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(54) **Title:** A RECTAL RESECTION DEVICE FOR RECTAL RESECTION

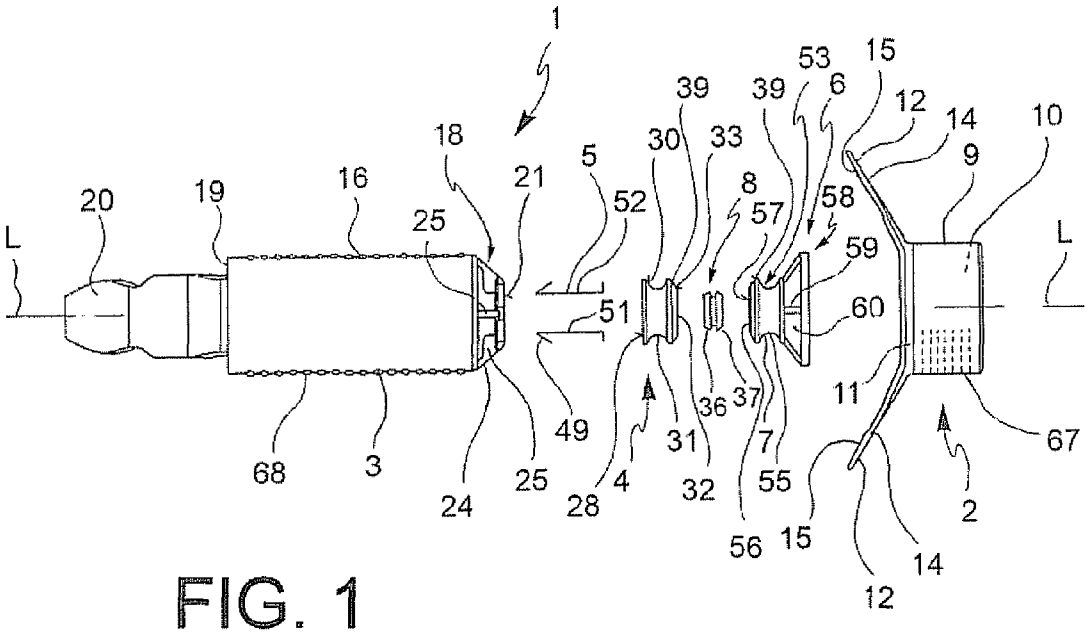

FIG. 1

(57) **Abstract:** A surgical device for use in rectal resection surgery, includes a rectal stump closure device (1) with a circular anal dilator (2) defining a passage opening (10), an anoscope (3) configured to be insertable through the passage opening (10) of the circular anal dilator (2), the anoscope (3) having a distal end portion (18), a plug device (4, 7) connected to the anoscope (3) distal end portion (18) and defining a rectal resection zone, a cutting device (62; 64) configured to form a snare which can be arranged around the outside of the rectum (46) and moved from the outside of the rectum against the rectal resection zone of the plug device (4, 7), wherein the plug device (4, 7) forms in the rectal resection zone a cutting block for the cutting device (62; 64).

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A RECTAL RESECTION DEVICE FOR RECTAL RESECTION

DESCRIPTION

The present invention relates to surgical devices and methods for the resection of the lower rectum, particularly in the treatment of patients with small or medium size rectal carcinoid tumors.

A known surgical technique to perform the resection of the lower rectum is the so called *low anterior resection* (LAR) which can be performed either by open surgery or laparoscopically using the *Knight-Griffen technique*, also known as double staple technique. Under general anesthesia the rectum is mobilized from the sacrum including division of the lateral ligaments under direct view of the laparoscope or by open surgery. The bowel is divided, e.g. between the sigmoid colon and the rectum using a linear stapler. The lower rectum (containing the tumor) is then transected using a linear or contour stapler.

In this way, a stapled proximal colon stump and a stapled rectal stump are formed, which need to be joined in order to reestablish colon - rectum continuity.

To this end, an anvil of a circular stapler is introduced into the proximal colon stump through a small skin incision, e.g. on the left lower abdomen, and the

shaft and cartridge device of the circular stapler is inserted through the rectal stump via the anus. The shaft and the anvil of the circular stapler are then re-approximated under laparoscopic view, closed and fired. During this end-to-end anastomosis, a circular staple line is fired over the previous lines of staples used to perform the rectal transection (staple crossing) which can lead to leakage at the anastomotic site.

Moreover, with known devices and procedures in both laparoscopic and open surgery, it is difficult for the surgeon to reach the resection site and to place the surgical cutting instrument (cutter-stapler) in a correct position with respect to the tumor to be excised. Particularly in cases in which the position of the tumor makes it impossible to evert the rectum through the anal canal and the transverse transection of the rectal stump is formed by open or laparoscopic stapling, the excision is performed blind without direct tumor visualization.

Consequently, with reference to low anterior rectal resection and end-to-end anastomosis of the colon and rectal stumps, there is a need to have at one's disposal a surgical device and method which overcome the deficiencies of prior art instruments and methods.

The aim of the present invention is therefore to provide

a surgical device for rectal stump closure in a combined endoluminal-laparoscopic or endoluminal-open rectal resection intervention having features which overcome the drawbacks cited with reference to the prior art.

Within the scope of the above aim, a particular aim of the present invention is to propose a rectal stump closure device and method which obviates or reduces the crossing of staple-lines during the end-to-end anastomosis of colon and rectal stumps.

A further particular aim of the present invention is to propose a rectal resection device and method which allows direct eye control of the tumor or lesion to be excised.

These aims are achieved by a surgical device for use in rectal resection surgery, including a rectal resection device, comprising:

- a circular anal dilator defining a passage opening,
- an anoscope configured to be insertable through said passage opening of said circular anal dilator, said anoscope having a distal end portion,
- a plug device connected to said anoscope distal end portion and defining a rectal resection zone,
- a cutting device configured to form a snare which can be arranged around the outside of the rectum and moved from the outside of the rectum against said rectal

resection zone of said plug device,

wherein said plug device forms, in said rectal resection zone, a cutting block for said cutting device.

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

- Figure 1 is an exploded side view of a surgical device for rectal stump closure according to an embodiment of the invention;
- Figure 2 is a cross sectional view of the device in figure 1 in a longitudinal cross sectional plane, the device being in an assembled configuration;
- Figures 3 to 14 illustrate the use of the device in figure 1 together with a tie up device and a resection device in different phases of a method for rectal resection, rectal stump closure and colon – rectal stump end-to-end anastomosis according to an embodiment of the invention;
- Figures 15 to 17 illustrate the use of the device in figure 1 together with an alternative tie up device and

resection device in phases of a method for rectal resection and rectal stump closure according to a further embodiment of the invention;

- Figure 18 is a partial side view of a surgical device according to a further embodiment of the invention;

- Figure 19 is an exploded perspective view of the device in figure 18;

- Figure 20 is a perspective view of a tie up tape applier according to an embodiment of the invention;

- Figure 21 illustrates a detail of the applier in figure 20.

Referring to the drawings where like numerals denote like components throughout the several views, figure 1 depicts a surgical device 1 for rectal stump closure in a rectal resection intervention.

The device 1 comprises a circular anal dilator 2, an anoscope 3, a rectal stump closure plug 4, a plug connector 5, a distal plate 6 with a distal plug 7 and a latching member 8.

Throughout the description of the surgical device, the expressions "distal" and "proximal" are referred to the surgeons point of view. With reference to the gastric intestinal tract, the expression "distal" indicates "toward the mouth" and the expression "proximal" indicates "toward the anus".

The circular anal dilator 2 (CAD) comprises a circular cylindrical ring wall 9 adapted to be transanally inserted into the rectum and defining internally a passage opening 10 which provides a transanal access opening for visualization and surgery and protects the internal sphincter muscle and the anal wall from damaging. A connecting portion 11 is arranged at a proximal end of the ring wall 9 and adapted to hold the ring wall 9 inside the rectum. The connecting portion 11 comprises two flat opposite wings 12, 13 protruding laterally outward from the ring wall 9 and inclined proximally to adapt to the anatomy of the anus and perianal region of the patient. Each wing 12, 13 forms a narrowed bottleneck section 14 and a ring shaped end portion 15 adapted to be sutured to the perianal skin of the patient in order to fixate the position of the device 1 inside the anus.

The anoscope 3 comprises a side wall 16 having the shape of a longitudinally straight cylinder defining a working channel 17 as well as a distal end portion 18. The side wall 16 is insertable, longitudinally (in a distal-proximal direction D-P) translatable and rotatable inside the ring wall 9 of the circular anal dilator 2 and comprises a proximal edge 19 or flange which might extend radially beyond the internal surface of the ring

wall 9 to define an end of stroke surface which prevent the anoscope 3 from being inserted too far through the ring wall 9 inside the rectum. A flat handle portion 20 protrudes laterally-proximally from the proximal edge 19 and is configured to enable manual rotation and translation of the anoscope 3 inside the ring wall 9 of the anal dilator in order to adjust the position of the distal end portion 18 to which the rectal stump closure plug and distal plate are connected, with respect to the tumor or lesion intended to be removed.

The distal end portion 18 of the anoscope 3 comprises a distal end wall 21 adapted to provide an abutment surface for the rectal stump closure plug 4 and one or more seats adapted to receive one or more plug connectors 5 which hold the rectal stump closure plug 4 firmly against the distal end wall 21 of the anoscope 3. In accordance with an embodiment, the distal end wall 21 comprises a substantially flat ring wall arranged approximately perpendicularly to a longitudinal axis of the anoscope 3. The ring wall 21 forms a through hole 22 dimensioned in a manner that the plug connector 5 can be passed through the ring wall 21 and engage the rectal stump closure plug 4, in order to lock the latter against the anoscope distal end portion 18.

In accordance with an alternative embodiment, the distal

end wall 21 defines a seat for directly engaging the rectal stump closure plug 4, e.g. by snap-engagement by screwing or by press-fit.

In accordance with a yet further embodiment, the rectal stump closure plug 4 is integrally formed with the anoscope 3 and connected to the distal end wall 21 or to the side wall 16 by a connector, such as a breaking tie, a breaking rib or a breaking wall having points or lines at which a break is intended to occur in order to separate the rectal stump closure plug 4 from the anoscope 3.

The distal end portion 18 of the anoscope 3 further comprises one or more window openings 23 which extend radially beyond the rectal stump closure plug 4 and the distal plug 5 in order to enable direct transanal visualization of the tumor 48 or of other lesion and its margins. This enables the surgeon to precisely place the surgical devices with respect to the tumor and, hence, to better control the location of resection and rectal stump formation.

In accordance with an embodiment, the distal end portion 18 of anoscope 3 comprises an approximately truncated cone shaped window ring 24 with at least one, preferably three or four inclined bars 25 connecting a distal edge of the cylindrical side wall 16 (which forms the major

base of the truncated cone) to the distal end wall 21 (which forms the minor base of the truncated cone), wherein the window openings 23 defined between bars 25, distal end wall 21 and side wall 16 extend radially outside the distal end wall 21 and provide direct visual access or also instrument access to the region distally from the plugs 4 and 7.

At the internal concave surface 26 of the side wall 16, a graduated sequence of marks 27 indicating e.g. a centimeter-scale is printed, embossed or otherwise applied to provide an immediate visual indication of the depth of insertion of the anoscope and of the distance of distal end portion 18 from the anal verge. Each mark 27 may comprises a central numeral indicating a distance from a fixed reference point at the proximal end region of the side wall 16 and one or two reference lines extending on either side of the numeral so that a certain distance can easily be associated also to instruments which do not lay very close to the numeral without being impaired by the difficult visual prospective provided by the comparatively long tubular working channel 17.

As already mentioned, the anoscope 3 is slidably and rotatably received by the ring wall 9 of the circular anal dilator 2 and has a length such that it protrudes

distally from the ring wall 9 in order to provide access to a depth of about 5 to 15 cm from the anal verge.

