Abstract: An apparatus or device and a method of using such device for lifting, separating, or removing a first material (e.g., targeted tissue) from a second material (e.g., tissue of a body lumen in a patient) is presented. The method generally comprises placing the distal end of the device to a location that is proximate to the first material; deploying a first anchor member (e.g., a T-anchor) fastened to a suture strand into the first material; deploying a second anchor member (e.g., loop anchor) spaced away from the first anchor member, whereas the suture strand is slidably received by the second anchor member; applying tension to the suture strand; and cutting the first material at a predetermined depth around the periphery of the first material, and separating or removing the first material along with the first anchor member. The tension applied to the suture strand maintains the first material in a raised position and/or allows the operator to manipulate the first material relative to the second material.
HOOD METHOD AND DEVICE FOR MATERIAL DISSECTION

FIELD

[0001] This disclosure relates generally to the separation or movement of one material relative a second material (e.g. fabrics, cloth, polymers, elastomers, plastics, tissue, and rubber). More specifically, this disclosure relates to an apparatus and method for lifting and manipulating tissue endoscopically, such as for performing an endoscopic submucosal dissection (ESD) or endoscopic mucosal resection (EMR) of tissue.

BACKGROUND

[0002] Diagnostic and therapeutic gastrointestinal endoscopy is a common technique used to gain access to the digestive tract for the purpose of removing tissue. Endoscopic mucosal resection (EMR) is one method of performing the biopsy necessary to obtain tissue for pathology examination. An EMR procedure also may be used for curative purposes, such as to remove sessile benign tumors and intramucosal cancers. In fact, EMR is a well-accepted treatment for early gastric cancer.

[0003] It has been discovered that during curative removal of a mucosal lesion, it is desirable to remove the lesion as one piece. If the lesion is removed as multiple fragments, it is believed that rates of local tumor recurrence may be increased. In addition, medical examination and assessment using fragmented tissue samples can be more difficult to perform than a similar assessment done with a single piece of tissue.

[0004] During an EMR procedure, it may be desirable to mark and subsequently resect a portion of tissue surrounding a lesion to help ensure that the lesion can be completely removed as a single piece. In addition to removing the mucosal tissue, a portion of the submucosa also may be removed. It is often difficult to tell if the entire lesion has been removed because of unclear delineation between the lesion and the surrounding tissue. Often a larger section of tissue that includes the lesion and a portion of the surrounding tissue is removed. One drawback to EMR is that this procedure is generally not recommended for large lesions, e.g., lesions that are greater than about two centimeters in diameter.

[0005] More recently, a technique called endoscopic submucosal dissection (ESD) has been described in which mucosal lesions are removed by the dissection of the submucosa
tissue under the lesion using an incision device, such as an endoscopic knife. When compared to EMR, this ESD procedure facilitates the resection of larger lesions and yields improved removal of the lesion as one piece. However, one drawback to this technique is that the peripheral boundary of the lesion becomes difficult to ascertain as the tissue is surgically cut. One skilled in the art will recognize that a similar problem exists in distinguishing the peripheral boundary between two layers of a material (e.g., fabrics, cloth, polymers, elastomers, plastics and rubber) when attempting to separate one layer from the other layer.

[0006] In view of the drawbacks of current technology, it is desirable to develop apparatus and methods for ESD and EMR procedures that may efficiently remove a mucosal or submucosal lesion as a single piece. It is further desirable for the same apparatus and methods to be applicable for use in other industries during the performance of dissection or material separation procedures.

SUMMARY

[0007] The present disclosure provides an apparatus or device, as well as a method of using such device for lifting, separating, or removing a first material (e.g., targeted tissue) relative to a second material (e.g., the surrounding tissue in a body lumen of a patient). In one embodiment of the device, constructed in accordance with the teachings of the present disclosure, the device is generally characterized by a strand of fiber, a first anchor member, a second anchor member, a flexible delivery needle, and a stylet. The stylet is in communication with the first anchor member such that it can cause the first member to exit the needle in order for the operator to couple the first member to the first material. The stylet can also cause the second member to exit the needle.

[0008] One embodiment of the method, constructed in accordance with the teachings of the present disclosure, generally comprises placing the distal end of the device (e.g., an endoscope) proximate to the first material (e.g., targeted tissue); deploying a first anchor member (e.g., a T-anchor) fastened to a strand of fiber (e.g., suture strand) into the first material; deploying a second anchor member (e.g., a loop anchor) whereas the fiber strand is slidably received by the second anchor member; applying tension to the strand of fiber to lift the first material; cutting the first material at a predetermined depth around the periphery of the first material; and separating or removing the first material along with the first anchor member.
Preferably, the second anchor member is deployed into the second material (e.g., tissue of the body lumen generally opposite the targeted tissue).

