



US009629649B2

(12) **United States Patent**
Smith et al.

(10) **Patent No.:** **US 9,629,649 B2**
(45) **Date of Patent:** ***Apr. 25, 2017**

(54) **TISSUE RESECTION BANDER AND RELATED METHODS OF USE**

(58) **Field of Classification Search**
CPC A61B 17/32056; A61B 17/320016; A61B 17/12013

(71) Applicant: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

(Continued)

(72) Inventors: **Paul Smith**, Smithfield, RI (US); **Oscar Carrillo, Jr.**, Attleboro, MA (US)

(56) **References Cited**

U.S. PATENT DOCUMENTS

(73) Assignee: **BOSTON SCIENTIFIC SCIMED, INC.**, Maple Grove, MN (US)

5,269,789 A 12/1993 Chin et al.
5,398,844 A 3/1995 Zaslavsky et al.

(Continued)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

FOREIGN PATENT DOCUMENTS

This patent is subject to a terminal disclaimer.

JP 2010/022697 2/2010
JP 2010042084 2/2010

Primary Examiner — Alyssa M Alter

(21) Appl. No.: **14/842,544**

(74) *Attorney, Agent, or Firm* — Fay Kaplun & Marcin, LLP

(22) Filed: **Sep. 1, 2015**

(57) **ABSTRACT**

(65) **Prior Publication Data**

US 2015/0366577 A1 Dec. 24, 2015

Related U.S. Application Data

(63) Continuation of application No. 13/727,006, filed on Dec. 26, 2012, now Pat. No. 9,155,554.

(Continued)

A tissue resection cap assembly configured to be secured to the distal end of an elongated medical device, such as an endoscope, and a method for resecting tissue. The cap assembly may include a cap structure comprising a working channel and a resection device channel, wherein the resection device channel extends inside the cap structure to a resection device track positioned substantially around the working channel adjacent the distal end of the cap structure. The resection device channel is adapted to direct a resection device from the working channel of the endoscope to the resection device track. The cap assembly further includes one or more ligation bands on the outside surface of the cap structure and a trigger line for deploying the ligation bands from the distal end of the cap structure. The method includes deploying a ligation band around tissue and using a resecting loop to cut the tissue.

(51) **Int. Cl.**

A61B 17/32 (2006.01)

A61B 17/12 (2006.01)

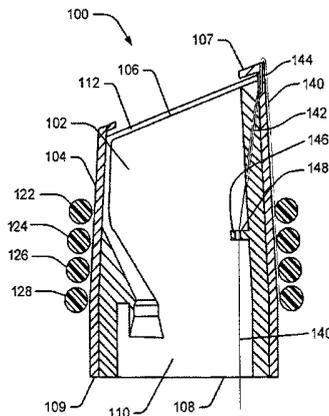
(Continued)

(52) **U.S. Cl.**

CPC **A61B 17/320016** (2013.01); **A61B 17/12013** (2013.01); **A61B 17/32056** (2013.01);

(Continued)

21 Claims, 7 Drawing Sheets



Related U.S. Application Data					
(60)	Provisional application No. 61/580,819, filed on Dec. 28, 2011.	5,913,865	A	6/1999	Fortier et al.
		5,968,056	A	10/1999	Chu et al.
		5,972,009	A	10/1999	Fortier et al.
		5,976,158	A	11/1999	Adams et al.
		RE36,629	E	3/2000	Zaslowsky et al.
(51)	Int. Cl.	6,059,719	A	5/2000	Yamamoto et al.
	<i>A61B 17/3205</i> (2006.01)	6,077,275	A	6/2000	Bryars
	<i>A61B 17/00</i> (2006.01)	6,235,040	B1	5/2001	Chu et al.
	<i>A61B 17/30</i> (2006.01)	6,306,081	B1	10/2001	Ishikawa et al.
		6,471,987	B1	10/2002	McBride-Sakal et al.
(52)	U.S. Cl.	6,632,228	B2	10/2003	Fortier et al.
	CPC <i>A61B 2017/00269</i> (2013.01); <i>A61B 2017/00296</i> (2013.01); <i>A61B 2017/12018</i> (2013.01); <i>A61B 2017/306</i> (2013.01)	7,063,709	B2	6/2006	Fortier
		7,727,249	B2	6/2010	Rahmani
		9,155,554	B2*	10/2015	Smith A61B 17/32001
		9,204,782	B2*	12/2015	Nguyen A61B 17/32056
(58)	Field of Classification Search	2004/0158124	A1	8/2004	Okada
	USPC 606/47	2007/0066985	A1	3/2007	Geitz et al.
	See application file for complete search history.	2008/0015613	A1	1/2008	Saeed et al.
		2008/0091218	A1	4/2008	Richardson
		2008/0097478	A1	4/2008	Doughty et al.
(56)	References Cited	2011/0077666	A1	3/2011	McCahon et al.
		2013/0110109	A1	5/2013	Nguyen et al.
		2013/0172918	A1	7/2013	Smith et al.
		2016/0058464	A1	3/2016	Nguyen et al.
	U.S. PATENT DOCUMENTS				
	5,853,416 A 12/1998 Tol koff				
	5,857,585 A 1/1999 Tol koff et al.				

