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Medical device with multiple degrees of freedom and related methods

Abstract

A medical device having multiple degrees of freedom independent of each other. The medical device includes a handle, an end effector, and a tubular section extending between the handle and the end effector. The end effector is configured to be rotated about a first axis extending through the tubular section without rotating the tubular section. And, the tubular section is configured to be rotated about the first axis with the end effector.

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Background/Summary

(1) This application is a § 371 National Stage Application of pending International Application No. PCT/IB2020/001038, filed Dec. 8, 2020, which claims the benefit of priority from U.S. Provisional Application No. 62/946,483, filed Dec. 11, 2019, each of which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

(1) Various aspects of this disclosure generally relate to medical devices for manipulating and/or treating tissue during a procedure. In particular, aspects of this disclosure relate to medical devices having multiple degrees of freedom and methods for performing a procedure using the disclosed devices.

BACKGROUND

(2) A wide variety of medical techniques and instruments have been developed for diagnosis and/or treatment within a patient's body, such as within a patient's gastrointestinal (GI) tract. Endoscopic mucosal resection (EMR), endoscopic sub-mucosal resection (ESR), polypectomy, mucosectomy, etc., are minimally invasive treatment methods for both malignant and non-malignant lesions. Endoscopic medical procedures, such as, for example, EMR, may be used to excise sessile adenomas or other unwanted tissue (e.g., tumors attached to a bodily surface) from the surface of an anatomical lumen. Such procedures often require the resection of one tissue plane while leaving an underlying tissue plane intact. Commonly, during such medical procedures, endoscopic medical devices (such as, for example, snares, graspers (e.g., hemostatic forceps), radiofrequency (RF) knives, etc.) are inserted into the body, through the lumen of a delivery scope (such as, for example, an endoscope, gastroscope, colonoscope, bronchoscope, laryngoscope, cystoscope, duodenoscope, enteroscope, ureteroscope, etc., or another device having a lumen), and used for resecting tissue from a target site within the patient's body.

(3) However, many conventional endoscopic medical devices operate in only one degree of freedom, for example, into and out of the delivery scope. In such devices, the distal tip of the delivery scope is deflected from side-to-side to move the medical device side-to-side within the body. That is, manipulation of the medical device inside the body is dependent on the tip deflection of the delivery scope used to insert the device into the body. Thus, the maneuverability of the endoscopic medical device and the ability to control the device within the body may be limited. Additionally, the user may be required to hold and/or manipulate the delivery scope with one hand, and hold and/or manipulate the medical devices introduced into the body through the delivery scope with the other hand. Additionally or alternatively, additional medical professionals may be required to assist the user with holding and/or manipulating the delivery scope and/or the inserted medical devices. These limitations may increase the duration, cost, and/or complexity of the medical procedure. Embodiments of the disclosed medical devices and methods may rectify some of the above-described deficiencies and/or address other aspects of the art. The scope of this disclosure, however, is defined by the attached claims, and not by the ability to solve any specific problem.

SUMMARY

(4) Embodiments of this disclosure relate to, among other things, medical devices and methods for performing medical procedures using these medical devices. Each of the embodiments disclosed herein may include one or more of the features described in connection with any of the other disclosed embodiments.

(5) In some embodiments, a medical device is disclosed. The medical device may include a handle,

an end effector, and a tubular section extending between the handle and the end effector. The end effector may be configured to be rotated about a first axis extending through the tubular section without rotating the tubular section. And, the tubular section may be configured to be rotated about the first axis with the end effector.

(6) Various embodiments of the disclosed medical device may alternatively or additionally include one or more of the following features: the handle may include a rotation actuator, wherein actuation of the rotation actuator may rotate the end effector about the first axis without rotating the tubular section; the end effector may be rotatably coupled to the tubular section such that the end effector can rotate about the first axis with the end effector; the handle may include an actuation actuator configured to actuate the end effector; the medical device may further include a core wire extending through the tubular section and coupled to the actuation actuator and the end effector, wherein actuation of the actuation actuator may cause translation of the core wire in the handle; the core wire may be rotatably coupled to the actuation actuator, and wherein actuation of the rotation actuator may rotate the core wire in the actuation actuator; wherein a cavity in the rotation actuator may accommodate the core wire and have one or a square, a rectangular, a triangular, or a polygonal cross-sectional shape; a hypotube may be attached to a portion of the core wire extending through the cavity of the rotation actuator, the hypotube may have a same cross-sectional shape as the cavity; actuation of the actuation actuator may cause the hypotube to translate with the core wire in the cavity of the rotation actuator; the medical device may further include (a) an articulation region coupled to a distal end of the tubular section and (b) a steering actuator on the handle, wherein actuation of the steering actuator may bend the articulation region in a first plane passing through the first axis; the medical device may further include one or more steering wires coupled to the steering actuator and extending through the articulation region along the first plane, wherein actuation of the steering actuator may apply tension to at least one of the one or more steering wires to bend the articulation region in the first plane; the articulation region may include multiple links that are rotatably coupled together; the one or more steering wires may include one steering wire or two steering wires.

(7) In some embodiments, a method of using a medical device including a handle, an end effector, and a tubular section extending between the handle and the end effector is disclosed. The method may include rotating the end effector about a first axis extending through the tubular section, without rotating the tubular section. The method may also include rotating the tubular section about the first axis with the end effector.

(8) Various embodiments of the disclosed method may alternatively or additionally include one or more of the following features: rotating the end effector may include actuating a rotation actuator on the handle, and rotating the tubular section may include rotating the handle; the method may further include inserting at least a portion of the tubular section into a body cavity prior to rotating the end effector and rotating the tubular section.

(9) In some embodiments, a medical device is disclosed. The medical device may include a handle including a steering actuator, a rotation actuator, and an actuation actuator. The medical device may also include an end effector configured to be actuated by the actuation actuator, and a tubular section extending between the handle and the end effector. Actuation of the rotation actuator may be configured to rotate the end effector about a first axis extending through the tubular section without rotating the tubular section. And, rotation of the handle may be configured to rotate the tubular section about the first axis with the end effector.

(10) Various embodiments of the disclosed medical device may alternatively or additionally include one or more of the following features: the medical device may further include a core wire coupled to the end effector and extending through the tubular section, the core wire may be coupled to the actuation actuator and the rotation actuator such that (a) actuation of the actuation actuator causes translation of the core wire in the handle, and (b) actuation of the rotation actuator rotates the core wire in the handle; the core wire may extend through a cavity in the rotation actuator, and wherein

(a) the cavity may have one of a square, a rectangular, a triangular, or a polygonal cross-sectional shape, and (b) a hypotube may be attached to a portion of the core wire extending through the cavity, the hypotube may have the same cross-sectional shape as the cavity; actuation of the actuation actuator may cause the hypotube to translate with the core wire in the cavity.

(11) It may be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the disclosure, as claimed.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate exemplary aspects of this disclosure and together with the description, serve to explain the principles of the disclosure. For simplicity and clarity of illustration, the figures depict the general structure and/or manner of construction of the various embodiments described herein. Descriptions and details of well-known features and techniques may be omitted for brevity and to avoid obscuring other features. Elements in the figures are not necessarily drawn to scale. The dimensions of some features in the illustrated figures may be exaggerated relative to other features to improve understanding of the exemplary embodiments. Cross-sectional views are simplifications provided to help illustrate the relative positioning of various regions and/or components. One skilled in the art would appreciate that the cross-sectional views are not drawn to scale and should not be viewed as representing proportional relationships between different regions and/or components.

(2) FIG. 1 illustrates medical devices of this disclosure performing an exemplary medical procedure.

(3) FIG. 2 illustrates an exemplary medical device used in the medical procedure of FIG. 1.

(4) FIGS. 3A-3C illustrate different views of an exemplary handle of the medical device of FIG. 2.

(5) FIGS. 4A-4F illustrate different regions/components of the handle of the medical device of FIG. 2.

(6) FIGS. 5A-5D illustrate the tubular portion of the medical device of FIG. 2 in different exemplary embodiments.

