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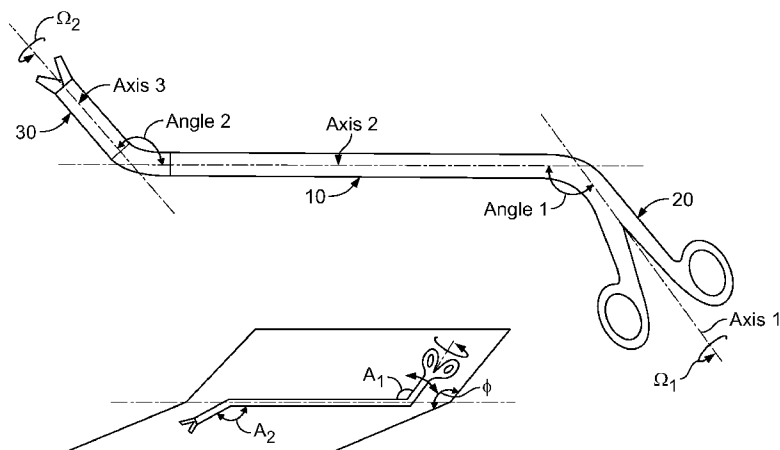


FIG. 1

(57) Abstract: A surgical instrument for use in minimally invasive surgery, or in open procedures with difficult to access surgical fields. The instrument includes a proximal handle which is connected proximally via a first joint, to a central portion. The central portion is connected distally via a second joint, to a distal effector. The handle is linked rotationally to the distal effector such as via a transmission shaft having two or more joints, such as universal joints, located within the regions of the first and second joints. The resulting instrument provides for full natural motion dexterity and control of the effector end with high precision whereby: 1) flexion of the handle flexes the effector; 2) rotation of the handle about the angle of flexion produces a corresponding rotation of the effector; and 3) opening and closing of the handle operates the effector.

MINIMALLY INVASIVE SURGICAL INSTRUMENT

CLAIM OF PRIORITY

[0001] This application claims the benefit of priority under 35 U.S.C. § 119(e) to U.S. provisional application serial nos. 61/021,615, filed January 16, 2008, and 61/027,028, filed February 7, 2008, both of which are incorporated herein by reference in their entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to a surgical instrument for use in minimally invasive surgery, and more particularly to a surgical instrument that provides multiple degrees of freedom of movement using a single intuitive control feature.

BACKGROUND

[0003] Minimally invasive surgery, such as laparoscopic (abdominal) surgery, thoracoscopic, or endoscopic surgery, utilizes surgical instruments that are inserted into the body via small punctures, incisions, or natural openings (ports) instead of a large incision as used in traditional, “open” surgery. Because of reduced patient pain, more discrete and less obtrusive scarring, more successful outcomes, and shortened hospital stays, minimally invasive procedures have gained acceptance as a superior alternative to open surgery for many operations.

[0004] A price to be paid for a reduced incision is that the instruments that are carrying out the operations inside the body must themselves be controlled from without, with the surgeon viewing the operative field on an external monitor. Thus, a surgeon must direct the movements of the surgical instrument via its control features from outside the patient’s body — a surgical technique that is usually more difficult than open surgery, especially with the limited dexterity and functionality of current endoscopic instrumentation.

[0005] Generally, surgical instruments used in minimally invasive surgery have a control handle attached to a central member, such as a rod, which extends to working elements such as scissors, staplers, graspers, needle holders, or electrocautery devices. Examples of endoscopic surgery instruments are described as far back as 1938 – *e.g.*, U.S. Patent No. 2,113,246 for a set of endoscopic forceps. The principal drawbacks of such older instruments and most of the instruments in general

use today in, for example, laparoscopy, are that they are based on a rigid structure that has limited degrees of freedom of movement. Attempts to provide the surgeon with minimally invasive surgical instruments that permit enhanced dexterity have produced instruments that: 1) are inconvenient to use, having steep surgeon learning curves often with many cumbersome control features; 2) are complicated and impractical to manufacture, such as by having expensive gearing or a myriad of inter-locking parts; 3) have mechanisms that do not offer the surgeon enough precision or rigidity; or 4) are prohibitively expensive for routine operations, because they employ computers and robotic controls and can therefore be justified for only the most highly reimbursed and complicated procedures.

[0006] Accordingly, there is a need for a surgical instrument that can deliver significantly enhanced precision and dexterity at an economical price-point, especially in light of growing concerns over escalating costs of advancing medical technology.

[0007] The discussion of the background to the technology herein is included to explain the context of the technology. This is not to be taken as an admission that any of the material referred to was published, known, or part of the common general knowledge as at the priority date of any of the claims.

[0008] Throughout the description and claims of the specification the word “comprise” and variations thereof, such as “comprising” and “comprises”, is not intended to exclude other additives, components, integers or steps.

SUMMARY

[0009] A surgical instrument, comprising: a handle having a first axis; a middle portion having a second axis that intersects the first axis; and an end effector having a third axis that intersects the second axis, wherein the first axis and the second axis subtend a first angle, and the third axis and the second axis subtend a second angle; and wherein the instrument is configured to have at least the following degrees of freedom of movement: an opening or closing of the second angle, thereby causing the end effector to move in a plane containing the third axis and the second axis, accomplished by a flexion of the handle that, correspondingly, opens or closes the first angle; a rotation of the end effector about the third axis, accomplished by a corresponding rotation of the

handle about the first axis and communicated through the middle portion independently of the opening or closing of the first or second angles.

[0010] A surgical instrument, comprising: a central member having a proximal end and a distal end; a proximal handle connected to the proximal end of the central member at a point within a first flexing region; a distal effector connected to the distal end of the central member at a point within a second flexing region; a control member coupling the proximal handle to the distal effector, wherein the control member is configured to communicate a first angle of angulation between the handle and the central member to a corresponding second angle of angulation between the effector and the central member; and a transmission member coupling the proximal handle to the distal effector, wherein the transmission member comprises a flexible drive shaft configured to transmit rotational motion even when proximal and distal ends of said drive shaft whether or not the proximal and distal ends are collinear with one another, and wherein the transmission member is configured so that, independent of a motion of the control member, a rotation of the handle about an axis passing through the handle and at a fixed or moving first angle of angulation is communicated to a rotation of the effector about an axis passing through the effector and also at a correspondingly fixed or moving second angle of angulation.

[0011] A surgical instrument, comprising: a central member having a proximal end and a distal end; a proximal handle connected to the proximal end of the central member at a point within a first flexing region; a distal effector connected to the distal end of the central member at a point within a second flexing region; a control member coupling the proximal handle to the distal effector, wherein the control member is configured to communicate a first angle of angulation between the handle and the central member to a corresponding second angle of angulation between the effector and the central member; and a transmission member coupling the proximal handle to the distal effector, wherein the transmission member comprises a first universal joint connected to the proximal handle in the first flexing region, and a second universal joint connected to the distal effector in the second flexing region, and a rigid coupling member coupling the first and second universal joints to one another, and wherein the transmission member is configured so that a rotation of the handle about an axis passing through the handle and at a fixed first angle of angulation is communicated to a rotation of the effector about an axis passing through the effector and also at a fixed second angle of angulation.

[0012] A handheld minimally invasive surgical instrument comprising a handle, an effector, and a central member, wherein the handle and the effector can be configured to adopt a collinear and a staggered configuration with respect to a longitudinal axis of the central member, and wherein a flexible transmission member permits a rotation of the handle about a handle axis that is not collinear with or parallel to the axis of the central member, to cause a rotation of the effector about an effector axis that is not collinear with or parallel to the axis of the central member when the handle and the effector are in a staggered configuration.

[0013] A surgical instrument having a transmission member comprising one or more universal joints, wherein the one or more universal joints each comprise a gimbal configured with a sufficiently large central aperture to permit a control member disposed in a central axis of the transmission member to pass through the central aperture.

[0014] A method of using the surgical instruments described herein in surgery on a subject, such as a human patient, or an animal.

[0015] A method of making the surgical instruments described herein, the method of making including one or more of: fashioning various elements of the instruments, and assembling the instrument from the various elements.

[0016] The technology described herein provides a platform that can allow a surgeon to perform numerous useful and intuitive operative motions with an effector end of an instrument but using a single control feature on a handle end, for example by opening or closing an opposing lever type handle or pushing a button on a simple grip handle. To allow for maximum surgical dexterity and for intuitive ease of use, the technology described herein allows for seven degrees of freedom of movement: 1) sliding the instrument in and out through the port site (incision or entry point into a body cavity of a subject through which the instrument is inserted); 2) levering the effector end vertically (up and down with respect to the floor) with the port site as the fulcrum point; 3) levering the effector end horizontally (sideways to the left and right with respect to the floor) with the port site as the fulcrum point; 4) rotating about a central axis of the device; 5) opening and closing jaws or otherwise actuating a tool on the effector; 6) flexing the effector end with respect to the central member; and 7) rotating the effector end about an axis of flexion. The last rotational capability is a feature that even many sophisticated devices such as robotic arms cannot provide. Also, existing

surgical instruments cannot perform this effector rotation function with precision or by utilizing a single handle based control feature for controlling all degrees of freedom of movement.

