 goes through the previously caught loop of suture. The thread catch 15 then releases the previously caught loop of suture and picks up the
new loop and the process repeats.

[0025] In accordance with an embodiment (Figures 1 through 10), the fastening assembly 4 comprises a proximal portion 18 having an annular distal clamping surface which forms the first sewing surface 10, and a distal anvil 19 having an annular proximal clamping surface which faces the distal clamping surface and forms the second sewing surface 12. The anvil 19 is movable relative to the proximal portion 18 for clamping a ring shaped tissue portion 6 between the first and second sewing surfaces 10, 12. In this embodiment, the stitching path and, hence, the sewing slots 11, 13 have a closed annular, preferably circular shape.

[0026] The fastening assembly 4 may further comprise a ring shaped lining seat 20 adapted to receive the tubular lining 2 such that an elongate body portion 21 of the lining is held in a collapsed (substantially ring shaped), e.g. wrapped, folded, compressed or rolled up, configuration with regard to a lining longitudinal extension and a ring shaped anchoring portion 22 of the lining 2 is held to overlap one of said first and second sewing surfaces 10, 12 and sewing slots 11, 12.

[0027] This assures a correct relative positioning of the lining 2 anchoring portion 22, the stitching mechanism 9 and the sewing surfaces 10, 12. Moreover, the positioning of the lining 2 on the lining seat 20 may take place extracorporeal and does not change during the endoluminal insertion of the applier 1 and during applying the running suture.

[0028] In accordance with an embodiment, the lining seat 8 is formed in the anvil 19 and comprises a distal containment wall 23 (Figure 9) against which the collapsed and "packed" tubular lining 2, e.g. an endoluminal sleeve, rests so that it keeps its collapsed and "packed" shape until the lining 2 is pulled or pushed distally over the containment wall 23 during withdrawal of the applier 1 from the sutured sleeve 2.

[0029] The anvil 19 may be translatably connected to the proximal portion 18 by at least one, preferably two diametrically opposite anvil shafts 24 slidably received in one or more guide holes 25 of the proximal portion 18 and connected with an anvil moving mechanism adapted to move the anvil 19 relative to the proximal portion 18.

[0030] The suction apertures 8 of the suction device 7 are connectable to an extracorporeal suction pump and may be arranged in the fastening cavity 5 radially internal of the sewing slots 11, 13 in a manner to assure an acquisition and positioning of the tissue and lining over the sewing slots.

[0031] The suction apertures 8 can be formed in the first sewing surface 10 and/or in the region of the anvil shaft or shafts 24. Suction apertures 8 may be also formed in a radially external surface of a ring shaped suction wall 26 provided in the fastening cavity 5 radially
inside with respect to the sewing slots 11, 13.

[0032] The anvil moving mechanism is connected through one or more flexible anvil movement transmitters with an extracorporeal anvil movement activation mechanism provided e.g. at a proximal handle portion of the applier 1. The stitching mechanism 9 can be mechanically activated by flexible rotation transmitters or it can be electrically energized by flexible electric cables. Both

[0033] the anvil movement transmitters and the stitching movement transmitters or electric cables are arranged inside the flexible shaft 27 of the applier 1.

[0034] In accordance with a further embodiment (Figures 12 through 15), the fastening assembly 4 forms a continuous annular needle path 28 which crosses the fastening cavity 5 and which is formed inside an unobstructed disentangling space 29 defined inside the fastening assembly 4, and the stitching mechanism 9 comprises a needle 30 and needle drive assembly 31 arranged for movement of the needle 30 along the needle path 28. A suture 17 is secured to the needle 30 and extends from the needle 30 through the disentangling space 29 and through the fastening cavity 5 outside the fastening assembly 4, so that the needle 30 can repeatedly move along the entire needle path 28 (with the attached suture thread 17 repeatedly forming and disentangling open loops, compare Figure 13A, and) without winding the suture 17 around any part of the fastening assembly 4.

[0035] A thus configured applier allows a sequential acquisition and suturing of a plurality tissue and lining portions along a circumference of the hollow organ by a single continuous suture thread, thereby creating a purse string suture which secures the lining 2 to the wall of the hollow organ, particularly of a section of GI tract.

