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INTERFACE MECHANISM FOR REPOSITIONING AND DEPLOYMENT OF OVER THE SCOPE CLIP

Abstract

A system for treating tissue includes a cap mounted over a distal end of an endoscope, a clip mountable over the cap and including first and second jaws movably connected to one another between an insertion configuration, in which the first and second jaws extend over the cap to receive a target tissue therebetween, a review configuration, in which at least a portion of the clip extends into a field of view of the optical system of an endoscope, and a deployed configuration in which the clip is moved distally off of the cap so that the first and second jaws are drawn toward one another. A control element is configured so that movement proximally through the cap via a first distance moves the clip from the insertion configuration to the review configuration and a second distance moves the clip from the review configuration to the deployed configuration.

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Background/Summary

PRIORITY CLAIM [0001] The present application is a Continuation of U.S. patent application Ser. No. 17/815,816 filed on Jul. 28, 2022; which claims priority to U.S. Provisional Patent Application Ser. No. 63/260,412 filed on Aug. 19, 2021. The disclosures of the above application(s)/patent(s) are incorporated herewith by reference.

FIELD

[0002] The present disclosure relates to endoscopic devices and, in particular, relates to endoscopic clipping devices for treating tissue along the gastrointestinal tract.

BACKGROUND

[0003] Physicians have become more willing to perform aggressive interventional and therapeutic endoscopic gastrointestinal (GI) procedures, which may increase the risk of perforating the wall of the GI tract or may require closure of the GI tract wall as part of the procedure. Such procedures may include, for example, the removal of large lesions, tunneling under the mucosal layer of the GI tract to treat issues below the mucosa, full thickness removal of tissue, entering the body via the GI tract and penetrating tissue to exit the GI tract to operate on tissue outside the GI tract, and endoscopic treatment/repair of post-surgical issues (e.g., post-surgical leaks, breakdown of surgical staple lines, and anastomotic leaks).

[0004] Currently, tissue may be treated via endoscopic closure devices including through-the scope clips or over-the-scope clips. Over-the-scope clips may be particularly useful for achieving closure of larger tissue defects. These endoscopic closure devices can save costs for the hospital and may provide benefits for the patient. In some cases, however, current endoscopic closure devices may be difficult to use, time consuming to position, or insufficient for certain perforations, conditions and anatomies. For example, current over-the-scope clips generally require launching of the clip from a position in which the clip itself is not visible to the operator. That is, prior to clipping the operator may view the target tissue to be clipped and, based on this visualization of the target tissue may determine that the distal end of the device and the clip are in a desired position relative to the target tissue. Based on the observation of the target tissue, the operator then deploys the clip without being able to see the clip itself until it is deployed.

SUMMARY

[0005] The present embodiments are directed to a clipping system for treating tissue comprising a cap configured to be mounted over a distal end of an endoscope, the cap extending longitudinally from a proximal end to a distal end and including a channel extending therethrough so that the cap may be located adjacent to target tissue within a living body. A clip is configured to be mounted over the cap, the clip including first and second jaws movably connected to one via a hinge biased to draw the first and second jaws toward one another, the clip movable relative to the cap between: (a) an insertion configuration, in which the first and second jaws extend over the cap so that the first and second jaws are separated from one another to receive a target tissue therebetween and so that obstruction of an optical system of an endoscope on which the cap is mounted is minimized; (b) a review configuration, in which the clip is moved distally relative to the cap so that a portion of

the clip extends distally until at least a portion of the clip extends into a field of view of the optical system of an endoscope on which the cap is mounted; and (c) a deployed configuration in which the clip is moved distally off of the cap so that the first and second jaws are drawn toward one another under the bias of the hinge to close and clip tissue received between the first and second jaws. A control element extends from a distal end releasably coupled to the clip, through the channel of the cap and the endoscope to which it is connected, to a proximal end which, in use, remains outside the living body while the cap is adjacent to the target tissue. The control element is configured so that movement of the control element proximally through the cap moves the clip distally relative to the cap, the control element being configured so that movement of the control element proximally through the cap via a first distance moves the clip from the insertion configuration to the review configuration and movement of the control element proximally through the cap via a second distance moves the clip from the review configuration to the deployed configuration.

[0006] In an embodiment, the system may further comprise an actuator assembly connected to a proximal end of the control element, the actuator assembly including a first actuator configured so that, when actuated, the control element is moved proximally through the endoscope via the first distance to move the clip from the insertion configuration to the review configuration.

[0007] In an embodiment, the first actuator may include first and second longitudinal members pivotally coupled to one another so that when proximal portions of the first and second longitudinal members are drawn toward one another, distal portions of the first and second longitudinal members are correspondingly drawn toward one another.

[0008] In an embodiment, the actuator assembly may further include a second actuator configured so that, when actuated, the control element is moved proximally through the endoscope via the second distance to move the clip from the review configuration to the deployed configuration.

[0009] In an embodiment, the actuator assembly may further comprise a moving element and a pulley mechanism, the control element being routed through the pulley mechanism to be connected to the moving element so that, when the first and second longitudinal members are drawn toward one another, the moving element is moved from a proximal position relative to a housing of the actuator assembly toward a distal position to pull the control element proximally through the endoscope such that the clip is moved from the insertion configuration toward the review configuration.

[0010] In an embodiment, the second actuator may include a push button including a tab extending into a housing of the actuator assembly such that when the clip is in the review configuration, the tab engages a portion of the control element so that pushing the push button exerts an additional tension along the control element which moves the clip from the review configuration toward the deployed configuration.

[0011] In an embodiment, the actuator assembly may further comprise a biasing element biasing the first actuator toward the insertion configuration.

[0012] In an embodiment, the actuator assembly may include a locking mechanism for locking the clip toward the review configuration.

[0013] In an embodiment, the first actuator may include a handle portion configured to be gripped via an operator of the system and a lever movably coupled thereto, the proximal end of the control element connected to the lever so that, when the lever is pressed against the handle portion, the control element is moved proximally through the endoscope via the first distance to move the clip from the insertion configuration toward the review configuration.

[0014] In an embodiment, the first actuator may include a housing and a rotary handle rotatably couple thereto, the proximal end of the control element connected to a moving element threadedly coupled to a portion of the rotary handle so that a rotation of the rotary handle relative to the housing moves the control element proximally through the endoscope.

[0015] The present embodiments are also directed to a clipping system for treating tissue,

comprising an endoscope including a shaft extending longitudinally from a proximal end to a distal end. A cap extending longitudinally from a proximal end to a distal end includes a channel extending therethrough so that the cap is slidably mounted over a distal portion of the shaft of the endoscope. A clip includes first and second jaws movably connected to one another via hinges, at least one of the hinges being biased to draw the first and second jaws toward one another, the clip mountable over the cap such that the first and second jaws extend over opposing portions of the cap so that the first and second jaws are separated from one another to receive a target tissue therebetween. A distal movement of the cap relative to the endoscope from a proximal position along the endoscope to a distal position along the endoscope moves the clip from an insertion configuration toward a review configuration, in which the clip extends distally until at least a portion of the clip extends into a field of view of an optical system of the endoscope. A distal movement of the clip relative to the cap moves the clip from the review configuration toward a deployed configuration, in which the clip is moved distally off of the clip so that the first and second jaws are drawn toward one another under the bias of the at least one hinge to close over tissue received therebetween. A repositioning element extends from a distal end coupled to the cap, through the channel of the cap and the endoscope, to a proximal end that, in use, remains outside the living body. The repositioning element is configured so that moving the repositioning element proximally through the endoscope moves cap distally along the endoscope from the insertion configuration toward the review configuration. A deployment element extends from a distal end releasably coupled to the clip, through the channel of the cap and the endoscope, to a proximal end which, in use, remains outside the living body. The deployment element is configured so that a proximal movement of the deployment element through the endoscope moves the clip distally relative to the cap toward the deployed configuration. An actuator assembly includes a first actuator configured to control a movement of the repositioning element and a second actuator configured to control a movement of the deployment element.

[0016] In an embodiment, the actuator assembly may further comprise a housing through which the proximal ends of the repositioning element and the deployment element extend to be connected to the first and second actuators.

[0017] In an embodiment, the first actuator may include a lever pivotally coupled to a handle, the proximal end of the repositioning element connected to a portion of the handle so that, when the lever is moved toward the housing, the repositioning element is moved proximally through the endoscope to move the cap and the clip from the insertion configuration toward the review configuration.

[0018] In an embodiment, the second actuator may include a push button extending into the housing and connected to the proximal end of the deployment element so that, when the push button is pressed further into the housing, the deployment element is moved proximally through the endoscope to move the clip distally relative to the cap from the review configuration toward the deployed configuration.

