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Steerable platform repositionable over the scope clip

Abstract

A clipping system for treating tissue including an adapter, a clip, an extending member and a control wire. The adapter couplable to an insertion device via steering members. The steering members extend alongside the insertion device and connect to the adapter to steer the adapter between a first position and a second position. The clip mounted over the adapter. The clip includes first and second jaws connected to one another and movable between an insertion configuration and an initial deployed configuration. The extending member slidably received within one of the steering members. The control wire slidably received within the extending member and extends through the first jaw such that simultaneous longitudinal movement of the control wire and the extending member relative to the adapter moves the clip between the insertion configuration, the initial deployed configuration, and a review configuration in which the clip is separated from the adapter.

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Background/Summary

PRIOR CLAIM (1) The present disclosure claims priority to U.S. Provisional Patent Application Ser. No. 63/266,807 filed Jan. 14, 2022; the disclosure of which is incorporated herewith by reference.

FIELD
(1) The present disclosure relates to endoscopic devices and, in particular, relates to endoscopic clipping devices for treating tissue along the gastrointestinal tract.
BACKGROUND

(2) 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, treatment of issues on other organs by passing outside of the GI tract, and endoscopic treatment/repair of post-surgical issues (e.g., post-surgical leaks, breakdown of surgical staple lines, and anastomotic leaks). 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.

(3) 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. Once deployed, such current over-the scope clips are generally incapable of being repositioned.

SUMMARY

(4) The present disclosure relates to a clipping system for treating tissue including an adapter, a clip, a first extending member and a first control wire. The adapter includes a proximal portion configured to be coupled to a distal end of an insertion device via steering members extending from proximal ends to distal ends. The steering members extends alongside the insertion device with distal ends of the steering members connected to the proximal end of the adapter so that moving the steering members longitudinally relative to the insertion device steers the adapter between a first position, in which the adapter is substantially aligned with a longitudinal axis of the insertion device, and a second position, in which the adapter is angled away from the longitudinal axis of the insertion device. The clip is mounted over a distal portion of the adapter. The clip includes first and second jaws connected to one another such that the first and second jaws are movable between an insertion configuration, in which the first and second jaws extend about opposing portions of the distal portion of the adapter and are separated from one another to receive tissue therebetween, and an initial deployed configuration, in which the clip is moved distally off of the adapter so that the first and second jaws are drawn toward one another to grip tissue therebetween. The first and second jaws are biased toward the initial deployed configuration. The first extending member is slidably received within one of the steering members so that a distal end of the first extending member extends distally toward the clip. The first control wire is slidably received within the first extending member and through an opening extending through the first jaw of the clip so that an enlarged distal end of the first control wire extends distally of the opening, the enlarged distal end of the first control wire and the distal end of the first extending member being sized, shaped and configured such that the clip is held therebetween so that a simultaneous longitudinal movement of the first control wire and the first extending member relative to the adapter moves the clip between the insertion configuration, the initial deployed configuration, and a review configuration in which the clip is physically separated from the adapter to enhance visual observation of the clip.

(5) In an embodiment, the enlarged distal end of the first control wire is connected to a remaining length thereof via a joint configured to separate the enlarged distal end from the remaining length when subject to a force exceeding a predetermined threshold value.

(6) In an embodiment, each of the enlarged distal end of the first control wire and the distal end of the first extending member has a cross-sectional area that is larger than a cross-sectional area of the

opening of the first jaw.
(7) In an embodiment, the proximal portion of the adapter includes a first hole extending longitudinally through a wall thereof to slidably receive the first extending member therein such that the distal end of the first extending member extends distally of the first hole toward the clip.
(8) In an embodiment, the system further includes a second extending member received slidably through another one of the steering members so that a distal end of the second extending member extends distally toward the clip; and a second control wire slidably received within the second extending member and through an opening extending through the second jaw of the clip so that an enlarged distal end of the second control wire extends distally of the opening of the second jaw, the enlarged distal end of the second control wire and the distal end of the second extending member being sized, shaped and configured such that the clip is held therebetween and a simultaneous longitudinal movement of the second control wire and the second extending member relative to the adapter moves the clip between the insertion configuration, the initial deployed configuration, and the review configuration.
(9) In an embodiment, the system further includes outer shafts extending alongside the insertion device from proximal ends to distal ends, each of the outer shafts configured to slidably house a corresponding one of the steering members therein.
(10) In an embodiment, each of the steering members is configured as a hollow braided pebax.
(11) In an embodiment, each of the steering members includes at least two steering wires extending longitudinally through a wall thereof.
(12) The present disclosure relates to a clipping system for treating tissue. The system includes an endoscope extending longitudinally from a proximal end to a distal end; an adapter including a proximal portion and a distal portion, the proximal portion configured to be mountable over the distal end of the endoscope and connected thereto via first and second steering members extending from proximal ends to distal ends, the steering members extending alongside the endoscope with distal ends of the steering members connected to the proximal end of the adapter so that moving the steering members longitudinally relative to the endoscope steers the adapter between a first position, in which the adapter is substantially aligned with a longitudinal axis of the endoscope, and a second position, in which the adapter is angled away from the longitudinal axis of the endoscope; a clip configured to be mounted over the distal portion of the adapter, the clip including first and second jaws connected to one another such that the first and second jaws are movable between an insertion configuration, in which the first and second jaws extend about opposing portions of the distal portion of the adapter and are separated from one another to receive tissue therebetween, and an initial deployed configuration, in which the clip is moved distally off of the adapter so that the first and second jaws are drawn toward one another to grip tissue therebetween, the first and second jaws being biased toward the initial deployed configuration; first and second extending members, each of the first and second extending member extending longitudinally through a corresponding one of the first and second steering members so that distal ends of the first and second extending members extend through the proximal portion of the adapter distally toward the clip; and first and second control wires, each of the first and second control wires slidably received within a corresponding one of the first and second extending members and through an opening extending through a corresponding one of the first and second jaws of the clip so that an enlarged distal end of the first and second control wire extend distally of the openings, the enlarged distal ends of the first and second control wire and the distal ends of the first and second extending members being sized, shaped and configured such that the clip is held therebetween, and a simultaneous longitudinal movement of the first control wire and the first extending member relative to the adapter moves the clip between the insertion configuration, the initial deployed configuration, and a review configuration in which the clip is physically separated from the adapter to enhance visual observation of the clip.
(13) In an embodiment, each of the enlarged distal ends of the first and second control wires is

