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Repositionable over the scope clip

Abstract

A clipping system includes a pusher element, a holder mounted over an insertion device and clips stacked along a length of the holder. The holder includes a longitudinally channel. Each clip extends along a curvature defining a tissue-receiving space therewithin and extends about the holder with an exterior surface of the holder holding the clip open with the first and second ends of the clip separated from one another to receive a tissue therein. Each clip is independently deployable from the holder so that, upon release of the clip from the holder, the clip reverts to a closed configuration. In the closed configuration, the first and second ends are moved toward one another to reduce a size of the tissue-receiving space so that tissue is gripped therewithin. The element is mounted over the holder and moved distally along the holder to independently deploy each clips.

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Background/Summary

PRIORITY CLAIM (1) The present disclosure claims priority to U.S. Provisional Patent Application Ser. No. 63/203,802 filed Jul. 30, 2021; 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. In addition, current over-the scope clips devices are only able to place one clip upon insertion of the endoscope into the body. In order to place a second clip, the operator must remove the endoscope after deployment of the first clip, reload the endoscope with a new clip, and reinsert the endoscope to a target site to position and deploy the second clip over a target tissue.

SUMMARY

(4) The present disclosure relates to a clipping system for treating tissue which includes a holder configured to be mounted over a distal end of an insertion device, the holder extending longitudinally from a proximal end to a distal end and including a channel extending longitudinally therethrough; a plurality of clips mountable over the holder so that the plurality of clips are stacked along a length thereof, each clip extending along a curvature from a first end to a second end, the curvature defining a tissue-receiving space therewithin, each clip mountable over the holder so that the clip extends about the holder and an exterior surface of the holder holds the clip in an open configuration, in which first and second ends of the clip are separated from one another and the tissue-receiving space is configured to receive a tissue therein, each clip being independently deployable from the holder so that, upon release of the clip from the holder, the clip is permitted to revert to a biased closed configuration, in which the first and second ends are moved toward one another to reduce a size of the tissue-receiving space so that tissue is gripped therewithin; and a pusher element mounted over the holder, proximally of the plurality of clips, the pusher element configured to be moved distally along the holder to independently deploy each of the plurality of clips from the holder, from a distal-most one of the clips to a proximal-most one of the clips.

(5) In an embodiment, the holder is formed of a transparent material.
(6) In an embodiment, the clip includes a plurality of gripping features along an interior surface thereof.
(7) In an embodiment, the gripping features include teeth extending radially into the tissue-receiving space from the interior surface of the clip.
(8) In an embodiment, a distal portion of the holder includes a plurality of longitudinal slots extending therealong and through a wall thereof so that the longitudinal slots are open at the distal end of the holder, the longitudinal slots configured to receive teeth of the clips therein, when the clips are mounted over the holder in the open configuration.
(9) In an embodiment, the pusher element is configured as a ring mounted over the holder so that the pusher element extends about the holder proximally of the proximal-most one of the clips.
(10) In an embodiment, the clip is formed of a shape memory alloy.
(11) In an embodiment, the system further includes a control element extending from a distal end attached to the pusher element and extending distally therefrom along an exterior of the holder and received within a distal opening of the insertion device so that the control element extends proximally through a channel of the insertion device so that, when the control element is drawn proximally relative to the insertion device, the pusher element is moved distally relative to the holder to push the distal-most one of the clips off of the holder.
(12) In addition, the present disclosure relates to a tissue clipping system which includes an endoscope including extending longitudinally from a proximal end to a distal end; a transparent holder extending longitudinally from a proximal end to a distal end and including a channel extending longitudinally therethrough, the holder mounted to the distal end of the endoscope so that the channel of the holder is substantially aligned with a longitudinal axis of the endoscope, the holder including a proximal portion configured to be coupled to an endoscopic shaft and a distal portion extending distally past the distal end of the endoscope; a plurality of clips mountable over the distal portion of the holder so that the plurality of clips are stacked along a length thereof and visible via a visualization system of the endoscope, each clip extending along a curvature from a first end to a second end, the curvature defining a tissue-receiving space therewithin, each clip mountable over the holder so that the clip extends about the holder and an exterior surface of the holder holds the clip in an open configuration, in which first and second ends of the clip are separated from one another and the tissue-receiving space is configured to receive a tissue therein, each clip being independently deployable from the holder so that, upon release of the clip from the holder, the clip is permitted to revert to a biased closed configuration, in which the first and second ends are moved toward one another to reduce a size of the tissue-receiving space so that tissue is gripped therewithin; and a pusher element mounted over the holder, proximally of the plurality of clips, the pusher element configured to be moved distally along the holder to independently deploy each of the plurality of clips from the holder, from a distal-most one of the clips to a proximal-most one of the clips.
(13) In an embodiment, each clip is formed of a shape memory alloy biasing the clip toward the closed configuration so that, when the clip is pushed distally off of the holder, the clip reverts toward the closed configuration.
(14) In an embodiment, each clip includes teeth extending radially into the tissue-receiving space from an interior surface of the clip to facilitate gripping of tissue therewithin.
(15) In an embodiment, a distal portion of the holder includes a plurality of longitudinal slots extending therealong and through a wall thereof so that the longitudinal slots are open at the distal end of the holder, the longitudinal slots configured to receive teeth of the clips therein, when the clips are mounted over the holder in the open configuration.
(16) In an embodiment, the system further includes a control element extending from a distal end attached to the pusher element and extending distally therefrom along an exterior of the holder and received within a distal opening of an insertion device so that the control element extends