[0019] In an embodiment, the system may further comprise a biasing element extending between a distal end of the cap and a stop at a distal-most end of an endoscope on which the cap is mounted, the biasing element biasing the cap toward the insertion configuration, in which an entirety of the clip mounted over the cap is proximal of the distal-most end of the endoscope so that when the lever is released, the cap and the clip revert toward the insertion configuration.

[0020] The present embodiments are also directed to a method for treating tissue. A clip is inserted to a target area in a body lumen via an endoscope in an insertion configuration in which the clip is mounted over a distal end of an endoscope via a transparent cap, a proximal end of the cap extending over the distal end of the endoscope and a distal portion of the cap extending distally of the distal end of the endoscope, the clip mounted over a proximal portion of the cap so that jaws of the clip are separated from one another, in the insertion configuration. A suction force is applied through a working channel of the endoscope so that tissue is drawn into a channel of the cap and

between the jaws of the clip. A first actuator is actuated to move a control element releasably coupled to the clip proximally through the endoscope via a first distance so that the clip is moved toward a review configuration, in which the clip is moved distally along the cap to extend over the distal portion of the cap such that clip is in a field of view of the endoscope in the review configuration. It is determined, when the clip is in the review configuration, whether the clip is in a desired position relative to a target tissue. A second actuator is actuated to apply additional tension to the control element while the clip is in the review configuration so that the control element moves further proximally relative to the endoscope via a second distance to move the clip distally off of the cap toward a deployed configuration, in which the clip reverts toward a biased closed configuration in which the jaws are drawn toward one another to grip the tissue therebetween.

Description

BRIEF DESCRIPTION

[0021] FIG. **1** shows a longitudinal side view of a distal portion of a tissue clipping system according to an exemplary embodiment of the present disclosure, in an insertion configuration;

[0022] FIG. **2** shows a longitudinal side view of the distal portion of the system of FIG. **1**, in a review configuration;

[0023] FIG. **3** shows a longitudinal side view of the distal portion of the system of FIG. **1**, in a deployed configuration;

[0024] FIG. **4** shows a perspective view of an actuator assembly for controlling movement of a clip according to the system of FIG. **1**;

[0025] FIG. **5** shows a cross-sectional longitudinal side view of the actuator assembly of FIG. **4**, in a first configuration;

[0026] FIG. **6** shows a cross-sectional longitudinal side view of the actuator assembly of FIG. **4**, in a second configuration;

[0027] FIG. **7** shows a perspective view of an actuator assembly according to another exemplary embodiment of the present disclosure;

[0028] FIG. **8** shows another perspective view of the actuator assembly of FIG. **7**;

[0029] FIG. **9** shows a cross-sectional side view of the actuator assembly of FIG. **7**, in a first configuration;

[0030] FIG. **10** shows a cross-sectional side view of the actuator assembly of FIG. **7**, in a second configuration;

[0031] FIG. **11** shows perspective view of an actuator assembly according to another exemplary embodiment of the present disclosure;

[0032] FIG. **12** shows a side view of the actuator assembly of FIG. **11**;

[0033] FIG. **13** shows a cross-sectional side view of the actuator assembly of FIG. **11**, in a first configuration;

[0034] FIG. **14** shows a cross-sectional side view of the actuator assembly of FIG. **11**, in a second configuration;

[0035] FIG. **15** shows another cross-sectional side view of the actuator assembly of FIG. **11**, in the first configuration;

[0036] FIG. **16** shows another cross-sectional side view of the actuator assembly of FIG. **11**, in the second configuration;

[0037] FIG. **17** shows a perspective view of an actuator assembly according to yet another exemplary embodiment of the present disclosure;

[0038] FIG. **18** shows a transparent perspective view of the actuator assembly of FIG. **17**;

[0039] FIG. **19** shows cross-sectional side view of the actuator assembly of FIG. **17**;

[0040] FIG. **20** shows a transparent perspective view of a distal portion of the actuator assembly of

FIG. **17**;
[0041] FIG. **21** shows a longitudinal side view of a distal portion of a tissue clipping system according to another exemplary embodiment of the present disclosure, in an insertion configuration;
[0042] FIG. **22** shows a longitudinal side view of the distal portion of the system of FIG. **21**, in a review configuration;
[0043] FIG. **23** shows a longitudinal side view of the distal portion of the system of FIG. **21**, in a review configuration;
[0044] FIG. **24** shows a perspective view of an actuator assembly for controlling movement of a clip according to the system of FIG. **21**; and
[0045] FIG. **25** shows a cross-sectional side view of the actuator assembly of FIG. **24**.

DETAILED DESCRIPTION

[0046] The present disclosure may be further understood with reference to the following description and the appended drawings, wherein like elements are referred to with the same reference numerals. The present disclosure relates to a clipping system and, in particular, relates to an over-the-scope endoscopic clipping system, in which an initial placement of a clip may be viewed and adjusted prior to a deployment thereof via an actuator assembly. Exemplary embodiments of the present disclosure comprise a clip mountable over a distal end of an endoscope via cap and an actuator assembly controlling movement of the clip relative to the endoscope between an insertion configuration, a review configuration and a deployed configuration. In the insertion configuration, the clip is mounted over the distal end of the endoscope so that the jaws of the clip are separated from one another toward an open configuration in which tissue may be received therebetween.
[0047] In the review configuration, the clip is moved distally relative to the endoscope so that at least a portion of the clip extends within a field of view of the endoscope. In this review configuration, the clip remains mounted over the cap toward the open configuration, with the jaws separated from one another to receive target tissue therebetween, while also being visible via the endoscope so that an operator of the system may determine whether the clip is in a desired position relative to the target tissue. If the clip is determined to be in the desired position relative to the target tissue, the clip may be moved toward the deployed configuration.
[0048] In the deployed configuration, the clip is moved distally off of the cap so that the clip reverts toward a biased closed configuration to grip the target tissue between the jaws thereof. The actuator assembly is releasably coupled to the clip via a control element to facilitate movement of the clip relative to the endoscope between the insertion, review and deployed configurations. It will be understood by those of skill in the art, that upon movement of the clip toward the deployed configuration, the clip is entirely separated from the endoscope and is permanently released within the body. It will be understood by those of skill in the art that terms proximal and distal, as used herein, are intended to refer to a direction toward and away from, respectively, a user of the device.
[0049] As shown in FIGS. **1**-**6**, a tissue clipping system **100** for treating tissue defects and/or perforations according to an exemplary embodiment of the present disclosure comprises a clip **102** configured to be mounted over a distal end **106** of an endoscope **104** via a transparent cap **108**. The clip **102** is releasably coupled to a control element **110** such that tensioning of the control element **110** moves the clip **102** distally relative to the endoscope **104** (and the cap **108** mounted thereon) from an insertion configuration, as shown in FIG. **1**, towards a review configuration, as shown in FIG. **2**. Upon determination via an operator of the system **100** (e.g., a surgeon) that the clip **102** is in a desired position relative to a target tissue, further tensioning of the control element **110** moves the clip **102** from the review configuration toward a deployed configuration, as shown in FIG. **3**, in which the clip **102** is released from the cap **108** and closed over target tissue. In the insertion configuration, as shown in FIG. **1**, the clip **102** is mounted over the cap **108** so that the cap **108** holds the clip **102** in an open position with jaws **114** of the clip **102** spread apart from one another

about the cap **108** so that tissue to be clipped may be drawn through a channel **116** of the cap **108** and between the jaws **114**.

[0050] In this insertion configuration, an entirety of the clip **102** (including the jaws **114**) of this embodiment is mounted over a proximal portion **138** of the cap **108** minimizing obstruction of the visual field of the optical system of the endoscope **104** so that the user may fully observe the tissue adjacent to the cap **108** through the open end of the cap **108** as well as through the wall of the cap **108**. To move the clip **102** from the insertion configuration toward the review configuration, as shown in FIG. **2**, the control element **110** is tensioned to push the clip **102** distally along the cap **108** until a portion of the clip **102** abuts a protrusion **120** formed on the cap **108**. This provides tactile feedback to the operator indicating that the clip **102** is in the review configuration. In the review configuration, the jaws **114** remain spread out over a distal portion **140** of the cap **108**, which extends distally past the distal end **106** of the endoscope **104**, with the jaws **114** being maintained open and separated from one another by the cap **108**. Since the cap **108** is transparent, when the clip **102** is mounted over the distal portion **140** of the cap **108**, the clip **102** is within a field of view of the optical system of the endoscope **104**.

