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(54) **Title**: MANUALLY ARTICULATING DEVICES

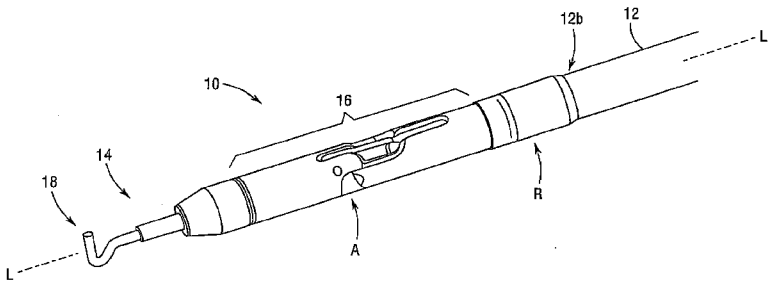

Fig.1A

(57) **Abstract**: A surgical device is disclosed. The device includes an elongate shaft having a distal end coupled to a proximal end of an articulation joint, and an actuation wire extending through the elongate shaft and the articulation joint. The device further includes an end effector having a distal tip coupled to a distal end of the articulation joint and receiving therethrough a distal end of the actuation wire. The end effector includes a hook knife disposed adjacent the distal tip and having a proximal end connected to the distal end of the actuation wire. The actuation wire is translatable along a longitudinal axis of the elongate shaft to extend and retract the distal end of the hook knife relative to the distal tip of the end effector, and the articulation joint is laterally articulatable relative to the longitudinal axis of the elongate shaft to allow the end effector to be angularly oriented relative to the elongate shaft.

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MANUALLY ARTICULATING DEVICES

BACKGROUND

[0001] In laparoscopic surgical procedures, a small incision is made in the body and an elongate shaft of a surgical device is inserted through the incision to position a distal end of the shaft at a surgical site. In endoscopic procedures, the elongate shaft of a surgical device is inserted through a natural orifice, such as the mouth or anus, and is advanced along a pathway to position a distal end of the device at a surgical site. Endoscopic procedures typically require the use of a flexible shaft to accommodate the tortuous pathway of the body lumen, whereas rigid shafts can be used in laparoscopic procedures. These tools can be used to engage and/or treat tissue in a number of ways to achieve a diagnostic or therapeutic effect.

[0002] Many current laparoscopic and endoscopic devices utilize articulating effectors to provide the user with more control over the orientation of the working end of the instrument. Integration of the controls for articulating, as well as actuating, a working end of a laparoscopic or endoscopic device tend to be complicated by the size constraints of the relatively small pathway through which it is inserted. The controls for an endoscopic device are further complicated by the flexibility of the shaft. Generally, the control motions are all transferred through the shaft as longitudinal translations, which can interfere with the flexibility of the shaft. There is also a desire to lower the force necessary to articulate and/or actuate the working end to a level that all or a great majority of surgeons can handle. One known solution to lower the force-to-fire is to use electrical motors. However, surgeons typically prefer to experience feedback from the working end to assure proper operation of the end effector. The user-feedback

effects are not suitably realizable in present motor-driven devices. What is needed is an improvement over the foregoing.

FIGURES

[0003] The novel features of the various embodiments are set forth with particularity in the appended claims. The various embodiments, however, both as to organization and methods of operation, together with further advantages thereof, may best be understood by reference to the following description, taken in conjunction with the accompanying drawings as follows:

[0004] FIG. 1A is a perspective view of a distal end of a surgical device according to one embodiment;

[0005] FIG. 1B is a disassembled view of the distal end of the device of FIG. 1A;

[0006] FIG. 1C is a cross-sectional view of the distal end of the device of FIG. 1A;

[0007] FIG. 1D is a cross-sectional view of the distal end of the device of FIG. 1A in an articulated state;

[0008] FIG. 1E is a perspective view of a link for use within a distal end of a surgical device according to one embodiment;

[0009] FIG. 1F is a perspective view of an articulating coupling configured for use with the link of FIG. 1E according to one embodiment;

[0010] FIG. 1G is a perspective view of a three-bar linkage according to one embodiment;

[0011] FIG. 1H is an assembled view of the three-bar linkage of FIG. 1G;

[0012] FIG. 2A is a disassembled view of the end effector of FIG. 1A;

[0013] FIG. 2B is a cross-sectional view of the end effector of FIG. 1A;

[0014] FIGS. 2C-2D illustrates extended and retracted states of the end effector of FIG. 1A according to one embodiment;

[0015] FIG. 3A is a perspective view of a handle portion of a surgical device according to one embodiment;

[0016] FIG. 3B is an exploded view of the handle portion of FIG. 3A;

[0017] FIG. 3C is a cross-sectional view of the handle portion of FIG. 3A;

[0018] FIG. 3D is a cross-sectional view of the actuation controller of FIG. 3A; and

[0019] FIG. 4 illustrates a system according to one embodiment.

DESCRIPTION

[0020] Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated material does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

[0021] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate preferred embodiments of the invention, in one form, and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

[0022] Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the various embodiments of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present application.

[0023] The present invention generally provides methods and devices for controlling movement of a working end of a surgical device, and in particular for performing various surgical procedures using an instrument having an end effector that can be articulated relative to an elongate shaft of the device. In certain embodiments, the end effector can also optionally rotate relative to the elongate shaft of the device, and/or the shaft can rotate relative to a handle portion of the device. Articulation and rotation of the end effector will allow the end effector to be positioned at various locations during a surgical procedure, thereby providing the user with precise control over the end effector. A person skilled in the art will appreciate that the present invention has application in endoscopic procedures, laparoscopic procedures, and in conventional open surgical procedures, including robotic-assisted surgery.

[0024] FIGS. 1A-1B illustrate one exemplary embodiment of an insertion portion 10 of a manually articulating device. A handle portion 50 of the device will be discussed in more detail below in connection with FIGS. 3A-3D. It will be appreciated that the terms "proximal" and

"distal" are used herein with reference to a clinician gripping the handle portion 50 of the device. Thus, the insertion portion 10 is distal with respect to the more proximal handle portion 50. The insertion portion 10 is preferably configured to be inserted into a patient's body, and it can be rigid for laparoscopic applications, flexible for endoscopic applications, or it can have rigid and flexible portions as may be desired. As shown in FIG. 1A, the insertion portion 10 generally includes a hollow elongate shaft 12 having a working end or end effector 14 coupled to a distal end 12b thereof by a three-bar linkage 16. Operation of the three-bar linkage 16 is described in commonly-owned U.S. Application Serial No. 11/610,803 to Nobis et al. entitled MANUALLY ARTICULATING DEVICES, the disclosure of which is incorporated herein by reference it its entirety. While the end effector 14 can have various configurations, in the illustrated embodiment the end effector 14 is configured for use with a hook knife 18. The three-bar linkage 16 allows the end effector 14 to be oriented at an angle relative to a longitudinal axis L of the elongate shaft 12. The device can also optionally be configured to allow the end effector 14 to rotate relative to and about the longitudinal axis L of the elongate shaft 12. In the illustrated embodiment, the three-bar linkage 16 is rotatably coupled to the distal end 12b of the elongate shaft 12, and thus the three-bar linkage 16, as well as the end effector 14 coupled thereto, can be positioned in various axial orientations. The location of the rotation joint R proximal of the articulation joint A is particularly advantageous in that rotation of the end effector 14 can change the location of the plane within which the end effector 14 articulates.

[0025] The three-bar linkage 16 can have a variety of configurations, but in an exemplary embodiment, as shown in more detail in FIGS. 1B-1D, it includes three links 20, 22, 24 that are pivotally coupled to one another. Each link can have a variety of configurations, but in an exemplary embodiment the first and second links 20, 22 each have a generally hollow elongate

shape and the third link 24 is in the form of an elongate rod or bar. The first link 20 can have a proximal end 20a that is coupled to the distal end 12b of the elongate shaft 12 via first and second rotation couplings 26, 28, which will be discussed in more detail below. The distal end 20b of the first link 20 can be pivotally coupled to a proximal end 22a of the second link 22, e.g., by a pivot joint. The distal end 22b of the second link 22 can in turn be coupled to the end effector 14, which will be discussed in more detail below. The third link 24 can extend at least partially through the first and second links 20, 22, and it can have a distal end 24b that is pivotally coupled to the second link 22, e.g., by a pivot pin, to form a three-bar linkage mechanism. The particular location at which the third link 24 mates to the second link 22 can vary, but it is preferably pivotally mated at a location that will allow the third link 24 to apply a force to the second link 22 to cause the second link 22 to articulate relative to the first link 20. A proximal end 24a of the third link 24 can be coupled to an articulation actuator 30 extending through the elongate shaft 12 and at least partially through the first link 20. The articulation actuator 30 can have a variety of configurations, but in an exemplary embodiment the articulation actuator 30 is in the form of a hollow elongate shaft or tube. Such a configuration allows an actuation wire 32 to extend therethrough for actuating the end effector 14, as will be discussed below. FIG. 1B also illustrates an articulation coupling 34 for connecting the articulation actuator 30 to the third link 24. The coupling 34 may be a tubular member that fixedly mates to the articulation actuator 30 and pivotally mates to the proximal end 24a of the third link 34. A person skilled in the art will appreciate that the articulation actuator 30 can alternatively be directly mated to the third link 24.

[0026] In use, proximal movement of the articulation actuator 30 relative to and along the longitudinal axis L of the elongate shaft 12 will apply a proximally-directed force to the third

link 24. The third link 24 will thus apply a proximally-directed force to the second link 22, causing the second link 22 to pivot laterally relative to the longitudinal axis L of the elongate shaft 12. As a result, the second link 22, with the end effector 14 coupled thereto, will move laterally in a single plane to allow the end effector 14 to extend at an angle relative the longitudinal axis L of the elongate shaft 12, as shown in FIG. 1D. The end effector 14 can be returned to the original, longitudinally-aligned position, shown in FIGS. 1A and 1C, by moving the articulation actuator 30 distally relative to the elongate shaft 12.

