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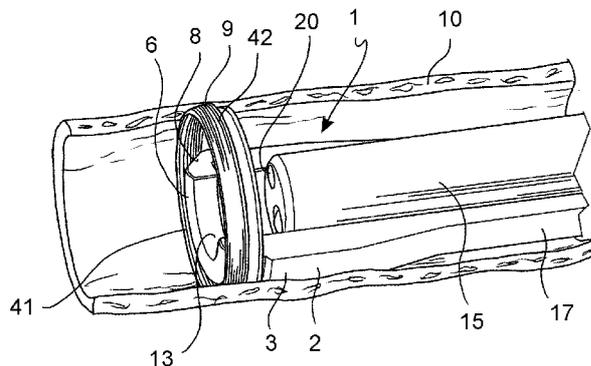


FIG. 2

(57) **Abstract:** An endoluminal applier (1) for anchoring a tubular lining (9) to a hollow organ (10) comprises a staple fastening assembly (2) with an open arch shaped cartridge device (3) and an open arch shaped anvil (6) movable relative to the cartridge device (3) for clamping a tissue portion between first and second clamping surfaces (5, 7) and adapted to form the ends of staples exiting from the cartridge device (3), wherein the staple fastening assembly (2) comprises an open arch shaped lining seat (8) adapted to unilaterally holding the tubular lining (9) such that a ring shaped anchoring portion (12) of the lining (9) is constrained to overlap one of the clamping surfaces (5, 7) and the row of staples (4) along a first part (41) of a circumference of the anchoring portion (12), and the anchoring portion (12) extends outside said clamping surfaces (5, 7) along a second part (42) of its circumference.



"AN APPLIER AND A METHOD FOR ANCHORING A LINING TO A HOLLOW ORGAN"

DESCRIPTION

FIELD OF THE INVENTION

5 [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

10 [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.

15 [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.

20 [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

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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 a good visual control and verification of the correct target site for anchoring the endoluminal sleeves.

[0010]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.

[0011]Moreover, the known devices and methods do not sufficiently address the needs and specific problems arising in case of removal, substitution or relocation of endoluminal sleeves.

[0012]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

[0013]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.

[0014]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 staple fastening assembly with an open arch shaped cartridge device which houses at least one open arch shaped row of staples and which forms a first clamping surface, and an open arch shaped anvil which forms a staple forming surface and a second clamping surface facing the first clamping surface. The anvil is movable relative to the cartridge device and is adapted to cooperate with the cartridge device for clamping a tissue portion between the first and second clamping surfaces and forming the ends of the staples exiting from the cartridge device.

[0015]The staple fastening assembly comprises an open arch shaped lining seat adapted to unilaterally holding the tubular lining such that:

- a ring shaped anchoring portion of the lining is constrained to overlap one of said clamping surfaces and said row of staples along a first part of a circumference of the anchoring portion, and
- the anchoring portion extends outside said clamping surfaces along a second part of its circumference.

[0016]This assures a correct relative positioning between the first circumferential part of the anchoring portion, the row of staples and the clamping surfaces, while leaving the second circumferential part of the anchoring portion unconstrained.

This permits the surgeon to fasten the lining within a GI tract by stapling its anchoring portion only partially around its circumference, or by progressively stapling selected circumferential sections of the anchoring portion in a selectable sequence. Moreover, the partially constrained lining and the open clamping surfaces allow bending, pulling and deformation of both the lining and the intestinal wall tissue near the staple row during clamping and stapling, which makes the use of the applier much more flexible and versatile compared to a circular stapler which would constrain the lining and the intestinal wall along the entire circumference.

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[001 7]The applier allows an easy and reliable extracorporeal initial positioning of the lining on the lining seat and a safe endoluminal insertion of the applier, but it allows also to select subsequent stapling positions along the circumference of the lining in dependency of the actual anatomical conditions and their changes during surgery.

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[001 8]In accordance with an aspect of the invention, the staple fastening assembly forms a laterally open channel extending longitudinally along the cartridge device and the anvil, the open channel being adapted for attaching the applier to an endoscope to visualize both the space between the first and second clamping surfaces and the space distally ahead of the staple fastening assembly and, possibly, to slide the applier endoluminally along said endoscope to a target site in the hollow organ.

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[001 9]The applier allows an improved guidance through the GI tract and continuous visualization by the endoscope received in the open channel, both during endoluminal insertion and withdrawal of the applier and during fastening of the staples.

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[0020]In accordance with a further aspect of the invention, the applier comprises a tissue acquisition mechanism adapted to acquire a tissue portion of the hollow organ in the space between the first and second tissue clamping surfaces. The tissue acquisition mechanism may comprise opposing proximal and distal hook means arranged at the anvil and at the cartridge device and movable towards each other by approximating the anvil to the cartridge device. The hook means are movable in a retracted position inside the staple fastening assembly and in a

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protruding position outside the staple fastening assembly and, in the protracted position, the hook means can hook in a tissue adjacent to the staple fastening assembly and push the tissue between the first and second clamping surfaces during approximation of the anvil to the cartridge device.

5 [0021] In this manner, the tissue acquisition and the immediately following clamping of the acquired tissue and the anchoring portion of the lining is accomplished by a single approximation movement of the anvil to the cartridge device.

[0022] These and other aspects and advantages of the present invention shall be
10 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

15 -Figure 1 is an exploded view of an endoluminal applier for anchoring a tubular lining to a hollow organ, a compacted tubular lining and an endoscope in accordance with an embodiment;

-Figure 2 illustrates the applier of figure 1 in a closed configuration inside (a longitudinally sectioned) portion of intestine;

20 -Figure 3 illustrates the applier of figure 1 in an open configuration inside (a longitudinally sectioned) portion of intestine;

-Figure 4 illustrates a transoral introduction of the applier of figure 1 to a duodenum;

25 -Figure 5 illustrates a method step in which the applier is opened after positioning in a target location in the GI tract;

-Figure 6 illustrates an especially adapted applier and a method for acquiring tissue of the hollow organ (e.g. intestine) to which the tubular lining is intended to be fastened;

30 -Figure 7 illustrates the applier in a closed configuration in which the acquired tissue and an anchoring portion of the lining is clamped between an anvil and a cartridge device of the applier ready for the application of the fasteners;

-Figure 8 is a schematic cross-sectional view of a tubular lining anchored to a

target location of the hollow organ, but still in a collapsed or packed shape;

-Figure 9 illustrates the tubular lining after anchoring and full extension within a section of the GI tract;

-Figure 10 illustrates different possible positions of the tubular lining within the GI tract of a patient;

-Figure 11A illustrates an anchoring portion for a tubular lining after anchoring within a section of the GI tract;

-Figure 11B illustrates a tubular lining connected to the previously placed anchoring portion in figure 11A;

-Figure 12 is a partial side view of the applier in accordance with a further embodiment;

-Figure 13 is sectional view in plane XIII-XIII in figure 12;

-Figures 14 and 15 are partial side views of the applier during method steps in accordance with a further embodiment,

-Figure 16 illustrates the applier in accordance with a further embodiment in an open configuration;

-Figure 17 is a partial side view of the applier in accordance with a further embodiment;

-Figure 17A is a enlarged view of a detail in figure 17;

-Figure 18 illustrates the applier in figure 17 during a tissue acquisition step;

-Figures 19 and 20 are schematic illustrations of staple driving mechanisms of the applier in accordance with embodiments of the invention;

-Figure 21 illustrates the applier during a tissue acquisition step in accordance with a further embodiment.

DETAILED DESCRIPTION OF EMBODIMENTS

[0023]Referring to the drawings where like numerals denote like anatomical structures and components throughout the several views, figures 1 and 2 depict an endoluminal applier 1 for anchoring a tubular lining 9 to a hollow organ 10, particularly to a section of the GI tract of a patient. The applier 1 comprises a staple fastening assembly 2 with an open arch shaped cartridge device 3 which houses at least one open arch shaped row of staples 4 and which forms a first clamping surface 5, and an open arch shaped anvil 6 which forms a staple forming

surface 33 and a second clamping surface 7 facing the first clamping surface 5. The anvil 6 is movable relative to the cartridge device 3 and is adapted to cooperate with the cartridge device 3 for clamping a tissue portion between the first and second clamping surfaces 5, 7 and forming the ends of the staples exiting from the cartridge device 3.

[0024]The staples 4 may comprise titanium staples intended to permanently remain anchored in the stapled tissue ring or, time dependently biodegradable or bioabsorbable staples for a temporary anchoring of bypass sleeves in the hollow organ.