[0051] In the review configuration, the operator may visually determine whether the clip **102** is in the desired position relative to the target tissue (e.g., a portion of tissue drawn into the cap **108**). If, the operator determines that the clip **102** is not in the desired position relative to the target tissue, the tissue may be released from the cap **108** and the distal end **106** of the endoscope **104** is then repositioned until the target tissue is drawn into the cap **108** between the jaws **114** of the clip **102**, as desired. When it is determined that the clip **102** is in the desired positioned and the target tissue is drawn into the cap **108** (e.g., by applying suction or a grasper through a working channel of the endoscope **104**).

[0052] The clip **102** is then deployed by tensioning the control element **110** until a force exerted thereon exceeds a predetermined force which pushes the clip **102** over the protrusion **120**, off of the cap **108**, as shown in FIG. **3**. When the clip **102** is pushed off the cap **108**, the jaws **114** of the clip **102** close under their natural bias gripping the tissue that had been drawn into the cap **108**. As will be described in further detail below, an actuator assembly **124** at a proximal end of the endoscope **104** is connected to the control element **110** to control the tensioning thereof and a movement of the clip **102** relative to the endoscope **104** between the insertion, review and deployed configurations.

[0053] The clip **102** of this embodiment may be mounted to any standard endoscope **104** via the cap **108** which is sized, shaped and configured to be mounted over the distal end **106** of the endoscope **104** (e.g., slid over the distal end **106** and retained thereon via a friction fit). As will be understood by those of skill in the art, the endoscope **104** is configured to be inserted through a body lumen to a target area within the lumen and thus, must be sufficiently flexible to navigate through even tortuous paths of the body lumen although the devices described herein may be configured to operate with any other type of scope or insertion device as would be understood by those skilled in the art.

[0054] According to an exemplary embodiment, a proximal end of the endoscope **104** includes a handle member which remains outside the body accessible to a physician or other user permitting the user to guide the endoscope **104** through the body lumen (e.g., gastrointestinal tract) to a target site. In one embodiment, the actuating assembly **124** is coupled to the handle member of the endoscope **104**. In another embodiment, the actuating assembly **124** is usable independently of the handle member of the endoscope **104**. Although the exemplary embodiments describe use of the clip **102** with the endoscope **104**, it will be understood by those of skill in the art that the cap **108** may be sized and shaped to be mounted over the distal end of any insertion device (flexible or rigid) suitable for accessing a target site within a body at which a tissue to be clipped is located.

[0055] The cap **108** extends longitudinally from a proximal end **136** to the distal end **118** and includes the channel **116** extending longitudinally therethrough. The cap **108** is configured to be mounted over the distal end **106** of the endoscope **104** so that the channel **116** of the cap **108** is

substantially aligned with a longitudinal axis of the endoscope **104** and in communication with a channel of the endoscope **104**. The channel **116** extends away from the distal end **106** of the endoscope **104** so that occlusion of the field of view of the endoscope **104** is minimized. The cap **108** is sized and shaped to correspond to a cross-sectional shape of the endoscope **104** so that the cap **108** fits thereover via a friction fit.

[0056] The cap **108** is configured so that, when the cap **108** is mounted over the distal end **106** of the endoscope, the proximal portion **138** of the cap **108** extends over an endoscopic shaft while the distal portion **140** of the cap **108** extends distally past the distal end **106** of the endoscope **104**. The cap **108** is formed of a transparent material so that portions of the clip **102** extending over the distal portion **140** of the cap **108**, or therebeyond, are within the field of view of the endoscope **104**. According to one exemplary embodiment, a length of the distal portion **140** of the cap **108** is selected so portions of the clip **102** remain visible even when tissue is suctioned into the cap **108**. In one example the distal portion **140** may have a length of approximately 10 mm.

[0057] The cap **108** includes one or more protrusions **120** extending from an exterior surface **142** thereof. The protrusions **120** are configured to engage a portion of the clip **102**. In one embodiment, the cap **108** includes a pair of protrusions **120** diametrically opposed from one another and positioned along the cap **108** so that, when the clip **102** engages the protrusion **120**, the clip **102** extends over the cap **108** in the review configuration. The protrusion **120** is sized, shaped and configured so that, when a distal force exceeding a predetermined threshold value is applied to the clip **102**, the clip **102** is moved distally over the protrusion toward the deployed configuration.

[0058] The clip **102** includes a pair of jaws **114** connected to one another via hinges **126**, which permit movement of the jaws **114** relative to one another between the open configuration, in which the jaws **114** are separated from one another, and the closed configuration, in which the jaws **114** are moved toward one another to grip tissue. Each of the jaws **114** of this embodiment extends along a curve from a first end **128** to a second end **130** so that a first one of the hinges **126** connects the first ends **128** of the jaws **114** to one another, while a second one of the hinges **126** connects the second ends **130** of the jaws **114** to one another. According to one exemplary embodiment, each of the hinges **126** is a living hinge including a groove **132** sized and shaped to engage the protrusion **120** of the cap **108**. The hinges **126** in this embodiment are spring biased, biasing the jaws **114** toward the closed configuration. In one exemplary embodiment, each of the jaws **114** includes gripping features such as, for example, teeth **122**, so that when the jaws **114** are moved toward one another to the closed configuration, tissue is gripped between the jaws **114** via the teeth **122**.

[0059] When the clip **102** is mounted over the cap **108**, the jaws **114** are stretched open over opposing portions of the cap **108** so that the exterior surface **142** of the cap **108**. The cap **108** holds the clip **102** open with the jaws **114** separated from one another in the open configuration so that tissue drawn into the channel **116** of the cap **108** passes between the jaws **114**. As would be understood by those skilled in the art, the tissue may be drawn into the channel **116** via, for example, a suction force applied through the endoscope **104** or a grasping device inserted through a working channel of the endoscope **104**.

[0060] In the insertion configuration, the clip **102** is positioned over the proximal portion **138** of the cap **108**. In the review configuration, however, the clip **102** is moved distally relative to the cap **108** until the grooves **132** of the clip **102** engage the protrusions **120** and the clip **102** extends over the distal portion **140** of the cap **108**. In one embodiment, the teeth **122** of the clip **102** extend distally past the distal end **118** of the cap **108** in the review configuration. Thus, the clip **102**, and the position of the teeth **122** relative to the target tissue, are visible to the operator via the optical system of the endoscope **104**.

[0061] When the clip **102** is moved distally off the cap **108**, the clip **102** reverts to its biased closed configuration to grip between the jaws **114** any tissue that had been drawn into the channel **116**. It will be understood by those of skill in the art that the hinges **126** and/or jaws **114** of the clips **102** may be formed of any of a variety of materials so long as the hinges **126** bias the jaws **114** toward

the closed configuration, as described above with force sufficient to apply a desired clipping force to the tissue. In one example, portions of the clip **102** (e.g., the hinges **126**) may be formed of a shape memory alloy such as, for example, Nitinol.

[0062] As described above, the clip **102** may be moved relative to the cap **108** from the insertion configuration toward the review configuration and from the review configuration toward the deployed configuration via the control element **110**. The control element **110** may be formed as a thread wire, strand, filament or other similar flexible longitudinal element extending from a distal end **144** releasably coupled to the clip **102** to a proximal end **145** connected to the actuating assembly **124**.

[0063] According to an exemplary embodiment, the distal end **144** includes an enlarged end which, in one example, is configured as a knot or enlarged end. A distal portion **148** of the control element **110** is looped about a portion of the clip **102** so that a portion of the control element **110** is crimped between the clip **102** and the exterior surface **142** of the cap **108** and the knot engages a portion of the clip **102**. A remaining length of the control element **110** extends distally from the clip **102** so that it extends through a distal opening of the channel **116** of the cap **108**, proximally through the channel **116** and the working channel of the endoscope **104** to the actuating assembly **124**.

[0064] In one embodiment, the distal portion **148** of the control element **110** is looped about a first one of the jaws **114** with the knot engaging the clip **102** between two adjacent teeth **122**. More specifically, the knot at the distal end **144** of the control element **110** is engaged between the adjacent teeth **122**, looped about the first one of the jaws **114** so that a portion of the control element **110** immediately proximal of the knot is crimped between the clip **102** and the exterior surface **142** of the cap **108**, the distal portion **148** being looped about the first of the jaws **114** so that the remaining length of the control element **110** extends distally from the clip **102**, through the distal opening of the channel **116** of the cap **108**, and proximally through the channel **116** and the working channel of the endoscope **104**. Thus, when the control element **110** is drawn proximally relative to the endoscope **104**, applying a tension thereto, the clip **102** is moved distally relative to the cap **108**.