connected to a remaining length thereof via a joint configured to separate the enlarged distal ends from the remaining lengths when subject to a force exceeding a predetermined threshold value.
(14) In an embodiment, the enlarged distal ends of the first and second control wires and the distal ends of the first and second extending members have a cross-sectional area that is larger than a cross-sectional area of the openings of the jaws.
(15) In an embodiment, the system further includes outer shafts extending alongside an insertion device from proximal ends to distal ends, each of the outer shafts configured to slidably house a corresponding one of the steering members therein.
(16) In an embodiment, the system further includes a user interface including a first actuator configured to control a longitudinal movement of the first and second steering members relative to the endoscope, a second actuator configured to control a longitudinal movement of the first and second extending members relative to the adapter, and a third actuator configured to control a longitudinal movement of the first and second control members relative to the adapter.
(17) In an embodiment, the user interface further includes a locking mechanism locking the second and third actuators relative to one another such that actuation of one of the second and third actuators simultaneously moves the first and second extending members along with the first and second control wires in the same longitudinal direction relative to the adapter.
(18) In an embodiment, the user interface further includes a locking mechanism configured to lock the second actuator relative to the endoscope so that the third actuator is actuatable to move the first and second control wires relative to the first and second extending members and the endoscope to cause the joint to separate.
(19) In addition, the present disclosure relates to a method for treating tissue. The method includes inserting a clip to a target area in a body lumen via an endoscope, the clip mounted over a distal end of the endoscope, via an adapter, in an open insertion configuration in which jaws of the clip are separated from one another; drawing tissue into a channel of the adapter and between jaws of the clip; moving the clip from the open insertion configuration toward an initial deployed configuration by releasing a tension along a control wire, the clip held between an enlarged distal end of the control wire and a distal end of an extending member so that a simultaneous distal longitudinal movement of the control wire and the extending member relative to the adapter permits the jaws to revert to a biased closed configuration, in which the jaws extend toward one another to grip the tissue received therebetween; and drawing the endoscope proximally away from the clip, while the clip remains held between the distal ends of the control wire and the extending member, toward a review configuration in which a visualization of the clip via the endoscope is enhanced.
(20) In an embodiment, steering the adapter between a first position, in which the adapter is substantially longitudinally aligned with the endoscope, and a second position, in which the adapter is angled away from a longitudinal axis of the endoscope, via steering members connecting the adapter to the endoscope to further enhance a visibility.
(21) In an embodiment, when it is determined that the clip requires repositioning, simultaneously moving the control wire and the extending member proximally relative to the endoscope until the clip is drawn proximally over the adapter toward the open insertion configuration and repositioning the clip over the target tissue.
(22) In an embodiment, the method further includes moving the clip from the review configuration toward a final deployed configuration by drawing the control wire proximally relative to the extending member so that the enlarged distal end is pulled against the distal end of the extending member until a force exerted thereon exceeds a predetermined threshold force, separating the enlarged distal end of the control wire from a remaining length thereof to release the clip from the endoscope.
(23) In an embodiment, the method further includes locking a movement of the control wire

relative to the extending member to facilitate a simultaneous longitudinal movement of the control wire and the extending member relative to the endoscope.

Description

BRIEF DESCRIPTION

(1) FIG. **1** shows a perspective view of a distal portion of a system according to an exemplary embodiment of the present disclosure, an adapter of the distal portion steerable from a first position to a second position;

(2) FIG. **2** shows a longitudinal side view of the distal portion of the system according to FIG. **1**, with a clip of the system in an insertion configuration;

(3) FIG. **3** shows a longitudinal side view of the distal portion of the system according to FIG. **1**, with the clip of the system in the review configuration and the adapter in the first position;

(4) FIG. **4** shows a perspective view of the distal portion of the system according to FIG. **1**, with the adapter moved toward the second position;

(5) FIG. **5** shows a side view of the clip according to the system of FIG. **1**;

(6) FIG. **6** shows a perspective view of a steering member according to the system of FIG. **1**;

(7) FIG. **7** shows a longitudinal side view of an extending member according to the system of FIG. **1**;

(8) FIG. **8** shows an enlarged side view of a control wire and the extending member coupled to the clip according to the system of FIG. **1**;

(9) FIG. **9** shows an enlarged side view of a control wire and the extending member during a final deployment of the clip according to the system of FIG. **1**;

(10) FIG. **10** shows an enlarged side view of the control wire and the extending member separated from the clip upon final deployment of the clip according to the system of FIG. **1**;

(11) FIG. **11** shows a perspective view of a user interface according to the system of FIG. **1**;

(12) FIG. **12** shows a cross-sectional perspective view of the user interface according to the system of FIG. **1**; and

(13) FIG. **13** shows an enlarged side view of the user interface according to the system of FIG. **1**.