[0025]The staple fastening assembly 2 further comprises an open arch shaped lining seat 8 adapted to unilaterally holding the tubular lining 9 such that:

- a ring shaped anchoring portion 12 of the lining 9 is constrained to overlap one of the clamping surfaces 5, 7 and the row of staples 4 along a first part 41 of a circumference of the anchoring portion 12, and

- the anchoring portion 12 extends outside said clamping surfaces 5, 7 along a second part 42 of its circumference.

[0026]This assures a correct relative positioning between the first circumferential part 41 of the anchoring portion 12, the row of staples 4 and the clamping surfaces 5, 7, while leaving the second circumferential part 42 of the anchoring portion 12 unconstrained by the lining seat 8. This permits the surgeon to fasten the lining 9 within a GI tract by stapling its anchoring portion 12 only partially around its circumference, or by progressively stapling selected circumferential sections of the anchoring portion 12 in a selectable sequence. Moreover, the only partially constrained lining and the clamping surfaces which act on only a part of the circumference of the lining 9 (but also of the involved tissue) allow bending, pulling and deformation of both the lining and the intestinal wall tissue near the staple row 4 during clamping and stapling. This makes the use of the applier 1 much more flexible and versatile compared to a circular stapler which would constrain the lining and the intestinal wall along the entire circumference.

[0027]In accordance with an embodiment, the unconstrained second part 42 of the circumference of the anchoring portion 12 has an angular extension of 120° to 240°, preferably of 160° to 200°, even more preferably of about 180°.

[0028]Accordingly, the open arch shape of the cartridge device 3 and of the anvil 6 defines a circular arch of 120° to 240°, preferably of 160° to 200°, even more preferably of about 180°(semi-circular shape).

[0029]In accordance with an embodiment, the lining seat 8 is further adapted to
5 hold an elongate body portion 11 of the lining 9 in a collapsed (substantially ring shaped), e.g. wrapped, folded, compressed or rolled up, configuration with regard to a lining longitudinal extension.

[0030]In accordance with an embodiment, the lining seat 8 is formed in the anvil 6 and comprises a distal containment wall 29 (Figure 12) against which the
10 collapsed and "packed" tubular lining 9, e.g. an endoluminal sleeve, rests so that it keeps its relative position with respect to the second clamping surface 7. The lining seat 8 may further contribute to hold the lining 9 in its collapsed and "packed" shape until the lining 9 is pulled or pushed distally over the containment wall 29.

[0031]The staple fastening assembly 2 forms a longitudinally extending laterally
15 open channel 13 on a concave side of the cartridge device 3 and on a concave side of the anvil 6. The open channel 13 is adapted for attaching the applier 1 to an endoscope 15 to visualize both the clamping space 14 between the first and second clamping surfaces 5, 7 and the space distally ahead of the staple fastening
20 assembly 2 and, possibly, to slide the applier 1 endoluminally along the endoscope 15 to a target site in the hollow organ 10 or to guide the entire applier 1 or at least the staple fastening assembly 2 by means of the endoscope 15 endoluminally to the target site.

[0032]In accordance with embodiments, the endoscope 15 can be a flexible
25 standard endoscope or a component of the applier 1 especially configured to fit in the lateral open channel 13 thereof and to perform, additional to visualization and guidance, further functions of the applier, such as e.g. tissue acquisition which will be described further below.

[0033]In accordance with an embodiment, the staple fastening assembly 2 is
30 provided at a distal end 16 of a flexible shaft 17 which can be slidably or fixedly attached to the endoscope 15.

[0034]However, it is important to note that the cartridge device 3 with the first

clamping surface 5 and the anvil 6 with the second clamping surface 7 have a laterally open arch shape so that selected regions of the lining anchoring portion 12 around its circumference can be stapled to the surrounding tissue in a freely selectable sequence and the endoscope 15 may be moved laterally out of the channel and any instruments (e.g. endoscopic graspers) guided by the endoscope may move laterally out of the channel 13 (also when the staple fastening assembly 2 is closed during firing of the staples) and reach e.g. an interstice between the applier 1 and the surrounding tissue.

[0035]In accordance with an embodiment, the anvil 6 is translatably connected to the cartridge device 3 by at least one, preferably two anvil shafts 25 slidably received in one or more guide holes 28 of the cartridge device 3 and connected with a moving mechanism adapted to move the anvil 6 relative to the cartridge device 3. The two guide holes 28 and the two anvil shafts 25 are arranged at two opposite lateral ends of the anvil 6 and cartridge device 3.

[0036]Alternatively, only one guide hole 28 and the associated anvil shaft 25 is arranged at one lateral end of the anvil 6 and cartridge device 3, so that the anvil 6 protrudes as a cantilever from the anvil shaft 25.

[0037]The anvil shaft 25 or shafts may be arranged circumferentially outside the row of staples 4 (Figure 13). Alternatively, the anvil shaft 25 or shafts may be arranged circumferentially within the extension of the row of staples 4, but radially inside the row of staples 4, in order to allow the applier to be withdrawn from the stapled seam.

[0038]The anvil shafts 25 can have a very limited circumferential extension in order to not obstruct the visualization of the tissue clamping space 14.

[0039]The anvil shafts 25 comprise preferably hollow tubular profiles with a high torque resistance for a given external dimension and their total circumferential extension with regard to a longitudinal axis of the applier 1 is less than 90°, preferably less than 45°, even more preferably less than 30°, in order to leave sufficient unobstructed space between the shafts 25 to allow the clamping space 14 to be comfortably visualized and accessed.

[0040]In accordance with an exemplary embodiment (Figures 14 and 15), the tubular lining 9 or sleeve is held in its substantially ring shaped collapsed or

"packed" configuration by means of a removable wrap 31, e.g. a casing or packing string. The wrap 31 has a stripping portion 32 connectable to the applier 1, for example to a dedicated stripping catch of the lining seat 8, such that upon removing the applier 1 from the anchored lining 9 over a certain distance, the stripping portion 32 is pulled and breaks or removes the wrap 31 from the lining 9 (Figure 15), which is now released to unfold longitudinally. For this purpose, a distal end of the lining may be provided with one or more concentrated masses 34, such as metallic rings or spheres which facilitate a longitudinal extension of the lining along the planned section of the GI tract.

5 [0041] In accordance with an embodiment, the removable wrap 31 is configured to hold the lining so that the ring shaped anchoring portion 12 protrudes radially inward from the remaining elongate body portion 11. This allows to easily access and staple circumferential sections of the anchoring portion 12 during subsequent stapling phases after an initial fastening of the lining 9 to the hollow organ and reduces the risk of perforating the body portion of the lining 9 during stapling.

15 [0042] For this purpose, both the wrap 31 and the staple fastening assembly 2, particularly the lining seat 8 of the anvil 6, may have positioning aids adapted to guide the staple fastening assembly 2 to a plurality of correct positions along the circumference of the anchoring portion 12 held by the wrap 31. The expression "correct positions" indicate positions in which the anchoring portion 12 of the lining 9 overlaps one of the clamping surfaces 5, 7 and the row of staples 4.

[0043] In accordance with an embodiment, the positioning aids may comprise magnetic positioning means 23, 24 (Figure 1) which magnetically attract the staple fastening assembly 2 to a correct position with respect to the anchoring portion 12.

25 [0044] In accordance with an alternative embodiment, the positioning aids may comprise geometric references, e.g. taps or pins formed at the wrap 31 and fitting in corresponding seats formed at the staple fastening assembly 2 or vice versa, only when the staple fastening assembly 2 is correctly positioned with respect to the anchoring portion 12.

30 [0045] In accordance with an embodiment, the applier 1 comprises a tissue acquisition mechanism 18 adapted to acquire a tissue portion 19 of the hollow organ 10 in the clamping space 14 between the first and second clamping

surfaces 5, 7. The tissue acquisition mechanism 18 may be arranged at the staple fastening assembly 2, preferably radially external of the lateral channel 13. In this way, the channel 13 is not obstructed by the tissue acquisition mechanism 18 and allows unobstructed access and visualization by the endoscope 15 also during
5 tissue acquisition.

[0046]Alternatively, the tissue acquisition mechanism 18 and the endoscope 15 may be configured to be received together and contemporaneously in the channel 13, e.g. by passing the tissue acquisition mechanism 18 through an instrument channel 20 of the endoscope 15 while the endoscope 15 is slidably or fixedly
10 received in the channel 13 of the staple fastening assembly 2. In accordance with embodiments, the tissue acquisition mechanism 18 may comprise mechanical graspers (Figure 6), suction means (Figures 12, 13), or hook means (Figures 17, 18).

