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ANASTOMOTIC APPLIER AND METHOD FOR PERFORMING ENDOLUMENAL AND/OR TRANSLUMINAL ANASTOMOSIS

An anastomotic ring applier system (30) for deploying a first compression πng (36) and a second compression πng (39) comprises an anastomotic applier (32) with a second πng carrier (38) adapted to hold the second compression ring (39), a πng approximation device (37) with a first portion (42) connectable to an external first πng carrier device (31) which supports the first compression πng (36) and a second portion (43) connected to the second πng carrier device (38), wherein the first portion (42) forms a first thread (47) and the second portion (43) forms a second thread (48) meshing the first thread (47). A rotary device (49) is configured to rotate the first and second portions (42, 43) to one another so that they translate to one another to approximate and interconnect the compression πngs (36, 39).
DESCRIPTION

"AN ANASTOMOTIC APPLIER AND METHOD FOR PERFORMING
ENDOLUMINAL AND/OR TRANSLUMINAL ANASTOMOSIS"

The present invention relates, in general, to devices and methods for surgically modifying organs and vessels and more particularly to a surgical instrument and method for performing an endoluminal and or transluminal anastomosis, particularly of the digestive tract, such as gastro-jejunostomy, jejuno-jejunostomy or similar interventions as for example colo-proctostomy, jejuno-colostomy or anastomoses involving the Chole duct, by applying an anastomotic ring device comprising two snap-connectable rings.

The known surgical methods and instruments for performing the above mentioned anastomoses by applying anastomotic ring devices involve traditional open surgery or laparoscopic surgical techniques, which are rather invasive and require the use of quite complex and cumbersome surgical devices. As a result the risk of post-operative complications is undesirably high.

Moreover, the known devices and methods are not suitable to perform the anastomosis by a pure or at least partially endoscopic or endolumenal approach. Such an endolumenal approach, if assisted by a suitable instrumentation, would sensibly reduce the disadvantages
of the traditional open surgery and laparoscopic methods. Particularly, endolumenal operations would reduce the invasiveness of the intervention, thereby reducing the risk of complications and shortening the post operative course of the patient.

Even though the endoscopic and endolumenal approach to anastomosis is very promising, it is presently very difficult to use such an approach in practice, e.g. for performing an anastomosis of the digestive tract, since neither the instrumentation nor the methods are mature enough to assure for instance an adequate ring positioning, a controlled tissue approximation and a reliable alignment and connection of the rings during deployment. As a result, operative and post operative complications cannot be excluded.

The object of the present invention is therefore to provide a surgical instrumentation, particularly an anastomotic applier, especially developed and adapted for performing endoluminal or transluminal anastomoses, particularly of the digestive tract, by an endolumenal approach.

A further object of the invention is to provide a surgical method for performing an endolumenal or translumenal anastomosis, particularly of the digestive tract, by an endolumenal or endoscopic approach which is
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less invasive than the currently employed open surgery and laparoscopic approaches.

These and other objects are achieved by an anastomotic compression ring applier system according to claim 1 and by the method described in the following description. Advantageous embodiments are claimed in the dependent claims.

For better understanding the invention and appreciating the related advantages, a detailed and non-limiting description of embodiments is provided with reference to the accompanying drawings, in which:

- Figure 1 is a sectioned view of an endoluminal anastomotic ring applier according to an embodiment of the invention;
- Figure 2 is a perspective view of a detail of the endoluminal anastomotic ring applier in figure 1;
- Figure 3 is a sectioned view of the detail in figure 2;
- Figure 4 is a perspective view of a further detail of the endoluminal anastomotic ring applier in figure 1;
- Figure 5 is a perspective view of an inflatable coupling portion of a coupling device of an endoluminal anastomotic ring carrier device according to an embodiment of the invention;
- Figure 6 is a perspective view of an anastomotic
compression ring device intended to be deployed by means of an anastomotic applier according to the invention;

- Figures 7, 8 and 9 illustrate a series of steps of a method for performing a transluminal anastomosis by means of the anastomotic ring applier system in figures 1 to 6 according to the invention;
- Figure 10 is a perspective view of an inflatable coupling portion of a coupling device of the anastomotic applier system in a disengaged configuration according to an embodiment of the invention;
- Figure 11 is a perspective, sectioned view of the coupling device of figure 10 in an engaged configuration;
- Figure 12 is a schematic illustration of the general functional units of an anastomotic compression ring deployment system according to the invention;
- Figure 13 illustrates a creation of a guide wire loop in preparation of an anastomosis (gastro-jejunostomy);
- Figure 14 illustrates a creation of an anastomosis (gastro-jejunostomy).

For the sake of clarity and for better evidencing the technical effect of the features of the anastomotic applier system according to the invention and its interaction with the particular environment of application, the following detailed description of the
invention will first deal with the surgical method thought up by the inventors and subsequently describe the anastomotic applier and surgical instruments for carrying out the method.