proximally through a channel of the insertion device to a proximal end accessible to a user of the system.

(17) In an embodiment, the system further includes an actuator assembly including a handle member attached to the proximal end of the endoscope and a wheel rotatably attached to the handle member, a proximal end of a control member connected to the wheel so that a rotation of the wheel moves the control element proximally relative to the endoscope to move the pusher element distally relative to the holder.

(18) In an embodiment, the wheel is connected to the handle member via a ratchet mechanism so that rotation of the wheel relative to the handle member along one ratchet tooth corresponds to a deployment of a single clip from the holder.

(19) Furthermore, the present disclosure relates to a method for clipping tissue which includes inserting an endoscope to a target area within a body lumen and positioning a distal end of the endoscope over a first target tissue, a plurality of clips mounted over the distal end of the endoscope via a transparent holder, the plurality of clips mounted over the holder so that the plurality of clips are stacked along a length thereof and visible via a visualization system of the endoscope, each clip extending along a curvature from a first end to a second end and mounted over the holder in an open configuration, in which first and second ends of the clip are separated from one another and a tissue-receiving space defined via the curvature is configured to receive a tissue therein; applying a suction force through a working channel of the endoscope so that the first target tissue is drawn into a channel of the holder and within the tissue-receiving space of a first distal-most one of the clips; determining whether the first clip is in a desired position relative to the first target tissue; and pushing the plurality of clips distally along the holder via a pusher element positioned proximally of the plurality of clips until the first clip is pushed distally off of the holder, reverting to a biased closed configuration in which the first and second ends are drawn toward one another to reduce a size of the tissue-receiving space so that the first target tissue is gripped therewithin.

(20) In an embodiment, the method further includes repositioning the distal end of the endoscope relative to the first target tissue if it is determined that the first clip is not in a desired position relative to the first target tissue.

(21) In an embodiment, the pusher element is moved distally along the holder by drawing a control member proximally relative to the endoscope, the control member extending distally from a distal end attached to the pusher element along an exterior of the holder and received within a distal opening of the endoscope so that the control member extends proximally through a channel of the endoscope.

(22) In an embodiment, movement of the control member is actuated via an actuator assembly including a handle member attached to the proximal end of the endoscope and a wheel rotatably attached to the handle member via a ratchet mechanism, the proximal end of the control member connected to the wheel so that a rotation of the wheel along one ratchet tooth corresponds to a deployment of a single clip from the holder.

(23) In an embodiment, the method further includes positioning the distal end of the endoscope over a second target tissue; applying a suction force through the working channel of the endoscope so that the second target tissue is drawn into the channel of the holder and within the tissue-receiving space of a second, currently distal-most clip; determining whether the second clip is in a desired position relative to the second target tissue; and pushing the plurality of clips distally along the holder via a pusher element positioned proximally of the plurality of clips until the second clip is pushed distally off of the holder, reverting to a biased closed configuration in which the first and second ends of the second clip are drawn toward one another to reduce a size of the tissue-receiving space of the second clip so that the second target tissue is gripped therewithin.