[0047]Figure 6 shows an exemplary embodiment, in which a grasper 21 is arranged and operable to move from the clamping space 14 radially outward and to grasp the tissue portion 19 of the hollow organ 10 and pull the grasped tissue portion 19 into the clamping space 14, for instance by partial or complete withdrawal of the grasper 21 inside the cartridge device 3 or inside the instrument channel 20 of the endoscope 15. The grasper 21 can be connected through one or
15 more acquisition activation movement transmitters with an extracorporeal acquisition activation mechanism provided e.g. at a proximal handle portion of the applier 1 or near a proximal end portion of the endoscope 15.

[0048]The grasper 21 may be connected directly or indirectly with the staple fastening assembly 2, particularly with the cartridge device 3 in a region radially external of the channel 13 and radially internal of the row of staples 4 or,
25 alternatively, the grasper 21 and the endoscope 15 may be configured to be received together and contemporaneously in the channel 13, e.g. by passing the grasper 21 through the instrument channel 20 of the endoscope 15 while the endoscope 15 is received in the channel 13 of the staple fastening assembly 2.

[0049]Figure 21 illustrates an embodiment in which the tissue acquisition mechanism may have some or all of the features described in connection with the embodiment of figure 6 with the only exception that the grasper 21 is replaced by a
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rotatable and steerable corkscrew retractor 50.

[0050] In accordance with a further exemplary embodiment (Figures 12 and 13), the tissue acquisition mechanism 18 comprises one or more suction apertures 22 connectable by a suction line to a preferably extracorporeal suction pump. The suction apertures 22 are arranged and operable to apply a suction in the clamping space 14 with the aim to acquire surrounding tissue and to hold it between the first and second clamping surfaces 5, 7.

[0051] The suction apertures 22 can be formed in the first clamping surface 5 of the cartridge device 3 in a region extending between the channel 13 and the annular row of staples 4. Alternatively, suction apertures 22 may be also formed in a radially external surface of an arch shaped suction wall 26 provided in the clamping space 14 radially outside the channel 13 and radially inside the row of staples 4. The suction wall 26 may be slidably housed in the cartridge device and movable from a rest position in which the suction wall 26 is proximally retracted inside the cartridge device 3 to an activated position in which the suction wall 26 is distally protracted towards the anvil 6.

[0052] In accordance with an embodiment, the movement of the suction wall 26 between the rest position and the activated position can be linked to and operated in dependency from the movement of the anvil 6 with respect to the cartridge device 3. For instance, upon opening the staple fastening assembly 2, the anvil is moved distally away from the cartridge device 3 and the suction wall 26 is moved in its activated position and upon closing the staple fastening assembly 2, the anvil 6 moves proximally towards the cartridge device 3 and the suction wall 26 is retracted in its rest position.

[0053] In accordance with a yet further embodiment (Figures 17 and 18), the tissue acquisition mechanism 18 may comprise opposing proximal and distal hook means 51, 52 arranged at the cartridge device 3 and at the anvil 6 and movable towards each other by moving the anvil 6 towards the cartridge device 3. The hook means 51, 52 are movable in a retracted position (solid line in Figure 17) inside the staple fastening assembly 2 and in a protruding position (broken line in Figure 17) outside the staple fastening assembly 2. In the protracted position the hook means 51, 52 can hook in the tissue portion 19 adjacent to the staple fastening

assembly 2 and push the hooked tissue portion 19 together and between the first and second clamping surfaces 5, 7 while the anvil 6 moves close to the cartridge device 3.

[0054]The hook means can comprise one or more pointed proximal barbs 51 connected (e.g. hinged) to the cartridge device 3 (e.g. in proximal hook seats formed in the first clamping surface 5) and one or more pointed distal barbs 52 connected (e.g. hinged) to the anvil 6 (e.g. in distal hook seats formed in the second clamping surface 7). The distal hook means or barbs 52 are connected to the anvil 6 radially inside the staple forming surface 33 and movable to the protracted position in which the distal hook means or barbs 52 proximally overlap (or, in other words: extend on a proximal side of) the staple forming surface 33 and the second clamping surface 7.

[0055]In this way, during tissue acquisition and stapling, the anchoring portion 12 of the lining 9 is interposed between the second clamping surface 7 and the distal hook means or barbs 52, thereby obviating the risk of perforating the lining with the barbs.

[0056]In accordance with a further embodiment, the tissue acquisition means may comprise only the above described distal hook means or barbs 52, but not the proximal hook means 51, and acquire the tissue between the clamping surfaces 5, 7 during a proximal movement of the anvil 6 with respect to a surrounding tissue.

[0057]The hook means 51, 52 can be protracted and retracted by a mechanical, spring loaded, magnetic or electrical hook activating mechanism.

[0058]The hook means 51, 52 are shaped so they withdraw from the tissue during opening of the staple fastening assembly 2 without damaging the tissue. After letting go the tissue, the hook means 51, 52 can be reused during a subsequent stapling phase or retracted before the applier 1 is closed and withdrawn from the hollow organ.

[0059]As already mentioned above, the applier 1 comprises an anvil moving mechanism 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, as well as a staple driving mechanism 27 adapted to drive the staples 4 distally out of the staple slots 30 and against the

staple forming surface 33 of the anvil 6.

[0060] Also the staple driving mechanism 27 is connected through one or more flexible driving movement transmitters 43 with an extracorporeal staple firing mechanism provided e.g. at a proximal handle portion of the applier 1. Both the
5 anvil movement transmitters and the driving movement transmitters 43 are arranged inside the flexible shaft 17.

[0061] In accordance with embodiments (Figures 19, 20), the staple driving mechanism 27 is configured to drive individual staples 4 successively out of the staple slots 30 and against the staple forming surface 33 of the anvil 6, thereby
10 minimizing the required staple driving force. The staple driving mechanism 27 may be configured to drive the staples 4 one at the time or with a certain time overlap such that while a staple is about to be formed, the next staple is started to be driven towards the staple forming surface 33.

[0062] In accordance with an embodiment (Figure 19) the staple driving mechanism 27 may comprise a wedge shaped sled or slider 44 guided to move
15 along the row of staples 4 and adapted to engage inclined surfaces of pushers 45 extending inside the staple slots beneath the staples 4, so that the pushers 45 push the staples 4 distally out of the staple slots. The wedge shaped slider 44 is connected to or directly formed as a single piece with a toothed belt 46 which
20 meshes with a gear wheel 47. The gear wheel 47 can be rotated by a torque cable 43 to fire the staples 4.

[0063] Figure 20 illustrates an alternative embodiment in which the wedge shaped slider 44 is connected to or directly formed as a single piece with a pulling cable
25 48 guided about a pulley 49 and extended as pull resistant movement transmitter 43 along the flexible shaft 17.

[0064] The lining 9 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 9 and
30 the staples 4 could be bioabsorbable and adapted to completely dissolve over time.

[0065] Figure 16 illustrates an exemplary embodiment of the applier, in which the

first clamping surface 5 of the cartridge device and the second clamping surface 7 (which provides the staple forming surface 33) of the anvil 6 have a generally wavy shape, which may be obtained by a locally stepped or otherwise offset configuration. Particularly, the stepped first clamping surface 5 is composed of a series of lands 37 and risers 38, wherein the lands 37 are perpendicular to the longitudinal axis X of the staple fastening assembly 2 and the exit openings of the staple slots 30 are defined in the lands 37. Analogously, also the second clamping surface 7 of the anvil is composed of a series of lands 39 and risers 40, wherein the lands 39 are perpendicular to the longitudinal axis X of the staple fastening assembly 2 and the staple forming recesses are defined in the lands 39.

[0066]In both the first clamping surface 5 and the second clamping surface 7, the lands 37, 39 define with the risers 38, 40 an obtuse angle in order to reduce local tissue tensioning during clamping and stapling.

[0067]This allows to create a longer and softer staple seam so that the anchoring site of the tubular lining can follow within certain limits the physiological expansion and retraction movement of the intestine, e.g. during peristalsis.

[0068]Figures 11A and 11B illustrate an embodiment, in which the lining 9 is connected (magnetically, by snap on connecting means or by a bayonet connecting means) to an initially separate permanent anchoring flange 35 which has been anchored in an intestine by means of the applier 1. This embodiment allows the lining 9 to be easily removed and replaced.

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

[0069]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 endosleeve 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 1 with the compacted tubular lining

9 placed over the lining seat 8, as shown in FIG. 1, and attach the applier 1 to the endoscope 15 to guide it under endoscopic visualization down the patient's esophagus and stomach to a target location in the GI tract, e.g. in the duodenum. Once in place, the physician uses the endoscope 15 in the open channel 13 of the applier 1 to view and select an area suitable for the application of the fastener, i.e. the staples.

