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(54) **LAPAROSCOPIC DEVICES WITH FLEXIBLE ACTUATION MECHANISMS**

(52) **U.S. Cl. .... 606/205**

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(57) **ABSTRACT**

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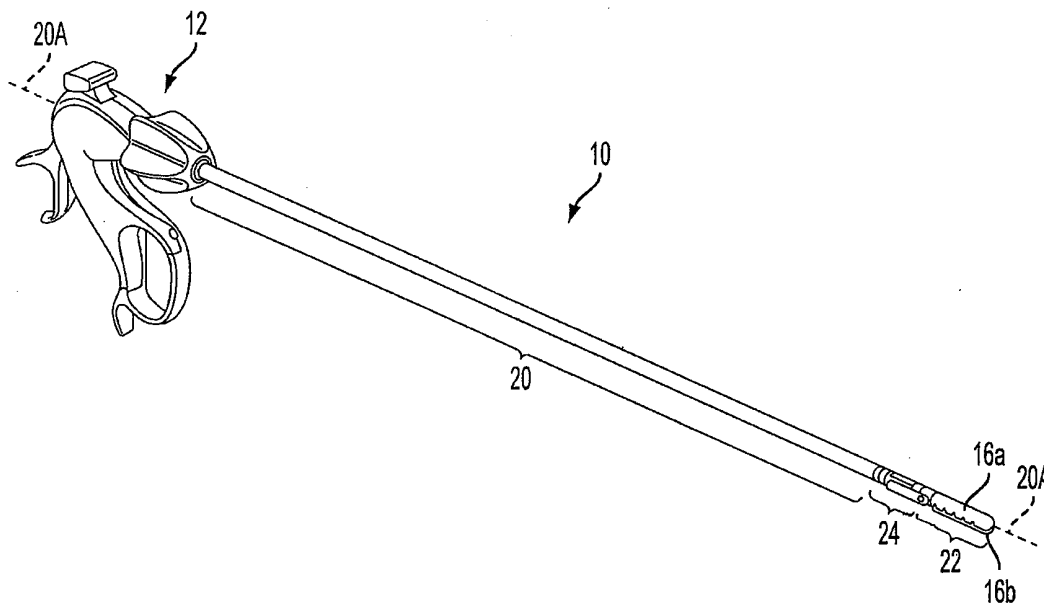
Methods and devices are provided for performing minimally invasive surgical procedures. In one embodiment, a surgical device is provided that includes an elongate shaft having an end effector at a distal end thereof. The end effector can be configured to be movable between a first configuration in which the end effector is longitudinally aligned with or linear relative to the shaft and a second configuration in which the end effector is articulated at an angle beyond 45 degrees relative to the shaft. With the end effector in the first configuration or in the second configuration, the device can be configured to allow selective actuation of the end effector.

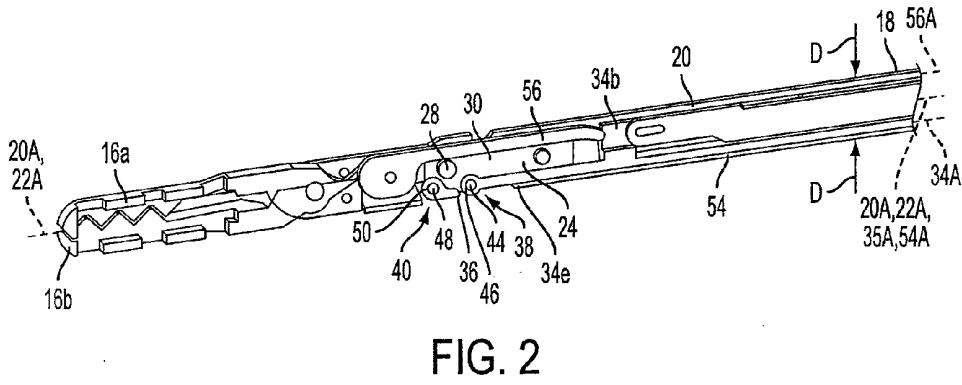
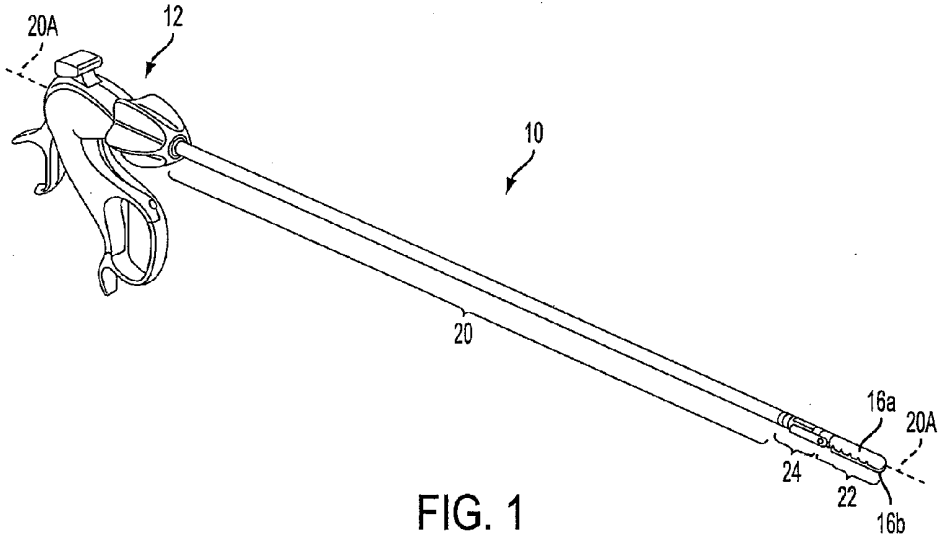
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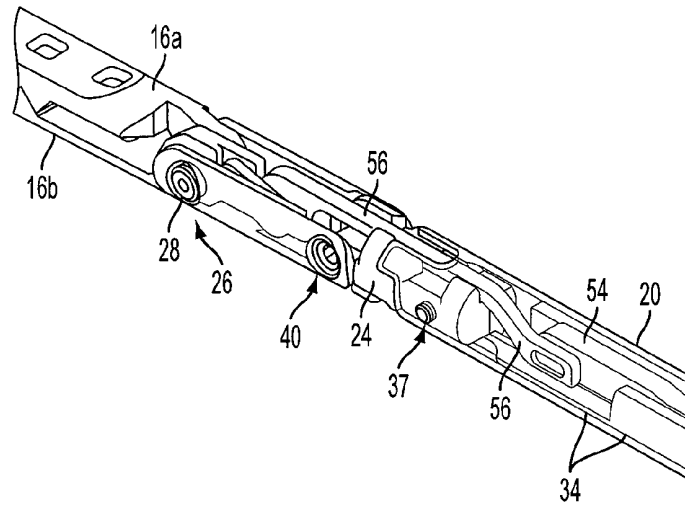