[0036] Specifically, the applier 1 can be positioned with the fastening cavity 5 over a portion of tissue 6 and lining 2, acquire the tissue portion 6 and lining 2 in the fastening cavity (by suction), sending the needle 30 with the suture 17 through the acquired tissue portion and lining, then releasing the tissue portion and lining from the fastening cavity 5, rotating or moving the fastening cavity 5 to the next portion of tissue and lining and moving the needle 30 along the annular needle path 28 to an initial needle position (without entangling the suture 17, compare Figure 13A), and repeating the same sequence until a complete running suture, e.g. a circumferential purse string suture, is created (Figure 15).

[0037] In order to facilitate a rotation of the fastening assembly 4 to a subsequent tissue portion and lining region and, at the same time, enable a suture feeding to and through the previously sutured portions of tissue and lining, the fastening assembly 4 may comprise an
externally continuously open annular suture feeding channel 32 which extends all around the fastening assembly 4 and which is adapted for feeding the suture 17 from any point along the suture feeding channel 32.

For this purpose, a reel 33 of suture 17 may be arranged inside the suture feeding channel 32 and adapted to slide along the suture feeding channel 32, thereby allowing the suture 17 to be unwound from the reel 33 along any point of a circumference of the fastening assembly 4.

In accordance with an embodiment, the fastening assembly 4 comprises a side wall 34 which develops circumferentially about a longitudinal axis X. The fastening cavity 5 is formed in the side wall 34 and has a circumferential extension with respect to the axis X and a longitudinal axial extension parallel to the axis X, wherein the circumferential extension is preferably smaller than the axial extension. The fastening cavity 5 is delimited by a first sewing surface 10 and an opposite second sewing surface 12 which define a needle outlet aperture 35 (in the first sewing surface 10) and an opposite needle inlet aperture 36 (in the second sewing surface 12). The first and second sewing surfaces 10, 12 may be planar and parallel to the longitudinal axis X and may define planes which are radially oriented with respect to the longitudinal axis X. The needle path 28 may be circular and may extend coaxially and perpendicular to the longitudinal axis X of the fastening assembly 4, whereas the disentangling space 29 may be provided as an internally open disc-shaped empty space which encloses the needle path 28 and which is externally delimited and partially closed by the side wall 34 of the fastening assembly 4. The disentangling space 29 intersects the first and second sewing surfaces 10, 12 and the fastening cavity 5 at the needle outlet aperture 35 and needle inlet aperture 36.

The suture feeding channel 32 can be formed in the side wall 34 separate and at a distance from the fastening cavity 5, thereby preventing the end of the suture which is fed out of the feeding channel 32 to become entangled with the suture end secured to the needle 30. The suture feeding channel 32 may have a substantially circular shape and extend perpendicular to the longitudinal axis X around a circumference of the side wall 34.

In this embodiment, the suction apertures 8 may be formed in the sewing surfaces 10, 12 or, alternatively, the suction apertures 8 may open in the disentangling space 29 which is in communication with the fastening cavity 5.

Also, the opposing sewing surfaces 10, 12 may be movable towards each other by a moving mechanism 37. In accordance with an embodiment (Figures 12, 13) the opposing sewing surfaces 10, 12 are formed on two jaws 38 which are movable towards each other.
and away from each other for clamping the acquired tissue portion 6 and lining 2 before passing the needle 30 through them, and for releasing the tissue portion and lining after the passage of the needle 30.

[0043] In the exemplary embodiment of figure 12, the jaws 38 are rotatable about an axis parallel to the longitudinal axis X or about the longitudinal axis X in order to improve the compatibility of the jaw movement and the circular needle path 28.

[0044] For the purpose of releasing the sutured tissue portion 6 and lining 2 from the fastening cavity, a pushing fluid, e.g. air or C0₂ or saline solution may be pumped through (a suction line connected with) the suction apertures 8 into the fastening cavity 5 or through a separate fluid feeding line with apertures opening into the fastening cavity 5. Also for the purpose of deploying and or unfolding the lining 2, a pushing fluid, e.g. air or C0₂ or saline solution may be pumped through (a suction line connected with) the suction apertures 8 into the fastening cavity 5 or through a separate fluid feeding line with apertures opening into the fastening cavity 5.

