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TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).**Declarations under Rule 4.17:**

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(H))
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(54) Title: ROTATIONAL MECHANISM FOR ENDOSCOPIC DEVICES

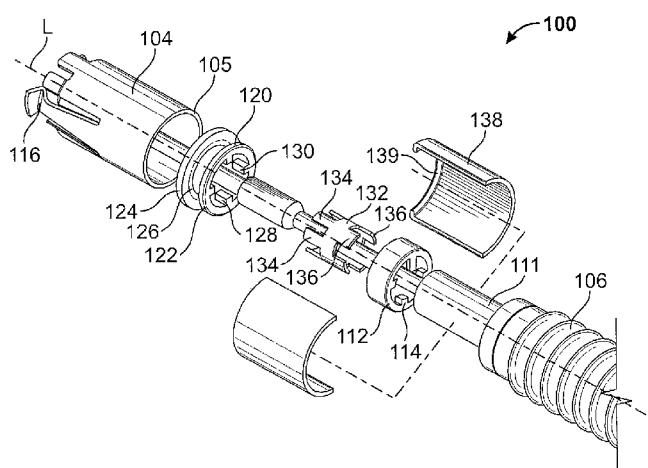


FIG. 2

(57) **Abstract:** A medical device includes (a) a flexible member extending from a handle at a proximal end to a distal end sized and shaped for insertion to a target position and having a first channel extending longitudinally therethrough; (b) an elongated rotation tube positioned in the first channel and being rotatable relative to the member; and (c) a rotation drive device ("RDD") at a distal end of the rotation tube, a proximal end of RDD being permanently attached to the rotation tube. A distal end of RDD has a first protrusion extending distally therefrom and a drive element has a substantially cylindrical shape with a groove on an inner wall thereof mating with the first protrusion of RDD. The drive element transmits rotational movement of the rotation tube to an end effector connected to a distal end thereof to rotate the rotation tube relative to the member.



ROTATIONAL MECHANISM FOR ENDOSCOPIC DEVICES

Inventors: Colby HARRIS and Gary JORDAN

Priority Claim

[0001] This present application claims the priority to the U.S. Provisional Application Serial No. 61/576,159, entitled " Rotational Mechanism For Endoscopic Devices " filed on December 15, 2011. The specification of the above-identified application is incorporated herewith by reference.

Background

[0002] Pathologies of the gastro-intestinal ("GI") system, the biliary tree, the vascular system and other body lumens are commonly treated through endoscopic procedures, many of which require active and/or prophylactic hemostasis to control internal bleeding. Tools for deploying hemostatic clips via endoscopes are often used to control internal bleeding by clamping together the edges of wounds or incisions.

[0003] In the simplest form, these clips grasp tissue surrounding a wound bringing edges of the wound together to allow natural healing processes to close the wound. Specialized endoscopic clipping devices are used to deliver the clips to desired locations within the body and to position and deploy the clips at the desired locations after which the clip delivery device is withdrawn, leaving the clip within the body. Endoscopic hemostatic clipping devices are generally designed to reach tissues deep within the body (e.g., within the GI tract, the pulmonary system, the vascular system or other lumens and ducts) via a working lumen of an endoscope. Thus, the dimensions of such clipping devices are limited by the dimensions of endoscopic working lumens.

Summary of the Invention

[0004] The present invention relates to a medical device, comprising a flexible member extending from a handle at a proximal end to a distal end sized and shaped for insertion to a target position in a living body and having a first channel extending longitudinally therethrough in combination with an elongated rotation tube positioned in the first channel and being rotatable relative to the flexible member and a rotation drive device at a distal end of the rotation tube, a proximal end of the rotation drive device being permanently attached to the rotation tube, a distal end of the rotation drive device having a first protrusion extending distally therefrom and a drive element having a substantially cylindrical shape with a groove on an inner wall thereof mating with the first protrusion of the rotation drive device, the drive element configured to transmit rotational movement of the rotation tube to an end effector connected to a distal end thereof to rotate the rotation tube relative to the flexible member.

Brief Description of the Drawings

[0005] Fig. 1 shows a first perspective view of a device according to a first exemplary embodiment of the present invention in a first operative configuration;

Fig. 2 shows an exploded view of a distal rotation mechanism of the device of Fig. 1; and

Fig. 3 shows a perspective view of a proximal rotation mechanism of the device of Fig. 1.