DETAILED DESCRIPTION

(14) 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 the final deployment thereof. Exemplary embodiments of the present disclosure comprise a clip mountable over a distal end of an endoscope via an adapter.

(15) According to an exemplary embodiment, the adapter is coupled to the distal end of the endoscope via steering members, which enable movement of the adapter relative to the endoscope. In one embodiment, the steering members are configured to steer the adapter relative to the endoscope by, for example, angling the adapter away from a longitudinal axis of the endoscope to improve control and visualization via the endoscopic vision system. The clip is mountable over the adapter and is releasably coupled to extending members so that the clip may be moved relative to the adapter between an insertion configuration, an initial deployed configuration, and a review configuration, in which the clip can be viewed prior to being finally deployed. The steering members may be used to move (e.g., steer) the adapter relative to the endoscope during any of the insertion configuration, the initial deployed configuration, and the review configuration.

(16) In the insertion configuration, the clip is mounted over the adapter in a proximal position maintained in the insertion configuration ready to receive tissue between jaws thereof while the clip's position minimizes its occlusion of the field of view of the endoscopic vision system. The

insertion configuration is configured to facilitate insertion of the endoscope to a target site adjacent to tissue to be clipped while the system allows the clip to be deployed and clipped over tissue in an initial deployed configuration. The device permits the endoscope to be withdrawn proximally away from the clip and the tissue over which it is clipped while the clip remains coupled to the device in a review configuration.

(17) As the endoscope is withdrawn proximally while the clip remains in place over the target tissue, the field of view of the vision system of the endoscope widens to show the clip and the tissue clipped thereby so that the operator can determine whether the position of the clip is desirable or in need of adjustment. If the operator determines that the clip is positioned as desired, the clip is deployed by releasing the clip from the clasps of the extending members and left in place clipped over the target tissue. If the operator determines that the position of the clip needs adjustment, the endoscope and the adapter coupled thereto are moved distally to a position adjacent to the clip. The clip is then drawn proximally over the adapter to reopen the clip which is drawn proximally over the distal end of the adapter forcing the clip to open against its natural bias as the clip slides proximally back over the adapter to return to the insertion configuration.

(18) After the clip has been removed from the tissue and returned to the insertion configuration, the operator can re-position the endoscope and device as desired, draw target tissue into the adapter (e.g., under suction or a grasper applied via a working channel of the endoscope) and once more deploy the clip from the adapter over the target tissue in the initial deployed position. The endoscope is then withdrawn proximally once again as the clip remains coupled to the device so that the device moves again into the review configuration. The position of the clip and the clipped tissue are again observed and, this process may be repeated until the clip is positioned as desired. When the operator sees that the tissue over which the clip is closed is the desired portion of tissue, the clip may be released from the extending members to be moved toward the final deployed configuration. 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.

(19) As shown in FIGS. **1-12**, a clipping system **100** for treating tissue defects and/or perforations according to an exemplary embodiment comprises a clip **102** configured to be inserted through, for example, a body lumen to a target area to clip a target tissue thereof. The clip **102** is insertable to the target area via an insertion device **104** including, for example, an endoscope **106** and an adapter **108**, which couples the clip **102** to a distal end **110** of the endoscope **106**. The adapter **108** is coupled to the distal end **110** of the endoscope **106** via steering members **112**, which facilitate movement of the adapter relative to the endoscope between a first position and a second position, as shown in FIG. **1**.

(20) In the first position the adapter **108** may be substantially aligned relative to the endoscope **106** while in a second position the adapter **108** may be angled or bent away from a longitudinal axis of the endoscope **106**. The clip **102** is mountable over a portion of the adapter **108** and is movable relative to the endoscope **106** via extending members **114**, to which the clip **102** is releasably coupled via control wires **116**. Each of the control wires **116** extends through a corresponding one of the extending members **114** and includes an enlarged distal end **118** that is configured to be releasably engaged with a portion of a corresponding jaw **120** of the clip **102** to, together with the extending members **114**, facilitate movement of the clip **102** relative to the endoscope **106** between an insertion configuration, an initial deployed configuration, a review configuration, and a final deployed configuration.

(21) According to one embodiment, the enlarged distal end **118** of each of the control wires **116** is configured to engage an opening **122** extending through a corresponding one of the jaws **120**. The openings **122** of this embodiment are sized and shaped to prevent passage of the enlarged distal ends **118** therethrough. Thus, when the enlarged distal ends **118** of the control wires **116** are positioned distally of the clip **102** and distal ends **124** of the extending members **114** are positioned

proximally of the clip **102**, the clip **102** is held between the distal ends **118**, **124** of the control wires **116** and the extending members **114** so that a simultaneous motion of the control wires **116** and the extending members **114** relative to the adapter **108** controls movement of the clip **102** between the insertion configuration, the initial deployed configuration and the review configuration, as will be described in further detail below.

(22) In the insertion configuration, as shown in FIG. **2**, the clip **102** is mounted over the adapter **108** with jaws **120** of the clip **102** separated from one another to receive tissue that is drawn therebetween. To move the clip **102** from the insertion configuration toward the deployed configuration, the extending members **114** and the control wires **116** are moved distally relative to the adapter **108** and/or the endoscope **106**, permitting the clip **102** to be moved distally off of the adapter **108** toward a closed configuration, in which the jaw **120** are moved toward one another to grip tissue that has been drawn into the adapter **108**.