[0065] When the clip **102** is mounted over the cap **108** in the insertion configuration, the control element **110** may be drawn proximally relative to the endoscope **104** over a first distance selected so that the grooves **132** of the clip **102** abut the protrusions **120** and the clip **102** is drawn to the review configuration. From the review configuration the control element **110** may be drawn further proximally relative to the endoscope **104** over a second distance, applying a force exceeding the predetermined threshold value, so that the clip **102** moves distally over the protrusion **120** toward the deployed configuration. When the clip **102** is moved distally off of the cap **108** toward the deployed configuration, the distal portion **148** of the control element **110** unravels, disengaging the clip **102** and thereby releasing the clip **102** from the rest of the apparatus, leaving the clip **102** clipped over the target tissue while the scope and the cap **108** are withdrawn from the body. Thus, it will be understood by those of skill in the art that the control element **110** must be able to withstand forces exceeding the predetermined threshold value.

[0066] Since, in the review configuration, the clip **102** remains mounted over the cap **108** with the jaws **114** of the clip **102** in the open configuration, if it is determined that the clip **102** is not in a desired position relative to the target tissue, the operator may simply release the tissue from the channel **116** and reposition the distal end **106** of the endoscope **104** as desired. In particular, the distal end **106** may be repositioned until the operator visually confirms that the target tissue has been drawn into the channel **116** between the jaws **114** of the clip **102**, as desired. As described above, in the review configuration, the clip **102** extends over the distal portion **148** of the cap **108**, distally of the distal end **106** of the endoscope **104** so that the clip **102** is within the field of view of the endoscope **104**.

[0067] The actuating assembly **124**, as shown in FIGS. **4-6**, may be used to actuate the control element **110** by applying a tension therealong to move the clip **102** from the insertion configuration

to the review configuration and, upon visual confirmation of the desired positioning of the clip **102** relative to the target tissue, from the review configuration toward the deployed configuration. In one embodiment, the actuating assembly **124** may be coupled to the handle member at the proximal end of the endoscope **104** and connected to the proximal end **145** of the control element **110**, which extends through the channel of the endoscope **104**. In another embodiment, the actuating assembly **124** may be utilized independently of the endoscope **104**. In other words, the actuating assembly **124** may be utilized without being directly coupled to any portion of the handle member of the endoscope **104** or any portion of a shaft of the endoscope **104**. In particular, the proximal end **145** of the control element **110** may extend out of a proximal end of the endoscope **104** to be connected to the actuating assembly **124**.

[0068] According to an exemplary embodiment, as shown in FIGS. **4-6**, the actuating assembly **124** includes a first actuator **161** for actuating movement of the clip **102** from the insertion configuration toward the review configuration and a second actuator **185** for actuating movement of the clip **102** from the review configuration toward the deployed configuration. In one embodiment, the first actuator **161** includes first and second longitudinal members **162**, **164** pivotally coupled to one another and movable relative to one another to move the clip **102** from the insertion configuration toward the review. The first and second longitudinal members **162**, **164** are pivotally connected to one another in a substantially scissor-like fashion via, for example, a connecting pin **165** so that when proximal portions **166**, **168** of the first and second longitudinal members **162**, **164** are drawn toward one another, distal portions **170**, **172** are also drawn toward one another. The distal portions **170**, **172** are received within a housing **125** and are movably coupled to a moving element **174**, which is connected to the proximal end **145** of the control element **110**.

[0069] In one exemplary embodiment, the distal portions **170**, **172** is coupled to the housing **125** via the connecting pin **165** so that the housing **125** is longitudinally fixed with respect to the longitudinal members **162**, **164**. The distal portions **170**, **172**, however, may be moved toward and away from one another within the housing **125** and are connected to the moving element **174** so that, when the distal portions **170**, **172** are drawn toward each other, the moving element **174** moves from a proximal position relative to the longitudinal members **162**, **164** toward a distal position relative to the longitudinal members **162**, **164**.

[0070] In one exemplary embodiment, the moving element **174** is connected to the distal portions **170**, **172** via a sliding pin **176** extending from the moving element **174** and received within a longitudinal slot **178** along the distal portion **170** of the first longitudinal member **162**. The pin **176** of the moving element **174** is slidably received within the slot **178** so that, when the proximal portions **166**, **168** of the first and second longitudinal members **162**, **164** are drawn toward one another to correspondingly move the distal portions **170**, **172** toward one another, the pin **176** slides distally along the slot **178** to move the moving element **174** from the proximal position to the distal position. It will be understood by those of skill in the art, however, that the moving element **174** may be coupled to the first and second longitudinal members **162**, **164** in any of a number of ways so long as the moving element **174** is coupled thereto in a manner that permits a longitudinal sliding of the moving element **174** relative thereto, between the proximal and distal positions, as described above.

[0071] In one exemplary embodiment, the proximal portions **166**, **168** are biased away from one another via, for example, a compression spring **182**. The compression spring **182** prevents the proximal portions **166**, **168** from being inadvertently drawn together to move the clip **102** toward the review configuration. In this embodiment, the proximal portions **166**, **168** include a ratchet mechanism **184** extending therebetween so that, as the proximal portions **166**, **168** are drawn toward one another, the proximal portions **166**, **168** are prevented from reverting toward their biased configuration. Thus, once the proximal portions **166**, **168** have been drawn toward one another, the moving element **174** is locked in the distal position so that the clip **102** is locked in the

review configuration. Upon locking of the proximal portions **166**, **168** toward the review configuration, the clip **102** may be visualized and readjusted, as necessary, without having to continually hold the proximal portions **166**, **168** toward one another to keep the clip **102** in the review configuration.

[0072] As shown in FIG. **5-6**, the control element **110** is routed through a pulley mechanism **180** within the housing **125** to be coupled to the moving element **174**. In particular, the control element **110** extends from the distal end **144** connected to the clip **102**, through the endoscope **104** and through the housing **125** to be routed through the pulley mechanism **180** so that the proximal end **145** is connected to the moving element **174**. The pulley mechanism **180** is configured so that when the moving element **174** is moved from the proximal position to the distal position, the proximal end **145** of the control element **110** is moved proximally, moving the control element **110** along the pulley mechanism **180** so that tension is applied to the control element **110**. The first and second longitudinal members **162**, **164** are configured so that when the proximal portions **166**, **168** are drawn toward one another, a tension applied to the control element **110** is sufficient to move the clip **102** from the insertion configuration to the review configuration, a portion of the clip **102** engaging the protrusion **120**.

[0073] In one embodiment, the pulley mechanism **180** is positioned within a portion of the housing **125** that is substantially longitudinally aligned with the proximal end **145** of the control element **110** when the moving element **174** is in the proximal position (see FIG. **5**). When the proximal portions **166**, **168** are drawn toward one another and the moving element **174** is moved toward the distal position, however, the proximal end **145** of the control element **110** is also moved distally so that a portion of the control element **110** extends from the pulley mechanism **180** along a portion of the housing **125** that is in communication with second actuator **185** (see FIG. **6**).

[0074] The second actuator **185** for actuating movement of the clip **102** from the review configuration toward the deployed configuration, in one exemplary embodiment, includes a push button **186**. The push button **186** includes a push portion **188** accessible to the user along an exterior of the housing **125** and a tab **190** extending into the housing **125**. As shown in FIG. **6**, when the moving element **174** is moved from the proximal position toward the distal position, a portion of the control element **110** is moved into engagement with the tab **190** of the push button **186** while the tension is being applied along the control element **110**. Thus, when it is desired to move the clip **102** from the review configuration toward the deployed configuration, the operator of the system **100** presses the push portion **188** so that the tab **190** is moved further into the housing **125** and pressed into the portion of the control element **110** with which it is engaged. Thus, when the push portion **188** is pressed, the tab **190** is pressed further into the control element **110**, applying additional tension along the control element **110** which causes a length of the control element **110** extending through the endoscope to be moved proximally relative to the endoscope **104** at a force sufficient to move the clip **102** distally over the protrusion **120** along the cap **108**, from the review configuration toward the deployed configuration. As the clip **102** is pushed distally off of the cap **108**, the clip **102** reverts toward its biased configuration to be clipped over the target tissue.

[0075] According to an exemplary method for tissue closure utilizing the system **100**, as shown in FIGS. **1-6**, the endoscope **104** with the cap **108** and the clip **102** mounted thereon are inserted into a natural body orifice into and through a body lumen such as, for example, the gastrointestinal tract, to a target area within the lumen. As described above, in the insertion configuration, as shown in FIG. **1**, the clip **102** is mounted over the proximal portion **138** of the cap **108**, which is mounted over the distal end **106** of the endoscope **104**, so that the jaws **114** are separated from one another toward the open configuration. The clip **102** is guided to the target area via the endoscope **104**, and positioned over target tissue. The target tissue is then drawn into the cap **108** via, for example, a suction force applied through a working channel of the endoscope **104**.