[0070] Once the applier 1 is positioned in the selected anatomical location, the staple fastening assembly 2 is opened by distal movement of the anvil 6, to expose the clamping space 14 to the surrounding tissue within the duodenum and the tissue acquisition mechanism, either vacuum or mechanical grasping, piercing or hooking, is activated and tissue 19 is drawn into the clamping space 14 along a first portion of the circumference of the lining anchoring portion 12.

[0071] The entire tissue acquisition step may be directly endoscopically visualized by the endoscope 15.

[0072] After the desired amount of tissue 19 has been acquired into the clamping space 14 and clamped between anvil 6 and cartridge device 3, the staple driving mechanism 27 of applier 1 is actuated to engage the row of staples or fastening elements through the acquired tissue segment 19 and through the anchoring portion 12 of lining 9 which is arranged on the anvil to overlap the second clamping surface and the staple forming surface, thereby fastening the lining 9 in place in a partially circumferential fashion. The fastening step can now be repeated in other positions along the circumference of the lining anchoring portion 12. Subsequently, the ring shaped anchoring place can be endoscopically visualized and the applier 1 is removed. In doing so, the anvil 6 of the applier 1 may be pulled through the newly-created ring or plication of stapled tissue 19 and anchoring portion 12 of the lining 9, leaving the yet compacted lining 9 in place. During withdrawal of the applier from the anchored lining, a wrap 31 which holds the lining in the compacted shape may be broken or removed from the lining, allowing the latter to expand and unfold longitudinally along the planned section of the hollow organ, as shown in figures 8 and 9. In this way a bypass conduit is created which would channel food directly from the anchoring place into a target place of the small intestine 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.

[0073] Particularly, the described procedures and devices help to mimic the effects of gastric bypass in resolution of type 2 diabetes and facilitate weight loss, improve

5 glycemic control and reduce or eliminate other co-morbidities of severe obesity.

Moreover, the described procedures and devices 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

10 least, the described procedures and devices allow a reversible procedure with a relatively easy removal or self-removal (by biodegradation) of the endoluminal lining or sleeve once the desired effect has been achieved.

[0074] 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

15 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 staple fastening assembly (2) with an open arch shaped cartridge device (3) which houses at least one open arch shaped row of staples (4) and which forms a first clamping surface (5), and an open arch shaped anvil (6) which forms a staple forming surface (33) and a second clamping surface (7) facing the first clamping surface (5), said anvil (6) being movable relative to the cartridge device (3) for clamping a tissue portion between the first and second clamping surfaces (5, 7) and adapted to form the ends of the staples exiting from the cartridge device (3),
- 5
- wherein the staple fastening assembly (2) comprises an open arch shaped lining seat (8) adapted to unilaterally holding the tubular lining (9) such that:
- a ring shaped anchoring portion (12) of the lining (9) is constrained to overlap one of the clamping surfaces (5, 7) and the row of staples (4) along a first part (41)
 - 15 of a circumference of the anchoring portion (12),
 - the anchoring portion (12) extends outside said clamping surfaces (5, 7) along a second part (42) of its circumference.
2. Endoluminal applier (1) according to claim 1, comprising a tissue acquisition mechanism (18) adapted to acquire a tissue portion (19) of the hollow organ (10)
- 20 in a clamping space (14) between the first and second clamping surfaces (5, 7).
3. Endoluminal applier (1) according to claim 2, wherein the tissue acquisition mechanism comprises opposing proximal and distal hook means (51 , 52) arranged at the cartridge device (3) and at the anvil (6) and movable towards each other by moving the anvil (6) towards the cartridge device (3), said hook means
- 25 (51 , 52) being movable in a retracted position inside the staple fastening assembly (2) and in a protruding position outside the staple fastening assembly (2), wherein in the protracted position the hook means (51 , 52) can hook in the tissue portion (19) adjacent to the staple fastening assembly (2) and push the hooked tissue portion (19) together and in the clamping space (14) while the anvil (6) moves
- 30 close to the cartridge device (3).
4. Endoluminal applier (1) according to claim 3, in which the hook means comprise one or more pointed proximal barbs (51) connected to the cartridge device (3) and

one or more pointed distal barbs (52) connected to the anvil (6) radially inside the staple forming surface (33), wherein the distal barbs (52) proximally overlap the staple forming surface (33) and the second clamping surface (7) in said protracted position.

- 5 5. Endoluminal applier (1) according to claim 2, wherein the tissue acquisition mechanism comprises distal hook means (52) arranged at the anvil (6) and movable in a retracted position inside the staple fastening assembly (2) and in a protruding position outside the staple fastening assembly (2), wherein in the protracted position the hook means (52) can hook in the tissue portion (19)
- 10 adjacent to the staple fastening assembly (2) and push the hooked tissue portion (19) in the clamping space (14) when the anvil (6) is moved proximally with respect to the surrounding tissue.
6. Endoluminal applier (1) according to claim 3 or 5, wherein the hook means (51, 52) are shaped so they withdraw from the tissue during opening of the staple
- 15 fastening assembly (2).
7. Endoluminal applier (1) according to any one of the preceding claims, comprising a staple driving mechanism (27) adapted to drive individual staples (4) successively out of staple slots (30).
8. Endoluminal applier (1) according to claim 7, wherein the staple driving
- 20 mechanism (27) comprises a wedge shaped slider (44) movable along the row of staples (4) and adapted to engage inclined surfaces of pushers (45) arranged inside the staple slots beneath the staples (4), so that the pushers (45) push the staples (4) distally out of the staple slots, the wedge shaped slider (44) being connected to a toothed belt (46) meshing with a gear wheel (47).
- 25 9. Endoluminal applier (1) according to claim 7, wherein the staple driving mechanism (27) comprises a wedge shaped slider (44) movable along the row of staples (4) and adapted to engage inclined surfaces of pushers (45) arranged inside the staple slots beneath the staples (4), so that the pushers (45) push the staples (4) distally out of the staple slots, the wedge shaped slider (44) being
- 30 connected to a pulling cable (48) extending about a pulley (49) and along the flexible shaft (17).
10. Endoluminal applier (1) according to any one of the preceding claims, wherein

the lining seat (8) is adapted to hold an elongate body portion (11) of the lining (9) in a collapsed configuration with regard to a lining longitudinal extension.

11. Endoluminal applier (1) according to any one of the preceding claims, wherein the staple fastening assembly (2) forms a longitudinally extending laterally open
5 channel (13) on a concave side of the cartridge device (3) and on a concave side of the anvil (6), said channel (13) being adapted for attaching the applier (1) to an endoscope (15) such that the endoscope (15) can be moved laterally out of the channel (13).

12. Endoluminal applier (1) according to any one of the preceding claims,
10 comprising a removable wrap (31) which holds the tubular lining (9) in a substantially ring shaped compacted configuration so that the anchoring portion (12) protrudes radially inward from the elongate body portion (11).

13. Endoluminal applier (1) according to claim 12, comprising positioning aids adapted to guide the staple fastening assembly (2) to a plurality of correct stapling
15 positions along the circumference of the anchoring portion (12) held by the wrap (31).

14. Endoluminal applier (1) according to claim 13, in which the positioning aids comprise one of:

- magnetic positioning means (23, 24) which magnetically attract the staple
20 fastening assembly (2) to correct stapling positions with respect to the anchoring portion (12),

- geometric references formed at the wrap (31) and at the staple fastening assembly (2) and fitting into each other only when the staple fastening assembly (2) is correctly positioned with respect to the anchoring portion (12).

25 15. Endoluminal applier (1) according to claim 12, in which the wrap (31) has a stripping portion (32) connectable to the applier (1) such that upon removing the applier (1) from the anchored lining (9) over a distance, the stripping portion (32) is pulled and removes the wrap (31) from the lining (9).