[0009] The tension applied to the first material, maintains the first material in a raised position relative to other material and/or allows the operator (e.g., physician) to manipulate the first material, thereby, rendering the first material more visible during the separation procedure. The amount of tension applied to the strand of fiber may be adjusted as the first material is being cut.

[0010] In another embodiment of the present disclosure, an injection needle may be optionally inserted into a section of material (e.g., tissue) proximate to the first material (e.g., targeted tissue). A fluid can then be injected beneath the section of material proximate to the first material in order to raise the first material.

[0011] According to another aspect of the present disclosure, incision markings may be placed in the second material (e.g., mucosa tissue) around the periphery of the first material (e.g., targeted tissue) if desired. For example, an injection needle may be inserted into either the mucosa tissue or submucosa tissue and a fluid is injected. This fluid preferably comprises a saline solution or sodium hyaluronate. The injected fluid forms a fluid pocket between the muscularis propria tissue and the submucosa tissue, between the submucosa tissue and the mucosa tissue, or entirely within the submucosa tissue.

[0012] According to yet another aspect of the present disclosure, at least one of steps of applying and adjusting the tension on the strand of fiber is applied to the strand either by hand or using a device, instrument, or a robot. Similarly, the adjustment of the tension may be accomplished in the same or similar manner.

[0013] The cutting of the material around the periphery of the first material is done using an electrified or mechanical cutting instrument. The cutting instrument may have a hollow end or ceramic tip in order to assist in cutting only to a predetermined depth. After the periphery of the first material has been completely incised, the first material may be separated and/or removed using a retrieval device, such as a snare or forceps. Optionally, the second anchor member may also be removed.

[0014] Further areas of applicability will become apparent from the description provided herein. It should be understood that the description and specific examples are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.
BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The drawings described herein are for illustration purposes only and are not intended to limit the scope of the present disclosure in any way.

[0016] Figure 1 is a schematic representation of a method or method according to one embodiment of the present disclosure;

[0017] Figure 2A is a side view of a method step that may be used according to the teachings of the present disclosure;

[0018] Figure 2B is a side view of an optional method step that may be used according to the teachings of the present disclosure;

[0019] Figure 2C is a side view of another optional method step that may be used according to the teachings of the present disclosure;

[0020] Figure 2D is a side view of another method step that may be used according to the teachings of the present disclosure;

[0021] Figure 2E is a side view of another method step that may be used according to the teachings of the present disclosure;

[0022] Figure 2F is a side view of another method step that may be used according to the teachings of the present disclosure;

[0023] Figure 2G is a side view of another method step that may be used according to the teachings of the present disclosure;

[0024] Figure 2H is a side view of another optional method step that may be used according to the teachings of the present disclosure;

[0025] Figure 2I is a side view of another method step that may be used according to the teachings of the present disclosure;

[0026] Figure 3 is a front view of one embodiment of a tissue anchor constructed in accordance with the teachings of the present disclosure;

[0027] Figure 4 is a cross-sectional view taken about the line 4-4 in Figure 3;

[0028] Figure 5A is a cross-sectional view of a medical device constructed according to the teachings of the present disclosure;

[0029] Figure 5B is another cross-sectional view of the device of Figure 5A engaged in the deployment of the first anchor member; and

[0030] Figure 5C is yet another cross-sectional view of the device of Figure 5A engaged in the deployment of the second anchor member.
DETAILED DESCRIPTION

[0031] The following description is merely exemplary in nature and is in no way intended to limit the present disclosure or its application or uses. For example, while endoscopy and the use of an endoscope are described to illustrate the present disclosure, other types of procedures and their associated devices, such as laparoscopy are contemplated to be within the scope of the disclosure. Likewise, procedures other than ESD and EMR that require tissue to be raised or lifted may also employ the teachings of the present disclosure. It should be understood that throughout the description and drawings, corresponding reference numerals indicate like or corresponding parts and features.

[0032] It will be recognized by those skilled in the art that, while the methods described in this disclosure generally include placing the tissue devices in tissue through an internal bodily lumen, it will be recognized that these systems, devices and methods may be used on any layer of material (e.g. fabrics, cloth, polymers, elastomers, plastics and rubber) that may or may not be associated with a human or animal body and a bodily lumen. For example, the systems, devices and methods can find use in laboratory and industrial settings for placing devices through one or more layers of material that may or may not find application to the human or animal body, and likewise closing holes or perforations in layers of material that are not bodily tissue.