(23) Upon clipping of the tissue via the jaws **120** in the initial deployed configuration, the clip **102** is moved toward the review configuration, as shown in FIG. **3**, by moving the extending members **114** and the control wires **116** distally away from the endoscope **106** (or drawing the endoscope **106** proximally relative to the extending members **114** and control wires **116**) so that the clip **102** is distanced from the adapter **108**, while remaining tethered to the insertion device **104** via the extending members **114** and the control wires **116**. This widens the field of view of the endoscope vision system relative to the clip **102** and the target tissue and allows for some movement of the endoscope **106** relative to the clip **102** to enable more extensive observation of the placement and/or position of the clip **102** relative to the target tissue.

(24) As described below, if the user determines the position of the clip **102** is incorrect or sub-optimal, the user may move the endoscope **106** distally to a position adjacent to the clip **102** and then retract the clip **102** back over the distal end of the adapter **108** to re-open the clip **102** and release any clipped tissue (i.e., to move the clip **102** back toward the open insertion configuration). The user may then reposition the endoscope **106** and the clip **102** and repeat these steps so that the placement and/or position of the clip **102** relative to target tissue may be adjusted, as desired, prior to a final deployment of the clip **102**. That is, if the operator determines in the review configuration that the clip **102** is not positioned as desired (i.e., that tissue has not been clipped as desired or that a desired portion of tissue to be clipped has not been clipped as desired), the clip **102** may be re-opened and removed from the tissue so that the device can be re-positioned until the clip **102** is closed over the desired portion of tissue.

(25) During any of the insertion configuration, the initial deployed configuration and the review configuration, the user may move the adapter **108** relative to the endoscope **106** via the steering members **112** to control and/or enhance a visualization of the clip **102** and/or tissue. It will be understood by those of skill in the art, however, that it may be particularly useful to steer the adapter **108** relative to the endoscope **106** during the review configuration, as shown in FIG. **4**, to better confirm whether the desired tissue has been clipped. As will be described in further detail below, once it is determined that the clip **102** has been clipped over the desired tissue, the control wires **116** may be drawn proximally relative to the extending members **114** until the enlarged distal ends **118** are pulled against the clip **102**.

(26) When a predetermined threshold force is exerted on the enlarged distal ends **118**, the enlarged distal ends **118** are separated from a remaining length of the control wires **116**, to release the clip **102** from the insertion device **104** deploying the clip **102** in the body. As will be understood by those of skill in the art and as will be described in further detail below, actuation of each of the steering members **112**, extending members **114** and the control wires **116** to control the movement of the clip **102** between the insertion configuration, the initial deployed configuration, the review configuration and the final deployed configuration may be controlled via a user interface **126** which, in one embodiment, as shown in FIGS. **11-13**, is coupled to a proximal end of the endoscope **106**.

(27) As shown in FIG. **5**, the clip **102** includes a pair of jaws **120** connected to one another via hinges **128**. In one embodiment, each of the jaws **120** extends along a curve from a first end **130** to a second end **132** so that a first one of the hinges **128** connects the first ends **130** of each of the jaws **120** to one another, while a second one of the hinges **128** connects the second ends **132** of each of the jaws **120** to one another. In one embodiment, the hinges **128** are spring biased, biasing the jaws **120** toward the initial deployed configuration in which the jaws **120** are moved toward one another, in a closed configuration. Each of the jaws **120** of this embodiment includes one or more gripping features **134** such as, for example, teeth, so that, in this initial deployed configuration, the gripping features **134** of one of the jaws **120** contact the gripping features **134** of the other jaw **120**. In particular, in the initial deployed configuration, the jaws **120** extend toward one another so that target tissue may be gripped between the jaws **120** via the gripping features **134**.
(28) However, when the clip **102** is mounted over the adapter **108** in the insertion configuration, the jaws **120** extend about opposing portions of the adapter **108** so that an exterior surface **136** of the adapter **108** maintains the clip **102** in an open configuration, with the jaws **120** separated from one another. Thus, when the clip **102** is mounted over the adapter **108**, target tissue may be drawn into the space between the jaws **120**. When the clip **102** is moved distally off of the adapter **108**, the clip **102** is free to close under the natural bias of the hinges **128**. It will be understood by those of skill in the art that the hinges **128** and/or jaws **120** of the clip **102** may be formed of any of a variety of materials so long as the hinges **128** bias the jaws **120** toward the initial deployed configuration, as described above, and so that the bias is sufficiently strong to maintain the clip **102** in clipped position over target tissue after the clip has been finally deployed. In one example, portions of the clip **102** (e.g., the hinges **128**) are formed of a shape memory alloy such as, for example, Nitinol to provide and/or add to the bias toward the closed configuration.
(29) According to an exemplary embodiment, as described above, each of the jaws **120** includes an opening **122** extending therethrough from a first surface **138** of the clip **102**, which faces the adapter **108**, to a second surface **140** of the clip **102**, which faces away from the adapter **108**. In one embodiment, the opening **122** extends through each of the jaws **120** midway between the first and the second ends **130**, **132** thereof so that the openings **122** extend through opposing portions of the clip **102**. Each opening **122** is sized, shaped, and configured to receive a portion of a corresponding one of the control wires **116** therein. In particular, the enlarged distal end **118** is positioned distally of the second surface **140** so that a remaining length of the control wire **116** passes proximally through the opening **122**.
(30) As discussed above, the clip **102** may be mounted to the insertion device **104**, as shown in FIGS. **1-4**, which may include any standard endoscope **106**. The clip **102** may be mounted to the endoscope **106** via the adapter **108**, which is sized, shaped, and configured to be coupled to the endoscope **106**. In one embodiment, the adapter **108** is mountable over the distal end **110** of the endoscope **106** and configured to be movable relative thereto via steering members **112**. The adapter **108** may be moved longitudinally relative to the endoscope **106** and/or angled with respect to the longitudinal axis of the endoscope **106** to steer the adapter **108** relative to the endoscope **106** between the first position, in which the adapter **108** is substantially aligned with the endoscope **106**, and second position, in which the adapter **108** is angled and/or bent away from the longitudinal axis of the endoscope **106**. As will be understood by those of skill in the art, the endoscope **106** 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.
(31) The adapter **108** extends from a proximal end **142** to a distal end **144** and includes a channel **146** extending therethrough. A proximal portion **143** of the adapter **108** is configured to be mountable over or otherwise couplable to the distal end **110** of the endoscope **106** while a distal portion **145** is configured to receive the clip **102** thereover in the insertion configuration. The proximal portion **143** of the adapter **108** may be mounted to the endoscope **106** via, for example, a friction fit, so that the channel **146** of the adapter **108** is substantially longitudinally aligned with a