[0045] The needle drive assembly 31 is adapted to move the needle 30 along the needle path 28, release the needle 30 after having pushed the needle 30 out of the needle outlet aperture 35 into the fastening cavity 5, and catch the needle 30 when it enters the needle inlet aperture 36. For this purpose the needle drive assembly 31 may comprise a plurality of rotatable toothed gear wheels 39 or toothed sliders arranged along the needle path 28, but outside the disentangling space 29, and engaging a toothed surface 40 of the needle 30. The needle 30 itself may have a guide portion 41 which slidingly engages a guide 42 extending along the needle path 28 and adapted to guide and stabilize the needle 30 during its movement along the needle path 28.

[0046] In accordance with a yet further embodiment (Figures 16, 17, 18), the fastening assembly 4 forms a plurality of fastening cavities 5 arranged along a circumference of the fastening assembly 4 and a continuous annular needle path 28 which crosses all fastening cavities 5 and which extends inside a continuously radially externally open annular sewing groove 43 formed along a circumference of the fastening assembly 4. The stitching mechanism 9 comprises a needle 30 and a needle drive assembly 31 arranged for movement of the needle 30 along the needle path 28. A suture 17 is secured to the needle 30 and extends from the needle 30 inside the annular sewing groove 43, so that the needle 30 can repeatedly move along the entire needle path 28 (Figure 17) and the resulting loop of suture 17 can be moved radially out of the sewing groove 43 (Figure 18).

[0047] This embodiment allows to contemporaneously acquire a plurality of tissue portions
6 and lining portions along a circumference around the fastening assembly 4, then sending
the needle 30 successively through all acquired tissue and lining portions, thereby obtaining
a running purse string suture between the lining 2 and the tissue of the hollow organ 3, and
eventually releasing the purse string sutured tissue and lining from the applier 1.

[0048] In accordance with an embodiment, a suture feeder, e.g. a reel 33 of suture may be
arranged inside the fastening assembly 4 and adapted to release the suture 17 through a
feeding channel 32 which opens into the sewing groove 43, preferably near a needle outlet
aperture 35 at one of the fastening cavities 5. In this way the needle 30 can be sent one or
more times along the entire annular needle path 28 and through the acquired tissue and
lining portions, while the required suture 17 is fed through the feeding channel 32 near a
first entrance point of the suture 17 in the tissue and lining.

[0049] Similar to the embodiment of figures 12 to 14, also in the embodiment of figures 16
to 18 the fastening assembly 4 may comprise a side wall 34 which develops
circumferentially about a longitudinal axis X. The fastening cavities 5 are formed in the side
wall 34 and have each a circumferential extension with respect to the axis X and a
longitudinal axial extension parallel to the longitudinal axis X, wherein the circumferential
extension is preferably smaller than the axial extension. Each fastening cavity 5 can be
delimited by a first sewing surface 10 and an opposite second sewing surface 12 which
define a needle outlet aperture 35 (in the first sewing surface 10) and an opposite needle
inlet aperture 36 (in the second sewing surface 12). The first and second sewing surfaces
10, 12 may be planar and parallel to the longitudinal axis X and may define planes which
are radially oriented with respect to the longitudinal axis X. The needle path 28 may be
circular and may extend coaxially and perpendicular to the longitudinal axis X of the
fastening assembly 4, whereas the sewing groove 43 may be provided as an externally
open ring groove which encloses the needle path 28 and which intersects the sewing
surfaces 10, 12 and the fastening cavity 5 at the needle outlet apertures 35 and needle inlet
apertures 36.

[0050] Also in this embodiment, the suction apertures 8 may be formed in the sewing
surfaces 10, 12 or, alternatively, the suction apertures 8 may open into the fastening
cavities 5 from a radially internal side of the fastening cavities 5, as illustrated in figures 16
and 17.

[0051] Also, the opposing sewing surfaces 10, 12 may be movable towards each other by a
moving mechanism 37. In accordance with an embodiment the opposing sewing surfaces
10, 12 are formed on two jaws 38 which are movable towards each other and away from
each other for clamping the acquired tissue portions 6 and lining 2 before suturing, and for releasing the tissue portions and lining after completion of the suture.

[0052] In the exemplary embodiment of figure 16, the jaws 38 are rotatable about an axis parallel to the longitudinal axis X or about the longitudinal axis X in order to improve the compatibility of the jaw movement and the circular needle path 28.

[0053] For the purpose of releasing the sutured tissue portion 6 and lining 2 from the fastening cavities, a pushing fluid, e.g. air or CO₂ or saline solution may be pumped through (a suction line connected with) the suction apertures 8 into the fastening cavities 5 or through a separate fluid feeding line with apertures opening into the fastening cavities 5.