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;
(2) FIG. **2** shows an exploded perspective view of the distal portion of the system of FIG. **1**;
(3) FIG. **3** shows a perspective view of a holder according to the system of FIG. **1**;
(4) FIG. **4** shows a perspective view of a clip according to the system of FIG. **1**;
(5) FIG. **5** shows a plan view of the clip of FIG. **4**, in an open configuration;
(6) FIG. **6** shows a plan view of the clip of FIG. **4**, in a closed configuration;
(7) FIG. **7** shows a longitudinal cross-sectional view of a distal portion of the system of FIG. **1**;
(8) FIG. **8** shows a side view of an actuator assembly according to the system of FIG. **1**; and
(9) FIG. **9** shows a cross-sectional view of a wheel of the actuator assembly of FIG. **8**.
DETAILED DESCRIPTION
(10) 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 multiple clips may be placed to treat multiple tissue defects and/or a larger tissue defect without having to remove the endoscope for reloading of a clip. Exemplary embodiments of the present disclosure comprise a plurality of clips mountable over a distal end of an endoscope via a clip holder that is coupled to a distal end of the endoscope so that each of the clips is independently releasable therefrom. Each of the clips may be configured, for example, as a tensile C-shaped circlip in which ends thereof are separated from one another when the clip is in in the open configuration and drawn toward one another or even drawn past one another so that the sides of the clip overlap when the clip is drawn a closed configuration (e.g., under its natural bias). Each of the clips is mountable over the clip holder so that an exterior surface of the clip holder holds each of the clips in the open configuration.
(11) In this open configuration, each clip extends about the clip holder with the clips aligned sequentially along the length of the clip holder. In use, an endoscope including the clip holder is inserted to a target site of the body (e.g., through a natural body lumen accessed via a naturally occurring bodily orifice) until the distal end of the clip holder is positioned adjacent to a first target portion of tissue. The clip holder may be transparent so that a position of the clips relative to the first target tissue may be visualized through the open distal end of the clip holder and through the side wall of the clip holder via the optical system of the endoscope. Upon confirmation that the first target portion of tissue is in a desired position relative to the clip holder, the first target portion of tissue is drawn into the clip holder (e.g., using suction or a grasper inserted through a working channel of the endoscope), a distal-most first one of the clips is moved distally off of the clip holder so that, as the first clip reverts toward the closed configuration under its natural bias, it closes over the first target portion of tissue that had been drawn into the clip holder.
(12) In the closed configuration, the ends of the clip are drawn toward one another, reducing a size of the space within the clip (e.g., a space defined radially within the curvature of the clip) so that the first target portion of tissue is clipped via the first clip within this reduced space. In particular, the first target portion of tissue is encircled and compressed by the clip. The distal end of the endoscope may then be positioned adjacent to a second target portion of tissue, as desired. The second target portion of tissue may then be drawn into the clip holder and a second (now distal-most) clip is then drawn distally off of the clip holder so that the second clip closes over the second target portion of tissue. This process may be repeated until each of the clips has been deployed over a respective target portion of tissue or until all of the target portions of tissue have been clipped as desired. 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.
(13) FIGS. **1-10** show a clipping system **100** for treating tissue defects and/or perforations according to an exemplary embodiment of the present disclosure. The clipping system **100** comprises a plurality of clips **102** configured to be mounted over a clip holder **108** configured to be mounted to distal end **106** of an endoscope **104** or other insertion device configured to be inserted through intervening anatomy to reach a target site within the body at which tissue to be clipped is located. The clips **102** of this embodiment are independently releasable from the holder **108** so that each clip **102** may be deployed to a separate corresponding target portion of tissue allowing the multiple clips **102** to be deployed to treat multiple tissue defects and/or multiple separated parts of a larger tissue defect.
(14) Each of the clips **102** is curved from a first end **112** to a second end **114** and is movable between an open configuration, in which the first and second ends **112**, **114** are separated from one another so that tissue may be received within a space **116** defined within the curvature of the clip **102**, and a closed configuration, in which the first and second ends **112**,**114** are drawn toward one another so that an area of the space **116** defined via the curvature is reduced to grip tissue therein. The clips **102** of this embodiment are biased toward the closed configuration and the clip holder **108** is sized so that, when the clips **102** are mounted over the holder **108**, an exterior surface **118** of the holder **108** holds each of the clips **102** spread open into the open configuration. In one exemplary embodiment, each of the clips **102** extends about a perimeter (e.g., diameter) of the holder **108** and the clips **102** are positioned sequentially along a length of the holder **108** from a first distal-most one of the clips **102** to a proximal-most one of the clips **102**.
(15) In one embodiment, the holder **108** is formed of a transparent material so that, when tissue is drawn into a channel **174** of the clip holder **108** (e.g., via suction or a tissue grasper applied though a working channel of the endoscope **104**), and the tissue is drawn into the space **116**, the tissue and the position of the clips **102** relative thereto may be visualized through the channel **174** and through the clip holder **108** using a visualization system of the endoscope **104**. If, upon visualization, an operator of the system (e.g., surgeon) determines that the clips **102** are in a desired position relative to a target tissue, the first distal-most one of the clips **102** is deployed to grip the target tissue that has been drawn into the channel **174**. If the user determines at this point that the first target portion of tissue is not positioned as desired the clip holder **108** may be repositioned until the proper positioning is achieved.
(16) When the proper positioning is achieved and the first target portion of tissue is drawn into the holder **108** as desired, in one embodiment, the pusher element **110**, which is positioned along the holder **108** proximally of the proximal-most one of the clips **102**, is moved distally relative to the holder **108** to push the proximal-most clip **102** distally along the holder **108**. This distally directed pushing force is transmitted sequentially via the intervening clips **102** until the first distal-most clip **102** is pushed distally off of the distal end of the clip holder **108**. When the first distal-most clip **102** is moved distally off of the holder **108**, the first distal-most clip **102** is freed to revert, under its natural bias, to the closed configuration in which it radially compresses about and grips the first target portion of tissue. The gripped first target portion of tissue may then be released (e.g., by discontinuing the suction or releasing the grasper), endoscope **104** may then be moved to a different area within the target site until the clip holder **108** is adjacent to a second target portion of tissue.
(17) The second target portion of tissue may then be drawn into the holder **108** as described above and a second (now distal-most) clip **102** may be deployed to clip this second target portion of tissue in the same manner described above for the first clip **102**. This process may be repeated, as necessary until the target site has been treated, as desired or until all of the available clips **102** have been deployed. As will be described in further detail below and as shown in FIGS. **8** and **9**, the pusher element **110** may be actuated via an actuator assembly **120** at a proximal end **146** of the endoscope **104**.