channel of the endoscope **106**. Thus, tissue may be viewed through the channel **146** via an optical system of the endoscope **106**. In another embodiment, to enhance a visibility of the tissue and/or the clip **102**, the adapter **108** may be formed of a transparent material.

(32) In an exemplary embodiment, the proximal portion **143** of the adapter **108** includes a pair of holes **148** extending longitudinally through a wall **150** thereof. Each of the holes **148** is configured to slidably receive a corresponding one of the extending members **114** therein. As will be described in further detail below, the extending members **114** are received within the holes **148** so that the distal ends **124** of the extending members **114** extend distally of the holes **148** toward the clip **102**, which is mounted over the distal portion **145** of the adapter **108**. In one embodiment, the holes **148** extend through diametrically opposing portions of the adapter **108**.

(33) An outer diameter of the distal portion of the adapter **108** is sized, shaped, and configured to receive the clip **102** thereover, in the insertion configuration. In one exemplary embodiment, the distal portion **145** tapers toward the distal end **144** so that the clip **102** is biased toward the initial deployed configuration. When the clip **102** is mounted over the distal portion **145** of the adapter **108** with each of the jaws **120** extending over opposing portions thereof, the exterior surface **136** of the adapter **108** holds the clip **102** in the insertion configuration with the jaws **120** of the clip **102** separated from one another. The clip **102** may remain mounted over the adapter **108** in the open insertion configuration so long as a sufficient proximally directed tension is applied thereto via the control wires **116**. If the tension is removed from the control wires **116**, a natural bias of the clip **102** draws the jaws **120** toward one another pushing the clip **102** distally over the tapered surface of the distal portion **145** of the adapter **108** until the clip **102** slides distally off of the adapter **108**. In one embodiment, the control wires **116** and the extending members **114** may be moved simultaneously, in a distal direction relative to the adapter **108** and/or endoscope **106**, to release a tension along the control wires **116** so that the clip **102** may be moved toward the initial deployed configuration.

(34) In one embodiment, the distal portion **145** of the adapter **108** includes features for reducing friction between the clip **102** and the exterior surface **136** thereof to facilitate the sliding of the clip **102** therealong. For example, the distal portion **145** may include flat portions **152** distributed about a circumference thereof. In another embodiment, the distal portion **145** may also include features configured to facilitate the re-opening of the jaws **120** as the clip **102** is moved from initial deployed configuration back toward the insertion configuration. For example, the distal portion **145** may include a plurality of projections **154** extending distally from the distal end **144** of the adapter **108** at an angle relative to a longitudinal axis of the adapter **108** so that, when the clip **102** is drawn proximally from the initial deployed configuration the jaws **120** abut the projections **154** with the angle of the projections **154** facilitating the re-opening of the jaws **120**, against their natural bias, toward the open insertion configuration. That is, the jaws **120** slide proximally over the projections **154** to re-open the jaws **120** so that the clip **102** is released from the clipped tissue and can be slid proximally back into the adapter **108**.

(35) The insertion device **104** of an exemplary embodiment includes steering members **112** which extend along a length of the endoscope **106** from proximal ends **156** accessible to the user via, for example, the user interface **126**, to distal ends **158** which are connected to the adapter **108**. In an exemplary embodiment, as shown in FIG. **6**, each of the steering members **112** of one embodiment is formed of a hollow braid of Pebax (or any other suitable material) including at least two steering wires **160** through a wall **162** thereof. Although each steering member **112** is shown and described as including two steering wires **160**, it will be understood by those of skill in the art that the steering members **112** may include more than two steering wires to facilitate additional directions of motion of the adapter **108** relative to the endoscope **106**. The distal ends **158** are connected to the adapter **108** so that each of the steering members **112** is substantially aligned with a corresponding one of the holes **148** extending through the wall **150** of the proximal portion **143** of the adapter **108**. In particular, each of the steering members **112** of one embodiment are coaxially