The ring wall 9 of the anal dilator 2 defines at its internal surface a group of circumferentially extending parallel latching ribs 67 and the side wall 16 of the anoscope 3 defines at its external surface a group of circumferentially extending parallel counter-latching ribs 68 configured in a manner that the counter-latching ribs 68 can be engaged and disengaged from the latching ribs 67 by a rotational movement of the anoscope 2 with respect to the anal dilator 2, wherein, in the disengaged configuration the anoscope 3 can translate inside the anal dilator 2 in a distal - proximal direction and in the engaged configuration the anoscope 3 is locked with respect to the anal dilator 2.

To this end the latching ribs 67 and the counter-latching ribs 68 extend only along a limited portion of the circumferences of the facing surfaces of the anal dilator and the anoscope, so that in the unlocked configuration the latching ribs 67 can be positioned in a counter-latching rib free zone of the anoscope 3.

The rectal stump closure plug 4 comprises a ring body with a substantially flat proximal end face 28 adapted to be held against the distal end wall 21 of the anoscope 3. A passage zone 29 is formed in the ring body

and configured to enable a trocar 40 of a circular stapling device 41 to pass through the rectal stump closure plug 4 in order to couple a staple fastening assembly 42 and an anvil 43 of the stapling device 41 during the end-to-end anastomosis. Such passage zone 29 can be embodied as a channel 29 or, alternatively, as a portion made of an easily penetrable material, such as rubber or expanded polymer. Accordingly, the ring body of the rectal stump closure plug 4 takes its annular shape not necessarily from the beginning, but when pierced through by the trocar 40 of the circular stapling device 41.

The ring body of the rectal stump closure plug 4 comprises a first external circumferential tie up surface 30 which extends all around the plug 4 and is intended to provide an abutment against which the lumen of the rectum 46 can be tied up from outside in order to form a closure of the rectal stump 47.

In accordance with an embodiment, the first tie up surface 30 comprises a circumferential groove 31 to facilitate positioning and tightening of a snare 34 which can be positioned about the rectum and subsequently tightened by open surgery or by laparoscopy. Thanks to the circumferential groove 31, during tightening the snare 34, the latter is biased to

position itself exactly above the first tie up surface 30 and a ring of the rectum 46 is pressed between the snare 34 and the first tie up surface 30 inside the circumferential groove 31.

The rectal stump closure plug 4 further comprises a coupling seat 32 which is provided for the connection of the distal plate 6 to the rectal stump closure plug 4. In accordance with an embodiment, the coupling seat 32 is formed near a distal end face 33 of the rectal stump closure plug 4 and may be embodied as a groove or as a cavity having an undercut suitable for engaging a corresponding tooth or edge of the distal plate 6 or, alternatively, of a dedicated separate latching member 8.

The plug connecter 5, if provided, couples the rectal stump closure plug 4 to the distal end portion 18 of the anoscope 3. As already described above, the plug connecter 5 can be embodied as an integral part of the anoscope 3 and of the rectal stump closure plug 4 which are manufactured as a single piece and provided with points or lines at which a break is intended to occur in order to separate the rectal stump closure plug 4 from the anoscope 3.

Alternatively, the plug connecter 5 can be embodied as a connection portion formed on either of the rectal stump

closure plug 4 and anoscope distal end portion 18 and configured to removably engage the other, respectively.

In accordance with the exemplary embodiment illustrated in figures 1 and 2, the plug connector 5 comprises two elastic springs 51, 52 which engage both the rectal stump closure plug 4 and connector receiving seats in the distal end portion 18 of the anoscope. When in their operational position, the elastic springs 51, 52 extend through the hole 22 of distal end wall 21 and at least partially through the passage channel 29 of the rectal stump closure plug 4. A proximal end portion 49 of springs 51, 52 is positioned in a manner to be accessible by a grasping instrument 50 through the working channel 17 of the anoscope 3. This makes it possible to grip the springs 51, 52 and remove, cut or break them to separate the anoscope 3 from the rectal stump closure plug 4.

In accordance with an embodiment, the plug connector comprises a bayonet connector 69 rotatably supported by the anoscope distal end portion 18. The bayonet connector 69 comprises a distal bayonet key 70 configured to removably engage a corresponding bayonet seat 71 formed in the rectal stump closure plug 4 and an activation portion 72 proximally protruding into the anoscope working channel 17 and destined to be

transanally grasped and rotated by a surgical grasping device. The activation portion 72 has a flat plate like shape and the bayonet connector 69 is configured such that, in a plug coupling configuration, the activation portion 72 is aligned with the inclined bars 25 of the anoscope window ring 24 in order not to obstruct visual access (figures 18, 19).

The distal plate 6 comprises a distal plug 7 arranged distally from the rectal stump closure plug 4 and having a second circumferential tie up surface 52.

Analogously to the rectal stump closure plug 4, also the second tie up surface 52 may extend all around the distal plug 7 and is intended to provide an abutment against which the lumen of the rectum 46 can be tied up from outside in order to form a closure of the portion 54 of rectum intended to be removed.

In accordance with an embodiment, the second tie up surface 52 comprises a second circumferential groove 55 to facilitate positioning and tightening of a second snare 34' which can be positioned about the rectum 46 and subsequently tightened by open surgery or by laparoscopy. Thanks to the second circumferential groove 55, during tightening the snare 34', the latter is biased to position itself exactly above the second tie up surface 52 and a ring of the rectum 46 is pressed

between the snare 34' and the second tie up surface 52 inside the circumferential groove 55.

The distal plate 6, and more precisely the distal plug 7 thereof, comprises a coupling seat 56 which is provided for the connection of the distal plate 6 to the rectal stump closure plug 4.

In accordance with an embodiment, the coupling seat 56 is formed near a proximal end face 57 of the distal plug 7 and may be embodied as a groove or as a cavity having an undercut suitable for engaging a corresponding tooth or edge of the rectal stump closure plug 4 or, alternatively, of the dedicated separate latching member 8.

In accordance with an embodiment, the distal plate 6 comprises a distal widening portion, for instance a widening ring 58 arranged distally from the distal plug 7 and having a diameter which is smaller than the internal diameter of the passage opening 10 of anal dilator 2, in order to allow insertion of the anoscope 3 equipped with rectal stump closure plug 4 and distal plate 6.

The widening ring 58 is connected to the distal plug 7 by at least one, preferably three or four inclined bars 59, wherein the free spaces defined between bars 59 and widening ring 58 provide window openings 60 which extend

radially outside the distal plug 7 and provide direct visual access or also instrument access to the region distally from the distal plug 7 and from the widening ring 58.

In accordance with an aspect of the invention, the surgical device is designed so that the distance between the distal widening ring 58 and the distal tie up plane (defined by distal plug 7 tie up surface 53) as well as the resection plane (between plugs 4 and 7) provides a sufficient margin between a tumor or lesion border and the resection plane and tissue squeezing zone, so that a correct positioning of widening ring 58 in front of a tumor automatically determines a standardized and repeatable positioning of the resection plane.

In accordance with an aspect of the invention the distal plug 7 is configured as a substantially impermeable block, so that leakage and tumor seeding are prevented both during resection and removal of the rectum portion 54.

The overall truncated cone shape of distal plate 6 and the overall truncated cone shape of the distal end portion 18 of anoscope 3 define an overall circumferential groove which provides guidance and facilitate the correct positioning of tie up snares 34, 34', bands or tapes 35 which will be described in detail

below.

As already mentioned before, the distal plate 6 can be connected to the rectal stump closure plug 4 in different ways. In accordance with an embodiment, a latching member 8 can be provided, which has a proximal flange 36 adapted to engage with the coupling seat 32 of the rectal stump closure plug 4 and a distal flange 37 adapted to engage with the corresponding coupling seat 56 formed in the distal plug 4 of distal plate 6. In order to separate the healthy rectal stump 47 and the unhealthy lumen portion containing the tumor 48 after tightening them around the respective plugs 4, 7, it is desirable to configure the latching member 8 such that it provides a removable or reversible connection between the plugs 4, 7.

This can be obtained by configuring the coupling flanges 36, 37 of latching member 8 and the respective coupling seats 32 and 56 of plugs 4, 7 so that they can removably engage, e.g. by snap-fit or press fit, or by manufacturing the latching member 8 in a material (rubber, polymer) which can be cut through by the same cutting device which is employed for rectal resection.

To this end, the latching member 8 can be configured to form a cutting block for the cutting device, e.g. a laparoscopic radiofrequency snare 62.

Moreover, opposite circumferential guide surfaces 39 can be formed in the latching member 8 itself or in plugs 4, 7 which define alone or together with the latching member 8 a circumferential cutting groove 61 which invites the cutting device to position itself in a predetermined cutting plane between first and second tie up planes determined by the corresponding first and second tie up surfaces 30, 53.

In accordance with an embodiment, the rectal stump closure plug 4 and the distal plug 7 are approximately coaxial to a longitudinal axis L of the anoscope 3 and have a diameter which is smaller than the diameters of the anoscope side wall 16 and of the distal plate widening ring 58 in order to enable direct transanal tumor visualization over both plugs 4, 7.

Turning again to the tightening snares 34, 34', in accordance with an embodiment, toothed zip ties may be used for tying up the rectum 46 against the rectal stump closure plug 4 and the distal plug 7, respectively (fig. 4, 6). The toothed zip ties provide a ratchet like one way and non return tightening.

The tie up snares 34, 34' can be applied laparoscopically or by open surgery.

Alternatively (figs. 15 - 17), the tightening snares may be tied up around the rectum 46 and locked in their

tissue pressing configuration by a locking member, e.g. a staple or clip 63 or a ratchet like toothed locking portion.

In accordance with an embodiment, an internal surface of the tightening snares or a tightening band destined to face the first and second tie up surfaces 30, 53 are shaped approximately complementary to the shape of the tie up surfaces 30, 53, particularly to the shape of circumferential grooves 31, 55.

It is also contemplated to provide a tie up tape 35 which has a width such as to extend over both the rectal stump closure plug 4 and the distal plug 7 and which can be cut through between both tie up planes during rectal transection by means of the same cutting instrument used to transect the rectum lumen.

In accordance with an embodiment, the tie up snare and the cutting instrument are integrated in a single open surgery or laparoscopic device including the looped tape 35 having a width covering both the rectal stump closure plug 4 and the distal plug 7, as well as a cutting snare, e.g. a radiofrequency snare 64 or mechanical or mechanical vibrating cutting snare which is fixed to the looped tape 35 and extends parallel to the extension of tape 35 along a center line of the latter. In this way the tightened tape 35 assures a correct position of the

integrated cutting snare (e.g. RF snare 64) during cutting.

Figures 20, 21 illustrate an exemplary, non limiting embodiment of an open surgery and or laparoscopic tie up tape applier 73. The applier 73 comprises a proximal handle 74, a distal tape fastening assembly 75 and an elongate straight or curved shaft 79 which extends from handle 74 to the tape fastening assembly 75. The tape fastening assembly 75 comprises a tape holder seat 76 which supports the tape 35 during positioning and tightening, a tape pulling mechanism activatable by a lever 77 or other manual operating member and a tape locking device which can be embodied as a staple fastener, a clip applier, or as a ratchet like toothed locking seat directly provided at one end of the tape.

The tape applier 73 also comprises a cutting mechanism involving a mechanical cutting blade housed in the tape fastening assembly 75 and connected to a cutting mechanism which is manually operable through a cutting activation member, e.g. knob 78. Alternatively, a heatable e.g. resistive cutting edge with associated energizing circuit can be provided and activated by operating an electrical switch at the handle 74.

In case a RF or mechanical cutting snare is integrated in the tie up tape 35, the tape applier 73 may also

include a cutting snare pulling mechanism and an energizing circuit for the cutting snare.