(7) FIGS. 6A-6G illustrate different regions/components of the articulation region of the medical device of FIG. 2.

(8) FIGS. 7A-8B illustrate different regions/components of the distal portion of the medical device of FIG. 2.

(9) FIGS. 9A-9D illustrate different embodiments of articulation regions that may be used in the medical device of FIG. 2.

(10) FIGS. 10A-10D illustrate different regions/components of an exemplary steering knob that may be used in the medical device of FIG. 2.

(11) FIGS. 11A-11G are schematic illustrations of exemplary operating modes of the medical device of FIG. 2

DETAILED DESCRIPTION

(12) It should be noted that the description set forth herein is merely illustrative in nature and is not intended to limit the embodiments of the subject matter, or the application and uses of such embodiments. Any device, method, or implementation described herein as exemplary is not to be construed as preferred or advantageous over other implementations. Rather, the term “exemplary” is used in the sense of example or “illustrative,” rather than “ideal.” The terms “comprise,” “include,” “have,” “with,” and any variations thereof are used synonymously to denote or describe a non-exclusive inclusion. As such, a device or a method that uses such terms does not include only those elements or steps, but may include other elements and steps not expressly listed or inherent to

such device and method.

(13) The terms “proximal” and “distal” are used herein to refer to the relative positions of the components of the medical system or medical device being described. As used herein, “proximal” refers to a position relatively closer to the exterior of the body or closer to a medical professional using the system or device. In contrast, “distal” refers to a position relatively further away from the medical professional using the system or device, or closer to the interior of the body. Further, as used herein, the terms “first,” “second,” and the like, do not denote any order, quantity, or importance, but rather are used to distinguish one element from another. Similarly, terms of relative orientation, such as “top,” “bottom,” “left,” “right,” etc. are used with reference to the orientation of the structure illustrated in the figures being described. Moreover, the terms “a” and “an” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item. Further, all relative terms such as “about,” “substantially,” “approximately,” etc. are used to indicate a possible variation of $\pm 10\%$ (unless noted otherwise or another variation is specified). Moreover, in the claims, values, limits, range of values (e.g., range of thickness, etc.) mean the value, limit, and/or range $\pm 10\%$.

(14) Examples of this disclosure include medical devices and methods for using these medical devices in a medical procedure. Reference will now be made in detail to the examples described above and illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used to refer to the same or like parts.

(15) FIG. 1 illustrates an exemplary medical procedure being performed at a target location within a patient's body using exemplary medical devices **500** of this disclosure. FIG. 2 illustrates an exemplary medical device **500** used in the medical procedure of FIG. 1. In the discussion below, reference will be made to both FIGS. 1 and 2. In some embodiments, as illustrated in FIG. 1, medical devices **500** may be introduced into the body through the lumen of a delivery scope **1000**. Any suitable delivery scope **1000** (such as, for example, gastroscopes, colonoscopes, bronchoscopes, laryngoscopes, cystoscopes, duodenoscopes, enteroscopes, ureteroscopes, catheters, etc.) may be used to introduce medical devices **500** into the body. In some embodiments, medical device **500** may be configured to be inserted into the body through a delivery scope having, for example, a 2.8 mm diameter lumen. As previously explained, the use of a delivery scope **1000** to insert medical devices **500** into the body is not a requirement. For example, it is contemplated that, in some embodiments, medical devices **500** may be inserted into the body directly (e.g., without using a delivery scope). The disclosed medical devices **500** may be used to perform any suitable medical procedure at any suitable location of the patient's anatomy (such as, for example, portions of the large intestine, small intestine, cecum, esophagus, other portions of the gastrointestinal tract, cardiovascular, reproductive, etc.). For example, one or more medical devices **500** may be used to visualize, cut, resect, energize, treat, remove, couple, and/or manipulate target tissue in an endo-luminal space, or facilitate the process thereof.

(16) During a medical procedure, the delivery scope **1000** may be inserted into the body of the patient through a natural orifice (mouth, rectum, etc.), or an incision, and pushed in such that its distal end **1000A** is positioned at a desired worksite (e.g., a tissue lesion, etc.) within the body. An end effector **120**, at the distal-most end of medical device **500**, is then inserted into a lumen of delivery scope **1000** through its proximal end, and pushed in such that the end effector **120** extends out of the distal end **1000A** of delivery scope **1000** into the body. For example, with reference to the XYZ triad illustrated in FIGS. 1 and 2, when medical device **500** is pushed into delivery scope **1000** from the proximal end, the end effector **120** of medical device **500** moves in the $-X$ direction out of the distal end **1000A** of delivery scope **1000**. That is, translation of end effector **120** of medical device **500** along the X-axis at the worksite is achieved by pushing and pulling medical device **500** into and out of delivery scope **1000**. Conventionally, translation of the end effector **120** in the YZ plane (i.e., movement in the Y direction or the Z direction, referred to herein as side-to-side motion) is achieved by moving the distal end **1000A** of the delivery scope **1000** side-to-side.

That is, manipulation of conventional medical devices inserted into the body via a delivery scope is achieved largely via manipulation of the delivery scope. In contrast, in some embodiments of this disclosure, the disclosed medical devices **500** may be manipulated at the target site (e.g., moved towards and away from tissue, moved side-to-side, rotated, actuated, etc.) independent of the delivery scope **1000**. Therefore, aspects of the disclosed medical devices **500** may provide the user with the ability to separately control some or all of the position, direction, movement, and actuation of medical devices **500** independent of the delivery scope **1000**.

(17) In general, the disclosed medical devices **500** may include any type of end effector **120** suitable for the medical procedure being performed. For example, the disclosed medical devices **500** may include an end effector **120** in the form of one or more of a clip, a snare, a grasper, a camera, an illumination device, a needle, a knife, scissors, forceps, an electrosurgical knife (e.g., an endoscopic submucosal dissection knife), etc. For the sake of simplicity, however, in the discussion below, an end effector **120** having the configuration of a grasper will be used to describe aspects of this disclosure. However, it should be noted that the concepts described with reference to the grasper may be applied to an endoscopic medical device **500** having any type of end effector **120**. Components of medical device **500** may be made of, or include, any suitable biocompatible material (such as, for example, a metallic material, a plastic material, a shape memory metal (such as Nitinol), a shape memory polymer, a polymer, or any combination of biocompatible materials).

(18) With reference to FIG. 2, medical device **500** may include a proximal manipulation portion **100** and a distal insertion portion **200**. Manipulation portion **100** includes a handle **10** having controls that may be used to manipulate medical device **500**, for example, within the patient's body. Handle **10** is configured to be held by a user (medical professional, etc.) during use of device **500**, and may be configured in accordance with human factor interface design (HFID) principles. Insertion portion **200** includes a flexible tubular section **50** (or a core) that extends from handle **10** to a distal portion **250** of the device **500**. It should be noted that the distal portion **250** is shown exaggerated in FIG. 2 to clearly illustrate structural features of this portion. The flexible nature of the tubular section **50** enables it to bend and flex while device **500** is introduced into the body through the lumen of delivery scope **1000**. Distal portion **250** of the device **500** includes, among other regions, an articulation region **60**, a rotation region **90**, and the end effector **120**. These regions of distal portion **250** will be described in detail later.

(19) Handle **10** includes a body **12** coupled to tubular section **50** at a sleeve cap **20**. Body **12** includes a gripping portion **11** that may be generally shaped to be held by the hand (left or right hand) of the user. Body **12** also supports control devices, actuation devices, or actuators, which may be used to manipulate the distal portion **250** and the end effector **120** of the device **500**. In the discussion below, these actuation device will be referred to as “knobs.” It should be noted, however, that reference to actuation devices as knobs is merely for the sake of convenience and is not as an indication of their geometry. In some embodiments, the actuation devices on handle **10** may include a first actuator (referred to herein as a steering knob **14**), a second actuator (referred to herein as a rotation knob **16**), and a third actuator (referred to herein as an actuation knob **18**).