[0027] As previously indicated, in addition to articulating movement, the end effector 14 can also be configured to rotate relative to the elongate shaft 12, thus allowing the end effector 14 to be positioned in multiple angular orientations. The particular location of the rotation joint R can vary, and it can be located proximal to the three-bar linkage 16, at a mid-portion of the three-bar linkage 16, or distal to the three-bar linkage 16. In an exemplary embodiment, the rotation joint R is located proximal to the three-bar linkage 16, and more preferably proximal to the articulation joint A formed between the first and second links 20, 22. As shown in FIGS. 1A-1D, the first link 20 can be rotatably coupled to the distal end 12b of the elongate shaft 12 by one or more rotation couplings. The illustrated embodiment includes first and second rotation couplings 26, 28. The first rotation coupling 26 has a generally elongate hollow shape with a proximal end 26a that is fixedly mated to the elongate shaft 12 and a distal end 26b having deflectable tabs 26c formed therearound. The tabs 26c can be formed by longitudinally-extending cut-outs formed in and spaced radially around the distal end 26b of the first rotation coupling 26. Each tab 26c can include an annular flange or lip (not shown) formed on an inner surface thereof. The second rotation coupling 28 can also have a generally elongate hollow shape, and it can include a groove or cut-out 28c formed therein. The first and second rotation

couplings 26, 28 can be mated by advancing the tabs 26c over the proximal end 28a of the second rotation coupling 28. The tabs 26c will deflect until the annular flange or lip on the tabs 26c extends into and engages the groove 28c formed in the second rotation coupling 28. The two rotation couplings 26, 28 can thus rotate relative to one another, allowing the first link 20, which is fixedly mated to the distal end 28b of the second rotation coupling 28, to rotate relative to the first rotation coupling 26 and the elongate shaft 12. It will be appreciated that the particular construction the rotation joint described above is provided by way of example only, and that the function of the rotation joint may be realized using any of a variety of different components.

[0028] Rotation of the end effector 14 relative to the elongate shaft 12 can be achieved by rotating the articulation actuator 30. In particular, rotation of articulation actuator 30 relative to and about the longitudinal axis L of the elongate shaft 12 will rotate the third link 24, which is coupled to the second link 22, which in turn is coupled to the end effector 14 and the first link 20. As a result, the entire three-bar linkage 16 will rotate with the end effector 14 relative to and about the longitudinal axis L of the elongate shaft 12. Rotation can also be performed while the end effector 14 is articulated, thereby changing the plane within which the end effector 12 articulates.

[0029] FIGS. 1E-1H illustrate alternative embodiments of a three-bar linkage. In one embodiment, shown in FIGS. 1E-1F, the third link 24 of FIGS. 1B-1D can be replaced with a flexible link. While the flexible link can have a variety of configurations, and it can be in the form of a flexible cable or similar member, FIG. 1E illustrates a flexible wire 24'. As shown, the wire 24' has a generally elongate shape with first and second terminal ends 24a', 24b' that are bent to extend at an angle, e.g., 90°, relative to the remainder of the wire 24'. The ends 24a', 24b' are configured to replace the pivot pins used to pivotally couple the third link 24 to the first and

second links 20, 22 of the embodiment shown in FIGS. 1A-1D. Thus, the ends 24a', 24b' can extend into and pivotally couple to the first and second links 20, 22 (FIGS. 1B-1D) to allow the first, second, and third links 20, 22, 24' to pivot relative to one another. In use, proximal movement of the articulation actuator 30 relative to and along the longitudinal axis L of the elongate shaft 12 will apply a proximally-directed force to the third link 24'. The third link 24' will thus flex or buckle, thereby causing the second link 22 to pivot laterally relative to the longitudinal axis L of the elongate shaft 12. As a result, the second link 22, with the end effector 14 coupled thereto, will move laterally in a single plane to allow the end effector 14 to extend at an angle relative the longitudinal axis L of the elongate shaft 12. The end effector 14 can be returned to the original, longitudinally-aligned position, shown in FIGS. 1A and 1C, by releasing the articulation actuator 30 to allow the flexible link 24' to return to its original, non-flexed position shown in FIG. 1E, thereby forcing the articulation actuator 30 to move distally relative to the elongate shaft 12. The flexible link 24' can also be used to transfer rotational forces to effect rotation of the end effector, but in an exemplary embodiment the articulating coupling 34 (FIGS. 1B-1D) is modified to be non-rotatably coupled to the first link 20. As shown in FIG. 1F, which illustrates an alternative embodiment of an articulating coupling 34', this can be achieved by inserting a pin member (not shown) through a bore 34a' formed in the articulating coupling 34', and positioning the pin member such that it is slidably disposed within a longitudinal slot (not shown) formed in the first link 20. As a result, when the articulation actuator 30 is rotated relative to and about the longitudinal axis L of the elongate shaft 12, the articulating coupling 34' will rotate therewith, thereby causing the first and second links 20, 22 to rotate, as well as the end effector 14. As a result, the entire three-bar linkage 16 will rotate with the end effector 14 relative to and about the longitudinal axis L of the elongate shaft 12. Rotation can also be done

while the end effector 14 is articulated, thereby changing the plane within which the end effector 12 articulates.

[0030] FIGS. 1G-1H illustrate another embodiment of a three-bar linkage that is similar to the three-bar linkage shown in FIGS. 1A-1D. However, in this embodiment a cam 24" replaces both the third link 24 and the articulating coupling 34 of the previous embodiment. As shown in FIG. 1G, the cam 24" is generally hook-shaped and includes a curved slot 24a" formed therein. A proximal end 24p" of the cam 24" can be fixedly mated to the distal end of the articulation actuator 30, and a pin 25" can be slidably disposed through the slot 24a". The pin 25" can be fixedly mated to or formed on an inner wall of the third link 22. As with the embodiment shown in FIGS. 1B-1D, the first and second links 20", 22" can be pivotally coupled to one another. In FIG. 1G, the first link 20" is similar to first link 20 of FIGS. 1B-1D, however link 20" has opposed bores 20a", 20b" spaced a distance apart from the distal end 20d" of the link 20" for receiving opposed pins (only one pin 22b" is shown) formed on the proximal end 22a" of the second link 22". In use, as shown in FIG. 1H, distal movement of the articulation actuator 30 will move the cam 24" distally. As the cam 24" is moved relative to the pin 25", the cam slot 24a" will force the pin 25" to follow the path of the slot 24a". As a result, the second link 22" is caused to pivot laterally relative to a longitudinal axis of the elongate shaft (not shown). As a result, the second link 22", with the end effector (not shown) coupled thereto, will move laterally in a single plane to allow the end effector to extend at an angle relative the longitudinal axis of the elongate shaft. The end effector can be returned to the original, longitudinally-aligned position by moving the articulation actuator 30 proximally and thereby pulling the cam 24" proximally. Again, the cam slot 24a" will cause the pin 25" to slid therein and follow the path of

the slot 24a", thus causing the second link 22" to return to its original, longitudinally aligned position.

[0031] FIGS. 2A-2B illustrate exploded and cross-sectional views, respectively, of the end effector 14 of FIGS. 1A-1B. Also shown is the distal end 22b of the second link 22 to which the end effector 14 is attached in an assembled state of the device. The end effector 14 may comprise, in addition to the hook knife 18, a distal tip 36, a sleeve 37, and a distal end 32b of the actuating wire 32. The hook knife 18 may be fabricated from a biocompatible material of suitable hardness and durability, such as, for example, medical grade stainless steel, and comprise a generally hook-shaped distal end 18b having a sharpened inner edge 18c formed thereon for cutting tissue when pulled therethrough. A proximal end 18a of the hook knife 18 may be configured for attachment to the distal end 32b of the actuating wire 32 using, for example, a press fit or other suitable attachment technique. In one embodiment, the hook knife 18 may be detachable from the distal end 32b of the actuating wire 32 so that it may be replaced. In another embodiment, the hook knife 18 may be permanently affixed to the distal end 32b.

[0032] The sleeve 37 may be generally cylindrical in shape and comprise a longitudinal bore 38 through which the distal end 32b of the actuating wire 32 coaxially extends. As shown in FIG. 2A, a proximal end 37a of the sleeve 37 may comprise an outer diameter larger than that of more distal portions of the sleeve 37 for enabling the proximal end 37a to be slidably retained within the distal end 22b of the second link 22, as discussed in more detail below. The longitudinal position of the sleeve 37 on the actuating wire 32 may be such that a distal end 37b of the sleeve 37 is adjacent, or in contact with, the proximal end 18a of the hook knife 18. In one embodiment, the longitudinal position of the sleeve 37 on the actuating wire 32 may be fixed using, for example, a crimp 38 (FIG. 2B) or other fastening device affixed to the actuating wire

32 adjacent the proximal end 37a of the sleeve 37. Accordingly, the sleeve 37 may be retained on the actuating wire 32 between the proximal end 18a of the hook knife 18 and the crimp 38 such that the actuating wire 32 (and thus the hook knife 18) are independently rotatable relative to a longitudinal axis of the sleeve 37. Alternatively, the longitudinal position of the sleeve 37 on the actuating wire 32 may be fixed using, for example, a suitable adhesive material disposed within the bore 38. In this embodiment, rotation of the actuation wire 32 and hook knife 18 will result in corresponding rotation of the sleeve 37. In one embodiment, the sleeve 37 may be constructed of an electrically non-conductive biocompatible plastic. In other embodiments, the sleeve 37 may be constructed of an electrically non-conductive and suitably heat-resistant biocompatible material, such as, for example, a ceramic material. A heat-resistant construction of the sleeve 37 may be used, for example, in electrosurgical configurations of the device, as discussed in more detail below.