In accordance with a further embodiment, a circumferential cutting blade can be provided between the first and second tie up surfaces and configured so that the rectum lumen is pressed against it and cut through from the inside during cinching of the rectum against the first and second tie up surfaces. Alternatively, a cutting blade may be rotatably mounted between the first and second tie up surfaces and driven through the lumen wall tissue by a rotating movement generated by means of a manually operable rotating rod which torsionally engages the cutting blade and which extends inside the anoscope working channel 17.

As will be appreciated by those skilled in the art, the above described tie up tape applier makes it possible to comfortably access the low anterior rectal region by laparoscopy or open surgery and to apply the tie up tape with controllable pulling force and perform resection in a more favorable working position compared to prior art techniques.

In accordance with a further aspect of the present invention, a circular stapling device 41 is provided which includes a stapler main body 65 with a handle, an insertion shaft, a staple fastening assembly 42 to which

an anvil approximating mechanism, a staple driving mechanism and a cutting mechanism are associated. The circular stapling device 41 further comprises an anvil 43 with a proximal staple forming surface and a proximally protruding connecting shaft 44. A connecting trocar 40 is operatively linked to the anvil approximating mechanism and protrudes distally from the staple fastening assembly 42. Connecting trocar 40 and connecting shaft 44 are configured to removably engage each other and to couple anvil 43 in a tension force transmitting manner to the main body 65 of circular stapling device 41. The circular stapling device 41 is particularly adapted for an end-to-end anastomosis of the rectal stump 47 with a proximal colon stump 66. To this end the external diameter of the staple fastening assembly 42 is slightly smaller than the internal diameter of the passage opening (10) of anal dilator (2).

Moreover the staple fastening assembly 42 and or the anvil 43 define a tissue receiving cavity 45 having a diameter and a depth greater than the external diameter and axial length of the rectal stump closure plug 4.

Particularly, the tissue receiving cavity 45 has a diameter and a depth sufficient to receive the rectal stump closure plug 4 together with the tie up snare

(whose overhanging laces can be cut away before performing the anastomosis) and the clamped tissue ring.

In accordance with a yet further embodiment, the surgical device comprises illumination means configured to mark the first and/or second tie up surfaces 30, 53 and or the resection plane by a light signal which is sufficiently strong to be go through the rectal wall and to be visible from the outside of the rectum lumen in order to indicate the correct position of the tie up snares and of the resection. Such illumination means may comprise optical fiber light transmitting means extending along the anoscope and terminating near the first and second tie up surfaces 30, 53 which can be at least partially transparent.

Figures 3 - 14 illustrate a method for performing a rectal resection, rectal stump closure and rectal stump end-to-end anastomosis by means of the surgical device according to the invention.

After introducing the circular anal dilator 2 in the anus of a patient and fixating it with stay sutures on the perianal skin, the anoscope 3 holding the rectal stump closure plug 4 and the distal plate 6 is introduced in the passage opening 10 of the dilator 2 and locked in position against the latter (fig. 3).

During insertion of the anoscope 3 through the circular

anal dilator 2, the anoscope is held in an angular position to the anal dilator so that the latching ribs 67 of anal dilator 2 and the counter-latching ribs 68 of the anoscope 3 do not interfere, thereby enabling longitudinal (proximal - distal) movement of the anoscope 3. Once the anoscope 3 is positioned at the correct insertion depth, it is turned with respect to the anal dilator 2 so that the latching ribs 67 engage the counter-latching ribs 68, thereby locking the anoscope 3 longitudinally with respect to the anal dilator 2.

First and second tie up snares, particularly zip ties 34, 34' are looped around the rectum 46 by laparoscopy or by open surgery (fig. 4).

Positioning of the anoscope and the zip ties is assisted by direct transanal visualization through the window openings 23, 60 of the anoscope distal end portion 18 and of the distal plate 6 (fig. 5).

It is to be noted that the surgical device is designed so that the distance between the distal widening ring 58 and the distal tie up plane (defined by distal plug 7 tie up surface 53) as well as the resection plane (between plugs 4 and 7) determine a correct margin between a tumor or lesion border and the resection plane and tissue squeezing zone. It is therefore possible, by

positioning the distal plate 6 with the distal widening ring 58 in front of the tumor, to obtain a standardized and repeatable margin between the tumor and the tissue squeezing zone and resection plane.

Once the correct positioning of the rectal stump closure plug 4 with respect to the tumor 48 is achieved, the zip ties 34 are tightened about the first and second tie up surfaces 30, 53 of the rectal stump closure plug 4 and the distal plug 7, respectively, thereby cinching the rectal stump around the plugs 4, 7 which are supported and stabilized by anoscope 3 to which they are still firmly connected. In this stage, the circumferential grooves 31 and 55 of plugs 4, 7 receive the zip ties 34, 34' and assure their correct positioning (figs. 6, 7).

After having the rectum 46 sealed against the plugs 4, 7, resection can be performed between the two tie up planes. To this end, an open surgery or laparoscopic cutting device is brought into position and the rectum is transected between both zip ties 34, 34'. In accordance with an embodiment, the use of an RF snare (fig. 8) is contemplated, which is inserted over the rectal stump 47 and tightened between the distal plug 7 and the rectal stump closure plug 4. Thanks to the guide surfaces 39, a cutting groove 61 is provided between both plugs 4, 7 which enables self alignment of the RF

snare 62 during transection.

In accordance with an embodiment of the invention, the cutting instrument cuts completely through both the rectum and the latching member 8, thereby separating the rectal stump from the rectal lumen portion 54 to be removed and the rectal stump closure plug 4 from the distal plate 6 (figs. 8, 9, 10).

In accordance with another embodiment, the cutting instrument cuts through the rectum, but it doesn't transect the latching element 8, which can be subsequently disengaged from the distal plug or from the rectal stump closure plug in order to separate them from one another.

Once the rectal resection is complete (fig. 10), the unhealthy lumen portion 54 containing the tumor 48 or lesion is removed from the patient.

The healthy rectal stump 47 can be thoroughly washed and rinsed in order to remove residual tumor cells which might have been accidentally seeded or squeezed into the healthy tissue.

The healthy rectal stump 47 still bound by the tie up snare (zip tie 34) is now ready for an end-to-end anastomosis with the proximal colon stump 66 previously prepared by a purse string closure or by linear stapling.

To provide access space for a circular stapling device 41, anoscope 3 must be removed from the circular anal dilator 2 and, hence, it must be detached from the rectal stump closure plug 4. This is done by means of a surgical grasping instrument 50 which is inserted through the working channel 17 of the anoscope 3 up to the distal end portion thereof, and subsequently operated to grasp the proximal portion 49 of plug connector 5 to disengage the latter from rectal stump closure plug 4 (figs. 10, 11).

In accordance with an embodiment, anoscope 3 can be detached from rectal stump closure plug 4 by breaking one or more connecting bridges between the anoscope distal end portion 18 and the rectal stump closure plug 4.

Circular stapling device 41 is now introduced through the anal dilator 2 until its staple fastening assembly 42 reaches the rectal stump closure plug 4. A connecting trocar 40 distally projecting from the staple fastening assembly 42 is inserted or pierced through the passage zone 29 of plug 4. Anvil 43 of circular stapling device 41 is introduced into the proximal colon stump 66 through a small incision and a purse string is performed around its connecting shaft 44. Shaft 44 and trocar 40 are then connected under laparoscopic view, the stapling

device 41 is closed and fired. The so called cut-out tissue donut together with the rectal stump closure plug 4 and tie up snare 34 is encapsulated inside a dedicated tissue receiving space 45 (figs. 13, 14).

The circular stapling device 41 is then proximally withdrawn from the patient, tissue donuts are checked and a leak test is performed to assure that the anastomosis is air-liquid tight.

The above described device and method have many advantages. They enable direct eye control of the tumor to be excised prior to the rectal stump creation and obviate cross-stapling by creating a staple free rectal stump which can be completely housed in the tissue receiving cavity of the stapler. This eliminates the risk of leakage associated with the prior art double staple techniques.

While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention to restrict or in any way limit the scope of the appended claims to such detail.

CLAIMS

1. A surgical device for use in rectal resection surgery, including a rectal resection device (1), comprising:

- a circular anal dilator (2) defining a passage opening (10),
- an anoscope (3) configured to be insertable through said passage opening (10) of said circular anal dilator (2), said anoscope (3) having a distal end portion (18),
- a plug device (4, 7) connected to said anoscope (3) distal end portion (18) and defining a rectal resection zone,
- a cutting device (62; 64) configured to form a snare which can be arranged around the outside of the rectum (46) and moved from the outside of the rectum against said rectal resection zone of said plug device (4, 7),

wherein said plug device (4, 7) forms, in said rectal resection zone, a cutting block for said cutting device (62; 64).

2. A surgical device according to claim 1, wherein said plug device (4, 7) comprises a rectal stump closure plug (4) having a first circumferential tie up surface (30) configured such that the rectum (46) can be tied up against it from the outside of the rectum (46),

- a plug connector (5) removably connecting said rectal

stump closure plug (4) to said anoscope (3) distal end portion (18),

- a distal plug (7) arranged distally from the rectal stump closure plug (4) and having a second circumferential tie up surface (53) configured such that the rectum (46) can be tied up against it from the outside of the rectum (46), so that said first and second tie up surfaces (30, 53) define two adjacent tie up planes,

- a latching member (8) connecting said rectal stump closure plug (4) and said distal plug (7) between said two adjacent tie up planes, said latching member (8) forming said cutting block for resection of the rectum (46) between said two tie up planes.

3. A surgical device according to claim 2, wherein said tie up surfaces (30, 53) of said rectal stump closure plug (4) and of said distal plug (7) form circumferential grooves (31, 55) to facilitate positioning and tightening of tie up snares (34, 34'; 35) around rectal stump closure plug (4) and distal plug (7).

4. A surgical device according to claim 2, including a toothed zip tie (34, 34') for tying up the rectum (46) against said rectal stump closure plug (4) and against said distal plug (7), respectively.

5. A surgical device according to claim 2, comprising a radio frequency snare (62) adapted to be inserted over the rectal stump (47) and to transect the rectum (46) distally from the first tie up surface (30) and between the first and second tie up surfaces (30, 53), respectively.

6. A surgical device according to claim 3, wherein an internal surface of the tightening snares intended to face the first and second tie up surfaces (30, 53) are shaped approximately complementary to the shape of the tie up surfaces (30, 53).

7. A surgical device according to claim 2, comprising a tie up tape (35) which has a width such as to extend over both the rectal stump closure plug (4) and the distal plug (7) and which can be cut through between both tie up planes during rectal transection by means of the said cutting instrument during transecting the rectum lumen.

8. A surgical device according to claim 7, wherein the tie up snare and the cutting instrument are integrated in a single open surgery or laparoscopic device including said looped tape (35) having a width covering both the rectal stump closure plug (4) and the distal plug (7), as well as a cutting snare (64) which is fixed to the looped tape (35) and extends parallel along a

center line of tape (35).

9. A surgical device according to claim 2, including a tie up tape applier (73),

the tape applier (73) comprising:

- a proximal handle 74,
- a distal tape fastening assembly (75),
- an elongate shaft (79) which extends from handle (74) to the tape fastening assembly (75),

wherein the tape fastening assembly (75) comprises a tape holder seat (76) which supports the tape (35) during positioning and tightening, a tape pulling mechanism activatable by a manual operating member (77) and a tape locking device.

10. A surgical device according to claim 9, wherein the tape applier (73) also comprises a cutting mechanism with a mechanical cutting blade housed in the tape fastening assembly (75) and manually operable through a cutting activation member (78).

11. A surgical device according to claim 9, wherein the tape applier (73) also comprises a resistive cutting edge with associated energizing circuit, operable by means of an electrical switch at the handle (74).