(18) Clip holders **108** may be configured in a variety of sizes and/or shapes so that they may be mounted over the distal ends **106** of any number of endoscopes **104**, via, for example, a friction fit. As will be understood by those of skill in the art, the endoscope **104** is an elongated, flexible shaft configured to be inserted through a body lumen to a target area within the body (and may even be passed out of the lumen to reach target sites external to the lumen in, e.g., NOTES procedures) and thus, must be sufficiently flexible to navigate through even tortuous paths of the body lumen to reach a target site. In an exemplary embodiment, the holder **108** extends longitudinally from a proximal end **122** to a distal end **124** and includes a channel **174** extending longitudinally therethrough to a distal opening into which target tissue to be clipped may be drawn.
(19) As shown in FIGS. **1** and **2**, the holder **108** is configured to be mounted to the distal end **106** of the endoscope **104** so that, when the holder **108** is mounted thereover, the channel **174** of the holder **108** is substantially aligned with a longitudinal axis of the endoscope **104** and in communication with a working channel **126** of the endoscope **104** (i.e., so that suction or devices passed through the channel **126** will operate within the channel **174**. Although exemplary embodiments show and describe the holder **108** as coupled to the endoscope **104**, it will be understood by those of skill in the art that, in an alternative embodiment, the holder **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.
(20) As described above, in one embodiment, the holder **108** is formed of a transparent material so that, when clips **102** are mounted over the distal end **106** of the endoscope **104** via the holder **108**, all, several of, or at least the distal-most one of the clips **102** is (are) within a field of view of the endoscope **104**. In one embodiment, the holder **108** is substantially cylindrical. It will be understood by those of skill in the art, however, that the holder **108** may have any of a variety of shapes and sizes so long as the holder **108** is configured to be mounted over the distal end **106** of the endoscope **104** or other insertion device and that the channel **174** is sufficiently sized to permit the entry therein of a desired portion of tissue to be clipped.
(21) In one exemplary embodiment, a proximal portion **128** of the holder **108** is configured to be mounted over the distal end **106** of the endoscope **104** while a distal portion **130** of the holder **108** extends distally past the distal end **106**. Thus, some or all of the clips **102** mounted over the distal portion **130** are within the field of view of the endoscope **104** and visible to the operator of the system **100** through a wall **150** of the holder **108** via the visualization system of the endoscope **104**. As also shown in FIG. **3**, the distal portion **130** may include longitudinal slots **132** extending longitudinally therealong through the wall **150** of the holder **108** so that the slots **132** are in communication with the channel **174** of the holder **108** and open to the outside of the wall **150** as well as at the distal end **124** of the holder **108**. In one embodiment, each of the slots **132** is equidistantly spaced relative to one another about a circumference of the holder **108**. It will be understood by those of skill in the art, however, that the slots **132** may have any of a variety of spacings relative to one another so long as the slots **132** engage the clips **102** to guide them as they move distally over the holder **108**, as will be described in further detail below.
(22) As shown in FIGS., **4-6**, each of the clips **102** extends along a curvature from the first end **112** to the second end **114** and, in one exemplary embodiment, is a substantially C-shaped circlip. The curvature of the clip **102** defines the space **116** within which target tissue may be received when the clip **102** is in the open configuration (as shown in FIGS. **4** and **5**). Thus, when the clip is pushed off of the holder **108**, the clip **102** closes (as shown in FIG. **6**) to grip/clip the tissue that had been drawn therethrough. In other words, the clip **102** is configured to be expanded to receive and substantially encircle target tissue drawn therethrough so that, when the clip **102** is released this target tissue is clipped by the radially contracting clip **102**. As described above, the clips **102** of one embodiment are formed of an elastic or tensile material biased toward the closed configuration. In one embodiment, the clip **102** may be formed of a shape memory alloy such as, for example, Nitinol. As also described above, when received on the holder **108**, the clip **102** is held in the open