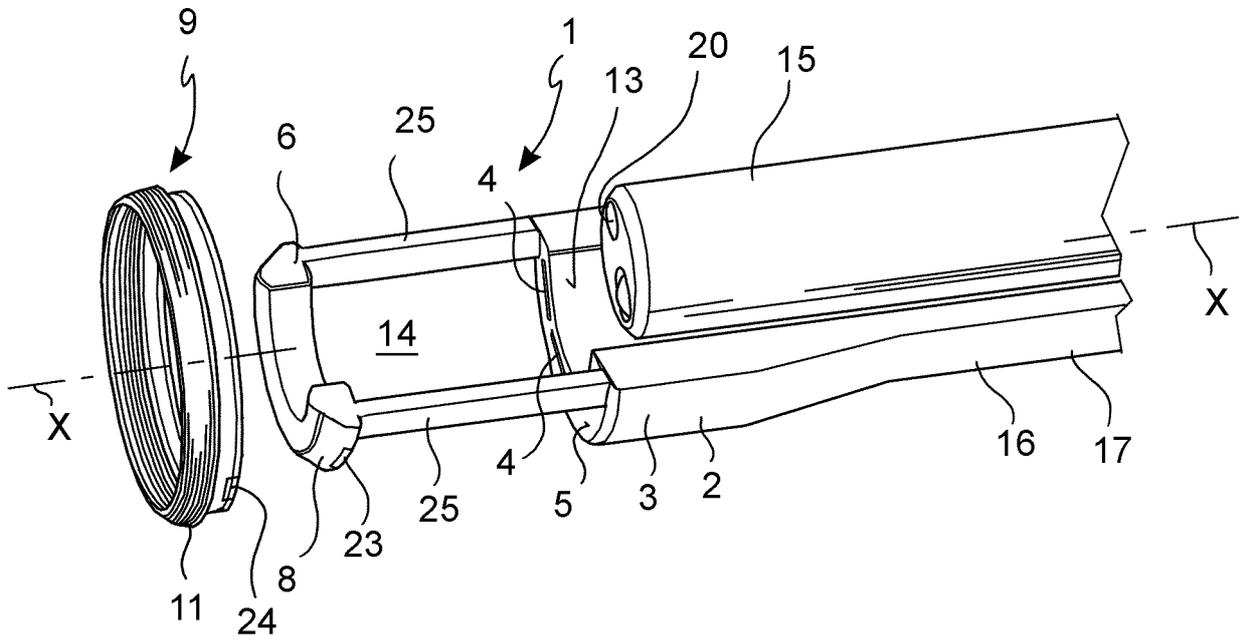


FIG. 1

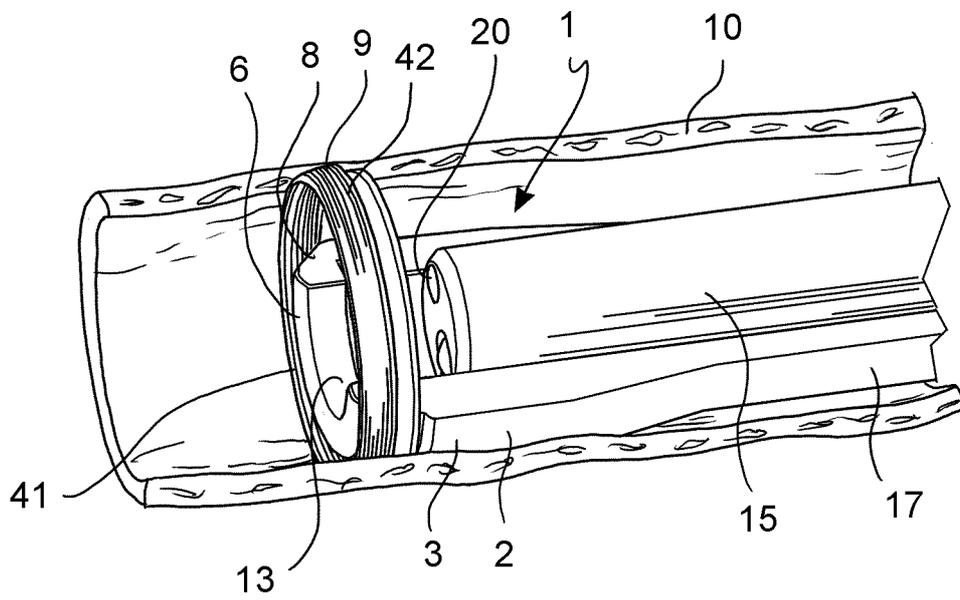


FIG. 2

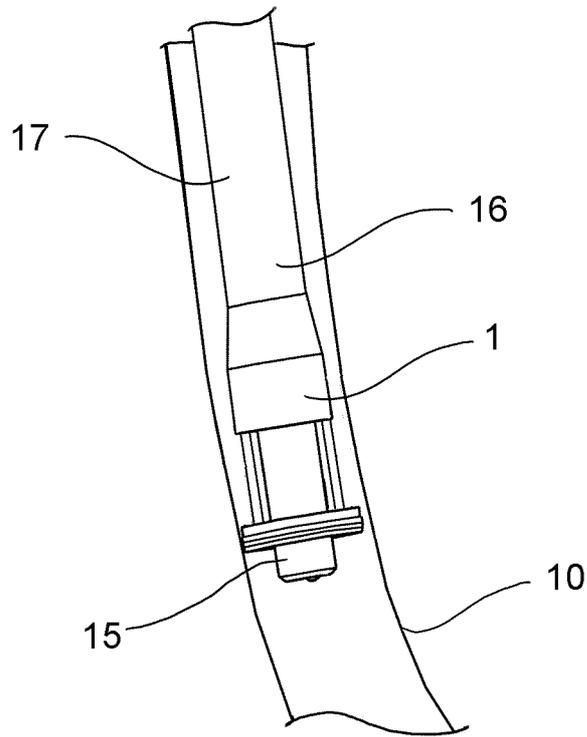


FIG. 5

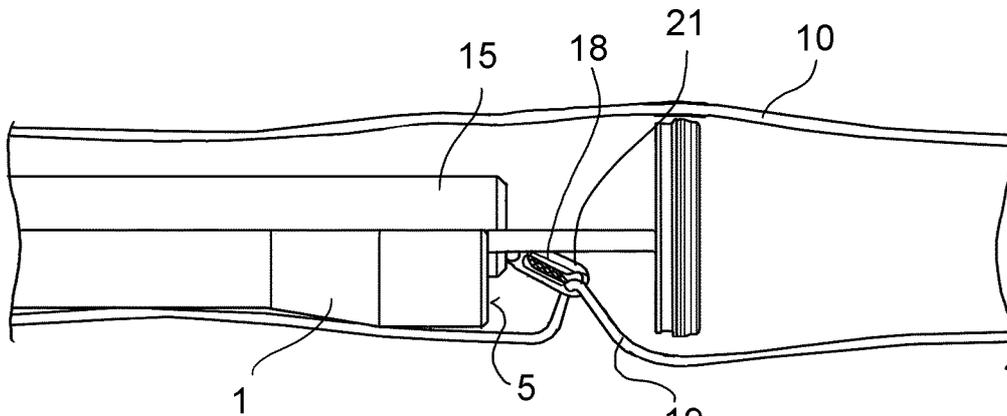


FIG. 6

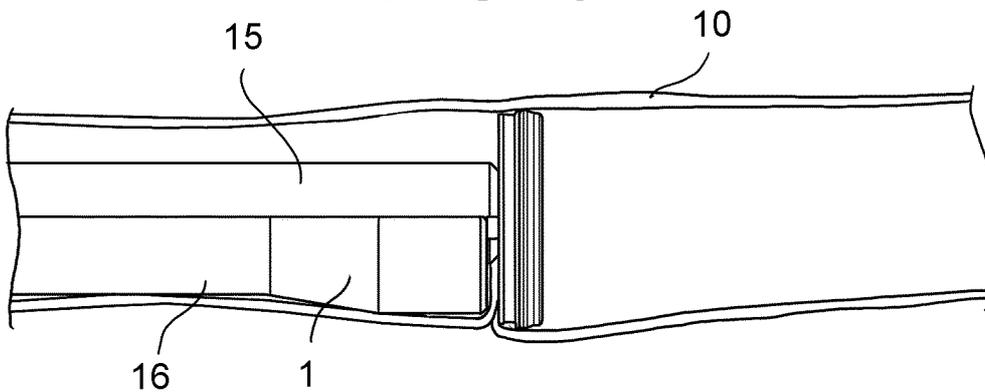


FIG. 7

