(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 August 2018 (16.08.2018)

WIPO | PCT

(10) International Publication Number
WO 2018/148474 A1

(51) International Patent Classification:
A61B 17/068 (2006.01) *A61B 17/3205* (2006.01)

(21) International Application Number:
PCT/US2018/017523

(22) International Filing Date:
09 February 2018 (09.02.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/456,768 09 February 2017 (09.02.2017) US

(71) Applicants: **SOUTHERN RESEARCH INSTITUTE** [US/US]; 2000 9th Avenue South, Birmington, AL 35205 (US). **THE UAB REASERCH FOUNDATION** [US/US]; 701 20th Street South, AB 770, Birmingham, AL 35294 (US).

(72) Inventors: **SCHEXNAILDER, Patrick J.**; 165 Brook Trace Drive, Hoover, AL 35244 (US). **HERGENROTHER, Robert W.**; 105 Caber Court, Vestavia Hills, AL 35242 (US). **CHU, Daniel I.**; 795 Provence Drive, Vestavia Hills, AL 35242 (US). **KENNEDY, Gregory D.**; 3413 Brook Mountain Lane, Mountain Brook, AL 35223 (US).

(74) Agent: **BROWNING, C. Brandon** et al.; Maynard, Cooper & Gale, PC, 1901 Sixth Avenue North, Suite 2400, Birmingham, AL 35203 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(54) Title: ENDO-LUMINAL ANASTOMOTIC STAPLING DEVICE

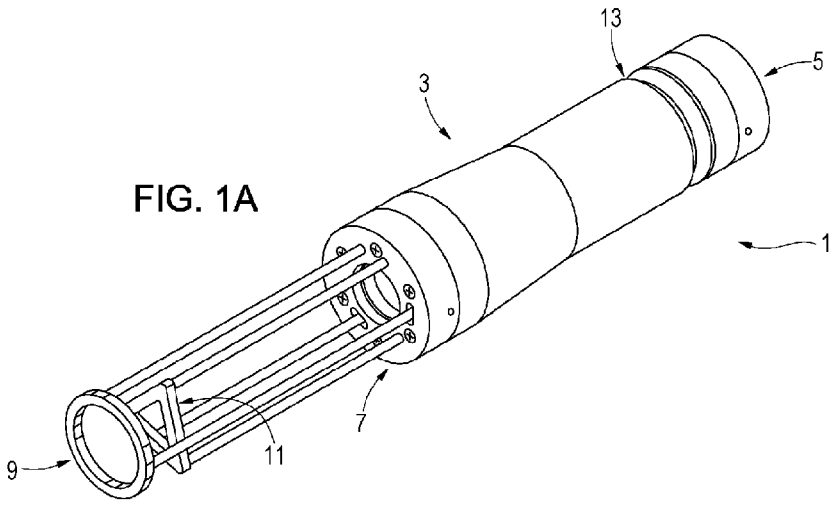

FIG. 1A

(57) Abstract: The present disclosure relates to devices and methods for the removal of a section of tissue from a subject, such as the removal of a section of colon from within the lumen of the large intestine of a subject. The device generally comprises a cylindrical housing comprising an inlet, an outer cavity connected to the inlet, an inversion device, a stapling controller and a cutting controller, wherein the stapling controller is configured to operate a stapling head located within the housing and wherein the cutting controller is configured to operate a cutting head located within the housing. The housing may surround a portion of an endoscope, such as a colonoscope, such that the colonoscope passes through an inner cavity of the device. Methods of using the device generally comprise the steps of: inserting the device into a subject's rectum; advancing the device through the colon to the area of interest; inverting of the area of interest using the inversion device; stapling non-adjacent areas of the colon together; resecting the area of interest; and retracting the device.

WO 2018/148474 A1

[Continued on next page]

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

ENDO-LUMINAL ANASTOMOTIC STAPLING DEVICE

Cross Reference To Related Application

[0001] This application claims priority to U.S. Provisional Patent Application No. 62/456,768, entitled "Endo-Luminal Anastomotic Stapling Device" and filed on February 9, 2017, which is incorporated herein by reference.

Technical Field

[0002] A number of conditions, such as cancer, diverticular disease, and inflammatory bowel disease may require a surgeon to remove a portion of a patient's large intestine. For the patient to maintain gastrointestinal continuity and evacuate stool in a normal manner, the surgeon must reconnect the ends of the intestines where the diseased portion was removed, forming an anastomosis. Using current methods, to properly reconnect the ends of the intestines, the surgeon must make one or more incisions into the patient's abdomen. Bowel ends must be prepared and then the proximal and distal margins must be connected using sutures or staples.

[0003] A common method of creating a colonic anastomosis is to use an end-to-end anastomotic (EEA) stapler. In this approach, the head of a detachable anvil is placed in the lumen of the colon after the diseased section has been removed, and the anvil is temporarily secured in place using a purse string suture. This portion of the procedure is performed outside the lumen of the bowel and via an abdominal incision with either open or minimally-invasive techniques. Next, the handle mechanism is inserted into the distal colon lumen via the anus up to the very end, which was previously closed during the removal of the diseased section. A metal spike is pushed through this blind end and then interfaced with the hollow anvil. The anvil and the end of the handle mechanism are then brought together. The EEA stapler staples the two ends of the colon together (creating the anastomosis) and cuts a ring of tissue (e.g., the donuts) to create a continuous lumen with a similar internal diameter throughout the anastomotic region.

[0004] While minimally-invasive surgery has improved recovery times and reduced complication rates compared to open surgery, these intestinal anastomoses still require extra-luminal preparation with the potential for spillage and surgical site infections. Therefore, developing a technique for a completely endo-luminal approach to intestinal anastomoses could translate to further improved clinical outcomes.

Background of Invention

[0005] In one embodiment, the present disclosure relates to an anastomosis device, comprising: a housing, wherein the housing includes an outer cavity; a stapling controller; a cutting controller; an inversion device; at least one stapling head located within the outer cavity of the housing and positioned radially about the longitudinal axis of the device, wherein the at least one stapling head is connected to the stapling controller; at least one stapling anvil; and at least one cutting head located within the outer cavity of the housing and positioned radially about the longitudinal axis of the device, wherein the at least one cutting head is connected to the cutting controller; wherein the housing includes an inlet spanning the circumference of a portion of the housing and connected to the outer cavity of the housing. In certain embodiments, the device further comprises an endoscope. In certain embodiments, the endoscope extends through the longitudinal axis of the device. In certain embodiments, the device further comprises at least one delivery port. In certain embodiments, the delivery port contains a biological sealant. In certain embodiments, each stapling head comprises at least one staple cartridge, each staple cartridge containing at least one staple. In certain embodiments, each cutting head comprises at least one cutting device. In certain embodiments, the device further comprises at least one cutting anvil. In certain embodiments, the device further comprises at least one secondary cutting head configured to be flush with each cutting head. In certain embodiments, the inversion device comprises a suction device. In certain embodiments, the inversion device comprises a mechanical grasping device.

[0006] In certain embodiments, the present disclosure relates to a method of forming an anastomosis in the colon of a subject, comprising the steps of: inserting the device of described in the preceding paragraph into the subject's rectum; advancing the device to the area of interest; activating the inversion device to invert the area of interest inside the device via an inlet; activating the stapling controller to advance at least one stapling head to staple and connect previously non-adjacent sections adjacent to the area of interest together; activating the cutting controller to advance the at least one cutting head to remove the area of interest; releasing the colon; and retracting the device. In certain embodiments, the area of interest remains within the device. In certain embodiments, the area of interest is inverted inside the device using

suction. In certain embodiments, the area of interest is inverted inside the device mechanically. In certain embodiments, the device further includes a delivery port and further comprising the step of activating the delivery port. In certain embodiments, the delivery port contains biological sealant. In certain embodiments, the delivery port is activated after the cutting controller is activated.

[0007] In certain embodiments, the present disclosure relates to a method of forming an anastomosis in the tissue of a subject, comprising the steps of: inserting the device of paragraph [0004] into the subject; advancing the device to the area of interest; activating the inversion device to invert the area of interest inside the device via an inlet; activating the stapling controller to advance the at least one stapling head to staple and connect previously non-adjacent sections adjacent to the area of interest together; activating the cutting controller to remove the area of interest; releasing the tissue; and retracting the device. In certain embodiments, the tissue is inverted inside the device using suction. In certain embodiments, the tissue is inverted inside the device mechanically. In certain embodiments, the device further includes a delivery port and further comprising the step of activating the delivery port.

[0008]

Brief Description Of The Drawings

[0009] The disclosure can be better understood with reference to the following drawings. The elements of the drawings are not necessarily to scale relative to each other, emphasis instead being placed upon clearly illustrating the principles of the disclosure. Furthermore, like reference numerals designate corresponding parts throughout the several views.

[0010] FIG. 1A is an isometric view of an illustration of a first exemplary embodiment of a colectomy device. FIG. 1B is an illustration of a side view of the colectomy device, depicted in FIG. 1A.

[0011] FIG. 2A is an illustration of the leading side of the colectomy device, depicted in FIG. 1A. FIG. 2B is an illustration of the trailing side of the colectomy device, depicted in FIG. 1A.

[0012] FIG. 3 is an illustration of a cross section of the colectomy device, depicted in FIG. 1A.

[0013] FIG. 4A is an illustration of a cross section of the colectomy device, depicted in FIG. 1A, wherein the cutting controller is slideably advanced. FIG. 4B is an

illustration of a cross section of the colectomy device, depicted in FIG. 1A, wherein the stapling controller and cutting controller are slideably advanced.

[0014] FIG. 5 is an illustration of an expanded cross section of the colectomy device, depicted in FIG. 1A, wherein the cutting controller is slideably advanced.

[0015] FIG. 6 is an illustration of an expanded cross section of the colectomy device, depicted in FIG. 1A, wherein the stapling controller and cutting controller are slideably advanced.

[0016] FIG. 7 is an isometric view of the leading side of the colectomy device depicted in FIG. 1A.

[0017] FIG. 8A is a view of the stapling head of the colectomy device depicted in FIG. 1A. FIG. 8B is an alternate view of the stapling head of the colectomy device depicted in FIG. 1A.

[0018] FIG. 9 is an illustration of a second exemplary embodiment of a colectomy device.

[0019] FIG. 10 is an illustration of a cross section of the colectomy device, depicted in FIG. 9.

[0020] FIG. 11 is an illustration of a cross section of the colectomy device, depicted in FIG. 9, with the colon being inverted upon itself after entering the inlet. Vacuum and/or mechanical methods (not shown) may be used to correctly position the colon within the colectomy device.

[0021] FIG. 12 is an illustration of a cross section of the colectomy device, depicted in FIG. 9, illustrating the stapling head advanced and circumferentially connecting non-adjacent regions of the colon.

[0022] FIG. 13 is an illustration of a cross section of the colectomy device, depicted in FIG. 9, illustrating the cutting head resecting the area of interest.

[0023] FIG. 14 is an illustration of a cross section of the colectomy device, depicted in FIG. 9, illustrating the stapling head retracted. The area of interest is captured within the outer cavity of the colectomy device.

[0024] FIG. 15 is a photograph of the individual components comprising the colectomy device of FIG. 9.

[0025] FIG. 16 is a photograph showing the first step of a method of assembling the colectomy device of FIG. 9 in which the distal cap, cutting head, stapling head, distal spacers, and distal collet form a rear housing unit and are connected to the collet connector over the colonoscope.

[0026] FIG. 17 is a photograph showing the second step of a method of assembling the colectomy device of FIG. 9 by attaching the distal exterior housing to the rear housing unit.

[0027] FIG. 18 is a photograph showing the third step of a method of assembling the colectomy device of FIG. 9 by positioning the proximal exterior housing, proximal spacers and proximal collet (in that order) over the colonoscope before screwing the proximal collet into the collet connector.