* cited by examiner

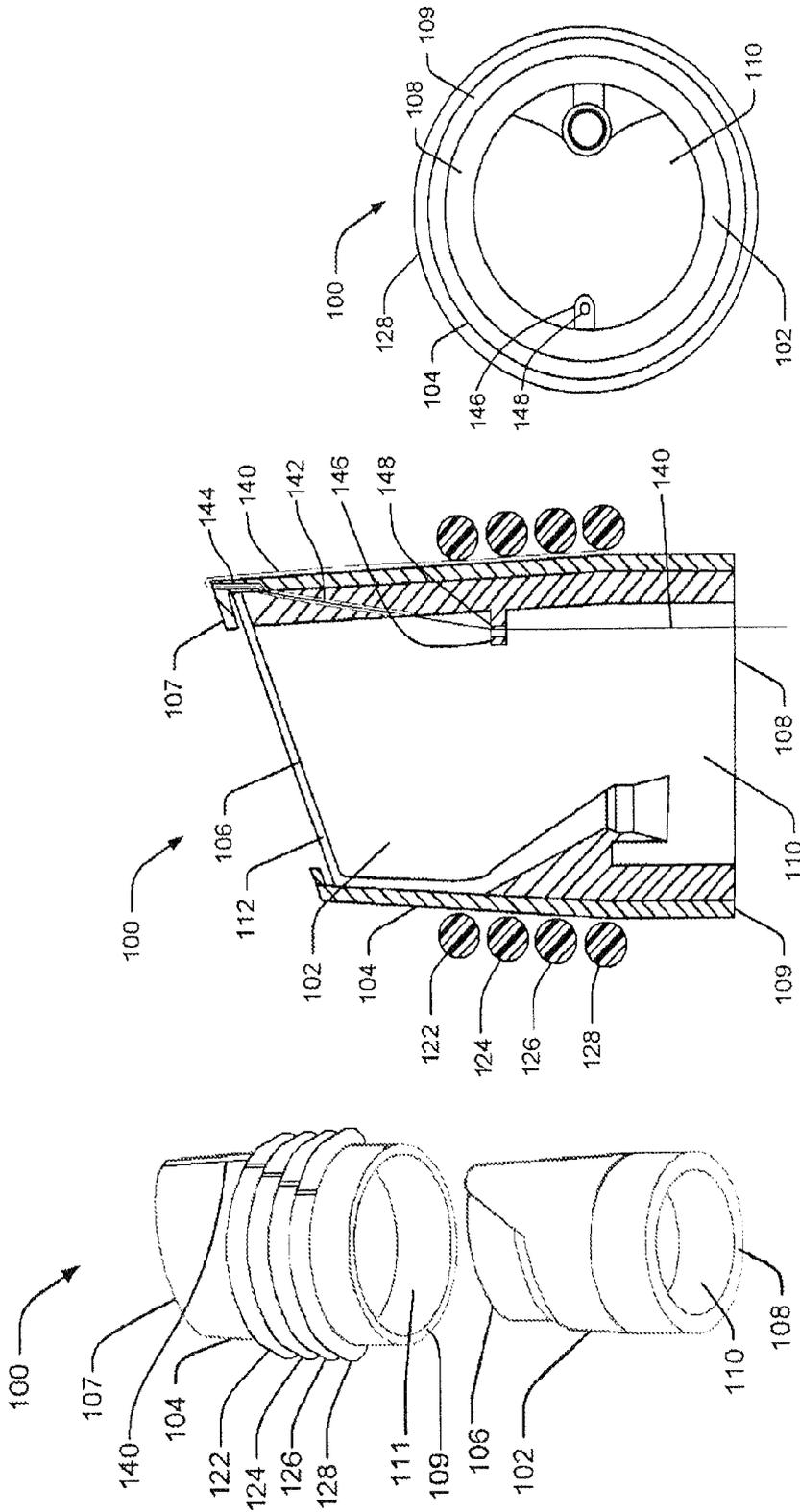


FIG. 1C

FIG. 1B

FIG. 1A

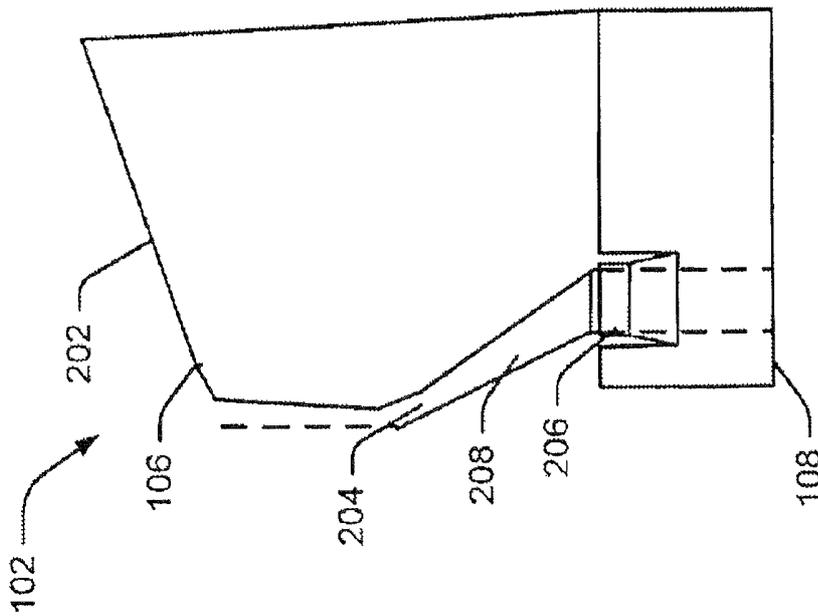


FIG. 2A

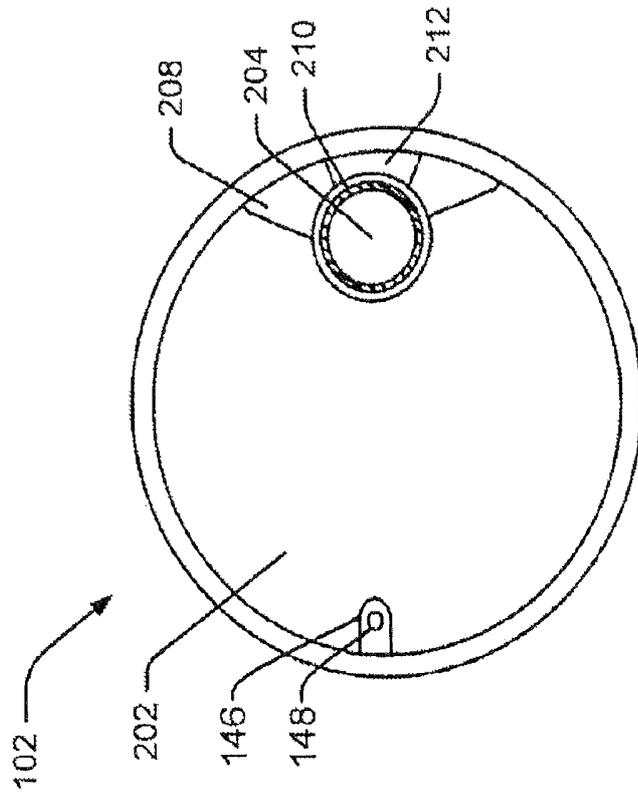


FIG. 2B

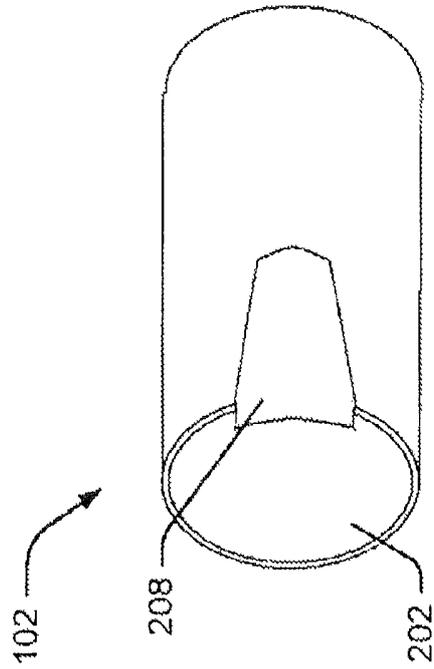


FIG. 2D

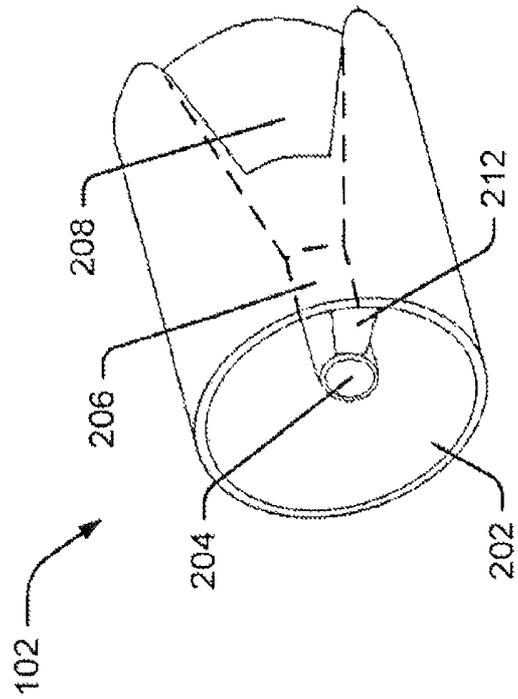


FIG. 2C

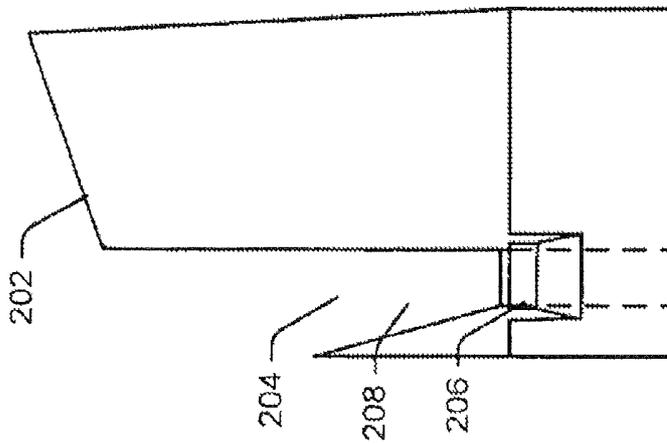


FIG. 3A

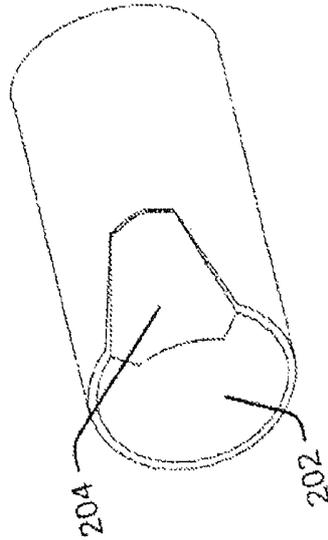


FIG. 3B

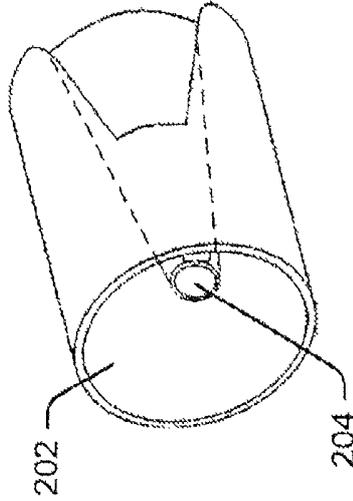


FIG. 3C

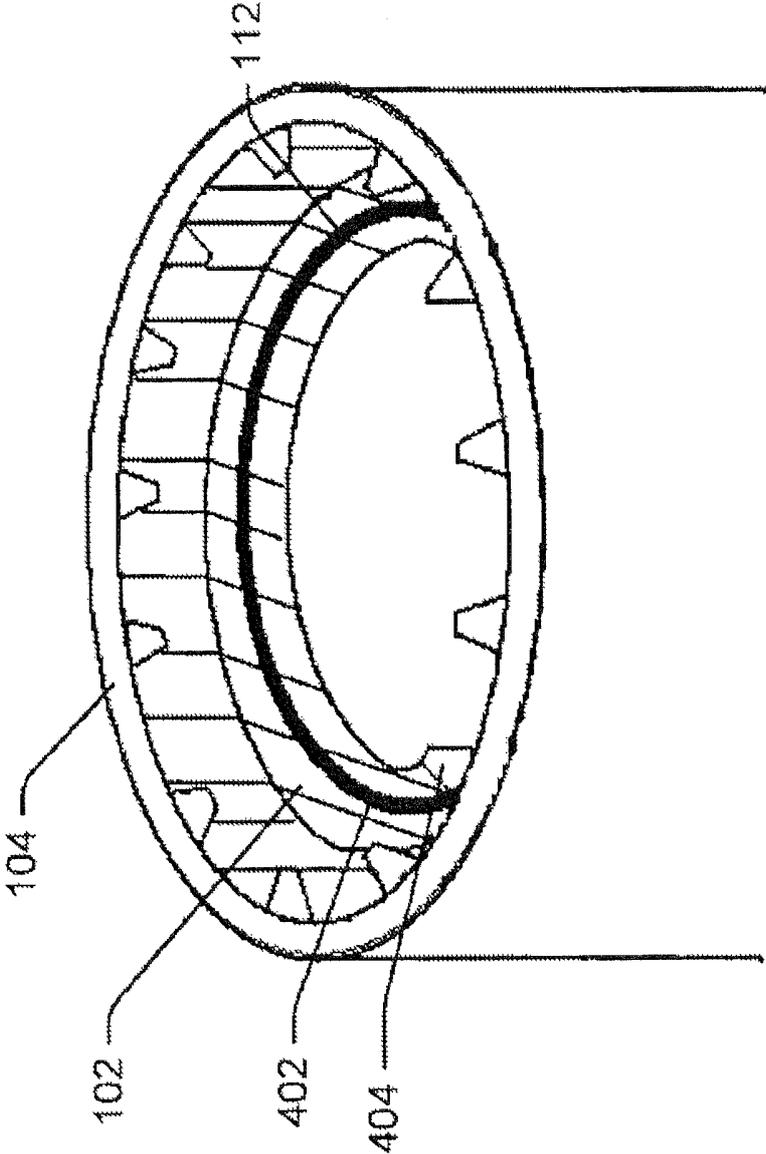


FIG. 4

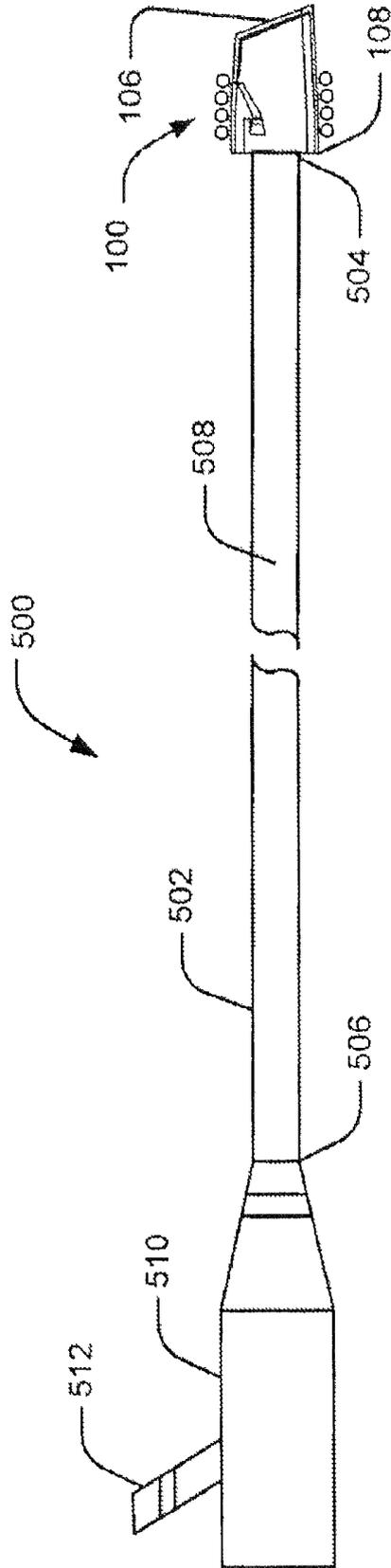


FIG. 5

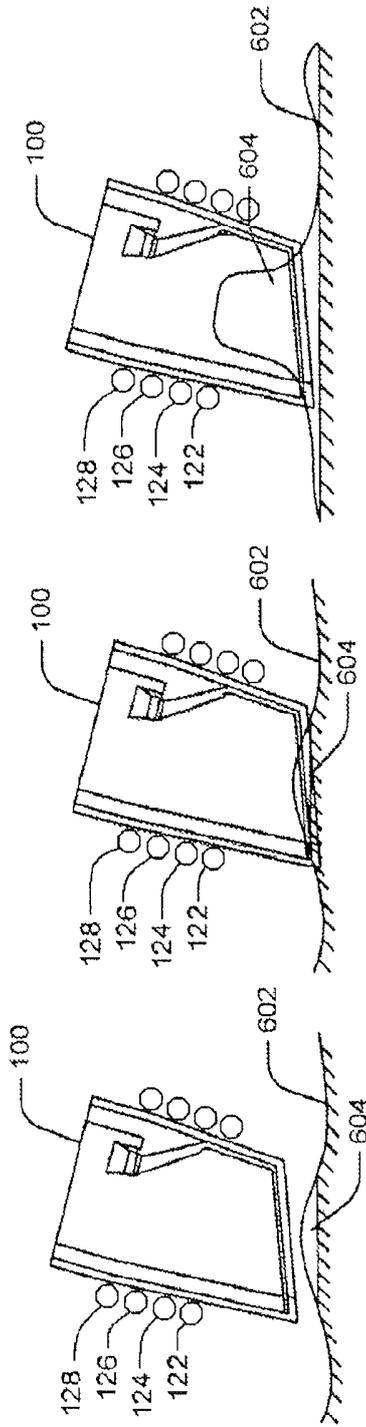


FIG. 6C

FIG. 6B

FIG. 6A

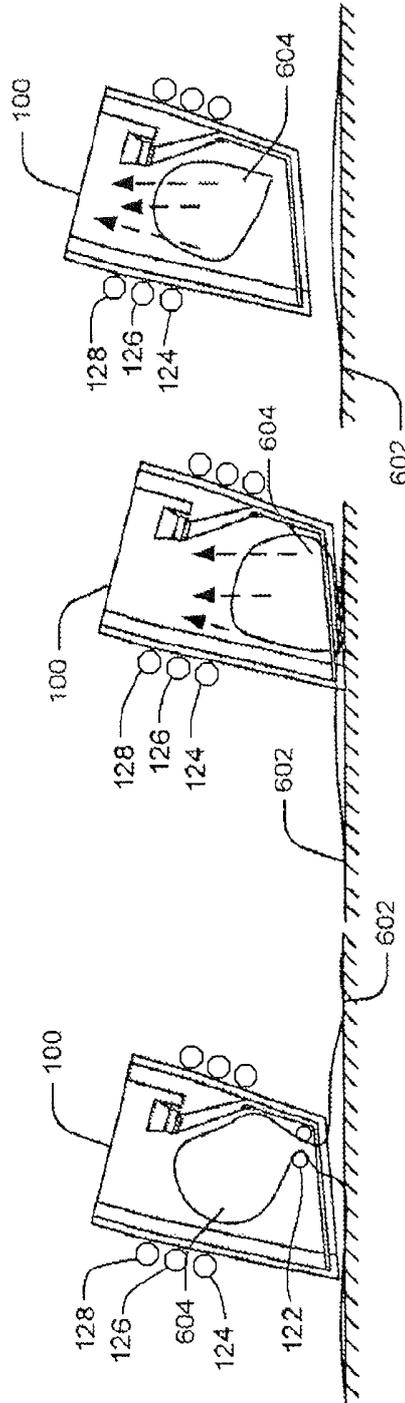


FIG. 6F

FIG. 6E

FIG. 6D

TISSUE RESECTION BANDER AND RELATED METHODS OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a Continuation of U.S. patent application Ser. No. 13/727,006 filed on Dec. 26, 2012, now U.S. Pat. No. 9,155,554; which claims priority to U.S. Provisional Patent Application Ser. No. 61/580,819 filed on Dec. 28, 2011. The entire disclosure of the above patents/applications is expressly incorporated herein by reference.

DESCRIPTION OF THE INVENTION

Field of the Invention

This disclosure relates generally to systems and methods for resecting tissue. More particularly, certain embodiments of the claimed invention relate to systems for endoscopic mucosal resection.

Background of the Invention

Organ walls may be composed of several layers: for example, the mucosa (the surface layer), the submucosa, the muscularis (muscle layer), and the serosa (connective tissue layer). In gastrointestinal, colonic, and esophageal cancer, small polyps or cancerous masses may form along the mucosa and often extend into the lumens of the organs. Conventionally, that condition has been treated by cutting out and removing a portion of the affected organ wall. This procedure, however, may cause extensive discomfort to patients, and poses health risks. Recently, physicians have adopted a minimally invasive technique called endoscopic mucosal resection (EMR), which removes the cancerous or abnormal tissues (polyps) or normal tissues, while keeping the walls intact.

EMR is generally performed with an endoscope, which is a long, narrow tube equipped with a light, an imaging system such as a video camera, and channels to receive other instruments. During EMR, the endoscope may be passed down the throat or guided through the rectum to reach tissue in the affected organ or otherwise targeted tissue. The distal end of the endoscope, further equipped for example with a cap, may be guided towards the abnormality. Once there, a suction pump attached to the tube may be started to draw the abnormality towards the endoscope cap. When the tissue is sufficiently drawn into the cap, a wire loop, which extends through a working channel of the endoscope, may be closed around the tissue, resecting it from the organ wall. Subsequently, excised tissue may be extracted by, e.g., the vacuum, for examination or disposal.