FIG. 3

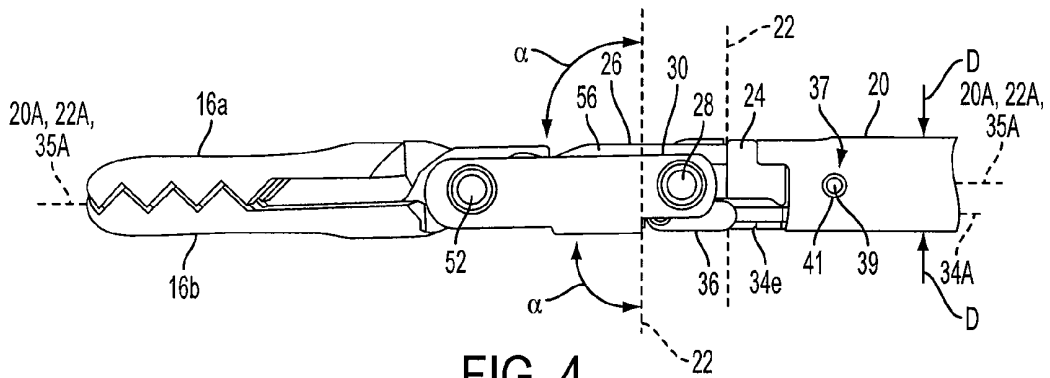


FIG. 4

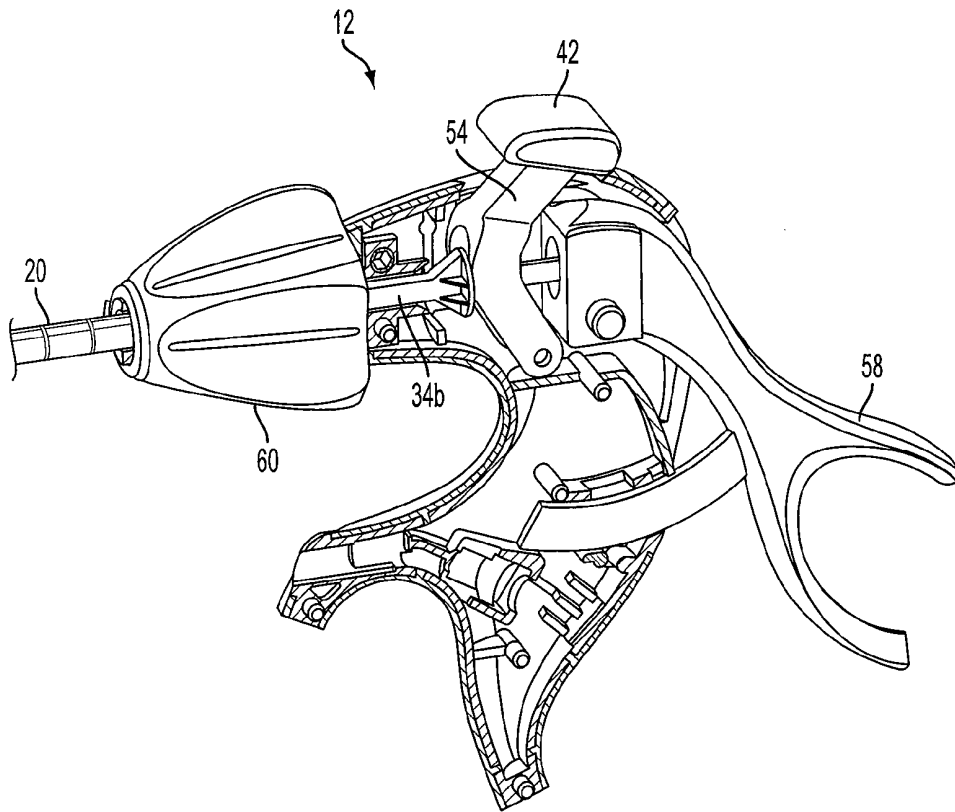


FIG. 5

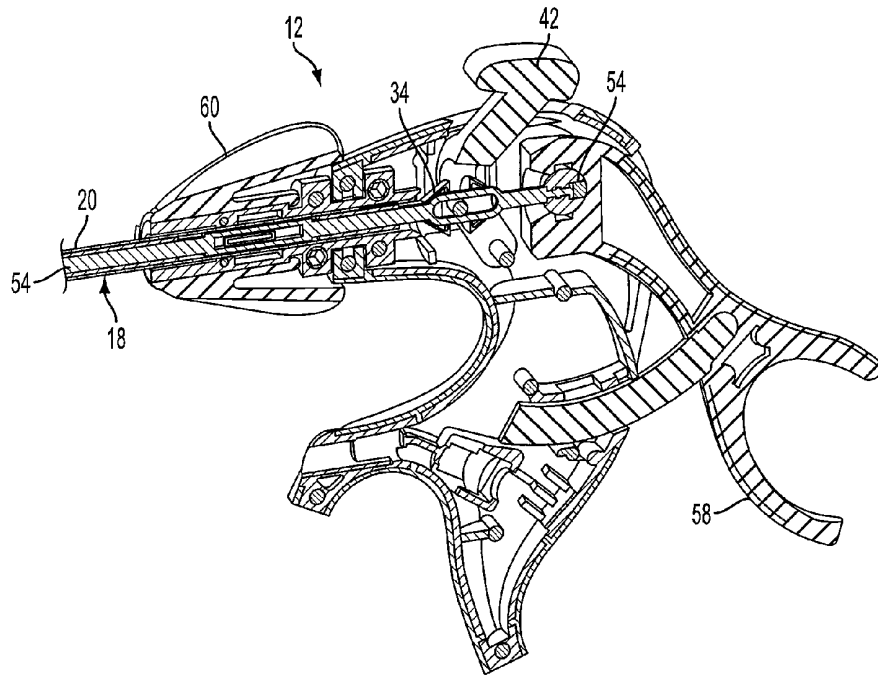


FIG. 6

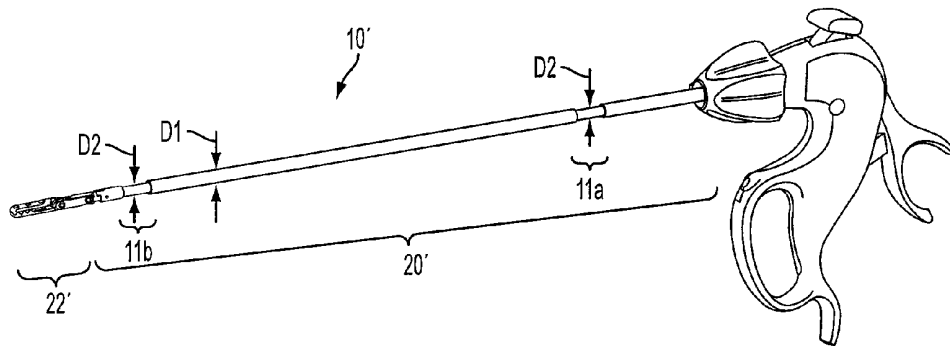


FIG. 7

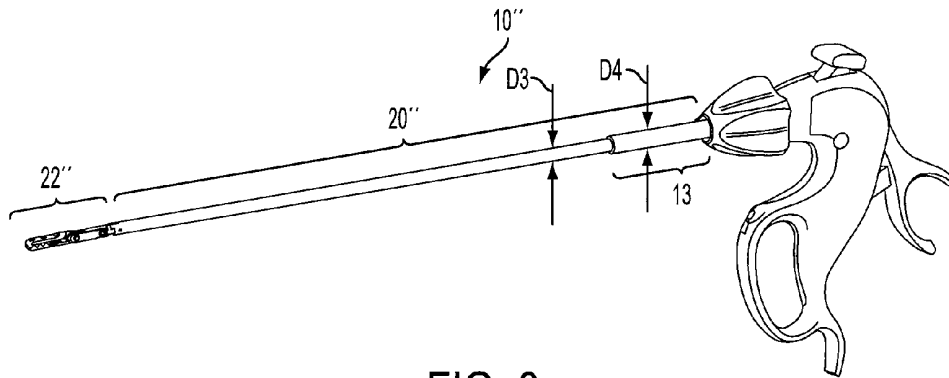


FIG. 8

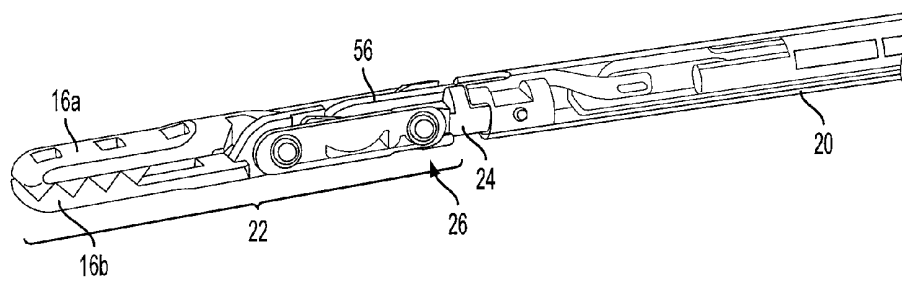


FIG. 9

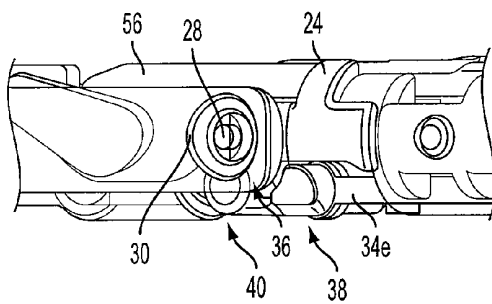


FIG. 10

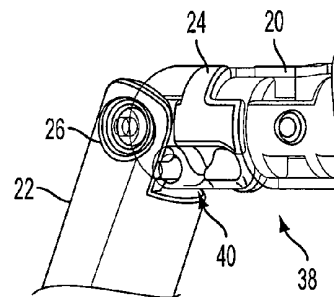


FIG. 11

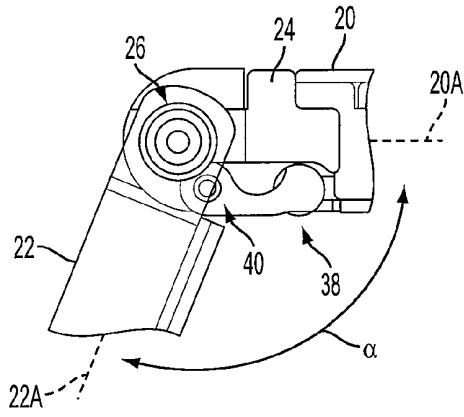


FIG. 12

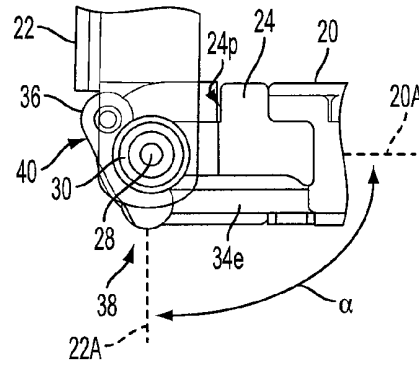


FIG. 13

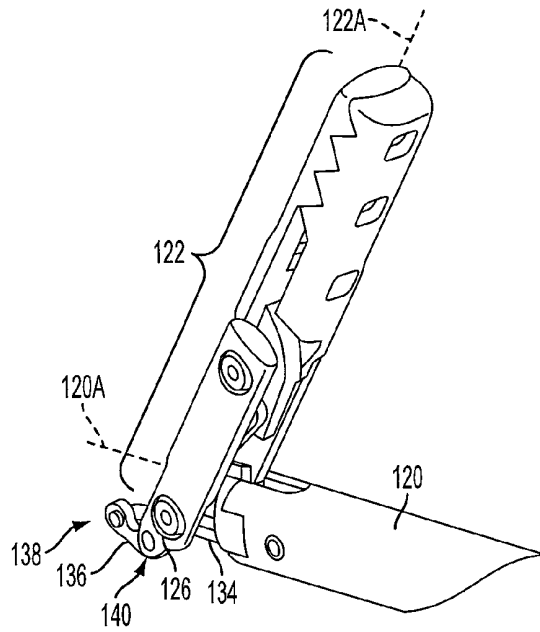


FIG. 14

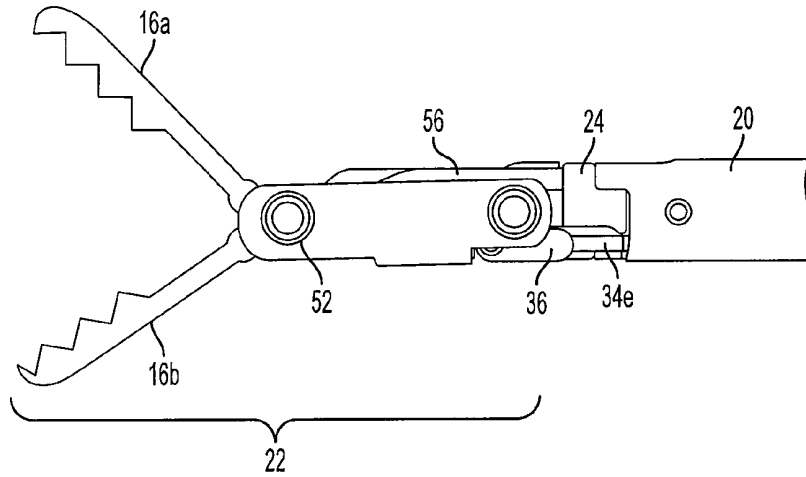


FIG. 15

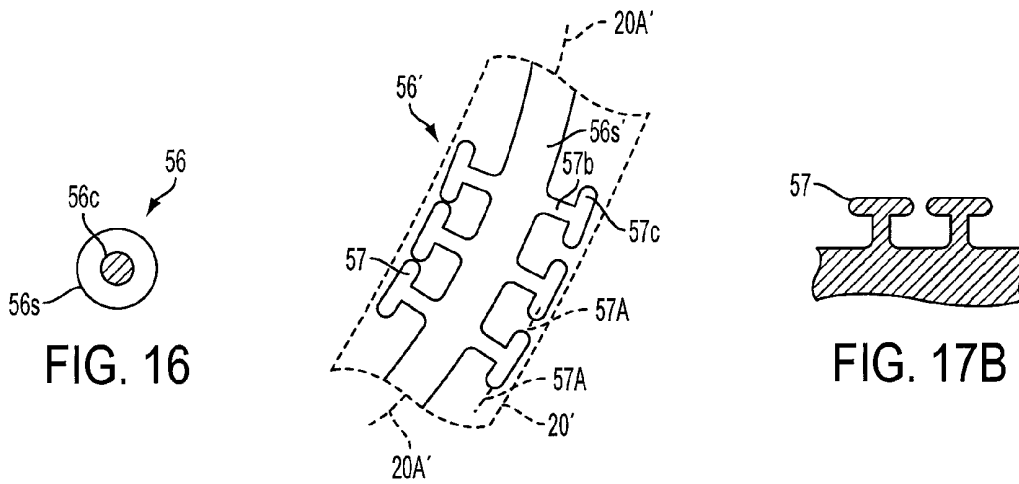


FIG. 16

FIG. 17A

FIG. 17B

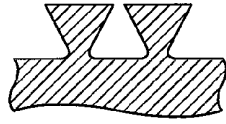


FIG. 17C



FIG. 17D

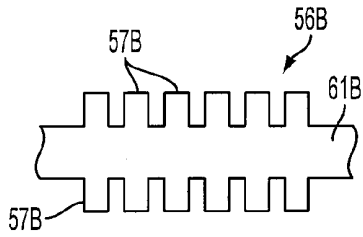


FIG. 17E

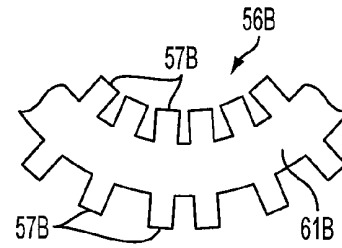


FIG. 17F

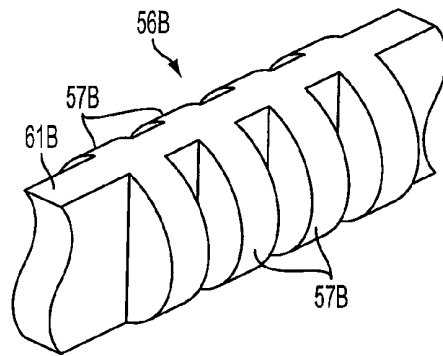


FIG. 17G

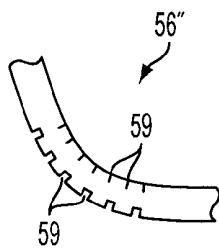


FIG. 18

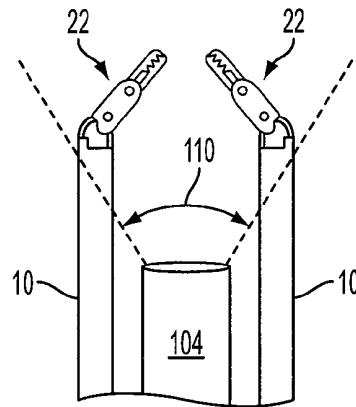


FIG. 20

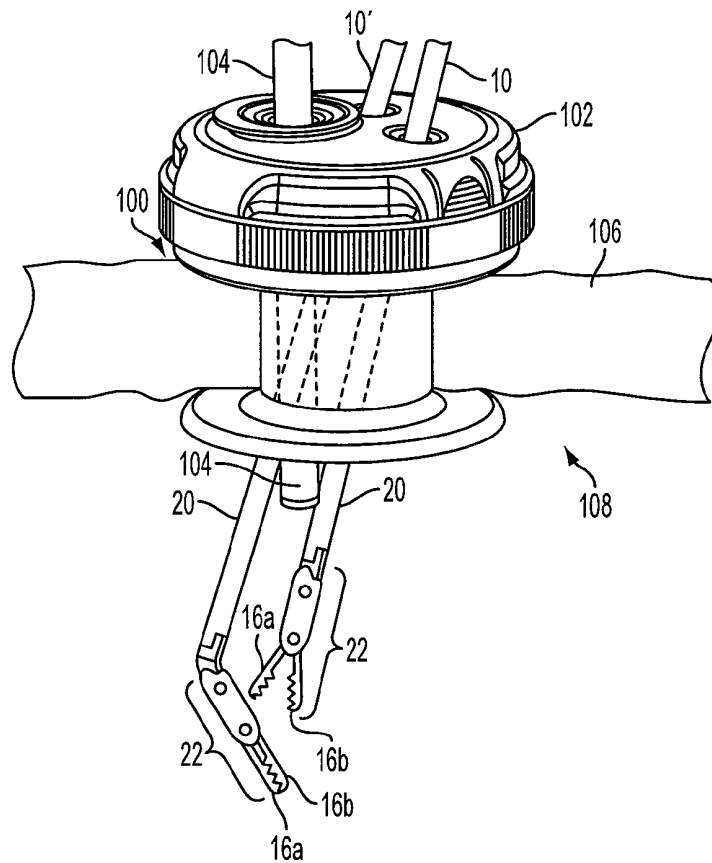


FIG. 19

## LAPAROSCOPIC DEVICES WITH FLEXIBLE ACTUATION MECHANISMS

### FIELD OF THE INVENTION

**[0001]** The present invention relates to methods and devices for performing minimally invasive surgical procedures.

### BACKGROUND OF THE INVENTION

**[0002]** Many surgical procedures involve inserting various instruments through the working channel of a surgical access device. The instruments are used to view, engage, and/or treat tissue within a body cavity or other surgical site to achieve a diagnostic or therapeutic effect. In laparoscopic abdominal procedures for example, the abdominal cavity is generally insufflated with CO<sub>2</sub> gas to a pressure of around 15 mm Hg. The abdominal wall is pierced and a plurality of tubular cannulas, each defining a working channel, are inserted at various points into the abdominal cavity. A laparoscopic telescope connected to an operating room monitor can be used to visualize the operative field and can be placed through one of the cannulas. Other laparoscopic instruments such as graspers, dissectors, scissors, retractors, etc. can be placed through the other cannula(s) to facilitate various manipulations by the surgeon. In this type of procedure, because of the positioning of the cannulas, it can be relatively easy to bring the tips of two separate surgical instruments together in a working relationship within the abdominal cavity. For example, a first instrument could be passed through a cannula in the left side of the patient's abdomen and operated with the surgeon's left hand while a second instrument could be passed through another cannula in the right side of the patient's abdomen and operated with the surgeon's right hand. The surgeon can then easily bring the tips of the two instruments together at an internal point, e.g., in the center of the patient's abdomen. A laparoscope viewing instrument can also be passed through a third cannula, positioned for example in the center of the patient's abdomen, such that the tips of the two instruments can be easily visualized from above.

**[0003]** In other surgical procedures, however, visualization and triangulation is not as straightforward. For example, in Single Incision Laparoscopic Surgery (SILS) or Single Site Laparoscopic Surgery (SSLs), a single laparoscopic entry point is formed, e.g., through the navel. An access device having one or more working channels, and typically a plurality of working channels, is then installed in the entry point and all instruments required for performing the surgery are inserted through this same access device. In such procedures, the elongate shafts of the various instruments end up being generally parallel to one another while inserted through the access device. This can make it very difficult to bring the tips of two instruments together within the abdominal cavity, especially if the instruments do not have distal articulation capabilities. In addition, since the viewing scope is inserted generally along the same axis as the various other instruments, it can be difficult or impossible to see the tips of the instruments. These problems can unduly lengthen the duration of the surgery, potentially increasing the risk of patient complications. Also, in cases where it is impossible to achieve adequate positioning of the instruments' tips and/or visualization, a second or even third entry point must be formed, increasing trauma to the patient and creating additional scars.

**[0004]** Furthermore, when a surgical instrument inserted in any way into the body, it can be difficult to optimally position the instrument's tip relative to target tissue at the surgical site. Particularly when an instrument is inserted from above a surgical site, e.g., through the abdominal wall, there are limited angles of approach to target tissue at the surgical site, which can make effective and quick use of the instrument difficult. Attempting to position an instrument's distal tip at an optimal position relative to a target tissue can require the surgeon's hand to be awkwardly positioned to hold the instrument at a desired angle to optimally position the instrument's distal tip. It can also be difficult for a surgeon to operate the instrument's tip, e.g., grab tissue using graspers, cut tissue using scissors, etc., when the surgeon's hand is bent at an awkward angle.

**[0005]** Moreover, if an instrument has distal articulation abilities, it can be difficult to effectively operate the instrument's tip when the instrument is distally articulated. Providing an adequate force around a bend in the distal articulated area to operate the tip can be difficult, e.g., because of size limitations of the instrument and remote operation of the tip from the instrument's handle.

**[0006]** Accordingly, there is a need for methods and devices which allow laparoscopic procedures to be performed with an enhanced ability to position and visualize surgical instruments.

### SUMMARY OF THE INVENTION

**[0007]** The present invention generally provides methods and devices for performing minimally invasive surgical procedures. In one embodiment, an articulating laparoscopic device is provided that includes a cannulated elongate shaft having proximal and distal ends defining a longitudinal axis extending therebetween, an end effector coupled to the distal end of the shaft, and an articulator element effective to angularly orient the end effector beyond 45 degrees relative to the longitudinal axis of the shaft. The articulator element includes first and second rigid links. The first rigid link extends through the shaft and is movable longitudinally along a first link axis parallel to the longitudinal axis of the shaft. The second rigid link has a proximal end pivotally coupled to a distal end of the first rigid link, and has a distal end pivotally coupled to a proximal end of the end effector. Pushing the first rigid link distally along the first link axis causes the end effector to move from a first position in which the end effector is longitudinally aligned with the longitudinal axis of the shaft to a second position in which the end effector is angularly oriented relative to the longitudinal axis of the shaft.