[0028] FIG. 19 is a photograph showing the fourth step of a method of assembling the colectomy device of FIG. 9 by using a temporary spacer to align the proximal and distal exterior housing units collinearly before tightening the proximal collet to secure the orientation.

[0029] FIG. 20 is a photograph showing the fifth step of a method of assembling the colectomy device of FIG. 9 by assembling the proximal cap to the proximal exterior housing and removing the temporary spacer.

[0030] FIG. 21 is a photograph showing the sixth step of a method of assembling the colectomy device of FIG. 9 by inserting a mechanical grasping device through the outer cavity of the device and positioning the grasping hooks of the mechanical grasping device at or near the inlet between the proximal and distal exterior housings.

Detailed Description

[0031] The present disclosure relates to devices and methods for the removal of a section of tissue from a subject, such as the removal of a section of colon from within the lumen of the large intestine of a subject. The device generally comprises a cylindrical housing comprising an inlet, an outer cavity connected to the inlet, an inversion device, a stapling controller and a cutting controller, wherein the stapling controller is configured to operate a stapling head located within the housing and wherein the cutting controller is configured to operate a cutting head located within the housing. The housing may surround a portion of an endoscope, such as a colonoscope, such that the colonoscope passes through an inner cavity of the device. Methods of using the device generally comprise the steps of: inserting the device into a subject's rectum; advancing the device through the colon to the area of interest; inverting of the area of interest using the inversion device; stapling non-adjacent areas of the colon together; resecting the area of interest; and retracting the device.

[0032] As used herein, “area of interest” means the area of tissue selected for resection. For example, the area of interest, for a colectomy, may include the area of tissue to be stapled and the area of excess tissue to be removed.

[0033] As used herein, “subject” means an animal, preferably a mammal, and more preferably a human.

[0034] As used herein, "therapeutic" means an agent utilized to discourage, combat, ameliorate, prevent or improve an unwanted condition, disease or symptom of a subject. For example, therapeutic may include, but is not limited to, a sealant, designed to mitigate or prevent leakage from an anastomosis, an antibiotic, or other agent designed to improve tissue viability.

[0035] FIGS. 1A and 1B show exterior views of a first exemplary embodiment of a anastomosis device 1 described in this disclosure configured to perform a colectomy. The device 1 is configured to remove a section of the colon from within the lumen of the large intestine of a subject (e.g., no extra-luminal manipulation or need for incisions on the subject anywhere other than the colon). The device 1 includes a housing 3 with an approximately cylindrical shape that includes a leading side 5 and an opposing trailing side 7. The housing 3 may be a single continuous body with smooth sides and approximately consistent diameter. Alternatively, the housing 3 may be approximately cylindrical with a tapered diameter. Preferably, the leading side 5 and trailing side 7 of the housing 3 are curved to allow for easier insertion and removal of the device 1. The exterior of the housing 3 of the device 1 further includes a stapling controller 9, a cutting controller 11 and an inlet 13. The stapling controller 9 and cutting controller 11 may each extend from the trailing side 7 of the device 1. Further, a passageway 15 is present on both the leading side 5 and trailing side 7 of the housing 3 such that each passageway 15 connects to an inner cavity 23 (FIG. 3) within the housing 3. Each passageway 15 is flanked by one or more clamps 17 (FIGS. 2A and 2B).

[0036] The inlet 13 is an opening in the housing 3 spanning the circumference of a portion of the housing 3, serving as a conduit to the outer cavity 21 (FIG. 3) of the housing 3. The inlet 13 must be sufficiently wide to allow the passage of tissue. The width of the inlet 13 may be adjustable.

[0037] The stapling controller 9 is connected to, and is configured to operate, a stapling head 25 located within the outer cavity 21 (FIG. 3). The cutting controller 11 is connected to, and is configured to operate, a cutting head 27 located within the outer cavity 21. The stapling controller 9 and cutting controller 11 may be connected to, and

operated by action of, a handle assembly (not shown). Handle assemblies are known in the art, for example as described in WO/2015/065625, and may be operated by a user to control the device 1. A handle assembly may be connected to the device 1, for example, by a flexible shaft. The stapling controller 9 and cutting controller 11 may be connected to the handle assembly by wire or wirelessly. For example, the handle assembly may contain a lever (not shown) for operation of the stapling head 25 and a separate lever for operation of the cutting head 27.

[0038] The inner cavity 23 may be physically separated from the outer cavity 21.The outer cavity 21 of the device 1 may further include an inversion device (not shown) configured to draw tissue proximal to the inlet 13 into the outer cavity 21. The inversion device may be a suction device, such as a vacuum pump, configured to draw tissue, proximal to the inlet 13, into the outer cavity 21. Such a suction device may be located within the housing 3, for example proximally to the inlet 13, or in the colonoscope 31 (FIG. 9), for example in the handle (not shown). Alternatively, or in addition to a suction device, the inversion device may comprise a mechanical grasping device configured to extend radially outward from the inlet 13, grasp tissue proximal to the inlet 13, and retract into the outer cavity 21 while grasping such tissue. For example, such a mechanical grasping device may comprise a plurality of clips (FIG. 21), wherein the clips extend from the device 1 and close when in contact with tissue.

[0039] The stapling head 25 includes a plurality of staple cartridges (not shown) and stapling anvils (not shown), positioned radially about the longitudinal axis 33 (FIG. 9) of the device 1. The stapling head 25 is configured to allow the stapling of tissue such that two concentric, offset rings of staples are formed (FIGS. 8A and 8B), configured to allow for two rings of staples to pierce the area of interest 43 (FIG. 10), as known in the art. Each staple cartridge contains at least one staple and is connected to the stapling head 25. Each stapling head 25 is configured to drive a staple from the staple cartridge, by operation of the stapling controller 9, to a stapling anvil before retracting. Each stapling anvil is configured to crimp a staple when the staple is driven into the stapling anvil by a stapling head 25. The staples are surgical-grade and may be composed of stainless steel, titanium or other bio-compatible material known in the art. Different sizes of staples may be used depending on the application and the tissue, as known in the art. Alternatively, in lieu of staples, the stapling head 25 may use sutures, direct compression devices, or other stapling devices known in the art suitable for reconnecting tissue.

[0040] In certain embodiments, the cutting head 27 includes at least one cutting device (not shown) and a secondary cutting head 29, positioned radially about the longitudinal axis 33 of the device 1 (FIGS. 5 and 6). Each secondary cutting head 29 may be configured to overlap or be flush with the cutting head 27 such that tissue is sheared along the plane of contact between the cutting head 27 and secondary cutting head 29. Alternatively, in other embodiments, the cutting head 27 includes at least one cutting device (not shown) and cutting anvil 49 positioned radially about the longitudinal axis 33 of the device 1 (FIGS. 10-14). Each such cutting head 27 may be positioned proximal to a stapling head 25. The cutting device may be a blade, cautery device, or other cutting device known in the art suitable for cutting tissue. Each cutting controller 11 may be configured to drive the cutting head 27, by operation of the cutting controller 11, to a secondary cutting head 29 or, alternatively, a cutting anvil 49 before retracting. The device 1 may be configured to remove a pre-determined area of interest 43, such as a portion of a subject's colon, for example by adjusting the suction or mechanical force applied by the inversion device. In certain embodiments, the device 1 is configured to remove a length of about 2-10 cm of a subject's colon, although the device 1 may be configured to remove different lengths of tissue in other embodiments.

[0041] The device 1 may further include an endoscope, such as a colonoscope 31 (FIGS. 9-14). A colonoscope 31 may, for example, pass through the length of the device 1 approximately along the longitudinal axis 33 of the device. The device 1, for example, may surround a portion of the colonoscope 31 by passing the colonoscope 31 through a passageway 15, located at both the leading side 5 and the trailing side 7 of the device 1, and through the inner cavity 23 (see, e.g., FIG. 10). The colonoscope 31 may be secured relative to the device 1 by one or more clamps 17, located at each passageway 15, which may be tightened by adjustment of one or more tightening screws 19 (see, e.g., FIG. 7) such that the clamps 17 are in contact and flush with the exterior of the colonoscope 31. Alternatively, the colonoscope 31 may be positioned on or near the exterior of the housing 3. The colonoscope 31 may be positioned such that the viewing camera (not shown) of the colonoscope 31 extends from the leading side 5 of the device 1. Alternatively, the viewing camera may be about flush with the leading side 5 of the housing 3. In certain embodiments, the stapling controller 9 and cutting controller 11 may be located within the colonoscope 31.

[0042] Anastomotic leaks remain a concern and may lead to sepsis and death in patients. As such, the device 1 may further include a delivery port (not shown), which may be

located within the outer cavity 21 or on the exterior surface of the housing 3. The delivery port, which may be controlled by the user of the device 1 by using the handle, may include a reservoir containing at least one therapeutic. Activation of the delivery port using the handle allows the delivery port to open, releasing the at least one therapeutic. In some embodiments, the delivery port is located proximal to the stapling anvil to allow for targeted delivery of the at least one therapeutic to the stapled tissue.

[0043] FIGS. 9 through 14 depict an alternative embodiment of the device 1 disclosed herein. In this alternative embodiment, the housing 3 is comprised of a distal cap 35, distal exterior housing 37, proximal exterior housing 39 and proximal cap 41 (FIG. 9). The distal cap 35 and the distal exterior housing 37 may be threaded to enable connection. The inner cavity 23 of this alternative embodiment is formed by a distal collet 47 and proximal collet 53 connected by a collet connector 51 (FIG. 10). Further, this alternative embodiment may include at least one distal spacer 45 and at least one proximal spacer 49 (which may also serve as a cutting and stapling anvil) to assist with alignment of the components described in this paragraph.

[0044] The alternative exemplary embodiment shown in FIGS. 9-14 may be assembled from the components comprising those shown in FIG. 15. A rear housing unit comprises a distal cap 35, cutting head 27, stapling head 25, at least one distal spacer 45 and distal collet 47. The first step for assembling such embodiment includes the step of passing a colonoscope 31 through the collet connector 51 and a distal collet 47 (which, in lieu of clamps 17, may serve as a clamp for the colonoscope 31) which in turn are passed through the rear housing unit (FIG. 16). The second step of assembly includes the step of attaching the distal exterior housing 37 to the rear housing unit (FIG. 17). The third step of assembly includes the step of positioning a proximal exterior housing 39, then at least one proximal spacer 49, then a proximal collet 53, over the colonoscope 31 followed by attaching the proximal collet 53 to the collet connector 51 (FIG. 18). The fourth step of assembly includes the step of aligning the proximal exterior housing 39 and distal exterior housing 37 using a temporary spacer (FIG. 19). The fifth step of assembly includes the step of attaching a proximal cap 41 to the proximal exterior housing 39 and removing the temporary spacer (FIG. 20). The sixth and final step of assembly includes the step of inserting a mechanical grasping device through the outer cavity 21 of the device 1 such that the mechanical grasping device may extend out from the inlet 13 (FIG. 21). This method of assembling an exemplary embodiment of the device 1 is

exemplary and non-limiting. Both this exemplary embodiment and other embodiments contemplated herein may be assembled using alternative methods.