5 Overall procedure to perform the anastomosis

A method for performing an endoluminal or transluminal anastomosis, such as e.g. a gastro-jejunostomy, a jejunoo-jejunostomy, a colo-proctostomy, a jejunoo-colostomy or anastomoses of the choleduct, comprises generally the following steps:

- Creating a loop of guide wire means by placing guide wire means 88 in the body of a patient in a way that the guide wire means 88 extend from an extracorporeal proximal end 88' into the body where it goes through a proximal first tissue portion 45 and through a distal second tissue portion 44 which are planned to be joined in anastomosis and out of the body up to an extracorporeal distal end 88''.

In the following, if not otherwise specified, the terms "proximal" and "distal" are referred to the directions along the guide wire loop and to the above defined proximal 88' and distal ends 88'' thereof.

- Fixing a proximal first ring 36 of an anastomotic ring device to the proximal end 88' of the guide wire means 88 and delivering the proximal first ring 36 to the
proximal first tissue portion 45 by pulling the distal extracorporeal end 88' of the guide wire means 88 in a distal direction until the proximal first ring 36 reaches the proximal first tissue portion 45,

- Slidably connecting a distal second ring 39 of the anastomotic ring device to the distal end 88'' of the guide wire means 88 and pushing it proximally along the guide wire means 88 until it reaches the distal second tissue portion 44.

- Contemporaneously pulling the proximal first compression ring 36 distally and pushing the second distal compression ring 39 proximally to approximate the proximal and distal rings, thereby tearing the first and second tissue portions 45, 44 situated upon the guide wire means 88 between the first and second rings 36, 39 in compression contact to another,

- Widening the tissue internally overhanging the anastomotic ring device to open the anastomotic lumen,

- Connecting the first and second rings 36, 39, thereby clamping the first and second tissue portions between them,

- Pulling the proximal end 88' of the guide wire means 88 to remove the guide wire means 88 from the body.

The loop of the guide wire means 88 starts and ends either in natural orifices, like mouth, nose, anus or,
alternatively, in artificially created openings in the body, such as colostomy, abdominal incisions, wound or fistulas. Preferably, the guide wire means enters and exits the body through natural ducts (e.g. mouth, Figs. 13 and 14).

While the guide wire means can comprise one or more single flexible guide wires, it is preferable to provide only one single guide wire which penetrates the proximal and distal tissue portion.

Creation of the loop of the guide wire means

The loop of the guide wire means 88 can be created by means of the following procedural steps:

- Transluminally (e.g. transorally) introducing an elongate insertion device through the proximal inlet port (e.g. mouth) for the guide wire means and pushing the insertion device from outside the body distally towards the proximal tissue portion (e.g. a jejunal anastomotic site),

- Transporting the distal end of the guide wire means to the proximal tissue portion through one or more guide wire canals formed in the insertion device and perforating the proximal tissue portion with the guide wire end or needle guide wire end. Alternatively, the proximal tissue portion is perforated by a distinct radio frequency needle device having a sheath which is
insertable along the guide wire canal and which defines
two or more internal canals (one for the RF needle and
one for the guide wire).
In this way the distal guide wire end protrudes distally
from the proximal tissue portion (e.g. into the
previously CO2 insufflated abdominal space),
- Removing the insertion device from the body by pulling
it proximally out of the proximal inlet port (e.g.
mouth) and leaving the guide wire means in place,
- Transluminally introducing a grasping device through
the distal inlet port for the guide wire means which
might but need not coincide with the proximal inlet port
(e.g. mouth) and pushing the grasping device from
outside the body proximally (with reference to the loop
direction) towards the distal tissue portion, e.g. the
gastric wall tissue,
- Creating a hole in the distal tissue portion, e.g. by
means of a radiofrequency needle or equivalent
penetration devices and, preferably, widening the hole
with a balloon catheter which is preferably transported
to the distal tissue portion through a working channel
of the grasping device.
- Passing the grasping device through the previously
widened hole (gastrotomy) of the distal tissue portion
into the same space where the distal guide wire end lays
and pushing it towards the distal end of the guide wire means.
- Inserting a snare through the working or instrument delivery canal formed in the grasping device and advancing the snare proximally until it exits from the grasping device and reaches the distal guide wire end.
- Feeding the snare over the distal guide wire end and closing or tightening it around the guide wire means in order to catch it, subsequently pulling the snare together with the distal end of the guide wire means distally through the perforation of the distal tissue portion (e.g. gastric wall) and distally withdrawing the grasping device together with the distal guide wire end through the distal inlet port (e.g. transorally) out of the body.

Advantageously, the transluminal introduction of the grasping device and the snare is performed by a pure endoscopic or endolumenal approach. Alternatively, this procedural step is performed under laparoscopic supervision. In this case the hole does not need to be widened and only the snare (preferably a radio frequency snare adapted to pierce through the gastric wall) creates the hole and is passed through it into the abdominal space. The distal guide wire end is then
laparoscopically fed into the snare hole to be caught by the latter.