Detailed Description

[0006] The present invention may be further understood with reference to the following description and the appended drawings, wherein like elements are referred to with the same

reference numerals. The present invention relates to a device permitting rotation of an end effector of a flexible endoscopic device during insertion of the end effector to a target site within a living body. For example, one embodiment of the invention is directed to a hemostasis clipping device for applying one or more hemostatic clips, the device permitting rotation of the clip(s) during insertion of the clip to a target site in a living body. It is noted that although the exemplary device according to the invention has been described with respect to clipping devices, the device may also be designed to perform any of a variety of endoscopic procedures including, but not limited to, band ligation, injection therapy, thermal electrohemostasis, combination therapy needle, biopsies and fine-needle aspiration. The exemplary device according to the present invention is formed as an elongated member extending from a handle at a proximal end to an end effector (e.g., a clipping device) at a distal end. It should be noted that the terms "proximal" and "distal," as used herein, are intended to refer to a direct toward (proximal) and away from (distal) a user of the device.

[0007] As shown in Figs. 1 - 3, a device 100 according to an exemplary embodiment of the invention extends longitudinally from a proximal end including a handle accessible to a physician or other user in an operative configuration to a distal end which, in use, is inserted into a living body to a site adjacent to target tissue. Except as specifically pointed out, the device 100 according to this embodiment is formed substantially similarly to the device described in U.S. Application Serial No. 12/107,559 entitled "Single Stage Hemostasis Clipping Device" filed on April 22, 2008 to Cohen et al., hereinafter referred to as "the '559 Application", the entire disclosure of which is incorporated herein by reference thereto. The end effector according to this embodiment comprises a clip containing capsule 102 attached to a bushing 104 at a proximal end thereof. The bushing 104 is connected to a flexible member 106 extending to a handle 101 configured to remain outside the body in an operative configuration. The flexible member 106 is preferably sized for insertion through a working channel of an endoscope (i.e., with an outer diameter less than an inner diameter of the working channel).

[0008] In an exemplary embodiment, the flexible member 106 is formed as an elongated coil defining a hollow channel 108 extending therethrough. A rotation tube 110 extends longitudinally through the hollow channel 108 and extends distally therepast by a predetermined

distance to a clip (not shown) coupled to the distal end thereof. In an exemplary embodiment, the rotation tube 110 may be formed of one or more of Nitinol, Inconel, carbon-filled PEEK, glass-filled PEEK and any other biocompatible material having similar column strength, torsional stiffness and longitudinal flexibility. Actuation of the clip (not shown) may be performed by a control wire (also not shown) extending through the rotation tube 110, as will be described in greater detail hereinafter. An outer diameter of the rotation tube 110 may be substantially similar to an inner diameter of the flexible member 106. A portion 111 of the rotation tube 110 extending past the distal end of the flexible member 106 is dimensioned to receive a rotation tube restraint 112 thereover. The restraint 112 is formed as a substantially cylindrical hollow element having a substantially smooth outer surface and a non-smooth inner surface. Specifically, an inner wall of the restraint 112 comprises one or more protrusions 114 configured to receive a driver 132, as will be described in greater detail later on.

[0009] In an exemplary embodiment, the bushing 104 includes tabs 116 adjacent a distal portion thereof, the tabs 116 being configured to deflect radially outward when a bushing support (not shown) applies an expanding pressure thereto. Specifically, the bushing support (not shown) provided within the bushing 104. The exemplary bushing support (not shown) according to the invention may be formed as slidable element movable along a longitudinal axis of the bushing 104 to permit movement of the tabs 116 between an expanded configuration and a biased, non-expanded configuration. In an exemplary embodiment, the bushing support (not shown) is formed with a non-cylindrical shape configured to engage the tabs 116 in an operative configuration. A substantially cylindrical drive element 120, which may be considered in this embodiment a bushing base, is received at least partially within the distal portion of the bushing 104. In an operative configuration, the drive element 120 may be welded or otherwise permanently affixed to a proximal end 105 of the bushing 104. The drive element 120 may be configured and dimensioned to be partially encapsulated within a socket 138 in an operative configuration to affix the bushing 104 and capsule 102 to the flexible member 106. That is, the drive element 120 is locked in position within the socket 138 to prevent longitudinal movement of the bushing 104 relative to the flexible member 106. However, in this position, the drive element 120 is still rotatable relative to the flexible member 106, as will be described in greater detail later on. Upon engagement with the bushing support (not shown), the tabs 116 engage the