[0045] The present disclosure also includes methods for the formation of anastomoses in a subject. For example, in one embodiment, the method is for the removal of an area of interest 43, in particular a section of the colon from within the lumen of the large intestine of a subject (i.e., a colectomy method), although other tissues may be resected in other embodiments. Such colectomy method may be performed by first inserting the device 1, leading side 5 first, into the subject's rectum. The device 1 may then be advanced through the colon to the area of interest 43 (FIG. 10). A colonoscope 31 may be used to position the device 1 appropriately at the area of interest 43. The area of interest 43 may then be inverted using the device 1 (using suction and/or mechanical methods, not shown) circumferentially inside the device 1 via an inlet 13 (FIG. 11). Once the area of interest 43 has been intussuscepted, or inverted, and positioned correctly, the stapling controller 9 may be slideably advanced, thereby extending at least one stapling head 25 such that each stapling head 25 drives at least one staple from a staple cartridge through the area of interest 43 to a stapling anvil, circumferentially connecting the previously non-adjacent areas of the area of interest 43 together (FIG. 12). Such stapling allows formation a first circumferential ring of staples and a second circumferential ring, wherein the staples of the second ring are offset by approximately 50% the length of each staple from the first ring and wherein the two rings of staples are separated (see, e.g., FIGS. 8A and 8B). A cutting controller 11 may then be slideably advanced, thereby extending at least one cutting head 27 such that the at least one cutting head 27 is driven through the area of interest 43 to a cutting anvil, thereby removing excess tissue (FIG. 13). Alternatively, a cutting controller 11 may be slideably advanced, thereby extending at least one cutting head 27 such that the at least one cutting head 27 is driven through the area of interest 43 flush with a secondary cutting head 29, thereby removing the area of interest 43 (FIGS. 4A and 5). If one cutting head 27 is used, the cutting device may be an approximately circular blade. If multiple cutting heads 27 are used, the cutting heads 27, collectively, may be configured to form an approximately circle shape when cutting. The stapled colon may then be released by the device 1 (FIG. 14), and the device 1 may be retracted. The removed area of interest 43 may remain within the outer cavity 21 of the device 1, as the device 1 is withdrawn, for later disposal.

[0046] The inlet 13, stapling head 25 and cutting head 27 each, instead of extending circumferentially around the device 1, may span a portion of the circumference of the

device 1. Such alternative embodiments of the device 1 enable the resection of an arc or segment of tissue as opposed to a circumferential ring.

[0047] The methods described herein may further include the step of delivering one or more therapeutics to the area of interest upon resection by releasing the therapeutic or therapeutics from a delivery port (not shown). The delivery port located within the outer cavity 21 of the device 1 or on the exterior surface of the housing 3. For example, the method may include the step of releasing a biological sealant from the delivery port to assist with preventing leakage from the anastomosis.

[0048] One advantage of the device and methods of using the same described herein is that, unlike conventional anastomosis devices and methods, no external incisions or extra-luminal manipulations are required for colectomies, allowing procedures that are far less invasive than current laparoscopic and open colectomy devices and methods. Another advantage of the device and methods described herein is that the device and methods of using the same may be applied for colectomies and in any other surgeries requiring anastomoses including vascular surgery (vascular anastomoses), other parts of the gastrointestinal tract such as the foregut (esophagus) and midgut (small bowel), and even urology (ureteral anastomoses) by inserting the device, suitably sized for the area of interest (e.g., adjusting the diameter of the device as needed) into the subject and resecting the area of interest using the method disclosed herein.

[0049] References to items in the singular should be understood to include items in the plural, and vice versa, unless explicitly stated otherwise or clear from the text. Grammatical conjunctions are intended to express any and all disjunctive and conjunctive combinations of conjoined clauses, sentences, words, and the like, unless otherwise stated or clear from the context. Thus, the term “or” should generally be understood to mean “and/or” and so forth.

[0050] The various embodiments of the systems and methods described herein are exemplary. Various other embodiments for the systems and methods described herein are possible.

CLAIMS

Now, therefore, the following is claimed:

1. An anastomosis device, comprising:

a housing, wherein the housing includes an outer cavity;

a stapling controller;

a cutting controller;

an inversion device;

at least one stapling head located within the outer cavity of the housing and positioned radially about the longitudinal axis of the device, wherein the at least one stapling head is connected to the stapling controller;

at least one stapling anvil; and

at least one cutting head located within the outer cavity of the housing and positioned radially about the longitudinal axis of the device, wherein the at least one cutting head is connected to the cutting controller;

wherein the housing includes an inlet spanning the circumference of a portion of the housing and connected to the outer cavity of the housing.

2. The device of claim 1, wherein the device further comprises an endoscope.

3. The device of claim 2, wherein the endoscope extends through the longitudinal axis of the device.

4. The device of claim 1, wherein the device further comprises at least one delivery port.

5. The device of claim 4, wherein the delivery port contains a biological sealant.

6. The device of claim 1, wherein each stapling head comprises at least one staple cartridge, each staple cartridge containing at least one staple.

7. The device of claim 1, wherein each cutting head comprises at least one cutting device.

8. The device of claim 1, wherein the device further comprises at least one cutting anvil.

9. The device of claim 1, wherein the device further comprises at least one secondary cutting head configured to be flush with each cutting head.

10. The device of claim 1, wherein the inversion device comprises a suction device.

11. The device of claim 1, wherein the inversion device comprises a mechanical grasping device.

12. A method of forming an anastomosis in the colon of a subject, comprising the steps of:

inserting the device of claim 1 into the subject's rectum;

advancing the device to the area of interest;

activating the inversion device to invert the area of interest inside the device via an inlet;

activating the stapling controller to advance at least one stapling head to staple and connect previously non-adjacent sections adjacent to the area of interest together;

activating the cutting controller to advance the at least one cutting head to remove the area of interest;

releasing the colon; and

retracting the device.

13. The method of claim 12, wherein the area of interest remains within the device.

14. The method of claim 12, wherein the area of interest is inverted inside the device using suction.

15. The method of claim 12, wherein the area of interest is inverted inside the device mechanically.

16. The method of claim 12, wherein the device further includes a delivery port and further comprising the step of activating the delivery port.

17. The method of claim 16, wherein the delivery port contains biological sealant.

18. The method of claim 16, wherein the delivery port is activated after the cutting controller is activated.

19. A method of forming an anastomosis in the tissue of a subject, comprising the steps of:

inserting the device of claim 1 into the subject;

advancing the device to the area of interest;

activating the inversion device to invert the area of interest inside the device via an inlet;

activating the stapling controller to advance the at least one stapling head to staple and connect previously non-adjacent sections adjacent to the area of interest together;

activating the cutting controller to remove the area of interest;

releasing the tissue; and

retracting the device.

20. The method of claim 19, wherein the tissue is inverted inside the device using suction.

21. The method of claim 19, wherein the tissue is inverted inside the device mechanically.

22. The method of claim 19, wherein the device further includes a delivery port and further comprising the step of activating the delivery port.

23. A method of forming an anastomosis in the colon of a subject, comprising the steps of:

inserting an apparatus into the subject's rectum;

advancing the apparatus to an area of interest of the colon;

inverting the area of interest inside the apparatus via an inlet in the apparatus;

using the apparatus to staple and connect previously non-adjacent sections adjacent to the area of interest together;

removing the area of interest;

releasing the colon; and

retracting the apparatus.

24. The method of claim 23, including activating an inversion device of the apparatus to invert the area of interest inside the device via the inlet.

25. The method of claim 23, including activating a stapling controller of the apparatus to advance at least one stapling head to staple and connect the previously non-adjacent sections adjacent to the area of interest together.

26. The method of claim 23, including activating a cutting controller of the apparatus to advance at least one cutting head to remove the area of interest.

27. The method of claim 23, including inverting the area of interest inside the apparatus using suction.

28. The method of claim 23, including inverting the area of interest inside the apparatus mechanically.

29. The method of claim 23, activating a delivery port of the apparatus, wherein the delivery port contains biological sealant.

30. The method of claim 23, activating a delivery port of the apparatus after a cutting controller of the apparatus is activated.