[0033] With reference to FIG. 2B, the proximal end 37a of the sleeve 37 may be slidably disposed within a recess 39 defined by the distal end 22b of the second link 22. As shown, the recess 39 may form the distal-most portion of a bore 40 extending longitudinally through the second link 22. The distal end 37b of the sleeve 37 may distally protrude from the recess 39 and pass through a longitudinal bore 41 defined by the distal tip 36. The distal tip 36 may be longitudinally aligned with and coupled to the distal end 22b of the second link 22 such that a proximally-facing surface 42 formed by a restriction of the bore 41 partially encloses the recess 39 at its distal end. The distal tip 36 may be coupled to the distal end 22b using, for example, a threaded connection or other suitable connection technique. Distal movement of the sleeve 37 relative to the distal tip 36 is thus limited by engagement of the outer diameter of the proximal end 37a of the sleeve 37 by the proximally-facing surface 42 of the distal tip 36. Similarly,

proximal movement of the sleeve 37 relative to the distal tip 36 is limited by engagement of the outer diameter of the proximal end 37a of the sleeve 37 by a surface 22c at a proximal end of the recess 39. Distal and proximal movement of the actuating wire 32 (FIGS. 2C-2D, respectively) therefore results in a corresponding extension and retraction of the hook knife 18 relative to the distal tip 36, as well as a corresponding telescopic extension and retraction of a portion of the sleeve 37 relative to the distal tip 36. The amount of the extension and retraction is limited by the degree of longitudinal movement of the proximal end 37a of the sleeve 37 within the recess 39 (FIG. 2B). Additionally, because the actuation wire 32 may be rotated independently about its longitudinal axis relative to the longitudinal axis of the distal tip 36 (e.g., by rotating the actuation wire 32 within the sleeve 37 or by rotating the actuation wire 32 and the sleeve 37 together within the recess 39 of the second link 22), the hook knife 18 may be rotationally positionable relative to the longitudinal axis of the distal tip 36. As discussed below, distal, proximal and rotational movement of the actuating wire 32 relative to the distal tip 36 may be controlled via the handle portion 50 of the device.

[0034] As previously indicated, the device can also include a handle portion coupled to the proximal end of the elongate shaft and having various controls formed thereon for controlling and manipulating the device. A person skilled in the art will appreciate that the particular configuration of the handle portion can vary, and that various techniques known in the art can be used for effecting movement of various portions on the device. FIGS. 3A-3D illustrate one exemplary embodiment of a handle portion 50 for use with the insertion portion 10 of the device shown in FIG. 1A. As shown in FIG. 3A, the handle portion 50 has a generally elongate cylindrical configuration to facilitate grasping thereof. The handle housing 52 can have an integral or unitary configuration, or it can be formed from two housing halves 52a, 52b that mate

to enclose various components therein. The housing halves 52a, 52b are shown in FIG. 3B. The various component disposed within the handle housing 52 can also vary, but in an exemplary embodiment the handle portion 50 includes a first knob 54 for articulating and rotating the end effector 14, and an actuation controller 56 for actuating the end effector 14.

[0035] The first knob 54 is shown in more detail in FIGS. 3B and 3C, and as shown the first knob 54 has a generally cylindrical configuration. The first knob 54 can have an integral or unitary configuration, or it can be formed from two halves 54a, 54b that mate together, as shown. A proximal end 30a of the articulation actuator 30 can mate to the first knob 54 such that rotation and translation of the first knob 54 will cause corresponding rotation and translation of the articulation actuator 30, thereby rotating and articulating the end effector 14, as previously described. While various techniques can be used to mate the articulation actuator 30 to the first knob 54, in an exemplary embodiment the articulation first knob 54 includes an axle 58 fixedly disposed therein and engaged between the knob halves 54a, 54b. The articulation actuator 30 extends through an inner lumen of the axel 58 and is fixedly mated thereto. Various mating techniques can be used to mate the articulation actuator 30 to the axel 58 including, for example, an interference or compression fit, an adhesive, or other mechanical or chemical mating techniques known in the art.

[0036] In order to translate and rotate the first knob 54, the handle housing 52 can include an elongate cavity 52c (FIG. 3B) formed therein that slidably and rotatably receives the first knob 54. The handle housing 52 can also include one or more cut-outs formed therein for allowing a user to access the first knob 54. FIGS. 3A-3B illustrate opposed cut-outs 52d, 52e formed in the handle housing 52. The first knob 54 can also include features to facilitate movement thereof. For example, the first knob 54 can include one or more surface features

formed on an external surface thereof for allowing the user to more easily grasp the first knob 54. In the illustrated embodiment, the first knob 54 includes a series of ridges 54r formed therein, as well as a series of longitudinally-oriented teeth 54t formed on a portion thereof. In one embodiment, the ridges 54r may be selectively engaged by a thumb screw 53 accessible from the exterior of the handle housing 52 such that the articulation and rotational positions may be selectively maintained. In another embodiment, the ridges 54r can provide a detent feature to maintain the position of the articulation. A corresponding detent snap can be located in the cavity 52c.

[0037] In use, the first knob 54 can be grasped by a user and rotated about its longitudinal axis (i.e., about the longitudinal axis L of the shaft 12 and handle portion 50). Rotation of the knob will cause corresponding rotation of the axel 58 and the articulation actuator 30. The actuation wire 32, which extends through the articulation actuator 30, will not rotate with the articulation actuator 30 since it is not coupled thereto. As previously explained, rotation of the articulation actuator 30 will cause corresponding rotation of the three-bar linkage 16 and the end effector 14 coupled thereto. The first knob 54 can also be slid or translated longitudinally along its axis L, and within the elongate cavity 52c formed in the handle housing 52. Proximal movement of the first knob 54 within the handle housing 52 will pull the articulation actuator 30 proximally, thereby articulating the end effector 14, as previously explained. Distal movement of the first articulation knob 54 within the handle housing 52 will in turn move the articulation actuator 30 distally, thereby returning the end effector 14 to its original longitudinally-aligned position.

[0038] As indicated above, the handle portion 50 can also include an actuation controller 56 for actuating the end effector 14 (e.g., extending, retracting and/or rotating the hook knife 18

relative to the distal tip 36). The actuation controller 56 can have a variety of configurations, but in the illustrated embodiment the actuation controller 56 comprises a second knob 70 attached to a proximal end 71a of a rotation tube 71 that is slidably disposed through a distal opening 52g formed in the handle housing 52. The second knob 70 may generally form the proximal end of the handle portion 50. Longitudinal movement of the second knob 70 along the longitudinal axis of the handle housing 52 causes corresponding longitudinal movement of the rotation tube 71 within the handle housing 52. Similarly, rotational movement of the second knob 70 about the longitudinal axis of the handle housing 52 causes corresponding rotational movement of the rotation tube 71 within the handle housing 52.

[0039] The actuation controller 56 may also include a third knob 72 accessible from the exterior of the handle housing 52 and longitudinally slidable relative to the handle housing 52 via a slot 52f formed therein. The third knob 72 may be coupled to a yolk 73 (FIGS. 3B-3C) that extends from the third knob 72 into the interior of the handle housing 52. The yolk 73 may be received through a circumferential slot 71c formed on a distal end 71b of the rotation tube 71. Because the yolk 73 is received through the circumferential slot 71c of the rotation tube 71, longitudinal movement of the rotation tube 71 via the second knob 70 causes corresponding longitudinal movement of the yolk 73, and, therefore, corresponding longitudinal movement of the third knob 72, relative to the slot 52f. Because the yolk 73 is not otherwise attached to the rotation tube 71, the yolk 73 does not prevent rotational movement of the rotation tube 71 via the second knob 70.

[0040] In one embodiment, the third knob 72 may be threadingly coupled to the yolk 73 such that the third knob 72 is selectively tightenable and untightenable relative to the yolk 73. In a tightened, or "locked", state of the third knob 72, a base 72a (FIG. 3D) of the third knob 72

may be pushed into contact with an adjacent outer perimeter of the slot 52f, thereby causing an opposing portion of the yolk 73 to be pulled into contact with an adjacent inner perimeter of the slot 52f. In this way, a portion of the handle housing 52 may be clamped between the third knob 72 and the yolk 73 such that the rotation tube 71 is immovably fixed, or locked, into position relative to the longitudinal axis of the handle housing 52. In an untightened, or "unlocked", state of the third knob 72, the base 72a of the third knob 72 may no longer be pushed into contact with the outer perimeter of the slot 52f, in which case the handle housing 52 is no longer clamped between the third knob 72 and the yolk 73. Accordingly, the rotation tube 71 is freely movable along the longitudinal axis of the handle housing 52 using the second knob 70. As noted above, because the yolk 73 is received through the slot 71c of the rotation tube 71 and is not otherwise attached thereto, the rotation tube 71 remains rotatable irrespective of the locked or unlocked state of the third knob 72.

[0041] In addition to the second and third knobs 70, 72, the rotation tube 71, and the yolk 73, the actuation controller 56 may further comprise a shaft 74, at least a portion of which is coaxially disposed within a bore 71d defined by the rotation tube 71. According to one embodiment and as shown in FIGS. 3C-3D, the shaft 74 may define a longitudinal bore 74c through which the proximal end 32a of the actuation wire 32 may partially extend. The proximal end 32a of the actuation wire 32 may be retained within the bore 74c using, for example, one or more set screws (not shown) transversely extending into the bore 74c from an exterior surface of the shaft 74 to engage the distal end 32b. A proximal end 74a of the shaft 74 may comprise a reduced outer diameter, with the proximal end 74a aligned with and adjacent an opening 70a formed through the second knob 70. As shown in FIG. 3D, a connector 75 may extend through the opening 70a and into the bore 71d of the rotation tube 71 to engage an inner surface of the

opening 70a and the distal end 74a of the shaft 74, thus maintaining the position of the shaft 74 relative to the rotation tube 71. In certain embodiments, the shaft 74 may be constructed from an electrically conductive material (e.g., stainless steel), and the connector 75 may comprise an electrical connector (e.g., a male banana plug connector 75 as shown) that is accessible from the exterior of the handle portion 50. An electrical path may thus be established between the connector 75 and the hook knife 18 via the shaft 74 and the actuation wire 32, and, as discussed in further detail below, the hook knife 18 may be used for electrosurgical procedures by connecting to the connector 75 to a suitable source of electrical energy.