Certain polyps, such as pedunculated polyps, may be characterized by a stalk attached to the mucosal layer. Drawing such polyps into the cap without drawing in any other tissue is readily accomplished. Certain other polyps, such as sessile polyps, however, may exhibit a broad base and may lay flat on the mucosal surface, devoid of a stalk. It can be difficult to grasp these polyps without drawing in a part of the muscularis layer.

To overcome this problem, saline solution is typically injected beneath the target tissue to raise the mucosal tissue and to create a buffer layer. The raised tissue can then readily be severed, for example with a resection loop, often in several segments (segmental resection) depending on the size and location of the tissue.

In addition, the depth of the cut into the tissue is critical. As discussed above, if the cut is too deep, the muscularis layer may be injured, which may further cause a perforation.

Conversely, a cut too shallow may not remove enough of the affected tissue and therefore may require additional procedures or worse, contribute to the development of metastatic cancer. Typically, more than 2 mm of cancerous tissue clearance is required to assure complete removal. EMR, as performed with conventional devices and methods, may result in complications such as perforation, bleeding, and/or strictures.

There exists a need for an improved resection loop device that improves the speed and accuracy of the procedures desired to be performed.

SUMMARY OF THE INVENTION

Embodiments of the present disclosure provide devices and methods for resecting undesired tissue from a patient's body using a minimally invasive surgical system.

In accordance with an aspect of the present disclosure, a tissue resection cap assembly for resecting tissue from a body is described. The cap assembly may be configured to be coupled to the distal end of an elongated medical device having a working channel, such as an endoscope, guide tube or the like. The cap assembly may include a cap structure comprising a proximal end, a distal end, an outside surface, and a working channel extending from the proximal end to the distal end; at least one ligation band, for example an elastic band, positioned on the outside surface of cap structure; and a trigger line for deploying the ligation band(s) from the distal end of the cap structure. The cap structure further comprises a resection device channel and a resection device track in communication with the resection device channel. A proximal end of the resection device channel is adapted for communication with a working channel of the endoscope or other elongated medical device. The resection device channel may extend distally to the resection device track adjacent the distal end of the cap structure. The resection device track may substantially surround the working channel of the cap structure adjacent the distal end of the cap structure.