[0054] Alternatively or additionally, the fastening assembly 4 may be radially expandable and/or retractable in a manner to stretch the suture circumferentially (while feeding suture into the stretching zone to avoid rupture of the suture) and/or to withdraw radially from the released sutured tissue and lining. A radially expansion of the fastening assembly can be e.g. obtained through a wedge mechanism adapted to drive a e.g. conical wedge slider between a plurality of circumferentially arranged expansion segments 44 of the fastening assembly 4.

[0055] The needle drive assembly 31 is adapted to move the needle 30 along the needle path 28, release the needle 30 after having pushed the needle 30 out of the needle outlet aperture 35 into the fastening cavity 5, and catch the needle 30 when it enters the needle inlet aperture 36. For this purpose the needle drive assembly 31 may comprise a plurality of rotatable toothed gear wheels 39 or toothed sliders arranged along the needle path 28 and meshing with a toothed surface 40 of the needle 30. The needle 30 itself may have a guide portion 41 which slidingly engages a guide 42 extending along the needle path 28 and adapted to guide and stabilize the needle 30 during its movement along the needle path 28.

[0056] In order not to hinder the removal of the applier 1 from the sutured tissue and lining, the length of the needle 30 may be such that the needle 30 can be stopped within at least one section of the fastening assembly 4 without protruding into a fastening cavity 5. Alternatively, after releasing some of the tissue and lining portions from some of the fastening cavities 5 the needle 30 may be moved partially into an emptied fastening cavity 5, thereby withdrawing from a previously partially occupied neighboring fastening cavity 5.

[0057] Figure 19 illustrates a yet further method and device for securing a lining inside a hollow organ. A flexible endoluminal suturing device 45 with a rotatable and steerable shaft 46 and a distal clip applier 47 can be advanced through an instrument channel 48 of an endoscope 49 and is adapted to secure a lining in any desired section of the GI tract, e.g. at
the esophagus, pylorus or duodenum. The clipping or suturing technique implemented by
the device 45 may comprise also clipping and suturing techniques known from laparoscopic
suturing devices. Thanks to the steerable shaft 46, the device can comfortably apply a
suture or clip along a 360° circumference of lumen and lining. Specifically, a flexible
endoscope is transorally inserted through the mouth and esophagus into the stomach and
from the stomach further through the pylorus into the duodenum up to a target section of
small intestine to which the lining is intended to be secured. The lining is transported to the
target section of intestine by the endoscope. For instance, the lining may be inserted over a
distal portion of the endoscope and released (e.g. pushed distally away) from the
endoscope after the latter has reached the target section of intestine. Alternatively, the
lining may be fed through an instrument channel of the endoscope and expelled from the
instrument channel at the distal end of the endoscope. After positioning a proximal
anchoring portion of the lining within the target section of intestine, the flexible suturing
device 45 with the rotatable and steerable shaft 46 and the distal clip applier 47 is passed
through the instrument channel of the endoscope so that a rotatable and steerable distal
end portion of the shaft 46 with the clip applier 47 protrudes outside the endoscope. Then
the shaft 46 is bent laterally so that the clip applier 47 can engage the lining and the
surrounding intestinal wall in a first securing point. By activating the clip applier 47, the
lining is secured to the intestinal wall in said first securing point. Subsequently, the clip
applier 47 is recharged and prepared for the application of a further clip or suture. The
rotatable and steerable shaft 46 is then rotated at a suitable angular pitch with respect to
the first securing point and bent laterally (radially outward) to engage the lining and the
surrounding tissue in a further securing point. The clip applier is again activated to apply a
second clip or suture to the lining and tissue, thereby securing the lining also in the further
securing point. The procedure can be repeated until the lining is secured to the surrounding
tissue in a plurality of securing points along a circumference of the lining. After completion
of the anchoring step, the distal end portion of the shaft is straightened and proximally
withdrawn into the instrument channel of the endoscope. Then the entire suturing device 45
is withdrawn through the instrument channel of the endoscope and out of the patient's
body.