(20) With reference to FIG. 2, during use of device **500**, the steering knob **14** may be used to steer, or move, the end effector **120** and the distal end of device **500** from side-to-side (e.g., in any direction in the YZ plane). Rotation knob **16** may be used to rotate the end effector **120** independent of distal portion **250**, for example, about the X-axis. And, actuation knob **18** may be used to actuate, for example, open and close, the end effector **120**. The end effector **120** (along with the distal end of device **500**) may be moved in the X direction by moving the handle **10** in the X direction (e.g., by pushing device **500** into and out of delivery scope **1000**). And as will be described in more detail later, the tubular section **50** may be rotated, for example, about the X-axis, by rotating the handle **10** which will rotate the distal portion **250** and end effector **120** together.

(21) It should be noted that, although a specific configuration of the handle **10** is illustrated in FIG. 2, this is only exemplary. In general, handle **10** may have any configuration and its control knobs

may have any suitable configuration, and may be positioned at any location. In some embodiments, the shape of the handle **10** and the location of the steering knob **14**, the rotation knob **16**, and the actuation knob **18** on the handle **10** may be determined based on HFID principles. In some embodiments, when the gripping portion **11** of the handle **10** is grasped by a user's hand, the thumb may be used to activate the steering knob **14**, the middle finger may be used to activate the actuation knob **18**, and the forefinger may be used to activate the rotation knob **16**. Among other possible modifications, in some embodiments, the locations of rotation knob **16** and actuation knob **18** on handle **10** may be interchanged. It should be noted that, the disclosed actuating system (e.g., steering knob **14**, the rotation knob **16**, and the actuation knob **18**) on handle **10** has many advantages when compared with actuation systems of known medical devices and endoscopes. One advantage is that some or all of the disclosed actuators (e.g., steering knob **14**, the rotation knob **16**, and/or the actuation knob **18**) enable a long stroke of the steering wires **32**, **34** and/or the pull wire **36**, which translates to more motion at the distal end of device **500**. Another advantage is that the disclosed actuators of handle **10** provide mechanical advantage as compared to actuation systems of known devices and endoscopes that have limited mechanical advantage. Increasing mechanical advantage of an actuator reduces the force and effort needed to actuate the actuator.

(22) FIGS. 3A-3C are illustrations of different views of an exemplary handle **10** of device **500**. Body **12** of handle **10** may include two parts or two halves—a first part **12A** and a second part **12B**—which when joined together form the two opposite sides of the handle **10**. FIG. 3A is a side view of handle **10** with its second part **12B** shown in shadow to illustrate the components and features within the handle **10**. And, FIGS. 3B and 3C are side views of the first and second parts **12A**, **12B**, respectively, of handle **10**. In the discussion below, reference will be made to FIGS. 3A-3C. When first part **12A** is joined with second part **12B** to assemble handle **10**, pins **24A** on first part **12A** engage with (e.g., forms an interference fit with) corresponding pin slots **24B** in second part **12B** to couple the two parts together. The two parts **12A** and **12B** can be joined by other means like press fit, glue together. First and second parts **12A** and **12B** include recesses or cavities configured to support the steering knob **14**, the rotation knob **16**, and the actuation knob **18**. When the handle **10** is assembled: the steering knob **14** is supported between cavities **14A** and **14B** of the first and second parts **12A**, **12B**; the rotation knob **16** is supported in cavities **16A** and **16B** of the first and second parts **12A**, **12B**; and the actuation knob **18A** is supported between cavities **18A** and **18B** of the first and second parts **12A**, **12B**. First and second parts **12A**, **12B** also include external (e.g., male) screw threads **20A**, **20B** that are configured to engage with corresponding screw threads on the sleeve cap **20** to couple the sleeve cap **20** to the handle **10**.

(23) With reference to FIG. 3A, steering wires **32**, **34** extend through recessed pathways on body **12** of handle **10** from an end proximate the sleeve cap **20** to the steering knob **14**. One end of each of the steering wires **32**, **34** is coupled to steering knob **14**, and the opposite end of each of the steering wires **32**, **34** is coupled to an articulation cap **68** (see FIG. 7A) in the distal portion **250** of device **500** (see FIG. 2). In general, the steering wires **32**, **34** may be coupled to the steering knob **14** and the articulation cap **68** in any suitable manner, such as, for example, by crimping, welding, using a fastener, mechanical locking feature, tie knot, etc. With reference to FIGS. 3B and 3C, first part **12A** includes steering wire slots **32A**, **34A**, and second part **12B** includes steering wire slots **32B**, **34B**, that are together configured to receive the steering wires **32**, **34** when handle **10** is assembled. In some embodiments, first part **12A** may include pins **22A** located on steering wire slots **32A**, **34A**, and second part **12B** may include correspondingly located recesses **22B** configured to receive these pins **22A** when handle **10** is assembled. Pins **22A** may include a transverse pathway or slot **22C** (see FIG. 4B) at its base extending over steering wire slot **32A**, **34A** to permit the steering wires **32**, **34** to pass therethrough.

(24) FIG. 4A is an enlarged view of the portion of body **12** that supports steering knob **14**, and FIG. 4B is an enlarged view of the corresponding portion of first part **12A** of body **12**. As best seen in FIG. 4A, pivots **26** project outwards from opposite side surfaces of the steering knob **14**. When the

handle **10** is assembled with steering knob **14** positioned in the steering knob cavities **14A**, **14B** of the first and second parts **12A**, **12B**, pivots **26** will be received in recesses **26A**, **26B** (see FIGS. 3B, 3C) on the first and second parts **12A**, **12B** (see FIG. 4A). After assembly of the handle **10**, an extension **14C** of steering knob **14** protrudes from the body **12** of handle **10**. To actuate the steering knob **14**, the user may apply a force (push or pull) on the extension **14C** to rotate the steering knob **14** (as illustrated by the double-headed arrow on FIG. 4A) about its pivots **26**. When the steering knob **14** is actuated, or rotated about its pivots **26**, the resulting forces (e.g., tension) on the steering wires **32**, **34** cause links in the articulation region **60** of device **500** to rotate about their respective pivots, and cause the distal end of the device **500** to move side-to-side. For example, as schematically illustrated in FIGS. 11A and 11B, when the steering knob **14** is rotated in one direction (e.g., clockwise), a pulling force (or tension) is applied to one of the steering wires (e.g., steering wire **32**). And, when the steering knob **14** is rotated in the opposite direction (e.g., counter-clockwise), a pulling force is applied to the other steering wire (e.g., steering wire **34**). The direction of articulation is controlled by the location of steering wire **32** or **34** crimping on the steering knob **14**. When the steering wire **32** is crimped into the hole **14E** and steering wire **34** is crimped into hole **14D**, the steering knob **14** rotation in clock wire direction puts the steering wire **32** in tension. In other concept, if the crimping location is interchanged, steering wire **32** crimped in hole **14D** and steering wire **34** in **14E**, steering knob **14** clockwise rotation will put steering wire **34** in tension. As will be described in more detail later, when tension is applied to steering wire **32**, the articulation region **60** bends (or curves) in the direction of steering wire **32**, and when tension is applied to steering wire **34**, the articulation region **60** bends in the direction of steering wire **34**. The bending of the articulation region **60**, resulting from the actuation of the steering knob **14**, causes the end effector **120** at the distal end of device **500** to move side-to-side.

(25) In some embodiments, similar to body **12**, the steering knob **14** may also include a first part **14A'** and a second part **14B'** that may be joined together to form the steering knob **14**. FIGS. 4C and 4D illustrate the first and second parts **14A'**, **14B'** of steering knob **14** in an exemplary embodiment. As illustrated in FIG. 4C, first part **14A'** of the steering knob **14** may include holes or cavities **14D** and **14E** configured to receive locking features (not shown) of the steering wires **32**, **34** and couple the steering wires **32**, **34** to the steering knob **14**. Second part **14B'** of the steering knob **14** may include recessed regions **14D'** and **14E'** configured to receive the locking features of the steering wires **32**, **34** that are received in cavities **14D** and **14E** of first part **14A'**. In some embodiments, these locking features may include a crimp, lock nut, or another feature attached to an end of each of the steering wires **32**, **34**. The locking feature of each steering wire **32**, **34** may engage with a different one of cavities **14D** and **14E** to couple both steering wires **32**, **34** to steering knob **14**.