configuration via the exterior surface **118** of the holder **108**.

(23) For example, in one embodiment, an outer diameter of the holder **108** is selected to be larger than a diameter of the space **116** when the clip **102** has reverted to the biased closed configuration. Thus, when the clip **102** is mounted over the holder **108**, the clip **102** is stretched and held in the open configuration. In one embodiment, in the open configuration, the first and second ends **112**, **114** are separated from one another although those skilled in the art will understand that this is not necessary. In this open configuration, the space **116** defined via the curvature of the clip **102** is sized to permit tissue to be received therein.

(24) In one embodiment, in the closed configuration, the first and second ends **112**, **114** are moved toward one another until they come into contact with one another, substantially forming a closed ring. In another embodiment, when the clip **102** closes, the first and second ends **112**, **114** move past one another so that the sides of the clip **102** that are separated in the open configuration overlap one another to form an even smaller space **116**. In yet another embodiment, the first and second ends **112**, **114** are moved toward one another, but do not come into contact with one another.

(25) One or more of the clips **102** may also include radially inwardly facing gripping features **136** which, when the clip **102** closes over target tissue, contact the target tissue in a manner that facilitates or enhances a gripping of tissue received within the space **116** making the clip **102** more secure in its position clipped over the target tissue. The gripping features **136** may include, for example, one or more teeth **136** extending radially inwardly from an interior surface **134** thereof. In one embodiment, the teeth **136** are equally spaced from one another circumferentially about an inner diameter of the clip **102**. In another embodiment, adjacent ones of the teeth **136** are variably spaced about the inner circumference of the clip **102** in any manner deemed effective to enable the teeth **136** to grip tissue received within the space **116**. Although the exemplary embodiments show and describe the gripping features **136** as teeth, it will be understood by those of skill in the art that the gripping features may include any of a variety of configurations such as, for example, other protrusions or a roughened interior surface **134**, so long as the features facilitate gripping of tissue received within the space **116**.

(26) As described above, the clips **102** are mounted over the holder **108** stretched and held in the open configuration so that each clip **102** extends about the holder **108** and the clips **102** are stacked sequentially along a length of the holder **108**. In one embodiment, the clips **102** are mounted over the distal portion **130** so that each of the teeth **136** of each of the clips **102** extends through a corresponding one of the longitudinal slots **132**. In particular, each clip **102** extends about the exterior **118** of the holder **108** with each of the teeth **136** extending radially inward through a corresponding one of the longitudinal slots **132** into the channel **174** of the holder **108**. This helps guide the proximal to distal movement of the clips **102** as the distal-most clip is pushed distally by the series of clips **102** mounted proximally thereto. In one embodiment, positions of the teeth **136** relative to a portion of tissue suctioned into the channel **174** are also visible via the endoscope **104**. In one embodiment, the clips **102** are aligned relative to one another so that, for example, the first ends **112** and the second ends **114** of the clips **102** are aligned (i.e., at substantially the same positions circumferentially about the holder **108**) along a length of the holder **108**.

(27) The pusher element **110** also extends about the holder **108**. The pusher element **110**, however, extends proximally of a proximal-most one of the clips **102**. In one embodiment, the pusher element **110** is configured as a ring extending about the holder **108** abutting the proximal-most one of the clips **102**. Thus, when the pusher element **110** is moved distally relative to the holder **108**, the proximal-most clip **102** is pushed distally against the next most proximal clip **102** which pushes against the distally adjacent clip, etc., until the force is applied to the distal-most clip **102** by the second most distal of the clips **102**. The user can observe the motion of the clips **102** along the holder **108** so that the user can see when the distal-most clip is pushed distally off of the holder **108** to clip tissue that had been drawn into the channel **174**.