aligned with the corresponding one of the holes **148**.
(36) According to an exemplary embodiment, each steering member **112** extends through an outer shaft **164** extending along a length of the endoscope **106** from a proximal end **166** connected to the user interface **126** to a distal end **168**. The steering members **112** are longitudinally movable relative to the outer shafts **164** to steer the adapter **108** relative to the distal end **110** of the endoscope **106** between the first and second positions. The steering members **112** extend through the outer shafts **164** so that distal ends **158** extend distally out of the shafts **164** to be connected to the adapter **108** at the distal end **110** of the endoscope **106**. According to an exemplary embodiment, the outer shafts **164** extend along opposing longitudinal sides of the endoscope **106** so that the steering members **112** extend therethrough to be connected to the adapter **108**, as described above. In one embodiment, the outer shafts **164** have a coil configuration to facilitate a flexing thereof as the endoscope **106** is inserted through a body lumen.
(37) Extending members **114** are slidably received within the hollow steering members **112**. In this embodiment, each extending member **114** extends from a proximal end **115** connected to the user interface **126** through a corresponding one of the steering members **112** and through the corresponding one of the holes **148** so that distal ends **124** extend distally from the holes **148** toward the clip **102**. In one embodiment, the extending members **114** are configured as nitinol hypotubes. In one example, as shown in FIG. **7**, one or more of the nitinol hypotube includes alternating cuts thereabout to facilitate a bending thereof as the steering members **112** are bent to control a movement of the adapter **108** relative to the endoscope **106**.
(38) As shown in FIG. **8**, the control wires **116** extend through the extending members **114** from proximal ends **117** connected to the user interface **126** to the enlarged distal ends **118**, which extend distally of the distal ends **124** of the extending members **114**. The enlarged distal ends **118** of the control wires **116** engage the second surface **140** of the clip **102** so that a remaining length of the control wires **116** extends proximally through the openings **122** of the jaws **120** and through the extending members **114** to the user interface **126**. As described above, the enlarged distal ends **118** are sized, shaped, and configured so that the enlarged distal ends **118** cannot be passed proximally through the openings **122** of the jaws **120**.
(39) Similarly, the openings **122** are sized, shaped, and configured to prevent a distal passage of the distal ends **124** of the extending members **114** therethrough. Thus, the clip **102** is held between enlarged distal ends **118** of the control wires **116** and the distal ends **124** of the extending members **114**. As will be described in further detail below, while the control wires **116** are slidably received within the extending members **114**, the control wires **116** and the extending members **114** may be locked relative to one another so that the control wires **116** and the extending members **114** may be moved simultaneously to control a movement of the clip **102** relative to the adapter **108** between the insertion configuration, the initial deployed configuration, and the review configuration.
(40) Each enlarged distal end **118** is connected to the remaining length **170** of the control wire **116** via a joint **172** configured to break, fail, release or otherwise separate when subject to a predetermined threshold force. In one embodiment, the joint **172** may be configured as a reduced diameter portion of the control wire **116**. In another embodiment, the joint **172** may be configured as an adhesive subject to fail when subject to the predetermined force. In yet another embodiment, the joint may be configured as a releasable coupling. It will be understood by those of skill in the art, however, that the joint **172** may have any of a variety of configurations so long as the joint **172** is configured to separate the enlarged distal end **118** from the remaining length **170** when subject to the predetermined threshold force.
(41) Thus, when it is desired to move the clip **102** toward the final deployed configuration, the control wires **116** are drawn proximally relative to the extending members **114** so that the enlarged distal ends **118** and the clip **102** are pulled proximally against the distal ends **124** of the extending members **114**, as shown in FIG. **9**. The control wires **116** are pulled proximally against the extending members **114** until a force exerted on the joint **172** exceeds a predetermined threshold

value so that the enlarged distal ends **118** separate from the remaining lengths **170**, as shown in FIG. **10**, thereby releasing the clip **102** from the insertion device **104**.

(42) According to an exemplary embodiment, as shown in FIGS. **11-13**, the user interface **126** includes a handle member **174**, a first actuator **176** for controlling the steering members **112**, a second actuator **178** for controlling the extending members **114**, and a third actuator **180** for controlling the control wires **116**. In an exemplary embodiment, each of the first, second and third actuators **176**, **178**, **180** may be configured as knobs rotatable relative to the handle member **174**, each of the knobs including a shaft **184**, **186**, **188**, respectively, extending into the handle member **174** and about which proximal ends of the steering members **112**, the extending members **114** and the control wires **116** may be coupled.

(43) Proximal ends **156** each of the steering members **112** may be coupled to the shaft of the first actuator **176** so that when, for example, the first actuator **176** is rotated relative to the handle member **174**, the first actuator **176** is moved between the first position, in which the first actuator **176** is substantially aligned relative to the longitudinal axis of the endoscope **106**, and the second position, in which the first actuator **176** is angled and/or bent with respect to the longitudinal axis of the endoscope **106**. Proximal ends **115** of the extending members **114** may be coupled to the shaft **186** of the second actuator **178** with proximal ends **117** of the control wires **116** coupled to the shaft **188** of the third actuator **180** so that rotation of the second and third actuators **178**, **180** relative to the handle member **174** moves the extending members **114** and the control wires **116**, respectively, longitudinally relative to the endoscope **106**. The steering members **112**, the extending members **114** and the control wires **116** may be coupled to the first, second and third actuators **176**, **178**, **180**, respectively, in any of a variety of different ways. In the embodiment shown in FIG. **13**, the steering members **112**, the extending members **114** and the control wires **116** are coupled to the first, second and third actuators **176**, **178**, **180**, respectively, via a crimp **190**.

(44) The user interface **126** may further include a locking mechanism **182** for locking the second and third actuators **178**, **180** relative to one another, so that the extending members **114** and the control wires **116** may be moved simultaneously in the same direction relative to the longitudinal axis of the endoscope **106** to move the clip **102** between the insertion configuration, the initial deployed configuration, and the review configuration by rotating just one of the second and third actuators **178**, **180**. The locking mechanism **182** may include a friction ring, which when engaged, locks the second and third actuators **178**, **180** relative to one another. In another embodiment, the locking mechanism **182** may lock the second actuator **178** relative to the handle member **174** so that, during movement of the clip **102** toward the final deployment, the third actuator **180** may be rotated relative to both the handle member **174** and the second actuator **178** to draw the control wires **116** proximally relative to the clip **102** and the extending members **114**.