[0058] Figure 20 illustrates a yet further method and device for securing a lining inside a
hollow organ. A flexible endoluminal grasping device 50 with a grasper 51 adapted to
create small folds 52 of tissue and lining is combined with a suturing device 53 adapted to
apply a T-tag or to stitch a needle 30 with a suture thread 17 through the fold 52. Also in
this case the combined device is rotatable to reach any desirable position along a 360° perimeter of tissue lumen and lining.

[0059] The lining 2 intended to form an endoluminal bypass conduit may be formed of any suitable biocompatible graft material such as polyester or PTFE, rubber, Teflon, Nylon, Dacron, polyethylene, polystyrene, polyurethane, polyethylene terephthalate, etc. In accordance with a further embodiment, both the lining 2 and the running suture could be bioabsorbable and adapted to completely dissolve over time.

[0060] 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 applier (1) for anchoring a tubular lining (9) to a hollow organ (10), the applier (1) comprising:
   - a fastening assembly (4) forming a fastening cavity (5) adapted to receive a tissue portion (6) of the hollow organ (3) together with a portion of the lining (2),
   - a suction device (7) with one or more suction apertures (8) opening into the fastening cavity (5) for acquiring the tissue portion (6) and lining (3) into the fastening cavity (5),
   - a stitching mechanism (9) adapted to stitch into the fastening cavity (5) and to apply a running suture to the acquired tissue portion (6) and lining (2).

2. Endoluminal applier (1) according to claim 1, in which the fastening cavity (5) has a first sewing surface (10) defining a first sewing slot (11) extending along a stitching path and an opposite second sewing surface (12) facing the first sewing surface (10) and defining a second sewing slot (13) extending along the stitching path, wherein the stitching mechanism (9) comprises a perforating needle (14) arranged in the first sewing slot (11), a thread catch (15) arranged in the second sewing slot (13), and a needle driving assembly (16) adapted to:
   - repeatedly moving the perforating needle (14) and the thread catch (15) with respect to each other to create said running suture through the fastening cavity (5),
   - moving the perforating needle (14) and the thread catch (15) along the first and second sewing slots (11, 13) thereby extending the running suture along said stitching path.

3. Endoluminal applier (1) according to claim 2, in which the fastening assembly (4) comprises a proximal portion (18) having an annular distal clamping surface which forms the first sewing surface (10), and a distal anvil (19) having an annular proximal clamping surface which faces the distal clamping surface and forms the second sewing surface (12), the anvil (19) being movable relative to the proximal portion (18) for clamping the acquired tissue portion (6) and lining between the first and second sewing surfaces (10, 12).

4. Endoluminal applier (1) according to claim 3, in which the sewing slots (11, 13) have a closed annular shape.

5. Endoluminal applier (1) according to claim 1, wherein the fastening assembly (4) forms a continuous annular needle path (28) which crosses the fastening cavity (5) and which is formed inside an unobstructed disentangling space (29) inside the fastening assembly (4), wherein the stitching mechanism (9) comprises a needle (30) and needle drive assembly (31) arranged for movement of the needle (30) along the needle path (28), wherein a suture (17) is secured to the needle (30) and extends from the needle (30) through the
disentangling space (29) and through the fastening cavity (5) outside the fastening assembly (4), so that the needle (30) can repeatedly move along the entire needle path (28) without winding the suture (17) around any part of the fastening assembly (4).

6. Endoluminal applier (1) according to claim 5, wherein the fastening assembly (4) comprises an externally continuously open annular suture feeding channel (32) extending all around the fastening assembly (4) and a suture feeder adapted for feeding the suture (17) from inside the suture feeding channel (32) at any point along the suture feeding channel (32).

7. Endoluminal applier (1) according to claim 5 or 6, wherein said suture feeding channel (32) is formed separate and at a distance from the fastening cavity (5).

8. Endoluminal applier (1) according to any one of claims 5 to 7, wherein the needle path (28) is circular and extends coaxially to the longitudinal axis (X), and the disentangling space (29) is an internally open disc-shaped empty space which encloses the needle path (28) and intersects the fastening cavity (5).

9. Endoluminal applier (1) according to claim 1, in which the fastening assembly (4) comprises:
   - a plurality of said fastening cavities (5) arranged along a circumference of the fastening assembly (4),
   - a continuous annular needle path (28) crossing all fastening cavities (5) and extending inside a continuously radially externally open annular sewing groove (43) formed along a circumference of the fastening assembly (4),

wherein the stitching mechanism (9) comprises a needle (30) and needle drive assembly (31) arranged for movement of the needle (30) along the needle path (28), and a suture (17) secured to the needle (30) and extended from the needle (30) inside the annular sewing groove (43), such that the needle (30) can repeatedly move along the entire needle path (28) and the suture (17) can be moved radially out of the sewing groove (43).