In case of a gastro-jejunostomy, the insertion device needs to be advanced transorally through the esophagus and the stomach and across the pylorus into the duodenum, which is not always easy to point at. During this step of the procedure a guiding or protective tube might be pushed through the patients mouth down the esophagus into the stomach and the insertion device can be advantageously guided inside the guiding or protective tube up to and across the pylorus.

Delivering the proximal ring of the anastomotic ring device to the anastomotic site and approximation of the proximal and distal tissue portions

The proximal first ring 36 is delivered to the anastomotic site by means of the following procedural steps:

- Detachably connecting the proximal ring with a, preferably distinct, carrier member 33 outside the body of the patient.

- Extracorporeal attachment of the carrier member 33 (which holds the proximal ring) to the proximal end 88' of the guide wire means 88, e.g. by inserting it over the single guide wire, and locking the carrier member in a manner to prevent it from sliding along the guide wire.
means. The carrier member 33 is preferably locked by means of locking elements, such as clips which can be clamped around the guide wire and which are adapted to provide an obstacle against sliding of the carrier member. After having connected the carrier member to the proximal guide wire end, it is introduced in the proximal endoscopic inlet port and pulled to the anastomotic site, i.e. to the proximal first tissue portion (e.g. intestinal wall 45) by pulling the distal guide wire end 88'' distally.

Alternatively, the locking of the carrier member to the guide wire might be obtained by locking features, for instance clamping portions, integrated in the carrier member. According to a yet further embodiment, the carrier member has been fabricated and distributed together with the guide wire or previously connected to it in a manner that, after completion of the guide wire loop, it is sufficient to introduce the carrier member together with the proximal ring into the proximal inlet port (e.g. mouth and esophagus) and deliver it to the proximal tissue portion 45 by pulling the distal guide wire end 88' distally.

Alternatively, the carrier member can be slid along the guide wire up to the proximal tissue layer, wherein the guide wire acts as a guide rail for the carrier member.
Subsequently, the proximal tissue portion 45 (e.g. intestinal tissue) can be approximated towards the distal tissue portion 44 (e.g. gastric wall) until they are in intimate contact by pulling the distal guide wire end 88'' distally so that the carrier member urges the proximal ring, particularly a distal tissue contact surface thereof, against the proximal tissue portion and moves the latter distally towards and in contact with the distal tissue portion.

Delivering the distal ring of the anastomotic ring device to the anastomotic site and connection of the distal and proximal rings

The distal ring is delivered to the anastomotic site by means of the following procedural steps:

- Inserting the distal second compression ring 39 over the distal guide wire end 88'' and pushing it proximally along the guide wire means 88 towards the anastomotic site and, hence, towards the proximal first compression ring 36. Thanks to the guide wire loop and possibly further guide means, the first and second compression rings 36, 39, together with the first and second tissue portions 45, 44 are axially aligned in the anastomotic site.

According to an embodiment, the distal compression ring is pushed along the guide wire by means of an apposite
anastomotic applier which is advantageously adapted to perform an angular positioning, if required, of the distal compression ring with respect to the proximal compression ring in order to enable their mutual connection. Alternatively, the compression rings are provided with connecting features which enable their mutual connection in different angular positions or independently from their reciprocal angular position.

- Connecting the compression rings and, hence the tissue portions clamped between them, by pushing the distal compression ring proximally in engagement with the proximal compression ring or pulling the proximal compression ring distally in engagement with the distal compression ring. To this end, the anastomotic applier system includes a coupling device 1 and an approximation device 37. In this way it is possible to couple (preferably in or near the operational site) the carrier of the first compression ring to the approximation device 37 (which in turn is connected to the second compression ring) and to apply a reciprocal pushing or pulling force on the compression rings.

In accordance with an embodiment, the compression rings are connected by applying a distinct locking device adapted to engage both compression rings and to maintain them connected at a desired reciprocal distance.
The method of connecting the compression rings to another can additionally comprise the step of fixating the tissue portions to the compression rings in order to effectively prevent the tissue from radially slipping out of the grip engagement with the compression rings. This additional step might be performed before or contemporaneously with the application of the locking device. This additional fixation step is preferably performed by compressing the tissue portions between the distal and proximal ring device and by driving a plurality of needles into and across the ring device and the tissue portions so that the needles provide the above said additional fixation.

As the delivery of the locking device and the group of needles (if provided) to the anastomotic site is concerned, according to an embodiment of the method, the locking device is inserted extracorporeally over the distal guide wire end 88' and pushed proximally along the guide wire 88 towards the anastomotic site and towards the proximal compression ring. Preferably, both the distal compression ring and the distinct locking device (and, if provided, the needle group) are arranged on a distal end (here the term "distal" is referred to the surgeons viewpoint and not to the guide wire loop) of the anastomotic applier and pushed by means of the
latter to the anastomotic site and in engagement with the proximal compression ring.

Alternatively, and inversely with respect to the above described embodiment both the proximal first compression ring and the distinct locking device (and, if provided, the needle group) are fixed to the proximal ring carrier device 33 and transported to the anastomotic site and urged in engagement with the distal compression ring.