slots 118. Specifically, the tabs 116 are configured and dimensioned to engage slots 118 in the capsule 102 to lock the capsule 102 to the bushing 104. The tabs 116 are constructed to be biased towards a central longitudinal axis L of the bushing 104, as would be understood by those skilled in the art. The bushing support (not shown) is configured and dimensioned so that, when
5 slid within the bushing 104 to a desired position, the bushing support engages an inner surface of each of the tabs 116 maintaining the tabs 116 in a locking position in which they are engaged with corresponding slots 118 in the capsule 102. In operation, the bushing support (not shown) applies a radially expansive pressure to the tabs 116.

10 [0010] The drive element 120 is formed as a hollow substantially cylindrical element having a proximal rim 122, a distal rim 124 and a grooved portion 126 extending therebetween. The grooved portion 126 is configured and dimensioned to engage a lip 139 provided on a distal end of the socket 138. As those skilled in the art will understand, a reduced diameter of the proximal rim 122 permits pivoting movement of the bushing 104 relative to the socket 138. An inner wall
15 of the drive element 120 is provided with protrusions 128 disposed around a circumference thereof configured to define a non-cylindrical channel 130 extending therethrough. The shape and position of each of the protrusions 128 is selected to permit engagement with the driver 132 having distal drive teeth 134. In an exemplary embodiment, the driver 132 may be formed of one of laser-cut metal, stamped metal, a formed metal, a carbon-filled polymer, a glass-filled
20 polymer and any other plastic having similar mechanical properties.

[0011] In an operative configuration, a rotation tube restraint 112 having a larger outer diameter than an inner diameter of the flexible member 106 is positioned over the portion 111 of the rotation tube 110. Proximal drive teeth 136 of the driver 132 extending through the rotation
25 tube restraint 112 between the protrusions 114 of the restraint 112 are affixed to the portion 111 of the rotation tube 110 to lock the rotation tube restraint in a desired position at the distal end of the rotation tube 110. As the outer diameter of the rotation tube restraint 112 is greater than an inner diameter of the flexible member 106, a proximal end of the rotation tube restraint 112 defines a limit to the withdrawal of the rotation tube 110 proximally into the flexible member
30 106. At the same time, engagement of the proximal drive teeth 136 with the protrusions 114

prevents rotation of the restraint 112 relative to the rotation tube 110. The socket 138 is provided over the restraint 112 and driver 132 to cover this arrangement.

[0012] To load a clip onto the rotation tube 110, the distal drive teeth 134 are inserted into the drive element 120 between the protrusions 128 to couple the drive element 120 to the rotation tube 110 via the driver 132. Whereas conventional devices employ a crimped or welded connection with the bushing 104, the exemplary distal drive teeth 134 according to the invention permit greater articulation of the bushing 104. In an exemplary embodiment, the bushing 104 is permitted to pivot by approximately 10° in all directions relative to the socket 138, as shown in Fig. 1. The bushing support (not shown) is then moved distally within the bushing 104 until the tabs 116 are urged radially outward to engage slots 118 in the capsule 102 to lock the capsule 102 to the bushing 104. The drive element 120 is then fixed to the proximal end 105 of the bushing 104, as described in greater detail earlier.

[0013] As shown in Fig. 3, the handle 101 according to the invention also permits an increased amount of rotation and movement of the flexible member 106 relative thereto. That is, whereas conventional devices require that the flexible member 106 be crimped, welded or otherwise attached to the handle 101, the apparatus according to the exemplary embodiment of the invention comprises an anchor 140 coupling the flexible member 106 to the handle 101 while permitting free rotation thereof. Thus, the flexible member 106 may be rotated as needed within the handle 101 preventing wind-up of the flexible member 106 (i.e., the buildup of torque therealong) during rotation of the handle 101, as those skilled in the art will understand. The anchor 140 is configured to lockingly engage a proximal portion of the flexible member 106. The handle 101 may be molded in two parts and the flexible member 106 with the attached anchor 140 inserted into a cavity thereof. The two parts may then be brought into alignment with one another and bonded together via any known technique (e.g., ultrasonic welding, etc.).