[0042] In use, the second knob 70 can be grasped by a user and, with the third knob 72 in an unlocked state, slidably manipulated through the opening 52g of the handle housing 52 along the longitudinal axis of the handle housing 52. Movement of the second knob 70 in the distal direction will cause the rotation tube 71 and the shaft 74, and thus the actuation wire 32, to be correspondingly moved in the distal direction. As discussed above in connection with FIGS. 2C-2D, this results in an extension of the hook knife 18, and a corresponding telescopic extension of a portion of the sleeve 37, relative to the distal tip 36. In the same way, movement of the second knob 70 in the proximal direction will result in a retraction of the hook knife 18, and a corresponding telescopic retraction of a portion of the sleeve 37, relative to the distal tip 36. Generally, the second knob 70 may be used to provide any degree of extension/retraction of the hook knife 18 and sleeve 37 between their fully extended and fully retracted positions. Additionally, subsequent to achieving a desired extended/retracted position of the hook knife 18 and the sleeve 37, the position may be maintained by tightening the third knob 72 relative to the yolk 73, as discussed above.

[0043] Additionally, the rotational position of the rotation tube 71 and the shaft 74 relative to the handle portion 52, and thus the rotational position of the actuation wire 32 about the longitudinal axis of the distal tip 36, may be controlled by rotating the second knob 70 about the longitudinal axis of the handle portion 50. In this way, the rotational position of the hook knife 18 relative to the distal tip 18 may be controlled via the second knob 70.

[0044] In certain embodiments and as previously mentioned, the end effector 14 may be suitable for use in electrosurgical procedures by virtue of a conductive path formed between the hook knife 18 and the connector 75 of the handle portion 50. FIG. 4 illustrates a system 80 for performing electrosurgical procedures according to one embodiment. The system may comprise a manually articulating surgical device 81 comprising an insertion portion 10 and a handle portion 50 as described above wherein the hook knife 18 is electrically coupled to the connector 75 (e.g., a male banana connector) via the shaft 74 and the actuation wire 32. To ensure that the articulation wire 32 is suitably insulated from other components within the device 81, electrical insulation (e.g., plastic tubing or an insulative coating) may cover at least a portion of the actuation wire 32. The system 80 may further comprise an energy source 82 comprising a first output 82a electrically coupled to the connector 75 via a first wire 82b, and a second output 82c electrically coupled to a patient to be treated (not shown) via a second wire 82d and a grounding pad 82e. It will be appreciated that this configuration of the system 80 corresponds to a monopolar mode of operation. In one embodiment and as shown, the energy source 82 may comprise a radio frequency (RF) generator to produce RF waveforms at predetermined frequencies, amplitudes, polarities, and pulse widths. The RF generator may be a conventional bipolar/monopolar electrosurgical generator such as one of many models commercially available, including Model Number ICC 350, available from Erbe, GmbH. In use, the insertion

portion 10 of the device 81 may be introduced into the patient (e.g, via a flexible endoscope) such that the hook knife 18 of the end effector 14 is adjacent a surgical site comprising an area of tissue. RF energy may be introduced to the tissue by suitably contacting the tissue with the hook knife 18. It will appreciated that RF energy may operate to enhance the cutting ability of the hook knife 14 and/or to perform other electrosurgical procedures, such as, for example, fulguration and desiccation. As discussed above, the sleeve 37 may be fabricated from a heat-resistant material (e.g., a ceramic material) in order to insulate and protect the distal tip 36 from potentially damaging heat dissipated by the hook knife 18 during an electrosurgical procedure.

[0045] As indicated above, the various devices disclosed herein for controlling movement of a working end of a surgical device can be used in a variety of surgical procedures, including endoscopic procedures, laparoscopic procedures, and in conventional open surgical procedures, including robotic-assisted surgery. In one exemplary endoscopic procedure, an elongate shaft of a surgical device, such as one previously disclosed herein, can be inserted through a natural orifice and a body lumen to position an end effector located at a distal end of the elongate shaft adjacent to tissue to be treated. An articulation actuator can be translated along a longitudinal axis of the elongate shaft to cause a three-bar linkage to laterally articulate the end effector in a direction substantially perpendicular to a longitudinal axis of the elongate shaft to allow the end effector to be angularly oriented relative to the elongate shaft. This can be achieved by actuating one or more articulation mechanisms formed on a handle of the device. The method can also include rotating the end effector relative to the elongate shaft. In one embodiment, the three-bar linkage can rotate with the end effector relative to the elongate shaft. For example, the articulation actuator can be rotated relative to the elongate shaft to rotate both the three-bar linkage and the end effector. In another embodiment, the end effector can rotate

relative to the three-bar linkage. For example, an actuation wire coupled to the end effector and extending through the elongate shaft and the three-bar linkage can be rotated. Once the end effector is suitably positioned, the end effector may be actuated using one or more actuation mechanisms formed on the handle of the device.

[0046] The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[0047] Preferably, the invention described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The

sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

[0048] It is preferred that device is sterilized. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, steam.

[0049] It is to be understood that the figures and descriptions of the present application have been simplified to illustrate elements that are relevant for a clear understanding of the disclosed subject matter. Those of ordinary skill in the art will recognize that these and other elements may be desirable. However, because such elements are well known in the art and because they do not facilitate a better understanding of the present application, a discussion of such elements is not provided herein.

[0050] While several embodiments have been described, it should be apparent that various modifications, alterations and adaptations to those embodiments may occur to persons skilled in the art with the attainment of some or all of the advantages disclosed in the present application. It is therefore intended to cover all such modifications, alterations and adaptations without departing from the scope and spirit of the present application as defined by the appended claims.

CLAIMS

What is claimed is:

1. A surgical device, comprising:

an elongate shaft comprising proximal and distal ends;

an articulation joint comprising proximal and distal ends, the proximal end coupled to the distal end of the elongate shaft;

an actuation wire extending through the elongate shaft and the articulation joint; and

an end effector, comprising:

a distal tip coupled to the distal end of the articulation joint, the distal tip receiving therethrough a distal end of the actuation wire;

a hook knife disposed adjacent the distal tip and comprising proximal and distal ends, the proximal end of the hook knife attached to the distal end of the actuation wire;

wherein the actuation wire is translatable along a longitudinal axis of the elongate shaft to extend and retract the distal end of the hook knife relative to the distal tip; and

wherein the articulation joint is articulatable relative to the longitudinal axis of the elongate shaft to allow the end effector to be angularly oriented relative to the elongate shaft.

2. The device of claim 1, comprising an insulating sleeve rotatably disposed on the distal end of the actuation wire in a position adjacent the proximal end of the hook knife, wherein extension and retraction of the distal end of the hook knife relative to the distal tip causes a corresponding telescopic extension and retraction of the sleeve relative to the distal tip.

3. The device of claim 1, wherein the actuation wire is rotatable about the longitudinal axis of the elongate shaft to rotate the distal end of the hook knife relative to the distal tip.

4. The device of claim 1, wherein the proximal end of the articulation joint is rotatably coupled to the distal end of the elongate shaft.

5. The device of claim 4, comprising an articulation actuator extending through the elongate shaft and coupled to the articulation joint, wherein the articulation actuator is translatable along the longitudinal axis of the elongate shaft to articulate the articulation joint, and wherein the articulation actuator is rotatable within the elongate shaft to rotate the articulation joint about the longitudinal axis of the elongate shaft.

6. The device of claim 5, wherein the articulation joint comprises:

a first articulating link comprising a proximal end coupled to the distal end of the elongate shaft;

a second articulating link comprising a proximal end pivotally coupled to a distal end of the first articulating link, and a distal end coupled to the distal tip of the end effector; and

a third articulating link comprising a proximal end pivotally coupled to the articulation actuator, and a distal end pivotally coupled to the second articulating link.

7. The device of claim 5, wherein the articulation actuator comprises a hollow elongate tube.

8. The device of claim 7, wherein the actuation wire is disposed through the articulation actuator.

9. The device of claim 8, wherein rotation and translation of the actuation wire are independent of rotation and translation of the articulation actuator.

10. The device of claim 5, comprising a handle coupled to the proximal end of the elongate shaft, the handle comprising:

a first knob coupled to the articulation actuator, the first knob to at least one of translate and rotate the articulation actuator relative to the longitudinal axis of the elongate shaft; and

a second knob coupled to the actuation wire, the second knob to at least one of translate the actuation wire relative to the longitudinal axis of the elongate shaft and rotate the actuation wire about the longitudinal axis of the elongate shaft.

11. The device of claim 10, wherein the handle comprises a third knob for fixing the longitudinal position of the actuation wire relative to the longitudinal axis of the elongate shaft.

12. The device of claim 11, wherein the second knob and the third knob are coupled to the actuation wire via a common shaft.

13. The device of claim 10, wherein the handle is electrically coupled to the hook knife via the actuation wire, and wherein the handle comprises an electrical connector for coupling the hook knife to a source of electrical energy.

14. The device of claim 1, wherein the elongate shaft is flexible.

15. A method for processing the device of claim 1 for surgery, comprising:

obtaining the device of claim 1;

sterilizing the device; and

storing the device in a sterile container.

16. A surgical method, comprising:

inserting an elongate shaft of a surgical device through a body lumen to position an end effector adjacent tissue to be treated, wherein the device comprises an articulation joint disposed on a distal end of the elongate shaft, and wherein the end effector comprises:

a distal tip coupled to a distal end of the articulation joint and receiving therethrough a distal end of an actuation wire, the actuation wire extending through the elongate shaft and the articulation joint; and

a hook knife disposed adjacent the distal tip and comprising proximal and distal ends, the proximal end of the hook knife attached to the distal end of the actuation wire;

translating the actuation wire along a longitudinal axis of the elongate shaft to at least one of extend and retract the distal end of the hook knife relative to the distal tip;

translating an articulation actuator along a longitudinal axis of the elongate shaft to cause the articulation joint to articulate the end effector such that the end effector is angularly oriented relative to the elongate shaft; and

rotating the articulation actuator about the longitudinal axis of the elongate shaft to cause the end effector to rotate relative to the elongate shaft.