**[0008]** The end effector can have a variety of configurations. The end effector can include, for example, graspers having opposed jaws movable between a closed position and an open position. In one embodiment, the end effector can be configured to articulate beyond 90 degrees relative to the longitudinal axis of the shaft. The second rigid link can be configured to pivot beyond 90 degrees relative to the longitudinal axis of the shaft to articulate the end effector beyond 90 degrees relative to the longitudinal axis of the shaft. In another embodiment, the end effector can be configured to articulate beyond 45 degrees relative to the longitudinal axis of the shaft in both clockwise and counterclockwise directions from the first position.

**[0009]** The first and second links can have also have a variety of configurations. For example, the first rigid link can be configured to move proximally along the first link axis to

cause articulation of the end effector. For another example, pulling the first rigid link proximally along the first link axis can cause the end effector to move from the second position to the first position.

**[0010]** The device can optionally include a coupler coupling the end effector to the shaft and/or a stop element configured to limit articulation of the end effector to about 90 degrees relative to the longitudinal axis of the shaft. The coupler can alternatively or in addition be configured to limit articulation of the end effector to about 90 degrees relative to the longitudinal axis of the shaft.

**[0011]** In another embodiment, an articulating laparoscopic device is provided that includes a cannulated rigid elongate shaft having proximal and distal ends defining a longitudinal axis extending therebetween, an end effector coupled to the distal end of the shaft, and a rigid articulator element extending through the shaft. The articulator element is configured to move relative to the shaft to articulate the end effector about a pivot point at an articulation angle beyond 90 degrees relative to the longitudinal axis of the shaft.

**[0012]** The articulator element can vary in any number of ways. In one embodiment, the articulator element can be configured to articulate the end effector from a first position in which the end effector is longitudinally aligned with the shaft such that the articulation angle is about zero degrees to a second position in which the articulation angle is at least about 120 degrees. In another embodiment, the articulator element can include first and second rigid links. The first rigid link can extend through the shaft and can be configured to move longitudinally relative to the longitudinal axis of the shaft. The second rigid link can be coupled to a distal end of the first rigid link and can be configured to pivot in response to longitudinal movement of the first rigid link relative to the longitudinal axis of the shaft to cause articulation of the end effector. The end effector can be longitudinally aligned with the shaft such that the articulation angle is about zero degrees. Pushing the first rigid link distally can increase the articulation angle, or, in another embodiment, pulling the first rigid link proximally can increase the articulation angle.

**[0013]** The end effector, e.g., at least one of graspers, a dissector, a retractor, a light, a biopsy probe, a snare loop, forceps, scissors, a needle knife, and a sphincterotome, can also vary in any number of ways. For example, the end effector can be configured to articulate at least 45 degrees relative to the longitudinal axis of the shaft in both clockwise and counterclockwise directions from a position in which the end effector is longitudinally aligned with the longitudinal axis of the shaft. The end effector can be configured to articulate beyond 90 degrees relative to the longitudinal axis of the shaft in one of the clockwise and counterclockwise directions and to articulate no greater than 90 degrees relative to the longitudinal axis of the shaft in the other of the clockwise and counterclockwise directions.

**[0014]** In another aspect, a laparoscopic device is provided that includes an elongate shaft having proximal and distal ends defining a longitudinal axis extending therebetween, an end effector coupled to the distal end of the shaft, and an actuator element coupled to the end effector. The shaft has an inner lumen extending therethrough between the proximal and distal ends. The actuator element extends between the proximal and distal ends of the shaft along the longitudinal axis through the inner lumen, and the actuator element is configured to move relative to the shaft to actuate the end

effector. The actuator element has at least a distal portion formed of a composite material.

**[0015]** The actuator element can have a variety of configurations. Rotation of the actuator element can be effective to move the opposed movable jaws of the end effector between open and closed positions. In one embodiment, the distal portion of the actuator element can be flexible, and a proximal portion of the actuator element can be rigid. The distal portion can include a core formed of a first material and an outer sheath surrounding the core. The outer sheath can be formed of a second material, e.g., a plastic, having a greater flexibility than a flexibility of the first material, e.g., a metal. In another embodiment, the distal portion can have a stiffness configured to change during actuation of the end effector.

**[0016]** The end effector can also have a variety of configurations. For example, the end effector can be configured to articulate up to an angle of at least 90 degrees relative to the longitudinal axis of the shaft.

**[0017]** The laparoscopic device can include an articulator element coupled to the end effector and extending through the inner lumen of the shaft between the proximal and distal ends of the shaft. The articulator element can be configured to articulate the end effector to angularly orient the end effector relative to the longitudinal axis of the shaft. The articulator element can extend through the inner lumen on one side of the inner lumen, and the actuator element can extend through the inner lumen on an opposite side of the inner lumen.

**[0018]** In another embodiment, a laparoscopic device is provided that includes a cannulated elongate shaft having proximal and distal ends defining a longitudinal axis extending therebetween, an end effector coupled to the distal end of the shaft, and an actuator element coupled to the end effector and extending through the shaft. The actuator element is configured to move relative to the shaft to actuate the end effector, and the actuator element includes a feature configured to change a stiffness of the actuator element when the actuator element moves to actuate the end effector.