[0076] The clip **102** is then moved toward the review configuration by moving the clip **102** distally

relative to the cap **108** utilizing the first actuator **161**. In particular, the proximal portions **166**, **168** of the first and second longitudinal members **162**, **164** are moved toward one another so that the moving element **174**, to which the proximal end **145** of the control element **110** is attached, is moved from the proximal position toward the distal position, as described above. The first and second longitudinal members **162**, **164** may then be locked relative to one another via the ratchet mechanism **184** so that the clip **102** is locked toward the review configuration. In the review configuration, the clip **102** extends over the distal portion **140** of the cap **108** so that a position of the clip **102** relative to the target tissue is within the field of view of the endoscope **104**. Thus, in the review configuration, the user determines whether the clip **102** is in the desired gripping position relative to the target tissue.

[0077] As discussed above, the actuating assembly **124** may be locked toward the review configuration. Thus, if it is determined during the review configuration that the clip **102** is not in the desired position relative to the target tissue, the tissue drawn into the cap **108** is released therefrom and the distal end **106** of the endoscope **104**, and thereby the clip **102**, are repositioned over the target tissue. The clip **102** may be repeatedly repositioned relative to the target tissue, as necessary during the review configuration, until the user is able to visually confirm that the clip **102** is positioned over the target tissue, as desired.

[0078] Once the user confirms that the target tissue has been drawn into the channel **116** between the jaws **114**, as desired, the clip **102** may be moved from the review configuration to the deployed configuration via the second actuator **185** to move the clip **102**. In particular, the operator presses the push button **186** so that the tab **190** extends further into the portion of control element **110** in engagement therewith. A force exerted on the control element **110** via the tab **190** exceeds a predetermined threshold level, which allows the clip **102** to be moved distally over the protrusion **120** of the cap **108** toward the deployed configuration. The clip **102** is moved distally relative to the cap **108** until the clip **102** is moved distally off the cap **108** and the clip **102** reverts to its biased closed configuration gripping the target tissue. As described above, when the clip **102** is moved toward the deployed configuration, the control element **110** disengages the clip **102** releasing the clip **102** in the body, clipped over the target tissue as the endoscope **104** and the cap **108** are withdrawn from the body.

[0079] As shown in FIGS. **7**-**10**, an actuator assembly **224** according to another exemplary embodiment is substantially similar to the actuator assembly **124** and is similarly utilized with the clip **102** and the endoscope **104**, as described above with respect to the system **100**. Similarly to the actuator assembly **124**, the actuator assembly **224** comprises a first actuator **261** for moving the clip **102** from the insertion configuration toward the review configuration and a second actuator **285** for moving the clip **102** from the review configuration toward the deployed configuration. Similarly to the actuator assembly **124**, the actuator assembly **224** may, in one embodiment, be coupled to a handle of the endoscope **104** to be utilized therewith. In another embodiment, the actuator assembly **224** may utilized independently (i.e., without direct coupling to the handle of the endoscope **104**) to control movement of the control element **110** and thereby the clip **102**.

[0080] Rather than having pivotally engaged components, however, the first actuator **261** may include a lever **264** movable relative to a handle portion **262** to move the control element **110**. The proximal end **145** of the control element **110** is connected to an end of the lever **264** so that, when the lever **264**, is pressed, the control element **110** is moved proximally relative to the endoscope **104**, thereby moving the clip **102** distally along the cap **108** from the insertion configuration toward the review configuration. The lever **264** should remain pressed to maintain the tension along the control element **110** toward the review configuration. In one embodiment, similarly to the first actuator **161**, the lever **264** may be biased away from the handle portion **262** via, for example, a compression spring **282** extending therebetween. Thus, the actuator assembly **224** may further include a lock **284** for locking the lever **264** relative to the handle portion **262** toward the review configuration.

[0081] Similarly to the actuator assembly **124**, the actuator assembly **224** includes a pulley mechanism **280** within a housing **225** thereof through which a proximal portion of the control element **110** is routed to be connected to the lever **264**. The pulley mechanism **280** routes the control element **110** through the housing **225** so that the control element **110** interfaces with the second actuator **285**. Thus, when it is desired to move the clip **102** from the review configuration toward the deployed configuration, the second actuator **285** is employed to provide a further tension to the clip **102**, which is sufficient to move the clip **102** distally over the protrusion **120** of the cap **108**. Similarly to the second actuator **185**, the second actuator **285** includes a push button **286**. The push button **286** includes a push portion **288** accessible to the user along an exterior of the housing **225** and a tab **290** extending into the housing **225**.
[0082] As shown in FIGS. **9-10**, when it is desired to move the clip **102** from the review configuration toward the deployed configuration, the push portion **288** is pressed moving the tab **290** further into the housing **225** and pressing it against the control element **110**. Thus, when the push portion **288** is pressed, the tab **290** is pressed further into the control element **210**, applying additional tension along the control element **110** moving causes a length of the control element **110** extending through the endoscope proximally relative to the endoscope **104** at a force sufficient to move the clip **102** distally over the cap **108** past the protrusion **120** from the review configuration toward the deployed configuration. As the clip **102** is pushed distally off of the cap **108**, the clip **102** is reverts to its biased configuration clipping the tissue drawn into the cap **108**.
[0083] As shown in FIGS. **11-16**, an actuator assembly **324** according to another exemplary embodiment is substantially similar to the actuator assemblies **124**, **224**, and may be utilized with the clip **102** and the endoscope **104**, as described above with respect to the system **100** for actuating movement of the clip **102** between the insertion configuration, review configuration and deployed configuration. Similarly to the actuator assemblies **124**, **224**, the actuator assembly **334** comprises a first actuator **361** configured to move the clip **102** from the insertion configuration to the review configuration and a second actuator **385** configured to move the clip **102** from the review configuration toward the deployed configuration. The actuator assembly **324** may be coupled to the endoscope **104**, as shown in FIG. **11**, or may be utilized independently of the endoscope, as shown in FIG. **12**.
[0084] A handle portion **362** in this embodiment, is, for example, an ergonomic, substantially T-shaped handle configured to be gripped by the operator of the system **100**. In particular, in one embodiment, a handle portion **362** extends substantially perpendicularly to a housing portion **325** through which the control element **110** extends from the endoscope **104**. Further, rather than a long lever or handle as described above with respect to the actuator assemblies **124**, **224**, the first actuator **361** in this embodiment includes a lever **364** extending along the handle portion **362** so that the lever **364** may be gripped there against via a power grip. The proximal end **145** of the control element **110** is connected to the lever **364** so that, when it is pressed against the handle portion **362**, a length of the control element **110** passing through the endoscope **104** is moved proximally relative to the endoscope **104**, moving the clip **102** distally along the cap **108** from the insertion configuration toward the review configuration.
[0085] Similarly to the previously described actuator assemblies, the lever **364** is biased away from the handle portion **362** via, for example, a compression spring **382** extending between the handle portion **362** and the lever **364**. To maintain a tension along the control element **110** and to lock the clip **102** toward the review configuration, the actuator assembly **324** further includes a lock **384**. The lock **384**, in this embodiment, includes a button located on the handle portion **362** so that, when pressed thereinto, a portion of the button engages a portion of the lever **364** received within the handle portion **362** to engage the lever **364** and hold the lever **364** relative to the handle portion **362** in a position corresponding to the review configuration. (see FIG. **14**). In particular, as shown in FIG. **16**, a portion of the button of the lock **384** extends into and engages a slot **392** within the lever **364** to lock the lever **364** relative to the handle portion **362**.