[0014] As also shown in Fig. 3, a proximal portion of the rotation tube 110 is attached to an anchor block 142 positioned over an outer portion thereof. In an exemplary embodiment, the anchor block 142 is welded to the rotation tube 110. It is noted however that any other suitable method of attachment may be employed without deviating from the scope of the invention (e.g.,

adhesive, friction fit, etc.). In another embodiment, the anchor block 142 is integrally formed with the rotation tube 110. The handle 101 comprises a longitudinal cavity 103 extending therethrough. A distal portion 103' of the cavity 103 is configured and dimensioned to receive the flexible member 106. A diameter of a proximal portion 103" of the cavity 103 is substantially similar to an outer diameter of the anchor block 142 to permit slidable movement of the anchor block 142 therewithin. The anchor block 142 is formed with a non-circular cross-sectional shape and dimensioned to be slidable through the proximal portion 103" of the cavity 103. In an exemplary embodiment, the anchor block 142 has a substantially rectangular cross-sectional shape. The proximal portion 103" is formed with a substantially circular cross-sectional shape. In operation, the anchor block 142 is longitudinally movable within the proximal portion 103" but is prevented from rotating therewithin due to the mismatched cross-sectional shapes. This configuration permits a user to control axial movement of the rotation tube 110. Specifically, as those skilled in the art will understand, the flexible member 106 may change an effective length thereof due to bending when inserted through tissue along a tortuous path. Thus, as a length of the flexible member 106 increases, the anchor block 142 moves distally within the proximal portion 103", so that the length of a portion of the rotation tube 110 extending distally from the handle 101 is increased. Accordingly, the exemplary anchor block 142 and proximal portion 103" of the invention permit the flexible member 106 to be readily traversed through tissue along a tortuous path. Conversely, as the flexible member 106 is straightened, the anchor block 142 moves proximally within the proximal portion 103" withdrawing a portion of the rotation tube 110 proximally into the handle 101.

[0015] In accordance with an exemplary method according to the invention, the flexible member 106 is inserted through an endoscope until a distal end of the device 100 comprising a clipping device or end effector (not shown) extends from the distal end of the endoscope exposed to a target portion of tissue. During insertion, the anchor block 142 automatically slides within the proximal portion 103" to adjust a length of the rotation tube 110 extending from the handle 101. As discussed above, this length adjustment enhances the flexibility of the flexible member 106 during insertion. In another embodiment of the invention, a physician or other user may manually move the anchor block 142 within the proximal portion 103" of the longitudinal cavity 103 as needed. The bushing 104 may also pivot relative to the socket 138 during insertion.

Once inserted to the target position, a clipping device (not shown) is positioned to grasp a target portion of tissue. The bushing 104 is then separated from the capsule 102 and subsequently removed from the body, as described in greater detail in the '559 Application. Specifically, once the device 100 has been inserted to the target position, the control wire (not shown) extending through the rotation tube 110 is withdrawn proximally, the proximal movement also drawing the clipping device (not shown) connected to a distal end thereof proximally. A frangible connection provided between the control wire (not shown) and clipping device (not shown) is configured to fracture or otherwise separate upon application of a predetermined load to the control wire through, for example, manipulation of an actuator. As the control wire is drawn proximally, arms of the clipping device are drawn into the capsule 102 so that contact with the capsule 102 draws distal ends of the arms toward one another, compressing tissue located therebetween. Distal portions of the arms may be configured to be wider than proximal portions thereof, defining a maximum extent to which the arms may be drawn into the capsule 102. Thus, as the control wire is drawn proximally and the distal ends of the arms approach one another, the force required to compress tissue gripped thereby applies a load to the control wire. After the arms have been drawn into the capsule 102 to the maximum extent, operating the actuator to draw the control wire further proximally applies an increasing amount of tension to the control wire and, consequently, to the frangible connection, causing the frangible connection to fail and separate the control wire from the clipping device. Furthermore, failure of the frangible connection releases tabs (not shown) of the clipping device to move laterally outward to engage the slots 118 of the capsule 102 locking the clipping device closed within the capsule 102, maintaining the clipping device constrained within the capsule 102 to keep the arms closed over tissue gripped therebetween.