[0017] Controlling a surgical instrument with a handle in the manner described herein provides a particularly familiar way for a surgeon to use the instrument because it is similar to the way that surgeons presently use standard surgical instruments to achieve various degrees of freedom of movement in an open surgical field. Accordingly, the steep learning curve typically associated with mastering endoscopic surgery will be mitigated at least in part with the technology described herein.

[0018] The subject technology can be produced with few uncomplicated moving parts and provide the surgeon with significantly enhanced precise procedural dexterity without the requirement of complex robotic systems. The unique flexible transmission shaft and end effector rotational capability about an axis of angulation can, however, be a useful attachment to robotically driven instrumentation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] FIG. 1 shows an arrangement of various axes as may be aligned with components of a surgical instrument described herein.

[0020] FIG. 2 shows an embodiment of the surgical instrument incorporating a flexible transmission drive described herein;

[0021] FIG. 3 shows an embodiment of a surgical instrument incorporating a universal joint based transmission drive;

[0022] FIG. 4 shows a spring based flexible segment of a flexible drive shaft as used in a surgical instrument described herein;

[0023] FIGs. 5A and 5B show representative universal joints that can be used in a flexing region of a flexible drive shaft; and

[0024] FIG. 6 shows an embodiment of a drive shaft with hollow tubes and a universal joint having a gimbal that permits a control member (not shown) to pass through it.

[0025] As is apparent from further description herein, like reference numerals refer to like elements in the various figures.

DETAILED DESCRIPTION

[0026] The instant disclosure describes a surgical instrument, suitable for endoscopic applications, and having several independently controllable internal degrees of freedom that permit a surgeon to carry out a number of surgical operations inside a subject's body by controlling the required tools manually from outside the subject's body.

Internal degrees of freedom

[0027] The surgical instrument described herein typically comprises three connected portions, a proximal handle, a central member or middle portion (such terms being used interchangeably herein), and a distal effector. As used herein, the terms proximal and distal correspond with the manner in which they are customarily used in medicine and surgery, *i.e.*, the proximal portion of an apparatus is that which resides – during operation – closer to the user, operator, or surgeon, than the remainder of the apparatus. Conversely, the distal portion of an apparatus is that which – during operation – is situated closer to the patient or subject than the remainder of the apparatus.

[0028] FIG. 1 shows, schematically, relationships between a middle portion 10, proximal handle 20, and a distal or end effector 30. The proximal handle 20 has a longitudinal Axis 1 (shown in dashed line) that intersects and subtends Angle 1 at a longitudinal Axis 2 (also shown as a dashed line) of middle portion 10. End effector 30 has a longitudinal Axis 3 (also shown as a dashed line) that intersects and subtends Angle 2 at longitudinal Axis 2. The lower panel of FIG. 1 shows a geometric relationship in three dimensions of the three axes and their internal angles A_1 and A_2 . In the lower panel of FIG. 1, Axes 1 and 3 are shown, as if situated on the pages of a partially-opened book. Axis 2 runs along the spine of the book, and Axes 1 and 3 are in the planes of adjacent but opposing pages. An azimuthal angle, denoted ϕ (Greek phi), can range from 0° to 360° . At 0° , when looking down Axis 2, the end effector and the handle would eclipse one another. At 180° the end effector and the handle are staggered from one another to the greatest extent possible. Other values of angle ϕ represent intermediate configurations. In general, most embodiments of the present technology will be constructed so that angle ϕ is fixed at 180° or at approximately 180° so that the handle and effector are coplanar or are approximately coplanar. In another form, axes 1 and 3 can lie

in planes that are not parallel to one another. In certain embodiments, a locking mechanism can be employed to ensure that the angle remains at or near 180° , or some other chosen angle. In such embodiments, the locking mechanism can be opened or released to permit the instrument to adopt a more compact configuration for packing, transport, or storage.

[0029] The configuration shown in the upper panel of FIG. 1, wherein ϕ is 180° and Axes 1 – 3 lie in the plane of the paper, admits of internal degrees of freedom in addition to an internal rotation of Axes 1 or 3 about Axis 2. An internal degree of freedom is one that is not equivalent to a wholesale translation of the instrument in a particular direction, or a wholesale rotation of the instrument about an axis fixed in space rather than an axis fixed with respect to the instrument or a portion of the instrument. Accordingly, then, an opening or closing of Angle 1, such as by causing proximal handle 20 to move relative to middle portion 10, represents a internal degree of freedom of the instrument. Furthermore, an opening or closing of Angle 2, such as by causing end effector 30 to move relative to middle portion 10, represents another internal degree of freedom of the instrument. In most embodiments considered herein, however, the opening or closing of Angles 1 and 2 are coupled to one another such that, for example, an opening of Angle 1 by an amount δ will occur concurrently with a corresponding opening of Angle 2 by the same amount δ . Manners by which Angles 1 and 2 are so coupled are further described herein. In other embodiments, opening of Angles 1 and 2 are coupled so that an opening of one angle by an amount δ is translated into an opening of the other angle by a constant fraction or multiple of δ , such as 2δ or $\delta/2$, or by $\delta \pm$ a fixed increment α .

[0030] Still further internal degrees of freedom of the instrument as depicted in FIG. 1 are rotations of handle 20 and end effector 30 about, respectively, Axes 1 and 3. Although such rotations can also be accomplished independently of one another, so that, for example, a rotation of handle 20 about Axis 1 can be carried out while leaving end effector stationary relative to Axis 3, this is not typically the case. In most embodiments, rotations about Axes 1 and 3 are coupled to one another so that a controlled rotation of handle 20 about Axis 1 leads directly to a corresponding concurrent rotation of end effector 30 about Axis 3. In one embodiment, a rotation of handle 20 by a value of angle Ω_1 about Axis 1 translates into a simultaneous rotation of end effector 30 about Axis 3 by the same value of angle Ω_2 . In other embodiments, rotations about angles Ω_1 and Ω_2 are coupled so that a rotation about Ω_1 by an amount ω is translated into a rotation about angle Ω_2 by a constant fraction

or multiple of ω , such as 2ω or $\omega/2$, or by $\omega \pm$ a fixed increment β . Manners in which rotations about angles Ω_1 and Ω_2 are coupled are further described herein.

Surgical Instrument having multiple degrees of freedom

[0031] In FIGs. 2 and 3 are depicted embodiments of the surgical instrument as described herein. The instrument has a middle portion 110, a handle 120, and an end effector 130. Longitudinal axes 121 and 131 of handle and end effector respectively are shown superimposed on the instrument. In the depiction of FIG. 2, a cut-out from the center of middle portion 110 is present, illustrating the fact that a particular length and proportion of the middle portion 110 is not intended to be limiting herein. During operation, middle portion 110 extends through the port site.

[0032] Middle portion 110 typically comprises a outer housing 160, that may be made of a rigid material such as a plastic, a metal or metal alloy. The housing may have a circular or near-circular cross-section to facilitate smooth movement about the port site (not shown). The outer housing may be constructed to permit a telescoping of the middle portion 110 so that the instrument can be shortened or lengthened at the discretion of, and to assist the comfort of, the surgeon. Such telescoping function may be obtained by constructing housing 160 out of several (such as two or more) interlocking or overlapping segments, as shown as elements 160-1, 160-2, and 160-3 in cross-sectional view in the inset of FIG. 3.

[0033] In some embodiments, outer housing 160 has a non-stick or low-friction coating such as Teflon® on its outer surface to facilitate insertion and removal through a port-site. Thus, during most periods of normal use, an area of middle portion 110 is disposed at the port site.

[0034] The instrument can therefore obtain certain degrees of freedom of movement by using the port site as if a fulcrum of a lever. For example, imagine two orthogonal and arbitrarily disposed axes (not shown in FIG. 2), fixed in space, and intersecting at the port site in a plane orthogonal to the longitudinal axis of the middle portion 110. The instrument can pivot about the port site in a direction parallel to each of those axes. Arbitrarily, motion parallel to one axis can be called pitching (motion 'up' and 'down' from one perspective), and motion parallel to the other axis can be called yawing (motion from 'side' to 'side'). Furthermore, any movement of the instrument in any other direction about that pivot can be presented as a linear combination of two components of motion in respectively directions parallel to the two aforementioned axes. Since middle portion 110 of the instrument is rigid or relatively rigid, such pitching or yawing motions, or combinations thereof, lead

to motions of the end effector, while inside the region of the patient that is receiving surgery. Such motions are effected by the surgeon, however, by a simple and intuitive motion of the handle without the need to learn specific control features. Thus, for example, a yawing of the handle end and the middle portion 110 in a leftwards direction as viewed by the surgeon looking down the instrument from handle end towards the patient, causes the end effector to move towards the right. This is far from counter-intuitive.