Widening the tissue at the anastomotic site

The distal and proximal tissue portions intended to be joined in anastomosis are widened by means of the following procedural steps:

- widening the passage apertures of the tissue portions through which the guide wire means, preferably a single guide wire, passes by cutting or forced tissue extension after the tissue portions have been approximated in mutual contact but, preferably, before the distal and proximal compression rings are definitely connected. According to an advantageous embodiment, the passage openings of the tissue portions are widened by a balloon dilator 11 which can also act as expandable anchoring head 4 of the coupling device 1 (which will be described further ahead). The balloon dilator 11 can be inserted over the guide wire 88 and delivered towards and at least partially across the passage openings in the
tissue portions. Successively, the balloon dilator is insufflated to an extent that it fills approximately a central aperture of the distal compression ring, thereby widening the anastomotic lumen to substantially the same extent and at the same time performing the coupling action between the first ring carrier and the anastomotic applier.

In accordance with an advantageous embodiment, prior to or after the inflation of the balloon dilator of the coupling device, the proximal first compression ring (the locking device together with the needle group is preferably preassembled with one of the compression rings) is inserted over a portion of the balloon dilator such that the inflated balloon dilator provides a guide for the successive approximation and alignment of the compression rings.

Removing the instrumentation and guide wire means from the body of the patient.

After the connection of the compression rings, the balloon dilator is deflated and detached from the a catching portion of the anastomotic applier. The anastomotic applier with the catching portion are withdrawn from the body of the patient. Also the carrier member with the coupling portion are detached from the proximal first compression ring and removed,
preferably together with the guide wire 88, by pulling the proximal guide wire end 88' in proximal direction. As the proximal first ring is definitely locked to the distal ring, during proximal traction of the guide wire 88 the carrier member (which received the proximal ring by a weaker connection, e.g. by friction fit) detaches from the proximal compression ring which rests connected to the distal compression ring. Even though the method of performing an anastomosis has been described and illustrated with reference to a gastro-jejunostomy which is performed starting from the jejunum, such a gastro-jejunostomy might also be performed starting from the stomach. In this case, it might be advantageous to introduce a shielding device into the jejunum in order to prevent piercing of the intestine wall opposite the one intended to be anastomized. Possibly, the tightness of the anastomosis can be tested using methylene blue. The above described method can be advantageously performed endolumenally or partially endolumenally during a gastro-jejunostomy. In case the above described method forms part of a procedure for creating a gastro-intestinal bypass, it is possible to proceed with a performance of a further anastomosis involving the small
intestine (e.g. a jejuno-jejunostomy or an ileo-jejunostomy), possibly by applying the above described steps in analogous manner also to the further anastomosis.

From the foregoing description of the general steps of the method and of their specific application to a gastro-jejunostomy, those skilled in the art will appreciate that the method enables a continuous control of the positioning and of the forces applied to the single parts of the anastomotic ring device during deployment. The method further consents to perform the anastomosis endoluminally even though laparoscopic or partially laparoscopic steps in assisting and performing the anastomosis are not excluded.

The described method, particularly the use of an anastomotic applier having coupling and ring approximating features is not only advantageous for gastro-jejunostomy and jejuno-jejunostomy, but also for performing for example colo-proctostomy, jejuno-colostomy or anastomoses involving the Chole duct.

In the following, an anastomotic ring applier system will be described which has been especially developed and adapted for performing an anastomosis in accordance with the proposed method.

The instrumentation comprises advantageously one or more
of the following components:
- first and second anastomotic rings 36, 39;
- fixation needles 81;
- first ring carrier member 33;
- locking device 82;
- insertion device (not illustrated in the figures);
- grasping device (not illustrated in the figures);
- anastomotic applier 32;
- anchoring head/balloon dilator 14/11;
- guide wire 88;
- snare (not illustrated in the figures),
some of which will be in the following described in
further detail by means of illustrative embodiments.

General description of the anastomotic ring applier

With reference to figure 12, an anastomotic ring applier
system 30 comprises a first compression ring carrier
device 31 (dashed line - - - ) and an anastomotic applier
32 (dotted dashed line - . - ). The first compression
ring carrier device 31 comprises a first (e.g. jejunal)
ring carrier 33 adapted to hold a first compression ring
36 and connectable or connected to the guide wire device
88. The first ring carrier 33 can be connected to a
balloon dilator 11 which is built up around the guide
wire and which can be connected to the guide wire
outside the body of the patient or near an inflatable head of the balloon dilator, e.g. by means of a discrete gluing point (or more generally a locking portion 35) which doesn't hinder the fluid communication from the fluid duct of the balloon dilator to its inflatable head.

The first compression ring carrier device 31 can be coupled to and uncoupled from the ring approximation device 37 of the anastomotic applier 32 (which will be described below) by means of the previously mentioned coupling device 1 (----- double dotted dashed line in figure 12).

The anastomotic applier 32 further comprises a second (gastric) ring carrier 38 adapted to hold a second compression ring 39 for instance by means of a ring connecting portion 40 which is configured to engage the second (gastric) compression ring 39 by snap-fit or friction-fit or press-fit.