[0086] As the control element **110** is drawn proximally relative to the endoscope **104** from the insertion configuration toward the review configuration, a proximal portion of the control element is drawn proximally past a portion of the housing **325** which interfaces with the second actuator **385**. Similarly to the previously described actuator assemblies, the second actuator **385** in this embodiment includes a push button **386** including a push portion **388** and a tab **390** extending into the housing **325**. When it is desired to move the clip **102** from the review configuration toward the deployed configuration, the operator pushes the push portion **388** moving the tab **390** further into the housing **325** so that the tab **390** is pressed against the control element **110** imparting additional tension to the control element **110**. This tension moves a length of the control element **110** extending through the endoscope **104** proximally relative to the endoscope **104** at a force sufficient to move the clip **102** distally over the protrusion **120**, from the review configuration toward the deployed configuration. As the clip **102** is pushed distally off of the cap **108**, the clip **102** reverts toward its biased configuration to be clipped over the target tissue.
[0087] While the exemplary embodiments show and describe target tissue being drawn into the channel **116** of the cap **108** via suction applied through, for example, the working channel of the endoscope **104**, it will be understood by those of skill in the art that tissue may also be drawn into the channel **116** using other methods. For example, in other embodiments, tissue may be drawn into the channel and between the separated jaws **114** of the clip **102**, when the clip **102** is in, for example, the review configuration, by using devices such as tissue graspers passed through the endoscope **104** to the distal end **106** thereof. The actuator assembly **324** further includes a port **396** extending through a proximal end **397** of the housing **325** configured to receive devices such as tissue graspers therein. Tissue graspers may be inserted through the port **396** and through the working channel of the endoscope **104** so that tissue adjacent the distal end **106** may be drawn into the channel **116** of the cap **108**, substantially as described above with respect to the system **100**. In one embodiment, tissue graspers (or other similar devices) are inserted into the port **396** and through a corresponding channel extending through the housing **325** and lever **364**.
[0088] As shown in FIGS. **17-20**, an actuator assembly **424** according to another exemplary embodiment is substantially similar to the actuator assemblies described above. The actuator assembly **424** may be utilized to control movement of the clip **102** relative to the endoscope **104**, as described above with respect to the system **100**. The actuator assembly **424**, however, comprises a single actuator **461** capable of controlling both the movement of the clip **102** from the insertion configuration to the review configuration and the movement of the clip **102** from the review configuration toward the deployed configuration.
[0089] According to an exemplary embodiment, the actuator assembly **424** includes a rotary handle **464** rotatable about a housing **425** through which the control element **110** is received from the endoscope **104**. The rotary handle **464** extends from a first end **490** coupled to the housing **425** to a second end **492** that remains accessible to the operator of the system so that the rotary handle **464** may be rotated about the housing **425**. In one embodiment, the first end **490** includes a coupling member **491** rotatably received within the housing **425** and configured to receive therein a moving element **474**. The moving element **474** in this embodiment is threadedly received within the coupling member **491** of the rotary handle **464** so that, when the rotary handle **464** is rotated about the housing **425**, the moving element **474** is moved longitudinally relative to the housing **425** as it rotates.
[0090] In one embodiment, when the rotary handle **464** is rotated in a first direction relative to the housing **425**, the moving element **474** moves proximally relative to the housing. The proximal end **145** of the control element **110** is connected to the moving element **474**. Thus, when the rotary handle **464** is rotated in the first direction, the control element **110** moves proximally relative to the housing **425**, and thereby the endoscope **104**, to move the clip **102** distally along the cap **108**.
[0091] Similarly to the actuator assemblies described above, the actuator assembly **424** includes, for example, a compression spring or other biasing element biasing the rotary handle toward the

insertion configuration. To move the clip **102** toward the review configuration, the operator actively rotates the rotary handle. In one exemplary embodiment, the housing **425** includes a pin **494** or other protrusion along a portion of the housing **425**. The pin **494** interfaces with the rotary handle **464** as the rotary handle **464** is rotated about the housing **425**. The pin **494** is positioned along the housing **425** so that, as the rotary handle **464** is rotated about the housing **425**, the rotary handle **464** engages the pin **494** until the control element **110** has been moved by a proximal distance sufficient to move the clip **102** from the insertion configuration toward the review configuration.
[0092] Engagement between the pin **494** and the rotary handle **464** provides tactile feedback to the operator indicating the clip **102** is engaged with the protrusion **120** along the cap **108** and is in the review configuration. When it is desired to move the clip **102** from the review configuration toward the deployed configuration, the operator further rotates the rotary handle **464** about the housing **425** in the first direction, pushing the rotary handle **464** past the pin **494**. As the rotary handle **464** is rotated past the pin **494**, the clip **102** is correspondingly pushed distally beyond the protrusion **120** until the clip **102** is pushed distally off of the cap **108** and permitted to revert to its biased closed configuration to grip the target tissue.
[0093] Similarly to the actuator assembly **324**, the actuator assembly **424** further includes a port **496** extending through a proximal end **497** of the housing **425** configured to receive devices such as tissue graspers therein. Tissue graspers may be inserted through the port **496** and through the working channel of the endoscope **104** so that tissue adjacent the distal end **106** may be drawn into the channel **116** of the cap **108**, substantially as described above with respect to the system **100**. In one embodiment, tissue graspers (or other similar devices) may be inserted into the port **496** and through a corresponding channel extending through the moving element **474** to be received within the endoscope **104**.
[0094] As shown in FIGS. **21**-**25**, a tissue clipping system **500** according to another exemplary embodiment is substantially similar to the system **100**, comprising a clip **502** mountable over a distal end **506** of an endoscope **504** via a cap **508** so that the clip **502** is movable relative to the endoscope **504** between an insertion configuration, a review configuration and a deployed configuration. Similarly to the system **100**, the clip **502** may be moved from the insertion configuration, as shown in FIG. **21**, to the review configuration, as shown in FIG. **22**, and then, upon confirmation that the target tissue is received between jaws **514** of the clip **502** as desired, the clip **502** is moved from the review configuration toward the deployed configuration, as shown in FIG. **23**. The system **500**, however, is configured such that, if during the review configuration, an operator of the system **500** determines that the clip **502** is not in a desired position relative to the target tissue, the clip **502** may be moved from the review configuration back toward the insertion configuration so that the distal end **506** and the clip **502** may be repositioned relative to the target tissue when the clip **502** is in the insertion configuration.
[0095] The system **500** thus further comprises a repositioning element **512** configured to facilitate movement of the clip **502** between the insertion configuration and the review configuration and a deployment element **510** configured to facilitate movement from the review configuration toward the deployed configuration, when it is determined that the clip **502** is in a desired position relative to the target tissue. As described above, the deployment element **510** and the repositioning element **512** are connected to an actuator assembly **524** substantially similar to the actuator assemblies **124**-**324** described above with respect to the system **100**. The actuator assembly includes a first actuator **561** for moving the clip **502** between the insertion configuration and the review configuration, and a second actuator **585** for moving the clip **502** from the review configuration toward the deployed configuration.
[0096] Similarly to the system **100**, in the insertion configuration the clip **502** is mounted over the cap **508** in the open configuration with the jaws **514** thereof separated from one another to receive tissue therebetween. The clip **502** is preferably inserted to a target site within a body in this insertion configuration. The clip **502** may be moved from the insertion configuration to the review

configuration, by moving the clip **502** distally relative to the endoscope **504** to enhance a field of view of the endoscope **504** so that a position of the clip **502** relative to the target tissue is visible to an operator (e.g., surgeon or other user) of the system **500**.

[0097] Rather than moving the clip **502** relative to the cap **508**, however, the cap **508**—with the clip **502** mounted thereon—is moved distally relative to the endoscope **504** to move the clip **502** from the insertion configuration toward the review configuration. The clip **502** is mounted over the cap **508** such that a portion of the clip **502** extends distally past a distal end **518** of the cap **508** while maintaining the clip **502** in the open position so that, when the cap **508** is moved distally relative to the endoscope **504** toward the review configuration, a portion of the clip **502** extends distally of the distal end **506** of the endoscope **504** so that the portion of the clip **502** extending distally beyond the distal end **506** is within the field of view of the endoscope **504**.

[0098] If the operator determines that the clip **502** is in a desired position relative to the target tissue, the clip **502** may be moved from the review configuration toward the deployed configuration. If, however, the operator determines that the clip **502** is not in the desired position relative to the target tissue, the clip **502** may be moved from the review configuration back toward the insertion configuration so that any tissue drawn into the cap **508** may be released and the clip **502** may be repositioned as desired relative to the target tissue.

[0099] To facilitate movement of the cap **508** and clip **502** relative to the endoscope **504** between the insertion configuration and the review configuration, the system **500** further comprises a biasing element **520** extending between the cap **508** and a distal-most end **507** of the endoscope **504** to bias the cap **508**, and the clip **502** mounted thereover, toward the insertion configuration. The repositioning element **512**, a distal end **550** of which is connected to the cap **508**, may be used to move the cap **508** and clip **502** between the insertion configuration and the review configuration, as necessary, until the operator determines that the clip **502** is in the desired configuration relative to the target tissue.

[0100] Once the operator has determined that the clip **502** is in the desired position relative to the target tissue, the deployment element **510**, a distal end **544** of which is releasably coupled to the clip **502**, may be used to move the clip **502** distally off of the cap **508** toward the deployed configuration. In the deployed configuration, the clip **502** reverts under its natural bias toward the closed configuration to grip the target tissue received between the jaws **514**. Manipulation of the deployment element **510** and/or the repositioning element **512** for moving the clip **502** between the insertion, review and deployed configurations may be controlled via an actuator assembly **524** at a proximal end of the endoscope **504**.