17. The method of claim 16, comprising rotating the actuation wire about the longitudinal axis of the elongate shaft to rotate the distal end of the hook knife relative to the distal tip.

18. The method of claim 16, wherein translating and rotating the articulation actuator comprise translating and rotating the articulation actuator using a first knob disposed on a handle coupled to the elongate shaft.

19. The method of claim 16, wherein translating and rotating the actuation wire comprise translating and rotating the actuation wire using a second knob disposed on the handle.

20. The method of claim 16, comprising transmitting electrical energy to the hook knife via the actuation wire.

21. The method of claim 16, comprising sterilizing the surgical device after at least one use.

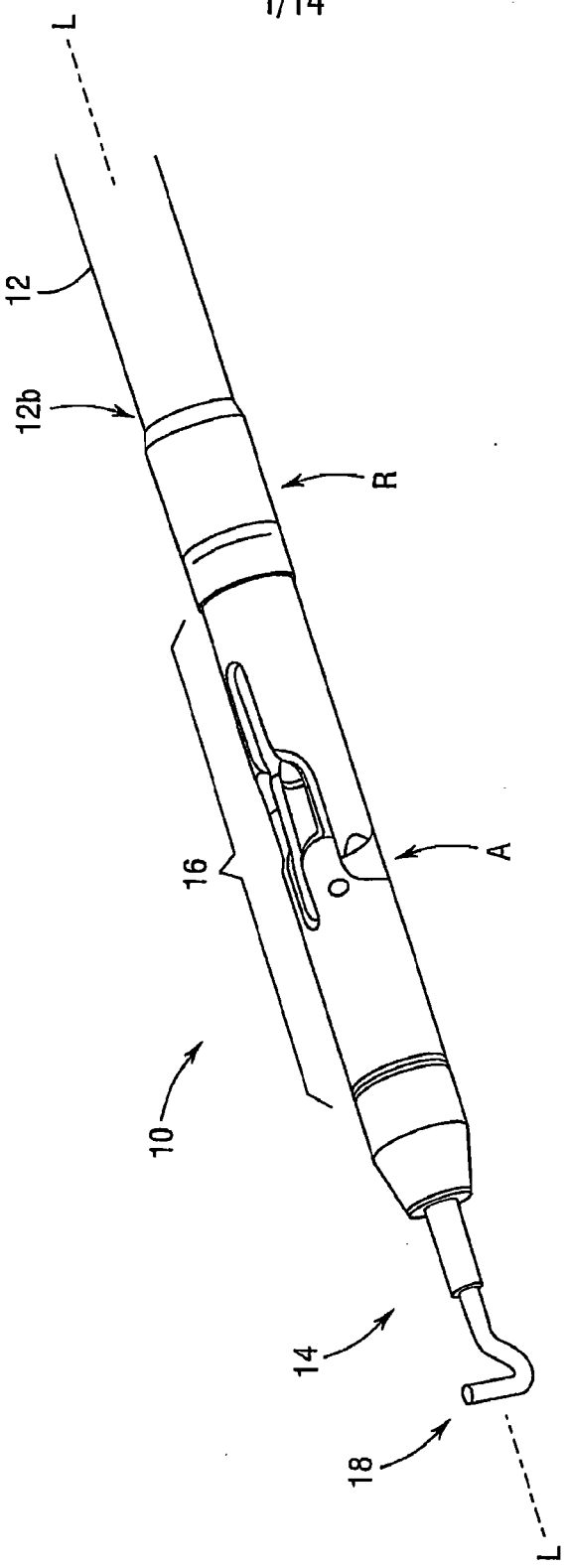

Fig.1A

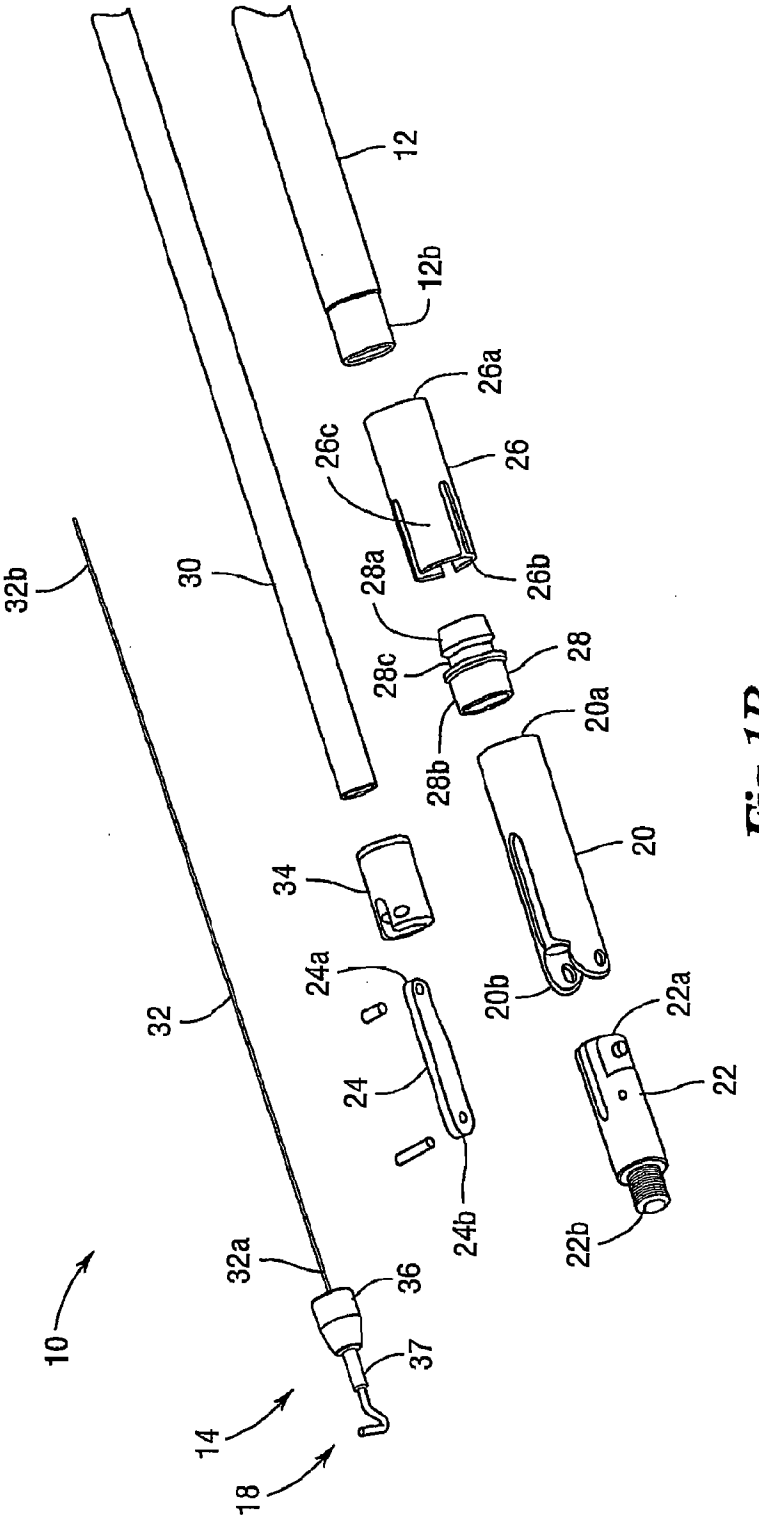
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Fig.1B