(26) It should be noted that the geometry, configuration, and features of steering knob **14** described above are only exemplary. In general, steering knob **14** may have a different configuration, for example, as described with reference to FIGS. 10A-10D. In some embodiments, the steering knob **14** may be configured as a joy stick or a cylindrical component with surface features to increase grip. As a person of ordinary skill in the art would recognize, any type of actuation device that is adapted to selectively apply tension to the steering wires **32**, **34** may be used as the steering knob of handle **10**. In general, any type of wire (single strand, multi-strand, etc.), made of any material (e.g., stainless steel, Nitinol, nylon, etc.) having any dimension may be used as steering wires **32**, **34**. In some embodiments, the steering wires **32**, **34** may be coated with or include a sleeve made of a different material (e.g., a lubricious material). Since steering wires **32**, **34** that may be used with endoscopic medical devices are known in the art, they are not described in detail herein.

(27) Referring back to FIG. 3A, in addition to steering wires **32** and **34**, a core wire or a pull wire **36** (or a control element) also extends through the body **12** of handle **10**. The passageways on handle **10** through which the pull wire **36** and the steering wires **32**, **34** extend may be sized such that these wires pass freely through their respective passageways without interference. In some

embodiments, a tube made of a lubricious material, such as, for example, polytetrafluoroethylene (PTFE) may be provided in, or attached in, some or all of these passageways to promote free movement of the wires therein. Like the steering wires **32**, **34**, the pull wire **36** may also include any type of wire (single strand, multi-strand, etc.), made of any material (e.g., stainless steel, Nitinol, nylon, etc.) having any dimension. In some embodiments, the pull wire **36** may be coated with or include a sleeve made of a different material (e.g., a lubricious material).

(28) The pull wire **36** may be coupled to the rotation knob **16** and the actuation knob **18**. At its proximal end, the pull wire **36** is fixedly coupled (or attached) to a sleeve **42** that is rotatably coupled to the actuation knob **18**. That is, sleeve **42** is coupled to the actuation knob **18** such that it can rotate with the square sleeve **38** in the rotation knob **16** and translate with the actuation knob **18**. The pull wire **36** may be attached to the sleeve **42** in any manner (welded, crimped, glued, etc.). In some embodiments, the pull wire **36** may be crimped to the sleeve **42**. Sleeve **42** may be rotatably positioned in the actuation knob **18** in any manner. The pull wire **36** extends distally from the handle **10** to the distal portion **250** of the device **500** (see FIG. 2) through sleeve cap **20**. At its distal end, pull wire **36** is coupled to the end effector **120** such that, when the actuation knob **18** is moved forwards (i.e., moved distally) and backwards (i.e., moved proximally), the end effector **120** operates (e.g., opens and closes in an embodiment where the end effector **120** is a grasper).

(29) The pull wire **36** also extends through a channel **16C** in the rotation knob **16**. In some embodiments, channel **16C** may have a square cross-sectional shape. A correspondingly shaped hypotube (e.g., a square hypotube **38**) may be slidably positioned in channel **16C**. That is, the square hypotube **38** is configured to slide back and forth in channel **16C** of the rotation knob **16**. The square hypotube **38** may be fixedly coupled (e.g., crimped) to the pull wire **36** that extends therethrough. Due to the square cross-sectional shape of channel **16C** and hypotube **38**, when the rotation knob **16** is rotated, the hypotube **38** and the pull wire **36** rotate with the rotation knob **16**, thereby rotating the end effector **120** independent of distal shaft **250**. Since the hypotube **38** is slidably coupled to the rotation knob **16**, when the actuation knob **18** is moved back and forth, the hypotube **38** and pull wire **36** translate in the rotation knob **16** with the actuation knob **18**. Since the sleeve **42** is rotatably coupled to the actuation knob **18**, when the rotation knob **16** rotates, the pull wire **36** and the sleeve **42** rotate in the actuation knob **18**.

(30) It should be noted that the specific configuration of the hypotube **38** and the channel **16C** described above is only exemplary and many variations are possible. For example, although the cross-sectional shape of channel **16C** and hypotube **38** is described as being square, this is only exemplary. In general, the channel **16C** and the hypotube **38** may have any suitable non-circular shape (triangular, polygonal, hexagonal, rectangular, etc.). It should also be noted that the coupling of the pull wire **36** to rotation knob **16** described above is only exemplary. In general, the pull wire **36** may be coupled to the rotation knob **16** in any manner such that the pull wire **36** rotates with the rotation knob **16** and translates with the actuation knob **18**.

(31) Similar to steering knob **14**, the rotation knob **16** may also have two parts, or halves, that join together to form the complete rotation knob **16** when the handle **10** is assembled. Note that FIG. 3A illustrates one half of the rotation knob **16** and FIG. 2 illustrates the complete rotation knob **16**. The two halves of the rotation knob **16** may have mating features that engage with each other to couple the two halves together when the handle **10** is assembled. These mating features may also assist in aligning the two parts **12A** and **12B** of the body **12** together when the handle **10** is assembled. In some embodiments, as illustrated in FIG. 3A, these mating features may include pins **16A** and correspondingly shaped cavities **16B** (in both halves of the rotation knob **16**) that engage with each other to couple the two halves of the rotation knob **16** together when the handle **10** is assembled. With reference to FIG. 2, the external surface of the rotation knob **16** may have features (e.g., grooves, etc.) that provide grip to the user during use. It should be noted that although the rotation knob **16** is illustrated as having a cylindrical configuration with grooves on the surface (or a thumbwheel), this is only exemplary. As a person of ordinary skill in the art would recognize, the

rotation knob **16** may have any suitable configuration.

(32) The actuation knob **18** enables the user to operate or actuate the end effector **120** of device **500**. For example, in embodiments where the end effector **120** is a grasper with jaws that open and close when actuated, the actuation knob **18** may be used to open and close the jaws. For example, moving the actuation knob **18** proximally may close the jaws, and moving the actuation knob **18** in the opposite distal direction may open the jaws (or vice versa). Actuation knob **18** includes a cavity or a slot **18A** that serves as an interface (e.g., a finger interface) for the user. In use, the user may insert a finger through slot **18A** and pull and push the actuation knob **18** proximally and distally to actuate the end effector **120**. The stroke (i.e., the length labeled A in FIG. 3A) of the actuation knob **18** may enable the jaws to open and close by different amounts. For example, moving the actuation knob **18** by a distance of, for example, $\frac{1}{3}$ A may open and close the jaws of the end effector **120** by a smaller amount than moving the jaws by a distance of A. Body **12** (e.g., first part **12A** and second part **12B** of body **12**) of the handle **10** and the actuation knob **18** have correspondingly located mating features that engage with each other to enable the actuation knob **18** to move in a predefined path (e.g., linear path, etc.) in the handle **10**. These mating features may include a linear cavity **18B** on the actuation knob **18**, and mating projections **12C** on the first and second parts **12A**, **12B** of body **12** that fits into cavity **18B**. For example, when the handle **10** is assembled, the projections **12C** of the first and second part **12A**, **12B** join to form a single projection that fits into the elongate cavity **18B** in the actuation knob **18** (see FIGS. 3B, 3C) to enable the actuation knob **18** to slide along the path defined by the cavity **18B**. Actuation knob **18** may also include additional features (e.g., projections, cavities, etc.) (not labeled in the figures) that mate with corresponding features on the handle body **12** to align the actuation knob **18** on handle **10**.