12. A surgical device according to claim 9, wherein a cutting snare is connected to said tie up tape (35) and said tape applier (73) comprises a cutting snare pulling

mechanism and an energizing circuit for the cutting snare.

13. A surgical method for performing a rectal resection, comprising the steps of:

- creating a rectal stump (47),
- creating a proximal colon stump (66),
- performing an end-to-end anastomosis to join said rectal stump (47) and proximal colon stump (66) with lumen continuity,

wherein the step of creating a rectal stump (47) comprises the steps of:

- transanal insertion of a plug device (4, 7) into the rectum (46), said plug device (4, 7) defining a rectal resection zone,
- positioning a cutting device (62; 64) from the outside around the rectum (46), said cutting device being configured to form a snare,
- moving the cutting device (62; 64) from the outside of the rectum (46) against said rectal resection zone of said plug device (4, 7) arranged inside the rectum (46),
- using the rectal resection zone of said plug device (4, 7) as cutting block for said cutting device (62; 64) to transect the rectum (46).

14. A surgical method for performing a rectal resection,

- positioning at least one tie up snare (34; 35) around

the rectum (46) and closing said rectal stump (47) by tightening said tie up snare (34; 35) to press said rectum against at least one tie up surface (30) of said plug device (4, 7),

- transecting the rectum (46) adjacent to said at least one tie up surface (30).

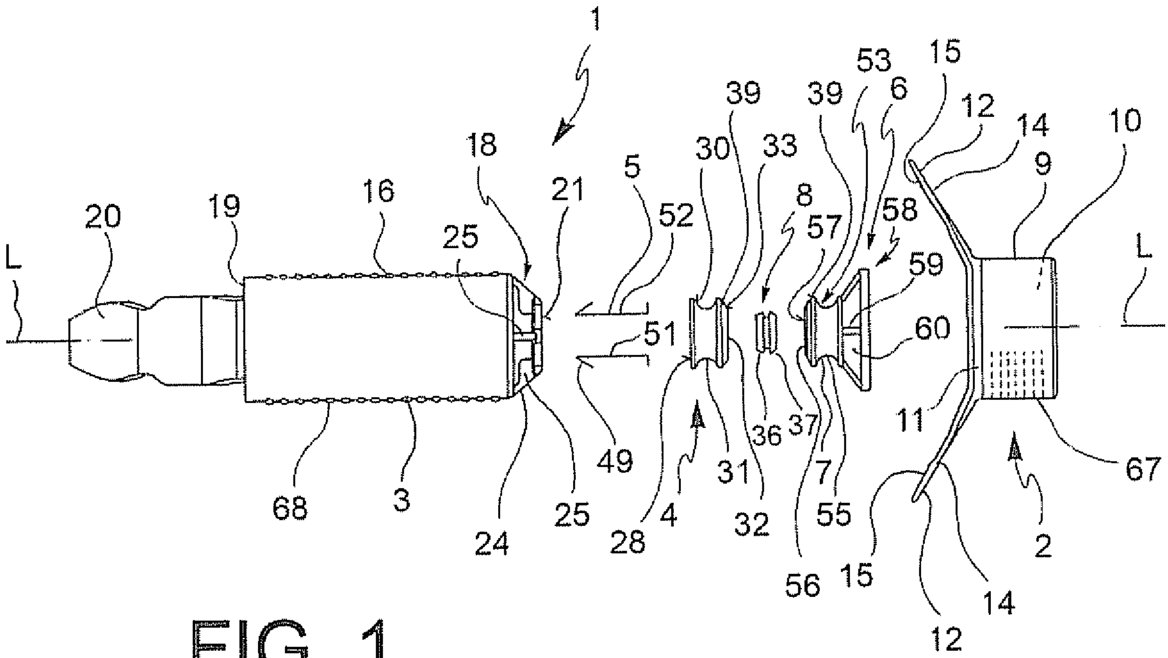
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FIG. 1

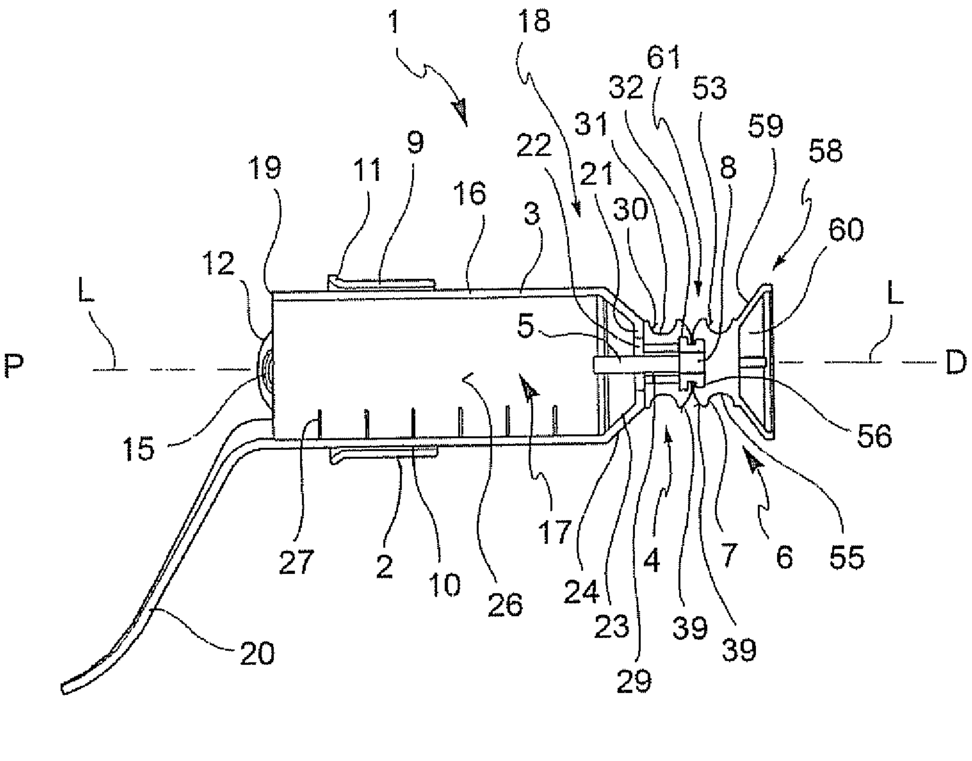
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FIG. 2