[0035] The instrument also gains a degree of freedom of movement, described as in-and-out motion, by moving the middle portion 110 relative to the port site in a direction along the longitudinal axis of the middle portion. Such a motion can also be brought about by the surgeon grasping the handle end of the instrument and pushing or pulling the instrument towards or away from the patient in order to access regions of the surgical field more or less remote from a current position of the end effector.

[0036] A still further degree of freedom of movement is obtained by rotating middle portion 110 of the instrument about its longitudinal axis. Such a motion can be carried out without simultaneously moving the instrument in and out of the patient, and without simultaneously moving the instrument in a pitch or yaw motion (as described herein), or in a combination of pitch and yaw motions. Thus, a surgeon holding handle 120 of the instrument can turn the handle in such a manner that the instrument rotates about a longitudinal axis down the middle portion and thereby causes the end effector to move. In this motion, the spatial relationship of the handle and effector to one another remains fixed and the entire instrument rotates.

[0037] The foregoing motions are, subject to the constraint imposed by the fixed location of the port-site through which the middle portion is situated, wholesale motions of the instrument. The instrument however additionally affords a surgeon control over various internal degrees of freedom, now described in conjunction with the exemplary embodiment of instrument 100 in FIG. 2.

[0038] End effector 130 may be equipped with one or more of a number of tools. Such tools include but are not limited to: needle drivers, needles of various gauges, scissors, staplers, graspers, forceps, clamps, electrocautery tools, lancets, drill-bits, rasps, trocars, cannula, dilators, specular microscopy tools, suction tips and tubes, irrigation and injection needles, powered devices such as drills and dermatomes, scopes and probes such as endoscopes and tactile probes, carriers and applicators

for optical, mechanical and electrical devices, ultrasound tissue disruptors, tissue cutting guides, and measurement tools such as calipers and rulers.

[0039] Exemplary handle 120 is shown in FIG. 2 as having a “scissors” construction, with a pair of finger pieces 125, 127. Other embodiments of handle 120, although not shown, are consistent with the description herein. For example, other embodiments of handle 120, may have a turning element that operates on a screw-thread; still other embodiments have one or more controls of electrical circuitry associated with the instrument; and yet other embodiments of handle 120 have still other types of hand grips or controls that permit a user to control internal and external degrees of freedom of the instrument as further described herein.

[0040] Shown in FIG. 2 is an exemplary tool 175 having two jaws that may be controlled by handle 120. One mechanism by which such control may be effected is by use of a wire 180 that connects tool 175 to handle 120. The wire may be attached to tool 175 and handle 120 by a number of different types of attachment. Shown in FIG. 2 is a protrusion 182 on finger piece 125, and a point on tool 175, to which wire 180 is affixed and which transmits a pushing or pulling force to jaws of tool 175 from finger-pieces 125 and 127 of handle 120. Wire 180 may be enclosed in a hollow flexible transmission shaft 192 as shown in the embodiment of FIG. 2 or in a separate flexible tubing (e.g., 188 in FIG. 3) to provide a path through which a pushing or pulling force on the wire produced by opening and closing the handle is transmitted to the effector jaws to open and close them. The separate tubing for this wire disposed within housing 160 is flexible to permit the wire to adjust its position as the instrument adopts various configurations during use. Thus, in use, the exemplary embodiment of FIG. 2 is configured so that when a surgeon closes finger pieces 125 and 127 of handle 120, wire 180 is pulled and correspondingly pulls jaws of tool 175 closed upon one another. Correspondingly, an opening motion of finger pieces 125 and 127 causes jaws of tool 175 to open. Other control methods can be contemplated by which a surgeon can utilize a tool attached to the effector end 130 by operating the handle 120, such as a single button on a grip to actuate electrocautery tools, or two levers to actuate a stapling device.

[0041] The embodiment in FIG. 2 is representative and demonstrates that operation of, for example, jaws of a scissors tool 175 as depicted is extremely intuitive and similar to the manner in which a pair of long handled scissors would be used during open surgery with the edge of the operative wound acting as a fulcrum for the long handle. The operation of the tool 175 as described

hereinabove can be accomplished when the instrument is disposed in, potentially, any angle or orientation with respect to the port site, and also in any of its other internal configurations as further described herein.

[0042] A further internal degree of freedom of an instrument as described herein, and as depicted in FIG. 2, is an angle of flexion, or as also referred to herein, an angle of angulation. A first angle of angulation (as previously described with respect to FIG. 1 herein) is defined as the angle subtended by longitudinal axis 121 of handle 120 with a longitudinal axis (not shown) of middle portion 110. Middle portion 110 is typically straight or approximately straight, as opposed to being curved, kinked, or zig-zagged, although one skilled in the art can conceive of embodiments of this instrument to be adopted in a fully flexible endoscope as well. Thus, first angle of angulation may be adjusted by moving handle 120 relative to middle portion 110. Such a motion is permitted because, at location 140, is a first flexing region such as a hinge or a series of hinges that permits relative motion of handle 120 with respect to middle portion 110, independently of other degrees of freedom described herein. First flexing region 140 is typically covered in an air-tight membrane 145 that seals the joint between handle 120 and middle portion 110 whilst permitting the relative motions of the two as described herein. Thus membrane 145 stops air from entering the middle portion of the instrument as well as permits flexibility of relative motion between two or more connected parts.

[0043] Similarly, a second angle of angulation may be changed by a motion of end effector 130 relative to middle portion 110. Such a motion is permitted because, at location 150, is a second flexing region such as a hinge or series of hinges that permits relative motion of end effector 130 with respect to middle portion 110, independently of other degrees of freedom described herein. Having a flexing region comprised of a hinge like member wherein the flexion can occur only in one plane offers advantages of precision and rigidity over other flexing or bending members that can roll or swivel independent of rotation of the middle member. It should be noted that this limitation of angulation of the effector and handle within a single plane offers no disadvantage in freedom of movement because all degrees of freedom of positioning and movement of the end effector can be accomplished by flexion of the end effector within a single plane and by the ability to rotate the end effector about this flexion axis in combination with rotation about the central axis of the middle member. Second flexing region 150 is also typically covered in an air-tight membrane 155, which may be akin to membrane 145, and that seals the joint between end effector 130 and middle portion 110 whilst permitting the relative motions of the two as described herein. Thus membrane 155 stops

air from entering middle portion 110 of the instrument as well as permits flexibility of relative motion between two or more connected parts. Membrane 155 also stops air leaking out of the middle portion of the instrument and into the body of the patient because membrane 155 will typically be disposed internally to the patient or subject during a surgical procedure.

[0044] An internal degree of freedom afforded by the instrument described herein is a coupled motion of first and second angles of angulation wherein a motion of handle 120 relative to middle portion 110, thereby changing the first angle of angulation, causes a corresponding change in the second angle of angulation between the end effector and middle portion 110. A coupling of these angular motions of handle and end effector can be achieved by joining a control member between handle 120 and effector 130. The control member can pass within the housing 160 of middle portion 110. The control member can be two wires 190 attached to suitable fixed points near the second flexing region 150 within the end effector 130, and to suitable fixed points near the first flexing region 140 within the handle 120. Thus, when in a staggered configuration as depicted in FIG. 2, one wire will be in tension, and the other wire will be relatively slack. Use of a pair of wires in this manner and, subject to appropriately chosen wire lengths, ensures that the wires will accurately keep the two angles of angulation in a one-to-one relationship with respect to one another. The action of the pair of wires may be duplicated by a wire loop that is fixed at two points, one at handle 120 (or finger-pieces 125, 127 in FIG. 2), and one at end effector 130, so that one arc of the loop is in tension when the other arc is relatively slack, and similarly in an opposite loop configuration.

[0045] It is understood that such a configuration is both ergonomically and intuitively advantageous for a surgeon. Thus the surgeon can envisage a line of sight down – or approximately down – the longitudinal axis of middle portion 110 and, by bringing his grip or lever based handle downwards away from him, immediately envisage a corresponding movement of the end effector upwards and towards him. Such a motion corresponds to using the instrument as a lever and is intuitively reasonable. It does not, however, preclude the possibility of configuring the instrument in other different configurations to suit a particular surgeon or a particular operating field. Thus, the handle 120 and end effector 110 need not be staggered with respect to one another as shown in FIG. 2, and need not be coplanar, as described by analogy with FIG. 1. To this end, instrument 100 may be equipped with a locking mechanism (not shown) that permits a surgeon to choose a preferred operating configuration (such as staggered, as shown in FIG. 2) and to lock the handle and end effector in that configuration with respect to one another for the duration of surgery, but

simultaneously permitting (and not limiting) the other degrees of freedom of movement described herein.

[0046] The function of wire 190 as depicted in FIG. 2 and as described hereinabove may be substituted by a rod 190, as shown in the embodiment of FIG. 3, which by being fixed in length and suitably rigid, has the effect of constraining the angular motions of handle 120 and effector 130 to be coupled to one another. Thus, in the embodiment of FIG. 3, if the surgeon moves handle 120 in a manner so as to open the first angle of angulation by a fixed amount, the second angle of angulation will also open by a corresponding fixed amount. The configuration of FIG. 3 shows handle 120 and end effector 130 staggered with respect to one another.