[0016] It will be understood by those of skill in the art that individual features of the embodiments described above may be omitted and or combined to form alternate embodiments. Furthermore, it will be understood by those skilled in the art that various modification can be made in the structure and the methodology of the present invention, without departing from the spirit or scope of the invention. For example, although the present invention has been described with respect to a clipping device, the exemplary system and method may also be used to perform biopsy procedures or any other medical procedure wherein improved rotation of a component is

required in combination with a function of opening/closing a device, extending/retracting a device into tissue, etc., as those skilled in the art will understand. Furthermore, although the present invention has been described with respect to a removable capsule 102, the exemplary rotation drive mechanism according to the invention may also be used with a biopsy tool or any
5 other medical device non-removably attached to the rotation drive mechanism. It is therefore respectfully submitted that the exemplary rotation drive mechanism according to the invention may be employed in any other medical device requiring precise rotational control without deviating from the spirit and scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided that they come within
10 the scope of the appended claims and their equivalents.

What is claimed is:

1. A medical device, comprising:

a flexible member extending from a handle at a proximal end to a distal end sized and shaped for insertion to a target position in a living body and having a first channel extending longitudinally therethrough;

an elongated rotation tube positioned in the first channel and being rotatable relative to the flexible member; and

a rotation drive device at a distal end of the rotation tube, a proximal end of the rotation drive device being associated with the rotation tube, a distal end of the rotation drive device having a first protrusion extending distally therefrom and a drive element having a substantially cylindrical shape with a groove on an inner wall thereof mating with the first protrusion of the rotation drive device, the drive element configured to transmit rotational movement of the rotation tube to an end effector connected to a distal end thereof to rotate the end effector relative to the flexible member.

2. The device of claim 1, wherein the end effector comprises a bushing having a proximal end connected to the distal end of the drive element, a distal end and a channel extending therethrough, the bushing comprising a plurality of arms extending distally from the distal end, the arms being maintained by a bushing support in a connection configuration in which distal ends of the arms engage a capsule to couple the capsule to the flexible member, the arms being biased toward a release configuration in which engagement surfaces at distal ends thereof are retracted radially into the channel to release the capsule from the flexible member.

3. The device of claim 2, wherein the drive element is permanently attached to a proximal end of the bushing.

4. The device of claim 1, further comprising a socket formed as a substantially cylindrical shell positioned over at least a portion of an outer surface of the drive element.
- 5 5. The device of claim 2, further comprising a bushing support slidably received within the channel of the bushing supporting the first and second arms to extend radially outward when in a first configuration.
- 10 6. The device of claim 4, wherein the drive element comprises a circumferential groove on an outer wall thereof configured to lockingly engage the socket to prevent axial movement of the drive element relative to the flexible member while allowing rotational movement of the drive element relative to the flexible member.
- 15 7. The device of claim 1, further comprising a substantially cylindrical restraint permanently engaging a second protrusion formed on a proximal end of the rotation drive device, the restraint being slidably received over a distal portion of the rotation tube.
- 20 8. The device of claim 7, wherein the restraint is locked to the rotation tube by one of a friction fit, a weld, and adhesive.
- 25 9. The device of claim 1, wherein the end effector includes a clipping device, the device further comprising a control wire inserted through the rotation tube, a proximal end of the control wire being actuatable by a user and a distal end of the control wire being connected to the clipping device.
- 30 10. The device of claim 1, further comprising an anchor block positioned over an outer surface of the rotation tube within the handle, the anchor block being slidable within a predetermined portion of the handle to affect longitudinal movement of the rotation tube relative to the handle.

11. The device of claim 10, wherein the anchor block is configured and dimensioned to prevent rotation of the rotation tube relative to the handle.

12. The device of claim 1, further comprising a coil anchor attached to an outer surface of the flexible member and locking an axial position of the flexible member relative to the handle.

13. A system for performing a medical procedure, comprising:

a flexible member extending from a handle at a proximal end to a distal end sized and shaped for insertion to a target position in a living body and having a first channel extending longitudinally therethrough;

an elongated rotation tube positioned in the first channel and being rotatable relative to the flexible member;

a rotation drive device at a distal end of the rotation tube, a proximal end of the rotation drive device being associated with the rotation tube, a distal end of the rotation drive device having a first protrusion extending distally therefrom;

a drive element having a substantially cylindrical shape with a groove on an inner wall thereof mating with the first protrusion of the rotation drive device, the drive element being configured to transmit rotational movement of the rotation tube to a medical device connected to a distal end thereof, wherein the rotation tube is rotatable relative to the flexible member; and

an end effector attached to a distal end of the drive element.