(45) According to an exemplary method for tissue closure utilizing the clipping system **100**, the clip **102** may be inserted through a body lumen such as, for example, the GI tract, to a target area within the body lumen via the insertion device **104** which, in one embodiment, includes the endoscope **106**. As described above, in the insertion configuration, the clip **102** is mounted to the distal end **110** of the endoscope **106** via the adapter **108** so that jaws **120** are separated from one another in the insertion configuration. The clip **102** is guided to the target area via the visualization system of the endoscope and positioned over target tissue. A suction force and/or tissue graspers may be applied (e.g., through a working channel of the endoscope **106**) to draw the target tissue into the channel **146** of the adapter **108**. Thus, when the clip **102** is moved toward the initial deployed configuration by releasing tension along the control wires **116** (e.g., by moving the control wires **116** distally relative to the endoscope **106**), the clip **102** is permitted to slide distally along the adapter **108** toward the biased closed configuration. As described above, clip **102** is held between the distal ends **118** of the control wires **116** and the distal ends **124** of the extending members **114** so that the control wires **116** and the extending members **114** may be moved simultaneously in the same direction to release the tension along the control wires **116**. The clip

102 may be moved toward the initial deployed configuration via rotation of one of the second and third actuators **178**, **180**, which may be locked relative to one another, as described above.

(46) It will be understood by those of skill in the art that suctioning and/or gripping of the tissue in this initial deployed configuration may obstruct an imaging/optical lens of the endoscope **106** making it difficult or impossible for a user to clearly visualize clipped tissue to determine whether desired target tissue has been properly clipped. Thus, the clip **102** may be moved toward the review configuration by drawing the endoscope **106** proximally relative to the clip **102**, while the clip **102** remains engaged between the distal ends **118**, **124** of the control wires **116** and the extending members **114**. A distance between the adapter **108** and the clip **102** widens a field of view of the endoscope **106** so that the clip **102**, and the tissue gripped thereby, may be viewed via the optical/visualization system of the endoscope **106**.

(47) In this review configuration, the user may desire to steer the adapter **108** relative to the distal end **110** of the endoscope **106** from the first position, in which the adapter **108** is substantially aligned with the endoscope **106**, toward the second position, in which the adapter **108** is angled or bent away from the longitudinal axis of the endoscope **106**, to further enhance a visualization of the clip **102** and/or tissue. The clip **102** and adapter **108** may be steered between the first and second positions via the first actuator **176**, which controls a movement of the steering members **112**, as described above. It will be understood by those of skill in the art, however, that although the adapter **108** is described and shown as being moved between the first and second positions in the review configuration, the adapter **108** may be moved between the first and second positions during any of the insertion configuration, the initial deployed configuration, and the review configuration, if so desired.

(48) If, upon visualization, the user determines that the clip **102** requires an adjustment and/or a repositioning relative to the target tissue, the control wires **116** and the extending members **114** may together be translated proximally relative to the endoscope **106** until the clip **102** is moved proximally over the adapter **108**, as described above, toward the open insertion configuration. In particular, the endoscope **106** may be moved distally relative to the control wires **116** and extending members **114**, while rotating the second and/or third actuator **178**, **180** relative to the handle member **174**, so that the clip **102** and the adapter **108** are drawn toward one another. As the clip **102** is moved toward the open configuration, the tissue gripped thereby is released, permitting the clip **102** to be repositioned over the target tissue, as desired. The clip **102** may then once again moved toward the initial deployed configuration, and then again toward the review configuration. This process may be repeated, as necessary, until the user is able to visually confirm that the clip **102** has been clipped over the target tissue, as desired.

(49) As discussed above, the clip **102** remains engaged between the enlarged distal end **118** of the control wires **116** and the distal ends **124** of the extending members **114** during movement of the clip **102** relative to the endoscope **106** between the insertion, initial deployed and reviewed configurations. Once the user confirms that the target tissue has been clipped as desired, the clip **102** may be moved from the review configuration toward the final deployed configuration by drawing the control wires **116** proximally relative to the extending members **114**. In particular, the second and third actuators **178**, **180** are unlocked so that they are movable relative to one another, and the second actuator **178** may be locked relative to the handle member **174** so that rotating the third actuator **180** moves the control wires **116** relative to both the handle member **174** and the extending members **114**. The control wires **116** are drawn proximally relative to the extending members **114** until a force exerted on the joint **172** exceeds a predetermined threshold value, causing the joint **172** to fail, break or otherwise separate the enlarged distal ends **118** from remaining lengths **170** of the control wires **116**. Thus, the insertion device **104**, including the remaining lengths **170** of the control wires **116** and the extending members **114**, may be withdrawn proximally away from the clip **102** and out of the body, leaving the clip **102** clipped over the target tissue in the final deployed configuration.