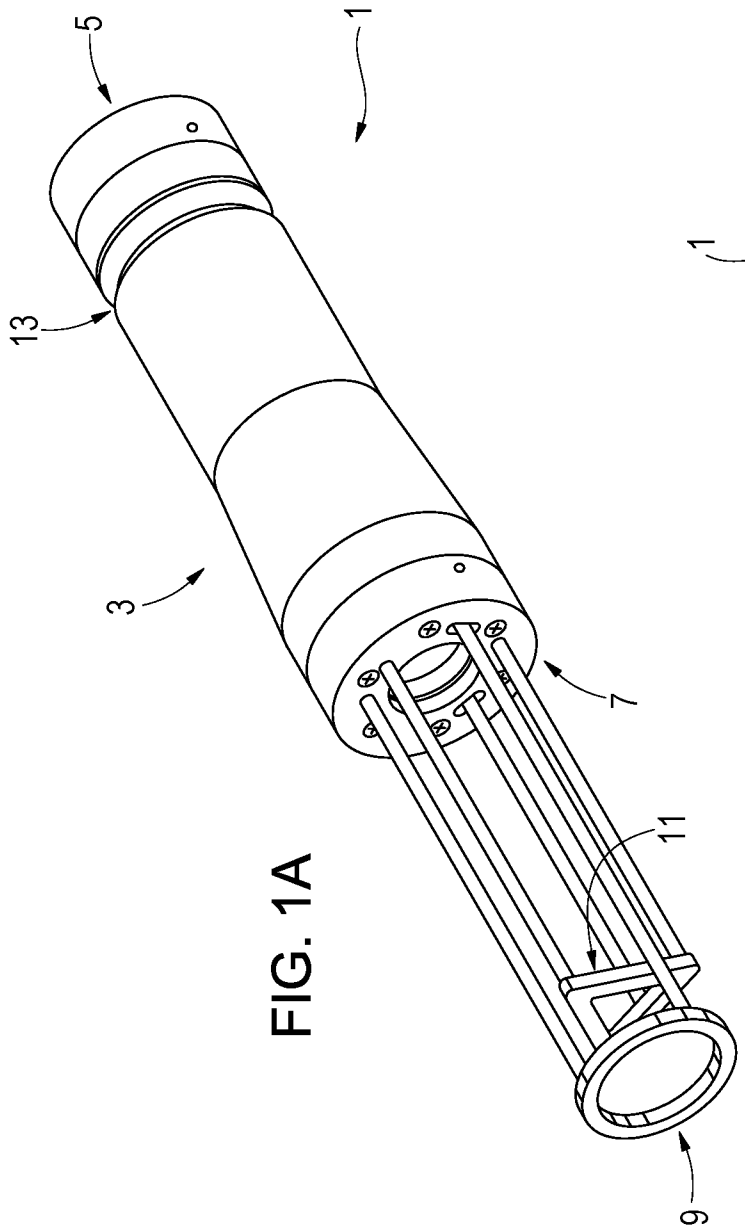

FIG. 1A

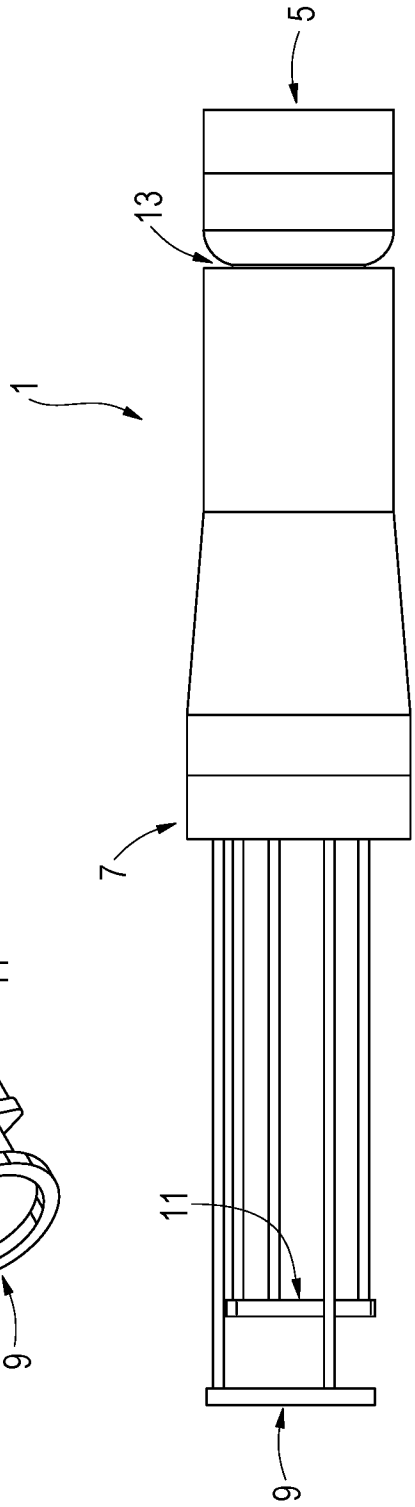

FIG. 1B

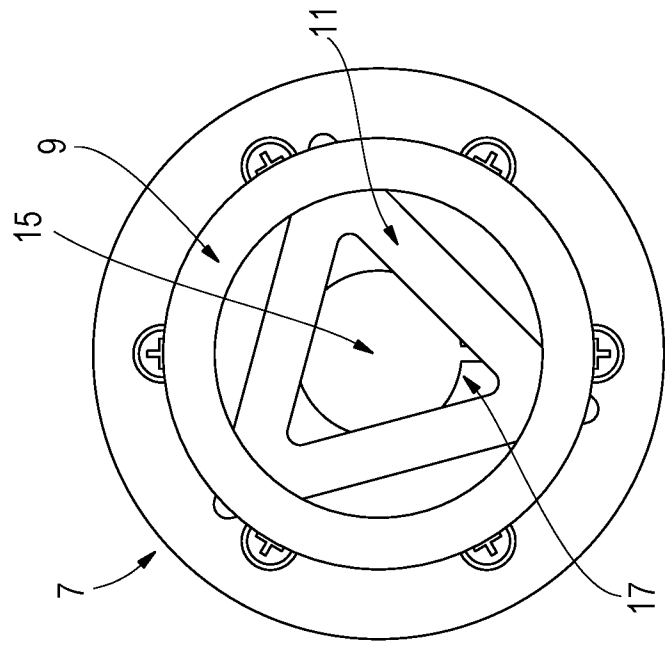

FIG. 2B

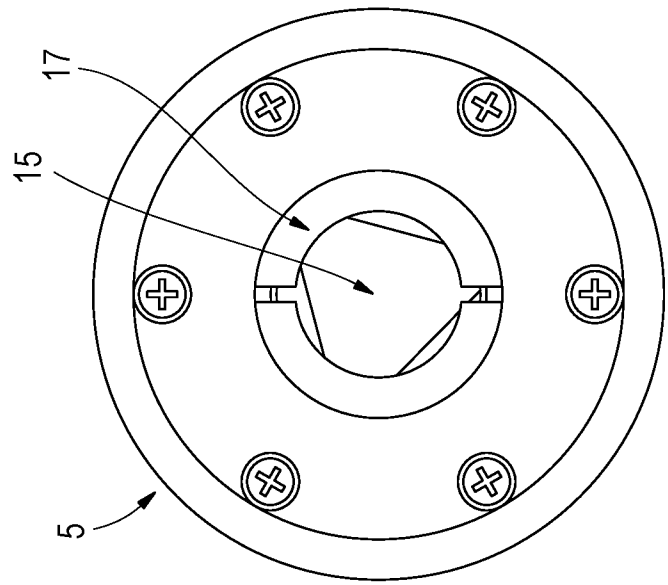

FIG. 2A

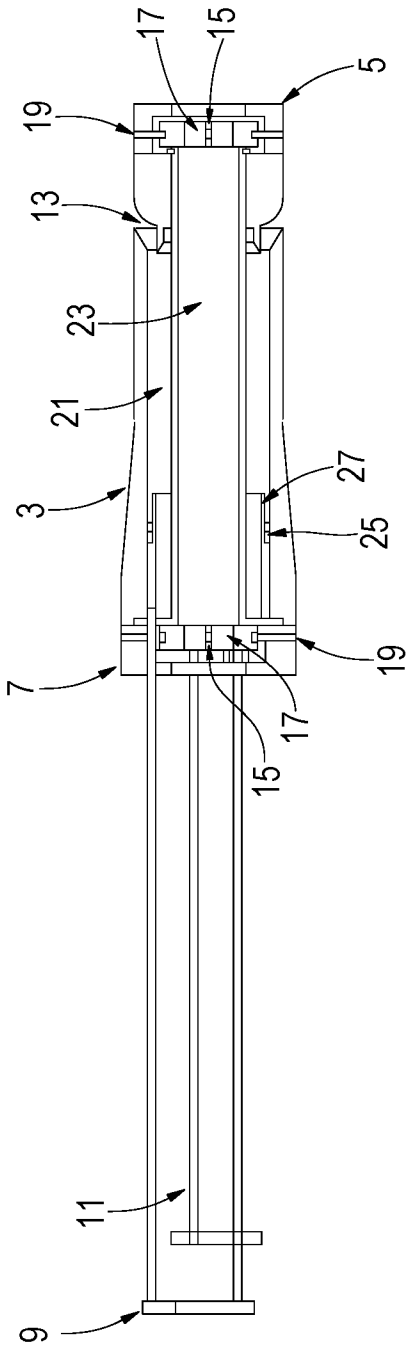

FIG. 3

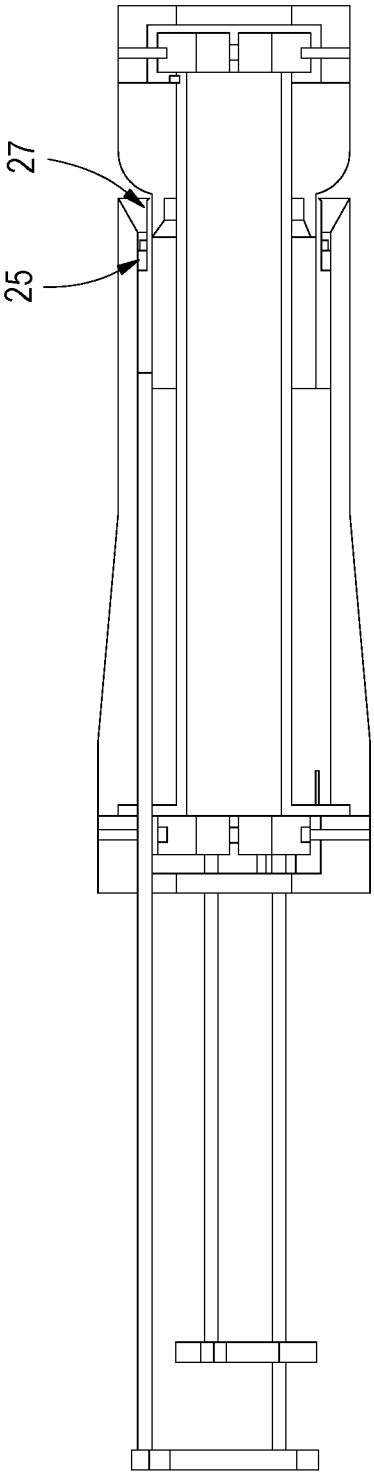

FIG. 4A

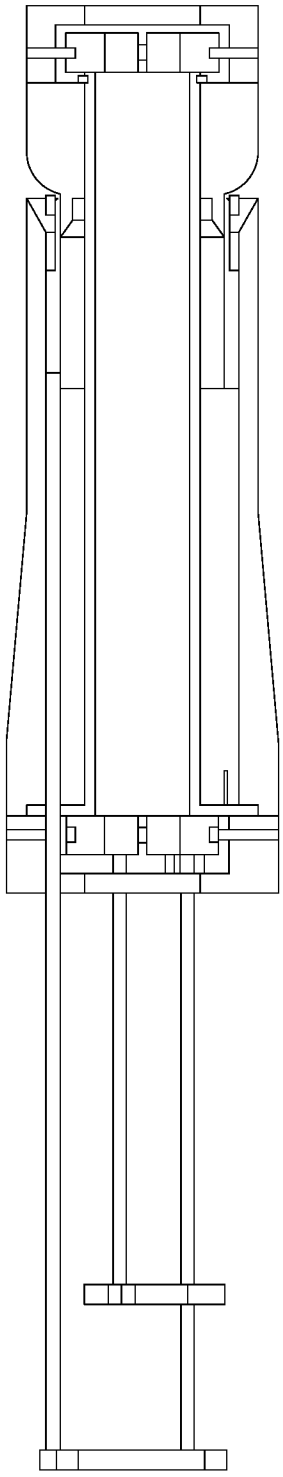

FIG. 4B

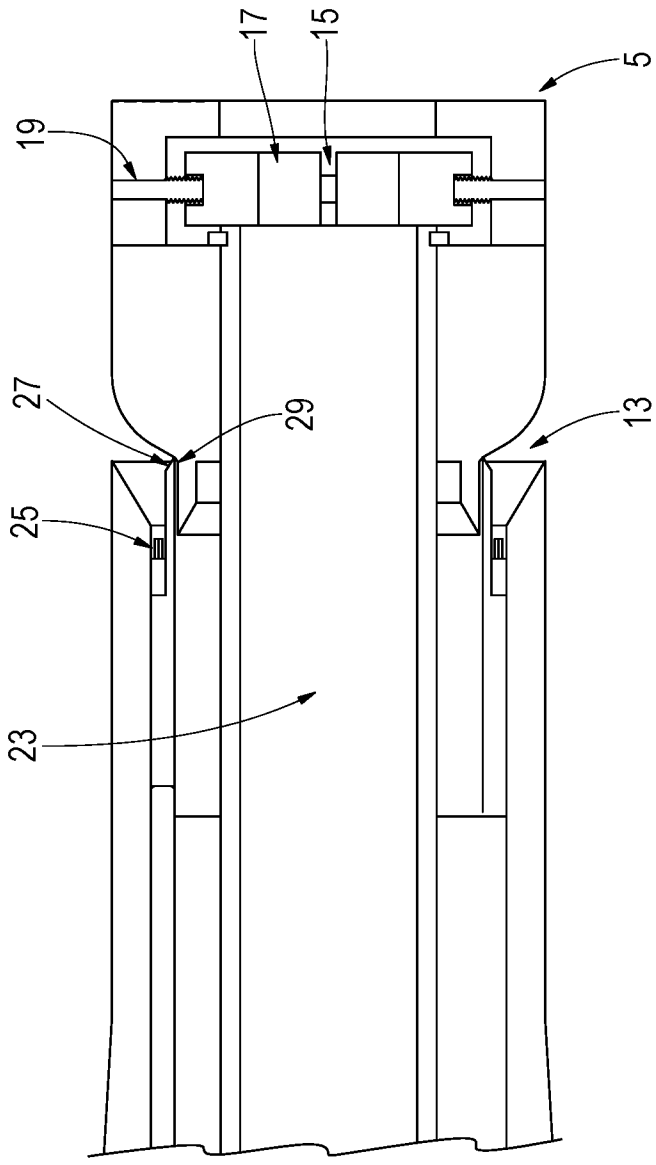

FIG. 5

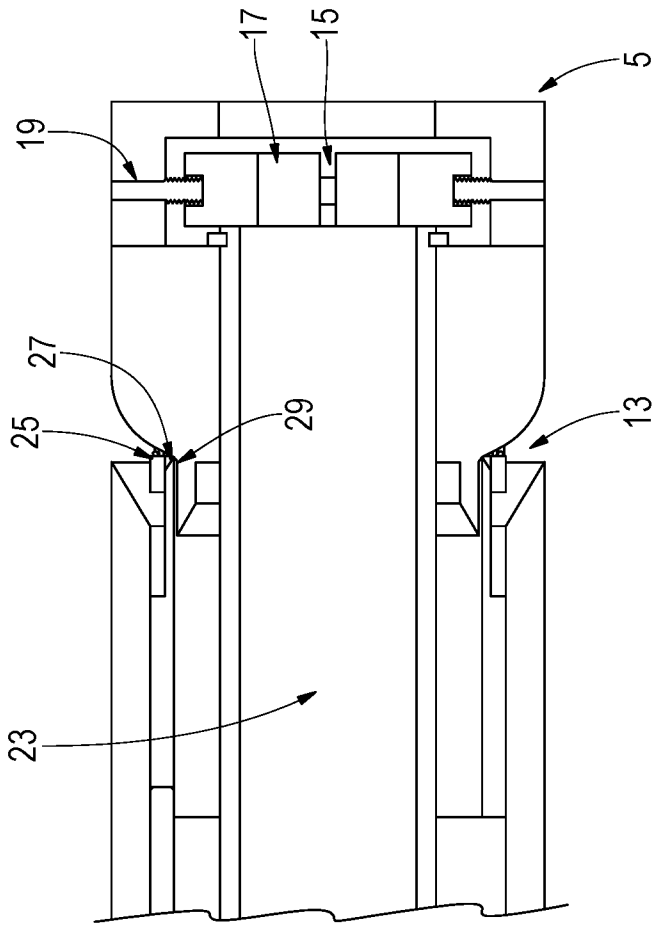

FIG. 6

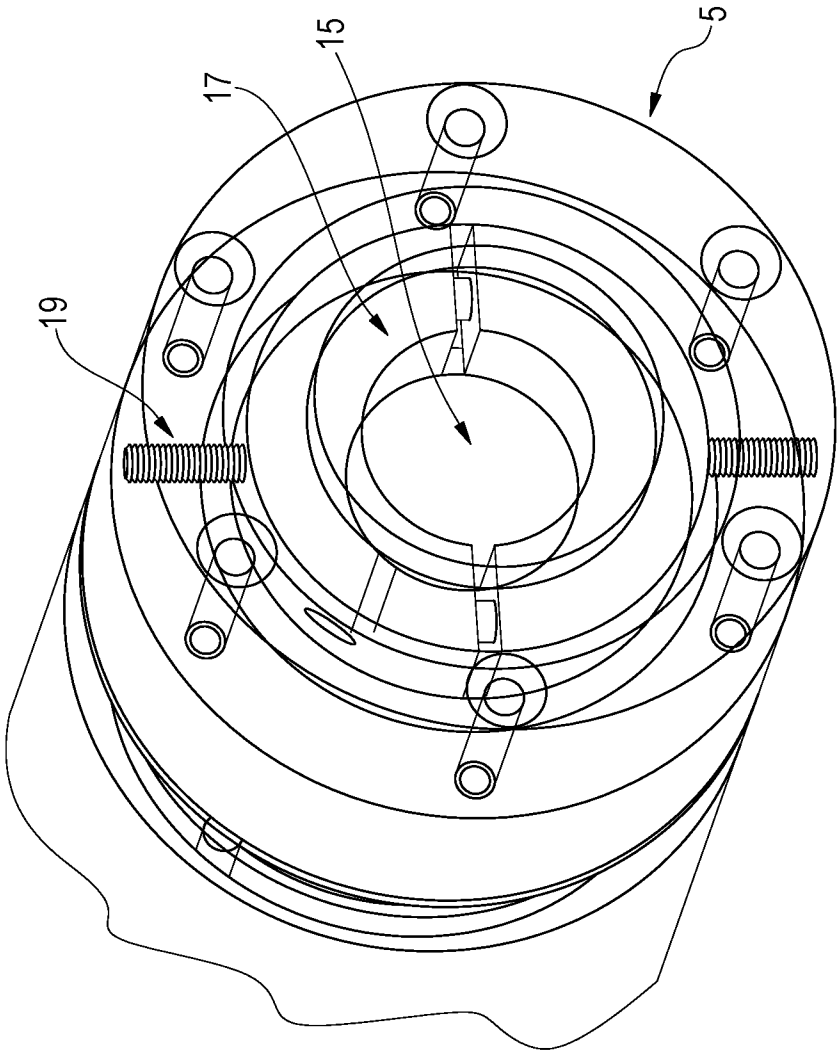

FIG. 7

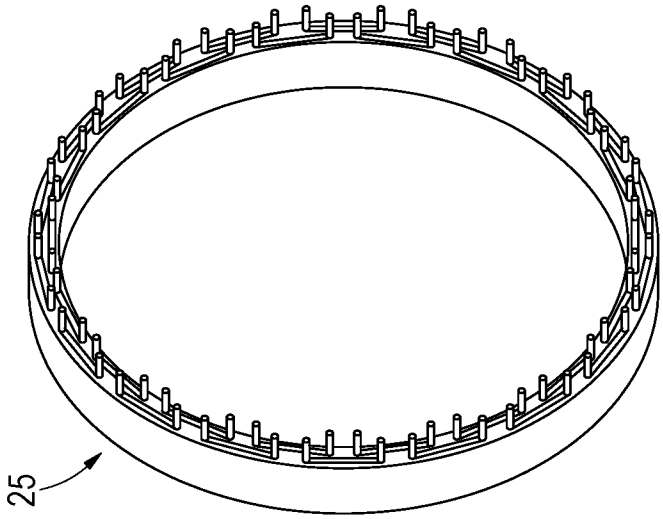

FIG. 8B

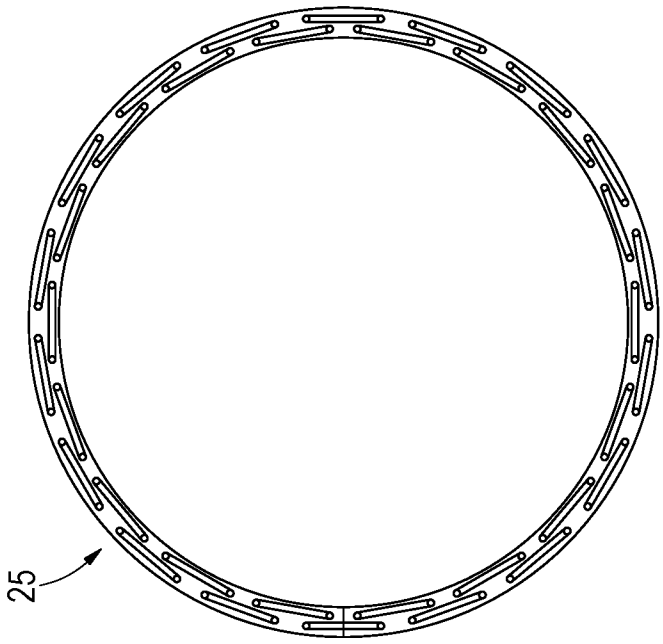

FIG. 8A

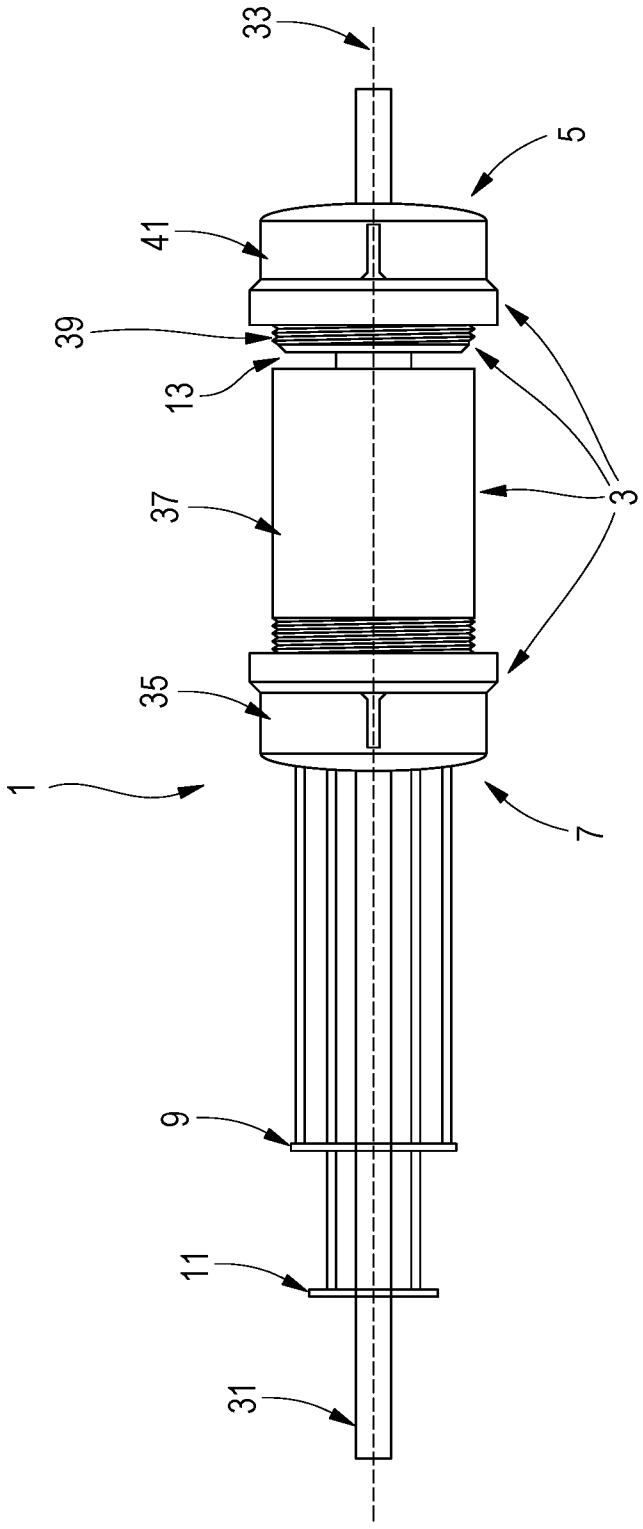

FIG. 9

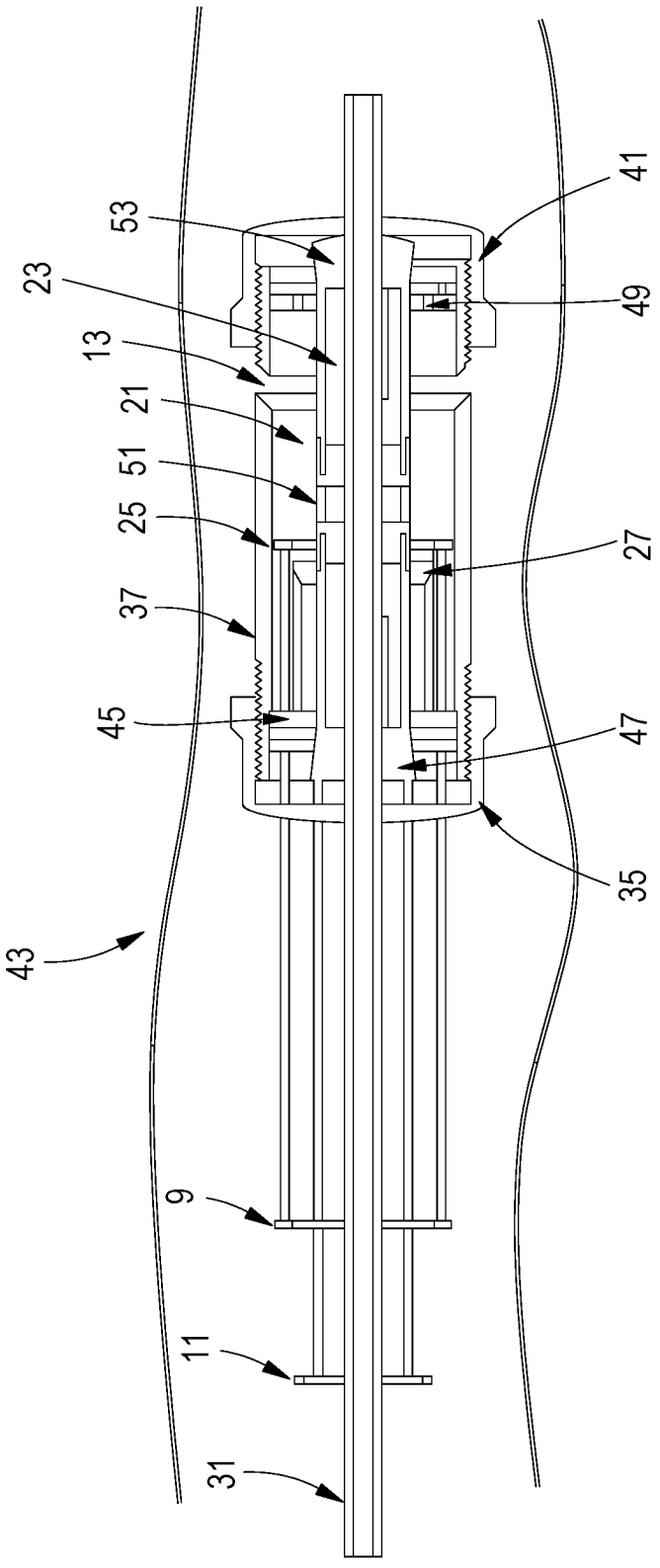

FIG. 10

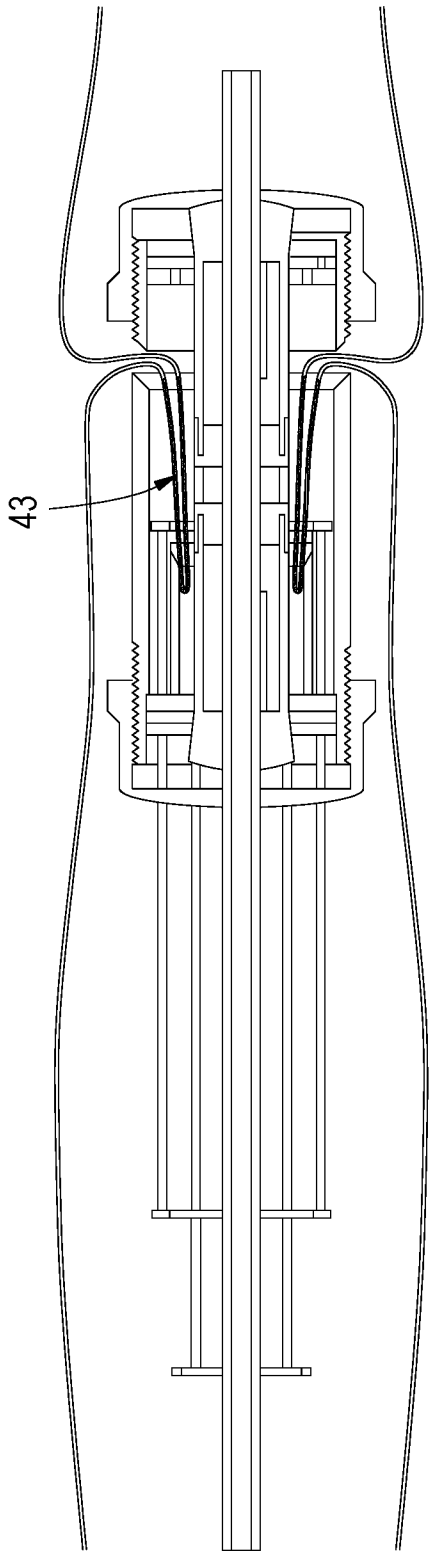

FIG. 11

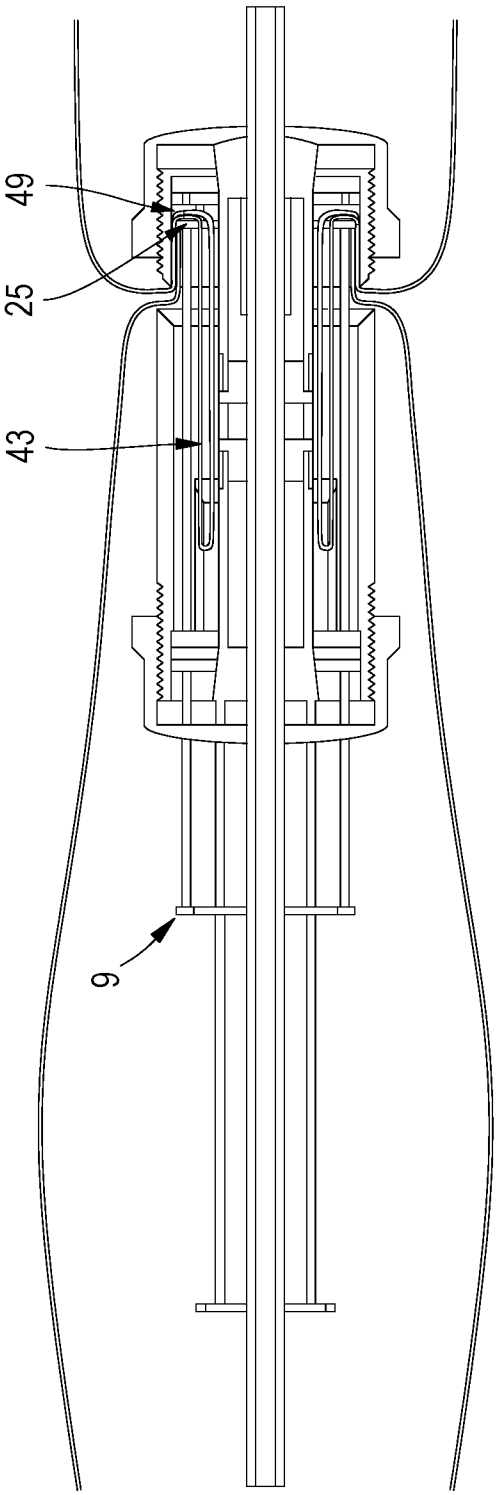

FIG. 12

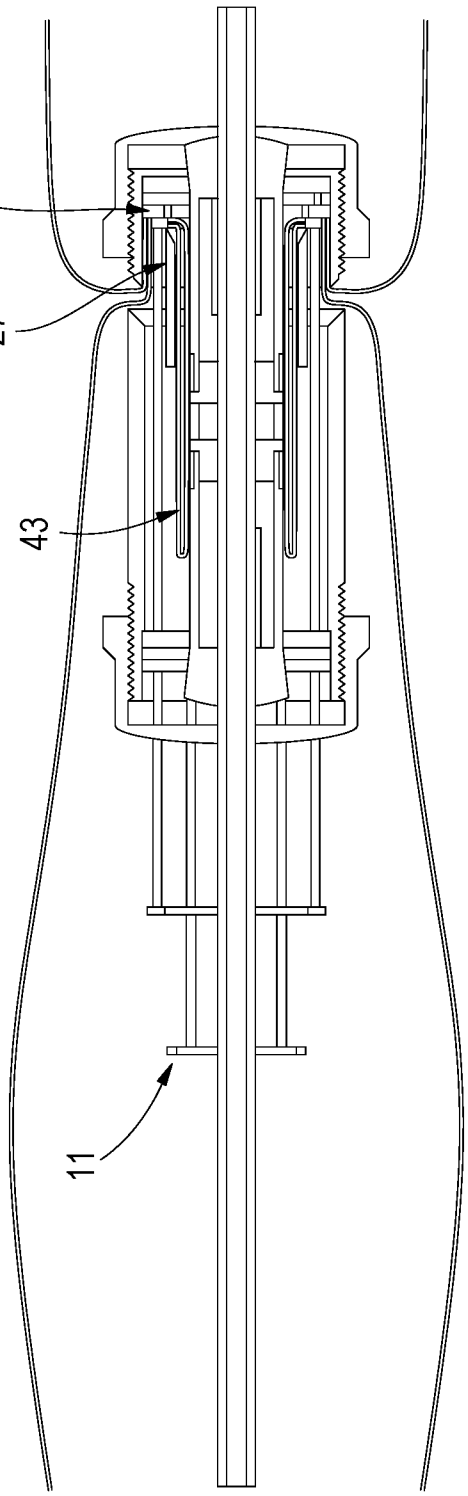

FIG. 13

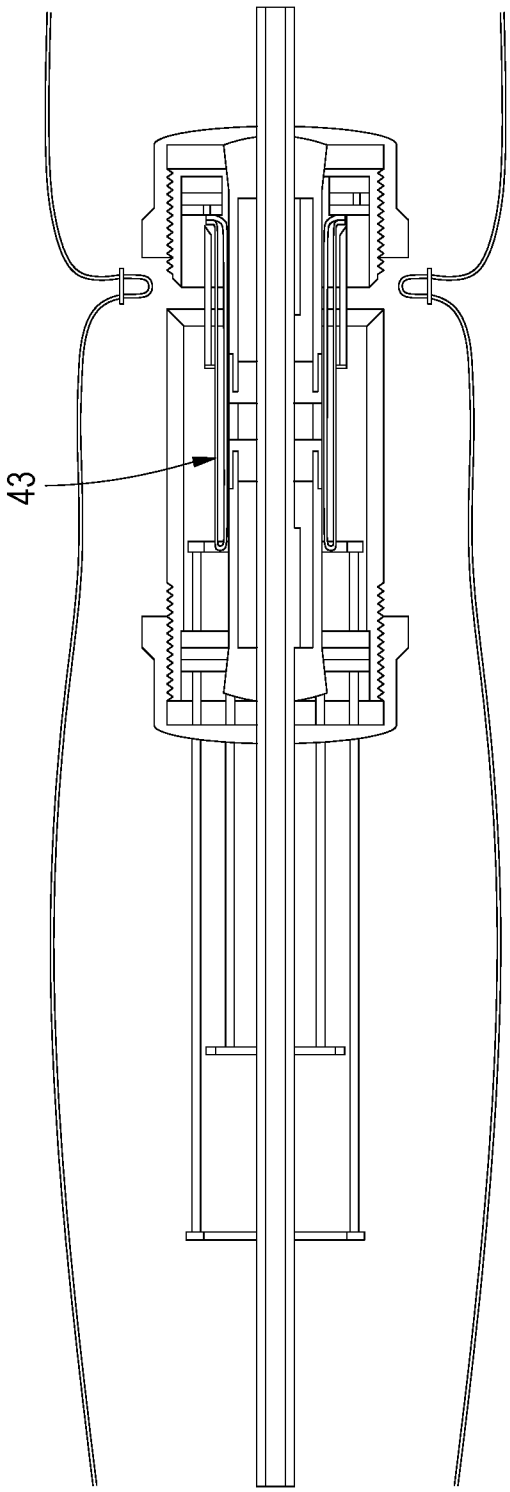

FIG. 14

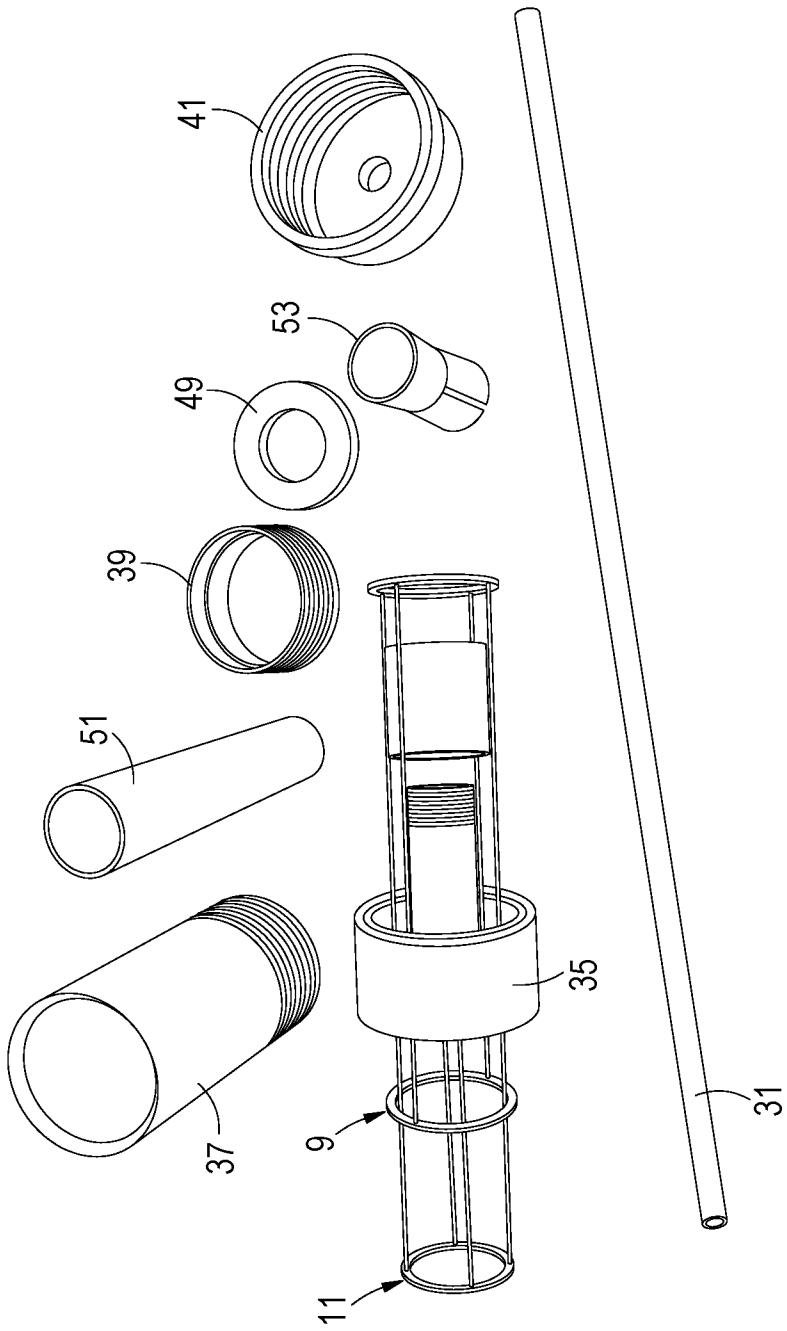

FIG. 15

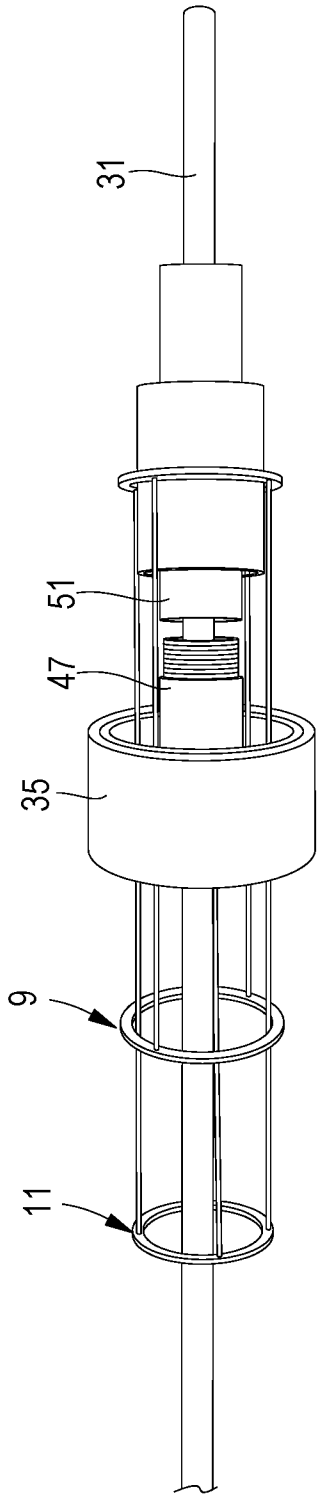

FIG. 16

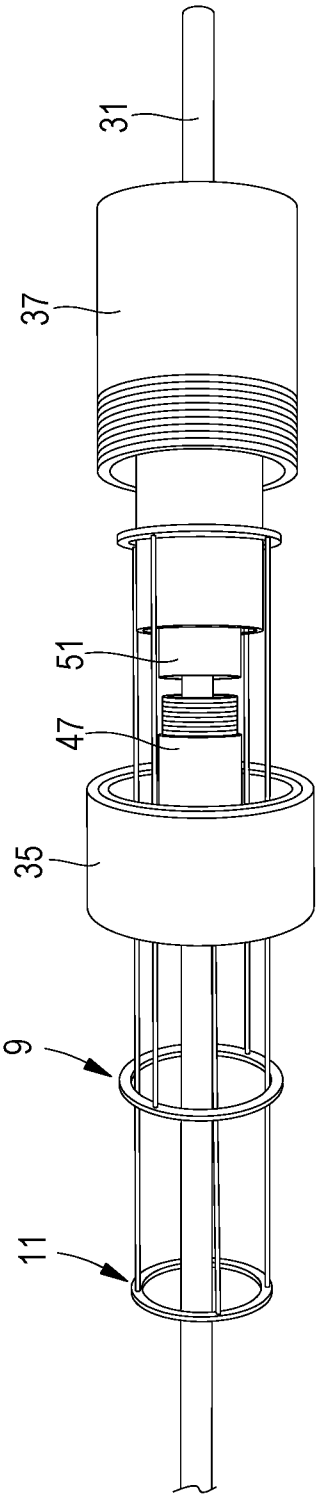

FIG. 17

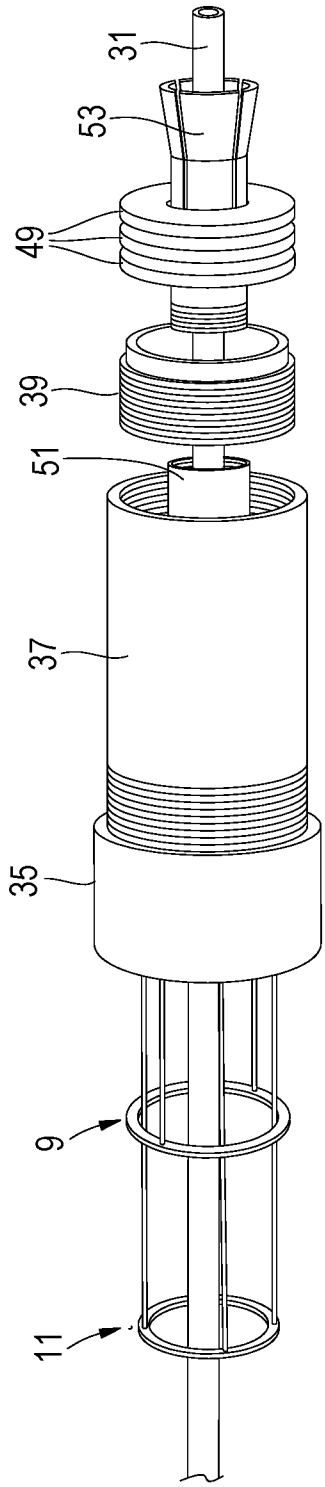

FIG. 18

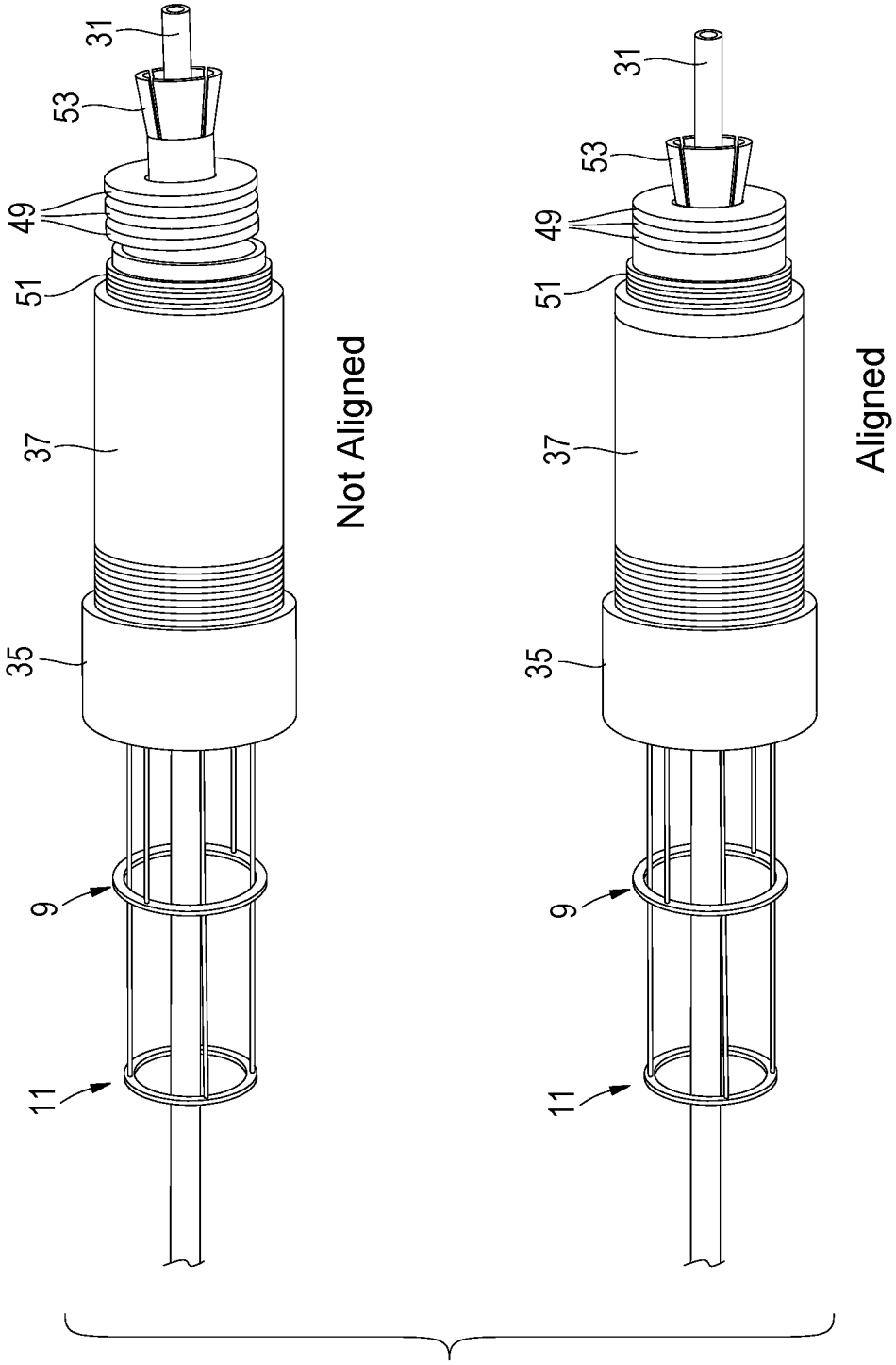

FIG. 19

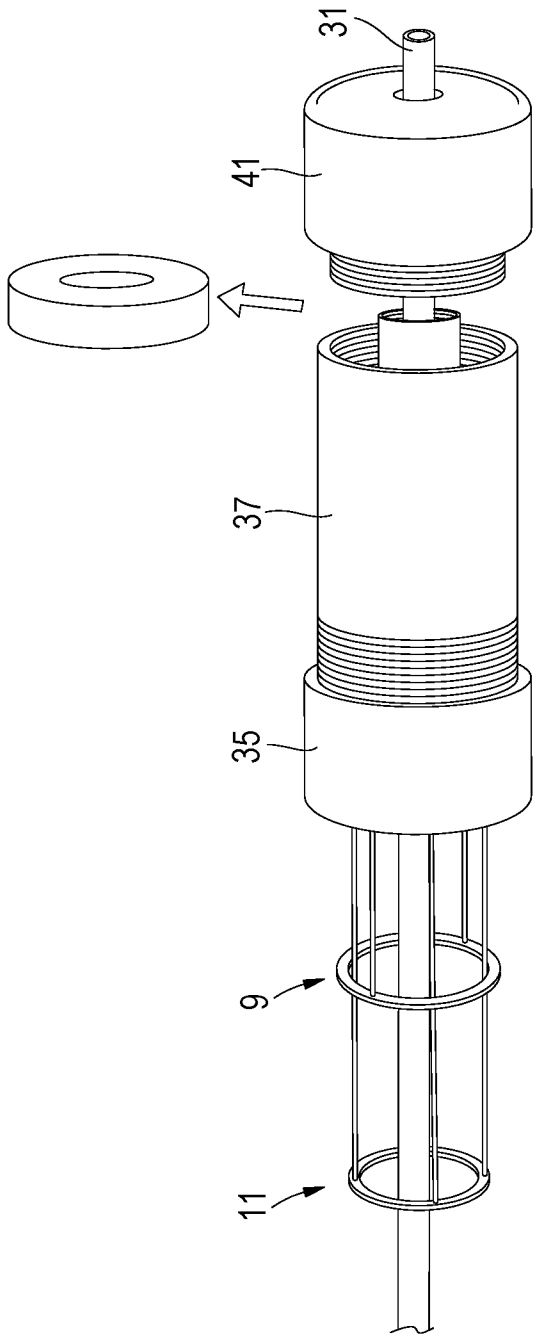

FIG. 20

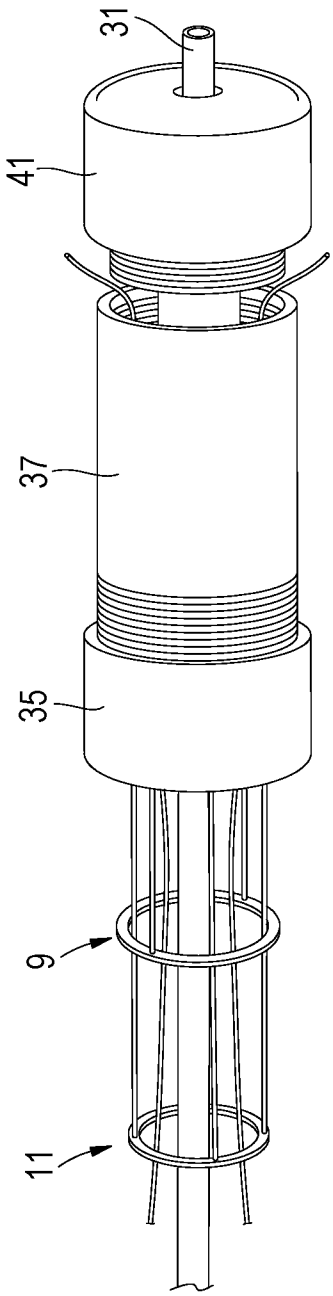

FIG. 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/017523

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/068(2006.01)i, A61B 17/3205(2006.01)i

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 17/068; A61B 17/072; A61B 17/11; A61B 17/10; A61B 17/115; A61M 37/00; A61B 17/00; A61B 17/04; A61B 17/08; A61B 17/3205