**[0019]** The actuator element can vary in any number of ways. For example, the actuator element can be formed of a composite material. For another example, the actuator element can include a rigid proximal portion and a flexible distal portion. The flexible distal portion can include the feature, which can include an outer sheath surrounding a central core. The core is formed of, e.g., a metal, and the outer sheath can be formed of, e.g., a plastic. The outer sheath can optionally include a plurality of ribs extending radially outward from the core. The ribs can be configured to compress together to increase the stiffness of the actuator element when the actuator element moves to actuate the end effector. For yet another example, the actuator element can include a rigid actuator member extending through the shaft, and a flexible actuator member formed of a composite material. The flexible actuator member can have a proximal end coupled to a distal end of the rigid actuator member, and have a distal end coupled to the end effector. The rigid actuator member can be configured to translate longitudinally through the shaft to move the flexible actuator member relative to the shaft and to change the stiffness of the flexible actuator member to actuate the end effector.

**[0020]** The laparoscopic device can include an articulator element extending through the shaft along the longitudinal axis. The articulator element can be configured to articulate the end effector at an angle relative to the longitudinal axis of the shaft. The articulator element can extend through the shaft

along one side thereof, and the actuator element can extend through the shaft along an opposite side thereof.

[0021] In another aspect, a laparoscopic surgical method is provided that includes inserting a cannulated elongate shaft of a surgical device into a body of a patient to position an end effector at a distal end of the shaft within the body. The device includes an actuator element extending through the shaft, and the actuator element is formed of a composite material in at least a flexible distal portion thereof. The method also includes translating the actuator element relative to the shaft to change a shape of at least the flexible distal portion to actuate the end effector.

[0022] The method can vary in any number of ways. In one embodiment, changing the shape of at least the flexible distal portion can include compressing together ribs extending radially outward from a central core of the flexible distal portion.

[0023] In another embodiment, a laparoscopic surgical method is provided that includes inserting a rigid elongate shaft of a surgical device into a body of a patient to position an end effector at a distal end of the shaft within the body, and translating a rigid articulator element extending through an inner lumen of the shaft along an axis parallel to a longitudinal axis of the shaft to articulate the end effector about a pivot point beyond 90 degrees relative to the longitudinal axis of the shaft.

[0024] The method can have any number of variations. In one embodiment, translating a rigid articulator element can include pushing the articulator element distally along the axis parallel to the longitudinal axis of the shaft.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

[0026] FIG. 1 is a perspective view of a laparoscopic device including a handle and a shaft extending distally from the handle, the shaft having an articulatable end effector coupled to a distal end thereof;

[0027] FIG. 2 is a cross-sectional perspective view of a distal portion of the device of FIG. 1;

[0028] FIG. 3 is a perspective, partially transparent view of a distal portion of the device of FIG. 1;

[0029] FIG. 4 is a side view of a distal portion of the device of FIG. 1;

[0030] FIG. 5 is a perspective view of a proximal portion of the device of FIG. 1, with a housing removed from a handle of the device;

[0031] FIG. 6 is a cross-sectional perspective view of a proximal portion of the device of FIG. 1;

[0032] FIG. 7 is a perspective view of another embodiment of a laparoscopic device including a handle and a shaft extending distally from the handle, the shaft having an articulatable end effector coupled to a distal end thereof;

[0033] FIG. 8 is a perspective view of yet another embodiment of a laparoscopic device including a handle and a shaft extending distally from the handle, the shaft having an articulatable end effector coupled to a distal end thereof;

[0034] FIG. 9 is another perspective, partially transparent view of a distal portion of the device of FIG. 1;

[0035] FIG. 10 is a perspective, partially transparent view of a distal portion of the device of FIG. 1;

[0036] FIG. 11 is a perspective, partially transparent view of a distal portion of the device of FIG. 1 showing the end effector in an articulated configuration;

[0037] FIG. 12 is a side, partially transparent view of the distal portion of the device of FIG. 11;

[0038] FIG. 13 is a side, partially transparent view of a distal portion of the device of FIG. 1 showing the end effector in an articulated configuration;

[0039] FIG. 14 is a perspective view of a distal portion of another embodiment of a laparoscopic device including a shaft having an articulatable end effector coupled to a distal end thereof, the end effector being shown in an articulated configuration;

[0040] FIG. 15 is a side view of the distal portion of the device of FIG. 4 showing the end effector with its jaws in an open position;

[0041] FIG. 16 is a cross-sectional view of an actuator element of the device of FIG. 1;

[0042] FIG. 17A is a top view of another embodiment of an actuator element having a plurality of T-shaped ribs showing the actuator element in a bent configuration;

[0043] FIG. 17B is side, partial view of the actuator element of FIG. 17A showing the actuator element in a bent configuration;

[0044] FIG. 17C is a side partial view of another embodiment of an actuator element having a plurality of triangular-shaped ribs;

[0045] FIG. 17D is a side partial view of another embodiment of an actuator element having a plurality of truncated V-shaped ribs;

[0046] FIG. 17E is a top view of another embodiment of an actuator element having a plurality of semicircular ribs showing the actuator element in an unbent configuration;

[0047] FIG. 17F is a top view of the actuator element of FIG. 17E showing the actuator element in a bent configuration;

[0048] FIG. 17G is a perspective view of the actuator element of FIG. 17E;

[0049] FIG. 18 is a top view of another embodiment of an actuator element having a plurality of slits;

[0050] FIG. 19 is a perspective, partially cross-sectional view of a surgical access device positioned within a tissue opening and having first and second laparoscopic devices and a scoping device inserted therethrough and positioned within a body cavity, the first laparoscopic device having an end effector in an articulated configuration, and the second laparoscopic device having an end effector in a straight configuration; and

[0051] FIG. 20 is a side view of distal portions of the laparoscopic devices and the scoping device of FIG. 19 positioned in the body cavity, the end effectors each being in an articulated configuration.

#### DETAILED DESCRIPTION OF THE INVENTION

[0052] 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 skilled 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 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 invention.

**[0053]** Various exemplary devices and methods are provided for performing minimally invasive surgical procedures. In general, the devices and methods allow a working end of a surgical instrument to articulate at an angle beyond 45 degrees, thereby facilitating optimal positioning of the working end relative to a surgical site and to any nearby surgical instruments. In an exemplary embodiment, a laparoscopic device includes an elongate shaft having an end effector at a distal end thereof. The end effector can be configured to be movable between a first configuration in which the end effector is longitudinally aligned with or linear relative to the shaft and a second configuration in which the end effector is articulated at an angle beyond 45 degrees relative to the shaft. With the end effector in the first configuration or in the second configuration, the device can be configured to allow selective actuation of the end effector, e.g., opening and/or closing of jaws, application of energy such as for cutting or for cauterization, extension of a needle, collection of a biopsy sample, etc. In this way, the end effector can achieve a relatively high degree of articulation, e.g., beyond 45 degrees, while still being functionally effective. The device can thus be inserted into a patient's body with the end effector in the first configuration, and the device can be subsequently manipulated to move the end effector from the first configuration to the second configuration to allow the device's working distal end, e.g., the end effector, to be optimally angled within the body relative to a surgical site and/or to any other nearby surgical instruments. By being articulatable beyond 45 degrees, an instrument can be inserted substantially above a surgical site, e.g., inserted into the abdominal cavity through the navel, while being configured to approach the surgical site and/or other instruments at a variety of angles and while being selectively actuatable at any articulated position. Such an instrument configuration can also be particularly advantageous where two or more instruments are inserted into a patient's body cavity through the same entry port in tissue because it can allow the instruments' working ends to each angle beyond 45 degrees to be brought together without requiring awkward surgeon positioning. In particular, distal tips of the instruments can be brought together at a single point within the body cavity, even though the instruments' shafts extend generally parallel to one another.

**[0054]** A person skilled in the art will appreciate that while the methods and devices are described in connection with laparoscopic procedures in which one or more surgical instruments are inserted into a patient's body through an artificial opening, e.g., an incision, the methods and devices disclosed herein can be used in numerous surgical procedures and with numerous surgical instruments. By way of non-limiting example, the methods and devices can be used in open surgical procedures.

**[0055]** A person skilled in the art will also appreciate that the devices disclosed herein can be inserted into a body in any way, such as through a natural orifice, through an incision or puncture hole formed in tissue, etc. The devices can be inserted directly into a patient's body or can be inserted through an access device having a working channel through which a shaft of a surgical instrument can be advanced. A person skilled in the art will further appreciate that an access device can be configured to allow insertion of a single surgical instrument therethrough, such as with a straight cannula, or to allow simultaneous insertion of multiple instruments there-

through, such as with a surgical access device having multiple sealing ports each defining a working channel. Devices disclosed herein can alternatively or additionally be introduced into a body through an auxiliary passageway along the outside of a scoping device or other surgical instrument, as will be appreciated by a person skilled in the art. Exemplary embodiments of a surgical instrument that provides such an auxiliary passageway are described in more detail in U.S. Pat. No. 7,615,005 issued Nov. 10, 2009 entitled "Medical Apparatus For Use With An Endoscope," which is hereby incorporated by reference in its entirety.

**[0056]** In an exemplary embodiment, shown in FIG. 1, a surgical device 10 is provided that includes a proximal handle 12 having an elongated tubular shaft 20 extending distally therefrom. The shaft 20 can have a working element or end effector 22, generally referred to as an "end effector," at a distal end thereof. A rigid coupler 24 can optionally couple the end effector 22 to the shaft 20, with a proximal end of the coupler 24 being coupled to a distal end of the shaft 20 and a distal end of the coupler 24 being coupled to a proximal end of the end effector 22. The end effector 22 in the illustrated embodiment includes a tissue grasper having a pair of opposed jaws 16a, 16b configured to move between open and closed positions, but as will be appreciated by a person skilled in the art, the end effector 22 can include any tool, e.g., a grasper, a dissector, scissors, forceps, a retractor, a light, a biopsy probe, a snare loop, a needle knife, a sphincterotome, etc. As discussed further below, the handle 12 can be configured to operate the end effector 22 and/or to rotate the shaft 20.

**[0057]** The shaft 20 can have a variety of sizes, shapes, and configurations. The shaft 20 can be rigid, flexible, or a combination thereof, but in an exemplary embodiment it is rigid, e.g., made from a generally non-bendable material such as a hard polymer or titanium. Portions of the shaft 20 can be less flexible or more rigid than a remainder of the shaft 20 to facilitate insertion through tissue. As mentioned above, the shaft 20 can be tubular, and it can have an inner lumen 18 extending through at least a proximal portion thereof, as shown in FIGS. 2 and 3. As discussed further below, an articulator element and an actuator element can each be at least partially positioned within the inner lumen 18. Generally, the articulator element can be configured to move relative to the shaft 20 to angularly orient the end effector 22 relative to a longitudinal axis 20A of the shaft 20, and the actuator element can be configured to move relative to the shaft 20 to actuate the end effector 22, e.g., to open and close the jaws 16a, 16b.

**[0058]** The shaft 20 can have any longitudinal length, although in an exemplary embodiment it is long enough to allow the handle 12 to be manipulated outside a patient's body when the shaft 20 extends through an opening in the body with the end effector 22 disposed within a body cavity, e.g., have a longitudinal length of about 33 cm. In this way, the end effector 22 can be easily manipulated when the device 10 is in use during a surgical procedure. As illustrated in FIGS. 2 and 4, the shaft 20 can have any diameter D, e.g., less than or equal to about 10 mm, and more particularly less than or equal to about 5 mm, to allow for insertion of the shaft 20 through an access device, such as during a laparoscopic surgical procedure. The end effector 22 mated to the shaft's distal end, and in one embodiment can have a diameter equal to or less than the shaft's diameter D, at least when the jaws 16a, 16b are in

a closed position, to further facilitate insertion of the device's distal portion into a patient's body.