10. Endoluminal applier (1) according to claim 9, in which the fastening assembly (4) is radially expandable and retractable.

11. Endoluminal applier (1) according to any one of claims 5 to 10, wherein the fastening assembly (4) comprises a side wall (34) which develops circumferentially about a longitudinal axis (X) and the one or more fastening cavities (5) are formed in the side wall (34) and have each a circumferential extension with respect to the axis (X) and a longitudinal axial extension parallel to the longitudinal axis (X), said circumferential extension being smaller than said axial extension.
12. Endoluminal applier (1) according to any one of claims 5 to 11, wherein said one or more fastening cavities (5) are each delimited by a first sewing surface (10) forming a needle inlet aperture (35) and an opposite second sewing surface (12) forming a needle outlet aperture (36), said fastening assembly comprising a moving mechanism (37) operable to move said first and second sewing surfaces (10, 12) towards each other.

13. Endoluminal applier (1) according to any one of the preceding claims, in which the suction device (7) is adapted for a pushing fluid to be pumped through the suction apertures (8) into the fastening cavity (5).

14. Method for endoluminally securing a lining inside a target section of a gastrointestinal tract, the method comprising:

A) transorally inserting a flexible endoscope to the target section of the GI tract, the endoscope having a longitudinal instrument channel;

B) transorally inserting a flexible lining to the target section of GI tract;

C) advancing a suturing device through the instrument channel of the endoscope to the target section of the GI tract, the suturing device having a flexible shaft with a rotatable and steerable distal end portion and a distal clip applier provided at a distal end of the shaft;

D) bending the distal end portion of the shaft laterally and engaging the lining and the surrounding intestinal wall by means of said clip applier in a first securing point;

E) then activating the clip applier to secure the lining to the intestinal wall in said first securing point;

F) subsequently rotating the distal end portion of the shaft with respect to the first securing point and bending the distal end portion of the shaft laterally to engage the lining and the surrounding tissue in a further securing point;

G) then activating the clip applier to secure the lining to the intestinal wall in said further securing point;

- repeating steps E to G until the lining is secured to the surrounding tissue in a plurality of securing points along a circumference of the lining;

H) straightening the distal shaft portion and proximally withdrawing the straightened distal shaft portion into the instrument channel of the endoscope.
A. **CLASSIFICATION OF SUBJECT MATTER**

**INV. A61B17/04**

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)

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 practicable, search terms used)

EPO-Internal, WPI Data

C. **DOCUMENTS CONSIDERED TO BE RELEVANT**

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<th>Relevant to claim No.</th>
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<td>GB 2 200 072 A (UNIV LONDON UNIV LONDON [GB]) 27 July 1988 (1988-07-27) page 3, paragraph 5 - page 6, paragraph 2</td>
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<td>Y</td>
<td>US 2010/160934 AI (KELLEHER BRIAN [US] ET AL) 24 June 2010 (2010-06-24) paragraph [0133]; figures 30-37</td>
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<td>X</td>
<td>US 5 891 159 A (SHERMAN BENJAMIN [US] ET AL) 6 April 1999 (1999-04-06) col umn 10, lines 57-59</td>
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Further documents are listed in the continuation of Box C.

See patent family annex.

*X* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"A" document member of the same patent family

Date of the actual completion of the international search: **19 November 2012**

Date of mailing of the international search report: **28/11/2012**

Name and mailing address of the ISA:

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer: **Angel i, Markus**

Form PCT/ISA/210 (second sheet) (April 2005)
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### Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. **Claims Nos.:**
   - 14
   - because they relate to subject matter not required to be searched by this Authority, namely:
     - Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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

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

### Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

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.
- [x] No protest accompanied the payment of additional search fees.
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-4

   An endoluminal applicator with a needle driving assembly adapted to move the perforating needle and the thread catching along the first and second sewing slots.

2. claims: 5-12

   An endoluminal applicator with a needle fastening assembly forming a continuous annular needle path for repeatedly moving the needle along the entire needle path without winding the suture around any part of the fastening assembly.