The anastomotic applier 32 further comprises a ring approximation device 37 with a first portion 42 connectable by means of the coupling device 1 to the first ring carrier device 31 and a second portion 43 connected or connectable to the second ring carrier device 38.

The first and second portions 42, 43 of the ring
approximation device 37 are movable to one another in a way to approximate the first and second ring carrier devices 31, 38 thereby approximating the two tissue layers (e.g. gastric tissue layer 44 and jejunal tissue layer 45) held between the two compression rings 36, 39 and interconnecting the compression rings 36, 39 to complete the anastomosis.

In accordance with the invention, the ring approximation device 37 of the anastomotic applier 32 comprises a screw drive device 46, wherein the first portion 42 forms a first thread 47 and the second portion 43 forms a second thread 48 meshing the first thread 47 and a rotary device 49 cooperates with at least one of the first and second portions 42, 43 to rotate them to one another. The relative rotation of the first and second portions 42, 43 causes them to translate to one another and to approximate the first and second ring carrier devices 31, 38 and the two tissue layers (e.g. gastric tissue layer 44 and jejunal tissue layer 45) held between the two compression rings 36, 39 and to interconnect the compression rings 36, 39.

As mentioned before, the anastomotic ring applier system 30 as a whole may further comprise a coupling device 1 and, hence, the anastomotic applier 32 may comprise a coupling portion 2 or a catching portion 3 of such
coupling device 1 to allow reversible coupling of the
anastomotic applier 32 to the first ring carrier device
31 (compare figure 12) at or near the operational site.

Embodiment description of the coupling device 1 of the
anastomotic ring applier system 30

According to an embodiment, the coupling device 1
comprises a coupling portion 2 and a catching portion 3
configured to trap and hold the coupling portion 2. The
coupling portion 2 comprises a first connector 5 for
connecting the coupling portion 2 to the first ring
carrier device 31 and an inflatable anchoring head 4, as
well as an activating device 6 connected to the
anchoring head 4 and suitable to deform (insufflate and
deflate) the anchoring head 4 such that it can take on
an expanded configuration (Fig. 10) and a retracted
configuration (Fig. 5, 7).

The catching portion 3 comprises a second connector 58,
7 for connecting the catching portion 3 to the
anastomotic applier 32, particularly to the second ring
carrier device 38 thereof, which is intended to be
coupled with the first ring carrier device 31. The
catching portion 3 further comprises an anchoring seat 8
which defines a receiving space 9 for receiving at least
part of the anchoring head 4 and an access aperture 10
through which the anchoring head 4 can be inserted from
outside the catching portion 3 into the receiving space 9. The access aperture 10 is configured to allow insertion and withdrawal of the anchoring head 4 when it is retracted and to lock the at least partially inserted anchoring head 4 to the catching portion 3 when it is expanded.

In accordance with an embodiment, the anchoring head 4 comprises said balloon catheter or balloon dilator 11 which can be actuated by a fluid pump device which is connected in fluid communication with the balloon dilator 11 through a preferably flexible pressure fluid duct 12. As illustrated in figures 1, 5 and 10 respectively, the balloon dilator 11 can assume a substantially elongate filiform retracted shape and, if subject to fluid pressure, a substantially elongate cylindrical expanded shape.

In accordance with an embodiment, the balloon dilator 11 has an internal inflatable chamber 14 defined by a flexible (in the sense of bending deformation) but inextensible wall 13 such that it can adapt to the shape of the anchoring seat 8 even and particularly if it is only partially inserted into the receiving space 9. The balloon dilator 11 has a tapered distal (from a surgeon's point of view) insertion end 15 which is preferably substantially convex and narrowed towards the end, e.g.
ogive shaped, and which can further have a central pin shaped tip 16 or needle in order to facilitate the insertion of the anchoring head through tissue portions and into the access aperture 10 of the catching portion 3.

According to an embodiment, the first connector of the coupling portion 2 comprises a longitudinal channel 17 which is configured to receive for instance the guide wire 88 of the first ring carrier device 31. The guide wire channel 17 is advantageously coaxial to the cylindrical expanded shape of the balloon dilator 11 and can be directly glued to the guide wire 88 or, alternatively, the balloon dilator 11 can be latched to the guide wire 88 by clamping devices such as clips etc.

Turning again to the catching portion 3, in accordance with an embodiment of the invention the catching portion 3 comprises a housing 18 with a preferably but not necessarily cylindrical side wall 19 and a distal end wall 20 which define together at least part of the receiving space 9. The end wall 20 delimits the above said access aperture 10 through which the inflatable anchoring head 4 can be at least partially introduced into the receiving space 9 and the edge of which constricts the anchoring head 4 after it has been expanded.
In accordance with an embodiment, the end wall 20 has an internal locking surface 21 which faces into the receiving space 9 and which is substantially perpendicular to the direction of insertion (X) of the anchoring head 4 or defines a circumferential shoulder inclined towards the inside of the receiving space 9 so that it locks the partially introduced, expanded and constricted anchoring head 4 in order to prevent slippage of the latter once it undergoes traction forces.