[0033] The present disclosure generally provides a device and a method of using the device for lifting, separating, and/or removing a first material (e.g., targeted tissue) relative to a second material (e.g., the surrounding tissue in a body lumen of a patient). Referring to Figure 1, the method 95 comprises placing the distal end of a device (e.g., an endoscope) 100 to a location that is proximate to the first material; deploying a first anchor member (e.g., a T-anchor) 115 fastened to a strand of fiber (e.g., a suture) through the first material; deploying a second anchor member (e.g., a loop anchor) 120, whereas the fiber strand is slidably received by the second anchor member; applying tension 130 to the fiber strand; cutting the second material 135 at a predetermined depth around the periphery of the first material; and separating or removing the first material 145 from the second material. Preferably, the first anchor member (e.g., loop anchor) is deployed into the second material (e.g., tissue of the body lumen) generally opposite the first material (e.g., targeted tissue), but the first anchor member may be circumferentially spaced from the target any degree. The device or apparatus may be a single channel or a multi-channel endoscope.
Although more broadly applicable, the following description of the apparatus or device and method of utilizing such device in the present disclosure employs endoscopic ESD and EMR as a convenient means through which the device and method can be adequately depicted and described. The tension applied 130 to the first material (e.g., targeted tissue) maintains the targeted tissue in a raised position relative to the second material (e.g., other tissue in the body lumen) proximate to the targeted tissue and/or allows the operator (e.g., a physician) to manipulate the targeted tissue, thereby, rendering the targeted tissue more visible during the surgical procedure. The amount of tension applied to the fiber strand (e.g., suture) may be adjusted as the targeted tissue is being cut.

The method may optionally include the steps of inserting an injection needle 105 into a section of first material proximate to the second material (e.g., targeted tissue); and injecting a fluid 110 beneath the section of the second material proximate to the first material or targeted tissue in order to raise the targeted tissue. Alternatively, the method may optionally include the steps of disposing at least a portion of a balloon 155 beneath the first material; and inflating the balloon 160 in order to raise the first material. These optional steps may assist the physician in being able to ascertain the periphery of the targeted tissue.

Referring now to Figure 2A, a device or endoscope 30 is maneuvered towards the targeted tissue 25 using general endoscopy techniques that are well known to those skilled in the art. For example, the endoscope 30 may be maneuvered into a patient's body lumen 5, such as but not limited to the mouth, down through the esophagus, stomach, and duodenum, to a position that is proximate to the targeted tissue 25. The targeted tissue 25 may comprise a lesion, for example, a growth that is indicative of gastric cancer. This lesion or growth may be fully or partially confined within the second layer of material (e.g., mucosal tissue) 20 and/or the submucosal tissue 15 with the muscularis propria tissue 10 residing beneath the submucosal tissue 15.

The distal region of an endoscope 30 preferably comprises a working channel and auxiliary lumen with the working channel sized to accommodate various components used to perform an endoscopic submucosal dissection (ESD) or endoscopic mucosal resection (EMR) procedure, such as a needle, needle knife, anchors, suture, and the like. One skilled in the art will realize that the endoscope 30 may comprise any number of lumens or channels to achieve the objects of the present disclosure. The endoscope 30 may also comprise optical elements, which employ fiber optic components for illuminating and capturing an image distal
to the endoscope 30 for viewing by the physician performing the procedure. It will also be recognized that other visualization techniques may be employed including catheter-based fiber optic systems, fluoroscopy, ultrasound or the like. For example, a needle or other endoscopic tool can have markings designed for viewing under fluoroscopy, and the distal end of the needle can have a surface of enhanced ultrasonic reflectivity, such by being roughened, having dimples or other incongruities, or having embedded particles. In the latter case, the endoscope 30 may comprise an ultrasound-enabled endoscope system (EUS) permitting placement of the tool under EUS guidance, thereby facilitating placement within or between layers of tissue (e.g. within the submucosal layer) or preventing puncture of other organs or tissue behind the selected body wall.

[0038] Once the device 30 (e.g., endoscope) is positioned proximate to the first material 25 (e.g., targeted tissue), the tending operator (e.g., physician) may examine the first material (e.g., lesion) and determine whether or not incision markings are necessary to help define the boundary of the first material 25. Placing incision markings 150 around the periphery of the first material 25 is an optional step in the method, which can be omitted when the first material 25 can readily be distinguished from the second material (e.g., surrounding mucosa tissue 20). If the peripheral boundary of the targeted tissue 25 is not readily discernible, then a needle knife may then be advanced from the endoscope 30 and used to engage the mucosa tissue 20 to create markings around the periphery of the targeted tissue 25. High frequency current may be applied to the needle knife tip to create these markings. Such methods for creating markings are well known to those skilled in the art of endoscopic surgery.