[0101] Those skilled in the art will understand that the endoscope **504** may be substantially similar to the endoscope **104** and extends longitudinally from a proximal end including a handle member **534** to the distal end **506**, over which the cap **508** is mounted. The endoscope **504** includes a channel **505** extending therethrough. In this embodiment, the endoscope **504** further includes a stop **570**, shoulder or other protrusion extending from an exterior surface **542** of the cap **508**, at the distal-most end **507**, for engaging a distal end **572** of the biasing element **520** and stopping the distal end **572** of the biasing element **520** from extending distally beyond the stop **570**.

[0102] The cap **508** may also be substantially similar to the cap **108**, extending longitudinally from a proximal end **536** to a distal end **518** and defining a channel **516** therein. The channel **516** corresponds to a size of the endoscope **504** so that the cap **508** may be movably mounted thereover. In one embodiment, the cap **508** also includes an opening extending through a wall thereof, the opening configured to receive the repositioning element **512** therein, as will be described in further detail below.

[0103] The biasing element **520** of this embodiment extends between the distal end **518** of the cap **508** and the stop **570** of the endoscope **504** to bias the cap **508** toward the insertion configuration. According to one exemplary embodiment, the biasing element **520** may be configured as a spring extending about the distal end **506** of the endoscope **504**, between the distal end **518** of the cap **508**

and the stop **570** at the distal-most end **507** of the endoscope **504**. In the insertion configuration, the clip **502**, which is substantially similar to the clip **102**, is mounted over the cap **508** so that jaws **514** of the clip **502** are stretched open over the cap **508**.

[0104] The exterior surface **542** of the cap **508** holds the jaws **514** open so that the jaws **514** are separated from one another and tissue may be received therebetween. The clip **502** may be mounted over the cap **508** so that, for example, teeth **522** extend distally past the distal end **518** of the cap **508**. In the insertion configuration, however, the distal end **518** of the cap **508** is separated from the distal-most end **507** of the endoscope **504** via a distance selected so that the teeth **522** do not extend distally past the distal-most end **507** of the endoscope **504**.

[0105] To move the clip **502** toward the review configuration, the cap **508** is moved distally relative to the endoscope **504**, compressing the biasing element **520** until the teeth **522** extend distally past the distal-most end **507** of the endoscope **504** so that the teeth **522** is within the field of view of the endoscope **504**. Thus, in the review configuration, the operator or user may determine whether the clip **502** is in the desired position relative to the target tissue. If the clip **502** is in the desired position, the clip **502** may be moved toward the deployed configuration by pushing the clip **502** distally off of the cap **508**.

[0106] If, however, it is determined that the clip **502** is not in the desired position relative to the target tissue, the compression force on the biasing element **520** is released so that the biasing element **520** reverts to its biased configuration, pushing the cap **508** proximally along the endoscope **504** toward the insertion configuration so that any tissue previously drawn into the cap **508** may be released and the clip **502** may be repositioned. As will be described in further detail below, movement of the clip **502** between the insertion configuration and the review configuration is controlled via the repositioning element **512** and movement of the clip **502** from the review configuration toward the deployed configuration is controlled via the deployment element **510**.

[0107] The deployment element **510** of this embodiment is substantially similar to the control element **110** includes, for example, a thread, wire, strand, filament or other similar flexible longitudinal element extending from the distal end **544** releasably coupled to the clip **502** to a proximal end connected to the actuator assembly **524**. The deployment element **510** of this embodiment is releasably coupled to the clip **502** in a manner substantially to the coupling between the clip **102** and the control element **110**. In an exemplary embodiment, a distal portion **548** of the deployment element **510** is looped about a portion of a first one of the jaws **514** so that a portion of the deployment element **510** is crimped between the clip **502** and the exterior surface **542** of the cap **508** while, for example, a knot or other enlargement, at the distal end **544** is engaged between adjacent teeth **522** of a first one of the jaws **514**.

[0108] A remaining length of the deployment element **510** extends distally from the clip **502** to pass through a distal opening of the channel of the endoscope **504** and extend proximally through the endoscope **504**. Thus, drawing the deployment element **510** proximally relative to the endoscope **504** moves the clip **502** distally relative to the cap **508** so that the clip **502** moves toward the deployed configuration. As described above, when the clip **502** is pushed distally off of the cap **508** toward the deployed configuration, the distal portion **548** of the deployment element **510** unwinds from the clip **502** so that the knot disengages the clip **502** and the clip **502** is released to clip the target tissue.

[0109] The repositioning element **512** may include, for example, a thread, strand, wire filament or other similar flexible longitudinal element. Rather than being releasably connected to the clip **502**, however, the distal end **550** of the repositioning element **512** may be non-releasably affixed to a portion of the cap **508**. According to one exemplary embodiment, the distal end **550** includes an enlarged end such as, for example, a knot, so that when the repositioning element **512** is passed through an opening extending through a wall of the cap **508**, the knot **552** prevents the distal end **550** from passing therethrough. Thus, the knot of the repositioning element **512** engages the cap **508** along an exterior surface **542** of the cap **508** so that a remaining length of the repositioning

element **512** extends through the opening, distally between an interior surface of the cap **508** and an exterior surface of the endoscope **504**, distally between the biasing element **520** and the exterior surface of the endoscope **504** so that the repositioning element **512** is received within the distal opening of the channel of the endoscope **504** to extend proximally through the endoscope **504**.
[0110] Thus, moving the repositioning element **512** proximally relative to the endoscope **504** moves the cap **508** distally relative to the endoscope **504** from the insertion configuration toward the review configuration. In this review configuration the biasing element **520** is maintained in a compressed configuration via tension along the repositioning element **512**. If, however, it is determined during the review configuration that the clip **502** is not in the desired position relative to the target tissue, the tension along the repositioning element **512** may be released permitting the biasing element **520** to revert to its biased configuration which moves the cap **508** proximally relative to the endoscope **504**, from the review configuration toward the insertion configuration.
[0111] Proximal ends of each of the deployment element **510** and the repositioning element **512** are, in this embodiment, connected to the actuator assembly **524** and coupled to a handle member of the endoscope **504**. The actuator assembly **524** is substantially similar to the actuator assemblies described above, comprising a first actuator **561** for moving the clip **502** from the insertion configuration toward the review configuration and a second actuator **585** for moving the clip **502** from the review configuration toward the deployed configuration. The actuator assembly **524** may also include a housing **525** through which the proximal ends of the repositioning element **512** and the deployment element **510** extend to be connected to the first and second actuators **561**, **585**.
[0112] According to an exemplary embodiment, as shown in FIGS. **24-25**, the actuator assembly **524** the first actuator **561** may include a lever **564** configured to control a movement of the repositioning element **512** relative to the endoscope **504** and the second actuator **585** may include a push button **586** for controlling a movement of the deployment element **510** relative to the endoscope **504**. The lever **564** may be pivotally coupled to the housing **525** so that when the lever **564** is pressed toward the housing **525**, the repositioning element **512** is drawn proximally through the endoscope **504**. In particular, the proximal end of the repositioning element **512** is connected to the lever **564** such that, when the lever **564**, is pressed, the repositioning element **512** is moved proximally relative to the endoscope **504**, thereby moving the cap **508** distally relative to the endoscope from the insertion configuration toward the review configuration. The lever **564** should remain pressed to maintain the tension along the repositioning element **512** and keep the biasing element **520** compressed toward the review configuration.
[0113] If, during this review configuration, the operator determines that the clip **502** is in the desired position relative to the target tissue, the operator presses the push button **586** using, for example, his/her thumb. The push button **586** extends into the housing **525** and is connected to the proximal end of the deployment element **510** so that, when pressed, the deployment element **510** is drawn proximally relative to the endoscope **504** moving the clip **502** distally relative to the cap **508** until the clip **502** is moved distally off the cap **508**. If, however, during the review configuration the operator determines that the clip **502** is not in the desired position relative to the target tissue, the operator releases the lever **564**, releasing tension therealong and permitting the biasing element **520** to revert to its biased configuration. As the biasing element **520** reverts toward its biased configuration, the biasing element **520** pushes the cap **508** proximally along the endoscope **504** from the review configuration toward the insertion configuration so that, after releasing any tissue that had been drawn into the cap **508**, the clip **502** may be repositioned, as necessary.
[0114] An exemplary method for clipping tissue using the clipping system **500** may be substantially similar to the method for clipping tissue using the system **100**. Similarly to the system **100**, the clip **502**, mounted over the distal end **506** of the endoscope **504** via the cap **508** in the insertion configuration, as shown in FIG. **21**, is inserted through a body lumen (e.g., of a gastrointestinal tract) to a target site within the body. As described above, the cap **508** is biased toward the insertion configuration via the biasing element **520**.