In accordance with an embodiment, the internal locking surface 21 defines an undercut for preventing the insufflated anchoring head 4 from slipping out of engagement with the catching portion 3.

Preferably, an external surface 22 of the distal end wall 20 defines a guide for facilitating the insertion of the anchoring head 4 into the anchoring seat 8.

Detailed description of embodiments of the anastomotic ring applier system

In accordance with the embodiment illustrated in Figs. 1 to 9, (the terms "proximal" and "distal refer to the surgeons point of view), the first portion 42 of the approximation device 37 is embodied as a rotor assembly 50 with an externally threaded outer housing 51 which defines a distal opening 52 and a proximal connecting
portion 53. A torque connector 54 connects a torsional cable or rotary rod 55 to the proximal connecting portion 53. The torsional cable or rotary rod 55 can be passed through a working channel of an endoscope (e.g. gastroscope, not illustrated) and has a proximal end extending outside the patients body where an appropriate torque and rotary movement can be applied to it by the surgeon. The torque connector 54 can comprise a connecting cap or plug (Fig. 2, 3) connected by radial connecting pins 56 to a tubular ring wall 57 of the outer housing 51 so that it can transmit torque and (possibly but not necessarily) traction from the torsional cable or rotary rod 55 to the threaded outer housing 51.

In this embodiment, the catching portion 3 of the coupling device 1 is arranged inside the outer housing 51 and free to rotate with respect to the latter. The access aperture 10 of the catching portion 3 is arranged in alignment with a distal end surface and preferably coaxial to the distal opening 52 of the outer housing 51.

In order to facilitate the free rotation of the outer housing 51 of the rotor assembly with respect to the catching portion 3 and, hence, with respect to the trapped anchoring head 4 of the coupling device 1, a
rotational bearing 58 can be interposed between the outer housing 51 and the catching portion 3.

In accordance with an embodiment, the access aperture 10 of the catching portion 3 is defined by a short tubular, preferably cylindrical collar having a diameter which is smaller than the diameter or transversal extension of the receiving space 9. The tubular collar has an outer cylindrical surface which engages an internal surface of the rotational bearing 58 which, in turn, is connected to the outer housing 51 near its distal opening 52 (compare Figs. 1 and 3).

In this embodiment, the second portion 43 of the ring approximation device 37 is embodied as a jackscrew device 59. The jackscrew device 59 comprises a tubular support structure 60, e.g. a rigid or at least partially flexible tube, with a proximal grounding portion 61, a distal ring connector portion 64 and an internal thread 48 which is configured to mesh with the external thread 47 of the rotor assembly 50.

The grounding portion 61 is adapted to connect the support structure 60 to an endoscope (e.g. gastroscope not illustrated in the figures) so that the endoscope can transmit push and/or pull forces and torque to the support structure 60. Alternatively, the support structure 60 can extend outside the body of the patient.
and the grounding portion 61 can be extracorporeally torsionally and axially held or grounded.
The distal ring connector portion 64 is configured to hold the second (e.g. gastric) compression ring 39, e.g. through a snap-fit, press-fit or friction-fit action which can be provided by a crown of elastic teeth, as has been illustrated in Fig. 4 and 7.
The coupling device 1 makes it possible to firmly couple the rotor assembly 50 to the first ring carrier device 33 by partially inserting and subsequently insufflating the anchoring head 4 inside the catching portion 3 and contemporaneously providing both a tissue widening means and a cylindrical guide (expanded anchoring head - balloon dilator 11) for the compression rings during approximation and snap-connection. After having coupled the first ring carrier means to the rotor assembly, a rotary movement of the torque cable can rotate the outer housing of the rotor assembly with respect to the axially and torsionally locked support structure 60, thereby causing the rotor assembly 50 together with the catching portion 3 to translate and, hence, to approximate and interconnect the anastomotic compression rings 36, 39.
In accordance with a further embodiment, the tubular support structure 60 is at least partially, preferably
completely transparent in order to enable a visualization by the endoscope (e.g. gastroscope) also across the tubular wall of the support structure.

For the sake of completeness of disclosure and with reference to figure 6, an illustrative embodiment of an anastomotic ring device and locking device will be described, which can be deployed by means of the anastomotic applier according to the invention. Figure 6 is a perspective view of an anastomotic ring device with the first (jejunal) ring 36 and the second (gastric) ring 39 which is not only but particularly adapted to perform a gastro-jejunostomy according to the previously described method. The first compression ring 36 (or "bowel ring" or "intestinal ring" 36) is adapted to bear against the first tissue portion 45 (jejunal tissue), while the second compression ring 39 (or "gastric ring" 39) is adapted to bear against the second tissue portion 44 (gastric tissue) opposite the first tissue portion 45 and the first ring 36.

The first and second rings 36, 39 are adapted to be latched together in at least one, preferably two or more locking positions corresponding to different compression rates acting on the tissue portions 44, 45 clamped between the rings.