[0039] Referring now to Figures 2B and 2C the targeted tissue 25 may be lifted or raised with respect to the muscularis propria tissue 10 to facilitate the removal of the targeted tissue 25. The targeted tissue 25 may optionally be raised by injecting a fluid 40 (Figure 2C), such as physiological saline solution or sodium hyaluronate, through a needle 35 that is inserted into the mucosa tissue 20 and/or submucosa tissue 15 proximate to the targeted tissue 25 (Figure 2B). The targeted tissue 25 may also be optionally raised by disposing at least a portion of a balloon beneath the targeted tissue, followed by inflating the balloon (not shown), as described in U.S. Patent Publication No. 2007/02601 78A1 published on November 8, 2007. One skilled in the art will recognize that the needle 35 and a needle knife or any other surgical tool that will be later used to cut the tissue may be disposed and advanced through the
same or different lumens of the endoscope 30. For example, the needle 35 may be disposed within an auxiliary lumen, while a needle knife is advanced through the working channel of the endoscope 30. Alternatively, the needle knife may be disposed within a hollow interior region of the needle 35, and the fluid 40 may be injected through the needle 35 so that it flows around the needle knife.

[0040] As shown in Figure 2C according to one embodiment of the present disclosure, the fluid 40 injected into the submucosa tissue 15 lifts or raises the targeted tissue 25 above the underlying muscularis propria tissue 10, by forming a fluid 40 filled pocket between the muscularis propria tissue 10 and the submucosa tissue 15. The fluid 40 filled pocket according to another aspect of the present disclosure may also be formed entirely within the submucosa tissue 15 or between the mucosa tissue 20 and submucosa tissue 15. Optionally, a balloon may be at least partially inserted beneath the targeted tissue 25 and inflated in order to raise the targeted tissue 25. The raising of the targeted tissue 25 helps to facilitate its removal during an EMR or ESD procedure. This step is optional and may be used in conjunction with the following steps or eliminated as the following steps can also be used to raise the targeted tissue 25 above the surrounding mucosa tissue 20. One skilled in the art will understand that other means of raising the targeted tissue, such as the use of a lever portion on the tip of the endoscope configured to lift the targeted tissue as described in U.S. Patent Publication No. 2008/0058586A1, published on March 6, 2008, may additionally be employed without exceeding the scope of the present disclosure.

[0041] Referring now to Figure 2D, a first anchor member (e.g., a T-anchor) 45 is deployed through the targeted tissue 25 using any technique known to one skilled in the art. A first anchor member 45 typically comprises an anchor bar having a longitudinal configuration and a fiber (e.g., suture) strand 50 attached or fixed to the bar and extending laterally from the bar. An introducer needle can be used to pass the anchor bar through the targeted tissue 25 and to deploy the anchor bar on the far side or underneath the targeted tissue 25. Guidance under EUS, fluoroscopy, visual markings, or using other depth indicating means may be employed, especially when a fluid filled pocket is not formed. The suture strand 50 extends through the targeted tissue 25, and has a bolster on the near side of the targeted tissue 25. The bolster is slidable along with the suture strand 50. As the suture strand 50 is pulled and the bolster is pushed, the anchor bar seats against the far-side of the targeted tissue 25. A knot
tied in the suture on the proximal side of the bolster maintains the T-anchor 45 in an operative position in the targeted tissue 25.

[0042] The anchor bar of the T-anchor 45 can be made out of any material that is compatible with the human body, including but not limited to plastics, such as polyethylene, and metals, such as stainless steel. The suture strand 50 may be comprised of any material known to one skilled in the art. Materials, such as 2-0 silk, 2-0 Ti-Cron, 4-0 polypropylene, 5-0 polypropylene, 6-0 polypropylene, and 7-0 polypropylene are preferred. Further details regarding T-anchors are disclosed in U.S. Patent No. 5,123,914 issued June 23, 1992. One skilled in the art will recognize that any other type of tissue anchoring members, such as an anchor, staple, clip, hook, or tack that can be secured or fastened to the targeted tissue may be used (see, for example, the tacks disclosed in U.S. Patent Application No. 12/428,226 filed on April 22, 2009). Preferably the suture strand 50 is selected with the appropriate level of abrasion resistance to withstand the movement of the suture strand 50 through the loop anchor 55.