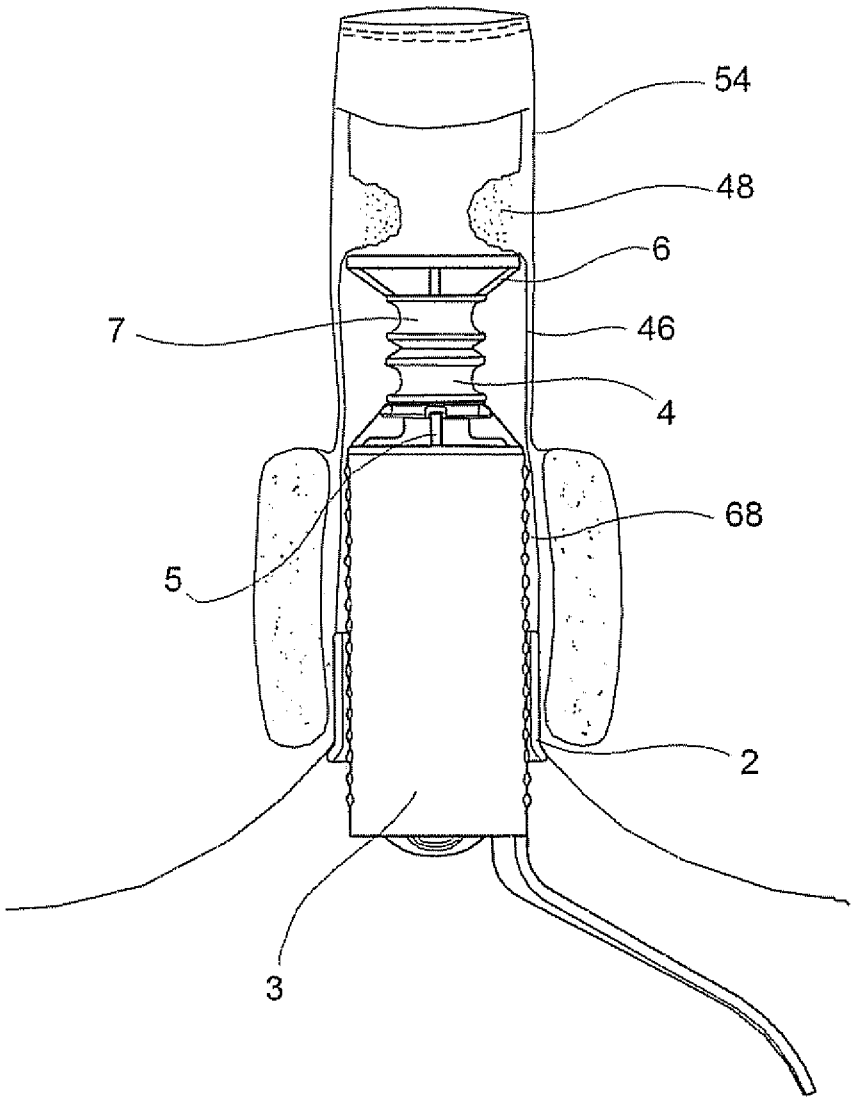

FIG. 3

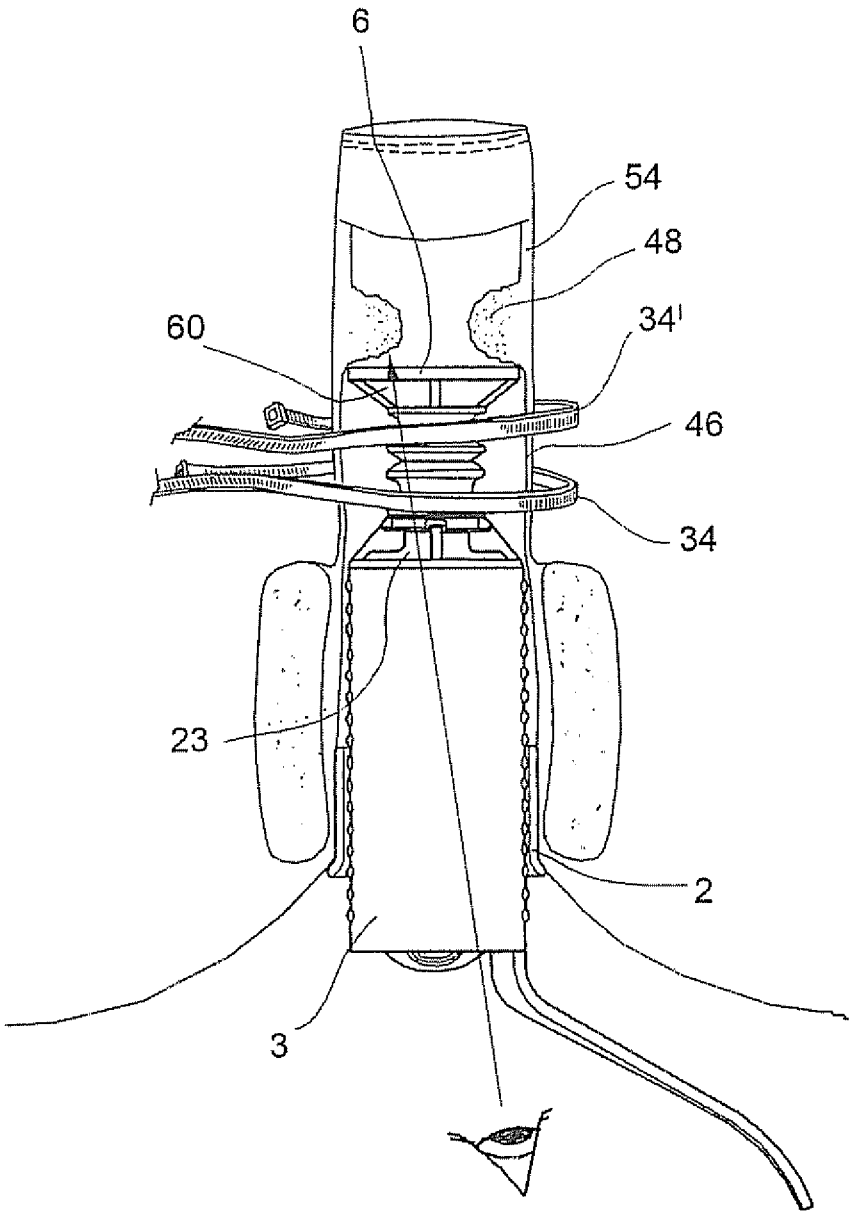

FIG. 4

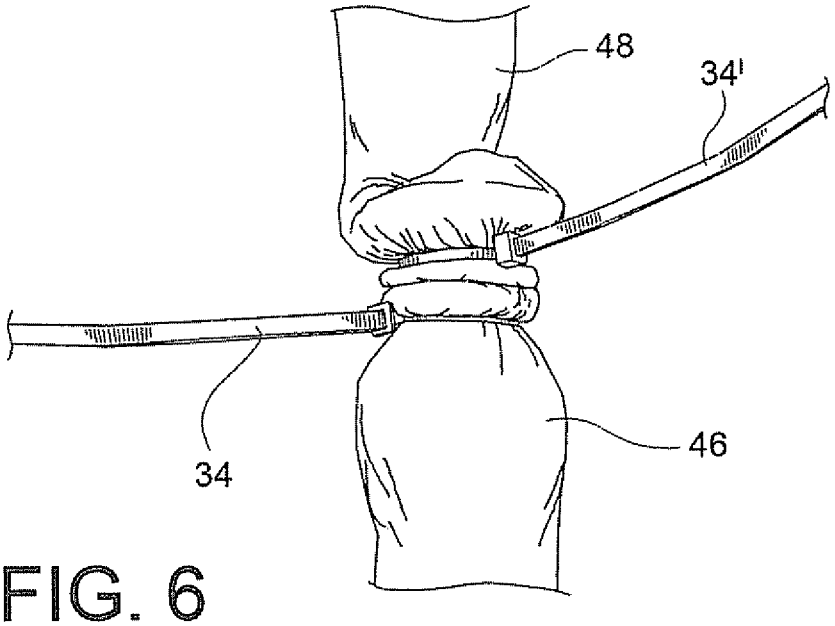

FIG. 6

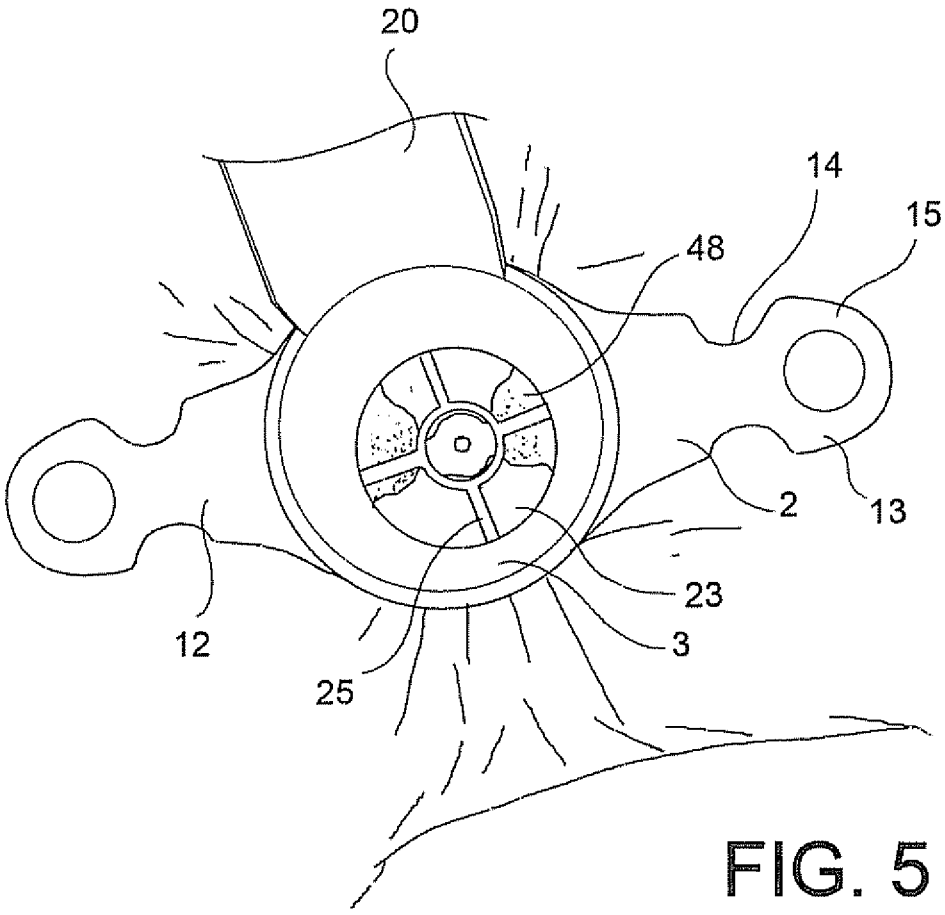

FIG. 5

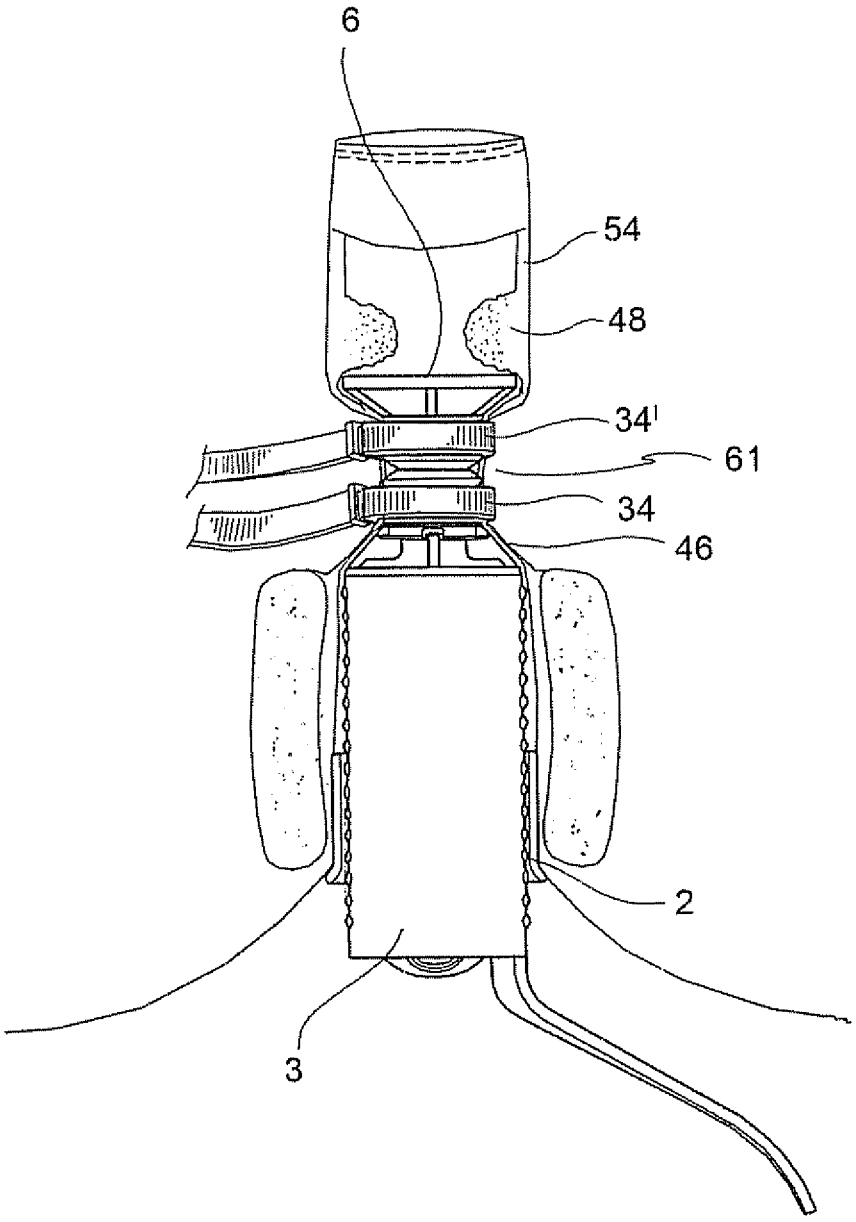

FIG. 7

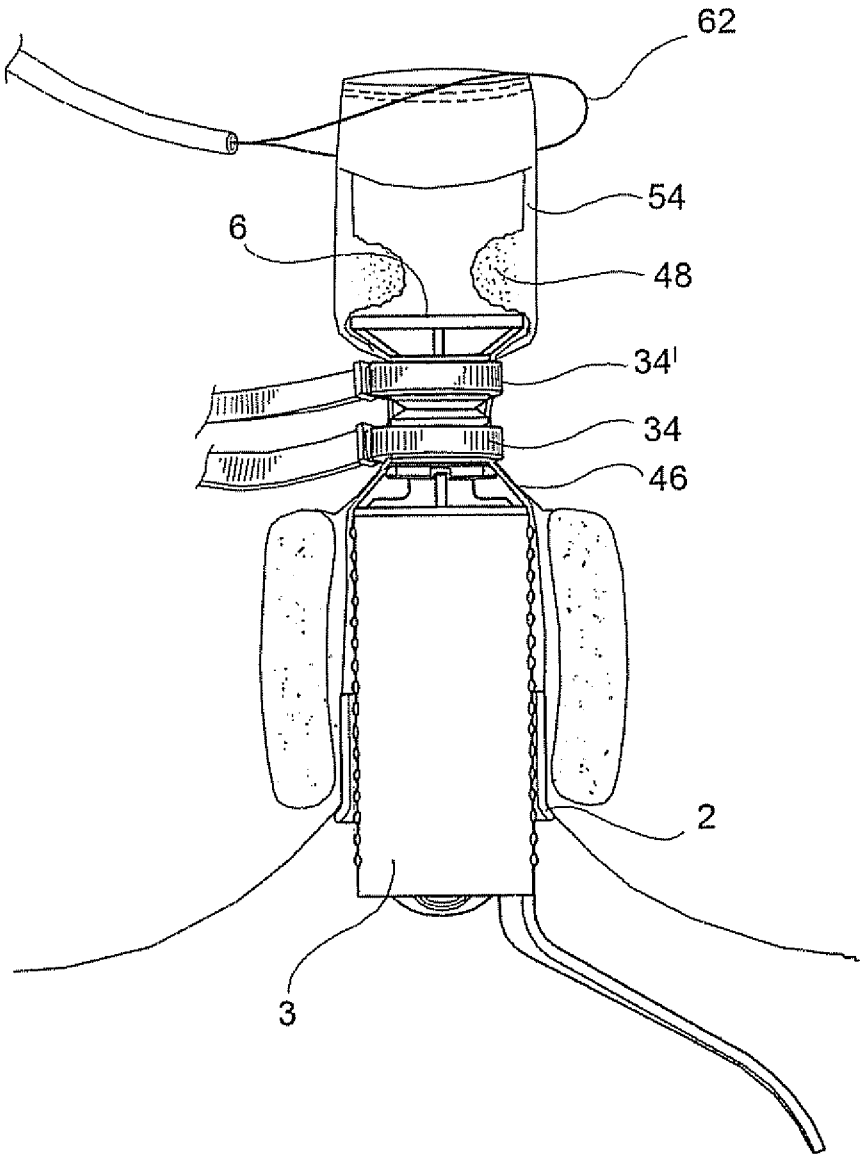

FIG.8

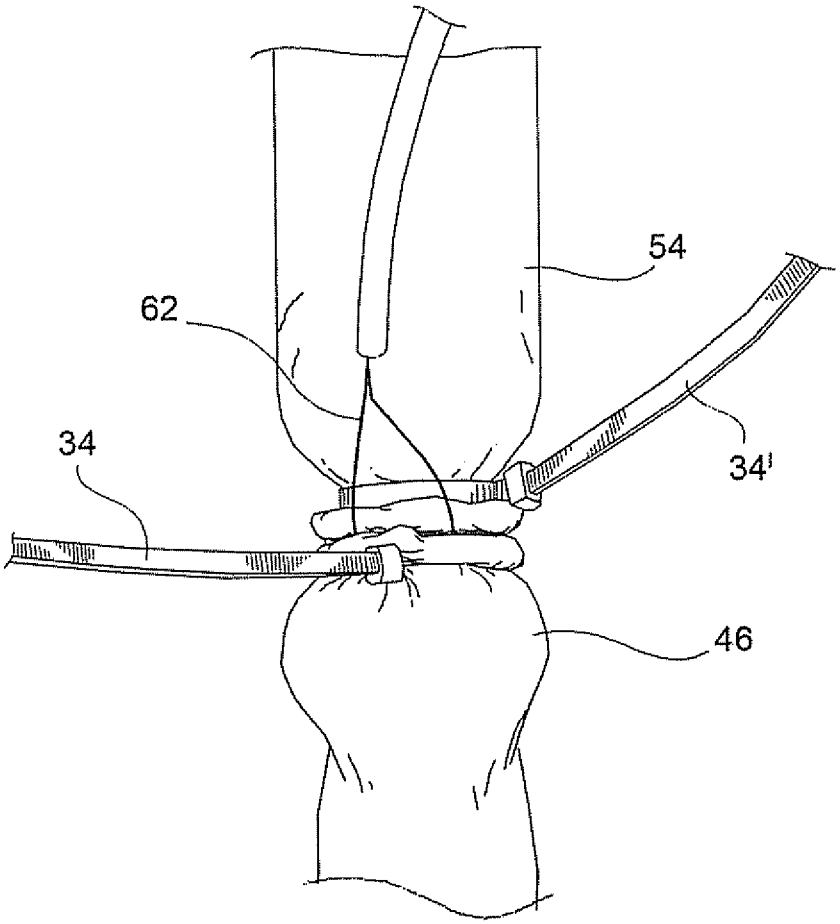

FIG. 9

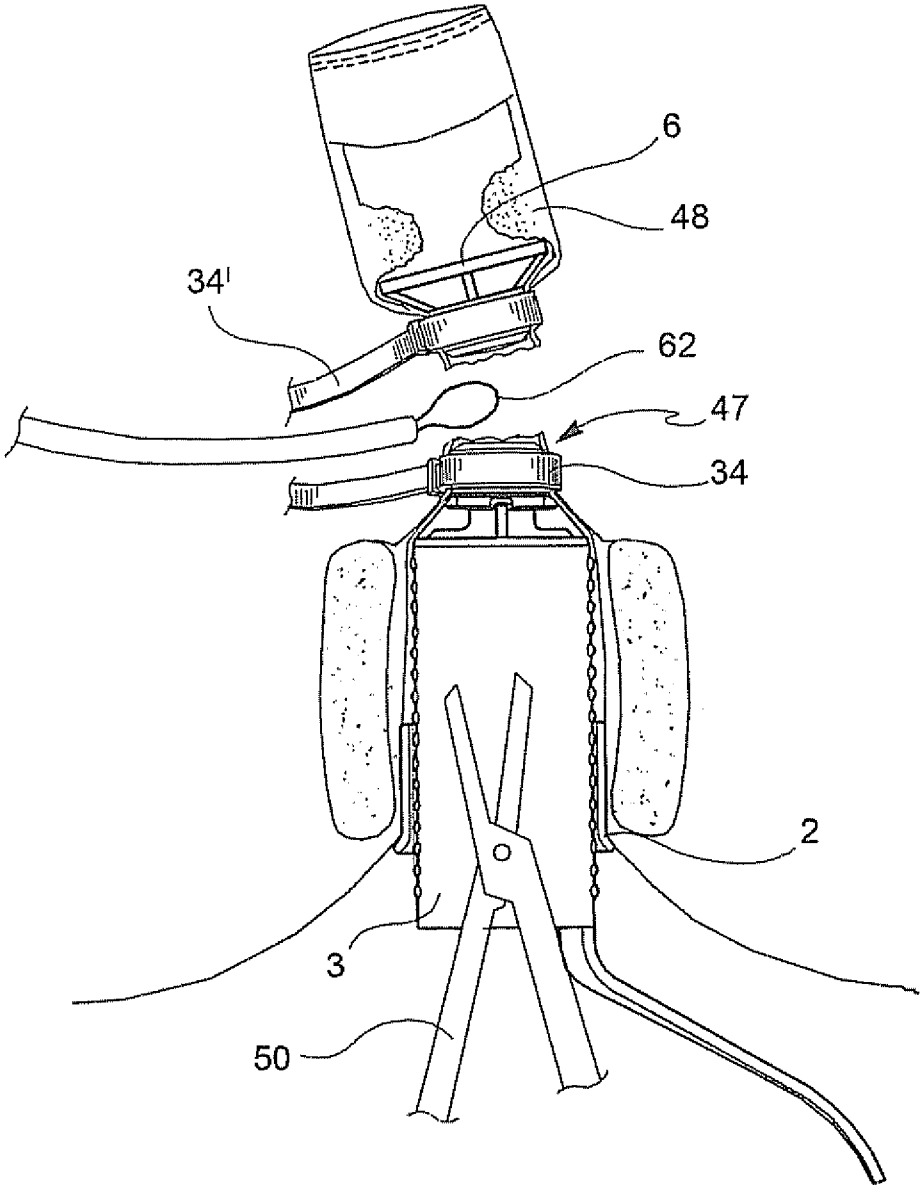

FIG. 10

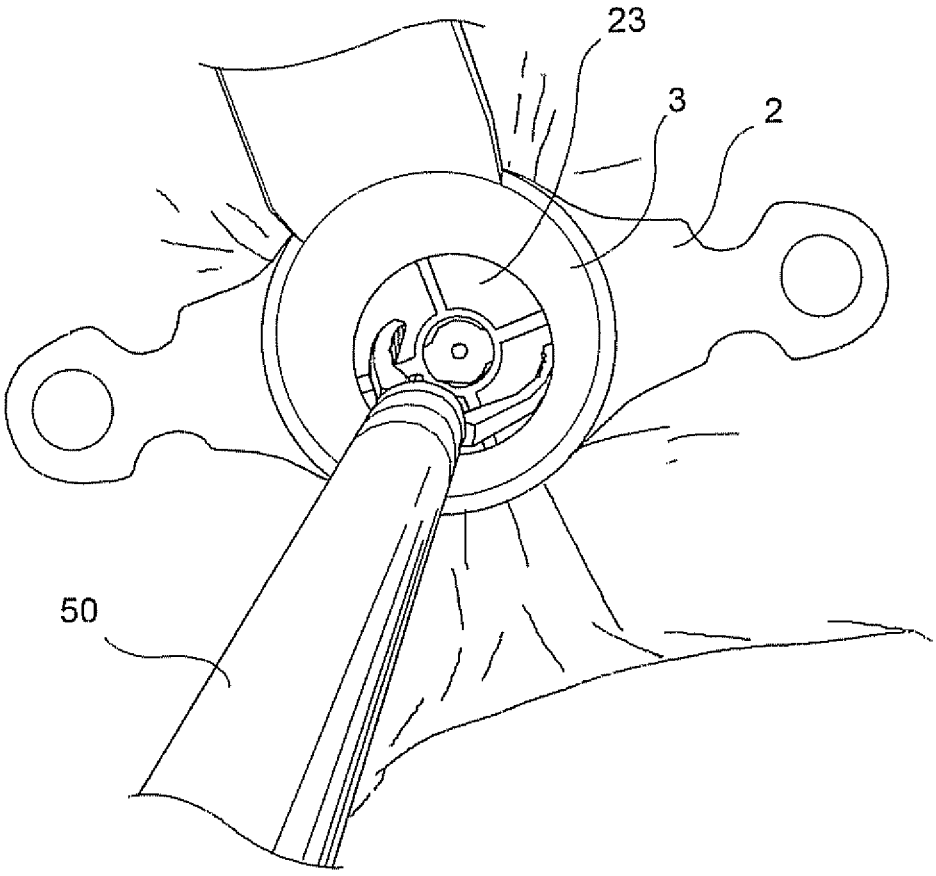

FIG. 11

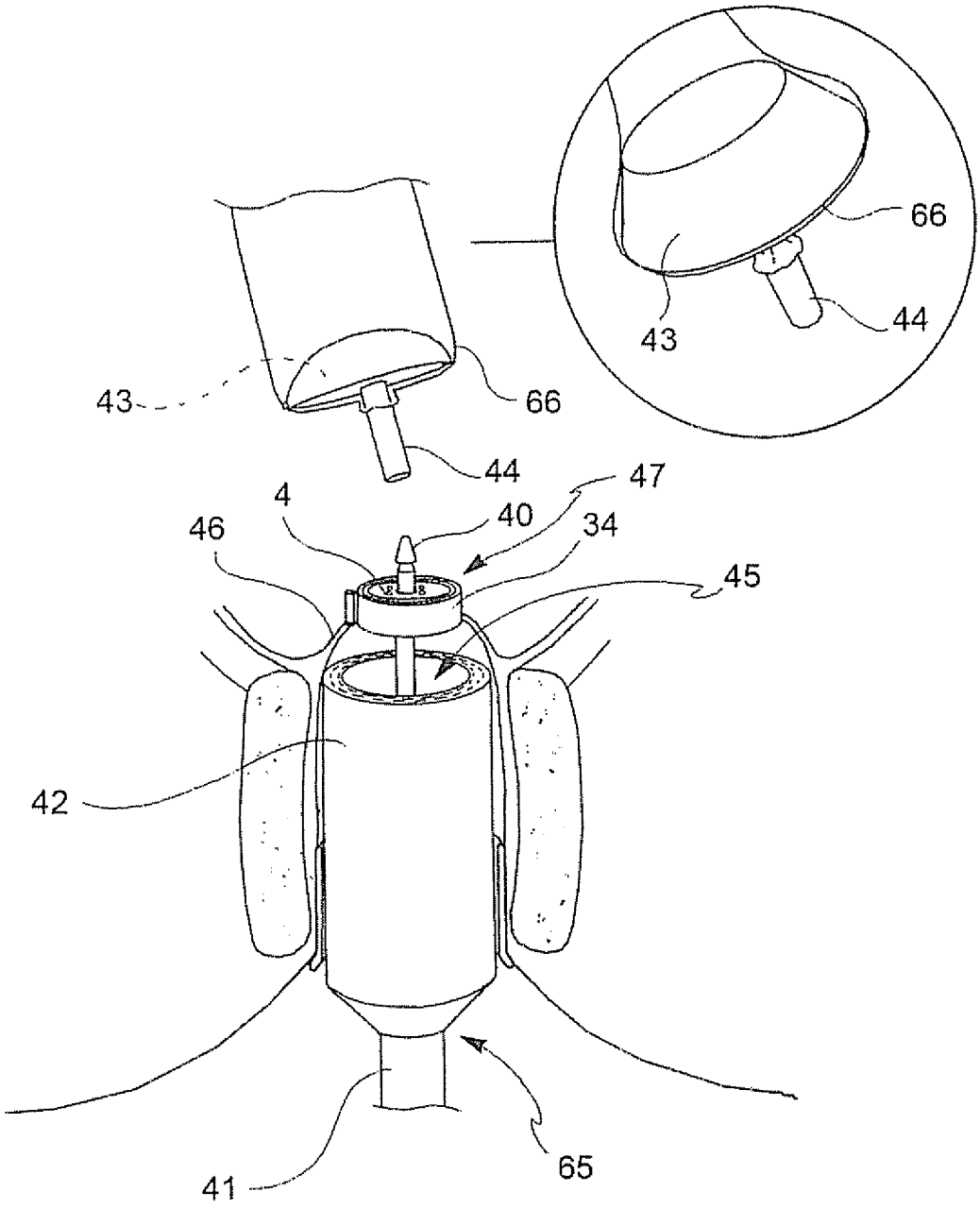

FIG. 12

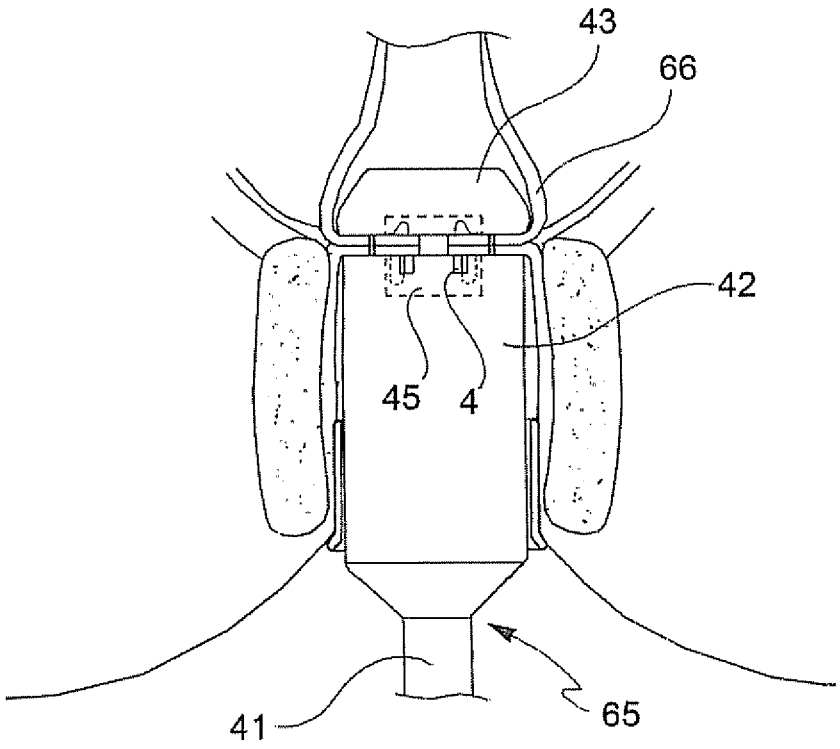

FIG. 13

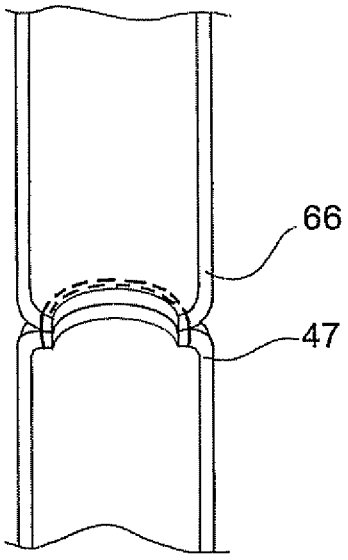

FIG. 14

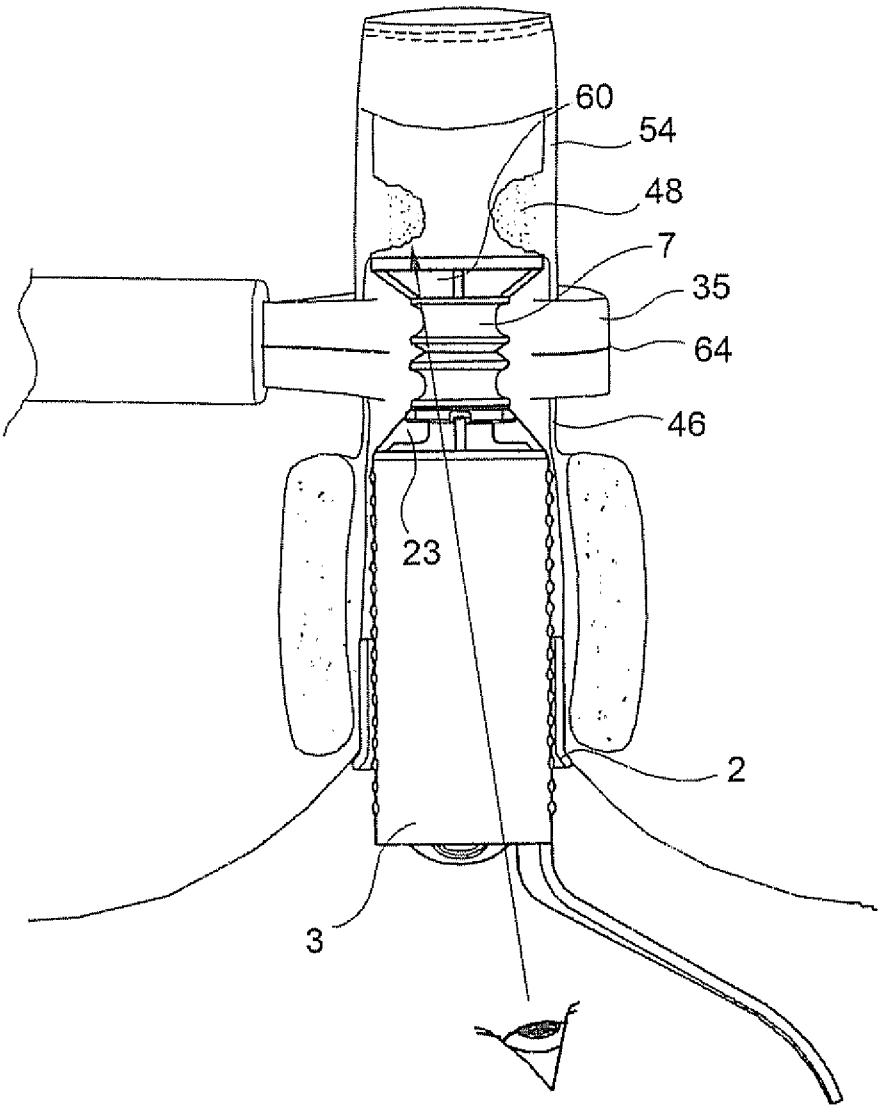

FIG. 15

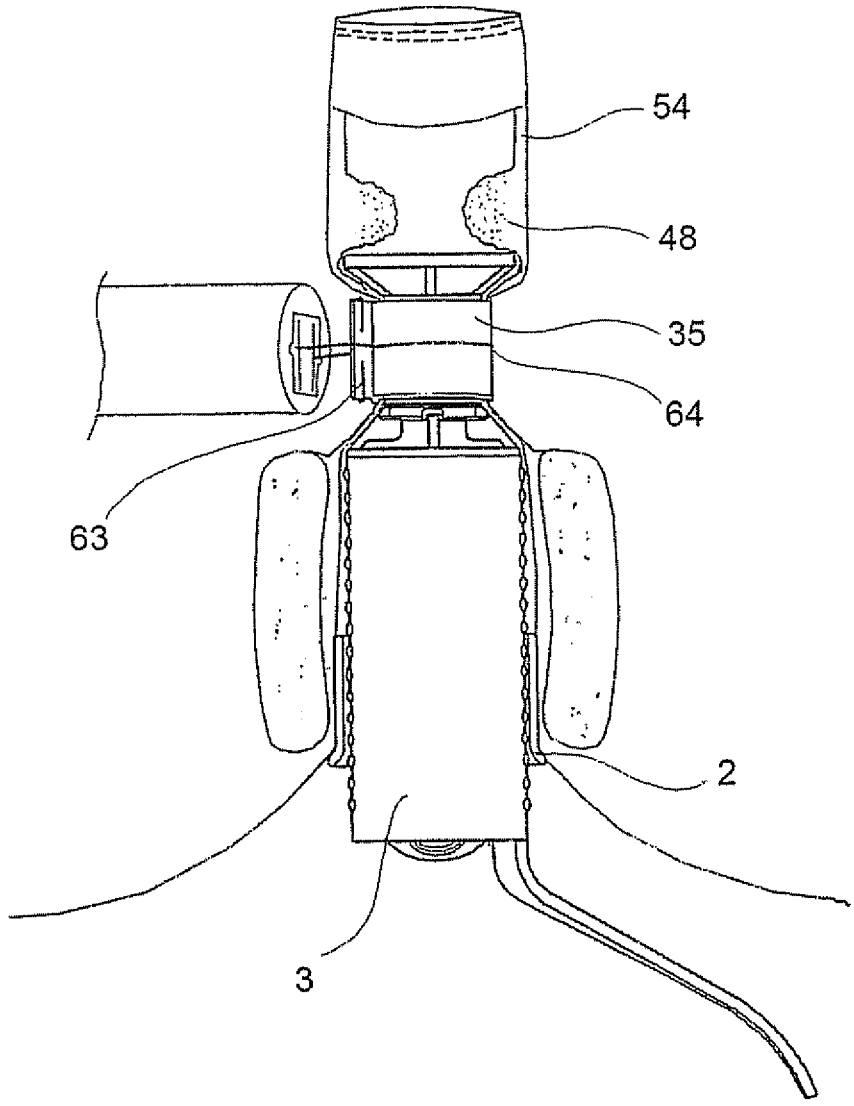

FIG. 16

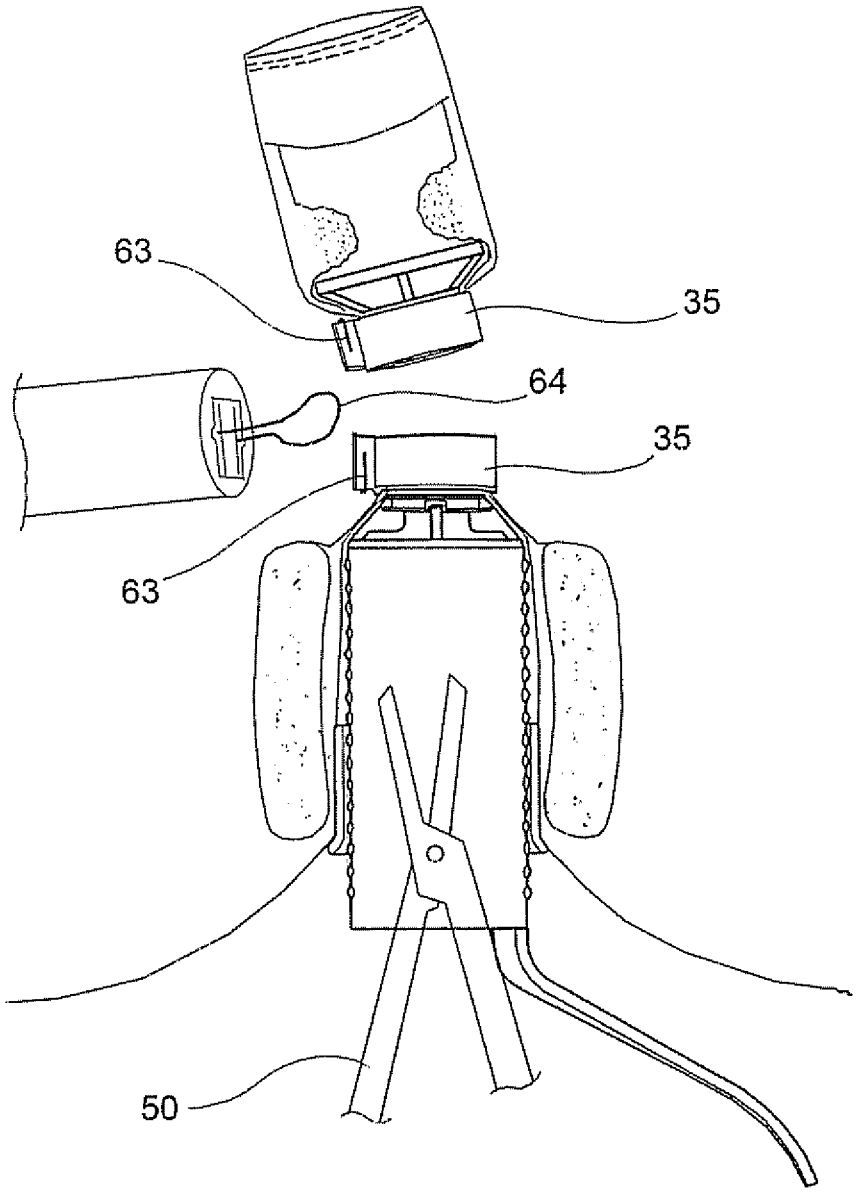

FIG. 17

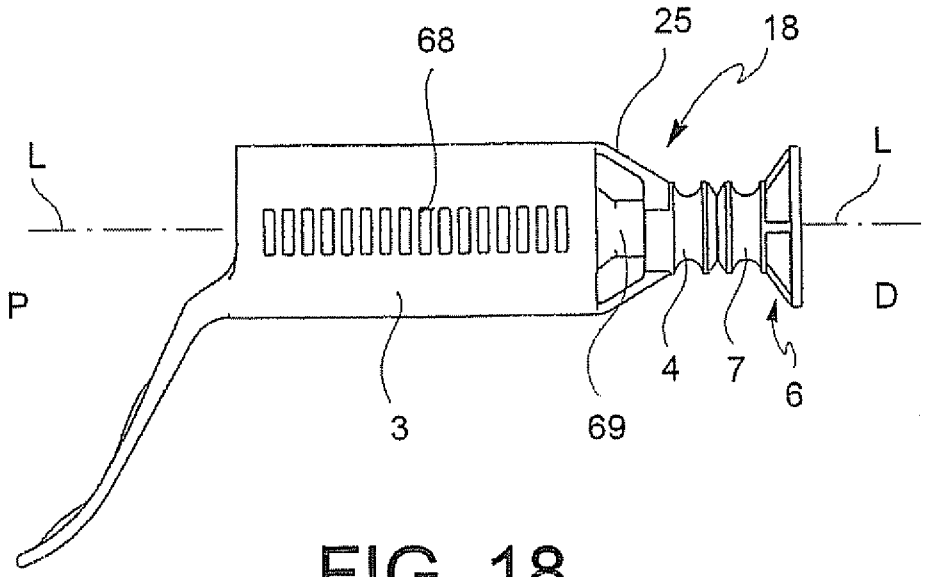

FIG. 18

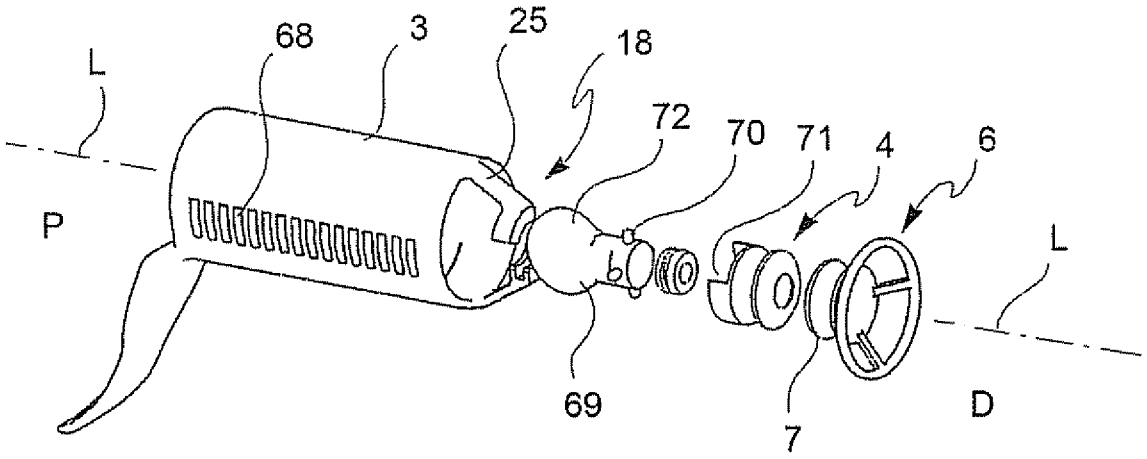

FIG. 19

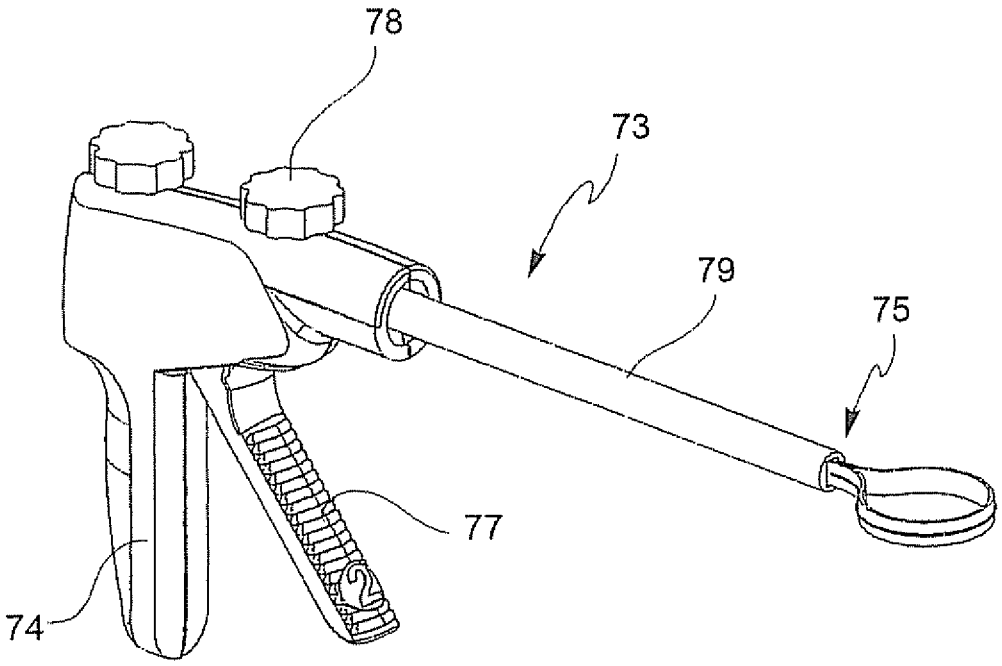

FIG. 20

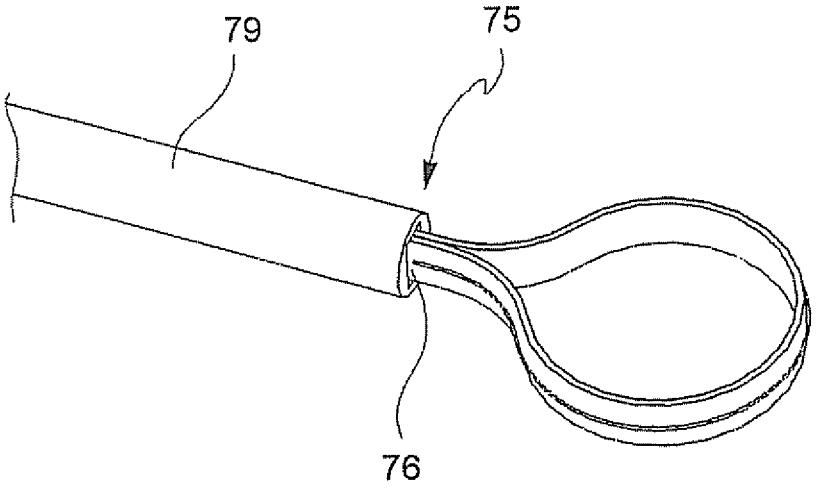

FIG. 21

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/052307