**[0059]** As shown in FIGS. 5 and 6, a proximal portion of the shaft 20 can be disposed within the handle 12 with a remainder of the shaft 20 extending distally from the handle 12. As shown in FIGS. 1, 5, and 6, the shaft 20 can extend distally from the handle 12 in a generally straight line along a longitudinal axis 20A. In other exemplary embodiments, the shaft 20 can have a bend or curvature near its proximal end. Such a bend or curvature can be helpful in preventing handles of two instruments from interfering with the other in a so-called "chopstick" effect when two or more instruments are inserted in closely-spaced instrument openings or closely spaced trocars. As will be appreciated by a person skilled in the art, a bend or curvature in the proximal portion of the shaft 20 can be fixed, or alternatively, it can be movable, such as in the form of a flexible "elbow" that can be adjusted, such as manually, at the point of use.

**[0060]** In an exemplary embodiment, the shaft 20 can be substantially cylindrical to help the shaft 20 pass smoothly into a body. The shaft 20 can have any constant or varying shape along its longitudinal length, and the shaft's diameter D can be uniform or non-uniform along its longitudinal length. In an exemplary embodiment, as shown in FIG. 1, the shaft 20 can have a substantially uniform diameter D along its longitudinal length.

**[0061]** In another embodiment, as shown in FIG. 7, a surgical device 10' can generally be configured and used similar to the device 10 of FIGS. 1-6, but an elongate tubular shaft 20' of the device 10' can have an end effector 22' at a distal end thereof and can have a first, substantially uniform diameter D1 along its longitudinal length except at one or more locations therealong, e.g., at first and second reduced diameter portions 11a, 11b, having a second diameter D2 less than the first diameter D1. Although the shaft 20' has two reduced diameter portions, a person skilled in the art will appreciate that the shaft 20' can have any number of reduced diameter portions. The reduced diameter portions 11a, 11b can facilitate surgery in any number of ways, e.g., help reduce surgical clutter and/or help facilitate visual confirmation of the device's position. The first and second reduced diameter portions 11a, 11b can, as in the illustrated embodiment, be respectively located in proximal and distal portions of the shaft 20', which can help facilitate visual confirmation of the device's position relative to a patient and/or other surgical instruments by the relative positioning of the first and second reduced diameter portions 11a, 11b to the patient and/or the other surgical instruments. As will be appreciated by a person skilled in the art, the first and second reduced diameter portions 11a, 11b can have same or different diameters from one another, and can be integrally formed with a remainder of the shaft 20' or can be discrete elements coupled thereto.

**[0062]** In another embodiment, as shown in FIG. 8, a surgical device 10" can generally be configured and used similar to the device 10 of FIGS. 1-6, but an elongate tubular shaft 20" of the device 10" can have an end effector 22" at a distal end thereof and can have a first, substantially uniform diameter D3 along its longitudinal length except at one or more locations therealong, e.g., at an enlarged diameter portion 13, having a second diameter D4 greater than the first diameter D3. Although the shaft 20" has one reduced diameter portion, a person skilled in the art will appreciate that the shaft 20" can have any number of enlarged diameter portions. The enlarged diameter portion 13 can facilitate surgery in any number of

ways, e.g., help facilitate manipulation of the device 10". The enlarged diameter portion 13 can, as in the illustrated embodiment, be located in a proximal portion of the shaft 20" and be configured as a stop member to help prevent the shaft 20" from being distally passed through an incision or an access device beyond a certain point, e.g., until a distal end of the enlarged diameter portion 13 abuts skin or an access device to stop the shaft 20" from further distal insertion into a patient's body. The devices 10', 10" of FIGS. 7 and 8 are discussed in more detail in U.S. patent application Ser. No. \_\_\_\_\_ [Atty. Dkt. No. 100873-414 (END6756USNP)] entitled "Bendable Shaft For Handle Positioning" filed on even date herewith, which is hereby incorporated by reference in its entirety.

**[0063]** Referring again to FIGS. 1-6, as mentioned above, the end effector 22 can be configured to articulate relative to the shaft 20 to angularly orient the end effector 22. The proximal end of the end effector 22 can be pivotally coupled to the distal end of the coupler 24 at a first pivot point 26, about which the end effector 22 can pivot or articulate, e.g., move in a single plane, relative to the coupler 24 and to the shaft 20. The end effector 22 and the coupler 24 can be pivotally connected together at the first pivot point 26 in a variety of ways to movably couple together, as will be appreciated by a person skilled in the art. As in the illustrated embodiment shown in FIGS. 2-6 and 9-13, a pin 28 can be inserted, e.g., by press fit, through a pivot hole 30 formed in the proximal end of the end effector 22 and a pivot hole 32 formed in the distal end of the coupler 24 to form a pivot hinge-type joint at the first pivot point 26 between the end effector 22 and the coupler 24. A proximal end of the coupler 24 can be coupled to a distal end of the shaft 20 in any way. As in the illustrated embodiment, shown in FIGS. 3 and 4, the coupler 24 and the shaft 20 can be non-pivotally coupled together at a non-pivoting point 37 with pins 39 extending radially outward from opposite sides of the coupler 24 being fixed in corresponding holes 41 formed in opposite sides of the shaft 20. The end effector 22 can be coupled to a distal end of the shaft 20 without the intervening coupler 24, as will be appreciated by a person skilled in the art.

**[0064]** As mentioned above, the device 10 can include an articulator element configured to articulate the end effector 22 to angularly orient the end effector 22 relative to the longitudinal axis 20A of the shaft 20. The articulator element can have a variety of configurations, but in the illustrated embodiment the articulator element includes a rigid element extending at least partially through the shaft 20 and the coupler 24 and being configured to move relative thereto to pivot or articulate the end effector 22 about the first pivot point 26. Having a rigid articulator element can help maximize stability and rigidity of the end effector's angulation and allow the end effector 22 to be more securely moved to and maintained at any angle throughout its range of motion. Generally, moving the articulator element relative to the shaft 20 can cause the end effector 22 to move between the first configuration in which a longitudinal axis 22A of the end effector 22 is aligned with or parallel to the shaft's longitudinal axis 20A, as shown in FIGS. 2-4, 9, and 10, and the second configuration in which the end effector 22 is articulated relative to the shaft's longitudinal axis 20A with the end effector's longitudinal axis 22A angled at a non-zero angle from the shaft's longitudinal axis 20A, as shown in FIGS. 11-13 and as shown in FIG. 4 with the end effector 22 in phantom lines.

**[0065]** As shown in FIGS. 2-6 and 9-13, the articulator element can include a rigid multi-bar system including a

proximal rigid articulator bar, link, or rod **34**, generally referred to as a “proximal link,” extending through the shaft **20** and a distal rigid articulator bar, link, or rod **36**, generally referred to as a “distal link.” The proximal and distal links **34**, **36** can each have a variety of sizes, shapes, and configurations. The proximal and distal links **34**, **36** can be solid or can have one or more hollow portions, same or different from one another. As in the illustrated embodiment, the distal link **36** can include a solid member having a longitudinal length that is less than a longitudinal length of the proximal link **34**, which as discussed further below can have a longitudinal length that allows it to extend from the handle **12**, through the shaft **20**, and distally beyond the distal end of the shaft **20** at least when the end effector **22** is articulated. The distal link **36** can have a longitudinal length that is less than the diameter *D* of the shaft **20**, e.g., less than an inner diameter of the shaft’s inner lumen **18**. In this way, throughout the distal link’s range of motion, e.g., with the distal link **36** pivoted at the second pivot point **38** to articulate the end effector **22** at any angle  $\alpha$  relative to the shaft’s axis **20A**, the distal link **36** can be configured to not extend beyond the shaft’s diameter *D*, thereby helping to prevent the device **10** from snagging on and/or damaging adjacent tissue when the end effector **22** is articulated. As discussed further below, the distal link’s longitudinal length can at least partially define a maximum degree of articulation of the end effector **22**.

[0066] The distal link **36** can have a proximal end pivotally coupled to a distal end of the proximal link **34** at a second pivot point **38**, and a distal end of the distal link **36** can be pivotally coupled to a proximal end of the end effector **22** at a third pivot point **40**. A proximal end of the proximal link **34** can be operatively coupled to a lever **42** at the handle **12**, illustrated in FIGS. **6** and **7** and discussed further below. Although in the illustrated embodiment the proximal link **34** extends from the handle **12** to the distal link **36**, in some embodiments, an additional rigid rod can couple to the proximal link’s proximal end and extend from the proximal link’s proximal end to the handle **12**. Furthermore, as will be appreciated by a person skilled in the art, the additional rigid rod can include multiple rigid rods.

[0067] As in the illustrated embodiment, the proximal link **34** can be an elongate tubular body **34b** at least partially slidably disposed in the inner lumen **18** of the shaft **20**. The interior of the proximal link **34** can be cannulated to allow the actuator element to be movably disposed therein, as discussed further below. A protrusion or extension **34e**, e.g., a rod, bar, or link, generally referred to as an “extension rod,” can extend distally from a perimeter or circumference of the elongate tubular body **34b** at a distal end thereof, and the extension rod **34e** can be coupled at its distal end to the distal link’s proximal end at the second pivot point **38**. The extension rod **34e** can have a diameter less than a diameter of the elongate tubular body **34b**, which can allow the extension rod’s longitudinal axis **34A** to be laterally or radially offset from the elongate tubular body’s central longitudinal axis as well as laterally or radially offset from the shaft’s central longitudinal axis. In the illustrated embodiment, the shaft’s central longitudinal axis is the same as the shaft’s longitudinal axis **20A**, and the elongate tubular body’s central longitudinal axis is the same as the elongate tubular body’s longitudinal axis **35A**. In other words, at least a distal portion of the articulator element can have a reduced diameter region, thereby allowing a distal portion of the actuator element to be disposed parallel thereto and on an opposite side of the shaft’s lumen **18**, as discussed

further below. A person skilled in the art will appreciate that while the articulator element extends at least partially through the shaft’s inner lumen **18** in the illustrated embodiment, at least a portion of the articulator element can be disposed outside the shaft **20**, e.g., be slidably movable within a channel formed in an exterior surface of the shaft **20**. Similarly, a person skilled in the art will appreciate that while the articulator element extends at least partially through a channel formed in an exterior surface of the coupler **24** in the illustrated embodiment, at least a portion of the articulator element can be disposed inside the coupler **24**, e.g., be slidably movable within an inner lumen of the coupler **24**.

[0068] The end effector **22** and the proximal and distal links **34**, **36** can be pivotally coupled together in any way at their associated ones of the second and third pivot points **38**, **40**, as will be appreciated by a person skilled in the art. As in the illustrated embodiment shown in FIG. **2** a second pin **44** can be inserted, e.g., by press fit, through respective second holes **46** formed in the distal end of the proximal link **34** and the proximal end of the distal link **36** to form a pivot hinge-type joint at the second pivot point **38** between the adjacent proximal and distal links **34**, **36**. Similarly, a third pin **48** can be inserted through respective third holes **50** formed in the distal end of the distal link **36** and the proximal end of the end effector to form a pivot hinge-type joint at the third pivot point **40** between the adjacent distal link **36** and end effector **22**.

[0069] When the end effector **22** is in the first configuration, e.g., the end effector’s longitudinal axis **22A** is co-axial or parallel to the shaft’s longitudinal axis **20A**, the articulator element can be in a corresponding straight configuration in which a longitudinal axis thereof is co-axial or parallel to the shaft’s longitudinal axis **20A**. In other words, when the end effector **22** is unarticulated, the longitudinal axes **35A**, **34A** of the proximal and distal links **34**, **36**, respectively, can be parallel to each other and co-axial or parallel to the shaft’s longitudinal axis **20A**, as shown in FIG. **2**. With the end effector **22** in the second, articulated configuration, the axes **22A**, **34A** of the end effector **22** and the distal link **34** can intersect the longitudinal axes **20A**, **35A** of the shaft **20** and the proximal link **34**.