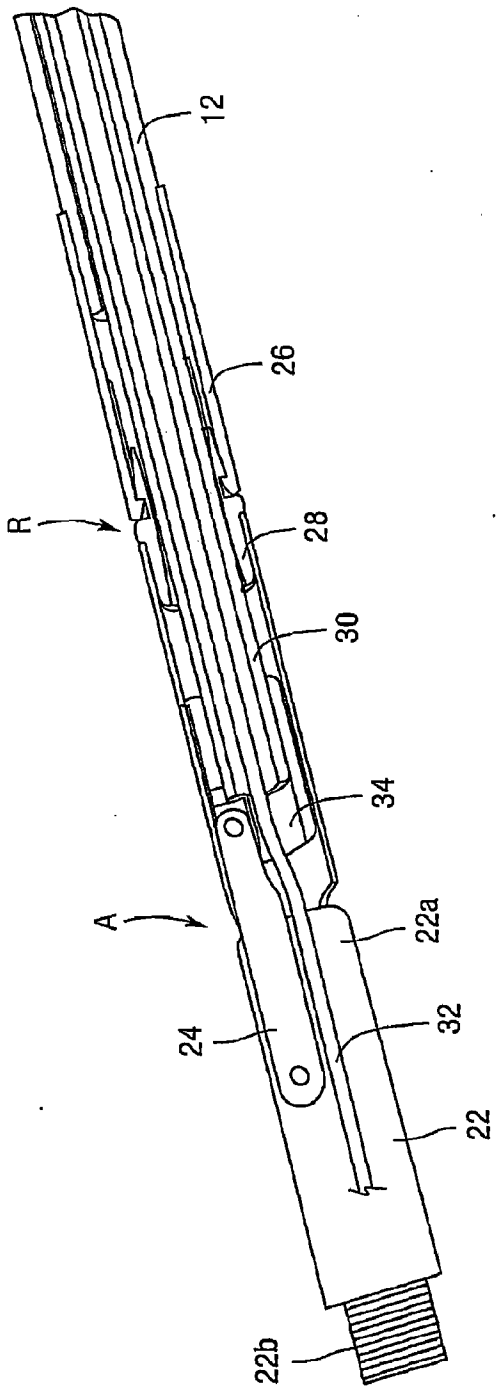

Fig.1C

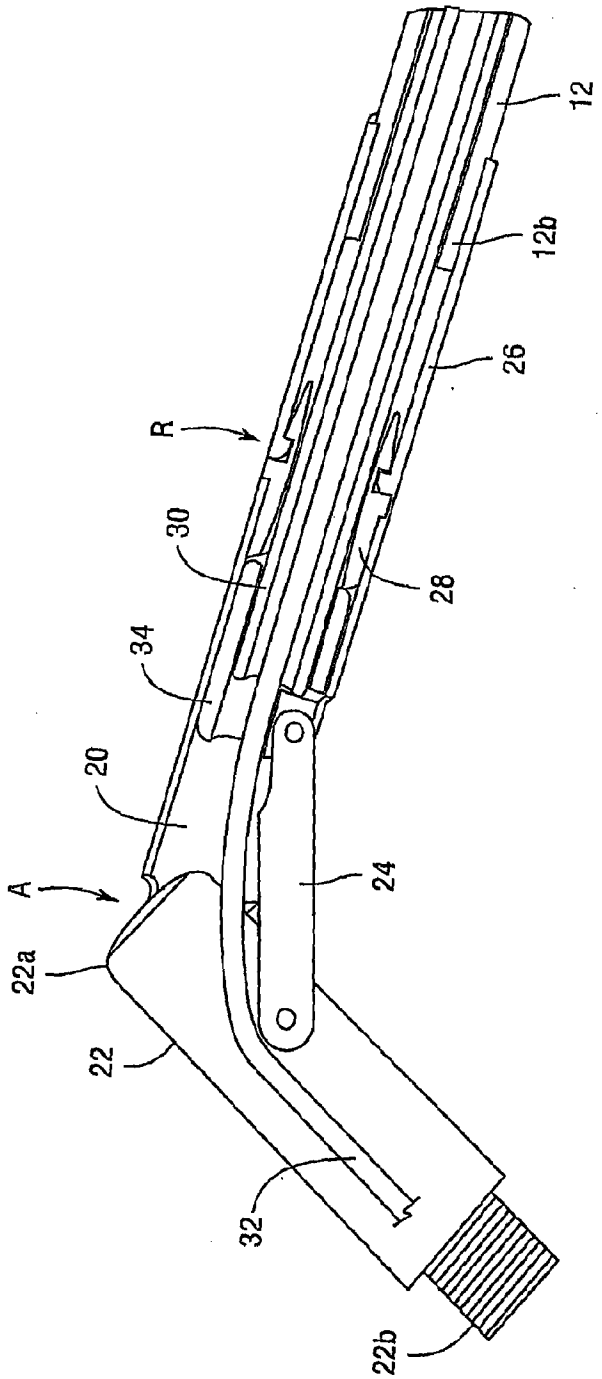

Fig.1D

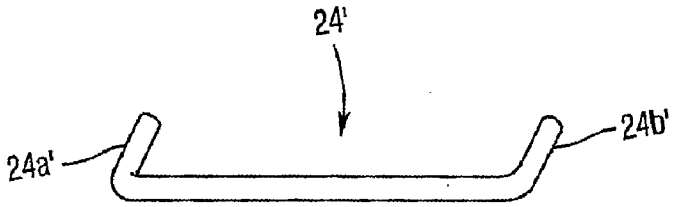

Fig.1E

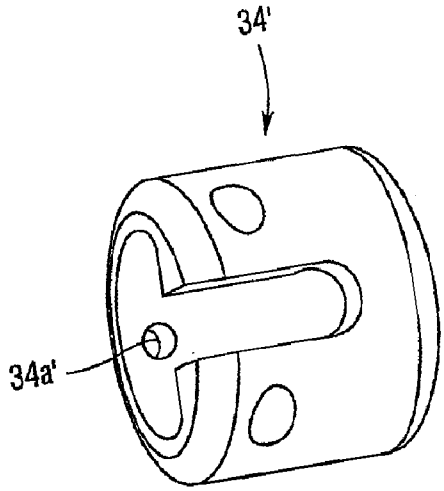

Fig.1F

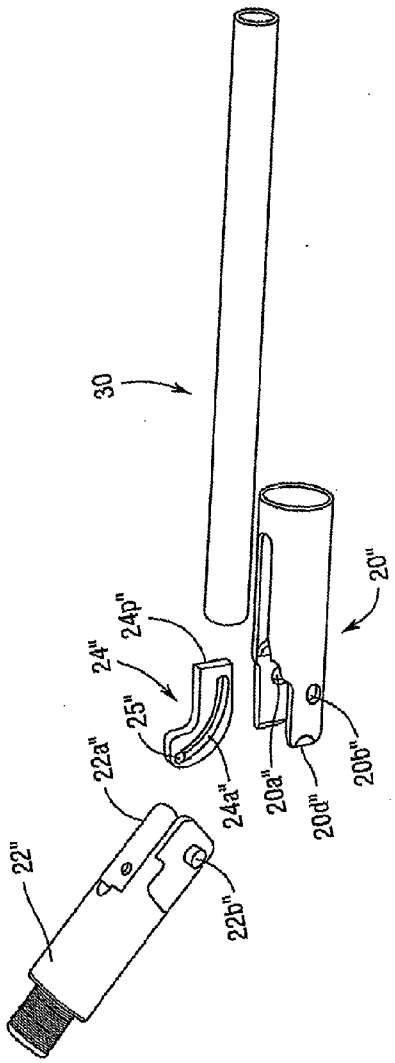

Fig.1G

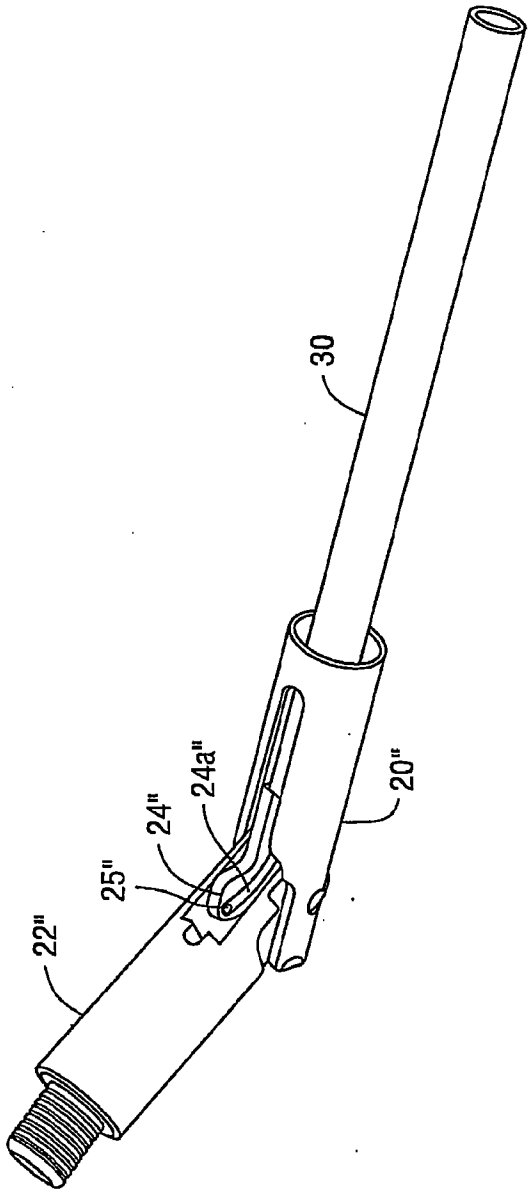

Fig.1H

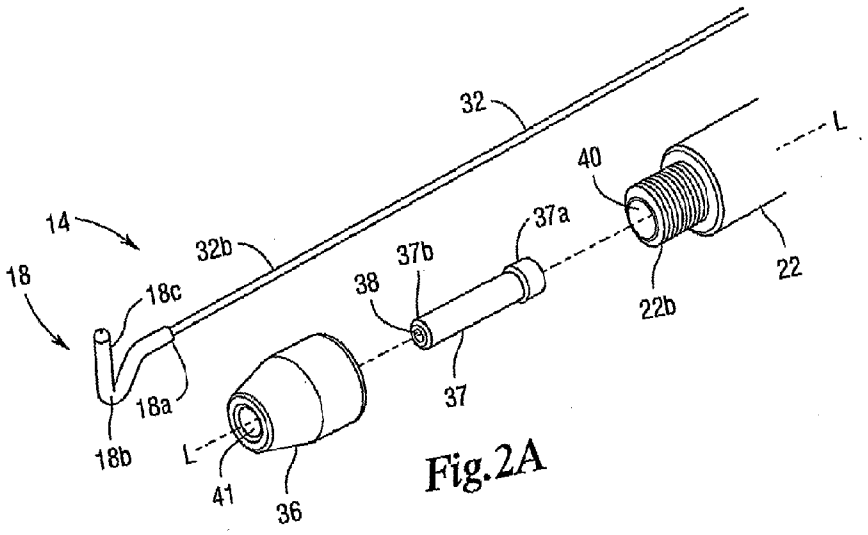
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Fig.2A

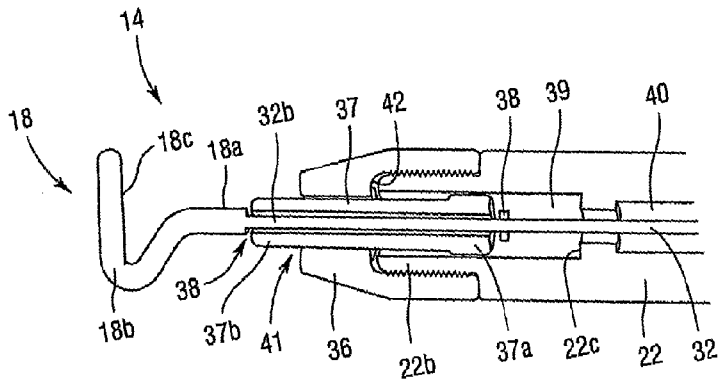
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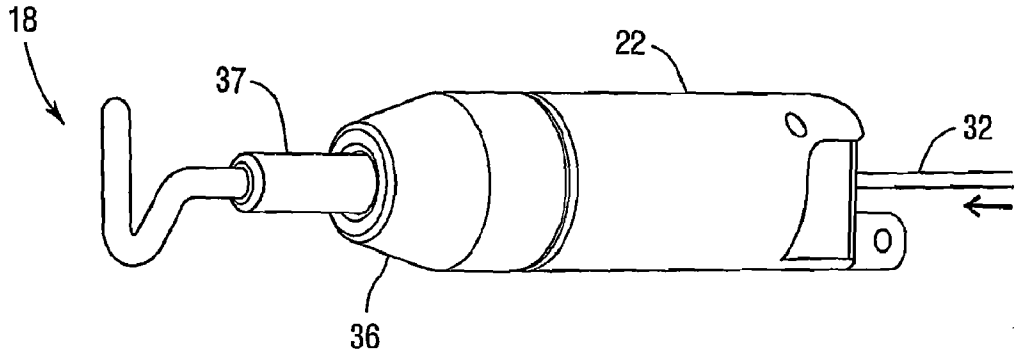
Fig.2B