In various embodiments, the cap structure may comprise a first cap and a second cap. The first cap may include a distal end having a first opening, and the second cap may include a distal end having a second opening. The first cap may define the resection device channel. The second cap may be configured to receive at least a portion of the first cap. A distal portion of the first cap and a distal portion of the second cap may cooperate to define the resection device track for receiving a distal portion of a resection device, which may be a resection loop.

In various embodiments, the device may include one or more of the following additional features: the resection device track may be disposed in a plane parallel to a plane of the second opening; the resection device track may extend at an angle to the resection device channel; the resection device channel may further include a resection wire lumen positioned inside the first cap; the first cap may define the working channel of the cap structure, extending from the distal end to the proximal end of the first cap; the resection device channel may be formed of a flexible wall configured to collapse the resection device channel when a resection device is not present in the resection device channel; a portion of the resection device channel may be configured to prevent distal movement of a sheath associated with a resection device; the cap assembly may be configured to bend or pivot relative to the distal end of the endoscope; a portion of the resection device channel may be defined by an outer wall of the first cap; the resection device channel may

further include a cylindrical section disposed within the first cap; the distal end faces of the first and second caps may be angled relative to a longitudinal axis of the cap assembly; and the resection device may comprise a resection loop that may further comprise an electrocautery tool.

A further aspect of the present disclosure includes a resection device comprising a first part and a second part. The first part defines a resection device channel, wherein the first part includes a distal end having a first opening. The second part is configured to receive at least a portion of the first part, wherein the second part includes a distal end having a second opening, wherein a distal portion of the first part and a distal portion of the second part cooperate to define a resection device track for receiving a resection device. The resection device further includes at least one ligation band positioned on the outside surface of the second part and a trigger line for deploying the ligation band from the distal end of the second part.

A further aspect of the present disclosure includes a method of resecting tissue. The method may include attaching a cap assembly to the distal end of an endoscope or other elongated medical device. The cap assembly may include a cap structure comprising a proximal end, a distal end, an outside surface, and a working channel extending from the proximal end to the distal end; at least one ligation band positioned on the outside surface of cap structure; and a trigger line for deploying the ligation band(s) from the distal end of the cap structure. The cap structure may further comprise a resection device channel and a resection device track in communication with the resection device channel. A proximal end of the resection device channel may be adapted for communication with a working channel of the endoscope. The resection device channel may extend distally to the resection device track adjacent the distal end of the cap structure. The resection device track may surround the working channel of the cap structure adjacent the distal end of the cap structure. The method further includes positioning the cap assembly adjacent to tissue to be resected and drawing tissue, for example with suction, within the cap assembly. The method may comprise actuating the trigger line to deploy a ligation band around the tissue, and then, if desired, actuating the resection device to cut the tissue. Alternatively, the method may comprise actuating the resection device to close the resection device loop around the tissue, evaluating the ensnared tissue, and then either further actuating the resection device to cut the tissue or opening the resection device loop to release the tissue. If the tissue is released, the method may further comprise actuating the trigger line to deploy a ligation band around the tissue, and then, if desired, again actuating the resection device to cut the tissue.

In various embodiments, the step of attaching the cap assembly to the distal end of the endoscope may include aligning the resection device channel with a working channel of the endoscope. After actuating the trigger line to deploy a ligation band and prior to actuating the resection device to cut the tissue, suction may be released to allow confirmation of proper positioning of the resection device.

The cap assembly may further comprise a channel for allowing the trigger line to extend from a working channel of the cap structure to the outside surface of the cap structure without having the trigger line extend through a resection loop of the resection device.

Additional objects and advantages of the claimed invention will be set forth in part in the description, which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and

advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate exemplary embodiments of the present disclosure and together with the description serve to explain the principles of the disclosure.

FIG. 1A is an exploded view of an EMR cap assembly, according to an embodiment of the present disclosure.

FIG. 1B is a sectional view of the EMR cap assembly of FIG. 1A.

FIG. 1C is an end view of the EMR cap assembly of FIG. 1A.

FIG. 2A is a schematic of an inner cap, according to embodiments of the present disclosure.

FIG. 2B is an end view of the inner cap of FIG. 2A.

FIG. 2C is an isometric view of the inner cap of FIG. 2A taken from the proximal end.

FIG. 2D is an isometric view of the inner cap of FIG. 2A taken from the distal end.

FIGS. 3A-3C illustrate various embodiments of the inner cap, according to embodiments of the present disclosure.

FIG. 4 illustrates the EMR cap assembly of FIG. 1 viewed from the distal end.

FIG. 5 illustrates an exemplary resection device incorporating the EMR cap assembly of FIG. 1, according to embodiments of the present disclosure.

FIGS. 6A-6F illustrate an exemplary method for resecting a tissue from a mucosal wall using the EMR cap assembly of FIG. 1, according to embodiments of the present disclosure.

DESCRIPTION OF THE EMBODIMENTS

Reference will now be made in detail to embodiments of the present disclosure, an example of which is illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts. The term "distal" refers to the end farthest away from a medical professional when introducing a device in a patient. By contrast, "proximal" refers to the end closest to the medical professional when placing a device in the patient.

Overview

Embodiments of the present disclosure relate to systems and methods for resecting and extracting foreign or undesirable objects from a patient's body. For example, the device may remove cancerous polyps or lesions from the mucosal walls of the colon, esophagus, stomach, duodenum, or any other suitable location. It should be understood that the resection device may perform the functions of both resecting and retrieving, but for convenience, the term "resection device" will be used throughout this application.

The resection device may include an end-effector, such as, e.g., an EMR cap assembly, fitted on the distal end of any tube, such as an endoscope, for ensnaring, cauterizing, and extracting tissue such as a polyp. The EMR cap assembly may include a working channel, as well as a resection loop channel aligned with and inserted into the working channel.

The EMR cap assembly may further include a track along its distal circumference in communication with the resection loop channel, such that a resection loop extending from the resection loop channel slides into the track when the resection loop is in an open position. In this position, the resection loop is parallel to the opening of the EMR cap assembly. When the EMR cap assembly is placed over an undesired tissue, tissue may be drawn into the working channel, for example by suction. One or more ligation bands may then be deployed from the distal end of the EMR cap assembly, for example by causing a trigger line to be pulled proximally, such that the ligation band is released and constricts around the tissue. This banding action may form a pseudo polyp. The suction may then be released, and the proper positioning of the resection loop may be confirmed, for example by visualizing the site with the endoscope. This can include a confirmation check that no muscularis is within the area to be resected by the resection loop. The resection loop may then be pulled proximally, reducing the diameter of the loop in the track and engaging the drawn tissue. Subsequently, the tissue may be cauterized and extracted. Because the resection loop extends substantially around the EMR cap assembly's distal opening, the operator can easily place the resection loop around the tissue to capture and cauterize it. Moreover, only the mass drawn into the EMR cap assembly's working channel is resected, ensuring that deeper layers of the organ wall are not affected.

In the following sections, embodiments of the present disclosure will be described using an exemplary body organ—the esophagus. It will be understood that this choice is merely exemplary and that the device may be utilized in any other suitable organ, such as the colon, duodenum, stomach, or any other organ that may be subject to polyps, lesions, stones, and the like.

Exemplary Embodiments

Exemplary EMR Cap Assembly

FIGS. 1A-1C presents three views of an EMR cap assembly **100** for resecting polyps, lesions, or otherwise unwanted tissue from, e.g., the mucosal walls of organs according to embodiments of the present disclosure. EMR cap assembly **100** is configured to be secured to a distal portion of an endoscope for advancing towards a target location with a patient. Particularly, FIG. 1A is an exploded view, FIG. 1B is a sectional view, and FIG. 1C is an end view of EMR cap assembly **100**. These figures will be commonly referenced to describe the structure and function of the EMR cap assembly **100**. The EMR cap assembly **100** may be detachably connected to the distal end of any flexible or rigid tube, such as an endoscope used for colonoscopy, resectoscopy, cholangioscopy, or mucosal resection.

EMR cap assembly **100** includes a cap structure comprising an inner cap **102** and an outer cap **104**. The inner and outer caps **102**, **104** may be hollow elongate members with distal ends **106**, **107**, respectively, and proximal ends **108**, **109**, respectively, with lumens **110**, **111**, respectively, extending between the respective distal and proximal ends. The outer cap **104** fits over the inner cap **102**, and this complete assembly is attached to a tube (not shown).

The inner cap **102** and outer cap **104** may have substantially circular cross-sections or cross-sections similar to those of body cavities. Where required by given applications, the EMR cap assembly **100** may include elliptical, semi-circular, rhombic, rectangular, or other non-circular profiles. Moreover, the diameter of the EMR cap assembly

100 may vary based on the size of the body lumens in which it operates. For example, if the EMR cap assembly **100** is inserted through the urethra, the diameter of the inner and outer caps may be very small. Conversely, if the device is inserted through the rectum, the diameter of the inner and outer caps may be larger.

Any suitable material may form inner and outer caps **102**, **104**. For instance, rigid or semi-rigid materials such as metals (including materials such as nitinol), polymers, resins, or plastics such as polycarbonate or polyethylene may be used. Further, a biocompatible material that does not irritate the body lumens may form a coating or layer over the outer surface of EMR cap assembly **100**.

As can be seen in FIGS. 1A-1C, the cap assembly **100** further includes a plurality of ligation bands **122**, **124**, **126**, **128** positioned on the outside surface of the outer cap **104**. The cap assembly **100** further includes a trigger line **140** for deploying the ligation bands **122**, **124**, **126**, **128** from the distal end **107** of the outer cap **104**.