14. The system of claim 13, wherein the end effector comprises a bushing having a proximal end coupled to the flexible member, a distal end releasably coupled to a capsule and a channel

extending therethrough, the bushing comprising a plurality of arms extending proximally from the distal end, the arms being maintained by a bushing support in a connection configuration in which distal ends of the arms engage a capsule of the end effector to couple the capsule to the flexible member, the arms being biased toward a release configuration in which engagement surfaces at distal ends thereof are retracted radially into the channel, the bushing being configured to removably engage the first protrusion of the rotation drive device so that the bushing is pivotable relative to a longitudinal axis of the rotation drive device.

10 15. The system of claim 14, wherein the drive element is permanently attached to a proximal end of the bushing.

16. The system of claim 14, further comprising a socket formed as a substantially cylindrical shell positioned over at least a portion of an outer surface of the drive element.

15 17. The system of claim 14, further comprising a bushing support slidably received within the channel of the bushing, the bushing support, in a first configuration, supporting the first and second arms in a radially outward position to lock the capsule to the bushing.

20 18. The system of claim 16, wherein the drive element comprises a circumferential groove on an outer wall thereof, the circumferential groove being configured to lockingly engage the socket to prevent axial movement of the drive element relative to the flexible member while allowing rotational movement of the drive element relative to the flexible member.

25 19. The system of claim 13, further comprising a substantially cylindrical restraint permanently engaging a second protrusion formed on a proximal end of the rotation drive device, the restraint being slidably received over a distal portion of the rotation tube.

30 20. The system of claim 19, wherein the rotation tube restraint is locked to the rotation tube by one of a friction fit, a weld, and adhesive.

21. The system of claim 13, wherein the end effector includes a clipping device, the device further comprising a control wire inserted through the rotation tube, a proximal end of the control wire being actuatable by a user and a distal end of the control wire being connected to the clipping device.

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22. The system of claim 13, further comprising an anchor block positioned over an outer surface of the rotation tube within the handle, the anchor block being slidable within a predetermined portion of the handle to affect longitudinal movement of the rotation tube relative to the handle, wherein the anchor block is configured and dimensioned to prevent rotation of the rotation tube relative to the handle.

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23. The system of claim 13, further comprising a coil anchor attached to an outer surface of the flexible member and locking an axial position of the flexible member relative to the handle while facilitating rotation of the flexible member relative to the handle.

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24. A method for deploying a medical device in a living body, comprising the steps of:

advancing a medical device to a target position in a living body, the medical device comprising a flexible member extending from a handle at a proximal end to a distal end sized and shaped for insertion to a target position in a living body and having a first channel extending longitudinally therethrough, an elongated rotation tube positioned in the first channel and being rotatable relative to the flexible member, a rotation drive device at a distal end of the rotation tube, a proximal end of the rotation drive device being associated with the rotation tube, a distal end of the rotation drive device having a first protrusion extending distally therefrom, and a drive element having a substantially cylindrical shape with a groove on an inner wall thereof mating with the first protrusion of the rotation drive device, the drive element being configured to transmit rotational movement of the rotation tube to a medical device connected to a distal end thereof, wherein the rotation tube is rotatable relative to the flexible member; and

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performing a target medical procedure using the medical device connected to the drive element.

25. The method according to claim 24, wherein a tissue clipping device is connected to the drive
5 element to perform a tissue clipping procedure.