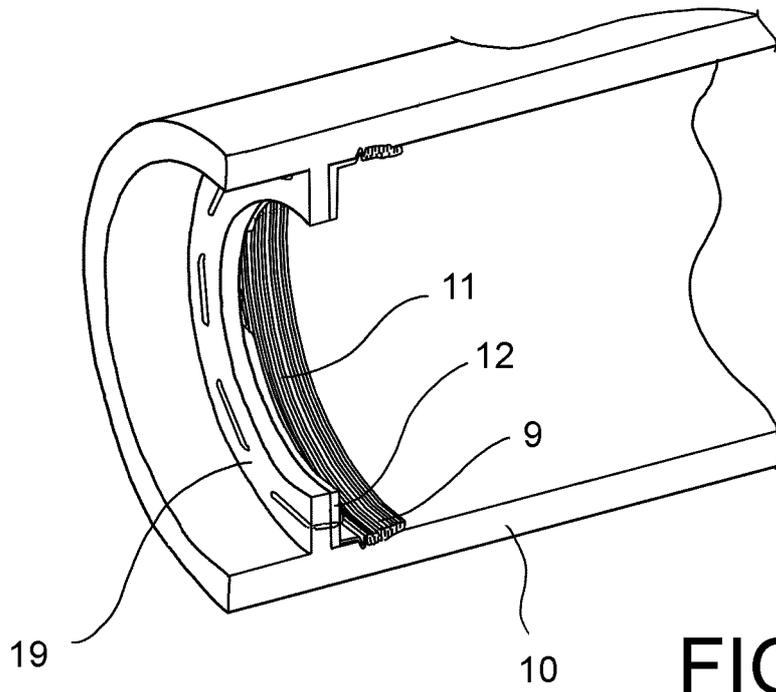


FIG. 8

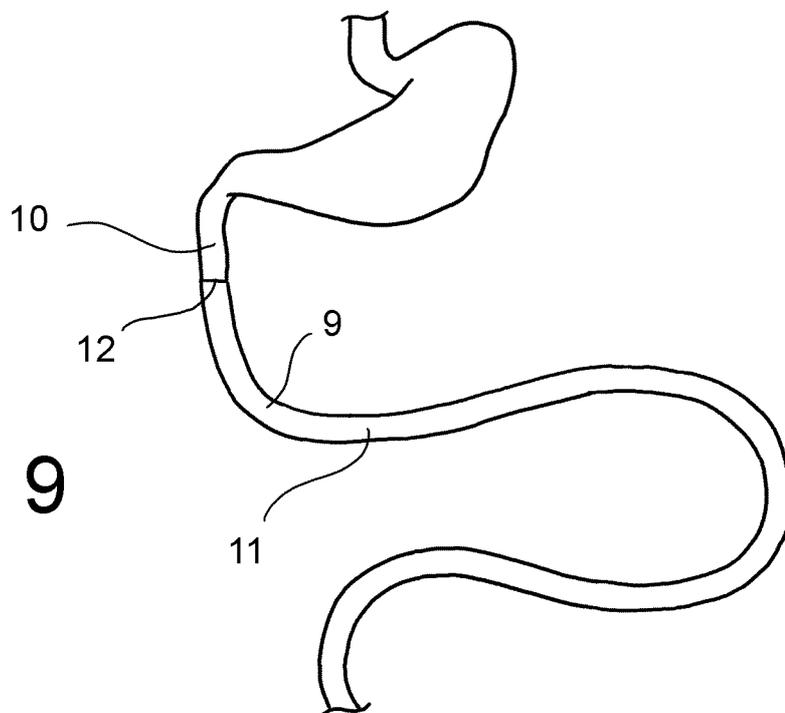


FIG. 9

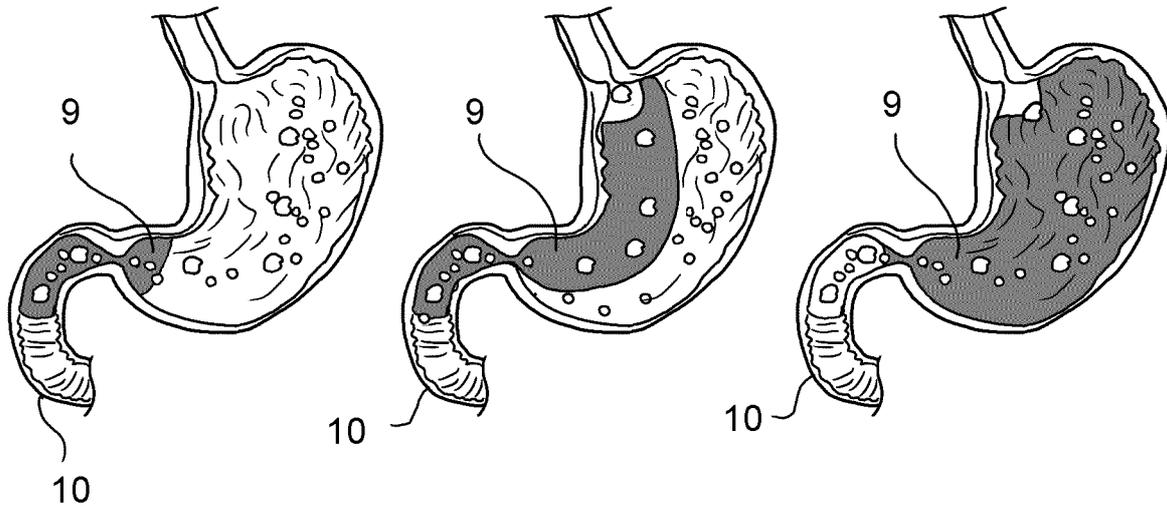


FIG. 10

FIG. 11A

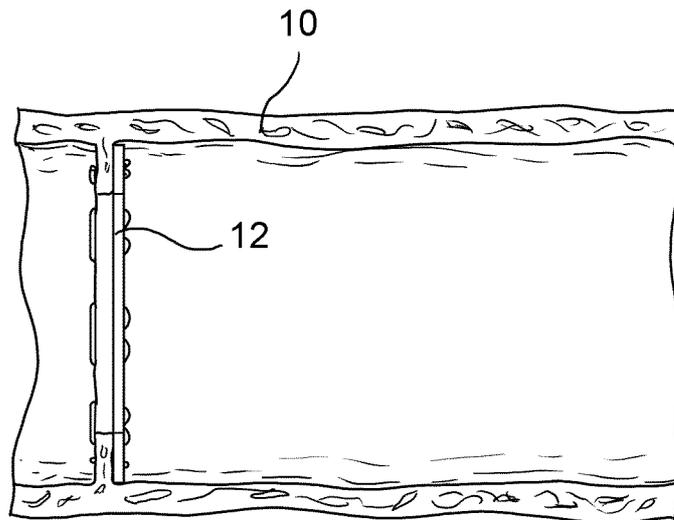
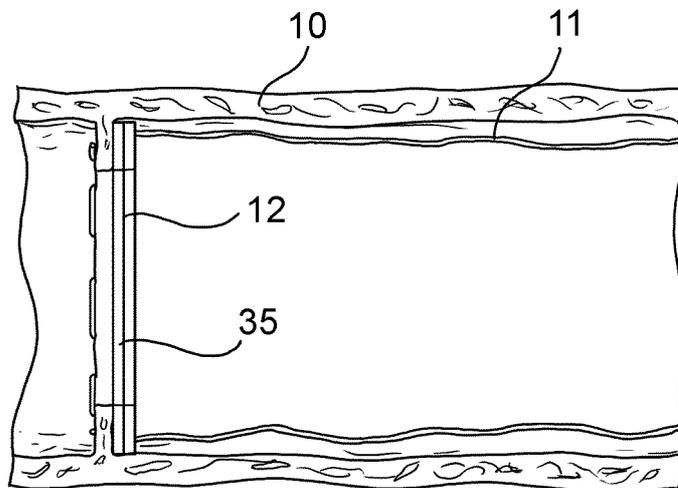