[0047] A further internal degree of freedom of movement of the instrument described herein is a rotation 202 of end effector 130 and tool 175 about longitudinal axis 131 of end effector 130, at a fixed axis of angulation. This additional internal degree of freedom is particularly advantageous because it permits a tool that has jaws, such as tool 175, to cut in any plane in space while maintaining a fixed orientation with respect to an item to be cut, or in suturing by turning a curved suture needle via the effector rotation. Rotation of end effector 130 and tool 175 about axis 131 may be accomplished at any angle of angulation and is independent of any change in angle of angulation.

[0048] Thus instrument 100 may be maneuvered through any number or combination of motions in other degrees of freedom, such as pitching about port site, moving in and out of port-site, or altering an angle of angulation, and then after such maneuvering, the end effector 130 may be rotated about internal axis of rotation 131 to provide further fine-scale adjustments to facilitate the surgical operation in question.

[0049] Of particular advantage is the manner, as depicted in exemplary form in FIG. 2, in which a rotation 202 of end effector 130 about axis 131 may be brought about. The surgeon, holding handle 120, may accomplish such a rotation simply by rotating handle 120 about longitudinal axis 121 of handle 120, as shown by arrow 201 in FIGs. 2 and 3. Accordingly, such a motion may be accomplished without imposing ergonomic stress and without requiring a control feature additional to the aspects of the handle heretofore described. In fact, just as the other degrees of freedom of instrument 100 as described herein may be accomplished by a motion – for example an angular motion – of handle 120, so may the rotation 202 of end effector 130 about axis 131 be achieved by a corresponding rotation 201 of the same handle 120 about axis 121 while maintaining, for example, a

fixed angle of angulation at the handle (*i.e.*, a fixed angle between axis 121 and a longitudinal axis of the middle portion 110). Rotations 201 and 202 correspond to variations of angles Ω_1 and Ω_2 respectively in FIG. 1.

[0050] A rotation of handle 120 about axis 121 is communicated to end effector 130, and translated into a corresponding rotation of end effector 130 and tool 175 about axis 131, by a transmission member that couples handle 120 and end effector 130. A transmission member typically comprises a number of parts. In particular, a transmission member includes various elements in the first and second flexing regions that permit communication of a rotation of handle 120 about axis 121 to a rotation of effector 130 about axis 131.

Flexible Drive Shaft

[0051] In some embodiments, as exemplified in FIG. 2, a transmission member comprises, for example, a flexible drive shaft 192 comprising a hollow cylindrical tube which is interrupted in the first and second flexing regions by spring based flexing tubes 195 and 197 that allow for flexing but retain sufficient torsional stiffness to accurately transmit rotational force about the longitudinal axis of the shaft from the handle to the effector.

[0052] FIG. 4 shows an example of a counterwoven spring based flexing region 195, 197 of a flexible drive shaft 192 for transmitting rotational motion from handle to effector end. Such a spring based flexing region is comprised of outer and inner coaxial springs that are wound in opposing directions so that one provides torsional stiffness in one rotational direction and the other spring torsional stiffness in the opposite rotational direction. An advantage of such a construction is that it is streamlined, concentric with the transmission member, and also that the transmission shaft is hollow thereby permitting other control features such as a control wire for opening and closing the jaws of an effector end to simply go through the drive shaft.

Universal Joints

[0053] In other embodiments of the instrument described herein, the first and second flexing regions each comprise one or more universal joints, as shown by way of example in FIG. 3. First and second universal joints 194, 196, if used, are attached respectively to the handle 120 and end effector 130. Through their respective connections to the rotational shaft 192 of the transmission member, a

rotation of handle 120 about axis 121 is communicated into an equivalent rotation of end effector 130 about axis 131.

[0054] FIGs. 5A and 5B show examples of a universal joint 400 that can be part of a flexible drive shaft in another embodiment of the instrument described herein. It would be understood by one skilled in the art that a number of different rotational flexing joints can also be put in place of such a joint, including, but not limited to, a “Constant Velocity” joint, “Cardan”, “Double Cardan” joint, Hardy-Spicer joint, U-joint, Thompson coupling, Hooke joint, etc. Exemplary universal joint 400 in FIG. 5A has two pieces 401 and 402, connected to one another via gimbal 403. Similarly, the joint in FIG. 5B, shown in perspective view, has two pieces interconnected by a gimbal. It is further understood that the term “universal joint” is not intended to be limited to a specific joint. It is to be understood that a number of different mechanical joints may be suitable to achieve the rotational flexibility of the device herein. Many such joints may be referred to, in the art, as “universal joints”. Thus the term “universal joint” is used herein to refer to a type of joint that permits rotational as well as bending degrees of freedom in the manner described in connection with the instrument herein.

[0055] FIG. 6 shows (in exploded view) another embodiment 600 of a universal joint, for use with surgical instruments herein, wherein the gimbal 603 has an aperture 604, such as a centrally positioned aperture, that permits a control member (not shown) that passes through both of the hollow shafts 601, 602 on either side of the gimbal to also pass through the gimbal with no or minimal inhibition of freedom of operation of the universal joint. Such a control member, if present, could follow an axis aligned with dashed line 605 and can also function with a shaft in a flexed conformation. The embodiment of FIG. 6 is advantageous at least because, with a control member such as 180 (in FIG. 2) passing through the internal structure of the shafts and joint, the overall thickness of the instrument is reduced relative to embodiments in which a control member runs along the outside of the transmission member. As an alternative, however, to the gimbal shown in FIG. 6, an external ring gimbal may be used. In such an embodiment, as would be understood by those of skill in the art, the gimbal ring is positioned external to the joint where the shafts couple with one another.

[0056] The embodiment in FIG. 6 is particularly suited for use in a surgical instrument as described herein because shafts 601, 602 are shaped so that they connect to gimbal 603 without having an increased diameter in the region of the gimbal. It is advantageous if all portions of the

transmission member are as narrow as possible, including in joint regions. Universal joint 600 may be engineered in this way regardless of whether any of the shafts 601, 602 or gimbal 603 is hollow.

[0057] Any of the options shown in FIGs. 5A, 5B and 6 may be utilized in an embodiment of the present instrument if the flexible drive shaft configuration allows for sufficient lateral flexibility with torsional stiffness and axial stiffness in appropriate locations. Thus it is to be understood that the technology described herein is not limited to use of specific universal joints as depicted in the embodiment of FIG. 3.

[0058] In use, a surgeon, holding handle 120, and looking down the middle portion of the instrument towards the patient, can twist handle 120 about axis 121 in the manner of an internal rotation of handle 120 while keeping a particular flexed angle of angulation, and envisage a corresponding and simultaneous rotation of end effector 130 about axis 131. The universal – or other – joints can be chosen so that the angles rotated through by handle 120 and end effector 130 are the same and in the same sense (*i.e.*, both are clockwise when looking down the same axis). The joints can also be chosen such that the angles rotated through by handle and end effector are equal in magnitude but opposite in sense, or can be chosen such that the angles are a constant ratio of one another and in the same or opposite senses. Thus, for example, it may be desirable to have a small twisting motion of the handle translate into a larger motion of the end effector, or it may be desirable for a large motion of the handle to translate into a smaller motion of the end effector.

[0059] It would be understood by one of skill in the art that a universal joint – or some equivalent joint – although providing a beneficial degree of flexibility, may give rise to certain undesirable constraints such as certain restrictions on angular variation. In such instances, one or more of the universal joints may be replaced by a pair of universal joints coupled to one another.

Methods of use

[0060] Accordingly, with respect to the present technology, as exemplified by the embodiment of FIGs. 2 and 3, independent motions of a handle 120 may be communicated into corresponding independent motions of end effector 130 and tool 175 in such a manner that control of the tool is provided in multiple degrees of freedom. It should be noted that separate and independent control mechanisms to effect changes in angulation with stable and torsionally rigid hinge joints and to effect changes in effector rotation with a separate drive shaft are particularly advantageous in that they provide a high level of precision and rigidity in the use of the instrument. Although it is consistent

with the spirit of the present technology that such degrees of freedom are controlled solely by motions – such as but not limited to rotations and angulation – of the handle, it is possible that one or more such motions may be controlled by separate and additional control features that are disposed in convenient locations readily accessible to the surgeon during use and without resulting in ergonomic stress.

[0061] It is also to be understood that the surgical instrument as described herein permits simple control of motion of the end effector in at least seven degrees of freedom, including one that corresponds to an internal motion – such as a cutting motion – of a tool at the end effector.

[0062] Through the advantages of construction described herein, a surgeon, using an embodiment of the instrument described herein may carry out any form of minimally invasive surgery, particularly laparoscopy, thoracoscopic, or endoscopic surgery on a subject, such as a human patient. Applications in veterinary surgery, such as carried out on domestic pets or agricultural animals, are also within the scope of use of the instrument described herein.