Both the first 36 and second compression ring 39 have a
preferably closed circular annular shape (Fig. 11, 12) in order to enable their mutual alignment and connection independently from their relative angular position. The pressure surfaces of the first and second rings 36, 39 destined to contact and clamp the first and second tissue portions 45, 44 are substantially plane or circumferentially wavy in order to increase the circumference of the anastomotic lumen with respect to the external ring circumference (not shown in the figures). Advantageously, the pressure surfaces are roughened or locally profiled in order to prevent the tissue 45, 44 to squeeze radially out of the ring device in response to the axial pressure. In accordance with a preferred embodiment, the second compression ring 39 (gastric ring) comprises a shape or a specific interaction portion suitable to be engaged (e.g. by snap-fit, friction-fit, shape-fit or press-fit) by the second ring carrier 38. Both compression rings are made advantageously partially or completely of bio-absorbable or bio-fragmentable material.

In order to provide an additional fixation of the tissue portions to the compression rings 36, 39 to prevent the tissue from slipping out of engagement with the ring device, a group of needles 81 or staples is provided
which is anchored in at least one of the compression rings and adapted to pierce through the tissue clamped therebetween.

The needles 81 can be directly fixed to a compression ring or to a ring locking device 82 or, as shown in figure 11, the group of needles 81 comprise a self supporting needle ring 83 which can be e.g. received by an apposite seat defined at the locking device 82 in order to anchor the needles 81 reliably to the ring device during and after its deployment.

Both the needles and the needle ring are advantageously but not necessarily made of bio-absorbable or bio-fragmentable material.

Turning now to the locking device itself, in accordance with an embodiment (e.g. fig. 6, Fig. 7), the locking device 82 comprises an annular proximal shoulder 84 with a distal engaging surface 85 suitable to engage the proximal end surface of the first (jejunal) compression ring 36 and a tubular longitudinal portion 86 which protrudes distally from the proximal shoulder 84. The longitudinal portion 86 has a shape adapted to be inserted through the central openings of both the first and second compression rings 36, 39 and forms one or more elastically supported snapper teeth 87 adapted to snap engage a corresponding edge or surface of the
second (gastric) compression ring 39 (in the description of the locking device 82 the terms "proximal" and "distal" are referred to the direction of deployment). The provision of a distinct locking device allows the compression rings to be designed specifically to meet the requirements of the delivery and anastomosis, thereby avoiding compromises between these requirements and those of the connection of the compression rings. The tubular shape of the locking device 82 stabilizes the shape of the anastomotic lumen and provides a protective lining which isolates the tissue portions 45, 44 clamped between the compression rings from fluids and contents passing through the anastomotic lumen at least during the period of wound healing. The locking device 82 is made advantageously partially or completely of bio-absorbable or bio-fragmentable material.

As can be appreciated from the foregoing description, the anastomotic ring applier system 30 has many advantages. Its coupling device allows to couple and uncouple the first ring carrier device with respect to the second ring carrier device endoluminally at or near the operational site and the screw drive approximating device allows to approximate the compression rings in a well controllable manner without any need to apply the
push-pull forces from outside the body of the patient along the entire instrument path up to the anastomotic rings. Furthermore, the expandable anchoring head of the coupling device can act at the same time as tissue widening device and as guide device for the compression rings.

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 embodiment, but to cover all modifications and alternative constructions falling within the scope of the invention.
CLAIMS

1. An anastomotic ring applier system (30) for deploying a first compression ring (36) and a second compression ring (39), comprising an anastomotic applier (32) including:
- a second ring carrier (38) adapted to hold the second compression ring (39);
- a ring approximation device (37) with a first portion (42) connectable to an external first ring carrier device (31) which supports said first compression ring (36) and a second portion (43) connected to said second ring carrier device (38), wherein the first portion (42) forms a first thread (47) and the second portion (43) forms a second thread (48) meshing the first thread (47);
- a rotary device (49) acting on at least one of said first and second portions (42, 43) and configured to rotate the first and second portions (42, 43) to one another so that they translate to one another to approximate and interconnect the compression rings (36, 39).

2. An anastomotic ring applier system (30) according to claim 1, further comprising said first compression ring carrier device (31) which includes a first ring carrier (33) adapted to hold said first compression ring (36)
and which can be coupled to and uncoupled from the ring approximation device (37) of said anastomotic applier (32).

3. An anastomotic ring applier system (30) according to claim 1 or 2, further including a coupling device (1) which comprises:

- a coupling portion (2) connected to the first ring carrier (33) and having an inflatable anchoring head (4),

- a catching portion (3) connected to the ring approximation device (37) and defining a receiving space (9) for receiving at least part of the anchoring head (4) and an access aperture (10) through which the anchoring head (4) is insertable from outside the catching portion (3) into the receiving space (9),

- an activating device (6) connected to the anchoring head (4) and configured to deform the anchoring head (4) such that it can take on an expanded configuration and a retracted configuration,

wherein the access aperture (10) is configured to allow insertion and withdrawal of the anchoring head (4) when it is retracted and to lock the at least partially inserted anchoring head (4) to the catching portion (3) when it is expanded such as to firmly couple the approximation device to the first ring carrier device.
4. An anastomotic ring applier system (30) according to the preceding claim, wherein the anchoring head (4) comprises a balloon dilator (11) and the activating device (6) comprises a fluid pump device connected in fluid communication with the balloon dilator (11).