[0070] In response to selective movement of the lever **42**, the proximal link **34** can be configured to move longitudinally in both proximal and distal directions along its longitudinal axis **35A** co-axial or parallel to the shaft’s longitudinal axis **20A**. A person skilled in the art will appreciate that as an alternative to the lever **72**, other types of controls, e.g., a trigger, a knob, a button, a spring mechanism, etc., can be included with the handle **12** for applying a longitudinal force to the proximal link **34** co-axial or parallel to the shaft axis **20A** to articulate and/or straighten the end effector **22**. Longitudinal movement of the proximal link **34** can be configured to impart force or motion to the distal link **36**, thereby causing the end effector **22** to pivot about the first and third pivot points **26**, **40** to be angularly oriented relative to the shaft’s axis **20A**. Longitudinal movement of the proximal link **34** can cause the distal link **36** to move longitudinally along the distal link’s axis **34A** parallel to the shaft’s axis **20A**, e.g., if the proximal link **34** is pulled, or cause the distal link **36** to pivot about the second pivot point **38** such that the distal link **36** is angularly oriented relative to the shaft’s axis **20A**. In other words, movement of the proximal link **34** can be fixed along its longitudinal axis **35A**, while the distal link **36** can be configured to pivot or rotate away from the shaft’s axis **20A** relative to the proximal link **34** and to the shaft **20**. The

presence of the coupler 24 can help provide sufficient space for the articulator element to move distally beyond the shaft 20 to articulate the end effector 22 without the articulator element extending distally beyond the end effector 22 or extending beyond the shaft's diameter D.

[0071] Generally, pushing the articulator element distally relative to the shaft 20 can cause the end effector 22 to move from the first configuration in which the longitudinal axis 22A of the end effector 22 is co-axial or parallel to the shaft's longitudinal axis 20A, as shown in FIGS. 2-4, 9, and 10, to the second configuration in which the end effector 22 is articulated relative to the shaft's longitudinal axis 20A with the end effector's longitudinal axis 22A angled at a non-zero angle from the shaft's longitudinal axis 20A, as shown in FIGS. 11-13 and with phantom dotted lines in FIG. 4. Similarly, when the end effector 22 is in the second configuration, pulling the articulator element proximally relative to the shaft 20 can move the end effector 22 from the second configuration to the first configuration. The end effector 22 is shown in FIG. 13 at a maximum articulated position of 90°, e.g., at an angle  $\alpha$  of 90° relative to the shaft's axis 20A.

[0072] The end effector 22 can be configured to move from the first configuration to the second configuration by pivoting about the first pivot point 26 in clockwise and/or counterclockwise directions. As in the illustrated embodiment, as shown by the end effector 22 in phantom dotted lines in FIG. 4, the end effector 22 can be configured to pivot 90°, e.g., with the angle  $\alpha$  between the end effector's axis 22A and the shaft's axis 20A equaling 90°, in both clockwise and counterclockwise directions about the first pivot point 26. The end effector 22 can be moved from the first configuration by pivoting in one of the clockwise and counterclockwise directions by pushing the articulator element, e.g., moving the articulator element proximally relative to the shaft 20, as shown in FIG. 13. As the proximal link 34 is pushed distally by a driving force in the handle 12, e.g., by moving the articulator lever 74 in a proximal direction, the proximal link 34 in turn pushes the distal link 36 distally relative to the shaft 20. As the links 34, 36 are pushed distally, the proximal link 34 applies a force on the distal link 36 to pivot the distal link 36 about the second pivot point 38 such that the distal end of the distal link 36 moves radially or laterally away from the extension rod's longitudinal axis 34A while the distal link's proximal end pivots about the second pivot point 38. The movement of the distal link's distal end applies a force on the end effector 22 to pivot the end effector 22 about the first pivot point 26 to angularly orient the end effector 22 relative to the shaft's axis 20A. The off-center locations of the second and third pivot points 38, 40, e.g., along the distal link's axis 34A radially offset from the shaft's central axis 20A, can result in the distal link 36 and the end effector 22 pivoting in a predetermined direction in response to the pushing force of the proximal link 34. Similarly, the end effector 22 can be moved from the first configuration by pivoting in the other one of the clockwise and counterclockwise directions by pulling the articulator element, e.g., moving the articulator element proximally relative to the shaft 20, as shown in FIGS. 11 and 12. FIGS. 11 and 12 also illustrate that when the articulator element is pulled to pivot the end effector 22 in the other one of the clockwise and counterclockwise directions, the distal link 36 moves along an axis parallel to the shaft's axis 20A and coaxial with or parallel to the extension rod's longitudinal axis 34A, e.g., the distal link's distal end does not move radially or laterally relative to the extension rod's longitudinal

axis 34A. In this way, the end effector 22 can be optimally positioned in a variety of angular positions, e.g., by angling clockwise or counterclockwise, without requiring rotation or other movement of the shaft 20. FIGS. 11 and 12 also show the end effector 22 in the second configuration with the angle  $\alpha$  being between the end effector's minimum 0° and maximum 90°.

[0073] The articulator element can also be moved proximally and/or distally relative to the shaft 20 to move the end effector 22 from one articulated configuration to another articulated configuration, e.g., between different non-zero angles  $\alpha$ , including between +/- values of the same angle  $\alpha$ . The device 10 can optionally include a lock mechanism configured to fixedly hold the end effector 22 in the second configuration, e.g., at a selected angular orientation. As will be appreciated by a person skilled in the art, the lock mechanism can have a variety of configurations, such as a toothed rack and pawl, a depressible button configured to engage any one of a plurality of holes, etc. The degree of the angle  $\alpha$  between the end effector's and shaft's axes 22A, 20A can be varied by varying the pulling/pushing force on the articulator element. Varying the size of the angle  $\alpha$  can change the direction of approach of end effector 22 to an intended site, which can assist in allowing for more precise positioning of the end effector 22. A person skilled in the art will appreciate that the force imparted from the proximal link 34 to the distal link 36 and from the distal link 36 to the end effector 22 can be simultaneous despite the presence of minimal delays as forces translate along the articulator element.

[0074] As mentioned above, the longitudinal length of the distal link 36 can at least partially define the maximum value of the angle  $\alpha$ , with longer longitudinal lengths of the distal link corresponding to smaller maximum values of the angle  $\alpha$ . In the illustrated embodiment, the distal link's longitudinal length is substantially equal to the shaft's diameter D. The coupler 24 can also be configured to at least partially define the maximum value of the angle  $\alpha$ . The coupler 24 can have a proximal surface 24p, as shown in the illustrated embodiment in FIG. 13, configured to engage and abut an exterior surface of the end effector 22 when the end effector 22 is articulated to a certain angle  $\alpha$ , thereby preventing the angle  $\alpha$  from increasing beyond a certain maximum value by preventing the end effector 22 from pivoting further about the first and third pivot points 26, 40. In this way, even if an attempt was made to push the articulator element distally when the end effector 22 abuts the coupler's proximal surface 24p, the articulator element would be prevented from so moving distally, or, indeed, at all. In the illustrated embodiment, the articulation angle  $\alpha$  can be in a range from -90° to +90°.

[0075] In another embodiment, illustrated in FIG. 14, a surgical device can be similar to the device 10 of FIGS. 1-6 and 9-13, however can be configured to allow an end effector 122 at a distal end of the elongate tubular shaft 120 to articulate beyond 90° relative to the shaft's longitudinal axis 120A, e.g., to at least about 120°, such as up to about 130°. As shown in FIG. 14, the device can include a rigid articulator element including rigid proximal and distal links 134, 136, with a distal end of the proximal link 134 being coupled to a proximal end of the distal link 136 at a second pivot point 138. The distal link 136 of FIG. 14 also has a longitudinal length less than that of the distal link 36 in the device 10 of FIGS. 1-6 and

9-13, which can define a degree of articulation of the end effector 122 great than that in the device 10 of FIGS. 1-6 and 9-13.

[0076] The articulator element can be configured to be moved proximally and distally relative to the shaft 120 to articulate the end effector 122, similar to that discussed above regarding the articulator element of the device 10. When the end effector 122 is in a first configuration in which the end effector 122 is longitudinally aligned with or linear relative to the shaft 120, the articulator element can be pushed distally to pivot the distal link 136 about the second pivot point 138 and about a third pivot point 140 and to pivot the end effector 122 about a first pivot point 126 and the third pivot point 140. When the end effector 122 has pivoted such that the end effector's longitudinal axis 122 and the shaft's longitudinal axis 120A are perpendicular, the articulator element can still be pushed distally, as shown in FIG. 14, with the distal link 136 being configured to "flip" with its proximal end flipping to a distal position. In other words, the distal link's distal end can pivot about the third pivot point 140 as the proximal link 134 pushes the distal link's proximal end distally to pivot the distal link's proximal end about the second pivot point 138 and move the distal link's proximal end toward a distal-most position. Such "flipping" can allow the end effector 122 to be angularly oriented beyond 90°. The end effector 122 can also be configured to move from the first configuration to a second configuration in which the end effector 122 is angularly oriented relative to the shaft 120 by pulling the articulator element. In this illustrated embodiment, pulling the articulator element can pivot the end effector 122 about the first and third pivot points 126, 140 in an opposite direction than pushing the articulator element, with the end effector 122 being configured to angle beyond 45°, e.g., up to about 60°, in response to the proximal movement of the articulator element. In other words, the end effector 122 can be configured to pivot beyond 45° in both clockwise and counterclockwise directions relative to the shaft 20, and more particularly, can be configured to pivot up to about 130° in one of the clockwise and counterclockwise directions and to pivot up to about 60° in the other one of the clockwise and counterclockwise directions.

[0077] Referring again to the embodiment illustrated in FIGS. 1-6 and 9-13, as mentioned above, the device 10 can include an actuator element configured to actuate the end effector 22, regardless of whether the end effector 22 is in the first configuration or the second configuration. The actuator element can have a variety of configurations, but in the illustrated embodiment, the actuator element extends between the handle 12 and the end effector 22 and is configured to move relative thereto to actuate the end effector 22. Generally, as shown in FIGS. 2 and 15, the actuator element can be configured such that selective movement of the actuator element relative to the shaft 20 can cause the end effector 22 to pivot the jaws 16a, 16b about a fourth pivot point 52 to selectively open and close the jaws 16a, 16b. As further discussed below, the actuator element can be configured to have a least a portion along its longitudinal length that changes in stiffness during actuation of the end effector 22, which can help facilitate actuation of the end effector 22, particularly when the end effector 22 is articulated relative to the shaft 20.

[0078] As shown in FIGS. 2-6, 9, 10, and 15, the actuator element can be a multi-bar system including a proximal rigid actuator bar, link, or rod 54, generally referred to as a "proximal link," extending through the shaft 20 and a distal flexible actuator bar, link, or rod 56, generally referred to as a "distal

link." The proximal and distal links 54, 56 can each have a variety of sizes, shapes, and configurations. As mentioned above, and as shown in FIGS. 2, 5, and 6, at least a portion of the actuator element, e.g., the proximal link 56, can extend through the shaft 20 within a cannulated interior of the articulator element, e.g., within an inner passageway of the articulator element's proximal link 34. In this way, manipulation of the trigger 58 can allow the actuator element to longitudinally, slidably move within the shaft 20, relative to the shaft 20, to actuate the end effector 22 regardless of the relative position of the articulator element, e.g., regardless of the end effector's angle relative to the shaft's axis 20A.

[0079] The distal link 56 can have a diameter less than a diameter of the proximal link 54, which can allow the distal link's longitudinal axis 56A to be laterally or radially offset from the proximal link's central longitudinal axis 54A as well as laterally or radially offset from the shaft's central longitudinal axis 20A. In other words, at least a distal portion of the actuator element can have a reduced diameter region, thereby allowing a distal portion of the actuator element, e.g., the distal link 56, to be disposed parallel to the distal portion of the articulator element, e.g., the extension rod 34e, such that their axes 34A, 56A can be parallel to one another on opposite sides of the shaft's lumen 18. A person skilled in the art will appreciate that while the actuator element extends at least partially through the shaft's inner lumen 18 in the illustrated embodiment, at least a portion of the actuator element can be disposed outside the shaft 20, e.g., be slidably movable within a channel formed in an exterior surface of the shaft 20. Similarly, a person skilled in the art will also appreciate that while the actuator element extends at least partially through a channel formed in an exterior surface of the coupler 24 in the illustrated embodiment, at least a portion of the actuator element can be disposed inside the coupler 24, e.g., be slidably movable within an inner lumen of the coupler 24. Furthermore, a person skilled in the art will appreciate that a surgical device can include an actuator element including the proximal and distal links 54, 56 and an articulator element different from the one including the proximal and distal links 34, 36, and vice versa with a device including the illustrated articulator element but a different actuator element.