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords:anastomosis, housing, stapling controller, cutting controller, inversion device, stapling anvil, cutting head, inlet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 8590764 B2 (HARTWICK, D. et al.) 26 November 2013 See abstract; column 2, lines 39-63; column 3, line 43 - column 4, line 6; column 4, lines 43-59; column 5, line 34 - column 7, line 7; and figures 1, 9-13.	1-3,6-11
Y		4,5
Y	US 7517356 B2 (HEINRICH, R.) 14 April 2009 See column 17, line 17 - column 18, line 8; and figures 7-10.	4,5
X	US 2004-0232198 A1 (ADAMS, R. D. et al.) 25 November 2004 See paragraphs [0052]-[0059], [0064], [0066]-[0075], [0099]; and figures 1-13.	1-3,6-11
Y		4,5
Y	WO 01-62158 A2 (POWERMED, INC.) 30 August 2001 See page 10, line 10 - page 11, line 9; page 12, line 15 - page 13, line 12; and figures 3-6.	4,5
X	US 2004-0217146 A1 (BECK, J.) 04 November 2004 See abstract; paragraphs [0057]-[0070]; and figures 1-7.	1,6-10
Y		2-5,11

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 May 2018 (21.05.2018)	**21 May 2018 (21.05.2018)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea
Facsimile No. +82-42-481-8578

Authorized officer
LEE, Dong Wook
Telephone No. +82-42-481-8163

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2012-072138 A1 (ETHICON ENDO-SURGERY, INC.) 07 June 2012 See page 6, line 26 - page 8, line 19; page 9, line 24 - page 10, line 13; and figures 1-9.	2,3,11
Y	US 2016-0206865 A1 (ETHICON, INC.) 21 July 2016 See abstract; paragraphs [0057]-[0067]; and figures 1-5.	4,5