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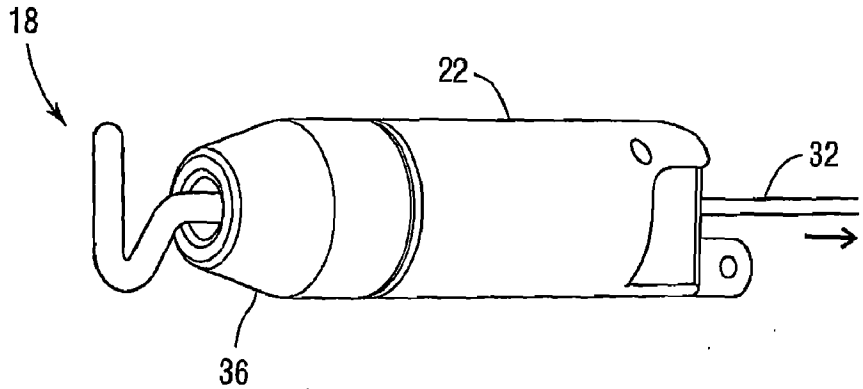

Fig.2D

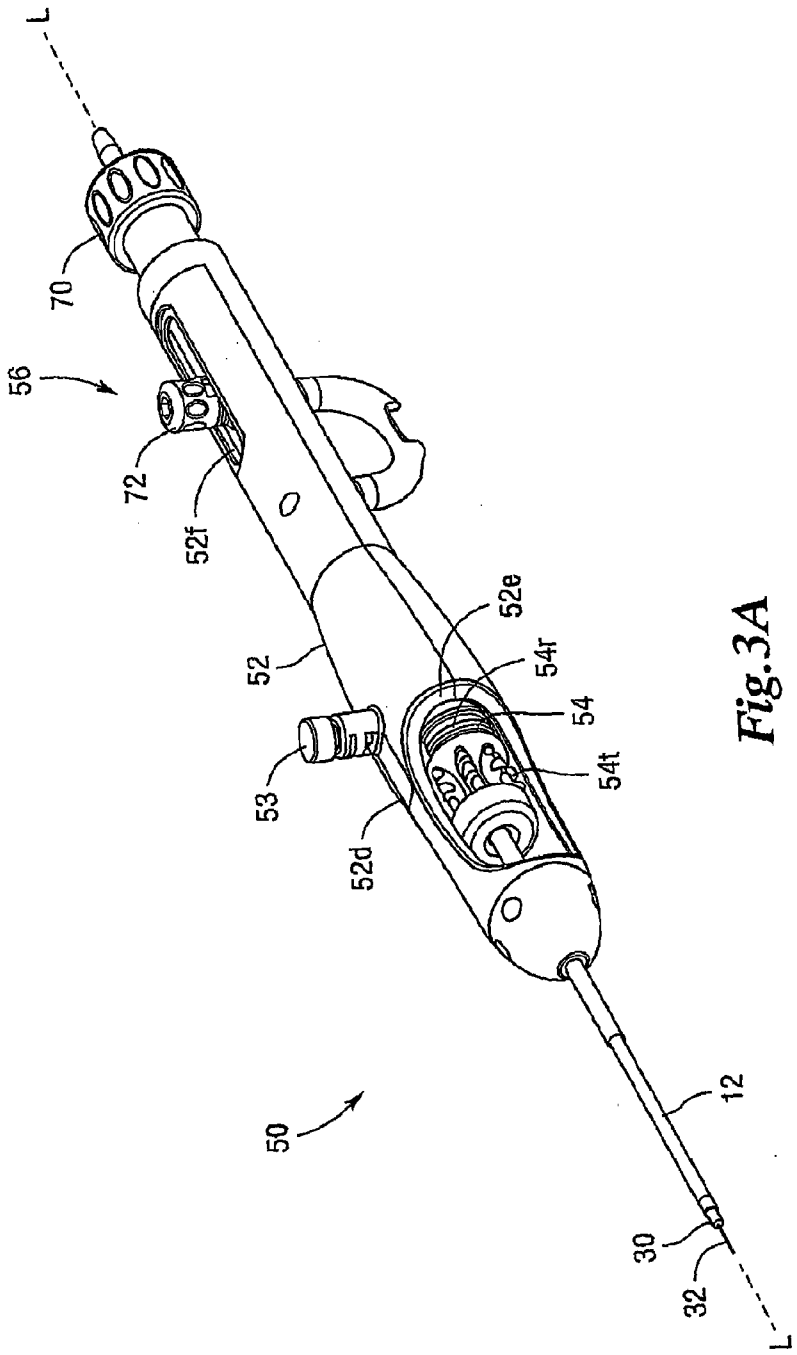

Fig.3A

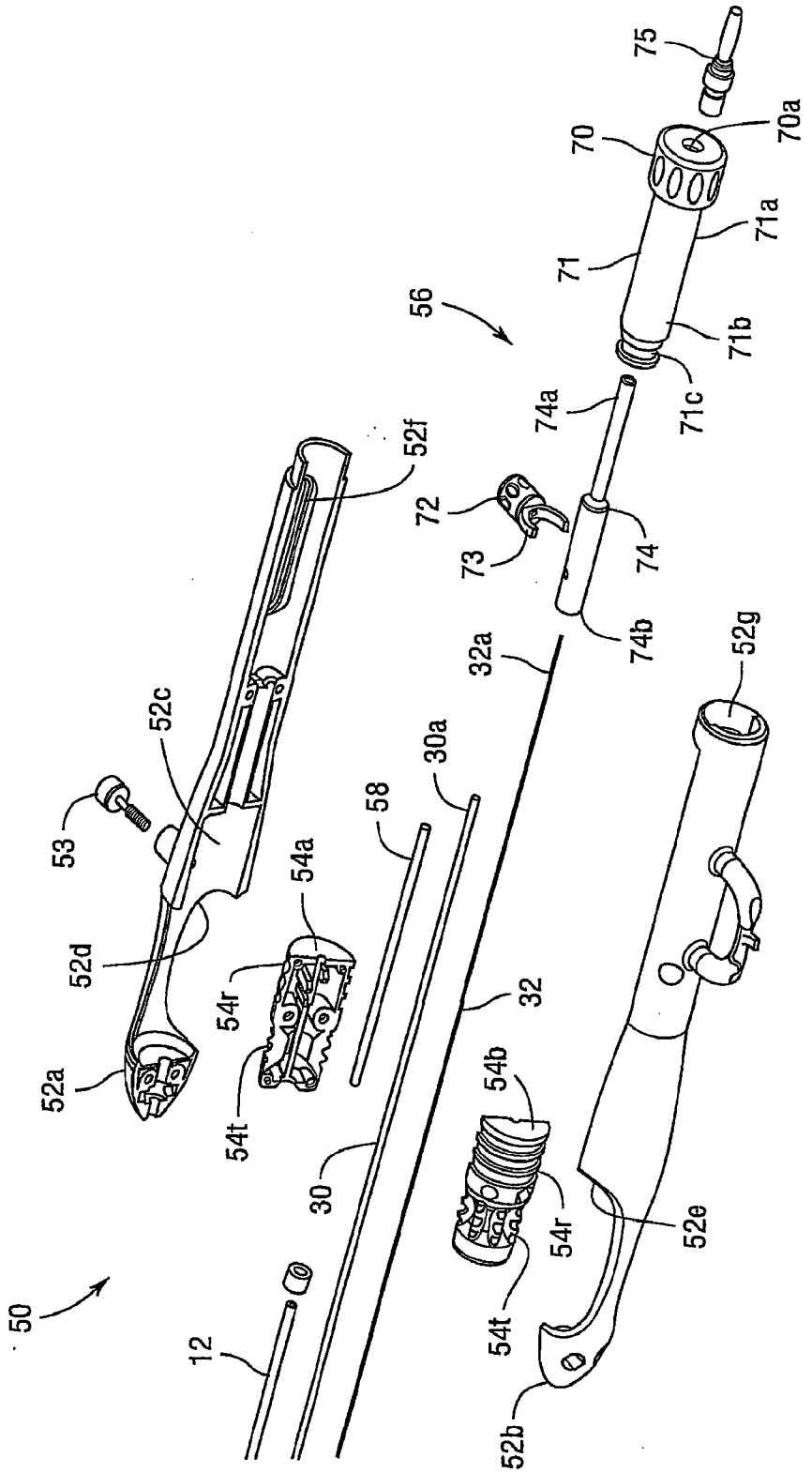
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Fig.3B