(28) When it is desired to deploy one of the clips **102**, the user operates the actuator assembly **120** to push the pusher element **110** distally relative to the holder **108** over a specific distance selected to only push one clip **102** (i.e., a distal-most one of the clips **102** on the holder **108**) off of the holder **108**. That is, for example, a stroke of the actuator assembly is selected so that actuation of the assembly **120** through its complete range of motion (or through a single deployment range of motion of the actuator assembly **120**) corresponds to a range of motion of the pusher element **110** required to deploy a single one of the clips **102**. The same process may be repeated for each clip **102** when a new portion of tissue has been drawn into the channel **174** so that operation of the actuator assembly **120** allows an operator to generate a controlled movement of the pusher element **110** that deploys one and only one clip **102** at a time.
(29) As shown in FIG. **7**, movement of the pusher element **110** is controlled via a control element **138**, which, in one embodiment, is configured as a cable, strand, thread, wire or other longitudinally extending element. In one exemplary embodiment, the control element **138** extends from a distal end **140** attached to the pusher element **110** to a proximal end **142** connected to the actuator assembly **120**. According to an exemplary embodiment, the control element **138** extends distally from the pusher element **110** along the exterior **118** of the holder **108** so that a remaining length extends through a distal opening **144** of the channel **174** to be passed proximally through the channel **126** of the endoscope **110** to be coupled to the actuator assembly **120**. Thus, proximal movement of the control element **138** relative to the endoscope **104** moves the pusher element **110** distally relative to the holder **108** to deploy the clip **102**. In one embodiment, the control element **138** extends from the pusher element **110** along the exterior **118**, between the first and second ends **112**, **114** of the clips **102** so as not to interfere with a deployment of the clips **102**.
(30) According to an exemplary embodiment, the actuator assembly **120**, as shown in FIGS. **8** and **9**, includes a handle member **148** connected to the proximal end **146** of the endoscope **104** and a wheel **152** rotatably coupled to the handle member **148**. The proximal end **142** of the control element **138** in this embodiment extends proximally through the endoscope **104** and the handle member **148** to be coupled to the wheel **152** so that, when the wheel **152** is rotated relative to the handle member **148**, the control member **138** is moved proximally relative to the endoscope **104** to move the pusher element **110**, and thereby the clips **102**, distally relative to the holder **108**. As those skilled in the art will understand, the actuating assembly **120** may be configured to give an indication (e.g., tactile, auditory or visual) of an amount of motion that corresponds to a range of motion of the pusher element **110** that is required to deploy a single clip **102**.
(31) In one embodiment, the wheel **152** is coupled to the handle member **148** via a ratchet mechanism **154** so that the wheel **152** will “click” upon rotation of the wheel **152** relative to the handle member **148** via a specific amount configured to release just one of the clips **102** (i.e., a distal-most clip **102** along the holder **108**) from the holder **108**. In one example, the wheel **152** includes a plurality of ratchet teeth **156** and is engaged to the handle member **148** via a spring-biased cam **158**. The ratchet teeth **156** in this embodiment extend from an interior surface **168** of the wheel **152** toward a center **172** of the wheel **152**. Each of the ratchet teeth **156** includes a first sloped surface **160** and a second sloped surface **162** which meet at a point **164** of the tooth **152**. A valley **166** is formed between adjacent ones of the teeth **152**. The second sloped surface **162** is much steeper than the first sloped surface **160** so that, when the wheel **152** is rotated relative to the handle member **148** in a first direction, the spring-biased cam **158** slides along the first surface **160** and is compressed until the cam **158** moves past the point **164** and along the second surface **162**.
(32) Upon rotation of the wheel **152** so that the cam **158** is moved past the point **164**, the cam **158** reverts toward its biased configuration, “clicking” as it is received within the valley **166**. This “clicking” provides a tactile and/or auditory feedback to the user indicating that the control element **138** has been moved by the specific distance required to deploy just one of the clips **102**—e.g., a first distal-most clip **102**. This may be confirmed visually by the operator using the vision system of the endoscope as would be understood by those skilled in the art.