[0043] Referring now to Figure 2E, a second anchor member (e.g., a loop anchor) 55 is deployed into the tissue of the bodily lumen 5, preferably, opposite the targeted tissue 25 using any technique known to one skilled in the art. In general, a loop anchor 55 has a crossbar that is inserted into the tissue, and defines a loop or at least one cavity capable of slidably receiving a suture strand 50. Further details of this type of anchor and other types of anchors may be found in U.S. Patent Publication No. 2008/0132948A1, published on June 5, 2008. One skilled in the art will recognize that any other type of anchor, staple, clip or tack, in which the suture strand 50 can be slidably received may be used. For example, a tack such as those disclosed in U.S. Patent Publication No. 2009/0270912A1, published on October 29, 2009 might be employed.

[0044] The currently preferred second anchor member (e.g., loop anchor) 220 is shown in Figures 3 - 4. The anchor 220 generally includes a crossbar 224 having opposing ends 226 and 228 and defining a longitudinal axis 214. The crossbar 224 is preferably elongated, but may take any form suitable for connecting the suture 50 to the bodily wall 212. A strand 230 is connected to the crossbar 224 and is configured to form a loop 232. As best seen in Figure 4, the crossbar 224 is constructed of a cannula having a tubular wall 234 defining a lumen 236. An elongated aperture 238 is formed in the tubular wall 234, and the strand 230 passes through the aperture 238. The ends of strand 230 are secured within the lumen 236 of the
cannula by welds 244. It will be recognized by those skilled in the art that the strand 230 may be secured to the crossbar 224 using any now known or hereinafter developed attachment means, including mechanical fasteners, adhesives or various welding or soldering techniques.

[0045] The strand 230 is preferably formed from a metal wire, including single filament and multi-filament wires, and wound and braided wires, although the strand 230 can have other constructions such as suture material, plastic strings, rope and the like.

[0046] As best seen in Figure 3, the strand 230 is structured to include a revolution thereby defining a loop 232 through which the suture 50 passes. The loop 232 is positioned longitudinally in-line with the elongated aperture 238 so that it projects through the aperture 238 and away from the longitudinal axis 214. Accordingly, it will be seen that the strand 230 and its loop 232 are flexible and may adjust its shape and orientation based on how the suture 50 is being tensioned. The size of the elongated aperture 238 and the flexibility of the strand 230 allow the loop 232 to travel longitudinally along the length of the strand 230. The loop 232 defines an apex A which is preferably located about 0.35 mm or greater away from the crossbar 224. The loop 232 also defines a cross-point CP where the ends of the strand 230 cross each other. The cross-point CP is preferably positioned radially outside the outer surface of the crossbar 224 including radially outside the side walls of the aperture 238, but also preferably as close to the crossbar 224 as possible. The aperture 238 preferably extends a longitudinal distance in a range of about 0.4 mm to about 3.0 mm, while the crossbar 224 typically has a length in the range of about 3.0 mm to about 10.0 mm. The strand preferably has a diameter less than about 50% of a diameter of the crossbar 224, and most preferably less than about 35%. The strand 230 preferably has a diameter in the range of about 0.20 mm to about 0.35 mm, and most preferably about .0254 mm. The crossbar 224 preferably has a diameter in the range of about 0.5 mm to about 1.0 mm, and most preferably about 0.8 mm. The strand 230 may be coated with a low-friction material such as known plastic or hydrophilic coatings.

[0047] This construction of the tissue anchor 224 and its loop 232 allows the suture 50 to be tensioned and slid through the loop 232 relative to the crossbar 224 while preventing the suture 50 from engaging the crossbar 224 or the edges defined by the elongated aperture 238. That is, no matter which direction the ends of the suture 50 are pulled or slid relative to the crossbar 24, the wire 230 and its loop 232 will serve as a barrier between the suture 50 and the cannula 224 to prevent any undesired abrasion there between. Generally, the strand 230 has a
length and the location of the apex A of the loop 232 are such that the loop 232 is sized to project through the bodily wall 212 when embedded therein, allowing reliable tensioning of the suture 50 and preventing abrasion of the tissue. One skilled in the art will understand that other loop anchor designs may be utilized without exceeding the scope of the present disclosure..

[0048] Referring now to Figure 2F, a predetermined amount of tension is applied to the suture strand 50 by the physician or operator. The application of tension to the suture strand 50 assists in raising the targeted tissue 25 above the surrounding mucosa tissue 20, thereby, making the periphery of the targeted tissue 25 easier to visualize. This tension may be applied and manipulated by hand, using a device or instrument, or by a robot. The tension can be adjusted and maintained using any type of a suture tensioning device known to one skilled in the art.