The ligation bands, trigger line, and configuration of the outer cap for deployment of the ligation bands may take any suitable form. Examples of ligation bands, trigger lines, and cap configurations for deployment of ligation bands are described and illustrated in U.S. Pat. Nos. 5,968,056; 5,976,158; 5,853,416; 6,077,275; 5,269,789; 5,398,844; 6,235,040; 5,972,009; 5,913,865; 5,857,585; 7,063,709; 6,471,987; 6,632,228; RE 36629 and U.S. Published Patent Application Nos. 2008-0097478, 2011-0077666 and 2008-0091218; the disclosures of these patents and patent applications are hereby incorporated herein by reference. For example, the cap assembly **100** may include a single trigger line **140** that is wrapped around the ligation bands **122**, **124**, **126**, **128** in a manner as described in U.S. Pat. No. 5,857,585, to allow for sequential deployment of the bands **122**, **124**, **126**, **128** by actuation of the trigger line **140**. The inner cap **102** and outer cap **104** may be transparent in whole or in part to improve the operator's field of vision, for example as described in U.S. Pat. No. 5,853,416. The distal end **107** of the outer cap **104** may have slots with different slot depths, and the trigger line may have suitable retentions elements (e.g., knots, etc.), as described in U.S. Pat. Nos. 6,235,040 and 5,913,865. The outer cap may have ridges for lifting the ligation bands **122**, **124**, **126**, **128** off of the trigger line **140** and/or for promoting rolling of the ligation bands **122**, **124**, **126**, **128**, for example as described in U.S. Pat. No. 7,063,709. The ligation bands may be comprised of any suitable elastic material or may be comprised of one or more less elastic materials, components or sections. For example, in some embodiments, the ligation bands may comprise filament loops which can be cinched around tissue.

The ligation bands **122**, **124**, **126**, **128** are configured such that when the trigger line **140** is actuated, for example by an operator causing the trigger line **140** to be pulled from a proximal end, each band is sequentially deployed off of the distal end **107** of the outer cap **104**. When positioned on the outer surface of the outer cap **104**, the ligation bands **122**, **124**, **126**, **128** are in a stretched condition. A first actuation of the trigger line **140** causes the first ligation band **122** to be deployed off of the distal end **107** of the outer cap **104**. When this happens, the first ligation band **122** constricts toward its relaxed, unstretched condition. When this deployment is performed with tissue inside of the working channel of the cap structure, the constriction of the ligation band **122** around the tissue forms a pseudo polyp. The use of multiple ligation bands **122**, **124**, **126**, **128** may allow the device to be repositioned for capturing additional tissue with sequential deployment of the bands without having to withdraw the

device from the patient. Thus, after repositioning, a second actuation of the trigger line 140 may cause the second ligation band 124 to be deployed off of the distal end 107 of the outer cap 104. Then, after further repositioning, a third actuation of the trigger line 140 may cause the third ligation band 126 to be deployed off of the distal end 107 of the outer cap 104, and, after further repositioning, a fourth actuation of the trigger line 140 may cause the fourth ligation band 128 to be deployed off of the distal end 107 of the outer cap 104.

It will be appreciated by persons of ordinary skill in the art that the trigger line 140 extends proximally from the distal end 107 of the outer cap 104, through the inside of the cap assembly 100, and through the endoscope toward the operator of the device. For clarity of illustration, the portion of the trigger line 140 that extends along the inside of the cap assembly 100 is not shown in FIG. 1A.

As can be seen in FIG. 1B, the cap assembly 100 may comprise a channel 142, 144 for allowing the trigger line 140 to extend from a working channel 110 of the first cap 102 to the outside surface of the second cap 104 without having the trigger line 140 extend through a resection loop of the resection device (described below). In this illustrated embodiment, the channel 142, 144 comprises a first channel segment 142 that extends through the wall of the first cap 102 and a second channel segment 144 that extends through the wall of the second cap 104 to the distal end 107 of the second cap 104. Because the trigger line 140 does not extend through a resection loop of the resection device (described below), the resection loop can be deployed without ensnaring the trigger line 140.

As can be further seen in FIG. 1B as well as in FIG. 1C, the inner cap 102 may have a guiding tab 146 with a bore 148 through which the trigger line 140 extends, thereby keeping the trigger line 140 generally along the inside of the wall of the inner cap 102. For clarity of illustration, the trigger line 140 is not shown in FIG. 1C.

A detailed discussion of inner cap 102 and outer cap 104 follows, in connection with FIGS. 2-4.

FIG. 2 illustrates four views of inner cap 102. More particularly, FIG. 2A is a schematic view, FIG. 2B is an end view, FIG. 2C is an isometric view taken from proximal end 108, and FIG. 2D is an isometric view taken from distal end 106. Lumen 110 of inner cap 102 includes a working channel 202 and a resection device channel or resection loop channel 204. The dimensions of these channels may vary considerably from one application to another. For example, in procedures where a resected mass is extracted through the tube, working channel 202 may be larger than resection loop channel 204. Otherwise, where no need for removal of a resected mass is presented, resection loop channel 204 may be larger than working channel 202. Moreover, working channel 202 may include numerous other channels to carry desired instruments, such as cameras, light sources, and other endoscopic instruments.

As illustrated in FIG. 2A, resection loop channel 204 extends from proximal end 108 to distal end 106 of inner cap 102. Moreover, a proximal portion of channel 204 may include a hollow or luminal section 206 (FIG. 2C), and this section may lead to a flared section 208 (FIGS. 2C and 2D) towards the cap's distal end 106.

Section 206 may accommodate an outer sheath of a resection device or resection loop (not shown). In one embodiment, the diameter of section 206 is substantially equal to or smaller than the diameter of the resection loop sheath. Moreover, section 206 may taper distally such that the diameter of the section's distal end is smaller than the

diameter of the sheath, preventing the sheath from extending beyond the distal end of section 206. Alternatively, section 206 may have a uniform diameter from its proximal end to its distal end, optionally including a ledge 210 on its distal end. The ledge 210 extends radially inwards, reducing the distal end's diameter to equal to or less than the sheath's inner diameter, thereby stopping the sheath from extending distally beyond the distal end of section 206. The shaded portion in FIG. 2B illustrates ledge 210.

It will be understood that instead of the ledge, any other structure may be employed to reduce the diameter of the cylindrical portion's distal portion. For example, some configurations may include actuatable protrusions, or barbs extending inwards in parallel to the distal end of the section 206.

Flared section 208 does not necessarily flare out radially in all directions; instead, it may flare out parallel to a portion of the cap's internal wall. In some embodiments, however, section 208 may fully flare out.

A portion or the entire resection loop channel 204 may be in contact with the inner wall. Alternatively, resection loop channel 204 may be positioned adjacent the inner wall. In this embodiment, a support block 212 may connect resection loop channel 204 with the inner wall. It will be understood that the resection loop channel's placement within lumen 110 may vary without departing from the scope of the present disclosure.

In some instances, section 206 may not abut the inner wall of the inner cap 102. Instead, it may be slightly spaced from the inner surface. Flared section 208, however, may make contact with the inner wall. Moreover, the width of flared section 208 may be smaller than or equal to the diameter of section 206. To maintain this width and to increase the working channel's area, flared section 208 may curve toward the inner wall. FIG. 2A illustrates this embodiment.

Alternatively, the width of flared section 208 may be greater than the diameter of section 206. In this case, the portion of the resection loop channel wall in contact with working channel 202 may extend parallel to the longitudinal axis of section 206, while the portion of the channel wall closer to the inner wall may flare out radially to contact the inner wall. FIGS. 3A and 3B illustrate this embodiment. Compared to FIG. 2A, it is evident that this embodiment features a broader resection loop channel 204, while the working channel 202 space is reduced.

In an alternative embodiment, the portion of the inner cap 102 abutting flared section 208 may be cut out or removed, leaving the resection loop channel with a partial wall. Outer cap 104 abuts flared section 208 (FIG. 1A) forming the remaining wall for resection loop channel 204.

The degree of angular displacement of the distal end of flared section 208 may vary based on numerous factors, such as tensile strength of the resection loop, size of resection loop, or diameter of inner cap 102. It will be understood, however, that flared section 208 may be sufficiently broad and wide to allow the resection loop to open completely into an active position. "Active position" refers to a position in which the resection loop is completely open and its loop diameter is approximately equal to or slightly smaller than or slightly greater than the diameter of inner cap 102.

Alternatively, resection loop channel 204 may not have a cylindrical section, and instead it may begin flaring from the proximal end 108 of the inner cap 102 (shown in FIG. 3C). It will be understood that the shape of flared section 208 may vary without departing from the scope of the present disclosure. For example, the flare's cross-section may have a

generally “U” shape, “V” shape, semicircular shape, semi-elliptical shape, square shape, rectangular shape, or any suitable shape.

In FIG. 2, resection loop channel 204 is permanently fixed in the inner cap and in the gap between the inner and outer caps. In another embodiment, however, resection loop channel 204 may be detachably connected to working channel 202. When the resection loop is not in use, resection loop channel 204 may be removed. In another embodiment, the resection loop channel 204 may be collapsible, i.e., formed of a flexible membrane. When the resection loop is not inserted in the cap, the flexible membrane may rest against the inner wall of inner cap 102 (converting the complete lumen into working channel 202). When the resection loop is inserted, it may push the flexible member away from the inner wall and into the working channel 202. Once the lesion is resected, the resection loop may be retracted, and the flexible member may return to its original position (against the inner wall of inner cap 102). Detachably connecting resection loop channel 204 or incorporating it with a flexible wall increases the working channel 202 width, allowing the resection device to extract large resected pieces.

Outer cap 104 includes a general cross-sectional shape similar to that of inner cap 102. An inner diameter of outer cap 104, however, is large enough to fit around inner cap 102. When fit over inner cap 102, distal end 107 of outer cap 104 extends distally beyond inner cap 102. The space between the distal ends of inner cap 102 and outer cap 104 may form a track for guiding the resection device or resection loop, such as the resection device track or resection loop track 112 shown in FIG. 1B.