[0080] The proximal and distal links 54, 56 can be solid or can have one or more hollow portions, same or different from one another. As in the illustrated embodiment, the proximal and distal links 54, 56 can each be solid, with at least a distal portion of the actuator element, e.g., the distal link 56, being formed of a composite material. The composite material can allow the distal link 56 to be flexible such that it can bend near the first pivot point 26 when the end effector 22 articulates about the first pivot point 26, while also allowing the distal link 56 to be strong enough to cause opening and closing of the jaws 16a, 16b. As will be appreciated by a person skilled in the art, a composite material generally includes a material made from at least two different component materials that are physically but not chemically combined such that the different component materials can be distinguishable in the composite material and can maintain their particular properties as part of the composite material. The distal link 56 can be formed of any two or more materials combined to form a composite material.

[0081] As in the illustrated embodiment, as shown in FIG. 16, the distal link 56 can include a core 56c surrounded by an outer sheath 56s. The core 56c and the sheath 56s each are shown in the illustrated embodiment as being substantially

cylindrical with circular cross-sections, but as will be appreciated by a person skilled in the art, they can have any shape, same or different from one another. The core 56c can be formed of a first material and the sheath 56s can be formed of a second material having a greater flexibility than a flexibility of the first material such that the distal link 56 can be formed of a composite material including the first and second materials. In this way, the sheath 56s can facilitate flexing of the distal link 56 without buckling while the core 56c can provide the distal link 56 with stability, which can facilitate the distal link's longitudinal movement relative to the shaft 20 and can help force opening and closing of the jaws 16a, 16b, as discussed further below. Although the first and second materials can include any materials as appropriate for a particular surgical device, the first material can include a metal, e.g., titanium, a shape memory material such as Nitinol, stainless steel, etc., and the second material can include, e.g., a plastic such as polypropylene or polyethylene, an elastomer, etc. The distal link 56 can be formed in any way, such as by molding the sheath 56s around the core 56c. The relative sizes of the sheath 56s and the core 56c can vary, but in an exemplary embodiment, the core 56c has a relatively small cross-sectional diameter relative to the sheath 56s to provide strength to the distal link 56 while still allowing bending of the distal link 56 when the end effector 22 is in an angled position relative to the shaft's axis 20A.

[0082] The proximal link 54 can also include a solid member as in the illustrated embodiment, and can have a longitudinal length that allows it to extend from the handle 12, through the shaft 20, and distally beyond the distal end of the shaft 20 at least when the end effector 22 is articulated. A proximal end of the proximal link 54 can be operatively coupled to a thumb trigger 58 at the handle 12, illustrated in FIGS. 5 and 6 and discussed further below. Although in the illustrated embodiment the proximal link 54 extends from the handle 12 to the distal link 56, in some embodiments, an additional rigid rod can couple to the proximal link's proximal end and extend from the proximal link's proximal end to the handle 12. Furthermore, as will be appreciated by a person skilled in the art, the additional rigid rod can include multiple rigid rods. A distal end of the proximal link 54 can be coupled to a proximal end of the distal link 54, as shown in FIG. 3. The cross-sectional view of the distal portion of the device 10 in FIG. 4 may appear to indicate that the proximal end of the distal link 56 is coupled to the distal end of the actuator element's elongate tubular body 34b rather than to the actuator element's proximal link 54, but that is merely because of where the device 10 is cross-sectioned in FIG. 2. A distal end of the distal link 56 can be coupled to proximal ends of the jaws 16a, 16b, as shown in FIGS. 2 and 3.

[0083] When the end effector 22 is in the first configuration, e.g., the end effector's longitudinal axis 22A is co-axial or parallel to the shaft's longitudinal axis 20A, the actuator element can be in a corresponding straight configuration in which a longitudinal axis thereof is co-axial or parallel to the shaft's longitudinal axis 20A. In other words, when the end effector 22 is unarticulated, longitudinal axes 54A, 56A of the proximal and distal links 54, 56, respectively, can be parallel to each other and co-axial or parallel to the shaft's longitudinal axis 20A, as shown in FIG. 2. With the end effector 22 in the second, articulated configuration, the axes 22A, 56A of the end effector 22 and the distal link 56 can intersect the longitudinal axes 20A, 54A of the shaft 20 and the proximal link 54.

[0084] In response to selective movement of the trigger 58, the proximal link 54 can be configured to move longitudinally along its longitudinal axis 54A co-axial or parallel to the shaft's longitudinal axis 20A in both proximal and distal directions. A person skilled in the art will appreciate that as an alternative to the trigger 58, other types of controls, e.g., a lever, a knob, a button, a spring mechanism, etc., can be included with the handle 12 for applying a longitudinal force to the proximal link 54 co-axial or parallel to the shaft axis 20A to actuate the end effector 22. Longitudinal movement of the proximal link 54 can be configured to impart force or motion to the distal link 56, thereby imparting force or motion to the jaws 16a, 16b to cause the jaws 16a, 16b of the end effector 22 to pivot about the fourth pivot point 52. A person skilled in the art will appreciate that the force imparted from the proximal link 54 to the distal link 56 and from the distal link 56 to the jaws 16a, 16b can be simultaneous despite the presence of minimal delays as forces translate along the actuator element. Longitudinal movement of the proximal link 54 along its axis 54A can cause the distal link 56 to move longitudinally along the distal link's axis 56A, which can be straight if the end effector 22 is not articulated or can be along a bend or arc at the first pivot point 26 if the end effector 22 is articulated. In other words, movement of the proximal link 54 can be fixed along its longitudinal axis 54A, while the distal link 56 can be configured to curve or bend relative to the proximal link 54 and to the shaft 20.

[0085] Generally, pushing the actuator element distally relative to the shaft 20 can cause the end effector's jaws 16a, 16b to move from a closed position to an open position such that the jaws 16a, 16b are angled at a non-zero angle from the end effector's longitudinal axis 22A, as shown in FIG. 15. Similarly, when the jaws 16a, 16b are in an open position, pulling the actuator element proximally relative to the shaft 20 can move the jaws 16a, 16b from the open position to the closed position. The actuator element can also be moved proximally and/or distally relative to the shaft 20 to move the jaws 16a, 16b from one open position to another open position, e.g., between different non-zero angles relative to the end effector's axis 22A.

[0086] The device 10 can optionally include a lock mechanism configured to fixedly hold the jaws 16a, 16b in the open position at a selected angular orientation. As will be appreciated by a person skilled in the art, the lock mechanism can have a variety of configurations, such as a toothed rack and pawl, a depressible button configured to engage any one of a plurality of holes, etc. The degree of the jaws' opening can be varied by varying the pulling/pushing force on the actuator element.

[0087] As mentioned above, the actuator element can be flexible and can change in stiffness during actuation, e.g., the actuator's elastic modulus can be lowered during actuation. As in the illustrated embodiment, the sheath 56s of the distal link 56 can be configured to compress longitudinally when the proximal link 54 is pushed to move tips of the jaws 16a, 16b farther apart, and to expand longitudinally when the proximal link 54 is pulled to move tips of the jaws 16a, 16b closer together. In this way, the actuator element can be configured to bend around the first pivot point 26 but have sufficient strength to push/pull the jaws 16a, 16b open/closed.

[0088] In another embodiment, illustrated in FIGS. 17A and 17B, a distal portion of an actuator element, e.g., a flexible distal link 56' extending distally from a rigid proximal link (not shown), can have a fishbone shape in which the distal link 56' includes a plurality of features configured to reduce

buckling, e.g., a plurality of laterally or radially extending teeth or ribs 57, generally referred to as "ribs." The actuator element can include a core (not shown) made of a first material surrounded by an outer sheath 56s' that includes the ribs 57, the sheath 56s' including the ribs 57 being made of a second material having a greater flexibility than the first material. Although the illustrated distal link 56' includes a same number of ribs 57 extending from opposite sides of the distal link 56', a person skilled in the art will appreciate that the distal link 56' can include any number of ribs 57 arranged anywhere around the distal link 56'. The ribs 57 can have any size, shape, and configuration. As in the illustrated embodiment, the ribs 57 can have a T-shape, with a base 57b of the "T" pointing laterally or radially inward toward the core. In other embodiments, the ribs can have, e.g., a triangular shape as illustrated in FIG. 17C, a V-shape, a truncated V-shape as illustrated in FIG. 17D, an 1-shape, etc. As in the illustrated embodiment, top "T" portions or crossbars 57c of the ribs 57 can have longitudinal axes 57A parallel to a longitudinal axis 20A' of a shaft 20' at least when an end effector (not shown) at a distal end of the shaft 20' is not articulated. In this way, when the distal link 56' is bent from an unbent configuration as shown in FIG. 17B, such as when the end effector is articulated, the crossbars 57c of the ribs 57 can be configured to move closer to one another on one side of the distal link 56', e.g., the left side as in FIG. 17A, and to move apart from one another on the opposite side of the distal link 56', e.g., the right side as in FIG. 17A. Upon sufficient bending, the crossbars 57c of the ribs 57 can contact or abut one another, as also shown on the left side of FIG. 17A. In this way, the fishbone shape of the distal link 56' can help facilitate bending of the actuator element at an angle beyond 45° without buckling while also allowing the actuator element to have sufficient strength, e.g., via the core and/or movement of the ribs 57 toward one another such that adjacent crossbars 57c contact with one another, to move the jaws 16a, 16b open and closed whether the end effector is articulated or not. The distal link 56' can be similarly unbent, with adjacent crossbars 57c on either side of the distal link 56' moving closer together or farther apart from one another to move the distal link 56' toward a linear or straight configuration.

[0089] FIGS. 17E-17G illustrate another embodiment of an actuator element including a distal portion, e.g., a flexible distal link 56B, having a fishbone shape. In this illustrated embodiment, the distal link 56B includes a plurality of half-moon or semicircular ribs 57B extending laterally or radially from a central portion 61B thereof. When the distal link 57B moves from an unbent configuration, shown in FIGS. 17E and 17G, to a bent configuration, shown in FIG. 17F, the ribs 57B can move similar to that discussed above regarding the distal link 56' of FIG. 17A with ribs 57B on one side of the distal link 56B moving closer to one another while ribs 57B on the other side move apart from one another.

[0090] In another embodiment, illustrated in FIG. 18, a distal portion of an actuator element, e.g., a flexible distal link 56" extending distally from a rigid proximal link (not shown), can have a fishbone shape in which the distal link 56" includes a plurality of features to reduce buckling in the form of cuts or slits 59, generally referred to as "slits," formed therein. The slits 59 can generally be configured similar to the ribs 57 discussed above, e.g., be formed in an outer sheath of the distal link 56" on opposite sides thereof. When the distal link 56" bends to accommodate articulation of the end effector (not shown), the slits 59 can compress together, e.g., as shown

on the right in FIG. 18, and expand apart, e.g., as shown on the left in FIG. 18, as necessary to facilitate bending of the distal link 56" and facilitate actuation of the end effector. If the slits 59 are of sufficient size and shape, pushing and pulling the actuator element can change a diameter of the distal link 56", with the distal link 56" increasing in diameter when pushed, e.g., as the slits 59 compress, and decreasing in diameter when pulled, e.g., as the slits 59 move apart from one another.