[0049] Optionally, after the T-anchor 45 and loop anchor 55 have been positioned, the endoscope 30 may be removed and reintroduced to a position proximate to the suture strand 50, e.g. alongside the suture strand 50. This optional step allows the physician additional freedom or latitude in approaching the targeted tissue 25 in order to make an incision; as well as insuring that the endoscope 30 does not affect the applied tension and makes the accessory channel of the endoscope 30 more easily accessible.

[0050] Referring now to Figure 2G, after the targeted tissue 25 has been sufficiently raised and appropriate tension has been applied to the suture strand 50 connected to the T-anchor 45, the creation of a mucosal or submucosal incision begins. A cutting instrument (e.g., needle knife) 60 or another electrified or mechanical endoscopic cutting instrument, such as a scalpel or the like, may be advanced distally through a channel or lumen in the endoscope 30. The incision may be made circumferentially around the targeted tissue 25 using the needle knife 60, as depicted by Figures 2G - 2I. An electrosurgical generator (not shown) may be coupled to the needle knife 60 to provide the electrical energy necessary to incise the cut tissue. The incision is preferably performed at a predetermined distance into or through the submucosa 15 tissue and at a predetermined angle with respect to muscularis propria tissue 10.

[0051] As the tissue is cut, the operator may optionally, as shown in Figure 2H, adjust the tension applied to the suture strand 50 in order to maintain the targeted tissue 25 in a raised position or preferably to manipulate (e.g., raise or lower) the targeted tissue 25 relative
to the surrounding mucosa tissue 20. Manipulating the targeted tissue 25 via the use of tension applied to the suture strand 50 is advantageous because it allows the physician to more easily determine the periphery of the targeted tissue 25 through which the incision is being made. This step makes cutting the tissue safer and faster because the physician more readily can see where he wants to make the incision. The ability to see the periphery of the targeted tissue 25 may reduce the time necessary for the medical procedure from more than 4 hours to about less than 1 hour. If the tension applied to the suture strand 50 does not allow the physician to manipulate the targeted tissue 25, it is possible that any fluid 40 released from the fluid 40 filled pocket (if present) upon the start of the incision may obscure the periphery of the targeted tissue 25, thereby, complicating the removal of the targeted tissue 25.

[0052] The needle knife 60 may be fabricated using any electrically conductive material known to one skilled in the art, including but not limited to stainless steel. Alternatively, the needle knife may be fabricated from a shape memory alloy such as nitinol, as described in U.S. Patent Publication No. 2008/001 5574A1, published on January 172008. Optionally, the needle knife 60 may comprise a non-conductive portion at its tip, such as a hollow or ceramic region, that will help prevent the needle knife from cutting too far into the tissue. The use of other such safety mechanisms will be apparent to one skilled in the art.

[0053] Referring now to Figure 2I, once the incised targeted tissue 25 is substantially separated from the surrounding mucosa tissue 20 and submucosa tissue 15, the needle knife 60 may be withdrawn and the tension applied to the suture strand 50 released. A retrieval device, such as a snare or forceps 65, then may be advanced through the auxiliary or working lumen of the endoscope 30 to subsequently remove the incised targeted tissue 25 along with its imbedded T-anchor 45 in substantially one piece. The removal of the targeted tissue 25 in substantially one piece assists in reducing the likelihood of the lesion or growth locally reoccurring in the patient. The endoscope 30 then may be removed from the patient to complete the procedure. Optionally, the loop anchor 55 may be left imbedded in the body lumen 5 or be removed by any technique known to one skilled in the art.

[0054] If desired, flushing fluid may be provided near the targeted tissue 25 at any time during the EMR or ESD procedure. For example, the flushing fluid may be delivered through the auxiliary lumen or working channel of the endoscope 30, and may be delivered around needle 35 and/or needle knife 60, as described in co-pending U.S. Patent Publication No. 2007/0270897A1, published on November 22, 2007.
[0055] A preferred device or apparatus (1) used to assist an operator in distinguishing a first layer (25) of a material from a second layer (20) of material that is adjacent thereto when the operator performs the procedure described above for lifting, separating, and/or removing the first material (25) relative to a second material (20) is shown in Figures 5A. This device or apparatus (1) is characterized by a strand of fiber (50), a first anchor member (45), a second anchor member (55), a flexible delivery needle (35), and a stylet (37).

[0056] The strand of fiber or suture (50) is defined by having a distal and proximal end. The first anchor member (45) has a bar fixed to the distal end of the fiber strand (50). The second anchor member (55) has a bar and a flexible loop projecting away from the bar.