FIG. 4 illustrates the track in detail. As shown, track 112 includes the circular-shaped distal surface of inner cap 102, and the inner walls of outer cap 104 extending distally beyond inner cap 102. Further, the track may be sufficiently wide and high to slidably receive a resection loop, such as resection loop 402. Moreover, the distal surface of outer cap 104 may include a support structure 404 such as an edge, ridge, ledge, or rail extending circumferentially inward such that the support structure is wide enough to cover the proximal surface of inner cap 102, thus providing a track surrounded on three sides (top, bottom, and outer edge) and open on one side (inner edge). Alternatively, support structure 404 may include multiple equidistant protrusions extending towards the lumen 110. These support structures allow the resection loop 402 to rest parallel to the distal opening of the EMR cap assembly 100 when the resection loop 402 is extended into track 112. It will be understood that any other structure to maintain the resection loop 402 within track 112 is conceivable and within the scope of the present disclosure.

In one embodiment, the distal openings of both inner cap 102 and outer cap 104 may lie perpendicular to the longitudinal axes of the caps. Alternatively, the distal openings may slant at an acute angle to the longitudinal axes. Because tissues may be present on the esophageal walls, out of the direct path of an endoscope advancing through that organ, the slanted distal opening provides a greater surface area contact between the EMR cap assembly’s distal opening and the tissues. It will be understood that the slant angle may vary based on the organ or the procedure. For example, a narrower body organ, such as the esophagus, may call for a distal opening slanted at a greater angle than for wider body organs, such as the stomach.

Resection loop channel 204, along with track 112, forms a path for the resection loop 402. The loop, enclosed within a sheath, may be inserted from the proximal end 108 into the

resection loop channel 204. The sheath may extend up to the distal end of section 206. From there, the resection loop may be advanced distally into the flared section 208. Because the channel 204 is flared, the resection loop is provided sufficient space to expand into the active position. Moreover, flared section 208 merges with track 112, allowing the resection loop to slide into track 112 in its active position, such that the loop rests along the circumference of the inner cap’s distal opening, between the inner and outer cap.

Pushing the resection loop distally can place it in the active position on track 112, while pulling the resection loop proximally closes the resection loop. Because the resection loop lies in track 112, it closes essentially parallel to the distal opening of the EMR cap assembly. This resection loop configuration allows the EMR cap assembly to grasp and hold flat tissues.

As described in this disclosure, the resection loop is a wire loop device used to cauterize a lesion, polyp, or any other tissue. The cross-sectional diameter of the wire may vary according to the application. In an embodiment, the resection loop may comprise a resecting hook comprising an generally arcuate shape surrounding a portion of the cap. Further, the resecting hook may have any cross-sectional geometry. For example, the cross-section may be flat, round, or triangular. In another embodiment, the resection loop may be a cauterizing resection loop that is energized by passing electrical energy through the loop. Moreover, the electrical energy may be sufficient to cauterize the tissue swiftly. The cauterizing resection loop may be mono-polar, where high frequency electrical current is passed from a single electrode and the patient’s body serves as ground or bipolar where high frequency electrical current is passed through the tissue from one electrode to another. It will be understood that instead of electrical energy, any other form of energy now known or known in the future may be supplied to the resection loop to resect the tissue from the organ wall. For example, high heat energy may be supplied, enabling the resection loop to burn the tissue from the organ wall. Similarly, other energy sources, e.g., RF, ultrasonic, laser and cryogenic, may be considered without departing from the scope of the present disclosure. In addition, the disclosed EMR cap assembly may be utilized with any suitable cutting device known to those skilled in the art, such as, for example, an energy actuated wire loop, a wire loop with no actuation, a hook, a knife, a blade, etc., all with or without activation.

The inner and outer caps may be detachably connected, permanently coupled, or formed into an integral component. Detachable connections may include, but are not limited to, snap fit assembly, screw fit assembly, luer-lock assembly, or force lock assembly. For example, a proximal portion of the outer cap’s inner wall may include one or more screw threads, while the corresponding portion of the inner cap’s outer wall may include corresponding screw threads. After placing outer cap 104 over inner cap 102, the outer cap 104 may be rotated to engage the screw threads of the inner and outer caps 102, 104. In another instance, inner cap 102 may include one or more protrusions along its outer wall, while outer cap 104 may include corresponding grooves on its inner wall. The protrusions may engage with the grooves when outer cap 104 is placed over inner cap 102, snap fitting them in place. It will be understood that other temporary or permanent connection techniques are well within the scope of the present disclosure. In one example embodiment, the outer and inner caps are permanently assembled together with a space between them forming the track. In another example embodiment, the outer and inner caps are capable

of being assembled together at the time of attaching the cap assembly to the endoscope. For example, the outer and inner caps may be capable of squeezing a membrane between them when attached together (e.g., by threading or snap fit) to create a releasable connection to the endoscope.

Permanent connection methods include gluing or spot-welding, depending on the cap material. Alternatively, these elements may be permanently sealed with a high-strength adhesive, such as epoxy. To form a single component, the EMR cap assembly may be made of a single component that includes a resection loop channel merging into a track parallel to its distal opening. The EMR cap may be formed as a single component by molding, lithography or any other suitable manufacturing technique.

The diameter of EMR cap assembly **100** may be configured to match the requirements of particular applications. In general, a uniform diameter along the length of the device may be preferred for most applications. In situations where tissues are small or when the body cavity is very narrow, a tapered EMR cap assembly may be preferred. Conversely, flared or tapered EMR cap assemblies may be utilized when the tissues are large or the body cavity is wide.

The distal edge of the cap assembly, e.g., around the opening, may be layered or coated with a pliant material like silicone to enable a better vacuum seal between the cap and tissue.

The following section describes a resection device that may implement the EMR cap assembly **100** for conducting endoscopic mucosal resection.

Exemplary Resection Device

FIG. **5** is a perspective view of a resection device **500** for cutting and extracting an undesired mass through an incision or a natural body opening. The device **500** includes an elongate tube **502**, such as an endoscope, with a distal end **504**, a proximal end **506**, joined by a lumen **508**. Proximal end **506** may be coupled to a handle **510**, while distal end **504** is coupled to EMR cap assembly **100**. The tube further includes one or more internal channels (not shown) having proximal and distal end openings.

Tube **502** may have a cross-sectional configuration adapted according to a desired body lumen. In the illustrated embodiment, tube **502** may include a generally circular cross-section, with a generally circular hollow interior lumen. Further, the tube **502** may have a uniform diameter or may be tapered at the distal end to allow convenient insertion within the body.

Depending upon the particular implementation and intended use, the length of tube **502** may vary. For example, tube **502** may be a few centimeters or less where a shallow body cavity or organ is involved. For long cavities or deeper organs such as the bowel or intestine, tube **502** may be relatively long. Similarly, depending upon the particular implementation and intended use, the tube can be rigid along its entire length, flexible along a portion of its length, or configured for flexure at only certain specified locations.

In one embodiment, tube **502** may be flexible, adapted for flexible steering within bodily lumens, as understood in the art. For example, tube **502** can be steered with controls to move at least a portion, generally distal end **504**, up and down, or side-to-side. Additional degrees of freedom, provided for example via rotation, translational movement of tube **502**, or additional articulation of bending sections, are also contemplated. In such an embodiment, resection device **500** may be provided with suitable steering systems for, among other things, articulating or steering distal end **504** of tube **502**. For example, a suitable steering system may

include one or more of pulleys, control wires, gearing, electrical actuators (such as servomotors), pneumatic actuators, and the like.

Such flexible tubes may be formed of any suitable material having sufficient flexibility to traverse body cavities and tracts. Suitable materials may include synthetic plastics, fiber, or polymers such as polyesters. Alternatively, tube **502** may be rigid or semi-rigid, formed from materials such as stainless steel or the like, including super-elastic or shape-memory alloys such as nitinol. Tube **502** may also be manufactured from any biocompatible material such as a sheath, with or without a PTFE outer layer.

Moreover, the tube **502** and EMR cap assembly **100** may be designed to impose minimum risk to the surrounding tissues while in use. To this end, the proximal or distal ends of these components may include geometrical structures, such as rounded or beveled terminal ends or faces, to reduce trauma and irritation to surrounding tissues. Further, the outer surface of the EMR cap assembly and tube may include any suitable coating or covering. For example, the outer surface may include a layer of lubricous material to facilitate insertion through a body lumen or surgical insertion. The distal end may be comprised of or include a soft polymer or other material, such as silicone or rubber, to help cushion the device on tissue as well as to help seal any vacuum used.

To effectively maneuver the tube **502** within a body cavity, the operator should know the exact location of the tube in the cavity at all times. To this end, one or more portions of resection device **500** may be radiopaque, produced by inclusion of material such as barium sulfate in plastic material or one or more metal portions, which provide sufficient radiopacity. Alternatively, the distal end of the tube or EMR cap assembly may include a radiopaque marker or sonoreflective marker (not shown). These markings facilitate detection of a position and/or orientation of tube **502** within the patient's body, and a surgeon, with the aid of suitable imaging equipment, may track the path followed by the endoscope system and avoid potential damage to sensitive tissues. In other embodiments, device **500** is designed to fit through a working channel of an endoscopic device and may be observed through the endoscopic device. Alternatively, the device **500** may be delivered adjacent to or over the endoscopic device.

To inhibit bacterial growth in the body cavity or in the mucosal wall, resection device **500** may be coated with an anti-bacterial coating. The coating may contain an inorganic antibiotic agent, disposed in a polymeric matrix, which adheres the anti-biotic agent to the device's surface. Further, a drug releasing coating may also be applied to the outer surface of resection device **500**, assisting in healing. In further embodiments, the resection device may be constructed from material impregnated with suitable antibiotic or therapeutic agents.