(33) As explained previously, the actuation knob **18** includes a sleeve **42** that the pull wire **36** is attached to. The sleeve **42** is rotatably secured in a cavity **18C** formed in the actuation knob **18**. Sleeve **42** is positioned in cavity **18C** in a manner such that (a) the sleeve **42** and the pull wire **36** can together rotate in actuation knob **18** when rotation knob **16** is rotated, and (b) the sleeve **42** and the pull wire **36** move along with the actuation knob **18** when the actuation knob **18** is translated (proximally and distally). It should be noted that the configuration of the actuation knob **18** illustrated in FIG. 3A is only exemplary and medical device **500** can include an actuation knob **18** having any suitable configuration.

(34) As explained previously, the pull wire **36** and the steering wires **32**, **34** of handle **10** extend to the distal portion **250** of the device **500** through the tubular section **50**. Handle **10** is coupled to the tubular section **50** using sleeve cap **20**. FIG. 4E is an illustration of an exemplary sleeve cap **20** coupling handle **10** with tubular section **50**. And, FIG. 4F is a sectional view of a sleeve cap **20** in an exemplary embodiment. As illustrated in FIG. 4E, in some embodiments, a threaded screw (e.g., a female threaded screw) of the sleeve cap **20** may engage with a corresponding threaded screw (e.g., a male threaded screw) of the handle body **12** to couple handle **10** to the tubular section **50**. It should be noted that, although the sleeve cap **20** is described as being attached to the handle **10** using threaded screws, this is only exemplary. In general, the sleeve cap **20** may be attached to the handle **10** in any manner (male threaded screw on sleeve cap **20** engaging with female threaded screw of handle **10**, glued, using pins, etc.). When the sleeve cap **20** is coupled to the handle **10**, a central passageway **28** of the sleeve cap **20** may fluidly couple with the passageways of handle **10** through which the pull wire **36** and steering wires **32**, **34** extend. Passageway **28** has a stepped configuration with a first portion **28A** proximate handle **10** having a larger width/diameter and a second portion **28B** proximate tubular section **50** having a smaller width/diameter. In the embodiment of sleeve cap **20** illustrated in FIG. 4F, the first portion **28A** of passageway **28** has a square (or rectangular) configuration having a larger width, and the second portion **28B** has a tubular configuration with a smaller width (or diameter).

(35) The proximal end of the tubular section **50** is coupled to a wire sleeve **40**, and the distal end of the tubular section **50** is coupled to the articulating section **60** in the distal portion **250** of device

500. In some embodiments, the wire sleeve **40** may be fixedly attached to (e.g., crimped to) the proximal-most end of the tubular section **50**. Wire sleeve **40** may be positioned in first portion **28A** of sleeve cap **20** (see FIG. **4E**). The wire sleeve **40** may have a shape or configuration similar to the shape or configuration of the first portion **28A** of passageway **28** (where the wire sleeve **40** is positioned in). That is, in embodiments where first portion **28A** has a square or rectangular shape, the wire sleeve **40** also has a corresponding square or rectangular shape. The outer width of the wire sleeve **40** may be smaller than the width of the first portion **28A** (of passageway **28**) and larger than the width of the second portion **28B** such that, when sleeve cap **20** is attached to handle **10**, the smaller width of the second portion **28B** prevents the wire sleeve **40** (and the tubular section **50**) from being separated from sleeve cap **20**. Since the width of the first portion **28A** is larger than the width of the wire sleeve **40**, a gap or a clearance exists between the wire sleeve **40** and the sleeve cap **20** in passageway **28**. As illustrated using the double-headed arrow in FIG. **4E**, when the sleeve cap **20** is coupled to handle **10**, the passageways in the handle **10** and the first portion **28A** of passageway **28** collectively form a combined passageway having a larger width than the wire sleeve **40**. This combined passageway enables the wire sleeve **40** and the tubular section **50** to freely translate (e.g., linearly) within the sleeve cap **20** and the distal end of the handle **10**, for example, when device **500** is inserted into the lumen of delivery scope **1000**. The ability of the wire sleeve **40** and the tubular section **50** to freely translate in this manner enables the tubular section **50** to extend through a tortuous lumen of the delivery scope **1000** without inducing tension therein.

(36) The steering wires **32**, **34** and the pull wire **36** extend from handle **10** to the tubular section **50** through the tubular section **50**. Wires **32**, **34**, **36** extend through the tubular section **50** such that they can move (rotate, translate, etc.) relative to, and independent of each other. For example, when steering knob **14** is turned to apply tension to steering wires **32**, **34**, these steering wires **32**, **34** can translate in tubular section **50** (i.e., translate relative to the tubular section **50**). Similarly, when rotation knob **16** is rotated to rotate the pull wire **36**, and when actuation knob **18** is translated to translate the pull wire **36**, the pull wire **36** can rotate and translate in the tubular section without moving the tubular section **50**.

(37) As explained above, in some embodiments, as illustrated in FIG. **4F**, the first portion **28A** of passageway **28** (of sleeve cap **20**) has a square or rectangular configuration. In some such embodiments, the wire sleeve **40** that is positioned in the first portion **28A** may also have a corresponding square (or rectangular) configuration, such that, when the handle **10** is rotated, the wire sleeve **40** and the tubular section **50** coupled to wire sleeve **40** also rotate along with the handle **10**. It should be noted that, in general, the first portion **28A** of passageway **28** and the wire sleeve **40** may have any configuration (e.g., triangular, polygon, etc.) that enables the rotation of the handle **10** to rotate the tubular section **50**.

(38) As explained above, the distal end of the pull wire **36** is coupled to the end effector **120**, and the distal end of the tubular section **50** is coupled to the articulating section **60** (see FIG. **2**). Since the pull wire **36** that extends through the tubular section **50** is not coupled to the wire sleeve **40**, when the handle **10** is rotated, the wire sleeve **40**, the tubular section **50**, distal portion **250** and distal assembly **120** rotates together. As schematically illustrated in FIGS. **11B** and **11C**, the user can rotate the steering knob **14** (e.g., in clockwise direction) to articulate in side direction, and the handle **10** can be rotated along with articulation distal portion **250** to reach the target tissue. This is. Similarly, when rotation knob **16** is rotated to rotate the pull wire **36**, the pull wire **36** rotates in tubular section **50** without rotating the tubular section **50**. Therefore, rotation of the rotation knob **16** rotates the pull wire **36** and the end effector **120** independent of the tubular section **50**, and rotation of the handle **10** rotates the articulation region **60** along with end effector **120**. As will be explained later, rotating the articulation region **60** enables the end effector **120** to be moved side-to-side in different directions in the YZ plane.

(39) FIG. **5A** illustrates the structure of tubular section **50** in an exemplary embodiment. Tubular section **50** includes a multi-lumen elongate member **52** positioned within a coil **54**. Coil **54** may

include a stainless steel or another suitable material (e.g., Nitinol, etc.) that provides sufficient stiffness to the tubular section **50**. In some embodiments, the coil **54** may include a wire wound around the elongate member **52**. In some embodiments, the coil **54** can be used without the multi lumen elongate member **52** and the steering wires **32**, **34** and pull wire **36** can be passed through coil **54** as illustrated, for example, in FIG. 5D. In some embodiments, the coil **54** may be attached to the external surface of the elongate member **52**, for example, by crimping, adhesive, heat-shrink, etc. The dimensions (thickness, etc.) of the coil **54**, and/or its configuration (pitch, etc.), may depend upon the desired stiffness of the tubular section **50**. Elongate member **52** may include lumens **56A**, **56B**, and **56C** that extend therethrough. The steering wires **32**, **34** and the pull wire **36** may extend from the handle **10** to the distal portion **250** of device **500** through these lumens **56A**, **56B**, **56C**. For example, as illustrated in FIG. 5A, steering wires **32** and **34** may extend through lumens **56A** and **56B** respectively, and pull wire **36** may extend through lumen **56C**. In general, these lumens **56A-56C** may be sized larger (e.g., slightly larger) than the wires that extend through the respective lumen so that these lumens impose minimal interference to the wire that passes therethrough. In some embodiments, tube **52** may be made of a lubricious material (such as, for example, PTFE, a Pebax® elastomer, silicone, etc.) to reduce friction between the tube and the wires (steering and pull wires, **32**, **34**, **36**) that pass therethrough.