[0115] Once the clip **502** is positioned over target tissue, the tissue is drawn into the cap **508** (e.g., via suction force may applied through a working channel of the endoscope **504**) to extend between the jaws **514** of the clip **502**. The clip **502** may then be moved from the insertion configuration toward the review configuration, as shown in FIG. **22**, by moving the repositioning element **512** proximally relative to the endoscope **504** so that the cap **508** is moved distally which compresses the biasing element **520**. In the review configuration, teeth **522** of this embodiment extend distally past the distal-most end **507** of the endoscope **504** so that a position of the teeth **522** relative to the target tissue is visible via the endoscope **504**.

[0116] When the clip **502** is in the review configuration, the operator may determine whether the clip **502** is in the desired position relative to the target tissue. If the clip **502** is not in the desired position, a tension along the repositioning element **512** may be released so that the biasing element **520** may revert toward its biased configuration to move the cap **508** from the review configuration back toward the insertion configuration. Any tissue drawn into the cap **508** may then be released and, as the clip **502** is now in the insertion configuration, the endoscope **504** and the cap **5089** may be repositioned relative to the target tissue until the cap **508** and the clip **502** are in a desired position relative to the target tissue. Then the clip **502** may once again be moved toward the review configuration and this process may be repeated, as necessary, until the clip **502** is determined to be in the desired position relative to the target tissue.

[0117] Once it has been determined that the clip **502** is in the desired position, the clip **502** may be moved toward the deployed configuration by moving the deployment element **510** proximally relative to the endoscope **504** until the clip **502** has been pushed distally off of the cap **508**, as shown in FIG. **23**. As described above, when the clip **502** is pushed distally off the cap **508**, the clip **502** is freed to revert toward its biased closed configuration so that the target tissue is gripped between the jaws **514**.

[0118] In addition, since the deployment element **510** is no longer crimped between the clip **502** and the cap **508**, the distal portion **548** of the deployment element **510** unwinds from the clip **502** so that the knot **546** disengages from and releases the clip **502** which remains clipped over the target tissue as the endoscope **504** along with the cap **508** are withdrawn from the body. It will be understood by those of skill in the art, that since the repositioning element **512** is connected to the cap **508** and is in no way connected to the clip **502**, the repositioning element **512** need not release or disengage from the cap **508**.

[0119] It will be apparent to those skilled in the art that various modifications may be made in the present disclosure, without departing from the scope of the disclosure. Furthermore, those skilled in the art will understand that the features of any of the various embodiments may be combined in any manner that is not inconsistent with the description and/or the functionality of the embodiments.

Claims

1-35. (canceled)

36. A device for clipping tissue, comprising: a cap extending longitudinally from a proximal end to a distal end and including a channel extending therethrough, the cap being configured to be mounted over a distal portion of an endoscope; a clip including first and second jaws movably connected to one another via hinges, at least one of the hinges being biased to draw the first and second jaws toward one another, the clip being mountable over the cap such that the first and second jaws extend over opposing portions of the cap so that the first and second jaws are separated from one another to receive target tissue therebetween, the cap being configured so that distal movement of the cap relative to the endoscope moves the clip from an insertion configuration to a review configuration in which at least a portion of the clip extends distally into a field of view of an optical device of the endoscope and distal movement of the clip relative to the cap moves the clip from the review configuration to a deployed configuration in which the clip is moved distally

off of the cap so that the first and second jaws are drawn toward one another under the bias of the at least one of the hinges to close over tissue received therebetween; a repositioning element extending from a distal end coupled to the cap, through the channel of the cap to a proximal end which, in use, remains outside a living body, the repositioning element being configured so that moving the repositioning element proximally moves the cap distally along the endoscope from the insertion configuration to the review configuration; a deployment element extending from a distal end releasably coupled to the clip, through the channel of the cap, to a proximal end which, in use, remains outside the living body, the deployment element being configured so that proximal movement of the deployment element moves the clip distally relative to the cap to the deployed configuration; and an actuator assembly including a first actuator configured to control movement of the repositioning element and a second actuator configured to control movement of the deployment element.

37. The device of claim 36, wherein the actuator assembly further comprises a housing through which the proximal ends of the repositioning element and the deployment element extend to be connected to the first and second actuators.

38. The device of claim 37, wherein the first actuator includes a lever pivotally coupled to a handle, the proximal end of the repositioning element connected to a portion of the handle so that, movement of the lever relative to the housing draws the repositioning element proximally to move the cap and the clip distally from the insertion configuration toward the review configuration.

39. The device of claim 37, wherein the second actuator includes a push button extending into the housing and connected to the proximal end of the deployment element so that, when the push button is pressed further into the housing, the deployment element is moved proximally to move the clip distally relative to the cap from the review configuration toward the deployed configuration.

40. The device of claim 36, further comprising a biasing element extending between a distal end of the cap and a stop configured to be positioned at a distal-most end of the endoscope on which the cap is mounted, the biasing element biasing the cap toward the insertion configuration so that when not subject to a distally directed force via the repositioning element, the cap and the clip revert to the insertion configuration.

41. The device of claim 38, further comprising a biasing element extending between a distal end of the cap and a stop configured to be positioned at a distal-most end of the endoscope on which the cap is mounted, the biasing element biasing the cap toward the insertion configuration so that when the lever is released, the cap and the clip revert to the insertion configuration.

42. The device of claim 40, wherein in the insertion configuration an entirety of the clip is proximal of the stop.

43. The device of claim 36, wherein in the insertion configuration and in the review configuration a distal portion of the clip extends distally beyond a distal end of the cap.

44. The device of claim 41, wherein the repositioning element is configured to apply a distally directed force to the cap that overcomes the bias of the biasing element to move the cap distally relative to the endoscope on which the cap is mounted.

45. The device of claim 36, wherein the repositioning element and the deployment element are configured to be fed through a working channel of the endoscope.

46. A device for clipping tissue, comprising: a cap extending longitudinally from a proximal end to a distal end and including a channel extending therethrough, the cap being configured to be mounted over a distal portion of an endoscope; a clip including first and second jaws biased toward a tissue clipping position in which the first and second jaws are adjacent to one another, the clip being mountable, in an insertion configuration, over the cap with the first and second jaws maintained spread apart from one another on an outer surface of the cap so that tissue drawn into a distal end of the cap is positioned between the first and second jaws, the cap being configured to be movable relative to the endoscope on which it is mounted so that distal movement of the cap

relative to the endoscope moves the clip from the insertion configuration to a review configuration in which at least a portion of the clip extends distally beyond a distal end of the endoscope into a field of view of an optical device of the endoscope; a repositioning element extending from a distal end coupled to the cap, through the channel of the cap to a proximal end which, in use, remains outside a living body, the repositioning element being configured to move the cap distally along the endoscope from the insertion configuration to the review configuration; and a deployment element extending from a distal end releasably coupled to the clip, through the channel of the cap, to a proximal end which, in use, remains outside the living body, the deployment element being releasably coupled to the clip so that movement of the deployment element moves the clip distally off the cap to a deployed configuration in which the first and second jaws are drawn toward one another under the bias of the first and second jaws to close over tissue received therebetween.

47. The device of claim 46, further comprising an actuator assembly including a first actuator configured to control movement of the repositioning element and a second actuator configured to control movement of the deployment element.

48. The device of claim 46 further comprising an actuator assembly including a first actuator configured to control movement of the repositioning element and a second actuator configured to control movement of the deployment element.

49. The device of claim 48, wherein the actuator assembly further includes a housing and wherein the first actuator includes a lever pivotally coupled to a handle, the proximal end of the repositioning element connected to a portion of the handle so that, movement of the lever relative to the housing draws the repositioning element proximally to move the cap distally from the insertion configuration to the review configuration.

50. The device of claim 49, wherein the second actuator includes a push button extending into the housing and connected to the proximal end of the deployment element so that, when the push button is pressed further into the housing, the deployment element is moved proximally to move the clip distally relative to the cap from the review configuration to the deployed configuration.

51. The device of claim 46, further comprising a biasing element extending between a distal end of the cap and a stop configured to be positioned at a distal-most end of the endoscope on which the cap is mounted, the biasing element biasing the cap toward the insertion configuration so that, when not subject to a distally directed force via the repositioning element, the cap reverts to the insertion configuration.

52. The device of claim 49, further comprising a biasing element extending between a distal end of the cap and a stop configured to be positioned at a distal-most end of the endoscope on which the cap is mounted, the biasing element biasing the cap toward the insertion configuration so that when the lever is released, the cap and the clip revert to the insertion configuration.