[0063] The instrument may also be used in conjunction with an imaging tool, such as an MRI scanner, or an ultrasound imager, that assists a surgeon in locating an internal region of a subject, at which to direct the end effector.

[0064] It is to be understood that variations of scale and form of the instrument described herein are consistent with the features and operation described herein. Thus, in some surgeries, more than one instance of the instrument – for instance having different sizes or equipped with different end effectors – may be deployed as needed in a given operation.

[0065] In some embodiments, the instrument – or one or more pieces thereof – is designed for a single use only, whereas in others it may be re-used, such as after having been cleaned and sterilized.

[0066] In some embodiments, the instrument is additionally connected, such as by a wire, to a foot-activated pedal that is configured to actuate the effector or a tool attached thereto.

Methods and materials of manufacture

[0067] It is known in the art that various flexible drive shaft embodiments can be made using solid wires, plastics, composites (especially those chosen for having appropriate axial and/or torsional rigidity), wound springs, braided cables, and with rigid materials such as gimbal based universal

joints as in FIGs. 5A, 5B, and 6 (*i.e.*, both with and without apertures), constant velocity joints, and other flexible rotational joints. Such materials are consistent with the instrument described herein.

[0068] Additionally, materials used for manufacture of various parts of the instrument, such as the end effector, handle, or middle portion, include surgical grade stainless steel, titanium, or other metal.

[0069] Various embodiments of the instrument described herein for use in different types of surgeries are also contemplated. Thus, the various embodiments may differ from one another in one or more dimensions, such as, but not limited to, length or thickness of middle portion. Other instances of the instrument may differ from one another in scale. Thus, different embodiments may differ from one another by a scale factor in the range 1 – 10.

[0070] Still other embodiments of the instrument are manufactured with a set of optional, removable, end effectors. Thus, an instrument may be made available as a kit, having a common middle portion, and a set of choosable and interchangeable end effectors (with one or more corresponding handle pieces, as applicable).

EXAMPLES

Example: Minimally Invasive Surgical Instrument

[0071] FIG. 3 shows an embodiment of the instrument described herein using a universal joint based flexible drive shaft.

[0072] In a further embodiment, not shown, the embodiment of FIG. 3 is configured with one or more universal joints having a gimbal with an aperture, as shown in FIG. 6, or an external ring gimbal, and hollow shafts 192 on either side thereof. Such an embodiment permits a control member 190 such as a rod or a wire to be disposed through the central shaft of the transmission member, thereby reducing the overall thickness of the middle portion 110 and outer housing 160.

[0073] The foregoing descriptions are intended to illustrate various aspects of the present technology. It is not intended that the examples presented herein limit the scope of the present technology. The technology now being fully described, it will be apparent to one of skill in the art that many changes and modifications can be made thereto without departing from the spirit or scope of the appended claims.

WHAT IS CLAIMED:

1. A surgical instrument, comprising:
a handle having a first axis;
a middle portion having a second axis that intersects the first axis; and
an end effector having a third axis that intersects the second axis,
wherein the first axis and the second axis subtend a first angle, and the third axis and the second axis subtend a second angle;
and wherein the instrument is configured to have at least the following degrees of freedom of movement:
 - an opening or closing of the second angle, thereby causing the end effector to move in a plane containing the third axis and the second axis, accomplished by a flexion of the handle that, correspondingly, opens or closes the first angle;
 - a rotation of the end effector about the third axis, accomplished by a corresponding rotation of the handle about the first axis and communicated through the middle portion independently of the opening or closing of the first or second angle.
2. The instrument of claim 1, wherein the first, second, and third axes are coplanar or collinear with one another.
3. The instrument of claim 1 wherein the middle portion comprises a flexible drive shaft.
4. The instrument of claim 3 wherein the flexible drive shaft is hollow.
5. The instrument of claim 3 wherein the flexible drive shaft has a rigid member interrupted by spring based flexing regions.
6. The instrument of claim 3 wherein the flexible drive shaft has one or more composite components.
7. The instrument of claim 3 wherein the flexible drive shaft has one or more plastic components.

8. The instrument of claim 3 wherein the flexible drive shaft has one or more woven components.
9. The instrument of claim 3 wherein a wire for controlling the effector runs coaxially or inside the flexible drive shaft.
10. The instrument of claim 1 wherein the middle portion comprises two or more joints selected from the group consisting of: universal joints, double cardan, Hooke, and constant velocity.
11. The instrument of claim 10, wherein a first universal joint is situated at the intersection of the first axis and the second axis, and wherein a second universal joint is situated at the intersection of the second axis and the third axis.
12. The instrument of claim 10, wherein a first pair of universal joints is situated at the intersection of the first axis and the second axis, and wherein a second pair of universal joints is situated at the intersection of the second axis and the third axis.
13. The instrument of claim 10, wherein the middle portion comprises two or more hollow shafts, and at least one of the universal joints comprises a gimbal that couples a pair of hollow shafts, and wherein the gimbal has a central aperture or is an external ring gimbal.
14. The instrument of claim 13, wherein a control member for controlling the effector passes through the hollow shafts and the gimbal.
15. The instrument of claim 1, wherein, during use, the middle portion is situated in a port site in the body of a subject, and wherein the degrees of freedom of movement of the instrument additionally comprise:
 - 1) sliding the middle portion into and out of the port site;
 - 2) levering the effector end up and down with the port site as the fulcrum point;
 - 3) levering the effector end sideways to the left and right with the port site as the fulcrum point;
 - 4) rotating about the second axis; and
 - 5) opening and closing jaws of a tool on the effector portion.

16. The instrument of claim 1, wherein a tool is removably affixed to the effector distal to the middle portion.
17. The instrument of claim 16, wherein the instrument is partially or wholly disposable.
18. The instrument of claim 16, wherein the tool has two or more jaws, and the two or more jaws may be opened and closed by the handle.
19. The instrument of claim 15, wherein all motions are controlled by the handle.
20. The instrument of claim 15, wherein control of the motions is accomplished without assistance of a robot or a computer.
21. The instrument of claim 1, configured to be controlled by a robot or a computer.
22. The instrument of claim 1, wherein the middle portion is coated in a low-friction substance to facilitate sliding the instrument in and out of a port in the body of a subject.
23. The instrument of claim 15, wherein the low-friction substance is Teflon.
24. The instrument of claim 1, wherein the middle portion comprises one or more telescoping components that permit the instrument to be extended or shortened in length.
25. A surgical instrument, comprising:
 - a central member having a proximal end and a distal end;
 - a proximal handle connected to the proximal end of the central member at a point within a first flexing region;
 - a distal effector connected to the distal end of the central member at a point within a second flexing region;
 - a control member coupling the proximal handle to the distal effector, wherein the control member is configured to communicate a first angle of angulation between the handle and the central member to a corresponding second angle of angulation between the effector and the central member; and

a transmission member coupling the proximal handle to the distal effector, wherein the transmission member comprises a flexible drive shaft that can flex in both the first flexing region and the second flexing region, wherein the transmission member is configured so that, independent of a motion of the control member, a rotation of the handle about an axis passing through the handle and at a first angle of angulation with respect to the central member is communicated to a rotation of the effector about an axis passing through the effector at a second angle of angulation with respect to the central member.

26. The instrument of claim 25, wherein the control member is a rod or a pair of cables.
27. The instrument of claim 25, wherein the central member comprises an outer housing made of plastic or metal.
28. The instrument of claim 27, wherein the outer housing of the central member is coated in a non-stick material.
29. The instrument of claim 28, wherein the non-stick material is Teflon.
30. The instrument of claims 1 or 28 wherein the instrument is electrically insulated to allow for use with electrocautery.
31. The instrument of claim 25, wherein the handle comprises a pair of levers such as but not limited to scissor handles, plier handles, or forcep handles and further comprises a tool attached to a distal end of the effector, wherein the levers of the handle and the tool are both configured to carry out an opening and closing motion, and the instrument further comprises a coupling element that communicates an opening or closing motion of the handle to a corresponding opening or closing motion of the tool.
32. The instrument of claim 25 wherein the handle comprises a rod grip with a button wherein the button activates or operates the effector.