(40) It should be noted that, although FIG. 5A illustrates a particular configuration of lumens **56A-56C** in the elongate member **52**, this is only exemplary. In general, lumens **56A-56C** may be arranged in any configuration in the elongate member **52**. FIGS. 5B and 5C illustrate exemplary elongate members **52** with lumens arranged in different configurations. In the embodiment of FIG. 5B, the lumens **56A-56C** are arranged in a substantially triangular configuration, and in the embodiment of FIG. 5C, the lumens **56A-56C** are arranged in a linear configuration. It should be noted that these configurations are exemplary and other configurations of lumens **56A-56C** are possible. It should also be noted that, although lumens **56A** and **56B** are illustrated as being substantially the same size, and lumen **56C** is illustrated as being larger than lumens **56A** and **56B**, this is only exemplary. In general, these lumens may have any size (same size or different sizes).

(41) With reference to FIG. 2, at its distal end, tubular section **50** is connected to the articulation region **60** of the distal portion **250**. FIGS. 6A-6C illustrate different views of an exemplary embodiment of the articulation region **60**. FIG. 6A illustrates a perspective view of the articulation region **60** in a curved configuration, and FIGS. 6B and 6C illustrate side views of the proximal and distal regions, respectively, of the articulation region **60**. Articulation region **60** enables the end effector **120** of the medical device **500** to move side-to-side in the YZ plane (see FIGS. 2 and 6C). The articulation region **60** includes a proximal end cap **62**, a distal end cap **66**, and multiple links **64** positioned between the proximal and distal end caps **62**, **66**. The multiple links **64** are stacked one over the other and coupled together such that each link **64** can rotate with respect to adjacent links **64**. FIGS. 6D and 6E illustrate perspective views of opposite end surfaces of the proximal end cap **62**, and FIGS. 6F and 6G illustrate perspective views of opposite ends of a link **64**.

(42) As can be seen in FIGS. 6B and 6E, the proximal end of proximal end cap **62** is attached to the distal end of the tubular section **50**, and its distal end includes a recess **62D**. As best seen in FIGS. 6F and 6G, the distal end of link **64** includes a recess **64D** and its proximal end includes a projecting region **64C**. The multiple links **64** of articulation region **60** are assembled such that the projecting region **64C** of one link **64** is positioned in the recess **64D** of an adjoining link **64**. The mating surfaces of the projecting regions **64C** and the recesses **64D** are curved such that each link **64** is configured to rotate about its adjacent link **64**. At its proximal end, the projecting region **64C** of a link **64** is similarly fit into the recess **62D** of the proximal end cap **62** such that this link **64** is configured to rotate about the proximal end cap **62**. For example, the top surface **64F** of projecting region **64C** of link **64** may have a shape and/or curvature that corresponds to the shape and/or curvature of base **62F**, **62F'** of recess **62D**, **64D** of proximal end cap **62** and link **64**. When the links **64** are assembled with the proximal end cap **62**, the curvature of the top surface **64F** and base **62F**,

62F' enables the links **64** to rotate with respect to each other. The distal end cap **66** is similarly coupled to a link **64** (see FIG. **6C**).

(43) Passages **62A**, **62B**, and **62C** pass through the proximal end cap **62** (see FIGS. **6D** and **6E**), passages **64A**, **64B**, and **64C** pass through each link **64** (see FIGS. **6F** and **6G**), and passages **66A**, **66B**, and **66C** pass through the distal end cap **66** (see FIG. **6C**). The end caps **62**, **66** and the links **64** are arranged such that passages **62A**, **64A**, and **66A** are aligned to form an aligned passageway, passages **62B**, **64B**, and **66B** are aligned to form an aligned passageway, and passages **62C**, **64C**, and **66C** are aligned to form an aligned passageway. The two steering wires **32**, **34** and the pull wire **36** pass through these aligned passageways of the articulation region **60**. For example, steering wire **32** passes through a passageway formed by passages **62A**, **64A**, and **66A**, steering wire **34** passes through a passageway formed by passages **62B**, **64B**, and **66B**, and pull wire **36** passes through a passageway formed by passages **62C**, **64C**, and **66C**.

(44) With reference to FIG. **6C**, an articulation cap **68** is coupled to the articulation region **60** distal to the distal end cap **66**. The steering wires **32** and **34** that pass through the aligned passageways of the articulation region **60** are attached to the articulation cap **68**. FIG. **7A** illustrates an enlarged view of a region of the distal portion **250** of device **500** showing the articulation cap **68**. And, FIG. **7B** shows the articulation cap **68** in an exemplary embodiment. Articulation cap **68** also includes passages **68A**, **68B**, and **68C** that are aligned with the aligned passageways of the articulation region **60**. The steering wires **32**, **34** and the pull wire **36** that extend from the articulation region **60** are directed through these passages **68A**, **68B**, and **68C**. While the pull wire **36** passes through articulation cap **68** via passage **68C**, the steering wires **32**, **34** are attached to the articulation cap **68**. In some embodiments, as illustrated in FIG. **7A**, the steering wires **32**, **34** may be attached to the articulation cap **68** using crimps (e.g., crimp **32'**) or welds.

(45) When a tension is applied to one of the steering wires **32**, **34** (or a steering wire is pulled) by turning the steering knob **14**, the links **64** rotate such that the articulation region **60** bends in the direction of the pulled steering wire. Although not a requirement, in some embodiments, the passageways through which the steering wires **32**, **34** pass in the articulation region **60** may be positioned opposite one another (e.g., about 180° apart). For example, as illustrated in FIG. **6C**, the steering wires **32** and **34** in the articulation region **60** may be aligned along the Z-axis. In such embodiments, when steering wire **34** is pulled (or a tension is applied to steering wire **34**), the articulation region **60** bends towards steering wire **34** and causes the end effector **120** to move in the $-Z$ direction. And, when steering wire **32** is pulled, the articulation region **60** bends towards steering wire **32** and cause the end effector **120** to move in the $+Z$ direction. That is, actuation of the steering knob **14** will cause the end effector **120** to move along the Z-axis. To move the end effector **120** along, for example, the Y-axis, the handle **10** may be rotated by 90° to rotate the tubular section **50** and the articulation region **60** by the same angle, and align the steering wires **32**, **34** along the Y-axis. Actuation of the steering knob **14** when the steering wires **32**, **34** are aligned along the Y-axis will move the end effector **120** along the Y-axis. In a similar manner, the end effector **120** may be moved in any direction in the YZ plane by rotating the handle **10** to align the steering wires **32**, **34** (in the articulation region **60**) in the desired direction and actuating the steering knob **14**. Note that, since rotation of the tubular section **50** (and articulation region **60**) is independent of the rotation of the pull wire **36**, when the articulation region **60** is rotated by rotating the handle **10**, both the pull wire rotation and tubular section rotation are independent of each other. When handle **10** is rotated, the tubular section rotates along with distal region **250** and end effector **120**. When rotating knob **16** is rotated, the pull wire **36** is rotated which rotates only the end effector **120** without rotating the tubular section **50** and distal region **250** as schematically illustrated in FIGS. **11E** and **11F**.

(46) With reference to FIG. **6C**, the pull wire **36** that extends out of the articulation cap **68** passes through a bushing **80** and a clevis **90** and is coupled to the end effector **120**, for example, via a four-bar link (or another suitable) mechanism (not shown). As would be recognized by a person

skilled in the art, the four-bar link mechanism may be configured to open and close the jaws of the end effector **120** in response to back and forth translation of the pull wire **36** along the X-axis. Since four-bar links and other suitable mechanisms that actuate end effectors in response to translation of a pull wire **36** are known in the art, they are not described herein.