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/11 A61B17/12 A61B1/31

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 A61F

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

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2004/008937 A (NITI MEDICAL TECHNOLOGIES LTD [IL]; MONASSEVITCH LEONID [IL]; SPENSER) 29 January 2004 (2004-01-29)	1
A	page 16, line 11 - page 31, line 21; figures	2-12

Y	CA 2 380 689 A1 (UNIV MCGILL [CA]) 5 October 2002 (2002-10-05)	1
A	page 2, line 25 - page 3, line 14 page 4, line 1 - line 11 figures	5,6

A	EP 1 815 802 A (ETHICON ENDO SURGERY INC [US]) 8 August 2007 (2007-08-08) paragraph [0026]; figures 8,9	1-12

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier document 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	Date of mailing of the international search report
30 July 2008	07/08/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nistor, Loredana

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/052307

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1 559 377 A (ETHICON INC [US]) 3 August 2005 (2005-08-03) paragraph [0016] - paragraph [0024]; figures	1,5,6
A	WO 2007/122223 A (CARPONOVUM AB [SE]; GROENBERG ANDERS [SE]; THORLACIUS HENRIK [SE]) 1 November 2007 (2007-11-01) page 14, line 6 - line 30; figures 21-23	1
A	DE 41 33 800 C1 (ETHICON GMBH & CO KG, 2000 NORDERSTEDT, DE) 21 January 1993 (1993-01-21) column 4, line 54 - column 5, line 17; figures	1
A	EP 1 671 594 A (OLYMPUS CORP [JP]) 21 June 2006 (2006-06-21) paragraph [0096] - paragraph [0097]; figures 20A-23	1,6-8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2008/052307

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.: 13, 14
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgeryRule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

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:

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 reportcovers 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

Information on patent family members