33. The instrument of claim 31 wherein the central member, the coupling element, and the transmission members can all telescope on themselves, thereby permitting the instrument to lengthen or shorten.
34. The instrument of claim 25, wherein the first angle of angulation of the handle and the second angle of angulation at the effector are the equal to one another, and wherein a change in the first angle of angulation produces an equal change in the second angle of angulation.
35. The instrument of claim 34, wherein the first angle of angulation of the handle and the second angle of angulation at the effector are different from one another but are related to one another by a constant ratio.
36. The instrument of claim 25 wherein the central member comprises a flexible drive shaft.
37. The instrument of claim 36 wherein the flexible drive shaft is hollow.
38. The instrument of claim 36 wherein the flexible drive shaft has a rigid member interrupted by spring based flexing regions.
39. The instrument of claim 36 wherein the flexible drive shaft has one or more composite components.
40. The instrument of claim 36 wherein the flexible drive shaft has one or more plastic components.
41. The instrument in claim 36 wherein the flexible drive shaft has one or more woven components.
42. The instrument in claim 36 wherein a wire for controlling the effector runs coaxially or inside the flexible drive shaft.
43. The instrument of claim 25, wherein, during use, the central member is situated in a port site in the body of a subject, and wherein the degrees of freedom of movement of the instrument additionally comprise:

- 1) sliding the central member into and out of the port site;
- 2) levering the effector end up and down with the port site as the fulcrum point;
- 3) levering the effector end sideways to the left and right with the port site as the fulcrum point;
- 4) rotating about the second axis; and
- 5) opening and closing jaws of a tool on the effector portion.

44. The instrument of claim 43, wherein control of the degrees of freedom is accomplished without assistance of a robot or a computer.

45. A surgical instrument, comprising:

- a central member having a proximal end and a distal end;
- a proximal handle connected to the proximal end of the central member at a point within a first flexing region;
- a distal effector connected to the distal end of the central member at a point within a second flexing region;
- a control member coupling the proximal handle to the distal effector, wherein the control member is configured to communicate a first angle of angulation between the handle and the central member to a corresponding second angle of angulation between the effector and the central member; and
- a transmission member coupling the proximal handle to the distal effector, wherein the transmission member comprises a first universal joint connected to the proximal handle in the first flexing region, and a second universal joint connected to the distal effector in the second flexing region, and a rigid coupling member coupling the first and second universal joints to one another, and wherein the transmission member is configured so that a rotation of the handle about an axis passing through the handle and at a fixed first angle of angulation is communicated to a rotation of the effector about an axis passing through the effector and also at a fixed second angle of angulation.

46. The instrument of claim 45, wherein the first flexing region comprises an additional universal joint coupled to the first universal joint and the proximal handle.

47. The instrument of claim 45, wherein the second flexing region comprises an additional universal joint coupled to the second universal joint and the distal effector.

48. The instrument of claim 45, wherein each of the first and second universal joints is independently selected from the group consisting of: universal joint, constant velocity joint, U joint, Cardan joint, Hardy-Spicer joint, or Hooke's joint.

49. The instrument of claim 45, wherein the central member comprises a hollow shaft, and wherein one or more of the proximal handle and the distal effector also comprise a hollow shaft, and at least one of the universal joints comprises a gimbal that couples two of the hollow shafts, and wherein the gimbal has a central aperture or is an external ring gimbal.

50. The instrument of claim 49, wherein a control member for controlling the effector passes through the two hollow shafts and the gimbal.

51. The instrument of claim 45, additionally comprising a tool, attached to a distal end of the effector, wherein the tool is selected from the group consisting of: scissors, staplers, graspers, needle holders, electrocautery devices, drills, screwdrivers, and other useful surgical implements.

52. The instrument of claim 45, wherein the handle comprises two independently movable pieces, controlled by: a multiple fingers and a thumb, two fingers; or a finger and a thumb.

53. The instrument of claims 25 or 45, wherein the first and second flexing regions are sealed within an air-tight covering.

54. The instrument of claim 53, wherein the air-tight covering is a flexible membrane.

55. A handheld minimally invasive surgical instrument comprising a handle, an effector, and a central member, wherein the handle and the effector can be configured to adopt a collinear and a staggered configuration with respect to a longitudinal axis of the central member, and wherein a flexible transmission member permits a rotation of the handle about a handle axis that is not collinear with or parallel to the axis of the central member, to cause a rotation of the effector about an effector

axis that is not collinear with or parallel to the axis of the central member when the handle and the effector are in a staggered configuration.

56. The instrument of claim 55, wherein the flexible transmission member has a rigid member interrupted by spring based flexing regions.

57. The instrument of claim 55, wherein a wire for controlling the effector runs coaxially or inside the flexible drive shaft.

58. The instrument of claim 1, wherein a tool is removably affixed to the effector distal to the central member.

59. The instrument of claim 58, wherein the tool has two or more jaws, and the two or more jaws may be opened and closed by the handle.

60. The instrument of claim 55, wherein the instrument is partially or wholly disposable.

61. The instrument of claim 55, wherein all motions are controlled by the handle.

62. The instrument of claim 55, wherein the central member is coated in a low-friction substance to facilitate sliding the instrument in and out of a port in the body of a subject.

63. The instrument of claim 55, wherein the central member comprises one or more telescoping components that permit the instrument to be extended or shortened in length.

64. The instrument of claim 55, wherein the central member comprises a flexible drive shaft.

65. The instrument of claim 64, wherein the flexible drive shaft is hollow.

66. The instrument of claim 64, wherein the flexible drive shaft has a rigid member interrupted by spring based flexing regions.

67. The instrument of claim 65 wherein the flexible drive shaft has one or more composite components.

68. The instrument of claim 65 wherein the flexible drive shaft has one or more plastic components.

69. The instrument in claim 65 wherein the flexible drive shaft has one or more woven components.

70. The instrument of claims 4 or 55 wherein the instrument is electrically insulated to allow for use with electrocautery.

71. The instrument of any one of claims 1, 25, 45, or 55, wherein the instrument is additionally connected to a foot pedal that is configured to actuate the effector or a tool attached thereto.

72. A surgical instrument having a transmission member comprising one or more universal joints, wherein the one or more universal joints each comprise a gimbal configured with a sufficiently large central aperture to permit a control member disposed in a central axis of the transmission member to pass through the central aperture.

73. A method of using a surgical instrument according to any one of the preceding claims, in a surgical operation on a subject.