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2018/017523

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 8590764 B2	26/11/2013	EP 1696804 A2	06/09/2006
		US 2005-0145675 A1	07/07/2005
		US 2014-0054356 A1	27/02/2014
		WO 2005-063132 A2	14/07/2005
		WO 2005-063132 A3	27/10/2005
US 7517356 B2	14/04/2009	AU 2003-228556 A1	03/11/2003
		AU 2003-228556 B2	24/01/2008
		CA 2481943 A1	30/10/2003
		CA 2481943 C	03/08/2010
		CA 2703164 A1	30/10/2003
		CA 2703164 C	08/10/2013
		EP 1494595 A2	12/01/2005
		EP 1494595 B1	02/03/2011
		EP 2298187 A1	23/03/2011
		EP 2298187 B1	07/06/2017
		EP 2401971 A2	04/01/2012
		EP 2401971 A3	05/09/2012
		EP 2401971 B1	15/03/2017
		EP 2404555 A2	11/01/2012
		EP 2404555 A3	05/09/2012
		EP 2404555 B1	15/03/2017
		ES 2360613 T3	07/06/2011
		ES 2622252 T3	06/07/2017
		ES 2622453 T3	06/07/2017
		ES 2631512 T3	31/08/2017
		JP 2006-506106 A	23/02/2006
		JP 2009-240798 A	22/10/2009
		JP 2012-040398 A	01/03/2012
		JP 4350529 B2	21/10/2009
		JP 4856741 B2	18/01/2012
		US 2005-0184121 A1	25/08/2005
		US 2008-0230583 A1	25/09/2008
		US 2010-0076429 A1	25/03/2010
		US 7635073 B2	22/12/2009
		US 8413869 B2	09/04/2013
		WO 03-088845 A2	30/10/2003
		WO 2003-088845 A3	08/04/2004
US 2004-0232198 A1	25/11/2004	AT 550998 T	15/04/2012
		AU 2002-318451 B2	25/09/2008
		AU 2003-246076 A1	09/10/2003
		AU 2003-246076 B2	09/03/2006
		AU 3975702 A	21/05/2002
		AU 3998399 A	05/12/2000
		AU 761832 B2	12/06/2003
		CA 2333690 A1	23/11/2000
		CA 2333690 C	22/02/2005
		CA 2450196 A1	30/01/2003

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2018/017523