5. An anastomotic ring applier system (30) according to the preceding claim, wherein the anchoring head (4) can assume a substantially elongate filiform retracted shape and, if subject to fluid pressure, a substantially elongate cylindrical expanded shape.

6. An anastomotic ring applier system (30) according to any one of the preceding claims, wherein the first portion (42) of the approximation device (37) comprises:

- a rotor assembly (50) with an externally threaded outer housing (51) defining a distal opening (52) and a proximal connecting portion (53),
- a torque connector (54) connecting a torsional cable (55) to the proximal connecting portion (53),

wherein the catching portion (3) is rotatably received inside the outer housing (51) and the access aperture (10) of the catching portion (3) is arranged near a distal end surface of the outer housing (51).

7. An anastomotic ring applier system (30) according to the preceding claim, wherein the torque connector (54)
comprises a connecting cap connected by radial connecting pins (56) to a tubular ring wall (57) of the outer housing (51).

8. An anastomotic ring applier system (30) according to claim 6 or 7, wherein a rotational bearing (58) is arranged between the outer housing (51) and the catching portion (3) to enable them to rotate to one another.

9. An anastomotic ring applier system (30) according to any one of claims 6 to 8, wherein said access aperture (10) of the catching portion (3) is defined by a tubular collar having a diameter which is smaller than the transversal extension of the receiving space (9), said tubular collar engaging an internal surface of the rotational bearing (58) which is connected to the outer housing (51) near its distal opening (52).

10. An anastomotic ring applier system (30) according to any one of claims 6 to 9, wherein the second portion (43) of the ring approximation device (37) comprises a jackscrew device (59) having a tubular support structure (60) with a proximal grounding portion (61), a distal ring connector portion (64) and an internal thread (48) configured to mesh with the external thread (47) of the rotor assembly (50).

11. An anastomotic ring applier system (30) according to the preceding claim, wherein said grounding portion (61)
is adapted to connect the support structure (60) to an endoscope so that the endoscope can transmit push and/or pull forces and torque to the support structure (60).

12. An anastomotic ring applier system (30) according to any one of claims 10 to 11, wherein said distal ring connector portion (64) is configured to hold the second compression ring (39) through friction-fit.

13. An anastomotic ring applier system (30) according to any one of claims 10 to 12, wherein said tubular support structure (60) is at least partially transparent.

14. (U.S. only) A method for performing an endoluminal or transluminal anastomosis, such as e.g. a gastro-jejunostomy, a jejuno-jejunostomy, a colo-proctostomy, a jejuno-colostomy or anastomoses of the choleduct, comprising the following steps:

- Creating a loop of guide wire means by placing guide wire means (88) in the body of a patient in a way that the guide wire means (88) extend from an extracorporeal proximal end (88') into the body where it goes through a proximal tissue portion (45) and through a distal tissue portion (44) which are planned to be joined in anastomosis and out of the body up to an extracorporeal distal end (88''),

- Fixing a first ring carrier device (31) with a first proximal ring (36) of an anastomotic ring device to the

- Fixing a first ring carrier device (31) with a first proximal ring (36) of an anastomotic ring device to the
proximal end (88") of the guide wire means (88) and delivering the first ring carrier device (31) together with the proximal ring (36) to the proximal tissue portion (45),

- attaching a distal ring (39) of the anastomotic ring device to a second ring carrier device (38) of an anastomotic applier system according to any one of the preceding claims,

- guiding the anastomotic applier from the distal end (88'') of the guide wire means (88) proximally along the guide wire means (88) until it reaches the distal tissue portion (44),

- coupling the first ring carrier device (31) across the proximal tissue portion (45) and the distal tissue portion (44) to a ring approximating device (37) of the anastomotic applier (32),

- activating the ring approximating device (37) to approximate and snap-connect the distal ring (6) with the proximal ring (5), thereby clamping the distal and proximal tissue portions between them.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
   INV. A61B17/11
   ADD. A61B17/00

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Category</th>
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Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents
  * "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
  * "K" document member of the same patent family

Date of the actual completion of the international search
28 January 2008

Date of mailing of the international search report
08/02/2008

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Form PCT/ISA/210 (second sheet) (April 2005)
**INTERNATIONAL SEARCH REPORT**

**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. **X** Claims Nos.  
   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 unit/ of invention is lacking (Continuation of item 3 of first sheet)

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

1.  
   As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable 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 applicants protest and, where applicable, the payment of a protest fee
- The additional search fees were accompanied by the applicants 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

Form PCT/ISA/21 0 (continuation of first sheet (2)) (April 2005)
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