[0057] The flexible delivery needle (35) defines at least one passageway that is sized to slidably receive the strand of fiber (50), the first member (45), and the second member (55). The first anchor member (45) is positioned distal to the second anchor member (55) within the needle (35). The strand of fiber (50) passes through the loop of the second anchor member (55) within the needle (35). Finally, the stylet (37) is sized to be slidably received by the delivery needle (35).

[0058] Referring now to Figures 5A-5C, the stylet (37) is also in communication with the second (55) anchor member such that the stylet (37) can cause the first member (45) to exit the needle (35) in order for the operator to couple the first member (45) to the first (25) material (Figure 5B). The stylet can also cause the second member (55) to exit the needle (Figure 5C). When tension is applied to the strand of fiber (50), the strand of fiber (50) slides through the loop of the second anchor member (55) to move the first anchor member (45) and lift or raise the first material (25) relative to the second material (20).

[0059] The device (1) further may further comprise a housing (30) that can be manipulated by the operator. The housing (30) has at least one passageway sized to slidably receive the delivery needle (35). An example of such a housing (30) is an endoscope. In addition, the device (100) may also includes a retrieval device (65) sized to be slidably received by a passageway of the housing (30); the retrieval device (65) capable of engaging the first material (25) to further separate the first material (25) from the second material (25).

[0060] The device (1) may also include a cutting instrument (60) sized to be slidably received in one passageway of either the needle (35) or the housing (30). The cutting instrument (60) is capable of being manipulated by the operator to separate the first material.
(25) from the second material (20). The cutting instrument (60) may have a hollow end or ceramic tip in order to assist in cutting only to a predetermined depth.

[0061] The foregoing description of various embodiments of the disclosure has been presented for purposes of illustration and description. It will be appreciated that the apparatus and methods described herein above may be used to treat various types of lesions, e.g., large superficial tumors and intraepithelial neoplasms, in virtually any body cavity, such as the stomach, esophagus and colon. It is not intended to be exhaustive or to limit the disclosure to the precise embodiments disclosed. Numerous modifications and variations are possible in light of the above teachings. The embodiments discussed were chosen and described to provide the best illustration of the principles of the disclosure and its practical application to thereby enable one of ordinary skill in the art to utilize the disclosure in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the disclosure as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.
CLAIMS

What is claimed is

1. A device that assists an operator in lifting first material (25) in relation to a second material (20) adjacent thereto, the device (1) characterized by:
   a strand of fiber (50) having a distal and proximal end;
   a first anchor member (45) having a bar fixed to the distal end of the fiber strand (50);
   a second anchor member (55) having a bar and a flexible loop projecting away from the bar
   a flexible delivery needle (35) defining at least one passageway sized to slidably receive the strand of fiber (50), the first member (45), and the second member (55); the first anchor member (45) positioned distal to the second anchor member (55) within the needle (35), the strand of fiber (50) passing through the loop of the second anchor member (55) within the needle (35); and
   a stylet (37) sized to be slidably received by the delivery needle (35); the stylet (37) being in communication with the second (55) anchor member such that the stylet (37) can cause the first member (45) and then the second member (55) to exit the needle (35) in order for the operator to couple the first member (45) to the first (25) material;
   wherein when tension is applied to the strand of fiber (50), the strand of fiber (50) slides through the loop of the second anchor member (55) to move the first anchor member (45) and lift the first material (25).

2. The device of Claim 1, wherein the device (1) is further characterized by a housing (30) that can be manipulated by the operator and has at least one passageway sized to slidably receive the delivery needle (35).

3. The device of Claim 1 or 2, wherein the device (100) is further characterized by a cutting instrument (60) sized to be slidably received in one passageway of either the needle (35) or the housing (30);
   wherein the cutting instrument (60) is capable of being manipulated by the operator to separate the first material (25) from the second material (20).
4. The device of Claim 1, wherein the second anchor member (220) comprises a crossbar (224) and a strand (230), the crossbar (224) having first (226) and second (228) opposing ends and defining a longitudinal axis (214), the crossbar (224) being defined by a tubular wall (212) having an aperture (238) between the first (226) and second (228) ends, the strand (230) having first and second opposing ends connected to the first (226) and second (228) opposing ends of the crossbar (224), respectively, the strand (230) making a revolution to define a loop (232), the strand (230) and its loop (232) projecting through the aperture (238) and away from the longitudinal axis (214), the loop (232) sized to slidably receive the strand of fiber (222) therein and protect the strand of fiber (50) from abrasion against the crossbar (224).

5. The device of Claim 4, wherein the strand (230) has a sufficient length to size the loop (232) to project through the second layer of material in which the second anchor member (220) is embedded.

6. The device of Claim 3, wherein the cutting instrument (60) has a hollow end or ceramic tip in order to assist in cutting only to a predetermined depth.