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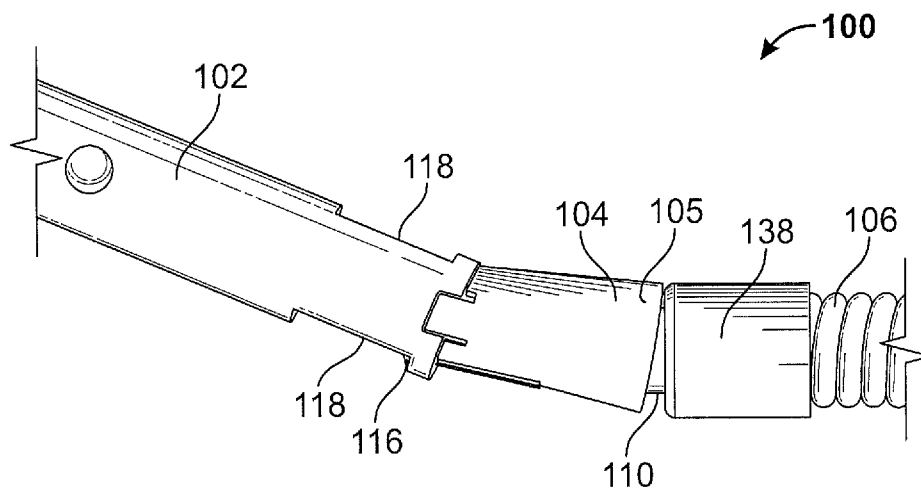