As discussed, tube **502** may include one or more channels. A typical configuration may include one or more working channels, such as a resection loop channel. Based on the application, other channels, such as a scope channel or a camera channel, may also be present. Through these channels, the operator may introduce one or more medical devices to extend out of the distal end of tube **502**. For example, during a resectomy, the operator may introduce a cautery device into one working channel, and introduce a resection loop into another working channel, the resection loop channel. In some embodiments, the operator may introduce, for example, a hot grasper, an injection needle or a suction device into one working channel. Additionally,

from time to time during the procedure, the operator may insert, for example, a light source, a camera, an injector, or a morcellator within a working channel. The distal ends of these channels may coincide with the working channel and resection loop channel of EMR cap assembly **100** while their proximal end may be coupled to the distal end of handle **510**. In other embodiments, light sources and optics, such as cameras, may be integrated into the walls of the tube. Optics may be integrated in the wall of the tube from the proximal end to the distal end. In other embodiment, wireless optic means may be integrated only in the distal end walls of the tube.

The proximal end **506** of tube **502** can be coupled to handle **510** for gripping by an operator such as a surgeon, while the distal end **106** remains open for medical devices to extend out. The handle **510** can be attached to tube **502** by, for example, welding, use of an adhesive, or integrally forming with tube **502**.

Handle **510** may include one or more ports **512** to introduce medical devices into the working channels of the tube. Moreover, vacuum pumps or irrigation feeds may be attached to port **512** to generate a suction force at the distal end of the tube, or deliver irrigation fluid to the desired location within a patient's body, respectively. Handle **510** may include the ability to steer the distal end of the resection device. Further, the handle portion may include an actuating mechanism to actuate one or more medical devices at the distal end of the elongate tube. For example, the handle may include an actuating mechanism to actuate and close the resection loop at the distal end of the resection device. Similarly, it may include a mechanism to power on or off the suction device attached to its working channel. The handle may further include a coating or covering of a soft polymer or other material to improve grip or ergonomics.

The EMR cap assembly **100** may be coupled to the distal end of the tube **502**. In one embodiment, the EMR cap assembly **100** may be detachably attached to the distal end of the tube **502** using any known coupling technique such as snap-fitting, friction fit, luer-lock, screw threading, etc. Before inserting the tube within a patient's body, the EMR cap assembly may be snapped on. Alternatively, the EMR cap assembly may be permanently coupled to the distal end of the tube. Techniques such as gluing, welding, or sealing may be used.

Further, a swivel mechanism may be introduced between the tube **502** and the EMR cap assembly **100**, such that the EMR cap assembly **100** may easily swivel to make a greater surface contact with a lesion and swivel towards the lesion. In some embodiments, the cap will swivel upon contact with tissue to allow alignment of the opening of the cap. In other embodiments, the cap may be controllably rotated for aligning the cap opening. Any suitable swivel mechanism may be used without departing from the scope of the present disclosure.

In other embodiments, the tube and the EMR cap assembly may be shaped such that the EMR cap assembly may be inserted into the lumen of the tube until it extends out from the distal end of the tube. Here, the diameter of the tube **502** and the EMR cap assembly **100** may taper from the proximal end to the distal end, such that the distal diameter of the tube **502** is lesser than the proximal diameter of the EMR cap assembly **100**. In this situation, when the EMR cap assembly **100** is pushed to the distal end, its proximal portion engages with the distal opening of the tube, wedging it in place.

It will be understood that other techniques to engage the proximal end of the EMR cap assembly with the distal end of the elongate tube may be contemplated without departing

from the scope of the present disclosure. For example, magnetic connection may be possible between the distal tube opening and the proximal EMR cap assembly opening.

Exemplary Resection Method

FIGS. **6A-6F** illustrate a method for resecting lesions or polyps or tissue from a patient's body. A typical location for a resection of this sort is the esophagus, and that location will be discussed here. As will be understood by those in the art, other patient locations would be equally suitable. An endoscopic device including the cap assembly may be inserted into the body lumens either through a percutaneous incision providing access to the esophagus, or through a natural opening, such as the mouth. Once inserted, the resection device **500** is advanced towards a location on a mucosal wall **602**. A light source and a camera may be inserted in the working channel to direct the device within the esophagus, and to spot the lesions. Alternatively, polyps and lesions may be identified by any suitable means prior to inserting resection device **500** into the patient. Pedunculated polyps may be easily identified within the esophagus. Low-lying and flat lesions, however, may be harder to discover. To detect these lesions, a biomarker or dye may be sprayed in the esophagus. Cancerous lesions emit a different wavelength when light falls on them, allowing operators to easily detect them.

In the illustrated embodiment, EMR cap assembly **100** is coupled to the distal end of elongate tube **502**, such as an endoscope, when the procedure begins. Alternatively, EMR cap assembly **100** may be actuated to extend out of the distal end of the tube **502** when required. As shown, the distal end of the EMR cap assembly **100** may then be placed over or proximate a lesion **604**. In case the lesion is situated at an unreachable position within the body, EMR cap assembly **100** may swivel to attain contact with the lesion and/or surrounding tissue. This position is depicted in FIG. **6B**.

Next, suction is applied to a working channel of the tube **502** and thereby to the working channel **202** of the EMR cap assembly **100** unit. The suction force draws the lesion **604** into the working channel **202** of the EMR cap assembly **100** (FIG. **6C**). In other embodiments, other tools such as graspers, pincers, baskets or the like may be used to draw in the tissue. In one embodiment, if the lesion is too flat along the esophageal wall, the lesion may be injected with a saline solution or any other suitable solution to create a buffer layer between the lesion and that wall. With the lesion sufficiently raised off the esophagus wall, suction may be more easily accomplished. In various embodiments, instruments such as needles are easily insertable and utilized at the tissue site.

Once the lesion **604** is forced into the working channel **202** of the EMR cap assembly **100**, the trigger line **140** may be pulled proximally, in order to deploy a first ligation band **122** off of the distal end of the cap structure. When this happens, the first ligation band **122** constricts toward its relaxed, unstretched condition, and the constriction of the ligation band **122** around the tissue forms a pseudo polyp, as shown in FIG. **6D**. The ligation band **122** remains around the tissue for resectioning (although, for clarity, the ligation band is not shown in FIGS. **6E** and **6F**).

In some embodiments, the suction device may be powered off or removed, and the area may be visualized. For example, lesion **604** may be examined to determine whether it is cancerous or not. Various techniques may be employed for this determination. In one embodiment, a fluorescent or biomarker dye may be sprayed on lesion **604**. If lesion **604** is cancerous, it will emit a particular color. Based on the emitted or projected color, physicians can determine whether the lesion is benign or cancerous. Alternatively, by

looking at lesion **604** under the microscope, physicians can make this decision. With the suction released, proper positioning of the resection loop track **112**, and thereby the resection loop **402**, may be confirmed. This can include a confirmation check that no muscularis is within the area to be resected by the resection loop **402**. The resection loop **402** (not shown in FIGS. 6A-6F) may be extended into the resection device track **112** at any step prior to its use, either before or after deployment of a ligation band. A tissue sample could be withdrawn via a needle, biopsy forceps or the like to help diagnose the tissue prior to use of the ligation bands or resection loop.

With the cap assembly placed into proper position over the banded tissue, which thereby positions the resection loop track **112** and consequently the resection loop **402** into proper position over the banded tissue, the proximal end of the resection loop **402** may be pulled proximally. This causes the resection loop **402** to begin closing by withdrawing into track **112**, reducing the resection loop's diameter in track **112**, and trapping lesion **604**. Subsequent pulling may contract resection loop **402** further, forming a tightened grip around lesion **604**.

The resection loop may be a cauterizing resection loop providing electrical energy to the trapped portion of the lesion **604**, and resecting it off the esophagus wall (as shown in FIG. 6E). With modifications in the EMR cap assembly **100** device, the electro-cautery device may be replaced with a laser device that heats the resection loop to resect the lesion. In some embodiments, the cap itself may have electrocautery capability, such as electrodes in the cap. Other resecting means may be contemplated, which will lie within the scope of the present disclosure.

Once the lesion is resected, the device may carry out any one of a number of procedures to remove the resected matter. For example, the resection device **500** may extract lesion **604** or morcellate it and then extract it. For extraction, any retrieval device known now or later may be employed. In one embodiment, the lesion **604** may be extracted with the help of suction force applied at the proximal end of the resection device **500** (FIG. 6F). In another embodiment, a basket, a grasper, or pincers may be used. These devices may be self-expandable or may expand by some actuation mechanism incorporated in the resection device's handle **510**. The retrieval device may be inserted in a collapsed state through the proximal end of the tube **502**; and it may extend out of the distal end **106** of the EMR cap assembly's working channel **202** in an expanded state. Once the device is placed over the resected lesion, it may be actuated to close in on the lesion, trapping it. Subsequently, the entire resection device **500** may be withdrawn from the patient's body. In another embodiment, the end of the inner cap may be flexible. After resection, the end of the cap may be actuated to close over the resected lesion, trapping it and subsequently removing it from the patient's body.

If lesion **604** is too large to fit in working channel **202** or to be grasped in the other retrieval tools, it may be morcellated prior to extraction. A morcellator (not shown) may be introduced in working channel **202** along with a suction device. The suction device holds lesion **604** around the opening of the EMR cap assembly **100**, while the morcellator breaks lesion **604** into smaller pieces. Subsequently, the retrieval devices suction or extract the pieces.