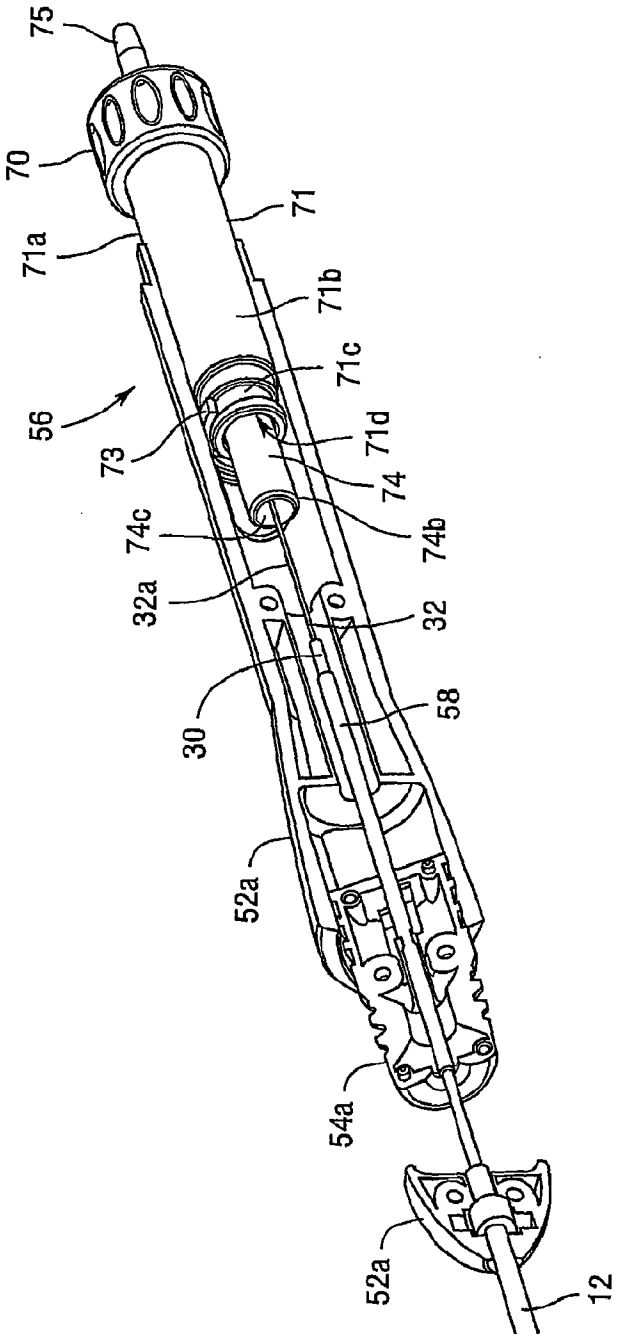
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Fig.3C

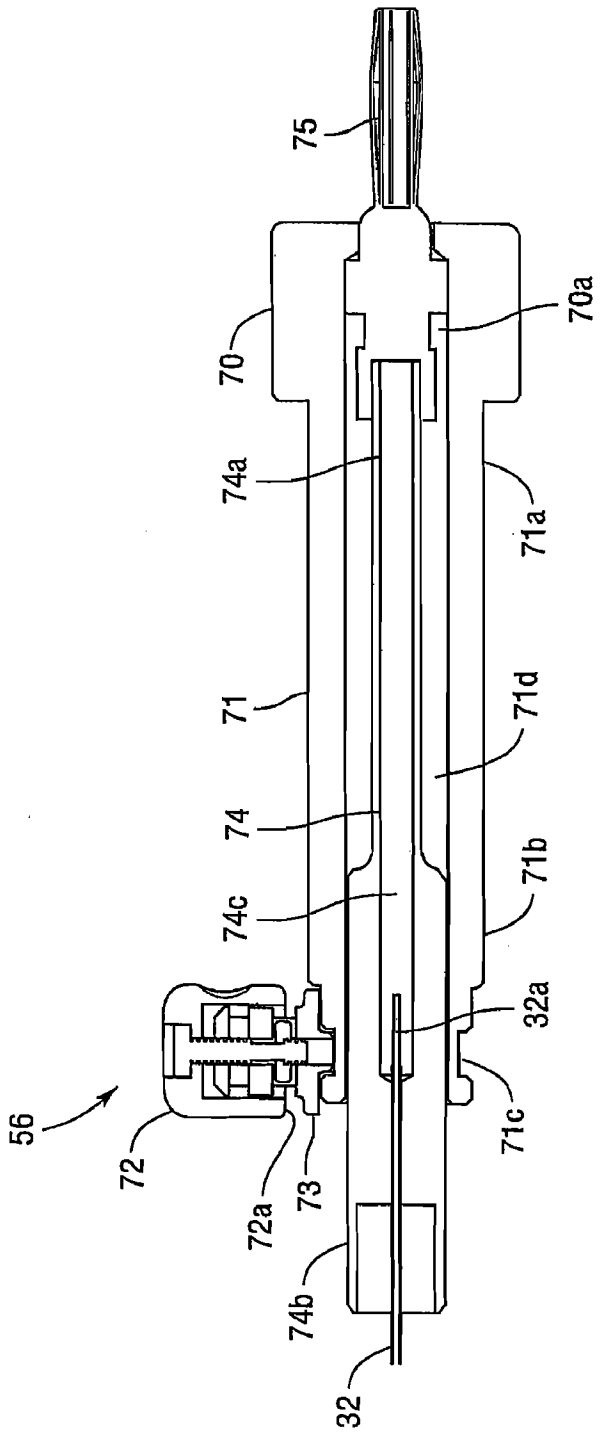

Fig.3D

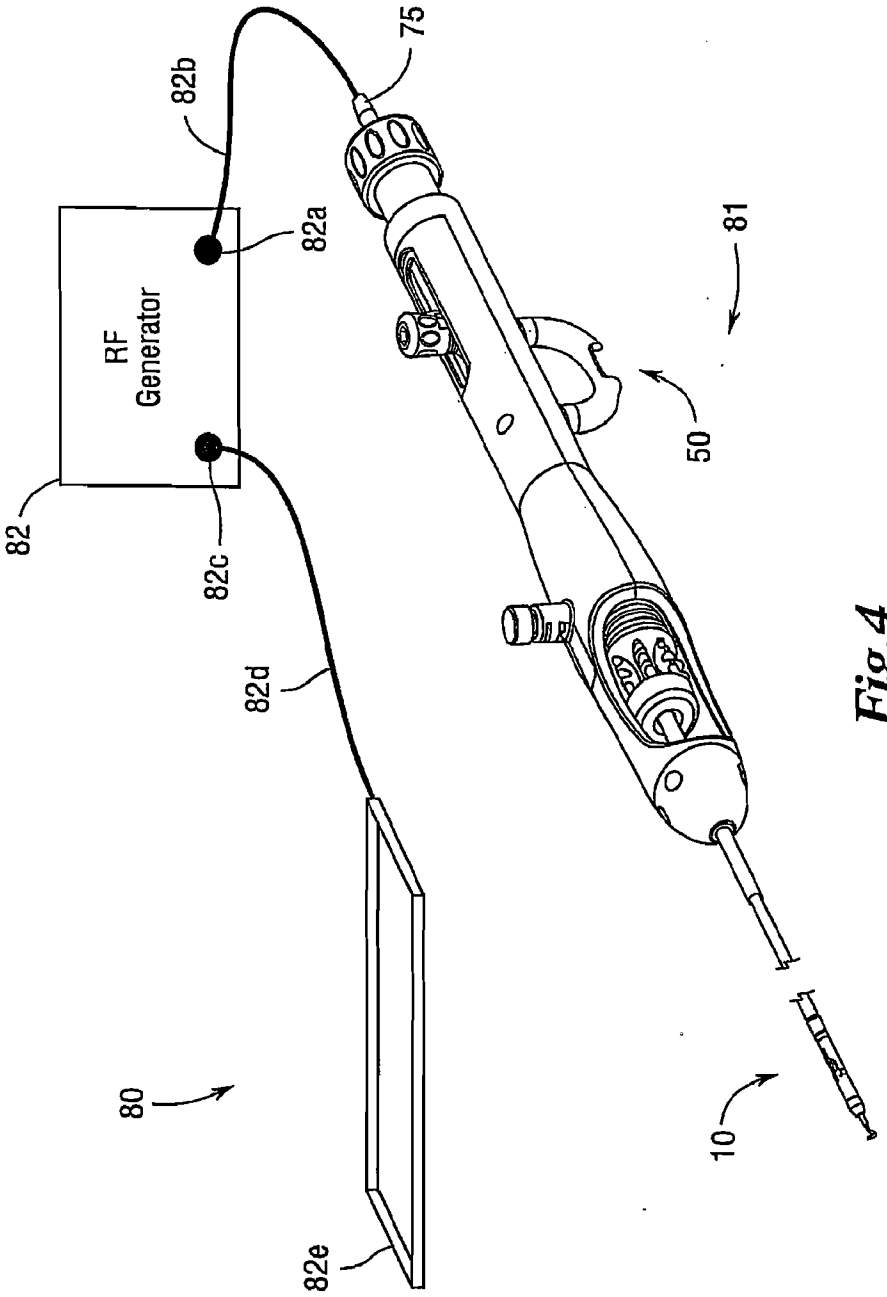

Fig.4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/046210

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/32 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 857 061 A (ETHICON ENDO SURGERY INC [US]) 21 November 2007 (2007-11-21) abstract; figures 1,2,8 paragraphs [0049], [0054]	1-15
Y	US 2008/015409 A1 (BARLOW DAVID E [US] ET AL) 17 January 2008 (2008-01-17) abstract; figures 1-6 paragraphs [0007], [0026], [0074]	1-15
A	DE 43 23 585 A1 (DELMA ELEKTRO MED APP [DE]) 19 January 1995 (1995-01-19) abstract; figures 1,3,8-8a,10-11a	1,2,4-13
A	US 2005/215996 A1 (OUCHI TERUO [JP]) 29 September 2005 (2005-09-29) abstract; figures 2,3,5,7 paragraphs [0007], [0013], [0046]	1-3

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 July 2009	24/07/2009

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

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/046210

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 491 691 B1 (MORLEY TRACEY A [US] ET AL) 10 December 2002 (2002-12-10) abstract; figures 3,5-7,12a-12c	1
P,A	WO 2008/076800 A (ETHICON ENDO SURGERY INC [US]; NOBIS RUDOLPH H [US]; NALAGATLA ANIL K) 26 June 2008 (2008-06-26) cited in the application abstract; figures 1b,1g,4a,4b paragraph [0062]	1-14
A	US 2005/143774 A1 (POLO OSCAR R [US]) 30 June 2005 (2005-06-30) abstract; claims 1,4-7; figure 1	4-12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/046210

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

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

1. [X] Claims Nos.: 16-21
because they relate to subject matter not required to be searched by this Authority, namely:

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

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

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

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

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

Remark on Protest

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

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

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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