7. The device of Claim 2, wherein the device (100) further includes a retrieval device (65) sized to be slidably received by a passageway of the housing (30); the retrieval device (65) capable of engaging the first material (25) to further separate the first material (25) from the second material (20).

8. A method for separating a portion of a first material relative to a second material adjacent thereto, the method characterized by the steps of:

   placing the distal end of a device (1) to a location that is proximate to the first material;

   the device (1) including a first anchor member coupled to a strand of fiber; a second anchor member defining a loop, the strand of fiber extending through the loop to position the second member proximate to the first member; a flexible needle having at least one passageway sized to slidably receive the strand of fiber, the first member and the second member; a stylet in
communication with the second member; a housing having at least one passageway that can slidably receive the needle; and a cutting instrument sized to be slidably received by a passageway in either the needle or the housing; deploying the first anchor member (115) fastened to the strand of fiber into the first material; deploying the second anchor member (120), whereas the strand of fiber remains slideably received by the second anchor member; applying tension (130) to the strand of fiber; cutting the first material (135) at a predetermined depth around the periphery of the first material; and separating the first material (145) along with the first anchor member from being in contact with the second material; wherein when tension is applied to the strand of fiber, the strand of fiber slides through the loop of the second anchor member to move the first anchor member.

9. The method of Claim 8, further including the steps of either inserting an injection needle (105) into a section of the first material; and injecting a fluid (110) beneath the section of first material; or disposing at least a portion of a balloon (155) beneath the first material; and inflating the balloon (160); wherein injecting the fluid or inflating the balloon raises the first layer of material.

10. The method of Claim 8, wherein during the step of deploying the second anchor member (120), the second anchor member is deployed into the second material positioned away from or generally opposite the first material.

11. The method of Claim 8, further including the step of adjusting the tension (140) applied to the strand of fiber as the first material is cut.

12. The method of Claim 8, further including the step of placing incision markings (150) in the second layer of material around the periphery of the first layer of material.
13. The method of Claim 11, wherein at least one of the steps of applying the tension (130) on the strand of fiber and adjusting the tension (140) on the strand of fiber is accomplished using one selected from the group of by hand, a device, an instrument, and a robot.

14. The method of Claim 8, wherein the step of cutting around the periphery (135) of the first material uses a cutting instrument with a hollow end or ceramic tip in order to assist in cutting only to the predetermined depth.

15. The method of Claim 8, wherein the step of separating (145) the first material includes using a retrieval device, such as a snare or forceps, to engage the first material.
Figure 1

100. Placing an endoscope proximate to the targeted tissue

105. Placing incision markings around the periphery of the targeted tissue

110. Injecting a fluid beneath a section of tissue proximate to the targeted tissue

115. Deploying a T-anchor through the targeted tissue

120. Deploying a loop anchor into the bodily lumens spaced away from the targeted tissue

125. Applying tension to the suture to elevate the targeted tissue

130. Placing incision markings around the periphery of the targeted tissue

135. Cutting the tissue around the periphery of the targeted tissue

140. Adjusting tension on the suture to manipulate the position of the targeted tissue

145. Removing the targeted tissue from the bodily lumens
INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/066732

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04
ADD. A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>WO 01/39671 A1 (SMITH &amp; NEPHEW INC [US]) 7 June 2001 (2001-06-07) pages 9-11; figures 1,2</td>
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Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X' document of particular relevance the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y' document of particular relevance the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents such combination being obvious to a person skilled in the art

A document member of the same patent family

Date of the actual completion of the international search

4 February 2010

Date of mailing of the international search report

17/02/2010

Name and mailing address of the ISA

European Patent Office P B 581 8 Patentlaan 2 NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040
Fax (+31-70) 340-3016

Authorized officer

Chopinaud, Marjorie
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### INTERNATIONAL SEARCH REPORT

**International application No**

PCT/US2009/066732

**Form PCT/ISA/210**

**Box No. II Observations where certain claims were found unsearchable**

(Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons.

1. **☐** Claims Nos
   
   because they relate to subject matter not required to be searched by this Authority, namely:

2. **☐** Claims Nos **8. 15**
   
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

   - see FURTHER INFORMATION sheet PCT/ISA/210

3. **☐** Claims Nos
   
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

**Box No. III Observations where unity of invention is lacking**

(Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. **☐** As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. **☐** As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. **☐** As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:  

4. **☐** No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.

**Remark on Protest**

- **☐** The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.

- **☒** The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.

- **☐** No protest accompanied the payment of additional search fees.
Continuation of Box I: 2

Claims Nos.: 8-15

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.
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