The use of multiple ligation bands **122**, **124**, **126**, **128** allows the device to be repositioned for capturing additional tissue with sequential deployment of the bands without having to withdraw the device from the patient. Thus, after repositioning of the device to position the cap assembly

adjacent a second target site, a second actuation of the trigger line **140** may cause the second ligation band **124** to be deployed off of the distal end **107** of the outer cap **104**. Then, after further repositioning, a third actuation of the trigger line **140** may cause the third ligation band **126** to be deployed off of the distal end **107** of the outer cap **104**, and, after further repositioning, a fourth actuation of the trigger line **140** may cause the fourth ligation band **128** to be deployed off of the distal end **107** of the outer cap **104**. The resectioning of a banded tissue section may be performed after that particular tissue section has been banded and before the next tissue section is banded. Alternatively, multiple tissue sections may be banded sequentially without intermediate resectioning, and subsequently the resectioning may be performed on one or more of the banded tissue sections.

In alternate embodiments, the device may be used in the following manner. The cap assembly may be positioned adjacent tissue to be resected. Then, the tissue may be drawn within the cap assembly. Then, a resection loop may be deployed around the tissue without severing the tissue. The tissue may be evaluated to see if there are any issues with carrying out full resectioning with the loop, for example if there is any muscularis ensnared by the loop. If there are no such issues, full resectioning may be carried out with the loop. If an issue such as ensnared muscularis is presented, the loop could be released, releasing the tissue. Subsequently, a ligation band could be deployed around the tissue. The ligation band deployment may be advantageous in that the band may squeeze out any muscularis. Then the resection loop may be deployed for resectioning of the tissue captured by the ligation band.

In certain embodiments, the proximal end of the cap may be flexible enough to allow the cap to bend at an angle to the endoscope. This bending may allow better positioning of the cap opening around tissue. In some embodiments, the cap may bend or rotate with the assistance of tensioning or steering filaments or wires or other steering means. The distal end of the cap may extend or be sloped at any suitable angle with respect to the longitudinal axis of the endoscope.

The resection loop may be resettable. For example, it may be configured such that it may be advanced distally into the resection device track multiple times. In some embodiments, the resection loop may be resettable by use of a tensioning filament or wire attached to the loop opposite the location of the filament or wire used to actuate the resection loop. The operator can use the resetting filament or wire to pull or redeploy the resection loop back into position to allow more than one resectioning while the device is in a useful position.

It will be appreciated that certain embodiments described herein comprise a tissue resection cap assembly secured to the distal end of an endoscope, but similar embodiments may also be configured to be secured to the distal end of any other suitable type of elongated medical device having a working channel, such as cystoscopes, duodenal scopes, colonoscopes, guide tubes, introducers, catheters with lumens, and the like.

It will be appreciated from the disclosure herein that various embodiments of the invention can improve the speed and accuracy of the procedures desired to be performed. For example, ligation bands can be deployed and a resection loop may be actuated without having to withdraw the endoscope or other elongated medical device. Various embodiments may also help avoid the time it would take to preset a snare or loop to match the opening of a cap. Having the cap structure include a resection device channel and a resection device track in communication with the resection

device channel can help lead the snare or loop to the correct position and can help improve speed and accuracy. With various embodiments of the invention, the deployment of the resectioning loop can be performed simultaneously with or immediately after or before ligation band deployment, without the need for switching or repositioning devices.

Embodiments of the present disclosure may be used in any medical or non-medical procedure, including any medical procedure where monitoring of an organ's activity is desired. In addition, at least certain aspects of the aforementioned embodiments may be combined with other aspects of the embodiments, or removed, without departing from the scope of the disclosure.

Other embodiments of the present disclosure will be apparent to those skilled in the art from consideration of the specification and practice of the embodiments disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. A tissue resection cap assembly, comprising:
 - a distal member extending from a proximal end to a distal end and including a working channel extending there-through, the distal member defining a resection device track at a distal end thereof;
 - a resection device received within the resection device track, in an operative position, to resect a target tissue received within the working channel;
 - a trigger line extending through the working channel and along an exterior surface of the distal member; and
 - a first ligating band mounted over exterior surface of the distal member in communication with the trigger line so that actuation of the trigger line deploys the first ligating band from the distal end of the distal member.
2. The cap assembly of claim 1, wherein the distal member includes:
 - an outer cap extending from a proximal end to a distal end and including a lumen extending therethrough; and
 - an inner cap received within the lumen of the outer cap, the inner cap extending from a proximal end to a distal end and defining the working channel, the resection device track being defined between the distal end of the outer cap and the distal end of the inner cap.
3. The cap assembly of claim 2, wherein the inner cap further defines a resection channel extending therethrough, the resection channel in communication with the resection device track to form a path for the resection device to be received in the operative position.
4. The cap assembly of claim 3, wherein a portion of the resection device track is defined via an exterior wall of the inner cap and an interior wall of the outer cap.
5. The cap assembly of claim 2, wherein the outer cap includes a support structure defining a surface of the resection device track so that, in an operative position, the resection device is received between the support structure and a distal face of the inner cap.
6. The cap assembly of claim 5, wherein the support structure is one of a edge, ridge, ledge and rail extending circumferentially inward from a radially inner surface of the outer cap.
7. The cap assembly of claim 1, wherein the resection device is a wire along which energy may be applied to cut the target tissue.
8. The cap assembly of claim 1, wherein the resection device receives one of electrical, ultrasonic, laser and cryogenic energy to cut the target tissue.

9. The cap assembly of claim 1, further comprising a second ligating band mounted over the distal member proximally of the first ligating band and in communication with the trigger line.

10. The cap assembly of claim 1, wherein the resection device includes a resection loop received within the resection device track, wherein drawing a proximal end of the resection device closes the resection loop around the target tissue.

11. The cap assembly of claim 1, further comprising a ridge extending about a circumference of the distal member for lifting the first ligating band off the trigger line.

12. A resection device, comprising:

an endoscope extending from a proximal end to a distal end;

a tissue resection cap assembly connected to the distal end of the endoscope, the tissue resection cap assembly including an outer cap extending from a proximal end to a distal end and including a lumen extending there-through and an inner cap received within the lumen of the outer cap, the inner cap extending from a proximal end to a distal end and defining a working channel, a resection device track defined between the distal end of the outer cap and the distal end of the inner cap;

a resection wire received within the resection device track, in an operative position, to resect a target tissue received within the working channel via cauterization;

a trigger line extending along an exterior surface of the outer cap and within the working channel of the inner cap; and

a first ligating band mounted over the outer cap in communication with the trigger line so that actuation of the trigger line deploys the first ligating band from the distal end of the outer cap.

13. The device of claim 12, wherein the inner cap further defines a resection channel extending therethrough, the resection channel in communication with the resection device track to form a path for the resection wire to be received in the operative position.

14. The device of claim 12, further comprising an electrical energy source connected to a proximal end of the resection wire.

15. The device of claim 12, wherein the resection wire includes a resection loop received within the resection device track.

16. The device of claim 12, further comprising a second ligating band mounted over the outer cap proximal of the first ligating band and in communication with the trigger line.

17. A method for resecting tissue, comprising:

inserting a cap assembly through a body lumen to a first target tissue to be treated, the cap assembly including an outer cap extending from a proximal end to a distal end and including a lumen extending therethrough and an inner cap received within the lumen of the outer cap, the inner cap extending from a proximal end to a distal end and defining a working channel;

drawing the first target tissue into the working channel of the inner cap;

deploying a first ligating band mounted over the outer cap in communication with a trigger line from the distal end of the outer cap by actuating the trigger line so that the first ligating band ligates the first target tissue to form a first polyp; and

resecting the first polyp via a resection device received within a resection device track defined between the distal end of the outer cap and the distal end of the inner cap.

18. The method of claim **17**, further comprising passing a resection loop of the resection device through a resection device channel to the resection device track, the resection device channel defined via the inner cap in communication with the resection device track to form a path for the resection device.

19. The method of claim **18**, further comprising drawing a proximal end of the resection device proximally to close the resection loop about the first polyp.

20. The method of claim **17**, further comprising supplying an energy to the resection device to resect the first polyp, wherein the energy is one of an electrical, ultrasonic, laser and cryogenic energy.

21. The method of claim **17**, further comprising:

drawing a second target tissue into the working channel of the inner cap;

deploying a second ligating band mounted over the outer cap in communication with the trigger line from the distal end of the outer cap by actuating the trigger line so that the second ligating band ligates a second target tissue to form a second polyp; and

resecting the second polyp via the resection device received within the resection device track.

* * * * *

专利名称(译)	组织切除术和相关使用方法		
公开(公告)号	US9629649	公开(公告)日	2017-04-25
申请号	US14/842544	申请日	2015-09-01
[标]申请(专利权)人(译)	波士顿科学西美德公司		
申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED , INC.		
当前申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED , INC.		
[标]发明人	SMITH PAUL CARRILLO JR OSCAR		
发明人	SMITH, PAUL CARRILLO, JR., OSCAR		
IPC分类号	A61B17/32 A61B17/12 A61B17/3205 A61B17/00 A61B17/30		
CPC分类号	A61B17/320016 A61B17/12013 A61B17/32056 A61B2017/00269 A61B2017/00296 A61B2017/12018 A61B2017/306 A61B1/00 A61B1/0008 A61B1/00087 A61B1/00131 A61B1/00137 A61B17/00234		
优先权	61/580819 2011-12-28 US		
其他公开文献	US20150366577A1		
外部链接	Espacenet USPTO		

摘要(译)

组织切除帽组件构造造成固定到细长医疗装置（例如内窥镜）的远端，以及用于切除组织的方法。帽组件可包括帽结构，帽结构包括工作通道和切除装置通道，其中切除装置通道在帽结构内部延伸到切除装置轨道，该切除装置轨道基本上围绕邻近帽结构的远端的工作通道定位。切除装置通道适于将切除装置从内窥镜的工作通道引导至切除装置轨道。盖组件还包括在盖结构的外表面上的一个或多个连接带和用于从盖结构的远端展开连接带的触发线。该方法包括在组织周围部署结扎带并使用切除环切割组织。