(33) When it is desired to deploy another clip **102**, the operator of the system **100** again rotates the wheel **152** relative to the handle member **148** in the first direction until the wheel **152** provides a "click" indicating that a second clip **102** (e.g., a current distal-most clip after deployment of the first clip) has been pushed off of the holder **108**. This process may be repeated until the target area has been treated, as desired, or until all of the clips **102** have been deployed. The second surface **162** is steep enough so that the second surface **162** engages the cam **158** preventing the wheel **152** from rotating relative to the handle member **148** in a second direction opposite the first direction. Thus, the control element **138** may be moved only proximally relative to the endoscope **104** to move the pusher element **110** distally relative to the holder **108**.

(34) In one embodiment, the wheel **152** includes three ratchet teeth **156**, equally positioned relative to one another along the interior surface **168** of the wheel **152**. It will be understood by those of skill in the art, however, that the wheel **152** may include any number of ratchet teeth **156** so long as the ratchet teeth **156** are configured to engage the cam **158** so that a single "click" corresponds to the deployment of a single, distal-most one of the clips **102** on the clip holder **108**. Furthermore, those skilled in the art will understand that the spacing between ratchet teeth **156** may be varied to achieve an equal distal movement of the pusher element **110** with each click. That is, if, as the wheel **152** is rotated a diameter about which the control member **138** is wound increases, it may be desired to slightly reduce the spacing between the second tooth **156** and a third one of the teeth **156** so that the slightly decreased angle of rotation of this increased diameter winds onto the wheel **152** a length of the control member **138** that is equal with each click. While the rotation of the wheel **152** clicks to provide auditory/tactile feedback to the user, the wheel **152** and/or the handle member **148** may also include markings **170** thereon providing a visual indication to the operator of the system **100** when the distal-most clip **102** on the holder **108** has been deployed.

(35) According to an exemplary method for tissue closure utilizing the clipping system **100**, the distal end **106** of the endoscope **104** (or other insertion device), including the holder **108** and the clips **102** mounted thereon in the open configuration, is inserted into a living body (e.g., via a body lumen (e.g., GI tract) accessed, for example, by a naturally occurring body orifice) to a target area within the body lumen. The distal end **106** is positioned over a first target portion of tissue to be clipped and a suction force (or a grasper) is applied through the working channel **126** of the endoscope **104** to draw the first target portion of tissue into the channel **174** of the holder **108**. Since the clips **102** are stretched about the holder **108** in the open configuration, the tissue drawn into the channel **174** is also within the space **116** defined via the curvature of at least the distal-most one of the clips **102**. The operator may then visualize whether first target portion of tissue and the distal-most one of the clips **102** are in a desired position relative to one another. If the clips **102** are not in the desired position, the tissue drawn into the channel **174** is released and a position of the distal end **106** of the endoscope **104** is adjusted relative to the surrounding tissue until the desired first portion of target tissue is drawn into the channel **174**.

(36) When the operator determines that the distal-most one of the clips **102** (first clip **102**) is in the desired position relative to the first target portion of tissue, the operator moves the actuator assembly **120** to deploy the first clip **102** from the holder **108**, as described above. In particular, operation of the actuator assembly **120** draws the control member **138** proximally. In this embodiment, as the control member **138** which extends through the working channel **126** out of the channel **174** around the distal end of the holder **108** to extend back to the pusher element **110** is drawn proximally through the working channel **126**, the portion extending proximally to the pusher element **120** is drawn distally over the holder **108** drawing the pusher element **110** distally until the first clip **102** is pushed off of the holder **108**. The first clip **102** then reverts to its biased closed configuration around the first target portion of tissue to clip this tissue. The first clip **102** may substantially encircle the first target tissue to grip the tissue within the space **116**. As described above, gripping features **136** such as, for example, teeth, facilitate gripping of the tissue when the tissue is clipped via the clip **102**.

(37) If upon deployment of the first clip **102** it is determined that there is additional tissue to be clipped, the first portion of target tissue is released and the distal end **106** of the endoscope **104** is positioned over a second target portion of tissue. The second target portion of tissue may then be drawn into the channel **174** of the holder **108** so that the operator may visualize a position of the newly distal-most one of the clips **102** (second clip **102**) on the holder **108** relative to the second target portion of tissue. When it is determined that the second clip **102** is in a desired position relative to the second target portion of tissue, the operator again actuates the actuator assembly **120** to push the second clip **102** off the of the holder **108** to clip the second target portion of tissue and this process may be repeated as desired until all of the tissue to be clipped has been clipped or until all of the clips **102** have been deployed.
(38) 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.