[0091] In another embodiment, the actuator element can include at least one cable, e.g., a braided cable. As will be appreciated by a person skilled in the art, the cable can be configured to be actuated from the handle 12 to actuate the end effector 22. Exemplary embodiments of cables configured to actuate an end effector are described in more detail in U.S. Patent Publication No. 2008/0147113 filed Dec. 14, 2006 entitled "Manually Articulating Devices," which is hereby incorporated by reference in its entirety.

[0092] Referring again to the embodiment of FIGS. 1-6, as will be appreciated by a person skilled in the art, the handle 12 can include a rotating mechanism configured to rotate the shaft 20, such as a knob 60 as shown in FIGS. 5 and 6, a lever, a wired or wireless electronic control, etc. The knob 60 can be configured to rotate the shaft 20 360° clockwise and/or counterclockwise about the shaft's longitudinal axis 20A. Rotation of the shaft 20 about its axis 20A can also rotate the end effector 22 about the shaft's axis 20A. The shaft 20 can be rotated when the end effector 22 in either the straight configuration or the articulated configuration to further increase the positioning range of the end effector 22.

[0093] In use, as shown in an exemplary embodiment in FIG. 19, one or more surgical devices 10 can be inserted through an opening 100 in tissue 106 to access a body cavity 108 underlying the tissue 106 where the devices 10 can perform any type of surgical procedure. Although the illustrated devices 10 are each those of FIG. 1, a person skilled in the art will appreciate that any one or more devices can be inserted into the body cavity 108. As mentioned above, a person skilled in the art will also appreciate that while the devices 10 are shown in the illustrated embodiment in use in a laparoscopic procedure and inserted into the body cavity 108, e.g., the abdominal cavity, through a multiple port access device 102 positioned in the tissue opening 100, e.g., an incision at the navel, any of the surgical devices disclosed herein can be used in a variety of surgical procedures and inserted into a patient's body in any number of ways. Prior to insertion of any instruments through the multiple port access device 102, insufflation can be provided through an insufflation port, as will be appreciated by a person skilled in the art. A scoping device 104 can also be inserted through the multiple port access device 102 to provide visualization. Non-limiting examples of a scoping device include an endoscope, a laparoscope, and a colonoscope.

[0094] The multiple port access device 102 can include multiple instrument openings each configured to receive an instrument inserted therethrough. Each opening can have an associated sealing port that can be configured to provide at least one instrument seal that forms a seal around an instrument disposed therethrough, but otherwise does not form a seal when no instrument is disposed therethrough, at least one channel seal or zero-closure seal that seals a working channel created by the sealing port when no instrument is disposed therethrough, or a combination instrument seal and channel seal that is effective to both form a seal around an instrument disposed therethrough and to form a seal in the working

channel when no instrument is disposed therethrough. Exemplary embodiments of multiple port access devices are described in more detail in U.S. patent application Ser. No. 12/399,482 filed Mar. 6, 2009 entitled "Methods And Devices For Providing Access Into A Body Cavity," U.S. patent application Ser. No. 12/399,473 filed Mar. 6, 2009 entitled "Methods And Devices For Providing Access Into A Body Cavity," U.S. patent application Ser. No. 12/512,542 filed Jul. 30, 2009 entitled "Methods And Devices For Providing Access Into A Body Cavity," U.S. patent application Ser. No. 12/512,568 filed Jul. 30, 2009 entitled "Methods And Devices For Providing Access Into A Body Cavity," U.S. patent application Ser. No. 12/399,633 filed Mar. 6, 2009 entitled "Methods And Devices For Providing Access Into A Body Cavity," U.S. patent application Ser. No. 12/399,625 filed Mar. 6, 2009 entitled "Methods And Devices For Providing Access Into A Body Cavity," U.S. patent application Ser. No. 12/399,547 filed Mar. 6, 2009 entitled "Surgical Access Devices And Methods Providing Seal Movement In Predefined Paths," U.S. patent application Ser. No. 12/399,656 filed Mar. 6, 2009 entitled "Surgical Access Devices And Methods Providing Seal Movement In Predefined Movement Regions," and U.S. patent application Ser. No. 12/766,086 filed Apr. 23, 2010 entitled "Methods And Devices For Accessing A Body Cavity," which are hereby incorporated by reference in their entireties.

[0095] The devices 10 can be simultaneously or sequentially inserted through the multiple port access device 102 with the end effectors 22 in straight configurations to position distal portions of the shafts 20 within the body cavity 108. The shafts 20 inserted through the multiple port access device 102 can each extend generally parallel to one another, e.g., have parallel longitudinal axes. After distal portions of the shafts 20 have been positioned within the body cavity 108, the handles 12 of the devices 10 can be manipulated, simultaneously or sequentially, to move the end effectors 22 from straight configurations to articulated configurations to allow the end effectors 22 at respective distal ends of the shafts 20 to be brought together in a non-interfering, cooperative, facing relationship and to be within a viewing range 110 of the scoping device 104, as also illustrated in FIG. 20. The end effectors 22 can be articulated any amount, including not at all, same or different from one another, and can be selectively adjusted during the surgical procedure to articulate more or less as desired. Because the end effectors 22 can articulate beyond 45°, the end effectors 22 can be configured to angle toward a target tissue and/or another device from a variety of relative positions, e.g., from above, from a side position, or from below. The shafts 20 can also be rotated relative to the handles 12, and the end effectors' jaws 16a, 16b can be opened and closed. The devices 10 can thus allow the shafts 20 to be easily inserted into a body in straight configurations through a single, relatively small opening 100 with the shafts 20' being substantially parallel, and the end effectors 22 can be subsequently articulated to optimally position the end effectors 22 relative to the surgical site, to each other, to the scoping device 104, and to any other tools within the body cavity 108. Because the device 10 can be articulated, its end effector 22 can be positioned at an angle with respect to a remainder of the shaft 20 thereof, positioning of the device and visualization of the device and the surgical site can be improved. In other words, even though the devices 10 and the scoping device 104 are inserted through a common incision, it is still possible to see the end effectors 22 of the devices 10'

and to bring the end effectors 22 of the two instruments devices 10 together in a facing relationship at a single point within the body cavity 108.

[0096] The shafts 20 can also be easily removed from the patient's body with the end effectors 22 unarticulated, first moving the end effectors 22 from articulated configurations to straight configurations if necessary. The multiple port access device 102 can be configured to allow further adjustment of instruments inserted therethrough, such as by allowing collective rotation of the instruments around a central axis of the multiple port access device 102.

[0097] A proximal housing portion of the multiple port access device 102 can be configured to be removable from a distal retractor portion of the multiple port access device 102. Thus, at any point before, during, or after a surgical procedure, the proximal housing portion can in full or part be released from the distal retractor portion, and the distal retractor portion can be removed from the tissue 106. With the proximal housing portion of the multiple port access device 102 disengaged from the distal retractor portion and with the distal retractor portion still positioned in the tissue opening 100, a working channel of the distal retractor portion can provide access to the body cavity 108 underlying the tissue 106. One or more of the devices 10 and/or other surgical instruments can be advanced through the working channel, such as a waste removal bag configured to hold waste material, e.g., dissected tissue, excess fluid, etc., from the body cavity 108. The bag can be introduced into the body cavity 108 through the distal retractor portion's working channel or other access port. A person skilled in the art will appreciate that one or more surgical instruments can be advanced through the distal retractor portion's working channel before and/or after the proximal housing portion has been attached to the distal retractor portion. A surgical drape can optionally be placed over the distal retractor portion and the tissue opening 100 during removal of the distal retractor portion to help reduce dispersion of bodily fluid outside the surgical space.

[0098] 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, e.g., a handle, a proximal housing portion of a surgical access device, an end effector, etc. 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.

[0099] 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 radi-

tion 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.

**[0100]** One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

1. A laparoscopic device, comprising:
  - an elongate shaft having proximal and distal ends defining a longitudinal axis extending therebetween, the shaft having an inner lumen extending therethrough between the proximal and distal ends;
  - an end effector coupled to the distal end of the shaft; and
  - an actuator element coupled to the end effector and extending between the proximal and distal ends of the shaft along the longitudinal axis through the inner lumen, the actuator element being configured to move relative to the shaft to actuate the end effector, and the actuator element having at least a distal portion thereof formed of a composite material.
2. The device of claim 1, wherein the distal portion of the actuator element is flexible, and a proximal portion of the actuator element is rigid.
3. The device of claim 2, wherein the distal portion includes a core formed of a first material and an outer sheath formed of a second material having a greater flexibility than a flexibility of the first material, the outer sheath surrounding the core.
4. The device of claim 3, wherein the first material comprises a metal and the second material comprises a plastic.
5. The device of claim 1, wherein the distal portion has a stiffness that is configured to change during actuation of the end effector.
6. The device of claim 1, wherein the end effector is configured to articulate up to an angle of at least 90 degrees relative to the longitudinal axis of the shaft.
7. The device of claim 1, further comprising an articulator element coupled to the end effector and extending through the inner lumen of the shaft between the proximal and distal ends of the shaft, the articulator element being configured to articulate the end effector to angularly orient the end effector relative to the longitudinal axis of the shaft.
8. The device of claim 7, wherein the articulator element extends through the inner lumen on one side of the inner lumen, and the actuator element extends through the inner lumen on an opposite side of the inner lumen.
9. The device of claim 1, wherein rotation of the actuator element is effective to move the opposed movable jaws of the end effector between open and closed positions.
10. A laparoscopic device, comprising:
  - a cannulated elongate shaft having proximal and distal ends defining a longitudinal axis extending therebetween;
  - an end effector coupled to the distal end of the shaft; and

an actuator element coupled to the end effector and extending through the shaft, the actuator element being configured to move relative to the shaft to actuate the end effector, and the actuator element including a feature configured to change a stiffness of the actuator element when the actuator element moves to actuate the end effector.

11. The device of claim 10, wherein the actuator element is formed of a composite material.

12. The device of claim 10, wherein the actuator element includes a rigid proximal portion and a flexible distal portion, the flexible distal portion including the feature, the feature comprising an outer sheath surrounding a central core.

13. The device of claim 12, wherein the core is formed of a metal, and the outer sheath is formed of a plastic.

14. The device of claim 12, wherein the outer sheath includes a plurality of ribs extending radially outward from the core.

15. The device of claim 14, wherein the ribs are configured to compress together to increase the stiffness of the actuator element when the actuator element moves to actuate the end effector.

16. The device of claim 10, wherein the actuator element comprises:

- a rigid actuator member extending through the shaft; and
- a flexible actuator member having a proximal end coupled to a distal end of the rigid actuator member, and having a distal end coupled to the end effector, the flexible actuator member being formed of a composite material; wherein the rigid actuator member is configured to translate longitudinally through the shaft to move the flexible actuator member relative to the shaft and to change the stiffness of the flexible actuator member to actuate the end effector.

17. The device of claim 10, further comprising an articulator element extending through the shaft along the longitudinal axis, the articulator element being configured to articulate the end effector at an angle relative to the longitudinal axis of the shaft.

18. The device of claim 17, wherein the articulator element extends through the shaft along one side thereof, and the actuator element extends through the shaft along an opposite side thereof.

19. A laparoscopic surgical method, comprising:

- inserting a cannulated elongate shaft of a surgical device into a body of a patient to position an end effector at a distal end of the shaft within the body, the device including an actuator element extending through the shaft, the actuator element being formed of a composite material in at least a flexible distal portion thereof; and
- translating the actuator element relative to the shaft to change a shape of at least the flexible distal portion to actuate the end effector.

20. The method of claim 19, wherein changing the shape of at least the flexible distal portion comprises compressing together ribs extending radially outward from a central core of the flexible distal portion.

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摘要(译)

提供了一种用于执行微创外科手术的方法和装置。在一个实施例中，提供了一种手术装置，其包括细长轴，该细长轴在其远端具有末端执行器。末端执行器可构造成可在第一构造和第二构造之间移动，在第一构造中，末端执行器与轴纵向对齐或线性对齐，在第二构造中，末端执行器以相对于轴超过45度的角度铰接。利用处于第一配置或第二配置的末端执行器，该装置可以配置成允许选择性地致动末端执行器。