FIG. 1

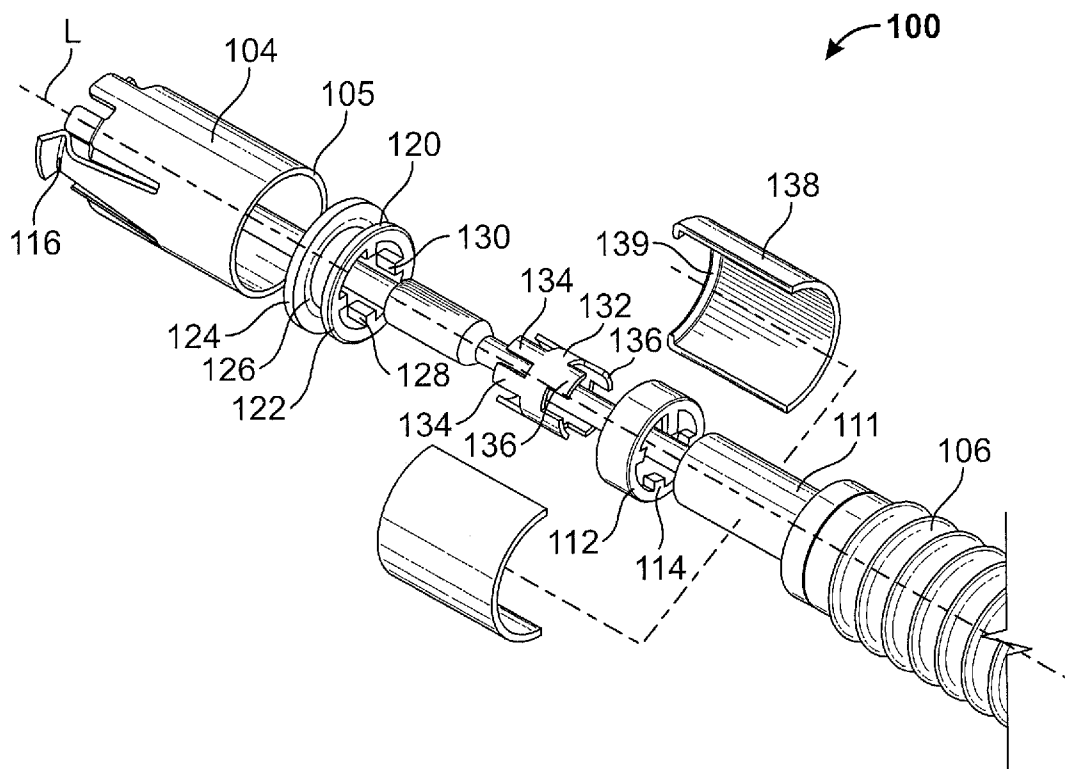


FIG. 2

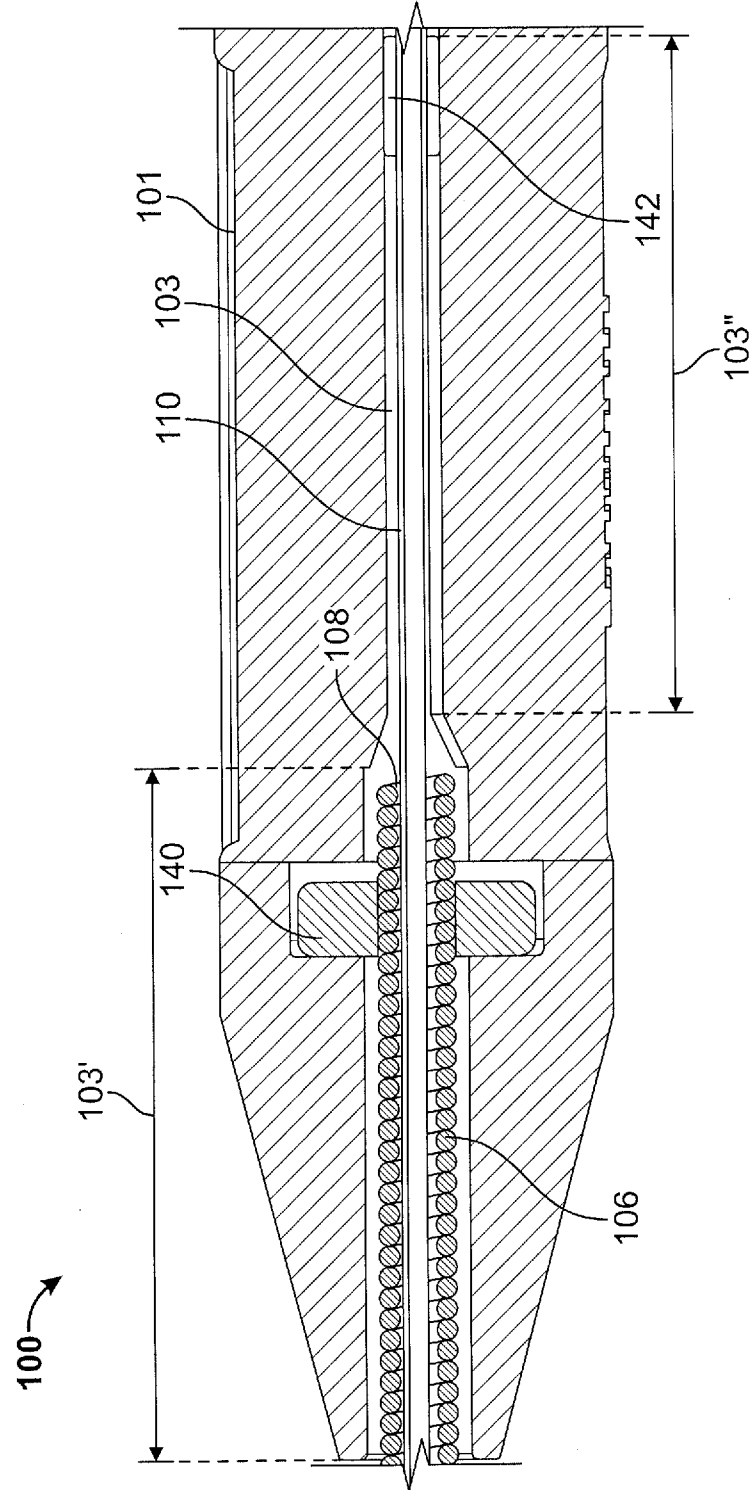


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/069476

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B17/128 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	wo 2008/073641 A2 (ATRICURE INC [US] ; PRIVITERA SALVATORE [US] ; GONYA JEFFREY A [US] ; WIN) 19 June 2008 (2008-06-19) col umns 28-29 ; claim 1; figures 11-13 ,31 ,36 -----	1,4, 13 , 16
X	US 5 662 662 A (BISHOP GREGORY D [US] ET AL) 2 September 1997 (1997-09-02) col umns 5-6; claim 1; figures 8,10-12 -----	1, 13
A	EP 0 621 009 A1 (ETHICON INC [US]) 26 October 1994 (1994-10-26) the whol e document -----	1-23
☐ 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 13 March 2013		Date of mailing of the international search report 22/03/2013
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Chopin aud, Marjori e

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/069476

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

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

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

2. ☒ Claims Nos.: **24, 25**
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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 all searchable claims.

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

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

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

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/069476

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box 11.2

Claims Nos.: 24, 25

Claims 24-25 disclose a method of treatment by surgery practised on the human body contrary to Rule 39.1(iv) PCT. Claims 24-25 pertain to a method for deploying a medical device in a living body comprising the step of inserting the medical device in a living body and of performing a target medical procedure using the medical device obviously forming part of a surgical procedure. The Authority is therefore not required to carry out international search preliminary examination.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.