(47) With reference again to FIG. **6C**, the end effector **120** is coupled to the clevis **90** at the distal end of the clevis **90**. The clevis **90** is coupled to the bushing **80** such that it can rotate on the bushing **80** about the X-axis. Rotation of the clevis **90** on the bushing **80** enables the end effector **120** to rotate along with the pull wire **36** independent of the articulation region **60**. That is, when the rotation knob **16** of the handle **10** is turned to rotate the pull wire **36**, the end effector **120** that is coupled to the distal end of the pull wire **36** also rotates. The clevis **90**, rotatably coupled to the bushing **80**, enables the end effector **120** to rotate independent of the actuation region **60** of the device **500**.

(48) FIG. **8A** illustrates a cross-sectional view of the bushing **80** and the clevis **90** coupled together. As can be seen in FIG. **8A**, bushing **80** is a substantially cylindrical component with multiple spaced-apart slits at its distal end. The slits reduce the stiffness of the bushing **80** at its distal end and enable the proximal end of the clevis **90** to be fit over the distal end of the bushing **80**. A collar **82** is defined at the distal end of the bushing **80**. The clevis **90** has a cylindrical region with an undercut **92** (or groove) at its proximal end. The cylindrical proximal end of the clevis **90** is fit over the distal end of the bushing **80** with the bush collar **82** positioned in the clevis undercut **92**. The bushing **80** and the clevis **90** are dimensioned to allow the clevis **90** to freely rotate on the bushing **80**. The distal end of the clevis **90** includes a pair of flanges **94** (or arms) with cavities **98** extending transversely through its distal end. The jaws of the end effector **120** are coupled to the cavities **98** of the flanges **94**.

(49) As would be recognized by a person skilled in the art, different embodiments of disclosed medical devices may include many variations of the above described features. For example, in some embodiments, as illustrated in FIG. **8B**, the proximal end of a clevis **90'** may have slits to decrease its stiffness (or increase its flexibility) and enable the clevis **90'** to be fit over the distal end of a bushing **80'**.

(50) In some embodiments, a disclosed medical device may include an articulation region having a configuration different from that described above. FIGS. **9A-9D** illustrate different exemplary configurations of articulation regions that may be used in the disclosed medical devices. In some embodiments, as illustrated in FIG. **9A**, articulation region **60A** of a disclosed medical device **500** may be formed of a flexible material (such as, for example, a Pebax® elastomer, a flexible PTFE, or another biocompatible flexible material). In some embodiments, articulation region **60A** may be a cylindrical or substantially cylindrical member with a constant (or substantially constant) outer diameter. As illustrated in FIG. **9A**, passages for the steering wires and the push wire may extend longitudinally through the flexible material. As described previously with reference to articulation region **60**, steering wires **32**, **34** and push wire **36** extend through the respective passages of articulation region **60A**. When one of the steering wires **32**, **34** is pulled, the flexible articulation region **60A** bends in the direction of the pulled steering wire. The resilience of the material used to form the articulation region **60A** may be such that the articulation region **60A** returns to its original configuration (e.g., linear) when the force on the pulled steering wire is released.

(51) In some embodiments, as illustrated in FIG. **9B**, articulation region **60B** may be formed by cutting alternate slits in a cylindrical (or substantially cylindrical) member to make it flexible. In some embodiments, the cylindrical member may be formed of a biocompatible metal. However, this is not a requirement. As illustrated in FIG. **9B**, the adjacent slits on the articulation region **60B** may be spaced apart along the longitudinal axis of the cylindrical member and may face in opposite directions. Longitudinal passages may be formed through the cylindrical member for the steering wires and the push wire. Although slits have a triangular cross-sectional shape are illustrated in FIG. **9B**, this is only exemplary. In general, these slits may have any configuration. As in

articulation region **60A** of FIG. **9A**, when one of the steering wires **32**, **34** of articulation region **60B** is pulled, the flexible articulation region **60B** bends in the direction of the pulled steering wire. And, the resilience of the material (used to form articulation region **60B**) may return articulation region **60B** to its original configuration (e.g., linear) when the steering wire is released.

(52) In some embodiments, as illustrated in FIG. **9C**, articulation region **60C** may have a spiral configuration. In some embodiments, an elongate member having a spiral configuration may be formed (by any process) and end caps having a cylindrical configuration may be attached to the opposite ends of the spiral elongate member (only one end seen in FIG. **9C**). In some embodiments, the central section (e.g., the section between two ends) of an elongate member may be machined (or processed in another manner) to have a spiral configuration. The articulation region **60C** may be formed of any biocompatible material (e.g., metal, etc.). Passages for the steering wires **32**, **34** and the push wire **36** may then be formed longitudinally through the elongate member. In some embodiments, the central passageway of the spiral elongate member may be used for extending the push wire **36**, and longitudinal passages may be formed through the spiral member for the steering wires **32**, **34**. The spiral configuration of the central section of the articulation region **60C** may impart flexibility to this section of the articulation region **60C**. When one of the steering wires **32**, **34** is pulled, the flexible spiral section of articulation region **60C** bends in the direction of the pulled steering wire. And, when the pulled steering wire is released, the spiral section returns to its original configuration.

(53) In some embodiments, an articulation region **60D** may be formed by providing longitudinally spaced-apart slits or slots through a cylindrical (or substantially cylindrical) member. The cylindrical member may be formed of any biocompatible material, the slots may have any configuration, and the slots may be spaced apart by any distance. In general, the cylindrical member of the articulation region **60D** may be flexible. The flexibility may be as a result of the material (used to form the articulation region **60D**) and/or as a result of the configuration and spacing of the slots. Longitudinal passageways may be formed through the flexible cylindrical member for the steering wires **32**, **34** and the pull wire **36**. As in each of articulation regions **60A**-**60C**, the centrally positioned passage may be used to pass the push wire **36** and the smaller passages on either side of the central passage may be used to pass the steering wires **32**, **34**. And, when one of the steering wires **32**, **34** is pulled, the flexible articulation region **60D** bends in the direction of the pulled steering wire. And, when the pulled steering wire is released, the articulation region **60D** returns to its original configuration.

(54) In some embodiments, the steering knob **14**, rotation knob **16**, and/or the actuation knob **18** may have a configuration different from those described above. FIG. **10A** illustrates a medical device **500** employing a different configuration of a steering knob **140**. FIG. **10C** illustrates steering knob **140** separated from medical device **500**. Steering knob **140** includes multiple supports **140A** (e.g., thumb supports) for rotation of the steering knob **140**. A wire holder **144** (see FIGS. **10A**-**10B**) is coupled to the steering knob **140** such that rotation of the steering knob **140** rotates the wire holder **144**. FIG. **10B** illustrates the wire holder **144** in an exemplary embodiment. The steering wires **32**, **34** of the device **500** are coupled to the wire holder **144**. Wire holder **144** includes a disc-like support region **144A** with a shaft **144B** extending therefrom. The shaft **144B** of the support region **144A** is coupled to the steering knob **140** (for example, using fasteners, adhesive, friction, etc.). The support region **144A** includes features that engage with corresponding features on the proximal end of the steering wires **32**, **34** to couple the steering wires **32**, **34** to the wire holder **144**. These features of support region **144A** may include holes or cavities **144C** that receive crimps **146** attached to an end (e.g., the proximal end) of the steering wires **32**, **34**. FIG. **10D** is a schematic illustration of an exemplary crimp **146** being attached to an end of a steering wire **32**, **34**. As illustrated in FIG. **10D**, an end of the steering wire **32**, **34** is inserted into a cavity **146A** of the crimp **146** and one or more transverse forces F are applied to deform surfaces of the crimp **146** and fixedly attach the crimp **146** to the steering wire **32**, **34**. The crimps **146** are then supported in the

cavities **144C**, and the steering wires **32**, **34** extend to the distal portion **250** of device **500** through passages in the body **12** of handle **10** as described previously.