(50) 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. A clipping system for treating tissue, comprising: an adapter including a proximal portion configured to be coupled to a distal end of an insertion device via steering members extending from proximal ends to distal ends, the steering members extending alongside the insertion device with distal ends of the steering members connected to the proximal end of the adapter so that moving the steering members longitudinally relative to the insertion device steers the adapter between a first position, in which the adapter is substantially aligned with a longitudinal axis of the insertion device, and a second position, in which the adapter is angled away from the longitudinal axis of the insertion device; a clip configured to be mounted over a distal portion of the adapter, the clip including first and second jaws connected to one another such that the first and second jaws are movable between an insertion configuration, in which the first and second jaws extend about opposing portions of the distal portion of the adapter and are separated from one another to receive tissue therebetween, and an initial deployed configuration, in which the clip is moved distally off of the adapter so that the first and second jaws are drawn toward one another to grip tissue therebetween, the first and second jaws being biased toward the initial deployed configuration; a first extending member slidably received within one of the steering members so that a distal end of the first extending member extends distally toward the clip; and a first control wire slidably received within the first extending member and through an opening extending through the first jaw of the clip so that an enlarged distal end of the first control wire extends distally of the opening, the enlarged distal end of the first control wire and the distal end of the first extending member being sized, shaped and configured such that the clip is held therebetween so that a simultaneous longitudinal movement of the first control wire and the first extending member relative to the adapter moves the clip between the insertion configuration, the initial deployed configuration, and a review configuration in which the clip is physically separated from the adapter to enhance visual observation of the clip.
2. The system of claim 1, wherein the enlarged distal end of the first control wire is connected to a remaining length thereof via a joint configured to separate the enlarged distal end from the remaining length when subject to a force exceeding a predetermined threshold value.
3. The system of claim 1, wherein each of the enlarged distal end of the first control wire and the distal end of the first extending member has a cross-sectional area that is larger than a cross-sectional area of the opening of the first jaw.
4. The system of claim 1, wherein the proximal portion of the adapter includes a first hole extending longitudinally through a wall thereof to slidably receive the first extending member therein such that the distal end of the first extending member extends distally of the first hole toward the clip.
5. The system of claim 1, further comprising: a second extending member received slidably through another one of the steering members so that a distal end of the second extending member extends distally toward the clip; and a second control wire slidably received within the second extending member and through an opening extending through the second jaw of the clip so that an enlarged distal end of the second control wire extends distally of the opening of the second jaw, the enlarged distal end of the second control wire and the distal end of the second extending member being sized, shaped and configured such that the clip is held therebetween and a simultaneous longitudinal movement of the second control wire and the second extending member relative to the adapter moves the clip between the insertion configuration, the initial deployed configuration, and

the review configuration.
6. The system of claim 1, further comprising outer shafts extending alongside the insertion device from proximal ends to distal ends, each of the outer shafts configured to slidably house a corresponding one of the steering members therein.
7. The system of claim 1, wherein each of the steering members is configured as a hollow braided pebax.
8. The system of claim 1, wherein each of the steering members includes at least two steering wires extending longitudinally through a wall thereof.
9. A clipping system for treating tissue, comprising: an endoscope extending longitudinally from a proximal end to a distal end; an adapter including a proximal portion and a distal portion, the proximal portion configured to be mountable over the distal end of the endoscope and connected thereto via first and second steering members extending from proximal ends to distal ends, the steering members extending alongside the endoscope with distal ends of the steering members connected to the proximal end of the adapter so that moving the steering members longitudinally relative to the endoscope steers the adapter between a first position, in which the adapter is substantially aligned with a longitudinal axis of the endoscope, and a second position, in which the adapter is angled away from the longitudinal axis of the endoscope; a clip configured to be mounted over the distal portion of the adapter, the clip including first and second jaws connected to one another such that the first and second jaws are movable between an insertion configuration, in which the first and second jaws extend about opposing portions of the distal portion of the adapter and are separated from one another to receive tissue therebetween, and an initial deployed configuration, in which the clip is moved distally off of the adapter so that the first and second jaws are drawn toward one another to grip tissue therebetween, the first and second jaws being biased toward the initial deployed configuration; first and second extending members, each of the first and second extending member extending longitudinally through a corresponding one of the first and second steering members so that distal ends of the first and second extending members extend through the proximal portion of the adapter distally toward the clip; and first and second control wires, each of the first and second control wires slidably received within a corresponding one of the first and second extending members and through an opening extending through a corresponding one of the first and second jaws of the clip so that an enlarged distal end of the first and second control wire extend distally of the openings, the enlarged distal ends of the first and second control wire and the distal ends of the first and second extending members being sized, shaped and configured such that the clip is held therebetween, and a simultaneous longitudinal movement of the first control wire and the first extending member relative to the adapter moves the clip between the insertion configuration, the initial deployed configuration, and a review configuration in which the clip is physically separated from the adapter to enhance visual observation of the clip.
10. The system of claim 9, wherein each of the enlarged distal ends of the first and second control wires is connected to a remaining length thereof via a joint configured to separate the enlarged distal ends from the remaining lengths when subject to a force exceeding a predetermined threshold value.
11. The system of claim 9, wherein the enlarged distal ends of the first and second control wires and the distal ends of the first and second extending members have a cross-sectional area that is larger than a cross-sectional area of the openings of the jaws.
12. The system of claim 9, further comprising outer shafts extending alongside an insertion device from proximal ends to distal ends, each of the outer shafts configured to slidably house a corresponding one of the steering members therein.
13. The system of claim 10, further comprising a user interface including a first actuator configured to control a longitudinal movement of the first and second steering members relative to the endoscope, a second actuator configured to control a longitudinal movement of the first and second extending members relative to the adapter, and a third actuator configured to control a longitudinal

movement of the first and second control members relative to the adapter.

14. The system of claim 13, wherein the user interface further comprising a locking mechanism locking the second and third actuators relative to one another such that actuation of one of the second and third actuators simultaneously moves the first and second extending members along with the first and second control wires in the same longitudinal direction relative to the adapter.

15. The system of claim 13, wherein the user interface further comprising a locking mechanism configured to lock the second actuator relative to the endoscope so that the third actuator is actuatable to move the first and second control wires relative to the first and second extending members and the endoscope to cause the joint to separate.