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		CA 2450196 C	05/04/2011
		EP 1091695 A1	18/04/2001
		EP 1091695 B1	28/03/2012
		EP 1328197 A2	23/07/2003
		EP 1328197 B1	10/12/2008
		EP 1406544 A1	14/04/2004
		EP 1406544 B1	21/11/2012
		ES 2384224 T3	02/07/2012
		JP 2002-543911 A	24/12/2002
		JP 2004-512892 A	30/04/2004
		JP 2005-319331 A	17/11/2005
		JP 2005-519650 A	07/07/2005
		JP 4091424 B2	28/05/2008
		JP 4102393 B2	18/06/2008
		JP 4328469 B2	09/09/2009
		US 2002-0020732 A1	21/02/2002
		US 2002-0047036 A1	25/04/2002
		US 2002-0063143 A1	30/05/2002
		US 2003-0018236 A1	23/01/2003
		US 2003-0019905 A1	30/01/2003
		US 2003-0127491 A1	10/07/2003
		US 2003-0132267 A1	17/07/2003
		US 2003-0192937 A1	16/10/2003
		US 2004-0049096 A1	11/03/2004
		US 2004-0134964 A1	15/07/2004
		US 2005-0065398 A1	24/03/2005
		US 2006-0191975 A1	31/08/2006
		US 2009-0242612 A1	01/10/2009
		US 2011-0108604 A1	12/05/2011
		US 6126058 A	03/10/2000
		US 6179195 B1	30/01/2001
		US 6241140 B1	05/06/2001
		US 6343731 B1	05/02/2002
		US 6478210 B2	12/11/2002
		US 6585144 B2	01/07/2003
		US 6601749 B2	05/08/2003
		US 6629630 B2	07/10/2003
		US 6695198 B2	24/02/2004
		US 6820791 B2	23/11/2004
		US 6827246 B2	07/12/2004
		US 6840423 B2	11/01/2005
		US 6866178 B2	15/03/2005
		US 6874669 B2	05/04/2005
		US 7059331 B2	13/06/2006
		US 7546939 B2	16/06/2009
		US 7896215 B2	01/03/2011
		US 8006889 B2	30/08/2011
		US 8043207 B2	25/10/2011
		WO 00-69344 A1	23/11/2000
		WO 02-038037 A3	22/08/2002

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2018/017523