(55) In some embodiments, as illustrated in FIG. **10A**, the proximal end of the steering wires **32**, **34** may be wound around the support region **144A** of wire holder **144** with the crimps **146** at their proximal-most end supported in cavities **144C**. The support region **144A** may include channels **144D** that receive the wound steering wires **32**, **34**. In some embodiments, as shown in FIG. **10A**, the proximal end of the steering wires **32**, **34** may form one loop around the support region **144A**. Although not a requirement, winding the proximal end of the steering wires **32**, **34** around the support region **144A** may reduce the likelihood of kinks developing in these wires **32**, **34** during operation. As explained previously, rotation of the steering knob **140** in one direction applies a pulling force (or tension) on one steering wire (e.g., steering wire **32**), and rotation of the steering knob **140** in the opposite direction applies a pulling force on the other steering wire (e.g., steering wire **34**).

(56) It should be noted that, although exemplary embodiments of medical devices **500** with two steering wires **32**, **34** have been described above, this is not a limitation. In general, the devices **500** of this disclosure may include any number (e.g., 1, 3, 4, etc.) of steering wires arranged around its articulation region (**60**, **60A**, etc.). These steering wires may be arranged in any configuration (e.g., angular spacing) around the articulation region. For example, in some embodiments, medical device **500** may only include a single (i.e., one) steering wire. In some embodiments, the single steering wire may be used to bend the articulation region of device **500** in different directions by using the steering wire in conjunction with the rotation of the handle **10**. For example, pulling the steering wire when the handle **10** is positioned in a first configuration (e.g., in the configuration illustrated in FIG. **2**) may bend the articulation region of device **500** in a first direction (e.g., in the +Y direction). And, rotating the handle **10** (by, for example, 180°) to rotate the articulation region, and then pulling the same steering wire may bend the articulation region in the opposite direction (e.g., in the -Y direction).

(57) In some embodiments, three steering wires may be spaced apart at an angle of about 120° around the articulation region. And, in some embodiments, four steering wires may be spaced apart at an angle of about 90° around the articulation region. These four steering wires may be actuated by the same or different steering knobs. For example, a first pair of oppositely positioned (e.g., spaced 180° apart) steering wires may be attached to and actuated by a first steering knob and a second pair of oppositely positioned steering wires may be attached to and actuated by a second steering knob. Applying a pulling force on one steering wire causes the articulation region to bend in the direction of the pulled steering wire.

(58) As explained above, exemplary medical devices **500** of this disclosure have multiple independent degrees of freedom that are decoupled from each other. Specifically, in various embodiments of device **500**, the independent degrees of freedom include (with reference to FIG. **2**): (a) the end effector **120** can be actuated (e.g., opened and closed) using the actuation knob **18**; (b) the end effector **120** can be moved (e.g., left-right and up-down) in the YZ plane using the steering knob **14**; (c) the end effector **120** can be rotated (clockwise and counter clockwise about the X-axis) using the rotation knob **16**; (d) the coil or tubular section **50** of device **500** can be rotated (clockwise and counter clockwise about the X-axis) by rotating the handle **10**; and (e) the end effector **120** can be moved in the X-direction by moving the handle **10** in the X-direction. And, each of these degrees of freedom is independent and decoupled from each other. During an exemplary medical procedure using a disclosed device **500**, the multiple independent degrees of freedom of the device **500** enable its end effector **120** to be manipulated in any desired manner independent of the delivery scope used to introduce the device **500** into the body of a patient.

(59) An exemplary medical procedure (e.g., endoscopic mucosal resection) using an exemplary disclosed medical device **500** will now be described. Since such medical procedures are well known in the art, only aspects of the procedure that highlight exemplary features of the disclosed

devices will be described below. In the discussion below, reference will be made to FIGS. 1, 2, 3A, and 6C. A delivery scope **1000** (e.g., an endoscope) may be inserted into the patient's body (e.g., into the patient's upper gastrointestinal tract through the mouth) and positioned with its distal end proximate target tissue. Endoscopic medical device **500** may be inserted into the body through a lumen of the delivery scope **1000**, and its end effector **120** suitably positioned proximate the target tissue. Initially, the steering wires **32, 34** in articulation region **60** of device **500** may be aligned along, for example, the Y-axis. When in this orientation, the steering knob **14** may be actuated (or turned) to bend the actuation region **60** and move the end effector **120** along the Y-axis. That is, turning the steering knob **14** in one direction will bend the articulation region **60** such that the end effector **120** moves in the +Y direction, and turning the steering knob **14** in the opposite direction will bend the articulation region **60** in the opposite direction such that the end effector **120** moves in the -Y direction. The rotation knob **16** may now be turned to independently rotate the end effector **120**. Since rotation of the end effector **120** is decoupled from the rotation of the tubular section **50** and the articulation region **60**, operation of the rotation knob **16** rotates the end effector **120** without changing, for example, the bent configuration of the articulation region **60**. The handle **10** may be rotated by, for example, 90°, to rotate the articulation region **60** by the same angle, and align the steering wires **32, 34** along the Z-axis. The steering knob **14** may now be actuated to bend the articulation region **60** along the Z-axis, and thereby move the end effector **120** along this axis. At any time during the process, the actuation knob **18** may be activated to open and close the jaws of the end effector **120**. The handle **10** can be moved in +/-X direction which will translate the end effector **120** in +/- direction (in-out of endoscope **1000**) as schematically illustrated in FIG. 11G.

(60) It should be noted that typical medical procedures using device **500** may include a number of known additional (or alternative) steps that have been omitted in the description above for the sake of brevity. Any above-described step may be omitted or modified, or other steps added, as long as the intended functionality of the disclosed medical devices **500** remains substantially unaltered. Further, although a certain order is described or implied in the described medical procedure, in general, the steps need not be performed in the described order. Further, the described procedure may be incorporated into a more comprehensive medical procedure not described herein.

(61) While principles of this disclosure are described herein with reference to illustrative aspects for particular applications, it should be understood that the disclosure is not limited thereto. Those having ordinary skill in the art and access to the teachings provided herein will recognize additional modifications, applications, aspects, and substitution of equivalents all fall within the scope of the aspects described herein. Accordingly, the disclosure is not to be considered as limited by the foregoing description.

Claims

1. A medical device, comprising: a handle including an actuation actuator and a rotation actuator; an end effector, wherein the actuation actuator is configured to actuate the end effector; a tubular section extending between the handle and the end effector, wherein the end effector is configured to be rotated about a first axis extending through the tubular section without rotating the tubular section, and the tubular section is configured to be rotated about the first axis with the end effector; and a core wire extending through the tubular section and coupled to the actuation actuator and the end effector, wherein actuation of the actuation actuator causes translation of the core wire in the handle, wherein the core wire is rotatably coupled to the actuation actuator, wherein actuation of a rotation actuator rotates the core wire in the actuation actuator, wherein a cavity in the rotation actuator accommodates the core wire and has one of a square, a rectangular, a triangular, or a polygonal cross-sectional shape, wherein a hypotube is attached to a portion of the core wire extending through the cavity of the rotation actuator, the hypotube having a same cross-sectional shape as the cavity, and wherein actuation of the actuation actuator causes the hypotube to translate

along with the core wire in the cavity of the rotation actuator.

2. The medical device of claim 1, wherein actuation of the rotation actuator rotates the end effector about the first axis without rotating the tubular section.
 3. The medical device of claim 1, wherein the end effector is rotatably coupled to the tubular section such that the end effector is rotatable about the first axis with the tubular section.
 4. The medical device of claim 1, further including (a) an articulation region coupled to a distal end of the tubular section and (b) a steering actuator on the handle, wherein actuation of the steering actuator bends the articulation region in a first plane passing through the first axis.
 5. The medical device of claim 4, further including one or more steering wires coupled to the steering actuator and extending through the articulation region along the first plane, wherein actuation of the steering actuator applies tension to at least one of the one or more steering wires to bend the articulation region in the first plane.
 6. The medical device of claim 5, wherein the articulation region includes multiple links that are rotatably coupled together.
 7. The medical device of claim 5, wherein the articulation region includes a flexible elongate member having multiple passages extending longitudinally therethrough.
 8. The medical device of claim 5, wherein the one or more steering wires include one steering wire.
 9. The medical device of claim 5, wherein the one or more steering wires include two steering wires.
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