FIG. 11B



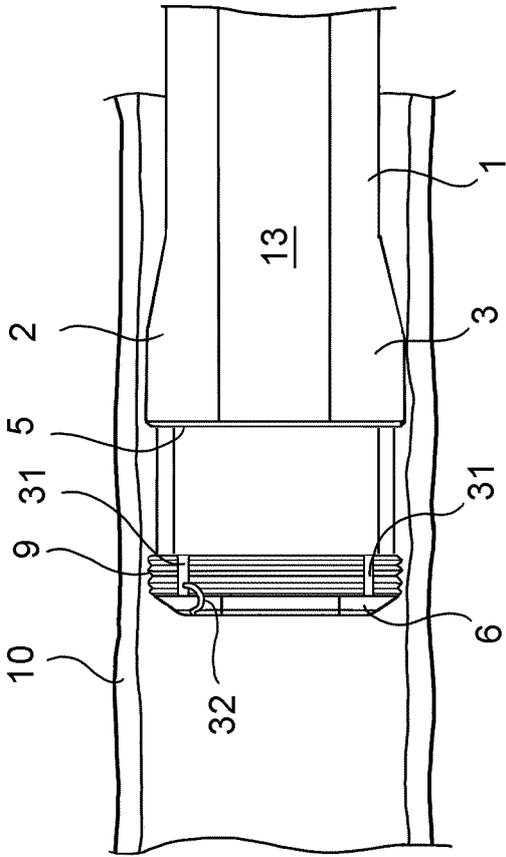


FIG. 14

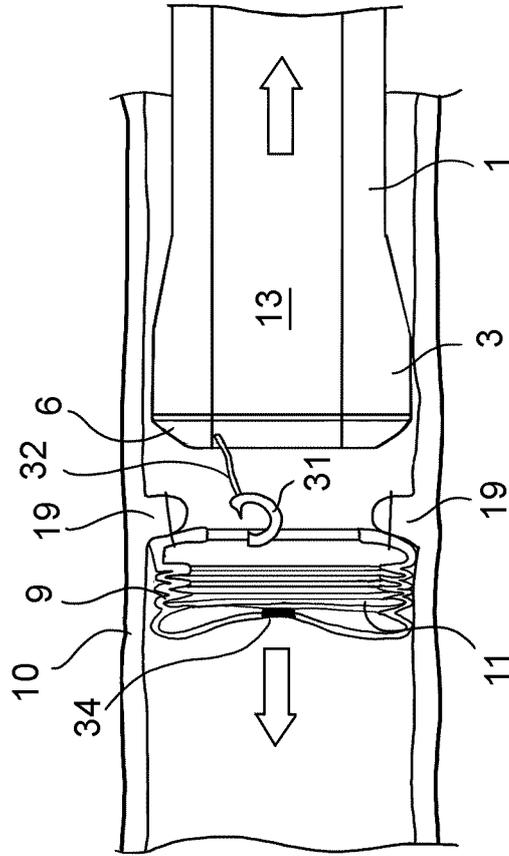


FIG. 15

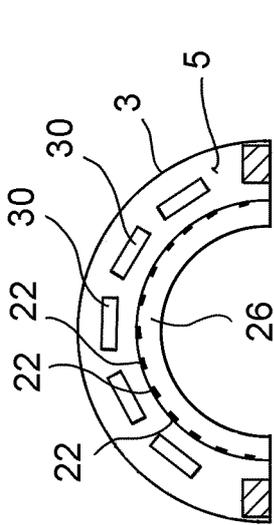


FIG. 13

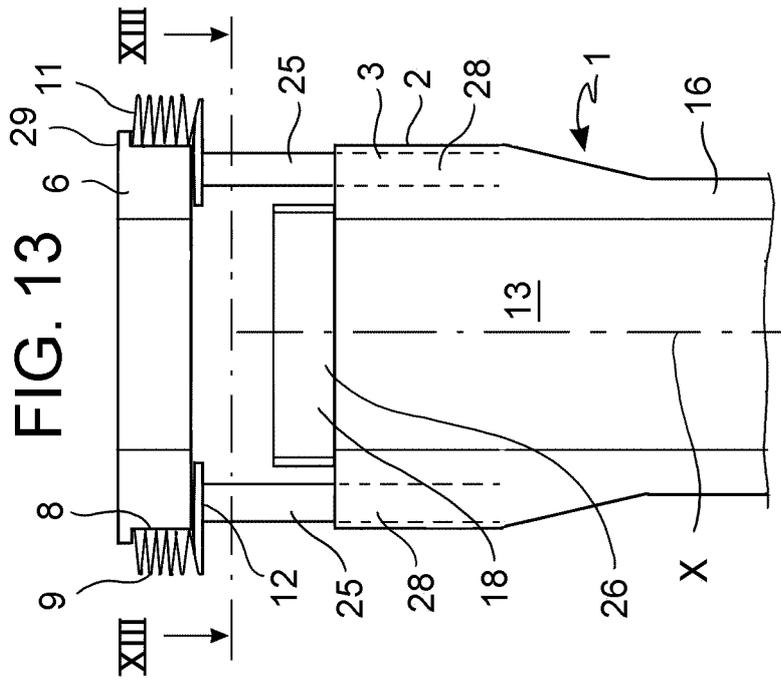


FIG. 12

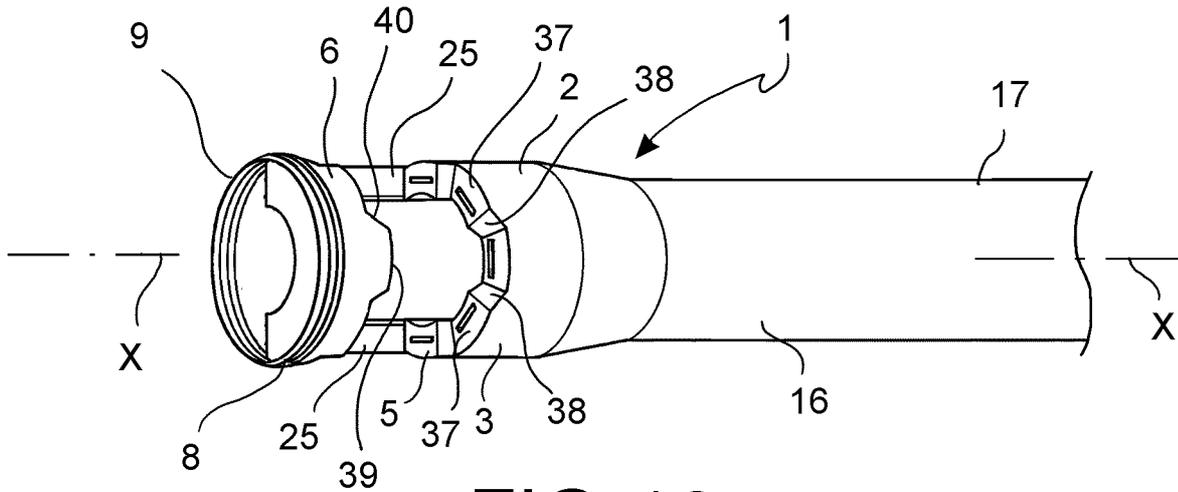


FIG. 16

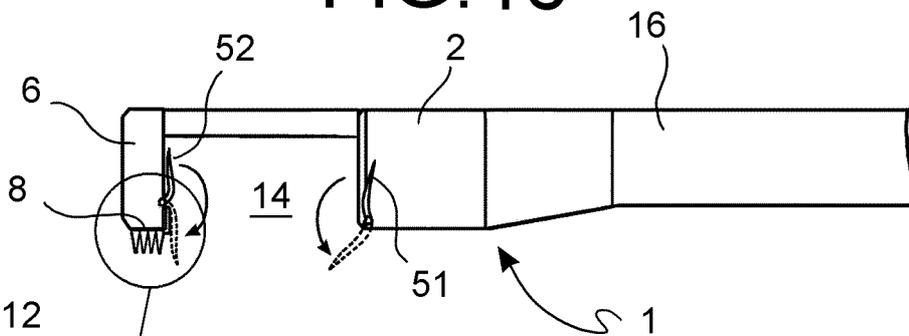


FIG. 17

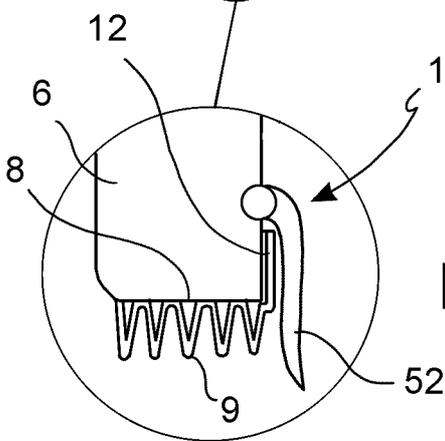


FIG. 17A

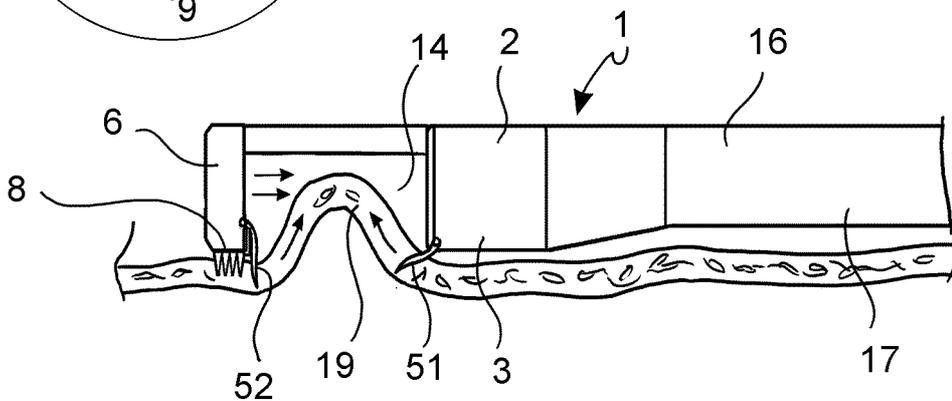


FIG. 18

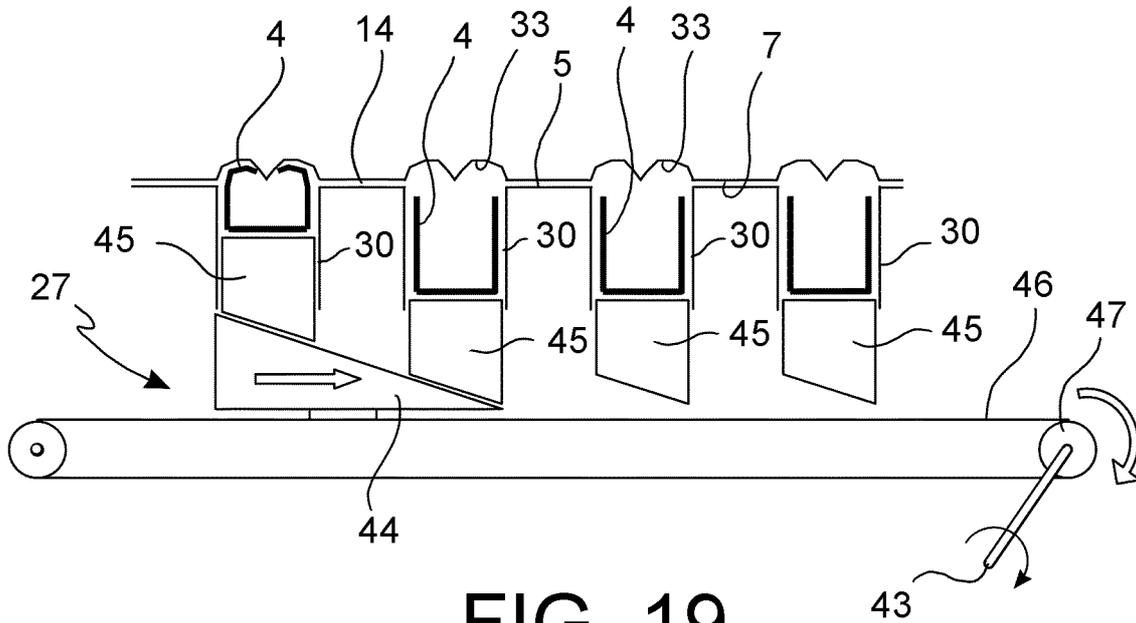


FIG. 19

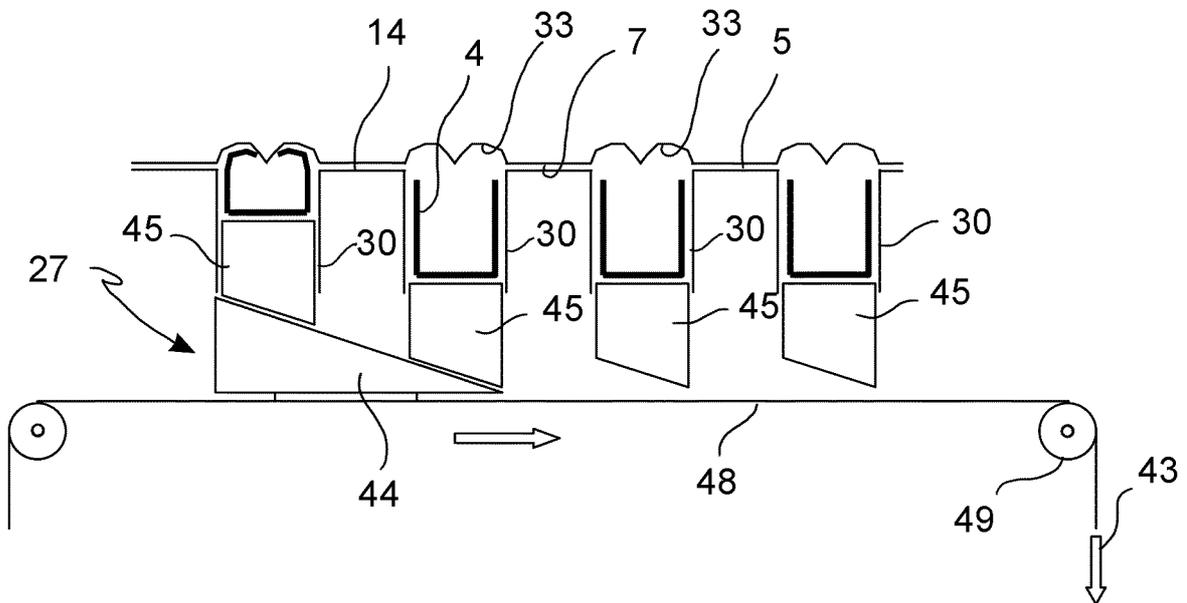


FIG. 20

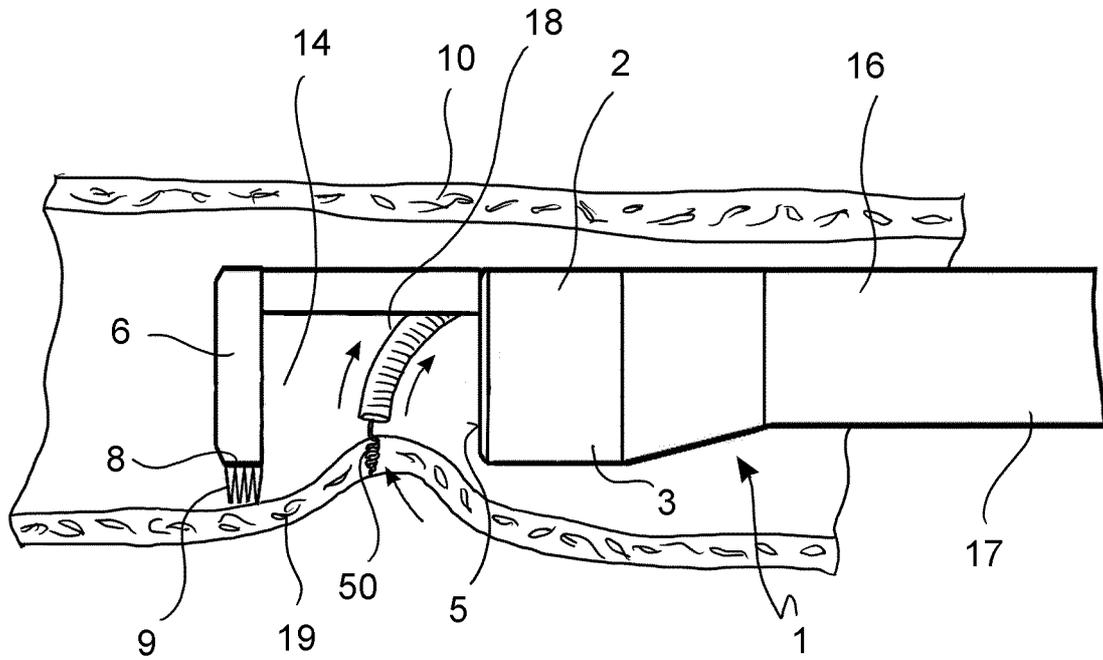


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/072559

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

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.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/072559

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/00 A61B17/072
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 practicable, search terms used)

EPO-Internal , WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/048988 AI (PASTORELLI ALESSANDRO [IT] ET AL) 25 February 2010 (2010-02-25) paragraphs [0032] , [0033] , [0046] , [0050] -----	1, 2, 10, 11
X	US 7 810 690 B2 (BI LOTTI FEDERICO [IT] BI LOTTI FEDERICO [IT] ET AL) 12 October 2010 (2010-10-12) column 5, lines 38-44 column 7, line 58 - column 8, line 31 -----	1, 10, 11
X	US 6 302 311 BI (ADAMS RONALD DAVID [US] ET AL) 16 October 2001 (2001-10-16) column 6, line 17 - line 39 column 6, line 65 - column 7, line 41 ----- -/- .	1, 7

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier 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

"&" document member of the same patent family

Date of the actual completion of the international search

20 November 2012

Date of mailing of the international search report

27/11/2012

Name and mailing address of the ISA/

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Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Angel i , Markus

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/072559

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010/160934 AI (KELLEHER BRIAN [US] ET AL) 24 June 2010 (2010-06-24) paragraph [0141] ; figure 37 -----	3
A	US 2007/213743 AI (MCGUCKIN JR JAMES F [US]) 13 September 2007 (2007-09-13) paragraph [0127] -----	8,9
A	US 2007/233162 AI (GANNOE JAMY [US] ET AL) 4 October 2007 (2007-10-04) cited in the application the whole document -----	1
E	W0 2012/072138 AI (ETHICON END0 SURGERY INC [US] ; D ARCANGELO MICHELE [IT] ; HARRIS JASON) 7 June 2012 (2012-06-07) the whole document -----	12

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/EP2011/072559
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wo 2012072138	AI	07-06-2012	NONE

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6, 11-15

An endoluminal applier for anchoring a tubular lining, directed to a tissue acquisition mechanism to acquire a tissue portion.

2. claims: 7-10

An endoluminal applier for anchoring a tubular lining, directed to a staple driving mechanism for driving staples.