International application No
PCT/EP2008/052307

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2004008937 A	29-01-2004	AU 2003245015 A1	09-02-2004
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		WO 2005032384 A1	14-04-2005
		US 2006253128 A1	09-11-2006

专利名称(译)	直肠切除装置用于直肠切除术		
公开(公告)号	EP2219532A1	公开(公告)日	2010-08-25
申请号	EP2008709213	申请日	2008-02-26
[标]申请(专利权)人(译)	伊西康内外科公司		
申请(专利权)人(译)	爱惜康内镜手术，INC.		
当前申请(专利权)人(译)	爱惜康内镜手术，INC.		
[标]发明人	CSIKY LASZLO DARCANGELO MICHELE PASTORELLI ALESSANDRO		
发明人	CSIKY, LASZLO D'ARCANGELO, MICHELE PASTORELLI, ALESSANDRO		
IPC分类号	A61B17/11 A61B17/12 A61B1/31		
CPC分类号	A61B1/31 A61B17/1114 A61B17/115 A61B17/1155 A61B17/12013 A61B17/3423 A61B2017/3452 A61B2018/1407		
优先权	PCT/EP2007/062351 2007-11-14 WO		
外部链接	Espacenet		

摘要(译)

一种用于直肠切除手术的外科手术装置，包括直肠残端闭合装置（1），其具有限定通道开口（10）的圆形肛门扩张器（2），瞄准器（3），其构造成可通过通道开口插入（10）圆形肛门扩张器（2），具有远端部分（18）的肛门镜（3），连接到肛门镜（3）远端部分（18）并限定直肠切除术的塞装置（4,7）区域，切割装置（62; 64），其构造成形成圈套，该圈套可围绕直肠（46）的外侧布置并且从直肠的外侧抵靠插塞装置（4,7）的直肠切除区域移动，其中插塞装置（4,7）在直肠切除区中形成切割装置（62; 64）的切割块。