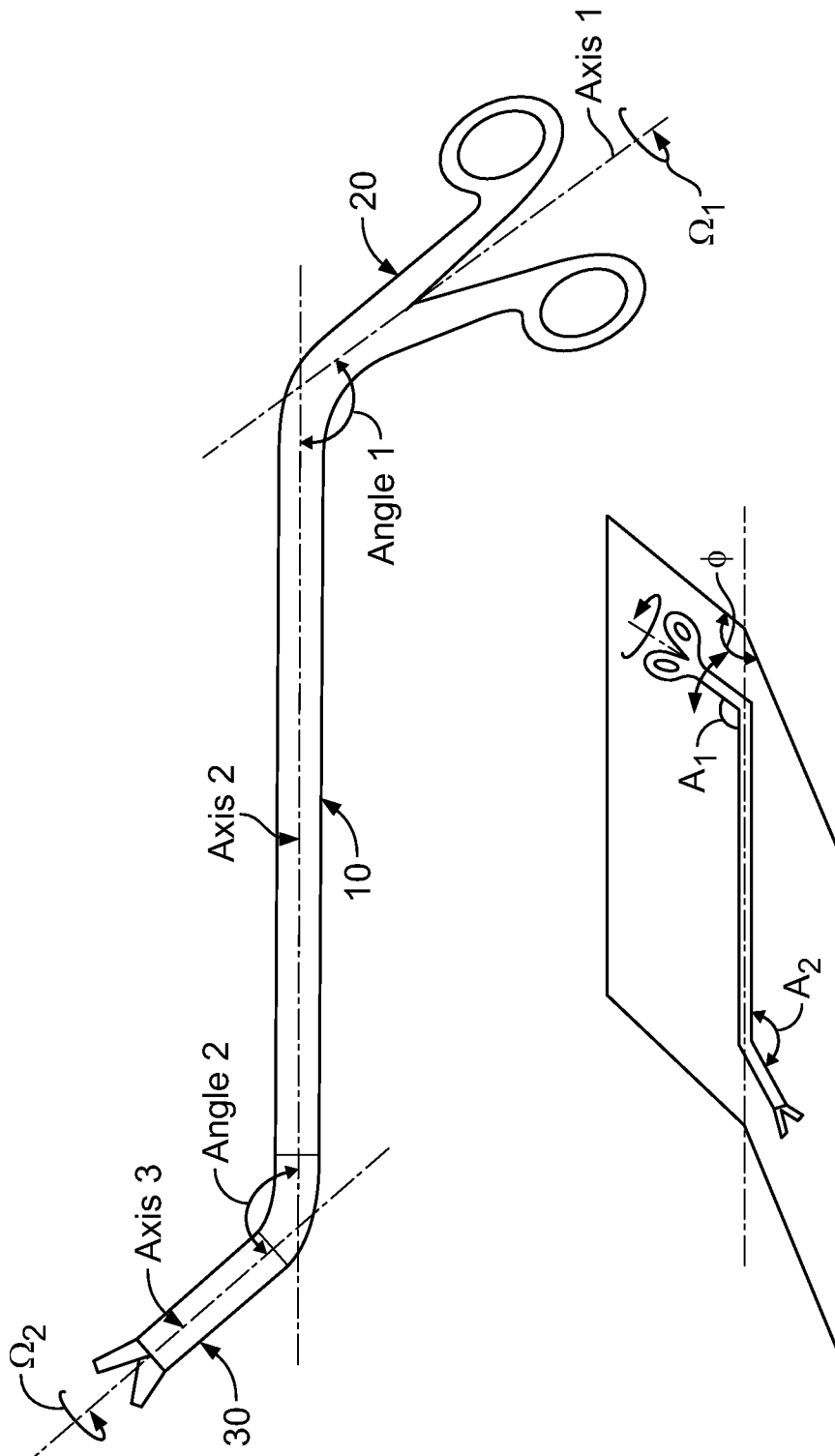
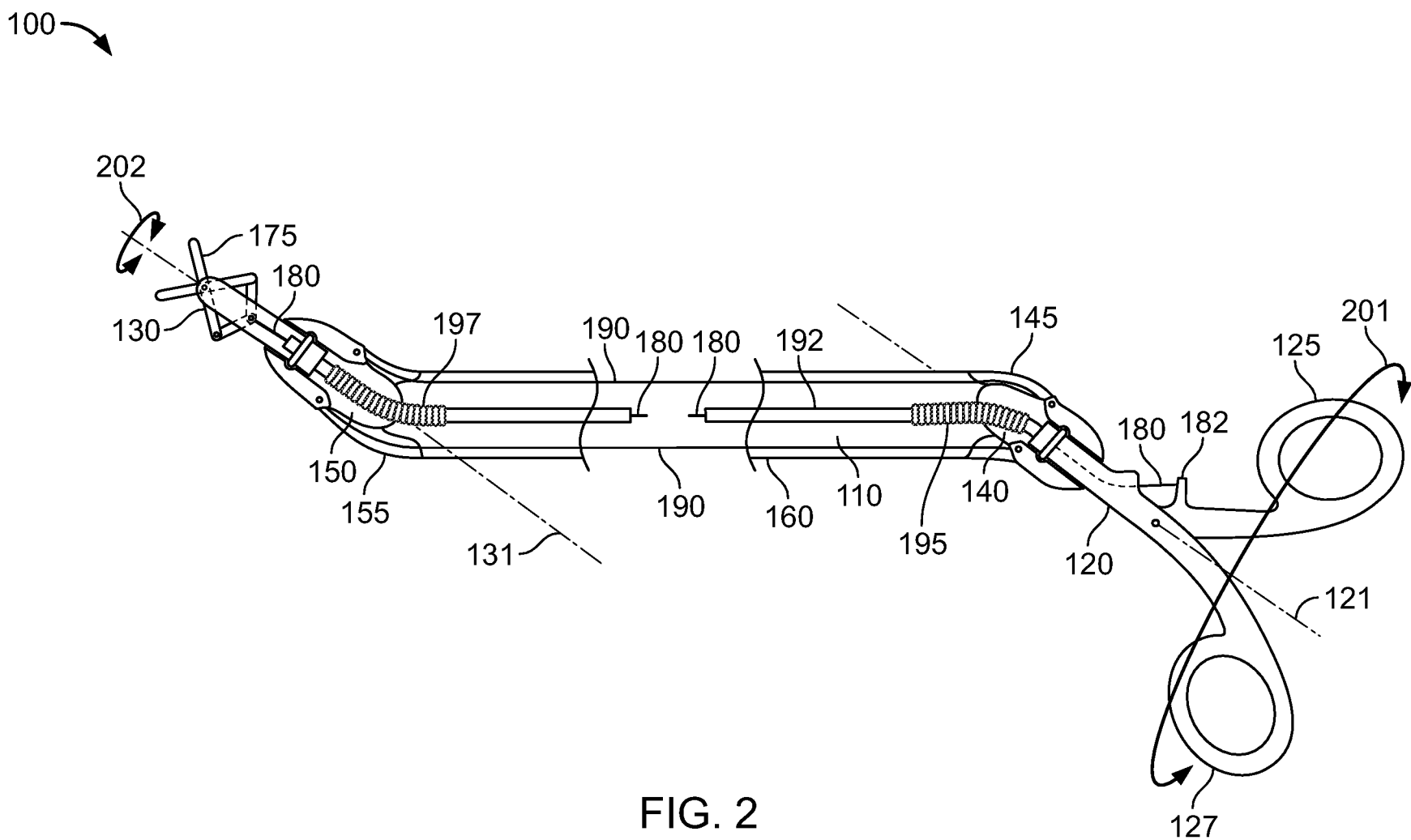


FIG. 1

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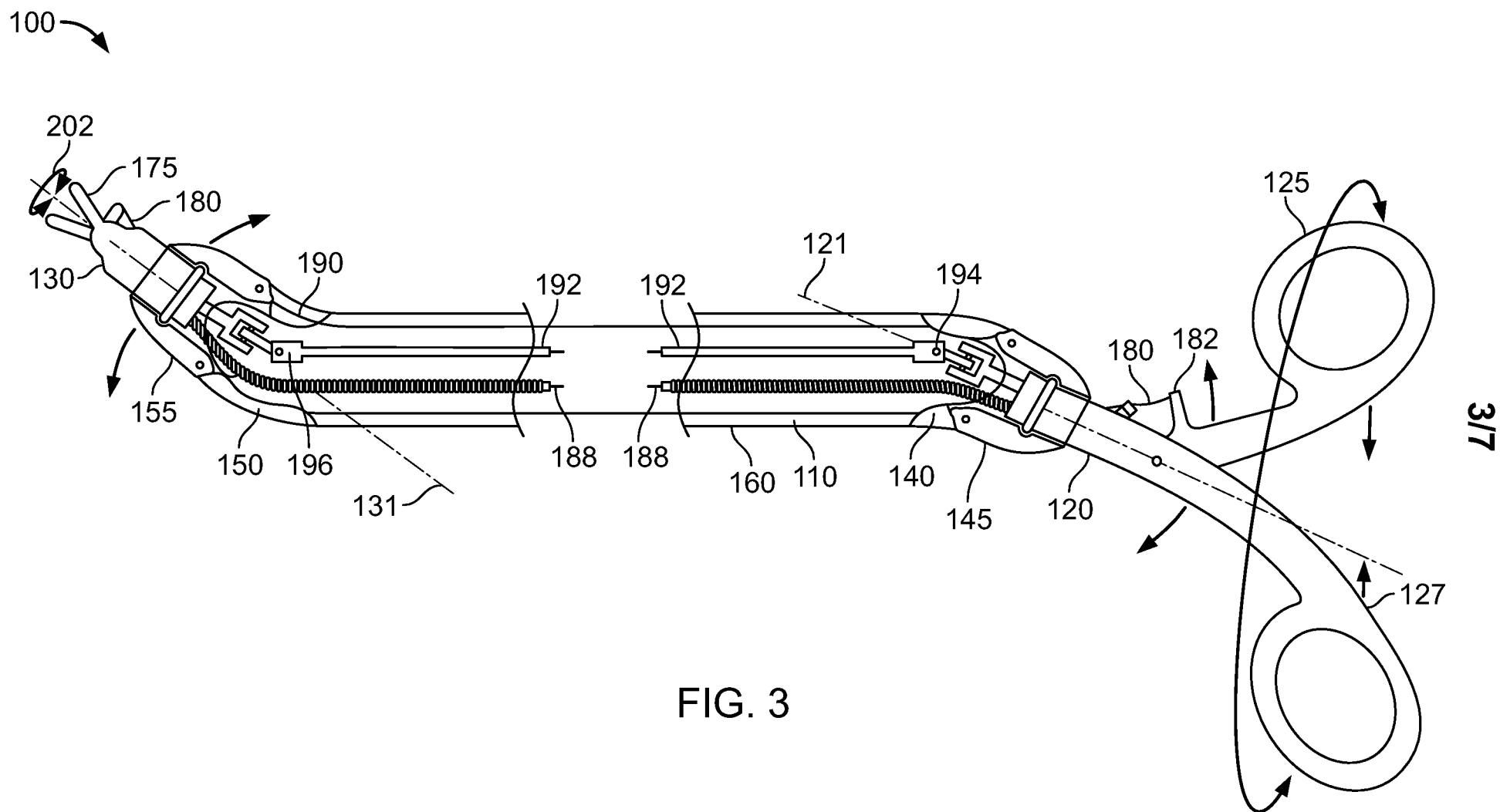