Claims

1. A clipping system for treating tissue, comprising: a holder configured to be mounted over a distal end of an insertion device, the holder extending longitudinally from a proximal end to a distal end and including a channel extending longitudinally therethrough; a plurality of clips mountable over the holder so that the plurality of clips are stacked directly adjacently along a length thereof, each clip of the plurality of clips extending along a curvature from a first end to a second end, the curvature defining a tissue-receiving space therewithin, each clip of the plurality of clips mountable over the holder so that each clip of the plurality of clips extends about the holder and an exterior surface of the holder holds each clip of the plurality of clips in an open configuration, in which the first and second ends of each clip of the plurality of clips are separated from one another and the tissue-receiving space is configured to receive a tissue therein, each clip of the plurality of clips being independently deployable from the holder so that, upon release of each clip of the plurality of clips from the holder, each clip of the plurality of clips is permitted to revert to a biased closed configuration, in which the first and second ends are moved toward one another to reduce a size of the tissue-receiving space so that the tissue is gripped therewithin; and a pusher element mounted over the holder, proximally of the plurality of clips, the pusher element configured to be moved distally along the holder to independently deploy each of the plurality of clips from the holder, from a distal-most one of the plurality of clips to a proximal-most one of the plurality of clips.
2. The system of claim 1, wherein the holder is formed of a transparent material.
3. The system of claim 1, wherein at least one clip of the plurality of clips includes a plurality of gripping features along an interior surface thereof.
4. The system of claim 3, wherein the gripping features include teeth extending radially into the tissue-receiving space from the interior surface of the at least one clip.
5. The system of claim 1, wherein the pusher element is configured as a ring mounted over the holder so that the pusher element extends about the holder proximally of the proximal-most one of the plurality of clips.
6. The system of claim 1, wherein at least one clip of the plurality of clips is formed of a shape memory alloy.
7. The system of claim 1, further comprising a control element extending from a distal end attached to the pusher element and extending distally therefrom along an exterior of the holder and received within a distal opening of the insertion device so that the control element extends proximally through a channel of the insertion device so that, when the control element is drawn proximally relative to the insertion device, the pusher element is moved distally relative to the holder to push the distal-most one of the plurality of clips off of the holder.
8. The system of claim 1, wherein the pusher element is positioned along the holder proximally of the proximal-most one of the plurality of clips and is configured to move distally relative to the

holder to push the proximal-most clip of the plurality of clips distally along the holder to sequentially transmit a force via one or more intervening clips of the plurality of clips until the first distal-most clip of the plurality of clips is pushed distally off of the distal end of the holder.

9. A clipping system for treating tissue, comprising: a holder configured to be mounted over a distal end of an insertion device, the holder extending longitudinally from a proximal end to a distal end and including a channel extending longitudinally therethrough; a plurality of clips mountable over the holder so that the plurality of clips are stacked directly adjacently along a length thereof, each clip of the plurality of clips extending along a curvature from a first end to a second end, the curvature defining a tissue-receiving space therewithin, each clip of the plurality of clips mountable over the holder so that each clip of the plurality of clips extends about the holder and an exterior surface of the holder holds each clip of the plurality of clips in an open configuration, in which the first and second ends of each clip of the plurality of clips are separated from one another and the tissue-receiving space is configured to receive a tissue therein, each clip of the plurality of clips being independently deployable from the holder so that, upon release of each clip of the plurality of clips from the holder, each clip of the plurality of clips is permitted to revert to a biased closed configuration, in which the first and second ends are moved toward one another to reduce a size of the tissue-receiving space so that the tissue is gripped therewithin; and a pusher element mounted over the holder, proximally of the plurality of clips, the pusher element configured to be moved distally along the holder to independently deploy each of the plurality of clips from the holder, from a distal-most one of the plurality of clips to a proximal-most one of the plurality of clips, wherein at least one clip of the plurality of clips includes a plurality of gripping features along an interior surface thereof, the gripping features including teeth extending radially into the tissue-receiving space from the interior surface of the at least one clip; and wherein a distal portion of the holder includes a plurality of longitudinal slots extending therealong and through a wall thereof so that the longitudinal slots are open at the distal end of the holder, the longitudinal slots configured to receive the teeth of the one or more of the plurality of clips therein, when the plurality of clips are mounted over the holder in the open configuration.

10. The system of claim 9, wherein the pusher element is positioned along the holder proximally of the proximal-most one of the plurality of clips and is configured to move distally relative to the holder to push the proximal-most clip of the plurality of clips distally along the holder to sequentially transmit a force via one or more intervening clips of the plurality of clips until the first distal-most clip of the plurality of clips is pushed distally off of the distal end of the holder.