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		WO 02-038037 A9	17/07/2003
		WO 02-083008 A2	24/10/2002
		WO 02-083008 A3	13/02/2003
		WO 02-38037 A2	16/05/2002
		WO 03-007822 A1	30/01/2003
		WO 03-007822 A9	26/02/2004
WO 01-62158 A2	30/08/2001	AT 310452 T	15/12/2005
		AU 3857401 A	03/09/2001
		DE 60115209 T2	27/07/2006
		EP 1257216 A2	20/11/2002
		EP 1257216 B1	23/11/2005
		ES 2248288 T3	16/03/2006
		JP 2003-523251 A	05/08/2003
		JP 2010-057965 A	18/03/2010
		JP 2012-106002 A	07/06/2012
		JP 4491566 B2	30/06/2010
		JP 5059091 B2	24/10/2012
		JP 5563606 B2	30/07/2014
		US 2003-0073982 A1	17/04/2003
		US 6488197 B1	03/12/2002
		US 6681979 B2	27/01/2004
		WO 01-62158 A3	14/02/2002
US 2004-0217146 A1	04/11/2004	AU 2002-361842 A1	09/07/2003
		EP 1455658 A1	15/09/2004
		WO 03-053255 A1	03/07/2003
WO 2012-072138 A1	07/06/2012	CN 103237505 A	07/08/2013
		CN 103237505 B	20/04/2016
US 2016-0206865 A1	21/07/2016	AU 2016-206797 A1	13/07/2017
		CN 107205742 A	26/09/2017
		EP 3244808 A1	22/11/2017
		JP 2018-501907 A	25/01/2018
		WO 2016-115190 A1	21/07/2016

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/017523

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. ☒ Claims Nos.: 12-30
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 12-30 pertain to methods for treatment of the human body by surgery and thus relate to a subject-matter which this International Searching Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).

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 addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.