FIG. 3

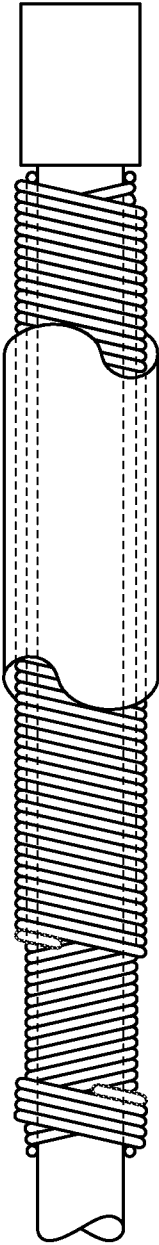


FIG. 4

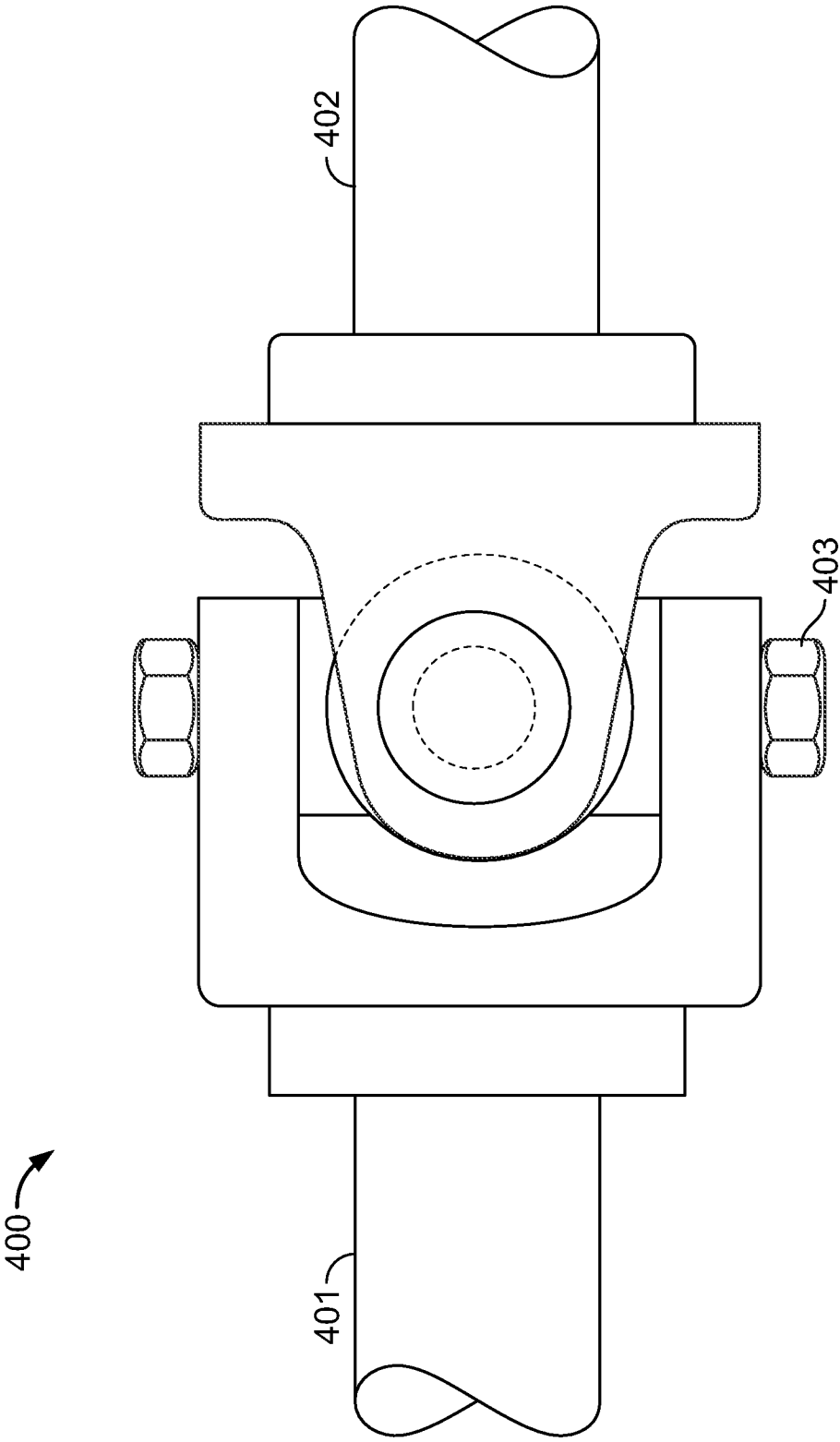


FIG. 5A

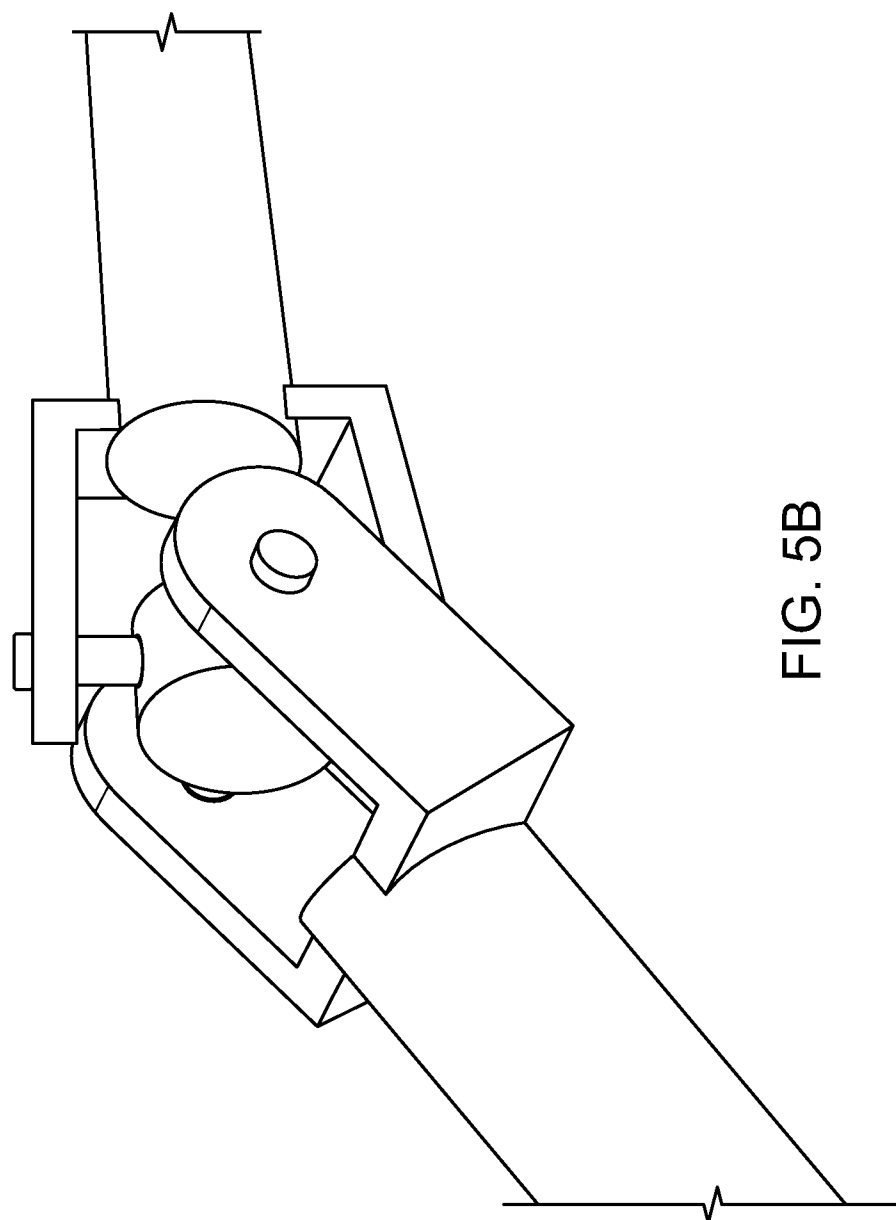


FIG. 5B

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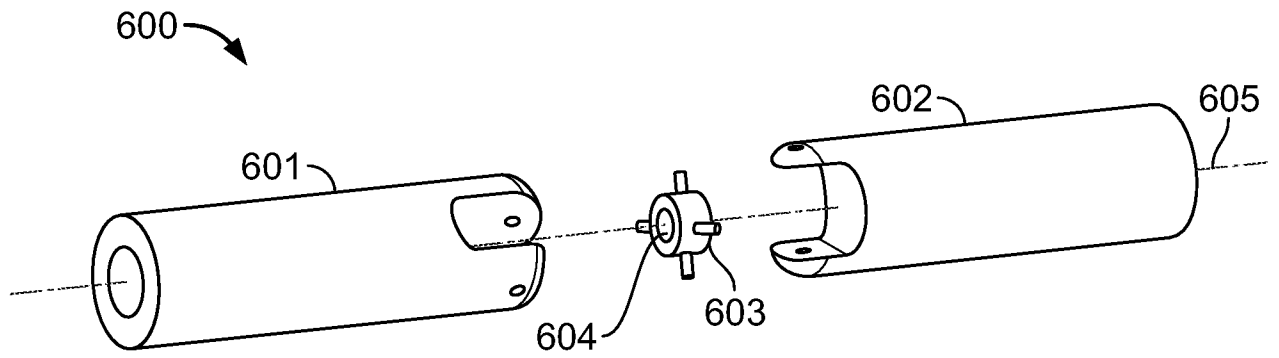


FIG. 6